

1200 Centre Street
Roslindale MA 02131

Participant Training Manual

Table of contents

PART 1: GENERAL INFORMATION.....	2
1.1. Study Contact Information.....	2
1.2. General Instructions.....	2
PART 2: EQUIPMENT DESCRIPTIONS.....	4
2.1. Equipment Overview.....	4
2.1.1. Microsoft Surface Pro Tablet.....	4
2.1.2. NE Brain Stimulation Box.....	4
2.2. Equipment Contents.....	4
2.2.1. Contents of the NE Stimulation Box.....	4
2.2.2. Contents of the Microsoft Surface Pro Box.....	7
PART 3: ASSEMBLING EQUIPMENT.....	7
3.1. Turn on the Surface Go Tablet.....	7
3.2. Connect the Surface Go Tablet to Stimulation Device.....	8
3.3. Assembling Equipment from NE Stimulation Box.....	10
3.4. Starting the Home Brain Stimulation	14
PART 4: EQUIPMENT CLEANING.....	22
PART 5: EQUIPMENT CHARGING.....	22
5.1. Charging of the NE Bluetooth Device.....	22
5.2. Charging of the Tablet.....	23
PART 6: TROUBLESHOOTING.....	24
6.1. Connectivity Check.....	24
6.2. Reload Your Session.....	26
PART 6: ADVERSE EVENTS.....	28

PART 1. General Information

1.1. Study Contact Information:

- Project Director
 - Phone:
 - Email:
- Principal Investigator
 - Phone:
 - Email:
- Co-Investigator
 - Phone:
 - Email:
- Co-Investigator
 - Phone:
 - Email:
- Co-Investigator
 - Phone:
 - Email:
- Research Assistant
 - Phone:
 - Email:

1.2. General Instructions

Prior to the start of the brain stimulation, please **READ** the following important points:

- a. For any questions, please contact the study staff listed on the front page. Your primary study staff contact member is: _____.
- b. Please keep and store the equipment as you would for any technology:
 - Do not place liquids in close proximity that if spilled, could damage the tablet.
 - Minimize the risk of damage due to accidental dropping by keeping the equipment in the predetermined location within your home.
 - As with all computers, laptops and tablets, it is important to avoid exposure to temperature extremes.
- c. Hair should be fully dry prior to each stimulation session.

- d. Participant should not have coffee prior to and during the stimulation session.
- e. Check scalp for lesions prior to the session. If you see lesions on the scalp, **DO NOT** start the session. Please give us a call for further instructions.
- f. The app will only allow you to start the session in a specific time window that you scheduled with us. If you miss a session, start your session on the following day in your scheduled time window.
- h. Please remove your earrings on your right earlobe. You can leave your hearing aid on, if you have one, as long as it does not block the right earlobe.
- i. **Use the restroom** if you need to before starting the session. Please allow about 1 hour for the overall session for set up/preparation, administration of the stimulation, and equipment care and storage following the session.
- j. Once the session starts, participants are required to stay sitting and stay awake. Try to avoid talking if possible.
- k. Participant administrator should stay close to the participant throughout the session. Please remind the participant to stay awake if he/she falls asleep.
- l. During the stimulation session, you may experience tingling and itching. You can abort the session anytime if it becomes too painful.
- m. When you are ready for the session, please proceed to PART 2.

PART 2: Equipment Descriptions

2.1. Equipment Overview

2.1.1. Microsoft Surface Go Tablet



2.1.2. NE Brain Stimulation Box



2.2. Equipment Contents

2.2.1. Contents of the NE Stimulation Box

a. Stimulation Device (1 piece)



b. Electrode Cable (1 piece)



c. Charging Cable for the Stimulation Device (1 piece)



d. USB WiFi Dongle (1 piece)



e. Earclip (1 piece)



f. Electrodes (7 pieces)



g. Electrode Gel (1 bottle)



h. Curved Syringe (1 piece)



i. Clear Tape (1 piece)



j. Headcap (1 piece)

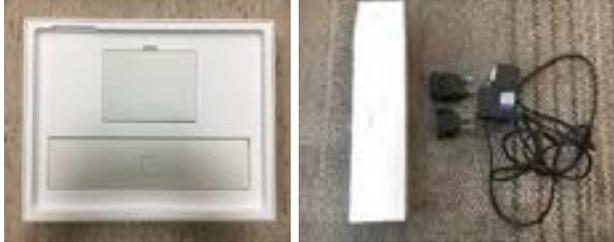


2.2.2. Contents of the Microsoft Surface Go Box

a. Tablet (1 piece)



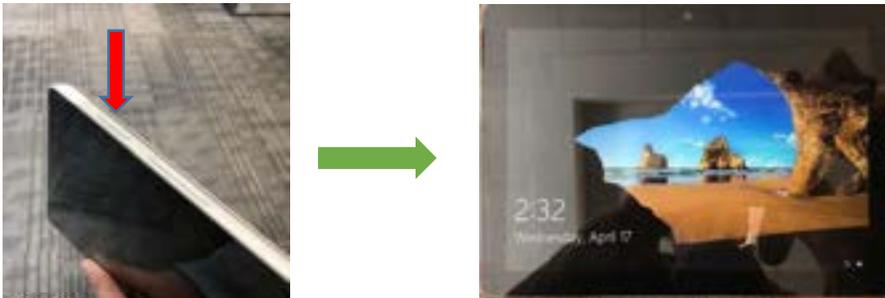
b. Charging Cable (3 parts)



PART 3: Assembling Equipment

3.1. Turn on the Surface Pro Tablet

a. Press the POWER button located on one of the long sides of the tablet.



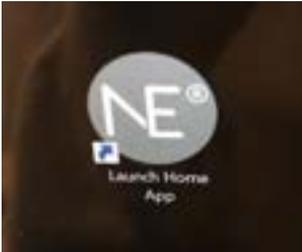
b. Swipe up on the screen to unlock the tablet.



c. Tap on the "Sign in" button to sign in to **Patient** account.



d. You should see “Launch Home App” on the screen.



