StimRouter™
Neuromodulation System

Clinician's Guide

DRAFT

Bioness®

Bioness®

Worldwide Corporate Office
Bioness Inc
25103 Rye Canyon Loop
Valencia, CA 91355 USA
Telephone: 800.211.9136
Email: info@bioness.com
Website: www.bioness.com

Manufactured by
Bioness Neuromodulation Ltd.
19 Ha'Haroshet Street
PO Box 2500
Industrial Zone
Ra'Anana 43654, Israel

EC REP
European Authorized Representative
NESS Europe B.V.
Stationsweg 41
3331 LR Zwijndrecht, The Netherlands
Telephone: +31.78.625.6088
Email: international@nl.bioness.com
Website: www.bioness.com

Rx Only

612-00578-001 Rev. A

StimRouter™

Neuromodulation System

Clinician's Guide

DRAFT

Rx Only

Bioness®

Guarantees
Bioness Inc reserves the right to modify, without prior notice, information relating to its products to improve their reliability or operating capacity.

Registered Trademarks
StimRouter™, Bioness, the Bioness Logo® and LiveOn® are trademarks of Bioness Inc. in the United States or other countries.| www.bioness.com

Patents Pending
This device is protected under one or more of the following U.S. Patents: U.S. Pat. No. 7,502,652. U.S. and foreign patents pending.

Disclaimer
Bioness Inc shall not be liable for any injury or damage suffered by any person, either directly or indirectly, as a result of the unauthorized use or repair of Bioness Inc products. Bioness does not accept any responsibility for any damage caused to its products, either directly or indirectly, as a result of use and/or repair by unauthorized personnel.

Environmental Policy
Service personnel are advised that when changing any part of the StimRouter 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 StimRouter 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 Bioness Inc. Bioness is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

Bioness®

Worldwide Corporate Office
Bioness Inc
25103 Rye Canyon Loop
Valencia, CA 91355 USA
Telephone: 800.211.9136
Email: info@bioness.com
Website: www.bioness.com

EC REP

European Authorized Representative
NESS Europe B.V.
Stationsweg 41
3331 LR Zwijndrecht, The Netherlands
Telephone: +31.78.625.6088
Email: international@nl.bioness.com
Website: www.bioness.com

Manufactured by
Bioness Neuromodulation Ltd.
19 Ha'Haroshet Street
PO Box 2500
Industrial Zone
Ra'Anana 43654, Israel

Conformity Certification

C ETL US LISTED
Intertek
3106069

List of Symbols

	Caution or Warning
	Double Insulated (Equivalent to Class II of IEC 536)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This Product Must Not Be Disposed of with Other Household Waste
	Consult Instructions for Use
REF	Re-Order Number
LOT	Lot Number
SN	Serial Number
	Complies with United States and Canadian Product Safety Standards
	Single Patient Use
	Storage Temperature
CE 0473	Complies with the European Union Medical Device Directive
	Quantity

Table of Contents

1

Introduction

The Bioness StimRouter Neuromodulation System consists of the following components and accessories:

- An implantable multi-electrode lead with integrated receiver in loader.
- Surgical tools for implantation of the StimRouter lead.
- An external programming system with a clinician programmer, a clinician programmer cradle and charger, a tester and accessories.
- A patient-operated system with a rechargeable EPT, an external patient programmer, a system charger and accessories.
- Disposable StimRouter electrodes.

This guide describes the external programming components of the StimRouter Neuromodulation System, which are provided in the StimRouter Clinician Kit.

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

Refer to the StimRouter User's Guide for a description of the StimRouter User Kit, including the StimRouter electrode, EPT, patient programmer, external accessories, package contents, device specifications and instructions for use.

2

Warnings and Cautions

Clinicians and patients should know the limitations, warnings and precautions associated with the StimRouter Neuromodulation System. Clinicians should review the warnings and precautions and instructions for use with the patient. If at any time the clinician or patient is concerned about the safety or effectiveness of the StimRouter system, then call your local distributor.

The StimRouter programming system and patient-operated system should only be used under proper medical guidance and as described in this StimRouter Clinician's Guide and in the StimRouter User's Guide.

Indications for Use

The Bioness StimRouter Neuromodulation System is intended to provide electrical stimulation via an implanted lead to a target peripheral nerve, for aid in the management of adults that have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g. medications). The StimRouter is not intended to treat pain in the craniofacial region.

Contraindications

The Bioness StimRouter Neuromodulation System is contraindicated for:

- Patients who have any active implanted device such as an implanted demand cardiac pacemaker or defibrillator, or any metallic implant in the immediate area intended for implant. Maintain a minimum safe separation distance of 15 cm (6 in.) between the SimRouter system and all other active implanted devices and metallic implants.

A risk/benefit determination should be performed before using the StimRouter system for:

- Patients exposed to diathermy. Shortwave, microwave and/or therapeutic ultrasound diathermy should not be used on patients who have a StimRouter Neuromodulation System. The energy generated by diathermy can be transferred through the StimRouter system components, causing tissue damage at the lead site and potentially resulting in severe injury. Diathermy may also damage the StimRouter 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.
- Patients who are unable to operate the StimRouter system.
- Patient who are high surgical risks or poor surgical candidates in general.
- Patients who have a cancerous lesion present near the target stimulation point or near to where the StimRouter electrode will adhere.
- Patients who are known or suspected to have a nickel allergy. The handles of the tunneling needle and tunneling needle stylet are nickel plated.
- Patients with bleeding disorders or active anticoagulation that cannot be stopped for a few days close to the time of the surgical procedure.

Implantation Setting

The StimRouter should be implanted in an appropriately outfitted physician office, outpatient surgical center or hospital surgical center. Fluoroscopy and/or ultrasound should be available if deemed necessary and be used at the implanting physician's discretion.

Patient Screening

Candidates for StimRouter therapy should be appropriately screened for selection and fully informed about the therapy risks and benefits, the surgical procedure, system operation and self-treatment responsibilities.

Select patients carefully to ensure that:

- Their symptoms are of an anatomical and/or physiological origin.
- They are appropriate candidates for surgery.
- They can properly operate the StimRouter system.

Bioness highly recommends the following screening procedure prior to StimRouter lead implantation:

- Nerve block using local anesthesia.
- Psychological screening using techniques traditionally used for similar types of procedures and systems.

Bioness recommends the following optional screening procedure prior to StimRouter lead implantation:

- Transcutaneous electrical nerve stimulation (TENS) to determine the patient's tolerance of stimulation near the anticipated site for the StimRouter electrode. Please note that some individuals are very sensitive to the sensation to electrical stimulation applied to the skin.

Warnings

Magnetic Resonance Imaging

MRI Warnings and Precautions

- Do not scan patients with a specific absorption rate (SAR) level exceeding 2 W/kg. A scan above 2 W/kg may increase the risk of MR-related heating.
- Do not place a local RF transmit coil directly over the Bioness implanted lead.
- The entire Bioness implanted lead must always be outside the MR coil and must not be exposed to any radio frequency field.

StimRouter External Component Restrictions

All external components of the StimRouter system are contraindicated for the MRI environment. Therefore, the StimRouter electrode, external pulse transmitter and patient programmer must be removed before the patient is allowed into the MRI environment.

MRI Information

Non-clinical testing has demonstrated that the StimRouter lead is MR Conditional. Patients with an implanted StimRouter lead can be scanned safely, immediately after implantation, on MRI cylindrical bore systems that meet the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3 T.
- Highest spatial magnetic gradient of 2500 gauss/cm or less.
- MR system reported, whole-body-averaged SAR does not exceed 2 W/kg at 1.5 T and 2 W/kg at 3 T.
- Do not scan patients with a SAR level exceeding 2 W/kg. A scan above 2 W/kg may increase the risk of MR-related heating.
- The entire StimRouter lead must be at least 50 cm from the center of the MR system's bore (the iso-center of the bore) and at least 16 cm outside of the MR coil measured from the edge of the MR coil, to ensure patient safety relative to MRI-related heating. See Figure 2-1.

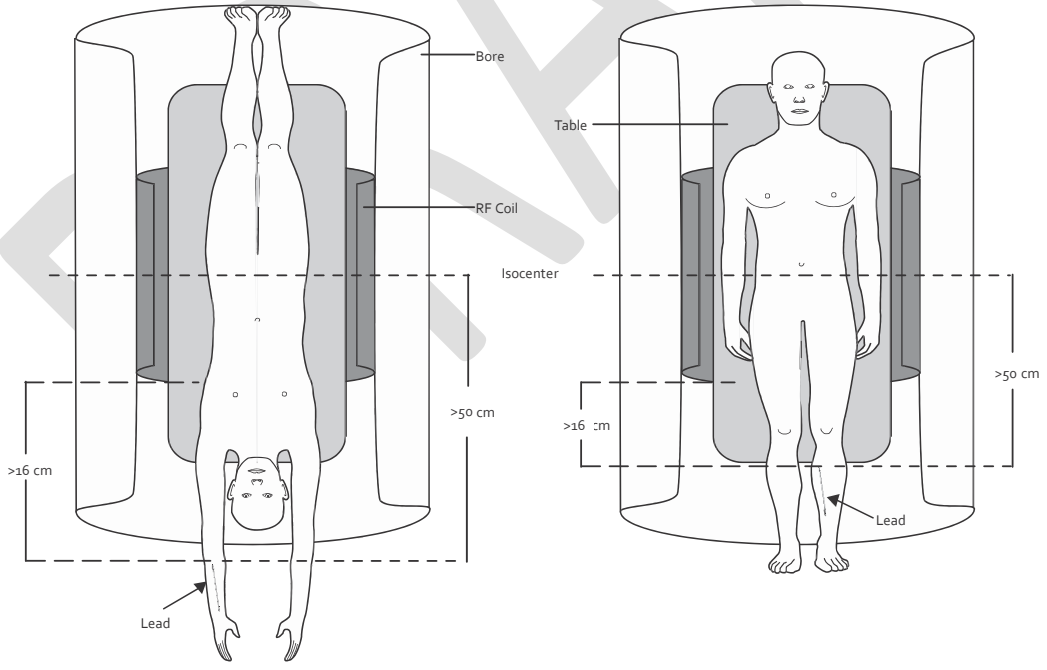


Figure 2-1. The entire StimRouter lead must be at least 50 cm from the center of the MR system's bore (the iso-center) and at least 16 cm outside of the MR coil measured from the edge of the MR coil. Left: lead implanted in the forearm. Right: Lead implanted in the lower leg.

- Communication is maintained with the patient so that the scan can be promptly terminated in the event of painful nerve stimulation or other adverse event.

Information regarding the position of the lead is necessary for routine MRI procedures. Review of the patient's Medical Device Identification Card, direct communication with the implanting physician or obtaining an x-ray is recommended to determine the location of the implanted lead.

Patients must be screened for previously implanted (active or abandoned) medical devices, leads, lead extenders or lead adapters.

MRI-Related Heating: Supplemental Information

1.5 T/64 MHz

Temperature changes of the electrodes of the StimRouter lead were measured at 1.5 T/64 MHz according to ASTM F2182 (GE Signa, 46- 258170G1, whole body transmit radio frequency (RF) coil). With the lead in an orientation and a position in the phantom to produce worst-case heating, the greatest measured temperature rise scaled to a background local SAR of 1 W/kg was 3.9°C after six minutes of RF power application. This temperature change was with the lead in an elongated, "straight" configuration (i.e., no curves), which produced the highest temperature change. With the lead in curved or looped configurations, temperature changes were less.

A computer simulation that incorporated the worst-case measured rise and a whole-body-averaged SAR of 2 W/kg predicts a worst case in the patient during MRI of less than 2°C provided that the entire StimRouter lead is at least 50 cm from the center of the bore of the MR system and at least 16 cm outside of the MR coil measured from the edge of the MR coil.

3 T/128 MHz

Temperature changes of the electrodes of the StimRouter lead were measured at 3 T/128 MHz according to ASTM F2182 (GE Signa, 3T HDx, Software Version 15/LX/MR, 15.0.M4.0910a). With the lead in an orientation and a position in the phantom to produce worst-case heating, the greatest measured temperature rise scaled to a local background SAR of 2 W/kg was 2.9°C after six minutes of RF power application. This temperature change was with the lead in an elongated, "straight" configuration (i.e., no curves), which produced the highest temperature change. With the lead in curved or looped configurations, temperature changes were less.

A computer simulation that incorporated the worst-case measured rise and a whole-body-averaged SAR of 2 W/kg predicts a worst case in the patient during MRI of less than 1°C provided that the entire StimRouter lead is at least 50 cm from the center of the bore of the MR system and at least 16 cm outside of the MR coil measured from the edge of the MR coil.

Image Artifacts

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the StimRouter lead. Therefore, optimization of MR imaging parameters to compensate for the presence of the StimRouter lead may be necessary.

Induced Currents

The electric fields induced in the patient with the StimRouter lead by the pulsed gradient fields were calculated. The induced current will be less than the stimulation threshold if the StimRouter lead is at least 50 cm from the center of the bore and at least 16 cm outside of the MR coil measured from the edge of the MR coil.

Potential Adverse Events

Use of MRI could result in excessive heating of the lead if the MRI conditions of use are not followed. Induced voltages in the lead may occur, possibly causing uncomfortable levels of neurostimulation.

Note: The StimRouter lead is not a life-sustaining device and could be explanted prior to an MRI procedure.

Pregnancy

The effects of electrical stimulation on pregnancy are unknown. Patients should avoid exposure to electrical stimulation for the entire duration of pregnancy.

Long-Term Effectiveness of Neurostimulation

The long-term effectiveness of neurostimulation is unknown.

Programming

The StimRouter components should only be programmed by the treating clinician and/or under proper medical guidance.

Device Components

The use of non-Bioness components with the StimRouter system may result in damage to the system and increased risk to the patient.

Flammable Fuel or Chemicals

Advise patients to turn the StimRouter system (patient programmer and stimulation) off when near a refueling point, flammable fuel, fumes or chemicals. The operation of the StimRouter could cause the chemicals or fumes to ignite, causing severe burns, injury or death.

Driving and Operating Machinery

StimRouter stimulation should be off while driving and operating machinery.

Electromagnetic Compatibility Warnings

Medical Devices/Therapies

The following medical therapies or procedures may turn stimulation off, may cause permanent damage to the external components and may injure the patient, particularly if used in close proximity 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 StimRouter system:
- Computerized Axial Tomography (CT or CAT) scans
- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy

Note: Advise patients to remove the StimRouter electrode before undergoing medical therapies or procedures.

