

Bard Singapore Pte Ltd
No 1 Coleman Street #06-07
The Adelphi
Singapore 179803
Tel: (65) 6580 5988
Fax: (65) 6337 3588
Co Reg No. 199901639R



URGENT: Customer Notification

Dear Valued Customer,

October 03, 2016

This letter is to inform you of an additional *Warning* for the **Medivance, Inc. ARCTIC SUN[®] Temperature Management System**.

Additional Warning: *The ARCTIC SUN[®] Temperature Management System is not intended for use in the operating room environment.*

An insert sheet (Attachment 2) is being provided for you to use in conjunction with the Operator's Manual: *Chapter 1, Warnings and Precautions*.

Product Codes Impacted:

Product Name	Product Code*
ARCTIC SUN [®] 5000 Temperature Management System (220-240 V UK)	5000-01-02

*Product codes may also exist in your records without a hyphen

Clinical Risk Statement:

Bard has completed a Health Hazard Evaluation and concluded that the ARCTIC SUN[®] Temperature Management System would not pose an incremental risk of Nontuberculous Mycobacterium (NTM) bacterial transmission to a patient based on use of the device under existing labeling and that the probability of harm to a patient is considered remote.

However, in abundance of caution and after discussion with FDA, Medivance, Inc. has agreed with FDA to add a warning to the device labeling to exclude the use of the device in the operating room environment to mitigate the potential for NTM infection.

Action Required:

- Examine your inventory and identify any product subject to this communication. Attachment 2 is to be used in conjunction with the ARCTIC SUN[®] Temperature Management System Operator's Manual: *Chapter 1, Warnings and Precautions*.
- If you may have further distributed or transferred this product, please identify the respective company and notify them at once of this product communication. Your notification to these

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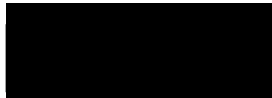


- companies may be enhanced by including a copy of this product communication letter and accompanying attachments. This correction should be carried out to the unit level.
- Complete and return the accompanying **Acknowledgment Receipt Form** (Attachment 1) to acknowledge receipt and understanding of this letter.

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 Bard Representative. You may also email Complaints.Singapore@crbard.com

Sincerely,



Mary Kennell

Director of Regulatory Affairs & Quality, Australia, New Zealand and South East Asia

Attachments (2):

1. Acknowledgment Receipt Form
2. ARCTIC SUN® Temperature Management System Operator's Manual Addendum Insert Sheet

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Attachment 1:

Acknowledgment Receipt Form

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

Please complete this form by **October 14, 2016** or email a scanned copy to
Complaints.Singapore@crbard.com

1. By signing below, you are acknowledging receipt and understanding of the attached letter. You are also confirming that you will attach the insert sheet provided in Attachment 2 into the current version of your Operator's Manual.

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. Please email a scanned copy to Complaints.Singapore@crbard.com
Attn: RA/QA

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Attachment 2

ARCTIC SUN® Temperature Management System

OPERATOR'S MANUAL ADDENDUM

See Next Two Pages

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OPERATOR'S MANUAL ADDENDUM ARCTIC SUN® Temperature Management System



English	<p>This addendum is to be used in conjunction with the Arctic Sun® Temperature Management System Operator's Manual.</p> <p>Additional Warning: The Arctic Sun® Temperature Management System is not intended for use in the operating room environment.</p>
Français	<p>Le présent addendum doit être utilisé avec le guide de l'utilisateur du système de gestion de la température Arctic Sun®.</p> <p>Avertissement supplémentaire : Le système de gestion de la température Arctic Sun® n'est pas destiné à être utilisé au bloc opératoire.</p>
Deutsch	<p>Dieser Nachtrag muss zusammen mit der Bedienungsanleitung für das Arctic Sun® Temperatormanagementsystem verwendet werden.</p> <p>Zusätzliche Warnung: Das Arctic Sun® Temperatormanagementsystem ist nicht für die Verwendung im Operationssaal geeignet.</p>
Italiano	<p>Questo addendum deve essere utilizzato in combinazione con il Manuale dell'operatore del sistema di gestione della temperatura Arctic Sun®.</p> <p>Avvertenza supplementare: Il sistema di gestione della temperatura Arctic Sun® non è destinato all'uso in sala operatoria.</p>
Español	<p>Esta adición ha de usarse junto con el Manual de instrucciones del sistema de gestión de temperatura Arctic Sun®.</p> <p>Advertencia adicional: El sistema de gestión de temperatura Arctic Sun® no está diseñado para utilizarse en quirófano.</p>
Nederlands	<p>Dit addendum dient te worden gebruikt in combinatie met de gebruikershandleiding voor het Arctic Sun® Temperatuurbeheersysteem.</p> <p>Extra waarschuwing: Het Arctic Sun® Temperatuurbeheersysteem is niet bedoeld voor gebruik in de operatiekamer.</p>
Português	<p>Esta adenda deve ser utilizada juntamente com o Manual do Utilizador do Sistema de Gestão de Temperatura Arctic Sun®.</p> <p>Aviso adicional: O Sistema de Gestão de Temperatura Arctic Sun® não se destina à utilização no ambiente das salas de operações.</p>
Português-Brazil	<p>Esta adenda deve ser utilizada juntamente com o Manual do Utilizador do Sistema de Gestão de Temperatura Arctic Sun®.</p> <p>Aviso adicional: O Sistema de Gestão de Temperatura Arctic Sun® não se destina à utilização no ambiente das salas de operações.</p>
Ελληνικά	<p>Αυτό το συμπλήρωμα προορίζεται για χρήση σε συνδυασμό με το εγχειρίδιο χειριστή του συστήματος διαχείρισης θερμοκρασίας Arctic Sun®.</p> <p>Πρόσθετη προειδοποίηση: Το σύστημα διαχείρισης θερμοκρασίας Arctic Sun® δεν προορίζεται για χρήση στο περιβάλλον χειρουργείου.</p>
Dansk	<p>Dette tillæg skal anvendes sammen med brugervejledningen til Arctic Sun® temperaturkontrollsystemet.</p> <p>Yderligere advarsel: Arctic Sun® temperaturkontrollsystemet er ikke beregnet til brug på operationsstuer.</p>
Svenska	<p>Detta tillägg ska användas tillsammans med bruksanvisningen till Arctic Sun® temperaturhanteringssystem.</p> <p>Ytterligare varning: Arctic Sun® temperaturhanteringssystem är inte avsett för användning i operationssalar.</p>
Suomi	<p>Tämä liite on tarkoitettu käytettäväksi yhdessä Arctic Sun® -lämpötilanhallintajärjestelmän käyttöohjeen kanssa.</p>

