

Axium™
Neurostimulator System

PATIENT PROGRAMMER
USER MANUAL
MODEL MN10600-02



R_{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	1
INTRODUCTION	3
Description	3
Trial Neurostimulator (TNS)	3
Implantable Neurostimulator (INS).....	3
Implant Leads / Trial Leads / Lead Extension	3
Connector Cable	3
Additional Accessories	4
Indications for Use	4
Contraindications	4
Warnings and Precautions	4
Warnings.....	4
Warnings Regarding the Trial Neurostimulator	7
Warnings - For Use in Home or Work Environments	7
Precautions – For Your Programmer and Your Stimulator	9
Precautions – For Your Therapy	10
Adverse Events.....	12
RF Operating Frequencies.....	13
PROGRAMMER OVERVIEW.....	14
Programmer Features.....	14
Charging the Battery	15
Programmer Power Up	15
MAIN MENU	15
STIMULATOR BINDING.....	17
Magnet.....	17
CONNECTING WITH YOUR STIMULATOR.....	17
Pain Control Screen.....	18
ID Heading	18
Select Group	19

Back to Main Menu	19
Programmer Status Bar	19
ADJUSTING YOUR STIMULATOR SETTINGS	20
Turn OFF All Stimulation.....	20
Pain Control Tab	20
Turn Stimulation On or Off for a Body Region	20
Adjust Stimulation to a Body Region.....	21
DEVICE, PHYSICIAN AND CLINIC INFORMATION.....	21
My Info Tab	21
Device Tab and Physician Tab	21
Stimulator Identification Information.....	22
Physician Information.....	22
Clinic Tab	22
TO USE WITH YOUR TNS DEVICE	22
TO USE WITH YOUR INS DEVICE	23
CLEANING YOUR PROGRAMMER	23
DISPOSAL OF YOUR PROGRAMMER.....	23
ENVIRONMENTAL CONDITIONS FOR STORAGE AND OPERATION... 23	
GUIDANCE AND MANUFACTURER'S DECLARATIONS	24
APPENDIX I: TROUBLESHOOTING	27
TROUBLESHOOTING OTHER ISSUES.....	28

Explanation of Symbols on Product or Package Labeling

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

Glossary

Lead – Surgical wire: takes electrical signals from the neurostimulator to the stimulation area

Stimulation – Small electrical pulses: produces a tingling sensation and replaces pain signals

Stimulator – Device that makes electrical pulses that will stimulate the nerves in your spine: can refer to either the Trial Neurostimulator or Implantable Neurostimulator

Trial Neurostimulator (TNS) – External Stimulator that clips onto your belt: attaches to the connector cable, which is connected to the leads that are implanted in the area near your spine

Implantable Neurostimulator (INS) – Stimulator implanted in your back or abdomen: attaches to leads implanted in the area near your spine

Connector Cable – Cable that connects the leads to your Trial Neurostimulator

Programmer – Portable, hand-held device: allows you to adjust your stimulation settings

Clinical Programmer – Portable, hand-held device: allows the physician to program your Stimulator.

Computer Tomography (CT) Imaging – Computerized X-ray imaging: produces electronic images of tissues and organs

Diathermy – High energy heat: used to cut or cauterize during surgery or a type of therapy

Electromagnetic Interference (EMI) – Electrical signals that interfere with the device function

Magnetic Resonance Imaging (MRI) – Medical imaging: produces electronic images of tissues and organs

Paresthesia – Tingling sensation felt during therapy delivery: produced by dorsal root ganglion stimulation

Precaution – Situation that could cause uncomfortable stimulation and possible damage to the Stimulator or Programmer

Program – Instructions or changes to stimulation settings that are put into the Programmer and transmitted to the Stimulator

Stimulation Level – Amount of stimulation: can be increased or decreased within a range set up by your doctor

Warning – Potentially serious hazard that could cause injury or death

Introduction

Your Axium Patient Programmer is used to program your Trial or Implantable Stimulator. This User Manual gives detailed instructions on how to safely use your Programmer and your Stimulator. See your doctor if you have any questions.

Description

The Axium Patient Programmer is a portable, hand-held device. It is used to communicate with your Stimulator. Your Programmer contains information about your Stimulator. You will use it to adjust your stimulation settings or turn stimulation off. It can run on its rechargeable battery. It can also be plugged into a power outlet.

A Clinical Programmer is used by your doctor to initially set up your Stimulator and make adjustments later if needed. Only your doctor and/or Spinal Modulation clinical personnel use the Clinical Programmer.



Trial Neurostimulator (TNS)

The external TNS device connects to the Trial Lead(s) or Lead Extensions and is worn for up to 30 days during the trial period. The TNS device has a belt clip for your convenience.



Implantable Neurostimulator (INS)

The Axium Implantable Neurostimulator (INS) is a non-rechargeable, 4-channel electronic device. It uses microelectronic circuitry, powered by a hermetically sealed battery, to generate a pulsed waveform to stimulate neural tissue.



Implant Leads / Trial Leads / Lead Extension

- **Implant / Trial Leads:** The Leads are designed for implant into your body. Leads are comprised of surgical wire which takes electrical signals from the neurostimulator to the stimulation area.
- **Lead Extension:** The Lead Extension is intended to extend the length of the lead and provide a connection between the lead and the Connector Cable or the lead and the Implantable Neurostimulator. The Lead Extension is intended for chronic implantation as a component of the Axium Neurostimulator System.

