Clinical Programmer
Model MN0700
User Manual

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CAUTION – Investigational Device
Limited by Federal (US) Law to Investigational Use

LP0014 Rev E, June 2011

TABLE OF CONTENTS

Explanation of Symbols on Product or Package Labeling

Model Number

Serial Number


Read the Manual


Consult the Manual

Contents of Package are Non-Sterile


Manufacturing Date


Manufacturer


Warning. Pay attention.

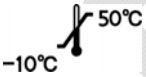

Protected against Electric Shock

Not waterproof. Applies to the Programmer when it is not in its carrying case.

Limited waterproof. Applies to the TNS.
Applies to the Programmer in its carrying case.


Turns the Programmer ON and OFF.
Turns stimulation OFF on the TNS.


Keep Dry



Store between -10°C and 50°C (14°F and 122°F)

Store between 0 and 93% humidity


The device is a radio transmitter


Magnet. Shows the location of the Programmer magnet.


Australia C-tick

Authorized European Representative

Introduction

The Clinical Programmer (MN0700) is part of the Spinal Modulation Neurostimulator System. It is intended to be used by the clinical investigator or a Spinal Modulation representative to query and program the Neurostimulator (NS), to retrieve data from the NS and to allow for adjustment of the patient's therapy. This User Manual gives detailed instructions on how to use the Clinical Programmer safely, how to recharge it and how to use it to set up the patient's pain management therapy.

Indications for Use

The Spinal Modulation Neurostimulator System is indicated as an aid in the management of chronic, intractable, neuropathic pain of the lower limbs-including unilateral or bilateral pain, associated with the following conditions: radicular pain, peripheral neuropathies.

Description

Patients who are indicated for Spinal Modulation's Implantable Neurostimulator System (INS) system will first undergo a trial period using an external Trial Neurostimulator System (TNS) connected to leads placed within the epidural space near the dorsal root ganglion (DRG). Up to four leads may be placed and connected to the Neurostimulator.

Although the leads and stimulator hardware used differ, the programmer hardware and instructions for programming the TNS and INS devices are the same.

> *NOTE: In this manual the general abbreviation "NS" is used for information which applies to both TNS and INS. In all other cases the specific abbreviations "TNS" or "INS" are used.*

For specific description of the TNS and INS system components and implant procedures, refer to the relevant labeling.

Two programmers are available to interact with the NS device.

1. The Clinical Programmer described in this user manual is used to program the stimulation parameters for the NS, as determined by the investigator. The NS delivers the programmed stimulation parameters (energy) to the implanted Leads.
2. The Patient Programmer allows the patient to adjust the stimulation settings of the NS devices within limits preset by the investigator. The Patient Programmer also allows the patient to turn stimulation off, if necessary. For further information and instructions related to the patient programmer, refer to the respective user manual.

⚠

Warnings

The Warnings listed below pertain to the Clinical Programmer only:

- The investigator must be trained by Spinal Modulation personnel before using the Clinical Programmer.
- Do not use the Clinical Programmer with a NS device that appears to be faulty or fails to properly communicate.
- Improper use of the Clinical Programmer may cause irreversible injury to the patient. All subjects are to be awake and conversant during the procedure to minimize the likelihood of any nerve damage.
- Always set the NS device amplitude to 0 µA when repositioning a lead or attaching the Connector Cable to the external TNS. When restarting stimulation, increase the NS amplitude slowly until the desired paresthesia is achieved.

RF Operating Frequencies

Nearby equipment emitting strong magnetic fields can interfere with RF communication, even if the other equipment complies with CISPR emission requirements. The operating characteristics are as follows:

MICS band: 402-405 MHz

The effective radiated power is below the limits as specified in

Europe: EN ETSI 301 839-2

USA FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1219

FCC ID: Y8L-MN0700

This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

⚠

Precautions

The following precautions should be taken to avoid damage to the Clinical Programmer and to assure proper function:

- Do not drop or mishandle the Clinical Programmer. Physical damage to the Clinical Programmer may impair its function.
- Do not spill fluids on or wash the Clinical Programmer. Excessive moisture may impair its function. If cleaning is necessary, remove soil with a soft damp cloth.
- Do not use abrasive or caustic cleaning products on the Clinical Programmer.
- Do not attempt to open the case of the Clinical Programmer. Attempts to open the case may expose the Clinical Programmer to elements that alter its function.
- The Clinical Programmer has an internal magnet. Keep the Clinical Programmer away from any credit cards, hard drives or magnetic storage devices as it may demagnetize them.
- Do not operate the Clinical Programmer outside the temperature range of -5°C to 45°C. Rapid temperature changes may affect proper device operation.
- Do not store the Clinical Programmer outside the temperature range of -10°C to 50°C.
- Do not leave the Clinical Programmer in a car or other places where temperatures can exceed 50°C.
- Do not burn or otherwise dispose of the Clinical Programmer. Fire may cause the internal battery to explode.
- Do not allow unauthorized use of the Clinical Programmer to avoid injury to patients.
- The NS device can only be programmed using Spinal Modulation's Clinical or Patient Programmer. Do not try to use any other manufacturer's device to program it.
- Do not use the Clinical Programmer or NS in the presence of explosive or flammable gases as this may cause serious injury.
- If there is any concern regarding the proper function of the Spinal Modulation NS System, please contact your Spinal Modulation representative.
- Do not use the Programmer Charger if the power cord is damaged, excessively worn or frayed. This may cause injury or damage the Programmer.
- Frequent programming of the implanted device will cause the battery to deplete faster. Avoid unnecessary programming.
- The TNS should always be worn either outside of clothing or outside the dressing holding the leads in place.

Clinical Programmer System Overview

The Clinical Programmer allows you to establish two-way communication with the patient's NS device for querying and programming.

It is a portable, hand-held device that can be plugged into a power outlet or be powered by an internal battery. The battery is rechargeable using the Programmer Charger provided and a power outlet.

The Clinical Programmer System includes:

- Clinical Programmer (with Stylus) MN0700
- Programmer Charger MN3400
- External Auxiliary Magnet MN3300
- Carrying Case MN3500
- Clinical Programmer User Manual (this document)

Stylus

Programmer Charger

Clinical Programmer

The Carrying Case will keep the Programmer dry. Store and transport the Programmer in the Carrying Case when you are not using it.

Clinical Programmer Features

With the Clinical Programmer, you can:

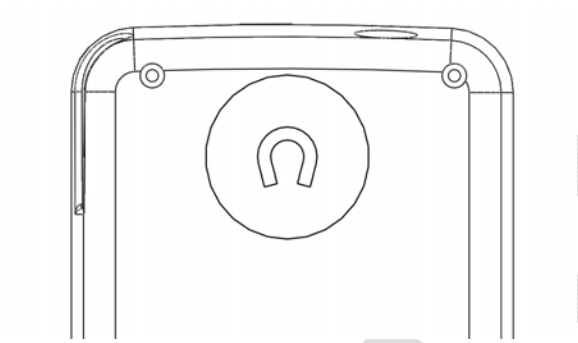
- Turn OFF all stimulation.
- Turn stimulation ON for up to four leads and measure lead impedance.
- Change stimulation settings for each lead.
- Configure Patient Controlled Therapy settings for each lead.
- Enter patient and lead identification information, clinician and clinic name and contact information, and clinician's notes.
- Create and name groups of stimulation sets with each group containing up to four leads with different settings on each lead.
- Perform a real time trial (test) to assess the patient stimulation response for each lead.
- Acquire identification, diagnostic, and historic information about the NS device.

Magnet

A magnet is built into the Clinical Programmer. It is located on the back side of the Programmer underneath the indent with the magnet symbol (shown below).

The NS system has the capability of detecting the presence of a magnet. The magnet puts the NS device in communication mode, allowing it to connect to the Programmer.

An alternate function of the magnet is that by holding the magnet over the device long enough, all stimulation therapy will be switched off. (Refer to "Workspace - Profile>System" section for more information).



⚠ **PRECAUTION: Keep the programmer magnet away from credit cards. It may erase the magnetic strip and render the card useless.**

Charging the Clinical Programmer Battery

You will need the Programmer Charger provided, to charge the battery in your Clinical Programmer. It takes approximately 2–4 hours to fully charge the battery. The battery charge level is indicated in the "Programmer Status Bar" at the bottom of the screen.

1. Connect the Charger to a power outlet.

   Input: 100-240 VAC, 50-60 Hz, 0.6A

   Output: 5V ⎓ 3.0A

2. Connect the Charger to your Programmer.
3. When the battery is charging, the battery icon on the screen contains "AC". When the charging is complete, the indicator next to the battery icon will be at approximately 100%.

When the Clinical Programmer is connected to a power outlet as described above, it is powered by the outlet and will not use battery power. When the Clinical Programmer is charging, the Programmer battery icon reflects the current status of the battery. Connect the Clinical Programmer to the Charger and attach to an outlet regularly to keep it charged.

Programmer Power Up

Turn the Clinical Programmer ON by pressing the "⏻"button. The Main Menu will be displayed.

NOTE: If the Clinical Programmer screen does not turn on, follow the instructions for charging the battery, and try again.

