Axium™
Neurostimulator System

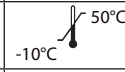
Clinical Programmer User Manual

Model MN10700

℞ only Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Table of Contents

Explanation of Symbols on Product or Package Labeling

REF	Model Number	IP 20	Not waterproof. Applies to the Programmer when it is not in its carrying case.
SN	Serial Number	IP 22	Limited waterproof. Applies to the TNS. Applies to the Programmer in its carrying case.
	Read the Manual		Turns the Programmer ON and OFF. Turns stimulation OFF on the TNS.
	Consult the Manual		Keep Dry
	Contents of Package are Non-Sterile		Store between -10°C and 50°C (14°F and 122°F)
	Manufacturing Date		Store between 0 and 93% humidity
	Manufacturer		The device is a radio transmitter
	Caution		Warning. Pay attention.
	Protected against Electric Shock		Magnet. Shows the location of the Programmer magnet.
	Quantity		Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Do not use if package is damaged.		MR Unsafe
	Electrical Safety Certification		

Introduction

The Clinical Programmer is part of the Spinal Modulation Axium Neurostimulator System. It is intended to be used by the clinician 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.

Description

Patients who are indicated for the Axium Neurostimulator System system will first undergo a trial period using an external Trial Neurostimulator 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 physician. 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 physician. 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.

Indications for Use

The Axium Neurostimulator System is indicated for spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable* pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types I and II.**

*Study subjects from the ACCURATE clinical study had failed to achieve adequate pain relief from at least 2 prior pharmacologic treatments from at least 2 different drug classes and continued their pharmacologic therapy during the clinical study.

**Please note that in 1994, a consensus group of pain medicine experts gathered by the International Association for the Study of Pain (IASP) reviewed diagnostic criteria and agreed to rename reflex sympathetic dystrophy (RSD) and causalgia, as complex regional pain syndrome (CRPS) types I and II, respectively.

Contraindications

Patients contraindicated for the Axium Neurostimulator System are those who:

- Are unable to operate the system
- Are poor surgical risks

Patients who fail to receive effective pain relief during trial stimulation are contraindicated to proceed to the INS procedure.

Warnings, Precautions and Adverse Events

Refer to the Physician Implant Manual for a complete list of warnings, precautions and adverse events for the Axium Neurostimulator System.

Warnings

The Warnings listed below pertain to the Clinical Programmer only:

- The physician must be trained by Spinal Modulation personnel before using the Clinical Programmer. The Clinical Programmer must be used and maintained in accordance with the information in this manual.
- Do not use the Clinical Programmer with an 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 patients 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.

Procedural Warning

- Once the ENABLE function is ON for a specific therapy target, any parameter change will be immediately active.

Precautions

The following precautions should be taken to avoid damage to the Clinical Programmer and to ensure 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 for the Clinical Programmer. Attempts to open the case may expose the Clinical Programmer to elements that alter its functionThe 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 specified temperature range of 5°C to 40°C (41°F to 104°F). Rapid temperature changes may affect proper device operation.
- Do not store the Clinical Programmer outside the specified temperature range of -10°C to 50°C (14°F to 122°F).
- Do not leave the Clinical Programmer in a car or other places where temperatures can exceed 50°C (122°F).
- 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.
- 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.
- If there is any concern regarding the proper function of the Spinal Modulation NS System, please contact your Spinal Modulation representative.

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:

MedRadio/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.

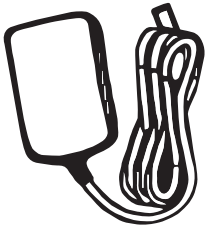
Clinical Programmer System Overview

The Axium 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 power supply provided and a power outlet.

The Clinical Programmer System includes:

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

Stylus



Programmer Charger

Clinical Programmer

Clinical Programmer Features

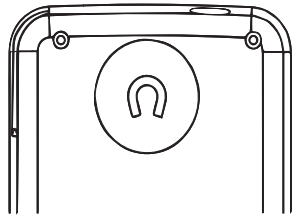
With the Clinical Programmer, you can:

- 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 the “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.

