Clinician Programmer

40100

Enterra Entrust®



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 product or package labeling



Serial number



Consult instructions for use at this website
www.enterramedical.com/hcp/manuals



Manufacturer



MR Unsafe



Medical Device



Catalogue/REF



LOT number



Manufactured date



UDI



Country of origin

Refer to the appropriate Instructions for Use for indications, contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.

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Device description

The Enterra Entrust® Model 40100 Clinician Programmer is part of a neurostimulation system for Enterra® Therapy.

This manual provides the information needed to program and troubleshoot the Enterra Ascent® Model 10102 Implantable Pulse Generator (IPG).

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 18 to 70 years. The effectiveness of this device for this use has not been demonstrated.

Introduction

Enterra Entrust Clinician Programmer

App icon. Tap the icon to open the Enterra Entrust app.

Touchscreen display. The touchscreen display allows you to navigate the application and access all functions. To use the touchscreen, lightly tap the desired function on the screen using the pad of your finger. Do not use sharp objects, such as pencils, pens, and paper clips, on the touchscreen. Use only your fingertip.

Power key. Press the Power key on the tablet to turn the tablet on and off and to reactivate it after Stand-by mode. To access the tablet's Home screen, tap the power key and swipe up on the screen and then navigate to the Enterra Entrust app.

Compliances and authorizations. For compliance with the limits for a Class B digital device, refer to the tablet's resources that are included on the manufacturer's website.

Navigation and status

Navigation panel

The navigation panel provides access to the application menus and programming functions. Tap the desired icon to navigate to the screen(s) for that function.



By default, the navigation panel is in a collapsed state (Figure 1) and shows the icons only. To expand the navigation panel (Figure 2) and show the icon descriptions, tap ☰ at the top of the panel. (Tap it again to collapse the panel or tap outside the panel).

Figure 1:
Collapsed navigation panel

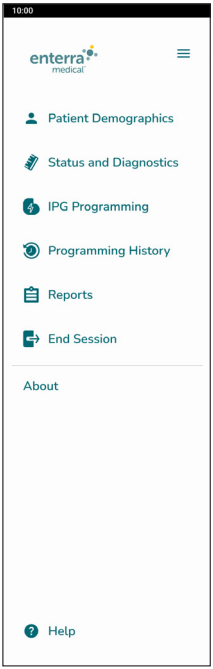

Figure 2:
Expanded navigation panel

Patient Demographics. View and edit patient information.

Status and Diagnostics. View the patient's IPG battery status, IPG usage time, and view and measure electrode lead impedance.

IPG Programming. Program the patient's IPG.

Programming History. View a history of the patient's IPG programming sessions.

Reports. Generate reports of the programming sessions.

End Session. End the session. The Enterra Entrust app will disconnect from the patient's IPG. Any settings that have not been sent to the IPG will not be saved.

About. Display system information, such as the current software version installed on the tablet.

Help. Provides details on navigating and operating the programmer.

Note: If a value or button appears gray, that option is not available during the current function.

Connecting to an IPG

This section describes how to establish a connection between the Enterra Entrust Clinician Programmer and a patient's IPG.

1. • Turn the tablet on, and then tap the power key and swipe up on the screen to access the tablet's Home screen.
   • Ensure that Bluetooth is enabled.
   • Tap the Enterra Entrust app icon.
2. When you launch the Enterra Entrust Clinician Programmer application, it automatically searches for nearby IPGs.

When the patient's IPG serial number appears, select it and tap **Connect**.

Please refer to the patient's Enterra ID Card or Patient Records to verify the serial number.

If no IPG is detected, ensure that you are within a 1.5-meter range of the IPG, close the Enterra Entrust app, and then re-launch it.

If you are able to discover the patient's IPG serial number but are unable to connect to it, move closer to the front of the patient in a direct line of sight, and ensure that nothing stands between you and the patient. Additionally, avoid any potential interfering equipment during a programming session.

If any Security errors occur, follow the on-screen

instructions to resolve the problem.

If a Bluetooth error occurs, follow the on-screen instructions to enable Bluetooth on the device settings, and then re-open the app.

If these errors persist, please contact Enterra Medical for assistance.

3 If the IPG is out of the box, it will be in a low-power state, also referred to as "Shelf-Mode." When asked if you want to connect in Shelf Mode, tap **Connect**.

