

## URGENT Medical Device Recall

7/30/2019

Dear Valued Customer,

This is to inform you that Gentherm Medical, LLC (formerly Cincinnati Sub-Zero) is conducting a voluntary product recall involving:

**Blanketrol III Hyper-Hypothermia System and CoolBlue Hyper-Hypothermia System, Models 233 and Innercool**

**Affected Serial Numbers are:** Model 233 (071-3-00123 – 193-3-09498)  
Innercool (073-CB-00001 – 162-CB-00294)

See enclosed product labels in Appendix A for ease in identifying the product at the user level.

The purpose of this letter is to advise you that warnings have been clarified stating that exceeding 40°C for extended periods may cause tissue damage. Additionally, a caution was added and clarifications were made regarding the use of the Automatic modes. See Appendix B for specific changes that have been made to the device manuals.

Immediately examine your inventory and update manual(s) subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall letter.

### INSTRUCTIONS TO CUSTOMERS:

- 1) Access updated manuals and ensure that obsolete manuals are removed from service. Updated manuals may be accessed via [www.gentherm.com](http://www.gentherm.com) or physical copies may be requested from Gentherm Medical, LLC at 1-888-437-5608.
- 2) Ensure that all users are informed of the contents of this letter. If you have further distributed this product, please provide those accounts with a copy of this notice.
- 3) Please **complete and return the enclosed response form** as soon as possible to acknowledge receipt of this notification and to inform Gentherm Medical, LLC that you have performed and completed the requested actions. Return the form by e-mail to [FA2019-004/010@gentherm.com](mailto:FA2019-004/010@gentherm.com), or mail to:

Gentherm Medical, LLC  
12011 Mosteller Road  
Cincinnati, OH 45241

This recall should be carried out to the user level. Your assistance is appreciated and necessary to prevent tissue damage or unintended therapy. If you have any questions, call Gentherm Medical Technical Support at 1-888-437-5608.

This recall is being made with the knowledge of the Food and Drug Administration.

Sincerely,

A handwritten signature in blue ink that reads "Stephanie Vocke".



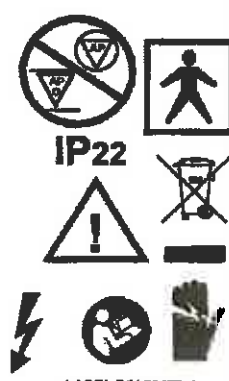

Stephanie Vocke  
Quality & Regulatory Engineer

12011 Mosteller Road Cincinnati OH 45241

P 1.513.772.8810 F 1.513.772.9119 [www.gentherm.com](http://www.gentherm.com)

## Appendix A: Blanketrol III Product Labels

<h1>BLANKETROL<sup>®</sup> III</h1>		
<p><b>CAUTION:</b> FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.</p> <p><b>DANGER:</b> RISK OF EXPLOSION DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.</p> <p><b>SN</b></p> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	<p><b>REF 233</b></p> <p><b>10.2A 50/60Hz</b></p> <p><b>115V~</b></p> <p><b>REFRIGERANT R134a 15oz.</b></p> <p><b>DESIGN PRESSURES</b></p> <p><b>HIGH SIDE 240 PSIG</b></p> <p><b>LOW SIDE 240 PSIG</b></p>	<div style="display: flex; justify-content: space-around;">  </div> <div style="display: flex; justify-content: space-around;">  </div> <p style="text-align: center; font-size: 1.2em;"><b>68.5 kg</b></p>
<p><b>DANGER:</b> RISK OF ELECTRICAL SHOCK, DISCONNECT POWER BEFORE SERVICING.</p>	 <b>A GENTHERM COMPANY</b> <small>Cincinnati Sub-Zero Products, LLC          12611 Mosteller, Cincinnati, Ohio, U.S.A. 45241          www.cszmedical.com 1-800-988-7373</small>	<p style="font-size: 0.8em;">MODEL 233 MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, IEC60601-2-35, ASTM F2188-02, IEC60601-1-2, AND CAN/CSA-C22.2 No. 601.1</p>

