

ATTENTION – MEDICAL DEVICE FIELD CORRECTION

**BiPAP®Focus™ Ventilator System
Power Supply / Power Cord Failure**

September 22, 2008

Dear Customer/Distributor:

Respironics California, Inc. is conducting a voluntary field action to correct an issue with the BiPAP Focus Ventilator power cord (see figure 1). This action is being taken to address power supply failures which have occurred on some ventilators. A discrepancy between the power supply strain relief clip and the power cord connector may allow unwanted movement of the cord and the unit's power supply. A disconnection or intermittent electrical connection between the power cord and the unit's power supply during operation or charging can result in transient power surges, which may cause damage to components within the power brick. A power surge may exceed the power supply capacity, causing the power supply to lose power. These failures were discovered through routine product monitoring and to date Respironics California Inc. has received no reports of patient injury.

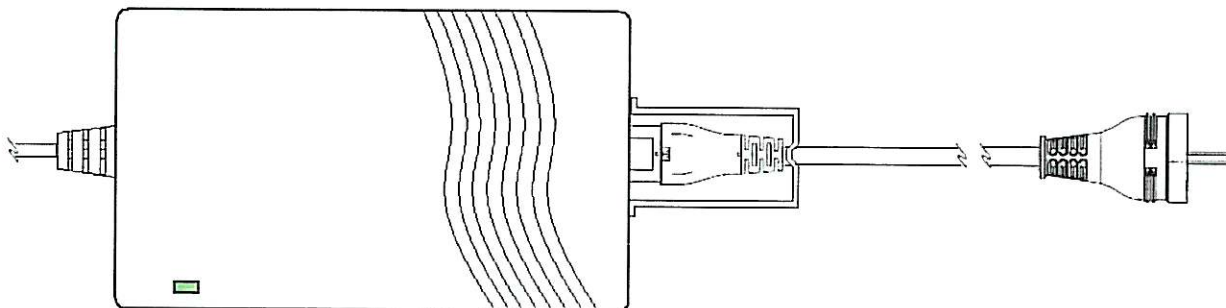


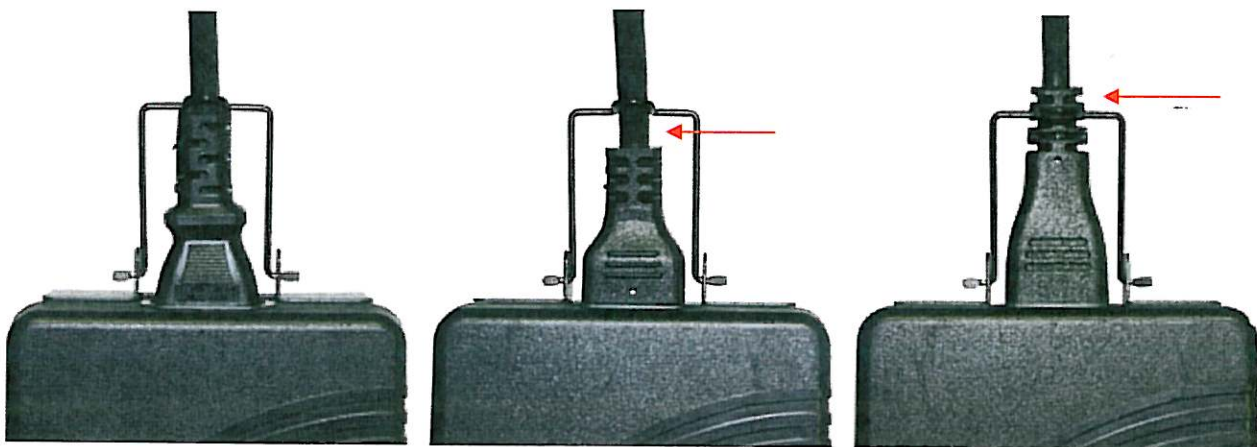
Figure 1

To correct this issue Respirationics has modified the power cord to eliminate the unwanted movement, and is taking the following corrective actions:

1. Power cords on all affected BiPAP Focus Ventilators will be replaced with the new power cord.
(Ref: Ventilator Serial Number on the attached Business Response Form)
2. Power cords shipped as separate stock on or before April 11, 2008 will be replaced with the new power cord. Part numbers are listed below.
(Ref: stock quantity on the attached Business Response Form).

| Power Cord Description | Part Number |
|---------------------------------|--------------------|
| Cord, US, Power | 1029989 |
| Service, Powercord, Europe | 1029985 |
| Service, Powercord, Denmark | 1029991 |
| Service, Powercord, Italy | 1034953 |
| Service, Powercord, India/RSA | 1034954 |
| Service, Powercord, Switzerland | 1034955 |
| Service, Powercord, Australia | 1034956 |
| Service, Powercord, UK/Ireland | 1029982 |

3. NOTE: If your power cords are no longer with the original ventilator shipped or your power cord inventory has become mixed, you will need to inspect your stock per the Power Cord Acceptance Criteria below. Any power cord that is the "bad" configuration will need to be replaced. If you have a power cord that is the correct "good" configuration, you do not need to replace it.



Good

Bad - Short

Bad - Long

The attached Business Response Form identifies all of the affected BiPAP Focus Ventilators by serial number that our records indicate are under your control. Also noted is the number of power cords that our records indicate were ordered as a separate stock item. Please confirm that the ventilator or parts on the Business Response Form are under your control and report any discrepancies to Respiroics immediately.

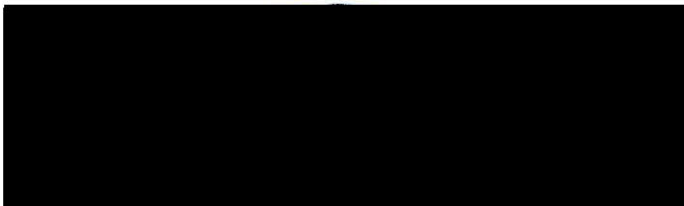
All replacement power cords will be sent, at no cost to you, for each product on the attached list. You do not need to contact Respiroics to place an order for your replacement parts. Upon receipt of the new power cords please replace and destroy all affected power cords. Once the upgrades are complete, record all relevant information on the Business Response Form. Please sign and return the enclosed Business Response Form by fax to 1.760.918.0169 or in the enclosed self addressed return envelope to:

Respiroics California, Inc.
2271 Cosmos Court
Carlsbad, CA 92011
Attn: BiPAP Focus Power Cord Field Action

The BiPAP Focus Ventilator may continue to be used following standard clinical practice and normal patient monitoring. If there is a failure of the power supply during operation, the device will switch to back-up-battery power, initiate an audible alarm and display the messages "Loss of AC" and "On Battery". The device will continue to operate for approximately 45 minutes (at default setting) given a fully charged battery.

We apologize for the inconvenience this will cause you. Thank you for your diligent attention to this matter. If you have any questions or need additional information about this field action or your upgrades, please contact your local distributor or Respiroics US Customer Service at 1.800.345.6443, Option #5 then select Option #1, or Respiroics International Customer Service at 1.724.387.4000.

Sincerely,



Vice President, Quality Assurance and Regulatory Affairs
Respiroics California Inc.