3.2. Connect the Tablet to WiFi

a. Take the USB WiFi Dongle out from the **NE Stimulation Box**



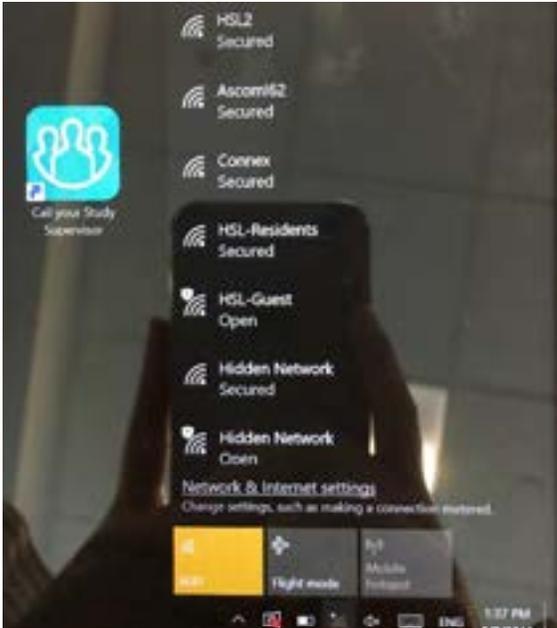
b. Insert the Dongle to the USB port located on the short side of the tablet. The LED on the USB Dongle should blink green when it is plugged in



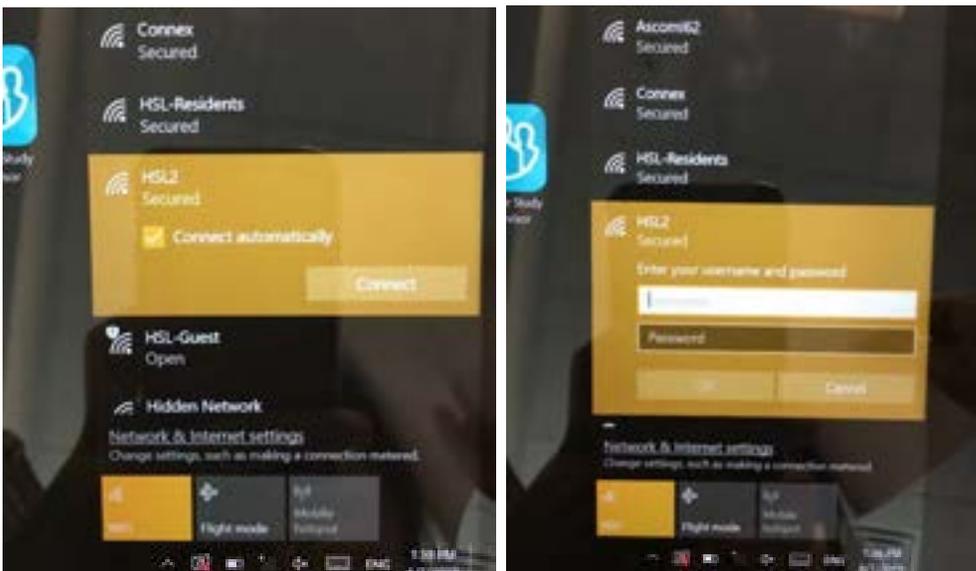
c. Check the WiFi connection at lower right bottom of the screen. If the WiFi icon is gray and has an asterisk sign on its top left as shown in the picture below, it means the tablet is not connected to WiFi.



d. Tap on the WiFi icon, a list of WiFi networks should show up.



e. Find your home WiFi on the list. Make sure to check the box "Connect automatically" and tap "Connect". Enter password when prompted.



f. Check the WiFi icon again. The asterisk sign should disappear when the tablet is connected to WiFi.



3.3. Assembling Equipment from NE Stimulation Box

a. Take out 6 white electrodes and the headcap out from the **NE Stimulation Box**.



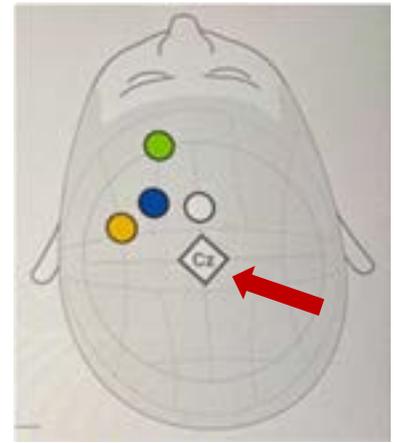
b. Unscrew the white electrodes.



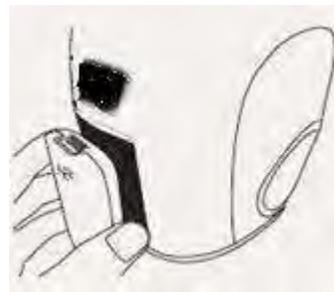
c. Insert the bottom parts of the white electrodes into all the 6 holes on the headcap.



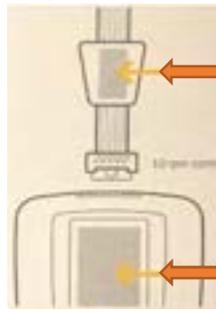
d. Place the headcap on participant's head. Make sure the headcap is aligned so that it starts slightly above the eyebrows and **CZ** is at the midpoint from ear to ear. Then, fasten the headcap comfortably.



e. Attach the Stimulation Device to the large Velcro located at the back of the headcap.



f. Connect the Electrode Cable to the Stimulation Device and attach it to the small Velcro on the headcap.



Small
Velcro

Large
Velcro



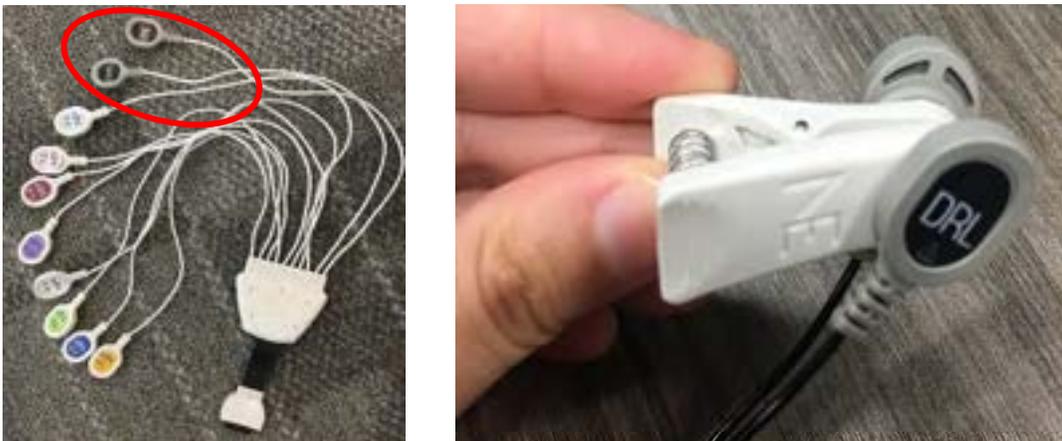
g. Take the Curved Syringe and Electrode Gel out from the NE Stimulation Box and fill up the syringe with gel.



h. Take the earclip out from the NE Stimulation Box. Open the earclip by pressing the ends together. Place a drop of gel between the connector pads.



i. On the Electrode Cable, there are two **Gray cables** on the right that say CMS and DRL. Connect the two Gray cables to the earclip. It does not matter which side of the earclip they attach to.



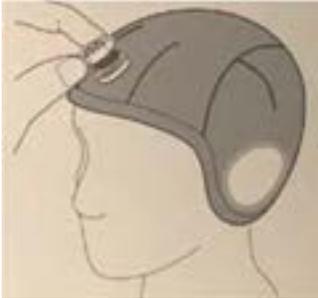
j. Secure the earclip onto the participant's right earlobe. Make sure the earclip does not slide off from the earlobe.



