

# Central Sleep Apnea Detection and the Enhanced AutoSet Algorithm

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## Abstract

The ability to detect central apneas is a useful addition to an automatic algorithm for the treatment of OSA. The ResMed AutoSet algorithm has recently been enhanced to include a Central Sleep Apnea Detector (CSAD). This paper describes the CSAD as part of the enhanced AutoSet algorithm on the S9 flow generator and documents the process of validation which included early human testing, bench testing and clinical trial results. The enhanced AutoSet algorithm and CSAD showed that it identified and appropriately treated the different types of apneas with a very high degree of accuracy leading to better overall therapy.

## Introduction

Auto-adjusting positive airway pressure (APAP) is well accepted as a treatment for obstructive sleep apnea (OSA). The AutoSet (ResMed, CA), which responds to inspiratory-flow shape, snoring and apneas, is the best characterized and most commonly used APAP algorithm. The algorithm has not changed for 10 years, but has recently been enhanced to increase sensitivity to flow limitation, decrease reliance on snore and introduce central sleep apnea detection (CSAD).

The ability to detect central apneas is a useful addition to an automatic algorithm used in the treatment of OSA. Automatic algorithms respond to the presence of apneas (assumed to be obstructive) by raising delivered pressure because, although this does not treat the apnea that is detected, the pressure increase reduces the likelihood of further obstructive events occurring. If the apnea, however, is central an increase in pressure is inappropriate and may increase the chance of further central apneas. This may potentially lead to the device “running away” with progressive increases in pressure causing increasing numbers of central apneas. To prevent this from occurring the previous AutoSet algorithm would not increase pressure in response to apneas beyond 10 cm H<sub>2</sub>O. While this prevents the device from “running away” it is not ideal as obstructive apneas above 10 cm H<sub>2</sub>O are not responded to and central apneas occurring at pressures less than 10 cm H<sub>2</sub>O cause inappropriate increases in pressure. It is for this reason that APAP devices are generally not recommended for patients known to have conditions, such as congestive heart failure, that predispose to central apneas.

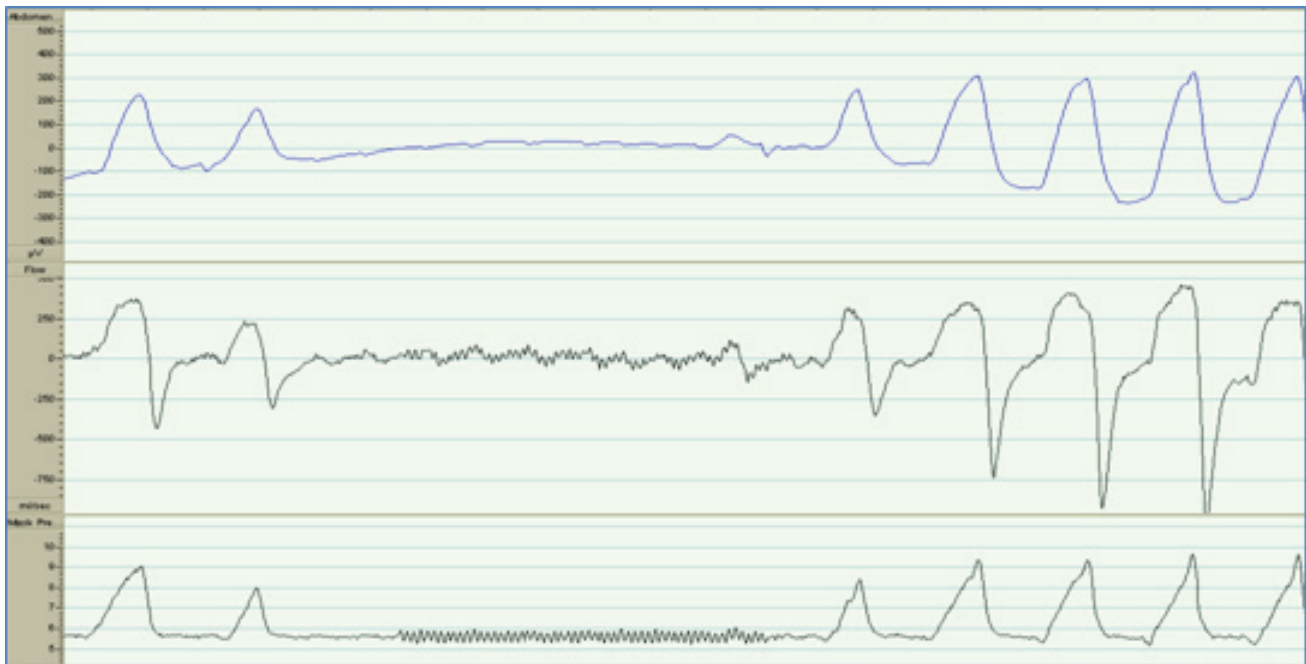
The forced oscillation technique (FOT) has been used in clinical practice since the 1950s [1] and is well established as a method for the noninvasive measurement of respi-