Electrosurgery Devices

Electrosurgery devices should not be used in close proximity to an implanted StimRouter lead. Contact between an active electrode of the electrosurgery device and the implanted lead can cause direct stimulation of the target stimulation point and severe injury to the patient.

High-Frequency Surgical Equipment

Simultaneous connection of a patient to the StimRouter components and high-frequency surgical equipment may result in skin burns where the gel electrodes adhere to the skin and may damage the StimRouter EPT. Advise patients to remove the StimRouter electrode before medical treatment.

Body-Worn Devices

Although unlikely, body-worn medical devices may interfere with the RF communication used in the StimRouter system. Stimulation control may be delayed. Examples of a body-worn device are an insulin pump and a monitoring device. The patient programmer will emit visual alerts if interference occurs. To minimize interference, maintain a minimum safe separation distance of 15 cm (6 in.) between the SimRouter system and all other electronic devices. See the Troubleshooting section for help. See the Appendix for more information.

The StimRouter system 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 StimRouter system.
- Pass through the 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 StimRouter system and all other electronic devices.

Precautions

Clinician Training

Bioness requires that clinicians involved with the use of the StimRouter system be formally trained by Bioness in the system's operation and use.

Post-Operative Care

Clinicians should adequately observe the incision site and monitor for infection, possible device rejection or other possible adverse effects. If the patient notices excessive redness or discharge around the incision site, then the implant physician should be contacted immediately to check for infection and administer proper treatment following standard medical procedures.

Implant Location

Advise patients to never manipulate the StimRouter lead. If the lead is moved from the target stimulation point, then it may not function correctly or effectively. In some instances a lead can move from its original location, thus causing a loss of stimulation at the target stimulation point. If the lead moves, then the lead may need to be replaced.

For Single Patient Use Only

The StimRouter electrode is meant to be worn only by the patient for whom it is prescribed and in the location for which it is prescribed. The StimRouter electrode should not be adhered to any other person or any other place on the patient's body.

Postural Changes

Changes in posture or abrupt movements may decrease or increase the perceived level of stimulation. Advise patients to turn off stimulation before making extreme posture changes or abrupt movements such as stretching, lifting of arms overhead or exercising.

Keep out of Reach of Children

The StimRouter components should be kept out of the reach of children.

Skin Abnormalities

Do not adhere the StimRouter electrode to sites that are swollen, infected or inflamed, or that have skin eruptions such as phlebitis, thrombophlebitis and varicose veins. Do not adhere the StimRouter electrode to skin that is breached.

Skin Irritation

It is normal for the skin under the StimRouter electrode to become red. The redness should disappear in approximately one hour once the user patch is removed. However, some patients may experience skin irritation, an allergic reaction, or hypersensitivity to the electrical stimulation or the gel electrodes. Persistent redness, lesions or blisters are signs of irritation. Use of the StimRouter components should be temporarily halted until the irritation is resolved. In some cases, irritation can be avoided by removing the StimRouter electrode periodically to allow the skin to breathe and changing the stimulation parameters. Patients should consult their clinician if irritation persists.

Known or Suspected Heart Problems

Use caution when treating patients with suspected or diagnosed heart problems.

StimRouter Electrode Placement and Stimulation

- Electrical stimulation should not be applied trans-thoracically or at the heart such that current may travel into or through the cardiac tissue, as such introduction of electrical current may cause heart rhythm disturbances.
- Turn off stimulation before adhering, removing or handling the StimRouter electrode.
- StimRouter electrode placement and stimulation settings should be determined by the implanting physician and/or treating clinician.
- Do not apply the StimRouter electrode over any obstruction that would reduce the designated electrode surface area (for example, an adhesive bandage). A smaller electrode surface area could result in serious injury to the patient.
- Do not apply the StimRouter electrode over skin folds, scarred tissue, irritated skin, uneven skin surfaces or broken skin.

- Always inspect the gel electrodes before use. Do not apply the StimRouter electrode if the gel electrodes appear dried out, worn, dirty or irregular.
- Make sure the gel electrode liners are removed before applying the user patch.
- Do not handle the StimRouter electrode with both hands while stimulation is on; serious injury can result from current passing through the cardiac tissues.

Expiration Date

Do not use a StimRouter electrode with a “Use by” date that has expired.

Implant Failure

Leads may fail at any time because of random component failure or lead breakage. If component failure or lead breakage occurs, then the lead may need to be replaced.

Storage and Handling

All StimRouter components and accessories should be handled with care. Components and accessories should not be dropped. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the components on hard surfaces, or other rough handling, can permanently damage the components.

Refer to the HP product literature included in the Clinician Kit for storage temperatures for the Hewlett Packard iPAQ 210 Enterprise Handheld.

Tester Storage Temperature Range: -20°C to +60°C.

Adverse Effects

In the unlikely event that any of the following occurs, patients should stop using their StimRouter components, remove the StimRouter electrode and immediately consult their clinician or their implant physician.

Risks Related to the Implant Procedure

Suboptimal lead placement may necessitate therapeutic adjustment and/or lead explant. Nerve injury is possible, although unlikely. Possible surgical complications include infection, cellulitis, abscess, fever, sepsis, bleeding and temporary pain at the implant site.

Risks Related to Stimulation

- Operation of the StimRouter components may cause increased pain in an area other than the lead site. This pain may be caused by stimulation of the tissue surrounding the stimulation electrodes (e.g., skin, fascia and muscle).
- Patients may also experience an undesirable motor response during stimulation.

If patients experience any pain or discomfort during stimulation, or notice any skin abnormalities, they should stop stimulation immediately, remove the StimRouter electrode and contact their clinician.

Additional Risks Related to the StimRouter System

- Migration of the lead may cause changes in stimulation effectiveness.
- While very unlikely, a tissue reaction to any of the implanted materials may occur.
- External electromagnetic interference may cause the StimRouter components to malfunction and may affect stimulation.
- Patients may experience persistent pain at the implant site of the lead.
- Although rare, the skin overlying the lead may erode.
- Portable and mobile radio frequency communications equipment can affect medical electrical equipment.
- The StimRouter external components could overheat if the components fail, which could cause burning.

If patients experience any pain or discomfort during stimulation, or notice any skin abnormalities, they should stop stimulation immediately, cease contact with the StimRouter components and notify their clinician.

3

Environmental Conditions that Affect Use

Storage and Handling

All StimRouter components should be kept dry and protected from extreme changes in temperature and humidity. Do not use or store components where they could come in contact with water, such as by sinks, bathtubs and shower stalls. Do not expose components to weather conditions such as rain or snow, or to any other source of water.

Do not store StimRouter components in a car or elsewhere where hot or cold temperatures could exceed the acceptable ranges of the components. Temperature extremes can damage the StimRouter components.

To avoid condensation when transporting StimRouter components from hot to cold temperatures, place the components in an air-tight plastic bag first. Let them adjust slowly (for at least two hours) to the change in temperature before use.

Radio Communication Information

Several components of the StimRouter 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 located near to or operating in conjunction with any other antenna or transmitter.

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

Conformity Certification

The StimRouter 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.

4

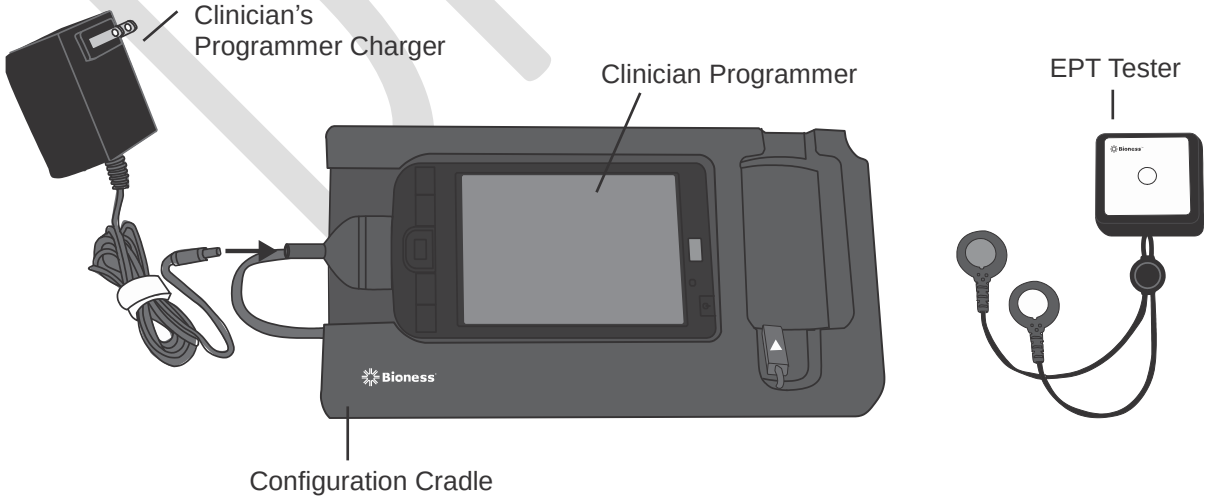
StimRouter Clinician Kit

Description

The StimRouter Clinician Kit contains the clinician programming components of the StimRouter Neuromodulation System, used to program the StimRouter EPT and Patient Programmer.

Your StimRouter Clinician Kit includes the following:

- Clinician Programmer with Software
- Clinician Programmer Memory Card
- Clinician's Programmer Charger
- Configuration Cradle
- Tester
- Clinician's Reference Card
- HP product literature



5

Device Description

Clinician Programmer with Software

The StimRouter clinician programmer is used to program, test and save stimulation parameters and programs on the StimRouter EPT and patient programmer. See Figure 5-1. All stimulation parameters and programs are stored on the clinician programmer as well.

When connected to the StimRouter clinician programmer cradle and patient programmer, the clinician programmer can wirelessly communicate with the EPT.

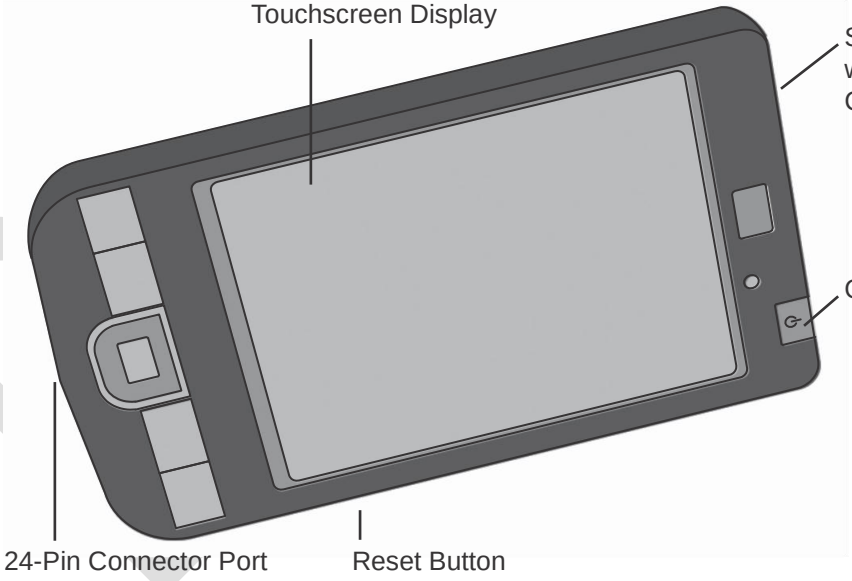


Figure 5-1. The StimRouter clinician programmer.

The clinician programmer is portable and comes with the StimRouter software installed, a memory (SD) card installed, a rechargeable Lithium- Ion battery installed and a clinician programmer charger.

⚠ **WARNING:** The clinician programmer should only contain the installed Windows Mobile® operating system and Bioness Inc proprietary StimRouter software. Do not use the clinician programmer for any purpose other than that described in this manual. Third-party software packages are not supported and may interfere with proper operation of the StimRouter components, thus voiding the warranty.

Component Description

Hewlett Packard iPAQ 200 Enterprise Handheld internally powered personal digital assistant with StimRouter proprietary software installed.

Note: Refer to the HP web site for a description of the Hewlett Packard iPAQ 200 Enterprise Handheld, device specifications and instructions for use.

Operating Buttons

On/Off. Used to turn the clinician programmer on and off.

Reset. Used to soft reset the clinician programmer.

LEDs

Power Indicator Light.YELLOW when the clinician programmer is charging; GREEN when the clinician programmer battery charge is complete.

Bluetooth Enabled Indicator Light. BLUE when Bluetooth is ON.

SD Slot

Contains the clinician programmer memory (SD) card.

Battery

Removable/rechargeable 2200 mAh Lithium-Ion battery.

⚠ **CAUTION:** Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to local regulation.

Touchscreen Display

Used to navigate the StimRouter application, read statuses and enter data. Use the pointed end of the stylus to make contact with the display screen. Use only the stylus. Do not use sharp objects such as pencils or pens on the touchscreen display.

24-Pin Connector Port

For use with the connector cable on the clinician programmer cradle.

Wireless Bluetooth Communication

Used for high-speed, low-power, short-range wireless communication with a Bioness-approved Bluetooth printer.

Clinician Programmer Memory Card

Used to back up and restore the clinician programmer database. The memory card is supplied installed in the SD slot of the clinician programmer.

Clinician's Programmer Charger

Used to recharge the clinician programmer battery.

⚠ **WARNING:** Use only the clinician programmer charger included in the StimRouter Clinician Kit (Manufacturer Model No. PHIHONG, PSC11R/PSM11R).

Configuration Cradle

Used to connect the clinician programmer to the patient programmer and to the clinician's programmer charger. The configuration cradle is designed to house the patient programmer and the clinician programmer in a convenient, portable unit. See Figure 5-2.

