StimTrial™
neuromodulation system

Clinician Guide

bioventus®
Innovations For Active Healing

Environmental Policy

Service personnel are advised that when changing any part of the StimTrial system, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled. When the life cycle of a StimTrial component has been completed, the product should be discarded according to the laws and regulations of the local authority. For more information regarding these recommended procedures, please contact Customer Service. Bioventus is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

bioventus®

Innovations For Active Healing

Bioventus LLC
4721 Emperor Blvd Suite 100
Durham, NC 27703, USA
(888) 453-2136
StimTrial.com

List of Symbols

	Caution
	Warning
	Class II Equipment (Double Insulated)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This Product Must Not Be Disposed of with Other Household Waste
	Refer to Instruction Manual/Booklet
	Consult Instructions for Use
REF	Re-Order Number
LOT	Lot Number
SN	Serial Number
	MR Unsafe
	Storage Temperature
	Humidity Limitation
	Atmospheric Pressure Limitation
IP22	Protection Against Ingress of Water
	Keep Dry
	Use By
	Quantity
Rx Only	Prescription Only
MD	Medical Device

Table of Contents

Chapter 1: Introduction **1**

Chapter 2: Clinician Kit **3**

Chapter 3: Warnings and Cautions **5**

Indications for Use 5
Device Use and Suitability 5
Device Materials 5
Essential Performance 5
Contraindications 5
Warnings 6
- Magnetic Resonance Imaging (MRI) Safety Information 6

Pregnancy 6
Programming 7
Flammable Fuel, Chemicals or Environment 7
Driving and Operating Machinery 7
Electromagnetic Compatibility Warnings 7
- Medical Devices/Therapies 7
- Electrosurgery Devices 7
- High-Frequency Surgical Equipment 7
- Body-Worn Devices 7
- Security Screening Devices 8
- Cell Phones 8

Precautions 8
- Post-Operative Care 8
- Known or Suspected Heart Problems 8
- StimTrial Lead Failure 8
- Postural Changes 9
- For Single Use Only 9
- Keep Out of Reach of Chilcren 9
- Skin Abnormalities 9
- Skin Irritation and Discomfort 9
- Sensations Caused by Stimulation 9
- Gel Electrode Expiration Date 9
- Gel Electrode Placement and Stimulation 9

Adverse Effects 10
- Risks Related to the Procedure 10
- Risks Related to Stimulation 10
- Additional Risks Related to the StimTrial System 10

Temperature 11
End-Of-Life Waste Management 11

Chapter 4: Environmental Conditions that Affect Use **13**

Storage and Handling 13
Radio Communication Information 13
- Conformity Certification 13

Chapter 5: Device Description 15
Clinician's Programmer 15
Operating Buttons 15
Micro SD Slot 15
Touchscreen Display 15
Clinician's Programmer Micro SD Card 15
Clinician's Programmer Charger 16
Clinician Programming Software 16
Operating Modes 16
Online 16
Offline 16
Information Icon 16
Drop-Down Lists 17
Menu Bars and Menus 17
Exit 17
Patients 17
Programs 17
Tools 17
Tabs 17
Navigation Buttons 18
Intensity Level Bar 19
Program Bar 19
Add Program Icon 19
Delete Program Icon 19
Program Bar Arrows 19
Stimulation Parameters 20

Chapter 6: Clinician's Programmer Set-Up 21
Connecting the Clinician's Programmer 21
Logging into the Clinician Programming Software 21
Connecting External Stimulator via Bluetooth 22

Chapter 7: Operating Instructions 23
Patient Records 23
Adding a New Patient 23
Copying a Record for an Existing Patient to an Unassigned System 24
Adding a Patient with an Assigned System 24
Opening a Patient Record 24
Modifying a Patient Record 25
Removing a Patient Record 25
Searching a Patient Record 25
History 25
View Usage History 26
Select a Stimulation Program 26
Select a Time Period 26
Select Duration 26
Select Intensity 26

Change Date Ranges 27
View Sessions History 27
Save Usage Data 28

Chapter 8: Patient Set-Up and Programming Instructions 29
Preparing the Patient's Skin 29
Connecting the Gel Electrode and External Stimulator 29
Adhering the Gel Electrode and Connecting the Lead Adaptor Cable 30
Confirming Set-Up 31
Removing the Gel Electrode 32
Programming Instructions 33
Programming Stimulation Settings 33
Programming Time Settings 34
Programs 34
Adding a Program 34
Deleting a Program 35

Chapter 9: Software Tools 37
Clearing Patient Data from the External Stimulator 37
Restart the External Stimulator from the External Stimulator Buttons 37
User Administration 37
Adding a User/Administrator 38
Removing a User/Administrator 38
Changing a User Password 39
Clinician's Programmer Database Backup and Restore 39
Enabling Automatic Database Backup 39
Manually Backing Up the Database 39
Restoring the Database 40

Chapter 10: Maintenance and Cleaning 41
Replacing Gel Electrode 41
Cleaning: Clinician Kit Components 41
Cleaning: External Stimulator and Accessories 41
Electronic Components 41

Chapter 11: Troubleshooting 43
Patient Loses External Stimulator 43
Copying Patient Data to New Components 43
Troubleshooting Tables 44
Incident Reporting 45

Chapter 12: Technical Specifications 47
External Stimulator Charger Specifications 47
External Stimulator Specifications 47
Lead Adaptor Cable Specifications 48
Gel Electrode Specifications 49
System Characteristics 49
Privacy of Wireless Communication 50

Chapter 13: Network Safety, Security, and Privacy 51

Chapter 14: Appendix - EMI Tables 53

Guidance and Manufacturer's Declaration Electromagnetic Emissions.....53

Guidance and Manufacturer's Declaration Electromagnetic Immunity.....54

Recommended Separate Distances for Device.....56

1

Introduction

The StimTrial Neuromodulation System is intended to help determine patient candidacy for a permanent implant to help manage pain of peripheral nerve origin. The StimTrial System works by sending electrical impulses from an external stimulator to a lead that is percutaneously placed next to a target nerve. These impulses are intended to interrupt or change the pain signals, inducing the feeling of tingling or numbness (paresthesia), and possibly reducing or replacing the feeling of pain.

The StimTrial Neuromodulation System includes:

- A partially implanted StimTrial lead
- An external stimulator with charging accessories
- An external cable for transmitting signal from the external stimulator to the lead
- Gel electrode
- A clinician programming system with accessories

Note: The External Stimulator may be used for multiple trials on different patients. Do not use if the External Stimulator appears to be damaged

⚠ **WARNING:** Do not use Stimulator if the housing is cracked, the button overlay is peeling, or any other damage is observed.

This guide describes the clinician programming system components of the StimTrial Neuromodulation System, which are provided in the Clinician Kit. The clinician programming components are used by trained clinicians to program the patient's External Stimulator. The External Stimulator and other external components are intended to be used by patients.

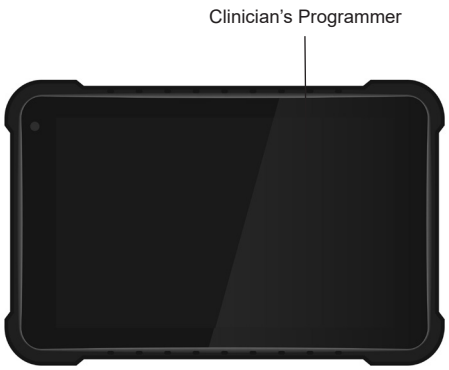
Refer to the StimTrial Procedure Manual for a description of the StimTrial Surgical Kit, package contents, device specifications and the StimTrial implant procedure.

Refer to the StimTrial User's Guide in the StimTrial Patient Kit for a full description of the User Kits (Patient Kit and Stimulator Kit), Gel Electrode, External Stimulator, external accessories, package contents, device specifications, and instructions for use.

Clinician Kit

The Clinician Kit (PNS-1000) includes the following:

- Clinician's Programmer Tablet with Software and Stylus
- Clinician's Programmer MicroSD Card
- Clinician's Programmer Charger



3

Warnings and Cautions

Use the StimTrial system only as instructed in the User's Guide.

Indications for Use

The StimTrial System is indicated for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for the StimRouter® Neuromodulation System's permanent (long term) implant indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy used in a multidisciplinary approach and not intended to treat pain in the craniofacial region.

Device Use and Suitability

The StimTrial Neuromodulation System is designed to reduce pain in patients with chronic pain of peripheral nerve origin. Components of the StimTrial Surgical Kit and StimTrial Clinician Kit are for use by trained clinicians, and components of the StimTrial User Kit are for use by individual patients. Additional information, including clinical safety and performance, can be found at www.StimTrial.com.

The StimTrial Neuromodulation System may not be suitable for pain that is not of peripheral nerve origin, or for patients whose required stimulation parameters cannot be met by the StimTrial Neuromodulation System. The StimTrial Neuromodulation System implant procedure may be performed in any sterile surgical setting.

Device Materials

Materials in the User Kits that may contact the patient during device use include:

- Hydrogel
- Plastic
- Wound closure adhesives and materials

All materials have been tested to verify biocompatbility.

Essential Performance

The StimTrial System does not have Essential Performance as there is no performance necessary (as defined by IEC 60601) to avoid unacceptable risks, in that all sources of identified risk have been mitigated (through application of appropriate risk control measures) to the greatest extent possible and to an acceptable degree. There are no sources of residual risk which outweigh the benefits accrued from the use of the device and which would thus be deemed unacceptable.

Contraindications

The StimTrial Neuromodulation System is contraindicated for:

- Patients who are unable to operate the StimTrial Neuromodulation System.
- Patient who are identified or assessed as poor surgical candidates for the StimTrial procedure; this

includes patients with bleeding disorders or taking active anticoagulants that cannot be stopped for a few days close to the time of the surgical procedure.

- Patients who have a cancerous lesion present near the target stimulation point or directly under where the Gel Electrode will adhere.
- Patients who are unable to remove the External Stimulator.
- Patients who are unable to communicate a device malfunction.

Warnings

- The StimTrial Neuromodulation System may interfere with other implanted devices such as cardiac pacemakers, defibrillators, and other implanted stimulators. The effect of other implanted devices, including but not limited to implanted drug pumps and other stimulation devices on the StimTrial Neuromodulation System is unknown.
- Patient's skin could become irritated while using the Gel Electrode. Patient should check their skin for irritation after removing the Gel Electrode from their skin. Some redness is normal. To minimize irritation, refer to the Cleaning & Care instructions.
- The components of the StimTrial System are not waterproof — Do not submerge the system components in water (i.e. take a bath or go swimming), alcohol, other fluids, or dust. Exposure to fluids (like water) or dust could damage the System. This may cause it to stop working or produce discomfort.
- Implantation of StimTrial system beyond the 30-day use period may lead to increased risks related to infection or lead explantation difficulties.

