StimRouter®
Neuromodulation System

User's Guide

Bioness®

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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.

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Conformity Certification

CE 0086

ETL CLASSIFIED
C ETL US
Intertek
3106069

Table of Contents

List of Symbols

	Caution
	Warning
	Class II Equipment (Double Insulated)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This Product Must Not Be Disposed of with Other Household Waste
	Refer to Instruction Manual/ Booklet
	Consult Instructions for Use
REF	Re-Order Number
LOT	Lot Number
SN	Serial Number
ETL CLASSIFIED c ETL us Intertek 3106069	Complies with United States and Canadian Product Safety Standards
	Single Patient Use
	Storage Temperature
CE 0086	Complies with the European Union Medical Device Directive
EC REP	European Authorized Representative
	Humidity Limitation
	Atmospheric Pressure Limitation
IPX3	Protection Against Ingress of Water
	Keep Dry
	Use By
	Quantity
Rx Only	Prescription Only

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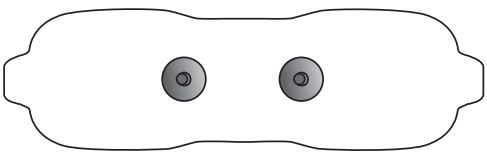
Introduction

The Bioness StimRouter Neuromodulation System is intended to help manage your pain. The StimRouter system works by providing electrical impulses to a target area in the body. These impulses are intended to interrupt or change the pain signals, inducing the feeling of tingling or numbness (paresthesia), and possibly reducing or replacing the feeling of pain. The StimRouter system includes:

- An implanted lead.
- An External Pulse Transmitter (EPT).
- A StimRouter Electrode.
- A Patient Programmer.

Lead



StimRouter Electrode

EPT

Patient Programmer

This guide includes important safety information about your StimRouter system, describes the external components of your StimRouter system that are used to stimulate the implanted lead, and reviews how to set up and use your system. Be sure to read this guide before using your StimRouter system. Ask your physician to explain and demonstrate any procedures you do not understand.

Note: Your StimRouter User Kit contains a Medical Device Identification (ID) Card. Complete your card as soon as possible and carry it with you at all times. Your Medical Device ID Card identifies you as a person with an implanted medical device.

You may need this card to bypass security screening devices, which are common at airports, grocery stores, libraries, etc. You may also need this card if you require medical treatment. This card includes the website address for Bioness. A copy of the StimRouter User's Guide is posted on the Bioness website.

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Warnings and Cautions

Be sure to follow your physician's guidance. Use your StimRouter system only as instructed in the User's Guide.

Indications for Use

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

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 StimRouter Electrode with External Pulse Transmitter 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.
- Patients 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 with bleeding disorders or active anticoagulation that cannot be stopped for a few days close to the time of the surgical procedure.
- Do not use the transmit/receive RF head coil if the StimRouter Lead is implanted above the shoulder.

⚠ Warnings

Magnetic Resonance Imaging (MRI) Warnings and Precautions

- An MRI examination performed on a patient with an implanted StimRouter Neuromodulation System Lead (i.e., StimRouter Lead) should only be done if there is a valid indication as determined by the supervising physician, and then only if all guidelines are carefully followed.
- All external components of the StimRouter system are contraindicated for the MR system room. Therefore, the StimRouter Electrode, External Pulse Transmitter, and Patient Programmer must be removed **before** the patient is allowed into the MR system room.
- Do not conduct an MRI examination on a patient with an implanted StimRouter Neuromodulation System Lead (i.e., StimRouter Lead) until you read and fully understand the information in the Clinician's Guide. Failure to follow all warnings and guidelines related to MRI can result in **SERIOUS INJURY** to the patient.
- The implanted StimRouter Lead should not be within transmit RF body coil unless the specific restrictions are followed for reduced radiofrequency (RF) power deposition (i.e., WBA SAR or B_{1+RMS} values) as presented in the Tables 2-1 and 2-2.
- Do not scan patients using a whole-body-averaged, specific absorption rate (SAR) level that exceeds 2 W/kg (i.e., with the MR system operating in the Normal Operating Mode). An MRI examination performed using a whole-body-averaged SAR above 2 W/kg may increase the risk of MRI-related heating, resulting in injury to the patient.

StimRouter External Component Restrictions

All external components of the StimRouter system are contraindicated for the MR system room. Therefore, the StimRouter Electrode, External Pulse Transmitter, and Patient Programmer must be removed before the patient is allowed into the MR system room.

MRI Safety Information

MRI Conditional

Non-clinical testing demonstrated that the StimRouter Lead is **MR Conditional**. A patient with an implanted StimRouter Lead can be scanned safely, immediately after implantation, under the following conditions:

- Static magnetic field of 1.5 T or 3 T, only
- Maximum spatial field gradient magnetic field of 2,500 gauss/cm (25 T/m)
- Specific conditions (see below) must be followed to ensure patient safety relative to the prevention of excessive heating of the StimRouter Lead
- If the entire StimRouter Lead is at least 50 cm away from the center of the bore of the MR system and the center of the transmit RF body coil, the reported, whole-body-averaged SAR must not exceed 2 W/kg at 1.5 T/64 MHz or a whole-body-averaged SAR of 2 W/kg at 3 T/128 MHz in the Normal Operating Mode of operation for the MR system
- Limit B1 and or SAR to values in Table 2.1 if the entire StimRouter is not at least 50 cm from the center of the MRI bore. (This is the Reduced RF Zone.)
- The patient must be conscious. Maintain communication with the patient so that the MRI examination can be terminated in the event of painful nerve stimulation or other adverse or unusual event
- Skin above StimRouter must not be in direct contact with the wall of the MRI bore. Use insulating padding of at least 1 cm thickness between the skin above StimRouter and the wall of the bore.
- Legs of patient do not touch each other.
- Arms of patient are not in contact with each other or the side of the body.
- MR system is in Normal Operating Mode for gradient magnetic fields.

Note: The precise anatomical position of the implanted StimRouter Lead is necessary to know prior to the MRI exam. Therefore, before initiating an MRI exam, the supervising clinician (e.g., the radiologist) should review the patient's Medical Device Identification Card, communicate directly with the implanting physician, and/or obtain an x-ray to determine the precise anatomic location of the implanted StimRouter Lead in the patient's body. Additionally, the patient must undergo a proper MRI screening procedure to determine the presence of a previously implanted (active or abandoned) medical device, including leads, lead extenders, lead adapters, and passive implants.

Position	WBA SAR 1.5 T	WB SAR 3 T	B1 +rms 1.5 T	B1 +rms 3 T
Upper Arm	0.4	0.6	1.2	0.7
Intercostal	0.4	0.6	1.2	0.7
Lower Leg	0.2	0.6	1.2	0.7
Upper Leg	0.4	0.6	1.2	0.7

Table 2.1. Whole body SAR and B1+rms limits for StimRouter inside the Reduced RF Zone, i.e. within 50 cm of center of the RF body coil. If B1+rms is not displayed on the MR system console, the whole bodySAR limit is to be used.

WARNING: If the StimRouter Lead is at least 50 cm from the center of the bore of the MR system and the center of the transmit/receive RF body coil, DO NOT perform an MRI exam on the patient above a whole-body-averaged SAR of 2 W/kg in the Normal Operating Mode for a 1.5 T/64 MHz or a 3 T/128 MHz MR system. For a StimRouter Lead implant located inside the Reduced RF Zone (see Figures and Tables in this Guide) a reduced value of the whole-body-averaged SAR or, alternatively, the value of the B_{1+RMS} must be utilized in order to ensure acceptable tissue temperature increases based on the MRI conditions that are used for the MRI exam.

The **"Reduced RF Zone"** is defined as the anatomic area of the patient that will receive the RF power deposition during an MRI exam. When all or part of the StimRouter Lead is within a 50 cm distance from the center of the bore of the MR system and the center of the transmit RF body coil, this is referred to as the "Reduced RF Zone." A reduced value of the whole-body-averaged SAR or, alternatively, the value of the B_{1+RMS} must be utilized in order to ensure acceptable tissue temperature increases based on the MRI conditions that are used for the MRI exam. See Tables 2-1 and 2-2 for the acceptable whole-body-averaged SAR and B_{1+RMS} values.

To ensure safety for a patient with an implanted StimRouter Lead, MRI healthcare professionals must adhere to the following conditions:

Using the Transmit Body RF Coil

When the entire StimRouter Lead is outside of the Reduced RF Zone and a receive-only RF coil is being used (note, any type of receive-only RF coil is permitted for use under these circumstances), the reported whole-body-averaged SAR must not exceed 2 W/kg at 1.5 T/64 MHz and 2 W/kg at 3 T/128 MHz (Figure 2-1). Do not perform MRI in patients using a whole-body-averaged SAR level that exceeds 2 W/kg. An MRI exam scan performed using a whole-body-averaged SAR level above 2 W/kg may increase the risk of unacceptable MRI-related heating of the implanted StimRouter Lead.

When all or part of the StimRouter Lead is inside the Reduced RF Zone (Figure 2-1), reduced values of the whole-body-averaged (WBA) SAR or the B_{1+RMS} value must be used to result in acceptable tissue temperature increases. See Tables 2-1 and 2-2 for the WBA SAR or the B_{1+RMS} recommended for use when all or part of the StimRouter Lead is within the Reduced RF Zone during the MRI exam.

Using the Transmit RF Body Coil and the Receive-Only RF Head Coil

When all or part of the StimRouter Lead is inside of the Reduced RF Zone and a receive-only RF head coil is being used (Figure 2-2), reduced values of the whole-body-averaged (WBA) SAR or the B_{1+RMS} value must be used to result in acceptable tissue temperature increases. See Tables 2-1 and 2-2 for the WBA SAR or the B_{1+RMS} recommended for use when all or part of the StimRouter Lead is within the Reduced RF Zone during the MRI exam. Do not use the transmit RF Body Coil if the StimRouter Lead is implanted above the shoulder.

Using the Transmit/Receive RF Head Coil

Limit the head SAR to 3.2 W/kg using the Normal Operating Mode of operation for the MR system if the StimRouter Lead is located in the patient's shoulder or a lower anatomic position (Figure 2-3).

As previously mentioned in the contraindication section, do not use the transmit/receive RF head coil if the StimRouter Lead is implanted above the shoulder. Please refer to Chapter 2 for a complete list of contraindications.

Using the Transmit/Receive RF Knee Coil

MRI scans with the Transmit/Receive RF Knee Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

Using the Transmit/Receive RF Hand/Wrist Coil

MRI scans with the Transmit/Receive RF hand/wrist Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

Using the Transmit/Receive RF Foot/Ankle Coil

MRI scans with the Transmit/Receive RF foot/ankle Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

Note: The StimRouter Lead is considered to be outside of the “Reduced RF Zone” if the entire lead is located outside of the transmit RF body coil as shown in Figures 2-1 and 2-2, StimRouter Lead (A).

Note: The bore dimensions of clinical MR systems and associated transmit/receive RF coils will vary according to the type of MR system used on the patient with the StimRouter Lead.

