Important Medical Device Advisory

NM Implantable Pulse Generator
Inaccurate Elective Replacement Indicator

12 September 2017

Dear Physician,

In an effort to keep you continually informed, and to ensure optimal care of your patients, Abbott is advising physicians that our company is aware of instances in which the elective replacement indicator (ERI) in some devices has triggered earlier than intended. In these cases, the ERI alerts were triggered early due to an error in how the device calculates the actual remaining battery life in the impacted implantable pulse generators (IPG). As you know, ERI alerts estimate battery life based on programmed device parameters and patient usage and are unique to each patient. Importantly, you should be aware that this issue is an error in software *calculation* and is *not* an indication of the devices' actual battery performance.

Currently, all implanted IPGs within the Proclaim family are affected by this advisory.

As of July 11, 2017, among the approximately 21,208 Proclaim Elite Spinal Cord Stimulation (SCS) and Proclaim Dorsal Root Ganglion (DRG) IPG devices sold worldwide, ERI messages have occurred earlier than intended in approximately 1.5% of devices. To date, of the devices that have received early ERI messages, 100 devices (0.5%) have been explanted and replaced. In addition, there is a low risk that the ERI alert will not trigger prior to a device's end of battery life, though this has *not* been observed to date.

We are contacting physicians to provide details regarding risk and patient management recommendations, thereby enabling physicians to make a determination with their patients on whether they should consider an elective device replacement in these circumstances.

Identifying Systems Subject to Inaccurate Battery Indications

Currently, the patient controller (PC) battery capacity indicator may display less than full upon first use due to this calculation error. In this situation, the battery continues to function normally and **no action is recommended**.

When the clinician programmer (CP) or PC display an ERI message, physicians are advised to follow patient management recommendations outlined below.   Pictures of the current ERI messages in both the PC and CP can be found in Appendix A.

Patient Management Recommendations

Abbott is planning to address inaccurate longevity information in two phases. The first phase requires an individual assessment of the device prior to any replacement decisions when an ERI message is received. The second phase is a software update that addresses the error in ERI calculation, and will be deployed upon approval by local governing agencies.

Phase I: ERI Assessment

- If a patient reports that an ERI message is displayed on the PC, please contact your Abbott Representative to obtain the device-specific generator logs and to conduct the ERI Assessment using the steps in Appendix B prior to making an elective replacement decision.

- After the ERI Assessment is completed, follow-up communication from your Abbott representative will be provided in order to make appropriate decisions. The response will be one of two possible responses, specific to therapy model:
  - For the **Proclaim DRG model only**:
    1. ERI is valid at this time for this device, follow existing information provided by IFU and CP for the elective replacement window for this device.
    2. The device has the appropriate level of battery voltage to provide the existing therapy until the next assessment, which should occur no later than March 2018. During this period, the ERI message will be displayed on the PC at the start of each session. This message may be dismissed to enter the session on the PC.
  - For **Proclaim SCS models only:**
    1. ERI is valid at this time for this device, follow existing information provided by IFU and CP for the elective replacement window for this device.
    2. The device has the appropriate level of battery voltage to provide the existing therapy until the next assessment. Schedule a follow up appointment to re-perform the Elective Indication Assessment in approximately two (2) months. During this period, the ERI message will be displayed on the PC at the start of each session. This message may be dismissed to enter the session on the PC.

Phase II: ERI Software Update

Abbott will deploy a software upgrade, upon approval by local governing agencies that addresses the errors in calculation causing the inappropriate ERI message. When this software update is deployed, the Phase I ERI assessment process is no longer needed. After the CP is updated, replacement decisions can be made following the revised instructions for use, which will be available at *manuals.sjm.com*. Once approved for use in your area, notification of the availability of this software update will occur through the Apple® Public App Store for the PC and through the SJM App Catalog for the CP.

Should you have questions about patient management, including questions regarding error messages related to IPGs, please contact your local Sales Representative or Abbott Support at **1-800-727-7846 (Opt3) (U.S)** and **+46 8 474 4147 (Outside the U.S.).**

We apologize for any difficulties this may cause you and your patients. Abbott is committed to providing the highest quality products and support.

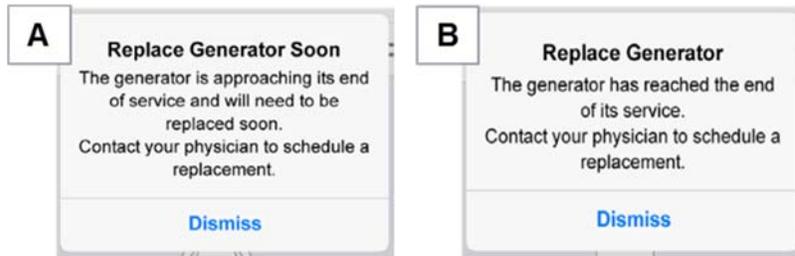**Thank you for your continued support.**

Sincerely,

Susan Jezior Slane
Divisional Vice President, Quality Assurance and Compliance
Abbott Cardiovascular and Neuromodulation

Attachments

APPENDIX A: Replacement Indication Messages

The images below show the current Patient Controller (PC) displays for Elective Replacement Indicator (A) and End-of-Service (B).

