Medtronic (Schweiz) AG
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UPDATE TO URGENT FIELD SAFETY NOTICE

Percept™ PC Implantable Neurostimulator (INS) Model B35200 Unable to be Interrogated, INS Failure After Cardioversion and A610 Replacement workflow with DBS Pocket Adaptor affecting MRI eligibility display

Software Update

January 2025

EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Health Care Professional,

Our records indicate that you have a Medtronic Clinician Tablet(s) (Model CT900B, CT900C, CT900D, or CT900E) with Deep Brain Stimulation (DBS) Clinician Programmer Application (CPA) Model A610 installed.
Medtronic has begun distribution of a new tablet, model CT900F, and a software update for the DBS clinician programmer application A610 version 5.0 (and later). This CT900F tablet with application A610 version 5.0 is the solution to three previously identified Medical Device Corrections:

- Percept™ PC Model B35200 Implantable Neurostimulator (INS) Mitigations Reducing INS Failure After Cardioversion Procedure (Medtronic Reference FA1206) (see enclosed copy)
- Percept™ PC Implantable Neurostimulator (INS) Model B35200 Unable to be Interrogated (Medtronic Reference FA1231) (see enclosed copy)
- A610 Replacement workflow with DBS Pocket Adaptor affecting MRI eligibility display (Medtronic Reference FA1412) (see enclosed copy).

If you are supporting active DBS patients, please contact your local Medtronic sale representative for distribution of updated Clinician Tablet Model CT900F and updated CPA Model A610 version 5.0. In the meantime, you can continue to use your existing clinician tablet and software following the required actions provided in the enclosed notices.

Following review of this letter, sign and return the enclosed Acknowledgment Form via email to rs.dusregulatory@medtronic.com.

Medtronic has notified the Competent Authority of your country of this action.

We remain dedicated to ensuring the highest level of quality and will continue to monitor the performance of our products to ensure we meet your needs and those of your patients.

Sincerely,

Medtronic (Schweiz) AG

Enclosures:

- Copy of previous notification dated January 2022 titled Urgent Field Safety Notice: Percept™ PC Model B35200 Implantable Neurostimulator (INS) Mitigations Regarding INS Failure After Cardioversion Procedure (FA1206)
- Copy of previous notification dated March 2022 titled Urgent Field Safety Notice: Percept™ PC Implantable Neurostimulator (INS) Model B35200 Unable to be Interrogated (FA1231)
- Copy of previous notification dated May 2024 titled Urgent Field Safety Notice: A610 Replacement workflow with DBS Pocket Adaptor affecting MRI eligibility display (FA1412)
- Customer Acknowledgement Form

Medtronic

FA1206, FA1231, FA1412 January 2025 Customer Acknowledgement Form - Response is required

Medtronic Clinician Tablet(s) (Model CT900B, CT900C, CT900D, or CT900E) with Deep Brain Stimulation (DBS) Clinician Programmer Application (CPA) Model A610 installed.

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title:_____

Direct Phone #:_____

Email:_____

Account Name:_____

Account Number:_____

Account Address:_____

City: _____Zip Code:_____

Country:_____

I have read and understand the instructions provided and acknowledge receipt of the **notification** regarding the **Medtronic Clinician Tablet with DBS A610 installed** by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone who need to be aware of this notification.

_____ _____ _____

Name: (print) Signature: Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL THIS ACKNOWLEDGEMENT TO:

rs.dusregulatory@medtronic.com

Medtronic

URGENT FIELD SAFETY NOTICE

Percept™ PC Model B35200 Implantable Neurostimulator (INS)

Mitigations Regarding INS Failure After Cardioversion Procedure

January 2022

Medtronic Reference: FA1206 Phase II

Dear Healthcare Professional,

In October 2021, Medtronic issued a notification informing users that a cardioversion procedure may damage the electronics in the Medtronic Model B35200 Percept PC Implantable Neurostimulator (INS), making the INS unresponsive and non-functional, meaning that the INS cannot be turned back on. As a follow-up, this letter is intended to inform you of recommended mitigations to reduce the likelihood of cardioversion procedure-related damage to the Percept PC INS device.

From January 14, 2020 through November 24, 2021, Medtronic has received four complaints on this issue from patients implanted with Percept PC INS, all of which have resulted in or are planned for an explant procedure.

