Implant manual

Enterra Ascent® Neurostimulator

10102



Rx Only
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.

enterra medical®

Explanation of symbols on product or package labeling

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 at this website
www.enterramedical.com/hcp/manuals



Date of manufacture



Manufacturer



Use by

SN	Serial number
	Caution for specific warnings or precautions associated with the medical device.
Rx Only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
	Country of origin
REF	Catalogue or reference number
	Double sterile barrier system with protective packaging inside.
MD	Medical device
	MR conditional

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Information available for the system:
The Instructions For Use (IFU) provides information about indications, contraindications, warnings, precautions, adverse events, sterilization, patient selection, individualization of treatment, interference and electromagnetic compatibility, clinical studies, FCC information, and component disposal.

Product manuals, such as programming guides and implant manuals provide device descriptions, package contents, device specifications, product-specific warnings and precautions, and instructions for use.

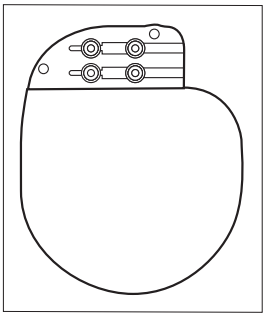


Refer to the MRI Guidelines for the Enterra Ascent System for MRI conditions and MRI-specific information for conducting an MRI scan.

Description

The Enterra Ascent® Model 10102 Neurostimulator is a programmable device designed to deliver therapy through gastric electrical stimulation when connected to a lead system. The neurostimulator generates electrical pulses and delivers stimulation through two leads. These components are the implantable portion of the Enterra Ascent System. The operation of the neurostimulator is controlled by a Clinician Programmer.

Figure 1. Enterra Ascent Neurostimulator



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

Programmable parameters include amplitude, pulse width, rate, and cycling. The neurostimulator provides current parameter information, via Bluetooth® LE, when used with the Clinician Programmer.[1]

1. The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Enterra Medical Inc. is under license. Other trademarks and trade names are those of their respective owners.

System components

- Neurostimulator: (One) Enterra® model 10102
- Leads: (Two) Enterra model 4351 Unipolar Lead or Enterra ReliaStim® model 30101 Unipolar Lead in any combination
- Controller Device: Enterra Entrust® model 40100 Clinician Programmer

Indications

The Enterra Ascent 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 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.

Package contents

- Neurostimulator
- Torque wrench
- Product literature

Note: The contents of the inner package are sterile and for single use only.

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 Ascent Model 10102 Neurostimulator is powered by a hermetically sealed QMR technology, a primary single-cell battery, which combines the advantages of SVO and CFx chemistries. To further protect the neurostimulator components from body fluids, the electronics and lithium battery are hermetically sealed within an oval-shaped titanium enclosure.

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

Other features of the Model 10102 Neurostimulator include software to limit accidental high energy 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.

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 voltage 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.

Table 1. Operating values for the Enterra Ascent Model 10102 Neurostimulator

Programmable parameter	Operating values and increment
Electrode Configuration	Electrodes 1 and 2 as anode (+), cathode (-), or Off. Case as anode (+) or Off
Amplitude	0 to 20 mA, 0.5 mA increment
Pulse Width	60 to 450 µs (30 µs increment)
Rate	2 to 130 Hz (Increment: 1 Hz from 2 Hz to 20 Hz, 5 Hz from 20 Hz to 130 Hz. Specific value, 28 Hz, is also available)
On/Off 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 Ascent Model 10102 Neurostimulator

Programmable parameter	Initial value
Electrode Configuration	Electrode 1 = cathode (-) and Electrode 2 = anode (+)
Amplitude	0 mA
Pulse width	330 µs
Rate	14 Hz
On/Off Cycling	On: 0.1 sec, Off: 5 sec

Device specifications

Device specifications

Table 3. Physical characteristics of the Enterra Ascent Model 10102 Neurostimulator

Description	Value
Connector Type	Quadripolar, two bore
Height	62 mm (2.4 in)
Length	50 mm (2.0 in)
Case Thickness	11.7 mm (0.5 in)
Header Thickness	12.65 mm (0.5 in)
Maximum Weight	45 g (1.6 oz)
Volume	28 cm^3 (1.7 in^3)
Materials and substances to which the patient can be exposed[a, b, c, d]	Titanium, polyurethane, silicone, silicone medical adhesive
Power Source	5.3 Amp hours total capacity, 3.2 V to 2.1 V operating range, QMR lithium primary cell.
Expected Lifetime[e]	4 to 7 years
Serial number model designator[f]	EMT
Radiopaque Identification (ID) code	EM3
Transmitter	Bluetooth® LE

All measurements are approximate.

[a] Discuss any allergies or other intolerances related to the materials and substances with the patient before the procedure.

