Clinical applications guide

REMstar Auto

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Introduction to the REMstar Auto with A-Flex

The disease known as Obstructive Sleep Apnea (OSA) is characterized by intermittent narrowing and total closure of the upper airway during sleep. Untreated OSA has been associated with increased sympathetic activation, cardiovascular disease, high blood pressure, stroke, diabetes, and clinical depression. The first commercial CPAP device was introduced in the 1980s, and its success in treating patients with OSA established CPAP as the gold standard therapy. CPAP treatment depends upon an accurately determined fixed pressure level. Prior to the past decade, the primary method of obtaining this optimal fixed pressure level was manual titration during an overnight sleep study conducted under physician supervision in a sleep laboratory. For some patients, issues arise with the single positive pressure level delivered by CPAP devices, leading to less than optimal long-term therapy.

Short-term and long-term changes in the patient's condition may lead to many limitations with CPAP. CPAP pressure may minimize the apnea/hypopnea index (AHI); however, patients do not typically need the same fixed pressure throughout the night or from night to night to achieve the same AHI. This may be due to changing sleep positions, alcohol consumption, and medication. Long-term changes in the patient's condition also may influence pressure needs to achieve the same AHI. These changes may involve issues with unresolved mask leak, changes in body mass index and other comorbid health conditions.

In the last decade, Auto-adjustable Positive Airways Pressure (APAP) devices have been developed by several manufacturers. The therapeutic concept of APAP is to maintain airway patency by constantly adapting the delivered pressure according to the specific auto algorithm in response to partial and total closure of the upper airway. APAP devices do not require an initial titration and, therefore, may reduce the adaptation time to therapy, as well as streamline resources and cost effectiveness. Several studies have shown that patients may obtain similar adequate treatment for their OSA from CPAP and APAP.[1,2] Additionally, the time and process from diagnosis to established treatment was shorter for patients using APAP than CPAP, potentially resulting in lower total costs of therapy per patient for those using APAP versus those using CPAP.

APAP devices are not simple black boxes that deliver positive air pressure. They include intelligent algorithms that determine when and how pressure should be delivered. The operational algorithms of each manufacturer's device differ considerably. Physicians are encouraged to understand the intricate details of the detection and response to respiratory events in order to determine the best algorithm and device to use in their treatment protocol.

[1] Mulgrew, A., et al., *Sleep Breath* 2007; 11:31-37
[2] Nussbaumer, Y., et al., *Chest* 2006; 129:638-643

REMstar Auto clinical studies

Several studies have investigated the clinical impact of APAP, however, differences in the mechanisms of action of the operational algorithms of each device mean that results obtained from one cannot be extrapolated to the others.

We encourage medical professionals to review and evaluate the clinical evidence that has been presented and published on auto-adjusting positive airway pressure devices and understand the differences in auto technology as they pertain to treatment performance and patient satisfaction.

The following studies address important clinical topics related to:
• Treatment efficacy of REMstar Auto compared to CPAP
• Event detection and titration of REMstar Auto compared to PSG
• Patient satisfaction and preference of REMstar Auto

Many of these studies are available from Philips Respironics. Please contact your Philips Respironics account representative for more information.

REMstar Auto treatment

Efficacy and patient satisfaction with autoadjusting CPAP with variable expiratory pressure vs standard CPAP: a two-night randomized crossover trail

Mulgrew A., et al.

Find this study

Sleep Breath 2007;11:31-37

Aim

The study was designed to assess treatment efficacy and patient preference of the REMstar Auto with C-Flex to standard CPAP.

Method

Fifteen patients who had previously undergone PSG for titration of CPAP were randomized to a treatment of either REMstar Auto with C-Flex or conventional CPAP for one night, then in a crossover design were placed on the second therapy the following night. The following morning all patients reported their satisfaction with therapy via visual analog scales. All interventions performed during the study were recorded by the technicians.

Results

REMstar Auto with C-Flex was as effective as CPAP with no significant differences in sleep characteristics, pressure delivery, or respiratory indices between the two devices. The Visual Analog Scales conducted on the following morning demonstrated a trend toward increased patient satisfaction while using the REMstar Auto with C-Flex compared to standard CPAP.

Conclusion

Both modes of treatment were effective at abolishing sleep-related respiratory events, while patients expressed a preference for the REMstar Auto with C-Flex mode of treatment, which may lead to increased adherence to this form of therapy.

Outcomes with RSA C-Flex vs standard CPAP			
	RSA C-Flex	CPAP	P value
AHI (events/h)	4.2±	2.4±0.7	0.1
Sleep latency (min)	17.0±5	12.3±3	0.4
Sleep efficiency (%)	82±2	83±2	0.6
WASO (min)	67±14	65±12	0.9
REM %	25±2	24±2	0.7
Stage 3/4 (%)	4±1.5	1.6±0.5	0.13
Mean oxyhemoglobin saturation (%)	97.3±0.3	97.2±0.3	0.93
PLMI (7)	2.8±1.0	3.8±1.5	0.59

Value given as mean ±SEM

AHI Apnea hyponea index, WASO wake after sleep onset, PLMI periodic limb movement index
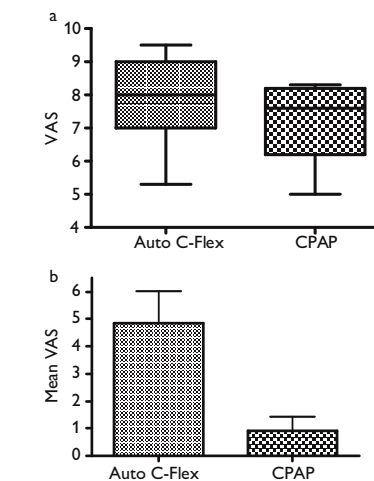
a. Mean VAS scores were calculated for individual patients and compared using a paired t test. A trend towards increased score was noted in the C-Flex group (7.9 vs 7.2, p=0.07). b. Patient scored their preference using VAS scores (1-10). A significant preference was noted for C-Flex (p<0.01).

REMstar Auto treatment

Equivalence of autoadjusted and constant continuous positive airway pressure in home treatment of sleep apnea
Nussbaumer, Y., et al.

Find this study
Chest 2006; 129: 638-643

Aim
The study was designed to assess treatment efficacy of the REMstar Auto with C-Flex to standard CPAP.

Method
Thirty sleep apnea patients were randomized in this double-blind, controlled, crossover trial. For one month, efficacy was compared between patients using standard CPAP and patients using auto therapy using the REMstar Auto with C-Flex.

Results
The study demonstrated that the AHI was similarly improved on each device (6.6 +/-0.6 and 4.6+/-0.7, all p<0.05 vs. baseline) and showed the accuracy of the 90% pressure value when CPAP mode was used. However, the mean applied mask pressure was significantly lower on the APAP device (9.2+/-0.4 and 7.9+/-0.5 cm H_2O, P<0.05). Additionally, 26 patients preferred APAP, and four patients preferred CPAP (p<0.001).

Conclusion
The effectiveness of REMstar Auto in improving major outcomes was equivalent to CPAP. Since REMstar Auto does not require titration, it is a simple and promising modality for sleep apnea home therapy. Study authors also concluded that patients with OSA preferred REMstar Auto over CPAP in the initial phase of therapy.
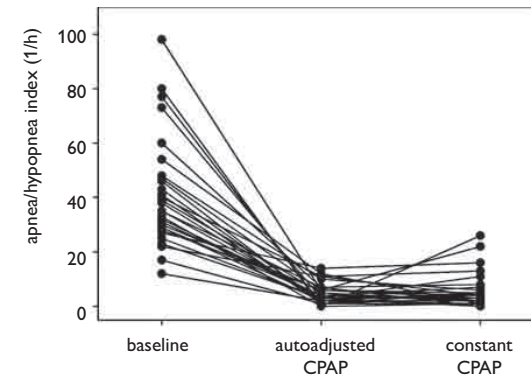
Individual results of AHI at baseline and with the two different treatment modes.

REMstar Auto accuracy

Validation of breathing event detection of the REMstar Auto M Series compared to clinical polysomnography
Kasai, T., et al.

Find This Study
Am. J. Respir. Crit. Care Med. 2008; Abstracts Issue; 177: A212

Aim
This study was designed to evaluate the performance of an auto-titrating CPAP device (REMstar Auto with C-Flex) compared to standard clinical polysomnography (PSG) to identify breathing events in patients with obstructive sleep apnea (OSA).

Method
Ninety consecutive participants underwent a standard clinical PSG for CPAP titration using a REMstar Auto device. During titration, the initial two hours were spent at a sub-therapeutic pressure of fixed 4 cm H_2O so that more breathing events could be seen. After two hours, the REMstar Auto device was switched to auto-adjusting mode for the remainder of the night.

Results
The correlation between device detected apnea-hypopnea index (AHI-M Series) and PSG determined AHI (AHI-PSG) at both sub-therapeutic pressure and whole night were assessed. When viewing the entire night of study (including the subtherapeutic portion as well as the autotitrating portion of the night), patients displayed a strong correlation between AHI-PSG and AHI-M Series (r=0.891, p<0.0001). During the portion of the night where sub-therapeutic pressure was fixed and more events were detected, patients displayed an even stronger correlation between AHI-PSG and AHI-M Series (r=0.956, P<0.0001).
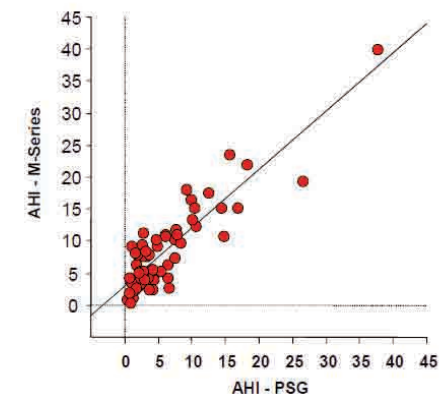
Conclusion
The AHI reported by the REMstar Auto is reliable and demonstrates a strong correlation between the AHI observed by PSG.

Sub-therapeutic portion of the night
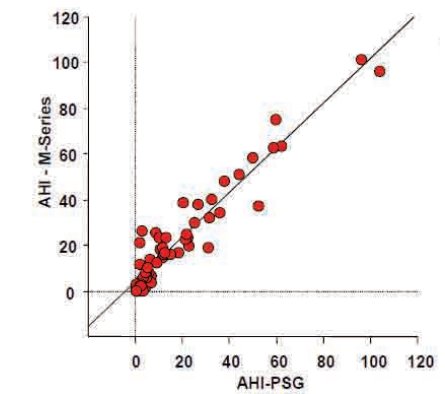
Correlation between AHI-M Series and AHI-PSG
r = 0.956, P<0.0001

Entire night of study

Correlation between AHI-M Series and AHI-PSG
r = 0.891, P<0.0001

REMstar Auto accuracy

Detection accuracy of obstructed airway apneas (OA) and clear airway apneas (CA) by proprietary algorithm in positive airway pressure (PAP) devices

Wellman, A., et al.