Medtronic is working on updating the Information for Prescribers (IFP) manual and applicable labeling to add warning language specific to a cardioversion procedure. Medtronic will communicate additional information when it becomes available.

Background on Recommended Mitigations:

To reduce the likelihood of damage to the Percept PC INS from a cardioversion procedure, Medtronic created a protocol, set forth in Attachments A and B, describing how to create a "Cardioversion Group" that is activated prior to the cardioversion procedure. This "Cardioversion Group" will produce very low (non-therapeutic) electrical current and will help protect the Percept PC INS during a cardioversion procedure. Medtronic has tested this protocol to ensure the INS functions as intended following a cardioversion procedure. However, there is still a remote possibility for energy from a cardioversion procedure to damage the implantable device, which may require INS replacement. Therefore, it is important to confirm the device is functional following the cardioversion procedure and restore the patient's therapy settings. If you would like more information about this protocol, contact your Medtronic Representative.

Medtronic

Additional Required Actions for Patients Requiring a Scheduled Cardioversion Procedure:

1. Develop a "Cardioversion Group" using the directions in **Attachment A** and ensure one of the following:
   - **If the patient or patient's caregiver is able to use the Patient Programmer (TH91D):** ensure they understand the steps to select the "Cardioversion Group" with their Patient Programmer immediately prior to their cardioversion procedure found in **Attachment B.**
   - **If the patient or patient's caregiver is unable to use the Patient Programmer:** Coordinate with local Medtronic DBS Representative for assistance.
2. Notify the patient's managing cardiologist to make sure they are aware that the patient has a Percept PC INS device implanted and the need to select the "Cardioversion Group" prior to the cardioversion procedure.
3. Following the cardioversion procedure, ensure the patient, patient's caregiver or the Medtronic DBS Representative return to the active therapy group and confirm Percept PC neurostimulation system function.
   - **If the patient or patient's caregiver is able to use the Patient Programmer (TH91D):** ensure they understand how to restore the active therapy group with their Patient Programmer. Refer to **Attachment B.**
   - **If the patient or patient's caregiver is unable to use the Patient Programmer:** Coordinate with local Medtronic DBS Representative for assistance.
4. As the managing DBS physician, you may elect to schedule a follow-up appointment with the patient for further observation or to confirm, restore, or possibly reconfigure their therapy as necessary following the cardioversion procedure.
5. Contact your Medtronic DBS Representative to make them aware of the date, time, and cardiologist performing the cardioversion procedure, so they can be available, or ON-CALL, if any questions should arise.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Enclosures: Attachment A – Creating Cardioversion Group
Attachment B – How to Enable the Cardioversion Group with the Patient Programmer

