

## **URGENT**

# **Medical Device Field Action**

Pradeep Gupta  
Director of Quality and Regulatory Compliance  
Cincinnati Sub-Zero Products, Inc.  
12011 Mosteller Road  
Cincinnati, OH 45251

April 22, 2010

**REF:** ECMO Heater Models 333 & 333W Field Action

To Whom It May Concern:

This is to inform you of a field action involving the following products:

- **ECMO Heater Model 333 Device**
  - **Affected Serial Numbers Range: 864-E1180 through 924-E2528**
- **ECMO Heater Model 333W Device**
  - **Affected Serial Numbers Range: 942-E2979 through 031-E5150**

Note: CSZ serializes the ECMO Heater devices beginning with the last two digits of the year manufactured, followed by the quarter of manufacture, the letter "E" and then a sequential number. For example, a unit with serial number 031-E5150 was manufactured in the first quarter of 2003 with a sequential number of 5150.

This field action has been initiated because Cincinnati Sub-Zero Products, Inc. (CSZ) has discovered a problem with ECMO Heater devices manufactured prior to serial number 033-E5286. CSZ discovered that, on those devices, the probe jack contacts (terminals) are located too close to the solid state relay contacts (terminals), which could lead to these terminals coming into contact with each another. If this occurs, the service technician, user, and/or patient could be exposed to electric shock (injury) during servicing and/or use.

One (1) incident, with no serious injury, has been reported related to this issue to date. However, as mentioned above, use of this product has the potential to cause an injury.

To prevent the probe jack terminals from coming into contact with the solid state relay terminals, CSZ has made a product improvement that incorporates a polycarbonate shroud for the solid state relay, which goes between the probe jack and the relay contacts (terminals), insulating the two (2) components from each other. All devices manufactured prior to serial number 033-E5286 require this shroud be installed. Your device(s) can be upgraded to include this shroud with the upgrade kit(s) that have been provided with this notification. The kit(s) include the following:

1. One (1) polycarbonate shroud that can be installed on each device to separate the probe jack and the relay contacts (terminals),
2. A detailed instruction sheet, in English, outlining shroud installation procedures, and
3. An Upgrade Confirmation Form that should be used to inform CSZ that your facility has completed the requested actions outlined in the shroud installation procedures.

## INSTRUCTIONS TO CUSTOMERS:

- 1) **Complete the FIELD ACTION RESPONSE FORM:** Please complete and return the enclosed field action response form as soon as possible to acknowledge receipt of this notification and to identify the ECMO Heater devices in your facility that require upgrade kit(s). Return the form by fax to (513)772-9119, scan and e-mail the information to [ECMOHeater2011@cszinc.com](mailto:ECMOHeater2011@cszinc.com), or mail to:  
Cincinnati Sub-Zero  
12011 Mosteller Road  
Cincinnati, OH 45241 U.S.A.
- 2) **Return all ECMO Heater devices to your Service Department:** Collect and return all affected ECMO Heater devices your facility is currently in possession of to your Biomedical Engineering and/or Service Department.
- 3) **Upgrade the Device(s):** Following the instructions included with the provided upgrade kit(s), install the polycarbonate shroud in all affected ECMO Heater devices your facility is in possession of. If your facility needs additional upgrade kit(s), please contact our ECMO Heater field action administrator by email at [ECMOHeater2011@cszinc.com](mailto:ECMOHeater2011@cszinc.com) or by phone at 1-800-989-7373 or (513) 772-8810 to request additional kits.
- 4) **Complete the CONFIRMATION FORM:** When your facility has completed the field upgrade, confirm installation of the polycarbonate shroud by completing and returning the confirmation form included in the kit(s) to CSZ.

If you are not the right person to receive this notification, please pass this on to the appropriate person. If you are no longer the owner of the device(s) please let us know. If you may have further distributed this product, please identify your customers and notify them at once of this field action on the ECMO Heater Models 333 & 333W devices. Your notification to your customers may be supported by including a copy of this field action letter.

We apologize for any inconvenience this may cause you and thank you for your cooperation. If you have any questions, please contact our ECMO Heater field action administrator listed below.

Sincerely,

*Pradeep Gupta*

Pradeep Gupta  
Director of Medical Quality and Regulatory Compliance

**Cc: ECMO Coordinator / Perfusionist (letter only)**

### ECMO Heater Field Action Administrator:

Kristiina Gilkey  
e-mail: [ECMOHeater2011@cszinc.com](mailto:ECMOHeater2011@cszinc.com)  
phone: 1-800-989-7373 or (513) 772-8810  
fax: (513) 772-9119



# Field Action Response Form

## ECMO Heater Models 333 & 333W

**Affected Serial Numbers: 864-E1180 through 924-E2528 (Model 333)  
942-E2979 through 031-E5150 (Model 333W)**

Please complete this form after your facility has performed the instructions provided in the April 22, 2011 field action letter. Return the completed form by fax to (513)772-9119, or scan and e-mail the information to [ECMOHeater2011@cszinc.com](mailto:ECMOHeater2011@cszinc.com), or mail to Cincinnati Sub-Zero, 12011 Mosteller Road, Cincinnati, OH 45241 U.S.A.

**Please check ALL appropriate boxes.**

- I have read and understand the field action instructions provided in the April 22, 2011 letter.
- My facility has \_\_\_\_\_ ECMO Heater devices.

(quantity)

List of device serial number(s):

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- I will have a trained service technician install the polycarbonate shroud on all the ECMO Heater devices my facility is in possession of.
- I have identified and notified my customers that were shipped or may have been shipped this product by \_\_\_\_\_; OR  
(specify date and method of notification)
- Attached is a list of customers (including contact information) who received/may have received this product. I would like CSZ to notify my customers.

Please check the appropriate box(es) to describe your facility/business:

- Hospital/Medical Facility       Laboratory       Other: \_\_\_\_\_
- Distributor       Sales Representative

\_\_\_\_\_  
Signature/Date

\_\_\_\_\_  
Facility Name

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Facility's Complete Shipping Address

\_\_\_\_\_  
Email Address

\_\_\_\_\_  
Phone Number



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Cincinnati Sub-Zero Products, Inc.  
12011 Mosteller Road  
Cincinnati, OH 45241-1528  
Attn: Quality Department, Medical Division

