NOTICE

This NeuroStar® System Instructions For Use is released by Neuronetics®, Inc., as a guide for the operators and administrators of the NeuroStar System®. It provides information that is necessary for the safe and effective operation of the System. This document is to be used in conjunction with the TrakStar Instructions For Use.

The contents of this document, which reflect current Neuronetics standards, are subject to revision or change without notice. Hardware or software packages and revised or new features released after the publication of this document will be documented in addenda or later versions of these Instructions For Use.

For additional information, please contact your Neuronetics service representative.

If you have questions or comments regarding these Instructions For Use or other Neuronetics technical documents, contact the Neuronetics Technical Publications Department at: customersupport@NeuroStar.com.

Preface

This document provides operating instructions and guidelines for the use of the Neuronetics NeuroStar 3.5 System for Model Number 81-01315-000 and Model Number 81-02315-000.

NOTE  Federal (U.S.A.) law restricts this device to sale to or on the order of a physician.

The NeuroStar 3.5 System contains software that is compatible with previously released hardware components and provides the latest software updates and features to existing NeuroStar Systems. The images used in this Instructions For Use document may differ slightly from existing NeuroStar Systems that utilize previously released versions of hardware and software. If operation is functionally affected due to these differences, the images provided in this Instructions For Use will be an exact match of the specific NeuroStar System’s hardware components and software.

In the event that the information provided in this Instructions For Use document does not provide a sufficient level of detail or explanation, please refer to the original Instructions For Use document that accompanied the NeuroStar System upon purchase and installation. All prior Instructions For Use documents are available on the Neuronetics website NeuroStar University Application (https://success.neuronetics.com).
Operator Requirements and Training

The NeuroStar System is used by prescription only under the supervision of a physician. The instructions in this document assume that the operator has been trained in the proper use of the NeuroStar System and has the required medical education and experience to operate the device safely and effectively. All operators should complete NeuroStar System training. If additional training is needed, please contact Neuronetics.

Intended Use and Indication

NeuroStar Advanced Therapy® is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Intended Use Environment

The NeuroStar System is intended for use only in a professional healthcare environment.

Patents

Equipment and software that comprise the NeuroStar System are covered by patents (found at the website address, https://neurostar.com).

Trademark Information

The following are registered trademarks of Neuronetics, Inc.:

Neuronetics®, NeuroStar®, NeuroStar TMS Therapy System®, NeuroStar® Advanced Therapy, TMS Therapy™, MT Assist®, SenStar®, SenStar Connect®, SenStar Treatment Link®, TrakStar®

This document also contains the following trademarks of other companies:

Microsoft®, Windows®, Velcro®, Lysol®, Arquad®, Earscan®

NeuroStar TMS Therapy System® and NeuroStar® Advanced Therapy represent a name change only. The names can be used interchangeably and represent the same medical device. Note that “NeuroStar® Advanced Therapy” is the treatment; “NeuroStar® System” is the device.
Certification

Contact Information

<table>
<thead>
<tr>
<th>United States</th>
<th>Neuronetics, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3222 Phoenixville Pike</td>
</tr>
<tr>
<td></td>
<td>Malvern, PA 19355-1245</td>
</tr>
<tr>
<td></td>
<td>Tel: 877-600-7555, +1 610-640-4207</td>
</tr>
<tr>
<td></td>
<td>FAX: 610-640-4206</td>
</tr>
</tbody>
</table>

| Other Distribution Regions | Visit neurostar.com/en/worldwide |

Alternatively, you can send your questions to the following E-mail address: customersupport@neuronetics.com.

The Neuronetics Web site address is https://neurostar.com.

To purchase supplies, accessories, or additional NeuroStar Systems, contact Customer Service. For technical issues, call the main number and follow the prompts to reach Technical Support.

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Instructions For Use Symbols

The NeuroStar System Instructions For Use includes icons that are designed to draw attention to special types of information provided. These icons are explained below:

**Warning**: Dangerous Electricity

**General Warning**

Serious injury or death may result if the operator does not follow the associated instructions.

**Caution**

The following may result if the operator does not follow the associated instructions:

- System damage
- Non-serious injury
- Inadequate treatment

**NOTE**

Important guidance in using the NeuroStar System is provided.
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1 Introduction

The NeuroStar® System (see Figure 1-1) is a computerized electromechanical instrument that produces and delivers brief duration, rapidly alternating (pulsed) magnetic fields to induce electrical currents in localized regions of the cerebral cortex.

NeuroStar Advanced Therapy® is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. The NeuroStar System is available upon the prescription of a licensed physician. It can be used in both inpatient and outpatient settings including physicians’ offices, clinics, and hospitals.

“Prescription” means that the attending physician has determined that the NeuroStar System is indicated for use in a particular patient. In addition to patient selection, the attending physician should oversee initial patient motor threshold determinations, treatment parameter definitions and overall TMS treatment course planning for each patient.

“Supervision” means that the attending physician is medically responsible for coordination of the overall clinical care of a patient for whom NeuroStar Advanced Therapy has been considered clinically indicated and for the safe and effective use of the NeuroStar System. If the attending physician is not performing the daily NeuroStar treatment sessions, then the attending physician should assign properly trained personnel who may perform the daily treatment...
sessions. The attending physician is medically responsible for the routine evaluation of the patient during the course of their TMS Therapy treatment.

The NeuroStar System is offered in the following configurations:

- Single mobile console configuration: mobile console, treatment coil, head support system, treatment chair, and TrakStar patient data management system.
- Multiple mobile consoles/TrakStar system configurations to address the needs of facilities with large patient populations.

1.1 Overview

Since the NeuroStar System produces a time varying magnetic field, its intended effect derives fundamentally from Faraday’s Law, which asserts that a time-varying magnetic field produces an electrical current in an adjacent conductive substance. During TMS, the conductive substance of interest is the brain, in particular the region of the cortex that lies beneath the NeuroStar System treatment coil.

The electric current induced in this region of the cortex travels in a path orthogonal to the direction of the alternating magnetic field with the point of maximum field strength and greatest current located directly beneath the center of the coil, which is the NeuroStar System component that rests against the patient’s head and transmits magnetic pulses to the patient’s brain. The induced current is tangential to the scalp at the cortical surface, and diminishes in magnitude with increasing depth.

In the targeted area of the motor cortex, where field strength achieves the stimulation threshold, it is postulated that neuronal depolarization occurs. This type of magnetic field is not intended to induce a seizure during therapeutic use. The peak magnetic field strength achieved with each pulse in the cortex is approximately 0.5 Tesla.

Although the mechanism of action is unknown, it is hypothesized that the NeuroStar System causes neuronal depolarization and changes in brain functional activity that may be associated with various physiologic changes in the brain associated with symptomatic relief of depression in the indicated population.

1.2 Indications

NeuroStar Advanced Therapy is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Summary of Clinical Trials

The efficacy and safety of the NeuroStar System in adult patients with major depressive disorder (MDD) who failed to receive satisfactory improvement from prior antidepressant medication was established in two randomized controlled trials (O’Reardon, et al., 2007; Janicak, et al., 2008; George, et al., 2010).

Clinical efficacy outcomes of the use of NeuroStar Advanced Therapy in adult patients with major depression in real world clinical practice was demonstrated in a multisite naturalistic study in 42 US centers under conditions of general clinical use (Carpenter, et al, 2012; Janicak, et al, 2013).
In clinical trials, medication adequacy was determined using the Antidepressant Treatment History Form (ATHF), or similar validated method (Study 19-50001), which identified those medications given at or above the minimal effective dose and duration as defined in the product labeling. Failure of benefit was defined as no more than a minimal clinical response to the antidepressant medication as assessed by the clinician. In cases where patients were untreated or insufficiently treated in the current episode, the medication history from the most recent prior episode was utilized to determine medication adequacy.

A major depressive episode as defined in the DSM-5 implies a prominent and relatively persistent (nearly every day for at least two weeks) depressed or dysphoric mood that represents a change from previous functioning, and includes at least five of the following nine symptoms, one of which is either of the first two symptoms:

- Depressed mood
- Markedly diminished interest or pleasure in usual activities
- Significant change in weight and/or appetite
- Insomnia or hypersomnia
- Psychomotor agitation or retardation
- Fatigue or loss of energy
- Feelings of worthlessness or excessive or inappropriate guilt
- Slowed thinking or impaired concentration
- Recurrent thoughts of death or suicidal ideation or a suicide attempt.

Additional details on study design and outcomes for the NeuroStar System clinical trials are provided in Appendix A.

A company-independent, randomized controlled trial funded by the National Institute of Mental Health, evaluated the safety and efficacy of TMS using a clinical trial version of the NeuroStar System in adult patients (N=197, 4 sites) with moderate to severe major depressive disorder and who failed to benefit from 1-4 adequate antidepressant medication trials, as defined using the Antidepressant Treatment History Form (ATHF), or who could not tolerate 3 or more antidepressant medications (George, et al, 2010).

The study evaluated 197 outpatients across 4 sites, ages 21-70 years, most with a recurrent course of major depression (~97%), with the maximum duration of the current episode of depression of ≤3 years. Patients had received a median of 1.6 total prior antidepressant medications at an adequate dose and duration in the current episode or a median of 4 treatment attempts at any dose and duration.

The primary outcome measure was remission using the HAMD24 (HAMD24 total score ≤3 or 2 consecutive HAMD24 total scores <10) through 6 weeks of acute treatment. A statistically significant benefit of active TMS as compared to sham treatment for the HAMD24 remission outcome (Active TMS: 13.4% vs Sham TMS: 5.0%, P=0.0173) was observed in the ITT study population (N=197). An adjusted odds ratio of achieving remission with active TMS was 4.05 (95% confidence interval (CI), 1.28-12.83) as compared to sham TMS. The baseline to endpoint change score outcome using the HAMD24 also favored active TMS to sham treatment (-2.11, 95% CI: -4.30, 0.08; P=0.0588).
Baseline to endpoint outcomes for patients treated with active TMS were statistically significant as compared to sham treatment as measured using the MADRS (P=0.0136), CGI-S (P=0.0181) and the patient-rated IDS-SR (P=0.0008). For the categorical endpoints, higher rates of remission were observed for patients receiving active TMS as compared to sham treatment as measured using the MADRS (P=0.0170) and the patient-rated IDS-SR (P=0.1199), and for response (50% improvement from baseline) for all three measures (HAMD24, P=0.0104; MADRS, P=0.0063; IDS-SR, P=0.0145). Standardized effect size estimates for the continuous outcome endpoints range from 0.43 to 0.67, indicating a moderate to large effect size in this patient population.

Study 101 evaluated the safety and efficacy of NeuroStar Advanced Therapy in 301 adult outpatients across 23 sites with moderate to severe major depressive disorder and who failed to benefit from 1 through 4 prior antidepressant medication trials administered at an adequate dose and duration, and verified using the ATHF (O’Reardon, et al., 2007; Janicak, et al., 2008). The patient population was similar to patients enrolled in the independent NIMH-funded trial.

Outcome on the primary efficacy endpoint (MADRS change from baseline at 4 weeks) favored NeuroStar Advanced Therapy (P=0.057) over sham treatment for the ATHF 1-4 population. A subgroup analysis of the overall study population demonstrated that the device was safe and effective for patients who had failed to achieve satisfactory improvement from one prior antidepressant medication (N=164 patients, P=0.0006, MADRS, primary efficacy endpoint) in the current episode.

Open Label Trials

Study 19-50001 was a multisite naturalistic study in 42 US centers that evaluated the acute efficacy and 12-month durability of NeuroStar Advanced Therapy under conditions of general clinical use (Carpenter, et al, 2012, Janicak, et al., 2013). The study enrolled adult patients (N=307) with MDD who failed to benefit from any number of antidepressant medications administered at an adequate dose and duration (mean of 2.5, range 0-14) in the current episode.

There was a statistically significant improvement from baseline in CGI-S total score (CGI-S, −1.9 ± 1.4, P < .0001, primary efficacy outcome) at end of acute treatment. A similar pattern and magnitude of clinical improvement was observed in the two patient self-reported outcome measures, the PHQ-9 (−8.7 ± 7.2, P <0.0001) and the IDS-SR (−18.3 ± 14.9, P<0.0001). Categorical response and remission rates were consistent in clinical magnitude on all three outcome measures i.e., CGI-S (58.0% response; 37.1% remission), PHQ-9 (56.4% response; 28.7% remission), and IDS-SR (41.5% response; 26.5% remission).

Study 19-50001 evaluated the durability of acute benefit with NeuroStar Advanced Therapy during 12 month follow up in patients maintained on antidepressant medication and/or with periodic TMS reintroduction for symptom worsening (Neuronotics data on file). Overall, 36.2% of patients required re-treatment with TMS over 12 months. Amongst remitters, 29.5% of patients experienced relapse through 12 months.
1.3 Contraindications

The NeuroStar System is contraindicated for use in some situations as identified below and further described in Section 7. All patients must be screened for the following contraindications.

The NeuroStar System treatment coil produces strong pulsed magnetic fields which can affect certain implanted devices or objects. The magnetic field strength diminishes quickly with increasing distance from the coil. Within 30 cm of the face of the treatment coil, the peak magnetic field can be greater than 5 Gauss, which is the recommended static magnetic field exclusion level for many electronic devices.

Metallic Objects in or near the Head

The NeuroStar Advanced Therapy System is contraindicated for use in patients who have conductive, ferromagnetic, or other magnetic-sensitive metals implanted in their head within 30 cm of the treatment coil. Examples include cochlear implants, implanted electrodes/stimulators, aneurysm clips or coils, stents, bullet fragments, jewelry and hair barrettes. Failure to follow this restriction could result in serious injury or death.

NOTE

Removable objects that may be affected by the magnetic field should be removed from the patient before treatment to prevent possible injury. (Examples include jewelry and hair barrettes). Once these objects are removed, NeuroStar Advanced Therapy is not contraindicated for these patients.

NOTE

Examples of metallic objects in or near the head that are acceptable under certain conditions include standard amalgam dental fillings, single post dental implants, and dental bridge work. The conditions for TMS treatment when these objects are present are clarified in Section 7.

Implanted Stimulator Devices in or near the Head

The NeuroStar Advanced Therapy System is contraindicated for use in patients who have active or inactive implants (including device leads), including deep brain stimulators, cochlear implants, and vagus nerve stimulators. Contraindicated use could result in serious injury or death.

1.4 Warnings

All operators must consider the following warnings before proceeding to treatment.

NeuroStar Advanced Therapy has not been evaluated in patients with psychoses or with psychiatric emergencies where a rapid clinical response is needed, such as marked physical deterioration, catatonia, or immediate suicide risk. Use of NeuroStar Advanced Therapy in the treatment of these patients is not recommended since rapid onset of effect in these high-risk populations has not been established.

Following acute treatment with NeuroStar Advanced Therapy, patients will need to be monitored and may need to resume antidepressant medications. This device has not been evaluated for durability of antidepressant effect in controlled clinical trials.
Introduction

Worsening Depression or Suicidality

Patients who have Major Depressive Disorder may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are being treated with an antidepressant, and this risk may persist until significant remission of symptoms occurs.

Observe patients undergoing treatment for Major Depressive Disorder closely for worsening symptoms and signs of suicidal behavior and/or unusual behavior. If worsening of symptoms continues, consideration should be given to changing the therapeutic regimen, including discontinuation of treatment with the NeuroStar System. Families and caregivers should also observe patients and notify the treatment provider if symptoms worsen.

Screening Patients for Bipolar Disorder

A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with antidepressant therapy may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Prior to initiating antidepressant treatment, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that NeuroStar is not approved for use in treating bipolar depression.

Effects on Medical Devices Containing Electronics or Ferromagnetic Material

The NeuroStar System should be used only with caution in the situations identified below. All patients must be screened for the conditions noted and appropriate cautionary measures should be taken.

Implants Controlled by Physiologic Signals

The NeuroStar System should be used with caution in patients who have an implanted device that is activated or controlled in any way by physiologic signals, even if the device is located outside the 30 cm distance. This includes patients with pacemakers and implantable cardioverter defibrillators (ICDs) or patients using wearable cardioverter defibrillators (WCDs) even if the device is removed due to the potentially unstable cardiac condition of such patients. Failure to follow this restriction could result in serious injury or death.

Implants Not Controlled by Physiologic Signals

Patients who have implanted devices or metallic objects located in areas outside the 30 cm distance from the treatment coil may receive NeuroStar Advanced Therapy. However, care must be taken by the NeuroStar System operator to ensure that the treatment coil is never placed within 30 cm of these implants. Otherwise, serious injury could result. (Examples of these devices include staples and implanted insulin pumps.)
Wearable or Removable Devices or Objects

If patients have removable devices or objects that may be affected by the magnetic field, the device(s) should be removed from the patient area before treatment to prevent possible injury to the wearer or damage to the device. (Examples include wearable monitors, bone growth stimulators, earrings, hearing aids, eyeglasses, jewelry, hair barrettes, cell phones, MP3 players, etc.)

Use Near Magnetic Resonance Imaging (MRI) Devices

Keep the NeuroStar System mobile console outside of MRI-restricted access areas due to possible interaction with the MRI magnetic field.

Metallic Object and Implant Checklist

Prior to treatment, each patient should be screened for the presence of metallic objects or implants that could affect the safe use of the NeuroStar System. A list of items for which all patients should be screened is provided in Section 7 of these Instructions For Use.

This list summarizes compatibility requirements for devices and conductive objects in the vicinity of the NeuroStar System treatment coil and provides guidance for whether the device is contraindicated for use or may be used if specific precautionary measures are taken.

Clinical Warnings

All operators must consider the following clinical warnings before proceeding with patient treatment.

Risk of Seizure

Generalized seizures have been reported with the use of TMS in the clinical trial literature. No seizures were reported with use of the NeuroStar System in over 10,000 treatment sessions in trials conducted prior to FDA clearance of the NeuroStar System. Since the introduction of the NeuroStar System into clinical practice, seizures have been rarely reported. The estimated risk of seizure under ordinary clinical use is less than 1 in 30,000 treatments (<0.003% of treatments) or less than 1 in 1000 patients (<0.1% of patients). Nevertheless, the NeuroStar System should be used with caution in patients who have a history of seizures, or a potential for alteration in seizure threshold, as stated below.

In order to reduce the potential risk of seizure, observe the published 1998 National Institute of Neurological Disorders and Stroke (NINDS) Workshop report guidelines (“Appendix A. NeuroStar Advanced Therapy Clinical Studies” in these Instructions For Use). Treatment with stimulation parameters that lie outside of these guidelines is not recommended.

TMS should be applied to the left dorsolateral prefrontal cortex using the coil placement methods described in these Instructions For Use. Failure to follow these procedures may increase the risk of seizure.

Be alert for signs of an imminent seizure and terminate the treatment session if those signs appear. If a medication that may alter seizure threshold has been taken since the last treatment session, the motor threshold determination should be
repeated prior to the next treatment session. Patients at potential increased risk of seizure include those who have:

- History (or family history) of seizure or epilepsy
- History of stroke, head injury, severe headaches, or unexplained seizures
- Presence of other neurological disease that may be associated with an altered seizure threshold (such as CVA, cerebral aneurysm, dementia, increased intracranial pressure, head trauma, or movement disorder)
- Concurrent medication use such as tricyclic antidepressants, neuroleptic medications, or other drugs that are known to lower the seizure threshold
- Secondary conditions that may significantly alter electrolyte balance or lower seizure threshold
- No quantifiable motor threshold such that TMS dosage cannot be accurately determined.

1.5 Cautions

All operators must consider the following cautions before proceeding with patient treatment:

- The acute effectiveness of NeuroStar Advanced Therapy has not been established beyond a six-week treatment course for MDD.
- NeuroStar Advanced Therapy has not been studied as an adjunct to antidepressant treatment in controlled trials; it has been administered safely in the presence of antidepressant medication.
- Speech arrest
  Patients may experience speech/language dysfunction during active TMS treatment, including partial or complete speech arrest. This dysfunction is transient, occurring only during active stimulation and resolves after stimulation has stopped.
- Hand/finger twitching
  Patients should be monitored for finger, hand or arm twitching during treatment, and, if observed, managed according to procedures outlined in Section 12.5 of these Instructions For Use.

The patient and the operator of the NeuroStar System must always wear earplugs or similar hearing protection devices with a rating of 30 dB of noise reduction during treatment. When used with appropriate hearing protection, NeuroStar Advanced Therapy did not have an effect on auditory threshold.

Longer term effects of exposure to the NeuroStar System magnetic field are not known. Experimental and observational evidence indicates that exposure to the type of magnetic fields produced by the NeuroStar System coil does not present any significant risk of acute or long-term adverse effects.

Patients should be monitored for seizures, and seizure management procedures should be available.

1.6 Special Populations

The safety and effectiveness of NeuroStar Advanced Therapy has not been established in the following patient populations or clinical conditions through a controlled clinical trial.

- Patients who have had no prior antidepressant medication failure.
- Patients who have a suicide plan or have recently attempted suicide.
- Patients with seasonal affective disorder.
• Patients younger than 22 years of age or older than 70 years of age.
• Patients with a history of substance abuse, obsessive compulsive disorder, or post-traumatic stress disorder.
• Patients with a psychotic disorder, including schizoaffective disorder, bipolar disease, or major depression with psychotic features.
• Patients with neurological conditions that include a history of seizures, cerebrovascular disease, dementia, movement disorders, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the CNS.
• Patients with metal in or around the head, including metal plates, aneurysm coils, cochlear implants, ocular implants, deep brain stimulation devices and stents.
• Patients with vagus nerve stimulators or implants controlled by physiologic signals, including pacemakers, and implantable cardioverter defibrillators.
• Patients with major depressive disorder who have failed to receive clinical benefit from ECT\textsuperscript{*} or VNS.
• Patients who are pregnant or nursing.

\textsuperscript{*} NeuroStar Advanced Therapy has not been demonstrated to be equivalent in efficacy to ECT for the treatment of major depressive disorder

1.7 Procedural Warnings and Precautions

This section lists the warnings and cautions associated with the operation of the NeuroStar System.

Risk of explosion. Do NOT use the NeuroStar System in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Risk of electrical shock. To avoid risk of electrical shock the NeuroStar System MUST only be connected to a supply mains with a protective earth connection.

Risk of electrical shock. Do NOT use the NeuroStar System in or near water or other liquids, or place liquids on or near the mobile console or any of the cables or the coil.

Risk of electrical shock. Do NOT open the panels of the NeuroStar System mobile console. There are no operator-serviceable parts in the system. If the system malfunctions, contact Customer Service for assistance.

Do NOT place the NeuroStar System near other medical equipment during operation. The effects of the NeuroStar System on other equipment are unknown and could result in serious injury or death.

NO modification of the NeuroStar System is allowed.
Introduction

Discontinue treatment with the NeuroStar System in any patient who has a continued significant adverse reaction or discomfort during or immediately after use. (Temporary mild discomfort at the site of stimulation is normal during and/or shortly after treatment.)

If the treatment coil temperature warning message is displayed on the touchscreen, the patient’s scalp is in contact with a surface that may exceed 41° C. Clinical judgement should be used to determine whether or not treatment should continue for a patient with impaired ability to sense heat/pain. Patients who may be at increased risk of thermal injury include patients with:

- Diabetes mellitus
- History of stroke
- Under the influence of alcohol
- Current use of any sleep medication.

To avoid injury and equipment or property damage, always install the gantry block in front of the gantry base when the mobile console needs to be moved from one location to another.

Risk of chair tip-over. The NeuroStar treatment chair may tip over if excessive weight is applied to either the back support or the leg support when they are positioned near their horizontal positions. To avoid tip-over, make sure the patient is properly seated against the back support before elevating the leg support. Do not sit or stand on the foot rest.

Risk of pinching. Do NOT place fingers near the mechanisms under the treatment chair when it is being operated; injury could result. Observe the yellow warning triangles located in hazardous areas.

A 10-minute interval between patient treatment sessions is required to guarantee that the coil operates within temperature specifications. Failure to observe the 10-minute interval between treatment sessions could result in an unexpected system shutdown.

Operate the NeuroStar System only with parts and components provided and/or recommended by Neuronetics, Inc. The performance of the NeuroStar System cannot be guaranteed if other parts or components are used. Use of other parts may void the warranty.

Do not place computer discs, audio recording tapes, credit cards, hotel room keys, or electronic automotive ignition keys on or near the coil while operating. The NeuroStar System produces time-varying magnetic fields that may affect the integrity of data stored on these types of magnetic media if placed near an operating coil.

Class 1 Laser Caution – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
Speech arrest – Patients may experience speech/language dysfunction during active TMS treatment, including partial or complete speech arrest. This dysfunction is transient, occurring only during active stimulation and resolves after stimulation has stopped.

Hand/finger twitching – Patients should be monitored for finger, hand or arm twitching during treatment, and, if observed, managed according to procedures outlined in Section 12.5 of these Instructions For Use.

A Class 1 laser is incorporated into the A/P bar to assist in patient positioning. Although the laser meets internationally accepted standards to be “safe to eye and skin under all reasonably foreseeable conditions of operation,” it is prudent to avoid prolonged or unnecessary exposure of the eye to the laser.

Operation of the NeuroStar System requires special precautions regarding electromagnetic compatibility (EMC). The system needs to be installed and put into service according to the following EMC information:

- Portable and mobile radio frequency communications equipment can affect the operation of the NeuroStar System.
- Use of a power cord other than the one provided may result in increased emissions or decreased EMC immunity of the NeuroStar System.

Do not use the NeuroStar System adjacent to or stacked with non-medical equipment. If adjacent or stacked use is necessary, observe the NeuroStar System to verify that it is operating normally.

For more information on the electromagnetic compatibility of the NeuroStar System, see “Appendix E. Electromagnetic Compatibility”.

1.8 Adverse Events

There were no deaths or seizures reported in the NeuroStar System controlled clinical trials.

The most common adverse events reported were application site pain and headache. Application site pain was the most frequently reported device-related adverse event with greater frequency in the active TMS treatment group as compared to sham TMS. Headache was reported by about half of patients and nearly equally in both active TMS and sham TMS treatment groups. In general, application site pain and headache were transient and dissipated rapidly with time. These adverse events were graded as mild to moderate in severity for the majority of patients.

For more details, see “Appendix A. NeuroStar Advanced Therapy Clinical Studies” in these Instructions For Use.

For details of adverse events reported by iTBS patients, see Appendix A “Common Adverse Events found in Theta Burst Study” on page A-10 in these Instructions for Use.
1.9 Medical Event Reporting

All events should be reported to Customer Service:

- Any medical event that the prescribing physician considers to be related to the NeuroStar System.
- Additionally, report any of the following events of special interest, even if unrelated to NeuroStar System:
  - A patient experiences a seizure
  - A patient being treated or was recently treated reports a pregnancy
  - A patient experiences significant worsening of illness resulting in hospitalization during treatment course
  - A patient with an implantable medical device receives TMS Therapy

1.10 Cognitive Function and Auditory Threshold

There was no evidence of cognitive function testing change at either 4 weeks or 6 weeks associated with acute treatment with the NeuroStar System.

There was no evidence of auditory threshold change at either 4 weeks or 6 weeks associated with acute treatment with the NeuroStar System (with use of 30 dB hearing protection during TMS treatment).

1.11 Operator Qualifications

The NeuroStar System is used by prescription only by or under the supervision of a licensed physician trained in the use of the NeuroStar System.

The physician or operator should provide the patient with the “NeuroStar Advanced Therapy Patient Guide for Treating Depression,” prior to treatment, to allow each patient sufficient time to review the information about the device and the procedure and discuss this information with his/her physician and family.

It is recommended that the NeuroStar System operator be a clinical professional who is conducting TMS Therapy under the supervision of a physician. The NeuroStar System operator should possess, in the opinion of the physician, sufficient clinical expertise to monitor the patient during the conduct of a TMS treatment session.

The operator must be able to observe the patient’s physical status for the potential occurrence of adverse events, and make routine adjustments as required and consistent with product labeling, or determine circumstances under which treatment interruption or treatment termination should be considered. The NeuroStar System operator should be present in the treatment room with the patient at all times.

The operator must be qualified to monitor the patient for seizure activity and to provide seizure management care.

1.12 General System Description

The NeuroStar System consists of the following equipment and software. (See Section 2.2 for complete descriptions.)

- Mobile Console (includes processor module, display, power module, mast, gantry, halo, and display arm)
- System Software
- TrakStar Patient Data Management System software
- Treatment Coil
1.13 Supplies and Disposables Overview

- Head Support System (includes laser positioning aid and coil positioning guide)
- Treatment Chair
- Positioning Cushions (to enhance the comfort and positioning of the patient in the required posture for the duration of the treatment session)

When the multiple-use SenStar Connect Treatment Link is used with the NeuroStar System it requires the following supplies and disposables for each treatment session. (See Section 2.4 for additional details on the SenStar Connect Treatment Link, Hygiene Barrier, and treatment session purchasing and redemption.)

- Head cushion liner (single-use disposable)
- Head side pad liner (single-use disposable)
- Head positioning straps (single-use disposable)
- Side pad (multiple-use consumable)
- Earplugs (single-use disposable)
- SenStar Connect Treatment Link (a multiple-use consumable medical device)
- Hygienic Barrier for use with the SenStar Connect Treatment Link (single-use disposable)

When using the SenStar Treatment Link with the NeuroStar System it requires the following supplies and disposables for each treatment session. (See Section 2.4.)

- Head cushion liner (single-use disposable)
- Head side pad liner (single-use disposable)
- Head positioning straps (single-use disposable)
- Side pad (multiple-use consumable)
- Earplugs (single-use disposable)
- SenStar Treatment Link (a single-use disposable medical device)

1.14 Connection to Other Equipment

TrakStar software communicates patient data with a single or multiple NeuroStar Mobile Console(s) through a network connection. To avoid or minimize disruption of NeuroStar System communications, ensure that your network meets the specifications outlined in the NeuroStar System Technical Data Sheet.

Network infrastructure refers to the hardware and software resources of an entire network that enables network connectivity, communication, operations and management of an enterprise network. Failure to follow the network specifications outlined in the NeuroStar System Technical Data Sheet or connection of additional devices on the IT Network could result in previously unidentified risks to patients, operators or third parties. Changes to the network by the responsible organization require the network system integrator to identify, analyze, evaluate, and control any new risks and hazards. Changes to the network would include but not be limited to:

- Changes in the network configuration
- Connection of additional items to the network
- Disconnecting items from the network
- Update of equipment connected to the network
- Upgrade of equipment connected to the network
The hazardous situations that could occur based on network changes would include but not be limited to:

- Loss of data
- Inappropriate data interchange
- Corrupted data
- Inappropriate timing of data
- Unexpected receipt of data
- Unauthorized access to data

If connection of the NeuroStar System to any other systems or equipment is planned, be sure to observe the following precaution.

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g., IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with these requirements for medical electrical systems (IEC 60601-1-1 or clause 16 of the 3 Ed. of IEC 60601-1, respectively). Anyone who connects additional equipment to existing medical electrical equipment by definition has configured a medical system and is responsible that the system complies with the requirements for medical electrical systems. Local laws may take priority over these requirements. If in doubt, contact Customer Service.

Patient data is securely stored. Access to the system is controlled by operator name/password combinations. Password entry is unreadable on the display screen. Patient identification information is kept confidential and is accessible only to authorized system users. The system maintains patient records through unique identifiers.

TrakStar communicates with the mobile console and protects patient-sensitive information by using a secure communications method. This maintains the confidentiality of patient data.

Access to the NeuroStar System and to TrakStar software requires a unique operator ID/password combination.
2 NeuroStar System Components and Controls

This section provides a guide to the individual NeuroStar System components and controls and explains the basic terminology used in these Instructions For Use.

2.1 System Overview

The NeuroStar System consists of a combination of hardware, software, disposable, and consumable supplies, which are required for the operation of the system.

Major hardware components are illustrated in Figure 2-1.

NeuroStar System components and supplies are not made with natural rubber latex.

2.2 Component Descriptions

The basic configuration includes the following components which are described in this section:

- Mobile Console – An enclosed module that forms the NeuroStar System wheeled base and integrates various subsystems into a single package. It houses the processor module and the power module, and it supports the gantry, the display arm, the mast, and the display.

- System Software – A proprietary application that provides the NeuroStar System graphical user interface (GUI) and incorporates work flow management to guide the system operator through a TMS procedure. It also supervises and controls various subsystems.

- Treatment Chair – An operator-controlled, adjustable chair that positions the patient comfortably at a desired height and angle for TMS treatment and provides lumbar support.

- Head Support System – An electromechanical device that is attached to the treatment chair and that consists of several parts that are designed to provide maximum patient comfort and reliable treatment coil position measurement of the patient’s MT location and TMS treatment location. It includes a battery-powered Class 1 laser that aids in patient positioning.

- TrakStar PC – Hardware that runs the TrakStar software. It is connected with the Mobile Console through a network.

- TrakStar Software – Software that enables the operator to manage patient data and print reports; it can be local or in the cloud.
### System Controls

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- **A** Head Support System – Provides comfortable head support and MT location coordinates.
- **B** Treatment Coil – Applies TMS pulses to the patient’s head to stimulate the brain.
- **C** Halo – Supports the treatment coil.
- **D** Gantry – Supports the halo.
- **E** Mast – Supports the gantry and the display arm.
- **F** Display – Functions as the main user interface.
- **G** Display Arm – Supports the display.
- **H** Mobile Console – Houses the power and processor modules and provides support for the mast, the gantry, and the display arm.
- **I** Treatment Chair – Provides comfortable patient seating during treatment sessions.

**FIGURE 2-1. NeuroStar System Main Hardware Components**
**Mobile Console**

The mobile console is the central workstation for the NeuroStar System. The mobile console houses the power module, the processor module, the gantry assembly, mast, and the display arm assembly. The mobile console has an enclosed frame with rear doors for service. This unit provides interfaces for input power, treatment coil power, and networking. Containment in this enclosure keeps these connections out of the reach of the operator and out of view.

The mobile console is mounted on medical grade locking wheels with sufficient radius to clear elevator thresholds and other small irregularities in floor surfaces. It also has a handle that the operator grips when positioning for treatment or moving it to a new location.
**Display**

As illustrated in Figure 2-2, the display has touch-activated images of alphanumeric keys and buttons for operator interaction with the system, and displays graphic representations of system activity, messages, and alarms.

![Image of NeuroStar display with touchscreen](image)

**FIGURE 2-2. Display with Touchscreen**

The display is capable of presenting graphics, text displays, and touch controls and provides graphics system resolution of 1024 x 768 with a 15 inch (38 cm) display. It is readable from 10 feet (3 m) away in ambient light up to 100 foot candles.
The position of the display is adjustable for comfortable viewing by the operator during various stages of the workflow. It can swing both sides for both left and right side placement. During normal touchscreen operation, the display remains stationary.

The display has a viewing angle of at least 150° from side to side. It has two degrees of freedom:

- Rotation around the vertical axis
- Rotation about the horizontal axis

The display presents graphical user interface screens as described in various sections of these Instructions For Use.

The green light on the lower right-hand corner of the display indicates that the display is getting power. If the system is shut down, as described in Section 13.1 of this document, but with the power switch in the **ON** position, the green light flashes on and off at three-second intervals.

**Gantry**

The gantry consists of a mast, a balance arm, and a halo assembly that connects to the treatment coil, as shown in Figure 2-3. Movement and positioning of the gantry are tracked by software that runs in the mobile console.

![Gantry Diagram](image)

**FIGURE 2-3. Gantry: Showing the Treatment Coil, Halo, Mast, Display Arm**

<table>
<thead>
<tr>
<th>A</th>
<th>Gantry</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>Mast</td>
</tr>
<tr>
<td>C</td>
<td>Display Arm</td>
</tr>
<tr>
<td>D</td>
<td>Treatment Coil</td>
</tr>
<tr>
<td>E</td>
<td>Halo</td>
</tr>
<tr>
<td>F</td>
<td>Halo Brake</td>
</tr>
</tbody>
</table>
The gantry supports the weight of the treatment coil and allows free movement for easy placement of the treatment coil on the patient’s head. It incorporates electromechanical brakes that automatically lock four degrees of motion when the push-button switch on the treatment coil is released, or when commanded under software control. The brakes are designed to lock upon loss of power or when the mobile console is not powered.