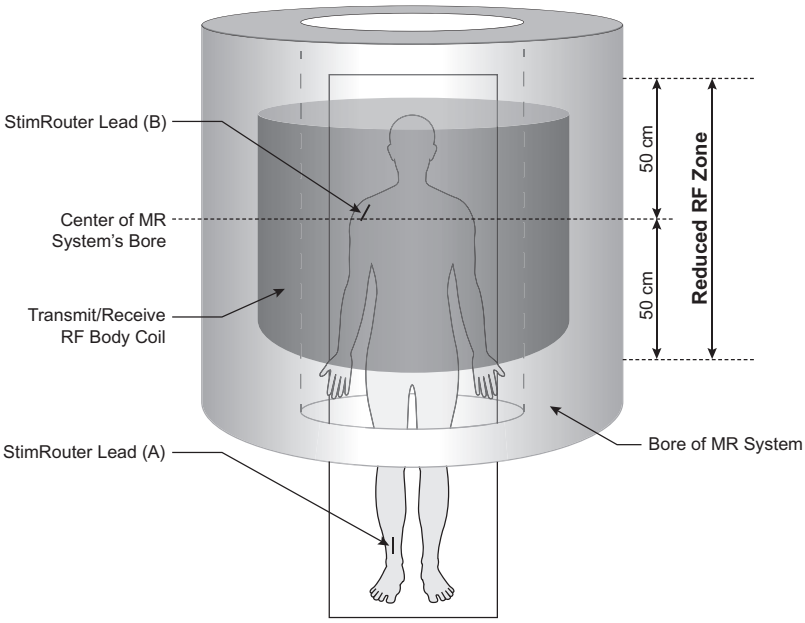


Figure 2-1: The StimRouter Lead (A) is located outside of the Reduced RF Zone and is more than 50 cm away from the center of the MR system's bore and the transmit/receive RF body coil. In this case, a whole-body-averaged SAR must not exceed 2 W/kg at 1.5 T/64 MHz or a whole-body-averaged SAR of 2 W/kg at 3 T/128 MHz in the Normal Operating Mode of operation for the MR system. The StimRouter Lead (B) is located inside of the Reduced RF Zone. The use of reduced WBA SAR or B_{1+RMS} values are required.

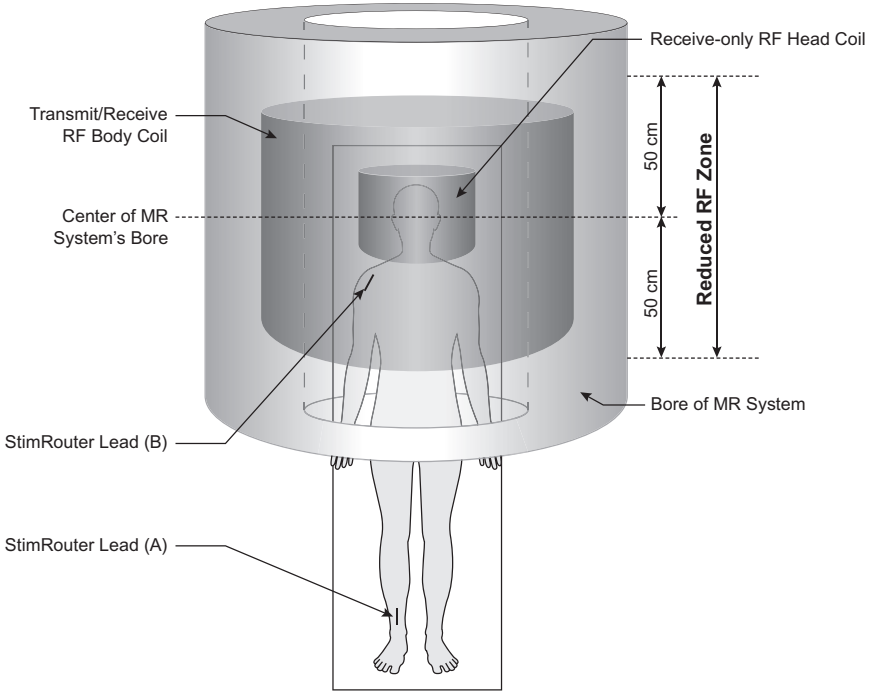


Figure 2-2: The transmit RF body coil and the receive-only RF head coil are being used with the StimRouter Lead (B) inside of the Reduced RF Zone. The use of reduced WBA SAR or B_{1+RMS} values are required.

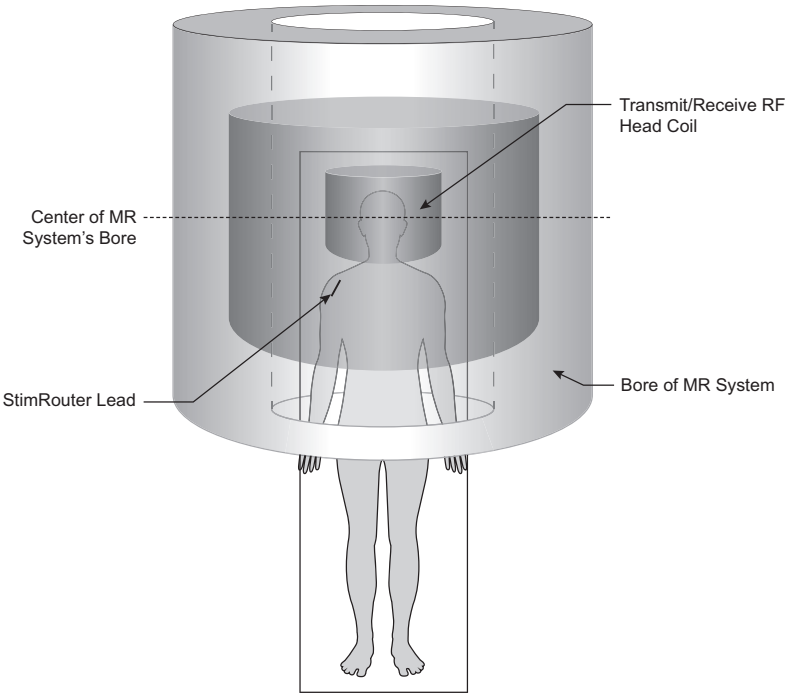


Figure 2-3: The transmit/receive RF head coil is being used.

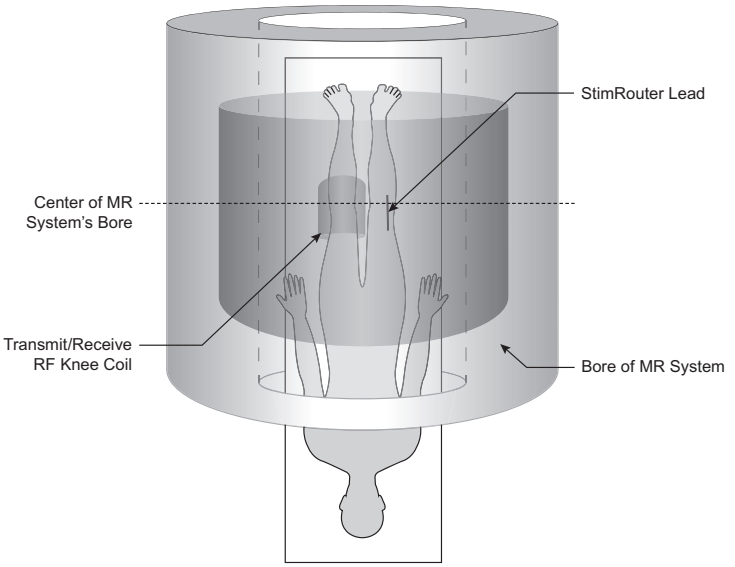


Figure 2-4: MRI scans with the Transmit/Receive RF Knee Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

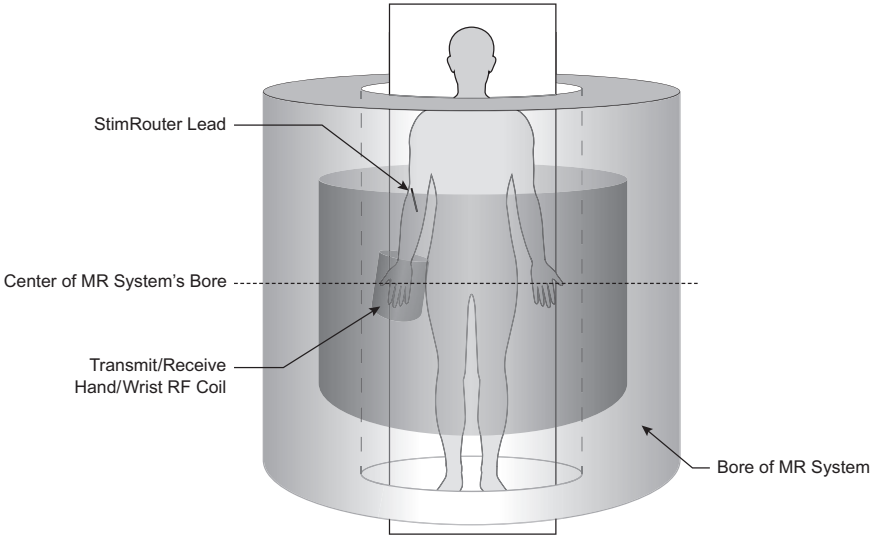


Figure 2-5: MRI scans with the Transmit/Receive RF hand/wrist Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

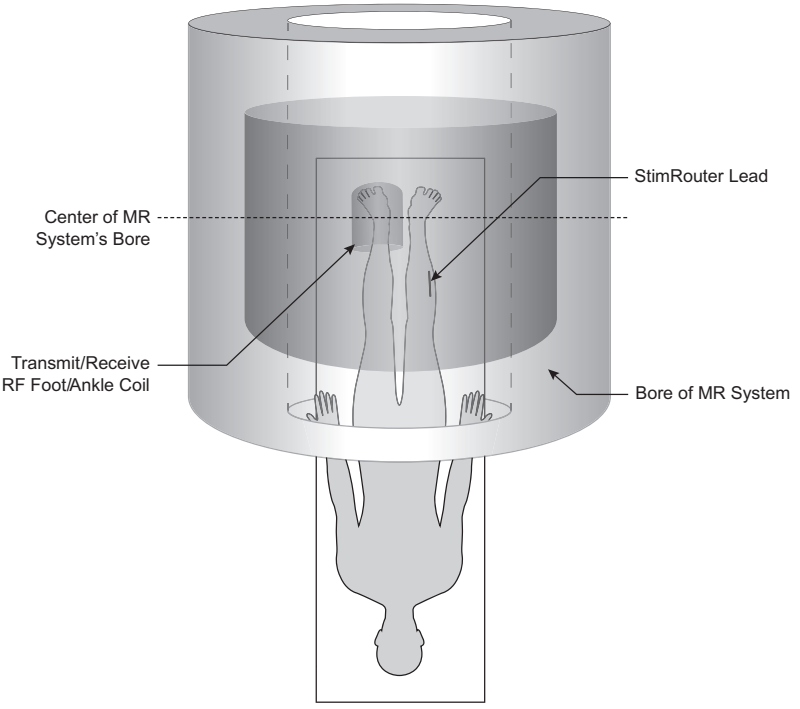


Figure 2-6: MRI scans with the Transmit/Receive RF foot/ankle Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

MRI-Related Heating of the StimRouter Lead: Supplemental Information

1.5 T/64 MHz

For situations where the entire StimRouter Lead is located **outside** of the Reduced RF Zone:

Temperature changes of the electrodes of the StimRouter Lead were measured at 1.5 T/64 MHz according to American Society for Testing and Materials (ASTM) International F2182 (i.e., using a 64-MHz transmit RF body coil). With the StimRouter Lead in an orientation and a position in the phantom[1] 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 the application of RF power. This temperature change was with the StimRouter Lead in an elongated, "straight" configuration (i.e., no

[1]A "phantom" is a container filled with gelled saline that allows for the testing of MRI-related heating for implants.

curves), which produced the highest temperature rise. With the StimRouter Lead in curved or looped configurations, temperature rises were less.

