Human Factors Validation Testing of Medical Devices

Validation assessments are required by the Human Factors FDA regulators to validate medical devices operate efficiently and effectively. The FDA requires that data collected be objective, participants represent intended users, and participant interactions with the device are realistic. PSE keeps abreast of FDA guidelines and standards (e.g. ANSI/AAMI HE75:2009/(R)2013) to ensure our assessments meet current standards.

Problem/Challenge:

Evaluate a device used on a daily basis by nurses and medical assistants.

Approach:

Perform a validation assessment with 20 representative users in our laboratory. Collect objective data (e.g. menu selection errors) for all possible device interactions.

Solution:

PSE recruited 'potential patients' to simulate actual use of the device. To comply with FDA requirements for participant sessions, a think aloud protocol was not used. However, user feedback was collected following the validation assessment. A repeated measures design was used to analyze use situations (e.g. standing versus sitting). A human factors report was delivered in concurrence with FDA requirements (e.g. protocol, analysis).

Benefits of our Approach:

- Compliance with current Human Factors FDA regulatory requirements
- Validate design modifications and device use safety
- Maximize end user time by collecting user feedback following validation assessment
- Validate design strategies implemented to mitigate risks are effective