

Date: April 20, 2015

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

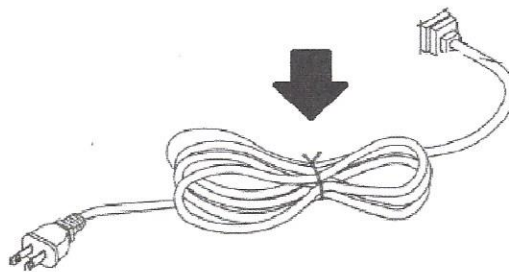
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A voluntary Field Correction is being conducted for the instruction manual that pertains to the Roscoe Mini Nebulizer Compressor System (item #NEB-ROS) distributed.

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](mailto: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.

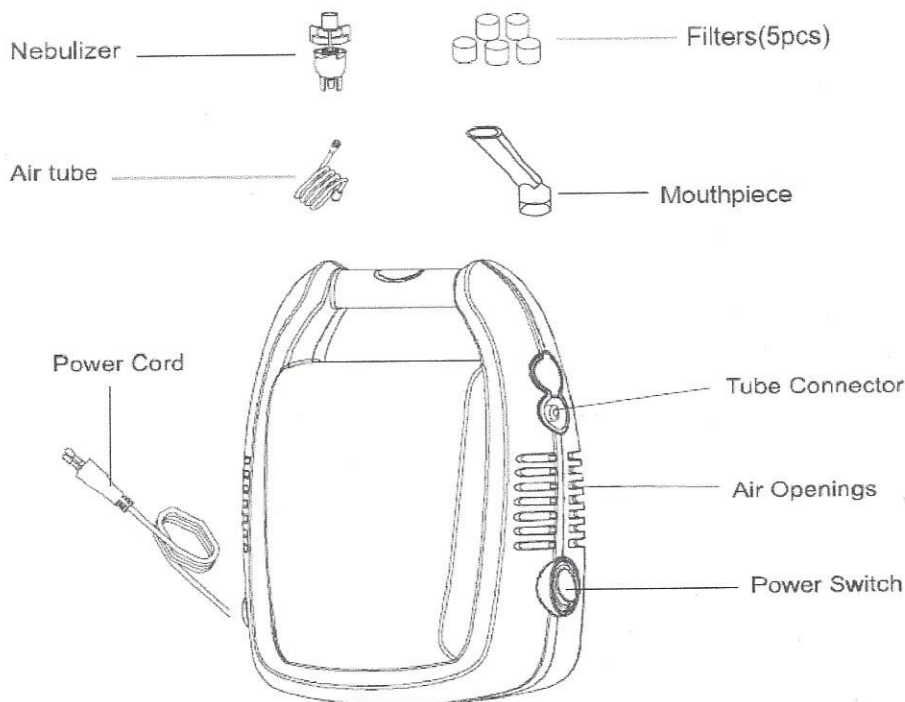
Thank you,



Tracee Wesolowski  
Quality Assurance Manager



this guidebook to learn about the features of this product. Any use of this product other than its intended use should always be avoided.

## 2. PRODUCT IDENTIFICATION



## 3. IMPORTANT SAFEGUARDS

 **NOTE:** Read all instructions carefully before use.

 The following basic precautions are needed when using an electrical product:  
 **CAUTION:** Failure to read and observe all precautions could result in personal injury or equipment damage.

 **PRODUCT CAUTIONS:**

1. **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.**
2. To avoid electrical shock: Keep the unit away from water • Do not immerse the power cord or the unit in liquid • Do not use while bathing • Do not reach for a unit that has fallen into water – immediately unplug the unit.
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.
4. The unit should not be used where flammable gas, oxygen or aerosol spray products are being used.



5. Disconnect the unit from the electrical outlet before cleaning, filling and after each use.
6. Do not use other attachments unless recommended by manufacturer.

### **OPERATING CAUTIONS:**

1. Connect this product to an appropriate voltage outlet for your model. Do not use with power strips or extension cords.
2. Do not run this product unattended.
3. 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.
4. If any abnormality occurs, discontinue use immediately until the unit has been examined and repaired.
5. Always unplug the product immediately after use.
6. Never allow the power supply 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 into the appliance, causing it to rupture and short. Handle the cord carefully for longer life.
7. Never block the air openings of the main unit or place it where the air openings may be obstructed.

### **STORAGE CAUTIONS:**

1. Do not store the unit under direct sunlight, high temperature or humidity.
2. Keep the unit out of reach of small children.
3. Keep the cord away from heated surfaces. Do not wrap the cord around the appliance.
4. Always keep the unit unplugged while not in use.

### **CLEANING CAUTIONS:**

1. Do not immerse the unit in water. It may damage the unit.
2. Disconnect the unit from the electrical outlet before cleaning.
3. Clean all necessary parts after each use as instructed in this guidebook.

## **4. OPERATING YOUR COMPRESSOR NEBULIZER**

**Note:** Prior to initial operation, the nebulizer should be thoroughly cleaned.

1. Place your Compressor Nebulizer on a flat and stable surface. Be sure that you can easily reach the controls when you are seated.
2. Get accessories ready.  
**Important:** Prior to initial operation, the nebulizer should be thoroughly cleaned referring to the "Cleaning Procedures" in the manual.
3. Gently twist the top part of the nebulizer counter-clockwise to disassemble the nebulizer.