Medtronic

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URGENT FIELD CORRECTIVE ACTION NOTICE
Newport™ HT70 and Newport™ HT70 Plus Ventilators

5 March 2017

Attention: Directors of Inpatient and Home Respiratory Care, Critical Care Units, and Risk Management Distributors of Newport™ HT70 and HT70 Plus ventilators
CC: The Chairman Medical Board and relevant Head of Departments

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is issuing a voluntary field corrective action notice 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 your local Medtronic Representative 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 your local Medtronic representative to provide information regarding those events so regulatory reporting obligations can be fulfilled.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required.

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

Sincerely,

[redacted]

Diana Teo
QA Supervisor, SEA
Medtronic

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ACKNOWLEDGEMENT FORM
Newport™ HT70 and Newport™ HT70 Plus Ventilators

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	**By E-mail:**
Address:	**By Post:**
Telephone no:	
Fax no:	
E-mail:	

Tick ☐ here: If the unit (s) have been obsoleted, and fill up the serial # of the affected unit(s) in below table

Indicate in the columns below all serial numbers you have in your facility. If you have forwarded affected **Newport HT70 / Newport HT 70 plus** to other persons or facilities, provide the serial numbers and the recipient's name and address, if known. Forward the Field Safety Notice notification to these facilities:

Newport HT70 and Newport 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)

I have read and understand the instructions provided and acknowledge receipt of the Field Corrective Action Notice regarding the Newport HT 70/Newport HT 70 plus ventilators by signing below. I also agree to further distribute and communicate this important information within my facility as required.

Name: _____ (print) Signature: _____ Stamp: _____ Date:_____