<h1>ZOLL STx<sup>™</sup></h1>		
<p><b>CAUTION:</b> FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.</p> <p><b>DANGER:</b> RISK OF EXPLOSION DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.</p> <p><b>DANGER:</b> RISK OF ELECTRICAL SHOCK, DISCONNECT POWER BEFORE SERVICING.</p>	<p><b>REF 8700-000836-01</b> (25-01)</p> <p><b>P/N: 86000 (P11982-001)</b></p> <p><b>10.2A 50/60Hz</b></p> <p><b>115V~</b></p> <p><b>SN</b> <span style="border: 1px solid black; padding: 2px;">YYQCBXXXX</span></p> <p> <span style="border: 1px solid black; padding: 2px;">YYYY-MM-DD</span></p> <div style="border: 1px solid black; height: 30px; width: 100%; text-align: center; margin-top: 10px;"> <p><b>BARCODE</b></p> <p style="font-size: 0.8em;">(01) GTIN (11) MFG. DATE (21) SERIAL NUMBER</p> </div> <p style="font-size: 0.8em; text-align: center;">ZOLL Circulation, Inc.          2000 Ringwood Avenue          San Jose, California 95131 USA          t: 1-408-541-2140          f: 1-408-541-1030</p>	<p><b>REFRIGERANT R134a 15oz.</b></p> <p><b>DESIGN PRESSURES</b></p> <p><b>HIGH SIDE 240 PSIG</b></p> <p><b>LOW SIDE 240 PSIG</b></p> <div style="display: flex; justify-content: space-around;">  </div> <p style="text-align: center; font-size: 1.2em;"><b>IP22</b></p> <p style="text-align: right; font-size: 0.8em;">LABEL PN 86476-J</p>
<p style="font-size: 0.8em;">MODEL 25-01 MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, IEC60601-2-35, ASTM F2188-02, CAN/CSA-C22.2 No. 601.1 AND IEC60601-1-2</p>	<p style="font-size: 0.8em;">CLASSIFIED            16HV</p>	<p style="font-size: 0.8em;">Cincinnati Sub-Zero Products, LLC          12611 Mosteller Rd          Cincinnati, Ohio 45241          U.S.A.</p>

## Appendix B: Blanketrol III Hyper-Hypothermia System Manual Updates

Affected Manual	Updates
<p>Changes are designated in <b>RED</b>  <b>See updated manual(s) for more details.</b></p>	
<p>56201 (115 and 230V Operation &amp; Technical Manual),                      57201 (115 and 230V Operation Manual),                      57299 (100V Operation &amp; Technical Manual),                      57259 (100V Operation Manual)</p> <p><b>WARNINGS section, Sections 2-5, 3-3, 3-4, 3-5, 3-6 and 3-7</b></p>	<p><b>WARNING:</b> A physician's order is required for setting blanket temperature and use of equipment. At least every 20 minutes, or as directed by physician, check patient's temperature and skin integrity of areas in contact with blanket; also, check the BLANKETROL III's water temperature. Pediatric patients, temperature-sensitive patients with vascular disease, surgical patients, diabetics and patients with Raynaud's Disease <b>are at greater risk for developing tissue injuries, and this should be considered when selecting the temperature, duration of therapy and frequency of skin checks.</b> Notify the physician promptly of any change in patient status in order to avoid serious injury or death.</p>
<p>56201 (115 and 230V Operation &amp; Technical Manual),                      57299 (100V Operation &amp; Technical Manual)                      57259 (100V Operation Manual)</p> <p><b>WARNINGS section, Sections 2-5, 3-3, 3-4, 3-5, 3-6 and 3-7</b></p> <p>57201 (115 and 230V Operation Manual): <b>WARNINGS section, Sections 3-3, 3-4, 3-5, 3-6 and 3-7</b></p>	<p><b>WARNING:</b> The method of temperature control provided by all hyper-hypothermia units presents the danger of heating or cooling body tissues, particularly the skin, to a point where they are injured, i.e., burns or frostbite, respectively. <b>The clinician is responsible for determining the appropriateness of the temperature limits in dependency to time. Exceeding 40°C water temperature for extended periods can cause tissue damage and burns. Clinical judgement should be used to determine the safe maximum contact periods based on patient age, clinical condition, and current medications.</b> Depending on the extent and severity of a burn, very serious and even fatal complications may arise.</p>
<p>56201 (115 and 230V Operation &amp; Technical Manual)                      57299 (100V Operation &amp; Technical Manual)</p> <p><b>CAUTIONS section, Sections 1-1, 1-5, 2-5, 3-3, 3-6, and 3-7</b></p> <p>57201 (115 and 230V Operation Manual)                      57259 (100V Operation Manual)</p> <p><b>CAUTIONS section, Sections 1-1, 1-5, 3-3, 3-6, and 3-7</b></p>	<p><b>CAUTION:</b> Do not use <b>GRADIENT VARIABLE MODE</b> or <b>GRADIENT VARIABLE 10C MODE</b> without <b>SMART MODE</b>. Unintended therapy could occur.</p> <p>Clarifications were added on the use of Automatic modes, including clinical recommendations for when these modes are to be used.</p> <p>The three Automatic modes include:                      1) <b>AUTO CONTROL MODE</b>                      2) <b>GRADIENT 10C SMART MODE</b>                      3) <b>GRADIENT VARIABLE SMART MODE</b></p>

