

FIELD SAFETY NOTICE

FlexTherm Heater Cooler Device

Affected Devices:	FlexTherm Heater Cooler Device (product code: 16-70-00)
Date:	06. February 2017
Reference No:	9611109-02/06/17-001-R
Attention:	Risk/ Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices
Reason:	Reported quality issues of the FlexTherm Heater Cooler device

Dear Valued LivaNova¹ Customer,

The purpose of this formal notification is to inform you about the discontinuation of the FlexTherm Heater Cooler sales and distribution activities and the voluntary removal of all devices installed at customer sites.

LivaNova conducted a thorough review of the FlexTherm Heater Cooler design, which has been marketed since June 2015 and came to conclusion that the design concept does not fully meet user requirements.

LivaNova acknowledges the obligation to promptly inform our customers of the intent to exit products to enable our customers to prepare for options and alternatives. This communication will assist you in the next steps for a smooth transition.

LivaNova appreciates and values our business relationship with you and looks forward to your continued interest in our products. While we regret any inconvenience this announcement may cause, we are eager to supply your future product requirements with our world-class quality product lines.

¹ LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including Sorin Group Deutschland GmbH. In this document, we refer to all entities using the brand name LivaNova.

If FlexTherm on the attached list are in use, there is no evidence to suggest that immediate removal from service is necessary. You may continue to safely use the heater cooler devices in accordance with the Operator's Manual and the supplied instructions below until the necessary device removal has been completed.

Advice on action to be taken by the user:

- The LivaNova or Distributor Representative will contact you to agree on the return or local disposal of the affected product.
- LivaNova will replace the affected product with a heater cooler HC3T including new connectors and tubing at no charge.
- All affected products including accessories (connectors and tubes) must be returned or disposed of within 30 days of the agreed date. Any affected product that is being applied for return after August 31st, 2017 will not be eligible for replacement.
- To confirm receipt and understanding of this notification, fill the attached customer acknowledgement form and return it to your Sales or Distributor Representative.
- If you require any assistance with returning or disposing product, please contact your local Sales Representative or LivaNova directly.
- LivaNova has discontinued the production of the FlexTherm and does not intend to offer it again to the market in the future

In case of local disposal please follow section *6.1.4 Disposal in accordance with environmental regulations* of the instructions for use and provide a certificate of destruction to the LivaNova or Distributor Representative.

We recognize the removal of the Flextherm product may be disruptive to your facility and we apologize for any inconvenience this may cause.

Transmission of this Field Safety Notice:

Please assure that this notice is passed on to all personnel within your organization who need to be aware of this Field Safety Notice. In case you have transferred products to a third party please pass this information on to them and also inform the below mentioned contact person.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

For questions regarding this Field Safety Notice, please contact Christian Peis, Director QA, Sorin Group Deutschland GmbH at +49 89 323 01 152, via fax at +49 89 323 01 333 or via e-mail at SGD.fsca@sorin.com

A copy of this Field Safety Notice has been provided to the appropriate Regulatory Agency who are aware of these actions.

Thank you for your cooperation in this matter. LivaNova is committed to provide quality products and service to its customers and we apologize for any inconvenience this situation may have caused.

Sincerely,

Enclosures:

Attachment 1: Affected Product List

Attachment 2: Customer Response Form

Attachment 1

Affected Product List

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FlexTherm Heater Cooler Device
Reference # 9611109-02/06/17-001-R

Product Code	Product description	Serial Numbers
16-70-00	FlexTherm Heater Cooler Device	All

Please refer to Attachment 2 for affected Systems at your site.

Attachment 2 Customer Response Form

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According to our records you have the following affected products:

<Fill in the customer related serial numbers only- Use A2_Tracelist Affected Systems (Excel File)>

Product Code	Product description	Affected Serial Number
16-70-00	FlexTherm Heater Cooler Device	

Please return this completed form to:

Sorin Site/ Distributor Name: LivaNova Nederland N.V.
Country: Nederland
Contact Name: Annette Bel->>
E-mail: Annette.bel@livanova.com
Fax No.: 020-311 32 19
Phone Number: 0613191514

Section 1 - Please Complete:

1. We HAVE reviewed and understand the attached Field Safety Notice
2. We DO NOT understand the attached Field Safety Notice and request more information

Please contact us:

Christian Peis, Quality Director, Sorin Group Deutschland GmbH, at +49 (0)89 323 01 152, via fax at +49 (0)89 323 01 333 or via e-mail at SGD.fsca@sorin.com

Customer Name: <<Print Your Company name here>>
Country: <<Print Your Country here>>
Contact Name: << Print Your Contact Name here>>
E-mail: <<Print Your E-mail address here>>
Fax No.: <<Print Your Fax No. here>>
Phone Number: <<Print Your Phone No. here>>

Submitted by
Signature Date/...../.....