C. R. Bard GmbH
Wachhausstrasse 6
76227 Karlsruhe
Germany

[Contact Name]

[Department/Title]
[Hospital Name]
[Address Line 1]
[Town/City]
[Postal Code]
[Country]

[Date]

Reference: FA2015-30

URGENT FIELD SAFETY NOTICE

ARCTIC SUN® 5000 Temperature Management System

Dear [Contact Name]

This letter is to inform you of a Field Safety Corrective Action initiated by Bard Medical Division (BMD), a wholly owned subsidiary of C.R. Bard, Inc.

Reason for Field Safety Notice:

Bard has identified that certain serial numbers of ARCTIC SUN® 5000 Temperature Management Systems may contain electronic components that lead to a premature drainage of the internal control panel coin cell battery responsible for maintaining the system clock and Static Random Access Memory (SRAM). This premature coin cell battery drainage could render your device unresponsive upon system start-up.

If your device is currently in clinical use, it can continue to be used without concern for this failure. The battery drainage issue only occurs when the unit is off and in stand-by mode. This failure mode does not exist when the unit is actively providing therapy.

Bard will be inspecting all units shipped from April 2011 to February 2015 to determine if they are affected by this premature drainage of the internal control panel coin cell battery. Not all serial numbers within this bounded population will be affected but all will be inspected. It is estimated that the issue will have an occurrence rate of 23% (i.e. approximately one of every 4 devices from the bounded population is estimated to be impacted by the premature depletion of the battery).

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 Notice.

Clinical Risk Statement:

The ARCTIC SUN® 5000 Temperature Management System is intended for monitoring and controlling patient temperature. The ARCTIC SUN® 5000 Temperature Management System is a thermoregulatory device that includes a Control Module and disposable ARCTICGEL™ Pads. The system is designed to monitor and control patient temperature within a range of 32°C to 38.5°C (89.6°F to 101.3°F). The early discharge of the coin cell battery presents a potentially serious issue

Phone:+49 (0) 721 9445-124 • Fax: :+49 (0) 721 9445-230

since the system is used to control patient temperatures within a pre-set range and has the potential of not being available to provide therapy when needed.

Fever management has become the standard of care. If the ARCTIC SUN® 5000 Temperature Management System is not used, standard fever management may include antipyretic drug therapy using acetaminophen or ibuprofen, and external/physical cooling. Physical cooling may include surface cooling with water or air cooling blankets, icepacks, naso-gastric or rectal lavage, or alcohol baths.

Pharmacological agents such as acetaminophen, aspirin, or other nonsteroidal anti-inflammatory agents and corticosteroids appear to inhibit the febrile response by inhibiting prostaglandin synthesis, thus interfering with prostaglandin-mediated action on the hypothalamus. In most clinical practices, antipyretic drugs are often prescribed to combat temperatures greater than 38.5 degrees C.

External cooling by different methods such as using fans and sponging the body surface with water may also be used.

Our records show that you received the product as listed in the attached Reply Effectiveness Check Form. Therefore we require you and/or your Healthcare Facility to take the following actions:

1. Pass this Field Safety Notice to 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. If the device is currently in clinical use, it can continue to be used without concern for this failure. The battery drainage issue only occurs when the unit is off and in stand-by mode. This failure mode does not exist when the unit is actively providing therapy.
4. A Bard affiliated technician will contact you and/or your healthcare facility to arrange a visit to inspect and potentially replace the affected electronic components of the Arctic Sun® 5000 Temperature Management System(s) if it is determined to exhibit the condition described. The inspection will require that the unit is made available at the agreed upon visit time.
5. If you have further distributed this product, please identify that organisation in the attached Reply Effectiveness Check Form and notify them at once of this notification. You may include a copy of this letter in your notification. A Bard affiliated technician will contact the organisation directly to arrange testing the device(s).
6. Please complete the attached Reply Effectiveness Check Form with the current location of the listed devices and return to Bard either **by fax to +49 (0) 721 9445-230** or **by email to [redacted]@crbard.com.**
   Note: It is extremely important that we receive this information as soon as possible..

When the Bard affiliated technician has inspected and/or repaired the ARCTIC SUN® 5000 Temperature Management System(s) they will complete a Service Report Form. Bard will provide replacement components and labour as needed at no cost.

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 on +49 (0) 721 9445-124.

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

[redacted]

RA/QA Specialist Germany, Austria, Switzerland
Tel: +49 (0)721 9445-223

REFERENCE: FA2015-30

REPLY EFFECTIVENESS CHECK FORM

ARCTIC SUN® 5000 Temperature Management System

By completing the below information you confirm that the Field Safety Notice Reference Number FA2015-30 has been received by your Healthcare Facility or Organisation and that it has been read and understood.

Our records show that you have received the following units affected by the bounding of this Field Safety Corrective Action. Please confirm the current location of these devices

Catalogue Number	Serial Number	Current Location		
		Address	Contact Person	Telephone
[pre-populated]	[pre-populated]			
[pre-populated]	[pre-populated]			
[pre-populated]	[pre-populated]			
[pre-populated]	[pre-populated]			
[pre-populated]	[pre-populated]			
[pre-populated]	[pre-populated]			
[pre-populated]	[pre-populated]			

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

Please return completed form to:

[redacted]
RA/QA Specialist Germany, Austria, Switzerland
C. R. Bard GmbH, Wachhausstrasse 6, 76227 Karlsruhe, Germany
Phone: +49 (0)721 9445-[redacted] • Fax: +49 (0) 721 9445-230
e-Mail: miriam.miller@crbard.com