

Nujno varnostno obvestilo

Sistemska napaka pri preverjanju veljavnosti podatkov v programski opremi Intellis™ Posodobitev programske opreme modela A710 na različico 1.3.130 Posodobitev programske opreme

December 2020

Referenca družbe Medtronic: FA949

Spoštovani,

družba Medtronic prostovoljno izdaja nujno varnostno obvestilo, na podlagi katerega vas poziva, da **posodobite programsko opremo Intellis™ modela A710, ki se uporablja v tabličnem programatorju za zdravnika CT900, na različico 1.3.130**. V prejšnji različici 1.3.80 programske opreme Intellis A710 se neveljavni podatki v pomnilniku morda ne ponastavijo pravilno, kar lahko povzroči nezmožnost posodabljanja nastavitve terapije, spremeni prikaz na programatorju za bolnika, zagotovi dostop do neodobrenih funkcij v programatorju za bolnika in/ali povzroči izgubo terapije. **Skladno z zagotovljenimi navodili namestite programsko opremo Intellis A710 različice 1.3.130, da preprečite to težavo.**

Opis težave

Družba Medtronic je med januarjem 2020 in 24. novembrom 2020 prejela štirinajst (14) poročil, v katerih so uporabniki prijavili to napako preverjanja veljavnosti (Slika 1) v različici 1.3.80 programske opreme Intellis A710 programatorja za zdravnika CT900, ki ji je sledila sistemska napaka (Slika 2 **Error! Reference source not found.**), in navedli, da programske posodobitve stimulatorja ni bilo mogoče dokončati. Po preiskavi je bilo ugotovljeno, da je na določeni lokaciji pomnilnika stimulatorja prišlo do poškodbe podatkov in da programska oprema Intellis A710 različice 1.3.80 ni počistila poškodovanih podatkov, kot je bila zasnovana, zaradi česar je prišlo do sistemske napake. Ta sistemska napaka ni pogost dogodek, poročana stopnja pogostnosti pa je nižja od 1 na 10.000.

Takojšnji ukrep:

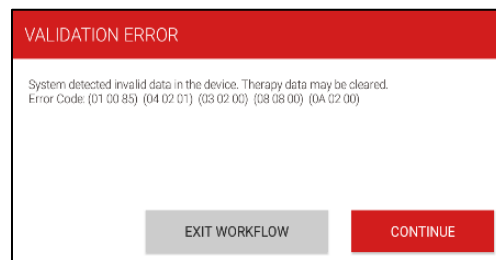
V programator za zdravnika CT900 skladno z zagotovljenimi navodili prenesite najnovjšo posodobitev programske opreme Intellis A710, različico 1.3.130.

To obvestilo delite z osebami v svoji ustanovi, za katere so te informacije ustrezne.

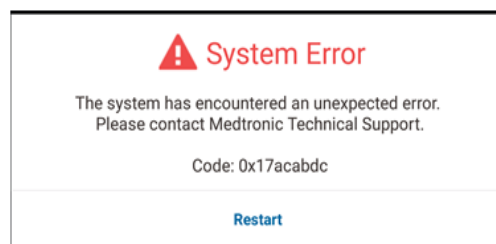
Koraki za ublažitev posledic težave pred prenosom različice 1.3.130 aplikacije programatorja za zdravnika:

Ta težava je prepoznana in se pojavi v kliničnem okolju, ko je bolnik v oskrbi zdravstvenega delavca. Če se napaka VALIDATION ERROR (Napaka preverjanja veljavnosti) (kot je prikazano) s kodo napake (01 00 85) (04 02 01) (03 02 00) (08 08 00) (0A 02 00) prikaže, **preden** namestite najnovjšo različico 1.3.130 programske opreme Intellis A710, izberite možnost **CONTINUE** (Nadaljuj). Če izberete **EXIT WORKFLOW** (Izhod iz poteka dela), znova vzpostavite komunikacijo in pri prikazu napake VALIDATION ERROR (Napaka preverjanja veljavnosti) (slika 1) izberite **CONTINUE** (Nadaljuj).

Ko izberete možnost **CONTINUE** (Nadaljuj) in se vam prikaže **System Error** (Sistemska napaka) (slika 2), se za pomoč pri prenosu najnovjše različice 1.3.130 programske opreme Intellis A710 obrnite na predstavnika družbe Medtronic. Ko prenesete najnovjšo različico 1.3.130 programske opreme Intellis, znova vzpostavite komunikacijo in izberite **CONTINUE** (Nadaljuj), da odpravite to težavo.



Slika 1: Poziv napake preverjanja veljavnosti



Slika 2: Poziv sistemske napake

Dodatne informacije

Pristojni organ v vaši državi (JAZMP) je o tem ukrepu obveščen.

Cenimo vašo pomoč in obžalujemo morebitne nevšečnosti, ki vam jih ta težava morda povzroča. Če imate vprašanja ali potrebujete pomoč pri nameščanju različice 1.3.130 programske opreme Intellis A710, se obrnite na predstavnika družbe Medtronic g. Martina Štefaniča na martin.stefanic@medtronic.com ali na Medtronic Adriatic d.o.o., Folnegovićeva 1c, 10000 Zagreb, Hrvaška.

Lep pozdrav,

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Dodatek A: Navodila za namestitev programske opreme

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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.

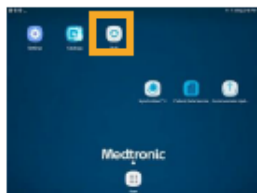
Close Apps: Close any open applications.

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

STEP 2: UPDATING AGENT TO HUB

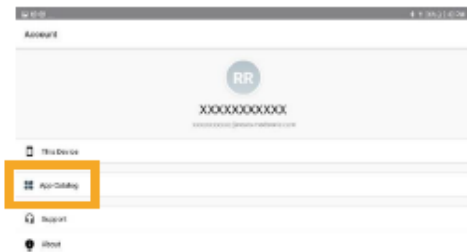
Medtronic applications can be updated using the Hub app, which replaced Agent. If you see the Agent app, wait 5-10 minutes for Agent to automatically update to Hub in the background. (DO NOT USE THE GOOGLE PLAY STORE FOR UPDATING). If Hub is already installed proceed to step 3.

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.

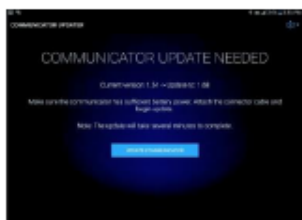


UPDATING COMMUNICATOR AND COMM MANAGER APP

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

- Remove tablet cover and any accessories preventing USB connection of the communicator cable.
- After updating **Comm Manager** in the **App Catalog**, open the **Communicator Updater** application.
- Power the communicator on and connect it to the tablet with the pairing cord.
- 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.

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