

Urgent Field Safety Notice

Update to Address SynchroMed II™ Pump Memory Error Via Model A810 SynchroMed™ II Software Application Version 1.1.342 Software Update

July 2020

Medtronic Reference: FA921

Dear Customer,

Medtronic is voluntarily issuing an Urgent Field Safety notice, requesting that the Model A810 SynchroMed™ II Software Application, used with the CT900 Clinician Tablet Programmer, be updated to version 1.1.342. Previous software versions do not resolve a specific pump memory error that can potentially inhibit the completion of a pump update command. Please install the A810 SynchroMed II Software application, version 1.1.342, per the enclosed instructions to mitigate this issue.

Issue Description

Since the introduction of the A810 SynchroMed II Software Application for use with the CT900 Clinician Programmer in June 2018, Medtronic has received three (3) reports of users observing an alert on the CT900 Clinician Programmer indicating that the pump programming update could not be completed. After investigation, it was determined that there was an error within a specific location of the pump memory and the A810 SynchroMed II Software application did not clear the error, resulting in an indication that the pump could not be updated. Memory errors are rare; some are resolved automatically by the pump, and others are resolved by manual configuration with the Clinician Programmer, allowing for continued programming activity and therapy delivery. With the assistance of Medtronic Technical Services, the three reported events were resolved with no patient harm.

This issue occurs and is recognized in the clinical setting where the patient is under care of the HealthCare Professional. The patient will continue to receive therapy as previously programmed, the pump will continue to function as intended, and alarms will sound when triggered. If the pump cannot be updated when a change to the therapy is needed, symptom management for excessive or inadequate therapy, or potential hospitalization could be required.

Actions

Please download the latest update to the A810 SynchroMed II Software Application, version 1.1.342, to the CT900 Clinician Programmer following the enclosed instructions

Please share this notification, as appropriate, with those in your organization that require this information.

Additional Information

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

We appreciate your assistance and regret any inconvenience this may cause you. If you have questions or require assistance installing the A810 SynchroMed II Software Application version 1.1.342, please contact your Medtronic Representative direct or via Tel No.01923 212213.

Sincerely,



Keith Taverner

Regulatory Affairs Manager UK & Ireland

Attached Customer Acknowledgement Form to be completed and returned to Medtronic.

Appendix A: Software Installation Instructions

Appendix A: Software Installation Instructions



STEP 1: PREPARATION

Power: Ensure the clinician programmer is plugged in or has more than 25 percent battery power prior to installing any updates.

Wi-Fi: Connect to Wi-Fi.

Close Apps: Close any open applications.

Time: Depending on the network bandwidth, this process could take up to 30 minutes.

STEP 2: UPDATING AGENT TO HUB

Medtronic applications can be updated using the Hub app, which replaced Agent. If you see the Agent app, please follow these instructions to update to Hub.

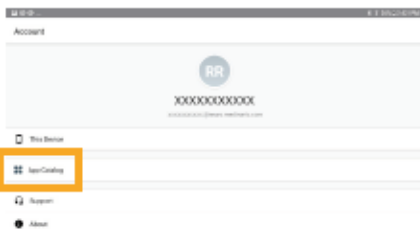


- 1. Navigate to Google Play Store app.
- 2. Tap menu icon.
- 3. Select **My Apps & Games**.
- 4. Update **Intelligent Hub** app.



STEP 3: APPLICATION UPDATE PLANNING

- 1. Click on **Hub** app. Then select **App Catalog** to view apps available for installation or update.



- 2. Only update therapy apps that you are educated on how to use.
- 3. Determine which therapy apps need updating.
- 4. Maintain up-to-date supporting applications. Check for updates for:
 - PDSApplication.** This is the Patient Data Services Application that supports reporting.
 - CommManager.** This software supports the communicator. Updates to the communicator require use of the communicator cable. See further instructions on second page.

Note: More than one application can update at the same time.

STEP 4: APPLICATION UPDATE PROCESS

- 1. While in **App Catalog**, click on **Update** (if an update is available) to update the apps you use.
- 2. Click on the **Confirm Installation** pop-up.

The screen will display **Processing** while the application is updating and will not change when installation is complete.

- 3. To check for installation completion, go to **Managed Apps in Hub**.
- 4. Once installation completes, confirm the correct software version in the Managed Apps or in the app's "About" section.



UPDATING COMMUNICATOR AND COMM MANAGER APP

After updating the communicator software, it is **crucial** to pair the communicator to the clinician programmer because the original coupling is lost.

STEPS FOR UPDATING THE COMMUNICATOR

- 1 Remove tablet cover and any accessories preventing USB connection of the communicator cable.
- 2 After updating **Comm Manager** in the **App Catalog**, open the **Communicator Updater** application.
- 3 Power the communicator on and connect it to the tablet with the pairing cord.
- 4 Select **Update (or Recover) Communicator**.



- While the communicator is updating, **DO NOT DISCONNECT THE COMMUNICATOR**.
- The update will take several minutes to complete. Please wait until the **Update Successful** screen appears.
- Once you have reached the **Update Successful** screen, select **Done** and proceed to communicator pairing.

PAIRING THE COMMUNICATOR

Ensure the communicator is powered on and connected to the tablet. An implantable device is not necessary for pairing the communicator.

- 1 Launch the therapy application and attempt to connect to an implantable device.
- 2 If the screen says, "Searching for Device" and not "Searching for Communicator," the communicator is now successfully paired.
 - The LED between the communicator and tablet icons will be solid green once connected.
 - If you encounter any issues, contact Digital Connectivity.

SPECIALIZED IT SUPPORT

Medtronic Digital Connectivity handles non-therapy IT-related questions such as:

- Password resets
- Lost/Stolen reports
- Connectivity issues
- Cellular/Wi-Fi
- Bluetooth
- Printing issues (not related to Model 8840)
- Software updates
- Unresponsive Samsung device programmer issues (e.g., not powering up)
- Unable to download therapy app

HOW TO CONTACT DIGITAL CONNECTIVITY SUPPORT:

- Technical Services will provide live support during the hours of 9 AM to 5 PM CET.
- On-call support will be provided 24/7 (English only).
- Contacts details: rs.tsneuro@Medtronic.com or +31 (0)45 566 88 44

USER ID CARD

Use the user ID card that came with the clinician programmer when calling Digital Connectivity.



See the device manual for detailed information regarding the instructions for indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu

For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat Reader® with the browser.