THERMAL INTERNATIONAL (S) PTE LTD
1 Commonwealth Lane #07-13 One Commonwealth Singapore 149544
Tel: (65) 6225 2911 Fax: (65) 6223 4569
Co. Reg. No. 197600551C GST Reg. No. M2-0023830-3

19 August 2019

URGENT FIELD SAFETY NOTICE

Blanketrol III hyper-hypothermia system, model 233

FA2019-004, 010 correction

Affected serial numbers model 233: [redacted]

On 13 August 2019, we received an urgent field safety notice from the manufacturer, Gentherm Medical, LLC (formerly Cincinnati Sub-Zero).

One of the affected devices is the Blanketrol III system, model 233. The device is used to lower or raise a patient's temperature and/or maintain a desired patient temperature through conductive heat transfer.

Purpose of the field safety notice is to advise users that **warnings have been clarified stating that exceeding 40°C (water temperature) for extended periods may cause tissue damage**.
Additionally, a **caution was added and clarifications were made regarding the use of the Automatic modes**.

Please read the enclosed manufacturer's field safety notice, Appendix A and Appendix B.

Download the updated manuals and ensure obsolete manuals are removed from service. Physical copies are available when requested.

Ensure all users in your organisation including clinicians and relevant Head of Departments and Chairman Medical Board are aware of this field safety notice.

Download the list of affected units and check the serial numbers. Let us know if any of the affected unit is no longer in service.

Please complete and return us the Customer Response Form to acknowledge receipt of this notification; that you have performed and completed the requested actions in the manufacturer's field safety notice. Kindly return the form by email to sales@thermal.com.sg or fax to 62234569.

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cont. -

URGENT FIELD SAFETY NOTICE

Blanketrol III hyper-hypothermia system, model 233

FA2019-004, 010 correction

Affected serial numbers model 233: [redacted]

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

[redacted] [redacted]

Melissa Thia
Senior Sales Executive
[redacted]
email: sales@thermal.com.sg

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

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)

[redacted]

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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12011 Mosteller Road
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Tel 513-772-8810
Fax 513-772-9119
www.genthermcsz.com

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,

[redacted]

Stephanie Vocke
Quality and Regulatory Engineer

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Cincinnati, Ohio 45241-1528

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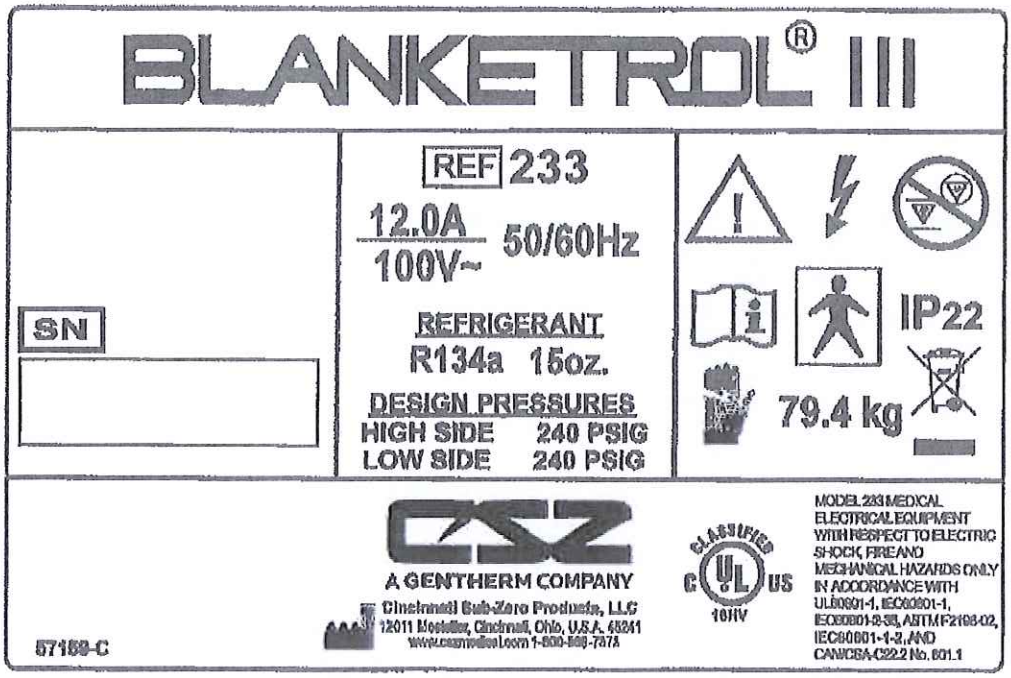
Fax 513-772-9119
www.genthermcsz.com

