

RS-4i[®] *Plus*

Instructions for Use



Before using the RS-4i Plus Sequential Stimulator with Intersperse®

Please read the entire Instructions For Use before using the RS-4i Plus. The RS-4i Plus is a prescription device. It is to be used only by the person for whom it is prescribed and only for the treatments prescribed.

Caution: Federal law restricts this device to sale by or on the order of a physician or any other practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

User assistance

Read these Instructions For Use. If after reading it you have any questions about the RS-4i Plus or its use, call RS Medical Customer Service, toll-free, at 800-935-7763.

Additional information, including videos and interactive demonstrations, is available at:

www.rsmedical.com

If you have any questions about your medical condition, call your prescribing physician.

For assistance, please contact
RS Medical Customer Service
toll-free at
800-935-7763

Para obtener ayuda,
póngase en contacto con
RS Medical Servicio
de Cliente
al número gratuito
800-935-7763

When you call customer service, please have your stimulator serial number handy.



The serial number is located underneath the battery. Remove the battery by holding the stimulator with both hands, battery facing up. Press the oval button with one thumb and use your other thumb to release the battery.



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Prescribing Information

Please take time to read through the following prescribing information. Incorrect use of the stimulator can result in bodily harm or damage to the device.

This stimulator should be used only under the continued supervision of your physician. Contact your prescribing physician if there is any change in an existing condition or if any new condition develops. (You may also refer to *If You Experience a Problem*, page 28.)

Indications For Use

Interferential Stimulation (all Pain Relief modes)

- Relieve acute pain
- Relieve and manage chronic pain

Muscle Stimulation (all Muscle Therapy modes)

- Relax muscle spasm
- Prevention or retardation of disuse atrophy
- Maintain or increase range of motion
- Increase local blood circulation
- Re-educate muscle
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Contraindications

These are the conditions under which this electrical stimulator should not be used:

- Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device because this may cause electric shock, burns, electrical interference, or death.
- Do not use this device whenever pain syndromes are undiagnosed, until etiology (cause) is established.

Warnings

- Do not apply stimulation over the neck because this type of application could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across the chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal.
- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins.) Apply stimulation only to normal, intact, clean, healthy skin.
- Do not apply stimulation over, or in proximity to, cancerous lesions.

- Do not apply stimulation in the presence of electronic monitoring equipment (such as ECG monitors and ECG alarms) which may not operate properly when stimulation is in use.
- Do not apply stimulation when in the bath or shower.
- Do not apply stimulation while sleeping.
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
- Consult your physician before using this device because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.
- Electrical nerve stimulation is a symptomatic treatment intended to suppress or lessen the sensation of pain, which would otherwise serve as a protective mechanism.
- Operation of the device may be affected by shortwave or diathermy therapy, high-frequency surgical equipment, x-rays from computed tomography (CT) scanning, magnetic resonance imaging (MRI), and other ionizing radiation sources.
- Do not use the device in an environment where flammable gases may be present.
- Simultaneous connection of a patient to a high frequency surgical device may result in burns at the site of the electrode pads and possible damage to the device.
- Keep the stimulator and all other items in a cool, dry place, away from liquids, chemicals, cosmetics, direct heat, freezing conditions, and bright sunlight.
- Do not submerge the device in liquids or expose it to large amounts of water; do not use in the bath or shower.
- The size, shape, type and electrical performance characteristics of the electrode pads may affect the safety and effectiveness of electrical stimulation.
- Using electrodes that are too small, incorrectly applied or partially adhering to the skin could result in discomfort or skin burns. Electrodes should be no smaller than 2 inches round or have a minimum 3.14 square inches of surface area.
- You should contact RS Medical if you do not know if the electrode pads can be used with the stimulation device.
- Patients should not share electrode pads with other persons because of the risks of adverse skin reactions and disease transmission.
- Do not modify this equipment without authorization of the manufacturer. Unauthorized modification of any part may result in injury.

Precautions

- CAUTION: Device can get hot during use. Do not place stimulator directly on skin during treatment.
- The long-term effects of electrical stimulation are unknown.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- The safety of electrical stimulation during pregnancy or birth has not been established.
- Some patients may experience skin irritation or hyper-sensitivity due to the electrical stimulation or electrical conductive medium.
- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physician.
- Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physician.
- Use caution when there is a tendency to bleed internally, such as following injury or fracture.
- Use caution following recent surgical procedures when stimulation may disrupt the healing process.
- Use caution when applying electrical stimulation over a menstruating or pregnant uterus.
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep this device out of the reach of children.
- Use this device only with the cables, battery, electrode pads, and accessories recommended by RS Medical. Do not substitute or use any other components other than those supplied with the device. Components include: electrode pads, connecting cables, lithium-ion battery, AC adapter, and battery charging dock.
- Use this device only under the continued supervision of a licensed practitioner.
- Treatment outcome will be influenced by the patient's psychological state and use of drugs.
- Stimulation near or over metallic structures or implants may cause discomfort.
- Interferential stimulation (all Pain Relief modes) has no curative value.
- Interferential stimulation (all Pain Relief modes) is not effective for pain of central origin (including headache).
- Do not remove or reposition the electrode pads when the stimulator is on. Touching the conductive gel of the electrodes during treatment may cause an unpleasant transfer of all stimulation directly to your fingertip.
- Isolated cases of skin irritation may occur at the site of electrode pad placement following long-term application (beyond the prescribed treatment time).
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
- Electrode pad placement and stimulation settings should be based on the guidance of the prescribing physician. The device should be used only under the continued supervision of your physician. Contact your prescribing physician if there is any change in an existing condition or if any new condition develops.
- Do not use if the device appears to be damaged from shipping or the carrying case is opened or damaged; if this occurs, call RS Medical Customer Service at 800-935-7763.

Adverse Effects

- Patients may experience skin irritation and burns beneath the electrode pads applied to the skin.
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
- Patients should stop using the device and should consult with their physician if they experience adverse reactions from the device.



About the RS-4i Plus

For many patients, a muscle condition is painful, and may limit their ability to complete common daily activities. The RS-4i Plus Sequential Stimulator with Intersperse® provides non-invasive, non-habit forming therapy to both relieve pain and restore muscle function in a single treatment.

Because the RS-4i Plus is designed for you to use in your home or to be easily transported, you can fit treatments into your daily schedule when it is convenient to you. The RS-4i Plus is prescribed by your physician, so you can be confident you are receiving the treatment you need.

What Will I Feel?

When the RS-4i Plus is working to relieve your pain (all Pain Relief modes), you will feel a gentle, tingling sensation at the area being treated. The sensation is similar to when your hand or leg has “gone to sleep” and is a normal result of the stimulation.

Over time your body may get used to this sensation as the nerves in the treatment area are overwhelmed by the stimulation, which can cause a numbing effect. Although you may no longer feel the stimulation the therapy will continue to provide pain relief.

While using the stimulator for muscle therapy (all Muscle Therapy modes), you will feel your muscles in the treatment area contract and relax. Contractions will feel like strong, comfortable involuntary muscle movements. Between each contraction your muscles will relax.

For more detailed descriptions of all the treatments available in the RS-4i Plus, please refer to *Appendix A: Treatment Descriptions*, page 36.

How Does the RS-4i Plus Work?

When working to relieve your pain, the RS-4i Plus uses an interferential waveform that blocks pain signals from passing along the nervous system to the brain. Pain Relief treatment segments can help:

- Relieve acute pain
- Relieve and manage chronic pain

During muscle therapy, the stimulator uses a muscle stimulation waveform that causes the muscle fibers to shorten and the muscle to contract. The waveform is similar to the signal your brain uses to tell your muscles to contract voluntarily. Following each contraction the waveform will turn off to allow the muscle to relax.

Muscle Therapy modes are intended to:

- Relax a muscle spasm
- Prevent or retard muscle atrophy caused by disuse
- Maintain or increase the range of motion of a muscle
- Increase local blood circulation
- “Re-educate” a muscle
- Prevent venous thrombosis (blood clot) after surgery by stimulating the calf muscles

During an Intersperse segment, Pain Relief and Muscle Treatment are combined. A light tingling on your skin will alternate with muscle contractions.

