TALISMANN®

neuromodulation system

Clinician Guide

bioventus®

Innovations For Active Healing

Environmental Policy

Service personnel are advised that when changing any part of the TalisMann 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 TalisMann 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 Bioventus. Bioventus is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

bioventus®

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List of Symbols

⚠	Caution
⚠	Warning
▣	Class II Equipment (Double Insulated)
🧍	Type BF Applied Part(s)
((•))	Non-Ionizing Radiation
ᙢ	Date of Manufacture
🏭	Manufacturer
⌧	This Product Must Not Be Disposed of with Other Household Waste
📖	Refer to Instruction Manual/Booklet
📖i	Consult Instructions for Use
REF	Re-Order Number
LOT	Lot Number
SN	Serial Number
(1🧍)	Single Patient Multiple Use
⚠MR	MR Conditional
②	Single Use
🌡	Storage Temperature
💧%	Humidity Limitation
⊙	Atmospheric Pressure Limitation
IP68	Protection Against Ingress of Water
☂	Keep Dry
⧗	Use By
⬚x	Quantity
Rx Only	Prescription Only
MD	Medical Device

Table of Contents

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Introduction

The TalisMann Neuromodulation System is intended to help relieve chronic pain of peripheral origin. The TalisMann Neuromodulation System is made up of implanted components from the TalisMann Pulse Generator and Receiver and Implant Kit (TM-1000) and external components from the User Kit (PNS-5000). Additional components from the Clincian Kit (PNS-1000) are also referenced in this guide. The TalisMann System consists of the following:

- An implanted lead
- A TalisMann Pulse Generator and Receiver
- A clinician programming system with a Clinician Programmer and charger, Programming software, a Tester and accessories
- A rechargeable External Electric Field Conductor (E-EFC), charger, and accessories
- A Gel Electrode

This guide describes the clinician programming system components of the TalisMann Neuromodulation System, which are provided in the Clinician Kit. The clinician programming components are used by trained clinicians to program the patient's External Electric Field Conductor (E-EFC). The E-EFC and other external components are intended to be operated by patients.

Refer to the StimRouter Procedure Manual for a description of the StimRouter Implantable Lead and Lead Introducer Kit, package contents, device specifications and the StimRouter implant procedure.

Refer to the TalisMann User's Guide for a full description of the User Kit, Gel Electrode, External Electric Field Conductor (E-EFC), external accessories, package contents, device specifications, and instructions for use.

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Patient Components

StimRouter Lead with TalisMann Pulse Generator and Receiver

The StimRouter Lead is flexible and approximately 15 cm (6 in.) in length. The lead has a stimulation end and a receiver end. The lead implantation places the stimulation end near or at the targeted peripheral nerve. The TalisMann Neuromodulation Pulse Generator/Receiver is attached to the proximal end of the StimRouter lead and is placed under the skin into a surgically created pocket. The TalisMann Neuromodulation Pulse Generator/ Receiver receives the signal from the E-EFC and then generates the stimulation pulse through the lead to the stimulation end. See Figure 2-1.

Lead   Pulse Generator/Receiver

Figure 2-1: The StimRouter Lead and the TalisMann Pulse Generator and Receiver

External Electric Field Conductor (E-EFC)

The E-EFC generates the transcutaneous signal and transmits the signal via the Gel Electrode/Skin interface to the TalisMann Neuromodulation Pulse Generator/ Receiver. The E-EFC snaps onto the Gel Electrode (See Figure 2-2) and responds to wireless commands from the MAPP.
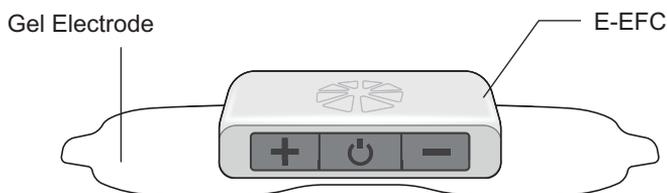
Gel Electrode   E-EFC

Figure 2-2: The E-EFC attached to the Gel Electrode

Charging Socket and Charging Light

The E-EFC charging socket is located on the front panel of the E-EFC. When the E-EFC is charging a green charging light will appear on the side panel of the E-EFC. See Figure 2-3.

E-EFC Charging Socket

Location of Charging Light
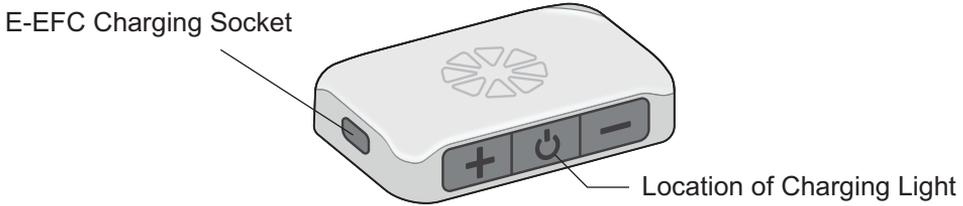
Figure 2-3: The E-EFC charging socket and charging light location

Gel Electrode

Gel Electrode features: (See Figure 2-4)

- Two gel pads that adhere the Gel Electrode to the skin. The gel pads also transmit the stimulation signal from the E-EFC to the receiver end of the lead.
- Two snaps for E-EFC placement.
- Two tabs for removing the Gel Electrode from the skin.
- A liner to protect the gel pads on the back of the Gel Electrode.

Snaps

Tabs
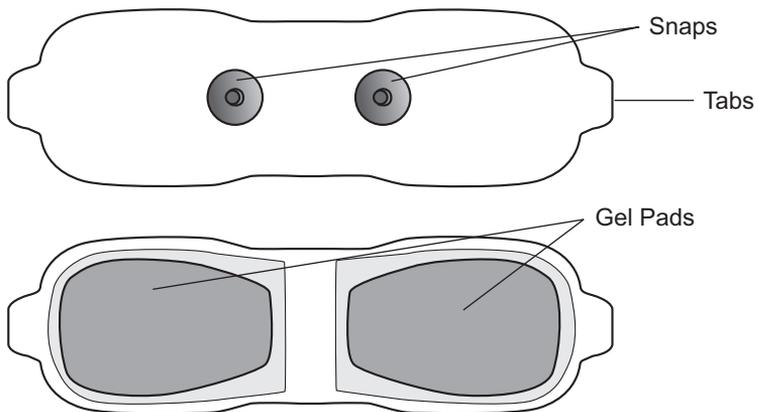
Gel Pads

Figure 2-4: Gel Electrode (top and bottom views)

The Gel Electrode is disposable and can be reused by the same patient as long as the gel pads are intact and can fully adhere to the skin or for a maximum of four days of use.

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 Gel Electrode is adhered and removed from the skin.
- Hygiene and skin care in the area of Gel Electrode placement.

Clinician Kit

The Clinician Kit includes the following:

- Clinician Programmer, Tablet with Software and Stylus
- Clinician Programmer Micro SD Card
- Clinician Programmer Charger

Clinician Programmer

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Warnings and Cautions

Indications for Use

The TalisMann Neuromodulation System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The TalisMann Neuromodulation System is not intended to treat pain in the craniofacial region.

Device Use and Suitability

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

The TalisMann Pulse Generator and Receiver System may not be suitable for treatment of acute pain, for pain that is not of peripheral nerve origin, or for patients whose required stimulation parameters cannot be met the TalisMann Pulse Generator and Receiver System. The TalisMann Pulse Generator and Receiver System implant procedure may be performed in any sterile surgical setting.

