



## URGENT MEDICAL DEVICE CORRECTION

Infinity™ DBS System (Model Numbers 6660, 6662)  
UDI 05415067030016, 05415067030023

Neuromodulation  
Abbott Medical  
6901 Preston Road  
Plano TX 75024  
USA

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Dear Doctor,

This letter is to notify you about important information regarding patients with an Infinity™ Neurostimulation System who require Magnetic Resonance Imaging (MRI). The patient controller includes a feature called MRI mode which allows the device to be safely scanned. The scope of this correction is related to the inability to exit MRI mode in specific situations. If additional troubleshooting steps are unsuccessful, the implanted device would be unable to exit MRI mode and additional surgery would be required.

### WHAT YOU NEED TO KNOW

**The Infinity™ implantable pulse generator (IPG) can still safely delivery therapy and the patient's ability to receive an MRI scan as determined by you has not changed.**

During standard use, a Bluetooth® paired Patient Controller is used to place a patient's implantable pulse generator in MRI mode, which in turn disables the delivery of therapy. Upon completion of the MRI, the paired Patient Controller is then used to exit MRI mode and allow therapy to resume. MRI mode is intended to protect the patient and the device during an MRI scan. Before any MRI, the Patient Controller (PC) should be used to enter MRI mode. After the MRI, the Patient Controller should be used to exit MRI mode.

In some instances, IPGs are unable to exit MRI mode if:

- Patient Controller is lost or damaged while the implant is in MRI mode.
- Patient Controller is locked out (e.g., forgotten Apple password) while the implant is in MRI mode.
- Patient Controller application and/or iOS® software is updated while implant is in MRI mode.
- Bluetooth® connection with the IPG is deleted from the list of available Bluetooth® devices on the Patient Controller while it is in MRI mode.

A Clinician Programmer is required to be paired to the IPG for initial programming. When available, this previously paired Clinician Programmer can also be used as a backup method to exit MRI mode if the Patient Controller is no longer paired to the IPG. If there is no previously paired Clinician Programmer available, or if the Clinician Programmer lost its Bluetooth® connection to the IPG, this will result in the inability to exit MRI mode. **In these instances, if troubleshooting steps are unsuccessful, an additional surgery would be required to replace the IPG to restore therapy.**

Between August 2015 and August 2023, there have been 2 occurrences worldwide where a patient needed additional DBS neurostimulator replacement surgery to restore therapy. This issue can be avoided by following the instructions in your patient manual and guidance in this communication.

## WHAT YOU NEED TO DO

Following the guidance currently available in the Instructions for Use and the patient manual, if your patients need to receive an MRI scan:

- Advise patients to contact the physician managing their DBS implant prior to receiving an MRI for any reason.
- Ensure patients have upgraded their Patient Controller to the latest “*Patient Controller NR - US*” application from the Apple® App Store® before attempting to place their device into MRI mode. This version of the application provides instructions for the user not to delete the IPG pairing while the system is in MRI mode.
- Advise Patients to disable automatic updates for the Patient Controller app and iOS® software before placing the IPG in MRI mode.
- Advise patients to switch the IPG to MRI mode within a reasonable timeframe before the MRI procedure. This should be done no more than 24 hours in advance, and as close to the MRI procedure as possible, based on the patient’s ability to tolerate being off therapy. Abbott representatives or your team can assist in this process.
- Advise Patients not to alter, damage, update, or lose their Patient Controller handheld while in MRI mode.
- Advise Patients not to update, install, or delete the Patient Controller app or Bluetooth® connection while in MRI mode.
- After MRI scan, use the Patient Controller to exit MRI mode and restore therapy. Patients may require the assistance of your Abbott representative or your team to do so.

If your patient is unable to use their Patient Controller to communicate with their implant while in MRI mode, a Clinician Programmer with a previously established Bluetooth® connection to the IPG can be used to exit MRI mode. If this is not available, please contact your Abbott representative, or Abbott Technical Support at 1-800-314-0940 immediately.

This information is also available on the Abbott Neuromodulation System website at [manuals.sjm.com](http://manuals.sjm.com) and [AbbottMRI.com](http://AbbottMRI.com)

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,



Carolyn Tabion  
Divisional Vice President, Quality  
Abbott Neuromodulation