Main Menu

The Main Menu displays three primary functions:

- **Demo:** Puts the system into a stand-alone demo mode allowing you to use all programmer functions without it being connected to a NS.
- **Programmer Setup:** Allows you to set the Clinical Programmer date and time, activate the FCE Workspace on the Programmer, and set and modify the Programmer password.
- **Connect to Stimulator:** Opens a screen that allows you to communicate with the NS device.

The Main Menu identifies the device as the Spinal Modulation Clinical Programmer. Furthermore, Programmer's Serial Number, Software Version, Basestation Firmware Version and Manufacturing date are displayed.

At the bottom of the Main Menu, the status bar displays the Programmer – NS connection status, the battery charge level and the time. *Refer to the section on the Programmer Status Bar in this User Manual.*

Demo

Select "Demo" on the Main Menu to initiate Demo mode. Buttons will be purple to indicate that the Programmer is operating in Demo mode. No NS device is needed for this mode —just the Programmer. The Programmer will have simulated NS data on it and will simulate the RF communication with the NS. This means that at the start of every Demo session, the data will always be the same.

Programmer Setup

Select "Programmer Setup" on the Main Menu to get the setup screen.

Change the Date

Select the drop down arrow on the right side of the "Set Date" box. A calendar will appear and you can set the month, day and year using your stylus.

Change the Time

To change the time (24 hour format), first select the hour or minute field that you would like to change.

To change the selected field, use the "Up" or "Down" arrows to increase, decrease or toggle the setting.

NOTE: Establishing a connection updates the NS device's clock to the newly set time.

Switch to FCE Programmer

By checking this box the Clinical Programmer will get additional functionality, which should only be used by Spinal Modulation's Field Clinical Engineers and Staff.

Establishing Communication with the NS Device

To change the patient's stimulation settings, you must first establish communication between the Clinical Programmer and the patient's NS device.

1. Make sure that the Clinical Programmer is turned on and the Main Menu screen is displayed
2. Press "Connect to Stimulator" on the Main Menu.
3. Select the text box next to "Stimulator SN:"
4. Enter the serial number using the pop-up keyboard. The Programmer is case sensitive so use uppercase letters only.

If the serial number format is valid for a NS device, the "Connect" button will be enabled.

5. Press the "Connect" button.

After pressing the "Connect" button, the "Cancel" button becomes enabled. If the Cancel button is pressed, the telemetry connection is cancelled.

6. Move the Clinical Programmer magnet over the NS device in a circular motion to connect.

The indicator status bar on the bottom left of the screen will display “Connected” if the connection attempt is successful. If the Programmer could not communicate with the NS device, an error message will appear and “Disconnected” will be displayed in the status bar.

NOTE: If after 2 minutes the Clinical Programmer has failed to communicate with the NS device, the programmer will automatically cancel the connection attempt. Try to communicate with the NS device by pressing the “Connect” button again moving the magnet symbol on the Clinical Programmer over the NS device in a circular fashion.

When a successful connection is established, the Programmer chimes and the NS device will be queried.

7. For the duration of the programming session keep the Clinical Programmer within 6 feet of the NS device. Moving the programmer too far away may cause telemetry connection to be lost.

Back to Main Menu

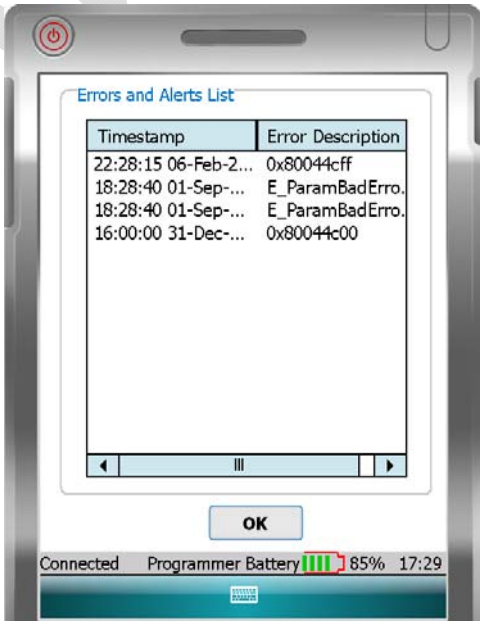
Located at the bottom right side of the Programmer Connect window, the “Exit” button is used to return to the Main Menu.

Navigation and screen elements

Neurostimulator Dashboard

Once the selected NS device is connected to the Clinical Programmer, the NS Dashboard is displayed in the screen’s header providing:

- **Patient ID:** the patient’s ID Number.
- **Stimulator Serial Number:** the NS device’s serial number.
- **Alerts button:** The button turns orange when any of the NS System Alerts become active. When the “Alerts” button is orange, press the button to display a window showing details of all the System Alerts. An example of the screenshot is shown to the right.

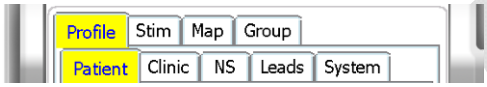


Programmer Status Bar

Located at the bottom of the Clinical Programmer screen, the Programmer Status Bar displays:

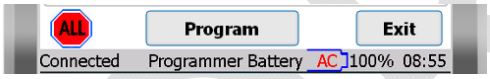
- **Programmer - NS Connection Status**: Displays the status of the communication between the Clinical Programmer and the NS device: "Connecting" is displayed when establishing a connection. "Connected" is displayed when there is communication between the Clinical Programmer and the NS device. "Disconnected" is displayed when there is no communication between the Clinical Programmer and the NS device.
- **Programmer Battery Level**: Displays the Clinical Programmer battery charge level. It is recommended that your Programmer be connected to the power supply provided and attached to an outlet when not in use.
- **Programmer Clock**: Displays the time. See User Manual section on Change the Time.

Workspace Navigation



Once the NS is connected, tabs are displayed for the systems' four main workspaces ("Profile", "Stim", "Map" and "Group"). The Workspaces are used to view and program the NS therapy settings and to obtain diagnostic information. A record of the programmed settings and diagnostic information is generated after every session. A fifth Workspace labeled "FCE" will only appear when FCE mode is ON.

Workspace screens and sub-screens are navigated by selecting the labeled tabs. Once selected, a tab will be highlighted in yellow.



Located at the bottom of each of the Workspaces are the "ALL", "Program" and "Exit" buttons.

- **Exit button:** is used to close the current window, end the patient therapy session, and return to the Main Menu.

NOTE: Returning to the Main Menu or turning off your Programmer will not change any of the programmed NS settings.

NOTE: When programming is complete, select the "Exit" button to conserve power.

- **Program button:** programs all changes made within the current Workspace.
- **ALL button:** is used to turn all stimulation off.

Temporary and Permanent Programming

Whenever a change is made to a parameter value or other data field while the NS is within telemetry range, this value immediately becomes **temporarily active**. The corresponding value or data selection appear in a red bold underlined font.

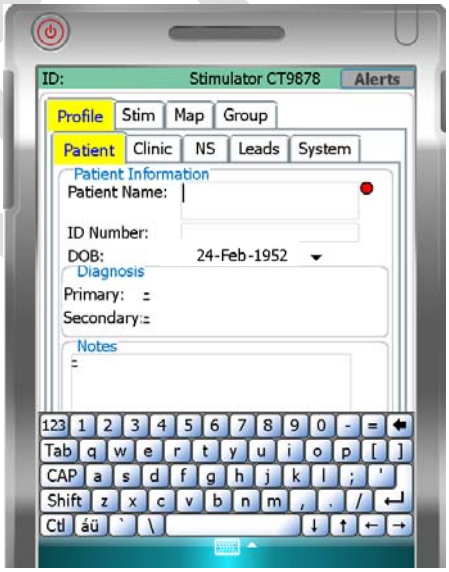
Temporary programmed values or text data can be **permanently programmed** by pressing the program button. The font color changes from red to black.

NOTE: When leaving a Workspace while values are temporarily active you will be prompted to either program these values permanently or cancel the pending changes.

NOTE: Parameters can be temporarily active on multiple tabs of the same Workspace.

More on editing text fields

NOTE: Selecting a text field will pop up a keyboard at the bottom of the screen, allowing the information to be revised. To close the keyboard after modifying the entry, press the keyboard key centered in the blue bar at the bottom of the screen.



While text fields are **being edited** they appear in a black bold font (no underline). At the same time to the right of the text field a red dot is shown indicating that editing is in progress. Editing can be in progress for multiple fields at the same time.

Once editing for a field is complete, tap the red-dot to make the change **temporarily active**. The red dot disappears and the font changes from black bold to red bold underlined.

Only upon pressing the programming button does the change become **permanently programmed** and the font color changes from red to black.

