

1K963250

NOV 14 1996



# RESPIRONICS INC.

## Non-Confidential Summary of Safety and Effectiveness

page 1 of 3

August 16, 1996

Respiroincs, Inc.  
1001 Murry Ridge Drive  
Murrysville, PA  
Tel - (412) 733-0200  
Fax - (412) 733-0299

<b>Official Contact:</b>	Francis X. Dobscha, Manager, Regulatory Affairs
<b>Proprietary or Trade Name:</b>	Pressure Valve
<b>Common/Usual Name:</b>	One-way valve
<b>Classification Name:</b>	Accessory for Ventilator, Passive Exhaust Port, Critical Care
<b>Device:</b>	Respiroincs Pressure Valve
<b>Predicate Devices:</b>	Instrumentation Industries, Inc. - Reusable One-Way Valve (Preamendment)

### Device Description:

The Pressure Valve is an in-line one-way valve which prevents oxygen or water in the patient circuit from backflowing into the Respiroincs CPAP or bi-level device when the unit is not functioning. The Pressure Valve incorporates a valve disc, spring, and housing. The device vents any backflow to the atmosphere when the pressure output of the Respiroincs CPAP or BiPAP unit drops below 0.5 cm H<sub>2</sub>O.

### Intended Use:

Indicated Use --	To prevent backflow of oxygen or water from patient circuit into Respiroincs CPAP or BiPAP device when the unit is not functioning
Environment of Use --	Hospital and Home
Equipment --	Respiroincs CPAP and bi-level systems indicated for use with supplemental oxygen and/or humidifiers.

page 3 of 54

**Non-Confidential Summary of Safety and Effectiveness  
(continued)**

page 2 of 3  
August 16, 1996

**Comparison to Predicate Devices:**

<b>Attribute</b>	<b>Intended device: Respironics, Inc. Pressure Valve</b>	<b>Instrumentation Industries, Inc. One-Way Valve</b>
<b>Use</b>		
<u>Intended Use</u> -- placed in-line in patient circuits	Yes	Yes
<u>Intended equipment</u> - to be used only with Respironics, Inc. CPAP and bi-level systems	Yes	No
<u>Indicated</u> - to establish directional flow in a patient circuit and thus prevent backflow	Yes	Yes
<u>Indicated</u> - prevents backflow of oxygen or water into CPAP or bi-level device when the unit is not functioning.	Yes	No
<u>Intended environment</u> - Hospital and Home	Yes	Yes
<b>Design</b>		
Placed in-line in patient breathing circuit	Yes	Yes
Has standard 22 mm fittings	Yes	Yes
Vents backflow to atmosphere	Yes	No
Reusable - multiple use, can be cleaned	Yes	Yes
Materials - Body Valve Spring	Polycarbonate Polycarbonate Phosphor Bronze	Polycarbonate Silicone Rubber N/A
<b>Performance Standards/Specifications</b>		
Has minimal resistance to flow while in-line	Yes	Yes
Meets design requirements after cleaning	Yes	Yes

**Non-Confidential Summary of Safety and Effectiveness  
(continued)**

page 3 of 3

August 16, 1996

**Differences Compared To Other Legally Marketed Predicate Device**

The differences between the intended device and the Instrumentation Industries, Inc., One-Way Valve are -

- \* The intended device is designed to be used only with the Respironics, Inc., CPAP and bi-level systems.
  
- \* The intended device vents any backflow of oxygen or water to the atmosphere, whereas the predicate device is generally placed in a circle type of circuit and is not required to vent to atmosphere.

There are no other significant differences in design, intended use, safety and effectiveness between the Pressure Valve and the predicate device.