



Medtronic

N'VISION[®] CLINICIAN PROGRAMMER
with SOFTWARE

8840
8870

Enterra[®] II neurostimulation system

03/14 Programmer guide for software version A

 USA Rx only

CE0123
2015

Explanation of symbols on product and package labeling.



Serial number



Consult instructions for use



www.medtronic.com/manuals

Consult instructions for use at this website



Temperature limitation



For USA audiences only



Non-ionizing electromagnetic radiation



IEC 60601-1/EN60601-1, Type BF Equipment



Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.



System meets the applicable Canadian (CAN/CSA-C22.2 No. 60601-1) electrical safety standard requirements.



Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See <http://recycling.medtronic.com> for instructions on proper disposal of this product.



Chinese Standard (SJ/T11364-2006) Logo: Electronic Information Products Pollution Control Symbol. (The date in this logo means the environmental protection use period of the product.)



Manufacturer



Authorized Representative in the European Community

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Refer to the indications sheet for indications and related information.

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

Refer to the device implant manual for device description, package contents, device specifications, and instructions for use.

[USA] Refer to the clinical summary booklet for information on the clinical study results of the neurostimulation system and individualization of treatment.

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Device description

The Medtronic Model 8840 N'Vision Clinician Programmer with the Medtronic Model 8870 Application Card is part of a neurostimulation system for Enterra Therapy.

This manual is designed to provide the information needed to program and troubleshoot the programmable parameters for the Enterra II Model 37800 Implantable Neurostimulator (INS).

Package contents

- Application card with case
- Product literature

Introduction

The Model 8840 N'Vision Clinician Programmer (Figure 1) with the Model 8870 Application Card is a hand-held device for programming Medtronic devices for Medtronic Neuromodulation therapies. The programmer is used to review and program device parameters using telemetry, a radio-frequency (RF) communication.

If using a programmer for the first time, refer to the set-up instructions on the Getting Started card that is packaged with the programmer.

Programmer components

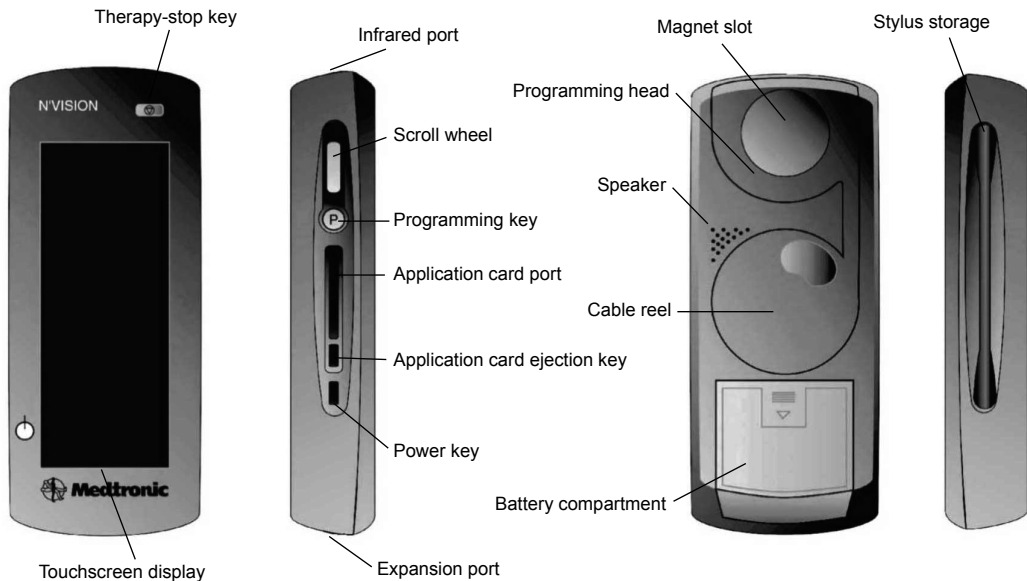


Figure 1. N'Vision clinician programmer components.

△ **Caution:** Do not use the expansion port. The expansion port is a testing port used by Medtronic personnel. Connecting any equipment to this port may damage the programmer.

- **Therapy-stop key** (⏏)—Stops all active therapy
- **Touchscreen display**—Programmer touchscreen for display and data input
- **Infrared (IR) port**—Allows communication with compatible printers or devices
- **Programming key** (P)—Pressing the key initiates interrogation or programming for some functions
- **Application card port**—Slot for the application card
- **Application card ejection key**—Ejects the application card from the programmer
- **Power key** (⏻)—Turns the programmer on and off; reactivates the programmer after Stand-by mode

- **Expansion port**—Do not use; currently only used for Medtronic testing
- **Scroll wheel**—Do not use; currently only used for other Medtronic therapies
- **Magnet slot**—Holds the Model 8529 Magnet (the Model 8529 Magnet is not used for all therapies and devices)
- **Programming head**—Allows the programmer to communicate with the device
- **Cable reel**—Stores a 1 meter (3.3 ft) extendable cable that connects the programming head to the programmer
- **Speaker**—Programmer speaker
- **Battery compartment**—Contains the programmer batteries
- **Stylus**—Use to enter data through the touchscreen display

Printer

The optional Model 3445 Seiko DPU Printer (Figure 2) communicates with the programmer via IR signals. The printer is available in the Medtronic Model 8527 Printer Kit.



Figure 2. Model 3445 Seiko DPU printer.

Most standard desktop printers with IR capability and protocol IrDA 1.0 compliant at data rates of 9600 and 57,600 bits per second may also be used with the programmer.

A desktop printer must have IR capability or must be fitted with a commercially available IR converter.

Note: IR functionality is only intended for communication between the N'Vision Programmer and the designated printers. Any other use is not certified by Medtronic.

Navigation, status, and data entry

The touchscreen display allows you to navigate through the application, read statuses, and enter data. When navigating or entering data, use the pointed end of the stylus to make contact with the display screen. Do not use sharp objects (eg, pencils, pens, paper clips) on the touchscreen display. Use only the stylus or your fingertip.

△ **Caution:** If stylus contact with the touchscreen display results in a different function, action, or therapy than expected, calibrate the touchscreen on the display.

Note: For instructions on calibrating the display, see "Calibrating the touchscreen" on page 56.

Navigation and status

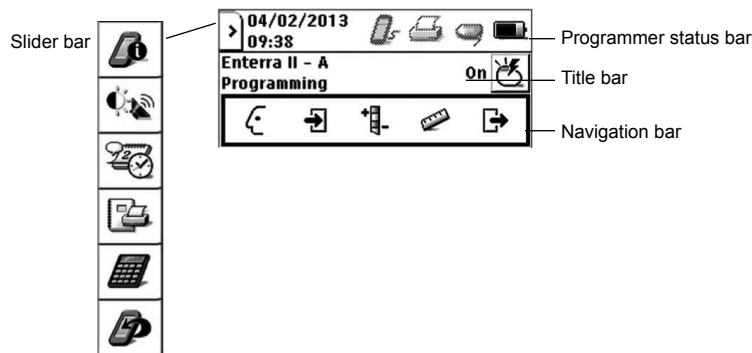


Figure 3. Navigation and status icons.

Navigation and status icons are in the following locations (Figure 3):


















- **Programmer status bar**—Displays system date and time as well as status of selected functions and components
- **Slider bar**—Provides access to programmer information, system settings, and accessories
- **Title bar**—Displays application name, active screen name, and the **Neurostimulator On/Off** button
- **Navigation bar**—Provides access to application menus

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

Programmer status bar

The programmer status bar shows the status of peripheral devices, the programming head, Demo mode, and the programmer battery.

Table 1. Programmer status bar icon descriptions

Nontelemetry communication port			
	Nontelemetry communication is active		Nontelemetry communication is inactive
Printer			
	Printing		Printing error
			Printing inactive
Programming head			
	Programming head present		Programming head not present
	Communication established between programming head and device		No communication between programming head and device
	Magnet present on programming head		Magnet present; telemetry successful
			Magnet present; telemetry not successful
Demo mode			
	Demo mode is active		
Programmer battery			
	High battery status		Medium battery status
	Low battery status		Depleted battery status (blinking)







Slider bar

The slider bar provides access to programmer information, operating system and touchscreen display settings, and printer and calculator functions. The slider bar can be accessed any time during a programming session by selecting the **Slider bar** button on the programmer status bar (Figure 4).



Figure 4. Slider bar button.

Table 2. Slider bar button descriptions

Button	Description
	Information <ul style="list-style-type: none"> • Display the names, model numbers, and version numbers for programmer, application, and associated software and peripheral devices
	Settings <ul style="list-style-type: none"> • Adjust the display contrast • Adjust the speaker volume • Adjust the key click sound • Calibrate the touchscreen
	Localization <ul style="list-style-type: none"> • Select the language preference • Select the date format and set the date • Select the decimal format • Set the time format
	Session data manager <ul style="list-style-type: none"> • Print session reports • View session reports • Delete session reports
	Calculator <ul style="list-style-type: none"> • Access the calculator
	Exit application <ul style="list-style-type: none"> • Return to the Application selection screen to select a new application

Title bar

The title bar displays the application name and active programmer screen. The title bar also provides access to the **Neurostimulator On/Off** button (Figure 5).



Figure 5. Title bar.

Navigation bar

The navigation bar provides access to the application menus and programming functions (Figure 6).

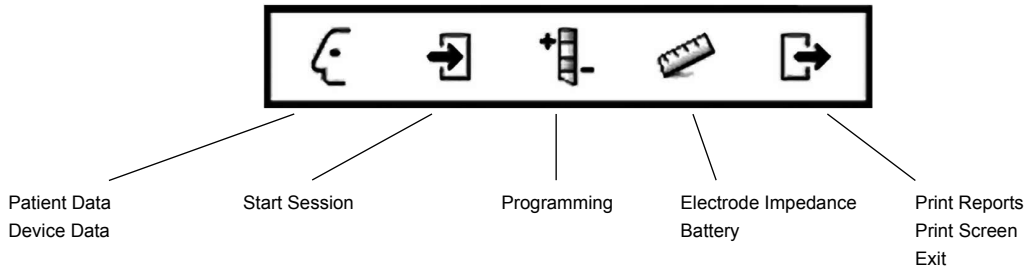







Figure 6. Navigation bar with available menu items.

Note: The **Profile** menu, the **Measurement** menu, and the **End Session** menu are drop-down lists. After selecting the **Profile** icon, the **Measurement** icon, or the **End Session** icon, select a destination from the drop-down list that appears directly below the icon.

Table 3. Menu descriptions

Menu	Function descriptions	
 Profile		<ul style="list-style-type: none"> • Enter patient and physician information • Enter neurostimulator implant information • Set neurostimulator date and time • View neurostimulator system information
 Start session		<ul style="list-style-type: none"> • Display name and date of patient session • Display initial therapy settings • Display initial patient use information • Display initial neurostimulator battery level status or service life • Display initial system status messages
 Programming		<ul style="list-style-type: none"> • Display therapy settings and details • Perform therapy measurements • Program amplitude, pulse width, rate, and cycling • Program electrode polarity • Return all settings to nominal values
 Measurement		<ul style="list-style-type: none"> • Perform electrode impedance measurements • Check battery service life
 End session		<ul style="list-style-type: none"> • Print a variety of session reports • Print screen • Exit application

Data entry

Enter data into the programmer through the touchscreen display. Most data are accepted through the following:

- **Drop-down list**—Select the arrow on the right side of a drop-down list. Select a value or entry.