#

Using the Workspaces

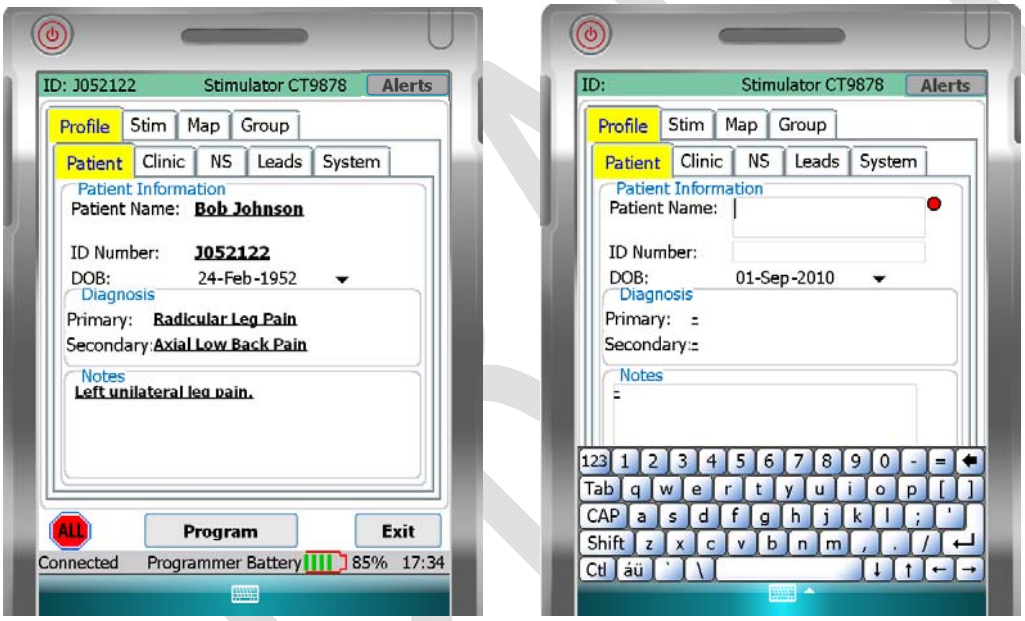
Profile Workspace

Press the “Profile” tab to access the Profile Workspace. The Profile Workspace is divided into five tabs (“Patient”, “Clinic”, “NS”, “Leads” and “System”) which are used to:

- Enter patient information;
- Enter clinician contact information;
- Enter NS device information;
- Enter lead identification information;
- Change basic system parameters;

Patient Information Tab [Profile >Patient]

Enter or modify the patient information in the fields provided:

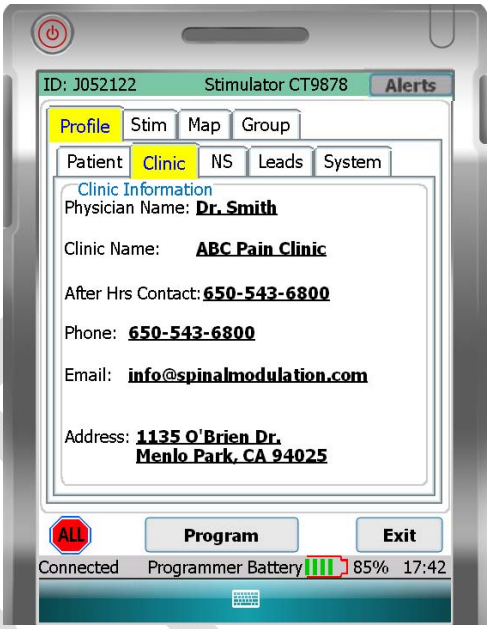


- **Patient Name:** Enter the patient’s name using the on-screen ke**yboard.**
- **ID:** Enter the patient’s unique identification using the on-screen keyboard.
- **Date of Birth:** Enter the patient's date of birth using the drop-down calendar.
- **Primary and secondary Diagnosis:** Select the patient's diagnosis from a drop-down list (Refer to Appendix I for selection set)
- **Notes:** Enter notes if needed.

Clinic Information Tab [Profile >Clinic]

Enter or modify the physician and clinic information in the text fields provided:

- **Physician Name**
- **Clinic Name**
- **Clinic after hours contact phone number**
- **Clinic Phone number**
- **Clinic Email**
- **Clinic Address**

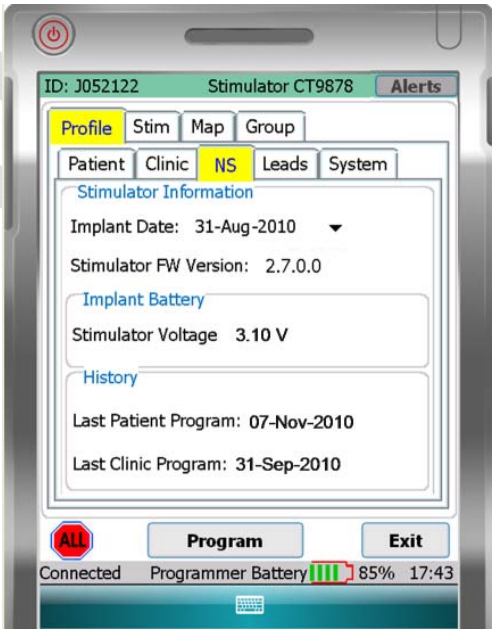


Stimulator Information Tab [Profile >NS]

The NS tab provides a summary of information related to the NS.

- **Date of Implant:** Enter the Stimulator date of use using the drop-down calendar.
- **Implant battery voltage:** the current battery voltage is automatically displayed here.
- **History:** shows recent programming history.

NOTE: The battery information pertains to an INS and does not pertain to the TNS.



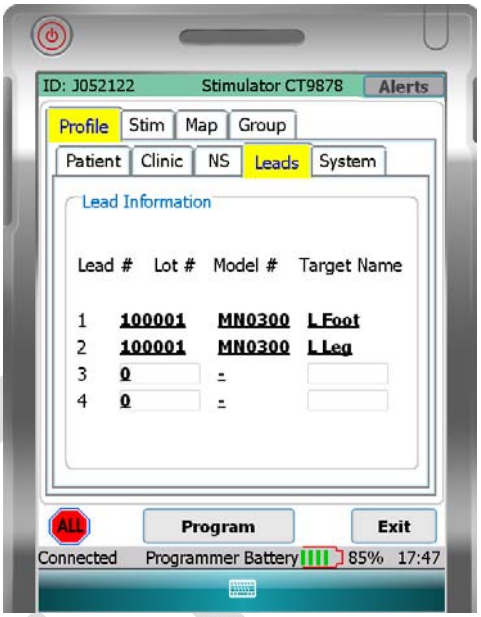
Leads Information Tab [Profile >Leads]

Lead 1 through Lead 4 are the default labels used to identify the implanted leads in the "Stim" Workspace. It is recommended that these names be changed into something more meaningful, for example the body region it covers.

- **Target Name:** for each of the implanted leads, enter the body region covered (text field).

For each of the leads enter the Lot and Model number:

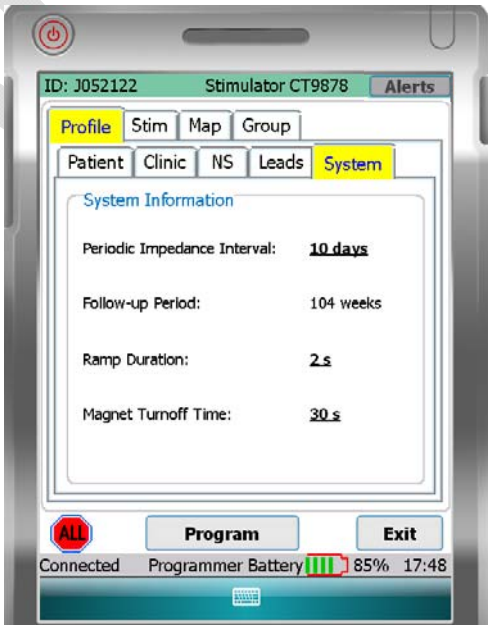
- **Lot #:** enter the last four digits of the Lot number found on the lead packaging.
- **Model #:** enter the lead Model number.



System Information Tab [Profile >System]

From the system tab the following system parameters can be managed:

- **Periodic Impedance interval:** set the periodicity with which you want the system to measure lead impedance.
- **Follow-up Period:** A calculated field which displays the recommended follow-up time based on the programmed settings. It is an indicator of when the programmer will run out of memory and will begin to overwrite old data.
- **Ramp Duration:** Ramp duration is how long it takes for the NS to reach the requested amplitude. If set to 8 seconds, the NS will take 8 seconds to get from 0 to the requested amplitude when a lead is switched from not enabled to enabled. Ramping also occurs when the step between the current amplitude and the next amplitude is greater than 100 mV.



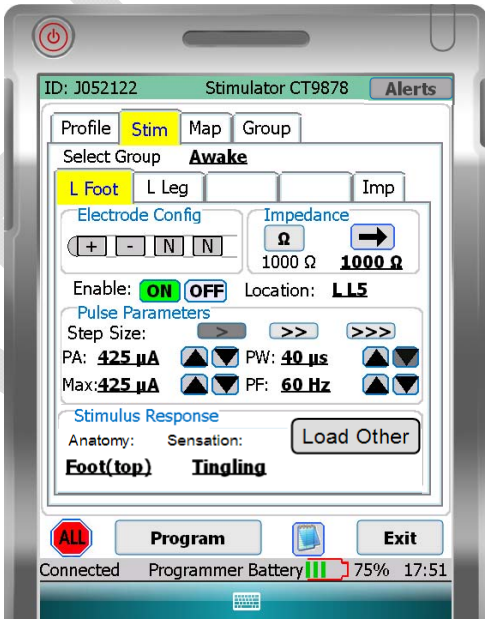
- **Magnet Turnoff Time:** allows you to control how long it takes before a magnet held over the device switches off delivered therapy.

