Implant manual

Enterra® II

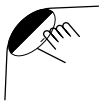
37800

Rx only
Humanitarian Device: Authorized by Federal (U.S.A.) Law for use in 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.

enterra medical™

Explanation of symbols on products and packaging

Refer to the appropriate product to see symbols that apply.


Open here


Do not use if package is damaged


Do not reuse

Do not resterilize

Sterilized using ethylene oxide


Consult instructions for use


Consult instructions for use at this website (https://www.enterramedical.com/hcp/manuals)


Caution for specific warnings or precautions associated with the medical device


Date of manufacture


Manufacturer


Use by

Serial number

MR Conditional

Table of contents

Information available for the system:

The information for prescribers manual provides information about warranty, indications, contraindications, warnings, precautions, adverse events, sterilization, patient selection, individualization of treatment, and component disposal.

MR Refer to the MRI Guidelines for Enterra System instructions for use manual for the MRI conditions and MRI-specific contraindications, warnings, and precautions for conducting an MRI scan.

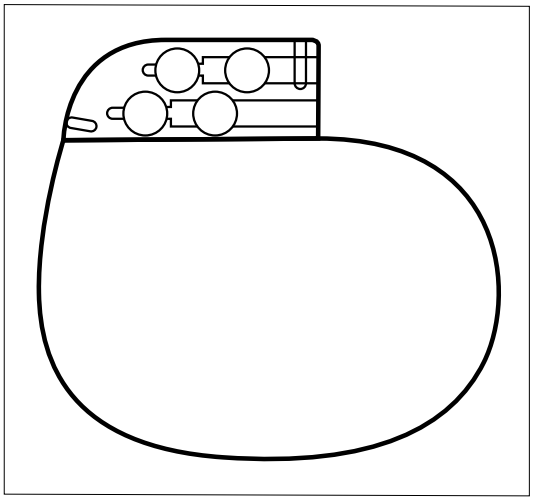
Description

The Enterra® II model 37800 neurostimulator is a programmable device designed to deliver therapy through gastric electrical stimulation when connected to a lead system. These components comprise the implantable portion of the Enterra II System. The operation of the neurostimulator is supported by a clinician programmer.

The neurostimulator (Figure 1) operates on a sealed battery and electronic circuitry to provide controlled electrical pulse stimulation, through the implanted lead system.

A wide range of noninvasively programmable parameters and stimulation modes is available. The neurostimulator provides current parameter information, via telemetry, when used with the clinician programmer.

Figure 1. Neurostimulator



System components

- Neurostimulator: Enterra II model 37800
- Controlling devices: Medtronic model 8840 Clinician Programmer with model 8870 Application Card. Model 8527 printer optional.
- Lead: Enterra model 4351 Unipolar Lead or Enterra ReliaStim™ model 30101 Unipolar Lead

Indications

The Enterra Therapy System for Gastric Electrical Stimulation (GES) is indicated for 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.

Humanitarian Device: Authorized by Federal (U.S.A.) Law for use in treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The effectiveness of this device for this use has not been demonstrated.

Package contents

- Neurostimulator
- Torque wrench
- Product literature
- Registration form
- Patient identification card

Patient identification card

A patient identification card is packaged with this device. Advise the patient to carry the identification card at all times.

The patient identification card packaged with the device is temporary; a permanent card will be mailed to the patient when Enterra Medical receives the registration form.

The implant registration form registers the device warranties and creates a record of the device in Enterra Medical's implant data system.

Device specifications

The Enterra model 37800 neurostimulator is powered by a hermetically sealed hybrid cathode silver vanadium oxide (HCSVO) single-cell battery. To further protect the neurostimulator components from body fluids, the electronics and power source are hermetically sealed within an oval-shaped titanium shield.

The neurostimulator has a self-sealing connector assembly with a corrosion-resistant titanium alloy body and titanium setscrews. Securing the lead system requires the use of a torque wrench which is packaged with the neurostimulator.

