 <b>Valley Inspired Products</b>		<b>Title:</b> Auto-Adjust CPAP Evaluation	
<b>Origination Date:</b> October 24, 2008	<b>Revision Date:</b> November 10, 2008	<b>Document Number:</b> 08015	<b>Rev:</b> A

## Purpose:

This report will summarize and compare selected response characteristics of four models of Auto-Adjusting CPAP units. Units tested include Fisher & Paykel's **SleepStyle 200**, Puritan Bennett's **GoodKnight 420 Evolution**, Resironics' **REMstar Auto M-Series with A-Flex**, and ResMed's **S8 AutoSet Vantage**. Each machine was presented with one normal and three disordered breathing patterns mimicked by a mechanical lung simulator. The breathing patterns presented to each device were first recorded directly from a patient undergoing a polysomnographic study then converted for use by the lung simulator. In total, four breathing patterns were recorded and used: Normal, Apnea, Flow Limitation, and Hypopnea. In instances where a humidifier is not an integral part of the CPAP machine design, the CPAP unit was equipped with the manufacturer-approved heated humidifier component. The water chamber was filled to the maximum recommended level during the test. Heat was not applied. The resulting pressure changes in the Auto-Adjust units, as they were subjected to each pattern, were recorded.


## Equipment:

### Units Under Test (UUT):

<i>Labeled in Report as</i>	<b>Manufacturer, Model and Serial Numbers of APAP/Humidifiers tested</b>
<b>SS 200</b>	<b>APAP: Fisher &amp; Paykel SleepStyle 200 Auto Series S/N 080919006131</b> Humidifier: Integrated w/APAP
<b>PB 420E</b>	<b>APAP: Puritan Bennett GoodKnight 420 Evolution S/N H397340005</b> Humidifier: GoodKnight H2O Heated Humidifier S/N 5467100273
<b>REMstar</b>	<b>APAP: Resironics REMstar Auto M-Series with A-Flex S/N M001807895</b> Humidifier: Resironics M-Series Heated Humidifier S/N H001326455
<b>S8</b>	<b>APAP: ResMed S8 AutoSet Vantage S/N 20060360484</b> Humidifier: ResMed HumidAire 3i S/N 20060405692

### Additional Equipment:

Series 1101 Breathing Simulator- Hans Rudolph, Inc.  
6' Smooth-Bore CPAP Tubing

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\*The PB 420E will use the proprietary CPAP tubing/pressure line  
Pressure Line Adapter- Hudson, RCI

\*Modified with 4mm passive exhalation port  
-per ISO 17510-1 clause 26

Model 7110R-5 Linear Resistor- Hans Rudolph Inc.

\*5cmH<sub>2</sub>O/L/Sec

SP-CPF CPAP Filter- SP Medical

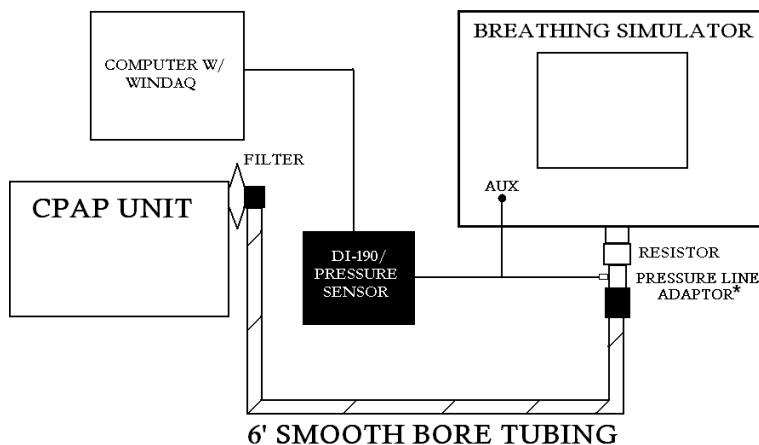
162PC01D Pressure Sensor- Honeywell Sensing and Control

DI-190 Data Acquisition Kit- DATAQ Instruments


Included WinDaq software used for data logging

## Procedure:

The DI-190 and WinDaq software was configured to read and record pressure from the Honeywell pressure sensor with a range of 0 cmH<sub>2</sub>O to 30 cmH<sub>2</sub>O, a sample rate of one data point every 10 seconds and file size of 3kb. Each CPAP unit was equipped with its respective heated humidifier components. The water chambers were filled to the manufacturer's recommended fill line with distilled water. Each CPAP unit was set up for testing using the diagram below:




\*PRESSURE LINE ADAPTOR IS MODIFIED TO ALLOW PASSIVE EXHALATION, 25LPM@20cmH<sub>2</sub>O

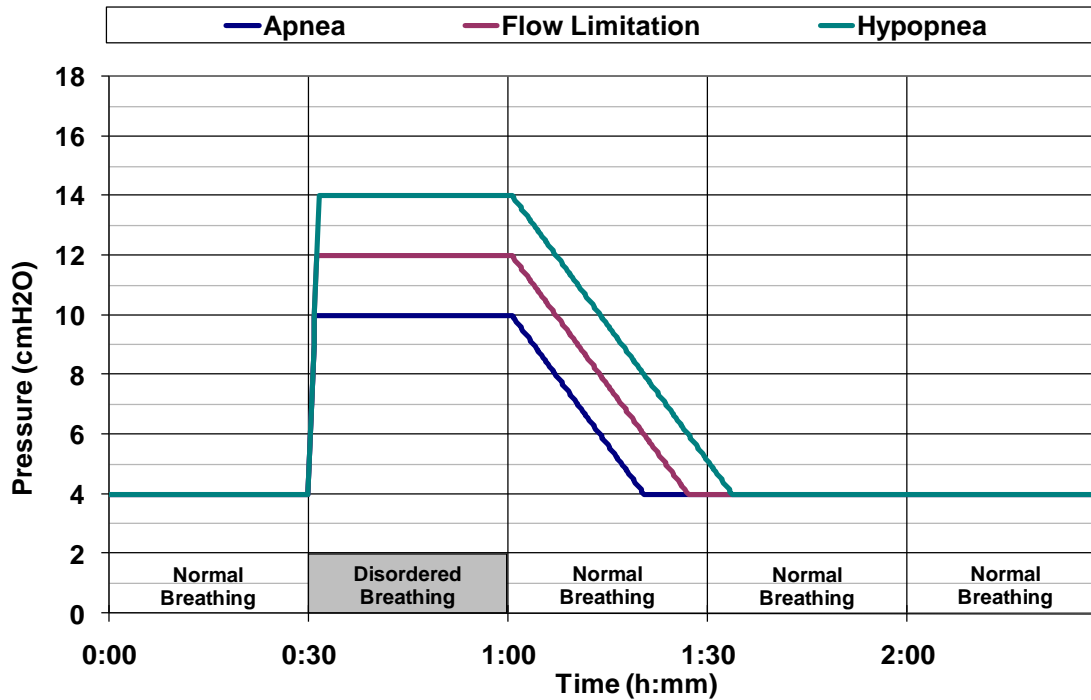
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The Breathing Simulator was set to operate in the Flow Mode and the “Normal” breathing pattern was initiated. The linear resistor was placed between the breathing simulator patient connection port and the modified pressure line adapter- since the breathing simulator operated in the “Flow Mode”, this dampened any “chatter” present in a breath without affecting the flow and volume generated by the simulator as it read the breathing signal flow rates. The CPAP machine was turned on and all clinician settings set to the default parameters. Expiratory pressure relief algorithms on the REMstar and S8 units were set to “Off”. On the SS 200 unit, the SensAwake™ feature was set to “On”. The heated humidifier on all units was set to “off”. The minimum pressure on the CPAP unit was set to 4 cmH<sub>2</sub>O and the maximum pressure to 20 cmH<sub>2</sub>O. The Apnea breathing pattern script file stored in the simulator memory was queued and initiated. Data was acquired using the WinDaq software. The Apnea script on the breathing simulator allowed the Normal breathing pattern to run for 30 minutes before initiating the Apnea pattern. The Apnea breathing pattern then ran for 30 minutes before reverting to the Normal breathing pattern for the remaining duration of the test. Data acquisition automatically ceased at ~2:40:00. This process was repeated for both the Hypopnea and Flow Limitation breathing patterns. Once all data was collected, the resulting data files were converted into a spreadsheet for data analysis.


The chart on the following page following displays example data from the process described above:

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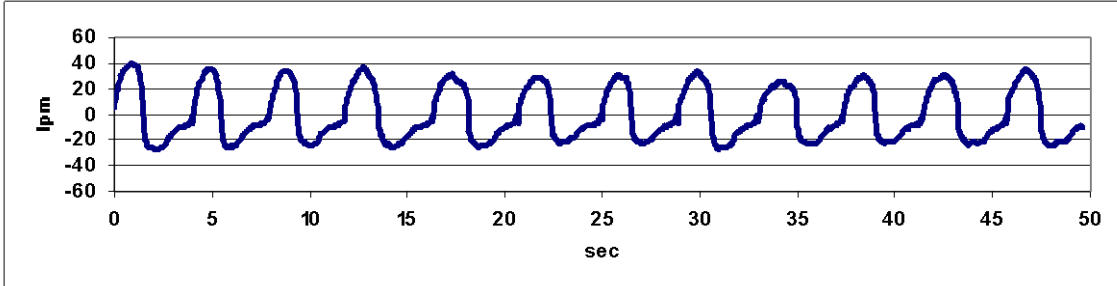
**Example Unit**