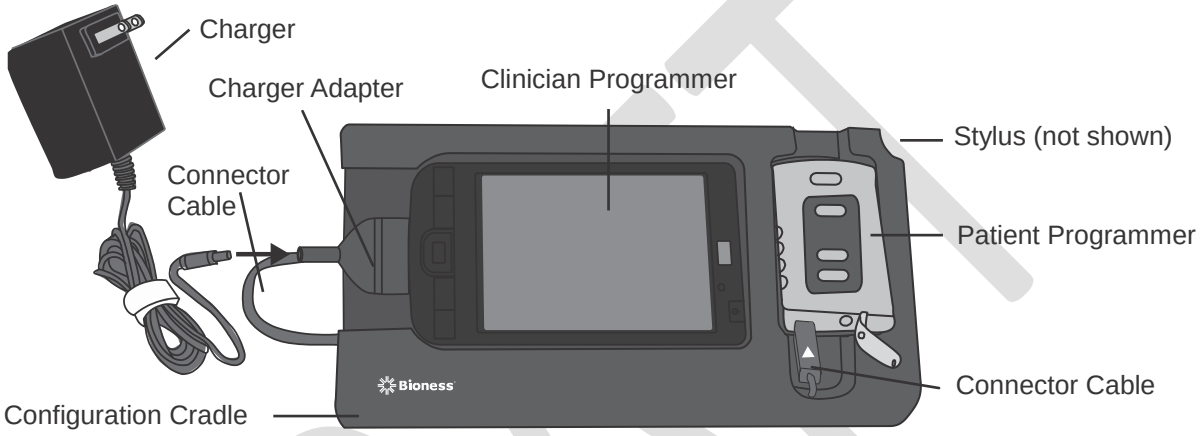


Figure 5-2. The configuration cradle with
the clinician programmer and patient programmer connected.

Connector Cable with Charger Adapter

Connects the clinician programmer to the patient programmer and to the clinician's programmer charger.

Stylus

A pen-shaped device used to input commands on the clinician programmer touchscreen display.

Tester

Used to confirm that the EPT is working properly. See Figure 5-3.

Figure 5-3. The tester.

The tester is used to diagnose stimulation problems in the EPT. It provides audio feedback when connected and stimulation is applied.

Clinician's Software Navigation

The StimRouter clinician's software is provided installed on the clinician programmer.

Operating Modes

The StimRouter application has two operating modes: online and offline.

Online. The StimRouter clinician programmer is online when connected to an operational StimRouter patient programmer and EPT. See Table 5-1.

Offline. The StimRouter clinician programmer is offline when not connected to an operational StimRouter patient programmer and EPT. See Table 5-1.

Operating Mode	Function Descriptions
Online	• Add a new patient. • Modify a patient name. • Open a patient record. • View/print a patient's history. • Program stimulation settings. • Program time settings. • Add or remove a stimulation program. • View the system information. • Reset the EPT and patient programmer. • Back up the database. • Restore the clinician programmer database. • Add a new user. • Remove a user. • Change a user password.
Offline	• Open any patient record. • Remove a patient record. • View/print a patient's history. • 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 5-1. StimRouter application operating modes and descriptions.

Information Icon

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

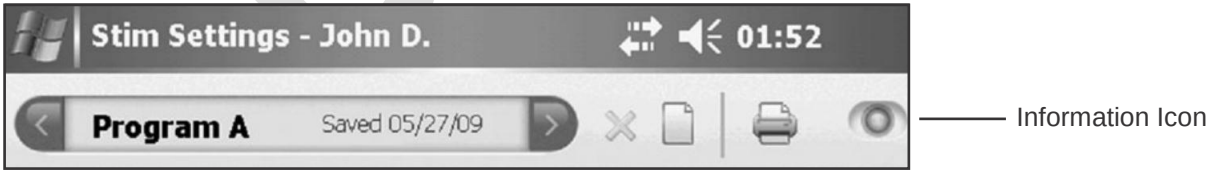


Figure 5-5. Location of the information icon.

- GREEN when the StimRouter is online; GRAY when no patient programmer is detected.

- FLASHING RED with “i” in the center when a patient programmer is connected and a correctable error has occurred (for example, RF communication failure).

- CONSTANT RED with “i” in the center when a patient programmer is connected and an error has occurred.

- FLASHING YELLOW with “i” in the center when the StimRouter patient programmer or EPT battery charge level is low.

Print Icon

Used to print patient reports.

Data Entry

Keyboard. Used to enter characters in a field that requires alphanumeric input. The keyboard appears collapsed at the bottom right or center of most screens. To enlarge or reduce the keyboard, touch the keyboard with the stylus. To enter data, select each character using the stylus.

Drop-Down Lists. Used to select a value. Press the down arrow to display the values. Use the stylus to select a value. See Figure 5-6.

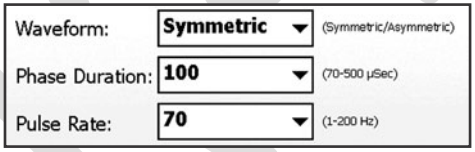


Figure 5-6. Illustrative drop-down lists for waveform, phase duration and pulse rate.

Menu Bar and Menus

The StimRouter application has five navigation menus, which appear on the menu bar. See Figure 5-7.

Figure 5-7. Menu bar.

Exit. Used to exit or logoff the StimRouter application.

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 or print a patient's usage log or session history. (Enabled when a patient record is open.)

Tools. Used to view system information and to reset the patient programmer and EPT. 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 StimRouter application has eight navigation tabs, or submenus, found under the five main menus. See Table 5-2.

Menu	Tab	Function Descriptions
Exit	No tabs	• Exit the StimRouter application. • Log off the StimRouter application.
Patients	No tabs	• 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. • View stimulation settings for each program saved. • Add/delete programs in online mode. • Print the selected program.
	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. • Print the selected program.
History	Usage	• View/print a usage log.
	Sessions	• View/print a session history.

Menu	Tab	Function Descriptions
Tools	Info	• View system information in online mode. • Reset the patient programmer and EPT in online mode.
	Users	• Add a new user. • Remove a user. • Change a user password.
	Backup	• Back up the clinician programmer database. • Enable/disable automatic database backup.
	Restore	• Restore the clinician programmer database from automatic backup. • Restore the clinician programmer from manual backup.

Table 5-2. StimRouter application navigation menus, navigation tabs and functions that can be performed from each menu/tab.

Buttons

When pressed, a navigation button will open a new screen or execute a command. See Figure 5-8. 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.

Figure 5-8. Illustrative navigation buttons.

Button	Function Descriptions
?	• Open help screens.
Change Password	• Change a user password (enabled for administrators only).
Clear	• Delete characters in a field.
Exit	• Exit the StimRouter application.
Login	• Log into the StimRouter application.
Log Off	• Log off the StimRouter application.
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.
Print	• Print the specified report to a Bioness-approved Bluetooth printer or to a PDF file on the memory (SD) card.
Remove	• Remove an existing patient record.
Remove User	• Remove a user (enabled for administrators only).
Reset Patient Programmer	• Resets the patient programmer so that it can be transferred from one EPT to another.
Reset Patient Programmer/EPT	• Restore factory settings on the patient programmer and EPT. (When selected, all patient data on the patient programmer and EPT are erased.)
Stop & Save	• Stop stimulation and save the stimulation and time settings.
Test	• Test the current stimulation and time settings.
View	• View session details.

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 5-9.

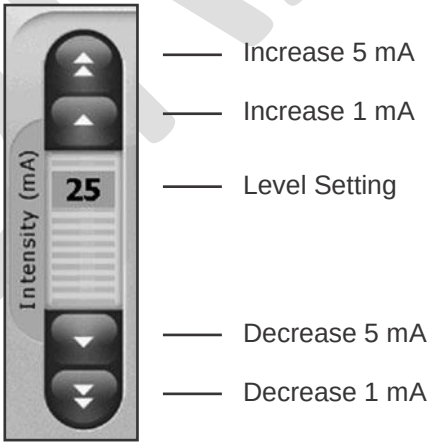


Figure 5-9. Intensity level bar. To adjust intensity, press the up or down arrows.

Program Bar

Used to add, delete and view up to eight clinician-set stimulation programs, labeled A-H. See Figure 5-10.

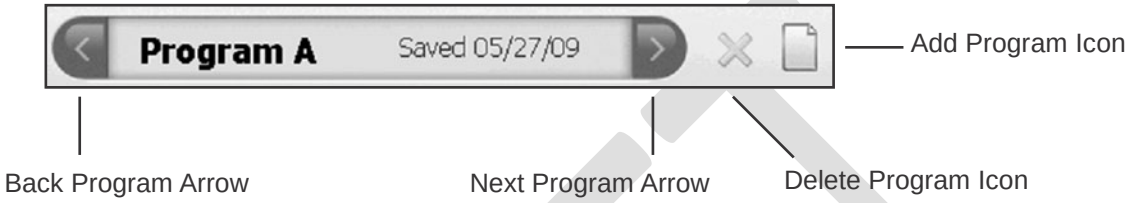


Figure 5-10. Program bar and icon definitions.

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.)

Search Bars

Used to search the clinician programmer database. See Figure 5-11.

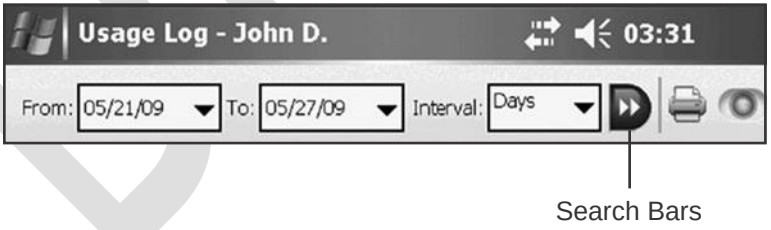


Figure 5-11. Search bars for usage log. Select a value from the drop-down lists or enter a value using the keyboard. Then press the double arrow to begin the search. Press the double arrow again to view additional matches found.

Programming Parameters

Patients require tailored stimulation patterns to help control their pain. The StimRouter system features eight programmable parameters and can store up to eight stimulation programs on the clinician programmer, patient programmer and EPT. Timing parameters are specified in Table 5-4. Pulse parameters are specified in Table 5-5.

Parameter	Definition	Specification
On Time	Time that stimulation is applied per cycle	1-60 seconds, 1-second resolution
Off Time	Time that stimulation is turned off per cycle	0-60 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”, 1- second resolution
Total Time	Duration from the initiation to the end of a stimulation program	10 minutes- 12 hours

Table 5-4. Timing parameters.

Parameter	Specification
Pulse	Balanced biphasic (pulse is hardware balanced — no DC component exists)
Waveform	Symmetric or Asymmetric
Intensity*	0-30 milliamperes peak, 1-milliampere resolution (positive phase)
Maximum Voltage	100 volts
Maximum Output	7 milliamperes root mean square, 40 volts root mean square
Maximum Charge Allowed	10 microcoulombs per phase
Electrode Current Density	Less than 1 milliampere root mean square per centimeter2
Positive Phase Duration**	70, 100, 150, 200, 250, 300, 350, 400, 450, 500 microseconds
Negative Phase Duration	Symmetric: Identical to the positive phase duration. Asymmetric: Four times the positive phase duration.

Parameter	Specification
Total Pulse Duration	Up to 2550 microseconds (depends on waveform)
Maximum Load	5000 ohms (subject to max voltage limitation) in parallel to 80 nanofarads
Typical Load	2700 ohms in parallel to 22 nanofarads
Minimum Load	100 ohms in parallel to 1 nanofarad
Pulse Repetition Rate* **	1, 2, 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 hertz

*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.

Table 5-5. Pulse parameters.

6

Set-Up Instructions

Programming Components and Software

This section describes how to connect the clinician programmer and cradle, charge the clinician programmer and launch the StimRouter application.

Connecting the Clinician Programmer and Cradle

To connect the clinician programmer and cradle:

1. Orient the clinician programmer in the configuration cradle with the touchscreen facing up and the 24-pin connector port facing left. See Figure 6-1.

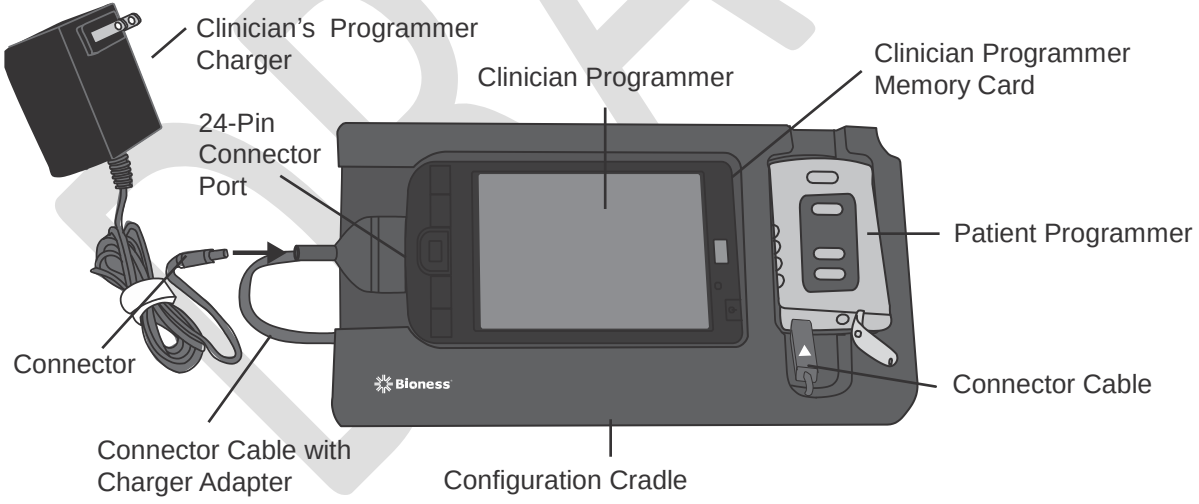


Figure 6-1. The clinician programming system set-up configuration.
Also shown is a patient programmer connected.

2. Plug the connector cable with charger adapter (on the configuration cradle) into the 24-pin connector port on the clinician programmer, with the arrows on the adapter facing up.

Charging the Clinician Programmer

To charge the clinician programmer:

1. Insert the connector on the clinician's programmer charger into the charger adapter on the connector cable. See Figure 6-1.

⚠ **WARNING:** Use only the clinician's programmer charger included in the StimRouter Clinician Kit (Manufacturer Model No. PHIHONG, PSC11R/PSM11R).

2. Plug the charger into a power socket.
3. Allow the clinician programmer to charge. The clinician programmer can take two to four hours to charge. When the clinician programmer is fully charged, the indicator light next to the On/Off button will be GREEN.

Logging into the StimRouter Application

To log into the StimRouter application:

1. Turn the clinician programmer on by pressing the on/off button on the lower right corner of the clinician programmer. See Figure 6-2.
2. If the login screen does not open automatically, then, using the stylus, press "Start" and then "StimRouter" to open the StimRouter application. Wait for the login screen to load. See Figure 6-2.

