

Preparing for New Patient Positioning

6.



2.

Enter patient information into **TrakStar**[®].



- Log in to the NeuroStar[®] System
 - Perform Pulse Test
 Select Patient ID from the touchscreen list



3. Zero out system.

- Raise the A/P bar to maximum position (A)
- Set the SOA indicator to zero "0"
- Set the A/P bar to zero "0"
- Align the A/P bar handle centering mark (B) with its centering line/groove located under the coil angle. (C)



5. Lift arm of chair up and have the patient sit upright on one side of the chair.



- Ask the Patient Pretreatment Questions:
 - "Do you need to use the bathroom?"
 - "Any metal in or around head?"
 - "Taking current medications as prescribed?"
 - "Change in medical history or medications?"
 - "Tell me about your typical caffeine and eating habits?"
 - "What are your typical sleep patterns?"

7. Demonstrate proper insertion of ear plugs in your ears and then ask patient to insert their own.

NOTE: Neuronetics recommends the use of earplugs for everyone in the room during treatment.



Overview of Primary Motor Strip and Homunculus





MDD Determining Motor Threshold (MT) Location



To apply MT Cap, have patient hold front edge of the cap on forehead, centering the cap seam above their eyebrows. Pull the MT Cap over ears and back of head (wrinkles at top of cap is common).

Ensure seam position is centered in between eyebrows.



Align the first vertical line printed on cap to beginning of ear.

- Have the patient swing their legs onto the treatment chair, sitting with lower back against the chair and centered
 - Lower the arm rest
 - Visually check that the patient is centered in the treatment chair



- Press the **M2** button on the Treatment Chair Controller
- Adjust the Head Cushion position up/down (using the large black knob) and forward/backward (using the medium black knob)

NOTE: Ensure the patients head is fully cradled in the head cushion with no gaps. The use of extra head cushion or seat cushion may be necessary. Confirm the patient is comfortable.



- Squeeze the white clip and move the center (A/P) bar all the way forward
- Push black button on top of bar to turn on red light beam
- Rotate the center bar towards you, pulling it down until it stops
- While having the patient look at fixed point on the wall, use the small black knob to line up the light beam to the outside corner of the eye
- Move the center bar back to an SOA of zero and turn on light beam, adjust the patient's head so light beam dissects the center seam of the cap



- Engage side head pad by moving the side cushion down to just above patients ear
- While gently adding slight counter pressure (to account for coil), push side pad against patients head until snug

Ensure patient's head is still centered in line with red light beam.

6.	Patient Positioning	
	Head Support 5.9	
	Head Support Front/Back 2.8	
	LC Setting +1.7	

- On the touchscreen, tap **Patient Positioning**
- Enter chair setup parameters into NeuroStar
- Have the provider confirm settings and tap **Save**
- Verify patient's name/DOB/picture and tap Confirm



- Pull the center (A/P) bar towards you until it stops
- Squeeze the white clips and push bar all the way back
- Push bar handle all the way in towards the head support until it stops
- Place the coil cord into the coil holder on the back of the chair



9.

- Place patient's arm on rectangular cushions
- Have patient hold arm up as if throwing a football (90° angle, straight wrist) with fingers relaxed

SWITCH TO MANUAL MT PULSES

Tap **Switch To Manual MT Pulses** on the touchscreen.





Tap Found MT Location



Preparing for Daily Patient Positioning



- Log in to the NeuroStar[®] System
- Perform Pulse Test



- 2. Attach the hygiene barriers to:
 - SenStar Connect/Coil
 - Side Head Pad
 - Head Cushion
- 3. Zero out system.
 - Raise the A/P bar to maximum position
 - Set the SOA indicator to zero "0"
 - Set the A/P bar to zero "0"
 - Align the **A/P** bar handle (A) centering mark (B) with its centering line/groove (C) located under the coil angle
- 4. Search by **Patient ID** on touchscreen.
 - Tap **Patient ID** from the touchscreen list
 - Tap Patient Positioning
 - Set Head Support System according to the measurements that are displayed
 - Tap **Cancel** to remove the pop-up notification
- 6. Lift arm of chair up and have the patient sit upright on one side of the chair.