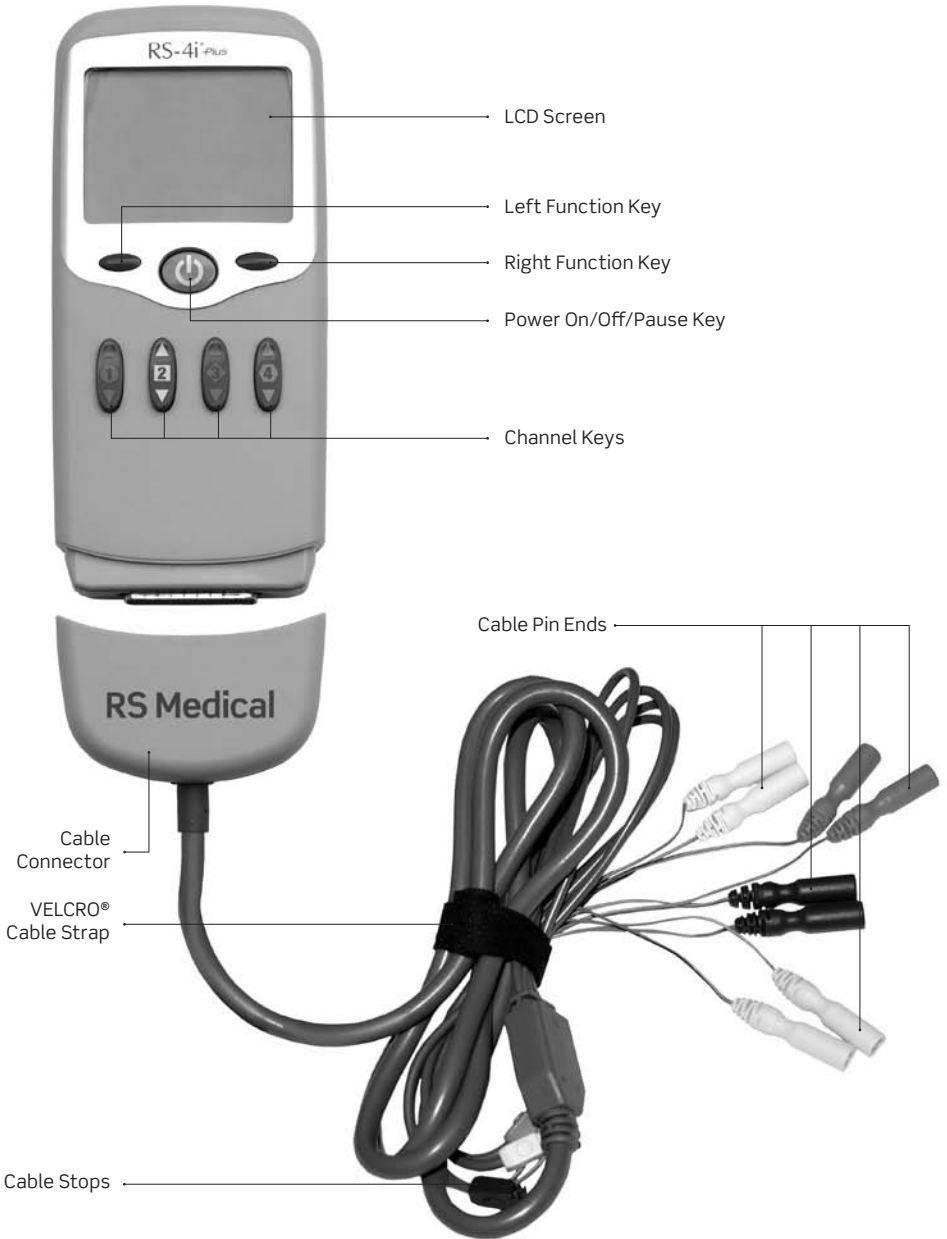
Caution: If you feel any unusual discomfort or physical symptoms as a result of using the stimulator, please refer to *If You Experience a Problem*, page 28.

The RS-4i Plus kit contains:

- 1 RS-4i Plus Sequential Stimulator with Intersperse
- 1 Four-channel, all-in-one cable with VELCRO® cable strap
- 8 2-inch round self-adhering electrode pads (2 packages each containing 4 pads)
- 1 Removable lithium ion battery
- 1 Charging dock
- 1 AC adapter for charging dock
- 1 Instructions for Use (this booklet)
- 1 Patient Information Booklet



If you are missing a component, need additional supplies, or if any part appears to be broken, frayed or damaged, contact RS Medical at 800-935-7763 to order a replacement. Do not substitute or use any other component with the RS-4i Plus other than those supplied by RS Medical.





If this is the first time you are using the stimulator, you should fully charge the battery before taking a treatment. Charge the battery when the battery indicator on the stimulator screen shows one bar remaining or a charge battery message appears.



1 Connect AC Adapter to Charging Dock

Plug into any 120V outlet. The green power light indicates the power is on and the charging dock is ready to charge a battery.



2 Locate Battery

If needed, remove the battery from the stimulator. Press the oval button with one thumb, and use your other thumb to gently press up to release the battery.



3
Status light blinks during charge;
solid when charge is complete.

3 Seat Battery Upright in Charging Dock


When the battery is charging, the green status light will blink. When the battery is fully charged, the status light stops blinking (but remains on).

NOTES

Charge the battery in a cool dry place, away from liquids, chemicals, cosmetics, direct heat, freezing conditions, and bright sunlight. See *Appendix B: Technical Specifications* on page 37 for the acceptable operating temperature range.

If the battery is completely depleted, the two green lights on the charging dock may remain lit until the battery begins to charge. At that point, the status light will blink until charging is complete.

You can read more about the battery in *Maintenance Tips*, page 23.



Prepare For Your Treatment

Wash and dry body areas where electrode pads will be applied

Make sure the skin in the treatment area is clean, dry, and free from lotion before using the stimulator. Lotions, oils, powders and many other skin preparations may reduce the adhesiveness and conductive properties of the electrode pads.

Get into a relaxed, comfortable position

Stimulation therapy works best when you are relaxed, so find a place where you can sit or lie down for the entire treatment time. Most program options last 35 minutes and all treatments are limited to 60 minutes.

Establish a regular daily and weekly routine with the RS-4i Plus to help ensure you do not miss a treatment. Pick times during the day that are the most convenient, such as when you read the newspaper or watch television.

Review your treatment

Take a moment to review the number of electrode pads required, their proper placement on your body, and any other special instructions you may have received on the use of the RS-4i Plus.

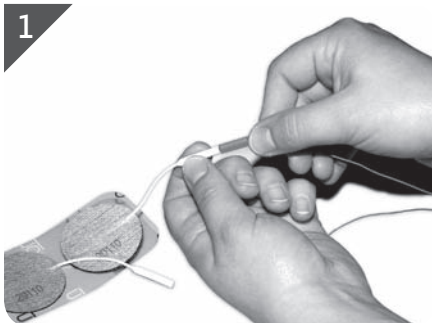
Your RS Medical representative or healthcare professional may have provided instructions for you on the figures in *Appendix C: Treatment Notes*, page 39. You can also find a table with treatment descriptions on page 36.

NOTES

Quadripolar Pad Placement

This indicates that the treatment requires electrode pads to be placed over the treatment area in a crisscross fashion or X pattern directly over a source of pain.

Quadripolar pad placement will include channels 1 and 2 crossed over one area of pain and channels 3 and 4 crossed over a second area. In this treatment mode the channel 1 key controls the intensity of channels 1 and 2 and the channel 3 key controls the intensity of channels 3 and 4.

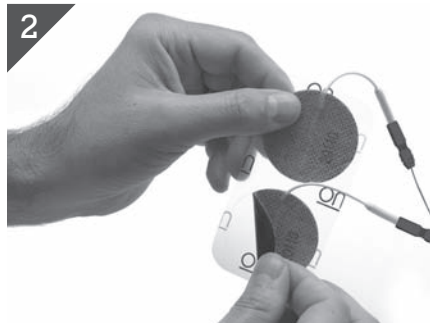


1

Attach Electrode Pads to Cable Pins

The stimulator cable has eight pins (two per channel) that connect to electrode pads that are to be placed on the body. The number of channels and electrode pads you use will depend on your prescription.

Insert the cable pins into the “tails” of the electrode pads.



2

Place Electrode Pads on Treatment Area

Working with one electrode pad at a time, remove the pad from the storage liner by grasping the edge of the pad and peeling it off, and then place the pad on the appropriate area of your body. Two cable pin ends with the same color make up one pair and correspond with the channel key colors on the device.

Keep the plastic liner for electrode pad storage between treatments.



3

Attach Cable Connector to the Device

When you are ready to take a treatment, and in a comfortable position, attach the cable connector to the device.



4

Turn on the Device

Press the On/Off/Pause key to turn on the device.

If the display reads “Recharge Battery,” follow the battery recharging instructions that appear on page 9.

OPTIONAL

VELCRO Cable Strap



Adjust Length of Cable

To increase the length of the cable, unhook the VELCRO cable strap and unroll the cable. To control cable length, coil and wrap the VELCRO cable strap to hook into place.

