CitiusTech
Shaping Healthcare Possibilities

Reliability testing

Key to successful product development

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Introduction

Performance testing is an integral component of the product development phase, irrespective of the end users. However, performance testing is only one piece of the puzzle when it comes to products like biomedical devices.

Medical devices are one of the essential building blocks in healthcare to support new-age medical requirements. With the fast-growing technology, there has been an increase in the number of devices deployed to hospital networks, year after year. Quality assurance and performance testing, currently practiced in many developmental environments, merely validates if a system or product meets business requirements (the functional aspects) but not how reliable the product is. What makes a medical device trustworthy is its dependability to the healthcare specialists and the patients in care. As such, a medical device could be catastrophic without its reliability! While failure in other devices can lead to mostly monetary loss, medical device malfunction can seriously threaten patient lives.

For instance, consider this scenario. Approximately 600,000 individuals are implanted with pacemakers each year globally. The reliability rate of these systems is likely 45% for 600,000 individuals. In that case, the chance of survival is a mere 45%, contingent upon doctors not being notified within a specific timeframe.[1]

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Other than mortal threats, there are also associated legal penalties. Recently, in Boston, a medical device company agreed to pay $42 million and pleaded guilty to resolve U.S. charges that concealed a malfunction in its medical devices, which resulted in thousands of children and other patients receiving inaccurate results.[2]

Keeping the criticality in mind, there are several medical device regulations for risk management. Below table shows some key international standards for medical device reliability and software reliability.[3]

Medical Device Standard	Description
ISO 13485	Establishes requirements for regulatory purposes of quality management systems for medical devices
ISO 14971	Defines application of risk management to medical devices
IEC 60812	Describes analysis techniques for system reliability – Procedures for failure mode and effects analysis (FMEA)
IEC 60601-1	Identifies general requirements for basic safety and essential performance for medical electrical equipment
IEC/TR 80002-1	Guidance on the application of ISO 14971 to medical device software

Figure 1: Different reliability standards for medical devices and medical software[3][4][5]

Let's delve into how reliability testing can be measured in medical product engineering.

Importance of availability SLAs (service level agreement) in reliability testing

Reliability testing is a vital component of the product development phase, assessing a system's capability to function seamlessly and reliably under several circumstances. The goal is to ensure the healthcare device works without unplanned downtime or faults when validated against actual user usage load and behavioral patterns. This is why you need to go beyond benchtop simulations. Your test team can assess a medical device's performance under real-world conditions by incorporating availability SLAs. They need to factor in metrics like:

- **System downtime:** Both planned maintenance and unexpected outages can impact device availability. Simulating realistic downtime scenarios will help your teams to identify potential risks and mitigation strategies.
- **Network connectivity:** For devices reliant on network connections, reliability, and availability, testing

considers potential network disruptions and their impact on functionality. Adding simulations for even lower speeds can give you a complete picture of your devices' performance under different network conditions.

- **Environmental factors:** Humidity, temperature, and other environmental attributes can affect performance and, in turn, the availability of a device. Reliability testing with these considerations will help ensure the device functions as intended in various settings.

Using availability SLAs will enhance patient safety and make you comply with several regulatory requirements. You can even protect your bottom line from future vulnerabilities as testing for availability SLAs helps identify weaknesses in design or components, allowing for early rectification and a more robust final product. But now, the bigger question: How do you develop a robust reliability strategy?

How to build a reliability test strategy

Like performance testing, reliability testing also requires proper planning and test implementation. Here's a simple guide to help develop a reliability testing strategy effectively:

1. Engineering the reliability:

Clearly define the SLAs for the expected product availability under test. For example, The product team must specify the availability of SLA for the healthcare system to be able to validate it during the development phase. They also need to define the meaning of failure and failure modes for the system under test. Failure metrics are essential in managing downtime and potential to harm an ongoing operation or intensive care to the patient. This process is also called FMEA – Failure Mode and Effects Analysis.

2. Develop operational/usage profile:

Create an operational profile that reflects the product's expected usage patterns, user interactions, and workload scenarios. This profile will help simulate realistic conditions during testing. For example, our clients expect ventilators to work round the clock without faults or downtimes in intensive care units.

3. Plan and execute tests:

Design test scenarios focusing on load, stress, endurance testing, and monitoring the product's health stats. HASS (Highly Accelerated Stress Screening) and HALT (Highly Accelerated Life Testing) tests are also conducted for device reliability testing.

HALT and HASS testing aim to evaluate a product's reliability in its intended environment over a required duration by subjecting the system to heat and vibrations. HALT is conducted during the development stage, followed by HASS in manufacturing. HASS also helps in confirming the working of design changes implemented during HALT. For instance, in the operating room, the anesthesia machine must be available 99.99% of the time, translating into a test scenario for reliability testing.