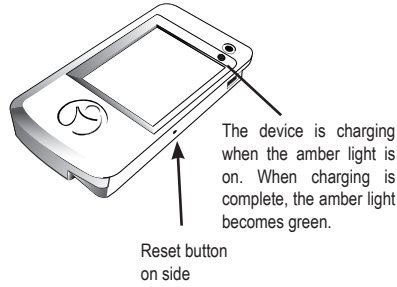
Charging the Clinical Programmer Battery

You will need the Programmer Charger provided to charge the battery in the 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 power supply to a power outlet.

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

   Output: 5V ⎓ 3.0A
2. Connect the Charger to the Programmer.
3. When the battery is charging, the battery icon on the screen contains “AC”. When the charging is complete, the indicator light turns green.



When the Clinical Programmer is connected to a power outlet as described above, it is being powered by the outlet and will not use battery power. The battery can be expected to last at least 500 discharge cycles with normal use. 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 an 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, 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

Programmer Setup

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

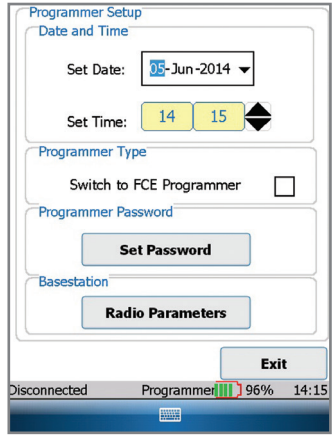
Change the Date and Time

To 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.

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

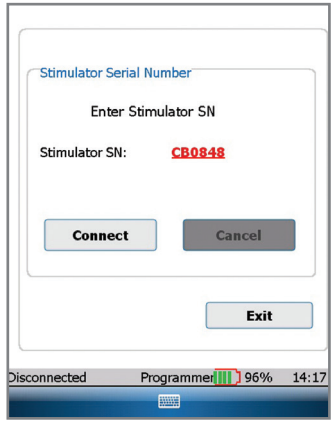
By checking this box the Clinical Programmer will get additional functionality, which should only be used by Spinal Modulation’s Field Clinical Engineers and Staff.

Set Password

A password may be set to limit access to the Programmer. The password is for the Programmer itself and is not associated with any NS.

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.

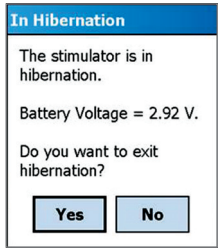
   If the serial number format is valid for an NS device, the "Connect" button will be enabled.
5. Press the "Connect" button.

   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 two 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 again pressing the "Connect" button, and begin moving the Clinical Programmer magnet symbol over the NS device in a circular fashion.*

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

NOTE: *If the 'In Hibernation' message is displayed, select 'Yes' to exit Hibernation. Hibernation is a low-power state that the NS is in prior to first use.*



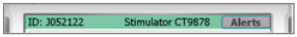
7. For the duration of the programming session, keep the Clinical Programmer near the NS device. Moving the Programmer too far away may cause the telemetry connection to be lost.

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.

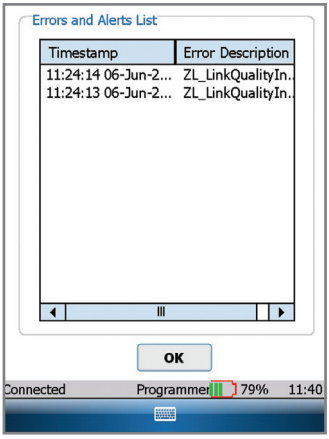
Navigation and Screen Elements

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 below.



Programmer Status Bar

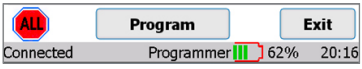
Located at the bottom of the Clinical Programmer screen, the Programmer Status Bar displays:

- **Programmer-Stimulator 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 the Programmer be plugged in and charging when not in use. Plug in and charge the Programmer before reaching 30% remaining life.
- **Programmer Clock:** Displays the time. See User Manual section on Change the Date and Time.

Workspace Navigation

Once the NS is connected, tabs are displayed for the systems’ four main workspaces (“Profile”, “Stim”, “Group” and “Utility”). 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.



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.
- **Program button:** programs all changes made within the current Workspace.
- **ALL button:** turns all stimulation off.

