Medtronic

N'Vision® Clinician Programmer with software

8840
8870

Enterra® Therapy Neurostimulation System for Gastric Electrical Stimulation (GES)

02/03 Programmer guide for software version A

! USA Rx Only

CE 0123 2002

Explanation of symbols on product and package labeling.

SN	Serial number
	Consult instructions for use
	Consult instructions for use at this website
	Temperature limitation
! USA	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
EC REP	Authorized representative in the European community

Table of contents

Device description

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

Package contents

- Application card with case
- Product literature

Introduction

System overview

Neurostimulator

The neurostimulator produces electrical pulses for neurostimulation and has a wide range of programmable parameters and modes.

Leads

Leads connected to the neurostimulator deliver electrical stimulation to the stomach muscle.

N’Vision clinician programmer

The N’Vision Clinician Programmer is used to program the stimulation parameters and modes of the neurostimulator via telemetry, the radio-frequency communication between the implanted device and the programming device.

Application card

The Model 8870 Application Card is a plug-in card that contains the necessary software to program the Enterra Therapy Neurostimulator.

Each neurostimulator has a unique recognition code that allows the programmer to use the appropriate software during programming.

⚠ **Warning:** Do not use the N’Vision Clinician Programmer and the installed Application Card to program any devices other than associated Medtronic neurostimulators. If an attempt to program an incompatible device is made, an error message will appear on the programmer.

Table 1 summarizes the functions of the system components. For detailed information on individual system components, refer to the associated technical manuals and/or Instructions for Use (IFU) sheets. For detailed information on programming the neurostimulator, refer to “Programming the neurostimulator” on page 24.

Table 1. *System component function.*

Component	Function
Neurostimulator	Produces electrical pulses for gastric electrical stimulation and is programmable.
Leads	Deliver electrical stimulation from the neurostimulator to specific areas of the anatomy.
Programmer with Application Card	Switches the neurostimulator on and off. Programs stimulation parameters: voltage, pulse width, rate, and electrode polarity.
	Selects or programs stimulation modes and special functions: Cycling, Control Magnet.
	Activates measurement functions: Battery Status, Battery Longevity, Electrode Impedance, Patient Use Data, System Impedance.

Programmer components

The N'Vision Clinician Programmer is a hand-held, portable device that offers a single platform for Medtronic Neuromodulation therapies and applications. The programmer is equipped with a touch screen for data entry and device programming and has an infrared port through which communication can be established with compatible printers. Figure 1 is a representation of the programmer and its components.

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

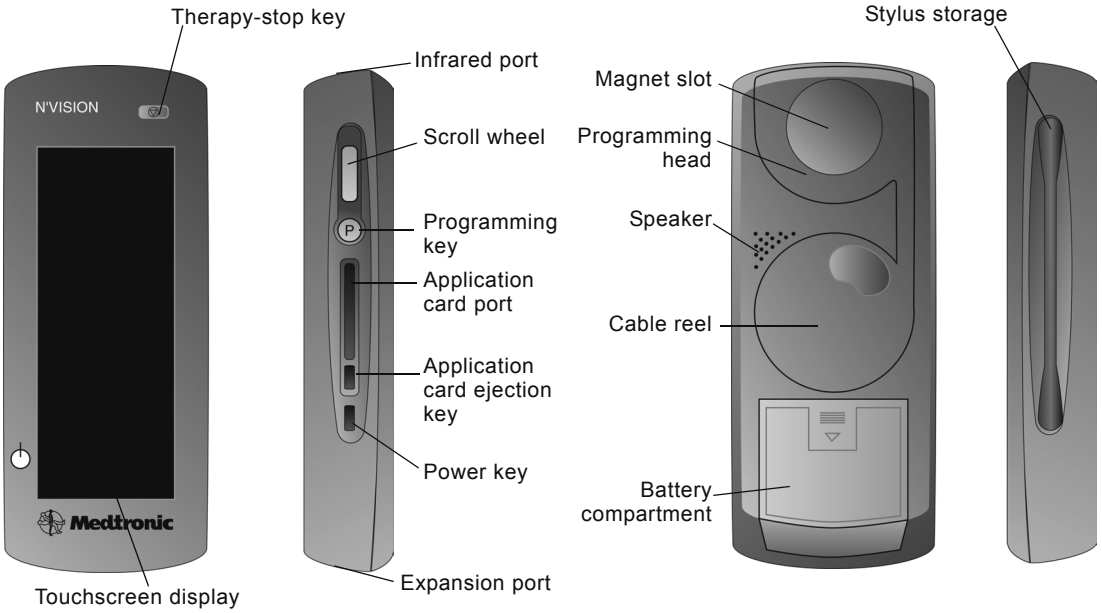

Figure 1. *N'Vision clinician programmer components.*

△ **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
- **Scroll wheel**—Turning the wheel scrolls up and down to adjust values for some functions
- **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
- **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.

Notes: For instructions on calibrating the display, see “Calibrating the touchscreen” on page 64.

Navigation and status

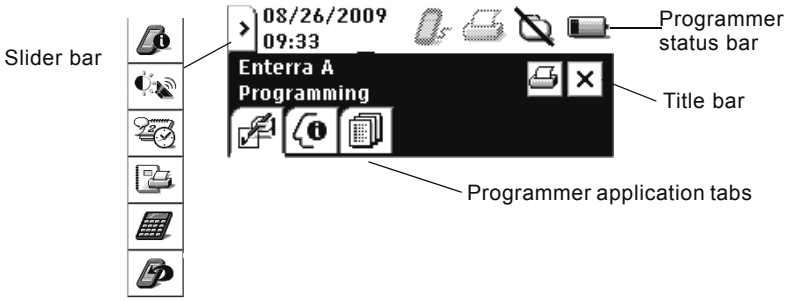

Figure 3. *Navigation and status icons.*

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 and active screen name, and provides access to selected functions
- **Programmer application tabs**—Provides access to application screens

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 2. *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 3. *Slider bar button descriptions.*

Button		Description
	Information	• Display the names, model numbers, and version numbers for programmer, application, and associated software and peripheral devices
	Settings	• Adjust the display contrast • Adjust the speaker volume • Adjust the key click sound • Calibrate the touchscreen
	Localization	• Select the language preference • Select the date format and set the date • Select the decimal format • Set the time format
	Session Data Manager	• Print session reports • View session reports • Delete session reports
	Calculator	• Access the calculator
	Exit application	• Return to the Application Selection screen to select a new application

Title bar

The title bar displays the application name and active programmer application tab. The title bar also provides access to the print screen and exit application functions.

Figure 5. *Title bar.*

Programmer application tabs

The programmer application tabs provide access to the programming functions.

Table 4. *Application tab descriptions.*

Application tab		Function descriptions
	Profile	• Patient information is entered on this screen.
	Programming	• This screen is used for programming device parameters, including: electrode polarity, voltage, pulse width, rate, Cycle On Time, Cycle Off Time, Output Mode, and Control Magnet Status.
	Data	• Various device measurements are taken from this screen, including: battery information, electrode impedance, and patient use. Reports can also be printed from this screen.

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 6):

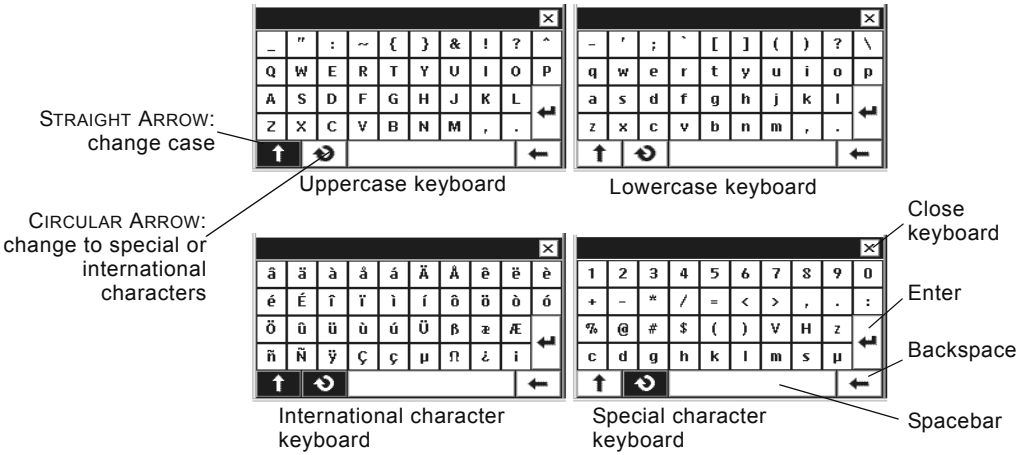

Figure 6. *Programmer keyboards.*

Alternate keyboards are available by selecting one of the following buttons:

- **Straight Arrow** ⇧ —Uppercase and lowercase alpha 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 7).
2. Store the magnet in the programmer carrying case.

