JOHNS HOPKINS UNIVERSITY eHIRB

Date: Sunday, April 14, 2019 9:35:08 PM

Print Close

New Application
PI: Emad Boctor
HIRB00008883

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.*

Emad Boctor

PI's HSR Training Date: 3/17/2016

PI's HSR Training Certificate:
Boctor HSR.pdf

2.0 * Full Study Title

Ultrasound scanning though cooperatively controlled robot arm for reducing sonographer strain

Development of software framework for robot assisted ultrasound imaging

3.0 * Type of submission
New

3.1 * Select the type of review requested:
Expedited

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.

This IRB submission is a follow-up to the work done in HIRB00003738, which also focused on robot-assisted ultrasound to reduce sonographer strain. In this work, we plan to study and evaluate newly developed robot motion algorithms aimed at improved cooperative control.

Intro:
Robot-assisted ultrasound will be of great importance in the future clinical environment as it aids in acquiring sturdy images and potentially relieves sonographers of the musculoskeletal strain they face when holding an ultrasound probe in contorted positions for long periods of time. In this project, we will design and test a robot motion software framework that assists a sonographer in manipulating an ultrasound probe during a scan by using a hand-guided, cooperatively-controlled robotic arm (UR5). Previous prototypes and their respective studies by Finocchi and Fang (cited below in “Related Work”) have shown success in accomplishing this goal, but their robot motion was less responsive and “transparent feeling” than desired and required in a clinical setting. This work focuses on testing improved algorithms for a more natural feeling robot-assistance.

Before designing a sonographer and patient centered study, the robot motion software framework needs to be developed and evaluated. For this purpose, we are required to have volunteers acquire images of phantoms while monitoring their physical exertion via surface electromyography (sEMG) sensors placed on the scanning forearm and suprascapular fossa. The sEMG system (FlexrGO) will use disposable electrodes to be discarded after single use.

The imaging results will help us quantify the probe stability achieved with and without robotic assistance, leading to deductions about the effectiveness of the system when it comes to acquiring sturdy images. The sEMG results will help quantify the effort that the volunteers exert when imaging with and without robotic assistance, leading to deductions about the effectiveness of the system when it comes to reducing musculoskeletal strain.

This study remains an evaluation of the technical functionality and effectiveness of the system (robot-assisted ultrasound), and is not a medical study. Since all images will be of a phantom, no clinical evaluation will be performed.

Objective:
- Develop robot software framework for hand-guided ultrasound probe manipulation
- Perform test acquisitions of ultrasound images on phantoms
- Acquire sEMG data from participants while they perform ultrasound scans on phantoms
- Gain knowledge to prepare IRB application for study with volunteer sonographers and patients
- Gain knowledge to prepare grant submission

Description of sEMG sensor:
The FlexrGO wearable sEMG sensor is “a leading edge wearable, surface EMG which provides clinical grade movement readings for biofeedback, neuromuscular re-education, and strength-power output.” The sensors operate wirelessly, providing data over Bluetooth to an iPad for data collection and plotting. The devices are registered FDA Class II devices that satisfy FDA requirements. The devices are also FCC certified and use batteries that are IEC62133 & MSDS certified as well.

Description of robot:
The UR5 is classified as a lightweight robot and is a jointed arm robot with 6 axes. UR5 is equipped with special safety-related features, which are purposely designed for collaborative operations with a human. With the safety features, the robot is able to understand if it hits a surface, and in that case, it stops the motion immediately. The robot has forced back-driving and manual brake release options to force movements of the robot joints. In the unlikely event of an emergency situation, there exists an emergency stop button to immediately stop all robot motion. While the subject is maneuvering the robot during the experiments, the inspector will be standing next to the subject. He will be holding the robot emergency button for any emergencies (for example a robot component failure). Additionally, the robot has software safety limits for maximum force, power, speed and momentum. Further robot safety information about UR5 can be found at: https://www.universal-robots.com/media/8704/ur5_user_manual_en_global.pdf