Appendix A: Blanketrol III Product Labels



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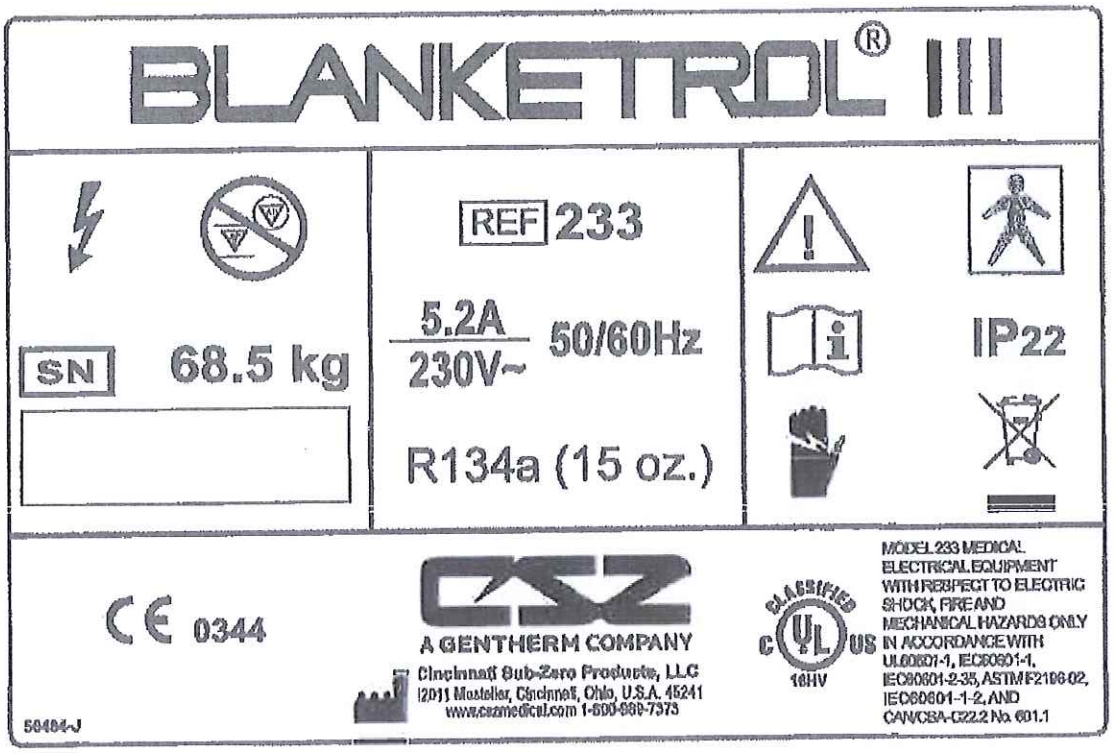