- **Setting input box**—A selection of values appears when the stylus contacts a setting input box. Select a value.



- **Keyboard**—The keyboard appears when the stylus contacts an input box that requires alphanumeric input. To enter data, select each character. Four keyboards are available (Figure 7):

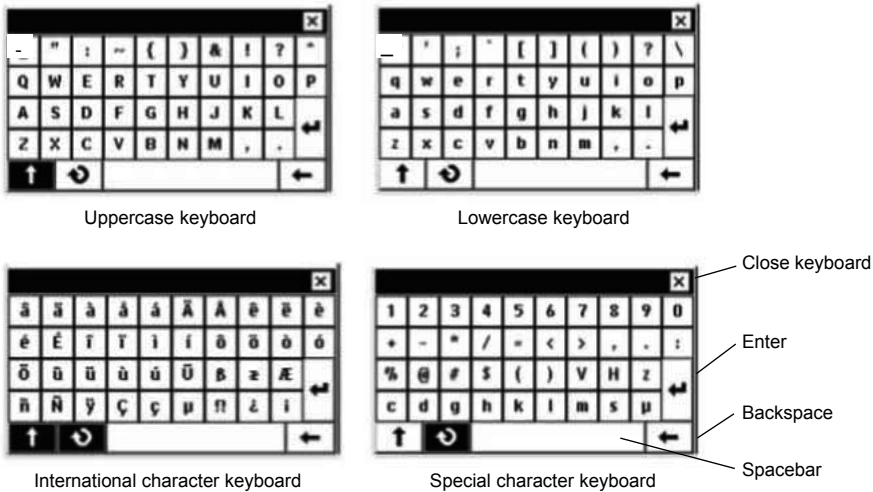




Figure 7. Programmer keyboards.

Alternate keyboards are available by selecting the following buttons:

- Straight arrow  —Uppercase alpha and international characters
- Circular arrow  —International and special characters

Using the programming head

After entering data into the clinician programmer, use the programming head to send the data to the device via telemetry.

Disconnecting the magnet

The magnet must be removed from the programming head before using it with any device except SynchroMed and SynchroMed EL pumps.

△ **Caution:** The Model 8529 Magnet is for use with Medtronic SynchroMed and SynchroMed EL Pumps only. Remove the magnet from the Model 8840 Clinician Programmer before approaching a patient with a different pump, a neurostimulator or another active implanted medical device (eg, pacemaker, defibrillator). If the magnet is too close to another active device, the therapy of the other device may change.

◆ **To disconnect the magnet from the programming head**

1. Unlock the magnet from the programming head by turning the magnet (Figure 8).
2. Store the magnet in the programmer carrying case.

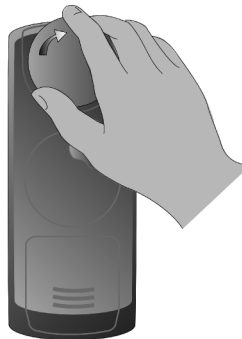


Figure 8. Unlocking the magnet from the programming head.

△ **Caution:** Do not place the magnet on or near computer monitors, magnetic storage disks or tapes, televisions, credit cards, or other items affected by strong magnetic fields. If the magnet is too close to these items, they may be damaged.

Extending and retracting the programming head

The programming head can be used while it is docked on the programmer or extended from the programmer.

△ **Caution:** To prevent the cable or electrical contact from being damaged, which could prevent further programming and cause unsaved data to be lost:

- do not use excessive force when extending the programming head.
- do not tangle the cable during extension or retraction.

- do not turn the cable reel counterclockwise.

◆ **To extend the programming head**

1. Press down and forward on the programming head until it snaps out of the docked position (Figure 9).



Figure 9. Extending programming head.

2. Extend the programming head to the desired position.

◆ **To retract and dock the programming head**

1. Turn the cable reel in the direction of the arrow until the programming head rests against the programmer (Figure 10).

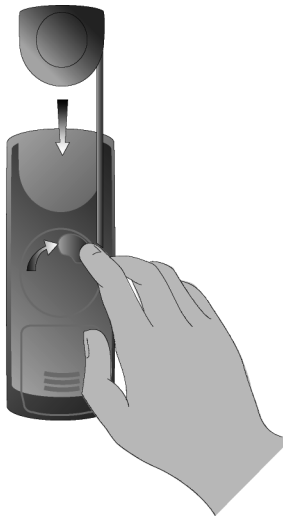


Figure 10. Retracting the programming head.

2. Gently push the programming head into place until it snaps into the docked position.

Preparing for a programming session

Before beginning a programming session, insert the appropriate application card, turn the programmer on, check the programmer battery status, and navigate to the **Neurostimulation Desktop** screen (Figure 11). The following tasks can be initiated from the **Neurostimulation Desktop** screen:

- Transfer patient information by selecting the **Utilities** tab.
- Work in demo mode by selecting the **To work in demo mode** button.
- Interrogate the neurostimulator and begin a programming session by pressing the **Programming (P)** key.

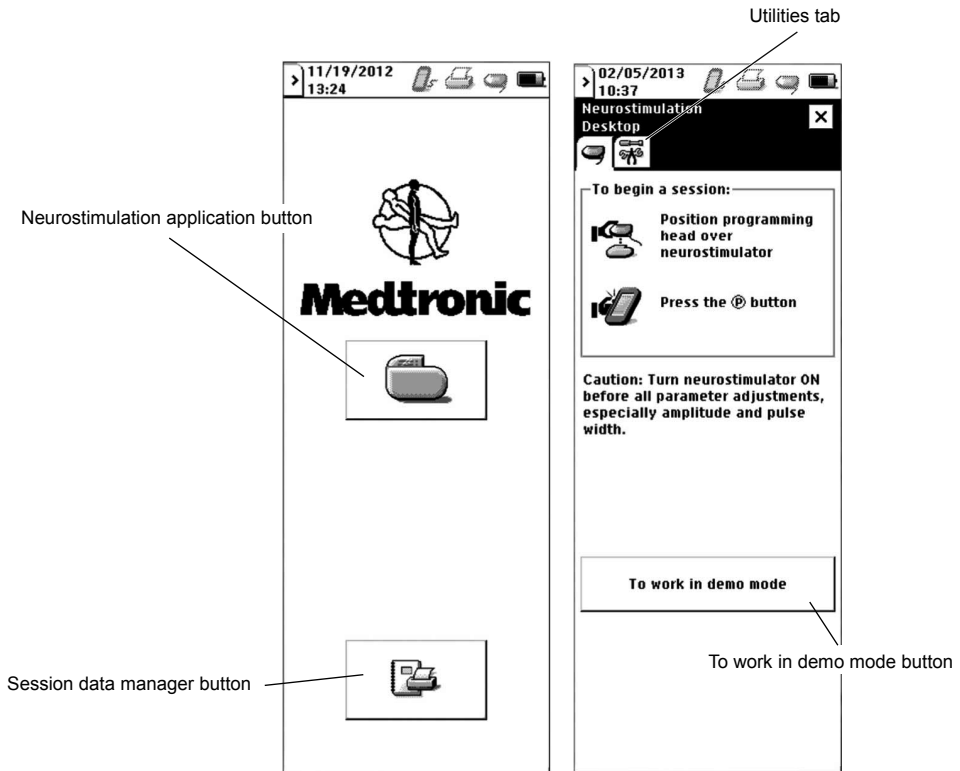


Figure 11. Application selection and Neurostimulation Desktop screens.

Navigating to the Neurostimulation Desktop

◆ To insert and eject the application card

1. Insert the application card (arrow and bar code side facing up and in the direction of the arrow) into the card slot until it is seated (Figure 12).

△ **Caution:** To avoid damaging the components, do not force the application card into the clinician programmer and do not insert non-Medtronic application cards.

2. To lock the application card in place, pull out the **Application card ejection key**, then flip it down and to the side so that it is flush with the opening.

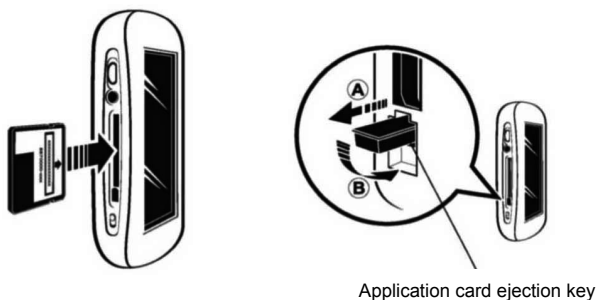


Figure 12. Inserting the application card.

3. To eject the application card, reverse the instructions in step 2, then push in the **Application card ejection key**.

Note: Do not remove the application card while the programmer is on. If the application card must be ejected, turn the programmer off, reinsert the card, then turn the programmer on.

△ **Caution:** Do not remove the application card while the application is active. If the application card is removed while the application is active, the session will automatically end and unsaved data will be lost.

◆ **To turn the programmer on or off**


- Slide and momentarily hold the **Power key** () (Figure 1 on page 10).

◆ **To check programmer battery status**

- View the **Battery status** icon on the status bar.

Note: For information on battery status and changing the programmer batteries, see "Changing the programmer batteries" on page 55.

◆ **To navigate to the Neurostimulation Desktop screen**

1. Turn the programmer on. The **Application selection** screen appears (Figure 11 on page 19).
2. Select the **Neurostimulation application** button (). The **Neurostimulation Desktop** screen appears (Figure 11 on page 19).

Transferring patient information

Patient data and session data are copied from one application card to another with the Copy Patient Data feature on the **Utilities** tab. Depending on the neurostimulator implanted, the data copied include:

- patient ID and lead configuration data.
- session reports.

◆ **To transfer patient information**

1. Ensure the **destination** card (Application Card 1) is inserted in the programmer.
2. From the **Neurostimulation Desktop** screen (Figure 11 on page 19), select the **Utilities** tab.
3. Select the **Copy patient data** button (Figure 13).

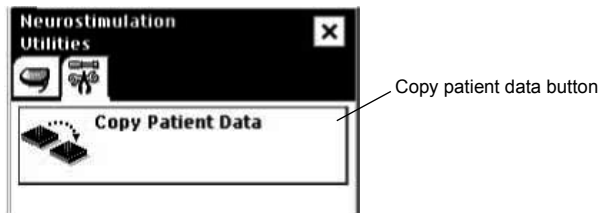


Figure 13. Utilities tab.

4. Select the checkbox for the type of data to be copied (Figure 14).

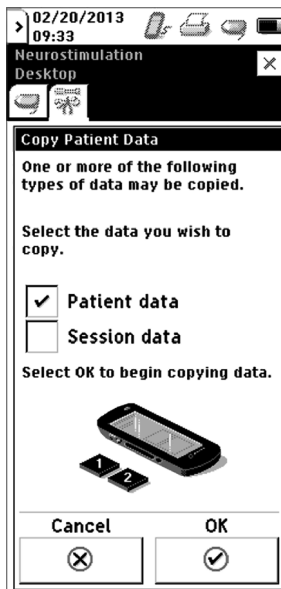


Figure 14. Copy patient data screen.