Stim Workspace

Press the "Stim" tab to access the Stimulation Settings Workspace. The Stimulation Settings Workspace is divided into five tabs which are used to:

- Activate (turn on) up to four leads
- Adjust electrode configurations
- Measure impedance
- Set nominal values to begin stimulation
- Perform trial mapping
- Confirm the response and sensation of specific body regions to be stimulated

Stim Tabs [Stim >Target Name]



The Stim tabs are the main tabs from which therapy is controlled and programmed. This can be done either temporarily (testing) or permanently.

- **Select group:** select the group for which you want to change the stimulation settings.

NOTE: in the Group Workspace, up to four different groups can be defined each with their own stimulation parameters. A group can be linked for example to a specific activity or posture. Refer to the Group Workspace section in this manual for more information.

- **Select the tab:** labeled with the target for which you want to adapt stimulation parameters. (In the sample screen eg. "L Foot")

NOTE: There are up to four tabs that can be labeled with the body region in which stimulation with the corresponding lead is targeting (defined in Profile>Leads). For each body region (lead) stimulation can be adjusted independently.

- **Electrode Configuration:** Each lead has four electrodes each of which can be programmed with a positive or negative polarity, or be programmed as neutral (off). There must be at least one positive and one negative electrode before the Clinical Programmer allows the amplitude to be adjusted and for the lead to be enabled.

  1. Select one of the four electrodes by clicking on it using the stylus. Clicking once will turn the electrode positive ("+"), clicking it twice will turn it negative ("-") and clicking it three times will turn it Neutral ("N") again. To exit from the electrode editing mode, click on the neighboring Impedance box.
  2. Continue, by setting each of implanted leads with at least one positive and one negative electrode for each body region to be treated.

- **Impedance:** Press the "Instant Impedance" button ("Ω") to measure the lead's impedance. Once pressed, the impedance value will be displayed underneath the button. If you want the NS

to use this Instant Impedance value for therapy delivery, press the “Transfer Instant Impedance” button (“→“).

NOTE: The patient may feel the effect of the impedance measurement. Alert the patient to the possible stimulation.

NOTE: A transferred impedance value is required before other stimulation parameters can be selected.

- **Enable:** Select “ON” to enable the lead so that it provides stimulation therapy to the patient. Select “OFF” if the lead is not being used.
    - When Enable is ON, the “ON” button will turn the color green.
    - When Enable is OFF, the “OFF” button will turn the color black.
    - The button border is red if the activation state is different from the programmed value.

⚠ **WARNING: Once Enable is ON for this target, any parameter change will be immediately active.**

NOTE: If a lead is enabled on a non active tab of the “Stim” Workspace, the tab will turn the color green. The active tab stays the color yellow.

NOTE: The lead is disabled and the amplitude is automatically changed to zero when the lead electrode configuration changes. The lead electrode configuration must be valid prior to activating the lead. A valid lead configuration must include at least one positive and one negative electrode.

- **Location:** Enter the spinal level where stimulation therapy is delivered by this trial lead
- **Pulse Parameters:** To select and change pulse parameters, first press the desired increment level: Fine (>), Medium (>>), Coarse (>>>).
    - Amplitudes below 2.0 mA (>: 25 µA, >>: 50 µA, >>>: 200 µA)
    - Amplitudes above 2.0 mA (>: 50 µA, >>: 100 µA, >>>: 400 µA)
    - Pulse Width (>: 10 µs, >>: 40 µs, >>>: 100 µs)
    - Frequency (>: 2 Hz, >>: 4 Hz, >>>: 10 Hz)
    - The UP(^) and Down(∨) buttons next to the specific pulse parameter will allow the user to change the setting at the desired increments.

The following table lists the pulse parameters, their range, increments and default value:

Specifications	Range	Step Size	Default Value
Pulse Amplitude - PA (µA) (Depending on measured impedance)	0 – 6000 µA	25 µA: 0-2000 µA 50 µA: 2000-6000 µA	0 µA
Maximum Pulse Amplitude - Max (µA) Programmable by Patient	Same as PA	Same as PA	0 µA
Pulse Width – PW (µs)	40 – 720 µs	10 µs	40 µs
Pulse Frequency - PF (Hz)	4 – 100 Hz	2 Hz	60 Hz

- **Maximum Amplitude:** Enter the maximum stimulation amplitude, from the clinically set amplitude up to 6.0 mA that the patient is allowed to set for each lead.

⚠ **WARNING: Unless the stimulation settings are known for a specific patient, start with a Pulse Amplitude of 0 µA.**

- **Stimulus Response:** Allows you to assign a descriptor to a set of programmed pulse parameters. The descriptor is composed of a body region where the sensation is felt and a description of the sensation. (Eg. Upper Back & Massaging → Upper Back Massaging). A Stimulus Response must be selected in order to Program the set of pulse parameters. The Load Other button pulls down a drop down menu and allows the user to load another Stimulus Response that has been previously saved for that lead.

NOTE: When restarting stimulation, increase the amplitude slowly until the desired effect is achieved.

Impedance Tabs [Stim >Impedance]

The impedance button (Ω) initiates impedance measurements between adjacent electrode couples in all of the configured leads and displays on the Imp screen.

Map Workspace

Press the "Map" tab to access the Map Workspace.

The Map Workspace allows you to define which lead connects to each of the NS ports. It therefore provides the ability to automatically move saved settings from one Port to another.

Each lead is identified by its location (spinal level) entered in the Stim Workspace.

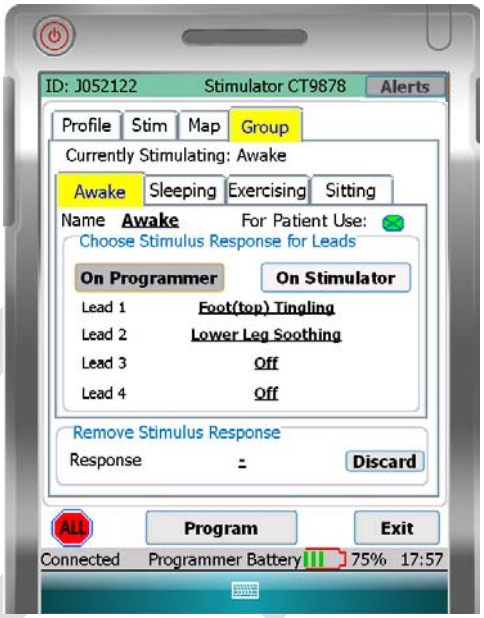
Group Workspace

Press the "Group" tab to access Group Workspace.

The Group Workspace is divided into four tabs (Groups) by default named "Awake", "Sleeping", Exercising" and "Sleeping"). Each tab summarizes Group specific settings for each of the implanted leads. These Groups can be easily programmed as needed by the patient using the Patient Programmer.

Lead Tabs [Group >Group Name]

Each Group can be configured by selecting the desired tab.



- **Name:** The Group can be renamed here (free-form text entry)
- **For Patient Use:** The Group will be displayed on the Patient Programmer only if this box is checked. Note that the currently active Group must be checked/enabled.
- **On Programmer / On Stimulator:** These buttons toggle to allow the user to view either the Programmer values (possibly not programmed yet to the Stimulator) or the values programmed on the Stimulator
- **Lead 1 through Lead 4:** The Stimulus Response for each Lead within a Group can be changed here. Stimulus Responses that have been previously saved for that Lead will be shown in the drop down menu.
- **Response / Discard:** Unwanted Stimulus Response definitions can be discarded here. This may be needed once the user has used up the maximum number of Stimulus Responses (12).

The Spinal Modulation Neurostimulator System complies with the following International Standards

- IEC 60601-1: 2005
- IEC 60601-1-11: 2010
- IEC 60601-1-2: 2007
- ISO 14708-1: 2000
- ISO 14708-3: 2008

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GUIDANCE AND MANUFACTURER'S DECLARATION *Electromagnetic Emissions*		
The Spinal Modulation Neurostimulator System is intended for use in the electromagnetic environment specified below. The customer or the user of the Spinal Modulation Neurostimulator System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions 1	Group 2	The Spinal Modulation Neurostimulator System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
		The Spinal Modulation Neurostimulator System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
CISPR 14-1	Complies	The Clinical Programmer is not intended to be connected to other equipment except the Model 3400 Programmer Charger

Guidance and manufacturer's declaration *Electromagnetic Immunity*			
The Spinal Modulation Neurostimulator System is intended for use in the electromagnetic environment specified below. The customer or the user of the Spinal Modulation Neurostimulator System should assure that it is used in such an environment.			
Immunity	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD)	IEC 61000-4-2	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Pass	Mains power quality should be that of a typical commercial or home environment
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth		Mains power quality should be that of a typical commercial or home environment
Voltage dips, short interruptions and voltage variations on power supply	input lines IEC 61000-4-11 <5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s NOTE *U*T is the a.c. mains voltage prior to application of the test level.		Mains power quality should be that of a typical commercial or home environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital, or home environment.