Attachment A – Creating Cardioversion Group

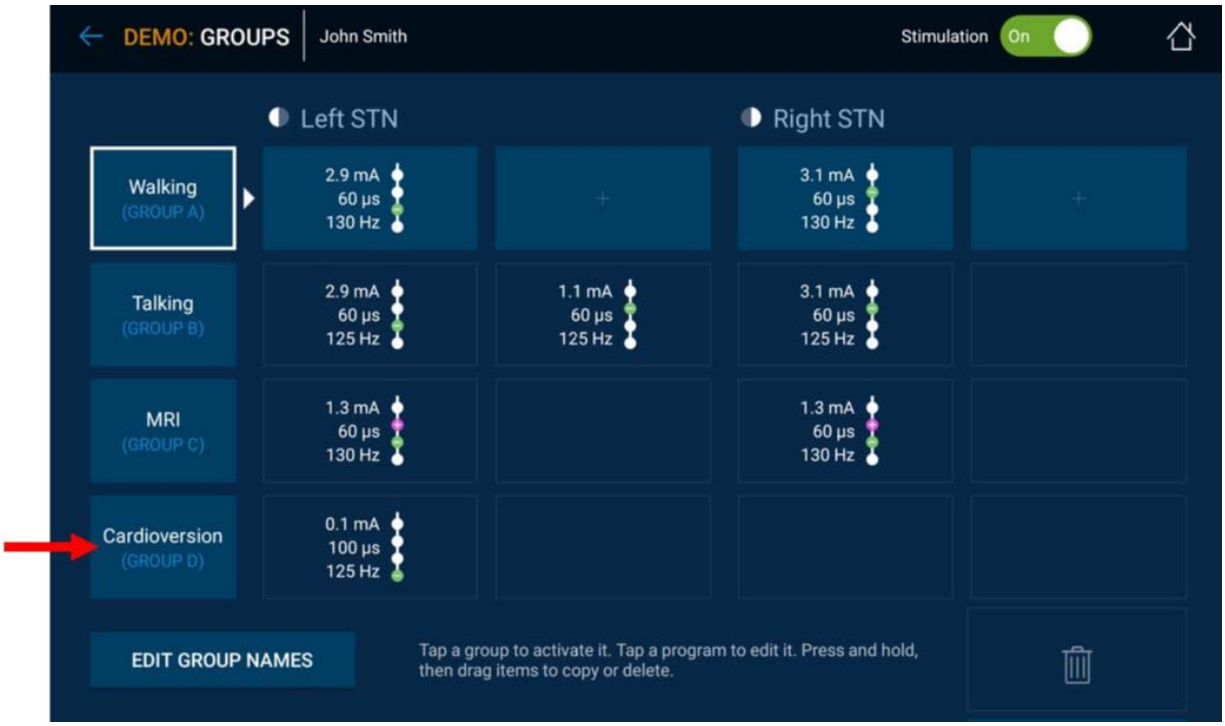
1. Connect the clinician programmer to the Percept PC neurostimulator:
    a. Turn on the clinician tablet containing the Model A610 DBS Clinician Programmer application and enter the passcode.
    b. Turn on the Model 8880T2 communicator. If necessary, use the communicator USB cable to connect the tablet with the communicator.
    c. Hold the communicator over the patient's Percept PC neurostimulator and select CONNECT.
2. Measure Impedance & Identify **Bipolar** Electrode pair:
    a. On the **Home** screen, select the IMPEDANCE tab. Select OK.
    b. On the lower left corner of the screen, select MEASURE ELECTRODE IMPEDANCE. Select START.
    c. From the Summary screen, determine a pair of electrode levels for the new group/program by choosing a pair that has green (OK range) bipolar impedances. If a segmented level is chosen for bipolar, all segments must have green impedances between the two electrode levels.
        i. **Note: If there are no OK bipolar impedances, identify a single monopolar electrode with OK impedance (ring or segment). If monopolar stimulation is used, artifact may be present on the ECG recording.**
        ii. **Note**: **Only one hemisphere needs to be programmed for this protocol, even if the patient has a lead in both hemispheres.**
    d. Navigate to the **Home** screen by selecting CLOSE in the bottom right corner.
3. Create the "Cardioversion Group":
    a. From the Home screen, select the STIMULATION tab. Select OK.
        i. **Note**: Observe and record which group is currently active; this will be used later to restore stimulation after the "Cardioversion Group" is created
    b. If there are less than 4 groups currently configured, select a new group, and select "+" to create a new program within the group.
        i. **Note**: If there are 4 groups configured, one group will need to be temporarily deleted. Press and hold the group that will be deleted, then drag the group to the trash icon. Select the new group to activate and select "+" to create a new program within the group.
        ii. **Note**: It is recommended that the deleted group is <u>not</u> the same as the active group recorded in Step 3.a.i.
    c. Select the chosen electrode levels from Step 2.c to create a negative (-) and positive (+) (bipolar configuration) and select UPDATE.
        i. **Note:** If monopolar, as determined in Step 2.c.i, create a single negative (-) (monopolar configuration) and select UPDATE.
    d. Increase stimulation to a delivered amplitude of 0.1 mA. Modify the pulse width to 100 µs and the rate to 125 Hz.
    e. Select the **back arrow** in the top left corner to return to the Stimulation Overview page.

f. In the bottom left corner, select EDIT GROUP NAMES. Name the new group to "Cardioversion" to allow for ease of group identification and activation. Select CLOSE.

g. Re-enable the previously active group to return therapy as noted in 3.a.i.

   i. **Note:** The "Cardioversion Group" does not need to be active until the cardioversion procedure

Figure 1: Example of "Cardioversion Group" Created But Not Active



h. End Clinician Programmer session by selecting the **back arrow** in the top left corner to return to the **Home** screen. Select the End Session icon in the top right corner and select END SESSION on the pop-up to confirm.