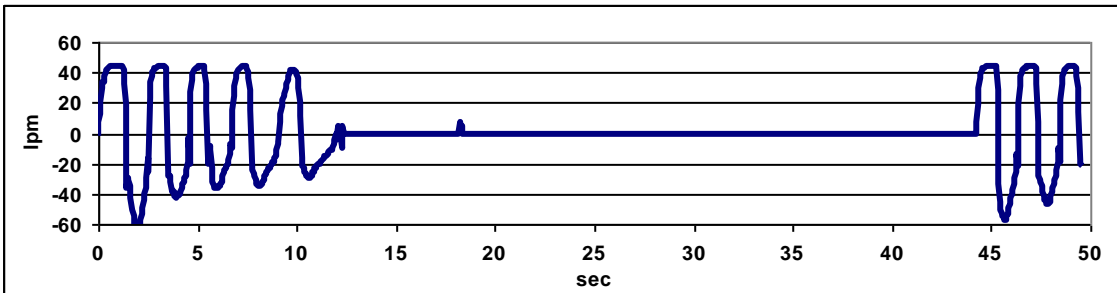
Shown on the following pages are 50-second samples of the four breathing patterns that were acquired from individual patients undergoing polysomnographic screening. The length of each pattern varies, with the Flow Limitation pattern running for approximately 8 minutes and the Hypopnea pattern running for approximately 12.5 minutes. Both the Normal and Apnea breathing patterns are approximately 10 minutes in length. These patterns are looped upon completion so that there is no break during the 30-minute disordered breathing section of this test.

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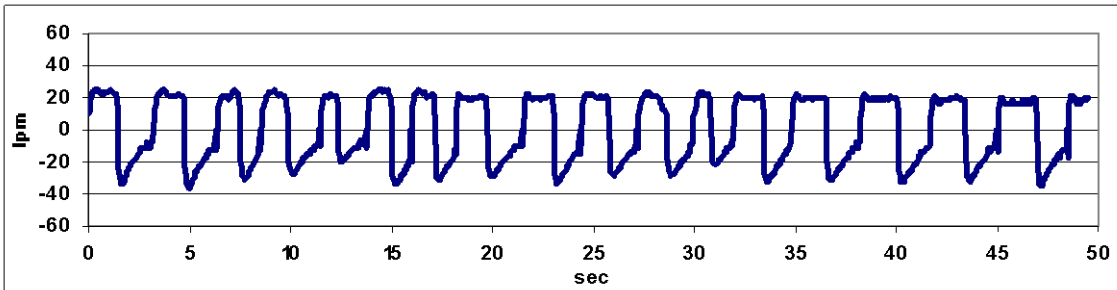
**Normal Breathing**




