# Patient Management Worksheet
# For Nausea and Vomiting Control

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**Reminder:** Programming decisions are the responsibility of the clinician and are based on the ability to establish settings that will provide optimal patient symptom relief, minimize patient discomfort, and maintain neurostimulator battery life to the best possible extent. Similarly, the clinician and patient together are responsible for the decision whether to proceed with an Enterra™ Therapy implant. The Manage-by-Fact 5 standard programs provide a range of electrical stimulation fields. A systematic assessment of patient response to these programs may help facilitate optimum program settings.

**For Provider Use Only**

Patient Name: _____ DOB: _____ Date of Implant: _____

Managing Healthcare Provider: _____ Implanting Surgeon: _____ INS Location: _____

| Pre-Implant Data | | Post Implant Data | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Program Name | | | | | | | | | | |
| Date | | | | | | | | | | |
| Battery Status (EOL, LOW, OK) | | | | | | | | | | |
| Therapy Measurement (Impedance) | | | | | | | | | | |
| Amplitude/Voltage | | | | | | | | | | |
| Cycle On/Off Time | | | | | | | | | | |
| Rate | | | | | | | | | | |
| **Nausea Diary (Average)** | **Baseline** | | | | | | | | | |
| #Nausea Hours in 24 hrs | | | | | | | | | | |
| Severity of Nausea (0-4) | | | | | | | | | | |
| **Vomiting Diary (Average)** | **Baseline** | | | | | | | | | |
| #Vomiting Episodes in 24 hrs | | | | | | | | | | |
| Vomiting Severity (0-4) | | | | | | | | | | |

**IF INADEQUATE SYMPTOM IMPROVEMENT:**
1. Review troubleshooting questions with patient
2 .Fill out a Symptom Diary
3. Compare current diary information with baseline
4. Check impedance and battery life when appropriate

| Standard Programs 1-5 | PGRM 1 | PGRM 2 | PGRM 3 | PGRM 4 | PGRM 5 |
|---|---|---|---|---|---|
| Electrode Configuration<br>Pulse Width 330, Rate 14 | 2-/3+ | 2+/3- | 2-/C+ | 3-/C+ | 2-,3-/C+ |

**Important Safety Information**
Enterra Therapy for treatment of chronic, resistant to medication nausea and vomiting associated with gastroparesis caused by diabetes or an unknown origin in patients aged 18 to 70 years: patients should always discuss potential risks and benefits of the device with their physician.

**Indications for Use:** The Enterra Therapy System for Gastric Electrical Stimulation (GES) is indicated for use in the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years.

**Contraindications:** The Enterra Therapy System is contraindicated in patients whom the physician determines are not candidates for surgical procedures and/or anesthesia due to physical or mental health conditions. Also, diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) is contraindicated because diathermy's energy can be transferred through the implanted system (or any of the separate implanted components), which can cause neurostimulation system or tissue damage and can result in severe injury or death. Patients should not have Magnetic Resonance Imaging (MRI).

**Warnings/Precautions/Adverse Events:** This system has not been evaluated for pregnancy, pediatric use, or patients under the age of 18, or over the age of 70. The system may be affected by or adversely affect cardiac devices. Strong electromagnetic interference (EMI) such as from electrocautery, defibrillation/cardioversion, therapeutic ultrasound, radiofrequency (RF)/microwave ablation, or MRI, can cause serious injury in implanted patients. These and other EMI sources can damage or turn off the system. EMI, postural changes, or other activities may cause shocking or jolting sensations. Patients on anticoagulation therapy may be at a greater risk for post-operative complications. The use of non-Enterra Medical components with this system may result in damage to Enterra Medical components, loss of therapy, or patient injury. When possible, identify and treat any infections remote to the implant site prior to surgery. Infections at the implant site almost always require the surgical removal of the implanted system. The lead can become entangled with or erode into the bowel, which may result in bowel obstruction/perforation and may progress to intra-abdominal infection and require laparotomy, bowel resection and system revision or removal. The lead(s) can erode through the stomach wall and result in gastric perforation with possible lead migration into the lumen of the intestine and may progress to intra-abdominal infection and require laparotomy and system revision or removal. Patients should avoid activities that may put undue stress on the implanted neurostimulation system components. Adverse events related to the system include infection, irritation/inflammation over implant site, implant site pain, device migration/erosion, lead penetration, extra-abdominal pain, seroma, hematoma, concomitant muscle stimulation, loss of therapeutic effect, system ceases to function due to battery depletion or other causes, programming difficulty, undesirable change in stimulation (described as a shocking or jolting sensations), gastrointestinal symptoms, and gastrointestinal complications including bowel obstruction/perforation or gastric perforation. Any of these may necessitate reprogramming, medical treatment or additional surgery.

**Humanitarian Device:** Authorized by Federal law for use in the treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years. The effectiveness of this device for this use has not been demonstrated.

For further information, please contact Enterra Medical at info@enterramedical.com.
USA Rx only.

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