# Appendix A: Robo-ELF Scope FDA Submission

The included CD-ROM contains pdf files of the included documents.

**FDA README**: 001_RoboELF_FDAReadme.pdf

**Response to Previous Concerns**: 002_RoboELF_response_to_fda_concerns_2013.pdf

**IRB Protocol**: 003_RoboELF_IRBProtocol.pdf

**Tech Desc(Technical Description)**: 004_RoboELF_technical_summary.pdf

**Software Desc(Software Description)**: 005_RoboELF_software_description.pdf

**User Manual**: 006_RoboELF_user_manual.pdf

**FMEA(Failure Modes Effects Analysis)/Test Plan**: 007_RoboELF_fmea.pdf, 008_RoboELF_test_plan.pdf

**Maintenance Manual and Checklist**: 009_RoboELF_maintainence_manual.pdf,
010_RoboELF_maintenance_checklist.pdf

**Publications**: 011_RoboELF_publication.pdf

**Meeting Attendance**: 012_RoboELF_meeting_attendance.pdf

Response to Concerns

1. You provide device description in many different sections of this submission. Please provide following clarifications for the device and its use:
    a. Under the section of Drugs/Substances/Devices (Page 5 of 8), to improve control of the scope while operating, you state that "we added a stiffening attachment to give the otherwise flexible scope shaft more 'memory' so that it could maintain its own position and be easier to control." However, you neither describe this stiffening attachment nor elaborate on its impact on endoscope function. Please clarify that adding the stiffening attachment will not result in a stiff shaft that would then have difficulty maneuvering and potential for increased risk of injury to the aerodigestive tract. Please quantify the amount of stiffening should be and explain whether or why those values are within safe limits.

    **Response: The stiffening attachment was used in prior cadaver experiments and will not be used in human trials. The current system contains smoothly maneuvering shafts.**

    **Status: Technical Description documents have been updated to reflect this.**

    **Documents: See Technical Description and IRB Protocol.**

    b. You describe two joy sticks that provide control over the Robo ELF's three active degrees of freedom. However, you provide minimal to no information on how the two joy sticks function together or independently to provide the view the operator is seeking. Please describe in more detail the function of two joy sticks in accomplishing the most desired view.

    **Response: Additional description of how the joysticks control the robot has been added to the Technical Description.**

    **Status: Technical Description has been updated.**

    **Documents: See Technical Description.**

2. It appears that your study using Robo ELF is limited to only visualization of the larynx/hypopharynx and no procedures (biopsy or resection) are proposed as part of the study. We agree that the study would be a non-significant risk study if the scope is limited to just visualization of the larynx and hypopharynx without any manipulation. However, in several sections of the submission, you indicate that this device will be used to maneuver esophagoscopies and bronchoscopies as well. Please clarify your position on the following issues:
    a. Please clarify if the feasibility study proposal is limited to just visualization of upper aerodigestive tract (larynx and Hypopharynx) or if you intend to include procedures like bronchoscopies and full length esophagoscopies.

    **Response: The Robo-ELF Scope will not be used for any biopsy or for visualization beyond that of the upper aerodigestive tract. Patients will undergo direct laryngoscopy with or without biopsy as dictated by their disease. This would be consistent with standard of care and not part of the study protocol. At the conclusion of the operative procedure, the study procedure will begin, with the docking of the flexible endoscope to the robot followed by the endoscopy**

**of the larynx and pharynx. At the conclusion of the endoscopy, the robot will be undocked, the procedure terminated and the patient awakened from anesthesia.**

**Status: The IRB Protocol has been updated to make this clear.**

**Documents: See IRB Protocol.**

b. If you are proposing the robot driver to perform esophagoscopies as well as bronchoscopies, endoscopes of different lengths and diameter will be required to accomplish these procedures. However, you provide no indication of devices that will be required to perform esophagoscopies and bronchoscopies and the adjustments required for their use in the Robo ELF.

**Response: Since we will only perform visualization of the larynx and pharynx in the proposed trial, only one endoscope type will be needed. The Technical Description has been updated to make this clear.**

**Status: Technical Description has been updated.**

**Documents: See Technical Description.**

c. For any future pivotal study, where actual procedures may be performed using the Robo ELF, we recommend that you submit your study design as another pre-IDE for our informal recommendations.

**Response: The recommendation has been noted.**

**Status: N/A**

**Documents: N/A**

3. You describe various tasks that are expected to be accomplished during the study. However, you do not include a step by step detail of the set up, actual procedure, and the sequence of analysis. Please clarify the following issues regarding the procedure:
   a. It is unclear exactly when in the study procedure robot is connected to the endoscope

**Response: A User Manual including setup, takedown, cleaning, and operation has been prepared to address this issue specifically.**

**Status: User Manual complete.**

**Documents: See Setup Instructions in User Manual.**

b. Size of the endotracheal tube and its position as it relates to the endoscope during the procedure is not described. Similarly, please clarify if a mouth gag and mouth guard is used during the procedure.

**Response: Patient set-up, positioning, and instrumentation for laryngoscopy will be identical to that used in routine practice. The smallest endotracheal tube to support adequate ventilation is chosen (usually #6), a rigid laryngoscope (e.g. Lindholm, Jako) is passed through**

**the oral cavity with dental protection and suspended from a Mustard stand. The study protocol does not require any deviation from standard of care.**

**Status: Issue addressed above.**

**Documents: N/A.**

c. It is unclear if the insertion of the flexible scope is transnasal or trans-oral.

**Response: The Robo-ELF scope is passed transorally through the rigid laryngoscope, similar to how a rigid telescope would be used for laryngoscopy.**

**Status: Issue addressed above and User Manual updated.**

**Documents: See User Manual.**

d. Although many figures are provided, none show the set up in the operating room illustrating surgeon's location when performing the procedure, his or her access to joy sticks, and the location of the monitor for viewing the target site while operating. Please provide this information.

**Response: Photos have been taken with the system set up in an OR environment to demonstrate how it is positioned with respect to the surgeon and other OR equipment. The scope video display will identical to standard procedures.**

**Status: User Manual has been updated to include these photos.**

**Documents: See User Manual.**

e. Please indicate if any safety checks will be needed on the system prior to beginning the use of endoscope. In addition, will set up of the device require training of the operating room technicians and other staff?

**Response: Both mechanical and software safety checks, including checking for mechanical stability and a software safety calibration, are described in the User Manual. The study team will be operating the system for all cases, so dedicated training of hospital staff is not required.**

**Status: User Manual Complete.**

**Documents: See User Manual.**

f. Although you mention the benefit of using the Robo ELF to target the difficult to reach areas like the Subglottis, your study procedure does not list them as the endpoints of the study. It is recommended that you pre-specify in the protocol the difficult to reach areas that you hope to target with the Robo ELF system which will then allow for a reasonable comparison from conventional therapy. In addition, to eliminate bias we recommended that analysis of the photographs be done by a blinded reviewer as opposed to the investigator themselves.

**Response: The IRB Protocol has been updated with a description of visualization targets, and evaluation of images by a blinded laryngologist.**

**Status: IRB Protocol updated.**

**Documents: See IRB Protocol.**

4. In your risk assessment, you state that "When used for visualization tasks in the upper airway, the Robo ELF system poses minimal risk to patients. The endoscope which is already used clinically is the only part of the system that touches the patient." While it is understandable that use of flexible scope is safer when a patient is awake, but the same instrument is may not be as safe when stiffened and used on a patient under anesthesia. Please present a comprehensive risk assessment: identify all possible risks related to endoscope use, the robotic system, mechanical failure of arms, locks, anchors, mounts, software failures, anesthesia, etc. along with mitigations to protect patient and surgeon / team from those risks.

   **Response: An FMEA has been created to evaluate risks associated with the system. As stated above, the scope will not be stiffened in this study.**

   **Status: FMEA Complete.**

   **Documents: See FMEA/Test Plan.**

5. Neither raw data nor any photographs from your cadaver study are presented for review. Please provide this information.

   **Response: The Technical Description has been updated to show the experimental setup for the cadaver study, and the publications have been included in the submission.**

   **Status: Technical Description updated.**

   **Documents: See Technical Description and publications.**

6. You define your primary objective as "To demonstrate comparable if not superior field of vision with the Robo-ELF scope over standard rigid telescopes."
   a. The term "telescope" is not technically incorrect, but we assume that you mean endoscope.

      **Response: Correct, "telescope" does refer to rigid endoscopes. The term "telescope" is often used in the laryngology literature to refer to rigid endoscopes.**

      **Status: Issue addressed above.**

      **Documents: N/A**

   b. It is unclear from the protocol how you plan to demonstrate non-inferiority to a rigid endoscope. A rigid endoscope does not appear to be included in the study for comparison.

      **Response: The IRB Protocol has been updated to describe how views with the two systems will be compared and evaluated by blinded laryngologists.**

**Status: IRB Protocol updated.**

**Documents: See IRB Protocol.**

c. If you mean superior field of vision compared to the unmodified FDA-cleared endoscope used in the robo-ELF, please explain how you intend to improve field of vision, a quantitative property of the scope, which you claim is unaltered aside from robotic controls. Please consider changing this language for clarity.

**Response: The Robo-ELF is being compared to manually manipulated rigid endoscopes, which are currently the standard equipment for this procedure. The Robo-ELF improves the field of view by maneuvering the tip of the scope, which the rigid endoscopes are not capable of doing. The IRB Protocol has been updated to reflect this.**

**Status: IRB Protocol updated.**

**Documents: See IRB Protocol.**

7. You define your first secondary objective as "To achieve optimal visualization of normally challenging anatomical areas with precise biopsy sampling." The phrase "Optimal visualization" is subjective and should be better defined or else removed from your list of objectives.

**Response: The IRB Protocol has been updated to describe how captured images from the different scopes will be evaluated and ranked by blinded laryngologists.**

**Status: IRB Protocol updated.**

**Documents: See IRB Protocol.**

8. You state in your system overview that your robot is compatible with the "Pentax VNL-1570STK (Pentax Corporation, Golden, CO)" and "any similar clinical endoscope could be used with minimal modification." Please address the following related to your investigational study:
   a. Please provide the FDA 510(k) application number for any endoscope(s) you test and deem to be compatible with your robot and define exactly the endoscope(s) you plan to use during the study.

**Response: We contacted Pentax and were told the endoscope was cleared as a class 1 device and was exempt from 510(k). A Pentax representative provided us with a customs clearance form for the device. This form includes an FDA clearance summary indicating the device is class 1 and exempt.**

**Status: Scope exempt from 510(k)**

**Documents: Annotated Clearance Form.**

   b. Please submit your testing protocol and acceptance criteria for the compatibility of endoscopes with your robot.

**Response: The Robo-ELF will only be used with the aforementioned endoscope in these trials. This compatibility of the endoscope has been validated through use with the Robo-ELF in our cadaver experiments. The User Manual has been updated to include acceptance criteria for endoscopes.**

**Status: User Manual Complete.**

**Documents: See User Manual.**

c. Please be advised that for any "minimal modification" you may make to a commercially available, FDA-cleared endoscope, you are responsible to validate that the modified endoscope performs to the original endoscope manufacturer's specifications. We advise that your goal and acceptance criterion for defining compatible endoscopes should center around having zero modifications to the endoscope. For example, if the attachment mechanism between the robot and the endoscope leaves any superficial surface marring, this becomes an area that can retain clinical soil and microbes, changing the end user's ability to effectively clean and high-level disinfect or sterilize the endoscope between patients. Even though the connection involves a part of the scope that does not contact the patient, user instructions and public health recommendations for all endoscopes are that the entire endoscope be reprocessed to the same specification as the insertion portion.

**Response: The endoscope will be completely unmodified. "Minimal modification" refers to the robot's scope holder, not the scope itself. The Robo-ELF scope holder has been designed so that only non-marring components directly contact the scope, so surface marring should not occur with proper use. The Technical Description will be updated to reflect this. The User Manual has also been updated to instruct the user to inspect the scope for marring after each use.**

**Status: Technical Description and User Manual updated.**

**Documents: See Technical Description and User Manual.**

d. User instructions for your system should prominently warn users only to use the endoscope(s) you have validated as compatible with your robot and not to attempt to use your system with other endoscopes, explaining why it is unsafe to use endoscopes that have not been validated for compatibility with your system. You should also provide a specific list of endoscopes you validated as compatible.

**Response: The User Manual has been updated to include a list of approved scopes. Currently one scope is approved for use with the Robo-ELF Scope.**

**Status: User Manual complete.**

**Documents: See User Manual.**

9. You state in your executive summary that the robot mounts to the surgical bed and later state that it mounts to the surgical bed rail. We believe that system stability, and thus patient and staff safety would

be best assured if the robot is anchored to a non-moveable part of the bed. Please clarify the correct and safest mounting location for the robot you propose to use in the operating room.

**Response: The User Manual and Technical Description has been updated to clearly state how the robot attaches to the bed rail. The User Manual will also be updated to clearly demonstrate to users how to attach the system to the bed rail.**

**Status: Technical Description and User Manual Updated.**

**Documents: See Technical Description and User Manual.**

10. You state under "OR compatibility" that "the entire system is designed to be wash-down resistant and cleanable using standard OR cleaners (except for the electronics enclosure which should only be wiped down)." You believe the system is built from corrosion resistant non-toxic materials on the exterior. You provide no draft of a user instructional document. Please be advised that there are no "standard OR cleaners." Hospitals tend to stock one or a select few cleaners and disinfectants for use. Your system is not patient contacting and connects to a non-patient contacting part of the endoscope. However, just like the non-contacting part of the endoscope, your system is subject to soiling from the patient's respiratory droplets and from the surgeon's soiled gloves. Therefore we advise that you search for FDA-cleared surgical drapes that may limit soiling of your system without compromising functionality of your system. Regardless of whether you use drapes or do not use drapes for your system, we advise that your system be validated for cleaning and intermediate-level disinfection between patients. Drapes limit soiling and make the validation and daily practice of reprocessing easier and more effective. However, drapes may be punctured or have microscopic defects, or soil from drapes may inadvertently contaminate equipment during removal. System components can also become contaminated from hospital staff hands / gloves during transport and disassembly all of which accounts for why it is important to validate cleaning and disinfection for the system between patients. Please provide the following:
    a. A schematic or photographic image of the recommended OR setup showing the relative positioning of the various system components and defining their typical distance from the patient – allowing for and incorporating the other necessary OR equipment (e.g., anesthesia machine, IVs, etc.).

    **Response: These photos have been added to the Technical Description and User Manual.**

    **Status: Technical Description and User Manual Updated.**

    **Documents: See Technical Description and User Manual.**

    b. Step-by-step user instructions for system set up and breakdown, including any tools needed for system assembly or disassembly, any draping and undraping (to include specific size, brand, materials, part numbers and source of compatible and effective drapes), the timing / sequence of events especially for when the robot is attached to and detached from the bed, when the robot is attached to and detached from the endoscope, all relative to when the endoscope is placed into and removed from the patient's airway.

**Response: The User Manual covers all of these procedures.**

**Status: User Manual complete.**

**Documents: See User Manual.**

c. Please validate cleaning and intermediate level disinfection for your system components, keep your validation documents on file, and provide to us a certificate of validation of reprocessing following "Statement 1" (see our 1996 guidance, pages 11 & 12), signed by the JHU legally responsible authority. You will also need to validate device functionality after cleaning / disinfection.

**Response: In response to these concerns, the system has been changed to incorporate a sterile, water-tight drape that covers the entire system. Since the drape will completely cover the robot, cleaning and disinfection procedures should be similar to those for draped operating room microscopes, which are not routinely disinfected. We are using a drape which is routinely used in our hospital for the da Vinci surgical robot. We have tested this drape with the Robo-ELF System to verify that it completely protects the system. The Technical Description has been updated to reflect these changes. The User Manual includes detailed instructions on draping and undraping the system.**

**Status: Technical Description and User Manual Updated.**

**Documents: See Technical Description and User Manual.**

d. Your validated reprocessing instructions for end users / investigators who use your system. Your user labeling should include at least one compatible cleaning and disinfection agent that is available in all settings in which your investigational device will be used and has an appropriate range of antimicrobial effectiveness. Please be sure to emphasize conformance to the labeled contact time for the disinfectant in your user labeling.

For additional guidance, you may wish to consult:

• FDA / ODE. (April 1996). *Labeling Reusable Medical Device for Reprocessing in Health Care Facilities: FDA Reviewer Guidance* available from http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf

• Rutala, W.A., Weber D. J., & HICPAC. (2008). *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.* Atlanta, GA: Centers for Disease Control.

Available from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf

• USEPA. (2009, Jan. 9). *Selected EPA-registered Disinfectants: EPA's registered sterilizers, tuberculocides, and antimicrobial products against certain human public health bacteria and viruses*. Available from http://www.epa.gov/oppad001/chemregindex.htm

**Response: Metrex Cavicide and Metrex Caviwipes have both been included in the User Manual as approved cleaning and disinfecting agents.**

**Status: User Manual updated.**

**Documents: See User Manual.**

11. Please explain whether patients with active infection or skin colonization, especially with resistant organisms will be included or excluded from your study. We recommend that your validated reprocessing methods and user instructions are aligned with hospital and public health guidelines related to prevention and control of such conditions if such patients are to be included. You may wish to consult the reference below for additional guidance. Please submit concurrence with your plans from your hospital infection control department if you choose to include such patients.

    Reference: Siegel, J. D., Rhinehart, E., Jackson, M., Chiarello, L., and HICPAC. (2007). *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*. Atlanta, GA: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infections Diseases, Division of Healthcare Quality Promotion. Available from http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html

    **Response: Patients with active infections would not be candidates for undergoing general anesthesia and laryngoscopy in general. These patients will be excluded from the IRB Protocol.**

    **Status: Issue addressed above.**

    **Documents: N/A.**

12. You state that your system contains rubber. Please clarify whether it contains any natural rubber latex and evaluate whether patients and healthcare providers with latex allergy should be excluded from participating in the study.

    **Response: The external components of the system do not contain latex, but we have not verified whether internal components may contain latex. The robot itself is sealed, and also covered by a water-tight sterile drape, so patients and healthcare providers cannot come into contact with latex during normal use.**

    **Status: Issue addressed above.**

    **Documents: N/A.**

JOHNS HOPKINS SCHOOL of MEDICINE eIRB2

Date: Thursday, April 24, 2014 11:05:33 AM

Print Close

**Application**
**NA_00051254**
**Jeremy Richmon**

# 1 - General Information

ID: NA_00051254

1. * **Principal Investigator:**
   *Click **Select** to choose PI:*

   Jeremy Richmon

2. * **Will the PI obtain consent for this study?**
   (●) **Yes** ( ) No

3. * **Indicate the PI's primary affiliation:**
   *(Select "Other (Affiliation Not Listed)" if the PI's primary affiliation is not listed):*
   Otolaryngology - Broadway

4. * **Title of Study:**
   Robotic Endo-Laryngeal Flexible (Robo-ELF) Scope:
   A Clinical Feasibility Study

5. * **Provide a BRIEF statement of your research question and plan:**
   Transcervical surgical approaches to the upper aerodigestive track result in disruption of the laryngotracheal framework with resultant sensory and motor deficits. Efforts to reduce the morbidity of external approaches have led to advances in endoscopic surgery that access the airway through the mouth. Technologic advances in binocular microscopy, rigid telescopes, microlaryngeal instrumentation, and lasers have led to dramatic improvements in the management of benign and malignant conditions of the airway. Nonetheless, this surgery continues to have disadvantages; namely, reduced depth perception, relatively small exposure, and the operator's distance from the surgical field. These limitations restrict the surgeon's ability to manipulate instruments from outside the oral cavity resulting in poor sensory feedback and magnification of the operator's tremor. In addition, the lack of distal dexterity risks injury to surrounding healthy tissue. Line of site limitations inherent in microscopic or telescopic visualization limit the ability to view around corners rendering certain areas challenging to visualize fully.
   Robotic surgery offers potential advantages with steerable modular instrumentation and three-dimensional viewing that are lacking in traditional airway surgery. A collaborate effort between the Otolaryngology and Engineering Departments of Johns Hopkins University led to the development of a simple robotically controlled endoscope system that may overcome some of the challenges faced today with transoral endoscopic surgery. This has been tested on cadavers and we seek to evaluate this technology in a live human population.

6. * **Select the type of review requested:**
   **If you are unsure what review type to request, please use the Review Type Wizard.**

   Expedited

7. * **Is this a retrospective chart review only?**
   ( ) Yes ( ) No

8. * **Is this a resubmission of an expired, terminated, withdrawn or disapproved application?**
   ( ) Yes (●) **No**

10. * **Is this a conversion of an active study already approved by an IRB (including the JHM All Children's Hospital IRB)?**
    ( ) Yes (●) **No**

14. * **Estimated time to complete this study:**
    6 months

15. **Study Team Members:**

*Click **Add** to add new Study Team members. Click **Update** to modify existing Study Team member information.*

| | Last | First | Degrees | JHED Dept | Primary Affiliation | Role | Consenting Hopkins participants | Receive Notifications | Agree To Participate |
|---|---|---|---|---|---|---|---|---|---|
| View | Best | Simon | M.D. | SOM Oto Laryngeal | | Co-Investigator | yes | no | yes |
| View | Yung | Rex | M.D. | SOM DOM Pulmonary | | Co-Investigator | yes | yes | yes |
| View | Akst | Lee | | | | Co-Investigator | yes | yes | yes |
| View | Hillel | Alexander | M.D. | SOM Oto Laryngeal | | Co-Investigator | yes | no | yes |
| View | Taylor | Russell | Ph.D. | Department of Computer Science | | Co-Investigator | no | yes | yes |
| View | Olds | Kevin | BS | Biomedical Engineering | | Other Staff | no | yes | yes |



## 2 - Study Team Compliance Training

1. **All Study Team Members listed below must complete indicated training requirements**

*PIs of active IRB Protocols must complete the **REWards training (Research Ethics Workshops)** or equivalent. PIs have one year from the date of their first eIRB submission to complete the **REWards** requirement.*

*For studies with a Prospective Reimbursement Analysis document (PRA), Clinical Research Billing Orientation (CRBO) training is required for study team members who have a role in the consenting process. Clinical Research Support Services will notify those members by email. The IRB cannot take final action until all training is complete.*

**Principal Investigator**

| Last Name | First Name | HSR Required | Date | H&R Required | Date | COI Required | Date | Date REWards Completed | CRBO Required | Date CRBO Completed |
|---|---|---|---|---|---|---|---|---|---|---|
| Richmon | Jeremy | yes | 11/13/2013 | yes | 9/2/2008 | yes | 9/3/2008 | 3/20/2010 | | 5/14/2009 |

**Study Team:**

| Last Name | First Name | HSR Required | Date | H&R Required | Date | COI Required | Date | Date REWards Completed | CRBO Required | Date CRBO Completed |
|---|---|---|---|---|---|---|---|---|---|---|
| Best | Simon | yes | 12/13/2010 | yes | 12/11/2010 | yes | 12/13/2010 | 1/5/2011 | | 10/10/2012 |
| Yung | Rex | yes | 3/15/2001 | yes | 2/24/2005 | yes | 11/3/2003 | 12/19/2006 | | 11/11/2008 |
| Akst | Lee | yes | 9/14/2010 | yes | 3/3/2010 | yes | 9/14/2010 | 10/19/2010 | | 10/18/2012 |
| Hillel | Alexander | yes | 9/5/2012 | yes | 10/20/2005 | yes | 10/20/2005 | 10/15/2012 | | 10/18/2012 |
| Taylor | Russell | yes | 2/12/2012 | yes | 1/31/2006 | no | | | | |
| Olds | Kevin | yes | 7/7/2011 | yes | 7/7/2011 | yes | 7/7/2011 | | | |

2. **If the dates above are blank or incorrect, upload copies of training certificates or myLearning Report and the JHM IRB staff will enter the dates for you.**

*Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

| Title | Date Modified | Version | Status |
|---|---|---|---|
| There are no items to display | | | |

# 5 – Protocol Information

1. * **Type of protocol:**

- [x] **JHM-IRB eForm A**
- [ ] **Outside Sponsor**
- [ ] **Investigator-Initiated**

2. * **Check the option that best describes this protocol:**

- [ ] **Protocol written by a Hopkins investigator/researcher**
- [ ] **Protocol written by a consortium or cooperative group not at Hopkins**
- [ ] **Protocol written by a federal sponsor**
- [ ] **Protocol written by a commercial sponsor**
- [ ] **Protocol written by a non-profit sponsor**

3. * **Clean Protocol:**

***Click Add to upload a new clean document. Click Update to upload a clean revised version of the existing document. (Click History to see all uploaded versions of an existing document.)***

| | Title | Date Modified | Version | Status |
|---|---|---|---|---|
| View | Robo-ELF eforma 11-2013, clean.doc(0.01) | 1/29/2014 11:01 PM | 0.01 | Submitted |

4. **Track Changes Protocol**

***Click Add to upload a new track change document. Click Update to upload a track change revised version of the existing document. (Click History to see all uploaded versions of an existing document.)***

| | Title | Date Modified | Version | Status |
|---|---|---|---|---|
| View | Robo-ELF eforma 11-13.doc(0.01) | 1/29/2014 11:02 PM | 0.01 | Submitted |

6. **Appendices/Sub-study protocol/Letter of Amendment**

***Click Add to upload a new document. Click Update to upload a revised version of the existing document. (Click History to see all uploaded versions of an existing document.)***

| | Title | Date Modified | Version | Status |
|---|---|---|---|---|
| View | Lary eval form(0.01) | 11/18/2013 10:15 PM | 0.01 | Submitted |
| View | Blinded eval form(0.01) | 11/18/2013 10:16 PM | 0.01 | Submitted |

7. * **Did this study receive a non-IRB scientific review?**

○ Yes ◉ **No**

10. **Additional pilot data or relevant publications**

***Click Add to upload a new document. Click Update to upload a revised version of the existing document. (Click History to see all uploaded versions of an existing document.)***

| | Title | Date Modified | Version | Status |
|---|---|---|---|---|
| View | Robo-Elf_6-6-11_final.docx(0.01) | 6/26/2011 9:36 AM | 0.01 | Submitted |
| View | Hamlyn Paper 3-27-11.doc(0.01) | 6/26/2011 9:36 AM | 0.01 | Submitted |

11. * **Check All of the below that apply to this study:**

- [ ] **There are procedures in this protocol that attempt to induce new symptoms in research participants, such as: procedures to provoke an allergic reaction (pulmonary, nasal, or GI), use of a glucose clamp or exercise stress test, or drugs being used to provoke a reaction.**
- [ ] **Normal volunteers or participants with a condition will undergo high risk, invasive procedures, such as: bronchoscopy, cardiac catheterization, or insertion of an arterial line.**
- [ ] **Participants will be placed at increased risk due to the circumstances under which they will be enrolled, consented, or undergo study related procedures, (for example: participants will be consented in the ER prior to emergency treatment, or participants will receive interventional procedures in an emergency situation where a waiver of consent has been granted).**
- [ ] **The protocol includes rescue medications.**
- [ ] **This is the first time you have been listed as PI on a more than minimal risk application.**

- [ ] **None of the above.**

**Application**
**NA_00051254**
**Jeremy Richmon**

## 6 - Clinical Trials Information

1. * **Is this a clinical trial?**
   ○ Yes ◉ **No**

**Application**
**NA_00051254**
**Jeremy Richmon**

## 7 - Conflict of Interest

1. **Does the PI or any study team member (or their spouse, domestic partner, or dependent children) have a financial interest or fiduciary relationship that**

   **1) could be affected by the research, or**
   **2) is in an entity that could be affected by the research?**

   **This applies to current interests/relationships and those within the past 12 months.**
   ○ Yes ◉ **No**

   ***All conflicted individuals must disclose potential conflicts of interest to the Office of Policy Coordination (OPC) before this application can be approved.***

5. * **To the best of your knowledge, does Johns Hopkins have a financial interest that 1) could be affected by the research or 2) is in an entity whose financial interest could be affected by the research?**
   ○ Yes ○ No

**Application**
**NA_00051254**
**Jeremy Richmon**

## 8 - Support Information

1. * **Check all sources of support (pending or awarded):**

   - [ ] **Monetary**
   - [ ] **Material or Equipment (e.g., drugs or devices)**
   - [x] **None of the above**

3. * **Will data from this study be submitted to a Genome Wide Association Studies (GWAS) NIH database (e.g., dbGaP)?**
   ○ Yes ◉ **No**

9. * **Will you apply to the Bayview Institute for Clinical and Translational Research - Clinical Research Unit (ICTR-CRU) (formerly GCRC) or JHH ICTR-CRU (includes NBRU) for funding or use of facilities?**
   ○ Yes ◉ **No**

10. **If ORA has requested IRB review of your grant or you have funding from the Maryland Stem Cell Research Fund, submit a copy of the complete grant, including the face page but excluding the appendices:**

    ***Click Add to upload a new document. Click Update to upload a revised version of the existing document. (Click History to see all uploaded versions of an existing document).***

| Title | Date Modified | Version | Status |
|---|---|---|---|
| There are no items to display | | | |

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## 9 - Study Location

1. **Check all sites where this research will be conducted:**

- [x] **Johns Hopkins Sites**
  - [ ] **All Children's Hospital**
  - [x] **Johns Hopkins Hospital**
  - [ ] **Johns Hopkins Bayview Medical Center**
  - [ ] **Kennedy Krieger Institute**
  - [ ] **F.M. Kirby Center**
  - [ ] **Howard County General Hospital**
  - [ ] **Suburban Hospital**
  - [ ] **Sibley Memorial Hospital**
  - [ ] **Johns Hopkins Singapore**
  - [ ] **Cardiovascular Specialists of Central Maryland**
  - [ ] **Johns Hopkins Applied Physics Laboratory**
  - [ ] **Other Hopkins sites**
- [ ] **Johns Hopkins Community Physicians (JHCP) sites** ***(Click on the help link for guidance and to download the JHCP Research Review Form.)***
- [ ] **Johns Hopkins ICTR-CRU sites**
- [ ] **Johns Hopkins Clinical Research Network (CRN) Sites**
- [ ] **Other sites with reciprocity or review agreements (e.g., NIA, NIDA, Medstar Facilities, BCHD)**
- [ ] **Multicenter sites where another PI will conduct the research**
- [ ] **Non-Hopkins/Affiliates sites where you will conduct the research**

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## 10 - Sample Size

1. * **Will this research involve intervention/interaction with participants?**
   (•) **Yes** ( ) No
2. * **How many participants will be consented (or enrolled with a waiver of consent) at Hopkins/Affiliates?**
   20
3. * **Will the study have a screening evaluation after consent has been obtained?**
   ( ) Yes (•) **No**
8. * **Will you need JHH nursing staff help with any research-related activities (e.g., blood draws, drug administration, device use, specimen collection, increased monitoring, survey administration)? This question does not apply to research conducted only on the ICTR-CRU units using ICTR-CRU nursing staff. If you will only be using ICTR-CRU nursing staff question 8.0 should be answered "no."**
   ( ) Yes (•) **No**

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## 11 – Participant Information

1. * **Will you obtain identifiable data, records, specimens, or samples, or have access to codes, links or identifiers?**
   (●) **Yes** ( ) No

2. * **Age ranges of participants (e.g., 0-17, 18-100):**
   18-100

3. * **Study population - check all that apply:**

   - [x] **Male adults (18+)**
   - [x] **Female adults (18+)**
   - [ ] **Male children (<18)**
   - [ ] **Female children (<18)**

4. **Special Study Populations - check all populations that may be enrolled:**

   - [ ] **Adults lacking capacity to consent**
   - [ ] **Pregnant Women**
   - [ ] **Non-viable neonates/neonates of uncertain viability**
   - [ ] **Prisoners**
   - [ ] **Non-English speakers**
   - [ ] **Children who are in foster care or wards of the state**

5. * **Will you enroll healthy volunteers?**
   ( ) Yes (●) **No**

6. **Hopkins Study Populations - check all populations that you will directly recruit and/or review charts/records:**

   - [ ] **JHH/JHBMC adult emergency department patients/records**
   - [ ] **JHH employees/records**
   - [ ] **JHU School of Medicine residents/interns/records**
   - [ ] **JHU School of Medicine students/records**
   - [ ] **Other JHU students/records**
   - [x] **Hopkins/Affiliates inpatients**
   - [x] **Hopkins/Affiliates outpatients**
   - [ ] **JHH obstetric patients**



## 12 - Recruitment Information

1. * **Check all sources of recruitment for this study:**

   - [ ] **No intervention/interaction with participants (e.g., chart record review)**
   - [x] **Individuals who are clinical patients of the PI or co-investigators**
   - [ ] **Review of clinical records of individuals who are not clinical patients of the PI or co-investigators prior to their consent**
   - [ ] **Referral of individuals by treating clinicians not on the study team**
   - [ ] **Prior Hopkins/Affiliates study participants**
   - [ ] **Individuals who learn about the study through advertisements or peer/network recruiting**

2. * **Describe the process for recruiting these individuals, including:**

   - **individual(s) responsible for approaching participant(s)**
   - **where and when recruitment will take place**
   - **how privacy issues will be addressed in recruitment process**

   Physicians within the Department of Otolaryngology and Department of Pulmonology (co-investigators and PI) at Johns Hopkins Hospital evaluating patients with lesions of the upper aerodigestive tract will approach the patient regarding this study. Interested patients will be given documentation explaning the study and consent process. This will take place in clinic during patient evaluation and management planning.

place in clinic during patient evaluation and management planning.

5. **Are you submitting recruitment materials and/or telephone screening scripts for review?**

   ○ Yes ◉ **No**

8. **Data Sources:**

   ☑ **Hopkins/Affiliates clinical databases or medical charts/records (including EPIC, EPR, department databases, patient registry logs, etc.)**
   ☐ **Non-Hopkins/Affiliates clinical databases or medical charts/records (including EPIC,EPR, department databases, patient registry logs, etc.)**
   ☐ **JHM IRB approved studies or research databases**
   ☐ **Non-Hopkins IRB approved studies**
   ☐ **Public databases/registries/repositories**
   ☐ **Administrative/claims data from Johns Hopkins Healthcare LLC**
   ☐ **Cancer registry data elements**
   ☑ **Imaging Data collected for research**
   ☐ **Other**

10. **Provide any additional information about your recruitment process:**

11. **JHM-IRB waiver of privacy authorization (HIPAA Form 4)**

    **Required for:**

    - **Chart/record review of individuals who are not patients or former study participants of the PI or study team**
    - **Receiving PHI from a referring Clinician not on the study team**
    - **Conducting telephone screening prior to obtaining written consent**

    ***Click Add to upload a new document. Click Update to upload a revised version of the existing document. Do <u>not</u> delete existing documents. (Click History to see all uploaded versions of an existing document.)***

| Title | Date Modified | Version | Status |
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| There are no items to display | | | |

**Application**
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## 13 - Consent and Waivers

1. * **Check the type(s) of consent planned for this study:**

   ☑ **Written Consent**
   ☐ **Oral Consent**
   ☐ **Consent Waiver**
   ☐ **Survey/questionnaire research**
   ☐ ***In vitro*** **diagnostics**
   ☐ **None of the above**

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## 14 - Written Consent

1. * **Describe the process for obtaining written informed consent/permission, including:**

- **where and when consent will be obtained**
- **time allotted for obtaining consent**
- **procedure to assess understanding**
- **whether participants will receive the consent form in advance**
- **how information will be provided if participants have a language or hearing impairment**
- **how information will be provided if non-English speakers will be enrolled**

Consent will be obtained by the PI and/or study team member (who is a consent designee) in clinic prior to posting the case to the operating room.

