Medtronic

N'VISION® CLINICIAN PROGRAMMER with SOFTWARE

8840
8870

RestoreADVANCED® and PrimeADVANCED®
neurostimulation systems for pain

09/07 Programmer guide for software version A

! USA Rx only

CE 0123 2006

Explanation of symbols on product and package labeling for non-USA audiences.

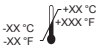
SN	Serial number
	Caution
	Consult instructions for use
	Temperature limitation
! USA	For USA audiences only
	Non-ionizing electromagnetic radiation
	IEC 60601-1/EN60601-1, Type BF Equipment
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 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

Description 7
Package contents 7
Introduction 8
Programmer components 8
Printer 9
Navigation, status, and data entry 10
Navigation and status 10
Programmer status bar 10
Slider bar 11
Title bar 12
Navigation bar 12
Data entry 14
Using the programming head 16
Disconnecting the magnet 16
To disconnect the magnet from the programming head 16
Extending and retracting the programming head 16
To extend the programming head 17
To retract and dock the programming head 17
Preparing for a programming session 18
Navigating to the Therapy Desktop 19
To insert and eject the application card 19
To turn the programmer ON or OFF 19

Refer to the indications sheet for indications and related information.

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

Refer to System Eligibility, Battery Longevity, Specifications reference manual packaged with the software application card for neurostimulator selection, battery longevity calculations and specific neurostimulator specifications.

Refer to the Model 8840 N'Vision Clinician Programmer user manual for programmer warnings and precautions, device description, package contents, device specifications, and instructions for use.

! USA **Refer to the clinical summary booklet packaged with the neurostimulator for information on the clinical study results of the neurostimulation system and individualization of treatment.**

To check programmer battery status 19
To navigate to the THERAPY DESKTOP screen 19
Transferring patient information 20
To transfer patient information 20
Using the programmer in Demo mode 21
To access Demo mode 22
Interrogating the neurostimulator 22
To interrogate the neurostimulator 22
Programming for intraoperative screening and postoperative test stimulation 23
ENS preparation 23
Selecting an application 23
Pain Test Stim intraoperative screening 24
To use the programmer for intraoperative screening 24
Pain Test Stim postoperative test stimulation (new and follow-up) 26
To use the programmer for a new test stimulation session 26
To use the programmer for a follow-up test stimulation session 26
Programming the neurostimulator 28
myStim groups and programs 28
High-output interlocks and shared electrodes 29
Programming warnings and cautions 30
Stand-by mode 30
To return to programming from Stand-by mode 31
Therapy stop 31
To stop therapy 31
Resolving pending values 31
Basic programming steps 32
Entering patient and physician information 36
To enter patient information 37
Entering device information 37
To program lead configuration 38
To enter lead model number 38
To enter neurostimulator information 39
Reviewing patient use information 40
To review patient use data 40
To review neurostimulation system information 41
To view the patient use data by group 41
To view the patient use data by day 41
Turning the neurostimulator ON or OFF 42
To turn the neurostimulator ON or OFF 42
Checking system performance 42
Recommendations when using measurement functions 42

Returning to initial settings during programming 47
To return to initial settings 47
Programming with groups and programs 48
To activate a group and select a program 48
Reviewing group settings during programming 49
To review group settings 49
To adjust amplitudes from the group tab 50
Reviewing/modifying stimulation parameters 51
To review/modify electrode polarities 51
To review/modify the pulse width or rate 52
To review/modify amplitude resolution and amplitude 53
Adding groups and programs 55
To add and activate a new undefined group 55
To add new programs to an existing group 55
Generating new groups using AutoFill 56
Adding/modifying programs using stored programs 57
To add/modify programs using stored programs 57
To save programs to the Working List 59
Programming using TargetStim and Optimizer 59
To create/modify programs using TargetStim 59
To refine programs using Optimizer 62
Naming a group 64
To name a group 64
Deleting groups and programs 65
To delete a group 65
To delete a program in a group 65
Customizing device settings 66
To review/modify SoftStart/Stop 67
To review/modify Cycling 67
Programming a neurostimulator for patient control 67
To set limits for all groups 70
To set amplitude or pulse width limits for a single group 71
To set rate limits for a single group 72
To enable GroupAdjust 73
To enable TARGETmyStim 73
Programming Scheduled Therapy 74
To schedule a new event 74
To modify a therapy event 75
To delete a therapy event 76
Completing the programming session 76
To review programmed settings 76
Printing session reports 77

To print a report during the session 78
To print a report after the session 78
To view a report from the Session Data Manager 79
Managing session data files 80
To delete patient session files 80
Printing the screen 81
To print the current screen 81
Ending the current patient session 81
To end the current patient session 81
Exiting the application 81
To exit the application 81
Troubleshooting 82
Troubleshooting reference guide 82
Telemetry failure checklist 82
Impedance and stimulation current measurements 83
Reading serial numbers 83
To read the neurostimulator serial number 83
To read the clinician programmer serial number 83
Physician Recharge Mode (RestoreADVANCED Neurostimulator) 84
To perform a physician charging session 84
Error and informational messages 85
System and programmer settings 93
Setting localization options 93
To set language, date, decimal, and time format 93
Changing programmer settings 93
To set contrast 94
To set speaker volume 94
To turn key click sound ON or OFF 94
Programmer maintenance 95
Changing the programmer batteries 95
To replace the programmer batteries 95
To replace the lithium back-up battery 96
Cleaning the programmer 96
To clean the programmer 96
Calibrating the touchscreen 96
To calibrate the touchscreen 97
Glossary 98

Device description

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

This manual is designed to provide the information needed to program and troubleshoot the programmable parameters for the:

- RestoreADVANCED Model 37713 Rechargeable Implantable Neurostimulator (INS)
- PrimeADVANCED Model 37702 Non-rechargeable Implantable Neurostimulator (INS)
- Model 37021 External Neurostimulator (ENS)
- Model 37022 External Neurostimulator (ENS)

Note: Figures showing screen information common to the PrimeADVANCED and RestoreADVANCED neurostimulation systems may display RestoreADVANCED in the title bar.

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 Neurological therapies. The programmer is used to review and program device parameters using telemetry, a radio-frequency (RF) communication. The programmer is also used to set limits for the patient control devices.

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

Programmer components

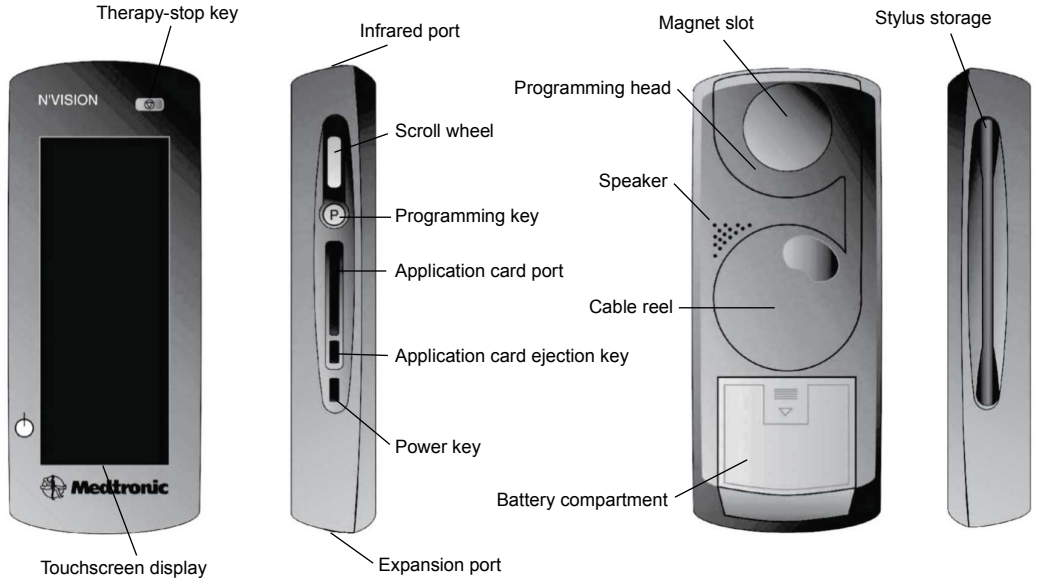


Figure 1. *N'Vision clinician programmer components.*

△ **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
- **Scroll wheel**—Turning the wheel scrolls up and down to adjust values for some functions
- **Programming key (Ⓟ)**—Depressing 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 1meter (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 96.

Navigation and status

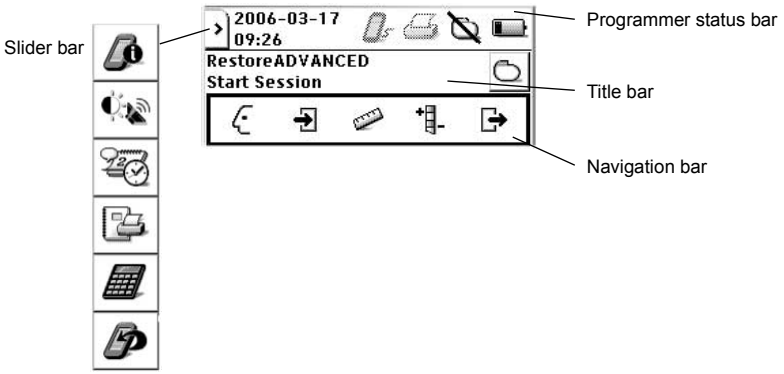


Figure 3. *Navigation and status icons.*

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	• 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 screen. The title bar also provides access to the NEUROSTIMULATOR ON/OFF button (Figure 5).

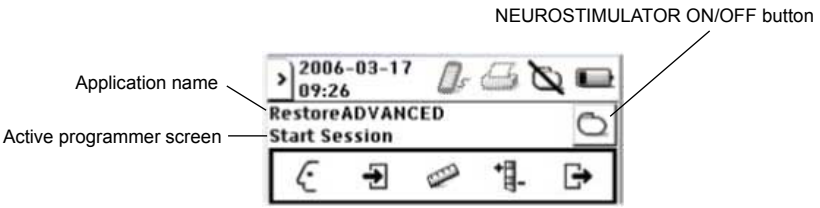


Figure 5. *Title bar.*

Navigation bar

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

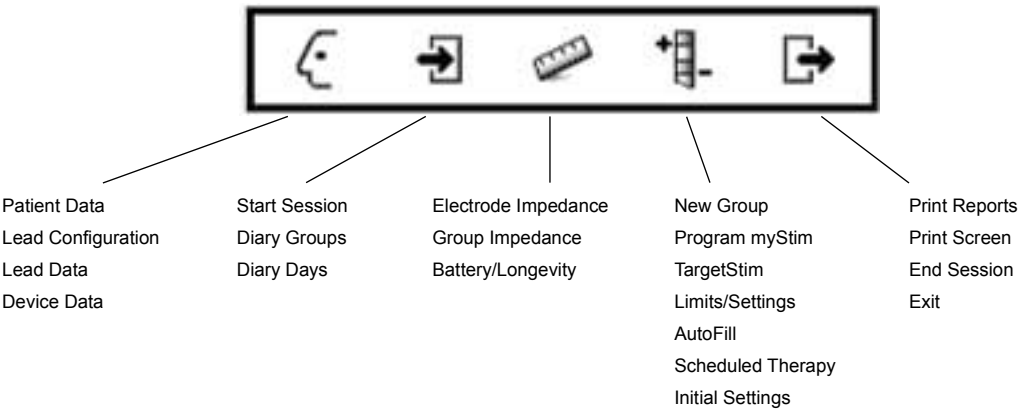


Figure 6. *Navigation bar with available menu items.*

Table 3. *Menu descriptions*

Menu		Function descriptions
	PROFILE	• Enter patient and physician information • Configure leads • Enter lead information • Enter neurostimulator implant information • Set neurostimulator date and time • View neurostimulator system information
	START SESSION	• Display name and date of patient session • Display initial active and available groups • Display initial patient use information • Display initial neurostimulator battery level status or service life • Display initial system status messages • View patient use data by groups or by days
	MEASUREMENT	• Perform electrode impedance measurements • Perform group (therapy) impedance measurements • Check battery level status or battery service life • Estimate battery longevity (during test stimulation) • Check charge information (RestoreADVANCED INS)

Table 3. *Menu descriptions (continued)*

Menu		Function descriptions
	PROGRAM mySTIM	• Display group settings and details • Create, add, and delete groups and programs • Program electrode polarity • Program amplitude, pulse width, and rate • Refine programs with Optimizer • Transition electrodes with TargetStim • Program Cycling and SoftStart • Program patient control limits, enable GroupAdjust and TARGETmyStim • Return all settings to initial values • Generate groups with AutoFill • Program a schedule of therapy that repeats every 24 hours
	END SESSION	• Display name of current patient session • Display active and available groups • Display group optional settings • End patient session • Print a variety of session reports • Exit application • Print 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 7):

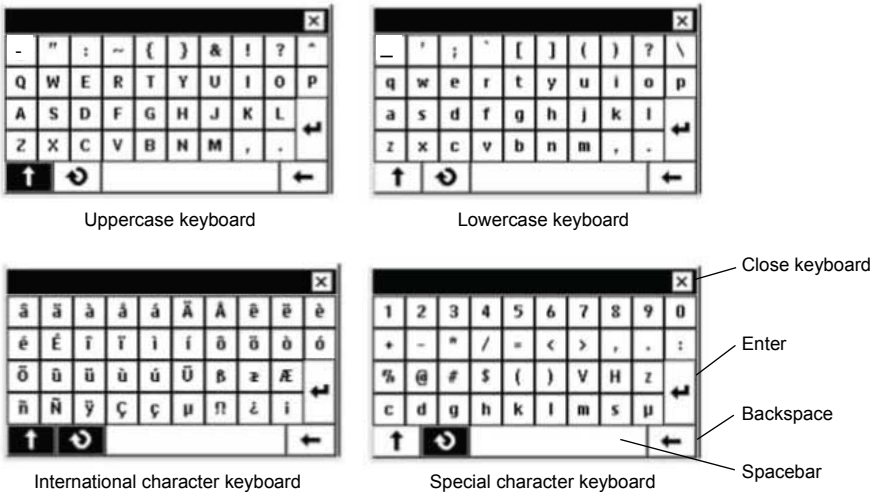


Figure 7. *Programmer keyboards.*

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.

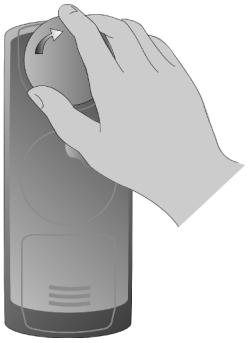


Figure 8. *Unlocking the magnet from the programming head.*

△ **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).

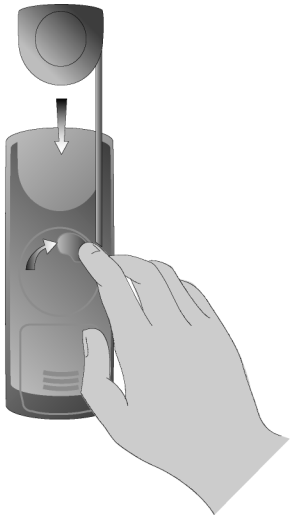


Figure 10. *Retracting the programming head.*

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 THERAPY DESKTOP screen (Figure 11). The following tasks can be initiated from the THERAPY 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.

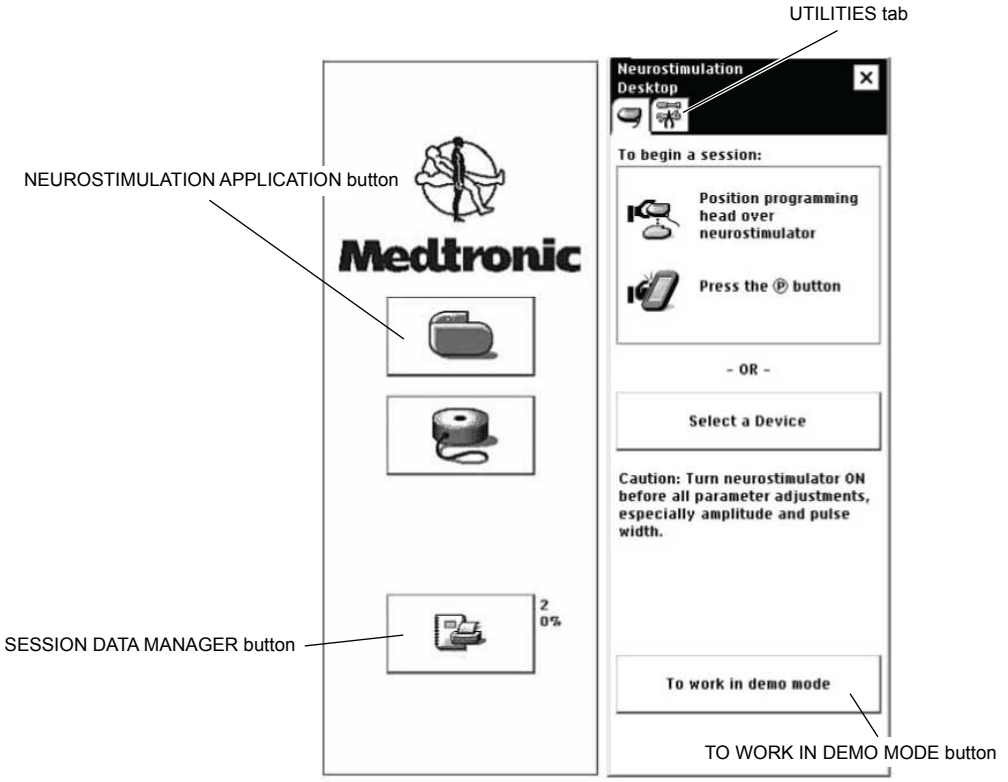


Figure 11. *APPLICATION SELECTION and THERAPY DESKTOP screens.*

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 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.

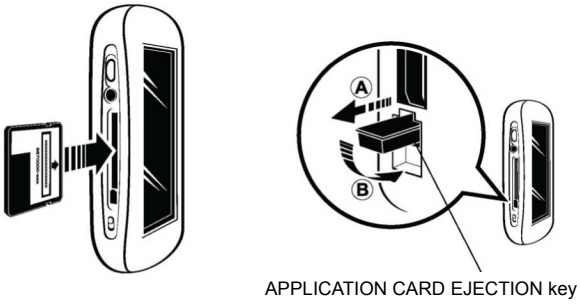


Figure 12. *Inserting the application card.*

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 8).

♦ *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 95.

♦ *To navigate to the THERAPY DESKTOP screen*

1. Turn the programmer ON. The APPLICATION SELECTION screen appears (Figure 11 on page 18).

2. Select the NEUROSTIMULATION APPLICATION button ( ). The THERAPY DESKTOP screen appears (Figure 11 on page 18).

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 THERAPY DESKTOP screen (Figure 11 on page 18), select the UTILITIES tab.
3. Select the COPY PATIENT DATA button (Figure 13).

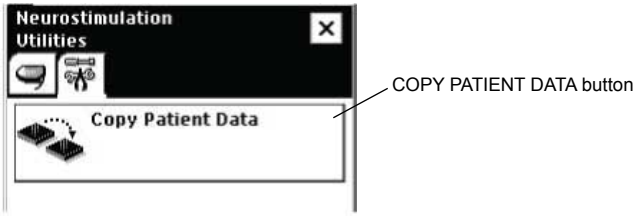


Figure 13. *UTILITIES tab.*

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 OK 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 THERAPY DESKTOP screen (Figure 11 on page 18), 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 THERAPY DESKTOP screen (Figure 11 on page 18), 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 key (P) 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 9 on page 85 for more information).

Programming for intraoperative screening and postoperative test stimulation

To program for intraoperative screening or postoperative test stimulation, the Model 37021 or Model 37022 External Neurostimulator (ENS) is connected to the Model 8840 Clinician Programmer. The Model 8870 Application Card provides the software to program the ENS for these procedures.