- a. Select the **Patient data** checkbox to add patient ID and lead configuration information from the source card to the destination card.

- b. Select the **Session data** checkbox to add patient reports stored on the source card to the destination card.
5. Select the **OK** button to begin copying data.
6. When prompted, remove Application Card 1 and insert the **source** application card (Application Card 2).
7. When prompted, remove Application Card 2 and reinsert Application Card 1.
8. Repeat steps 6 and 7 when prompted.
9. The card copy will notify you when the copy is complete. The files that were copied onto the destination card can now be used in a stim session.

Using the programmer in Demo mode

Note: Demo mode can be used to work with the programmer for training and demonstration purposes and to familiarize yourself with the programmer interface before a programming session. If Demo mode is selected, the programmer remains in Demo mode until the application is exited. Demo mode cannot be used to actually interrogate or program a device.

◆ **To access Demo mode**

1. From the **Neurostimulation Desktop** screen (Figure 11 on page 19), select the **To work in demo mode** button. The **Demo mode** screen appears.
2. Select a therapy.
3. Select a neurostimulator.
4. Select the **OK** button (.

Note: The neurostimulator icon on the programmer status bar and the Demo mode designation on the title bar show that Demo mode is active.

Interrogating the neurostimulator

Interrogating the neurostimulator begins a programming session. When the neurostimulator is interrogated, the programmer identifies the neurostimulator model and reads the current neurostimulator parameters.

△ **Cautions:**

- 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.
- To ensure successful telemetry, hold the programming head steady over the neurostimulator until telemetry is complete. If telemetry is interrupted before programming is complete and telemetry cannot be reestablished, the session will end and any unsaved data will be lost.
- Do not attempt telemetry near equipment that may generate electromagnetic interference (EMI). If EMI disrupts programming, move the programmer away from the likely source of EMI. Examples of

sources of EMI are magnetic resonance imaging (MRI), lithotripsy, computer monitors, cellular telephones, x-ray equipment, and other monitoring equipment.

◆ ***To interrogate the neurostimulator***

1. From the **Neurostimulation Desktop** screen (Figure 11 on page 19), position the programming head over the neurostimulator.

Note: If the programming head is docked on the programmer, position the programmer so that the programming head is closest to the neurostimulator.

2. Hold the programming head steady over the neurostimulator, then press the **Programming (P)** key or use the stylus to select anywhere in the To Begin a Session box.
3. If the programming head is extended, a status light is visible on the back of the programming head:
 - **Green light flashing**—Telemetry is successful.
 - **Amber light flashing**—Telemetry is unsuccessful. An error message appears on the screen (see the appropriate “Telemetry Failure” message in Table 8 on page 47 for more information).


Programming the neurostimulator

Programming the neurostimulator involves reviewing and modifying the information, settings, and optional features that are programmed in the neurostimulator. Information and settings may have been programmed in an earlier session or may be the default parameters.

During a programming session, telemetry transfers and retrieves data to and from the neurostimulator. The data transferred and retrieved include the following:

- **Stimulation parameters**
 - **Amplitude**—Strength of pulse in volts (V) or milliamps (mA).
 - **Pulse width**—Duration of each pulse in microseconds (μ s).
 - **Rate**—Frequency of pulses in Hertz (Hz).
 - **Cycling**—Cycles the neurostimulator on and off at programmed intervals.
 - **Electrode polarities**—Programmed positive (+), negative (-), or off.

Programming warnings and cautions

 When a patient's medical condition requires both a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator), physicians involved with both devices (eg, gastroenterologist, surgeon, neurologist, neurosurgeon, cardiologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery.

Possible effects of implanted device interaction include the following:

- Defibrillation therapy from an implanted defibrillator may damage the neurostimulator.
- The electrical pulses from the neurostimulation system may interact with the sensing operation from a cardiac device and could result in an inappropriate response of the cardiac device. To minimize or prevent the cardiac device from sensing the neurostimulator output, program the neurostimulator to a bipolar configuration and to a minimum rate of 60 Hertz. Program the cardiac device to bipolar sensing.

To minimize possible interactions, implant the devices on opposite sides of the body and follow any additional instructions.

Cautions:


- When the patient has a cochlear implant, minimize or eliminate the potential for unintended audible clicks during telemetry by keeping the external portion of the cochlear system as far from the programming head as possible or by turning off the cochlear implant during programming.
- The N'Vision Programmer is not certified for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the N'Vision Programmer near flammable atmospheres are unknown.
- When a patient has a neurostimulator and another active implanted device (eg, pacemaker, defibrillator, neurostimulator):

- To verify that inadvertent programming did not occur, clinicians familiar with each device should check the programmed parameters of each device before the patient is discharged from the hospital and after each programming session of either device (or as soon as possible after these times).
- Also, inform patients to contact their physician immediately if they experience symptoms that could be related to either device or to the medical condition treated by either device.
- End each programming session using the **End session** menu. If a session is not completed using the **End session** menu, important programming information could be lost or missed, possibly resulting in suboptimal therapy.


Stand-by mode

If the programmer receives no input for 6 minutes, the current session data is saved and Stand-by mode is activated. In Stand-by mode, the programmer screen is blank. If the programmer is in Stand-by mode for more than 1 hour, the programmer turns off.

◆ *To return to programming from Stand-by mode*


- Slide and momentarily hold the **Power** key (). The programmer returns to the screen that was displayed at the time Stand-by mode was activated.

Therapy stop

Pressing the **Therapy-stop** key () on the programmer turns the neurostimulator off. The **Therapy-stop** key is available immediately after the **Neurostimulation Desktop** screen appears (Figure 11 on page 19) and throughout a patient session. The **Therapy-stop** key is not available while the Model 8870 application is loading or when files are being copied to the application card.

During a patient session, if the **Therapy-stop** key is depressed during the electrode impedance test, the programmer turns the neurostimulator off and returns the neurostimulator parameters to the pretest settings.


◆ *To stop therapy*

- Hold the programming head steady over the neurostimulator, then depress the **Therapy-Stop** key ().

Resolving pending values

During a programming session, changes to parameters that have not yet been programmed to the neurostimulator are considered pending. While you have pending values on the screen, you cannot navigate (via the navigation bar) to any other screens unless you cancel or program the pending values.



Pending values are presented in two ways:

- A pending flag () appears next to the changed parameter or checkbox.

- The target (pending) value appears next to the current value, and an arrow appears between the values.

Programming pending values – Refer to the programming procedures in this manual for information on how to program pending values. When pending values are programmed, the following occurs:

- The pending flag disappears from the screen.
- The target (pending) value becomes the current value.

Cancelling pending values – When pending values are cancelled, the currently programmed values are again displayed on the screen. Cancel pending values by selecting the **Cancel** button () or the **Clear pending** button ().

Basic programming steps for initial implant

Table 4 presents an overview of the basic steps for a typical post-operative programming session.

Note: The clinician programmer and the installed application card do not program any devices other than associated Medtronic neurostimulators. If an attempt is made to program an incompatible device, an error message appears on the programmer.

Table 4. Programming process for initial implant

Procedure:	Do this:	Go to page:
Prepare for the programming session:		
1. Start programming session.	<ul style="list-style-type: none"> • Turn on the programmer. The Application selection screen appears. • Select the Neurostimulation application button. • The Neurostimulation Desktop screen appears. 	page 20 page 19
Set stimulation parameters:		
1. Interrogate the neurostimulator.	<ul style="list-style-type: none"> • Hold the programming head steady over the neurostimulator. • Press the Programming key. The light on the back of the programming head will flash green while telemetry is ongoing and will stop flashing when telemetry is finished. • Follow on-screen instructions until the Programming screen appears. 	page 22 page 45
2. Press the Nominal button to set stimulation parameters to their nominal settings. Note: A therapy measurement will be taken automatically.	<ul style="list-style-type: none"> • Access the Programming menu. • While holding the programming head steady over the neurostimulator, select the Nominal button. • Review impedance and stimulation current data. 	page 33
<ul style="list-style-type: none"> – 5.0 mA – 330 µs – 14 Hz – Cycling on 0.1 s – Cycling off 5 s 		

Table 4. Programming process for initial implant (continued)

Procedure:	Do this:	Go to page:
3. Adjust stimulation parameters as necessary.	<ul style="list-style-type: none"> • Set amplitude resolution and amplitude. • Set rate and pulse width. • Set cycling. • Set electrode polarities. 	page 37 page 39 page 40 page 36
4. Enter patient data.	<ul style="list-style-type: none"> • Access the Profile menu and select Patient Data. • Enter patient data using the onscreen keyboard. • Press the Program (P) button to save patient data to the neurostimulator. 	page 29
Complete the programming session:		
1. Print report.	<ul style="list-style-type: none"> • Ensure that the printer is on. • Access the End session menu and select Print Reports. • Select the desired reports. • Select the Print button. 	page 41
2. Exit application.	<ul style="list-style-type: none"> • Access the End session menu and select Exit. • Select the OK button. 	page 44

Basic programming steps for follow-up

Table 5 presents an overview of the basic steps for a typical follow-up programming session.

Note: The clinician programmer and the installed application card do not program any devices other than associated Medtronic neurostimulators. If an attempt is made to program an incompatible device, an error message appears on the programmer.

Table 5. Programming process for follow-up

Procedure:	Do this:	Go to page:
Prepare for the programming session:		
1. Check the programmer.	<ul style="list-style-type: none"> • Check/replace programmer batteries. • Ensure that the application card is properly installed. 	page 55 page 19
2. Turn the programmer on.	<ul style="list-style-type: none"> • Turn on the programmer. The Application selection screen appears. 	page 20
3. Select the Neurostimulation application button.	<ul style="list-style-type: none"> • The Neurostimulation Desktop screen appears. 	page 20
Review initial programming:		
1. Interrogate the neurostimulator.	<ul style="list-style-type: none"> • Hold the programming head steady over the neurostimulator. • Press the Programming key. The light on the back of the programming head will flash green while telemetry is ongoing and will stop flashing when telemetry is finished. • If no error messages appear, continue. (If an error message appears, see the troubleshooting section.) 	page 22 page 45
2. Review patient use data and neurostimulation system information.	<ul style="list-style-type: none"> • Review patient use information and programmed settings. • Review the neurostimulator service life displayed as OK, LOW, or EOS. • Check the Observations box for significant system events that have occurred. 	page 31


Table 5. Programming process for follow-up (continued)

