

BiPAP Vision Ventilator Testing with Various Patient Interfaces

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Prepared for
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Valley Inspired Products, LLC		Title: Vision Ventilator Interface Testing	Originator: PLB
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Background:

The Respironics BiPAP Vision is a bilevel ventilator which is used with a passive exhalation port (leak). The Vision uses a calibration step during setup to determine the magnitude of this ‘intentional’ leak. In this way, it can distinguish between the intentional leak and ‘unintentional’ or patient leak. The Vision will display the estimated patient leak if the leak test has been performed.

The purpose of this test is to evaluate the effect of not performing the leak test and/or performing the test with different exhalation ports combined with various mask interfaces. The ventilator reported tidal volume and leak flow, operation of low minute volume alarm and ability to deliver adequate pressure will be tested.

Interfaces Tested:

Description
Respironics Circuit with Full Face Mask
ResMed Full Face Mask with Integral Exhalation Port
ResMed Nasal Mask with Integral Exhalation Port

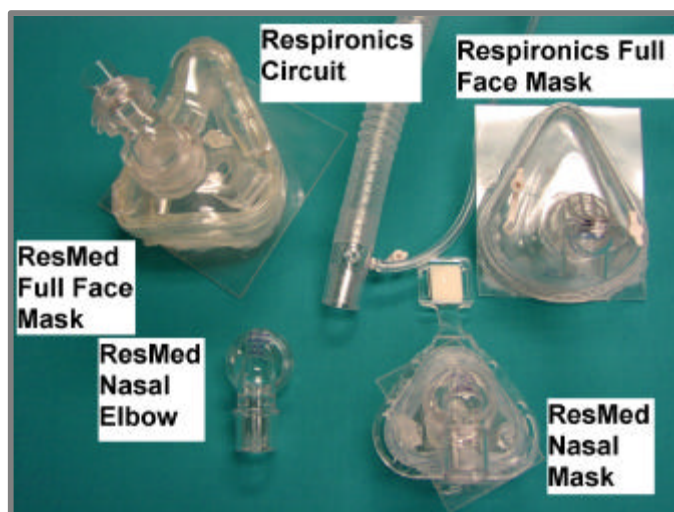


Figure 1. Units Tested

Methods:

Equipment

Breathing Simulator (Hans Rudolph series 1100)
Respironics BiPap Vision Ventilator Model 582059
Mass Flowmeter TSI Model 4040
Water Manometer Dwyer U-tube

Procedure

1. Tidal Volume/Leak Estimation Test

Install a flat plate to the patient side of each interface to be tested, with a 22 mm connector, so that the interface can be connected to the breathing simulator.

Set up Equipment per figure 2.

