Clinician Programmer

(Enterra Entrust® 40100) ON/OFF INSTRUCTIONS

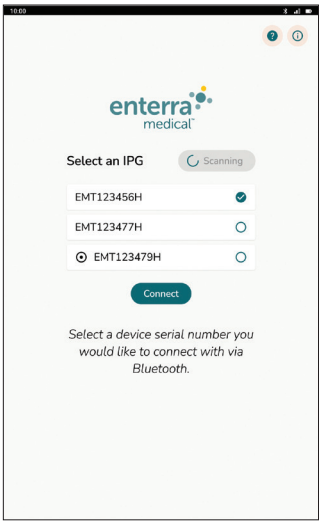
Enterra Ascent® has not been approved by the U.S. Food and Drug Administration (FDA). FDA has notified Enterra Medical that Enterra Ascent® and Enterra Entrust® may be distributed for implant under an FDA enforcement policy.

This document is not a substitute for approved labeling. Always refer to the full Instructions for Use and Implant Manual.

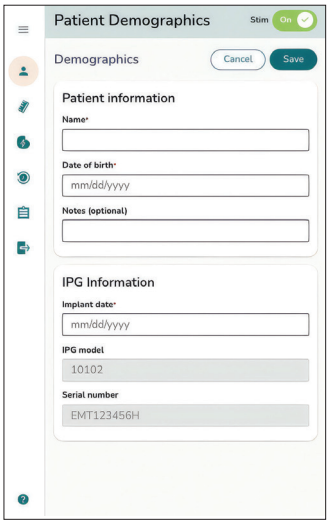
The following steps should be used as a guide to using the Enterra Entrust® Clinician Programmer during Enterra Ascent® device On/Off

Clinician Programmer Set Up & Device Connect

1. Turn the tablet on by pressing the Power button. Swipe to access the tablet's Home screen.
2. Ensure that Bluetooth® is enabled on the tablet.
3. Tap the Enterra Entrust app icon to launch the application.
4. Press the Scan button. Scan The programmer will automatically search for nearby IPGs (Implantable Pulse Generators) via Bluetooth.
5. A list of all detected Enterra Ascent devices will appear in the device selection area.
6. Locate the patient's device serial number and click the select button. Refer to the patient's Enterra Medical ID Card or Patient Records to verify the serial number.
7. Press the Connect button Connect to connect to the selected IPG.
8. Confirm patient information by selecting OK in the Confirm Patient Information window or by navigating to the Patient Demographics screen. Verify patient and IPG information.



Step 6

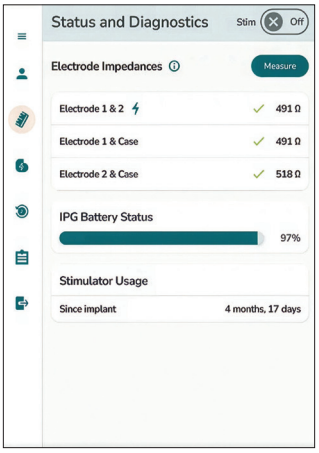


Step 8

Electrode Impedance Checks

When turning the device ON/OFF for MRIs, it is required to run an Impedance test to verify the IPG's system integrity.

9. Tap the Status icon on the navigation panel to navigate to the Status and Diagnostics screen.
10. Electrode impedance values are displayed. Press the Measure button Measure to run an impedance measurement. If all impedances are within range, a green checkmark appears next to each value.
11. Ensure impedances fall between 200 to 1000 ohms. If the impedance measurement is outside the recommended range, do not proceed with the MRI test and have the patient follow up with an Enterra provider.



Steps 9-11

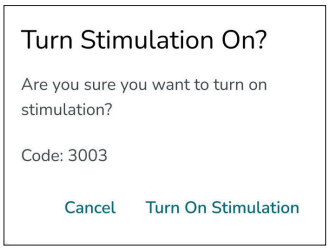
For programming questions, urgent technical questions, or to return the programmer, please contact Enterra Medical 24/7 at 1-855-768-3772.

Turning IPG stimulation ON and/or OFF

12 The current IPG stimulation setting is displayed in the upper right corner of the title bar on all programmer screens. This toggle button will indicate stimulation status:

ON (toggle green) Stim On | **OFF** (toggle gray) Stim Off

13 To turn the stimulator On or Off, tap the On/Off toggle in the title bar. A confirmation pop-up dialog box will display. Tap Turn On Stimulation or Turn Off Stimulation as appropriate.



Step 13

Clinician Programmer End Session & Return to Enterra Medical

14 Once the stimulation status reflects the desired setting, end the programming session by tapping the "End Session icon" on the navigation panel, then confirm by tapping "End Session" on the pop-up dialog.