If the IPG is already implanted, proceed to step 4.

4 After an IPG is connected, the Patient Demographics screen is displayed.

Note: When connecting to an IPG, if any errors occur as the result of an Authentication Failure, IPG Connection Failure, or Incompatible IPG Firmware, please follow the on-screen instructions to resolve the problem.

Note: After connecting to an IPG, a warning will appear at the top of every screen if the IPG indicates Elective Replace Indicator (ERI) or End of Service (EOS). Additional information can be found in the Checking system performance section.

Turning IPG stimulation On/Off

This section describes how to turn stimulation for the IPG on and off.

To turn stimulation for the IPG on or off, refer to the title bar at the top of the screen. The title bar displays the name of the active screen and provides access to the IPG stimulation On/Off toggle button (Figure 3).

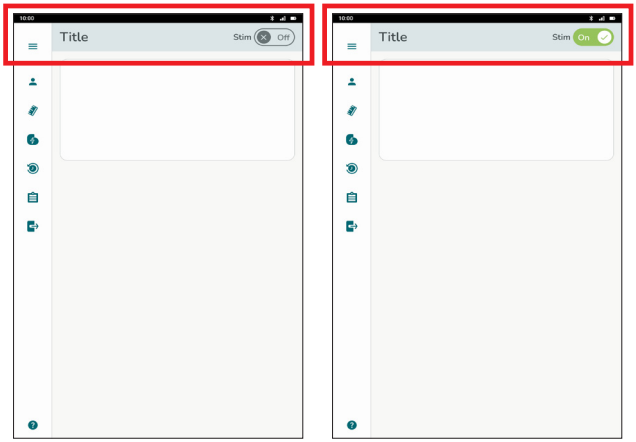

Figure 3. Title Bar

When turning stimulation on or off, a confirmation pop-up dialog box will display. Tap Turn On Stimulation or Turn Off Stimulation as appropriate.

Entering patient demographics

1 Upon connecting to a patient's IPG, the Patient Demographics screen is displayed. If this is the first-time connection to the IPG, the Patient Information fields will be blank.

Note: If you are connected to an already implanted IPG, or if you accessed this screen from the Patient Demographics icon on the navigation panel, the patient information will be in Read-only mode. To change any patient information, tap the **Edit** button and then proceed to update any of the patient information as necessary. Otherwise, verify that the Patient and IPG information is correct and proceed as necessary.

Note: If you receive a notice that the IPG has entered **Safe Mode**, please contact Enterra Medical for assistance. **Safe Mode** indicates that the IPG is in an error state and will not allow stimulation to be turned on and will not allow changes to the IPG settings. Electrode lead impedance measurements cannot be performed at this time as well.

2 Edit the information using the pop-up keyboard when necessary. To exit the keyboard, tap the return key or another field on the screen. An asterisk indicates a required field.

Name. Enter the patient's name.

Date of birth. Enter the patient's date of birth (MM/DD/YYYY) by selecting the date from the pop-up calendar.

Notes (optional). Enter optional notes about the patient in free-form format. The maximum number of characters allowed is 300.

Implant date. Enter the date on which the IPG was implanted (MM/DD/YYYY) by selecting the date from the pop-up calendar.

IPG model. Filled in automatically.

Serial number. Filled in automatically.

Note: If you need to discard any changes, tap **Cancel** and **Discard Changes** on the confirmation pop-up dialog. All pending patient demographic edits will be discarded.

3 When you are finished editing the patient and IPG information, tap **Save** and then tap **OK** on the confirmation pop-up dialog.

Note: If you exit the Patient Demographics screen without saving, a pop-up dialog asks if you want to exit without saving your changes. If you choose to exit without saving, all updates will be discarded and the app will navigate to the selected screen.

Checking system performance (Status and Diagnostics)

The Status and Diagnostics functions provide updated information of the IPG device performance and may also be used to assist with troubleshooting the patient's implanted neurostimulation system. Impedance measurements and diagnostic data obtained by the Enterra Entrust Clinician Programmer help you with your clinical assessment. However, as with any electronic system, internal and external factors can influence impedance measurements.