**Apnea**

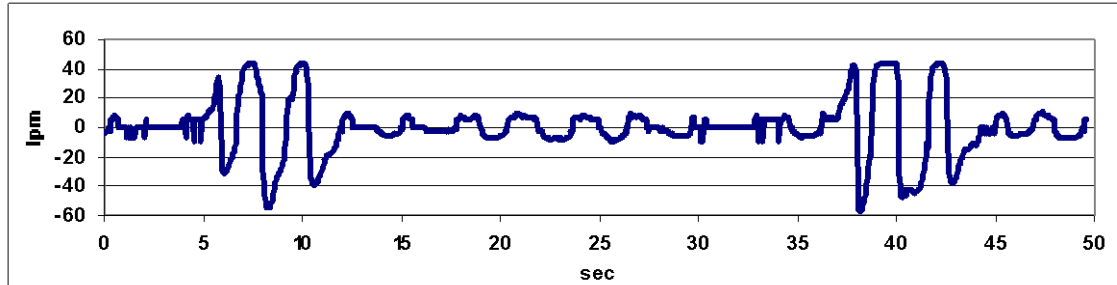


**Flow Limited**




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**Hypopnea**

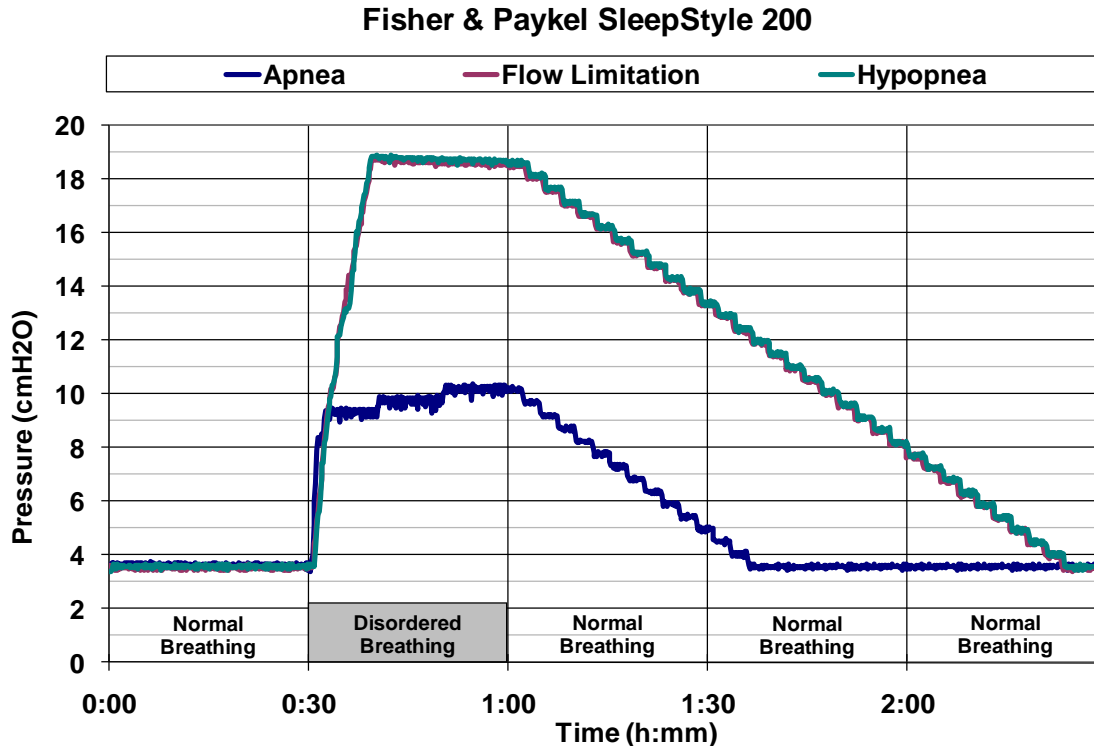


**Results and Observations:**


All devices tested were able to complete each series of tests in this evaluation without issue. All devices tested showed higher delivery pressures on their display screens than were recorded during the test, with the range between displayed and actual pressure generally increasing with an increase in therapy pressure. This is predominantly due to the pressure drop that occurs during flow delivery across the CPAP filter (which has a measured resistance of 1.9 cmH<sub>2</sub>O @ 60 LPM), with additional, smaller pressure drops occurring between the filled humidity chamber and 6' of CPAP tubing. Average differences between actual pressure delivered and the displayed 4.0cmH<sub>2</sub>O therapy pressure setting was -0.40 cmH<sub>2</sub>O on the SS 200, PB 420E and REMstar unit (ignoring the “hunting” pattern present on the Respironics device), and -0.25 cmH<sub>2</sub>O on the S8 unit. Differences at higher pressures are difficult to pinpoint during the actual test given that the unit may be continually fluctuating in delivery pressure during disordered breathing as well as during the return to lower pressures once the disordered breathing has ceased.

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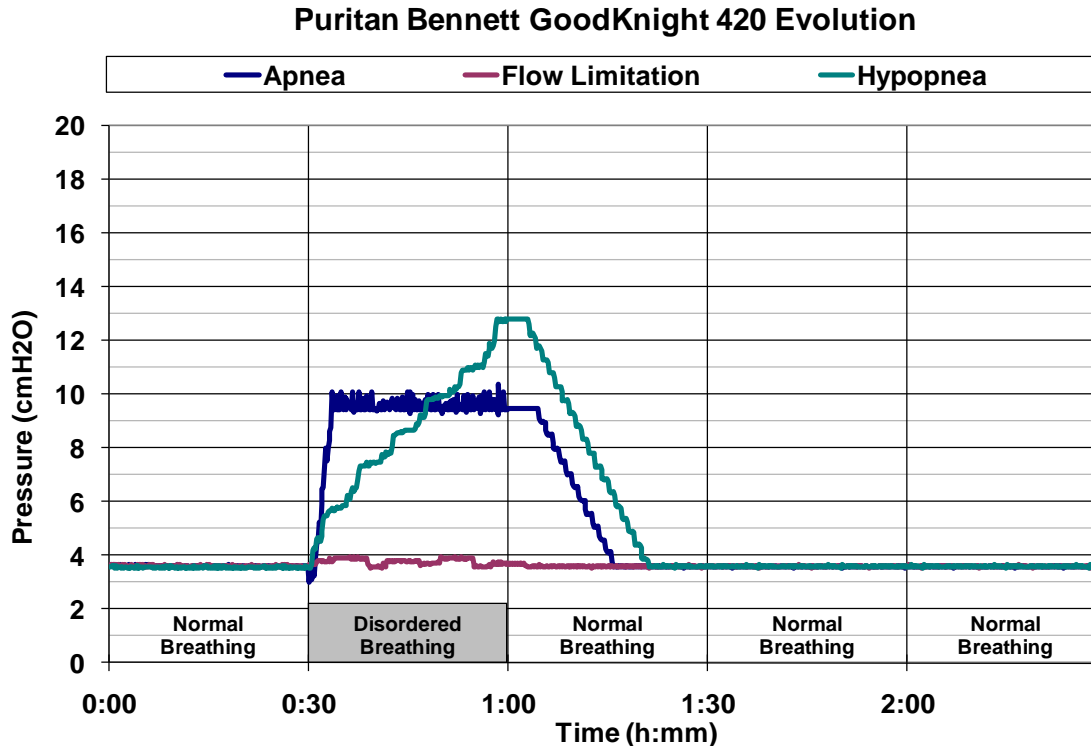
**Fisher & Paykel SleepStyle 200**




