User Manual

StimRouter™ Implantable Neurostimulator

Bioness Inc.

Rx Only

CAUTION: *United States federal law restricts this device to sale by or on the order of a physician.*

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

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

Enironmental Policy
Service personnel are advised that when changing any part of the StimRouter, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled. When the life cycle of the StimRouter has been completed, the product should be discarded according to the laws and regulations of the local authority.

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List of Symbols

Symbols	Definition
	Type BF Applied Part
	Electronic Testing Lab, indicates product meets U.S. and Canadian product safety standards. This device complies with UL 60601-1 and CSA C22.2 No. 601-1-M90.
	Non-Ionizing Radiation
	Class II Equipment
	Manufacturer
	Date of Manufacture
	Warning

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.

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CHAPTER

1

INTRODUCTION

Congratulations! Your physician has prescribed the StimRouter Implantable Neurostimulator to help manage your pain. The first step is to have the StimRouter lead implanted where neurostimulation will give you the most pain relief. After the lead is implanted and the skin above the implant site is healed, you can start your stimulation treatment.

Your StimRouter User Kit

The StimRouter Model STR-5000 User Kit contains the external components that supply and control your stimulation treatment. These components are the user patch, external pulse transmitter and remote control. Also included in your User Kit are accessories for these components.

This manual describes your StimRouter system and explains how to operate the external components to achieve maximum pain relief. Be sure to read this manual before operating your StimRouter. Ask your clinician to explain and demonstrate any procedures you do not understand.

Your Programming Session

As part of your programming session, you will learn:

- How to set up and operate your StimRouter system

- Where to place the user patch
- How to attach the external pulse transmitter to the user patch
- How to select a stimulation program
- How to fine-tune stimulation intensity

The clinician will program your StimRouter system with a series of stimulation settings that best fits your pain-management needs. The programs will be stored on your StimRouter remote control for you to access at home. Your clinician will explain how the programs differ, and when and how to choose which program to use.

User Registration Information

A User Registration Card is included in your StimRouter User Kit. The purpose of this card is to maintain traceability of all StimRouter products and to activate your StimRouter warranty. Fill out the registration card and return it to Bioness Inc. by mail or by fax as soon as possible.

Your Medical Device ID Card

Bioness will send you a Medical Device Identification (ID) Card once we receive your registration information. You should always have your Medical Device ID card with you. The Medical Device ID card identifies you as a person with an implanted medical device.

Bioness Customer Support

Bioness is dedicated to helping you achieve maximum effectiveness with your StimRouter system. Our customer support representatives are available to help you better understand how your StimRouter works and to answer any questions you may have with its operation and care.

Bioness Customer Support:

Telephone: (800) 211-9136

Fax: (661) 362-4851

email: info@bioness.com

CHAPTER

2

GENERAL WARNINGS AND CAUTIONS

Before using your StimRouter system, be certain to read, understand and practice the precautionary and operating instructions in this manual. Know the limitations and hazards associated with your StimRouter. Discuss any questions you have with your clinician. If at any time you are concerned about the safety or the effectiveness of your StimRouter, consult your treating clinician or **Bioness Customer Support Representative: Telephone: (800) 211-9136.**

The StimRouter should only be used under proper medical guidance and as described in this manual.

Indications for Use

The StimRouter Implantable Neurostimulator provides electrical stimulation via an implantable lead to a target stimulation point, for aid in the management of chronic intractable pain.

Contraindications

The StimRouter should not be used if you have any of the following:

- An implanted cardiac pacemaker or defibrillator
- Any electrical or metallic implant in the area intended for implant

- A cancerous lesion near the target stimulation area or near to where the user patch will adhere
- A fracture or dislocation near the target stimulation area or near to where the user patch will adhere

The StimRouter should not be used if you may require:

- Diathermy treatment
- Magnetic resonance imaging

Warnings

Diathermy

Shortwave, microwave and/or therapeutic ultrasound diathermy should not be used on patients who have a StimRouter Implantable Neurostimulator. The energy generated by diathermy can be transferred through the StimRouter, causing tissue damage at the lead site and resulting in severe injury or death.

Diathermy may also damage the neurostimulation components, resulting in loss of therapy and requiring additional surgery for lead replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off. All patients are advised to inform their health-care professional that they should not be exposed to diathermy.

Magnetic Resonance Imaging (MRI)

Patients implanted with the StimRouter Implantable Neurostimulator should not be subjected to MRI. MRI exposure may dislodge the implanted lead, heat the lead, damage the component electronics and/or cause voltage induction through the lead.

Implanted Stimulation Devices

Neurostimulators, such as the StimRouter, may interfere with the operation of implanted sensing stimulators such as pacemakers or

cardiovascular defibrillators. The effects of implanted sensing stimulators on neurostimulators are unknown.

Flammable Fuel or Chemicals

Turn the StimRouter (remote control and stimulation) off when near a refueling point, flammable fuel, fumes or chemicals. The operation of the StimRouter could cause the chemicals or fumes to ignite, causing severe burns, injury or death.

Electrosurgery Devices

Advise your health-care professional that electrosurgery devices should not be used in close proximity to an implanted neurostimulation lead. Contact between an active electrode of the electrosurgery device and an implanted lead can cause direct stimulation of the nerve or other target stimulation point and severe injury may result.