While an operator holds the brake release button, the gantry can be moved up or down and from side to side, and the mast can be moved forward or backward. Releasing the button engages the electromechanical brakes, which hold the gantry and the mast in place.

To avoid damage to the brakes, do NOT try to move the gantry or the mast unless the system is running. Always press and hold the brake release button on the treatment coil to make any adjustments to the position of the gantry or the mast.

Display Arm
The display arm moves separately from the gantry along a horizontal plane, enabling the operator to adjust the position of the display for better readability.

Halo
The arc-shaped halo is a mechanical device that helps to hold the treatment coil in place during treatment sessions. It is connected to the mechanical halo brake assembly, which is suspended from the gantry. The halo suspends the treatment coil at one end, which is attached to the halo through the treatment coil mounting hub.

Halo Brake
The halo has an adjustable knob that holds the treatment coil in place. Turning the halo brake clockwise tightens the hold on the halo, while turning the halo brake counterclockwise loosens the hold and enables the operator to move the treatment coil until a desired position is reached.

Combined with the brake release buttons on the treatment coil, the halo and the halo brake enable the system operator to adjust the treatment coil’s position against the patient’s head.

Treatment Coil
The treatment coil is an enclosed electromagnet with push-button controls. The treatment coil generates a pulsed magnetic field that penetrates the skull and reaches the patient’s cortex when the treatment coil is placed against the patient’s head. This pulsed field is controlled by the NeuroStar System power module and system software in response to the selected settings.

During treatment sessions, a SenStar Treatment Link is attached to the face of the treatment coil and provides the contact surface with the patient’s head. Alternately during treatment, a multiple-use SenStar Connect Treatment Link is attached to the face of the treatment coil and a disposable hygienic barrier is attached to the treatment link which provides the contact surface with the patient’s head. Treatment coil buttons for brake release, pulsing, and MT level adjustment are located just above the treatment coil handle, as illustrated in Figure 2-4 and Figure 2-5. For convenience a second brake release button is located under the handle.
For treatment coil positioning, the operator grasps the treatment coil handle with one hand and the treatment coil top with the other before pressing one of the brake release buttons.

As illustrated in Figure 2-5, the treatment coil has the following control buttons:

- **Pulse Button** – Pushing this button causes the treatment coil to emit a single pulse.
- **Brake Release Button** – Pushing and holding this button releases all gantry and mast brakes, enabling the operator to move the treatment coil and reposition it. Releasing this button locks the brakes and holds the treatment coil in place until the button is pushed and held again.
- **Increment Button** – Pushing this button increases the strength of the next manually induced pulse by one increment.
- **Decrement Button** – Pushing this button decreases the strength of the next manually induced pulse by one increment.
System Software

The NeuroStar System software controls all internal system functions, monitors system status to ensure safe operation and provides the operator with a graphical means to manage a course of TMS treatment. Three important operator features of the system software are the following:

- Graphical User Interface (GUI) – This is the operator’s graphical touchscreen interface with the system. Interactive buttons, fields, and images are displayed that enable the operator to direct and interact with system functions, such as entering data, starting and stopping treatment sessions, and running diagnostics.
- MT Assist - This program facilitates motor threshold determination by calculating a predicted MT value based on a series of observations of muscle twitches in response to treatment coil pulses.
- Diagnostics – The embedded diagnostic software consists of an automated set of instructions that test and verify the operation of system components.
Treatment Chair

The treatment chair is an electromechanical device on which the patient is seated during treatment sessions with the NeuroStar System.

The treatment chair includes a programmed wired push-button control unit that adjusts the chair height and the patient’s back support angle. The control unit includes two programmed chair positions. The patient **entry/exit** position is a pre-set fixed position (M1). The patient’s reclining **treatment** position is a pre-set fixed position (M2) to ensure reproducibility of the treatment from session to session.

**NOTE**

Any change to the treatment position using the seat tilt or back support buttons on the wired push-button unit may affect the reproducibility of returning to the same cranial treatment location from session to session and could affect successful treatment.

The treatment chair also includes a substantial base for overall stability and a built-in adjustable lumbar support cushion for patient comfort. The chair can accommodate a maximum weight of 400 lbs. (181 kg.).

Head Support System

The head support system consists of several parts that are designed to provide maximum patient comfort and reliable treatment coil position measurement of the patient’s motor threshold (MT) location. The individual parts are identified in Figure 2-6. The rear view of the head support system is illustrated in Figure 2-9.

The NeuroStar System was verified to navigate to motor threshold and treatment points within the specification of ±5 mm, which compared well, with slightly improved accuracy, as compared to the NeuroStar System model that was used in the clinical trials.

The head support system is a mechanical attachment mounted on the treatment chair that provides comfortable support for the patient’s head during treatment sessions. It can be adjusted to accommodate a range of patient positions and physical characteristics, and it can be adjusted freely in the anterior-posterior (front/back) as well as the inferior-superior (up/down) directions for patient comfort.

The following head support system components are used to establish and record the patient’s head position.

**Side Pad** – A moveable cushion that is mounted on the side pad arm. It is designed to be set up on either the left or right side of the patient’s head. The operator can move the side pad toward or away from the side of the patient’s head until a comfortable position has been established.

**Superior Oblique Angle (SOA) Scale** - An angle indicator located behind the head support cushion and associated with a pivot arm that supports the Anterior/Posterior (A/P) bar. The pivot arm allows the A/P bar to be rotated through a range of superior oblique angles +/- 45° from the mid-sagittal position in 1 degree increments.
**System Controls**

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**FIGURE 2-6. Head Support System with Patient Alignment Parts**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td>Head Cushion Liner</td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>Head Side Pad Arm</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>Head Side Pad and Liner</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td>Treatment Coil Angle Indicator</td>
</tr>
<tr>
<td><strong>E</strong></td>
<td>A/P Bar Brake Release Grip</td>
</tr>
<tr>
<td><strong>F</strong></td>
<td>A/P Arrow</td>
</tr>
<tr>
<td><strong>G</strong></td>
<td>Anterior/Posterior (A/P) Bar</td>
</tr>
<tr>
<td><strong>H</strong></td>
<td>A/P Alignment Scale</td>
</tr>
<tr>
<td><strong>I</strong></td>
<td>Superior Oblique Angle (SOA) Scale</td>
</tr>
<tr>
<td><strong>J</strong></td>
<td>Lateral Canthus (LC) Scale</td>
</tr>
</tbody>
</table>

**Anterior/Posterior (A/P) Bar** - A flat scale in centimeters with 1 millimeter increments that aids in accurately positioning the treatment coil. The A/P bar moves parallel to the patient’s A/P axis and provides a calibrated index of its position.

**Laser On/Off Button** – A push-button on the top of the A/P bar that controls activation and deactivation of the laser. The laser projects a straight line on the patient’s face and aids in aligning the patient’s head prior to treatment coil positioning for MT determination and TMS treatment.

**Laser Positioning Aid** - When activated, a laser light line is used to align the patient’s head in the head support system. The laser electronics are housed in the A/P bar. A printed circuit board drives laser activation and is powered by a 1.5 V AA battery (lithium), which is located in the A/P bar.
Lateral Canthus (LC) Scale - A flat scale in centimeters with millimeter increments that is oriented in the patient’s superior/inferior direction and is located behind the head support cushion. This scale is used to indicate a reference position for aligning the patient’s head to the head support system for repeatable positioning from session to session.

Treatment Coil Angle Guide and Treatment Coil Angle Indicator - A flat pivoting scale and an orange-colored straight edge that are attached to the end of the A/P bar. This combination is used to record the position of the treatment coil up to 35° to the left or right of the center location in 5° increments. As illustrated in Figure 2-7, the treatment coil angle indicator is a stationary straight-edge piece that is attached to the treatment coil angle guide. When the treatment coil angle assembly is placed flush against the side of the treatment coil (Figure 2-8), the treatment coil angle guide pivots, which enables the operator to read the angle.

Treatment Chair Push-button Controller – A wired controller that is used to raise or lower the chair’s height and to choose protocol-defined programmed positions.

Front/Back Adjustment Knob – A manually adjustable clamp that holds the head positioner in place or allows the head positioner to be moved backward or forward to attain a position that is both comfortable and correct for treatment.

Front/Back Scale – A flat scale in centimeters with 1 millimeter increments that is used to record the horizontal position of the head support system relative to the chair.

Head Support Handle – A molded plastic grip that assists in the movement of the head support system.

Lateral Canthus (LC) Adjustment Knob – A manually controlled knob that is used to raise or lower the head support system and to record the lateral canthus position for future treatment sessions.

Up/Down Scale – A flat scale in centimeters with 1 millimeter increments that is used to record the height of the head support system.

Up/Down Adjustment Knob – A manually controlled knob that is used to raise or lower the head positioner and to hold the head support system in place when a comfortable height has been established.

Treatment Coil Cable Guide – A molded plastic receptacle for holding the treatment coil cable in place during positioning and treatment sessions.
A  Up/Down Scale
B  Front/Back Scale
C  Radial Bar
D  Laser On/Off Button
E  LC Adjustment Knob
F  Head Support Handle
G  Treatment Coil Cable Guide
H  Front/Back Adjustment Knob
I  Up/Down Adjustment Knob
J  Lumbar Support Bulb
K  Treatment Chair Push-button Controller

FIGURE 2-9. Head Support System (with Treatment Chair) - Rear View
Head Support Inner Cushions

Two removable cushions that provide support for patient positioning and patient comfort. The set consists of the following:

- Top inner cushion (shown at right in Figure 2-10)
- Lower Inner cushion (shown at left in Figure 2-10)

Before the patient is seated, the lower inner cushion is positioned into the oval opening as far in as possible (Figure 2-10). If more support is needed for proper treatment coil positioning, the top inner cushion can be positioned in front of the lower inner cushion.

Cushion Set

A set of four cushions that provide patient comfort during the Motor Threshold search process and during treatment sessions:

- Seat cushion (Figure 2-11)
- Arm rest cushions (2) (Figure 2-12)
- MT wedge cushion (Figure 2-13)

NOTE

The cushions used with the NeuroStar System are reusable components. To prevent cross-contamination skin reactions, it is recommended to follow cleaning instructions in "4.1.1 Cleaning and Disinfecting".
Spacer Block
A molded foam block that fits between the mobile console and the base of the treatment chair. At installation, your local field service engineer will set the spacer block (Figure 2-14), which rests on the floor and maintains the recommended distance between these components for effective system operation. The spacer block rests on the floor and maintains the required distance between these major components for effective system operation.

FIGURE 2-14. Spacer Block

Treatment Room Sign
The NeuroStar System includes a sign that operators should consider posting in a prominent place as a safety precaution. (See “Appendix F. Informational and Instructional Labels”.)

2.3 TrakStar Software
The NeuroStar System may include a separate Windows personal computer set that is used to access the TrakStar software. TrakStar software communicates with the mobile console through a wired network.

The NeuroStar System may also be configured to access patient information via TrakStar Cloud. TrakStar Cloud communicates with the mobile console through an Internet connection.

TrakStar is a Patient Data Management System (PDMS) that is used with the NeuroStar System. Refer to the TrakStar Instructions For Use for details.

To connect the NeuroStar Console to TrakStar Local or TrakStar Cloud, use the NeuroStar Ethernet cable.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

2.4 Supplies and Disposables
Operating the NeuroStar System requires the use of the following disposables and supplies:

- SenStar Connect Treatment Link with Hygienic Barrier or SenStar Treatment Links
- Head Cushion Liners
- Head Positioning Straps
- Side Pads
- Side Pad Liners
- Earplugs
The SenStar Connect Treatment Link is a multiple-use consumable component (Figure 2-15 and Figure 2-16) that uses a disposable hygienic barrier component (Figure 2-19) that serves three primary purposes:

- It includes a contact-sensing element that detects when the treatment coil is properly positioned against the patient’s head.
- It detects the level of the magnetic field being applied by the treatment coil.
- It reduces the magnetic field at the patient’s scalp (without affecting the deeper therapeutic field in the cortex) to aid in patient comfort during treatment sessions.

**NOTE**

The SenStar Connect Treatment Link is used with a one-time use disposable hygienic barrier component (Figure 2-19) which are required for optimal performance of the NeuroStar System by providing the features listed above. The NeuroStar System will not operate without an active SenStar Connect Treatment Link. The SenStar Connect Treatment Link is intended for multiple-use and is deactivated after 3,000 patient treatment sessions. The SenStar Connect Treatment Link is intended to remain in place on the treatment coil for multiple treatment sessions and multiple patients. Do Not Remove the SenStar Connect Treatment Link from the Treatment Coil between treatment sessions or it will be damaged and require replacement. A new hygienic barrier is applied to the SenStar Connect Treatment Link prior to the start of each treatment session.

When using the multiple-use SenStar Connect Treatment Link, every treatment administered on a NeuroStar System mobile console requires that a NeuroStar Treatment Session be purchased and present in TrakStar (i.e., redeemed) before a treatment session can be conducted. Treatment sessions are automatically entered for users of TrakStar Cloud. Treatment sessions can be purchased in minimum batches of five, either online through the Web Store or by calling Customer Service. Reference the *TrakStar Instructions For Use* for information about purchasing and redeeming treatment sessions.

**FIGURE 2-15. SenStar Connect Treatment Link - Hygienic Barrier Contact Surface**

**FIGURE 2-16. SenStar Connect Treatment Link - Treatment Coil Contact Surface**
The SenStar Treatment Link is a one-time use disposable component (Figure 2-17 and Figure 2-18) that serves four primary purposes:

- It includes a contact-sensing element that detects when the treatment coil is properly positioned against the patient’s head.
- It detects the level of the magnetic field being applied by the treatment coil.
- It reduces the magnetic field at the patient’s scalp (without affecting the deeper therapeutic field in the cortex) to aid in patient comfort during treatment sessions.
- It provides a clean hygienic surface for each treatment session.

**NOTE**

The SenStar Treatment Link is required for use of the NeuroStar System by providing the features listed above. It is intended for single-use and is deactivated at the end of the patient treatment session. The NeuroStar System will not operate without an active SenStar Treatment Link. Because the SenStar Treatment Link is in contact with the patient’s hair and/or scalp, to prevent cross-contamination skin reactions, the SenStar Treatment Link is limited to single patient use.

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**System Controls**

**SenStar Treatment Link**

The hygienic barrier (Figure 2-19) is a thin, medical grade fabric disposable cover with adhesive on one side which is applied to the SenStar Connect Treatment Link in the treatment coil prior to the start of each treatment session. It provides a clean hygienic surface for each treatment session. Since the hygienic barrier is in contact with the patient’s hair and/or scalp, to prevent cross-contamination skin reactions, the hygiene barrier is limited to single patient use.

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The hygienic barrier (Figure 2-19) is a thin, medical grade fabric disposable cover with adhesive on one side which is applied to the SenStar Connect Treatment Link in the treatment coil prior to the start of each treatment session. It provides a clean hygienic surface for each treatment session. Since the hygienic barrier is in contact with the patient’s hair and/or scalp, to prevent cross-contamination skin reactions, the hygiene barrier is limited to single patient use.
**Head Cushion Liner**

The head cushion liner (Figure 2-20) is a thin, tissue-like disposable cover that is placed on the head cushion as a hygienic barrier for each patient session.

![Figure 2-20. Head Cushion Liner](image)

**Side Pad**

The side pad (Figure 2-21) is a replaceable foam pad that is mounted on the side pad bracket for further patient comfort. During treatment sessions, the side pad is covered by a disposable side pad liner.

![Figure 2-21. Side Pads](image)
**Side Pad Liner**  
The side pad liner (Figure 2-22) is a thin, tissue-like disposable cover that is placed on the side pad as a hygiene barrier for each patient session.

![Side Pad Liners](image)

**Ear Plugs**  
Hearing protection is provided by commercial-grade noise reduction ear plugs (Figure 2-23) made of malleable foam for custom fit in the ear canal. They are rated for 30 dB of noise reduction.

![Ear Plugs](image)
**Head Positioning Strap**

The head positioning strap (Figure 2-24) is a single-use enhanced paper tape that has Velcro and adhesive for a custom fit on the patient’s head. It is used to aid in maintaining the position of the patient’s head during MT search and treatment sessions.

![Head Positioning Strap](image)

*FIGURE 2-24. Head Positioning Strap*

**Treatment Pack**

A treatment pack contains these supplies (see Figure 2-25):

- Head Cushion Liner
- Side Pad Liner
- Head Positioning Strap
- Hygiene Barrier

*NOTE* To prevent cross-contamination skin reactions, it is recommended that the Treatment Pack components be limited to single patient use.

![Treatment Pack Contents](image)

*FIGURE 2-25. Treatment Pack Contents: Side Pad Liner, Head Cushion Liner, Head Positioning Strap, and Hygiene Barrier*
2.5 Starter Kit

Each NeuroStar System is delivered with a package of ancillary parts and enough supplies to start treating patients without delay. This package is called the “starter kit.” The starter kit contents are listed below. Quantities are subject to change.

**Quantity/Description:**

1. NeuroStar Room Sign - Caution
2. NeuroStar Side Head Pads
3. NeuroStar Ear Plug Pairs (Packs)
4. NeuroStar Chair Cushion
5. NeuroStar Arm Support Cushions
6. NeuroStar MT Wedge Cushion
7. NeuroStar Head Cushions
8. NeuroStar Mobile Console Spacer
9. Treatment Chair Foot Rest Cover
10. Lithium AA Batteries (2-Pack) for Use in the A/P Bar
11. CAT 6 Cable
12. Head Support Adjustment Knob
13. Quick Start Guide
15. Alcohol Prep Pads (Pack)

**Provided Separately:**

*Instructions For Use*
*Technical Data Sheet*
*TrakStar Personal Computer and Accessories*
*SenStar Connect Treatment Links or SenStar Treatment Links*
*Treatment Sessions*
*Treatment Packs*
*Ear Plug Packs*
3 System Management Using the Display

Overview

Section 3 of this volume and the TrakStar Instructions For Use provide system administration steps and technical information. System administration steps require an administrator’s operator ID and password combination for the mobile console and TrakStar.

Volume 2 of these Instructions For Use describes the daily clinical procedures for use of the NeuroStar System. For information on system start-up and log in, see Section 9.

System administration steps require an administrator’s operator ID and password combination for the mobile console and TrakStar.

The mobile console Configuration tab enables the operator to view the system’s license expiration date.

The Configuration tab also includes a DIAGNOSTICS button, which enables the administrator to perform the following additional system administration tasks:

- Change individual system parameters.
- Calibrate the touchscreen.
- Display the software version numbers associated with the mobile console.

To perform any of these tasks using the touchscreen:

1. Log in as a system administrator.
2. At the SenStar Treatment Coil Test screen, touch the GO TO CONFIG button to display the mobile console Configuration screen (Figure 3-1).

NOTE

The Coil contains a fan to keep the Coil cool. It will come on automatically at varying speeds as needed.
3.1 Changing System Configuration Parameters

The NeuroStar System is pre-configured upon delivery with the default values listed on the next page. To change any of the operator-accessible system parameters, touch the button for the corresponding parameter and use the slider to change the parameter.
## NeuroStar System Instructions For Use

### Volume 1, Section 3

#### System Management

### Display

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
<th>Options</th>
<th>Default</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alarm Sounds</td>
<td>Controls the activation of audible tones when the system experiences a malfunction that requires the operator’s attention.</td>
<td>ON/OFF</td>
<td>ON</td>
</tr>
<tr>
<td>Pre-Train Notification</td>
<td>Controls the activation of an audible tone preceding the start of a treatment session train.</td>
<td>ON/OFF</td>
<td>ON</td>
</tr>
<tr>
<td>End of Treatment Chime</td>
<td>Controls the activation of an audible tone that sounds 2 seconds before the end of a treatment session.</td>
<td>ON/OFF</td>
<td>ON</td>
</tr>
<tr>
<td>Contact Sensor Auto Pause</td>
<td>Controls the automatic sensor that stops the system from administering more trains when contact between the SenStar Treatment Link and the patient’s head has been lost due to patient or treatment coil movement.</td>
<td>ON/OFF</td>
<td>OFF</td>
</tr>
<tr>
<td>Allow Treatment Extension</td>
<td>Controls the addition of trains at the end of a session to make up for the trains that were missed because of lost SenStar Treatment Link contact with the patient’s head.</td>
<td>ON/OFF</td>
<td>ON</td>
</tr>
<tr>
<td>% MT Level Ramping</td>
<td>Controls the gradual increase of MT level at the start of a treatment session.</td>
<td>Off (no ramping) Short (5 trains) Long (10 trains)</td>
<td>Short</td>
</tr>
<tr>
<td>Speaker Volume</td>
<td>Controls the audible volume of system alarms and other system sounds.</td>
<td>1 – 10 (Soft – Loud) (adjusted at installation)</td>
<td>10</td>
</tr>
</tbody>
</table>

The “Configuration” screen provides the following additional capabilities through buttons located below the parameter fields.

<table>
<thead>
<tr>
<th>Button</th>
<th>Function</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostics</td>
<td>Enables the operator to calibrate the touchscreen and to display system software version numbers and IP addresses.</td>
<td>See Section 3.2, below.</td>
</tr>
<tr>
<td>License</td>
<td>Enables the operator to view the status of the system license.</td>
<td>None</td>
</tr>
</tbody>
</table>

Step-by-step instructions for each button are listed below.
3.2 Performing Diagnostic Functions

The **DIAGNOSTICS** button on the Configuration tab provides access to several additional functions. These functions are listed below.

<table>
<thead>
<tr>
<th>Button</th>
<th>Function</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Touchscreen</td>
<td>Enables the operator to ensure that the display is functioning properly.</td>
<td>None</td>
</tr>
<tr>
<td>Calibration</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Versions     | Enables the operator to display component identification numbers and TrakStar connection status. | Serial number  
Mobile console software version number  
Mobile console IP address  
Power module software version number  
Processor module software version number  
Treatment Coil module software version number  
TrakStar PC IP address and connection status |
| Configuration| Enables the operator to close the Diagnostics screen and to display the Configuration screen. | None                                                                    |
Figure 3-2. Diagnostics Screen

Touch the line that corresponds to an event in the list to display a description of that event in the field below the list.

**NOTE**

This list is important if there is a need to contact Customer Service for help.
3.3 **Calibrating the Touchscreen**

If the touch-sensitive area of the display does not appear to be in sync with the related screen image, the touchscreen calibration capability enables the operator to get the area and the image back in sync.

**NOTE**

Once this process is started, it can be stopped by waiting for the 10-second time-out countdown to finish.

At the NeuroStar System Diagnostics screen (Figure 3-2), touch the **TOUCHSCREEN CALIBRATION** button. In response, the system displays the “Touchscreen Calibration” screen with several animated targets, one at a time (Figure 3-3).

![Touchscreen Calibration](image)

**FIGURE 3-3. Touchscreen Calibration**

Touch the center of the target area on the screen each time the system repositions the target until the calibration process is finished.
After all targets have been touched, the system displays the calibration acceptance screen (Figure 3-4).

![Calibration Acceptance Screen](image)

FIGURE 3-4. Calibration Acceptance Screen

Touch the **Accept** button to finish the process or touch the **Cancel** button to end the calibration process and to display the Diagnostics screen (Figure 3-2). The **Cancel** button includes a 90-second countdown.

**NOTE**

If the **TOUCHSCREEN CALIBRATION** button is touched by accident, do not touch the screen for 10 seconds so that the calibration function may automatically time out. At that point, the system displays the Diagnostics screen (Figure 3-2).
3.4 **Displaying Software Version Numbers**

At the “Diagnostics” screen (Figure 3-2), touch the **VERSIONS** button to display the system “Version Information” dialogue box (Figure 3-5).

![Version Information Dialogue Box](image)

**FIGURE 3-5. “Version Information” Dialogue Box**

After viewing this information, touch the **OK** button.
3.5 Viewing System License Information

To view license information, touch the LICENSE button on the “Configuration” screen (Figure 3-1). In response, the system displays the “Licensing” screen (Figure 3-6).

FIGURE 3-6. Licensing Screen
3.6 **TouchStar Enabled Console**

If the optional TouchStar feature is enabled, the banner at the top of the console screen will change to indicate that the console is TouchStar enabled. The TouchStar icon and color-bar will appear at the top of every screen frame regardless of the operation being performed (including the Login screen) as shown in Figure 3-7 and Figure 3-8.

FIGURE 3-7. TouchStar Banner at top of the Login Screen
FIGURE 3-8. TouchStar Banner at top of the Treatment Screen

**NOTE**

The TouchStar banner change will take effect after the first login on the console once the TouchStar feature has been enabled.
4 Routine Maintenance, Alarms, and Troubleshooting

This section provides instructions for maintaining the NeuroStar System.

- **Routine Maintenance**
  Section 4.1 provides instructions for keeping the system clean and checking for damage.

- **Alarms Button**
  Section 4.2 describes the use of the Alarms button, which is displayed on each NeuroStar System screen.

- **Alarm Messages**
  Section 4.3 provides the possible display messages and their meanings.

- **Troubleshooting**
  Section 4.4 provides routine system observations and suggested corrective actions.

- **Changing the A/P Laser Battery for Model 81-03842-000**
  Section 4.5 provides the steps for replacing the A/P bar laser battery for this model number.

- **Changing the A/P Laser Battery for Models 81-00842-000 and 81-02842-000**
  Section 4.6 provides the steps for replacing the A/P bar laser battery for these model numbers.

- **Replacing the Treatment Chair Head Support Up/Down Locking Knob**
  Section 4.7 provides the steps for replacing the Head Support Locking Knob.

- **Cleaning the A/P Bar Rail**
  Section 4.8 provides steps for cleaning the A/P Bar Rail.

The NeuroStar System is designed to provide reliable service in a convenient self-contained package. The instructions in this section cover preventive maintenance steps and the most basic diagnostic and troubleshooting steps.

The NeuroStar System software has many self-checking features and displays error messages in the unlikely event that it encounters problems.

Except for the A/P bar laser battery and the Head Support Locking Knob, there are NO operator-serviceable parts in the NeuroStar System. NO components of the NeuroStar System can be serviced while in use on a patient. If the system is not operating properly, contact Technical Support. If the system malfunction has created a hazardous condition, unplug the power cord from the wall receptacle before contacting Technical Support for assistance.
4.1 Routine Maintenance

The NeuroStar System requires minimal routine maintenance, as described below.

4.1.1 Cleaning and Disinfecting

- With the power off and the system unplugged from the wall receptacle, use a damp cloth to wipe away dust or dirt on the mobile console, the power cable, the signal cable, the halo, the gantry, and the mast.
- Clean the surface of the treatment coil by wiping it with an isopropyl alcohol prep pad.

**Keep all cleaning fluids or damp sponges away from the SenStar Connect Treatment Link and the SenStar electrical connector on the treatment coil.**

- Clean the surface of the reusable cushions by wiping it with a damp sponge and/or by blotting with a clean cloth, using a water-based cleaning product or mild soap and water.
- Only the following cleaning agents should be used to clean the treatment chair, mobile console, and display housing:
  - 70% Isopropyl Alcohol
  - Arquad (a Quaternary Ammonium Chloride)
  - Professional Lysol Disinfectant Spray

- **Do NOT use any cleaner or damp cloth on the SenStar Connect Treatment Link; it is not meant to be cleaned.**
- Do NOT use bleach as a cleaner as it will discolor the fabric or paint.
- Do NOT use any cleaner with higher than 70% alcohol content as it will smear the logos on the housings.
- Do NOT use any type of solvent or lubricant on the component parts.
- Do NOT use acetone to clean any part of the system.
- Do NOT attempt to sterilize any part of the system.

**Failure to follow these procedures may result in damage to the device or may cause undue risk to the patient or operator.**

Use a damp cloth to clean the display. Do NOT use glass cleaner, cleanser, or any abrasive substance.
4.1.2 Routine Care

- Ensure that the proper local conditions match the system requirements. (See the system specifications, Section 5 of this volume.)
- Ensure that the power cable plug is intact and that the system is connected only to a grounded wall receptacle.
- Ensure that the mobile console housing, the gantry covers, and the display case are intact. If there are any cracked or broken areas, contact Technical Support for service.
- Use a sponge or cloth to soak up any small spills on the equipment. If the spill includes bodily fluids, observe all biohazard precautions.
- If a large amount of liquid is spilled on the unit, turn off the system, disconnect the power cable from the wall receptacle, and contact Technical Support for assistance.

4.1.3 Preventive Maintenance

A preventive maintenance visit from your local field service engineer is recommended every 12 months.

4.2 Alarms Button

The system displays the Alarms button on all screens. Touching this button displays the “Alarm” pop-up window and provides the following capabilities (see Figure 4-1):

- Viewing a list of active alarms.
- Muting only the tones for alarms that are already on the list by touching the SILENCE button.

For a list of alarm messages and what they mean, see Section 4.3, below.

FIGURE 4-1. Alarm Pop-Up Window
### 4.3 Alarm Messages

The following table lists the alarm icons along with the displayed text, likely causes, and remedies. The alarm icons are displayed in a box at the top of the display screens according to the following color assignment:

- **Warning** alarms are displayed in red.
- **Caution** alarms are displayed in orange.
- **Advisory** alarms are displayed in white.

**NOTE** References to “SenStar” apply to both SenStar Treatment Link and SenStar Connect Treatment Link usage unless otherwise stated.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Displayed Text</th>
<th>Activation Conditions</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Auto Pause Icon" /></td>
<td>Auto Pause</td>
<td>Poor treatment coil contact was detected during a treatment session and the treatment session is automatically paused.</td>
<td>Readjust the treatment coil’s position until contact has been reestablished. Note that the Auto Pause feature is configurable in the Configuration screen. (See Section 3.1.)</td>
</tr>
<tr>
<td><img src="image" alt="Treatment coil Standby Pressed Icon" /></td>
<td>Treatment coil Standby Pressed</td>
<td>The Treatment Coil Power switch is set to <strong>OFF</strong>.</td>
<td>If the treatment coil is properly connected and ready for use, move the Coil Power switch from <strong>OFF</strong> to <strong>ON</strong> (Figure 4-2).</td>
</tr>
<tr>
<td><img src="image" alt="Treatment Coil is not connected Icon" /></td>
<td>Treatment Coil is not connected</td>
<td>The system does not detect a treatment coil.</td>
<td>Check the connection between the treatment coil and the mobile console.</td>
</tr>
<tr>
<td><img src="image" alt="Coil Module Disconnected Icon" /></td>
<td>Coil Module Disconnected</td>
<td>The system detects that the treatment coil is disconnected from the mobile console.</td>
<td>Check the connection between the treatment coil and the mobile console.</td>
</tr>
<tr>
<td><img src="image" alt="Lost Treatment Coil Contact Icon" /></td>
<td>Lost Treatment Coil Contact</td>
<td>Treatment coil contact has been lost during a treatment session or while auto pulsing in MT level mode.</td>
<td>Adjust the side support or the treatment coil to re-establish treatment coil contact.</td>
</tr>
<tr>
<td><img src="image" alt="NO ICON Image" /></td>
<td>Magnetic Field Strength Failed</td>
<td>The pulse test timed out. The treatment coil does not detect a SenStar Treatment Link.</td>
<td>Make sure the SenStar is properly mounted on the treatment coil and retry. If after a few tries the pulse test continues to fail, try a different SenStar. If failures continue, contact Technical Support.</td>
</tr>
<tr>
<td>Icon</td>
<td>Displayed Text</td>
<td>Activation Conditions</td>
<td>Remedy</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>NO ICON</td>
<td>Magnetic Field Strength Failed</td>
<td>The pulse test generated a result that is outside of the programmed range.</td>
<td>Make sure the SenStar is properly mounted on the treatment coil and retry. If after a few tries the pulse test continues to fail, try a different SenStar. If failures continue, contact Technical Support.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The selected pulse sequence parameters exceed the NINDS safety guidelines.</td>
<td>A parameter has been changed in the protocol selection resulting in a Stimulus Interval that exceeds the 1998 NINDS Consensus Guidelines, as specified in the 1998 NINDS Consensus Guidelines Table. This alarm also is posted if a change to the %MT parameter during treatment causes these guidelines to be exceeded – in this case the alarm is automatically cleared after 10 seconds.</td>
<td>Review the parameters prior to treatment and before touching the CONFIRM PULSE SEQ. button. If the %MT parameter is changed during treatment, make sure that the change is necessary.</td>
</tr>
<tr>
<td></td>
<td>Selected TouchStar parameters may deliver lower MT dosage than prescribed.</td>
<td>A parameter (the %MT or Interpulse Interval) has been changed in the protocol selection resulting in a condition that could result in more than a 5% intensity drop from the first pulse to the 3rd pulse in the burst of pulses. This could result in delivering a lower MT dosage than prescribed.</td>
<td>Review the parameters prior to treatment and ensure the selected parameter values are necessary. Confirm the pulse sequence and confirm the change to proceed.</td>
</tr>
<tr>
<td></td>
<td>The selected pulse parameters exceed the expected limits.</td>
<td>The selected pulse parameters exceed the expected limits.</td>
<td>As stated in the alarm message, increase the interval one second at a time until the alarm resolves.</td>
</tr>
<tr>
<td>Icon</td>
<td>Displayed Text</td>
<td>Activation Conditions</td>
<td>Remedy</td>
</tr>
<tr>
<td>-------</td>
<td>-------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>☃️</td>
<td>Coil Temperature has reached 41 °C. Consider pausing treatments.</td>
<td>The temperature of the treatment coil has reached 41 °C. The operator may choose to pause the treatment session and wait for the treatment coil to cool or continue treatment.</td>
<td>If necessary, allow the treatment coil to cool when the alarm is displayed. To cool, move the treatment coil from the treatment position to a position away from the patient’s head and let the coil cool.</td>
</tr>
<tr>
<td>℃</td>
<td>Treatment Coil Temperature has reached 44 °C (maximum).</td>
<td>The treatment coil temperature is at the maximum of 44 °C at the surface. The session will automatically pause, and the <strong>RESUME</strong> button will be disabled until the treatment coil temperature has cooled to an acceptable level. This may take about 15 minutes, depending on the room temperature.</td>
<td>To cool, move the treatment coil from the treatment position to a position away from the patient’s head and let the coil cool. Reposition the treatment coil for treatment and touch the <strong>RESUME</strong> button after it becomes active, indicating that the treatment coil has sufficiently cooled. Contact Technical Support if the system continues to display this message after cooling for 15 minutes.</td>
</tr>
<tr>
<td>🚫</td>
<td>SenStar is not connected</td>
<td>The system detects that the SenStar Treatment Link is disconnected. The alarm is cleared once the SenStar Treatment Link is connected.</td>
<td>Check that the SenStar Treatment Link is properly connected. Install a new SenStar Treatment Link on the treatment coil.</td>
</tr>
<tr>
<td>🚫</td>
<td>SenStar changed during treatment.</td>
<td>The operator paused the system, removed the SenStar Treatment Link, and installed a different SenStar Treatment Link.</td>
<td>Install the original SenStar Treatment Link.</td>
</tr>
<tr>
<td>🚫</td>
<td>Power Module Low Voltage Temperature High or Power Module High Voltage, Temperature High</td>
<td>The temperature of the low voltage or the high voltage power supply has reached the power module’s high temperature set point. This alarm is cleared when the power module reports the temperature is below the set point.</td>
<td>Clear away anything that might be blocking the system’s air intake vents. Use the room thermostat to lower the temperature in the room. If these steps do not clear the alarm or if the fans are not working contact Technical Support.</td>
</tr>
<tr>
<td>Icon</td>
<td>Displayed Text</td>
<td>Activation Conditions</td>
<td>Remedy</td>
</tr>
<tr>
<td>------</td>
<td>----------------</td>
<td>-----------------------</td>
<td>--------</td>
</tr>
<tr>
<td>🚫</td>
<td>Incompatible treatment coil connected.</td>
<td>The treatment coil connected to the mobile console needs to be replaced.</td>
<td>Contact Technical Support.</td>
</tr>
<tr>
<td>📞</td>
<td>Call Service.</td>
<td>The system detects a failure in the treatment coil temperature monitoring subsystem. The room may be at or below 15º C at the start of the treatment day.</td>
<td>Contact Technical Support.</td>
</tr>
<tr>
<td>📞</td>
<td>Change in pulse duration was detected. Call Technical Support.</td>
<td>The pulse test generated a result that is outside of the programmed range.</td>
<td>Stop treatment and contact Technical Support.</td>
</tr>
<tr>
<td>🗣️</td>
<td>TrakStar Unavailable</td>
<td>The connection to TrakStar has been lost.</td>
<td>Check that the TrakStar PC is working. Check that the TrakStar is running. Check that the network connection is working. Check that the network cable is connected to both the TrakStar and the mobile console. Check for the proper settings for Windows Firewall (off) and Windows Automatic Updates (off). If using TrakStar Cloud, check that the internet connection is working. Treatments can continue offline for 72 hours as long as at least one treatment session is available. A “countdown” message with the amount of time remaining is displayed: &lt;HH.MM&gt; OFFLINE TIME Remaining</td>
</tr>
<tr>
<td>🎶</td>
<td>SenStar Connect needs to be replaced soon.</td>
<td>SenStar Connect Treatment Link is reaching end of life. 100 or fewer sessions left on SenStar Connect.</td>
<td>Order SenStar Connect Treatment Links as soon as possible.</td>
</tr>
<tr>
<td>🎶</td>
<td>You need to replace your SenStar Connect very soon.</td>
<td>SenStar Connect Treatment Link is close to reaching end of life. 10 or fewer sessions left.</td>
<td>Order SenStar Connect Treatment Links immediately.</td>
</tr>
<tr>
<td>🎶</td>
<td>This SenStar Connect has reached its End of Life. Please replace.</td>
<td>SenStar Connect Treatment Link has reached end of life. No more sessions left.</td>
<td>Replace SenStar Connect Treatment Link.</td>
</tr>
</tbody>
</table>
4.4 *Troubleshooting* In addition to these alarms, use the following table to remedy possible operating problems. If the steps in the “Remedy” column do not solve the problem, contact Technical Support.