Figure 6-2. The StimRouter application login screen.

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

Note: Always log off the StimRouter application before leaving the clinician programmer unattended.

Patient’s External Components

The patient-operated components of the StimRouter system are: the patient programmer, EPT and StimRouter electrode. See Figure 6-3.

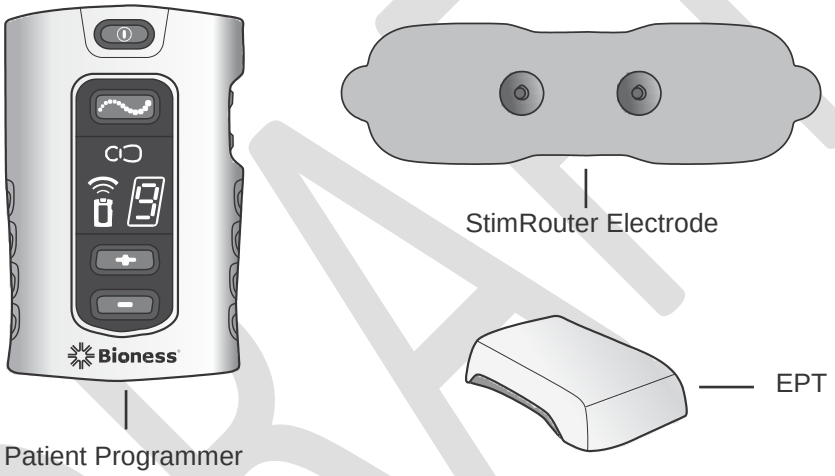


Figure 6-3. The StimRouter patient programmer, StimRouter electrode and EPT.

The StimRouter User Kit also provides a system charger set to charge the patient programmer and EPT.

When the clinician programmer is connected to an operational patient programmer and EPT, the clinician programmer is online and ready to program.

Connecting the Patient Programmer and Configuration Cradle

To connect the patient programmer and configuration cradle:

1. Open the flexible cover on the patient programmer.
2. If necessary, charge the patient programmer using the system charger set provided in the User Kit. Insert the Y cable connector into the charging socket; plug the charger into a power socket. See Figure 6-4.

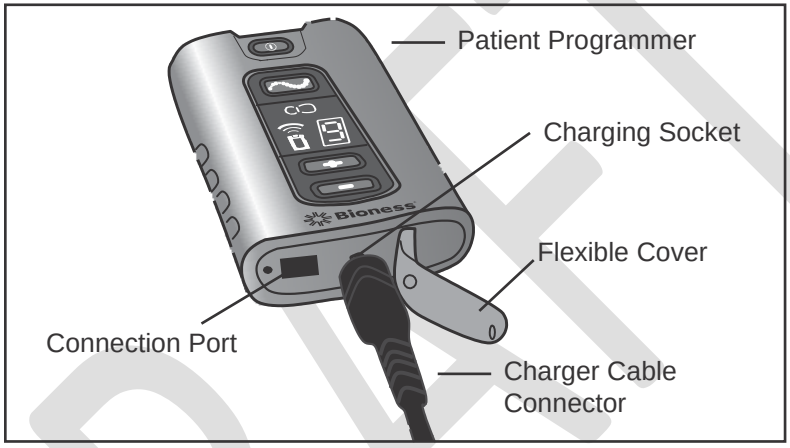


Figure 6-4. Charging the patient programmer.

⚠ **WARNING:** Use only the charger included in the StimRouter User Kit. (Refer to Manufacturer Model No. FRIWO FW7333SM/05 or FRIWO FW7333CM/05).

3. Plug the connector cable of the configuration cradle into the connector port of the patient programmer. The white arrow should be facing up. See Figure 6-5.

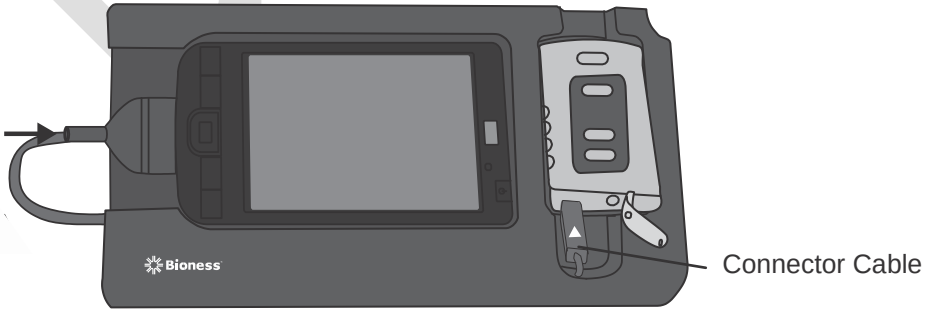


Figure 6-5. Patient programmer connection configuration.

4. Insert the patient programmer into the configuration cradle.

Connecting the StimRouter Electrode and EPT

To connect the StimRouter electrode and EPT:

1. Obtain an operational StimRouter electrode. Electrodes can be reused for as long as the gel electrodes can fully adhere to the skin.
2. Do not remove the the reusable StimRouter electrode liner from the gel electrodes at this time.

   Set the StimRouter electrode on a flat surface with the gel electrodes facing down.
3. Snap the EPT into the StimRouter electrode. See Figure 6-6.
4.

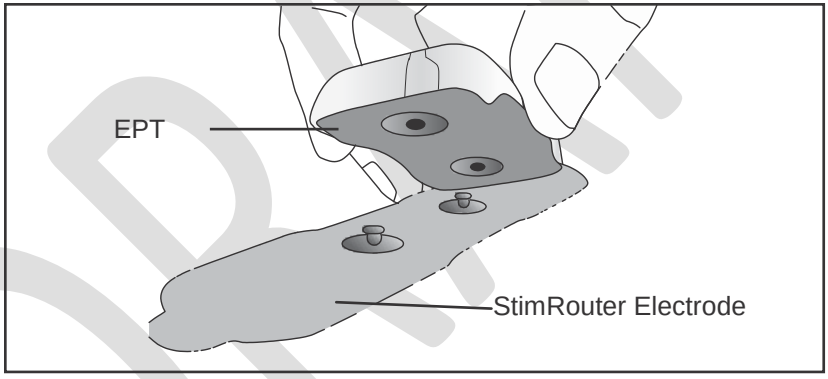


Figure 6-6. StimRouter electrode and EPT connection.

Note: To ensure proper electrical stimulation, the EPT must be connected to the StimRouter electrode properly. If the EPT does not work properly, then remove it from the StimRouter electrode and reconnect it, or connect it to a new electrode.

Adhering the StimRouter Electrode to the Skin

The StimRouter electrode with EPT attached should be placed on the skin directly over the receiver end of the lead. For optimal stimulation, the skin where the StimRouter electrode will adhere should be clean and dry. This section describes how to prepare the skin, and how to adhere and remove the StimRouter electrode.

Note: Transfer the EPT to a new StimRouter electrode when the gel electrodes adherence to the skin decreases..

To prepare the skin:

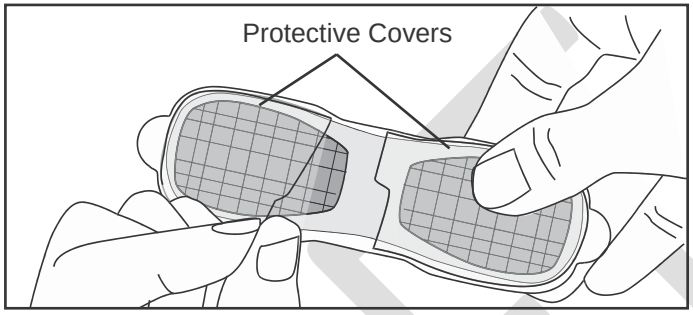
1. Locate the area where the receiver end of the lead is implanted.
2. Clean the skin above the receiver end of the lead with an alcohol swab or wet washcloth, and then dry. If the area has been treated with lotions or oils, then clean the skin with soap and water until all oils are removed, rinse well and dry.
3. If necessary, remove excess body hair from the skin area using scissors. Do not use a razor. A razor can irritate the skin.

⚠ **WARNING:** Do not touch the gel electrodes 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 StimRouter electrode.

⚠ **WARNING:** Do not apply the StimRouter electrode to anyone else or any other part of the body than that determined by the prescribing physician. The StimRouter electrode is for single patient use.

To adhere the StimRouter electrode:

1.



2. Remove the reusable StimRouter electrode liner and store it in the StimRouter electrode carrying case. The StimRouter electrode liner is larger than the electrode and is marked with the Bioness logo. See Figure 6- 8. Do not bend, break or soil the StimRouter electrode liner.

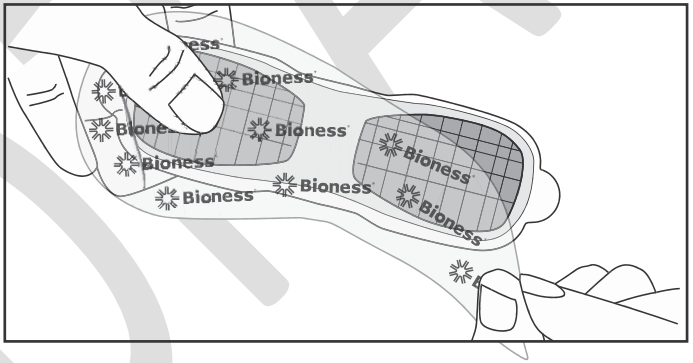


Figure 6-8. Remove the StimRouter electrode liner.

3. Visually inspect the gel electrodes. Make sure the gel is smooth and attached to the StimRouter electrode. The gel should align with the contour of the StimRouter electrode and completely cover the base of the StimRouter electrode. Make sure the gel electrodes are not dry.

4. Using the index finger and thumb, grasp the edges of the StimRouter electrode so that the gel electrodes face away from the palm. See Figure 6-9.

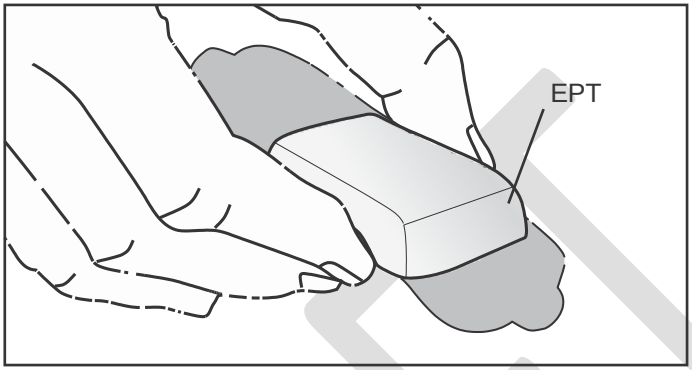


Figure 6-9. Grasp the edges of the EPT attached to the StimRouter electrode.

5. Align one end of the StimRouter electrode with EPT attached directly over the receiver end of the lead. If the StimRouter electrode is not directly over the receiver end of the lead, then stimulation may be uncomfortable or ineffective. See Figure 6-10. The effectiveness of the stimulation is sensitive to the alignment and rotation of the StimRouter electrode in relation to the receiver end of the lead. If the alignment or rotation of the StimRouter electrode changes, the stimulation intensity may need to be adjusted.
6. Position the other end of the StimRouter electrode where it will minimize discomfort and avoid muscle contractions.

⚠ **CAUTION:** Do not pinch or stretch the skin while adhering the StimRouter electrode.

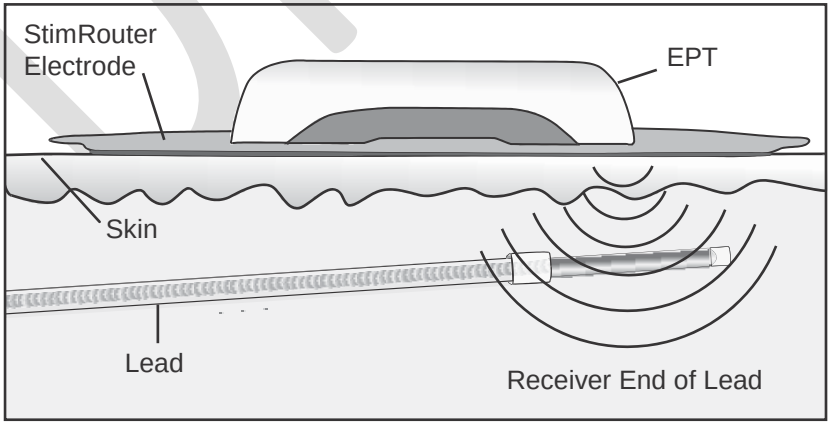


Figure 6-10. Optimal stimulation, position of the StimRouter electrode. (Illustration not to scale.)

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

7. Firmly adhere the StimRouter electrode to the skin, making sure that the electrode is in full contact with the skin. If the StimRouter electrode is not firmly adhered to the skin and moves, then stimulation may become uncomfortable or ineffective.
8. Make certain that the patient programmer is within 10 feet of the StimRouter electrode (with EPT attached).

Confirming Set-Up

If the clinician programmer, patient programmer, EPT 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 StimRouter electrode with the EPT attached is within 10 feet of the patient programmer.
3. If the information icon is still not GREEN, check all connections and charge the patient programmer and the EPT.
4. Test the EPT using the tester.
5. See the “Troubleshooting” section of this guide.
6.

Refer to the StimRouter User’s Guide for additional operational instructions for the StimRouter patient programmer, EPT and StimRouter electrode, including instructions on how to:

- Turn on the patient programmer.
- Charge the patient programmer.
- Adjust the volume of audio alerts on the patient programmer.
- Select a stimulation program using the patient programmer.
- Turn stimulation on using the patient programmer.

- Adjust stimulation intensity using the patient programmer.
- Save a new stimulation intensity level on the patient programmer.
- Turn stimulation off using the patient programmer.

Removing the StimRouter Electrode from the Skin/Body

It may be necessary during set up to remove the StimRouter electrode to reposition it or test the EPT.

To remove the StimRouter electrode:

1. To remove the StimRouter electrode, make certain that stimulation is turned off. Then grasp the tab on the StimRouter electrode and gently pull away from the skin. See Figure 6-13.