High-Frequency Surgical Equipment

Remove the user patch before medical treatment. Simultaneous connection to the StimRouter and high-frequency surgical equipment may result in skin burns where the gel electrodes adhere to the skin and may damage the external pulse transmitter.

Driving and Operating Machinery

Turn off stimulation while driving and operating machinery.

Pregnancy

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

Long-Term Effectiveness of Neurostimulation

The long-term effectiveness of neurostimulation is unknown.

System Programming

Only the treating clinician should program the StimRouter.

System Components

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

Precautions

Medical Devices/Therapies

The following medical therapies or procedures may turn stimulation off, or may cause permanent damage to the StimRouter lead and external components and injury to the patient, particularly if used in close proximity to the system components:

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

For Patient Use Only

Do not adhere the user patch to any other person or to any other part of your body. The StimRouter user patch is meant to be worn only by the patient for which it was prescribed and in the location where it was prescribed.

Postural Changes

Turn off stimulation before making extreme posture changes or abrupt movements such as stretching, lifting of arms overhead, or exercising.

Changes in posture or abrupt movements may decrease or increase your perceived level of stimulation.

Keep out of Reach of Children

Keep all StimRouter components out of the reach of children.

Skin Abnormalities

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

Skin Irritation

It is normal for the areas under the user patch to be red. The redness should disappear in approximately one hour. However, some patients may experience skin irritation, an allergic reaction, or hypersensitivity to the electrical stimulation or the electrical conductive medium. Persistent redness, lesions or blisters are signs of irritation. Use of the StimRouter should be temporarily halted until the inflammation is resolved. In some cases, irritation can be avoided by changing the stimulation parameters. Consult your treating clinician if irritation persists.

User Patch Placement and Stimulation

- Turn stimulation off before adhering, removing or handling the StimRouter user patch.
- Do not activate stimulation until the user patch is in place.
- Do not handle the user patch with both hands while stimulation is turned on; serious injury can result from electrical current passing through the chest area.
- Only the treating clinician should determine user patch placement and stimulation settings.
- Do not apply the user patch over any obstruction that would reduce the designated electrode surface area. A smaller electrode surface area could result in serious tissue injury during stimulation.

X-Ray Examinations

Do not wear the StimRouter user patch during x-ray examinations.

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.

Device Failure

Leads can fail at any time because of random component failure or lead breakage. If stimulation is no longer effective, contact your treating clinician or Bioness Customer Support.

Care and Handling of Components

Handle all system components and accessories with care. Do not drop components and accessories. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the components on hard surfaces, or other rough handling, can permanently damage the components.

Storage and Operation Temperatures

Do not expose components to extreme temperature conditions or moisture.

Expiration Date

Do not use a user patch with a use-by date that has expired.

Adverse Effects

Note: *In the unlikely event that any of the following occurs, stop using the StimRouter and immediately consult your treating clinician.*

Risks Related to Stimulation

- Operation of the StimRouter may cause increased pain in an area(s) other than the implant site. The pain may be caused by stimulation of the tissue surrounding the lead (skin, fascia and muscle).
- You may feel undesirable or unpleasant sensations related to stimulation because of cellular changes in tissue surrounding the lead.
- You may experience an undesirable motor response during stimulation.

Risks Related to the Device

- Migration of the lead may cause changes in stimulation.
- While very unlikely, a tissue reaction to any of the implanted materials may occur.
- External electromagnetic interference may cause the StimRouter to malfunction and may affect stimulation.
- Magnetic resonance imaging may result in heating of the lead, image artifact, induced voltages on the lead or lead movement.
- You may experience persistent pain at the implant site of the lead.
- The lead may fail or malfunction, requiring that the lead be explanted and a new lead be implanted.
- Rarely, the skin overlying the lead may erode.
- Portable and mobile radio frequency communications equipment can affect medical electrical equipment.

CHAPTER

3

USER KIT CONTENTS

The StimRouter STR-5000 User Kit contains the external components and accessories of the StimRouter implantable neurostimulation system for pain therapy:

- Remote Control
- Remote Control Charger
- Remote Control Neck Strap
- Remote Control Wrist Strap
- Remote Control Pouch
- User Patch (4)
- User Patch Carrying Case
- External Pulse Transmitter (EPT)

Also included:

- User Manual
- User Instruction Card
- User Registration Card
- Warranty Card

Check to make sure that all of the above components are included in your User Kit. If anything is missing, call Bioness Customer Support.

CHAPTER

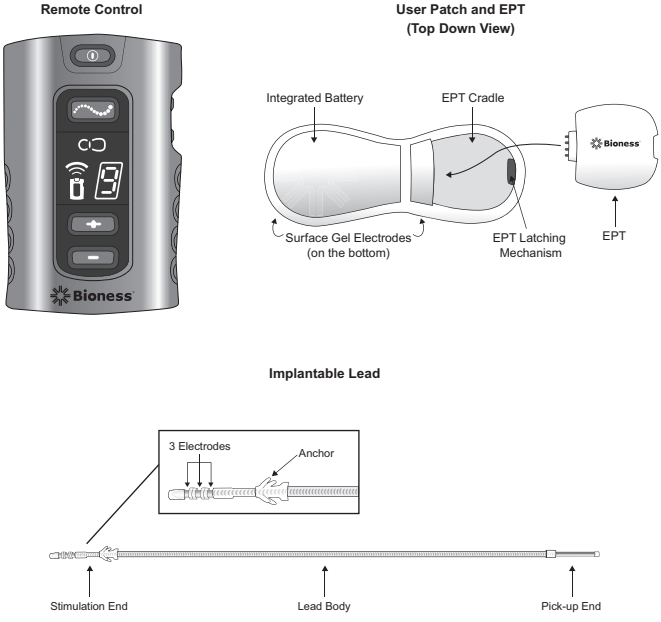
4

DEVICE DESCRIPTION

Your StimRouter system consists of four key components:

- An implantable lead
- An external user patch
- An external pulse transmitter (EPT)
- A portable remote control FIGURE 4-1.