NOTES

- Electrodes should be no smaller than 2 inches round or 1.8 inches square.
- Only remove or reposition the electrode pads when the stimulator is paused or turned off.
- When the stimulator is turned on, the backlight comes on for 30 seconds, and then turns off to conserve power. Pressing the down arrow on any channel key will cause the backlight to come back on.
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
- Cable pins are surrounded by a comfort grip to prevent the cable from being plugged into any power source, such as an electrical outlet.
- Removal of battery while the product is in use may cause a spark at the electrical connector. Do not use the device in an environment where flammable gases may be present.



Before each treatment you will be asked to describe your current level of pain on a scale from 0 (No Hurt) to 10 (Hurts Worst). Your answer will be saved by the stimulator to help track your level of success from using the RS-4i Plus.

Wong-Baker FACES™ Pain Rating Scale



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If this data is not necessary, the pain level question may be disabled by your clinician or RS Medical. To re-enable the questions, please see the instructions on page 22.



Adjust with Channel Keys

Press up (▲) on any channel key to increase the level of pain. Press down (▼) on any channel key to decrease the level of pain.

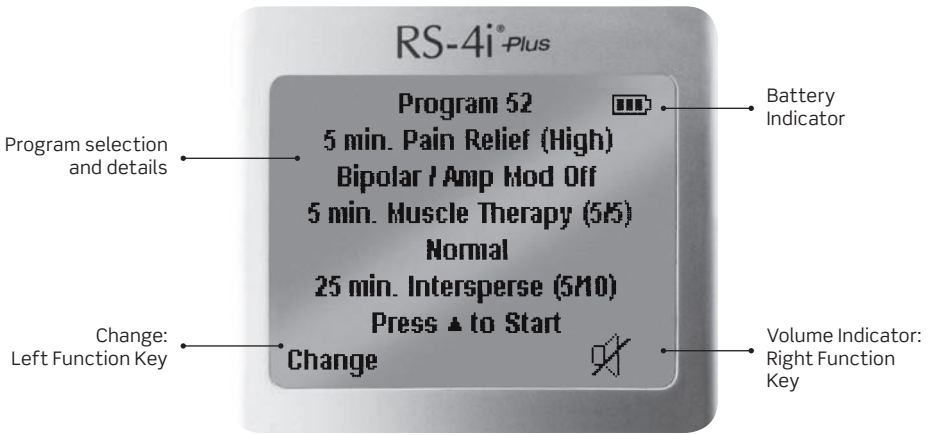


Accept or Skip with Function Keys

Once you see the number and face that indicates your current level of pain, press the right function key to accept the level. You may skip this question by pressing the left function key.

Take Your Treatment

The Program Selection screen contains a description of your default program setting, a battery indicator, access to change program, and adjust volume.



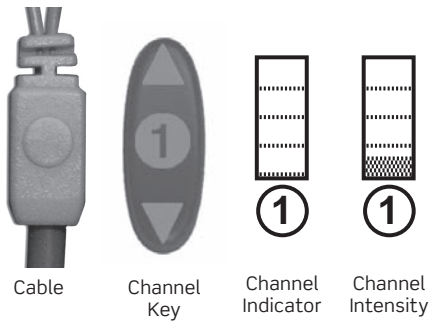
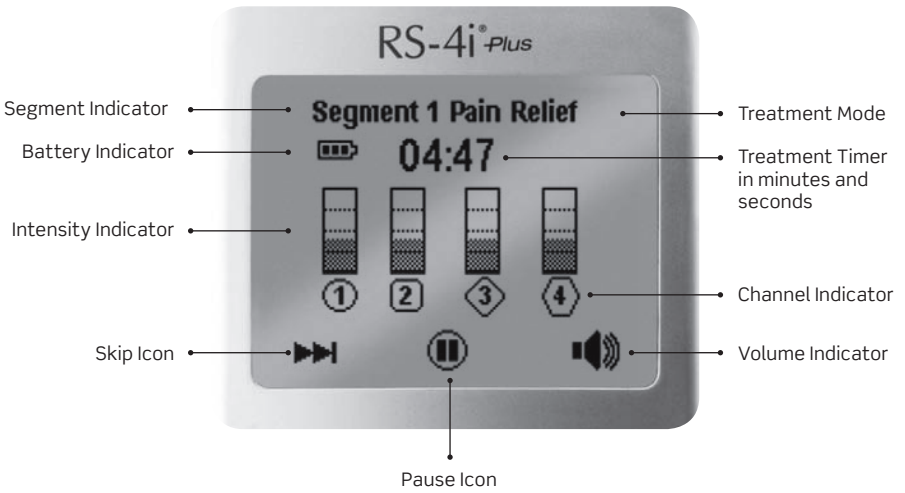
Select Your Program

You may have up to eleven programs to choose from, depending upon the group of programs selected for you by your physician. (If a custom program has been created for you, Program 99, you will only have access to your custom program option.) You can find description of how a program will feel by looking in *Appendix A: Treatment Descriptions*.



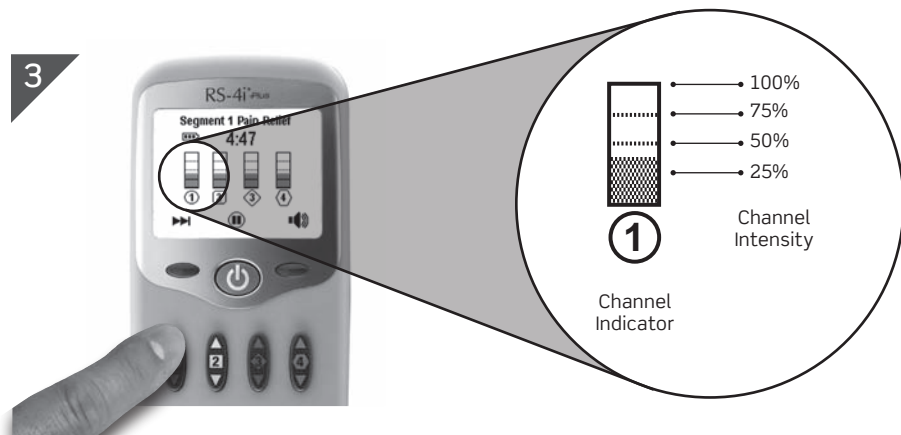
Start Your Program

With your desired program settings visible, press up (▲) on any channel key to start that program. The treatment screen will appear to indicate your current treatment status.



Each channel key controls the intensity of that channel. The color and symbol of the channel key match the color and symbol found on the cable and on the treatment screen.

3



Adjust the Intensity

As the intensity changes, the number of intensity indicator bars will change inside the channel indicator. You may need to press the intensity key a few times before you see the bars appear on the screen. One hundred key clicks are required to reach 100%, maximum intensity (if pressed one at a time). Always determine the intensity you need by how the treatment feels to you.

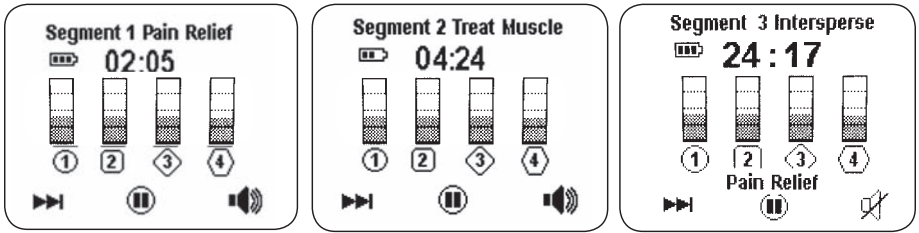
You may also press and hold the key to increase or decrease the channel intensity quickly.



Set Segment 1 Intensity

In most cases, Pain Relief will be your first treatment segment and you will set a comfortable intensity. In Pain Relief, it feels a little like the tingling you feel on your skin when your hand or leg has “gone to sleep”. Be careful not to increase the intensity too high. Your muscles should not contract during a Pain Relief segment. If your muscles move, decrease the intensity until your muscles no longer move. You may skip to the next segment at any time by pressing the left function key just below the skip icon **⏩** on the display.

To use the RS-4i Plus properly, you should be aware of whether the stimulator is in Pain Relief, Treat Muscle, or Intersperse mode. Depending on the treatment program selected, you may have one, two or three segments.



You get the most benefit during muscle stimulation if you increase channel settings to the highest intensity level that is comfortable to achieve a muscle contraction. For increased effectiveness, your physician may instruct you to increase the intensity to levels associated with discomfort. However, the safe use of muscle stimulation should not cause pain.

4



Start Next Segment(s)

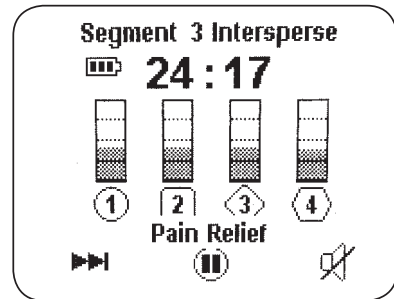
When your first segment is complete, a treatment complete screen appears, followed by the segment description screen for the next segment. To start a next segment, press up (▲) on any channel key.



Set Segment 2 Intensity

Your second treatment will most likely be a Treat Muscle segment and you will set a comfortable intensity. Press up (▲) on each channel key until you begin to experience a muscle contraction in the treatment area. Every time you increase the intensity a new muscle contraction will begin. Once you have reached your desired settings you will begin to feel your muscles contract and relax according to your program setting. In between each muscle contraction all channels will ramp down to zero to relax your muscles. This pattern is repeated for the entire Treat Muscle segment.

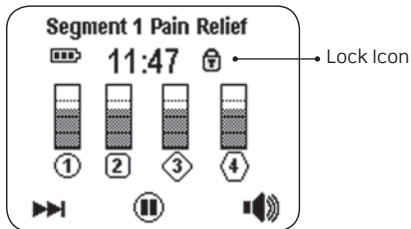
You get the most benefit during muscle stimulation if you increase channel settings to the highest intensity level that is comfortable to achieve a muscle contraction. For increased effectiveness, your physician may instruct you to increase the intensity to levels associated with discomfort. However, the safe use of muscle stimulation should not cause pain. You may skip to the next segment at any time.



Run Segment 3

Segment 3 will most often be an Intersperse treatment. If you ran segments 1 and 2 for at least two minutes, the intensity settings will auto run during segment 3 at the previously established levels. Muscle stimulation will alternate with pain relief throughout this segment. Use the channel keys to adjust intensities as needed throughout this segment. You will first feel a muscle contraction in the treatment area, as you did in the Treat Muscle segment. Between contractions, you will feel a tingling on your skin, as you did in the Pain Relief segment.

At the end of segment 3, your treatment is complete.



Auto-Lock Feature

After two minutes of button inactivity the channel and function keys are automatically locked. You can unlock the keys by clicking any channel or function key two times in quick sequence.

OPTIONAL

Adjust Your Program

You should follow your physician's instruction regarding frequency and length of treatment. There may be times, however, when you will want to adjust your treatment program. For example, you may want a longer pain treatment, or you may want to take only one segment of the treatment. The RS-4i Plus allows you to adjust your program.

While the 'Change' selection is showing, press the left function key to scroll through available program options.

OPTIONAL

Adjust the Speaker Volume

Press the right function key to control the volume of non-alert sounds.

Volume Indicators:



Pause a Treatment

If you need to pause your treatment, press the On/Off/Pause key once. The pause screen will appear. Each pause lasts five minutes, as indicated by the countdown timer on the screen.



Resume a Treatment

To resume your treatment, press any channel intensity key. The RS-4i Plus automatically increases the channel intensities to 85% of their previous settings. If you do not want the stimulator to automatically increase intensities, press any channel key again, and then manually adjust individual channel intensity as needed.



The RS-4i Plus will pause a treatment for 5 minutes and then shut off if the treatment has not resumed. If the stimulator shuts off, you will need to start your treatment over from the beginning.

End a Treatment

You may end a treatment at any time by pressing and holding the On/Off/Pause key for two seconds. The stimulator will turn off completely.



Get Help

If you experience any physical discomfort or problem with the stimulator, check *If You Experience a Problem*, page 28.

If the RS-4i Plus is dropped or roughly bumped during treatment it may cause damage to one or more parts. Intensity and treatment segment settings can be unintentionally changed if the keys are accidentally depressed during treatment and the auto-lock feature is not yet turned on.

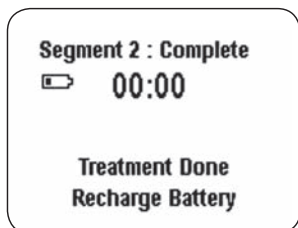
If your stimulator is dropped or bumped:

1. Turn the stimulator OFF by pressing and holding the On/Off/Pause key for two seconds.
2. Check all connections (electrode pads to skin, cables to pads, cable to stimulator, battery to stimulator).
3. Press the On/Off/Pause key to restart the stimulator.

After Your Treatment

After finishing the last segment of any program, the RS-4i Plus will display a Treatment Done screen. The message will be accompanied by three audible beeps. If the battery needs to be recharged, refer to the instructions on page 9.

1

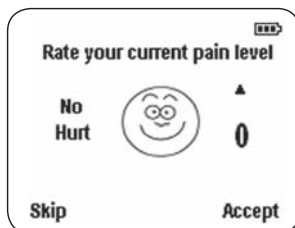


Recharge Battery as Needed

If the battery indicator at the end of treatment shows one bar remaining, or the 'Recharge Battery' message appears, a full recharge is recommended before your next treatment.

Instructions for recharging the battery are on page 9.

2



Rate Your Current Level of Pain

When the treatment is complete, you will briefly see the 'Treatment Done' screen, followed by another screen asking to rate your current pain level after treatment. Your answer will be saved by the stimulator to help track how effective the treatment was at relieving your pain.

Adjust the pain level using any channel key. Accept the pain level using the right Function key.

3

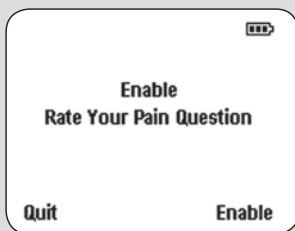


Remove Electrode Pads

After you turn the stimulator off, remove electrode pads from skin. Grasp the edge of the electrode pad and peel it off your skin. Do not pull on the wire, as this may damage the pad.

Return the pads to their clear plastic storage liners. (Place them on the "ON" side.) Place the storage liner back in the plastic pouches and seal. You may use clean wax paper if the plastic storage liners are not available.

NOTE



Re-Enable 'Rate Your Pain' Questions

If the *Rate Your Pain* questions have been disabled you will see the following message at the end of every treatment asking if you would like to enable the questions.

Press the right function key to enable the pain questions, or press skip to leave the pain questions disabled.



Proper maintenance and storage of the RS-4i Plus is essential. Here are a few simple things to do before and after each treatment to ensure proper handling and care.

How to Clean the RS-4i Plus

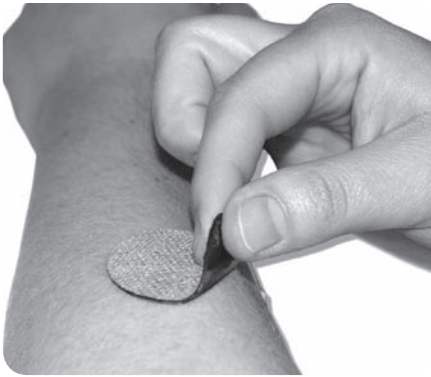
Many parts of the RS-4i Plus can be carefully cleaned, as needed, including the stimulator, cable, battery, charging dock, and AC adapter. Electrode pads are not designed to be cleaned.

To clean these parts, first carefully disconnect the part you want to clean from all other parts. Then, wipe clean with a small amount of soapy water on a clean cloth. The cloth should be damp, but not soaking wet. Do not use any harsh chemicals or solvents when cleaning the RS-4i Plus as they may cause damage.

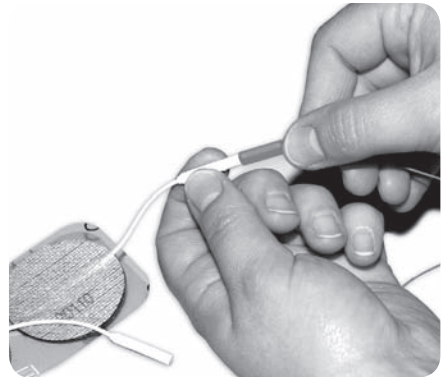
Do not submerge any RS-4i Plus component in liquids or expose it to large amounts of water.

