



Corporate Office
12011 Mosteller Road
Cincinnati, Ohio 45241-1528

Tel 513-772-8810
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www.genthermcsz.com

URGENT FIELD SAFETY NOTICE

**Blanketrol III Hyper-Hypothermia System
FA2019-004,010
Correction**

8/1/2019

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

For Attention of: Blanketrol III and CoolBlue user

Details on affected devices: Blanketrol III Hyper-Hypothermia System and CoolBlue Hyper-Hypothermia System, Models 233 and Innercool, Parts 86000 (Innercool, 115V), 86001 (Innercool, 230V), 86007 (233, 100V), 86102 (233, 115V), 86107 (233, 115V), 86139 (233, 115V), 86202 (233, 230V), 86203 (233, 230V), 86204 (233, 230V), and 86207 (233, 230V)

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

Description of device: The BLANKETROL III and InnerCool Systems are used to lower or to raise a patient's temperature and/or maintain a desired patient temperature through conductive heat transfer.

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

Description of the problem: 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 correction 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 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:



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The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organizations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

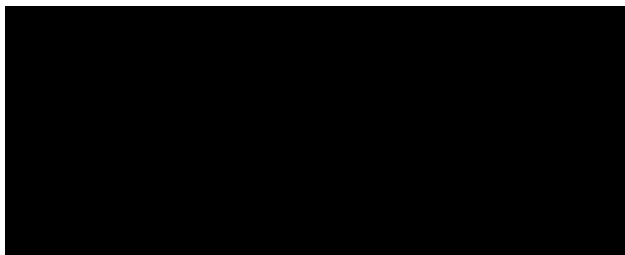
Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Contact reference person:






Stephanie Vocke
Gentherm Medical, LLC
12011 Mosteller Road
(513)719-3262

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.

Sincerely,



Appendix A: Blanketrol III Product Labels

<h1>BLANKETROL® III</h1>		
<p>SN</p> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	<p>REF 233</p> <p>12.0A 50/60Hz 100V~</p> <p>REFRIGERANT R134a 15oz.</p> <p>DESIGN PRESSURES HIGH SIDE 240 PSIG LOW SIDE 240 PSIG</p>	  <p>79.4 kg</p> 
 <p>A GENTHERM COMPANY Cincinnati Sub-Zero Products, LLC 12011 Mosteller, Cincinnati, Ohio, U.S.A. 45241 www.cszmedical.com 1-800-869-7373</p>		
57169-C		<p>MODEL 233 MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, IEC60801-2-33, ASTM F2198-02, IEC60801-1-2, AND CAN/CSA-C222 No. 801.1</p>

<h1>BLANKETROL® III</h1>		
<p>CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.</p> <p>DANGER: RISK OF EXPLOSION DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.</p> <p>SN</p> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	<p>REF 233</p> <p>10.2A 50/60Hz 115V~</p> <p>REFRIGERANT R134a 15oz.</p> <p>DESIGN PRESSURES HIGH SIDE 240 PSIG LOW SIDE 240 PSIG</p>	  <p>68.5 kg</p> 
 <p>A GENTHERM COMPANY Cincinnati Sub-Zero Products, LLC 12011 Mosteller, Cincinnati, Ohio, U.S.A. 45241 www.cszmedical.com 1-800-869-7373</p>		
56888-1		<p>MODEL 233 MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, IEC60801-2-33, ASTM F2198-02, IEC60601-1-2, AND CAN/CSA-C222 No. 801.1</p>

BLANKETROL® III

  <div style="border: 1px solid black; padding: 2px; display: inline-block;">SN</div> 68.5 kg <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	<div style="border: 1px solid black; padding: 2px; display: inline-block;">REF</div> 233 5.2A <hr style="width: 50%; margin: 0 auto;"/> 230V~ 50/60Hz R134a (15 oz.)	     
	 <p>A GENTHERM COMPANY Cincinnati Sub-Zero Products, LLC 12011 Mosteller, Cincinnati, Ohio, U.S.A. 45241 www.cszmedical.com 1-800-889-7373</p>	 <p>CLASSIFIED UL US 16HV</p>

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 F2198-02, IEC60601-1-2, AND CAN/CSA-C22.2 No. 601.1

56484-J

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.

