A Bench Comparison of Three Auto-Adjusting Positive Airway Pressure Devices: Response to Apnea, Hypopnea, Flow Limitation and Simulated Snore

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March 18, 2011

ABSTRACT

Introduction: Previous bench studies on auto-adjusting continuous positive airway pressure devices (APAP or Auto CPAP) have shown various dissimilar pressure response characteristics when compared across tested devices. New products are entering the market on a regular basis, bringing a need for up-to-date information on product performance, capabilities, applications and benefits. Not apparent to most patients or physicians are the performance differences between given products available to them, and whether or not a newer model of a device performs in the same manner as a previous model. **Objective**: Performance characteristics of three models of APAP units presented with various sleep-disordered breathing patterns via mechanical breathing simulator were compared. **Protocol**: Each APAP device was presented with one normal and three disordered breathing patterns mimicked by a mechanical lung simulator. Additionally, the devices were presented with simulated snore over the normal breath pattern reduced to 80% flow. The breathing patterns presented to each device were first recorded directly from a patient undergoing a polysomnography (PSG) study and then converted for use by the lung simulator. Simulated snore was applied by placing a speaker in-line with the circuit and applying vibrations at 70Hz during inhalation only. The resulting pressure changes in the APAP units were recorded as they were subjected to each pattern. **Results**: Tested APAP devices had comparatively dissimilar responses to a given disordered pattern. When presented with apneic and (flow-limited) hypopneic breath patterns, two units increased pressure more rapidly than the third device. All three units showed differing responses when presented with flow-limited breathing. One device showed no response to simulated snore. Pressure responses by newer models of a given device were generally consistent with previous models. **Conclusion**: Though the response to disordered breathing was different with each device, further clinical studies on a variety of patients will be necessary to determine the impact on outcomes with different APAP algorithms.

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INTRODUCTION

Auto-adjusting continuous positive airway pressure (APAP or Auto CPAP) is used routinely as a follow-up to a split–night diagnostic study or as an option for patients that require a lower mean airway pressure to stay compliant with therapy. There are a number of options available to the clinician in selecting a device; features and benefits are not the only issues that need to be considered. What may not be apparent to the clinician is the variability in performance of the different brands of APAP devices. APAP devices are not commodity and the variability in performance may impact the effectiveness of the therapy. If one APAP device is selected by a clinician to accomplish a specific therapy and its use does not create the desired result, another APAP device may produce the preferred result due to a different performance characteristic.

Previous research and publication in 2006[1] and 2009[2] has documented the variability of individual APAP response to different disordered breathing patterns. Some of the products tested in 2006 and 2009 have since evolved with newer hardware associated with the auto algorithm. Additional APAP devices have since entered the market as well. Clinicians are routinely presented with these product options without a complete understanding of how the devices respond and address disordered breathing.

Auto-adjusting CPAP devices are becoming more valuable as an option to improve the optimal therapeutic pressure on patients that may have a split-night sleep study or have had home sleep screening as their diagnostic test for obstructed sleep apnea. Additionally, auto-adjusting units have been shown to improve compliance on patients that have difficulty with higher pressures due to the benefits of a lower mean airway pressure compared to fixed CPAP.[3,4] While it has been shown that use of various APAP devices has resulted in differing mean airway pressures,[5] it is unknown what impact the variability in performance of the different adjusting algorithms may have on the mean airway pressure and the device-recommended fixed therapeutic pressure.

The purpose of this bench comparison of selected APAP devices is to present each APAP unit with the exact same sleep-disordered breathing signals on a mechanical lung simulator to determine the device's response. Eliminating the patient variable in this setup allows for an objective and direct comparison of each APAP device's response to the selected breathing patterns. The chosen breathing patterns used in this bench comparison do not represent *all* possible sleep-disordered breathing patterns. This study evaluates an APAP device's response to selected breathing patterns to help understand the unit's pressure response characteristics. This study did not aim to determine the therapeutic benefits of the different devices.

This study is an extension of and complement to the testing and data analysis presented in the 2009 R McCoy/R Diesem authored white paper, *A Bench Comparison of Five Auto-Adjusting Positive Airway Pressure Devices: Response to Apnea, Hypopnea and Flow Limitation*. For this 2011 study and white paper, a simulated snore test was added, two units were removed from the comparison testing, and updated models of three units were tested. The test methods remained largely the same between the two studies, though some minor changes were implemented. This 2011 white paper directly incorporates discussion and conclusions presented in the 2009 white paper.

