Medtronic

Hitna sigurnosna obavijest

Intellis™ Pogreška sustava provjere valjanosti podataka
Model A710 ažuriranje softvera na verziju 1.3.130
Ažuriranje softvera

Prosinac 2020.

Medtronicova referencija: FA949

Poštovani,

Medtronic dobrovoljno izdaje Hitnu sigurnosnu obavijest kojom traži da **ažurirate model A710 Intellis™ softversku aplikaciju, koja se koristi s CT900 programatorom kliničkog tableta, na verziju 1.3.130**. Prethodna A710 Intellis softverska aplikacija, verzija 1.3.80, možda neće ispravno resetirati nevažeću memoriju što može rezultirati nemogućnošću ažuriranja postavki terapije, uzrokovati promjene na zaslonu programatora pacijenta, omogućiti pristup neodobrenim funkcijama programatora pacijenta i/ili gubitak terapije. **Molimo, instalirajte A710 Intellis softversku aplikaciju, verziju 1.3.130, prema priloženim uputama kako biste ublažili ovaj problem.**

Opis problema
Medtronic je primio četrnaest (14) izvješća između siječnja 2020. i 24. studenog 2020. gdje su se korisnici susreli s ovom pogreškom provjere valjanosti (Slika 1) nakon čega je slijedila pogreška sustava (Slika 2**Error! Reference source not found.**) na CT900 kliničkom programatoru A710 Intellis softverske aplikacije, verzije 1.3.80, koja ukazuje na to da ažuriranje programiranja stimulatora nije moglo biti završeno. Nakon istrage, utvrđeno je da je došlo do kvara unutar određenog mjesta memorije stimulatora i da A710 Intellis softverska aplikacija verzija 1.3.80 nije očistila kvar onako kako je dizajnirana, što je dovelo do pogreške sustava. Ova pogreška sustava ne događa se često, a prijavljena stopa pojave niža je od 1 na 10 000.
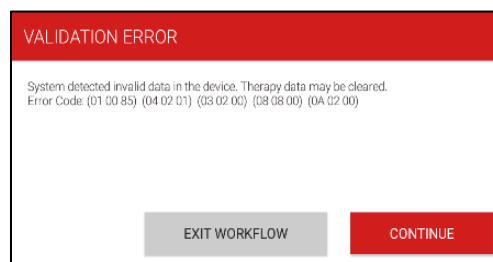
Postupak:
Molimo, preuzmite najnovije ažuriranje A710 Intellis softverske aplikacije, verziju 1.3.130, za CT900 klinički programator prema priloženim uputama.

Podijelite ovu obavijest, prema potrebi, s osobama u vašoj organizaciji kojima je potrebna ova informacija.
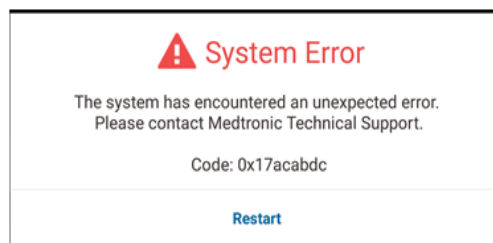
Koraci za ublažavanje prije preuzimanja CP App 1.3.130:
Ovaj se problem javlja i prepoznaje u kliničkom okruženju u kojem je pacijent pod nadzorom zdravstvenog radnika. Ako se pojavi VALIDATION ERROR (Pogreška provjere valjanosti) (kako je prikazano) sa šifrom pogreške (01 00 85) (04 02 01) (03 02 00) (08 08 00) (0A 02 00) **prije** instaliranja A710 Intellis softverske aplikacije v1.3.130, odaberite opciju „**CONTINUE**" (Nastavi). Ako je odabrano „**EXIT WORKFLOW**" (Izađi iz tijeka rada), ponovno uspostavite komunikaciju i odaberite „**CONTINUE**" (Nastavi) kada se pojavi VALIDATION ERROR (POGREŠKA PROVJERE VALJANOSTI) (Slika 1).

Slika 1: Poruka o pogrešci provjere valjanosti

Nakon odabira opcije „**CONTINUE**" (Nastavi), ako se prikaže „**System Error**" (Pogreška sustava) (Slika 2), obratite se svojem predstavniku tvrtke Medtronic za pomoć u preuzimanju najnovije A710 Intellis softverske aplikacije v1.3.130. Nakon preuzimanja najnovije Intellis softverske aplikacije v1.3.130, ponovno uspostavite komunikaciju i odaberite „**CONTINUE**" (Nastavi) kako biste ispravili ovaj problem.

Slika 2: Poruka o pogrešci sustava

Dodatne informacije

Hrvatska Agencija za lijekove i medicinske proizvode (HALMED) obaviještena je o ovoj radnji.

Cijenimo vašu pomoć i žao nam je zbog neugodnosti koje vam ovo može prouzročiti. Ako imate pitanja ili vam je potrebna dodatna pomoć pri instalaciji A710 Intellis softverske aplikacije verzije 1.3.130, obratite se svojem predstavniku tvrtke Medtronic Ivani Brkan na ivana.brkan@medtronic.com odnosno Medtronic Adriatic doo, Folnegovićeva 1c, 10000 Zagreb, Hrvatska.

S poštovanjem,

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Ivana Brkan

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Dodatak A: Upute za instalaciju softvera

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.

Agent   Hub
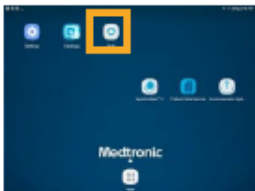
STEP 3: APPLICATION UPDATE PLANNING

A Click on **Hub** app. Then select **App Catalog** to view apps available for installation or update.
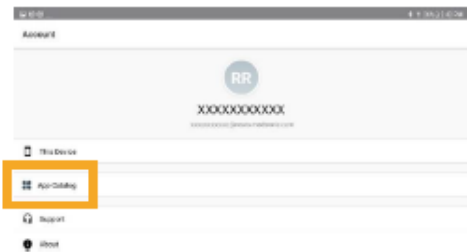
B Only update therapy apps that you are educated on how to use.

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.


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.**
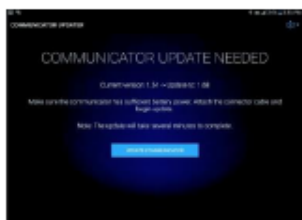
- While the communicator is updating, DO NOT DISCONNECT THE COMMUNICATOR.
- The update will take several minutes to complete. Please wait until the **Update Successful** screen appears.

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.

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