A computer simulation that incorporated the worst-case measured temperature rise at several anatomic locations and at a whole-body averaged SAR of 2 W/kg predicts a worst-case heating of an implanted StimRouter Lead in the patient during an MRI exam of less than 2°C after 15 minutes of continuous scanning (i.e., per pulse sequence) provided that the entire StimRouter Lead implant is outside of the Reduced RF Zone (see Figures 2-1 to 2-6).

For a StimRouter Lead implant located inside of the Reduced RF Zone, the worst-case heating was calculated to be less than 6°C for the values of whole-body-averaged (WBA) SAR and B1+RMS in Table 2.1.

3 T/128 MHz

For situations where the entire StimRouter Lead is located **outside** of the Reduced RF Zone:

Temperature changes of the StimRouter Lead electrodes were measured at 3 T/128 MHz according to ASTM International F2182 (i.e., using a 128-MHz transmit RF body coil). With the StimRouter Lead in an orientation and a position in the phantom[1] 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 application of RF power. The highest temperature rise occurred with the StimRouter Lead in an elongated, “straight” configuration (i.e., no curves). Temperature rises were less when the StimRouter Lead was in curved or looped configurations.

A computer simulation showed that there would be less than a 1°C heating of an implanted StimRouter Lead in the patient during an MRI exam, provided the entire StimRouter Lead implant was outside of the Reduced RF Zone (see Figures). The computer simulation incorporated the worst-case measured temperature rise at several anatomic locations and a whole-body-averaged (WAR) SAR of 2 W/kg.

For a StimRouter Lead implant located inside of the Reduced RF Zone, the worst-case heating was calculated to be less than 6°C for the values of whole-body-averaged (WBA) SAR and B1+RMS in Table 2.1.

Image Artifacts

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

Induced Currents

The electric fields induced in a patient with the StimRouter Lead by the time-varying, gradient magnetic fields used during MRI were calculated.

If the StimRouter Lead is at least 50 cm from the center of the bore of the MR system and outside the gradient coils of the MR system, the induced current will be less than the stimulation threshold. However, the induced current may reach the stimulation threshold if the StimRouter Lead is located less than 50 cm from the center of the bore of the MR system and the center of the transmit RF body coil (i.e., the approximate area inside the "Reduced RF Zone").

⚠ **CAUTION:** Electrical current induced in the StimRouter Lead during MR procedure may cause stimulation of the nerves proximal to the lead causing sensation, motor response, or nerve blocking.

Potential Adverse Events

The utilization of MRI could result in excessive heating of the StimRouter Lead if all MRI parameters and conditions of use are not carefully followed.

Induced voltages in the StimRouter Lead may occur due to the time-varying, gradient magnetic fields of the MR system, possibly causing uncomfortable levels of neurostimulation.

Note: Since the StimRouter Lead is not a life-sustaining device, it could be explanted from the patient prior to an MRI exam and re-implanted after the MRI exam.

Pregnancy

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

Long-Term Effectiveness of Neurostimulation

The long-term effectiveness of neurostimulation is not known.

Programming

Only your physician should program the StimRouter system.

Device Components

Use only Bioness components with your StimRouter system. Use of non-Bioness components may damage the system and cause injury.

No modification of this equipment is allowed.

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

Flammable Fuel, Chemicals or Environment

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

Turn off the Patient Programmer and stimulation when you are near a refueling station, flammable fuel, fumes or chemicals. If your system is on, it could ignite the chemicals or fumes, causing severe burns, injury or death.

Driving and Operating Machinery

Turn off stimulation while driving or operating machinery.

Electromagnetic Compatibility Warnings

Medical Devices/Therapies

Operation of the StimRouter system in close proximity (e.g., 1 meter) to shortwave or microwave therapy equipment may produce instability in the EPT output.

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

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

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

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

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

Electrosurgery Devices

If you require electrosurgery, tell your physician you have an implanted lead. Electrosurgery devices should not be used close to an implanted StimRouter lead. Contact between an active electrode of the electrosurgery device and the implanted lead can stimulate the lead and cause severe injury.

High-Frequency Surgical Equipment

Remove the StimRouter electrode before medical treatment. If you are connected to the StimRouter system and high-frequency surgical equipment, you may experience a skin burn where the gel electrodes adhere. Also, the StimRouter EPT may become damaged.

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 a pain pump or 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 StimRouter system and all other electronic devices. See the “Troubleshooting” section for help. See the “Appendix” for more information.

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

Security Screening Devices

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

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

Cell Phones

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

Precautions

Post-Operative Care

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

Contact your physician immediately if you have:

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

Known or Suspected Heart Problems

Consult your physician if you have or suspect you have a heart condition. Physicians should use caution when treating patients with suspected or diagnosed heart problems.

Implant Failure

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

Postural Changes

Changes in posture or abrupt movements may change the stimulation you feel. Turn off stimulation before stretching or exercising.

For Single Patient Use Only

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

Keep Out of Reach of Children

Keep all StimRouter components out of the reach of children.

Skin Abnormalities

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

Skin Irritation

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

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

Sensations Caused by Stimulation

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

StimRouter Electrode Expiration Date

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

StimRouter Electrode Placement and Stimulation

- Use only StimRouter Electrodes manufactured by Bioness Inc.
- Only your physician should decide where to place the StimRouter Electrode.
- Only your physician should program your StimRouter system.
- Turn off stimulation before adhering, removing or handling the StimRouter Electrode.
- Do not adhere the StimRouter Electrode across your chest or near your heart. Electrical stimulation of the heart may disturb heart rhythm.
- Apply user patch only to the areas recommended by your physician. Avoid placing the user patch across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus).
- Do not adhere the StimRouter Electrode over anything other than skin. Do not adhere it over an adhesive bandage, for example. The StimRouter Electrode must be in full contact with the skin or the stimulation could cause serious injury.
- Do not place the StimRouter Electrode over skin folds, scarred tissue, irritated skin, uneven skin surfaces or broken skin.
- Always check the StimRouter Electrode gel pads before use. Do not use the StimRouter Electrode if the gel appears dry, worn, dirty or irregular.
- Remove the clear protective cover from the StimRouter Electrode before using.
- Do not handle the StimRouter Electrode with both hands while stimulation is on. Serious injury can occur if electrical current passes through your heart.
- Do not apply the StimRouter Electrode to anyone else or any other part of the body than that determined by your physician.

Storage and Handling

Handle all StimRouter components with care. Dropping components on hard surfaces, or other rough handling, can damage them. Avoid exposing them to extreme temperatures or moisture.

Protect all StimRouter components from contact with water, such as from sinks, bathtubs, shower stalls, rain and snow.

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

External Pulse Transmitter (EPT) Storage Temperature Range: -20°C to +60°C (-4°F to +140°F)

Patient Programmer Storage Temperature Range: -20°C to +60°C (-4°F to +140°F)

Adverse Effects

In the unlikely event that any of the following occurs, stop using your StimRouter system, remove the StimRouter Electrode and immediately contact your physician.

Risks Related to the Implant Procedure

If the lead is not placed properly, it may need to be removed or your therapy may need to be adjusted. Nerve injury is possible, although unlikely. Possible surgical complications include infection and device rejection. Contact your physician immediately if you experience fever, swelling, bleeding or prolonged pain at the implant site.

Risks Related to Stimulation

- Stimulation of skin and muscles surrounding the lead may cause increased pain.
- You may have undesirable movements during stimulation. If this occurs please contact your physician.

If you experience any discomfort during stimulation, or notice any skin abnormalities:

- Stop stimulation immediately.
- Remove the StimRouter Electrode.
- Notify your physician.

Additional Risks Related to the StimRouter System

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

If you experience any discomfort during stimulation, or notice any skin abnormalities:

- Stop stimulation immediately.
- Stop contact with the StimRouter components.
- Notify your physician.

3

Clinical Experience

A clinical trial was conducted to evaluate the safety and effectiveness of the StimRouter System for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy. Ninety-four (94) subjects with intractable chronic pain were enrolled in the study, each of whom was implanted with a StimRouter Lead and randomly assigned to a treatment group or control group. The 45 subjects in the treatment group received active stimulation, and the 49 subjects in the control group received no stimulation. After three months, control group subjects crossed over to the treatment group and began to receive stimulation. Subjects recorded and reported pain on a numeric rating scale at a baseline evaluation prior to lead placement and at follow-up evaluations after lead placement. Adverse events were also reported at these follow-up evaluations, which were conducted approximately 1, 2, 3, 6, and 12 months after subjects were assigned to the treatment or control group.

Safety

The safety of the StimRouter System is based on all 94 patients implanted with a StimRouter lead. Of the 94 subjects implanted with the StimRouter lead, none experienced unanticipated or serious adverse events related to the device or therapy. Fifty-one (51) adverse events in 27 subjects were considered to be related to the device or therapy. The adverse events included: pain, numbness, bruising, or muscle spasm related to patch/stimulation (19 events); localized skin reaction related to stimulation site (18 events); post-procedure pain/swelling/pain at implant site (9 events); receiving end of lead exposed (2 events); lead broke during explant, leaving partial implant (1 event); infection at incision site post-implant (1 event); and nausea (1 event).

Effectiveness

Seventeen (37.8%) of the 45 subjects in the treatment group achieved 30% or greater reduction in pain, compared to 5 (10.2%) of 49 subjects in the control group. Because nerve stimulation creates a sensation in the affected area, it is possible that some subjects knew whether they were in the treatment or control group, which could cause the study results to overstate the difference in benefit between the control and treatment groups.

4

Environmental Conditions that Affect Use

Storage and Handling

Keep all of the StimRouter components dry and protect them from extreme changes in temperature and humidity. Do not use or store your components where they could come in contact with water, such as by sinks, bathtubs and shower stalls, or expose them to weather conditions such as rain or snow. Do not store your StimRouter components in a car where they can be exposed to extreme hot or cold temperatures.

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

Radio Communication Information

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

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

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

Changes to the StimRouter system not approved by Bioness could void your authority to operate the equipment.

Electromagnetic Emissions

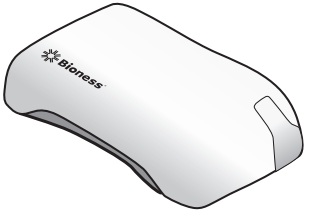
The StimRouter system is medical electrical equipment and was tested for electromagnetic compatibility (EMC) in accordance with International Electrotechnical Committee (IEC) 60601-1-2. The StimRouter system should be configured and used in accordance with the instructions provided in this manual.

