



## URGENT PRODUCT RECALL

Affected Product: Nebulizer Heater, Catalog Code 2M8021 (Manufactured prior to January 2005)

Date: July 15, 2011

22745 Savi Ranch Parkway  
Yorba Linda, CA 92887

Dear Valued Distributor:

CareFusion is performing a voluntary product recall on Nebulizer Heater, Catalog Code 2M8021, manufactured prior to January 2005.

### PROBLEM AND AFFECTED DEVICES

Investigation has confirmed the Nebulizer Heater can over time develop a failure mode that results in an internal electrical short. The short can result in smoke and sparks being emitted from the device. The condition of risk has been reported in five hospital accounts over the last eleven years. There have been no patient injuries reported with any of these complaints. In the presence of an oxygen enriched environment and a fuel source this failure results in a potential risk of fire. CareFusion is voluntarily recalling the affected devices to preclude the possibility of this risk.

**AFFECTED UNITS:** may be identified by a 6 digit alpha-numeric serial number on the device (see attached example). Nebulizer Heater units manufactured prior to January 2005 are affected by this recall action.

Current production devices and those manufactured in the last six years are NOT affected by this action. Current production can be identified by a 10 digit numeric serial number.

**ISSUE:** Nebulizer Heaters can over time develop a failure mode that results in an internal electrical short.

**POTENTIAL RISK:** An electrical short may form over time that can result in smoke and sparks being emitted from the device. In the presence of oxygen enriched environment and a fuel source this failure may result in a potential risk of fire.

### ACTION TO BE TAKEN

- 1) Examine your inventory and remove from service all affected units present in your facility. Please contact CareFusion's Technical Support department at 800-554-8933 (6:30 am to 5:00 pm PDST) to obtain an RMA (returned materials authorization) number for the return of the affected product (please be prepared to confirm the total number of affected units in your possession with their respective serial numbers as indicated on the sample). Upon receipt of your response, CareFusion will ship to you new replacement Nebulizer Heaters for the affected units.
- 2) Please initiate a notification to your customers for the affected product serial numbers of the AirLife® Nebulizer Heater, catalog code 2M8021. You may use the attached customer notification letter and example of a Customer Response Card. Please provide evidence of the notification of your consignees for our records.

OR

- 3) Provide a list of your consignees that have received the 2M8021 nebulizer heater prior to January 2005 and CareFusion will provide notification to them and coordinate the replacement product for affected serial numbers of this heater.

The US Food and Drug Administration have been notified of this action. Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

- Web: MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)
- Phone: 1800-FDA-1088
- Fax: 1-800-0178, or by
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

Please use the chart provided below for questions and support:

CareFusion Contact	Contact Information	Areas of Support
CareFusion Technical Support	800-554-8933	Recall Related Questions
Customer Advocacy	847-473-7439	Adverse Event Reports

Should you have any questions, please contact CareFusion's Technical Support department at 800-554-8933, (6:30 am to 5:00 pm PDST). Please acknowledge receipt of this communication by completing the enclosed reply form as indicated on the example and faxing or sending a copy by return mail to the address indicated on the Customer Reply Card.

Thank you for your prompt support to this matter. We appreciate your cooperation.

Sincerely,



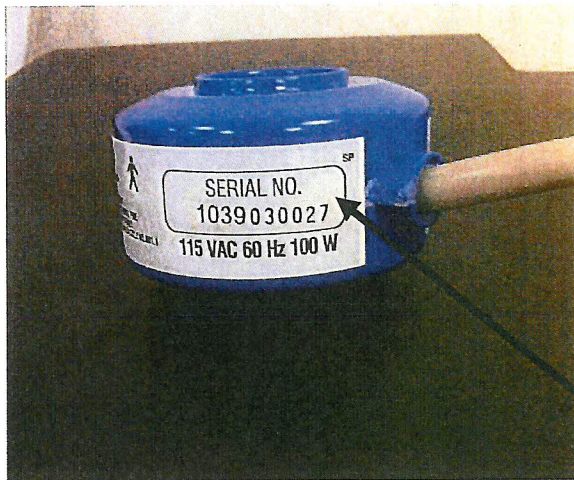
Charles Nehring  
Vice President QRA  
CareFusion – Respiratory Systems

**Enclosures:**

Nebulizer Heater example of Affected Serial Numbers  
Distributor Response Card  
Customer Notification Letter with Nebulizer Heater example of Affected Serial Numbers  
Example of a Customer Response Card

### Nebulizer Heater Affected Serial Numbers

Product Catalog Number	Serial Number Logic	Manufacture Date	Status
2M8021	<b>Sxxxxx or Txxxxx</b> (The Serial Number is located on the heater shell and on the power cord, see example below).	Prior to January 2005	<b>AFFECTED</b> by this Recall  (Action required)
2M8021	<b>XXXXXXXXXX</b> 10 Digit Numeric Serial Number  (The Serial Number is located on the heater shell and on the power cord, see example below).	January 2005 through Current	<b>NOT AFFECTED</b> by this Recall  (No action is required)



SERIAL NUMBER LOCATED ON SHELL

