



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Approval [PMA] Review

P890057/S14/A1, A2 and A3

Date: June 4, 2001

To: The Record

From: William A. Noe, Electrical Engineer

Office: HFZ-450

Division: DCRD/ARDB

Company Name: SensorMedics Corporation

Device Name: Model 3100B High-Frequency Oscillatory Ventilator

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I. Purpose

The sponsor has submitted this PMA supplement to gain FDA approval of a modified high-frequency oscillatory ventilator (HFOV) intended to accommodate larger patients than the approved Model 3100A HFOV.

II. Intended Use/Indications for Use

From the Summary of Safety and Effectiveness (see Amendment 1, page 8):

The SensorMedics 3100B is indicated for use in the ventilatory support and treatment of selected patients 35 kilograms and greater with acute respiratory failure.

The device has no specific contraindications.

III. Device Description

A. Summary

Life-supporting or life-sustaining?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Implant?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Sterile?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Single use?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

Prescription use?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Home use?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Transport use?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Drug or biological combination product?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Kit?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Software driven?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Electrically Operated?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

B. Design/Specifications

The SensorMedics 3100B HFOV consists of six subsystems, and is used with an external air/oxygen blender and an external humidifier. The six subsystems are: (1) pneumatic logic and control; (2) patient circuit; (3) oscillator subsystem; (4) airway pressure monitor; (5) electronic control and alarm subsystem; and (6) electrical power supply. The individual subsystems are now described.

Pneumatic Logic and Control

The pneumatic logic and control subsystem receives pressurized, blended gas from the external air/oxygen blender. The subsystem includes three pneumatic controls:

1. A bias flow control is provided to set the flow of the blended gas that continuously moves past the patient airway. The bias flow can be set as high as 60 L/min.
2. A mean pressure adjust control is provided to set the mean pressure level on which the oscillatory waveform is superimposed. The mean pressure set and the oscillatory waveform determines the actual mean airway pressure. This control opens and closes a variable restriction control valve in the patient circuit as described in the next section.
3. A patient circuit calibration set screw is provided, which is used to calibrate the pressure limit valve control. The set screw is adjusted only when the patient circuit is replaced or when the control valve diaphragm of the patient circuit is replaced.

Patient Circuit

The patient circuit provides the gas flow required for ventilation of a patient using HFOV techniques. In conjunction with the oscillator subsystem and the airway pressure monitor described below, the patient circuit provides: (1) means to convey bias flow/mean pressure from the humidifier; (2) means to convey pressure oscillations from the oscillator subsystem; (3) a pressure sensing port; and (4) pressure limiting valves.

1. During normal operation, blended, humidified gas flows from the humidifier into the continuous flow line on the inspiratory limb of the patient circuit. The bias flow passes through a wye coupler to which an endotracheal tube is connected, and into the expiratory limb of the patient circuit. Carbon dioxide is removed from the endotracheal tube by the gas mixing that occurs at the wye coupler. The expiratory limb includes two flow paths. One of the paths terminates in a variable restriction control valve controlled by the mean pressure adjust control described in the previous section. The other path terminates in a fixed orifice which ensures a minimum flow of fresh gas regardless of the setting of the control valve.
2. The inspiratory limb of the patient circuit conveys the oscillatory pressure from the oscillator subsystem to the patient through the wye coupler and the endotracheal tube.
3. An airway pressure sensing port at the wye coupler for connection of the airway pressure monitor.
4. The patient circuit includes two valves which limit the mean airway pressure:
 - a. The first valve is a pressure *limit valve* which is controlled by the pressure limit valve control described in the electronic control and alarm section below. If the mean airway pressure exceeds the maximum mean pressure level, the limit valve opens to release the excess pressure. When the mean airway pressure falls to approximately 80% of the maximum mean pressure level, the limit valve closes again.
 - b. The second valve is an electrically-controlled pressure *dump valve*, which opens if the mean airway pressure sensed by the airway pressure monitor is greater than 60 cm H₂O or less than 5 cm H₂O. When the dump valve opens, it remains open until the over-pressure or under-pressure condition is resolved and the device is reset.

Oscillator Subsystem

The oscillator subsystem comprises a linear motor driven by an electronic square-wave driver. The permanent magnet and the coil in the motor have no physical contact; instead, the coil is suspended near the permanent magnet. The coil drives a “piston” (i.e., diaphragm) to produce pressure oscillations which are conveyed to the patient through a patient circuit connected to the oscillator subsystem. The electronic square-wave driver is controlled by the electronic control and alarms subsystem,

wherein the oscillatory frequency can be set between 3 and 15 Hz; and the inspiratory time can be set between 30 and 50%. Two mechanical stops limit the displacement of the piston in the “full inspiration” and “full expiration” directions. The entire stroke volume from “full expiration” to “full inspiration” is approximately 365 mL.

The linear motor is air-cooled by a flow of 100 L/min past the coil. If the coil temperature reaches 150°C, a yellow caution LED in the electronic control and alarm subsystem is illuminated. If the coil temperature reaches 175°C, the oscillator shuts down and an audible alarm sounds.