5

StimRouter User Kit

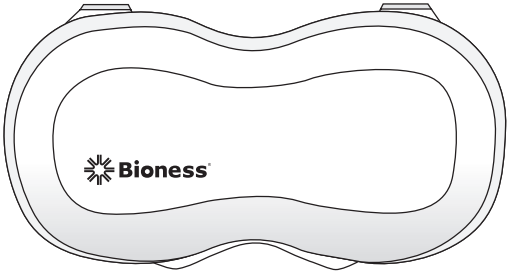
Your StimRouter User Kit includes the following:

- External Pulse Transmitter (EPT)
- Patient Programmer
- System Charger Set
- Patient Programmer Neck Strap
- Patient Programmer Wrist Strap
- StimRouter Electrode Carrying Case
- User's Guide
- User's Reference Card
- Medical Device Identification Card

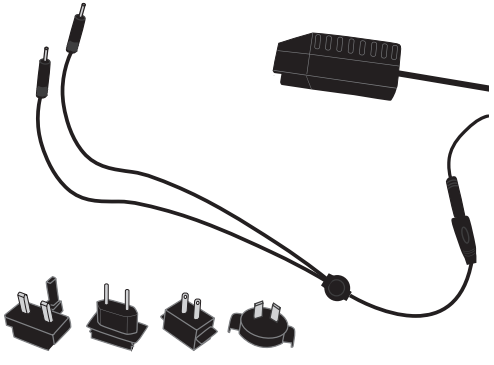


External Pulse Transmitter (EPT)

Patient Programmer

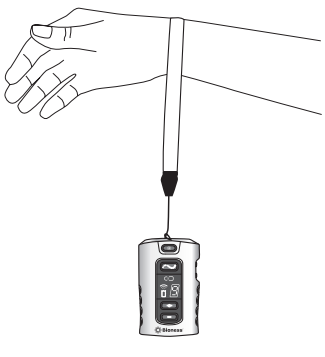


StimRouter Electrode Carrying Case



System Charger Set

Neck Strap



Wrist Strap

6

Device Description

This section describes the StimRouter Lead, External Pulse Transmitter (EPT), StimRouter Electrode and Patient Programmer.

StimRouter Lead

The StimRouter Lead is flexible and approximately 15 cm (6 in.) in length. The lead has a stimulation end and a receiver end. The stimulation end is implanted near or at the targeted peripheral nerve and the receiver end is implanted near the skin surface. The receiver end receives the stimulation signal from the EPT and then sends the signal through the lead to the stimulation end. See Figure 6-1.

Figure 6-1: The StimRouter Lead.

StimRouter External Pulse Transmitter (EPT)

The StimRouter EPT generates the stimulation signal and transmits the signal through the StimRouter Electrode to the StimRouter Lead. The EPT snaps onto the StimRouter Electrode (See Figure 6-2) and responds to wireless commands from the Patient Programmer.

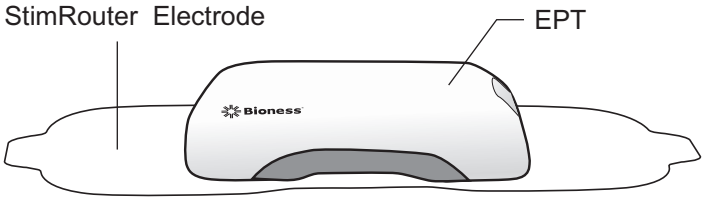


Figure 6-2: The EPT attached to the StimRouter Electrode.

Charging Socket and Charging Light

The EPT charging socket is located on the front panel of the EPT under the flexible cover. When the EPT is charging a green charging light will appear on the side panel of the EPT. See Figure 6-3.

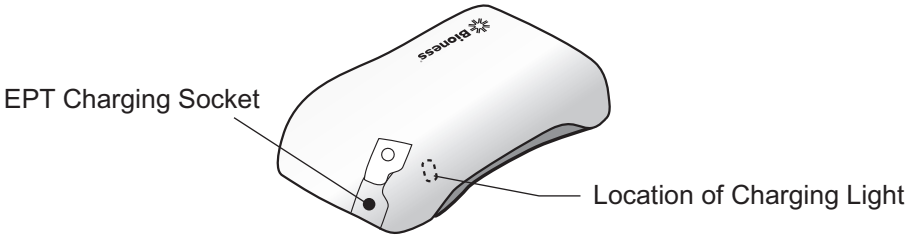


Figure 6-3: The EPT charging socket and charging light location.

StimRouter Electrode

The StimRouter Electrode features: (See Figure 6-4)

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

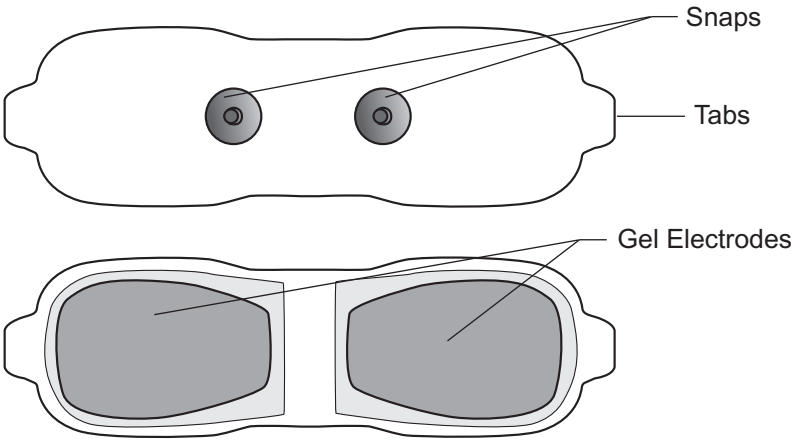


Figure 6-4: StimRouter Electrode (top and bottom views).

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

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

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

StimRouter Electrode Liner

Every StimRouter Electrode is shipped with an electrode liner. See Figure 6-5. The liner is used to keep the gel pads on the StimRouter Electrode from drying out.

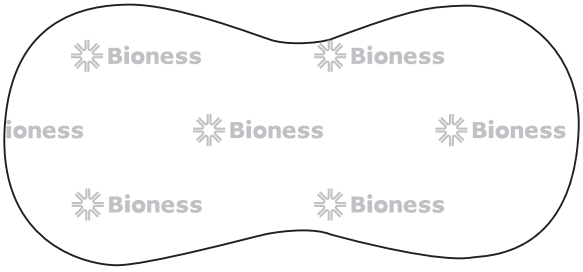


Figure 6-5: StimRouter Electrode liner.

Always store the StimRouter Electrode with the liner attached. Store the liner in the StimRouter Electrode Carrying Case between uses, to keep the liner clean and protected.

A liner can be reused for as long as it can adhere to the entire surface of the gel pads on the back of the StimRouter Electrode.

StimRouter Electrode Carrying Case

The StimRouter Electrode Carrying Case is used to store the EPT, StimRouter Electrode and the StimRouter Electrode liner. See Figure 6-6.

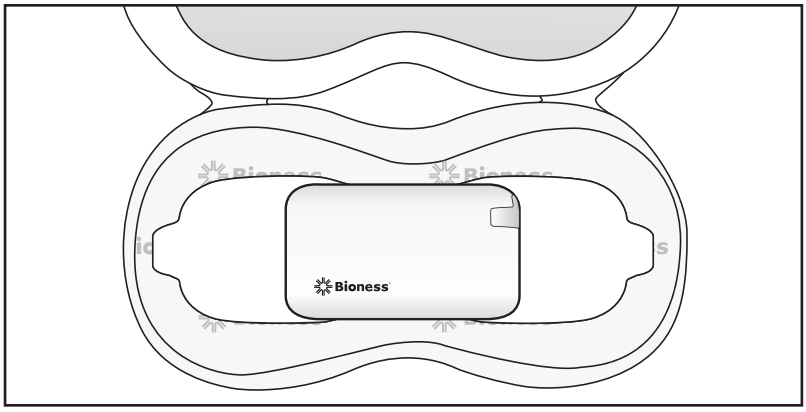


Figure 6-6. Inside of the StimRouter Electrode Carrying Case.

StimRouter Patient Programmer

The StimRouter Patient Programmer communicates wirelessly with the StimRouter EPT.

The Patient Programmer is used to:

- Turn stimulation on and off.
- Adjust stimulation intensity.
- Select a stimulation program.

Operating Buttons

The Patient Programmer operating buttons are shown in Figure 6-7.

On/Off Button

The on/off button is used to turn the Patient Programmer and EPT on and off.

Mode Button

The mode button is used to select one of three operating modes: standby, program or stimulation.

Plus/Minus Buttons

The plus and minus buttons are used to increase or decrease stimulation intensity and to select a stimulation program. The minus button is also used to save a preferred stimulation intensity level.

Volume Buttons

The volume buttons are used to increase, decrease and mute the sound level of the audio alerts.

Figure 6-7: Patient Programmer operating buttons.

Operating Modes

The Patient Programmer has three operating modes: standby, program and stimulation.

Standby Mode

In standby mode, the Patient Programmer is ON and ready for commands. The Patient Programmer turns on in standby mode and returns to standby mode when program mode and stimulation mode are exited.

Program Mode

In program mode, a user may select between different stimulation programs.

Stimulation Mode

In stimulation mode, the StimRouter components are stimulating the target treatment area. The user can adjust the intensity level of stimulation.

Indicator Lights

The Patient Programmer has three indicator lights. See Figure 6-8.

Patient Programmer Indicator Light

On/Off button FLASHES GREEN when the Patient Programmer is ON.

Stimulation Indicator Light

Mode button FLASHES YELLOW when stimulation is ON.

Program Mode Indicator Light

Mode button GLOWS YELLOW when program mode is selected.

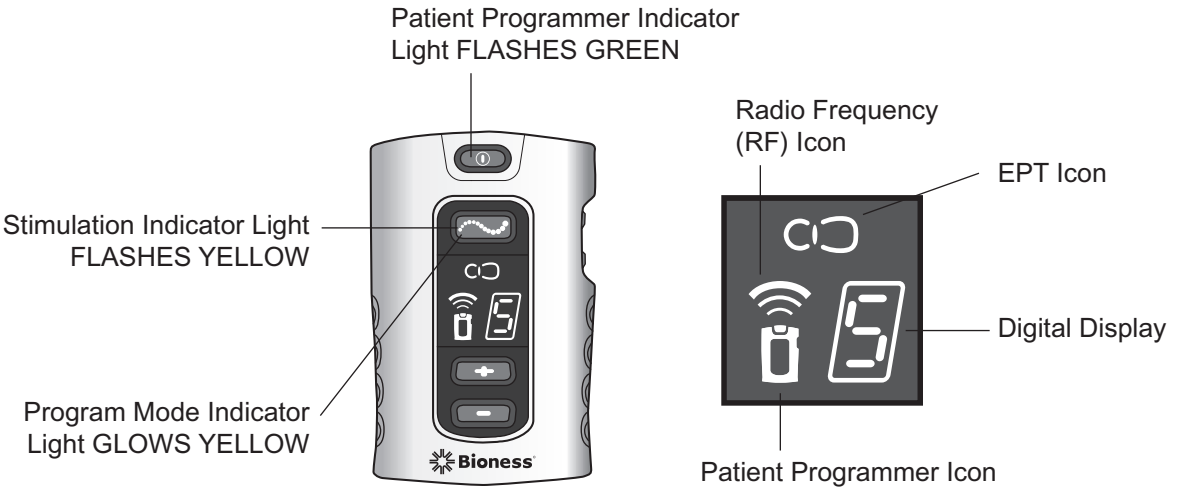


Figure 6-8: Patient Programmer indicator lights, information icons and digital display.

Information Icons

The Patient Programmer has three information icons. See Figure 6-8.

Patient Programmer Icon

- FLASHES YELLOW when the Patient Programmer battery charge level is low.
- GLOWS RED to indicate a Patient Programmer error and, when “E” appears in the digital display while charging, a battery charging error.

EPT Icon

- FLASHES RED to indicate faulty electrode contact and, when “E” flashes in the digital display, that the temperature of the EPT is out of range.
- GLOWS RED to indicate an EPT error. (“E” appears in the digital display as well.)
- FLASHES YELLOW when the EPT battery charge level is low.