Guidance and manufacturer's declaration Electromagnetic Immunity			
The Spinal Modulation Neurostimulation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Spinal Modulation Neurostimulation System should assure that it is used in such an environment			
Immunity test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of Spinal Modulation Neurostimulation System, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. The recommended separation distance is a minimum of 0.2 meter for transmitters of 80 MHz to 2.5 GHz Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distances between portable and mobile RF communications equipment and the Spinal Modulation Neurostimulation System			
The Spinal Modulation Neurostimulation System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Spinal Modulation Neurostimulation System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
0.01	0.12m	0.12m	0.23m
0.1	0.37m	0.37m	0.74m
1	1.17m	1.17m	2.33m
10	3.70m	3.70m	7.37m
100	11.70m	11.70m	23.30m
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix I: Programmable parameters and values

Parameter	Programmable Values	Default
Pulse Amplitude	0 – 6000 µA 0-2000 µA (25 µA increments) 2000-6000 µA (50 µA increments)	0 µA
Maximum Pulse Amplitude	Same as Pulse Amplitude	0 µA
Pulse Width	40 – 720 µs (10 µs increments)	40 µs
Pulse Frequency	4 – 100 Hz (2 Hz increments)	60 Hz

Data Field	Selectable Values
Diagnosis (Primary and Secondary)	Abdominal Pain; Axial Low Back Pain; Axial Neck Pain; CRPS Type 1; CRPS Type 2; Diabetic Peripheral Neuropathy; FBSS; FNSS; Lower Extremity Neuropathic Pain; Neuropathic Pain; Other; Peripheral Neuropathy; Phantom Pain; Post-Herpetic Neuralgia; Post Surgical Pain; Radicular Arm Pain; Radicular Leg Pain; Thoracic Pain; Upper Extremity Neuropathic Pain; Visceral Pain;
Periodic Impedance Interval	Off; 30 s; 1 min; 5 min; 20 min; 30 min; 1 h; 12 h; 1 days; 10 days; 30 days
Lead Model Number	MN0300; MN0400
Stimulus Response Anatomy	Off; Neck; Shoulder; Scapula; Upper Back; Middle Back; Lower Back; Back & Leg; Thigh; Knee; Lower Leg; Ankle; Foot(top); Foot(bottom); Toes; Chest; Axila; Ribs; Abdomen; Hip; Groin; Upper Arm; Elbow; Forearm; Hands; Fingers
Stimulus Response Sensation	Off; Burning; Buzzing; Cold; Comforting; Cramping; Heavy; Massaging; Numb; Other; Pain; Paresthesia; Pressure; Relief; Soothing; Spasm; Tapping; Tingling; Vibrating; Warm
Spine Location	L L1; R L1; L L2; R L2; L L3; R L3; L L4; R L4; L L5; R L5; L T1; R T1; L T2; R T2; L T3; R T3; L T4; R T4; L T5; R T5; L T6; R T6; L T7; R T7; L T8; R T8; L T9; R T9; L T10; R T10; L T11; R T11; L T12; R T12; L S1; R S1; L S2; R S2; L S3; R S3; L S4; R S4; L S5; R S5; L C1; R C1; L C2; R C2; L C3; R C3; L C4; R C4; L C5; R C5; L C6; R C6; L C7; R C7; L C8; R C8
Magnet Turnoff Time	Off; 1 s; 2 s; 3 s; 4 s; 5 s; 6 s; 7 s; 8 s; 9 s; 10 s; 15 s; 20 s; 25 s; 30 s; 40 s; 50 s; 1 min; 70 s; 80 s; 90 s; 100 s; 110 s; 2 min
Ramp Duration	0 s; 1 s; 2 s; 3 s; 4 s; 5 s; 6 s; 7 s; 8 s

Appendix II: INS Battery Life

The following four tables estimate INS battery life under the given load impedance conditions.
Tables 1 through 4 list estimated longevity based on 1-lead stimulation, active 24 hours a day. To estimate longevity for multiple active leads and to account for daily usage, use the following formula:

$$\text{Longevity for Multiple Leads} = \frac{3014}{C1 + C2 + C3 + C4 + 35}$$

Where,

$$C1 = \left(\frac{3014}{\text{Longevity for Lead 1 Settings}} - 35\right) * \text{Daily Usage Lead 1}$$

$$C2 = \left(\frac{3014}{\text{Longevity for Lead 2 Settings}} - 35\right) * \text{Daily Usage Lead 2}$$

$$C3 = \left(\frac{3014}{\text{Longevity for Lead 3 Settings}} - 35\right) * \text{Daily Usage Lead 3}$$

$$C4 = \left(\frac{3014}{\text{Longevity for Lead 4 Settings}} - 35\right) * \text{Daily Usage Lead 4}$$

And,
Daily Usage Lead 1, 2, 3 and 4 are fractional values equal to the number of hours stimulation is enabled for each lead daily divided by 24 hours.
Note: Do not enter values for C1, C2, C3 or C4 for corresponding leads that are inactive.

Example:
Estimate longevity for 2 lead stimulation with lead 1 settings of 0.8mA, 40Hz, 200µs across 600 ohms continuously stimulating, and lead 2 settings of 1.0mA, 60Hz, 400µs across 1Kohm stimulating for 16 hours per day.

From Table 1 (600 ohms), longevity for lead 1 settings = 58.9 months
From Table 2 (1 Kohm), longevity for lead 2 settings = 34.1 months
Calculated C1 = (3014 / 58.9 – 35) * (24 / 24) = 16.2
Calculated C2 = (3014 / 34.1 – 35) * (16 / 24) = 35.6

Estimated longevity for this example = 3014 / (16.2 + 35.6 + 35) = 34.7 months

Table 1: Load Impedance = 600 ohms

All longevity values are in months

		Pulsewidth								
Amplitude	**Frequency**	40uS	100uS	200uS	300uS	400uS	500uS	600uS	700uS	720uS
0.1mA	4Hz	83.9	83.8	83.6	83.4	83.2	83.0	82.8	82.7	82.6
	20Hz	81.5	80.9	80.1	79.2	78.3	77.5	76.7	75.9	75.8
	40Hz	78.6	77.6	76.0	74.5	73.0	71.6	70.2	68.9	68.6
	60Hz	76.0	74.6	72.4	70.3	68.3	66.5	64.7	63.1	62.7
	80Hz	73.5	71.8	69.1	66.6	64.2	62.1	60.0	58.1	57.8
	100Hz	71.2	69.2	66.1	63.2	60.6	58.2	56.0	53.9	53.5
0.2mA	4Hz	83.8	83.6	83.2	82.8	82.5	82.1	81.7	81.4	81.3
	20Hz	81.1	80.1	78.3	76.7	75.1	73.6	72.2	70.8	70.5
	40Hz	78.0	76.0	73.0	70.2	67.6	65.2	63.0	60.9	60.5
	60Hz	75.1	72.4	68.3	64.7	61.5	58.5	55.9	53.4	53.0
	80Hz	72.4	69.1	64.2	60.0	56.4	53.1	50.2	47.6	47.1
	100Hz	69.8	66.1	60.6	56.0	52.0	48.6	45.6	42.9	42.4
0.4mA	4Hz	83.7	83.2	82.5	81.7	81.0	80.3	79.6	78.9	78.8
	20Hz	80.4	78.3	75.1	72.2	69.4	66.9	64.6	62.4	61.9
	40Hz	76.7	73.0	67.6	63.0	58.9	55.4	52.2	49.4	48.9
	60Hz	73.3	68.3	61.5	55.9	51.2	47.2	43.8	40.9	40.4
	80Hz	70.1	64.2	56.4	50.2	45.2	41.2	37.8	34.9	34.4
	100Hz	67.3	60.6	52.0	45.6	40.5	36.5	33.2	30.4	29.9
0.6mA	4Hz	83.5	82.8	81.7	80.7	79.6	78.6	77.6	76.6	76.4
	20Hz	79.7	76.7	72.2	68.2	64.6	61.3	58.4	55.7	55.2
	40Hz	75.4	70.2	63.0	57.1	52.2	48.1	44.6	41.6	41.0
	60Hz	71.5	64.7	55.9	49.1	43.8	39.6	36.1	33.2	32.6
	80Hz	68.1	60.0	50.2	43.1	37.8	33.6	30.3	27.6	27.1
	100Hz	64.9	56.0	45.6	38.4	33.2	29.2	26.1	23.6	23.1
0.8mA	4Hz	83.4	82.5	81.0	79.6	78.2	76.9	75.7	74.4	74.2
	20Hz	79.0	75.1	69.4	64.6	60.3	56.6	53.3	50.4	49.8
	40Hz	74.2	67.6	58.9	52.2	46.9	42.5	38.9	35.9	35.3
	60Hz	69.9	61.5	51.2	43.8	38.3	34.1	30.7	27.9	27.4
	80Hz	66.1	56.4	45.2	37.8	32.4	28.4	25.3	22.8	22.3
	100Hz	62.7	52.0	40.5	33.2	28.1	24.4	21.5	19.3	18.9

Table 1: Load Impedance = 600 ohms (Continued)

