**Deep Pressure Proprioceptive Feedback Study: Script and Protocol**

Pre-Experiment Setup Prior to Subject’s Arrival

1. Make sure t-shirts are laundered and folded, ready to go.
2. Make sure consent form and pre-experiment survey are queued up on the iPad.
3. Prepare white noise soundtrack and/or user selected music. Have headphones and headphone covers available.
4. **Sanitize:** Wipe down wearable device with 70%EtOH. Wipe upper armband, rigid portions of the actuator device, and sanitize the sleeve with UV wand. Wipe down keypad and iPad. Change headphone covers.
5. Place the actuator device on its stand.
6. Make sure the force sensor and actuator cables are plugged in to the electronics.
7. Make sure the electronics power switch is off and that there is a flex strap in the flexible housing.
8. Position device such that electronics box has usb/power to the left, actuator connections to the bottom, curved surface up.
9. Plug in monitor to laptop and make sure it works.
10. Open Teenyduino and the firmwarePIEZO2LOF.ino on laptop.
11. Open iTerm on laptop. Shell > split vertically current profile. Cd to PIEZO2 directory on each side.
12. ~~Turn on power supply and make sure set to 12 V. Then turn it off.~~
13. Ensure power cable, usb cable and keyboard usb connector are all plugged in.
14. In Teensyduino, reset/upload and open serial monitor to begin serial output and then close the window.
15. In iTerm left-hand side, python calibration.py --mode KEY
16. Input subject number.
17. Turn on the power supply.
18. If power supply is 12 , turn on electronics power switch. When power switch is on, actuator should move and start at same level as soft device interface.
19. Use Calibration GUI to run the actuator calibration.
20. After actuator calibration is done, click done. Then turn off electronics power switch and power supply.

Pre-Experiment Setup with Subject

1. Thank the subject for their participation and offer them water to drink now or between breaks and hand sanitizer is available.

*Thank you for participating in this experiment. There is hand sanitizer available for your use. Can I offer you any water to drink now or between the breaks? Would you like to use the restroom before we begin?*

1. Pass iPad to the subject and have the subject sign a consent form

*Alright. Please take a seat here. Once again, I want to properly thank you for participating. Your time and participation today will be valuable for scientific research on haptics and medical device design. Now the first step for us is to go over some forms. To participate in this experiment, I need your written consent. This first form is a consent form detailing <XYZ>. Please review and sign at the marked sections if you consent.*

*Note that there is a section in the form about video. You will not be recorded; there is no video for this experiment. This is a standard consent format used for these types of experiments. The experiment will take approximately 1 hour. Please remember you can choose to drop out at any time. To be compensated you will need to complete the study. Please let me know if you have any questions.*

1. Once consent form is signed, pull up the pre-experiment survey on the iPad and have subject complete it.

*Our next form is a pre-experiment survey. Could you please fill this out? Thank you.*

1. In the Subject Record Document, write down the subject number and which protocol file number is being used. ??
2. Inform subject t-shirt is best for the experiment and not to wear jewelry on their right arm.

*For today’s study I’ll be asking you to wear a wearable device, and the device is worn directly against the skin on your forearm. Wearing a t-shirt and not wearing accessories on your right arm is best for the experiment.*

1. If subject is wearing accessories on their right arm:

*If you are wearing a watch, fitness tracker, bangles, and/or jewelry on your right arm, please remove what you can and keep it to the side for the experiment. Your items will be right next to you and within sight the whole time.*

1. **Case 0:** If subject is wearing a t-shirt already:

The attire you have is fine for this experiment. We can proceed.

1. **Case 1:** Else if subject wears a long-sleeve where the sleeve may roll up high enough:

*I can either offer you a clean t-shirt to wear for this experiment or you may roll up your sleeve if the material isn’t too thick. Which option would you prefer?*

* 1. If they choose to roll up their sleeve:

*Great. Please roll up your right sleeve to reveal your forearm.*

* 1. Once they’ve rolled their sleeve up, ask:

*How does the rolled up sleeve feel? Does it feel too tight? Is it applying a lot of pressure and/or cutting off your circulation? Do your fingers or arm feel tingly at all?*

* 1. If the answer to all the above questions are no  
     *Great. We can proceed.*
  2. If any of those questions are yes, proceed to case 2.

1. **Case 2:** else if the subject is wearing a sweater/sweatshirt/top that doesn’t allow for the forearm to be accessible

*The attire you’re currently wearing will not work for this experiment. I can offer you a clean-t-shirt to wear for the duration of the study. I have sizes ranging from small to XXL and will leave them out for you. Please wear whichever t-shirt you prefer. I don’t need to know your t-shirt size; I just ask that you place the worn shirt to the side at the conclusion of the experiment so I can launder it for my next subject. You may change in this room here; I will step out, close the door, and block this window so you may have privacy. Please open the door once you’ve worn the t-shirt. Does this sound ok?*

* 1. Once subject has changed and opened the door.