Note: Patient may shower provided they remove the External Stimulator, gel electrode and protect the Lead Adaptor Cable end that connects to the External Stimulator with a waterproof covering (plastic bag). The Lead Adaptor Cable should be secured to patient's skin with tape to prevent the Lead Adaptor Cable from moving excessively. Use caution so that the waterproof dressings are not disturbed during showering.

A risk/benefit determination should be performed before using the StimTrial Neuromodulation System for:

- Patients exposed to diathermy. Shortwave, microwave and/ or therapeutic ultrasound diathermy should not be used on patients who have a StimTrial. The energy generated by diathermy can be transferred through the StimTrial system components, causing tissue damage at the StimTrial Lead site and potentially resulting in severe injury. Diathermy may also damage the StimTrial system's components, resulting in loss of therapy. Injury or damage can occur during diathermy treatment whether neurostimulation is turned on or off. All patients are advised to inform their healthcare provider that they should not be exposed to diathermy.
- Patients exposed to therapeutic ultrasound.

Magnetic Resonance Imaging (MRI) Safety Information

The StimTrial Neuromodulation System and all external components of the StimTrial system, including the Gel Electrode, External Stimulator, Lead Adaptor Cable, Clinician's Programmer, and Clinician's Programmer Charger are **MR Unsafe** and contraindicated for the MR environment.

Do not bring them into the MR system room.

The StimTrial Lead and all components must be removed from the body before you have an MRI.

Pregnancy

The effects of electrical stimulation on pregnancy are not known. Pregnant patients should not use electrical stimulation

Programming

Only a trained clinician should program the StimTrial System.

Flammable Fuel, Chemicals or Environment

The StimTrial is not intended to be used in oxygen-rich environments.

Turn off stimulation when near a refueling station, flammable fuel, fumes, or chemicals. If the StimTrial System is on, it could ignite the chemicals or fumes, causing severe burns, injury, or death.

Driving and Operating Machinery

Turn off stimulation while driving or operating machinery.

Electromagnetic Compatibility Warnings

Medical Devices/Therapies

Operation of the StimTrial System in proximity (e.g., one meter or 3 feet or less) to shortwave or microwave therapy equipment may produce instability in the External Stimulator output.

The following medical therapies or procedures may turn stimulation off. They may also permanently damage the StimTrial external components and may cause injury, particularly if used close to the system components.

- Lithotripsy
- Electrocautery
- External defibrillation
- Ultrasonic scanning
- High-output ultrasound

Electromagnetic interference (EMI) from the following medical procedures is unlikely to affect the StimTrial system:

- Computerized Axial Tomography (CT or CAT) scans
- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy

Note: Turn off stimulation and remove the Gel Electrode before undergoing a medical procedure.

Electrosurgery Devices

Electrosurgery devices should not be used close to a percutaneous StimTrial Neuromodulation System. Contact between an active electrode of the electrosurgery device and the StimTrial Lead can cause severe injury.

High-Frequency Surgical Equipment

Remove the Gel Electrode before any high-frequency medical treatment. If the patient is connected to the StimTrial system and high-frequency surgical equipment, they may experience a skin burn where the Gel Electrodes adhere. Also, the StimTrial External Stimulator may become damaged.

Body-Worn Devices

Although unlikely, body-worn medical devices may interfere with the RF communication used in the StimTrial system. Stimulation control may be delayed. Examples of a body- worn device are a pain pump or an insulin pump and a monitoring device. To minimize interference, maintain a minimum safe separation distance of 15 cm (6 in.) between the StimTrial system and all other electronic devices. See the “Troubleshooting” section for help. See the “Appendix” for more information.

The StimTrial system's wireless technology may cause EMI to other body-worn medical devices. Refer to the instructions for use for those devices for information on recommended minimum separation distances.

Security Screening Devices

Certain types of security devices may affect stimulation. Examples include those used at the entrances and exits of public buildings such as libraries, airports, and retail stores. Ask for help to bypass the device. Show your Medical Device Identification Card if you must pass through the device:

- Turn off your StimTrial System.
- Pass through the security screening device quickly.
- Stay as far from the emitter as possible. Walk, for example, in the center of a pass-through security gate.

Cell Phones

There is potential for interference between electronic devices, including cell phones. Stimulation control may be delayed. If interference is suspected or anticipated, distance yourself from the source of interference. To minimize interference, maintain a minimum safe separation distance of 15 cm (6 in.) between the StimTrial system and all other electronic devices.

Precautions

Post-Operative Care

After the implant procedure, patient should frequently (daily) check for possible infection, device rejection or other possible adverse effects, for example:

A patient should contact a healthcare provider immediately if they have:

- Excessive redness or discharge/drainage around the dressing area.
- Prolonged pain at the incision site.
- Warmth and swelling of the incision site.
- A bad smell.
- Fever
- Dizziness
- Bleeding

Known or Suspected Heart Problems

Healthcare providers should use caution when treating patients with suspected or diagnosed heart problems.

StimTrial Lead Failure

StimTrial lead may fail at any time. If the lead fails or breaks, then the StimTrial system may need to be removed or replaced. It is possible that small fragments of the lead could remain at the implantation site after removal, which will indefinitely prevent the patient from being eligible for certain procedures, such as diathermy, therapeutic ultrasound, or MRI in the affected area. Patient should contact healthcare provider immediately if implant failure is suspected.

Postural Changes

Changes in posture or abrupt movements may change the stimulation. Patient should turn off stimulation before stretching or exercising.

For Single Patient Use Only

Do not adhere the Gel Electrode to any other person or any other part of the body.

Keep Out of Reach of Children

Keep all StimTrial components out of the reach of children.

Skin Abnormalities

Do not adhere the Gel Electrode to skin that is swollen, infected or inflamed or to skin that is broken. Do not adhere the Gel Electrode over veins that are swollen or inflamed.

Skin Irritation and Discomfort

Gel Electrode:

It is normal for the skin under the Gel Electrode to become red. The redness should disappear about one hour after the Gel Electrode is removed.

Some people may be allergic or hypersensitive to the electrical stimulation or the gel on the Gel Electrode. Persistent redness, lesions or blisters are signs of irritation. Stop using the StimTrial system until the irritation is gone. To avoid irritation, remove the Gel Electrode every three to four hours for 15 minutes. Talk to your healthcare provider if irritation persists.

Dressings and Bandages:

It is possible the provided dressings could cause an allergic reaction and/or skin irritation and discomfort in some patients. Patient should contact their healthcare provider if they experience an allergic reaction.

Sensations Caused by Stimulation

As with other nerve stimulation devices, the StimTrial Neuromodulation system achieves pain relief by causing different sensations to be felt in the area of treatment. These sensations (also referred to as “paresthesia”) include tingling and numbness. While these sensations are normal during StimTrial use, stimulation should not proceed to the point of being painful.

Gel Electrode Expiration Date

Do not use a Gel Electrode with a “Use by” date that has been exceeded (expired).

Gel Electrode Placement and Stimulation

- Only use Gel Electrodes supplied by Bioventus.
- Only the healthcare provider should decide where to place the Gel Electrode.
- Only the healthcare provider should program StimTrial system.
- Turn off stimulation before adhering, removing, or handling the Gel Electrode.
- Do not adhere the Gel Electrode across the chest or near the heart. Electrical stimulation of the heart may disturb heart rhythm.
- Do not adhere the Gel Electrode across the head, directly on the eyes, covering the mouth, or on the front of the neck, (especially the carotid sinus).
- Do not adhere the Gel Electrode over anything other than skin. Do not adhere it over an adhesive bandage, for example. The Gel Electrode must be in full contact with the skin, or the stimulation could cause serious injury.
- Do not place the Gel Electrode over skin folds, scarred tissue, irritated skin, uneven skin surfaces or broken skin.

- Always check the Gel Electrode gel pads before use. Do not use the Gel Electrode if the gel appears dry, worn, dirty or irregular.
- Remove the clear protective cover from the Gel Electrode before using.
- Do not handle the Gel Electrode while stimulation is on. Serious injury can occur if electrical current passes through the heart.
- Patient must be instructed not to apply the Gel Electrode to anyone else or any other part of the body than that determined by the healthcare provider.

Adverse Effects

In the unlikely event that any of the following occurs, the StimTrial system should be stopped, and the Gel Electrode removed.

Risks Related to the Procedure

If the lead is not placed properly, it may need to be removed or the therapy may need to be adjusted. Nerve injury is possible, although unlikely. Possible surgical complications include infection and device rejection. A patient should contact a healthcare provider immediately if they experience fever, swelling, bleeding or prolonged pain at the implant site.

Risks Related to Stimulation

- Stimulation of skin and muscles surrounding the StimTrial Lead may cause increased pain.
- A patient may have undesirable movements during stimulation. If this occurs, please contact your healthcare provider.

If a patient experiences any discomfort during stimulation, or notice any skin abnormalities they should:

- Stop stimulation immediately.
- Remove the Gel Electrode.
- Notify healthcare provider.

Additional Risks Related to the StimTrial System

- If the lead moves, it may change the stimulation effectiveness.
- While very unlikely, the tissue around the lead may react to the implanted materials.
- External electromagnetic interference (EMI) may cause the StimTrial components to malfunction. EMI may also affect stimulation.
- Persistent pain may occur at the implant site.
- Portable and mobile radio frequency communications equipment can affect medical electrical equipment.
- The StimTrial external components could overheat if the components fail. Overheating could cause burning.

Temperature

The StimTrial External Stimulator can heat up to 43°C during operation while in extremely hot areas/ rooms. If this occurs turn off stimulation, remove the External Stimulator, and set aside until temperature of the External Stimulator is within operational conditions.

End-Of-Life Waste Management

This Product Must Not Be Disposed of with Other Household Waste. When the life cycle of a StimTrial component has been completed, the product should be discarded according to the laws and regulations of the local authority.

4

Environmental Conditions that Affect Use

Storage and Handling

All StimTrial components should be kept dry and protected from extreme changes in temperature and humidity. Components should not be used or stored where they could come in contact with water, such as by sinks, bathtubs and shower stalls, or exposed to weather conditions such as rain or snow. StimTrial components should not be stored in a car where they can be exposed to extreme hot or cold temperatures. Temperature extremes can damage the StimTrial components.

StimTrial components should be placed in an air-tight plastic bag before moving them from hot to cold temperatures. Let them adjust slowly (for at least two hours) to the new temperature before use.

Changes or modifications to components not expressly approved by Bioventus could void the user's authority to operate the equipment.