15 The programmer is now able to be powered off by pressing the Power button.

16 Please package and return the programmer to Enterra Medical.

Troubleshooting

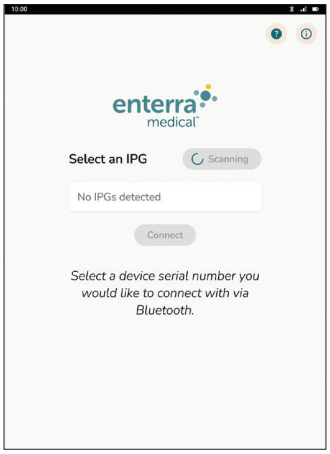
Connection failure

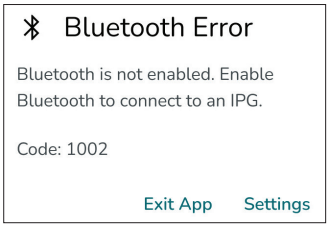
Connection failure occurs when the Enterra Entrust Clinician Programmer cannot establish a Bluetooth connection with the patient's IPG.

If the patient's IPG battery is completely depleted, or the programmer is not within range, the clinician programmer will not connect.

The most common steps to overcome connection failures:

- Ensure you are within a 1.5-meter range of the patient's IPG. Move closer to the front of the patient in a direct line of sight.
- Ensure nothing stands between you and the patient. Avoid any potential interfering equipment during a programming session.
- Move away from sources of possible Electromagnetic Interference (EMI) (e.g., computer monitors, other wireless devices).
- Close the Enterra Entrust app and re-launch it to restart the IPG search.
- If a Bluetooth error occurs, follow the on-screen instructions to enable Bluetooth on the device settings, then re-open the app.
- If errors persist, please contact Enterra Medical for assistance at 1-855-768-3772.





Connection issues

Enterra Ascent® has not been approved by the U.S. Food and Drug Administration (FDA). Because of a shortage of the Enterra® II device, FDA has notified Enterra Medical that Enterra Ascent may be distributed under an FDA enforcement policy for medical device supply shortages while FDA's review of the Enterra Ascent submission continues. This does not mean that FDA has approved Enterra Ascent or made any determination about its safety or probable benefit. Enterra Ascent is intended to provide the same therapy as Enterra II, but it has design changes that FDA has not yet fully reviewed. Before implanting Enterra Ascent, review the Enterra Ascent instructions for use, including all warnings, precautions, and potential adverse events.

Important Safety Information
Enterra® Therapy, with Enterra Ascent®, is 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 is indicated for use in the treatment of chronic, intractable (drug refractory) nausea and vomiting associated with gastroparesis caused by diabetes or an unknown origin in patients aged 18 to 70 years. **Contraindications:** The Enterra Therapy System is not intended for patients whom the physician determines are not candidates for surgical procedures and/or anesthesia due to physical or mental health conditions. Patients cannot have diathermy (deep heat treatment from electromagnetic energy) if they have an Enterra device. **Warnings/Precautions/Adverse Events:** This system has not been evaluated for pregnant women, or for use in patients under the age of 18 or over the age of 70. The system may be affected by or adversely affect cardiac devices. Strong sources of electromagnetic interference (EMI) such as from electrocautery, defibrillation/cardioversion, therapeutic ultrasound, radiofrequency (RF)/microwave ablation, or MRI, can result in serious injury, system damage, or operational changes to the system. EMI, postural changes, or other activities may cause shocking or jolting sensations.

The Enterra II and Enterra Ascent Implantable Systems are MR Conditional. This means that patients with the Enterra II System and Enterra Ascent System can safely have MRI examinations of some body parts under certain conditions. The conditions for MRI scans will vary with the type of MRI coil. Obtain the latest MRI guidelines by referring to the manuals at www.enterramedical.com/hcp/manuals.

The Enterra I System and the external components of the Enterra System, including the N'Vision® Clinician Programmer and the Enterra Entrust® Clinician Programmer, are MR Unsafe. These devices must NOT be taken into the MR scanner room (ACR Zone IV).

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. There is the possibility of an allergic or immune system response to the implanted materials. When possible, a physician is to identify and treat any infections prior to surgery. Infections at the implant site almost always require the surgical removal of the implanted system. The lead can become entangled with the bowel or perforate the stomach and cause life-threatening blockage or infections that require immediate medical attention and may require surgery. Patients should avoid activities that may put undue stress on the implanted system components (activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching that can cause component fracture or dislodgement). Adverse events related to the therapy, device, or procedure can include: infection, pain at the surgery site, device components may wear through the skin, bruising at the neurostimulator site, bleeding, loss of therapeutic effect, undesirable change in stimulation (described as a jolting, shocking, or burning sensation), gastrointestinal symptoms and gastrointestinal complications (in that the lead may perforate the stomach or device components may become entangled with or obstruct other internal organs, requiring surgery). The system could stop because of battery depletion or mechanical or electrical problems. Any of these situations may require additional surgery or cause symptoms to return. **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.

www.enterramedical.com

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