Device Materials

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

- Hydrogel
- Plastic

Both materials have been tested to verify biocompatbility.

Essential Performance

The TalisMann 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 TalisMann Pulse Generator and Receiver is contraindicated for:

- Patients who are unable to operate the TalisMann system.
- Patients who are poor surgical candidates.
- Patients who have a cancerous lesion present near the target stimulation point or near to where the Gel Electrode will adhere.
- Patients with bleeding disorders or active anticoagulation that cannot be stopped for a few days close to the time of the surgical procedure.
- Patients who are unable to remove the E-EFC.
- Patients who are unable to communicate a device malfunction from device use.

⚠ Warnings

- The TalisMann 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 TalisMann System is unknown.

A risk/benefit determination should be performed before using the TalisMann Pulse Generator and Receiver for:

- Patients exposed to diathermy. Shortwave, microwave and/ or therapeutic ultrasound diathermy should not be used on patients who have a TalisMann Pulse Generator and Receiver. The energy generated by diathermy can be transferred through the TalisMann system components, causing tissue damage at the implant site and potentially resulting in severe injury. Diathermy may also damage the TalisMann system 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 health-care professionals that they should not be exposed to diathermy.

- Patients exposed to therapeutic ultrasound.

Magnetic Resonance Imaging (MRI) Safety Information

- The TalisMann Pulse Generator and Receiver is MR Conditional. A person implanted with this device can be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe injury or device malfunction. Full MRI safety information is available in the MRI Guidelines Manual, which can be obtained at TalisMann.com or by calling 888-453-2136. An MRI examination of a patient with a TalisMann Pulse Generator and Receiver should not be conducted until the information in the Clinician Guide and MRI Guidelines is read and understood.

- All external components of the TalisMann system, including the Gel Electrode, E-EFC, Clinician Programmer and Clinician Programmer Charger are MR Unsafe and are contraindicated for the MR environment. Do not bring them into the MR system room.

Pregnancy

The effects of electrical stimulation on pregnancy are not known. Do not use electrical stimulation during pregnancy.

Programming

Only a trained clinician should program the TalisMann system.

Flammable Fuel, Chemicals or Environment

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

Turn off stimulation when you are near a refueling station, flammable fuel, fumes or chemicals. If your 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 TalisMann system in close proximity (e.g., 1 meter or 3 feet) to shortwave or microwave therapy equipment may produce instability in the E-EFC output.

The following medical therapies or procedures may turn stimulation off. They may also permanently damage the TalisMann 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 TalisMann 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 an implanted TalisMann Pulse Generator and Receiver. Contact between an active electrode of the electrosurgery device and the TalisMann Pulse Generator and Receiver can stimulate the receiver and cause severe injury.

High-Frequency Surgical Equipment

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

Body-Worn Devices

Although unlikely, body-worn medical devices may interfere with the RF communication used in the TalisMann 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 TalisMann system and all other electronic devices. See the "Troubleshooting" section for help. See the "Appendix" for more information.

The TalisMann 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. A patient should ask for help to bypass the device. The Medical Device Identification Card can be shown. If a patient must pass through the device, they should:

- Turn off their TalisMann 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 TalisMann system and all other electronic devices.

Precautions

Post-Operative Care

After the implant procedure, the incision site should be checked for infection, possible device rejection or other possible adverse effects.

A patient should contact you immediately if they have:

- Excessive redness or discharge around the incision site.
- Prolonged pain at the incision site.
- Warmth and swelling of the incision site.
- Fever
- Dizziness
- Bleeding

Known or Suspected Heart Problems

Caution should be used when treating patients with suspected or diagnosed heart problems.

Implant Failure

Implanted receivers may fail at any time. If a TalisMann fails or breaks, then the TalisMann system may need to be removed or replaced. It is possible that small fragments of the implant could remain at the implantation site after removal, which will indefinitely prevent you from being eligible for certain procedures, such as diathermy, therapeutic ultrasound, or MRI in the affected area. Immediately contact your doctor if implant failure is suspected.

Postural Changes

Changes in posture or abrupt movements may change the stimulation that is felt. Turn off stimulation before stretching or exercising.

For Single Patient Use Only

Do not adhere the Gel Electrode to any other person.

Keep Out of Reach of Children

Keep all TalisMann 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

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 TalisMann system until the irritation is gone. To avoid irritation, remove the Gel Electrode every three to four hours for 15 minutes.

Sensations Caused by Stimulation

As with other nerve stimulation devices, the TalisMann Pulse Generator and Receiver 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 TalisMann 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 expired.

Gel Electrode Placement and Stimulation

- Only use Gel Electrodes supplied by Bioventus
- Only the doctor should decide where to place the Gel Electrode.
- Only the doctor should program your TalisMann 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.
- Avoid placing the Gel Electrode across or through the head, directly on the eyes, covering the mouth, 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 with both hands while stimulation is on. Serious injury can occur if electrical current passes through the heart.

- Patient must be instructed to not apply the Gel Electrode to anyone else or any other part of the body than that determined by the doctor.

Adverse Effects

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

Risks Related to the Implant 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 you 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 lead may cause increased pain.
- A patient may have undesirable movements during stimulation.

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

- Stop stimulation immediately.
- Remove the Gel Electrode.
- Notify you.

Additional Risks Related to the TalisMann 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 TalisMann components to malfunction. EMI may also affect stimulation.

- Persistent pain may occur at the implant site.

- Although rare, the skin overlying the lead may erode.

- Portable and mobile radio frequency communications equipment can affect medical electrical equipment.

- The TalisMann external components could overheat if the components fail. Overheating could cause burning.

Temperature

The E-EFC can heat up to 43°C during operation in extremely hot areas/rooms. If this occurs turn off stimulation, remove E-EFC, and set aside until temperature is within operational conditions.

End-Of-Life Waste Management

WEEE Regulations place an obligation on distributors to offer consumers a take-back system where WEEE items can be disposed of free of charge.

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Environmental Conditions that Affect Use

Storage and Handling

All TalisMann 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 expose them to weather conditions such as rain or snow. TalisMann components should not be stored in a car where they can be exposed to extreme hot or cold temperatures. Temperature extremes can damage the TalisMann components.

To avoid condensation when transporting TalisMann components from hot to cold temperatures, the components should be placed in an air-tight plastic bag first and be allowed to adjust slowly (for at least two hours) to the change in temperature before use.

Radio Communication Information

Several components of the TalisMann system communicate via radio communication and 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 and, if not operated and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular environment. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, then try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/television technician for assistance.

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

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

Conformity Certification

The TalisMann 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.

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Device Description

Clinician Programmer

The Clinician Programmer is used to program, test and save stimulation parameters and programs on the E-EFC. The Clinician Programmer is a Windows® Tablet PC that comes with the Clinician Programming software and a memory card installed. The Clinician Programmer can wirelessly communicate with the E-EFC.

Operating Buttons

Buttons	Description	Function
	Power Button	Used to turn the Clinician 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 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 Programmer Micro SD Card

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

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

- Do not use the Clinician Programmer for any purpose other than that described in this manual.

- 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 Programmer Charger

Used to recharge the Clinician Programmer.

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

Clinician Programming Software

The Clinician Programming software is provided installed on the Clinician Programmer.

Operating Modes

The Clinician Programming software has two operating modes: online and offline.