4. **If there are more than one Percept PC neurostimulators implanted, repeat steps 1-3 on the remaining implanted Percept PC neurostimulators.**
5. For patients who have access to their Patient Programmer and Communicator ensure that the "Cardioversion Group" is available on the Patient Programmer handset (for each implanted neurostimulator).
6. For patients who have access to their Patient Programmer and Communicator, remind them to bring their fully charged Patient Programmer and Communicator to the cardioversion procedure.

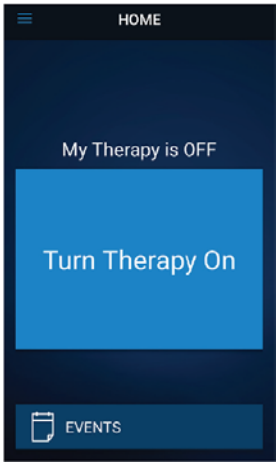
Attachment B – How to Enable the Cardioversion Group with the Patient Programmer

1. Turn on Patient Handset and Patient Communicator
    a. Prior to any patient anesthesia, turn on the handset and unlock the screen.
    b. Press the communicator power button (Location 3 in Figure below) and ensure a solid green light is visible (Location 1 in Figure below).

2. Connect to Neurostimulator
    a. If the app is not open on the handset, tap the DBS Therapy Application OPEN button or the My DBS Therapy app icon.

    b. Ensure the communicator is within 1 meter of the neurostimulator and handset. Tap the CONNECT button on the handset.

3. Switch to the "Cardioversion Group."
    a. Ensure therapy is ON. If therapy is OFF, turn therapy on by selecting Turn Therapy On, on the Home screen.



b. Tap the THERAPY button on the HOME screen.

c. Tap the GROUP Button.
   i. **Note**: Depending on the settings, the Therapy screen may not look exactly like the Figure below.

d. Observe and record which Group is currently active. The active group is outlined with a white box. This will be used later when restoring active stimulation following the cardioversion procedure.
   i. **Note**: Depending on the settings, the Group Select screen may not look exactly like the Figure below. In the example below, this would be the top-right tile titled "B".

e. Tap the group that contains the cardioversion settings. In the example below, this would be the bottom-right tile titled "CARDIOVERSION".
   i. **Note**: Upon activation, symptoms may return.

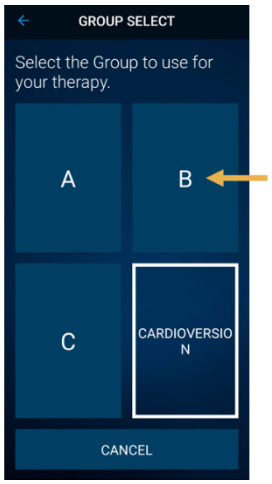
f. If there are more than one Percept PC neurostimulators implanted, repeat steps 1-3 on the remaining implanted Percept PC neurostimulators.
g. Patient has selected "Cardioversion Group" and is now ready for the cardioversion procedure.

4. Patient Receives Cardioversion [to be performed by the cardiology Healthcare Provider]
   a. Position the pads or paddles as far away from the neurostimulator as possible.
   b. Try to position the pads or paddles perpendicular to the implanted neurostimulator system.
   c. Use the lowest clinically appropriate energy output (joules [watt seconds]).
   d. Complete all necessary cardioversions, **waiting at least 60 seconds** between cardioversion attempts (as clinically appropriate) to allow the neurostimulator to recover.
5. Restore Stimulation to the Previously Active Group
   a. Open the My DBS Therapy app on the handset and turn on the patient communicator.
   b. If necessary, press CONNECT on the handset to connect to the communicator and INS.
   c. From the Home page, tap the THERAPY button on the HOME screen.

   d. Tap the GROUP Button.

   e. Tap the previously active group as noted in Step 3d to restore therapy.

i. **Note**: Depending on the settings, the Group Select screen may not look exactly like the Figure below.



ii. **Note**: If the Group cannot be changed to the previously active group, contact the managing DBS physician or the Medtronic DBS Representative.

f. Confirm the stimulation is ON with the correct therapy group active.

g. If there are more than one Percept PC neurostimulators implanted, repeat Step 5 on the remaining Percept PC devices.

Following the cardioversion procedure, ensure the patient, patient's caregiver, or Medtronic DBS Representative is able to restore DBS therapy. If therapy cannot be restored or if you have questions throughout this procedure, please contact your Medtronic Representative or patient's managing DBS physician.