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

When programming is complete, select the “Exit” button to conserve power.

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 appears in a red bold underlined font.

NOTE: *The "temporarily active" state does not apply to the Group workspace.*

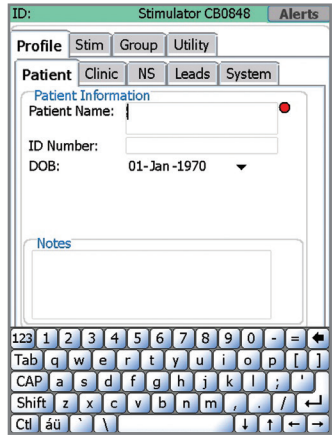
Temporary programmed values or text data can be **permanently programmed** by pressing the program button. The font color changes from red to black.

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.*

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. 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 indicates that editing is in progress.

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:

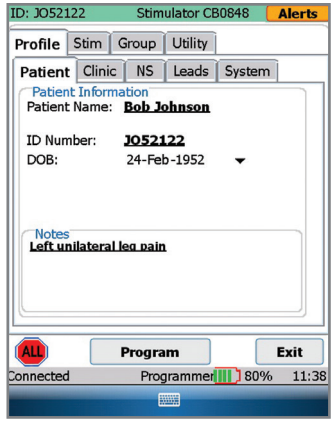
- Enter patient information
- Enter clinician contact information
- Enter NS device information
- Enter lead identification information
- Change basic system parameters

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 keyboard.
- **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.
- **Notes:** Enter notes if needed.

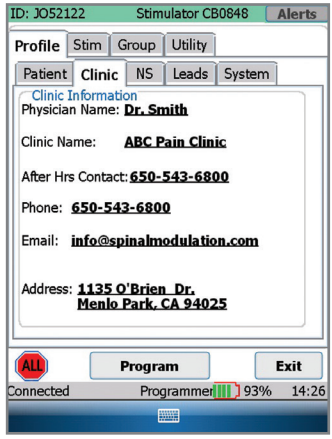
NOTE: *Pressing the “áü” button near the space bar allows the use of accented characters.*



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**

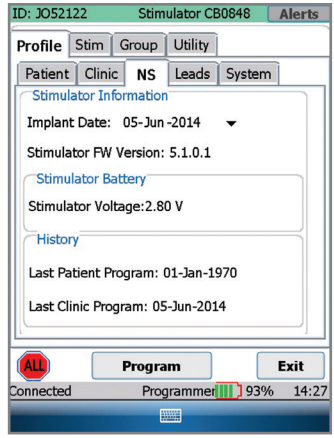


Stimulator Information Tab [Profile>NS]

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 at the start of follow-up.

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



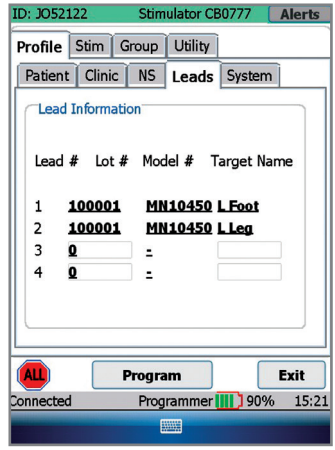
Leads Information Tab [Profile>Leads]

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).

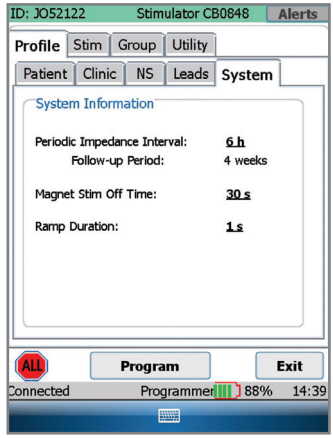
For each of the leads enter the Lot and Model number:

- **Lot #:** Enter the 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 frequency 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 NS 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 Stim Off Time:** Allows you to control how long it takes before a magnet held over the device switches off delivered therapy.