Online. The Clinician Programmer is online when connected to an operational E-EFC.

Offline. The Clinician Programmer is offline when not connected to an operational E-EFC.

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 E-EFC. • Back up the database. • Restore the Clinician 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 Programmer database. • Restore the Clinician Programmer database. • Add a new user. • Remove a user. • Change a user password.

Table 6-1: 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 6-1.
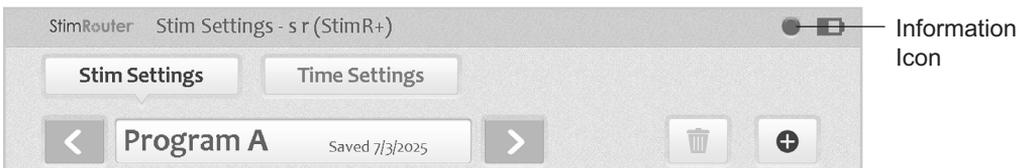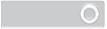

Figure 6-1: Location of the information icon

GREEN when the Clinician Programming Software is online and connected to an E-EFC; GRAY when no E-EFC is detected.

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

FLASHING YELLOW when the E-EFC 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 6-2.
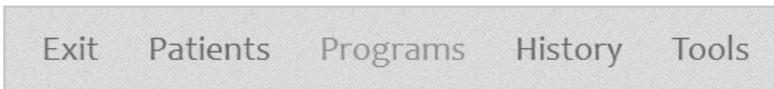
Figure 6-2: Menu bar

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.)

Tools. Used to view system information and to reset the E-EFC. Users with administrator privileges can also add and remove users, change a user password, and back up and restore the Clinician Programmer database.

Tabs

The Clinician Programming software has eight navigation tabs, or submenus, found under the five main menus. See Table 6-2.

Menu	Tab	Function Descriptions
Exit		• Exit the Clinician Programming software. • Log off the Clinician Programming software.
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, burst 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.
Tools	**Info**	• View system information in online mode. • Reset the E-EFC in online mode.

Menu	Tab	Function Descriptions
	Users	• Add a new user. • Remove a user. • Change a user password.
	Backup	• Back up the Clinician Programmer database. • Enable/disable database backup.
	Restore	• Restore the Clinician Programmer database from backup.

Table 6-2: 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 6-3.

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 E-EFC	• Restore factory settings on the E-EFC. (When selected, all patient data on the E-EFC is erased.)

Stop & Save	• Stop stimulation and save the stimulation and time settings.
Test	• Test the current stimulation and time settings.

Table 6-3: 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 6-3.
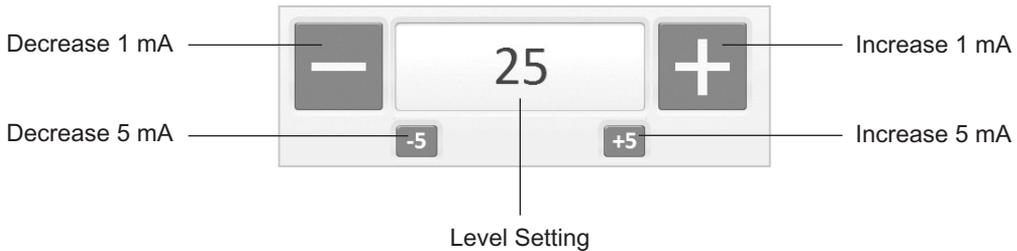

Figure 6-3: Intensity level bar

Program Bar

Used to add, delete and view up to eight clinician-set stimulation programs, labeled A-H. See Figure 6-4.

Figure 6-4: 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 system features eight programmable parameters and can store up to eight stimulation programs on the Clinician Programmer and E-EFC. Timing parameters are specified in Table 6-4. Burst parameters are specified in Table 6-5.

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	1-60 seconds, 1 second resolution (0 seconds = constant stimulation)
Ramp Up	Time to increase stimulation from zero to the set intensity	0-10 seconds, but not more than "On Time"/2, with 1 second resolution
Ramp Down	Time to 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 6-4: Timing parameters

Burst Parameter	Specification
Burst	Balanced biphasic
Intensity*	0 to 130 mA max and limited by Burst Duration and Burst Rate, 1 mA resolution
Maximum Voltage	130V
Maximum Output	16.8 mA (RMS)
Maximum Charge	32.5 microcoulombs per burst
Electrode Current Density	Less than 1.2 mA (RMS)/per cm^2
Burst Duration	100, 200, 300, 400, 500 µs
Typical Load	300 Ω in series with 30 nF
Burst Repetition Rate** **LED**	1, 2, 5, 10, 12, 15, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz Green light indication: • Constant when the battery is charged • 2Hz blinking at end of battery charge

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

Table 6-5: Burst parameters

Stimulation Mode

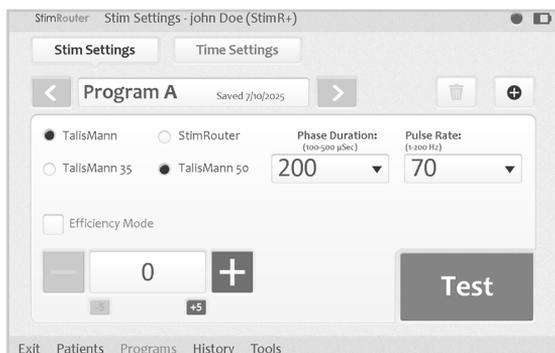Choose between TalisMann 35 and TalisMann 50.

Figure 6-6: TalisMann Stimulation Mode

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Clinician Programmer Set-Up

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

Connecting the Clinician Programmer

To connect the Clinician Programmer:

1. Insert the Clinician Programmer Charger into the Clinician Programmer charging port and plug the charger into a power socket. See Figure 7-1.
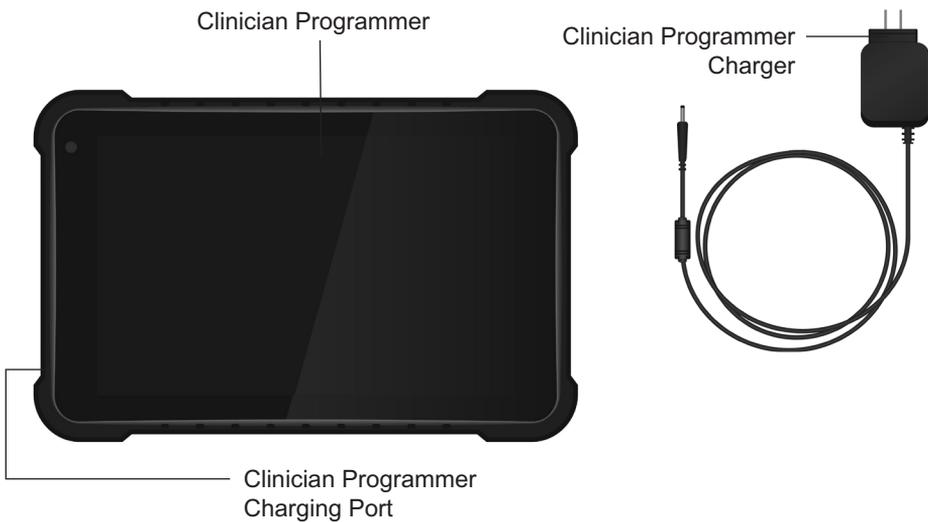

Clinician Programmer

Clinician Programmer Charger

Clinician Programmer Charging Port

Figure 7-1: The Clinician Programmer set-up

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

Logging into the Clinician Programming Software

To log into the Clinician Programming software:

1. Turn the Clinician Programmer on by pressing the on/off button on the upper left corner of the Clinician Programmer. A welcome screen is displayed (Figure 7.2)

Figure 7-2: The Clinician Programming Software Welcome Screen.