Figure 7. *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 8).

Figure 8. *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 9).

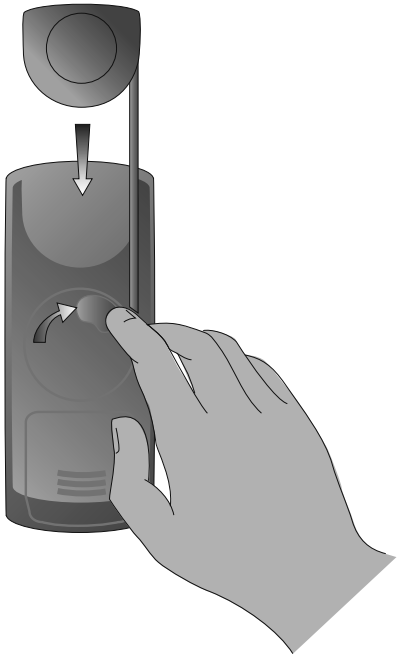

Figure 9. *Retracting the programming head.*

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 Therapy Desktop screen. The following tasks can be initiated from the Therapy Desktop screen:

- Work in demo mode by selecting the **To work in demo mode** button.
- Interrogate the neurostimulator and begin a programming session by pressing the **Program** button.

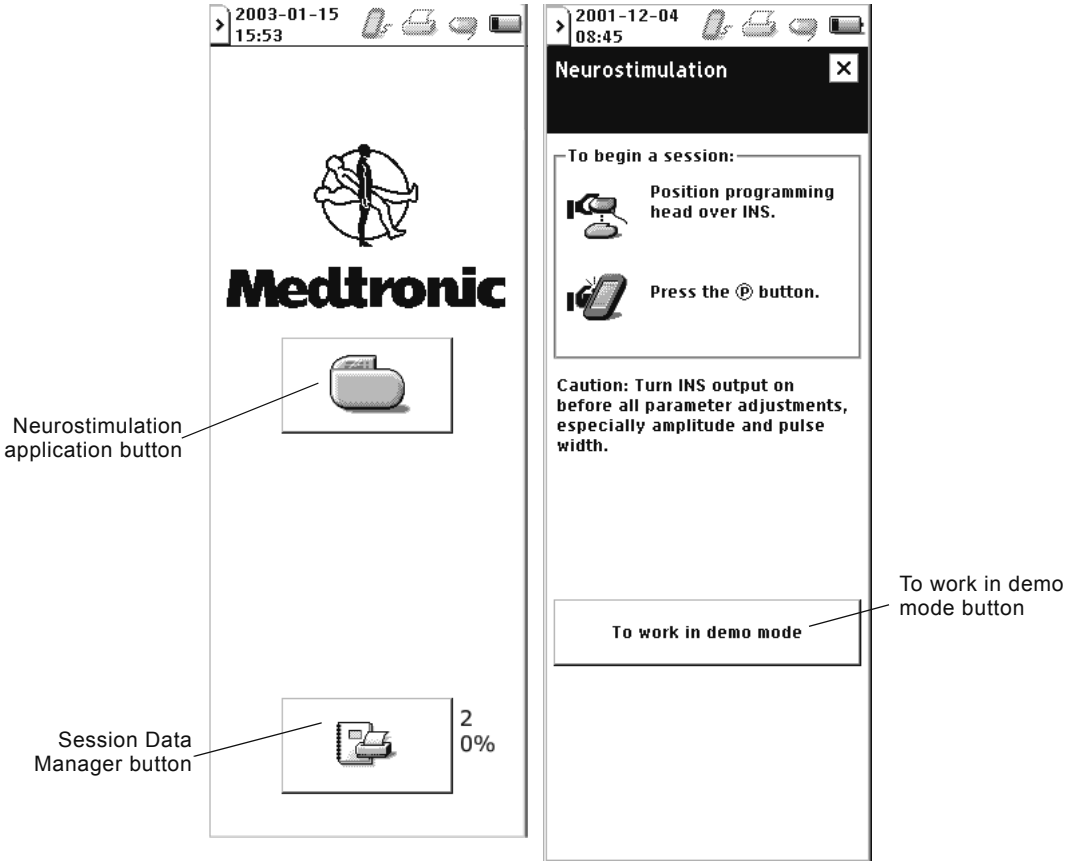

Figure 10. *Application Selection and Therapy Desktop screens.*

Navigating to the Therapy 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 11).

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.

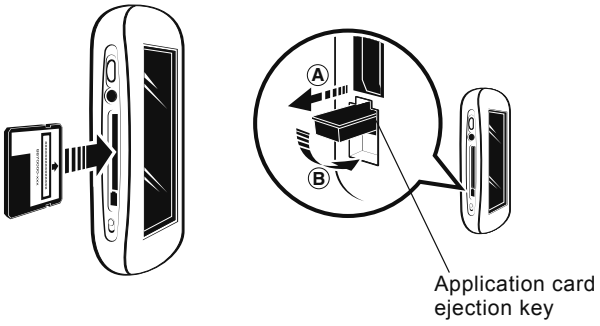

Figure 11. *Inserting the application card.*

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 9).

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 62.

To navigate to the Therapy Desktop screen

1. Turn the programmer on. The Application Selection screen appears (Figure 10 on page 20).
2. Select the **Neurostimulation application** button ( ). The Therapy desktop screen appears (Figure 10 on page 20).

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 Therapy Desktop (Figure 10 on page 20) select the **To work in demo mode** button.
2. Select a therapy.
3. In the Select a neurostimulator box, select a type of 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 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. Navigate to the Therapy Desktop screen (Figure 10 on page 20).
2. 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.
3. Hold the programming head steady over the neurostimulator, then press the **Programming** key (P) or use the stylus to select anywhere in the To Begin a Session box.
4. 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 9 on page 55 for more information).

Programming the neurostimulator

Initiate programming only after careful study of the appropriate technical manuals for all components. Refer to the appropriate technical manual for a complete list of indications, contraindications, warnings, precautions, and adverse events.

Table 5 presents an overview of the basic steps for a typical programming session with the application card and the programmer.

Table 5. *Programming Overview: Basic Programming Steps*

To:	Do this:
1. Turn the programmer on.	• Pull backward on the **Power** key on the programmer, and hold momentarily before releasing.
2. Navigate to the neurostimulation desktop for programming.	• Select the **Neurostimulator** icon on the touch screen.
3. Initiate telemetry between the neurostimulator and the programmer.	• Position the programming head over the implanted device and hold the programming head steady.
4. Interrogate the device.	• Press the **Programming** (P) key on the side of the programmer or select either icon on the desktop screen.The light on the back of the programming head will flash green while telemetry is ongoing and will stop flashing when telemetry is finished. Note: The programming head must be extended from the programmer to view the light. • Hold the programming head steadily over the device until the interrogation is complete.
5. Turn the device on.	• Touch the **Neurostimulator** icon with the stylus to toggle between on and off.
6. Select nominal settings.	• Select the **Nominal** button on the desktop screen.
7. Program.	• Hold the programming head over the neurostimulator, and press the **Programming** (P) key.
8. Print reports.	• Select the print option from the slider bar on the programmer touch screen or select the **Printer** icon in the title bar of the application.

Note: Remember that the N'Vision Programmer allows for batch programming of some parameters. You may set all target parameters on one screen, then program all parameters at once before navigating to a different screen.

Programming cautions

△ **Cautions:**

- 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) the radio-frequency (RF) signal used to program these devices may reset or reprogram the other device.

  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.

Stand-by mode

If the programmer receives no input for 6 minutes, 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

Depressing the **Therapy-Stop** key on the programmer turns the neurostimulator off. The **Therapy-Stop** key is available immediately after the Therapy Desktop screen appears (Figure 10 on page 20) 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 **.**

Nominal programming

Nominal programming quickly and automatically programs the neurostimulator to a set of nominal values. Selecting the **Nominal** button on the Application screen will reset the neurostimulator to the nominal values, perform a therapy measurement, and suggest a voltage for programming. For additional programmable features, refer to “Additional programming features” on page 38.

Note: When target values have not yet been programmed (when values are pending), many functions are not available. For example:

- When any target value is pending, navigation between tabs is not possible.
- When invalid electrode configurations are selected, the **Program** (P) button cannot be selected.

Inaccessible functions such as those listed above are “grayed out” on the screen.

Note: You cannot navigate from one screen to another if pending target parameters on a screen have not been programmed.

To program nominal values

Using the nominal programming feature, a typical sequence for programming stimulation settings consists of the following steps:

1. Using the stylus select the **Nominal** button (Figure 12).

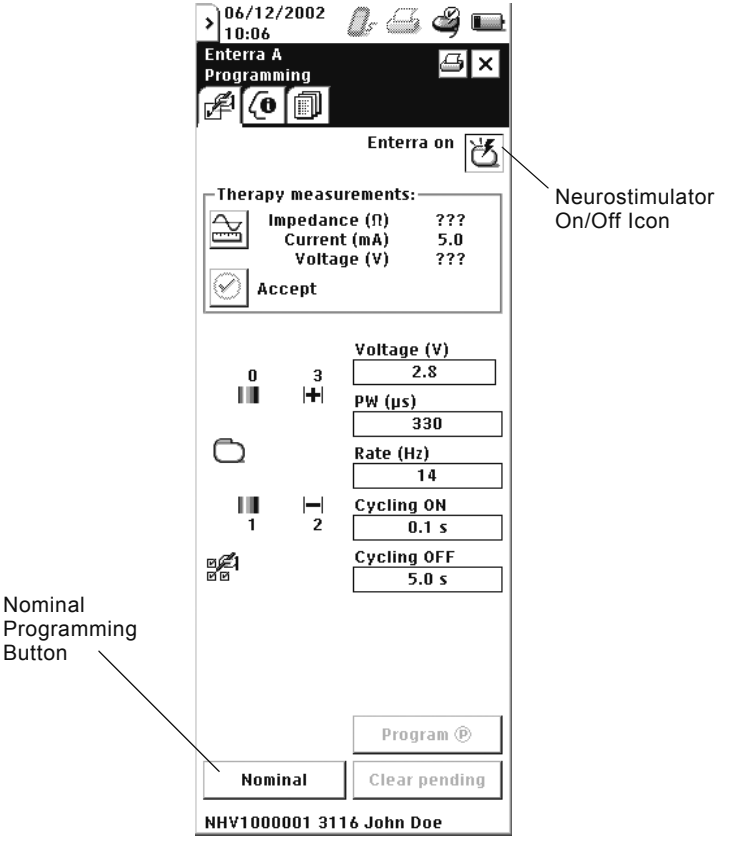

Figure 12. *Program to nominal values.*

2. Review the results, and if acceptable, use the stylus to select the **Program** button (Figure 13). To cancel changes made on the screen before programming, select the **Clear Pending** button.

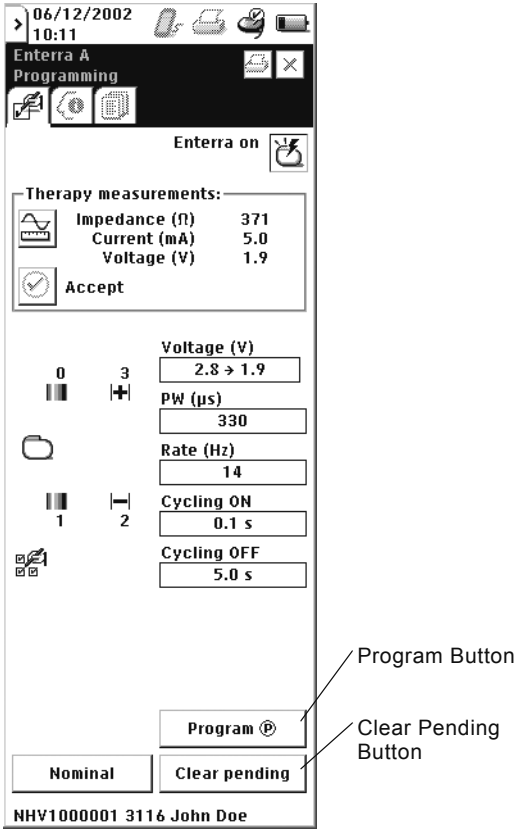

Figure 13. *Program nominal values.*

Therapy measurements

The therapy measurements area provides an impedance measurement, a targeted stimulation current, and a suggested voltage setting (Figure 14). The targeted stimulation current is used with the impedance measurement to suggest a voltage setting (Voltage = Impedance x Current). Selecting the **Accept** button will update the Voltage parameter to the value displayed in the therapy measurements area.

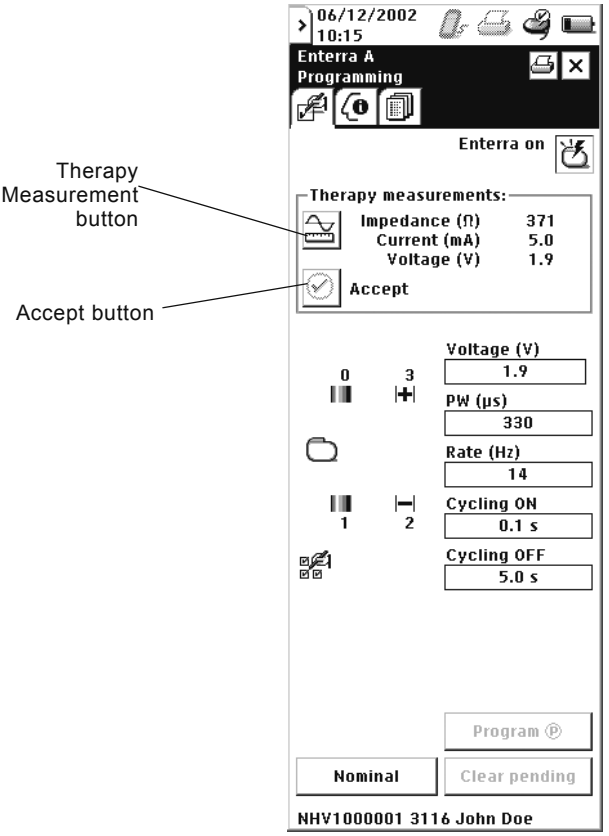

Figure 14. *Therapy measurements.*

Entering patient information

For new patients, neurostimulator default settings (set at shipping) should appear when the device is interrogated; for existing patients, the most recent programmed settings should appear.

The first time that a specific Model 8870 Application Card is used with a patient, you can enter patient information on the Profile Screen.

To enter patient information

1. Select the **Profile Screen** tab ( ) .
2. Using the stylus, touch the input box under the patient ID field. The keyboard appears (Figure 15).

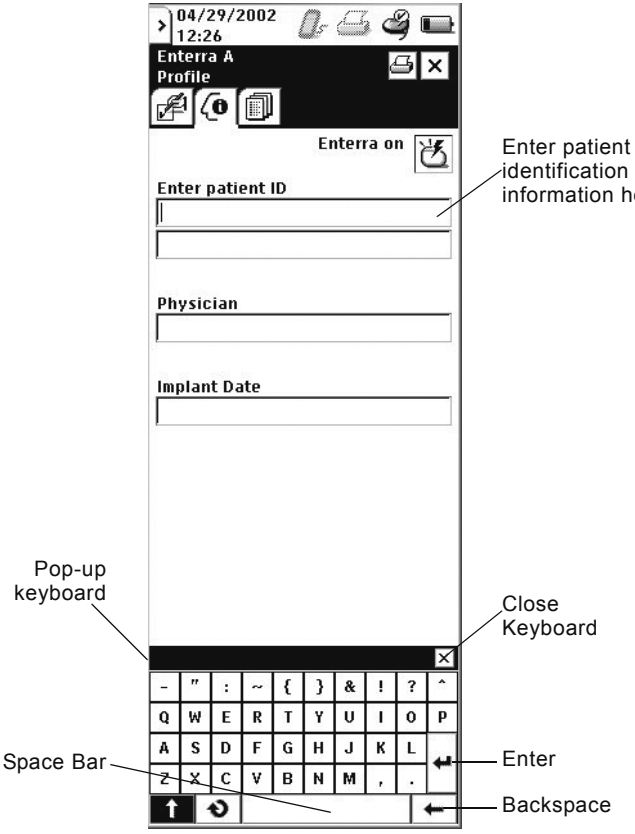

Figure 15. *Enter patient information.*

3. Using the stylus, enter the patient identification and any other desired information in the input boxes of the “Enter patient ID” field.

Using the data screen

Data screen overview

Enterra Therapy neurostimulation systems provide several measurement functions that are useful when you are assessing:

- Status of the neurostimulator battery and expected device longevity;
- Patient use data; or
- Electrode impedance.

Table 6. *Measurement functions.*

Measurement Function	What it Does	When to Use
Battery Status	Provides a general indication of the status of the neurostimulator battery [OK, Low, or EOL (End of Life)]	After each programming session or for troubleshooting
Battery Longevity	Calculates estimated battery life at the current neurostimulator settings	Within 2-3 days of implant
Patient Use Data	Reports use of the neurostimulator	During each patient follow-up
Electrode Impedance (Automated)	Measures each electrode pair to test all wires in the lead	For troubleshooting

Recommendations when using measurement functions

Measurements and diagnostic data obtained from the N’Vision Clinician Programmer are intended to aid in your clinical observations. However, as with any electronic system, internal and external factors can influence neurostimulator measurements. For example, changes in lead position can affect the load impedance measurement. If you obtain a reading that seems inconsistent with your observations, repeat the measurement.

Before using any measurement functions, please note:

- **In general, more accurate electrode impedance readings can be obtained at the default or at higher voltage and/or pulse width settings.** Under some conditions, such as low voltages or narrow pulse widths, a measurement cannot be obtained.
- **You should measure electrode impedance at the end of each programming session.** This provides historical information that may be useful for troubleshooting and isolating problems if they arise. For example, measurements that show a significant increase in load impedance can indicate a fractured lead conductor, a loose setscrew, etc. Conversely, a significant decrease in load impedance can indicate shorted conductors, a break in lead insulation, etc. In either case, it is very useful to know what the measured values were when the system was operating properly.

The Data Screen consists of three areas representing different types of diagnostic data that can be collected (Figure 16).

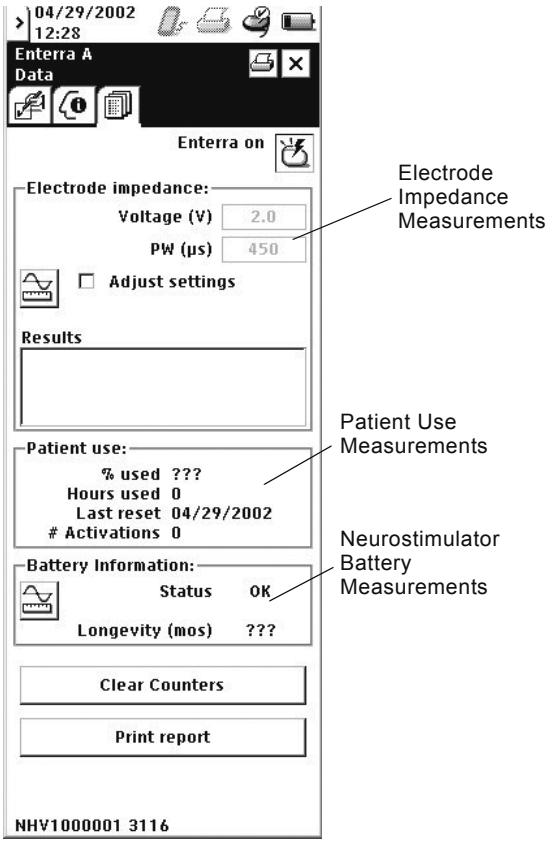

Figure 16. *Data screen components.*

Electrode impedance measurement

Default voltage and pulse width settings are available for use during electrode impedance measurement.

- Voltage – 2.0 volts
- Pulse Width – 450 msec

During the test, these default settings replace the settings you have programmed. At the end of the test, programmed settings are automatically restored.

If a patient is receiving unsatisfactory stimulation, measurement of electrode impedance may help detect problems with the system, such as a broken lead, loose connection, or short circuit.

To measure electrode impedance:

1. Using the stylus, select the **Measurement** icon () WHILE THE PROGRAMMING HEAD IS POSITIONED OVER THE NEUROSTIMULATOR.
2. After selecting the **Measurement** icon to begin the test, a pop-up message will display, asking whether to continue or cancel the test.
   a. If continue is selected, the test will begin, and a status bar will be displayed, allowing the progress of the test to be tracked. This second window will also contain a cancel test option that can be selected at any time during the test.

   Note: Many electrode combinations are tested, and the test may last up to 2 minutes. If the electrode impedance test is interrupted before completion, the neurostimulator will be programmed with the parameters used during the test. Allow the test to finish and check the final programmed parameters in the neurostimulator.

   b. If at any time cancel is selected, the programmer will automatically return stimulation parameters to the most recently programmed values. The **Therapy-Stop** key will also interrupt the test, but the neurostimulator will be turned off before stimulation parameters are reset.
3. When the test is complete, test results will display on the screen.

Battery information

The battery information area provides neurostimulator battery status information. The battery status is updated each time the neurostimulator is programmed and each time the battery status is reviewed. One of the following messages will display to describe the status of the neurostimulator battery: OK, Low, or EOL (end of life). Low or EOL display when less than 5% of original capacity remains.

After the neurostimulator battery is depleted, telemetry is no longer possible.

To measure battery status and battery longevity:

1. Use the stylus, select the **Measurement** icon () WHILE THE PROGRAMMING HEAD IS POSITIONED OVER THE NEUROSTIMULATOR.
2. When the test is complete, test results will display on the screen.

Patient use data

Patient use data provides information about the use of the neurostimulator. It includes measurement of neurostimulator activations, total therapy time, and total elapsed time.

Parameters that are available to review include: percent used (the percent of the time the neurostimulator was activated); hours used (the number of hours the neurostimulator was on and the voltage was greater than 0V); last reset (date of last counter reset, i.e., last follow up examination); and number of activations (the number of times the neurostimulator was turned on by a magnet or with a clinician programmer).

Reviewing and printing programmed settings

After the completion of a programming session, the programmed settings should be reviewed, printed, and placed in the patient file for future reference. The N'Vision Clinician Programmer contains an infrared (IR) port for communication with most IR capable printers. You can order an IR-compatible Model 3445 Seiko DPU printer through Medtronic. Brief directions for printing are presented below. For detailed information on printer selection and printing, refer to the technical manual packaged with the N'Vision Programmer.

To print a copy of the currently programmed settings:

Note: You must exit the application before a report on that session can be saved and accessed for printing in the Session Data Manager.

1. Move the N'Vision Programmer to within 1 meter (3.3 ft) of the desired printer. Ensure that the IR port on the programmer and the IR port on the printer are directly facing each other.

2. On the Data Screen, select **Print Report** button (Figure 17).

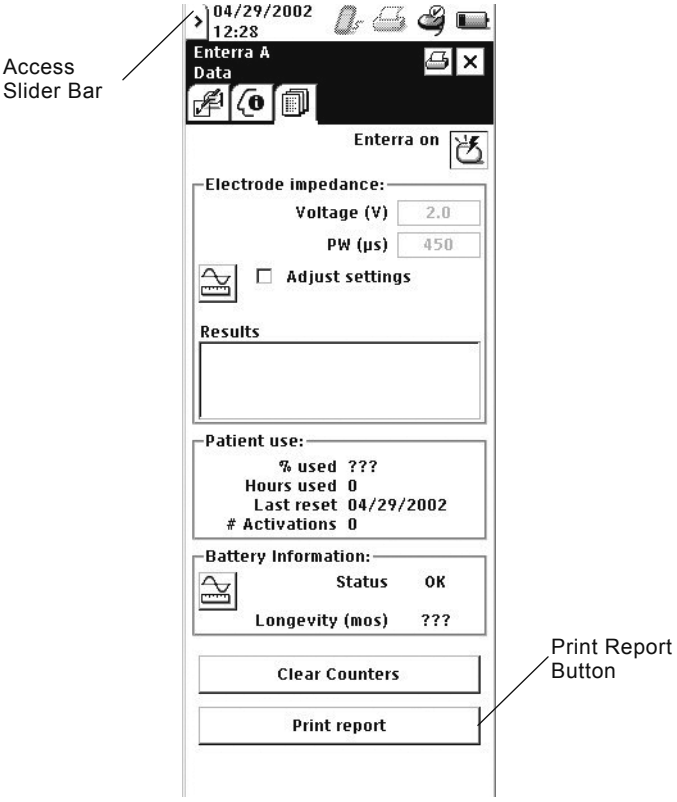

Figure 17. *Accessing the print function.*

3. A message screen will appear, giving you the option to cancel the print request. The report will print automatically unless you select cancel.

Note: The print function can also be accessed at any time by selecting the **Printer** ( ) icon at the top of any of the programmer screens, or by selecting the **Session Data Manager** ( ) icon from the slider bar. Figure 18 shows the print request screen and its options.

During the patient session, the initial and final programmed parameters are automatically saved to a unique report. The name of the report and that of the patient session are identical, and reports are automatically saved to the Session Data Manager.

