

Update to Urgent Field Safety Notice **Affinity Fusion™ Oxygenator Temperature Monitoring Adapter**

February 2023

Medtronic Reference: FA1302

Dear Healthcare Professional,

In December 2022 a notice was provided to customers regarding the Temperature Monitoring Adapter (TMA) located on the Affinity Fusion Oxygenator. Medtronic listed a range of serial numbers affected by that Urgent Field Safety Notice. The serial number range is being extended in this new letter, please note this does not change the recommendations or the patient risk, this notification increases the quantity range of devices affected by this situation. Medtronic has identified a solution and is actively working on implementation. The intent of the serial number range extension is to maintain product supply until the solution is available worldwide; therefore, Medtronic will continue to distribute Fusion Oxygenators as described in this letter.

Please review the enclosed letter and complete the customer actions, even if you have previously done so with the prior notifications. This letter (February 2023) supersedes the December 2022 letter.

We regret any inconvenience this may have caused. If you have questions regarding this communication, please contact your Medtronic representative.

Sincerely,
Medtronic GmbH