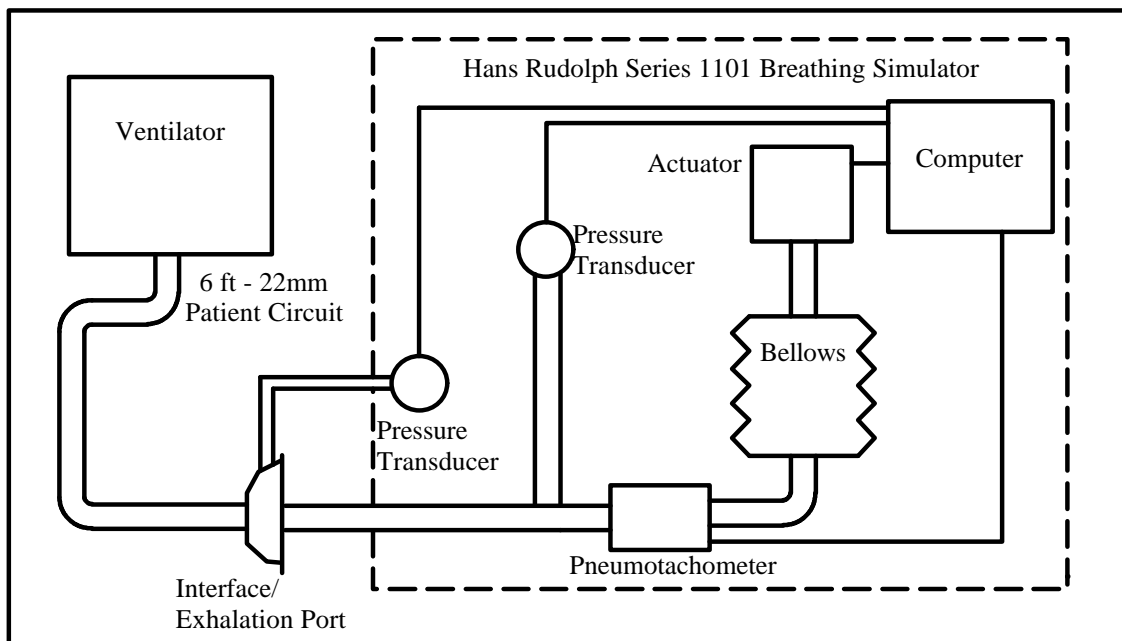


Figure 2. Test Setup

Calibrate all instruments.

Set the breathing simulator with the following settings:

Resistance 20 cmH₂O/liter/sec

Compliance 60 mL/cmH₂O

Frequency 20/min

Amplitude 5 cmH₂O

Slope 10

Insp. % 34

Set the Vision with the following settings

IPAP 20 cmH₂O

EPAP 4 cmH₂O

Freq. 12/min

Rise Time 0.1 sec

Perform the leak test after turning on the Vision. Perform the tidal volume/leak test by recording 10 consecutive tidal volumes as reported by the breathing simulator and by the Vision. Record the estimated leak as reported by the Vision.

Test the following combinations of interface used for ventilation/exhalation and interface used for the leak test. In some cases, the leak test is not performed at all.

Exhalation port used for Leak Test	Interface used for ventilation
Respironics Circuit	Respironics Circuit + Full Face Mask
Respironics Circuit	ResMed Full Face Mask
Respironics Circuit	ResMed Nasal Mask
No test performed	Respironics Circuit + Full Face Mask
No test performed	ResMed Full Face Mask
No test performed	ResMed Nasal Mask
ResMed Full Face Mask	ResMed Full Face Mask
ResMed Nasal Mask Elbow	ResMed Full Face Mask
ResMed Nasal Mask Elbow	ResMed Nasal Mask

Record patient flow, effort, and airway pressure for three breaths in each test condition.

Add an Rp 20 resistor in line between the interface and the breathing simulator. Change amplitude to 10.

For each combination of interface and exhalation port, record three breaths data. Calculate the inspiratory volume generated by patient effort before the ventilator is triggered from EPAP to IPAP. This method of trigger evaluation is chosen because the ventilator is designed to trigger when the measured inspiratory volume is 6 mL.

2. Low Minute Ventilation Alarm Test

Set the breathing simulator with the following settings:

Resistance 30 cmH₂O/liter/sec
Compliance 40 mL/cmH₂O
Frequency 12/min
Amplitude 4 cmH₂O
Slope 10
Insp. % 34

Set the Vision with the following settings

IPAP 10 cmH₂O
EPAP 4 cmH₂O
Freq. 4/min
Rise Time 0.1 sec
Low Minute Ventilation Alarm 3 liters/min

Reduce breathing frequency on the breathing simulator to assure that the low MV alarm sounds. Perform for the following combinations of leak.

Exhalation port used for Leak Test	Interface used for ventilation
Respironics Circuit	Respironics Circuit + Full Face Mask
Respironics Circuit	ResMed Full Face Mask
Respironics Circuit	ResMed Nasal Mask
ResMed Full Face Mask	ResMed Full Face Mask
ResMed Nasal Mask Elbow	ResMed Full Face Mask
ResMed Nasal Mask Elbow	ResMed Nasal Mask

3. High Flow/Pressure Test

Set the breathing simulator with the following settings:

Resistance 15 cmH₂O/liter/sec

Compliance 40 mL/cmH₂O

Frequency 8/min

Amplitude 6 cmH₂O

Slope 10

Insp. % 34

Set the Vision with the following settings

IPAP 35 cmH₂O

EPAP 4 cmH₂O

Freq. 4/min

Rise Time 0.1 sec

Run the leak test on the Vision using the ResMed Nasal Mask Elbow.

Install the ResMed Nasal Mask between the breathing simulator and the ventilator. This interface was selected because testing showed it to have the highest exhalation port flow.

Record patient flow and airway pressure during 3 breaths.

Repeat after installing an additional .190'' leak between the patient circuit and the mask, to simulate a significant unintentional mask leak.

4. Leak Flow Characterization

Connect a flow generator to each interface with the TSI flowmeter and monometer interposed. Plug the patient side of the interface.