*Great. We can proceed.*

1. In iTerm right hand side: python instructions.py.
2. Drag and drop gui to monitor, and then click back to the terminal to make sure key presses work.
3. Explain proprioception background:

*Today, you and I will be working together to study proprioception. Proprioception is our awareness of the position and movement of our own body. For example, while I’m talking to you, I’m aware where my arms are – if it’s in front of me, to my sides, even if my eyes are closed, I can feel if arms are above my head.*

*Different groups of people have impaired or no sense of proprioception, meaning they lack a sense of where their limbs and body are in space. Many individuals rely on visual feedback, meaning that they look directly at their limbs to navigate their environments.*

*Here is an example of a person looking directly at his feet to walk. (*[*13:20*](https://www.dailymotion.com/video/x12647t)*)*

*~~However, proprioception, this awareness of our body, isn’t perfect. Let’s do a quick activity to illustrate that.~~*

*~~First, please raise your arms above your head. Then bend your wrist and fingers so your fingers are horizontal, parallel to the ground. And then, bring your hands together so your fingertips touch at exactly the same height. It’s not quite easy! One hand may be higher or lower than the other hand and your hands may slip past each other. Evidently, proprioception - our awareness of where our bodies are – isn’t perfectly precise.~~*

*Today we’ll be working together to study proprioception and evaluate the effect of deep pressure proprioceptive feedback.*

*For today’s experiment, you will use an arm-worn haptic device today that applies a deep pressure on your arm, like a poke.*

1. Click blue key and then pass the keypad to the user
2. Go over experimental set up.

*I am going to explain the experimental setup. Here is a keypad for you to interact with the environment. Please only click the blue or white keys.*

*Slide 2: This graphic represents an arm, where the dots denote hand and elbow. Its angle will change.*

*Slide 3: For this study, you will control a virtual arm today.*

*Slide 4: As you move your virtual elbow, you will receive different types of pre-programmed pressure feedback, or possibly no feedback at all, on your actual arm. The pressure feedback is deep pressure feedback, like a strong poke.*

*Slide 5: Your goal is to move your virtual arm elbow and match its angle to the blue target angle you see on the screen*

*Slide 6: To receive the haptic feedback, you will wear this device on your right arm and rest that arm on this black platform. A curtain will prevent you from seeing the device and your arm. The screen in front of you will show the virtual arm and target angles. Do you have any questions?*

1. Direct subject to adjust seat height and footrest so they can rest their right arm on platform comfortably.

*Before I set up the arm-worn device for you, let’s adjust your seat so your ~~upper~~ arm is level with the arm rest. On the right hand side of the chair and in front of a round knob, you’ll see a lever piece with a blue dots. Please use the lever to adjust the seat height until your arm is comfortable on the arm rest. To lower the height of the chair, remain seated and pull up on the lever. And to increase the height, stand up and pull up on the lever. There also is a wooden footrest in front of you so please scoot your chair in to make sure you are comfortable.*

1. Once the subject is comfortable, command tab to open the calibration GUI.
2. Turn on power supply. Confirm the voltage is 12V.
3. Then turn on electronics 12V power switch on. When power switch is on, actuator should move and start at same level as soft device interface.
4. Have user put new headphone covers and wear noise cancelling headphones around their neck or kept to the side.

*During the study, I will ask you to wear these headphones. They will play white noise to block out any external noise, but you should still be able to hear me if I talk to you. Please put these new headphone covers over the headphones. You don’t need to wear the headphones now as we set up. You’re welcome to wear it around your neck or keep it to the side. Please let me know if these get uncomfortable at any time, and I will let you know when you’ll need to wear them over your ears for the study.*

1. Sanitize my hands and ask subject if I can put the device on their arm.

*Next, I am going to set you up for the experiment by putting on the device on your arm and then running some calibrations. Does that sound ok? Is it ok if I touch your arm to position the device properly? As I position the device and touch your arm, I will say exactly what I’m doing while I’m doing it so you know what is going on.  
  
Could you please rest your arm on the arm rest and extend your arm, with your palm facing down? Is placing the device on this part of your arm ok?*

1. Place actuator enclosure and electronics on their arm. Enclosure should be on outer, hairy side of arm and electronics on the inner arm side. Make sure sensor enclosure if pointing up towards their hands. When their palm is down and actuator is on hairy side, make sure electronics box placed against the left hand side of the forearm and the usb/power is to the left side (when palm facing up, electronics will be on the topside of the forearm and wires flipped so will be to their right). Say aloud what I’m doing so subject knows what’s going on.

