axium™

Clinical Programmer

Model MN20700-03

User Manual

Spinal Modulation

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Explanation of Symbols on Product or Package Labeling

REF	Model Number
SN	Serial Number
	Read the Manual
	Consult the Manual
NON STERILE	Contents of Package are Non-Sterile
	Manufacturing Date
	Manufacturer
	Warning. Pay attention.
	Protected against Electric Shock
IP 20	Not waterproof. Applies to the Programmer when it is not in its carrying case.
IP 22	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
50°C -10°C	Store between -10°C and 50°C (14°F and 122°F)
93 0	Store between 0 and 93% humidity
	The device is a radio transmitter
	Magnet. Shows the location of the Programmer magnet.
EC REP	Authorized European Representative

Introduction

The Clinical Programmer is part of the Spinal Modulation Axium 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 for the management of chronic intractable pain.

Description

Patients who are indicated for the Axium 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 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.

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 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 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.

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 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 specified temperature range of 5°C to 40°C. 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.
- 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.
- 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:

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-MN20700-03

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.

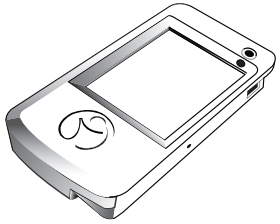
It is a portable, hand-held device that can be plugged into a power outlet or be powered by an internal battery. The battery is rechargeable using the power supply provided and a power outlet.

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:

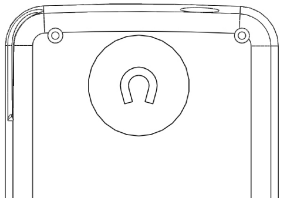
- Turn OFF all stimulation.
- Turn stimulation ON for up to four leads and measure lead impedance.
- Change stimulation settings for each lead.
- Configure Patient Controlled Therapy settings for each lead.
- Enter patient and lead identification information, clinician and clinic name and contact information, 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 or back on. (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.

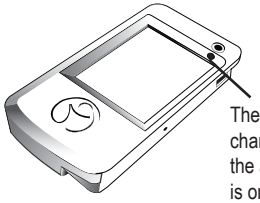
Charging the Clinical Programmer Battery

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 next to the battery icon will be at approximately 100%.



The device is charging when the amber light is on.

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

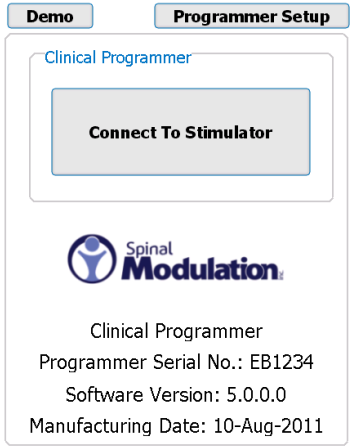
Turn the Clinical Programmer ON by pressing the "⏻" button. The Main Menu will be displayed.

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:

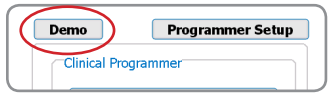
- **Demo:** Puts the system into a stand-alone demo mode allowing you to use all programmer functions without it being connected to a NS.
- **Programmer Setup:** Allows you to set the Clinical Programmer date and time, activate the FCE Workspace on the Programmer, and set and modify the Programmer password.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

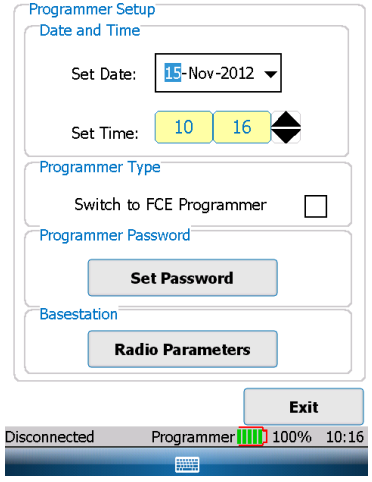
Change the Date and Time

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

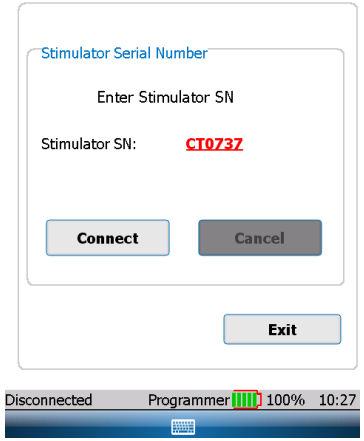
To change the patient's stimulation settings, you must first establish communication between the Clinical Programmer and the patient's NS device.

