Important Medical Device Advisory

Information about Proclaim™ DRG Neuromodulation Impedance Error

March 14, 2018

Dear Physician,

In an effort to keep you continually informed and ensure appropriate care of your patients, Abbott is advising physicians that a manufacturing process change has unintentionally caused impedance checks to not operate as intended in a limited number of Proclaim™ DRG (Dorsal Root Ganglion) Implantable Pulse Generator (IPG) Neurostimulator Systems.

Specifically, since February 16, 2018, Abbott has received information regarding ten (10) cases where error messages occurred during routine impedance checks on Proclaim DRG IPGs, model 3664. We have determined that eight (8) of those impacted devices were implanted, and we have received reports that four (4) of these implanted devices have been associated with transient over stimulation which created discomfort for the patients. The list of impacted devices distributed can be found in Appendix A, including seven (7) un-implanted units that were sold to customers that have now been contained. Your remaining inventory is not impacted.

Further details regarding risks and patient management recommendations are included below.

Description of Impedance Checks, Error Messages and Associated Risks

Impedance checks occur in three scenarios:

1. When initiated by the Clinician Programmer (CP) for diagnostic use,
2. When initiated by entering MRI Mode from either the CP or the Patient Controller (PC), and
3. During pre-programmed daily impedance measurements

In the affected Proclaim DRG IPGs, all three types of impedance checks are not functioning correctly. Those that are initiated from the CP or PC (scenarios 1 & 2) result in an error message stating: "*The system encountered a problem. Contact SJM if the problem persists.*" The screen views of applicable messages on the CP and PC can be found in Appendix B.

There are two primary effects of the inability to complete impedance checks. First, when programmed stimulation resumes after an attempted impedance check, a momentary over stimulation event occurs. Abbott has evaluated the extent of the over stimulation and has determined it will not cause tissue damage or permanent injury. Second, MRI Mode cannot be entered because it requires a successful impedance check.

Patient Management Recommendations

Abbott is planning to address the implanted devices in two phases. The first phase involves patient management recommendations to avoid over stimulation occurrences, and to provide guidance in the event that an MRI scan is needed. The second phase restores impedance check functionality and MRI Mode availability. This phase consists of a one-time update to the implanted devices, which will be deployed wirelessly following development and approval.

Phase I: Patient Management Recommendations and Guidance for MRI Scans

Prophylactic replacement of affected devices is not recommended. While not intended to serve as a substitute for your professional judgement, we recommend the following for patients implanted with an affected device:

To avoid over stimulation:

- Do not initiate an impedance check from the Clinician Programmer
- Turn off the optional IPG Impedance Log (daily impedance check) using the Clinician Programmer
- Do not attempt to place device in MRI mode from either the Clinician Programmer or Patient Controller, as this will initiate an impedance check

In cases where a MRI is requested prior to the one-time update to implanted devices:

- If the patient has a system that meets MR Conditional requirements as outlined in the Abbott MRI Procedure Information manual (located at *manuals.sjm.com*), review with the patient that the ability to have a MRI scan will not be available for this device until Phase II. Consider alternative imaging modalities.
- If the patient needs an emergent MRI prior to the one-time update, and alternative imaging modalities are not sufficient, a Physician's assessment of the risks and benefits should be evaluated when considering elective replacement of the IPG.

Phase II: Restoring Impedance Functionality

Impedance check functionality will be correctable with a one-time wireless update developed for the implanted devices, which is expected by September 2018. This correction will be made available to your patient by your local Abbott Representative.

A copy of this letter is available on *www.sjm.com/notices.* Should you have questions about patient management or this issue, please contact your local Abbott Representative or Abbott Support at **1-800-727-7846 (Opt3) (U.S.)**, 8:30am - 5:30pm Central Time Monday thru Friday. Please note that Abbott has reported this issue to the FDA and wants to make you aware that you are also able to report any adverse reactions or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

We sincerely apologize for any difficulties this may cause you and your patients. Please know that Abbott is committed to providing the highest quality products and support, and we look forward to continuing to work with you, and are grateful for your continued support.

