

Bard Singapore Pte Ltd

No 1 Coleman Street #06-07

The Adelphi

Singapore 179803

Tel: (65) 6580 5988

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Co Reg No. 199901639R



URGENT: MEDICAL PRODUCT RECALL

November 13, 2015

Dear Valued Customer,

This letter is to inform you of a voluntary Medical Product Recall initiated by Bard Medical, a division of C.R. Bard, Inc.

Reason for Recall:

Bard Medical Division (BMD) has identified that the ARCTIC SUN[®] 5000 Temperature Management System serial numbers listed in Attachment 1 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 startup.

Specific affected serial numbers of ARCTIC SUN[®] 5000 Targeted Temperature Management Systems are listed in Attachment 1. Our records show that you have purchased/distributed one or more of the affected product serial number units. If these units are currently in use they can continue to be used, providing that they continue to function normally.

All other serial number units not listed in Attachment 1 can continue to be used as they are not affected by this voluntary product recall.

Clinical Risk Statement:

BMD distributes the ARCTIC SUN[®] 5000 Targeted Temperature Management Systems product codes listed in Attachment 1. Recently, BMD has identified an increased incidence of the ARCTIC SUN[®] 5000 Temperature Management System devices not being active at startup due to early discharge of the coin cell battery. 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.

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 including the 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 increased incidence of early discharge of the coin cell battery presents a potentially serious issue since the system is used to control patient temperatures within a preset range and has the potential of not being available to provide therapy when needed.

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.

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

If any patient using this device has had an adverse event related to a recalled device, please report the event to your local authority.

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Instructions for your response:

- Our records show that you have purchased/distributed units affected by this voluntary field action.
- 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.
- You must provide Bard Singapore with the current location and contact information for each device you purchased/distributed.
- Bard Singapore will arrange for a technician to contact the facility to arrange for the evaluation and potential replacement of the affected electronic components of your ARCTIC SUN® 5000 Temperature Management System(s) if it is determined to exhibit the condition described.
- We ask that the unit be made available for inspection and potential repair at the agreed upon time.

Once the product affected by this field action has been inspected and/or repaired;

- The technician will fill out the **Field Action Effectiveness Check Form**. You will be asked to acknowledge the technician's visit. It is important that we receive this information.
- Bard Singapore will provide replacement components and associated labor as needed and at no cost to you.

Recall Reconciliation:

We need to complete a detailed reconciliation of all inspected/repaired units. BMD will maintain a completed **Field Action Effectiveness Check Form** for each unit to track the completion of all potentially affected units.

If you have any questions or concerns, please feel free to contact Bard Singapore representative Kathleen Leong using the following contact information:

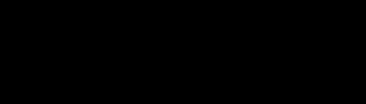
Phone: +65 6580 5999
E-mail: Kathleen.Leong@crbard.com

Please make every effort to accommodate the technician at the time scheduled. If you need to reschedule the time, please contact Kathleen Leong by phone or email as indicated above. Be sure to state the serial number(s) of each unit that you have responsibility for.

It is extremely important that we have the opportunity to evaluate these device(s). BMD must document its compliance with this voluntary field action. Distributors that receive this communication must comply with the instructions set forth in this communication.

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

Sincerely,



Mark Wallwork
Vice President & General Manager, Asia