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Urgent Field Safety Notice

SmartSync Software Update Available to Align Abort Button Behavior Across Programmer Platforms

Software Update Available: CareLink SmartSync™ Device Manager

June 2025

Medtronic Reference: FA1475

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

Dear Risk Manager or Health Care Professional,

A software update for Medtronic CareLink™ SmartSync™ Device Manager (SmartSync) is now available. The SmartSync update aligns the Abort button behavior within the EP Study screen with legacy Medtronic programmers. Once the update is applied, the Abort button cancels any therapy in progress initiated via the EP Study screen. In prior SmartSync application versions, the Abort button stopped the test that was selected. During an induction test, there was a limited window of time for the user to abort a therapy, thereby limiting the user's ability to cancel a high voltage therapy delivery. Through 30 April 2025, Medtronic has received four reports of unanticipated Abort button behavior with no serious adverse events or permanent harms reported. Medtronic has updated the SmartSync Abort button behavior for ease-of-use and consistency with the Medtronic 2090/Encore programmers. See Appendix for the list of device applications in scope of the update.

Customer Actions:

- Update SmartSync (to version 4.2.3 or higher). Refer to release notes provided by your local Medtronic representative for update instructions. If needed, Medtronic representatives are available to work with you to install or update the SmartSync application(s) on your tablet. See Appendix for instructions on how to verify the software update is complete.
- Share this notice with those who need to be aware within your organization or with any organization where SmartSync may be in use. Questions regarding this information should be directed to your local Medtronic Representative.

Additional Information:

The Competent Authority of your country has been notified 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 questions regarding this communication, please contact your local Medtronic Representative.

Sincerely,

Local / OU Manager

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Appendix – Applicable Applications

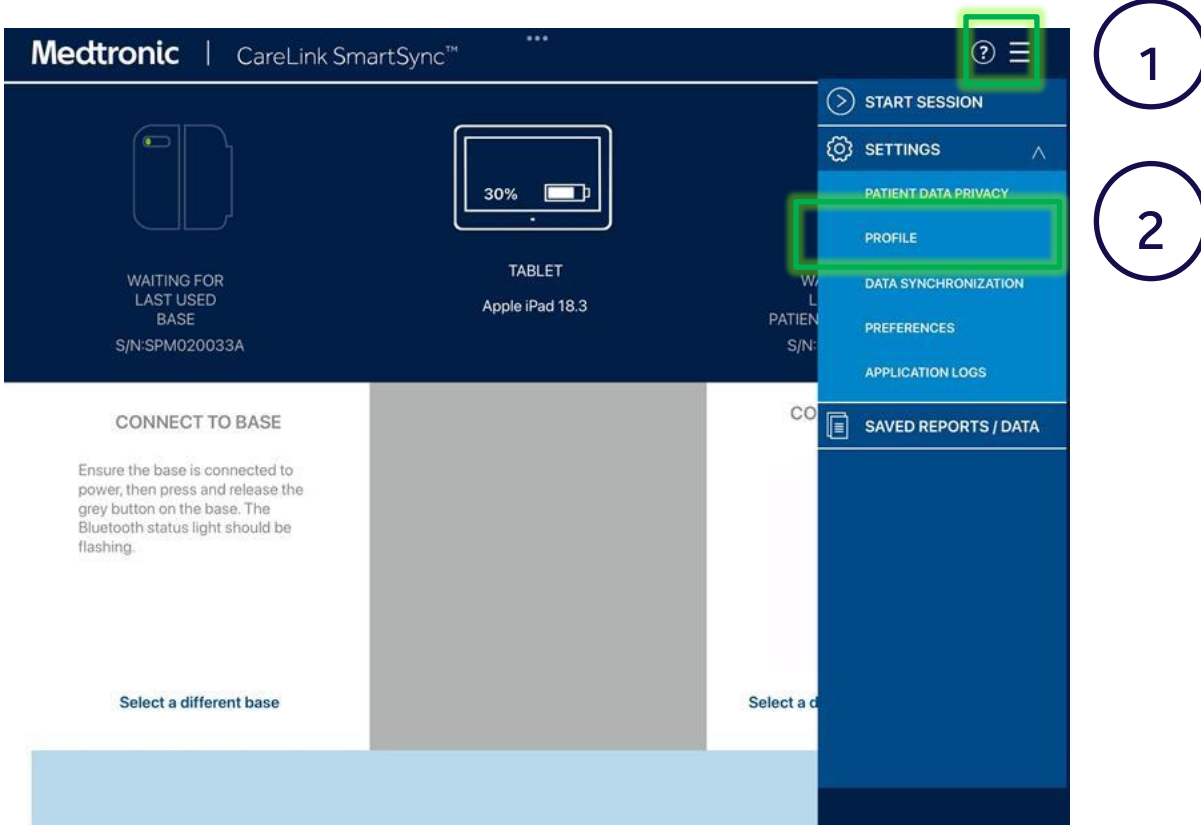| Software Component	Updated Software Version	Software Model	GTINS
Cobalt Crome application	9.5.2	D00U005	00763000002053
Claria Amplia Compia application	3.4.2	D00U009	00763000397883
Evera MRI application	3.4.2	D00U010	00763000397890
Visia AF application	3.4.2	D00U011	00763000397906
Viva Brava Evera application	3.4.2	D00U012	00763000397913

Appendix – Verify Software Update is Complete

For update instructions, please refer to the software release notes.

Confirm the updated application software version by:

      1) Selecting the MENU in the upper right corner of the SmartSync App [1]

      2) Selecting PROFILE [2]

      3) Selecting the SOFTWARE tab and scrolling through the SOFTWARE INFO list [3]

If the software update for this issue has already been installed, you will see the following versions listed:

The Common/Platform application version is 4.2.3 (or higher) and the software version for each application listed in the Applicable Applications Appendix is at the updated version (or higher).

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SOFTWARE COMPONENT	VERSION	SOFTWARE MODEL	UDI
Micra AV Application	3.4.5	D00U007	(01)00763000007355(10)050408
Micra VR2 AV2 Application	2.7.5	D00U022	(01)00763000544300(10)020705
Micra VR Application	3.4.6	D00U006	(01)00763000397852(10)030406
Azure Astra Application	5.5.7	D00U003	(01)00763000002039(10)050507
Cobalt Crome Application	7.5.2	D00U005	(01)00763000002053(10)070502
Common Application	4.4.1	M01A02	(01)00643169833739(10)040401
Platform	4.4.1	M01A01	(01)00643169833722(10)040401

CHECK FOR UPDATES

③ Updated Versions