

URGENT FIELD SAFETY NOTICE: RA 2018-1884239

Product: Altrix® Precision Temperature Management System Model: 8001

ATTN: Risk Management/ Fleet Manager

September 2018

FSCA identification: RA2018-1884239

Action Type: Correction

Affected product:

Model numbers	UDI
8001000001	07613327277555
8001000003	07613327277562
8001000008	07613327277630
8001000015	07613327277722
8001000016	07613327277586
8001000017	07613327277609
8001000018	07613327277678
8001000019	07613327277623
8001000023	07613327277777
Product description	
Altrix model 8001 units manufactured between October 4, 2016 and June 30, 2017	
Serial number(s)	
See Attachment	



The purpose of this letter is to advise you that Stryker Medical is voluntarily correcting specific serial numbers of Altrix Model 8001 Units.

Product description:

Altrix is a precision temperature management system that supplies water to an individual or multiple thermal transfer devices simultaneously with each of these circuits monitored separately. The system consists of a controller, reusable hose sets, thermal transfer devices (blankets, vests, and leg wraps), patient temperature probes, reusable cable adapter cables, and reusable patient temperature output cables.

Reason for Voluntary Recall:

1. Users may experience alarm fatigue due to frequent alarming relating to patient temperature deviation beyond 0.5°C while in Automatic mode.
2. Users may experience a Remove from Use code 9 (RFU 9) fault condition relating to inadvertent flow alarms.
3. Users may experience code RFU 27 fault condition relating to mechanical interference between the device fan and filter.

Risk to Health:

A Health Hazard Evaluation was completed which identified the potential hazard of interrupted therapy resulting from Remove from Use “RFU” codes. In addition, users may experience alarm fatigue due to patient temperature deviation.

There have been no reports of patient harm to date in relation to these events; however, Stryker has initiated a field action to address these potential hazards.

Actions to be taken by the Customer/User:

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Locate the units listed on the attached business reply form and identify the address where they can be serviced
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations.
 - a) Please provide contact details so that Stryker can inform the recipients appropriately.
 - b) If you are a Distributor, note that you are responsible for notifying your affected customers.
5. Please inform Stryker of any adverse events concerning the use of the subject devices.
 - a) Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.
7. Upon receipt of your business reply form, Stryker will contact you to arrange for the modification/repair of your Altrix unit.
8. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA.

If you have disposed of any of these units and they are no longer in use, please, advise us of their obsolescence by providing us with their serial number in the space provided on the business reply form.

We request that you respond to this notice within **XX** calendar days from the date of receipt.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name:	Position:	email:
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In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours sincerely,



**PRODUCT SAFETY NOTIFICATION
RA 2018-1884239**

ACKNOLEGEMENT FORM

FSCA identification: RA2018-1884239

Action Type: Correction

Affected product: Altrix model 8001 units manufactured between October 4, 2016 and June 30, 2017

I acknowledge receipt of the Field Safety Notice for RA2018-1884239 and can confirm that:

We have not located any of these devices in our inventory: (please delete if not applicable)				
We have located the following devices:				
Product description	Product Reference	Lot Number	Qty	Qty Quarantined
We have further distributed subject devices to the following organizations:				
Facility Name				
Facility Address				
Form completed by:				

Hospital Name _____ **Contact name** _____

Facility Stamp _____ **Contact Position** _____

Contact Tel No _____

_____ **Contact e-mail** _____

**PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING
THE EMAIL LISTED BELOW:**

email: liliana.tatoiu@stryker.com