2. * **How many different consent forms will be used?**

   1

3. **Consent form(s):**

   ***Click Add to upload a new consent form. Click Update to upload a tracked copy of a revised consent form. Do not delete existing consents. (Click History to see all uploaded versions of an existing consent)***

| | Title | Date Modified | Version | Status |
|---|---|---|---|---|
| View | FINAL_Richmon_NA_00051254_CF_021714_No_Logo.doc(0.01) | 2/19/2014 12:27 PM | 0.01 | Submitted |

4. **Sponsor sample consent (including DHHS) or approved consent form from other sites that require IRB review:**

   ***Click Add to upload a new consent form. Click Update to upload a tracked copy of a revised consent form. Do not delete existing consents. (Click History to see all uploaded versions of an existing consent)***

| Title | Date Modified | Version | Status |
|---|---|---|---|
| There are no items to display | | | |

5. * **Study Contact Information:**

   **PI's Primary Address:**

   **Contact Phone Number:**

   **24-Hour Contact Phone Number:**

   **Fax Number:**

6. * **Does this study involve HIV testing in the State of Maryland?**

   no

7. * **Will you consent participants on a non-JHM IRB template?**



## 18 – Contact for Future Research

1. * **Will you seek authorization from subjects to be contacted about future research?**
   ○ Yes ◉ **No**

**Application**
**NA_00051254**
**Jeremy Richmon**

## 19 - Supplemental Study Documents

1. **Upload supplemental study document(s) requiring a JHM IRB approval logo:**

   ***Click Add to upload a new document. Click Update to upload a revised version of the existing document. Do not delete existing documents. (Click History to see all uploaded versions of an existing document)***

| Title | Date Modified | Version | Status |
|---|---|---|---|
| There are no items to display | | | |

2. **Upload supplemental study document(s) not requiring a JHM IRB approval logo:**

   ***Click Add to upload a new document. Click Update to upload a revised version of the existing document. Do not delete existing documents. (Click History to see all uploaded versions of an existing document)***

| Title | Date Modified | Version | Status |
|---|---|---|---|
| There are no items to display | | | |

**Application**
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## 20 - Drugs

1. * **Will participants receive any drugs, substances, or biologicals that are specified by name in the protocol (FDA approved or investigational)?**
   ○ Yes ◉ **No**

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## 21 - Devices

1. * **Will any devices be studied in this research (including devices which are FDA-approved for marketing)?**
   ◉ **Yes** ○ No
2. * **Will any investigational devices (non-FDA-approved for marketing or used according to non-FDA-approved indications) be used in this research?**
   ○ Yes ○ No
3. ☐ **Device has FDA marketing clearance and is used for FDA-approved indication:**

   * **Click to Add new device. Click Update to modify existing device.**

| Name |
|---|
| There are no items to display |

4. ☐ **Device has an Investigational Device Exemption (IDE) issued by the FDA:**

   * **Click to Add new device. Click Update to modify existing device.**

Name

Name
There are no items to display

5. ☑ **Device is non-significant risk or exempt from IDE requirements:**

*** Click to Add new device. Click Update to modify existing device.**

| | Name |
|---|---|
| View | Robo-ELF |

6. ☐ **Humanitarian Device Exemption (HDE) for a Humanitarian Use Device (HUD)**

*** Click to Add new device. Click Update to modify existing device.**

Name
There are no items to display

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## 22 - Human Biological Samples

1. *** Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research?**
   ○ Yes ◉ **No**

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**Jeremy Richmon**

## 23 - IBC/RAC

1. *** Will any of the following be used in this research?**

   ☐ **Recombinant DNA**
   ☐ **Infectious agents and/or pathogens**
   ☐ **Toxins**
   ☐ **Gene Transfer or pathogens introduced into human subjects**
   ☑ **None of the above**

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## 24 - Genetic and Laboratory Testing

1. *** Does the study involve any of the following where an individual's results will be disclosed?**
   No Testing

**Application**
**NA_00051254**
**Jeremy Richmon**

## 25 - Imaging/Radiation

1. *** Does this study involve imaging (e.g., MRI, CT, PET, x-rays, ultrasound, fluoroscopy or nuclear medicine)?**
   ○ Yes ◉ **No**

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## 31 - Data Safety Monitoring Plan

1. * **Is the Data and Safety Monitoring Plan described in the protocol?**
   ○ Yes ○ No

2. * **Indicate the methods for data safety monitoring that will be used in your study:**

   ☑ **The principal investigator will have sole responsibility for monitoring and oversight of problem/events for this research**
   ☐ **A group of designated Hopkins/Affiliates faculty/staff will have responsibility for monitoring, oversight of adverse events and other protocol events for this research**
   ☐ **An independent individual or group of non-Hopkins/Affiliates individuals (e.g., coordinating center) will have responsibility of monitoring, oversight of adverse events and other protocol events for this research**
   ☐ **A designated medical monitor, or group of monitors for commercially or for not-for-profit sponsored studies, will have responsibility for monitoring, oversight of adverse events and other protocol events for this research**
   ☐ **The SKCCC CRO will perform data and safety monitoring, oversight of adverse events and other protocol events for this research**
   ☐ **A formal Data and Safety Monitoring Board (DSMB) will have responsibility for monitoring, oversight of adverse events and other protocol events for this research**

3. **Describe data and safety monitoring plan. If the research involves more than minimal risk, include:**

   - **procedures for analysis and interpretation of data**
   - **actions to be taken concerning specific events or end points**
   - **time points for review and reporting procedures**

   This research does not involve more risk than that associated with standard evaluation under anesthesia of the upper aerodigestive tract.

4. **Provide data safety monitoring information, including IND safety reports from other study sites:**

   ***Click Add to upload a new document. Click Update to upload a revised version of the existing document. Do not delete existing documents. (Click History to see all uploaded versions of an existing document)***

| Title | Date Modified | Version | Status |
|---|---|---|---|
| There are no items to display | | | |

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## 33 - SKCCC CRO

1. * **Is this study cancer related (e.g., cancer prevention, screening, therapeutic, diagnostic, etc.), involving cancer patients, using cancer center facilities/resources?**
   ○ Yes ◉ **No**

   * **Does this study involve a drug that will be administered/dispensed in the Weinberg IDS?**
   ○ Yes ○ No

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Jeremy Richmon

## 35 – Data Confidentiality

1. * **I confirm that all the procedures listed below will be used to protect the confidentiality of data and samples**

1. **I confirm that all the procedures listed below will be used to protect the confidentiality of data and samples collected and stored for research purposes:**
   (●) **Yes** ( ) No

   - **Only authorized persons will be granted access**
   - **Only authorized persons may enter and view study data**
   - **Passwords and system IDs will not be shared**
   - **Physical security of the workstations/files will be maintained**
   - **Adequate back-up plan is in effect**
   - **Staff trained on data entry system and importance of security procedures**
   - **Workstations with databases will not be left unattended**

3. * **Will a Certificate of Confidentiality be obtained for this study?**
   ( ) Yes (●) **No**

## Study Team Information

1. * **Study team member:**
   Simon Best
2. * **Study team role:**
   Co-Investigator
3. **Primary Affiliation:**
4. * **Will this study team member be consenting participants for this study?**
   (●) **Yes** ( ) No

## Study Team Information

1. * **Study team member:**
   Rex Yung
2. * **Study team role:**
   Co-Investigator
3. **Primary Affiliation:**
4. * **Will this study team member be consenting participants for this study?**
   (●) **Yes** ( ) No

## Study Team Information

1. * **Study team member:**
   Lee Akst
2. * **Study team role:**
   Co-Investigator
3. **Primary Affiliation:**
4. * **Will this study team member be consenting participants for this study?**
   (●) **Yes** ( ) No

## Study Team Information

1. * **Study team member:**
   Alexander Hillel
2. * **Study team role:**
   Co-Investigator
3. **Primary Affiliation:**
4. * **Will this study team member be consenting participants for this study?**
   (•) **Yes** ( ) No

## Study Team Information

1. * **Study team member:**
   Russell Taylor
2. * **Study team role:**
   Co-Investigator
3. **Primary Affiliation:**
4. * **Will this study team member be consenting participants for this study?**
   ( ) Yes (•) **No**

## Study Team Information

1. * **Study team member:**
   Kevin Olds
2. * **Study team role:**
   Other Staff
3. **Primary Affiliation:**
4. * **Will this study team member be consenting participants for this study?**
   ( ) Yes (•) **No**

## Study Team Conflict of Interest

**Study team member:**

Simon Best

1. **Does this study team member have a conflict of interest?**
2. **Will this study team member server as a non-conflicted designee?**

## Study Team Conflict of Interest

**Study team member:**

Rex Yung

1. **Does this study team member have a conflict of interest?**
   no
2. **Will this study team member server as a non-conflicted designee?**
   no

## Study Team Conflict of Interest

**Study team member:**

Lee Akst

1. **Does this study team member have a conflict of interest?**
   no
2. **Will this study team member server as a non-conflicted designee?**
   yes

## Study Team Conflict of Interest

**Study team member:**

Alexander Hillel

1. **Does this study team member have a conflict of interest?**
2. **Will this study team member server as a non-conflicted designee?**

## Study Team Conflict of Interest

**Study team member:**

Russell Taylor

1. **Does this study team member have a conflict of interest?**
   yes
2. **Will this study team member server as a non-conflicted designee?**
   no

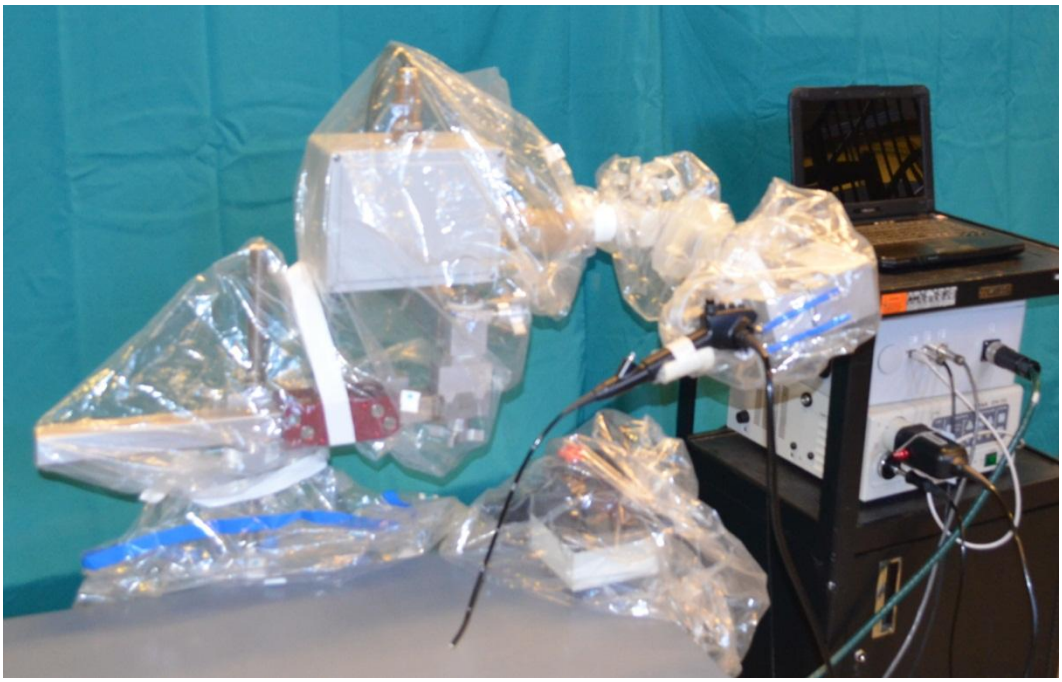
## Study Team Conflict of Interest

**Study team member:**

Kevin Olds

1. **Does this study team member have a conflict of interest?**
   yes
2. **Will this study team member server as a non-conflicted designee?**
   no

# The Robotic Endo-Laryngeal Flexible (Robo-ELF) Scope System



# Table of Contents

## Executive Summary

The Robotic Endo-Laryngeal Scope (Robo-ELF Scope) is a robotic system for the manipulation of unmodified clinical flexible endoscopes (Fig 1). It is designed to improve precision, coordination, ergonomics, and surgical capabilities when using flexible endoscopes in the operating room for visualization of the upper airway. The system includes a robot which is mounted to the rail of the operating table with a passive positioning arm, a joystick controller, a standard clinical flexible endoscope, an electronics enclosure, sanitary drapes, and a control PC. The robot is slow moving with limited range of motion, and incorporates several redundant layers of hardware, electronic, and software safety features (see Safety Systems and Procedures section). The tip and shaft of the endoscope, which is already approved for clinical use, are the only parts of the system that contact the patient. The highly flexible and compliant nature of the endoscope tip and shaft, and the insensitivity of upper airway tissues to the small forces involved, further reduce the risk to the patient. The Robo-ELF Scope has been tested in both phantoms and cadavers with positive results.

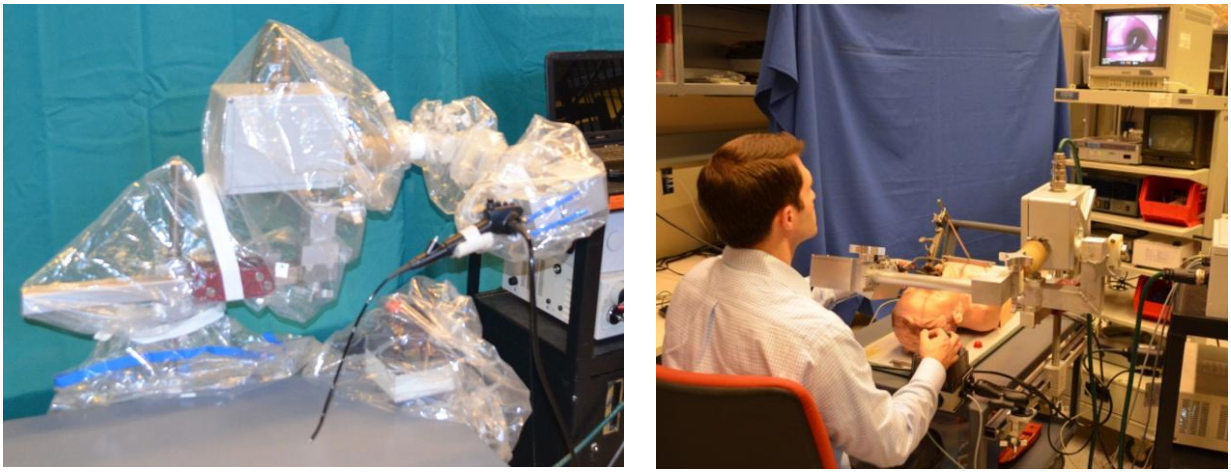


Figure 1: Left) The Robo-ELF Scope system. Right) The Robo-ELF Scope system in an artificial airway phantom.

## Risk Assessment

When used for visualization tasks in the upper airway, the Robo-ELF Scope system poses minimal risk to patients. The endoscope, which is already used clinically, is the only part of the system that contacts the patient. Since the endoscope tip and shaft are flexible and highly compliant, it is unlikely that any plausible manipulation of the endoscope body could cause damage in the upper airway. Similar visualization procedures are frequently done using identical manually manipulated endoscopes in humans. In terms of cross contamination, the Robo-ELF Scope is functionally equivalent to an operating room microscope in that it does not contact the patient, is draped with sterile drapes for procedures, and it manipulated by surgeons through the drapes.

The Robo-ELF Scope has a very limited range of motion, and software limited to move at very slow speeds (Table 1). The system also includes numerous mechanical, electrical, and software safety systems to prevent any unintended scope movements from occurring. Careful grounding, fuses, an isolated power supply, careful sealing of the system, and the use of only +/-12V or less outside of the AC/DC converter ensure electrical safety. Adjustable locking joints with gravity compensation ensure that the system can be quickly removed in case of an emergency, while simultaneously preventing any unintentional movement. The entire system except for the endoscope itself is sealed with sterile drapes during operation, preventing cross contamination. The Robo-ELF Scope has been tested in human cadavers and in an airway phantom performing visualization tasks, with successful results and no apparent safety issues. A Failure Modes and Effects Analysis (FMEA) was conducted, and a testing and validation plan to verify the detection and control functionality claimed in the FMEA was carried out (see FMEA/Test Plan document).

| | Scope Handle Manipulation (Joint A) | Scope Rotation (Joint B) | Scope Translation (Joint C) |
|---|---|---|---|
| Range of motion | 60 degrees | 270 degrees | 100 mm |
| Maximum Speed | 10 degrees per second | 20 degrees per second | 7 mm per second |

Table 1: Joint speeds and ranges of motion for Robo-ELF Scope.

## Background

There has recently been a significant movement in laryngeal surgery toward minimally invasive transoral techniques. A range of novel instrumentation including telescopes, microscopes, lasers, and microsurgical instruments has been developed to facilitate visualization and manipulation of the larynx through the mouth. However, while current techniques in transoral endoscopic surgery reduce the risk of complications encountered with classic open approaches such as scarring and infection, there remain significant challenges, particularly poor sensory feedback, reduced visibility, limited working area, and increased hand tremor due to long instruments [1]. Several robotic surgical systems, most notably the da Vinci robot (Intuitive Surgical, Inc.) have sought to remedy these problems in other surgical venues. The da Vinci was designed primarily for robotic laparoscopic surgery, in which instrument position and orientation simulate the normal hand position of a surgeon, with widely-spaced instruments. This configuration precludes parallel placement of closely spaced instrumentation, which is necessary in transoral laryngeal surgery. Although the daVinci has been reported for endolaryngeal surgery in select patents with favorable anatomy [2, 3], there is currently no robotic device available for general laryngeal procedures [4]. Therefore, the current state of the art in laryngeal surgery continues to utilize hand-held rigid endoscopes and microscopes to optimally view the endolarynx.

Flexible scopes are frequently used in the clinic for diagnostic purposes with an increasing breadth of therapeutic procedures being introduced. These endoscopes are very advanced, offering HD video, working ports, high range of motion tips, and full sterilizability. Although these endoscopes offer a wide array of functionality, the primary limitation is the requirement for bimanual control. In a typical procedure, one surgeon holds and actuates the endoscope, which requires both hands, while another uses instruments such as forceps and a laser to manipulate and ablate tissue. This may lead to a crowded working environment with cumbersome endoscopic control. Coordination between the two surgeons can be difficult and supporting and actuating the endoscope for long periods of time can result in fatigue and inaccuracy [5]. For these reasons flexible endoscopes have remained primarily for use in awake patients in clinic and have found limited roles for laryngeal procedures in the operating room.

Several groups have reported development of robotic actuation for the tip of flexible endoscopes. For example, Reilink *et al.* [6] combine computer vision techniques with robotic tip actuation for a hand-manipulated colonoscope. Although this assists the colonoscopist in controlling the view and advancing the endoscope, it still requires manual manipulation of the scope itself. Similarly, Eckl *et al.* [5] partially actuate a flexible endoscope for diagnostic use in the nasal cavity. This approach uses a two degree-of-freedom hand-held manipulator which controls scope rotation and tip angle, but not translation, which is left for the surgeon to control manually. This system is small and simple, but since the scope is not completely robotically controlled, its benefits during surgery are reduced. At the other extreme, a number of groups (e.g., [7-11]) have reported development of very sophisticated robotic systems for natural orifice surgery, providing bimanual telemanipulation of robotic arms and cameras at the end of flexible endoscopes. These systems, which are in various stages of development, tend to be complex and expensive. In the current project, we have sought to develop a low-cost, easily deployed robot to drive a flexible scope for use in the operating room in order to overcome some of the current limitations of transoral laryngeal surgery.

# System Description

## System Overview

The Robotic Endo-Laryngeal Flexible Scope (Robo-ELF Scope) is a small, inexpensive robot that takes full advantage of existing clinical equipment with the goal of using this technology in the operating room on anesthetized patients. It was designed to hold and actuate a clinical endoscope, allowing the surgeon to control the scope with one hand using a custom joystick console thereby freeing the other hand to operate, or to position the scope using the robot and operate bimanually. The Pentax VNL-1570STK (Pentax Corporation, Golden, CO) flexible laryngoscope has been used with the system.

Surgeons typically use three degrees of freedom when manipulating flexible endoscopes: bending of the scope's tip using the scope handle, rotation of the scope about its axis, and translation of the scope along the axis of the airway. These are the degrees of freedom that the Robo-ELF Scope was designed to actively control. To aid in positioning and removal of the scope, two passive lockable degrees of freedom were added to the robot, as well as a five-degree-of-freedom passive positioning arm (Fig 2). The power system and motor controllers are housed in an electronics enclosure separate from the robot itself, connected by a watertight cable and connectors. The system is controlled using a custom joystick interface which mounts to the rail of the operating table. A PC is used to interface to the motor controller through Ethernet. Numerous redundant hardware and software safety features have been incorporated to ensure that no single fault in the system can result in patient injury (see Safety Systems and Procedures section).

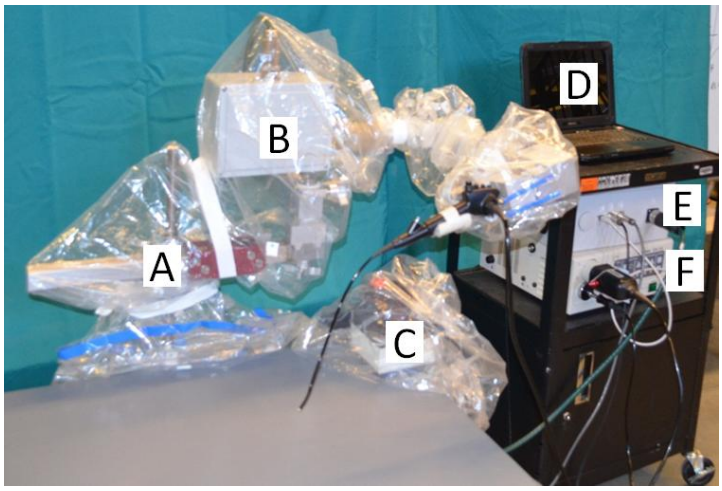



Figure 2: A) Passive positioning arm. B) Robotic scope manipulator with three active degrees of freedom. C) Joystick controller. D) Control PC. E) Electronics enclosure. F) Endoscope Video Processor.

## System Hardware Description

### Robot

The center of the Robo-ELF Scope system is its robotic scope manipulator (Fig 3). The robot has three active degrees of freedom: manipulation of the scope tip (joint A), rotation of the scope about its axis (joint B), and translation of the scope in and out of the patient (joint C). The robot also has two locking passive degrees of freedom, acting as an elbow and a wrist, which are controlled via shaft collars with large knobs. The scope is held by an adjustable plastic scope holder which, along with the rest of the robot, is completely covered by a sterile drape. The scope is attached by taping it onto the scope holder outside the drape with surgical cloth tape.

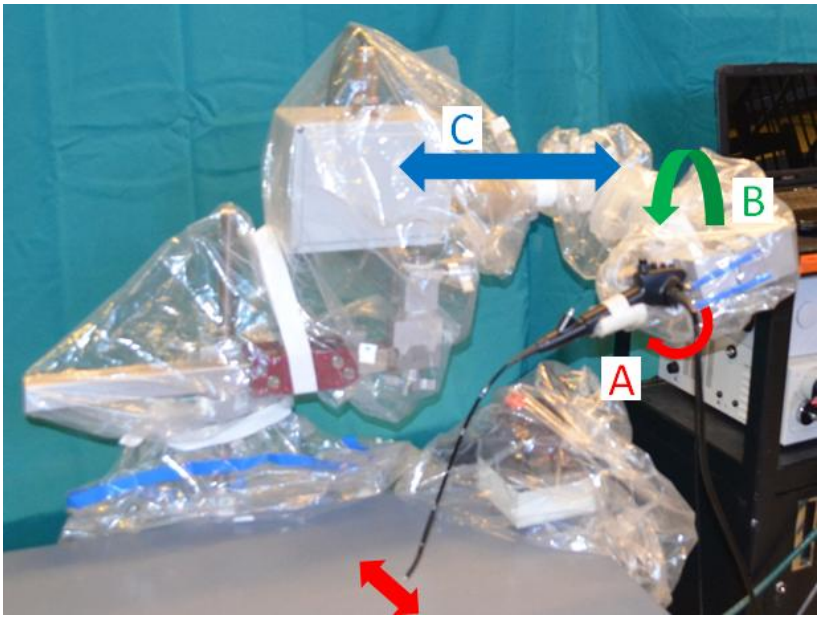



Figure 3: Robotic Scope Manipulator Degrees of Freedom. A) Scope tip manipulation joint. B) Scope rotation joint. C) Insertion/extraction joint.

To minimize weight over the patient the system was designed so that the largest motors for the scope translation and rotation degrees of freedom are located in the main enclosure. To transmit power from the main enclosure to the scope rotation joint a cable-pulley mechanism was used. Twelve volt DC servo motors with planetary gearheads and integrated magnetic encoders controlled all active degrees of freedom. Potentiometers were installed on each active degree of freedom for added safety. Motor control is achieved using a Galil DMC-4030 (Galil Motion Control Inc., Rocklin, CA) with built-in 1A linear amplifiers. Potentiometer signals are buffered and lowpass filtered before digitalization using the Galil controller's built-in analog/digital conversion.

Both active and passive robot joints are sealed with corrosion resistant sealed bearings, O-rings, or bellows, allowing the robot to remain fully watertight even when in motion. The electrical connection to the robot is achieved using a Soriau corrosion resistant waterproof electrical connector. All compartment covers are sealed with O-rings.

### Main Enclosure

The main enclosure consists of a wash-down rated NEMA fiberglass enclosure with an O-ring sealed bolt-on cover and re-enforced mounting holes (Fig 4). The main enclosure houses the entire mechanism for joint C, as well as the motor for joint B. The joint B motor, which is the largest of the system's three motors, was placed in the main box in order to avoid enlarging (and thus increasing the weight) other enclosures that are nearer to the patient. The motion from the joint B motor is transmitted to the rotation stage enclosure using two aircraft grade Bowden cables actuated by a pulley. Joint C is implemented as a DC servo motor with a planetary gearhead and integrated magnetic encoder driving a lead screw via a timing belt. The lead screw acts on a lead nut attached to a linear motion slide. Forward and reverse limit switches are mounted on the slide, and triggered by the enclosure walls when the slide nears the end of its approximately 100mm range of motion. A linear potentiometer is also actuated by the slide, which in addition to the motor's integrated magnetic encoder provides redundant sensing for additional safety. The robot arm's hollow shaft enters the main box through an O-ring sealed mounting flange, and attaches to the linear motion slide. The exterior of the flange mates with an FDA grade rubber bellows, forming a water-tight seal around the arm while still allowing it to translate in and out.

All electrical connections to the main box pass through a single Souriau 35 pin watertight connector, which ensures a water-tight seal. Electrical connections either pass directly to components in the main box, or pass through a circuit board on the main box mounting plate. The remaining electrical connections which connect to components in subsequent enclosures pass through the robot arm's hollow shaft along with the Bowden cables.

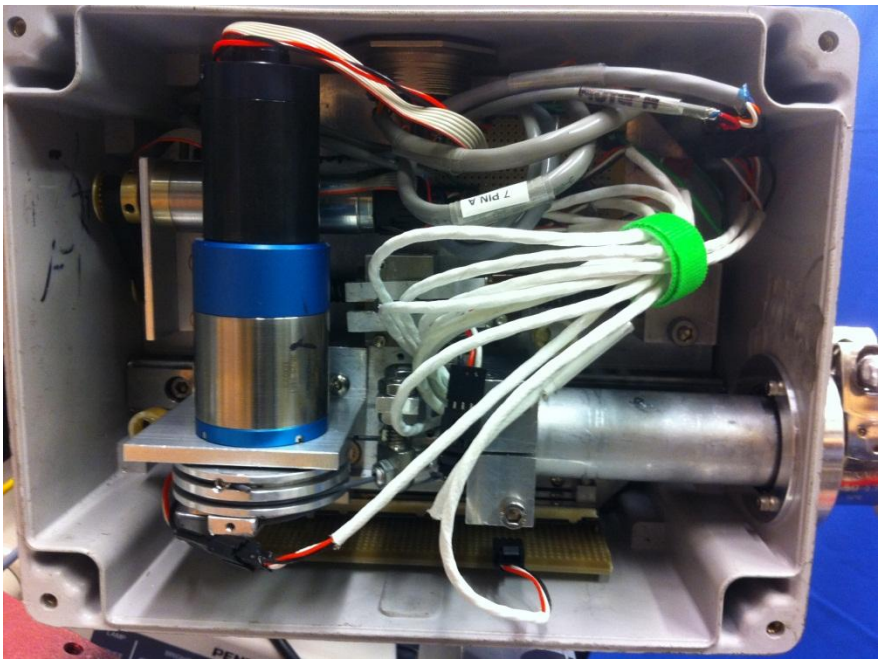


Figure 4: Main Enclosure Interior

### Elbow Joint

The robot arm's shaft emerges from the main enclosure and threads into the elbow joint (Fig 5). This joint allows the robot arm to swing away from the patient in case of emergency. The arm is held stationary by a shaft collar, which is tightened by a large knob. In order to prevent the arm from falling under the force of gravity when the collar is loosened, a high strength nylon two piece collar also grips

the arm to provide constant friction. Inside the elbow joint, an O-ring seals around the shaft to ensure the whole system remains watertight. On the distal side of the elbow joint, another hollow shaft emerges to connect to the rotation stage enclosure. This shaft is threaded and O-ring sealed in a similar way, but is fixed by a set screw rather than a shaft collar, since it is not adjustable by the operator. The other end of the shaft forms the robot's "wrist joint" where it connects to the rotation stage enclosure through a similar threaded, O-ring sealed shaft collar clamped design, providing the capability to adjust the angle of approach of the scope.

Figure 5: Elbow Joint and connecting shafts from main enclosure and rotation stage enclosure.

### Rotation Stage Enclosure

The rotation stage enclosure houses the mechanism for Joint B (Fig 6 Right). The enclosure itself is custom-made out of aluminum with an o-ring sealed bolt-on cover. As discussed above, the power for joint B is transmitted from motor B in the main enclosure via Bowden cables. Support for the rotational motion is provided by two sealed bearings pressed into the rotation stage enclosure, through which a hollow stainless steel shaft is pressed. This hollow shaft threads into the scope holder enclosure, providing access to its interior, and is sealed with an O-ring. A second pulley is mounted onto this hollow shaft, providing the attachment points for the Bowden cables. A rotary potentiometer is mounted coaxially with the pulley, which in addition to the integrated magnetic encoder on motor B, provides redundant sensing for added safety. Two limit switches are mounted along the face of the pulley, allowing adjustable stops mounted to the pulley to actuate them when the joint as reached the limit of its approximately 270 degree range of motion. A mechanical stop is mounted between the limit switches to ensure that the the joint cannot overreach its intended range.

### Scope Holder Enclosure

The scope holder enclosure contains all of the components for operating joint A, which manipulates the scope handle (Fig 6 Left). Motor A is mounted inside, and connects to the scope handle manipulator shaft via a four bar linkage. Adjustable stops are mounted on the linkage bar, which activate limit switches mounted adjacent to the bar when the manipulator reaches the end of its range of motion. A potentiometer is also mounted directly to the scope handle manipulator shaft to improve safety through redundant sensing. The scope manipulator shaft passes through a sealed bearing to the scope handle manipulator on the exterior of the endclosure. The scope handle manipulator is spring-loaded to compensate for variations in scope positioning, such as if the rotation axis of the scope handle is not aligned with the axis of rotation of the manipulator. The scope handle manipulator uses FDA grade plastic sleeve bearings to guide the spring mechanism.

The scope attaches to a plastic scope holder which is bolted to the scope holder enclosure. Since the entire robot, including the scope holder, is covered by a sterile drape, the scope is secured by taping it onto the scope holder from outside the drape using latex free cloth surgical tape. The scope holder enclosure uses a similar design to the rotation stage enclosure, using aluminum with an O-ring

sealed bolt-on cover. The scope holder is made of soft plastic which will prevent marring the scope handle.

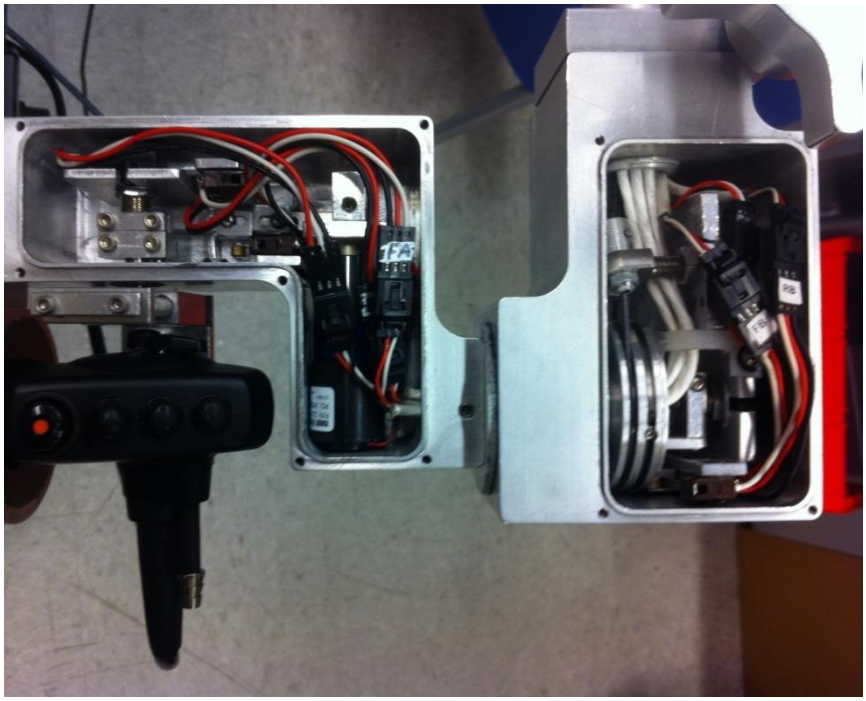


Figure 6: Left) Scope holder enclosure. Right) Rotation stage enclosure.

### Passive Positioning Arm

The robot is fixed to the operating table rail using a five degree of freedom passive positioning arm (Fig 7). The five degrees of freedom provided are X, Y, and Z translation of the robot, as well as rotation of the robot about horizontal and vertical axes. The main components of the passive positioning arm are: a support arm gripper which fixes the whole system to the operating table rail, a threaded height adjustment shaft with a hand nut for setting the robot's height, a support arm joint which clamps onto the height adjustment shaft, a horizontal slider joint which mounts on the support block and supports a square shaft with plastic plane bearings, a robot attachment block with allows the robot to be separated from the support arm, an L beam which mounts onto the square shaft with a shaft collar mechanism allowing a yaw rotation, and a robot mounting plate which attaches the robot main enclosure to the L beam with a shaft collar mechanism, allowing a tilt rotation. The robot itself also has two passive degrees of freedom, an elbow joint which allows the arm to be swung up, and a wrist joint which allows adjustment of the scope angle.

The arm attaches to the operating table rail using a screw-driven clamp which is operated via a large knob. The clamp jaw motion is guided by two shoulder bolts passing through food grade bushings. The height adjustment shaft is threaded into the top of the clamp and locked with two set screws. The height of the robot is determined by a large knurled hand nut which can be positioned anywhere along the threaded height adjustment shaft. The nut supports a mounting block which clamps the shaft using a screw-driven shaft-collar mechanism actuated by a large knob. An FDA grade PTFE thrust bearing prevents the hand nut from rubbing on the mounting block. The mounting block supports a square plane bearing assembly, which houses a square shaft, allowing the robot to translate toward and away from the patient. The square shaft can be clamped in place by a screw-driven clamp mounted in the support block and manipulated with a large knob.

The square shaft supports a screw-driven attachment joint which supports an L beam via a vertical shaft, which is clamped by a shaft collar assembly on the L beam. The joint parts are prevented from rubbing by two PTFE thrust bearings, and can be locked by turning a large knob which drives the shaft collar. The other end of the L beam supports the robot mounting plate through another shaft collar assembly. Without support, this joint would move due to gravity when the shaft collar is loosened, so a high strength nylon friction collar maintains constant friction to counteract gravity. This joint is similarly supported by two PTFE thrust bearings, and can be locked using a large knob which drives the shaft collar. The mounting plate is bolted to the robot's main enclosure using the enclosure's built-in mounting holes.

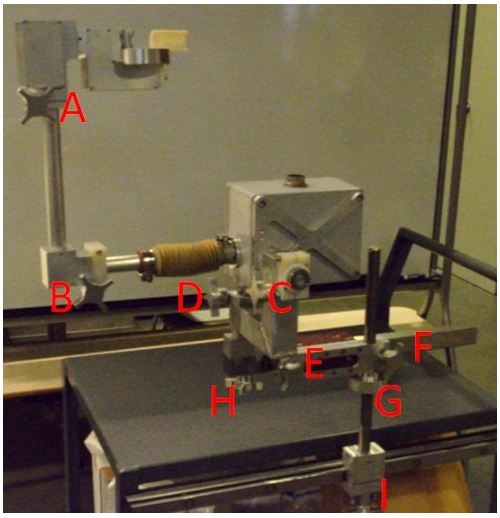



Figure 7: Passive Positioning Arm. A) Wrist joint. B) Elbow joint. C) Tilt joint. D) Yaw joint. E) Slider joint. F) Support arm joint. G) Heigh adtjustmetn joint. H) Robot attachment knob. I) Robot support arm gripper.

### Joystick System

The joystick system provides the surgeon with two joysticks, which together provide control over the Robo-ELF's three active degrees of freedom (Fig 8). The joystick enclosure also houses the system's emergency shutoff button, and PC controlled safety shutoff relay, both of which can directly cut power to the motors in the event of an emergency. The enclosure mounts to the operating table rail using an adjustable arm, which prevents it from sliding and eliminates the possibility of it being dropped, which could potentially send false commands to the robot.

The enclosure itself is a NEMA polycarbonate enclosure with an O-ring sealed bolt-on cover. All electrical connections to the enclosure are made either through water-tight cable glands, or a water-tight USB connector. The enclosure bolts onto an aluminum mounting plate through its built-in mounting holes. The mounting plate is supported by an anodized aluminum support arm, which in turn mounts to an operating table rail clamp. The support arm can be locked using a single plastic knob.

The joysticks themselves are watertight sealed industrial control joysticks which pass through the top of the enclosure. One of the joysticks is four-position, and the other is two-position, providing a total of three forward and reverse degrees of freedom. Each joystick position controls two independent SPST switches, switching between 3.3V and ground, resulting in twelve independent signals. The 3.3V, ground, and joystick signals pass through a sealed cable gland and terminate at the Galil controller extended IO port (See Electrical Schematic). The Galil controller reads these signals and passes the

information to the PC via Ethernet. The system is configured so that the robot will not move unless exactly one joystick position is on. Figure 8 demonstrates the mapping between the joystick axes and the robot degrees of freedom.

The joystick enclosure also contains a USB controlled electromechanical relay which is in series with a watertight harsh environment manual emergency stop button. The relay connects to the PC through a water tight USB connector. If the PC robot control software detects a fault in the system, then it can directly cut the motor power to the Galil controller. The surgeon can also directly cut power manually using the emergency stop button. The joystick is also enclosed in a sterile surgical drape to prevent cross contamination.

