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.

FIGURE 1-1. NeuroStar System

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.

Randomized Controlled Trials

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 (Neuronetics 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.

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

NOTE

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.

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* or VNS.
- Patients who are pregnant or nursing.

* *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.

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.

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*.

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, power module, mast, gantry, halo, and display arm)
- System Software
- TrakStar Patient Data Management System software
- Treatment Coil
- 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)

1.13 Supplies and Disposables Overview

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.

1.15 Protected Health Information

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.