APPENDIX B: Steps to Retrieve and Submit Generator Logs for ERI Assessment

At the patient evaluation visit, conduct these steps prior to any programming assessment or changes to programming from that which has been used resulting in ERI message displayed on the Patient Controller (PC). It is important to assess the as used state of the device prior to changes for ERI assessment.
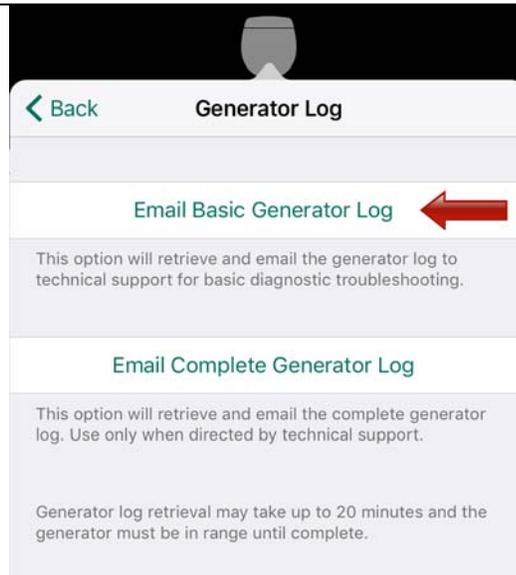

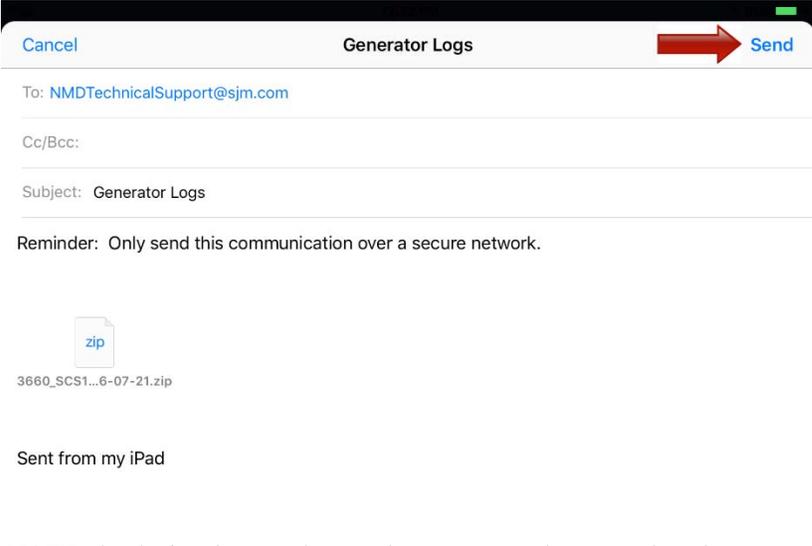| Extract the generator log and submit the generator log for ERI assessment.	**Environment Requirements in order to execute the extraction steps:**
	     SJM Clinician Programmer
	     Email Account on the Clinician Programmer
	     Network Connectivity

Connect to the IPG with the Clinician Programmer and press the IPG icon in the header to view the generator information screen and press the "Generator Log" option	NOTE: this screen content will vary slightly depending on therapy
Select the "Email Basic Generator Log" option and wait for process to complete	

After completion of the "Email Basic Generator Log" option an email is automatically generated. Press "Send" to email the log files to NMDTechnicalSupport@sjm.com	Cancel　　　　　Generator Logs　　　　　Send To: NMDTechnicalSupport@sjm.com Cc/Bcc: Subject: Generator Logs Reminder: Only send this communication over a secure network. zip 3660_SCS1...6-07-21.zip Sent from my iPad NOTE: the device does not have to be on a network to complete these steps
The extracted and submitted logs will be associated to a record ID for the assessment of the ERI event internally by Abbott	

After analysis by Abbott, if the response to ERI assessment is that the ERI is valid, follow existing Clinician Programmer guidance for remaining elective replacement window. This response will be provided to your Abbott representative.

After analysis by Abbott, if response to the ERI assessment is that a future assessment, after a provided period of time is recommended; please schedule a follow up with the patient to conduct that assessment.

- DRG: The ERI assessment is that the device has the appropriate level of battery voltage to provide the existing therapy until the next assessment; please schedule a follow up with the patient to conduct that assessment no later than March 2018
- SCS: The ERI assessment is that follow-up is recommended approximately 2 months from the date generator log files were obtained to re-conduct the ERI assessment.

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

Frequently Asked Questions is available on *www.sjm.com/notices* that you may use or provide to your patients to assist them with information regarding this issue, and the process to evaluate the ERI messages.