



# The Importance of Durability Testing in Medical Devices



The role of medical devices in preventing, diagnosing, and treating illnesses, diseases, and ailments is immense. Healthcare professionals are dependent on the accurate functioning of these devices to obtain crucial health parameters of patients in real time. The devices provide the exact status of a patient's health and enable doctors to make judicious decisions about the treatment protocol to be prescribed for them. Any malfunctioning of such medical devices can generate erroneous readings of the patients' health parameters, which may lead to a wrong diagnosis and treatment being prescribed - a risky proposition indeed. For instance, if an ECG machine generates inaccurate readings, the doctor can be misled into ascertaining the condition of the patient. In such a scenario, the doctor may end up prescribing an inadequate, inappropriate, or excessive dosage of medicine to the patient, thereby endangering his or her life.

Since most medical devices have sophisticated software applications running at their core, they need to function as per expectations. The types of such devices are legion, pacemakers, defibrillators, CT scan machines, MRIs, EEGs, and others. The groundbreaking technologies used in the manufacture of such devices enable them to perform with precision, and any glitch or vulnerability can prove fatal. No wonder medical device testing should be a mandatory

requirement to be pursued in the assembly line of manufacturing such devices. This is despite the fact that approximately 75% of companies involved in the manufacture of medical devices fail to reach the market for a variety of reasons, including:

- Use of poor quality materials and components
- Failure to test the devices properly
- Improper or insufficient maintenance according to the service manual
- Reuse of single-use devices and/or accessories
- The technical complexity of devices

It has been observed that many medical device companies prioritize seeking regulatory compliance to facilitate the market release of their products. However, in doing so, they do not necessarily focus on testing medical devices for durability. By skipping or downplaying medical device testing for durability aka stress or fatigue testing, they run the risk of putting patients' lives at risk.

### **What is durability testing?**

Durability testing validates the functioning of the devices for their intended lifecycle by subjecting them to physiological loading. Using hyper-physiologic loading levels and fatigue-to-fracture methods, it can identify design margins and device failures. As a crucial part of [medical equipment testing services](#), it helps prevent any unintentional product failures and their adverse consequences. In this type of medical devices validation, the devices are physically and repetitively loaded, similar to the loading faced by the human body. The testing procedure involves the application of both targeted and broad loading to specific components using torque, force, strain, rotation, pressure, and displacement. The two test methodologies used in durability testing include:

**Testing to success:** In this type of methodology, the devices are assessed for failure under the physiologically loading levels during their intended lifetimes. This is considered to be one of the final safeguards to ensure the safety of the devices for their intended lifetimes.

**Fatigue to fracture:** Here, the devices are pushed beyond their failure thresholds by subjecting them to larger loading magnitudes to identify their weakest components. Often used during the development of devices, the fatigue to fracture methodology offers insights that enable the refinement of the final design of the devices. The results are often submitted for regulatory compliance as strong evidence of the devices' design margins.

## Why is durability testing important?

Besides ensuring the precision of medical devices, their suitable performance during the intended lifetime should be tested as well. The reasons for doing so include:

**Reliability:** Medical devices need to perform flawlessly during their lifetime given their critical role in ensuring the well-being of patients. Durability testing detects failures and potential vulnerabilities in design, and ensures the devices' functionality throughout their lifecycle.

**Customer satisfaction:** Imagine getting into a medical facility where the performance of medical devices leaves a lot to be desired. In such cases, the diagnosis and treatment recommended by healthcare professionals based on the readings of such devices may not be reliable. On the other hand, if the medical devices are tested for durability by subjecting them to various thresholds of loading, then the level of patient satisfaction and trustworthiness will increase.

**Faster time to market:** Durability testing helps monitor and record fatigue and exposure conditions of medical devices, leading to identifying (and fixing) the root cause of any inherent issues. This enables the medical device testing company to reach the market faster and increase revenue.

## Conclusion

The conduct of durability testing to ensure medical device software validation is crucial for companies to generate trust and reliability in the design and functioning of their products. In a domain marked by stringent regulatory compliance, the durability [testing of medical devices](#) can safeguard patients, health professionals, and other stakeholders from uncertain and risky outcomes.

## Resource

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