2. If the login screen does not open automatically, then, press "Start" and then "StimRouter Plus" to open the Clinician Programming software. Wait for the login screen to load.
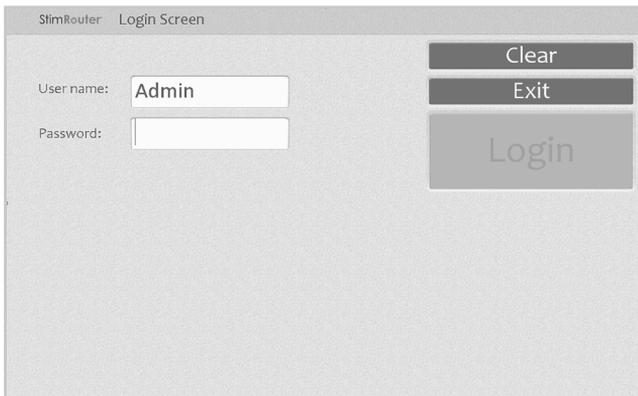

Figure 7-3: The Clinician Programming Software Login Screen

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 Programmer unattended.

Connecting E-EFC via Bluetooth

To connect an E-EFC via Bluetooth:

1. Open the Clinician Programming software on the Clinician Programmer and navigate to the Patient List screen.

2. Ensure the E-EFC is on, then simultaneously press and hold the Plus (+) and Minus (-) buttons on the E-EFC 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 E-EFC and Clinician Programmer will connect. See Figure 7-4.

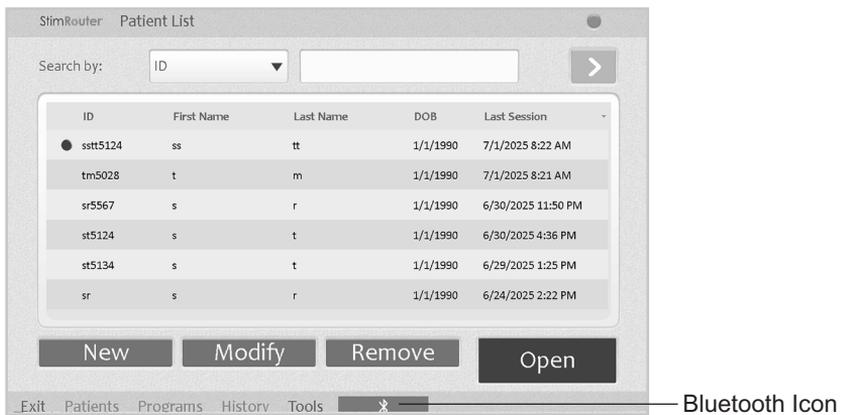4. For technical support, please contact Customer Service at 888-453-2136.

Figure 7-4: Bluetooth Icon on the Patient List screen.

8

Software Records and History

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 Programmer database and no data has been stored on the E-EFC. The patient is new and their system is unassigned.

To add a new patient to the Clinician Programmer database:

1. Connect the patient's E-EFC to the Clinician Programmer.

2. Connect the patient's E-EFC to a Gel Electrode. See "Connecting the Gel Electrode and E-EFC" section of this guide.

3. If the patient's E-EFC is unassigned, then the software should automatically prompt that no patient data was found on the system. Press the "OK" button. See Figure 8-1.
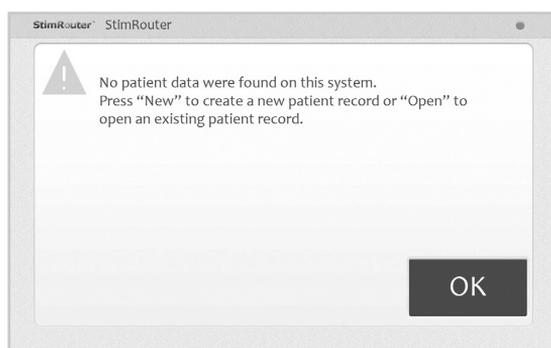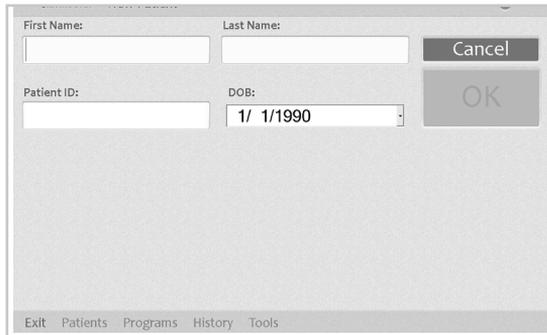

Figure 8-1: Unassigned system detected

4. If this prompt does not appear and the patient's components are new, then reset the patient's E-EFC. See "Resetting the Patient's E-EFC" section of this guide.

5. Press "New" to create a new patient record.

6. When the New Patient window opens, enter the patient's first and last names and a patient ID. See Figure 8-2.

Figure 8-2: New patient window

7. 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 Programmer database and no patient data has been stored on the connected E-EFC. 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 E-EFC to the Clinician Programmer.

2. Connect the patient's E-EFC to a Gel Electrode. See "Connecting the Gel Electrode and E-EFC" section of this guide.

3. If the E-EFC is unassigned, then the software should automatically prompt that no patient data was found on the system. Press "OK". See Figure 8-1.

4. 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 Programmer to the E-EFC.

Adding a Patient with an Assigned System

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

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

1. Connect the patient's E-EFC to the Clinician Programmer.

2. Connect the patient's E-EFC to a Gel Electrode. See "Connecting the Gel Electrode and E-EFC" section of this guide.

3. 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 8-3.

4. Proceed to the "Patient Set-Up and Programming Instructions" chapter of this guide.
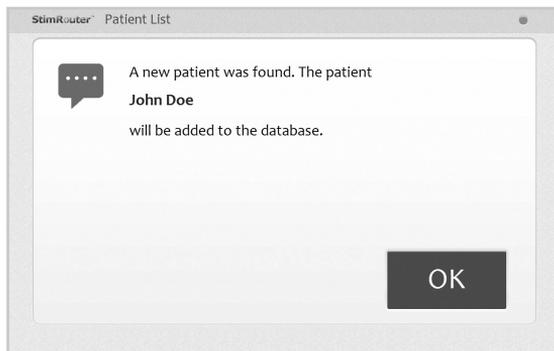
Figure 8-3: Adding a patient with an assigned system

Opening a Patient Record

Note: When the Clinician Programmer is in online mode and connected to an assigned E-EFC, then only the patient record corresponding to those components can be opened. If the Clinician 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 8-4.
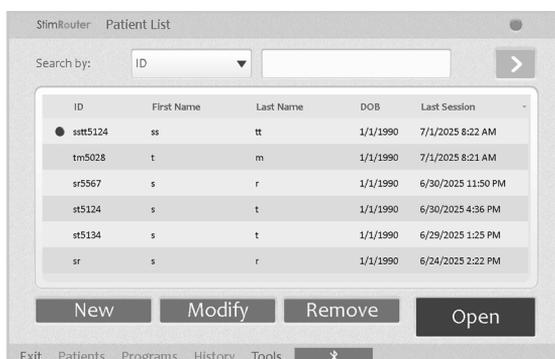
Figure 8-4: Opening a Patient Record

Modifying a Patient Record

Note: "Modify" is only enabled in online mode, when the Clinician Programmer is connected to a working E-EFC.

