Medtronic

Urgent Field Safety Notice

A610 DBS Clinician Programmer Application Version 1.0.3470

April 2019

Medtronic reference: FA861

Dear Healthcare Professional,

This letter is to inform you of a potential issue with the Medtronic's A610 Deep Brain Stimulation (DBS) Clinician Programmer Application. This application runs on the Medtronic CT900 Clinician Tablet and is intended for use by clinicians to program Medtronic neurostimulators for Deep Brain Stimulation.

Issue Description:
The A610 software includes a *Charge Density Warning* to alert clinicians during programming of settings that exceed 30 $\mu C/cm^2$/phase and provide a confirmation to use the selected value. Medtronic has identified during internal testing 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 $\mu C/cm^2$/phase vs the expected 30 $\mu C/cm^2$/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:

- Please consider the potential charge density difference when deciding to proceed or not proceed during ENS test stimulation until a software update can be provided for download. Please note that using the lowest effective amplitude and pulse width minimizes the charge density, the amount of stimulation applied to the patient over a given surface area. The maximum stimulation setting limits are correct and will continue to prohibit any use of stimulation parameters beyond allowable settings.

If you do not use a CT900 Clinician Tablet:

- You are not affected by this software issue.

You will be notified once the updated software is available for download.

The Competent Authority of your country has been notified 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,