

URGENT: Field Safety Notice **Newport™ HT70 and Newport™ HT70 Plus Ventilators**

April XX, 2017

Attention: Directors of Inpatient and Home Respiratory Care, Critical Care Units, and Risk Management Distributors of Newport™ HT70 and HT70 Plus ventilators

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is issuing a Field Safety Corrective Action (FSCA) for all its Newport™ HT70 and Newport™ HT70 Plus ventilators following reports that the ventilator may, on rare occasion, reset spontaneously during normal operation without an accompanying alarm. While the reports indicated that patients required transfer to another ventilator, no patient injury or impairment has been reported.

The reported incidence of the reset without alarm condition is approximately one (1) reset in every 7 million hours of ventilation. Following the reset, the ventilator enters standby mode and will not resume ventilation without intervention. Based on our internal review, including the low rate of incidence for this issue, Medtronic is advising that you may continue to use your Newport™ HT70 series ventilators in accordance with institutional policies and as described below.

Actions being taken by Medtronic:

Medtronic has established the root cause of this alarm failure and will provide a software service update to resolve the issue as soon as the correction can be implemented. We expect the service update to be available in May.

Actions you should take:

- Ensure patients on the Newport™ HT70 and HT70 Plus ventilators are appropriately monitored by trained caregivers as described in the Operator's Manual. 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 is in use on a patient.
 - If able, use the appropriate remote alarm/nurse call cable (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.

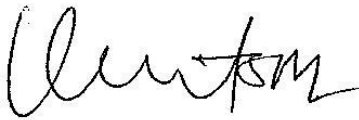
- If, at any time, the patient is not responding to ventilation appropriately, the patient should be taken off the ventilator immediately and connected to an alternate method of ventilation. Contact your health care provider or physician immediately.
- **Additional Actions you should take:**
 - Immediately notify all care environments in which the Newport™ HT70 and HT70 Plus ventilators are used about this notification.
 - If your facility has distributed Newport™ HT70 or HT70 Plus ventilators to other persons or facilities, please promptly forward a copy of this letter to those recipients.
 - Complete the attached form and return it as directed to confirm your receipt and understanding of this information.
 - Work with Medtronic Technical Support Department if you require assistance finding alternative ventilation devices.

If you are aware of any incidents related to these issues or if you have any questions, please contact our Technical Support Department immediately by Telephone: XXX-XXX or by e-mail to xxxx@medtronic.com, to provide information regarding those events so regulatory reporting obligations can be fulfilled.

This notification is being issued with the knowledge of the **[Insert Local Competent Authority]** and other global regulatory agencies.

Thank you for your attention to this notification. We sincerely apologize for any inconvenience this situation may cause you or your facility.

Sincerely,



Subu Mangipudi
Vice President, Quality Assurance
Patient Monitoring and Recovery
Medtronic

URGENT: MEDICAL DEVICE Field Safety Corrective Action
Newport™ HT70 and HT70 Plus Ventilators
VERIFICATION FORM

Please complete this form in its entirety.

[Please insert date the form was sent]

Customer Contact Details	Medtronic Contact Details
Hospital: Medtronic Account Number:	To: <i>[insert name Medtronic commercial office]</i>
Collection Address: Department: Street: City: Postal Code: Contact Person at Point of Collection: Opening Hours:	Address: <i>[insert Medtronic address]</i>
Telephone n°:	Telephone n°: <i>[insert Medtronic telephone number]</i>
Fax n°:	Fax n°: <i>[insert Medtronic fax number]</i>
E-mail:	E-mail: <i>[insert contact e-mail address]</i>

Indicate in the columns below all serial numbers you have in your facility. Please complete the form in full. If you have forwarded Newport™ HT70 and HT70 Plus ventilators to other persons or facilities, provide the serial numbers and the recipient's name and address, if known. Forward the Field Safety Notice to these facilities.

Newport™ HT70 and HT70 Plus ventilators Serial Numbers	Still in Service for Patient Use Yes/No	Sent to another facility Yes/No	Facility name and address (if different than above)

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- This action is being taken with the knowledge of the [add local Competent Authority]
- I have read and understand the instructions provided and acknowledge receipt of the Field Safety Corrective Action Notice regarding the Newport™ HT70 and HT70 Plus ventilators by signing below. I also agree to further distribute and communicate this important information within my facility as required.

Customer Name: (Please Print)	Signature:	Date: