

Therapy and Charging

(Continued)

4 I can't change my programs

To change programs, turn remote control on, and press PROG button once (do not hold it).

- The number will begin to flash. Press the PROG button again while the number is flashing to select your desired program.
- If the program number does not change, this indicates that you only have one program.



5 I can't get 2 green bars when charging

- Place charging coil over implant and watch bars. Shift position of coil and watch for charge link indicator change.
- If you hear 3 beeps and see the orange bar glow on charging link indicator, press the green button and try again to align charging coil.
- Aligning the coil will become easier as post-operative swelling decreases, and will become easier with practice.



Charger Audio Indicators

| | |
|--|---|
| 1 short beep | A remote button was pressed |
| 1 long beep (1 sec) & CLS battery level indicator glows | Charging is completed |
| 1 long beep (1 sec) | Charging was aborted by the patient |
| 3 beeps & 1 bar glows on the charger battery level indicator | Charging was aborted because charger battery is too low to charge implant |
| 3 beeps & orange bar glows on the charger link indicator | Charging was aborted due to poor charge link/connection |

Important Safety Information

For U.S. — Consult product manuals prior to use.

Indications for Use:

The Saluda Medical Evoke® SCS System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

Contraindications:

The Evoke System must not be used in patients who: Do not receive effective pain relief during trial stimulation, Are unable to operate the system, Are unsuitable surgical candidates.

Safety Information:

Although FDA has determined that the probable benefits outweigh the probable risks, there remains some uncertainty on the long term systemic toxicity risks of the leads, lead extensions, and anchors of the device. As a condition of approval, FDA is requiring the manufacturer to provide additional long term systemic toxicity information.

Warnings:

Sources of electromagnetic interference (e.g., diathermy, MRI, CT scans, electrosurgery, lithotripsy, external defibrillation, radiation therapy, ultrasonic scanning, highoutput ultrasound, TENS, psychotherapeutic procedures, laser procedures) can interact with the system, resulting in unexpected changes in stimulation, serious patient injury or death. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and electrical pulses from the neurostimulator may cause inappropriate response of the cardiac device. Allergic reaction to system components may occur. The Evoke System has not been tested for use in patients who are pregnant or nursing nor in patients under 18 years old.

Precautions:

Patients should avoid manipulating the Evoke System through the skin. Therapy should be discontinued immediately in the event of malfunction or failure of any component of the Evoke system.

Potential Risks:

Risks may include, but are not limited to epidural abscess, wound infection, lead breakage/fracture, lead migrations, IPG pocket pain, and muscle spasm or cramp.

Rx Only

EVOKE
powered by SmartLoop

Saluda Medical Remote Control and Charger

Troubleshooting Guide



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Remote Control Function

This guide is to assist you in helping patients troubleshoot using their remote control.

1 My Remote is not working

Ensure that the Remote Control is turned on when performing the steps below.

Check Remote Control Battery:

Patient needs to change their remote control batteries (2 x AAA) if they encounter any of the following:

- No lights come on when attempting to turn on remote.
- Remote made 6 beeps (auditory battery replacement notification).
- Low Battery indicator light is lit orange.



2 My Remote is not changing my stimulation intensity

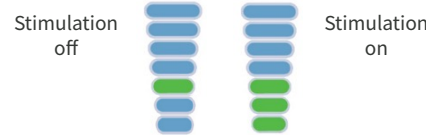
- Confirm that audio indicators are on — (see #5 in the center panel).
- Try to change the remote control again by pressing the up or down arrow button.
- 3 beeps means remote control is too far from implanted stimulator. Bring remote closer to implant and try again.

3 My Remote stimulation level indicator lights don't change when I turn stimulation up or down

- Not every click on the up or down arrow button makes a change to the lighted bars.
- Even multiple clicks may not change lighted bars even though stimulation is changing.

4 My Remote shows green lights but stimulation is not on

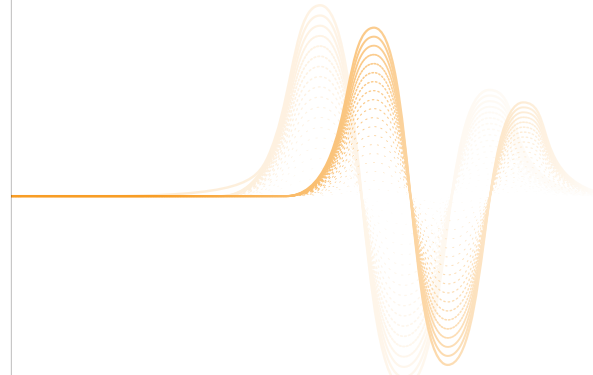
- When your stimulation is off, you will see a single green light to indicate the stimulation intensity level last time it was on.



5 I want to turn the audio beeps off (or back on)

- Audible beeps can be enabled/disabled.
- Start with the remote control off.
- To turn the audio indicators off, press/hold the and buttons at the same time until the remote control turns on.
- To turn audio indicators back on, hold the and buttons at same time until remote control turns on.

| Remote Audio Indicators | |
|-------------------------------------|---|
| 1 short beep | A remote button was pressed |
| 1 long beep | Implant successfully received command from remote |
| 2 short beeps | Request not accepted, at top or bottom stimulation limit |
| 3 short beeps | A button push from remote was not received by implant (need to move remote closer to implant) |
| 6 long beeps | Remote batteries are low, replace batteries |
| 10 long beeps + remote switches off | Implanted Stimulator has gone into Safe Mode, contact clinician |



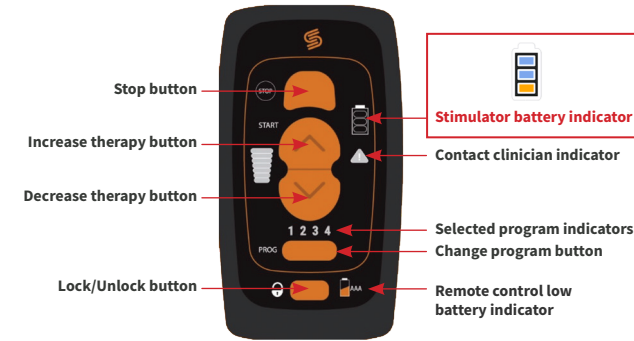
Therapy and Charging

This guide is to assist you in helping patients troubleshoot therapy and charging.

1 My therapy has stopped

The stimulator will stop if it detects an issue.

- First, try to use remote control to start stimulation: turn on remote with power button, hold remote close to implant and press up arrow button.
- If this doesn't work, check "Stimulator Battery Indicator" (top right on remote) to ensure that stimulator has adequate charge to communicate with remote control.



- If these do not work, patient may need to speak with their clinician.

2 My stimulation strength suddenly decreased

When stimulation reaches internal limits, it may automatically decrease in strength.

- You should be able to increase the strength again with your remote control by pressing up arrow button.
- If not, instruct the patient to contact their clinic for an appointment.

3 My stimulation strength is changing or fluctuating (recent implant)

- Some variations in stimulation intensity may occur after the procedure before the leads scar into place.
- If stimulation is no longer present or the area of stimulation has changed, patient may need to speak with their clinician.