

## 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 **3.0.1062** (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

# APP UPDATE USING HUB


Medtronic

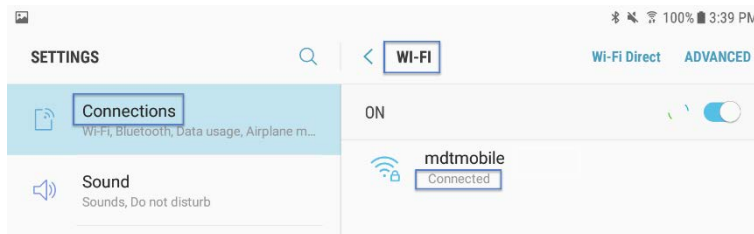
Medtronic controlled applications can be updated using the Hub app. Airwatch has been rebranded to be called Hub. If you have further questions not answered below, please contact 1-800-707-0933, and select option for Samsung Device Support.



The following instructions will guide you through updating the Hub app as well as any available app updates:

## 1. Connect the tablet to Wi-Fi

- Navigate to  Settings
- Tap Connections > Wi-Fi > and select the desired Wi-Fi Network
- Verify it says "Connected"



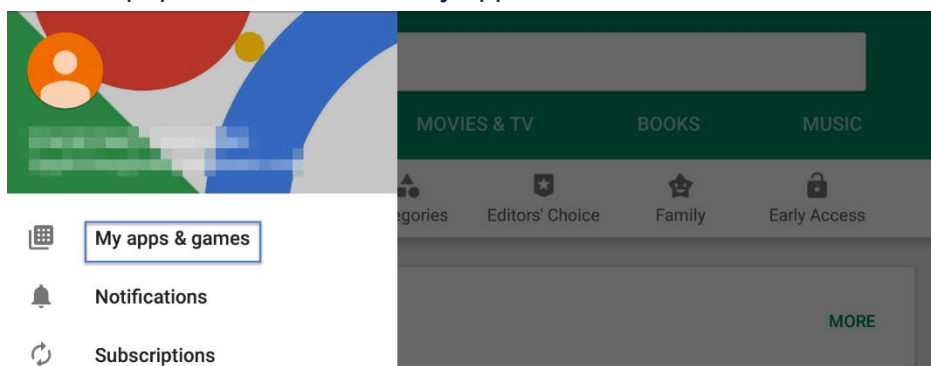
- Press the home button to return to the home screen

## 2. Navigate to the Google Play Store app

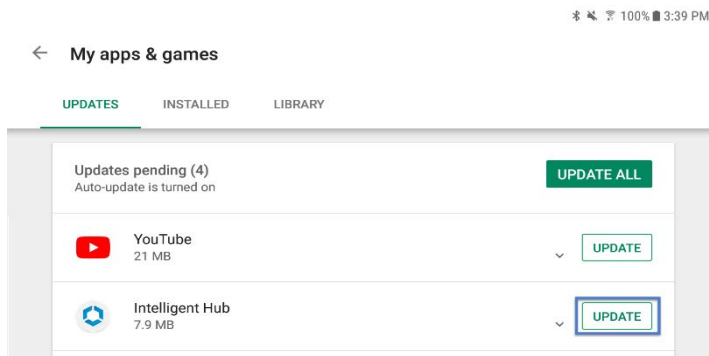
- Tap the menu icon next to the search bar



- From the pop-out menu, select "My Apps & Games"



- c. Available updates will display. Update the “Intelligent Hub” app. This is the only necessary update and other apps can be updated later



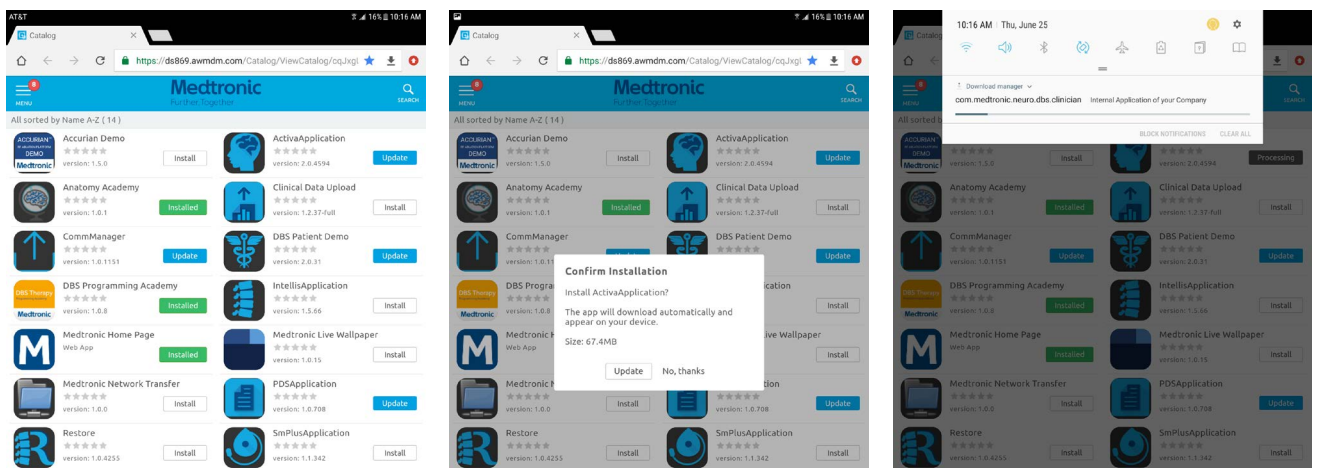
- d. Press the Home button to return to the home screen