Electrode Pad Care

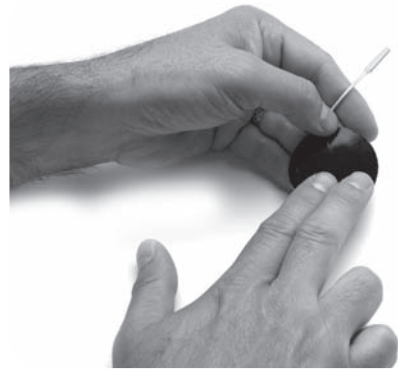
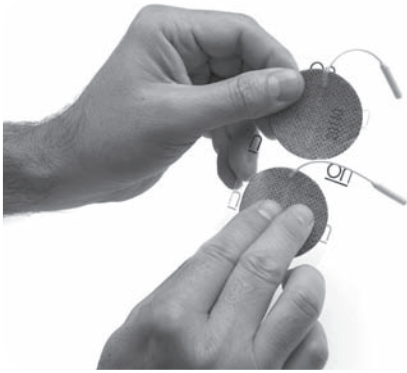
The electrode pads may be reused many times. The average lifespan of an electrode pad depends on skin type, skin preparation, storage, and climate. To maintain the adhesive backing of the electrode pads, follow these suggestions:



Hold the electrode pads lightly at the edge when applying or removing.



Always hold onto both the electrode pad tail and grips of the cable pins when disconnecting the pad.



Between treatments, replace the electrode pads onto their storage liners. Use wax paper if the storage liners are misplaced.

If the gel feels dry, rub a few drops of water over the gel surface and wait approximately 10 minutes (until the gel becomes tacky) before using.

- Wear the electrode pads during treatment only.
- DO NOT share electrode pads with another person. Sharing pads may cause skin irritation.
- If the electrode pads come in contact with liquids or chemicals other than water, check to see that they will stick to skin and discard if necessary. Contact Customer Service to order new pads.

Electrodes are disposable and usually need to be replaced about every 30 days, as they start to wear out. As electrodes age, they lose their ability to conduct stimulation. You may notice that you need to increase the intensity higher than normal. You may also notice the electrodes curling or lifting up around the edges, causing discomfort. If you experience any of these situations, contact RS Medical at 800-935-7763 for a new supply of electrodes.

Cable Care

Always hold onto both the stimulator and cable connector when disconnecting the cable.



If your cables have become worn or frayed they may no longer conduct stimulation. Do not touch exposed wiring during treatment. If you notice that your cables are damaged, worn or frayed, contact RS Medical at 800-935-7763 to order a replacement cable.

Battery Care

The RS-4i Plus uses a custom, rechargeable, lithium-ion battery. Rechargeable batteries have a limited number of uses and will eventually need to be replaced.

Battery life depends on frequency of use, storage, and operating temperatures and other environmental factors; results will vary. To increase the life of your battery:

- Allow battery indicator to reach one bar of power remaining before recharging battery.
- Keep the battery cool when using, charging and storing: never freeze the battery, avoid hot surfaces such as hot cars, heating vents, or radiators.

For battery charging instructions, see page 9.

When the battery approaches its end of life, a warning message will appear when you turn on the RS-4i Plus.



Contact Customer Service at 800-935-7763 to order a replacement battery as soon as possible.

You will be reminded by this message until a new battery is used.

When you need a new battery, or if you want to purchase a second battery for convenience, contact RS Medical Customer Service at 800-935-7763.

Charging Dock Care

The charging dock and AC adapter may be kept plugged in at all times for easy charging access. Be certain to set up in an area away from possible liquid spills or tampering by children or pets. When removing the AC adapter from the wall, grab and pull from the outlet, never pull using the cord.

Disposal

Electrode pads are disposable and can be discarded with household trash.

Improper disposal of electronic goods may result in pollution or land contamination. There are also many local, state, and federal laws that limit and strictly control the disposal of electronic goods and lithium batteries. Please recycle or dispose of the RS-4i Plus stimulator, battery, cable, charging dock, and AC adapter at a facility that specializes in the safe disposal of batteries and electrical devices.

If you do not have recycling services nearby, contact RS Medical Customer Service at 800-935-7763.

Storing the RS-4i Plus

- Keep all items clean and dry.
- Store the electrode pads on their plastic liners and inside the resealable bag.
- Keep the stimulator and all other items in a cool dry place, away from liquids, chemicals, cosmetics, direct heat, freezing conditions, and bright sunlight.
- It is not recommended to store the stimulator for more than 12 months without use. This may cause the backup battery in the stimulator to lose its charge and may result in an RTC Error. (See details about this error message on page 30.) If you experience an RTC error message, contact RS Medical Customer Service at 800-935-7763 to discuss your options.

If You Experience a Problem

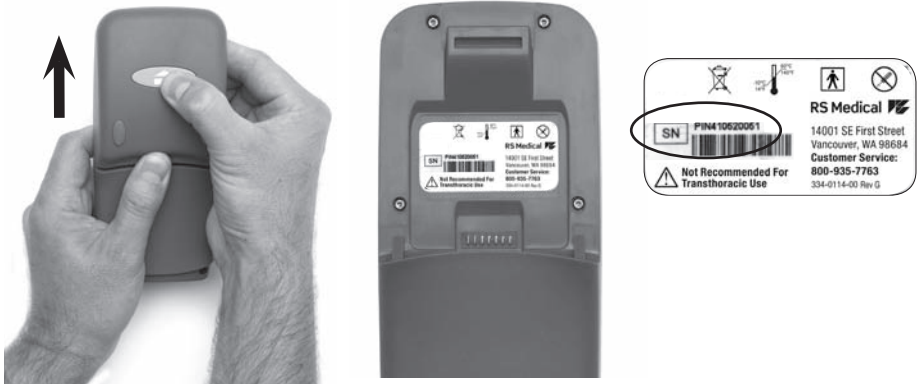
Warranty

The RS-4i Plus (including battery) is warranted to be free from defects in materials and workmanship one year from the date of invoice. For further warranty details, please refer to the Patient Information booklet that came with your RS-4i Plus.

If you experience a problem while using the RS-4i Plus, refer to the list below for help. If you can't find a solution here, please call an RS Medical Customer Service Representative at 800-935-7763.

Have the RS-4i Plus Serial Number Available Before You Call




To find the serial number, remove the battery by holding the stimulator with both hands, battery facing up. Press the oval button with one thumb and use your other thumb to release the battery. The stimulator serial number is located on the stimulator's label.






| Issue | Possible Causes and Solutions |
|--|--|
| <p>Skin irritation</p> | <p>Users with sensitive skin may develop skin irritations over time in the areas where electrode pads are placed during treatment. Here are some suggestions to prevent or limit irritation.</p> <ul style="list-style-type: none"> ➤ Wash the skin area where electrode pads will be placed before and after treatments. Use mild soap and warm water. Be sure to thoroughly dry the skin before electrode pad application. ➤ Apply the electrode pads to normal, intact, clean, healthy skin. ➤ Remove electrode pads between each treatment. Avoid wearing pads for more than one hour. ➤ Do not share electrode pads with other persons to avoid the risks of adverse skin reactions and disease transmission. ➤ Contact your physician if skin irritation develops or persists. <p>RS Medical offers special electrode pads for sensitive skin. To order, contact RS Medical Customer Service at 800-935-7763.</p> |
| <p>Sore muscles after a treatment</p> | <p>Mild muscle soreness after a treatment is common. Many patients recovering from chronic pain, injury and/or surgery have had little exercise or therapy. While mild muscle soreness is normal, severe soreness may be a sign that intensities need to be reduced during treatment.</p> |