**NOTE** References to “SenStar” apply to both SenStar Treatment Link and SenStar Connect Treatment Link usage unless otherwise stated.

<table>
<thead>
<tr>
<th>Observation</th>
<th>Likely Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>System does not start up when the Reset button is pressed, display is dark.</td>
<td>System is not getting power.</td>
<td>Check that the unit is plugged into an electrical receptacle and check that the mobile console Mains power switch is in the “ON” position. Check that the electrical receptacle is receiving power by trying a lamp or other device on the same receptacle. Check that the circuit breaker for the electrical receptacle has not been tripped. If it has been tripped, reset it. If the circuit breaker trips again, ask the building maintenance representative to check the circuit. Clear away anything that might be blocking the system’s air flow outlets.</td>
</tr>
<tr>
<td>System is getting power, but the power module has overheated and has shut down.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observation</td>
<td>Likely Cause</td>
<td>Remedy</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>System starts, but the treatment coil does not respond.</td>
<td>The Treatment Coil Power switch is in the OFF position.</td>
<td>Move the Treatment Coil Power switch to the ON position.</td>
</tr>
<tr>
<td></td>
<td>The treatment coil cable is not connected to the mobile console.</td>
<td>Connect the treatment coil cable to the mobile console.</td>
</tr>
<tr>
<td></td>
<td>The treatment coil buttons have been damaged.</td>
<td>If the treatment coil buttons are damaged, contact Technical Support.</td>
</tr>
<tr>
<td>Display does not illuminate.</td>
<td>Display cable is disconnected.</td>
<td>Connect the display cable to the display.</td>
</tr>
<tr>
<td></td>
<td>Display has failed.</td>
<td>If the cable is pinched, straighten it and try again.</td>
</tr>
<tr>
<td></td>
<td>Display cable is pinched or broken.</td>
<td>If the cable is broken, contact Technical Support.</td>
</tr>
<tr>
<td>Display image is distorted.</td>
<td>Display cable is loose.</td>
<td>Tighten the thumbscrews that hold the display cable connector in place.</td>
</tr>
<tr>
<td>System starts but does not allow the operator to log in.</td>
<td>More than 15 months have passed since a preventive maintenance visit.</td>
<td>Contact Technical Support.</td>
</tr>
<tr>
<td>Start-up diagnostics show failures for any tests.</td>
<td>Software failure.</td>
<td>Restart the system.</td>
</tr>
<tr>
<td></td>
<td>Hardware failure.</td>
<td>If using TrakStar Cloud, make sure the Internet connection is working.</td>
</tr>
<tr>
<td></td>
<td>TrakStar is not connected or TrakStar PC is turned off.</td>
<td>If not using TrakStar Cloud, make sure that the TrakStar PC is running and that the TrakStar software is active.</td>
</tr>
<tr>
<td>Display does not respond to commands.</td>
<td>Display/power supply connection problem.</td>
<td>Tighten the thumb screws that hold the display connector in place.</td>
</tr>
<tr>
<td></td>
<td>Display needs to be calibrated.</td>
<td>Hold a finger on the display until the display calibration screen is displayed.</td>
</tr>
<tr>
<td></td>
<td>Major software failure.</td>
<td>Complete the display calibration process (Section 3.3).</td>
</tr>
<tr>
<td></td>
<td>Display failure.</td>
<td>Press the system reset button located on the front of the mobile console (see Figure 4-2).</td>
</tr>
</tbody>
</table>

Contact Technical Support.
<table>
<thead>
<tr>
<th>Observation</th>
<th>Likely Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Display shows the following message: “Invalid SenStar. Please install a valid SenStar.”</td>
<td>A used SenStar Treatment Link has been installed.</td>
<td>Install a new SenStar Treatment Link.</td>
</tr>
<tr>
<td>System does not detect the presence of the SenStar Treatment Link by sounding the confirmation tone.</td>
<td>SenStar Treatment Link malfunction or system malfunction.</td>
<td>Check the SenStar Treatment Link installation and alignment. Try a different SenStar Treatment Link.</td>
</tr>
<tr>
<td>Treatment coil moves away from the patient’s head during MT search, MT determination, or treatment.</td>
<td>Halo brake is not locked. Brake system malfunction.</td>
<td>Tighten the halo brake. Reposition the treatment coil against the patient’s head. Contact Technical Support.</td>
</tr>
<tr>
<td>Gantry brakes do not respond to operator commands.</td>
<td>Brake system malfunction.</td>
<td>Make sure that the system is running. The unlock button on the treatment coil is active only while the system is powered on. Check that the Treatment coil Power Switch is in the On position. Press the system reset button. Log out and shut down the application, and press the reset button. Contact Technical Support.</td>
</tr>
<tr>
<td>Display and brakes do not respond to operator commands.</td>
<td>Operating system malfunction.</td>
<td>Press the system reset button located on the front of the mobile console (see Figure 4-2). Use the display to power the system down. Wait one minute and then press the reset button.</td>
</tr>
<tr>
<td>Display shows the following message: “Failure detected in treatment coil temperature monitoring. Periodically check the treatment coil temperature during treatment sessions. Call Technical Support.”</td>
<td>Treatment coil temperature monitoring system failure.</td>
<td>Contact Technical Support.</td>
</tr>
<tr>
<td>The green light on the display frame flashes off and on in rapid succession.</td>
<td>Hardware failure.</td>
<td>Contact Technical Support.</td>
</tr>
<tr>
<td>Observation</td>
<td>Likely Cause</td>
<td>Remedy</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>A/P bar slips or moves when the treatment coil is placed against the</td>
<td>A/P bar is not holding.</td>
<td>Wipe the A/P bar rail (on the underside of the A/P bar) with an alcohol wipe (70% IPA); see</td>
</tr>
<tr>
<td>Treatment Coil Angle Guide.</td>
<td></td>
<td>“Cleaning the A/P Bar Rail” on page 4-23. If the brake still slips, contact Technical Support.</td>
</tr>
<tr>
<td>Mobile console cannot be moved.</td>
<td>Mobile console wheels are locked.</td>
<td>Unlock the mobile console wheel locks.</td>
</tr>
<tr>
<td></td>
<td>Mobile console wheel locks are broken.</td>
<td>Contact Technical Support.</td>
</tr>
<tr>
<td>Treatment coil buttons are damaged.</td>
<td>Improper treatment coil cleaning.</td>
<td>Contact Technical Support.</td>
</tr>
<tr>
<td>Treatment coil housing is cracked or broken.</td>
<td>Treatment coil collided with a wall or other type of structure.</td>
<td>Discontinue treatment. Contact Technical Support.</td>
</tr>
<tr>
<td>Gantry cover is cracked.</td>
<td>Gantry collided with a wall or other type of structure.</td>
<td>Discontinue treatment. Contact Technical Support.</td>
</tr>
<tr>
<td>Gantry movement is stiff when the brake release button is pressed.</td>
<td>Gantry brake failure.</td>
<td>Discontinue treatment. Contact Technical Support.</td>
</tr>
<tr>
<td>Display arm is stuck or difficult to move.</td>
<td>Display arm failure.</td>
<td>Discontinue treatment. Contact Technical Support.</td>
</tr>
<tr>
<td>Observation</td>
<td>Likely Cause</td>
<td>Remedy</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>System and treatment room lost power during treatment.</td>
<td>Additional demand was put on the treatment room’s circuit, tripping the circuit breaker. Building power failure.</td>
<td>Move the mobile console Mains power switch to the OFF position and wait until power is restored. If not using TrakStar Cloud, restart the TrakStar PC. Restart the mobile console by moving the Mains power switch to the ON position and log in. On the display, touch the line that corresponds to the patient. In TrakStar, find the patient’s record, click the <strong>PATIENT</strong> tab, then click the <strong>Treatment</strong> button. View the patient’s treatment screen report number for the affected treatment session and view the number of pulses delivered. Use this number to calculate the number of pulses needed to complete the session. Start a new treatment session. Request an evaluation of the treatment room’s dedicated circuit load.</td>
</tr>
<tr>
<td>A/P bar laser does not illuminate.</td>
<td>A/P bar laser battery is dead and needs to be replaced. A/P bar laser malfunction.</td>
<td>Use the steps listed in Section 4.5 to replace the “Lithium-Ion AA” laser battery. Contact Technical Support.</td>
</tr>
<tr>
<td>A/P bar laser cannot line up properly.</td>
<td>A/P bar laser malfunction.</td>
<td>Contact Technical Support.</td>
</tr>
<tr>
<td>A/P bar laser does not turn off after 45 seconds.</td>
<td>A/P bar laser malfunction.</td>
<td>Contact Technical Support.</td>
</tr>
<tr>
<td>A/P bar is damaged or falls off.</td>
<td>Mechanical malfunction.</td>
<td>Contact Technical Support.</td>
</tr>
<tr>
<td>A/P bar laser line is blurred or is not continuous.</td>
<td>A/P bar laser lens is dirty or obstructed.</td>
<td>Try cleaning the lens with a soft cloth. Contact Technical Support.</td>
</tr>
<tr>
<td>SenStar Treatment Link registers patient contact when no contact is present.</td>
<td>SenStar Treatment Link failure.</td>
<td>Replace the SenStar Treatment Link.</td>
</tr>
<tr>
<td>Observation</td>
<td>Likely Cause</td>
<td>Remedy</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------</td>
<td>--------</td>
</tr>
<tr>
<td>SenStar Treatment Link does not register patient contact when patient contact is present.</td>
<td>Improper treatment coil placement. SenStar Treatment Link failure.</td>
<td>Reposition the treatment coil. Remove and reinstall the SenStar Treatment Link. (Pause the session, if necessary.) Replace the SenStar Treatment Link.</td>
</tr>
<tr>
<td>System does not detect a valid SenStar Treatment Link.</td>
<td>Improper installation of the SenStar Treatment Link. Defective SenStar Treatment Link.</td>
<td>Ensure that the SenStar Treatment Link is properly seated on the treatment coil.</td>
</tr>
<tr>
<td>The console message states that SenStar Connect needs to be replaced soon.</td>
<td>The installed SenStar Connect Treatment Link is close to reaching its limit of 3000 treatment sessions.</td>
<td>Have a new SenStar Connect Treatment Link ready to install when the limit is reached.</td>
</tr>
<tr>
<td>The SenStar test screen displays the message that the SenStar Connect needs to be replaced.</td>
<td>The installed SenStar Connect Treatment Link has reached its end-of-life (3000 treatment sessions).</td>
<td>Install another SenStar Connect Treatment Link.</td>
</tr>
<tr>
<td>The console message states that there are no treatment sessions remaining.</td>
<td>All the treatment sessions purchased and redeemed through TrakStar have been used.</td>
<td>Purchase additional treatment sessions through the Web Store (use the PURCHASE button on the TrakStar Treatment Session Inventory screen).</td>
</tr>
<tr>
<td>The console displays how much offline time is remaining.</td>
<td>The connection between NeuroStar System and TrakStar has been broken; you can continue to administer treatment sessions for 72 hours.</td>
<td>Restore the connection as soon as possible.</td>
</tr>
<tr>
<td>TrakStar is not available when a patient needs to be added.</td>
<td>Software failure. Hardware failure. Other</td>
<td>For Local TrakStar, check that the TrakStar PC is running. For Cloud TrakStar, check that the internet connection is working. Check that the NeuroStar System is running. Check that the TrakStar software is running by attempting to log in. Check the cable connections on each end. Add patients through the NeuroStar display until TrakStar is operating. Contact Technical Support.</td>
</tr>
<tr>
<td>Observation</td>
<td>Likely Cause</td>
<td>Remedy</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>--------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>TrakStar computer cannot connect to the NeuroStar (for operators not connected to TrakStar Cloud).</td>
<td>Software failure.</td>
<td>For <strong>Local TrakStar</strong>, check that the TrakStar PC is running. For <strong>Cloud TrakStar</strong>, check that the internet connection is working.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Check that the NeuroStar System is running</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Check that the web browser is running. If not, find the browser on the TrakStar PC desktop, and double-click on it.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Check for the proper settings of Windows Firewall (On) and Windows Automatic Update (On).</td>
</tr>
<tr>
<td></td>
<td>Hardware failure.</td>
<td>Check with the IT department to ensure that the facility’s Internet service is running properly.</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>Contact Technical Support if these steps do not remedy the problem.</td>
</tr>
<tr>
<td>TouchStar prescription or composite prescription containing theta burst cannot be applied, confirmed, and/or pulse sequence started.</td>
<td>Mobile Console is not TouchStar enabled.</td>
<td>Move the patient to a TouchStar enabled mobile console.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Contact Technical Support.</td>
</tr>
</tbody>
</table>

**NOTE**

The **ADVANCED DIAGNOSTICS** button is used only by your local field service engineer.
4.5 Changing the A/P Laser Battery for Model 81-03842-000

Although the Class I laser in the A/P bar is safe for use with the NeuroStar System, avoid pointing the light into someone’s eye. When it is properly installed in the head support system, the A/P bar laser assembly limits the direction of the laser beam. Access to the laser battery is shown below.

To replace the A/P bar laser battery use the following steps.

1. Rotate the A/P Bar Assembly to the 0° SOA position.
2. Squeeze the sides of the Battery Door and pull up on the Battery Door (Figure 4-3).

3. Remove the existing battery and insert the replacement Lithium-Ion AA battery with the negative (-) polarity end at the back of the A/P bar and the positive (+) polarity towards the front of the A/P Bar (Figure 4-4).
Inserting the laser battery in the wrong polarity will damage the laser electronics and cause the battery to drain rapidly.

4. Position the Battery Door above the A/P Bar battery opening and squeeze the sides of the Battery Door as shown. Continue to squeeze the sides of the Battery Door and push the Battery Door into the opening until the Battery Door is fully seated (Figure 4-5 and Figure 4-6).

5. Confirm the laser functionality by depressing the On button.

6. Clean the surface of the underside of the A/P bar rail with a prepackaged isopropyl alcohol pad; see “Cleaning the A/P Bar Rail” on page 4-23.
4.6 Changing the A/P Laser Battery for Models 81-00842-000 and 81-02842-000

**NOTE**

The model number can be found at the rear of the A/P Bar.

Although the Class I laser in the A/P bar is safe for use with the NeuroStar System, avoid pointing the light at someone's eye. When it is properly installed in the head support system, the A/P bar laser assembly limits the direction of the laser beam. Access to the laser and its PCB is limited by a mechanical stop that prevents the cover from being pushed back beyond the back of the battery compartment so that access to the laser can only be obtained by Field Service (Figure 4-8).

To replace the A/P bar laser battery use the following steps.

1. Tilt the A/P bar to the 45° mark on the SOA Right scale.
2. Use a No. 1 Phillips-head screwdriver to remove the screw on the underside of the A/P bar located at the 20.5 cm mark (Figure 4-7).

Never attempt to move the A/P bar cover without removing the A/P bar screw to prevent damage to the A/P bar.

3. Slide the top of the A/P bar cover forward to expose the battery holder (Figure 4-8).
4. Remove the existing battery and insert the replacement Lithium-Ion AA battery with the negative (-) polarity end at the back of the A/P bar and the positive (+) polarity towards the front of the A/P Bar (Figure 4-9).

![Battery Replacement](image)

<table>
<thead>
<tr>
<th>A</th>
<th>Positive &quot;+&quot; polarity</th>
</tr>
</thead>
<tbody>
<tr>
<td>B</td>
<td>Negative &quot;-&quot; polarity</td>
</tr>
</tbody>
</table>

**FIGURE 4-9. Battery Replacement**

Inserting the laser battery in the wrong polarity will damage the laser electronics and cause the battery to drain rapidly.

5. Slide the A/P bar cover back in place until the cover is positioned correctly flush against the back stop (Figure 4-10).

![Correct A/P Bar Cover Alignment](image)

| A | Cover closed, no gap |

**FIGURE 4-10. Correct A/P Bar Cover Alignment**

6. Confirm the laser functionality by depressing the On button.

7. Install the previously removed Phillips-head screw from Step 2.

8. Clean the surface of the underside of the A/P bar rail with a prepackaged isopropyl alcohol pad.
4.7 Replacing the Treatment Chair Head Support Up/Down Locking Knob

Follow these instructions to remove and replace the Locking Knob.

1. Using the Hand Held Controller on the Treatment Chair. Press M1 until the chair stops moving.

2. The Head Support Up/Down Locking Knob is located on the rear of the Treatment Chair – just below the Head Support System in the center of the chair back (see Figure 4-11).

3. Slowly turn the locking knob counterclockwise to begin to loosen it, taking pressure off of and freeing up the Head Support System (see Figure 4-12). If not already in this position, carefully lower the Head Support System until it rests on the top of the Treatment chair (see Figure 4-13).
4. Once the Head Support System is resting on the top of the Treatment Chair, continue to turn the Knob slowly counterclockwise until it can be completely removed from the Treatment Chair (see Figure 4-14).

5. Inspect the Treatment Chair Head Support Up/Down Locking Knob. If the Knob shows signs of wear and/or damage continue to next step. If no damage is evident the chair may need further servicing.
6. Remove the new Treatment Chair Head Support Up/Down Locking Knob from packing (see Figure 4-15).

![Figure 4-15. Packaged Locking Knob](image)

7. Align the new Knob to the same location as the removed Knob. Be sure it is perpendicular to the chair back so it will thread correctly into the chair (see Figure 4-16).

![Figure 4-16. Insert New Locking Knob](image)
8. Slowly turn the knob clockwise, being sure the knob is threading into the chair (see Figure 4-17). It should turn smoothly and easily. If there is any major resistance or it feels forced, stop and be sure that the angle is correct to avoid cross-threading. Tighten until snug.

9. To confirm that the system is functioning correctly, loosen the Knob and move the Head Support System up and then re-snug the Knob.
4.8 Cleaning the A/P Bar Rail

The A/P Bar rail is located underneath the A/P Bar. The rail should be cleaned when reduced brake friction is noticed.

To clean the rail:

1. Rotate the A/P Bar to the 0° SOA position.
2. Use an alcohol wipe to clean one side of the rail and then slide the rail to clean the other side as shown in Figure 4-14 and Figure 4-15.

FIGURE 4-18. Cleaning the A/P Bar Rail

FIGURE 4-19. Slide the Bar to Clean the Entire Rail
5 Technical Design and Specifications

This section contains technical and theoretical background information for individuals who want a better understanding of how the NeuroStar System works.

5.1 Principles of Operation

Transcranial Magnetic Stimulation (TMS) uses repetitive electromagnetic field pulses to non-invasively penetrate the skull and induce electric current in the brain, which stimulates cortical neurons at the site of stimulation and also results in indirect stimulatory effects on distal neurological pathways. For the treatment of major depression, the pulsed magnetic field is applied to the left prefrontal cortex and stimulates a specific volume of cortical tissue, which has been shown to result in biological effects and symptomatic relief of major depression.

The pulsed magnetic field is generated by initially charging a large capacitor with a high voltage power supply (Figure 5-1). A TMS pulse is created when a computer controlled trigger circuit switches a semiconductor switching device (i.e., silicon controlled rectifier – SCR) to the “on” state which immediately applies the voltage stored in the capacitor to the treatment coil. The capacitor and treatment coil form a resonant circuit that is tuned to about 5.4 kHz resulting in a sinusoidal current pulse with a period of 188 µS ± 5%. After one cycle, the trigger circuit switches the SCR off and the capacitor is recharged for the next pulse. This pulse of current through the treatment coil creates a sinusoidally varying magnetic field pulse between the pole faces of the treatment coil which is applied directly to the patient’s head over the stimulation target area. In a TMS treatment, for example, a train of ten pulses are generated per second for four seconds (i.e., 40 pulses) followed by a 26 second pause, followed by another train of 40 pulses, which is repeated until 3000 pulses have been applied.

![Diagram of TMS system](image_url)

FIGURE 5-1. Simplified Schematic of a Representative Transcranial Magnetic Stimulator

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charging Supply</td>
<td>Diode</td>
<td>Primary Capacitor</td>
<td>Diode</td>
<td>Lumped Circuit Resistance</td>
<td>Treatment Coil</td>
<td>Coil Current</td>
<td>SCR</td>
<td>Trigger Circuit</td>
<td>Isolation Coil</td>
</tr>
</tbody>
</table>
When the pulsing treatment coil is placed against the head, the rapidly changing magnetic field penetrates the scalp and skull unimpeded to a depth of ~ 2 cm into the cortex (Figure 5-2). Through Faraday’s principle of magnetic induction, the pulsed magnetic field induces an electric field within the cortex (since it is electrically conductive) in a region immediately beneath the treatment coil. The induced electric field in turn causes electric eddy currents to flow in the cortex. This current flow causes electrical charges to accumulate on neuronal membranes, and if the charge density is sufficiently high to reach the neuron activation potential, the neuron depolarizes, triggering release of neurotransmitters with resulting downstream biological effects.

![Brain Regions Relevant to TMS Therapy](image)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Treatment Coil</td>
</tr>
<tr>
<td>B</td>
<td>Prefrontal Cortex</td>
</tr>
<tr>
<td>C</td>
<td>Stimulated Area</td>
</tr>
<tr>
<td>D</td>
<td>Magnetic Field</td>
</tr>
</tbody>
</table>

**FIGURE 5-2. Brain Regions Relevant to TMS Therapy**

Certain characteristics of the magnetic field are critical for effective and repeatable TMS Therapy. Those characteristics that are determined by the stimulator design include the individual pulse duration and magnetic field spatial distribution. Those determined by the equipment operator include the treatment coil location, treatment level, pulse repetition rate, stimulation time, stimulation interval and total number of pulses administered.

The current induced in the cortex is proportional to the time rate of change of the magnetic field (dB/dt). Therefore, for a given treatment coil drive level, a shorter pulse has a higher dB/dt and induces more current in the cortex. Also, the target cortical neurons are non-myelinated and have relatively small diameters that make them more responsive to short duration pulses as compared to myelinated sensory neurons which are larger in diameter and slower to respond. The pulse duration (188 µS ± 5%) of the NeuroStar System is designed to more effectively stimulate cortical neurons than sensory neurons, thereby targeting the neurons associated with therapeutic efficacy.
The amount of current driving the treatment coil determines the strength of the magnetic field produced. The higher the drive level, the deeper the magnetic field penetrates into the cortex and the higher the dB/dt. Treatment levels must be determined for each individual patient due to differences in cortical excitability and cortical depth. The reference level for treatment is the Motor Threshold (MT) level. MT is determined using visual observation of the abductor pollicis brevis of the thumb for muscle twitch during motor cortex stimulation.

When using the NeuroStar System, the MT level is determined by varying the drive level of the treatment coil while observing the patient’s abductor pollicis brevis of the contralateral thumb. The system drive level that produces an observable twitch 50% of the time is the MT level for that patient. For NeuroStar Advanced Therapy, the treatment level is set at 120% of MT level. The output level units on the NeuroStar System are Standard Motor Threshold (SMT units). 1.0 SMT corresponds to a normalized average MT for patients receiving NeuroStar Advanced Therapy. For example, for a treatment level of 120% MT for an average patient with an MT of 1.0 SMT, the stimulator output is set at 1.2 SMT.

The location of the dorsolateral prefrontal cortex for TMS treatment is also determined relative to the MT location. For treatment, the treatment coil is moved 5 cm anterior from the MT location along a left superior oblique plane as guided by the NeuroStar head support system (reading is 5.5 standard units on the NeuroStar head support system).

NeuroStar Advanced Therapy is delivered using a set of well-defined treatment parameters that fall within TMS safety limits published in the 1998 National Institute of Neurological Disorders and Stroke (NINDS) Workshop on the Safety of TMS. The TMS Safety guideline is provided for reference in “5.2.1 NeuroStar System Specifications”.

The treatment parameters used to deliver TMS therapy were standardized for each treatment session, as further described in “8.1 Treatment Planning – Acute Treatment Course”, and used to establish safety and efficacy under controlled clinical trials. The NeuroStar System Performance Specifications described below in “5.2.1 NeuroStar System Specifications” provide the full range of treatment parameters that can be used by a treating physician to provide an individualized TMS therapy session at the discretion of the treating physician. Refer to “12.6 Changing Stimulation Parameters During Treatment” for more information.
### 5.2 Major Technical Specifications

#### 5.2.1 NeuroStar System Specifications

<table>
<thead>
<tr>
<th>PHYSICAL SPECIFICATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobile Console Weight</td>
</tr>
<tr>
<td>Chair Weight</td>
</tr>
<tr>
<td>Chair Maximum Capacity</td>
</tr>
<tr>
<td>Mobile Console Footprint</td>
</tr>
<tr>
<td>Chair Footprint</td>
</tr>
<tr>
<td>Overall System Footprint</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PERFORMANCE SPECIFICATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Level Range</td>
</tr>
<tr>
<td>* optional TouchStar feature – SMT values greater than 1.5 SMT may result in lower MT dosage than prescribed.</td>
</tr>
<tr>
<td>%MT Range</td>
</tr>
<tr>
<td>Pulses Per Second (pps) Range</td>
</tr>
<tr>
<td>Stimulation Time (pulse train duration) Range</td>
</tr>
<tr>
<td>Inter-Train Interval Range</td>
</tr>
<tr>
<td>Induced Electric Field at 2 cm at 1.0 SMT</td>
</tr>
<tr>
<td>Pulse Type</td>
</tr>
<tr>
<td>Pulse Width</td>
</tr>
<tr>
<td>Pulses Per Burst (PPB)</td>
</tr>
</tbody>
</table>
### PERFORMANCE SPECIFICATIONS

<table>
<thead>
<tr>
<th>Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impulse Interval (IPI)</td>
<td>20–2000 milliseconds (for optional TouchStar feature)</td>
</tr>
<tr>
<td>Bursts Per Second (BPS)</td>
<td>0.1–20.0 Hz (for optional TouchStar feature)</td>
</tr>
<tr>
<td>Maximum Pulses per Treatment Session</td>
<td>Nominal: 3000 Maximum: 5000 (The standard number of pulses is 3000. Additional pulses can be used to make up for pulse trains with poor contact.) Optional TouchStar feature Protocol Maximum: 2000 (The standard number of pulses for a TouchStar protocol is 600.)</td>
</tr>
<tr>
<td>Treatment Coil Type</td>
<td>High efficiency Field focusing Ferromagnetic core</td>
</tr>
<tr>
<td>Treatment Coil Positioning System</td>
<td>Integrated into Head Support System Designed for Inter Session Reproducibility Laser-aided Patient Alignment</td>
</tr>
<tr>
<td>Mobile Console Interface Ports</td>
<td>CAT 6 Ethernet USB (2)* RS232* BNC (2)* *Service Use Only</td>
</tr>
<tr>
<td>Treatment Quality Features</td>
<td>Magnetic Field Detection: Pulse Level &amp; Pulse Width Continuous Coil Contact Sensing</td>
</tr>
<tr>
<td>MT Level Determination Method</td>
<td>Proprietary MT Assist® algorithm</td>
</tr>
<tr>
<td>Patient Comfort Features</td>
<td>Surface field reduction Reclining chair and head support system</td>
</tr>
<tr>
<td>Operator Controls</td>
<td>15” (38 cm) color LCD touchscreen Graphical User Interface</td>
</tr>
</tbody>
</table>
PERFORMANCE SPECIFICATIONS

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Data Security</td>
<td>HIPPA-Compliant features</td>
</tr>
<tr>
<td></td>
<td>Back-up capable</td>
</tr>
<tr>
<td>Safety</td>
<td>Certified to IEC 60601-1 Ed. 3.0, 3.1, 4.0, IEC 60601-1-2 Ed. 4.0, and IEC 60825-1:2007-03 Ed. 2.0</td>
</tr>
<tr>
<td></td>
<td>Built-in NINDS limits</td>
</tr>
<tr>
<td>Auto Logout</td>
<td>After 2 hours of inactivity the Login screen will be displayed.</td>
</tr>
<tr>
<td>Expected Life</td>
<td>10 years with preventive maintenance and updates</td>
</tr>
</tbody>
</table>

5.2.2 Head Support System Laser Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Projected Light Line Length</td>
<td>7.5 cm at 5 cm from the source</td>
</tr>
<tr>
<td>Projected Light Line Width</td>
<td>2 mm at 5 cm from the source</td>
</tr>
<tr>
<td>Wavelength</td>
<td>650 ± 20 nm</td>
</tr>
<tr>
<td>Total Output Power</td>
<td>&lt;390 microwatts</td>
</tr>
<tr>
<td>Product Type</td>
<td>Class 1 per IEC 60825-1:2007-03 Ed. 2.0</td>
</tr>
<tr>
<td>Light Generation Safety Standard</td>
<td>IEC 60825-1:2007-03 Ed. 2.0</td>
</tr>
<tr>
<td>Automatic Shutoff Time</td>
<td>45 seconds</td>
</tr>
</tbody>
</table>

5.2.3 Essential Performance

Magnetic field output is maintained within ±10% of the desired Treatment Level (%MT).

The NeuroStar System is checked in the following manner to ensure that Basic Safety and Essential Performance are maintained:

- **Pulse Test**: Perform a pulse test before each patient treatment as described in “Running the Pulse Test” on page 9-24.
5.2.4 Loss of Essential Performance

Loss of Essential Performance may have the following effects:

- Higher level treatment than programmed by Operator may cause discomfort under or near the coil, consistent with most commonly reported events. For Operator instructions on monitoring Patients during treatment, see “Treatment” on page 12-1 and “Addressing Patient Discomfort” on page 12-16.

- Inadequate or lower level treatment than programmed by Operator does not cause potential patient harm as patient is treated to remission.

5.3 Environmental and Facility Requirements

<table>
<thead>
<tr>
<th>ENVIRONMENTAL AND FACILITY REQUIREMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mobile Console Power</strong></td>
</tr>
<tr>
<td>100 VAC, 120 VAC, or 220 VAC or 240 VAC (20A) (depending on the model)</td>
</tr>
<tr>
<td>Dedicated circuit</td>
</tr>
<tr>
<td><strong>Input Frequency</strong></td>
</tr>
<tr>
<td>50/60 Hz</td>
</tr>
<tr>
<td><strong>Treatment Chair Power</strong></td>
</tr>
<tr>
<td>100 VAC, 120 VAC, or 230 VAC (15A), 50/60 Hz (depending on the model)</td>
</tr>
<tr>
<td><strong>Recommended Space</strong></td>
</tr>
<tr>
<td>(to allow good clearance around NeuroStar)</td>
</tr>
<tr>
<td>9’ x 15’ (2.7 m x 4.6 m)</td>
</tr>
<tr>
<td><strong>Minimum Room Size</strong></td>
</tr>
<tr>
<td>8’ 6” x 12’ (2.6 m x 3.7 m) (7’ 6” ceiling) (2.3 m ceiling)</td>
</tr>
<tr>
<td><strong>Recommended Room Size</strong></td>
</tr>
<tr>
<td>12’ x 15’ (3.7 m x 4.6 m) (8’ ceiling) (2.4 m ceiling)</td>
</tr>
<tr>
<td><strong>Temperature</strong></td>
</tr>
<tr>
<td>60° – 77°F (15° – 25°C)</td>
</tr>
<tr>
<td>Recommended &lt;72°F (23°C)</td>
</tr>
<tr>
<td><strong>Humidity</strong></td>
</tr>
<tr>
<td>30% – 75% (non-condensing)</td>
</tr>
<tr>
<td><strong>Altitude</strong></td>
</tr>
<tr>
<td>To 9,843’ (3000 m)</td>
</tr>
</tbody>
</table>

**SHIPPING**

| **Temperature Range**                   |
| -4° – 140°F (-20° – 60°C)               |
| **Humidity**                            |
| 20% – 90% (RH non-condensing)           |
| **Altitude**                            |
| To 45,932 feet (14,000 meters)          |
5.4 Device Classification

The NeuroStar System is a moderate risk device, i.e., Class II (US). The NeuroStar System is a computerized, electro-mechanical medical device that produces and delivers non-invasive transcranial magnetic stimulation using brief duration (<200 microsecond) rapidly alternating, pulsed magnetic fields directed at the left prefrontal cerebral cortex for the treatment of adult patients with major depressive disorder. The NeuroStar System is an active therapeutic device to be used for the central nervous system, e.g., brain left prefrontal cortex.

5.5 Industry Standards Classification (IEC 60601-1 Ed. 3.1, IEC 60601-1-2 Ed. 4.0)

<table>
<thead>
<tr>
<th>Classification Area</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of electric shock protection</td>
<td>Class I Equipment</td>
</tr>
<tr>
<td>Degree of electric shock protection</td>
<td>Type BF</td>
</tr>
<tr>
<td>Degree of Protection Against Harmful Ingress of Water</td>
<td>Ordinary Equipment</td>
</tr>
<tr>
<td>Safety in the Presence of Flammable Material</td>
<td>Equipment is NOT suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide.</td>
</tr>
<tr>
<td>Mode of Operation</td>
<td>Continuous Operation with Short-Term Loading</td>
</tr>
</tbody>
</table>

5.6 Industry Standard Classification (IEC 60825-1: 2007-03 Ed. 2.0)

<table>
<thead>
<tr>
<th>Classification Area</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser Devices</td>
<td>Class 1</td>
</tr>
</tbody>
</table>

5.7 Electromagnetic Compatibility (EMC)

This equipment has been tested and been found to comply with the requirements of IEC 60601-1 Ed. 3.1, Medical Electrical Equipment Part 1: General Requirements for Safety, and Collateral Standard: Electromagnetic Compatibility – Requirements and Tests (IEC 60601-1-2 Ed. 4.0). These requirements are designed to provide reasonable protection against harmful interference when the equipment is installed and operated as specified. (See “Appendix E. Electromagnetic Compatibility” for details.)

