

March 2019

URGENT: MEDICAL DEVICE CORRECTION

A610 DBS Clinician Programmer Application Version 1.0.3470

Dear Healthcare Professional:

This letter is to inform you of an update to 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. 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 exceed $30 \mu\text{C}/\text{cm}^2/\text{phase}$ 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 $60 \mu\text{C}/\text{cm}^2/\text{phase}$ 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).
- Complete the enclosed confirmation form and return it to Medtronic per the instructions on the form. Please maintain a copy of this for your records.

If you do not use a CT900 Clinician Tablet:

- Complete the enclosed confirmation form and return it to Medtronic per the instructions on the form. Please maintain a copy of this for your records. You are not affected by this software issue.

Additional Information:

Please perform the actions above as soon as this notification is received. Approximately 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. 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.

If you have questions, please contact us:

- Physicians with device or therapy questions, contact Technical Services at 800-707-0933 or contact your Medtronic Representative.
- For application update questions, contact Medtronic Connected Care Mobility support at: 800-707-0933, option for Samsung Device.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. Medtronic will notify all applicable regulatory agencies about this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Jose Lima". The signature is fluid and cursive, with a large loop at the end.

Jose Lima
Vice President of Quality, Brain Therapies

Enclosures:

- *Physician Confirmation Form*
- *Software update instructions titled "App Update Using Hub"*