Vary pressure from 4 to 36 cmH₂O, recording resultant leak flow.

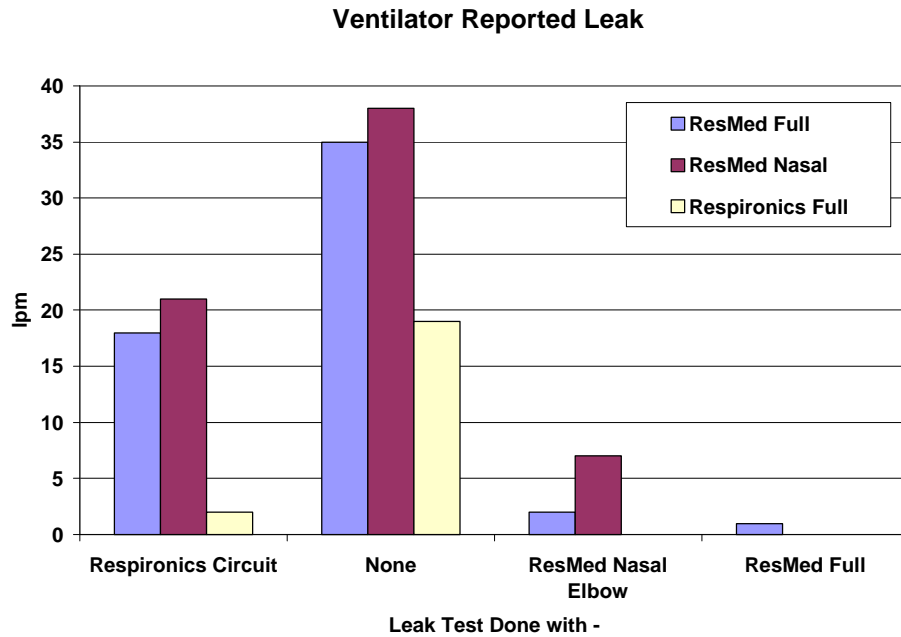
Results:

1. Tidal Volume / Leak Estimation / Triggering

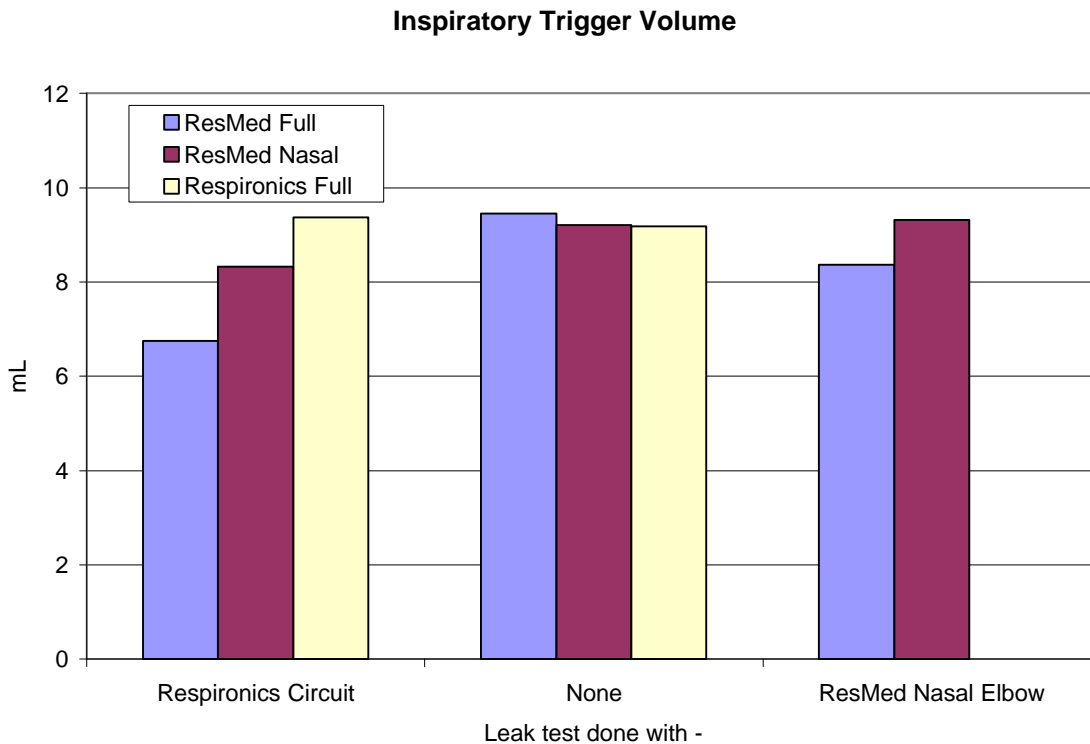
Exhalation Port used for Leak Test	Interface used for ventilation	Reported Leak lpm	Vision Tidal Volume	Simulator Tidal Volume	Deviation %
Respironics Circuit	Respironics Circuit + Full Face Mask	2	695	695	0.0%
Respironics Circuit	ResMed Full Face Mask	18	714	712	0.3%
Respironics Circuit	ResMed Nasal Mask	21	696	695	0.1%
No test performed	Respironics Circuit + Full Face Mask	19	702	704	-0.3%
No test performed	ResMed Full Face Mask	35	712	719	-1.0%
No test performed	ResMed Nasal Mask	38	691	699	-1.1%
ResMed Full Face Mask	ResMed Full Face Mask	1	707	714	-0.9%
ResMed Nasal Mask Elbow	ResMed Full Face Mask	2	702	690	1.8%
ResMed Nasal Mask Elbow	ResMed Nasal Mask	7	684	705	-2.9%

