Monitoring and Troubleshooting Adherence to PAP Devices and Understanding Device Downloads

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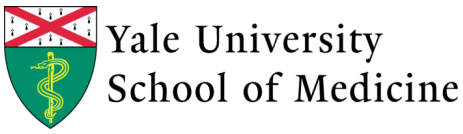
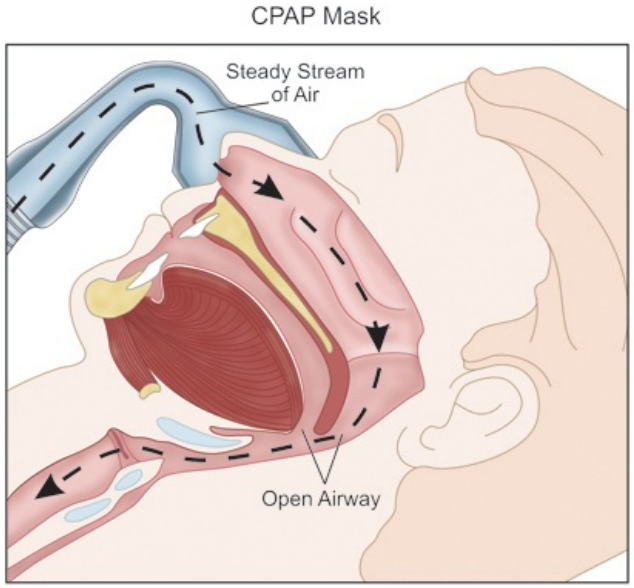


Outline

- Efficacy versus effectiveness: the problem of adherence
- Monitoring and troubleshooting adherence
  - “Smart” PAPs
  - Comfort settings
  - Personalized sleep medicine

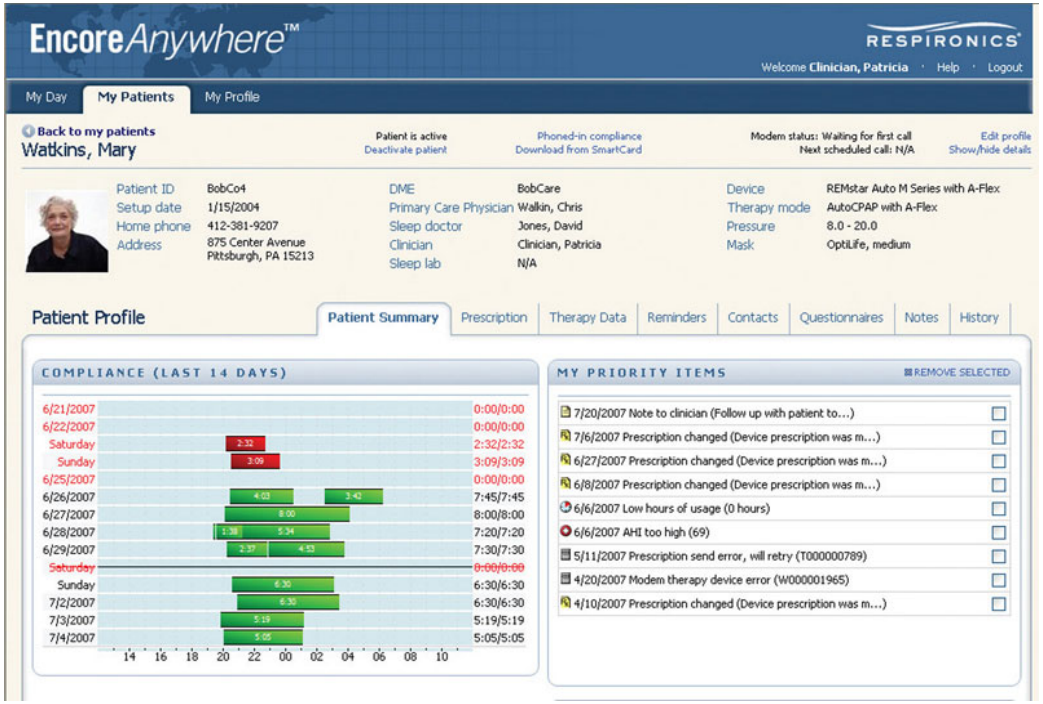
Continuous Positive Airway Pressure (CPAP)

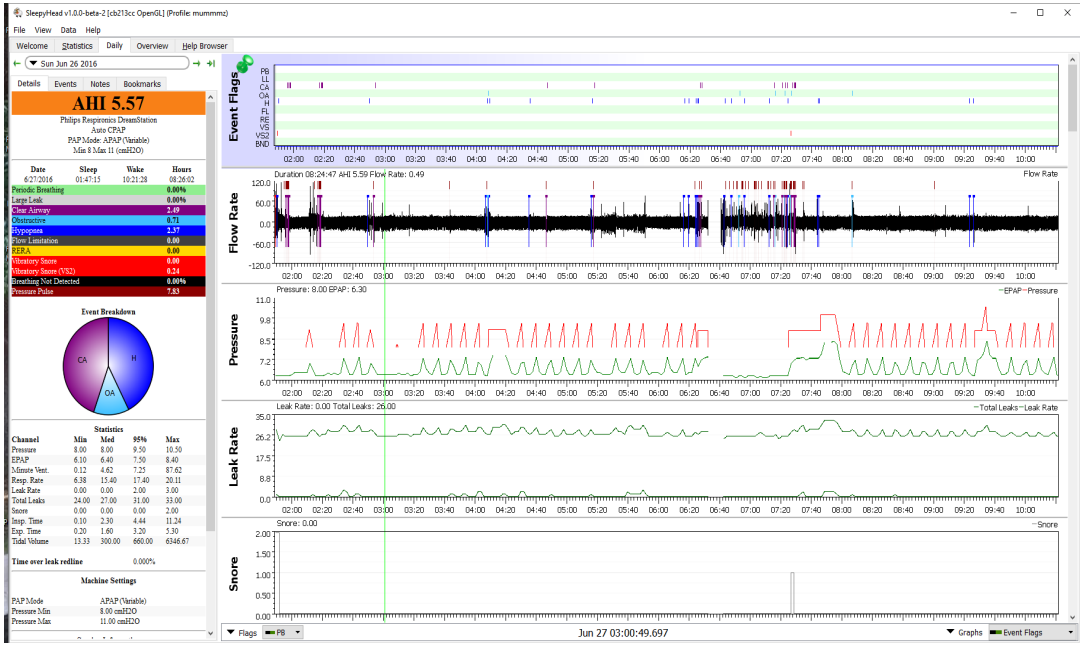
- Continuous PAP throughout inspiration and expiration
  - Pneumatic stent preventing airway collapse
  - Provides PEEP to recruit alveoli and improve ventilation
- CPAP must continually adjust for leak as well as respiratory variation to maintain a constant pressure



www.respshop.com

Monitoring treatment adherence and efficacy


EncoreAnywhere™
RESPIRONICS
Welcome Clinician, Patricia · Help · Logout
My Day
My Patients
My Profile
Back to my patients
Watkins, Mary
Patient is active
Deactivate patient
Phoned-in compliance
Download from SmartCard
Modem status: Waiting for first call
Next scheduled call: N/A
Edit profile
Show/hide details
Patient ID BobCo4
Setup date 1/15/2004
Home phone 412-381-9207
Address 875 Center Avenue Pittsburgh, PA 15213
DME BobCare
Primary Care Physician Walkin, Chris
Sleep doctor Jones, David
Clinician Clinician, Patricia
Sleep lab N/A
Device REMstar Auto M Series with A-Flex
Therapy mode AutoCPAP with A-Flex
Pressure 8.0 - 20.0
Mask OptiLife, medium
Patient Profile
Patient Summary
Prescription
Therapy Data
Reminders
Contacts
Questionnaires
Notes
History
COMPLIANCE (LAST 14 DAYS)
6/21/2007 0:00/0:00
6/22/2007 0:00/0:00
Saturday 2:32/2:32
Sunday 3:09/3:09
6/25/2007 0:00/0:00
6/26/2007 7:45/7:45
6/27/2007 8:00/8:00
6/28/2007 7:20/7:20
6/29/2007 7:30/7:30
Saturday 0:00/0:00
Sunday 6:30/6:30
7/2/2007 6:30/6:30
7/3/2007 5:19/5:19
7/4/2007 5:05/5:05
14 16 18 20 22 00 02 04 06 08 10
MY PRIORITY ITEMS
REMOVE SELECTED
7/20/2007 Note to clinician (Follow up with patient to...)
7/6/2007 Prescription changed (Device prescription was m...)
6/27/2007 Prescription changed (Device prescription was m...)
6/8/2007 Prescription changed (Device prescription was m...)
6/6/2007 Low hours of usage (0 hours)
6/6/2007 AHI too high (69)
5/11/2007 Prescription send error, will retry (T000000789)
4/20/2007 Modem therapy device error (W000001965)
4/10/2007 Prescription changed (Device prescription was m...)


