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Medtronic announces voluntary recall of select Newport™ HT70 and Newport™ HT70 Plus ventilators and certain related Newport™ service parts

Customers are being asked to remove the affected devices from use and replace with an alternate means of ventilation

June 11, 2025 – In May 2025, Medtronic issued a voluntary recall notification to global customers related to specific Newport™ HT70 and HT70 Plus ventilators and certain related Newport™ service parts. The FDA recently designated this voluntary action by Medtronic as a Class I recall. With this recall, Medtronic is advising discontinuation of clinical use of the affected devices. Investigation into customer complaints identified two separate capacitors on one of the ventilator's controller Printed Circuit Board Assembly (PCBA), that, in case of failure, may result in:

- The ventilator shutting down during use, or
- The shutdown alert alarm failing to sound effectively.

No instances of both capacitors failing on the same PCBA board have occurred, nor are they anticipated to occur.

If a ventilator fails and does not provide adequate ventilation, the patient may not be able to breathe on their own, leading to low oxygen levels, high carbon dioxide levels, and potentially severe consequences like brain injury or death. There have been 63 medical device reports (MDRs) associated with this issue, including two serious injuries and one death. HT70 and HT70 Plus ventilators are intended for use by home users, as well as for infant and paediatric patients who may be at higher risks of injury or death due to unanticipated ventilator failures.

Customer recommendations

Customers should remove the affected devices from use and replace with an alternate means of ventilation. Medtronic is not correcting these issues on affected ventilators or service parts and will no longer service affected ventilators identified in this notification. Customers with questions should contact Medtronic Customer Service at 800-962-9888. Adverse events or product quality concerns with this product should be reported to the FDA and Medtronic:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail)
- Call FDA at (800) FDA-1088 for MedWatch reports
- Call Medtronic Technical Support at 800-255-6774 option1, then option 1

Refer to the customer notification and the patient letter for additional information.

The Newport™ HT70 family of ventilators is intended to provide continuous or intermittent positive pressure mechanical ventilatory support for individuals who require mechanical ventilation through invasive or noninvasive interfaces. Specifically, the Newport™ HT70 family of ventilators is applicable for infant, pediatric, and adult patients greater than or equal to 5 kg (11 lbs) in hospital, sub-acute, emergency department, and home care environments as well as for transport and emergency response applications. The Newport™ HT70 operator's manual can be found here.

Medtronic will continue working directly with the U.S. Food and Drug Administration (FDA) and other regulatory bodies around the world on this voluntary recall. In February 2024, Medtronic announced its decision to exit its ventilator product lines, including the Newport™ ventilators. The company continues to serve the needs of its customers and their patients worldwide, and honor existing ventilator contracts, as they wind down the business over the coming years.

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Identifying Affected Product

https://news.medtronic.com/Medtronic-announces-voluntary-recall-of-select-Newport-TM-HT70-and-Newport-TM-HT70-Plus-ventilators-and-certain-related-Newport-TM-service-parts