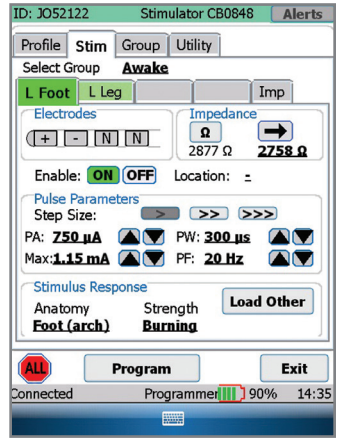
Stim Workspace

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:** To adapt stimulation parameters, choose the desired target labeled tab (The sample screen shows "L Foot" as the target.)

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 the 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.*

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: *When the lead electrode configuration changes, the lead is disabled and the amplitude is automatically changed to zero. 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. Lead “Enable” must be “ON” before the amplitude can be increased from 0 µA.*

- **Location:** Enter the spinal level where stimulation therapy is delivered by this 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(Λ) and Down(V) 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 – 1000 µs	10 µs	300 µs
Pulse Frequency - PF (Hz)	4 – 80 Hz	2 Hz	20 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.

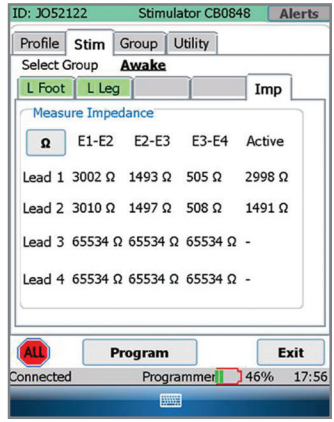
- **Stimulus Response:** Allows you to assign a descriptor to a set of programmed pulse parameters. The descriptor is composed of a body region where the sensation is felt and a description of the sensation. (E.g. Lower Back & Massaging → Lower Back Massaging). **A Stimulus Response must be selected 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 paresthesia 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.

NOTE: *65534 Ω indicates an open or missing lead.*



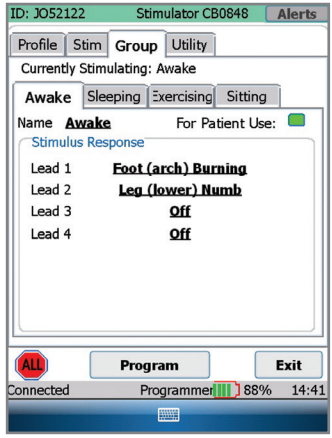
Group Workspace

Press the “Group” tab to access Group Workspace.
The Group Workspace is divided into four tabs (Groups) by default named “Awake”, “Sleeping”, Exercising” and “Sitting”). 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.

Group Tabs [Group>Group Name]

Each Group can be configured by selecting the desired tab.

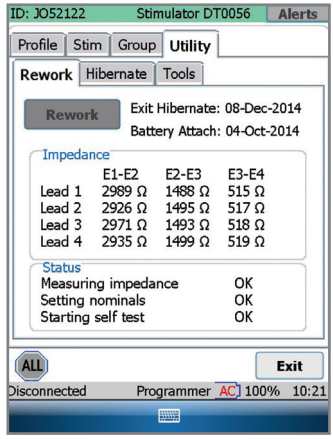
- **Name:** The Group can be renamed here (free-form text entry)
- **For Patient Use:** The Group will be displayed on the Patient Programmer only if this box is checked. Note that the currently active Group must be checked/enabled.
- **Lead 1 through Lead 4:** The Stimulus Response for each Lead within a Group can be changed here. Stimulus Responses that have been previously saved for that Lead will be shown in the drop-down menu.



Rework

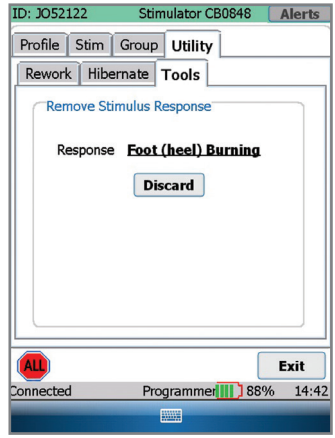
The Rework screen is used to rework a TNS between patient trials. The Rework button performs the following actions:

- Measures detected impedances. Impedances will display as 65k if no load is detected.
- Sets nominal values on the TNS. This will remove all settings from the previous patient.
- Performs a self-test on the TNS.



Discard

When you are close to using all 12 Stimulation Responses, the Discard button may be used to delete any unused Stimulation Responses.