[b] Tested for category 1A and category 1B carcinogenic, mutagenic, or toxic for reproduction (CMR) substances, and endocrine disrupting chemicals (EDC). No known CMRs or EDCs were found in the tested materials or substances.

[c] Does not contain natural rubber latex.

[d] Does not contain nickel.

[e] In rare situations with the highest settings, battery life could be less than 3 months.

[f] 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 Ascent Model 10102 Neurostimulator

	Component	Material
Materials and substances to which the patient can be exposed	**Case**	Titanium
	Header Outer	Polyurethane, silicone rubber, silicone medical adhesive
	Grommets, seals	Silicone rubber
	Setscrews, electrical contacts	Stainless Steel, MP35N Springs
	Adhesive	Silicone medical adhesive, silicone medical primer

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 Ascent System, operational and functional characteristics of the Enterra Ascent System, and experience in the continued management of patients by stimulation parameter adjustment. Before prescribing or implanting an Enterra Ascent System for the first time, physicians may contact Enterra Medical and request a referral to a physician experienced in the use of the Enterra Ascent 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.
- Using saline or other ionic fluids at connections, can cause a short circuit.

Verifying neurostimulator operation

Before opening the sterile neurostimulator package, verify that the neurostimulator is operable by using the Enterra Entrust® Clinician Programmer to interrogate the neurostimulator and read the neurostimulator's remaining battery capacity (refer to the Enterra Entrust 40100 Programming Manual, 800-02443-001, for instructions on how to read the remaining battery capacity).

⚠ **Caution:** Do not implant a neurostimulator if it was dropped onto a hard surface from a height of 30 cm (12 in) or greater. 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, follow the recommended guidelines below. Infections at the pocket 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 neurostimulator 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 movement or inversion in the pocket, do not make the pocket any larger than necessary to fit the neurostimulator and excess lead wires into the pocket. 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, communication with the neurostimulator may be unsuccessful.

Notes:

- Placing the pocket at least two finger breadths below the ribs and well 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 (1.5 in) beneath the surface of the skin in subcutaneous tissue. The neurostimulator must be placed parallel to the skin surface. The etched logo side of the neurostimulator should face outward toward the skin.

1. Create a subcutaneous pocket for the neurostimulator by blunt dissection of the subcutaneous tissue and anterior to the surface of the abdominal musculature. The neurostimulator is typically placed in the subcutaneous plane above the abdominal musculature at least two finger breadths below the rib margin in the left or right upper quadrant.
2. If necessary, (for example, during laparotomy), tunnel the leads subcutaneously from the abdominal cavity to the pocket.

⚠ **Caution:** Use caution when passing the leads from the abdominal cavity to the pocket to prevent additional trauma to tissue 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 leads 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. Carefully wrap excess lead wires around the device and place the device into the pocket with logo side facing outward. 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 stomach 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. Verify that the lead connector pins and the connector are free of body fluids or tissue before connecting to the neurostimulator.

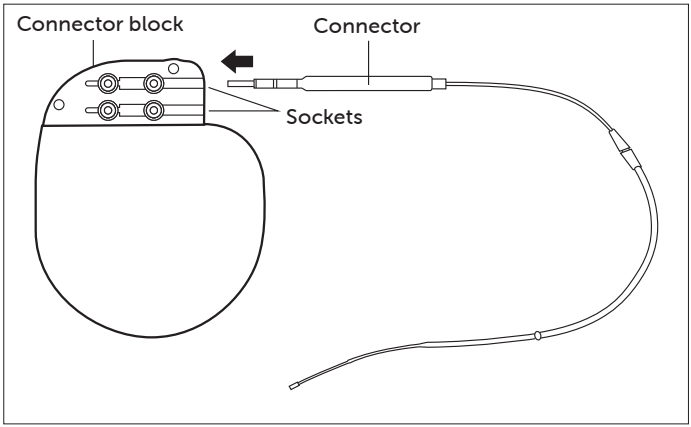
Connecting the leads to the neurostimulator

⚠ **Caution:** Before connecting the 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 neurostimulator sockets in the connector block 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.