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Urgent Field Safety Notice

Percept™ PC Implantable Neurostimulator (INS) Model B35200 Unable to be Interrogated

Notification

March 2022

Medtronic Reference: FA1231

Dear Healthcare Professional,

The purpose of this letter is to inform you that in rare instances (0.044%) the Percept™ PC Implantable Neurostimulator (INS) Model B35200 cannot communicate with the clinician programmer and/or the patient programmer system (HH90 Handset and TM91 Communicator). In these instances, the INS will continue to provide therapy to the patient within programmed parameters. While the occurrence is rare, Medtronic is raising awareness to inform and serve our customers.

Issue Description:

This occurrence may present in the following way:

- If the clinician programmer is not able to communicate with the INS, the clinician programmer will display “Searching for Device”.
- If the patient programmer system was set up, it will continue to communicate with the INS and allows therapy adjustments and group changes to be made within the clinician set limits; however, the patient programmer system will not be able to turn therapy off.
    - If the patient has previously been given the ability to turn their device off without requiring close communication, their ability to do so will be maintained.
    - If the patient has a bipolar group set up previously, they will maintain the ability to put the device into MRI mode.
- If there is no communication with the INS during the implant procedure, troubleshooting may delay the surgical procedure, and may require a replacement INS. There have been no reports of this occurring during implant.
- If there is no communication with the INS post procedure, it might not be possible to adjust therapy and may cause the patient to experience inadequate therapy (i.e., return of underlying disease symptoms). If communication cannot be restored to the INS (refer to recommended mitigation below), an unanticipated surgical intervention may be needed to explant and replace the INS.

Since the launch of Percept PC in January 2020 through the end of February 2022, Medtronic has received six (6) confirmed reports of this issue. Five (5) of these reports occurred within the United States of America and one (1) event occurred in Switzerland. Two (2) devices were explanted as a result of not being able to connect with the INS. Medtronic can perform an INS diagnostic and communication reset should this issue occur and is investigating changes to prevent the occurrence.

Recommended Mitigation:

If the INS cannot communicate with the clinician programmer and/or patient programmer system, contact your Medtronic Representative. If needed, Medtronic will schedule an in-field service appointment with the managing DBS physician and the patient to diagnose and reset the INS. This diagnostic and communication reset is possible only if the patient's programmer system is set up and working. If the communicator is not working, lost, or never provided to the patient, the INS cannot be reset and would need to be explanted.

Required Actions:

- At the patient's initial programming session, ensure the patient programmer system is set up to communicate with the patient's INS.
- If a patient's INS cannot communicate with the clinician programmer and/or patient programmer system, and it is not possible to make therapy adjustments or turn stimulation off, contact your Medtronic Representative.

Additional Information:

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

We regret any difficulties this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,

Medtronic (Schweiz) AG

Medtronic (Schweiz) AG
Weltpoststrasse 5
3015 Bern
www.medtronic.com

Urgent Field Safety Notice

A610 Replacement workflow with DBS Pocket Adaptor affecting MRI eligibility display

Customer Notification

May 2024

Medtronic Reference: FA1412
EU Manufacturer Single Registration Number (SRN): US-MF-0000019977

Dear Health Care Professional,
The purpose of this letter is to inform you of an issue related to the Magnetic Resonance Imaging (MRI) Eligibility status displayed in certain versions of the Deep Brain Stimulation (DBS) Clinician Programmer (Model A610) and DBS Patient Programmer (Model A620) applications. Patients implanted with a pocket adaptor (Model 64001 and/or 64002) are limited to “HEAD ONLY” MRI eligibility. With this issue, the clinician and patient programmers may incorrectly display MRI eligibility as “FULL BODY” scan eligible, as shown in Figure 1.

