ATTN Chuck

615-221-8104

CareFusion
Pulmonetic Systems
17400 Medina Road; Suite 100
Minneapolis, MN 55447-1341
763.398.8300 tel
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IMPORTANT PRODUCT RECALL FOLLOW-UP REQUEST REGARDING LTV VENTILATOR FEBRUARY 2008 RECALL - OUTSTANDING DEVICES REQUIRING REMEDIATION

American Home Patient, Inc.
19 Campion Rd Ste 7
New Hartford, NY 13413

Dear CareFusion Customer:

In February 2008, CareFusion voluntarily initiated a recall of certain LTV Ventilators. A copy of the Recall Notification is attached for your review. According to our records, the following Model/Serial Number LTV Ventilators which were in your inventory at the time of the recall notification have not had the necessary remediation completed.

Model LTV 950
Serial # C09341 and C04108

Please review your inventory to determine the location of these devices and contact CareFusion Technical Support at (800)754-1914 extension 2, to schedule these devices for necessary remediation at your earliest possible convenience. If these devices are no longer in your inventory, please contact CareFusion Technical Support.

Robert C. Samec

Robert C. Samec

Vice President-QRA
CareFusion 203, Inc.
Minneapolis, MN

Attachment- February 2008 Recall Notification

Cardinal Health
17400 Medina Road, Suite 100
Minneapolis, Minnesota 55447-1341
763.398.8300 tel
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CardinalHealth

www.cardinalhealth.com

February 22, 2008 (Certified Mail/Return Receipt Delivery)

URGENT MEDICAL DEVICE RECALL

This recall affects only certain Pulmonetic Systems Models LTV 1000, 950, 900 and 800 ventilators distributed in the period of September 2003 through January 2006.

To: Domestic Ventilator Consignees/Owners

Through ongoing field performance evaluation, Cardinal Health has received a number of reports of printed circuit board malfunctions resulting from the failure of an electronic component. These malfunctions could result in failure of the ventilator to breathe for the patient (Vent INOP) and/or failure of the ventilator to properly alarm to alert the caregiver (inaudible, intermittent, or distorted alarm), which could potentially result in injury or death if appropriate back-up ventilation is not provided by the caregiver. Cardinal Health has not received any field reports of a malfunction of these ventilators failing to provide breathing assistance without an accompanying audible alarm to alert the caregiver. Although this simultaneous malfunction is possible, it is very unlikely. As a precaution, Cardinal Health will modify the affected devices by replacing the suspect printed circuit board assembly.

A serial number list of ventilators affected by this notification in your inventory/control, according to our records, is attached for your review. These ventilators should be returned for service correction as soon as they can be made available. In the event that you no longer own or control the ventilators indicated in our records and on the attached serial number sheet, please immediately provide a record of any change in device location of these ventilators by faxing this information to Cardinal Health Customer Service at 763-398-8403.

Cardinal Health will correct the listed ventilators at no cost, at the Cardinal Health factory service center or a Cardinal Health authorized service center/technician location. The serial number listing of affected ventilators attached contains a Return Material Authorization (RMA) number for each affected ventilator. This RMA number should be listed on the outside of the shipping box when returning devices for correction to Cardinal Health or an authorized service center/trained technician location.

In the interim, we remind you that all ventilator-dependent patients should be constantly monitored by qualified personnel to ensure that if a malfunction were to occur, alternate ventilation can be provided.

As a further precaution, ventilator operation and audible alarm function should be verified on a daily basis.

To verify audible alarm function:

-If operating the ventilator on external AC or battery power, momentarily disconnect the ventilator from the external power source. Verify that the audible alarm sounds and the ventilator displays "Power Lost". Reconnect the external power source and verify that the alarm silences and that External Power LED illuminates. Press the Silence/Reset button to return the ventilator display to normal operation.

-If operating the ventilator on internal battery power, first connect the ventilator to external AC or battery power, and then disconnect it from the external power source. Verify that the audible alarm sounds and the ventilator displays "Power Lost". Press the Silence/Reset button two times to return the ventilator display to normal operation. Note that the internal battery is intended for use during short periods while switching between external power supply connections, emergency situations, or short duration transports. Care should be taken to connect the ventilator to an external AC or DC source as soon as possible.

Note: Ventilation is not interrupted during this alarm check test.

To verify ventilator operation:

With the ventilator turned on and connected to the patient, visually verify that the ventilator front panel display does not indicate an alarm condition.

If the ventilator fails either the ventilator operation check or the alarm function check, it should be removed from use and another ventilator should be placed on the patient.

If you have questions regarding this notification, please contact Cardinal Health Technical Support at 800/754-1914 extension 2 or 763-398-8500 Extension 2, or service@pulmonetic.com. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- OnLine: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

We recognize that this recall is an inconvenience for you, but we're certain that you share our commitment to patient care and well-being, and we thank you for your prompt attention to this matter.

Cardinal Health

Robert C. Samec
Vice President- Quality/Regulatory Affairs

Attachment: Affected Device Site Serial/RMA# Number Listing