Other features of the model 37800 neurostimulator include software to limit accidental high rate stimulation, two suture holes for securing the neurostimulator within the subcutaneous pocket, and a radiopaque identification symbol.

Table 1 lists the operating values for the neurostimulator. Table 2 provides the initial values when the neurostimulator is shipped. Table 3 lists the physical characteristics of the neurostimulator. Table 4 lists the materials used in each component.

Measurement functions

The measurement functions of the neurostimulator assist in identifying problems with system components or the entire implanted system.

These measurements, obtained from the clinician programmer, include the battery service life and electrode impedance. They are intended to aid in your clinical assessment.

However, as with any electronic system, internal and external factors can influence neurostimulator measurements. For example, changes in lead position can affect the stimulation current or the impedance measurement.

If you obtain a reading that seems inconsistent with your observations, repeat the measurement. Apply clinical judgment when interpreting any measurement.

Note: The Enterra II impedance measurement may show different results than the explanted Enterra device because Enterra II includes an improved measurement system.

Table 1. Operating values for the Enterra II model 37800 neurostimulator

Programmable parameter	Operating values and increment
Electrode configuration	Electrodes 2 and 3 as anode (+), cathode (-), or Off; Case as anode (+) or Off
Amplitude	0 to 10.5 V with 0.1 V increment
Pulse width	60 to 450 µs (30 µs increment)
Rate	2 to 130 Hz (Increment: 1 Hz from 2 Hz to 10 Hz, 10 Hz from 10 Hz to 130 Hz. Specific values 14 Hz, 28 Hz, and 55 Hz are also available)
Cycling	0.1 sec to 10 sec (increment: 0.1 sec from 0.1 sec to 1 sec; 1 sec from 1 sec to 10 sec)

Table 2. Initial values for the Enterra II model 37800 neurostimulator

Programmable parameter	Initial value
Electrode configuration	Electrode 2 = cathode (-) and Electrode 3 = anode (+)
Amplitude	0 V
Pulse width	330 µs
Rate	14 Hz
Cycling	On: 0.1 sec, Off: 5 sec

Table 3. Physical characteristics of the Enterra II model 37800 neurostimulator[a]

Description	Value
Connector type	Quadripolar, two bore
Height	55 mm (2.2 in)
Length	60 mm (2.4 in)
Thickness	11.4 mm (0.5 in)
Weight	45 g (1.6 oz)
Volume	28 cm^3
Power source	4.5 Amp hours, 3.2 V to 2.2 V operating range, HCSVO[b] primary cell
Serial number model designator[c]	NHX
Radiopaque identification (ID) code	NHV
Transmitter Carrier frequency Output level	 175 kHz <30 dBµA/m

[a] All measurements are approximate.

[b] Hybrid cathode silver vanadium oxide.

[c] The serial number is the model designator followed by a unique number. The clinician programmer displays the entire serial number beginning with the model designator.

Table 4. Device materials: Enterra II model 37800 neurostimulator

	Component	Material
Materials and substances to which the patient can be exposed	**Case**	Titanium
	Connector block	Polyurethane, silicone rubber, silicone medical adhesive
	Grommets, seals	Silicone rubber
	Setscrews, electrical contacts	Titanium alloy
	Adhesive	Silicone medical adhesive

Declaration of conformity

For additional information, contact Enterra Medical at the number listed on the back cover of this manual.

Instructions for use

Implanting physicians should have experience in the surgical and/or implantation techniques for the Enterra II System, operational and functional characteristics of the Enterra II System, and experience in the continued management of patients by stimulation parameter adjustment. Physicians may contact Enterra Medical before prescribing or implanting an Enterra II System for the first time, and request a referral to a physician experienced in the use of the Enterra II System. Implanting physicians should be thoroughly familiar with all product labeling.

⚠ **Cautions:**

- When using sharp instruments near the neurostimulator, be extremely careful to avoid nicking or damaging the case or the connector block. Damaging the neurostimulator may require surgical replacement.
- Do not use saline or other ionic fluids at connections, which could result in a short circuit.