Recommendations

Measure lead impedance at the beginning and end of each programming session. These measurements verify the integrity of the lead pathways. They may provide information on lead problems. For example, measurements that show a significant increase in impedance can indicate a fractured lead conductor, a loose setscrew, and so on. Conversely, a significant decrease in impedance can indicate shorted conductors, a break in lead insulation, and so on. Checking impedance at the beginning of the session may be useful in interpreting diagnostic data collected since the previous session.

1. Follow the **Connecting to an IPG** instructions to turn the tablet on and connect to an IPG.

2. On the navigation panel, tap the Status and Diagnostics icon to navigate to the Status and Diagnostics screen.

Electrode impedance values are displayed. A lightning bolt icon identifies the active electrodes.

IPG Battery Status is an estimate of the percentage of the remaining battery capacity.

Stimulator Usage shows the number of days of implant usage since the IPG was implanted.

3. Tap **Measure**. If all impedances are within range, a green checkmark appears next to each value.

For any questions regarding the Electrode Impedances, please select the information icon to learn more about this measurement.

If there is a problem or error, an alert icon appears next to the out-of-range value(s), and a shaded Warning banner pops up at the top of the screen with a brief description of the problem.

- An icon displays next to the first (top) alert. The color of the alert icon indicates the priority of the first alert.
- The circled number indicates the number of alerts.

- Select the down arrow to expand the banner and bring all warnings into view. Select the up arrow to collapse the banner.

Follow the on-screen instructions to resolve the problem.

If IPG Battery Status indicates ERI (Elective Replacement Indicator) or EOS (End of Service), please schedule an IPG replacement.

Adjusting the IPG stimulation settings

This section describes how to adjust the Stimulation settings to meet the patient's needs for Stimulation.

1. Follow the **Connecting to an IPG** instructions to turn the tablet on and connect to an IPG.

2. On the navigation panel, tap the IPG Programming icon to navigate to the IPG Programming screen.

At the top of the screen, Stimulation status indicates **Off** or **On**.

The Therapy Impedance for active electrodes is displayed.

The following are the nominal values for an IPG.

- **Current:** 5.0 mA
- **Frequency:** 14 Hz
- **Pulse width:** 330 µs
- **Cycle On/Off:** 0.1 sec On and 5 sec Off
- **Electrode 1:** cathode (-)
  (Scroll up to view these settings).
- **Electrode 2:** anode (+)
  (Scroll up to view these settings).
- **Case:** Off (Scroll up to view these settings).

3

A. Using the drop-down lists, select the values as necessary:

- **Current:** 0.5-20 mA in 0.5 mA increments
- **Frequency:** 2-20 Hz in 1 Hz increments, and 20-130 Hz in 5 Hz increments, plus 28Hz
- **Pulse width:** 60-450 µs in 30 µs increments
- **Cycle On:** 0.1-1.0 sec in 0.1 sec increments, and 1.0-10 sec in 1 sec increments
- **Cycle Off:** 0.1-1.0 sec in 0.1 sec increments, and 1.0-10 sec in 1 sec increments

B. Programming Session Notes. Enter session notes (optional). Edit the information as appropriate using the pop-up keyboard. To exit the keyboard, tap the return key or another field.

C. Electrode Configuration. Tap the Case icon, Electrode 1 icon, or Electrode 2 icon to set the configuration.

D. Therapy Electrode Impedance. When you are finished selecting parameters and setting the configuration, tap **Measure** to measure impedance and determine if the values are within acceptable ranges. If the therapy electrode impedance value is within range, proceed to the next step. Once the current and impedance values are available, the voltage is calculated and displayed on the screen. If the calculated voltage exceeds 10.5 volts, the IPG is providing the maximum voltage and therefore the max indicator is displayed.

E. Clear changes. You can undo any changes you start to make by selecting the **Clear changes** option next to the **Program IPG** button. *You must do this before you tap the **Program IPG** button.*

Note: For any questions regarding Calculated Voltage or Electrode Configuration, please tap the Information icon ⓘ to learn more about that feature.

4 After updating all Stimulation Parameters, perform a Therapy Impedance Measurement. When the impedance check passes and all of the Stimulation Parameters have been verified, tap **Program IPG.** The settings will be checked to determine if the configuration is valid and that the settings do not exceed the therapy limits.

If any errors occur, follow the on-screen instructions to resolve the problem before proceeding.

5 After the settings are validated, a screen pops up displaying the original parameters and the new parameters side-by-side.

Review and confirm the parameters, and then tap **Program IPG** again.