Gel Electrode Storage Temperature Range: 5°C to 27°C (41.0°F to 80.6°F)

External Stimulator Storage Temperature Range: -25°C to +60°C (-13°F to +140°F)

Radio Communication Information

Several components of the StimTrial system use radio communication. They have been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 (Radio Frequency Devices) of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential environment. This equipment generates, uses, and can radiate radio frequency energy. If not used as instructed, this equipment may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Move or adjust the receiving antenna.
- Move the equipment farther from the receiver.
- Contact the dealer or an experienced radio/television technician for assistance.

The antenna for each transmitter must not be near or operating with any other antenna or transmitter.

Conformity Certification

The StimTrial System complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

5

Clinician Device Description

Clinician's Programmer

The Clinician's Programmer is used to program, test, and save stimulation parameters and programs on the StimTrial External Stimulator. The Clinician's Programmer is a Windows® Tablet PC that comes with the clinician programming software and a memory card installed. The Clinician's Programmer can wirelessly communicate with the StimTrial External Stimulator.

Operating Buttons

Buttons	Description	Function
	Power Button	Used to turn the Clinician's Programmer on and off
	Volume Up Button	Used to turn the Clinician Programmer volume up
	Volume Down Button	Used to turn the Clinician Programmer volume down

Micro SD Slot

Contains the Clinician's Programmer micro SD card.

Touchscreen Display

Used to navigate the software, read statuses and enter data. Use the pointed end of the stylus to make contact with the display screen.

Clinician's Programmer Micro SD Card

Used to back up and restore the Clinician's Programmer database. The micro SD card is supplied installed in the SD slot of the Clinician's Programmer.

⚠ **WARNING:** The Clinician's Programmer should only contain the installed Windows® operating system and proprietary clinician programming software.

- Do not use the Clinician's Programmer for any purpose other than that described in this manual.
- Do not connect the Clinician's Programmer to Wifi or wired network.
- Do not install any third-party software packages, as they may interfere with proper operation of the system components, thus voiding the warranty.
- Do not update the Windows operating system software, unless supplied by Bioventus.

Clinician's Programmer Charger

Used to recharge the Clinician's Programmer.

⚠ **WARNING:** Use only the Clinician's Programmer Charger included in Clinician Kit.

Clinician Programming Software

Note: Illustrations are for reference and may not exactly match what is displayed on the Clinician's Programmer.

Operating Modes

The clinician programming software has two operating modes: online and offline.

Online. The Clinician's Programmer is online when connected to an operational StimTrial External Stimulator.

Offline. The Clinician's Programmer is offline when not connected to an operational StimTrial External Stimulator.

Operating Mode	Function Descriptions
Online	•Add a new patient. •Modify a patient name. •Open a patient record. •Program stimulation settings. •Program time settings. •Add or remove a stimulation program. •View the system information. •Reset the Stimulator. •Back up the database. •Restore the Clinician's Programmer database. •Add a new user. •Remove a user. •Change a user password.
Offline	•Add a new patient. •Open any patient record. •Remove a patient record. •View a patient's programs. •Back up the Clinician's Programmer database. •Restore the Clinician's Programmer database. •Add a new user. •Remove a user. •Change a user password.

Table 5-1: Clinician programming software operating modes and function descriptions

Information Icon

Used to communicate system status, error messages and troubleshooting solutions. When the icon is RED or YELLOW, press the icon for more information. **See Figure 5-2.**

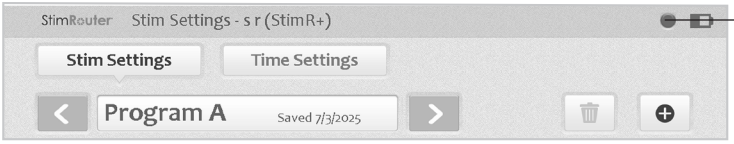


Figure 5-2: Location of the information icon

GREEN when the StimTrial is online and connected to an External Stimulator; GRAY when no External Stimulator is detected.

FLASHING RED when a External Stimulator is connected and a correctable error has occurred (for example, RF communication failure).

FLASHING YELLOW when the StimTrial External Stimulator battery charge level is low.

Drop-Down Lists

Used to select a value. Press the down arrow to display the values. Select a value.

Menu Bar and Menus

The clinician programming software has five navigation menus, which appear on the menu bar. **See Figure 5-3.**

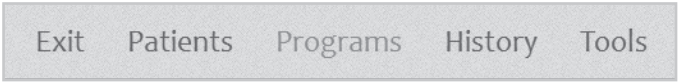


Figure 5-3: Menu bar

Exit

Used to exit or logoff the clinician programming software.

Patients

Used to open a patient record, add a new patient, modify a patient record or remove a patient record.

Programs

Used to program, test and save a set of stimulation and time settings. (Enabled when a patient record is open.)

History

Used to view patient usage history. (Enabled when a patient record is open.)

Tools

Used to view system information and to reset the External Stimulator. Users with administrator privileges can also add and remove users, change a user password, and back up and restore the Clinician's Programmer database.

Tabs

The clinician programming software has eight navigation tabs, or submenus, found under the five main menus. **See Table 5-2.**

Menu	Tab	Function Descriptions
Exit		• Exit the clinician programming software. • Log off the clinician programming software.

Menu	Tab	Function Descriptions
Patients		• Open a patient record in online mode. • Open any patient record in offline mode. • Remove a patient record in offline mode. • Add a new patient in online mode. • Modify a patient name in online mode.
Programs	**Stim Settings**	• Program, test and save waveform, phase duration, pulse rate and intensity settings in online mode. • Turn on Efficiency Mode feature. • View stimulation settings for each program saved. • Add/delete programs in online mode.
	Time Settings	• Program, test and save time on, time off, ramp up, total time and intensity settings in online mode. • View time settings for each program saved. • Add/delete programs in online mode.
History		• View patient usage history.
Tools	**Info**	• View system information in online mode. • Reset the External Stimulator in online mode.
	Users	• Add a new user. • Remove a user. • Change a user password.
	Backup	• Back up the Clinician's Programmer database. • Enable/disable database backup.
	Restore	• Restore the Clinician's Programmer database from backup.

Table 5-2: Clinician programming software navigation menus, navigation tabs and functions that can be performed from each menu/tab

Navigation Buttons

When pressed, a navigation button will open a new screen or execute a command. Depending on the operating mode, a button may be enabled or disabled. Disabled buttons are GRAY. For a list of commonly used buttons, **see Table 5-3.**

Button	Function Descriptions
Change Password	• Change a user password (enabled for administrators only).
Clear	• Delete characters in a field.
Exit	• Exit the clinician programming software.
Login	• Log into the clinician programming software.
Log Off	• Log off the clinician programming software.
Modify	• Modify an existing patient record.

New	• Add a new patient record.
New User	• Add a new user (enabled for administrators only).
Open	• Open an existing patient record.
Remove	• Remove an existing patient record.
Remove User	• Remove a user (enabled for administrators only).
Reset the External Stimulator	• Restore factory settings on the External Stimulator. (When selected, all patient data on the External Stimulator is erased.)
Stop & Save	• Stop stimulation and save the stimulation and time settings.
Test	• Test the current stimulation and time settings.

Table 5-3: Selected navigation buttons and their accompanying functions

Intensity Level Bar

Used to adjust stimulation intensity. Can be adjusted while stimulation is on or off. **See Figure 5-4.**

Figure 5-4: Intensity level bar

Program Bar

Used to add, delete and view up to eight clinician-set stimulation programs, labeled A-H. **See Figure 6-5.**

Figure 5-5: Program bar and icon definitions

Add Program Icon

Used to add a new stimulation program. Enabled in online mode when fewer than eight programs have been saved.

Delete Program Icon

Used to delete a stimulation program. Enabled in online mode when more than one program has been saved.

Program Bar Arrows

Used to scroll through the saved programs. Enabled when more than one program has been saved.

Stimulation Parameters

Patients require tailored stimulation patterns to help control their pain. The StimTrial system features eight programmable parameters and can store up to eight stimulation programs on the Clinician's Programmer and External Stimulator. Timing parameters are specified in Table 5-4. Pulse parameters are specified in Table 5-5.

Timing Parameter	Definition	Specification
Time On	Time that stimulation is applied per cycle	1-60 seconds, 1 second resolution
Time Off	Time that stimulation is turned off per cycle	0-60 seconds, 1 second resolution (0 seconds = constant stimulation)
Ramp Up / Ramp Down	Time to increase/decrease stimulation from zero to the set intensity Note: Ramp up and ramp down are always identical.	0-10 seconds, but not more than "On Time"/2, with 1 second resolution
Total Time	Duration from the initiation to the end of a stimulation program	10 minutes-8 hours
Constant Stimulation	Stimulation is constant when "Constant Stim" box is checked.	N/A

Table 5-4: Timing parameters

Burst Parameter	Specification
Intensity*	500uA – 10mA, 100 uA resolution (positive phase)
Maximum Output	1 mA (RMS)
Maximum Charge	5 microcoulombs per phase
Positive Phase Duration	100, 200, 300, 400, 500 microseconds
Typical Load	300 Ω
Pulse Repetition Rate**	1, 2, 5, 10, 12, 15, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hertz
LED	Green light indication: • Constant when the battery is charged • 2Hz blinking at end of battery charge

*Intensity: A measure of strength of the stimulation.
**Pulse repetition rate: The number of times per second a pulse is delivered.

Table 5-5: Pulse parameters

6

Clinician’s Programmer Set-Up

Note: Illustrations are for reference and may not exactly match what is displayed on the Clinician’s Programmer.

Connecting the Clinician’s Programmer

To connect the Clinician’s Programmer:

1. Insert the Clinician Programmer Charger into the Clinician Programmer charging port and plug the charger into a power socket. **See Figure 6-1.**

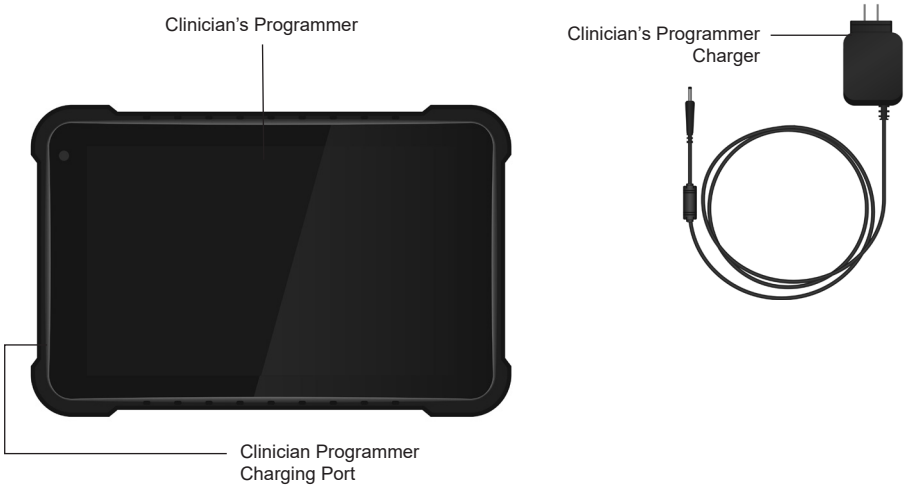


Figure 6-1: The Clinician’s Programmer set-up

⚠ **WARNING:** Use only the Clinician’s Programmer charger included in the Clinician Kit.