Verifying neurostimulator operation

Before opening the sterile neurostimulator package, verify that the neurostimulator is operable by using the clinician programmer to interrogate the neurostimulator and read the neurostimulator battery service life (refer to the Programming Manual, P/N 800-0020-002, for instructions on how to read the battery service life).

⚠ **Caution:** Do not implant a neurostimulator if it was dropped onto a hard surface from a height of 30 cm (12 in) or greater, because the neurostimulator may be damaged and fail to operate properly.

Note: The neurostimulator is provided sterile and does not require any soaking in antibiotic solution, which can possibly affect lead connections. Do not submerge the neurostimulator in fluid.

Creating a pocket for the neurostimulator

⚠ **Warning:** To reduce the possibility of infection, it is recommended that the following guidelines be used. Infections at the implant site often require the surgical removal of the neurostimulator and leads.

- When possible, identify and treat any infections remote to the implant site prior to surgery.
- Administer IV antibiotics during surgery and post-surgery.
- Irrigate the neurostimulator pocket with antibiotic solution during surgery.

⚠ **Warning:** Do not implant the neurostimulator near other implanted devices. Place the neurostimulator on the opposite side of the body from other implanted devices. Electrical impulses from the neurostimulation system may affect the sensing operation and cause inappropriate device response of other implanted devices.

⚠ **Warning:** Implant the device as far away as possible, and at least 20 cm (8 in) from another active implanted device (for example, pacemaker, defibrillator) to minimize possible interaction between the devices. For information on interactions between multiple devices, consult the manufacturer's labeling for risks associated with the other devices.

⚠ **Caution:** Select a neurostimulator implant location that meets the following criteria:

- Away from bony structures (for example, 3 - 4 cm [1.2 - 1.6 in]) to minimize discomfort at the neurostimulator site.
- Away from areas of restriction or pressure to minimize the potential for skin erosion, patient discomfort, or damage to components.

⚠ **Caution:** To prevent device inversion, do not make the neurostimulator pocket any larger than necessary to fit the neurostimulator and excess lead. Device inversion may result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site, requiring repeat surgery to restore therapy.

⚠ **Caution:** Ensure that the neurostimulator is placed no deeper than 4 cm (1.5 in) below the skin and is parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, telemetry may be unsuccessful.

Notes:

- Placement below the ribs and above the hip bone provides a comfortable location for most patients.
- To ensure proper programming, the neurostimulator should be located no more than 4 cm beneath the surface of the skin in subcutaneous tissue. The device must be placed parallel to the skin surface. The etched logo side of the neurostimulator should face out toward the skin.

1. Create a subcutaneous pocket for the neurostimulator by blunt dissection to the anterior surface of the muscle. The neurostimulator is typically placed in the abdomen.

2. If necessary, (for example, during laparotomy), create a subcutaneous tunnel for the leads to the pocket.

⚠ **Caution:** Use caution when approaching the pocket to avoid additional trauma to the patient as resistance to tunneling suddenly ceases.

   a. Tunnel the leads through the fascia to the pocket (create a separate tunnel for each lead).

⚠ **Warning:** The lead can become entangled with or erode into the bowel, which can result in bowel obstruction and perforation. Either may lead to life threatening intra-abdominal infections and may require laparotomy, bowel resection, and system revision. Avoid excess lead slack in the abdominal cavity. Post implant, consider lead entanglement or erosion as a possible etiology in patients with bowel obstruction symptoms.

⚠ **Caution:** Do not pull on the leads in such a way that the leads become dislodged from the muscle. Excessive force on the lead connector may damage the connector pin.

b. Do not pull the lead taut; allow just enough slack to minimize component stress, tension, or migration, and allow for patient movement and for physiological movement of the stomach and other abdominal organs.