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 F2198-02, CAN/CSA-C22.2 No. 601.1 AND IEC60601-1-2

**Cincinnati Sub-Zero Products, LLC
12011 Mosteller Rd.
Cincinnati, Ohio 45241
U.S.A.**


REF

8700-000836-01
(25-01)
P/N: 86000 (P11982-001)
10.2A


115V~ 50/60Hz

SN

YYQCBXXXX



YYYY-MM-DD




BARCODE



(01) GTIN (11) MFG. DATE (21) SERIAL NUMBER



**ZOLL Circulation, Inc.
2000 Ringwood Avenue
San Jose, California 95131 USA
t: 1-408-541-2140
f: 1-408-541-1030**



REFRIGERANT
R134a 15oz.




DESIGN PRESSURES
HIGH SIDE 240 PSIG
LOW SIDE 240 PSIG




















LABEL P/N 96476-J

ZOLL STx™



<p>CE 0344</p> <p>EC REP AUTHORIZED EUROPEAN REPRESENTATIVE: CEERTHERM BV ESDOORNLAAN 13 3861 DB MAARN THE NETHERLANDS</p> <p>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 F2108-02, CANCSA-C22.2 No. 601.1 AND IEC60601-1-2</p> <p>CLASSIFIED  16HV</p> <p> Cincinnati Sub-Zero Products, LLC 12011 Mosteller Rd. Cincinnati, Ohio 45241 U.S.A.</p>	<p>REF 8700-000837-01 (25-01)</p> <p>P/N: 86001 (P12045-001)</p> <p>5.2A 230V~ 50/60Hz</p> <p>SN YYQCBXXXXX  YYYYY-MM-DD</p> <div style="border: 1px solid black; width: 100%; height: 40px; margin: 10px 0; text-align: center;"> <p>BARCODE</p> <p>(01) GTIN (11) MFG. DATE (21) SERIAL NUMBER</p> </div> <p>ZOLL Circulation, Inc. 2000 Ringwood Avenue San Jose, California 95131 USA t: 1-408-541-2140 f: 1-408-541-1030</p>	<p>R134a 15oz.</p> <p>IP22 </p> <div style="display: flex; justify-content: space-around;">   </div> <div style="display: flex; justify-content: space-around;">   </div> <div style="display: flex; justify-content: space-around;">   </div> <p style="text-align: center;">LABEL P/N 57440-J</p>
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Appendix B: Blanketrol III Hyper-Hypothermia System Manual Updates

Affected Manual	Updates
<p>Changes are designated in RED See updated manual(s) for more details.</p>	
<p>56201 (115 and 230V Operation & Technical Manual), 57201 (115 and 230V Operation Manual), 57299 (100V Operation & Technical Manual), 57259 (100V Operation Manual)</p> <p>WARNINGS section, Sections 2-5, 3-3, 3-4, 3-5, 3-6 and 3-7</p>	<p>WARNING: 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.</p>
<p>56201 (115 and 230V Operation & Technical Manual), 57299 (100V Operation & Technical Manual) 57259 (100V Operation Manual)</p> <p>WARNINGS section, Sections 2-5, 3-3, 3-4, 3-5, 3-6 and 3-7</p> <p>57201 (115 and 230V Operation Manual): WARNINGS section, Sections 3-3, 3-4, 3-5, 3-6 and 3-7</p>	<p>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.</p>
<p>56201 (115 and 230V Operation & Technical Manual) 57299 (100V Operation & Technical Manual)</p> <p>CAUTIONS section, Sections 1-1, 1-5, 2-5, 3-3, 3-6, and 3-7</p> <p>57201 (115 and 230V Operation Manual) 57259 (100V Operation Manual)</p> <p>CAUTIONS section, Sections 1-1, 1-5, 3-3, 3-6, and 3-7</p>	<p>CAUTION: Do not use GRADIENT VARIABLE MODE or GRADIENT VARIABLE 10C MODE without SMART MODE. 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) AUTO CONTROL MODE 2) GRADIENT 10C SMART MODE 3) GRADIENT VARIABLE SMART MODE</p>

<p>11978 (InnerCool Operation & Technical Manual): WARNINGS section, Sections 2-5, 3-3, 3-4, 3-5 and 3-6</p>	<p>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.</p> <p>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.</p>
<p>11978 (InnerCool Operation & Technical Manual): CAUTIONS section, Sections 1-2, 1-7, 2-5, 3-3 and 3-6</p>	<p>CAUTION: Do not use GRADIENT VARIABLE MODE without PROGRESSIVE MODE. 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"> 1. PATIENT TEMP CONTROL MODE 2. GRADIENT VARIABLE PROGRESSIVE MODE



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URGENT FIELD SAFETY NOTICE Response Form

Please complete this form after your facility has performed the instructions provided in the correction 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 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