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 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.

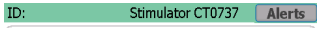
7. For the duration of the programming session keep the Clinical Programmer within 3 feet of the NS device. Moving the programmer too far away may cause telemetry connection to be lost.

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.

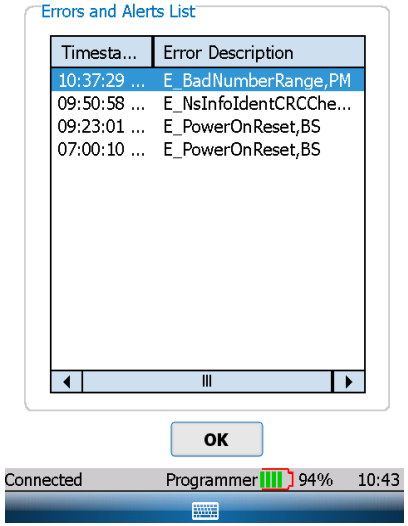
Navigation and Screen elements

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.

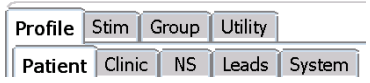


Programmer Status Bar

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

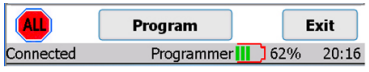
- **Programmer-Stimulator Connection Status:** Displays the status of the communication between the Clinical Programmer and the NS device: "Connecting" is displayed when establishing a connection. "Connected" is displayed when there is communication between the Clinical Programmer and the NS device. "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.

NOTE: 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.

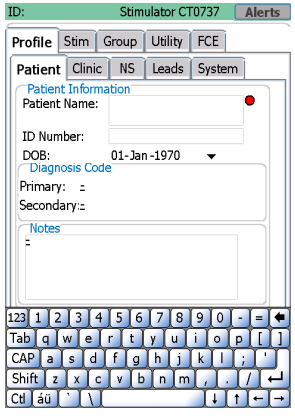
Temporary programmed values or text data can be **permanently programmed** by pressing the program button. The font color changes from red to black.

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.

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. 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:

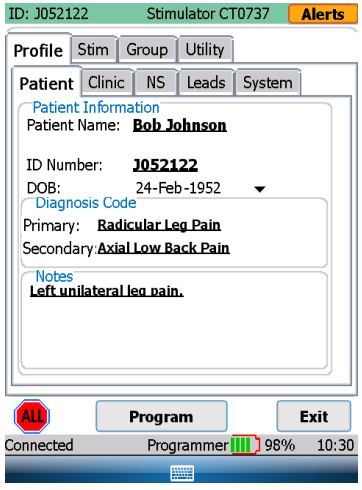
- Enter patient information
- Enter clinician contact information
- Enter NS device information
- Enter lead identification information
- Change basic system parameters

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.
- **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.

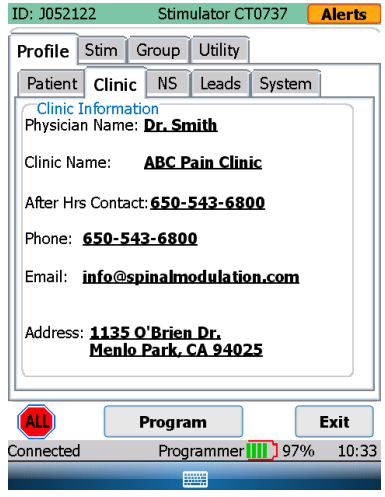
NOTE: *Pressing the "áü" button near the space bar allows the use of accented characters.*



