

URGENT:
CUSTOMER NOTIFICATION

Dear Hospital Risk Manager,

5/20/2016

This letter is to inform you of a potential safety concern while using Temperature Simulator Keys with the ARCTIC SUN[®] Temperature Management System in conjunction with treating a patient. This is a follow up communication to a Safety Alert that was distributed in July of 2014.

Our records indicate that your hospital has purchased one or more of the catalog numbers listed below. All ARCTIC SUN[®] serial numbers have the potential to be used with a Temperature Simulator Key. Please disseminate this information to all clinical personal that may operate the ARCTIC SUN[®] Temperature Management System.

PRODUCT DESCRIPTION	<p>Bard Medical Division supplies Temperature Simulators Keys for testing, training and demonstration purposes only. They are <u>Not for Clinical Use and should not be connected to the ARCTIC SUN[®] while in clinical use.</u></p> <p>They are about the size of a USB Flash drive. When in use, it occupies the connector on the patient temperature cable.</p>
PRODUCT CATALOG NUMBERS	<p>Temperature Simulator Keys:</p> <ul style="list-style-type: none"> - 748-00 (33, 37, 39°C) - 748-33 (33°C) - 748-37 (37°C) - 777-00 (37°C) - 748-39 (39°C) - 771-00 (Service Kit) <p>ARCTIC SUN[®] 5000:</p> <ul style="list-style-type: none"> - 5000-00-00 - 5000-01-01 - 5000-01-02 - 5000-01-03 - 5000-01-04 - 5000-01-05 - 5000-01-07 - 5000-01-08 - 5000-00-00E <p>ARCTIC SUN[®] 2000:</p> <ul style="list-style-type: none"> - 2000-02 - 2000-03 - 2000-04 - 2000-10 - 2000-11
MANUFACTURER	<p>Medivance, Inc., a wholly owned subsidiary of C. R. Bard, Inc. 321 South Taylor Avenue, Suite 200, Louisville, CO 80027</p>
REASON	<p>This customer notification is being initiated by Bard Medical Division (BMD) in order to inform you of a safety concern while using Arctic Sun Temperature Simulator Keys with the ARCTIC SUN[®] Temperature Management System.</p>





REASON (cont.)	Two adverse events were reported to BMD. In each instance, an ARCTIC SUN [®] Temperature Simulator Key was connected to the patient temperature cable instead of the patient temperature probe. Due to the false patient temperature reading from the temperature simulator key, improper targeted temperature therapy was delivered to the patients.
POTENTIAL HEALTH HAZARDS	<p>The Temperature Simulator Keys are for testing, training and demonstration purposes only and should <u>not be connected to the ARCTIC SUN[®] during clinical use.</u></p> <p>Never use a Temperature Simulator Key, or other method, to circumvent the normal patient temperature feedback control when the system is connected to the patient. Doing so may expose the patient to the hazards associated with severe hypothermia or hyperthermia.</p>
ACTION	<p>Temperature Simulator Keys should never be connected to the ARCTIC SUN[®] Temperature Management System while a patient is undergoing targeted temperature therapy.</p> <p>Prior to targeted temperature therapy per the <i>Instructions For Use</i>, the clinician should always:</p> <ul style="list-style-type: none"> • <i>Check that there <u>is not</u> a temperature simulator key connected to the patient temperature cable.</i> • <i>Verify that the patient temperature probe is properly placed on the patient.</i> • <i>Verify that the patient temperature probe is connected to a patient temperature cable.</i> <p>During targeted temperature therapy per the <i>Instructions For Use</i>, please remember:</p> <ul style="list-style-type: none"> • <i>Medivance recommends measuring patient temperature from a second site to verify patient temperature. Medivance recommends the use of a second patient temperature probe connected to the Arctic Sun[®] Temperature Management System Temperature 2 input as it provides continuous monitoring and safety alarm features. Alternatively, patient temperature may be verified periodically with independent instrumentation.</i> • <i>The displayed temperature graph is for general information purposes only and is not intended to replace standard medical record documentation for use in therapy decisions.</i> <p>Please review the ARCTIC SUN[®] Temperature Management Operator's Manual for Warnings and Cautions prior to using this device for targeted temperature management. The Operator's Manual and Temperature Simulator Key Instructions For Use are located at www.medivance.com/manuals.</p>
OTHER INFORMATION	<p>This notification is being made with the knowledge of the Food and Drug Administration.</p> <p>For questions or assistance, please call 1-800-793-8110 or email bmd.fieldaction@crbard.com.</p>
ATTACHMENTS	<p>Attachment 1: Screenshots comparing Patient Temperature with the Simulator Key versus an actual Patient Temperature Probe</p> <p>Attachment 2: Simulator Key Instruction For Use</p>

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



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

Sincerely,

A handwritten signature in black ink that reads "Janna Parks". The signature is fluid and cursive.