Connector Cable

- The Connector Cable connects the Leads or Lead Extension to the external TNS.

Additional Accessories

- **Medical Alert Card:** Identifies you as a user of the Neurostimulator System.
- **Programmer Charger:** To be used with the Patient Programmers to charge the battery or allow use of the Programmers while plugged into standard electrical outlets.
- **Programmer Carrying Case:** Protects the Programmer from water.
- **Auxiliary Magnet:** Allows you to turn off or communicate with the TNS or INS.

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 and Precautions

- Physicians should refer to the Physician Implant Manual for a complete list of warnings and precautions for the Axium Neurostimulator System.

Warnings

- Do not use your Programmer or the Stimulator until your doctor has trained you.
- The safety and effectiveness of this therapy has not been established for pregnancy, nursing, the unborn fetus, or delivery.
- The safety and effectiveness of the Axium Neurostimulator System has not been established for pediatric use.
- Do not use your Programmer until your doctor has set up your Stimulator.
- Before having a CT scan, tell your doctor that you have an implanted device. All stimulation for your device should be turned OFF before the procedure. After the scan, your doctor should turn it back on and make sure the system is working properly.
- Do not remove your leads or Connector Cable by yourself. This may cause serious injury and could cause an infection.

- Do not open or modify the Programmer or TNS. Keep them closed to protect them. Modifications to the device may cause improper operation.
- Do not transport the Programmer outside of its carrying case. Operate it only in a moisture-free environment. The Programmer may malfunction if it becomes wet.
- Power generators, arc welders and large magnetized speakers may cause interference. Do not stand near these or similar devices.
- Be aware of where you place your Charger. Pets, children or you can become entangled in the cord, which could cause a fall or strangulation.
- If contact with the Stimulator System causes a rash, report this to your doctor. If your throat or tongue starts to swell, get emergency aid immediately.
- Please contact your doctor if you experience unusual pain or discomfort during stimulation, or if the implant site is swollen, reddened, tender, or painful.
- **Other Active Implantable Devices** - The Axium system may interfere with other implanted stimulators, such as cardiac pacemakers and defibrillators which have sensing features, and may result in sensing problems or inappropriate responses. The effect of other implanted devices, including deep brain stimulators, peripheral nerve stimulators, implanted drug delivery pumps, and cochlear implants on the Axium system are unknown.
- **External Defibrillators** – Safety for use of external defibrillator discharges on those receiving neurostimulation has not been established. External defibrillation can cause induced currents in the lead-extension portion of the neurostimulation system. After defibrillation confirm the neurostimulation system is still working.
- **Magnetic Resonance Imaging** – The Axium System is MRI unsafe. Be advised to not undergo any elective magnetic resonance imaging (MRI) with the entire system, or (in the case of removal of the implanted generator) leads or lead fragments in place. Use of MRI in the vicinity of the lead(s) may result in forceful dislodgment of the lead(s), or damage to the Neurostimulator. If a voltage is induced through the lead, it may cause uncomfortable (“jolting” or “shocking”) levels of stimulation or injury. MRI may cause heating at the lead tip and unintended stimulation could result in tissue damage.
- **Computed Tomography (CT)** – Please inform your doctor and medical personnel conducting your CT scan that you have an implanted DRG system. You must turn your device off temporarily while the scan is being conducted. It is important that the person conducting your CT scan does the following:
 - Determines the device type;
 - If practical, tries to move external devices out of the scan range;
 - Minimizes x-ray exposure to the implanted or externally worn electronic medical device by:
 - Using the lowest possible x-ray tube current consistent with obtaining the required image quality; and
 - Making sure that the x-ray beam does not dwell over the device for more than a few seconds.

Important note: For CT procedures that require scanning over the medical device continuously for more than a few seconds, as with CT perfusion or interventional exams, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.

After CT scanning directly over the implanted or externally worn electronic medical device:

- You should turn your Axium system device back on.
- Check that the Axium system is working properly.
- Contact your doctor as soon as possible if you suspect the Axium system is not functioning properly after a CT scan.
- Tell your regular doctors or healthcare providers that you have a Stimulator. Do not have any elective medical procedures without first discussing them with your doctor. Some medical devices or therapies, such as those listed below, may interfere with your Stimulator:
 - Electrocautery – Uses an electric probe to cauterize blood vessels and stop bleeding during surgery.
 - Lithotripsy – Uses high-output shock waves to break up gallstones and kidney stones.
 - Therapeutic Radiation – Uses ionizing radiation to destroy cancer cells.
 - High-output ultrasound – Uses high frequency sound waves to treat bone and muscle injuries, or to stimulate muscle or improve blood flow.
 - RF Ablation – Uses radio frequency energy to cause controlled tissue damage.
 - Microwave Ablation – Uses high speed alternating electric field to cause controlled tissue damage.
 - Dental procedures, electrolysis, static field therapeutic magnets and diagnostic X-ray.
- **Ultrasonic Scanning** – Inform your doctor and medical personnel that ultrasonic equipment may cause mechanical damage to the lead if used directly over the site.
- **Electrosurgery Devices** – Inform your doctor and medical personnel that electrosurgery devices should not be used in close proximity to implanted lead(s). Contact between an active lead and the electrosurgical pencil can cause direct stimulation of the contacted nerve and can cause severe injury. Electrosurgery devices may also damage the lead and cause a loss of stimulation.
- **Implantation at Vertebral Levels above T10** – The safety and efficacy of implantation of leads implanted above the T10 vertebral level has not been evaluated.
- **Number of Leads Implanted** – The safety and efficacy of the implantation of greater than 4 leads has not been evaluated.
- **Back Pain** - The safety and efficacy for the treatment of patients who have back pain as the greatest region of pain has not been evaluated.