Aim

To determine the detection accuracy of a proprietary Philips Respironics PAP algorithm, as compared to full PSG, for the identification of obstructed airway (OA) or clear airway (CA) apneas.

Method

Nineteen sleep-disordered breathing patients were studied overnight under full standard PSG. OA and CA apneas, as identified by the device, were compared to scored polysomnography data collected during a clinical trial and recorded on Alice Sleepware.

In the absence of spontaneous breathing, the OA versus CA proprietary detection algorithm works by delivering one or more pressure pulses. The device evaluates the response of the patient's airway to the pressure pulse(s) and identifies OA or CA apneas based on the resulting patient flow (assuming all other criteria for an apnea are met). The airway is determined to be clear if the pressure pulse generates a significant amount of flow; otherwise the airway is determined to be obstructed.

Results

Figure 1 demonstrates the Obstructed Airway Apnea Index (OAI) as seen by the device versus OAI obtained from standard PSG scoring. The device OAI versus the PSG OAI shows a very strong correlation, as indicated by the intra-class correlation coefficient of 0.976.

Figure 2 demonstrates the Clear Airway Apnea Index (CAI) as seen by the device versus CAI obtained from specialized† PSG scoring. The device CAI versus the PSG CAI shows a very strong correlation, as indicated by the intra-class correlation coefficient of 0.968

Conclusion

By analyzing the flow response (caused by the device initiated pressure pulse during an apnea), the Philips Respironics proprietary PAP algorithm demonstrated a very strong correlation between device obstructed airway (OA) or clear airway (CA) apneas and those events identified by polysomnography.
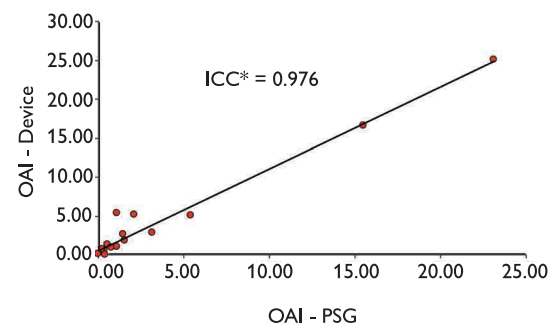

Figure 1. Intra-class Correlation Coefficient - Two-way random model assessing absolute agreement, for single measures.
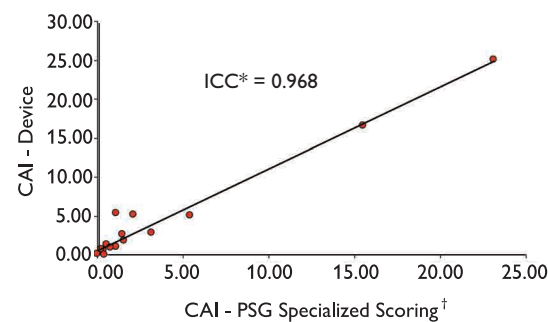

Figure 2. Intra-class Correlation Coefficient - Two-way random model assessing absolute agreement, for single measures
† Specialized Scoring – Due to the introduction of test pulse(s) during an apnea, some clear airway events may get misinterpreted as hypopneas during standard scoring, and thus were corrected as part of the specialized scoring.

REMstar Auto superiority

Titration efficacy of two auto-adjustable continuous positive airway pressure devices using different flow limitation-based algorithms

Hertegonne, K., et al.

Find this study

Respiration 2008; 75:48-54

Aim

In this study, the titration performance of the REMstar Auto operational algorithm and the ResMed AutoSet operational algorithm were compared based on detection of inspiratory flow limitation.

Method

Fifty obstructive sleep apnea patients were studied overnight using a split-night sleep study in a double-blind randomized crossover design.

Results

No significant differences were found in sleep parameters, objective sleep quality, and snoring index, however the REMstar Auto was associated with significantly lower AHI in comparison with the ResMed AutoSet (6.9 events vs. 9.4 events [p<0.004]) at significantly lower pressure levels (P95 = 9.2 cm H_2O vs. 10.2 cm H_2O [p=0.001]).

Conclusion

The operational algorithm of the REMstar Auto resulted in better control of the AHI at a significantly lower pressure level than the ResMed AutoSet. This study confirms the overall titration effectiveness of the REMstar Auto devices. A head-to-head device trial is a feasible way to evaluate the titration efficacy of the two auto-CPAP devices in addition to the treatment of sleep-disordered breathing indices and sleep quality.

Residual apnea, hypopnea, and snoring indexes in both treatment conditions			
	RR	RS	P-Value
Central apnea index, events/h	1.4 (6.4)	1.1 (1.8)	0.103 (NS)
Obstructive apnea index, events/h	0.5 (1.3)	1.2 (2.3)	0.002 *
Hypopnea index, events/h	5.0 (5.6)	7.1 (7.0)	0.013 *
Apnea-hyponea index, events/h	6.9 (11.6)	9.4 (9.2)	0.004 *
Snoring index, events/h	18.3 (60.9)	24.1 (97.1)	0.909 (NS)

(NS) = Not significant * = significant
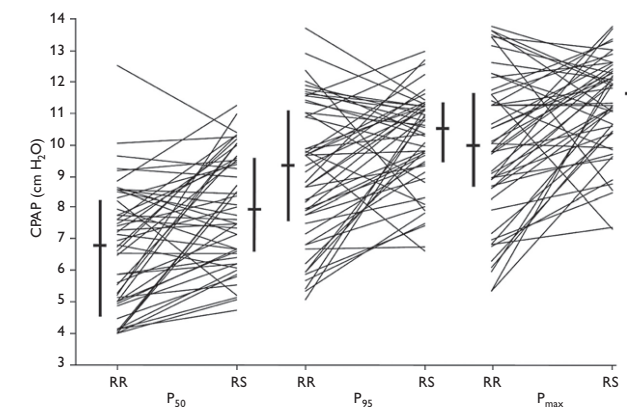
Distribution of P_{50}, P_{95} and P_{max} in the RR and RS devices. All three pressure variables are significantly lower in the RR (p ≤ 0.005).
RR = Respironics REMstar Auto   RS = ResMed AutoSet

Cardiovascular effects of CPAP and auto-CPAP during sleep in patients with OSA

Fixed and autoadjusting continuous positive airway pressure treatments are not similar in reducing cardiovascular risk factors in patients with obstructive sleep apnea[1]

Recent data suggests that despite significant effects on OSA indices and symptoms, differences between the operational algorithms of auto-CPAP devices may affect their ability to alter cardiovascular risk factors.

CPAP treatment has been shown to improve cardiovascular and metabolic outcomes on patients with OSA. Patruno et al. randomized 31 newly diagnosed, severe OSA patients to either CPAP (Weinmann Somnocomfort) or auto-CPAP (ResMed Autoset T). Over a three-month treatment period, the apnea/hypopnea (AHI) was significantly reduced in both groups, and compliance to therapy was similar.

Patruno measured cardiovascular risk factors at baseline and at the end of the three months of treatment, including C-reactive protein, blood pressure, and insulin resistance. C-reactive protein was reduced on both CPAP and auto-CPAP therapy, however, both blood pressure and insulin resistance did not show similar improvements on both treatment modes (as can be seen in Figures 1 and 2).

The author concluded that the results of that study should be regarded as limited to the specific brand of auto-CPAP device used, since auto-CPAP devices have different algorithms that might lead to different observations.
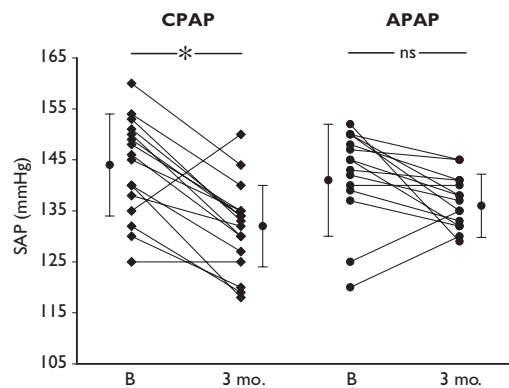
Effects of fixed and autoadjusting CPAP on cardiac sympathovagal balance during sleep in Obstructive Sleep Apnea patients[2]

At the 2008 SLEEP conference, further insights to support the conclusion of varying patient results based on the auto-CPAP device chosen were provided by Dr. Castronovo in collaboration with Dr. Patruno. Castronovo randomized 12 consecutive patients with severe OSA (AHI >30) to one month of CPAP and auto-CPAP treatment. In this case, the Respironics REMstar Auto was studied.

Patruno and Castronovo measured cardiovascular risk factors at baseline and at the end of therapy. Similar to the aforementioned study, the AHI was significantly reduced on both treatment modes, and compliance to therapy was similar.

This comparative study used the Respironics REMstar Auto, which contains a different operational algorithm. Unlike the Petruno study that did not show a difference in blood pressure reduction between the CPAP and ResMed Auto groups, titration with the REMstar Auto did lead to a reduction in systolic and diastolic blood pressure between the two groups.

These findings suggest that just like CPAP, the treatment of OSA by the Respironics REMstar Auto was effective in reducing blood pressure, a known cardiovascular risk factor.

Figure 1. Individual and average changes in SBP (SAP) in patients treated with CPAP or APAP. B = baseline. *p < 0.05. Average data are expressed as mean ±SD.
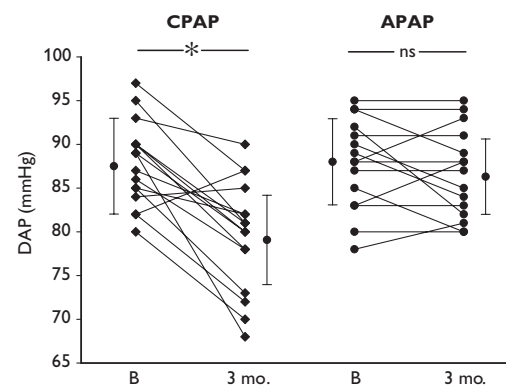

Figure 2. Individual changes in DBP (DAP) in patients treated with CPAP or APAP. See Figure 1 for expansion of abbreviations.

Since operational auto-CPAP algorithms differ significantly between manufacturers, your patient's outcomes will differ significantly as well.

The evidence presented by these two studies suggests that the REMstar Auto operational algorithm may provide treatment equivalent to fixed CPAP in terms of AHI, compliance, and blood pressure.

The ResMed AutoSet, for reasons that are unclear at this time, does not lead to the same decrement in cardiovascular risk that is seen with CPAP.

Only the Respironics REMstar Auto has been shown to treat the patient and, like regular CPAP, was effective in reducing blood pressure, a known cardiovascular risk.

[1]Patruno, V., et al., *Chest* 2007;131:1393-1399

Figures reprinted with permission.

[2]Castronovo, V., et al., *Sleep* 2008;31:A150

REMstar Auto technology

The main goal of the REMstar Auto algorithm is to normalize sleep by minimizing pressure.

What makes the REMstar Auto algorithm unique and different is its sophisticated three-layered algorithm. Unlike other auto-titrating devices in the market, the REMstar Auto can manage an event in the early stages rather than waiting for it to occur. The primary function of the algorithm is to conduct a proactive analysis of the patient's upper airway and its potential to collapse, and make subtle programmed adjustments in response to detected changes in flow.