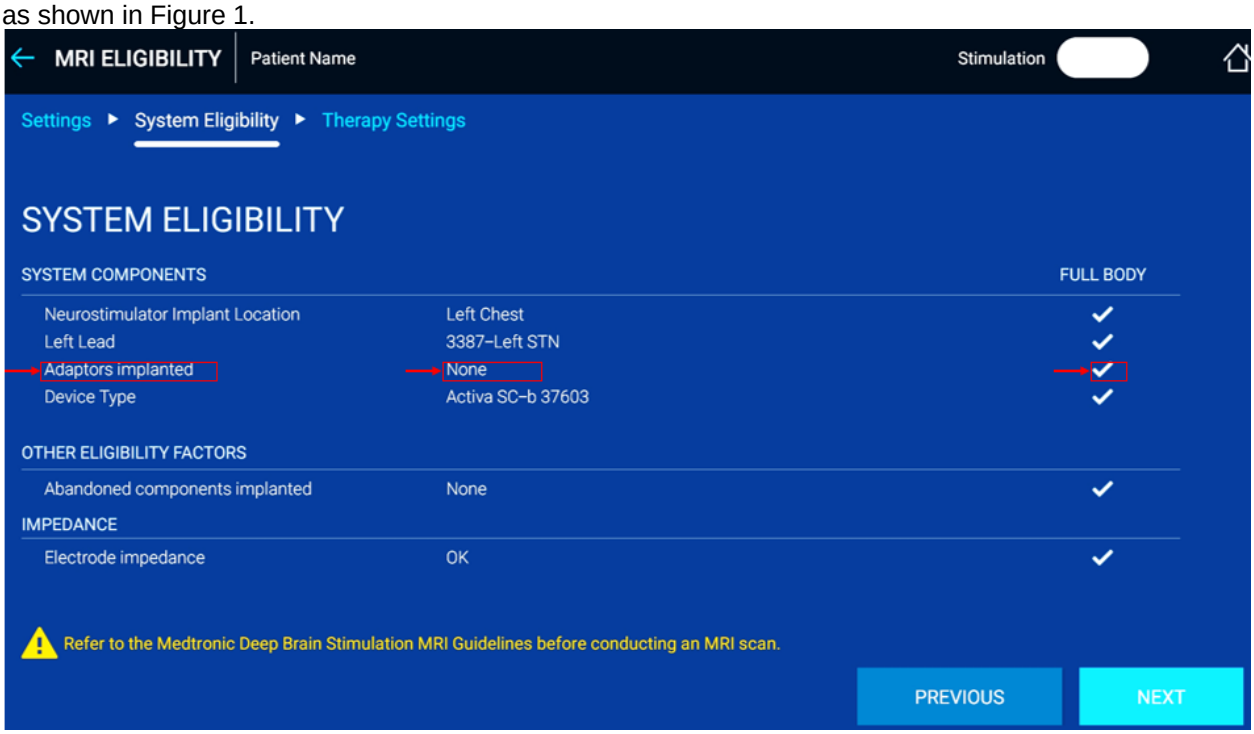

Figure 1: A610 Clinician Programmer MRI ELIGIBILTY workflow with red annotations added.

This issue only occurs when using the A610 “REPLACEMENT” workflow during an Implantable Neurological Stimulator (INS) replacement from Activa™ SC (Model 37602) to Activa™ SC (Model 37603), Percept™ PC (Model B35200), or Percept™ RC (Model B35300) and a pocket adaptor.

Issue Description:
Since January 2020 with the initial launch of A610 version 2.0 and higher, there has been one (1) reported event of this issue, which was identified during initial programming. As of April 2024, there have been no reported patient harms for this issue.

This issue impacts patients who have a pocket adaptor with INS Models Activa™ SC 37603, Percept™ PC B35200, or Percept™ RC B35300 that previously used the A610 ”REPLACEMENT” workflow to transfer settings from Model 37602. This issue may also impact patients who currently have an Activa SC™ Model 37602 implanted and are implanted with a pocket adaptor in the future during an INS replacement, with settings transferred using the A610 “REPLACEMENT” workflow.

This issue has the potential to result in exposure of the patient to an incorrect MRI (e.g., “Full Body” instead of “Head Only” scan eligibility), which could result in heating at the lead electrode(s) and potential tissue damage. Excessive heating can result in serious or permanent injury including coma, paralysis, and death.

This issue occurs only for those patients with a pocket adaptor and, for reasons related to the A610 “REPLACEMENT” workflow, the programmer does not display a pocket adaptor in the MRI ELIGIBILITY workflow. For patients where the programmer incorrectly displays no pocket adaptor, a pocket adaptor component can be added on the physician programmer SETUP workflow. This will set the “Adaptor implanted” status to “Yes” and lead to automatic correction of the MRI eligibility display. Detailed instructions are provided below. If the programmer does display a pocket adaptor, no further action is needed.