ratory mechanics [2]. FOT is also useful for determining the patency of the upper airway. The technique involves the production of high frequency, low amplitude pressure waves during apneas, and the measurement of the changes in flow that result from them. If the upper airway is open the increases in pressure significantly increase flow, but if it is closed very little flow results. By measuring upper airway resistance in this way the algorithm can determine whether the apnea is associated with a closed or open airway and can determine whether it is appropriate to increase the pressure or to make no response. This is not quite the same as determining whether the apnea is central or obstructive. By definition, all obstructive apneas are associated with a closed upper airway, but some central apneas can be associated with a closed airway if the pressure is below the airway closing pressure. If the airway is closed during a central apnea the appropriate algorithmic response is to increase the therapeutic pressure.

Two previous ResMed APAP devices have utilized FOT technology to determine the state of the airway during apneas: the AutoSet Clinical and AutoSet Portable PII+ [3]. These devices were designed for the sleep laboratory rather than home use. Recent advances in motor and microprocessor technology have enabled what was once relatively expensive and complicated equipment to be used in a home APAP device such as the S9 AutoSet.

## CSAD description

The enhanced AutoSet algorithm applies FOT only when an apnea is detected and turns it off once normal breathing has resumed. A 1 cm H<sub>2</sub>O amplitude sine wave at a frequency of 4Hz is superimposed on the current pressure and the resulting pressure and flow are measured within the device using a pneumotachograph.



**Figure 1. FOT applied during a central apnea.**

Traces are (top to bottom): abdominal effort, respiratory flow, mask pressure. Note the delay between the cessation of breathing and application of FOT. FOT ceases once normal breathing recommences. The flow trace displays two frequencies during the apnea: FOT (4Hz) and cardiogenic flow (~1Hz).

The 1 cm H<sub>2</sub>O amplitude pulses are able to be perceived by a patient if they are awake but are not large enough to arouse them from sleep. Figure 1 shows an example of the FOT process occurring during a central apnea.

The CSAD algorithm determines resistance of the upper airway. To do this accurately the impedance of the circuit needs to be known. CSAD works optimally when recommended circuit configurations are used, but it does not rely on correct menu setup<sup>1</sup>. The ability to determine resistance is also affected by large leaks. Small leaks are tolerated but the accuracy falls rapidly with leaks greater than 30 L/min.

Apneas are classified as being central (open upper airway), obstructive (closed upper airway) or unknown. Central apneas are scored when the resistance is low, and obstructive apneas when the resistance is high. The classifier labels apneas 'unknown' when the inadvertent leak exceeds 30 L/min or the resistance is indeterminate<sup>2</sup>. Central and unknown apneas do not cause an increase in delivered pressure.

## Validation

The accuracy of the CSAD algorithm was determined using bench tests, normal subjects simulating central and obstructive apneas, and clinical trials. As a similar algorithm

had been used in previous products there was a degree of confidence that it could accurately discriminate between obstructive and central apneas and that the amplitude of the pulses would not lead to arousal in sleeping patients. However with implementation being on a new hardware platform that utilizes smaller diameter circuits, integrated humidification and a wider range of mask types, an extensive validation process was performed.