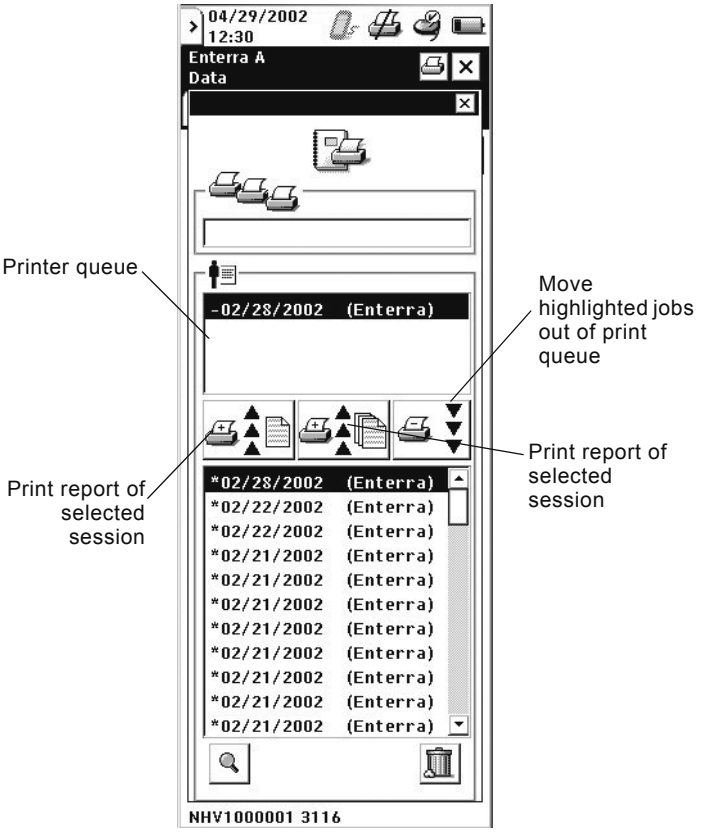

Figure 18. *Print request screen.*

♦ *To print a copy of the programmed settings from another patient session:*

1. Select the **Session Data Manager** ( ) icon from the slider bar at the top of the programmer screen.

2. A list of patient sessions will be displayed in the lower half of the Session Data Manager. Highlight the patient session(s) you wish to print.

3. Move the highlighted patient session(s) to the printer queue by selecting either print report option (Figure 18).

4. The programmer IR protocol is enabled as soon as you move the patient session(s) into the printer queue. Align the programmer IR port with an IR port on a compatible printer, and the reports will automatically print.

To delete patient sessions from the Session Data Manager, highlight the patient session(s) you wish to delete, and use the stylus to select the **Trash** icon on the lower right corner of the screen.

Additional programming features

Programming stimulation settings

Programming screen

In addition to using the Nominal Programming feature, the Enterra Therapy neurostimulator can be programmed by selecting individual voltage, pulse width, electrode polarities, and cycle times.

Typically, you should use the stylus to make selections on all programming screens. Thus, when you are directed to “select” a parameter or input box on the screen, use the stylus to touch the parameter or the input box associated with that parameter.

Remember that you do not have to program one parameter at a time; the N’Vision Programmer has a batch programming feature. Typically, you may set all target parameters on one screen, and program only once.

Note: When target values have not yet been programmed (when values are pending), many functions are not available. For example:

- When any target value is pending, navigation between tabs is not possible.
- When invalid electrode configurations are selected, the **Program** (P) button cannot be selected.

Inaccessible functions such as those listed above are “grayed out” on the screen.

Note: You cannot navigate from one screen to another if pending target parameters on a screen have not been programmed.

Programming electrode polarities

Programmable electrode polarity settings consist of a cathode (a negative “pole” designated on the programmer display with a “-” sign on the graphic electrodes) and an anode (a positive “pole” designated on the programmer display with a “+” sign on the graphic electrodes and neurostimulator case) (Figure 19). Any of the electrodes and the neurostimulator case can also be programmed off (designated on the screen by the absence of a “+” or “-” sign).

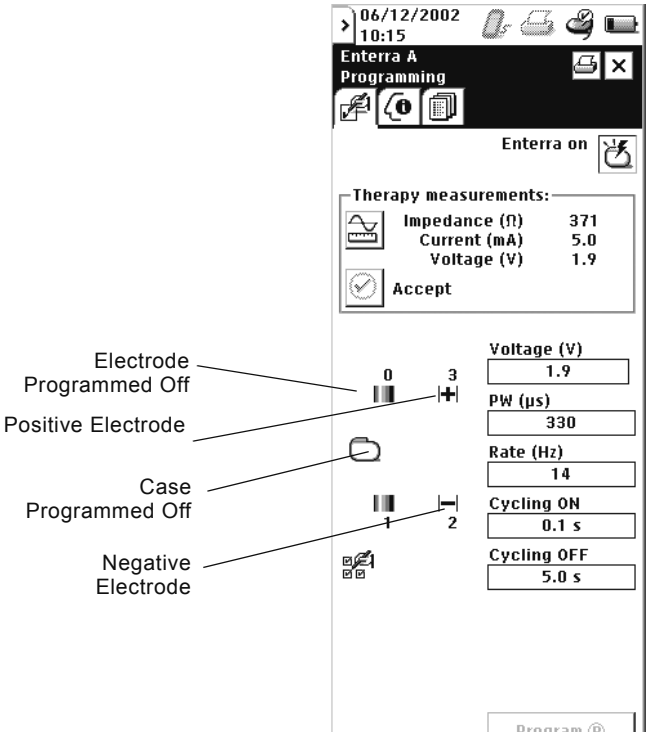

Figure 19. *Program polarities.*

Note the following restrictions when programming electrode polarity:

- If a bipolar configuration is desired, any polarity combination may be selected as long as at least one electrode is positive, one electrode is negative, and the neurostimulator case is off.

- If a unipolar configuration is desired, the neurostimulator case must be selected as the only positive electrode; the lead electrodes may be programmed in any combination of negative or off as long as at least one electrode is negative.

  Note: Invalid polarity programming parameters will not be accepted by the programmer. If you have selected invalid polarity combinations, you will see a message describing why they are invalid (Figure 20) and the **Program** button will be grayed out.

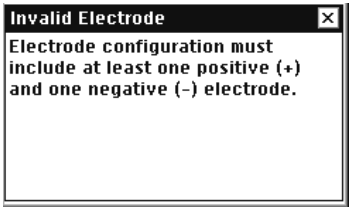

Figure 20. *Invalid electrode settings message.*

To program electrode polarities:

1. Using the stylus, select the **Programming** screen (Figure 19).
2. Using the stylus, select the electrode to program. Use the stylus to toggle the electrode through the "-," "+," or blank (off) options until the desired value appears.
3. Using the stylus, select the neurostimulator case. Use the stylus to toggle the appropriate "+" or blank (off) option.
4. Press the **Program** button, or set remaining parameters prior to programming.

Programming pulse width, rate, and voltage

Pulse width

Pulse width is the duration (in µsec) of a stimulation pulse.

To program the pulse width:

1. Using the stylus, touch the pulse width input box on the programming screen (Figure 21).

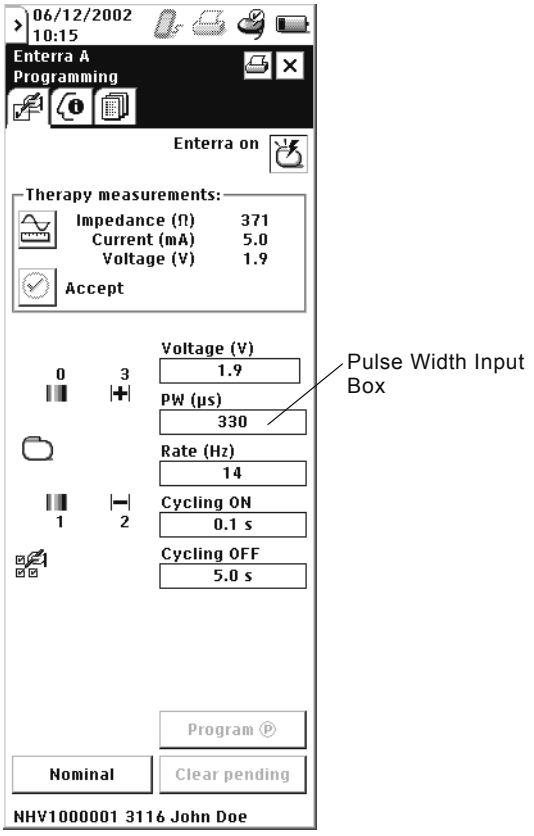

Figure 21. *Program pulse width.*

2. A list of available pulse width options will appear. Select the target value (Figure 22).

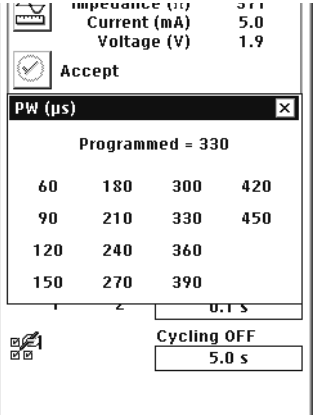

Figure 22. *Select pulse width value.*

3. In the pulse width input box, both the actual and target pulse width settings will appear, with an arrow pointing from the original setting to the newly selected pulse width.

4. Press the **Program** button, or set remaining parameters prior to programming.

5. Once programmed, the new pulse width setting will appear in the pulse width input box.

Rate

Rate is the frequency or speed [in hertz (Hz)] of the stimulation pulses.