Logging into the Clinician Programming Software

To log into the clinician programming software to program StimTrial System:

1. Turn the Clinician’s Programmer on by pressing the on/off button on the upper left corner of the Clinician’s Programmer. A welcome screen is displayed (Figure 6-2).
2. If the login screen does not open automatically, then, press “Start” and then StimRouter to open the clinician programming software. Wait for the login screen to load. **See Figure 6-3.**

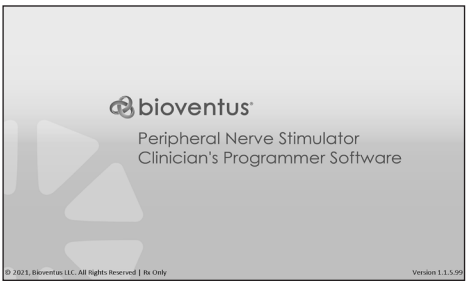


Figure 6-2: The Clinician Software Welcome Screen

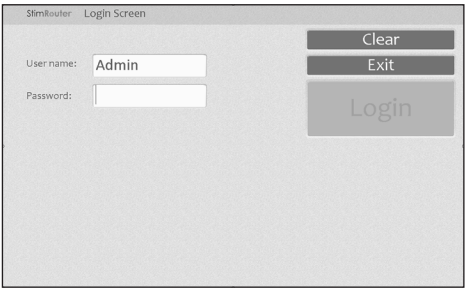


Figure 6-3: The StimRouter Plus Software Login Screen

3. To log in, enter a user name and password, and then press the “Login” button.

Note: Always log off the clinician programming software before leaving the Clinician’s Programmer unattended.

Connecting External Stimulator via Bluetooth

To connect an External Stimulator via Bluetooth:

1. Open the clinician programming software on the Clinician Programmer and navigate to the Patient List screen.
2. Ensure the External Stimulator is on, then simultaneously press and hold the Plus (+) and Minus (-) buttons on the External Stimulator until the light flashes blue.
3. Press the blue “Bluetooth” button on the bottom of the Patient List screen in the clinician programming software. The External Stimulator and Clinician Programmer will connect. **See Figure 6-4.**

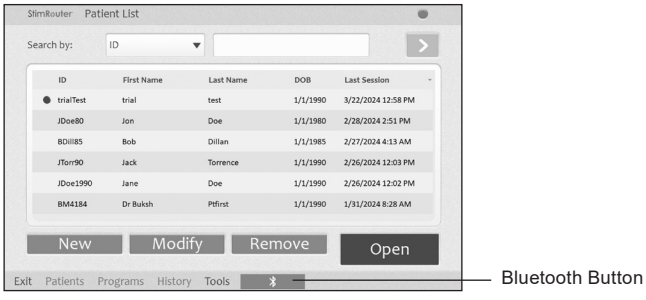


Figure 6-4: Bluetooth Icon on the Patient List Screen

4. For technical support, please contact Bioventus Customer Service at 888-453-2136.

7

Software Records and History

Note: Illustrations are for reference and may not exactly match what is displayed on the Clinician's Programmer.

Patient Records

This section reviews how to add, copy, open, modify, remove and search for a patient record.

Adding a New Patient

Follow these instructions when a patient does not have a record in the Clinician's Programmer database and no data has been stored on the External Stimulator. The patient is new, and their system is unassigned.

To add a new patient to the Clinician's Programmer database:

1. Connect the patient's External Stimulator to the Clinician's Programmer.
2. If the patient's External Stimulator is unassigned, then the software should automatically prompt that no patient data was found on the system. Press the "OK" button. **See Figure 7-1.**

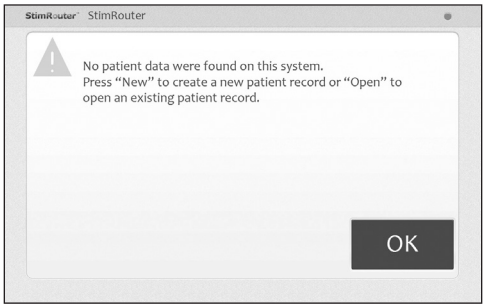


Figure 7-1: Unassigned system detected

3. If this prompt does not appear and the patient's components are new, then reset the patient's External Stimulator. See "Resetting the Patient's External Stimulator" section of this guide.
4. Press "New" to create a new patient record.
5. When the New Patient window opens, enter the patient's first and last names and a patient ID. **See Figure 7-2.**

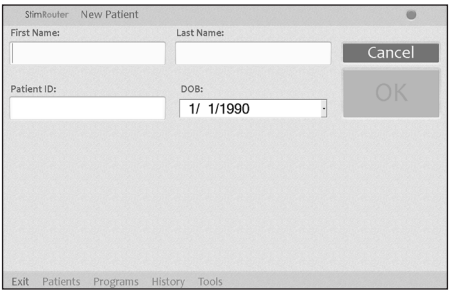


Figure 7-2: New patient window

6. Proceed to the "Patient Set-Up and Programming Instructions" chapter of this guide.

Copying a Record for an Existing Patient to an Unassigned System

Follow these instructions when a patient has a record stored in the Clinician's Programmer database and no patient data has been stored on the connected External Stimulator. This patient may have purchased replacement components, or the patient's components may have been reset.

To copy a record for an existing patient to an unassigned system:

1. Connect the patient's External Stimulator to the Clinician's Programmer.
2. If the External Stimulator is unassigned, then the software should automatically prompt that no patient data was found on the system. Press "OK". **See Figure 7-1.**
3. From the Patient List window, select the patient's record and press "Open". When the patient record opens, the patient data will automatically copy from the Clinician's Programmer to the External Stimulator.

Adding a Patient with an Assigned System

Follow these instructions when a patient does not have a record in the Clinician's Programmer database, but data has been stored on the patient's External Stimulator. This patient may be a referral from another clinic or from a physician using a different Clinician's Programmer.

To add a patient with an assigned system to the Clinician's Programmer database:

1. Connect the patient's External Stimulator to the Clinician's Programmer.
2. The clinician programming software will automatically prompt that a new patient was found and to add the patient to the clinician programmer database. Press "OK". **See Figure 7-3.**
3. Proceed to the "Patient Set-Up and Programming Instructions" chapter of this guide.

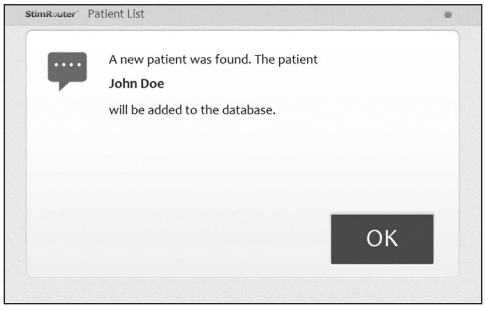


Figure 7-3: Adding a patient with an assigned system

Opening a Patient Record

Note: When the Clinician's Programmer is in online mode and connected to an assigned External Stimulator, then only the patient record corresponding to those components can be opened. If the Clinician's Programmer is in offline mode, then any patient record can be opened and viewed.

To open a patient record:

1. From the Patient List, select a patient and press the "Open" button. **See Figure 7-4.**

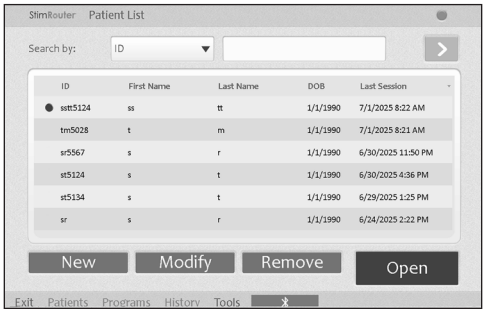


Figure 7-4: Opening a Patient Record

Modifying a Patient Record

Note: “Modify” is only enabled in online mode, when the Clinician’s Programmer is connected to a working External Stimulator.

To modify a patient record:

1. From the Patient List, press the “Modify” button.
2. Enter changes to the patient’s first or last name, and then press the “OK” button. **See Figure 7-5.**

Note: The Patient ID cannot be modified.

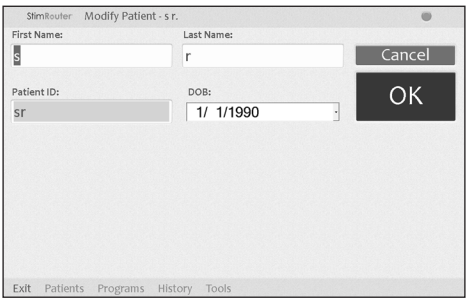


Figure 7-5: Modifying a Patient Record

Removing a Patient Record

To remove a patient record:

1. Make certain that the Clinician’s Programmer is not connected to an operational External Stimulator.
2. From the Patient List select the patient record to remove, and then press the “Remove” button. **See Figure 7-6.**
3. Press the “Yes” button in the Remove Patient window.

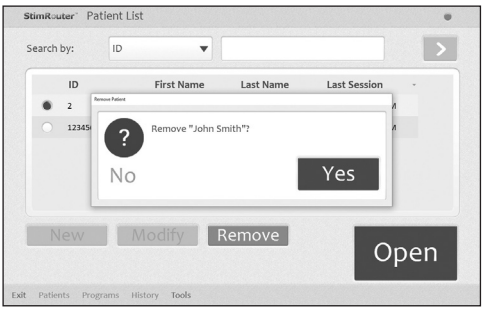


Figure 7-6: Removing a Patient Record

Searching for a Patient Record

To search for a patient record:

1. Make certain that the Clinician’s Programmer is not connected to an operational External Stimulator.
2. From the Patient List select the “Search by” drop-down list and pick a search criterion.
3. Enter the search data in the accompanying field, and then press the double arrow to start the search.
4. The first match found (if any) will be highlighted on the Patient List.
5. Press the double arrow again to view any additional matches found.

History

This section reviews how to view and save patient usage history of the connected External Stimulator.

View Usage History

Use the Usage button on the History tab to view detailed graphs of a patient's device usage during a specified time period.

Select a Stimulation Program

Select a stimulation program by choosing one of the eight programs, labeled A-H, or select All to see data for all stimulation programs saved on the selected External Stimulator. Select Total to see the total stimulation time for all programs used during the designated time period.