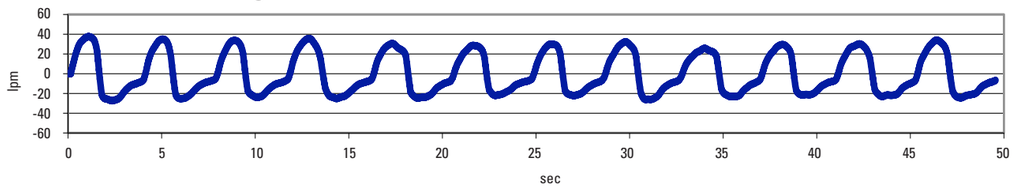
METHOD

Prior to this test, four breathing patterns, taken from data collected on patients who had undergone a polysomnography study and scored by a professional RPsgT—Normal, Apnea, Flow Limitation and Hypopnea—were converted for use by a mechanical test lung (Series 1101 Breathing Simulator, Hans Rudolph Inc.). The Normal pattern was also converted to 80% of its flow values, to be utilized in a test with simulated snore provided by an in-line speaker vibrating at 70Hz. The amount of data converted for each pattern varied, with the Flow Limitation pattern totaling approximately eight minutes in length and the Hypopnea pattern totaling approximately 12.5 minutes in length. Both the Normal and Apnea breathing patterns are approximately 10 minutes in length. Each file and script created for use was set to loop back to start at the conclusion of the recorded sample.

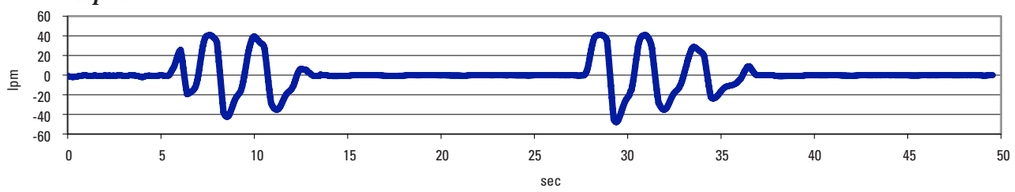
While the disordered breathing patterns are scored as Apnea, Flow Limitation and Hypopnea, there may be incidences of one type present in another signal. The Hypopnea pattern employed here is flow limited in nature, which may impact device response.

Shown below are 50-second samples of each type of breath pattern recorded and used for this comparison:

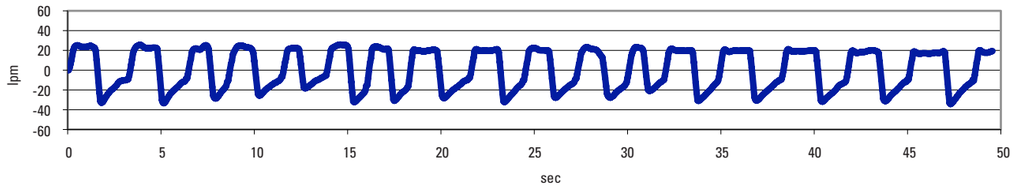
Normal Breathing



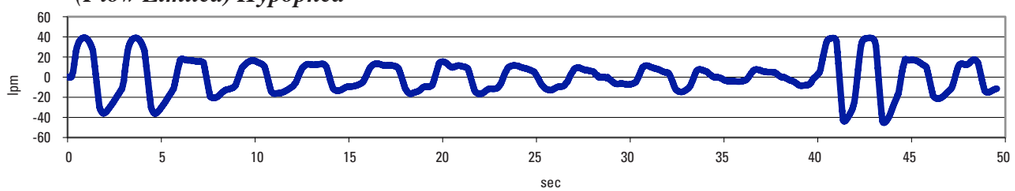
Apnea



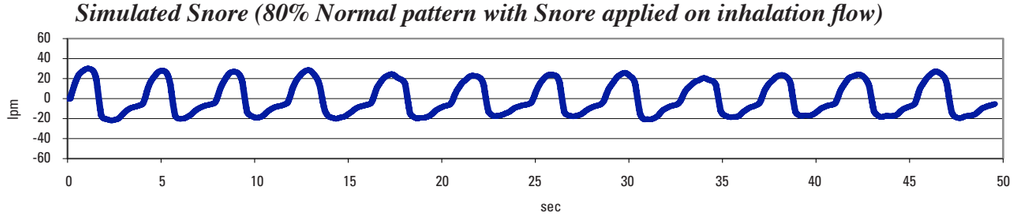
Flow Limitation



(Flow Limited) Hypopnea

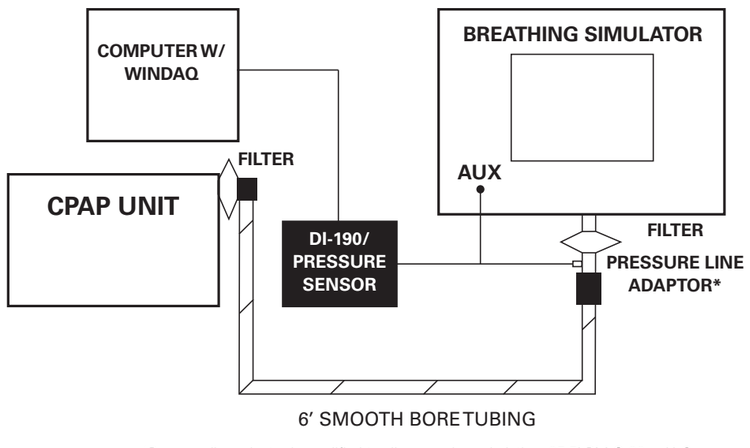


Simulated Snore (80% Normal pattern with Snore applied on inhalation flow)