Note: The screens presented in this manual are representative of specific Medtronic neurostimulator applications. Features represented may not be available with all external neurostimulator models during test stimulation or with all implantable neurostimulator models during programming.

ENS preparation

Refer to the ENS user manual for instructions for:

- connecting/disconnecting the ENS to the Model 8840 Clinician Programmer.
- connecting the snap-lid connector cable to the ENS.
- changing ENS batteries.

  Note: Put new batteries in the ENS prior to each new test stimulation.

Refer to the lead implant manual for instructions for connecting the snap-lid connector cable to the lead/extension.

Selecting an application

Screening and test stimulation options are available from the TESTSTIM SELECTION screen after initial interrogation when the ENS is identified (see Figure 15 on page 24).

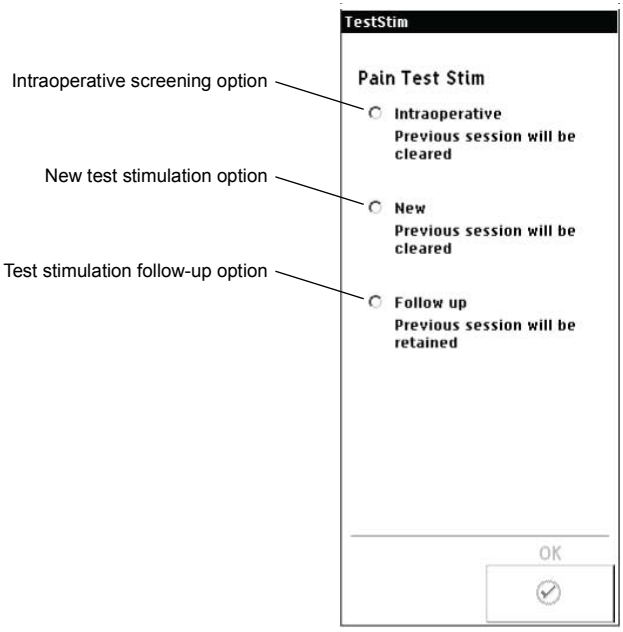


Figure 15. *TESTSTIM SELECTION screen for programming the ENS.*

When the intraoperative screening option or the new test stimulation option is selected, information from a previous session is cleared from the ENS.

Pain Test Stim intraoperative screening

Intraoperative screening is primarily used to identify optimal lead position. Refer to Table 4 on page 24 for basic instructions for screening with the Model 8870 application card. Use the reference page numbers listed in Table 4 to find additional information in other sections of the manual.

♦ *To use the programmer for intraoperative screening*

△ **Caution:** To prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation):

- program parameter changes in small increments above the perception threshold (the amplitude value[s] at which the patient first perceives paresthesia) while evaluating the patient's response.
- verify that the amplitudes are set to 0.0 V before turning on the neurostimulator.

Table 4. *Screening process with the ENS*

	Procedure:	Do this:	Go to page:
	Prepare for the screening process:		
1.	Check the programmer.	• Check/replace programmer batteries. • Ensure that the application card is properly installed.	page 95 page 19
2.	Turn the programmer ON.	• Turn ON the programmer. The APPLICATION SELECTION screen appears.	page 19

Table 4. *Screening process with the ENS (continued)*

	Procedure:	Do this:	Go to page:
3.	Select the NEUROSTIMULATION APPLICATION button.	• The THERAPY DESKTOP screen appears.	page 18
4.	Interrogate the neurostimulator.	• Connect the ENS to the programmer. • 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 23 page 82
5.	Select the intraoperative screening option.	• Select Intraoperative from the TESTSTIM SELECTION screen.	page 24
	Select lead configuration		
1.	Select lead configuration.	• On the LEAD CONFIGURATION screen, configure the leads to be consistent with the patient's lead setup.	page 38
	Check system performance:		
1.	Check electrode impedance, if desired. **Note: Perform this procedure at the beginning of the session.** These measurements verify the integrity of lead/extension/connector pathways.	• Access the MEASUREMENT menu and select Electrode Impedance. • Select the desired amplitude from the drop-down list. • Select the MEASUREMENT button. • Select the OK button to perform the test. • Review electrode impedance measurement results. **Note:** This procedure takes approximately 1 minute. In order to perform measurements, this procedure temporarily reprograms the stimulation settings.	page 42
2.	Check group (therapy) impedance, if desired. **Note: Perform this procedure at the end of the session.** These measurements provide documentation that pathways are intact and the current provided is sufficient for the selected therapy.	• Access the MEASUREMENT menu and select Group Impedance. • Select the MEASUREMENT button. • Select the OK button to perform the test. • Review impedance and stimulation current data. **Note:** This measurement is available only when a program has been defined.	page 44
	Set stimulation parameters:		
1.	Ensure that the neurostimulator is ON.	• If the neurostimulator is OFF, select the NEUROSTIMULATOR ON/OFF button.	page 42
2.	Set electrode polarities.	• Access the PROGRAM mySTIM menu and select Program myStim. • Use the stylus to select negative (-), positive (+), or OFF electrode polarities for the selected lead(s). Turn the scroll wheel to move electrode polarity assignments up and down on the selected lead.	page 51
3.	Set rate and pulse width.	• Select the rate input box, then select a rate. • Select the pulse width input box, then select a pulse width. • Press the PROGRAMMING (P) key or select the PROGRAM (P) button on the programmer screen.	page 52
4.	Set amplitude resolution and amplitude.	• Select the amplitude input box and select an amplitude resolution setting. • Select the amplitude input box again. • Select an amplitude setting. The amplitude ramps to the target value unless the STOP button or the AMPLITUDE TO ZERO button is selected.	page 53

Table 4. *Screening process with the ENS (continued)*

	Procedure:	Do this:	Go to page:
5.	If desired, set stimulation parameters by adding/modifying programs using stored programs.	• Access the PROGRAM mySTIM menu and select Program myStim. • Select an undefined program tab. • Select a program from the second drop-down list. • Press the PROGRAMMING (P) key or select the PROGRAM (P) button on the programmer screen.	page 57
6.	If desired, identify and refine stimulation parameters using TargetStim.	• Access the PROGRAM mySTIM menu and select TargetStim. • Select a program from the drop-down list or use the SCROLL RIGHT/SCROLL LEFT buttons. • Set or modify electrode polarities as needed. • Set or modify the amplitude as needed. • Use the TARGETSTIM buttons to transition electrodes while asking the patient to provide responses to the stimulation. • Select the OK button.	page 59
7.	If desired, refine stimulation parameters using Optimizer.	• Access the PROGRAM mySTIM menu and select Program myStim. • Select a numbered program tab in the active group. • Select the OPTIMIZER button. • Select an optimization from the drop-down list. • Press the PROGRAMMING (P) key or select the PROGRAM (P) button on the programmer screen. • Select the OK button.	page 62
	Complete the screening process:		
1.	Exit application.	• Access the END SESSION menu and select Exit. • View or print the temporary session report in the Session Data Manager.	page 81 page 77

Pain Test Stim postoperative test stimulation (new and follow-up)

♦ *To use the programmer for a new test stimulation session*

Note: Put new batteries in the ENS prior to each new test stimulation. See the ENS technical manual for instructions on changing the batteries.

1. Select New from the TESTSTIM SELECTION screen (refer to Figure 15 on page 24).

2. Follow the instructions given in this manual for programming the neurostimulator. Refer to Table 5 on page 32 for basic programming steps. Use the reference page numbers listed on the table to find additional information in other sections of the manual.

♦ *To use the programmer for a follow-up test stimulation session*

1. Select Follow up from the TESTSTIM SELECTION screen (refer to Figure 15 on page 24).

2. Follow the instructions given in this manual for programming the neurostimulator. Refer to Table 5 on page 32 for basic programming steps. Use the reference page numbers listed on the table to find additional information in other sections of the manual.

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 that were set during manufacturing.

Note: The screens presented in this manual are representative of specific Medtronic neurostimulator applications. Features represented may not be available with all external neurostimulator models during test stimulation or with all implantable neurostimulator models during programming.

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

- **Stimulation parameters**
  - **Electrode polarities**—Programmed positive (+), negative (-), or OFF
  - **Pulse width**—Duration of each pulse in microseconds (µs). The patient experiences pulse width as the strength or coverage of the paresthesia.
  - **Rate**—Frequency of pulses in Hertz (Hz). The patient experiences rate as the smoothness of the paresthesia.
  - **Amplitude**—Strength of pulse in volts (V). The patient experiences amplitude as the strength or coverage of the paresthesia.
- **Optional features**
  - **Cycling**—Cycles the neurostimulator ON and OFF at programmed intervals.
  - **SoftStart/Stop**—Slowly increases the amplitude when the stimulation is turned ON and slowly decreases the amplitude when the stimulation is turned OFF.
  - **Scheduled Therapy**—Turns specific groups ON and OFF at programmed times based on a 24 hour clock.
  - **Patient Control Limits**—Sets upper and lower limits for patient adjustment of parameters.
  - **GroupAdjust**—Allows the patient to increase or decrease all program amplitudes in the active group at the same time.
  - **TARGETmyStim**—Allows the patient to move stimulation settings from electrode to electrode up and down the lead.

myStim groups and programs

A program is a specific combination of pulse width, rate, and amplitude settings acting on a specific electrode combination (up to 16 electrodes per program). A program defines the stimulation pulses that will be delivered for therapy. Multiple programs can be used to maximize pain coverage. When using more than one program, the pulses are delivered sequentially—first a pulse from one program, then a pulse from the next program, and so on (Figure 16). Pulses from different programs are never delivered simultaneously.

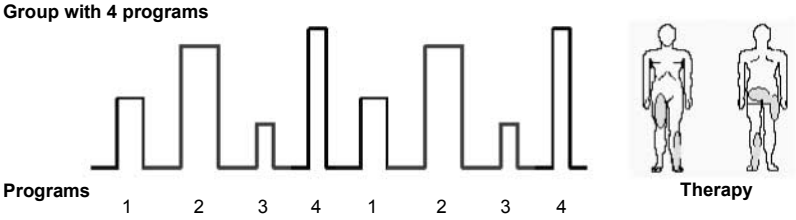


Figure 16. *Using multiple programs within a group to maximize pain coverage.*

Up to four programs can be combined into a myStim group. Each myStim group and its associated programs can be used to provide a therapy for specific areas of coverage or specific patient activities. Pulse width, amplitude, and electrode polarity are programmed separately for each program within a group, that is, each program within the group can have different values. Rate, rate limits, SoftStart/Stop, and cycling are programmed for each group, that is, each program within the group will have the same values. Amplitude and pulse width limits can be programmed for each program in a group. In addition, limits can be globally programmed for all defined groups (ie, the same limits are applied to all programs in all groups).

Groups are designated as A, B, C, etc, on the programmer screen and may be given names based on specific areas of coverage, specific patient activity, or time of use. Programs are designated as , , , and on the programmer screen. A maximum of 26 myStim groups are available for programming. A maximum of 32 programs are available between all groups.

Groups can be active, inactive, defined, or undefined. An active group is the group that is currently providing therapy. There may be other groups available, but they have not been selected—they are inactive. A defined group is a group that has associated programs. An undefined group has no associated programs but is available for creating programs. One or more programs within a group may be stimulating, programmed but not stimulating (amplitude is 0.0 V), or undefined. See "Programming with groups and programs" on page 48 for more information.

High-output interlocks and shared electrodes

High-output interlocks

Certain combinations of high amplitude, pulse width, and rate settings are not allowed by the clinician programmer. High-output interlocks can prevent certain values and features from being available for programming. If you attempt to program a parameter value (or limit) that will cause the settings to exceed the high output interlock limit, the desired parameter value can only be achieved by reducing one of the other parameter values.

Shared electrodes

One electrode may be active in more than one program within a group. When more than one electrode is shared by more than one program, certain restrictions are applied to prevent group rate and pulse width upper limits from exceeding 260 Hz for rate or 450 µs for pulse width. Group rate is calculated by multiplying the rate by the number of programs in that group. Group pulse width is the highest pulse width among all programs in that group.

Programming warnings and cautions

⚠ **Warning:** When a patient's medical condition requires both a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator), physicians involved with both devices (eg, neurologist, neurosurgeon, cardiologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery. To minimize or prevent the effects described below, implant the devices on opposite sides of the body and follow any additional instructions.

- Defibrillation therapy from an implanted defibrillator may damage the neurostimulator.
- The electrical pulses from the neurostimulation system may interact with the sensing operation of 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 Hz. Program the cardiac device to bipolar sensing.

△ **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) 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.
- To prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation):

– program parameter changes in small increments above the perception threshold (the amplitude value[s] at which the patient first perceives paresthesia) while evaluating the patient's response.

– verify that the amplitudes are set to 0.0 V before turning on the neurostimulator.

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 11 on page 18) 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 below the current value, and an arrow appears between the values.

Programming pending values – See 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 (Clear ⚑).

Basic programming steps

Table 5 presents an overview of the basic steps for a typical follow-up programming session. The steps apply for both the implantable neurostimulator (INS) and the external neurostimulator (ENS).

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

Table 5. *Programming process*

	Procedure:	Do this:	Go to page:
	Prepare for the programming session:		
1.	Check the programmer.	• Check/replace programmer batteries. • Ensure that the application card is properly installed.	page 95 page 19
2.	Turn the programmer ON.	• Turn ON the programmer. The APPLICATION SELECTION screen appears.	page 19
3.	Select the NEUROSTIMULATION APPLICATION button.	• The THERAPY DESKTOP screen appears.	page 19
	Review initial programming:		
1.	Interrogate the neurostimulator.	• 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 82
2.	If this is a new patient or if components have been changed, enter patient and component information and configure leads.	• Access the PROFILE menu. • Enter patient information. • Configure the leads. • Enter the lead information. • Enter neurostimulator and implant information. • Set neurostimulator date and time.	page 37
3.	Review patient use data and neurostimulation system information.	• Access the START SESSION menu and select Start Session. • Review patient use information. • Check the Observations box for significant system events that have occurred.	page 40
4.	Ensure that the neurostimulator is ON.	• If the neurostimulator is OFF, hold the programming head steady over the neurostimulator, then select the NEUROSTIMULATOR ON/OFF button.	page 42
	Check system performance:		
1.	Check neurostimulator battery information.	• Access the MEASUREMENT menu and select Battery. • Check the battery level icon (RestoreADVANCED INS and ENS). The icon displayed indicates the battery level status at 100%, 75%, 50%, 25%, or 0%. • Review the neurostimulator service life displayed as OK, ERI, or EOS. • Review the neurostimulator recharge information (RestoreADVANCED INS).	page 45

Table 5. *Programming process (continued)*

	Procedure:	Do this:	Go to page:
2.	Check electrode impedance. **Note: Perform this procedure at the beginning of the session.** These measurements verify the integrity of lead/extension/connector pathways.	• Access the MEASUREMENT menu and select Electrode Impedance. • Select the desired amplitude from the drop-down list. • 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 1 minute. In order to perform measurements, this procedure temporarily reprograms the stimulation settings.	page 42
3.	Check group (therapy) impedance, if desired. **Note: Perform this procedure at the end of the session.** These measurements provide documentation that pathways are intact and the current provided is sufficient for the selected therapy.	• Access the MEASUREMENT menu and select Group Impedance. • Select the desired group from the group selection drop-down list. • While holding the programming head steady over the neurostimulator, select the MEASUREMENT button. • Select the OK button to perform the test. • Review impedance and stimulation current data for the selected group.	page 44
4.	Review patient use information.	• Access the START SESSION menu and select Diary Groups to view patient use data by group. • Access the START SESSION menu and select Diary Days to view patient use data by day. • Access the START SESSION menu, select Diary Days, and select a specific day to review detailed information (eg, stimulation ON, recharge, etc.).	page 41
	Review/modify stimulation parameters (verify that desired program is selected):		
1.	Select a group and a program.	• Access the PROGRAM mySTIM menu and select Program myStim. • Select a group from the group selection drop-down list. • While holding the programming head steady over the neurostimulator, press the PROGRAMMING (P) key or select the ACTIVATE button on the programmer screen to make the group active. • Select a program tab.	page 48
2.	Review/modify electrode polarities.	• Use the stylus to select negative (-), positive (+), or OFF electrode polarities for the selected lead. Turn the SCROLL WHEEL to move electrode polarity assignments up and down on the selected lead(s). • Hold the programming head steady over the neurostimulator, then press the PROGRAMMING (P) key or select the PROGRAM (P) button on the programmer screen. (If desired, select values for rate and pulse width before programming electrode polarities.)	page 51
3.	Review/modify rate and pulse width.	• Select the rate input box, then select a rate. • Select the pulse width input box, then select a pulse width. • 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 52

Table 5. *Programming process (continued)*

	Procedure:	Do this:	Go to page:
4.	Review/modify amplitude resolution and amplitude.	• Select the amplitude input box and select an amplitude resolution setting. • Select the amplitude input box again. • While holding the programming head steady over the neurostimulator, select an amplitude setting. • Continue to hold the programming head steady over the neurostimulator until the amplitude ramps to the target value or the STOP button or the AMPLITUDE TO ZERO button is pressed.	page 53
5.	Review/modify stimulation parameters for additional programs.	• Select another program tab in the same or different group. • Repeat steps 1-4 of this procedure. **Note:** The rate for all programs in a group is always identical.	page 55
6.	If desired, add new groups using AutoFill.	• Access the PROGRAM mySTIM menu and select AutoFill. • Select the group to generate from, the degree of difference, and the number of groups to generate. • 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 56
7.	If desired, set stimulation parameters by adding/modifying programs using stored programs.	• Access the PROGRAM mySTIM menu and select Program myStim. • Select an undefined program tab. • Select Working List, Initial Programs, or Current Programs from the program types drop-down list. • Select a program from the program drop-down list. • Press the PROGRAMMING (P) key or select the PROGRAM (P) button on the programmer screen.	page 57
8.	If desired, identify and refine stimulation parameters using TargetStim.	• Access the PROGRAM mySTIM menu and select TargetStim. • Select a program from the drop-down list or use the SCROLL RIGHT/SCROLL LEFT buttons. • Set or modify electrode polarities as needed. • Set or modify the amplitude as needed. • Use the TARGETSTIM buttons to transition electrodes while asking the patient to provide responses to the stimulation. • Select the OK button.	page 59
9.	If desired, refine stimulation parameters using Optimizer.	• Access the PROGRAM mySTIM menu and select Program myStim. • Select a numbered program tab in the active group. • Select the OPTIMIZER button. • Select an optimization from the drop-down list. • Press the PROGRAMMING (P) key or select the PROGRAM (P) button on the programmer screen. • Select the OK button.	page 62

Table 5. *Programming process (continued)*

	Procedure:	Do this:	Go to page:
10.	If desired, review stimulation parameters for all programs in each group.	• Access the PROGRAM mySTIM menu and select Program myStim. • The stimulation parameters for all programs in the selected group appear on the screen. • Select other groups to review using the group selection drop-down list.	page 49
11.	If desired, estimate battery longevity. **Note:** This procedure is available during new or follow-up test stimulation.	• Access the MEASUREMENT menu and select Battery/ Longevity. • Select a group from the group selection drop-down list. • Select the MEASUREMENT button.	page 46
	Customize device settings: The following parameters and features are optional and are designed to increase patient comfort and ease of use as well as extend neurostimulator battery life and the interval between battery recharges (INS only).		
1.	If desired, review/modify SoftStart/ Stop.	• Access the PROGRAM mySTIM menu and select Limits/ Settings. • Select a group from the group selection drop-down list. • If needed, select the checkbox next to SoftStart/Stop to turn the feature ON. • Select the SoftStart/Stop input box. • Select a value. • Select the OK button. • Hold the programming head steady over the neurostimulator and program the SoftStart/Stop value.	page 67
2.	If desired, review/modify Cycling.	• Access the PROGRAM mySTIM menu and select Limits/ Settings. • Select a group from the group selection drop-down list. • If needed, select the checkbox to turn the feature ON. • Select the Cycling input box. • Select Cycling ON and OFF Time values. • Select the OK button. • Hold the programming head steady over the neurostimulator and program the Cycling values.	page 67
3.	Review/modify patient control limits.	• Access the PROGRAM mySTIM menu and select Limits/ Settings. • From the group selection drop-down list, select a letter for a single group, or select A-Z for all groups. • Select the desired radio button for the desired parameter. • If setting custom limits, select the amplitude limits, pulse width limits, or rate limits input box, then select the upper and lower limits for amplitude, pulse width, or rate. • Hold the programming head steady over the neurostimulator and program the settings.	page 67
4.	If desired, review/modify GroupAdjust.	• Access the PROGRAM mySTIM menu and select Limits/ Settings. • Select A-Z from the group selection drop-down list. • Select the checkbox next to GroupAdjust to turn the feature on. • Hold the programming head steady over the neurostimulator and program the settings.	page 73

Table 5. *Programming process (continued)*

	Procedure:	Do this:	Go to page:
5.	If desired, review/modify TARGETmyStim.	• Access the PROGRAM mySTIM menu and select Limits/ Settings. • Select A-Z from the group selection drop-down list. • Select the TARGETmySTIM button. • Select the applicable group or groups. • Select the OK button. • Hold the programming head steady over the neurostimulator and program the settings.	page 73
	Program Scheduled Therapy events:		
1.	If desired, program times for therapy groups to turn ON and OFF automatically.	• Access the PROGRAM mySTIM menu and select Scheduled Therapy. • If needed, select the SCHEDULED THERAPY checkbox to turn the feature ON. • Drag an event block to the 24 hour calendar. • On the EVENT DETAILS screen, select a group to define the new event and adjust the start and stop times for the event. • Select the OK button. • Create additional scheduled therapy events, or update events, as desired. • Hold the programming head steady over the neurostimulator and program the events.	page 74
	Complete the programming session:		
1.	Review programmed settings.	• Access the END SESSION menu and select End Session. • Access the PROGRAM mySTIM menu and select Program myStim to review the detailed programmed settings.	page 76 page 49
2.	Print report.	• Ensure that the printer is ON. • Access the END SESSION menu and select Print Reports. • Select the desired reports. • Select the PRINT button.	page 77
3.	Exit application.	• Access the END SESSION menu and select Exit. **Note:** To end the patient session without exiting the application, access the END SESSION menu and select End Session, then select the END PATIENT SESSION button ( ). • Select the OK button.	page 81

Entering patient and physician information

The programmer provides two fields for patient information, a drop-down list for patient diagnosis, 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.

