URGENT MEDICAL DEVICE RECALL CORRECTION (Update)

Liberta RC™ DBS System
Model Number 62400

Neuromodulation
Abbott Medical
6901 Preston Road
Plano TX 75024
USA

August 2024

Dear Doctor,

This letter is to notify you that Abbott has a system update available to correct the issue with Liberta RC™ DBS System stimulation turning off at approximately 50-day intervals. This update will be available starting August 12, 2024. The previous May 2024 communication related to this issue can be found at https://www.neuromodulation.abbott/us/en/product-advisories.html.

This update is recommended for all patients implanted with Liberta RC DBS system before August 12, 2024. Any Liberta RC DBS system implanted on or after this date will have the new software and will not require this update. The information provided below is intended to assist clinicians in understanding this update for implanted patients and the associated benefits and risks.

System Update Process Summary and Risk Assessment

The update will prevent stimulation turning off every 50-days and eliminate the need for stimulation off reminders. Without this update, stimulation will continue to turn off every 50-days and for some patients with increased severity of indication, loss of stimulation for a prolonged period may require acute medical intervention.

As with any software update, there is potential for malfunction associated with the update process. During device updates internally at Abbott, approximately 0.20% of devices tested experienced an incomplete upgrade. In this scenario, the previous software version was able to be restored. If such an event were to occur, stimulation will continue to turn off every 50-days. For recommendations on managing this stimulation off event, please refer to previous communications provided by Abbott. Additionally, a potential risk exists where adjustment of stimulation settings may become intermittently unavailable due to loss of communication with the Patient Controller (PC).

The system update includes updated Clinician Programmer (CP) application, Patient Controller (PC) application, and software within the generator. The generator software update is performed wirelessly in a clinic setting and is expected to take approximately 15 minutes. During this update, the patient's therapy will be turned off for a short time (approximately 5 minutes). An Abbott Representative will contact you regarding this notice and will be available to provide technical support while completing the system updates.

Patient Management Recommendations

- Educate patients on the benefits and risks of the system update. Abbott is also communicating availability of the update to all patients implanted with Liberta RC DBS system.

- Schedule time for each patient's update to be completed in-person. When scheduling an appointment, remind patients to:
    - Fully charge their generator and bring its charger to the appointment.
    - Bring their charged Patient Controller(s) to the appointment.

- Contact your Abbott representative to provide technical support related to the system update.

Steps to Perform the System Update
The update process will entail the following:

- When using an updated CP, connection to a Liberta RC™ DBS generator with previous software version will automatically prompt the user to complete a generator update requiring a two (2) step process.

- The wireless update is expected to take approximately 15 minutes. During this update, the patient's therapy will be turned off for a short time (approximately 5 minutes). Upon completion of the update, the generator will turn therapy back on at your previously programmed settings.

- After completing the two (2) update steps, reconnect to the generator to verify that the update was completed, and the generator is functioning appropriately.
  NOTE: If the generator update is interrupted or unsuccessful, the process will need to be repeated.

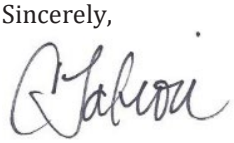
- The Patient Controller application will be updated to allow communication with the updated generator.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. To submit your report:

- Complete the voluntary Form FDA 3500 online
- Download form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete
- and return to the address on the pre-addressed from or submit by fax to 1-800-FDA-0178.

Abbott is committed to providing the highest quality products and support. Thank you for your understanding and support.

Sincerely,



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