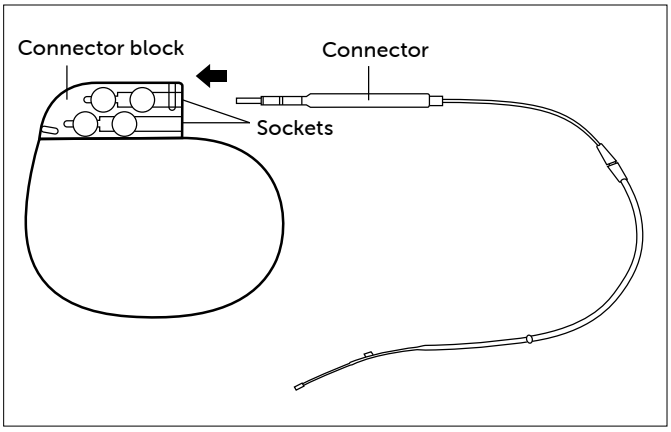
c. Check that the lead connector pins and connector bodies are free of body fluids or tissue before connecting to the neurostimulator.

Connecting the lead to the neurostimulator

⚠ **Caution:** Before connecting components, wipe off any body fluids and dry all connections. Fluids in the connection may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.

1. Wipe the lead connector pins with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution.
2. Make sure the connector block receptacles are dry and clean.
3. Insert the lead connector pins into the neurostimulator sockets until they are fully seated within the connector block (Figure 2). The connector pins can fit into either receptacle.

Figure 2. Insert the lead connector pins fully into the neurostimulator



Note: If resistance is felt while inserting the connector pins, use the torque wrench (packaged with the neurostimulator) to retract the setscrews.

⚠ **Cautions:**

- Do not insert the lead connector pins into the connector block if the setscrews are not sufficiently retracted. If the setscrews are not retracted, the setscrews may damage the lead connector pins, and the lead connector pins will not be seated fully into the connector block. This may result in intermittent or loss of stimulation.
- Limit counter-clockwise rotations of the neurostimulator setscrews when retracting them. Too many counter-clockwise rotations may disengage the setscrew from the connector block.
- Be sure the torque wrench is fully inserted into the self-sealing grommet. If the torque wrench is not fully inserted, the setscrew may be damaged, resulting in intermittent or loss of stimulation.
- Before tightening the setscrews, ensure that the lead connector pins are inserted into the connector block to prevent damaging the connector block. This could result in intermittent or loss of stimulation.
- Verify that each leaf of the self-sealing grommet is closed after the torque wrench is withdrawn. If fluid leaks through a grommet seal that is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant location, or intermittent stimulation or loss of stimulation may occur.

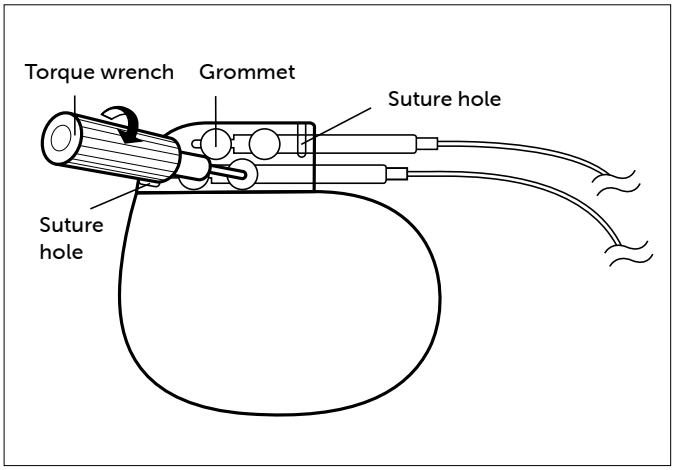
4. Fully insert the torque wrench into each self-sealing grommet of the connector block, and tighten each setscrew by turning the torque wrench clockwise until you hear a click (Figure 3)

Note: The torque wrench must be oriented to the same angle as the setscrew (Figure 3).

Note: The sealing rings within the neurostimulator connector block are designed to form a seal with the connector pins. No sealant or sutures are required to seal the connector pins.