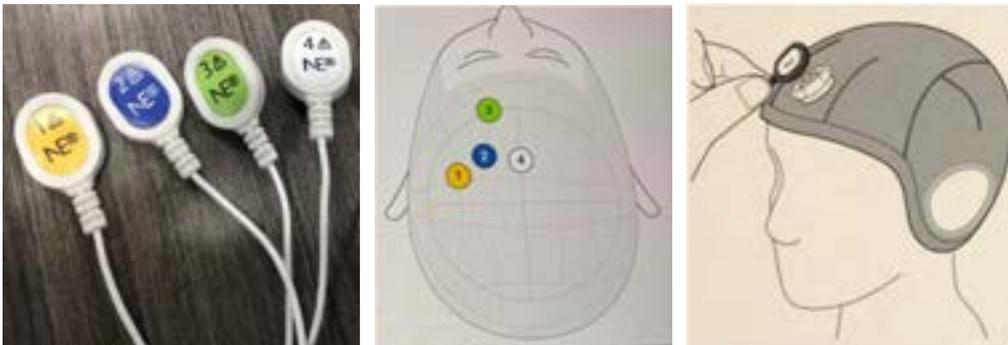
k. For each electrode, use the syringe to part the hair to expose the scalp. Place enough gel on the scalp to fill the electrode ensuring both top and bottom parts are full.



l. Screw the top and bottom parts of the electrodes together.



m. There are colored buttons near each electrode on the headcap. Clip on Cables 1 – 4 by matching the colored cables to the colored buttons on the headcap. Leave Cables 5 to 8 hanging loosely on the side.

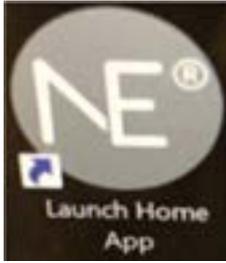


n. Use your finger to press down each electrode to check if every electrode is closely in contact with the scalp. If there is a gap between the electrode and the scalp, use the clear tape to tape the electrode down.

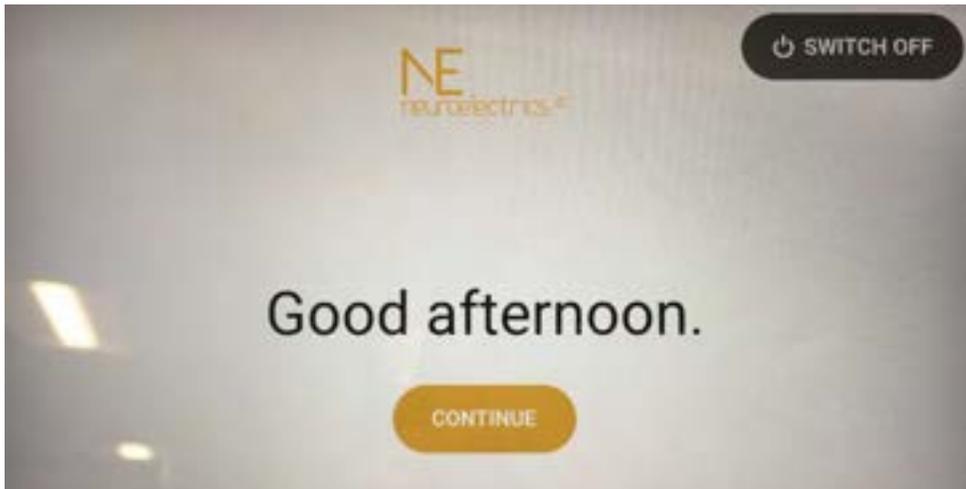


3.4. Start Home Brain Stimulation App

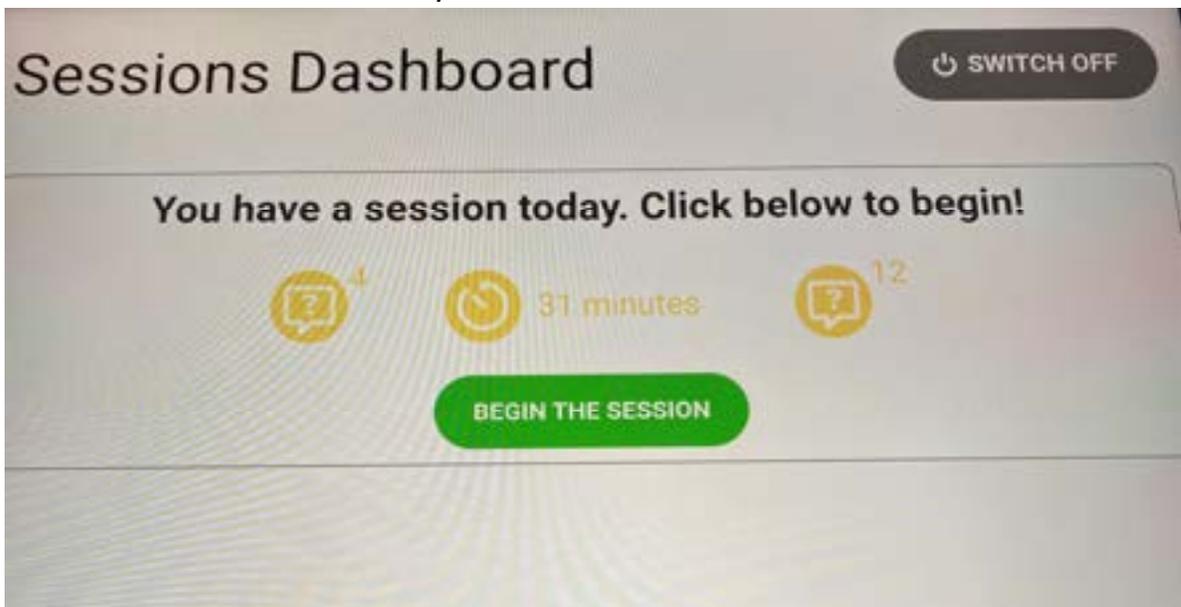
a. Double tap on the icon “Launch Home App” on the screen on the Tablet to open the app.



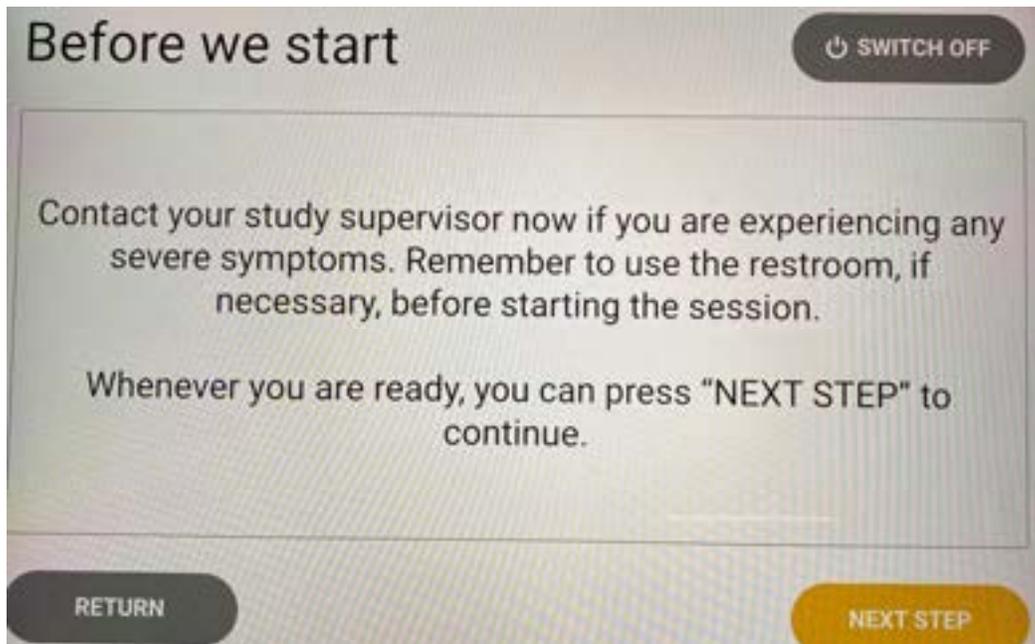
b. A welcome page will appear once you open the app.