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 8-5.

Note: The Patient ID cannot be modified.
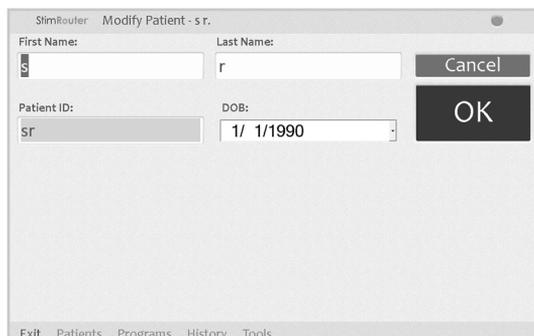
Figure 8-5: Modifying a Patient Record

Removing a Patient Record

To remove a patient record:

1. Make certain that the Clinician Programmer is not connected to an operational E-EFC.

2. From the Patient List select the patient record to remove, and then press the "Remove" button. See Figure 8-6.

3. Press the "Yes" button in the Remove Patient window.

Figure 8-6: Removing a Patient Record

Searching for a Patient Record

To search for a patient record:

1. Make certain that the Clinician Programmer is not connected to an operational E-EFC.

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 E-EFC.

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 E-EFC. Select Total to see the total stimulation time for all programs used during the designated time period.
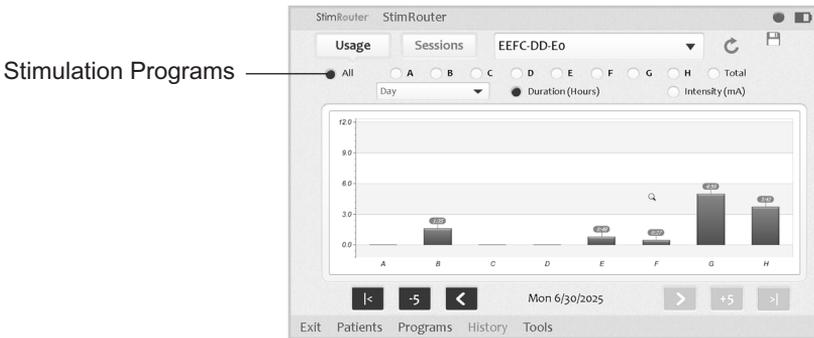
Figure 8-7: Select a Stimulation Program

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.
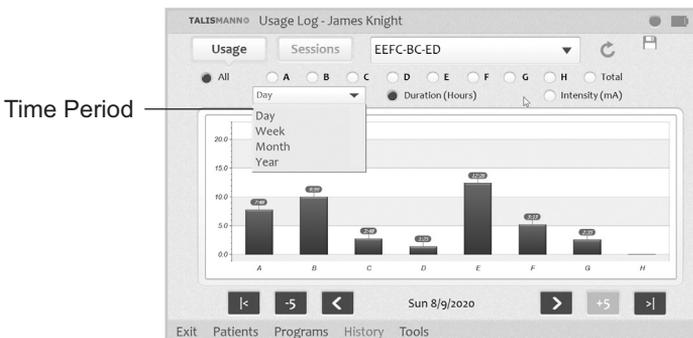
Figure 8-8: Select a Time Period

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.
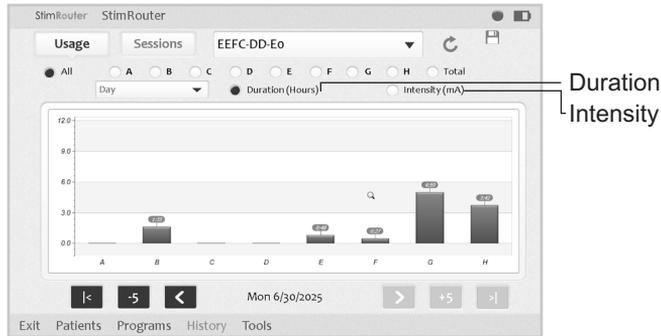
Figure 8-9: Select Duration or Intensity

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.
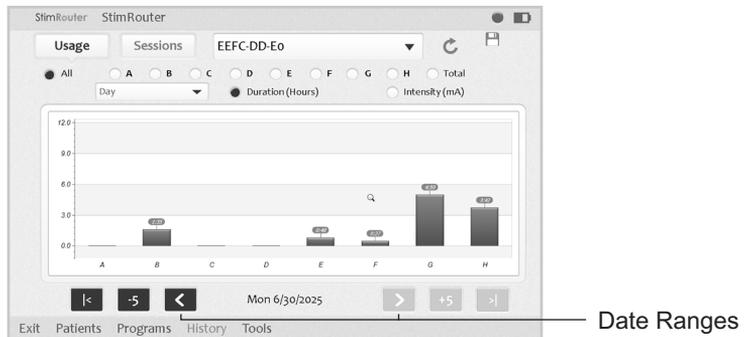
Figure 8-10: Change Date Ranges

View Sessions History

Use the Sessions button on the History tab to open a list of individual usage sessions for the connected E-EFC.

Figure 8-11: 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.
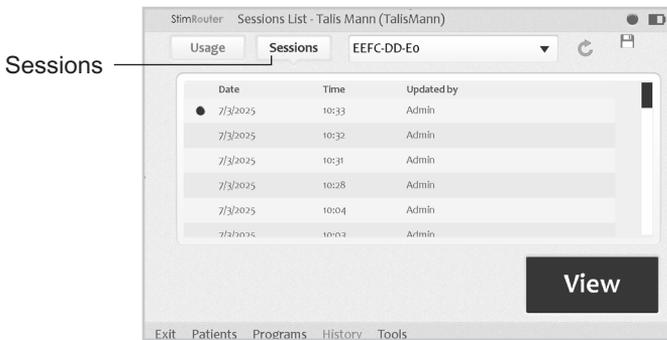
Figure 8-12: View individual session details

Save Usage Data

Use the Save icon to export the chosen usage data as a .CSV file.
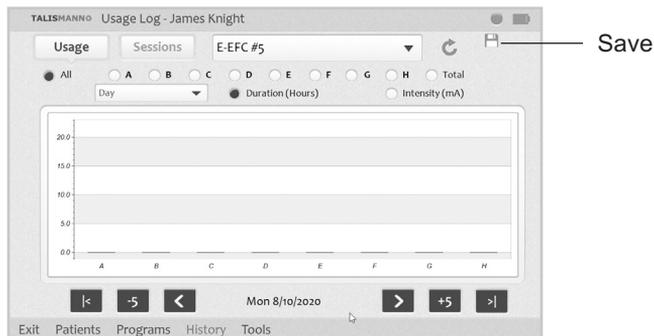
Figure 8-13: Save Usage Data.

9

Patient Set-Up and Programming Instructions

Preparing the Patient's 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. Do not shave with a razor in the area where the Gel Electrode will be placed because it can increase the risk of skin irritation. If necessary, remove excess body hair from the skin area using scissors or electric trimmers.

3. Always check the skin for redness or a rash.

Connecting the Gel Electrode and E-EFC

To connect the Gel Electrode and E-EFC:

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. Set the Gel Electrode on a flat surface with the gel pads facing down.