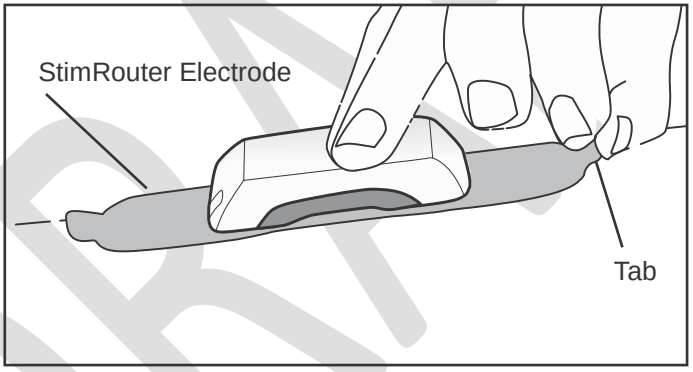


Figure 6-13. Removing the StimRouter electrode.

2. Obtain a StimRouter electrode liner to protect the gel electrodes from drying out. Attach the liner to the gel electrodes.
3. Store the StimRouter electrode with the liner attached in the StimRouter electrode carrying case.

Testing the EPT

The tester is used to test the functionality of an EPT. Before connecting the EPT to the tester, make sure the EPT is charged. Using the patient programmer or clinician programmer, stimulation can be turned on.

Using the tester:

1. Connect the Tester snaps to the EPT plug holes. See Figure 6-14.

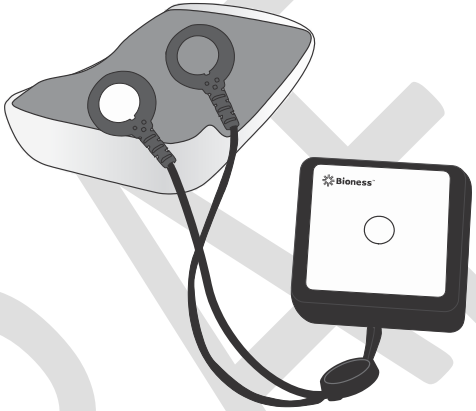


Figure 6-14. Connecting the tester to the EPT.

2. Press the patient programmer on/off button to turn on the system.
3. Press the mode button briefly to start stimulation, you should hear a buzzing coming from the tester when stimulation is on and no buzzing when stimulation is off.

7

Patient Records and History

Patient Records

This section reviews how to add, copy, open, modify, remove and search for a patient record; and how to view and print a patient's session and usage history.

Definition of Terms

Unassigned System: No patient data are stored on the EPT or patient programmer.

Assigned System: Patient data are stored on either the EPT or patient programmer.

Adding a Patient with an Unassigned System

Follow these instructions when a patient does not have a record in the clinician programmer database and no patient data have been stored on the EPT or patient programmer, i.e., the patient's system is unassigned and the patient is new.

Note: "New" is only enabled in online mode when the clinician programmer is connected to an unassigned StimRouter patient programmer and EPT.

To add a patient with an unassigned system to the clinician programmer database:

1. Make certain that the clinician programmer is connected to an operational patient programmer and EPT. See "Set-Up Instructions" section of this guide.
2. If the EPT and patient programmer are unassigned, then the application should automatically prompt that no patient data were found on the system. Press "OK." See Figure 7-1.

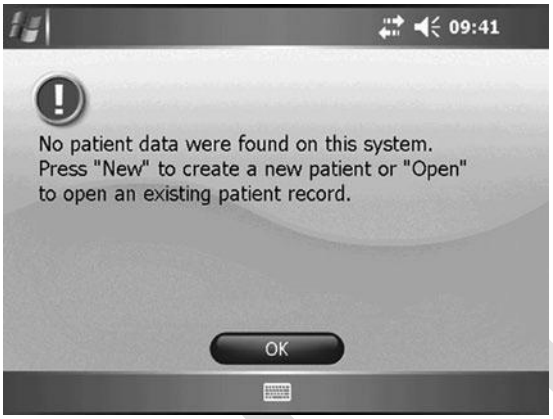


Figure 7-1. Unassigned system detected.

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

Figure 7-2. Adding a patient with an unassigned system.

6. Proceed to "Programming Instructions" section 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 have been stored on the EPT or patient programmer, i.e., the patient is not new but the patient's system is unassigned. 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. Make certain that the clinician programmer is connected to an operational patient programmer and EPT. See "Set-Up Instructions" section of this guide.
2. If the EPT and patient programmer are unassigned, the StimRouter application should automatically prompt that no patient data were found on the system. Press "OK." See Figure 7-1.
3. If this prompt does not appear and the patient's components are new, then reset the patient programmer and EPT. See "Tools" section of this guide.
4. Find the patient's record on the Patient List, and then press "Open." When the patient record opens, the patient data will automatically copy from the clinician programmer to the EPT and patient programmer.

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 are stored on the patient's EPT and patient programmer, i.e., the patient's system is assigned. This patient may be a referral from another clinic or from a clinician using a different clinician programmer.

To add a patient with an assigned system to the clinician programmer database:

1. Make certain that the clinician programmer is connected to an operational patient programmer and EPT. See "Set-Up Instructions" section of this guide.
2. The StimRouter application will automatically prompt that a new patient was found and add the patient to the clinician programmer database. See Figure 7-3.
3. Proceed to "Programming Instructions" section of this guide.

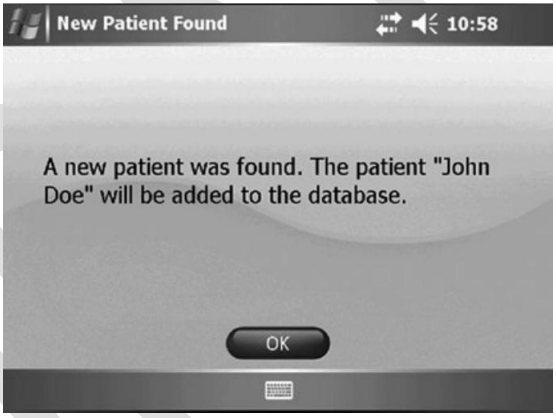


Figure 7-3. Adding a patient with an assigned system.

Opening a Patient Record

Note: When the clinician programmer is in online mode and connected to a patient programmer and an EPT that contain programs, only the patient record corresponding to those components can be opened. If the components do not contain programs, then any patient record can be opened and the patient data copied to the patient programmer and EPT. In offline mode, any patient record can be opened and viewed.

To open a patient record:

1. Press the PATIENTS MENU to open the Patient List.
2. Select a patient from the Patient List, and then press “Open.” See Figure 7-4.

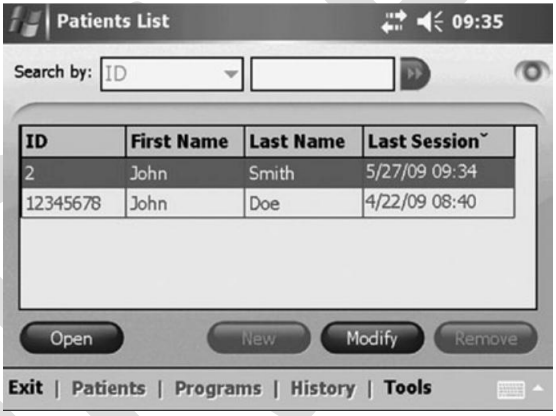


Figure 7-4. Opening a patient record.

Note: If a patient programmer and EPT are connected to the clinician programmer and have programs stored on them, then only the corresponding patient record can be opened.

Modifying a Patient Record

Note: “Modify” is only enabled in online mode, when the clinician programmer is connected to a working patient programmer and EPT.

To modify a patient record:

1. Press the PATIENTS MENU to view the Patient List.
2. From the Patient List, press “Modify.”
3. Enter changes to the patient’s first or last name, and then press “OK.” See Figure 7-6. Patient ID cannot be modified.

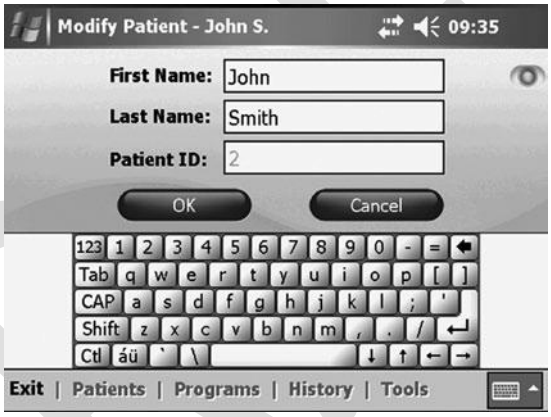


Figure 7-6. Modifying a patient record.

Removing a Patient Record

Note: “Remove” is only enabled in offline mode.

To remove a patient record:

1. Make certain that the clinician programmer is not connected to an operational patient programmer and EPT, i.e., that the clinician programmer is in offline mode. The information icon should not be GREEN.
2. Press the PATIENTS MENU to open the Patient List, select the patient record to remove, and then press “Remove.” See Figure 7-7.

Figure 7-7. 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 patient programmer and EPT, i.e., that the clinician programmer is in offline mode. The information icon should not be GREEN.
2. Press the PATIENTS MENU to open the Patient List.
3. Using the search bar, select a search criterion from the “Search by” drop- down list, 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.

Usage History

The patient usage history is stored on the EPT and is automatically retrieved when the clinician programmer is connected to an operational patient programmer and EPT.

Viewing a Usage History

To view a usage history:

1. From the PATIENTS MENU, select the patient on the Patient List, and then press “Open.”
2. From the HISTORY MENU, press the USAGE TAB to open the Usage Log.
3. In the “Display” drop-down list (bottom right of screen), select a program to view or select “All Programs.” See Figure 7-8.

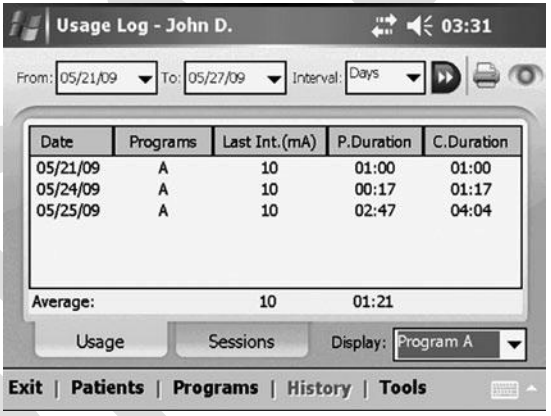


Figure 7-8. Sample usage log for program A.

Note: **Last Int. -** Intensity in mA when the system was turned off the last time that interval.
P. Duration - Program duration. How long that program was used in that interval.
C. Duration - Cumulative duration. The total of the program durations.
Average - Average of the program duration per interval.

4. In the “From,” “To” and “Interval” drop-down lists (top of screen), select a from date, a to date and an interval for viewing, and then press the double arrow. The usage history will open.

Printing a Usage History

To print a usage history:

1. Press the print icon on the Usage Log screen.
2. From the “Printer” drop-down list, select the installed printer or “Adobe PDF file,” and then press “Print.”

Note: Selecting “Adobe PDF file” saves the usage history as a PDF file on the clinician programmer memory (SD) card.

Session History

Session history can be viewed and printed from the SESSIONS TAB under the HISTORY MENU. Open a patient record to enable the HISTORY MENU.

Viewing a Session History

To view a session history:

1. From the PATIENTS MENU, select the patient on the Patient List, and then press “Open.”
2. From the HISTORY MENU, press the SESSIONS TAB, select a session to view, and then press “View.” See Figure 7-9.

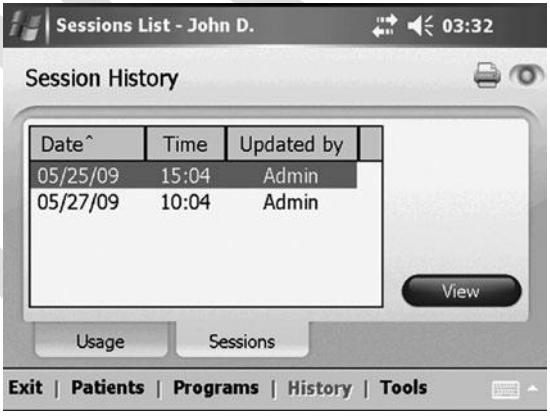


Figure 7-9. Viewing a session.

3. The session detail will open. See Figure 7-10.

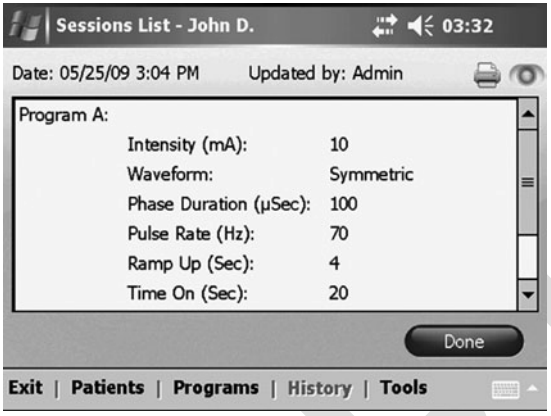


Figure 7-10. Session detail.

Printing a Session History

To print a session history:

1. With the session detail open, press the print icon.
2. From the “Printer” drop-down list, select the installed printer or “Adobe PDF file,” and then press “Print.”

Note: Selecting “Adobe PDF file” saves the session as a PDF file on the clinician programmer memory (SD) card.

Printing Multiple Sessions

To print multiple sessions:

1. Open the SESSIONS TAB.
2. Press the print icon.
3. When the Print Sessions screen opens, check the box next to each session to be printed, and then press “Print.” See Figure 7-11.
4. From the “Printer” drop-down list, select the installed printer or “Adobe PDF file,” and then press “Print.”

Note: Selecting “Adobe PDF file” saves the session as a PDF file on the clinician programmer memory (SD) card.

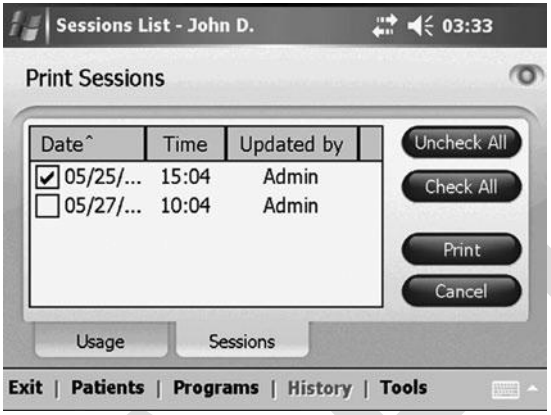


Figure 7-11. Printing multiple sessions. Check which sessions to print, and then press “Print.”