### 3. Navigate to the Hub app

- a. The one-time welcome screen will display
- b. Notice that the tablet’s unique ID is in a different spot than it was in Agent
- c. Go to Hub and under This Device select Sync device. Wait approximately 1 minute to allow any changes to take place.
- d. Open “App Catalog”



### 4. Request any available updates



## 5. App version and feature code can be verified on the about screen.

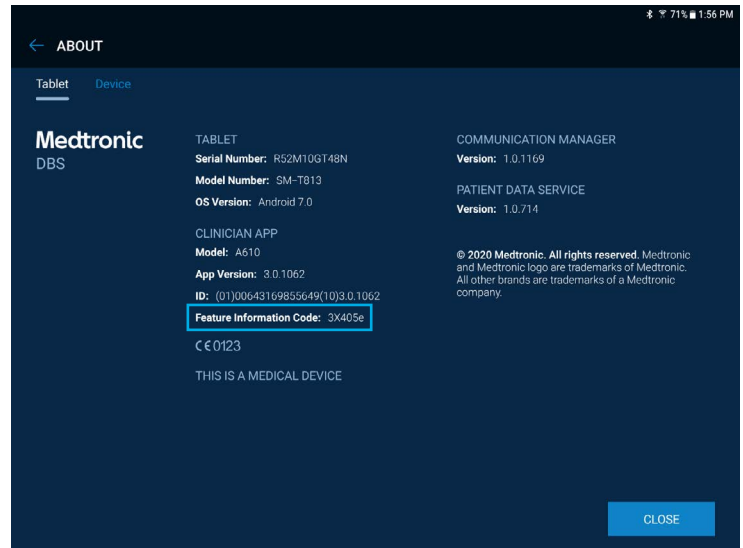
### ABOUT SCREEN

- Open the therapy application
- Tap the settings icon in the upper right and select "About"
- The version number will be displayed under "Clinician App"
- Important: Confirm feature code corresponds correctly with geography in the chart below.**

Code	Geographies	MRI	aDBS*	Digital Health
3x405f	US	Y	N	Y
3x40de	Japan	Y	Y	N
3x405e	All Other Geographies	Y	N	N

\*aDBS for Parkinson's Disease diagnosis only

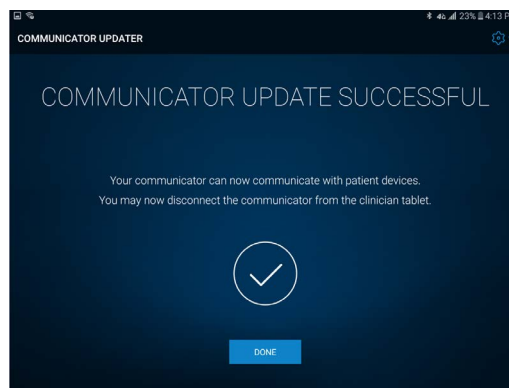
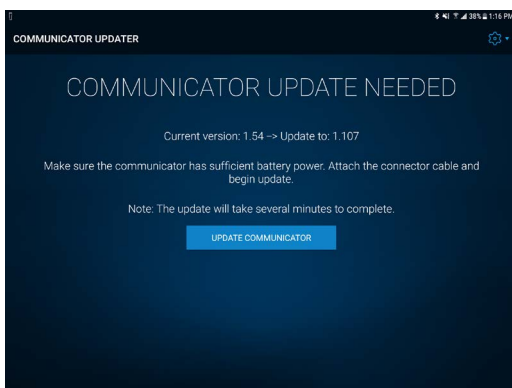
**IMPORTANT:** Always update A610 to at least version 3.0 prior to setting up or programming a SenSight™ Directional Lead System



## Updating the CTM firmware

You may be prompted to update the firmware of the communicator the first time you try to connect.

