

FDA Guidelines and Robotic Systems Development

Healthcare robotics systems are increasing in complexity due to the combination of multiple sub-systems (visualization, robot, data collection, etc.) that aid the healthcare provider in offering effective and predictable outcomes for patients. Traditionally, new product development processes that rely on prototyping and testing delay, limit product development due to the complexity of these systems. Prototypes of the system can be extremely expensive and require 6 months to a year to prototype the entire system. The FDA along with the industry has recently provided a pathway to address this problem by administering guidelines for establishing credibility of Computational Modeling and Simulation (CM&S) for medical devices. This guideline is ASME V&V 40 and it allows for medical device companies to prototype devices and subsystems virtually, so medical device companies have the knowledge to correlate the models relevance to the physical world by establishing the appropriate level of credibility for the decision being made.

The foundation for establishing credibility with these models is outlined in ASME V&V 40. These guidelines are no different than the standards of engineering practice in other industries such as aerospace, automotive and consumer products. These industries rely almost exclusively on models to prototype in their existing product development cycle. SES has been establishing credibility of models, in medical devices as well as these other industries, for almost 50 years by coupling our testing facilities with deep engineering expertise. Once a model has been developed it can live throughout the product life cycle and provide a digital twin of the system to aid in new product development, manufacturing, sustaining activities, and failure analysis.



Lab Feature - Servohydraulic Load Frames

SES provides custom data collection systems for challenging applications

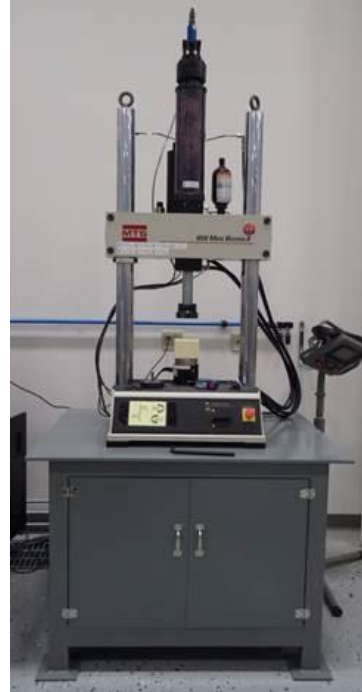
SES has a range of MTS servohydraulic load frames with both uniaxial and biaxial (tension/compression and rotation) capabilities. These frames are typically used for cyclic testing of medical devices/components or standardized material specimens. Cyclic testing may be performed to evaluate the fatigue strength of finished devices or subcomponents or to verify the durability of a device for its expected lifetime. Testing of standardized specimens may be performed to evaluate fatigue strength of materials, manufacturing/joining processes, thermal or surface treatments, or other factors. The load frames housed in SES's laboratory are capable of operating in force/torque control or in displacement/rotation control. They can provide precise control in tests that require only a few lb or in-lb of torque, and more demanding tests with load capacity up to 20,000 lb or torque up to 75 ft-lb, with cyclic rates of up to 85 Hz depending on the required displacement range. They can also be equipped with environmental chambers for testing at temperatures from -100 degrees celsius to 93 degrees celsius. In addition to freestanding and tabletop servohydraulic load frames, SES's laboratory includes a 27 sq. ft. t-slot table that can be flexibly configured with a variety of individual servohydraulic actuators to accommodate multiple axes of loading or components that are too large to fit in a standard load frame.



T-slot table configured for testing a medical equipment ceiling suspension system



MTS 858 bionix biaxial load frame set up to measure axial and rotational assembly forces



MTS 858 uniaxial servohydraulic load frame

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Track 3B - October 7th at 5:35pm



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LEARN MORE

Mark Burchnall, Senior Associate at Stress Engineering Services, will be speaking on *How to take Advantage of New FDA Guidelines for Healthcare Robotics Systems Development*.

While you're at the Healthcare Robotics and Device Talks forum, visit us at booth #302. More details to come soon!

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