



URGENT FIELD SAFETY NOTICE

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

7/29/2019

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

For Attention of: Blanketrol II user

Details on affected devices: Blanketrol II Hyper-Hypothermia System, Models 222R and 222S, Parts 86006 (222R, 100V), 86106 (222R, 115V), 86109 (222R, 240V), 86165 (222S, 115V), 86206 (222R, 230V), 86265 (222S, 230V)

Affected Serial Numbers: Model 222R [REDACTED]
Model 222S [REDACTED]

Description of device: The BLANKETROL II Hyper-Hypothermia System is 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. 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:

Gentherm Medical, LLC
12011 Mosteller Road
Cincinnati, OH 45241

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



Stephanie Vocke
Quality and Regulatory Engineer

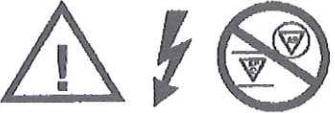


Appendix A: Blanketrol II Product Labels




BLANKETROL® II		
<p>DANGER: RISK OF EXPLOSION DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.</p> <p>SN</p> <p></p>	<p>222R</p> <p>11.6A 50/60Hz 100V~</p> <p>R134a</p>	<p></p> <p>DANGER: RISK OF ELECTRICAL SHOCK, DISCONNECT POWER BEFORE SERVICING.</p>
<p> CSZ Cincinnati Sub-Zero Cincinnati Sub-Zero Products, Inc. 12011 Mosteller, Cincinnati, Ohio, U.S.A. 45241 (513) 772-8810 e-mail: cszno@cszco.com</p> <p>56628-J</p>		

N/A

BLANKETROL® II		
<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> <p></p>	<p>222R</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></p> <p>DANGER: RISK OF ELECTRICAL SHOCK, DISCONNECT POWER BEFORE SERVICING.</p>
<p> CSZ Cincinnati Sub-Zero Cincinnati Sub-Zero Products, Inc. 12011 Mosteller, Cincinnati, Ohio, U.S.A. 45241 (513) 772-8810 e-mail: cszinc@cszinc.com</p> <p>56628-L</p>		

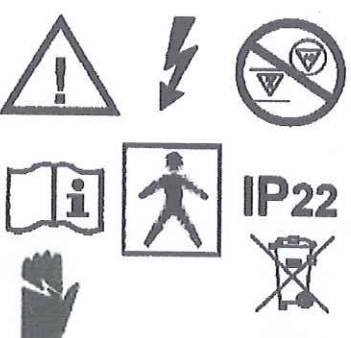
N/A

BLANKETROL® II		
<div style="border: 1px solid black; padding: 2px; display: inline-block;">SN</div> <div style="border: 1px solid black; height: 30px; width: 100%;"></div>	222R 5.2A 230V~ 50/60Hz TEMP. CLASS N R134a (15 oz.)	 
<div style="display: flex; justify-content: space-between; align-items: center;"> <div> CE 0344 </div> <div style="text-align: center;">  Cincinnati Sub-Zero Cincinnati Sub-Zero Products, Inc. <small>12011 Mosteller, Cincinnati, Ohio, U.S.A. 45241 (513) 772-8810</small> <small>e-mail: cszinc@cszinc.com</small> </div> <div> <small>50684-N</small> </div> </div>		

BLANKETROL® II		
<div style="border: 1px solid black; padding: 2px; display: inline-block;">SN</div> <div style="border: 1px solid black; height: 30px; width: 100%;"></div>	222R 5A 240V~ 50/60Hz TEMP. CLASS N R134a (15 oz.)	 
<div style="display: flex; justify-content: space-between; align-items: center;"> <div> CE 0344 </div> <div style="text-align: center;">  Cincinnati Sub-Zero Cincinnati Sub-Zero Products, Inc. <small>12011 Mosteller, Cincinnati, Ohio, U.S.A. 45241 (513) 772-8810</small> </div> <div> <small>50684-N</small> </div> </div>		

