Introduction

• The Robo-ELF, a robotic flexible endoscope manipulator, is meant to assist surgeons performing minimally invasive surgery inside the airway

• The system allows a single surgeon to operate with two hands while maintaining a view that is both stable and capable of a large range of motion

Goals

• Our main goal was to complete FDA requirements for human clinical trials with the RoboELF

• Requirements include:
  • Full documentation, testing and validation
  • Risk analysis and mitigation
  • Mechanical and software design updates and fixes
  • User manual

• Ensuring that the system is safe for the surgeon and the patient is the highest priority. We implement multiple safety checks to minimize the risk of injury.

• Our secondary goal was to add vision-based navigation to the system.

Technical Approach

• A Failure Mode Effects Analysis (FMEA) for the system verified that all potential risks have been accounted for and minimized.

• Testing and validation of all safety features

• A centralized, systematic software safety failure detection and handling scheme. Failures are separated into high- and low-risk requiring a full stop and removal of the system from the procedure or a simple restart and continuation

Outcomes and Results

• Our validation tests show that our safety features work as intended and minimize risks associated with the system.

• We produced a detailed user manual including step-by-step setup, breakdown and cleaning instructions, operating instructions, and an explanation of software error reports.

• We designed a new GUI that is more easily readable and useful to surgeons using the system in the OR.

• We did not have time to complete vision-based navigation.

Future Work

• We are preparing to send our FDA submission within the next month. Clinical trials will hopefully begin before the end of the year.

• Upgrades to the navigation and interface system will continue to be made. We would like to implement vision-based navigation during summer 2012

Lessons Learned

• Make sure electronics are done right the first time.

• Most work will take longer than expected to complete. Conservative goals and expectations are easier and more realistic.

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