

Cincinnati Sub-Zero Products, Inc.

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To: ECMO Centers

From: Mark Beran Vice President & General Manager

REF: Misusing Localized Heat Therapy for ECMO

Cincinnati Sub-Zero Products, Inc. (CSZ) recently became aware through the issuance of a MedWatch Report, that various hospitals domestically are incorrectly using the CSZ Micro-Temp product for ECMO therapy applications. Given the critical condition of a patient that is placed on ECMO, it is extremely dangerous to use localized heat therapy units in this application. The Micro-Temp Models SMS 2000, 727, and 737, and the Micro-Temp II, Model 747 are not intended for use as an ECMO Heater.

Localized heat therapy units whether manufactured by Cincinnati Sub-Zero or other manufacturers, have two distinct challenges when used for ECMO:

- **Temperature Control:** localized heat therapy units are designed to heat water delivered through a disposable pad. In this application, temperature regulation is not as important. In fact, temperatures vary up to 1.5C in localized heat therapy units. All manufacturers specify their units with broad temperature ranges.
- **Patient Monitor:** localized heat therapy units are not closed systems. The product has no monitoring capability to indicate the patient temperature. Patient monitoring is critical in an ECMO application where it is a necessity to precisely control the patient's temperature and indicate if a shift up or down in the patient's temperature occurs.

The CSZ Micro-Temp is designed and labeled appropriately as a localized heat therapy device, an application that requires far less precise temperature control than ECMO. Based on the design and the stated intended use, CSZ recommends that all impacted facilities discontinue the use of all Micro-Temp products for ECMO therapy.

Cincinnati Sub-Zero offers a product specifically designed for ECMO heating, the Model 333W. Unlike localized heat therapy units, the 333W has precise temperature control $\pm .1C$ and also has a temperature sensor that indicates swings in the patient's temperature. The ECMO product literature can be reviewed at www.cszinc.com. The CSZ Sales and Service Departments can also provide on-site training for your nursing and bio-medical teams on request.

Should you wish to pursue this product offering, please contact CSZ for further discussion at 1-800-989-7373.

Sincerely,

Mark Beran
Vice President and General Manager
Cincinnati Sub-Zero
Medical Division