A GENTHERM COMPANY

Corporate Office
12011 Mosteller Road
Cincinnati, Ohio 45241-1528

Tel 513-772-8810
Fax 513-772-9119
www.genthermcsz.com

URGENT FIELD SAFETY NOTICE

Norm-O-Temp Hyperthermia System
FA2019-005
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: Norm-O-Temp user

Details on affected devices: Norm-O-Temp Hyperthermia System, Models 111Z and 111W, Parts 86153 (111Z, 100V), 86154 (111Z, 115V), 86156 (111W, 100V), 86157 (111W, 115V), 86158 (111W, 230V), 86161 (111W, 240V)
Affected Serial Numbers: **Model 111Z (113-0001N – 193-0824N)**
Model 111W (091-N6646 – 193-N7940)

Description of device: The Norm-O-Temp hyperthermia system is used to raise and/or maintain a patient's 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 FA2019-005@gentherm.com, or mail to:

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Cincinnati, OH 45241

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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,

[redacted]

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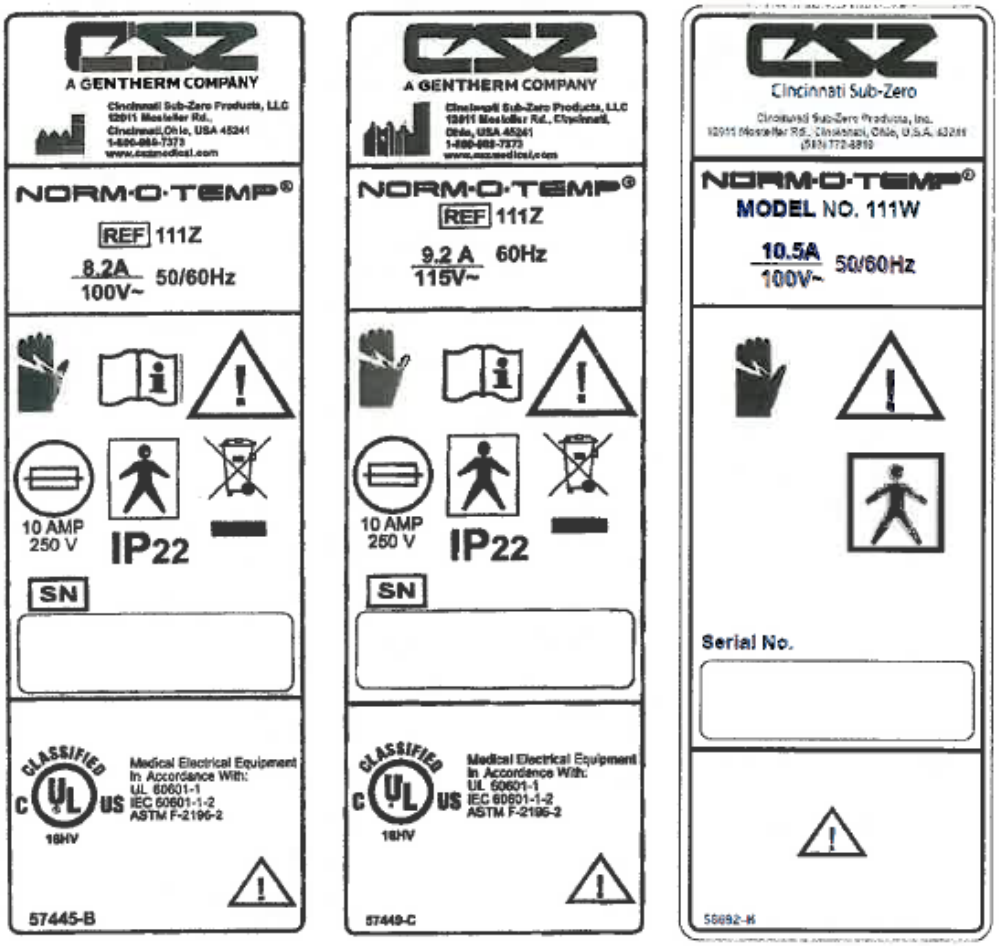
Appendix A: Norm-O-Temp Product Labels



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Appendix B: Norm-O-Temp Hyperthermia System Manual Updates

Affected Manual	Updates
Changes are designated in RED **See updated manual(s) for more details.**	
57225 (111Z 115V Operation and Technical Manual): **WARNINGS section** **59225** (111Z 230V Operation and Technical Manual): **WARNINGS section** **56430** (111W 230V Operation and Technical Manual): **WARNINGS section**	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. 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. 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.

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57425 (111Z 115V Operation Manual): **WARNINGS section** **59425** (111Z 230V Operation Manual): **WARNINGS section** **57127** (111W 230V Operation Manual): **WARNINGS section**	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. 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. 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 burn, very serious and even fatal complications may arise.
56203 (111W 115V Operation and Technical Manual): **WARNINGS section**	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. 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 burn, very serious and even fatal complications may arise.

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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 FA2019-005@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	

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