Urgent Field Safety Notice

Intellis™ Data Validation System Error
Model A710 Software Update to Version 1.3.130
Software update

December 2020

Medtronic Reference: FA949

Dear Customer,

Medtronic is voluntarily issuing an Urgent Field Safety Notice to request that you **update the Model A710 Intellis™ Software Application, used with the CT900 Clinician Tablet Programmer, to version 1.3.130**. The previous A710 Intellis Software Application version 1.3.80 may not reset invalid memory correctly which can result in the inability to update therapy settings, cause changes to the Patient Programmer display, provide access to unapproved functions of the Patient Programmer, and/or loss of therapy. **Please install the A710 Intellis Software application, version 1.3.130, per the enclosed instructions to mitigate this issue.**

Issue Description
Medtronic has received fourteen (14) reports between January 2020 and November 24, 2020 where users encountered this validation error (Figure 1) followed by a system error (**Error! Reference source not found.**) on the CT900 Clinician Programmer A710 Intellis Software Application version 1.3.80 indicating that the stimulator programming update could not be completed. After investigation, it was determined that there was corruption within a specific location of the stimulator memory and the A710 Intellis Software application version 1.3.80 did not clear the corruption as it was designed to, resulting in a system error. This system error is not a frequent event and the occurrence rate has been reported as lower than 1 in 10,000.

Immediate Action:
Please download the latest update to the A710 Intellis Software Application, version 1.3.130, to the CT900 Clinician Programmer following the enclosed instructions.

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

Mitigating steps prior to CP App 1.3.130 download:
This issue occurs and is recognized in the clinical setting where the patient is under the care of the healthcare professional. If you are presented with the VALIDATION ERROR (as shown) with Error Code (01 00 85) (04 02 01) (03 02 00) (08 08 00) (0A 02 00) **before** installing the latest A710 Intellis Software Application v1.3.130, please select the **"CONTINUE"** option. If "**EXIT WORKFLOW**" is selected, please reestablish communication and select "**CONTINUE**" when presented with the VALIDATION ERROR (figure 1).

Figure 1: Validation Error Prompt

After selecting the **"CONTINUE"** option, if this "**System Error**" (Figure 2) is displayed, please contact your Medtronic Representative for help in downloading the latest A710 Intellis Software Application v1.3.130. After downloading the newest Intellis Software Application v1.3.130, please reestablish communication and select "**CONTINUE**" to correct this issue.
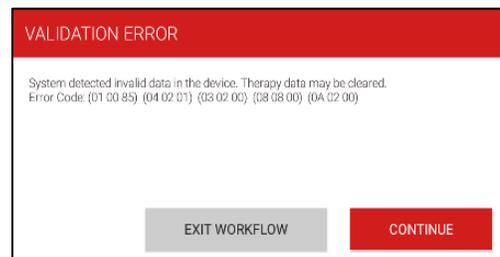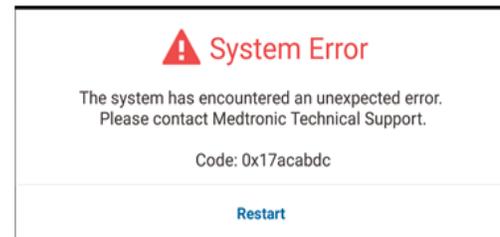

Figure 2: System Error Prompt

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 A710 Intellis Software Application version 1.3.130, please contact your Medtronic Representative.

Sincerely,

Appendix A: Software Installation Instructions

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UPDATING
CLINICIAN
PROGRAMMER
SOFTWARE

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, wait 5-10 minutes for Agent to automatically update to Hub in the background. (DO NOT USE THE GOOGLE PLAY STORE FOR UPDATING). If Hub is already installed proceed to step 3.

STEP 3: APPLICATION UPDATE PLANNING

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

B Only update therapy apps that you are educated on how to use.

C Determine which therapy apps need updating.

D 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

A While in **App Catalog**, click on **Update** (if an update is available) to update the apps you use.

B 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.

C To check for installation completion, go to Managed Apps in Hub.

D Once installation completes, confirm the correct software version in the Managed Apps or in the app's "About" section.

Medtronic
Further, Together

UPDATING COMMUNICATOR AND COMM MANAGER APP

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

STEPS FOR UPDATING THE COMMUNICATOR

A Remove tablet cover and any accessories preventing USB connection of the communicator cable.

B After updating **Comm Manager** in the **App Catalog,** open the **Communicator Updater** application.

C Power the communicator on and connect it to the tablet with the pairing cord.

D Select **Update (or Recover) Communicator**.
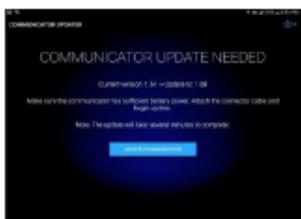
- ▣ While the communicator is updating, DO NOT DISCONNECT THE COMMUNICATOR.
- ▣ The update will take several minutes to complete. Please wait until the **Update Successful** screen appears.

E 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.

A Launch the therapy application and attempt to connect to an implantable device.

B 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 Technical Services.

SPECIALIZED IT SUPPORT

Medtronic Technical Services 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 TECHNICAL SERVICES :

- ▣ 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).
- ▣ Contact details: rs.tsneuro@medtronic.com or +31 (0)45 566 88 44 (option 2).

USER ID CARD

use the user ID card that came with the clinician programmer when calling Technical Services.

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.