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Warnings and Cautions

Physicians and patients should know the limitations, warnings and precautions associated with the StimRouter Neuromodulation System. Physicians should review the warnings and precautions and instructions for use with the patient. If at any time the physician or patient is concerned about the safety or effectiveness of the StimRouter system, then call Bioness at (800) 211-9136 or your local distributor.

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

Indications for Use

The 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 in the craniofacial region.

Contraindications

The Bioness StimRouter Neuromodulation System is contraindicated for:

- Patients who have any active implanted device such as an implanted demand cardiac pacemaker or defibrillator, or any metallic implant in the immediate area intended for implant. Maintain a minimum safe separation distance of 15 cm (6 in.) between the 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 Neuromodulation System.
- Patient who are high surgical risks or poor surgical candidates in general.
- Patients who have a cancerous lesion present near the target stimulation point or near to where the StimRouter Electrode will adhere.
- Patients who are known or suspected to have a nickel allergy. The handles of the tunneling needle and tunneling needle stylet, used in the implant procedure, are nickel plated.
- Patients with bleeding disorders or active anticoagulation that cannot be stopped for a few days close to the time of the surgical procedure.

Implantation Setting

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

Patient Screening

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

Select patients carefully to ensure that:

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

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

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

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

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

⚠ Warnings

Magnetic Resonance Imaging (MRI) Warnings and Precautions

- When using a full body transmit radio frequency (RF) coil, do not scan patients with a specific absorption rate (SAR) level exceeding 2 W/kg. A scan above 2 W/kg may increase the risk of MRI-related heating.
- When using head transmit RF coil, do not exceed head SAR of 3.2 W/Kg.
- Do not place a local RF transmit coil directly over the implanted StimRouter Lead.

StimRouter External Component Restrictions

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

MRI Information

Non-clinical testing has demonstrated that the StimRouter Lead is "MR Conditional". Patients with an implanted StimRouter Lead can be scanned safely, immediately after implantation, in MR cylindrical bore system that meets the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3 T; and
- Maximum spatial field gradient of 2500 gauss/cm (25 T/m); and
- To ensure patient safety, relative to potential heating of the StimRouter Lead, either one of the two following scenarios must exist:
    - When the entire StimRouter Lead is at least 50 cm (19.7in.) away from the center of the MR system's bore and at least 16 cm (6.3 in.) from the end of the RF coil (See Figure 2-1), the reported whole body averaged specific absorption rate (WB SAR) does not exceed 2W/kg at 1.5T or at 3.0T; or

- When all or part of the StimRouter Lead is either (a) less than 50 cm (19.7 in.) from the center of the MR system's bore; or (b) less than 16 cm (6.3 in.) from the end of the RF coil, whichever is the furthest distance from the center of the bore (i.e., referred to as the "Reduced Zone"), reduced values of WB SAR and B_1 are utilized in order to result in acceptable tissue temperature increases of 2°C, 5°C, and/or 6°C, whichever is determined by the clinician to be appropriate (See Tables 2-1 and 2-2).

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

To clarify further, the StimRouter Lead is considered to be "outside the Reduced Zone" if the entire lead is located outside of the Reduced Zone.