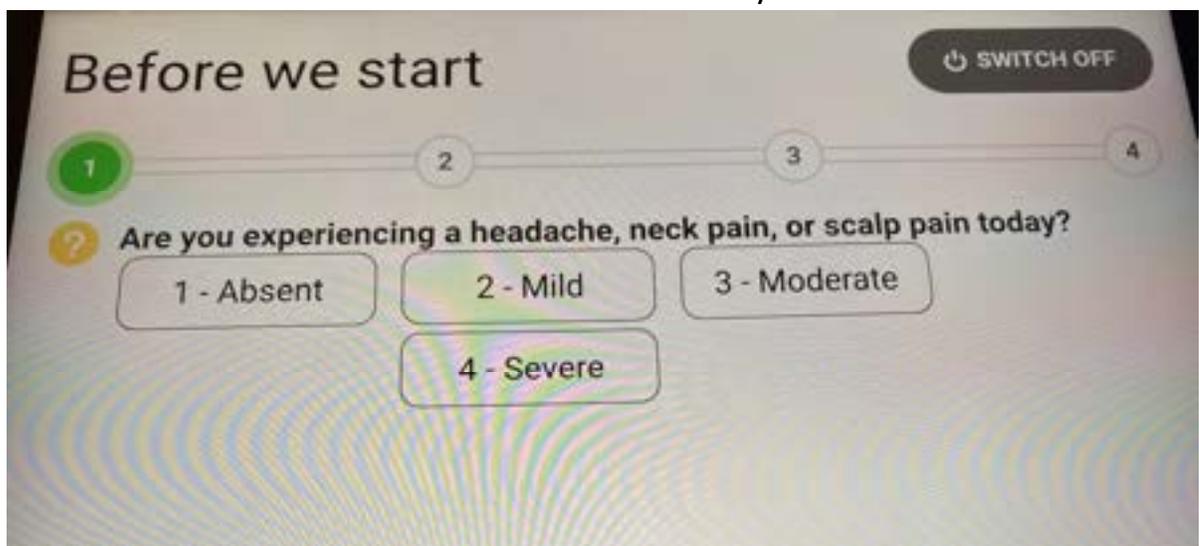
c. After you click “CONTINUE”, the screen below will let you know that you have a scheduled session for the day.



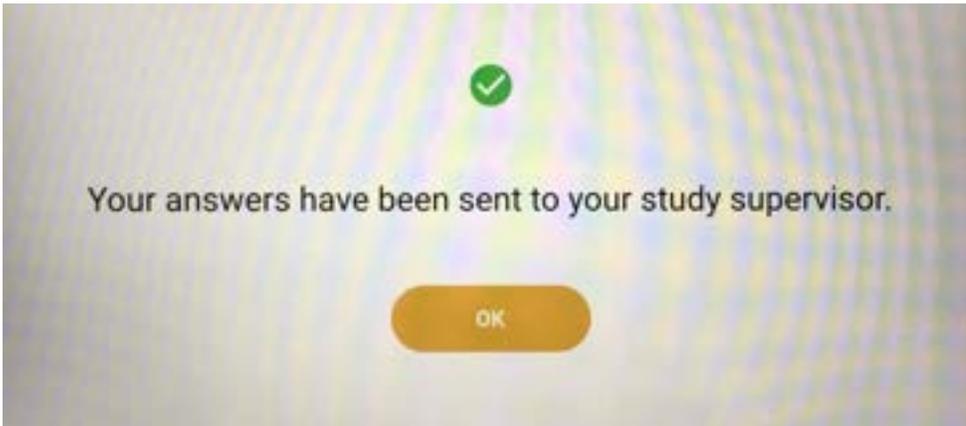
d. You will see this screen after you click “BEGIN THE SESSION”. If you are experiencing any severe symptoms, **DO NOT** continue. Please call your study team and we will assess the situation.



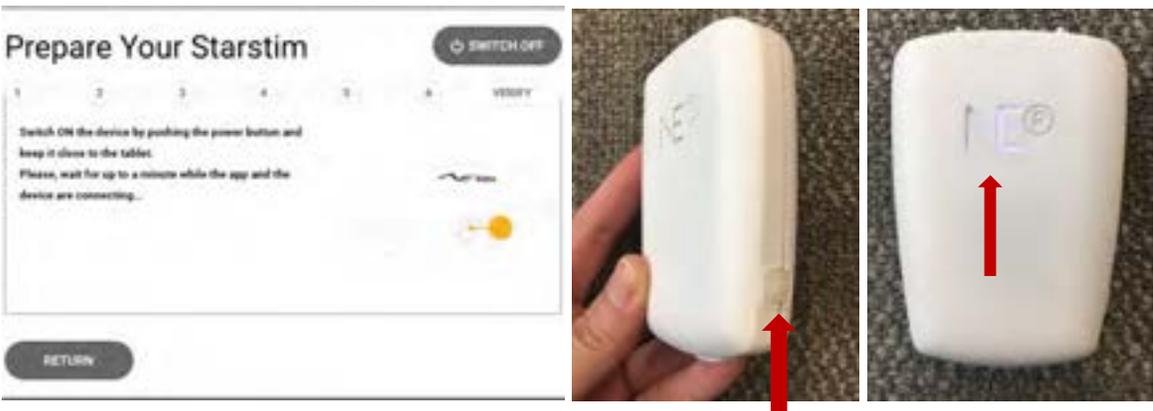
e. You are required to complete a questionnaire before the stimulation session. Please select the answers that best describe how you feel at the moment.



f. After you finish the questionnaire, your answers will be sent to the study team.

