

Newport Medical Instruments Inc. Recalls Newport™ HT70 & Newport™ HT70 Plus Ventilators Due to a Software Issue which May Cause an Unexpected Shutdown without Alarm

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

- Recalled Product: Newport™ HT70 & Newport™ HT70 Plus Ventilators
- Product Code: 73-CBK
- Distribution Dates: March 4, 2010 to February 2, 2017
- Manufacturing Dates: March 4, 2010 to January 26, 2017
- Devices Recalled in the U.S.: 7576 nationwide

Device Use

The Newport™ HT70 and HT70 Plus ventilators are intended to provide breathing support for individuals who require mechanical ventilation. These devices can be used with infant, pediatric or adult patients greater than or equal to 5kg (11lbs). These devices are used in hospitals, other health care facilities, and home care environments and may be used for transport and emergency response situations.



Reason for Recall

Newport Medical Instruments Inc., now a part of Medtronic, is recalling the Newport™ HT70 and Newport™ HT70 Plus ventilators because a software problem may cause the ventilator to shut down unexpectedly without sounding an alarm. If the ventilator shuts down, the patient may not receive enough oxygen and could suffer serious adverse health consequences such as brain damage, or even death.

Who May be Affected

- Health care providers using the Newport™ HT70 and Newport™ HT70 Plus ventilators.
- All patients who may be using these ventilators for breathing support.

What to Do

On April 3, 2017, Medtronic sent an Urgent Field Corrective Action Notice to all affected customers. The notice asked customers to:

- Ensure that patients on the Newport™ HT70 and HT70 Plus ventilators are appropriately monitored by trained caregivers as described in the **Operator's Manual** (http://www.medtronic.com/content/dam/covidien/library/us/en/product/portable-ventilation/Newport_HT70Plus_OperatorsManual_EN_OPRHT70-2G00.pdf). The descriptions include:
 - A patient connected to a ventilator requires the constant attention of trained caregivers to the patient's condition.
 - Always have an alternate power source and means of ventilation available when the ventilator is in use in case of a mechanical or system problem.
 - Always use appropriate monitors to ensure sufficient oxygenation and ventilation (such as a pulse oximeter and/or a capnograph) when the Newport™ HT70 or HT70 Plus ventilators are in use on a patient.
 - If able, use the appropriate remote alarm/nurse call cable (Newport Medical Instruments CBL3223 or 10104494) to project ventilator alarm states outside the patient room. This alarm will annunciate even with an unexpected reset. Consult the Operator's Manual or call Technical Service for further information on this accessory.
 - If, at any time, the patient is not responding to ventilation appropriately, the patient should be taken off the ventilator immediately and connected to an alternate method of ventilation. Contact your health care provider or physician immediately.
- Immediately notify all care environments in which the Newport™ HT70 and HT70 Plus ventilators are used about this notification.
- If a facility has distributed Newport™ HT70 or HT70 Plus ventilators to other persons or facilities, a copy of this should be promptly forwarded to those recipients.
- Complete the Customer Acknowledgment Form and return the completed form by fax to 203-492-7719 or email to FCAMITG@Medtronic.com
- Work with Medtronic Technical Support Department if further assistance is needed for finding alternative ventilation devices.

The notice also informed customers that Medtronic expects to issue a software update to resolve this issue in May 2017.

Contact Information:

Customers are instructed to contact Medtronic's Technical Support Department at 800-255-6774 with any questions related to this recall, or if they have information regarding incidents related to these issues.

Date Recall Initiated: March 31, 2017

Additional Resources

[Medtronic Press Release \(http://investorrelations.medtronic.com/phoenix.zhtml?c=76126&p=irol-newsArticle&ID=2259960\)](http://investorrelations.medtronic.com/phoenix.zhtml?c=76126&p=irol-newsArticle&ID=2259960)

[Newport HT70 Ventilator Operating Manual \(http://www.medtronic.com/content/dam/covidien/library/us/en/product/portable-ventilation/Newport_HT70Plus_OperatorsManual_EN_OPRHT70-2G00.pdf\)](http://www.medtronic.com/content/dam/covidien/library/us/en/product/portable-ventilation/Newport_HT70Plus_OperatorsManual_EN_OPRHT70-2G00.pdf)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **[MedWatch: The FDA Safety Information and Adverse Event Reporting Program \(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home\)](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)** either online, by regular mail or by FAX to 1-800-FDA-0178.

[More in Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/default.htm\)](/MedicalDevices/Safety/ListofRecalls/default.htm)

[2017 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm535289.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

[2016 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm480134.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)