



URGENT MEDICAL DEVICE RECALL CORRECTION (UPDATE)

Liberta RC™ DBS System Model 62400

Neuromodulation
Abbott Medical
6901 Preston Road
Plano TX 75024
USA

August 2024

Dear Patient,

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 made 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>.

Abbott recommends you receive the update at your earliest convenience to prevent further stimulation off events and eliminate the need for additional stimulation off reminders. This update must be completed in a clinical setting under a clinician's supervision and is expected to take about 15 minutes. 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 stimulation off events, 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). Please consult with your physician for any questions related to the update process risks and benefits.

What to expect during your appointment:

- Your Patient Controller application(s) will be updated to the latest version.
- The wireless update to your generator is expected to take about 15 minutes to complete.
- During the update, your therapy will be turned off for a short time (approximately 5 minutes).
- After update, the generator will turn therapy back on at your previously programmed settings.
- If the generator update is interrupted or unsuccessful, the process will need to be repeated.

After your appointment, if necessary, update your patient controller application:

- If you did not bring your PC to your appointment, your Abbott representative will follow-up to support update to the PC application.

NOTE: You will not be able to control your device using the PC until the PC application is updated.

For additional questions, please contact your Abbott representative or Abbott Technical Support at 1-800-727-7846. 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.

- 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 form 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.

Sincerely,

Carolyn Tabion
Divisional Vice President, Quality
Neuromodulation
Abbott