SleepyHead v1.0.0-beta-2 [cb213cc OpenGL] (Profile: mummmz)
File View Data Help
Welcome Statistics Daily Overview Help Browser
Sun Jun 26 2016
Details Events Notes Bookmarks
AHI 5.57
Philips Respironics DreamStation
Auto CPAP
PAP Mode: APAP (Variable)
Min 8 Max 11 (cmH2O)
Event Breakdown
Event Flags
Flow Rate
Pressure
Leak Rate
Snore
Jun 27 03:00:49.697

PAP data download: Summary

CPAP-Supply.com

Therapy Data Summary - All Data

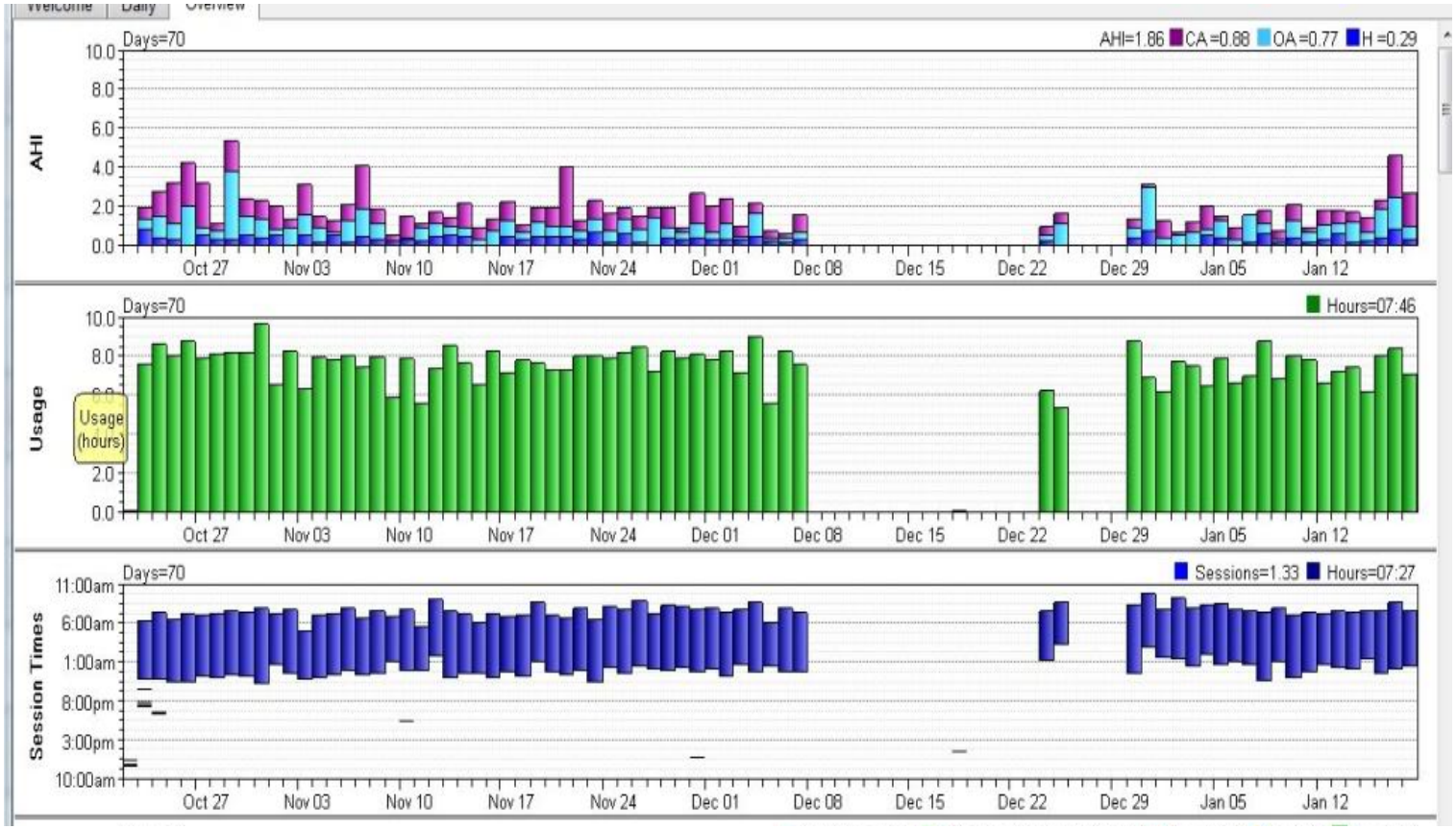
Compliance Summary

Date Range	10/18/2007 - 10/21/2007 (4 days)
Days with Device Usage	4 days
Days without Device Usage	0 days
Percent Days with Device Usage	100.0%
Cumulative Usage	1 day 4 hrs. 59 mins. 13 secs.
Maximum Usage (1 Day)	8 hrs. 20 mins. 3 secs.
Average Usage (All Days)	7 hrs. 14 mins. 48 secs.
Average Usage (Days Used)	7 hrs. 14 mins. 48 secs.
Minimum Usage (1 Day)	6 hrs. 22 mins. 31 secs.
Percent of Days with Usage >= 4 Hours	100.0%
Percent of Days with Usage < 4 Hours	0.0%
Total Blower Time	1 day 5 hrs. 39 mins. 13 secs.

