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Frequently Asked Questions (FAQs)

Abbott knows that you may have questions related to our recently announced medical device advisory related to a software calculation error in some of our Neuromodulation devices. To help you better understand what this advisory may mean, we have developed the following list of "Frequently Asked Questions."

1. **What is the purpose of the advisory?**
   Abbott has issued a voluntary medical device advisory to notify physicians that a small number of patients have experienced inaccurate elective replacement indicator (ERI) messages on their programmer due to a software calculation error. To date, all of these inaccurate ERI messages have been earlier than needed.

2. **Is this a battery issue?**
   No. This is not a battery issue. The batteries in our devices are functioning normally and continue to deliver therapy as intended. This is a software issue related to how the battery longevity is calculated and displayed on our programmers.

3. **What is an Elective Replacement Indicator (ERI)?**
   Elective Replacement Indicator, or ERI, is a warning message that appears on the clinical programmer app or patient controller app when replacement of the IPG should be considered.

4. **How do I know which devices are subject to this advisory?**
   This advisory applies to Proclaim™, Proclaim™ DRG, or Infinity™ DBS devices. The EPG (External Pulse Generator) is not affected by this issue.

5. **What caused the issue?**
   The inaccurate ERI message is appearing early due to an error in how the system software calculates actual remaining battery life. It is important to know that this is a *software calculation error* and therefore does *not* impact battery performance. The battery will continue to function normally and IPG will deliver therapy as intended.

6. **I am scheduled to implant an Abbott Neuromodulation device. Should I be concerned?**
   No. This is *not* an issue with the device's battery performance. The issue is related to calculations within the software that may cause inaccurate ERI alerts for some devices. These devices can be evaluated further to determine the appropriateness of the ERI message. In the future, a software update will be available that corrects the calculation issue.

7. **What is the likelihood that I would be impacted by this issue?**
   As of July 11, 2017:
   - Out of 21,208 Proclaim and Proclaim DRG SCS devices sold worldwide, ERI messages have occurred earlier than intended in approximately 1.5% of devices.
   - Out of the 1,277 Infinity DBS devices sold worldwide, ERI messages have occurred earlier than intended in approximately 0.8% of devices.

8. **What should I do if my patient received an ERI?**
   Schedule an appointment with your patient and Abbott representative to obtain and submit the generator log files for additional evaluation by Abbott. Follow the guidance contained in the Dear Physician Letter based on that evaluation.

9. **Can this software calculation error also impact overall longevity estimates?**
   Yes. Battery longevity estimates may be affected by the calculation error. The effect of the calculation error will be addressed when the software upgrade is approved and available. Other things that impact longevity are how the device is programmed and how the patient uses the device

10. **Can I use the assessment process if the device longevity displayed on the Clinician Programmer is not what I expected?**
    No. The additional evaluation process only applies to devices displaying an ERI message.