- **Non-Emergency Procedures** – Do not have non-emergency procedures while undergoing trial stimulation.
- **Emergency Procedures** – Designate a representative (family member or close friend) to notify any emergency medical personnel of your neurostimulator implant, if emergency care is required. You will be provided with a Medical Alert Card to carry with you to inform emergency medical personnel of your implant. Be advised to use caution when undergoing any procedure that could include RF or microwave ablation, defibrillation or cardio version.
- **Routine Medical Procedures** – Do not undergo dental procedures, diathermy, electrolysis, diagnostic ultrasound, static field therapeutic magnets, diagnostic X-ray, and high output ultrasonic lithotripsy. These procedures may provide interference that can affect TNS or INS device operation or use or damage components of the system that may cause patient harm. If you are given any medical treatment in which an electrical current is passed through your body from an external source, either the device should first be deactivated, or care should be taken to monitor the functioning of the neurostimulator during the initial stages of treatment.
- **Diathermy Therapy** – Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death. Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system removal and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off. All patients are advised to inform their health care professionals that they should not be exposed to diathermy treatment.
- **Explosive or Flammable Gases** – Do not use the patient programmer to communicate with the INS or TNS in an environment where explosive or flammable gas fumes or vapors are present. The operation of the programmer could cause them to ignite, causing severe burns, injury, or death.

Warnings Regarding the Trial Neurostimulator

- **Exposure to Fluids** – Exposure of the external TNS or the Connector Cable to water, body fluids, saline, or cleaning agents can cause corrosion and affect stimulation. Do not immerse the external TNS or Connector Cable in fluids.
- Wear the TNS on the outside of your clothing or on a belt.

Warnings - For Use in Home or Work Environments

- **Equipment Operation** - Patients who feel an uncomfortable change in paresthesia during motion should avoid driving a car or operating other potentially dangerous machinery while stimulation is on. You could be distracted from driving or device operation if sudden changes in stimulation occur.

- **Activities Related to Lead Movement** - Limit your activities to low or moderate levels during your trial stimulation period and the first six weeks of implantation of the INS. Failure to do so may result in migration of the leads causing loss of stimulation therapy, muscle stimulation or painful stimulation thereby requiring reoperation to reposition. You may turn off your device if stimulation becomes uncomfortable.
 - Do not rub or press on the implant site. This may cause the leads to move or your skin to erode. It may also cause the INS to move.
 - Avoid excessive bending, twisting and stretching. Do not lift objects over five pounds. These activities may cause the leads to move. You may experience higher or lower levels of stimulation.
- **Theft Detectors and Metal Screening Devices** – Certain types of anti-theft devices, such as those used at entrances/exits of department stores, libraries, and other public establishments, and/or airport security screening devices may affect stimulation. If you have implanted non-adjacent multiple leads or are sensitive to low stimulation thresholds you may experience a momentary increase in perceived stimulation, which has been described as uncomfortable or jolting. Use caution when approaching such a device and request assistance to bypass the device. If you must proceed through the device, turn off the NS and proceed with caution, being sure to move through the detector quickly.
- **Restricted Areas** – Seek medical guidance before entering environments which could adversely affect the operation of the implanted device, including areas protected by a warning notice preventing entry by patients fitted with a pacemaker.
- **Scuba Diving and Hyperbaric Chambers** – Avoid scuba diving and entering hyperbaric chambers above 150 kPa. These activities may damage the Axium System.
- **Cell Phones** - While interference with cell phones is not anticipated, cell phone technology continues to change, and interaction with an neurostimulator system is possible. Contact your physician if you have a concern about cell phone interaction with your neurostimulator system.
- **Electromagnetic Interference (EMI)** – Electromagnetic interference is a field of energy generated by equipment found in the home, work, medical or public environments that is strong enough to interfere with neurostimulator function. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. Keep away from areas of EMI and turn off the stimulator if they are in such an area. Sources of strong electromagnetic interference can result in the following:
 - **Operational changes** – Operational changes to the neurostimulator, causing it to turn on or off (particularly in neurostimulators enabled for magnet use), or to reset to power-on- reset (POR) settings, resulting in loss of stimulation, return of symptoms, and in the case of POR, requiring reprogramming by a clinician.

- **Unexpected changes in stimulation**, causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the device or injure you directly. In rare cases, as a result of the unexpected change in stimulation, patients have fallen down and been injured.

Sources of potentially strong EMI include the following:

- Microwave transmitters
- Communication equipment such as microwave transmitters, linear power amplifiers, and high voltage power lines and power generators
- Electric arc welding equipment
- Large, magnetized stereo speakers
- Radio frequency identification devices (RFID)
- Antenna of citizens band (CB) or ham radio
- Electric steel furnaces
- Dental drills and ultrasonic probes
- Electrolysis

Precautions – For Your Programmer and Your Stimulator

Follow these precautions to maintain proper function of your Programmer and Stimulator.