UR5 safety measures:
Stopping distances and stopping times in accordance with EN ISO 13850/ IEC 60204-1
Maximum joint speed allowed by redundant UR5 controllers is 180 deg/sec.
Maximum torque allowed for each joint limited are 150 Nm (base, shoulder, elbow) and 28 Nm (w1,w2,w3)
UR5 specifically comply with EN ISO 10218 (section 5.10.5, Collaborative operation) and EN ISO 10218-2 (Integrators that integrate the robots in their machines or installations).
Robot in compliance with EN ISO 13850 (Safety of machinery - Emergency stop), EN ISO 13849-1,EN ISO 13849-2 (Safety of machinery - Safety-related parts of control system), EN ISO 12100 (Safety of machinery), EN ISO 10218-1 (Safety requirements for industrial robots), EN 610006-4 + A1 (Electromagnetic compatibility (EMC)), EN 6100062-2
(Electromagnetic compatibility (EMC)), EN 61326-3-1 (Electrical equipment for measurement (EMC)), EN 61131-2(Equipment requirements and tests)

Description of the procedure (image acquisition, maintaining force, and sEMG sensing):
The phantom will be positioned on an appropriately positioned table present in Hackerman B08A. First, the participant will be outfitted with disposable sEMG electrodes on the scanning forearm and suprascapular fossa for muscle effort measurement during scans. Next, during a preparation phase, the volunteer will apply ultrasound gel to the phantom under guidance of the researcher. Subsequently, the ultrasound image acquisition procedure and robot motions will be explained. Furthermore, the volunteer will be instructed to stop the procedure (see "additional safety measures" below) in case of any discomfort (e.g. shoulder pain, too little gel in area of ultrasound transducer). The UR5 robot is placed next to the table, with the ultrasound transducer attached to the end-effector. The robot will be calibrated by the researcher before proceeding. The participant will then be instructed to complete five trials of two tasks performed four different ways. The two tasks will be to 1. Hold the ultrasound probe still against the phantom with a constant 20N (approx. 2kg = 4.4lbs) of force; and 2. Follow/trace a tube-like feature embedded within the phantom with the ultrasound probe while maintaining a constant 20N of force. The four ways of performing these tasks will be 1. Freehand scanning; 2. Freehand scanning with visual force feedback; 3. Scanning with robotic system without force constraint; 4. Scanning with the robotic system with maximum force constraint. Ultrasound images of the phantom and sEMG data will be collected throughout for evaluation. After concluding the necessary image acquisition procedures, the all sEMG electrodes will be removed and immediately disposed.

Additional safety measures:
- Only medical certified ultrasound transducer will be in contact with phantoms
- Safety zones will be defined near the phantom surface
- Quick-release mechanism allows removal of ultrasound transducer from robot
- Emergency stop switches on robot control panel, and on hand of volunteer allow full and safe stopping of robot. The researcher will be holding the robot control panel at a safe distance away from the robot, and keep a hand on the emergency stop in case needed.
- Maximum speed allowed by image acquisition framework is 100 mm/s
- Maximum joint speed will be set to 0.5 rad/sec.
- Safety lights indicate robot status (motion or locked)
- Robotic motion monitored by engineer. Immediate lock and move out possible.
- Entire system weight allows manual removal of complete setup.

Risks:
- minimal risk of discomfort
- minimal risk of skin irritation in region where adhesive sEMG electrode is applied

Related work:
- T. Fang, H. Zhang, R. Finocchi, R. Taylor and E. Boctor, "Force-assisted ultrasound imaging system through dual force sensing and admittance robot control", International Journal of Computer Assisted Radiology and Surgery, vol. 12, no. 6, pp. 983-991, 2017. Available:

10.1007/s11548-017-1566-9 : Second iteration of using cooperative force control to maneuver an ultrasound probe with a UR5 robot, using many of the algorithms from Finocchi, 2017 listed below. Similarly, the results were promising but the movement latency could be improved upon to make the motion feel more transparent.
- R. Finocchi, F. Aalamifar, T. Fang, R. Taylor and E. Boctor, "Co-robotic ultrasound imaging: a cooperative force control approach", Medical Imaging 2017: Image-Guided Procedures, Robotic Interventions, and Modeling, 2017. Available: 10.1117/12.2255271 : First iteration of using cooperative force control to maneuver an ultrasound probe with a UR5 robot. While showing promising results, the system lacked robot motion transparency and felt unnatural at times.
- R. Finocchi, “Co-robotic ultrasound imaging: a cooperative force control approach”, The Johns Hopkins University, 2016 : A thesis written on Finocchi’s work in robotic ultrasound cooperative force control using UR5.
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Summary:
- Noninvasive ultrasound scanning of phantoms
- Non-invasive sEMG measurement with FDA class II device using disposable electrodes
- Safe robot controls
- No patients
- Participants will be informed that their participation is voluntary and their nonparticipation will not have any effect on their evaluation, future employment, project membership, etc.