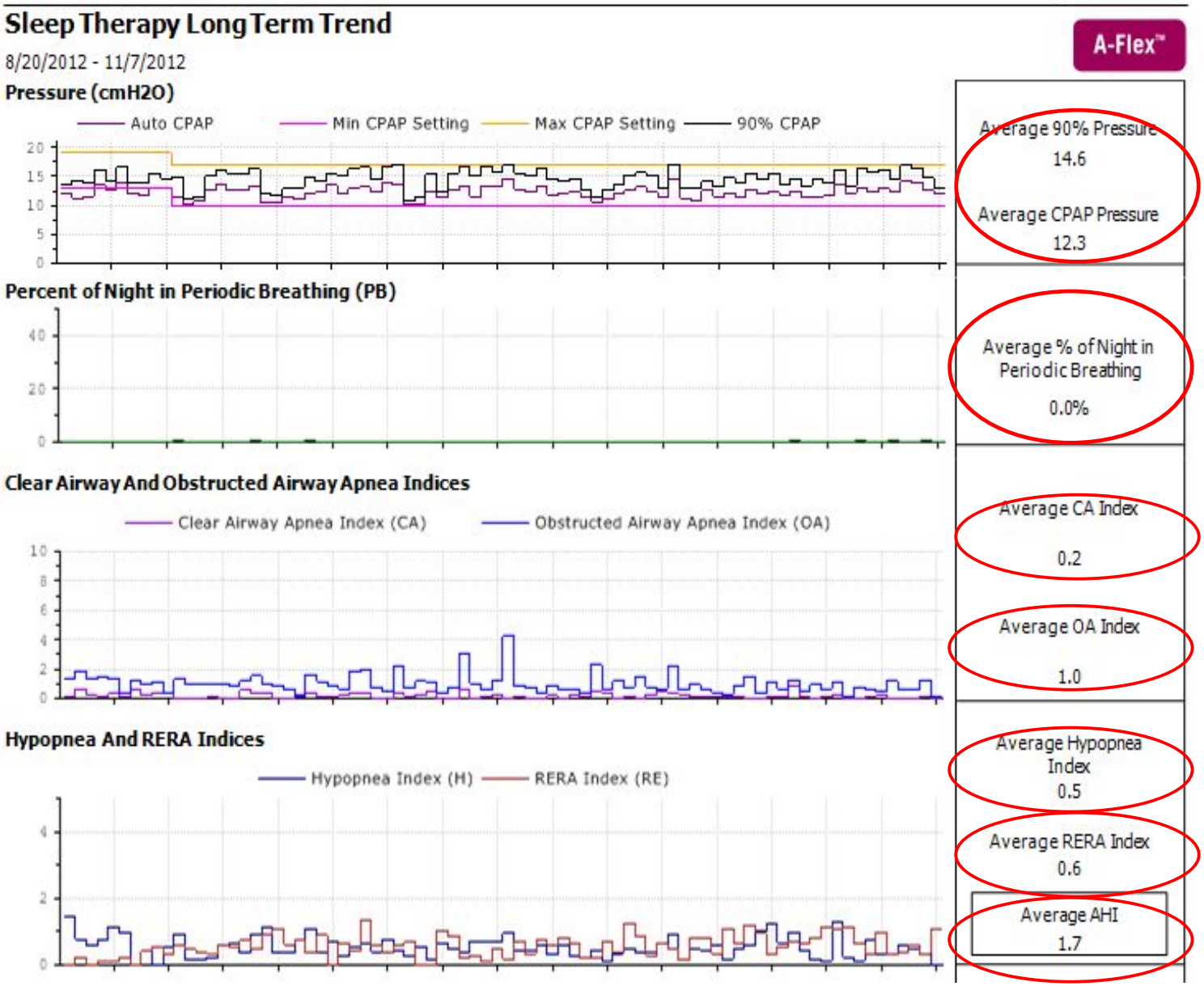
Auto CPAP Summary

Auto CPAP Mean Pressure	8.0 cm H2O
Auto CPAP Peak Average Pressure	8.8 cm H2O
Average Device Pressure <= 90% of Time	10.3 cm H2O
Average Time in Apnea Per Day	2 mins. 9 secs.
Average Time in Large Leak Per Day	0 secs.
Average AHI	6.0

