

## How to Know When to Change Batteries in Your Remote Control

An orange light on the Battery Indicator means it's time to change your Remote Control batteries



## How to Know When to Recharge your Implanted Stimulator

Periodically check Stimulator Battery Indicator to know if it's time to charge your implanted stimulator



Please refer to your Evoke® SCS System User Manual for detailed instructions on how to use your remote control, and for detailed safety guidance, or contact your health care team.

## Important Safety Information

**U.S. 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, Diabetic peripheral neuropathy of the lower extremities. **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. **Warnings:** Sources of electromagnetic interference (e.g., diathermy, MRI, CT scans, electrosurgery, lithotripsy, external defibrillation, radiation therapy, ultrasonic scanning, high-output 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. Surgical complications and adverse events may be more frequent and severe in diabetic patients. The physiologic closed-loop controlled (PCLC) stimulation mode and frequencies greater than 1200 Hz have not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population. **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. The severity of any surgical complication may be greater in diabetic patients, particularly those with inadequate pre-operative glycemic control. **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.

**International 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. **Contraindications:** The Evoke System must not be used in patients who: Are unable to operate the Evoke System. Are unsuitable surgical candidates. Are unsuitable candidates for SCS. **Safety Information:** Please see Evoke System manuals for detailed safety information regarding the Evoke System, including the following Warnings / Precautions and Adverse Effects: **Warnings / Precautions:** Diathermy, magnetic resonance imaging (MRI) scans, CT scans, implanted cardiac pacemakers or defibrillators, electromagnetic fields, charging the stimulator, other medical procedures, allergies to system components, cables and small parts, pregnancy, paediatric use, operation of equipment, care after surgery, scuba diving, extreme temperatures, and device damage. **Adverse Effects:** May include: undesirable changes in stimulation sensation and/or location; uncomfortable changes in stimulation (over and/or under stimulation); persistent post-surgical pain at hardware implantation sites; CLS migration, which may result in pain or difficulty in charging; seroma or haematoma at surgery sites; epidural haemorrhage; spinal cord injury and possible paralysis; lead migration resulting in stimulation changes; breakage of the lead or failure of other system components, which may result in loss of stimulation; rejection of or allergic reaction to the implanted components; infection; cerebrospinal fluid (CSF) leakage; inadequate pain relief; erosion of the lead or CLS through the skin; weakness or numbness. Additional information about the Evoke System, including system manuals, may be found on our website, [www.saludamedical.com](http://www.saludamedical.com). If you have any further questions, please contact your pain management team. Alternatively, you can contact Saluda Medical via email at [info@saludamedical.com](mailto:info@saludamedical.com).

Patients should consult a physician to understand the potential benefits and risks of treatment associated with Spinal Cord Stimulation (SCS). All patients do not respond the same way to SCS and experiences may vary.

The Evoke® System is available in select geographies.



Saluda and Evoke are registered trademarks of Saluda Medical Pty Ltd. Copyright © 2024 Saluda Medical Pty Ltd. All rights reserved.

CLIN-MKT-010034 Rev 3.00 GLOBAL-ENG

EVOKE®  
powered by SmartLoop. Technology

## Saluda Medical Remote Control Quick Guide



saluda MEDICAL

# Saluda Medical Remote Control

## Quick Guide

This Guide shows how to use your Remote Control to change programs. It also shows how to check the battery of your remote control and implant.


- ✓ You can use your remote control to help you control your implanted stimulator and your therapy.
- ✓ This guide shows how to use your Remote Control to turn stimulation On/Off or Up/Down.




When unlocking & using your remote, make sure to hold remote close to your implanted stimulator

## Whenever You Use Your Remote, Start by Unlocking It

- 1 **Unlock remote by pressing and holding the unlock button** near your implanted stimulator until lights come on, then release. 

- 2 **To turn stimulation on, press the “up” arrow button.**   
*If stimulation was off, level will return to where it was before being turned off*



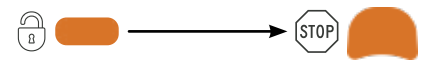
- 3 **To turn the stimulation up or down, press the “up” or “down” arrow buttons** until stimulation is at desired intensity. 

- 4 **Green lights will go up or down** as you turn stimulation up or down- but may require multiple button presses for the next bar to light.



Even multiple clicks may not change the lighted bars even though stimulation is changing

- 5 **To stop stimulation, first unlock the remote** by pressing the unlock button. Then press the STOP button. Remote must be unlocked first in order to stop stimulation.





**Remote will turn itself off after 2 minutes. Your stimulation will stay on.**

**To use remote again, go back to Step 1.**


## Changing Programs


Please do not change programs without guidance and advice of your clinical team

- 1 **Turn the remote on** by pressing and holding the unlock button until remote control lights come on, then release. 

- 2A To switch programs, press and release the **change program “PROG” button.** The active program numbers will flash.  **1234**

- 2B **Press “PROG” button again** to cycle through program numbers until desired program is lit up.  **1234**

- 3 Move remote control near your implant in order for the program change to be sent. **Press the Up button to start simulation.** 

- 4 **Turn the stimulation up or down** for the new program by pressing the up or down arrow buttons. 

**Note:** Some patients have only a single program. Not all patients require multiple programs.



Scan to see a video about using your remote control

