



Important Medical Device Advisory

NM Implantable Pulse Generator (IPG) Inoperable When Exposed to Monopolar Electrosurgery

02 June 2017

Dear Doctor,

We are advising you of a risk of loss of Neuromodulation therapy due to exposure of the IPG to monopolar electrosurgical devices (ESU) during medical procedures. As of April 30, 2017, among the approximately 14,500 IPG devices sold in the US, 189 have resulted in loss of therapy due to exposure to monopolar ESU. The vast majority of these devices required a new device to be implanted to restore neurostimulation therapy.

All implanted serial numbers of the below Neuromodulation Systems are affected by this advisory:

IPG Models Associated to the Neuromodulation Systems:

Proclaim Elite SCS IPG (3660, 3662)

Infinity DBS IPG (6660, 6662)

Infinity DBS IPG with MDT header (6661, 6663)

We are contacting physicians to provide details regarding risk and patient management recommendations due to the availability of a new feature, "Surgery Mode," on the Patient Controller (PC) and Clinician Programmer (CP). This feature increases the device's resistance to the effects of monopolar electrosurgery devices. In some cases, it will restore therapy to devices that have been exposed to monopolar ESU. The "Surgery Mode" feature is the same for all IPG devices and is not related to the therapy type.

Estimation of Loss of Therapy from Exposure to ESU

Among approximately 14,500 IPG devices sold in the United States as of April 30, 2017, one hundred eighty-nine (189) complaints have been associated with this issue. Of those, one hundred eighty-five (185) were Spinal Cord Stimulation therapy systems and four (4) were Deep Brain Stimulation therapy systems. There are no reported deaths or patient harms beyond early replacement of their IPG. The overall occurrence rate in the United States is 1.30%.

Mode and Identification of IPG Device Inoperable due to Exposure to Monopolar ESU

During these events, the CP displays the message "Generator Not Ready – Wait 30 Seconds." This message indicates that the IPG device has entered a state where therapy is not delivered. To restore therapy in these instances, replacement surgery is required.

Surgery Mode will provide greater protection against the potential effects of monopolar electrocautery, and will reduce the number of IPGs entering a state where therapy is not delivered. However, "Surgery Mode" does not completely eliminate the risk of an IPG becoming non-responsive and requiring a replacement surgery.

The updated CP and PC software applications contains "Surgery Mode" which is intended to be enabled by the patient, caregiver, or Abbott field representative prior to surgical procedures where ESU equipment may be used. The neurostimulation system will only be upgraded through a connection with an upgraded CP. The PC cannot place an IPG in Surgery Mode until the IPG has been upgraded.

Patient Management Recommendations

- After a one-time update to your Clinician Programmer is completed, new PCs will have “Surgery Mode” enabled on their device at initial programming session. For more detailed information, please see steps 1 and 2 in the Appendix.
- Currently implanted patients should update their PC to enable “Surgery Mode.” For detailed instructions on how to update the PC, please see steps 3 to 5 in the Appendix.
- If electrosurgery is used, we recommended using bipolar electrosurgery only. For detailed information on using electrosurgery devices during a procedure, please see the revised Warning in Figure 1 of the Appendix.
- All patients should follow the latest Instructions for Use regarding “Surgery Mode” for any upcoming surgery (see manuals.sjm.com). A reference guide is found in Figure 5 of the Appendix.

Should you have questions about patient management, including questions regarding error messages related to IPGs which are no longer delivering therapy, please contact your local Sales Representative or Abbott Support at **1-888-397-8828 (U.S)**.

We apologize for any difficulties this causes you and your patients.

Sincerely,



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

Attachments

APPENDIX

Steps for Surgery Mode Updates

1. Turn on your Clinical Programmer (CP).
2. As of the date of this letter, the software update with “Surgery Mode” will automatically download to your CP device when it communicates with a network. You may have noticed an UPDATE screen that directed you to this letter for more information.
3. Your CP has already been updated with the new software version; however existing patients must be connected to enable Surgery Mode on their device. First, the software update must be downloaded on the Patient Controller (PC). A similar UPDATE screen to yours will be displayed when this completes. However, the “Surgery Mode” feature is not yet enabled on their Patient Controller (PC).
4. To enable the feature, a single connection between the CP and the Patient Controller (PC) needs to occur. Once this connection completes, “Surgery Mode” the feature is enabled and can be turned on using the PC or the CP.
5. The software update to the CP/PC apps will now only allow up to 15 programs. If the patient’s IPG already contains 16 programs, a program will need to be deleted in order to enable the “Surgery Mode” feature.
6. To avoid damaging the IPG device, please review the updated information in the Instructions for Use regarding the WARNINGS related to use of electro-surgical devices. This information is provided in Figure 1 of the Appendix. Additionally the updated Instructions for Use can also be located at manuals.sjm.com.
7. Even when using “Surgery Mode”, there can be some cases where the IPG enters a state where therapy is not available. Please continue following the existing instructions to check the IPG functionality prior to pocket closure
8. Patient Frequently Asked Questions is available on sjm.com/SurgeryModeUpdate that you may provide to your patients to assist them with information regarding this issue, upgrading PCs, connecting their IPG to an upgraded Clinician Programmer (CP) and using the Surgery Mode feature during any future surgical procedures.