PAP data download: Usage



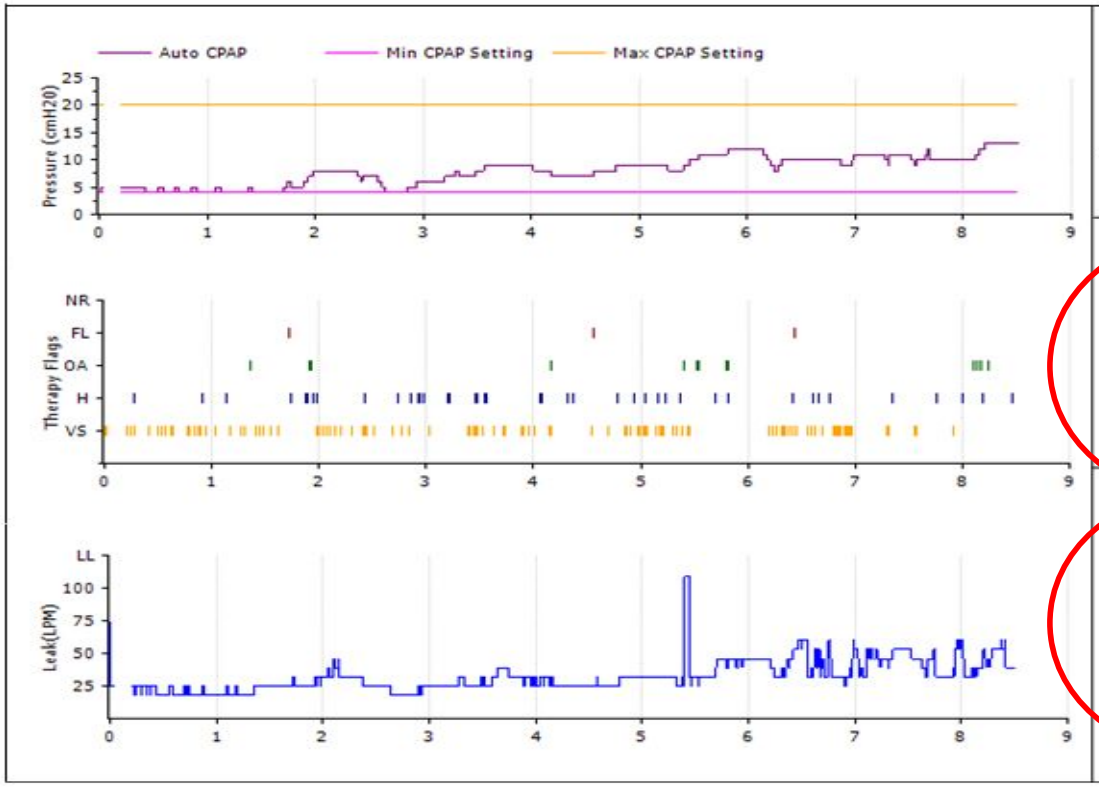
PAP data download: Efficacy



CPAP-Supply.com

Daily Details

10/18/2007 9:06 PM - 10/19/2007 5:36 AM



Average 90% CPAP
10.7

Average CPAP Pressure
8.0

Indices
NR: 0.0
FL: 0.4
OA: 1.9
H: 5.4
VS: 14.9
AHI: 7.3

Large Leak
0.0 mins
0 % of night

Average Leak
35.00

Daily Events per Hour

10/18/2007

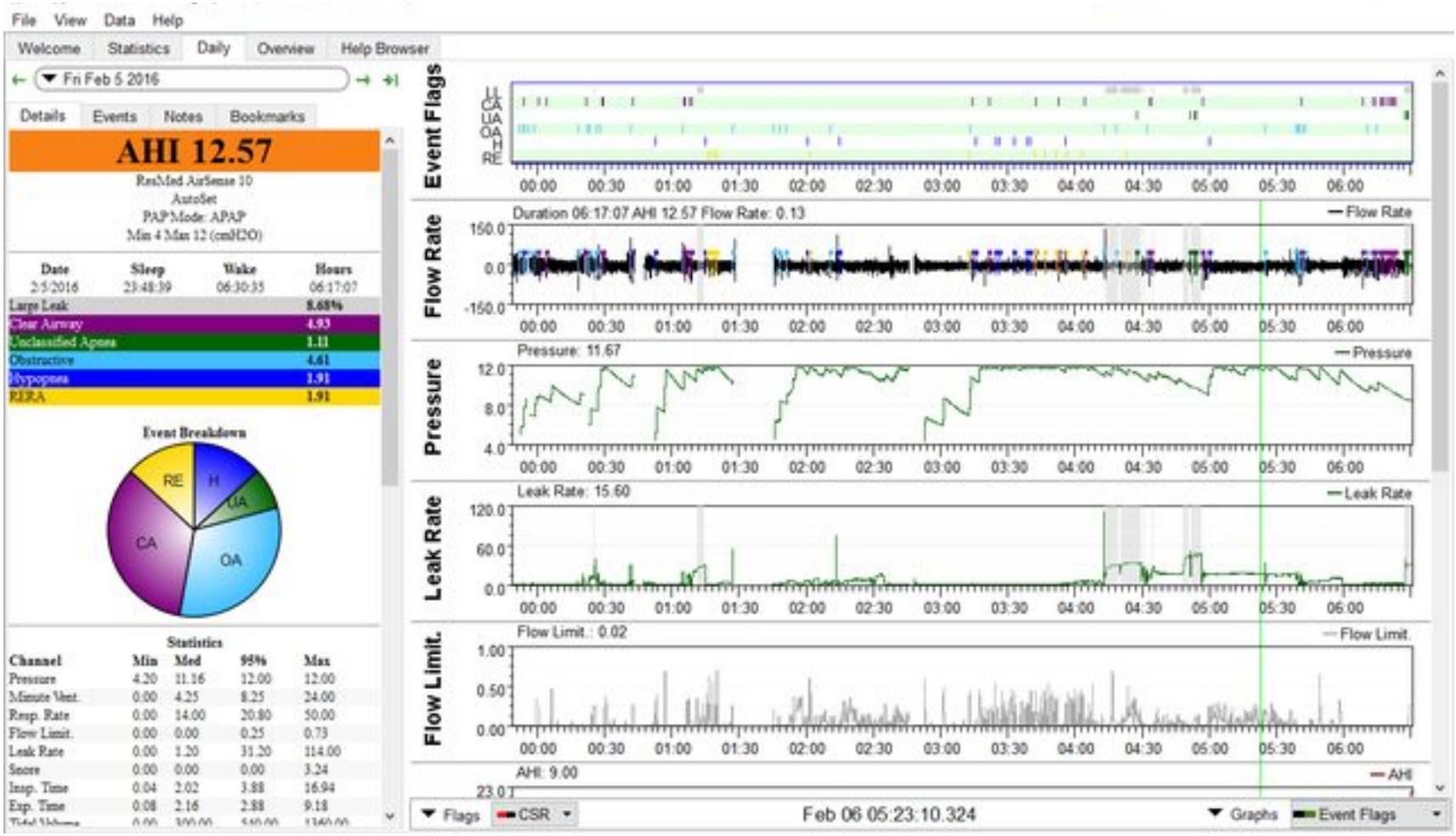
Total AHI:7.3

P	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
MaP	77.5	43.6	23.0	51.5	65.5	72.0	73.5	52.5	22.5	18.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0
%	15.5	3.7	4.6	10.3	13.1	14.4	14.7	10.5	4.5	3.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FL	0.0	1.4	0.0	1.2	0.0	0.0	0.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VS	20.1	12.4	2.6	11.7	19.2	30.0	17.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NR	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OA	0.8	0.0	2.6	1.2	1.8	0.0	1.6	5.7	5.3	5.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0
H	3.9	5.9	13.0	3.2	6.4	3.3	5.7	3.4	2.7	3.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AHI	4.7	5.9	15.6	9.4	8.2	3.3	7.3	9.1	3.0	9.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0

90%

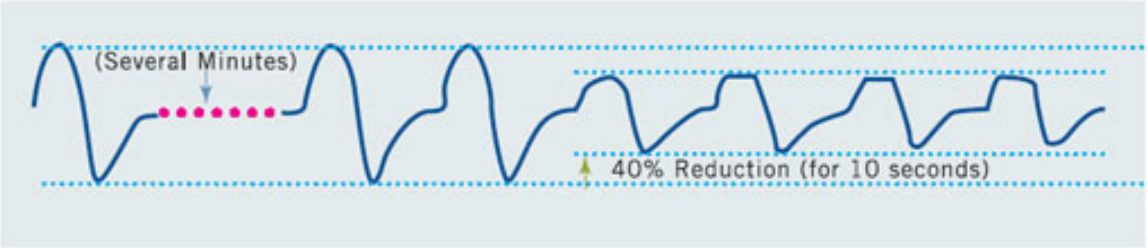
Legend P - Pressure, MaP - Minutes at Pressure, % - Percent of Night, FL - Flow Limitation, VS - Vibratory Snore, NR - Non-Responsive Apnea/Hypopnea, H - Hypopnea, OA - Obstructive Apnea, AHI - Apnea/Hypopnea Index

Auto-CPAP (APAP)



How do PAP machines determine hypopneas and apneas?

Flow is compared to recent flow to see if it remains under a threshold for at least 10 seconds



Hypopnea

Apnea

Flow determination

Root Mean Square (ResMed)

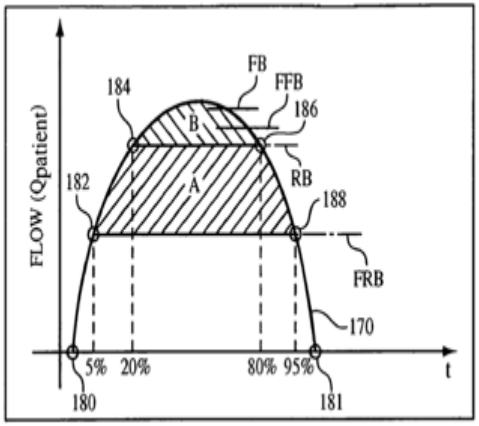
The Breathing Index at any given point in time is calculated as the square root of the variance of the digitized flow signal, f_n:

$$\text{breathing index} = \sqrt{\frac{\sum_{i=0}^{I-1} f_{n-i}^2 - \frac{1}{I}\left(\sum_{i=0}^{I-1} f_{n-i}\right)^2}{I}} \quad \text{where } I = 2 \cdot \text{sample rate}$$

The average variance calculated over a moving time window is compared with a Threshold by the level detector **127**, to generate an "airflow-ceased" trigger. This starts the timer **128**. If the trigger persists for more than 10 seconds,

US PATENT 6675797

Weighted peak flow (Respironics)



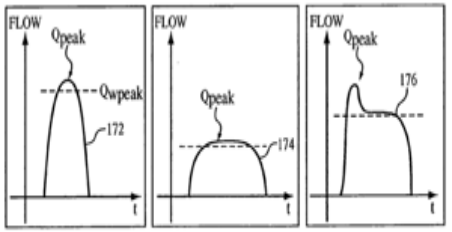


FIG. 4A FIG. 4B FIG. 4C

US PATENT 7827988

Differences in apnea and hypopnea detection

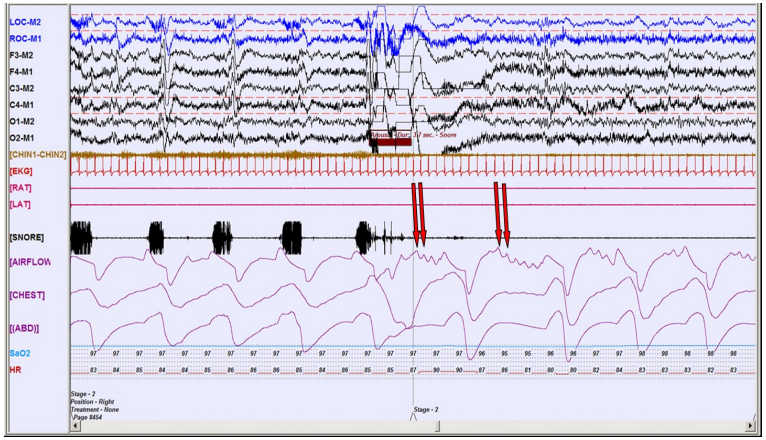
Device	ResMed S8/S9/S10 AutoSet	ResMed S10 AutoSet for Her	Respironics System One REMstar Auto	DeVilbiss IntelliPAP AutoAdjust	Devilbiss IntelliPAP AutoAdjust 2
Apnea detection	2 sec root mean square (RMS) moving average < 25% of prior 1 minute for 10 sec	2 sec RMS moving average < 25% of prior 1 minute for 10 sec	Weighted peak flow (WPF) per breath <20% of prior 4 minute for 10 sec, terminating with breath >30%	Recent 1 minute with flow amplitude <10% of prior 5 minute for 10 sec (or set 0-20% for 6-150 sec)	4 sec RMS moving average < 10% of surrounding 3 minutes for 10 sec
Non- OA detection	S8: None S9-S10: 1 cm 4Hz FOT throughout apnea with mixed apnea detection	1 cm 4 Hz FOT with mixed apnea detection	Pressure pulse few seconds into apnea but if larger than expected breath at end of apnea, event is defined as obstructive.	< 5% for 10 sec	Modulating 0.07 cm 3 ½-4 ½ Hz micro-oscillation throughout apnea
Hypopnea detection	S8: 12 sec RMS scaled average 25-50% for 10 sec S9-S10: Above with at least 1 obstructed breath	12 sec RMS scaled average 25-50% for 10 sec with at least 1 obstructed breath	20-60% for 10 sec and either 60 sec or a terminating breath over 75% of recent WPF	10-50% for 10 sec (adjustable to 30-70% for 6-150 sec)	RMS average 10-40% default (adjustable to 30-50%) for 10 sec

Adapted from Dr. Karin Johnson, Tufts Medical

How does a machine differentiate a central from obstructive apnea?