4. Snap the E-EFC onto the Gel Electrode. See Figure 9-1.
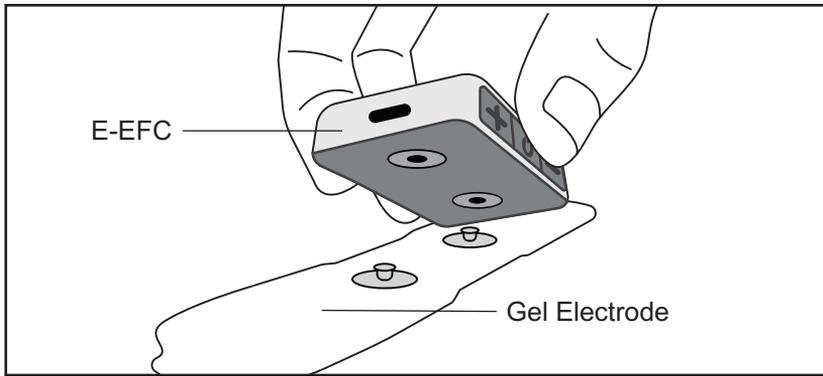
Figure 9-1: Gel Electrode and E-EFC connecting

Adhering the Gel Electrode to the Skin

⚠ **WARNING:** Do not touch the gel pads of the Gel Electrode with both hands while stimulation is turned on. Serious injury could result from electrical current passing across the chest cavity. Stimulation should be turned off before adhering, removing or handling the Gel Electrode.

To adhere the Gel Electrode:

1. Remove the liner and store it in the Gel Electrode Carrying Case. See Figure 9-2.
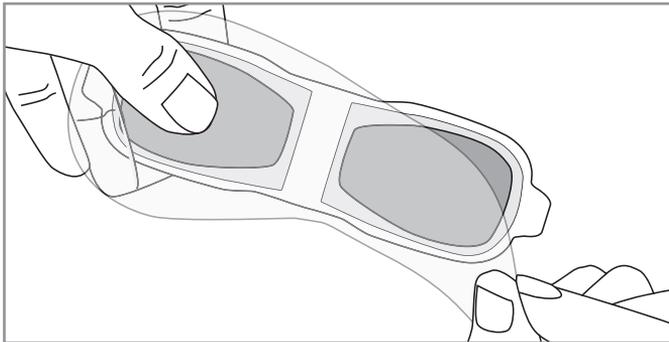
Figure 9-2: Remove the Gel Electrode Liner

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 E-EFC attached to the Gel Electrode so the gel pads face downward. See Figure 9-3.
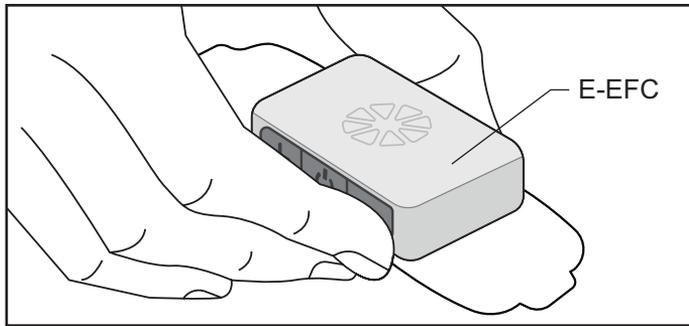
Figure 9-3: Grasp the edges of the E-EFC attached to the Gel electrode

4. There are two gel pads underneath the plus and minus buttons of the stimulator. The gel pad underneath the minus button should be placed on the skin above the TalisMann Pulse Generator and Receiver. See Figure 9- 4.
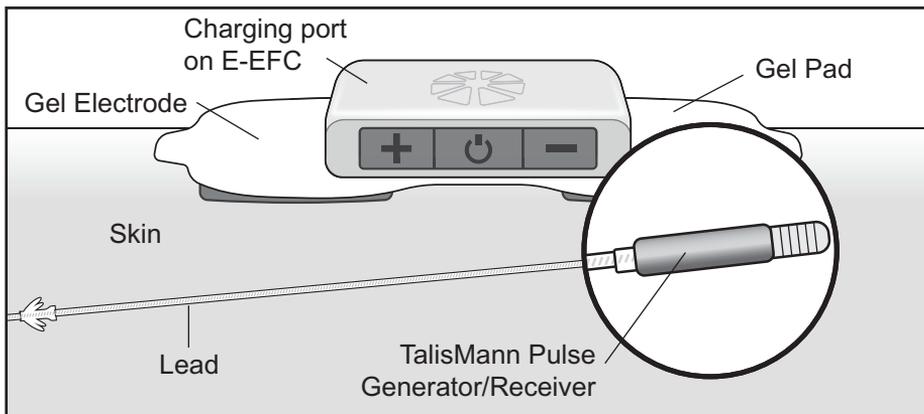
Figure 9-4: Optimal stimulation, position (Illustration not to scale)

Note: The effectiveness of the stimulation is sensitive to the alignment and rotation of the Gel electrode in relation to the receiver end of the lead. If the alignment of the Gel electrode changes, the stimulation intensity may need to be adjusted.

5. Position the other end of the Gel electrode where it will minimize discomfort and avoid muscle contractions.

⚠ **CAUTION:** Do not pinch or stretch the skin while adhering the Gel Electrode.

⚠ **CAUTION:** Make certain the adhesion site is free of obstructions (for example, bandages, clothing, etc.) before adhering the Gel Electrode. If the Gel Electrode is placed partially or wholly over a bandage or other obstruction, then skin irritation or tissue damage could occur during stimulation.

6. Firmly adhere the Gel Electrode to the skin, making sure that the electrode is in full contact with the skin. If the Gel Electrode is not firmly adhered to the skin and moves, then stimulation may become uncomfortable or ineffective.

7. Make certain that the Clinician Programmer is within 10 feet (3 meters) of the Gel Electrode with E-EFC attached.

Confirming Set-Up

If the Clinician Programmer, E-EFC, and Gel Electrode are connected correctly, the Clinician 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 E-EFC 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 E-EFC.

4. Test the E-EFC using the tester.

5. See the "Troubleshooting" section of this guide.

Refer to the TalisMann User's Guide for detailed operational instructions for the E-EFC and Gel Electrode.

Removing the Gel Electrode

To remove the Gel Electrode:

1. Make certain that stimulation is turned off. Then grasp the tab on the Gel Electrode and gently pull away from the skin. See Figure 9-5.

Figure 9-5: Removing the Gel Electrode

Tab
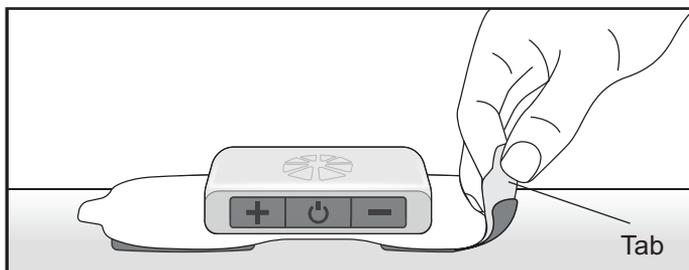
2. Attach the Gel Electrode liner to the gel pads. Without the liner attached, the gel pads on the back of the Gel Electrode will lose their adhesiveness.

3. Store the Gel Electrode with the liner attached in the Gel Electrode carrying case.

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.