4. Assessment of test results to derive decisions:

Analyze test results to validate if SLA conditions for test executions are met by checking for errors observed during the test and the health of the device components. This information can then be used to decide on the product's release or any required architectural improvements.

By addressing and mitigating the number of faults in the system and considering user behavior during system operation, we can prove the reliability of the healthcare device and avoid potential harm – to those who receive care and those who provide it

Use Case – Reliability testing of an embedded device in healthcare

Medical device integration tools mediate between medical devices such as anesthesia, infusion pumps, ventilators, and monitors. As it supports multiple protocols, the tool can collect, parse, and transfer medical data in real time over a physical connection to other medical devices.

Business requirement

Our client wanted to ensure 99.95% tool availability in real time over prolonged usage. They wanted to gain confidence in the product's ability to maintain constant performance levels under typical operations, along with defined failure modes and estimated risks.

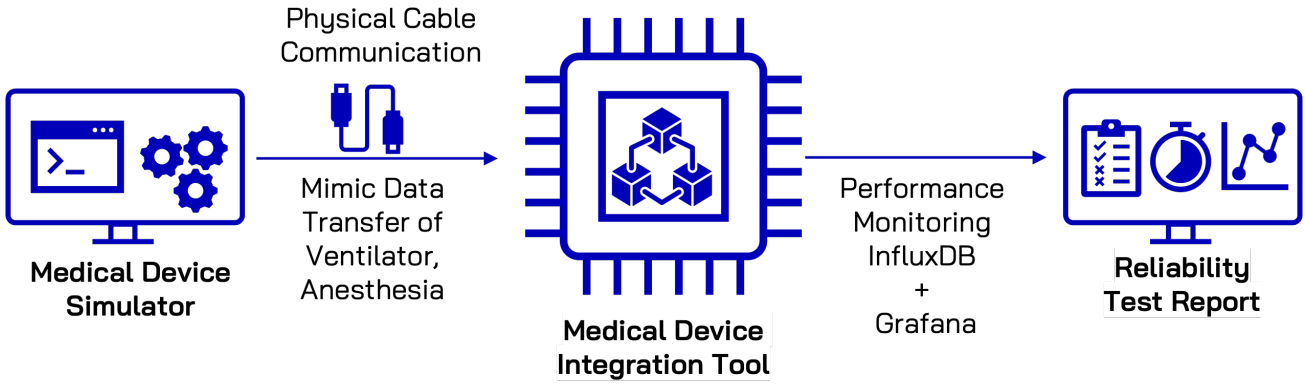

Figure 2: Solution schematic for medical device reliability testing

CitiusTech solution

CitiusTech started by comprehensively understanding the device's real-time implementation and target users. We then defined the workload for the device under test, which included the expected intake data rate and the number of connected medical devices and monitors. Next, we documented the device's production workflows.

We also helped the client define the availability SLA, which was 99.95%, and the failure modes for the product through thorough discussions with product owners & subject matter experts. Failure modes were further defined by considering the components of the healthcare device and defining expected failure counts and recovery times for every failure. We derived the MTTR (Mean Time to Recovery) for a year based on failure information.

$$\text{MTTR} = \frac{\text{Total hours of maintenance}}{\text{Total number of repairs}}$$

Using the availability equation, we also calculated the product's MTBF (Mean Time Between Failures).[7]

$$\text{Availability} = \frac{\text{MTBF}}{\text{MTBF} + \text{MTTR}}$$

We then used medical device simulators to send data to the device in our test setup — to help the reliability test showcase the real-time performance numbers of the device under test. The test environment was equipped with monitoring ability using free source tools like collected, Influx dB & Grafana to continuously provide feedback on the device's health under test.

While setting up the test environment, the client manufacturing team conducted the HALT (Highly Accelerated Life Testing) for the device hardware. During the test execution phase, the team conducted multiple and repetitive reliability test cycles, i.e., HASS (Highly Accelerated Stress Screening) – with each test ranging from 7 to 30 days.

Intermittently, performance feedback was provided on the targeted healthcare device CPU, memory, disk, and process health statistics, and the count of failures was recorded to validate whether expected and observed Mean Time Between Failures (MTBF) values matched.

At the end of the test cycles, it was concluded that we achieved the defined SLA as expected and observed (during tests) — and the numbers matched for MTBF, MTTR and availability.

Including reliability tests for a successful product release

According to the Musa-Okumoto Logarithmic Model[8], providing an estimate for the reliability of any product can help in better decisions regarding product development, testing, and release. Product reliability is critical, especially in healthcare, where our work directly impacts the patient's life. By using System Reliability Engineering concepts, which consider influential factors like failure rate, availability, MTTF, and recovery, we can validate the reliability aspects of a healthcare device.

A mindful approach to product reliability testing can help us save patients' lives more effectively and even reduce the penalty costs associated with unreliable healthcare products.

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