Figures 2, 3 and 4 in this Appendix provide screenshots of “Surgery Mode” enabled on the PC and CP.

**Figure 1 – Example Proclaim™ Implantable Pulse Generator
Models 3660, 3662, 3665, 3667 Clinician’s Manual Revised Warning, reference Page 2**

Electrosurgery. To avoid harming the patient or damaging the neurostimulation system, do not use monopolar electrosurgery devices on patients with implanted neurostimulation systems. Before using an electrosurgery device, place the device in surgery mode using the patient controller app or clinician programmer app. Confirm the neurostimulation system is functioning correctly after the procedure.

During implant procedures, if electrosurgery devices must be used, take the following actions:

- Use bipolar electrosurgery only.
- Complete any electrosurgery procedures before connecting the leads or extensions to the neurostimulator.
- Keep the current paths from the electrosurgery device as far from the neurostimulation system as possible.
- Set the electrosurgery device to the lowest possible energy setting.
- Confirm that the neurostimulation system is functioning correctly during the implant procedure and before closing the neurostimulator pocket.

Note: similar Warning is available in the Infinity™ Clinician Manual

Figure 2: Proclaim™ Clinician Programmer (CP) Screenshots with “Surgery Mode”

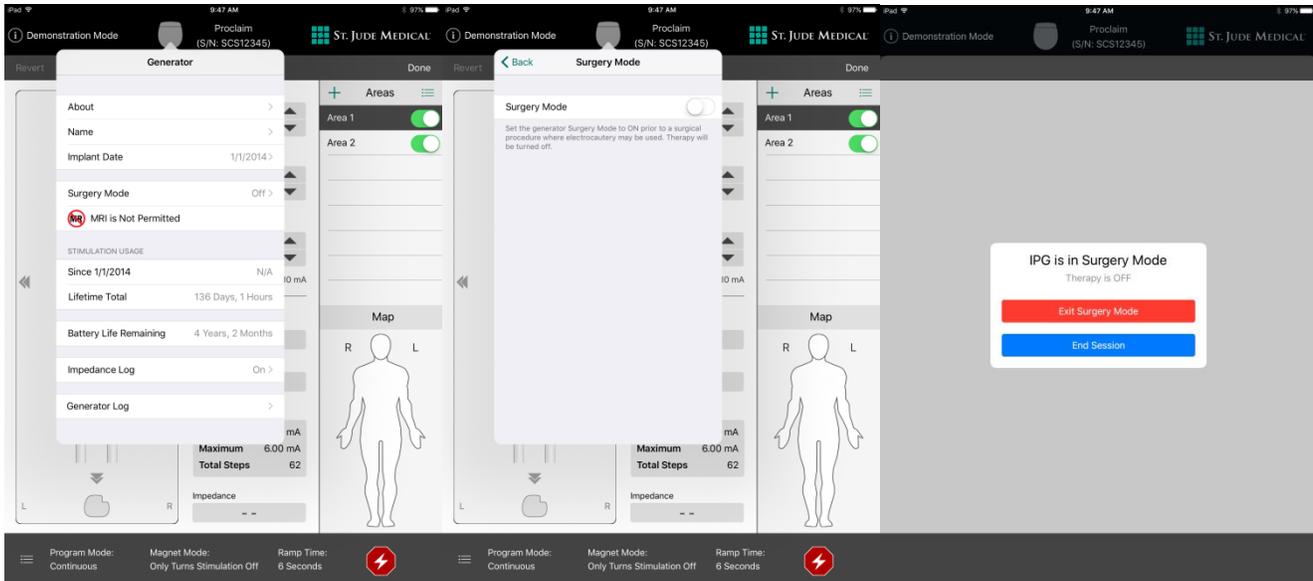


Figure 3: Infinity™ Clinician Programmer (CP) Screenshots with “Surgery Mode”