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 9-6. Ensure TalisMann is selected. Choose TalisMann 35 or TalisMann 50.

Figure 9-6: 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 Programmer and E-EFC. See Figure 9-7.
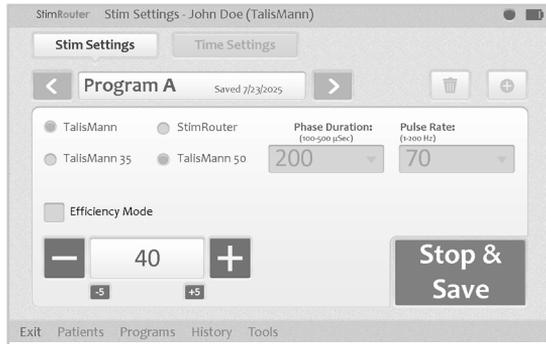
Figure 9-7: Press "Stop & Save" to stop testing and save the current stimulation settings

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 9-8. 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.
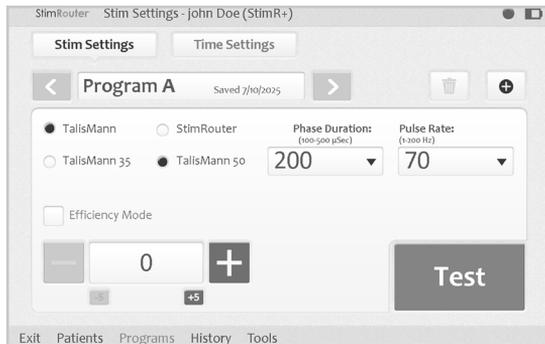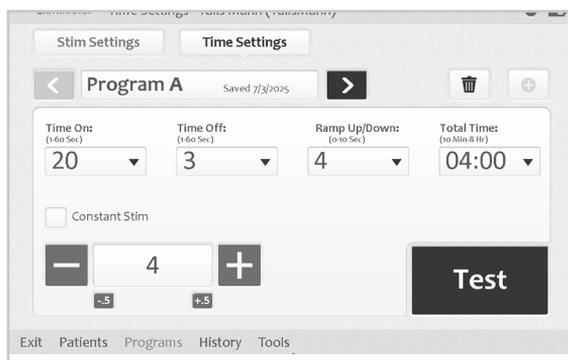

Figure 9-8: Time Settings window

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 Programmer and E-EFC.

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

Programs
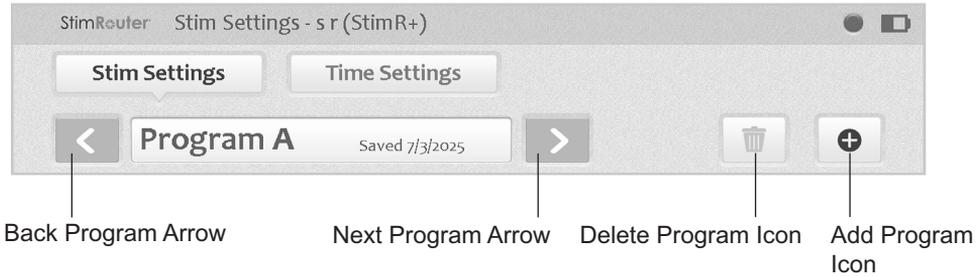
Figure 9-9: Program icons on the program bar

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 9-9.

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 Programmer database, and the E-EFC.

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 9-10.

10

Software Tools

Resetting the E-EFC

System information can be found on the Info Tab of the Tools Menu. From the Info Tab users can look up the installed software version on all components of the TalisMann system. For example, "E-EFC SW VER: 1.0.0.4" indicates to the user that the E-EFC software version is 1.0.4.

Reset the E-EFC from the CPS:

1. Connect the E-EFC to the Clinician Programmer.

2. Press "Tools" on the Menu Bar, then press the Stimulator Tab. See Figure 10-1.
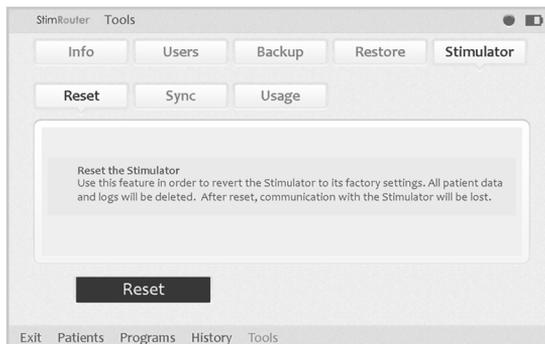
Figure 10-1: Resetting the Patient Programmer and E-EFC

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

Restart the E-EFC from the E-EFC Buttons:

1. Press and hold the power button on the E-EFC 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 Programmer database, manually restore the Clinician 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 10-2.

2. Enter a user name and password, confirm the password, select either "Users" or "Administrators" from the "Group" drop-down list, and then press the "Add" button. See Figure 10-3.
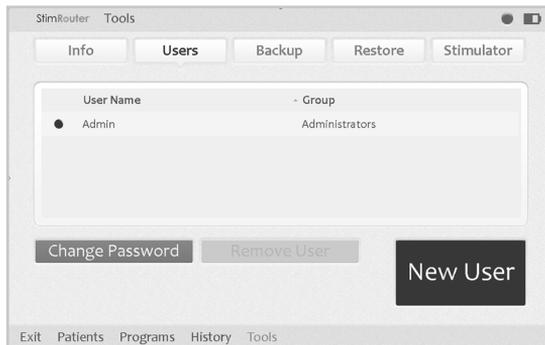
Figure 10-2: Adding a user/administrator
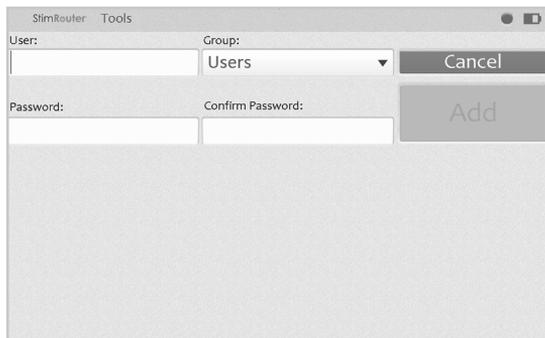
Figure 10-3: Add new user window

Removing a User/Administrator

To remove a user/administrator:

1. Press "Tools" on the Menu Bar, press the Users Tab, select a user name, and then press the "Remove User" button. Confirm "Yes" or "No" when prompted. See Figure 10-4.

Note: The administrator who is logged on cannot be removed.
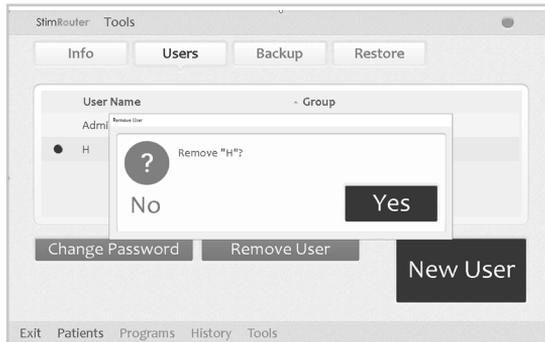
Figure 10-4: Removing a user

Changing a User Password

To change a user password:

1. Press "Tools" on the Menu Bar, press the Users Tab, select a user name, 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 Programmer Database Backup and Restore

Administrators can back up the Clinician 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 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 Programmer database will back up once daily and each time the software is exited. See Figure 10-5.
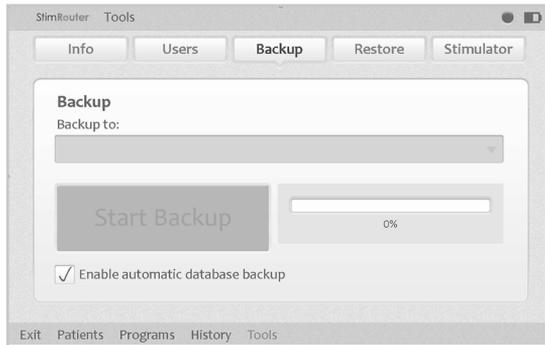
Figure 10-5: Backing up the Clinician Programmer database

Manually Backing Up the Database

To manually back up the Clinician 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 10-5.