Hibernate

Hibernate mode is used to conserve battery life of the INS while on the shelf.

Battery Longevity

Programmed settings impact the longevity of the implanted device. With 2 leads at 1600 ohms impedance programmed at nominal stimulation settings of 800 µA amplitude, 300 µsec pulse width, 20 Hz frequency, the battery may be expected to last 3.3 years. These nominal settings represent average settings seen in world-wide use of the Axium system. Higher stimulation settings, especially pulse amplitude and frequency, result in greater energy usage and therefore reduce the estimated battery longevity.

The system has two warnings about battery life – ERI which is Elective Replacement Indication when the battery is low but stimulation is still available, and EOS which is End of Service when stimulation has been permanently turned off. At nominal settings, there is a 1 month period between ERI and EOS. Depending on specific settings, the duration may range between 20 and 35 days.

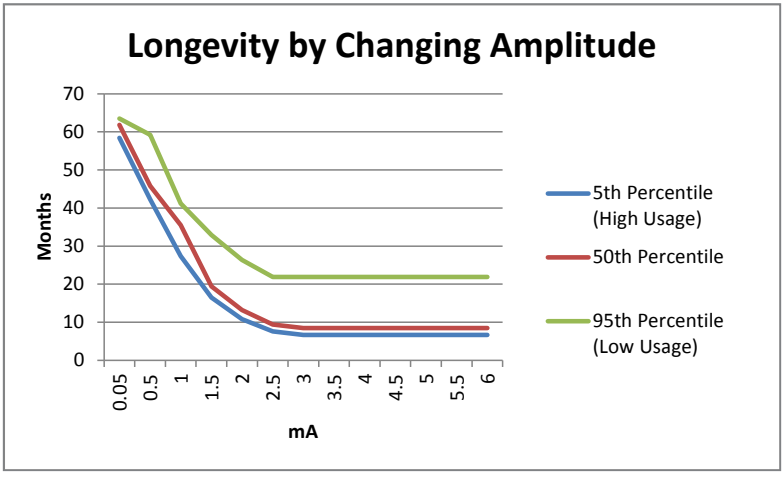
The table below includes patient settings used in the US ACCURATE Clinical Study. The 5th percentile, 50th percentile, and 95th percentile patients were selected based on estimated longevity. The Low Settings example shows the effect of reducing amplitude and frequency.

Patient Settings used in the US ACCURATE Clinical Study						
Patient	Amplitude (µA)	Pulse Width (µsec)	Frequency (Hz)	Impedance (ohms)	Leads	Estimated Longevity (Years)
5th Percentile	2750	410	20	1609	2	0.9
	1350	300	34	1796		
50th Percentile	675	1000	16	1727	1	3.5
95th Percentile	500	160	20	1886	1	4.9
Low Settings	650	110	10	1140	2	5.0
	350	230	10	1968		

The number of leads is not directly proportional to longevity, but on average the longevity decreases as multiple leads are added. The summation of energy delivered through the leads is the primary factor for longevity. Note that both the 0.9 year and the 5.0 year patients have two leads, but the 0.9 year patient is programmed with higher energy settings of 2.75 mA amplitude and 34 Hz frequency compared to the 5.0 year patient's lower energy settings of 350 µA amplitude and 10 Hz frequency.

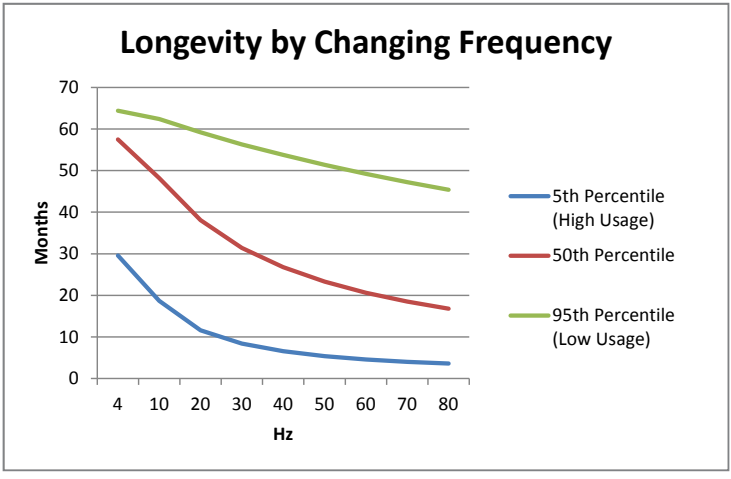
Impact of programmed amplitude on battery longevity