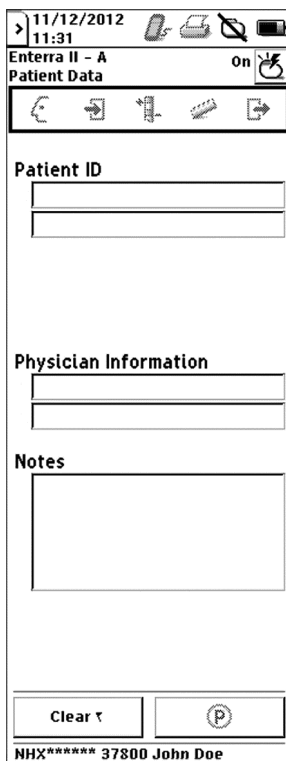
Procedure:	Do this:	Go to page:
3. Ensure that the neurostimulator is on.	<ul style="list-style-type: none"> • If the neurostimulator is off, hold the programming head steady over the neurostimulator, then select the Neurostimulation On/Off button. 	page 32
Check system performance:		
1. Check therapy measurements. Note: Perform this procedure at the beginning of the session. These measurements provide documentation that active pathways are intact.	<ul style="list-style-type: none"> • Access the Programming menu. • While holding the programming head steady over the neurostimulator, select the Measurement button. • Review impedance and stimulation current data. 	page 33
2. Check electrode impedance, if desired. Note: Perform this procedure at the end of the session or if the therapy measurement is out of range. These measurements verify the integrity of all lead/connector pathways.	<ul style="list-style-type: none"> • Access the Measurement menu and select Electrode Impedance. • While holding the programming head steady over the neurostimulator, select the Measurement button. • Select the OK button to perform the test. • Review electrode impedance measurement results. Note: This procedure takes approximately 10 seconds. In order to perform measurements, this procedure temporarily reprograms the stimulation settings. 	page 34
Review/modify stimulation parameters:		
1. Review/modify amplitude.	<ul style="list-style-type: none"> • Select the Amplitude input box and select an amplitude. • Select the OK button. • Hold the programming head steady over the neurostimulator, then press the Programming (P) key or select the Program (P) button on the programmer screen. 	page 37
2. Review/modify Cycling.	<ul style="list-style-type: none"> • Select the Cycling On or Cycling Off input box. • Select the Cycling On Time and the Cycling Off Time values. • Select the OK button. • Hold the programming head steady over the neurostimulator, then press the Programming (P) key or select the Program (P) button on the programmer screen. 	page 40
3. Review/modify pulse width and rate.	<ul style="list-style-type: none"> • Select the Pulse width input box, then select a pulse width. • Select the Rate input box, then select a rate. • Hold the programming head steady over the neurostimulator, then press the Programming (P) key or select the Program (P) button on the programmer screen. 	page 39
Complete the programming session:		
1. Print report.	<ul style="list-style-type: none"> • Ensure that the printer is on. • Access the End session menu and select Print Reports. • Select the desired reports. • Select the Print button. • Review the report to ensure that all settings are correct. 	page 41
2. Exit application.	<ul style="list-style-type: none"> • Access the End session menu and select Exit. • Select the OK button. 	page 44

Entering patient and physician information

The programmer provides two fields for patient information, two fields for physician information, and a field for physician notes. The patient and physician information is stored in the neurostimulator.

◆ **To enter patient information**

1. Access the **Profile** menu () and select Patient Data.



The screenshot shows a handheld device screen for entering patient data. At the top, the status bar displays the date 11/12/2012, time 11:31, and battery level. Below the status bar, the text 'Enterra II - A' and 'Patient Data' is visible, along with an 'On' indicator. A navigation bar contains several icons. The main area has three sections: 'Patient ID' with two input fields, 'Physician Information' with two input fields, and 'Notes' with a large text area. At the bottom, there are 'Clear' and 'Program (P)' buttons. The footer displays 'NHX***** 37800 John Doe'.

Figure 15. Patient data screen.


2. Enter patient name, ID number, or any other appropriate information in the patient ID fields (Figure 15).

Note: The patient session name includes the information from the first patient ID field. The patient session name will appear at the bottom of every screen and on session reports.

3. Enter physician name and phone number or any other appropriate information in the physician information fields and notes field (Figure 15).
4. Hold the programming head steady over the neurostimulator, then press the **Programming (P)** key or select the **Program (P)** button on the programmer screen.

Entering device information

◆ To enter neurostimulator information

1. Access the **Profile** menu () and select Device Data.

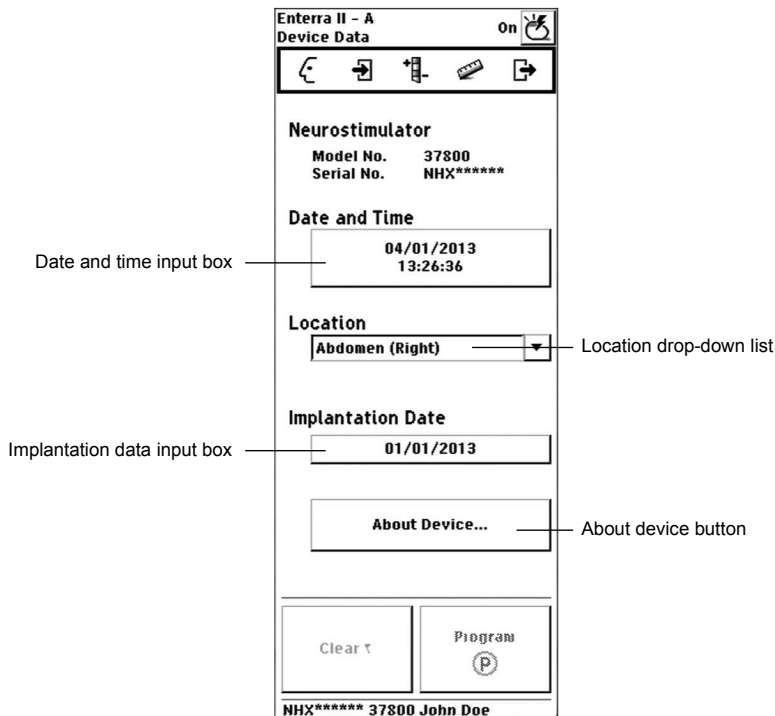


Figure 16. Device data screen.

2. Select the date and time input field to view the current date and time stored in the neurostimulator (Figure 16). To reset the date and time use the **Increase** and **Decrease** buttons or use the **Match N'Vision** button.
Note: The date and time stored in the neurostimulator are used when collecting patient use data.
3. Select the neurostimulator implant location from the location drop-down list or enter another location (Figure 16).
4. Enter the date the neurostimulator was implanted in the implantation date input box (Figure 16).
5. Hold the programming head steady over the neurostimulator, then press the **Programming (P)** key or select the **Program (P)** button on the programmer screen.

Reviewing patient use information

Review patient use information and neurostimulation system information on the **Start session** screen (Figure 17). The neurostimulator collects patient use data between sessions.

The neurostimulator collects the data based on the date and time entered on the **Device Data** screen (see "To enter neurostimulator information" on page 30).

Note: Patient use information can be viewed throughout the programming session by accessing the **Start Session** screen. Programming changes made during the session are not updated on this screen.

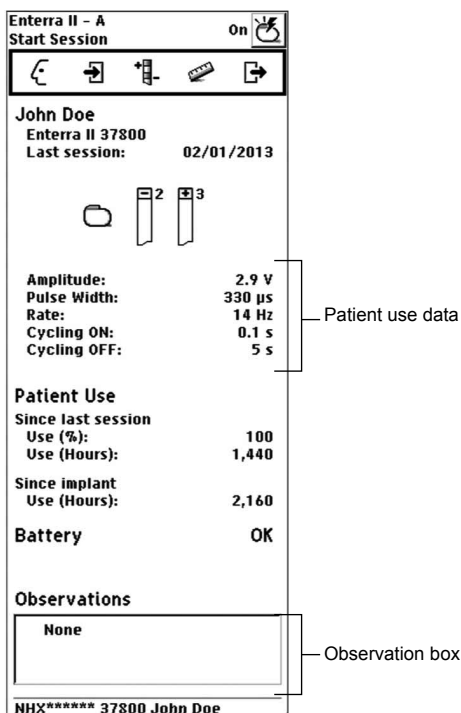



Figure 17. Start Session screen.


◆ To review patient use data

Patient use data are information about how the patient is using the neurostimulator.

1. Access the **Start Session** menu ().
2. View the following patient use data (Figure 17):
 - **Since last session - Use (%)**—Percentage of time that the neurostimulator was on since the last follow-up session
 - **Since last session - Use (Hours)**—Number of hours that the neurostimulator was on since the last follow-up session.

- **Since implant - Use (Hours)**—Number of hours that the neurostimulator was on since implant.



◆ **To review neurostimulation system information**

1. Access the **Start Session** menu ().
2. Review the Observations box for significant system events that have occurred (Figure 17). The observations are brief notifications (eg, Check INS clock, Stimulation off) that need to be investigated (see Table 10 on page 50).
3. Review the implanted neurostimulator battery service life displayed as:
 - OK
 - LOW
 - EOS (End of Service indicator)

Turning the neurostimulator on or off

Turning the neurostimulator on allows the neurostimulator to deliver stimulation to the patient.

◆ **To turn the neurostimulator on or off**

- Select the **Neurostimulator On/Off** button to turn the neurostimulator on () or off ().

Checking system performance

Recommendations when using measurement functions

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

Measurements and diagnostic data obtained from the clinician programmer 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. Typical impedance measurements may differ in other device types.


Before using any measurement functions, please note the following:

- **Check therapy measurements at the beginning of each programming session.** These measurements provide documentation that the pathways are intact and that the current provided is sufficient for the selected therapy.
- **Measure electrode impedance at the end of each programming session.** These measurements verify the integrity of lead/extension/connector pathways. They may provide information about lead problems (eg, lead breakage, short circuit, open circuit). For example, measurements that show a significant increase in impedance can indicate a fractured lead conductor, a loose setscrew, etc. Conversely, a significant decrease in impedance can indicate shorted conductors, a break in lead

insulation, etc. Measurements taken at the beginning of the session may be useful in interpreting diagnostic data collected since the previous session.

◆ **To check therapy measurements**

Therapy measurements are measurements of impedance and stimulation in the active stimulation pathways.

1. Access the **Programming** menu ().
2. Position the programming head over the neurostimulator.
3. Select the **Therapy Measurement** button (Figure 18).

Note: To stop the Therapy measurements test, do one of the following:

- Select the **Cancel** button ().
- Push the red **Therapy-Stop** key () to turn the neurostimulator off.

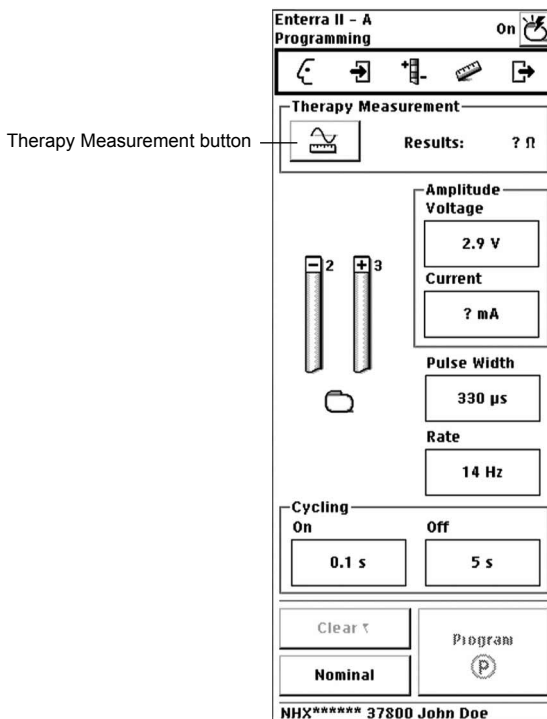


Figure 18. Therapy Measurements screen.