- The NeuroStar System generates and uses electromagnetic energy. It can radiate electromagnetic energy if it is not installed and used in accordance with the instructions in these Instructions For Use.
- If it is determined that the NeuroStar System is generating interference with other equipment, contact Customer Service.
Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g., IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with these requirements for medical electrical systems (IEC 60601-1-1 or clause 16 of the Ed. 3.1 of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Local laws may take priority over the above-mentioned requirements. If in doubt, contact Customer Service.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas – e.g., cell phones, portable transmitters, RF emitters) should be used no closer than 30 cm (12 inches) to any part of the NeuroStar System, including cables specified by Neurontics. Otherwise, degradation of the performance of this equipment could result. The user might need to take mitigation measures if the equipment is observed to not operate normally, such as relocating or re-orienting the equipment.

**NOTE**

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

### 5.8 Waste Disposal

Used SenStar Treatment Links and SenStar Connect Treatment Links, hygiene barriers, head cushion liners, side pad liners, ear plugs, and head positioning straps may be mixed with regular waste.

There are recyclable components in the NeuroStar System. Contact Customer Service for disposal or recycling instructions.
6 NeuroStar System Workflow

Volume 2 of these Instructions For Use provides step-by-step instructions for treating patients with the NeuroStar System. The following paragraphs provide an overview of the treatment steps, which are described in more detail in the following sections.

6.1 Process Description

The initial step in the use of the NeuroStar System is the selection of the proper candidate for treatment. Volume 2, Section 7 provides important safety screening information to be used in determining whether any safety precautions should be taken prior to patient treatment.

After patient screening, the NeuroStar System operator enters patient registration information through the TrakStar patient data management system (see the TrakStar Instructions For Use).

The process of delivering NeuroStar Advanced Therapy begins with the daily preparation steps listed in Section 9. This section provides a checklist for evaluating the functionality of the system, as well as a description of initial activities for the treatment day (Section 9.1 to Section 9.4). Section 9.1 must be completed prior to each therapy session.

Patients who are new to NeuroStar Advanced Therapy are first oriented to the equipment and the Advanced Therapy process, which includes seating and positioning for treatment (Section 10.2 through Section 10.6). From the list of patients whose information has been automatically transferred from TrakStar to the NeuroStar System mobile console, the operator selects the patient and verifies the patient’s information (Section 10.1).

After a new patient has been seated and positioned, the operator records the head support system positioning measurements in the mobile console for use in all subsequent sessions. When seating returning patients, the operator sets the head support system parameters to the patient’s previous position measurements.

Identifying the patient’s motor threshold (MT) location and level is the next step. For both MT location and level determination, the operator has the option of choosing either manual pulsing or auto pulsing (Section 11.4).

First, the patient’s MT location is identified either automatically (Section 11.5.1) or manually (Section 11.5.2). After the MT location has been identified, the patient’s MT level can be established through the NeuroStar System’s MT Assist feature, which is a tool that automatically adjusts the MT level (Section 11.7). The patient’s MT level can also be established manually (Section 11.7.1 and Section 11.7.2). (See Figure 6-1 in Section 6.2, below.)

The motor threshold determination process is used for new patients and for any patients for whom the motor threshold level needs to be confirmed or re-established following a change in the patient’s condition or prescription medication.

For new patients or returning patients, NeuroStar Advanced Therapy treatment steps are described in Section 12. Steps for accurate treatment coil placement for treatment are described in Section 12.2. Section 12.3 describes the steps for
conducting treatment sessions as well as for pausing, stopping, or completing a therapy session. Section 12.5 contains steps for addressing any patient discomfort that may arise during a treatment session.

If the prescribing physician determines that treatment coil contact was not ideal during a treatment session, Section 12.8 describes steps for extending a treatment session to compensate for the less-than-desired treatment coil contact treatment trains. (See the flowchart in Section 6.2, below.)

Section 13 describes end-of-day activities for use of the NeuroStar System.

6.2 NeuroStar Advanced Therapy Flowchart

FIGURE 6-1. NeuroStar Advanced Therapy Flowchart

* For new patients only.
7 Patient Selection

Prior to treatment with the NeuroStar System, consider for each patient the contraindications, warnings and cautions (Sections 1.3, 1.4, and 1.5) provided in Volume 1, Section 1, “Introduction,” of these Instructions For Use.

This section of the document provides guidance for screening patients for the presence of any devices or objects that may be affected by the NeuroStar System and that could present a safety issue for the patient.

The NeuroStar System treatment coil produces a strong pulsed magnetic field that can affect certain implanted devices or objects that are near the treatment coil. Electric current can be induced in conductive objects (i.e., those made from conductors like copper, iron, steel, and titanium). If the object is large enough and located in close proximity to the treatment coil, induced currents may be great enough to cause the object to become warm.

Never place the treatment coil directly over a conductive object, such as a titanium head plate. See Table 7-1 for more detail.

Also, performance of an implanted electronic device could be affected if the pulsed magnetic field induces an electrical current in its lead wires. Table 7-1 provides detailed guidance for placing the treatment coil in these circumstances.

The magnetic field strength diminishes quickly with increasing distance from the treatment coil such that the peak magnetic field at about 30 cm from the treatment coil will be less than 5 Gauss, which is the recommended static magnetic field exclusion level for many electronic devices. For this reason, 30 cm has been identified as the exclusionary zone for implants and electrical devices.

The following guidelines were developed to assist in categorizing possible interactions with common devices and objects. If unsure, check with the device manufacturer or Customer Service.

The NeuroStar System is contraindicated for use in some situations as identified below. All patients must be screened for the following contraindications.

Contraindications

Metallic Objects in or near the Head

The NeuroStar System is contraindicated for use in patients who have conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head within 30 cm of the treatment coil. Examples of contraindicated devices include cochlear implants, implanted electrodes/stimulators, aneurysm clips or treatment coils, stents, bullet fragments, jewelry and hair barrettes. See Table 7-1 for more detail. Failure to follow this restriction could result in serious injury or death.

NOTE
Removable objects that may be affected by the magnetic field should be removed from the patient before treatment to prevent possible injury. (Examples include jewelry and hair barrettes). Once these objects are removed, NeuroStar Advanced Therapy is not contraindicated for these patients.
NOTE

Examples of metallic objects in or near the head that are acceptable under certain conditions include standard amalgam dental fillings, single-post dental implants, and dental bridge work. The conditions for TMS treatment when these objects are present are clarified in Table 7-1.

**Implanted Stimulator Devices in or near the Head**

The NeuroStar System is contraindicated for use in patients who have active or inactive implants (including device leads), including deep brain stimulators, cochlear implants, and vagus nerve stimulators. Contraindicated use could result in serious injury or death.

No formal studies have been conducted on the potential interaction of TMS Therapy with pacemakers, implantable cardioverter defibrillators (ICDs) and other similar implants that are controlled by physiologic signals. Treating patients with such implanted devices is not recommended since the formal interaction studies have not been conducted. However, if the treating physician and patient, in consultation with the patient's cardiologist, elect to proceed with NeuroStar Advanced Therapy treatment, precautions must be taken. Specifically, the treatment coil (when pulsing) should never be placed closer than 30 cm to the implant or heating and damage to the implant could result. The patient must be monitored closely during NeuroStar Advanced Therapy for signs of unexpected or irregular cardiac symptoms, in which case NeuroStar Advanced Therapy must be discontinued immediately. The same precautions apply for patients using wearable cardioverter defibrillators (WCD) even if the device is removed, due to the potentially unstable cardiac condition of such patients. Failure to follow this warning could result in serious injury or death.

In summary, during NeuroStar Advanced Therapy, keep the treatment coil at least 30 cm away from implanted objects listed in the yellow section of Table 7-1, including operators of the NeuroStar System, patients, and others who have these implanted devices.

**Patient Screening for Magnetic Field Compatibility**

Prior to treatment, each patient must be screened for the items listed in Table 7-1, which summarizes compatibility requirements for devices and conductive objects in the vicinity of the NeuroStar System treatment coil.

This list is for guidance in screening a patient for magnetic field compatibility; it is non-inclusive, so prudent judgment must be applied for cases not listed. Contact the specific device manufacturer if compatibility is uncertain.
### Table 7-1: Partial List of Devices and Objects that may be affected by the NeuroStar System's Magnetic Field

<table>
<thead>
<tr>
<th>Device or Object (non-removable)</th>
<th>Possible Interaction with NeuroStar Magnetic Field</th>
<th>Potential Consequences of Operator Inaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Device / Object may become disabled</td>
<td>Device / Object may dislodge or move</td>
</tr>
<tr>
<td>Aneurysm clips or coils</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Carotid or cerebral stents</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Deep Brain Stimulators and electrodes</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Metallic devices implanted in the head</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Vagus Nerve Stimulators</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Magnetically activated dental implants</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Cochlear, otologic implants, implanted hearing aid anchors</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CSF Shunt</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Ferromagnetic ocular implants, ocular stent</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pellets, bullets, fragments &lt;30 cm from coil</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Facial tattoos with metallic ink</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Permanent makeup &lt;30 cm from coil</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
### Keep Treatment Coil >30 cm from the Following Objects

<table>
<thead>
<tr>
<th>Device or Object</th>
<th>Possible Interaction with NeuroStar Magnetic Field</th>
<th>Potential Consequences of Operator Inaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Device / Object may become disabled</td>
<td>Device / Object may dislodge or move</td>
</tr>
<tr>
<td>Cardiac Pacemakers, ICD's</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Cardiac stents, filters, valves</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Vagus Nerve Stimulators</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Wearable cardioverter defibrillator (WCD)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Wearable infusion pumps</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Implanted insulin pump</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Magnetically programmable shunt valves</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Radioactive seeds</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Staples, sutures</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>VeriChip microtransponder</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

### Remove the Following Objects from Patient Area During Treatment

<table>
<thead>
<tr>
<th>Device or Object (Removable)</th>
<th>Possible Interaction with NeuroStar Magnetic Field</th>
<th>Potential Consequences of Operator Inaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Device / Object may become disabled</td>
<td>Device / Object may dislodge or move</td>
</tr>
<tr>
<td>Wearable physiologic monitors (e.g., Holter)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Bone growth stimulators</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Portable glucose monitors</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Hearing aids</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Cell phones/PDA's</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Removable dentures / bridgework</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Jewelry and hair barrettes</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
### Objects for Conditional Use During Treatment

<table>
<thead>
<tr>
<th>Device or Object</th>
<th>Required Conditions for Use</th>
<th>Potential Consequences with Improper Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headphones, Earbuds</td>
<td>• Must provide &gt;30dB acoustic isolation&lt;br&gt;• Both ears must have isolation (earplugs or headphones)&lt;br&gt;• Must not mechanically interfere with treatment coil positioning&lt;br&gt;• Wires must drape straight downward and not form loops near the treatment coil</td>
<td>Auditory compromise</td>
</tr>
<tr>
<td>iPod, MP3 player</td>
<td>• Keep &gt;30 cm from treatment coil during pulsing</td>
<td>Device may become disabled</td>
</tr>
<tr>
<td>Eyeglasses</td>
<td>• Must not mechanically interfere with treatment coil positioning&lt;br&gt;• No wire rims around lens (conductive loop could heat)&lt;br&gt;• Must have plastic-covered or non-conductive ear pieces</td>
<td>Improper treatment coil placement during treatment could affect therapy&lt;br&gt;Heating of conductive material and related injury</td>
</tr>
<tr>
<td>Single-Tooth Posts, Amalgam Fillings, Metal dental braces, Non-removable bridgework, Conductive maxillofacial reconstruction hardware (e.g. screws, pins)</td>
<td>• Best if located contra-laterally or &gt;30 cm from treatment coil&lt;br&gt;• Monitor patient during therapy and have patient notify operator of warming or other sensation; cease TMS treatment in event of warming.</td>
<td>Heating and related injury</td>
</tr>
<tr>
<td>EEG Electrodes</td>
<td>• Use non-conductive electrode caps&lt;br&gt;Electrodes should not be placed under or in close proximity (&lt;5 cm) to the treatment coil during pulsing</td>
<td>Heating and related injury</td>
</tr>
<tr>
<td>Titanium Skull Plates, Cervical Fixation Device/Cervical Plate</td>
<td>• No plates directly under or within 10 cm of the treatment coil&lt;br&gt;• Not recommended with skull plates larger than ~5 cm as heating could result, depending on location</td>
<td>Improper treatment coil placement during treatment could affect therapy&lt;br&gt;Heating and related injury</td>
</tr>
</tbody>
</table>
8 TMS Treatment Planning and Patient Follow-Up

This section contains important clinical information for planning NeuroStar Advanced Therapy.

8.1 Treatment Planning – Acute Treatment Course

Treatment parameters for NeuroStar Advanced Therapy are standardized for each treatment session as follows:

- **Treatment Level**: 120% of the patient’s observed motor threshold. (Adjustments of treatment level are permitted to 110% of observed motor threshold if clinically indicated for tolerability.)
- **Repetition Rate**: 10 pulses per second.
- **Stimulation Time**: 4 seconds
- **Inter-train Interval**: as low as 11 seconds
- **Treatment Session Duration**: as low as 18.75 minutes
- **Magnetic Pulses Administered per Session**: 3000
- **Sessions per Week**: 5

These settings were used to establish safety and efficacy and are within the NINDS guidelines (see “Appendix B. 1998 NINDS Consensus Guidelines”). The above standardized treatment parameters provide delivery of TMS therapy during a typical treatment session for an average patient. An individualized, non-standardized treatment session can be developed to meet a specific patient’s needs at the discretion of the treating physician. Non-standardized treatment sessions should be used within the range of the NeuroStar System’s performance specifications, which are described in “NeuroStar System Specifications” on page 5-4. Refer to “Changing Stimulation Parameters During Treatment” on page 12-20 for more information.

In the NeuroStar clinical trials, treatment success was observed by efficacy measures by the fourth week of treatment. However, most patients continued treatment to complete a full course of six-weeks of acute TMS treatment. Therefore, all patients should be encouraged to complete six weeks of acute treatment prior to TMS taper unless tolerability or safety concerns emerge.

**Optional Feature – TouchStar**: Treatment parameters for TouchStar on the NeuroStar Advanced Therapy system are standardized for each treatment session as follows:

- **Treatment Level**: 120% of the patient’s observed motor threshold. (Adjustments of treatment level are permitted to 110% of observed motor threshold if clinically indicated for tolerability.)
- **Pulses per Burst**: 3 pulses
- **Interpulse Interval**: 20 milliseconds
- **Bursts per Second**: 5
- **Stimulation Time**: 2 seconds
- **Inter-train Interval**: 8 seconds
- **Treatment Session Duration**: 3.3. minutes
- **Magnetic Pulses Administered per Session**: 600
- **Session per Week**: 5
There are no NINDS guidelines established for the TouchStar settings.

Treatment sessions are conducted in five-day sequential blocks, typically with weekend days serving as non-treatment days.

As with any antidepressant treatment, symptom improvement should be evaluated at regular intervals to determine when acute treatment is complete and further treatment is not needed.

The safety of treatment with the NeuroStar System in conjunction with antidepressant medication has not been evaluated in controlled clinical trials. The treating physician should review the patient’s current treatment history and determine whether or not it is clinically appropriate to administer the NeuroStar System in conjunction with an antidepressant or to treat the patient with the NeuroStar System as a monotherapy antidepressant treatment.

If a medication is administered concurrent with NeuroStar Advanced Therapy, it is recommended that a motor threshold determination be performed after any medication change and prior to the next TMS treatment session.

8.2 Treatment Planning – TMS Taper and Continuation Anti-depressant Treatment

During the Neuronetics clinical studies, NeuroStar Advanced Therapy was tapered over a three-week period in a gradually decreasing schedule of treatment sessions each week:

- Three treatments for the first week
- Two for the second week
- One treatment in the final week.

Patients were transitioned to antidepressant monotherapy during TMS taper.

Thus, simultaneously with TMS treatment tapering, a medication continuation treatment may be chosen, or if a medication antidepressant treatment was already in progress, it should be continued.

Clinical monitoring should occur on a periodic basis. Some patients may experience recurrence or relapse of illness, and the physician should reevaluate the potential benefit of repeating the acute treatment with the NeuroStar System at that time.

NOTE

Patients did not undergo Tapering in the iTBS study. Patients were treated with concurrent antidepressant in the study of iTBS (Blumberger 2018).

9 Daily Treatment Preparation

This section provides steps to take at the beginning of each day to prepare the treatment room for TMS sessions.

9.1 Completing the Checklist

At the start of each treatment day, gather the SenStar Treatment Links and treatment packs that will be needed for the day. If using the multiple-use SenStar Connect Treatment Link with NeuroStar System, then gather the treatment packs and ear plug packs that will be needed for the day. When using SenStar Connect Treatment Links, every treatment administered on a NeuroStar System mobile console requires that a treatment session be purchased and entered into TrakStar (redeemed) before a treatment session can be conducted. Treatment sessions can be purchased in minimum batches of five. They can be purchased online through the Web Store or by calling Customer Service. Reference the TrakStar Instructions For Use for Treatment session purchasing and redemption details.

Use the following checklist to complete the steps in Section 9.2 and Section 9.3.

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Check that there are no cracks in or damage to the treatment coil housing, the gantry and mast covers, or the mobile console covers.</td>
</tr>
<tr>
<td>2.</td>
<td>Check that there is no visible damage to the power cable.</td>
</tr>
<tr>
<td>3.</td>
<td>Ensure that the room temperature is below 72 °F (22 °C).</td>
</tr>
<tr>
<td>4.</td>
<td>Ensure that the power cable is plugged into the wall receptacle.</td>
</tr>
<tr>
<td>5.</td>
<td>Ensure that the treatment coil cable is connected to the mobile console.</td>
</tr>
<tr>
<td>6.</td>
<td>Ensure that the mobile console is properly positioned behind the treatment chair and that the wheel casters on the mobile console are locked. (Figure 9-1).</td>
</tr>
<tr>
<td>7.</td>
<td>Check that the treatment coil Power switch is in the ON position.</td>
</tr>
<tr>
<td>8.</td>
<td>Check that the TrakStar program is running.</td>
</tr>
<tr>
<td>9.</td>
<td>Check that the mobile console is running. If the green LED below the touchscreen is flashing, press the Reset button. If the LED is not flashing, turn the Mains power switch to ON. (See Section 9.3.)</td>
</tr>
<tr>
<td>10.</td>
<td>At system start-up, verify that the touchscreen displays the system boot-up process and the Welcome screen.</td>
</tr>
<tr>
<td>11.</td>
<td>Verify that the following tests pass:</td>
</tr>
<tr>
<td></td>
<td>● System processor check</td>
</tr>
<tr>
<td></td>
<td>● Power module check</td>
</tr>
<tr>
<td></td>
<td>● Treatment coil check</td>
</tr>
<tr>
<td></td>
<td>● Processor module check</td>
</tr>
<tr>
<td></td>
<td>● TrakStar check.</td>
</tr>
<tr>
<td>12.</td>
<td>Verify that the display responds when the CONTINUE button is touched.</td>
</tr>
<tr>
<td>13.</td>
<td>Verify that pressing and holding the brake release button on the treatment coil enables the movement and repositioning of the treatment coil, gantry, and mast.</td>
</tr>
<tr>
<td>14.</td>
<td>Verify that releasing the treatment coil brake release button locks the treatment coil, gantry, and mast in place.</td>
</tr>
<tr>
<td>15.</td>
<td>Press the A/P bar laser button and verify that the laser works and then press the button again to switch off.</td>
</tr>
<tr>
<td>16.</td>
<td>Press and hold the M2 button on the treatment chair remote control until the treatment chair stops at the treatment position.</td>
</tr>
</tbody>
</table>
17. Press and hold the M1 button on the treatment remote control until the treatment chair stops at the patient entry/exit position.

18. If you are using SenStar Connect Treatment Links, make sure that there are enough Treatment Sessions available.

If there is a problem with any system-related item in this checklist, use the troubleshooting table in Volume 1, Section 4.4 of these Instructions For Use to identify the cause and possible remedy. For further assistance, contact Technical Support.

---

9.2 Preparing the Treatment Room

Prepare the equipment as follows. As noted, some steps apply only to new patients.

1. Move the side pad arm to the vertical position.
2. Position the A/P bar to 0° on the SOA scale.
3. Squeeze the A/P bar brake release grip and slide the bar all the way back.
4. Position the treatment coil angle indicator to the 0 position (new patient).
5. Turn the LC knob until the LC scale reads 0 (new patient).
6. Verify that there are enough disposables for the day.

To prevent the system from overheating, do NOT block the front and rear fan vents or position the fan vents against a wall or other obstacle.
Typically, the mobile console should be powered on at all times. The mobile console log-in screen includes the POWER DOWN button. Touching this button at the end of a treatment day, for example, puts the system in standby mode. In this mode, the cooling fans still run and the display LED flashes on and off every 3 seconds.

1. To activate the NeuroStar System when it is in standby mode, press the Reset (R) button on the back of the mobile console. (See Figure 9-2.) To start the system when the Mains power switch is in the “OFF” position, move the switch to the “ON” position and use the standby steps listed below.

2. When the Microsoft Windows self-diagnostics routine has finished, the system automatically runs the NeuroStar System self-diagnostics application and displays the diagnostic routine’s progress. Do not touch the screen during start-up.

   **NOTE**

   If the touchscreen is accidentally touched during start-up, the system displays the following question: “Do you want to continue touchscreen calibration?” Touch the NO button to return to the start-up screen.

3. If all diagnostics tests pass, the power-on diagnostics screen prominently displays the self-test screen. (See Figure 9-3.)

   **NOTE**

   When the self-diagnostics routine has finished, the system activates the brake release button on the treatment coil. Pressing and holding the brake release button enables the operator to move the treatment coil vertically and horizontally and to move the gantry backward and forward.
4. After five seconds, the system displays the operator login screen. (If the operator touches the **CONTINUE** button before five seconds have elapsed, the system advances to the login screen.) The “User ID” field displays the ID of the previous operator.

**NOTE**

If any of the first four diagnostics tests fails, the system is inoperable and the power-on diagnostics screen prominently displays the following message: “Not all startup tests passed. The system is inoperable. Contact Neuronetics System Help (877) 600-7555.” Contact Technical Support for service.

If the mobile console - TrakStar connection check does not establish contact with the TrakStar software, the NeuroStar System displays the following message:

“Still searching for TrakStar. – Please make sure:

1. The network connection is operating.
2. TrakStar is running.”

“System is functional. However, an alarm will be displayed until TrakStar connectivity is established.”

**FIGURE 9-3. System Self-Test Screen**
The system also registers an alarm and displays the icon in the alarm section of the display. In addition to the steps in the message, ensure that the TrakStar computer is connected to the mobile console through a wired connection. (See Section 4.3 and Section 4.4 for other troubleshooting steps.)

Touch the CONTINUE button on the display if connection with TrakStar cannot be re-established.

Treatment data will be stored in the mobile console and will be transferred to TrakStar when TrakStar connectivity has been established.

5. Press and hold the brake release button on the treatment coil, move the treatment coil up and out of the way, and move the gantry to the back of the mobile console.

6. Release the treatment coil brake release button.

**NOTE**

If the system displays the “Incompatible treatment coil connected” alarm message, contact Technical Support.

Anytime a treatment coil is connected to the right-side connector, the system displays a pop-up window with the following text: “Treatment coil connected for right-sided use.” If this message is displayed, remove the treatment coil from the right-side connector and connect it to the left-side connector. Right-sided use is a research option only. Contact Neuronetics for research use information.

If the NeuroStar System had been completely shut down, instead of being put into standby mode, move the Mains power switch, located on the back of the mobile console, to the ON position (Figure 9-4) and wait while the system powers on.

![Figure 9-4. Mains Power Switch in the ON Position](image)
9.4 Logging In to the Mobile Console

In compliance with security regulations, the NeuroStar System only allows authorized operators to log in. Each operator must be assigned a unique account. Operator accounts are created using TrakStar. For instructions on how to create an operator account, see the TrakStar Instructions For Use.

The NeuroStar System provides levels of operator privileges:

- Treater
- Attending Physician
- Administrator

Treaters and Attending Physicians can perform the following tasks:

- Select a patient record
- Position a patient
- Establish and record a patient’s motor threshold (MT) location.
- Administer TMS treatment

Administrators can perform the following tasks:

- Manage settings
- Get license information
- Get version information

Some of the functions in the section can be performed through TrakStar. For TrakStar instructions, see the TrakStar Instructions For Use.
1. Use the on-screen keyboard to type the assigned operator ID and password and touch the **LOGIN** button on the screen as illustrated in Figure 9-5.

![Login Screen](image)

**FIGURE 9-5. Login Screen**

2. When a valid ID and password combination has been typed and the **LOGIN** button has been touched, the system displays the “SenStar/Treatment coil Test” screen (Figure 9-33).

**NOTE**
After two hours of inactivity the automatic logout feature returns the display to the Login screen.

**NOTE**
If your password expires in seven days or less, the system displays a pop-up requesting that you update your password using TrakStar (Figure 9-6). You may continue to treat. The reminder will be shown every time you log in until your password is changed or has expired. If your password has expired you must use TrakStar to update it (Figure 9-7). To update your password, see the TrakStar *Instructions For Use*. 
FIGURE 9-6. “Your password will expire” Pop-up
9.5 **Software Updates**

If a NeuroStar update or System patch is available from TrakStar Cloud, a pop-up notification window will be displayed at log in (Figure 9-8). To apply the update, select **Now**. If you are not ready to install the update at this time select **Later**; an alarm will be displayed as long as the update is waiting to be installed (Figure 9-9). After 10 days, applying the update will be the only choice (Figure 9-10).

The software update installation process takes less than 5 minutes. At the completion of the process press **CONFIRM UPDATE** (Figure 9-11). The software will restart and the log in page will be displayed.

**FIGURE 9-7. “Your password has expired” Pop-up**

![Image of a login screen with a pop-up notification for an expired password]
FIGURE 9-8. Software Update Pop-up Window

FIGURE 9-9. Software Update Alarm Pop-up Window

FIGURE 9-10. Software Update "Install now" Pop-up Window
FIGURE 9-11. Software Update Installation Screen and Confirm Update Button
9.6 Attaching a SenStar Connect Treatment Link or a SenStar Treatment Link

9.6.1 Attaching a SenStar Connect Treatment Link and Hygiene Barrier

The NeuroStar System can accept both a SenStar Treatment Link and SenStar Connect Treatment Link.

When using a SenStar Connect Treatment Link with the NeuroStar System, the SenStar Connect Treatment Link is intended for multiple-use and is deactivated after 3,000 patient treatment sessions. The SenStar Connect Treatment Link is intended to remain in place on the treatment coil for multiple treatment sessions and multiple patients. Do Not Remove the SenStar Connect Treatment Link from the Treatment Coil or it will be damaged and require replacement.

Therefore, below Steps 1 through 10 are only needed when a SenStar Connect Treatment Link has reached end-of-life or failed (if the system displays a message to replace the SenStar Connect Treatment Link, a new SenStar Connect Treatment Link needs to be attached to the treatment coil). Otherwise, start at Step 11 to install a hygiene barrier on the SenStar Connect Treatment Link and treatment coil.

The following are the steps for removing and installing the SenStar Connect Treatment Link and installing a Hygiene Barrier:

1. Loosen the halo brake.

2. Position the treatment coil as illustrated in Figure 9-12 and tighten the halo brake.

![FIGURE 9-12. Treatment Coil](image)
3. Carefully remove the Treatment Link from the Treatment Coil by lifting the center bar as illustrated in Figure 9-13.

![FIGURE 9-13. Lift the Center bar of the Used SenStar Connect Treatment Link](image)

4. Pull back the used Treatment Link from the Coil as illustrated in Figure 9-14.

![FIGURE 9-14. Remove the Used SenStar Connect Treatment Link](image)
5. Clean the surface of the Coil using an alcohol wipe to remove any adhesive residue (see Figure 9-15 and Figure 9-16). Be sure to completely remove the old adhesive. Let the coil surface dry completely (about 60 seconds) before inserting a new Treatment Link. A clean dry lint-free cloth may be used, if necessary.

**NOTE**

Only use an alcohol wipe to clean the surface.

6. Obtain a new SenStar Connect Treatment Link and remove only the narrow adhesive liner strip from the center part of the new Treatment Link as illustrated in Figure 9-17.
7. Insert the connector of the Treatment Link into the connector receptacle of the Coil as illustrated in Figure 9-18.

![SenStar Connect Treatment Link - In Treatment Coil Connector](image)

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>SenStar Connect Connector</td>
<td>Treatment Coil Connector Receptacle</td>
<td>SenStar Connect Center Bar</td>
</tr>
</tbody>
</table>

FIGURE 9-18. SenStar Connect Treatment Link - In Treatment Coil Connector

8. Press the SenStar Connect Treatment Link center bar into the treatment coil center bar as illustrated in Figure 9-20. Apply smooth pressure across center bar surface several times to ensure proper adhesion.

9. With clean, dry hands remove the large liner from the rear surface of the Treatment Link and carefully affix the Link to the Coil as illustrated in Figure 9-19.
10. Apply smooth pressure across the SenStar Connect Treatment Link surfaces several times to ensure proper adhesion to the Treatment Coil as illustrated in Figure 9-20.

**NOTE**

Prior to installing a new Hygiene Barrier on the treatment coil, occasionally clean the perimeter edges and sides of the treatment coil with an alcohol prep pad and allow the edges to dry. This will ensure proper adherence of the Hygiene Barrier to the treatment coil surfaces.

**NOTE**

Do not use alcohol wipes or apply chemicals to the surface of the SenStar Connect Treatment Link.
NOTE

If the SenStar Connect Treatment Link is installed off center or incompletely in the treatment coil connector groove, the system displays the following error message: “Please reinsert the SenStar.”

11. Obtain a new Hygiene Barrier. The Hygiene Barrier comes into direct contact with the patient’s scalp, therefore, handle the Hygiene Barrier carefully and keep it away from contaminants or other substances.

12. With clean dry hands, carefully remove the release liner as illustrated in Figure 9-21.

FIGURE 9-21. Hygiene Barrier - Removing Release Liner

DO NOT COVER THE COIL VENTS WITH THE HYGIENE BARRIER.
13. Carefully position the Hygiene Barrier over the SenStar Connect Treatment Link and treatment coil with the adhesive side facing the coil surface as illustrated in Figure 9-22.

![FIGURE 9-22. Hygiene Barrier Over Treatment Coil](image)

14. First, apply the lower portion of the Hygiene Barrier to the coil face over the SenStar connector (near the vents by the handle) as illustrated in Figure 9-23. Then, apply the upper portion of the Hygiene Barrier as illustrated in Figure 9-24. Be sure it conforms smoothly to the curved treatment coil surface.

![FIGURE 9-23. Hygiene Barrier - Lower Portion Adhered to the Treatment Coil](image)
15. If the Hygiene Barrier is wrinkled, peel the Hygiene Barrier back and reapply so it’s centered and smoothly applied to the treatment coil.

16. Press down on the Hygiene Barrier to make sure that it is adhered to the edges of the treatment coil as illustrated in Figure 9-25.

FIGURE 9-24. Hygiene Barrier - Adhered Smoothly to the Treatment Coil

FIGURE 9-25. Hygiene Barrier - Installed On Treatment Coil
17. Proper completed installation of the SenStar Connect Treatment Link and Hygiene Barrier on a treatment coil is illustrated in Figure 9-26.

![Figure 9-26. SenStar Connect Treatment Link And Hygiene Barrier – Installed On Treatment Coil](image)

**NOTE**

To ensure the integrity and longevity of the SenStar Connect Treatment Link, remove the Hygiene Barrier starting from the connector side of the SenStar Connect Treatment Link.

### 9.6.2 Attaching a SenStar Treatment Link

When using a SenStar Treatment Link with the NeuroStar System, a new one needs to be attached to the face of the treatment coil for each patient session.

The SenStar Treatment Link comes into direct contact with the patient's scalp. Handle the SenStar Treatment Link carefully and keep it away from contaminants or other substances.

Each SenStar Treatment Link may only be used once and then should be disposed of as regular waste. However, the same SenStar Treatment Link may be used for both MT location and treatment when both are performed during the same session.

If a used SenStar Treatment Link has been installed, the system displays an error message. If this error message is displayed, install a new SenStar Treatment Link.

The following are the steps for installing the SenStar Treatment Link.

1. Loosen the halo brake.
2. Position the treatment coil as illustrated in Figure 9-27 and tighten the halo brake.

![Image of treatment coil and SenStar Treatment Link]

<table>
<thead>
<tr>
<th></th>
<th>SenStar Connector</th>
<th>SenStar Center Bar</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Treatment Coil Connector Groove</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**FIGURE 9-27. SenStar Treatment Link**

3. Press the SenStar Treatment Link connector into the treatment coil connector groove.

4. Press the SenStar Treatment Link center bar into the treatment coil center bar groove.

**NOTE**

If the SenStar Treatment Link is installed off center or incompletely in the treatment coil connector groove, the system displays the following error message: “Please reinsert the SenStar.”

### 9.6.3 Removing a SenStar Connect Treatment Link

When using a SenStar Connect Treatment Link with the NeuroStar System, the SenStar Connect Treatment Link is intended for multiple-use and is deactivated after 3,000 patient treatment sessions. Therefore, below Steps 1 through 6 are only needed when a SenStar Connect Treatment Link has reached end-of-life or failed (if the system displays an error to replace the SenStar Connect Treatment Link, a new SenStar Connect Treatment Link needs to be attached to the treatment coil).

The following are the steps for removing the SenStar Connect Treatment Link:

1. Loosen the halo brake.
2. Position the treatment coil as illustrated in Figure 9-28 and tighten the halo brake.

FIGURE 9-28. Treatment Coil

3. Carefully slide finger tips under the edges of the SenStar Connect Treatment Link as illustrated in Figure 9-29.

FIGURE 9-29. SenStar Connect Treatment Link - In Treatment Coil
4. With fingers squeezing corners of the SenStar Connect Treatment Link, gently pull the SenStar Connect Treatment Link straight out and away from the face of the treatment coil, resulting in disengagement of the connector from the treatment coil as illustrated in Figure 9-30.

![FIGURE 9-30. SenStar Connect Treatment Link - Connector Removal From Treatment Coil](image)

5. Grasp SenStar Connect Treatment Link and gently pull away from treatment coil as illustrated in Figure 9-31 and Figure 9-32.

![FIGURE 9-31. SenStar Connect Treatment Link - Grasping SenStar Connect Treatment Link](image)
6. Once removed from the treatment coil, dispose of the SenStar Connect Treatment Link in a regular waste container.

9.7 Running the Pulse Test

In this test, the system generates five pulse sets that measure the pulse levels at the treatment coil. It establishes that the output of pulses is within the acceptable range.

Keep the treatment coil away from the patient’s head or any other surface during this test. If the treatment coil detects contact, the system displays an error message and the TEST PULSE button remains disabled until the treatment coil has been moved away from the patient’s head or other surface.

NOTE

If a SenStar Treatment Link has not been attached to the treatment coil, or if the SenStar Treatment Link on the treatment coil has already been used, or the SenStar Connect Treatment Link needs to be replaced, the system prompts the operator to attach a new SenStar Treatment Link and disables the TEST PULSE button until this has been done.
1. Touch the **TEST PULSE** button on the display. In response, the system generates five sets of three pulses, each with varying loudness. It also displays a progress screen, as illustrated in Figure 9-33.

   **NOTE**

   There are slight variations in what is displayed on the console screens depending on what type of SenStar is installed. When a SenStar Connect Treatment Link is installed the screen will show the number of available treatment sessions: `<#> Tx SESSIONS AVAILABLE`. Treatment session information is not displayed when a SenStar Treatment Link is installed. See Figure 9-41 and Figure 9-42.

   ![Figure 9-33. Test Pulse Progress Screen](image-url)
NOTE

Pressing the pulse button on the treatment coil, as illustrated in Figure 9-34 also initiates the pulse test.

FIGURE 9-34. Treatment Coil Pulse Button
2. When the test is finished, the system displays the test pulse completion screen, as illustrated in Figure 9-35.

**FIGURE 9-35. Test Pulse Completion Screen**
If the system fails to detect the levels of these pulses, it prohibits the operator from proceeding and displays the Magnetic Field Strength Failed screen (see Figure 9-36).

If the system detects a change in the duration of these pulses it displays the Change in Duration screen (see Figure 9-37).

Stop patient treatments and contact Technical Support to inspect the system.