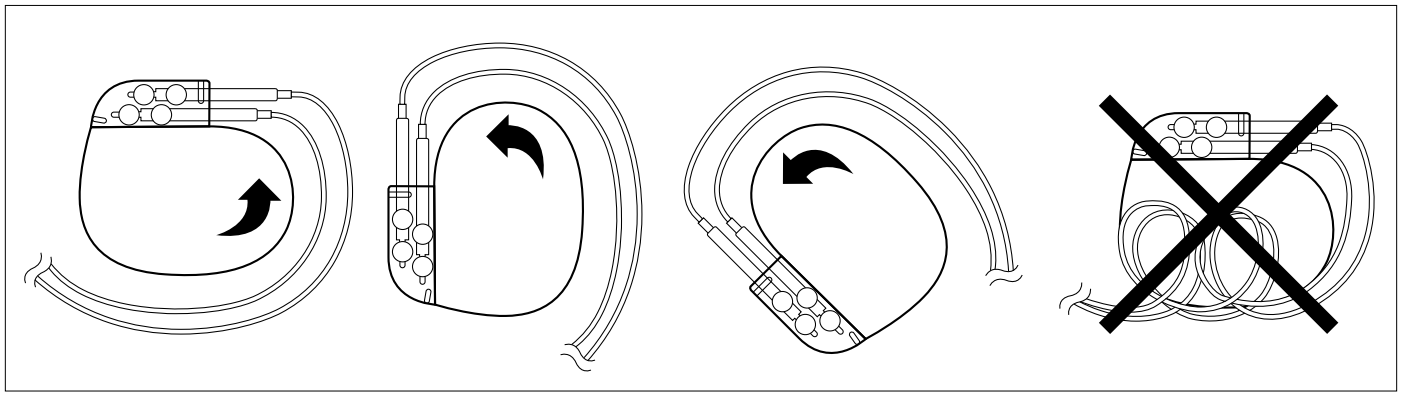
⚠ **Warning:** The lead can become entangled with or erode into the bowel, which can result in bowel obstruction and perforation. Either may lead to life-threatening intra abdominal infections and may require laparotomy, bowel resection, and system revision. Avoid excess lead slack in the abdominal cavity. Post implant, consider lead entanglement or erosion as a possible etiology in patients with bowel obstruction symptoms.

Figure 3. Tightening the setscrews in the self-sealing grommet



5. Refer to Figure 4 to coil excess lead wire loosely around the perimeter of the neurostimulator. Do not wrap more than two times and ensure that the leads are not twisted or bent sharply.

Figure 4. Wrap excess lead wire around the perimeter of the neurostimulator



⚠ **Caution:** Do not loop or coil the wire on top of the neurostimulator's logo side. Loosely wrap any excess wire around the perimeter of the neurostimulator. This avoids any increase in the subcutaneous pocket depth, minimizes potential damage during replacement surgery, and minimizes potential kinking of the wire, which could result in loss of therapy.

6. Place the neurostimulator into the subcutaneous pocket with the etched logo facing out toward the skin.

Checking system integrity

⚠ **Caution:** To use the nonsterile clinician programmer in a sterile field, place a sterile barrier between the patient and the programming head to prevent infection. Do not sterilize any part of the clinician programmer. Sterilization may damage the programmer.

Note: The neurostimulator should be in the pocket during system interrogation for integrity to ensure proper readings.

1. To ensure proper connection of the lead to the neurostimulator, use the Clinician Programmer to program basic stimulation parameters, check the battery status, and check the electrode impedances to rule out a short or open circuit.

⚠ **Caution:** Before closing the pocket, investigate the reason for an impedance measurement outside the normal 200 to 800 ohm range, should such a measurement occur. This may indicate that the integrity of the Enterra II electrical system is compromised, which could result in intermittent or loss of stimulation.