Recommended Actions to confirm or revise the MRI eligibility display on the programmer:

1. To check if a patient has an implanted pocket adaptor, review your patient’s medical records and determine if they have an implanted pocket adaptor with INS Models Activa™ SC 37603, Percept™ PC B35200, or Percept™ RC B35300.
2. For every patient identified, use the A610 CP application MRI ELIGIBILITY workflow to determine the status of the ‘Adaptors Implanted’. Note that the patient will need to be in the clinic for this step.

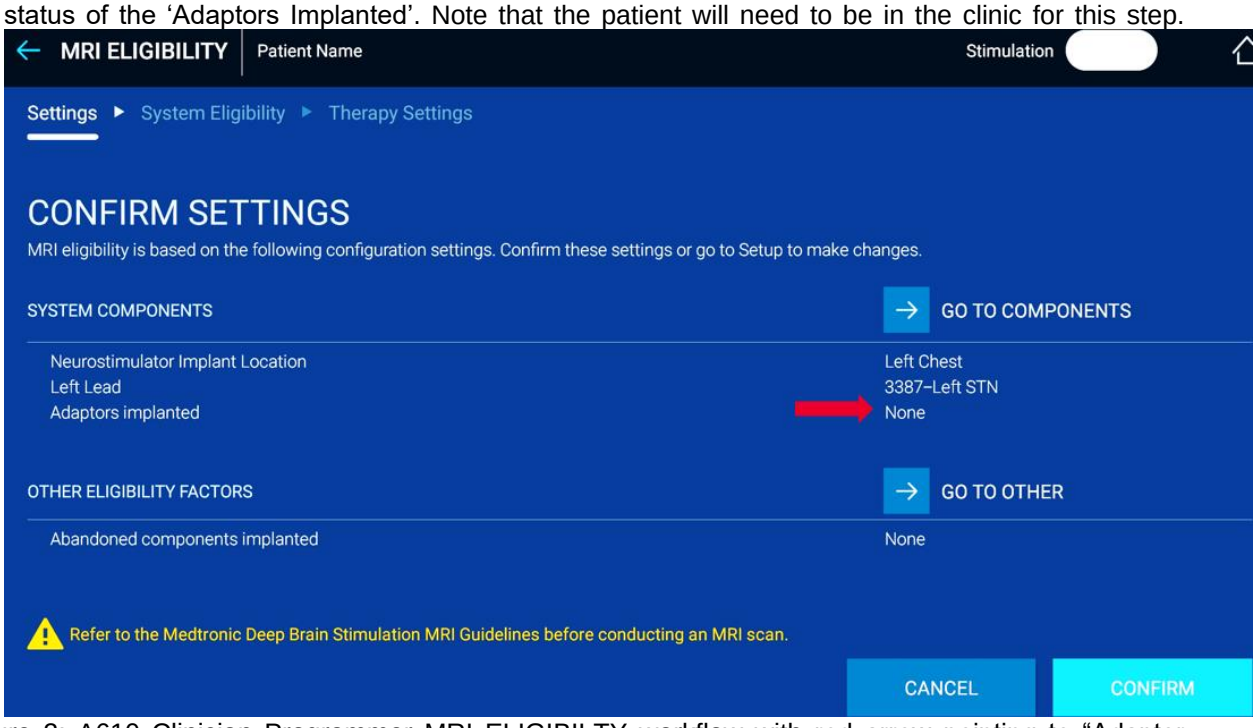

Figure 2: A610 Clinician Programmer MRI ELIGIBILTY workflow with red arrow pointing to “Adaptor implanted” status.

   2.1. If the status is ‘Yes,’ no further action is needed. This confirms the clinician programmer and patient programmer applications will display the correct MRI eligibility for that patient.
   2.2. If the status is “None” or “?” (Figure 2), follow steps 3 to 5 to revise the status of MRI eligibility on the programmer. Once these steps are completed, both the clinician programmer and patient programmer applications will display the correct MRI eligibility for that patient.

3. Obtain the current stimulation settings (i.e., via a session report) as you may be required to re-enter them.
4. Go to the SETUP workflow on the Clinician Programmer to determine if the pocket adaptor is shown in the Components screen.

