

Bard Singapore Pte Ltd
1 Harbourfront Avenue, #04-11/13
Keppel Bay Tower, Singapore 098632
Tel: (65) 6250 5988
Fax: (65) 6337 3588
GST Reg No. 19-9901639-R



URGENT: FIELD SAFETY NOTICE

ARCTIC SUN[®] 5000 Temperature Management System

9 February 2018

Dear Valued Customer,

This letter is to inform you that use of the ARCTIC SUN[®] 5000 Temperature Management System in excess of 2,000 system hours, without conducting preventative maintenance, may result in failure of certain components in the system.

This letter is applicable to all ARCTIC SUN[®] 5000 Temperature Management System units produced from October 2010 to present. No other Bard products are affected by this action. The following chart identifies the affected product:

Product Name	Product Code
ARCTIC SUN [®] 5000 Temperature Management System (100-120 V North America and Japan)	5000-00-00
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 (220-240 V Australia)	5000-01-03
ARCTIC SUN [®] 5000 Temperature Management System (220-240 V China)	5000-01-04
ARCTIC SUN [®] 5000 Temperature Management System (220-240 V Brazil)	5000-01-05
ARCTIC SUN [®] 5000 Temperature Management System (220-240 V Switzerland)	5000-01-07
ARCTIC SUN [®] 5000 Temperature Management System (220-240 V South Africa)	5000-01-08

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Issue identified

Failure is notable particularly in relation to the mixing pump, which runs continuously during operation.

- Failure of the mixing pump may cause the ARCTIC SUN[®] 5000 Temperature Management System to 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 treatment scenario likely to require treatment by a medical professional.
- There have been no serious injury adverse reports or other indications of injuries or diseases reported relating to insufficient cooling / pumping issues.

Corrective action concerning the ARCTIC SUN[®] 5000 Temperature Management System

The Operators Manual and the Service Manual for the ARCTIC SUN[®] 5000 Temperature Management System are currently being updated to include the additional information (see Attachment 2 and Attachment 3). These attachments are being provided for you to be placed with your Operator's Manual and Service Manual and retained for future reference. Bard also is proposing for customers a Preventative Maintenance Program to address potential issues before they occur and to maintain device availability, or customers may purchase individual system components for maintenance of the ARCTIC SUN[®] 5000 Temperature Management System (see below).

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[®] Temperature Management System that have over 2,000 hours of use. Parts serviced will be covered with a new one year limited warranty.

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

Recommended Actions

Should the ARCTIC SUN[®] 5000 Temperature Management System cease to function, alternative conventional methods to control the patient's temperature should be utilized. 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).

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To maintain system performance, the ARCTIC SUN® 5000 Temperature Management System requires periodic service of key components, including the mixing pump. As a result of this notification, please conduct the following:

- Examine your ARCTIC SUN® 5000 Temperature Management System inventory to determine the total system hours of use:
 - To determine the total system hours of use for an ARCTIC SUN® 5000 Temperature Management System:
 - 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.
- If you have an ARCTIC SUN® 5000 Temperature Management System approaching or exceeding 2,000 system hours, please contact your local Bard representative to obtain more information regarding enrollment in Bard's *Preventative Maintenance Program* or to purchase components recommended for replacement. If your system has less than 2,000 hours, please be aware that Bard proposes the *Preventative Maintenance Program* to address potential issues before they occur and to maintain device availability. Individual system components are also available for purchase.
- If you have distributed or transferred an ARCTIC SUN® 5000 Temperature Management System, please identify the respective organizations and notify them at once of this communication, including a copy of this communication letter and accompanying attachments. This should be carried out to the unit level.
- Complete and email Complaints.Singapore@crbard.com the accompanying **Acknowledgement Receipt Form** to acknowledge receipt and understanding of this letter (Attachment 1).

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action.

If you have any questions, comments or concerns, please contact your local Bard representative. You may also email Complaints.Singapore@crbard.com.

Sincerely,



Jocelyn Yen
Senior Regulatory Affairs Manager
South East Asia

CC: Chairman of Medical Board and relevant Head of Departments

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Attachment 1 – Acknowledgement Receipt Form

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ATTACHMENT 1:

Acknowledgement Receipt Form

ARCTIC SUN® 5000 Temperature Management System

Please complete this form and email a scanned copy to
Complaints.Singapore@crbard.com

1. By signing below, you are acknowledging receipt and understanding of the attached letter.

_____ have read and understand the instructions provided in this letter.
Print Name

Signature Date

2. Please PRINT CLEARLY your Complete Contact Information:

Name: _____ Title: _____

Phone: _____ Email: _____

Facility Name: _____ Account # _____

Address _____ City: _____ State _____ Zip _____

3. Email a scanned copy to Complaints.Singapore@crbard.com.

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Attachment 2 – Operator's Manual Update

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OPERATOR'S MANUAL ADDENDUM
ARCTIC SUN 5000® Temperature Management System



Preventative Maintenance: Use of the ARCTIC SUN® 5000 Temperature Management System in excess of 2,000 hours, without conducting preventative maintenance, may result in failure of certain system components and failure of the system to function as intended. To maintain system performance, the ARCTIC SUN® 5000 Temperature Management System requires periodic service of key components. For additional information, please refer to <http://www.medivance.com/manuals>, call 1-800-526-4455 or contact your local Bard representative.

Translate to all required languages



Manufacturer:

Medivance, Inc.
321 South Taylor Avenue, Suite 200
Louisville, Colorado 80027 USA
Phone: 303 926 1917

Toll Free: 800 526 4455
Fax: 720 880 5400
bmd.cs@orbard.com



Bard Limited, Forest House
Brighton Road
Crawley, West Sussex UK
RH11 8BP
+44 1293 527 888

PK28xxxxx 04/2017

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Attachment 3 – Service Manual Update

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SERVICE MANUAL ADDENDUM
ARCTIC SUN 5000® Temperature Management System



Preventative Maintenance: Preventative maintenance is required to maintain continued and uninterrupted use of the ARCTIC SUN® 5000 Temperature Management System. Should the ARCTIC SUN® 5000 Temperature Management System become unavailable for use, alternative methods to control patient temperature should be utilized.

To purchase a *Preventative Maintenance Program* through BARD or to purchase components, please call 1-800-526-4455 or contact your local Bard representative.

Preventative maintenance includes the assessment of four key components of the ARCTIC SUN® 5000 Temperature Management Systems that have over 2,000 hours of use. Parts serviced will be covered with a new one year limited warranty.

Components assessed during preventative maintenance include the Mixing Pump, Circulation Pump, Heater and Drain Valves.

Translate to all required languages



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