4. Review the therapy measurements test results.

Note: Unless the electrode configuration is changed, test results can be viewed at any time during the programming session by returning to the **Programming** screen.

◆ To check electrode impedance

During the electrode impedance test, preset rate and pulse width values are used. The preset values are displayed on the screen. The amplitude value can be modified for the electrode impedance test by choosing an amplitude value from the drop-down list on the screen. These settings are used only for the electrode impedance test, and at the end of the test, the most recently programmed settings are restored.

This procedure tests all unique bipolar and unipolar combinations. The procedure takes approximately 10 seconds.

1. Access the **Measurement** menu (📏) and select Electrode Impedance.

Note: Perform the lead impedance test at the 2.0 V (default) setting.

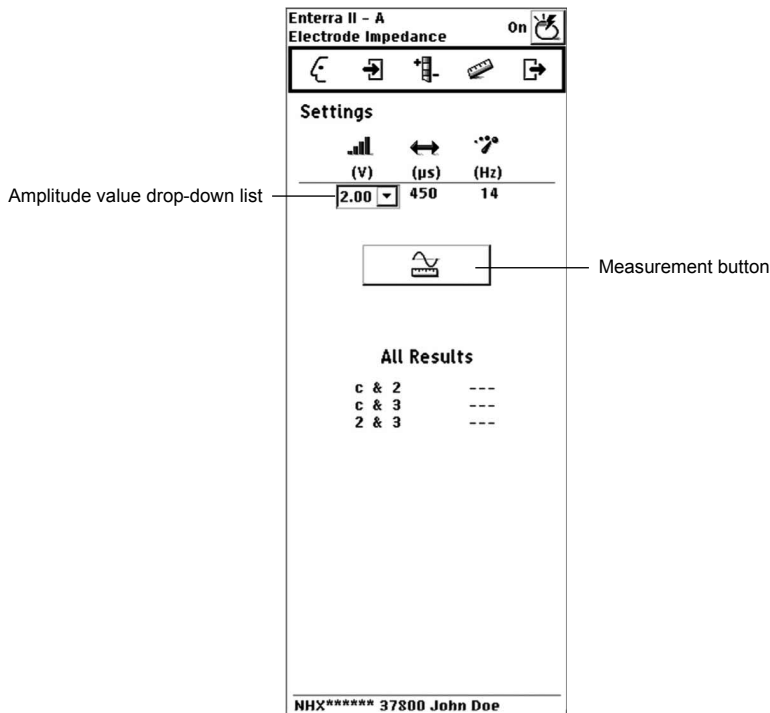


Figure 19. Electrode Impedance screen.

2. Position the programming head over the neurostimulator.
3. Select the **Measurement** button (Figure 19).
4. Select the **OK** button (☑) and maintain the position of the programming head over the neurostimulator for the duration of the test.

Note: To stop the electrode impedance test, do one of the following:

- Select the **Cancel** button (⊗).

— Push the red **Therapy-Stop** key (⏏) to turn the neurostimulator off.

5. Review the electrode impedance test results.

Note: Test results can be viewed any time during the programming session by returning to the **Electrode Impedance** screen.

◆ **To check neurostimulator battery information**

At initial interrogation, the neurostimulator battery service life displayed on the **Battery** screen is updated with the latest test results.

Note: Battery information is also available on the **Start Session** screen.

1. Access the **Measurement** menu (📏) and select Battery.



Figure 20. Battery screen.

2. Review the implanted neurostimulator battery service life (Figure 20) displayed as:


- OK
- LOW
- EOS (End of Service indicator)

Returning to nominal settings during programming

During a programming session, you can reset all parameters to nominal values:

- Electrode 2 as cathode (-), electrode 3 as anode (+)
- 5.0 mA
- 330 μ s
- 14 Hz
- Cycling On: 0.1 s, Cycling Off: 5 s

◆ *To return to nominal settings*

1. Access the **Programming** () menu.
2. Select **Programming**.
3. Select the **Nominal** button.
4. Select the **Program (P)** button.

Reviewing/modifying stimulation parameters

△ **Caution:** Due to the potential for uncomfortable stimulation (which some patients have described as a jolting, shocking or burning sensation), do the following:

- Take care when increasing the stimulation parameters to optimize or improve the therapeutic effect due to the potential for uncomfortable stimulation effects. Uncomfortable stimulation has been reported in neurostimulator settings at or above the typical or nominal settings.
- Following changes to stimulation parameters, direct patients to test various postural changes and movements that mimic daily activities to assess the potential for uncomfortable stimulation.
- If uncomfortable stimulation occurs, reduce the stimulation output to previously acceptable levels and adjust stimulation in smaller increments.
- Adverse effects related to stimulation parameter changes may not manifest immediately following parameter changes; direct patients to contact their clinician if they feel discomfort related to their stimulation.

Reviewing and modifying the stimulation parameters includes programming the electrode polarities, pulse width, amplitude, and rate.

◆ *To review/modify electrode polarities*

When programming electrode polarity, electrodes may be programmed +, -, or off. The electrode configuration must include at least one positive (+) and one negative (-) electrode.

The neurostimulator can be programmed to deliver unipolar stimulation (using the neurostimulator case as a positive electrode). When using the unipolar stimulation, only the neurostimulator case can be positive (+).

Note: Pending amplitude changes and therapy measurement results will be canceled when polarities are changed.

1. Access the **Programming** menu ().

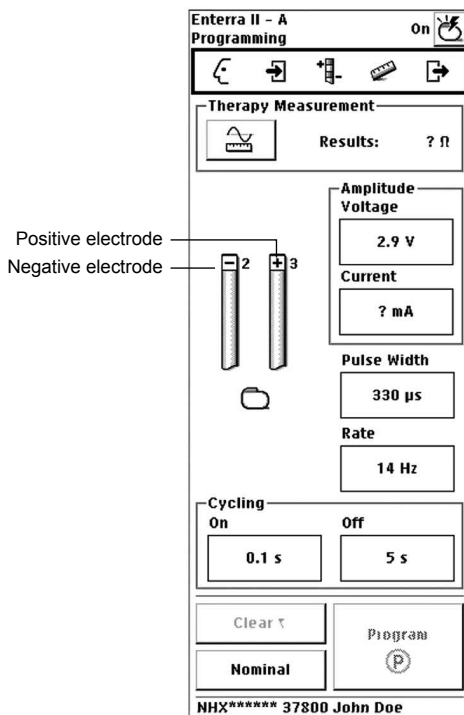


Figure 21. Programming electrode polarities.

2. Select each electrode to toggle between -, +, or blank (off) options (Figure 21).
3. If desired, set amplitude on this screen (refer to "To review/modify amplitude" on page 37).
4. If desired, set pulse width and rate on this screen (refer to "To review/modify the pulse width or rate" on page 39).
5. If desired, set cycling on this screen (refer to "To review/modify Cycling" on page 40).
6. Hold the programming head steady over the neurostimulator, then press the **Programming (P)** key or select the **Program (P)** button on the programmer screen.

◆ **To review/modify amplitude**

Amplitude is the strength of the pulse in units of either volts or milliamps.



 **Warning:** Tissue damage may occur for certain combinations of exposed electrode length, impedance, and programmed amplitude. See Table 6 for the maximum voltage to be applied to the electrode without inducing any tissue damage. At an electrode length of 10 mm, the neurostimulator may be programmed up to its maximum voltage of 10.5 volts if the measured impedance is 250 ohms or greater.

Table 6. Maximum programmable voltage to remain within 0.4 $\mu\text{C} / \text{mm}^2$ charge density

Impedance (in Ω)	Maximum voltage (in V)		
	Pulse width 210 μs	Pulse width 330 μs	Pulse width 450 μs
150	7.7	4.9	3.6
200	10.2	6.5	4.8
250	>10.5	8.1	6.0
300	>10.5	9.7	7.1
350	>10.5	>10.5	8.3
400	>10.5	>10.5	9.5
450	>10.5	>10.5	>10.5
≥ 500	>10.5	>10.5	>10.5

1. Access the **Programming** menu ().
2. Select the **Amplitude Voltage** input box or the **Amplitude Current** input box (Figure 22).

Note: To view or change the Current (mA) value, you must first take a therapy measurement by pressing the **Therapy Measurement** button.

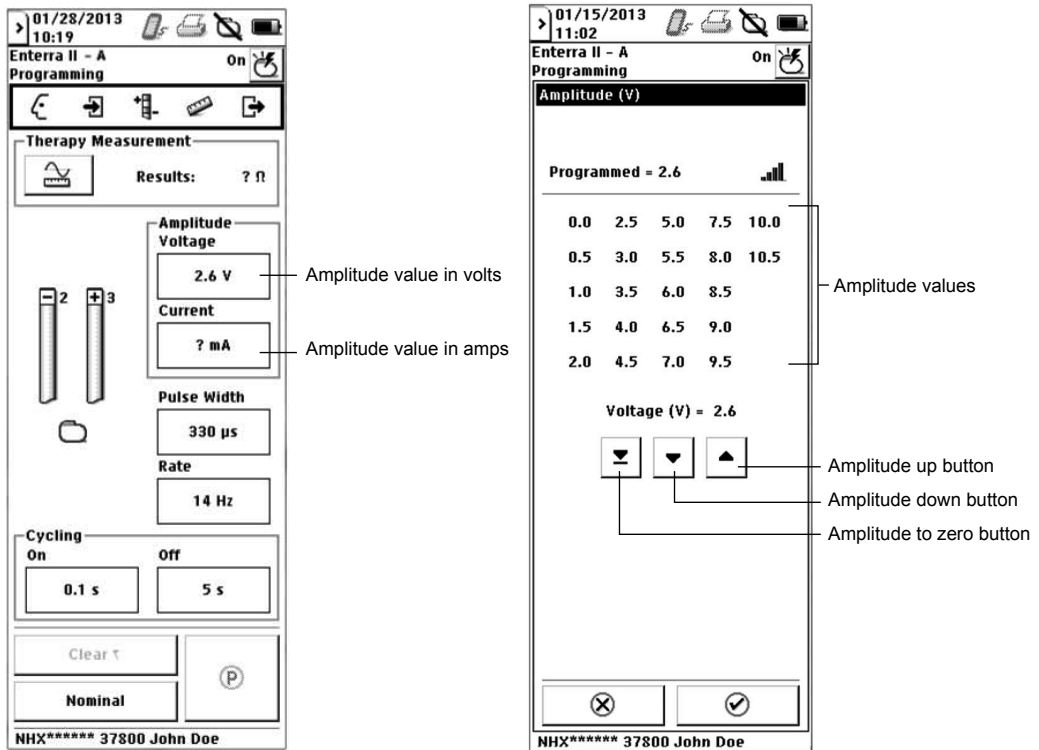


Figure 22. Programming amplitude and amplitude resolution.


3. To set the amplitude, select a target value from the amplitude values displayed.

4. If desired, fine tune the target value by using the arrow buttons to increase or decrease the target value.
5. Press the **OK** button. The actual and target values appear in the input box with an arrow pointing from the actual value to the target value.
6. Hold the programming head steady over the neurostimulator, then press the **Programming (P)** key or select the **Program (P)** button on the programmer screen.