Response to the disordered breathing occurred quickly, with the SS 200 unit increasing the pressure to ~20.0 cmH<sub>2</sub>O within 10 minutes of the start of the Flow Limitation and Hypopnea breathing patterns. On the Apnea pattern, the device reached its default 10 cmH<sub>2</sub>O limit for Apnea pressure response (actual pressure at the patient airway was slightly over 9.0 cmH<sub>2</sub>O), and any pressure increases after were a result of other breathing abnormalities in the Apnea pattern. Once Normal breathing resumed, the device returned to 4.0cmH<sub>2</sub>O by dropping therapy pressure by 0.5cmH<sub>2</sub>O approximately every 2.5 minutes. This equated to approximately 1:20:00 of time to return to 4cmH<sub>2</sub>O in the Flow Limitation and Hypopnea scenarios once Normal breathing resumed.

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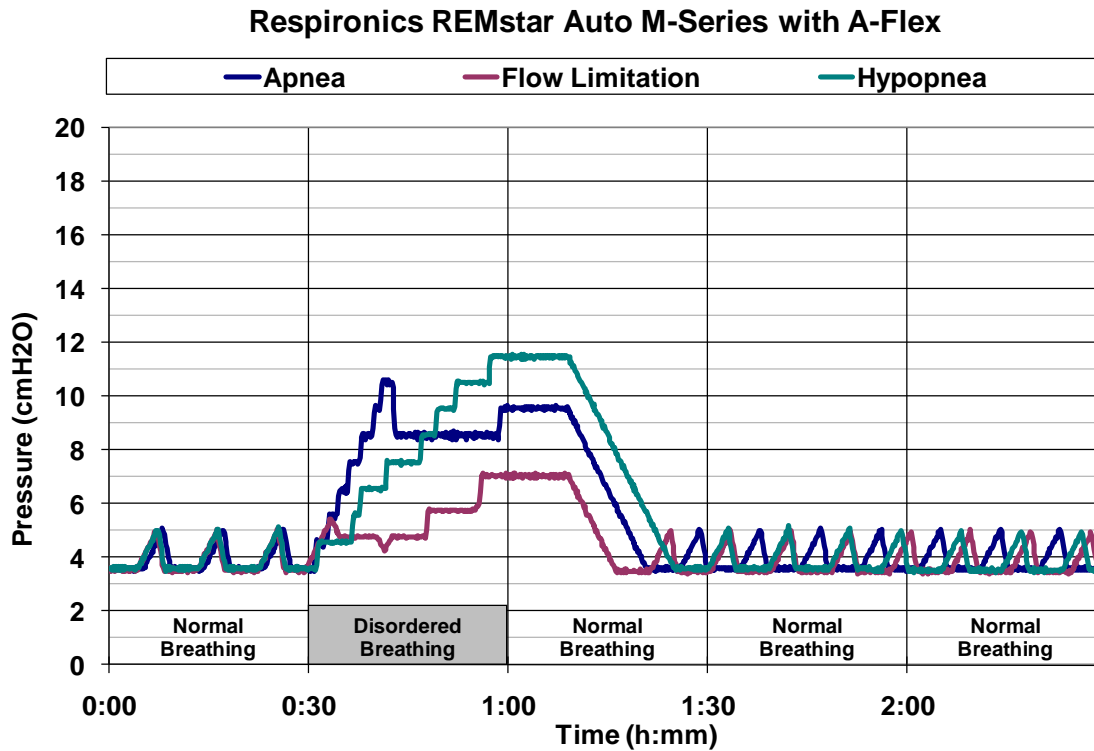
**Puritan Bennett GoodKnight 420 Evolution**




As with the SS 200 unit, the 420E unit has a default maximum response pressure of 10 cmH<sub>2</sub>O for Apnea events. This maximum was reached within 5 minutes of the Apnea pattern starting (actual pressure at the airway was ~9.5cmH<sub>2</sub>O) and remained there for the duration of the 30 minute session. There was very little response to the Flow Limitation pattern by the 420E. On the Hypopnea pattern, the 420E gradually increased the therapy pressure from 4.0 cmH<sub>2</sub>O up to 13.5 cmH<sub>2</sub>O (actual pressure at the airway from 3.6 cmH<sub>2</sub>O to 12.8 cmH<sub>2</sub>O) over the 30 minute session. Return to 4.0 cmH<sub>2</sub>O therapy pressure occurred within 15 and 20 minutes after cessation of the Apnea and Hypopnea patterns, respectively.