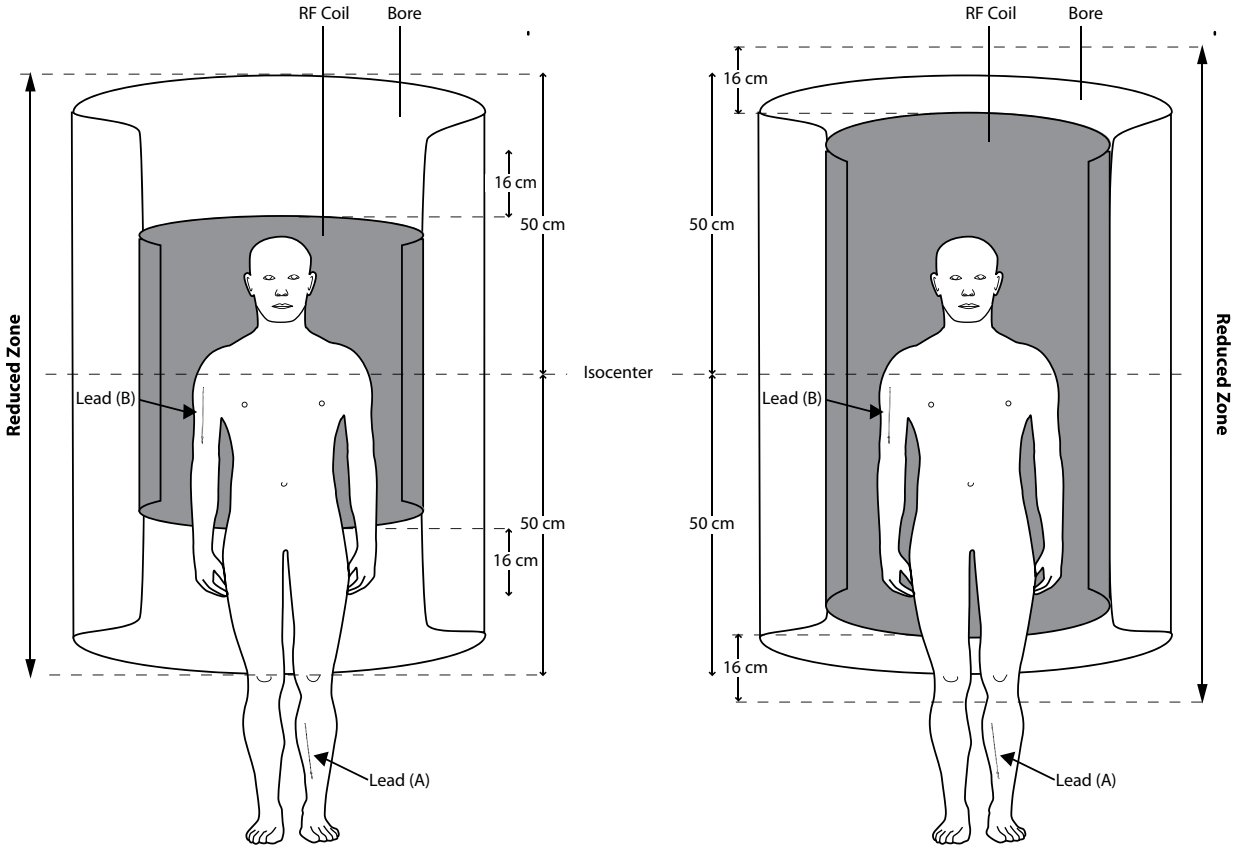

Figure 2-1: Figures show different relationships between the 50 cm measured from the center of the MR bore and the 16 cm measured from the edge of the MR coil.

In Figure 2-1 the StimRouter Lead (A) implant is **outside** the "Reduced Zone." The entire StimRouter Lead is at least 50 cm away from the center of the MR system's bore (the iso-center) and at least 16 cm outside of the MR coil measured from the edge of the MR coil. In Figure 2-1, the StimRouter Lead (B) implant is **inside** the "Reduced Zone." StimRouter Lead (A) is shown implanted in the lower leg and StimRouter Lead (B) is shown implanted in the arm.

To ensure patient safety relative to potential heating of the implanted StimRouter Lead, clinicians performing MR procedures on implanted patients should adhere to the following conditions:

When using full body transmit RF coil:

- When the entire StimRouter is **outside** of the Reduced Zone, the reported whole-body-averaged SAR does not exceed 2 W/kg at 1.5 T and 2 W/kg at 3 T. Do not scan patients with a SAR level exceeding 2 W/kg. A MR scan performed with a 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 Zone, reduced values of WB SAR and B_1 should be utilized in order to result in acceptable tissue temperature increases of 2°C, 5°C, and/or 6°C. See Tables 2-1 and 2-2 for the WB SAR and B_1 values recommended for use when all or part of the StimRouter Lead implant is within the Reduced Zone during the MR procedure.

When using head transmit RF coil:

- Limit head SAR to 3.2 W/Kg and otherwise follow normal operation procedures of the MR system for patients when all or part of the StimRouter Lead implant is located at the shoulder or at lower areas of the body.
- Do **not** use RF head transmit coil when all or part of the StimRouter Lead implant is located above the level of the acromioclavicular joint.
- Under these conditions, the maximum calculated temperature rise at the implanted StimRouter Lead did not exceed 0.1°C for the Lead implanted in either the shoulder or any area of the body below the shoulder.

Information regarding the precise anatomical position of the implanted StimRouter Lead is necessary for performing routine MRI procedures. Prior to initiating any MR procedure, the clinician 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 lead in the patient's body.

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

MRI-Related Heating: Supplemental Information

1.5 T/64 MHz

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

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

A computer simulation that incorporated the worst-case measured temperature rise at several anatomic locations and a whole-body averaged SAR of 2 W/kg predicts a worst-case heating of an implanted StimRouter Lead in the patient during MRI of less than 2°C, provided that the entire StimRouter Lead implant is outside of the Reduced Zone.

For a StimRouter Lead implant located inside the Reduced Zone, the worst-case Lead heating was calculated for the following values of WB SAR and B_1:

	RF Frequency = 64MHz					
	ΔT = 6°C		ΔT = 5°C		ΔT = 2°C	
Path	WB SAR [W/kg]	B_1 [μT]	WB SAR [W/kg]	B_1 [μT]	WB SAR [W/kg]	B_1 [μT]
Upper Arm	0.40	1.74	0.33	1.59	0.13	1.00
Intercostal	0.43	1.91	0.36	1.74	0.14	1.10
Lower Leg (below the knee)	0.24	2.68	0.20	2.45	0.08	1.55
Upper Leg (knee and/ or thigh)	0.26	3.38	0.22	2.17	0.09	1.37

Table 2-1. Values of WB SAR and B_1 in the Reduced Zone that will produce a maximum in-vivo rise of 2°C, 5°C or 6°C @ 64MHz RF.