To program the rate:

1. Using the stylus, touch the rate input box (Figure 23).

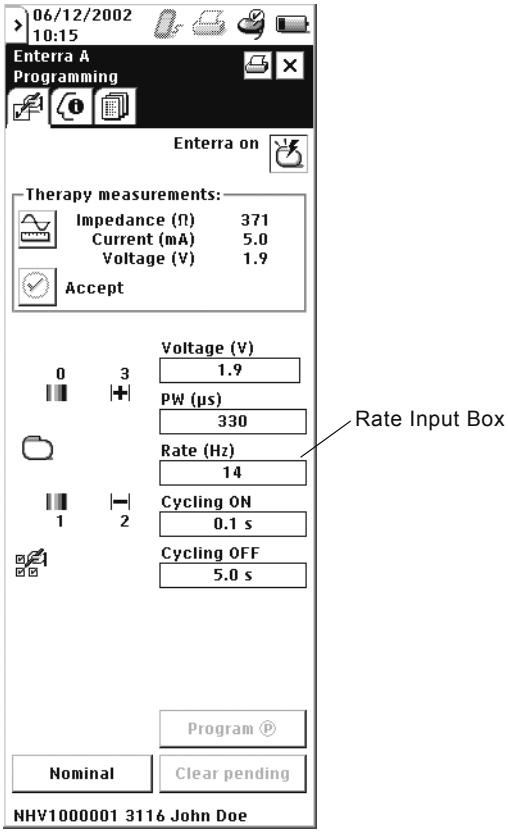

Figure 23. *Program rate.*

2. A list of available rate options will appear. Select the target value (Figure 24).

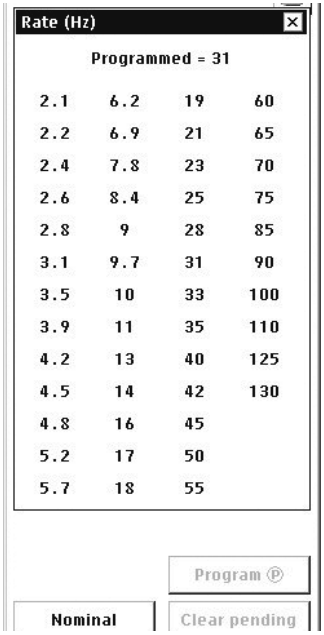

Figure 24. *Select rate value.*

3. In the rate input box, both the actual and target rate settings will appear, with an arrow pointing from the original setting to the target rate.

4. Press the **Program** button, or set remaining parameters prior to programming.

5. Once programmed, the new rate setting will appear in the rate input box.

Voltage

Voltage is the strength or intensity (in volts) of a stimulation pulse.

Warning: Tissue damage may occur for certain combinations of exposed electrode length, impedance, and programmed amplitude. See table 7 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 7. *Maximum Voltage*

Max. charge density **Pulse Width**	**0.4 µC/mm²** **0.21 ms** Electrode length 10(mm)
Impedance Ω	
150	7.7 V
200	10.2 V
250	>10.5 V
300	>10.5 V
350	>10.5 V
400	>10.5 V
450	>10.5 V
≥500	>10.5 V
Lead Area (mm²)	26.8

The table indicates the maximum voltage that can be applied between the electrodes without any muscle tissue damage. Only the voltages appearing in the shaded area should be avoided.

Maximum charge density of 0.4µC/mm^2 was extrapolated from: J.T. Mortimer, Kaufman D. and Roessmann U. Intramuscular electrical stimulation: Tissue damage. *Ann. of BME,* 2:235-244, 1980.

To program voltage:

1. Using the stylus, touch the voltage input box (Figure 25).

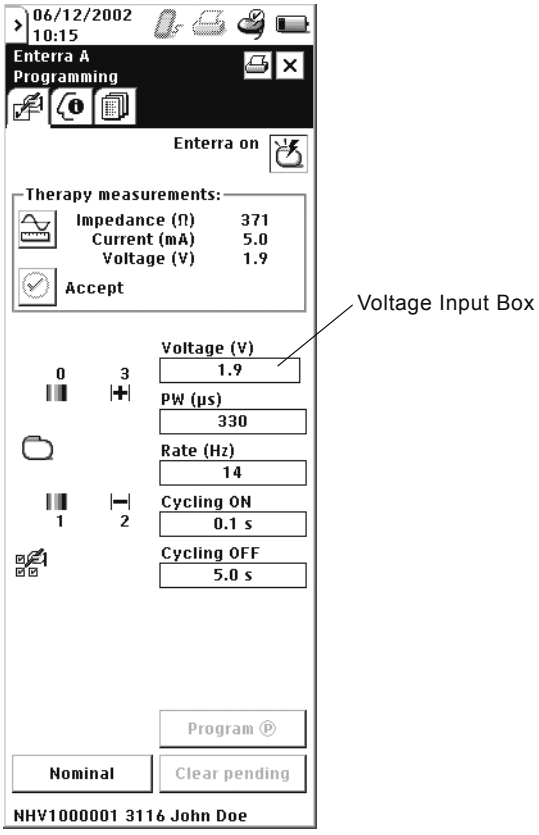

Figure 25. *Program voltage.*

a. A list of possible voltages will appear (Figure 26). Select a target voltage. If the desired voltage is greater or less than the target chosen, use the up or down arrow to reach the exact target.

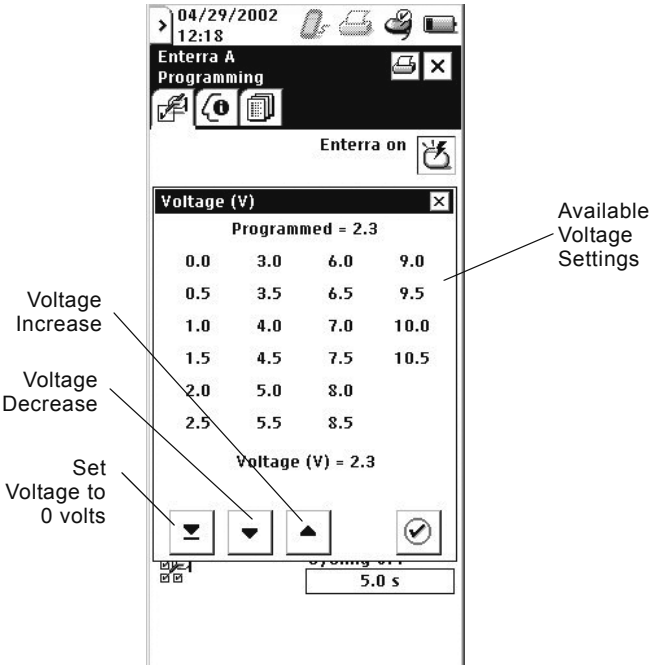

Figure 26. *Select voltage values.*

Note: The voltage can also be set to 0V by touching the down arrow with the line under it. This icon is positioned below the voltage setting box, next to the up and down arrows (Figure 26).

2. Select the **Checkmark** ( ) icon to save the settings and exit the pop-up screen.

3. In the voltage input box, both the actual and the target voltage settings will appear, with an arrow pointing from the original setting to the target setting.

4. Press the **Program** button, or set remaining parameters prior to programming. To cancel changes made on the screen before programming, select the **Clear Pending** button.

5. Once programmed, the new voltage setting will appear in the voltage input box.

Programming cycle times

Cycling Mode is the standard setting for Enterra Therapy. In Cycling Mode, stimulation is automatically cycled on and off, and the output is determined by programmed selection of: Cycling On times, and Cycling Off times (in seconds, minutes, or hours).

To program Cycle On and Cycle Off times:

1. Using the stylus, touch the Cycling ON input box (Figure 27). A pop-up screen appears.

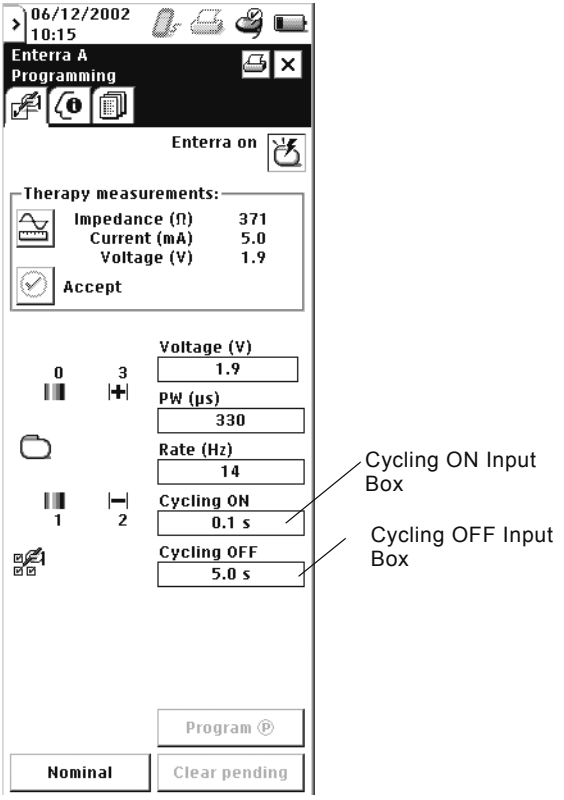

Figure 27. *Program cycling time.*

2. Select the range in which the target cycling time appears (Figure 28).

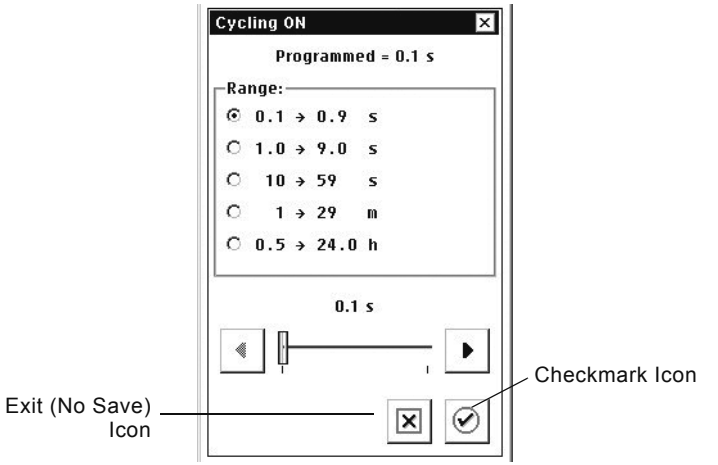

Figure 28. *Select target cycling time range.*

3. Use the sliding bar or arrows to select the exact target cycling time.
4. Select the **Checkmark** ( ) icon to save the settings and exit the pop-up screen.
5. Using the stylus, touch the Cycling OFF input box (Figure 27). A pop-up screen appears.
6. Select the range in which the target cycling time appears (Figure 28).
7. Use the sliding bar or arrows to select the exact target cycling time.
8. Select the **Checkmark** ( ) icon to save the settings and exit the pop-up screen.

   Note: Selecting the **Exit** ( ) icon will close the pop-up screen without saving changes.

9. Press the **Program** button. To cancel changes made on the screen before programming, select the **Clear Pending** button.

10. Once programmed, the new Cycle On Time and Cycle Off Time settings will appear in the Cycle On Time and Cycle Off Time input boxes.

Programming additional parameters

Advanced programming

Enterra Therapy neurostimulators should always be programmed for Cycling Mode and with the Control Magnet Function disabled. However, upon a Power-On-Reset (POR), the neurostimulator will return the manufacturing settings of Continuous Mode and with the Control Magnet Function enabled.

Note: Upon a POR, Cycling Mode and Control Magnet Function must be reprogrammed.

△ **Cautions:**

- Use Cycling Mode for Enterra Therapy. Failure to use Cycling Mode may result in inadequate therapy and return of symptoms.
- Disable the Control Magnet Function for Enterra Therapy. If the Control Magnet Function is not disabled, the neurostimulator may switch off or reset to default factory settings when exposed to certain types of electromagnetic environments. This may result in loss of stimulation, return of symptoms, and require reprogramming by the physician. Refer to the INS technical manual for detailed information on electromagnetic interference (EMI).

To reprogram the neurostimulator for Cycling Mode with the Control Magnet Function disabled:

1. Access Advanced Programming (Figure 29).

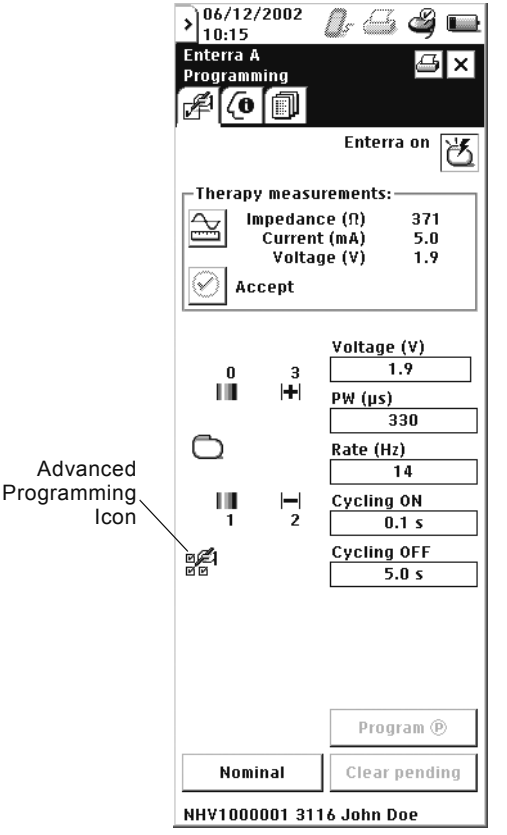

Figure 29. *Access advanced programming.*

2. Using the stylus, touch the Mode input box (Figure 30). Contact of the stylus with this area toggles the selection between Cycling Mode and Continuous Mode. Choose Cycling Mode.

3. Using the stylus, touch the Control magnet input box (Figure 30). Contact of the stylus with this area toggles the selection between On and Off. Choose Off.

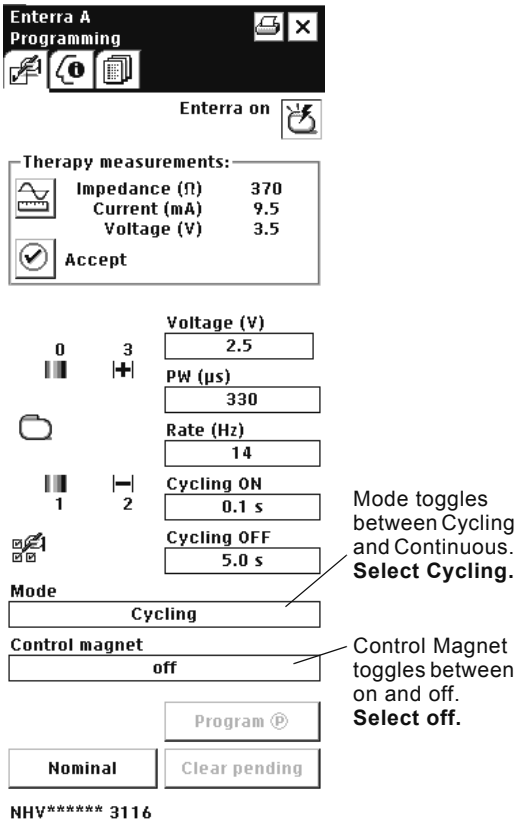

Figure 30. *Advanced programming.*

4. Select the **Program** 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 8. *Quick reference troubleshooting guide.*

Problem	Possible solution	In this manual, go to
• The power is on, but there is no display.	• Turn the programmer off, then on again.	page 21
• The programmer cannot be operated.	• Install new AA batteries in the programmer. Ensure the batteries are properly installed.	page 62
• Touchscreen does not respond.	• Calibrate touchscreen.	page 65
• Telemetry is interrupted or not initiated.	• Ensure that the application card is correctly inserted. • Check the battery status. • See the telemetry failure checklist.	page 21 page 13 page 54
• Power to the programmer is suddenly interrupted.	• Install new AA batteries in the programmer.	page 62
• The programmer is not communicating with the printer.	• 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.	page 64 page 35
• Telemetry cannot be established.	• See the telemetry failure checklist.	page 54
• The programmer is operating erratically.	• Move away from any equipment (eg, MRI, lithotriptor, computer monitor) that may be generating EMI. EMI may cause a disruption in programmer function.	page 23
• An error message or icon appears on the display.	• See instructions in the error messages section.	page 55

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 9 on page 55 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).

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 62). 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 9) and iconic (Table 10) error and informational messages.

Note: Before referring to Table 9, ensure that you have gone through the “Telemetry failure checklist” on page 54.

Table 9. *Error and informational messages.*

ERROR MESSAGE/TEXT	EXPLANATION
APPLICATION CARD FULL. The Application Card is full. Files for this session will not be saved. Consult the technical manual.	The application card is full; patient information will not be saved.
APPLICATION ERROR. The application has been halted because of an error. Contact Medtronic technical services.	The application has stopped because of an internal error.
AUTOMATED IMPEDANCE. This test will take approximately 1 to 2 minutes. All electrode pairs will be tested. Consult the technical manual for important patient information.	You have selected the automated impedance test function.
BATTERY WARNING. The programmer batteries are low. Turn the programmer off and replace the batteries.	Battery is low.
CARD FAILURE. The Application Card has been corrupted. Power down the programmer and contact Medtronic technical services.	Application card error.
CARD MISSING. The Application Card has been ejected. Reinsert the card to continue.	Application card was ejected.
CLEAR COUNTERS. Reset therapy counters?	You have selected the clear counters option.
CONTINUOUS MODE. Warning: Cycling is OFF. Please press CANCEL and program Cycling ON before proceeding.	You have selected Continuous Mode.
EXCESSIVE VOLTAGE. Warning: Programming high voltage values at low impedances may cause tissue damage. Consult the technical manual.	The voltage > 7.7 Volts and the impedance value is unknown or < 200 Ohms, or the voltage > 10.2 Volts and the impedance value is between 200 and 250 Ohms.