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

Minimal

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 and research team member will be coordinating every step and either one will be present during the usability studies.

Weekly meetings (usually Friday, 1pm, Hackerman 127) will be held to discuss the progress, and compliance with the study protocol and regulations. Additional meetings to coordinate the execution of the usability study will be organized.

The student investigator will send a written biweekly report to summarize progress and contents of meetings to both the PI and research team member.

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	Kevin	Gilboy	AE GR Graduate	yes	Student Investigator	2/17/2019	Yes
View	Mahya	Shahbazi	POSTDOCTORAL FELLOW	yes	Research Team Member	11/16/2018	Yes

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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 research with an outside entity whose financial interests could reasonably appear to be affected by the research?**

No

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5 - Clinical Trials

1.0 * **Is this study a clinical trial?**
○ Yes ● **No**

Registration on ClinicalTrials.gov is strongly encouraged or required for many studies that may not meet the definition of a "clinical trial" (i.e., medical journal guidelines, in the terms and conditions of Foundation or other sponsored research). If your protocol is registered at ClinicalTrials.gov, please enter the National Clinical Trials (NCT) number in Question 6.

6.0 **ClinicalTrials.gov identifier (NCT Number):**
Please enter only the eight digits of the registration number (without NCT)

xxx

6 - 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)**
- [ ] **Johns Hopkins School of Education**
- [ ] **Schools or Classrooms**

- [ ] **Community or Community Centers**
- [ ] **International**

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

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7 - Support Information

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

Not funded

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

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9 - Protocol Information

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

No **Student Education Records**
No **Chart/record review or analysis of data that's already been collected for another purpose**

- ☐ **Classified**
- ☐ **Devices**
- ☐ **Drugs/Biologics**
- ☐ **Focus group/group discussion**
- ☐ **Intervention or testing: Neuropsychological/ cognitive/ psychosocial/ behavioral/ educational**
- ☐ **Interviews**
- ☐ **Biospecimen/sample collection or banking**
- ☑ **Survey/Questionnaire**
- ☐ **Use of existing banked biospecimens**
- ☐ **Other**

2.0 Describe the purpose and goals of the study:

- Develop software framework for smooth robot-assisted sonography
- Perform test acquisitions of ultrasound images on phantoms
- Evaluate effects of robot-assisted sonography on image quality
- Evaluate effects of robot-assisted sonography on physical scanning effort/exertion
- Gain knowledge to prepare IRB application for study with volunteers and patients
- Gain knowledge to prepare grant submission

3.0 Describe the design and the methodology of the study:

This investigation does not contain systematic or theoretical analysis of the methods.

The software to control the robot and acquire images will be developed. The developers will be leading participants in scanning phantoms with and without the robot assist system to evaluate the effectiveness of the robot motion software, as well as analyzing sEMG data to deduce physical effort exerted during scanning. Main criteria for evaluation are:
- surface contact of transducer (robotics control)
- ability to follow/trace a tube-like feature embedded within the phantom with the ultrasound probe (will use computer vision to score this)
- sEMG readings during all participant scans

Description of the procedure (image acquisition, maintaining force, and sEMG sensing):
The phantom will be positioned on an appropriately positioned table present in Hackerman B08A. First, the participant will be outfitted with disposable sEMG electrodes on the scanning forearm and suprascapular fossa for muscle effort measurement during scans. Next, during a preparation phase, the volunteer will apply ultrasound gel to the phantom under guidance of the researcher. Subsequently, the ultrasound image acquisition procedure and robot motions will be explained. Furthermore, the volunteer will be instructed to stop the procedure (see "additional safety measures" below) in case of any discomfort (e.g. shoulder pain, too little gel in area of ultrasound transducer). The UR5 robot is placed next to the table, with the ultrasound transducer attached to the end-effector. The robot will be calibrated by the researcher before proceeding. The participant will then be instructed to complete five trials of two tasks performed four different ways. The two tasks will be to 1. hold the ultrasound probe still against the phantom with a constant 20N (approx. 2kg = 4.4lbs) of force; and 2. follow/trace a tube-like feature embedded within the phantom with the ultrasound probe while maintaining a constant 20N of force. The four ways of performing these

tasks will be 1. Freehand scanning; 2. Freehand scanning with visual force feedback; 3. Scanning with robotic system without force constraint; 4. Scanning with the robotic system with maximum force constraint. Ultrasound images of the phantom and sEMG data will be collected throughout for evaluation. After concluding the necessary image acquisition procedures, the all sEMG electrodes will be removed and immediately disposed.

