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Patient Frequently Asked Questions (FAQs)

Abbott knows that our patients may have questions related to our recently announced a medical device advisory related to 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. **Why did I get a letter?**

   Our records indicate you have an Abbott Proclaim™ or Infinity™ Neuromodulation system implanted. The letter you received was to inform you of the new "Surgery Mode" software feature that is now available on your iPod™ Patient Controller.

2. **What is the issue?**

   Abbott has issued a medical device advisory to notify physicians that a small number of patients have loss of therapy during surgical procedures due to interactions with other surgical equipment and the device, the specific equipment is called a monopolar electrocautery device.

3. **How do I know if my device is subject to this advisory?**

   This advisory applies only to our Proclaim Elite™ or Infinity™ IPG devices.

4. **I am scheduled to receive an Abbott Neuromodulation device. Will I have surgery mode?**

   Yes. All devices impacted by this advisory implanted after June 2, 2017 will come with the "Surgery Mode" feature available during your initial programming session with your care provider.

5. **What is the likelihood that I would be impacted by this issue?**

   The likelihood that this will impact your health is small, as the vast majority of devices sold worldwide have not experienced loss of their Neuromodulation therapy due to this issue. Not every patient has surgical procedures that use monopolar electrocautery, settings or surgical workflow that can cause this issue. If you require a future surgery, "Surgery Mode" should be enabled prior to any future surgery. It is important to note, "Surgery Mode" does not completely eliminate the risk of an IPG becoming non-responsive. If therapy is lost, "Surgery Mode" may restore therapy to the user. Otherwise, replacement surgery is required.

   Please follow your instructions for use when planning any surgical procedures and contact your physician to determine if the procedure will cause damage to your Neurostimulation system.

   Additionally, as of the date of the medical device advisory, a software update is available to you to improve your device's protection against these events, which is call "Surgery Mode". Please accept the medical device software update on your Patient Controller. This feature needs to be enabled by your physician or Abbott Representative. You can contact Abbott Technical Support at **1-888-397-8828** (U.S.) with any questions on how to update your Patient Controller software to receive the "Surgery Mode" Feature.

6. **What should I do if I am planning a surgery?**

   Please ensure that "Surgery Mode" is downloaded on your Patient Controller and that you have made the one-time connection to a Clinician Programmer to complete the update process prior to a surgery.

   Follow the general instructions to Turn **ON** "Surgery Mode" immediately before a surgical procedure, which are provided in the "Undergoing a Surgical Procedure" Guide.

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7. How can I tell if my device has lost therapy due to this issue?

Following a surgery, when turning your device back on, if you do not have Neurostimulation therapy, your device may have been affected. Please contact your physician to see if the Clinician Programmer (CP) displays the message "***Generator Not Ready – Wait 30 seconds***". This message may be an indication of exposure to surgical equipment during a medical procedure.