3 T/128 MHz

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

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

A computer simulation that incorporated the worst-case measured temperature rise at several anatomic locations and a whole-body averaged SAR of 2 W/kg predicts a worst-case heating of an implanted StimRouter Lead in the patient during MRI of less than 1°C, provided that the entire StimRouter Lead implant is outside of the Reduced Zone.

For a StimRouter Lead implant located inside the Reduced Zone, the worst-case Lead heating was calculated for the following values of WB SAR and B_1:

	RF Frequency = 128MHz					
	ΔT = 6°C		ΔT = 5°C		ΔT = 2°C	
Path	WB SAR [W/kg]	B_1 [μT]	WB SAR [W/kg]	B_1 [μT]	WB SAR [W/kg]	B_1 [μT]
Upper Arm	0.87	1.45	0.73	1.32	0.29	0.84
Intercostal	1.93	2.16	1.61	1.97	0.64	1.25
Lower Leg (below the knee)	0.70	2.61	0.58	2.38	0.23	1.51
Upper Leg (knee and/ or thigh)	0.78	2.00	0.65	1.83	0.26	1.15

Table 2-2. Values of WB SAR and B_1 in the Reduced Zone that will produce a maximum in-vivo rise of 2°C, 5°C or 6°C @ 128MHz RF.

Image Artifacts

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

Induced Currents

The electric fields induced in the patient with the StimRouter Lead by the pulsed gradient fields were calculated. The induced current will be less than the stimulation threshold if the StimRouter Lead is located outside of the Reduced Zone.

Potential Adverse Events

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

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

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

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

Device Components

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

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.

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

Driving and Operating Machinery

StimRouter stimulation should be off while driving 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, may cause permanent damage to the external components and may injure the patient, particularly if used in close proximity to the system components:

- Lithotripsy
- Electrocautery
- External defibrillation
- Ultrasonic scanning
- High-output ultrasound
- Electromagnetic interference (EMI) from the following medical procedures is unlikely to affect the StimRouter system:
    - Computerized Axial Tomography (CT or CAT) scans
    - Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
    - Diagnostic x-rays or fluoroscopy

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

Electrosurgery Devices

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

High-Frequency Surgical Equipment

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

Body-Worn Devices

Although unlikely, body-worn medical devices may interfere with the RF communication used in the StimRouter system. Stimulation control may be delayed. Examples of a body worn device are 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 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. Have patients ask for help to bypass the device. Show their Medical Device Identification Card. If they must pass through the device:

- Turn off the 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

Physician Training

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

Post-Operative Care

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

Implant Location

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

For Single Patient Use Only

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

Postural Changes

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

Keep out of Reach of Children

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

Skin Abnormalities

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

Skin Irritation

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

Known or Suspected Heart Problems

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

StimRouter Electrode Placement and Stimulation

- Electrical stimulation should not be applied trans-thoracically or at the heart such that current may travel into or through the cardiac tissue, as such introduction of electrical current may cause heart rhythm disturbances.
- Avoid placing the StimRouter Electrode across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus).
- Turn off stimulation before adhering, removing or handling the StimRouter Electrode.
- StimRouter Electrode placement and stimulation settings should be determined by the implanting physician.
- Do not apply the StimRouter Electrode over any obstruction that would reduce the designated electrode surface area (for example, an adhesive bandage). A smaller electrode surface area could result in serious injury to the patient.

- Do not apply the StimRouter Electrode over skin folds, scarred tissue, irritated skin, uneven skin surfaces or broken skin.
- Always inspect the gel pads on the back of the StimRouter Electrode before use. Do not apply the StimRouter electrode if the gel pads appear dried out, worn, dirty or irregular.
- Make sure the StimRouter Electrode liner is removed before adhering to the skin.
- Do not handle the StimRouter Electrode with both hands while stimulation is on; serious injury can result from current passing through the cardiac tissues.

Expiration Date

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

Implant Failure

Leads may fail at any time because of random component failure or lead breakage. If component failure or lead breakage occurs, then the lead may need to be removed or replaced. It is possible that there will be retained lead fragments during attempted explants, which will make certain procedures contraindicated indefinitely (e.g, diathermy, therapeutic ultrasound, or MRI in the affected area).

Storage and Handling

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

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

Adverse Effects

In the unlikely event that any of the following occurs, patients should stop using their StimRouter system, remove the StimRouter Electrode and immediately consult their physician.

Risks Related to the Implant Procedure

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

Risks Related to Stimulation

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

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

Additional Risks Related to the StimRouter System

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

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