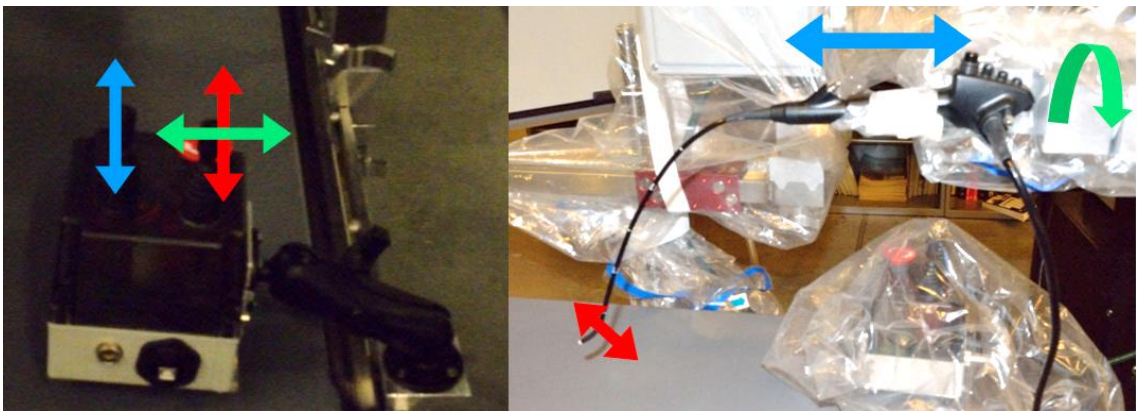


Figure 8: Joystick control system. The colored arrows demonstrate which robot degree of freedom is controlled by which joystick direction. The red emergency stop button is also visible on the top of the joystick enclosure.

The joysticks should be operated as on-off switches in that once they move far enough passed a threshold position, the robot will begin to move. Once the joystick is passed the threshold where the robot starts moving, moving them further will have no additional effect. Because of the on-off nature of the joysticks, the best way to move the robot a small distance is to tap the joystick quickly. Also, once the joystick passes the threshold, the speed of the robot ramps up over the course of one second, so initially the robot will move slowly.

### Electronics Enclosure

The electronics enclosure is a wash-down rated NEMA fiberglass enclosure with an O-ring sealed bolt-on cover (Fig 9). Since the electronics enclosure does not require surgeon interaction during surgery, it is only intended to resist incidental splashes and wipe-down cleaning. The electronics enclosure contains the system's AC/DC converter, Galil motor controller, and analog signal conditioning board (See Electrical Schematic). All of the signals entering and leaving the electronics enclosure pass through splash resistant connectors, except for the AC power input, which is on the back of the unit.

Power enters the enclosure through a standard hospital grade AC three prong plug. The plug connects to the enclosure through a power module which includes an on-off switch and a 2.5A fuse. The power is then connected to a linear isolated AC/DC converter with +12V and -12V outputs. A 12V cooling fan maintains air circulation through two air filters on opposite sides of the enclosure for cooling. The Galil controller has independent controller and motor power inputs. The controller power input is powered directly from the AC/DC converter, but the motor power input is in series with the safety relay

and manual emergency stop button in the joystick enclosure. This ensures that both the surgeon and the PC can cut the power to the motors even if the Galil is not functioning properly. Earth ground is connected to the chassis of the AC/DC converter and Galil controller. Earth ground also passes through the Souriau connector into the robot's main enclosure, where it connects to the robot chassis.

The Galil supports both A/D conversion and digital I/O, in addition to motor and encoder channels, so it is used to interface all signals between the PC and the rest of the robot. The analog potentiometer signals from the robot's joints are buffered and low pass filtered on an analog signal conditioning board before entering the Galil's A/D ports. Power for all of the peripheral electronics (potentiometers, signal conditioning board, limit switches) is provided by the Galil's 5V and 3.3V outputs.


Figure 9: Electronics enclosure interior. Note: High voltage (120V) warning is for maintenance safety. System is fully grounded and enclosure is closed during normal use.

## System Software

The software system for the RoboELF software provides functionality to control the RoboELF and implement safety mechanisms.

The software interacts with the hardware of the system in several places. The PC interacts with the Galil motor controller to gather sensor data and issue motion commands. The Galil receives information from encoders, potentiometers, input switches and other electronic sensors. All of the data is accessible to the PC program. The PC also interacts with the USB relay that controls the Emergency Stop switch. To perform control of the robot, the PC program sends commands to the Galil, which implements them using a PID control process.

Further description can be found in the software documentation.

## OR Compatibility

The system is designed to be fully covered by sterile drapes. The robot is covered by an Intuitive Surgical Camera Arm Drape Ref: 420022 Ver: -02, and the joystick by a Preferred Surgical Produces Band Bag with Tape 30”x30” Ref: BB-05. These drapes have been tested with the robot (see Testing and Evaluation section). The entire system is also designed to be wash-down resistant and cleanable using Metrex Cavicide and Metrex Caviwipes. All ingress points to the robot are sealed with O-rings, bellows, sealed bearings, or watertight connectors. Only corrosion resistant non-toxic materials are used on the exterior of the system, including: aluminum, stainless steel, USDA grade PTFE based food grade grease, FDA grade rubber bellows, silicone rubber, urethane rubber, fiberglass, nylon, polyethylene, nitrite rubber, polycarbonate, and Rulon.

## Safety Systems and Procedures

The Robo-ELF system incorporates several redundant layers of safety systems in hardware, electronics, and software. On start-up, the robot runs a calibration routine where it stores corresponding encoder and potentiometer values for each joint. This allows the system to check if the potentiometer and encoder values remain synchronized while the robot is running. If the values fall out of sync by greater than a pre-set threshold, then the system cuts the power to the motors and reports the error to the operator. The calibration routine also allows the robot to detect any limit switch faults, since the Galil can detect when a joint hits a mechanical stop without tripping a limit switch. Motor and encoder faults can also be detected directly by the Galil if the actual position of the motors deviates too far from the commanded position. See the Software Documentation document for more details.

The Robo-ELF also has several mechanisms to ensure electrical safety. An isolated AC/DC converter with 2.5A fuse was used to prevent power surges from endangering the patient. The AC/DC converter output is +/-12V, which powers everything else in the system, ensuring that no voltages beyond +/-12V exist outside of the AC/DC converter. The AC/DC converter, Galil controller, and robot chassis are connected to Earth ground, preventing any electrical fault from reaching an operator or patient (See Electrical Schematic).

There are several ways that both the system and the operator can respond to faults. If the operator detects a fault that the system has not caught, the system can be stopped using the manual emergency stop button on the joystick enclosures, which directly cuts the power to the motors. If the PC detects a fault, it can cut the power to the motors via the normally open USB controlled relay in the joystick enclosure. The Galil and PC also have a heartbeat function running in the background which intermittently sends messages and replies back and forth between the Galil and PC. If the PC detects that the Galil is not responding, then it can cut the motor power and alert the user. If the Galil detects that the PC is not responding, it will stop all motor movements and turn on its error LED. For additional safety, the Galil uses a position control method where small incremental position commands are sent from the PC to the Galil. If the PC drops out and stops sending position commands, and the Galil somehow does not detect it, then it will only move to the last commanded position and stop.

The joystick also includes several fault tolerance features. The robot will only move if exactly one of the joystick positions is on, which prevents inadvertent movement. The software is configured so that a joystick position is “on” when its signal is at ground, and “off” when it is at 3.3V. The Galil inputs for the joystick signals use pull-up resistors, so if any of the joystick signals is disconnected, it will automatically turn off. The joystick hardware uses two independent SPST switches for each position, adding redundancy to the joystick hardware.

There are also several ways to remove the robot and scope from the patient in case of emergency. The simplest is to remove the tape and take the scope out of the holder. This will remove the scope from the patient, but the robot arm will still be in position. To quickly get the robot arm and the scope away from the patient, the operator can unlock the elbow joint and rotate the entire arm up and away from the patient (Fig 10). If the surgeon prefers to remove the scope from the patient by sliding it out as they normally would without the robot, then the passive positioning arm’s slider assembly allows the surgeon to quickly slide the robot away from the patient, removing the scope from the patient’s mouth.

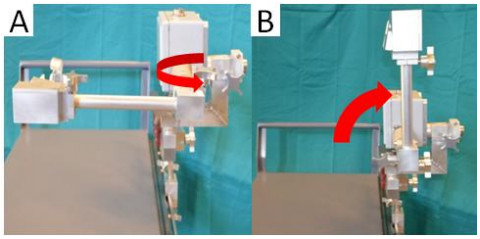



Figure 10: A) Elbow joint in normal position. B) Elbow joint with arm raised. The arm is raised by loosening the handle and flipping the arm up.

All of the procedures for using the Robo-ELF Scope, including setup, operation, takedown, and cleaning, have been documented in the User Manual. The procedures in this manual have been tested and validated (See FMEA/Test Plan document). The procedures for maintaining the system have also been formalized in a Maintenance Manual, which is to be used after every operation.

In order to prevent cross contamination, both the robot and the joystick are covered with sterile plastic drapes. In order to validate the draping procedure, the system was set up, draped, operated, then spray painted with red latex spray paint. While the paint was still wet, the drapes were removed according to the instructions in the User Manual and the system was checked for paint. No paint was found on any part of the robot or joystick. The system can also be cleaned using Metrex Cavicide and Metrex Caviwipes, which have been verified through repeated cleanings to do no damage to any part of the robot, joystick, or cables.

# Testing and Evaluation

## FMEA

In order to quantify the risks involved with using the Robo-ELF Scope, a Failure Mode and Effects Analysis (FMEA) was performed, evaluating potential failures including electrical, mechanical, software, and user error (See FMEA/Test Plan document). The FMEA was used to determine tests for failure detection and control mechanisms to validate that the system will behave as intended.

## Formal Testing

In order to validate the detection and control mechanisms in the FMEA, a formal test plan was developed (see FMEA/Test Plan document). These tests evaluate safety systems such as encoder-potentiometer cross checking, PC-motor controller heartbeat, friction collars, electrical safety, and integrity of surgical drapes. All tests were passed and the system functioned as expected.

## Clinical Studies

Several papers have been published detailing the results of cadaver and phantom tests of the Robo-ELF Scope [12-15]. [12] and [14] discuss the technical design of an earlier version of the Robo-ELF Scope. [13] presents a human cadaver study in which the field of view, ease of visualizing anatomical targets, and ability to perform two handed procedures were evaluated using the Robo-ELF Scope and compared to results obtained using standard rigid endoscopes. Performance was evaluated through surgeon subjective assessment. The setup for this experiment is shown in Figure 11. [15] presents a second study in human cadavers in which the Robo-ELF Scope was used by seven laryngology residents naïve to the system to visualize anatomical targets. The participants filled out an ease of use survey, and their performance was timed. All residents completed the visualization tasks in under 5 minutes, and rated the difficulty of the visualization tasks with the Robo-ELF Scope as very easy, easy, or neutral.

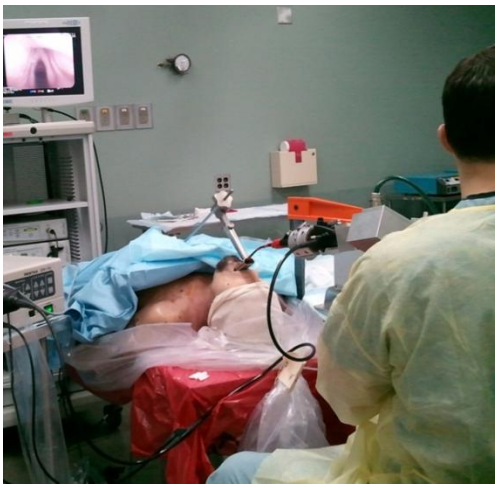


Figure 11: Setup for cadaver experiments.

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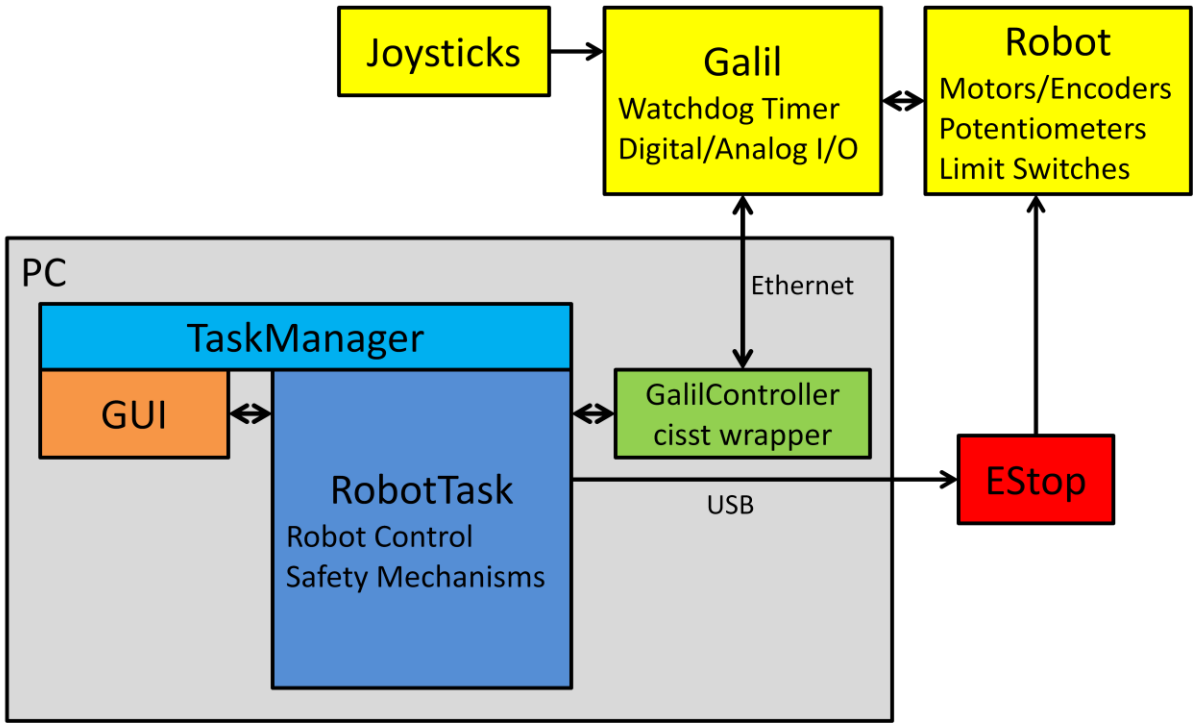
# RoboELF Software Description

# Software Overview and Dependencies

The software system for the RoboELF provides functionality to control the RoboELF and implement safety mechanisms. It is built around several existing software packages. The main applications make extensive use of the CISST libraries[1][2]. The CISST libraries are a set of software packages developed at the CIIST ERC at Johns Hopkins University. They include software designed for medical robotics and other computer integrated surgery applications. The GUI for the system is a Qt application[3]. Qt is a software package and development suite available from Digia. It provides a platform for creating graphical user interfaces. The RoboELF software system also makes use of the Galil C API and drivers to communicate with the Galil motor controller, a commercially available, 3-axis motor controller purchased from Galil Motion Control[5]. They provide a C-based software interface and hardware drivers to interact with their motion control products. The RoboELF software is designed to be built using CMake[6], a cross-platform open-source software building system. The RoboELF software currently runs on a laptop running the Ubuntu operating system[4], but can easily be extended to operate on other linux-based systems or on Windows. It has no other software dependencies.

The software interacts with the hardware of the system in several places. The PC interacts with the Galil motor controller to gather sensor data and issue motion commands. The Galil receives information from encoders, potentiometers, input switches and other electronic sensors. All of the data is accessible to the PC program. The PC also interacts with the USB relay that controls the Emergency Stop switch. To perform control of the robot, the PC program sends commands to the Galil, which implements them using a PID control process.



# Software Workflow

The RoboELF software is built using the CISST library's component-based design pattern and Multitask libraries. The software system contains three major component classes, `devGalilController`, `robotTask`, and `qtDisplayTask`. `devGalilController` is the CISST C++ wrapper for the Galil motor controller and inherits from `cmnGenericObject`. It contains functions to send commands to, and receive feedback from, the motor controller by calling to the Galil C++ API. It is the low-level software connection between the PC and the motor controller. `robotTask`, which inherits from `mtsTaskPeriodic`, contains an instance of the `devGalilController` class along with all of the functions to implement safety and control algorithms for the system. `qtDisplayTask`, which inherits from `QObject` and `mtsDevice`, is the GUI portion of the system. It contains a Qt class, `throatGUI`, that implements the display structure. It also contains CISST multitask functions to receive data from `robotTask` and display it in realtime on the GUI. There is also a small `main` program that instantiates and initializes all of the other components.

The general lifecycle of the system is as follows:

1. `robotTask` and `qtDisplayTask` objects instantiated and connected via CISST multitask interface.
2. `Startup` and `Configure` functions called on both task objects to execute setup and calibration. This is where `devGalilController` and `throatGUI` are instantiated.
3. The `Run` function in `robotTask` is called at a set interval(50ms) until the program is closed. This performs all of the control and safety procedures to run the system.
4. When the GUI window is closed, the `Cleanup` and `Kill` functions are called on all tasks. This shuts down and ends all task processes.

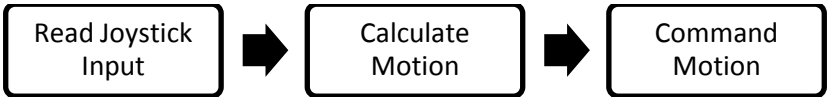
# Hardware Interfaces

The Galil motor controller communicates to the PC program through a standard Ethernet TCP/IP connection. Information is transferred in 512-byte packets. A software watchdog timer is implemented to prevent uncontrolled motion in the event of a lost connection.

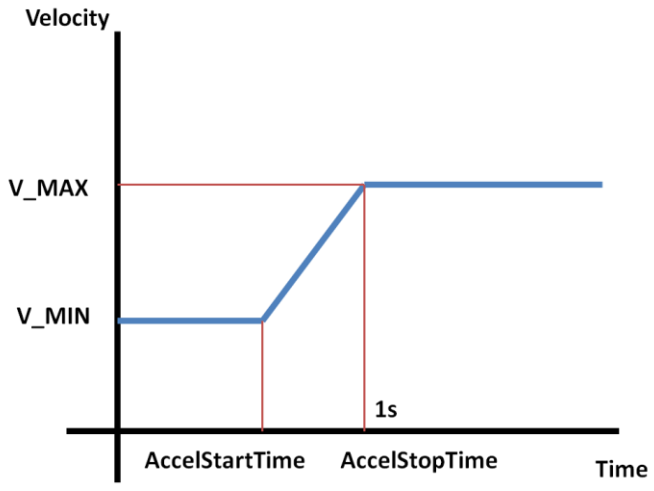
The PC connects to an Emergency Stop switch through a USB-powered relay. The relay behaves like a standard serial port device. The connection to the relay is checked every run loop to verify that a good connection is still active.

# Robot Control Algorithm

The robot control function contains three basic steps:




These steps are implemented in the ManualControl function. The theory behind the control function is to perform incremental position control by continually commanding relatively small position move commands with the assumption that a new command will be issued before the goal position of the current command is reached. A desired velocity is also specified with each position command at which the robot should move to the commanded position. For the most part, the robot moves at constant velocity. However to give a smoother start when motion is first commanded, at the start of motion, the velocity is ramped up over a specified acceleration time window. This window is defined by the start and end time-boundaries where the time is measured from the time at which the motion command was first detected on the joystick input. At the beginning of motion until the start of the acceleration window, the robot moves at a minimum velocity. Between the boundaries of the acceleration window, the robot moves with constant acceleration until it reaches its maximum velocity. It continues at this maximum velocity until a neutral input is detected. If at any time the input changes to neutral, motion stops.

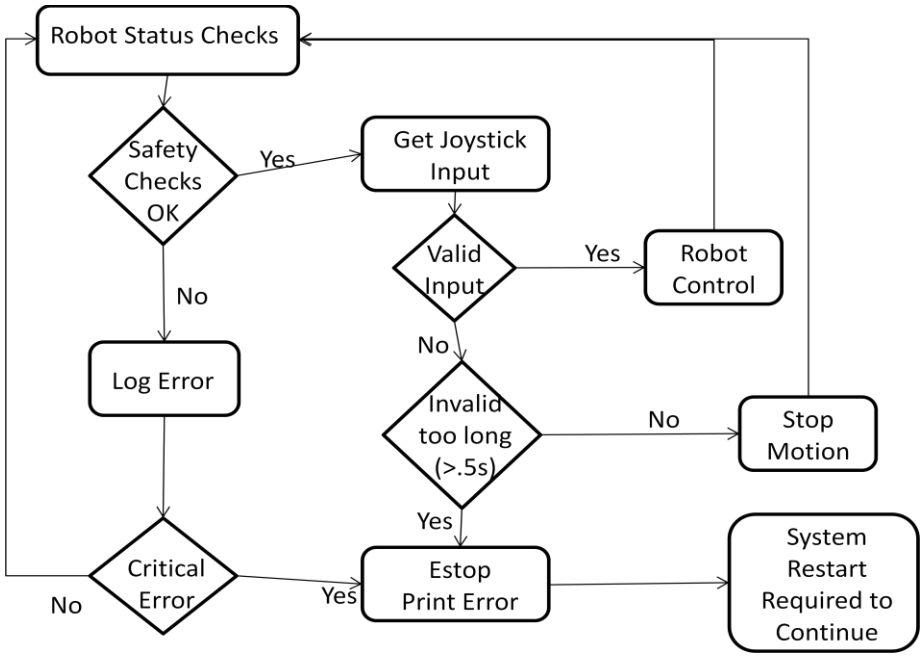


# Safety Mechanisms

Most of the safety mechanisms are present in the software. They include: a software-activated emergency stop switch, a watchdog timer between the PC and the motor controller, redundant checking between motor encoders and potentiometers, and hardware and software motion limits. The emergency stop immediately cuts power to the motors and can be triggered by the software system via a USB activated relay switch or by pressing a large red button. This is the mechanism used to stop the robot if any of the other safety checks fail. The watchdog timer runs on both the motor controller and the PC, checking that each one can communicate with the other. There are digital encoders on the motors and analog potentiometers attached to each axis of motion. The values read from each of them are continuously compared to verify that the encoders are functioning properly. If any of the software safety systems show an error, or the Galil controller shows an error or failure, the emergency stop is activated and an error message is displayed. This message contains information about the error and the proper course of action to take to recover from it.

All safety failure detections are reported through exceptions, implemented using CISST's `cmnThrow` function. All failures are recorded, often with more detailed error information, to a log file. All exceptions inherit from the exception class `RobotException` which is defined in `devGalilController.` Within the `devGalilController` class, several other classes of exceptions are defined to differentiate between types of errors. More exception classes are defined in `robotTask.` These classes are associated with errors and/or failures detected by the functions in `robotTask.` All exceptions are caught by reference(to retain inheritance structure) and rethrown until they are caught in one of the main CISST task functions(Startup, Configure, Run, Shutdown). There they are caught and handled according to their subclass.

Below is a diagram of the basic system safety check workflow:



## Emergency Stop

The emergency stop is the key to successfully implementing the software safety checks. It allows the PC to cut power to the robot motors at any time. It is important to verify that the connection to the emergency stop itself is working properly at all times. The USB relays used to activate the switch are accessed like a serial device, which can be accessed in the same manner as accessing a file in C++. One-byte messages are sent to the relays to turn them on or off. These messages are sent in the functions: `EStop_Startup`, `EStop_EmergencyStop`, and `EStop_TurnOff` in `robotTask`. To verify that the USB connection is still active and accessible, the PC program attempts to reopen it during each execution loop. This check is performed in the `EStop_CheckConnection` function in `robotTask`.

## Watchdog Timer

The watchdog timer verifies that the connection between the PC and Galil is still active. It is implemented through message-passing between the PC and the Galil. The time that each message is sent is recorded and if too much time passes before a return message is received, an error is thrown. Two time limits are implemented for two levels of errors: shorter limit that, when tripped, silently logs that the error occurred, but does not stop the system, and a longer limit that immediately triggers the emergency stop. The shorter time limit is 50% longer than the task period(75ms), and the longer limit is 2.5 times the task period(125ms). These limits were selected through testing to ensure both safety and system stability. The logic to implement the PC-side of the watchdog timer is contained in the `GalilWatchdog` function in `robotTask`. The logic to implement the Galil-side of the timer is contained in the "Watchdog.dmc" file.

## Encoder / Potentiometer Checking

To perform the encoder and potentiometer checking, a table of potentiometer values is read and stored during system startup. They can either be generated by running the calibration procedure or read from a file of old calibration results. The calibration procedure involves moving each axis of the robot through its full range of motion and recording the potentiometer values at a series of points along the axis. The points are identified by the encoder value at that position. Each point is an equal number of encoder counts away from the points around it, and the encoder value at the starting point is recorded. These two pieces of information can be used to calculate the encoder value corresponding to any point in the table of potentiometer values, therefore it is not necessary to store a table of encoder values. There are a number of specific checks during calibration and during runtime to verify the potentiometer values. When values are read during calibration, the potentiometers are checked to have monotonically increasing values over their range, and the total range of the potentiometer input is checked against known values to ensure they are accurate. During runtime the current encoder value is used to determine an expected potentiometer value by finding the value in the table that corresponds to the current encoder value. Linear interpolation is used to calculate expected values that fall between table

entries. The expected potentiometer value is compared to the current potentiometer value, and if the difference is greater than a certain threshold a safety error is thrown.

## Galil Over-Voltage Check

The Galil has built-in checks that cut power to the motors if too much voltage is applied to an axis motor while no motion is detected on that axis. This will stop motion in the event that some object is blocking the axis from moving or if some other mechanical malfunction is preventing motion. This function does not send any error message to the PC when the error is detected. To check for this error, the PC program reads the status of the motors during each execution loop. If any of the motors turn off unexpectedly, it is recorded as a safety failure. This check is performed in the `Check_MotorsActive` function in `robotTask`.

## Input Joystick Checking

The input joysticks each control two switches, the input of which are recorded by the Galil and queried by the PC program. In the PC program the inputs are read and interpreted as motion commands using a lookup table of switch states. The two switches provide redundancy that allows greater detection of errors. Any single-switch failure is detectable with this design. It is a safety failure if the joystick switches are in an invalid state. This design also allows false positives to occur in the error checks. Both switches do not throw simultaneously, so it is possible to record an input during a joystick transition that registers as an invalid state. Therefore, the check is implemented as an allowable length of time that the switches can be in an invalid state(the transition period). An error is triggered if the joystick switches are in an invalid state for longer than .5s. The joystick input reading and checking is performed in the `GetJoystickInput` function in `robotTask`.

# Class-by-Class Functional Description

Note: Mask parameters. Many functions take “mask” parameters to indicate on which axes commands should be applied. Wherever they appear, they behave in the same way. The mask variable is a Boolean vector containing as many elements as there are motors axes on the robot. The command is applied to all axes with a corresponding mask value of “true”.

## robotTask

robotTask is the class that contains all of the RoboELF-specific functions and data for the software system. It is a CISST mtsTaskPeriodic. It contains functions to implement safety mechanisms and perform high-level control operations.

### Inner Classes(Exceptions):

`EStopException`

This is the exception that is thrown when the connection with the Emergency Stop fails. It is generated by any of the EStop functions.

`EncoderException`

This is the exception that is thrown when the encoder/potentiometer check fails during a run. It is also thrown if a failure is detecting during the calibration procedure.

`MotionException`

This is the exception that is thrown when it is detected that the Galil has tripped its overvoltage limit and unpowered a motor. It is thrown by the `Check_MotorsActive` function.

`WatchdogException`

This is the exception that is thrown when the watchdog timer runs out, indicating a lost connection to the Galil. It is thrown by the `GalilWatchdog` function.

`InvalidInputException`

This is the exception that is thrown when an invalid joystick position is held for a longer than allowable time(.5s). It is thrown by the `GetJoystickInput` function.

## Important Class Members:

**Enums**:

`REV`, `STOP`, `FWD`

Indicate desired motion states of the motors, based on joystick state. The variable `CurMotion` is set to one of these values in `GetJoystickInput`.

`MLIMFWD`, `MLIMREV`

Identify the array index of forward and reverse software motion limit values.

`OPMODE`

Used as a flag to turn on or off or change the behavior of debugging and logging features for development or clinical use.

**Static Members**:

(* indicates the variable is settable via config file)

`NB_Actuators`

The number of joints on the robot.

`JOYSTICK_INPUTS`

An 6x2 array of integers that contains all valid pairs of joystick states. `GetJoystickInput` compares the current state to this table to check validity.

`NO_INPUT`

The integer code indicating joystick neutral position.

`ESTOP_ON/OFF`

The integer codes that should be sent to turn the Emergency Stop switch on or off.

`ALLOWED_ERROR`

The amount of error, as a decimal fraction, allowed in checking encoder/potentiometer values during runtime.

`INPUT_TIMEOUT`

The timeout value for invalid joystick input.

`MIN/MAX_VEL`

The minimum and maximum velocity of each axis of the robot.

`ConfigFileName`

The name of the configuration file containing values for many static constants. Default is “RoboELF.config”.

`TableStepSize` *

The distance in encoder counts between each sample in the encoder/ potentiometer checking table.

`AnalogRange` *

The approximate range of the analog potentiometers for each axis.

`VoltageLimits` *

The limit voltage that the Galil’s overvoltage protection should be set to.

`AccelStart/StopTime` *

The times defining the acceleration window in the velocity function.

`EStop_PORTNAMES` *

The names of the ports that the Emergency Stop can be plugged into. The value of `OPMODE` determines which name is used.

`GalilDefaultIP` *

The default IP address of the Galil. The program attempts to connect with this address before prompting to select from a list.

`GalilPIDGains` *

An array containing the PID gain values for the Galil.

**Non-static Members:**

`Timer`

CIIST Timer object used by all of the time-dependent functions including the watchdog and control functions.

`ActuatorState`

Variable containing the current state of the robot. Includes information such as encoder position, limit switch state, and motor state.

`AnalogInput`

Variable containing the current state of the analog potentiometers.

`Encoder/AnalogValues`

Variables containing the current state of the encoder and potentiometers.

`AnalogPrev`

Variable containing the previous recorded potentiometer value for comparison purposes during calibration.

`HomeOffset`

The offset in encoder counts required to treat the minimum range of the motors as the zero position.

`TableRange`

The total range in encoder counts of each motor axis.

`InputMismatch`

Flag indicating a joystick error has occurred.

`MotorLimits`

A 3x2 int array containing the forward and reverse motor limits in encoder counts.

`Galil/GalilConnected/GalilIP`

`Galil` is the instance of `devGalilController` used to interact with the Galil. `GalilConnected` is a flag indicating that a good connection is active. `GalilIP` is the IP address of the connected Galil.

`LastGalilWatchdog`

The time of the last received watchdog response from the Galil.

`Watchdog(Non)CriticalTimeout_Galil`

The timeout values in milliseconds for critical and non-critical watchdog timeouts.

`WatchdogDisable_Galil`

Flag indicating the watchdog timer has run out.

`CurMotion`

An int 3-vector containing the current state of motion of each motor axis, `REV`, `STOP` or `FWD`.

`StartTime`

The time that the current motion command was first detected on the joysticks.

`ACCEL`

The rate at which the robot will accelerate on each axis, calculated from the min/max velocity and acceleration window for each axis.

`InputIsValid`

Flag indicating that the joystick input is valid.

`InvalidInputTimeoutPeriod/FirstInvalid`

The length of the invalid joystick input timeout and the time at which the last invalid joystick position was detected.

`EStop_PortName`

The name of the Emergency Stop port to be used.

`EStop_IsConnected`

Flag indicating that the Emergency Stop is connected.

`SafetyOneShot`

Flag indicating that a safety failure has occurred. If this flag is set to true, the program will run until the user manually closes it, but will not run any control or safety functions until restarted.

## Important Class Functions:

`robotTask`()

Initializes non-static variables. Creates an instance of `mtsInterfaceProvided`, "ProvidesThroatRobot" which is used to provide information to `qtRobotDevice`. Reads configuration file by calling `ReadConfigFile`, which reads the file and sets the appropriate variables.

`Configure`()

Contains most of the startup and calibration routines. It opens a connection with the Emergency Stop, turning it on by calling `EStop_StartUp`. It starts a connection with the Galil by calling `Galil.Init`(). It sets several variables on the Galil including the command timeout period, the amount of time to wait for a response to a sent command, to 20ms. It configures the extended IO to the correct setting by sending the command "CO 0". It sets the PID gain values, sets and activates the Galil's overvoltage and position error safety limits. The values for all of those settings are read from the configuration file. It also sets the Galil's motor acceleration values to ten times the maximum velocity. This allows the assumption to be made that acceleration of the motors up to their commanded speed is instantaneous. Finally, Configure prompts the user to select a calibration method and calls the appropriate function to run calibration. If the user input is invalid, it requests new input until valid input is received. All of the functionality in Configure is contained in a try-catch block to handle any safety, or other, exceptions. Exceptions are caught and handled as described in the Safety Mechanisms section.

`Startup`()

Starts the watchdog timer between the Galil and PC. It downloads the watchdog program to the Galil by calling `Galil.ReadConfigFile`() and runs it by sending the command "XQ #wchdg". If all startup procedures have completed successfully, verified by checking the `SafetyOneShot` flag, it prints "RoboELF Ready for Use" to the command line output.

`Run`()

This function contains all of the normal runtime operations including safety checks and robot control. It is the CISST runtime function that is called repeatedly at a specified interval(50ms). It first runs all of the safety checks by calling `RunSafetyChecks` then if all checks passed, it calls `ManualControl` to run the control algorithm. If any safety failures occur during operation, the exception is caught in Run's catch block. All failures are logged and serious failures trigger the Emergency Stop.

`Cleanup`()

This is the CISST function that is called when the system is shutdown. It turns off the Emergency Stop and closes the Galil connection. If an error occurs, it is logged and any shutdown functions are continued if possible.

`Home`()

This function performs calibration procedures to build the tables that are used for encoder potentiometer checking. It first configures several settings on the Galil in preparation for calibration. It sets the desired velocity for all axes to their maximum and sets the software limits for each axis to the maximum possible value, effectively turning them off for calibration. It then moves the axes to their default zero position. Depending on the user input selection for calibration method, it rebuilds the calibration tables by calling BuildTables or reads them from a file by calling BuildTablesFromFile. If it does not find a valid calibration file, it rebuilds the tables normally. After completing calibration, it sets the software limits on the Galil to the values found during the calibration routine, either read from file or found during normal calibration. If calibration completes successfully, it prints "Calibration Successful". If calibration failed for any reason, it rethrows the exception.

`BuildTables` ()

This function implements the calibration procedure for the robot. The purpose is to build tables of potentiometer values that will be used to perform the encoder/potentiometer safety check during operation. A table is built for each motor axis. The values are stored in AnalogValues. A secondary purpose is to find the software motion limits for each axis, which are set after calibration is complete. The same procedure is followed for each axis, one at a time:

The axis is moved to the negative hard motion limit, then back to just off the limit. This position is saved as the reverse software limit and the first position in the table. Next the axis is moved forward incrementally until the forward hard limit is hit. After each incremental move the position is recorded in the table. The size each move is determined by TableStepSize, which contains a step size value for each axis. When the forward motion limit is hit, the axis moved back to just off the limit. This final position is saved as the forward software motion limit.

Several checks are implemented to ensure safety during calibration and verify that the calibration is accurate. The Galil overvoltage and position error checks are active during calibration and if either one is tripped, calibration is aborted. To verify that the potentiometers are giving accurate results, each new value is compared to the previous recorded value to check that values are always increasing over the length of the axis. At the end of calibration, the total range of the table is compared to a saved constant value. If the results of calibration are not consistent with the expected value, an exception is thrown and the run does not proceed. After all axes have been calibrated they are moved to the center of the range of motion. The results of the calibration are written to a file so that they can be read in later to allow a quick calibration that does not require moving each axis through its full range of motion.

`BuildTablesFromFile`()

This function performs a faster calibration be reading previously obtained values from a file instead of building new tables. It assumes that the values in the file are a valid calibration and so does not check them but simply reads and saves them. It also reads the forward and reverse software motion limits from the file. It places all axes at the center of their range of motion just as the normal calibration does.

`ReadConfigFile`()

This function reads and parses the configuration file to set constant values at the start of operation. If the file is not found, an error is logged and the program continues, using default hardcoded values for the constants.

`ManualControl`()

This function implements the control algorithm of the robot. It reads the current joystick input, calculates and sets the motor velocity, and commands a move. The joystick input is read by calling `GetJoystickInput` which sets the values in `CurMotion`. These values determine in which direction each axis moves, if at all. The velocity calculation procedure is repeated for each axis:

If `CurMotion` is set to `STOP`, the desired velocity is set to zero and no further computation is necessary. If `CurMotion` is set to `FWD` or `REV`, the velocity is calculated based on how long the axis has been in motion according to the procedure described in the Robot Control Algorithm section. Once a desired velocity has been calculated, it is sent to the Galil. Then a position move command is made. The logic for sending the command is to set an absolute position goal that is the current position of the axis plus a positive or negative offset. A command is given even if no motion is desired. If no motion is desired, no offset is added to the current position. The offset is arbitrarily set to the calibration table step size. If a safety failure occurs at any point, the exception is rethrown and no motion is commanded.

`RunSafetyChecks()`

This function runs safety checks during operation including the encoder and potentiometer checking in `Compare_Inputs`, the watchdog time in `GalilWatchdog`, the Emergency Stop connection in `EStop_CheckConnection`, and checks for the Galil overvoltage and position error limits by calling `Check_MotorsActive`. If any of the safety checks fail, they throw an exception and/or set a flag variable. These flags are checked after all functions have completed. If any flags have tripped, the `SafetyOneShot` flag is set to true. All exceptions are rethrown up to the `Run` function.

`UpdateActuatorState()`

This function calls `UpdateActuatorState` and `GetAnalogInputs` in `devGalilController` to update the state of the robot.