Since sEMG measurement is only one metric of many that we are interested in, we will be listing it as an optional component on our consent forms in the case that users are uncomfortable wearing the pads.

Description of sEMG sensor:
The FlexrGO wearable sEMG sensor is “a leading edge wearable, surface EMG which provides clinical grade movement readings for biofeedback, neuromuscular re-education, and strength-power output.” The sensors operate wirelessly, providing data over Bluetooth to an iPad for data collection and plotting. The devices are registered FDA Class II devices that satisfy FDA requirements. The devices are also FCC certified and use batteries that are IEC62133 & MSDS certified as well.

Description of robot:
The UR5 is classified as a lightweight robot and is a jointed arm robot with 6 axes. All motor units and current carrying cables are protected beneath cover plates. Each axis is protected by means of axis range sensors and can be adjusted by means of internal sensors. Each joint is equipped with a position sensor on the input side, torque sensors on the output side and temperature sensors. The robot can thus be operated with position and impedance control. The temperature sensors prevent thermal overloading of the robot.

UR5 safety measures:
Stopping distances and stopping times in accordance with EN ISO 13850/ IEC 60204-1
Maximum joint speed allowed by redundant UR5 controllers is 180 deg/sec.
Maximum torque allowed for each joint limited are 150 Nm (base, shoulder, elbow) and 28 Nm (w1,w2,w3)
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(Electromagnetic compatibility (EMC)), EN 61326-3-1 (Electrical equipment for measurement (EMC)), EN 61131-2(Equipment requirements and tests)

Additional safety measures:
- Only medical certified ultrasound transducer will be in contact with phantoms
- Safety zones will be defined near the phantom surface
- Quick-release mechanism allows removal of ultrasound transducer from robot
- Emergency stop switches on robot control panel, robot base and on hand of volunteer allow full and safe stopping of robot. The researcher will be holding the robot control panel at a safe distance away from the robot, and keep a hand on the emergency stop in case needed.
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- Non-invasive sEMG measurement with FDA class II device using disposable electrodes
- Safe robot controls
- No patients
- Participants will be informed that their participation is voluntary and their nonparticipation will not have any effect on their evaluation, future employment, project membership, etc.

4.0 Describe the importance of the knowledge expected to result from the study:

Robot-assisted ultrasound will be of great importance in the future clinical environment, as it aids in acquiring sturdy images and potentially relieves sonographers of the musculoskeletal strain they face when holding an ultrasound probe in contorted positions for long periods of time. In this project, we will design and test a robot motion software framework that assists a sonographer in manipulating an ultrasound probe during a scan by using a hand-guided, cooperatively-controlled robotic arm (UR5). Prior to this study, the robot motion software framework had been developed and evaluated in terms of functionality. To understand the quantitative and qualitative improvement this system can accomplish in reducing sonographer musculoskeletal strain during scanning, we are required to perform imaging procedures on phantoms while measuring acquired image quality and physical effort with and without the ultrasound robotic assist. This development is crucial in order to prepare an actual study with volunteer sonographers and patients (including preparation of IRB application and grant submission).

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:

The study will ask participants to perform multiple scans with and without the robotic assist on a phantom to validate system functionality and effectiveness. The trials will take place in Hackerman Hall on the Homewood campus, specifically in B08 and the "Mock Operating Room." While it was

stated in Section 6 that participants would be recruited from the SOM, no testing will be performed there and the participants (if they choose to partake in our study) will travel to Homewood instead.

A single participant will be asked to attend a single session, lasting no longer than 1 hour. At the conclusion of the session, the participant will be given a 6-question survey asking about their previous experience with ultrasound, as well as perceived strain and intuitiveness in using the robot assist system versus freehand. The survey used will be almost identical to the one used by Rodolfo in his 2016 thesis so that these results can be compared to evaluate if the current system has improved upon his work. Participants will also be issued a standard NASA Task Load Index (TLX) questionnaire to learn about their perceived operator workload. All survey responses will be deidentified, with participants using randomized ID numbers as opposed to their name. The responses will be uploaded to a secure file server hosted by the Whiting School of Engineering before being securely disposed.

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
Post-study Ease of Use Survey		3/5/2019 4:54 PM
Standard NASA TLX Survey		3/5/2019 4:54 PM

7.0 * Will any participants be audio recorded, video recorded or photographed?
No

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10 - Deception

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

○ Yes ● **No**

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14 - Recruitment and Participants

1.0 * Who will recruit participants for this study?