FIGURE 4-1. Your StimRouter system components.



Implantable Lead

The StimRouter lead is about 6 inches long. It has a stimulation end and a pick-up end. The entire lead is implanted.

Stimulation End

Stimulates the treatment area.

Pick-Up End

Receives (picks up) the stimulation signal from the external pulse transmitter and sends it to the stimulation end. The pick-up end can usually be felt by palpating the skin in the area of implant.

User Patch

The user patch is designed for short-term use and is worn on the skin directly over the pick-up end of the StimRouter lead. The user patch features two surface gel electrodes, an integrated battery and a cradle for the external pulse transmitter. The User Kit comes with several user patches, and with accessories for storing and carrying the patches.

Design Features

Two Surface Gel Electrodes

Used to adhere the user patch to the skin. Also used to emit the electrical signal from the external pulse transmitter to the pick-up end of the implanted lead.

Integrated Battery

Supplies the energy for the external pulse transmitter.

External Pulse Transmitter Cradle

Holds the external pulse transmitter.

EPT Latching Mechanism

Keeps the external pulse transmitter (EPT) in place.

Accessories

User Patch Carrying Case

Designed to carry an extra user patch or store a worn user patch. The case is small and portable and holds one user patch.

Patch Sleeves

Designed to help secure the user patch to the skin.

External Pulse Transmitter

The StimRouter external pulse transmitter (EPT) sends pain-relieving electrical stimulation to the implanted lead. The external pulse transmitter fits into the user patch and responds to wireless commands from the remote control. The external pulse transmitter is powered by the battery in the user patch.

The external pulse transmitter is transferred to a new user patch when a worn patch is disposed of.

Remote Control

The StimRouter remote control communicates wirelessly with the external pulse transmitter, turning stimulation on and off, fine-tuning stimulation intensity and controlling program selection. The remote control contains a rechargeable battery, and can contain up to eight stimulation programs. The remote control is small enough to be worn around the neck or wrist, or carried in a pocket or belt pouch.

Operating Modes

Standby

In standby mode, the remote control is activated and waiting for commands. The remote control starts in standby mode when first turned on, and returns to standby mode when program mode and stimulation mode are exited.

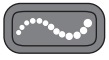
FIGURE 4-2. StimRouter remote control operating buttons.

Program
In program mode, the available stimulation programs are accessible. To choose a stimulation program, use the plus/minus buttons.

Stimulation
In stimulation mode, the StimRouter system is on; it is stimulating the target treatment area. Stimulation intensity can be fine-tuned using the plus/minus buttons.

Operating Buttons

On/Off
Used to turn the remote control on and off. (The remote control turns off automatically after 5 minutes of disuse.)



Mode
Used to select one of three operating modes: program, stimulation or standby.

Plus/Minus
Used to fine-tune stimulation intensity and select a stimulation program.

Volume
Used to increase or decrease sound level of the audio indicators.

On/Off Indicator Lights

Remote Control
On/Off button flashes green when the remote control is on.

Stimulation
Mode button flashes yellow when stimulation mode is on.

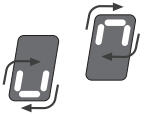
Program
Mode button glows yellow when program mode is on.

Digital Display

Shows stimulation intensity in stimulation mode, program selected in program mode, charging status, radio frequency registration status and system errors.

Intensity
Displayed as “0–9” in stimulation mode.

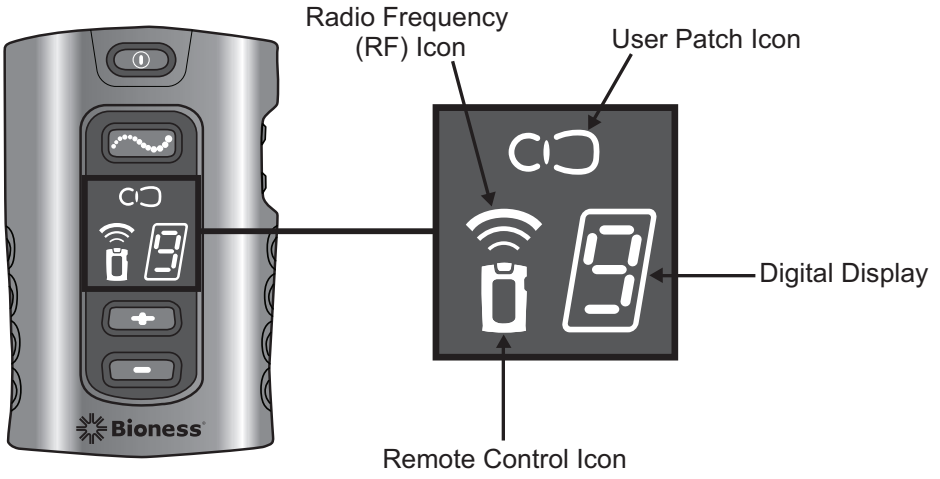
Program
Displayed as “A–H” in program mode.