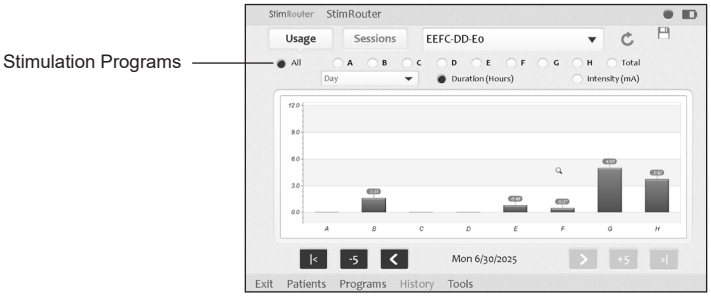


Figure 7-7: Select a Stimulation Program

Select a Time Period

Select a time period to view from the drop-down menu.

Note: The Day option is only available to view when All programs are chosen.

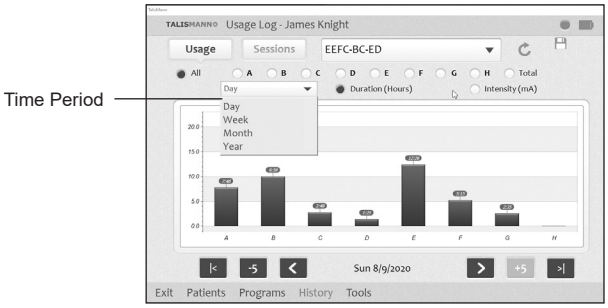


Figure 7-8: Select a Time Period

Select Duration

Select Duration to view the average number of hours the selected program was used during the designated time period.

Select Intensity

Select Intensity to view the last intensity value in mA for the selected program during the designated time period.

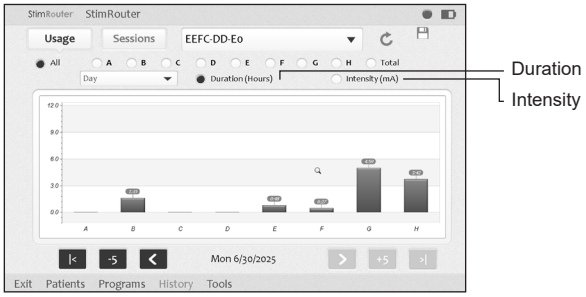


Figure 7-9: Select Duration or Intensity

Change Date Ranges

Use the arrows at the bottom of the Usage tab to change date ranges for the designated time period, or to go to the first or last usage record.

Figure 7-10: Change Date Ranges

View Sessions History

Use the Sessions button on the History tab to open a list of individual usage sessions for the connected External Stimulator.

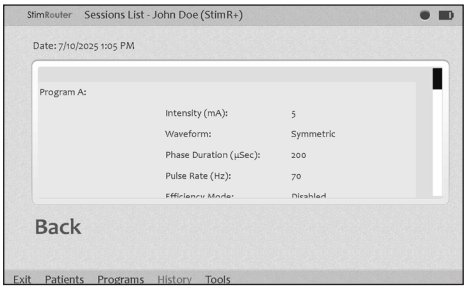


Figure 7-11: View Sessions History

Open individual session details by clicking to to the left of the session's date to highlight the session, then press View to open the session details.

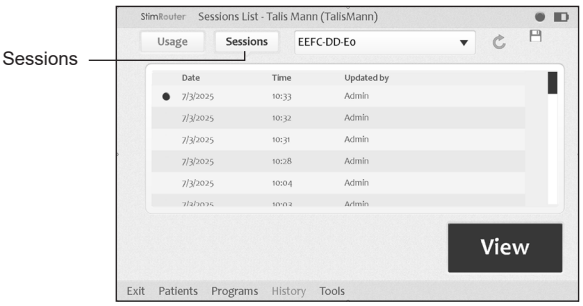


Figure 7-12: View individual session details

Save Usage Data

Use the Save icon to export the chosen usage data as a .CSV file.

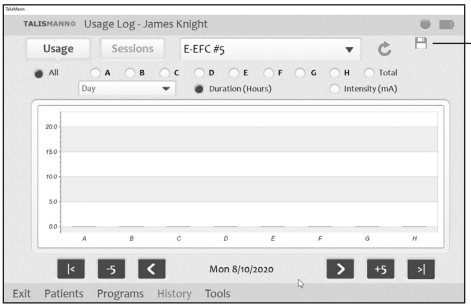


Figure 7-13: Save Usage Data.

8

Patient Set-Up and Programming Instructions

Inspect the External Stimulator for damage prior to use. Do not use External Stimulator if it is damaged.

⚠ **WARNING:** Do not use Stimulator if the housing is cracked, the button overlay is peeling, or any other damage is observed.

Preparing the Patient's Skin

The skin below the Gel Electrode should be clean, dry, and free from irritation, infection, or injury. It is important for the patient to develop a good skincare daily routine and to follow the steps listed in this section.

⚠ **CAUTION:** Skin inflammation in the region of the Gel Electrode may be aggravated by pressure from the electrode. If the skin is inflamed or swollen, StimTrial system should not be used until the inflammation is gone. If the skin has a cut or scrape, do not adhere the Gel Electrode to the damaged skin.

To prepare the skin:

1. Clean the skin where the Gel Electrode will adhere with a wet washcloth. If any lotions or oils are on the skin, then clean with soap and water. Rinse well and dry.
2. If necessary, remove/trim excess body hair from the skin area using scissors. Do not use a razor because it can irritate the skin.
3. Always check the skin for redness or a rash.

Connecting the Gel Electrode and External Stimulator

To connect the Gel Electrode and External Stimulator:

1. Obtain a new Gel Electrode.
2. Check the "Use by" date on the Gel Electrode box.
3. Do not remove the liner at this time.
4. Set the Gel Electrode on a flat surface with the gel pads facing down.
5. Snap the External Stimulator onto the Gel Electrode. **See Figure 8-1.**

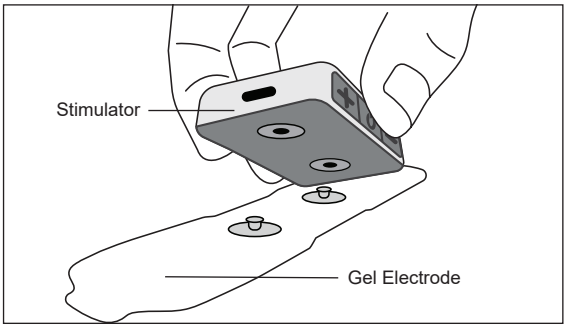


Figure 8-1: Gel Electrode and External Stimulation connection

Adhering the Gel Electrode and Connecting the Lead Adaptor Cable

A Gel Electrode can be reused as long as the gel pads are intact and can fully adhere to the skin or for a maximum of four days of use

WARNINGS:

- Do not touch the gel pads of the Gel Electrode while stimulation is on. Serious injury can occur if electrical current passes through your heart.
- Gel Electrode/External Stimulator and StimTrial Lead must always be on same side of body. Do not go across body midline between Gel Electrode/External Stimulator and StimTrial Lead, serious injury can occur if electrical current passes through your heart.
- Turn stimulation off before adhering, removing, or handling the Gel Electrode.
- Do not pinch or stretch the skin while adhering to the Gel Electrode.
- If the gel pads start to peel off at the edges or detach from the Gel Electrode, immediately dispose of and get a new Gel Electrode.
- Do not attempt to connect the Lead Adaptor Cable into any port other than the External Stimulator.

To adhere the Gel Electrode to skin and connect the Lead Adaptor Cable:

1. Remove the liner and store it in the Electrode Carrying Case. See Figure 8-2. Do not bend the liner. Keep the liner clean and protected so it can be reused when the Gel Electrode is removed from the skin.

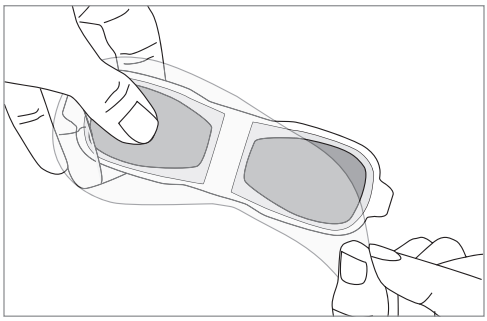


Figure 8-2: Remove the Gel Electrode liner.

2. Visually inspect the gel pads on the back of the Gel Electrode. Make sure the gel is smooth and the gel pads are not dry, worn or dirty.
3. Using the index finger and thumb, grasp the edges of the External Stimulator attached to the Gel Electrode, so the gel pads face downward. **See Figure 8-3.**

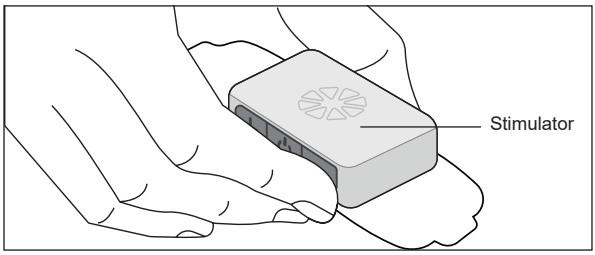


Figure 8-3: Grasp the edges of the External Stimulator attached to the Gel electrode.

4. Orient the Stimulator so that the cable port faces the Lead Adaptor Cable.
5. Connect the Lead Adaptor Cable into the Stimulator cable port. **See Figure 8-4.**

Note: Avoid tension on the Lead Adaptor Cable while connecting it to the USB C port of the Stimulator.

Note: The Stimulator must be connected to the Gel Electrode with liner removed before connecting the Lead Adaptor Cable.

Note: To ensure proper stimulation, the External Stimulator must be connected to the Gel Electrode and Lead Adaptor Cable properly.

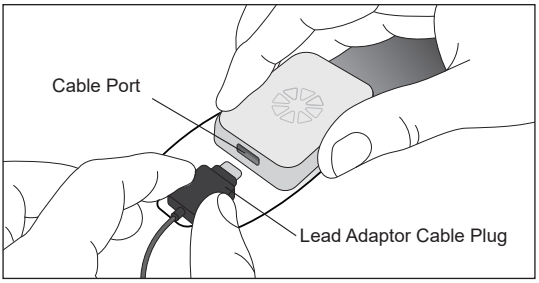


Figure 8-4: Connecting Lead Adaptor Cable to Stimulator.

6. Firmly adhere the Gel Electrode to the skin with a little slack in the Lead Adaptor Cable wire.

Note: Do not place the Gel Electrode/Stimulator across a body joint.

Note: Avoid tension or excessive wire slack on the Lead Adaptor Cable.

Note: If the Gel Electrode is not firmly adhered to the skin and moves, stimulation may become uncomfortable or ineffective.