The second layer consists of programmed responses to apneas, hypopneas, flow limitations, and vibratory snores.

Finally, in the third layer, the algorithm operates in a variety of exception conditions. For example, the algorithm ceases to increase pressure for patients who may be experiencing periods of central activity, and the algorithm decreases pressure when the patient is experiencing a large mask leak.

The result is clinically proven, effective therapy at minimal pressure.

REMstar Auto algorithm: proactive analysis

The REMstar Auto algorithm attempts to determine the optimal therapy level by proactively challenging the airway.

Typically, when positive airway pressure is low, the airway can become compromised, causing upper airway resistance to increase. This can be seen in Figure A where device pressure is plotted against upper airway resistance. On the other end of the curve, when device pressure is high, the airway is open and resistance is low.

The REMstar Auto starts off at the minimum pressure set point for five minutes. At this minimum pressure setting, the patient is awake and the airway is patent, meaning the upper airway resistance is low. As the patient falls asleep, the upper airway begins to collapse.

As illustrated in Figure B, the algorithm slowly increases pressure until it reaches the critical pressure to open the airway. Once the airway opens, the resistance in the upper airway falls dramatically. As pressure continues to increase, the airway continues to open. At a certain point, the curve is completely vertical and further pressure increases no longer decrease the resistance in the upper airway.

As illustrated in the pink circled region of Figure B, the algorithm holds pressure here for a short period of time to determine if the increase in pressure caused any therapeutic benefit to the patient.

If a benefit is detected, the algorithm will continue to slowly increase pressure until there is no further improvement. If the algorithm notices no change in upper airway resistance, the algorithm slowly decreases pressure. As it moves back down the curve, pressure decreases cause slight changes in upper airway resistance.
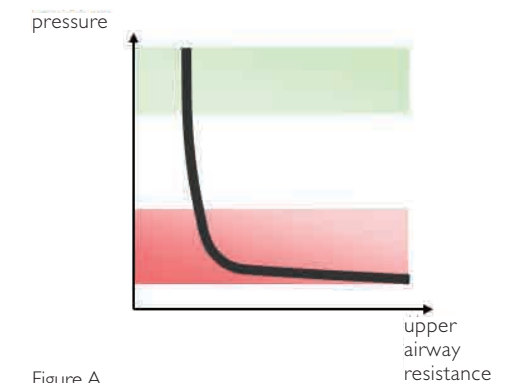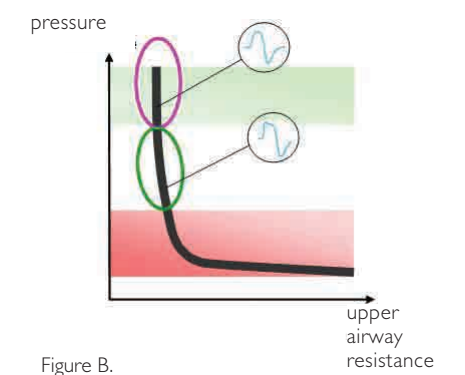

pressure

Figure A.

upper airway resistance

pressure

Figure B.

upper airway resistance

Eventually the pressure reaches a point where small pressure decreases cause significant changes in upper airway resistance (illustrated in the blue circled region in Figure C). When this is detected by the algorithm, pressure is increased.

With this in mind, the airway resistance curve can be divided into three regions, as seen in Figure D: region one (red) where slight pressure increases cause large changes; region two (white) where slight pressure changes cause slight changes; and region three (green) where pressure increases do not improve upper airway resistance. These three circled regions are known as P-critical, P-therapy and P-optimal.

During operation, the REMstar Auto proactively conducts a P-optimal search to identify the optimal pressure for the patient or a P-critical search to find the lowest necessary pressure. This allows it to identify the P-therapy pressure in which obstruction is not likely to occur, but pressure is not unnecessarily high. This analysis and adjustment is ongoing, because the upper airway curve changes as the patient moves and enters various sleep stages. Weight and lifestyle changes also alter the curve.
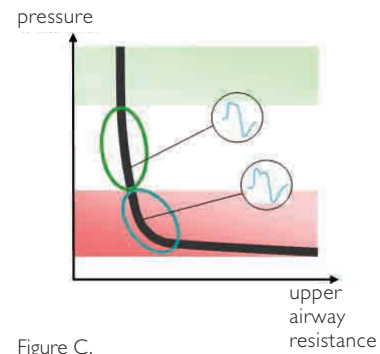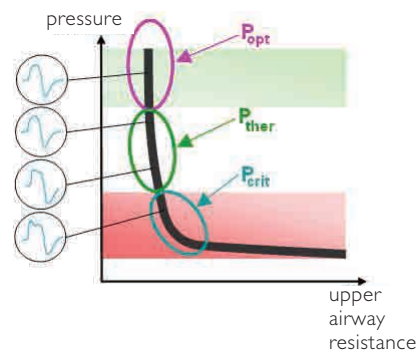

Figure C.

Figure D.

As illustrated in Figure E, at the end of a five-minute period, the algorithm may initiate a subtle proactive P-optimal search by slowly increasing pressure (0.5 cm H_2O / min) in an effort to challenge the airway. If the algorithm notices an improvement in flow at the end of this search, it will continue to increase pressure until no further improvement is detected. With this P-optimal searching feature, the algorithm is able to proactively achieve a higher pressure level prior to the occurrence of an event.
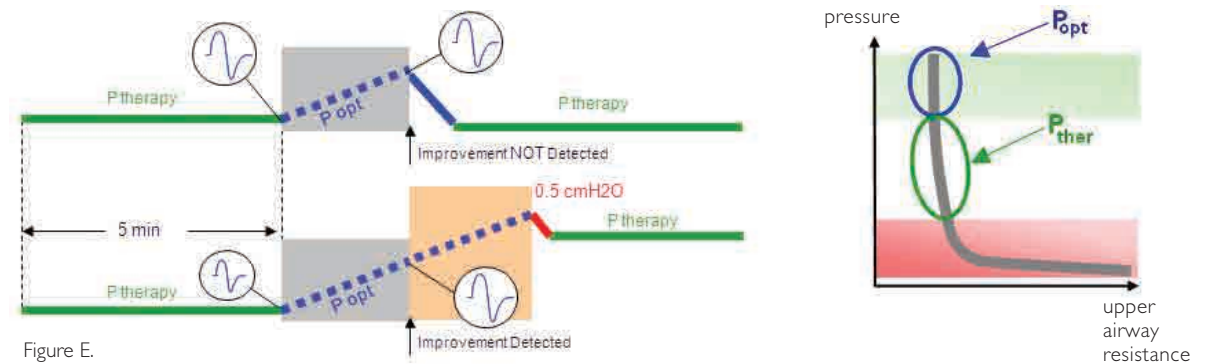

Figure E.

As illustrated in Figure F below, at the end of a five-minute period, the algorithm may initiate a proactive P-critical search where it challenges the airway by slowly decreasing pressure until a flow limitation is detected. Once this occurs, the algorithm will increase pressure slightly and establish a new therapeutic pressure level (P-therapy).
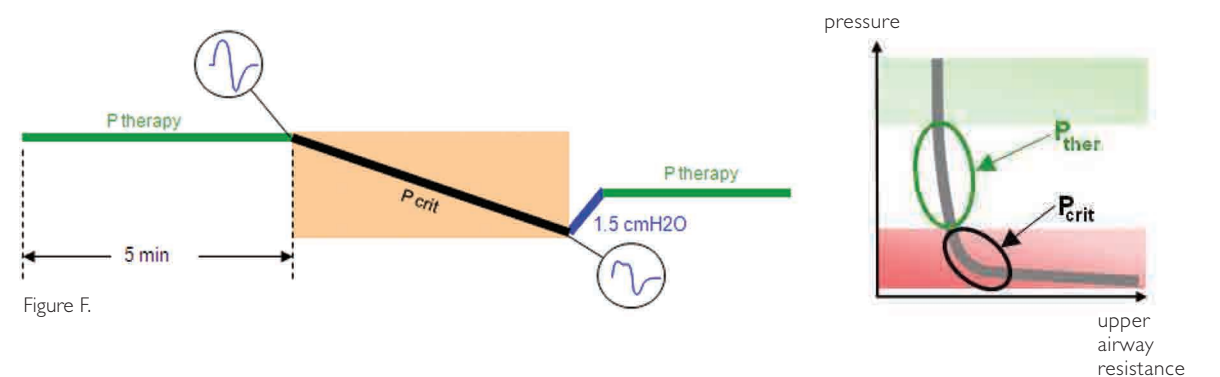

Figure F.

Since the proactive analysis in the REMstar Auto is continuous throughout the therapy session, the algorithm has the unique ability to always be slightly above the pressure necessary to ward off a potential event. Since the pressure delivered at any given time is slightly higher than the pressure level necessary to open the airway, if an event does occur, the device does not need to rapidly respond by increasing pressure quickly. When the REMstar Auto detects a clustering of events, it determines the patient's airway to be unstable and slowly increases pressure to achieve a higher level of CPAP for a new five-minute period.

REMstar Auto algorithm: safety net and complex patient identification

By analyzing each patient breath, the Philips Respironics REMstar Auto uses the most up-to-date signal processing techniques to accurately detect even the most subtle changes.

The Philips Respironics REMstar Auto has the ability to detect flow limitations, vibratory snores, respiratory effort-related arousals (RERAs), periodic breathing, hypopnea, obstructed airway apneas, and clear airway apneas,

This precise recognition of unique patient flow patterns is the reason why the REMstar Auto has been the choice of physicians throughout the world for over a decade.

Flow limitation

While other devices typically respond only to flatness and shape, the REMstar Auto algorithm analyzes changes in flatness, roundness, peak, and shape. These components of patient flow are compared throughout the night on a breath-by-breath basis. This precise recognition of unique flow patterns is the reason why the REMstar Auto reacts better than any other device on the market.

Peak Roundness Flatness Shape

Flow Limitation
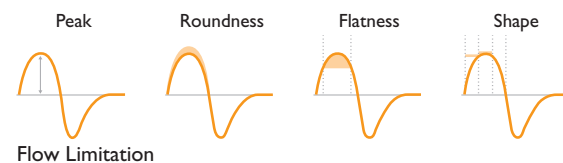
Vibratory snoring

Snoring is a measure of partial airway occlusion and is a strong indicator of potential respiratory events. The pressure sensor in the REMstar Auto identifies pressure fluctuations that occur in the patient's airway. Vibratory snore is disabled at pressures greater than 16 cm H_2O.