7. Ask the Patient Pretreatment **Questions:**

- "Do you need to use the bathroom?"
- "Any metal in or around head?"
- *"Taking current medications"* as prescribed?"
- *"Any change in medical history"* or medications?"
- "Any change in caffeine and eating habits?"
- "Any change sleep patterns?"
- "Any other changes since your last treatment?"
- 8. Have patient insert their ear plugs and you insert your own ear plugs.
- 9. Attach the **Head Positioning Strap** to the patient's forehead just above the eyebrows centering the point in between evebrows.
- 10. Instruct patient to sit back and center their body in chair with their back fully against chair back
 - Visually check that the patient is centered
 - Lower arm of chair
- 11. Press and hold M2 on the chair control until the chair stops.
- 12. Squeeze **center (A/P) bar** brake and move **center bar** forward until it stops.
- 13. Instruct patient to look at a fixed point to ensure patient remains centered; make sure that their head is straight.

5.



Preparing for Daily Patient Positioning

- **14.** Move **center bar** to the side with white base portion until it stops. Press the light beam button to activate. (*Light beam will turn off automatically after 45 seconds.*)
- 15.

Have the patient adjust their body up or down so that the light beam intersects with **the point where the eyelids meet**.



16. Return SOA to 0 and align the lightbeam through the point on the head strap by turning the patient's head.



* * * **REMINDER** * * * Any change in the Head Support Up/Down, Back/Front or LC settings will require reevaluation of the patient's MT.

- 17. Secure the top and left side HeadPositioning Straps to the HeadSupport System.
- 18. Secure the right side Head PositioningStrap to the Head Support System.
 - Lightly engage the **Side Head Pad** above the patient's right ear
 - Apply light counter pressure to account for the coil

- **19.** Verify patient's name/DOB/picture and tap **Confirm.**
- **20.** Position the coil in the treatment location according to the displayed parameters **SOA**, **A/P** and **Coil Angle**.
- Align the coil so that the centering line on the coil is perpendicular to the line on the Coil Angle Guide.



- **22.** Ensure good coil contact on touchscreen.
- **23.** Reconfirm coil placement parameters.
 - Tap **OK**
- **24.** Confirm listed pulse sequence settings and treatment plan.
 - Tap Confirm Pulse Sequence
- **25.** Inform patient treatment will be starting.
- **26.** Begin treatment by tapping **Start**.

NOTE:

Patients should be titrated to 120% MT Level within 3-5 sessions after beginning treatment.

Adjust for patient discomfort using the "Addressing Patient Discomfort" section of this guide.



MDD Redetermining Motor Threshold (MT) Level Only

To redetermine only the Motor Threshold Level (not a location change), follow these guidelines.





MDD Redetermining Motor Threshold (MT) Level Only



Tap Save MT

10.

Once the MT Level determination method has completed, the "**Saving MT will affect treatment**" pop-up will open.



Check the **Update treatment dose** (Level) box then tap **Update**. (If you do not want to save the updated treatment dose and want to return to the original MT setting, tap **Discard**.)

11. Move coil to the treatment location indicated on the touchscreen. Recheck coil settings and tap **OK**.

12. The system closes the pop-up window and activates the Confirm Pulse Sequence.

- Confirm the treatment settings and tap **Confirm Pulse Sequence**
- Tap Start





Addressing Patient Discomfort

Discomfort Under the Treatment Coil

- Reassure the patient that some discomfort is "Normal" and typically dissipates in 1. 2-4 days as their scalp acclimates to it.
- **2.** Assess level of discomfort. Consider activating **SoftStart**[™] protocol, and/or consider decreasing the % MT Level temporarily with the goal of returning to the 120% level within the next few treatment sessions.

Facial Discomfort



1. Pause treatment.

2. Rotate the coil in 5° increments, to a maximum of 20° from starting position. (Angle on the left side always positive and negative on the right side.)



3. **Resume** treatment after each coil movement to assess improvement.



If discomfort persists, adjust the **SOA** by reducing in 1° to 3° increments, to a maximum of 5°.



5. If repositioning of the coil does not improve patient comfort consider redetermining motor threshold location and level.

6. Once discomfort is alleviated, update the coil position on the touchscreen by tapping Update Position.

Finger/Hand Twitch or Foot Twitch During Treatment Stimulations

- Pause treatment. 1.
- 2. Move the A/P position forward from current treatment position in 0.5 cm increments up to a total of 1.5 cm until finger/hand twitch or foot/twitch is no longer noted.



- Update coil position on touchscreen by tapping Update Position.
- If finger/hand or foot twitch is still observed, consider redetermining motor threshold location and level.

Headache

1. Treat pre or post stimulation with an overthe-counter analgesic.



The most common side effect is pain or discomfort at or near the treatment site. These events are transient; they occur during the TMS treatment course and do not occur for most patients after the first week of treatment. There is a rare risk of seizure associated with the use of TMS therapy (<0.1% per patient). Visit neurostar.com for full safety and prescribing information.



