

## Urgent Field Safety Notice

### A610 DBS Clinician Programmer Application Version 1.0.3470

October 2019

Medtronic reference: FA861 phase II

Dear Healthcare Professional,

In a follow-up to our Field Safety Notice FA861 from April 2019, Medtronic is informing you that the updated A610 Deep Brain Stimulation (DBS) Clinician Programmer Application is now available to download to address the issue described below. This application runs on the Medtronic CT900 Clinician Tablet and is intended for use by clinicians to program Medtronic neurostimulators for Deep Brain Stimulation. The A610 software is being updated to Version 1.1.3484.

#### Issue Description:

The A610 software includes a *Charge Density Warning* to alert clinicians during programming of settings that may possibly damage nervous tissue. Medtronic has identified that under specific configurations this warning will not display when expected; specifically, when the External Neurostimulator (ENS) is used during test stimulation with a twistlock cable and neurostimulation lead model 3387 or 3389. In this configuration, the charge density warning on the A610 application will first appear at 60  $\mu\text{C}/\text{cm}^2/\text{phase}$  vs the expected 30  $\mu\text{C}/\text{cm}^2/\text{phase}$ . Medtronic has not identified any complaints or reports of injury related to this issue.

This issue **does not** affect any of Medtronic's DBS Implantable Neurostimulators.

#### Actions

##### If you use a CT900 Clinician Tablet with the A610 software application:

- Connect to WiFi and open the Hub application on the CT900 clinician programmer, then download and install version 1.1.3484 of the A610 software application (additional details are contained in the enclosed "App Update Using Hub" document).

##### If you do not use a CT900 Clinician Tablet:

- You are not affected by this software issue.

#### Additional Information:

Please perform the actions above as soon as this notification is received. Three months from this notification, any CT900 connected to WiFi that has not updated to A610 version 1.1.3484 will automatically have the A610 software version 1.0.3470 uninstalled by Medtronic. The automatic uninstall will interrupt all DBS functionality of the programmer during the process. If the A610 software on your CT900 is uninstalled, you can install version 1.1.3484 of the A610 software application per the enclosed instructions.

The Competent Authority of your country has been notified of this action.

We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions, please contact your Medtronic Representative directly or via Tel No: 01 511 1400

Sincerely,



Keith Taverner, Regulatory Affairs Manager UK & Ireland.

Enclosure:

- Software update instructions titled "App Update Using Hub"