



URGENT: Customer Notification

Dear Valued Customer,

March 31, 2017

This letter is to inform you that the continued 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, most notably the mixing pump, which runs continuously during operation.

- These mixing pump failures may cause the ARCTIC SUN® 5000 Temperature Management System to be unavailable for use which may result in the inability of the system to cool or rewarm the patient, as intended.
- To maintain system performance, the ARCTIC SUN® 5000 Temperature Management System requires periodic service of key components, including the mixing pump (see the product codes in the table below).

Clinical Risk Assessment

- Bard 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, 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 become unavailable for use, alternative conventional methods to control the patient's temperature should be utilized. These include:
 - Troubleshoot and restore temperature management.
 - Switch to another ARCTIC SUN® 5000 Temperature Management System if available.
 - Select different surface or intravascular targeted temperature management device, if available.
 - Revert to conventional means for inducing and maintaining hypo- or normothermia such as ice, cold packs, wet towels, fans or intravenous infusion of chilled saline to induce hypothermia.



Scope

This notification is applicable to all ARCTIC SUN® 5000 Temperature Management System units produced from October 2010 to present. The following chart provides specific product information:

Product Name	Product Code
ARCTIC SUN® 5000 Temperature Management System (100-120 V North America)	5000-00-00
ARCTIC SUN® 5000 Temperature Management System (100-120 V US)	5000-00-00E

No other Bard products are affected by this action.

In an effort to support customers in maintaining system performance, Bard is offering a *Preventative Maintenance Program* for the Medivance, Inc. 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.

Recommended Actions:

As a result of this notification, please conduct the following:

- Examine your inventory and identify the ARCTIC SUN® 5000 Temperature Management System that may qualify for preventative maintenance as follows:
 - Follow these steps to determine how many system hours are on your ARCTIC SUN® 5000 Temperature Management System:
 - Turn the device on
 - From the Therapy Selection screen press the 'Help' button on the lower left
 - 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 Bard Customer Service at 1-800-526-4455 Option 5 then Option 5 to obtain more detail regarding Bard's *Preventative Maintenance Program*. If your system has less than 2,000 hours, please be aware that we offer the *Preventative Maintenance Program* to address potential issues before they occur and to maintain device availability.
- 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 return (email or fax) the accompanying **Acknowledgment Receipt Form** by April 30, 2017 to acknowledge receipt and understanding of this letter (Attachment 1).

Bard Medical Division
C.R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014



This notification is being made with the knowledge of the Food and Drug Administration. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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 Bard Medical's Customer Service Department by phone at 1-800-526-4455, Option 5 then Option 4. You may also email BMD.FieldAction@crbard.com.

Sincerely,

A handwritten signature in black ink that reads "Michael J. Crader".

Michael J. Crader
Vice President Quality Assurance

Attachment 1 - Acknowledgment Receipt Form

Attachment 1:

Acknowledgment Receipt Form

Medivance, Inc. ARCTIC SUN[®] Temperature Management System

Please complete this form by April 30, 2017 and fax to 1-770-784-6469 or email a scanned copy to

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

I, _____, 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. Fax this form to **1-770-784-6469** or email a scanned copy to BMD.FieldAction@crbard.com,
Attn: Field Assurance