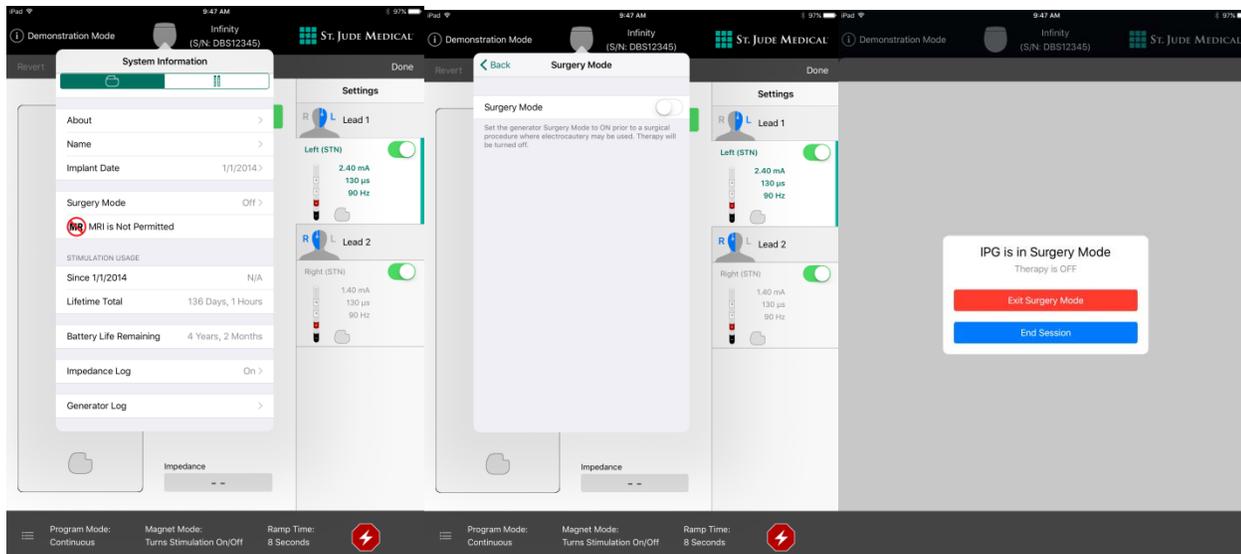


Figure 4: Patient Controller (PC) Screenshots with “Surgery Mode”

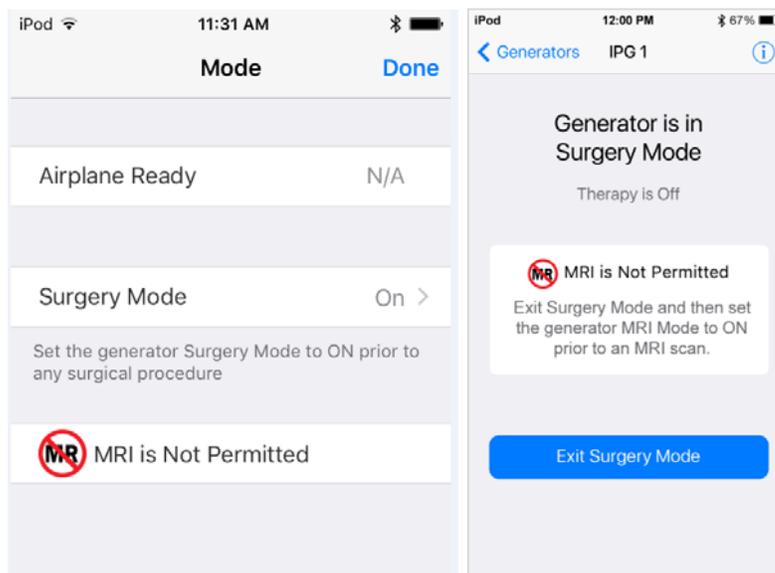
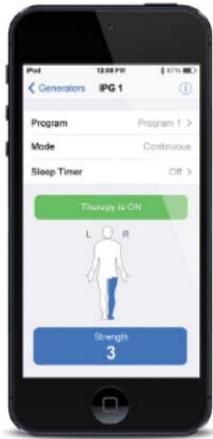


Figure 5: “Using Surgery Mode” Patient Guide



ST. JUDE MEDICAL™ PATIENT CONTROLLER

PLACING YOUR ST. JUDE MEDICAL IPG SYSTEM IN SURGERY MODE

Place your device into surgery mode before entering the OR for your procedure. Surgery Mode can be enabled directly from your patient controller device and will turn off stimulation from your implanted neuromodulation system. Turning off Surgery Mode before the completion of your procedure may cause unintended effects like unintended stimulation or damage to your neurostimulation system. Refer to your user guide for more information.

Activate surgery mode

- 1 Ensure that your patient controller application version is higher than version 3.3. This can be checked by clicking on the “i” icon shown in **Figure 1**.
- 2 Tap “Mode” on your Patient Controller Device, as shown in **Figure 1**.
- 3 Tap “Surgery Mode”, as shown in **Figure 2**.
- 4 Tap the toggle bar next to “Surgery Mode” to the right, as shown in **Figure 3**. Your device is now in Surgery Mode, as shown in **Figure 4**.



Figure 1

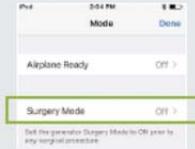


Figure 2



Figure 3

Turning Stimulation Back On After Your Procedure

Once your procedure is complete, disable Surgery Mode to resume normal stimulation.

- 1 To disable MRI Mode, tap “Exit Surgery Mode” as shown in **Figure 4**. The Therapy Screen will appear, showing stimulation therapy is off.
- 2 To start stimulation, tap “Therapy is OFF”, shown in **Figure 5**.

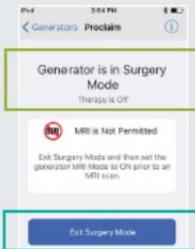


Figure 4



Figure 5