



URGENT MEDICAL DEVICE RECALL

Liberta RC™ DBS System Model 62400

Neuromodulation
Abbott Medical
6901 Preston Road
Plano TX 75024
USA

May 2024

Dear Patient,

Abbott is sharing important information about the use of your Liberta RC™ DBS System. The purpose of this recall communication is to inform you about an issue resulting in stimulation turning off at 50-day intervals on Liberta RC DBS System.

As of May 20, 2024, Abbott has received 13 complaints from patients with a Liberta RC DBS System who unexpectedly lost stimulation. For some of these 13 patients, the loss of stimulation resulted in recurrence of motor symptoms.

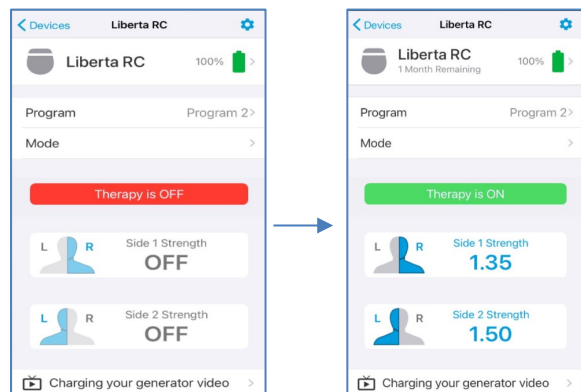
In all cases, stimulation was able to be turned back on using the Patient Controller or the Clinician's Programmer. Therapy was restored immediately once stimulation was turned back on, and no other device functionality was impacted. If the sleep schedule feature is enabled and programmed to turn stimulation on, therapy will automatically restore within 24 hours of stimulation turning off. To date, there have been no reports of permanent harm to patients resulting from this issue. However, for some patients with increased severity of indication, loss of stimulation for a prolonged period of time may require acute medical intervention. In rare cases, this may lead to permanent impairment or death.

Please be advised that your stimulation will first turn off 50 days after the system was activated and subsequently, this will recur every 50 days for your implanted Liberta RC DBS System.

Next Steps

Abbott is working on a resolution to address this issue. In the meantime, the following recommended steps can be taken to continue managing your therapy with the implanted Liberta RC System:

1. Ensure that your patient controller is always accessible to turn stimulation back on when required.
2. An Abbott representative can assist you to identify the initial date on which your stimulation may be interrupted. As that estimated interruption date approaches, you should continue to monitor your stimulation and be prepared to restore your therapy if it turns off. Restoring your therapy can be done by following the steps below:



Therapy is OFF screen

Therapy is ON Screen



- a. Launch the app and select your Liberta RC device to check the status of therapy.
 - b. When your therapy is off, a red button will be shown in the middle of the session screen reading “Therapy is OFF”. An example is shown in the image above on the left.
 - c. To restart therapy, tap the “Therapy is OFF” button. It will turn green and read “Therapy is ON”, as shown in the image above on the right.
 - d. Therapy should be restored immediately when you switch stimulation ON.
3. Additionally, an Abbott representative can help enable the sleep schedule feature to turn stimulation on and automatically restore therapy within 24 hours of stimulation turning off.
 4. If you have questions about how this may impact you, contact your physician.
 5. For additional questions about this issue, please contact your Abbott representative or Abbott Technical Support at 1-800-727-7846.

A copy of this letter is available on www.neuromodulation.abbott/us/en/product-advisories.html.

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.
- Call 1-800-FDA-1088 to report by telephone.
- 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 (Send only page 1 plus any continuation pages – do not send instruction pages).

Abbott is committed to providing the highest quality products and support. Thank you for your understanding; we apologize for any inconvenience this issue may have caused.

Sincerely,

A handwritten signature in black ink, appearing to read 'Carolyn Tabion'.

Carolyn Tabion
Divisional Vice President, Quality
Neuromodulation
Abbott