

Medtronic Ireland Limited

T Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47
Ireland
Tel: 01 511 1400
Fax: 01 807 7220
www.medtronic.ie

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.

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 directly or via Tel No: 01 511 1400

Sincerely,



Keith Taverner: Regulatory Affairs Manager UK & Ireland

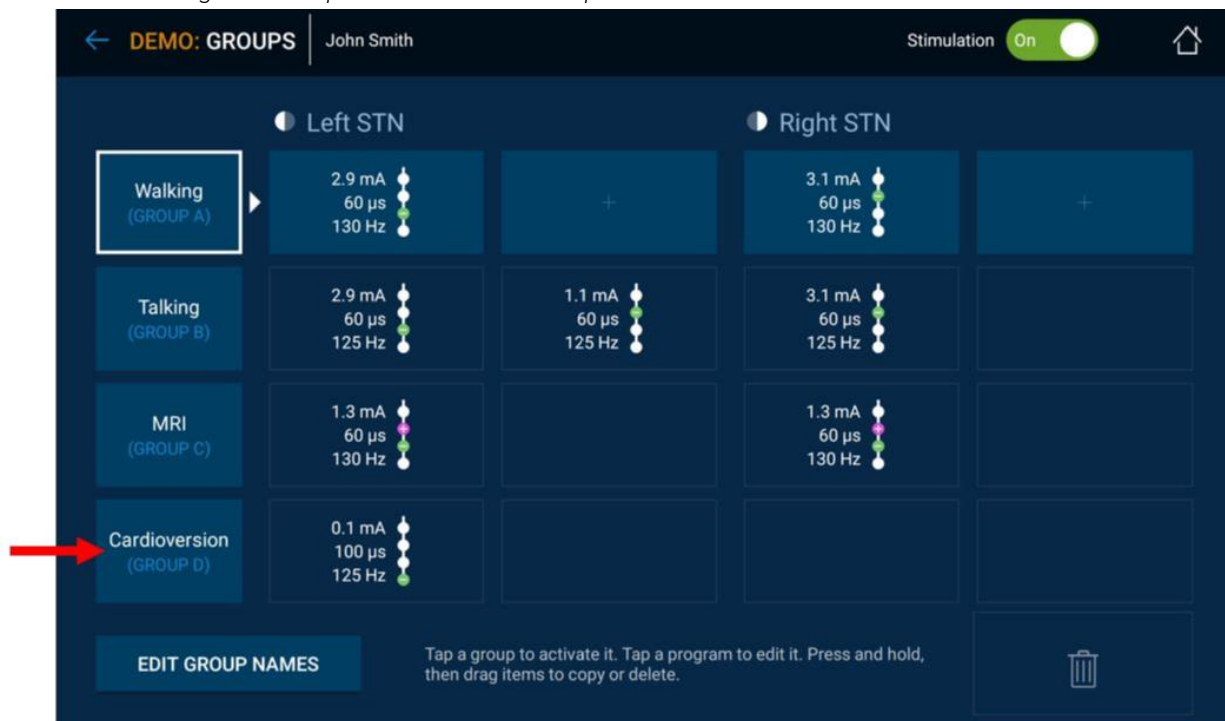
Enclosures: Attachment A - Creating Cardioversion Group
Attachment B - How to Enable the Cardioversion Group with the Patient Programmer

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 not 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 μ s 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).



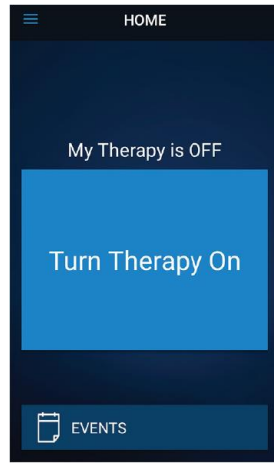
2. Connect to Neurostimulator
 - a. If the app is not open on the handset, tap the DBS Therapy Application OPEN button or the My DBS Therapy app icon.



- 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.

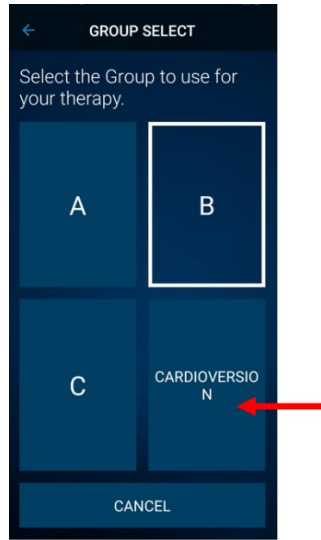


d. Observe and record which Group is currently active. The active group is outlined with a white box. This will be used later when restoring active stimulation following the cardioversion procedure.

- 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.

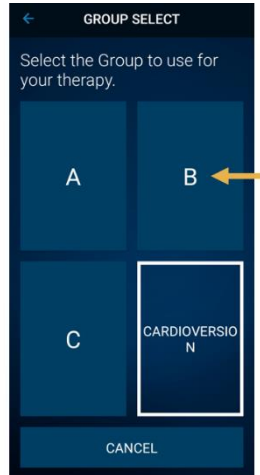


- d. Tap the GROUP Button.



- 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.