Medtronic

Urgent Field Safety Notice

Update to address Numerical Format Issue in the CT900 Clinician Programmer via Model A810 SynchroMed™ II Software Application for Version 1.1.342
Software Update

July 2020

Medtronic Reference: FA920

Dear Health Care Professional,

Medtronic is voluntarily issuing an Urgent Field Safety Notice to request that you update Model A810 SynchroMed™ II Software Application (the application used to program your SynchroMed II pumps on the tablet), used with the CT900 Clinician Tablet Programmer, to a new version 1.1.342. For the languages identified below, the previous software application version (1.1.300) is missing a decimal separator (a comma) for parameter range guidance values displayed on some of the programming screens. The comma does display appropriately for values entered by the user and is also correct on all review screens and reports. Please install the A810 SynchroMed II Software application, version 1.1.342, per the enclosed instructions to resolve this issue (Appendix B).

There are no special patient monitoring or follow up recommendations. These parameter range values are only used as guidance for the user. When parameters are manually entered, the correct value with the comma as a decimal separator is displayed.

Since the introduction of A810 version 1.1.300 in July 2019, there have been three (3) complaints for this issue; each of these reported that, during a pump implant, the calibration constant displayed on the A810 application was tenfold higher than expected. For example, the calibration constant was displayed as 1140 instead of 114,0. With the assistance of Medtronic Technical Services, the error in the displayed value was identified and the pump was successfully implanted; there has been no patient impact and no harms as a result of this issue. The scenario in which the issue could result in harm entails the HCP interpreting the incorrectly displayed values to be correct values and making decisions based only on that interpretation, without considering the confirmation information displayed with the decimal separator on the "Finish" screen, including the new programmed values, the percent change, and any associated alerts.

Issue Description

The parameter range values that are missing the comma as a decimal separator can be found on the following screens on the CT900 Clinician Tablet Programmer (see Appendix B for example illustrations):

Parameters	Screen
Catheter Length Range values (Removed length and Implanted Length) for both pump segment and tip segment (if 2-piece catheter) when catheter is a known model	Catheter
Catheter volume range values for "other" (unknown model) catheter types	Catheter
Réservoir volume range value	Reservoir
24-Hour Dose range values (Both numeric and percentage change)	Infusion
Base Rate and Base Dose range values	Infusion
Step Rate and Step Dose range values (Flex Pattern only)	Infusion
Advanced prime bolus volume range value	Bolus
Single bolus dose range values	Bolus
MyPTM™ Dose range values	myPTM
Low Reservoir Alarm Volume range values	Alarm

In addition to these parameter range values; the calibration constant parameter is also missing the comma as a decimal separator.

![Medtronic](Medtronic logo)

Product Scope – Affected Languages

The following languages have been identified as being affected by this issue:

- Bulgarian
- Brazilian Portuguese
- Croatian
- Danish
- Dutch
- Finnish
- French

- German
- Greek
- Hungarian
- Italian
- Norwegian
- Portuguese
- Romanian

- Russian
- Serbian
- Slovak
- Slovenian
- Spanish
- Swedish
- Turkish

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.

Additional Information

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

We appreciate your assistance and regret any inconvenience this causes you. If you have questions or require assistance installing the A810 SynchroMed II Software Application version 1.1.342, your Medtronic Representative at <XXXX>.

Sincerely,

Local / BU Manager

Appendix A: Software Installation Instructions

Appendix B: Example Illustrations of the CT900 Clinician Tablet Programmer with a missing decimal separator (a comma)

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, please follow these instructions to update to Hub.
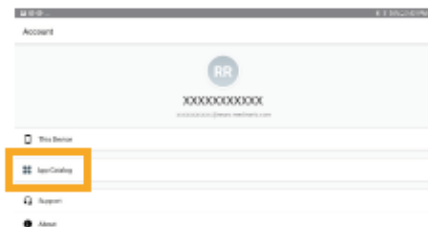
Agent → Hub

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.

- Only update therapy apps that you are educated on how to use.
- Determine which therapy apps need updating.
- 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.
5. 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.

Appendix B: Example Illustrations of the CT900 Clinician Tablet Programmer Screens with a Missing Decimal Separator (a comma)

Figure 1: Incorrect values displayed for the allowed range of the reservoir volume (200 – 400 ml): Data entered by HCP is correct (18.5 ml)
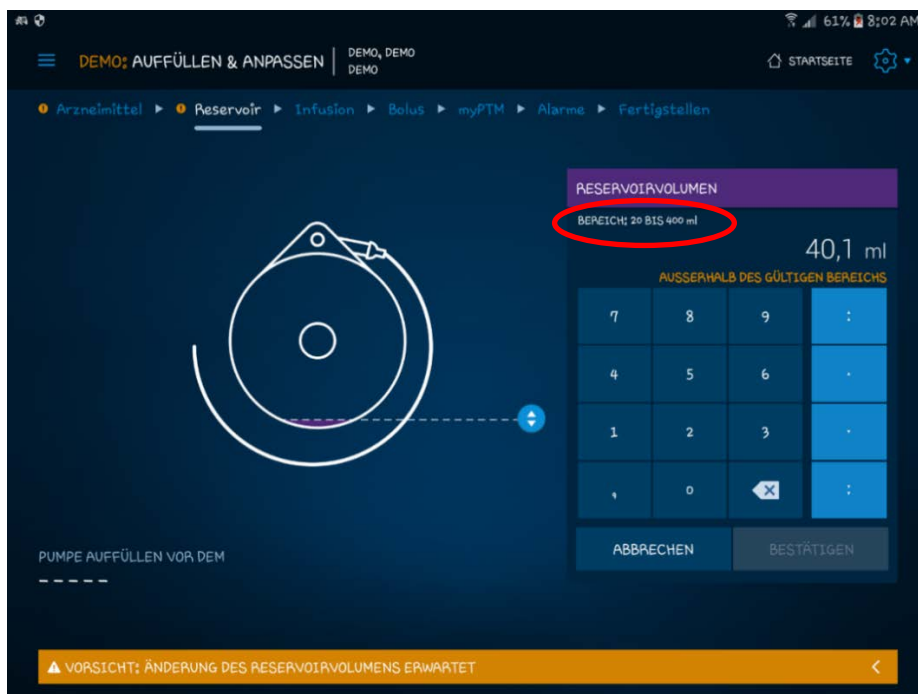

Figure 2: Value 40,1 cannot be entered even though the displayed range text indicates it can