URGENT Medical Device Notice – Initial Communication

Affected Device: Blanketrol III Hyper-Hypothermia System, Models 233, STx and Blanketrol II Hyper-Hypothermia System 222S

July 21, 2026

Dear Valued Customer,

Gentherm Medical, LLC has identified an issue affecting the Blanketrol II, Blanketrol III and Innercool CoolBlue devices. Reports have been received of circuit boards showing signs of overheating and/or ceased operation due to overheating under certain conditions.

Affected Product:

Blanketrol III 115v (Model 233), Blanketrol II 115v (Model 222S) and Innercool CoolBlue (Model STx) devices manufactured by Gentherm between 7/10/2014 and 7/13/2026, serial numbers 131-2-00580 through 262-3-20277.

Reported Issue:

Gentherm Medical has received complaints of overheated circuit boards in 0.53% of distributed devices. Overheating can cause the circuit board to stop operating, which may result in a device that shuts down at startup or during use on a patient. Discoloration was observed near the fuses on affected devices. In rare instances, an overheated circuit board has been indicated/observed by an acrid odor.

Gentherm Medical has determined that a correction is necessary and is developing a change to a component on the circuit board to be installed in distributed products. The company is currently conducting verification/validation activities to confirm the proposed design modification. Once that is complete, Gentherm will provide a follow-up notification with specific instructions for the correction. In the interim, Gentherm is providing this notification to ensure users are aware of the issue and can take appropriate precautions.

Potential Risk:

During device use, the circuit board could overheat and cause the Blanketrol unit to shut down. This could result in the patient not receiving therapy, or therapy being delayed.

The company has had no reports of direct patient or user harm from the malfunction.

Interim Recommendations:

1. Based on the low probability of harm, and absence of reported harm, associated with this issue, users may continue to use the device. In an abundance of caution, it is recommended to have an alternative means of providing therapy available.

2. Users should review and follow the device Instructions for Use, including the warnings listed below; users should routinely verify the device's function and patient's condition during use.

a. **Blanketroll III Warning:** A physician's order is required for setting blanket temperature and use of equipment. **At least every 20 minutes, or as directed by physician, check patient's temperature and skin integrity of areas in contact with blanket; also, check the BLANKETROL III's water temperature**. Pediatric patients, temperature-sensitive patients with vascular disease, surgical patients, diabetics and patients with Raynaud's Disease are at greater risk for developing tissue injuries, and this should be considered when selecting the temperature, duration of therapy and frequency of skin checks. Notify the physician promptly of any change in patient status in order to avoid serious injury or death.

b. **Blanketrol II Warning**: A physician's order is required for setting blanket temperature and use of equipment. **At least every 20 minutes, or as directed by the physician, check patient's temperature and skin integrity of areas in contact with blanket; also, check the BLANKETROL II's water temperature.** Pediatric patients, temperature-sensitive patients with vascular disease, surgical patients, diabetics and patients with Raynaud's Disease are at greater risk for developing tissue injuries, and this should be considered when selecting the temperature, duration of therapy and frequency of skin checks. Notify the physician promptly of any change in patient status in order to avoid serious injury or death.

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.

This Medical Device Correction Notification should be carried out to the user level. Your assistance is appreciated and necessary to prevent interruption of therapy or delayed surgery.

If you have any questions or if you have experienced the described issue or a related adverse event, call Gentherm Medical Technical Support at 1-888-437-5608.

Adverse reactions or quality problems experienced with the use of this device may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Sincerely,

Stephanie Vocke

Senior Manager, Regulatory Affairs