



**MRI Certification**  
**pNeuton Ventilators**

The pNeuton Ventilators Model A, Model S and mini are MRI compatible devices. They are all USA FDA cleared for use with MRI scanners. These ventilators will not produce image artifacts when used next to the bore of the MRI. The MRI will not effect the ventilator's operation and the ventilators will not be attracted into the magnet. There is no Gauss line restriction with any pNeuton Ventilator.

The pNeuton mini Ventilator was carefully tested following the most recent ASTM F2119 and F2213 Standards. Per the ASTM F2503 terminology standard the mini Ventilator was found to be MRI Conditional. The FDA cleared labeling is:

Non-clinical testing demonstrated that the pNeuton mini Infant Ventilator is MR Conditional and can be used in the MRI environment according to the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

The pNeuton models A and S were tested and approved before the issuance of the above ASTM standards. The labeling on each ventilator is slightly different based upon the FDA rules at the time of clearance. They are all manufactured using identical materials and components. If they were to be tested today they would have the same labeling as the pNeuton mini Ventilator.

The Mobile Stand (part numbers 21001, 21005) are made from non-ferrous materials. These stands have been tested and shown to be safe when used in the MRI. The Oxygen and Medical Air Cylinders (part number 21071, 21072) are made from non-ferrous materials. These cylinders have also been tested and shown to be safe when used in the MRI. All of these accessories may be used with any of our ventilators in MRI scanners up to 3 T.

Sincerely yours,

A handwritten signature in blue ink that reads "Eric Gjerde".

Eric Gjerde  
President & CEO

25 July, 2014