Cardiogenic pulse artifact

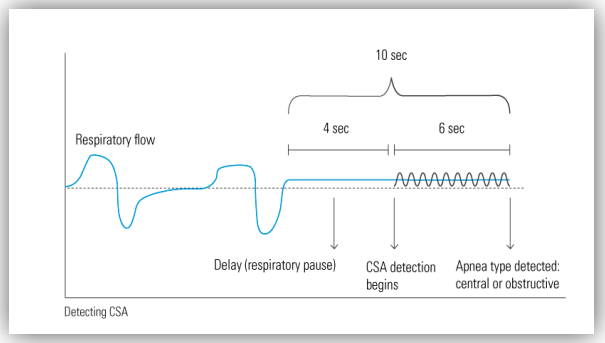
If the airway is open cardiogenic pulse artifact can be picked up by the machines pressure transducers

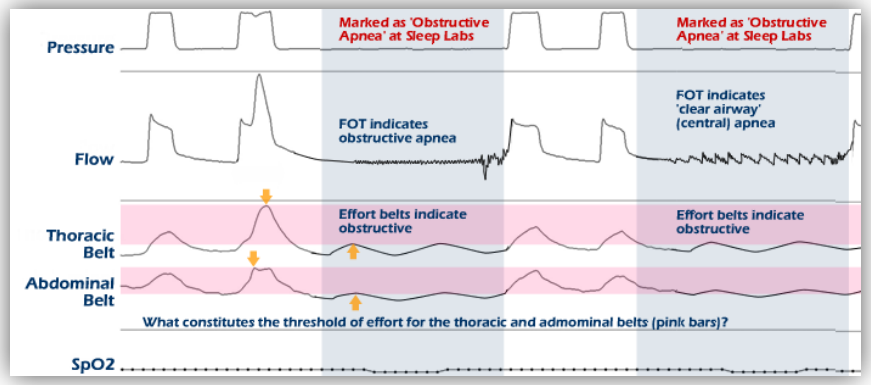


Berthon-Jones ML, inventor; ResMed Ltd, assignee. Determination of patency of the airway. United States Patent US 7730886. 2010 Jun 8.

Forced oscillation technique (FOT)

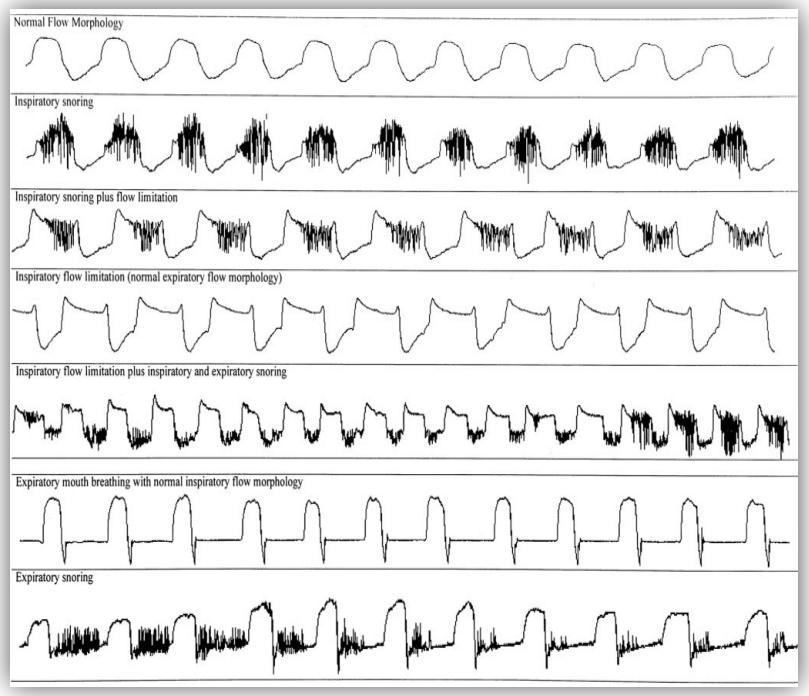
If the machine oscillates the flow and the airway is closed then the transducers will pick up the oscillations, but if the airway is open the oscillations will dissipate

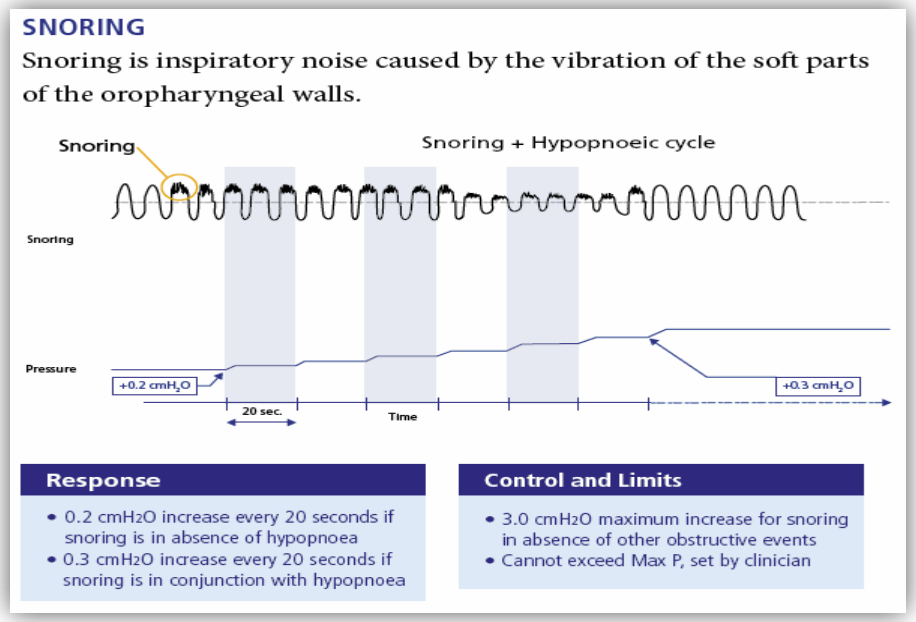




Snoring Detection

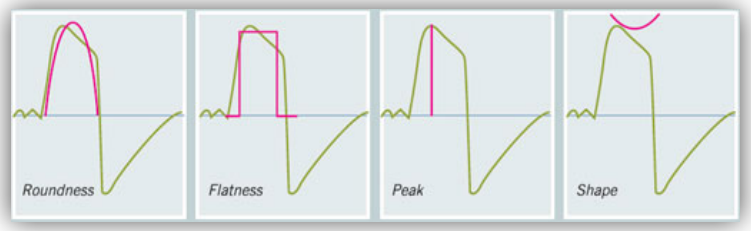
- Snore is detected by vibratory signals and flow oscillation
- Increased leak may appears as snore so machines may not respond to snore with high leaks