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Lisävaroitukset: Arctic Sun® -lämpötilanhallintajärjestelmän ei ole tarkoitettu käytettäväksi leikkaussaliympäristössä.

Norsk Dette tillegget skal brukes sammen med brukerhåndboken til Arctic Sun®-temperaturreguleringsystemet.

Ekstra advarsel: Arctic Sun®-temperaturreguleringsystemet skal ikke brukes i operasjonsrommet.

Polski Niniejszy dodatek należy stosować w połączeniu z podręcznikiem operatora systemu zarządzania temperaturą Arctic Sun®.

Dodatkowe ostrzeżenie: System zarządzania temperaturą Arctic Sun® nie jest przeznaczony do stosowania w warunkach sali operacyjnej.

Magyar Ez a kiegészítés az Arctic Sun® hőmérséklet-kezelő rendszer felhasználói kézikönyvéhez tartozik.

További figyelmeztetések: Az Arctic Sun® hőmérséklet-kezelő rendszer nem használható a műtőteremben.

Český Tento dodatek slouží k použití spolu s návodem k obsluze systému řízení teploty Arctic Sun®.

Dodatečné varování: Systém řízení teploty Arctic Sun® není určen k použití na operačním sálu.

Türkçe Bu ek, Arctic Sun® Sıcaklık Yönetim Sistemi Kullanım Kılavuzu ile birlikte kullanılmaya yöneliktir.

Ek Uyarı: Arctic Sun® Sıcaklık Yönetim Sistemi ameliyathane ortamında kullanılmaya yönelik değildir.

Română Această anexă urmează a fi utilizată împreună cu manualul de utilizare al sistemului de termoreglare Arctic Sun®.

Avertisment suplimentar: Sistemul de termoreglare Arctic Sun® nu este destinat utilizării în mediul din sălile de operație.

Slovenčina Táto príloha sa používa spolu s návodom na obsluhu systému na reguláciu teploty Arctic Sun®.

Ďalšie upozornenie: Systém na reguláciu teploty Arctic Sun® nie je určený na použitie v prostredí operačnej sály.

Россия Это дополнение следует использовать вместе с руководством для оператора к системе регулирования температуры Arctic Sun®.

Дополнительное предупреждение: Система регулирования температуры Arctic Sun® не предназначена для использования в условиях операционной.

日本語 本補足資料は、Arctic Sun®温度管理システムの操作マニュアルと併用するためのものです。

追加の警告: Arctic Sun®温度管理システムは、手術室環境での使用に適していません。

中文简体 本附录与 Arctic Sun® 体温控制仪操作手册结合使用。

附加警告 Arctic Sun® 体温控制仪不适用于手术室环境。

繁體中文 - 本附錄與 Arctic Sun® 體溫管理系統操作手冊一併使用。

其他警告: Arctic Sun® 體溫管理系統並不用於手術室環境中。

한국어 - 본 부록은 Arctic Sun® 온도 관리 시스템 작동자 매뉴얼과 함께 사용됩니다.

추가 경고: Arctic Sun® 온도 관리 시스템은 수술실 환경에서 사용하기 위한 시스템이 아닙니다.



Manufacturer:

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Phone: 303 926 1917

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