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

Explain

2.0 * Select all populations that you will directly recruit and/or review charts/records:

- [ ] **Children (individuals under 18 years of age)**
- [ ] **Individuals (<18) [who can consent for themselves as permitted by state law]**

- [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**
- [ ] **Children Who are in Foster Care or Wards of the State**
- [ ] **Cognitively Impaired/Impaired Decision Making Capacity**
- [ ] **Pregnant Women**
- [ ] **Prisoners**
- [ ] **Homeless or Economically Disadvantaged**
- [ ] **Educationally 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.**

The entirety of participant population consists of the developers in this project, members of the Laboratory for Computational Sensing and Robotics (LCSR), members of the Medical UltraSound Imaging and Intervention Collaboration (MUSiiC) lab with which the developers are affiliated, and volunteer sonographers from JHMI that are connections with close collaborators. No additional recruits will be included in the study.

It should be mentioned that Trauma Physicians from UMMC have asked to trial our device as non-study participants to evaluate it for potential usability in trauma procedures. They will simply be operating the device without any sEMG sensing and providing qualitative feedback to guide future research. They will be consented as such using the second consent form attached to this application. While all the same safety considerations outlined in this HIRB application will be enforced, they have told us that an IRB will not be required from UMMC since this is informal testing which will yield internal feedback that is not to be published.

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

30

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

The functionality and effectiveness of the robotic system must be evaluated for participants of different sizes and physique to ensure a more generalizable result. The number of participants is expected to be below 30 as this should indicate if the system performs within the desired parameters in a statistically significant way.

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

Neither coercion nor undue influence are applicable. The members of the "participant population" are experts in developing robotic systems for image guided interventions/image acquisitions, or sonographers who would be direct beneficiaries of development in this field.

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.**

Only the researchers, some of their affiliated lab members, and some clinical sonographers are involved in the experiment.

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

- Fear of robots or ultrasound
- Any type of injury that affects one's ability to perform an ultrasound scan (i.e. carpal tunnel, broken arm, etc.)
- Deaf, blind, or mute

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

Participants are not responsible for any research-related costs.

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?

No

13.0 * Are you using recruitment materials/scripts?

No

13.1 * Please explain and justify why recruitment materials/scripts are not being used for this research.

The participant pool is already well known by us, as most of them are close collaborators with whom the team has worked with before.

15 - Risk, Benefits and Confidentiality

1.0 * Describe the risks, discomforts, and inconveniences to participants including physical, psychological, emotional, social, legal, educational, and /or economic. Please include risks that would be associated with breach of confidentiality and loss of privacy.

Description of sEMG sensor:
The FlexrGO wearable sEMG sensor is “a leading edge wearable, surface EMG which provides clinical grade movement readings for biofeedback, neuromuscular re-education, and strength-power output.” The sensors operate wirelessly, providing data over Bluetooth to an iPad for data collection and plotting. The devices are registered FDA Class II devices that satisfy FDA requirements. The devices are also FCC certified and use batteries that are IEC62133 & MSDS certified as well.

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Robot in compliance with EN ISO 13850 (Safety of machinery - Emergency stop), EN ISO 13849-1,EN ISO 13849-2 (Safety of machinery - Safety-related parts of control system), EN ISO 12100 (Safety of machinery), EN ISO 10218-1 (Safety requirements for industrial robots), EN 610006-4 + A1 (Electromagnetic compatibility (EMC)), EN 6100062-2

(Electromagnetic compatibility (EMC)), EN 61326-3-1 (Electrical equipment for measurement (EMC)), EN 61131-2(Equipment requirements and tests)

Additional safety measures:
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- Safety zones will be defined near the phantom surface
- Quickrelease mechanism allows "oneclick" removal of ultrasound transducer from robot
- Emergency stop switches on robot control panel, robot base and on hand of volunteer allow full and safe stopping of robot. The researcher will be holding the robot control panel at a safe distance away from the robot, and keep a hand on the emergency stop in case needed.
- Maximum speed allowed by image acquisition framework is 100mm/s
- Safety lights indicate robot status (motion or locked)
- Robotic motion monitored by engineer. Immediate lock and move out possible.
- Entire system weight allows manual removal of complete setup.

Risks:
- minimal risk of discomfort
- minimal risk of skin irritation in region where adhesive sEMG electrode is applied

Confidentiality and Privacy:
- All data will be deidentified and stored on a secure Whiting School of Engineering file server.
- There will be no attempts to analyze sEMG data for any purposes other than effort exerted while performing sonography with and without the robotic ultrasound assist. The readings will not be clinically analyzed.