Battery Charging
A small green loop circles in the digital display. The loop appears in the lower half of the display when charge level is low and in the upper half when charge level is high.

Battery Fully Charged
A horizontal green line appears in the digital display.

FIGURE 4-3. StimRouter remote control digital display and LEDs.



Radio Frequency Registration Error
"E" appears in the digital display.

Radio Frequency Registration Complete
"C" appears in the digital display.

Radio Frequency Registration in Progress
A green arch alternates in the digital display.

LEDs

User Patch Icon

- Flashes red: faulty electrode contact or temperature error in the external pulse transmitter
- Glows red: component malfunction
- Flashes yellow: low battery

Radio Frequency (RF) Icon

- Flashes red: radio frequency error
- Glows green for a few seconds: RF registration is complete

Remote Control Icon

- Flashes yellow: low battery
- Glows red: component malfunction or battery charging error

Visual Alerts

Low Battery, Remote Control

- Remote control icon flashes yellow

Low Battery, User Patch

- User patch icon flashes yellow

Faulty Electrode Contact

- User patch icon flashes red
- Stimulation intensity number flashes green

Radio Frequency Failure

- Radio frequency icon flashes red

Component Malfunction

- Remote control or user patch icon glows red
- “E” appears in the digital display

Audio Alerts

Beep

The remote control beeps to indicate:

- The remote control is activated

- A button has been pressed
- The stimulation mode's duration has elapsed
- The remote control battery charge level is low
- The remote control battery is depleted
- The remote control battery is full
- The electrode contact is faulty
- The user patch battery is low
- The EPT is malfunctioning
- The remote control charger is connected
- The remote control charger is disconnected

Battery Compartment

The battery compartment contains a rechargeable AAA battery (installed). Refer to page 9-39 for battery replacement instructions.

Accessories

Remote Control Charger

Used to recharge the remote control battery.

Remote Control Neck Strap

Loops through the top of the remote control and is used to carry the remote control.

Remote Control Wrist Strap

Loops through the top of the remote control and is used to carry the remote control.

Remote Control Pouch

Features a clamp for attachment to a belt and is used to carry the remote control.

CHAPTER

5

TECHNICAL SPECIFICATIONS

Specifications, StimRouter User Patch

Classification	Internally powered, continuous operation, Type BF applied part(s)
Battery Type	2 AAA 1.5-V, lithium batteries
Dimensions	**Height** 14 mm (0.551 in.) **Width** 40 mm (1.574 in.) **Length** 115 mm (4.527 in.)
Weight	
Environmental Ranges	**Transport and Storage Temperature** 0°C to 60°C (32°F to 140°F) **Operational Conditions Temperature** 15°C to 40°C (59°F to 104°F) **Charging Temperature** 5°C to 40°C (41°F to 104°F) **Relative Humidity** 25% to 85% **Atmospheric Pressure** 0.9 kPA to 1.060 kPA

Specifications, StimRouter External Pulse Transmitter

Classification	Externally powered, continuous operation, Type BF applied parts
Operating Voltage	3 V

Specifications, StimRouter External Pulse Transmitter

Dimensions	**Height** 9 mm (0.354 in.) **Width** 35 mm (1.377 in.) **Depth** 38 mm (1.496 in.)
Weight	10 grams (0.352 oz.)
Environmental Ranges	**Transport and Storage Temperature** -20°C to 60°C (-4°F to 140°F) **Operational Conditions Temperature** 5°C to 40°C (41°F to 104°F) **Charging Temperature** 5°C to 40°C (41°F to 104°F) **Relative Humidity** 25% to 85% **Atmospheric Pressure** 0.9 kPA to 1.060 kPA

Specifications, StimRouter Remote Control

Classification	Internally powered, continuous operation
Operational Modes	Standby, program, stimulation
Battery Type	Rechargeable AAA NiMH 1.2-V, 1100 mAh
Operating Buttons	**On/Off** Used to turn the remote control on and off **Mode** Used to select one of three operating modes: program, stimulation or standby **Plus/Minus** Used to fine-tune stimulation intensity and change stimulation programs **Volume** Used to increase or decrease sound level of the audio indicators
LEDs	**User Patch Icon** User patch and external pulse transmitter status **Radio Refrequency Icon** Remote control and external pulse transmitter radio communication status **Remote Control Icon** Remote control status

Specifications, StimRouter Remote Control

Digital Displays	Relative stimulation intensity Program selected Error or status (charging, registration)
On/Off Indicator Lights	Remote Control Stimulation Program
Audio Alerts	**Beep** System errors Mode changes (stimulation and program) Volume changes
Carrying Options	Neck strap, wrist strap, belt pouch, pocket
Dimensions	**Height** 71 mm (2.8 in.) **Width** 46 mm (1.8 in.) **Depth** 17.5 mm (0.7 in.)
Weight	45 grams (1.5 oz.)
Environmental Ranges	**Transport and Storage Temperature** -20°C to 60°C (-4°F to 140°F) **Operational Conditions Temperature** 5°C to 40°C (41°F to 104°F) **Charging Temperature** 5°C to 40°C (41°F to 104°F) **Relative Humidity** 25% to 85% **Atmospheric Pressure** 0.9 kPA to 1.060 kPA

Specifications, Remote Control Power Supply

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

Input	
Voltage	100–240 V AC
Current	200 mZ
Frequency	50–60 Hz
Output	
Voltage	5 V ± 5%
Current	1300 mA

Specifications, Wireless Link	
Frequency Band	2.4 GHz, ISM band
Transmission Power	Complies with FCC 15.247 (for U.S.)

