



Airon

September 20, 2010

Subject: Patient Breathing Circuit Advisory

As the manufacturer of pNeuton Transport Ventilators and MACS CPAP Systems we are always concerned about patient safety. This advisory is to alert you to unauthorized patient breathing circuits being marketed by other companies. These circuits may cause ventilator malfunction and possible dangerous side effects for patients.

The reasons for using the Airon circuits are:

- 1. The performance of the pressure control systems in Airon products are dependent on the quality and operation of the patient circuit exhalation valve. Use of an improper exhalation valve may cause increased expiratory resistance and varying pressure application.***
- 2. The specifications for the expiratory valve were developed and extensively tested to insure the safety and effectiveness of the pressure control system. The FDA marketing clearance of the Airon's ventilators / CPAP is based upon this test data.***
- 3. Only Airon manufactured patient circuits have been tested to meet our quality standards. Circuits from other manufacturers have untested performance and unknown quality control.***
- 4. The liability of using unauthorized circuits on a life support medical device falls on the user. We strongly suggest you do not attempt to use unauthorized circuits.***

This advisory is based upon the experience of a major hospital who used unauthorized patient circuits. This hospital had 8 of their 12 ventilators cease to work properly after they began using circuits from a different manufacturer. Simple visual tests are not sufficient to ensure proper operation of the pNeuton ventilators when using unauthorized patient circuits.

Our patient circuits are competitively priced. The savings from unauthorized circuits are small compared to the potential liability. All Airon circuits are identified with FDA cleared labeling. We offer these circuits in 6 foot length (P/N 58001), 8 foot length (P/N 58051), 6 foot with non-invasive mask / headstrap (P/N 58011) and 6 foot with mask and expiratory filter (P/N 58021).

Please contact us if you have any questions regarding this advisory. For clarification of your local authorized Airon distributor, please call.

Sincerely yours,

G. Eric Gjerde
President & CEO

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