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**

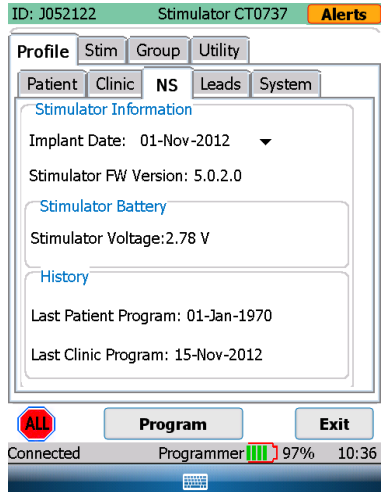


Stimulator Information Tab [Profile>NS]

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.

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



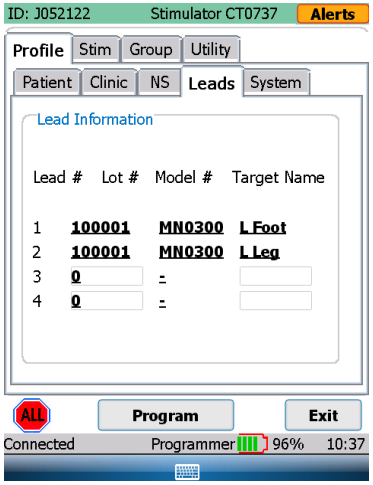
Leads Information Tab [Profile>Leads]

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:

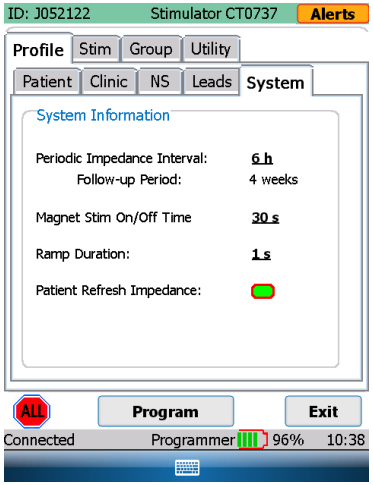
- **Lot #:** Enter the Lot number found on the lead packaging.
- **Model #:** Enter the lead Model number.



System Information Tab [Profile>System]

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

- **Periodic Impedance Interval:** Set the 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 for impedance measurements.
- **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 Magnet Stim On/Off Time:** Allows you to control how long it takes before a magnet held over the device switches off or back on delivered therapy.



- **Patient Refresh Impedance:** This allows the impedance to be remeasured and used for therapy on the Patient Programmer whenever the patient turns a Lead Enable from OFF to ON. ***NOTE:*** *the programmed Pulse Amplitude will be adjusted based on the updated impedance to maintain a constant therapy voltage.*

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]

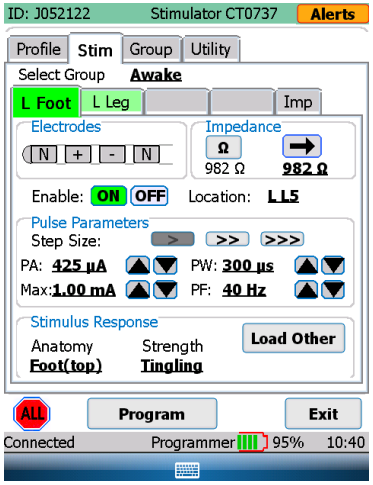
The Stim tabs are the main tabs from which therapy is controlled and programmed. This can be done either temporarily (testing) or permanently.

- **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 e.g. "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 posi tive ("+"), 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.

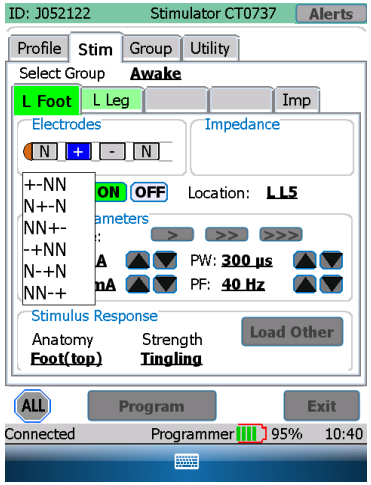
- **Impedance:** Press the "Instant Impedance" button ("Ω") to measure the lead's impedance. Once pressed, the impedance value will be displayed underneath the button. If you want the NS to use this Instant Impedance value for therapy delivery, press the "Transfer Instant Impedance" button ("→").