If programming is successful and the new parameters are accepted, a confirmation message briefly appears. See **Reviewing Programming History** instructions on page 22.

At any time, you can reset the values to the nominal values by tapping the **Reset to Nominal (i.e., default)** button and then tapping **Program IPG.** This causes all values to be reset to the nominal settings.

Reviewing Programming History

Use the Programming History screen to find and review previous programming sessions.

1. Follow the **Connecting to an IPG** instructions to turn the tablet on and connect to an IPG.

2. On the navigation panel, tap the Programming History icon to navigate to the Programming History screen.

The information on this screen is view-only.

Scroll up to display additional records that may be out of view. The header portion at the top of the screen is fixed.

Reports

Session reports contain the settings and system information from patient sessions. You can generate reports during and after patient sessions. The following reports are available:

- **Device and Programming Summary (PDF) report**. Contains device information, programming settings and history, and usage details.
- **Diagnostics (PDF) report**. Contains lead impedance and battery voltage details.

- **CSV Export report.** Contains raw device, programming, and diagnostics data exported in CSV format.

Reports are saved on the tablet's internal memory.

1. Follow the **Connecting to an IPG** instructions to turn the tablet on and connect to an IPG.

2. On the left navigation panel, tap the Reports icon to navigate to the Reports screen.

Note: When accessing the Reports screen for the first time, a pop-up dialog will display a password. Write down the password. You will need it to access the reports that are saved to the Downloads folder.

3. To generate one or more reports, tap the desired **Generate report** or **Export** button:

Note: When generating a report, a pop-up dialog will appear offering the option to open the report, cancel out of the pop-up dialog, or go to the Downloads folder on the tablet. All exported reports are saved in the Downloads folder.

- Device and Programming Summary report is a PDF that shows device information, programming settings, and usage details.
- Diagnostics report is a PDF that shows impedance, battery voltage, and events.
- CSV Export is a CSV summary of the IPG programming and diagnostics data.
- **Set New Password** generates a new password for future reports.

Note: To ensure that the reports are correctly generated from the IPG, please remain within 1.5 meters of the patient until all reports are generated as shown in the pop-up dialog box.

4 When the report is generated successfully, a pop-up dialog is displayed. Tap **Open Report** to view the report. A new screen will appear with the full report.

Note: To view the report later, it will be saved on the tablet's internal memory under the Downloads folder application. Once a report is saved to the Downloads folder application, it can be transferred to a USB flash drive and viewed on another device, such as a laptop.

If the Enterra Entrust Clinician Programmer fails to generate a report, a pop-up dialog is displayed. Tap **Try Again**. If this issue persists, please contact Enterra Medical for assistance.

5 To export raw data in CSV format, tap **Export**.

When the export is completed successfully, a confirmation message is displayed ("Exported"). To view this report, access the Downloads folder application.

Ending the session and exiting the application

When you exit the application, the application disconnects from the IPG and the programmed settings will be stored in the Program History Log and saved for future reference.

- On the navigation panel, tap the **End Session** icon.
- Tap **End Session** on the confirmation pop-up dialog.

The Home screen returns to view and the tablet will begin to search for nearby IPGs.

If you have any questions or need to return an Enterra Entrust Clinician Programmer, please contact an Enterra Medical representative at 1-855-768-3772.

Glossary

Amplitude - The strength or intensity of an electrical pulse.

Cycling - Output is alternately cycled on and off automatically.

Cycling off time - In cycling, the length of time between Stimulation periods; the time of the "resting" period.

Cycling on time - In cycling, the length of time that Stimulation is delivered.

Electrode impedance measurements - Measurements of the resistance of the lead(s), extension(s), and body tissue that can provide information about the condition of the implanted system (e.g., short circuit, open circuit).

Electrode polarity - Stimulation delivery flow between the cathode (-) and anode (+).

Elective Replacement Indicator (ERI) - The IPG is nearing its end of service and scheduling a replacement surgery is recommended.

End of Service (EOS) - The IPG is automatically set to a non-stimulation low power mode of operation.

Nominal Values - The default settings of an IPG.

Pulse width - The length of time, measured in microseconds (µs), that a particular pulse is delivered.

Rate - The number of times per second, measured in Hertz (Hz), that a neurostimulation pulse is delivered.

Therapy measurements - Measurements of impedance in the active Stimulation pathways.

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