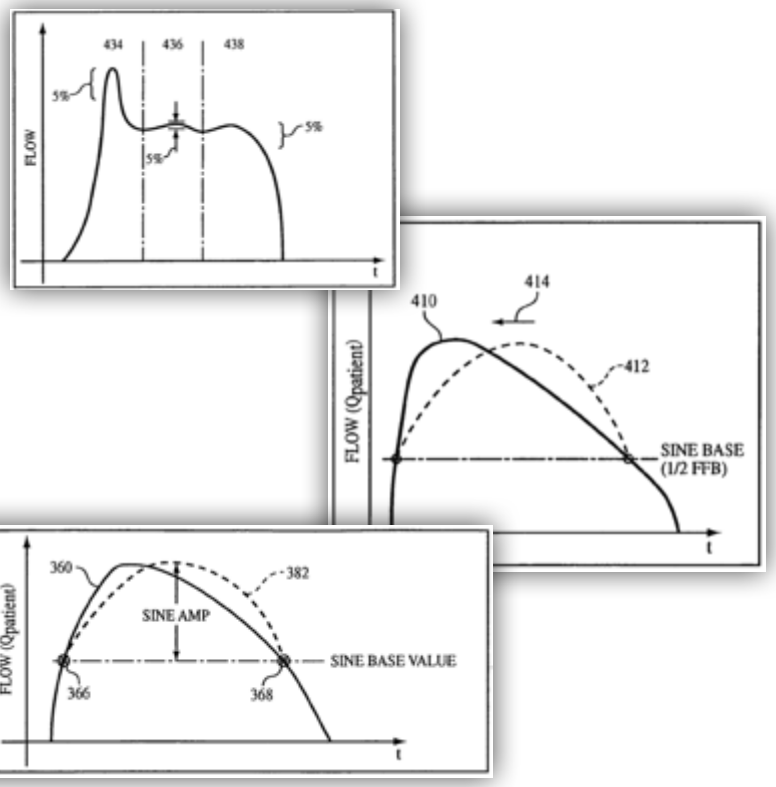


Puritan Bennett Sandman AutoPAP

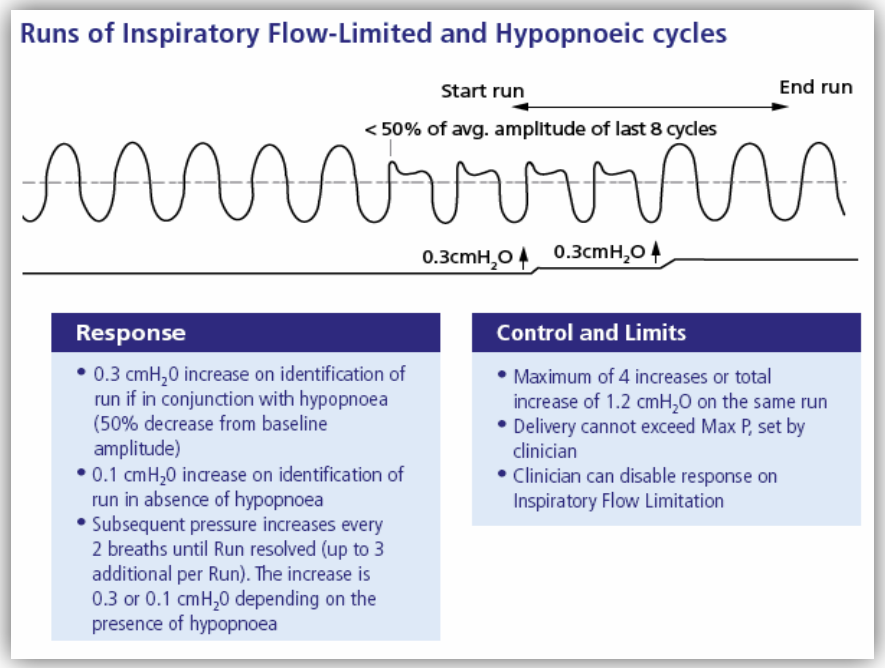
Detecting Flow Limitation



Respironics

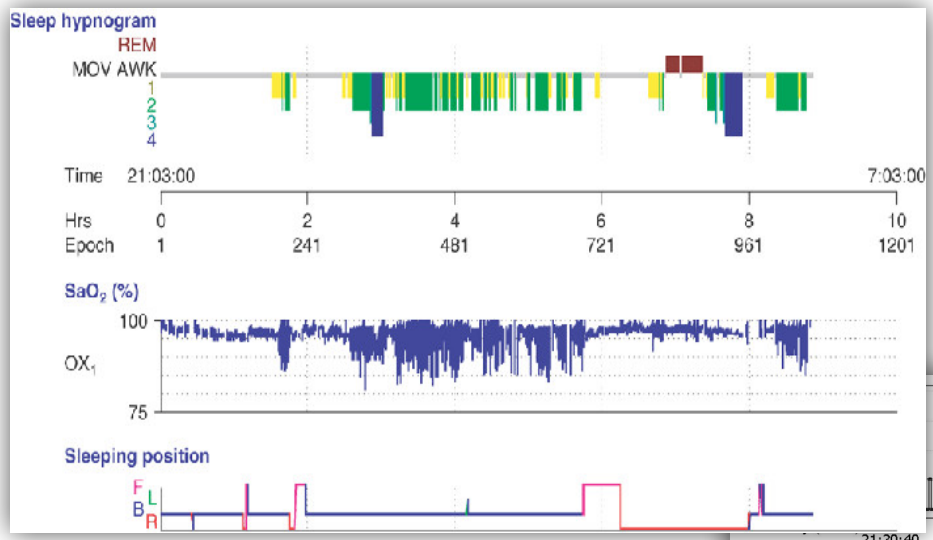


Resmed

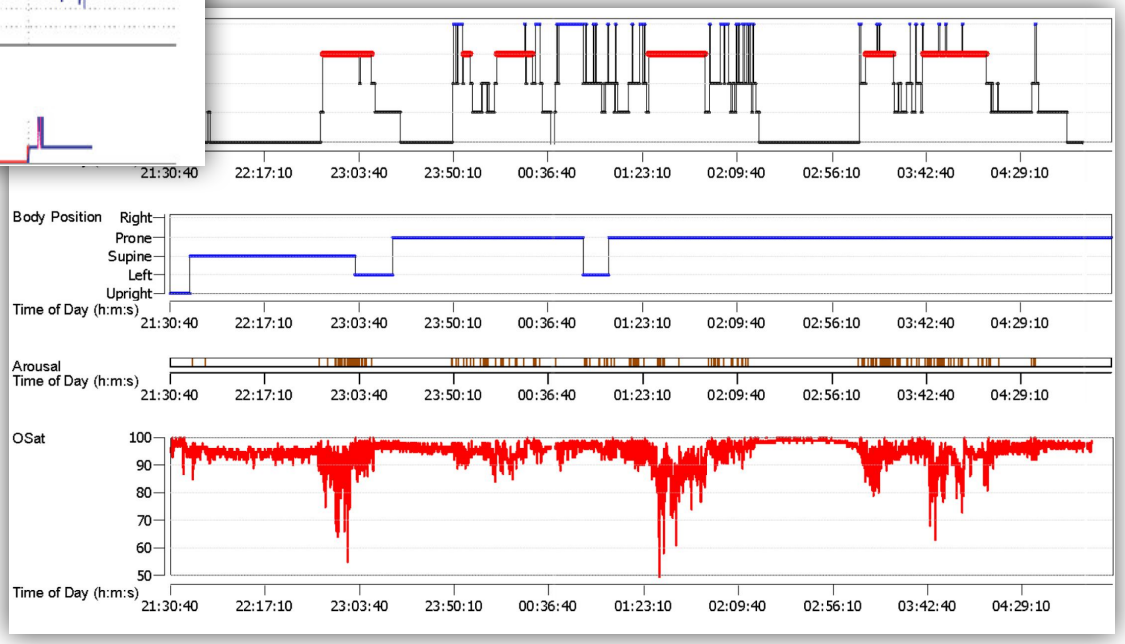


Puritan Bennett AutoPAP

AutoPAP 5-20 cmH2O: Benefits



Pillai et al, JCSM 2014



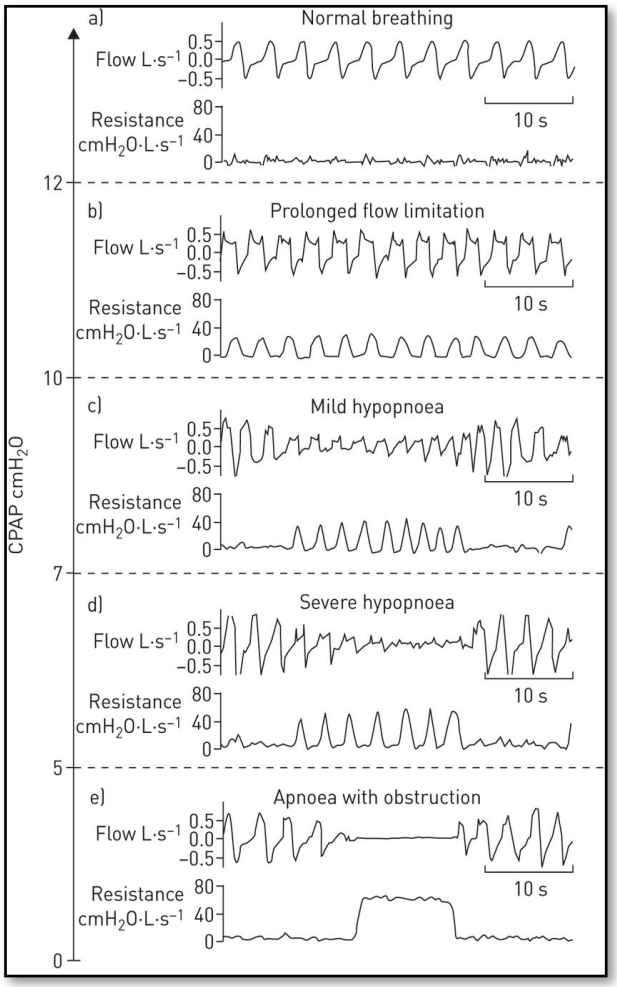
AutoPAP 5-20 cmH2O: Drawbacks

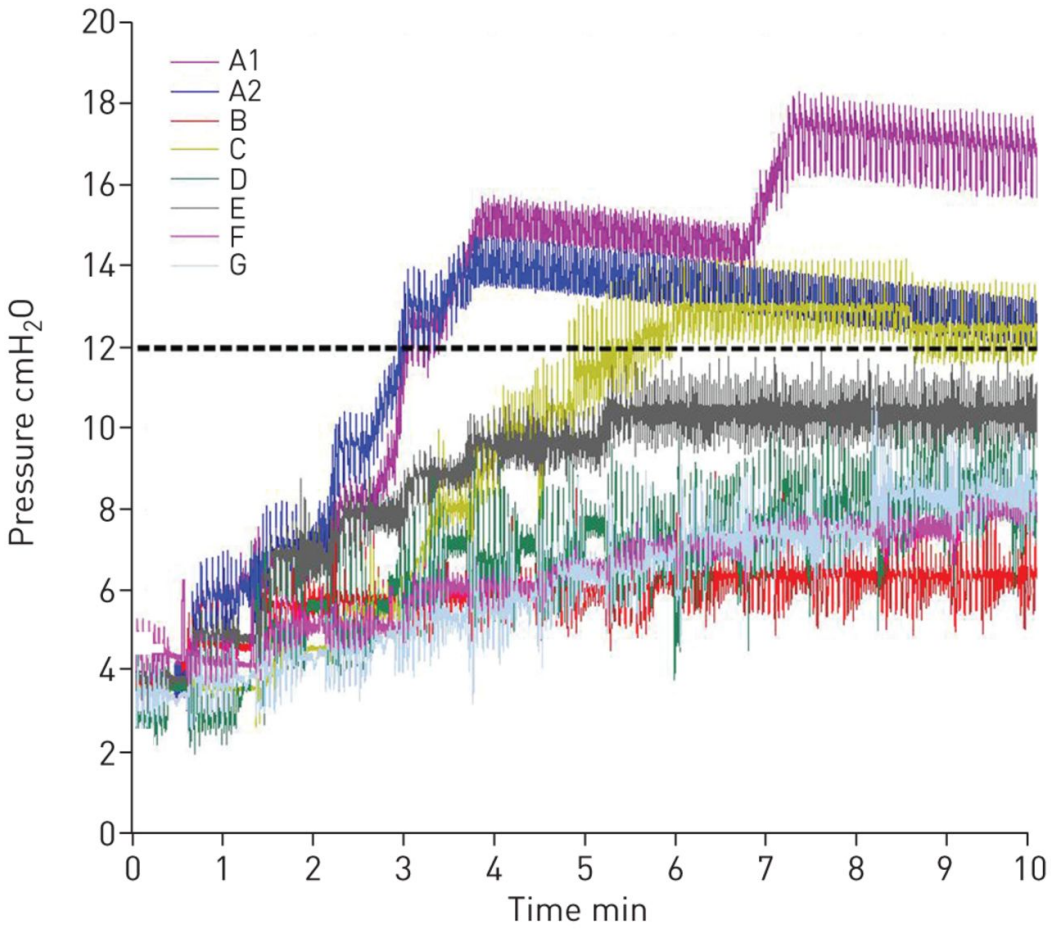
- Pressure requirements may quickly change (e.g. position change, REM sleep)
- Algorithm for pressure changes is reactive
- Time to complete control of apneic events may be delayed, and events are allowed to occur
- Risk of over-titrations, induced centrals, unstable airway

Algorithm for APAP pressure changes

	ResMed S9/S10 AutoSet (for Her)	Respironics System One REMstar Auto	Devilbiss IntelliPAP AutoAdjust 2
Pressure Increase	Increases pressure up to 3 cm/10 seconds for apneas and up to 0.5-6 cm/breath for flow limitation with decreasing response at higher pressures	Increases pressure up to 1 cm/min for at least 2 apneas or hypopneas or snore, Limits increase to 3 cm for apnea only	max 1 cm/min increase
Pressure Decrease	S9-S10: Gradual decrease to Pmin over 40 min after apnea, over 20 min after FL or snoring S10 For Her: Gradual decrease to Pmin over 40 min after apnea and over 20 min after snore and 60 min after flow limitation as soon as breathing is stable.	Pcrit search decreasing 0.5/min until Pmin or FL If high variable breathing is noted, if recent (5 min) pressure was stable then pressure stays same, if recent pressure decrease then increases by 0.5/min up to 2, and if recent pressure increase then decreases by 0.5/min up to 2 If large leak, reduces pressure by 1 over 10 sec and holds pressure for 2 min	Decides whether to decrease every min. If no events in 1 min period, small decrease of < 0.1/min. If no events in 6 min period, decrease by 0.1/min. If central apneas, pressure decreases and blocks increases for 6 minutes. If periodic breathing, blocks increases and if persists starts decreasing pressure
Pressure change considera-tions	If current pressure is high, less increase to apneas, flow limitation and snore If leak is high, less response to flow limitation and snore	If pressure is high, higher snore threshold must be reached to change pressure If leak is high, less response to flow limitation and snore	If leak is high, less response to flow limitation and snore