`Enable/DisableMotors()`
`ActuatorWaitMotion()`
`ActuatorPositionMove()`
`ActuatorVelocitySet()`

These functions call the functions in `devGalilController` with the same or similar names to perform the indicated behavior.

`Compare_Inputs()`

This function implements the encoder/ potentiometer checking during operation. The same procedure is applied to all axes of motion. The first step of this check is to find where in the table we expect to be, based on the current encoder readings. This can be calculated by finding the current position past zero, assuming zero is at the negative motion limit of the axis, or HomeOffset, and dividing by TableStepSize. This gives the index of the table value that is closest to the current potentiometer value that is also less than the current value. Linear interpolation is used in between table values to calculate an expected value for the potentiometer. This expected value is compared to the actual value. If the difference is larger than (1+ALLOWED_ERROR) times the difference between the two closest table values(the potentiometer value step size), an EncoderException is thrown.

`GetJoystickInput()`

This function reads the input from the Galil and interprets it into motion commands. It also checks it to ensure that it is valid. First, it reads the current state of the Galil's external IO, where the joysticks are wired. The first check it performs is to check if all joystick axes are in the neutral state by comparing their value to the `NO_INPUT` value. If they are in the neutral position, `CurMotion` is set to `STOP` to put all axes in the

stopped state. The input is recorded as valid. If the first check does not pass, the input state is compared to all valid states in `JOYSTICK_INPUTS`. If a match is found, the state for the appropriate axis in `CurMotion` is set to `FWD` or `REV`. If no appropriate match is found among the valid codes, the input is recorded as invalid.

When an invalid input is detected, `CurMotion` is set to all `STOP`, the time is recorded in `FirstInvalid` and the `InputIsValid` flag is set to `false`. If the `InputIsValid` flag is already `false`, an invalid input has been detected before. The current time is compared to the time stored in `FirstInvalid` and the difference compared to `InvalidInputTimeoutPeriod`. If the time since the first invalid input is greater than the timeout period, an `InvalidInputException` is thrown. If a valid input state is detected after an invalid one, but before the timeout period has fully elapsed, the `InputIsValid` flag is set back to `true`, and normal operation resumes.

`EStop_Startup/TurnOff` ()

These functions respectively turn the Emergency Stop on and off by opening a connection to the USB relay which is accessed like a normal file and sending the appropriate code identified by the constants `ESTOP_ON` and `ESTOP_OFF`. These functions are used during system startup and shutdown. If the function is unable to open a connection to the relay, it throws an EStopException.

`EStop_CheckConnection`()

This function verifies that a connection to the Emergency Stop is still active and it can be accessed normally. It does this by attempting to open a new connection, which looks like opening a file. If the connection is successful, it closes it and continues normally. If the connection is not successful, it throws an `EStopException`.

`EStop_EmergencyStop`()

This is the function used to activate the Emergency Stop and cut power to the robot when a safety failure occurs. It sends the command to open the relay switch, disconnecting the motor power circuit and logs that the Emergency Stop has been activated. If it is unable to connect to the Emergency Stop, it disables the motors through the `DisableMotors` function and throws an `EStopExcepion`.

`Check_MotorsActive`()

This function checks the motor state to check if any of the motors have been disabled, indicating that a position or overvoltage error has tripped on the Galil. It throws a `MotionException` if it detects a disabled motor.

`GalilWatchdog`()

This function implements the PC side of the watchdog timer between the Galil and the PC. The first thing it does is check how long it has been since the last message was received from the Galil. If that time is greater than WatchdogCriticalTimeout_Galil, the timer times out, sets the WatchdogDisableGalil flag to true, and throws a WatchdogException. If the time is greater than WatchdogNonCriticalTimeout_Galil, it logs the non-critical timeout and continues. If the time is less than WatchdogCriticalTimeout_Galil, it continues the watchdog procedure as normal. It first sends a message to the Galil then checks for a response. If it receives a response, it checks if the response is normal. If it is, it resets LastGalilWatchdog to the current time and returns. If it receives an error response, it throws a WatchdogException. If it does not receive a response, it returns normally but does not reset LastGalilWatchdog. If any errors occur in communication with the Galil, it rethrows the exception.

# devGalilController

devGalilController is the CISST wrapper for the Galil C API to communicate with the Galil motor controller. The Galil Command and User manuals should be consulted for details about Galil commands and behavior. Notably, it also contains the base class for all safety failure exceptions in the RoboELF software system, RobotException.

## Inner Classes(Exceptions):

RobotException

This is the base class for all error exceptions generated in the RoboELF software system. It is itself a subclass of std::runtime_exception. It is never explicitly instantiated anywhere but allows other exceptions to be caught in a more general way. It also contains a virtual function raise that allows it to be caught and rethrown by reference, preserving inheritance relationships.

ExcpCommError

This exception is thrown when a communication error occurs while attempting to send or receive messages and commands from the Galil.

ExcpSystemError

This is a generic exception that is thrown when a minor error occurs, such as a Galil command error. These errors are regarded as non-serious by robotTask when they are caught, therefore it is simpler to aggregate them into a single exception type. Separate errors are still logged when they occur for maintenance and debugging purposes.

ExcpMotionError

This exception is thrown when a non-communication-related problem is detected in a motion command function such as WaitMotion, SetPostionMove and SetVelocityMove.

ExcpPowerError

This exception is thrown when an error occurs while attempted to turn the motors on or off.

`ExcpWaitMotion`

This exception is thrown when an errors occurs in the `WaitMotion` function.

## Important Class Fields:

`galil`

Instance of the Galil API interface class.

`AnalogInput`

Vector containing values of the potentiometers on each axis.

`GalilIP`

String holding the current IP address of the Galil.

`NB_Actuators`

Enum defining the number of axis present on the robot.

## Important Class Functions:

`Init`()

This is the startup function. It takes an IP address as a parameter that will be used to connect to a Galil via TCP/IP connection. If a Galil is not found at that address, a menu prompt will be displayed with available addressable Galil controllers. If a Galil is found and a connection is made, the IP address is saved in GalilIP. If connection fails or another error occurs, an exception is thrown.

`Close`()

This is the shutdown function. It turns off the motors and deletes the galil object.

`Enable/DisableMotorPower`()

These functions turn the motors on and off using the “SH” and “MO” commands, respectively. They can be applied to all or some of the motors by passing a mask parameter. If no parameter is given, the command is applied to all axes. If an error occurs, an `ExcpPowerError` is thrown.

`StopMotion/All`()

These functions stop motion, but to not cut power from, all or some of the motors as indicated by the mask parameter(`StopMotionAll` calls `StopMotion` with all true mask parameter).

`GetGalilMessage`()

This function retrieves any messages in the queue that have been sent from the Galil to the PC. If no messages are in the queue, it returns an empty string.

`GetActuatorState`()

This function reads all necessary values from the Galil to populate a `prmActuatorState` variable. It also reads the current state of the analog inputs. The actuator state values include, for each axis: in motion, home switch and motor off flags, forward and reverse limit switch status and a timestamp.

`GetAnalogInputs`()

This function places the analog values read from the Galil in `GetActuatorState`() into a passed-by-reference parameter variable. They are not returned in `GetActuatorState` because they are not part of the `prmActuatorState` variable.

`ReadExIO`()

This function reads the Galil's external IO status. The external IO is configured in 4 blocks that must be read individually. `ReadExIO` takes a vctInt4 variable as a parameter to store the results and return them. To read each IO block, the command "TI [2,3,4,5]" is sent to the Galil(the blocks are numbered 2 through 5). The response to each command(the status of that IO block) is stored in the parameter variable. If an error occurs, a `ExcpSystemError` is thrown.

`SetPositionMove`()

This function is used to command motion with the Galil. It puts the Galil into Position Tracking mode which allows an absolute goal position(specified in encoder counts) to be given and updated on the fly while motion is already under way. The goal position is given as a masked input parameter. If there is an error, an `ExcpMotionError` is thrown.

`SetVelocity`()

This function sets the velocity at which each axis will move when given a motion command. The desired velocity is given as a masked input parameter. If there is an error, an `ExcpSystemError` is thrown.

`SetAc/Decceleration`()

These functions set the acceleration/deceleration with which each axis will move when given a motion command. The desired value is given as a masked input parameter. If there is an error, an `ExcpSystemError` is thrown.

`SetFwd/RevSoftwareLimits`()

These functions set the forward and reverse software motion limits, given in encoder values, on the Galil. By default these values are set to maximum range and do not affect motion. After they have been set the Galil will prevent the motors from moving past the specified limits.

`Set/Activate/DeactivateOverVoltageLimit`()

These functions set a value for, activate and deactivate the Galil's overvoltage safety limit. The Galil's overvoltage limit turns off a motor if it detects that voltage over a specified limit is being applied, but the motor is not moving. By default this feature is turned off and the default voltage threshold is about 1.5V. Note that this feature does not send any notification when it disables a motor. If an error is detected, an `ExcpSystemError` is thrown.

`Set/Activate/DeactivatePositionErrorLimit`()

These functions set a value for, activate and deactivate the Galil's position error safety limit. The Galil's position error limit turns off a motor if the current position is farther from the commanded goal position than a specified threshold. By default this feature is turned off. Note that this feature does not send any notification when it disables a motor. If an error is detected, an `ExcpSystemError` is thrown.

`SetGains`()

This function sets the PID gain values on the Galil. It takes the values as a one-dimensional int array organized in the following manner:

[kdA, kpA, kiA, kdB, kpB, kiB, kdC, kpC, kiC]

`ReadConfigFile`()

This function downloads a program file to the Galil's ROM. The file name is passed as a string parameter. If an error is detected, an `ExcpSystemError` is thrown.

`WaitMotion`()

This function blocks until the axes indicated by a mask parameter have stopped moving, or until a timer runs out. It loops every .002 seconds and interrogates the Galil to see if the given axes are in motion. It also checks if the timer has run down. If the timer runs out first, an `ExcpWaitMotion` is thrown. If motion stops, it returns normally.

`SendCommand`()

This function is used by almost every other function listed to send commands to the Galil. It calls the Galil API function to send a command to the Galil and returns the Galil's response. All commands and responses are sent as strings. If the Galil returns an error, `SendCommand` throws an exception, a `ExcpCommError` if it is an invalid command or timeout error, an `ExcpSystemError` it is anything else other than a command error. Command errors are ignored to reduce log file clutter. They occur most often when a motion command cannot be completed for a non-dangerous reason, for example if it is at a range limit.

`CreateCommand`()

This is a helper function that assembles string commands for axes specified by a mask parameter. It takes as parameters the command to send, a mask variable indicating which axes it applies to, and a list of axis-specific parameters to pass along to the Galil. It creates string commands of the form "<command> <axis A param>, <axis B param>, <axis C param>". For example "FL 10000,20000,30000".

`CreateComandForAxis`()

This is a helper function that assembles string commands for axes specified by a mask parameter. In contrast to the CreateCommand function, it does not pass axis-specific parameters to the Galil. It creates string commands of the form "<command> <axis><axis>…". For example: "SH ABC".

# qtRobotDevice

Contains an instance of the GUI class and fields and functions to populate and update the GUI during runtime. It uses the CISST library's command pattern to get data from `robotTask`.

## Important Class Fields:

`ActuatorState`

Holds information about the current robot state including encoder counts and limit switch state.

`AnalogInput`

Contains the current values of the analog potentiometers.

`GetActuatorState`
`GetAnalogInput`
`GetEncoderRange`
`GetEncoderOffset`

These are all CISST Multitask `mtsFunctionRead` functions that have definitions in `robotTask`. They read the indicated variables in `robotTask`.

`SliderValues`

The current position values for the dials and slider on the GUI.

`RobotGUI`

An instance of `throatGUI` that defines the GUI.

## Important Functions:

`qtRobotDevice`():

Constructor initializes an instance of `mtsInterfaceRequired`, named "RequiresThroatRobot". This is what allows `qtRobotDevice` to communicate with `robotTask`. The constructor also initializes and starts the update time for the GUI.

`Configure`():

`Configure`() sets the size and position of the GUI and displays it.

`QSlotTimerUpdate`():

This function is called every time the update timer runs down. It refreshes the values on the GUI. It reads the current values from `robotTask` by calling its CISST Multitask functions and sets the displayed values to these new ones.

`ConvertSliderValues`():

This function is called in `QSlotTimerUpdate`(). It uses the encoder position and offset values read from `robotTask` to set the position of the dials and slider on the GUI. To display properly, these values must be scaled to a 0-100 scale.

## throatGui

Contains one function, a constructor, that defines and initializes the GUI components. The GUI uses `QLCDNumber`s for all of the active display fields and `QLabel`s for all of the static text labels. It uses `QDial`s for the rotational axis displays and a `QSlider` for the linear axis.

## References

[1] CIIST Libraries. CIIST ERC. http://cisst.org

[2] Kazanzides P., DiMaio S., Deguet A., Vagvolgyi B., Balicki M., Schneider C., Kumar R., Jog A., Itkowitz B., Hasser C., Taylor R. The Surgical Assistant Workstation (SAW) in Minimally-Invasive Surgery and Microsurgery. 2010 Jun.

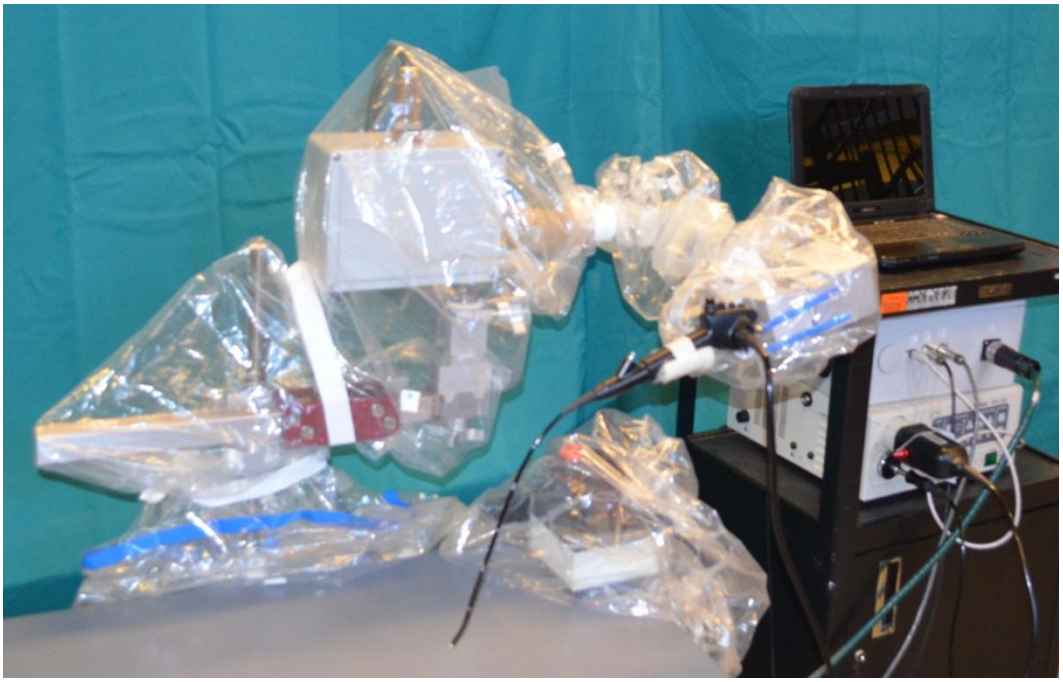
[3] Qt. http://qt-project.org, http://qt.digia.com

[4] Ubuntu Operating System. http://www.ubuntu.com

[5] Galil Motion Control. http://www.galilmc.com

[6] Cross Platform Make(CMake). http://www.cmake.org

# Robotic EndoLaryngeal Flexible (Robo-ELF) Scope User Manual



# Table of Contents

# I. System Overview

The Robotic Endo-Laryngeal Scope (Robo-ELF Scope) is a robotic system for the manipulation of unmodified clinical flexible endoscopes (Fig 1). It is designed to improve precision, coordination, ergonomics, and surgical capabilities when using flexible endoscopes in the operating room for visualization of the upper airway. The system includes a robot which is mounted to the rail of the operating table with a passive positioning arm, a joystick controller, a standard clinical flexible endoscope, an electronics enclosure, and a control PC. The robot and joystick are designed to be draped for easy cleanup. The robot is slow moving with limited range of motion, and incorporates several redundant layers of hardware, electronic, and software safety features. The tip and shaft of the endoscope, which is already approved for clinical use, are the only parts of the system that contact the patient. The Robo-ELF can be operated with one hand using its joystick, enabling steady, precise positioning of the scope tip with no fatigue or hand tremor. The Robo-ELF Scope enables manipulation of a standard flexible endoscope in three degrees of freedom: tip flexion, scope rotation, and insertion/extraction. Each degree of freedom is controlled by an independent joystick axis, providing simple, direct control of the scope. In the event of an emergency, the scope can be quickly removed and the robot arm swung out of the way, providing direct access to the patient in seconds.

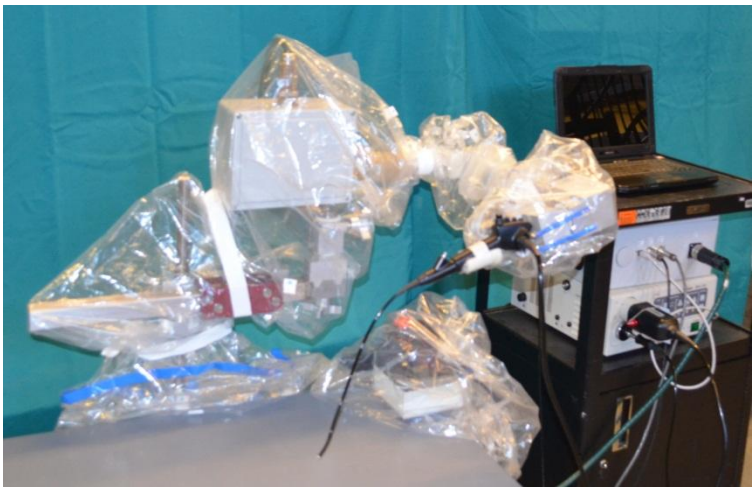


Figure 1: The Robo-ELF Scope

# II. Usage Instructions

## A. Compatible Scopes

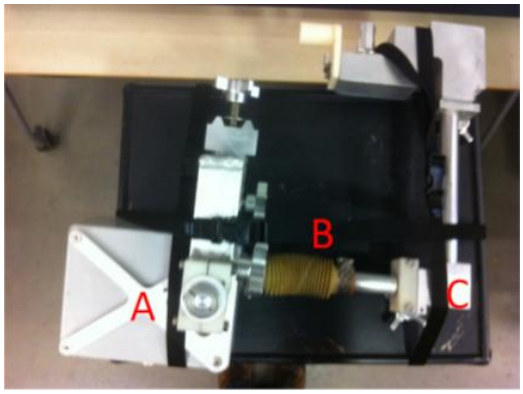
The following list of scope(s) has been approved for use with the Robo-ELF Scope system. Use of unlisted scopes is prohibited.

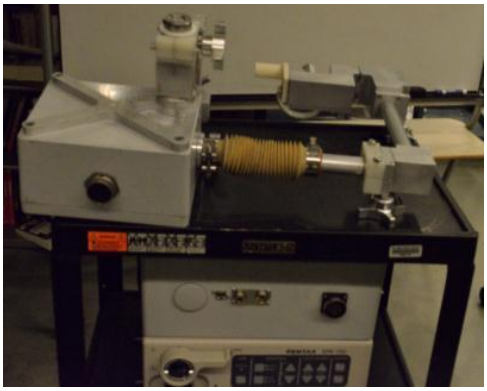
- PENTAX VNL-1570STK naso-pharyngo-laryngoscope

## B. Set Up Instructions

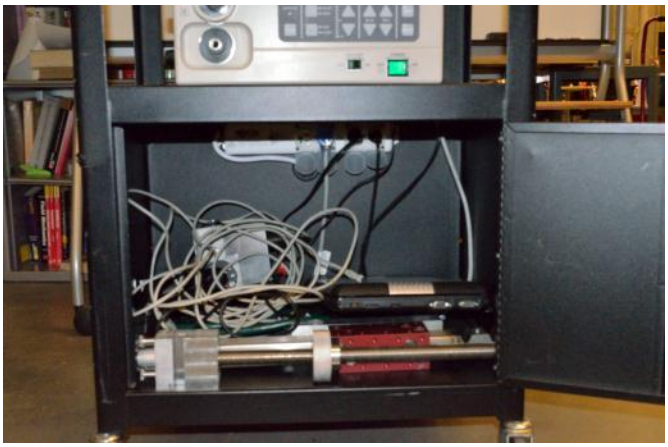
1. Remove cover from cart

2. Remove the three straps (A, B, C) securing robot

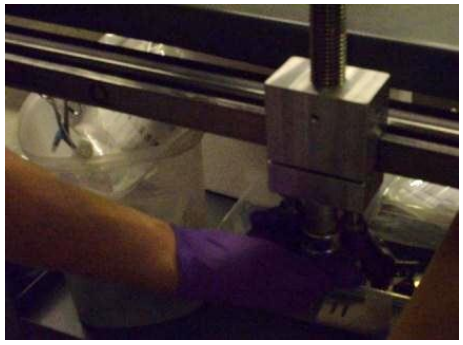


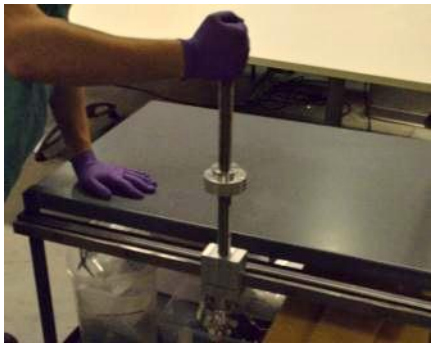
3. Remove the support arm shaft from the cart



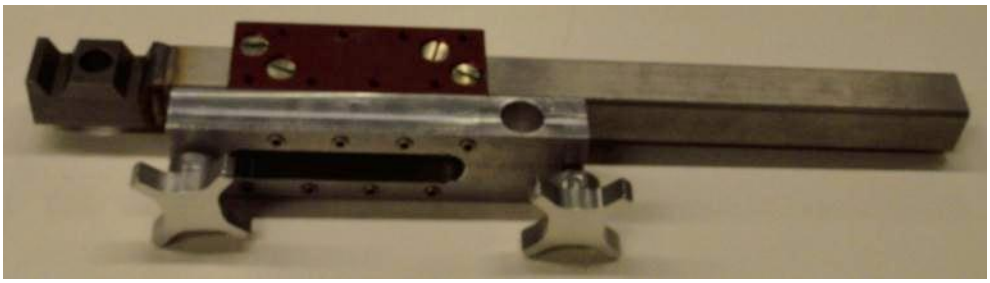
4. Align support arm shaft gripper with bed rail and slide it along the bed rail until the desired position is reached. Tighten the knob to secure the gripper in the desired position.



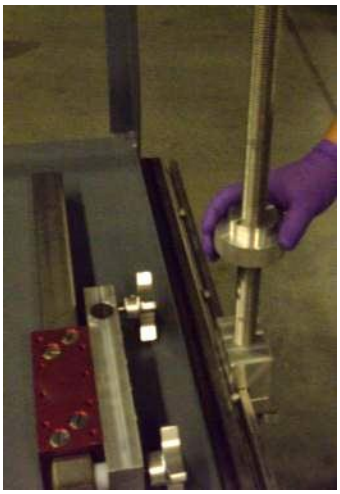
5. Grab the support arm shaft at the top of the threaded rod and try to move it back and forth to test the strength of the connection. If the tip of the rod moves more than 1cm, tighten the handle further.



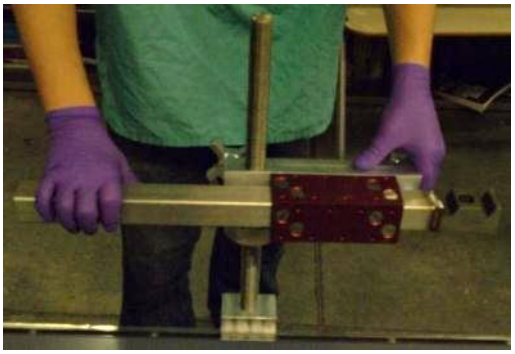
6. Remove the support arm from the cart



7. Adjust the height adjustment knob until the desired height is reached

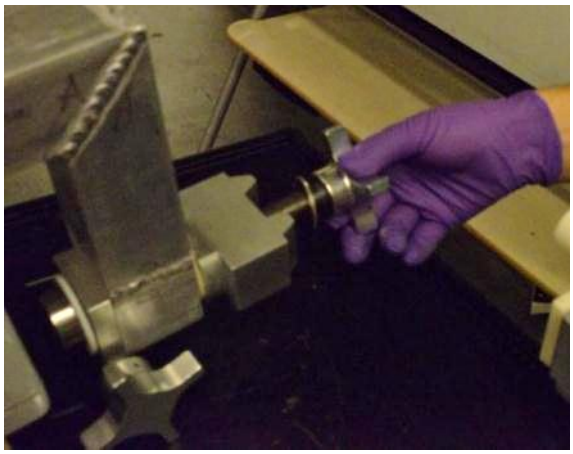


8. Place the support arm onto the support arm shaft

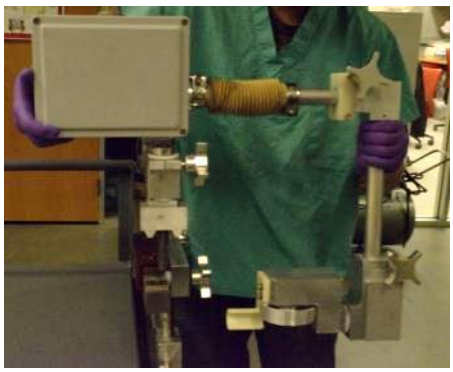


9. Tighten the support arm knob to secure the support arm onto the support arm shaft

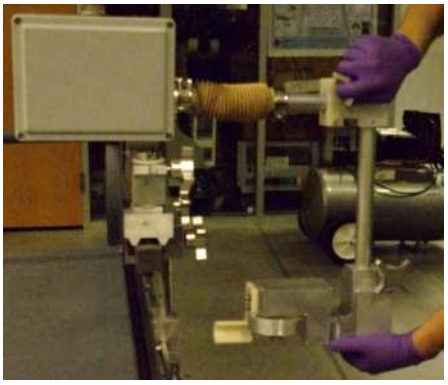
10. Remove the robot attachment knob and washer from the robot on the cart



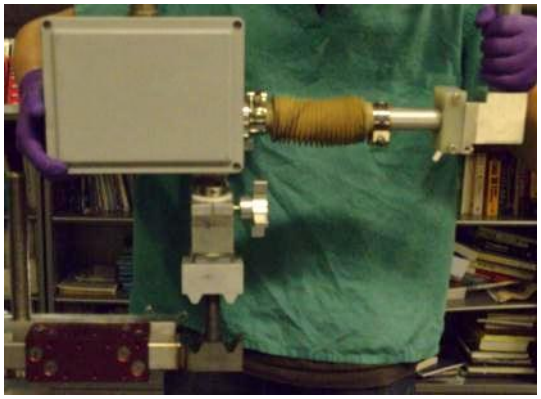
11. Pick up the robot from the cart as shown and place it in adjustment position on the support arm so that the attachment shaft on the robot passes through the hole in the support arm.



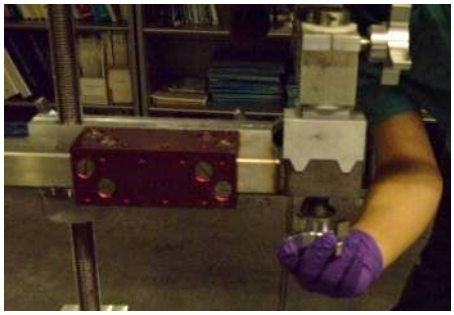
12. Loosen the elbow knob of the robot and rotate the robot arm 180 degrees away from the support arm so that it is in the upright position, then retighten the knob.



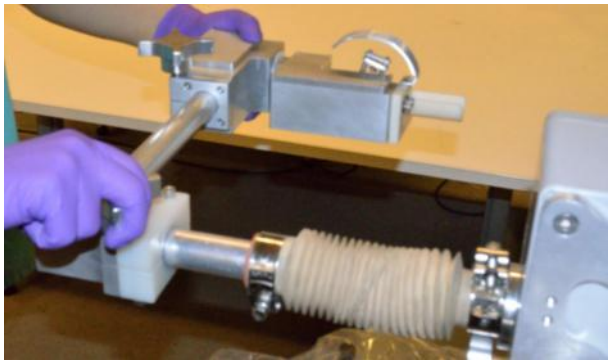

13. Lift the robot off of the support arm and place it back on the support arm in operating position (rotated 90 degrees from adjustment position)



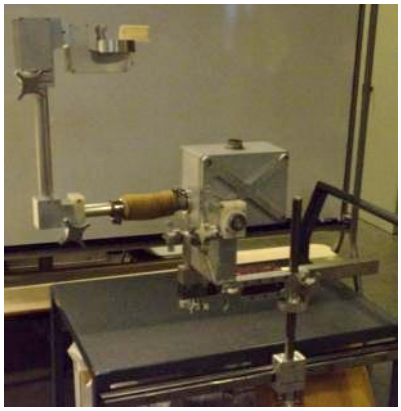
14. Screw the robot attachment knob and washer back onto the robot and tighten fully



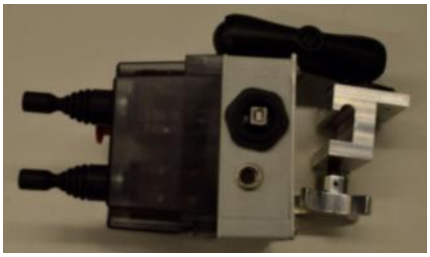
15. Loosen the elbow knob and rotate the robot arm into ready position. Press down on the arm to make sure the friction collar will not allow the arm to fall.

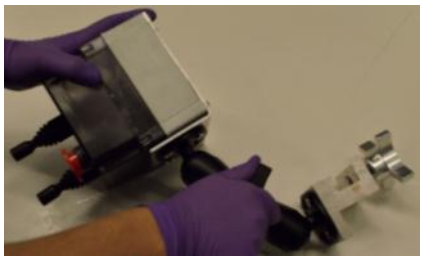


16. The robot should appear as pictured.

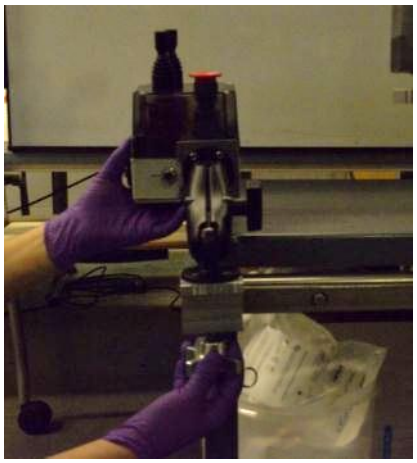


17. Tighten all of the knobs to ensure that the robot is secure
18. Remove the joystick from the cart and unfold the joystick arm by loosening the joystick adjustment knob, positioning the joystick arm, and retightening the knob.

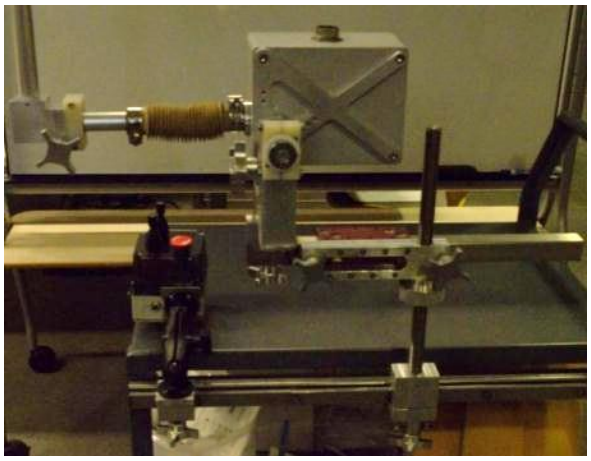




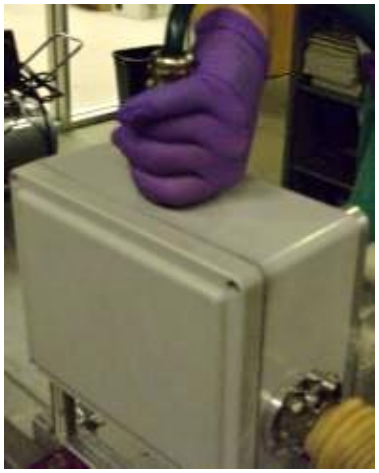
19. Align the joystick gripper with the end of the bed rail and slide the joystick along the bed rail to the desired position (loosen the joystick gripper knob if needed to slide it onto the rail). Tighten the joystick gripper knob to secure it in place.



20. The system should look as pictured

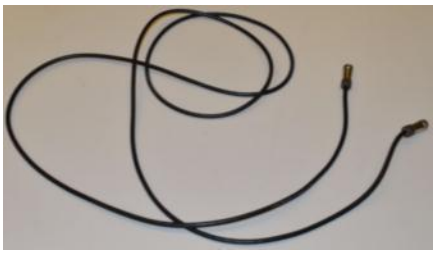


21. Take the robot cord out of the cart and plug the metallic end into the robot, twisting the end of the connector to lock it in place.



22. Plug the plastic end into the robot box. Twist the end of the connector to lock it in place.

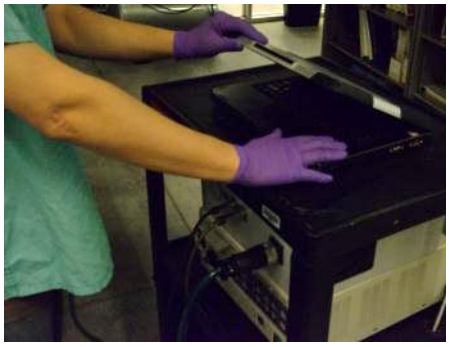

23. Take the joystick power cord out of the cart and plug it into the joystick and robot box, turning the end of the connector to lock it in place.



24. Take the joystick signal cord out of the cart and plug it into the joystick and robot box, turning the end of the connector to lock it inplace.

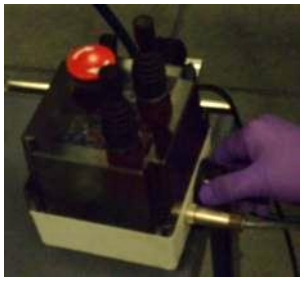


25. Take the laptop out of the cart and place it on top

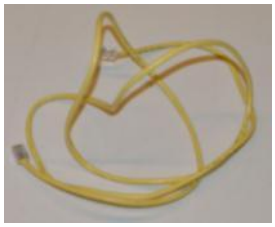


26. Feed the laptop power cord through the cable feed-through holes in the cart and plug it into the laptop


27. Take the USB cord out of the cart and plug it into the laptop and joystick, screwing in the joystick end to secure it.