Modifying programmed amplitude can impact the longevity of an implanted device. The graph below depicts expected battery longevity for the selected percentile patients. The patient's pulse width and frequency settings are kept fixed, and the Amplitude setting is varied across the X-axis for all leads. Longevity ranges from 5.3 years to 7 months, depending on the programmed amplitudes for the leads. Note: When the INS reaches maximum output, the expected longevity plateaus.



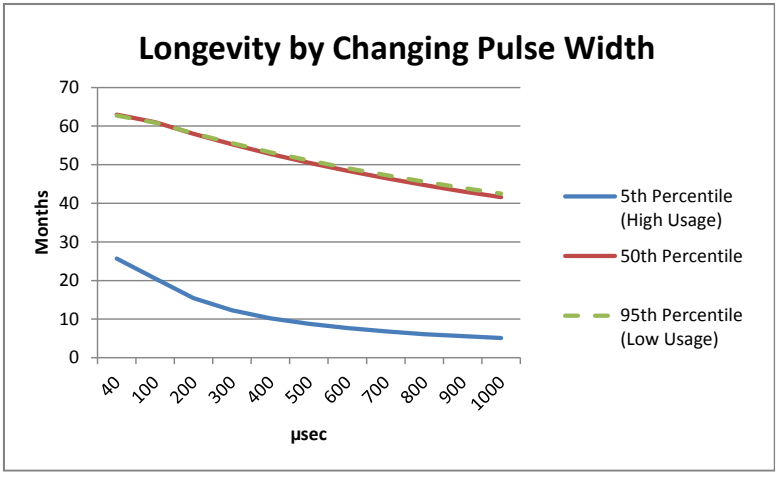
Impact of programmed frequency on battery longevity

Modifying programmed frequency can also impact the longevity of an implanted device. The graph below depicts expected battery longevity for the selected percentile patients. The patient's pulse width and amplitude settings are kept fixed, and the Frequency setting is varied across the X-axis for all leads. Longevity ranges from 5.4 years to 4 months, depending on the programmed frequencies for the leads.



Impact of programmed pulse width on battery longevity

Modifying programmed pulse width can impact the longevity of an implanted device. The graph below depicts expected battery longevity for the selected percentile patients. The patient's amplitude and frequency settings are kept fixed, and the Pulse Width setting is varied across the X-axis for all leads. Longevity ranges from 5.3 years to 5 months, depending on the programmed pulse widths for the leads. Note: The amplitude and frequency settings are very similar for the 50th and 95th percentile patients, so the lines overlap each other.



Guidance and Manufacturer's Declarations

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 Programmer Charger.

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.			
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% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s NOTE UT 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 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 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 Neurostimulator 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 Neurostimulator System

The Spinal Modulation Neurostimulator 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 Neurostimulator 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 – 1000 µs (10µs increments)	300 µs
Pulse Frequency	4 – 80 Hz (2 Hz increments)	20 Hz

Data Field	Selectable Values
Periodic Impedance Interval	Off; 30 s; 1 min; 5 min; 20 min; 30 min; 1 h; 6h; 12 h; 1 days; 3 days; 7 days; 10 days; 30 days
Lead Model Number	MN10350, MN10450
Stimulus Response Anatomy	Off; Lower Back; Back & Leg; Thigh; Knee; Lower Leg; Ankle; Foot (top); Foot (bottom); Toes; Hip; Groin
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 T10; R T10; L T11; R T11; L T12; R T12; L L1; R L1; L L2; R L2; L L3; R L3; L L4; R L4; L L5;R L5; L S1; R S1; L S2; R S2
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	1 s; 2 s; 3 s; 4 s; 5 s; 6 s; 7 s; 8 s

Appendix II: Troubleshooting

Pop-up Messages

Pop-up Messages	Condition	Buttons	Resolution
All stimulation has been turned OFF.	All stimulation turned off due to data corruption.	"OK"	Contact your Spinal Modulation Representative.
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.
Communication is poor.	All RF channels have noise levels above the noise threshold.	"OK"	Hold the Programmer closer to the Stimulator, turn off other equipment in the area, or move to another area in the building, etc.
Connection with stimulator was lost. Please reconnect.	Dropped RF connection.	"OK"	
Do you want to program changes?	A new Workspace or Exit button was selected without saving (programming) changes.	"Yes" "No" "Cancel"	
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 (4.6V).	"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.

