

Urgent Field Safety Notice

Model A610 DBS Version 3.0.x

Clinician Programmer Tablet Application Displays System Error During Interrogation - Notification

September 2021

Medtronic Reference: FA1188

Dear Health Care Professional,

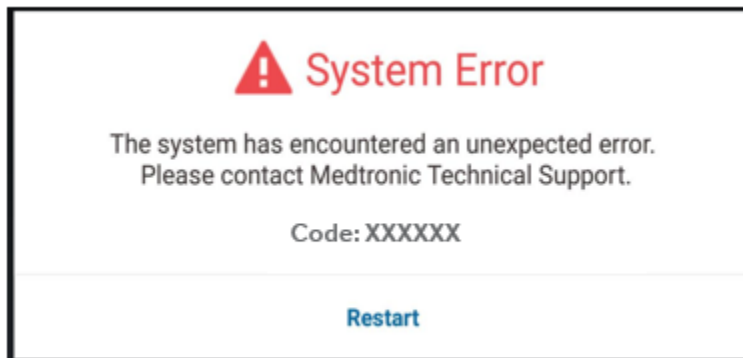
The purpose of this letter is to inform you of the potential for the Medtronic model A610 DBS Clinician Programmer Tablet Application Version 3.0.x (3.0.1048, 3.0.1057, and 3.0.1062) to display a system error and terminate the session during interrogation of an Activa™ Dual-Channel Implantable Neurological Stimulator (INS) when a particular configuration exists as described below.

Issue Description:

Medtronic has identified an anomaly with the clinician programmer application (A610) when interrogating an Activa PC or Activa RC. In rare instances, this anomaly may present during a follow-up session if the patient was previously programmed with an A610 DBS Clinician Programmer Application Version v.2.0.x (2.0.4584, 2.0.4594, 2.0.4630, and 2.0.4605) and later that same patient's device is interrogated with a clinician programmer tablet running A610 3.0.x (3.0.1048, 3.0.1057, and 3.0.1062).

Under these circumstances, the clinician programmer application may display a recurring system error and terminate the session, preventing interrogation or programming of the device. The patient will continue to receive therapy and the patient programmer can be used to adjust therapy within clinician set limits.

If this issue occurs, you will encounter a system error message similar to the one below:



Error codes seen with this issue include, but may not be limited to, codes 0x4b81f1a3 and 0x791ebfe0.

As a result of this issue, adjustments using the clinician programmer are not possible, and this may result in inadequate or excessive therapy if changes are required. If this issue presents during an ongoing surgical procedure, the patient may experience prolonged surgical time to allow for troubleshooting. As of August 26, 2021, Medtronic has received six complaints related to this issue, none of which has resulted in patient injury.

If you experience this recurring system error message, contact your Medtronic Representative. Medtronic is developing a software update to address this issue and will inform you once this is available.

Required Actions:

If you experience this issue, contact your Medtronic Representative to troubleshoot and coordinate appropriate next steps.

Additional Information:

Please share this notification with others in your organization as appropriate.

Please maintain a copy of this communication in your records. Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions, please contact your Medtronic Representative at <XXXX>.

Sincerely,

Local / BU Manager