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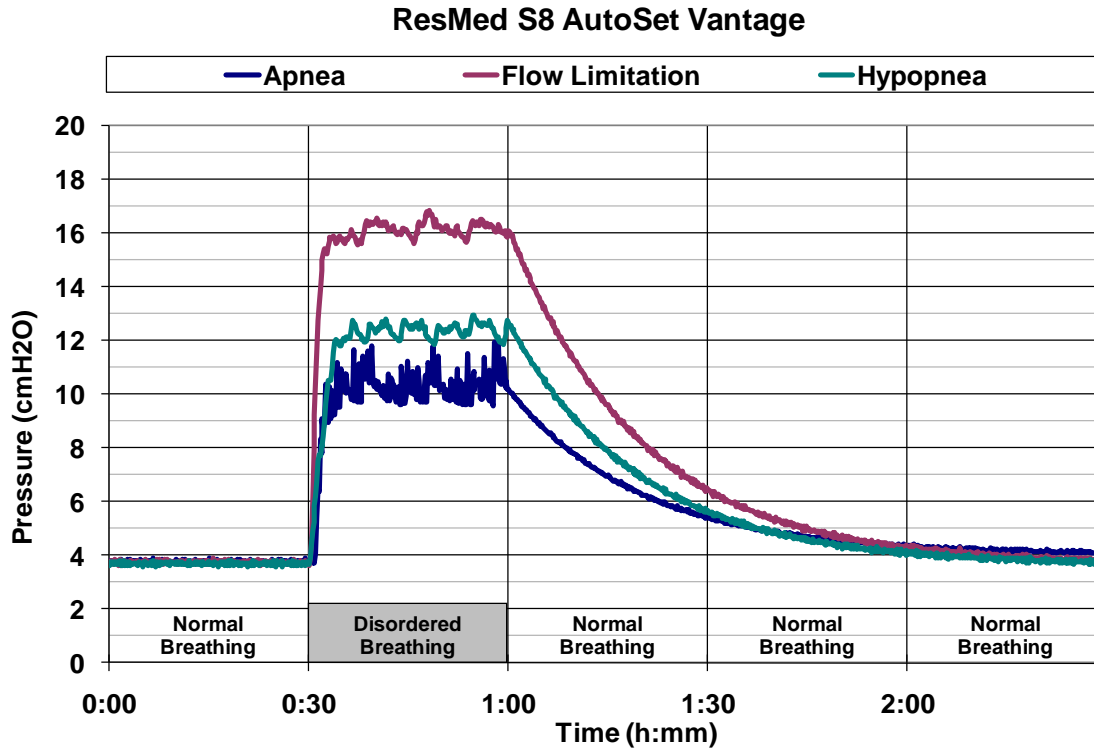
**Respironics REMstar Auto M-Series with A-Flex**




The REMstar unit features a “hunting” algorithm during Normal breathing, illustrated by the short pressure increases during the Normal Breathing sections of the chart. Only on the Hypopnea pattern did the REMstar unit have a patterned response over the 30 minute session, occasionally increasing pressure by ~1 cmH<sub>2</sub>O for the duration of the test, peaking at a therapy pressure of 12cmH<sub>2</sub>O at the end of the disordered breathing session. Pressure increased by ~1 cmH<sub>2</sub>O increments more quickly during the Apnea session but after approximately 12 minutes pressure was suddenly dropped by 2 cmH<sub>2</sub>O and remained there until just before the end of the session. Once Normal breathing returned, the device stayed at its current pressure setting for approximately 10 minutes before returning to initial pressure at a rate of ~0.5 cmH<sub>2</sub>O per minute.

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**ResMed S8 AutoSet Vantage**