Radio Frequency (RF) Icon

- FLASHES RED to indicate an RF communication error.
- GLOWS GREEN for a few seconds to indicate RF registration is complete. (“C” also appears in the digital display.)
- GLOWS RED for a few seconds and “E” appears in the digital display to indicate an RF registration error.
- GLOWS RED for a few seconds, and “E” and then “0” appear in the digital display to indicate an RF registration error: no EPT detected.
- GLOWS RED for a few seconds, and “E” and then “2” appear in the digital display to indicate an RF registration error: multiple EPTs detected.

Digital Display

The Patient Programmer digital display indicates stimulation intensity level, program selection, system errors, charging status and RF registration status. See Figure 6-8.

Stimulation Intensity Level

The stimulation intensity level is displayed as a number ranging from “0” to “9,” with “0” equaling no stimulation.

Program Selection

The selected program is displayed as a letter, ranging alphabetically from “A” to “H.” See Figure 6-9. Only programs set by your physician can be selected.

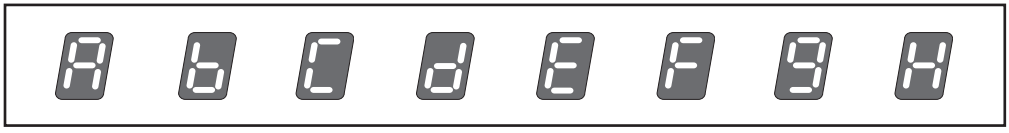


Figure 6-9: Stimulation programs A through H, as represented on the Patient Programmer digital display.

System Errors

If an “E” appears in the digital display and one of the information icons (EPT icon, RF icon or patient programmer icon) is GLOWING or FLASHING RED, an error has occurred. For more information on error indicators, please refer to the “Troubleshooting” chapter in this guide.

Charging Status

When the Patient Programmer is charging, a small GREEN LOOP CIRCLES in the digital display. The loop appears in the lower half of the digital display when the charge level is low. The loop appears in the upper half of the digital display when the charge level is high.

When the Patient Programmer battery is fully charged, a HORIZONTAL GREEN LINE appears in the digital display until the charger is disconnected.

A charging error is indicated by an “E” in the digital display while charging. See Figure 6-10.

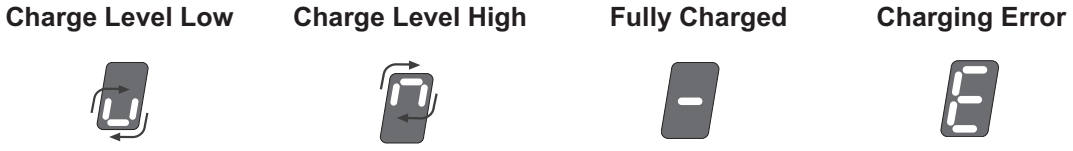


Figure 6-10: Charging status indicators, as represented in the Patient Programmer digital display.

Audio Alerts

The Patient Programmer emits a variety of audio alerts to signal updates, changes and errors.

An audio alert may signal that:

- The Patient Programmer has been turned on/off.
- A mode has been changed.
- A button has been pressed.
- The stimulation program's total time has elapsed.
- The Patient Programmer battery charge level is low.
- The Patient Programmer battery is fully charged.
- The electrode contact is faulty.
- The EPT battery level is low.
- The EPT or Patient Programmer has experienced an error.
- The Patient Programmer charger has been connected/ disconnected.

Charging Socket

The Patient Programmer charging socket is located at the bottom of the Patient Programmer, under the flexible cover. To expose the charging socket, open the cover. See Figure 6-11.

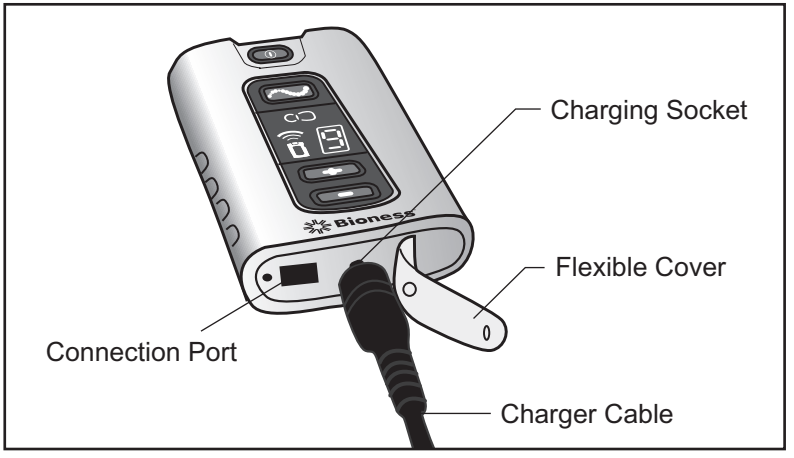


Figure 6-11: Patient Programmer charging socket and connection port.

Connection Port

The connection port of the Patient Programmer is also located at the bottom of the Patient Programmer, under the flexible cover. The connection port is used to connect the Patient Programmer to the configuration cradle and clinician programmer during a programming session. See Figure 6-11.

Battery Compartment

The Patient Programmer battery compartment is opened from the back of the Patient Programmer. The battery compartment contains a rechargeable AAA NiMH battery. For battery replacement instructions, see “Replacing the Patient Programmer Battery” section of this guide.

Patient Programmer Neck and Wrist Straps

Your User Kit includes a Patient Programmer neck strap and wrist strap for carrying the Patient Programmer. See Figure 6-12.

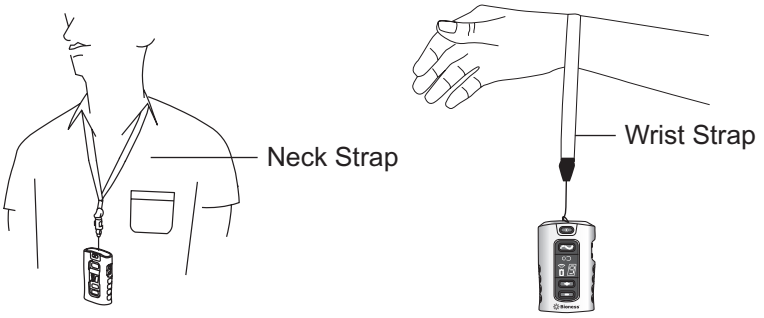


Figure 6-12: StimRouter Patient Programmer accessories.

System Charger Set

The system charger set is a plug-in AC/DC adapter that connects to a main power supply and includes a “Y” cable, a charger, and interchangeable blades for U.S. and international outlets. The system charger set is used to charge the Patient Programmer and EPT battery. See Figure 6-13.

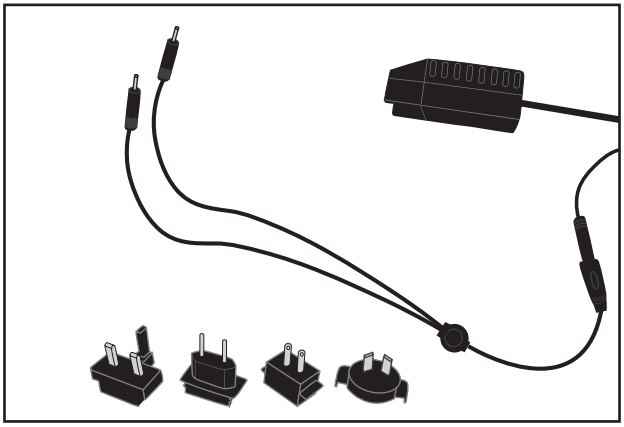


Figure 6-13: System charger set.

⚠ **CAUTION:** Use only the charger included in your StimRouter System Kit. Use of any other charger could damage the system.

⚠ **CAUTION:** To completely disconnect the power input, the AC/DC adapter portion of the system charger set must be disconnected from the main power supply.

7

Set-Up Instructions

Charging the Patient Programmer and EPT

The Patient Programmer comes with a rechargeable AAA NiMH battery installed. The EPT comes with a rechargeable Lithium Polymer battery installed. Charge the Patient Programmer daily and when the patient programmer icon on the Patient Programmer display FLASHES YELLOW. Charge the EPT daily and when the EPT icon on the Patient Programmer display FLASHES YELLOW.

Note: Charge the Patient Programmer for at least four hours and the EPT for at least two hours immediately before a programming session.

WARNING: Use only the charger included in the StimRouter User Kit. Use of any other charger could result in serious injury. (Refer to Manufacturer Model No. FRIWO FW7555M/05.)

To charge the Patient Programmer and EPT:

1. Open and assemble the System Charger Set. The System Charger set comes with interchangeable blades for U.S. and international outlets. Select the appropriate blade that fits the chosen power outlet and slide the blade onto the end of the charger. Then connect the “Y” cable to the charger cable.
2. Open the flexible cover on the bottom of the Patient Programmer and on the front panel of the EPT.
3. Connect the “Y” cable to the patient programmer and EPT. See Figure 6-1
4. Plug the charger into a power outlet.
5. Monitor the Patient Programmer digital display. When the Patient Programmer is charging, a small GREEN LOOP circles in the digital display. The loop appears in the lower half of the digital display when the charge level is low. The loop appears in the upper half of the digital display when the charge level is high. See Table 7-1.

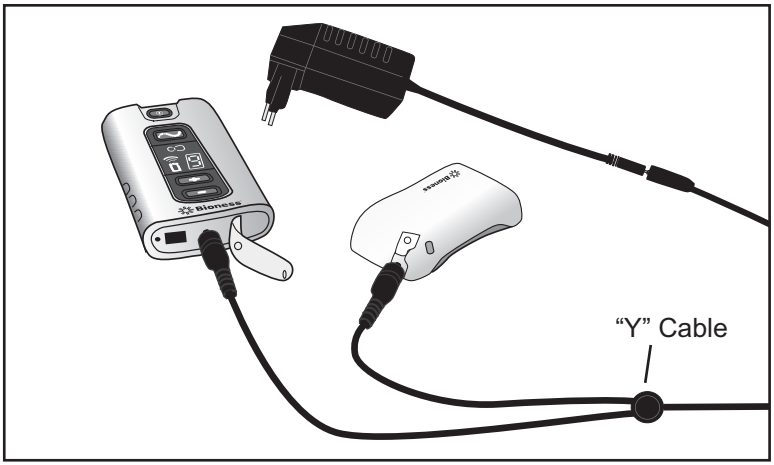


Figure 7-1: Charging set-up.

Charge Level Low	Charge Level High	Fully Charged	Charging Error
			

Table 7-1: Patient Programmer charging indicators, as shown in the digital display.

6. The charging process for the Patient Programmer should last approximately four hours. When the battery is fully charged, a HORIZONTAL GREEN LINE appears in the digital display until the charger is disconnected.
7. If an “E” appears in the digital display on the Patient Programmer and the patient programmer icon glows red while charging, then a charging error has occurred. The battery may need to be repositioned or replaced.
8. A constant green light will appear on the EPT when charging. When the battery is fully charged the green light flashes. The charging process should last approximately one to two hours.

Note: It is possible to charge the Patient Programmer and EPT separately, but Bioness recommends that the Patient Programmer and EPT be charged at the same time.

Preparing the Skin

The skin below the StimRouter Electrode should be clean and dry, and free from irritation, infection or injury. It is important to develop a good skin care daily routine and to follow the steps listed in this section. Always check your skin before using the StimRouter system. If you have any concerns, contact your physician.