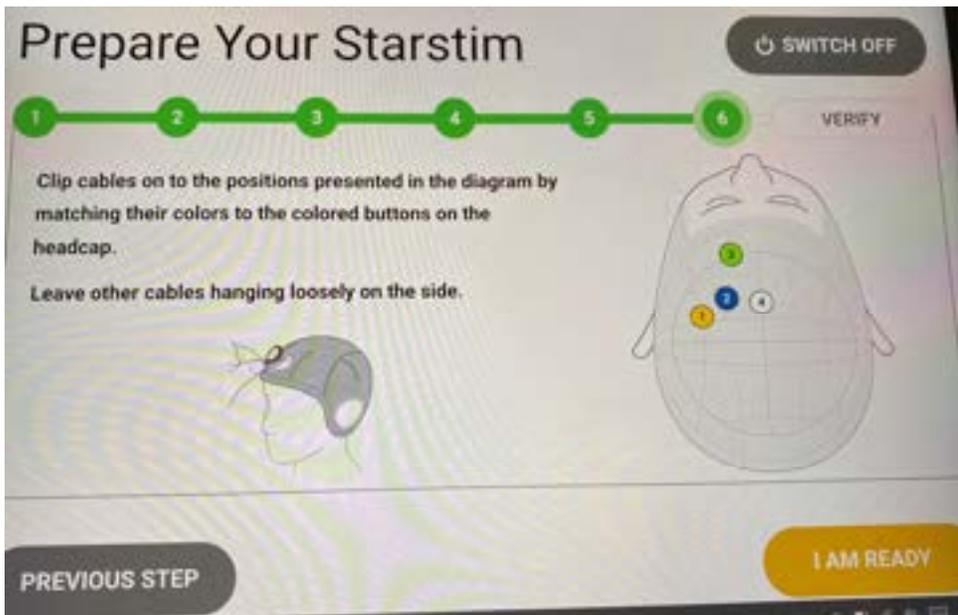


g. Once you click “OK”, this screen will appear to tell you to turn on the stimulation device. Push the Power button on the right side. The LED behind the logo “NE” will light up to indicate the normal operation of the device. Please wait patiently to allow the app to connect to the device.



h. Once the app and the device are connected, the app will provide instructions and guide you to set up the devices. You can use this opportunity to double check if all the devices are correctly placed/attached and keep hitting “NEXT STEP”.

i. You will see this screen at the end to of the instruction page. Once you click on the button “I AM READY”, the app will check the connectivity of electrodes.



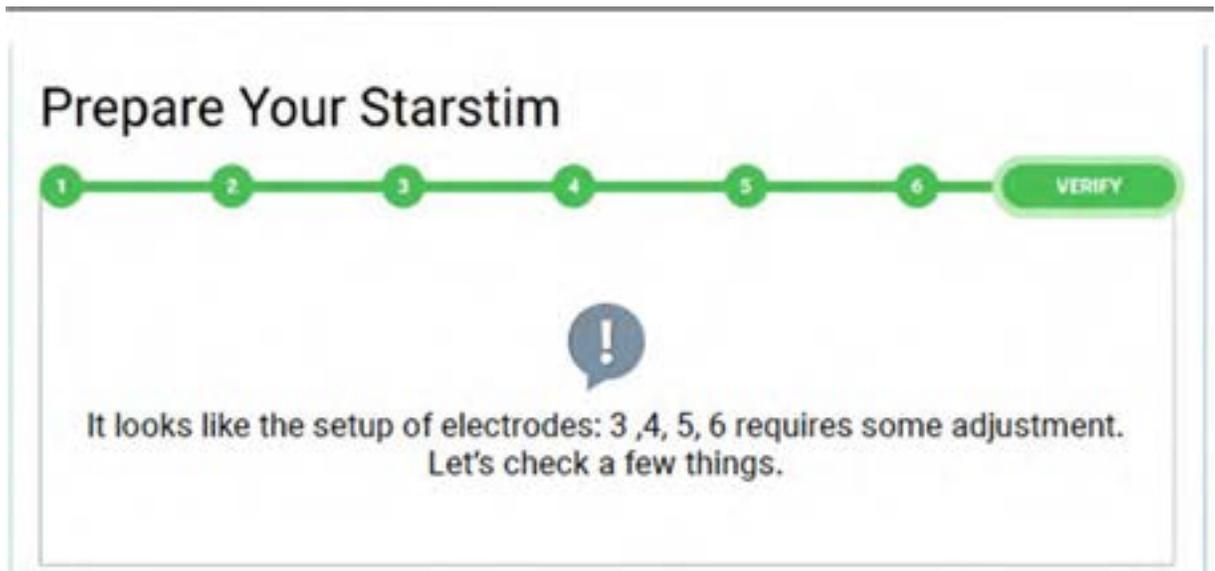
j. Please wait while the system is checking the connectivity for all 4 electrodes.

k. If everything looks good, you will see the screen below.