◆ **To review/modify the pulse width or rate**

Pulse width is the duration of the pulses.

Rate is the frequency of pulses in hertz.

1. Access the **Programming** menu ().
2. Select the **Pulse Width** input box or the **Rate** input box (Figure 23).

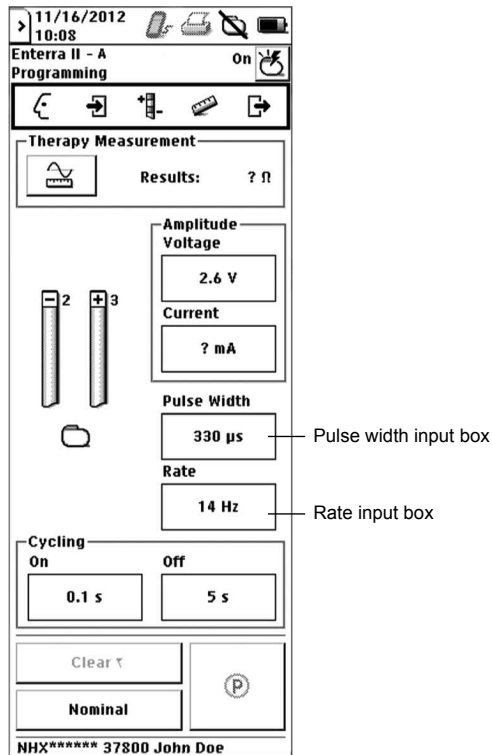


Figure 23. Programming pulse width or rate on a program tab.

3. Select a target value from the list of values that appears in the value window. The actual and target values appear in the input box with an arrow pointing from the actual value to the target value.
4. Hold the programming head steady over the neurostimulator, then press the **Programming (P)** key or select the **Program (P)** button on the programmer screen.

◆ To review/modify Cycling

Cycling turns the neurostimulator on and off at clinician-determined intervals (eg, 0.1 to 10 seconds). Due to a carryover effect, the patient may continue to experience symptom suppression during the Cycling off time.

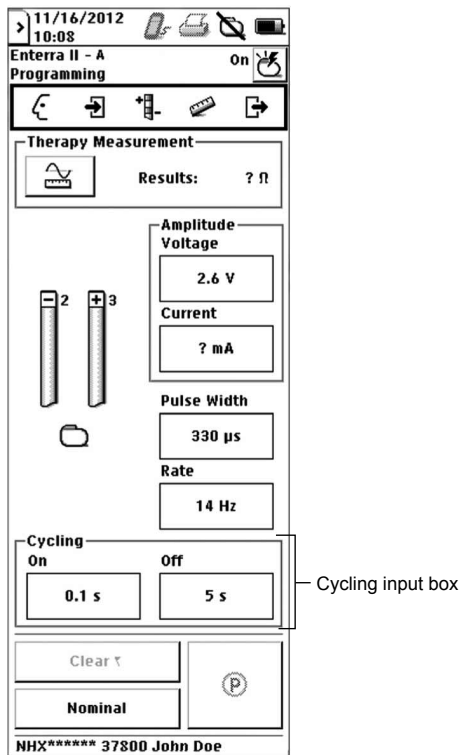



Figure 24. Programming Cycling.

1. Access the **Programming** menu ().
2. Select the **Cycling On** input box or the **Cycling Off** input box (Figure 24 on page 40).
3. Use the selection bar or arrow buttons to select the Cycling On Time and the Cycling Off Time.
4. Press the **OK** button. The actual and target values appear in the input box with an arrow pointing from the actual value to the target value.
5. Hold the programming head steady over the neurostimulator, then press the **Programming (P)** key or select the **Program (P)** button on the programmer screen.

Printing session reports



Session reports contain the settings and patient and system information from patient sessions. You can print reports during and after patient sessions. The following reports can be selected for printing:

- **Summary report**—neurostimulator data and history (this report is always available as indicated by the check mark by the title)
- **MDT Data report**—data that can be provided to Medtronic Technical Services (this report is a separate file in the Session Data Manager)



Reports selected to be printed after a patient session are saved in the Session Data Manager and named with the patient session name.

You can print saved session reports from the Session Data Manager or print current settings any time during the programming session. Session reports are saved to the application card, so the appropriate application card must be inserted into the programmer.

◆ *To print a report during the session*

1. Ensure the printer is on.
2. Access the **End session** menu () and select Print Reports.
3. Select the checkbox in the “Now” column next to the reports on the list.
4. Move the programmer to within 1 meter (3.3 ft) of the printer, with the printer and programmer IR ports directly facing each other.
5. Select the PRINT button ().

◆ *To print a report after the session*

1. Ensure that the printer is on.
2. Access the **End session** menu () and select Print Reports.
3. Select the checkbox in the “Later” column next to the reports on the list.
4. Exit the application.
5. Move the programmer to within 1 meter (3.3 ft) of the printer, with the printer and programmer IR ports directly facing each other.
6. Select the **Session data manager** button () from the slider bar. The **Session data manager** screen appears (Figure 25).

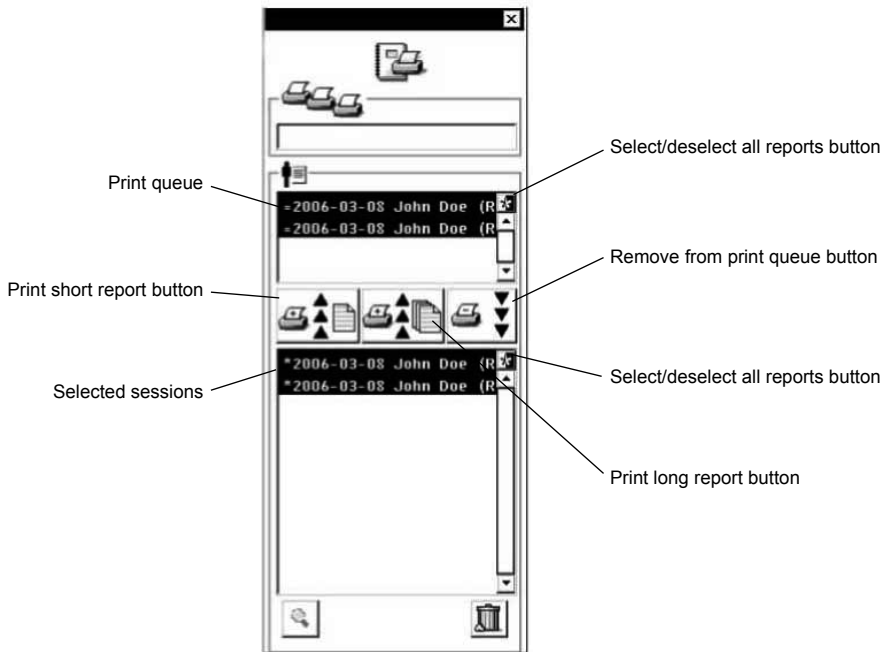








Figure 25. Session data manager screen.

7. Select an individual report to print by highlighting the report or print all reports by selecting the **Select/ Deselect all reports** button ().
8. Select a print report button to move sessions into and out of the print queue:
 - **Print short report** button ()
 - **Print long report** button ()
 - **Remove from print queue** button ()

Note: The MDT Data report and the Summary report can be printed with either the short report or long report option.

◆ **To view a report from the Session Data Manager**

1. Select the **Session data manager** button () from the slider bar.
2. Select an individual report.
3. Select the **View** button ().

Managing session data files

As long as there is space on the application card, a new session data file is generated at the end of each programming session. Session data files are stored in the Session Data Manager. Approximately 100 sessions can be stored on the programmer.

The **Application selection** screen displays the session data file status when the Model 8840 Clinician Programmer is turned on (Figure 26 on page 43):

- Number of sessions saved
- Percentage of memory used

If the percentage of memory used approaches 100% or a message that the Session Data Manager is full appears when the application is launched, delete unneeded files.

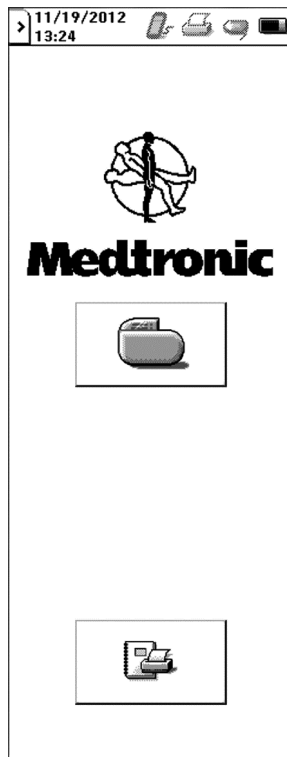


Figure 26. Application selection screen.

◆ **To delete patient session files**


1. Select the **Session data manager** button (Figure 26) from the **Application selection** screen or the slider bar (Figure 4 on page 13).
2. Select a patient session or sessions.
3. Select the **Delete** button (🗑️).

4. Select the **Delete** button () again.

Printing the screen

You can print the current screen displayed on the programmer and send the image to a printer.

◆ *To print the current screen*

1. Ensure the printer is on.
2. Access the **End session** menu () and select Print Screen.
3. Move the programmer to within 1 meter (3.3 ft) of the printer, with the printer and programmer IR ports directly facing each other.

Exiting the application



When you exit the application, the session settings are saved to a session data file. Session data files are saved in the Session Data Manager and named with the session name.

◆ *To exit the application*

Caution:

End each programming session using the **End session** menu. If a session is not completed using the **End session** menu, important programming information could be lost or missed, possibly resulting in suboptimal therapy.

Notes:

- Any pending parameters will be lost.
 - Additional informational messages could be missed.
1. Access the **Exit session** menu () and select Exit.
Note: Refer to "Printing session reports" for printing instructions.
 2. Select the **OK** button ()

Troubleshooting

This section covers noninvasive troubleshooting and error messages relating to the Model 8840 Clinician Programmer with the Model 8870 Application Card.

Approach troubleshooting conservatively. Prior to performing invasive procedures, ensure that all noninvasive causes have been considered, and contact the appropriate Medtronic representative listed on the inside back cover of this manual.