Restoring the Database

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

To restore the Clinician Programmer database:

1. Insert the memory card with the backup files into Clinician 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 10-6.
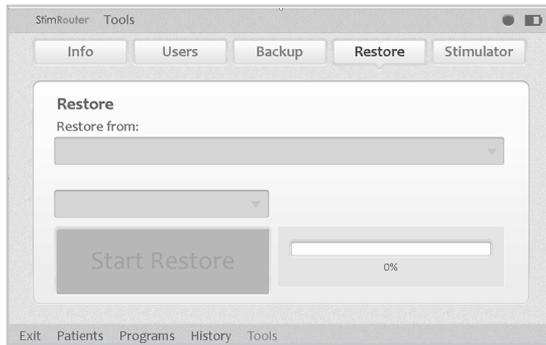
Figure 10-6: Restoring the Clinician Programmer database

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.

11

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

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

Disinfecting

Electronic Components

All Clinician Kit electronic components may be cleaned and low-level disinfected using CaviWipes™ or equivalent (if available), or wipes or cloths saturated (but not dripping) with 70% isopropyl alcohol (IPA).

Note: Do not attempt to disinfect the Gel Electrode. If infection is a concern, discard the Gel Electrode and use a new electrode.

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

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Troubleshooting

The tables at the end of this section describe the visual indicators that may appear on the Clinician 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 E-EFC.
- The patient brings a new E-EFC.

Patient Forgets E-EFC

If a patient forgets to bring his or her E-EFC to a follow-up session, reschedule the programming session. Do not substitute a clinic E-EFC for the patient's E-EFC.

Patient Loses E-EFC

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

Patient Brings New E-EFC and New Patient Programmer

If a patient receives a replacement E-EFC, then the patient will need to return to the clinic to have their TalisMann system reprogrammed. The patient data stored on the Clinician Programmer database must be copied to the new E-EFC.

Copying Patient Data to New Components

To copy patient data to new components:

1. Make sure the patient's E-EFC is charged.

2. Make sure the Clinician Programmer and the E-EFC are no more than a few inches apart and not touching.

3. The Clinician Programming software will detect the unregistered E-EFC and ask if you want to register this E-EFC now.

4. Press "Yes".

5. Once the E-EFC 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 E-EFC.

Troubleshooting Tables

Clinician 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: E-EFC or Patient Programmer** • Press the information icon to view error message and list of solutions. • Charge the E-EFC.
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 Programmer Will Not Turn On	• Charge the Clinician Programmer and verify that the charging LED is ON. • Contact Customer Service or your local distributor.

Table 12-1: Troubleshooting - Clinician Programmer

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 Customer Service at 888-453-2136.

E-EFC and Stimulation	Solutions
Stimulation Not As Effective As Usual	• Check the position of the Gel Electrode, it should be over the receiver end of the lead. • Make sure the Gel Electrode is securely adhered to the skin. • Visually inspect the Gel Electrode to make sure the gel pads are smooth and not dry. • Review the skin care instructions. Clean the skin with a damp cloth. • Change the Gel Electrode, if the skin is dry. • Trim hair from the Gel Electrode site.
Undesirable Motor Response	• Decrease the stimulation intensity level. • Check the placement of the Gel Electrode.
E-EFC Charging Light Does Not Turn On	• Check the connection. • Check the USB C cable (disconnect it and connect charger directly). • Check that the charger light turns on. • Contact Customer Service or your local distributor.

Table 12-2: Troubleshooting, E-EFC and stimulation

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Technical Specifications

E-EFC Charger Specifications

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

Manufacturer's Model No.	FRIWO FW7555M/05
Input	
Voltage	100-240 volts AC
Current	400 mA
Frequency	50-60 hertz
Output	
Voltage	5 V ± 5%
Current	2400 mA
Charging Cable	1 meter long USB A to USB C

E-EFC 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 310mAh capacity
Dimensions	**Length** 57 mm (2.25 in.) **Width** 33 mm (1.3 in.) **Height** 11.5 mm (0.45 in.)
Weight	28g (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: 50kPa 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	IP68 per IEC 529
FCC ID #	RYYEYSHSN
Burst Parameters	
Burst	Balanced biphasic
Burst Waveform	E-EFC - symmetric
Intensity*	0-130mA peak, 1mA resolution (positive phase)
Maximum Voltage	130 V
Maximum Output	16.8mA (RMS)
Maximum Charge	32.5 microcoulombs per burst
Electrode Current Density	1.2mA RMS / cm^2
Burst Duration	100, 200, 300, 400, 500 µs
Typical Load	2700 Ω in parallel to 22 nF
Burst 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 - 12 hours
Conformity Certification	The 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, and 2. This device must accept any interference received, including interference that may cause undesired operation.

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

Gel Electrode Specifications

Electrode Size	7.5 cm² each
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 TalisMann 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 TalisMann System was designed and tested to have a response rate of 10-100ms latency.

- **Wireless Interference:** The TalisMann System was designed and tested to not have interference from other RF devices (including other TalisMann Systems, WiFi networks, Cellular Devices, Microwaves and other Bluetooth® devices).

TalisMann 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 TalisMann System is affected by other equipment, the user should turn the TalisMann 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.

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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.

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Appendix - EMI Tables

Electromagnetic Emissions

The TalisMann 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 TalisMann 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 TalisMann system and all other electronic devices. If interference is suspected or anticipated, distance yourself from the source of interference

Guidance and Manufacturer's Declaration Electromagnetic Emissions

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

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

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The TalisMann 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 MAPP, E-EFC and clinician programmer, could affect medical electrical equipment.
RF emissions CISPR 11	Class B	The RF-enabled components of the TalisMann 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 TalisMann system is intended for home use in addition to use in the electromagnetic environment specified below. The user of the TalisMann 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	±8 kV contact ±15 kV air	±8 kV contact ±15 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	±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	Mains power quality should be that of a typical commercial or hospital environment. The TalisMann system continues operation during power mains interruptions, as it is normally powered by each component battery.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
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 TalisMann system is intended for home use in addition to use in the electromagnetic environment specified below. The customer or the user of the TalisMann 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 Vrms 150 kHz to 80 MHz	Recommended separation distance (d) $d = 1.2\sqrt{P}$

⚠ **WARNING:** Portable and mobile RF communications equipment should be used no closer to any part of the TalisMann system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Otherwise, degradation of the perform

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
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

[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 TalisMann system is used exceeds the applicable RF compliance level above, the TalisMann system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TalisMann 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 TalisMann System

The TalisMann system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TalisMann system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TalisMann 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 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.

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