Three auto-adjusting CPAP units (ICON Auto, Fisher & Paykel Healthcare; S9 AutoSet, ResMed Corp.; System One REMstar Auto, Respironics, Inc.) were equipped with their respective heated humidifier component and the water chamber was filled to the manufacturer's recommended fill line with distilled water. Each APAP unit was set to operate in the Auto-Adjust mode with a pressure output range of 4.0 to 20.0 cmH_2O. Maximum apnea response pressure on each unit was set to 10cmH_2O, a typical default value, on units featuring such a setting. The humidification feature on each unit was set to Off. If an APAP unit had an expiratory relief feature, the feature was set to Off. Ramp features were also set to Off. A DI-190 Data Acquisition Kit (DATAQ Instruments) was configured to read pressure values from a 162PC01D pressure sensor (Honeywell Sensing & Control) at a range of 0 to 30 cmH_2O. Data acquisition was set to record in WinDAQ software (DATAQ Instruments) configured to log a pressure data point once every 10 seconds.

Prior to test initiation, each APAP unit was set up for testing according to the following diagram:

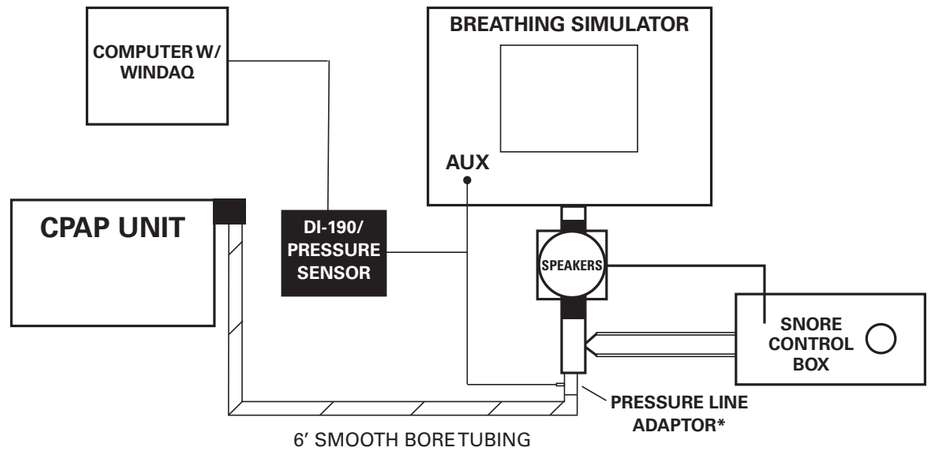


*Pressure line adaptor is modified to allow passive exhalation, 25.5LPM @ 20cmH_2O

A Pressure Line Adapter (Hudson RCI) was modified with a 4mm-diameter leak hole to serve as the passive exhalation port with a measured exhaust flow of 25.5LPM @ 20cm-H_2O. A CPAP filter (SP-CPF; SP Medical) was inserted between the Breathing Simulator patient connection port and the pressure line adapter to reduce flow "chatter" present in the breathing signal (Note: this does not affect the flow and volume generated by the Breathing Simulator as it read the breathing signal). A pressure tee connected to the Auxiliary Pressure port on the Breathing Simulator was placed between the pressure sensor and pressure line adapter to monitor real-time pressure at the patient connection port.

All devices under test were allowed to run with a standard breathing pattern for at least 15 minutes before any testing was initiated. Once the warm-up period was completed, each unit was restarted and data acquisition initiated. The Normal pattern was then activated. The Normal breathing pattern ran for 30 minutes before the Breathing Simulator switched to mimicking the Apnea pattern. The Apnea pattern then ran for 30 minutes before reverting to Normal breathing for the remainder of the test period. Data acquisition on all units was stopped after 2 hours, 40 minutes. This process was repeated for both the Flow Limitation and Hypopnea breathing signals.