FIGURE 9-36. Magnetic Field Strength Failed Screen  FIGURE 9-37. Change in Duration Screen
If the system detects that the SenStar Connect Treatment Link installed into the Coil is close to reaching end of life (100 or fewer sessions left), it displays the SenStar Connect Treatment Link End of Life message alarm (see Figure 9-38) and lets the operator proceed. Touch the alarm icon to see the message.

**Figure 9-38. SenStar Connect Treatment Link Replace Soon Message Screen**
If the system detects that the SenStar Connect Treatment Link installed into the Coil is close to reaching end of life (10 or fewer sessions left), it displays the SenStar Connect Treatment Link End of Life message screen (see Figure 9-39) and lets the operator proceed.

If the system detects that the SenStar Connect Treatment Link installed into the Coil has reached end of life (No more sessions left), it prevents the treatment delivery and displays the SenStar Connect Treatment Link End of Life message screen (see Figure 9-40).

![Figure 9-39. SenStar Connect Treatment Link Replace Very Soon Message Screen](image1)

![Figure 9-40. SenStar Connect Treatment Link End of Life Message Screen](image2)
3. Touch the **CONTINUE** button to display the “Select Patient” screen (Figure 9-41 and Figure 9-42).

**NOTE**

After five seconds, the system automatically advances to the “Select Patient” screen if the operator has not touched the **CONTINUE** button by then.

---

**FIGURE 9-41. Select Patient Screen with SenStar Treatment Link Installed**

**FIGURE 9-42. Select Patient Screen with SenStar Connect Treatment Link Installed**
9.8 Screen Navigation

As illustrated in Figure 9-41 and Figure 9-42, the NeuroStar System display screens all share six tabs at the bottom of each screen:

- The Patient ID tab is the first tab from the left. Touching this tab enables the operator to search for or select a patient whose information is stored in the system. When this tab is selected, the Select Patient screen (Figure 9-41, Figure 9-42) is displayed.

- The MT Locate tab is the second tab. Touching this tab starts the process of finding the patient’s MT location. When this tab is selected, the “MT Locate” dialog screen is displayed. See Figure 11-10 in Section 11.

- The MT Level tab is the third tab. Touching this tab starts the process of determining the patient’s MT level. When this tab is selected, the “MT Level Search” screen is displayed. See Figure 11-16 in Section 11.

- The Treatment tab is the fourth tab. Touching this tab starts the treatment session for a selected patient. When this tab is selected the “Patient Treatment” screen is displayed. See Figure 12-3 in Section 12.

- The End Session tab is the fifth tab. Touching this tab ends a patient’s treatment session. When this tab is selected, the End Session screen is displayed. See Figure 12-15 in Section 12. After this tab has been touched during an MT or treatment session, the SenStar Treatment Link becomes inactive and must be replaced with a new one; a SenStar Connect Treatment Link treatment session is over.

- The Config. tab is the last tab. Touching this tab enables the operator to change system operational settings. When this tab is selected, the Configuration screen is displayed. See Figure 3-1 in Section 3.

Not all tabs are active during some operations, but they are always included in the screens.

When a SenStar Connect Treatment Link is installed, the upper left corner of the screen displays the available treatment sessions. See Figure 9-42 in Section 9.7. Press the refresh icon [②]; next to the number of treatment sessions available] to refresh the screen with the current number of available treatment sessions.
10 Patient Session Preparation Steps

This section provides steps for beginning each patient’s MT or treatment session.

**NOTE**

The NeuroStar displays an alarm at the top of the screen if there is no connection with TrakStar. Notify technical support to correct the problem. When the connection is re-established, log off of NeuroStar and then log back on.

10.1 Selecting a Patient

Patient records in the “Select Patient” screen can be listed by patient ID number (default), by date of birth, or by date of the last session. To change the order of the list, touch the appropriate table column heading. The system also displays “up” and “down” arrows next to the selected table column heading. Touching the arrow causes the system to display the list by highest to lowest number or by most recent to oldest date.

1. After the operator has logged in, has attached a valid SenStar Treatment Link or ensured that a SenStar Connect Treatment Link is installed in the treatment coil, and completed the pulse test, the system displays the “Select Patient” screen (Figure 10-1).

![Select Patient Screen](image)

**FIGURE 10-1. “Select Patient” Screen**
2. If the patient’s ID number is not displayed on the screen, use the up and down arrows in the “Search for an existing patient record” area of the screen to view the rest of the list.

3. Alternatively, use the touchscreen keyboard to type the patient’s ID number in the “Search on Patient ID:” field. As the numbers are typed, the system displays a list of patient ID numbers that begin with the numbers that have been entered.

4. In a multiple-office practice, the Data View button switches between the Local view and Global View of data. The patient list and search feature defaults to the Local data view, showing only those patients that have been treated at that office. Touch the LOCAL view button \[\text{LOCAL}\] to switch to the GLOBAL data view that will access patients treated in any other offices. Touch the GLOBAL view button \[\text{GLOBAL}\] to switch back to the Local data view. (See Figure 10-2 and Figure 10-3.)

![FIGURE 10-2. Searching the Local View Screen](image1)

![FIGURE 10-3. Searching the Global View Screen](image2)
5. Touch the line that corresponds to the specific patient. When a patient’s ID number has been selected from the list, the system automatically enables the CONFIRM PATIENT button and the PATIENT POSITIONING button and populates the following fields:
- Patient name
- Patient ID
- Patient Photo (if saved)
- Gender
- DOB
- Last session
- Office (where the patient was last treated)
- LC setting

**NOTE**
See the TrakStar Instructions For Use for steps to save a patient photo.

**NOTE**
If a new patient was entered through TrakStar after the operator has logged into the mobile console, that new patient will not be in the patient list on the display. Touching the SYNC button in the “Select Patient” screen (Figure 10-1) causes the mobile console to add the new patient to the patient list. The NeuroStar displays the “Please Wait. Syncing Data” message during this process. The SYNC button is only available if there is a connection with TrakStar.

**NOTE**
To protect the privacy of patient information, the operator can at any time mask personal information that is displayed (name, photo, gender, and date of birth) by touching that area of the screen. In response, the system replaces the displayed information with asterisks (*). Touching that area of the screen again restores the personal information.

6. If this is the patient’s first visit or if the patient’s position needs to be updated, touch the PATIENT POSITIONING button. In response, the system displays the “Patient Positioning” pop-up window (Figure 10-4). Leave this window open for completion of the steps in Section 10.5; follow the steps in Section 10.2 through Section 10.5.

**NOTE**
The SAVE button in the “Patient Positioning” pop-up window remains disabled until values have been entered in the “LC Setting,” “Head Support Up/Down,” and “Head Support Front/Back” fields.

7. If this is a patient’s return visit, touch the CONFIRM PATIENT button and follow the steps in Section 11 and/or Section 12, as appropriate.

**NOTE**
The CONFIRM PATIENT button is active ONLY when the patient’s LC setting, head support up/down setting, and head support front/back values have been recorded. The steps for determining and recording these values are in Section 10.5, below.

New patient records should be entered through TrakStar (see the TrakStar Instructions For Use). However, if TrakStar is not available when new patient data needs to be entered, touch the NEW PATIENT button in the “Select Patient” screen on the display and use the display keyboard to enter the patient information (see Section 10.1.1, “Working Offline if NeuroStar and TrakStar are Disconnected”).
FIGURE 10-4. Patient Positioning Pop-Up Window
10.1.1 Working Offline if NeuroStar and TrakStar are Disconnected

The NeuroStar gets a copy of the patient database from TrakStar once per day at a scheduled time. Treatments can continue even if NeuroStar is disconnected from TrakStar (this can happen for a variety of reasons, including: a faulty network connection, TrakStar hardware problem, etc.).

During the time the NeuroStar is disconnected from TrakStar:

- Patients who have been treated before can continue to be treated. Both Standard and Custom treatments are available.
- New patients can be entered at the NeuroStar Mobile Console for treatment using the **NEW PATIENT** button. Only the Standard treatment is available for these patients.
- If NeuroStar remains disconnected from TrakStar, new patients should return to the same NeuroStar Mobile Console for treatment, where they can be selected from the Patient List. If they are treated at a different NeuroStar Mobile Console, then they must be entered as a **NEW PATIENT** and a Motor Threshold procedure must be performed again.

Once connection between TrakStar and the NeuroStar is re-established, records of the treatments during the disconnected period are transferred to TrakStar. If the newly-treated patients were entered on the TrakStar during this period, their treatment records will be automatically added to their Treatment History. If there is a mismatch between the patient information entered into TrakStar and NeuroStar, or the patient has not yet been added at TrakStar the operator must manually assign the treatments to a patient using the Unassigned Treatments function of the TrakStar **TOOLS** tab (for more information see the *TrakStar Instructions For Use*).

**NOTE**

If the NeuroStar System is disconnected from the TrakStar when a SenStar Connect Treatment Link is installed, treatments can still be administered at the NeuroStar System console for the next 72 hours — as long as there was at least one treatment session available when the disconnection occurred. During this 72-hour period a countdown timer is displayed and as many treatments as necessary can be delivered (see Figure 10-5).

At the end of the 72 hours, the console will no longer be able to administer treatment sessions. When the NeuroStar System console is reconnected with TrakStar, the used treatment sessions will be deducted from the available treatment sessions. If the number of treatment sessions used exceeds the number of available treatment sessions the console will show a negative number until additional treatment sessions are purchased.
FIGURE 10-5. Countdown Timer Showing Amount of Offline Time Remaining
10.1.2 Using the New Patient Function

The **NEW PATIENT** button is only available when there is no connection with TrakStar. When this occurs, NeuroStar provides basic patient registration through the display. This procedure requires patient registration measurements. To record these measurements, seat the patient in the treatment chair, as described in Section 10.4.

1. With the “Select Patient” screen displayed, touch the **NEW PATIENT** button (see Figure 10-5).

2. At the “New Patient” screen (Figure 10-6), use the display keyboard to type an identification number in the “Patient ID” field. This is a required field.

![Add Patient Information](image)

**FIGURE 10-6. Mobile Console New Patient Screen Add Patient Information**

3. Use the display keyboard to type the patient’s first and last name. When the patient’s ID and name have been entered, the **PATIENT POSITIONING** button is enabled and turns green.
4. Touch the **PATIENT POSITIONING** button to display the “Patient Positioning” pop-up window (Figure 10-7).

![Image](image_url)

**FIGURE 10-7. “Patient Positioning” Pop-Up Window**

5. Based on the position measurements that were established as part of patient positioning (as explained in Section 10.4), touch each section and use the “up” or “down” arrows to record the patient’s position.

6. Touch the **SAVE** button. In response, the system saves the measurements and removes the “Patient Positioning” pop-up window.
7. At the “New Patient” screen (Figure 10-8), touch the **SAVE NEW PATIENT** button. In response, the system saves the patient data and displays the “MT Locate – Auto Pulsing” screen (see Figure 11-11 in Section 11).

![Figure 10-8](https://example.com/figure10-8.png)

**FIGURE 10-8. Mobile Console “New Patient” Screen with Data**

8. If any required fields are blank, the **SAVE NEW PATIENT** button remains disabled until the required information has been entered and validated.
10.2 Readying the NeuroStar System for Patient Positioning

This section lists the steps for setting up the treatment chair and the head support system before the patient is seated.

**NOTE**

The NeuroStar System is designed for reproducible placement of the treatment coil within 5 mm from treatment to treatment for a patient whose treatments are conducted using the same NeuroStar system.

If a patient is moved from one NeuroStar System to another NeuroStar System, a 5 mm reproducibility in the treatment coil may not be maintained.

**Tripping Hazard.** Make sure that the power cords for the mobile console and the treatment chair are safely out of the path of the patient and of everyone else in the treatment room.

1. Press and hold the **M1** button on the treatment chair wired remote until the chair stops moving (Figure 10-9).

![Treatment Chair Wired Remote](image)

FIGURE 10-9. Treatment Chair Wired Remote
2. Place a fresh liner on the head cushion and a fresh liner on the side pad. Tuck the top of the head cushion liner behind the top of the head cushion to hold it in place (Figure 10-10).

Sanitary Use. Always place fresh liners over the head support cushion and the side pad before seating the patient. At the end of a treatment session, dispose of the liners and hygiene barrier with regular waste.

3. When using a SenStar Connect Treatment Link, adhere a new hygiene barrier on the SenStar Connect Treatment Link and treatment coil surface (see Section ).

4. Grasp the treatment coil handle, press and hold the brake release button, move the mast to the back of the console, and raise the treatment coil as high as it will go. Then, release the brake release button (if the treatment coil is not already in that position).

   NOTE
   To avoid unexpected treatment coil movement, hold the treatment coil handle firmly while pressing the brake release button.

5. Make sure that the treatment coil cable is not in the treatment coil cable guide. (See Figure 10-20 for the location of the cable guide.)

6. Turn the LC Adjustment Knob until the LC scale reads 0.

7. Grasp the A/P bar handle and move it to the center of the treatment chair until the SOA indicator lines up with 0° on the SOA scale feeling the detent of the 0° indicator.

   When moving the A/P bar up or down or rotating it from side to side, always hold the A/P bar handle. Do not use the A/P bar if it is bent or broken. Contact Technical Support for a replacement.
8. Squeeze the A/P bar brake release grip and slide the A/P bar toward the back of the treatment chair until the 0 on the A/P bar scale lines up with the A/P arrow.

9. Release the A/P bar brake release grip.

10. Grasp the head support handle and loosen the front/back adjustment knob.

11. Slide the head support system until the number “3” on the front/back scale is visible just in front of the treatment coil cable guide (Figure 10-11).

12. Tighten the front/back adjustment knob.

13. Grasp the head support system below the treatment coil cable guide and loosen the up/down adjustment knob.

14. Slide the head support system until it reaches the “10” mark on the up/down scale.

15. Tighten the up/down adjustment knob.

16. Move the side pad arm to its vertical position.

17. Lift the arm of the treatment chair to its vertical position.
10.3 Introducing a New Patient to the NeuroStar System

1. Review with the patient the treatment plan, including the schedule, the treatment steps, and the patient instructions.

2. Briefly describe the major NeuroStar System components:
   - Mobile console
   - Treatment coil
   - Display
   - Treatment chair
   - Head support system with laser positioning aid
   - SenStar Treatment Link or SenStar Connect Treatment Link

3. Briefly describe the supplies:
   - Hygiene Barrier (used in conjunction with SenStar Connect Treatment Links)
   - Head cushion and side pad liners
   - Head positioning strap
   - Positioning pads
   - Side pad
   - Earplugs

4. Describe any required safety precautions:
   - Contraindications (Ensure that none apply to the patient. See Section 7.1.)
   - Use of earplugs
   - Distance of metallic objects from the treatment coil
   - Possible adverse effects

**NOTE**

Ask the patient about changes in over-the-counter or prescription medication use. If there are changes, see the TrakStar Instructions For Use to update the patient’s record when possible. Also, decide if an MT needs to be redetermined.
10.4 Seating a Patient

For effective treatment, ensure that the patient is comfortable and properly aligned with the NeuroStar System. Ensure that the treatment chair is adjusted at a height that provides comfortable operator access for positioning the treatment coil.

When seating a returning patient, use the positioning values that have already been recorded in TrakStar. These values can be retrieved by touching the PATIENT POSITIONING button on the “Select Patient” screen (Figure 10-1).

This section lists the steps for finding the patient position for effective treatment.

Explain to the patient how to properly insert the earplugs.

1. Compress and roll the first earplug, pull up on the ear, and insert the compressed earplug into the ear canal.

2. Hold the earplug in place until the earplug has expanded to fill the ear canal.

3. Repeat steps #1 and #2 for the remaining earplug.

4. With the treatment chair in the seating position (Figure 10-12), ask the patient to sit on the side of the treatment chair.

FIGURE 10-12. Treatment Chair in the Seating Position

The capacity limit for NeuroStar System treatment chair operation is 400 lbs. (182 kg.).
5. Obtain the head positioning strap.

Head positioning straps cannot be reused. Inspect the head positioning strap before using it.

6. Peel off the adhesive cover from the back of the head positioning strap.

7. Line up the point at the end of the head positioning strap with the patient’s nasion and apply the head positioning strap close to, but not touching, the patient’s eyebrow. The point must remain centered over the patient’s nasion.

8. Ask the patient to swing his or her legs around and to sit back in the treatment chair.

9. Lower the treatment chair arm (Figure 10-13).

10. Ask the patient to center his or her body in the treatment chair and to fully sit up, if necessary.

11. Stand at the foot of the treatment chair facing the patient and ascertain that the patient is centered in the treatment chair. If necessary, ask the patient to move to the left or to the right.

12. Shift the patient into the treatment position by pressing and holding the M2 button on the treatment chair wired remote until the chair stops moving. Adjust the leg support as needed for patient comfort (Figure 10-13).

13. Observe the head support system while holding the M2 button. Release the M2 button if the head support system will collide with the mobile console. To avoid a collision, release the mobile console wheel locks and move the mobile console back to clear the head support system.

Failure to grasp and restrain the head support system when fully extending may cause system damage and result in injury.

![FIGURE 10-13. Patient in Treatment Position](image-url)
14. With one hand, grasp and hold the head support system below the treatment coil guide.

15. With your other hand, turn the up/down adjustment knob counterclockwise until the head support system moves freely up and down.

16. Move the head support system up or down until the back of the patient’s head is centered in the head cushion.

17. Turn the up/down adjustment knob clockwise and tighten it to hold the head support system in place.

18. With one hand, grasp and hold the head support handle.

19. With your other hand turn the front/back adjustment knob counterclockwise until the head support system moves freely back and forth.

20. With the patient’s help identify a position that provides comfortable support for the patient’s head.

21. Turn the front/back adjustment knob clockwise and tighten it to hold the head support system in place.

If necessary, adjust the lumbar support cushion for patient comfort. See Section 10.6.

Possible Patient Injury. Always use care when repositioning the head support system or its components to avoid collision with the patient.
10.5 Aligning a Patient’s Head

1. Attach the top head positioning strap to the top of the head support system.
2. Move to the back of the treatment chair, grasp the A/P bar handle, and lift it until it reaches its mechanical stop and is clear of the top of the patient’s head.
3. Move the A/P bar to the 0° position on the SOA scale.
4. Grasp the A/P bar handle and tilt the A/P bar left or right until the centering mark is aligned with the center indentation (Figure 10-14).

5. Grasp the A/P bar with one hand, and squeeze the A/P bar brake release grip to unlock the A/P bar.
6. Slide the A/P bar fully forward and release the A/P bar brake release grip.
7. Move the treatment coil angle indicator left or right until the 0° mark lines up with the center point at the tip of the A/P bar.

**FIGURE 10-14. Centering Mark and Center Indentation**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>A/P Bar Handle</td>
</tr>
<tr>
<td>B</td>
<td>Centering Mark</td>
</tr>
<tr>
<td>C</td>
<td>Center Indentation</td>
</tr>
</tbody>
</table>
8. Press the laser on/off button on the A/P bar to activate the laser (Figure 10-15).

Avoid prolonged or unnecessary exposure of the eye to the laser light. The laser used to assist in patient positioning meets internationally accepted safety standards which state it is "safe to eye and skin under all reasonably foreseeable conditions of operation." However, it is always prudent to avoid any unnecessary exposure of the eye to laser light.
9. Align the laser so that the laser line bisects the patient’s point on the head positioning strap. If needed, ask the patient to turn to the right or left for alignment (Figure 10-16).

![Figure 10-16. Centered Patient](image)

10. Stand in front of the treatment chair and check that the patient’s head is still centered and that the laser is aligned with the nasion.

11. Instruct the patient to turn his or her head to a centered position, if necessary.

12. Press the laser on/off button to turn off the laser. (The laser turns itself off automatically after 45 seconds.)

13. Grasp the A/P bar handle and move it to the patient’s left side until it stops.

14. Instruct the patient to look at a fixed point in front. Also, ask the patient to keep his or her eyes open. Closing them will change the measurement.

15. Squeeze the A/P bar brake release grip, carefully slide the A/P bar back until the laser lines up with the patient’s lateral canthus (LC), and release the A/P brake release grip.

16. Press the laser on/off button to activate the laser.
17. Turn the LC adjustment knob until the laser line is aligned with the patient’s lateral canthus (Figure 10-17).

![Figure 10-17. Laser Aligned with Lateral Canthus](image)

18. If needed when seating a returning patient, instruct the patient to move up or down in the treatment chair until the laser line is aligned with the patient’s LC.

19. Establish a straight line on the side of the patient’s head between the patient’s LC and the point at which the patient’s ear attaches to the scalp.

20. If needed, instruct the patient to tilt his or her head up or down until the laser line connects the lateral canthus to the point at which the patient’s ear connects to the scalp.

21. Press the laser on/off button to turn off the laser.

22. Grasp the A/P bar handle and pull the A/P bar fully away from the patient.

23. Move the A/P bar to its full vertical position (stop) and ensure that its marker lines up with 0° on the left SOA scale.

24. Press the laser on/off button. The red line projected by the laser should bisect the center point of the head strap. If it does not, loosen the head straps, ask the patient to turn right or left as needed, and reattach the side straps.

25. Press the laser on/off button to turn the laser off.

26. Slide the A/P bar backward to the “0” mark on the A/P scale.
27. Move to the patient’s left side and attach the left-side head positioning strap to the Velcro strip on the left side of the head support system.

28. Move to the patient’s right side and attach the right-side head positioning strap to the Velcro strip to the right side of the head support system.

**NOTE**

Ensure that the top head positioning strap and the side head positioning strap are not too tight, which may cause patient discomfort. Be sure to instruct the patient that pulling the long end of the head strap disengages the head strap from the Velcro attachments on the head support system. This feature provides the patient with control in exiting the device in case of an emergency or in case of discomfort.

29. At the “Patient Positioning” pop-up window (Figure 10-18), use the arrow buttons or the slider to record each setting:

- **Lateral Canthus (LC) Setting:** Range is –2.5 to 2.5
- **Head Support System Up/Down:**
  - For Model 81-00878-000 the Range is 0.0 to 16.0
  - For Model 81-01020-000 the Range is 0.0 to 23.0
- **Head Support System Front/Back:**
  - For Model 81-00878-000 the Range is 0.0 to 9.0
  - For Model 81-01020-000 the Range is –1.0 to 9.0
- **Seat Cushion:** Options are “Yes” and “No”
- **Extra Head Cushion:** Options are “Yes” and “No”

Use “zero” Back position when the software interface value is entered as a negative.
30. Touch the **SAVE** button to accept the changes.

**NOTE**

The “Head Support Up/Down,” “Head Support Front/Back,” and “LC Setting” are required fields. While the system activates the **SAVE** button when any of these fields has a value, the **CONFIRM PATIENT** button in the “Select Patient” screen (Figure 10-1) is disabled until all three fields have been filled. If the **CONFIRM PATIENT** button is gray, touch the **PATIENT POSITIONING** button to display the “Patient Positioning” pop-up window and fill in the required fields.

31. Swing the side pad bar down from its vertical position, and then loosen the side pad by turning the blue side pad knob counterclockwise.
32. Slide the side pad forward or backward as needed to center it above the patient’s right ear (Figure 10-19) for MT or in the temple area for treatment.

33. Turn the side pad knob clockwise to hold the side pad in place.

34. Lightly engage the side pad to the patient’s head by gently moving the side pad arm forward and in toward the center of the head support system.

35. Release the side pad arm support. The pressure from the patient’s head against the side pad will hold the side pad arm support in place.
36. Place the treatment coil cable in the treatment coil cable guide with a generous loop (Figure 10-20).

![Coil Cable in Coil Cable Guide](image)

FIGURE 10-20. Coil Cable in Coil Cable Guide

37. To establish the patient’s MT location and level, follow the steps in Section 11.
10.6 Adjusting the Lumbar Support

The NeuroStar System treatment chair is equipped with an inflatable cushion that is designed to support the lumbar vertebrae. This adjustable cushion can increase patient comfort during MT or treatment. As illustrated in Figure 10-21, the bulb pump enables the operator to increase the lumbar support gradually.

Pressing the valve allows stored air to escape.

With the cushion valve in the closed position, repeatedly squeeze the bulb until the patient reports comfortable lumbar support.

At the conclusion of the treatment session, release the lumbar support stored air.

Possible Patient Injury. Always use care when repositioning the head support system or its components to avoid collision with the patient.
11 Motor Threshold Determination

This section covers finding a patient’s motor threshold location and determining a patient’s motor threshold (MT) level.

A patient’s MT can be determined automatically through the system’s MT Assist program or manually by increasing or decreasing the MT level using the buttons on the treatment coil or on the display. With either method the operator alternately increases and decreases the MT level and incrementally narrows the range of magnetic field intensity until the patient’s MT location has been identified.

As illustrated in Volume 1, Section 2, the treatment coil has two buttons that release the system brakes and facilitate the movement of the treatment coil for accurate positioning. One button is on the treatment coil housing and is printed with the image of an unlocked padlock. The other is an elongated button on the underside of the treatment coil handle.

When positioning the treatment coil against the patient’s head, be sure to keep the patient’s hair from becoming entangled with the NeuroStar System parts.

NOTE

When a SenStar Connect Treatment Link is installed, an unlimited number of motor threshold determinations can be performed. A motor threshold determination does not deduct from the number of available treatment sessions.

11.1 Positioning the Treatment Coil to Find the Patient’s MT Location

Determining the MT location for treatment is a necessary step for each new patient.

1. Set the SOA to 30°.
2. Turn the halo brake counterclockwise to loosen it.
3. Move the treatment coil down to the patient’s head so that the top of the treatment coil is at the top of the head. Line up the coil handle with the middle of the patient’s upper arm/shoulder. Align a pen behind the tragus at the angle of the patient’s head (50 degrees). The center of the coil line beneath the handle (Figure 11-1) should be in line with the pen.

NOTE

If the treatment coil will not reach this position, release the mobile console wheel locks, remove the spacer block, align the mast to the center of the head support system, and move the mobile console closer to the treatment chair. Relock the mobile console wheel locks.
Motor Threshold Determination

A Coil Line (beneath coil handle)

FIGURE 11-1. Treatment Coil in MT Hunt Position

4. Release the brake release button.
5. Turn the halo brake clockwise to tighten it.
6. Move the side pad toward the right side of the patient’s head above the right ear until it is firmly pressing against the patient.
7. Squeeze and hold the A/P bar lock.
8. Move the A/P bar forward until it is flush against the side of the treatment coil.
9. Release the A/P bar lock.
10. Adjust the treatment coil’s position to align the center line on the treatment coil with 0° on the treatment coil angle guide (Figure 11-2). In this position, the treatment coil is now aligned at a starting SOA of 30°.

11. Check the display to ensure that contact is maintained. If necessary, adjust the side pad to re-establish contact. A green mark in the “Contact Sensor” portion of the “MT Locate” screen indicates that the treatment coil detects contact.

12. Squeeze the A/P bar lock and move the A/P bar back to 0.

11.2 Maintaining Treatment Coil Contact

The “Contact Sensor” area is part of the MT location, MT determination, and treatment screens and provides important information.

As mentioned in Step #11 of the treatment coil positioning procedure, a green contact circle mark indicates that the treatment coil is maintaining contact with the patient’s scalp (Figure 11-3).

When an orange “X” mark is displayed, contact has been lost (Figure 11-4). The area over the image of the human head shows the points of contact of the treatment coil against the surface of the patient’s head.

If the treatment coil loses contact with the patient’s head during MT location, MT determination, or treatment, as illustrated in Figure 11-4, take the following steps:
If the treatment coil moves away from the patient's head during MT search, MT level determination, or treatment, the patient will not receive proper treatment. Try to reposition the treatment coil on the patient's head and check that the halo lock is holding. If the treatment coil again moves away from the patient's head, contact Customer Service.

1. If the auto pulse option is active (see section 11.3 for a description of options), touch the **PAUSE** button.

2. Press and hold the brake release button on the back of the treatment coil while gently pressing the treatment coil toward the patient’s head until contact has been reestablished and the contact sensor display shows a green indication.

3. Release the brake release button.

4. Adjust the side pad position as needed.

Check the “Contact Sensor” portion of the display to ensure that the treatment coil is making contact.

**NOTE**

If the treatment coil is making contact at only one of the two points on the patient's scalp, MT search and treatment can still be done.

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![FIGURE 11-3. Treatment Coil Contact at Two Points](image-url)
11.3 Choosing Operating Modes

In finding a patient’s MT location and in establishing the patient’s MT level, the NeuroStar System provides the flexibility to choose from the following operating modes:

- Use the built-in program to deliver pulses at set intervals (auto-pulsing).
- Control both the timing and the level of the pulsing (manual pulsing).

Sections 11.5 and 11.6 describe the steps for each option, as follows:

Finding a patient’s MT location (Section 11.5)

- Using auto pulsing (Section 11.5.1). (This is the default option.)
- Manually pulsing (Section 11.5.2).
- Switching the treatment coil to the right side (Section 11.5.3)

Determining a patient’s MT level (Section 11.6)

- Using the MT Assist program to pulse and adjust the MT level automatically (Section 11.7). (This is the default option.)
- Manually adjusting the MT level with automatic pulsing (Section 11.7.1)
- Manually pulsing and adjusting the MT level (Section 11.7.2).
11.4 Starting the Patient’s MT Search

The patient is now positioned to begin the MT location search. Start searching on a coronal plane, which falls at the level from the top of the subject’s left ear to the vertex (top) of the head.

As long as the brake release button is held, the treatment coil can be freely moved until the button has been released. If there is mechanical stiffness or resistance when moving the treatment coil, or if the treatment coil still moves after the button has been released, contact Technical Support.

The treatment coil housing can be damaged if the treatment coil collides with a solid stationary object. If the treatment coil has any cracks in the housing or other damage to the housing, discontinue treatments and contact Customer Service.

11.5 Finding the Patient’s MT Location

The NeuroStar System offers two alternative methods of finding the patient’s MT location. As described in Section 11.5.1, the auto pulse method causes the software to administer pulses at regular timed intervals, freeing the operator to concentrate on moving the treatment coil to different locations on the patient’s head.

Alternatively, as described in Section 11.5.2, the operator can turn off the auto pulse software and use the treatment coil push-button to administer pulses.

Start looking for the optimal site of the left motor cortex region of the brain. Stimulation of this site causes movement of the right abductor pollicis brevis (APB) muscle, which produces a noticeable twitch of the patient’s right thumb. Be sure that the face of the treatment coil is flat against the patient’s head at all times during these steps.

If you can not find an MT location on the left-hand side, switch the treatment coil to the right side. See “11.5.3 Coil Placement for MT Procedure on the Right Side” on page 11-13 for instructions.
11.5.1 Using the Auto Pulsing Mode

The auto pulse mode is the default setting for MT location. To change to manual pulsing, see “11.5.2 Using the Manual Pulsing Mode” on page 11-12.

1. Instruct the patient to hold his or her right hand in a position that enables you to observe a twitch in the right thumb APB muscle, as illustrated in Figure 11-5.

![FIGURE 11-5. MT Hunt Observation Position](image)

2. Explain that when the treatment coil is pulsing the patient will feel a mild sensation on the scalp where the treatment coil is positioned.

3. Position the treatment coil at a starting location that was previously described in “Positioning the Treatment Coil to Find the Patient’s MT Location” on page 11-1.

4. On the “MT Locate – Auto Pulsing” screen (Figure 11-11), touch the START button on the display. In response, the system automatically generates a pulse every 3 seconds. (The frequency can be decreased to 1 pulse every 3-10 seconds. To change the frequency of pulses, touch the “Pulse Interval” field, illustrated in Figure 11-11, and use the “up” arrow or the slider until the longer time interval is displayed in that field.)

![NOTE](image)

Results of previous MT procedures (the MT History) will be shown on the MT Locate screens (Figure 11-6 and Figure 11-11) while a connection is established with TrakStar. If disconnected from TrakStar, the complete MT History may not be available (Figure 11-7).

5. The default starting MT level is 0.68 Standard Motor Threshold (SMT) units. Gradually increase the MT setting to a suprathreshold level, which is generally 1.00 to 1.10 SMT units by either touching and moving the slider in the lower left-hand side of the display or using the increase (+) button on the treatment coil, as illustrated in Figure 11-11.

6. If no APB muscle stimulation is observed, begin a systematic search for the patient’s MT location.
7. Press and hold the brake release button on the treatment coil and move the treatment coil to a new possible MT location.

8. Release the brake release button and wait for the next pulse. If the patient’s thumb does not twitch in response to the pulse, use a grid-like pattern and move the treatment coil to another possible MT location until you observe the patient’s thumb twitch.

9. If no thumb twitch is observed after the systematic search is completed, increase the MT level in 0.10 SMT unit increments and repeat steps 6 to 8 until a reliable thumb twitch is observed.

10. The optimal MT location will be the treatment coil position where there is a consistent thumb twitch at the lowest possible MT level.

11. Once the MT location has been identified, press the **PAUSE** button on the display.
12. Squeeze the A/P bar lock and slide the A/P bar forward to the treatment coil’s side, aligning the treatment coil angle guide to the center line on the side of the treatment coil (Figure 11-8).

![Figure 11-8. Treatment Coil Angle Guide Alignment](image)

13. Use the “up” and “down” arrows or the slider on the touchscreen to record the following MT location coordinates in the “MT Locate” screen:
   - Superior Oblique Angle (SOA) Setting – Range is 45º L to 45º R from the midline.
   - Anterior/Posterior (A/P) Position – Range is 0 cm to 22 cm.
   - Treatment coil Angle – Range is -35º to 35º.

14. Verify that the patient’s MT location falls within these ranges. If they do not, use the positioning cushions to adjust the patient's position until the MT location measurements fall within the ranges.

15. Squeeze the A/P bar lock and slide the A/P bar backward.

Be careful in recording the MT coordinates. A mistake in recording these coordinates will result in an incorrect treatment location. The software has built-in limits for the input fields to ensure that the coordinates fall within the acceptable ranges.
16. Touch the **FOUND MT LOCATION** button on the display. In response, the system displays the “MT Assist – MT Level” tabular view screen (Figure 11-9).

![Figure 11-9. MT Assist – MT Level Tabular View Screen](image)
**NOTE**

The system requires values in the SOA, A/P, and treatment coil angle fields before it enables the operator to record the patient’s MT level and continue to treatment. If any of these fields is blank when the **FOUND MT LOCATION** button is touched, the system displays a pop-up error message until values have been entered in all three fields (Figure 11-10).

**FIGURE 11-10. “Enter Values” Pop-Up Message**

17. Proceed to Section 11.7 or 11.7.1, depending on the mode that will be used to determine the patient’s MT level.
11.5.2 Using the Manual Pulsing Mode

Determining the patient’s MT level by using the manual pulsing mode is an optional alternative to using the auto pulsing mode that is described in Section 11.5.1.

To use the manual pulse button on the treatment coil to find the patient’s MT location, touch the **SWITCH TO MANUAL MT PULSES** button in the “MT Locate Auto Pulsing” screen (Figure 11-11). In response, the system displays the “MT Locate – Manual Pulsing” screen (Figure 11-11).

The steps for establishing a patient’s MT location in manual mode are the same as the steps for the automatic mode, except that the system does not automatically pulse. When the treatment coil is positioned at a possible MT location, press the pulse button on the treatment coil handle OR touch the **PULSE** button in the “MT Locate – Manual Pulsing” screen. An MT pulse cannot be delivered more frequently than every 3 seconds.
Motor Threshold Determination

11.5.3 Coil Placement for MT Procedure on the Right Side

The default coil placement is on the patient’s left side using the left-side connector. If an MT procedure requires coil placement on the patient’s right side, the coil must be positioned over the right side of the patient’s head, and the coil connector must be connected to the right-side connector.

Follow these steps to move the coil cable connector:

**Failure to follow the below Treatment Coil connector use steps may cause system damage and result in Operator’s arm movement that could result in minor injury.**

1. Move the coil Power switch from “ON” to “OFF”.
2. Grasp the coil connector Pull Ring and pull it until the connector releases (left picture in Figure 11-12) or grasp the coil connector grip, push in and twist to the left until the coil connector unlocks from the treatment coil interface (right picture in Figure 11-11).