| Issue | Possible Causes and Solutions |
|---|---|
| <p>Burning sensation during a treatment</p> | <p>A burning sensation may occur due to the following situations:</p> <ul style="list-style-type: none"> ➤ When an electrode pad is not adhering completely to the skin. If your pads are worn, frayed, or no longer stick to your skin, order new electrode pads by contacting RS Medical Customer Service at 800-935-7763. (See page 23 for additional information on electrode pad care.) ➤ When electrode pads are removed or repositioned during use. Touching the conductive gel of the electrodes during treatment may cause an unpleasant transfer of all stimulation directly to your fingertip. Turn the stimulator off, and then move the pads. ➤ Skin allergies and irritation can cause burning sensations. (See recommendations for resolving Skin Irritation.) ➤ Hypersensitivity to touch. If your condition includes a hypersensitivity symptom, discuss this with your physician. |
| <p>The electrode pads aren't sticking to my skin</p> | <p>If the electrode pad gel feels dry, rub a few drops of water over the gel surface and wait approximately 10 minutes until gel becomes tacky before using.</p> <p>Electrodes are disposable and usually need to be replaced about every 30 days, as they start to wear out. As electrodes age, they lose their ability to retain water and conduct stimulation. Dry electrode gel could lead to less comfortable or less effective treatment. You may notice that you need to increase the stimulator settings higher than normal to achieve treatment. You may also notice the electrodes curling or lifting up around the edges, causing a biting or stinging sensation around the edge of the electrode during treatment. If you experience any of these situations, contact RS Medical at 800-935-7763 for a new supply of electrodes.</p> <p>For additional instructions on <i>Electrode Pad Care</i>, see page 23.</p> |
| <p>The charging dock is plugged into an outlet, but the power light is not turning on</p> | <p>Confirm power is flowing to the outlet by plugging in a lamp you know works and turning it on, or try another wall outlet. If that doesn't solve the problem, the charging dock may be damaged.</p> <p>Check for wear or damage to the charging dock or frays or wear to the AC adapter and cord. If damaged, contact RS Medical at 800-935-7763 for repair or replacement.</p> |
| <p>A battery is in a charging dock with power, but the status light is not turning on</p> | <p>Remove the battery from the charging dock. Check the battery and charging dock for damage or any item that may be blocking or covering the connector of either part.</p> <p>If the battery or charging dock is damaged, contact RS Medical at 800-935-7763 for repair or replacement.</p> |
| <p>A battery has been in the charging dock for more than four hours, but the status light continues to blink</p> | <p>Remove the battery from the charging dock. Check the charging dock and battery for damage or any item that may be blocking or covering the connectors where the battery and charging dock mate. Operate only within a temperature range of 50°F to 90°F (10°C to 32°C).</p> <p>You can also insert the battery onto the stimulator and turn the stimulator on to check the battery indicator.</p> <ul style="list-style-type: none"> ➤ If the battery indicator shows a fully charged battery, the charging dock is working, but there may be damage to the status light on the charging dock. ➤ If the battery indicator shows no change in battery power, there may be damage to the charging dock or battery. Contact RS Medical at 800-935-7763 for repair or replacement. |
| <p>Both status lights are solid, but the stimulator battery indicator shows no charge</p> | <p>This indicates that the battery is fully depleted, which can happen when a battery has been stored without use for an extended period, and requires extra time in the charging dock. Put that battery in the charging dock.</p> <p>After several hours, a blinking status light indicates the battery is charging normally. Leave the battery in the charging dock until both status lights are solid. This may take more than four hours.</p> |

| Issue | Possible Causes and Solutions |
|---|---|
| <p>The stimulator doesn't seem to be working</p> | <p>If you can not feel the stimulation, there may just be a disconnection. Pause or stop the treatment. Then check:</p> <ul style="list-style-type: none"> ➤ That the cable connector is firmly attached to the stimulator. ➤ That each electrode pad is firmly connected to the cable. ➤ That every pad is making full contact with your skin. <p>A completely blank screen may indicate that the battery needs to be charged or replaced. (See Blank Screen description below).</p> |
| <p>A blank screen is displayed when the stimulator is turned on</p> | <p>When the RS-4i Plus is turned ON, a blank screen usually indicates the battery is completely dead. Charge the battery fully using the instructions on page 9, and try again.</p> <p>If this does not resolve the problem you may need to replace your battery. Call Customer Service at 800-935-7763 to order a new battery.</p> |
| <p>The plastic enclosure of the stimulator, cable, or battery is cracked or broken</p> | <p>If the damage is severe do not use the part. If the damage is minor it may eventually lead to other problems because the enclosure helps protect the part.</p> <p>Contact Customer Service at 800-935-7763 to discuss repair or replacement options.</p> |
| <p>The cable is frayed or the cable pins are broken</p> | <p>If your cables have become worn or frayed they may no longer conduct stimulation. Touching exposed wiring during treatment may cause an unpleasant transfer of all stimulation directly to your skin.</p> <p>If you notice that your cables are damaged, worn or frayed, contact RS Medical at 800-935-7763 to order a replacement cable.</p> |
| <p>Other device errors</p> | <p>If any of the following device errors appear, the device will not work and will require repair by an RS Medical technician. Contact Customer Service at 800-935-7763 to discuss repair or replacement options.</p> <p>RTC error - displayed when the real time clock (RTC) has been disrupted or has lost charge.</p> <p>RAM error - displayed when a problem is detected in the device's random access memory (RAM).</p> <p>Flash error - displayed when a problem is detected in the device's flash memory.</p> <p>EEPROM error - displayed when a problem is detected in the device's electrically erasable programmable read-only memory (EEPROM).</p> <p>Output error - displayed after the stimulator has experienced an output error of any sort.</p> <p>High voltage error - displayed after the stimulator has experienced a high voltage event.</p> <p>Battery pack error (1) (2) (3) or (4) - displayed when a problem is detected in the battery or battery to stimulator connection.</p> |

| Issue | Possible Causes and Solutions |
|---|--|
|  <p style="text-align: center;">Device Error Battery Capacity Low.</p> | <p>This message is displayed when the battery needs to be charged. Charge the battery by following the directions on page 9.</p> |
|  <p style="text-align: center;">Replace Battery Contact RS Medical</p> | <p>This screen is displayed when the battery is near the end of its life. Contact Customer Service at 800-935-7763 to order a replacement battery as soon as possible. Allow a few days for shipping and handling to avoid any gaps in your treatment.</p> <p>Treatment will continue until the battery has completely lost its ability to hold a charge. You will be reminded by this message until a new battery is used.</p> |
|  <p style="text-align: center;">Segment 1 Pain Relief 04:54 Check Cable and Pads!</p> <p style="text-align: center;">① ② ③ ④</p> | <p>This screen is displayed if the intensity is above 5 clicks and one of the following conditions applies:</p> <ul style="list-style-type: none"> ➤ A cable is loose or broken ➤ An electrode pad is not adhering to your skin ➤ Skin is too dry, oily, dirty, or too many dead skin cells are present to conduct electrical stimulation <p>The number of the channel with the faulty connection will be flashing and the treatment on all channels will be paused.</p> <p>To remedy the problem:</p> <ul style="list-style-type: none"> ➤ Check that the cable is fully connected to the stimulator at one end and to every electrode pad at the other end. ➤ Check that all electrode pads are sticking to your skin completely. If your skin is dry, dirty, or oily, remove pads, wash and dry your skin and re-apply pads. If a pad's adhesive backing is worn or no longer sticks to the skin, replace with a new pad. ➤ Press any channel intensity key once to resume treatment. The intensity levels will automatically return to 85% of the previous settings. <p>If the problem occurs repeatedly after checking all connections, there could be damage to one of the parts. Contact Customer Service at 800-935-7763 to discuss repair or replacement options.</p> |

| Issue | Possible Causes and Solutions |
|---|---|
| <div data-bbox="78 255 372 482"> <p>Service Required </p> <p>Contact RS Medical</p> <p>Treatment Remaining 4</p> <p>Press Proceed to Service</p> <p>or Other Key to Treatment</p> <p>S/N: PIN410520009</p> <p>Proceed to Service</p> </div> | <p>These messages are reminders to perform the maintenance necessary to keep your RS-4i Plus working at its best. Contact Customer Service at 800-935-7763 to discuss maintenance options.</p> <p>You can choose to continue your treatment by pressing any channel key. There will be four reminders to contact RS Medical for maintenance before the product is disabled.</p> |
| <div data-bbox="78 520 372 746"> <p>S/N: PIN410520009 </p> <p>Contact RS Medical for Assistance</p> </div> | <p>If you own the RS-4i Plus and do not want maintenance performed, Customer Service will provide easy-to-follow instructions over the phone to reset or remove this reminder.</p> |
| <div data-bbox="78 796 372 1022"> <p>S/N: PIN410520009 </p> <p>ENTER RESET CODE</p> <p>1</p> <p>Back Accept</p> </div> | <p>In some instances the unit may need to be returned to RS Medical for servicing.</p> <p>You will see this message after pressing the Proceed to Service function key while viewing the annual maintenance reminder (see above).</p> <p>Contact Customer Service at 800-935-7763 to discuss maintenance options. In some instances the unit may need to be returned to RS Medical for servicing.</p> |

Other questions?

Here are some appropriate sources of information:

- For medical information contact your physician.
- For more information on how to use the RS-4i Plus, read these instructions, visit www.rsmedical.com, or contact RS Medical Customer Service at 800-935-7763.
- For more information on how to renew your prescription contact your physician, RS Medical Representative or RS Medical Customer Service at 800-935-7763.