8

Tools

Both users and administrators have access to the INFO TAB of the TOOLS MENU. Only administrators have access to the USERS, BACKUP and RESTORE tabs of the TOOLS MENU.

System Information and Component Reset

System information can be found on the INFO TAB of the TOOLS MENU. From the INFO TAB, users can also reset the patient programmer, if, for example, a clinic patient programmer is to be used. Users can also reset the patient programmer and EPT, which restores the components to their factory settings. All patient data and logs are deleted.

Resetting the Patient Programmer and EPT

To reset the patient programmer:

1. Connect the patient programmer to the configuration cradle.
2. Press the TOOLS MENU, and then, on the INFO TAB, press “Reset Patient Programmer/EPT.” See Figure 8-1.

Figure 8-1. Resetting the patient programmer and EPT.

3. Select “Reset the Patient Programmer,” and then press “Reset.” See Figure 8-2.

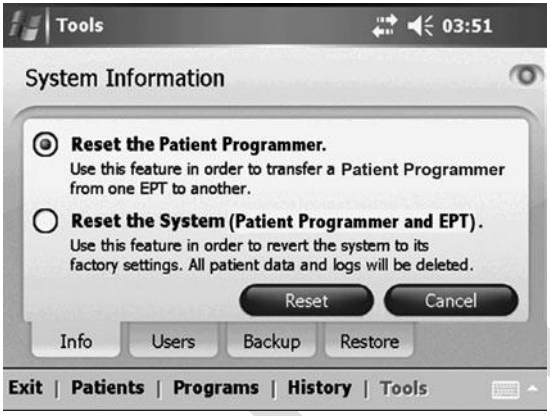


Figure 8-2. Select a reset option, and then press “Reset.”

To reset the patient programmer and EPT:

1. Make certain the clinician programmer is in online mode. Select “Reset the System (Patient Programmer and EPT),” and then press “Reset.” See Figure 8-2.

User Administration

The StimRouter application supports two levels of users: users and administrators. Administrators have extended authorizations. 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. From the TOOLS MENU, press the USERS TAB and then “New User.” See Figure 8-3.

Figure 8-3. Adding a user/administrator.

2. Enter a user name and password, confirm the password, select either “Users” or “Administrators” from the “Group” drop-down list, and then press “Add.” See Figure 8-4.

Figure 8-4. Adding a user/administrator.

Removing a User/Administrator

To remove a user/administrator:

1. From the TOOLS MENU, press the USERS TAB, select a user name, and then press “Remove User.” Confirm “Yes” or “No” when prompted. See Figure 8-5. (The administrator who is logged on cannot be removed.)

Figure 8-5. Removing a user. Select the user, and then press “Remove.”

Changing a User Password

To change a user password:

1. From the TOOLS MENU, press the USERS TAB, select a user name, and then press “Change Password.”
2. Enter and confirm the new user password, and then press “OK.” See Figure 8-6.

Figure 8-6. Changing a user password.

Note: Bioness recommends that passwords be changed at least every three months.

Clinician Programmer Database Backup and Restore

Manually Backing Up the Database

Note: Only administrators have access to the BACKUP TAB.

To manually back up the clinician programmer database:

1. From the TOOLS MENU, press the BACKUP TAB. See Figure 8-7.

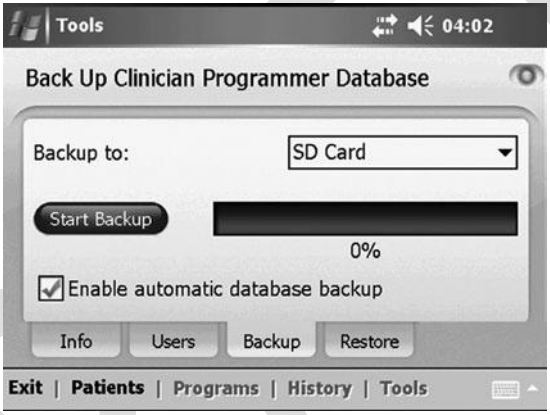


Figure 8-7. Backing up the clinician programmer database.

2. From the “Back up to” drop-down list, select “SD Card,” and then press “Start Backup.”

Enabling Automatic Database Backup

To enable automatic database backup:

1. From the TOOLS MENU, press the BACKUP TAB, and then check “Enable automatic database backup.” The clinician programmer database will back up once per day and each time the application is exited. See Figure 8-7.

Restoring the Database

Note: Only administrators have access to the RESTORE TAB.

To restore the clinician programmer database:

1. From the TOOLS MENU, press the RESTORE TAB.
2. From the “Restore from” drop-down list, select “SD Card.”See Figure 8-8.

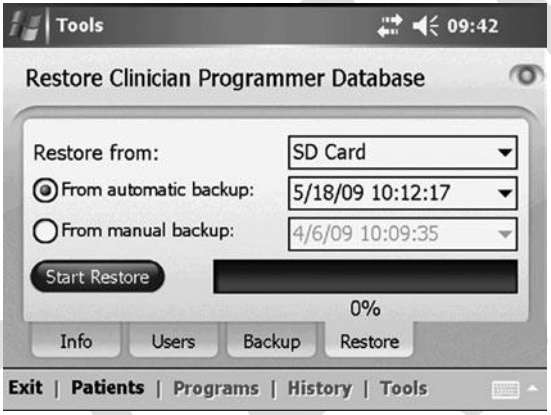


Figure 8-8. Restoring the clinician programmer database.

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

9

Programming Instructions

The programming session can begin once the StimRouter electrode with EPT attached is adhered, the clinician programmer and patient programmer are set up, and the patient's record is added and opened. This section describes how to program stimulation and time settings, and how to add a program, view a program, delete a program and print a program.

Stimulation and Time Settings

Programming Stimulation Settings

To program stimulation settings:

1. Make sure that the StimRouter application is in online mode (the information icon should be GREEN). See "Confirming Set-Up" section of this guide.
2. From the PATIENTS MENU, press "Open" to view the STIM SETTINGS TAB. See Figure 9-1.

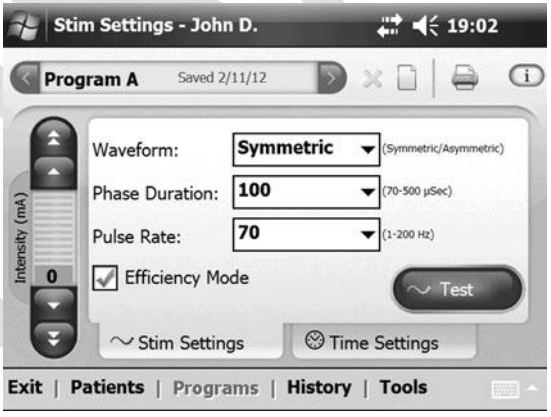


Figure 9-1. Programming stimulation settings.

3. Adjust the stimulation settings using the drop-down lists next to "Waveform," "Phase Duration" and "Pulse Rate."

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

4. Press “Test” to test the stimulation settings; stimulation will turn on.

Note: If the combination of parameters exceeds the maximum charge level allowed (10 microcoulombs per phase), then a warning will appear with directions to reduce the total charge. “Test” will be disabled. See Figure 9-2.

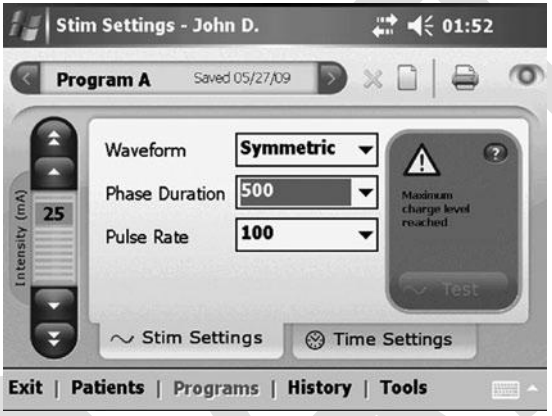


Figure 9-2. Maximum charge level exceeded.

5. Slowly increase the intensity to a level that is tolerable for the patient and achieves the desired therapy.
6. Press “Stop & Save” to stop stimulation and save the stimulation settings to the clinician programmer, patient programmer and EPT. See Figure 9-3.

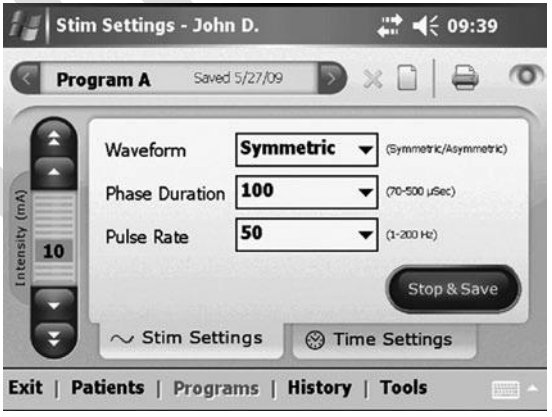


Figure 9-3. Press “Stop & Save” to stop testing and save the current stimulation settings.

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

Note: If an intensity adjustment during testing causes the maximum charge level to be reached, then a notification will appear. No further increase will be allowed. See Figure 9-4.

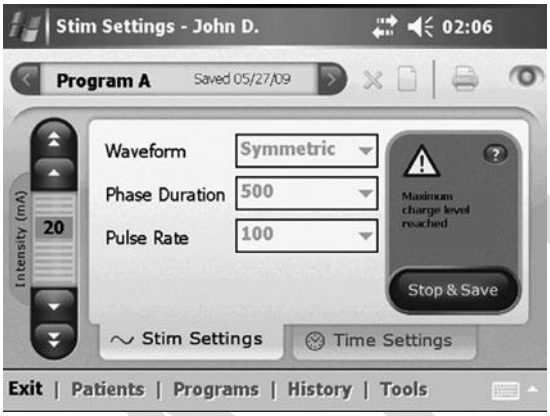


Figure 9-4. Maximum charge level reached.

Programming Time Settings

To program time settings:

1. From the STIM SETTINGS TAB, 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” and “Total Time” can be adjusted. To change the duty cycle, uncheck “Constant Stim” and adjust “Time On” and “Time Off.” See Figure 9-5.

Figure 9-5. Programming time settings.

3. Press “Test” to test the time settings; stimulation will turn on.
4. Fine-tune the intensity level (using the up/down arrows).

Note: If an intensity adjustment during testing causes the maximum charge level to be reached, then a notification will appear. No further increase will be allowed. See Figure 9-6.

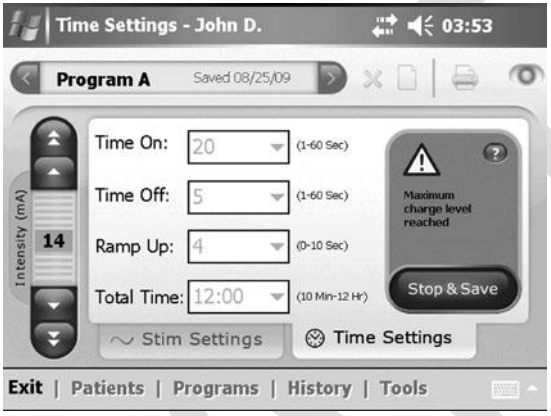


Figure 9-6. Maximum charge level reached.

5. Press “Stop & Save” to stop stimulation and save the time settings to the clinician programmer, patient programmer and EPT.
6. The program save date will appear on the Program Bar.

Programs

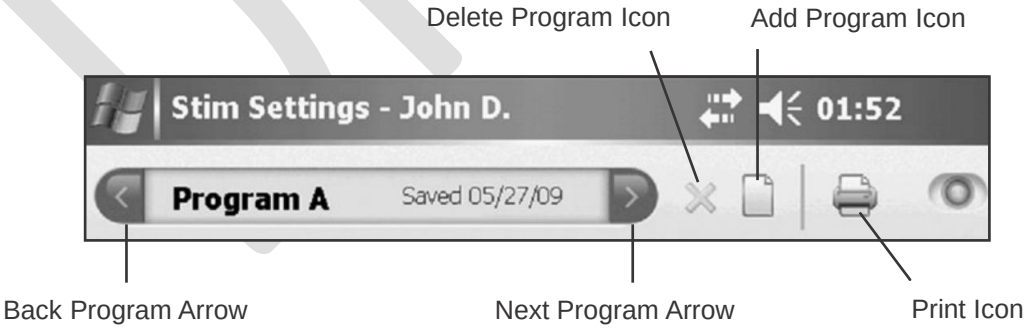


Figure 9-7. Add a program icon, back program arrow, next program arrow, delete program icon, and print icon.

Adding a Program

Note: The StimRouter application must be in online mode to add a new stimulation program.

To add a program:

1. From the STIM SETTINGS TAB or TIME SETTINGS TAB press the add program icon on the Program Bar. See Figure 9-7.
2. The new program will open with default settings. The new program label (A-H) will appear in the Program Bar.
3. After the program has been tested and “Stop & Save” pressed, the program will be saved to the clinician programmer database, the patient programmer and the EPT. The date the program was saved will appear in the center of the program bar.

Note: The StimRouter can support up to eight programs, labeled A-H.

Viewing a Program

To view a program:

1. From the STIM SETTINGS TAB or the TIME SETTINGS TAB, press the left or right arrow on the Program Bar and scroll to the desired program. If only one program is saved, then the arrows on the Program Bar will be disabled. See Figure 9-7.

Deleting a Program

Note: The StimRouter application must be in online mode to delete a stimulation program.

To delete a program:

1. From the STIM SETTINGS TAB or the TIME SETTINGS TAB, select a program to delete.
2. Press the delete program icon on the Program Bar. See Figure 9-7.

Printing a Program

To print a program:

1. Open the selected program and press the print icon. See Figure 9-7.
2. Select a printer or “Adobe PDF file” from the drop-down list, and then press “Print.” See Figure 9-8.

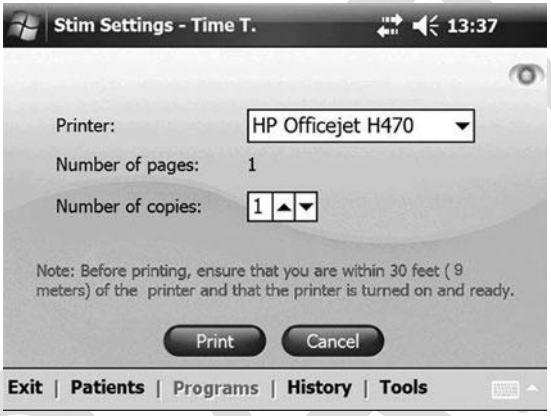


Figure 9-8. Select a printer (or “Adobe PDF file”) from the drop-down list, and then press “Print.”

