

**URGENT FIELD SAFETY NOTICE**  
**UV Treo™ Advanced Temperature Management System**  
**FSCA FA2021-003**  
**Correction**

02-Jul-2021

Attention: Distributors, Service Representatives and Users of the UV Treo™ System

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

UV Treo™ Advanced Temperature Management System, Model 404M ("UV Treo") with serial numbers as identified below:

171-0101UVT, 171-0102UVT, 173-0103UVT, 173-0104UVT,  
193-0105UVT, 193-0106UVT, 193-0107UVT, 193-0108UVT,  
193-0109UVT, 194-0110UVT, 194-0111UVT, 194-0112UVT,  
194-0113UVT, 194-0114UVT, 194-0115UVT, 194-0116UVT,  
201-0117UVT, 201-0118UVT, 201-0119UVT, 201-0120UVT,  
201-0121UVT, 201-0122UVT, 201-0123UVT, 201-0124UVT,  
201-0125UVT, 201-0126UVT, 201-0127UVT, 201-0128UVT,  
201-0129UVT, 201-0130UVT, 201-0131UVT, 201-0132UVT,  
201-0133UVT, 201-0134UVT, 201-0135UVT, 201-0136UVT,  
202-0138UVT, 202-0140UVT

UV Treo™ Advanced Temperature Management System is indicated for use to raise, lower or maintain the temperature of water flowing through a heat exchanger during cardiopulmonary bypass procedures. It may also be used with a hyper/hypothermia blanket.

Gentherm Medical, LLC ("Gentherm") has identified that the UV Treo is causing interference displayed on ECG (also referred to as EKG) monitors when UV Treo and an ECG monitor are electrically connected to a patient at the same time. Possible risk to patient includes loss of appropriate therapy, indeterminate injury or life-threatening situations.

**INSTRUCTIONS TO DISTRIBUTORS AND/OR SERVICE REPRESENTATIVE:**

- 1) Immediately examine your inventory and quarantine affected product.
- 2) Ensure that all users are informed of the content of this letter. If you have further distributed this product, please provide those accounts with a copy of this notice.
- 3) Your distributor will contact you to coordinate receipt/installation of the necessary kit.
- 4) Please follow all instructions in the kit. Once the kit has been installed please complete and return the enclosed response form provided in this letter as soon as possible to acknowledge receipt of this notification and to inform Gentherm Medical, LLC that you have performed the requested actions.

12011 Mosteller Road Cincinnati OH 45241

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



**Transmission of this Field Safety Notice:**

This notice should 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.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

**Contact reference person:**

[REDACTED]  
Gentherm Medical, LLC  
12011 Mosteller Road

[REDACTED]  
1-513-719-3262

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.

Sincerely,

[REDACTED]

[REDACTED]  
Quality Engineering Supervisor  
Gentherm Medical, LLC



## URGENT FIELD SAFETY NOTICE

### Response Form

Please complete this form after your facility has performed the instructions provided in the 02-Jul-2021 correction letter. Return the completed form by mail to Gentherm Medical, LLC, 12011 Mosteller Road, Cincinnati, OH 45241, or scan and e-mail to [FA2021-003@gentherm.com](mailto:FA2021-003@gentherm.com)

**Please check ALL appropriate boxes.**

- ☐ I have read and understand the field notification instructions.
- ☐ My device(s) has been corrected

Please list UV Treo serial number(s) of corrected device(s).

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|                        |  |
|------------------------|--|
| _____<br>Signature     | _____<br>Date                                    |
| _____<br>Printed Name  | _____<br>Email Address                           |
| _____<br>Facility Name | _____<br>Facility Address, City, State, Zip Code |
| _____<br>Phone Number  |  |

Return the form by fax or e-mail.

E-mail: [FA2021-003@gentherm.com](mailto:FA2021-003@gentherm.com)

Fax: 513-772-9119