# Depression Patient’s Manual

for Transcranial Magnetic Stimulation with the NeuroStar TMS Therapy® System

October 2008

This Depression Patient’s Manual is a supplement to the NeuroStar TMS System User Manual. It does not take the place of consultation and advice from your physician. For a complete discussion of indications for use, contraindications, precautions, warnings, and potential side effects, talk to your doctor. Specifically, talk with your doctor about:

- How this device is used
- Who should not be treated with this device
- Side effects
- Warnings

Your doctor’s phone number:

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## Introduction to NeuroStar TMS Therapy

Your doctor has prescribed NeuroStar TMS Therapy® to reduce the symptoms of your depression. TMS stands for “Transcranial Magnetic Stimulation”. In NeuroStar TMS Therapy, TMS is delivered by the NeuroStar TMS System as powerful magnetic field pulses. NeuroStar TMS Therapy has been shown to be safe and effective in the treatment of patients with depression who have failed to achieve satisfactory improvement from one prior antidepressant medication at or above the minimal effective dose and duration in the current episode. NeuroStar TMS Therapy has not been shown to be effective for the treatment of patients who have failed 2 or more antidepressant medications at or above the minimal effective dose and duration in the current episode or who have had no prior antidepressant treatment. Your physician will use a medication checklist to help determine whether or not your antidepressant medication history makes you a potential candidate for NeuroStar TMS Therapy. Further details on the medication checklist can be obtained from your provider.

NeuroStar TMS Therapy is performed in your psychiatrist’s office under his or her supervision. The treatment is non-invasive and non-systemic which means that it does not involve surgery and does not circulate in the bloodstream throughout the body. Treatment with NeuroStar TMS Therapy does not involve anesthesia or sedation, and patients are awake and alert during the treatment session. A typical treatment course consists of 5 treatments per week over a 4-6 week period for a total of 20-30 separate treatment sessions. Each treatment session lasts approximately 40 minutes.

NeuroStar TMS Therapy is not an appropriate treatment for all patients with depression. You should review this patient manual and discuss the information with your doctor in order to determine if NeuroStar TMS Therapy is an appropriate treatment option for you.

## How Does NeuroStar TMS Therapy Work?

During treatment with the NeuroStar TMS System, the NeuroStar treatment “coil” is positioned gently on the left front side of the head over a region of the brain called the Left Prefrontal Cortex. By sending short bursts of electricity through the treatment coil, the NeuroStar TMS System generates magnetic fields that turn on and off very rapidly. These magnetic fields are the same type and strength as those used in magnetic resonance imaging (MRI) machines.

The rapidly pulsing magnetic fields that are generated by the NeuroStar go directly through the hair, scalp and skull and create small electric currents in the area of the brain directly under the treatment “coil”. The electric currents created in the brain make nerve cells in that region become active.

## When Can NeuroStar TMS Therapy Be Used?

### Indications for Use

NeuroStar TMS Therapy is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication at or above the minimal effective dose and duration in the current episode.

### When Should NeuroStar TMS Therapy Not Be Used?

NeuroStar TMS Therapy should not be used in patients who have magnetic-sensitive metals implanted in their head or are non-removable and near (within 12 inches) the NeuroStar treatment coil.

NeuroStar TMS Therapy should not be used in patients who have an implanted device that may not properly function in the presence of the NeuroStar TMS System, even if the device is located outside this (12 inch) distance.

Your doctor will ask you to list any metal devices or objects in your head or body in order to determine if those devices could be affected by the NeuroStar TMS System. Use of NeuroStar TMS Therapy in the presence of these objects could result in serious injury or death.

Standard amalgam dental fillings are not affected by the magnetic field and are acceptable in patients being considered for treatment with NeuroStar TMS Therapy.

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## NeuroStar TMS Therapy Safety Information

The safety of NeuroStar TMS Therapy was determined in clinical trials of 323 patients with moderate to severe Major Depressive Disorder who ranged in age from 18 to 70 years, and who had failed to achieve satisfactory improvement from prior antidepressant treatment.

- Less than 5% of all patients dropped out of the clinical trial because of side effects from the treatment.
- There were no deaths or seizures in patients who took part in the clinical trial.
- Systemic side effects such as weight gain, sexual problems, stomach problems, sleepiness, and dry mouth were not observed.
- Tests of memory function during treatment showed no change during the clinical trial.

This section provides information about adverse events observed with the use of the NeuroStar TMS System in clinical trials.

**Worsening Depression or Suicidality**

Depression is a serious medical illness. Not all patients treated with an antidepressant will get better with treatment. Because of this, some patients may experience worsening of their depression before they begin to see improvement of their symptoms. NeuroStar TMS Therapy may require up to 4-6 weeks of treatment before symptom improvement occurs and has not been studied in patients who need rapid improvement in their depression symptoms.