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

To prepare the skin:

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

Connecting the StimRouter Electrode and EPT

To connect the StimRouter Electrode and EPT:

1. Obtain a new StimRouter Electrode or one with gel pads that can still fully adhere to the skin.
2. Check the “Use by” date on the StimRouter Electrode box.
3. Do not remove the liner at this time.
4. Set the StimRouter Electrode on a flat surface with the gel pads facing down.
5. Snap the EPT onto the StimRouter Electrode. See Figure 7-2.

Note: To ensure proper stimulation, the EPT must be connected to the StimRouter Electrode properly.

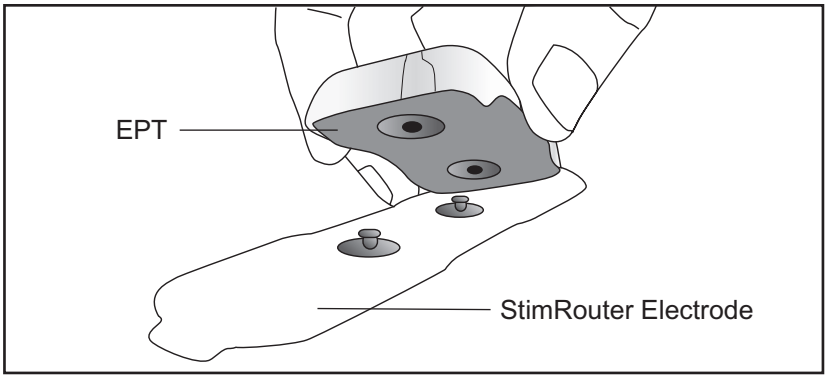


Figure 7-2: StimRouter EPT and StimRouter Electrode connecting.

Adhering the StimRouter Electrode

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

WARNINGS:

- Do not touch the gel pads of the StimRouter Electrode with both hands while stimulation is on. Serious injury can occur if electrical current passes through your heart.
- Turn stimulation off before adhering, removing or handling the StimRouter Electrode.
- Do not pinch or stretch the skin while adhering the StimRouter Electrode.
- If the gel pads start to peel off at the edges or detach from the StimRouter Electrode, immediately dispose of and get a new StimRouter Electrode.

To adhere the StimRouter Electrode:

1. Remove the liner and store it in the StimRouter Electrode Carrying Case. See Figure 7-3. Do not bend the liner. Keep the liner clean and protected so it can be reused when the StimRouter Electrode is removed from the skin.
2. Visually inspect the gel pads on the back of the StimRouter Electrode. Make sure the gel is smooth and the gel pads are not dry, worn or dirty.
3. Using the index finger and thumb, grasp the edges of the EPT attached to the StimRouter Electrode so the gel pads face downward. See Figure 7-4.

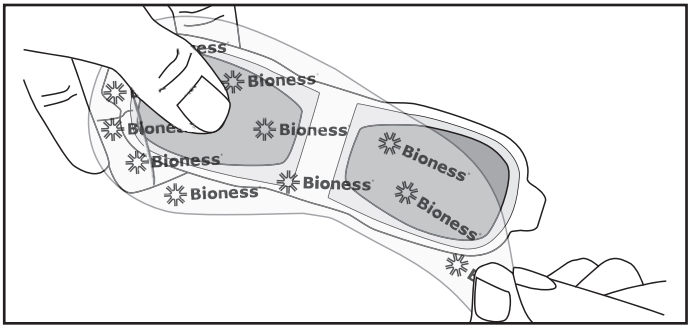


Figure 7-3: Remove the StimRouter Electrode liner.

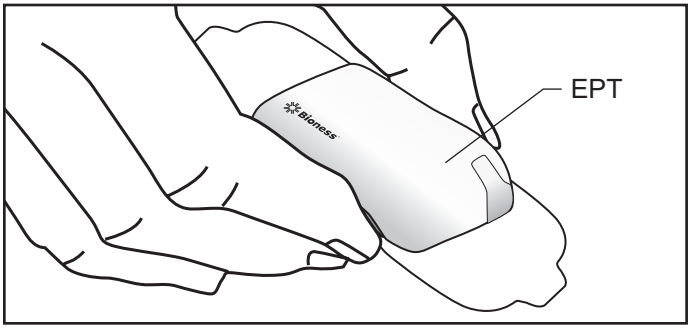


Figure 7-4: Grasp the edges of the EPT attached to the StimRouter Electrode.

4. Align the end of the StimRouter Electrode with the EPT charging port directly over the receiver end of the lead. The center of the gel pad should be above the receiver end of the lead. See Figure 7-5. If the StimRouter Electrode is not directly over the receiver end of the lead, then stimulation may be uncomfortable or ineffective.

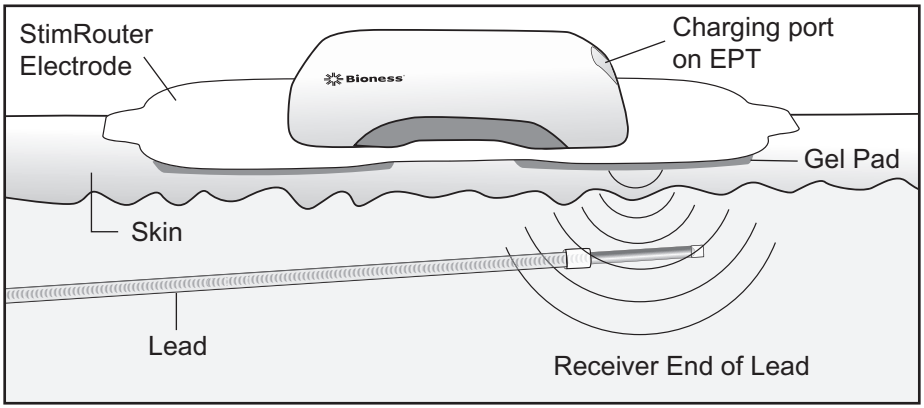


Figure 7-5: Correct stimulation position. (Illustration not to scale.)

Note: 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.

5. Firmly adhere the StimRouter Electrode to the skin. Make sure the StimRouter Electrode is in full contact with the skin. If the StimRouter Electrode is not firmly adhered to the skin and moves, stimulation may become uncomfortable or ineffective.

8

Operating Instructions

⚠ **CAUTION:** Use only the Bioness components designed and manufactured for the StimRouter system. The use of non-Bioness components may damage your system and cause injury.

This section includes instructions on how to operate your StimRouter system, including instructions for:

- Turning the Patient Programmer on/off.
- Adjusting the volume of audio alerts.
- Selecting a stimulation program.
- Turning stimulation on.
- Adjusting stimulation intensity.
- Saving a new stimulation intensity level.
- Turning stimulation off.
- Removing the StimRouter Electrode.
- Removing the EPT from the StimRouter Electrode.

Before you operate your StimRouter system, be sure to read the previous sections of this guide. Important safety information and features of your StimRouter components are described. If you have any questions, problems or experience any new symptoms or painful areas, contact your physician for appropriate diagnosis and treatment. Your physician is familiar with your specific situation and the best source of additional guidance.

Turning the Patient Programmer On/Off

The Patient Programmer on/off button is located at the top of the Patient Programmer. See Figure 8-1.

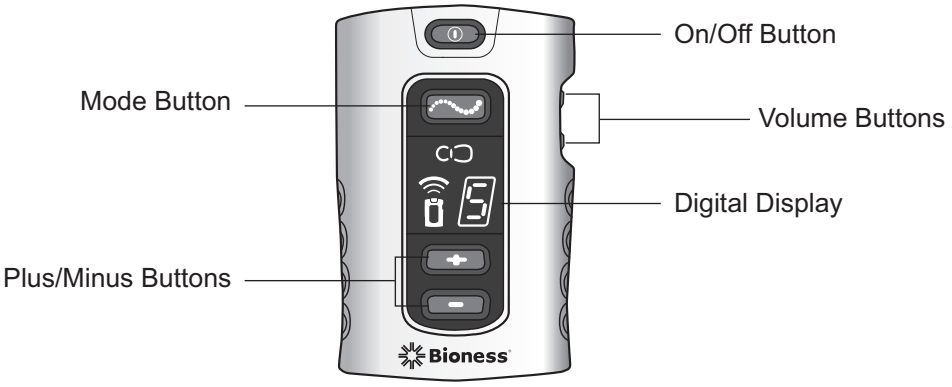


Figure 8-1: Patient Programmer operating buttons.

To turn on the Patient Programmer:

1. Press the on/off button once and release. The Patient Programmer will perform a brief self test causing the display indicators to light up and emit an audio alert. The Patient Programmer turns on in standby mode and the on/off button will FLASH GREEN. The default stimulation intensity level (5) will appear in the digital display.

To turn off the Patient Programmer:

1. Press the on/off button once and release. The Patient Programmer will sound an audio alert and turn off. The on/off button will stop flashing.

Note: When the Patient Programmer is turned on or off it also turns the EPT on or off.

Note: In standby mode, the Patient Programmer turns off automatically after 5 minutes of nonuse.

Adjusting the Volume of Audio Alerts

The volume buttons are located on the side of the Patient Programmer. See Figure 8-1. Each time a button is pressed, the Patient Programmer demonstrates the new sound level for audio alerts.

- To increase the sound level, press the up arrow.
- To decrease the sound level, press the down arrow.
- To mute the audio alerts, press and hold the down arrow for at least three seconds. When the Patient Programmer is turned off, the last volume level is saved.

Note: The audio alerts for faulty electrode contact and EPT temperature out of range can not be muted.

Selecting a Stimulation Program

Your physician can store up to eight programs on your EPT and Patient Programmer. Programs are labeled alphabetically from A to H. See Figure 8-2.

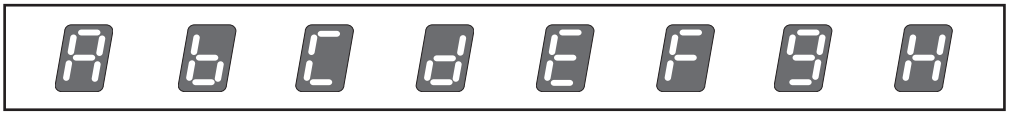


Figure 8-2: Stimulation programs A through H.

If your physician stored more than one program on your EPT and Patient Programmer, you can change stimulation programs in program mode using the plus/minus buttons on the Patient Programmer.

To select a stimulation program:

1. Turn the Patient Programmer on. From standby mode, press and hold the mode button for at least three seconds until the mode button GLOWS YELLOW and sounds an audio alert.
2. When the mode button GLOWS YELLOW, the Patient Programmer is in program mode. The letter of the selected program will appear in the digital display. See Figure 8-3.

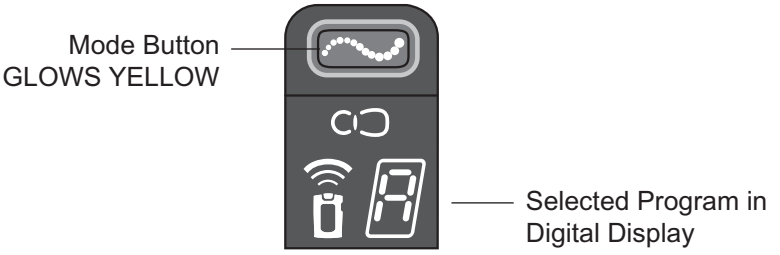


Figure 8-3: Program mode.

3. Press the plus or minus button to select a different program. The selected program will appear in the digital display.
4. Press the mode button briefly to return to standby mode. The Patient Programmer will sound an audio alert and the mode button light will turn off. The default stimulation intensity level will appear in the digital display.

Turning Stimulation On

To turn stimulation on:

1. From standby mode briefly press the mode button. The Patient Programmer will sound an audio alert and the mode button will FLASH YELLOW, indicating stimulation. Stimulation is ON.
2. For a few seconds, the digital display will alternately show the active program (A-H) and the active stimulation intensity level (0-9). After a few seconds, the digital display will show only the stimulation intensity level. See Figure 7-4.

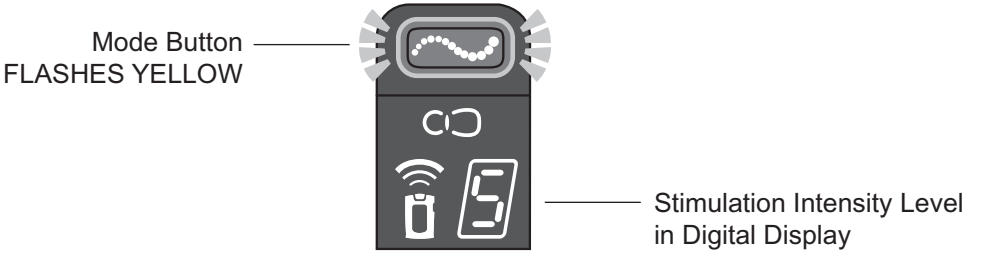


Figure 8-4: Stimulation mode.

3. After a few minutes, the digital display will disappear to save energy. The Patient Programmer (and stimulation) will still be ON. The on/off button will continue to FLASH GREEN. To have the digital display reappear press one of the volume buttons.

Adjusting Stimulation Intensity

When the Patient Programmer is first turned on, the stimulation intensity level will be “5”. This level is set by your physician. To adjust stimulation intensity, press the plus or minus button on the Patient Programmer. A level of “0” equals no stimulation.

To adjust stimulation intensity:

1. In standby or stimulation mode, press the plus or minus button once for each level of change. The Patient Programmer will sound an audio alert and the new intensity level will show in the digital display.

Note: Stimulation intensity should be increased until you feel a tingling sensation, numbness, skin crawling, itching or a feeling of “pins and needles” (paresthesia) in the treatment area. Be careful not to increase the stimulation intensity level beyond your physician’s recommendation or to a painful level. Allow the system to demonstrate a change in setting before making another change.

Note: If the default setting is the maximum level set by your physician, you will not be able to increase stimulation intensity.

Saving a New Stimulation Intensity Level

To save a new stimulation intensity level:

1. Select a stimulation program.
2. From standby mode, adjust the stimulation intensity level to the desired level using the plus/minus buttons.
3. From standby mode, press and hold the minus button for at least three seconds. The patient programmer will sound an audio alert. The new saved intensity level will briefly flash in the digital display.

Note: The stimulation intensity level resets to the saved level when the Patient Programmer is turned on and the saved level number will appear in the digital display.

Turning Stimulation Off

Once you turn stimulation on, your EPT will continue to stimulate whether the patient programmer is within RF range or not. **Always carry your Patient Programmer with you.**

To turn stimulation off use one of the following methods:

- Press the mode button briefly. The Patient Programmer will return to standby mode, and the mode button light will turn off.
- Turn the Patient Programmer off. Press the on/off button once and release. The Patient Programmer can be turned off at all times.
- If you cannot turn stimulation off using the Patient Programmer, then carefully grasp the tab on the StimRouter Electrode. Quickly pull the StimRouter Electrode away from the skin. Do not touch the gel pads on the back of the electrode with both hands while stimulation is turned on. See the “Removing the StimRouter Electrode” section in this guide.

Removing the StimRouter Electrode

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

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

To remove the StimRouter Electrode:

1. Stop stimulation and turn the Patient Programmer off.
2. Grasp the tab on the StimRouter Electrode and gently pull the electrode away from the skin. See Figure 8-5.

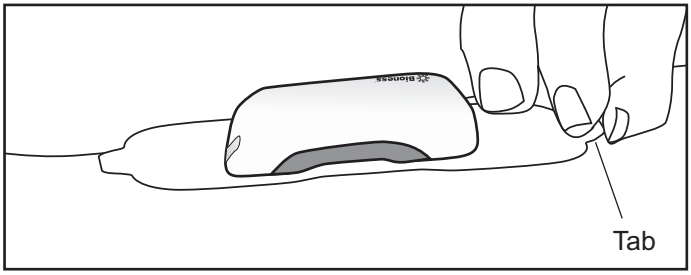


Figure 8-5: Grasp the tab on the StimRouter Electrode to remove.

WARNING: Do not grasp the gel pads on the back of the electrode. See Figure 8-6. If stimulation is not turned off and the gel pads are touched, electrical shock could occur.

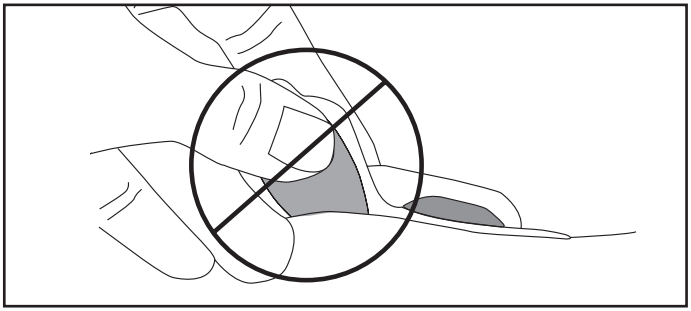


Figure 8-6: Do not grasp the gel electrodes.

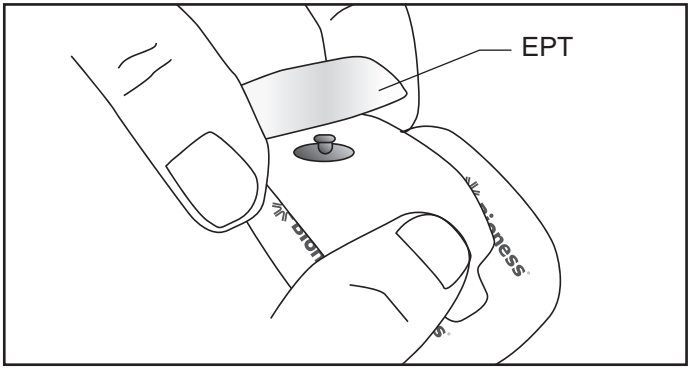
3. Attach the StimRouter Electrode liner to the gel pads. Without the liner attached, the gel pads on the back of the StimRouter Electrode will lose their adhesiveness.
4. Store the StimRouter Electrode and EPT in the StimRouter Electrode Carrying Case.

Removing the EPT from the StimRouter Electrode

Remove the EPT from the StimRouter Electrode when the gel pads can no longer adhere to the skin or after a maximum of four days of use.

To remove the EPT:

1. Make sure the StimRouter Electrode liner is on.
2. Hold the EPT with your thumb and index finger and gently pull the StimRouter



Electrode away from the EPT to unsnap it. See Figure 8-7

Figure 8-7: Removing the EPT from the StimRouter Electrode.

3. Store the EPT in the User Kit or the StimRouter Electrode Carrying Case or attach it to a new StimRouter Electrode.

Note: Do not discard the EPT.

9

Maintenance and Cleaning

⚠ **CAUTION:** Do not attempt to repair any of the components in your StimRouter User Kit. If a component does not work, contact Bioness or your local distributor. Unauthorized repair can void your warranty. Use only StimRouter components with your StimRouter system.

Recharging the Patient Programmer Battery

Charge the Patient Programmer battery:

- For at least four hours immediately before a programming session at a physician's office.
- Daily.
- After extended storage.
- When the Patient Programmer icon FLASHES YELLOW. See "Charging the Patient Programmer and EPT" section of this guide.

If the Patient Programmer discharges rapidly after being fully charged, contact Bioness or your local distributor.

⚠ **WARNING:** Use only the charger included in the StimRouter User Kit. Use of any other charger could damage the system.

Replacing the Patient Programmer Battery

The Patient Programmer battery should be replaced approximately every two years.

⚠ **WARNING:** Use only a rechargeable 1.2-volt NiMH AAA battery (900, 1000 or 1100 milliampere-hours). A non-rechargeable battery can damage and overheat the Patient Programmer. Overheating may lead to tissue injury or burns.

To replace the battery:

1. Remove the label on the back of the Patient Programmer. The label covers a small screw. See Figure 9-1.

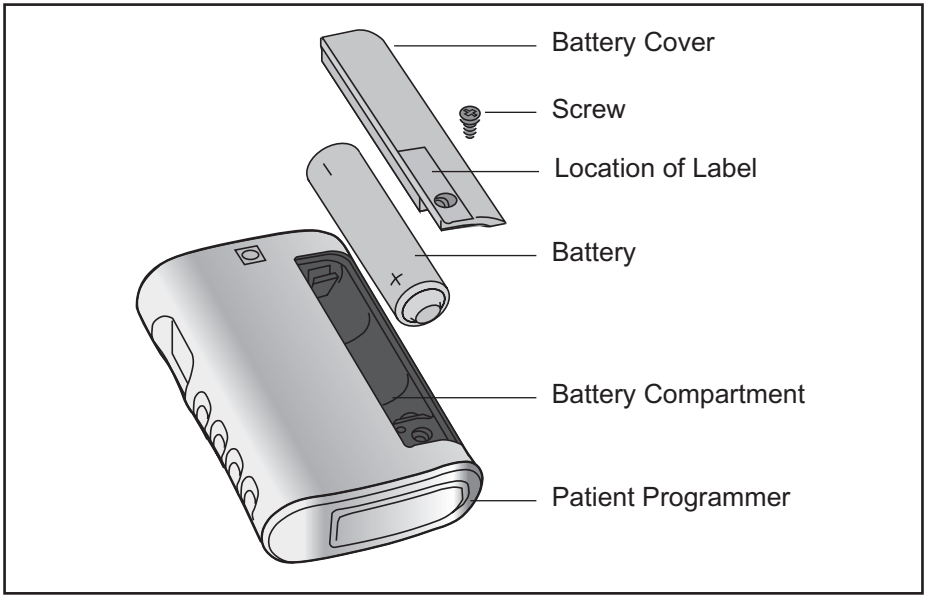


Figure 9-1: Replacing the patient programmer battery.

2. Remove the screw and battery cover.
3. Remove the old battery.
4. Insert a new rechargeable AAA NiMH 1.2-volt battery (900, 1000 or 1100 milliampere-hours). Align the +/- marks with those on the battery compartment.
5. Reattach the battery cover and tighten the screw.
6. Replace the label.
7. Fully charge the new battery before first use.

Properly dispose of the old battery according to your local environmental regulations.

Recharging the EPT Battery

Charge the EPT battery:

- For at least two hours immediately before each programming session.
- Daily.
- After extended storage.
- When the EPT icon on the patient programmer FLASHES YELLOW. See “Charging the Patient Programmer and EPT” section of this guide.

WARNING: Use only the charger included in the StimRouter User Kit. Use of any other charger could damage the system.

Replacing the StimRouter Electrode

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

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

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

Dispose of the StimRouter Electrode when any of the following occurs:

- The gel pads start to peel off at the edges or detach from the StimRouter Electrode.
- The gel pads appear worn or dirty.
- The gel pads lose their adhesiveness.
- After a maximum of four days of use.

