Medtronic
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URGENT MEDICAL DEVICE CORRECTION NOTIFICATION

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

Software Update Available: CareLink SmartSync™ Device Manager

19 June 2025 | 15:38 SGT

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

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.
- Sign and return the enclosed confirmation form to your local Medtronic representative and 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:

Medtronic is communicating this information to the appropriate regulatory agency in your country.

Per your facility's standard medical device complaint procedures, report to Medtronic any adverse reactions or quality problems if the issue described above has been observed.

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,

Signed by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 19 June 2025 | 15:17 SGT

90D0724C9B1C402A99B286449A1644B8

Quality and Regulatory Affairs Director

Southeast Asia

Enclosure:

Customer Confirmation Form

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

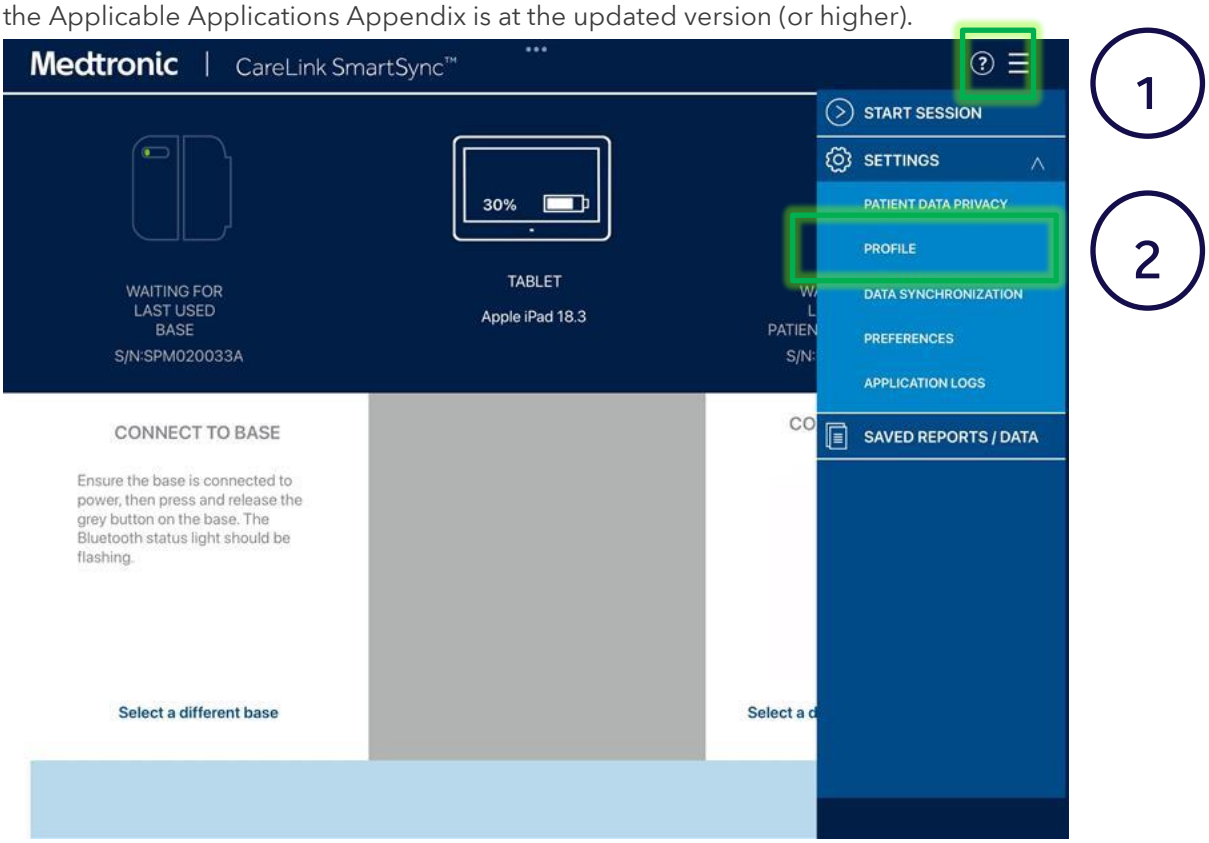
For update instructions, please refer to the software release notes provided by your local Medtronic representative.

