Model 3100B High-Frequency Oscillatory Ventilator - P890057/S014

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	Model 3100B High-Frequency Oscillatory Ventilator
Manufacturer:	SensorMedics Corporation
Address:	22705 Savi Ranch Parkway, Yorba Linda, CA 92887-4645
Approval Date:	September 24, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p890057s014a.pdf

What is it, and how does it work? The Model 3100B High-Frequency Oscillatory Ventilator is used to help patients who suffer from a severe condition called Acute Respiratory Distress Syndrome (ARDS) that makes it impossible to breathe on their own. Like a conventional ventilator, the Model 3100B is connected to a patient's airway to deliver a humidified mixture of air and oxygen. Unlike a conventional ventilator, it breathes for the patient in very shallow, rapid breaths much in the way a dog pants (3 to 15 breaths a second). This improves breathing, by keeping the patient's lungs slightly inflated at all times. The ventilator has alarms to warn of conditions that may be dangerous to the patient, such as airway pressures that are too high or too low; or a failure in the ventilator that makes it unable to breathe for the patient.

When is it used? The Model 3100B ventilator is used to treat patients who have ARDS and weigh at least 35 kilograms (77 pounds). There are two other models of this ventilator:

1. Model3100 was approved by the FDA in 1992 for newborns with respiratory failure and injury from excess pressure to the lungs (barotrauma) and **2.** Model 3100A was approved in 1995 expanding the indications for use to include selected pediatric patients who are failing conventional ventilation.

What will it accomplish? Like all ventilators, this device will breathe for a patient by delivering oxygen to the patient's lungs and removing carbon dioxide. However, this high-frequency ventilator may produce less injury than conventional ventilators. A clinical study showed better survival for patients treated with the high-frequency ventilator as compared to those treated with a conventional ventilator. Also, the high-frequency ventilator patients were more likely to successfully breathe on their own after six months. However, patients treated with the high-frequency ventilator were less likely to breathe on their own after

only one month.

When should it not be used? The ventilator should not be used to deliver drugs in the form of a mist (aerosolized drugs). In addition, the benefits and risks of using the ventilator to treat patients with severe chronic obstructive pulmonary disease (COPD) or asthma are unknown.

Additional information: The SSED and Labeling will be available at: http://www.fda.gov/cdrh/pdf/p890057s014.html

Other:

- National Library of Medicine's lung disease information: http://medlineplus.nlm.nih.gov/medlineplus/ency/article/000103.htm
- National Heart, Lung, and Blood Institute (NHLBI)
- List of general lung information: http://www.nhlbi.nih.gov/health/public/lung/index.htm
- Brochure on lung diseases: http://www.nhlbi.nih.gov/health/public/lung/other/res_fail.pdf

(Updated 2/20/02)