NOTE: 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 (>: 20 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 – 720 µs	20 µs	300 µs
Pulse Frequency - PF (Hz)	4 – 80 Hz	2 Hz	2 0 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.

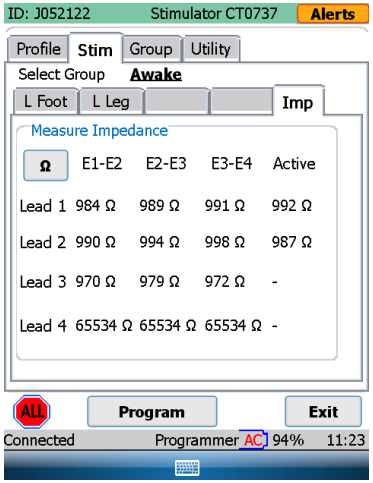
WARNING: Unless the stimulation settings are known for a specific patient, start with a Pulse Amplitude of 0 µA.

- **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. 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.



Group Workspace

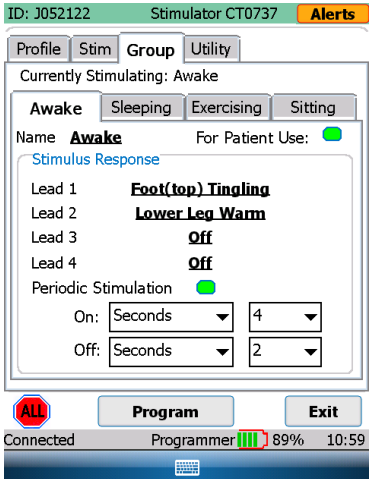
Press the "Group" tab to access Group Workspace.

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.

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.
- **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.



Periodic Stimulation

Periodic Stimulation can be toggled On or Off (green button indicates On). When On, the clinician can program Stimulation On and Off durations independently. Once programmed, therapy will turn on and off according to the programmed durations when:

• out of session, or

• in session in the Group Workspace (this allows the clinician to evaluate and optimize On/Off durations)

When in session in the Stim Workspace, Periodic Stimulation will be inactive (stimulation will remain ON) to allow the clinician to optimize pulse parameters.

Rework Tabs [Utility>Rework]

This screen provides one-button automation of the normal TNS rework procedure:

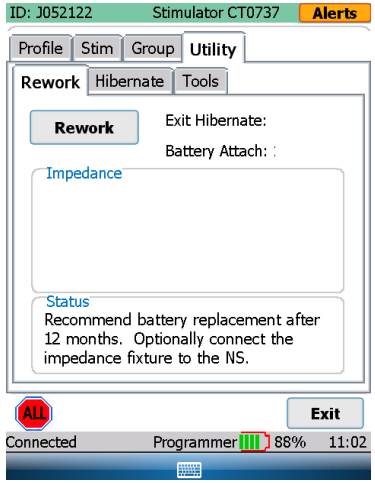
The following steps are performed:

1. Impedance Check: Electrode impedances are measured on all leads and compared against expected load fixture values.

NOTE: the user should connect the standard load fixture prior to this test. If the fixture is not available, this step can be ignored and the remaining two steps will still occur.

2. Set Nominal values: all patient values are cleared in the NS and therapy settings are set to nominal.

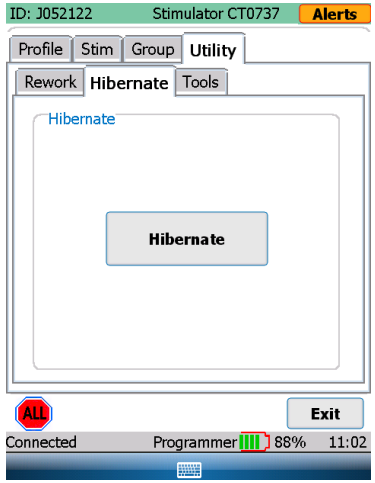
3. Perform NS self-check: a self-test is started on the NS. Upon next connection, the Programmer Alert screen will show any detected NS problems.