For the test with Snore applied, a "snore box" was placed in-line between the patient port and the modified pressure line adapter, as seen below:



*Pressure line adaptor is modified to allow passive exhalation, 25.5LPM @ 20cmH_2O

The snore box applied simulated Snore to inspiratory airflow via a speaker vibrating at 70Hz. The pattern used for this test was the Normal pattern adjusted to 80% of all flow values (i.e. flow reduction of 20%). As in the tests above, when the Snore script was initiated, the Normal pattern ran for 30 minutes (with no Snore applied). At the 30-minute mark, the 80% Normal pattern was initiated, with "Snoring" applied on inhalation only. After 30 minutes, the pattern reverted to the original Normal pattern, with no Snore applied, for the remainder of the test period.

It is important to note that this test protocol does not allow for the tested devices to overcome the sleep-disordered breathing signals being presented. This open loop test method is a limiting factor in gauging each device's response to changing physiology as the unit can never alter the breathing signal. Given these limitations the protocol does, however, allow for a direct comparison due to the static nature of the test.

RESULTS

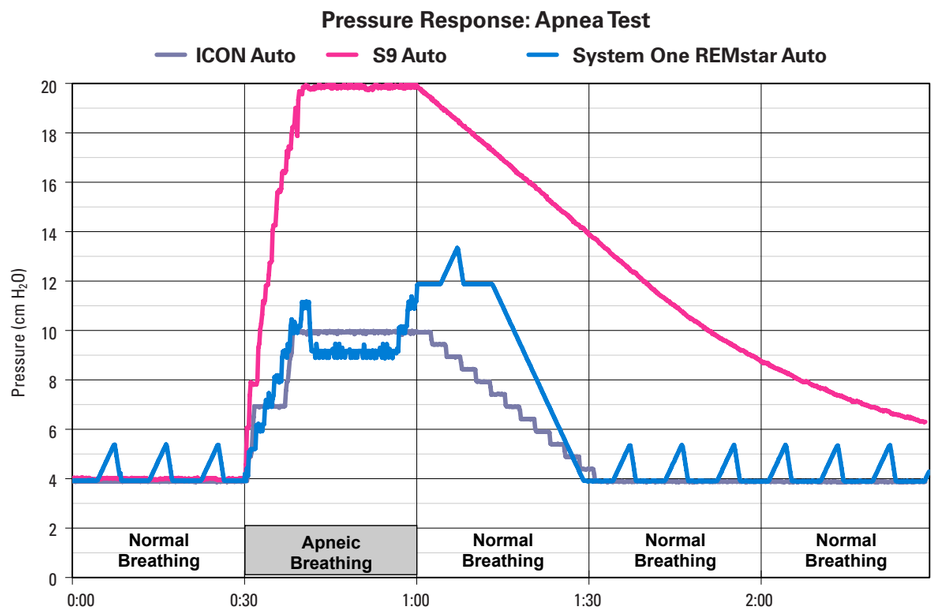
Each unit was able to complete each series of tests in this evaluation without issue. All devices showed higher delivery pressures on the display screen compared to the recorded pressures during the test, with the range between displayed and actual pressure generally increasing with an increase in therapy pressure. This is primarily due to the test setup rather than the device, as there is pressure drop that occurs during flow delivery across the 6' of CPAP tubing (and snore box in the Snore test). Average differences between actual pressure delivered and the displayed 4.0cmH_2O therapy pressure was -0.10cmH_2O. Differences at higher pressures are difficult to pinpoint during the actual test given that the unit may be displaying continual fluctuations in pressure during disordered breathing as well as during the return to lower pressures once the disordered breathing has ceased.

Common in the Respironics APAP models is a "Ptherapy" search pattern, as part of the device's algorithm is to find optimum therapy pressures in the face of airway resistance. The unit will increase pressure by 1.5cmH_2O over the course of three minutes and monitor the flow to see if there is an improvement. If there is none, the unit returns to the original pressure within one minute. If an improvement in airflow is recorded during the 1.5cmH_2O pressure increase phase, the device will lower the pressure by only 0.5cmH_2O. As there is no physiological component in this bench test, the unit consistently returned to the original pressure setting during periods of Normal breathing. These are seen in the resulting device pressure profiles as triangular pressure increases/decreases. The Fisher & Paykel ICON Auto unit features a "SensAwake" algorithm which detects breath to breath changes that indicate the CPAP user is awake, and drops pressure very rapidly when an awake state is detected. This feature was left on for these tests but, as expected, there was no indication the algorithm was triggered at any time.

When Normal breathing resumed after 30 minutes of disordered breathing, each unit had unique methods of pressure reduction. The ICON Auto unit reduced pressure 0.5cmH_2O every 2.5 minutes, resulting in a step pattern, until pressure reached the minimum setting. The S9 AutoSet initially decreased pressure at a fixed rate (about 1cmH_2O every 5 minutes). As the pressure neared the 4.0cmH_2O minimum set pressure, this rate became variable, slowing as the pressure continued to be reduced. Pressure reduction rates on the System One REMstar Auto were a fixed 0.5cmH_2O per minute.