## Early human tests

The CSAD algorithm was tested in 18 normal awake subjects who had been taught to simulate central and obstructive apneas while using CPAP at pressures of 5, 10 and 15 cm H<sub>2</sub>O and with various degrees of mask leak. This set of experiments yielded information about the accuracy of the algorithm under conditions of extreme leak and differing baseline CPAP pressures. It was also used to tune the algorithm and define the amount of leak that led to inaccurate classification of apneas.

Although tests in normal subjects were useful to tune the algorithm it was found that normal subjects tended to either have very obstructed or very open airways and therefore may not have accurately represented the situation in sleeping patients. Hence a clinical trial in sleeping patients was performed.

An early clinical trial was performed using experimental hardware in laboratory conditions. An algorithm development phase (n=30) allowed for fine tuning of the algorithm,

<sup>1</sup> Very high impedance combinations such as an AB filter and 15 mm diameter tubing should not be used.

<sup>2</sup> For example, in the scenario that the device cannot achieve the correct oscillation amplitude.

especially airway resistance ranges, and circuit and leak effects. It was also determined that patients were not aroused from sleep by CSAD. A further 20 patients were then tested without modification to the algorithm. All patients were treated appropriately and two with CSA were correctly identified by the CSAD system (CAI > 5/h): one with Cheyne-Stokes respiration-CSA, the other with opioid associated CSA [4].

## Bench tests

Bench tests permit the CSAD algorithm to be tested under a wide range of variables including different delivered pressures, circuit configurations, mask types and leaks. A patient simulation running on hardware (ASL 5000 test lung, Ingmar Medical, PA) with realistic control of breathing, upper airway tone and sleep state was used. This setup allowed for a consistently responding physical simulation capable of both closed- and open-airway apnea sequences. In addition, passive devices were used to simulate a closed airway (shut valve) and an open airway (valve open to 65 L barrel). This equipment was used in both formal and informal verification testing of devices with CSAD in both open- and closed-loop fashion (realistic device-patient simulation interaction). Mask and circuit compatibility testing was included in formal verification.