28. Take the Ethernet cord out of the cart and plug it into the robot box and the laptop, making sure to feed it though the cable feed-through hole on the cart's upper level



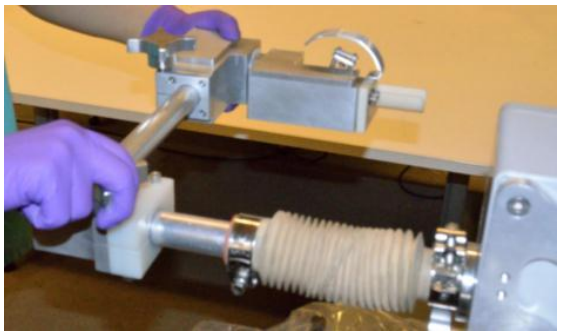
29. Check that the robot box, scope box, and laptop are all plugged into the internal power strip inside the cart

30. Close the door on the cart

31. Place the joystick cords behind the joystick adjustment handle

32. Remove one joystick drape from its package and place it over the joystick until the elastic band in the drape is around the joystick cords below the joystick gripper

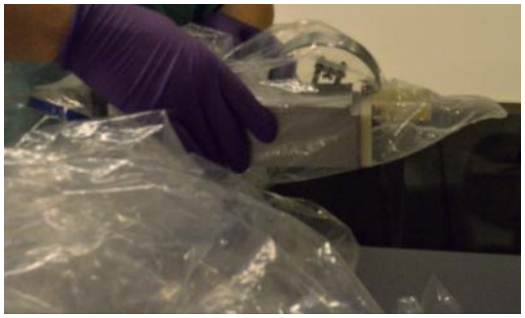
33. Put the robot arm into ready position

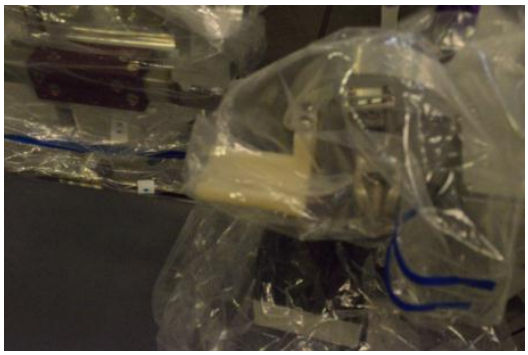
34. Open and unfold the robot drape



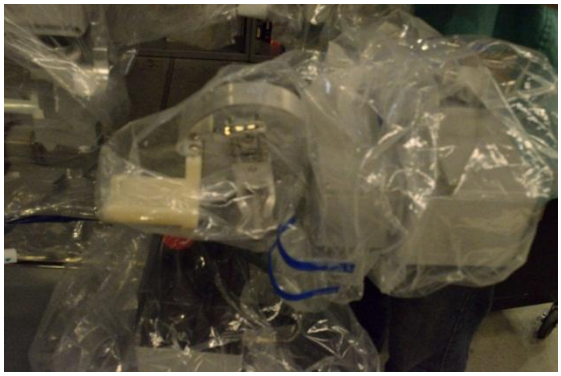
35. Slide the drape over the robot beginning at the scope holder



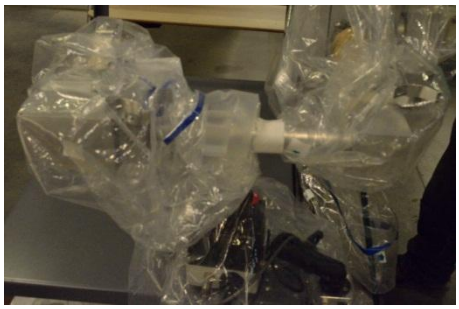
36. Fold the drape tip into the scope holder

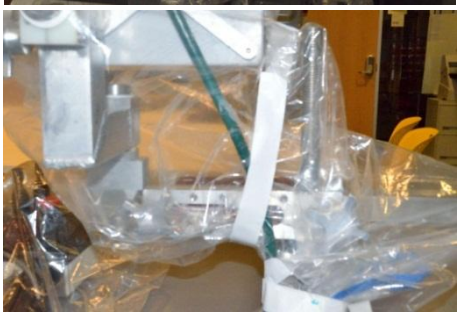
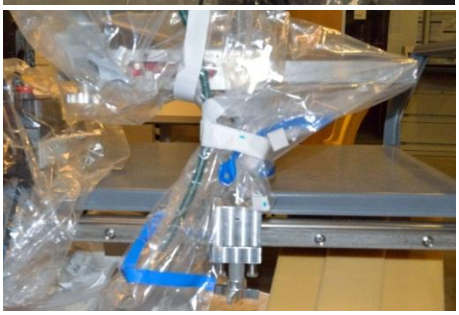



37. Adjust the drape over the scope holder so that it appears as shown

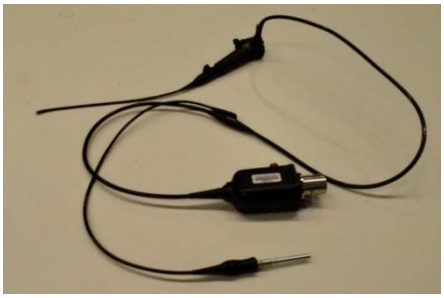
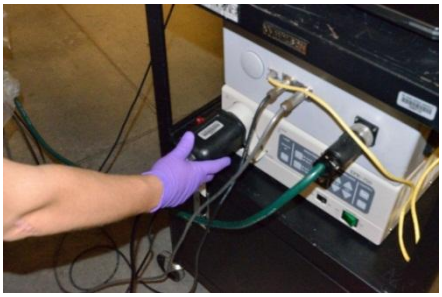


38. Tighten the four white tape strips around the drape as shown, making sure to leave enough room for each knob to turn

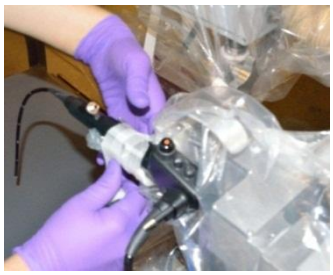


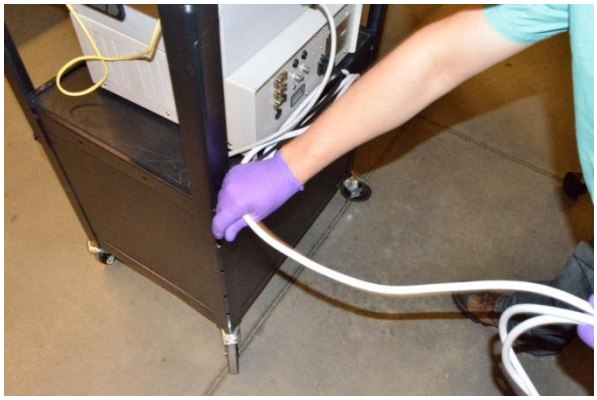
39. Connect the scope control box to the video display according to the instructions for the scope and display.
40. Inspect the scope for any surface marring that could compromise sterility. Only un-marred scopes should be used.
41. Plug in the scope's video feed and light source cables to the scope control box

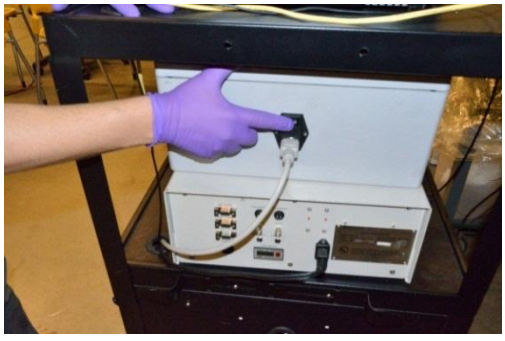
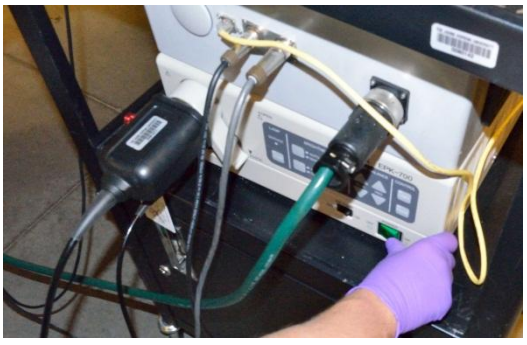
42. Use silk tape to attach the scope onto the scope holder so that the scope's handle axis is aligned with the scope handle manipulator's axis on the robot. Make sure that the scope handle is well seated inside the scope holder. Run the scope cables **in front** of the joystick box on the operating table and underneath the robot's arm, place the scope within the clasp, being sure that the axis of rotation of the scope lines up with the groove of the rotation of axis of the robot's arm. See figure.




43. Plug the main power cord on the cart into the wall socket



44. Turn on the robot box and scope box

45. Turn on the computer

46. Boot the computer into Ubuntu(First option on boot list)

47. Run the program by double clicking the Run RoboELF icon on the Desktop
    47.1. Select the “Run in Terminal” option on the popup menu
    47.2. You may be prompted to enter the admin password(Robot)
48. Enter ‘y’ and press <Enter> to continue when prompted.
49. The following menu will be presented to select the desired calibration option:

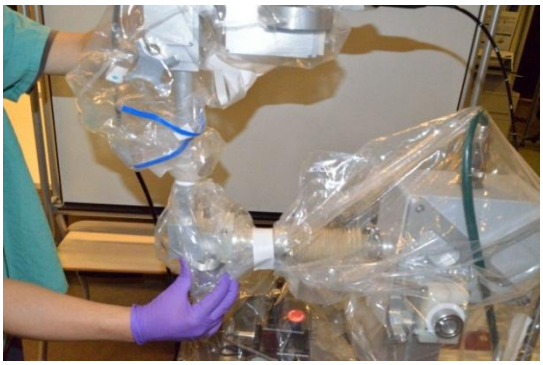
    “Do you want to:
    [1] Normal Recalibration
    [2] Load Previous Calibration From File”

    Enter the number in brackets([ ]) and press the <Enter> key to make a selection.

    Option [1], “Normal Recalibration”, should be used in most situations. This will run the robot through its full range of motion to build calibration tables for each axis. The new values are checked to make sure they are close to expected values.

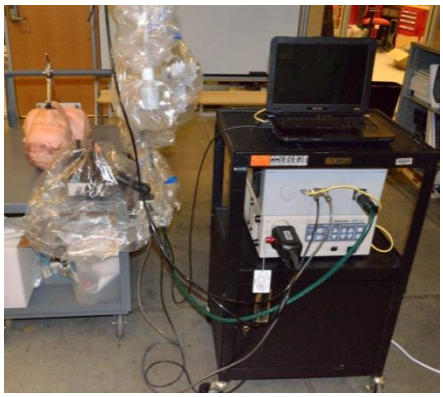
    Option [2], “Load Previous Calibration From File”, will reload the most recent calibration table that is stored on file. This option should only be used in the event of a quick restart during an ongoing procedure. It should only be used if the system has not encountered encoder errors prior to shut down, and then only if it was already calibrated successfully at the start of this procedure.
50. Stay clear of the robot while it performs automatic calibration routines. It will move through its full range of motion. DO NOT touch the robot or impede its motion during this time. When automatic calibration is complete, the system will display the message “Calibration Successful”. If the calibration failed for any reason, it will display an error message. See Appendix for an explanation of error codes.
51. When calibration has successfully completed, the system will display the message “RoboELF Ready for Use”.

52. Put the robot into upright position in preparation for bringing in the patient

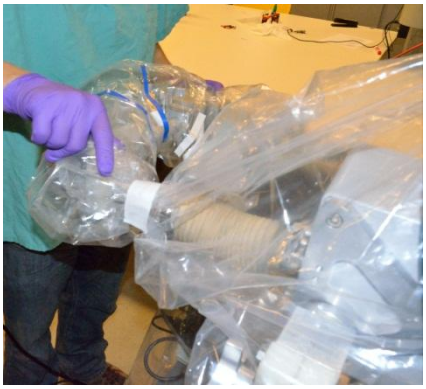


53. Let the OR staff transport the patient to the OR, administer anesthesia, and suspend the patient with the laryngoscope

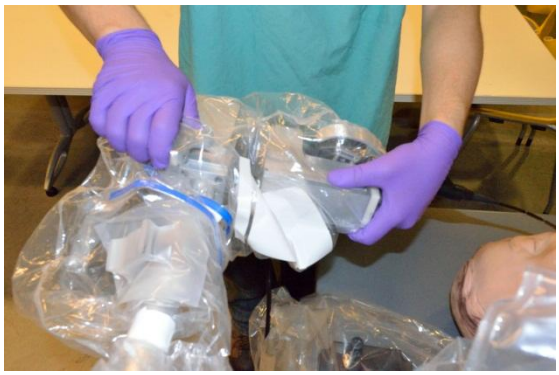
54. Once the patient is ready, the system should look as pictured



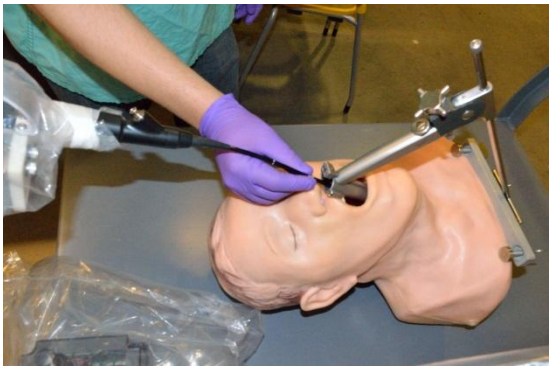
55. Put the robot into ready position



56. Adjust passive degrees of freedom so that scope shaft points down laryngoscope



57. Put scope into laryngoscope

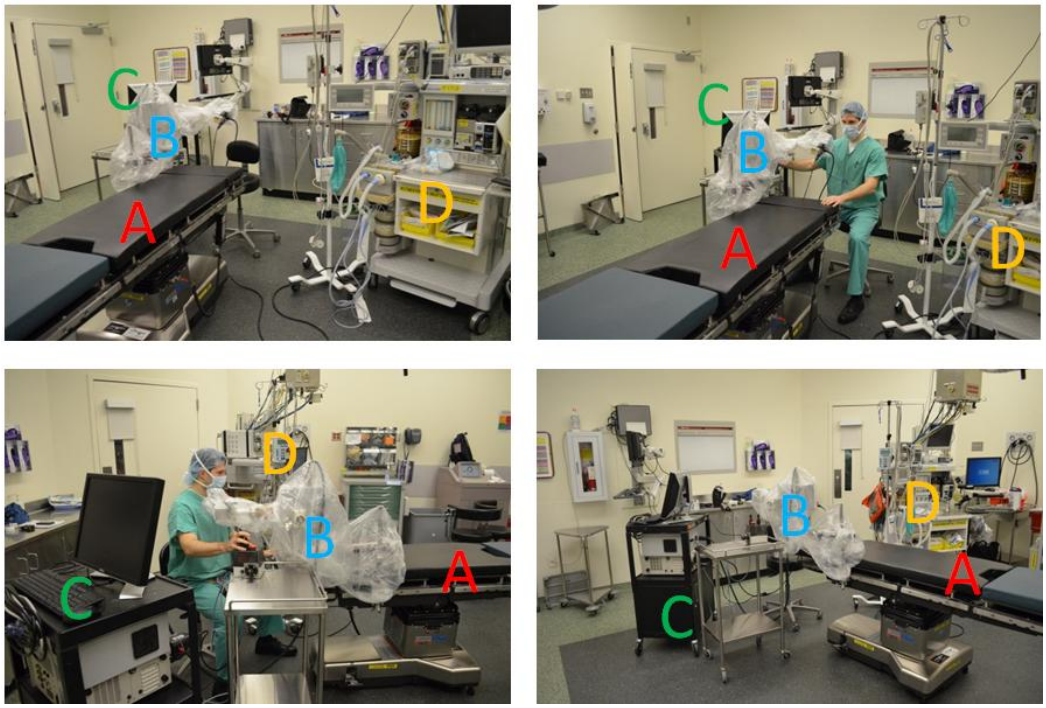


58. Adjust passive degrees of freedom so that view is optimized. See Appendix Section IV.C for details on adjusting passive degrees of freedom.

## C. Proper Use

### 1. Positioning the Robo-ELF in the OR

The figure below shows the recommended positioning of the Robo-ELF Scope relative to the other equipment in the OR.

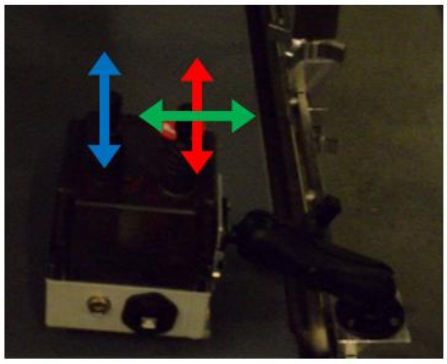


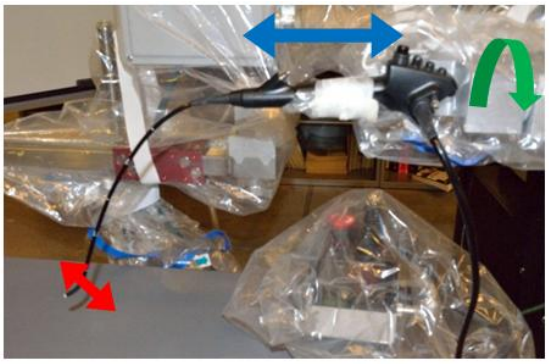

A) Surgical Bed B) Robo-ELF robot C) Robo-ELF cart D) Anesthesia cart E) (not shown near the foot of the bed) AV cart with scope screen display

### 2. Adjustment of the Robo-ELF Passive Arm

The Robo-ELF passive arm may be adjusted during the procedure if necessary. See Appendix Section IV.C for details on adjusting passive degrees of freedom.

## 3. Controlling the Scope





The Robo-ELF Scope system controls the endoscope with three degrees of freedom: bending of the scopes tip using the scope handle (RED), rotation of the scope about its axis (GREEN), and scope insertion/extraction (BLUE). These degrees of freedom are actively controlled by the joysticks. The joysticks should be operated as on-off switches in that once they move far enough passed a threshold position, the robot will begin to move. Once the joystick is passed the threshold where the robot starts moving, moving them further will have no additional effect. Because of the on-off nature of the joysticks, the best way to move the robot a small distance is to tap the joystick quickly. Also, once the joystick passes the threshold, the speed of the robot ramps up over the course of one second, so initially the robot will move slowly. Since the joysticks act as on-off switches, they should never be operated by moving them very slowly over the threshold position. It is also important not to use more than one joystick at once since this makes control more difficult.

*Safety Tips*

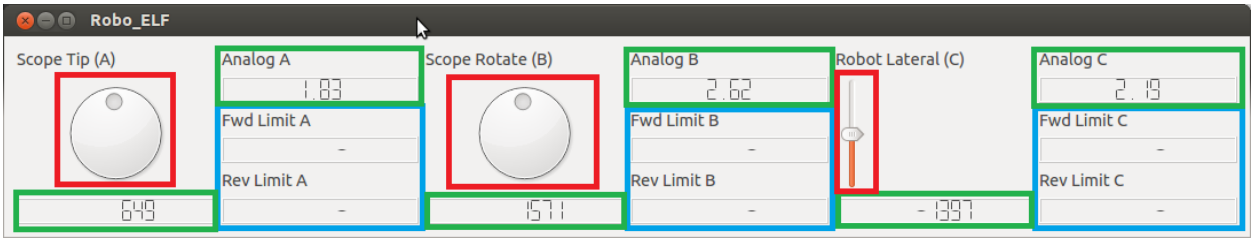
- Be careful to lock knobs and adjust passive joints carefully to avoid unwanted movement.
- Be careful of the position of cords to avoid cord tangles. This particularly important for the scope cord, especially when putting the robot into upright position.

The RoboELF GUI window displays the current status of the robot. The current position of the axes are shown in three formats, a graphical representation as a dial or slider, the current encoder count of the axis motor, the current analog output value of the axis potentiometer. The graphical display will be most useful during procedures. The others are more useful for maintenance of the system. The scope tip and rotation axes are represented by circular dials with tip motion on the far left and rotation in the center. Insertion/extraction is represented by a vertical slider on the right of the window. The dials and slider will move along with the robot, illustrating where in its range of motion the robot currently is.

Motor limit indicators are also shown on the GUI. The limit indicators display one of three symbols. When an axis has reached a software or hard limit, it will not move any farther in that direction.

- "-" indicates free to move.
- "S" indicates software limit reached.

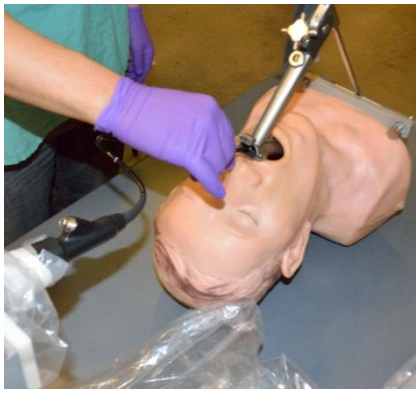
- “H” indicates hard limit reached.



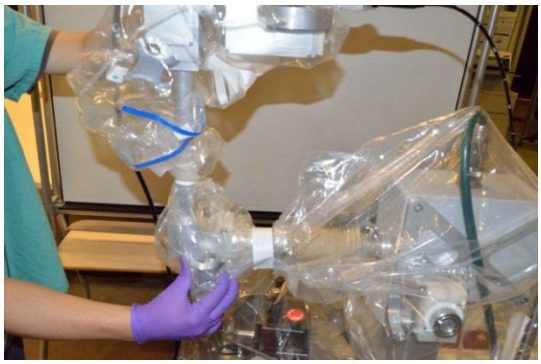

The areas highlighted in RED are the graphical current position indicators. The areas highlighted in GREEN are the text value position displays. The areas highlighted in BLUE are the forward and reverse motion limit indicators.

## D. Take Down Instructions

1. Remove scope shaft from laryngoscope



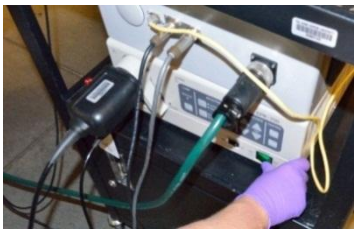
2. Put the robot into upright position



3. Let OR staff attend to the patient to remove the laryngoscope and transport the patient out of the OR

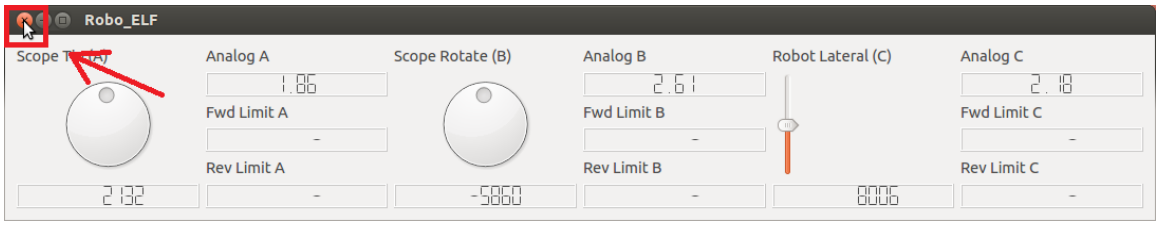
4. Put the robot into ready position

5. Turn off the scope box, unplug the scope from the scope box, and un-tape the scope from the robot

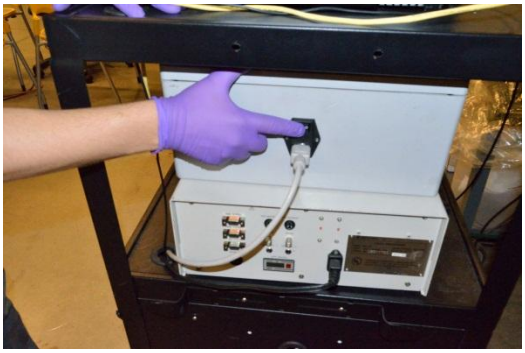


6. Check the scope for any surface marring and send the scope for reprocessing according to its instructions.

7. Click the close “x” on the GUI window. The message “Shutting Down” should be displayed on the terminal prompt. Before shutting the system down, ensure that none of the axes are in contact with a hard limit as this may cause improper calibration on restart.



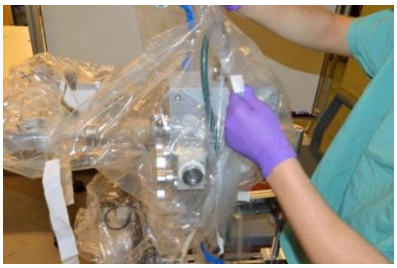

8. Turn off laptop and robot box

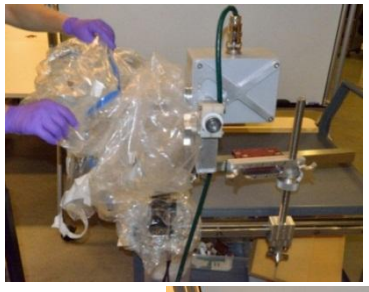



9. Unplug and roll up cart main power cord

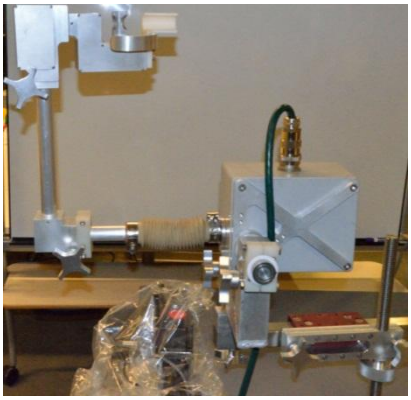
10. Unstick all four white adhesive strips on robot drape

11. Unroll the drape from the robot so that it turns inside out, taking care that the outside of the drape does not contact the robot. Dispose of the used drape.

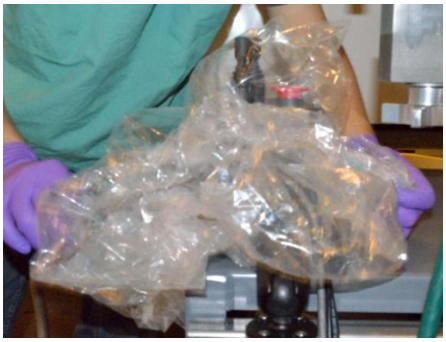


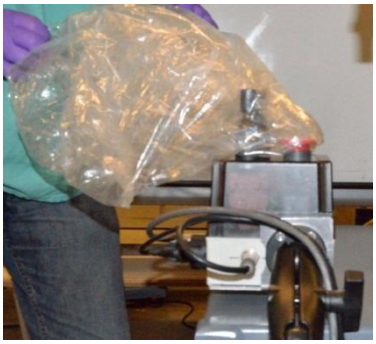


12. Put the arm upright



13. Unroll the drape from the joystick and dispose, again making sure the outside of the drape does not contact the joystick

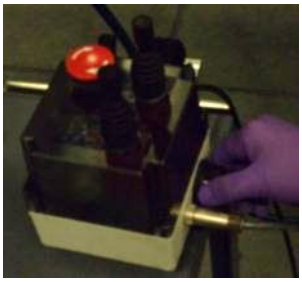




14. Spray the robot, passive arm, and joystick with Metrex Cavicide until all surfaces are wetted, and wait for the required contact time according to the Metrex Cavicide instructions. Wipe down cords with Metrex CaviWipes, making sure to wet every surface with disinfectant.

15. Unplug Ethernet cord and store in cart

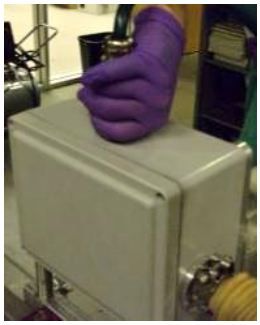
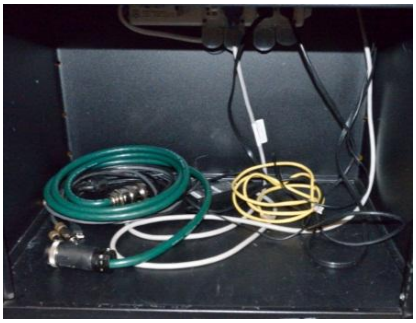
16. Unplug USB cord and store in cart



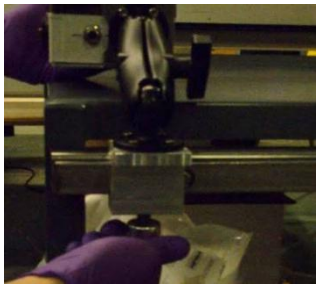

17. Unplug Joystick power cord and store in cart


18. Unplug Joystick signal cord and store in cart

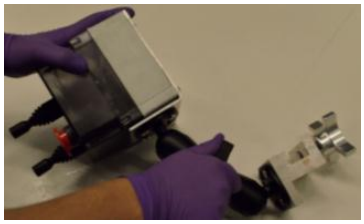

19. Unplug Robot cord and store in cart

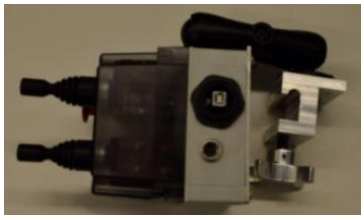



20. Detach joystick from bed

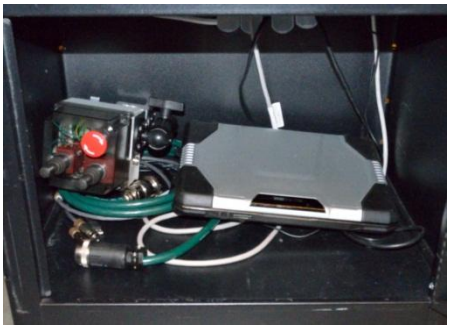


21. Fold into storage configuration and store in cart

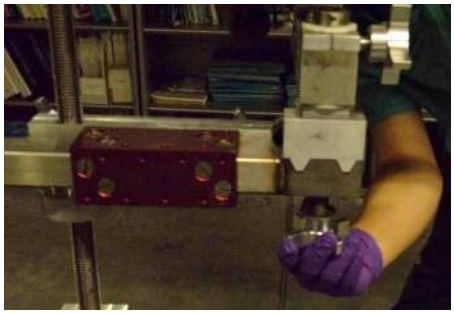




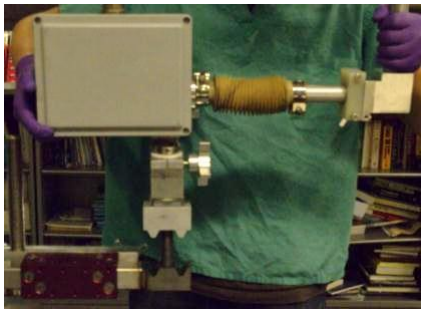
22. Close laptop and store in cart



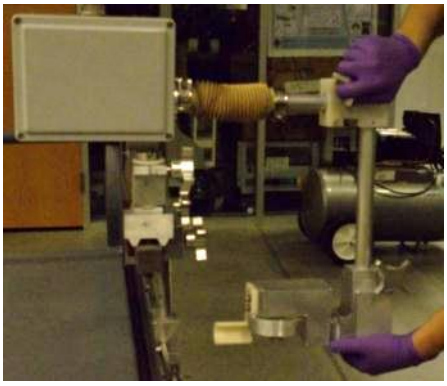
23. Remove robot attachment knob and washer



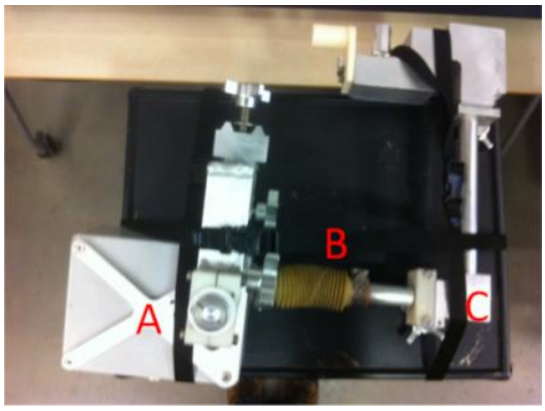
24. Lift robot from support arm and rotate robot 90 degrees into adjustment position



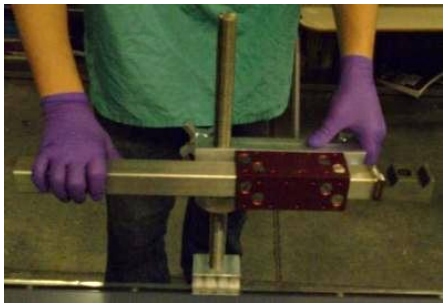
25. Rotate robot arm 180 degrees into storage position



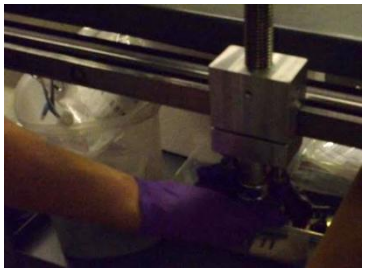
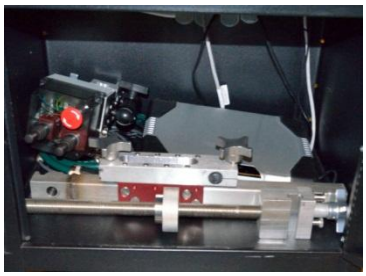
26. Place robot on cart, screw on attachment knob and washer for storage, and secure with straps A, B, and C



27. Detach support arm from support arm shaft and place in cart


28. Detach support arm shaft from bed and place in cart

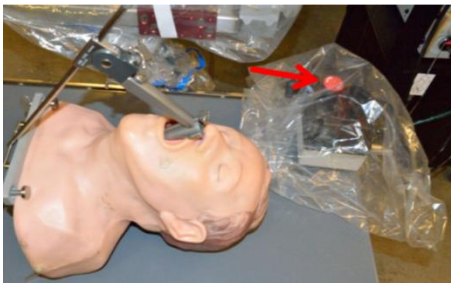



29. Close cart, cover, and store system


# III. Safety/Emergency Protocol

## A. Emergency Shutoff Methods

- Robot issue automatically detected
    - Robot will stop when internal safety relay shuts off
    - Check command prompt for information
    - If not recoverable:
        - Turn off robot
        - Remove scope from robot
        - Put robot in upright position
        - Continue operation manually
- Robot issue undetected by software or other emergency involving robot
    - Press e-stop button on joystick enclosure



    - Remove scope from robot
    - Put robot arm upright position
    - Continue operation manually
- Patient issue unrelated to robot
    - Pull scope shaft out of laryngoscope
    - Put robot arm in upright position
    - Attend to patient

# IV. Appendix

## A. Software Messages

Below is a brief explanation of error messages generated by the Robo-ELF system and the proper response for dealing with each one, as well as other system failures. Where it is indicated to "Shutdown the software", the user should close the program window for the software(Step 7 in shutdown instructions) but not turn off the laptop or Robot Box unless otherwise indicated. This makes a safe, quick restart possible. If the Robot Box is turned off or loses power at any point during the procedure, a full recalibration must be performed.

**Computer/Program crash**

In the case that the program or computer crashes without reporting an error message, a full system restart may be attempted, but if multiple crashes continue to occur, the system should be shut down and sent for maintenance.

**Calibration Error**!

- Indicates that there was an error in the calibration of the system. The system cannot be guaranteed safe to use if calibration is not successful.
- Can occur during calibration(Full recalibration or from file)
- If error occurs during calibration from file, a full recalibration may fix the issue.
    - Shutdown and restart the software, selecting Option [1] for recalibration.
- If error occurs during full recalibration, it cannot be guaranteed that the system is safe to use until a maintenance check has been performed.
    - Shutdown the system and do not attempt to use it until maintenance is complete.

**System Error! EStop Connection Failed**

- Indicates that the PC cannot communicate with the Emergency Stop switch. Without proper connection to the Emergency Stop, the robot cannot stop itself in the event of a safety failure.
- Can occur at any point after completed calibration due to system failure or if the USB cable becomes disconnected or broken.
- Shutdown the software.
- Check the USB connection between the PC and the Joystick Box. Verify that the cable is properly plugged in.
- Restart the system(step 44 in startup instructions)
    - The script "Estop.sh" must be run prior to running the RoboELF program to ensure proper connection with the Emergency Stop switch.
- If a successful calibration was completed prior to the error, the system may be restarted using the previous calibration data instead of re-running the calibration routine(Option

[2] on the calibration selection). If this error continues to occur, send the system for maintenance.

- If this error continues to occur, send the system for maintenance.

**Connection Error! Check Connections and Restart System**

- Indicates that the PC cannot properly communicate with the Robot Box. If the PC cannot communicate with the Robot Box, it cannot issue commands to move or stop the robot.
- Can occur at any time after completed calibration due to a system failure or if the Ethernet cable becomes disconnected or broken.
- Shutdown the software.
- Check the Ethernet connection between the PC and the Robot Box. Verify that the cable is connected properly at both ends.
- Restart the system(step 44 in startup instructions)
- If a successful calibration was completed prior to the error, the system may be restarted using the previous calibration data instead of re-running the calibration routine(Option [2] on the calibration selection). If this error continues to occur, send the system for maintenance.
- If this error continues to occur, send the system for maintenance.

**System Error! Encoder Failure**

- This message indicates a problem with the motors and/or internal sensors in the system. If the motors or sensors(potentiometers and encoders) are not functioning properly, the robot cannot be properly controlled.
- Can occur at any time after completed calibration due to malfunctioning motors or sensors. The system may give false positives if it is too close to an error condition.
- Shutdown the software.
- A system restart may be attempted in case the error was a false positive.
    - Restart the system(step 44 in startup instructions)
    - Full recalibration (Option [1] on the selection menu) should be used in this case.
- If this error continues to occur, send the system for maintenance.

**Error! Motor Error Detected!**

- This message usually indicates that something is blocking the motion of the robot or that there is a mechanical problem with the robot.
- Shutdown the software.
- A system restart may be attempted in the case that the error was a false positive.
    - Restart the system(step 44 in startup instructions)
    - If a successful calibration was completed prior to the error, the system may be restarted using the previous calibration data instead of re-running the calibration routine(Option [2] on the calibration selection).

- If the error persists after restart, the Robo-ELF should be shut down, and the procedure finished by hand.

**Joystick Error Detected**

- Indicates an error in the joysticks. If the joysticks are not functioning properly, the robot cannot be properly controlled.
- Can occur due to joystick failure or improper use of the joysticks(multiple joysticks depressed at the same time, joystick not fully depressed during use)
- Shutdown the software.
- A system restart may be attempted in the case that the error was a false positive.
    - Restart the system(step 44 in startup instructions)
    - If a successful calibration was completed prior to the error, the system may be restarted using the previous calibration data instead of re-running the calibration routine(Option [2] on the calibration selection).
- If the error persists after restart, the Robo-ELF should be shut down, and the procedure finished by hand.
    - Send the system for maintenance.

**System Error!**

- This message indicates a serious failure of the software or hardware system.
- Shutdown the RoboELF system. The procedure should be finished by hand.
- A system restart is not advised in this case.