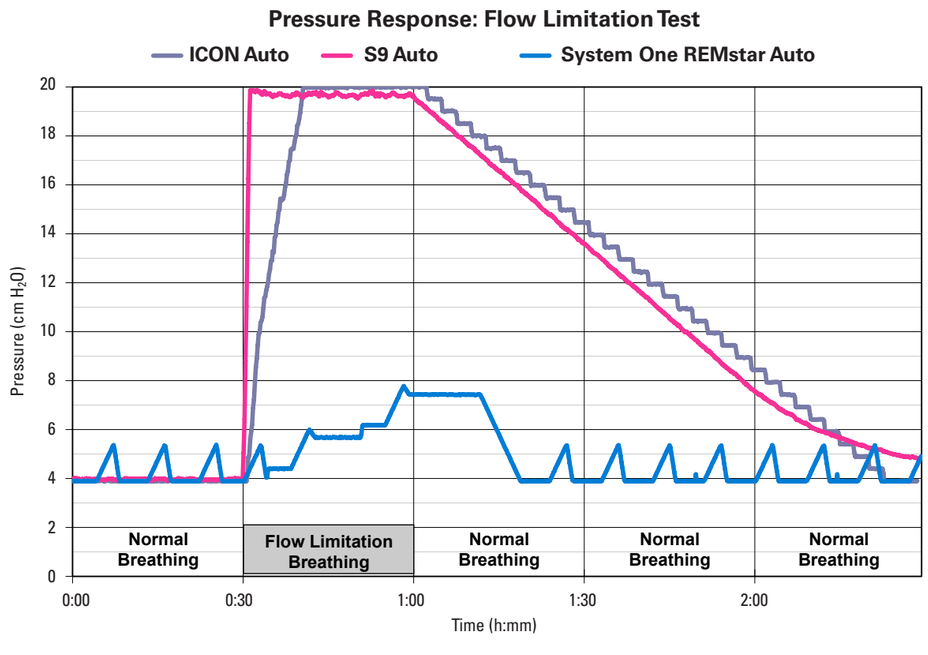
The following charts display each unit under test's response to each of the disordered breathing patterns.

Apnea



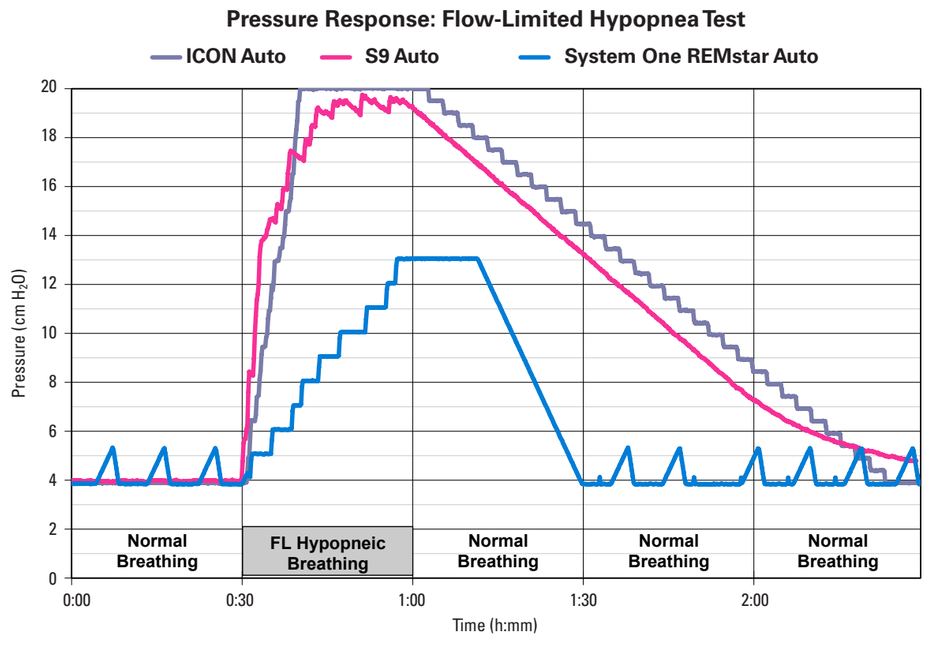
All devices exhibited pressure response to the change from Normal to Apneic breathing. Both the ICON Auto and S9 AutoSet units showed a rapid pressure response once the Apnea pattern began. The ICON Auto reached 7.0cmH_2O in less than two minutes, where it plateaued for five minutes before rapidly increasing pressure to 10cmH_2O, the unit's default apnea "cap." The S9 AutoSet unit, which does not appear to have an adjustable apnea cap setting, reached a maximum of 20cmH_2O in less than 10 minutes, where it remained until Normal breathing resumed. The System One REMstar unit showed a slower pressure response compared to the other two units, increasing pressure over a 10-minute period to 11cmH_2O at the patient connection. The unit did not detect improved patient airflow over that span, so it decreased pressure by 2cmH_2O, where it remained for 15 minutes. This is a programmed response by the device as its algorithm has recognized that there is no change in breath pattern from the "patient" to the increases in pressure. The drop in therapy pressure is to ensure the patient is not receiving too high a pressure in the event that the apnea is central in nature, possibly resulting in a Hering-Breuer reflex. After 15 minutes of stable pressure delivery at 9cmH_2O, therapy pressure was then increased, at the same rate seen at the beginning of the Apnea period, until Normal breathing resumed.