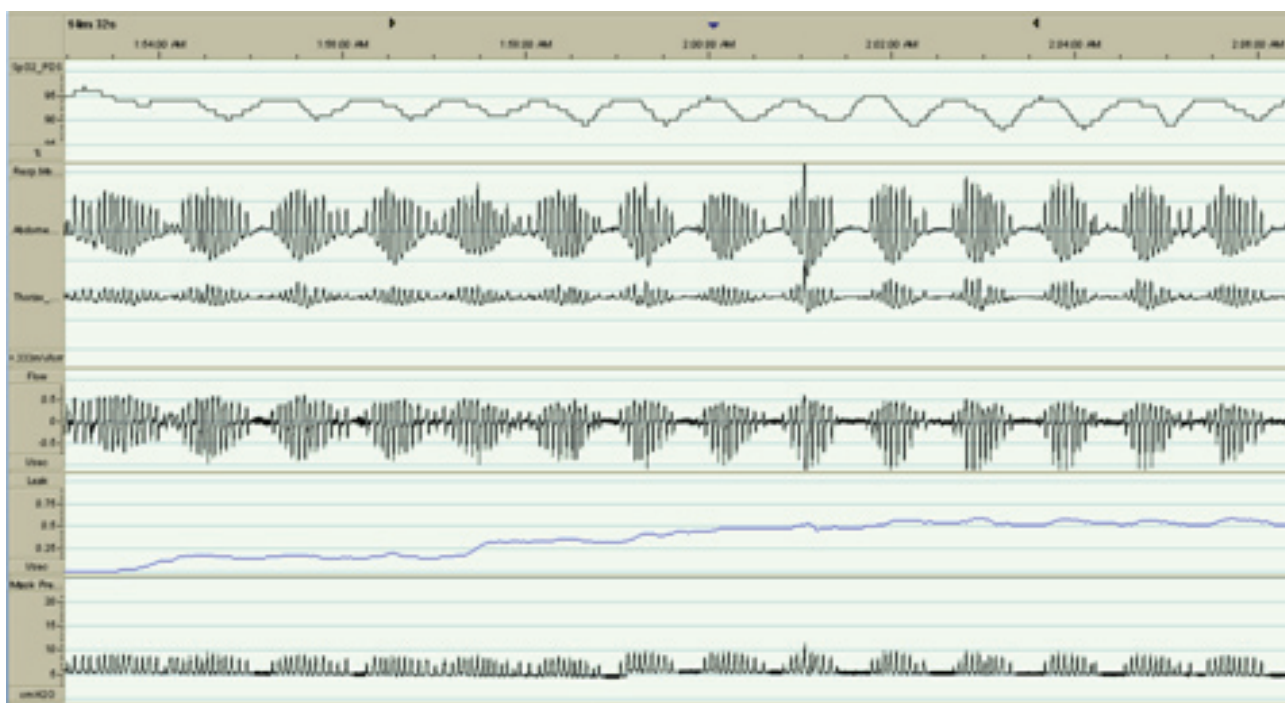
## Clinical trial

The aim of the clinical study was to determine the accuracy, sensitivity and specificity of the enhanced AutoSet and CSAD algorithms in its final production implementation [5].

## Methods

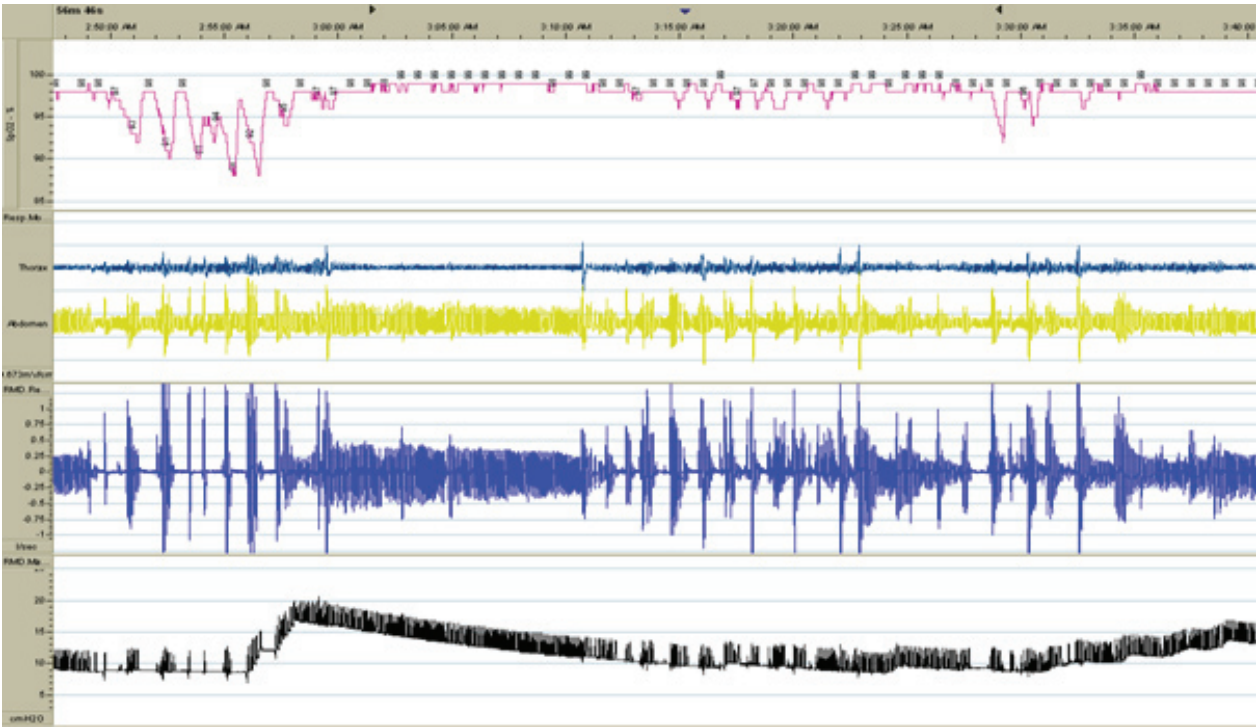
20 subjects with OSA (AHI > 15 during diagnostic PSG) and who were regular users of APAP (> 6 hrs /night) for more than 6 months were enrolled. The study was approved by the Ethics Committee of the University of New South Wales and all subjects gave informed consent.

Subjects underwent unattended polygraphy (Embletta, Embla) for one night while on therapy with the enhanced AutoSet and CSAD algorithms using expiratory pressure relief (EPR) of 3 cm H<sub>2</sub>O and a pressure range of 4 to 20 cm H<sub>2</sub>O. Polygraphy was scored according to 2007 AASM recommendations. Flow was measured using the output from the pneumotachograph of the device, which provides a more sensitive and accurate measure of flow than measurement of mask or nasal pressure. Manual scoring of an apnea occurred when there was a reduction in the flow signal to less than 1/10th of the recent (3 minute) average for more than 10 seconds. Apneas were classified as obstructive if there was continued thoracoabdominal effort during the event and central if there was no movement. Mixed apneas were classified as obstructive. Central apneas were considered to have an open airway if cardio-

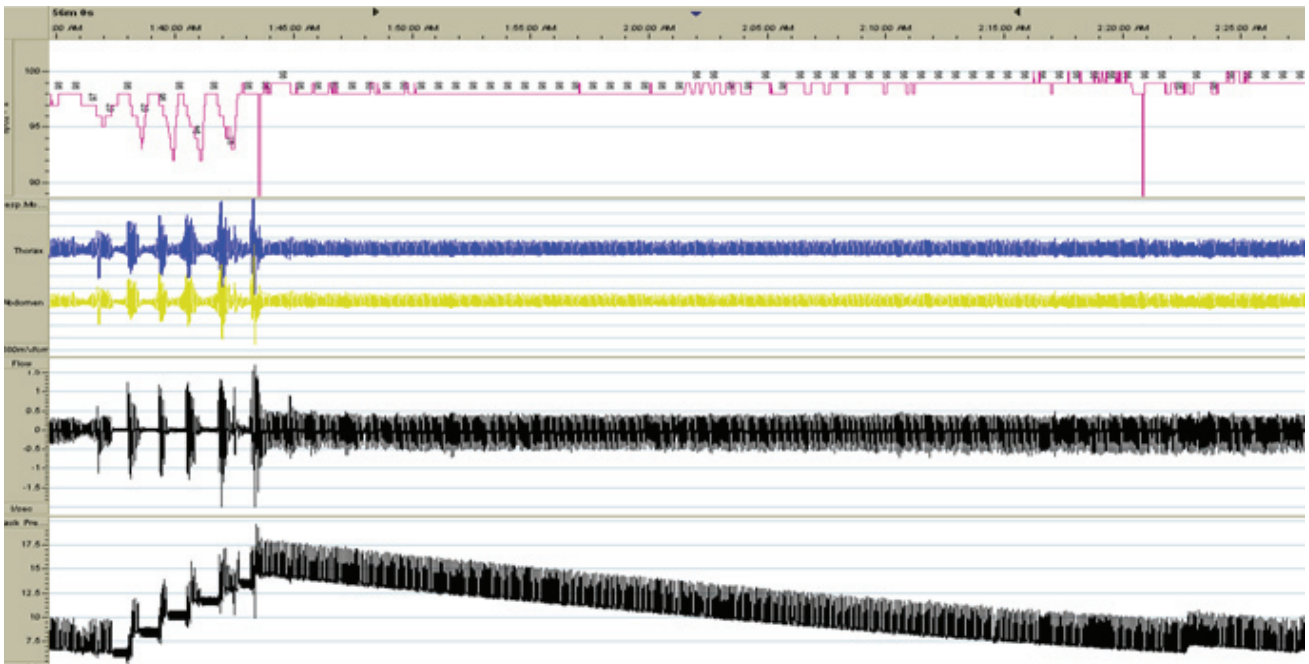


**Figure 2. A typical example of a run of central apneas where leak eventually exceeded 30 L/min.**

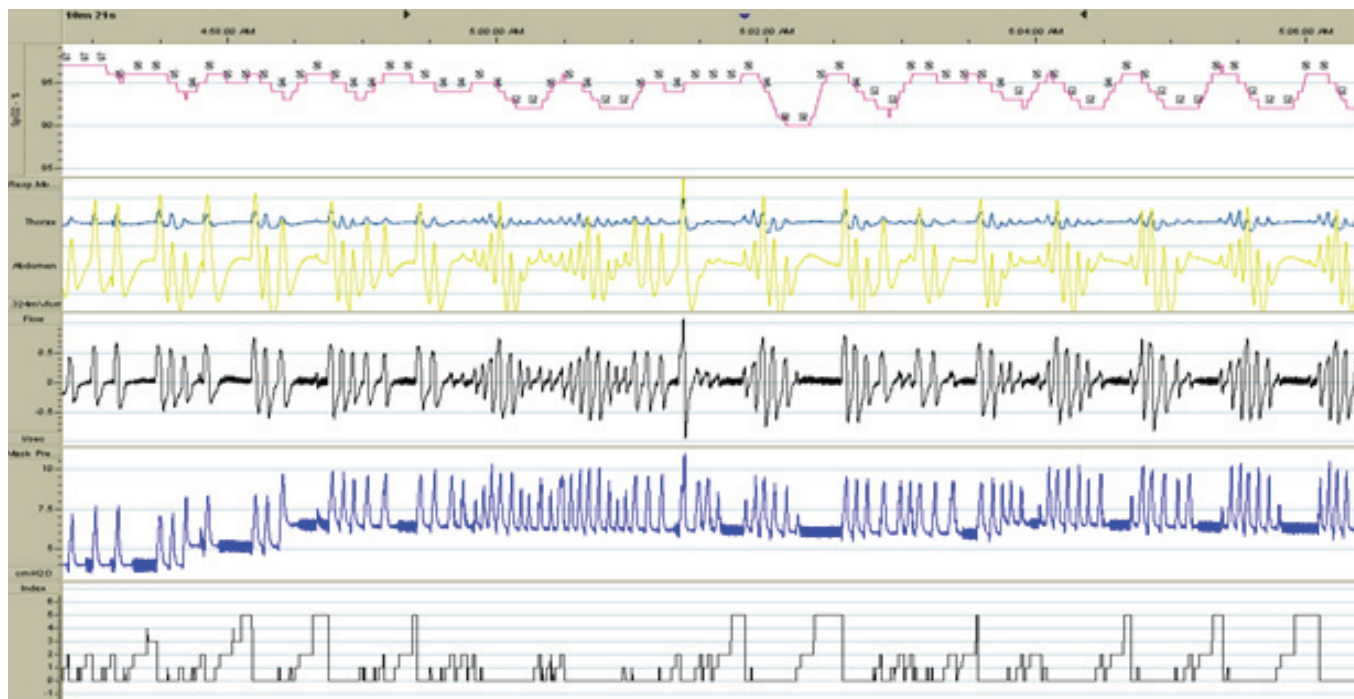
Traces top to bottom: pulse oximetry (SpO<sub>2</sub>), thoracoabdominal effort, respiratory flow estimate, leak and treatment pressure.



**Figure 3. A subject with obstructive apneas treated with the previous AutoSet algorithm.**  
 Traces top to bottom: SpO<sub>2</sub>, thoracoabdominal effort, respiratory flow estimate and treatment pressure.



**Figure 4. The same subject as Figure 3 treated with the enhanced AutoSet and CSAD algorithms.**  
 Traces top to bottom: SpO<sub>2</sub>, thoracoabdominal effort, respiratory flow estimate and treatment pressure.



**Figure 5. A subject with central apneas and the enhanced AutoSet and CSAD algorithms not increasing pressure.**

Traces top to bottom: SpO<sub>2</sub>, thoracoabdominal effort, respiratory flow estimate, treatment pressure and apnea state.

genic flow was visible and a closed airway if cardiogenic flow was not observed.

CSAD accuracy was determined by comparing the polygraphy scoring of apneas with the algorithm classification. Apneas classified as unknown by the CSAD were excluded from the analysis. Closed-airway central apneas and mixed apneas classified as “obstructive” by CSAD were considered true positive results. A true negative result was recorded when both the CSAD algorithm and the scorer classified the apnea as central.