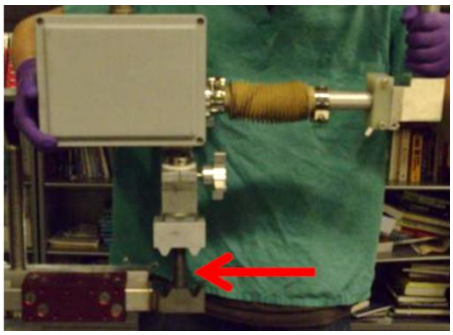
# B. Terminology

## 1. Components

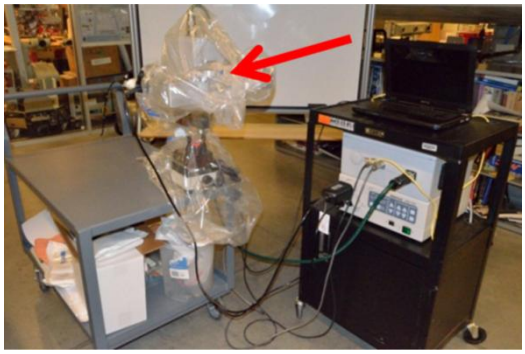
- Support arm shaft

- Support arm

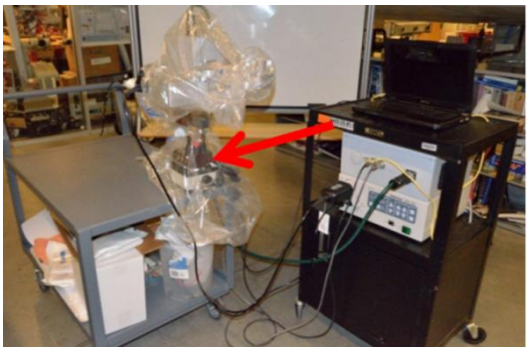
- Attachment shaft



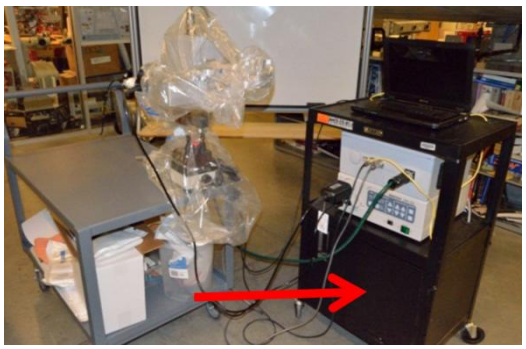
- Robot



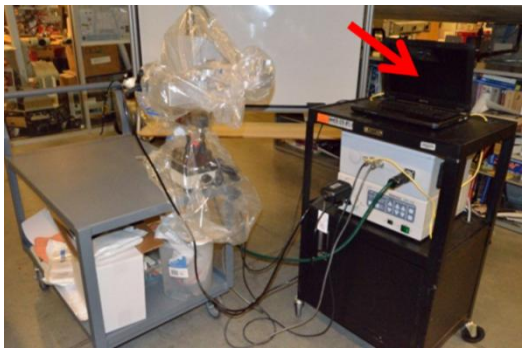
- Joystick



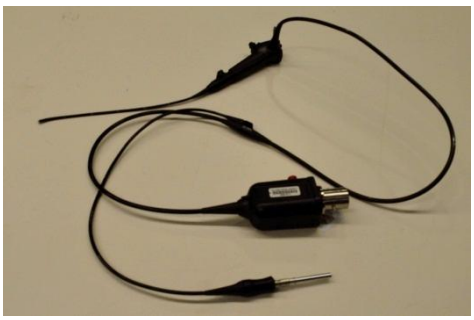
- Cart



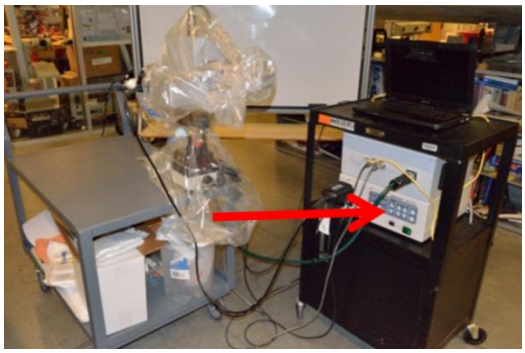
- Laptop



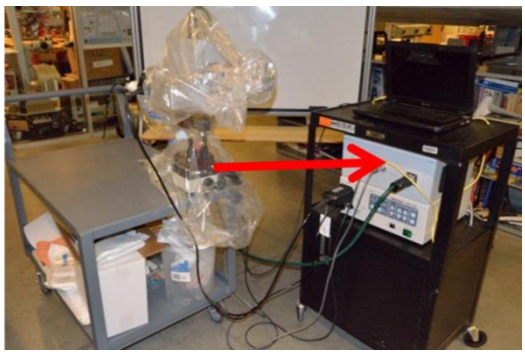
- Scope



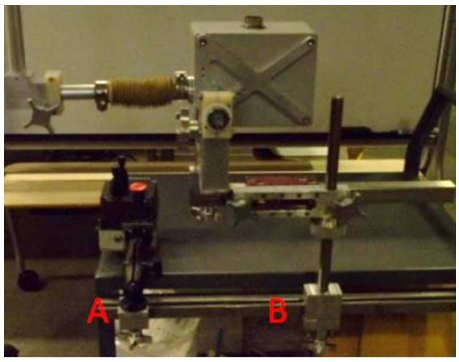
- Scope box



- Robot box



## 2. Grippers

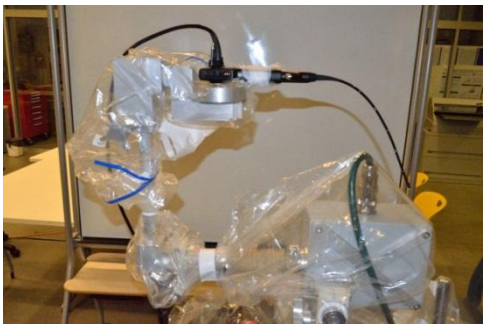



A. Joystick gripper
   - Attaches Joystick to bed rail.

B. Support arm gripper
   - Attaches support arm to bed rail.

## 3. Drapes

- Robot drape
  Intuitive Surgical Camera Arm Drape Ref: 420022 Ver: -02

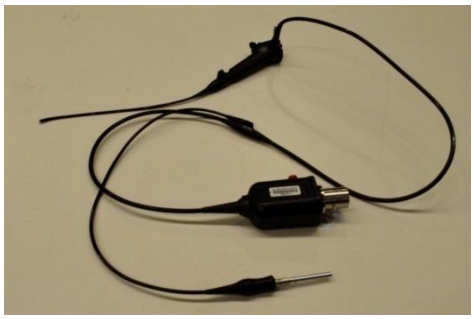



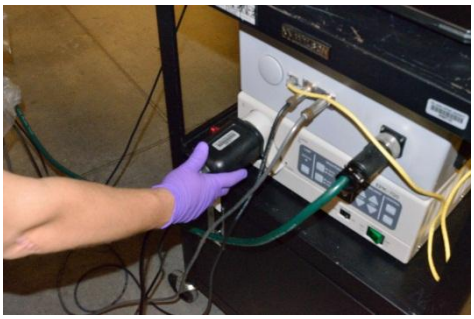
- Joystick drape
  Preferred Surgical Produces Band Bag with Tape 30”x30” Ref: BB-05


## 4. Cords

- AC power cord

- Scope cord

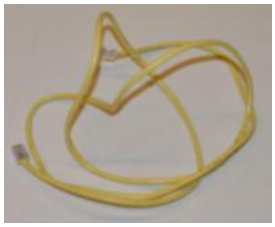




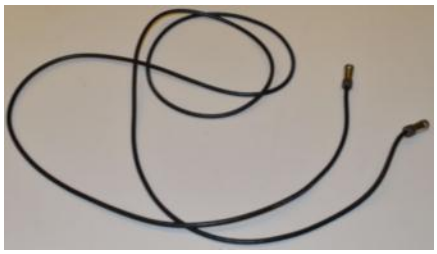
- Robot cord

- USB cord

- Ethernet cord



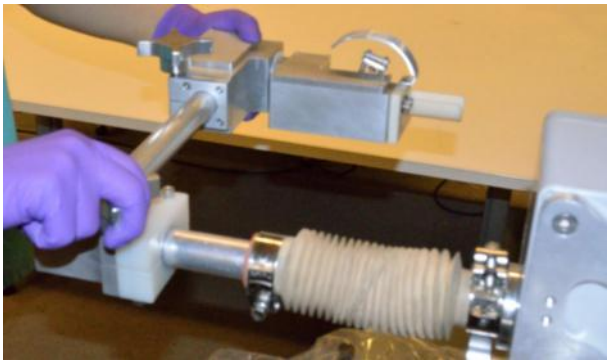
- Joystick power cord



- Joystick signal cord

## C. Passive Joints and Adjustment

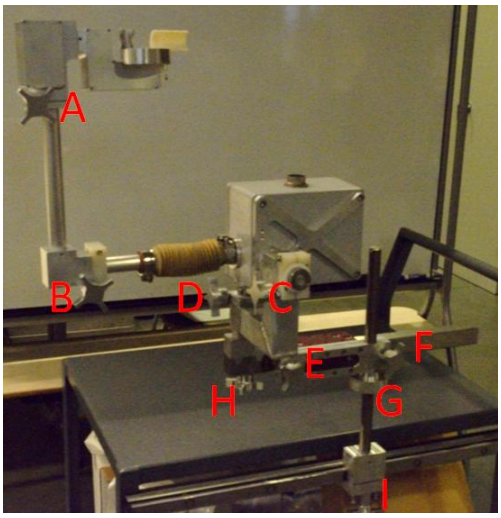
Passive joints that can be moved by gravity alone if loosened have friction collars to prevent accidental motion; however it is still necessary to adjust the joints correctly to minimize the possibility of unintended motion.

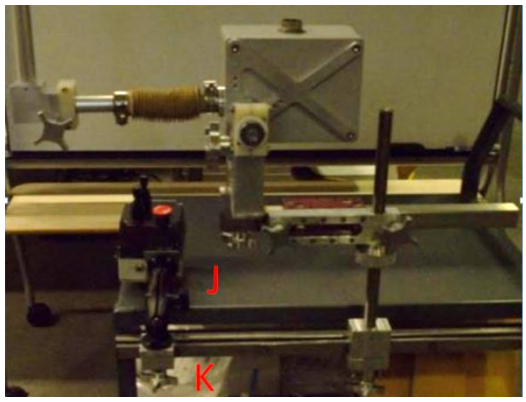


1. Firmly hold the robot distal along the robot to the joint being adjusted
2. Loosen the adjustment knob of the desired joint to unlock it
3. Use the hand holding the robot to adjust the joint position.
4. When in the desired position, re-tighten the knob to lock the joint
5. Test that the joint is properly locked by lightly attempting to further adjust it

Note: never release the robot when one of the joints has been unlocked, always have one hand holding the robot until the joint is confirmed to be locked. Whenever adjusting a joint, the scope cords should be checked to ensure that they do not catch on anything, damaging the scope.

## 1. Knobs/joints




a. Wrist joint, wrist knob
    i. Adjusts the scope angle. Use the wrist knob to align the scope shaft so that it points directly down the laryngoscope.
b. Elbow joint, elbow knob
    i. Rotates the robot arm and scope away from the patient. Use the elbow knob to switch the robot between the "Ready", "Upright", and "Storage" positions.
    ii. When adjusting the elbow joint, check that the scope cords don't catch on anything.
    iii. Never bend the elbow joint so that the scope holder is beyond the back half plane of the robot
c. Tilt joint, tilt knob
    i. Adjust the insertion angle of the scope.
d. Yaw joint/ knob
    i. Adjusts the angle of the robot in the plane of the surgical bed.
e. Slider joint/knob
    i. Adjusts the length of the support arm.
f. Support arm joint/knob
    i. Adjusts the angle of the support arm in the plane of the surgical bed.
    ii. Use the planar positioning knobs together to adjust the robots position and orientation in the plane of the surgical bed.
g. Height adjustment joint/knob
    i. Adjusts the height at which the support arm holds the robot. Use the height adjustment knob to set the height of the support arm before the robot has been attached.
h. Robot attachment knob
    i. Attaches the robot to the positioning arm.
i. Robot gripper knob

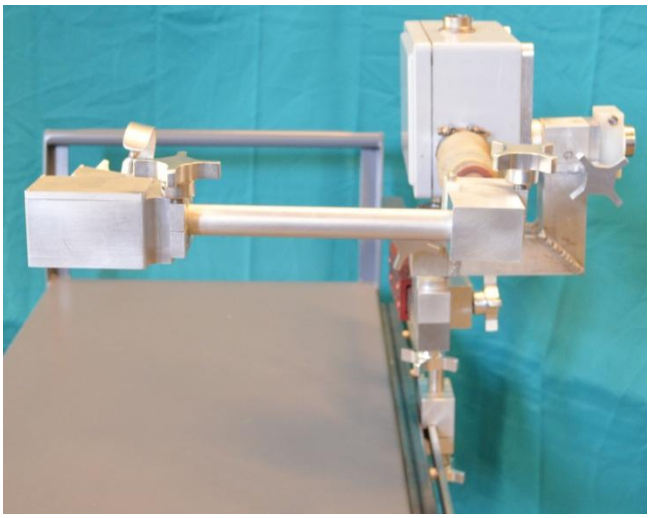
i. Tightens the support arm gripper onto the bed rail

j. Joystick adjustment knob

k. Joystick gripper knob

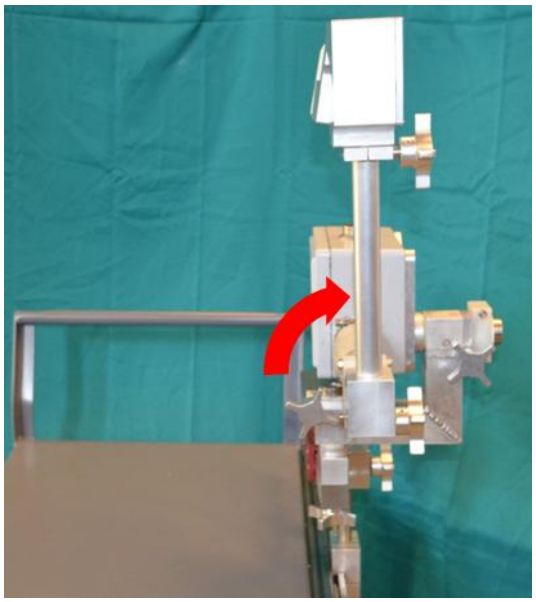
## 2. Robot Positions and Configurations

- Elbow Joint Positions
  - Ready Position



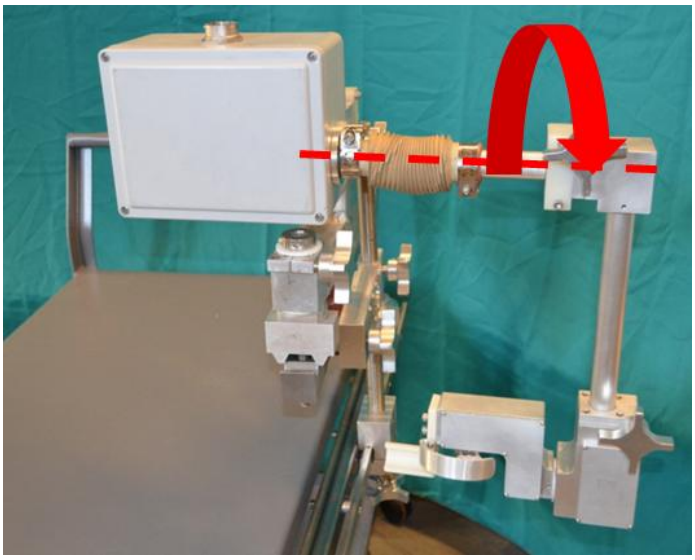
Elbow joint is parallel to the bed top. Ready position is used for draping/undraping, and operating the system.

  - Upright Position



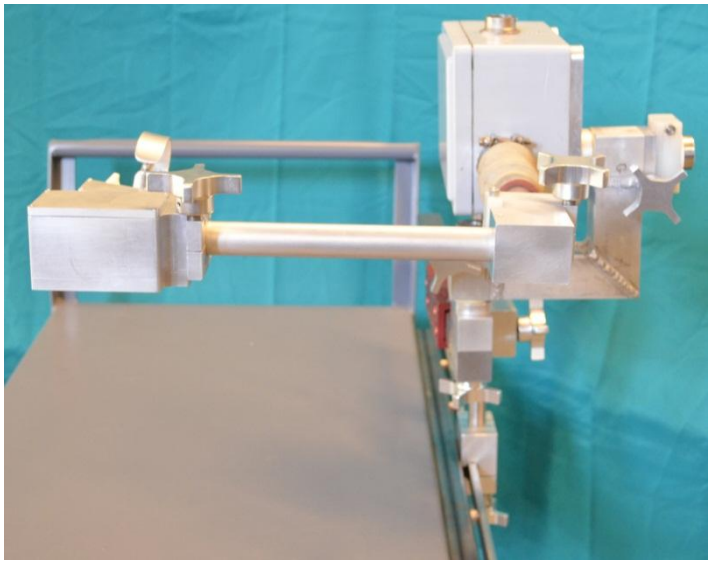
Elbow joint is at a 90 degree angle up with respect to the bed. Upright position is used when the arm cannot impede access to the bed.

- Storage Position



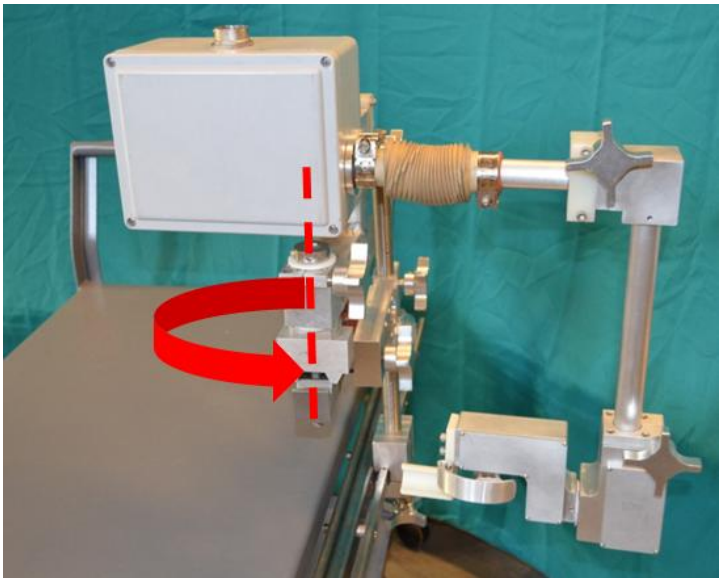
Elbow joint is at a 90 degree angle down with respect to the bed. Storage position is used when the robot is going into storage on its cart. Note, storage position should only be used in Adjustment configuration (see below).

- Robot Attachment Configurations
  - Operating Configuration



In Operating Configuration, the robot is mounted such that the axis of the elbow joint is parallel to the bed rail. Operating Configuration should always be used except when the robot is going into/coming out of storage.

- Adjustment Configuration



In Adjustment Configuration, the robot is rotated 90 degrees about the axis of the attachment joint from Operating Configuration. Adjustment Configuration is used when the robot is being put into storage configuration, in order to avoid collision between the scope holder and the bed.

Severity Scale:

| | |
|---|---|
| 1 | No harm to patient or operator and minimal disturbance to procedure |
| 2 | Minimal harm/chance of harm to patient or operator (very minor injury or disturbance to procedure) |
| 3 | Moderate harm/ chance of harm to patient or operator (minor injury or disturbance to procedure) |
| 4 | Serious harm/chance of harm to patient or operator (serious injury or significant disturbance of procedure) |
| 5 | Severe harm/chance of harm to patient or operator (life threatening or procedure failure) |

Occurrence scale:

| | |
|---|---|
| 1 | Extremely unlikely (should not occur during trials) |
| 2 | Minimal chance of occurrence (may occur once during whole set of trials) |
| 3 | Moderate chance of occurrence (may occur once in 10 procedures) |
| 4 | Likely chance of occurrence (may occur once in every 2-3 procedures) |
| 5 | Certain occurrence for each procedure |

Detection scale:

| | |
|---|---|
| 1 | Detection certain (fault will always be detected) |
| 2 | Detection probable (fault is likely to be detected) |
| 3 | Detection possible (fault has approximatley 50% chance of being detected) |
| 4 | Detection unlikely (fault will probably be undetected) |
| 5 | Detection impossible (fault will never be detected) |

| Item/ Function | Potential Failure Mode | Potential Effects of Failure | S | Potential Cause(s) | How Failure is Detected | O | Current Controls | D | RPN (SxOxD) | Reccomended Actions |
|---|---|---|---|---|---|---|---|---|---|---|
| **RoboELF** | Unsanitary draping/undraping procedure | Spread of contamination between patients | 4 | Unsanitary draping/undraping procedure | Observation of torn drape or improper drape coverage, Observation of potentially contaminating splatter on robot | 2 | Draping and cleaning procedure; disposable parts | 1 | 8 | Follow proper draping and cleaning procedures |
| | Physical Injury to Patient or Operator | Robot falls on patient or operator | 4 | Incorrect Installation: Improper attachment to bedrail | Check stability in setup procedure | 1 | Check robot stability during setup; large margin for error in bedrail attachment system | 1 | 4 | Tighten joints as specified in manual; verify stability during setup |
| | | | 2 | Incorrect installation: Improper tightening of joint collars | Check tightening of joint collars in setup procedure | 2 | Check robot stability during setup; all joints that could move due to gravity have friction collars to prevent unintended motion | 1 | 4 | Tighten joints as specified in manual; verify stability during setup |
| | | | 3 | Incorrect maintenance: Improper tightening of friction collars | Check tightening of friction collars during setup and maintenance procedures | 1 | Proper maintenance and checks during setup | 1 | 3 | Tighten friction collars according to maintenance specification |
| | | Robot becomes electrified | 3 | Broken wire due to fatigue or improper assembly | Check robot grounding during maintenance, Fuse on robot electronics will trip if fault occurs in use. Circuit breaker on power strip as well. | 1 | Proper maintenance and electrical fuse on robot, proper grounding during manufacturing | 1 | 3 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | Robot Becomes Unresponsive(Active), Possible uncontrolled motion, Robot could drive itself or endoscope into patient or operator | Computer could not accurately determine robot position | 2 | Simultaneous failure of potentiometer and encoder, preventing cross-checking | Detected by motor controller motion error | 1 | Galil Overcurrent check | 2 | 4 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | | | 2 | Encoder or potentiometer failure due to manufacture defect, fatigue or faulty system wiring | Detected by cross checking between encoders and potentiometers | 1 | Cross checking between encoders and potentiometers; the controller stops the robot and informs the user of the error. | 1 | 2 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | 2 | Loss of Ethernet Connection because of physical break or software error | Detected by Watchdog Timer | 1 | Watchdog Timer | 1 | 2 | Attempt to reinitialize system. If reinitializes successfully, then resume. If not able to reinitialize, then stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | Motor could move without a user command | 2 | Motor malfunction due to manufacture defect, fatigue or faulty wiring | Detected by motor controller motion error or cross checking between encoders and potentiometers | 2 | Galil Overcurrent check, Cross checking between encoders and potentiometers | 1 | 4 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | | 2 | Joystick malfunction due to manufacture defect, fatigue or faulty wiring | Detected by checking for inconsistent joystick commands or user observation of uncommanded motion | 2 | Emergency stop button, checks for inconsistent joystick commands | 1 | 4 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| Robot Becomes Unresponsive(Non-Active), No possible motion | PC unexpectedly becomes disabled | 1 | Internal Software error | Watchdog timer on Galil will stop system | 1 | Watchdog Timer | 1 | 1 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | | 1 | Power surge damages computer | Surge protector on power strip | 1 | Surge protector | 1 | 1 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| Scope damage | Scope cord not slack enough and becomes caught on something | 3 | Incorrect installation | Check range of motion of robot before procedure | 1 | Detailed setup instructions | 1 | 3 | Correct training for setup and surgeon |
| Robot damage | Robot runs into/tries to move past physical limits | 2 | Limit switch failure due to fatigue or manufacture defect | Detected by motor controller motion error | 2 | Galil Overcurrent check, Soft limits act as backup | 1 | 4 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | Object blocking arm or internal jam in arm | 3 | Obstacles in range of motion, internal mechanical problem | Motor controller motion error | 1 | Follow setup instructions | 1 | 3 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |

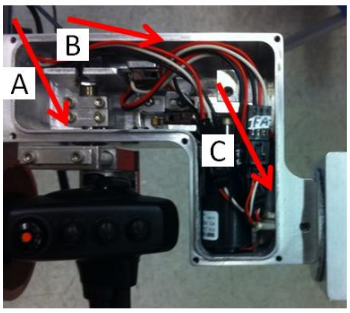
| Failure Mode | Test Method | Expected Results | Error Message | Actual Results | Date | Testers | Signatures |
|---|---|---|---|---|---|---|---|
| **Draping/Cleaning** | | | | | | | |
| Water gets into motor controller enclosure and causes damage to controller | Pour water on all parts of robot to test seal | No water should get through seals | NA | No water penetrated seals | 3/7/2013 | Jonathan Kriss, Kevin Olds | |
| Inadequate draping/undraping procedure | Spray drape with paint before removal | No paint should get through drape. | NA | No paint penetrated drape | 1/30/2013 | Jonathan Kriss, Kevin Olds | |
| Drape tears | Attempt to tear drape during normal operations, adjust handles, scope, etc. | Drape should not tear during normal operation | NA | The drape did not tear under normal working conditions | 1/30/2013 | Jonathan Kriss, Kevin Olds | |
| **Joint/Arm Mechanical Failure** | | | | | | | |
| Passive arm joint clamp becomes loose | Loosen joint clamp | Friction Collar should stop motion. | NA | Friction Collars(Properly tightened) stop motion as expected | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| Friction collars not tightened correctly | Loosen collars | Loose joint will be clearly noticable while trying to make adjustments during setup. | NA | Joints are able to fall is joint is loosened. Add check in set up instructions to verify tight enough friction collars | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| Incorrect Attachment to bedrail | Loosen attachment to bedrail | Robot should be unstable but not fall | NA | Robot is slightly unstable but not in danger of falling in any way, as expected. | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| Object blocking arm or internal jam in arm | Block joint with immovable object, do not damage robot. | Galil current/torque limits stop robot. | Error! Motor Error Detected! | Galil error stops motion and turns off motors, as expected | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| Motor failure due to broken wire or short | Disconnect power from a motor during motion. | Robot will not move on that axis. | None | Motion Stops, no error, as expected | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| Mechanical break between the motor and joint | Loosen pot attachment during operation then command motion. | PC pot/encoder check will fail and stop motion. Estop activated. | System Error! Encoder Failure | Axis A: Encoder Failure Error, as expected. Axis B: Encoder Failure Error, as expected. Axis C: Encoder Failure Error, as expected. | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| **Switch/Joystick Failure** | | | | | | | |
| Broken wire, short causes robot to become electrified | Test that case is properly grounded(Using multimeter) | All metal parts of the case should be electrically grounded. | NA | Case is properly earth-grounded. | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| Limit switch mechanically fails during operation | Disconnect each limit switch in turn during operation | Software limits/physical limits stop motion. No apparent change in behavior | None | Software limits stop all axes, as expected. | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| Limit switch mechanically fails before operation begins | Remove each limit switch in turn before operation | Physical limits should stop robot during calibration. Galil Motion Error should stop calibration | Calibration Fail | Motor Error during calibration, as expected | 1/22/2013 | Jonathan Kriss, Kevin Olds | |
| Joystick mechanical failure: joystick cannot change switch settings | Remove switch assembly. | Robot should not respond to commands. Program should throw an error. | Joystick Error | Joystick Error, as expected. | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| Joystick double switch failure | Simulate single switch failure(short switch) | Robot should not respond to commands. Program should throw an error. | Joystick Error | Joystick Error, as expected. | 1/10/2013 | Jonathan Kriss, Kevin Olds | |

| Failure Mode | Test Method | Expected Results | Error Message | Actual Results | Date | Testers | Signatures |
|---|---|---|---|---|---|---|---|
| **Potentiometer/Encoder Failure** | | | | | | | |
| Pot has electrical or mechaincal failure before operation begins | Disconnect wires from each pot in turn before operation | Calibration will fail or runtime checks will fail. Estop activated | Calibration Failed | Calibration Failed, as expected | 1/22/2013 | Jonathan Kriss, Kevin Olds | |
| Pot has electrical or mechaincal failure during operation | Disconnect wires from each pot in turn during operation | Runtime checks will fail immediately. Estop activated | Encoder Error | Encoder Error, as expected | 1/22/2013 | Jonathan Kriss, Kevin Olds | |
| Encoder has electrical or mechanical failure before operation begins | Disconnect each encoder in turn before operation | Calibration will fail or runtime checks will fail. Estop activated | Calibration Failed OR Encoder Error | Calibration Failed, as expected | 1/22/2013 | Jonathan Kriss, Kevin Olds | |
| Encoder has electrical or mechanical failure during operation | Disconnect each encoder in turn during operation | Runtime checks will fail immediately. Estop activated | Encoder Error | Encoder Error, as expected | 1/22/2013 | Jonathan Kriss, Kevin Olds | |
| Both encoder and pot have electrical or mechanical failure | Disconnect several combination of pots/encoders(same, different axes) during and before operation | Calibration will fail or runtime checks will fail. Estop activated | Calibration Failed OR Encoder Error | Calibration Failed, as expected | 1/22/2013 | Jonathan Kriss, Kevin Olds | |
| **Commuincation Failure** | | | | | | | |
| Estop gets disconnected from PC | Unplug USB cord before/during run. | Before: Program should give error on startup. During: Program should stop. Power will be disconnected from motors. | System Error! Estop Connection Failed | Estop Connection Error, as expected | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| Ethernet failure: motor controller loses communication with PC | Disconnect ethernet cable during different operation states (Initialization, Calibration, Runtime) | Init: Should see error during startup. Calibration: Robot should complete last issued move command then stop. Runtime: Watchdog timer should stop robot from PC. Estop activated | Connection Error! Check Connections and Restart System | Robot stops and an error is thrown as expected | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| Galil Controller crashes or loses power | Turn off Galil during operation. | Watchdog timer should stop robot from PC. Estop activated | Connection Error! Check Connections and Restart System | Connection Error, Estop, as expected. | 1/10/2013 | Jonathan Kriss, Kevin Olds | |
| Computer crash due to power surge or other failure | Kill PC program process during different operation states. | Watchdog timer should stop robot from Galil. | NA | Galil enters Abort mode and stops all motion, as expected | 1/10/2013 | Jonathan Kriss, Kevin Olds | |

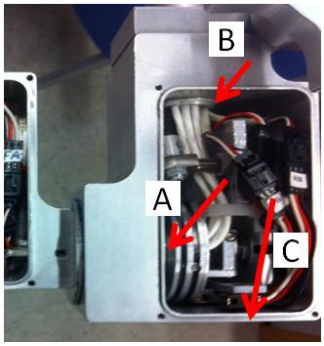
# Maintenance Manual for the Robotic EndoLaryngeal Flexible (Robo-ELF) Scope

1. Review log of last operation and check for problems
2. Boot up robot according to user manual but without drape or scope and recalibrate
3. Check joystick by testing each of the joystick axes and check that the system moves appropriately.
4. Check e-stop by pushing the e-stop button while holding one of the joystick axes and check that the system stops moving.
5. Check relay by unpluging the USB cord, which will cause the relay to open, while holding one of the joystick axes and check that the system stops moving.
6. Use a multimeter to check that robot case is grounded to earth ground by checking the connectivity between the ground plate in the electronics enclosure and the scope holder enclosure.

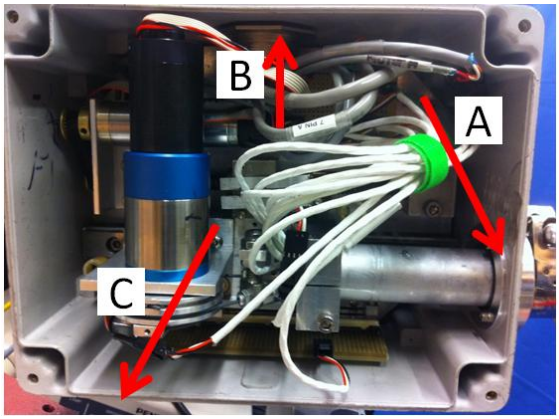

7. Remove scope holder enclosure cover and check cover and bearing seals for degradation or any sign of penetration.
    A. Scope manipulator bearing seal
    B. Cover seal
    C. Roll bearing seal



8. Remove roll stage enclosure cover and check cover and bearing seals for degradation or any sign of penetration.
    A. Roll bearing seal
    B. Arm joint seal
    C. Cover seal




9. Remove main enclosure cover and check cover and bearing seals for degradation or any sign of penetration.
    A. Arm flange seal
    B. Connector seal
    C. Cover seal




10. Loosen elbow locking collar and check friction collar will not move from the influence of gravity with a 10 pound load applied to the rotation stage enclosure. If the joint does move, tighten the friction collar screws until it does not.
11. Loosen tilt locking collar and check friction collar will not move from the influence of gravity with a 10 pound load applied to the rotation stage enclosure. If the joint does move, tighten the friction collar screws until it does not.
12. Tighten all locking collars and try to move robot with reasonable operating force, and verify that the robot does not move.

# Maintenance Check List for the Robotic EndoLaryngeal Flexible (Robo-ELF) Scope

Date:

Person Performing Maintenance:

| Checklist Item | Results |
|---|---|
| 1. Log Review | |
| 2. Boot up robot and recalibrate | |
| 3. Check Joystick | |
| 4. Check e-stop | |
| 5. Check relay | |
| 6. Check grounding | |
| 7A. Scope manipulator bearing | |
| 7B. Cover seal | |
| 7C. Roll bearing seal | |
| 8A. Roll bearing seal | |
| 8B. Arm joint seal | |
| 8C. Cover seal | |
| 9A. Arm flange seal | |
| 9B. Connector seal | |
| 9C. Cover seal | |
| 10. Elbow friction collar | |
| 11. Tilt friction collar | |
| 12. Locking collars | |

*The Laryngoscope*


# Robotic Endolaryngeal Flexible (Robo-ELF) Scope: A Preclinical Feasibility Study

Kevin Olds, BE; Alexander T. Hillel, MD; Elizabeth Cha, BS; Martin Curry, DO; Lee M. Akst, MD; Russell H. Taylor, PhD; Jeremy D. Richmon, MD

**Objectives/Hypothesis:** This article presents a novel robotic endolaryngeal flexible (Robo-ELF) scope driver for minimally invasive laryngeal surgery. The Robo-ELF consists of a simple, robust robotic scope driver with three active and two passive degrees of freedom, allowing it to manipulate any standard flexible endoscope. The system is controlled by a joystick-like three dimensional mouse that interfaces with the scope driver via a laptop. Because the scope is supported and controlled by the robot, motor control and therefore visualization are enhanced. Additionally, because the robot remains stationary when the mouse is not being manipulated, the surgeon can position it and operate bimanually.

**Methods:** The system was validated by performing visualization and biopsy procedures on two human cadavers with the Robo-ELF and comparing this with standard rigid endoscopes with three different angles.

**Results:** The Robo-ELF outperformed the rigid scopes in both image quality and range of motion, overcoming line of site constraints, and allowing visualization of otherwise hidden anatomy. The system also demonstrated a rapid learning curve and enhanced motor control over a manually operated flexible endoscope.

**Conclusions:** The Robo-ELF is a novel robot to assist in driving a flexible endoscope for surgery of the upper aerodigestive tract.

**Key Words:** Robot, larynx, minimally-invasive, endolaryngeal, surgery, flexible fiberoptic scope.

**Level of Evidence:** N/A.

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## INTRODUCTION

Transcervical laryngeal surgery results in disruption of the laryngeal framework with resultant sensory and motor deficits. Efforts to reduce the morbidity of external approaches have led to advances in endoscopic laryngeal surgery that access the endolarynx through the mouth. Technologic advances in binocular microscopy, rigid telescopes, microlaryngeal instrumentation, and lasers have led to dramatic improvements in the management of benign and malignant conditions of the larynx. Nonetheless, endolaryngeal surgery continues to have disadvantages, namely, reduced depth perception, relatively small exposure, and the operator's distance from the surgical field. These limitations restrict the surgeon's ability to manipulate instruments from outside the oral cavity, resulting in poor sensory feedback and magnification of the operator's tremor. In addition, the lack of distal dexterity risks injury to surrounding healthy tissue. Line-of-sight limitations inherent in microscopic or telescopic visualization limit the ability to view around corners, rendering areas such as the anterior commissure, subglottis, and ventricle challenging to visualize fully.

Robotic surgery offers potential advantages with steerable modular instrumentation and three-dimensional (3D) viewing that are lacking in traditional endolaryngeal surgery, improving the laryngologist's distal dexterity and suturing ability.[1] Currently, the da Vinci robot (Intuitive Surgical, Inc., Sunnyvale, CA) is U.S. Food and Drug Administration-approved for transoral surgery of benign and malignant early stage lesions of the upper aerodigestive tract. The da Vinci surgical robot's 3D optics system creates a high-definition, wide-view image of the surgical field.[2,3] Furthermore, its maneuverable endoscope allows a high-fidelity view of the surgical field that can be rotated and positioned to enhance surgical precision. Motor control is enhanced by scaling movement, modulating tremor, and additional instrument freedom of motion.[2,4–5] Instrument control is further enhanced with distal articulation by the da Vinci's EndoWrist design, providing seven degrees of freedom for finer tissue manipulation.

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Institutional approval for use of the cadavers was obtained prior to the study.

Kevin Olds, BE, and Alexander T. Hillel, MD, contributed equally to this study.

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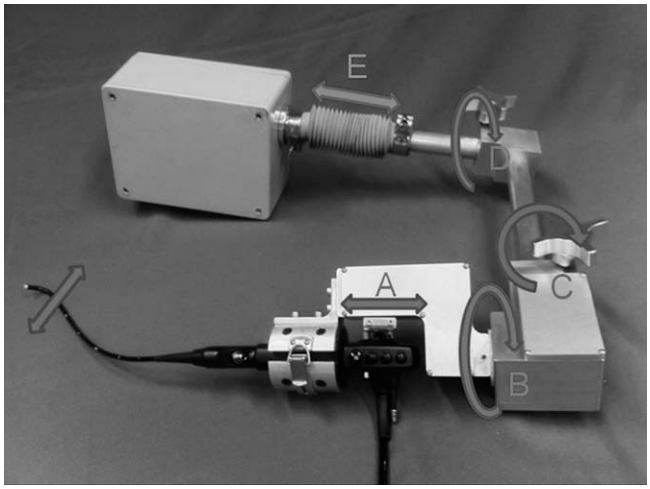


Fig. 1. The robotic endolaryngeal flexible scope with attached flexible fiberoptic laryngoscope. A = active scope tip manipulator; B = active axial rotation of the scope; C = passive lockable joint to adjust scope entry angle; D = passive lockable joint to adjust scope height; E = active in-out translation.