Vibratory Snore
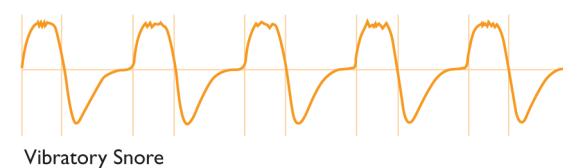
Respiratory effort-related arousal (RERA)

RERA is defined as an arousal from sleep that follows a 10 second or longer sequence of breaths that are characterized by increasing respiratory effort, but which does not meet criteria for an apnea or hypopnea. Snoring, though usually associated with this condition, need not be present. The RERA algorithm monitors for a sequence of breaths that exhibit both a subtle reduction in airflow and progressive flow limitation. If this breath sequence is terminated by a sudden increase in airflow along with the absence of flow limitation, and the event does not meet the conditions for an apnea or hypopnea, a RERA is indicated.


RERA >10 sec
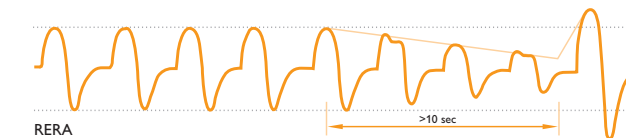
Periodic breathing

Periodic breathing is defined as a persistent waxing and waning breathing pattern that repeats itself between 30 and 100 seconds. The nadir of the breathing pattern is characterized by at least a 40 percent reduction in airflow from an established baseline flow. The pattern must be present for several minutes before it can be identified as periodic breathing.


Periodic Breathing
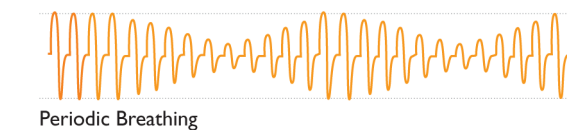
Hypopnea

The REMstar Auto detects a hypopnea as a 40 percent reduction from the established baseline flow that lasts at least 10 seconds.


(Several minutes)

Hypopnea 40% reduction (for 10 seconds)
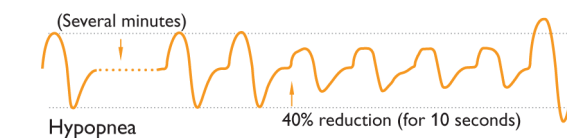
Obstructed airway apnea

An apnea is detected when there is at least an 80 percent reduction in airflow from baseline for at least 10 seconds.

(Several minutes)

Obstructed Airway Apnea   80% reduction (for 10 seconds)
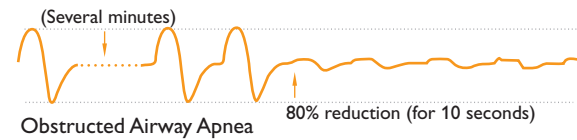
Clear airway apnea

An apnea is detected when there is an 80 percent reduction in airflow from baseline for at least 10 seconds, or if there is no airflow detected for 10 seconds. During the apnea, one or more pressure test pulses are delivered by the device. The device evaluates the response of the patient to the test pulse(s) and assesses whether the apnea has occurred while the patient has a clear airway or an obstructed airway. If the pressure test pulse generates a significant amount of flow, the airway is determined to be clear.


(Several minutes)

Clear Airway Apnea   80% reduction (for 10 seconds)
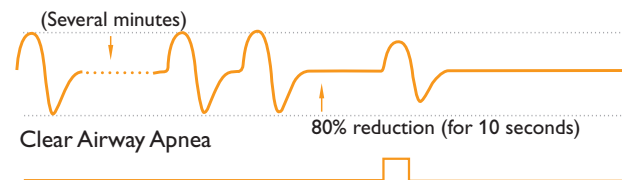
## Clear Airway Apnea (CA) vs. Obstructed Airway Apnea (OA)

If the algorithm does not detect the expected onset of inspiration, one or more 2 cm H_2O pressure test pulses are delivered by the device. The device evaluates the response of the patient to the test pulse(s) in order to assess whether the patient's airway is clear or obstructed. If the pressure test pulse generated a significant amount of flow, the airway is determined to have been clear. If the pressure test pulse did not generate a significant amount of flow, the airway is determined to have been obstructed. Provided the criteria were met to be considered an apnea (at least an 80% reduction in flow for at least 10 seconds), the event will be marked as either a Clear Airway Apnea (CA) or an Obstructed Airway Apnea (OA).


(Several minutes)

Clear Airway Apnea   80% reduction (for 10 seconds)
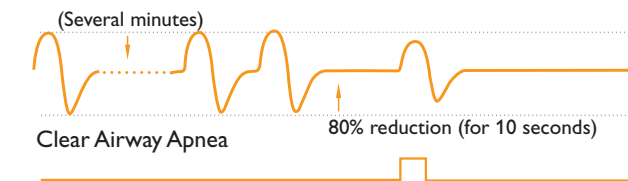
Shown below are several examples displaying how the device algorithm analyses OA vs. CA.
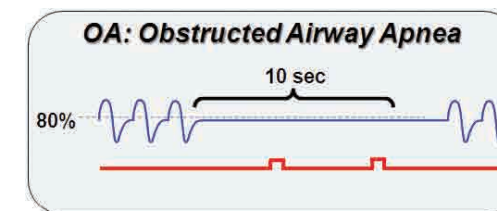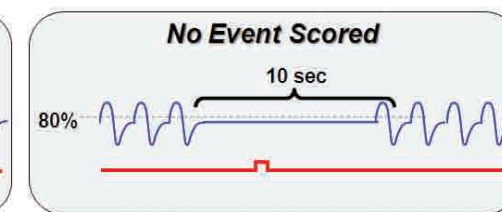

OA: Obstructed Airway Apnea

10 sec

80%

In this example, the algorithm determined patient respiration failed to occur, and two pressure pulses were delivered. No resulting flow response is seen.
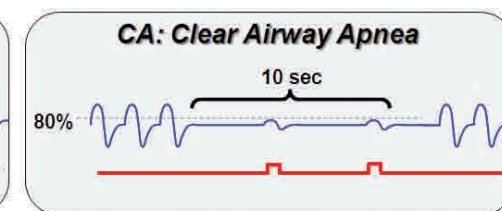
CA: Clear Airway Apnea

10 sec

80%

In this example, the algorithm determined patient respiration failed to occur, and two pressure pulses were delivered. A significant amount of flow is seen, and a clear airway apnea is reported.

OA: Obstructed Airway Apnea

10 sec

80%
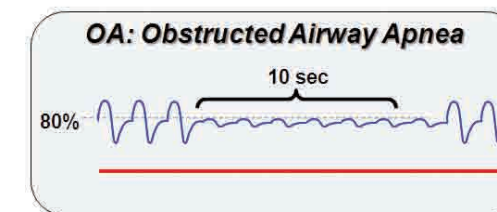
In this example, since the algorithm detects slight respiration, no pressure pulses were necessary to determine an obstructed airway apnea.

No Event Scored

10 sec

80%

In this example, the algorithm determined patient respiration failed to occur and one pressure pulse was delivered. No resulting flow response is seen, however the criteria were not met to be recorded an apnea (less than 10 sec).

Large Leak

Thinking of the mask and device as a closed system, under conditions when the mask is perfectly sealed to the patient's face, the only area of leak in the system comes from the exhalation port. When the device delivers a higher pressure, a high intentional leak results from the exhalation port; when the device delivers a lower pressure, a low intentional leak results from the exhalation port. The instruction sheet of every Philips Respironics mask displays a plot of intentional leak at different pressures. This relationship between intentional leak from the exhalation port and pressure delivered by the device is also maintained in the memory of the REMstar Auto device.

total leak

average intentional leak
from exhalation port

unintentional leak
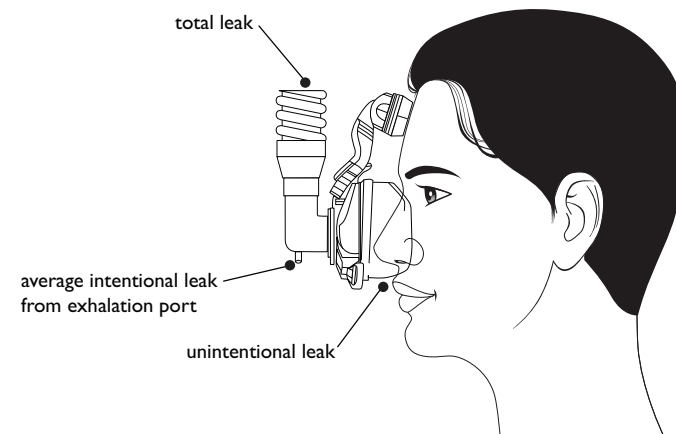
When the patient has a perfect mask seal, the device will notice a total leak value that is equal to the intentional leak from the exhalation port. Any leaks between the cushion and the patient's face will be detected by the REMstar Auto and considered to be unintentional leaks. The REMstar Auto is able to tolerate a wide range of unintentional leaks and still continue to be statistically accurate in its event detection.

For any given pressure, subtracting the known intentional leak of the exhalation port from the measured total leak resulting from the system, the REMstar Auto can accurately report the unintentional leak, or the leak occurring between the cushion and the patient's face.

If a large mask leak occurs, the device will notice the unintentional leak has significantly increased above the level where it can maintain statistical accuracy of event detection. If the measured unintentional leak remains at this level for an extended period of time, the advanced Encore report indicates this large leak by displaying a black bar at the top of the leak illustration.

Our novel technology compensates by decreasing pressure in an attempt to re-seal the mask on the patient's face. The result is a safe and comfortable way for the patient to achieve uninterrupted sleep while maintaining effective therapy.

Flex pressure relief technologies

The introduction of positive airway pressure as the gold standard for sleep apnea treatment was a major milestone in the field of sleep medicine. But another important revolution began when Philips Respironics began searching for a way to increase compliance by making pressure delivery more comfortable.

The Philips Respironics Flex Family of pressure relief technologies offers every sleep therapy patient a comfortable, clinically proven enhancement to ordinary pressure therapy – and a great way to get a good night's sleep.

Flex technologies
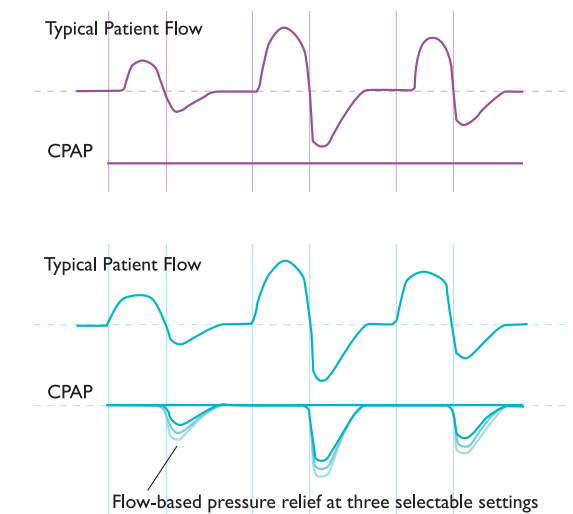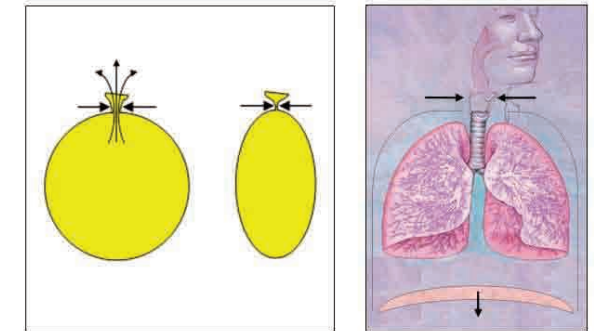
The REMstar algorithm is paired with Philips Respironics' unique Flex technologies that are clinically proven to improve patient compliance. The REMstar Auto includes C-Flex and A-Flex comfort technologies.