Troubleshooting reference guide

Table 7. Quick reference troubleshooting guide

Problem	Possible solution	In this manual, go to
<ul style="list-style-type: none"> • The power is on, but there is no display. • The programmer cannot be operated. 	<ul style="list-style-type: none"> • Turn the programmer off, then on again. • Install new AA batteries in the programmer. Ensure the batteries are properly installed. 	<ul style="list-style-type: none"> page 32 page 55
<ul style="list-style-type: none"> • Touchscreen does not respond. 	<ul style="list-style-type: none"> • Calibrate touchscreen. 	<ul style="list-style-type: none"> page 56
<ul style="list-style-type: none"> • Telemetry is interrupted or not initiated. 	<ul style="list-style-type: none"> • Ensure that the application card is correctly inserted. • Check the battery status. • See the telemetry failure checklist. 	<ul style="list-style-type: none"> page 19 page 20 page 45
<ul style="list-style-type: none"> • Power to the programmer is suddenly interrupted. 	<ul style="list-style-type: none"> • Install new AA batteries in the programmer. 	<ul style="list-style-type: none"> page 55
<ul style="list-style-type: none"> • The programmer is not communicating with the printer. 	<ul style="list-style-type: none"> • Clean the IR lens. • Ensure that the programmer and printer are directly facing and within 1 meter (3.3 ft) of each other. • Contact the printer manufacturer for printer-specific troubleshooting information. 	<ul style="list-style-type: none"> page 56 page 41
<ul style="list-style-type: none"> • Telemetry cannot be established. 	<ul style="list-style-type: none"> • See the telemetry failure checklist. 	<ul style="list-style-type: none"> page 45
<ul style="list-style-type: none"> • The programmer is operating erratically. 	<ul style="list-style-type: none"> • Move away from any equipment (eg, MRI, lithotripter, computer monitor) that may be generating EMI. EMI may cause a disruption in programmer function. 	<ul style="list-style-type: none"> page 22
<ul style="list-style-type: none"> • An error message or icon appears on the display. 	<ul style="list-style-type: none"> • See instructions in the error and informational messages section. 	<ul style="list-style-type: none"> page 47

For clinician programmer maintenance questions, repairs, and returns contact the appropriate Medtronic representative listed on the inside back cover of this manual.

Telemetry failure checklist

The most common corrections for telemetry failures are listed below. Refer to Table 8 on page 47 for explanations of specific error messages.

- Decrease the distance between the programming head and the neurostimulator, pressing the programming head firmly over the implanted neurostimulator.

- Hold the programming head steady over the neurostimulator, then press the **Programming (P)** key or select the **Program (P)** button.
- If telemetry fails while holding the programming head steady, move the programming head around slowly near the implanted neurostimulator. Press the **Programming (P)** key or select the **Program (P)** button.
- When holding the programming head over the implanted neurostimulator, do not drape your hand over the back of the programming head. Hold the programming head at the base.
- Ensure that the programmer batteries are not depleted.
- Move away from sources of possible EMI (eg, computer monitors).

Impedance and stimulation current measurements

Electrode impedance and stimulation current are electrical values that can be measured by the neurostimulator and interrogated with the programmer (see "Checking system performance" on page 32). The values listed below may help to further define the system problem.

Once the impedance test is performed, results can be viewed at any time during the programming session by returning to the **Electrode Impedance** screen. You can also print the Summary report or end the session to save the Summary report to the Session Data Manager to print the reports later.

- If a patient's symptoms return and a system problem (eg, a broken wire, a loose connection, or highly resistive tissue) is suspected, check for high impedance values such as:
 - At 0.25 V: >4000 ohms
 - At 0.70 V: >10000 ohms
 - At 2.00 V: >20000 ohms
 - At 3.00 V: >40000 ohms

Note: When electrode impedance measurements show abnormally high impedance values (eg, >10000 ohms) at the default amplitude setting, perform the test again at a higher amplitude (within the patient's comfort range) to gather data that may help determine the likely cause of the circuit problem.


- If a patient is experiencing symptoms or a system problem that suggest a short circuit (eg, abnormal or intermittent stimulation, an inappropriate stimulation location, a significant stimulation current, or rapid battery depletion), check for low impedance values such as:
 - At 0.25 V: <50 ohms
 - At 0.70 V: <50 ohms
 - At 2.00 V: <50 ohms
 - At 3.00 V: <150 ohms

Reading serial numbers

◆ *To read the neurostimulator serial number*

1. Interrogate the neurostimulator.
2. Read the neurostimulator serial number from the bottom of any of the programmer screens.

◆ *To read the clinician programmer serial number*

- Do one of the following:
 - Remove the battery compartment cover and batteries (see "Changing the programmer batteries" on page 55). The clinician programmer serial number is located inside the battery compartment.
 - Select the **Information** button  from the slider bar. The clinician programmer serial number is located next to the programmer icon.

Error and informational messages

The clinician programmer displays text (Table 8 below and Table 10 on page 50) and iconic (Table 9 on page 50) error and informational messages.

Note: Before referring to Table 8, ensure that you have gone through the "Telemetry failure checklist" on page 45.

Table 8. Error and informational messages

Message	Explanation
APPLICATION CARD MISSING The application card has been removed. Exit application.	When the application card is removed the current session will end and unsaved data will be lost. Reinserting the card will start a new session.
APPLICATION CARD FAILURE The application card has been corrupted. Turn the programmer OFF and contact Medtronic technical services.	There is a problem with the application card and it cannot be used. A new card must be obtained before a session can be started.
APPLICATION FAILURE The application has stopped because of an error. Contact Medtronic technical services with the following information:	There is a problem with the application. An unrecoverable software error has occurred. Contact Medtronic with the service code.
BATTERY STATUS Programmer batteries are low. Replace batteries soon.	The programmer batteries are low and may not last an entire programming session. Replace the batteries before starting a session.
BATTERY WARNING Neurostimulator battery is fully depleted. Exit application.	Therapy from the neurostimulator is no longer available.
CLEAR PENDING VALUES All pending parameters will be cleared prior to starting the therapy impedance measurement test.	A therapy measurement cannot be performed while there are parameters pending. Press Continue to clear pending parameters and continue with the measurement, or press Cancel to keep pending parameters and not perform the measurement.






Table 8. Error and informational messages (continued)

Message	Explanation
<p>CURRENT UNAVAILABLE The Current (mA) value cannot be calculated when the therapy measurement is less than 200 or greater than 1000 ohms. For further evaluation, take an electrode impedance measurement on the Electrode Impedance screen. Programming amplitude in voltage remains available.</p>	<p>The amplitude cannot be calculated in milliamperes when the impedance is less than 200 or greater than 1000 ohms. Programming amplitude in volts is still available.</p>
<p>DEVICE NOT SUPPORTED Detected device is not supported by this version of application card. Contact Medtronic technical services.</p>	<p>This device cannot be programmed by the clinician programmer using this version of the application card.</p>
<p>DEVICE NOT SUPPORTED This neurostimulator was last programmed with an incompatible version of the application card. Press Cancel to exit application and contact Medtronic technical services or press OK to clear all settings and start session.</p>	<p>The device was programmed by a clinician programmer using a different (newer) version of the application card. It can be programmed using this version of the application card, but the device settings will be cleared.</p>
<p>DEVICE NOT SUPPORTED Detected device is not supported by this version of application card. Refer to the technical manual for a listing of supported devices. Press OK to end this session.</p>	<p>The device cannot be programmed by this clinician programmer. A new application card must be obtained.</p>
<p>END OF SERVICE Neurostimulator has reached End of Service (EOS). Replace neurostimulator.</p>	<p>The device battery is depleted. Replace the device.</p>
<p>ENTERRA II If neurostimulator will be implanted, press OK to proceed. This will begin device service life. If neurostimulator will not be implanted at this time, press Cancel to end session.</p>	<p>Neurostimulator service life can be checked without beginning device life. Device life begins the first time a lead is configured.</p>
<p>EXCESSIVE VOLTAGE Programming high voltage values at low impedances may cause tissue damage. Consult the technical manual.</p>	<p>One of two possible scenarios has occurred:</p> <ul style="list-style-type: none"> • The voltage is greater than 7.7 volts and the impedance value is unknown or less than 200 Ohms, or • The voltage is greater than 10.2 Volts and the impedance value is between 200 and 250 Ohms.
<p>EXIT APPLICATION Select OK to exit application.</p>	<p>Selecting OK will end this patient session. The application will return to the Neurostimulation Desktop screen.</p>
<p>INVALID ELECTRODE Modify the electrode configuration to include at least one positive (+) and one negative (-) electrode.</p>	<p>An invalid electrode setting exists. Electrode configuration must be changed to a valid setting before continuing.</p>
<p>INVALID SETTING Invalid settings have been detected. All settings will be cleared.</p>	<p>Device cannot be programmed using the detected settings. Selecting OK will clear the settings, and you will be required to reprogram the device.</p>
<p>MEASUREMENT SETTINGS All electrode pairs will be tested. Stimulation will change to the following settings during this measurement: Press OK to start measurement.</p>	<p>You have chosen to run a measurement test during which stimulation parameters will be set to the values that are listed. This will affect patient stimulation while the test is in progress.</p>

Table 8. Error and informational messages (continued)

Message	Explanation
<p>OUT OF RANGE The therapy measurement is out of range. If performing an implant, check the lead insertion into the neurostimulator. For further evaluation, take an electrode impedance measurement on the Electrode Impedance screen. Additional details are found in the technical manual.</p>	<p>To return to nominal settings, a therapy measurement was performed and the impedance was measured outside the range of 200 to 800 Ohms. Amplitude will be set pending to 0 volts. All other parameters will be set pending to nominal values.</p>
<p>OUT OF RANGE The therapy measurement is out of range. If performing an implant, check the lead insertion into the neurostimulator. For further evaluation, take an electrode impedance measurement; press the Continue button to navigate to the Electrode Impedance screen. Additional details are found in the technical manual.</p>	<p>A therapy measurement has been performed and the impedance was measured outside the range of 200 to 800 Ohms. Press Continue to navigate to the Electrode Impedance screen, or press Cancel to return to the Programming screen.</p>
<p>OUT-OF-REGULATION The delivered amplitude may be lower than the programmed amplitude because of low impedance. For further evaluation, take an electrode impedance measurement on the Electrode Impedance screen. Additional details are found in the technical manual.</p>	<p>Adding electrodes lowers the lead impedance and makes it harder to deliver the desired voltage.</p>
<p>POWER ON RESET Power on reset has occurred. Session will restart.</p>	<p>An interruption in power has caused the device to reset. The current session will end and any unsaved data will be lost. Contact Medtronic technical services. Service Code:</p>
<p>PRINTER STATUS Printing in progress.</p>	<p>A print request was sent from the programmer to the printer, but the printer did not respond. The IR ports of both devices must be positioned within 1 meter of each other and facing each other directly.</p>
<p>SESSION DATA MANAGER The Session Data Manager is full. Please press the OK button to open the Session Data Manager and delete old records. Press Cancel to proceed without deleting any records. In this case, data will not be saved.</p>	<p>The session data manager is full. Records must be deleted before more records can be added.</p>
<p>SESSION INTERRUPTED Another programmer has communicated with neurostimulator. Exit application.</p>	<p>A different programmer has communicated with the neurostimulator and could have changed settings.</p>
<p>STIMULATION OFF Stimulation is OFF. To turn stimulation ON and continue, press Yes. To leave stimulation OFF and program, press No.</p>	<p>The device is being programmed while stimulation is off. Press Yes to turn stimulation on and program parameters, or press No to leave stimulation off and program parameters.</p>
<p>TELEMETRY FAILURE There was no response from the neurostimulator. Reposition the programming head and press Retry. To exit the application, press the Cancel button.</p>	<p>Telemetry did not complete because of electrical or magnetic interference from the environment or other devices nearby. To complete telemetry the programming head must be placed closer to the neurostimulator or you must move away from sources of the interference.</p>
<p>THERAPY MEASUREMENT REQ'D To view or change the Current (mA) value, you must first take a therapy measurement by pressing the Therapy Measurement button.</p>	<p>Amplitude in milliamperes cannot be changed without a valid therapy measurement.</p>

Table 9. Iconic error messages

Error message	Explanation
	Application card missing
	Application card error
	Therapy-Stop key pressed with no application active
	Programming (P) key pressed with no application active
	Hardware/software failure message Contact the appropriate Medtronic representative listed on the inside back cover of this manual.