- Do not drop or mishandle your Programmer or Stimulator. Physical damage to the devices may keep them from working properly.
- Do not wash the Programmer or TNS device. Excess water may keep them from working properly. Use a soft damp cloth to gently wipe the devices if needed.
- Do not use abrasive or caustic cleaning products on your Programmer or TNS device.
- Avoid contact with body fluids for the TNS and Programmer. Contamination may cause damage to the devices.
- Do not shower or bathe with the TNS device. You may take a sponge bath. You must take care not to get the TNS device wet.
- Do not use any equipment or accessories that are not supplied with your Programmer.
- Do not place your Programmer close to cards with magnetic strips. The Programmer has a magnet that could demagnetize your cards. Keep the Programmer away from computer hard drives and magnetic storage devices.
- Do not operate the Programmer or Stimulator outside the temperature range of 5°C to 40°C (41°F to 104°F). Rapid temperature changes may affect device operation.
- Do not store the Programmer outside the temperature range of -10°C to 50°C (14°F to 122°F).

- Do not leave the Programmer in a car or other places where temperatures can reach 50°C (122°F).
- An unlikely failure of your Stimulator System is possible due to random component failure. If any part of your Stimulator System stops working or changes how it works, turn stimulation OFF. Contact your doctor during normal business hours.
- Return your Programmer and your TNS to your doctor at the end of the trial period, or when no longer being used. Do not discard or burn the TNS or Programmer. Fire may cause the internal batteries to explode.
- Do not attempt to dispose of the TNS or Programmer yourself.
- Do not replace the TNS or Programmer battery by yourself, even if it does not seem to be working. Only Spinal Modulation personnel should replace the TNS or Programmer batteries.
- Do not use any other company's device to program your Stimulator. Use only the Programmer provided by Spinal Modulation.
- Do not allow unauthorized use of your Programmer. This may cause unwanted changes in the programming.
- Do not use the Charger if the power cord is damaged. This may cause injury or damage your Stimulator.
- To remove power from the Charger when not in use, unplug it from the power outlet.
- Avoid unnecessary programming of your device. Frequent usage will wear the battery down faster.
- Do not open or shred the battery.
- Do not short-circuit the battery.
- Do not subject the battery to mechanical shock.
- In the event of a battery leak, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
- In case of a non-responding unit, Spinal Modulation personnel will observe the plus (+) and minus (–) marks on the battery and equipment and ensure correct use. They will also wipe the battery terminals with a clean dry cloth if they become dirty.
- Keep the battery out of the reach of children.
- Seek medical advice immediately if a battery has been swallowed.
- Keep the Programmer clean and dry to prevent affecting the battery.

Precautions – For Your Therapy

Follow these precautions to maintain appropriate therapy:

- Follow the proper wound care techniques given to you by your doctor.
- When programming, temporary discomfort may be experienced due to quick changes in stimulation output. Talk to your physician about enabling the Ramp feature if this occurs.

- Appoint a family member or friend to tell emergency medical personnel that you have a Stimulator, in case you need emergency care. You will be given a Medical Alert Card to carry with you. This card will inform emergency medical personnel that you have a Stimulator.
- **High Stimulation Outputs** – Stimulation at high outputs may cause unpleasant sensations or motor disturbances or may render you incapable of controlling the patient programmer. If unpleasant sensations occur, the device should be turned off immediately.
- **Stimulation Parameters** – Stimulation parameters must be determined under the supervision of your physician. Do not adjust stimulation parameters within prescribed programs unless ordered to do so by your physician.
- **Transcranial Magnetic Stimulation (TMS) and Electroconvulsive Therapy (ECT)** – Inform your doctor and medical personnel that safety has not been established for TMS or ECT with your implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.
- **Transcutaneous Electrical Nerve Stimulation** – Inform your doctor and medical personnel that safety has not been established for transcutaneous electrical nerve stimulation (TENS) electrodes and may cause TENS current to pass over part of the neurostimulation system. If you feel that the TENS may be interfering with the implanted neurostimulator, discontinue using the TENS until they talk with their doctor.
- **Therapeutic Radiation** – Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been performed and no definite information on radiation effects is available. Sources of therapeutic radiation include x-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted INS should be shielded with lead.
- **Long-Term Effectiveness of DRG Stimulation** – The long-term effectiveness of DRG stimulation has been documented. You may not realize long-term benefits from DRG stimulation. Stimulation effectiveness has been established for one year.

Adverse Events

The implantation of a neurostimulation system involves risk. In addition to those risks commonly associated with surgery, the following risks are also associated with implantation and use of the Axium Neurostimulator System:

- Pain (where the needle has been inserted)
- Pain (caused by understimulation due to lead migration)
- Pain over the implantable neurostimulator site
- Escalating pain
- Bleeding (where the needle has been inserted)
- Headache
- Infection
- Localized collection of serous (clear) fluid at injection site
- Discomfort during the treatment
- Allergic or rejection response to implant materials
- Constant pain at the lead site
- Stimulation of the chest wall
- Lead migration (movement) and/or local skin breakage
- Weakness
- Clumsiness
- Numbness
- Temporary muscle activation
- Cerebral Spinal Fluid (CSF) leakage
- Tissue damage
- Nerve damage
- Spinal cord compression
- Paralysis
- Hematoma
- Swelling
- Seroma
- Sensory loss
- Skin erosion around the INS or leads
- Battery failure and/or battery leakage
- Lead breakage requiring replacement of the lead
- Hardware malfunction requiring replacement of the neurostimulator
- Pain from a non-injurious stimulus to the skin (allodynia)
- An exaggerated sense of pain (hyperesthesia)
- Change in stimulation, possibly related to tissue changes around the electrodes, shifts in electrode position, loose electrical connections, lead or extension fractures, which has been described by some patients as uncomfortable stimulation (jolting or shocking sensation).

- Formation of reactive tissue in the epidural space around the lead can result in delayed spinal cord compression and paralysis, requiring surgical intervention. Time to onset can range from weeks to many years after implant.

Additional risks, as a result of the placement and stimulation of the lead in the area of the DRG, include pain due to setting the stimulation parameters too high. This may occur once the lead is in place and is connected to the neurostimulator and activated. The neurostimulator is controlled by a trained operator and the starting point for the stimulation will be set to the lowest available settings. Additionally, all patients will be awake and conversant during the procedure to minimize the impact.

If you have any concerns about your Stimulator, contact your doctor during normal business hours.

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-MN20600-02

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.

Programmer Overview

Your Axiom Patient Programmer is a portable, hand-held device. It is powered by an internal rechargeable battery. The Programmer can also be plugged into a power outlet for use or for recharging. Your Programmer communicates with your Stimulator to control your stimulation. Your doctor will explain how to use the Programmer to adjust stimulation for your best pain relief.

Keep your Programmer near you at all times. This will allow stimulation adjustment, if needed. Carry your Programmer in its carrying case. The case provides protection from water.

Your Programmer System consists of:

- Programmer (and internal magnet)
- Stylus
- Auxiliary Magnet
- Charger
- Carrying Case
- Patient Medical Alert Card
- Patient Quick Guide
- Patient Programmer User Manual (this document)



Programmer



Stylus



Programmer Charger

Programmer Features

With your Axiom Patient Programmer, you can:

- Turn stimulation ON or OFF for each body region
- Adjust the stimulation level for each body region
- Change the Group for stimulation - See "Select Group" under the "Pain Control Screen" section
- Turn OFF all stimulation if needed
- View your Stimulator ID information
- View your ID number
- View your lead implant date
- View your doctor's name, clinic name and contact information

Charging the Battery

The Programmer System comes with a Charger. The Programmer must be fully charged before using it for the first time. It takes approximately two to four hours to fully charge the battery. The Programmer Status Bar at the bottom of the screen shows the battery charge level.

1. Plug the Charger into a power outlet.
2. Connect the Charger to your Programmer.

When the battery is charging, the battery icon on the screen shows "AC". When charging is complete, the amber light becomes green.

Your Programmer will operate when it is connected to a power outlet. It does not use battery power when connected to an outlet. Connect your Programmer to the Charger and plug it into an outlet regularly to keep it charged above 30%. Do not leave Charger plugged into a power outlet overnight.

NOTE: Use only the Model MN23400-U Charger. It was included with your Programmer. Use of any other charger could damage your Programmer.

The battery can be expected to last at least 500 discharge cycles with normal use. Once it fails to hold a charge, it should be replaced by Spinal Modulation personnel only. Do not attempt to change the battery. Your Programmer and Charger can be expected to last up to two years with normal use.

Programmer Power Up

Press the  button to turn ON your Programmer screen. The Main Menu will display.

NOTE: If your Programmer does not turn ON, charge the battery and try again.

Main Menu

The Programmer Main Menu displays two main functions:

- **Connect:** Allows you to connect to your Stimulator; also allows you to adjust stimulation settings.
- **Programmer Setup**  : Allows you to set your Programmer date and time, and to view information about your Stimulator.

The device is charging when the amber light is on.



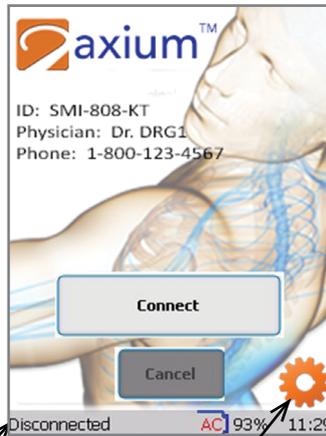
Press here to turn on Programmer screen.



Reset pinhole is on the back.

The Main Menu also shows your physician, and the clinic phone number.

The Programmer status bar is at the bottom of the Main Menu. It displays your Programmer–Stimulator connection status, the battery charge level and the time. See the “Programmer Status Bar” section in this User Manual for more detail.

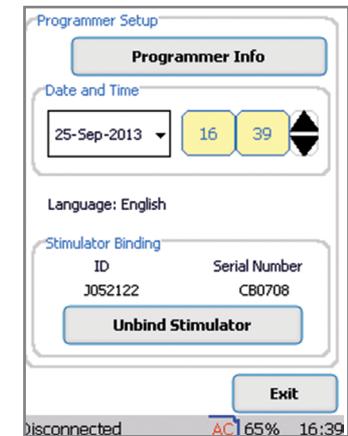


Programmer status bar

Programmer Setup button

You can change the time and date and access the Programmer Info screen from the Setup screen. You can also view your Stimulator serial number and your patient ID.

The Programmer Info screen displays your programmer serial number, programmer software version, firmware version and manufacturing date.

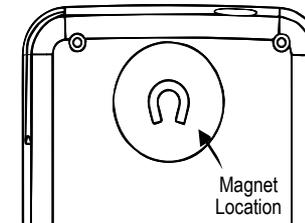


Stimulator Binding

Your doctor will bind and unbind your Stimulator to your Programmer. You cannot edit this information.

Magnet

A magnet is located under the magnet symbol on the back side of the Programmer. Place the magnet over the Stimulator to initiate connection between the Programmer and Stimulator. See the “Connecting with Your Stimulator” section below for more detail.



Connecting with Your Stimulator

Use your Programmer to communicate with your Stimulator.

- Turn ON your Programmer. The Main Menu will display.

- Press the “Connect” button. The Programmer will begin searching for the Stimulator. An icon shows on the screen to show that it is busy.
- Hold the magnet on the Programmer over your Stimulator and move it around in a circular motion to start communication.
- The Programmer chimes when it is connected to your Stimulator. Hold your Programmer steady over your Stimulator for a few seconds after the chime. The Pain Control screen will then display. “Connected” shows in the status bar at the bottom left of the screen. If your Programmer cannot connect to your Stimulator (~10 s), an error message displays. “Disconnected” shows in the status bar.
- If your Programmer cannot connect to your Stimulator, go back to the Main Menu. Press “Connect” again. Move the magnet in a circular fashion over your Stimulator. Repeat until the Programmer connects to the Stimulator.
- Your Programmer should always be held near your Stimulator to maintain a good connection (~1 ft / 30 cm).

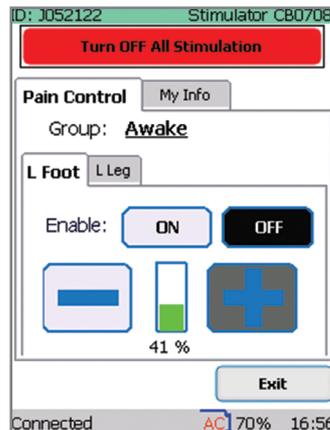
NOTE: *If after two minutes your Programmer cannot connect to the Stimulator, place the Programmer over the Stimulator again. An error message may display. The message asks you to confirm that your Programmer is near enough to the Stimulator. After confirming that your Programmer is near your Stimulator, press “OK”. Press “Connect” again.*

Pain Control Screen

The ID Heading is at the top of the Pain Control Screen. The “Turn OFF All Stimulation” button is just below the ID Heading.

Two tabs are below the “Turn OFF All Stimulation” button: the “Pain Control” tab and the “My Info” (Information) tab. See the “Adjusting Your Stimulator Settings” section in this User Manual for more detail.

The “Exit” button at the bottom right side of the screen returns you to the Main Menu.



ID Heading

ID: J052122 **Stimulator CB0708**

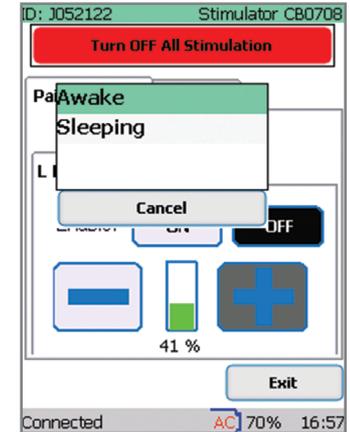
Located at the top of the screen, the ID Heading displays the following information:

- **ID:** Displays your identification number (ID).
- **Stimulator Serial Number:** Displays your Stimulator’s serial number.

Select Group

The “Group” button is in the center of the Pain Control screen. Press the displayed “Group” to show a drop down menu. The drop down menu has up to four groups defined by your doctor. When you select a group name, the Stimulator switches settings to the new group.

NOTE: *When changing Groups, temporary discomfort may be experienced. To avoid sudden change in stimulation, set Lead Enable to OFF before leaving a Group.*



Back to Main Menu

The “Exit” button closes the Pain Control window. The session ends, and returns to the Main Menu.

NOTE: *When programming is complete, select the “Exit” button. Turn off the Programmer to conserve power.*

Programmer Status Bar



The Programmer Status Bar is located at the bottom of the Programmer screen. The status bar shows the Programmer-Stimulator connection status, the battery charge level and the time.

- **Programmer-Stimulator Connection Status:**
 - Shows “Connecting” when the Programmer is trying to connect to the Stimulator.
 - Shows “Connected” when the Programmer is connected to the Stimulator.
 - Shows “Disconnected” when the Programmer is disconnected from the Stimulator.
- **Battery Level:** Shows the Programmer battery charge level.
- **Clock:** Shows the time. See the “Main Menu” section in this User Manual for more detail.

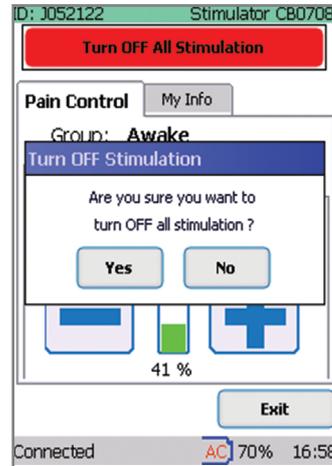
Adjusting Your Stimulator Settings

You can adjust your Stimulator settings from the Pain Control screen. Stimulation can be turned ON or OFF for up to four regions of your body. You can also adjust the stimulation level for any of those regions.

Turn OFF All Stimulation

- Press the “Turn OFF All Stimulation” button to stop all stimulation therapy. A window appears, asking you to confirm that you want to turn OFF all stimulation.

NOTE: After turning OFF all stimulation, you can restore stimulation therapy for each of the body regions individually. See “Turn Stimulation On or Off for a Body Region” section below.



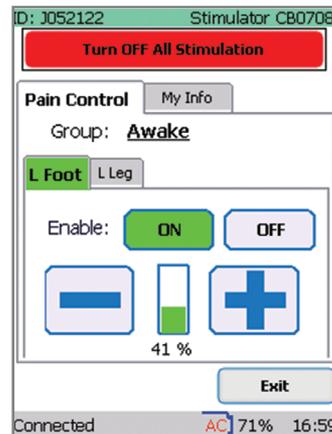
Pain Control Tab

Select the “Pain Control” tab on the “Pain Control” screen. From the “Pain Control” tab, you can turn stimulation ON or OFF for each body region. You can also adjust the stimulation level for each body region.

Turn Stimulation On or Off for a Body Region

Your Programmer shows the names of one to four designated body regions that your leads affect. To turn stimulation ON or OFF for a body region:

- Select the body region by pressing the desired tab.
- Press the “OFF” button to stop stimulation to that region. When stimulation is OFF, the “OFF” button is black.
- Press the “ON” button to start stimulation to that region. When stimulation is ON, the “ON” button is green.



Adjust Stimulation to a Body Region

Select the correct body region tab on the Pain Control screen. Be sure that “Enable” is “ON”.

- Press the “-” button to decrease the stimulation level.
- Press the “+” button to increase the stimulation level.

Stimulation Level Indicator:

The stimulation level indicator is between the “-” and “+” buttons. The indicator moves up or down as you adjust the stimulation level for the selected body region. The indicator shows the current stimulation level as compared to the maximum set by your doctor.

NOTE: The indicator bar is completely green when you have reached the maximum stimulation level.

Be sure that “Enable” is ON when adjusting the Stimulation Level. If “Enable” is OFF, the “+” button will not respond.

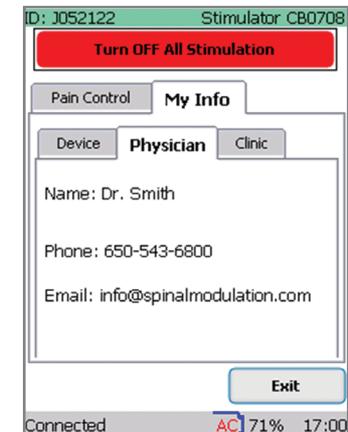
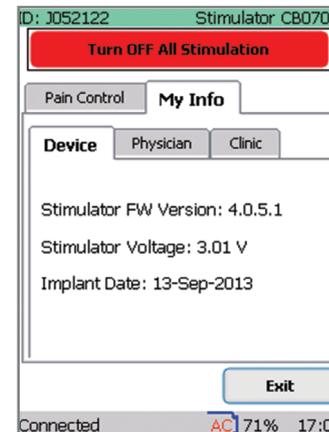
Device, Physician and Clinic Information

My Info Tab

The “My Info” (Information) tab contains three tabs, the “Device” tab, the “Physician” tab, and the “Clinic” tab.

Device Tab and Physician Tab

The “Device” tab and “Physician” tab display the following information:



Stimulator Identification Information

- **Stimulator Firmware Version**
- **Stimulator Voltage Information**

NOTE: The battery voltage information is for an INS device. It is not for an external TNS device.

- **Implant Date:** The date the INS device was implanted. This information is not for the external TNS device.

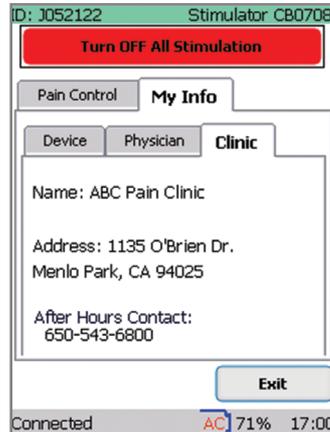
Physician Information

- **Name:** Your doctor's name
- **Phone:** Your doctor's contact phone number
- **Email:** Your doctor's email contact

Clinic Tab

"Clinic" tab displays the following information:

- **Clinic Name:** Your clinic's name
- **Address:** Your clinic's address
- **After Hours Contact:** A phone number to call in case of an emergency



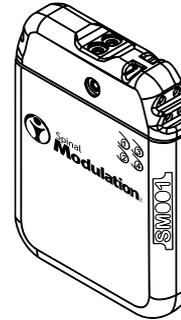
To Use with Your TNS Device

To connect your Programmer to your TNS, push the "Connect" button on the Programmer. Move the Programmer magnet over the TNS in a circular motion. The Programmer will chime when connection is made. You may then use the Programmer to adjust your stimulation settings.



To quickly turn OFF stimulation, press the red button on the TNS for more than two seconds or push the "Turn OFF all Stimulation" button on the Programmer screen. To enable stimulation after pressing either button, you must connect with your Programmer and turn the stimulation back on.

To Use with Your INS Device



To connect your Programmer to your INS, push the "Connect" button on the Programmer. Move the Programmer magnet over the implant location in a circular motion. The Programmer will chime when connection is made. You may then use the Programmer to adjust your stimulation settings.

Cleaning your Programmer

To clean your Programmer, wipe carefully with a damp – but not wet – soft cloth. Do not get the Programmer wet. Always follow the Precautions listed above. They instruct you not to wash the Programmer or TNS. Excess water may keep them from working properly.

Disposal of your Programmer

Return your Programmer and your TNS to your doctor at the end of the trial period or when no longer being used. Do not discard or burn the TNS or Programmer. Fire may cause the internal batteries to explode. Do not attempt to dispose of the TNS or Programmer yourself.

Environmental Conditions for Storage and Operation

Storage Temperature/Humidity: -10°C to 50°C (14°F to 122°F) at relative humidity up to 93%

Storage Altitude: 700 hPa to 1060 hPa

Operating Temperature/Humidity: 5°C to 40°C at relative humidity from 15% to 93%

Operating Altitude: 700 hPa to 1060 hPa

Guidance and Manufacturer's Declarations

GUIDANCE AND MANUFACTURER'S DECLARATION <i>Electromagnetic Emissions</i>		
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 Patient Programmer is not intended to be connected to other equipment except the Programmer Charger.

GUIDANCE AND MANUFACTURER'S DECLARATION <i>Electromagnetic Immunity</i>			
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 0.2 meter, based on 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	

GUIDANCE AND MANUFACTURER'S DECLARATION <i>Electromagnetic Emissions</i>			
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.

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		
	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

Conforms to AAMI STD ES60601-1, IEC STDS 60601-1-6, 60601-1-11 & 62366

Certified to CSA STD C22.2 No. 60601-1

Appendix I: Troubleshooting

Pop Up Message	Possible Solution
Connection with your Stimulator was lost. Please reconnect.	<ul style="list-style-type: none"> Move your Programmer over your Stimulator to establish connection and reconnect to the device. If you still have difficulty connecting, bring your Programmer closer to your Stimulator and continue to move the magnet over your Stimulator. Move to another location, as there may be interference in your current location.
Unable to connect to your Stimulator. Please contact your physician during normal business hours.	<ul style="list-style-type: none"> Hit "OK" and try to reconnect to your Stimulator. Contact your doctor during normal business hours if the problem does not go away.
Unable to connect to your Stimulator. Please try again.	<ul style="list-style-type: none"> Move your Programmer over your Stimulator to establish connection and reconnect to the device. If you still have difficulty connecting, bring your Programmer closer to your Stimulator and continue to move the magnet over your Stimulator. Move to another location, as there may be interference in your current location.
Your Stimulator battery is low. It will need to be replaced soon. Please contact your physician during normal business hours.	<ul style="list-style-type: none"> Contact your doctor during normal business hours to set up an appointment. Your battery has reached the Elective Replacement Interval (ERI).
Your Stimulator battery needs to be replaced. Stimulation has been turned OFF permanently. Please contact your physician during normal business hours.	<ul style="list-style-type: none"> Contact your doctor during normal business hours to set up an appointment. Your battery has reached End of Service (EOS) and will not stimulate until it has been replaced.
Stimulation for one or more leads has been turned OFF. Please contact your physician during normal business hours.	<ul style="list-style-type: none"> Move your Programmer over your Stimulator to establish connection and reconnect to the device. Go to the Pain Control screen and turn on the lead that has been turned off. If it does not allow you to turn it back on, contact your doctor during normal business hours.
All stimulation has been turned OFF. Please contact your physician during normal business hours.	<ul style="list-style-type: none"> Contact your doctor during normal business hours.
Stimulation has been turned OFF due to a magnet. Please use your Programmer to restore stimulation.	<ul style="list-style-type: none"> Move your Programmer over your Stimulator to establish connection and reconnect to the device. Go to the Pain Control screen and turn on each lead one at a time.

Pop Up Message	Possible Solution
You have turned OFF all Stimulation. Please use your Programmer to restore stimulation.	You have turned off the device by pressing the switch on the TNS or by pushing the "Turn OFF All Stimulation" button on your Programmer. <ul style="list-style-type: none"> • Move your Programmer over your Stimulator to establish connection and reconnect to the device. • Go to the Pain Control screen and turn on the leads that have been turned off.
Programmer battery is low. Please recharge.	<ul style="list-style-type: none"> • The battery has reached 30% on your Programmer and needs to be recharged.
Communication is poor. (This is a <u>status</u> message that would show on the Main screen.)	<ul style="list-style-type: none"> • Move to another location, as there may be interference in your current location.
The file "PProgrammerMobile" 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.	<ul style="list-style-type: none"> • Contact your doctor during normal business hours.
All other messages	<ul style="list-style-type: none"> • Attempt to perform the actions again if possible. • Contact your doctor during normal business hours if the problem does not go away.

Troubleshooting Other Issues

Condition	Resolution
Your Programmer is unresponsive (frozen screen, unable to power on, etc.).	Locate the reset pinhole on the back of your Programmer. Insert a straightened paper clip into the pinhole. Release and wait for your Programmer to restart. This will not change your Stimulator settings. You will need to reset the time and date on your Programmer.
Lead Disabled message (due to impedance) is displayed for an inactive lead.	Discuss with your clinician on your next visit.
Temporary decrease in stimulation.	The neurostimulator performs a self-check during regular intervals. In rare circumstances during this time, some patients may experience a momentary decrease in stimulation. Stimulation will return to normal levels.
Stimulator voltage is displayed as 65.00V on the My Info/Device Screen.	The battery voltage measurement has been cleared and will be updated at a later time.



ST. JUDE MEDICAL™

Manufacturer:

Spinal Modulation

1135 O'Brien Drive
Menlo Park, CA 94025
United States
+1.650.543.6800