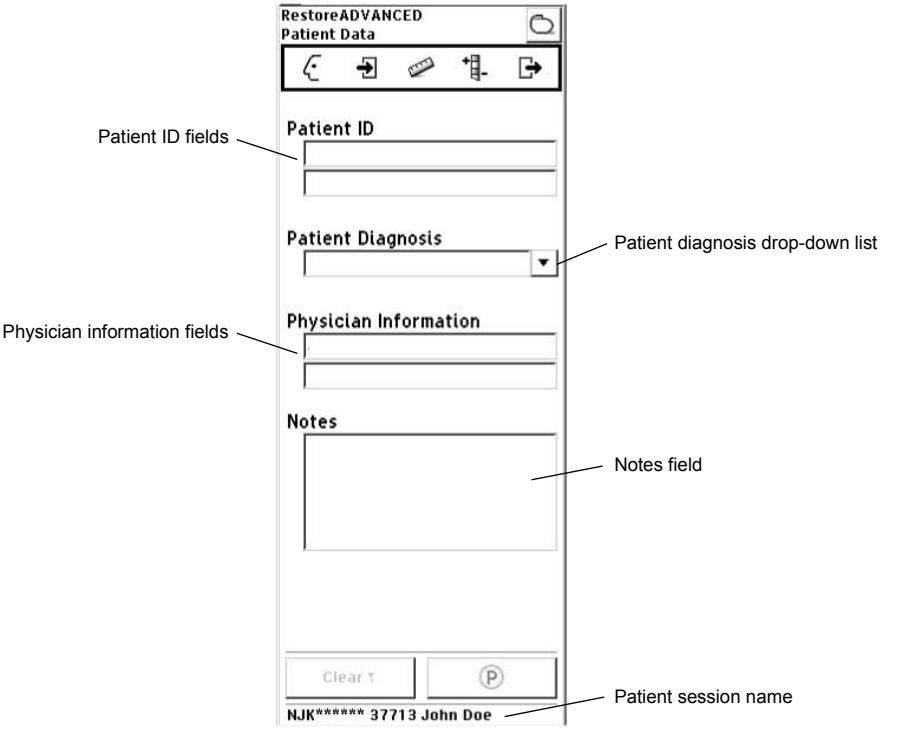


Figure 17. *PATIENT DATA screen.*

2. Enter patient name, ID number, or any other appropriate information in the patient ID fields (Figure 17).

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. Select a patient diagnosis from the drop-down list or enter another diagnosis (Figure 17).

4. Enter physician name and phone number or any other appropriate information in the physician information fields and notes field (Figure 17).

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.

Entering device information

Note: Changing the lead configuration or numbering will delete all groups and programs associated with the current lead configuration.

♦ *To program lead configuration*

1. Access the PROFILE menu ( ) and select Lead Configuration.

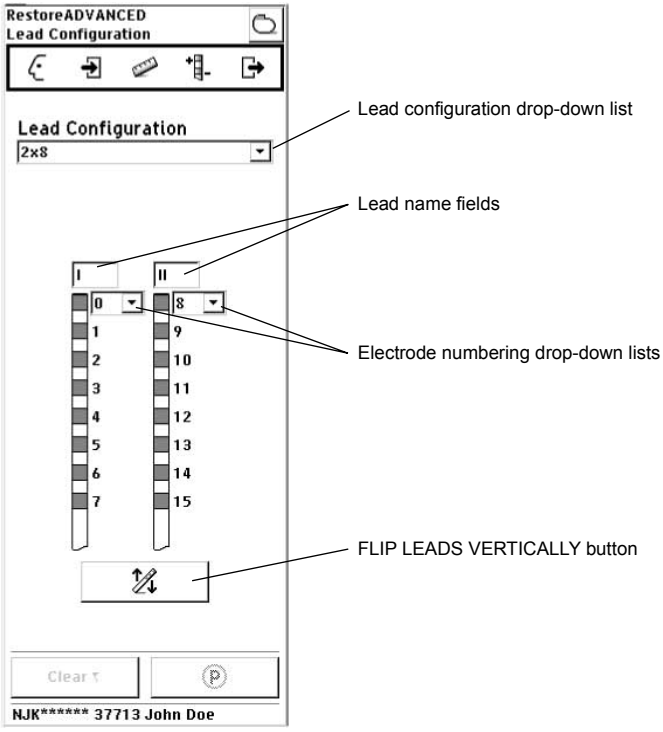


Figure 18. *LEAD CONFIGURATION screen.*

2. Select the appropriate lead configuration from the lead configuration drop-down list (Figure 18).

Note: Configurations in the drop-down list with parentheses around them represent surgical leads. A forward slash "/" indicates the leads are separated in the body and it may not be possible to program them together using the TargetStim feature.

3. If appropriate, enter lead names in the lead name fields (Figure 18).

4. If appropriate, renumber the electrodes using the electrode numbering drop-down list (if lead connection to the neurostimulator is different than pictured).

5. If appropriate, select the FLIP LEADS VERTICALLY button (if lead orientation is different than pictured). The electrodes may also be renumbered from this screen (Figure 18).

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 enter lead model number*

1. Access the PROFILE menu ( ) and select Lead Data.

2. Enter lead model numbers in the lead model number fields.

3. Select the YES button if an extension was used.
4. View the lead orientation and configuration on the screen.
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.

♦ *To enter neurostimulator information*

1. Access the PROFILE menu ( ) and select Device Data.

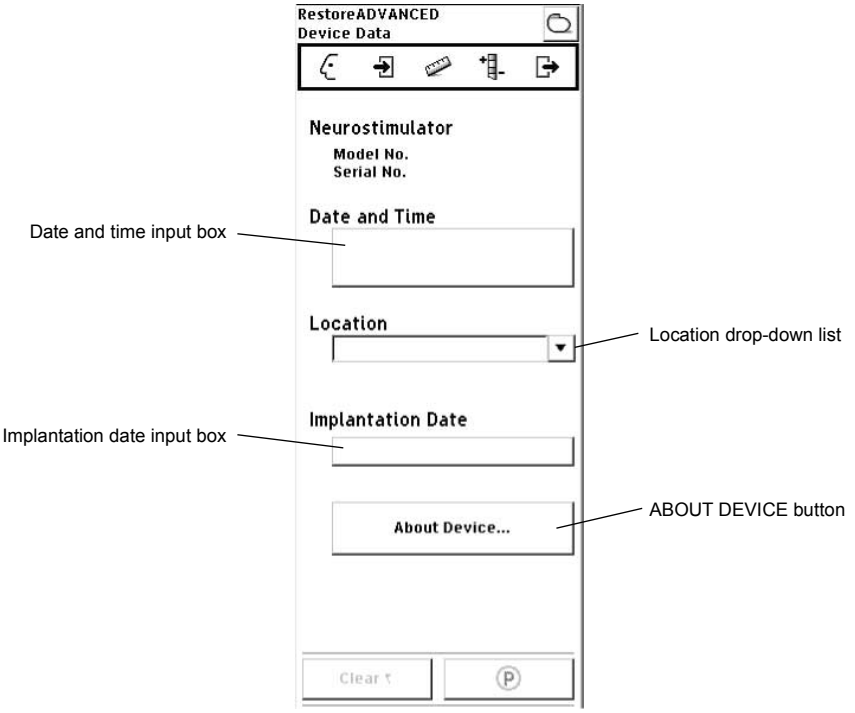


Figure 19. *DEVICE DATA screen.*

2. Select the date and time input field to view the current date and time stored in the neurostimulator (Figure 19). 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 and when activating any stimulation parameters that are scheduled to occur based on a 24 hour period (see "Programming Scheduled Therapy" on page 74).
3. Select the neurostimulator implant location from the location drop-down list or enter another location (Figure 19).
4. Enter the date the neurostimulator was implanted in the implantation date input box (Figure 19).
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 20). The neurostimulator collects patient use data between sessions. The collected data can also be viewed by group and by day.

The neurostimulator collects the data based on the date and time entered on the DEVICE DATA screen (see "To enter neurostimulator information" on page 39). The time can also be changed by the patient with the patient programmer. If a clock change has been programmed by the patient, the clinician programmer displays a caution on the screen that the data might be inaccurate (ie, therapy times are offset because of the clock change).

Note: Patient use information can be viewed throughout the programming session by accessing the START SESSION menu. Programming changes made during the session are not updated on the screens associated with this menu.

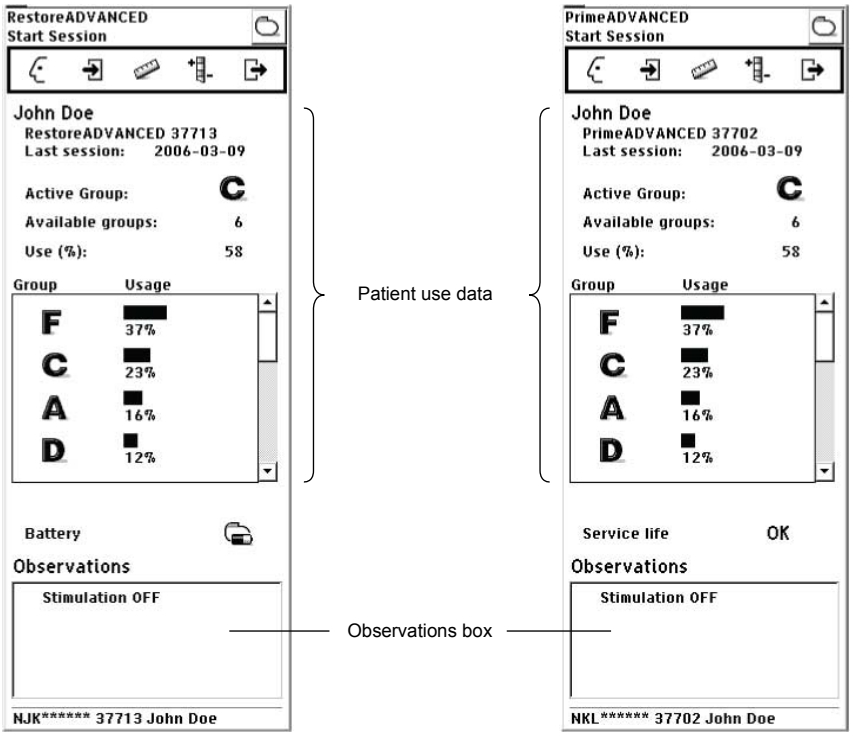


Figure 20. *START SESSION screen.*

♦ *To review patient use data*

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

1. Access the START SESSION menu ( ) and select Start Session.

2. View the following patient use data (Figure 20):
   - **Active group**—the group that is currently providing therapy
   - **Available groups**—the initially interrogated number of groups
   - **Use (%)**—Percentage of neurostimulator ON time since the last follow-up session
   - **Group Usage**—Bar graph presentation of the percentage of neurostimulator ON time for the available groups

♦ *To review neurostimulation system information*

1. Access the START SESSION menu ( ) and select Start Session.
2. Review the Observations box for significant system events that have occurred (Figure 20). The observations are brief notifications (eg, Check INS clock, Stimulation off) that need to be investigated (see Table 11 on page 90).
3. Check the battery level status (RestoreADVANCED INS). The icon displayed indicates the battery level status at 100% ( ), 75% ( ), 50% ( ), 25% ( ), or 0% ( ).
4. Review the implanted neurostimulator battery service life (PrimeADVANCED INS) displayed as:
   - OK
   - ERI (Elective Replacement Indicator)
   - EOS (End of Service)
5. For additional information on checking battery status, refer to "To check neurostimulator battery information" on page 45.

♦ *To view the patient use data by group*

1. Access the START SESSION menu ( ) and select Diary Groups.
2. If desired, select the appropriate button to sort the displayed data by group alphabetically or by percentage used.
3. Review the group use data.

♦ *To view the patient use data by day*

1. Access the START SESSION menu ( ) and select Diary Days.
2. Review the patient use data per day on the collection period calendar.
3. Select a specific day on the calendar to view the patient use data in detail for that day. Events displayed include:
   - Active groups
   - Number of patient adjustments
   - Stimulation ON periods
   - Recharge periods (RestoreADVANCED INS)
   - Low battery periods (RestoreADVANCED INS and ENS)

Turning the neurostimulator ON or OFF

Turning the neurostimulator ON allows the neurostimulator to deliver stimulation to the patient. Before changing any parameters during a session, turn the neurostimulator ON so that the patient can feel the changes being programmed.

Note: Patients with extremely high sensitivity to stimulation may sense the transmission of the telemetry signals.

△ **Caution:** Before turning on the neurostimulator, decrease the amplitude(s) to 0.0 V. Decreasing the amplitude(s) prevents possible uncomfortable or unexpected stimulation (jolting or shocking sensation) when stimulation is turned on.

♦ *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.

Before using any measurement functions, please note the following:

- **Measure electrode impedance at the beginning 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.
- **Measure group (therapy) impedance at the end of each programming session.** These measurements provide documentation the pathways are intact and the current provided is sufficient for the selected therapy.

♦ *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. At the end of the test, the most recently programmed settings are restored.

This procedure tests all unique bipole combinations. The procedure takes approximately 1 minute.

1. Access the MEASUREMENT menu ( ) and select Electrode Impedance.
2. Select an amplitude value from the drop-down list (Figure 21).

   Note: Perform the lead impedance test at the 0.7 V (default) setting. Additional amplitude values are available to confirm test results.

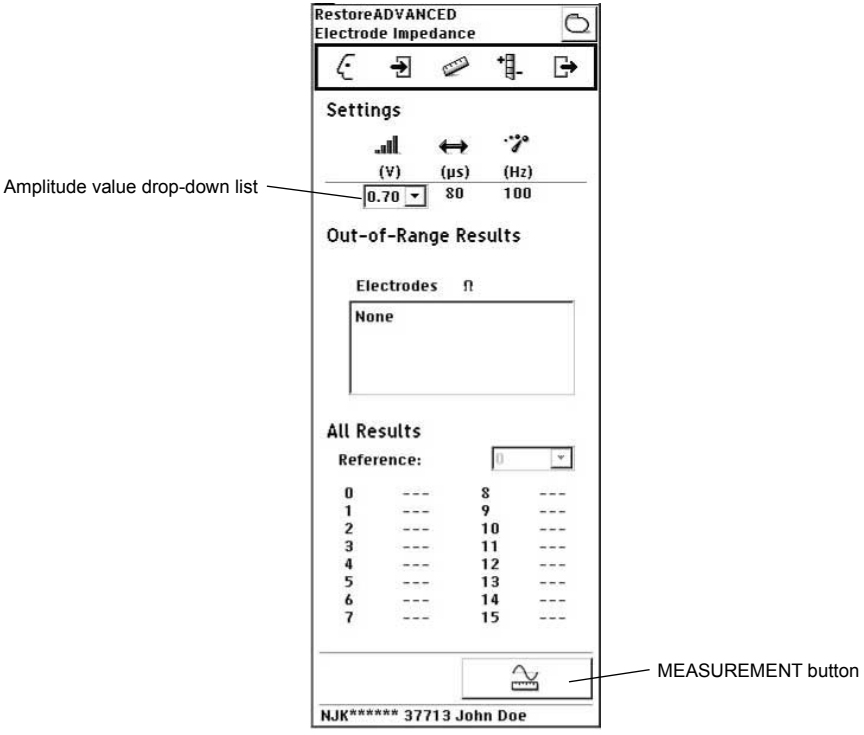


Figure 21. *ELECTRODE IMPEDANCE screen.*

3. Position the programming head over the neurostimulator.
4. Select the MEASUREMENT button (Figure 21).
5. 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.
6. Review the electrode impedance test results.

   Notes:

   - If the test results show high impedance (possible open circuit), confirm the result by performing the test at different voltage settings.

– Test results can be viewed any time during the programming session by returning to the ELECTRODE IMPEDANCE screen.

♦ *To check group (therapy) impedance*

Group (therapy) measurements are impedance and stimulation current measurements taken at the programmed settings for each program in a group.

Notes:

- Under some conditions, such as low amplitudes (less than 0.25 V) or narrow pulse widths, a measurement cannot be obtained.
- You may need to decrease parameters to avoid patient discomfort.
- The neurostimulator reports current measurement values as current delivered during the stimulation pulse instead of current averaged over the rate period. Current measured during the pulse does not change with rate settings and the values are higher than current that is averaged.

1. Access the MEASUREMENT menu ( ) and select Group Impedance.
2. Position the programming head over the neurostimulator.
3. Select a group from the group selection drop-down list (Figure 22).