Unfortunately, there have been limited reports of successfully utilizing the da Vinci robot within the endolarynx.[4,5] This is because the current da Vinci robot was designed for opposing arms via widely spaced ports of entry for abdominal and thoracic surgery with large diameter instruments predicated on laparoscopic instruments. The arms of the robot were designed to mimic the opposition of a surgeon's hands in conventional surgery, a task quite different from parallel ports of instrument entry with manipulation coaxial with the lumen of a laryngoscope. Development of laryngeal robotic surgery is further limited by the endotracheal tube occupying space in the operative field, laryngeal suspension allowing for sufficient exposure, and manipulation of the robotic instrument arms in the crowded, narrow oral, pharyngeal, and laryngeal spaces.[6]

A collaborate effort between the otolaryngology and engineering departments of Johns Hopkins University led to the development of a simple robotically controlled endoscope system that may overcome some of the challenges faced today with transoral endoscopic laryngeal surgery.

## MATERIALS AND METHODS

A robotic endoscope driver was designed to have the potential to connect to a variety of commercially available endoscopes. The scope of choice for these experiments was the Pentax VNL-1570STK distal-chip flexible laryngoscope (Pentax Corp., Golden, CO). To give the surgeon adequate control of this otherwise unmodified clinical endoscope, it was determined that at least three active degrees of freedom were needed. These include manipulation of the scope's tip, rotation of the scope about its axis, and linear translation of the scope in and out of the patient. To increase the versatility of the system, two passive lockable degrees of freedom were also included to assist with positioning the scope in relation to the patient (Figs. 1 and 2). The active degrees of freedom are powered by brushed coreless 12 V, DC motors with planetary gearheads and integrated magnetic encoders (Micromo Micro Motion Solutions, Clearwater, FL). Each active degree of freedom also has a potentiometer directly on the joint. This redundant sensing allows for greater safety and better control of the robot. The active joints all have limit switches to prevent them from exceeding the desired range. The scope holder portion of the robot is highly adjustable, and has a custom molded urethane rubber scope gripper, which can be easily changed to fit other commercially available scope models. To improve control of the scope while operating, we added a stiffening attachment to give the otherwise flexible scope shaft more "memory" so that it could maintain its own position and be easier to control. The entire robot is built to satisfy Johns Hopkins Hospital clinical engineering specifications, including waterproof seals, operating room-safe materials, proper electrical grounding with fusing, and an isolated power supply with no voltages greater than 12 V. The robot is operable in wet environments and pending a final clinical engineering inspection.

The robot uses a simple proportional-integral-derivative velocity controller implemented using a Galil model DMC 40x3 motor controller (Galil Motion Control Inc., Rocklin, CA). The motor controller interfaces with a laptop via ethernet, allowing joystick-like control using a SpaceNavigator 3D mouse (3DConnexion, Rochester, MI) [Fig. 3]. This configuration allows for rapid setup and adjustment. The software is based on the open source CISST libraries developed by the Engineering Research Center for Computer Integrated Surgical Systems and Technology at Johns Hopkins University.

### *Clinical Validation*

Two fresh human cadavers were obtained from the University of Maryland State Anatomy Board after approval by the Johns Hopkins Hospital Minimally Invasive Surgical Training Center. Both were male with full dentition. Each cadaver was suspended with a Steiner laryngoscope to afford visualization of the endolarynx. Standard microlaryngoscopy was performed initially using 0°, 30°, and 70° rigid scopes. Representative photographs were taken of the endolarynx with each scope. The robotic endolaryngeal flexible (Robo-ELF) scope was then mounted to the bedside and advanced through the scope.

### *Task 1*

The goal of the first task was to demonstrate comparable if not superior field of vision with the Robo-ELF scope. After

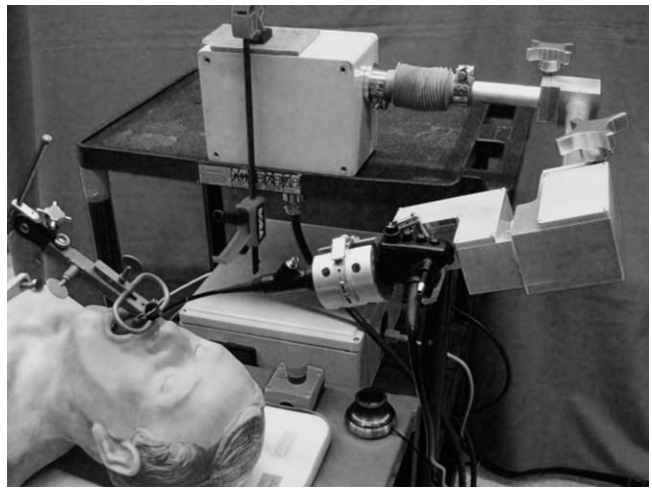

Fig. 2. The robotic endolaryngeal flexible scope mounted to a cart with an airway phantom. Controlling joystick is present in the mid-lower portion of the photo.

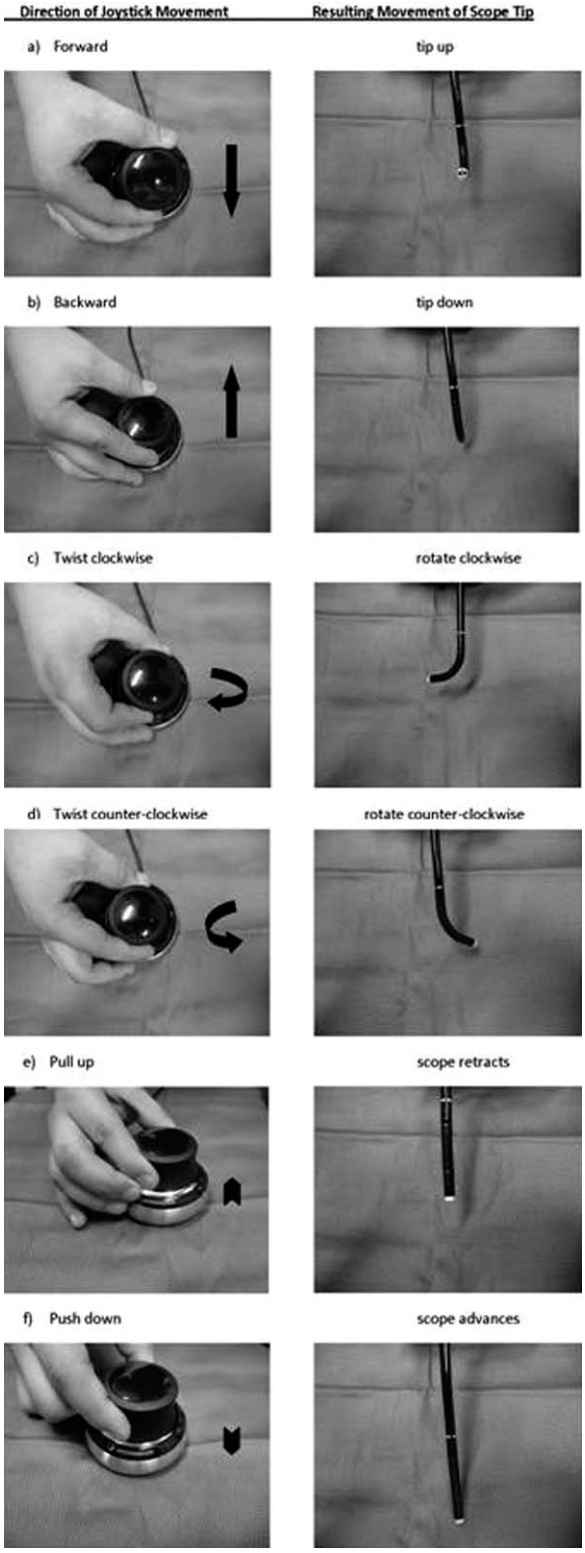


Fig. 3. The primary directions of scope movement are demonstrated by joystick control.

the Robo-ELF was positioned, the 3D mouse was used to manipulate the scope to obtain the same endoscopic views afforded by the rigid scopes. The entire field of vision navigated by the Robo-ELF was then compared to that of the rigid scopes.

### *Task 2*

The goal of the second task was to achieve optimal visualization of normally challenging anatomical areas with precise biopsy sampling. With one hand controlling the joystick and the other manipulating a laryngoscopic biopsy forceps, attempted biopsies were taken of the subglottis, anterior commissure, and ventricle.

### *Task 3*

The goal of the third task was to demonstrate the ability to perform two-handed microlaryngoscopic procedures with the Robo-ELF in a fixed position. The Robo-ELF was driven to an optimal position above the vocal cords and left in position such that two-handed microlaryngeal surgery could be performed.

Photo and video documentation of the above tasks were reviewed by the authors to compare the effectiveness of the Robo-ELF to the traditional rigid scopes.

## RESULTS

The Robo-ELF was easily positioned through the Steiner laryngoscope and movement in all three active degrees-of-freedom was smooth, consistent, and reproducible. The speed of robotic movement was reliably translated by the amount of force placed on the joystick. No erratic or sudden movement was present. The Robo-ELF provided a wider field of vision than that of the three rigid endoscopes. The flexible tip was capable of driving around the arytenoids into the piriform sinuses and through the vocal cords into the subglottis, thereby overcoming limitations of line-of-sight. The distal chip scope provided a high-resolution image, and navigating the scope was intuitive with virtually no learning curve. The scope is controlled by a single hand joystick allowing instrument manipulation with the other hand. Visualization of the intended biopsy sites was successful in both cadavers. However, in the first cadaver the larynx was anteriorly positioned, and despite a clear view of the subglottis and anterior commissure with the Robo-ELF in a flexed position, the straight laryngoscopic forceps were unable to reach these areas. Finally, it was established that after positioning the Robo-ELF above the vocal cords there was still ample room to use two instruments to perform bimanual endolaryngeal surgery. A video demonstration of the Robo-ELF is available online (http://www.youtube.com/watch?v=66KSw0pt5IY).

## DISCUSSION

In this study we demonstrated the advantages of a robotically controlled endolaryngeal flexible scope. The Robo-ELF is manipulated with a single hand on the 3D mouse and maintains its position when released, allowing for both one-handed and two-handed surgery. The flexible distal-chip scope allows for a high-resolution image that can curve around corners, thereby bypassing line-of-sight limitations inherent in rigid telescopes and microscopes. Furthermore, the Robo-ELF is able to achieve a field of vision wider than that achieved with multiple rigid telescopes all within a single instrument without having to exchange scopes. The flexible endoscope has the added advantage of a working port with

which to operate a $CO_2$ or potassium-titanyl-phosphate laser fiber for therapeutic purposes. As this study demonstrates, the learning curve to use the system is minimal.

The technologic advantages of the Robo-ELF are substantial. This robot is inexpensive compared with other microscopic and robotic techniques, with an anticipated cost of $30,000 to $50,000, and will accept any standard commercial flexible laryngoscope. Because the robot does not contact the patient, sterilization is not necessary and it can be quickly wiped down with alcohol facilitating equipment maintenance in the operating suite. The actual flexible scope is processed according to existing practices. Of great promise is the ability to eventually adapt the Robo-ELF to other flexible surgical endoscopes, such as bronchoscopes, esophagoscopes, and colonoscopes where more complex manipulation can be achieved with a single joystick. There is potential for microvascular surgery at the base of the skull, as well as single port gastrointestinal and thoracic access surgery. Furthermore, the Robo-ELF can be married with other technology, such as image overlay, ultrasound, optical coherence tomography, and can be manufactured with two distal chips for 3D vision, greatly expanding its applications.

## CONCLUSION

We have developed a novel robotic endoscope driver to be used in procedures of the upper aerodigestive tract. This robot has potential to overcome some of the challenges of traditional laryngoscopic surgery, such as line-of-site constraints, single-hand instrument manipulation, and tremor. Additionally, its use may be expanded to include other endoscopes and much broader clinical applications.

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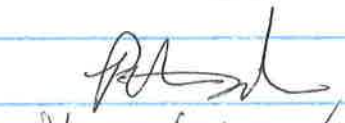
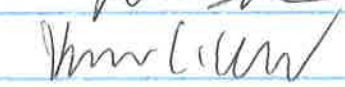
# RoboELF Test Plan Review

Date: 8/21/2012

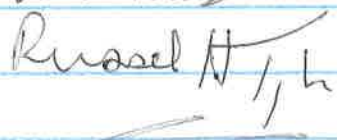
Time: 9:15 AM

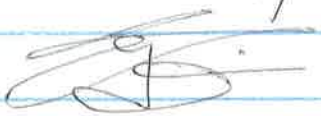
Attendees:


Peter Kazanzides, Assoc. Research Prof.


Kevin Olds, PhD candidate


Jonathan Kriss, MSE student


Russell Taylor Professor


Min Yang Jung, PhD student (CS)

# RoboELF Software & Design Review

December 4, 2012

Attendees

| | | |
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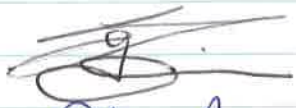
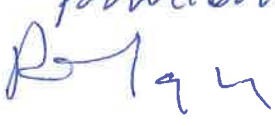
| Jon Kriss | CS Masters student |  |
| Min Yang Jung | CS Ph.D. student |  |
| Peter Kazanzides | CS Professor |  |
| Kevin Olds | BME phD student |  |
| Jeremy Richmond | OHNS MD |  |

# Robo-ELF Software Review

Nov 7, 2012

## Attendees

| | | |
|---|---|---|
| Peter Kazanzides | Assoc. Research Prof. |  |
| Min Yang Jung | CS Ph.D |  |
| Kevin Olds | BME PhD |  |
| Russell H Taylor | CS Professor |  |
| Jon Kriss | CS ~~Student~~ MS Student |  |

# Appendix B: Robo-ELF Scope IRB Protocol

Date: January 29, 2014
Principal Investigator: ___Jeremy Richmon, MD_____
Application Number: _ NA_00051254 _____

# Johns Hopkins Medicine - eForm A

- **Use the section headings to write the eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.**
- **When submitting eForm A (new or revised), enter the date submitted to the field at the top of eForm A.**

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## 1. Abstract

Transcervical surgical approaches to the upper aerodigestive track result in disruption of the laryngotracheal framework with resultant sensory and motor deficits. Efforts to reduce the morbidity of external approaches have led to advances in endoscopic surgery that access the airway through the mouth. Technologic advances in binocular microscopy, rigid telescopes, microlaryngeal instrumentation, and lasers have led to dramatic improvements in the management of benign and malignant conditions of the airway. Nonetheless, this surgery continues to have disadvantages; namely, reduced depth perception, relatively small exposure, and the operator's distance from the surgical field. These limitations restrict the surgeon's ability to manipulate instruments from outside the oral cavity resulting in poor sensory feedback and magnification of the operator's tremor. In addition, the lack of distal dexterity risks injury to surrounding healthy tissue. Line of site limitations inherent in microscopic or telescopic visualization limit the ability to view around corners rendering certain areas challenging to visualize fully.

Robotic surgery offers potential advantages with steerable modular instrumentation and three-dimensional viewing that are lacking in traditional airway surgery. A collaborate effort between the Otolaryngology and Engineering Departments of Johns Hopkins University led to the development of a simple robotically controlled endoscope system (Robo-ELF) to drive commercially available endoscopes that may overcome some of the challenges faced today with

transoral endoscopic surgery. This has been tested on cadavers and we seek to evaluate this technology in a live human population.

**2. Objectives**

**Primary:**

**1)** To demonstrate comparable if not superior field of vision with the Robo-ELF scope over standard rigid telescopes.

**Secondary:**

**1)** To achieve full visualization of normally challenging anatomical areas

**2)** To drive the Robo-ELF to a desired position and leave it in a fixed position in order to demonstrate the ability to perform two-handed endoscopic procedures.

**3. Background** (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Current means of evaluating the upper aerodigestive tract depend on both open and endoscopic techniques. Open transcervical approaches to the upper aerodigestive tract result in disruption of the laryngotracheal framework with resultant sensory and motor deficits. Efforts to reduce the morbidity of external approaches have led to advances in endoscopic surgery that access the airway through the mouth. Technologic advances in binocular microscopy, rigid telescopes, microlaryngeal instrumentation, and lasers have led to dramatic improvements in the management of benign and malignant conditions of the airway. Nonetheless, each of these techniques has inherent limitations. Binocular microscopy allows for bimanual manipulation but is restricted in that the optics are outside the patient and only structures along the line of site can be visualized. The more distal the structure, the poorer the visualization. Rigid telescopes allow for endoluminal optics with superb magnification but are limited in the need for one hand to drive the scope (precluding bimanual surgery) and further line of site limitations with zero, 30, and 70 degree scopes making frequent scope changes necessary and cumbersome. Flexible scopes require two hands to manipulate but are ideal at providing a high-definition, magnified image with a flexible tip with multiple degrees of freedom providing a wide and guidable field of vision. Their use however

has been limited in the operating room since two handed control is the rule making a secondary assist necessary to perform diagnostic and therapeutic procedures.

A collaborate effort between the Otolaryngology and Engineering Departments of Johns Hopkins University led to the development of a simple robotically controlled endoscope system (Robo-ELF) that may overcome some of the limitations mentioned above. The robot attaches to commercially available FDA approved endoscopes that are already frequently used in clinical practice. The robot allows for joystick manipulation of the flexible endoscope in the upper aerodigestive tract permitting a wider field of vision than that afforded by standard microscopy and telescopic endoscopes. There are no line of site limitations and both single and bimanual endoluminal instrument manipulation is possible using the Robo-ELF. The robot was built to satisfy all clinical engineering requirements of Johns Hopkins Hospital. The Robo-ELF has been successfully tested on cadavers (manuscript in submission) and we seek to evaluate this technology in a live human population.

## 4. Study Procedures

Patients undergoing routine evaluation under anesthesia for lesions of the upper aerodigestive tract are eligible to participate in this study. This would include patients scheduled for diagnostic pharyngoscopies, laryngoscopies, esophagoscopies, and bronchoscopies. Participants in this study would undergo their routine procedure with the additional evaluation by the Robo-ELF.

Task 1: A complete direct laryngoscopy with standard traditional rigid endoscopes will be performed. Photos of each anatomic area (i.e. subglottis, vocal cords, anterior commissure, ventricles, vocalis processes, etc) will be obtained.

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*Task 2:* A full laryngoscopy will then be performed with the Robo-ELF. After the Robo-ELF is positioned the entire field of vision will be navigated with the 3-D joystick. Still images will be obtained of each anatomic area mentioned above. The operator will compare the ease of use and functionality of the Robo-ELF and standard rigid scopes. (See Laryngoscopic Evaluation Form)

*Task 3*: To achieve full visualization of normally challenging anatomical areas. With one hand controlling the joystick and the other manipulating a biopsy forceps, the subglottis, anterior commissure and ventricle (areas challenging to visualize with traditional scopes) will be visualized. Views will be graded according to a Likert scale assessing the quality and extent of the view obtained. No biopsies will be performed through the working port of the robo-ELF or with the robot itself.

*Task 4*: To demonstrate the ability to perform two-handed endolaryngeal procedures with the Robo-ELF in a fixed position. The Robo-ELF will be driven to an optimal position above the vocal cords and left in position such that two-handed microlaryngeal surgery could be performed. No actual tissue manipulation will be performed.

All photos of the above tasks will be printed from the endoscopic towers within the OR and placed in a research file without a patient identifying label and later reviewed by a blinded laryngologist to compare the endoscopic views obtained with the Robo-ELF to those of traditional rigid scopes. (see Blinded Evaluation Form)

As this is a feasibility study of a novel robotic scope driver using commercially available endoscopes, we believe a convenience sample of 20 subjects would be sufficient to evaluate this technology.

## 5. Inclusion/Exclusion Criteria

Study group: 20 patients undergoing diagnostic evaluation under anesthesia (EUA) of the upper aerodigestive tract will be consented to meet the accrual goal of 20 patients. Each patient will serve as his/her own control as they will undergo both traditional and robo-ELF endoscopic evaluation.

**Inclusion Criteria**:

Patients undergoing a diagnostic evaluation under anesthesia of the upper aerodigestive tract

Age >= 18

**Exclusion Criteria**:

Inability to read or write English

Any patient on contact restrictions (i.e. MRSA, VRE, TB).

## 6. Drugs/ Substances/ Devices

A robotic endoscope driver was designed to have the potential to connect to a variety of commercially available endoscopes. In order to give the surgeon adequate control of an otherwise unmodified clinical endoscope it was determined that at least three active degrees of freedom were needed. These include manipulation of the scope's tip, rotation of the scope about its axis, and linear translation of the scope in and out of the patient. To increase the versatility of the system, two passive lockable degrees of freedom were also included to assist with positioning the scope in relation to the patient (Figures 1 and 2). The active degrees of freedom are powered by brushed coreless 12V DC motors with planetary gearheads and integrated magnetic encoders (Micromo Micro Motion Solutions, Clearwater, FL). Each active degree of freedom also has a potentiometer directly on the joint. This redundant sensing allows for greater safety and better control of the robot. The active joints all have limit switches to prevent them from exceeding the desired range.

The scope holder portion of the robot is highly adjustable, and has a custom molded urethane rubber scope gripper, which can be easily changed to fit other commercially available scope models. To improve control of the scope while operating, we added a stiffening attachment to give the otherwise flexible scope shaft more "memory" so that it could maintain its own position and be easier to control. The entire robot is built to satisfy Johns Hopkins Hospital clinical engineering specifications, including waterproof seals, operating room safe materials, proper electrical grounding with fusing, and an isolated power supply with no voltages greater than 12V. The robot uses a simple proportional-integral-derivative (PID) velocity controller implemented using a Galil model DMC 40x3 motor controller (Galil Motion Control Inc., Rocklin, CA). The motor controller interfaces with a laptop via Ethernet, allowing joystick-like control using a SpaceNavigator 3D mouse (3DConnexion, Rochester, MI) [Figure 3]. This configuration allows for rapid setup and adjustment. The software is based on the open source CISST libraries developed by the Computer Integrated Surgery at the Engineering Research Center at JHU. A video demonstration of the Robo-ELF is available on-line: http://www.youtube.com/watch?v=66KSw0pt5IY

**Figure 1**

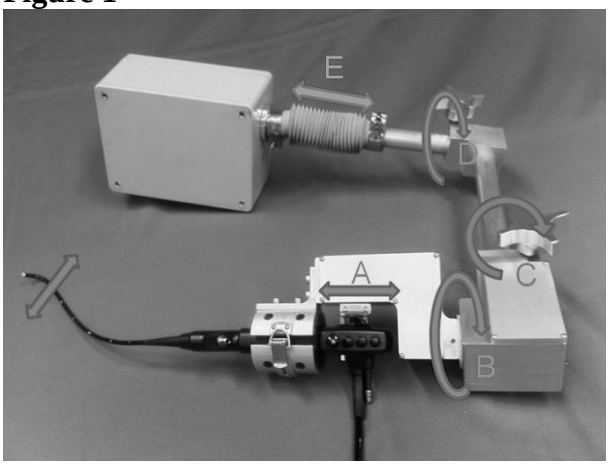



**Figure 2**

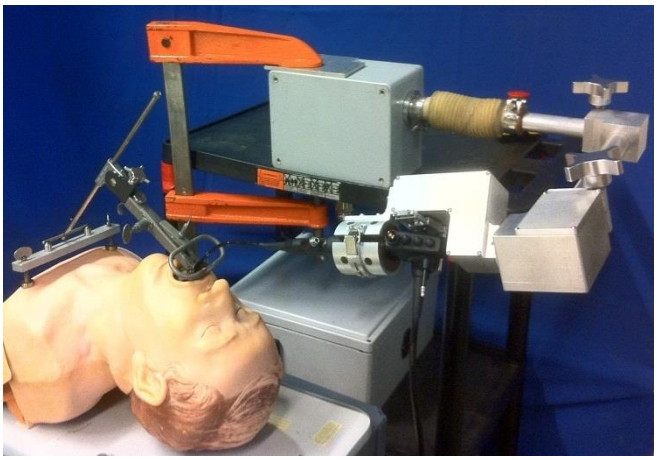
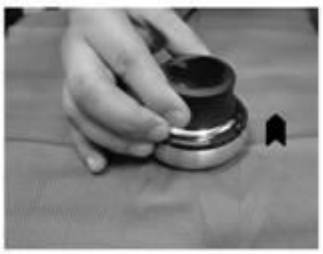


**Figure 3**

| Direction of Joystick Movement | Resulting Movement of Scope Tip |
|---|---|
| a) Forward | tip up |
|  |  |
| b) Backward | tip down |
|  |  |
| c) Twist clockwise | rotate clockwise |
|  |  |
| d) Twist counter-clockwise | rotate counter-clockwise |
|  |  |
| e) Pull up | scope retracts |
|  |  |
| f) Push down | scope advances |
|  |  |

**7. Risks**

Use of the Robo-ELF introduces no more risk than that of traditional upper aerodigestive tract endoscopy. The flexible scopes that can be used with the Robo-ELF are FDA approved for endoscopy and are frequently approved for this application at JHH. Only the scope itself enters the patient's airway. The Robo-ELF does not contact or enter the patient. The Robo-ELF was built to satisfy Johns Hopkins Hospital clinical engineering guidelines and meets all the necessary safety requirements.

The main risk of this study is the additional time under general anesthesia. Based on our cadaver study it is estimated that evaluation of the Robo-ELF will require 15 additional minutes of anesthesia time. This is estimated to increase the entire length of the procedure by approximately 25%.

**8. Benefits**

Participants most likely will not directly benefit from this study. It is possible that a few participants may have lesions that are unable to be visualized and biopsied with traditional endoscopic techniques and therefore derive benefit from being evaluated with the Robo-ELF. In such a case the traditional endoscopes would be re-inserted to locate the lesion to allow biopsy. No biopsies will be performed with the Robo-ELF. Patients will benefit from knowing that their participation in this study will allow other patients to benefit from this new technology in the future.

**9. Payment and Remuneration**

a. none

**10. Costs**

a. There are no costs associated with this study.

# Appendix C: REMS Laryngeal IRB Protocol

*Precision manipulation task description*

This sub-study will compare participants' performance on a precision manipulation task with and without robotic assistance to determine whether the robot improves performance. The precision manipulation task will consist of navigating a surgical instrument through a synthetic phantom. The phantom and instrument are made of a conductive material, so that any contact between them can be detected by the change in electrical conductivity. Different parts of the phantom are connected to different circuits so that the part of the phantom being contacted by the instrument can be determined.

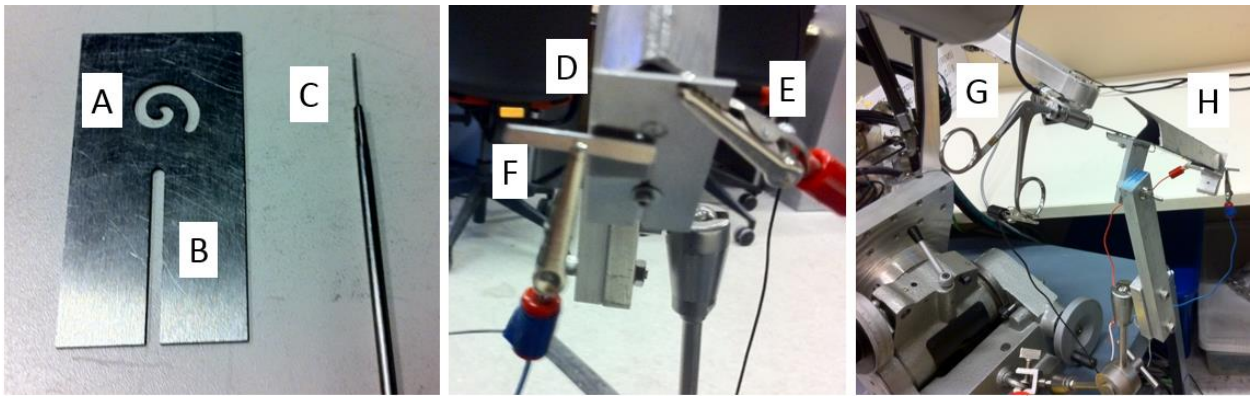



Fig. 1. Left) Phantom and instrument A) slot instrument must be navigated through B) mounting slot C) instrument tip. Center) Phantom mounted on training laryngoscope D) phantom E) failure electrode F) success electrode. Right) Phantom and training laryngoscope mounted for robotically assistance G) laryngeal instrument H) training laryngoscope

*System description*

The Robotic Ear nose and throat Microsurgery System (REMS) is a robotic system for enhancing surgical precision that is currently under development at JHU. The REMS is cooperatively controlled, meaning that the surgeon and robot hold the surgical tool together, and the robot senses the surgeon's intent through a force sensor at the end of the robot arm, and moves to comply. The primary intent of the REMS is to help surgeons overcome hand tremor and fatigue by providing tremor cancelling and enhanced stability for high-precision work. The REMS has a changeable tool holder which allows a variety of instruments to be used with it, such as standard forceps, laser probes, and pointers, as well as custom instruments. The REMS is designed to hold instruments by their shaft, leaving the handle free for the user to hold. To use the REMS, the user holds the handle of the instrument and moves the instrument as they normally would. The robot feels the forces this generates through its force sensor on the back of the tool holder, and moves to comply. However, since the robot is holding the tool, it can remove undesirable movement such as hand tremor from the user's hand motion. Fig. 2 shows the REMS setup for this experiment.

The REMS has many safety features to make the system as safe as possible to use. The robot's range of motion is mechanically limited to a 150 mm (~6 inch) diameter sphere, and its speed is software limited to 50 mm/s (~2 inches/sec). There is also an emergency stop button which will stop the robot immediately when pressed. The user's hand holding the instrument handle is the only part of his/her body near the robot during operation. The user is in no way coupled to the robot, and can easily release the instrument handle at any time. A foot pedal is used to control the speed of the robot (the

further the pedal is pressed, the faster the robot will move up to its speed limit), and the robot will only move when this pedal is pressed.


Fig. 1. Left: REMS Overview: A) Robot B) Microscope C) Laryngeal instrument D) Phantom mounted to training laryngoscope E) Emergency stop button F) Robot control pedal. Middle/Right: Example setup of REMS in use

*Study Procedures*

After consent has been obtained at the site of the experiment, each participant will be given hands-on training with the REMS surgical robot and instruction about the goals of the experiment to ensure the study procedures are understood. Participants will be asked to navigate the instrument from a starting location, through the phantom, avoiding contact with the phantom until a goal location (which is on a different circuit from the rest of the phantom) is reached. If the instrument contacts the phantom anywhere except the goal location, this is registered as a failed attempt. If the instrument contacts the goal location without contacting the rest of the phantom, this is registered as a successful attempt. Both the number of successful attempts out of the total number of attempts, and the time taken per successful attempt will be recorded. The study will be conducted in two blocks, a manual block consisting of manual attempts, and a robotic block consisting of robotically assisted attempts. The order in which each participant will do these blocks will be randomized based on random numbers generated before the study begins. Participants will be asked to practice this task both manually and robotically until they feel comfortable before the recorded runs begin.

The proportion of successful attempts, time taken per successful attempt, and all robot data including position, speed, force sensor readings, and foot pedal level will be recorded. Photographs or videos of the operating area will be recorded, though the participant's face will not be shown. Once the experiment is complete, participants will be asked to fill out a short anonymous questionnaire about their experience with the robot. Each participant will only be asked to participate in one session which is expected to take no longer than one hour in total. No identifiable data on the participants will be kept except for the consent form. No information will be kept linking the participants to their study results. Participant's faces will not be photographed or video recorded as part of this study.

# Appendix D: REMS Sinus IRB Protocol

eHIRB Electronic Homewood Institutional Review Board

Date: Wednesday, January 28, 2015 9:57:40 PM

Print Close

**Amendment**
**PI: Russell Taylor**
**AM00002641 (HIRB00001625)**

# 1 - General Information

**1.0**

*** Select ALL the categories of amendment(s) you are requesting and thoroughly explain the change as well as the reason for the change(s). If you are changing language in the application, consent form, or other documents, you must provide the new language and the language being removed below in the description of the amendment. You must then make the change(s) to the application as well as upload any new/revised documents to the appropriate section of the application. Do not delete the previous versions.**

- [ ] **Change in Study Title**
- [ ] **Change in Principal Investigator**
- [x] **Addition of/change in research personnel**

*** Describe**
Adding a postdoc to the study team. this individual is helping with system development and will provide engineering support

- [ ] **Change to study design, methods or procedures**
- [ ] **Addition of/change to study population**
- [ ] **Addition of/change to recruitment or recruitment materials**
- [ ] **Addition of/change to survey(s), questionnaire(s), or other research instruments**
- [ ] **Addition of/change that would impact privacy and confidentiality**
- [ ] **Addition of/change to informed consent/assent document(s)**
- [ ] **Other changes**

**2.0** *** Are any of these changes the result of something that occurred during human participant interaction or an unexpected event?**

No

xxx

2 - Update Application

**All of the changes you have just requested must also be made on the revised study**

**application. This includes any changes to application answers, new documents, and/or changes to uploaded documents (e.g., protocol, consents).**

**Click Continue to revise any relevant sections of the application.**

**New Application**

# 1 - General Information

**1.0** * **Principal Investigator**

*PI must be faculty or senior staff. Click **Select** to choose a PI, or **Update** to modify the PI.*

Russell Taylor

**PI's HSR Training Date:** 2/12/2012

**PI's HSR Training Certificate:**
citi Rtaylor.pdf

**2.0** * **Full Study Title**

Objective assessment of a surgeon's skill before and after robotic intervention.

**3.0** * **Type of submission**

New

**5.0** * **Briefly describe your proposed project**

*Include the overall objectives, general description of the procedures, and a description of the subject population or the types of data or specimens to be studied. You will be asked to provide more details later in the application.*

The goal of this research is to determine whether robotic surgical assistance improves surgical skill compared to unaided surgery. The surgical task for this evaluation will be navigating a tracked instrument to contact anatomical targets in the sinuses of a cadaver head. First, an expert group will perform the task to determine a baseline and gather data on how the robot affects expert surgeons. Then 20 novice participants will be divided into two randomized groups. The first group will be trained using the standard training method. The second group will be trained using the robotic training method. Both groups will then be assessed using a standard assessment method to determine whether robotic surgical assistance increases surgical skill, and whether these benefits of robotic training are retained even when operating conventionally.

**6.0** * **Select amount of risk involved with this study**

Greater than minimal

**xxx**

3 - Research Personnel

**1.0** *** Is this research being submitted as a student research project?**

Yes

**1.1**

*** Describe and outline the plan for the PI's supervision and oversight of this project, including regular meetings and communication between the student and PI.**

The PI (Taylor) meets regularly with the student (Olds) in a weekly advising meeting and also meets frequently in informal meetings within the laboratory. The PI and surgeon study team members (Ishii) will review the protocol and experimental procedures and will run through the experiment before it is attempted with study participants.

**2.0** **Team Members**

*Click **Add** to add all Student Investigators and Study Team Members. Click **Update** to modify existing people on this list.*

***NOTE: You do not have to list the PI again on this list. If you are not the PI, you must add yourself here or you will not have access to the application when you click "Continue" to go to the next page.***

| | First Name | Last Name | Degree | Title | Receive Notifications | Role | HSR Training Date | HSR Certificate Uploaded |
|---|---|---|---|---|---|---|---|---|
| View | Narges | Ahmidi | n/a | AE GR Graduate | yes | Student Investigator | 5/18/2012 | Yes |
| View | Marcin | Balicki | MS | AE GR Graduate | no | Research Team Member | 1/12/2015 | Yes |
| View | Preetham | Chalasani | | AE GR Graduate | no | Student Investigator | 11/20/2013 | Yes |
| View | Gary | Gallia | | ASSISTANT PROFESSOR | no | Research Team Member | 10/9/2012 | Yes |
| View | Masaru | Ishii | M.D., Ph.D. | ASSOCIATE PROFESSOR | yes | Research Team Member | 6/3/2012 | Yes |
| View | Kevin | Olds | BS | Graduate student | yes | Student Investigator | 7/6/2011 | Yes |

xxx

4 - Conflict of Interest

**1.0**

*** Does the PI, any study team member (or their spouse, domestic partner, or**

**dependent children), or any other person responsible for the design, conduct, or reporting of this research have a financial or economic interest (e.g., royalty, equity, consulting, employment) or fiduciary relationship (e.g., board service, office role, director role) with the sponsor and/or manufacturer of products used in this researcher with an outside entity whose financial interests could reasonably appear to be affected by the research?**

No

xxx

5 - Research Sites

**1.0** * **Will the research involve collaboration with a non-Hopkins entity?**

No

**2.0** * **Where will the JHU researchers recruit participants for the research?**

*Check all that apply.*

- [x] **Johns Hopkins University Homewood campus**
- [ ] **School of Advanced International Studies (SAIS)**
- [ ] **Applied Physics Lab (APL)**
- [ ] **Carey Business School**
- [ ] **Kennedy Krieger Institute (KKI)**
- [ ] **Peabody Institute**
- [x] **Johns Hopkins School of Medicine (SOM)**
- [ ] **Johns Hopkins School of Nursing (SON)**
- [ ] **Johns Hopkins School of Public Health (JHSPH)**
- [ ] **Schools or Classrooms**
- [ ] **Community or Community Centers**
- [ ] **International**

- [x] **Internet/email**
- [ ] **Telephone**
- [ ] **Mail**
- [ ] **Other sites where another PI will conduct the research**
- [ ] **Only data analysis of pre-existing data**
- [x] **Other**

* **Other: (Explain)**
Will recruit with posters, email solicitation, and word of mouth.

