

## **URGENT Medical Device Recall Hemotherm CE Dual Reservoir Cooler/Heater Model 400CE, 115V**

6/17/2021

Dear Perfusionists and BioMedical Engineering,

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

Hemotherm CE Dual Reservoir Cooler/Heater Model 400CE, 115V Manual,  
**Affected Serial Numbers are:** (092-10011CE – 212-11511CE)

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

The Hemotherm® (Model 400CE) Dual Reservoir Cooler/Heater is used to lower, maintain, or raise the temperature of the water flowing through a Blood Oxygenator / Heat Exchanger that is used to cool or warm blood during cardiopulmonary bypass procedures lasting 6 hours or less. The Hemotherm Dual Reservoir Cooler/Heater may also be used with a hyper / hypothermia blanket under the patient to provide warming through conductive heat transfer.

This recall has been initiated to provide a labeling update with additional guidance on the disinfection process for the Hemotherm CE and accessories.

There is a potential risk of device contamination and patient infection associated with the use of the Hemotherm CE devices because of the potential for organisms (including Nontuberculous mycobacteria (NTM)) to grow in the water systems of any heater-cooler device, and contaminated water from any heater-cooler device has the potential to aerosolize into the operating room during surgery which could lead to patient infection. Suggested mitigations to reduce this risk are outlined below and further validation of cleaning and disinfection will be completed. Any updates to cleaning and disinfection procedures will be communicated.

Suggested mitigations to reduce the risk of contamination include:

- Do not use tap water to rinse, fill, refill, or top-off heater-cooler water tanks since this may introduce NTM organisms. Use only sterile water or water that has been passed through a filter of less than or equal to 0.22 microns.
- Use new accessories, tubing, and connectors to prevent possible recontamination when using a different heater-cooler device.
- Immediately remove from service heater-cooler devices that show discoloration or cloudiness in the fluid lines/circuits. This may indicate contamination.
- If you have continued concerns about device contamination or you have a device taken out of service due to contamination please contact Medical Technical Service at [medtechsupport@gentherm.com](mailto:medtechsupport@gentherm.com) and 1-888-437-5608.

12011 Mosteller Road Cincinnati OH 45241

**P** 1.513.772.8810 **F** 1.513.772.9119 [www.gentherm.com](http://www.gentherm.com)

**INSTRUCTIONS TO CUSTOMERS:**

- 1) Immediately examine your inventory, access updated manuals and ensure obsolete manuals are removed from service.
- 2) Updated manuals may be accessed via [www.gentherm.com](http://www.gentherm.com) or physical copies may be requested from Gentherm Medical, LLC at 1-888-437-5608.
- 3) 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.  
*For your convenience, the additional guidance on the disinfection process for the Hemotherm CE is attached.*
- 4) 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 [FA2021-004@gentherm.com](mailto:FA2021-004@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 provide a more robust cleaning and disinfection procedure. If you have any questions call Gentherm Medical Technical Support at 1-888-437-5608.

Any adverse events experienced relating to Hemotherm 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)

This recall is being made with the knowledge of the Food and Drug Administration.

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 [FA2021-004@gentherm.com](mailto:FA2021-004@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 Hemotherm devices.

Please list your Hemotherm serial numbers:

|  |  |  |
|--|--|--|
|  |  |  |
|  |  |  |
|  |  |  |

- I have replaced our current Hemotherm Operation & Technical Manual and Operation Manual with the updated manuals.

\_\_\_\_\_  
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

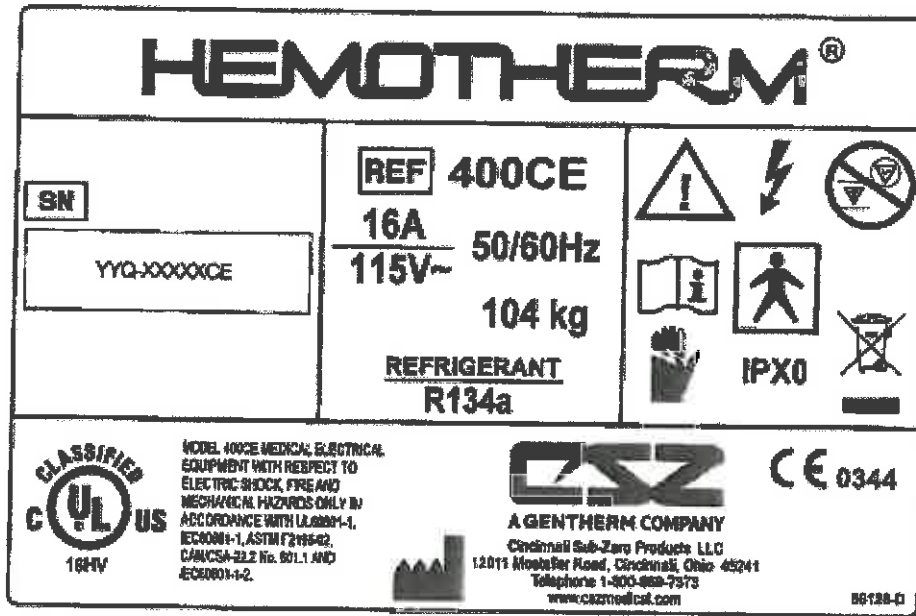
- Attached is a list of customers who received/may have received this product. I would like Gentherm Medical to notify my customers.

**Return the form by fax or e-mail.**

**E-mail:** [FA2021-004@gentherm.com](mailto:FA2021-004@gentherm.com)

**Fax:** 513-772-9119

## Appendix A: Hemotherm 400CE Product Label



## Appendix B: Summary of Hemotherm 400CE Manual Updates

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- If you have continued concerns about device contamination, please contact Medical Technical Service at [medtechsupport@gentherm.com](mailto:medtechsupport@gentherm.com) and 1-888-437-5608.