Note: If the position of the Gel Electrode changes, the stimulation intensity may need to be adjusted.

7. Make certain that the patient programmer is within 10 feet (3 meters) of the Gel Electrode with External Stimulator attached.

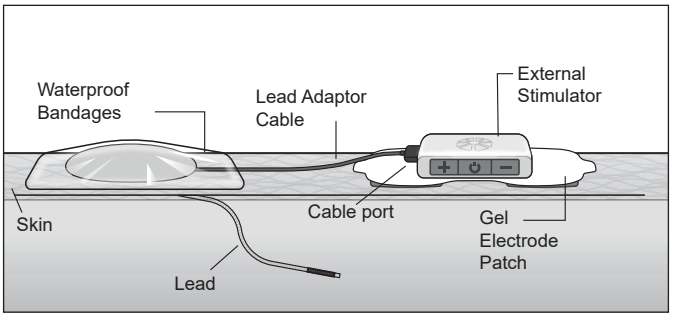


Figure 8-5: Correct component positions (Illustration not to scale)

Confirming Set-Up

If the Clinician's Programmer, External Stimulator, and Gel Electrode are connected correctly, the Clinician's Programmer information icon will be GREEN, confirming online mode.

To confirm the clinician programmer is in online mode:

1. Check that the information icon on the clinician programmer is GREEN.
2. If the information icon is not GREEN, make certain that the Gel Electrode with the External Stimulator attached is within 10 feet (3 meters) of the Clinician Programmer.
3. If the information icon is still not GREEN, check all connections, charge the External Stimulator.
4. Test the External Stimulator using the tester.
5. See the "Troubleshooting" section of this guide.

Refer to the StimTrial User's Guide for detailed operational instructions for the StimTrial External Stimulator and Gel Electrode.

Removing the Gel Electrode

Remove the Gel Electrode from the skin every three to four hours for 15 minutes to allow the skin under the electrode to breathe. The skin may become irritated from prolonged contact with the gel pads on the Gel Electrode.

⚠ **WARNING:** Do not handle the Gel Electrode while stimulation is on. Serious injury can result if electrical current passes through your heart. Turn stimulation off before adhering, removing, or handling the Gel Electrode.

To remove the Gel Electrode:

1. Make certain that stimulation is turned off.
2. Disconnect the Lead Adaptor cable from the External Stimulator.
3. Secure (tape) the Lead Adaptor cable in place to avoid dislodging the lead when removing the Gel Electrode **(Figure 8-6)**.

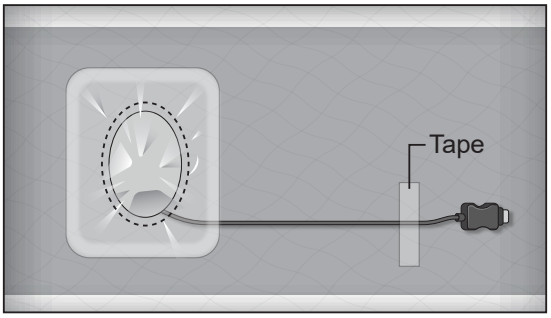


Figure 8-6: Apply tape provided in Patient Kit

4. Grasp the tab on the Gel Electrode and gently pull the electrode away from the skin. See Figure 8-7.
5. Attach the Gel Electrode liner to the gel pads. Without the liner attached, the gel pads on the back of the Gel Electrode will lose their adhesiveness.
6. Store the Gel Electrode with the liner attached in the Gel Electrode carrying case.

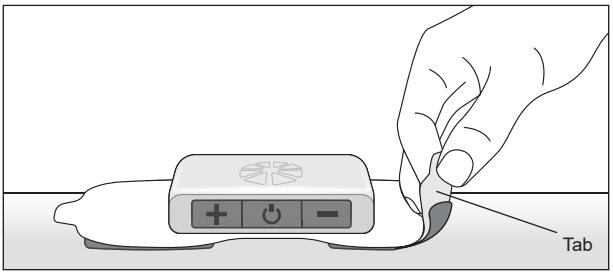


Figure 8-7: Removing the Gel Electrode

⚠ **WARNING:** Do not grasp the gel pads on the back of the electrode. **See Figure 8-8.** If stimulation is not turned off and the gel pads are touched, a tingling sensation could occur.

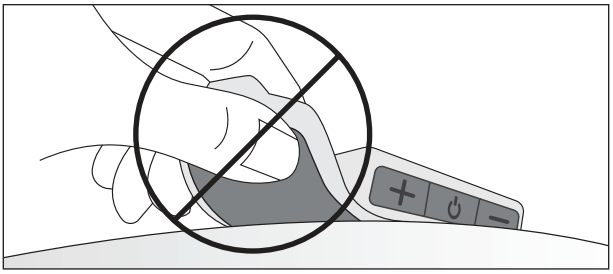


Figure 8-8: Do not grasp the gel electrodes.

Programming Instructions

This section describes how to program stimulation and time settings, and how to add a program, view a program, delete a program, save a program, and print a program.

Note: Illustrations are for reference and may not exactly match what is displayed on the Clinician's Programmer.

Programming Stimulation Settings

To program stimulation settings:

1. Make sure that the clinician programming software is in online mode (the information icon should be GREEN). See "Confirming Set-Up" section of this guide.
2. From the Patients List, select a patient and press "Open". The Stim Settings window will open. **See Figure 8-9.**

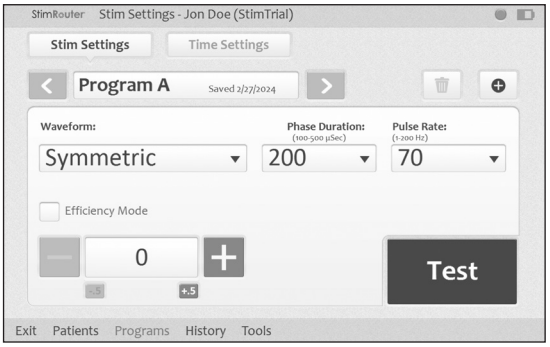


Figure 8-9: Stim Settings window.

3. Press the "Test" button to test the stimulation settings; stimulation will turn on.
4. If needed, adjust the stimulation settings using the drop-down lists.

Note: The stimulation settings have a constant ramp-up and ramp-down of 1 second, during which the patient may not feel any stimulation. Account for ramp-up and ramp-down time during the adjustment process.

Note: Efficiency mode is used to save battery power, but this mode does change the sensation of the stimulation. Efficiency mode may be considered being turned on to help maximize battery consumption with heavy users.

5. Slowly increase the intensity to a level that is tolerable for the patient and achieves paresthesia.
6. Press the "Stop & Save" button to stop stimulation and save the stimulation settings to the Clinician's Programmer, Patient Programmer and External Stimulator. **See Figure 8-10.**

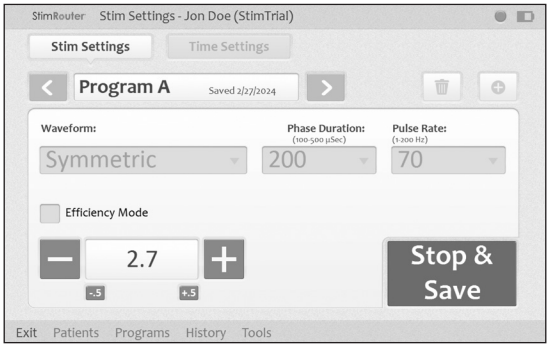


Figure 8-10: Press "Stop & Save" to stop testing and save the current stimulation settings.

7. The program save date will appear on the Program Bar.

Programming Time Settings

To program time settings:

1. From the Stim Settings window, press the Time Settings Tab.
2. The default time setting is constant stimulation. When “Constant Stim” is checked, “Time On” and “Time Off” are disabled; “Ramp Up/Ramp Down” and “Total Time” can be adjusted. **See Figure 8-11.** To change the “Time On” and “Time Off” settings, uncheck “Constant Stim” box and adjust “Time On” and “Time Off” using the drop-down lists.

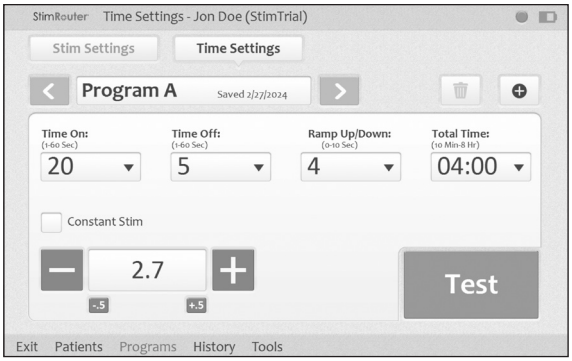


Figure 8-11: Time Settings window

3. Press the “Test” button to test the time settings; stimulation will turn on.
4. If needed adjust the intensity level.
5. Press the “Stop & Save” button to stop stimulation and save the time settings to the Clinician’s Programmer, Patient Programmer and External Stimulator.
6. The program save date will appear on the Program Bar.

Programs

Figure 8-12: Program icons on the program bar

Adding a Program

To add a program:

1. From the Stim Settings Window or Time Settings Window press the add program icon on the Program Bar. **See Figure 8-12.**
2. The new program Stim Settings window will open with default settings. The clinician programming software can support up to eight stimulation programs, labeled (A-H) which will appear in the Program Bar.
3. Program the settings, test the settings and press the “Stop & Save” button to save the new settings.
4. The new program will be saved to the Clinician’s Programmer database, and the External Stimulator.

Note: The clinician programming software must be in online mode to add a program.

Deleting a Program

To delete a program:

1. From the Stim Settings Window or Time Settings Window, select a program to delete.
2. Press the delete program icon on the Program Bar. **See Figure 8-12.**

9

Software Tools

Note: Illustrations are for reference and may not exactly match what is displayed on the Clinician's Programmer.

Clearing Patient Data from the External Stimulator

Note: External Stimulator Patient Data must be cleared when a trial is completed and before being used on another patient.

System information can be found in the Info Tab of the Tools Menu. From the Info Tab users can look up the installed software version on all components of the StimTrial system. For example, "External Stimulator SW VER: 1.0.0.4" indicates to the user that the External Stimulator software version is 1.0.0.4.

