



THERMAL INTERNATIONAL (S) PTE LTD

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Co. Reg. No. 197600551C GST Reg. No. M2-0023830-3

25 July 2019

Urgent Field Safety Notice

FA2019-005 / Correction / Cincinnati Sub-Zero

Norm-O-Temp hyperthermia system, model 111W

Affected serial numbers are: 091-N6646 to 193-N7940

On 22 July 2019, an urgent field safety notice was sent by the manufacturer, Cincinnati Sub-Zero / Gentherm Medical, LLC.

The purpose is to advise all users of the Norm-O-Temp hyperthermia system, model 111W, that **warnings have been clarified stating that exceeding 40° C water temperature for extended periods may cause tissue damage.**

This communication and the manufacturer field safety notice, including attachments are sent to you via email. The specific changes on warnings are found in the manufacturer letter – see Appendix: Norm-O-Temp Hyperthermia System Manual Updates.

The email attachments include updated manuals for the Norm-O-Temp system, model 111W. Operation Manual is for users (clinicians, nurses, technicians) and Operation And Technical Manual for BME department.

There is a one page attachment (extracted from page 4 of the Operator Manual), which clarifies the specific changes on warnings. Ensure all users in your organisation are aware of the changes on warnings, especially your anaesthetists and physicians, who order use of this warming system.

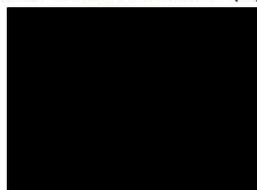
Access the updated manuals and ensure the obsolete manuals are removed from service. Please continue to read and understand all the WARNINGS and CAUTIONS printed in the manuals to ensure your patients safety when using the system. Kindly communicate with us should you need hard copies of the manuals or further explanation of this field safety notice.

Sincerely,

For and on behalf of Thermal International (S) Pte Ltd



Melissa Thia
Senior Sales Executive



email: sales@thermal.com.sg

URGENT FIELD SAFETY NOTICE

Norm-O-Temp Hyperthermia System FA2019-005 Correction

7/22/2019

Attention:

Details on affected devices:

Norm-O-Temp Hyperthermia System, Models 111Z and 111W

Affected Serial Numbers are: Model 111Z (113-0001N - 193-0824N)

Model 111W (091-N6646 - 193-N7940)

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 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 FA2019-005@gentherm.com, or mail to:

Gentherm Medical, LLC
12011 Mosteller Road
Cincinnati, OH 45241

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.

Please transfer this notice to other organizations on which this action has an impact.

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.

12011 Mosteller Road Cincinnati OH 45241

P 1.513.772.8810 F 1.513.772.9119 www.gentherm.com



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.

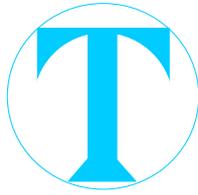
Sincerely,


Stephanie Vocke
Quality and Regulatory Engineer

Appendix: Norm-O-Temp Hyperthermia System Manual Updates

Affected Manual	Updates
<p>Changes are designated in RED See updated manual(s) for more details.</p>	
<p>57225 (111Z 115V Operation and Technical Manual): WARNINGS section N/A</p> <p>59225 (111Z 230V Operation and Technical Manual): WARNINGS section N/A</p> <p>56430 (111W 230V Operation and Technical Manual): WARNINGS section</p>	<p>WARNING: A physician's order is required for the use of the device and setting the temperature of the blanket/pad. At least every 20 minutes, or as directed by physician, check patient's temperature and skin condition of areas in contact with blanket/pad; also, check blanket/pad water temperature. Pediatric patients, temperature-sensitive patients with vascular disease, surgical patients and diabetic 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. If patient's temperature does not reach desired set point or differs drastically from recommended set point, notify physician. Notify the physician promptly of any change in patient status in order to avoid serious injury or death.</p> <ol style="list-style-type: none"> 1. Pediatrics – Infants' and children's body temperatures are often more responsive to surface heating and cooling than adults. Due to their size, the effect of heating or cooling a child is likely more pronounced because of their higher ratio of skin contact area to body mass. 2. Temperature Sensitive Patients – Patients with impaired peripheral blood circulation and patients who are incapacitated may be more sensitive to temperature changes than patients with normal circulation. 3. Surgical Patients – Patients with poor circulation due to inadequate heart function, loss of blood, or impaired peripheral blood circulation may be more sensitive to temperature changes. <p>WARNING: The method of temperature control provided by all hyperthermia units presents the danger of heating body tissues, particularly the skin, to a point where they are injured. 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 base on patient age, clinical condition, and current medications. Avoid placing additional heating or cooling sources between the patient and blanket/pad. Depending on the extent and severity of a burn, very serious and even fatal complications may arise.</p>
<p>57425 (111Z 115V Operation Manual): WARNINGS section N/A</p> <p>59425 (111Z 230V Operation Manual): WARNINGS section N/A</p> <p>57127 (111W 230V Operation Manual): WARNINGS section</p>	<p>WARNING: A physician's order is required for the use of the device and setting the temperature of the blanket/pad. At least every 20 minutes, or as directed by physician, check patient's temperature and skin condition of areas in contact with blanket/pad; also, check blanket/pad water temperature. Pediatric patients, temperature-sensitive patients with vascular disease, surgical patients and diabetic 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. If patient's temperature does not reach desired set point or differs drastically from recommended set point, notify physician. Notify the physician promptly of any change in patient status in order to avoid serious injury or death.</p> <ol style="list-style-type: none"> 1. Pediatrics – Infants' and children's body temperatures are often more responsive to surface heating and cooling than adults. Due to their size, the effect of heating or cooling a child is likely more pronounced because of their higher ratio of skin contact area to body mass.

	<p>2. Temperature Sensitive Patients – Patients with impaired peripheral blood circulation and patients who are incapacitated may be more sensitive to temperature changes than patients with normal circulation.</p> <p>3. Surgical Patients – Patients with poor circulation due to inadequate heart function, loss of blood, or impaired peripheral blood circulation may be more sensitive to temperature changes.</p> <p>WARNING: The method of temperature control provided by all hyperthermia units presents the danger of heating body tissues, particularly the skin, to a point where they are injured. 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 base on patient age, clinical condition, and current medications. Depending on the extent and severity of a bum, very serious and even fatal complications may arise.</p>
<p>50203 (111W 115V Operation and Technical Manual): WARNINGS section N/A</p>	<p>WARNING: A physician's order is required for setting 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, or if the patient's temperature is not responding properly, or does not reach the prescribed temperature in the prescribed time, or there is a change in the prescribed temperature range. Failure to inform the physician of the deviation may result in injury to the patient.</p> <p>WARNING: The method of temperature control provided by all hyperthermia units present the danger of heating body tissues, particularly the skin, to a point where they are injured, i.e., burns. 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 base on patient age, clinical condition, and current medications. Depending on the extent and severity of a bum, very serious and even fatal complications may arise.</p>



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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**

Attention : Melissa Thia

To : Thermal International (S) Pte Ltd

Contact : 6225 2911 (office) XXXXXXXXXX

FIELD SAFETY NOTICE

Reference: Norm-O-Temp hyperthermia system, model 111W
FA2019-005 / 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 devices and shall follow the field safety notice "Instructions To Customers".

Comments:

Acknowledged by

Name

Designation

Department stamp

Date