

**Informed Consent:  
Tremor Mitigation DAQ**

**Primary Contacts:**  
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**Introduction**

You are invited to participate in a research study to validate the functionality of a Tremor Mitigation Data Acquisition, intended to be used to collect and correlate muscle signal and positional acceleration data of the wrist. The decision to join, or not to join, is up to you. In this research study, we are testing a system prototype in an effort to determine whether or not our new device is easy to use, comfortable, non motion impairing, and accurate in collecting muscle EMG and positional data. This is a senior design project that is part of the Kate Gleason College of Engineering core curriculum.

**What is Involved in this Study?**

You will be asked to test the new device by performing specific motions under observation while the Tremor DAQ is collecting data. Following the testing procedure you will be asked to complete a brief survey. This study will take approximately 30 minutes to complete. The investigators may stop the study or take you out of the study at any time they see fit. You can stop participating at any time.

**Risks**

This study involves a few minor risks. The first is the possibility of mild discomfort due to the housing of the device. This can occur if the device is applied too tightly. When the device is attached, you will be able to adjust the straps to comfortably secure it to your arm. Another risk is of mild shock in case the device fully fails. If this occurs, the mitigation DAQ will be removed and you may leave the study at your discretion. Uncomfortable heat due to battery use may occur. If it does, inform the investigators who will remove the device. You may halt the test at any time due to this discomfort and leave at any time. These are the primary risks associated with this study; however, there may also be other risks that we cannot predict.

**Benefits to Taking Part in the Study**

The device you will be testing is only a prototype and will not be available for immediate use. It is reasonable to expect that this study will result in better knowledge of how essential tremors are caused; however, we cannot guarantee that you will personally experience benefits from participating in this study. Others may benefit in the future from the information gathered in this study.

**Confidentiality**

Your name or image will not be used in any effect, including if data from this study is presented to an audience. Every effort will be made to keep your information confidential. We will take the

following steps to keep information about you confidential, and to protect it from unauthorized disclosure, tampering, or damage. The RIT researchers will store all information on a password-protected server at RIT, accessible only to researchers working on this study.

**Your Rights as a Research Participant**

Participation in this study is voluntary. You have the right not to participate at all or to leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any penalty, and data collected will remain secure. If you decide to leave the study, you must notify the researcher identified below by phone or email. If you leave the study, any survey information you have already provided to us will remain as part of the study, and will remain confidential.

**Contact for Questions or Problems**

If you have any questions about the study or any problems, please contact:

**William Shambach:** [wts8582@g.rit.edu](mailto:wts8582@g.rit.edu)

**Frank Howard:** [fch3809@g.rit.edu](mailto:fch3809@g.rit.edu)

**Consent of Subject (or Legally Authorized Representative)**

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Signature of Subject or Representative

Date

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(Upon Signing, the subject or the legally authorized representative will receive a copy of this form, and the original will be held in a subject's research record.)

## **Anticipated User Survey for System Testing**

### **Easy to Use:**

1. Was the device confusing in appearance or in functionality? If so, how?
  
  
  
  
  
  
  
  
  
  
2. Was the device difficult to put on? If so, how?

### **Comfortable**

1. Was any part of your arm uncomfortable during testing due to the device itself? If so, what part of the device caused the discomfort, and what was the cause of discomfort?
  
  
  
  
  
  
  
  
  
  
2. Did the device feel heavy at all?

### **Motion Impairing**

1. Were any of the movements performed during testing impaired by the device? If so, what motions were impaired, and how so?

### **Robustness**

1. How secure/robust did you feel the device was during testing? Did any components feel loose or poorly connected? If so, please describe the issues you feel are present with the device.

### **Confidence in System:**

1. Please rate the confidence you have in the system from your experience from a scale of 1 (not confident) to 10 (extremely confident), and give your reasoning.

**Other Suggestions/Comments**

1. Feel free to offer any other suggestions or comments for improvement that were not previously covered.