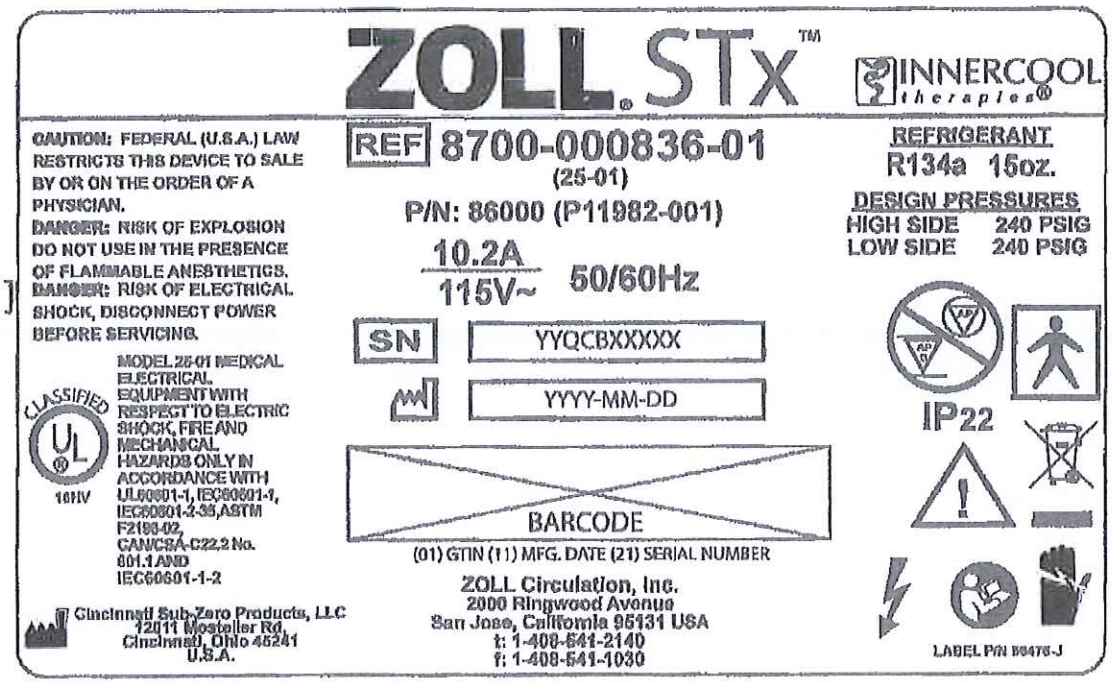

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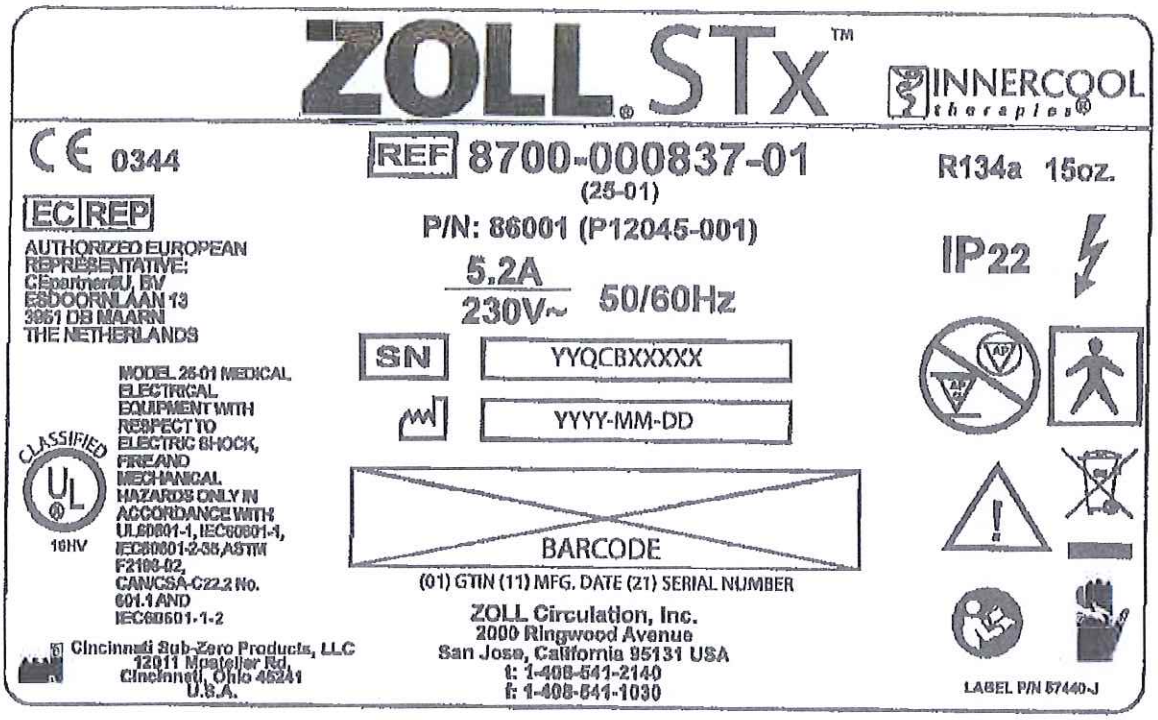

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Appendix B: Blanketrol III Hyper-Hypothermia System Manual Updates

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

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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

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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 or fax) to:

Email:	**sales@thermal.com.sg**		
To:	Thermal International (S) Pte Ltd		
Attn.:	Melissa Thia	[redacted]	
Tel:	6225 2911	Fax:	6223 4569

FIELD SAFETY NOTICE

Reference: Blanketrol III hyper-hypothermia system, model 233
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 and Designation Signature

_____ _____
Department stamp Date