Airway Pressure Monitor

The airway pressure monitor senses the pressure within the patient circuit through a tube that runs from the wye coupler of the patient circuit (i.e., the proximal end of the endotracheal tube”) to the transducer in the airway pressure monitor. A dry gas flow of 500 mL/min flows through the sensing tube to keep it free of water vapor. The mean airway pressure is obtained by low-pass filtering of the instantaneous pressure signal. The change in pressure is obtained by subtracting the oscillatory trough pressure from the oscillatory peak pressure.

Electronic Control and Alarm Subsystem

The electronic control and alarm subsystem includes: (1) oscillator subsystem controls and indicators; and (2) alarm indicators and controls.

1. The oscillator subsystem controls provide input to the electronic square-wave driver which drives the piston in the oscillator subsystem to produce pressure oscillations in the patient circuit.
 - a. A power control potentiometer is provided to adjust the magnitude of the pressure oscillations produced by the piston in the oscillator subsystem. The magnitude associated with the set power is displayed on a digital indicator.
 - b. A percent inspiratory time control potentiometer is provided to adjust the proportion of the oscillator cycle time that the piston is travelling toward or at its final inspiratory position. The control can be set between 30 and 50%. The set percent inspiratory time is displayed on a digital meter. At high oscillator frequencies, a decrease in the percent inspiratory time can decrease the magnitude of the pressure oscillations because the shorter inspiratory times may not give the piston sufficient time to reach its final inspiratory position.

- c. A frequency control potentiometer is provided to adjust the frequency of the oscillations produced by the oscillator subsystem. The frequency control can be set between 3 and 15 Hz. The set frequency is displayed on a digital meter.
 - d. A start/stop control is provided to enable and disable the oscillator subsystem.
2. The alarms indicators notify the clinician when an alarm condition is met, and the alarm controls allow the user to set some alarm levels, to temporarily silence the audible alarms and to reset the device after an alarm condition has been corrected.
- a. The maximum mean airway pressure can be set between 0 and 59 cm H₂O using a thumbwheel control. If the mean airway pressure is greater than the set level, audible and visible alarms are annunciated and a limit valve in the patient circuit opens to release the excess pressure. When the mean airway pressure falls to approximately 80% of the maximum mean pressure level set, the audible alarm resets and the limit valve closes again. The visible alarm remains annunciated until the alarm reset is activated.
 - b. The minimum mean airway pressure can be set between 0 and 59 cm H₂O using a thumbwheel control. If the mean airway pressure is less than the set level, audible and visible alarms are annunciated. When the alarm condition is corrected, the audible and visible alarms automatically reset.
 - c. If the mean airway pressure exceeds 60 cm H₂O for more than 1.5 seconds, audible and visible safety alarms are annunciated; the dump valve in the patient circuit opens; and the oscillator subsystem automatically shuts down. The dump valve remains open and the pressure in the patient circuit approaches the ambient pressure. The bias flow continues to provide fresh gas to the patient through the patient circuit. The dump valve remains open, and the alarms continue to annunciate until the alarm reset is activated.
 - d. If the mean airway pressure is less than 5 cm H₂O, audible and visible safety alarms are annunciated; the dump valve in the patient circuit opens; and the oscillator subsystem

automatically shuts down. The dump valve remains open and the pressure in the patient circuit approaches the ambient pressure. The bias flow continues to provide fresh gas to the patient through the patient circuit. When the alarm condition is corrected, the audible alarm resets. The dump valve remains open and the visible alarm continues to annunciate until the alarm reset is activated.

- e. If the electrical power to the device is lost, audible and visible power failure alarms annunciate. The alarms continue to annunciate until the alarm reset is activated.
- f. If the oscillator is enabled and the magnitude of pressure oscillations is less than approximately 7 cm H₂O, audible and visible “oscillator stopped” alarms annunciate. When the alarm condition is corrected, the alarms reset.
- g. If the temperature of the oscillator coil reaches 150°C, a visible caution annunciates to indicate that the coil is overheating, but the device continues to operate. When the caution condition is corrected, the caution resets. If the temperature of the coil reaches 175°C, the oscillator shuts down, and the oscillator stopped alarm (described in item f, above) annunciates.
- h. If the voltage on the battery that supplies the power failure alarms is low, a visible caution annunciates to indicate that the battery should be changed as soon as possible to ensure continued operation of the power failure alarm. When the caution condition is corrected, the caution resets.
- i. If the gas pressure at the “inlet from blender” connection or the “air cooling” connection is less than 30 psig, a visible caution is annunciated. When the caution condition is corrected, the caution resets.
- j. Audible alarms can be silenced by activating a 45-second silence button. When the button is pressed, the audible alarm is silenced for a period of 45 seconds. During this time, a visible caution is annunciated, but no audible alarms will sound.
- k. The alarm reset button resets the safety alarms and the power failure alarm when pressed. To begin operation of the device after a safety alarm, the alarm condition must be corrected, the oscillator must be enabled and the alarm

reset button must be pressed until the dump valve in the patient circuit closes and the mean airway pressure is greater than 5 cm H₂O.