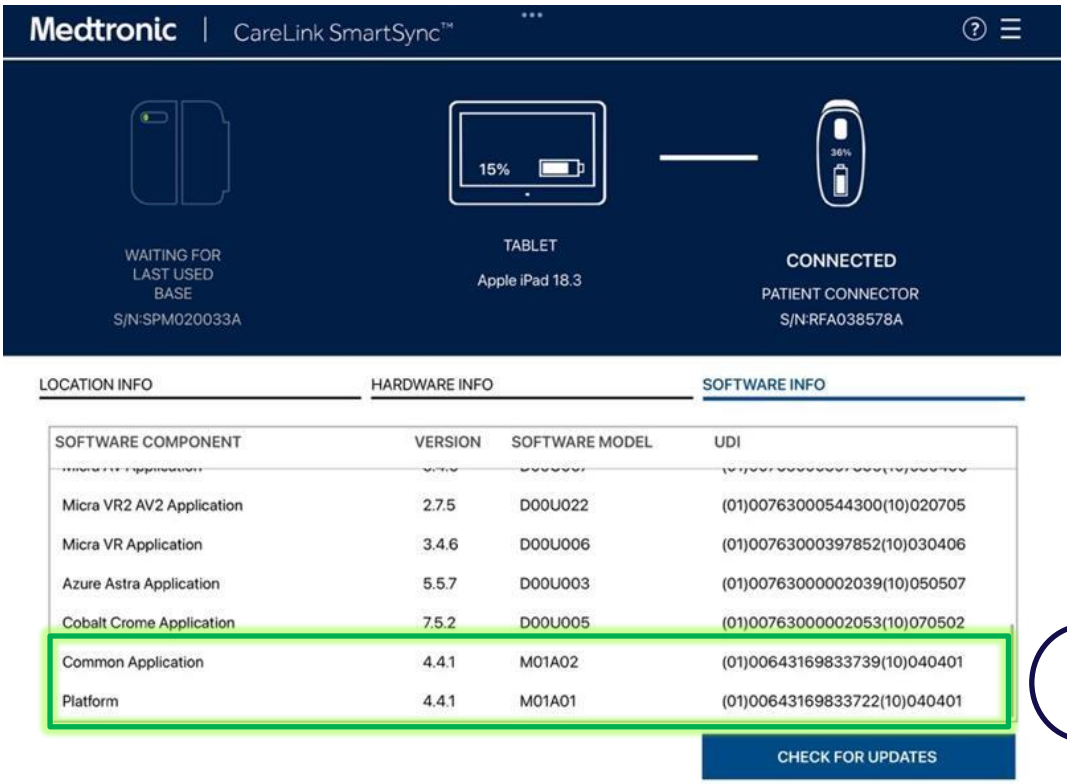
Confirm the updated application software version by:

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).





3 Updated Versions

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Customer Confirmation Form

URGENT MEDICAL DEVICE CORRECTION NOTIFICATION

SmartSync Software Update Available to
Eliminate Potential Erroneous Electrical Reset Message and
Align Abort Button Behavior Across Programmer Platforms

For completion by Medtronic Customers Only – Please complete all fields below and return immediately

Customer Contact Details		Medtronic Contact Details
Distributor/Hospital/Clinic/Patient name:		**Name:**
		Contact:
Address:		**Email:**
Phone no:	**Email:**	

Programmer Model	Serial Number	Remarks

*If this table is not enough, please use the additional page provided. Additional pages and/or attachments must be signed and dated.

By signing this form, I confirm that I have read the Urgent Medical Device Correction Notification Letter, dated 19 June 2025 | 15:38 SGT **from Medtronic regarding the SmartSync Software Update Available to Eliminate Potential Erroneous Electrical Reset Message and Align Abort Button Behavior Across Programmer Platforms and taken appropriate action.**

Please complete all fields and sign the form as indicated below and return the completed form to your local Medtronic field representative.

Name (print): _____ Signature: _____ Stamp: _____ Date: dd Mmm yyyy

For questions, contact your local Medtronic Representative.

Note: The addressee may continue to receive reminders of this notice until a response is received.

****Please fill out the previous table first** and list the remaining on this page.
This page must also be signed and dated.**

Programmer Model	Serial Number	Remarks

Name (print): _____ Signature: _____ Stamp: _____ Date: dd Mmm yyyy