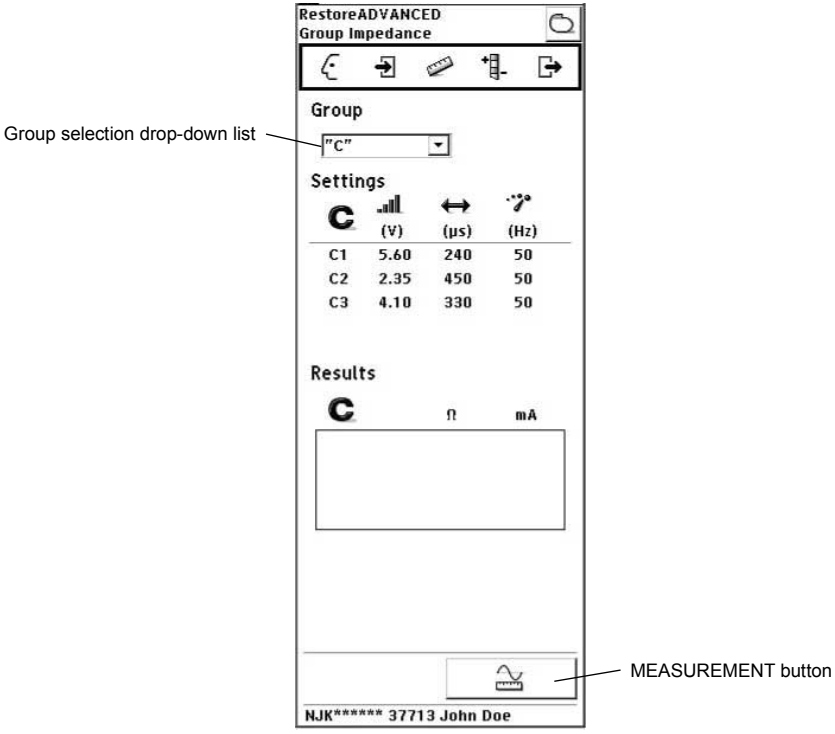


Figure 22. *GROUP IMPEDANCE screen.*

4. Select the MEASUREMENT button (Figure 22).

5. 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 group impedance test, do one of the following:

   - Select the CANCEL button ( ).
   - Push the red THERAPY-STOP key to turn the neurostimulator OFF.

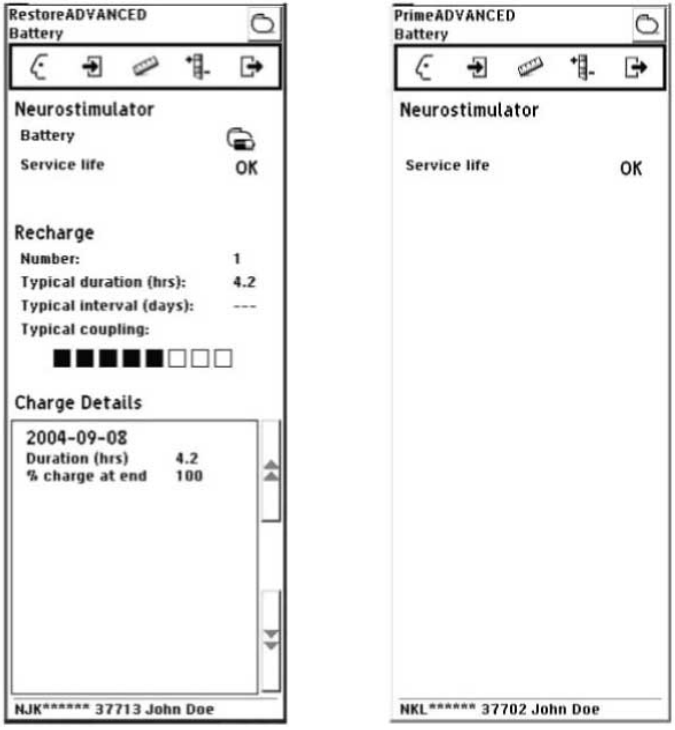
6. Review the group impedance test results.

   Note: Test results can be viewed at any time during the programming session by returning to the GROUP IMPEDANCE screen.

♦ *To check neurostimulator battery information*

At initial interrogation, the neurostimulator battery level status (RestoreADVANCED INS) and service life on the BATTERY screen are updated with the latest test results.

1. Access the MEASUREMENT menu ( ) and select Battery.



RestoreADVANCED PrimeADVANCED

Figure 23. *BATTERY screen.*

2. Check the battery level status icon (Figure 23, RestoreADVANCED INS). The icon displayed indicates the battery level status at 100% ( ), 75% ( ), 50% ( ), 25% ( ), or 0% ( ).
3. Review the implanted neurostimulator battery service life (Figure 23) displayed as:
   - OK
   - ERI (Elective Replacement Indicator)
   - EOS (End of Service)
4. Review the implanted neurostimulator battery recharge information **since the last programming session** (Figure 23, RestoreADVANCED INS):
   - **Number**—Number of recharges
   - **Typical duration (hrs)**—Recharge duration (an extended duration may indicate coupling problems)
   - **Typical interval (days)**—Interval between recharges
   - **Typical Coupling**—Recharge antenna and implantable device couplings performed by the patient. A higher coupling number indicates better positioning and faster, more efficient recharging.
5. Review the details of the charging session (Figure 23, RestoreADVANCED INS):
   - Date of the charging session
   - Duration of the charging session (an extended duration may indicate coupling problems)
   - Battery charge level at the end of the recharging session.

♦ *To estimate battery longevity during test stimulation*

During postoperative test stimulation programming (see "Pain Test Stim postoperative test stimulation (new and follow-up)" on page 26), an estimated time from implant until EOS (End of Service) can be calculated for the current test stimulation settings. This may be useful when programming therapy settings and considering an implanted neurostimulator for your patient.

Notes:

- Estimated longevity is calculated using a group impedance test.
- The battery longevity calculation is available only when a program has been defined (refer to "Programming with groups and programs" on page 48).
- Under some conditions, such as low amplitudes (less than 0.25 V) or narrow pulse widths, a battery longevity calculation cannot be obtained.
- You may need to decrease parameters to avoid patient discomfort. If parameters are adjusted, the longevity calculation will be affected.

1. Access the MEASUREMENT menu ( ) and select Battery/Longevity.

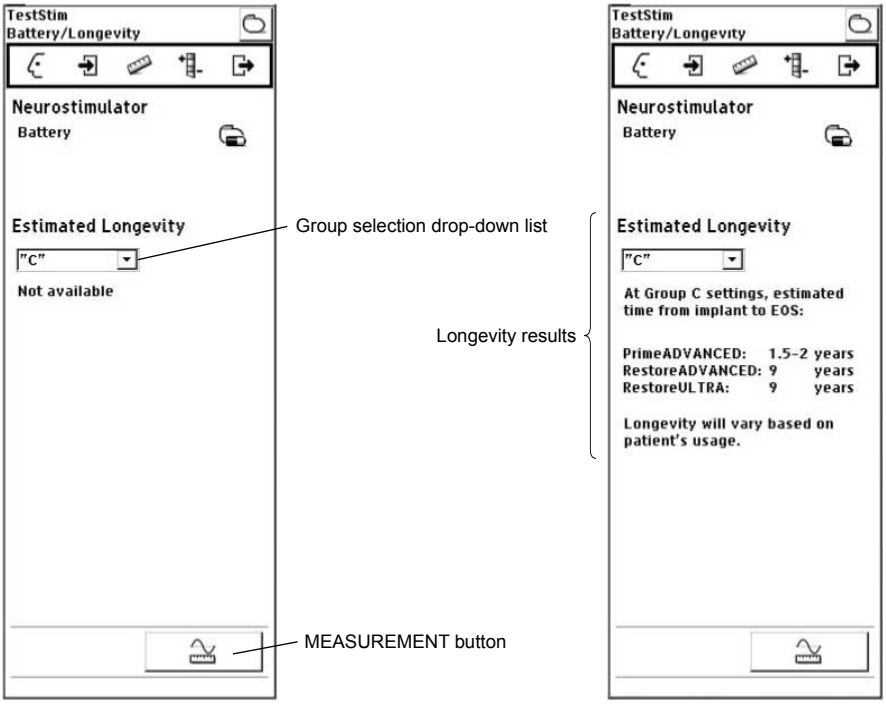


Figure 24. *BATTERY/LONGEVITY screens.*

2. Select a group from the group selection drop-down list (Figure 24).

Notes:

- The group selected can be active or inactive.
- If no groups are defined, the group selection field will be empty.
- "Not available" appears on the screen until the test is run.

3. Select the MEASUREMENT button (Figure 24).

4. Review the longevity test results for the estimated time from implant until EOS (End of Service).

Returning to initial settings during programming

During a programming session, you can reset all parameters to values in effect at the start of the session. If you return to initial settings, however, you will lose all changes made to group and program parameters, including Scheduled Therapy groups, during the session.

♦ *To return to initial settings*

1. Access the PROGRAM mySTIM ( ) menu.

2. Select Initial Settings.

Programming with groups and programs

To program stimulation parameters, a therapy group must be selected and activated. Within an active group, 1 to 4 programs of stimulation may be programmed, with any or all programs in the group providing stimulation. A program provides stimulation when the amplitude is set greater than 0.0 V. See Figure 25 for an example of an active group with programs that could appear on the PROGRAM mySTIM screen.

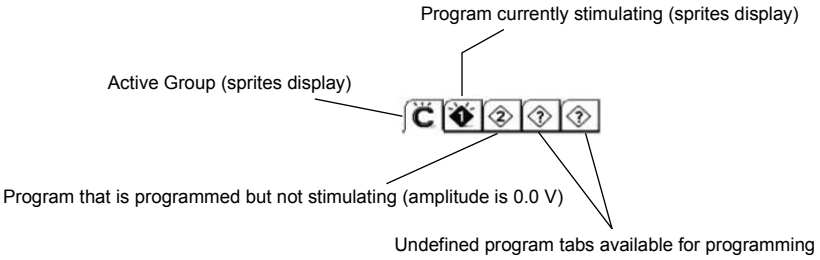


Figure 25. *Active group with programs.*

Notes:

- When the maximum number of programs (between all groups) has been programmed, the remaining program tabs are identified as unavailable with an “X” ( ).
- To program the implanted neurostimulator for the first time, stimulation parameters (except for amplitude) must be programmed in the selected group before the group becomes active. For more information on programming a new group see "Adding groups and programs" on page 55.

♦ *To activate a group and select a program*

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.
2. Select a group from the group selection drop-down list (Figure 26).

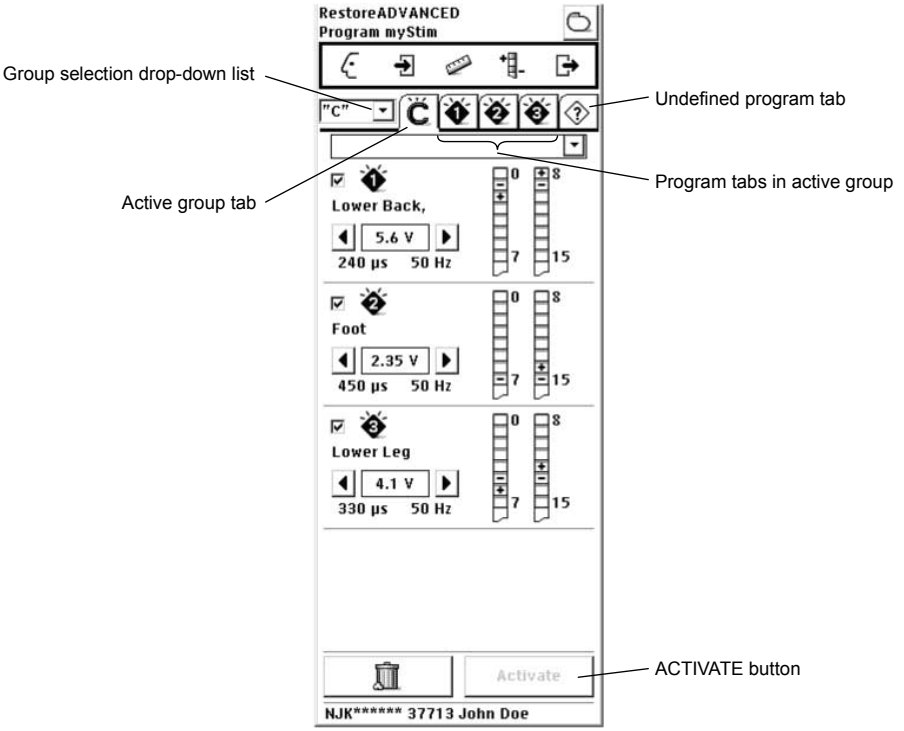


Figure 26. *PROGRAM mySTIM screen.*

3. To activate the group, hold the programming head steady over the neurostimulator, then press the PROGRAMMING (P) key or select the ACTIVATE button on the programmer screen.
4. Select a numbered program tab to modify settings for a program or select an undefined program tab in the group to create a new program (see "Adding groups and programs" on page 55).
5. Select the group tab to return to the active group settings or to select a new group.

   Note: To create or modify programs using stored programs, refer to "Adding/modifying programs using stored programs" on page 57.

Reviewing group settings during programming

You can review stimulation parameter settings for all programs in a group on the PROGRAM mySTIM screen (group tab selected) at any time during programming. The settings on the PROGRAM mySTIM screen are updated throughout the session as programming changes are made.

Note: It is not necessary for the group to be active to view the group parameter settings.

♦ *To review group settings*

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.

2. Select a group (Figure 26 on page 49) from the group selection drop-down list. The selected group letter appears on the group tab.
3. Review the stimulation parameters for all programs in the selected group.
4. To review settings for the programs in another group, select the group from the drop-down list.

♦ *To adjust amplitudes from the group tab*

Note: Amplitude settings can also be adjusted from the program tabs (refer to "To review/modify amplitude resolution and amplitude" on page 53).

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.
2. Select a group from the group selection drop-down list. The selected group letter appears on the group tab.
3. Activate the group by selecting the ACTIVATE button (Figure 26 on page 49).

   Note: The group must be active to adjust amplitude settings.
4. Use the AMPLITUDE ADJUSTMENT buttons to set the desired amplitudes for each program (Figure 27).
5. To turn a program stimulation OFF (amplitude is 0.0 V), select the checkbox next to the program icon so the check mark is removed.

   Note: To reactivate the previous amplitude for the program, select the checkbox again.

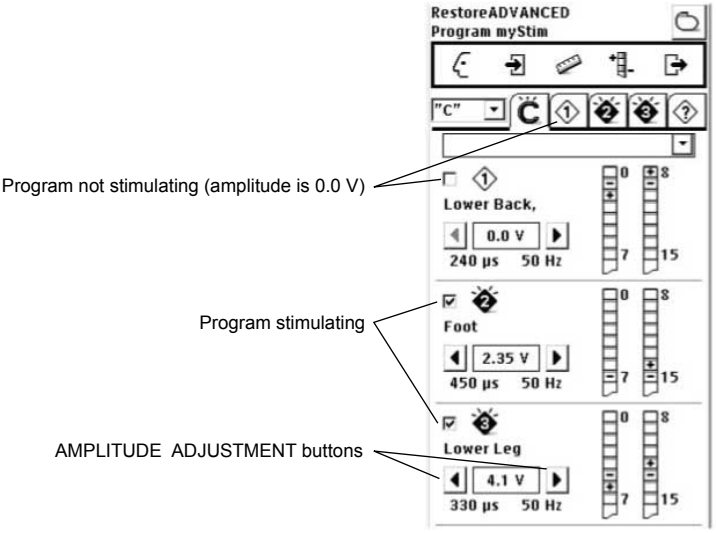


Figure 27. *Adjusting amplitude on the PROGRAM mySTIM screen (group tab selected).*

Reviewing/modifying stimulation parameters

Reviewing and modifying the stimulation parameters includes programming the electrode polarities, pulse width, amplitude resolution and amplitude for each program in a group. Rate is programmed for all programs in a group.

△ **Caution:** To prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation) when stimulation is turned on, program parameter changes in small increments above the perception threshold (the amplitude at which the patient first perceives paresthesia).

Selecting and programming groups and programs – Refer to "Programming with groups and programs" on page 48 when selecting groups and programs to review/modify.

Using the scroll wheel for programming – If desired, the scroll wheel on the clinician programmer can be used to make fine adjustments when programming stimulation parameters. When a stimulation parameter value is selected with the stylus, the SCROLL WHEEL icon ( ) appears next to the selected parameter, indicating the value can be adjusted by the scroll wheel. See further instructions for using the scroll wheel in the sections on reviewing/modifying electrode polarities, pulse width and rate, and amplitude.

♦ *To review/modify electrode polarities*

The neurostimulator is bipolar only (ie, the neurostimulator case is not used as a positive electrode). When programming electrode polarity, electrodes may be programmed +, -, or OFF. The electrode configuration must include at least one positive (+) and one negative (-) electrode.

Notes:

- An electrode may be unavailable for programming (X), if it is shared by more than one program.
- The amplitude automatically changes to 0.0 V when polarities are changed.

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.
2. Select and program a group.
3. Select a program tab in the selected group.

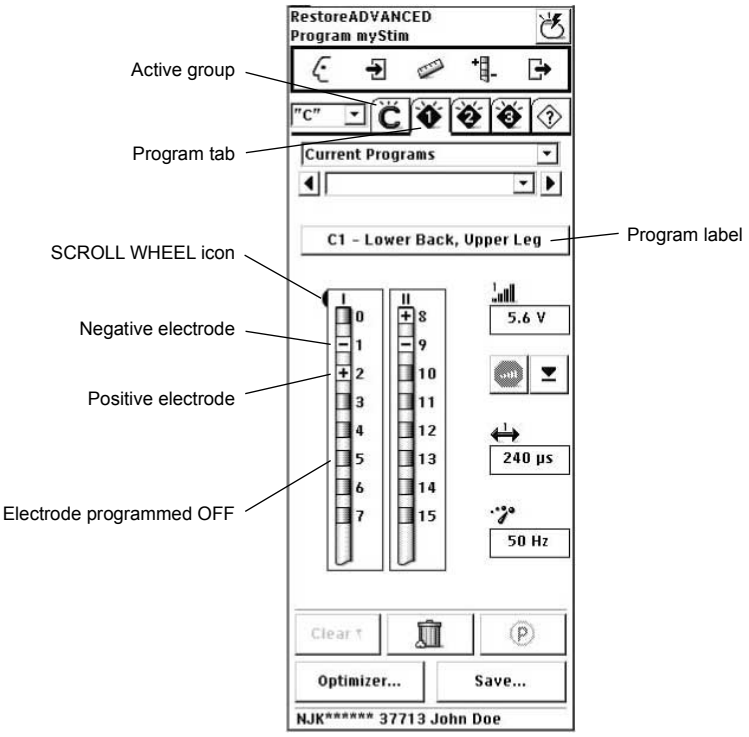


Figure 28. *Programming electrode polarities on a program tab.*

4. Select the electrode -, +, or blank (OFF) options on the lead to be programmed. The SCROLL WHEEL icon appears next to the selected lead input box (Figure 28).
5. If desired, turn the scroll wheel to move electrode polarity assignments up or down one lead at a time or as a pair. To move polarity assignments as a pair, both leads must be selected so the SCROLL WHEEL icon appears next to both input boxes. To deselect one lead from the pair, select a nonelectrode area in the lead input box for the unwanted lead. The SCROLL WHEEL icon disappears.
6. If desired, set other parameters on this screen (refer to "To review/modify the pulse width or rate" on page 52).

   Note: If you are creating a new program, you must select electrode polarities and pulse width and rate values before programming (see "Adding groups and programs" on page 55).
7. 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. The patient experiences pulse width as the strength or coverage of the paresthesia.

Rate is the frequency of pulses in hertz. The patient experiences rate as the smoothness of the paresthesia.

△ **Caution:** To prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation), decrease the amplitude to the perception threshold (the amplitude at which the patient first perceives paresthesia) before changing the pulse width. After changing the pulse width, slowly increase the amplitude.

Note: When using more than one program in a group, the rate is the same for all programs in the group.

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.
2. Select and program a group.
3. Select a program tab in the selected group.
4. Select the pulse width input box or the rate input box (Figure 29).