3. If the page does not print, then verify that the printer is within 30 feet of the clinician programmer, is turned on, has paper in the paper tray and is not displaying an error message.

10

Maintenance and Cleaning

Battery Replacement

Replacing the Clinician Programmer Battery

During extended periods of nonuse, remove the battery from the clinician programmer. Refer to the iPAQ product instructions for information on battery removal and replacement.

⚠ **CAUTION:** Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to local regulation.

Cleaning

All StimRouter Clinician Kit components may be cleaned by carefully wiping them with a damp cloth. Use water. Do not use detergents or other cleaning agents. Do not clean the gel electrodes on the StimRouter electrode.

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

Disinfecting

Electronic Components

All StimRouter Clinician Kit electronic components may be cleaned and low-level disinfected using CaviWipes™ (Metrex, Orange, CA), or wipes or cloths saturated with 70% isopropyl alcohol (IPA) per the instructions below:

1. Use one saturated disinfectant wipe or cloth to thoroughly wet the component surface.
2. Use a second saturated disinfectant wipe or cloth to remove any surface contaminants. Soil, etc., will impede the disinfectant's effectiveness, if not removed.

3. As needed, use additional saturated disinfectant wipes or cloths to keep the component surface wet for 10 minutes.

⚠ **Note:** Be sure to follow the Bioness instructions for the specified contact time to ensure an effective bacteria kill.

Clinician Kit Carrying Case

The StimRouter Clinician Kit carrying case may be cleaned and low-level disinfected using CaviCide® (Metrex, Orange, CA) or 70% isopropyl alcohol (IPA) per the instructions below:

CaviCide:

1. Spray the entire surface of the Clinician Kit carrying case with CaviCide.
2. Use a clean towel to remove any surface contaminants. Soil, etc., will impede the disinfectant's effectiveness, if not removed.
3. Spray the entire surface of the Clinician Kit carrying case again with CaviCide.
4. Keep spraying the entire carrying case surface as needed to keep it wet for 10 minutes.

70% IPA:

1. Wipe the entire surface of the Clinician Kit carrying case with a wipe or cloth saturated with 70% IPA.
2. Use a new wipe or cloth saturated with 70% IPA to remove any surface contaminants. Soil, etc., will impede the disinfectant's effectiveness, if not removed.
3. Wipe the entire surface of the Clinician Kit carrying case again with a new wipe or cloth saturated with 70% IPA.
4. Use additional new wipes or cloths as needed to keep the entire surface of the carrying case wet with 70% IPA for 10 minutes.

Note: Be sure to follow the Bioness instructions for the specified contact time to ensure an effective bacteria kill.

Note: Do not use other cleaning/disinfecting agents such as a diluted bleach mixture, Lysol or Clorox wipes. Bioness has not tested these products' effectiveness on the StimRouter components.

Metrex products are sold through authorized dealers worldwide; 70% IPA is widely available. If you need assistance, please contact your local distributor.

11

Troubleshooting

The tables at the end of this section describe the visual indicators that may appear on the clinician
programmer and patient programmer, and possible solutions for troubleshooting. In addition, this section describes solutions for the following scenarios that may arise during a programming

- The patient forgets to bring the patient programmer.
- The patient forgets to bring or has lost the EPT.
- The patient brings a new patient programmer and EPT.
- The patient forgets the StimRouter electrode.

Patient Forgets Patient Programmer

If a patient forgets to bring his or her patient programmer to a follow-up session, an alternate “clinic” patient programmer can be used. The clinic patient programmer must be reset and then registered to the patient’s EPT to proceed. Once the clinic patient programmer and patient’s EPT are registered, patient data stored on the EPT can be retrieved by the clinician programmer and new data can be stored on the EPT.

The patient will need to re-register his or her EPT and patient programmer later. The new data stored on the EPT will overwrite the data stored on the patient programmer.

Note: The information stored on an EPT will always overwrite the information stored on a patient programmer.

Using a Clinic Patient Programmer

To use a clinic patient programmer:

1. Connect the clinic patient programmer to the clinician programmer cradle.
2. Make sure the EPT and the patient programmer are charged (if not, connect them to a charger).
3. Make sure the patient programmer and the EPT are no more than a few inches apart and not touching.
4. From the TOOLS MENU, press “Reset Patient Programmer/EPT.”
5. Select “Reset the Patient Programmer” and press “Reset.”
6. The StimRouter application will detect the unregistered patient programmer and ask

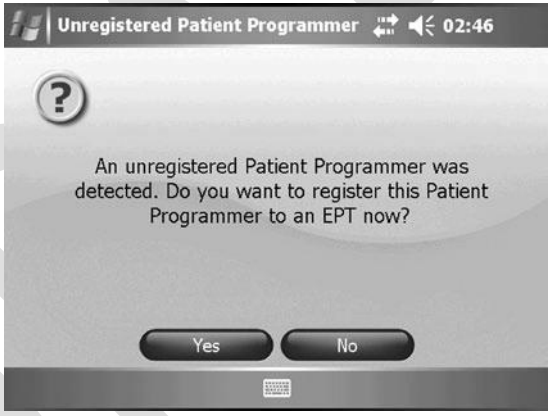


Figure 11-1. Unregistered patient programmer detected.

7. Press “Yes.”
8. Once the patient programmer and EPT are registered, press “OK.”
9.

10. From the Patient List, press “Open” to open the patient’s record.

Note: The patient Usage Log is stored on the EPT and is automatically retrieved when the patient programmer and EPT are connected.

11. Proceed with the programming session. Programming changes will be automatically saved to the EPT.
12. Before the session ends, remind the patient to re-register his or her EPT and patient programmer at home. Review with the patient the following instructions for RF registration.

Registering the Patient Programmer/EPT

The patient programmer and EPT must be electronically registered to each other to operate.

To register the patient programmer/EPT:

1. If necessary, charge the patient programmer.
2. Ensure that the patient programmer is turned off (the on/off button should not be FLASHING GREEN). See Table 11-1.

Patient Programmer OFF	Patient Programmer ON
	 Flashing Green

Table 11-1. Patient programmer on/off indicators.

3. Make sure the EPT is charged (if not, connect the EPT to a charger).
4. Place the patient programmer and the EPT close together on a table. Make sure the patient programmer and the EPT are no more than a few inches apart and not touching.
5. Make certain that any other EPT is at least 10 feet away from the components to be registered.
6. Simultaneously press and hold for three seconds the mode and minus buttons on the patient programmer to start the registration process. See Figure 11-2. The patient programmer will sound an audio alert, indicating the registration process has begun.
7. The patient programmer digital display should show two ALTERNATING GREEN ARCHES, indicating registration is in progress.

Figure 11-2. StimRouter Patient Programmer operating buttons and RF registration status indicators.

8. When the digital display shows the letter “C” and the RF icon turns GREEN for a few seconds, the registration procedure is complete.

Note: If the digital display shows the letter “E” and the RF icon turns RED for a few seconds, then an error has occurred and the procedure must be repeated. If the problem persists, reconnect the charger to the EPT. If the error indication continues to appear, see Table 11-7.

Patient Forgets EPT

If a patient forgets to bring his or her EPT to a follow-up session, reschedule the programming session. Do not substitute a clinic EPT for the patient’s EPT; only the patient programmer can be substituted. The information stored on an EPT will always overwrite the information stored on a patient programmer. If a clinic EPT is used, then the patient’s EPT will overwrite any new information stored on the patient programmer.

Patient Loses EPT

When a patient loses an EPT, he or she will need to electronically register the patient programmer and new EPT. See “Registering the Patient Programmer/EPT” section of this guide. All data stored on the patient programmer will copy to the new EPT. However, since the usage history is stored on the EPT, any usage history that was not copied to the clinician programmer database is lost with the lost EPT.

Patient Brings New EPT and New Patient Programmer

If a patient receives a replacement EPT and patient programmer, then the patient will need to return to the clinic. The patient data stored on the clinician programmer database must be copied to the new EPT and patient programmer.

Copying Patient Data to New Components

To copy patient data to new components:

1. Connect the patient programmer to the clinician programmer and the configuration cradle.
2. Make sure the patient’s EPT and the patient programmer are charged (if not, connect them to a charger).
3. Make sure the patient programmer and the EPT are no more than a few inches apart and not touching.
4. The StimRouter application will detect the unregistered patient programmer and ask whether you want to register this patient programmer to an EPT now.
5. Press “Yes.”
6. Once the patient programmer and EPT are registered, press “OK.”
7. 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 patient programmer and EPT.
8.

Patient Forgets StimRouter Electrode

If a patient forgets to bring his or her StimRouter electrode to a follow-up session, use a clinic StimRouter electrode or reschedule the programming session

Troubleshooting Wireless Technology

Clinician Programmer	Problems/Solutions
 **FLASHING RED Information Icon**	**A User-Correctable Error such as Faulty Electrode Contact, Radio Communication Failure** • Press the information icon to view the error message and list of solutions.
 **FLASHING YELLOW Information Icon**	**Low Battery Detected: EPT or Patient Programmer** • Press the information icon to view the error message and list of solutions. • Charge the patient programmer. • Charge the EPT.
 **RED Information Icon**	**Software or Hardware Error** • Press the information icon to view the error message and list of solutions.
Unexpected Error in the StimRouter Application	Contact your local distributor.
Clinician Programmer Will Not Turn On	• Press the clinician programmer reset button. • Charge the clinician programmer and verify that the amber LED is ON. If the light does not turn on, refer to the HP instructions for use. • Contact your local distributor.

Table 11-2. Troubleshooting, clinician programmer.

Tester	
Tester Will Not Buzz	• Check to see if EPT is charged. • Replace the tester.

Table 11-3. Troubleshooting, tester.

Patient Programmer Indicator	Problems/Solutions
Patient Programmer Will Not Turn On	**Battery Failure; Charger Failure; Patient Programmer Failure** • Charge the patient programmer. • Change the battery in the patient programmer. • Contact your local distributor.

Table 11-4. Troubleshooting, patient programmer.

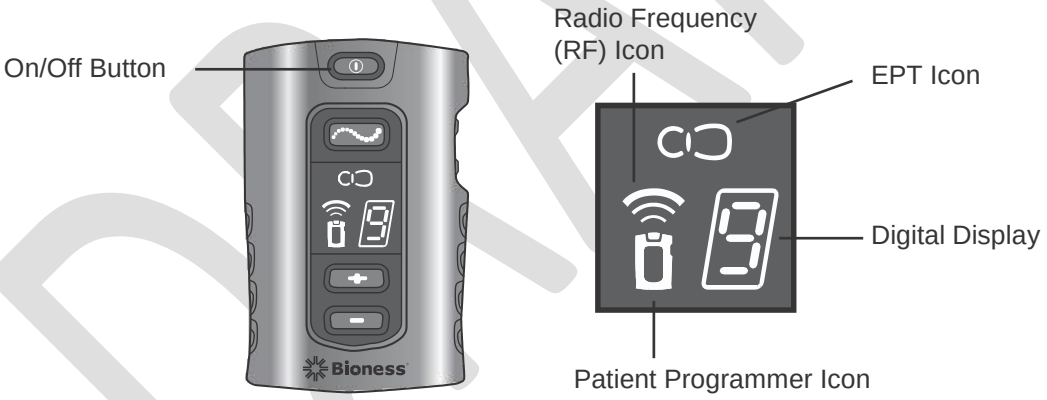


Figure 11-3. Patient programmer icons and digital display.

EPT Icon		Problems/Solutions
	EPT Icon FLASHES YELLOW	**EPT Battery Charge Level is Low** • Charge the EPT.
	EPT Icon GLOWS RED and “E” appears in the Digital Display	**EPT Malfunction** • • Contact your local distributor. .
	EPT Icon FLASHES RED and “E” FLASHES in the Digital Display	**EPT Temperature Error** • The EPT is either too hot or too cold and will cease activity until its working temperature range is restored. Restore the EPT to its working temperature range.
	EPT Icon FLASHES RED and Intensity Level FLASHES in the Digital Display	**Faulty Electrode Contact** • Turn off the patient programmer. • Remove the StimRouter electrode from the skin. • Check to see that the protective covers were removed from the StimRouter electrode. • Check to see that the EPT is correctly attached to the StimRouter electrode. If necessary, reattach the EPT into the StimRouter electrode. • Make sure that nothing is on the gel electrodes or on the skin that would interfere with electrode contact with the skin. • Re-adhere the StimRouter electrode to the skin. • Replace the StimRouter electrode. • Clean the skin.

Table 11-5. Troubleshooting, patient programmer, EPT icon.

Patient Programmer Icon	Problems/Solutions
 While Charging, Patient Programmer Icon GLOWS RED and “E” Appears in the Digital Display	**Charging Error** • Reconnect the charger cable to the patient programmer. • Replace the battery in the patient programmer.
 Patient Programmer Icon GLOWS RED and “E” Appears in the Digital Display	**Patient Programmer Malfunction** • Turn the patient programmer off and then back on. • Check to see if one of the buttons is stuck and, if so, try to release it. • Contact your local distributor.
 Patient Programmer Icon FLASHES YELLOW	**Patient Programmer Battery Charge Level is Low** • Charge the patient programmer.

Table 11-6. Troubleshooting, patient programmer, patient programmer icon.

RF Icon	Problems/Solutions
 RF Icon GLOWS RED and “E” Appears in the Digital Display Immediately After the Registration Attempt	**Registration Failure; Unknown Reason** • Retry the process.
RF Icon GLOWS RED, and “E” and then “2” Appear in the Digital Display Immediately After the Registration Attempt	**Registration Failure; More than One EPT Found** • Make sure only one EPT is within 10 feet of the patient programmer. • Retry the process.
RF Icon GLOWS RED, and “E” and then “0” Appear in the Digital Display Immediately After the Registration Attempt	**Registration Failure; No EPT Found** • Make sure the EPT is within inches of the patient programmer but not touching. • Connect the EPT to the charger. • • Retry the process.

RF Icon	Problems/Solutions
 RF Icon FLASHES RED	**Radio Communication Failure or EPT Battery Failure** • Make sure the patient programmer and EPT are within 10 feet of each other. • If the components are within range, then turn the patient programmer off and back on. • Connect the EPT to the charger.• Re-register the components. • Contact your local distributor

Table 11-7. Troubleshooting, patient programmer, RF icon.

