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, 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,

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

BLANKETROL® III

CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

DANGER: RISK OF EXPLOSION DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

SN

REF 233
10.2A 50/60Hz
115V~
REFRIGERANT R134a 15oz.
DESIGN PRESSURES
HIGH SIDE 240 PSIG
LOW SIDE 240 PSIG

68.5 kg

DANGER: RISK OF ELECTRICAL SHOCK, DISCONNECT POWER BEFORE SERVICING.

A GENTHERM COMPANY
Cincinnati Sub-Zero Products, LLC
2971 Houser Road, Cincinnati, Ohio U.S.A. 45214
www.gentherm.com 1-800-840-7273

ZOLL STx

CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

DANGER: RISK OF EXPLOSION DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

DANGER: RISK OF ELECTRICAL SHOCK, DISCONNECT POWER BEFORE SERVICING.

REF 8700-000836-01
10.2A
115V~ 50/60Hz
P/N: 66000 (P11982-001)
REFRIGERANT R134a 15oz.
DESIGN PRESSURES
HIGH SIDE 240 PSI
LOW SIDE 240 PSI

SN [YYQCBX0000] [YYY-MM-DD]

BARCODE

(01) GTIN (11) MFG. DATE (21) SERIAL NUMBER
ZOLL Circulation, Inc.
2900 Ringwood Avenue
San Jose, California 95131 USA
T: 1-408-841-2140
F: 1-408-841-1630

Template 0637.3
Document ID 10419
# Appendix B: Blanketrol III Hyper-Hypothermia System Manual Updates

<table>
<thead>
<tr>
<th>Affected Manual</th>
<th>Updates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes are designated in RED</td>
<td><strong>WARNING</strong>: 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 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. Notify the physician promptly of any change in patient status in order to avoid serious injury or death.</td>
</tr>
<tr>
<td>56201 (115 and 230V Operation &amp; Technical Manual),</td>
<td></td>
</tr>
<tr>
<td>57201 (115 and 230V Operation Manual),</td>
<td></td>
</tr>
<tr>
<td>57299 (100V Operation &amp; Technical Manual),</td>
<td></td>
</tr>
<tr>
<td>57259 (100V Operation Manual)</td>
<td></td>
</tr>
<tr>
<td>WARNINGS section, Sections 2-5, 3-3, 3-4, 3-5, 3-6</td>
<td></td>
</tr>
<tr>
<td>and 3-7</td>
<td></td>
</tr>
<tr>
<td>56201 (115 and 230V Operation &amp; Technical Manual),</td>
<td><strong>WARNING</strong>: 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. 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. Depending on the extent and severity of a burn, very serious and even fatal complications may arise.</td>
</tr>
<tr>
<td>57299 (100V Operation &amp; Technical Manual)</td>
<td></td>
</tr>
<tr>
<td>57259 (100V Operation Manual)</td>
<td></td>
</tr>
<tr>
<td>WARNINGS section, Sections 2-5, 3-3, 3-4, 3-5, 3-6</td>
<td></td>
</tr>
<tr>
<td>and 3-7</td>
<td></td>
</tr>
<tr>
<td>57201 (115 and 230V Operation Manual): WARNINGS section, Sections 3-3, 3-4, 3-5, 3-6 and 3-7</td>
<td></td>
</tr>
<tr>
<td>56201 (115 and 230V Operation &amp; Technical Manual)</td>
<td><strong>CAUTION</strong>: Do not use GRADIENT VARIABLE MODE or GRADIENT VARIABLE 10°C MODE without SMART MODE. Unintended therapy could occur.</td>
</tr>
<tr>
<td>57299 (100V Operation &amp; Technical Manual)</td>
<td>Clarifications were added on the use of Automatic modes, including clinical recommendations for when these modes are to be used.</td>
</tr>
<tr>
<td>CAUTIONS section, Sections 1-1, 1-5, 2-5, 3-3, 3-6,</td>
<td></td>
</tr>
<tr>
<td>and 3-7</td>
<td>The three Automatic modes include:</td>
</tr>
<tr>
<td>57201 (115 and 230V Operation Manual)</td>
<td>1) AUTO CONTROL MODE</td>
</tr>
<tr>
<td>57259 (100V Operation Manual)</td>
<td>2) GRADIENT 10°C SMART MODE</td>
</tr>
<tr>
<td>CAUTIONS section, Sections 1-1, 1-5, 3-3, 3-6, and 3-7</td>
<td>3) GRADIENT VARIABLE SMART MODE</td>
</tr>
</tbody>
</table>
**11978 (InnerCool Operation & Technical Manual): WARNINGS section, Sections 2-5, 3-3, 3-4, 3-5 and 3-6**

**WARNING:** 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 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. Notify the physician promptly of any change in patient status in order to avoid serious injury or death.

**WARNING:** 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. 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. Depending on the extent and severity of a burn, very serious and even fatal complications may arise.

**11978 (InnerCool Operation & Technical Manual): CAUTIONS section, Sections 1-2, 1-7, 2-5, 3-3 and 3-6**

**CAUTION:** Do not use GRADIENT VARIABLE MODE without PROGRESSIVE MODE. Unintended therapy could occur.

Clarifications were added on the use of Automatic modes, including clinical recommendations for when these modes are to be used.

The two Automatic Modes include:
1. PATIENT TEMP CONTROL MODE
2. GRADIENT VARIABLE PROGRESSIVE MODE
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.

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                  Date

_________________________  _________________________
Printed Name               Email Address

_________________________  _________________________
Facility Name              Facility Address, City, State, Zip Code

_________________________  _________________________
Phone Number               

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