3. Pull the coil cable connector away from the treatment coil interface.
4. Slide the coil interface door to expose the right-side coil interface (Figure 11-13).
5. Align the raised embossed logo on the coil cable connector with the raised embossed logo on the coil interface connector. (Figure 11-14).

![Coil Cable Connector](image)

FIGURE 11-14. Coil Cable Connector

6. Gently push the coil cable connector into the coil interface connector until it is fully inserted (left picture) or twist the connector grip to the right until it locks in place (right picture).

7. Move the coil Power switch from “OFF” to “ON”.
   
   If the coil is connected to the right-side interface without a right-sided protocol, the system displays a confirmation pop-up window (Figure 11-15).
The system records an alarm if there is no coil connected. When a coil is reconnected, the system clears the alarm.

### 11.6 Determining the MT Level

After the patient’s MT location has been identified and the SOA setting, the A/P bar position, and the coil angle have all been recorded in the “MT Locate screen,” the patient’s MT level must be determined through the following steps.

In the MT Assist mode, the system applies predetermined MT levels to establish the lowest level that causes an observable movement of the thumb 50 percent of the time.

The system now displays the MT level initial screen (see Figure 11-16). This screen has the following fields:

- **Name**
- **ID**
- **Session #** – This field contains the number that corresponds to the patient’s session number.
- **P1, P2, P3, etc. MT=** – This field contains the average MT level for the passes in the corresponding column.
- **Y/N (Yes/No)** – This column displays the recorded observation for the corresponding attempt number.
- **Recommended MT Level**: – This field contains the computed MT level based on the power levels and the recorded responses.
- **Current MT Level** – This field contains the patient’s most recent MT level.
- **Pulse Interval**: – This field displays the number of seconds between each pulse
- **SOA Setting** – This field contains the patient’s setting of the left superior oblique angle (LSOA) guide on the head support system.
- **A/P Position** – This field contains the patient’s setting of the A/P bar on the head support system.
- **Treatment Coil Angle** – This field contains the patient’s setting of the treatment coil angle indicator on the head support system.
Motor Threshold Determination

FIGURE 11-16. Initial MT Level Search Screen: Tabular View

**NOTE**

With MT Assist, the NeuroStar System provides two options for displaying the progress of the search in the upper half of the screen:

- Tabular View
- Simple View
In the tabular view (Figure 11-17), the system displays four columns, which correspond to the four passes (P1, P2, P3, and P4) that the system executes to identify the patient’s MT level. It also lists the attempts in each column and lists the number, power, and the observational response (yes or no) for each attempt.

![Tabular View](image)

**FIGURE 11-17. Tabular View**

This view provides more information on the progress of the MT search than the simple view. To select the simple view, touch the *Switch to Simple View* button below the table.

In the simple view (Figure 11-18) the system displays a progress bar for the pass (P1, P2, P3, or P4) that the system is executing.

![Simple View](image)

**FIGURE 11-18. Simple View**

For the tabular view, touch the *Switch to Tabular View* button.
11.7 Using the MT Assist Mode

1. Position the patient’s right hand in a relaxed, supported position using the wedge cushion, as shown in Figure 11-19. Place wedge cushion under right hand with palm on the corner of the wedge so that fingers and thumb hang freely.

![A Wedge Cushion](image)

FIGURE 11-19. MT Determination Hand Position

2. Touch the START button. In response, the MT Assist software automatically starts at 1.08 and generates a pulse every 10 seconds.
3. After a pulse has been generated, the system displays a “Twitch Observed” window that includes **YES** and **NO** buttons (Figure 11-20).

![Image](image_url)

**FIGURE 11-20. “Twitch Observed” Window**

4. Observe the patient’s hand for a visible twitch. Touch **YES** or **NO** depending on the observation of a thumb or finger twitch. In response, the system adjusts the MT level up or down and displays another 10-second countdown to the next pulse.

5. Ensure that the face of the treatment coil maintains contact with the patient’s head.

   Carefully observe the patient at each pulse and accurately select either the **YES** button or the **NO** button on the display. Errors in this step will result in the incorrect recording of the patient's MT level.

   **NOTE**

   If no response is input via the **YES** or **NO** buttons, pulses will continue at the current level until the operator touches one of the two buttons.
6. Repeat step #4 for each successive pulse.
   To temporarily interrupt the treatment session, touch the PAUSE button.
   Touch the REDO button to repeat pulsing at the pulsing level of the previous attempt, if needed.

   **NOTE**
   As illustrated in Figure 11-21, the software runs four passes to ensure the accuracy of the patient's MT level. Upon completion of the first pass (P1), the system enables the SAVE MT button. Touch this button at any time to save the patient's MT level and end the MT Assist program, if desired. However, answering "No" to all "Has a twitch been observed?" prompts on the first pass will stop the MT Assist program and will cause the system to display the following message: "MT level cannot be determined with MT Assist. Use Manual MT to determine MT level."

![Figure 11-21. Complete MT Level Search Screen](image-url)
7. Touch the **SAVE MT** button when the patient’s MT level has been established. If an MT Location and Level has been established, the system displays a confirmation screen for the treatment position by adding 5.5 cm to the A/P position that was identified during the MT Location steps (Figure 11-23).

If an MT Location and Level has previously been established and a new MT Level and Location is determined, the system will display a pop-up window offering the operator several options (Figure 11-22). By touching the **DISCARD** button the current MT data will be ignored and the previous MT data will continue to be used for treatment. There are two other possible options for using the new data, **Update treatment dose** and **Update treatment location**. Checking one or both of these options will modify the treatment according to the option(s) selected. These include Updating the MT level with the newly found level and/or Updating the treatment location based on the New MT level location. When one or both of these options are selected the **UPDATE** button becomes active (GREEN) and may be selected to store the chosen information. In Figure 11-22 the **UPDATE** button starts as GRAY and turns GREEN once one of the options is checked.

![FIGURE 11-22. Saving MT Options Pop-Up Window](image1)

![FIGURE 11-23. Treatment Position Confirmation Pop-Up Window](image2)

The **UPDATE POSITION** button is available to modify the existing treatment coil position parameters.
NOTE

To provide more operator control in determining a patient’s MT level, the NeuroStar System provides two options:

- Manual MT – Auto Pulsing

When the operator has selected Manual MT – Auto Pulsing, the system automatically generates a pulse every three seconds. After each pulse the operator can adjust the patient’s MT level by increasing or decreasing the number in the MT level field on the display. In this mode, the system continues to pulse every three seconds until the operator touches the **PAUSE** button or the **SAVE MT** button.

When Manual MT – Manual Pulsing, has been selected, the operator touches the **PULSE** button on the display or presses the pulse button on the treatment coil to generate a pulse. If no thumb twitch is observed, the operator adjusts the patient’s MT level by increasing or decreasing the number in the “MT Level” field on the display. After this adjustment, the operator generates another pulse. As with the Manual MT – Auto Pulsing mode, the system remains in this mode until the operator touches the **SAVE MT** button.

Instructions for each mode are in the following sections.
11.7.1 Using the Manual MT Level – Auto Pulsing Mode

To find the patient’s MT level without using MT Assist, touch the **MANUAL MT** button in the initial MT search screen (Figure 11-16). In response, the system displays the “Manual MT Level – Auto Pulsing” screen, illustrated in Figure 11-24.

1. Position the patient’s hand for MT value determination, as illustrated in Figure 11-19.

2. Ensure that the treatment coil is at the established MT location and touch the **PULSE** button on the screen or on the back of the treatment coil.

3. Touch the **START** button to start the pulsing every three seconds.

4. After each pulse, use the slider or the “up” or “down” arrows in the “MT Level” field (See Figure 11-24). Repeat this step until the motor threshold value has been determined for the patient.

5. When the patient’s MT level has been determined, touch the **SAVE MT** button on the display.

**NOTE**

MT pulses cannot be delivered more frequently than 1 pulse every 3 seconds.
The steps for establishing a patient’s MT level in Manual MT Level – Manual Pulsing mode are the same as the steps for Manual MT level – Auto Pulsing mode, except that the system does not automatically pulse when an MT level has been set. The operator must activate each pulse. The “Manual MT Level – Manual Pulsing” screen is illustrated in Figure 11-25.

1. When the treatment coil is positioned at a possible MT location, press the pulse button on the treatment coil handle OR touch the PULSE button in the “Manual MT Locate – Manual Pulsing” screen.

2. After each pulse, adjust the MT level up or down on the display.

3. When the patient’s MT level has been determined, touch the SAVE MT button on the display.
12 Treatment

This section provides important information on how to initiate a treatment session after the patient’s MT location and MT level have been established.

Operations using the NeuroStar System are governed by NINDS safety guidelines for TMS therapy, which are presented in “Appendix B. 1998 NINDS Consensus Guidelines” of these Instructions For Use, however, the operator must be able to monitor the patient's physical status for the potential occurrence of adverse events, and be available to make adjustments as clinically indicated consistent with product labeling, or determine circumstances under which treatment interruption or treatment termination should be considered. The NeuroStar System operator should be present in the treatment room with the patient at all times.

The operator must be qualified to monitor the patient for seizure activity and to provide seizure management care. Seizures have been reported rarely with the NeuroStar System in post-market use (incidence <0.003% of treatments and <0.1% of patients). However, the patient should be observed during TMS Therapy for any clinical signs or symptoms that may precede the development of a seizure.

If a seizure occurs during treatment, follow the steps listed in Section 12.1, below.

Make sure that the wheels of the mobile console are in the locked position before positioning the treatment coil for a treatment session.

The optional TouchStar feature is not currently covered by the NINDS guidelines.

NOTE

Through TrakStar, changes can be made to patient data during a treatment session. However, those changes will not be reflected in the patient's record until the treatment session has ended.

12.1 Emergency Procedures

If a patient emergency situation happens that requires immediate cessation of treatment, take the following steps immediately:

1. Touch the PAUSE button or the STOP button on the display to stop the treatment.

2. Press the brake release button on the treatment coil and move the treatment coil away from the patient.

3. Manage the patient’s condition and/or call for help.

If a seizure occurs, follow your institution’s standard operating procedures for first response emergency.

In the event of an emergency building evacuation during a treatment session, press the PAUSE button on the screen then press the brake release button on the treatment coil and move the treatment coil away from the patient. Assist the patient in getting up from the treatment chair.
12.2 Placing the Coil at the Treatment Location

Accurate placement of the treatment coil is critical for the reproducible application of TMS Therapy. This section assumes that MT location has already been determined for the specific patient. If not, return to Section 11.5, “Finding the Patient’s MT Location”.

As an option the Target Method used to determine the treatment location can be saved for each treatment. The default Target Method is 5 cm. For further explanation on how to set the Target Method, see “Performing a Treatment Session” on page 12-5.

NOTE
The NeuroStar System is designed for reproducible placement of the treatment coil within 5 mm from treatment to treatment for a patient whose treatments are conducted using the same NeuroStar system.

If a patient is moved from one NeuroStar System to another NeuroStar System, a 5 mm reproducibility in the treatment coil may not be maintained.

If the patient’s hairstyle has changed in a way that potentially alters the distance from the treatment coil to the patient’s scalp since the last treatment session or prior motor threshold determination, consider re-evaluating the motor threshold level.

NOTE
The system displays “Move the coil to the treatment location” pop-up window (Figure 12-1) over the treatment screen at the conclusion of the motor threshold determination process (Section 11) and when a returning patient has been selected from the Patient List screen.

NOTE
If the A/P bar slips or moves when the treatment coil is placed against the treatment coil angle guide, wipe the sides of the A/P bar (on the underside of the A/P bar) with an alcohol prep pad.

Before performing the treatment steps it is very important to ensure that the patient is positioned correctly according to the procedure in Section 10, with particular attention to Section 10.4. Proper patient positioning is necessary for repeatable TMS treatment.

NOTE
The A/P position, as displayed in the “Move the coil to the treatment location” pop-up window (Figure 12-1), is the sum of the patient’s MT location A/P measurement plus 5.5 cm. The system automatically performs this calculation to display the location for treatment.

1. Squeeze the A/P bar lock.
2. Move the A/P bar until the indicator lines up with the position value that is displayed in the pop-up window (Figure 12-1).

![Move the coil to the treatment location](image)

**FIGURE 12-1. "Move the coil to the treatment location" Pop-Up Window**

3. Release the A/P lock.

4. Adjust the A/P bar downward until it is as close to the head as possible without touching the patient.

**NOTE**

For returning patients move the treatment coil to the A/P position, SOA setting, and treatment coil angle values displayed in the "Move the coil to the treatment location" pop-up window before moving to the next step.

5. Gently move the treatment coil down to the patient’s head adjacent to the treatment coil angle guide so that the treatment coil angle guide is flush against the side of the treatment coil and aligned with the centering line as shown in Figure 12-2. Also, ensure that the treatment coil is in uniform contact with both the patient’s head and the treatment coil angle guide.

![Coil Properly Placed against the Coil Angle Guide](image)

**FIGURE 12-2. Coil Properly Placed against the Coil Angle Guide**
6. Ensure that the treatment coil centering mark (A) matches the centering mark on the treatment coil angle guide and that the settings displayed on the display match the settings of the head support system (Figure 12-2).

   If the patient reports a change in medication or other physical conditions, consider whether or not to re-evaluate the patient's motor threshold.

   **NOTE**

   If a new MT is needed, touch the **REDO MT** button to display the “MT Locate” screen. See directions in Section 11.

7. Touch the **OK** button in the “Move the coil to the treatment location” pop-up window (see Figure 12-1). In response, the system removes the pop-up window and activates the **CONFIRM PULSE SEQ** button.

8. Follow the steps in “Performing a Treatment Session” on page 12-5.
12.3 Performing a Treatment Session

NOTE

TouchStar is an optional feature available for the NeuroStar system. The TouchStar feature uses additional treatment parameters and prescriptions. To enable the optional TouchStar feature, please contact Customer Service or your local representative.

1. Check the “Contact Sensor” portion of the display to verify that the treatment coil is properly positioned against the patient’s head and is providing contact. A green mark in the “Patient Treatment” screen indicates that contact has been established (Figure 12-3). If the optional TouchStar feature is enabled, the “Patient Treatment” screen will appear like that shown in Figure 12-4. See the NeuroStar Performance Specifications in Section 5.2.1 for a list of the parameters and their ranges.

![Image of the "Patient Treatment" Screen]
The safety and effectiveness of iTBS has only been established using the parameters shown in Figure 12-4 during a controlled clinical trial.

FIGURE 12-4. “Patient Treatment” Screen for TouchStar

**NOTE**

The treatment graph at the top of the treatment screen consists of two scales. The vertical scale represents the percent of the patient’s MT level that the system is administering. Typically, the system gradually increases the MT level to 100% at the beginning of a treatment session. The horizontal scale represents the amount of time remaining in the treatment session. The name of the treatment being administered appears below the treatment graph.

**NOTE**

To access the patient head support system settings, use the UPDATE POSITION button.

**NOTE**

The %MT value used to start this prescription the last time it was administered is shown above the MT Level.
2. Remind the patient that the TMS treatment will cause a clicking sound and may produce a tapping sensation on the head. Emphasize the importance of remaining still for the duration of the treatment session. If the patient needs to move, he or she must first inform the NeuroStar operator.

3. Review the treatment parameters that are displayed and make sure that they are correct for this patient’s treatment session.

4. Review the **Target Method** selection. The default is **5 cm**, but you can choose **Beam F3** or **Other** as shown in Figure 12-5. Unless changed the Target Method will remain 5 cm. To change it, tap the **Target Method** button. It cannot be modified once the treatment starts. The **Target Method** will be shown on the TrakStar reports.

5. Select the **TMS PRESCRIPTION** button to change the treatment being administered.

6. Select the **STANDARD** treatment or any other treatment entered in TrakStar (e.g., composite treatments) for this patient.

   **NOTE**
   
   For returning patients the treatment parameters will be the same as the last treatment administered; for new patients the Standard treatment parameters are displayed. These fields: Pulse/Sec., Stim Time, Interval, Number of Pulses, and %MT — can be changed using either the “up” or “down” buttons or the slider. Changes to the treatment parameters will be reflected in the TrakStar Treatment Details panel of the Treatment screen (highlight a treatment session to show the Treatment Details and display the Tx Modifications) and in the Treatment History Report’s change events.

7. Touch the **CONFIRM PULSE SEQ.** button to activate the **START** button.

   **NOTE**
   
   If the patient’s last treatment included the TouchStar prescription (optional feature), the **CONFIRM PULSE SEQ.** button will be disabled if the mobile console in use is not TouchStar enabled. A different prescription must be selected or the patient must be moved to a TouchStar enabled mobile console.
NOTE  
If the percent MT adjustment exceeds NINDS guidelines, the system sounds an alarm, pauses, and displays the “MT Adjustment” pop-up window (Figure 12-6). The pop-up window is displayed until the operator touches the OK button.

![MT Adjustment Pop-up Window](Figure 12-6)

NOTE  
If the optional TouchStar feature is enabled it is possible that the MT level and %MT values may result in delivery of a lower MT dosage than prescribed. In this case the %MT will be automatically set to the device maximum. The pop-up window in Figure 12-7 will be displayed until the operator touches the OK button.

![TouchStar Lower MT Dosage Pop-up Window](Figure 12-7)
MT Adjustment Pop-Up Window

To start treatment when a SenStar Connect Treatment Link is installed, there must be at least one treatment session available. Once the START button is pressed, one treatment session will be deducted from the available total. If there are no treatment sessions available (i.e., the Current Total is zero), the pop-up window shown in Figure 12-8 opens. When the operator touches OK, the End Session screen is displayed.

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NOTE

To increase patient comfort, the initial stimulation trains ramp up to the selected power level. This progressive increase is illustrated in the “Treatment Graph” portion of the screen. The system delivers all subsequent pulse trains at the treatment level for the remainder of the session.

Ensure that the face of the treatment coil maintains contact with the patient’s head throughout the entire treatment. If the treatment coil is making contact at only one of the two points on the patient’s scalp (one green circle in the “contact sensor” area of the screen), treatment can still be delivered. However, make every effort to maintain full treatment coil contact (two green circles).

If the contact sensor auto pause parameter is ON (Section 3.1) and the system detects no contact with the patient’s head during a train, the system automatically pauses before the next train and remains paused until the operator touches the RESUME button. This gives the operator the opportunity to adjust the patient’s treatment coil position for treatment coil contact during treatment.
Once the stimulation sequence has started, the system displays the “Active Treatment” screen, as illustrated in Figure 12-9. The Treatment Graph and the “Treatment Time Remaining” box show the length of time remaining in the current treatment.

![Figure 12-9. Active Treatment Screen Showing Time Remaining](image)

The system counts down the seconds and minutes remaining until the end of the current treatment session in the “Treatment Time Remaining” field.

To see the number of pulse trains that are remaining in this treatment session, touch the “Treatment Time Remaining” field; the field changes to “Trains Remaining” and displays the number of remaining pulse trains as shown in Figure 12-10.
To temporarily hide patient data, touch the patient’s “Name” field; the patient identifier data (name, ID, session number) will change to all asterisks (*).

To pause or stop the treatment at any time, touch the **PAUSE** button or the **STOP** button.

**NOTE**
If the system has been paused for more than 2 hours, it will automatically log out the current user and display the Login screen.

**NOTE**
To silence the chime that normally sounds when a treatment train is about to begin, touch the speaker icon, located above the **PAUSE** button.

**NOTE**
As the treatment session progresses, the treatment screen is updated every second. If the “Trains Remaining” field is displayed, updates are displayed with each successive pulse train completion, for example, 70…69…68…67, etc., until all pulse trains have been delivered and the treatment session is complete.

Two seconds before the end of a treatment session, the system sounds a tone that announces that the treatment session is complete. This tone can be deactivated through the system configuration screen (see Section 3.1).
12.4 Performing a Composite Treatment

1. Ensure that the patient has been prescribed the necessary composite treatment in TrakStar.

2. Select a patient at the “Select Patient” screen.

3. Touch the CONFIRM PATIENT button.

4. At the “Move the coil to treatment location” pop-up window, touch the OK button.

5. Touch the TMS PRESCRIPTION button to choose one of the treatments assigned to the patient. In response, the system displays a list of treatments in the TMS Prescription pop-up window (see Figure 12-11).

6. Touch the line that corresponds to the treatment to be used.

FIGURE 12-11. TMS Prescription Window
7. Touch the **APPLY** button. In response, the system displays the treatment screen for the selected treatment screen with the “Move the coil to the treatment location” pop-up window (Figure 12-12).

**NOTE**

If the patient's prescription history includes the TouchStar prescription (optional feature) as part of a composite treatment, it will be shown in the prescription list. If the mobile console in use is not TouchStar enabled, the **APPLY** button will be disabled. A prescription must be chosen that does not include the TouchStar feature, or the patient must be moved to a TouchStar enabled mobile console.

![Figure 12-12. "Move the coil to the treatment location" Screen](image-url)
NOTE

For Composite treatments the “Move the coil to the treatment location” pop-up window will indicate whether the left and right MT Location values are the same or different as shown in Figure 12-13. Use this as a reminder that an MT Location might need to be redone.

FIGURE 12-13. "Left and Right MT values are different" Screen
8. At the “Move the coil to the treatment location” pop-up window, touch the **OK** button to display the Patient Treatment screen (Figure 12-14).

![Image of Patient Treatment Screen]

**FIGURE 12-14. Patient Treatment Screen**

9. Touch the **CONFIRM PULSE SEQ** button after verifying that the parameters are correct. Touching the **CONFIRM PULSE SEQ** button enables the **START** button (Figure 12-14).

**NOTE**

If the patient's last treatment included the TouchStar prescription (optional feature), the **CONFIRM PULSE SEQ** button will be disabled if the mobile console in use is not TouchStar enabled. A different prescription must be selected or the patient must be moved to a TouchStar enabled mobile console.

10. Touch the **START** button to begin the treatment. For a composite treatment, this will be the first treatment of the composite. At the end of the first treatment of the composite and for each subsequent treatment in the composite, the system pauses and displays the “Move the coil to the treatment location” pop-up window.
To start treatment when a SenStar Connect Treatment Link is installed, there must be at least one treatment session available. Once the **START** button is pressed one treatment session will be deducted from the available total. If there are no treatment sessions available (i.e., the Current Total is zero) the pop-up window shown in Figure 12-8 opens. When the operator touches **OK**, the **End Session** screen is displayed.

11. Follow the instructions in this pop-up window and touch the **OK** button. In response, the system displays the treatment screen for the next treatment in the composite.

12. Review the treatment parameters.

13. Touch the **CONFIRM PULSE SEQ.** button to activate the **START** button.

14. Touch the **START** button to begin the next treatment in the composite.

15. Continue these steps for each treatment in the composite pulse sequence in the group until all treatments have been completed and the system displays the “End Session” screen (Figure 12-15).

---

**FIGURE 12-15. End Session Screen**
If the optional TouchStar feature was used during the treatment, the treatment screen will include the TouchStar parameters as shown in Figure 12-15.

![End Session Screen (with TouchStar option)](image)

**FIGURE 12-16.** End Session Screen (with TouchStar option)

16. To stop the delivery of any portion of a Composite Treatment, see Section 12.11.
12.5 Addressing Patient Discomfort

The patient may report discomfort during treatment stimulations including the following:

- Uncomfortable rhythmic pulsing at the treatment coil contact point on the scalp.
- Uncomfortable rhythmic pulling at the forehead, around the eye, or at the jaw.

If the patient reports these kinds of discomfort, the following steps can be used in an effort to decrease the discomfort.

**Treatment Coil Contact Discomfort**

1. Touch the PAUSE button.
2. Reassure the patient that this discomfort is common.
3. Assess the level of patient discomfort. If the discomfort is not tolerable, decrease the treatment %MT temporarily with the goal of returning to the 120% MT level within the next few days.

**Facial Discomfort**

1. Touch the PAUSE button.
2. Press and hold the brake release button and move the treatment coil away from the patient’s head.
3. Release the brake release button.
4. Using the treatment coil angle guide as a reference, rotate the treatment coil angle clockwise 5° (Figure 12-17).

![FIGURE 12-17. Rotating the Coil Angle Clockwise 5°](image)

5. Press and hold the brake release button and move the treatment coil against the patient’s head at the new angle.
6. Release the brake release button.
If the new treatment coil angle resolves the discomfort, record the new treatment coil angle in the patient’s record by touching the **UPDATE POSITION** button.

If the new treatment coil angle does not resolve the discomfort or reduce it to a tolerable level, continue to move in 5° clockwise increments up to 20° from the starting treatment coil angle.

If the above changes don’t alleviate patient discomfort, proceed with the steps below:

8. Touch the **PAUSE** button.

9. Move the A/P bar towards the center of the patient’s head, decreasing the SOA angle by 3° (Figure 12-18).

![FIGURE 12-18. Decreasing the SOA by 3°](image)

10. Press and hold the brake release button and move the treatment coil against the patient’s head at the new SOA angle.

11. Release the brake release button.


If the new SOA angle does not resolve the discomfort or reduce it to a tolerable level, continue to decrease the SOA angle by an additional 2° for a total of 5°.

If the new SOA angle resolves the discomfort or reduces it to a tolerable level, record both the new treatment coil angle and the new SOA in the patient’s record.

If repositioning the treatment coil does not improve patient comfort sufficiently, adjust the treatment intensity down temporarily by touching the %MT field and using the slider or the arrows in the “Treatment” tab. In clinical trials, scalp discomfort attenuated with successive treatments. Therefore, treatment at 120% should be attempted at every treatment session.
Finger or Hand Twitching During Treatment Stimulations

1. Touch the **PAUSE** button.
2. Press and hold the brake release button and move the treatment coil away from the patient’s head.
3. Release the brake release button.
4. Move the A/P position forward from the treatment location in 0.5 cm increments until finger and/or hand twitching is no longer observed.
5. Update the treatment coil position in the patient record.
6. Consider re-evaluation the MT location at a future session to ensure optimal treatment coil location.

If the treatment coil position numbers need to be changed because of differences in the patient’s position that resulted from addressing patient discomfort, touch the **UPDATE POSITION** button and make the necessary changes.

12.6 Changing Stimulation Parameters During Treatment

NOTE

This procedure only applies when using a High Performance Treatment Coil system, model 81-01000-000. The model number can be found at the rear of the coil.

To change the stimulation parameters (MT Level, Pulses per Second, Stimulation Time, Interval, Number of Pulses, % MT) or the optional TouchStar feature (if enabled) parameters (Pulses per Burst, Interpulse Interval, Bursts per Second) during a treatment session, follow these steps:

1. Touch the **PAUSE** button.
2. Touch each field that corresponds to a parameter that needs to be changed and use the “up” or “down” arrows to make the required changes.
3. After all changes have been made, touch the **RESUME** button and confirm the changes.

Changes to the treatment parameters will redraw the Treatment Graph using the modified parameters. These changes are displayed on the Treatment Details Panel of a selected treatment on the TrakStar Treatments screen. For more information, see the TrakStar Instructions For Use.

Modified treatment parameters will be saved for the next treatment session.

Treatments are limited to less than 24 hours each. The **CONFIRM** and **START** buttons are disabled and the operator is notified if changes to treatment parameters result in the extension of a treatment beyond 24 hours.

NOTE

If the optional TouchStar feature is enabled, the mobile console will automatically limit the parameter fields from being set to values outside of the normal operating limits.
12.7 Monitoring Coil Temperature During Treatment

This section addresses the treatment coil temperature.

NOTE

Wait 10 minutes between patient treatment sessions to ensure that operation is not automatically paused during treatment due to treatment coil heating. Failure to observe the 10-minute interval between treatment sessions could result in longer delays imposed during treatment.

It is normal for the treatment coil to feel warm during treatment. However, if the patient reports discomfort from excessive warmth under the treatment coil, immediately touch the PAUSE button to temporarily stop the treatment. Remove the treatment coil from contact with the patient's scalp. Contact Customer Service for assistance before attempting further treatments.

If the “Coil Temperature has reached 41 °C” alarm (Figure 12-19) is displayed, the patient's scalp is in contact with a surface that may exceed 41 °C. Clinical judgement should be used to determine whether or not treatment should continue for a patient with impaired ability to sense heat/pain. Patients who may be at increased risk of thermal injury include patients with:

- Diabetes Mellitus
- History of Stroke
- Under the Influence of Alcohol
- Current Use of Any Sleep Medication

To see the temperature of the coil in this treatment session, touch the “Treatment Time Remaining” field; the field changes to “Trains Remaining.” Touch the field again to display the coil temperature.

The temperature is displayed in green when the coil temperature is below 40 °C (Figure 12-20). Coil temperatures between 41 °C and 43 °C are displayed in an orange color (Figure 12-21). Coil temperatures 44 °C and above are displayed in a red color (Figure 12-22).

As the coil cools after the system has displayed the “Coil Has Reached 44 °C (Maximum)” pop up, the temperature indicator changes – first to orange when the coil is below 43 °C and then to green when the coil cools below 39 °C. The treatment cannot be resumed until the coil temperature has returned to below 39 °C and the temperature indicator is green.

If the system displays the “Coil Temperature Has Reached 41 °C” alarm, the operator can choose to pause the treatment and wait for the treatment coil to cool. If the operator decides to wait, the system removes the alarm when the treatment coil has cooled below 41 °C. To expedite the cooling process, see Section 4.3.

**NOTE**

When this alarm is displayed, the system also sounds the alarm tone every 30 seconds until the treatment coil has cooled. To turn off the alarm tone, touch the **SILENCE** button.
FIGURE 12-20. Green Condition: Coil Temperature 40° C and Below
FIGURE 12-21. Orange Condition: Coil Temperature At or Above 41° C and Less Than 44° C
The system may later display the “Coil Temperature has reached 44° C (Maximum)” pop-up window (Figure 12-23). This may happen if the patient’s motor threshold is high or if the room temperature is high. This window is displayed when the treatment coil temperature reaches 44° C and the system automatically pauses, requiring a waiting period while the treatment coil cools to 39° C. Cooling from 44° C typically takes about 15 minutes. (To expedite the cooling process, see Section 4.3.)
12.8 Extending the Treatment Session (if necessary)

At the end of a simple treatment session, after the last pulse set has been delivered, the system displays “Extended Treatment Option” pop-up window, which includes the number of trains that were administered when the treatment coil was not in contact with the patient’s scalp (Figure 12-24). (This can happen if the patient shifted or otherwise changed position during treatment.) When the system displays this screen, the operator can decide to administer more pulses to make up for the non-contact trains.

To choose this option, touch the RESUME button. Otherwise, touch the STOP button to complete the treatment session without additional pulses.

NOTE

The system’s default setting for the “Allow Treatment Extension” parameter is “ON.” (See Section 3.1.)

NOTE

Extending the treatment is an option only for Simple treatments not for Composite treatments.
12.9 Pausing the Treatment Session

A treatment session can be temporarily interrupted. Touching the PAUSE button temporarily stops the generation of pulses until the operator touches the RESUME button. While the system is in Pause mode, it displays the “Treatment Paused” screen illustrated in Figure 12-25.

![FIGURE 12-25. Treatment Paused Screen](image)

Touch the RESUME button to continue the session, or touch the STOP button to stop the treatment session.

**NOTE**

If the facility experiences a brief power failure during a patient’s treatment session, determine the duration of the treatment session prior to the power failure. To determine the number of pulses that were delivered, go to TrakStar and find the patient’s record, click the PATIENT tab and then the Treatment button. In the Treatment Details panel of the Treatment screen (highlight a treatment session to show the Treatment Details), scroll down and click Summary to display the Pulses Delivered; for more information, see the TrakStar Instructions For Use.

If TrakStar is not available, estimate the amount of time remaining in the patient’s session and restart the treatment until the estimated remaining treatment time has elapsed. At that point, stop the treatment by touching the STOP button on the display.
12.10 Stopping a Simple Treatment Session (if necessary)

To stop a session before the system has finished a complete set of treatment cycles, touch the STOP button or touch the “End Session” tab at the bottom of the screen. In response, the system displays the “Stopping will use a treatment session or SenStar. Do you want to CONTINUE or STOP treatment?” confirmation pop-up window, as illustrated in Figure 12-26. While this pop-up window is displayed, the treatment is paused until either the CONTINUE button or the STOP button is selected.

TREATMENT TREATMENT data to the point at which the treatment session was stopped is displayed on the “End Session” screen (Figure 12-28).

FIGURE 12-26. Treatment Termination Confirmation
Touch the **STOP** button to stop the session. In response, the system displays the “End Session” screen (Figure 12-28). TrakStar automatically records in the patient’s treatment record the number of pulse trains delivered. (This will indicate an incomplete treatment.) The treatment number will be incremented. For example, if treatment #1 was stopped or completed, the next treatment session will display as treatment #2. If the **CONTINUE** button was touched, touch the **RESUME** button to resume treatment session.

**NOTE**

If a SenStar Treatment Link is installed and a treatment session has been stopped (as opposed to paused) in the middle of the session, install a new one to start a new treatment session. If a SenStar Connect Treatment Link is installed a new treatment session can be started as long as there are treatment sessions available (see Figure 9-35).

**NOTE**

If a NeuroStar Advanced Therapy treatment has been stopped due to a medical event, report the event to Customer Service.
12.11 Stopping or Skipping Through a Composite Treatment Session

To stop a session before the system has finished a complete set of treatment cycles, touch the STOP button or touch the “End Session” tab at the bottom of the screen. In response, the system displays the “Do you want to Stop, Skip to Next or Continue with the current treatment” confirmation pop-up window, as illustrated in Figure 12-27. While this pop-up window is displayed, the treatment is paused.

- Touch the STOP button to display the End Session screen.
- Touch the SKIP button to stop delivery of the current simple treatment and advance to the next simple treatment in the composite.
- Touch the CONTINUE button to resume delivery of the treatment from the current point.

NOTE

Treatment data to the point at which the treatment session was stopped is displayed on the “End Session” screen (Figure 12-15).

FIGURE 12-27. Treatment Termination Confirmation

When the composite treatment is stopped TrakStar automatically records in the patient’s treatment record the number of pulse trains delivered. (This will indicate an incomplete treatment.) The treatment number will be incremented. For example, if treatment #1 was stopped or completed, the next treatment session will display as treatment #2.

NOTE

If a SenStar Treatment Link is installed and a composite treatment session has been stopped (as opposed to paused), install a new one to start a new treatment session. If a SenStar Connect Treatment Link is installed a new treatment session can be started as long as there are treatment sessions available (see Figure 9-42).

NOTE

If a NeuroStar Advanced Therapy treatment has been stopped due to a medical event, report the event to Customer Service.
12.12 Completing the Treatment Session

After the treatment session has been completed, the system displays the summary treatment session information in the “End Session” screen, as illustrated in Figure 12-28. If the treatment coil needed to be repositioned during the treatment session, touch the **UPDATE POSITION** button and record the changes.

![End Session Screen](image)

**FIGURE 12-28. End Session Screen**

1. Press and hold the brake release button on the treatment coil and carefully move the treatment coil away from the patient’s head.

2. Grasp the side pad arm, move it out away from the patient’s head, and rotate it up to its vertical position.

To avoid patient injury, ensure that the treatment coil and all treatment coil positioning parts are clear of the patient before instructing the patient to leave the treatment chair.
3. Remove the head positioning strap from the patient’s head and dispose of it in a regular waste container.

4. Ask the patient to remove his or her ear plugs and to dispose of them in a regular waste container.

5. Touch the **LOGOUT** button. As illustrated in Figure 12-29, the system will display a warning if TrakStar is not communicating with the mobile console at logout. Click the **OK** button if this message is displayed. Data will be synchronized at the next log in.

6. Press and hold the **M1** button on the treatment chair controller.

7. Move the treatment chair arm to its vertical position.

![FIGURE 12-29. TrakStar Communication Warning Pop-Up Message](image)
8. After the treatment chair stops moving, ask if the patient feels dizzy or light-headed. Some patients may experience these sensations after being in a reclined position for the duration of the treatment session. If the patient reports these sensations, wait until the sensations have passed before helping the patient out of the treatment chair. Otherwise, help the patient out of the treatment chair.