Tidal volumes shown are the average of 10 breaths for both the Vision and the Breathing Simulator.

The following graph shows the leak reported by the ventilator. When no leak test was performed, the Vision's reported leak is labeled 'Total Leak', when the leak test is performed it is labeled 'Patient Leak'.



The following graph shows the inspiratory volume required from patient effort before the ventilator cycled from EPAP to IPAP. Results are the average of 3 breaths.



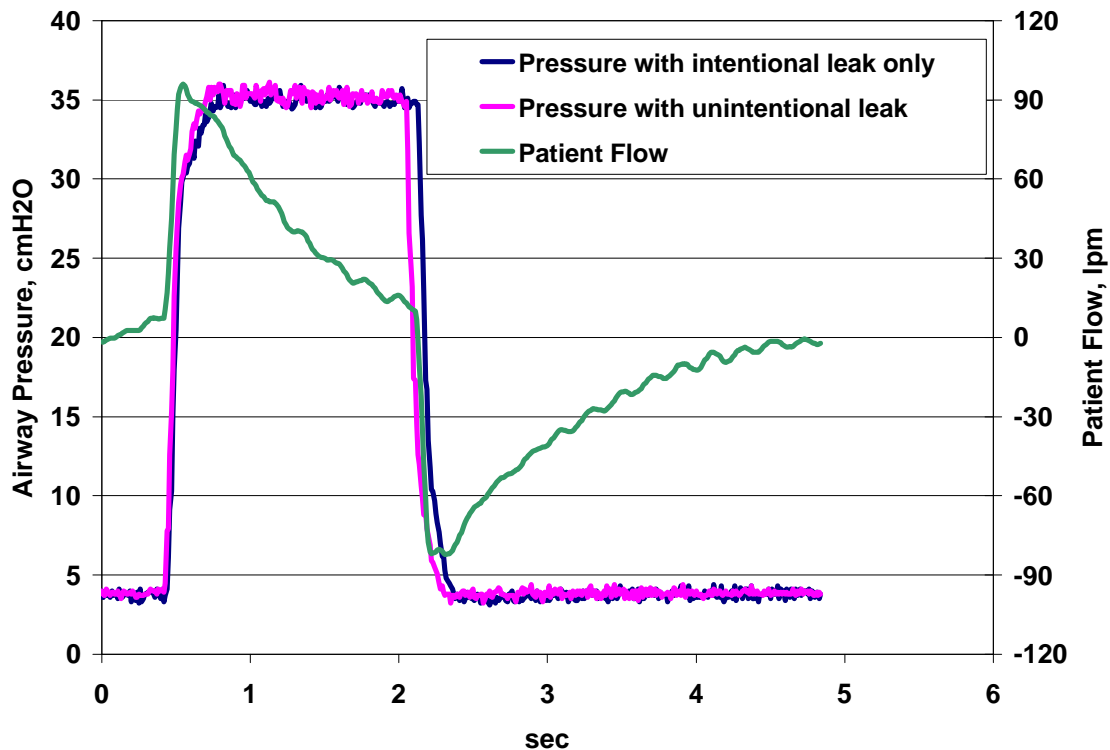
2. Low Minute Volume Alarm Test

In all combinations of interfaces and exhalation ports, the low minute volume alarm was triggered with simulator reported minute volumes in the range of 2.5 to 3 liters per minute. The Vision reports minute volume as an integer (no data to the right of the decimal), so it is difficult to judge the accuracy of the minute volume indicator in this range, but the indicator showed either 2 or 3 liters per minute during all tests.