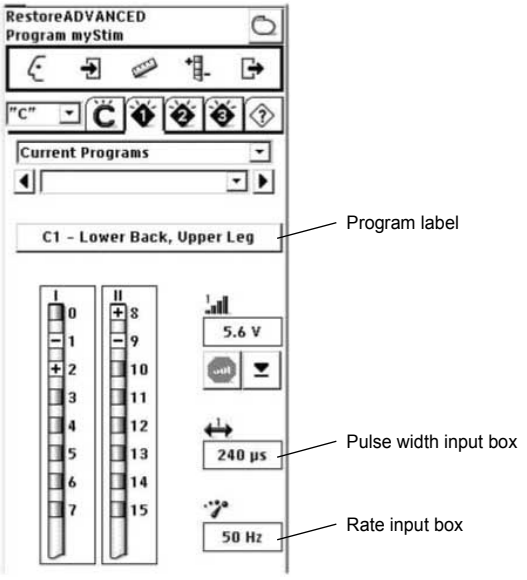


Figure 29. *Programming pulse width or rate on a program tab.*

5. 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.

   Note: Some values may not be available due to high-output interlocks or shared electrodes (page 29).

6. If desired, fine tune the target value by turning the scroll wheel to increase or decrease the target.
7. 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 resolution and amplitude*

Amplitude is the strength of the pulse in volts. The patient experiences amplitude as the strength or coverage of the paresthesia. Amplitude resolution is the size of the incremental or decremental steps during the time that the amplitude is ramping (increasing or decreasing) and when the patient adjusts the amplitude setting with the patient programmer.

Notes:

- To avoid possible sudden unpleasant stimulation for the patient, ensure that the neurostimulator is ON before programming the amplitude.
- Amplitude is automatically programmed when a target value is selected. Ramping to the new value begins immediately. This differs from pulse width and rate programming, which require the clinician to press the PROGRAMMING (P) key or select the PROGRAM (P) button on the programmer screen before the new values take effect.
- Amplitude values may also be modified from the group tab (see "To adjust amplitudes from the group tab" on page 50).

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.
2. Select and program a group.
3. Select a program tab in the selected group.
4. Select the amplitude input box (Figure 30).

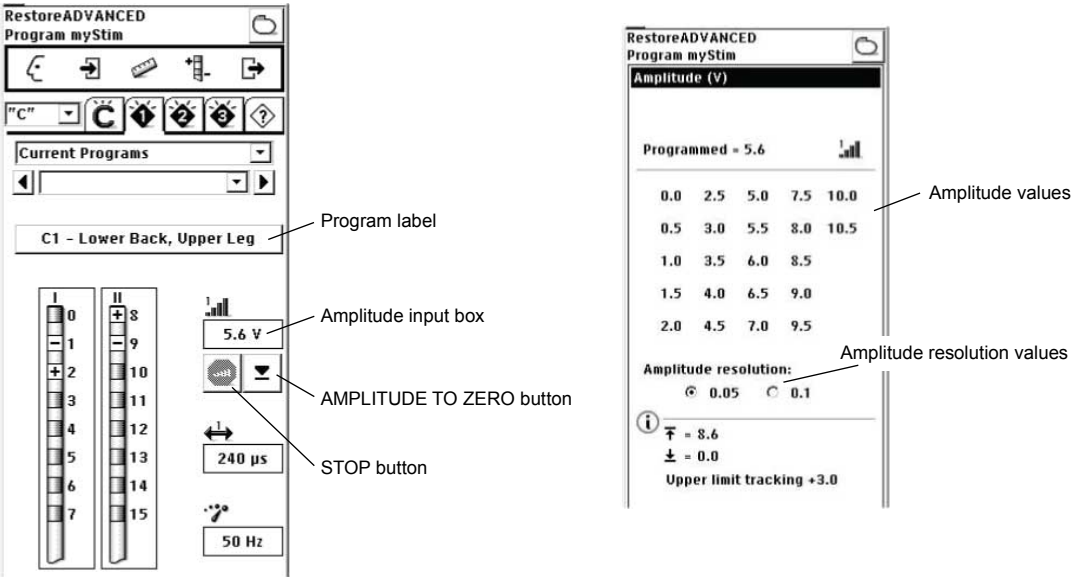


Figure 30. *Programming amplitude and amplitude resolution.*

5. Select an amplitude resolution (Figure 30).
6. Select the amplitude input box again.
7. To set amplitude, hold the programming head steady over the neurostimulator and select a target value from the amplitude values displayed. Ramping to the target value begins immediately, and the input box displays an arrow pointing from the actual value to the target value.

Notes:

- If desired, fine tune the target value by turning the scroll wheel to increase or decrease the target.

- To stop the amplitude while it is ramping, select the STOP button or depress the scroll wheel.
- To immediately set the amplitude to zero (0.0 V), select the AMPLITUDE TO ZERO button.
- To go directly to the target amplitude, select the PROGRAM (P) button on the programmer screen or PROGRAMMING key while the amplitude is ramping.

Adding groups and programs

To provide additional therapy options for your patient, you may wish to add new groups or to add new programs to existing groups. New groups can be undefined (programs are undefined) or defined and created from a previously programmed group. Adding defined groups provides an efficient method to assemble multiple new groups (see "Generating new groups using AutoFill" on page 56).

♦ *To add and activate a new undefined group*

1. Access the PROGRAM mySTIM menu ( ) and select New Group.

   Note: Alternatively, select Program myStim, then select New from the group selection drop-down list.

2. Select an undefined program tab (Figure 31).

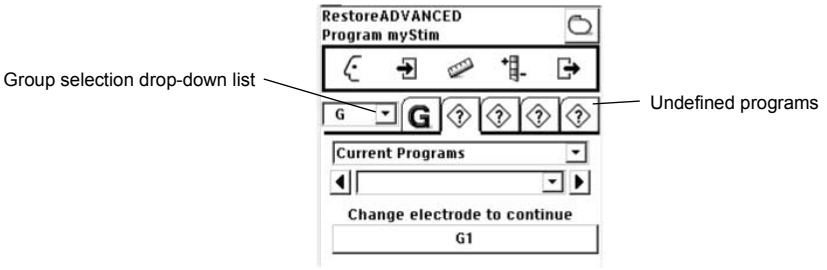


Figure 31. *Creating a new undefined group.*

3. Select values for electrode polarities, pulse width, and rate.
4. To activate the group and program the new stimulation settings, hold the programming head steady over the neurostimulator, then press the PROGRAMMING (P) key or select the PROGRAM (P) button on the programmer screen.
5. Select an amplitude value.

♦ *To add new programs to an existing group*

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.
2. Select and program a group (refer to "Programming with groups and programs" on page 48).
3. Select an undefined program tab in that group (Figure 31).
4. Select values for electrode polarities and pulse width.

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.
6. Select an amplitude value.

Generating new groups using AutoFill

To provide additional therapy options for your patient, you may wish to add new groups created from a previously programmed group. AutoFill provides an efficient method to assemble multiple, new groups.

Note: All new groups generated have program amplitudes set at 0.0 V.

♦ *To add and activate new groups*

1. Access the PROGRAM mySTIM menu ( ) and select AutoFill.

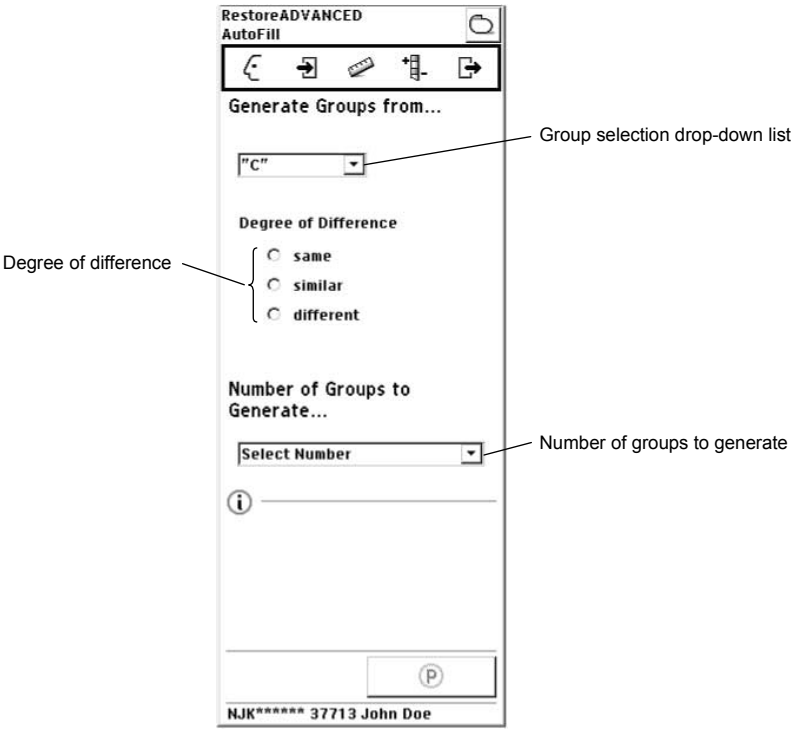


Figure 32. *Creating new defined groups using AutoFill.*

2. Select the starting group from the group selection drop-down list (Figure 32).
3. Select the degree of difference for the electrode patterns (rate and pulse width are unchanged) (Figure 32). The following options are available:
   - **same**—The generated group(s) will be identical to the starting group.

- **similar**—The generated group(s) will be created using the Optimizer algorithm to provide new electrode patterns.
- **different**—The generated group(s) will be created using the Optimizer algorithm to provide new electrode patterns. Selecting this option generally provides the highest degree of difference in electrode patterns.

4. Select the number of groups to generate using the drop-down list (Figure 32).

   Note: The number of new groups that can be generated may vary based on the number of programs currently programmed. A maximum of 32 programs are available between all groups.

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.
6. Review the informational message that appears on the screen.

Adding/modifying programs using stored programs

Programs retrieved from the neurostimulator at the start of a programming session or programs created during the current session may be recalled to quickly assemble new programs. See Table 6 for a description of the types of programs available.

Table 6. *Program types*

Program type	Definition
Initial programs	The programs retrieved from the neurostimulator at the start of the session
Current programs	All programs as currently programmed during the session
Working lists	Saved programs created during a session. These programs are deleted at the end of a programming session.

♦ *To add/modify programs using stored programs*

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.
2. Select and program a group (refer to "Programming with groups and programs" on page 48).
3. To add a new program, select an undefined program tab in the group (Figure 33). To modify a program, select a numbered program tab in the group.
4. Select one of the program types (refer to Table 6) from the first drop-down list on the PROGRAM mySTIM screen (Figure 33).

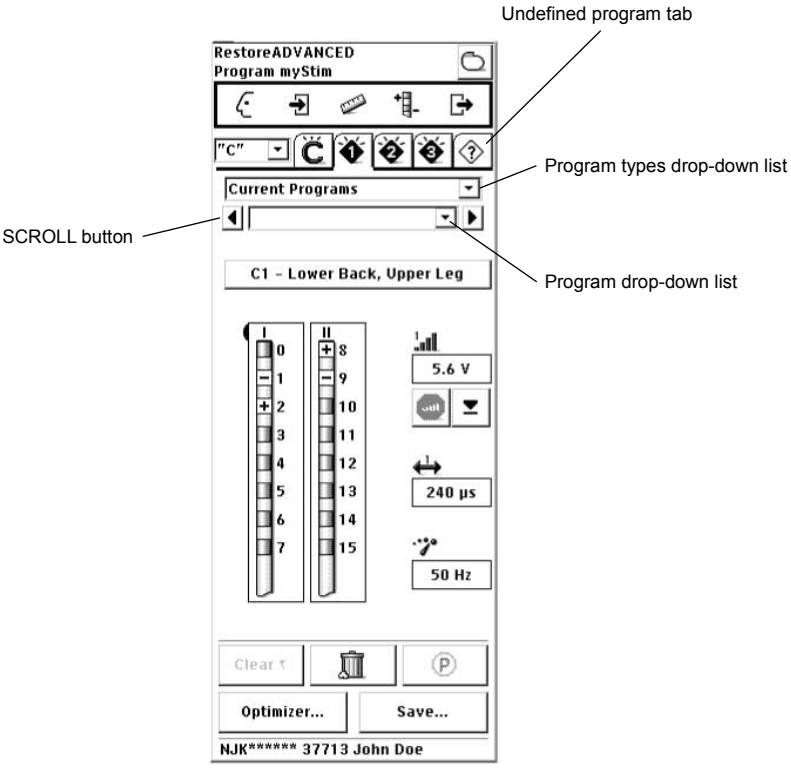


Figure 33. *Using stored programs.*

5. From the second drop-down list on the screen, select a program (Figure 33). The SCROLL RIGHT/ SCROLL LEFT buttons provide an alternative method to view and select a program.

Notes:

- Only programs that have the same lead configuration as the interrogated neurostimulator are available in the drop-down lists.
- The settings for the selected program are displayed.
- The rate setting will be the same for all the programs in the group. The rate setting may change depending on whether the imported program is the first in the group and on how many programs are in the group.

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 save programs to the Working List*

During a programming session, you may wish to save newly created or modified programs to the Working List. These programs are saved in the Model 8840 Clinician Programmer and are available for use until the end of the programming session.

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.
2. Select and program a group (refer to "Programming with groups and programs" on page 48).
3. Select a numbered program tab or an undefined program tab.
4. Adjust the parameter settings for that program.

   Note: Amplitude value cannot be 0.0 V.
5. Select the SAVE button to label the new program and save it to the Working List.
6. Label the new program.
   a. Select a percentage rating indicating the effectiveness of the program, according to the patient, from the rating list box.
   b. Select the body location that the program is stimulating or the activity being done from the drop-down list.
   c. Select the bilateral spread checkbox, and set the percentage rating for bilateral stimulation. Use the SCROLL LEFT or SCROLL RIGHT buttons or the selection bar to select the appropriate values.
7. Hold the programming head steady over the neurostimulator, then select the OK button ( ) to save the newly labeled program to the Working List.

Programming using TargetStim and Optimizer

TargetStim and Optimizer provide optional, advanced methods of adding programs to groups and refining stimulation settings.

TargetStim transitions electrode patterns by using interleaved pulses and ramping amplitude to locate effective therapy. It can be used to quickly identify and refine therapy settings during intraoperative test stimulation, or it can be used to refine therapy settings during follow-up sessions.

Optimizer can be used to quickly refine programs using variations of the initial program electrode settings.

♦ *To create/modify programs using TargetStim*

TargetStim is available for groups and programs that meet the following criteria:

- The electrode pattern for the program must be able to move up and down the lead.
- There must be at least 1 undefined program.
- The group pulse width (sum of all pulse widths in the group) must not exceed 450 µs.

- The group rate (rate multiplied by the number of programs in the group) must not exceed 260 Hz.

1. Select and program a group (refer to "Programming with groups and programs" on page 48) or go to next step if using TargetStim with no groups currently defined.

2. Access the PROGRAM mySTIM menu ( ) and select TargetStim. The TARGETSTIM screen is displayed.

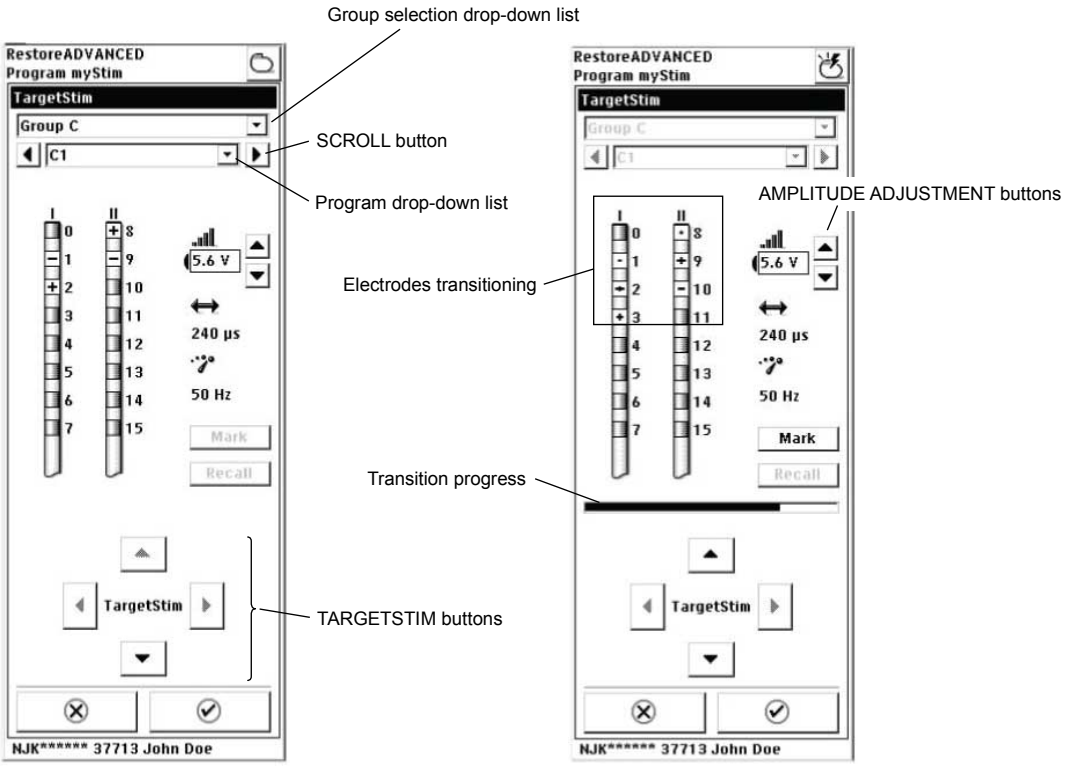


Figure 34. *Using TargetStim.*

3. Select a group from the group selection drop-down list (Figure 34).

   Note: If no groups are currently defined, New Group appears in the group selection drop-down list, and default settings for rate (50 Hz) and pulse width (450 µs) will be applied. Amplitude will be set to zero (0.0 V).

4. Hold the programming head steady over the neurostimulator while performing the remaining programming functions.

5. From the second drop-down list on the screen, select a program (Figure 34). The SCROLL RIGHT/ SCROLL LEFT buttons provide an alternative method to view and select a program.

Notes:

- If no groups are currently defined, “New Program” will appear with gray text in the drop-down list indicating that option is not available for the current function. Electrodes will need to be programmed.
- If a group is defined and New Program is selected, a default pulse width (450 µs) will be applied. Amplitude will be set to zero (0.0 V) and the rate will be applied from the group. Electrodes will need to be programmed.
- If a group is defined and a program is selected, rate, pulse width, and amplitude will be applied from the group selected and the program will be providing stimulation at the programmed settings.

6. Set or modify electrode polarities as needed. Select the electrode , +, or blank (OFF) options on the lead to be programmed.
7. Set or modify the amplitude as needed. Use the scroll wheel or the AMPLITUDE ADJUSTMENT buttons (Figure 34) while asking the patient to provide responses to the stimulation.

   Note: The amplitude will be set to zero (0.0 V) if the neurostimulator is turned OFF.
8. Use the TARGETSTIM buttons (Figure 34) to transition the electrodes while asking the patient to provide responses to the stimulation.

   △ **Caution:** To prevent or minimize uncomfortable or unexpected stimulation (jolting or shocking sensation):

   - wait for the patient’s response to stimulation changes while transitioning electrodes.
   - if the patient experiences uncomfortable stimulation, decrease the amplitude, reverse the electrode transition, or turn the neurostimulator off.

   Notes:

   - The transition progress bar fills to indicate status. When the electrodes are fully transitioned, the bar fills and disappears.
   - Depending on the lead configuration selected and the status of the electrodes (ie, fully transitioned + / -), the TARGETSTIM buttons are enabled or disabled and transitioning the electrodes is possible up, down, or across the leads.
9. If desired, use the MARK button to save an effective therapy setting and continue transitioning the electrodes.

   Notes:

   - The RECALL button returns to the last therapy setting marked.
   - Ensure either the OK button () or the CANCEL button () is selected once TargetStim is initiated. Programmed SoftStart parameters can change during TargetStim use.
10. Select the OK button () to activate the group.

    Note: The patient will feel a change in therapy immediately when you activate the group.
11. If the selected stimulation is a combination of two programs, a message appears (Figure 35).
    a. Evaluate the patient’s response to each of the options by selecting the radio button to activate each option.

b. Select the radio button next to the preferred option.

c. Select the OK button ( ).