MDD Redetermining Motor Threshold Location & Level

To redetermine both the Motor Threshold (MT) Location and Motor Threshold (MT) Level, follow these guidelines.

Considerations to reassess MT Level and Location would be:

No improvement after reaching the midpoint of the treatment course Unable to resolve pain or discomfort following the guidance in the "Addressing Patient Discomfort" section of this Guide Significant change in the patient's hair style



Log in to the **NeuroStar® System**, and select your patient.

2.

If no changes in the head support system is needed, set up using the existing Patient Positioning parameters.

OR

If patient's head support system has changed, follow steps 1 through 5 of *MDD Determining Motor Threshold (MT) Location* section in this training guide. Make adjustments and enter parameters on patient positioning screen. **Tap Save**.

- Tap Confirm Patient
- **3.** The Treatment Location pop-up will open. Tap Redo MT.



Follow steps 1 through 15 of MDD
 Determining Motor Threshold (MT)
 Location section in this training guide.

 Once the MT Level determination method has completed, the "Saving MT will affect treatment" pop-up will open.

Saving MT will affect treatment.								
Choose the data you want to save: Update treatment dose								
Update treatment location								
CANCEL 🗙	DISCARD	UPDATE						

Choose the data you want to save. Check the "**Update treatment dose**" (Level) and "**Update treatment location**" boxes to save the MT Level and/or Location and tap **Update**. (If you do not want to save updated treatment dose/location and want to return to the original MT settings, tap **Discard**.)

- 6. Move coil to the treatment location indicated on the touchscreen. Recheck coil settings and tap **OK**.
- 7. The system closes the pop-up window and activates the Confirm Pulse Sequence.
 - Confirm the treatment settings and tap **Confirm Pulse Sequence**
 - Tap Start

NOTE: It is possible that the MT Level does not change.



OCD

2.

Determining Motor Threshold (MT) Location

9.

10.

1. Prior to patient entering: **ZERO OUT** the NeuroStar: set center (A/P) handle, center (A/P) bar, and SOA to zero.

Place coil cord in coil holder on back of chair.

- Log into the NeuroStar System
- Perform Pulse Test
- Select Patient ID from the touch screen
- Attach hygiene barriers



Seat patient on side of the treatment chair. Ask the patient pretreatment questions:

Do you need to use the restroom?Any metal in or around head?

- Taking current medications as prescribed?
- Change in meals?
- What is your average daily caffeine consumption?
- What is your sleep pattern?
- **4.** Attach the Head Positioning Strap to the patient's forehead just above the eyebrows, the point should be centered where the forehead meets the nose (nasion), Have patient Insert ear plugs.



Have the patient remove their footwear and swing their legs onto the treatment chair. Sitting with lower back against the chair and centered. Lower the arm rest.

- 6. Press and hold M3 on the chair control until the chair stops. Ensure patient's back remains fully against back of chair.
 - Tap **Patient Positioning** on the touchscreen
 - Using the large black knob, adjust the Head Support System (HSS) <u>up/down</u> and ensure patient's head is cradled in headrest without gaps
 - Using the medium black knob, adjust the HSS <u>front/</u> <u>back</u> to patient comfort

8. Gently attach only the top Head Strap to the center Velcro strip. Set center (A/P) bar all the way forward.



Have the patient look at a fixed point and press black button on A/P bar to activate the soft red light. Align the light through the "point" on the center of the Head Strap – by gently turning the patient's head.

• Attach side straps to side of head support



While holding the white base portion of center (A/P) bar, move center (A/P) bar to the left side of the patient's head until it stops. Turn on red light beam and align to the corner of the patient's eye using small black knob.

• Return center (A/P) bar to **SOA** of zero



Lightly engage side head pad: move the side cushion down to just above patients ear, gently place the side pad against patient's head.

- **12.** Enter head support/chair setup parameters into NeuroStar
 - Have provider confirm chair parameters
 - Provider confirms patient
- **13.** To associate the MT search with the OCD MT location and level:
 - Touch MDD on touchscreen (current default)



 A pop-up will be displayed asking which MT determination you want.
 Select the OCD option as shown and touch OK

WITCH TO MANUAL OCD



START

• The button changes to **OCD** to let you know that the MT search is for **OCD**

FOUND MT LOCATION

The patient is now positioned to begin the OCD MT determination

7.





Using MT Cap to Determine Motor Threshold Location



POWER

Power - Line up coil center line on orange dot, purple line with edge of coil. Increase power by 0.10 until robust and repeatable movement is seen.