Additional: The 'Exit Hibernate' and 'Battery Attach' dates are provided to assist the user in determining when the TNS battery should be replaced.

Hibernate Tabs [Utility>Hibernate]

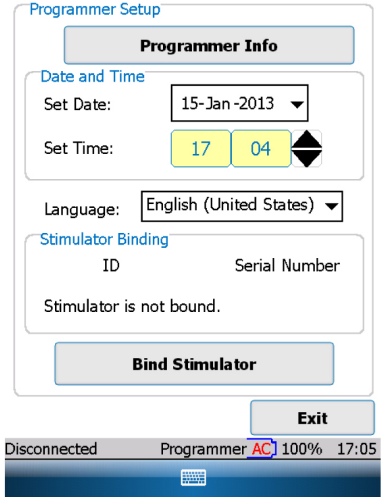
'Hibernate' is used to keep the NS in a low-power state after manufacturing, while in storage, prior to initial clinical use. When connecting a Clinical Programmer to a device in Hibernation, the user will have the option to exit Hibernation. 'Hibernate' is normally not needed after initial clinical use.



Stimulator Binding

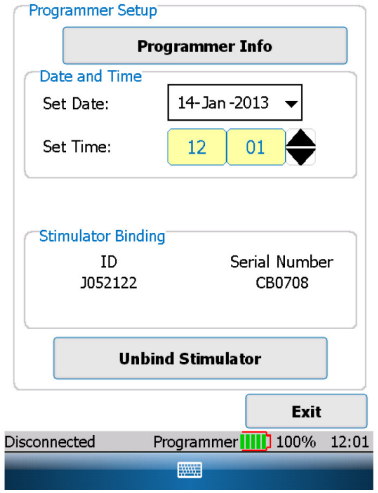
The Binding process pairs a Patient Programmer to a single NS. After the mandatory binding, the Patient Programmer can only connect with that particular NS. The NS can still communicate with other Programmers.

To perform Binding from the Patient Programmer's Programmer Setup screen, select the desired language then press the Bind Stimulator button. Follow the sequence of prompts to enter the target NS serial number and complete the Binding process. The Programmer will reboot upon completion.



Stimulator Unbinding

On a bound Patient Programmer, press the Unbind Stimulator button to remove the binding. This will free the Patient Programmer to bind to another NS. The Programmer will reboot upon completion..



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 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	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:

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 (20µs increments)	300 µs
Pulse Frequency	4 – 80 Hz (2 Hz increments)	20 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; Peripheral Vascular Disease; 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; 6h; 12 h; 1 days; 3 days; 7 days; 10 days; 30 days
Lead Model Number	MN0300; MN0400, MN10350, MN10450, MN20350, MN20450
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; Axilla; 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	1 s; 2 s; 3 s; 4 s; 5 s; 6 s; 7 s; 8 s

Appendix II: Troubleshooting

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.
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.	“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.
The stimulator is in hibernation.			
Battery Voltage = xxx			
Do you want to exit hibernation?			

Pop-up Messages (Cont.)	Condition	Buttons	Resolution
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, Programmer detected an error or the Programmer is launched for the first time.		Press Power button.
Programmer storage space is low. Please contact your Spinal Modulation representative for maintenance.	PDA storage is at full capacity (log files are stored on the PDA with each significant operation such as programming). Message is displayed and file logging continues by deleting old log files to make room for new log files. 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 Stim On/Off Time programmable parameter.	“OK”	Stimulation can be turned back on by applying magnet for the same “Magnet Stim On/Off Time”.
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.

Pop-up Messages (Cont.)	Condition	Buttons	Resolution
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. All stimulation is disabled.	“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.