Flow Limitation



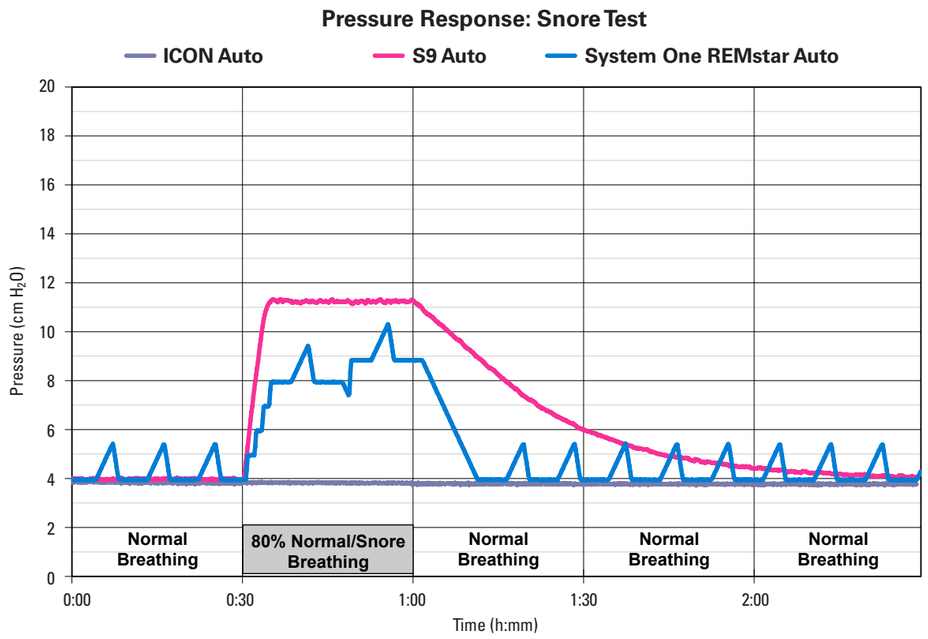
All devices exhibited pressure response to the change from Normal to Flow-Limited breathing. The ICON Auto unit showed a rapid pressure response, reaching a maximum of 20cmH_2O within 15 minutes of the Flow Limitation pattern starting. The S9 AutoSet unit responded even more rapidly, reaching 20cmH_2O within two minutes of the Flow Limitation pattern starting. Both units remained at 20cmH_2O until the end of the 30-minute Flow Limitation run. The System One REMstar unit's responses during disordered breathing appeared related more to the "Ptherapy" algorithm function than anything related to the Flow Limitation pattern, reaching a peak of 8cmH_2O, 12cmH_2O less than either of the other two units tested.

Hypopnea (Flow Limited)



All devices exhibited pressure response to the change from Normal to (Flow-Limited) Hypopneic breathing. Both the ICON Auto and S9 AutoSet units showed a rapid pressure response once the Hypopnea pattern began. Both units reached a maximum of 20cmH_2O within 15 minutes of the Hypopnea pattern starting. The System One REMstar unit showed less rapid, periodic 1cmH_2O increases in delivered pressure, reaching a peak of 13cmH_2O by the end of the 30-minute run, 6cmH_2O less than the other two units during this time.

Snore



Two devices exhibited pressure response to the change from Normal to Snore breathing. The S9 AutoSet unit showed a rapid pressure response to the Snore test, increasing pressure to just over 11.5cmH_2O within six minutes, where it remained until the Normal breath pattern resumed. The System One REMstar unit increased pressure up to 8cmH_2O in approximately five minutes where it then plateaued, except for a 1.5cmH_2O increase appearing to relate to the "Ptherapy" algorithm. There was no pressure response from the ICON Auto unit to the Snore pattern.

DISCUSSION

The pressure response findings in this bench comparison of APAP devices was mostly similar to data collected in 2006[1] and 2009[2], suggesting that, although each manufacturer has unique and proprietary software to control their device's response, little has changed in the overall structure of these auto-adjust response algorithms. One response characteristic of note seen in this current evaluation is the five-minute pressure plateau provided by the ICON Auto unit during the Apnea pattern. This is a new response characteristic compared to the responses seen in previous Fisher & Paykel Auto CPAP models (like the SleepStyle 200), where pressure would continually increase up to the apnea cap setting without interruption.