Reset the External Stimulator from the Clinician Programmer:

When an External Stimulator with existing patient information is paired to the Clinician Programmer, a popup will be generated, prompting the clinician to clear the patient information on the device. After the patient information is cleared, the device will reset, and the clinician must re-pair the External Stimulator to proceed with device configuration for the new patient. Additionally, an External Stimulator can be reset by following the steps below:

1. Connect the External Stimulator to the Clinician Programmer.
2. Press "Tools" on the Menu Bar, then press the Reset Tab. **See Figure 9-1.**

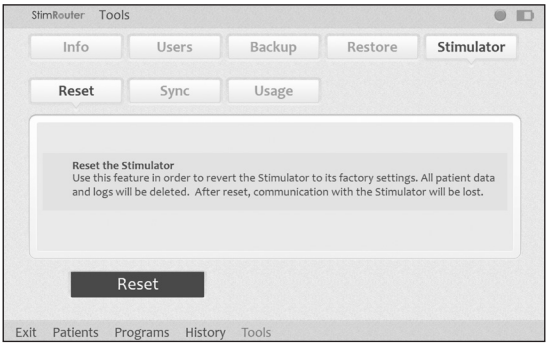


Figure 9-1: Resetting the Patient Programmer and External Stimulator

3. To reset the External Stimulator, press the "Reset" button. Resetting the External Stimulator from the Clinician Programmer will restore the External Stimulator to its factory settings. All patient data and logs will be deleted.

Restart the External Stimulator from the External Stimulator Buttons:

1. Press and hold the power button on the External Stimulator for 16 seconds.

User Administration

The clinician programming software supports two levels of users: users and administrators.

Both users and administrators have access to the Info Tab of the Tools Menu. Administrators have extended

authorizations and have access to the Users, Backup and Restore tabs of the Tools Menu. Administrators can define automatic backup options, manually back up the Clinician's Programmer database, manually restore the Clinician's Programmer database, add, and remove users/administrators, and change user passwords.

Adding a User/Administrator

To add a user/administrator:

1. Press "Tools" on the Menu Bar, press the Users Tab and then press the "New User" button. See Figure 9-2.
2. Enter a username and password, confirm the password, select either "Users" or "Administrators" from the "Group" drop-down list, and then press the "Add" button. **See Figure 9-3.**

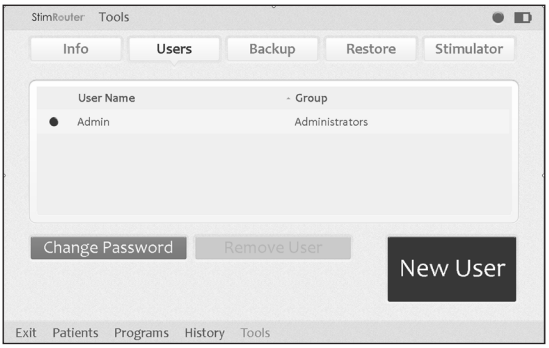


Figure 9-2: Adding a user/administrator.

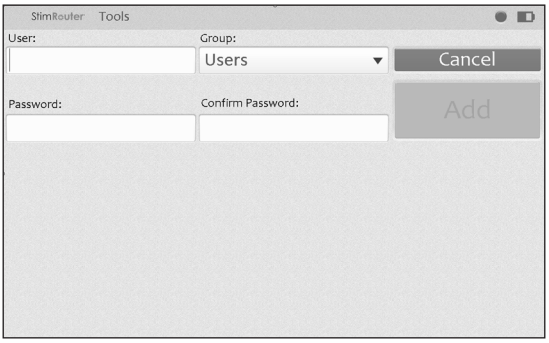


Figure 9-3: Add new user window.

Removing a User/Administrator

To remove a user/administrator:

1. Press "Tools" on the Menu Bar, press the Users Tab, select a username, and then press the "Remove User" button. Confirm "Yes" or "No" when prompted. **See Figure 9-4.**

Note: The administrator who is logged on cannot be removed.

Figure 9-4: Removing a user.

Changing a User Password

To change a user password:

1. Press “Tools” on the Menu Bar, press the Users Tab, select a username, and then press the “Change Password” button.
2. Enter and confirm the new user password, and then press the “OK” button.

Note: Passwords should be changed at least every three months.

Clinician’s Programmer Database Backup and Restore

Administrators can back up the Clinician’s Programmer database to the memory card automatically or manually at any time. When a memory card is installed and automatic backup is enabled, the Clinician’s Programmer will automatically back up the database periodically and whenever the clinician programming software is exited.

Enabling Automatic Database Backup

To enable automatic database backup:

1. Press “Tools” on the Menu Bar, press the Backup Tab, and then check “Enable automatic database backup”. The Clinician’s Programmer database will back up once daily and each time the software is exited. **See Figure 9-5.**

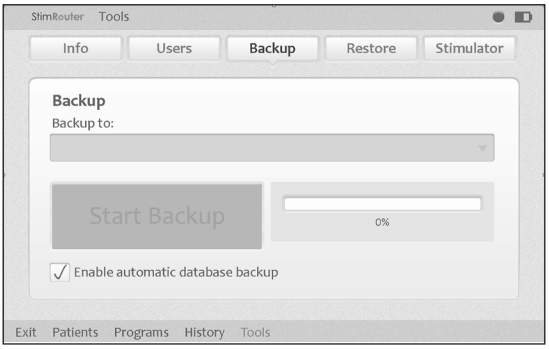


Figure 9-5: Backing up the Clinician’s Programmer database.

Manually Backing Up the Database

To manually back up the Clinician’s Programmer database:

1. Press “Tools” on the Menu Bar and then press the Backup Tab.
2. From the “Back up to” drop-down list, select SD Card drive, and then press the “Start Backup” button. **See Figure 9-5.**

Restoring the Database

Administrators can restore the database when the Clinician's Programmer is replaced, or the database is corrupted.

To restore the Clinician's Programmer database:

1. Insert the memory card with the backup files into Clinician's Programmer.
2. Press "Tools" on the Menu Bar and then press the Restore Tab.
3. From the "Restore from" drop-down list, select SD Card drive. **See Figure 9-6.**

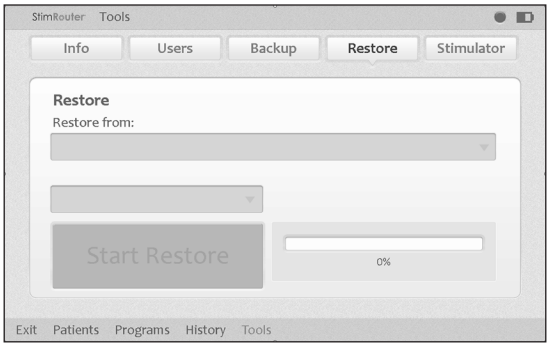


Figure 9-6: Restoring the Clinician's Programmer database.

4. Select "From automatic backup" or "From manual backup", and then choose a backup date and time from the drop-down lists.
5. Press the "Start Restore" button.

10

Maintenance and Cleaning

Replacing the Gel Electrode

The typical lifespan of the Gel Electrode is two to four days, depending on:

- The number of hours of use.
- The number of times the electrode is adhered to and removed from the skin.
- Hygiene and skin care in the area of Gel Electrode placement.

To ensure maximum Gel Electrode lifespan and performance, always attach the electrode liner to the gel pads when storing the Gel Electrode.

Instruct patients to dispose of the Gel Electrode when any of the following occurs:

- The gel pads start to peel off at the edges or detach from the Gel Electrode.
- The gel pads appear worn or dirty.
- The gel pads lose their adhesiveness.

Cleaning: Clinician Kit Components

All Clinician Kit components may be cleaned by carefully wiping them with a damp cloth using water only. Do not use detergents or other cleaning agents. Do not clean the gel pads on the back of the Gel Electrode.

The screen of the Clinician Programmer can be cleaned using any commercially available screen cleaner for liquid crystal displays (LCD) and computer screens.

Note: StimTrial electronic components are not waterproof; do not immerse them in water.

Cleaning: External Stimulator and Accessories

⚠ **WARNING:** The External Stimulator must be cleaned at the end of the trial and before use with another patient. There should be no visible signs of contamination, damage or soiled surfaces.

⚠ **WARNING:** Do not reuse any items from the StimTrial Surgical Kit or the StimTrial Patient Kit across multiple patients. Components are for single use only. Discard unused contents at the end of a trial.

Electronic Components

The External Stimulator must be cleaned using CaviWipes™ or equivalent (if available). Make sure to wear protective gloves when using CaviWipes™ to avoid skin contact. Use a presaturated CaviWipe™ cloth to gently rub all exterior surfaces of the components without undue pressure for two to three minutes. Attempts should be made to avoid collecting fluid at the USB openings.

Use a clean, dry cloth to remove any residual moisture as needed.

After cleaning and drying, the components shall be inspected under normal lighting conditions without the aid of magnification. All external surfaces are to be visibly free of any surface contamination or soil. All labels shall be legible. There shall be no obvious signs of damage to any component surfaces.

Any component shall be removed from service if the labels are not legible, the housing or surfaces shows signs of damage or soil and contamination cannot be removed by the defined cleaning process.

Note: Do not attempt to clean the Gel Electrode. If contamination or soil is a concern, discard the Gel Electrode and use a new electrode.

Note: Do not attempt to modify, disassemble or repair the External Stimulator. There are no user serviceable parts inside the External Stimulator.

11

Troubleshooting

The tables at the end of this section describe the visual indicators that may appear on the Clinician's Programmer, and possible solutions for troubleshooting. In addition, this section describes solutions for the following scenarios that may arise during a programming session:

- The patient forgets to bring or has lost the External Stimulator.
- The patient brings a new External Stimulator.

Patient Loses External Stimulator

When a patient loses an External Stimulator, he or she will need to obtain a new External Stimulator and electronically register it to the Clinician Programmer. See "Registering the External Stimulator" section of this guide. All data stored on the Clinician Programmer will copy to the new External Stimulator. However, since the usage history is stored on the External Stimulator, any usage history that was not copied to the Clinician's Programmer database is lost with the lost External Stimulator.

Copying Patient Data to New Components

To copy patient data to new components:

1. Make sure the patient's External Stimulator is charged.
2. Make sure the Clinician Programmer and the External Stimulator are no more than a few inches apart and not touching.
3. The clinician programming software will detect the unregistered External Stimulator and ask if you want to register this External Stimulator now.
4. Press "Yes".
5. Once the External Stimulator is registered, press "OK".
6. From the Patient List, select the patient's record and press "Open". Once the patient record is opened, all patient data except for history will copy to the patient's new External Stimulator.

Troubleshooting Tables

Clinician's Programmer	Problems/Solutions
 **FLASHING RED Information Icon**	**User-Correctable Error: Faulty Electrode Contact, Radio Communication Failure** • Press the information icon to view error message and list of solutions.
 **FLASHING YELLOW Information Icon**	**Low Battery Detected: External Stimulator or Patient Programmer** • Press the information icon to view error message and list of solutions. • Charge the External Stimulator.
 **RED Information Icon**	**Software or Hardware Error:** • Press the information icon to view error message and list of solutions.
Unexpected Error in the Software	Contact Customer Service or your local distributor.
Clinician's Programmer Will Not Turn On	• Charge the Clinician's Programmer and verify that the charging LED is ON. • Contact Customer Service or your local distributor.

