Clinician Programmer

(N'VISION® 8840) ON/OFF INSTRUCTIONS

enterra® medical

The following steps should be used as a guide to using the Clinician Programmer



On/Off Instructions

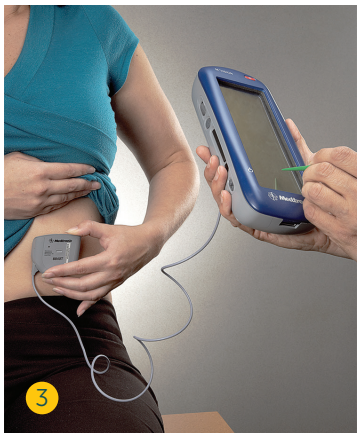
1. Turn the 8840 programmer on by sliding the power button for 1 second, located on the left-hand side of device.

2. Slide the telemetry head off the programmer.

3. Place the telemetry head over the patient's neurostimulator (logo facing outward) over the location of the implant (on the skin or over top of light clothing).

4. When the programmer turns on, tap the neurostimulator symbol in the center of the screen.

5. Tap inside the "to begin a session" box on screen, or press the "P" button on the side of the programmer.





Determining if patient's neurostimulator is ON or OFF

6. After connecting to the patient's neurostimulator, locate INS icon in the top right corner of the screen.

   Icon will indicate battery status:

   on () | off ().



7. To turn the stimulator On or Off, use the stylus tap icon to confirm it is indicating desired setting "On" or "Off". Once the battery icon status is reflecting proper neurostimulator status, remove programming head and turn off programmer.

8. Programmer will shut down after one minute of inactivity, or slide the power button to turn off programmer. When ready to return the programmer, please return it using the enclosed prepaid shipping label.

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

MRI: Impedance Check

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



A After confirming the neurostimulator is ON, locate the  icon in the top left corner of the screen under 'Therapy Management'

B Ensure impedance falls between 200 to 800 ohm range.

C 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.

Troubleshooting

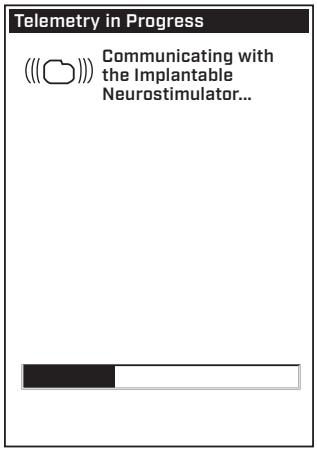
Telemetry or connection failure

Telemetry failure is a failure of the programmer and neurostimulator to connect.

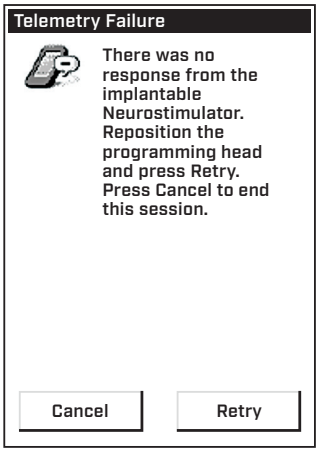
If the patient's neurostimulator is completely depleted, or the telemetry head is not positioned properly over the neurostimulator, the clinician programmer will not connect.

The most common steps to overcome telemetry failures:

- Decrease the distance between the programming head and the neurostimulator, pressing the programming head firmly over the implanted neurostimulator.
- Slightly reposition the telemetry head over the implanted neurostimulator, then click the "retry" button.
- Move away from sources of possible Electromagnetic Interference (EMI) (e.g., computer monitors).
- In patients with more tissue, pressing of the head to connect may be necessary.
- Green illuminated light on the telemetry head indicates proper telemetry connection with the neurostimulator.
- Amber light indicates poor telemetry connection.



During telemetry, the Progress bar will be displayed



If the clinician programmer cannot connect an error message will display





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 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. You cannot have diathermy (deep heat treatment from electromagnetic energy) if you have an Enterra device. **Warnings/Precautions/Adverse Events:** This system has not been evaluated for pregnant women, for use in patients under the age of 18, or patients 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 Implantable System is MR Conditional. This means that patients with the Enterra II 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 external components of the Enterra System, including the Model 8840 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-Medtronic components with this system may result in damage to Medtronic 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 your 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 your 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 your 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.

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