Table 9. *Error and informational messages.*

ERROR MESSAGE/TEXT	EXPLANATION
IMPEDANCE OUT OF RANGE. Warning: The system impedance may be outside of the acceptable range. Consult the technical manual.	The measured impedance is less than 200 Ohms, greater than 800 Ohms, or invalid (???).
INVALID ELECTRODE. Electrode configuration must include at least one positive (+) and one negative (-) electrode.	An invalid electrode setting exists.
INVALID ELECTRODE. The Case is positive (+). No other electrodes can be positive (+).	An invalid electrode setting exists.
INVALID INS SETTING. Invalid parameters have been detected in the Implantable Neurostimulator. Press Continue to program the device to valid settings.	Invalid parameters have been detected in the neurostimulator.
INVALID SERIAL NUMBER. An invalid serial number has been detected. Reenter the serial number and press Continue. If you do not know the serial number of the device, press Cancel.	The serial number at session start was invalid.
INVALID SERIAL NUMBER. Reenter the serial number and press Continue. If you do not know the serial number of the device, press Cancel.	The serial number you entered was invalid.
MAGNET ON. Warning: The Control Magnet is ON. Please press CANCEL and turn OFF Control Magnet before proceeding.	You have selected Control Magnet on.
MAGNET PRESENT. The programming head has detected a magnet. Remove the magnet to continue.	A magnet was detected on the telemetry module.
NEW INS DETECTED. A different Implantable Neurostimulator has been detected. Reposition the programming head over the original device and press Retry. Press Cancel to quit this session.	A new neurostimulator was detected.
OUTPUT OFF. The INS Output is off. Do you wish to exit the session?	You have selected the Exit icon when the INS Output is programmed off.

Table 9. *Error and informational messages.*

ERROR MESSAGE/TEXT	EXPLANATION
PARAMETERS HAVE CHANGED. Parameters have been changed by another programmer. Check the new parameter values.	Stimulation parameters have been reprogrammed during a session with a different programmer.
POWER ON RESET. The Implantable Neurostimulator has undergone a reset. Refer to the technical manual. Reenter the serial number and press Continue. If you do not know the serial number of the device, press Cancel.	The neurostimulator has undergone a power on reset.
PRINTING IN PROGRESS. Printing in progress.	Printing is in progress.
PRINT FAILURE. Printing failed. Check the printer or reposition the programmer and attempt to print again.	Printing failed because the printer is out of paper or the printer connection is lost.
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.	The Session Data Manager is full.
TELEMETRY FAILURE. There was no response from the Implantable Neurostimulator. Reposition the programming head and press Retry. Press Cancel to end this session.	The neurostimulator did not respond.
TELEMETRY FAILURE. There was interference while communicating with the Implantable Neurostimulator. Reposition the programming head or move away from potential sources of interference and press Retry. Press Cancel to end this session.	Interference occurred during communication with the neurostimulator.
TELEMETRY IN PROGRESS. Communicating with the Implantable Neurostimulator.	The programmer is attempting device interrogation.
THERAPY STOP. Stopping therapy...	You have pressed the Therapy Stop key.
UNCONFIRMED VALUES. Unconfirmed parameter values exist. Start a new session and verify all parameters.	The programmer cannot confirm the most recently programmed values.

Table 10. *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.

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 back-up 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 31).

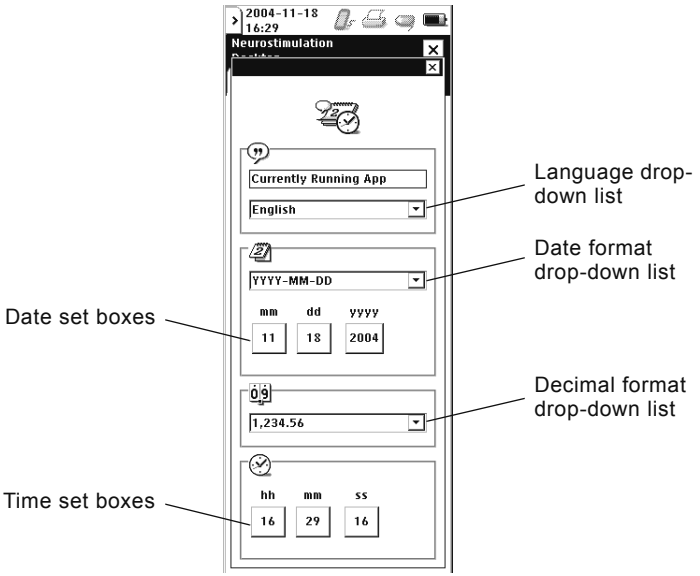

Figure 31. *Localization options screen.*

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.

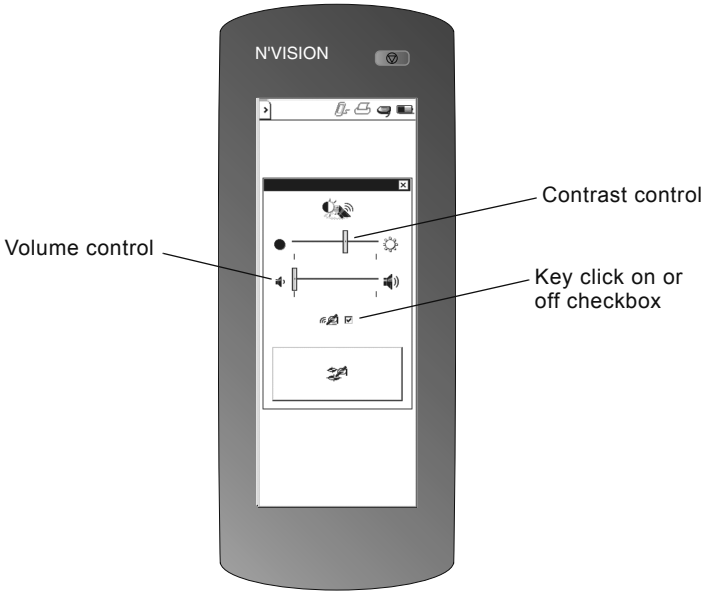

Figure 32. *Programmer settings screen*

To set contrast

1. Access the slider bar.
2. Select the **Settings** button ( ).
3. Slide the contrast control bar to desired setting (Figure 32).

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 32).

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 32).

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 33).

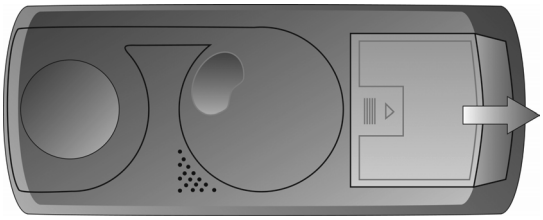

Figure 33. *Removing the battery compartment cover.*

5. Replace all 4 AA batteries. (Do not use rechargable 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 59.
- 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.

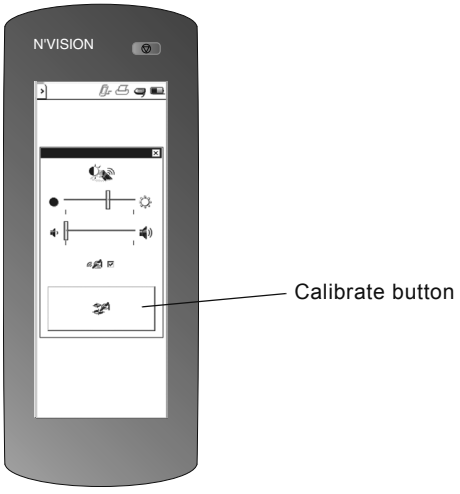

Figure 34. *Calibrating the display.*

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 34).
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

Application card – A small memory card on which Medtronic Neuromodulation therapy applications are housed.

Batch programming – The action of changing all target (pending) values to actual values during a single communication between the programming head and the implanted device.

Counters – The mechanisms by which specific neurostimulator parameters are tracked, for example, patient activations.

Cycling mode – A mode in which the output is alternately cycled on and off automatically.

Cycling Off Time – In a cycling mode, the length of time between stimulation periods; the time of the “resting” period.

Cycling On Time – In a cycling mode, the length of time that stimulation is delivered.

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

Lead impedance – A measure of the resistance of the lead(s) and body tissue to device stimulation.

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

Mode – A type of stimulation delivery.

Program – A combination of electrode, pulse width, rate, and voltage settings.

Pulse width – A measure, in microseconds, of the duration of each stimulating pulse.

Rate – The frequency or speed of stimulation pulses.

Session Data Manager – A clinician programmer feature that allows collection and storage of patient data information gathered during patient sessions.

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 transmissions between the programmer and the implanted device.

Voltage – A measure of the electrical intensity delivered in a stimulating pulse, measured in volts.

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