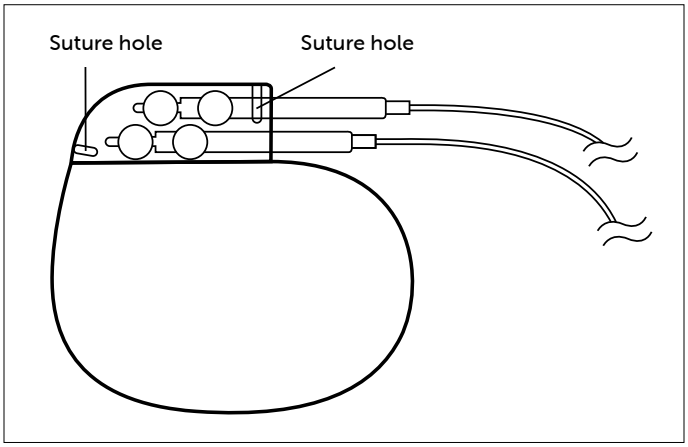
2. If the system integrity test results are not acceptable, refer to Connecting the lead to the neurostimulator on page 10.

Completing the implant procedure

⚠ **Caution:** Secure the neurostimulator using both suture holes. Failure to use both suture holes may increase the risk of device migration or rotation, which can cause component damage, skin erosion, unintended stimulation effects, or lead dislodgement.

1. Secure the neurostimulator in the subcutaneous pocket using both suture holes in the connector block (Figure 5).
2. Close and dress all incisions.
3. Check the Enterra II System impedance after the incision is closed, but before the patient leaves the operating room. This procedure is to verify electrical continuity between the leads and the neurostimulator.
4. Verify and document lead and neurostimulator locations by obtaining lateral and anterior-posterior X-rays of the abdominal region up to 48 hours after the implantation procedure.

Figure 5. Securing the neurostimulator using both suture holes



Note: If desired, the neurostimulator may be turned on at this time, otherwise it can remain off until a later time.

5. Complete the device tracking and patient registration paperwork and return the documents to Enterra Medical at the address listed on the back cover of this manual.
6. Schedule regular patient follow-up appointments to monitor the condition of the neurostimulator battery and to confirm that the programmed parameter values are appropriate.

Estimating and monitoring battery longevity

The longevity tables in this section provide an approximate number of years that a new Enterra II model 37800 neurostimulator battery will last. The estimates are based on the respective amplitude, rate of usage, and cycling parameters given in Table 5, Table 6, Table 7, and Table 8.

⚠ Cautions:

- High-energy program configurations could result in less than one year of battery longevity. If all programmable parameters are set to their upper limit, battery longevity could be less than 3 months.
- If programming a high-energy program configuration, consider the increased risk of revision surgery, due to reduced battery longevity, against the benefit of therapy for the patient.

Notes:

- Programming parameter values outside of those provided in Table 5, Table 6, Table 7, and Table 8 may significantly affect battery longevity.
- Refer to Table 9 to assess the impact of a high-energy program configuration on battery longevity.
- All battery longevity calculations are based on a pulse width of 330 microseconds, and bipolar stimulation (- and + on leads).

Table 5. Longevity in years[a] (programming amplitude with current)

Amp (mA)	Rate (Hz)	Cycling		Longevity (years)		
		On (sec)	Off (sec)	800 ohms	500 ohms	200 ohms
5	14	0.1	5	7.2	7.2	7.1
7.5	14	0.1	5	7.4	7.3	7.0
10	14	0.1	5	7.5	7.4	7.0
10	14	1	4	5.4	6.2	6.8
10	14	2	3	4.1	5.4	6.5
10	28	2	3	2.7	3.9	5.5
10	55	2	3	1.6	2.6	4.2

[a] If the selected amplitude/rate/cycling values are not shown, find the next highest variable of interest, and use the associated longevity number.