You should inform your psychiatrist if your symptoms do not improve, or if they get worse. If you have thoughts of death or suicide you should immediately discuss this with your doctor. Your doctor will determine whether NeuroStar TMS Therapy should be discontinued and, if so, what other treatment options are available. You should be carefully monitored for worsening symptoms, signs or symptoms of suicidal behavior and/or unusual behavior. Families and caregivers should also be aware of the need to observe the patient and notify the treatment provider if symptoms worsen.

**Risk of Ineffective Therapy**

NeuroStar TMS Therapy is indicated for patients who have failed to receive satisfactory improvement from one prior antidepressant medication given at a high enough dose for a long enough period of time to be effective. In clinical trials, patients had also received additional antidepressant medication attempts in their current episode of depression, but only one antidepressant had been given at the adequate dose and duration for it to be effective.

The clinical trial included patients who had failed to achieve satisfactory improvement from one to four antidepressant medications. The device was not demonstrated to be effective for patients who had failed to benefit from two or more antidepressant medications. Therefore, it is important that your prior antidepressant medication history is carefully evaluated by your doctor to determine if NeuroStar TMS Therapy is right for you.

**Other Risks**

Seizures (sometimes called convulsions or fits) have been reported with the use of other types of TMS devices. However, no seizures were observed with use of the NeuroStar TMS System in clinical trials that included over 10,000 treatment sessions. You should discuss with your doctor if you have had a seizure, or if you have a medical condition that you have been told may put you at increased risk of having a seizure. Your doctor will decide if it is appropriate for you to receive NeuroStar TMS Therapy.

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

- Patients who have failed to receive benefit from 2 or more antidepressant medications given at or above minimal effective dose and duration in the current episode or patients who have had no prior antidepressant medication.
- Patients who can not tolerate withdrawal of antidepressant medications.
The following table presents a summary of adverse events that occurred in the clinical trial in patients treated with the NeuroStar TMS System, while this occurred in less than 5% of patients treated with sham (placebo), suggesting that this is a direct effect of NeuroStar TMS Therapy. Inform your doctor if you experience discomfort during treatment. Your doctor can decrease the NeuroStar TMS dose or move the NeuroStar TMS coil slightly to ease or eliminate the discomfort. Discomfort during treatment was seen during a 24-week follow-up period. However, effectiveness has not been established for treatment beyond a single six week course.

Longer term effects of exposure to the NeuroStar TMS System magnetic field are not known. However, exposure to other devices (such as MRI scanners) with the same magnet type and strength of magnetic fields produced by the NeuroStar TMS System coil are not associated with significant short-term or long-term safety concerns.

### Adverse Events

Temporary pain or discomfort at the area of the head where the treatment coil was placed was reported in about a third of patients who were treated with the NeuroStar TMS System, while this occurred in less than 5% of patients treated with sham (placebo), suggesting that this is a direct effect of NeuroStar TMS Therapy.

Inform your doctor if you experience discomfort during treatment. Your doctor can decrease the NeuroStar TMS dose or move the NeuroStar TMS coil slightly to ease or eliminate the discomfort. Discomfort during treatment was seen during a 24-week follow-up period. However, effectiveness has not been established for treatment beyond a single six week course.

Longer term effects of exposure to the NeuroStar TMS System magnetic field are not known. However, exposure to other devices (such as MRI scanners) with the same magnet type and strength of magnetic fields produced by the NeuroStar TMS System coil are not associated with significant short-term or long-term safety concerns.

#### Table 1. Adverse Events Reported with NeuroStar TMS Therapy:

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Active TMS (N=165 Patients)</th>
<th>Sham TMS (N=158 Patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye pain</td>
<td>10 (6.1%)</td>
<td>3 (1.9%)</td>
</tr>
<tr>
<td>Toothache</td>
<td>12 (7.3%)</td>
<td>1 (0.6%)</td>
</tr>
<tr>
<td>Application site discomfort</td>
<td>18 (10.9%)</td>
<td>2 (1.3%)</td>
</tr>
<tr>
<td>Application site pain</td>
<td>56 (35.8%)</td>
<td>6 (3.8%)</td>
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<tr>
<td>Facial pain</td>
<td>11 (6.7%)</td>
<td>5 (3.2%)</td>
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<tr>
<td>Muscle twitching</td>
<td>34 (20.6%)</td>
<td>5 (3.2%)</td>
</tr>
<tr>
<td>Pain of skin</td>
<td>14 (8.5%)</td>
<td>1 (0.6%)</td>
</tr>
</tbody>
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