CHAPTER

6

ENVIRONMENTAL CONDITIONS THAT AFFECT USE

Storage and Handling

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

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

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

Radio Communication Information

Several components of the StimRouter system communicate via radio communication and have been tested and found to comply with the limits

for a Class B digital device, pursuant to Part 15 (Radio Frequency Devices) of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential environment. This equipment generates, uses and can radiate radio frequency energy and, if not operated and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular environment. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver

Consult the dealer or an experienced radio/television technician for assistance.

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

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

Security Screening Devices

Certain types of antitheft devices, such as those used at the entrances and exits of public buildings such as libraries, airports and retail stores, may affect stimulation. Use caution when approaching a security screening device. Ask for assistance to bypass the device by showing your patient ID card. If you must pass through such a device, make certain that the stimulation is turned off on your StimRouter system, and pass through the device quickly.

Cell Phones

While we do not anticipate any interference with cell phones, the full effects of interaction with cell phones are unknown at this time.

CHAPTER

7

SET-UP INSTRUCTIONS

Charging the Remote Control

The remote control comes with a rechargeable AAA battery already installed, and a charger. The battery should be charged daily and when the remote control icon flashes yellow.

A new remote control battery supports at least 24 hours of typical usage before needing to be recharged.

The remote control can be operated while it is being charged.

WARNING:

Use only the charger included in the StimRouter User Kit. Use of any other charger can result in serious injury.

To charge the remote control battery:

1. Open the cover over the charging socket on the bottom of the remote control.
2. Insert the charger cable connector into the charging socket.
3. Plug the charger into a power socket.
4. Monitor the remote control digital display to verify that the remote control is charging. When the remote control battery is charging and the remote control is in standby mode, a small green loop will circle in the digital display. The loop will circle in the lower half of the display when the charge level is low. It will circle in the upper half when the charge level is high. FIGURE 7-1.

5 The charging process should last approximately four hours.

6 When the remote control battery is fully charged, a horizontal green line will appear in the digital display.

7 Unplug the charger cable from the power socket and from the charger socket. Store the charger in the User Kit.

FIGURE 7-1. When the remote control is turned off, the digital display continuously shows the charging status. In standby, stimulation or program mode, the charging status appears only briefly when the charger is first connected.

Preparing the Skin

For optimal stimulation, the skin below the user patch should be clean and dry.

CAUTION: *If the skin is inflamed or swollen, do not use the StimRouter. Inflammation in the region of the user patch may be aggravated by pressure from the user patch. Use of the StimRouter should be temporarily halted until the inflammation is resolved.*

To prepare the skin:

1 Locate the area where the pick-up electrode is implanted. If necessary, palpate the area until the pick-up electrode can be felt.

2 Clean the skin above the pick-up electrode with an alcohol swab or wet washcloth and dry. If the area has been treated with lotions or oils, then clean the skin with soap and water, rinse well and dry.

If necessary, remove excess body hair from the skin area with scissors. Do not use a razor. A razor can irritate the skin.

CHAPTER

8

OPERATING INSTRUCTIONS

CAUTION: *Use only the Bioness components designed and manufactured for the StimRouter. Do not substitute any components for those supplied in the StimRouter User Kit.*

Overview

This section includes the following instructions for performing a StimRouter treatment session:

- Attaching the External Pulse Transmitter to a User Patch
- Applying the User Patch to the Skin
- Turning On the Remote Control
- Adjusting the Volume Level of Audio Alerts
- Selecting a Stimulation Program
- Turning Stimulation On
- Adjusting Stimulation Intensity
- Saving a New Default Stimulation Level
- Turning Stimulation Off
- Taking Off the User Patch
- Removing the External Pulse Transmitter

Before operating the StimRouter, read the previous sections of this manual that describe the components and their features. To gain the maximum benefit from your StimRouter, carefully follow your clinician's instructions. If you have any questions or problems, or experience any new symptoms or painful areas, contact your treating clinician for appropriate diagnosis and treatment. Your clinician is familiar with your specific situation and the best source of additional guidance.

Attaching the EPT to a User Patch

To attach the external pulse transmitter (EPT) to a user patch:

1. Hold the EPT with the label facing toward the user patch.
2. Align the gold connector on the EPT with the connector's port on the user patch. Push the EPT forward into the port. Press the EPT into the cradle on the user patch to lock the latching mechanism.

Note: *To ensure proper electrical stimulation, the external pulse transmitter must be connected to the user patch properly.*

Applying the User Patch to the Skin

A user patch can be reused for as long as its battery is functional and its gel electrodes can adhere to the skin.

WARNING:

Do not touch the gel electrodes with both hands while stimulation is turned on; serious injury could result from electrical current passing through the body. Stimulation should be turned off before adhering, removing or handling the user patch.

Do not apply the user patch to anyone else or any other part of the body than that determined by the treating clinician.

Before putting the user patch on, remove the gel electrode cover and store the cover in the user patch carrying case. (Reapply the cover whenever the user patch is stored.)