Observation window messages – The Observation box appears on the **Start session** screen when the **Start session** menu () is accessed. The Observation box provides brief messages about significant system events that need to be investigated. These messages and their explanations are displayed in Table 10.

Table 10. Observation box messages and explanations

Event message ^a	Explanation
Check INS clock	The time difference between the INS clock and the clinician programmer clock is greater than one hour. Check the INS clock setting to ensure it is set properly.
INS is at EOS	The INS has reached end of service (EOS) and therapy is not available. Replace the device.

Table 10. Observation box messages and explanations (continued)

Event message^a	Explanation
INS is at LOW	The INS is within weeks of its scheduled end of service. Replace the device before the end of service is reached. Refer to the <i>Enterra II Model 37800 Neurostimulator Implant Manual</i> .

^a Messages remain in the Observation box from session to session until the needed action is taken.

System and programmer settings


This section covers the programmer and operating system settings that can be changed by the user.

Setting localization options

The **Localization** screen allows you to change the language, date, time, and decimal format.

Note: The first time the programmer is turned on, or after the lithium backup battery is replaced, the **Localization** screen does not allow you to change the language selection. To change the language selection, reenter the **Localization** screen through the slider bar.

◆ To set language, date, decimal, and time format

1. Access the slider bar.
2. Select the **Localization** button ().
3. Select a language, date, decimal, or time format option (Figure 27).

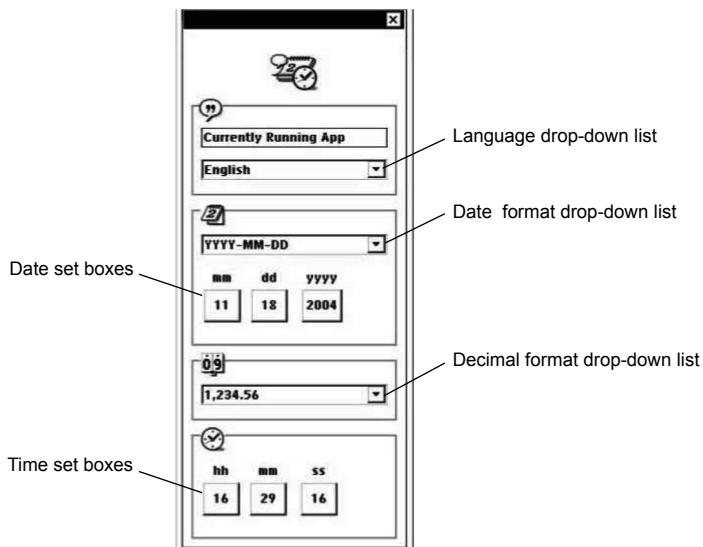


Figure 27. Localization screen.

4. Select the desired format from the drop-down list.

Changing programmer settings

The programmer settings control the contrast, volume, and key click. The speaker volume setting adjusts the volume for tones that signal programming events and conditions (eg, success, error, alert, failure). This setting does not control the volume of the key click sound. The key click is the sound made when the stylus contacts the touchscreen. The key click sound can be turned on and off.

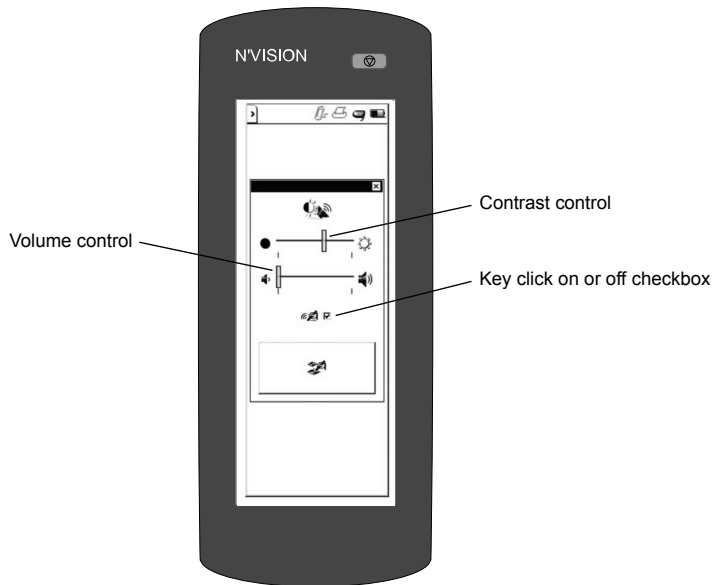


Figure 28. Programmer settings screen.

◆ **To set contrast**

1. Access the slider bar.
2. Select the **Settings** button (🔧).
3. Slide the contrast control bar to desired setting (Figure 28).

Note: Two shades of gray should be visible for optimal viewing of icons and text in the application.

◆ **To set speaker volume**

1. Access the slider bar.
2. Select the **Settings** button (🔧).
3. Slide the speaker volume control bar to desired setting (Figure 28 on page 53).

◆ **To turn key click sound on or off.**

1. Access the slider bar.
2. Select the **Settings** button (🔧).

3. Select the **Key click on or off** checkbox (Figure 28 on page 53).

Programmer maintenance

This section covers changing the programmer batteries, cleaning the programmer, and calibrating the touchscreen.

- △ **Caution:** Do not use the clinician programmer or application card if they were transported or stored above or below the operating temperature range [10 °C (50 °F) to 40 °C (104 °F)]. Refrain from using devices until they are stabilized to room temperature and fall within the operating temperature range. Devices have potential to malfunction if used outside of the operating temperature range.

Changing the programmer batteries

The programmer operates on four AA alkaline batteries. Batteries should be replaced after 40 hours of use or when the battery status icon indicates a low battery (🔋). Batteries must be replaced when the battery status icon indicates the batteries are depleted (blinking).

When no AA batteries are installed, the programmer clock runs on a lithium back-up battery that is supplied with the programmer. The life expectancy of the lithium battery is 3 years.

△ **Cautions:**

- Check the battery status to determine if the batteries in the programmer will last the entire programming session. Loss of power during a programming session may cause unsaved data to be lost.
- If the programmer will not be used for several weeks, remove the AA batteries from the programmer. Batteries left in the programmer may corrode, causing damage to the electronic components.

◆ **To replace the programmer batteries**

1. Ensure that the appropriate application card is in place.
2. Exit the application, if necessary.
3. Turn the programmer off.
4. Press down lightly on the battery compartment cover and push the cover in the direction of the arrow, then rotate the cover upwards (Figure 29 on page 55).

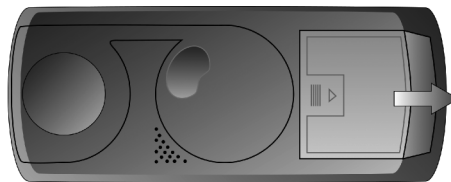


Figure 29. Removing the battery compartment cover.

5. Replace all 4 AA batteries. (Do not use rechargeable batteries.) Correct battery polarity is indicated inside the battery compartment.
6. Replace the battery compartment cover by sliding the cover until it snaps into place.

7. Turn the programmer on. If the programmer does not turn on, verify that the batteries have been installed with the correct polarity.

Note: Dispose of depleted batteries in accordance with local regulations.

◆ ***To replace the lithium back-up battery***

1. Remove the AA programmer batteries.
2. Remove the lithium battery from the compartment located inside the AA battery compartment.
3. Insert a new lithium battery (BR1225 standard lithium coin cell).
4. Replace the AA batteries.

Notes:

- After replacing the lithium back-up battery, you need to reset the Localization parameters. For instructions, see "Setting localization options" on page 52.
- Dispose of depleted batteries in accordance with local regulations.
- Return nonfunctioning devices to Medtronic for disposal.

Cleaning the programmer

◆ ***To clean the programmer***

1. Clean the exterior surfaces of the programming head, IR lens, and magnet with a damp sponge or soft cloth moistened with water, mild detergent, or alcohol. Be careful to not allow liquid into any programmer components.
2. When programming in a sterile field, if the programming head comes in contact with a patient's skin, wipe the programming head with an antibacterial solution.
3. Clean the touchscreen only with a soft, dry, lint-free cloth. Do not use cleansers on the touchscreen.

△ **Caution:** Scratches on the touchscreen may interfere with selecting an option. If the touchscreen is not responding appropriately, return the programmer to Medtronic for repair or replacement.

Calibrating the touchscreen

The touchscreen may require periodic calibration. When calibrating the touchscreen, the programmer compares the points of contact with known locations.

If the calibration fails, the programmer restarts the calibration procedure until the procedure is successfully completed.

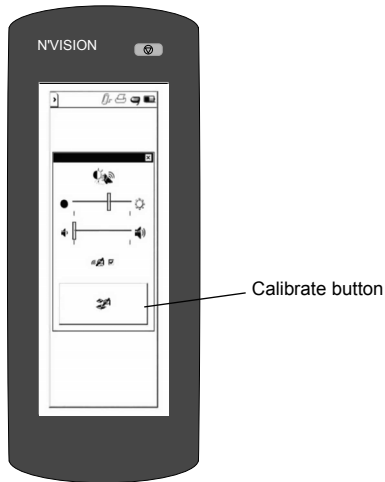


Figure 30. Calibrating the display.

◆ **To calibrate the touchscreen**

1. To begin calibration do one of the following:
 - Press and hold the **Programming (P)** key while the programmer is powering up.
 - From the slider bar, select the **Settings** button (🔧), then select the **Calibrate** button (👤) (Figure 30 on page 57).
2. Select the center of each of the four calibration targets as they appear. To ensure proper calibration, make your selection as close to the center of the calibration target as possible.

Glossary

Amplitude - The strength or intensity of an electrical pulse.

Application card - A small, removable memory card that provides mass storage for the programmer—contains applications and user data.

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.

Depleted - The battery status of a nonrechargeable battery; a state of reduced energy of a battery. Condition requires that the external device battery be replaced or the implanted device be replaced.

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 (eg, short circuit, open circuit).

Electrode polarity - State of each electrode for all implanted leads: positive, negative, or off.

End of Service (EOS) - Condition of an implantable device at the time it is no longer able to operate successfully.

Final settings - Settings in effect at the end of the patient session.

Initial settings - Settings in effect at the start of the patient session.

Input box - An area on the programmer touchscreen that, when activated, initiates the appearance of another screen or an action by the programmer.

Localization parameters - Options for selecting country-specific formats for date, time, numbering schemes, and language.

Power on reset - A neurostimulator safety feature that turns stimulation OFF.

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.

Session Data Manager - Allows collection and storage of patient data information gathered during patient sessions. Report data from previous sessions can be viewed and printed.

Stylus - A blunt pen-shaped or pencil-shaped device used to make contact with a touchscreen on a device such as a computer or programmer.

Target value - Before programming, the intended value of a parameter.

Telemetry - Radio-frequency communication between a clinician programmer and an implanted neurostimulator.

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

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