To demonstrate how the Flex technologies improve comfort of PAP therapy, consider a balloon as an illustration for the patient's lungs. Squeezing the tip of a balloon simulates a physical obstruction in a patient's upper airway. An expanded balloon represents the time when the lungs are inflated directly before the patient exhales. By applying a small amount of pressure at the tip of the balloon, it is difficult to stop air from flowing due to the elasticity of the balloon contracting on itself and forcing the air to escape. Eventually a point occurs when it is very easy to stop air from flowing out of the balloon, while air is still trapped inside. Like this illustration, it is very difficult for an obstruction to occur in the patient's upper airway at the beginning of exhalation due to physiological forces, such as elasticity of the thorax, gravity, etc. Eventually, toward the end of exhalation, the patient may exhibit an obstruction.


Based on these physiological dynamics of the airway, Philips Respironics developed Flex technologies that proportionally decrease pressure at the beginning of exhalation and return to therapeutic pressure before the end of exhalation. As the figure on the right shows, when the patient takes a small breath, there is a small amount of air in the lungs, so C-Flex delivers only a small amount of relief (only at the beginning of exhalation). When the patient takes a large breath and there is a significant amount of air in the lungs, C-Flex delivers a larger amount of relief (only at the beginning of exhalation).

Also visible in the illustration are the three settings for C-Flex. While the relief is breath-to-breath dependent, the three C-Flex settings easily allow the physician to customize the relief for their patients on every breath.

Typical Patient Flow

CPAP

Typical Patient Flow

CPAP

Flow-based pressure relief at three selectable settings

CPAP

For decades, CPAP therapy has delivered the same constant pressure during inhalation and exhalation. Although it is therapeutic, CPAP therapy does not deliver the highest comfort to the patient, and, as a result, patients are not always compliant. Using an esophageal balloon, you can measure the necessary pressure to open the airway at any given point throughout one breath. The green line below illustrates the profile of necessary pressure throughout the breath. The difference between the pressure required to maintain an open airway and the prescribed CPAP pressure is unnecessary pressure that is delivered to the patient. This is represented by the red shaded region in the figure below.
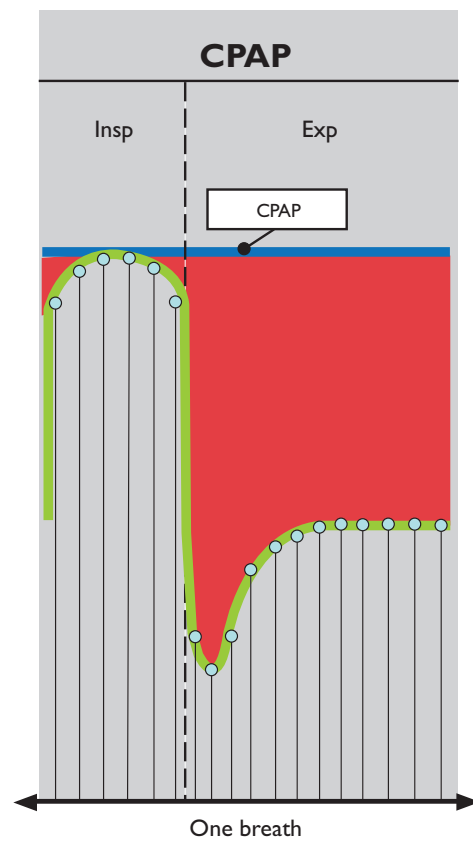
C-Flex

Striving to provide more comfortable PAP therapy to patients, in 2002, Respironics introduced its revolutionary C-Flex pressure relief technology. As with fixed CPAP, patients displayed the same necessary pressure profile to open the airway, but C-Flex delivers a lower pressure during the beginning portion of exhalation, while returning to therapeutic pressure at the end of exhalation. This illustration shows less unnecessary pressure delivered to the patient than CPAP. C-Flex has been proven to increase compliance over traditional CPAP therapy.[3]

[3]Aloia, M.S., et al., *Chest* 2005; 127: 2085-2093
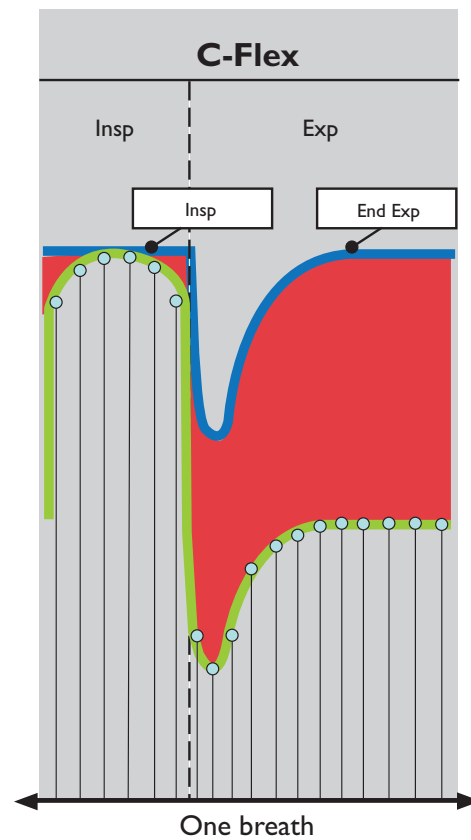
A-Flex

In 2007, Respironics enhanced its Flex comfort mode for CPAP with the release of A-Flex in its REMstar Auto. With A-Flex, patients still displayed the same necessary pressure profile to open the airway, but A-Flex delivers even more pressure relief during the beginning portion of exhalation while returning to a pressure that is no more than 2 cm H_2O below inhalation pressure. This illustration shows even less unnecessary pressure delivered to the patient. A-Flex gives patients a whole new level of comfort for their CPAP therapy.
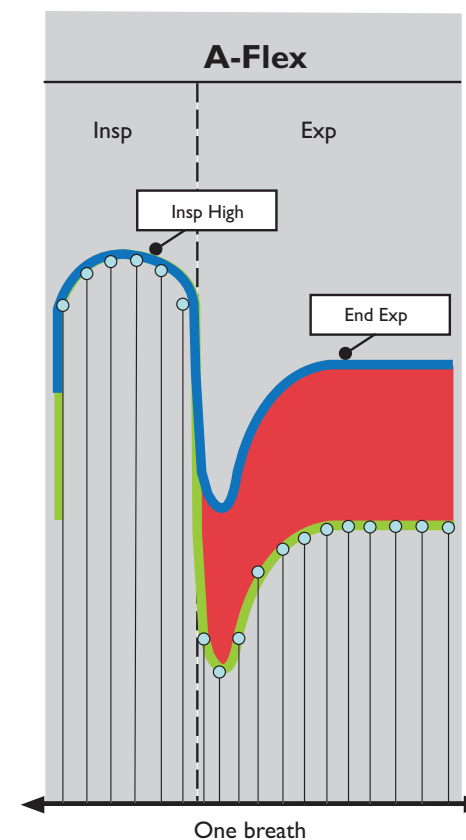
Bi-Flex

Respironics was the first company to introduce bi-level positive airway pressure therapy to sleep medicine. Patients still displayed the same necessary pressure profile to open the airway throughout a breath, but bi-level positive airway pressure delivers a fixed pressure during inhalation with a lower fixed pressure during exhalation. The illustration below shows significantly less unnecessary pressure delivered to the patient. With Bi-Flex, patients also get the additional pressure relief of three critical points in the breathing cycle: the transition from exhalation to inhalation; the transition from inhalation to exhalation; and during exhalation.
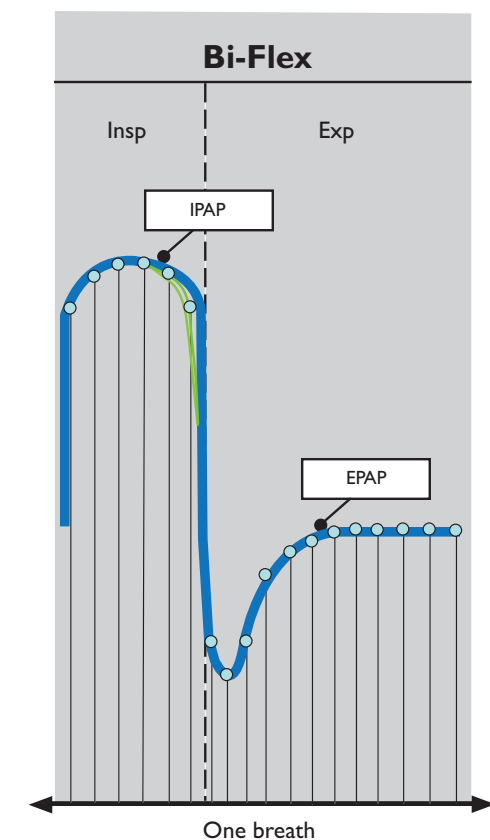
Encore reporting

Encore patient management software solutions provide physicians and sleep providers with the ability to manage their patients' sleep data objectively.

EncorePro client-based and EncoreAnywhere Web-based platforms monitor and report basic and advanced compliance information using data collected from Philips Respironics sleep therapy devices. Data is collected and transferred via a SmartCard, SD Card, or modem (EncoreAnywhere only).

Through graphical and statistical illustrations, patients' therapeutic histories are displayed, allowing you to better manage your patients and their compliance outcomes.

Encore software solutions also can help manage patient files, create cross patient reports and track the overall treatment progress of your patient populations.

Daily details

Full-detail Encore reports display up to the last seven nights of Daily Details each on their own separate page. This report provides extremely useful information about short-term treatment efficacy. These reports display a "tick mark" each time one of the seven events displayed on the next page occurs within any one session.

All the data on this sample Daily Details report displays everything the patient experienced while on the device for the specified night.