Stimulator Display

| Icon or Symbol | Definition |
|----------------|--|
| | <p>Battery indicator: Shows how much battery power remains in the battery during use. One bar indicates low battery status, less than 10%, need to recharge battery. Two bars indicate that there is 11% to 45% battery power remaining. Three bars indicate that there is 46% to 100% battery power remaining.</p> |
| | <p>Wong-Baker FACES Pain Rating Scale: Used to save user-reported pain levels before and after each treatment. Information is saved and may be retrieved at a later date to better understand the effectiveness of treatment.</p> |
| | <p>Channel intensity bars: Display the level of stimulation being delivered to electrode pads.</p> |
| | <p>Channel indicators: When a treatment is in progress, channel indicators appear beneath channel intensity bars and number each active channel.</p> |
| | <p>Skip icon: Indicates that the function key below can be used to skip to the next segment of the program.</p> |
| | <p>Channel key up arrow: Used to scroll up through options or increase treatment intensity.</p> |
| | <p>Channel key down arrow: Used to scroll down through options or decrease treatment intensity.</p> |
| | <p>Remaining time (In minutes and seconds) for treatment or for pause.</p> |
| | <p>Volume indicator: Volume has been muted, all non-alert beeps turned off.</p> |
| | <p>Volume indicators: Volume setting at levels 1, 2 and 3.</p> |
| | <p>Pause button indicator: The button below this symbol can be used to pause treatment when visible.</p> |
| | <p>Inactive channel: When any channel is not connected to a cable during treatment, it displays as inactive.</p> |

Product Labeling

| Icon or Symbol | Definition |
|--|---|
|  | A circle is used to indicate Channel 1 on channel key and matching cable ends and on the screen during treatment. |
|  | A square is used to indicate Channel 2 on channel key and matching cable ends and on the screen during treatment. |
|  | A diamond is used to indicate Channel 3 on channel key and matching cable ends and on the screen during treatment. |
|  | A hexagon is used to indicate Channel 4 on channel key and matching cable ends and on the screen during treatment. |
|  | On/Off/Pause key: To be used to turn ON the stimulator or can be used to PAUSE or turn OFF the stimulator during use. |
|  | Warning for Potential Hazard: Consult these <i>Instructions for Use</i> for any part containing this symbol. |
|  | Do not tamper with or attempt to open the case or plastic enclosure. There are no user-serviceable parts in the device. |
|  | Do not get near open flame or excessive heat. |
|  or  Li-ion | Please Recycle |
|  | Do not throw item in the trash: The RS-4i Plus adheres to strict standards for the Restriction of Hazardous Substances (RoHS). However, the electrical parts still contain materials that may be harmful to the environment. Improper disposal may result in pollution or land contamination. Dispose of the RS-4i Plus at a facility that specializes in the safe disposal of electrical devices. |
|  | Reference number: Also known as the part number. Use this number to order a new part. |
|  | Serial number: The unique identification number given to the individual unit. |

| Icon or Symbol | Definition |
|---|---|
|  | <p>Lot number: The unique identification number given to a manufacturing batch of parts. This number will be the same for all parts in the same manufacturing batch.</p> |
|  | <p>Store and use the part within the temperature range indicated to the left and right side of this symbol.</p> |
|  | <p>Type BF Applied Part. This means that the product is applied to the user through conductive contact with the patient (electrode pads).</p> |
|  | <p>Press and push up to remove. Located on the release button for the RS-4i Plus battery.</p> |
|  | <p>Consult these Instructions for Use for any part containing this symbol.</p> |

Appendix A: Treatment Descriptions

The RS-4i Plus will be preset with one or perhaps multiple treatment programs according to your physician's prescription to provide the maximum therapeutic value for your condition. Each segment of treatment will feel different. Find the treatment indicator below for a description of what you will feel during each segment.

| Treatment Indicator | Description of how will it feel |
|---|--|
| Pain Relief (High) | Feels like a buzz or tingle in the treatment area. |
| Pain Relief (Wide) | At low frequency, user may feel a tapping or slow pulsations in the treatment area. As frequency increases, the tapping sensation will change to a buzz or tingle. |
| Pain Relief (Low) | Patient may feel a tapping or slow pulsation sensation in the treatment area. |
| Pain Relief (C-0) | Feels like a buzz or tingle. "0" indicates the number of beats per second created by the interferential waveform. |
| Muscle Therapy 5/5 | Muscles will contract for 5 seconds and relax for 5 seconds. |
| Muscle Therapy 5/2 | Muscles will contract for 5 seconds and relax for 2 seconds. |
| Muscle Therapy 2/2 | Muscles will contract for 2 seconds and relax for 2 seconds. |
| Muscle Therapy 2/10 | Muscles will contract for 2 seconds and relax for 10 seconds. |
| Muscle Therapy 5/5 | Alternating muscle stimulation where muscles contract and relax in a specific, alternating pattern to increase joint flexibility: channels 1 and 2 will contract for 5 seconds, all channels will relax for 5 seconds, and finally channels 3 and 4 will contract for 5 seconds. |
| Muscle Therapy (Run) | This segment mimics how your upper leg muscles contract and relax when running. |
| Intersperse 5/5 | Treat muscle for 5 seconds, a short delay, then Pain Relief for 5 seconds. |
| Intersperse 5/10 | Treat muscle for 5 seconds, a short delay, then Pain Relief for 10 seconds. |
| Intersperse 5/20 | Treat muscle for 5 seconds, a short delay, then Pain Relief for 20 seconds. |
| Intersperse 10/10 | Treat muscle for 10 seconds, a short delay, then Pain Relief for 10 seconds. |
| Intersperse 10/20 | Treat muscle for 10 seconds, a short delay, then Pain Relief for 20 seconds. |
| Custom Program Options (settings only apply to Program 99 Custom Programs) | |
| Pain Relief (C-50) | Feels like a buzz or tingle. "50" indicates the number of beats per second created by the interferential waveform. |
| Pain Relief (C-100) | Feels like a buzz or tingle. "100" indicates the number of beats per second created by the interferential waveform. |
| Pain Relief (C-150) | Feels like a buzz or tingle. "150" indicates the number of beats per second created by the interferential waveform. |
| Pain Relief (C-200) | Feels like a buzz or tingle. "200" indicates the number of beats per second created by the interferential waveform. |
| Muscle Therapy #/# | Muscles will contract and relax according to the numbers shown. |



Dimensions

| | |
|-----------------------------------|--|
| Outer packaging | 13" W x 10.5" H x 3" D (33.8cm W x 27.3cm H x 8.4cm D) |
| Stimulator with battery and cable | 3.2" W x 8" H x 1.8" D (8cm W x 20cm H x 4cm D) |
| Cable length | 60" (152cm), adjustable using Velcro cable strap |
| Charging dock | 4" W x 3" H x 2" D (10cm W x 8cm H x 5cm D) |
| Charging dock with battery | 4" W x 4.5" H x 2" D (10cm W x 11cm H x 5cm D) |
| AC adapter cord length | 58" (147cm) |

Weight

| | |
|-------------------------------|------------------|
| Fully assembled kit | 3.6 lbs. (1633g) |
| Stimulator | 9 oz. (255g) |
| Battery | 6.2 oz. (176g) |
| Charging dock with AC adapter | 6.4 oz. (181g) |

Accessories

| | |
|----------------------------|---|
| Battery | Custom, rechargeable lithium-ion battery pack made to power the RS-4i Plus stimulator. Includes custom lock and release design for safety during use with stimulator. |
| Four-channel cable (leads) | Custom all-in-one four-channel cable with eight leads, 60" long from connector to pin. Each lead is shrouded in a plastic comfort grip so the lead can be plugged easily into an electrode pad and protect the patient from conductive pin exposure during use. |
| Charging dock | Custom charging dock made to recharge RS-4i Plus battery. |
| AC adapter | Electrical connection from the charging dock to a standard household electrical outlet. |
| Electrodes | Reusable water-based gel no smaller than 2" round or 1.8" square. |

Power Requirements

| | |
|---------------------------------|------------------------------------|
| Stimulator (from battery) | 7.2 to 7.4 V, 2Ah |
| Battery (from charging dock) | 0.9 C |
| Charging dock (from AC adapter) | 9 V, 1.0A |
| AC adapter (from power outlet) | 90 to 240 V AC, 50 to 60 Hz, 0.5 A |

Environmental Requirements

| | |
|---|-------------------------------|
| During transport and storage | 14°F to 104°F (-10°C to 40°C) |
| Operating temperature range (includes stimulator in use and battery charging) | 50°F to 90°F (10°C to 32.2°C) |
| Atmospheric pressure range | 50 kPa to 106 kPa |
| Relative humidity range | 20% to 85% |

Electromagnetic Environment

The RS-4i Plus has been designed for use in electromagnetic environments according to the following electrical safety standards: ANSI/AAMI/IEC 60601-1:2005, ANSI/AAMI/IEC 60601-1-2:2007, UL IEC 60601-1, CEI IEC 601-2-10:1987, IEC 60601-2-10 Amendment 1 Edition 1.0 en:2001, ANSI/AAMI/IEC 62304:2006, CEI IEC 60601-1-6:2006, UL2054, UN/DOT and ANSI/AAMI/ISO 10993-1:2009.