To put the user patch on:

1. Locate the area where the pick-up electrode is implanted. If necessary, palpate the area until the pick-up electrode can be felt.
2. Clean the skin above the pick-up electrode with an alcohol swab or wet washcloth and then dry the skin area. If the area has been treated with lotions or oils, then clean the skin with soap and water, rinse well and dry. If necessary, remove excess body hair from the skin area with scissors. Do not use a razor. A razor can irritate the skin.
3. Hold the user patch between the index finger and thumb, with the gel electrodes facing toward the site of adhesion.

CAUTION: *Do not pinch or stretch the skin while adhering the user patch.*

4. Orient the user patch so that the center of one of the gel electrodes is positioned directly over the pick-up end of the lead. If the user patch is not placed directly over the pick-up end of the lead, stimulation may be uncomfortable or ineffective.

CAUTION: *Make certain that the adhesion site is free from any obstructions, i.e., bandages, clothing, etc., before adhering the patch. Placing the user patch partially or wholly over a bandage or other obstruction could cause skin irritation or tissue damage during stimulation.*

5. Firmly adhere the user patch to the skin, making sure that the patch is in full contact with the skin. If the user patch is not firmly adhered to the skin and moves, stimulation may become uncomfortable or ineffective.

Turning On the Remote Control

Note: *The remote control must be within 10 feet of the external pulse transmitter when the system is activated to ensure optimal radio communication. If the components are not within 10 feet of each other, the radio frequency icon will flash red.*

Remote Control Off **Remote Control On**

The remote control on/off button is located at the top of the remote control front panel.

To turn the remote control on:

1 Press the on/off button once and release. The remote control will beep and start a self test. All display indicators will light up briefly. When the self test is finished, the remote control will beep again, the lights will turn off, and the on/off button will flash green.

Note: The remote control turns on in standby mode. The default stimulation intensity level will appear as a number in the digital display.

To turn the remote control off:

2 Press the on/off button once and release. The remote control will beep and turn off. The on/off button will stop flashing. (The remote control turns off automatically after 5 minutes of disuse.)

Adjusting the Volume of Audio Alerts

The volume control buttons are located on the right side of the remote control (up/down arrows). Each time an arrow is pressed, the remote control will beep to demonstrate the new sound level.

Tomute the audio alerts:

1 Press and hold the down arrow for at least three seconds or decrease the volume to the minimal level.

When the remote control is turned off, the active volume level is saved. If the active level is "mute," the default volume setting is restored when the remote control is turned back on.

Selecting a Stimulation Program

FIGURE 8-1. Stimulation programs A–H, as represented on the digital display.

The remote control can store up to eight clinician-set stimulation programs. These programs are labeled "A–H" and can be selected using the plus/minus buttons in program mode. See FIGURE 8-1.

To select a stimulation program:

1. From standby mode, press and hold the mode button for at least three seconds, until the remote control beeps and the mode button glows yellow. A letter will appear in the digital display, indicating the active program.
2. Press the plus or minus button to change the active program. The new active program will appear in the digital display.
3. Press the mode button briefly to return to standby mode. The remote control will beep, the mode button will turn off, and the default stimulation intensity level will appear in the digital display.

Turning Stimulation On

To turn stimulation on:

Stimulation Off **Stimulation On**

1. From standby mode briefly press the mode button. The remote control will beep and the mode button will start flashing yellow.

2. Few a few seconds, the digital display will alternately show the active program and active stimulation intensity level.
3. After a few seconds, the digital display will show only the stimulation intensity level.
4. After a few minutes, the digital display will go dark.

Adjusting Stimulation Intensity

The remote control stores up to nine stimulation intensity settings. These settings are numbered “1–9”; “0” equals no stimulation. When the remote control is first turned on, the stimulation intensity level should be “5,” which is the customary default level set by the clinician. Normally,

this level will be most appropriate for use. Stimulation intensity can be adjusted, however, using the plus/minus buttons.

CAUTION: *Be careful not to set the stimulation intensity too high. Pain can result.*

To temporarily adjust stimulation intensity:

1. Either from standby mode or while stimulating in stimulation mode, press the plus or minus button *once for each level of change.* The remote control will beep and the new level will show on the digital screen.

2. Allow time for the system to demonstrate a change in setting before making another change.

CAUTION: *If the intensity level is changed while stimulation has cycled off in stimulation mode, or while the system is in standby mode, the new intensity level will not activate until the system cycles back on. Be certain to test each level before advancing stimulation to a different level, especially to a higher level.*

Saving a New Default Stimulation Intensity Level

You can save a new default stimulation intenstity level for each program stored on the remote control.

To save a new default stimulation intensity level:

1. Select a stimulation program (“Selecting a Stimulation Program” on page 8-32).
2. Return to standby mode.

3. Adjust the stimulation intensity level to the desired level (“Adjusting Stimulation Intensity” on page 8-33).
4. From standby mode, press and hold the minus button for at least three seconds. The remote control will beep and the new default intensity level will flash on the digital display for a few seconds while saving.

The saved level will be the default level whenever the stimulation program is started or until a new default level is saved.

Turning Stimulation Off

To turn stimulation off:

Stimulation Off **Stimulation On**

1 Press the mode button briefly. The remote control will return to standby mode and the mode button will turn off. Stimulation will stop.

Remote Control Off **Remote Control On**

2 *Or,* turn the remote control off. The remote control can be turned off at all times. When the remote control is turned off, stimulation will stop.

