



## ***THERMAL INTERNATIONAL (S) PTE LTD***

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*Co. Reg. No. 197600551C GST Reg. No. M2-0023830-3*

18-April-2017

### **Hemotherm dual reservoir cooler-heater communication**

On 23-October-2015, a safety communication notice was sent by Cincinnati Sub-Zero (CSZ), manufacturer of the Hemotherm cooler-heater devices. It was a FDA medical device safety communication regarding Nontuberculous Mycobacterium (NTM) Infections associated with heater-cooler devices. The FDA communication was to heighten awareness about infections associated with heater-cooler devices and steps healthcare providers and health facilities can take to mitigate risks to patients.

All users of the Hemotherm cooler-heater devices in Singapore have been notified of this FDA medical device safety communication.

#### **Overall summary and recommendations:**

- User reminded to read and understand all the information in the appropriate sections in the manuals.
- Follow CSZ's cleaning, disinfection procedures and preventive maintenance schedule stated in the Operation & Technical manual to minimize the risk of bacterial growth and subsequent patient infection.
- Use only distilled water. Do not use tap water to rinse, fill, refill or top-off water tanks.  
(Note: De-ionized water and sterile water created through reverse osmosis is not recommended because it may promote corrosion of the metal components of the system.)
- Immediately remove from service, any cooler-heater device that shows discoloration or cloudiness in the fluid lines/circuits, which may indicate bacterial growth.
- Replace all external water lines and hoses that show discoloration or cloudiness.
- Direct the cooler-heater's vent exhaust away from the surgical field to mitigate the risk of aerosolizing cooler-heater tank water into the sterile field and exposing the patient.  
(Note: The exhaust vent on the Hemotherm device is on the bottom of the unit and is not directed towards the surgical site.)
- Contact CSZ local representative if user has any questions or suspect the cooler-heater device has led to patient infections.

#### **Thermal International (S) Pte Ltd**

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(cont.) **Hemotherm dual reservoir cooler-heater communication**

CSZ is proactively communicating with FDA and national health agencies to better understand the risk and to develop further strategies to minimize patient exposure. Any additional information will be communicated as it becomes available.

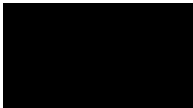
The user manual is updated and waiting FDA clearance to be released. The manufacturer will initiate a field safety notice once the manual is ready.

Reminder to user:

Strictly follow the procedure for water reservoir cleaning and disinfection with bleach and preventive maintenance in the user manual.

Sincerely,

For and on behalf of Thermal International (S) Pte Ltd



Melissa Thia  
Senior Sales Executive