Back side of tab is a blank page

Daily details

Daily Details

8/11/2009 12:47 PM

Pressure (cmH2O)

Auto CPAP — Min CPAP Setting — Max CPAP Setting

Sleep Therapy Flags

PB, CA, OA, H, FL, VS, RE

Total Leak (LPM)

Normal Mask Fit — Large Leak — Total Leak

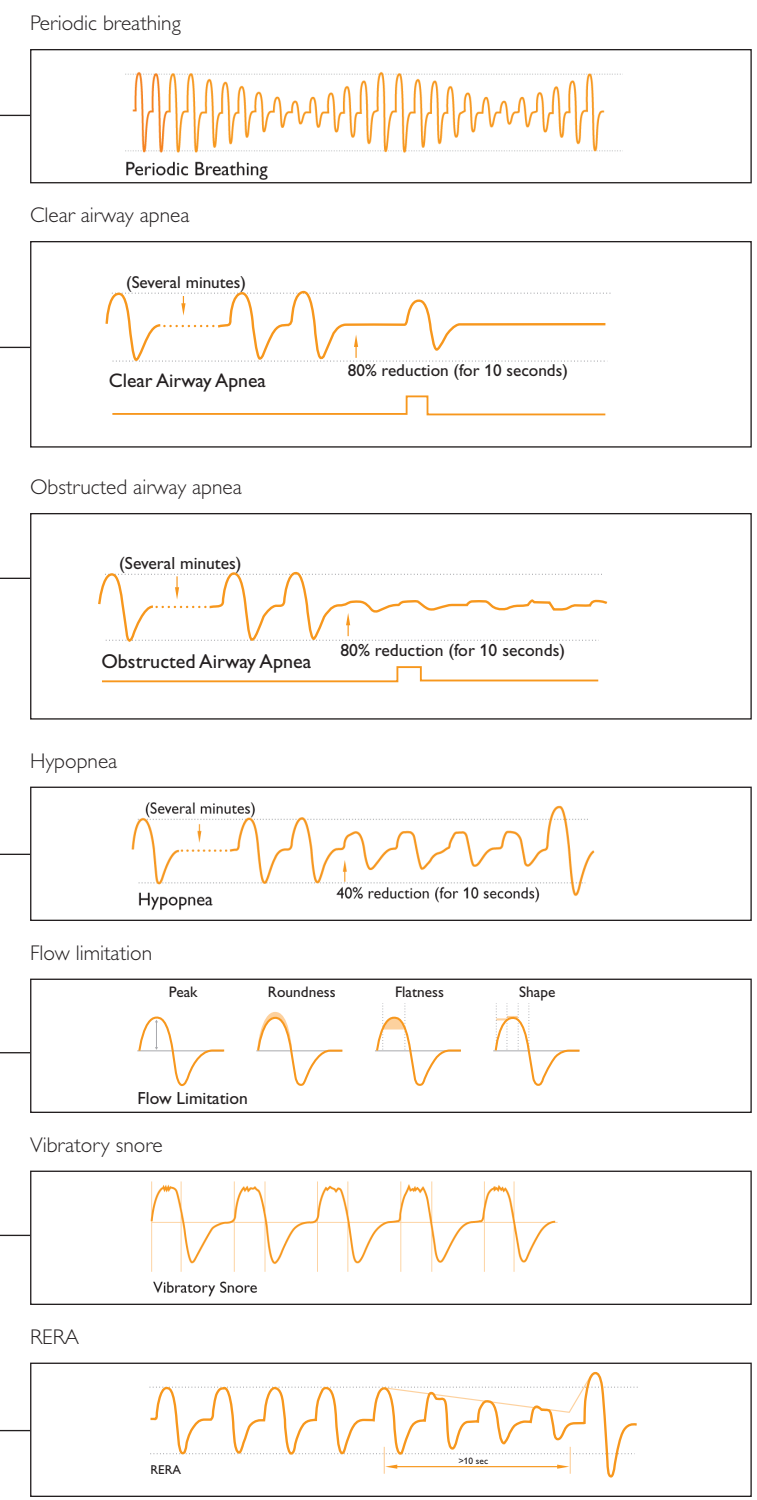Mask fit info
Good fit
Large leak

A-Flex™

90% Pressure

90% Pressure
13.0

Auto Pressure Profile

Average CPAP Pressure
10.4

Indices
4.4   % of Night in PB
CA: 1.4
OA: 0.7
H: 2.6
FL: 0.6
VS: 8.1
RE: 4.1
AHI: 4.7

Mask Leak Information

Min in Large Leak
12.0 mins

% of Night in Large Leak
2.8 % of Night

Average Leak
30.0

Daily Events Per Hour

8/11/2009   Total AHI: 4.7

P	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
MaP	0.0	5.2	2.3	4.7	28.1	35.1	171.8	87.1	15.7	53.0	16.7	14.6	1.7	0.0	0.0	0.0	0.0
%	0.0	1.2	0.5	1.1	6.4	8.0	39.4	20.0	3.6	12.2	3.8	3.4	0.4	0.0	0.0	0.0	0.0
FL	0.0	0.0	0.0	0.0	0.0	1.7	0.0	0.7	0.0	1.1	3.6	0.0	0.0	0.0	0.0	0.0	0.0
VS	0.0	46.3	213.3	25.7	27.8	13.7	6.3	0.0	19.1	1.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OA	0.0	0.0	26.7	12.9	2.1	1.7	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CA	0.0	0.0	0.0	0.0	2.1	0.0	0.7	2.8	0.0	3.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0
H	0.0	0.0	0.0	12.9	6.4	10.3	2.1	0.0	3.8	1.1	0.0	4.1	0.0	0.0	0.0	0.0	0.0
RE	0.0	0.0	0.0	0.0	0.0	3.4	6.3	3.4	0.0	3.4	0.0	8.2	0.0	0.0	0.0	0.0	0.0
AHI	0.0	0.0	26.7	25.8	10.6	12.0	3.1	2.8	3.8	4.5	0.0	4.1	0.0	0.0	0.0	0.0	0.0

90%

Legend	P - Pressure, MaP - Minutes at Pressure, % - Percent of Night, FL - Flow Limitation, VS - Vibratory Snore, PB - Periodic Breathing, CA - Clear Airway Apnea, RE - RERA, H - Hypopnea, OA - Obstructed Airway Apnea, AHI - Apnea/Hypopnea Index

Indices
4.4% of Night in PB

CA: 1.4
OA: 0.7
H: 2.6
FL: 0.6
VS: 8.1
RE: 4.1
AHI: 4.7

Periodic breathing

Periodic Breathing

Clear airway apnea

(Several minutes)
Clear Airway Apnea   80% reduction (for 10 seconds)

Obstructed airway apnea

(Several minutes)
Obstructed Airway Apnea   80% reduction (for 10 seconds)

Hypopnea

(Several minutes)
Hypopnea   40% reduction (for 10 seconds)

Flow limitation

Peak   Roundness   Flatness   Shape
Flow Limitation

Vibratory snore

Vibratory Snore

**RERA**

RERA   >10 sec

Long-term trends

The Long Term Trend report provides information about treatment efficacy in the form of event indices over a period of time (up to six months of data). Any long-term change in the patient's condition will be visible on this report.

For example, if the patient's Clear Airway Apnea Index is increasing over time, it is quite possible the patient has developed mixed apnea and should be brought back in for re-evaluation.

Another example would be if the patient's Average % of Night in Periodic Breathing is at a level high enough to suggest the patient is developing some comorbidity and is no longer strictly an obstructive apnea patient.

It is useful to review each parameter individually (a horizontal review) as well as assess the correlations between the parameters (the vertical review).

As this sample Long Term Trends report shows, all the changing indices are displayed over the period of time shown on the bottom horizontal line of the report. This is helpful with interpretation for clinical application.
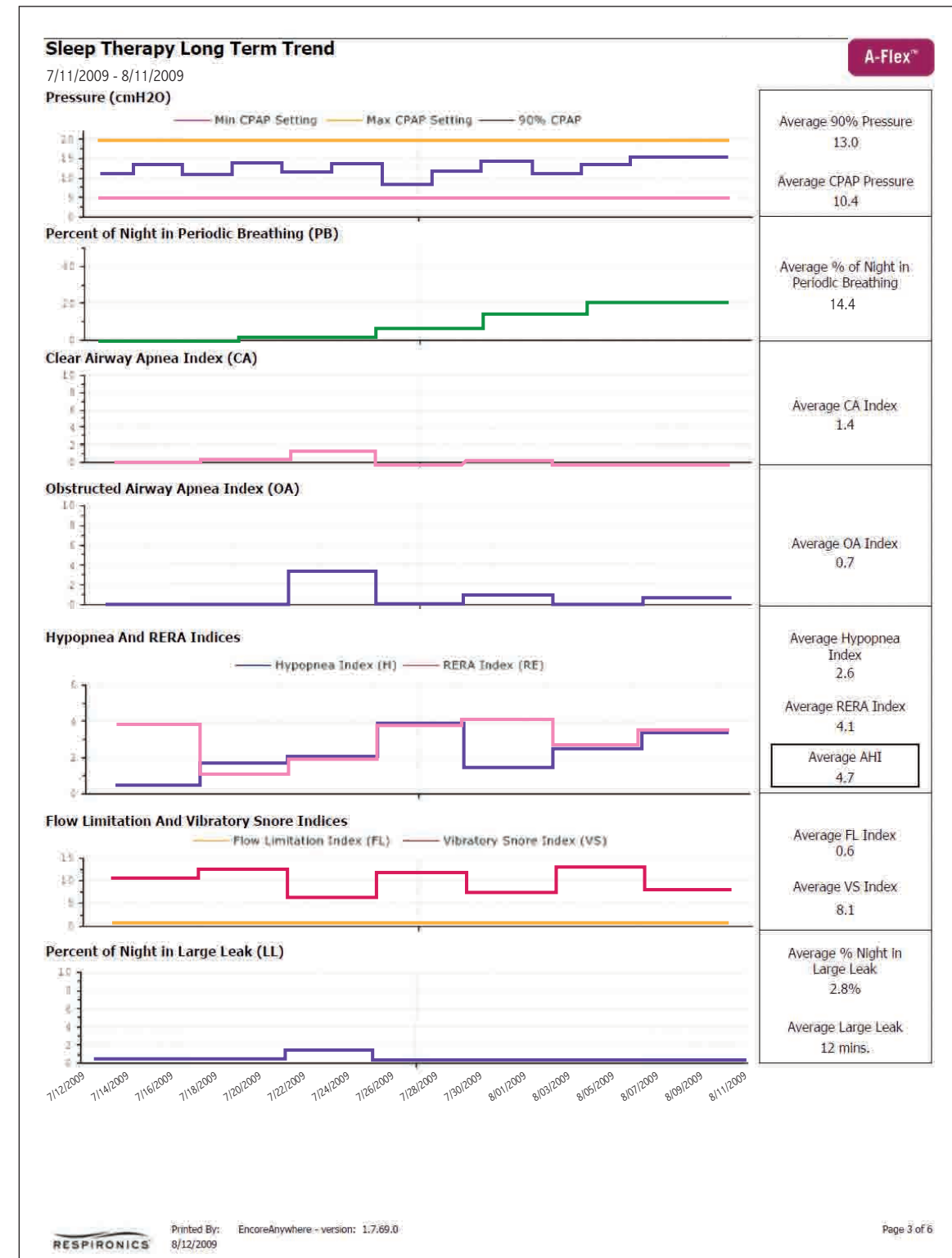
Patient flow and event reporting

The Patient Flow and Event Report enables you to view detailed information about your patient. It displays critical details that help physicians accurately identify and assess your patient's sleep conditions. As the illustration shows, patient data is highlighted with specific colors and labels for easy identification.