## Results

No subjects reported disturbance of sleep due to the CSAD. A total of 232 apneas were detected by polygraphy of which 128 were scored as obstructive and 104 as central. Central apneas were subclassified as open (n=87) or closed airway (n=17) depending on the presence of cardiogenic airflow. As mentioned above, closed airway centrals are grouped with obstructive apneas. This results in 145 obstructive and 87 central apneas measured by polygraphy. The CSAD algorithm correctly detected all apneas, and scored 153 as obstructive (closed upper airway) and 79 as central (open upper airway). There were an additional 53 events classified as unknown (excluded from analysis).

The CSAD algorithm falsely classified 10 apneas as obstructive that were scored as central and 2 apneas as central

that were scored as obstructive on polygraphy. The majority of these were post-arousal central pauses where, while cardiogenic flow was present, the airway was presumed to be partially collapsed due to a lack of tone.

## CSAD accuracy

The estimates of CSAD accuracy compared to polygraphy are shown in Table 1.

**Table 1. Sensitivity and specificity for CSAD**

	CSAD	Lower confidence interval	Upper confidence interval
Sensitivity	0.99	0.97	1.00
Specificity	0.89	0.82	0.95
Accuracy	0.95	0.92	0.98

Many of the unknown apneas occurred during runs of central apneas where lack of upper airway and jaw-tone neural drive caused inadvertent mask or mouth leak. Figure 2 shows a typical example. Midway through the plot the leak exceeded 30 L/min and the apneas were scored as unknown. No pressure rise was accorded in the sequence of apneas classified as unknown or central.

## Therapy examples

Figure 3 shows a subject (treated with the previous AutoSet algorithm) experiencing obstructive apneas over

a (approximately) one hour period. The treatment pressure in the first 8 minutes is limited to 10 cm H<sub>2</sub>O which is insufficient to prevent recurrent apneas, and the pressure rise between 8 and 10 minutes is due to snoring and flow limitation.

The same subject treated with the enhanced AutoSet and CSAD (Figure 4) shows obstructive apneas being treated effectively with pressures over 10 cm H<sub>2</sub>O.

Another subject treated with the enhanced AutoSet and CSAD experiencing central apneas at a pressure below 10 cm H<sub>2</sub>O is shown in Figure 5. The pressure has not increased. The previous algorithm would have increased pressure to 10 cm H<sub>2</sub>O.

## Discussion

Testing the accuracy of CSAD in clinical trials is problematic as the algorithm prevents most obstructive apneas during therapy. Therefore it is difficult to test multiple circuit configurations, and mask types at varying levels of pressure and inadvertent leak in a clinical trial. This was overcome by extensive bench testing using patient simulators.

A further methodological problem is the difference between apnea classification (based on upper airway resistance) and the usual classification method using effort bands. In the clinical study the presence of cardiogenic flow was used as an indicator of airway state. The use of a pneumotachograph to measure flow is more sensitive than a mask or nasal pressure transducer and makes the presence of cardiogenic flow much easier to detect. There is, however, limited published evidence of the use of cardiogenic flow to determine the state of the upper airway. As the subjects in the clinical trial all had a diagnosis of OSA, and therefore had a propensity to upper airway collapse it was not surprising to find that 20% of central apneas scored by polygraphy were associated with evidence of airway closure.

The presence of CSAD with the enhanced AutoSet algorithm makes the device suitable for the treatment of patients with a mixture of obstructive and central apneas. Such patients will have a lower mean pressure as central apneas do not cause an increase in delivered pressure, while obstructive apneas can be treated with the full pre-

scribed pressure range of the device. CSAD also serves an important role in fixed CPAP in reporting the state of the apneas that have occurred during therapy which may assist with therapy reviews.

## Conclusion

The enhanced AutoSet algorithm on the S9 AutoSet now includes CSAD for the classification of apneas using the FOT. CSAD was extensively tested using patient simulators, normals simulating obstructive and central apneas and clinical trials. CSAD correctly identified and the enhanced AutoSet correctly treated obstructive, central and unknown apneas with a very high degree of accuracy. The enhanced AutoSet and CSAD algorithms have been shown to treat patients appropriately, including those with predominantly central apneas, and without causing disturbance to sleep.

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