All longevity values are in months

		Pulsewidth								
		40uS	100uS	200uS	300uS	400uS	500uS	600uS	700uS	720uS
1.0mA	4Hz	83.2	82.1	80.3	78.6	76.9	75.4	73.8	72.4	72.1
	20Hz	78.3	73.6	66.9	61.3	56.6	52.5	49.0	46.0	45.4
	40Hz	73.0	65.2	55.4	48.1	42.5	38.1	34.5	31.6	31.0
	60Hz	68.3	58.5	47.2	39.6	34.1	29.9	26.6	24.0	23.6
	80Hz	64.2	53.1	41.2	33.6	28.4	24.6	21.7	19.4	19.0
	100Hz	60.6	48.6	36.5	29.2	24.4	20.9	18.3	16.3	15.9
1.5mA	4Hz	82.8	81.2	78.6	76.1	73.8	71.7	69.6	67.7	67.3
	20Hz	76.7	70.1	61.3	54.5	49.0	44.6	40.8	37.7	37.1
	40Hz	70.2	59.9	48.1	40.2	34.5	30.3	26.9	24.3	23.8
	60Hz	64.7	52.3	39.6	31.9	26.6	22.9	20.1	17.9	17.5
	80Hz	60.0	46.4	33.6	26.4	21.7	18.4	16.0	14.2	13.8
	100Hz	56.0	41.7	29.2	22.5	18.3	15.4	13.3	11.7	11.4
2.0mA	4Hz	82.5	80.3	76.9	73.8	71.0	68.3	65.9	63.6	63.2
	20Hz	75.1	66.9	56.6	49.0	43.3	38.7	35.0	32.0	31.4
	40Hz	67.6	55.4	42.5	34.5	29.1	25.1	22.1	19.7	19.3
	60Hz	61.5	47.2	34.1	26.6	21.9	18.6	16.1	14.2	13.9
	80Hz	56.4	41.2	28.4	21.7	17.5	14.7	12.7	11.1	10.9
	100Hz	52.0	36.5	24.4	18.3	14.6	12.2	10.5	9.2	8.9
4.0mA	4Hz	56.6	53.8	49.7	46.2	43.1	40.5	38.1	36.0	35.6
	20Hz	46.3	38.2	29.6	24.1	20.4	17.6	15.5	13.9	13.6
	40Hz	37.7	28.0	19.6	15.1	12.3	10.3	8.9	7.8	7.7
	60Hz	31.8	22.1	14.7	11.0	8.8	7.3	6.3	5.5	5.3
	80Hz	27.5	18.3	11.7	8.6	6.8	5.6	4.8	4.2	4.1
	100Hz	24.3	15.6	9.8	7.1	5.6	4.6	3.9	3.4	3.3
6.0mA	4Hz	52.6	47.4	40.8	35.8	31.8	28.7	26.1	24.0	23.6
	20Hz	35.3	25.9	17.9	13.7	11.1	9.3	8.0	7.0	6.9
	40Hz	25.0	16.5	10.5	7.7	6.1	5.0	4.3	3.7	3.6
	60Hz	19.4	12.1	7.4	5.4	4.2	3.5	2.9	2.5	2.5
	80Hz	15.8	9.6	5.8	4.1	3.2	2.6	2.2	1.9	1.9
	100Hz	13.3	7.9	4.7	3.3	2.6	2.1	1.8	1.6	1.5

Table 2: Load Impedance = 1 Kohm

All longevity values are in months

		Pulsewidth								
Amplitude	**Frequency**	40uS	100uS	200uS	300uS	400uS	500uS	600uS	700uS	720uS
0.1mA	4Hz	83.9	83.8	83.6	83.4	83.2	83.0	82.8	82.7	82.6
	20Hz	81.5	80.9	80.1	79.2	78.3	77.5	76.7	75.9	75.8
	40Hz	78.6	77.6	76.0	74.5	73.0	71.6	70.2	68.9	68.6
	60Hz	76.0	74.6	72.4	70.3	68.3	66.5	64.7	63.1	62.7
	80Hz	73.5	71.8	69.1	66.6	64.2	62.1	60.0	58.1	57.8
	100Hz	71.2	69.2	66.1	63.2	60.6	58.2	56.0	53.9	53.5
0.2mA	4Hz	83.8	83.6	83.2	82.8	82.5	82.1	81.7	81.4	81.3
	20Hz	81.1	80.1	78.3	76.7	75.1	73.6	72.2	70.8	70.5
	40Hz	78.0	76.0	73.0	70.2	67.6	65.2	63.0	60.9	60.5
	60Hz	75.1	72.4	68.3	64.7	61.5	58.5	55.9	53.4	53.0
	80Hz	72.4	69.1	64.2	60.0	56.4	53.1	50.2	47.6	47.1
	100Hz	69.8	66.1	60.6	56.0	52.0	48.6	45.6	42.9	42.4
0.4mA	4Hz	83.7	83.2	82.5	81.7	81.0	80.3	79.6	78.9	78.8
	20Hz	80.4	78.3	75.1	72.2	69.4	66.9	64.6	62.4	61.9
	40Hz	76.7	73.0	67.6	63.0	58.9	55.4	52.2	49.4	48.9
	60Hz	73.3	68.3	61.5	55.9	51.2	47.2	43.8	40.9	40.4
	80Hz	70.1	64.2	56.4	50.2	45.2	41.2	37.8	34.9	34.4
	100Hz	67.3	60.6	52.0	45.6	40.5	36.5	33.2	30.4	29.9
0.6mA	4Hz	83.5	82.8	81.7	80.7	79.6	78.6	77.6	76.6	76.4
	20Hz	79.7	76.7	72.2	68.2	64.6	61.3	58.4	55.7	55.2
	40Hz	75.4	70.2	63.0	57.1	52.2	48.1	44.6	41.6	41.0
	60Hz	71.5	64.7	55.9	49.1	43.8	39.6	36.1	33.2	32.6
	80Hz	68.1	60.0	50.2	43.1	37.8	33.6	30.3	27.6	27.1
	100Hz	64.9	56.0	45.6	38.4	33.2	29.2	26.1	23.6	23.1
0.8mA	4Hz	83.4	82.5	81.0	79.6	78.2	76.9	75.7	74.4	74.2
	20Hz	79.0	75.1	69.4	64.6	60.3	56.6	53.3	50.4	49.8
	40Hz	74.2	67.6	58.9	52.2	46.9	42.5	38.9	35.9	35.3
	60Hz	69.9	61.5	51.2	43.8	38.3	34.1	30.7	27.9	27.4
	80Hz	66.1	56.4	45.2	37.8	32.4	28.4	25.3	22.8	22.3
	100Hz	62.7	52.0	40.5	33.2	28.1	24.4	21.5	19.3	18.9

Table 2: Load Impedance = 1 Kohm (Continued)

All longevity values are in months

		Pulsewidth								
		40uS	100uS	200uS	300uS	400uS	500uS	600uS	700uS	720uS
1.0mA	4Hz	83.2	82.1	80.3	78.6	76.9	75.4	73.8	72.4	72.1
	20Hz	78.3	73.6	66.9	61.3	56.6	52.5	49.0	46.0	45.4
	40Hz	73.0	65.2	55.4	48.1	42.5	38.1	34.5	31.6	31.0
	60Hz	68.3	58.5	47.2	39.6	34.1	29.9	26.6	24.0	23.6
	80Hz	64.2	53.1	41.2	33.6	28.4	24.6	21.7	19.4	19.0
	100Hz	60.6	48.6	36.5	29.2	24.4	20.9	18.3	16.3	15.9
1.5mA	4Hz	82.8	81.2	78.6	76.1	73.8	71.7	69.6	67.7	67.3
	20Hz	76.7	70.1	61.3	54.5	49.0	44.6	40.8	37.7	37.1
	40Hz	70.2	59.9	48.1	40.2	34.5	30.3	26.9	24.3	23.8
	60Hz	64.7	52.3	39.6	31.9	26.6	22.9	20.1	17.9	17.5
	80Hz	60.0	46.4	33.6	26.4	21.7	18.4	16.0	14.2	13.8
	100Hz	56.0	41.7	29.2	22.5	18.3	15.4	13.3	11.7	11.4
2.0mA	4Hz	58.4	57.2	55.1	53.3	51.5	49.9	48.3	46.9	46.6
	20Hz	53.1	48.2	41.8	36.9	33.0	29.8	27.3	25.1	24.7
	40Hz	47.7	40.3	32.1	26.6	22.8	19.9	17.6	15.9	15.5
	60Hz	43.2	34.6	26.0	20.8	17.4	14.9	13.0	11.6	11.3
	80Hz	39.6	30.4	21.9	17.1	14.0	11.9	10.3	9.1	8.9
	100Hz	36.5	27.0	18.9	14.5	11.8	9.9	8.6	7.5	7.4
4.0mA	4Hz	53.0	49.1	43.6	39.2	35.7	32.7	30.2	28.0	27.6
	20Hz	36.3	28.4	20.9	16.5	13.6	11.6	10.1	9.0	8.8
	40Hz	26.1	18.6	12.6	9.6	7.7	6.4	5.5	4.8	4.7
	60Hz	20.3	13.9	9.1	6.7	5.3	4.4	3.8	3.3	3.2
	80Hz	16.7	11.0	7.1	5.2	4.1	3.4	2.9	2.5	2.5
	100Hz	14.1	9.2	5.8	4.2	3.3	2.7	2.3	2.0	2.0
6.0mA	4Hz	51.4	46.5	40.2	35.4	31.6	28.6	26.1	24.0	23.6
	20Hz	32.7	24.5	17.4	13.4	10.9	9.2	8.0	7.0	6.9
	40Hz	22.4	15.4	10.1	7.6	6.0	5.0	4.3	3.7	3.7
	60Hz	17.1	11.3	7.2	5.3	4.2	3.4	2.9	2.5	2.5
	80Hz	13.8	8.9	5.5	4.0	3.2	2.6	2.2	1.9	1.9
	100Hz	11.6	7.3	4.5	3.3	2.6	2.1	1.8	1.6	1.5