Each page of the Patient Flow and Event Report will show up to one hour of patient flow and event data displayed as six minutes per line and 10 lines per page. The entire report will contain up to eight pages of hourly flow in a compact PDF file.
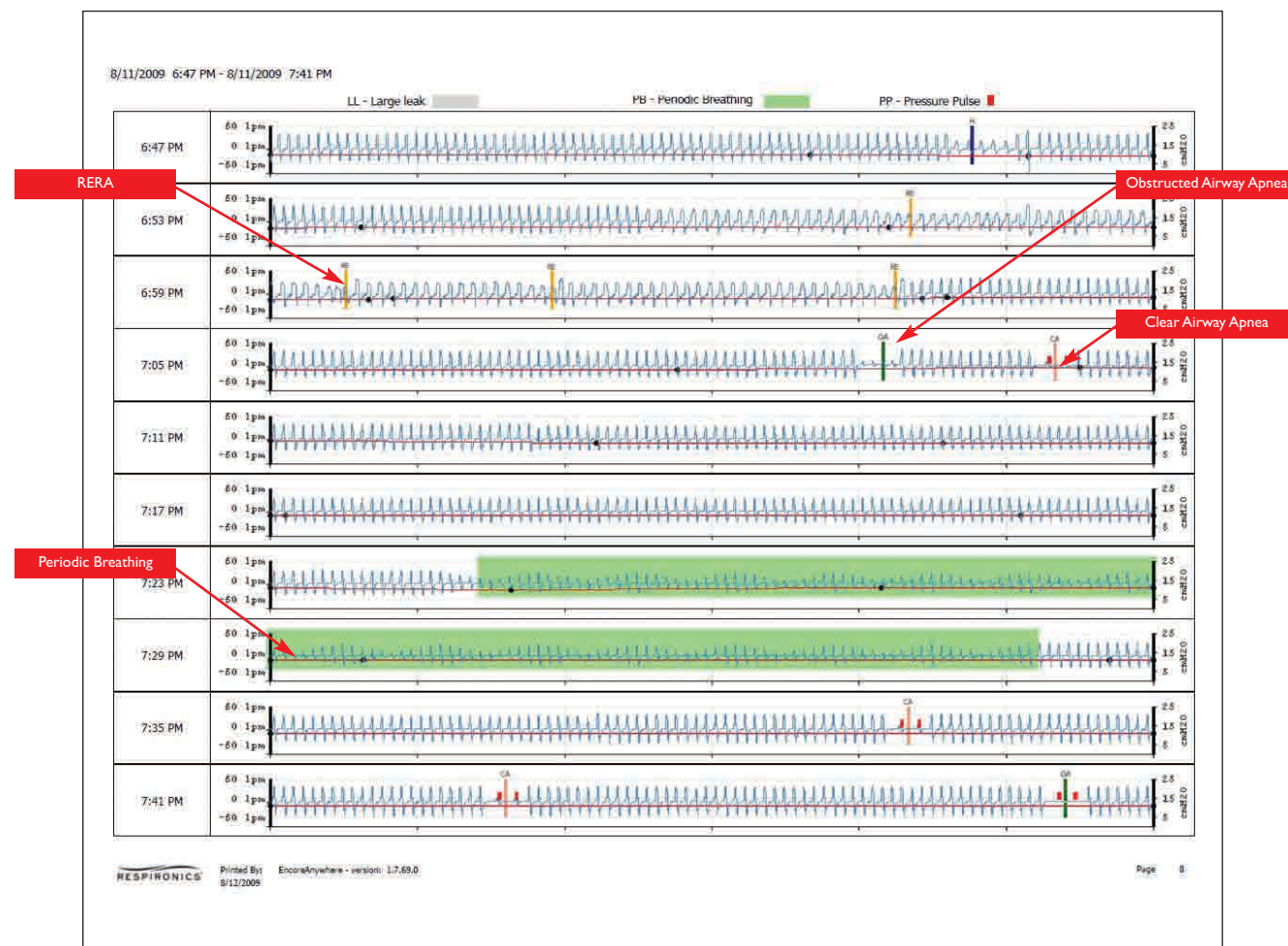
REMstar Auto Case studies

Encore reports can be a valuable tool in diagnosing the treatment for your patients. The following case studies address a variety of ways Encore reports can assist in managing patient care.

• Managing Single Night Large Leak
• Managing Continual Large Leak
• Managing Incorrect Device Setup Constraints
• SmartRamp: The correct balance between comfort and safety
• Periodic Breathing Detection and Treatment

Case studies

Case 1: Managing single night large leak

The Philips Respironics REMstar Auto device has been preprogrammed with the characteristics of the mask's exhalation port and, therefore, knows the intentional leak (or leak coming from the exhalation port) for any given pressure being delivered. The default advanced Encore Daily Details report will automatically subtract out the intentional leak and report only the unintentional leak. The green line at the bottom of the chart below represents this unintentional leak escaping between the mask and the patient's skin.

As indicated on the illustration, the green outlined portion at the top shows the time when the patient was experiencing a good mask fit while the black shaded portion represents times of large mask leak (or the times when the leak was significantly higher than what the device expected for the pressure delivered by the device at that particular time).
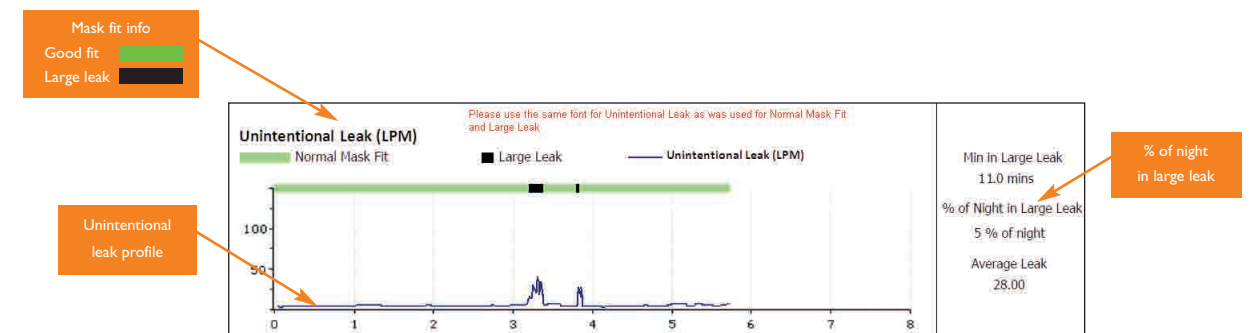
There are two pieces of information that should be examined closely when reviewing an Encore report for mask fit information:

1. Periods shaded in green represent a good mask fit.
2. For a good mask fit, percentage of night in large mask leak should be low.

As this Encore report example shows, the patient had a good mask fit for most of the night (represented by the green region) and only experienced a large leak for five percent of the night.

Case II: Managing continual large leak

As Case I described, the Encore Daily Details report displays the percentage of night in large leak for any single night the patient uses the device. By viewing the Long Term Trends page of an Encore report, it is possible to see how the percentage of night in large leak can change over several months of usage.

The example below shows the leak portion of the Long Term Trends page of an Encore report. The time scale represents six months of device and mask usage. As the green line indicates, the patient's percentage of night in large leak changed over time. When the patient began using the mask, the percentage of night in large leak was minimal, but as time progressed, the percentage of night in large leak increased.

After being alerted to this, it was determined that the patient's mask cushion had hardened over the six months and caused the percentage of night in large leak to increase over time. Making no adjustments to the patient's therapy, the clinician supplied the patient with a new mask and the result was a decreased percentage of night in large leak and an increase in compliance (device usage).
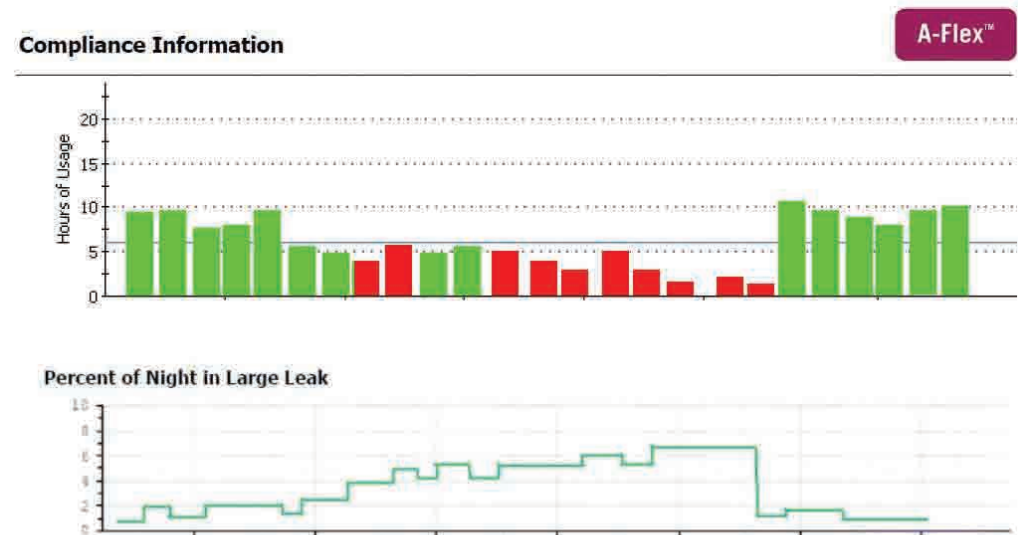
Case III: Managing incorrect device setup constraints

The default operating range of the REMstar Auto is between 4 cm H_2O and 20 cm H_2O. Since the REMstar Auto is able to determine the difference between obstructed airway apneas and clear airway apneas, it is smart enough to prevent over-titration due to potential central events. Because of this, there is no need to lower the maximum pressure setting of the device. The product has been tested and certified to safely operate all the way to 20 cm H_2O without the need to limit the maximum constraint.

