

## Urgent Field Safety Notice

### Model A610 DBS Clinician Programmer App Versions 2.0.4584, 2.0.4594, 2.0.4605, and 3.0.1057

#### INS Replacement Cycling & Application Crash Issues Software Update

July 2021

Medtronic Reference: FA968 & FA969

Dear Healthcare Professional,

This communication is a follow-up to inform you that a new software version for the A610 Clinician Programmer App is now available to address issues communicated in March 2021 for application versions 2.0.4584, 2.0.4594, 2.0.4605, and 3.0.1057. Please install the new A610 Clinician Programmer App version **3.0.1062** (or higher), per the enclosed instructions.

#### Background:

There were two issues that Medtronic previously communicated:

1. When copying settings from a previously implanted device with cycling enabled to a new Percept PC device using the "Replacement" function of the A610 clinician programmer application, the cycling settings are not copied properly. As a result, the application shows cycling as "On" in all reports and User Interface screens when it is actually not enabled for any programs.
2. In rare conditions, the clinician programmer A610 Software application version 2.0.4584, 2.0.4594, 2.0.4605, and 3.0.1057 can crash when it is interrogating the Percept PC INS. Due to the repetitive nature of the crash, the health care professional can only program the device in one-minute sessions between crashes.

#### Actions:

1. Please download version **3.01062** (or higher) of the A610 Clinician Programmer App following the enclosed instructions. Your Medtronic representative can assist you with the update.
2. With the new A610 application version:
  - a. Users previously experiencing a crash approximately 1 minute after interrogation will no longer see the crash.
  - b. The Replacement function from Activa to Percept PC will now work correctly with cycling settings for future patients.
  - c. When interrogating a Percept PC that already has the cycling issue present:
    - i. The application will inform you of invalid therapy or that invalid group(s) are present
    - ii. You will need to press Continue, which will clear those invalid group(s).
    - iii. Once the settings are cleared, you will need to reprogram the affected group(s) in order to deliver therapy
3. Please share this notification, as appropriate, with those in your organization that require this information.

#### Additional Information:

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

We regret any inconvenience and difficulty this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter.

If you have questions related to this issue, please contact your local Medtronic representative.

Sincerely,

[Local / BU Manager](#)

Enclosure: Software update Instructions