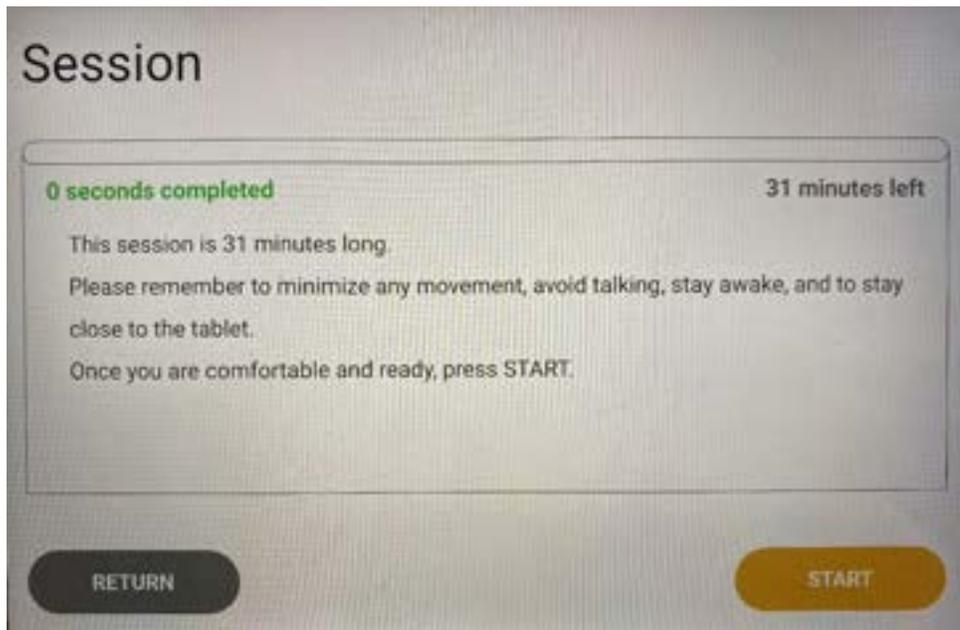


OR

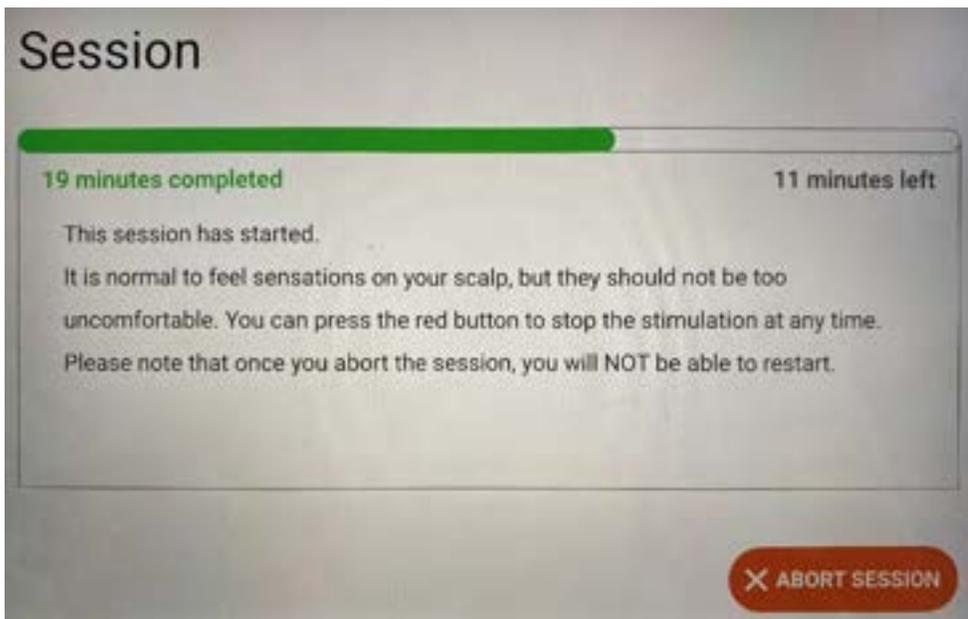
If the connectivity is too low, the screen will tell you which electrodes need to be adjusted. Then it will also present you step by step instructions to check the setup again. You can also refer to Page 24 for instructions.



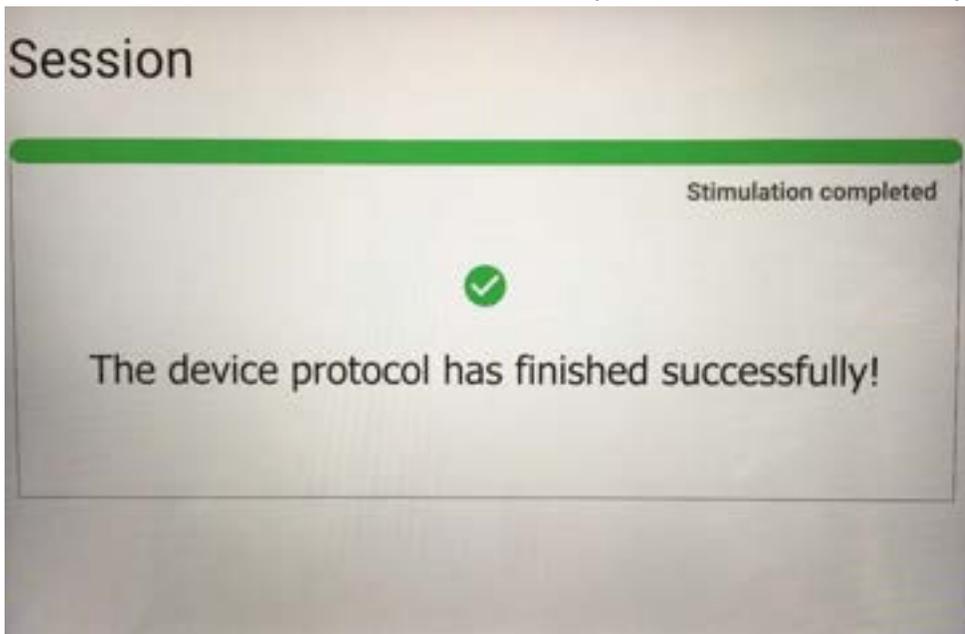
l. Once you pass the connectivity check, you can click “START” to start the session.



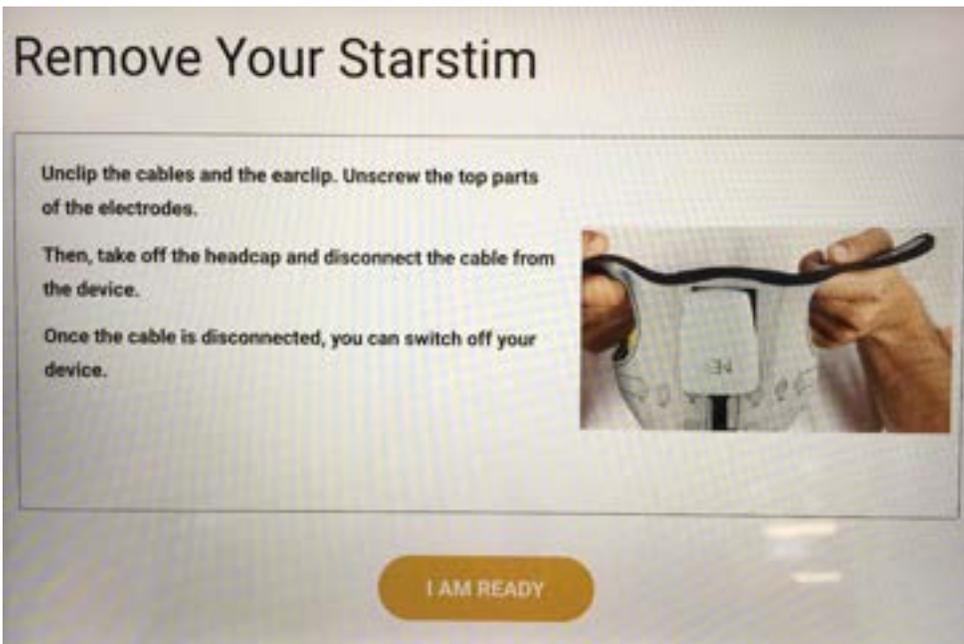
m. During the stimulation, it's normal to feel sensations on your scalp. But they should not be too uncomfortable. You can abort the session anytime by tapping on the red button. Please note that once you abort the session, you will **NOT** be able to restart. Only use the button when you feel it is necessary.



