

Date: 9/28/2015

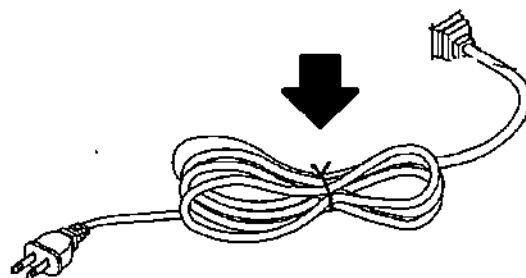
Subject: **3rd NOTICE URGENT RECALL FIELD CORRECTION
ACTION REQUIRED**
User Manual for Roscoe Mini Nebulizer Compressor System

A voluntary Field Correction was conducted 4/20/2015 for the instruction manual that pertains to the Roscoe Mini Nebulizer Compressor System (item #NEB-ROS) distributed.

Reason for Field Correction: Roscoe Medical has recently identified the need to update its user manual with additional warning statements regarding proper handling and storage of the nebulizer. These warnings are to better inform end users of proper care when using and storing a Roscoe Medical Nebulizer to reduce user damage (wear & tear) to the power cord.

To date, Roscoe Medical has received 37 customer complaints over the last 16 months for power cords fraying or sparking on product ranging from 42 months of age to 6 months of age at the high flex point of the nebulizer cord. After a detailed product trend analysis of the nebulizer with the Manufacturer, it was established that power cord incidents were due to users not following the proper care and storage instructions for the nebulizers and did not warrant removing the nebulizers from the field. This conclusion was based on the inspection of returned product and overall low product failure rate.

However, Roscoe Medical takes patient safety seriously, and the Company wants to ensure this potential cord issue is avoided. Power cord should not be wrapped around the compressor (main unit). Users should disconnect the power plug by pulling the plug, not by pulling on the compressor (main unit), or the cord. Users should not allow heavy objects on the power cord, or bend and pull the cord harder than necessary. Power cord should be wrapped in a coil as seen below prior to storage.



Additionally, the instruction manual was revised to include the following additional cautions for proper care and storage:

1. **CAUTION:** Failure to read and observe all precautions could result in personal injury or equipment damage (Important Safeguards Section, pg. 3).

2. WARNING IF ANY OF THE MOTOR HOUSING PARTS SHOULD BECOME DETACHED OR BROKEN, EXPOSING THE MOTOR OR ANY OTHER ELECTRICAL COMPONENTS, OPERATION SHOULD BE DISCONTINUED IMMEDIATELY TO AVOID PERSONAL INJURY OR FURTHER PRODUCT DAMAGE (Product Cautions Section, Pg. 3 - item 1).
3. Never operate the unit if it has any damaged parts (including power cord), if it has been dropped or submersed in water. Promptly send it to a service center for examination and repair (Product Cautions Section, Pg. 3 - item 3).
4. Never operate if this unit has a damaged cord or plug, if it has been dropped, or in any way, into water, if it does not work properly. Return it to a service center for repair (Operating Cautions Section, pg. 4 - item 3).
5. Never allow the power cord to be pulled, jerked, strained, twisted, or severely bent, especially at the plug connections. Damage will occur at the high flex point of entry to the device, causing it to rupture and short (Operation Cautions Section, pg. 4 - item 6).
6. Keep the cord away from heated surfaces. Do not wrap the cord around the appliance (Storage Cautions Section, pg. 4 - item 3).

Please take the following actions:

- Ensure all affected personnel are fully informed of this notice.
- Forward this notice to your Regulatory Compliance Manager, Purchasing Manager, Customer Service Manager and Field Technicians.
- Advise your customers regarding the proper care and storage of the nebulizers.
- Your customers should discard their NEB-ROS User Manual and immediately download the latest versions [HERE](#).
- If they are unable to download the most recent version, hard copies can be provided. Please contact Roscoe Medical Customer Support at (800) 376-7263 Monday-Friday 8:00 am EST - 5:00 pm EST.
- Complete and return the attached Recall Field Correction Response Form to Roscoe Medical within fifteen (15) days of receipt of this field correction notification confirming your acknowledgement. Send completed form to Roscoe Medical via fax number (440) 572-4261 or via email at corporate@roscoemedical.com.

This voluntary Field Correction notification is being conducted with the knowledge of the United States Food and Drug Administration (FDA) in accordance with U.S. regulations. Any complaints and/or adverse events experienced with the use of this product must be reported promptly to Roscoe Medical Customer Support at (800) 376-7263 Monday-Friday 8:00 am EST - 5:00 pm EST and/or to the FDA through its MedWatch program.

Roscoe Medical appreciates your immediate attention to this urgent matter and recognizes the inconvenience this may cause.

Thank you,



Tracee Wesolowski
Quality Assurance Manager

ATTACHMENT A – FIELD CORRECTION REPLY FORM – RESPONSE REQUIRED
Roscoe Mini Nebulizer Compressor System (item #NEB-ROS)

April 20, 2015

Complete and return the attached Recall Field Correction Response Form to Roscoe Medical within fifteen (15) days of receipt of this field correction notification confirming your acknowledgement. Send completed form to Roscoe Medical via fax number (440) 572-4261 or via email at corporate@roscoemedical.com.

Please check ALL appropriate boxes (print clearly).

- I have received the letter and have notified my Regulatory Compliance Team.
- I have reviewed and downloaded the NEB-ROS Patient Manual_rev2 from the Roscoe Medical website.
- Wholesaler/Distributor only: I have identified and notified all customers that purchased product.

Check which method of notification was used:

Mail____; E-mail____; Fax____; Phone____

- Have you distributed the product further to the retail level? Yes____ No____

If yes, have you notified your retail customers? Yes____ No____

Check which method of notification was used:

Mail____; E-mail____; Fax____; Phone____

CUSTOMER CONTACT PERSON INFORMATION (PLEASE PRINT CLEARLY):

Name: _____ Title: _____

Address: _____ City: _____

State: ____ Zip Code: _____ Country: _____ Telephone #: _____

Email Address: _____

Signature: _____ Date: _____