Note: *The remote control is designed to mitigate unintentional stimulation or stimulation at an intensity level that is too high. If stimulation is inadvertently set too high or turned on unintentionally, and cannot be corrected using the remote control, remove the user patch. If the remote control malfunctions, or an unexpected response or stimulation level is experienced, take the user patch off and contact Bioness Customer Support.*

Taking Off the User Patch

Note: *Remove the user patch before bathing, when the battery wears out and when the gel adhesive, with or without the assistance of a patch sleeve or strap, can no longer keep the user patch in place.*

Periodically, the user patch will also need to be removed to allow the skin to breathe. Skin irritation can result from prolonged contact with the surface gel electrodes.

To remove the user patch:

1. Stop stimulation and turn the remote control off.
2. If a patch strap or sleeve was used, take the strap off.
3. Grasp the tab on the user patch and gently pull the patch away from the skin.
4. Place the electrode cover over the gel electrodes.
5. If the user patch is still operational, store the patch in the user patch carrying case.
6. If the user patch is no longer operational, remove the external pulse transmitter (EPT) from the user patch and dispose of the patch according to local regulations.

Note: *Do not dispose of the EPT.*

Removing the External Pulse Transmitter

To remove the external pulse transmitter (EPT):

1. Gently pull the latching mechanism on the user patch back and away from the EPT.
2. Lift out the EPT.

Note: *Do not dispose of the EPT.*

3. Store the EPT in the User Kit or the user patch carrying case, or attach it to a new user patch.

CHAPTER

9

MAINTENANCE AND CLEANING

CAUTION: *Do not attempt to repair any of the components supplied in the StimRouter User Kit. If a component malfunctions or is lost, contact Bioness Customer Support.*

Recharging the Remote Control Battery

The remote control battery should be charged daily, after extended storage and when the remote control icon flashes yellow. The battery must be charged for stimulation to be effective and comfortable. See "Charging the Remote Control" on page 7-27.

Replacing the Remote Control Battery

The remote control battery should be replaced approximately every two years.

To replace the battery:

1. Remove the screw from the battery cover on the back of the remote control. The screw is under a label. Gently peel up the corner of the label, taking care not to damage the label.
2. Remove the battery cover.

3 Remove the old battery.Insert a new *rechargeable* AAA NiMH 1.2-V battery, orienting it to match the polarity marks on the battery socket.

WARNING: *Use only a rechargeable 1.2-V NiMH AAA battery. Use of a non-rechargeable battery can damage and overheat the remote control, and may lead to tissue injury or burns.*

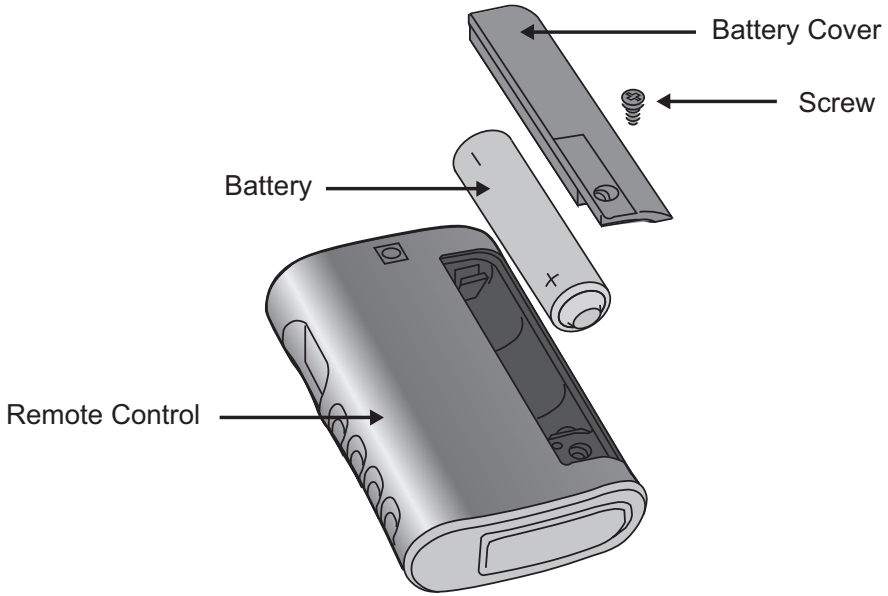
4 Reattach the battery cover.

5 Tighten the screw.

6 Reattach the label.

7 Dispose of the old battery according to your local environmental regulations.

FIGURE 9-1. Diagram for opening the remote control battery compartment.



Registering a New Component

When you replace your remote control or external pulse transmitter, the new working components must be electronically registered to each other for your StimRouter to operate.

To perform the registration procedure, both the remote control and the external pulse transmitter must be operational. Make sure the remote control is charged and that the external pulse transmitter is attached to a user patch with a working battery.

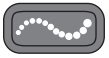
***Note**: Please read all of the instructions below before beginning the registration procedure.*

To register the remote control and the external pulse transmitter:

1. If necessary, charge the remote control.
2. Ensure that the remote control is turned off (the on/off button should *not* be flashing green).

Remote Control Off	Remote Control On
	

3. Attach the external pulse transmitter to a user patch with a working battery.
4. Place the remote control and user patch *with external pulse transmitter attached* close together on a table. Make make sure the remote control and the external pulse transmitter are no more than a few inches apart and not touching.
5. Make certain that any other external pulse transmitter is at least 10 feet away from the components to be registered.



6. Simultaneously press and hold for three seconds the mode and minus buttons on the remote control to start the registration process. You should hear a beep, indicating the registration process has begun.

7. The remote control digital readout should display two alternating green arches, indicating registration is in progress.

Registration in Progress	
	

Registration Connected	
Registration Error	

8 When the readout displays the letter “C” (meaning connected), and the radio frequency icon turns green for a few seconds, registration is complete. The system will automatically turn on. If the radio frequency icon is not flashing red, registration was successful.

Note: *If the readout displays the letter “E” (meaning error) and the radio frequency icon turns red for a few seconds, an error has occurred and the procedure must be repeated. If the error indication continues to appear, contact Bioness Customer Support.*

Replacing the User Patch

The user patch is disposable; when the battery loses its charge or the gel electrodes lose their adhesiveness and do not provide stable positioning with or without the aid of a patch sleeve, dispose of the patch according to your local regulations.

To replace a user patch:

1 Stop stimulation and turn the remote control off.

2 If a patch sleeve was used, take the sleeve off.

3 Grasp the patch tab and gently pull the patch from the skin.

4 Place the electrode cover over the gel electrodes.

5 Gently pull the latching mechanism back and away from the external pulse transmitter (EPT) and lift out the EPT.

Note: *Do not discard the EPT.*

6 Open a new user patch.

7 Hold the EPT with the label facing toward the new user patch.

8 Align the gold connector on the EPT with the connector's port on the user patch. Push the EPT forward into the port. Press the EPT toward the patch to lock the latching mechanism.

Note: *To ensure proper electrical stimulation, the external pulse transmitter must be connected to the user patch properly.*

Cleaning the Components

- All StimRouter components may be cleaned by carefully wiping with a damp cloth.
- StimRouter electronic components are not waterproof; do not immerse them in water to clean.

Cleaning the Patch Sleeves

- Wash by hand in lukewarm water, separately from other items
- Hang dry in shade without folds
- Do not iron
- Do not dry in a dryer
- Do not leave the sleeves rolled up when wet
- Avoid contact with rough or hard surfaces
- Avoid contact with lotions, oils and other chemicals

CHAPTER

10

TROUBLESHOOTING

Should a technical problem occur that is not covered in this section, contact **Bioness Customer Support: Telephone: (800) 211-9136.**

Note: *Do not attempt to repair any of your StimRouter components.*

User Patch

Faulty Electrode Contact

Indicators

- Beep
- User patch icon flashes red
- Intensity level flashes in digital display

Corrective Actions

1. Turn off the remote control.
2. Remove the user patch from the body.
3. Check to see that the electrode cover was removed from the patch.
4. Make sure that nothing is on the electrodes or on the skin that would interfere with electrode contact with the skin.

5 Check to see that the external pulse transmitter is snugly attached to the user patch.

6 Re-adhere the user patch to the skin.

7 If the problem persists, adhere a new user patch.

8 If the problem persists, contact Bioness Customer Support.

Battery Low Charge

Indicators

- Beep
- User patch icon flashes yellow

Corrective Actions

1 Change the user patch.

2 If the problem persists, contact Bioness Customer Support.

Battery Failure

Indicator

- Radio frequency icon flashes red

Corrective Actions

1 Reattach the external pulse transmitter to the same user patch.

2 Replace the user patch. Use a new user patch and connect the external pulse transmitter to the new patch.

3 If the problem persists, contact Bioness Customer Support.

Remote Control

Battery Low Charge

Indicators

- Beep
- Remote control icon flashes yellow

Corrective Actions

1. Charge the remote control battery.
2. If the problem persists, replace the battery.

Battery Failure

Indicator

- When the remote control is turned on, none of the icons lights up; no self test is performed

Corrective Actions

1. Charge the battery.
2. If the problem persists, replace the battery.

Battery Discharges Rapidly

Indicator

- Remote control battery discharges rapidly (the battery should last for about 24 hours of normal use)

Corrective Action

1. Replace the battery.

Battery Charging Error

Indicator

- *While charging,* the letter “E” appears on the digital display and the remote control icon glows red

Corrective Actions

1. Reconnect the charger cable to the remote control.
2. If the problem persists, replace the battery in the remote control.
3. If the problem persists, contact Bioness Customer Support.

External Pulse Transmitter

Temperature Error

Indicator

- The user patch icon flashes red and “E” flashes in the digital display

Corrective Action

1. The external pulse transmitter is either too hot or too cold and will cease activity until its working temperature range is restored.

Component Malfunction

Indicators

- Beep
- User patch icon is glows red *or* remote control icon glows red and“E” appears in the digital display

Corrective Actions

1. Turn off the remote control and then turn it back on.
2. If the problem persists, contact Bioness Customer Support.

Radio Communication Failure

Indicators

- Beep
- The radio frequency icon flashes red

Corrective Actions

1. Make sure that the remote control and the external pulse transmitter (EPT) are within 10 feet of each other.
2. Make sure that the remote control battery is charged.
3. If the components are within range and working properly, turn the remote control off and then back on.
4. Check to see that the external pulse transmitter is snugly attached to the user patch.
5. Replace the user patch: use a new user patch and connect the external pulse transmitter to the new patch.
6. If the problem persists, reregister the components.
7. If the problem still persists, contact Bioness Customer Support.

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