9. Remove the side pad liner and the head support liner, and dispose of them in a regular waste container.

10. When using the SenStar Connect with the NeuroStar System, Do Not Remove the SenStar Connect Treatment Link from the treatment coil. The SenStar Connect Treatment Link is intended to remain in place on the treatment coil for multiple treatment sessions and multiple patients. If the SenStar Connect Treatment Link is inadvertently removed from the treatment coil, it will be damaged and require replacement. Remove the hygiene barrier from the SenStar Connect Treatment Link and treatment coil and dispose of it in a regular waste container.

11. When using the SenStar Treatment Link with the NeuroStar System, remove it from the treatment coil by grasping the SenStar Treatment Link tab and pulling it gently straight away from the face of treatment coil.

12. Dispose of the used SenStar Treatment Link in regular waste. Reuse of SenStar Treatment Links is prohibited.

**NOTE**
There are recyclable components in the NeuroStar System. Contact Customer Service for disposal or recycling instructions.
13 End-of-Day Steps

The most recent patient list is sent from TrakStar to the mobile console once per day. At the end of the day, log out and leave the mobile console on so that the patient data can be transferred. The “update time” can be set by the service technician.

**NOTE**

For non-TrakStar Cloud operators, avoid the time and effort required to re-enter patient data, by using the TrakStar to back up the patient data to some type of recoverable medium on a regular basis. (See the TrakStar Instructions For Use for back-up steps.) The end of the day is a convenient time to back up the data.

13.1 Powering Down

If the NeuroStar must be powered down, use the following steps to move the treatment coil out of the way:

1. Grasp the treatment coil handle and press and hold the brake release button.
2. Raise the treatment coil as high as it will go.
3. Move the mast towards the rear of the mobile console.
4. Release the brake release button.
5. Unlock the Halo brake to ensure that the coil is in a vertical position (as shown in Figure 13-1) with the coil cable inserted into the treatment coil guide.

![FIGURE 13-1. End-of-Day Position for Treatment Coil](image)

With the treatment coil out of the way, use the following steps to shut the system down:

1. Touch the **End Session** tab at the bottom of the display.
2. At the session login screen, touch the **POWER DOWN** button. In response, the system displays a confirmation pop-up window that asks, “Are you sure you want to power down the system?”

3. Touch the **YES** button. This step shuts down the processor module, but the power module will continue to run.

**NOTE**

There is no need to turn off the mobile console through the Mains power switch. After touching the **POWER DOWN** button, do not turn the Mains power switch to OFF. However, if the treatment room power fails, turn the Mains power switch (Figure 13-2) to OFF until room power has been restored.

![FIGURE 13-2. Mobile Console Mains Power Switch in the OFF Position](image-url)
Appendix A. NeuroStar Advanced Therapy Clinical Studies

A.1 Study Results

NeuroStar Advanced Therapy is indicated for the treatment of major depressive disorder (MDD) in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

The efficacy and safety of the NeuroStar System in adult patients with major depressive disorder (MDD) who failed to receive satisfactory improvement from antidepressant medication was established in two randomized controlled trials (George, et al, 2010; O’Reardon, et al., 2007; Janicak, et al., 2008).


A.1.1 Study Results: Evidence of Efficacy in the Treatment of Major Depressive Disorder [NIMH-funded Independent Study]

A company-independent, NIMH-funded randomized controlled trial utilized a clinical trial version of the NeuroStar System to evaluate the safety and efficacy of TMS in adult patients (N=197) with moderate to severe major depressive disorder and who failed to benefit from 1-4 adequate antidepressant medication trials as defined using the Antidepressant Treatment History Form (ATHF). The ATHF is an instrument designed to assess adequacy of medication trials for major depression.

After determination of protocol eligibility and medication washout, patients participated in a multi-site, parallel group, double-blind, sham-controlled, randomized comparison of active TMS and sham treatment for a fixed trial period of 3 weeks. At the end of this period, patients who showed a criterion level of improvement were eligible to continue with their blinded randomized assignment for up to 3 additional weeks in a duration adaptive manner based on twice weekly determinations of clinical progress.

Treatment was according to the standard treatment protocol used for the NeuroStar System for major depression standardized at 120% magnetic field intensity relative to the patient’s resting Motor Threshold (MT), at 10 pulses per second for 4 seconds on time, with an off time of 26 seconds. During the first week of the acute phase only, treatment intensity could be reduced to 110% for tolerability but then had to return to 120% from week 2 onward. Treatment sessions lasted for 37.5 minutes (75 trains) for a total of 3000 pulses each session. During the 3-week fixed-treatment phase and in the 3-week blinded duration adaptive phase, TMS sessions were scheduled daily in a 5-day sequence, typically Monday through Friday, for a total of 15-30 sessions. MT was determined weekly using electromyographic measurement or visual monitoring of the resting right thumb (abductor pollicis brevis [APB]). The scalp spatial coordinates of the MT and treatment positions were recorded using the device’s mechanical coil positioning system, allowing reliable repositioning.

Demographic and clinical features of the enrolled population were not statistically significantly different between the active TMS and sham TMS treatment groups. Roughly half of the population was female and the average age was 47 years. Patients had moderate to severe major depression by symptom measures. Current episode treatment resistance averaged 1.6 failed research-quality adequate treatment trials (verified by ATHF criteria), which translates approximately to 3 to 6 clinical antidepressant medication attempts in the current episode. During their lifetime, patients had failed 3.3 research-adequate treatment trials (approximately 9 clinical attempts) (Table A-1).
<table>
<thead>
<tr>
<th>Demographic variables</th>
<th>Sham (N=100)</th>
<th>TMS (N=97)</th>
<th>P-value</th>
<th>Total (N=197)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females (N (%))</td>
<td>52 (52.0)</td>
<td>61 (62.9)</td>
<td>0.1224</td>
<td>113 (57.4)</td>
</tr>
<tr>
<td>Age (years, mean ± SD)</td>
<td>46.5 (12.2)</td>
<td>47.0 (10.9)</td>
<td>0.7399</td>
<td>46.7 (11.6)</td>
</tr>
<tr>
<td>Age range (years)</td>
<td>23-69</td>
<td>21-69</td>
<td>—</td>
<td>21-69</td>
</tr>
<tr>
<td>Current episode duration (weeks, mean ± SD)</td>
<td>80.9 (65.3)</td>
<td>72.9 (64.0)</td>
<td>0.3839</td>
<td>77.0 (64.6)</td>
</tr>
<tr>
<td>Range (weeks)</td>
<td>3-260</td>
<td>8-280</td>
<td>—</td>
<td>3-280</td>
</tr>
</tbody>
</table>

**Antidepressant treatment history**

| Number of antidepressant treatment failures in current illness episode by ATHF (mean ± SD) | 1.4 (1.0) | 1.6 (1.4) | 0.2143 | 1.5 (1.2) |
| Range | 0-4 | 0-6 | — | 0-6 |
| Lifetime number of antidepressant treatment failures by ATHF (mean ± SD) | 3.3 (2.1) | 3.4 (2.7) | 0.9205 | 3.3 (2.4) |
| Range | 0-9 | 0-14 | — | 0-14 |

| Low antidepressant resistance by ATHF (N (%)) | 70 (70.0) | 57 (58.8) | 0.0995 | 127 (64.5) |
| High antidepressant resistance by ATHF (N (%)) | 30 (30.0) | 40 (41.2) | — | 70 (35.5) |

**Baseline symptoms scores**

| HAMD24 (mean ± SD) | 26.6 (4.9) | 26.4 (4.9) | 0.7425 | 26.5 (4.9) |
| Range | 20-42 | 20-43 | — | 20-43 |
| MADRS (mean ± SD) | 29.9 (6.4) | 29.6 (6.8) | 0.7266 | 29.8 (6.6) |
| Range | 12-44 | 12-44 | — | 12-44 |
| IDS-SR (mean ± SD) | 40.5 (10.1) | 41.1 (9.1) | 0.6713 | 40.7 (9.6) |
| Range | 18-65 | 24-63 | — | 18-65 |
| CGI-S (mean ± SD) | 4.6 (0.7) | 4.6 (0.7) | 0.9319 | 4.6 (0.7) |
| Range | 3-7 | 3-6 | — | 3-7 |
The primary outcome measure was the clinically significant categorical outcome of remission, defined as HAMD24 ≤ 3 or 2 consecutive HAMD24<10 through 6 weeks of treatment according to a pre-specified duration adaptive design. There was a statistically significant effect of active TMS on remission rate as compared to sham control (P=0.0173) in the ITT sample (N=197). There were 13.4% remitters in the TMS arm and 5.0% in the sham arm; the adjusted odds ratio was 4.05 (95% confidence interval (CI), 1.28-12.83) (Table A-2). Remission occurred as early as week 3, with most patients achieving remission across weeks 4-5 (George, et al, 2010).

### Table A-2. RCT: Primary Outcome (N=197, ITT)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Active TMS N=97</th>
<th>Sham TMS N=100</th>
<th>P-Value (Favoring Active TMS)</th>
<th>Adjusted odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remission</td>
<td>13.4%</td>
<td>5.0%</td>
<td>0.0173</td>
<td>4.05 (1.28-12.83)</td>
</tr>
</tbody>
</table>

1 Odds ratios were adjusted for site (categorical), age (continuous), duration of current depressive episode, and medication resistance (low vs. high).

A pre-specified analysis of treatment resistance as a covariate with outcome was not statistically significant in the primary analysis logistic regression model thereby establishing efficacy across the ATHF 1-4 study population.

The baseline to endpoint change score outcome using the HAMD24 favored active TMS to sham treatment (P = 0.0588). Baseline to endpoint outcomes for patients treated with active TMS were statistically significant as compared to sham treatment as measured using the MADRS (P = 0.0136), CGI-S (P = 0.0181) and the patient-rated IDS-SR (P = 0.0008).

The results for these continuous outcome measures are shown in Table A-3 with 95% confidence intervals for the treatment difference, and estimates of the standardized effect size. Standard effect sizes range from 0.43 to 0.67 indicating a moderate to large treatment effect for TMS in this study.

### Table A-3. RCT: Continuous Outcomes Measures (N=197, ITT)

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Treatment Group</th>
<th>Baseline</th>
<th>End of Acute Phase</th>
<th>Treatment Effect (95% CI)</th>
<th>Standardized Effect Size</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAMD24</td>
<td>Active</td>
<td>26.4 (4.9)</td>
<td>97</td>
<td>21.8 (9.2)</td>
<td>85</td>
<td>−2.11 (−4.30, 0.08)</td>
</tr>
<tr>
<td>HAMD24</td>
<td>Sham</td>
<td>26.4 (4.9)</td>
<td>100</td>
<td>23.5 (7.4)</td>
<td>93</td>
<td></td>
</tr>
<tr>
<td>MADRS</td>
<td>Active</td>
<td>29.6 (6.9)</td>
<td>97</td>
<td>24.8 (11.5)</td>
<td>85</td>
<td>−3.41 (−6.12, −0.71)</td>
</tr>
<tr>
<td>MADRS</td>
<td>Sham</td>
<td>29.9 (6.5)</td>
<td>100</td>
<td>27.9 (9.0)</td>
<td>93</td>
<td></td>
</tr>
<tr>
<td>CGI-S</td>
<td>Active</td>
<td>4.6 (0.7)</td>
<td>95</td>
<td>4.0 (1.2)</td>
<td>84</td>
<td>−0.36 (−0.65, −0.06)</td>
</tr>
<tr>
<td>CGI-S</td>
<td>Sham</td>
<td>4.6 (0.7)</td>
<td>100</td>
<td>4.3 (0.9)</td>
<td>92</td>
<td></td>
</tr>
</tbody>
</table>
### NeuroStar System Instructions For Use

#### Appendix A

#### NeuroStar Advanced Therapy

#### Clinical Studies

### NeuroStar System Instructions For Use

#### Appendix A

#### NeuroStar Advanced Therapy

#### Clinical Studies

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Treatment Group</th>
<th>Baseline</th>
<th>End of Acute Phase</th>
<th>Treatment Effect (95% CI)</th>
<th>Standardized Effect Size</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>N</td>
<td>Mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IDS-SR</td>
<td>Active</td>
<td>41.1 (9.1)</td>
<td>91</td>
<td>32.7 (15.3)</td>
<td>-6.46 (-10.19, -2.74)</td>
<td>-0.67</td>
</tr>
<tr>
<td></td>
<td>Sham</td>
<td>40.5 (10.1)</td>
<td>96</td>
<td>37.1 (14.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For the categorical endpoints, higher rates of remission were observed for patients receiving active TMS as compared to sham treatment as measured using the MADRS (P = 0.0170) and the patient-rated IDS-SR (P = 0.1199), and for response (50% improvement from baseline) for all three measures (HAMD24, P = 0.0104; MADRS, P = 0.0063; IDS-SR, P = 0.0145). The results for these categorical outcome measures are shown in Table A-4.

### Table A-4. RCT: Categorical Secondary Outcome Measures (N=197, ITT)

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Sham (N=100)</th>
<th>NeuroStar TMS (N=97)</th>
<th>Between-groups differences (P-Value)</th>
<th>Odds Ratio (95% CI)¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>MADRS Remission</td>
<td>5.0%</td>
<td>12.4%</td>
<td>0.0170</td>
<td>4.19 (1.29, 13.60)</td>
</tr>
<tr>
<td>IDS-SR Remission</td>
<td>7.0%</td>
<td>12.4%</td>
<td>0.1199</td>
<td>2.23 (0.81, 6.10)</td>
</tr>
<tr>
<td>HAMD24 Response</td>
<td>5.0%</td>
<td>14.4%</td>
<td>0.0104</td>
<td>4.44 (1.42, 13.90)</td>
</tr>
<tr>
<td>MADRS Response</td>
<td>6.0%</td>
<td>15.5%</td>
<td>0.0063</td>
<td>4.48 (1.53, 13.14)</td>
</tr>
<tr>
<td>IDS-SR Response</td>
<td>8.0%</td>
<td>16.5%</td>
<td>0.0145</td>
<td>3.40 (1.28, 9.05)</td>
</tr>
</tbody>
</table>

¹ Odds ratios were adjusted for site (categorical), age (continuous), duration of current depressive episode, and medication resistance (low vs. high).

#### A.1.2 Study Results: Evidence of Efficacy in the Treatment of Major Depressive Disorder [Study 101]

Study 101 was a randomized sham-controlled clinical trial (RCT) designed to evaluate the safety and efficacy of the NeuroStar System for the treatment of patients with MDD (N=301) who have failed to receive benefit from 1 to 4 prior antidepressant medications verified by the ATHF. Patients meeting ATHF 1 criteria comprised the majority of the overall study population (N=164, 54.5% of the total study population).

The primary efficacy measure, the Montgomery Asberg Depression Rating Scale (MADRS) at 4 weeks, favored the NeuroStar System over sham treatment in the overall patient population (ATHF 1-4, MADRS, P = 0.057). A subgroup analysis of the original dataset according to the number of antidepressant medications to which the patient had failed to respond, indicated that the device was safe and effective and showed a statistically significant benefit for NeuroStar Advanced Therapy over sham treatment for the ATHF 1 subgroup (MADRS, P = 0.0006, Table A-5). As shown, for the primary outcome measure, treatment with active NeuroStar Advanced Therapy resulted in a greater than three-fold improvement in symptoms as compared to sham treatment.
### Table A-5. Study 101 RCT: Primary Outcome Measure (mITT, ATHF 1 Population, N=164)

<table>
<thead>
<tr>
<th>Primary Outcome Measure</th>
<th>Week 4 Change from Baseline(^{1,2}) (±SEM)</th>
<th>Mean Difference (±SEM) Between Treatment Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NeuroStar TMS (N=88)</td>
<td>Sham TMS (N=76)</td>
</tr>
<tr>
<td>Montgomery-Asberg Depression Rating Scale (MADRS) Total Score</td>
<td>-7.1(1.0)</td>
<td>-2.1(1.2)</td>
</tr>
</tbody>
</table>

1. The average baseline score was active TMS = 32 points and sham (placebo) treatment = 33 points.
2. LS means for the change from baseline (SEM) and the differences of LS means (SEM) are derived using the following ANCOVA model: Change from baseline = Baseline score, center, and treatment.

Secondary efficacy outcome evaluations pre-specified in Study 101 for the overall patient population were further evaluated for the ATHF 1 population. These included clinician and patient-rated efficacy outcomes utilizing depression rating scales, global wellness scales, and quality of life assessments. Table A-6 summarizes the categorical outcomes by proportion of patients who met criteria for response (i.e., percentage of patients achieving a 50% or greater reduction in total score from baseline) or remission (i.e., full resolution of depressive symptoms, MADRS total score < 10, HAMD24 score < 11 or HAMD17 < 8, respectively).

### Table A-6. Study 101 Secondary Outcome Measures (Categorical Variables) for ATHF 1 Population: Response and Remission Rates for NeuroStar Advanced Therapy and Sham Treatment at Week 4 and Week 6\(^1\)

<table>
<thead>
<tr>
<th>Secondary Outcome Measures (Categorical Variables)</th>
<th>NeuroStar TMS (N=88)</th>
<th>Sham TMS (N=76)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Week 4</td>
<td>Week 6</td>
</tr>
<tr>
<td>Response Rates (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- MADRS</td>
<td>20.5%</td>
<td>25.0%</td>
</tr>
<tr>
<td>- HAMD24</td>
<td>21.6%</td>
<td>25.0%</td>
</tr>
<tr>
<td>- HAMD17</td>
<td>25.0%</td>
<td>27.3%</td>
</tr>
<tr>
<td>Remission Rates (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- MADRS</td>
<td>8.0%</td>
<td>15.9%</td>
</tr>
<tr>
<td>- HAMD24</td>
<td>10.2%</td>
<td>17.0%</td>
</tr>
<tr>
<td>- HAMD17</td>
<td>9.1%</td>
<td>14.8%</td>
</tr>
</tbody>
</table>

1. Percentage response or remission at the week 4 and week 6 time points is presented in a last observation carried forward (LOCF) analysis and shows the number of patients meeting the stated categorical outcome criterion at that time point as a percentage of the total enrolled sample for each treatment group (N=88 active TMS, N=76 sham TMS)

**NOTES:**
- MADRS = Montgomery-Asberg Depression Rating Scale; HAMD = Hamilton Depression Rating Scale
- Response = ≥ 50% improvement at endpoint compared to baseline score.
- Remission = MADRS total score of < 10, a HAMD24 total score of < 11, or a HAMD17 total score of < 8 at endpoint
A.1.3 Study Results: Evidence of Post-Market Efficacy in the Treatment of Major Depressive Disorder [Study 19-50001]

Study 19-50001 evaluated 307 patients with a primary clinical diagnosis of unipolar, non-psychotic MDD who were determined by their physician to be an appropriate candidate for NeuroStar Advanced Therapy.

The enrolled patient population was similar in demographic and clinical characteristics to those studied in the OPT-TMS and Study 101 randomized controlled trials. The mean number of antidepressant medication exposures of adequate dose and duration (verified by the Antidepressant Treatment Record [ATR]) in the current episode was 2.5 (SD = ± 2.4) with a range of 0-14.

There was a statistically significant improvement from baseline in CGI-S total score (CGI-S, −1.9 ± 1.4, P < 0.0001, primary efficacy outcome) at end of acute treatment. A similar pattern and magnitude of clinical improvement was observed in the two patient self-reported outcome measures, the PHQ-9 (−8.7 ± 7.2, P < 0.0001) and the IDS-SR (−18.3 ± 14.9, P < 0.0001). Categorical response and remission rates were consistent in clinical magnitude on all three outcome measures, i.e., CGI-S (58.0% response; 37.1% remission), PHQ-9 (56.4% response; 28.7% remission), and IDS-SR (41.5% response; 26.5% remission).

Study 19-50001 evaluated the durability of acute benefit with NeuroStar Advanced Therapy during 12 month follow-up in patients maintained on antidepressant medication and/or with periodic TMS re introduction for symptom worsening (Neuronetics, data on file). Compared with baseline scores obtained prior to acute treatment, there was a statistically significant reduction in mean [SD] CGI-S, PHQ-9 and IDS-SR total scores at the end of acute treatment (Baseline vs. End of Acute Treatment: 5.0 [0.9] vs. 3.0 [1.4], 18.0 [5.3] vs. 8.8 [6.7], and 44.9 [11.1] vs. 25.7 [15.5] respectively, all P < 0.0001), which was sustained throughout the one year follow-up (End of 12 Months Follow-Up: 2.8 [1.5], 8.6 [6.9], and 25.6 [15.8] respectively, all P < 0.0001). The proportion of patients who achieved remission at the conclusion of acute treatment remained similar to that observed following the conclusion of the long-term follow-up phase: CGI-S (total score 1 or 2), 41.2% (end of acute) and 45.1% (end of long-term); PHQ-9 (total score < 5), 31.1% (end of acute) and 37.0% (end of long-term); IDS-SR (total score < 15), 29.7% (end of acute) and 29.3% (end of long-term).

A total of 120 (46.5%) patients met IDS-SR responder or remitter criteria at entry into long-term follow-up, and among these, 75 (62.5%) met criteria for sustained response by IDS-SR criteria at every time point throughout the 12 month follow-up period. In a separate analysis, the proportion of patients who achieved remission (QIDS-SR < 6) and subsequently experienced illness relapse (QIDS-SR score > 11) at any point during long term follow-up was 29.5% (N=23 patients). Following completion of tapering of acute treatment with NeuroStar Advanced Therapy, 93 of the 257 patients in long term follow-up (36.2% of all patients) subsequently received reintroduction of TMS based on clinician decision for clinical worsening. In this group, the mean [SD] number of TMS treatment days was 16.2 [21.1] over the period of long term follow-up.

A.2 Clinical Studies – Summary of Safety

Safety data obtained from Study 101 during acute treatment through 6 months of follow-up forms the basis of evidence for the safety of the NeuroStar System in the acute treatment of patients with MDD (Janicak, et al., 2008). This includes safety data from Study 102 (Avery, et al., 2009), an open-label acute efficacy study for Study 101 non-responders and Study 103 (Janicak, et al., 2010), a 6-month maintenance of effect study for responders in Study 101 and Study 102. In Study 101, 323 patients were randomized to a treatment condition and received at least one of their assigned treatment sessions and therefore comprised the overall human safety exposure population. Safety data from Studies 102 and 103 and the independent NIMH-funded RCT (George, et al., 2010) were consistent with the results obtained in Study 101 in all safety outcomes.
A.2.1 Active TMS Treatment Session Exposures

10,096 active TMS treatment sessions were conducted in the overall safety exposure study population. The average (SD) number of sessions for patients in Study 101 acute treatment (to week 6) was 26.3 (13.0) sessions. In Study 102, the open-label study for Study 101 non-responders, TMS treatment was provided for an additional 6 weeks, with the average (SD) number of sessions being 54.4 (10.8) for patients who received active TMS exposure across Studies 101 and 102.

A.2.2 Serious Adverse Events (All Studies)

A listing of serious adverse events observed in the overall safety exposure study population across all studies is shown in Table A-7. As is seen in Table A-7, in Study 102, the type and incidence of serious adverse events was consistent with those reported for Study 101 with the exception of a single serious adverse event of facial numbness that occurred during open-label TMS treatment and fully resolved following discontinuation of treatment. Serious adverse events in Study 103 were also consistent with the two prior studies. Note that serious adverse events in Study 103 also reflect the concurrent exposure of all patients in the study to antidepressant pharmacologic monotherapy according to protocol criteria.

Table A-7. Serious Adverse Events Across All NeuroStar System Clinical Studies (Studies 101, 102 and 103)

<table>
<thead>
<tr>
<th>Serious Adverse Event</th>
<th>Study 101</th>
<th>Study 102</th>
<th>Study 103</th>
<th>Relationship of Adverse Event to TMS Device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prior to Randomization (Lead-In Phase)</td>
<td>Sham TMS</td>
<td>Active TMS</td>
<td>Open-Label Active TMS</td>
</tr>
<tr>
<td>Worsening depression only</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Suicidal ideation only</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Worsening depression and suicidal ideation</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Operator error (exceeded maximum specified treatment duration)</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Device malfunction/first degree burn</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Suicide attempt</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Device malfunction/severe pain at treatment site</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Lower lobe pneumonia</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Bowel obstruction</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Shortness of breath and increased heart rate</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Left-sided facial numbness</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Coronary artery disease (catheterization and stent placement)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Bladder tumor (surgical removal)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hip pain</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
A.2.3 Common Adverse Events and Study Discontinuations

A.2.3.1 Common Adverse Events [Study 101 Controlled Trial Data]

Adverse event verbatim terms were collected at each clinical visit and subsequently coded using the current version of the Medical Dictionary for Regulatory Activities (MedDRA) and reported by MedDRA preferred terms. The most commonly occurring adverse events in the randomized controlled Study 101 are shown in Table A-8, for those events occurring with an incidence of 5% or greater in the active TMS treatment group and twice the rate for the sham TMS treatment group.

Table A-8. Adverse Events with an Incidence in Active TMS at a Rate of > 5% and at Least 2x Sham in the Safety Exposure Study Population in Study 101

<table>
<thead>
<tr>
<th>Body System</th>
<th>Active TMS (N=165)</th>
<th>Sham TMS (N=158)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Eye disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Eye pain</td>
<td>10 (6.1)</td>
<td>3 (1.9)</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Toothache</td>
<td>12 (7.3)</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>General disorders and site administration conditions</td>
<td>18 (10.9)</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>- Application site discomfort</td>
<td>59 (35.8)</td>
<td>6 (3.8)</td>
</tr>
<tr>
<td>- Facial pain</td>
<td>11 (6.7)</td>
<td>5 (3.2)</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Muscle twitching</td>
<td>34 (20.6)</td>
<td>5 (3.2)</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Pain of skin</td>
<td>14 (8.5)</td>
<td>1 (0.6)</td>
</tr>
</tbody>
</table>

A.2.3.2 All-Cause Discontinuation and Discontinuation Due to Adverse Events [Study 101]

Adherence to the study protocol in Study 101 through the primary efficacy time point (Week 4) was excellent. The all-cause discontinuation rate was low and was similar in the active TMS (7.7%) and sham TMS (8.2%) treatment groups. Discontinuation due to adverse events was also uncommon and similar across treatment conditions (4.5% in active TMS vs. 3.4% in sham TMS patients).

A.2.3.3 Time Course of Common Adverse Events During Acute Treatment

The most common adverse events reported in the study population were headache and application site pain. Headache was reported at nearly equal frequencies in both active TMS and sham TMS treatment groups, 58.2% and 55.1%, respectively. Application site pain was reported with greater frequency in the active TMS treatment group compared to sham TMS, 35.8% and 3.8%, respectively. Unblinding due to treatment related adverse events, such as application site pain, was a concern in this study. Sensitivity analyses for this concern were not conclusive.

In general, these adverse events were transient and dissipated rapidly with time (see Figure A-1 and Figure A-2 for a summary of the time course of these events in Study 101). Investigator clinical assessment of these adverse events was graded as mild to moderate in severity for the majority of patients.
A.2.3.4 Concomitant Medication Use [Study 101 Taper Phase and Study 103]

In Study 101, patients were entered into a TMS taper phase at the end of 6 weeks. During this taper phase study period, patients were transitioned onto a monotherapy antidepressant medication as they were simultaneously tapered from NeuroStar Advanced Therapy treatment (3 treatments during week 7, 2 treatments during week 8, 1 treatment during week 9). In addition, thirty-five patients in the ATHF 1 study population from Study 101 were enrolled into Study 103, an open-label study, during which they were continued on open-label medication antidepressant that was received during the Study 101 taper phase. Patients were followed for up to 24 weeks. There were no unanticipated adverse events.

A.2.4 Cognitive Function Testing

Cognitive function was assessed by standardized testing at baseline, Week 4 and Week 6 of the acute treatment phase for the blinded and open-label studies and at the end of treatment for the maintenance of effect study. These assessments surveyed general cognitive function (Mini Mental Status Exam), short term and delayed recall (Buschke Selective Reminding Test) and long-term retrieval (Autobiographical Memory Interview). No adverse effects on cognitive function were observed.

A.2.5 Audiometry Testing

No differences in air conduction thresholds were detected between treatment groups or within treatment groups, evaluated using the Earscan™ device (Micro Audiometrics, Inc., Murphy, NC) at baseline, Week 4, and Week 6 of the acute treatment phase for the blinded and open-label studies and at the end of treatment for the maintenance of effect study.

All patients used earplugs during treatments with a 30 dB ear protection rating. Treaters were also instructed to use ear protection during treatments.

A.2.6 Additional Safety Analyses [Study 101]

A.2.6.1 Manic Reaction

There were no reports of mania or hypomania with the NeuroStar System.

A.2.6.2 Worsening of Depressive Symptoms and Emergent Suicidal Ideation

Because a risk of disease worsening is inherent in the treatment of major depression, specific safety analyses were performed to define further the incidence of disease worsening or the risk of emergent suicidal ideation in the study
population. These analyses were conducted for the randomized controlled Study 101, where a direct comparison to the background sham treatment condition could be performed.

During Study 101, six patients experienced serious adverse events with worsening of their depression and resulting in hospitalization. None of the six patients had been allocated to active TMS treatment; four patients were in the pre-randomization phase of the study and two had been randomized to sham treatment.

In Study 101, there were seven patients who were hospitalized following the development of suicidal ideation or a suicide attempt. Two patients were in the pre-randomization phase, two were on active TMS treatment, and three patients were assigned to sham treatment. The one patient who experienced a suicide attempt and was hospitalized was among the sham treated patients.

### A.3 Common Adverse Events found in Theta Burst Study

In a randomized trial comparing 10 Hz TMS and iTBS (Blumberger, et al, 2018), the patients were continued on a single antidepressant medication. No seizures occurred in any patients in the study. Three serious adverse events occurred in the iTBS group (agitation that lead to hospitalization, one subject with worsening depression, and one with worsening suicidal ideation) and one unrelated serious event of myocardial infarction in the 10 Hz TMS group.

The number of events reported during treatment or after are shown in Table A-9.

<table>
<thead>
<tr>
<th>Event</th>
<th>10 Hz TMS Group (N=204)</th>
<th>iTBS Group (N=208)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>131 (64%)</td>
<td>136 (65%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>22 (11%)</td>
<td>14 (7%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>8 (4%)</td>
<td>18 (9%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>14 (7%)</td>
<td>16 (8%)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>14 (7%)</td>
<td>10 (5%)</td>
</tr>
<tr>
<td>Anxiety or agitation</td>
<td>8 (4%)</td>
<td>9 (4%)</td>
</tr>
<tr>
<td>Back or neck pain</td>
<td>7 (3%)</td>
<td>6 (3%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1 (&lt;1%)</td>
<td>1 (&lt;1%)</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>1 (&lt;1%)</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>Migraine aura</td>
<td>3 (1%)</td>
<td>4 (2%)</td>
</tr>
<tr>
<td>Abnormal sensations</td>
<td>2 (1%)</td>
<td>4 (2%)</td>
</tr>
</tbody>
</table>

Appendix B. 1998 NINDS Consensus Guidelines

Anytime an operator sets the pulse parameters at levels that exceed the 1998 NINDS Consensus Guidelines, as specified in the table below, the NeuroStar System posts the “Parameters Exceed 1998 NINDS Consensus Guidelines” alarm.

The table below shows the 1998 NINDS Consensus Guidelines for maximum single train durations, in seconds, depending on %MT and pulses per second (PPS):

Table B-1. Maximum Duration of Single Trains (seconds)

<table>
<thead>
<tr>
<th>PPS</th>
<th>100</th>
<th>110</th>
<th>120</th>
<th>130</th>
<th>140</th>
<th>150</th>
<th>160</th>
<th>170</th>
<th>180</th>
<th>190</th>
<th>200</th>
<th>210</th>
<th>220</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&gt;1800</td>
<td>&gt;1800</td>
<td>360</td>
<td>&gt;50</td>
<td>&gt;50</td>
<td>&gt;50</td>
<td>27</td>
<td>11</td>
<td>11</td>
<td>8</td>
<td>7</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>&gt;10</td>
<td>&gt;10</td>
<td>&gt;10</td>
<td>&gt;10</td>
<td>7.6</td>
<td>5.2</td>
<td>3.6</td>
<td>2.4</td>
<td>1.6</td>
<td>1.4</td>
<td>1.6</td>
<td>1.2</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>&gt;5</td>
<td>&gt;5</td>
<td>4.2</td>
<td>2.9</td>
<td>1.3</td>
<td>0.8</td>
<td>0.9</td>
<td>0.8</td>
<td>0.5</td>
<td>0.6</td>
<td>0.4</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>20</td>
<td>2.05</td>
<td>1.6</td>
<td>1.0</td>
<td>0.55</td>
<td>0.35</td>
<td>0.25</td>
<td>0.25</td>
<td>0.15</td>
<td>0.2</td>
<td>0.25</td>
<td>0.2</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>25</td>
<td>1.28</td>
<td>0.84</td>
<td>0.4</td>
<td>0.24</td>
<td>0.2</td>
<td>0.24</td>
<td>0.2</td>
<td>0.12</td>
<td>0.08</td>
<td>0.12</td>
<td>0.12</td>
<td>0.08</td>
<td>0.08</td>
</tr>
</tbody>
</table>

Note: Numbers preceded by > are the longest durations tested. No after discharge or spread of excitation has been encountered with single trains of rTMS at these combinations of stimulus frequency and intensity.

# Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="TUV certification" /></td>
<td>TUV certification of compliance to the industry standard listed on the label</td>
</tr>
<tr>
<td><img src="image2" alt="TUV certification" /></td>
<td>TUV certification of compliance to the industry standard listed on the label</td>
</tr>
<tr>
<td><img src="image3" alt="CE Mark" /></td>
<td>CE Mark with Notified Body number</td>
</tr>
</tbody>
</table>

Refer to *Instructions For Use*.

- Read and understand the *Instructions For Use* before operating the NeuroStar System.
- Failure to follow the *Instructions For Use* could place the patient or operator at risk.

[See Note A1 in “Symbol Reference Source”]

Refer to *Instructions For Use*.

- Read and understand the *Instructions For Use* before operating the NeuroStar System.
- Failure to follow the *Instructions For Use* could place the patient or operator at risk.
- The *Instructions For Use* are provided electronically online, either through TrakStar access or the NeuroStar University website.

[See Note A1 in “Symbol Reference Source”]

Refer to *Instructions For Use*.

The *Instructions For Use* are provided electronically online, either through TrakStar access or the NeuroStar University website.

[See Note A2 in “Symbol Reference Source”]

**Warning: Dangerous Electricity**

[See Note A8 in “Symbol Reference Source”]

**General Warning**

Serious injury or death may result if the operator does not follow the associated instructions.