- [ ] **N/A**

xxx

6 - Support Information

**1.0** * **What is the funding status of this research?**

Not funded

**2.0** **Enter any additional information regarding funding.**

xxx

8 - Protocol Information

**1.0** * **Type(s) of research this study involves:**

No **Chart/record review or analysis of data that's already been collected for another purpose**
No **Classified**
No **Devices**
No **Drugs/Biologics**
No **Focus group/group discussion**
Yes **Intervention or testing: Neuropsychological/ cognitive/ psychosocial/ behavioral/ educational**
No **Interviews**
No **Specimen/sample collection or banking**
Yes **Survey/Questionnaire**
No **Use of existing banked specimens**
Yes **Other**

**Specify the type of research this study involves.**
In this study, participants will perform simple model surgical tasks on a human cadaver head with and without a surgical robot.

**2.0** **Describe the purpose and goals of the study.**

The primary objective of this study is to objectively assess whether robotic sinus surgery results in an improvement in surgical skill compared to conventional surgery.

A secondary objective of this study is to objectively determine whether skill improvement gained from robotic sinus surgery training is retained when operating manually
Another secondary objective of this study is to examine the difference between experts operating manually and with the robot, including subjective feedback.

Hypothesis 1: robotic sinus surgery results in improved surgical skill compared to conventional surgery.

Hypothesis 2: Skill improvement gained from robotic sinus surgery training is retained when operating manually.

Hypothesis 3: Robotic sinus surgery reduces hand tremor in experts compared to conventional surgery.

**3.0** *** Describe the design and the methodology of the study.**

One alcohol fixed human cadaver head will be obtained from the Maryland board of anatomy. CT marking screws will be fixed onto the head, and it will be CT scanned. An optical tracking marker will be fixed onto the head. Optimal tool trajectories will be computed based on the CT scan. Five experts, (surgeons and fellows from Johns Hopkins Hospital) and 20 novices (graduate and undergraduate students from Johns Hopkins University) will be recruited. The experts will receive training in the operation of the robot, and will be instructed to use a probe instrument with an optical tracking marker to touch several anatomical targets in the sinuses of both nostrils of the cadaver head, while the tool tracking data is recorded.
The group of 20 novices will be split into two randomized groups of 10, the robotic training group, and the conventional training group. Both groups will be given an introduction to sinus anatomy and sinus surgery. The conventional group will then be instructed to train using the tracked probe to touch the same anatomical targets in one nostril of the sinus. Participants will then be instructed to touch the same targets in the other nostril as an evaluation. In order to control for the asymmetry of the sinuses, the nostrils used for training and evaluation will be randomized for each participant. The robotic training group will receive additional instruction in how to use the robot, and will be instructed to train to touch the same targets in one nostril with the tracked probe mounted in the robot. The robot will use a virtual fixture computed from the optimal trajectory to constrain their motion. The robotic group will then be evaluated with and without robotic assistance. In order to control for learning effects, the order of these three evaluations and which nostril they will be conducted in will be randomized for each participant. The tracking data from the evaluations of the robotic and conventional groups will then be compared to the data from the experts using ANOVA to determine which group operates with the most surgical skill. Data from the robotic group will also be similarly compared to determine whether surgical skill improvement from using the robot is retained when operating manually. The data from the expert trials will be analyzed to determine what effect the robot has on expert surgeons, including subjective feedback.

**4.0** *** Describe the importance of the knowledge expected to result from the study.**

Endoscopic sinus surgery is one of the most frequently performed head and neck procedures, whether for the treatment of sinus ailments such as sinusitis, or to access other areas like the eye and brain. One of the most difficult aspects of sinus surgery is to navigate instruments through the complex and delicate sinus anatomy without damaging surrounding tissues. The anatomy of the sinuses can vary dramatically from person to person, making it difficult to orient instruments and track where instrument shafts will contact surrounding tissue. Because of these difficulties, optical tracking systems such as the Polaris are typically used to help surgeons navigate through the sinuses. However, even if the position of the tool within the sinuses is known relative to pre-operative images, significant training is required before training surgeons can optimize the trajectory of the tool to maximize economy of movement and visualization quality, while minimizing undesired contact with anatomy. Previous work has shown that expert surgeons tend to converge on very similar optimal tool path solutions, and that surgical skill can be evaluated by quantitatively comparing tool trajectories to those of experts. However, in order for this skill metric to be applied to improving surgical training, real-time feedback is required. One method of delivering this feedback is through robotic assistance.

The Robotic ENT Microsurgery System (REMS) is a prototype surgical robot that has been developed at Johns Hopkins University in collaboration with the department of Otolaryngology at Johns Hopkins Hospital. The REMS holds surgical instruments along with the surgeon, sensing the surgeon's intent with a force sensor. However, since the REMS has control of the instrument, it can constrain the surgeon's motion and block undesirable motions such as hand tremor. Using a robot with pre-programmed constraints to constrain a surgeon's motion is a technique known as virtual fixtures, which has been extensively explored in the medical robotics literature. A preliminary evaluation of the REMS by a surgeon, fellow, and novice performing a precision needle insertion task has already been conducted. This study will determine whether surgical training using the REMS to provide real-time force feedback results in improved surgical skill compared to conventional training.

**5.0** **Describe the study's procedures and activities that participants will be asked to perform or take part in, including the number and duration of sessions. If the study involves surveys, tests, interventions, or tasks, please describe them in detail here. If the study involves interviews or focus groups, explain the topics to be covered. You will be asked to upload these documents next.**

See section 3.0 above. Each participant will be given up to 30 minutes of training in the task, half with the robot and half without. Participants will continue practicing the surgical task for 30 minutes at their own pace. Participants will then be evaluated for no longer than 30 minutes. Participants will be given the opportunity to rest after each repetition, and each session will last no longer than 90 minutes, and each participant will only participate in one session. Photos and videos may be take showing the surgical field, but the participants will not be shown.

**6.0** **Upload a copy of all assessments, surveys, questionnaires, tests, tasks, interview questions, or focus group questions. Please assign them a clear title.**

*Click **Add** to upload a new document. Click **Upload Revision** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

| Name | Description | Modified Date |
|---|---|---|
| REMS Sinus Survey Questions.docx \| History | | 12/17/2013 4:14 PM |

**7.0** * **Will any participants be audio recorded, video recorded or photographed?**

Yes

**8.0** * **Type of Recording:**

Yes **Still Photography**
Yes **Video**
No **Audio**
No **Other**

xxx

9 - Deception

**1.0** * **Do any of the research procedures, including tests and tasks, involve deception of any**

**of the participants?**

No

xxx

13 - Recruitment and Participants

**1.0** * **Who will recruit participants for this study?**

Check all that apply.

- [ ] **PI**
- [x] **Study Team Member(s)**
- [x] **Student Investigator**
- [ ] **No recruitment (Data analysis of existing data ONLY)**
- [ ] **Other**

**2.0** * **Will you be specifically recruiting ANY of the following populations?**

Check all that apply.

- [ ] **Children (individuals under 18 years of age)**
- [x] **JHU Students (all at least 18 years old. If you are unsure if all students will be 18, please select 'Children' as well)**
- [x] **Johns Hopkins Employees**
- [ ] **Non-English Speakers**
- [ ] **Emancipated Minors**
- [ ] **Wards of the State**
- [ ] **Cognitively Impaired/Impaired Decision Making Capacity**
- [ ] **Pregnant Women**
- [ ] **Critically Ill or Injured Patients**
- [ ] **Prisoners**
- [ ] **Homeless or Economically Disadvantaged**
- [ ] **None**

**4.0** * **Sex of participants**

- [x] **Male**
- [x] **Female**

**5.0** **Describe your participant population and how you will recruit them for the study.**

Participants will include Johns Hopkins Homewood and School of medicine students and employees over the age of 18. Participants will be recruited through e-mail, fliers, and word of mouth advertising.

**6.0** * **Provide the maximum number of participants to be enrolled.**

25

**6.1** * **Provide justification for recruiting the above number of participants.**

The number 25 was chosen based on our experience as to what is needed to produce useful data for what will be effectively a pilot study for new technology.

**7.0** * **Describe measures that will be implemented to avoid participant coercion or undue influence.**

The person doing the recruiting will not be a supervisor of the study participants.
The study is voluntary, and the participants will be told this.

**8.0** * **List the criteria participants must meet to be included in the study. Please describe how you will verify that participants meet this criteria and how this will be documented in your study files.**

Over 18 years old.
Student or employee of Johns Hopkins University or School of Medicine.
Fluent in English.
Must be capable of performing basic manual tasks.
Participants must complete blood-borne pathogens certification before participating and must present proof of completion.

**9.0** * **List the criteria for excluding individuals from the study.**

Inability to comply with instructions.

**10.0** **If the participant is responsible for any research-related costs, identify and estimate the dollar amount.**

None.

**11.0** **Will participants receive payment (money, gift certificates, coupons, etc.) or be offered incentives (entered into a drawing, class credit) for their participation in this research?**

Yes

**12.0** **Describe payment and/or incentives to participants.**

Participants will receive a gift of nominal value (a $5 gift certificate).

**13.0** * **Are you using recruitment materials/scripts?**

Yes

**14.0** **Upload recruitment materials here, including flyers, posters, email scripts, phone scripts, etc.**

Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)

| | Name | Description | Modified Date |
|---|---|---|---|
| View | REMS sinus poster.pptx | | 3/17/2014 11:41 AM |
| View | REMS sinus recruitment script.docx | | 1/15/2014 2:47 PM |

xxx

14 - Risk, Benefits and Confidentiality

**1.0** *** Describe the risks to participants and the steps for minimizing the risks. Please include risks that would be associated with loss of confidentiality and privacy.**

A fixed human cadaver head will be used in this study. The primary risk to the participants is transmission of infection from the cadaver head. Standard procedures for surgical training with cadavers will be used. Considering the large number of experiments and training programs at JHU that use cadavers without incident, the risk is low. Also, all participants will have completed the online blood borne pathogen training course through myLearning@johnshopkins before participating in the study.

**2.0** *** Describe the potential benefit(s) to participants. If none, state this.**

Participants will not benefit directly from this study. Participants may learn about surgical tasks and surgical robots, and their surgical skill may be improved.

**3.0** *** Describe the potential benefit(s) to society. If none, state this.**

This study could lead to important knowledge that surgical robotics offers value to surgical skills assessment and training.

**4.0** *** Will research data be identifiable, meaning linked to participants' identifiable information through a code or other way at any point in the study? (If audio recording, video recording, or still photography of participants will take place as part of the study, then the data are likely to be considered identifiable so please select "yes".)**

No

**7.0** *** Where will research data be kept and how will data be stored and secured? Describe security measures used to protect study data from loss or inappropriate use (locked office, password protection, restricted access to database, database backup etc.).**

The research data will be kept on a shared server at Johns Hopkins University. This server will be backed up routinely. Further details are in the data management management plan in the proposal.
NO personally identified data will be placed on any file system or server.

**8.0** * **Indicate who will be responsible for collection and storage of data. Who will have access to research data?**

Access to this data will be restricted to the investigators at JHU.
It is expected that the data will be published and will be made available to other researchers.
However, NO personally identifiable data will be kept.

**9.0** * **How long do you plan to store the data? Please note that data must be kept by the PI for at least three years after the completion of the research. Describe how and when you plan to destroy the data.**

5 years. There is no plan to destroy the data, but no data will be personally identifiable.

xxx

15 - Informed Consent and Consent Waivers – Adults

**Please note that this section is only asking about informed consent from an ADULT who is participating in the research. If this is a study is involving ONLY CHILDREN, select 'None of the above' below. You will answer questions about assent and parental permission later.**

**1.0** * **Select all types of participant informed consent and/or waivers requested for this study.**

Yes **Written Informed Consent**
No **Waiver of Written Consent (Oral Informed Consent)**
No **Waiver of Informed Consent or Alteration of Informed Consent**
No **Survey/questionnaire research (Exempt research only: Consent text added to beginning of survey rather than participants filling out a separate consent form)**
No **None of the above**

**2.0** * **Describe the process for obtaining written informed consent/permission, including:**

- **where and when consent will be obtained**
- **time allotted for obtaining consent**
- **procedure to assess participants' understanding of the research**
- **how information will be provided if non-English speakers may be enrolled.**

We will review the protocol and instructions with each participant at the start of each study session. Participants will be given a chance to review the consent form and ask any questions before signing the consent form.
Only English speakers will participate in the study.
It is expected that this will take at most 15 minutes.

**3.0** * **Upload all of your Written Consent Forms for approval in Microsoft Word only.**

**Please make sure your documents are clearly labeled and contain a title that accurately describes the type of consent to be obtained with the document. Under no circumstances should copies of these versions be distributed to participants. When this research submission is approved by the IRB, your consent forms will contain an IRB stamp.**

*Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

| | Name | Description | Modified Date |
|---|---|---|---|
| View | REMS sinus consent form.doc | | 3/17/2014 11:35 AM |

xxx

Finalize Application

**Additional Documents**

**You may upload any documents not requested in the application but which may help with the review process. You may also upload Human Participants Training certificates here.**

*Click **Add** to upload a new document. Click **Upload Revision** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

| Name | Description | Modified Date |
|---|---|---|
| Gallia HR protection update.pdf \| History | | 12/6/2013 3:27 PM |
| Ishii HSR certificate new.pdf \| History | | 1/15/2014 2:37 PM |
| Kevin Olds HSR certificate.pdf \| History | | 12/2/2013 11:39 AM |
| narges_ahmidi_cert_CITI.pdf \| History | | 12/2/2013 11:39 AM |
| Preetham HSR form.pdf \| History | | 11/25/2013 7:38 PM |

**To complete this Homewood IRB application:**

- Click **Hide/Show Errors** above or below to check the application for completeness. All required fields must be completed in order to submit.
- Click **Finish** below to return to the New Application workspace.
- Finally, click **Submit** on the left side of the workspace.
- NOTE: ONLY THE PI CAN SUBMIT THE APPLICATION.

# Study Team Conflict of Interest

**1.0 Study Team Member**

Narges Ahmidi

**2.0** * **Does this study team member have a conflict of interest?**

**3.0** * **Will this study team member serve as a non-conflicted designee?**

## Study Team Conflict of Interest

**1.0** **Study Team Member**

Marcin Balicki

**2.0** * **Does this study team member have a conflict of interest?**

**3.0** * **Will this study team member serve as a non-conflicted designee?**

## Study Team Conflict of Interest

**1.0** **Study Team Member**

Preetham Chalasani

**2.0** * **Does this study team member have a conflict of interest?**

**3.0** * **Will this study team member serve as a non-conflicted designee?**

## Study Team Conflict of Interest

**1.0** **Study Team Member**

Gary Gallia

**2.0** * **Does this study team member have a conflict of interest?**

**3.0** * **Will this study team member serve as a non-conflicted designee?**

# Study Team Conflict of Interest

**1.0** **Study Team Member**

Masaru Ishii

**2.0** * **Does this study team member have a conflict of interest?**

**3.0** * **Will this study team member serve as a non-conflicted designee?**

# Study Team Conflict of Interest

**1.0** **Study Team Member**

Kevin Olds

**2.0** * **Does this study team member have a conflict of interest?**

**3.0** * **Will this study team member serve as a non-conflicted designee?**

**Document:**

REMS sinus poster.pptx(0.04) | History
**Document:**

REMS sinus recruitment script.docx(0.02) | History
**Document:**

REMS sinus consent form.doc(0.02) | History

# Appendix E: REMS Otology IRB Protocol

Date: _____5/23/14_____
Principal Investigator: _____Russell Taylor_____
Application Number: _____IRB00038568_____

# JHM IRB - eForm A – Protocol

- **Use the section headings to write the JHM IRB eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.**
- **When submitting JHM IRB eForm A (new or revised), enter the date submitted to the field at the top of JHM IRB eForm A.**

**********

## 1. Abstract

Stapedotomy is a common surgical procedure used to treat patients with conductive hearing loss caused by fixation of the stapes footplate. One of the most difficult parts of stapedotomy is laser stapes footplate fenestration (LSFF), which involves using a laser to ablate 50-100um diameter holes in an approximately 700um diameter circular window to provide clearance for a prosthesis. This surgery can be challenging when done manually because of the very high precision required. If the window is not the correct size and shape, the prosthesis will not fit and more holes will have to be ablated. It is also desirable to minimize the number of laser shots used, and to prevent the laser from shooting into an already opened hole, since this can damage of the structures in the cochlea, leading to hearing impairment.

The goal of this research is to evaluate whether the Robotic Ear Nose and Throat Microsurgery System (REMS), a novel surgical robot being developed at JHU, can improve surgical precision in a model of LSFF over conventional manual methods. This study will involve recruiting surgeons, fellows, and residents from Johns Hopkins Hospital who are trained in LSFF. Participants will perform a simulation of LSFF on a synthetic phantom both conventionally and with the REMS. The phantoms will be analyzed to determine if the REMS was able to improve surgical precision over conventional manual operating methods. No identifiable information from the participants will be kept except for the consent form, and no information will be kept linking participants to their experimental results.

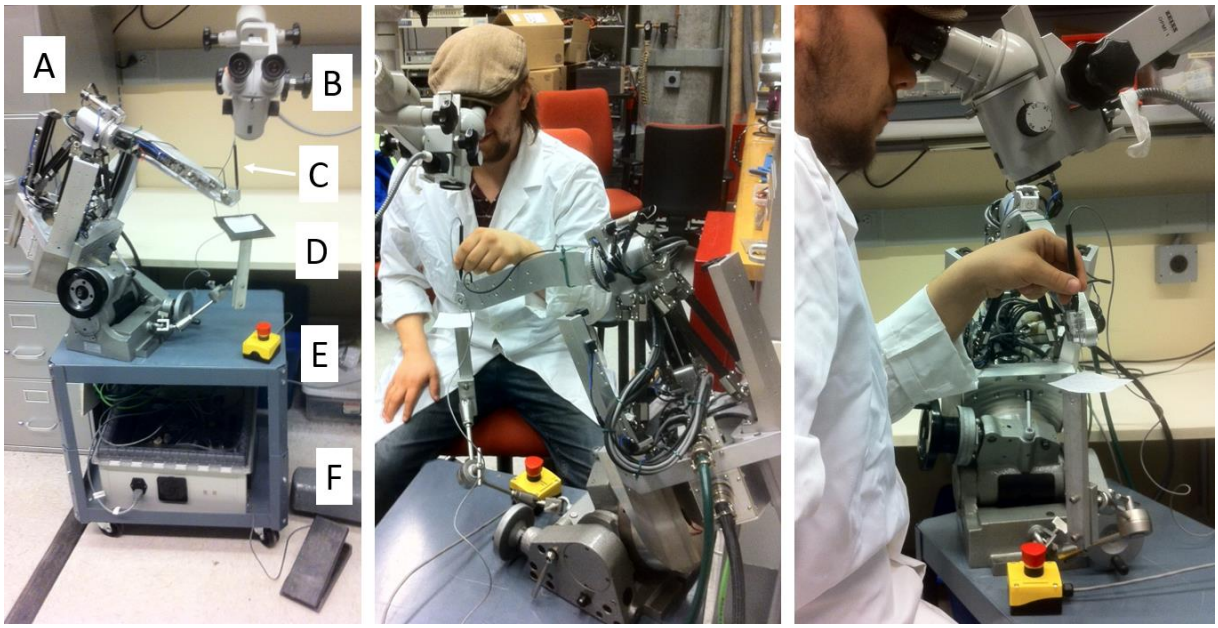
*Hypothesis:* Fewer laser shots will be needed to ablate a correct size/shape fenestration when using the REMS vs. operating manually. Fenestration shape and size will be closer to specifications when using the REMS than when operating manually.

## 2. Objectives

The primary objective of this study is to determine whether a novel surgical robot improves surgical precision in laser stapes footplate fenestration compared to manual operation in a synthetic phantom.

## 3. Background

The REMS is a robotic system for enhancing surgical precision that is currently under development at JHU. See the "REMS summary appendix" document which has been uploaded for detailed description of the REMS.




Left: REMS Overview: A) Robot B) Microscope C) Laser probe D) Synthetic phantom E) Emergency stop button F) Robot control pedal
Middle/Right: Example setup of REMS in use

One of the primary application areas of the REMS is middle ear surgery. LSFF will be used as a model operation for evaluating the REMS in middle ear surgery. LSFF involves the creation of an opening in the stapes footplate for a prosthesis, typically done using a laser. The laser is used to ablate a series of small holes (50-100 um in diameter) in a circular pattern (700 um in diameter) in order to create the opening. The main challenges include making the window the right size and shape for the prosthesis, and avoiding heating of the fluid in the inner ear, which can cause tissue damage. LSFF was chosen to evaluate the REMS because it offers clear, quantifiable objectives which can be used to determine whether the REMS can improve surgical precision.

## 4. Study Procedures

After consent has been obtained at the site of the experiment, each participant will be given hands-on training with the REMS surgical robot and instruction about the phantom and goals of the experiment to ensure the study procedures are understood. Participants will then have a brief practice period to practice laser stapes footplate fenestration manually and robotically. Participants will then perform a laser stapes footplate fenestration on the phantom manually and robotically in a randomized order. All robot data including position, speed, force, etc. will be recorded. The number of laser shots for each trial will also be recorded. Photographs or videos of the laser tip and the phantom will be recorded, though the participant's face will not be shown. The phantoms will be retained after each trial and analyzed later. Participants will be asked to fill out a short anonymous questionnaire about their experience with the robot. Each participant will only be asked to participate in one session which is expected to take no longer than one hour in total. No identifiable data on the participants will be kept except for the consent form. No information will be kept linking the participants to their study results. Photos and videos of the operating area will be taken, which will show the participants' hands, but the participants' faces will not be shown.

## 5. Inclusion/Exclusion Criteria

Inclusion: Surgeon, fellow, resident, or medical student at Johns Hopkins Hospital or School of Medicine who has received training in laser stapes footplate fenestration.

Exclusion: Not able to speak English fluently to understand instructions

**6. Drugs/ Substances/ Devices**

This is a user study to determine whether a novel surgical robot can improve surgical precision in a synthetic phantom, so no drugs, substances, or devices will be used on any participants. Also, since synthetic phantoms are being used, participants will not come into contact with any biological specimens or samples as part of this study. The surgical robot being used is a research system being developed at JHU (see background section), and the surgical laser being used is the same laser that is used for laser stapes footplate fenestration clinically.

**7. Study Statistics**

a. The primary outcome variable is the error between the actual window shape/size cut from the phantom, and the ideal shape/size. This will be measured by photographing the phantoms with a microscope and digitally analyzing the size and shape of the fenestration.
b. A secondary outcome variable is the number of laser shots required to perform the operation.
c. Since this is a preliminary evaluation, and there is no preliminary data on the potential effect size, a sample size of 20 participants was chosen for this study based on our experience with other robot studies for what is needed to produce useful data for what will be effectively a pilot study for new technology.

**8. Risks**

a. The primary risk to the participants in this study is injury from the clinical laser. However, since only participants trained and experienced with the laser will be recruited, and standard safety procedure used for the laser in the operating room will be followed (laser goggles, etc.), the risk is low. The laser system will be completely unmodified and the user still retains full control over when the laser is fired. The laser is independently controlled by a foot pedal that is part of the laser unit.
b. Another possible risk is injury from the robot itself. In order to minimize this risk, users will be trained in the use of the robot at the beginning of the study and shown a demonstration of its proper use. The robot's safety features are outlined in the appendix describing the REMS.
c. Participants may also encounter fatigue as part of this study. To avoid this, the setup will be adjusted at the beginning of the study so that the participants are comfortable. They will also be told that they can take a break at any time.

**9. Benefits**

a. Participants will not benefit directly from this study other than the educational benefit of working with emerging technologies.
b. Testing and evaluation of human performance using the assistive system and technology that are the participants of this research are essential elements in determining its value in improving surgical performance. Also, this information is an essential element in guiding the development and further improvement of these systems. This knowledge will enable eventual development of clinically deployed systems that will permit surgeons to perform surgery more effectively and more safely.

**10. Payment and Remuneration**

a. Participants will not receive any payment for participating in this study.

**11. Costs**

a. There are no costs associated with this study.

# Appendix F: REMS Microvascular Suturing IRB Protocol

Date: 4/24/14
Principal Investigator: Russell Taylor
Application Number: IRB00027647

**Johns Hopkins Medicine - eForm A**

- **Use the section headings to write the eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.**
- **When submitting eForm A (new or revised), enter the date submitted to the field at the top of eForm A.**

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## 1. Abstract

Robotic surgical systems continue to become more prevalent in many surgical domains. Their use has led to improved care in terms of both resectability of disease and overall patient outcomes. Specifically within the field of head and neck surgery, transoral robotic surgery for tumors involving the upper aerodigestive tract and transaxillary thyroid surgery have become common place. Many major institutions integrate the use of Intuitive Surgical's da Vinci Surgical System into their standard training programs. The use of robotic systems continues to expand within Otolaryngology and is poised to soon include skull base, sinus, and otologic applications as well. However, despite the increasing presence of robotic platforms, there are specific surgical tasks have yet to benefit from the improved accuracy and dexterity that robotics can provide. One particular area of surgery that has remained technically challenging is microvascular surgery. The reanastamosis of delicate vessels for free flaps during reconstructive surgery is still difficult for even the most experienced surgeons. Although the da Vinci has many benefits on a macro scale, the lack of haptic feedback and bulky system makes it difficult and impractical to incorporate with microsurgery. Current technologies, like the microvascular microscope, only serve to enhance visualization and do nothing in the way of

enhancing the surgeon's technical skills. What we propose is a unique robotic platform that addresses this issue. The Robotic Ear Nose and Throat Microsurgery System (REMS) an external, non-invasive gantry unit serves as a stabilizing mechanism for the surgeon's primary instrument, a custom microvascular tool serving as a needle driver. A force-feedback control system eliminates the surgeon's intrinsic tremor, enhances control over fine motor movements and maintains one-to-one haptic feedback for the user. The following user study describes a way to validate the efficacy of the aforementioned robotic platform for microvascular surgical techniques using a simple chicken thigh model.

## 2. Objectives

**Primary:**

-Initial user study to determine if robotic system with custom microvascular needle drivers improves efficiency in simulated microvascular surgical techniques using chicken thigh model

-Evaluate use of robotic system in simulated microvascular surgical tasks for individuals with no training in microvascular surgery (but who have received general training in suturing) compared to trained microvascular surgeons

## 3. Background

Robotic surgical systems have become a mainstay of many surgical fields, including Otolaryngology – Head and Neck Surgery. There are numerous peer-reviewed articles centered around the role of robotics across various areas of Otolaryngology, including otology, skull base, oncology, and thyroid surgery [1]. The incorporation of these devices may contribute to improved respectability and outcomes compared to the current standard of care. As technology continues to

develop, so will the role of robotic systems in these fields. The most prevalent robotic device is the DaVinci Surgical Robotic System (Intuitive, Inc., Sunnyvale, CA), which has FDA approval within the field of Otolaryngology for transoral resection of tumors in the upper aerodigestive tract and transaxillary thyroidectomy. However, one of the most technically challenging aspects of various head and neck procedures remains microvascular surgery, for which the DaVinci system is not well suited. In fact, no robotic platform is currently capable of improving the surgeon's dexterity or operative efficiency for these intricate procedures.

Microvascular surgery is at the cornerstone of several reconstructive procedures throughout Otolaryngology – Head and Neck Surgery and has become commonplace in training programs across the country, with more than one in eight academic Otolaryngologists reporting microvascular training [2]. Specifically, free flaps remain the preferred method of reconstruction for complex defects after ablative procedures including oncologic resections. These procedures have continued to improve over the past 10 years and currently demonstrate success rates exceeding 95% in most literature [3-7]. However, these procedures continue to have a high overall cost due in large part to lengthy hospital stays and long operating times [8]. In many cases the microvascular re-anastamosis of vessels during free tissue transfer remains one of the largest contributors to overall time.

In addition to technical complexities of microvascular techniques, a surgeon's inherent dexterity and essential tremor are limiting factors to operative time and surgical efficiency. The most experienced surgeons have maximized their surgical proficiency and minimized their tremor, more novice surgeons struggle with mastery of certain techniques. This is especially true in microvascular surgery where the hard skills and, especially, inherent tremor of the operator are magnified. The Robotic Ear Nose and Throat Microsurgery System (REMS) is a custom external robotic platform that allows the user to optimize their surgical skills in a more rapid manner by dampening the tremor

of the surgeon's dominant hand while providing more controlled and precise movements. Additionally, the external nature of the robot preserves the one to one haptic feedback of the instrument. A primary force sensor and customizable control systems allow for fine and consistent adjustment of user velocity and acceleration. The applications for such a device extend well beyond microvascular surgery alone. Within the domain of Otolaryngology, these include, but are not limited to, otology, laryngology, sinus and skull base surgeries. Details of the REMS robotic platform are covered in the "REMS summary appendix" document which has been uploaded.

Combining the REMS with a custom fabricated microvascular needle driver allows for one of the many unique applications of this gantry system. Specifically, it creates a unique robotic platform that enhances the operator's inherent procedural ability while providing a potential solution to the steep learning curve and difficulty associated with microvascular surgery. Our goal is to assess the impact of this system on task specific microvascular surgical skills using a simple chicken thigh model [9] and basic suturing task boards in this user study. We believe that the validation of this system and its initial proof of concept through a user study will be the first steps towards eventual incorporation in various operative aspects of microvascular surgery.

## 4. Study Procedures

In this user study, we seek to assess the validity of a novel robotic platform (REMS) that will be used to enhance the operative ability of surgeons performing microvascular surgery. Several other robotic systems have been developed and refined through partnerships between the Department of Otolaryngology – Head and Neck Surgery at the Johns Hopkins School of Medicine and the Mechanical Engineering Department at the Johns Hopkins

University. However, to our knowledge, no robotic platform has addressed the inherent challenge of performing microvascular surgery. This domain of surgery remains one of the most technically difficult aspects of any operation. Our goal is to make these tasks easier to perform while facilitating the development of essential skills for novice surgeons.

Participants will include medical students and professionals with previous experience and training with suturing techniques: third and fourth year medical students attending the Johns Hopkins School of Medicine as well as residents and faculty from the Department of Otolaryngology – Head and Neck Surgery. These individuals will be asked to perform simple tasks on suture training task boards under the direct supervision of study proctors.

Participation from individuals at various stages in training will allow us to interpret the impact of the robotic system on pre-existing surgical skills and its ability to circumvent the steep learning curve associated with microsurgery. Approximately 30 medical student participants will be recruited as volunteer study participants. Residents and faculty from the Department of Otolaryngology – Head and Neck Surgery will also solicited for their participation as volunteers.

**Phase 0: System familiarity**

All participants will be assigned a randomized study number at the beginning of the study. Participants will be randomized to perform the basic microvascular skills either with the robot or manually first. Before performing the surgical skills, they will be provided with a brief 5 minute tutorial explaining how to use the standard microsurgical tools as well as the modified robotic platform. Each participant will then be given 5 minutes before performing the specified tasks to familiarize themselves with both the standard and robotic tools.

**Phase 1: Basic Skills on Task Board and re-anastamosis without robotic platform**

Microvascular instruments and a microvascular microscope will be provided to all participants with instruction regarding their use. This set will include a needleholder, dissecting scissors, adventitia scissors, straight forceps, a vessel dilator, clamp applying forceps, and a vessel approximator clamp.

After a brief tutorial, participants will be asked to complete a set of basic skills on the task board – throwing basic sutures, tying, and cutting. They will then be asked to complete two microvascular anastamoses using a suturing technique of their choosing. These re-anastamoses will be performed on a grocery store bought chicken thigh as described previously. The entirety of the simulation and various tasks will be recorded and judged by a preceptor from the Department of Otolaryngology – Head and Neck Surgery with extensive experience in microvascular surgery. Video of the performed skills will be recorded to allow for assessment of individual performance at a later time. Performance will be measured by objectively structured assessment of technical skills (OSATS) derived largely from the aforementioned chicken thigh surgery simulation model. Both task specific microvascular OSATS (Table I) and an OSATS global rating scale (Table II) will be used.

**Phase 2: Basic Skills on Task Board and re-anastamosis with robotic platform**

Microvascular instruments, a microvascular microscope, and the robotic platform will be provided to all participants with brief instruction regarding their use. This set will include a custom robotic needleholder, dissecting scissors, adventitia scissors, straight forceps, a vessel dilator, clamp applying forceps, and a vessel approximator clamp.

After a brief tutorial, participants will be asked to complete a set of basic skills on the task board – throwing basic sutures, tying, and cutting. They will then be asked to complete two microvascular anastamoses using a suturing technique of their choosing. These re-anastamoses will be performed on a grocery store bought chicken thigh as described previously. The entirety of the simulation and various tasks will be recorded and judged by a preceptor from the Department of Otolaryngology – Head and Neck Surgery with extensive experience in microvascular surgery. Video of the performed skills will be recorded to allow for assessment of individual performance at a later time. Performance will be measured by objectively structured assessment of technical skills (OSATS) derived largely from the aforementioned chicken thigh surgery simulation model. Both task specific microvascular OSATS (Table I) and an OSATS global rating scale (Table II) will be used.

**Phase 3 : Exit Questionnaire and OSAT Comparison**

After successfully completing tasks both with and without the robotic platform, participants will complete an exit questionnaire. This questionnaire will focus on the individual's subjective experience at performing the tasks both with the robotic platform and manually without the robot. Participants will grade ease of use, perceived accuracy, and their overall preference for each platform. Basic surgical skills along with specific experience using microsurgical tools will be self-assessed within the questionnaire to provide an appropriate baseline for overall experience. Preceptors will review both video trials for each individual, grading them objectively using the pre-determined OSATS rating scale. Video data will also be analyzed using computer vision algorithms to quantify individual tremor for both trials (with and without the robot).

**Microvascular Objectively Structured Assessment of Technical Skills (OSAT):**

The microvascular OSATS consists of both task specific (Table I) and global rating (Table II) scales. The task specific OSATS uses a fourteen point binary checklist. Tasks will be scored as correct or incorrect, with a correct assessment being issued if the specific task is completed over 75% of the time. The global rating scale uses standard skill-related variables in operative procedures that are graded on a five point scale. OSATS assessments of surgical skill has shown good inter-rater, test-retest and internal consistency. These specific OSATS have also been validated in the literature for use in conjunction with a novel chicken thigh model for microvascular surgery assessment.

**Table 1:** Microvascular OSATS Task Specific Score [9]

| | **Correct** | **Incorrect** |
|---|---|---|
| **Passing Needle Through Tissue** | | |
| 1. Loads needle in drive 1/2 to 2/3 from needle tip | | |
| 2. Needle does not wobble in driver | | |
| 3. Needle enters tissue perpendicularly | | |
| 4. Forceps handle vessel adventitia, providing counter traction | | |
| 5. Dilator appropriately used | | |
| 6. Needle is pulled through tissue following its curve | | |
| 7. Suture is pulled parallel to the tissue | | |
| 8. Suture tails are left at correct length | | |
| 9. Appropriate depth tissue bite on each side | | |
| 10. Sutures are spaced appropriately | | |
| **Knot Tying** | | |
| 11. Three or more square throws are tied | | |
| 12. Efficient handling of suture while tying | | |
| 13. Appropriate tension on suture while tying | | |
| 14. Tissue well-approximated but not strangulated | | |

**Table 2:** Microvascular OSATS Global Rating Scale [9]

| | Worst | | | | Best |
|---|---|---|---|---|---|
| Economy of Motion | 1 | 2 | 3 | 4 | 5 |
| Instrument Handling | 1 | 2 | 3 | 4 | 5 |
| Respect for Tissue | 1 | 2 | 3 | 4 | 5 |

| | | | | | |
|---|---|---|---|---|---|
| Flow of Operation | 1 | 2 | 3 | 4 | 5 |
| Overall Result | 1 | 2 | 3 | 4 | 5 |

## 5. Inclusion/Exclusion Criteria

**Inclusion:**

Participants at various stages in training for microvascular surgery will be recruited. These individuals will include third and fourth year medical students from the Johns Hopkins School of Medicine who have had basic surgical training during clerkship training, Otolaryngology – Head and Neck Surgery residents at the Johns Hopkins Hospital, and Otolaryngology – Head and Neck Surgery faculty at the Johns Hopkins Hospital.

**Exclusion**:

Medical students who have not yet had Surgery or OBGYN core clerkships or other similar rotations that require basic suturing skills will not be eligible to participate in the study.

## 6. Drugs/Substances/Devices

This user study seeks to validate the use of a custom robotic platform for performing microsurgery. Participants will use the REMS to perform simple physical skills – no patients or biological materials will be used. Similarly, no drugs, substances or other devices will be used.

## 7. Risks

Minimal risk is expected for all participants and will not be greater than that of routine surgical training for medical students. No direct risk is anticipated for completion of questionnaires

or surgical tasks. The chicken thigh model used for microvascular re-anastamosis will be store bought (grocery store) and poses no intrinsic or extrinsic biological risk to study participants. The REMS has many safety features outlined in the REMS summary appendix document to ensure the risk of using it is minimum. In order to avoid fatigue, the experimental equipment will be adjusted to ensure each participant is comfortable. Participants will also be told they can take a break at any time.

## 8. Benefits

All participants will receive exposure to microvascular surgery techniques and exposure to new technologies for robotic assisted surgery.

## 9. Payment and Remuneration

None

## 10. Costs

This project is anticipated to cost $500 and is supported by funding from the Department of Otolaryngology – Head and Neck Surgery.

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