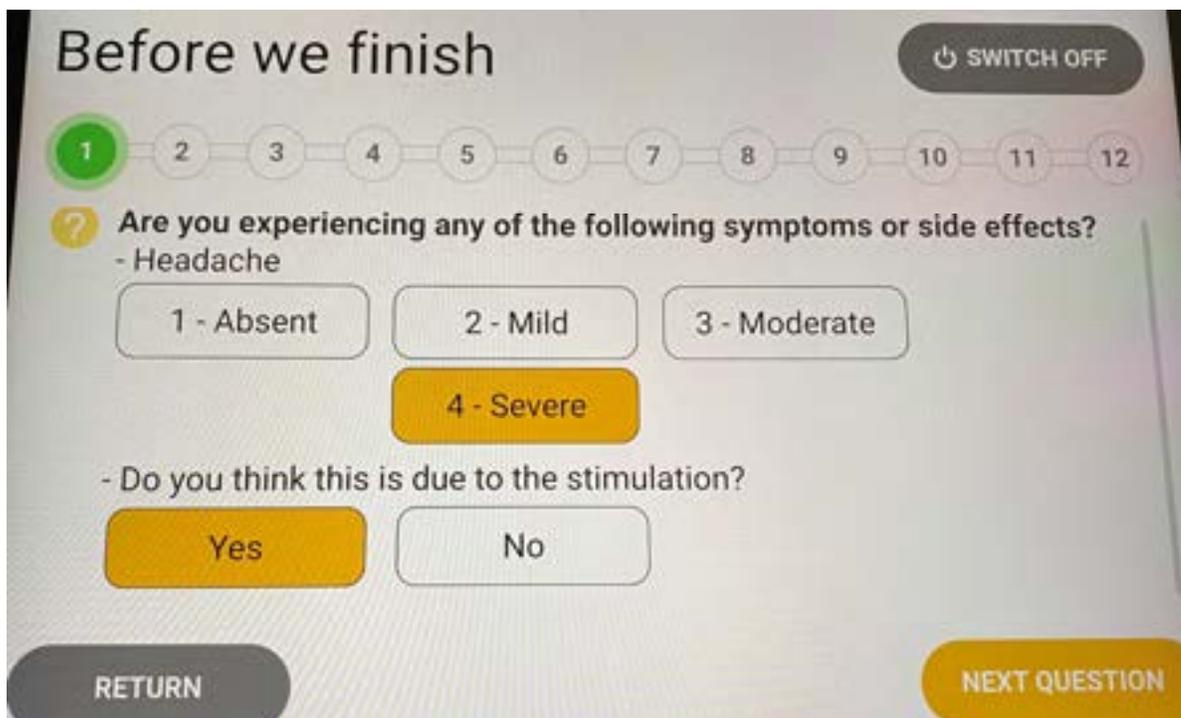
n. When the stimulation session is complete, this screen will appear.



o. After a few seconds, instructions will appear to guide you to remove all the devices. Tap "I AM READY" to continue.



p. You are required to complete a second questionnaire regarding the side effects of the stimulation. Please choose the answers that best describe how you feel at the moment.



q. After you complete all the questions, you can close the App.

PART 4. Equipment Cleaning

- a. To switch off the stimulation device, **push and hold** the Power button until the LED light behind the Logo “NE” turns off.



- c. Rinse the **headcap, electrodes, earclip** and **syringe** with warm tap water to wash off the remaining gel. Please **DO NOT** soak them in hot water!
- d. Hang the headcap to air dry. Lay out clean electrodes, earclip and the syringe on top of a dry towel until they are fully dry.
- e. Put the equipment back to the boxes and store them at a secure location.

PART 5. Equipment Charging

The tablet will not let you start your session if the battery is below 50%.

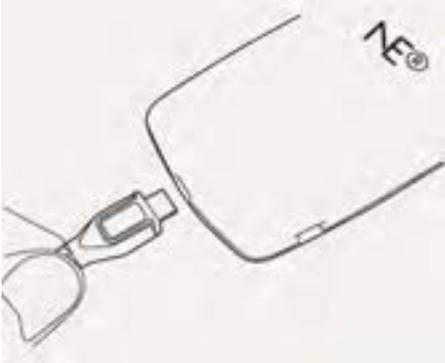
Please leave the Stimulation Device and the tablet to charge to prepare for the next stimulation session after each session.

5.1. Charging of the NE Bluetooth Device

- a. Take the charging cable out from the NE Stimulation Box.



b. Connect the charging cable to the Stimulation Device.



d. Plug the power supply into an electrical outlet. The LED near the charging port will light up to indicate normal charging of the device.

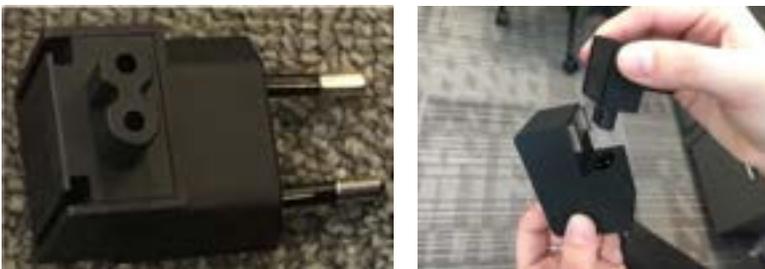


5.2. Charging of the Tablet

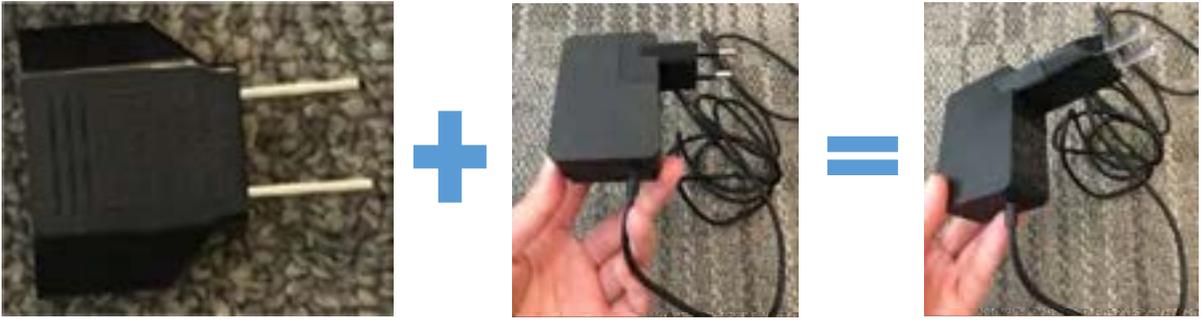
a. Take the charging cable out from the Microsoft Surface Pro Box.



b. Connect these two parts by sliding the small part into the block as shown below.



c. Attach the last piece as shown below.



d. Connect the charging cable securely to the charging port as shown below. The charging port is located on short side of the Tablet.



e. Plug the power supply into an electrical outlet. The LED on the charging cord should light up to indicate normal charging.



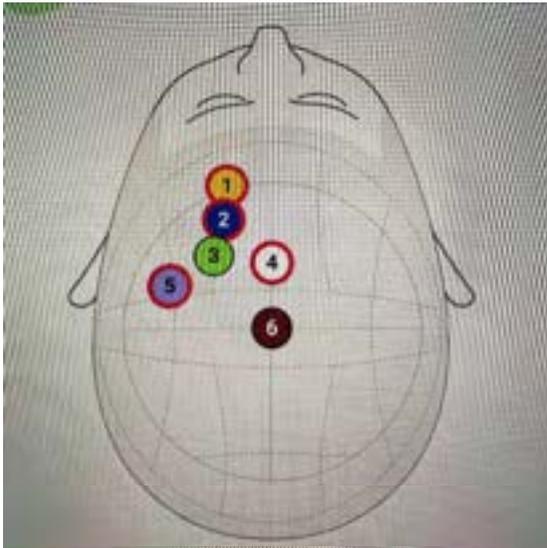
PART 6. Troubleshooting

6.1. Checking Connectivity

Before starting the stimulation session, the Home App will check the connectivity of each electrode. The system will not let you continue until all electrodes demonstrate a good connection. It's likely that you might not pass the connectivity check on your first try. You will see a screen like this that tells you 1 or more electrodes need some further adjustments.