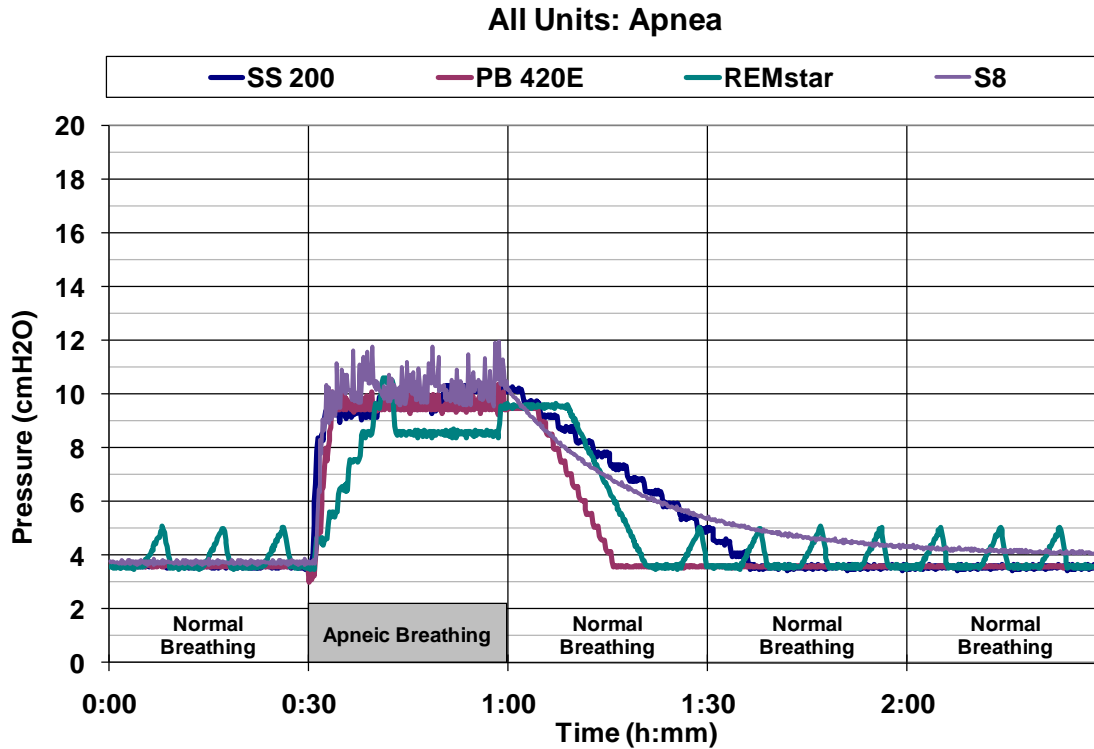


Response by the S8 unit to all three disordered patterns occurred quickly, with the unit reaching its initial peak pressure within the first five minutes of the session for each pattern tested. Once this initial peak pressure was achieved, the unit delivered fluctuating pressure for the remainder of the sessions (~2 cmH<sub>2</sub>O range for the Apnea pattern, ~1 cmH<sub>2</sub>O for the remaining two patterns). Once Normal breathing resumed, pressure was decreased slowly throughout the remainder of the test session, just reaching the initial therapy pressure of 4.0 cmH<sub>2</sub>O at the 2:30:00 mark.


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**Device Performance Comparison Charts**

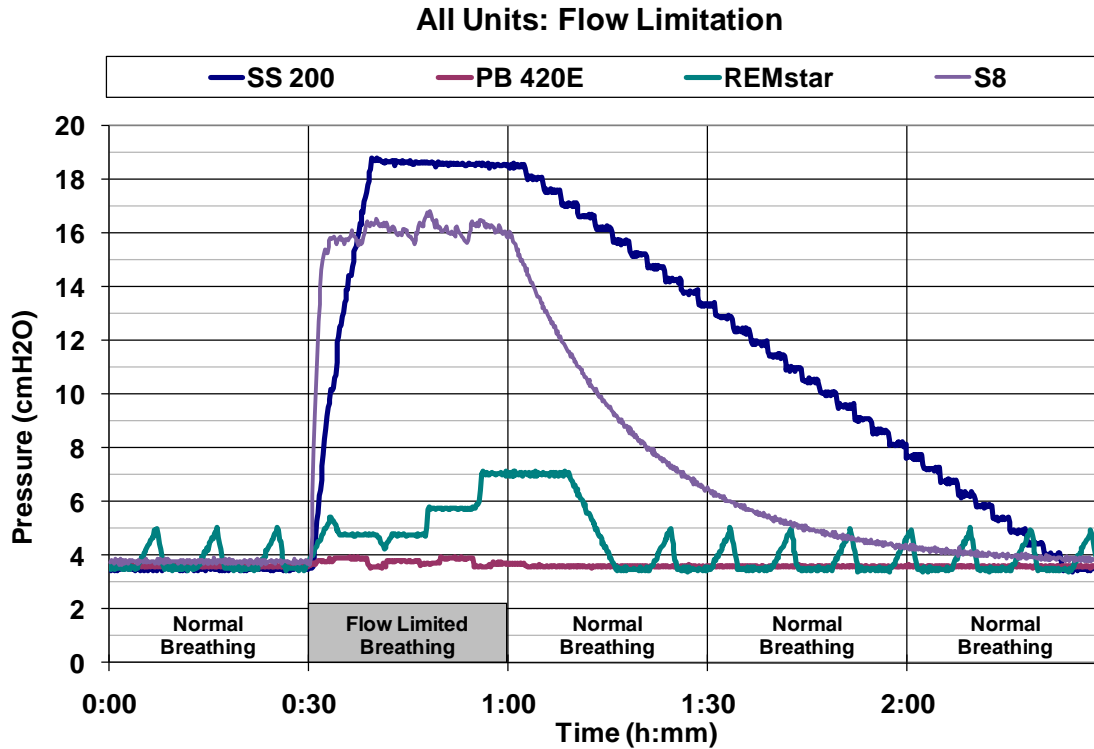
**Apnea**




All devices exhibited responses to the change from Normal to Apneic breathing. All but the REMstar unit quickly reached a pressure of 10 cmH<sub>2</sub>O (default pressure for Apneic events on these units), but response on all units was dissimilar after this point. The return to the initial therapy pressure once Normal breathing resumed varied for each unit.

