Medtronic

URGENT FIELD SAFETY NOTICE

Nitron CryoConsole™ Software Anomaly – Balloon Catheter Invalid after 31 December 2025

Notification

Model	GTIN, UDI	Serial Number
NITRON	00763000593902, 00763000593919.	N2408A0063, N2414A0125, N2424A0234, N2443A0484

May 2026

Medtronic Reference: FA1563

<For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000019977>

Dear Healthcare Professional/ Risk Manager,

The purpose of this letter is to advise you that Medtronic has initiated a field action regarding the Nitron CryoConsole™ cardiac cryoablation system. This notification is being provided as a formal notice to ensure awareness and transparency. No further action is required at this time, as your device has already been updated.

Issue Description:

Medtronic identified a software issue in Nitron CryoConsole software versions 1.0 and 1.1 related to the catheter authentication process. Specifically, all Arctic Front Advance (AFA) and Arctic Front Advance PRO (AFA Pro) balloon catheters will fail to authenticate after 31 December 2025, which could render the catheter unusable. As stated above, no further action is required at this time, as your device has already been updated.

Prior to the system update, potential impacts associated with this issue included procedure delay or procedure cancellation.

Up until 28 April 2026, Medtronic has received one (1) complaint reporting a Nitron CryoConsole software anomaly that resulted in a delayed procedure because the case was attempted prior to the software update but after 31 December 2025. There have been no reports of patient injury related to

this issue. Alternate catheters such as focal point catheters (Freezor, Freezor Xtra, Freezor Max) and alternate generators are not affected by this issue and may be used to complete the case where applicable.

Customer Actions:

- No further action is required at this time, as your Nitron CryoConsole device has already been updated.
- Please complete and return the enclosed Customer Acknowledgment Form even if you do not have any affected products in your inventory, to acknowledge that you have read and understand this letter.
- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please maintain a copy of this communication in your records.

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 Confidential business information

Sincerely,

Confidential business information

Enclosed:

- Customer Acknowledgement Form