Janna Parks
Senior Manager, Field Assurance
Bard Medical Division
C. R. Bard, Inc.

Attachment 1

The screenshots below display the visual difference in “Patient Temperature” when a Temperature Simulator Key is plugged in as compared to an actual Patient Temperature Probe.

Patient Temperature vs. Patient Temperature Set Point vs. Water Temperature	Comparison
<p>The graph displays three data series over a 30-minute period. The red line (Patient Temperature) is constant at 39.0°C. The green line (Patient Temperature Set Point) is constant at 33.0°C. The blue line (Water Temperature) starts at approximately 35.5°C, drops to 33.0°C by 5 minutes, and then fluctuates between 32.5°C and 33.5°C. A red arrow points to the 39.0°C level on the red line.</p>	<p><u>Incorrect Set-up</u></p> <p>The first screenshot shows no fluctuation in patient temperature (red).</p> <p>The 39°C Temperature Simulator Key is plugged in, and the red line stays constant at that level regardless of the Patient Temperature Set Point (33°C) or Water Temperature (blue).</p>
<p>The interface shows a patient temperature of 36.9°C and a set point of 33.0°C. The water temperature is 30.2°C. The graph shows a yellow solid line (actual patient temperature) fluctuating around a solid dotted line (set point) and a blue line (water temperature). The water temperature is shown as 30.2°C.</p>	<p><u>Correct Set-up</u></p> <p>The second screenshot shows a normal temperature therapy session as displayed on the ARCTIC SUN[®] with a Patient Temperature probe plugged in.</p> <p>The actual patient temperature (yellow solid line) fluctuates along with the Patient Temperature Set Point (solid dotted line) and Water Temperature (blue).</p>

Attachment 2

English

Temperature Simulator Keys

Instructions for Use

Caution: Medivance supplies temperature simulators (fixed value resistors) for testing, training and demonstration purposes only. Never use this device, or other method, to circumvent the normal patient temperature feedback control when the system is connected to the patient. Doing so exposes the patient to the hazards associated with severe hypo- or hyper-thermia.

The intended use for the temperature simulator keys is to test, train and demonstrate the ARCTIC SUN[®] Temperature Management System. The Temperature Simulator Keys are Not for Clinical Use. Each key has a fixed temperature value that represents an artificially simulated patient temperature to the ARCTIC SUN[®] Temperature Management System.

Visually inspect the Temperature Simulator Keys prior to use. There are three configurations that the Temperature Simulator Keys can be ordered. Three keys attached on a Simulator Key Hang Tag (748-00), a 37°C key packaged alone (777-00), or within an In-Service Training Kit (771-00).

The three following keys should be present on the Simulator Hang Tag:

- 39°C - represented in the color Red
- 37°C - represented in the color White
- 33°C - represented in the color Blue

To simulate a patient temperature, select the appropriate Temperature Simulator Key for the desired testing, training, or demonstrating outcomes. Connect the selected Temperature Simulator Key into the patient temperature cable. Once connected, insert the opposite end of the patient temperature cable into the patient temperature port on the back side of the ARCTIC SUN[®] Temperature Management System.

Temperature Simulator Keys are Not for Clinical Use and should never be used while a patient is undergoing targeted temperature therapy. In order for the patient to receive proper targeted temperature management, a patient temperature probe must be connected to the patient temperature cable which is connected to the ARCTIC SUN[®] Temperature Management System.

Prior to targeted temperature therapy, the clinician should always:

- Check that there is not a temperature simulator key connected to the patient temperature cable.
- Verify that the patient temperature probe is properly placed on the patient.
- Verify that the patient temperature probe is connected to the ARCTIC SUN[®] Temperature Management System.