Note: Do not discard the EPT.

If you have questions about StimRouter Electrode performance, contact Bioness or your local distributor.

Registering a New Component

The EPT and Patient Programmer must be electronically registered to each other to communicate. The components in your User Kit are already electronically registered to each other.

You will need to re-register the components if:

- You purchase a replacement component.
- You forget to take your Patient Programmer to a programming session and your physician uses a clinic Patient Programmer.

During registration, the digital display on the Patient Programmer displays the registration status of your EPT and Patient Programmer: (See Figure 9-2)

- “U”: The EPT and Patient Programmer are not registered.
- Two ALTERNATING GREEN ARCHES: Registration is in progress.
- “C”: Registration is complete.
- “P”: Registration is complete. No programs are stored.
- “E”: A registration error occurred.

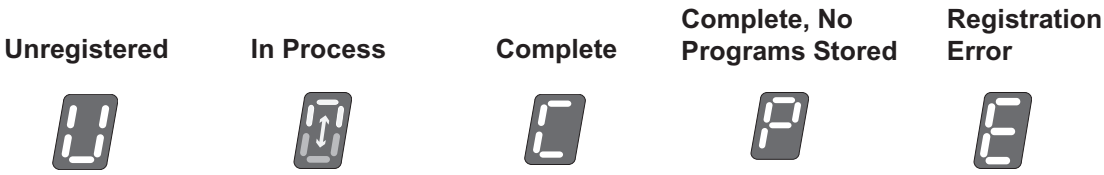


Figure 9-2: RF registration status indicators.

To register the Patient Programmer and EPT:

1. If necessary, charge the Patient Programmer and EPT.
2. Turn off the Patient Programmer. The on/off button should not be FLASHING GREEN.
3. Place the Patient Programmer and EPT close together on a table. They should be no more than a few inches apart and should not be touching.

4. Make certain that any other EPT is at least 10 feet away from the components to be registered.
5. To start the registration process, simultaneously press the mode and minus buttons on the Patient Programmer and hold for three seconds. An audio alert indicates that the registration process has begun.
6. The Patient Programmer should display two ALTERNATING GREEN ARCHES, indicating that the registration is in progress.
7. When a “C” is displayed and the RF icon turns GREEN, registration is complete.

Note: If the digital display shows an “E” and the RF icon turns RED, an error has occurred. Repeat the procedure. If the problem persists, reconnect the EPT to the system charger.

Cleaning

All StimRouter User Kit components may be cleaned with water by carefully wiping them with a damp cloth. Do not use detergents or other cleaning agents, unless otherwise specified below. Do not clean the StimRouter Electrode.

Note: StimRouter electronic components are not waterproof. Do not immerse them in water.

Neck Strap and Wrist Strap

The Patient Programmer neck strap and wrist strap may be machine washed on a delicate cycle in cold water.

StimRouter Electrode Liner

The StimRouter Electrode liner may be cleaned using a damp cloth and lukewarm water.

StimRouter Electrode Carrying Case

The StimRouter Electrode Carrying Case is made of polypropylene and is not dishwasher safe. It may be cleaned by wiping with a damp cloth using mild detergent.

Disinfecting

Electronic Components

All StimRouter User Kit electronic components may be disinfected using CaviWipes™ (if available), or wipes or cloths saturated (but not dripping) with 70% isopropyl alcohol (IPA) per the instructions below:

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

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.

10

Troubleshooting

Should a technical problem occur that is not covered in this section or cannot be resolved by the suggested solutions in this section, please contact Bioness at 800.211.9136 or your local distributor. Do not attempt to repair your StimRouter components.

Patient Programmer	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 Bioness or your local distributor.

Table 10-1: Troubleshooting, Patient Programmer.

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 Bioness or your local distributor.
 Patient Programmer Icon FLASHES YELLOW	**Patient Programmer Battery Charge Level is Low** • Charge the Patient Programmer.

Table 10-2: 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 no touching. • Connect the EPT to the system charger.
 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 system charger. • Re-register the EPT and Patient Programmer. • Contact Bioness or your local distributor.

Table 10-3: Troubleshooting, Patient Programmer, RF icon.

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 Bioness or 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 to see that the liner was removed from the StimRouter Electrode. • Check to see that the EPT is correctly attached to the StimRouter Electrode. If necessary, reattach the EPT to the electrode. • Make sure that nothing is on the gel pads on the back of the StimRouter Electrode 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 10-4: Troubleshooting, Patient Programmer, EPT icon.

EPT and Stimulation	Solutions
Stimulation Not As Effective As Usual	• Check the orientation of the StimRouter Electrode. Align the end of the StimRouter Electrode with the EPT charging port cover directly 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 pads are smooth and not dry. • 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. • Contact Bioness or your local distributor.
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). • Contact Bioness or your local distributor.

Table 10-5: Troubleshooting, EPT and stimulation.

11

Technical Specifications

Patient Programmer Charger Specifications

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

Manufacturer's Model No.	FRIWO FW7555M/05
Input	
Voltage	100-240 volts AC
Current	400 milliamperes
Frequency	50-60 hertz
Output	
Voltage	5 volts ± 5%
Current	2400 milliamperes

EPT Specifications

Classification	Internally powered , or Class II Equipment when operated with a charger, continuous operation, type BF applied parts
Operating Voltage	Rechargeable Lithium Polymer 3.7 volt battery 250mAh capacity
Dimensions	**Length** 57 mm (2.25 in.) **Width** 33 mm (1.3 in.) **Height** 11.5 mm (0.45 in.)
Weight	20 grams (0.704 oz.)
Environmental Ranges	**Transport and Storage Temperature:** -20°C (-4°F) to +60°C (+140°F) **Operational Conditions Temperature:** 5°C (41°F) to 40°C (104°F) **Relative Humidity:** 25% to 85% **Atmospheric Pressure:** 50 kilo pascal to 106 kilo pascal **Protection Against Ingress of Water:** IP03 per IEC 529
Service Life	3 years
FCC ID #	TVF-STRP-EPT-V00

EPT Specifications (continued)

Pulse Parameters	
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	12 milliamperes root mean square
Maximum Charge	15 microcoulombs per phase
Electrode Current Density	Less than 1 milliampere root mean square per centimeter square
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.
Total Pulse Duration	Up to 2550 microseconds (depends on waveform)
Max 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, 12, 15, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 hertz
LED	Green light LED indication: Constant while charging 2Hz blinking at end of battery charge
Timing Parameters	
On Time	1-60 seconds, 1 second resolution
Off Time	0-60 seconds, 1 second resolution (0 second = constant stimulation)
Ramp Up / Ramp Down	0-10 seconds, but not more than “On Time”/2 with 1 second resolution
Total Time	10 minutes - 12 hours
Conformity Certification	The 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.

*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.

Wireless Link Specifications

Frequency Band	2.4 gigahertz, ISM band
Transmission Power	Complies with FCC 15.249 (for U.S.)

Patient Programmer Specifications

Classification	Internally powered when not attached to a charger, or Class II Equipment when operated with a charger. Continuous operation, type BF applied part(s).
Operational Modes	Standby; program; stimulation
Battery Type	Rechargeable AAA NiMH 1.2 volts, 900, 1000 or 1100 milliampere- hours
Operating Buttons	**On/Off:** Used to turn the patient programmer on and off. **Mode:** Used to select program, stimulation or standby mode. **Plus/Minus:** Used to fine-tune stimulation intensity and change programs. Minus button is used to save new default settings. **Volume:** Used to increase or decrease sound level of audio alerts.
LEDs	**EPT Icon:** Communicates StimRouter electrode and EPT status. **Radio Frequency Icon:** Communicates patient programmer and EPT registration status. **Patient Programmer Icon:** Communicates patient programmer status.
Digital Displays	Communicates relative stimulation intensity, program selected, errors and charging/registration status.
Indicator Lights	Patient programmer; stimulation; program mode
Audio Alerts	System errors; stimulation/program mode changes; volume changes
Carrying Accessories	Neck Strap and Wrist Strap
Dimensions	**Length** 74 mm (2.91 in.) **Width** 47 mm (1.85 in.) **Height** 18 mm (0.71 in.)
Weight	45 grams (1.5 oz.)

Patient Programmer Specifications (continued)

Environmental Ranges	**Transport and Storage Temperature:** -20°C (-4°F) to +60°C (+140°F) **Operational Conditions Temperature:** 5°C (41°F) to 40°C (104°F) **Charging Temperature:** 5°C (41°F) to 40°C (104°F) **Relative Humidity:** 25% to 85% **Atmospheric Pressure:** 50 kilo pascal to 106 kilo pascal
Service Life	3 years
FCC ID #	TVF-STRP-PP-V00
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.

StimRouter Electrode Specifications

Electrode Size	7.5 sq cm each
Dimensions	**Length** 119 mm (4.68 in.) **Width** 33.5 mm (1.31 in.) **Height** 2.3 mm (0.09 in.)
Weight	10 grams
Environmental Ranges	**Transport and Storage Temperature:** 5°C (41.0°F) to 27°C (80.6°F) **Operational Conditions Temperature:** 15°C (59°F) to 40°C (104°F) **Relative Humidity:** 25% to 85% **Atmospheric Pressure:** 50 kPa to 106 kPa
Service Life	2-4 days

Wireless (RF) Communications Specifications

Capabilities	Communication between the patient programmer and EPT.
Functions	RF communication is used between the EPT and patient programmer to perform the following functions: • Control stimulation (e.g., start/stop stimulation, change programs, adjust stimulation amplitude) • EPT status (e.g., low battery indication, status and error messages)
Modes	Use mode (patient programmer controls EPT actions in Stimulation mode and Program mode), Standby mode, and Registration mode.
Characteristics	EPT and patient programmer • Frequency band: 2.4000 up to 2.417 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 • Bit rate: 0.25 Mbps • Modulation type: Minimum Shift Keying (MSK) • Transmit power (EIRP): EPT, 0 dBm; patient programmer, 2 dBm • Modulation baud rate: 250 kHz • Modulation bandwidth (6dB bandwidth): 380 kHz

Locations and Ranges	The patient programmer and EPT communicate when an object-free line of sight is available, up to 22 ft (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%

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 registered components.
- Proprietary communication protocol.
- Use of two frequency channels.
- Use of whitening function (data randomizing).

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

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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.
RF emissions CISPR 11	Class B	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.
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 IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Recommended separation distance (d) $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2.5 GHz	10 V/m 26 MHz to 1 GHz 3 V/m 1 GHz to 2.5 GHz	$d = 0.4\sqrt{P}$ 80 MHz to 800 Mhz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and Manufacturer's Declaration Electromagnetic Immunity

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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√P***	**80 MHz to 800 MHz** ***d = 0.4√P***	**800 MHz to 2.5 GHz** ***d = 2.3√P***
0.01	4.7 in. (0.12 m)	1.6 in (0.04 m)	9.1 in. (0.23 m)
0.1	15 in. (0.38 m)	4.7 in. (0.12 m)	2 ft 5 in. (0.73 m)
1	3 ft 11 in. (1.2 m)	15.7 in. (0.4 m)	7 ft 7 in. (2.3 m)
10	12 ft 6 in. (3.8 m)	4 ft 2 in. (1.26 m)	24 ft 11 in. (7.3 m)
100	39 ft 4 in. (12 m)	13 ft 1 in. (4 m)	75 ft 6 in. (23 m)

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

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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