Some physicians may desire the ability to lower the maximum pressure on their patients. While it is easy to adjust custom minimum and maximum pressure settings, quite often incorrect constraints are entered into the device. The illustration below shows a common example of what happens when the maximum pressure has been set too low. As illustrated, the patient had persistent snores and apneas that instructed the device to increase pressure. Since the maximum pressure was set too low, the algorithm was unable to increase pressure for the patient. The result is an incorrectly high AHI and high Vibratory Snore (VS) Index.
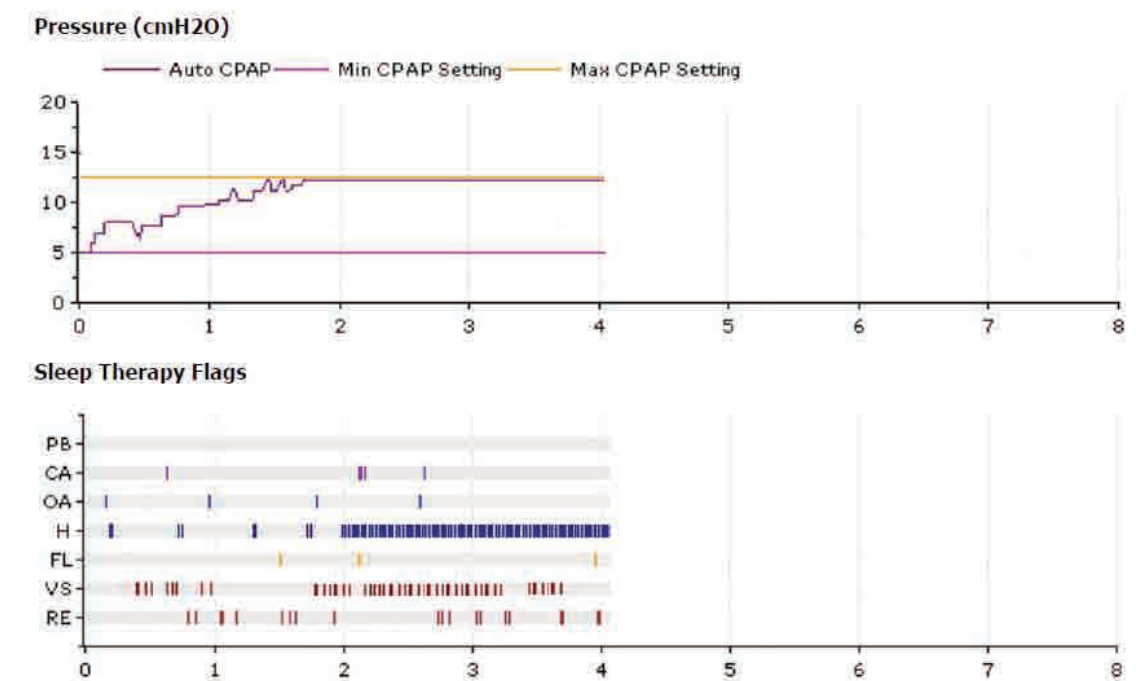
# Case IV: SmartRamp – the correct balance between comfort and safety

After detecting two obstructed airway apneas or hypopneas within a three-minute period, the algorithm increases pressure by 1 cm H_2O to a new level of CPAP. At the beginning of this new level of CPAP, if obstructed airway apneas and hypopneas continue to persist, the device will detect and record these events, however the sophisticated REMstar Auto algorithm's safety feature prevents a rapid succession of pressure increases. This is most noticed when patients who have higher pressure needs begin the night at a starting pressure that is too low, as can be seen at the beginning portion of the night in Example 1. Notice the clustering of events at the beginning of the night with a gradual corresponding pressure increase.

Using the SmartRamp feature, the patient can start therapy at a comfortably low level that makes it easy to fall asleep. The caregiver can be confident the SmartRamp logic will identify events and will increase its pressure response to meet the patient need. As is demonstrated in Example 2, the novel SmartRamp feature in the REMstar Auto allows physicians to customize the time the device will ramp from minimum ramp pressure to minimum therapy pressure. When the patient presses the ramp button, pressure drops from minimum therapy pressure to minimum ramp pressure, and the device increases pressure based on the time selected by the physician. Notice in this illustration how the SmartRamp feature detected obstructed airway apneas and increased pressure faster due to the events.

Example 1: SmartRamp not enabled (minimum pressure too low)
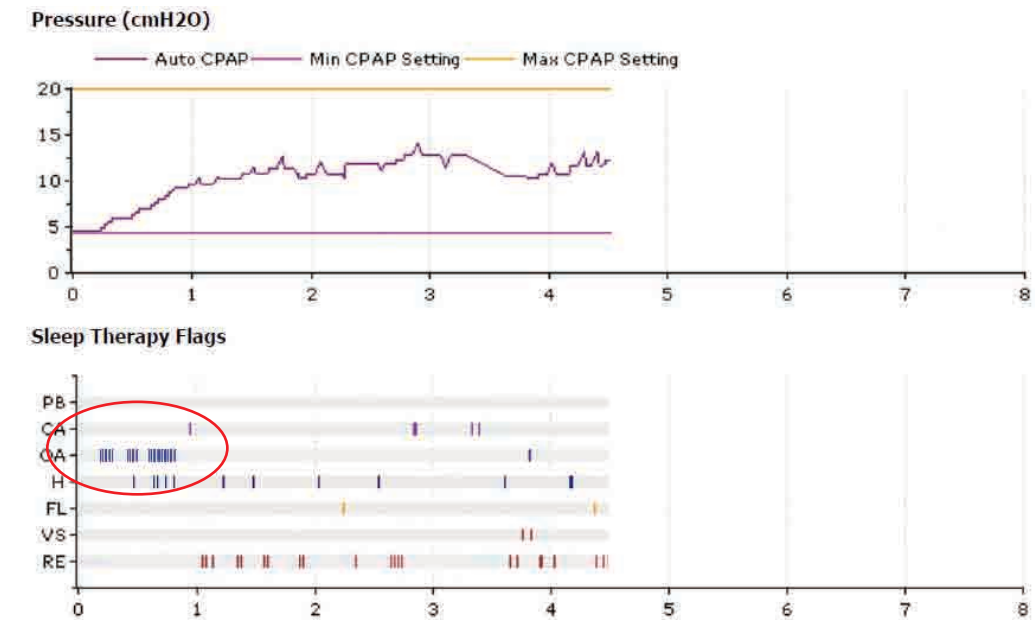
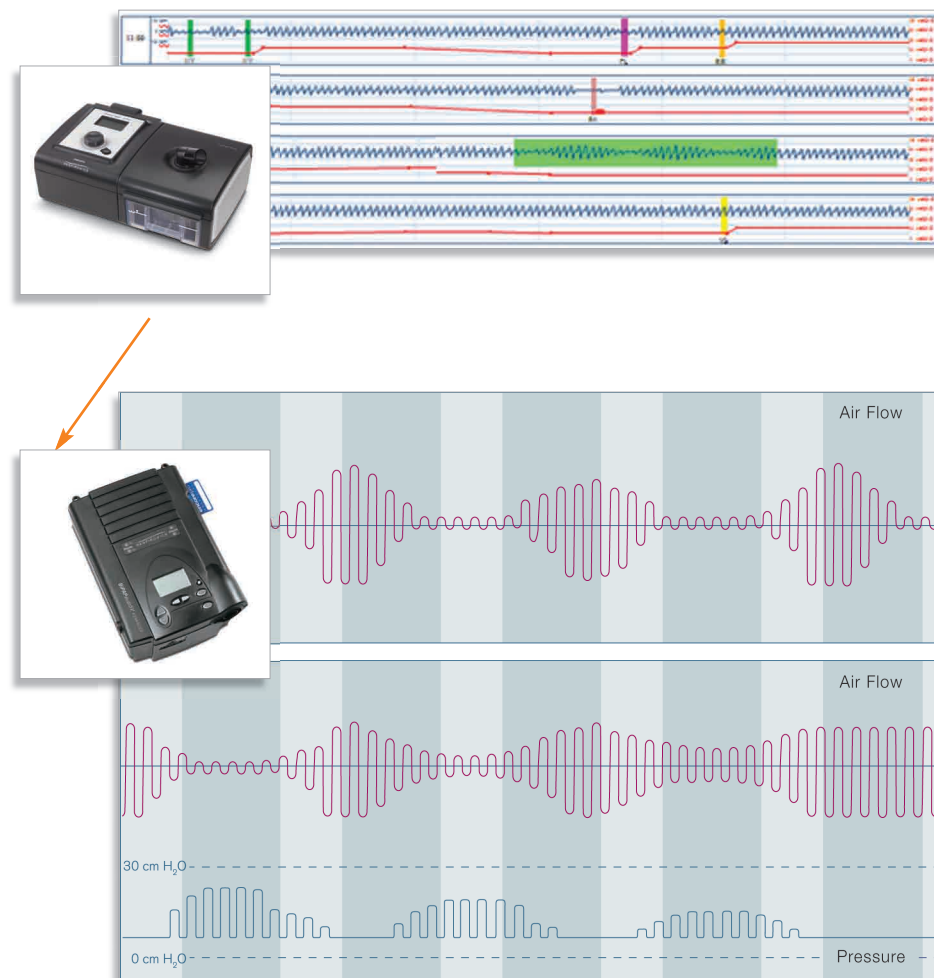**Example 2: SmartRamp enabled (higher minimum pressure)**
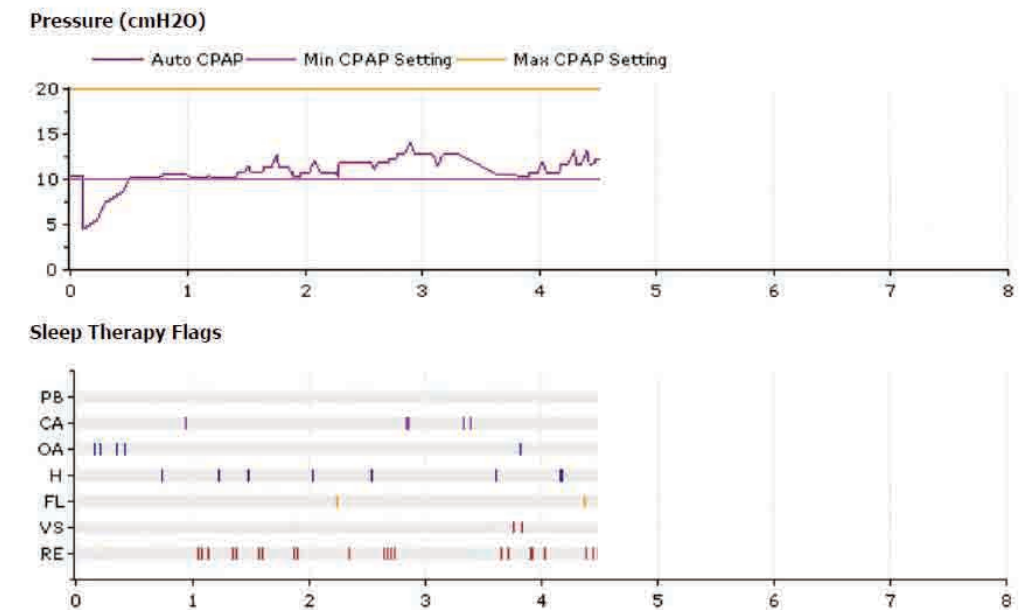
Case V: Periodic breathing detection and treatment

The patient in the example below was initially determined to be a standard OSA patient and was issued a REMstar Auto. After the patient began using the device, episodes of periodic breathing were demonstrated in both the Encore Daily Detail flags and in the Patient Flow & Event report shown below. The device detected this change in breathing pattern and flagged the event.

The patient was brought back into the sleep lab and re-evaluated for emerging comorbidities. The patient was then placed on a Respironics BiPAP autoSV to treat the underlying condition. On a breath-by-breath basis, the BiPAP autoSV was able to change pressure support to maintain a stable breathing pattern. This algorithm rapidly helped normalize respiration and returned the pressure to the minimum required therapeutic pressure while maintaining normalized ventilation.

Whether this patient had periodic breathing that was not detected in the initial PSG or the patient developed periodic breathing over long-term use, the REMstar Auto detected this irregular breathing pattern and alerted the caregiver that the patient needed to be re-evaluated.

Air Flow

Air Flow

30 cm H$_2$O

0 cm H$_2$O

Pressure

REMstar Auto clinical applications guide

PHILIPS
RESPIRONICS