EPT and Stimulation	Solutions
Stimulation Not As Effective As Usual	• Check the orientation of the StimRouter electrode, it should be over the receiver end of the lead. • Make sure the StimRouter electrode is securely adhered to the skin. • Visually inspect the StimRouter electrode to make sure the gel is aligned with the contour of the electrode. • Review the skin care instructions. • Clean the skin with a damp cloth. • Change the StimRouter electrode, if the skin is dry. • Trim hair from the StimRouter electrode site. • Test the EPT using the tester.
Undesirable Motor Response	• Decrease the stimulation intensity level. • Check the placement of the StimRouter electrode.
EPT Charging Light Does Not Turn On	• Check the connection. • Check the Y cable (disconnect it and connect charger directly). • Check that the charger light turns on. • Contact your local distributor.

Table 11-8. Troubleshooting, EPT and stimulation.

12

Technical Specifications

Wireless (RF) Communications Specifications

Capabilities	• Communication between the patient programmer and EPT • Communication between the Clinician Programmer and Bluetooth-enabled printer
Functions	RF Communication is used between the EPT and patient programmer, enabling the Clinician Programmer to perform the following functions: • Define stimulation parameters and programs (e.g., pulse width, amplitude) • Control stimulation (e.g., start/stop stimulation, change programs, adjust stimulation amplitude) • Display system status (e.g., battery charge level, error codes) • Retrieve patient stimulation session data Bluetooth communication is used between the clinician programmer and the HP printer to print stimulation parameters and use history.
Modes	• Online Clinician Programmer mode (Clinician Programmer connected to patient programmer and EPT)
Characteristics	EPT and patient programmer • Frequency band: 2.400 up to 2.4835 GHz • RF Frequency channels: 29 channels • Channel spacing: 580.810 kHz • Antenna type: Integrated chip antenna • Transceiver duplexing scheme: TDD • Frequency synthesizer settling time: < 1 msec • Modulation frequency: 0.5 Mbps • Modulation type: Minimum Shift Keying (MSK) • Transmit power (EIRP): EPT, -16 dBm; patient programmer, 4.1 dBm • Modulation baud rate: 500 kHz • Modulation bandwidth: 590 kHz Clinician Programmer • Bluetooth 2.0

Locations and Ranges	The patient programmer and EPT communicate when an object-free line of sight is available, up to 7 m distance between them. The communication range will be shortened if conductive objects, such as metal or the human body, are in the communication path between the patient programmer and EPT. The patient programmer alerts visually when loss of communication with the registered EPT occurs. Intermittent RF communication may also cause some delay in user-controlled operations.
Minimum Quality of Service	• Delay in delivery of RF command of <1 second • Packet error rate of <1%
Bluetooth Specifications	
Bluetooth Type	Class 2, Bluetooth v2.0
Frequency	2400 MHz to 2483.5 MHz (2.4 GHz Industrial Scientific Medical Band)
Modulation Scheme (automatically selected)	GFSK, pi/4-DQPSK, 8-DPSK
Maximum Data Rate	3 Mb/s
Maximum Power	4 dBm (2.5 mW)
Maximum Range	10 m
HP PDA iPAQ 210,	
Maximum Power	-3 dBm (0.5 mW)
Encryption	8 to128 bit encryption key
HP bt500 Bluetooth USB 2.0 Wireless Adapter	
Maximum Power	4 dBm (2.5 mW)
Encryption	8 to 128 bit encryption key

Troubleshooting Wireless Technology

The patient programmer will emit audio and visual alerts if RF communication fails. See below. Report problems your local distributor.

Privacy of StimRouter Wireless Communication

While the frequency band used by the StimRouter wireless system can be used by other users of the band, the privacy of the StimRouter wireless system is ensured by:

- The unique ID of paired components.
- Proprietary communication protocol.
- Use of randomized frequency channels (frequency hopping).
- Use of whitening function (data randomizing).
- Bluetooth communication is used exclusively in the clinician's office.
- Bluetooth serves for the communication between the Clinician's Programmer System (CPS) and a HP printer using a paired HP bt500 wireless adapter.

There is a risk of an interruption in the wireless communication resulting in the StimRouter system not responding to the user input.

 RF Icon FLASHES RED	**Radio Communication Failure or EPT Battery Failure** • Make sure the patient programmer and EPT are within 10 feet of each other. • If the components are within range, then turn the patient programmer off and back on. • Connect the EPT to the charger.• Re-register the components. Contact your local distributor.

13

Appendix - EMI Tables

Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The StimRouter 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 StimRouter patient programmer, EPT and clinician programmer, could affect medical electrical equipment. The RF-enabled components of the StimRouter 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.
RF emissions CISPR 11	Class B	
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 StimRouter system is intended for use in the electromagnetic environment specified below. The user of the StimRouter 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 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 StimRouter 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: UT is the a.c.mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration Electromagnetic Immunity

The StimRouter system is intended for use in the electromagnetic environment specified below. The customer or the user of the StimRouter 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 StimRouter system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF	3 Vrms	3 Vrms	Recommended separation distance (d) $d = 1.2\sqrt{P}$
IEC 61000-4-6	150 kHz to 80 MHz	150 kHz to 80 MHz	
Radiated RF	3 V/m	10 V/m	$d = 0.4\sqrt{P}$ 80 MHz to 800 Mhz
IEC 61000-4-3	80 Mhz to 2.5 GHz	26 MHz to 1 GHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
		3 V/m	
		1 GHz 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: 

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.

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

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

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.

14

Bluetooth Printer Set-Up

The StimRouter clinician programmer and a Bluetooth printer are Bluetooth-enabled devices. To communicate, the clinician programmer and the printer must be within 30 feet of each other and turned on.

Enabling Bluetooth

To set up a Bluetooth printer:

1. Turn the clinician programmer on, press “Start” and then “Settings.” See Figure 14-1.

Figure 14-1. Press “Start” and then “Settings.”

2. The Settings screen will open. Press the CONNECTIONS TAB and then the Bluetooth icon. See Figure 14-2.

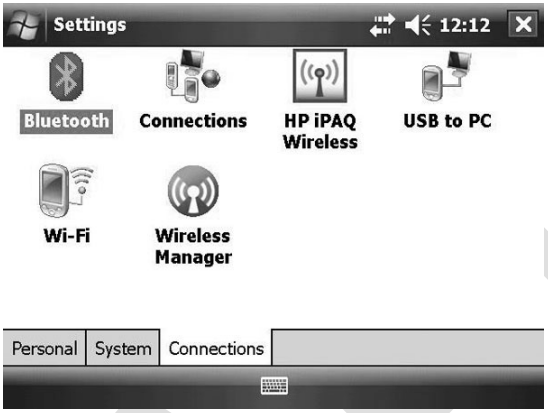


Figure 14-2. Press the Bluetooth icon.

3. From the GENERAL TAB, press “Turn on” (under “Bluetooth status”) and then the “Bluetooth Manager” hyperlink. See Figure 14-3.

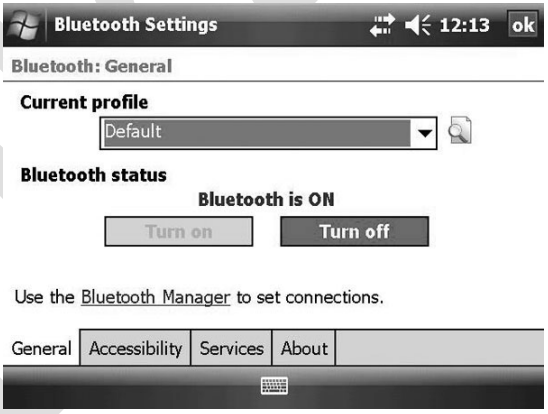


Figure 14-3. Press “Turn on.”

4. The Bluetooth Manager screen will open. Press “New.” See Figure 14-4.

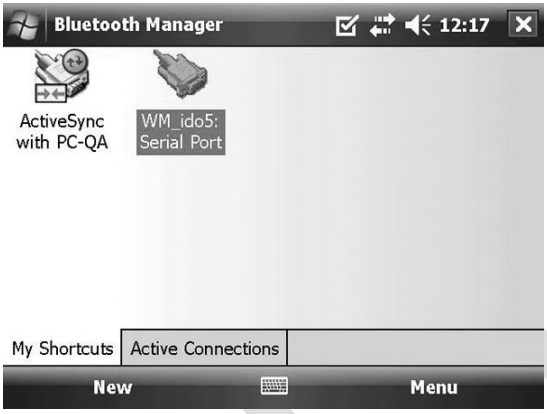


Figure 14-4. Press “New.” (Your screen icons may vary.)

5. The Connection Wizard will open. Press “Explore a Bluetooth device.” See Figure 14-5.

Figure 14-5. Press “Explore a Bluetooth device.”

6. Wait for the application to process, press “Officejet H470” and then “Next.” See Figure 14-6.

Figure 14-6. Press “Next.”

7. Press “Serial Port” under “Service Selection” and then “Next.” See Figure 14-7.

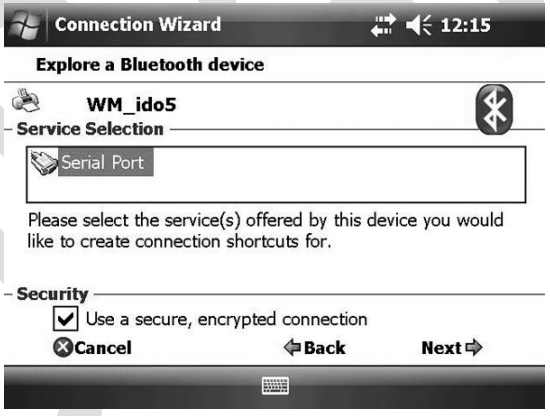


Figure 14-7. Press “Serial Port” and then “Next.”

8. Press “Finish.” See Figure 14-8.

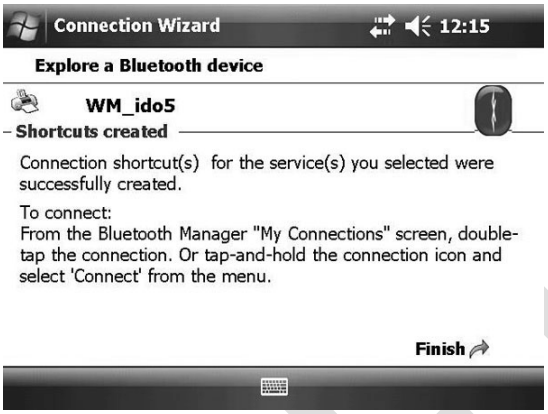


Figure 14-8. Press “Finish.”

Device Pairing

To pair the clinician programmer with a Bluetooth printer:

1. Return to the Bluetooth manager screen, and then press “Menu.” See Figure 14-9.

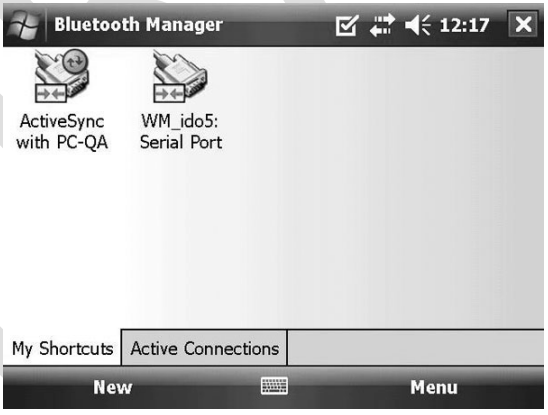


Figure 14-9. Press “Menu.” (Your screen icons may vary.)

2. From the pop-up menu, press “Paired Devices” and then “Add.”
3. Under “Bluetooth: Device Pairing” press the lookup icon (right of the “Device” field). See Figure 14-10.

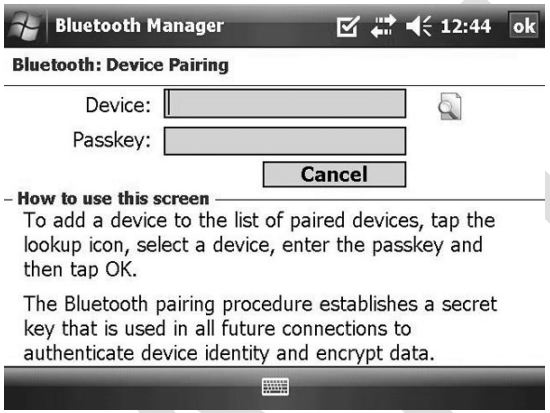


Figure 14-10. Press the lookup icon.

4. From the Bluetooth Browser, select “Officejet H470” and press “View.” See Figure 14-11.

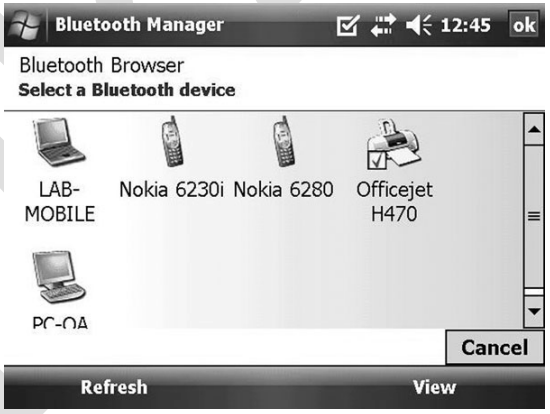


Figure 14-11. Select the Officejet H470 icon and then “View.”

5. Enter “0000” in the “Passkey” field and press “ok.” See Figure 14-12.

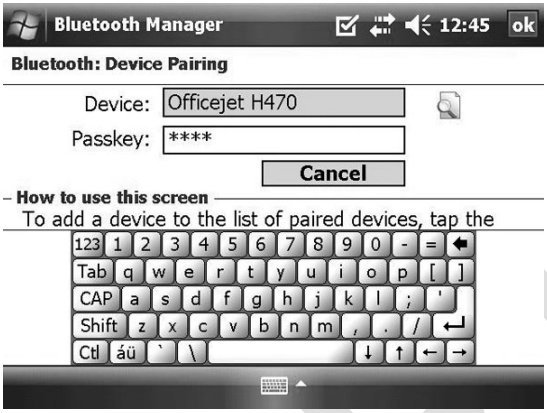


Figure 14-12. Enter “0000” in the “Passkey” field. Press “ok.”