Pop-up Messages	Condition	Buttons	Resolution
Programmer battery is low. Please recharge.	Programmer 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 Programmer was pressed, Programmer detected an error or the Programmer is launched for the first time.	"OK"	Press Power button "  ".
Programmer storage space is low. Please contact your Spinal Modulation representative for maintenance.	Programmer storage is nearing full capacity (log files are stored on the Programmer 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 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.
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.

Pop-up Messages	Condition	Buttons	Resolution
The stimulator is in Upgrade Mode. Please reconnect with programmer in FCE mode or contact your Spinal Modulation representative.	NS in Boot mode. All stimulation is disabled.	"OK"	Contact your Spinal Modulation Representative.
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.
Unable to connect to stimulator. Make sure the programmer is close to the stimulator and try again.	Cannot connect to the NS.	"OK"	Move the Programmer above the Stimulator in circular motions.
The file "CProgrammerMobile" cannot be opened. Either it is not signed with a trusted certificate, or one of its components cannot be found. If the problem persists, try reinstalling this file.	Programmer cannot operate due to file corruption.	"OK"	Contact your Spinal Modulation Representative.
All other messages		"OK"	• Attempt to perform the actions again if possible. • Contact your Spinal Modulation Representative.

Error messages may contain additional troubleshooting information such as "*Code P-162, Key: NsNotProgrammed*". This is an aid for Spinal Modulation engineers to debug errors.

When you receive such error codes, please take note of the error code and contact your SMI representative.

Troubleshooting Other Issues

Condition	Resolution
The Programmer is unresponsive (frozen screen, unable to power on, etc.).	Press the reset button on the side of the Programmer. Note: this will not change the Stimulator or Programmer settings.
Impedance measurements may timeout when all measured leads are below 8Hz.	Increase Pulse Frequency to 8Hz to measure impedance and then return to desired Pulse Frequency.
Depending on NS programmed settings, stimulation amplitude may slightly dip during periodic impedance (nominally every 6 hours) and may be noticeable to the patient.	Increasing the stimulation amplitude may decrease the dip in amplitude. Also, the Periodic Impedance interval can be adjusted for less frequent occurrence.
Lead Disabled message (due to impedance) is always shown on Connection.	The message can only be cleared when a valid impedance measurement occurs on the lead that was disabled. If it cannot be cleared, contact your Spinal Modulation representative.
NS Battery voltage is displayed as 65.00 V.	This is the initial NS battery measurement value. A valid value will automatically replace it when the next periodic battery measurement occurs.
Keyboard is stuck on display.	Try to navigate to another screen. If the keyboard remains stuck, press the reset button on the side of the Programmer. This will not change the Stimulator or Programmer settings.
Data fields on non-therapy screens (such as Date of Birth) may display incorrectly. This is a display issue that does not impact therapy.	Reprogram the data.
Basestation Firmware version on the Clinical Programmer start-up screen shows as “FV”.	Connect to an NS device then press the Reset button. This will not change the Stimulator or Programmer settings.
A spinning icon is displayed on the Alerts screen, possibly blocking full view of the alerts.	Navigate away and then return to the Alerts screen.
Spine location setting may change after an NS reset.	Reprogram Spine location.
When the Pulse Frequency is programmed for less than 8 Hz, it may take up to twice as long for the programmed Ramp Duration to reach the desired Amplitude.	Decrease the programmed Ramp Duration or increase the programmed Pulse Frequency.
Following a magnet reset, another magnet reset is not possible until the NS is programmed with a Clinical Programmer.	Use the Clinical Programmer to re-program the NS after a magnet reset. If unsuccessful, contact your Spinal Modulation representative.

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