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Class 2 Device Recall Blanketrol III HyperHypothermia Temperature Management System



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Class 2 Device Recall Blanketrol III HyperHypothermia Temperature Management System



Date Initiated by Firm	July 13, 2026
Date Posted	August 14, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-2970-2026
Recall Event ID	99478 ²³
510(K)Number	K101589 ²⁴
Product Classification	System, thermal regulating ²⁵ - Product Code DWJ ²⁶
Product	Blanketrol III, Model 233; Thermal regulating system.
Code Information	UDI: 1061303186102, UDI: 1061303186107, UDI: 1061303186139, UDI: 1061303187107, UDI: 1061303187307, Serial Numbers:131-2-00580 through 262-3-20277
FEI Number	1516825
Recalling Firm/ Manufacturer	Gentherm Medical, LLC 12011 Mosteller Rd FI 3 Blue Ash OH 45241-1528
Manufacturer Reason for Recall	Overheating of the 115V CPU board may cause the device to shut down.
FDA Determined Cause ²	Device Design
Action	Gentherm issued an URGENT Medical Device Notice to its consignees on 7/17/2026 via email. The notice explained the issue, potential risk, and request the following: "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; users should routinely verify the device s function and patient s condition during use. 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." For questions or if you have experienced the described issue or a related adverse event, call Gentherm Medical Technical Support at 1-888-437-5608.
Quantity in Commerce	9714 units
Distribution	Worldwide - US Nationwide distribution including in the territories of Puerto Rico, and the countries of Brazil, Canada, Chile, Colombia, Costa Rica, El Salvador, Guatemala, Mexico, Republic of Panama, Saudi Arabia, Taiwan, Thailand, Bahamas, and Trinidad and Tobago.
Total Product Life Cycle	TPLC Device Report ²⁷

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)²⁸.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database

[510\(K\)s with Product Code = DWJ](#)²⁹

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