<p><b>11978</b> (InnerCool Operation &amp; Technical Manual): <b>WARNINGS</b> section, Sections 2-5, 3-3, 3-4, 3-5 and 3-6</p>	<p><b>WARNING:</b> A physician's order is required for setting pad temperature and use of equipment. At least every 20 minutes, or as directed by physician, check patient's temperature and skin integrity of areas in contact with pad; also, check the STx Console's water temperature. Pediatric patients, temperature-sensitive patients with vascular disease, surgical patients, diabetics and patients with Raynaud's Disease <b>are at greater risk for developing tissue injuries, and this should be considered when selecting the temperature, duration of therapy and frequency of skin checks.</b> Notify the physician promptly of any change in patient status in order to avoid serious injury or death.</p> <p><b>WARNING:</b> The method of temperature control provided by all hyper-hypothermia units presents the danger of heating or cooling body tissues, particularly the skin, to a point where they are injured, i.e., burns or frostbite, respectively. <b>The clinician is responsible for determining the appropriateness of the temperature limits in dependency to time. Exceeding 40°C water temperature for extended periods can cause tissue damage and burns. Clinical judgement should be used to determine the safe maximum contact periods based on patient age, clinical condition, and current medications.</b> Depending on the extent and severity of a burn, very serious and even fatal complications may arise.</p>
<p><b>11978</b> (InnerCool Operation &amp; Technical Manual): <b>CAUTIONS</b> section, Sections 1-2, 1-7, 2-5, 3-3 and 3-6</p>	<p><b>CAUTION:</b> Do not use <b>GRADIENT VARIABLE MODE</b> without <b>PROGRESSIVE MODE</b>. Unintended therapy could occur.</p> <p>Clarifications were added on the use of Automatic modes, including clinical recommendations for when these modes are to be used.</p> <p>The two Automatic Modes include:</p> <ol style="list-style-type: none"> <li>1. <b>PATIENT TEMP CONTROL MODE</b></li> <li>2. <b>GRADIENT VARIABLE PROGRESSIVE MODE</b></li> </ol>

## Recall Response Form

Please complete this form after the instructions provided in the recall letter. Return the completed form by mail to Gentherm Medical, LLC, 12011 Mosteller Road, Cincinnati, OH 45241, by fax to (513)772-9119 or scan and e-mail to [FA2019-004/010@gentherm.com](mailto:FA2019-004/010@gentherm.com).

**Please check ALL appropriate boxes.**

- I have read and understand the field notification instructions.
- I have ensured that all users are informed of the contents of this letter
- Indicate disposition of recalled product:
  - Corrected: \_\_\_\_\_  
(Specify serial number(s) and date)
  - Returned: \_\_\_\_\_  
(Specify serial number(s), and date)
  - Destroyed: \_\_\_\_\_  
(Specify serial number(s), and date)
- I have identified and notified my customers that were shipped or may have been shipped this product by;  
(Specify date and method of notification)  
OR
- Attached is a list of customers who received/may have received this product. I would like Gentherm Medical to notify my customers.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Facility Name

\_\_\_\_\_  
Phone Number

\_\_\_\_\_  
Date

\_\_\_\_\_  
Email Address

\_\_\_\_\_  
Facility Address, City, State, Zip Code

