

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Thoratec LLC Recalls HeartMate Mobile Power Unit

Recall Date	Product Description	Recalling Firm	Recall Reason
04/17/2025	HeartMate Mobile Power Unit: REF: 107754, NA; 107758, EU; 107758AU, AU; 107758UK, UK; L107758, EU Rental. Used with HeartMate 3 and II Left Ventricular Assist System.	Thoratec LLC	Left Ventricular Assist System Mobile Power Unit (MPU) may have electrical component that may cause MPU not to turn on, unprompted shut down, or turning off/restarting, may cause system controller to indicate Yellow Wrench or No External Power alarms. If MPU loses power, System Controller can support the pump up to 15 minutes, and if not switched to rechargeable batteries, pump may lose power.

Recall Class	Product Identification	Distribution	Affected Dates
I	UDI-DI: 05415067038234. MPUs distributed between April 2024 and February 2025. Serial Numbers: 20226263, 20226264, 20226265, 20226266, 20226267, 20226268, 20226269, 20226270, 20226271, 20226272, 20226273, 20226274,	1661 Worldwide - US Nationwide distribution in the states of WA, NE, VA, PA, DC, KY, CA, IL, WI, TX, MA, AR, MS, MI, OH, FL, NC, TN, LA, NJ, UT,	March 2025 and Prior

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