Table 3: Load Impedance = 1.5 Kohm

All longevity values are in months

		Pulsewidth								
Amplitude	**Frequency**	40uS	100uS	200uS	300uS	400uS	500uS	600uS	700uS	720uS
0.1mA	4Hz	83.9	83.8	83.6	83.4	83.2	83.0	82.8	82.7	82.6
	20Hz	81.5	80.9	80.1	79.2	78.3	77.5	76.7	75.9	75.8
	40Hz	78.6	77.6	76.0	74.5	73.0	71.6	70.2	68.9	68.6
	60Hz	76.0	74.6	72.4	70.3	68.3	66.5	64.7	63.1	62.7
	80Hz	73.5	71.8	69.1	66.6	64.2	62.1	60.0	58.1	57.8
	100Hz	71.2	69.2	66.1	63.2	60.6	58.2	56.0	53.9	53.5
0.2mA	4Hz	83.8	83.6	83.2	82.8	82.5	82.1	81.7	81.4	81.3
	20Hz	81.1	80.1	78.3	76.7	75.1	73.6	72.2	70.8	70.5
	40Hz	78.0	76.0	73.0	70.2	67.6	65.2	63.0	60.9	60.5
	60Hz	75.1	72.4	68.3	64.7	61.5	58.5	55.9	53.4	53.0
	80Hz	72.4	69.1	64.2	60.0	56.4	53.1	50.2	47.6	47.1
	100Hz	69.8	66.1	60.6	56.0	52.0	48.6	45.6	42.9	42.4
0.4mA	4Hz	83.7	83.2	82.5	81.7	81.0	80.3	79.6	78.9	78.8
	20Hz	80.4	78.3	75.1	72.2	69.4	66.9	64.6	62.4	61.9
	40Hz	76.7	73.0	67.6	63.0	58.9	55.4	52.2	49.4	48.9
	60Hz	73.3	68.3	61.5	55.9	51.2	47.2	43.8	40.9	40.4
	80Hz	70.1	64.2	56.4	50.2	45.2	41.2	37.8	34.9	34.4
	100Hz	67.3	60.6	52.0	45.6	40.5	36.5	33.2	30.4	29.9
0.6mA	4Hz	83.5	82.8	81.7	80.7	79.6	78.6	77.6	76.6	76.4
	20Hz	79.7	76.7	72.2	68.2	64.6	61.3	58.4	55.7	55.2
	40Hz	75.4	70.2	63.0	57.1	52.2	48.1	44.6	41.6	41.0
	60Hz	71.5	64.7	55.9	49.1	43.8	39.6	36.1	33.2	32.6
	80Hz	68.1	60.0	50.2	43.1	37.8	33.6	30.3	27.6	27.1
	100Hz	64.9	56.0	45.6	38.4	33.2	29.2	26.1	23.6	23.1
0.8mA	4Hz	83.4	82.5	81.0	79.6	78.2	76.9	75.7	74.4	74.2
	20Hz	79.0	75.1	69.4	64.6	60.3	56.6	53.3	50.4	49.8
	40Hz	74.2	67.6	58.9	52.2	46.9	42.5	38.9	35.9	35.3
	60Hz	69.9	61.5	51.2	43.8	38.3	34.1	30.7	27.9	27.4
	80Hz	66.1	56.4	45.2	37.8	32.4	28.4	25.3	22.8	22.3
	100Hz	62.7	52.0	40.5	33.2	28.1	24.4	21.5	19.3	18.9

Table 3: Load Impedance = 1.5 Kohm (Continued)

All longevity values are in months

		Pulsewidth								
		40uS	100uS	200uS	300uS	400uS	500uS	600uS	700uS	720uS
1.0mA	4Hz	83.2	82.1	80.3	78.6	76.9	75.4	73.8	72.4	72.1
	20Hz	78.3	73.6	66.9	61.3	56.6	52.5	49.0	46.0	45.4
	40Hz	73.0	65.2	55.4	48.1	42.5	38.1	34.5	31.6	31.0
	60Hz	68.3	58.5	47.2	39.6	34.1	29.9	26.6	24.0	23.6
	80Hz	64.2	53.1	41.2	33.6	28.4	24.6	21.7	19.4	19.0
	100Hz	60.6	48.6	36.5	29.2	24.4	20.9	18.3	16.3	15.9
1.5mA	4Hz	58.2	57.1	55.4	53.8	52.3	50.8	49.5	48.2	47.9
	20Hz	52.0	47.9	42.5	38.1	34.6	31.6	29.1	27.0	26.6
	40Hz	45.9	40.0	32.9	27.9	24.3	21.5	19.3	17.4	17.1
	60Hz	41.1	34.2	26.8	22.1	18.7	16.3	14.4	12.9	12.6
	80Hz	37.2	30.0	22.7	18.2	15.2	13.1	11.5	10.2	10.0
	100Hz	33.9	26.6	19.6	15.5	12.8	10.9	9.5	8.5	8.3
2.0mA	4Hz	56.4	54.6	51.9	49.5	47.2	45.2	43.3	41.6	41.3
	20Hz	45.7	40.4	33.8	29.1	25.6	22.8	20.5	18.7	18.4
	40Hz	36.9	30.4	23.6	19.2	16.2	14.1	12.4	11.1	10.9
	60Hz	30.9	24.4	18.1	14.4	11.9	10.2	8.9	7.9	7.7
	80Hz	26.6	20.4	14.7	11.5	9.4	8.0	6.9	6.1	6.0
	100Hz	23.4	17.5	12.3	9.5	7.8	6.5	5.7	5.0	4.9
4.0mA	4Hz	52.6	49.1	44.2	40.2	36.9	34.1	31.6	29.5	29.1
	20Hz	35.3	28.5	21.6	17.4	14.5	12.5	10.9	9.7	9.5
	40Hz	25.0	18.7	13.2	10.1	8.3	7.0	6.0	5.3	5.2
	60Hz	19.3	13.9	9.5	7.2	5.8	4.8	4.2	3.6	3.6
	80Hz	15.8	11.1	7.4	5.5	4.4	3.7	3.2	2.8	2.7
	100Hz	13.3	9.2	6.1	4.5	3.6	3.0	2.6	2.2	2.2
6.0mA	4Hz	52.6	49.1	44.2	40.2	36.9	34.1	31.6	29.5	29.1
	20Hz	35.3	28.5	21.6	17.4	14.5	12.5	10.9	9.7	9.5
	40Hz	25.0	18.7	13.2	10.1	8.3	7.0	6.0	5.3	5.2
	60Hz	19.3	13.9	9.5	7.2	5.8	4.8	4.2	3.6	3.6
	80Hz	15.8	11.1	7.4	5.5	4.4	3.7	3.2	2.8	2.7
	100Hz	13.3	9.2	6.1	4.5	3.6	3.0	2.6	2.2	2.2

Table 4: Load Impedance = 2 Kohm

All longevity values are in months

		Pulsewidth								
Amplitude	**Frequency**	40uS	100uS	200uS	300uS	400uS	500uS	600uS	700uS	720uS
0.1mA	4Hz	83.9	83.8	83.6	83.4	83.2	83.0	82.8	82.7	82.6
	20Hz	81.5	80.9	80.1	79.2	78.3	77.5	76.7	75.9	75.8
	40Hz	78.6	77.6	76.0	74.5	73.0	71.6	70.2	68.9	68.6
	60Hz	76.0	74.6	72.4	70.3	68.3	66.5	64.7	63.1	62.7
	80Hz	73.5	71.8	69.1	66.6	64.2	62.1	60.0	58.1	57.8
	100Hz	71.2	69.2	66.1	63.2	60.6	58.2	56.0	53.9	53.5
0.2mA	4Hz	83.8	83.6	83.2	82.8	82.5	82.1	81.7	81.4	81.3
	20Hz	81.1	80.1	78.3	76.7	75.1	73.6	72.2	70.8	70.5
	40Hz	78.0	76.0	73.0	70.2	67.6	65.2	63.0	60.9	60.5
	60Hz	75.1	72.4	68.3	64.7	61.5	58.5	55.9	53.4	53.0
	80Hz	72.4	69.1	64.2	60.0	56.4	53.1	50.2	47.6	47.1
	100Hz	69.8	66.1	60.6	56.0	52.0	48.6	45.6	42.9	42.4
0.4mA	4Hz	83.7	83.2	82.5	81.7	81.0	80.3	79.6	78.9	78.8
	20Hz	80.4	78.3	75.1	72.2	69.4	66.9	64.6	62.4	61.9
	40Hz	76.7	73.0	67.6	63.0	58.9	55.4	52.2	49.4	48.9
	60Hz	73.3	68.3	61.5	55.9	51.2	47.2	43.8	40.9	40.4
	80Hz	70.1	64.2	56.4	50.2	45.2	41.2	37.8	34.9	34.4
	100Hz	67.3	60.6	52.0	45.6	40.5	36.5	33.2	30.4	29.9
0.6mA	4Hz	83.5	82.8	81.7	80.7	79.6	78.6	77.6	76.6	76.4
	20Hz	79.7	76.7	72.2	68.2	64.6	61.3	58.4	55.7	55.2
	40Hz	75.4	70.2	63.0	57.1	52.2	48.1	44.6	41.6	41.0
	60Hz	71.5	64.7	55.9	49.1	43.8	39.6	36.1	33.2	32.6
	80Hz	68.1	60.0	50.2	43.1	37.8	33.6	30.3	27.6	27.1
	100Hz	64.9	56.0	45.6	38.4	33.2	29.2	26.1	23.6	23.1
0.8mA	4Hz	83.4	82.5	81.0	79.6	78.2	76.9	75.7	74.4	74.2
	20Hz	79.0	75.1	69.4	64.6	60.3	56.6	53.3	50.4	49.8
	40Hz	74.2	67.6	58.9	52.2	46.9	42.5	38.9	35.9	35.3
	60Hz	69.9	61.5	51.2	43.8	38.3	34.1	30.7	27.9	27.4
	80Hz	66.1	56.4	45.2	37.8	32.4	28.4	25.3	22.8	22.3
	100Hz	62.7	52.0	40.5	33.2	28.1	24.4	21.5	19.3	18.9