External Stimulator and Stimulation	Solutions
Undesirable Motor Response	• Decrease the stimulation intensity level. • Check the placement of the Gel Electrode.
External Stimulator Charging Light Does Not Turn On	• Check the connection. • Check the charging cable (disconnect it and connect charger directly). • Contact Bioventus.
External Stimulator is not responsive	• Perform a hard reset by pressing and holding the power button of the External Stimulator for 8 seconds.
Continuous beeps, blinking red LED	• Connect to the MAPP application to receive details on the specific error and detailed troubleshooting steps.
3 beeps, blinking pink LED	
3 beeps, blinking amber LED	
LED solid pink, External Stimulator unresponsive	• Hard reset the External Stimulator by holding the power button down for greater than 10 seconds (or until the red LED disappears), then turn the External Stimulator back on. If the condition persists, contact your healthcare provider or Bioventus.

Table 11-1: Troubleshooting

Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer. For any issues relating to technical support, please contact Bioventus Customer Service at 888-453-2136.

12

Technical Specifications

External Stimulator Charger Specifications

Use medical Class II safety approved power supply provided/approved by Bioventus with the following ratings:

Manufacturer's Model No.	FRIWO FW8002.1MUSB/05
Input	
Voltage	100-240 VAC
Current	160-80 mA
Frequency	50-60 Hz
Output	
Voltage	5 V ± 5%
Current	1400 mA
Charging Cable	1 meter long USB A to USB C

External Stimulator Specifications

Classification	Internally powered, or Class II Equipment when operated with a charger, continuous operation, type BF applied parts
Operating Voltage	Rechargeable Lithium Polymer 3.7-volt battery 310 mAh capacity
Dimensions	**Length** 57 mm (2.25 in.) **Width** 33 mm (1.3 in.) **Height** 11.5 mm (0.45 in.)
Weight	28 grams (1 oz.)
Environmental Ranges	**Operating Conditions** Temperature: 5°C to 40°C (41°F to 104°F) Relative Humidity: 25% to 85% (non-condensing) Atmospheric Pressure: 70kPa to 106kPa **Transport and Storage Conditions** Temperature: -25°C to 60°C (-13°F to 140°F) Relative Humidity: 10% to 90% Atmospheric Pressure: 50kPa to 106 kPa
Service Life	2 years
Ingress Protection Rating	IP22 per IEC 60529. Protected against solid objects over 12.5mm (e.g. a finger) and protected against falling drops of water, if the case is disposed at any angle up to 15 degrees from vertical.
FCC ID #	RYYEYSHSN

Pulse Parameters	
Pulse	Balanced biphasic
Waveform	Symmetric or Asymmetric
Intensity*	200uA – 10mA, 100 uA resolution (positive phase)
Maximum Output	3.16 mA (RMS)
Maximum Charge	5 microcoulombs per phase
Current Density (return electrode)	0.226 mA rms/cm^2
Positive Phase Duration**	100, 200, 300, 400, 500 µs
Negative Phase Duration	Symmetric: Identical to the positive phase duration Asymmetric: Three times the positive phase duration
Typical Load	330 Ω in series with 100 nF
Pulse Repetition Rate ***	1, 2, 5, 10, 12, 15, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz
Timing Parameters	
On Time	1-60 seconds, 1 second resolution
Off Time	0-60 seconds, 1 second resolution (0 second = constant stimulation)
Ramp Up / Ramp Down	0-10 seconds, but not more than “On Time”/2 with 1 second resolution
Total Time	10 minutes - 8 hours
Conformity Certification	The StimTrial complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: 1. This device may not cause harmful interference, and 2. This device must accept any interference received, including interference that may causeundesired operation.

*Intensity: A measure of strength of the stimulation.
**Positive phase duration: A measure of the duration of a pulse.
***Pulse repetition rate: The number of times per second a pulse is delivered.

Lead Adaptor Cable Specifications

Description	Applied part. Cable with custom USB-C connector to Lead Connector, single conductor.
Dimensions	Length: 34.6 cm (13.625 in)
Insulation Material	Medical grade TPE, medical grade PVC

Gel Electrode Specifications

Description	Applied part. Metal snap connects to gel electrode which adheres to skin. Return path for electrical signal from tissue to External Stimulator.
Electrode Size	7.5 cm^2
Dimensions	**Length** 119 mm (4.68 in.) **Width** 33.5 mm (1.31 in.) **Height** 2.3 mm (0.09 in.)
Weight	10 grams
Environmental Ranges	**Transport and Storage Temperature:** 5°C (41.0°F) to 27°C (80.6°F) **Operational Conditions Temperature:** 15°C (59°F) to 40°C (104°F) **Relative Humidity:** 25% to 85% **Atmospheric Pressure:** 50 kPa to 106 kPa
Service Life	2-4 days

System Characteristics

The StimTrial System communicates wirelessly between components.

Description	Industry-standard Bluetooth® Low Energy (BLE) 4.0 communication protocol
Operating Frequency Band	2.4 Ghz, ISM band (2402-2480 MHz)
Type of Modulation	FSK
Type of Modulating Signal	Binary data message
Data Rate [=Frequency of Modulating Signal]	250 Kbps
Effective Isotropic Radiated Power	4 dBm
Receiver Bandwidth	812 kHz around a selected frequency
EMC Testing	Complies with FCC 15.2473 (for U.S.) regulations Complies with IEC 60601-1-2 Complies with IEC 60601-2-10

- **Quality of Service (QOS):** The StimTrial System was designed and tested to have a response rate of 10-100ms latency.
- **Wireless Interference:** The StimTrial System was designed and tested to not have interference from other RF devices (including other StimTrial Systems, WiFi networks, Cellular Devices, Microwaves and other Bluetooth® devices).

StimTrial System is not susceptible to the wide range of expected EMI emitters, such as Electronic Article Surveillance Systems (EAS), Radio Frequency Identification Systems (RFID), Tag Deactivators, and Metal Detectors. However, there is no guarantee that interference will not occur in a particular situation.

⚠ **CAUTION:** If performance of the StimTrial System is affected by other equipment, the user should turn the StimTrial System off and move away from the interfering equipment.

Privacy of Wireless Communication

The privacy of wireless communication is ensured by the use of encrypted patient information and authenticated Bluetooth connections for security.

13

Network Safety, Security, and Privacy

The security of products is an important factor in protecting information and systems from external and internal threats. Therefore, customers must take responsibility for maintaining a secure IT environment that is compliant with general IT standards. Customers are encouraged to implement the following industry-standard practices:

- Physical Security (e.g. do not allow unauthorized individuals to use the Clinician Programmer tablet and application)
- Operational Security:
  - Do not leave a logged-in tablet unattended; Do not connect the tablet to any network;
  - Do not install unauthorized software, including antivirus software;
  - Only connect USB flash drives or SD cards provided by Bioventus. Use of unauthorized USB flash drives or SD cards could introduce malware and impact system performance, thus voiding the warranty.
- Procedural Security (e.g. create awareness of the dangers of social engineering, create separate login credentials for each user for the Clinician Programmer application, and disable unused accounts)
- Risk Management
- Security Policies
- Contingency Planning

If a cybersecurity event is suspected, contact Bioventus. Additional information related to security, privacy, or available software updates can also be requested from Bioventus.

14

Appendix – EMI Tables

Electromagnetic Emissions

The StimTrial system is medical electrical equipment and was tested for electromagnetic compatibility (EMC) in accordance with International Electrotechnical Committee (IEC) 60601-1-2. The following tables provide information regarding the EMC testing and guidance for safe use of the system. The StimTrial system should be configured and used in accordance with the instructions provided in this manual.

There is potential for interference between electronic devices, including cell phones and other medical devices such as a body- worn insulin pump. Stimulation control may be delayed. Maintain a minimum safe separation distance of 15 cm (6 in.) between the StimTrial system and all other electronic devices. If interference is suspected or anticipated, distance yourself from the source of interference.

⚠ **CAUTION:** Using cables or accessories other than those supplied with the StimTrial system could result in increased emissions or decreased immunity.

Guidance and Manufacturer's Declaration Electromagnetic Emissions

The StimTrial system is intended for home use in addition to use in the electromagnetic environment specified below. The customer or the user of the StimTrial system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The StimTrial system uses RF energy for short-range communications. Therefore, its RF emissions are very low, about 100 times lower than a commercially available cell phone. Though unlikely, portable and mobile RF communications equipment, such as the StimTrial External Stimulator and clinician programmer, could affect medical electrical equipment.
RF emissions CISPR 11	Class B	The RF-enabled components of the StimTrial system are 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration Electromagnetic Immunity

The StimTrial system is intended for home use in addition to use in the electromagnetic environment specified below. The user of the StimTrial system should assure that it is used in such an environment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±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 tbe at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for Power supply lines ±1 kV for input/ output lines	±2 kV for Power supply lines Not applicable. No input/ output lines.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line (s) to line(s) ±2 kV to earth	±1 kV line to line Not applicable. No grounded interconnections.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	The main power supply quality should be that of a typical commercial or hospital environment. The StimTrial system continues operation during power mains interruptions, as it is normally powered by each component battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the A.C.mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration Electromagnetic Immunity

The StimTrial system is intended for home use in addition to use in the electromagnetic environment specified below. The customer or the user of the StimTrial system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the StimTrial system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Recommended separation distance (d) $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2.5 GHz	10 V/m 26 MHz to 1 GHz 3 V/m 1 GHz to 2.5 GHz	$d = 0.4\sqrt{P}$ 80 MHz to 800 Mhz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and Manufacturer's Declaration Electromagnetic Immunity

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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the StimTrial system is used exceeds the applicable RF compliance level above, the StimTrial system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the StimTrial system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the StimTrial System

The StimTrial system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the StimTrial system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the StimTrial system as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 0.4\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	4.7 in. (0.12 m)	1.6 in (0.04 m)	9.1 in. (0.23 m)
0.1	15 in. (0.38 m)	4.7 in. (0.12 m)	2 ft 5 in. (0.73 m)
1	3 ft 11 in. (1.2 m)	15.7 in. (0.4 m)	7 ft 7 in. (2.3 m)
10	12 ft 6 in. (3.8 m)	4 ft 2 in. (1.26 m)	24 ft 11 in. (7.3 m)
100	39 ft 4 in. (12 m)	13 ft 1 in. (4 m)	75 ft 6 in. (23 m)

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.

Bioventus LLC
4721 Emperor Blvd Suite 100
Durham, NC 27703
USA

(888) 453-2136
StimTrial.com

Rx Only

LBL-000760 Rev A
07/2025