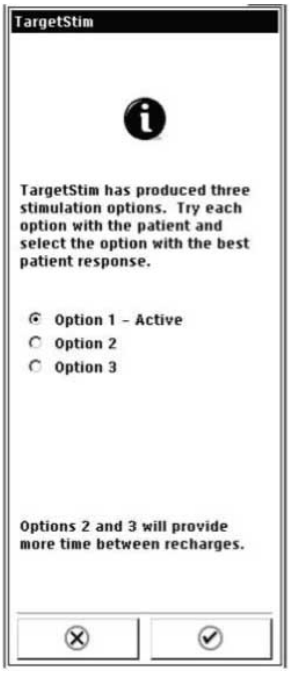


Figure 35. *TARGETSTIM OPTIONS screen.*

♦ *To refine programs using Optimizer*

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.
2. Select and program a group (see "Programming with groups and programs" on page 48).
3. Select a numbered program tab in the active group.

   Note: The selected program will become the initial program in the optimization drop-down list.
4. Select the OPTIMIZER button (Figure 36).

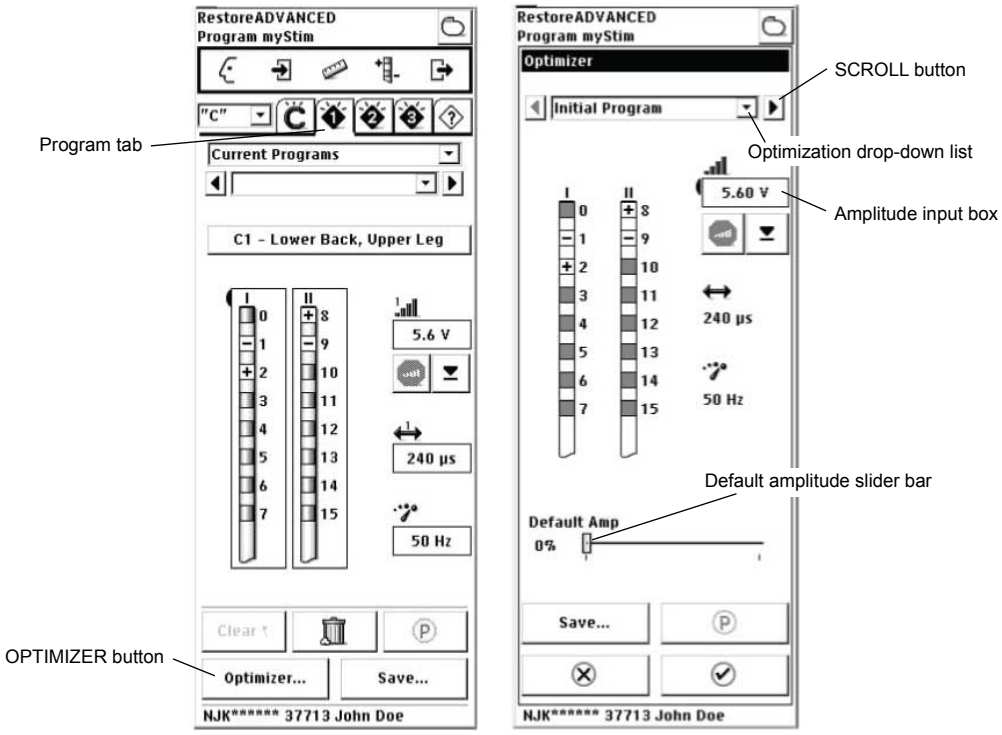


Figure 36. *Using Optimizer.*

5. Slide the default amplitude slider bar to the desired setting (Figure 36).

Note: The default amplitude setting is a percentage (0%–100%) of the Initial Program amplitude value and establishes a starting amplitude value for the optimized program.

6. If desired, select the amplitude input box to modify the amplitude setting (see "Reviewing/modifying stimulation parameters" on page 51).

7. Select an optimization from the optimization drop-down list (Figure 36). The SCROLL RIGHT/ SCROLL LEFT buttons provide an alternative method to view and select an option.

Notes:

- Some optimizations may not be available (X) due to shared electrodes within the selected group.
- The pending values for electrode settings and amplitude are displayed as each option is selected. Review all settings and verify that they are appropriate for your patient.

8. Hold the programming head steady over the neurostimulator, then press the PROGRAMMING (P) key or select the PROGRAM (P) button on the programmer screen.

Note: The pending values for the electrode settings and amplitude become the new settings for the optimized program.

Naming a group

Groups are designated as A, B, C, etc, on the programmer screen and may be given names based on specific areas of coverage, specific patient activity, or time of use. Group names selected during programming will be available to the patient as icons or text when they use their patient programmer.

Notes:

- This programming feature is not available during intraoperative screening or test stimulation.
- At least one program must be defined to use this feature.

♦ *To name a group*

1. Access the PROGRAM mySTIM menu () and select Program myStim.
2. Select a group from the group selection drop-down list.
3. Activate the group (if needed) by selecting the ACTIVATE button (refer to "To activate a group and select a program" on page 48).
4. Select a name (icon with text) for the group from the group name drop-down list. The name selected for the group appears on the screen.

Note: The patient programmer allows the patient to select how the group name is displayed on the patient programmer screen (text, icon, or letter). Refer to the manual packaged with the patient programmer for more information.

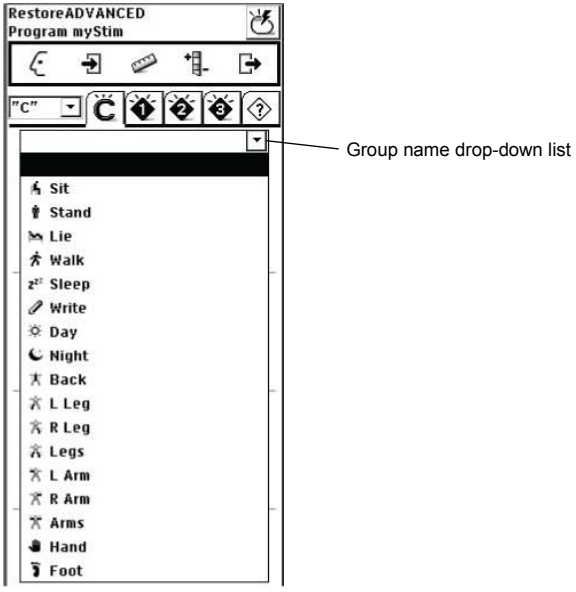


Figure 37. *Naming a group.*

Deleting groups and programs

♦ *To delete a group*

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.
2. Select a group from the group selection drop-down list.
3. Select the DELETE button ( ).

Notes:

- When a group is deleted, all programs in the group are deleted, and the group is removed from the scheduled therapy groups event table and the group selection drop-down list.
- When a group is deleted, its associated letter becomes available for creating a new group.

♦ *To delete a program in a group*

1. Access the PROGRAM mySTIM menu ( ) and select Program myStim.
2. Select and program a group (refer to "Programming with groups and programs" on page 48).
3. Select the numbered tab for the program you want to remove.

4. Select the DELETE button ( ).

   Note: If the deleted program was the only remaining program in the group, the group will be deleted also.

5. Select the OK button ( ).

Customizing device settings

The SoftStart/Stop and Cycling features located on the LIMITS/SETTINGS screen are optional. These features are designed to increase patient comfort and ease of use as well as increase device longevity (PrimeADVANCED INS) or extend the interval between necessary charges (RestoreADVANCED INS). Programmed settings for these features are the same for all programs in a group. These features can be programmed for each individual group, or the features can be programmed for all existing and new groups using the A-Z group selection.

Note: The screens presented in this manual are representative of specific Medtronic neurostimulator applications. Features represented may not be available with all external neurostimulator models during test stimulation or with all implantable neurostimulator models during programming.

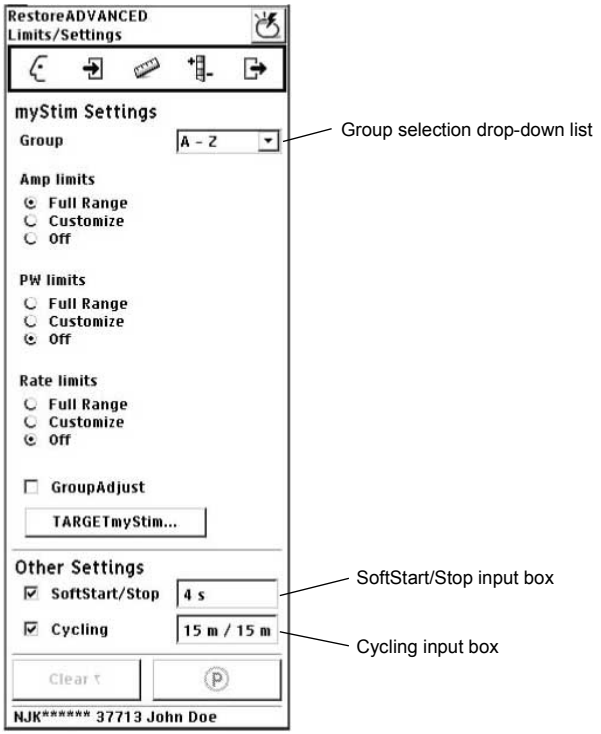


Figure 38. *Programming SoftStart/Stop and Cycling.*

♦ *To review/modify SoftStart/Stop*

SoftStart/Stop slowly increases the amplitude when the neurostimulator is turned ON and slowly decreases the amplitude when the neurostimulator is turned OFF. The slow ramping may feel more comfortable to sensitive patients.

1. Access the PROGRAM mySTIM menu ( ) and select Limits/Settings.
2. To program SoftStart/Stop for a specific group, select a group from the group selection drop-down list, or select A-Z to program SoftStart/Stop for all existing and new groups (Figure 38).
3. Select the checkbox next to SoftStart/Stop to enable the feature (if it is not currently active).

   Note: To disable SoftStart/Stop, deselect the checkbox and go to step 6.
4. Select the SoftStart/Stop input box (Figure 38).
5. Select a setting, then select the OK button ( ).
6. Hold the programming head steady over the neurostimulator.
7. Select the PROGRAM button ( ).

♦ *To review/modify Cycling*

Cycling turns the neurostimulator ON and OFF at clinician-determined intervals (eg, 0.1 second to 30 minutes). Cycling may increase device longevity (PrimeADVANCED INS) or extend the interval between necessary charges (RestoreADVANCED INS). Due to a carryover effect, the patient may continue to experience symptom suppression during the Cycling OFF time.

1. Access the PROGRAM mySTIM menu ( ) and select Limits/Settings.
2. To program Cycling for a specific group, select a group from the group selection drop-down list, or select A-Z to program Cycling for all existing and new groups (Figure 38 on page 66).
3. Select the checkbox next to Cycling to enable the feature (if it is not active).

   Note: To disable Cycling, deselect the checkbox and go to step 6.
4. Select the Cycling input box (Figure 38 on page 66).
5. Use the selection bar or arrow buttons to select the Cycling ON TIME and the Cycling OFF TIME, then select the OK button ( ).
6. Hold the programming head steady over the neurostimulator.
7. Select the PROGRAM button ( ).

Programming a neurostimulator for patient control

Patient control limits for amplitude, pulse width, and rate are set by the clinician and programmed to the neurostimulator before the patient leaves the clinic. The patient uses a patient programmer to adjust the stimulation parameter values within the clinician-set limits. If appropriate for the patient, the group adjust feature (GroupAdjust) can be enabled to allow the patient to increase or decrease all program amplitudes in the active group at the same time. Also, if appropriate for the patient, TARGETmyStim can be enabled to allow the patient to move stimulation settings from electrode to electrode up and down the lead.

Note: The patient can use the patient programmer to reset stimulation parameters to the original clinician settings.

To program the ranges in which a patient can adjust the amplitude, pulse width, and rate, you must set an upper limit value and a lower limit value for each stimulation parameter. For amplitude and pulse width, program upper and lower limits individually for each program in a group. Rate limits, however, are always programmed for all programs in a group. Limits can be set for active or inactive groups.

Limits can be set for individual groups or globally programmed for all defined groups using the A-Z group selection (ie, the same limits are applied to all programs in all groups). Three limit types are available for each stimulation parameter (Table 7).

Table 7. *Limit types*

Limit type	Definition
Full Range	If this limit type is selected, the patient is able to adjust the value for the selected stimulation parameter within the entire range provided by the neurostimulator.
Customize	If this limit type is selected, clinician-set limits (custom or tracking) are programmed. The patient is able to adjust the selected stimulation parameter within these limits.
Off	If this limit type is selected, the patient is not able to adjust the value for the selected stimulation parameter.

When using the A-Z group selection, **all limits for all groups are changed at once**, and the settings apply to existing and new groups.

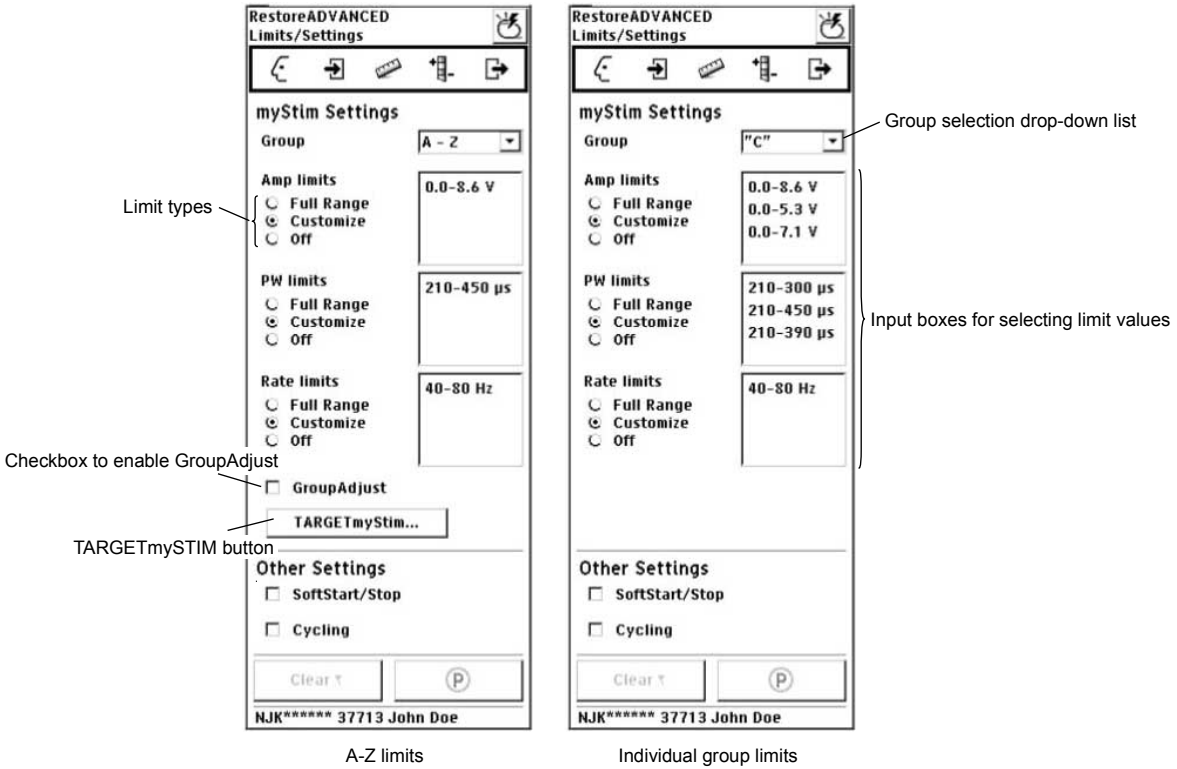


Figure 39. *Programming patient control limits.*

If clinician-set limits are programmed (CUSTOMIZE radio button selected), the following options are available:

Upper limits – To set upper limits you may choose one of two programming options:

- Tracking upper limit—adjusts with changes made to the stimulation parameter value (eg, amplitude) during a session.
- Custom upper limit—fixed regardless of changes made to the stimulation parameter (eg, amplitude) during a session.

Both of these programming methods result in fixed final upper limit values for the patient when the session is ended.

Lower limits – To set lower limits you are only allowed a custom limit selection. The lower limit may be set from the lowest available value to the programmed value for amplitude, pulse width, or rate.

Note: In order to enable TARGETmyStim, the amplitude lower limit must be set to 0.0 V.

△ **Cautions:**

- Program the lower limit for amplitude to 0.0 V. If the patient cannot set the amplitude to 0.0 V, the patient may experience uncomfortable or unexpected stimulation (jolting or shocking sensation) when stimulation is turned on.
- If using custom limits, set these limits as the final programming step. Setting custom limits before the final step may cause an upper limit to be inadvertently increased to a higher setting, which may result in unexpected stimulation to the patient.

♦ *To set limits for all groups*

A-Z is the default group selection when the LIMITS/SETTINGS screen is first displayed. If using the A-Z group selection, the following items apply:

- The limit settings will be programmed for all existing and new groups, and all programs within each group will have the same set limit values.
- **All limits for all groups are changed at once.**
- Limits for a specific, individual group can be set later to override the A-Z limits.

1. Access the PROGRAM mySTIM menu () and select Limits/Settings. The LIMITS/SETTINGS screen is displayed (Figure 39 on page 69).
2. Select A-Z from the GROUP SELECTION drop-down list (Figure 39 on page 69).
3. Select the CUSTOMIZE radio button for the desired parameter (amplitude limits, pulse width limits, or rate limits).
4. Select the entry from the input box. The AMP LIMITS screen, PW LIMITS screen, or RATE LIMITS screen appears (Figure 40).

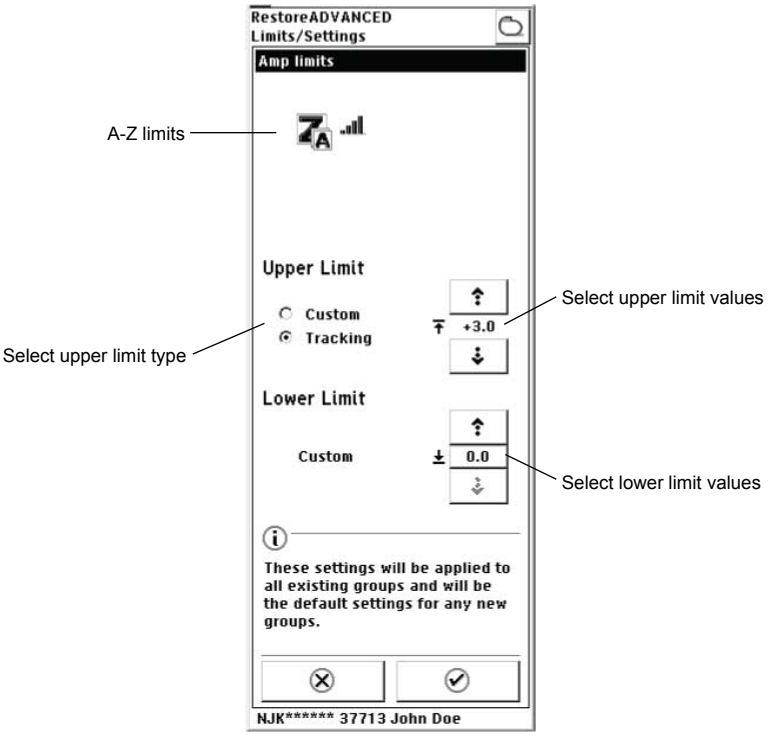


Figure 40. *Programming A-Z limits (AMP LIMITS screen shown).*

5. Select values for the upper limit (tracking or custom) and lower custom limit (amplitude lower limit should be set to 0.0 V).
6. Select the OK button ( ).
7. Hold the programming head steady over the neurostimulator and select the PROGRAM button ( ).

