

## **URGENT Medical Device Recall Electri-Cool II Cooling System Second Notice**

12/20/2021

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. Gentherm will also be adding these instructions to the 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](mailto: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](http://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](mailto: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](mailto:FA2021-012@gentherm.com)  
Fax: 513-772-9119


## Appendix A: Electri-Cool II Product Label

**ELECTRI-COOL® II**  
**REF 767**

INPUT 100-240VAC 3.5A 50-60Hz

**QUICK OPERATING INSTRUCTIONS**

1.  Read product manual before use.
2. Make sure that the main power switch is in the "OFF" position.

OFF  ON

3. Make sure that the unit is placed at least 61cm (approx. 2 feet) away from any objects that may obstruct good ventilation from unit.
4. Fill reservoir with sterile water or water that has been passed through a filter less than or equal to 0.22 microns only up to the level marked "MAX".
5. Connect pad and hose to unit.
6. Refer to pad application instructions.
7. Plug power cord into unit first then into wall outlet.
8. Turn main power switch "ON". Unit will go through a startup sequence.
9. Select the desired setting on the control panel.
10. To discontinue use, simply turn main power switch "OFF".

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**INDICATION CONDITIONS**

1. Low Water - Distilled water must be added to resume pumping and cooling.
2. Low Temp - A water temperature of 2.2 °C (36 °F) has been reached; pumping and cooling are automatically stopped.
3. High Temp - An internal component has reached a high temperature condition; pumping and cooling are automatically stopped.

**MANUFACTURERS RECOMMENDATIONS**

1. Check air filter for cleanliness before each use.
2. Drain reservoir before storage or transportation of unit.
3. Store in a dry environment.

**SN**

**ECIREP**  
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Esdoornlaan 13  
3951 DB Maarn  
The Netherlands  
www.CEpartner4U.eu

**UL**  
CLASSIFIED  
C UL US  
5R37

**MEDICAL DEVICE  
IPX0 RATING**

IEC60601-1-2  
UL60801-1, IEC60601-1,  
CAN/CSA C22.2 No. 601.1.

**CSZ**  
A GENTHERM COMPANY  
Cincinnati Sub-Zero Products, LLC  
12011 Mosler Rd.  
Cincinnati, OH, USA 45241  
1-800-999-7373  
www.cszmedical.com

## Appendix B: Electri-Cool II Manual Addition

### Pad Instructions:

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