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

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



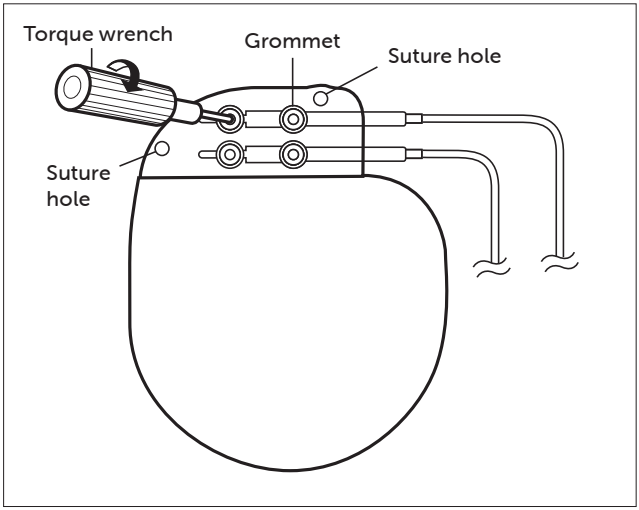
⚠ Cautions:

- Do not insert the lead connector pins into the sockets in 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 total 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 total loss of stimulation.
- Before tightening the setscrews, ensure that the lead connector pins are inserted firmly into the connector block to prevent damaging the connector block. Not following this instruction could damage the connector block and cause intermittent or total 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 total 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)

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



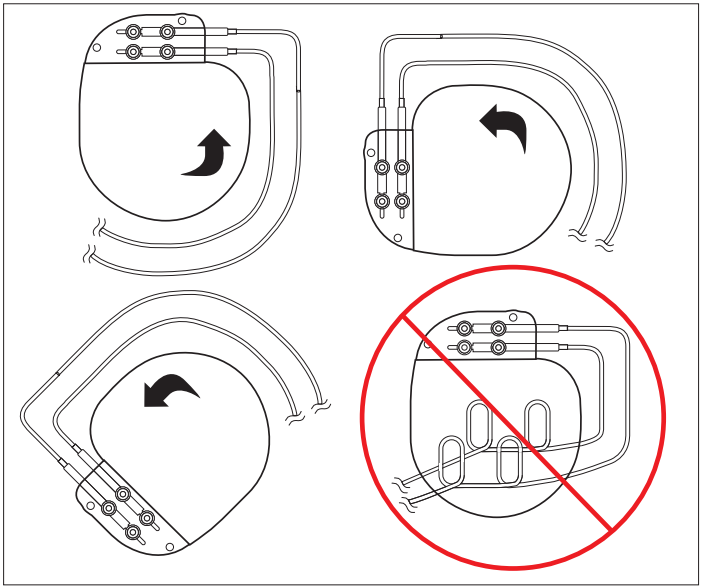
Note: To properly access the setscrew (Figure 3), the torque wrench must be perpendicular to the neurostimulator.

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 wire in the abdominal cavity. Post implant, consider lead entanglement or erosion as a possible etiology in patients with bowel obstruction symptoms.

5. Coil excess lead wires loosely around the perimeter of the neurostimulator (refer to Figure 4). Do not coil the lead wires more than two times, and ensure that the leads are not twisted or bent sharply.

Figure 4. Wrap the excess lead wires 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 outward toward the skin.

Checking system integrity

⚠ **Caution:** The Clinician Programmer can be used outside the sterile field. Do not sterilize any part of the Clinician Programmer. Sterilization may damage the Clinician Programmer.

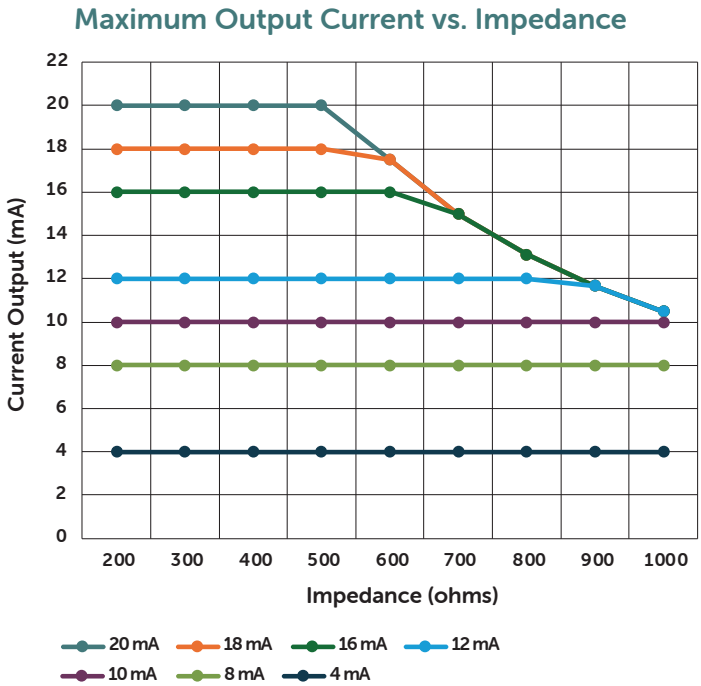
Note: The neurostimulator should be in the pocket during system interrogation for integrity to ensure proper readings.

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 1000 ohm range, should such a measurement occur. This may indicate that the integrity of the Enterra Ascent electrical system is compromised, which could result in intermittent or total loss of stimulation.