The effect of not performing the leak test on the low minute volume alarm was not evaluated.

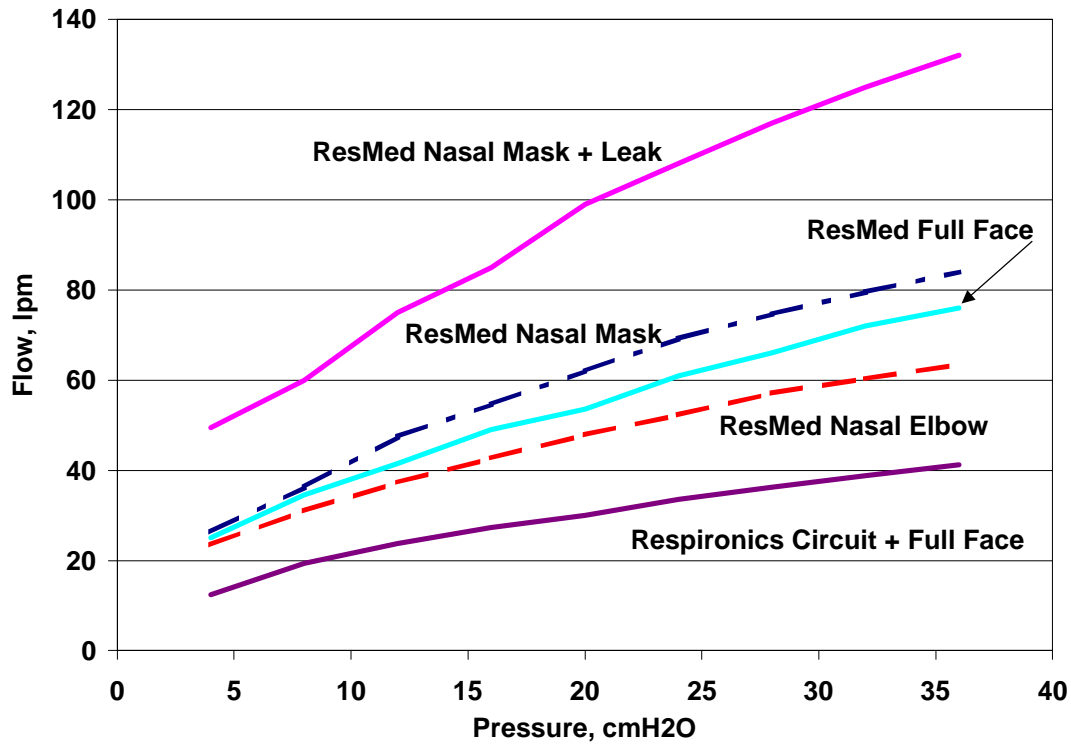
3. High Flow/Pressure Test

In both test conditions (using ResMed Nasal Mask, with and without added unintentional leak), the ventilator achieved the desired pressure. The following is a graph of the patient flow and the airway pressure for both conditions.



4. Leak Characterization

The following graph shows the measured leak flow at different pressures. The maximum intentional leak was achieved when using the ResMed Nasal Mask. The lowest leak was with the Respiroics Circuit and Full Face Mask. Also included in the chart are the values from the ResMed Nasal Mask combined with the .190" diameter 'unintentional' patient leak, which was used in the high flow/pressure test.



Observations

Use of various patient interfaces with the BiPAP Vision ventilator during this bench comparison did not affect its ability to accurately measure tidal volumes, trigger breaths, trigger the low minute volume alarm or deliver adequate pressure.

It appears that the leak test has the principal purpose of allowing measurement of patient leak separate from the intentional leak.

Caution should be used in extrapolating these bench results into the clinical setting, with a much wider variety of patient conditions. Measures should always be taken to assure that patients are receiving adequate ventilation.

Testing was completed at the offices of Valley Inspired Products, LLC in Burnsville MN February 5th through 15th 2002.

Signed:

A handwritten signature in black ink, appearing to read 'P. Bliss', is written over a horizontal line.

Peter L. Bliss
Technical Director
February 19, 2002