Sincerely,

Christopher J. Gallivan
Divisional Vice President, Quality
Abbott Neuromodulation

APPENDIX A: Affected Devices

Model	Lot	Serial Number
3664	6210852	AVA560.1
3664	6263128	AVB119.1
3664	6263128	AVD400.1
3664	6242908	AVD426.1
3664	6210849	AVE640.1
3664	6278155	AVK896.1
3664	6210849	AVM174.1
3664	6210852	AVA214.1
3664	6210852	AVL027.1
3664	6242908	AVA922.1
3664	6263128	AVA622.1
3664	6263128	AVD431.1
3664	6263128	AVE633.1
3664	6263128	AVK678.1
3664	6263128	AVN837.1
3664	6268723	AUV770.1
3664	6268723	AVW805.1

APPENDIX B: Applicable Screen Messages

Figure 1 shows the error message on the Clinician Programmer (CP) which is displayed when an impedance check is attempted. This error message will also display on the CP or PC if entry into MRI mode is attempted.

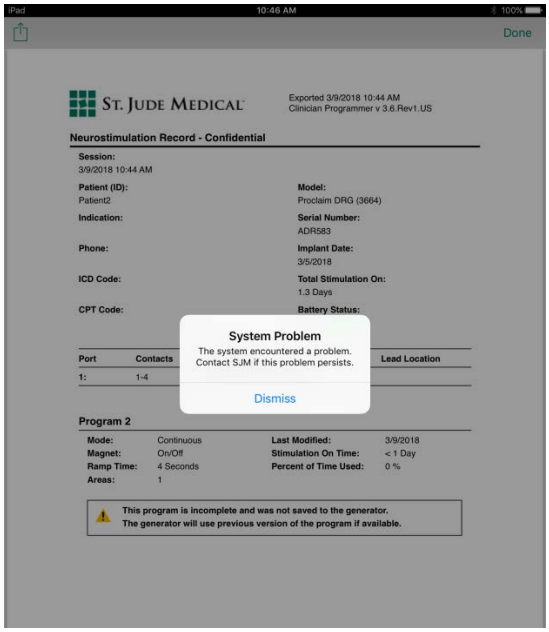

Figure 1: Clinical Programmer Error Message

Figure 2 shows where MRI Mode is found on the Patient Controller (PC) within the MODE screen. In the default state, MRI Mode is not enabled, which is displayed below. Enabling MRI Mode is not recommended until the one-time update to restore impedance check functionality is available, as this action will initiate an impedance check which may result in uncomfortable stimulation.

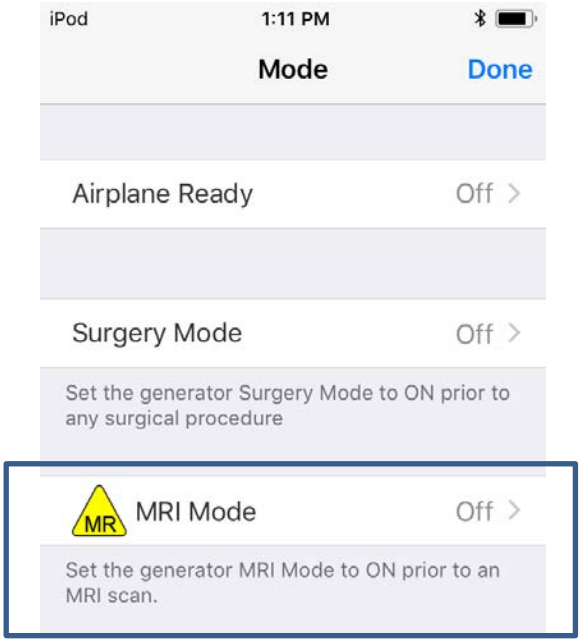

Figure 2: Patient Controller MRI Mode Status Indicator

Instructions for Use can also be located at *manuals.sjm.com* for additional information regarding CP / PC messages.