Urgent Medical Device Recall
Evoke Closed Loop Stimulator

14 October 2026

Dear Physician or Healthcare Provider,

Purpose:
The purpose of this letter is to provide you with important information regarding a subpopulation of Saluda Evoke® Closed Loop Stimulators (CLSs). Saluda Medical has received reports of unintended stimulation during charging or the inability for the CLS to charge when the charger is applied. This situation has been reported in approximately 0.66% of potentially impacted CLSs distributed worldwide. Based on currently available information, Saluda's analysis shows the mean expected survivability to be greater than 97% for potentially affected devices. Based on currently available information, Saluda has received no reports of permanent impairment or death associated with this issue, and such outcomes are not expected.

You are receiving this letter because our records indicate that you may have potentially affected devices in your inventory, please refer to Attachment 1 -Affected S/N List included with the Field Safety Notification (FSN) accompanying this letter. Saluda has conducted a thorough investigation into the root cause and has implemented corrective actions designed to prevent recurrence. As a result, Saluda can confirm that S/N not included in the Affected List are not anticipated to experience this issue.

The identified malfunction occurs only during charging-related activities in the affected devices. Potential manifestations include unintended stimulation occurring during charging, or inability of the implanted device to accept charge from the charging system. If the device cannot be successfully recharged, interruption of therapy may eventually occur due to depletion of battery capacity.

Description of the Issue and Risks (how to recognise occurrence of the issue):
The device may be affected if:

- *Patient reports unintended stimulation when they try to charge the device AND*
- *Patient reports unintended stimulation when they start stimulation AND*
- *Patient reports unintended stimulation during an impedance check.*

OR

- *Patient reports their device won't charge.*
  - *Confirmed with multiple chargers.*
  - *Confirm that CLS is implanted at correct depth and orientation and is not flipped.*

If the patient’s symptoms match / present as provided above, contact a Saluda representative.

The primary risks identified for this issue are temporary unintended stimulation, interruption of therapy, and potential loss of therapy due to battery depletion. Should this occur, it may require IPG

explantantion or replacement or keeping the non-functional device implanted. In any of these scenarios, the leads may remain in place.

Product Information:

Product Name	Reference Number	Serial Numbers	Distribution Dates
Evoke Closed Loop Stimulator (CLS)	1042	See Attachment 1	31 October 2024 through 14 Oct 2026

Clinical Management of Implanted Patients

Saluda is not recommending prophylactic replacement or explantation of implanted devices that may be within the affected population.

Based on currently available information, greater than 97% of potentially affected devices are expected to continue to perform as intended. There is currently no validated method to identify which individual implanted devices may experience the issue prior to occurrence.

The identified failure modes **are limited to charging-related activities** and may manifest as unintended stimulation during charging or an inability to charge the device. The issue does not result in continuous unintended stimulation independent of charging activity.

Because there is currently no available intervention that can predict the occurrence of the issue in implanted devices, and because the vast majority of potentially affected devices are expected to continue functioning normally, Saluda is not recommending prophylactic replacement or explantation of implanted devices, nor is Saluda requesting any specific patient outreach activities as part of this recall. Physicians should continue routine patient management and communicate with patients as they deem clinically appropriate.

Patients who report unintended stimulation during charging or inability to successfully charge their device should be clinically evaluated to determine whether continued observation, device replacement, or other intervention is appropriate based on their individual circumstances. More specifically, contact a Saluda representative if:

- *Patient reports unintended stimulation when they try to charge the device AND*
- *Patient reports unintended stimulation when they start stimulation AND*
- *Patient reports unintended stimulation during an impedance check.*

OR

- *Patient reports their device won't charge.*
  - *Confirmed with multiple chargers.*
  - *Confirm that CLS is implanted at correct depth and orientation and is not flipped.*

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Instructions for Use can be found at https://manuals.saludamedical.com/.

Actions to be taken by you:

1. Review your inventory and if you have potentially impacted product (see Attachment 1 - Affected SN List included with the FSN), quarantine and cease implantation of the affected devices.
2. Contact your Saluda Representative to return the non-implanted potentially impacted devices.
3. Return the enclosed Acknowledgement Form via email to Saluda Medical at FCA@saludamedical.com within 5 days.
4. Please forward this notification to anyone within your organisation who may need to be aware of this action.

In addition to reporting complaints through your Saluda representative, adverse reactions or quality problems experienced with the use of this product may be reported to the national competent authority. A list of competent authorities and contact information can be found on the European Medicines Agency Website at https://www.ema.europa.eu/. This action is being conducted as a voluntary recall. Saluda has notified regulatory agencies of this action and will notify all required regulatory agencies of future reports.

Saluda has conducted a thorough investigation into the root cause and has implemented corrective actions designed to prevent recurrence.

For questions regarding this recall, contact Saluda Medical at FCA@saludamedical.com.

We sincerely regret any inconvenience this situation may have caused. Patient safety remains Saluda's highest priority.

Sincerely,

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Evoke Closed Loop Stimulator
Recall Acknowledgement Form

Response is Required

Customer Information:

Customer Name
Contact Name
Street Address
Town, State, Zip Code
Country

To assist in this recall, please complete and sign this Acknowledgement Form and email to FCA@saludamedical.com.

Please indicate recall response (Check One):

☐ I have read and understand the recall instructions and do not currently have any potentially affected product remaining.

☐ I have read and understand the recall instructions. We have reviewed our inventory and have potentially affected product. We will/have quarantined the affected product. Serial Number(s) are as follows:

_____ _____ _____

_____ _____ _____

_____ _____ _____

Product Information:

Product Name	Reference Number	Serial Numbers	Distribution Dates
Evoke® Closed Loop Stimulator (CLS)	1042	See Attachment 1	31 October 2024 through 14 October 2026

Signature of Receipt _____

Name	
Title	
Telephone	
Email address	

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