Environmental Impact

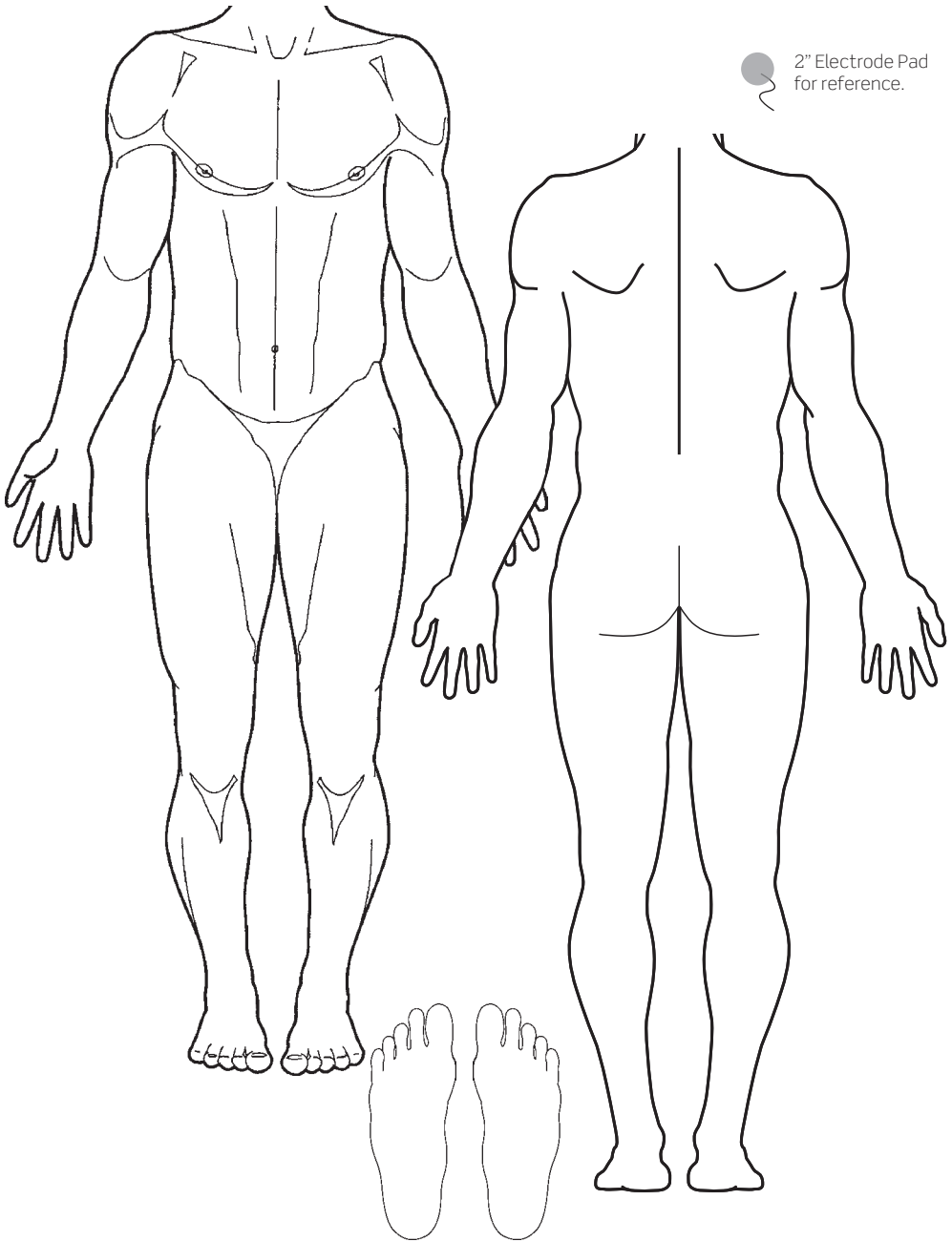
RS Medical is concerned about our impact on the environment and have taken the steps to comply with the directive for the Restriction of Hazardous Substances (RoHS). The RS-4i Plus adheres to the RoHS Directive 2002/95/EC in its design and manufacturing processes.

Interferential Stimulation

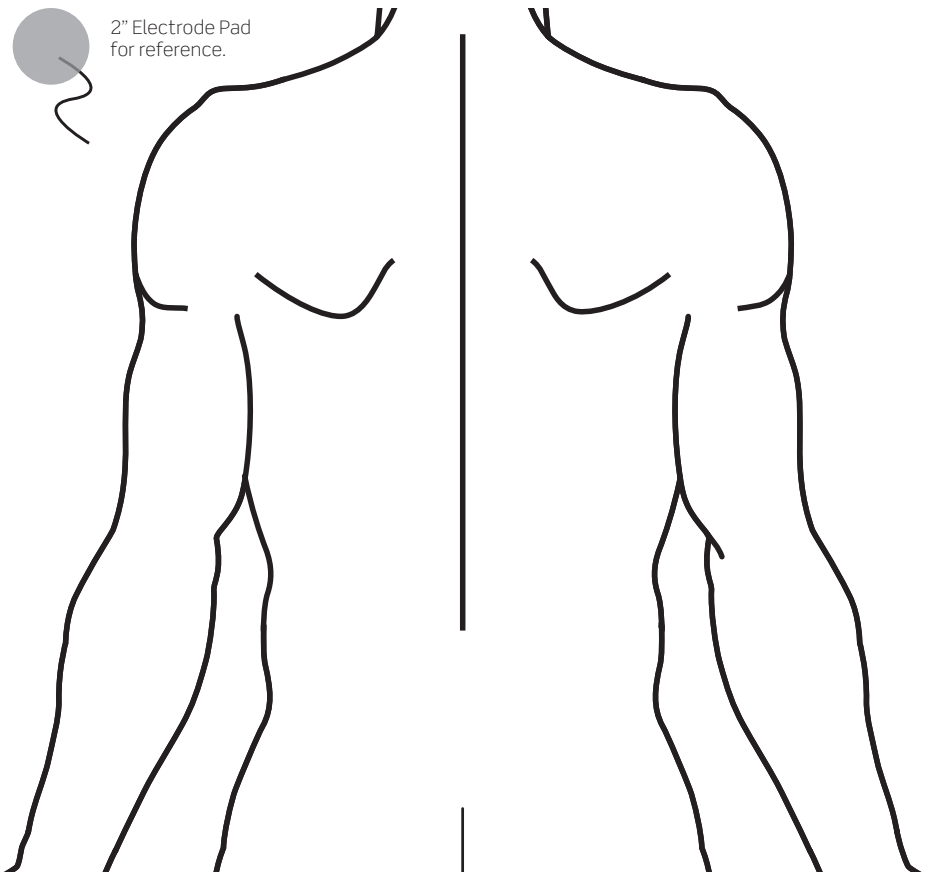
| | |
|------------------------|---|
| Voltage | 0-50 volts peak (+/-10%) measured at maximum battery voltage using a 500 Ohm load |
| Current | 0-100 milliamps peak (+/- 10%) into a 500 ohm load with a fully-charged battery |
| Carrier frequency | 5000 cycles per second |
| Interference frequency | 0-200 beats/second, programmable |
| Cycle time | 10 seconds |
| Amplitude modulation | None or 50%, programmable |
| Modes | Pain Relief (High), Pain Relief (Wide), Pain Relief (Low), Pain Relief (C-0), Pain Relief (C-50), Pain Relief (C-100), Pain Relief (C-150), Pain Relief (C-200) |
| Treatment timer | 1-60 minutes with automatic shut-off, programmable |

Muscle Stimulation

| | |
|---------------------|--|
| Voltage | 0-50 volts peak (+/- 10%) measured at maximum battery voltage using a 500 Ohm load |
| Current | 0-100 milliamps peak (+/- 10%) into a 500 ohm load with a fully-charged battery |
| Waveform attributes | Alternating, bi-phasic, balanced |
| Phase duration | 0-421 microseconds |
| Pulse interval | 7.04 milliseconds |
| Cycle frequency | 50 or 71 (+/- 5%) cycles per second, program specific, where one cycle is defined as one positive pulse followed by one negative pulse |
| Relax duty cycle | 0 to 60 seconds, programmable |
| Contract duty cycle | 0 to 60 seconds, programmable |
| Ramp time | 0.5 to 8.0 seconds, programmable |
| Modes | Muscle Therapy #/# which indicates contract time/relax time, Muscle Therapy Alt, and Muscle Therapy (Run) |
| Treatment timer | 1-60 minutes with automatic shut-off, programmable |



2" Electrode Pad
for reference.



14001 SE First Street
Vancouver, WA 98684-3509
800 935 7763

www.rsmedical.com