*Now I’m going to fasten the device to your arm. The strap should feel tight but not to the point where it hurts. As I tighten it, could you let me know how it feels – if it’s too tight or loose?*

1. Once the device is worn, turn on power supply. Confirm the voltage is 12V.
2. Then turn on electronics 12V power switch. When power switch is on, actuator should move and start at same level as soft device interface.
3. Calibrate the device to the subject by setting maximum pressure

*Now we’re going to calibrate the device to you and will set the max amount of pressure that will be applied to your arm. The device will apply some pressure to your arm and progressively increase the pressure. When it starts to feel uncomfortable, let me know. We’ll repeat this process a few times. Are you ready?*

1. Click calibrate in the gui and click the screen when subject indicates discomfort. Write down the command number that is max pressure for subject. *Ok, we’re going to apply increasing amount of pressure again and you let me know when it’s uncomfortable. Are you ready?*
2. Repeat step 43 at least 2 more times. Then check in with the subject.

*Does the haptic feedback feel ok? Is it painful at all? Would it be helpful to do this a few more times to set a different maximum?*

1. If subject is wants to repeat, repeat step 43. Move on past 44 once subject is satisfied.
2. After repetitions are done, inform subject that I will apply maximum pressure selected by user to their arm to confirm that feels ok.

*I’m going to now apply the maximum pressure you selected to your arm to confirm that feels ok for you. It will be the same as before, increasing pressure until it reached the maximum pressure you chose. Does that sound ok? Are you ready?*

1. Click calibrate in the gui and click the screen at the exact command number you wrote down. Then check in with subject.

*Did that feel ok? Would it be helpful to do the calibration again?*

1. If subject would like to repeat, jump to step 42. Otherwise proceed

*We’ve completed calibration. Let’s begin the study.*

1. Have user wear noise cancelling headphones – Play white noise

Run Experiment

1. Explain task and learning phase

*Your goal is to move your virtual arm with the keypad and match its angle with a given target angle. When you think your virtual arm matches the target angle – or is as close as possible to the target angle - click the blue key on the keypad and you’ll be shown the next target angle.*

*As you do this task, you may (or may not) receive pressure feedback*

*You also may (or may not)receive visual feedback from your virtual arm. Which means sometimes you may see your virtual arm shown by the orange line segment. And other times you won’t see your virtual arm at all and there will be no orange line segment. Please note that even if your virtual arm is not visible on the screen, the virtual arm is still there and you are still controlling its position via the keypad.*

*We will begin with a learning phase where you can get acclimated to the environment and haptic feedback. The learning phase consists of four distinct parts.*

*First there is an exploratory period where you can move your virtual arm freely, see your virtual arm, observe the haptic feedback, and learn to associate the haptic feedback with your virtual arm’s angle. During this learning phase, please pay attention to the pressure feedback you receive on your arm and how that corresponds to where your virtual arm is. The orange line segment may not appear in the task later on and you will have to rely only on haptic feedback to know your virtual arm’s position. Really think about how the feelings on your arm correspond to the orange line segment that shows you where your virtual arm is.*

*In the second stage of the learning, you will get to practice the task. Blue target angles will be shown on the screen, and you will attempt to match your virtual arm with the target angle using only haptic feedback. The orange line segment representing your virtual arm will not appear.*

*After each of your angle attempts, you will click the blue key on the keypad and it will show you how close you actually were to the target angle. Your virtual arm will be displayed in orange only for a few moments to show you it’s true position. you will have <20> of these practice angles and then an optional 5 minute break.*

*Do you have any questions? Are you ready to begin?*

1. In iTerm: python pilotStudy.py. After learning, pause and ask if they’d like a break
2. Use timer for 1 minute break
3. Explain testing phase

*Now we will begin the testing phase with the same activity as before: match your virtual elbow angle with the blue target angle.*

*The only difference this time is that after each of your angle attempts, you won’t be shown how close you were to the target angle. After clicking the blue key on the keypad, it will automatically proceed to the next target angle.*

*During this testing phase, you may (or may not) receive pressure feedback and there may (or may not) be an orange line segment showing you where your virtual arm actually is. Please note that in testing phase, we are testing the device and the effect of haptic feedback, not you! So do your best and that will be more than enough. The testing phase consists of 40 angles with an optional break at the halfway point.*

*Do you have any questions for me? Once you’re ready, click on the blue key to begin.*

1. Once they click the keypad and begin testing phase, every 10 trial angles, click the button and make sure haptic feedback is turning on and off
2. Monitor data on iTerm to make sure nothing is off.
3. After 20 trial angles, ask if they’d like a X minute break. Use timer to monitor and then have them click blue key to proceed
4. 56 and 57

Post Experiment

1. Ask the Subject to fill out the post-experiment survey and the compensation form

*Please fill out the 2nd page of this document and this compensation form for the gift card!*

1. Thank the subject for their participation.