♦ *To set amplitude or pulse width limits for a single group*

Note: When programming limits for individual programs in a group, there are 3 options:

- **Full Range**—you cannot select specific values for limits.
- **Customize**—you may select either custom or tracking for the upper limits, and you may select different values for each program.
- **Off**—you cannot set any limits.

1. Access the PROGRAM mySTIM menu ( ) and select Limits/Settings.
2. Select a group from the group selection drop-down list (Figure 39 on page 69).
3. Select the appropriate radio button for amplitude limits or pulse width limits (Figure 39 on page 69).
4. If you selected the CUSTOMIZE radio button, select the specific values for the limits:

a. Select an entry from the amplitude limits input box or the pulse width limits input box (Figure 39 on page 69). The AMP LIMITS screen or the PW LIMITS screen appears (Figure 41).

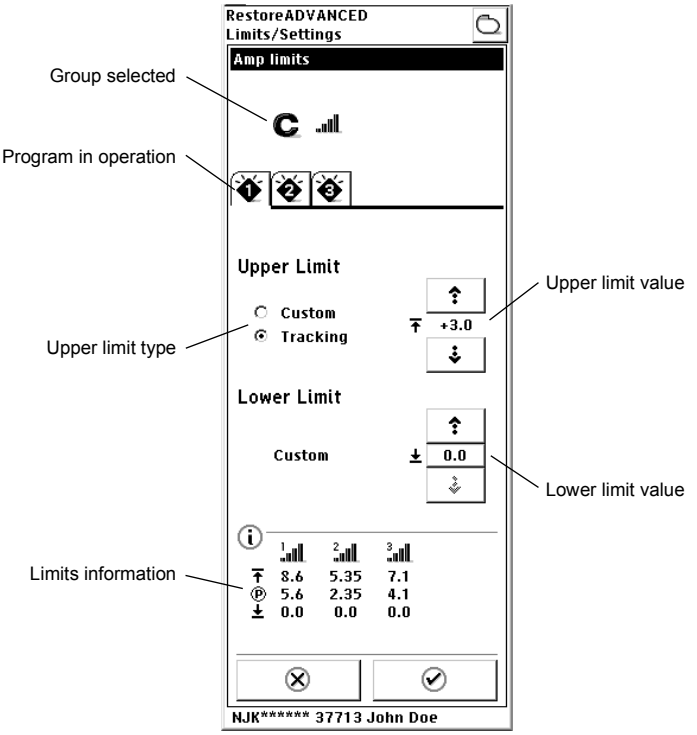


Figure 41. *Programming individual program limits.*

b. Select values for the upper limit (tracking or custom) and lower custom limit (amplitude lower limit should be set to 0.0 V) (Figure 41).

Note: The limits are displayed in the information area of the screen.

c. Select the OK button ( ).

5. Hold the programming head steady over the neurostimulator and select the PROGRAM button ( ).

♦ *To set rate limits for a single group*

Note: The rate is the same for all programs in a group. You cannot program rate for individual programs.

1. Access the PROGRAM mySTIM menu ( ) and select Limits/Settings.

2. Select a group from the group selection drop-down list (Figure 39 on page 69).

3. Select the appropriate radio button for rate limits (Figure 39).

4. If you selected the CUSTOMIZE radio button, select the specific values for the limits:

a. Select the entry from the rate input box for the rate. The RATE LIMITS screen appears.

b. Select values for the upper limit (tracking or custom) and lower custom limit.

Note: The limits are displayed in the information area of the screen.

c. Select the OK button ( ).

5. Hold the programming head steady over the neurostimulator and select the PROGRAM button ( ).

♦ *To enable GroupAdjust*

If appropriate for the patient, the group adjust feature can be enabled to allow the patient to increase or decrease all program amplitudes in the active group at the same time.

1. Access the PROGRAM mySTIM menu ( ) and select Limits/Settings.
2. Select A-Z from the group selection drop-down list.
3. Select the checkbox next to GroupAdjust (Figure 39 on page 69) to enable the feature (if it is not active).
4. Hold the programming head steady over the neurostimulator and select the PROGRAM button ( ).

♦ *To enable TARGETmyStim*

1. Access the PROGRAM mySTIM menu ( ) and select Limits/Settings.
2. Select A-Z from the group selection drop-down list.
3. Select the TARGETmySTIM button (Figure 39 on page 69).
4. Select a group or groups from the TARGETmySTIM screen (Figure 42).

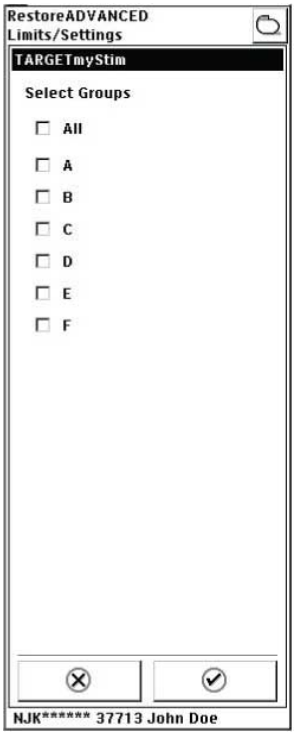


Figure 42. *TARGETmySTIM screen.*

5. Select the OK button ( ).

6. Hold the programming head steady over the neurostimulator and select the PROGRAM button ( ).

Programming Scheduled Therapy

Therapy groups can be scheduled to activate and deactivate at specific times during a 24 hour period. Each activation and deactivation of a group is called an event. Up to 8 scheduled events may be programmed.

Note: Scheduled Therapy operation will be suspended at the beginning of a patient session to prevent scheduled therapy changes from occurring during the session. When the session is exited, Scheduled Therapy operation resumes.

♦ *To schedule a new event*

1. Access the PROGRAM mySTIM menu ( ) and select Scheduled Therapy.

2. Select the Scheduled Therapy checkbox (Figure 43) to enable the feature (if Scheduled Therapy is not active).

Note: To disable Scheduled Therapy, deselect the checkbox and go to step 8.

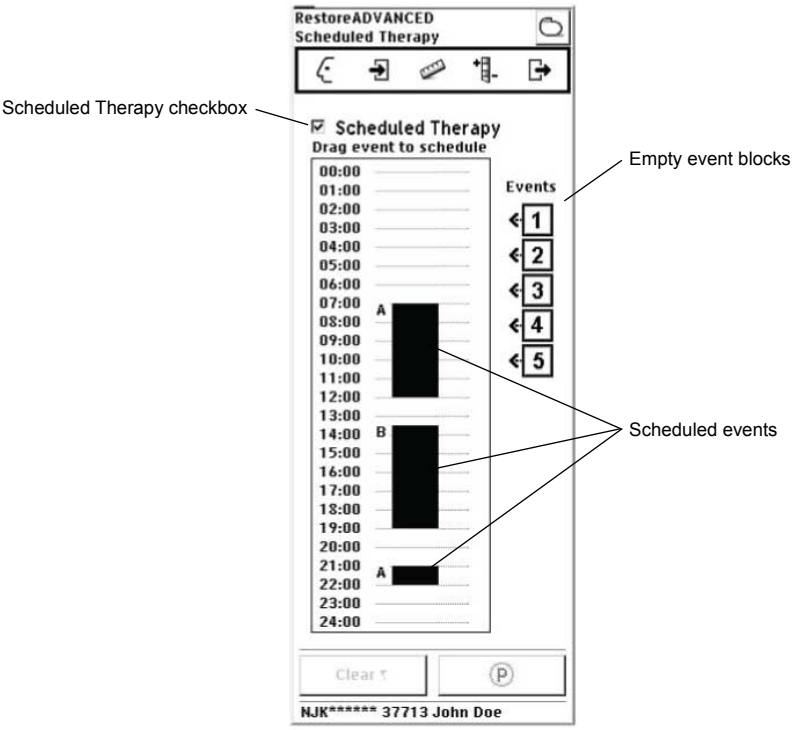


Figure 43. *Programming Scheduled Therapy.*

3. To create a new scheduled therapy event, drag an empty event block to the 24 hour event table that displays all scheduled events (Figure 43). The EVENT DETAILS screen appears.
4. Select a group from the group selection drop-down list on the EVENT DETAILS screen.
5. Use the INCREASE and DECREASE buttons to set the scheduled therapy ON and OFF times.

   Note: The application prevents overlapping scheduled events by using the end of the previous event and the start of the next event to adjust event blocks appropriately.
6. Select the OK button ( ) to place the new event(s) on the event table.
7. Drag additional empty event blocks to the event table, as desired, and repeat steps 4-6.
8. 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 modify a therapy event*

1. Access the PROGRAM mySTIM menu ( ) and select Scheduled Therapy.
2. Select a scheduled event on the 24 hour event table (Figure 43 on page 75). The EVENT DETAILS screen appears.

3. Use the INCREASE and DECREASE buttons to modify the scheduled therapy ON and OFF times, or use the group selection drop-down list to change the group for that time period.
4. Select the OK button ( ) to place the new event(s) on the event table.
5. Select additional scheduled events, as desired, and repeat steps 3 and 4.
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 delete a therapy event*

1. Access the PROGRAM mySTIM menu ( ) and select Scheduled Therapy.
2. Select a scheduled event on the 24 hour event table (Figure 43 on page 75). The EVENT DETAILS screen appears.
3. Select the DELETE button ( ).
4. Select the OK button ( ).
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.

Completing the programming session

♦ *To review programmed settings*

A summary of neurostimulator settings programmed during the session are displayed on the END SESSION screen. Details of the settings are displayed on the PROGRAM mySTIM screen.

1. Access the END SESSION menu ( ) and select End Session.
2. Review settings on the END SESSION screen (Figure 44).

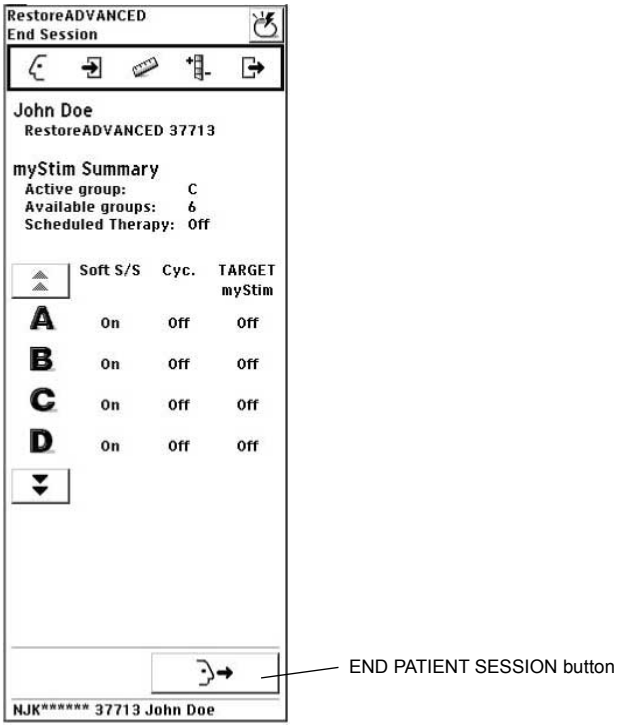


Figure 44. *END SESSION screen.*

3. To review detailed settings, access the PROGRAM mySTIM menu ( ) (see "Reviewing group settings during programming" on page 49).

   Note: Always check the patient control limit settings on the LIMITS/SETTINGS screen prior to the patient leaving the office.

4. To correct settings or make changes, access the PROGRAM mySTIM menu ( ).

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, depending on whether data exist for the report:

- **Summary report**—neurostimulator data and history (this report is always available as indicated by the check mark by the title)
- **Groups report**—group and program information
- **Measurements report**—results from the electrode impedance test and group impedance test
- **myStim Diary report**—group use data since the last session

- **Working List report**—information on all programs in the Working List
- **Patient report (for the patient)**—information on patient settings, available patient limits, and Scheduled Therapy
- **MDT Data report**—data that can be provided to Medtronic Technical Services (this report is a separate file in the Session Data Manager)
- **All Reports**—all reports are selected for printing

Reports selected to be printed after a patient session are saved as a single report 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. 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 SESSION DATA MANAGER button ( ) from the slider bar. The SESSION DATA MANAGER screen appears (Figure 45).

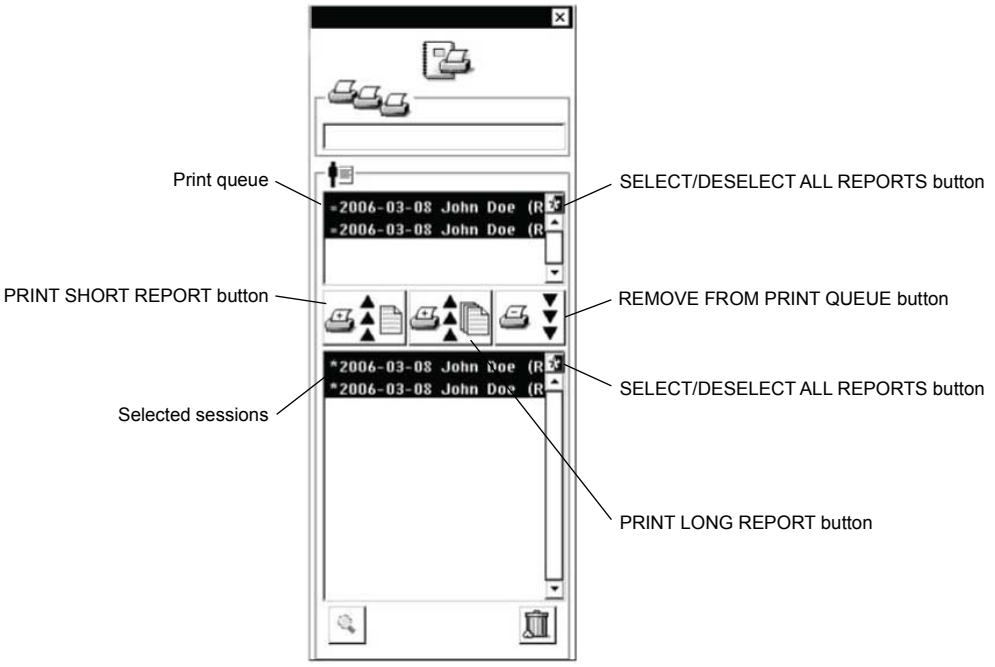


Figure 45. *SESSION DATA MANAGER screen.*

6. Select an individual report to print by highlighting the report or print all reports by selecting the SELECT/DESELECT ALL REPORTS button ( ).
7. 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

   Notes:

   – The long report includes all reports selected using the print later option; the print short report option includes the summary report only.
   – The MDT Data 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 50 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 46 on page 80):

- 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.

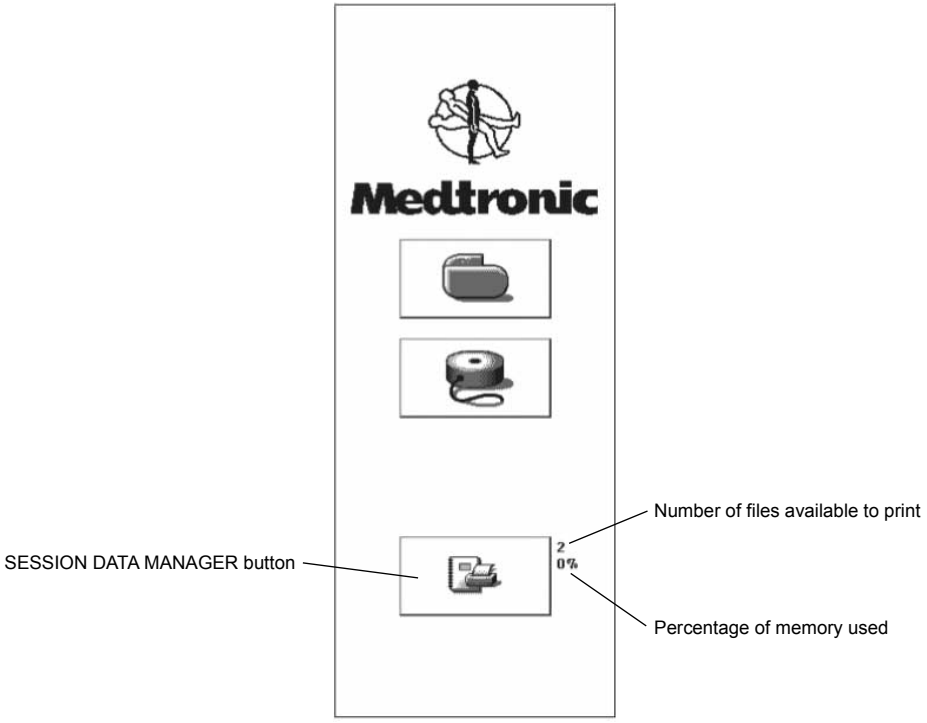


Figure 46. *APPLICATION SELECTION screen.*

♦ *To delete patient session files*

1. Select the SESSION DATA MANAGER button (Figure 46) from the APPLICATION SELECTION screen or the slider bar (Figure 4 on page 11).
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.

Ending the current patient session

You can end the current patient session without exiting the application entirely. When you end the current patient session, the session settings are saved to a session data file and can no longer be updated.

♦ *To end the current patient session*

1. Access the END SESSION menu ( ) and select End Session.
2. Select the END PATIENT SESSION button ( ).
3. Select the OK button ( ).

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*

1. Access the END SESSION menu ( ) and select Exit.
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 8. *Quick reference troubleshooting guide*

Problem	Possible solution	In this manual, go to
• The power is ON, but there is no display. • The programmer cannot be operated. • Touchscreen does not respond.	• Turn the programmer OFF, then ON again. • Install new AA batteries in the programmer. Ensure the batteries are properly installed. • Calibrate touchscreen.	page 42 page 95 page 96
• Telemetry is interrupted or not initiated.	• Ensure that the application card is correctly inserted. • Check the battery status. • See the telemetry failure checklist.	page 19 page 11 page 82
• Power to the programmer is suddenly interrupted.	• Install new AA batteries in the programmer.	page 95
• 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 96 page 78
• Telemetry cannot be established.	• See the telemetry failure checklist.	page 82
• 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 22
• An error message or icon appears on the display.	• See instructions in the error and informational messages section.	page 85

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 85 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 42). The values listed below may help to further define the system problem.

- For an open circuit (broken wire, loose connection, highly resistive tissue), check for impedance as follows:
  - At 0.25 V: >4000 ohms
  - At 0.7 V: >10000 ohms
  - At 1.5 V: >20000 ohms
  - At 3.0 V: >40000 ohms
- For a short circuit (crossed wires, significant stimulation current), check for impedance as follows:
  - At 0.25 V: <50 ohms
  - At 0.7 V: <50 ohms
  - At 1.5 V: <50 ohms
  - At 3.0 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 95). 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.

Physician Recharge Mode (RestoreADVANCED Neurostimulator)

If the patient allows the implanted neurostimulator to overdischarge, telemetry is no longer available from the neurostimulator. The patient will not be able to charge the neurostimulator battery using the charging system.

The patient must return to the clinic, and the physician must charge the neurostimulator battery using the Physician Recharge Mode on the recharger. Typically, the neurostimulator will return to normal charging mode in less than 60 minutes. If it does not, the process should be repeated. If the neurostimulator cannot be charged, it must be replaced.

Notes:

- If the battery is successfully recharged, it regains functionality but may require more frequent charging sessions by the patient.
- The neurostimulator battery can be restored with the Physician Recharge Mode only twice. If the battery is allowed to overdischarge a third time, the neurostimulator will reach end of service.

♦ *To perform a physician charging session*

1. Palpate the patient's skin to determine the best location for the charging antenna, and place the antenna over the neurostimulator.
2. Simultaneously press and hold down the START key and AUDIO key located on the front of the recharger (Figure 47) for 10 seconds. A screen with a 60 minute timer will appear, and charging begins.

Figure 47. *Recharger.*

3. Continue charging until the recharger displays a new screen indicating the neurostimulator battery charge level and charging efficiency (Figure 48).

