Medtronic

Urgent Field Safety Notice
Model A610 DBS Version 3.0.x

Clinician Programmer Tablet Application Displays System Error During Interrogation - Software Update

March 2023

Medtronic Reference: FA1188
EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Health Care Professional,

This communication is a follow-up to inform you that a new software version for the Medtronic Model A610 DBS Clinician Programmer Tablet Application, version 3.0.1098, is now available to address issues communicated in September 2021 related to interrogation of an Activa PC or Activa RC Implantable Neurological Stimulator (INS). Please install the new A610 Clinician Programmer App version 3.0.1098 (or higher).

Issue Background:

In a letter dated September 2021, Medtronic had communicated that an anomaly with the Model A610 DBS Clinician Programmer Tablet Application Version 3.0.x (3.0.1048, 3.0.1057 and 3.0.1062) could lead to a System Error message. This error could occur during interrogation of an Activa™ Dual-Channel Implantable Neurological Stimulator (INS) and display a system error and terminate the programming session. As of 17 March 2023, Medtronic has received 14 complaints worldwide (9 in the USA, 2 in United Kingdom, 1 in Netherlands, 1 in Belgium, and 1 in Canada) related to this issue, none of which have resulted in patient injury.

Medtronic has developed a new software version for the A610 DBS Clinician Programmer Tablet Application to address the anomaly detailed above. To mitigate the issue, complete the following actions.

Actions to Be Taken:

1. Download version 3.0.1098 (or higher) of the A610 DBS Clinician Programmer Tablet Application. Your Medtronic representative can assist you with the update.
   a. With this new A610 application version you will not experience the issue when interrogating an Activa PC or Activa RC device.
2. Share this communication within your organization, with other organizations where affected devices have been transferred, and with any other associated organizations that may be impacted by this action.
3. Maintain a copy of this notice in your records.
4. If you experience this issue, contact your Medtronic Representative to troubleshoot and coordinate appropriate next steps.

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5. Complete the enclosed Customer Confirmation Form even if you don't have inventory, please return the form to rs.dusregulatory@medtronic.com.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience or difficulty this issue 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.

Sincerely,

Enclosure:

Attachment 1: FA1188 Urgent Field Safety Notice dated September 2021

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<p style="text-align:center; color:red;">Urgent Field Safety Notice</p>

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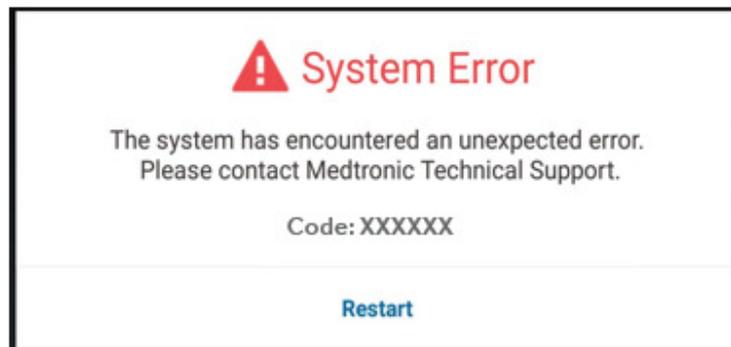
Error codes seen with this issue include, but may not be limited to, codes 0x4b81f1a3 and 0x791ebfe0.

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:

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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.

Sincerely,

Medtronic

FA1188 Phase II: Customer Acknowledgement Form - Response is required.
Model A610 DBS Version 3.0.x

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title: _____

Direct Phone #: _____

Email: _____

Account Name: _____

Account Number: _____

Account Address: _____

City: _____ Zip Code: _____

Country: _____

I have read and understand the instructions provided and acknowledge receipt of the notification regarding the use of the Model A610 DBS Version 3.0.x by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed Model A610 DBS Version 3.0.x as required.

_____ _____ _____
Name: (print)   Signature: Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL THIS ACKNOWLEDGEMENT TO:

rs.dusregulatory@medtronic.com