C. Comparison of the Approved Model 3100A and the Model 3100B

The table below compares the Model 3100B and the approved Model 3100A HFOV.

Specification	3100A (approved)	3100B	Units
Min. safe mean airway pressure	20% of user-set max. mean airway pressure	5	cm H ₂ O
Max. safe mean airway pressure (i.e., safety dump pressure)	50	60	cm H ₂ O
Safety dump delay	0	1.5	seconds
User-set min. mean airway pressure	0–49	0–59	cm H ₂ O
User-set max. mean airway pressure	0–49	0–59	cm H ₂ O
Mean airway pressure limit	10–45	Linked to user-set max. mean airway pressure	cm H ₂ O
Max. oscillator driver voltage	42	75	V pk-pk
Max. pressure oscillation (ΔP)	≈105	≈140	cm H ₂ O
Oscillator frequency	3–15	3–15	Hz
% inspiratory time	30-50	30-50	%
Piston centering	Manual	Automatic	
Oscillator cooling gas flow	60	100	L/min
Patient circuit length	25	51	inches
Max. bias flow	60	60	L/min

D. Risk Analysis

An summary of an FMEA analysis is provided on pages 89-104 of the submission. This analysis identifies foreseeable risks incurred with the use of the Model 3100B and the measures taken to mitigate those risks.

E. Materials/Biocompatibility

The materials in the device are apparently identical to those in the previously approved Model 3100A.

F. Performance Testing

Tidal Volumes

A graph provided on page 44 of the submission summarizes the tidal volumes attained with endotracheal tubes of various diameters (5, 7, and 9 mm) and various oscillator frequencies (3 and 15 Hz) and amplitudes. The greatest tidal volume, obtained with an 9 mm endotracheal tube, an oscillator frequency of 3 Hz and amplitude of 10 (uncalibrated) was 260 mL. Additional performance testing is provided in the operator's manual (see pages 516-520 of the submission). We note that the maximum driver power for the Model 3100B is greater than the maximum driver power for the approved Model 3100A. The sponsor should clarify whether these performance graphs are for the Model 3100B.

Mean Time Before Failure

Page 46 of the submission summarizes testing of the Model 3100B to determine its mean time to failure. Three units were run essentially continuously with an oscillator frequency of 3 Hz, an inspiratory time of 50% and at full power. All of the units continued to operate for at least 2000 hours and the mean time to failure was 2680 hours. In each case, the failure was due to a torn driver diaphragm. A fourth unit was run essentially continuously at 50% power, and had not failed as of November 14, 2000, when it had accumulated 6792 hours of operation. In the course of the clinical study, at least six driver diaphragm ruptures occurred over less than 457 total days of ventilation with the Model 3100B. The associated estimate of the mean time to failure is 1828 hours. The sponsor should discuss the relevance of this issue to the safety and effectiveness of this device, and should describe how the risk to the patient to an intra-procedure failure of the Model 3100B is mitigated.

Validation Report

A validation report for the Model 3100B is presented on pages 47-86 of the submission. The report verifies:

1. the performance of the user-set maximum mean airway pressure alarm and the limit valve in Section B of the report;
2. the maximum safe mean airway pressure alarm and the dump valve in Section C;
3. the minimum safe mean airway pressure and the dump valve in Section D;
4. the maximum bias flow in Section E;

5. the cooling gas flow in Section F;
6. the automatic centering of the oscillator piston in Section G;
7. the acceptability of a patient circuit with total length of 51 inches in Section H;
8. the maximum oscillatory pressure amplitude in Section J.

Explicit acceptance criteria are provided for each test, and two units have been shown to meet all acceptance criteria.

G. Clinical Study

Pages 105-434 of the submission summarize the clinical study of performed to assess the safety and effectiveness of the device under review. This material is the subject of a separate clinical review, and I have not reviewed it.

H. Other Clinical Information

Pages 435-484 of the submission present other published clinical information relevant to the review of this device. I have not completed a review of this material.

I. Labeling

I have reviewed the technical content of the operator's manual for the device and I believe that the manual adequately describes the technical aspects of the device.

IV. Recommendation

I believe that the following information should be requested of the sponsor:

1. In your submission (on page 46), you summarize testing of your device to determine its mean time to failure. Three units were tested, and each was shown to operate for at least 2000 hours. The mean time to failure was 2680 hours. In each case, the failure was due to a torn driver diaphragm. However, in the course of the clinical study, at least six driver diaphragm ruptures occurred over the less than 457 total days of ventilation with the Model 3100B. The associated estimate of the mean time to failure is 1828 hours. Please explain why failure of the driver diaphragms does not affect the safety and effectiveness of this device, and describe how the risk to the patient from an intra-procedure failure of your device is mitigated. It is

possible that more frequent replacement of the oscillator assembly (which is now replaced every 2000 hours) would more effectively mitigate this risk.

2. The operator's manual for your device includes graphs which summarize its performance (see pages 516-520 of the submission). We note that the maximum driver power for the Model 3100B is greater than the maximum driver power for the approved Model 3100A. Please confirm that these performance graphs are for the Model 3100B.

William A. Noe