Table 4: Load Impedance = 2 Kohm (Continued)

All longevity values are in months

		Pulsewidth								
		40uS	100uS	200uS	300uS	400uS	500uS	600uS	700uS	720uS
1.0mA	4Hz	58.9	58.2	57.2	56.1	55.1	54.2	53.3	52.4	52.2
	20Hz	55.0	52.2	48.2	44.8	41.8	39.2	36.9	34.8	34.4
	40Hz	50.7	46.3	40.3	35.7	32.1	29.1	26.6	24.5	24.2
	60Hz	47.1	41.5	34.6	29.7	26.0	23.1	20.8	18.9	18.6
	80Hz	44.0	37.7	30.4	25.4	21.9	19.2	17.1	15.4	15.1
	100Hz	41.2	34.5	27.0	22.2	18.9	16.4	14.5	13.0	12.7
1.5mA	4Hz	56.7	55.4	53.2	51.3	49.5	47.8	46.2	44.7	44.4
	20Hz	46.7	42.4	36.8	32.5	29.1	26.4	24.1	22.2	21.8
	40Hz	38.2	32.8	26.6	22.3	19.2	16.9	15.1	13.6	13.3
	60Hz	32.4	26.8	20.8	17.0	14.4	12.4	11.0	9.8	9.6
	80Hz	28.1	22.6	17.1	13.7	11.5	9.8	8.6	7.7	7.5
	100Hz	24.8	19.6	14.5	11.5	9.5	8.1	7.1	6.3	6.2
2.0mA	4Hz	54.5	52.3	49.1	46.2	43.6	41.3	39.2	39.2	37.0
	20Hz	40.1	34.7	28.4	24.1	20.9	18.4	16.5	16.5	14.6
	40Hz	30.1	24.5	18.6	15.1	12.6	10.9	9.6	9.6	8.3
	60Hz	24.1	18.9	13.9	11.0	9.1	7.7	6.7	6.7	5.8
	80Hz	20.1	15.4	11.0	8.6	7.1	6.0	5.2	5.2	4.5
	100Hz	17.2	13.0	9.2	7.1	5.8	4.9	4.2	4.2	3.6
4.0mA	4Hz	53.2	50.5	46.5	43.1	40.2	37.7	35.4	33.4	33.0
	20Hz	36.7	31.0	24.5	20.3	17.4	15.1	13.4	12.1	11.8
	40Hz	26.5	20.9	15.4	12.2	10.1	8.7	7.6	6.7	6.6
	60Hz	20.7	15.7	11.3	8.8	7.2	6.1	5.3	4.6	4.5
	80Hz	17.0	12.6	8.9	6.8	5.5	4.7	4.0	3.6	3.5
	100Hz	14.4	10.6	7.3	5.6	4.5	3.8	3.3	2.9	2.8
6.0mA	4Hz	53.2	50.5	46.5	43.1	40.2	37.7	35.4	33.4	33.0
	20Hz	36.7	31.0	24.5	20.3	17.4	15.1	13.4	12.1	11.8
	40Hz	26.5	20.9	15.4	12.2	10.1	8.7	7.6	6.7	6.6
	60Hz	20.7	15.7	11.3	8.8	7.2	6.1	5.3	4.6	4.5
	80Hz	17.0	12.6	8.9	6.8	5.5	4.7	4.0	3.6	3.5
	100Hz	14.4	10.6	7.3	5.6	4.5	3.8	3.3	2.9	2.8

Appendix III: Troubleshooting

Pop-up Messages	Condition	Buttons	Resolution
All stimulation has been turned OFF.	All stimulation turned off due to data corruption or Device being in Hibernate mode.	"OK"	Contact your Spinal Modulation Representative.
Cancelled Connect Request	Cancel was pressed with connecting attempt in progress.		
Changes since last programming were lost due to loss of connection with the stimulator. Please reconnect to stimulator.	Communication was lost prior to programming attempt.	"OK"	Reconnect to stimulator and re-enter program changes.
Connected to stimulator. Communication is poor.	All RF channels have noise levels above the noise threshold.		Try moving to an area with fewer sources of noise.
Connecting to stimulator...	"Connect" button on the main menu was pressed.		
Connection Established.	Connection attempt was successful.	"OK"	
Connection with stimulator was lost. Please reconnect.	Dropped RF connection.	"Yes" "No" "Cancel"	
Do you want to program changes?	A new Workspace or Exit button was selected without saving (programming) changes.	"OK"	
Invalid FCE password. Please try again.	Invalid FCE password was entered.	"OK"	Only Spinal Modulation representatives should access the FCE mode.
Lead N detected a Current Too High condition.	During an impedance measurement, the measured current was too high.	"OK"	Repeat measurement. If problem reoccurs, contact your Spinal Modulation representative.
Lead N impedance of NNN Ω is out of range.	Lead impedance is out of range	"OK"	Repeat measurement or accept as is.
Maximum stimulation output has been reached.	Maximum stimulation output has been reached (5.2V).	"OK"	Investigate lead integrity.
Please specify a Stimulus Response before programming	Attempt to program a set of pulse parameters without a Stimulus Response Name.	"OK"	Select stimulus response.
Programmer battery is low. Please recharge.	PDA battery reaches 30%.	"OK"	Recharge as soon as possible.
Programmer is booting after a reset. When you click OK the Programmer will switch off. Press the Power button to restart.	Hardware reset Button on the PDA was pressed or the Programmer is launched for the first time.		Press Power button.
Programmer storage space is full. File logging has stopped. Please contact your Spinal Modulation representative for maintenance.	PDA storage is full. After user acknowledgement, normal operation continues.	"OK"	Contact your Spinal Modulation Representative.

Pop-up Messages (Cont.)	Condition	Buttons	Resolution

Programmer storage space is low. Please contact your Spinal Modulation representative for maintenance.	PDA storage is nearing full capacity (log files are stored on the PDA with each significant operation such as programming). Message is displayed and file logging should continue. Normal operation continues after user acknowledgement.	"OK"	Contact your Spinal Modulation Representative.
Stimulation for one or more leads has been turned OFF.	One or more leads turned off due to Low Impedance.	"OK"	Perform impedance measurement and re-enable if within range. Otherwise, investigate lead integrity.
Stimulation has been turned OFF due to a magnet.	Stimulation can be turned off by applying a magnet for the duration specified by the *Magnet Turnoff Time* programmable parameter.	"OK"	
Stimulation has been turned OFF.	Stimulation can be turned off, either by the "All Stim OFF" software button on the INS programmer, or the Off switch on the TNS.	"OK"	
Stimulator battery has reached End of Service (EOS). Stimulation has been turned OFF permanently.	Battery has reached EOS voltage. Stimulation is disabled in order to preserve power for RF communication.	"OK"	Schedule replacement of the Stimulator.
Stimulator battery has reached the Elective Replacement Indicator (ERI).	Battery has reached ERI voltage.	"OK"	Schedule replacement of the Stimulator.
Stimulator clock is HH:MM. Do you want to update Stimulator clock?	The NS internal time is out of sync with the Programmer time.	" Yes" "No"	
The stimulator has been set to default values.	The Programmer has encountered an NS with unreadable or invalid data. Parameters have been set and programmed to default values.	"OK"	Setup device parameters as desired.
The stimulator has unreadable data. Please reconnect with programmer in FCE mode or contact your Spinal Modulation representative	NS has unreadable data (such as Trim data)	"OK"	Contact your Spinal Modulation Representative.
The stimulator is in Upgrade Mode. Please reconnect with programmer in FCE mode or contact your Spinal Modulation representative.	NS in Boot mode.	"OK"	Contact your Spinal Modulation Representative.
Unable to connect to stimulator. Make sure the programmer is close to the stimulator and try again.	Can't connect to the NS.	"OK"	Move the programmer above the Stimulator in circular motions.

Error messages may contain additional troubleshooting information such as "*Error Code: 04-123, BadParameterValue*". This is an aid for Spinal Modulation engineers to debug errors.