INTENSITY

Intensity - Move coil forward to next color that intersects with the front to back purple line and pulse. Determine if response is stronger or weaker. Repeat until 2 responses in a row have been weaker. Return to the color that had the strongest movement.



THUMB (or FOREFINGER)

Thumb or

forefinger – Move the coil down to the next intersecting color keeping the strongest



movement color in line with the coil and identify which fingers move. Continue until forefinger or thumb moves.

Lock coil and halo. Push bar forward until it touches coil, line up the coil guide with the center line on the coil.

Enter **SOA**, A/P position, coil angle on screen.



Tap green "Found	MT"	on
touchscreen.		

Tap **Fast MT.**

Tap TMS Prescription.

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Dash		3	3000							
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Treatment Seque	nce									
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	APPLY		▼			SYNC Q				

NeuroStar, Quick Reference Guide

OCD

Determining Motor Threshold (MT) Location



POWER

- SOA to 5° & Coil Angle to 0°, set A/P bar to 3.0 cm
 may need to move A/P to 2.5 cm
 - may need to search at SOA 3° or 7°
- Aligns with the center mark on the **Coil Angle** guide
- Initial power level default 1.2
- Initiate a pulse watch the feet for any movement.
 - increase MT (power) by 0.10 increments until movement is seen – must be repeatable



INTENSITY

- Move the **A/P** bar forward in 0.5 cm movements
- Deliver a pulse was response/intensity (foot movement) weaker/ stronger - document on MT Worksheet
- Repeat until 2 responses in a row have been weaker
- Return to the location that had the greatest intensity



TOE/FOOT

- Lock coil in
- Enter SOA, A/P Position,
 Coil Angle tap "Found MT" from touchscreen

Position coil at treatment location Attach head positioning strap. 6. (SOA "0"). M3 - Position patient in chair. TMS Prescription, tap OCD. 7. 2 Initiate patient provocation to a 4-7 out Remove footwear. 8. 3 of 10 using the Visual Analog Scale. Associated MT search with OCD. 4 9. Start treatment. Tap Fast MT. 10. OCD treatment is 100% of MT. 5.



System Components

A Completely Integrated Clinical Solution for Transforming Lives

Precise, Repeatable Targeting Ensures Consistent, Safe Dosing

High-Performance Coil Contact Sensing 3-D Laser Positioning System

Treatment Chair

Provides comfortable patient seating during treatment sessions

Powerful Data Management

TrakStar[®] Cloud Automated Data Management System

Track, Manage & Analyze patient outcomes

Web-enabled technology allows secure HIPAA-compliant access anywhere, anytime



Graphical User Interface

Intuitive system software guides system operator through step-by-step treatment workflow

Fast MT[™] and MT Assist[®]

Proprietary software makes finding the right treatment dose easy

Halo Break Gantry Halo Halo

NeuroStar .

HEAD SUPPORT ASSEMBLY





Replacing Your SenStar[®] Connect Treatment Link

IMPORTANT: When replacing your multi-use SenStar[®] Connect Treatment Link, it is advised to do so at the end of the day or during a down period in order for the adhesive to properly cure.

1. Carefully remove the used Treatment Link from the coil by popping up the center bar and then pull back the old Treatment Link.





 Clean the coil surface well with an alcohol wipe to remove any adhesive residue. Only use an alcohol wipe to



clean the surface. Be sure to completely remove the old adhesive.

- **3.** Let the coil surface dry completely before inserting Treatment Link (a dry, lint-free cloth may be used if necessary).
- Remove only the narrow adhesive liner strip from the center bar of a new SenStar Connect Treatment Link.



5. Insert the connector of the Treatment Link into the connector receptacle of the coil.

Connector

Visit **neurostar.com** for full safety and prescribing information.

- 6. Secure the center bar of the Treat-ment Link into the coil.
- 7. Remove the large adhesive liner from the rear surface of the Treatment Link and carefully affix to the coil.





8. Apply smooth pressure across the surfaces several times to ensure proper adhesion.



9. If you wish to clean the NeuroStar coil between patients, use an alcohol wipe (lightly) on the sides of the coil. Do not use alcohol wipes or apply chemicals to the surface of the SenStar Connect Treatment Link.

NOTE: To ensure integrity and longevity of the SenStar Connect Treatment Link, remove the Hygiene Barrier with care after each use.

The NeuroStar Advanced Therapy System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.

The NeuroStar Advanced Therapy system is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).