

2 Medtronic ventilators can stop working without notice

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Two models of Medtronic ventilators used in pediatric and adult care can reset during operation and stop working, according to a safety notice from the Food and Drug Administration (FDA).

The prescription Newport HT70 and HT70 Plus ventilators are used to support breathing in clinical settings and in the home. If the ventilators reset spontaneously while in operation, they enter standby mode without an accompanying alarm and will not resume ventilation without intervention. If this occurs, health care professionals and caregivers must transfer the patient to another ventilator. Families also should contact their physician immediately.

A software update is expected to become available in May. Meanwhile, the firm said the HT70 series ventilators still can be used but cautions caregivers to provide constant monitoring of the patient's condition. In addition, they should have an alternate power source and means of ventilation available and use appropriate monitors to ensure sufficient oxygenation and ventilation (such as a pulse oximeter and/or a capnograph) when these ventilators are in use.

Since 2012, Medtronic has received 12 reports of resets without an accompanying alarm, and 11 patients required a ventilator transfer. One incident did not involve a patient.

For assistance finding alternative ventilation devices, call Medtronic at 800-255-6774.

More information is available in the MedWatch safety alert at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm551021.htm.

Health care professionals and patients are asked to report any adverse events to the FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch/report or by calling 800-332-1088.