[See Note A9 in “Symbol Reference Source”]
### Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚠️</td>
<td>Caution&lt;br&gt;The following may result if the operator does not follow the associated instructions:&lt;br&gt;• System damage&lt;br&gt;• Non-serious injury&lt;br&gt;• Inadequate treatment</td>
</tr>
<tr>
<td>⏎</td>
<td>Power Off&lt;br&gt;[See Note A5 in “Symbol Reference Source”]</td>
</tr>
<tr>
<td>✋</td>
<td>Power On&lt;br&gt;[See Note A4 in “Symbol Reference Source”]</td>
</tr>
<tr>
<td>⚭</td>
<td>Type BF Equipment&lt;br&gt;[See Note A6 in “Symbol Reference Source”]</td>
</tr>
<tr>
<td>~</td>
<td>AC Power&lt;br&gt;[See Note A3 in “Symbol Reference Source”]</td>
</tr>
<tr>
<td>☢️</td>
<td>For Single Use Only. Reuse is prohibited.&lt;br&gt;[See Note A7 in “Symbol Reference Source”]</td>
</tr>
<tr>
<td>℃</td>
<td>Storage Temperature Upper Limit&lt;br&gt;[See Note A10 in “Symbol Reference Source”]</td>
</tr>
<tr>
<td>🧴</td>
<td>This product is not made with natural rubber latex.</td>
</tr>
<tr>
<td>⚡</td>
<td>Electrostatic Sensitive Device&lt;br&gt;[See Note A16 in “Symbol Reference Source”]</td>
</tr>
<tr>
<td>🔒</td>
<td>Lock</td>
</tr>
<tr>
<td>⛺️</td>
<td>Release</td>
</tr>
<tr>
<td>⚡️</td>
<td>Pulse</td>
</tr>
<tr>
<td>⏹️</td>
<td>Reset</td>
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## Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="USB Port" /></td>
<td>USB Port (Service Use Only)</td>
</tr>
<tr>
<td><img src="image" alt="Network Connection" /></td>
<td>Network Connection</td>
</tr>
<tr>
<td><img src="image" alt="Sync In" /></td>
<td>Sync In</td>
</tr>
<tr>
<td><img src="image" alt="Sync Out" /></td>
<td>Sync Out</td>
</tr>
<tr>
<td><img src="image" alt="Serial Interface" /></td>
<td>Serial Interface (Service Use Only)</td>
</tr>
<tr>
<td><img src="image" alt="Treatment Coil Power" /></td>
<td>Treatment Coil Power</td>
</tr>
</tbody>
</table>
| ![Electromagnetic interference](image) | Electromagnetic interference may occur in the vicinity of equipment.  
*See Note A15 in “Symbol Reference Source”* |
| ![Magnetic Field Warning](image) | Magnetic Field Warning |
| ![Imanted Electronic Device Warning](image) | Imanted Electronic Device Warning: Persons with implanted electronic devices should not be in the vicinity of the treatment coil when it is active. Device malfunction and serious injury could result. |
| ![Limited Access Caution](image) | Limited Access Caution |
| ![Identification of the Gantry](image) | Identification of the gantry and mast position that ensures safe movement of the system. |
| ![Patient Treatment Right Side](image) | Patient Treatment Right Side |
| ![Patient Treatment Left Side](image) | Patient Treatment Left Side |
| ![Device Model Number](image) | Device Model Number  
*See Note A13 in “Symbol Reference Source”* |
### Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Device Serial Number" /></td>
<td>Device Serial Number [See Note A14 in “Symbol Reference Source”]</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer [See Note A12 in “Symbol Reference Source”]</td>
</tr>
<tr>
<td><img src="image" alt="Date of Manufacture" /></td>
<td>Date of Manufacture [See Note A11 in “Symbol Reference Source”]</td>
</tr>
<tr>
<td><img src="image" alt="Waste Electrical and Electronic Equipment Directive" /></td>
<td>Waste Electrical and Electronic Equipment Directive: Requires collection and proper recycling by distributor or manufacturer.</td>
</tr>
<tr>
<td><img src="image" alt="Lost treatment coil contact" /></td>
<td>Lost treatment coil contact.</td>
</tr>
<tr>
<td><img src="image" alt="Auto Pause is active" /></td>
<td>Auto Pause is active.</td>
</tr>
<tr>
<td><img src="image" alt="Contact Technical Support" /></td>
<td>Contact Technical Support.</td>
</tr>
<tr>
<td><img src="image" alt="The treatment coil temperature is approaching the threshold for an automatic pause" /></td>
<td>The treatment coil temperature is approaching the threshold for an automatic pause.</td>
</tr>
<tr>
<td><img src="image" alt="The measured treatment coil temperature is 44°C. The session is automatically paused. The RESUME button is disabled until the internal treatment coil temperature is below 39°C." /></td>
<td>The measured treatment coil temperature is 44°C. The session is automatically paused. The RESUME button is disabled until the internal treatment coil temperature is below 39°C.</td>
</tr>
<tr>
<td><img src="image" alt="Low-Voltage Power Supply Temperature High or High-Voltage Power Supply Temperature High" /></td>
<td>Low-Voltage Power Supply Temperature High or High-Voltage Power Supply Temperature High</td>
</tr>
<tr>
<td><img src="image" alt="The treatment coil power switch is in the OFF position." /></td>
<td>The treatment coil power switch is in the OFF position.</td>
</tr>
<tr>
<td><img src="image" alt="The system does not detect a treatment coil." /></td>
<td>The system does not detect a treatment coil.</td>
</tr>
<tr>
<td><img src="image" alt="Incorrect treatment coil model is attached." /></td>
<td>Incorrect treatment coil model is attached.</td>
</tr>
</tbody>
</table>
### Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Symbol" /></td>
<td>Coil module is disconnected.</td>
</tr>
<tr>
<td><img src="image2" alt="Symbol" /></td>
<td>The pulse parameters that were entered exceed the device limits.</td>
</tr>
<tr>
<td><img src="image3" alt="Symbol" /></td>
<td>The pulse parameters that were entered are outside of the NeuroStar System safety limits. If the optional TouchStar feature is selected, the parameters entered may result in a lower MT dosage than prescribed.</td>
</tr>
<tr>
<td><img src="image4" alt="Symbol" /></td>
<td>TrakStar is not available.</td>
</tr>
<tr>
<td><img src="image5" alt="Symbol" /></td>
<td>The system detects that the SenStar Treatment Link is disconnected, or that a different SenStar Treatment Link was installed during a session.</td>
</tr>
</tbody>
</table>
### Symbols Reference Source: Safety Symbols used in Labeling without Adjacent Text

<table>
<thead>
<tr>
<th>Note No.</th>
<th>Symbol Reference Number &amp; Symbol Title</th>
<th>Title &amp; Designation Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>ISO 7010-M002  Follow Instructions For Use</td>
<td></td>
</tr>
<tr>
<td>A2</td>
<td>ISO 7000-1641  Operating Instructions</td>
<td></td>
</tr>
<tr>
<td>A3</td>
<td>IEC 60417-5032  Alternating Current</td>
<td></td>
</tr>
<tr>
<td>A4</td>
<td>IEC 60417-5007  “ON” (power)</td>
<td></td>
</tr>
<tr>
<td>A5</td>
<td>IEC 60417-5008  “OFF” (power)</td>
<td></td>
</tr>
<tr>
<td>A6</td>
<td>IEC 60417-5333  Type BF Applied Part</td>
<td></td>
</tr>
<tr>
<td>A7</td>
<td>ISO 7000-1051  Do Not Reuse</td>
<td>IEC TR 60878:2015 Ed. 3.0  Graphical Symbols for electrical equipment in medical practice.</td>
</tr>
<tr>
<td>A8</td>
<td>ISO 7010-W012  Warning, Electricity</td>
<td></td>
</tr>
<tr>
<td>A9</td>
<td>ISO 7010-W001  General Warning Sign</td>
<td></td>
</tr>
<tr>
<td>A10</td>
<td>ISO 7000-0533  Upper Limit Of Temperature</td>
<td></td>
</tr>
<tr>
<td>A11</td>
<td>ISO 7000-2497  Date Of Manufacture</td>
<td></td>
</tr>
<tr>
<td>A12</td>
<td>ISO 7000-3082  Manufacturer</td>
<td></td>
</tr>
<tr>
<td>A13</td>
<td>ISO 7000-2493  Catalogue Number</td>
<td></td>
</tr>
<tr>
<td>A14</td>
<td>ISO 7000-2498  Serial Number</td>
<td></td>
</tr>
<tr>
<td>A15</td>
<td>IEC 60417-5140  Non-ionizing Electromagnetic Radiation</td>
<td></td>
</tr>
<tr>
<td>A16</td>
<td>IEC 60417-5134  Electrostatic Sensitive Devices</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix D. Abbreviations, Terms, and Definitions

Highlighted terms refer to the main NeuroStar System components.

<table>
<thead>
<tr>
<th>Term</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Air Core Stimulators</strong></td>
<td>Stimulators that use coil designs without a ferromagnetic core.</td>
</tr>
<tr>
<td><strong>Alignment Guide</strong></td>
<td>A mechanical system that the clinician uses to register a patient’s anatomical landmarks to help identify the coordinates and replicate the motor threshold and treatment positions on the patient’s head.</td>
</tr>
<tr>
<td><strong>A/P</strong></td>
<td>Anterior/Posterior (used in defining the patient’s MT location).</td>
</tr>
<tr>
<td><strong>A/P Bar</strong></td>
<td>A sliding element of the head support system that is used to determine the A/P position of the treatment coil.</td>
</tr>
<tr>
<td><strong>APB</strong></td>
<td>Abductor pollicis brevis, the muscle used in the so-called method of limits using either observation of twitch in the right APB muscle (thumb), or electromyography to measure muscle activity.</td>
</tr>
<tr>
<td><strong>BDI</strong></td>
<td>Beck Depression Inventory. A tool for assessing the severity of 21 symptoms of depression.</td>
</tr>
<tr>
<td><strong>Brake</strong></td>
<td>Locking mechanisms within the gantry and mobile console that hold the gantry and treatment coil in place. The brakes are released by manually pressing and holding the brake release button on the treatment coil.</td>
</tr>
<tr>
<td><strong>Burst</strong></td>
<td>A group of magnetic field pulses spaced according to the Interpulse Interval value. A burst is used in the TouchStar treatment option.</td>
</tr>
<tr>
<td><strong>Bursts per Second (BPS)</strong></td>
<td>Number of bursts provided per second in the TouchStar treatment option.</td>
</tr>
<tr>
<td><strong>CGI</strong></td>
<td>Clinician Global Impression, a global illness rating scale</td>
</tr>
<tr>
<td><strong>Coil or Treatment Coil</strong></td>
<td>The electromagnet assembly that produces a pulsed electromagnetic field that stimulates cortical neurons when properly positioned on the patient’s head. The treatment coil incorporates electronics that interface with the SenStar Treatment Link or SenStar Connect Treatment Link and operator-controlled switches.</td>
</tr>
<tr>
<td><strong>Coil Angle</strong></td>
<td>Angle of the treatment coil with respect to the A/P bar at either the MT or treatment location.</td>
</tr>
<tr>
<td>Term</td>
<td>Meaning</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Coil Guide System</strong></td>
<td>The device used to register a patient within the head support system and achieve the MT and treatment positions on a patient’s head.</td>
</tr>
<tr>
<td><strong>Contact Sensing</strong></td>
<td>Sensor and software that are used to detect contact between the treatment coil and the patient’s head.</td>
</tr>
<tr>
<td><strong>Contact Sensing Auto-Pause</strong></td>
<td>Configurable setting that allows the clinician to automatically pause after a pulse train was delivered with poor contact. This setting can be either On or Off.</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>Touchscreen and LCD combination that provides the user interface for the NeuroStar System. This is also the main operator input device.</td>
</tr>
<tr>
<td><strong>EMC</strong></td>
<td>Electromagnetic Compatibility</td>
</tr>
<tr>
<td><strong>Field Sensing (Field Detect)</strong></td>
<td>Capability of detecting the magnetic field strength of the treatment coil during a test pulse sequence prior to each treatment session.</td>
</tr>
<tr>
<td><strong>FRU</strong></td>
<td>Field Replaceable Unit. The highest level of unit to which a malfunctioning component is integrated.</td>
</tr>
<tr>
<td><strong>Gantry</strong></td>
<td>A mechanical apparatus that suspends the treatment coil in space for positioning on a patient’s head.</td>
</tr>
<tr>
<td><strong>Halo</strong></td>
<td>Adjustable mechanical device to which the treatment coil is attached. It is used to position the treatment coil properly against the patient’s head, and it includes a manual brake so the resistance can be adjusted by the operator.</td>
</tr>
<tr>
<td><strong>HAMD</strong></td>
<td>Hamilton Depression Rating Scale. A tool for assessing the severity of 17 or 24 symptoms of depression.</td>
</tr>
<tr>
<td><strong>Head Cushion</strong></td>
<td>Soft, pliable cushion on the head support system that provides comfort for the patient’s head.</td>
</tr>
<tr>
<td><strong>Head Cushion Liner</strong></td>
<td>A disposable, single-use, hygienic paper sheet that is applied to the head cushion.</td>
</tr>
<tr>
<td><strong>Head Support System</strong></td>
<td>The head support assembly including the head cushion and treatment coil alignment apparatus.</td>
</tr>
<tr>
<td><strong>HIPAA</strong></td>
<td>Health Insurance Portability and Accountability Act, a US Federal law that covers healthcare-related data processing identifiers and transactions, and that mandates security and privacy in data processing and communication.</td>
</tr>
</tbody>
</table>
### Abbreviations, Terms, and Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hygiene Barrier</td>
<td>A disposable, single-use, medical grade, adhesive backed, fabric hygienic barrier. It is applied to the face of the SenStar Connect Treatment Link and Treatment Coil surfaces prior to the start of patient contact and treatment.</td>
</tr>
<tr>
<td>Interpulse Interval (IPI)</td>
<td>This is the time, in milliseconds, between the magnetic field pulses in a burst of the TouchStar treatment option.</td>
</tr>
<tr>
<td>Interval</td>
<td>The period of time between pulse trains (in seconds).</td>
</tr>
<tr>
<td>iTBS</td>
<td>intermittent Theta Burst Stimulation</td>
</tr>
<tr>
<td>Laser Positioning Aid</td>
<td>A Class 1 medical grade laser embedded into the A/P bar that produces a light line to register the patient’s head in the head support system.</td>
</tr>
<tr>
<td>LSOA</td>
<td>Left Superior Oblique Angle. The angle formed by tilting a mid-sagittal plane around an A/P axis (used in locating the patient’s MT position).</td>
</tr>
<tr>
<td>Lumbar Cushion</td>
<td>An adjustable lower back support in the treatment chair.</td>
</tr>
<tr>
<td>MADRS</td>
<td>Montgomery-Asberg Depression Rating Scale. A tool for assessing the severity of 10 symptoms of depression.</td>
</tr>
<tr>
<td>Mast</td>
<td>The vertical pole portion of the gantry.</td>
</tr>
<tr>
<td>MDD</td>
<td>Major Depressive Disorder</td>
</tr>
<tr>
<td>MEP</td>
<td>Motor-Evoked Potential</td>
</tr>
<tr>
<td>Mobile Console</td>
<td>NeuroStar System component that houses system electronics and controls, and provides a mobile support platform for the gantry and display arm.</td>
</tr>
<tr>
<td>MT</td>
<td>Motor Threshold.</td>
</tr>
<tr>
<td>MT Assist</td>
<td>A patented computer program that enables the NeuroStar System operator to determine MT level.</td>
</tr>
<tr>
<td>MT Level</td>
<td>Motor Threshold Level. The minimum stimulator setting that induces an observable motor response by the patient in 50% of the applied pulses, usually as observed by movement of the thumb.</td>
</tr>
<tr>
<td>MT Position</td>
<td>The Motor Threshold location on a patient’s head.</td>
</tr>
<tr>
<td>NeuroStar</td>
<td>Brand name of the Neuronetics TMS System.</td>
</tr>
<tr>
<td>Term</td>
<td>Meaning</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>NINDS</td>
<td>National Institute for Neurological Disorders and Stroke</td>
</tr>
<tr>
<td>PC</td>
<td>Personal computer</td>
</tr>
<tr>
<td>PDF</td>
<td>Portable Document Format</td>
</tr>
<tr>
<td>PDMS</td>
<td>Patient data management system. See “TrakStar.”</td>
</tr>
<tr>
<td>PGI</td>
<td>Patient Global Impression, a global illness rating scale. A patient-rated tool for assessing global illness using a 7-item scale.</td>
</tr>
<tr>
<td>Positioning Pad Set</td>
<td>Set of cushions that help enhance the comfort and positioning of the patient in the desired posture for the duration of the treatment session.</td>
</tr>
<tr>
<td>Power Module</td>
<td>Hardware that contains the power supply, power storage, discharge circuits, and the controlling logic.</td>
</tr>
<tr>
<td>Pre-Train Notification</td>
<td>The configurable setting that allows the clinician to turn off or on the audible notification of a pulse train.</td>
</tr>
<tr>
<td>Processor Module</td>
<td>Hardware that contains the computer and boards that control the user interface and that drive the NeuroStar System.</td>
</tr>
<tr>
<td>Pulse Detect</td>
<td>See “Field Sensing (Field Detect).”</td>
</tr>
<tr>
<td>Pulse Repetition Rate</td>
<td>Measurement that defines the number of magnetic field pulses occurring in a second. The unit for this parameter is in Pulses per Second (PPS).</td>
</tr>
<tr>
<td>Pulse Test</td>
<td>A preliminary NeuroStar System test in which the system generates pulses of 1.2 and 2.1 SMT units. The system takes a reading for each set. If the system fails to generate these pulses, it displays a failure message and prevents the operator from performing treatments or MT.</td>
</tr>
<tr>
<td>Pulse Train</td>
<td>The group of NeuroStar System electromagnetic pulses occurring during treatment stimulation time.</td>
</tr>
<tr>
<td>Pulses per Burst (PPB)</td>
<td>Value that defines the number of magnetic field pulses occurring in one burst of the TouchStar treatment option.</td>
</tr>
<tr>
<td>Radial Arm</td>
<td>The component of the head support guide system that defines the position of the treatment coil on the left and right sides of the patient and supports the A/P bar.</td>
</tr>
<tr>
<td>Registry</td>
<td>De-identified electronic data containing information on patient treatments and basic patient demographics.</td>
</tr>
<tr>
<td>Save MT</td>
<td>MT Assist® software option that enables the operator to store in the system the MT level for the patient.</td>
</tr>
</tbody>
</table>
### Abbreviations, Terms, and Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>SenStar Connect Treatment Link</td>
<td>A multiple-use consumable integrated flexible circuit that must be attached to the treatment coil prior to MT or treatment to facilitate contact sensing and magnetic field detection and to decrease the magnetic field at the scalp surface to enhance tolerability during treatment. This device is used in conjunction with a hygiene barrier. Delivering a treatment while using a SenStar Connect Treatment Link will use a treatment session.</td>
</tr>
<tr>
<td>SenStar Treatment Link</td>
<td>A single-use disposable integrated flexible circuit that must be attached to the treatment coil prior to MT or treatment to facilitate contact sensing and magnetic field detection and to decrease the magnetic field at the scalp surface to enhance tolerability during treatment.</td>
</tr>
<tr>
<td>Side Pad</td>
<td>Soft, pliable cushion that offers counter forces to the treatment coil to hold the patient’s head in the desired position.</td>
</tr>
<tr>
<td>Simple View</td>
<td>MT Assist® program screen that lists the patient’s MT level, the MT search pass number, and a progress bar for the current search. (See also, Tabular View).</td>
</tr>
<tr>
<td>SMT</td>
<td>Standard Motor Threshold</td>
</tr>
<tr>
<td>SMT Unit</td>
<td>Standard Motor Threshold Unit: a measure for setting the output level of the NeuroStar System. 1.0 SMT is the output setting that corresponds to an induced electric field of 135 V/m at a point located 2.0 cm along the central axis of the treatment coil from the surface of the scalp into the patient’s cortex. This corresponds to the average MT Level observed in a large patient population.</td>
</tr>
<tr>
<td>SOA Setting</td>
<td>Superior Oblique Angle setting (for a particular patient) for either MT location or treatment location.</td>
</tr>
<tr>
<td>Stimulation Time (“Stim Time”)</td>
<td>The duration of a pulse train (seconds).</td>
</tr>
<tr>
<td>Stimulation Volume</td>
<td>The region of cortical tissue within the magnetic field that is above the threshold of cortical stimulation, i.e., the 3-dimensional volume where the induced electric field achieves a value ≥ 80% of that observed at 1.0 SMT.</td>
</tr>
<tr>
<td>System Processor Board</td>
<td>Hardware containing the main processor and other PC components.</td>
</tr>
<tr>
<td>System Software</td>
<td>The main software residing in the processor module and running on the NeuroStar System processor board.</td>
</tr>
<tr>
<td>Term</td>
<td>Meaning</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Tabular View</td>
<td>MT Assist&lt;sup&gt;®&lt;/sup&gt; program screen that lists for each pass in table format the following: the MT Level, the MT Assist&lt;sup&gt;®&lt;/sup&gt; pass number, and a yes/no field for the clinician to record the observation of the patient’s thumb twitch. (See also, Simple View.)</td>
</tr>
<tr>
<td>Theta Burst Stimulation (TBS)</td>
<td>A specific form of TMS therapy that provides short bursts of stimulation (magnetic field pulses) at high frequencies as provided by the optional TouchStar feature.</td>
</tr>
<tr>
<td>TMS</td>
<td>Transcranial Magnetic Stimulation, a method of using very short pulses of magnetic energy to stimulate nerve cells in the brain. TMS will be used synonymously with Repetitive Transcranial Magnetic Stimulation, which refers to TMS with repetition rates greater than 1 pps.</td>
</tr>
<tr>
<td>TouchStar</td>
<td>An optional feature for the NeuroStar Advanced Therapy System.</td>
</tr>
<tr>
<td>TrakStar</td>
<td>The NeuroStar System patient management and reporting software that communicates with the mobile console through a wired connection. The TMS software can be localized or in the cloud.</td>
</tr>
<tr>
<td>Treatment Chair</td>
<td>Adjustable chair and head support that is used to comfortably position the patient for the TMS procedure.</td>
</tr>
<tr>
<td>Treatment Coil</td>
<td>The electromagnet assembly that produces a pulsed electromagnetic field that stimulates cortical neurons when properly positioned on the patient’s head. The treatment coil incorporates electronics that interface with the SenStar Treatment Link or SenStar Connect Treatment Link and operator-controlled switches.</td>
</tr>
<tr>
<td>Treatment Extension</td>
<td>Feature that enables the clinician to extend a just-completed treatment session with additional trains to make up for any trains that experienced poor contact. This feature is operator-configurable in the mobile console.</td>
</tr>
<tr>
<td>Treatment Record</td>
<td>Electronic record containing the details of the patient’s TMS treatment sessions.</td>
</tr>
<tr>
<td>USB</td>
<td>Universal Serial Bus. Port used to connect external devices to the NeuroStar System hardware. (Service Use Only)</td>
</tr>
<tr>
<td>Wrist</td>
<td>Part of the gantry that holds the halo and the treatment coil.</td>
</tr>
<tr>
<td>%MT</td>
<td>Amount of pulse output applied by the NeuroStar System relative to a patient’s MT value.</td>
</tr>
</tbody>
</table>
Appendix E. Electromagnetic Compatibility

NOTE

Electromagnetic compatibility (EMC) testing was conducted on the NeuroStar System, described in Table E-1, Table E-2, Table E-3, and Table E-4, below.

Table E-1. Neuronetics Declaration: Electromagnetic Emissions

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Group 1</td>
<td>The NeuroStar System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td>
</tr>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Class A</td>
<td>The NeuroStar System is to be only used in a professional healthcare environment. It is not intended to be connected to the public mains AC network. The NeuroStar System requires connection to a dedicated circuit.</td>
</tr>
<tr>
<td>Harmonic Emissions IEC61000-3-2</td>
<td>Class A</td>
<td>—</td>
</tr>
<tr>
<td>Voltage Fluctuations/ Flicker Emissions</td>
<td>Not applicable</td>
<td>The NeuroStar System is to be only used in a professional healthcare environment. It is not intended to be connected to the public mains AC network.</td>
</tr>
</tbody>
</table>
## Table E-2. Neuronetics Declaration: Electromagnetic Immunity

The NeuroStar System is intended for use in the electromagnetic environment specified below. The customer or operator of the NeuroStar System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601-1-2 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>± 2, 4, 8 kV contact ± 2, 4, 8, 15 kV air</td>
<td>± 2, 4, 8 kV contact ± 2, 4, 8, 15 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>± 0.5, 1, 2 kV for power supply lines ± 0.25, 0.5, 1 kV for input/output lines</td>
<td>± 0.5, 1, 2 kV for power supply lines ± 0.25, 0.5, 1 kV for input/output lines</td>
<td>Mains power quality should be that of a typical professional healthcare environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>± 0.5, 1 kV line(s) to line(s) ± 0.5, 1, 2 kV line(s) to earth</td>
<td>± 0.5, 1 kV line(s) to line(s) ± 0.5, 1, 2 kV line(s) to earth</td>
<td>Mains power quality should be that of a typical professional healthcare environment.</td>
</tr>
<tr>
<td>Voltage dips, and interruptions on AC input lines IEC 61000-4-11</td>
<td>0% UT, 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT, 1 cycle and 70% UT, 25/30 cycles single phase at 0 degrees 0% UT, 250-300 cycles at 0 degrees</td>
<td>0% UT, 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT, 1 cycle and 70% UT, 25/30 cycles single phase at 0 degrees 0% UT, 250-300 cycles at 0 degrees</td>
<td>Mains power quality should be that of a typical professional healthcare environment. If the operator of the NeuroStar System requires continued operation during power mains interruptions, it is recommended that the NeuroStar System be powered from an uninterruptible power supply or battery.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>30 A/m</td>
<td>30 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical professional healthcare environment.</td>
</tr>
</tbody>
</table>

**NOTE**

UT is the a.c. mains voltage prior to application of the test level.
Table E-3. Neuronetics Declaration: Electromagnetic Immunity

The NeuroStar System is intended for use in the electromagnetic environment specified below. The customer or operator of the NeuroStar System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601-1-2 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms 150 kHz</td>
<td>—</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>6 Vrms ISM bands</td>
<td>6 Vrms ISM bands</td>
<td>—</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80 MHz to 2.7 GHz</td>
<td>3 V/m 80 MHz</td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td></td>
<td>2.7 GHz</td>
<td><img src="image" alt="RF Symbol" /></td>
</tr>
<tr>
<td>RF Close Field Proximity</td>
<td>9 to 28 V/m</td>
<td>9 to 28 V/m</td>
<td>Portable RF communications equipment (including peripherals such as antenna cables and external antennas – e.g., cell phones, portable transmitters, RF emitters) should be used no closer than 30 cm (12 inches) to any part of the NeuroStar System, including cables specified by Neuronetics. Otherwise, degradation of the performance of this equipment could result. The user might need to take mitigation measures if the equipment is observed to not operate normally, such as relocating or re-orienting the equipement.</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>15 discrete frequencies</td>
<td>15 discrete frequencies</td>
<td>—</td>
</tr>
</tbody>
</table>
Table E-4. Recommended separation distances between portable and mobile RF communications equipment and the NeuroStar System.

The NeuroStar System is intended for use in the electromagnetic environment (as specified in Tables E-1, E-2, E-3) in which radiated RF disturbances are controlled. The customer or the operator of the NeuroStar System should assure that it is used in such an environment. The customer or operator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NeuroStar System as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of Transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td>(d = 1.2 \sqrt{P})</td>
<td>(d = 1.2 \sqrt{P})</td>
</tr>
<tr>
<td>0.01</td>
<td>.012</td>
<td>.012</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>

* Regardless of the separation distance calculated, portable RF communications equipment (including peripherals such as antenna cables and external antennas – e.g., cell phones, portable transmitters, RF emitters) should be used no closer than 0.30 m (12 inches) to any part of the NeuroStar System, including cables specified by Neuronetics. Otherwise, degradation of the performance of this equipment could result. The customer or operator should observe the NeuroStar system for abnormal behavior. The customer or operator might need to take mitigation measures if the equipment is observed to not operate normally, such as relocating or re-orienting the equipment.

For transmitter rated at a maximum output power not listed above, the recommended separation distance \(d\) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where \(P\) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Some RF emitters may not be visible to the customer or operator of the NeuroStar System. The NeuroStar System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NeuroStar System.

**NOTE** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
Appendix F.  Informational and Instructional Labels

<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Label Image" /></td>
<td>Location: Mobile Console, Rear Panel  Main device label for system with model number, serial number, manufacturer, date of manufacture, certification, and Unique Device Identifier (UDI) labeling.  Main device label may vary depending on location of installation.  Refer to “Appendix C. Symbols” for an explanation of symbols.</td>
</tr>
<tr>
<td><img src="image2.png" alt="Label Image" /></td>
<td>Location: Mobile Console, Rear Panel  Console mains power, see Instructions For Use for safe use, electrical safety warning and Mains On/Off switch positions. Mains rating depends on model.  Mains ratings for model 81-02315-000 as shown on the label and additional ratings not shown are:  100 VAC 50/60 Hz, 6A (19A)  220 VAC 50/60 Hz, 3A (8A)  240 VAC 50/60 Hz, 3A (8A)  Note: First rating “5A” is steady state current rating and second reference “(15A)” is momentary current rating.  Mains ratings for model 81-01315-00 (not shown) are:  100 VAC 50/60 Hz, 10.4A (15A)  120 VAC 50/60 Hz, 15A  220 VAC 50/60 Hz, 4.8A (8A)  240 VAC 50/60 Hz, 4.4A (8A)  Mains rating for model 81-00315-00 (not shown) is:  110 VAC 50/60 Hz, 15A</td>
</tr>
</tbody>
</table>
## Informational and Instructional Labels

<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
</table>
| ![Mains Label](image1) | Location: Mobile Console, Rear Panel  
Console mains power, see *Instructions For Use* for safe use, electrical safety warning and Mains On/Off switch positions. Mains rating depends on model.  
Mains ratings for model 81-01315-000 as shown on the label and additional ratings not shown.  
Mains ratings for model 81-01315-00 are:  
- 100 V AC 50/60 Hz, 10.4A (15A)  
- 120 V AC 50/60 Hz, 15A  
- 220 V AC 50/60 Hz, 4.8A (8A)  
- 240 V AC 50/60 Hz, 4.4A (8A)  
Mains rating for model 81-00315-00 (not shown) is:  
- 110 V AC 50/60 Hz, 15A  
*NOTE:* First rating “5A” is steady state current rating and second reference “(15A)” is momentary current rating. |
| ![Mains Label](image2) | Location: Mobile Console, Power Module  
Internal AC Mains power input. Externally viewable label. |
| ![Safety Warning Label](image3) | Location: Mobile Console, Rear Cover  
Electrical safety warning for cover removal. Refer to *Instructions For Use* for safe use. |
| ![Safety Warning Label](image4) | Location: Mobile Console, Rear Cover  
Electrical safety warning for cover removal. Refer to *Instructions For Use* for safe use. |
| ![Safety Warning Label](image5) | Location: Treatment Coil  
Treatment coil damage electrical safety warning. Refer to *Instructions For Use* for safe use. |
<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
</table>
| ![Label Image](image1.png) | Location: Head Support System, Rear Cover  
Certification label for Class 1 laser.  
This label may vary depending on location. |
| ![Label Image](image2.png) | Location: Treatment Coil  
Implanted electronic device malfunction warning.  
Refer to Instructions For Use for safe use. |
| ![Label Image](image3.png) | Location: Mobile Console, Front Panel  
Treatment coil connection high Voltage electrical warning and location of Treatment Coil on patient head side label. Degree of electric shock protection (BF rating) and refer to Instructions For Use for safe use. |
| ![Label Image](image4.png) | Location: Mobile Console, Front Panel  
Treatment coil connection high Voltage electrical warning and location of Treatment Coil on patient head side label. Refer to Instructions For Use for safe use. |
| ![Label Image](image5.png) | Location: Mobile Console, Front Panel  
Treatment coil connector high Voltage electrical warning. Refer to Instructions For Use for safe use. |
### Informational and Instructional Labels

<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
</table>
| ![DANGER HIGH VOLTAGE](image) | Location: Mobile Console, Front Panel  
Treatment coil connector high Voltage electrical warning. Refer to *Instructions For Use* for safe use. |
| ![Halo brake lock/release](image) | Location: Mobile Console, Halo Cover  
Halo brake lock/release. |
| ![SenStar Treatment Link](image) | Location: SenStar Treatment Link  
Model number, serial number, date of manufacture.  
CE mark. |
| ![SenStar Connect Treatment Link](image) | Location: SenStar Connect Treatment Link  
Model number, serial number, date of manufacture.  
CE mark. |
| ![Head Support Display](image) | Location: Head Support  
Display  
Processor Module (internal; no operator access)  
Power Module (internal; no operator access)  
Identification labels for subsystems. Model number, serial number, manufacturer, and date of manufacture.  
Do not dispose. Return to Customer Service for proper recycling. |
| ![Treatment Coil](image) | Location: Treatment Coil  
Identification label for subsystem - Model number, serial number, manufacturer, date of manufacture, and degree of electric shock protection (BF rating). Do not dispose. Return to Customer Service for proper recycling. |
<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
</table>
| ![Identification label](image1.png) | Location: Head Support System, A/P Bar  
Identification label. Model number, serial number, manufacturer, and date of manufacture. Do not dispose. Return to Customer Service for proper recycling. |
| ![Identification label](image2.png) | Location: Head Support System, A/P Bar  
Identification label. Model number, serial number, manufacturer, and date of manufacture. Do not dispose. Return to Customer Service for proper recycling. |
| ![Align before transport](image3.png) | Location: Mobile Console, Top Panel, Mast (top)  
Mast and gantry position that ensures safe movement of the system when the wheels are unlocked. Refer to Instructions For Use for safe use. |
| ![Align before transport](image4.png) | Location: Mobile Console, Gantry cover  
Gantry position that ensures safe movement of the system when the wheels are unlocked. Refer to Instructions For Use for safe use. |
| ![Treatment coil interface](image5.png) | Location: Treatment Coil, Push-Button Switch Interface  
Treatment Coil controls: brake release for operator treatment coil positioning, increment MT level, decrement MT level, and emit a single pulse by Treatment Coil. |
<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
</table>
| ![Image](image1.png) | Location: Treatment Coil, Push-Button Switch Interface  
Treatment Coil controls: brake release for operator treatment coil positioning, increment MT level, decrement MT level, and emit a single pulse by Treatment Coil. |
| ![Image](image2.png) | Location: Treatment Chair, Remote Control  
Instructional buttons for Treatment Chair positioning:  
| Raise chair height | Lower chair height |
| Raise back support | Lower back support |
| Increase tilt angle | Decrease tilt angle |
| Raise leg support | Lower leg support |
| ![Image](image3.png) | M1 and M2 recall predetermined treatment positions.  
M3 and M4 are available for programming treatment positions. |
| ![Image](image4.png) | Location: Head Support System, A/P Bar  
Alignment scale in cm. |
<table>
<thead>
<tr>
<th>Label Description</th>
<th>Location: Head Support System, Lower Support Bracket</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front/Back scale in cm.</td>
<td>Location: Head Support System, Lower Support Bracket Up/Down scale in cm.</td>
</tr>
</tbody>
</table>
## Informational and Instructional Labels

<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Label" /></td>
<td>Location: Treatment Coil Alignment Guide - Left, Right.</td>
</tr>
<tr>
<td><img src="image2" alt="Label" /></td>
<td>Location: Head Support System, A/P Bar Coil Angle Guide scale in degrees.</td>
</tr>
<tr>
<td><img src="image3" alt="Label" /></td>
<td>Location: Head Support System, A/P Bar Coil Angle Guide scale in degrees.</td>
</tr>
<tr>
<td><img src="image4" alt="Label" /></td>
<td>Location: Head Support System, Rear Cover Lateral Canthus scale in cm (left or right).</td>
</tr>
<tr>
<td>Label</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
<td>-------------</td>
</tr>
</tbody>
</table>
| ![LSOA](image1) ![RSOA](image2) | Location: Head Support System, Rear Cover  
Superior Oblique Angle scales in degrees (left and right). |
| ![RSOA](image3) ![LSOA](image4) | Location: Head Support System, Rear Cover  
Superior Oblique Angle scale indicator (right and left). |
| ![RLC](image5) ![LLC](image6) | Location: Head Support System, Rear Cover  
Lateral Canthus scale indicator (right and left). |
| ![Front/Back Scale](image7) | Location: Head Support System, Lower Support Bracket  
Front/Back scale indicator. |
| ![Up/Down Scale](image8) | Location: Head Support System, Lower Support Bracket  
Up/Down scale indicator. |
| ![Mobile Console Interface](image9) | Location: Mobile Console, Rear Interface Panel  
Reset button, network connector, sync in/out, and treatment coil on/off power switch. The USB and RS232 connectors are for Service Use Only. Refer to *Instructions For Use* for safe use. |
<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
</table>
| ![CAUTION label](image) | Location: Treatment Room Entry Door  
Caution for active treatment coil proximity to implanted medical devices. |
| ![Notice label](image) | Location: Mobile Console, Rear Panel  
Magnetic field restricted access notice. |