Outside of the individual manufacturer, it is typically not known how these algorithms are determined, tested and validated for effectiveness. The variability of product performance and the relatively unknown aspect of how the algorithms determine response suggest that the manufacturers should publicly specify the characteristics of the abnormal flow pattern detection and the algorithms used by their device to respond to the abnormal flow.[6] The sophistication of the algorithm for each device may include individual responses to a combination of signals and snoring to determine how the device will respond. This study is limited in that the units tested were only provided one particular sample of each type of disordered breathing pattern for apnea, hypopnea and flow limitation. Additionally, simulated snoring was only applied in a scenario with a 20% reduction of flow. This may have contributed to the lack of response from the ICON Auto in the test with simulated snoring.

The test results presented in this white paper suggest that both the ResMed S9 AutoSet and the Fisher & Paykel ICON Auto units employ algorithms meant to overcome airway obstruction as quickly as possible. With the exception of the Snore test, both the ICON Auto and S9 AutoSet units responded to the disordered breath patterns in a rapid manner, typically reaching maximum set pressures within 2–15 minutes of the initiation of continual disordered breathing. The System One REMstar unit never achieved its maximum set pressure output in any of the four tests, with the highest pressure achieved by the unit occurring during the 30-minute disordered portion of the (Flow-Limited) Hypopnea pattern, where it reached 13cmH_2O. The differences in pressure response rates between both the S9 AutoSet and ICON Auto units and the System One REMstar unit raises the question of whether or not APAP patients needing higher pressures to overcome airway obstruction might experience a greater number of sleep disturbances on the System One REMstar unit (due to the time needed for the unit to reach higher pressures). One example may be patients who experience rapid onset obstructive apnea, where obstructions could possibly be overcome earlier on one of the S9 AutoSet or ICON Auto units compared to the System One REMstar Auto. Another question these results raise, as it relates to the rapid response times of the S9 AutoSet and ICON Auto, is whether or not some patients might experience discomfort and/or wakefulness due to the fairly sudden rise in mask pressure, which may exacerbate such common compliance issues as mask leak disturbances and noise issues. Further study would be needed to assess the validity of these potential issues.

In all instances of APAP pressure responses to disordered breathing, confusion regarding individual device performance and effectiveness could be alleviated if clinicians knew when and how these responses occur on a given product. Typically these are only known to the manufacturer; it would be of great value to many in the sleep field to know what the specific sleep parameters a product is responding to and if there is evidence of effectiveness and outcomes that was collected during the product's development. To their credit, both ResMed and Respironics published white papers detailing the newest additions to their respective auto-adjusting algorithms, both of which tout their devices' abilities to differentiate between obstructive and central apneas.[7,8] On the S9 AutoSet unit, when an apnea is detected by the device, the unit imposes 1.0cmH_2O pressure oscillations at 4Hz at the unit's current pressure setting. This technique helps the unit to determine if there is airway obstruction by using pressure and flow feedback from the pressure oscillations to determine the airway resistance. Low airway resistance is scored by the device as a central apnea and high airway resistance is scored as an obstructive event, and the unit responds as appropriate. The System One REMstar Auto unit also uses a method of airway obstruction detection but it is unlike the S9 Auto unit in that, instead of continuous pressure oscillations when an apnea is detected, the unit periodically delivers 2cmH_2O "pulses" of pressure on top of the current therapy pressure. The flow feedback from these pulses is analyzed by the device and, if flow was significantly increased during the pulse, the unit determines the airway to be clear; if there is little to no flow increase during the pulses, the unit determines the airway to be obstructed. In this bench study, due to the nature of the test setup, obstructions could not be simulated. The S9 Auto's response to Apnea suggests that the device scored the Apnea pattern as obstructive. This may be due to the inclusion of a filter between the CPAP circuit and breathing simulator as well as the mechanics of the breathing simulator itself, creating a higher airway resistance than specified by the unit's algorithm to score the event as central. On the System One REMstar Auto unit, the response to Apnea in this bench test was nearly identical to responses seen on previous Respironics APAP models, which did not feature the airway detection algorithm, suggesting that the addition of the airway detection algorithm did not affect how the unit responded to the Apnea pattern.

CONCLUSION

Sleep therapy is evolving as technology is providing more options to treat disorganized breathing. Auto-adjusting positive airway pressure devices are an option to help determine therapeutic pressures and to assist in patient compliance with therapy. There are currently several APAP units available in the US market with features and capabilities that are designed to address disordered breathing, yet all of these units respond differently to different breathing patterns. Further study of these products and their performance variability is strongly recommended. It is important for the clinician to understand the variability of products so that they can select a product they feel is most appropriate for their patient to gain therapeutic value and improved outcomes.