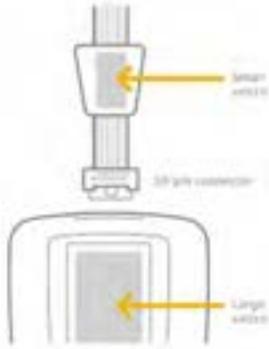


All the electrodes that have low connectivity will have a **RED** edging (see example below).



There are a few things you can do to improve the connectivity of the electrodes circled in **RED**:

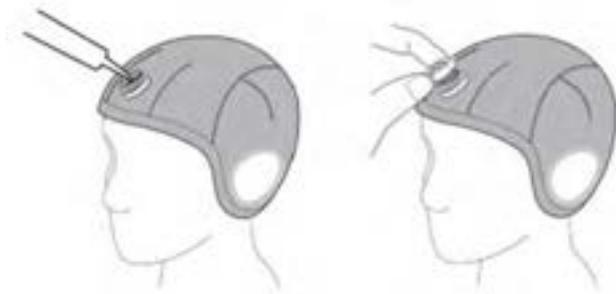
- a. Make sure that the cable is properly inserted into the device.



- b. Make sure there is gel on the connector pads inside the earclip. The earclip should be securely placed on participant's right earlobe and does not slide down.



- c. Unscrew the top part of the highlighted electrodes. Use either the syringe or a Q-tip to part the hair to expose the scalp. Then fill the electrodes half way with gel and screw the top and bottom parts of the electrodes together.



- d. Make sure the cables are clipped correctly by color matching the cables to the colored buttons on the headcap.



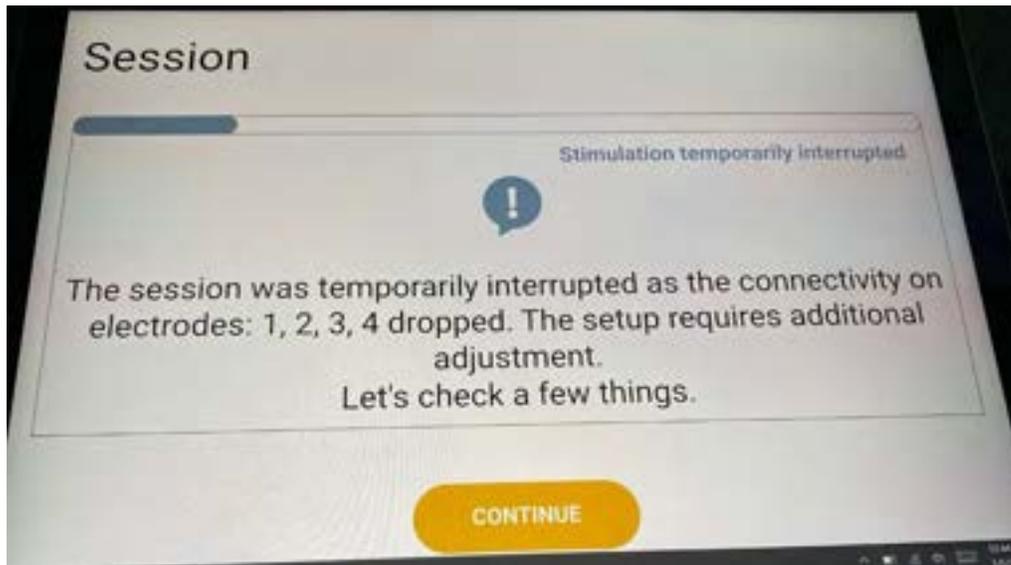
- e. Press down each electrode to check if they are closely in contact with the scalp. If there is air gap in between, use a tape to tape the electrode down.



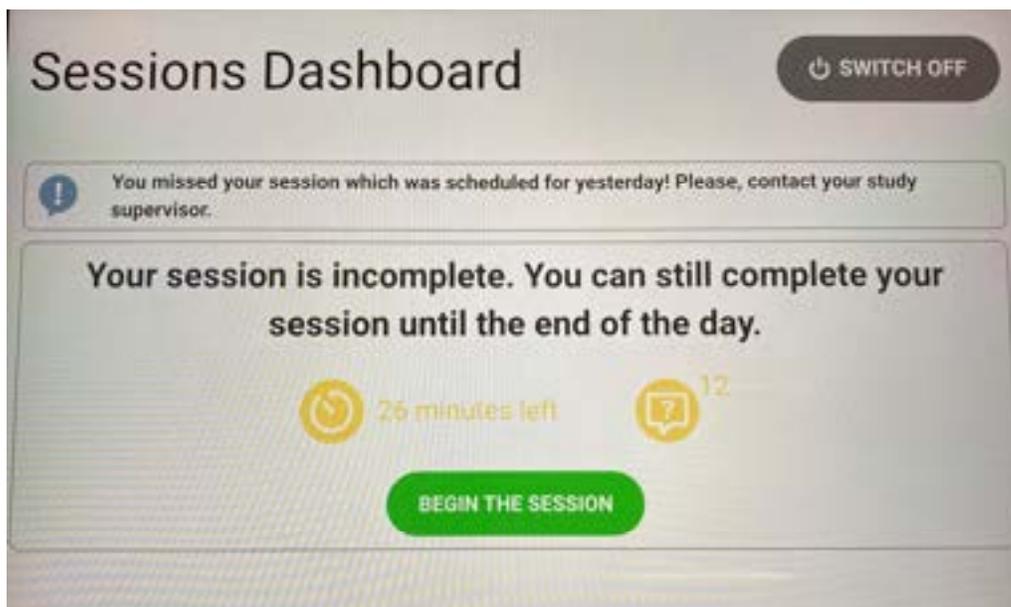
- f. After following the steps displaying on the screen, the system will check connectivity again. You may need to try multiple times to get it right. If you still experience connectivity issues after a few tries, please call your study team for help.

6.2 Reload Your Session

A session might auto-abort itself when the stimulation is in progress when the connectivity on one or few electrodes become too low. When this happens, you still have a chance to reload the session. The app will show you which electrode needs fixing.



Please DO NOT remove the headcap and click “BEGIN THE SESSION” to reload. The home app will walk you through the instruction pages and check connectivity again. You can also refer to the manual at Page 24 to follow the instructions there. Please use this opportunity to double check your set up.



To prevent auto-abort from happening again, the administrator should regularly check all electrodes by pressing them down to ensure they are always in close contact with the scalp.

If one or more electrodes start to become loose, quickly add a tape to tape them down tightly. The administrator should also make sure the earclip stays on and does not slide off of participant's earlobe the entire time.

PART 6. Adverse Events

- *Reported short term side effects of brain stimulation include temporary headache, dizziness, nausea, itchiness and irritation under the area of the electrodes.*
- You should contact the study team right away if you experience these or any other side effects or discomforts.
- The brain stimulation should not be painful or very uncomfortable in any way. If you feel pain or very uncomfortable during a session, please stop the session right away and call the study team.