<h1>BLANKETROL® II</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: 30px; width: 100%;"></div>	<p>REF 222S</p> <p>10.2A 115V~ 50/60Hz</p> <p>REFRIGERANT R134a 15oz.</p> <p>DESIGN PRESSURES HIGH SIDE 240 PSIG LOW SIDE 240 PSIG</p>	 <p>IP22</p>
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;"> <p>CLASSIFIED  16HV</p> <p>MODEL 222S 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, IEC60601-1-2, AND CAN/CSA-C22.2 No. 601.1</p> </div> <div style="text-align: center;">  Cincinnati Sub-Zero Cincinnati Sub-Zero Products, Inc. 12011 Mosteller, Cincinnati, Ohio, U.S.A. 45241 (513) 772-8810 e-mail: cszinc@cszinc.com </div> <div style="text-align: right;"> <p>DANGER: RISK OF ELECTRICAL SHOCK, DISCONNECT POWER BEFORE SERVICING.</p> <p>CE 0344</p> <p>57037-C</p> </div> </div>		

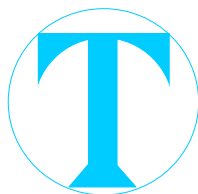
N/A

<h1>BLANKETROL® II</h1>		
<p>DANGER: RISK OF EXPLOSION DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.</p> <p>DANGER: RISK OF ELECTRICAL SHOCK, DISCONNECT POWER BEFORE SERVICING.</p> <p>SN</p> <div style="border: 1px solid black; height: 30px; width: 100%;"></div>	<p>REF 222S</p> <p>5.2A 230V~ 50/60Hz</p> <p>REFRIGERANT R134a 15oz.</p> <p>DESIGN PRESSURES HIGH SIDE 240 PSIG LOW SIDE 240 PSIG</p>	 <p>IP22</p>
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;"> <p>CLASSIFIED  16HV</p> <p>MODEL 222S 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, IEC60601-1-2, AND CAN/CSA-C22.2 No. 601.1</p> </div> <div style="text-align: center;">  Cincinnati Sub-Zero Cincinnati Sub-Zero Products, Inc. 12011 Mosteller, Cincinnati, Ohio, U.S.A. 45241 (513) 772-8810 website: cszmedical.com e-mail: cszinc@cszinc.com </div> <div style="text-align: right;"> <p>CE 0344</p> <p>57038-B</p> </div> </div>		

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Appendix B: Blanketrol III Hyper-Hypothermia System Manual Updates

Affected Manual	Updates
Changes are designated in RED See updated manual(s) for more details.	
<p>✓ 56230 (222R Operation and Technical Manual): WARNINGS section</p> <p>✓ 57126 (222R Operation Manual): WARNINGS section</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 condition of areas in contact with blanket; also, check blanket water temperature. Pediatric, temperature-sensitive, patients with vascular disease and operating room patients 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 judgment 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>✓ 57947 (222S Operation and Technical Manual): WARNINGS section, Sections 2-4, 3-2, 3-3, and 3-4</p> <p>✓ 56277 (222S Operation Manual): WARNINGS section, Sections 3-2, 3-3 and 3-4</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 the physician, check patient's temperature and skin integrity of areas in contact with blanket; also, check the BLANKETROL II's water temperature. Pediatric patients, temperature-sensitive patients with vascular disease, surgical patients, diabetics and patients with Raynaud's Disease 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>✓ 57947 (222S Operation and Technical Manual): WARNINGS section and Section 2-4</p> <p>✓ 56277 (222S Operation Manual): WARNINGS section</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 judgment 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>



THERMAL INTERNATIONAL (S) PTE LTD

1 Commonwealth Lane #07-13 One Commonwealth Singapore 149544

Tel: (65) 6225291 Fax: (65) 62234569

Co. Reg. No.: 197600551C

FIELD SAFETY NOTICE Customer Response Form

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

Return the completed form (via email) to:

Email: **sales@thermal.com.sg**

Attn.: Melissa Thia

To: Thermal International (S) Pte Ltd

Contact: 6225 2911 (office) / 9732 6283 (mobile)

FIELD SAFETY NOTICE

Reference: Blanketrol II hyper-hypothermia system, model 222R and model 222S
FA2019-004, 010 / Correction

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.
- ☐ I have notified all relevant Head of Departments and Chairman Medical Board.
- ☐ I have identified the affected device and shall follow the field safety notice
"Instructions To Customers"

Comments:

Acknowledged by:

Name

Designation

Department stamp

Date