2. If the system integrity test results are not acceptable, refer to **Connecting the lead to the neurostimulator** on page 17.

Note: The graph below shows programmed current as a function of impedance. The device can deliver up to 20 mA depending on impedance. Current is limited by the maximum output voltage of 10.5 V for safety and decreases at higher impedance.

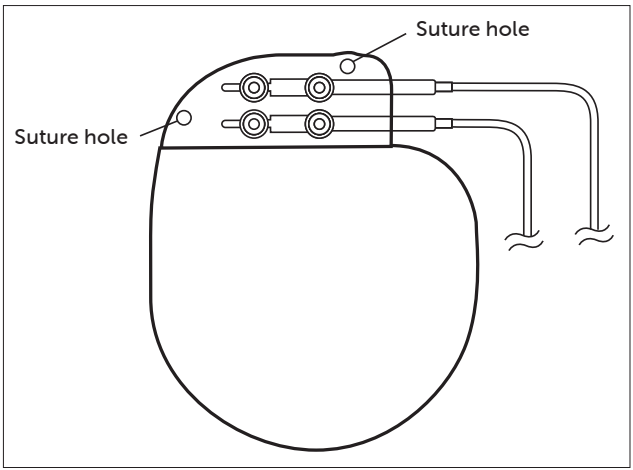


Completing the implant procedure

Caution: If settings and impedance measurements are appropriate and if endoscopy was normal and show no lead exposure in the stomach lumen, then secure the neurostimulator in the pocket 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).

Figure 5.



2. Close and dress all incisions.
3. Check the Enterra Ascent System therapy lead impedance after the incision is closed, but before the patient leaves the operating room. The purpose of this procedure is to verify electrical continuity between the leads and the neurostimulator.
4. Verify and document the lead and neurostimulator locations by obtaining lateral and anterior-posterior X-rays of the abdominal region up to 48 hours after the implantation procedure.

Note: If desired, turn on the neurosti mulator 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 life

The battery longevity tables in this section provide an approximate number of years that a new Enterra Ascent Model 10102 Neurostimulator battery will last. The estimates are based on the respective amplitude, rate of usage, and cycling parameters provided in **Table 5**.

⚠ Cautions:

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

Notes:

- Programming parameter values outside of those provided in **Table 5** may significantly affect battery longevity.
- Refer to **Table 6** 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 µs, 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	10	10	10
7.5	14	0.1	5	10	10	10
10	14	0.1	5	10	10	10
10	14	1	4	9.1	10	10
10	14	2	3	5.3	7.5	9.3
10	28	2	3	2.9	4.1	5.3
10	55	2	3	1.6	2.3	2.9

[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 demonstrates the effect of high-energy program configurations. Four amplitude values (8mA, 12mA, 16mA, and 20mA) are assessed in relation to several rate (Hz) and cycling (%) parameter combinations. Each program configuration has a pulse width of 330 ms and an impedance of 500 ohms.

If an amplitude value is unshaded in Table 6, patients can expect at least one year of battery longevity with that chosen program configuration. If an amplitude value is shaded, patients 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 6. Assessing the impact of high-energy program configurations

Rate (Hz)	Cycling (% Cycle On Time)									
	2%		20%		40%		60%		80%	
14Hz	8mA	12mA	8mA	12mA	8mA	12mA	8mA	12mA	8mA	12mA
	16mA	20mA	16mA	20mA	16mA	20mA	16mA	20mA	16mA	20mA
28Hz	8mA	12mA	8mA	12mA	8mA	12mA	8mA	12mA	8mA	12mA
	16mA	20mA	16mA	20mA	16mA	20mA	16mA	20mA	16mA	20mA
55Hz	8mA	12mA	8mA	12mA	8mA	12mA	8mA	12mA	8mA	12mA
	16mA	20mA	16mA	20mA	16mA	20mA	16mA	20mA	16mA	20mA
110Hz	8mA	12mA	8mA	12mA	8mA	12mA	8mA	12mA	8mA	12mA
	16mA	20mA	16mA	20mA	16mA	20mA	16mA	20mA	16mA	20mA

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; etc.).

Battery Status Indicators

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

As the neurostimulator battery drains, the battery status will eventually change to **Elective Replacement Indicator (ERI)** which occurs when the average battery voltage drops below 2.6 volts or after 10 years have elapsed, whichever occurs first. The remaining battery life ranges from a few days to a few months, depending on the patient's therapy. The greater the battery current drain, the shorter the remaining battery life.

As the neurostimulator battery depletes below 2.1 volts, the battery status will change to **End of Service (EOS).** At this point, the neurostimulator will turn the stimulation therapy Off. Lead impedance measurements will no longer be taken and logged. Battery voltage measurements and logging will continue.

Manufacturer

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800-2127-002, Rev A 2026-10

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