1.1 * **Describe the steps for minimizing the risks and research burden for participants. Include a description of how participant privacy will be protected during data collection if sensitive questions are included in surveys or interviews, and if study visits occur in the home or public setting.**

The surveys do not include sensitive questions as they only ask participants about their personal evaluation of the robot and its effect on their perceived physical exertion. The trials will be performed in private in Hackerman B08A, and all data will be immediately deidentified through the use of participant numbers (which will not be linked to their name in any form) before being uploaded to a secure Whiting School of Engineering file server.

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

Since the participants are researchers themselves, participating in this study will allow them to gain knowledge to prepare IRB application for study with volunteers and patients and knowledge to prepare grant submission.

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

This study will be an important step towards clinical application of autonomous robot assisted ultrasound acquisition and tomography. If it is found that the robotic assist system also reduces sonography effort/exertion, it will be beneficial to sonographers who commonly suffer from musculoskeletal disorders as a result of holding ultrasound probes in contorted positions for long periods of time (A. Schoenfeld, J. Goverman, D. Weiss and I. Meizner, "Transducer user syndrome: an occupational hazard of the ultrasonographer", European Journal of Ultrasound, vol. 10, no. 1, pp. 41-45, 1999. Available: 10.1016/s0929-8266(99)00031-2.).

4.0 * **Will research data or biospecimens 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 considered identifiable so please select "yes".)

○ 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, secure server, cloud/web-based, encryption, etc.).**

There will be no paper data, all data saved will be digital de-identified digital data will be stored on a secure file server hosted by the Whiting School of Engineering. We have no plans to destroy the de-identified data. Identifiable digital data will be stored on a password-protected USB key or hard drive in the PI's office and will be destroyed after three years.

8.0 * **Will Protected Health Information (PHI) or other confidential information (such as student or employment records, financial data, SSNs, or other research data), be stored on laptops or other mobile devices (such as mobile phones, tablets, netbooks, flash drives and other portable storage devices) for this study?**

○ Yes ● **No**

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

Kevin Gilboy, in the role of researcher, will be responsible for collecting and storing data collected from the participant population. All team members (Boctor, Shahbazi, Gilboy) will be visually inspecting the system functionality and will have access to the data.

10.0 * **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.**

Data are stored for a minimum of three years following the publication of the results. In many cases, we store de-identified data for additional years because it allows us to do large, cross-experiment assessments in a large project like this one. When the three year limit is passed and data are no longer being tracked over the longer term of the project, all pencil-and-paper tests will be shredded, files will be securely deleted from computers, and dedicated hard drives will be destroyed.

13.0 **Does this research propose to access and/or utilize Personally Identifiable Information (PII), Personal Health Information (PHI), Limited Data Sets, and/or DeIdentified Data from Johns Hopkins Medical Institutions (including Johns Hopkins University School of Medicine)?**

○ Yes ● **No**

15.0 * **I confirm that all the procedures listed below will be used to protect the confidentiality of data and/or samples collected and stored for research purposes:**

- **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**

● **Yes** ○ No

Data confidentiality pertains to the treatment of information that an individual has disclosed with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

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16 - Informed Consent and Consent Waivers – Adults

Please note that this section is only asking about informed consent from an ADULT (and an individual under 18 who can consent for themselves) who is participating in the research. If this is a study 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 Documentation of Consent (including Oral Informed Consent)**
No **Waiver 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.

At the time of the experiment, the study investigator will explain, to the participant, in very plain terms that the purpose of the study. The study investigator will then remind them that the study is voluntary, and provide the participant, at that time, with the Informed Consent form (attached, similar to that from HIRB00003738). The participant will be given as much time as they need to read the form and, if they wish, sign the form. The study investigator will ask the participants if they have any questions before getting started.

We have no plans to enroll non-English speakers or individuals who are unable to provide their own consent.

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	Consent form for clinician study participants (no sEMG sensing, just want their feedback)		3/27/2019 12:19 PM
View	Consent form for non-clinician study participants (incl optional sEMG sensing)		3/27/2019 12:19 PM

3.1 * **How many different written consent forms will be used?**
2

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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

There are no items to display

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**

Kevin Gilboy

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**

Mahya Shahbazi

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:

Consent form for clinician study participants (no sEMG sensing, just want their feedback)(0.01)

Document:

Consent form for non-clinician study participants (incl optional sEMG sensing)(0.01)