This study was limited to the specific breathing patterns utilized and only represents the tested products' response to one sample of a given disordered breathing pattern on a mechanical lung simulator. As clinical assessment and judgment are key factors in achieving patient benefits, the value of this study is for the clinician to understand that product responses generally are very different. Clinical testing on an adequate number of patients on a variety of auto-adjusting CPAP equipment could provide the evidence as to which devices are able to provide the most appropriate response for patient benefits and outcomes in specific sleep-disordered breathing scenarios.

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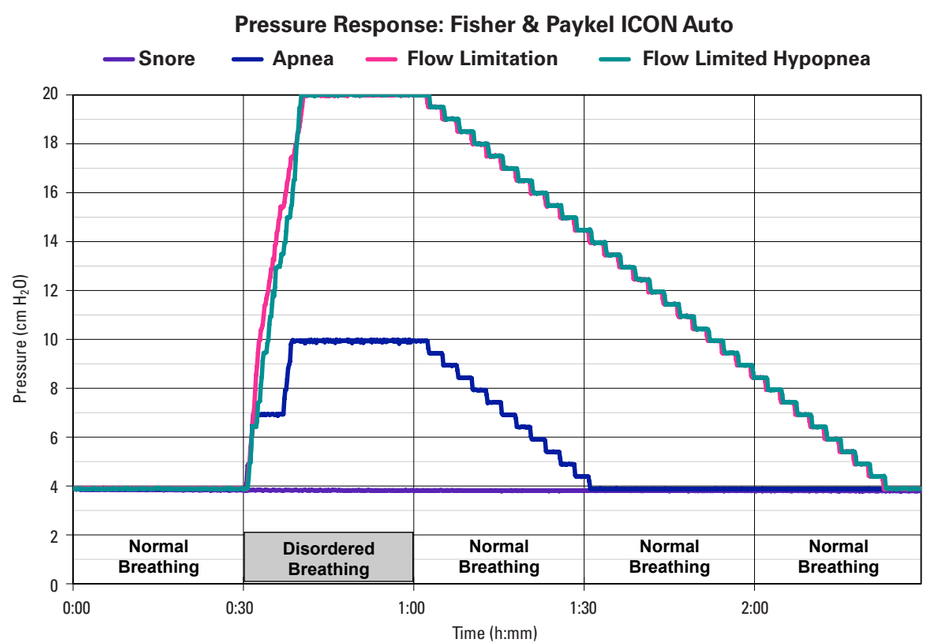
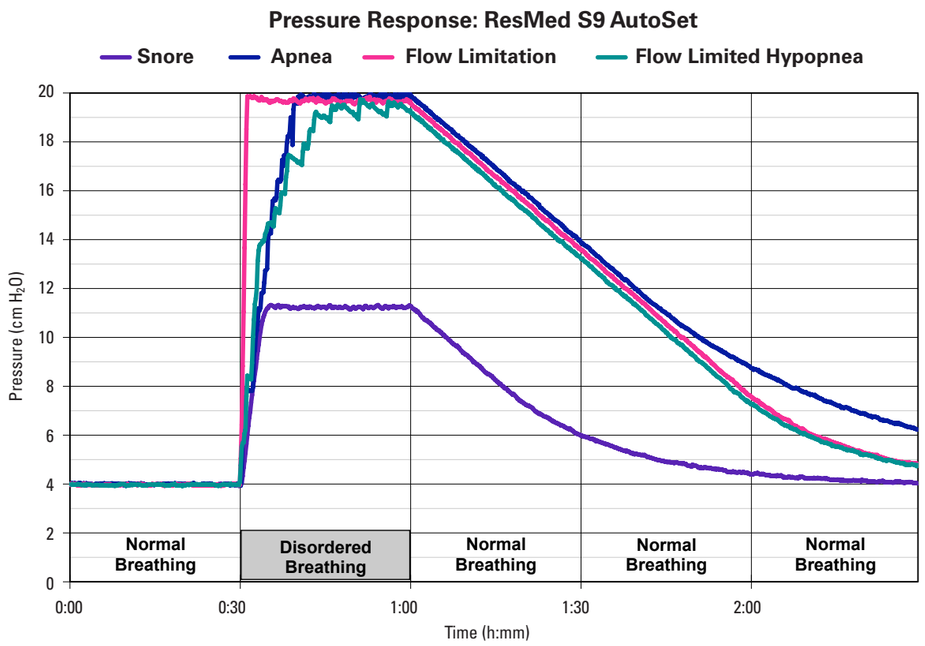
APPENDIX

Additional Product Charts

Fisher & Paykel ICON Auto



ResMed S9 AutoSet



Respironics System One REMstar Auto