- Connect Communicator to the Tablet via USB cable**
- Select "Update Communicator"**
  - The update will begin and take several minutes to complete.
- Select "Done" on communicator update successful screen.**



**IMPORTANT! DO NOT** disconnect USB cable to power off the Tablet of the Communicator, until update progress is completed and "Communicator update successful" screen appears. During the update the LEDs of the Communicator will **NOT** be lit and the unit may appear non-functional.

## Troubleshooting

If issues are encountered following the above steps, below are more steps that could resolve the problem. If the below steps do not resolve the problem, contact Medtronic Technical Services.

Problem	Possible Solutions
Application is not installed	<ol style="list-style-type: none"><li>1. Confirm Wi-Fi is connected, and <b>HUB</b> is at the latest version available. Using <b>HUB</b> under <b>THIS DEVICE</b> select <b>SYNC DEVICE</b></li><li>2. Using <b>HUB</b>, under <b>THIS DEVICE</b> select <b>PROFILES</b>, and choose <b>REAPPLY PROFILE</b> for these items:<ul style="list-style-type: none"><li>▪ Blacklist</li><li>▪ Whitelist</li></ul></li></ol>
Application version is not updated	<ol style="list-style-type: none"><li>1. Confirm Wi-Fi is connected, and <b>HUB</b> is at the latest version available. Using <b>HUB</b> under <b>THIS DEVICE</b> select <b>SYNC DEVICE</b></li><li>2. Using <b>HUB</b>, under <b>THIS DEVICE</b> select <b>PROFILES</b>, and choose <b>REAPPLY PROFILE</b> for these items:<ul style="list-style-type: none"><li>▪ Blacklist</li><li>▪ Whitelist</li></ul></li></ol>
Application shows as "Processing" and does not seem to be installed after waiting several minutes.	<ol style="list-style-type: none"><li>1. Refresh the <b>APP CATALOG</b> page.</li><li>2. Confirm Wi-Fi is connected, and <b>HUB</b> is at the latest version available. Using <b>HUB</b> under <b>THIS DEVICE</b> select <b>SYNC DEVICE</b></li><li>3. Using <b>HUB</b>, under <b>THIS DEVICE</b> select <b>PROFILES</b>, and choose <b>REAPPLY PROFILE</b> for these items:<ul style="list-style-type: none"><li>▪ Blacklist</li><li>▪ Whitelist</li></ul></li></ol>
Initialization Error is present the first time the DBS application is opened, or Feature Code is "--"	<ol style="list-style-type: none"><li>1. Open the <b>DBS</b> application. On the home screen, select the <b>GEAR DROP-DOWN</b>, then <b>ABOUT</b>, then <b>CLOSE</b>, and the message might be dismissed.</li><li>2. Confirm Wi-Fi is connected, and <b>HUB</b> is at the latest version available. Using <b>HUB</b> under <b>THIS DEVICE</b> select <b>SYNC DEVICE</b></li><li>3. Using <b>HUB</b>, under <b>THIS DEVICE</b> select <b>PROFILES</b>, and choose <b>REAPPLY PROFILE</b> for these items:<ul style="list-style-type: none"><li>▪ Feature Flag</li></ul></li></ol>
Feature Code is not correct	<ol style="list-style-type: none"><li>1. Confirm Wi-Fi is connected, and <b>HUB</b> is at the latest version available. Using <b>HUB</b> under <b>THIS DEVICE</b> select <b>SYNC DEVICE</b></li><li>2. Using <b>HUB</b>, under <b>THIS DEVICE</b> select <b>PROFILES</b>, and choose <b>REAPPLY PROFILE</b> for these items:<ul style="list-style-type: none"><li>▪ Feature Flag</li></ul></li><li>3. If the Feature Flag profile noted above is not present, perform the following steps:<ul style="list-style-type: none"><li>▪ Close the DBS or PDS applications or reboot the tablet.</li><li>▪ Using <b>HUB</b>, select the <b>APP CATALOG</b> and choose <b>INSTALL</b> for PDS, even if it is already noted as <b>INSTALLED</b>. This will force the feature flag profile to be re-downloaded to the tablet.</li><li>▪ After this is completed, using <b>HUB</b>, under <b>THIS DEVICE</b> select <b>PROFILES</b>, and choose <b>REAPPLY PROFILE</b> for these items:<ul style="list-style-type: none"><li>– Feature Flag</li></ul></li><li>▪ Finally, using <b>HUB</b> under <b>THIS DEVICE</b> select <b>SYNC DEVICE</b>, and check the feature flag setting on the application.</li></ul></li></ol>