URGENT Medical Device Recall
Electri-Cool II Cooling System
Third Notice

1/19/2022

Dear User,

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

Electri-Cool II Cooling System, Manual
Affected Serial Numbers are: (164-76703084 Through 213-76703694)

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

The Electri-Cool® II, Model 767 Portable Cold Therapy Unit is used to provide cold therapy immediately following the surgical procedure at the wound site. The system is composed of a water reservoir, a thermoelectric sub-assembly, a circulating pump, a micro-processor control board, a fan and a local therapy pad.

This recall has been initiated to provide a labeling update with revised instruction how to operate the Electri-Cool II unit with Cold Therapy pads. You will be notified when an updated manual is available.

There is a potential slip risk when using the Electri-Cool II unit with Cold Therapy pads due to water overflow in the reservoir. Instructions on how to use the Cold Therapy Pad to reduce this risk are included in Appendix B and outlined below. These instructions are also included in Electri-Cool II manual.

Pad Instructions:
***red text is an addition to the manual**

1. Read and understand operation manual before connecting pad to Electri-Cool® II.
2. Read and understand pad application instructions accompanying GENTHERM pad.
3. Connect hose to unit by inserting connectors on hose into connectors on unit. Connectors should "click" as they lock together.
4. Apply pad to patient and attach pad to hose by inserting connectors on pad into hose connectors. Normal use of the pad is to be applied in direct contact with the patient. Pad may be used over or under a patient, in the flat state or wrapped around patient.
5. Turn unit "ON" and set to temperature.
6. After pad has filled, check water level in unit. Add sterile water or water that has been passed through a filter less than or equal to 0.22 microns, only if necessary.
7. When therapy needs to be paused, disconnect the pad from the Electri-Cool II and allow the unit to continue to run. NOTE: Reconnect the pad when ready to resume therapy.
8. When therapy is no longer needed disconnect pad from hose by pressing metal clips. Dispose of pad.
9. Turn unit "OFF" at the power switch and unplug the power cord from the outlet

12011 Mosteller Road Cincinnati OH 45241
P 1.513.772.8810 F 1.513.772.9119 www.gentherm.com

INSTRUCTIONS TO CUSTOMERS:

1) Immediately examine your inventory and add this letter and/or Appendix B to Electri-Cool II manual.
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 FA2021-012@gentherm.com, or mail to:

   Gentherm Medical, LLC
   12011 Mosteller Road
   Cincinnati, OH 45241

This recall should be carried out to the user level. Your assistance is appreciated and necessary to reduce potential slip risk. If you have any questions call Gentherm Medical Technical Support at 1-888-437-5608.

Any adverse events experienced relating to Electri-Cool II devices, should also be reported to the FDA's MedWatch Program:
Phone: +1(800)FDA-1088
Web: www.fda.gov/medwatch/report.htm

Sincerely,

Stephanie Vocke
Quality Engineering Supervisor

Recall Response Form

Please complete this form after the instructions provided in the recall 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 FA2021-012@gentherm.com.

Please check ALL appropriate boxes.

☐ I have read and understand the field notification instructions.

☐ I have checked my inventory and my facility has _____affected Electri-Cool II devices.

Please list your Electri-Cool II serial numbers:

☐ I have informed all users of the content in this letter.

Signature _____ Date _____

Printed Name _____ Email Address _____

Facility Name _____ Facility Address, City, State, Zip Code _____

Phone Number _____

Distributors Only:

☐ I have identified and notified my customers that were shipped or may have been shipped this product by;

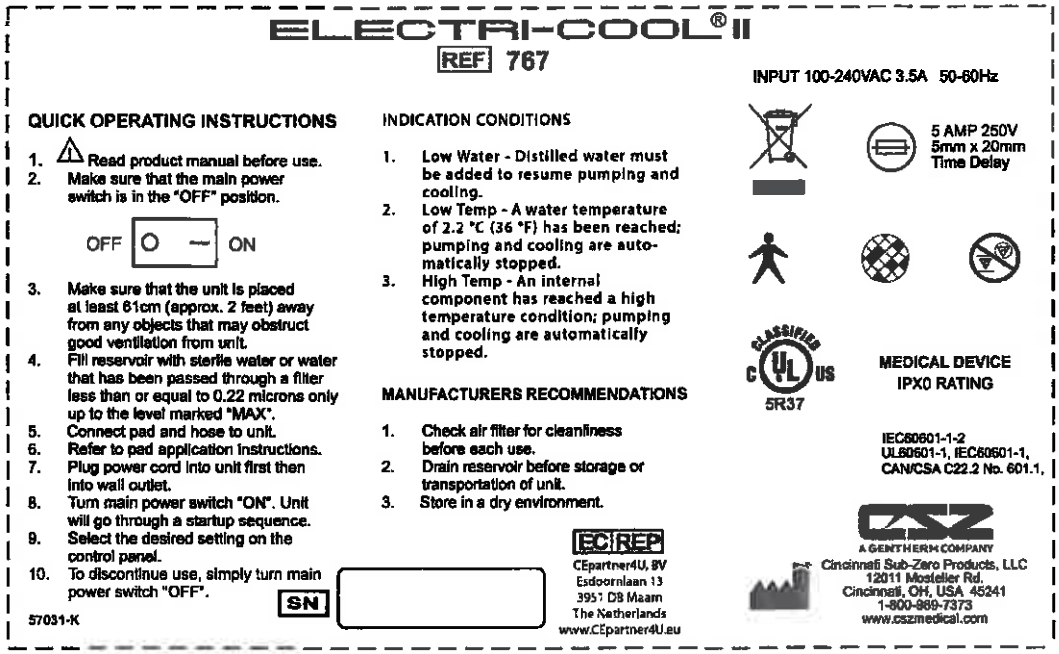
(Specify date and method of notification)

OR

☐ Attached is a list of customers who received/may have received this product. I would like Gentherm Medical to notify my customers.

Return the form by fax or e-mail.
E-mail: FA2021-012@gentherm.com
Fax: 513-772-9119

Appendix A: Electri-Cool II Product Label



Appendix B: Electri-Cool II Manual Addition

Pad Instructions:

***red text is an addition to the manual**

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2. Read and understand pad application instructions accompanying GENTHERM pad.
3. Connect hose to unit by inserting connectors on hose into connectors on unit. Connectors should "click" as they lock together.
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8. When therapy is no longer needed disconnect pad from hose by pressing metal clips. Dispose of pad.
9. Turn unit "OFF" at the power switch and unplug the power cord from the outlet