



Urgent Field Safety Notice
FA-Q223-NM-1- Update

Proclaim™ XR SCS and Proclaim™ Elite SCS System
(Model Numbers 3660, 3662)

UDI 05415067031419, 05415067031426, 05415067020192, 05415067020222

Proclaim™ DRG Neurostimulation System (Model Number 3664)

UDI 05415067020215

Infinity™ DBS System (Model Numbers 6660, 6662)

UDI 05415067030016, 05415067030023

Clinician Programmer Application and Patient Controller Application
(Model Numbers 3874, 3875) when used with the IPGs above

December 2023

Dear Doctor,

This letter is a follow up to the original July 2023 communication regarding additional important information for patients with Proclaim™ or Infinity™ Neurostimulation Systems 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 Proclaim™ and Infinity™ implantable pulse generators (IPGs) can still safely deliver 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 an IPG is unable to exit MRI mode and 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:

- 131 SCS/DRG occurrences worldwide for permanent loss of therapy and 75 of those have resulted in IPG replacement surgery to restore therapy.
- Two (2) DBS occurrences of permanent loss of therapy, both of which resulted in IPG replacement surgery to restore therapy.

Loss of therapy may require acute medical intervention such as additional monitoring, medication and/or intervention to compensate for the loss of therapy and/or to prevent deterioration in a patient's condition, with special consideration for DBS (Dystonia or Parkinson's) patients.



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Neuromodulation
Abbott
6901 Preston Road
Plano TX 75024
USA

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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 this communication, if your patients need to receive an MRI scan:

- Advise patients to contact the physician managing their implant prior to receiving an MRI for any reason
- Ensure patients have upgraded their Patient Controller to the latest version of the application from the Apple® App Store® before attempting to place their device into 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 set the IPG to MRI mode within a reasonable timeframe before the MRI procedure:
 - For SCS/DRG, this should be done within a day prior to arrival for the MRI procedure.
 - For DBS, 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.
- Advise patients to not update, install, or delete the Patient Controller app or Bluetooth® connection while in MRI mode.
- Advise patients not to alter, damage, update, or lose their Patient Controller handheld while in MRI mode.
- After the MRI scan, use the Patient Controller to exit MRI mode and restore therapy. Patients may require the assistance of your Abbott representative or your medical 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.

Adverse reactions or quality problems experienced should be reported directly to Abbott. Should you have any questions about this notice, please contact your local Abbott Representative.

Abbott is committed to providing the highest quality products and support. We apologize for any inconvenience this may cause you and your patients, and we appreciate your support in ensuring patient safety and customer satisfaction.

Sincerely,

Carolyn Tabion
Divisional Vice President, Quality
Neuromodulation
Abbott