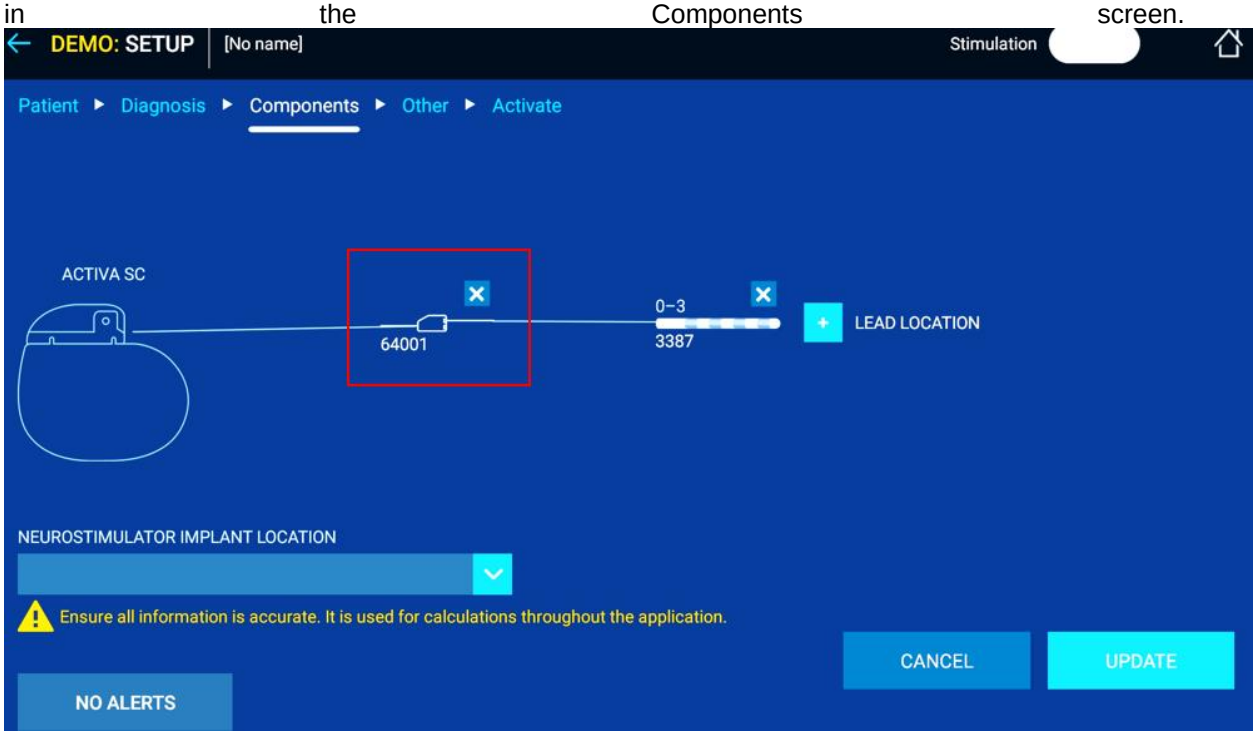

Figure 3: Example of A610 Clinician Programmer SETUP workflow for Activa SC with a pocket adaptor with red annotation added.

4.1. If the pocket adaptor is NOT shown in the Components screen, add a pocket adaptor into the connected components of the system; OR

4.2 If the pocket adaptor is shown in the Components screen e.g., as the example in Figure 3, remove the pocket adaptor and then add the pocket adaptor back into the connected components.

5. Confirm that the 'Adaptors implanted' status within the MRI ELIGIBILITY workflow indicates 'Yes.'

For patients that have an Activa SC Model 37602 and who may undergo an INS replacement in the future, if a pocket adaptor is used during that replacement, perform these recommended actions during initial setup and programming of the INS.

Required Actions:

- Complete and return the Customer Acknowledgement Form enclosed with this letter acknowledging receipt of this information.
- Pass on this notice to all those who need to be aware within your organization and to other organizations on which this action has an impact.
- Please keep a copy of this letter in your file.

Additional Information:

Medtronic is working on a Clinician Programmer software update to address this issue and will notify you once it is available. Medtronic has notified the Competent authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative

Sincerely,
Medtronic (Schweiz) AG

Enclosures:

- Customer Acknowledgement Form