Table 6. Longevity in years[a] – 200 Ohms (programming amplitude with voltage)

Amp (V)	Rate (Hz)	Cycling		Longevity (years) 200 ohms
		On (sec)	Off (sec)	
1	14	0.1	5	7.1
1.5	14	0.1	5	7.0
2	14	0.1	5	7.0
2	14	1	4	6.8
2	14	2	3	6.5
2	28	2	3	5.5
2	55	2	3	4.2

[a] If the selected amplitude/rate/cycling values are not shown, find the next highest variable of interest, and use the associated longevity number.

Table 7. Longevity in years[a] – 500 Ohms (programming amplitude with voltage)

Amp (V)	Rate (Hz)	Cycling		Longevity (years) 500 ohms
		On (sec)	Off (sec)	
2.5	14	0.1	5	7.2
3.75	14	0.1	5	7.3
5	14	0.1	5	7.4
5	14	1	4	6.2
5	14	2	3	5.4
5	28	2	3	3.9
5	55	2	3	2.6

[a] If the selected amplitude/rate/cycling values are not shown, find the next highest variable of interest, and use the associated longevity number.

Table 8. Longevity in years[a] – 800 Ohms (programming amplitude with voltage)

Amp (V)	Rate (Hz)	Cycling		Longevity (years) 800 ohms
		On (sec)	Off (sec)	
4	14	0.1	5	7.2
6	14	0.1	5	7.4
8	14	0.1	5	7.5
8	14	1	4	5.4
8	14	2	3	4.1
8	28	2	3	2.7
8	55	2	3	1.6

[a] If the selected amplitude/rate/cycling values are not shown, find the next highest variable of interest, and use the associated longevity number.

Table 9 demonstrates the effect of high-energy program configurations. Four amplitude values (4V, 6V, 8V and 10V) are assessed in relation to several rate (Hz) and cycling (%) parameter combinations. Each program configuration has a pulse width of 330 microseconds and an impedance of 500 ohms.

If an amplitude value is unshaded, patients can expect at least one year of battery longevity with that chosen program configuration. If an amplitude value is shaded, users can expect less than one year of battery longevity with that chosen program configuration.

If the chosen amplitude, rate, or cycling parameter setting is not identified, use the next highest parameter value.

Table 9. Assessing the impact of high-energy program configurations

Rate (Hz)	Cycling (% Cycle On Time)							
	2%		20%		40%		80%	
14Hz	4V	6V	4V	6V	4V	6V	4V	6V
	8V	10V	8V	10V	8V	10V	8V	10V
28Hz	4V	6V	4V	6V	4V	6V	4V	6V
	8V	10V	8V	10V	8V	10V	8V	10V
55Hz	4V	6V	4V	6V	4V	6V	4V	6V
	8V	10V	8V	10V	8V	10V	8V	10V
110Hz	4V	6V	4V	6V	4V	6V	4V	6V
	8V	10V	8V	10V	8V	10V	8V	10V

Cycling percentages indicate the Cycle On time of the neurostimulator (2% equals 0.1 sec Cycle On time and 5 sec Cycle Off time; 20% equals 1 sec Cycle On time and 4 sec Cycle Off time).

Battery Status Indicators

The Enterra Medical Clinician Programmer allows you to monitor your patient's neurostimulator battery status. The majority of the time, the programmer display will show battery status as OK indicating that the battery has enough capacity to continue to provide therapy as expected.

As the neurostimulator battery depletes, the battery status will eventually change to **Low**. When this occurs, less than 10% of the battery capacity remains. The remaining battery life ranges from a few days to a few months, depending on the patient's therapy. The higher the battery current drain, the shorter the remaining battery life.

As the neurostimulator battery depletes further, the battery status changes to **End of Service (EOS).** After the neurostimulator battery has been depleted, stimulation and telemetry are no longer possible.

Manufacturer

Enterra Medical, Inc.
5353 W. Wayzata Blvd., #400
St. Louis Park, MN 55416
USA

www.enterramedical.com
Tel. +855-7-nterra or
+855-768-3772

800-0009-004, Rev A 2024-06

enterra medical™