

[Contact Name]

[Department/Title]

[Hospital Name]

[Address Line 1]

[Town/City]

[Postal Code]

[Country]

[Date]

Reference: FA2017-14

URGENT FIELD SAFETY NOTICE **ARCTIC SUN Temperature Management System**

Dear [Contact Name]

This letter is to inform you of a Field Safety Corrective Action initiated by Medivance (Bard), a wholly owned subsidiary of C.R. Bard, Inc., involving the ARCTIC SUN® 5000 Temperature Management System.

Reason for Field Safety Notice (FSN):

Bard is issuing a Field Safety Notice to advise users of an update to the instructions for use for the ARCTIC SUN® 5000 Temperature Management System, per the enclosed Labelling Addendum. This Labelling Addendum should be used together with the current Operator's Manual and Service Manual for your device and will be included in the labelling of all future units distributed by Bard.

The Labelling Addendum advises that periodic servicing and maintenance of the ARCTIC SUN® 5000 Temperature Management System is recommended to reduce the risk of failure of certain components.

This communication also provides details on a Preventive Maintenance Program offered by Bard to assist in the regular servicing and maintenance of your device.

This is not a product recall and Bard is not requesting that any units be returned from the market as a result of this notification.

Our records show that your facility has purchased one or more units of the product under the scope of this Field Safety Notice as listed in Table 1 below.

Product Name	Product Code
ARCTIC SUN® 5000 Temperature Management System (220-240 V Europe)	5000-01-01
ARCTIC SUN® 5000 Temperature Management System (220-240 V UK)	5000-01-02
ARCTIC SUN® 5000 Temperature Management System (230 V Switzerland)	5000-01-07
ARCTIC SUN® 5000 Temperature Management System (230 V South Africa)	5000-01-08

Table 1: Affected Product Codes

Clinical Risk Statement

Should certain components of the ARCTIC SUN® 5000 Temperature Management System fail, the system could cease to function as intended, resulting in no availability of cooling or rewarming therapy for the patient.

Bard has completed a Health Hazard Evaluation to evaluate the risks associated with the ARCTIC SUN® 5000 Temperature Management System being unavailable for use. The analysis resulted in a moderate risk rating, which is defined as a failure that may contribute to a scenario likely to require



Bard Limited

Forest House, Tilgate Forest Business Park
Brighton Road, Crawley
West Sussex, RH11 9BP
England, UK.



treatment by a medical professional but is not likely to be associated with permanent impairment of a body function or permanent damage to a body structure.

There have been no serious injury adverse reports or other indications of injuries or diseases reported relating to insufficient cooling / pumping issues.

Should the ARCTIC SUN® 5000 Temperature Management System cease to function as intended, alternative conventional methods to control the patient's temperature should be utilised. These include:

- Switch to another ARCTIC SUN® 5000 Temperature Management System, if available
- Select a different targeted temperature management device, if available
- Revert to conventional means for inducing and maintaining hypo- or normothermia (e.g., ice, cold packs, wet towels, fans, or intravenous infusion of chilled saline to induce hypothermia).

Please be aware that your Competent Authority is being notified of this Field Safety Corrective Action. As part of this action, we require that you follow the instructions below and notify Bard of your compliance with this Field Safety Corrective Action.

Preventive Maintenance Program

To support customers in maintaining system performance, Bard is proposing a Preventative Maintenance Program for the ARCTIC SUN® 5000 Temperature Management System. This program is being implemented to encourage you to periodically service key components of the ARCTIC SUN® 5000 Temperature Management System to maintain system performance.

Preventative maintenance includes the assessment and potential replacement of four key components (i.e., mixing pump, circulation pump, heater, and drain valves) of the ARCTIC SUN® 5000 Temperature Management System that have over 2,000 hours of use.

To purchase a preventative maintenance program through Bard, or to purchase individual components, please contact your local Bard representative

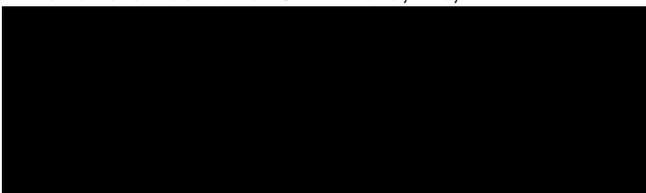
Required actions for you and your Healthcare Facility as part of this FSN

1. Pass this Field Safety Notice to all personnel involved with the use of ARCTIC SUN® 5000 Temperature Management System.
2. Ensure the contents of this Field Safety Notice are understood by the associated personnel.
3. The enclosed Labelling Addendum is to be used in conjunction with the ARCTIC SUN® 5000 Temperature Management System Operator's Manual and Service Manual
4. If you have further distributed this product, please identify that organisation and notify them at once of this notification. You may include a copy of this letter in your notification.
5. Please complete the attached Reply Effectiveness Check Form and return to Bard either by fax to +44(0)1293 524691 or by email to Rachael.Lloyd-Smith@crbard.com.

Note: Although Bard is not requiring that you return affected product, it is extremely important that we receive your completed Reply Effectiveness Check Form as soon as possible.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action. Should you have any questions or require assistance in this matter, please contact your local sales specialist or local Bard Customer Service Representative.

Yours faithfully,
For and on behalf of C. R. Bard, Inc,



Attachment 1: Operator's Manual Addendum

Attachment 2: Service manual Addendum



INVESTOR IN PEOPLE

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REPLY EFFECTIVENESS CHECK FORM

ARCTIC SUN® 5000 Temperature Management System

By completing the below information you confirm that the Field Safety Corrective Action Reference Number FA2017-14 has been received by your Healthcare Facility or Organisation and that it has been read and understood.

1. Determine the system hours on your device(s)

- Turn the device on
 - Go to the Therapy Selection screen and press the 'Help' button located at the lower left corner of the screen
 - Press the 'Help Index' button
 - Select 'Maintenance and Service' topic
 - Select 'System Diagnostics' subtopic.
 - Press 'Display'.
- Scroll to the bottom of the page to find the system hours

2. Provide the system hours for each of your devices

Serial Number	Current System Hours

Please PRINT Your Contact Information and fill form out completely	
Name	
Title	
Name of Account / Hospital	[Pre-populated field]
Contact Phone Number	
Signed	
Date	

Please return completed form to:
 Rachael Lloyd-Smith, RA/QA Manager, UKI
 Email: Rachael.Lloyd-Smith@crbard.com
 Telephone: +44 (0)1293 60652
 Fax: +44(0)1293 524691
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