



Urgent Field Safety Notice
Activa PC+S Implantable Neurostimulator (INS)
Model 37604

August 2018

Medtronic reference: FA836

Dear Physician-Investigator of an Activa PC+S Clinical Study,

This letter is to notify you of a potential issue identified in the Activa PC+S firmware. This anomaly can result in the Activa PC+S (model 37604) implantable neurostimulator (INS) not being able to communicate with programming instruments such as the patient programmer (model 37642) or 8840 Clinician Programmer. The issue also affects Activa PC+S devices that have been updated with the investigational Nexus-E firmware. The Activa PC+S is used in physician-sponsored clinical studies as part of Medtronic's External Research Program (ERP). Activa PC, RC, and SC are not affected.

Background on Issue:

Medtronic is aware of two instances where, during an in-clinic research visit, a Patient Programmer (model 37642) was used to interrogate an Activa PC+S INS while the Sensing Programmer Telemetry Module (SPTM) was actively retrieving recorded data and transferring it to the Sensing Programmer (SP). This patient programmer interrogation during a data upload resulted in the INS entering a "busy" scheduling loop and prevented communication with other programming instruments. Therapy is unaffected when the INS is in this scheduling loop (i.e. stimulation remains in the state it was in prior to entering the loop), however it cannot be adjusted. In these instances, a Medtronic ERP Project Manager assisted the clinician with instructions on restoring communication with the INS.

In these two events, no patient harm occurred beyond the inconvenience to resolve the communication issue. There is a potential for harms associated with loss of therapy if this issue were to occur while therapy is turned off. Based on known use cases, the issue would only occur during a clinical visit.

Recommendation:

Medtronic recommends avoiding the simultaneous use of two instruments when interfacing with an Activa PC+S. Only one antenna or telemetry head should be placed over the INS at any point in time. If the issue is encountered and communication between the INS and programming devices ceases, please contact your Medtronic ERP Project Manager, who can assist with instructions on resetting the INS to resolve the issue.

Action Required:

1. Please sign and return the enclosed response form to acknowledge that you have read and understand this letter. Retain a copy of this letter and completed response form for your records.
2. Please assess this information for any regulatory reporting requirements that you may have as the Sponsor of your clinical study. Please assess the risk regarding this communication issue as it relates to your study protocol and/or informed consent form and whether it has impact on patient safety, or impact to the rights, safety or welfare of patients in the study.

We appreciate your assistance with this matter and are committed to continuing to improve our product performance and services to enable you to manage your patients and conduct your research in a safe and effective manner.

If you have questions related to this issue, please contact your **Medtronic ERP Project Manager** at **<insert phone number>**.

Sincerely,

Medtronic ERP Project Manager