sagentia
innovation

Human Factors Engineering in the development of the TMINI® Miniature Robotic System

THINK Surgical

Expertise and domain knowledge

- IEC62366 and FDA compliant Human Factors (HF) processes
- Workflow and task analysis
- Use-related risk management
- Ergonomic assessments
- Analysis of global markets
- Contextual studies
- HF formative evaluations (incl. cadaver labs)
- HF validation (summative) documentation

THINK® SURGICAL

Our client asked:

As part of our work on the main development of the TMINI® Miniature Robotic System, Sagentia Innovation was asked to provide the primary HF expertise to ensure the TMINI® system was designed and developed for safe and effective use. We recognised that usability would be critical to the success of the product.

Results: deliverables and outcomes

Compilation of a well-structured and comprehensive Usability Engineering File (UEF) for the successful premarket submission of the TMINI® robotic system. The UEF contained extensive evidence pertaining to the system's safe and effective use, including identification, evaluation, and final assessment of all potential use-related hazards.

In addition to applying a proficient usability engineering process, we supported the development of an intuitive system with a well-considered workflow and refined user interfaces. This led to a system that is believed to be simple to set up, easy to use and integrates well into the normal OR layout and surgeon workflow.

Contact us

info@sagentiainnovation.com
+44 1223 875200
sagentiainnovation.com

THINK Surgical and TMINI are trademarks of THINK Surgical, Inc.

The project story:

All aspects of system operation and workflows (from installation, procedure setup, surgery, teardown, cleaning, and maintenance to emergency scenario responses) were assessed and evaluated. The Sagentia Innovation HF team was involved in the full development process, from initial concept generation to the final HF validation.

We applied our expertise in IEC62366 and the FDA Guidance for Applying Human Factors and Usability Engineering to Medical Devices to plan and undertake a diverse range of HF activities:

- Useability Engineering Plan
- Use specification and user interface specifications
- Ergonomic assessments with representative users using non-functioning form factor models
- International user survey (quantitative primary research)
- Contextual studies (day in the life studies) at US, UK and European hospitals
- Task analysis (incl. perception, cognition, action analysis) and use-error risk analysis
- Supported the design and development of the Graphical User Interface and Instructions for Use
- Expert reviews with surgeons, OR staff and sterilisation technicians in the US & UK, using prototypes and mock-ups
- Formative evaluations incorporating cognitive walkthroughs and simulated use scenarios with representative users (i.e., surgeons and OR staff). Formative studies included cadaver procedures at specialist facilities in the US.
- Maintained IEC62366-compliant UEF throughout
- Supported the HF validation (summative) evaluations, including creation of the protocol and final report compilation