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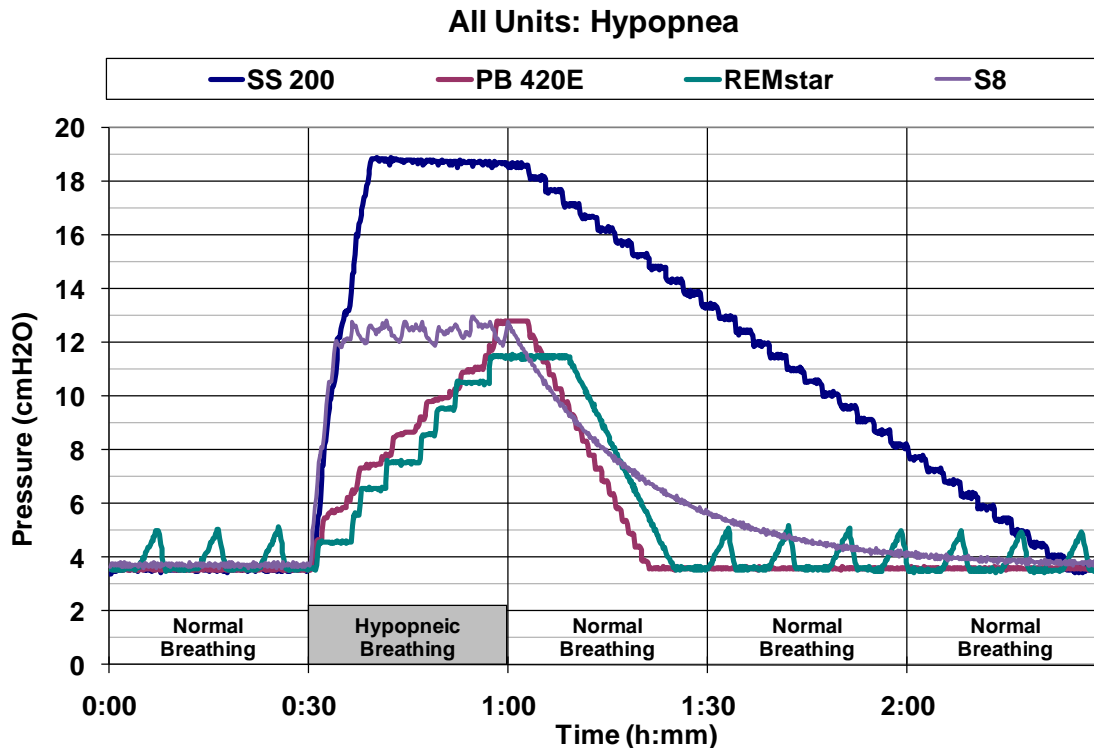
**Flow Limitation**




All devices exhibited a response to the change from Normal to Flow Limited breathing, though the PB 420E unit did not show significant changes in delivered pressure from pressure during the normal breathing period. Both the SS 200 and S8 units had aggressive response to the pattern, with the S8 unit achieving 16-17 cmH<sub>2</sub>O within three minutes of the start of Flow Limited breathing, and the SS 200 achieving ~19cmH<sub>2</sub>O within ten minutes. The REMstar unit responded much differently, achieving a maximum pressure of ~7.0 cmH<sub>2</sub>O at the end of the 30 minute period. Again, the return to the initial therapy pressure once Normal breathing resumed varied for each unit.

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## Hypopnea

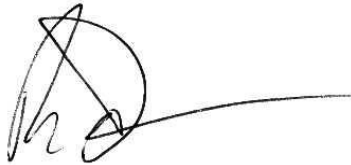


All devices exhibited a response to the change from Normal to Hypopneic breathing. Again, the S8 and SS 200 units showed aggressive response, quickly reaching an initial peak pressure of ~12.5 cmH<sub>2</sub>O within five minutes (S8) and ~19.0 cmH<sub>2</sub>O within 10 minutes (SS 200). Both the PB 420E and REMstar unit exhibited a similar, slower rise in therapy pressure throughout the 30 minute session. As with the other two disordered patterns tested, the return to the initial therapy pressure once Normal breathing resumed varied for each unit.

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All testing was completed and Rev0 report compiled at Valley Inspired Products from October 14-24, 2008. RevA completed November 10, 2008.

Signed:



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Ryan Diesem, Research Associate