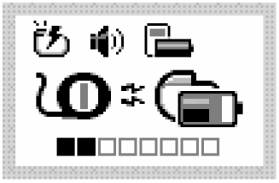


Figure 48. *Screen displaying charge level and charge efficiency.*

4. Repeat steps 1-3 if the new screen does not appear within 60 minutes.
5. Use the clinician programmer to check settings and to turn stimulation ON.

Error and informational messages

The clinician programmer displays text (Table 9 below and Table 11 on page 90) and iconic (Table 10 on page 90) error and informational messages. The patient programmer displays messages that may require patients to contact their physicians (Table 12 on page 92).

Note: Before referring to Table 9, ensure that you have gone through the "Telemetry failure checklist" on page 82.

Table 9. *Error and informational messages*

Message	Explanation
APPLICATION CARD MISSING	When the application card is removed the current session

Table 9. *Error and informational messages (continued)*

Message	Explanation
The application card has been removed. Exit application.	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 been stopped because of an error. Contact Medtronic Technical Services: Service Code: _____	There is a problem with the application. An unrecoverable software error has occurred. Contact Medtronic with the service code.
BATTERY WARNING The programmer batteries are low. Turn the programmer OFF. Replace batteries now.	The programmer batteries are low and may not last an entire programming session. Replace the batteries before starting a session.
BATTERY WARNING Neurostimulator batteries are depleted. Replace batteries now. Exit application.	The ENS batteries must be replaced now for the ENS to function properly.
BATTERY WARNING Neurostimulator battery is discharged. Exit application.	Therapy from the neurostimulator is no longer available (PrimeADVANCED INS).
BATTERY WARNING Neurostimulator battery is discharged. Charge battery now. Exit application.	Neurostimulator battery must be charged now. Therapy from the neurostimulator is no longer available (RestoreADVANCED INS).
CONFIGURATION CHANGE All groups and programs associated with current configuration will be deleted. Press OK to change configuration.	Changing lead configuration will delete all device and session information associated with the current lead configuration.
DELETE GROUP Select OK to delete this group.	Deleting the group will delete the group and all programs associated with the group. If the group is active, it will also be deleted from the device.
DELETE PROGRAM Select OK to delete this program.	If this is the only program in a group, deleting this program will delete the program and the group from the device and the group list.
DELETE EVENT Select OK to delete this event from schedule.	Selecting OK will delete this event from the Scheduled Therapy 24 hour event table.
DEVICE NOT SUPPORTED	This device cannot be programmed by the clinician

Table 9. *Error and informational messages (continued)*

Message	Explanation
Detected device is not supported by this version of application card. Contact Medtronic technical services.	programmer using this version of the application card.
DEVICE NOT SUPPORTED This neurostimulator was last programmed with an incompatible version of the application card. Press Cancel to exit the application and contact Medtronic technical services or press OK to clear all settings and start session.	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.
DEVICE NOT SUPPORTED The detected device is not supported by this application card. Refer to the technical manual for a listing of supported devices. Press OK to end this session.	The device cannot be programmed by this clinician programmer. A new application card must be obtained.
END SESSION Select OK to end session.	Selecting OK will end this patient session without exiting the application.
EXIT APPLICATION Select OK to exit application.	Selecting OK will end this patient session. The application will return to the THERAPY DESKTOP screen.
HIGH PULSE WIDTH Higher pulse widths are unavailable because programs share 2 or more electrodes.	When more than 1 program within a group uses the same electrode, certain restrictions are applied to prevent the highest pulse width of the group from exceeding 450µs.
INITIAL SETTINGS Press OK to reset all parameters to values in effect at start of session.	Initial settings are the settings observed on the PROGRAM mySTIM screen at the beginning of the current session. Returning to initial settings will delete any values that were changed or are pending in the current session.
INVALID ELECTRODE Electrode configuration must include at least one positive (+) and one negative (-) electrode.	An invalid electrode setting exists. Electrode configuration must be changed to a valid setting before continuing.
INVALID SETTINGS Invalid settings have been detected. All settings will be cleared.	Device cannot be programmed using the detected settings. Selecting OK will clear the settings, and you will be required to reprogram the device.

Table 9. *Error and informational messages (continued)*

Message	Explanation
MEASUREMENT SETTINGS All electrode pairs will be tested. Stimulation will change to the following settings during this measurement: Press OK to start measurement.	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.
MEASUREMENT SETTINGS Notify patient that stimulation may change during this measurement. Press OK to start measurement.	During the group (therapy) impedance measurement, stimulation may change to the parameter values for each program as the impedance is measured for the group. This will affect patient stimulation while the test is in progress.
OUT-OF-REGULATION The delivered amplitude may be lower than the programmed amplitude for the indicated programs because of low impedance.	Adding electrodes lowers the lead impedance and makes it harder to deliver the desired voltage.
POWER ON RESET Power on reset has occurred. Session will restart.	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: _____
PRINTER STATUS Printing in progress. Position the programmer with the printer to begin or resume printing.	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.
RATE REDUCED Rate has been reduced to stay within maximum system capability.	Certain combinations of high amplitude, pulse width, and rate settings are not allowed because of high-output interlock limits. The desired parameter value can only be achieved by reducing one of the other parameter values. In this case rate has been reduced automatically.
SESSION DATA MANAGER Session data manager is full. Press OK 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. Records must be deleted before more records can be added.

Table 9. *Error and informational messages (continued)*

Message	Explanation
SESSION INTERRUPTED Another programmer has communicated with the neurostimulator. Exit application.	A different programmer has communicated with the neurostimulator and could have changed settings.
SHARED ELECTRODE This electrode is unavailable because of high pulse width or rate settings.	Certain restrictions are applied to prevent the highest group pulse width or the group rate (rate multiplied by the number of programs in the group) from exceeding 450µs or 260 Hz. If the values are high, then additional electrodes are unavailable.
TARGETmySTIM DISABLED TARGETmyStim is no longer available for one or more groups because of change in parameters. Refer to the programming guide for additional information.	Stimulation settings have been changed and are no longer compatible with TARGETmyStim. Make sure the electrode pattern in the program is able to move up and down the lead, the amplitude limits are enabled, and the amplitude lower limit is 0.0 V. In addition, make sure group pulse width does not exceed 450 µs and group rate does not exceed 260 Hz.
TELEMETRY FAILURE There was interference while communicating with the neurostimulator. Reposition the programming head or move away from potential sources of interference and press Retry. Press Cancel to exit application.	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.
TELEMETRY FAILURE There was no response from the neurostimulator (device). Reposition the programming head and press Retry. Press Cancel to exit application.	Telemetry did not occur because of the location or movement of the programming head during the telemetry attempt.
WELCOME 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.	Neurostimulator service life (PrimeADVANCED INS) or battery level status (RestoreADVANCED INS) can be checked without beginning device life. Device life begins the first time a lead is configured.

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.

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 11.

Table 11. *Observation box messages and explanations*

Event message[a]	Explanation
Check TestStim clock	The time difference between the ENS clock and the clinician programmer clock is greater than

Table 11. *Observation box messages and explanations (continued)*

Event message[a]	Explanation
	one hour. Check the ENS clock setting to ensure it is set properly.
TestStim clock has changed	The patient has changed the ENS clock using the patient programmer. Check the ENS clock to ensure it is accurate. myStim Diary data may appear offset because of the change.
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 clock has changed	The patient has changed the INS clock using the patient programmer. Check the INS clock to ensure it is accurate. myStim Diary data may appear offset because of the change.
Recharge soon	The INS battery charge level is low and therapy will not be available soon. Charge the neurostimulator battery (RestoreADVANCED INS).
INS is at EOS	The INS has reached end of service (EOS) and therapy is not available. Replace the device.
INS is at ERI	The RestoreADVANCED INS is within 6 months of its scheduled end of service. The PrimeADVANCED INS is within weeks of its scheduled end of service. Replace the device before the end of service is reached. Refer to the *System Eligibility, Battery Longevity, and Specifications Neurostimulation Systems for Pain* reference manual.
Charge sooner	Since the last physician session, the INS batteries were depleted at least once to a low enough level that stimulation was disabled between rechargings (RestoreADVANCED INS).
Charge daily	The INS needs to be recharged at least once a day to provide 24 hour stimulation. This may be due to high parameter settings or reduced battery capacity. Parameter adjustment or INS replacement may be needed to increase therapy time between charges (RestoreADVANCED INS).
Stimulation OFF	Stimulation was OFF when the ENS/INS was interrogated by the programmer at the start of the session.

[a] Messages remain in the Observation box from session to session until the needed action is taken. The only exceptions are the Charge sooner or Charge daily messages that are cleared at the end of a session.

Patient programmer messages – The patient programmer also displays text and iconic error and informational messages. Some messages provide an error code and tell the patients to contact their physician. These error codes and their troubleshooting procedures are displayed in Table 12. Contact the

appropriate Medtronic representative listed on the inside back cover of this manual if additional assistance is needed.

Table 12. *Patient programmer Contact Physician error codes*

Error code	Explanation
536	Moisture was detected inside the ENS. The ENS must be dried with a towel, the battery removed, and the battery compartment allowed to air dry at room temperature.
537	The EMERGENCY STOP key on the ENS is active. Check the key and replace the device if needed.
574	No programs or groups were saved by the clinician programmer. The neurostimulator must be reprogrammed.
OOR	Out-of-Regulation situation has occurred. Decrease settings or reduce the number of electrodes.
POR	The neurostimulator has undergone a power on reset. No therapy is available until the device is re-activated. The patient programmer can be used to re-activate the neurostimulator up to 8 times between clinician sessions. After 8 times, the clinician programmer must be used to re-activate the neurostimulator.
556/589	The RestoreADVANCED INS battery was overcharged or the wrong batteries were placed in the ENS. The patient must come into the clinic, and the clinician programmer must be used to determine device status.
575/578	Invalid settings were detected in the INS/ENS. The device must be reset and valid settings entered.
0 to 250	Invalid settings were detected in the patient programmer. The patient should remove the programmer batteries and re-insert them after a few seconds. The error code should disappear. If it reappears, the patient programmer may need to be replaced.

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 49).

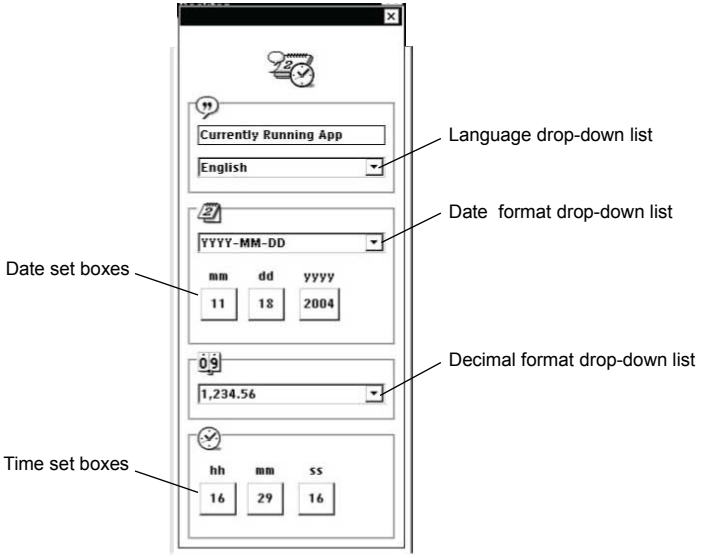


Figure 49. *LOCALIZATION screen.*

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.

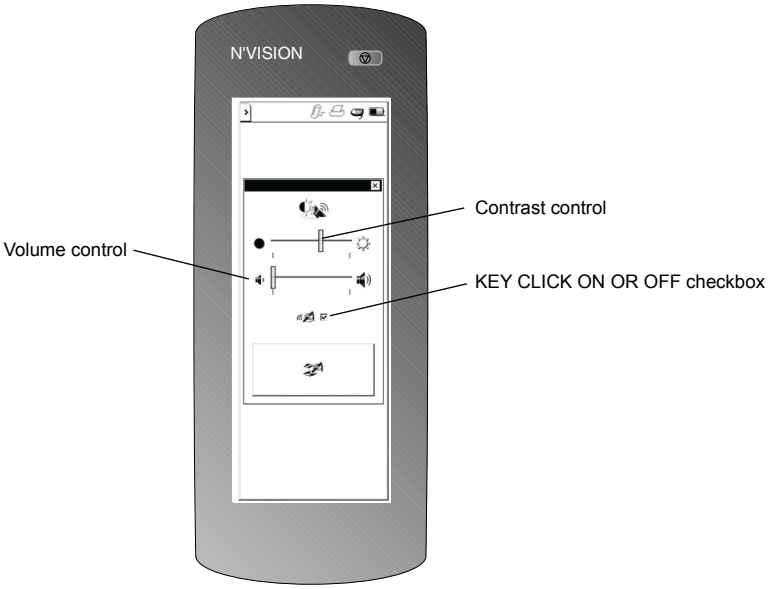


Figure 50. *PROGRAMMER SETTINGS screen.*

♦ *To set contrast*

1. Access the slider bar.
2. Select the SETTINGS button ( ).
3. Slide the contrast control bar to desired setting (Figure 50).

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 50 on page 94).

♦ *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 50 on page 94).

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 51 on page 95).

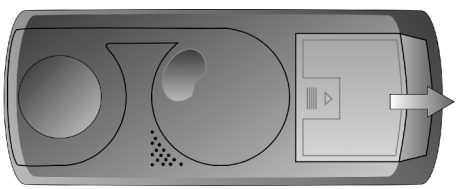


Figure 51. *Removing the battery compartment cover.*

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 93.
- 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.

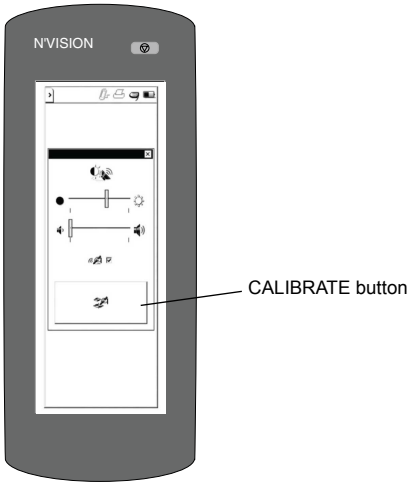


Figure 52. *Calibrating the display.*

♦ *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 52 on page 97).

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 of a pulse, measured in volts (V).

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

AutoFill - Adds new, defined groups based on previously programmed groups.

Current settings - Settings the patient experiences during a patient session.

Custom limit - Patient control limit that is set at a fixed value by the clinician.

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.

Discharged - The battery charge level for a rechargeable battery; state of reduced energy of a battery. Condition requires that the battery be charged.

Elective Replacement Indicator (ERI) - Notification that the INS is nearing end of service.

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.

Group - Collection of programs that work together for a particular effect or area.

GroupAdjust - Allows patients to use their patient programmer to increase or decrease all program amplitudes for the active group at the same time.

Group (therapy) impedance measurements - Impedance and stimulation current measurements taken at the programmed settings.

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.

Lead configuration - The number of leads and electrodes.

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

Optimizer - Refines programs using variations of the initial program electrode settings.

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

Programs - A specific combination of amplitude, rate, and pulse width parameters acting on a specific electrode set that determines the stimulation pulses that are delivered.

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.

Screening - Intraoperative testing to determine best paresthesia coverage.

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.

SoftStart/Stop - Allows stimulation to begin with a ramped output to prevent the sensation of a sudden “burst” of stimulation when the neurostimulator is turned on and gradually decreases the amplitude to 0.0 V when the neurostimulator is turned off.

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.

TargetmyStim - Allows the patient to refine therapy settings by transitioning electrode patterns using interleaved stimulation pulses.

TargetStim - Identifies and refines therapy settings by transitioning electrode patterns using interleaved stimulation pulses.

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

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

Test stimulation - A postoperative multiday trial period of a patient’s reaction to stimulation using an external neurostimulator and implanted leads.

Tracking limit - Patient control limits that automatically remain at the specified value above the clinician-programmed value. Tracking limits change when the programmed value is changed with the clinician programmer.

Contacts:

Asia: Medtronic International Ltd.
Tel. 02891-4068
Fax 02591-0313

Medtronic Asia Ltd.
Tel. (02)-548-1148
Fax (02)-518-4786

Australia: Medtronic Australasia Pty. Ltd.
97 Waterloo Road
North Ryde, NSW 2113
Australia
Tel. +61-2-9857-9000
Fax +61-2-9878-5100
Toll free 1-800-668-6700

Austria: Medtronic Österreich GmbH
Tel. 01-240440
Fax 01-24044-100

Belgium: Medtronic Belgium S.A.
Tel. 02-456-0900
Fax 02-460-2667

Canada: Medtronic of Canada Ltd.
Tel. (1-905)-460-3800
Fax (1905)-826-6620

Czech Republic: Medtronic Czechia s.r.o.
Tel. 2-965-795-80
Fax 2-965-795-89

Denmark: Medtronic Danmark A/S
Tel. 45-32-48-18-00
Fax 45-32-48-18-01

Finland: Medtronic Finland Oy/LTD
Tel. (09)-755-2500
Fax (09)-755-25018

France: Medtronic France S.A.S.
Tel. 01-5538-1700
Fax 01-5538-1800

Germany: Medtronic GmbH
Tel. (02159)-81490
Fax (02159)-8149100

Greece: Medtronic Hellas S.A.
Tel. 210-67-79-099
Fax 210-67-79-399

Hungary: Medtronic Hungária Kft.
Tel. 1-889-06-00
Fax 1-889-06-99

Ireland: Medtronic Ireland Ltd.
Tel. (01)-890-6522
Fax (01)-890-7220

Italy: Medtronic Italia SpA
Tel. 02-241371
Fax 02-241381

Tel. 06-328141
Fax 06-3215812

Japan: Medtronic Japan
Tel. 3-6430-2016
Fax 3-6430-7110

Latin America: Medtronic, Inc.
Tel. (1305)-500-9328
Fax (1786)-709-4244

Norway: Medtronic Norge AS
Tel. 067-10-32-00
Fax 067-10-32-10

Poland: Medtronic Poland Sp. z.o.o.
Tel. (022)-465-69-00
Fax (022)-465-69-17

Portugal: Medtronic Portugal, Lda.
Tel. 21-724-5100
Fax 21-724-5199

Russia: Medtronic Russia
Tel. (8495) 580-7377
Fax (8495) 580-7378

Slovakia Medtronic Slovakia, o.z.
Tel. 0268 206 911
Fax 0268 206 999

Spain: Medtronic Ibérica, S.A.
Tel. 91-625-0400
Fax 91-650-7410

Sweden: Medtronic AB
Tel. 08-568-585-00
Fax 08-568-585-01

Switzerland: Medtronic (Schweiz) AG
Tel. 031-868-0100
Fax 031-868-0199

The Netherlands: Medtronic B.V.
Tel. (045)-566-8000
Fax (045)-566-8668

U.K.: Medtronic U.K. Ltd.
Tel. 01923-212213
Fax 01923-241004

USA: Medtronic, Inc.
Tel. (1763)-505-5000
Fax (1763)-505-1000
Toll-free: (1-800)-328-0810

Medtronic
Alleviating Pain · Restoring Health · Extending Life

Manufacturer
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA.
www.medtronic.com
Tel. 1-763-505-5000
Fax 1-763-505-1000

Authorized Representative in the European Community EC REP
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel. 31-45-566-8000
Fax 31-45-566-8668

Europe/Africa/Middle East Headquarters
Medtronic International Trading Sàrl
Route du Molliau 31
Case Postale 84
CH-1131 Tolochenaz
Switzerland
www.medtronic.eu
Tel. 41-21-802-7000
Fax 41-21-802-7900

Asia-Pacific
Medtronic International Ltd.
Suite 1602 16/F, Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel. 852-2891-4068
Fax 852-2591-0313

Contacts for specific countries are listed inside this cover.

M929032A019

M929032A019