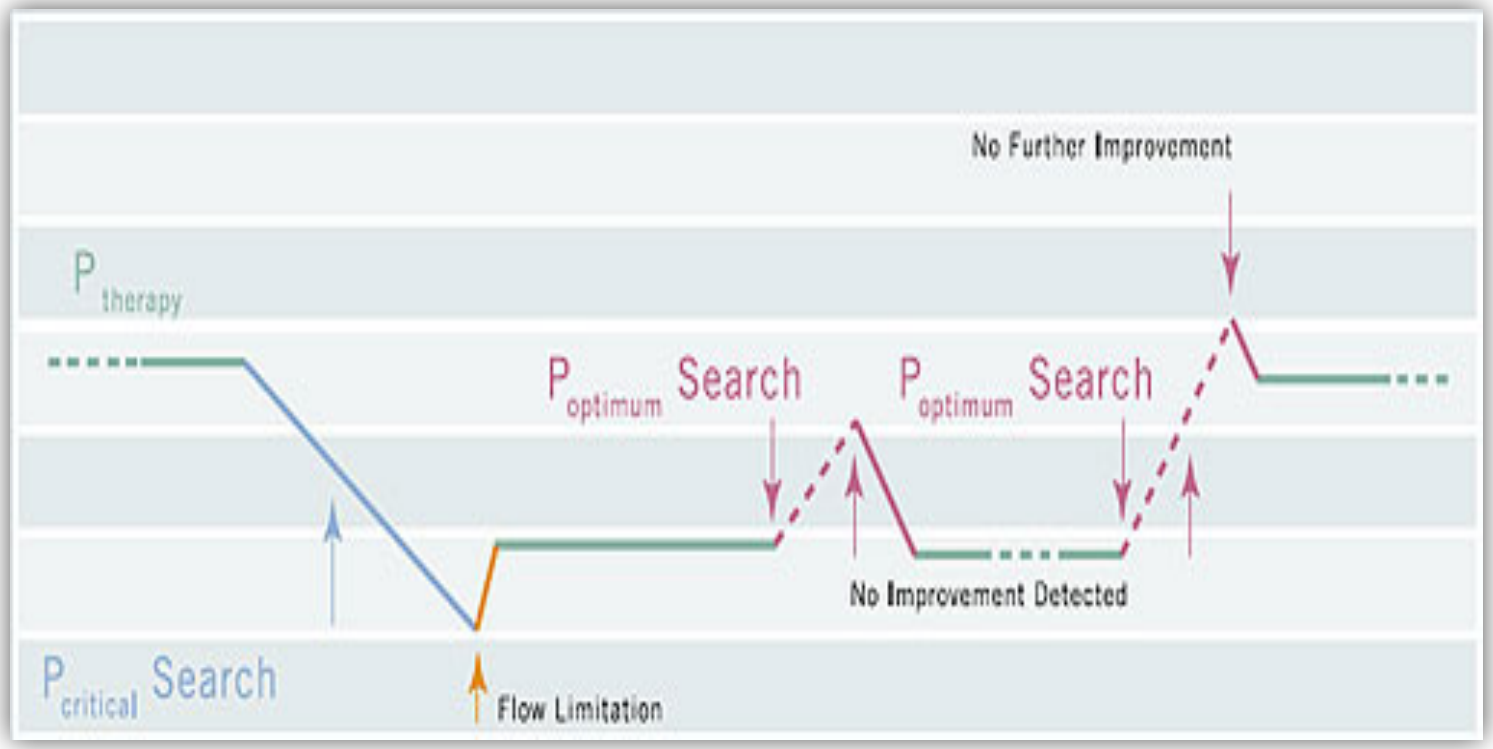
Pressure increase delivered by APAP devices during the first 10 min of the bench test





Valentina Isetta et al. ERJ Open Res 2015;1:00031-2015

Searching for an optimal pressure

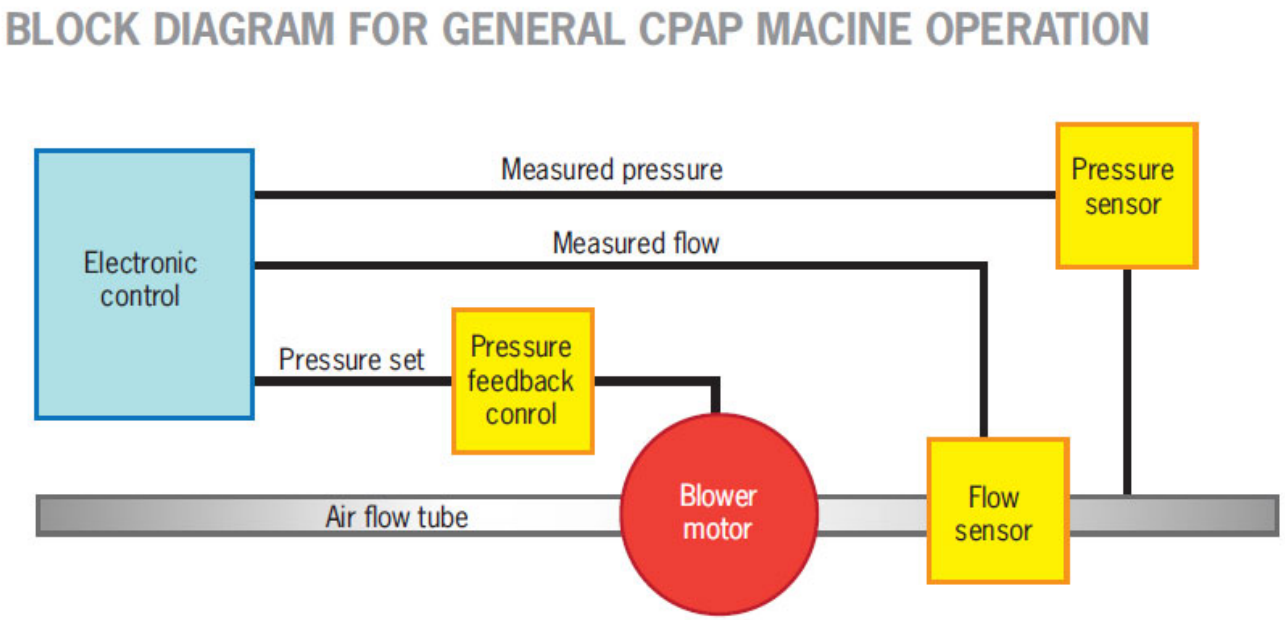


Respironics

APAP algorithms for more targeted therapy (Respironics)

CPAP-Check	Opti-Start	Auto-Trial
Checks the 90% pressure every 30 hours Decides whether to leave the EPAPmin unchanged, or changes the EPAPmin up or down by 1 but not more than 3 from set EPAP.	Monitor average pressure needed over 30 hrs use, and start therapy at this pressure	Sets pressure at AutoCPAP 4-20 for 3 to 30 days then reverts to CPAP at the pressure that the patient was at or below 90% of the time

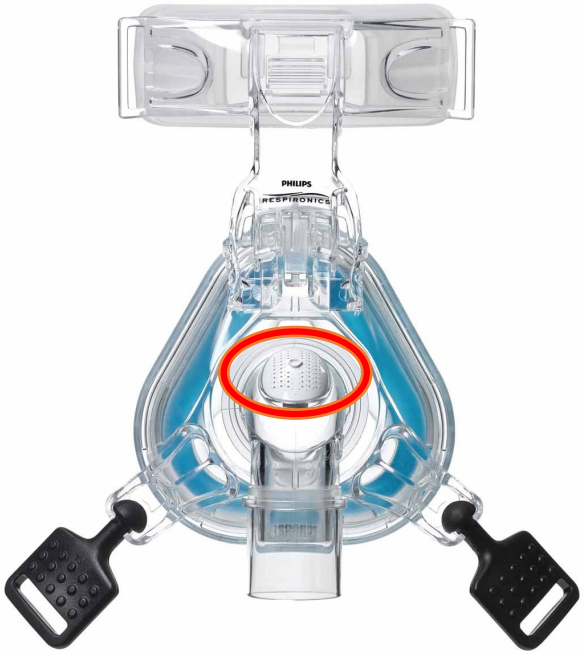
How can the machine calculate flow and pressure at the mask?



Berthon-Jones ML, inventor; Resmed Ltd, assignee. Assisted ventilation to match patient respiratory need. United States Patent US 6532957. 2003 Mar 18.

What is expected leak?

- Expected leak from leak through exhalation ports on the mask
- Expected leak varies by mask type and pressure level
- Unintentional leak arises from the mouth or around the mask
- In general, compensated leak ~24 L/min with nasal masks and ~36 L/min with full face masks



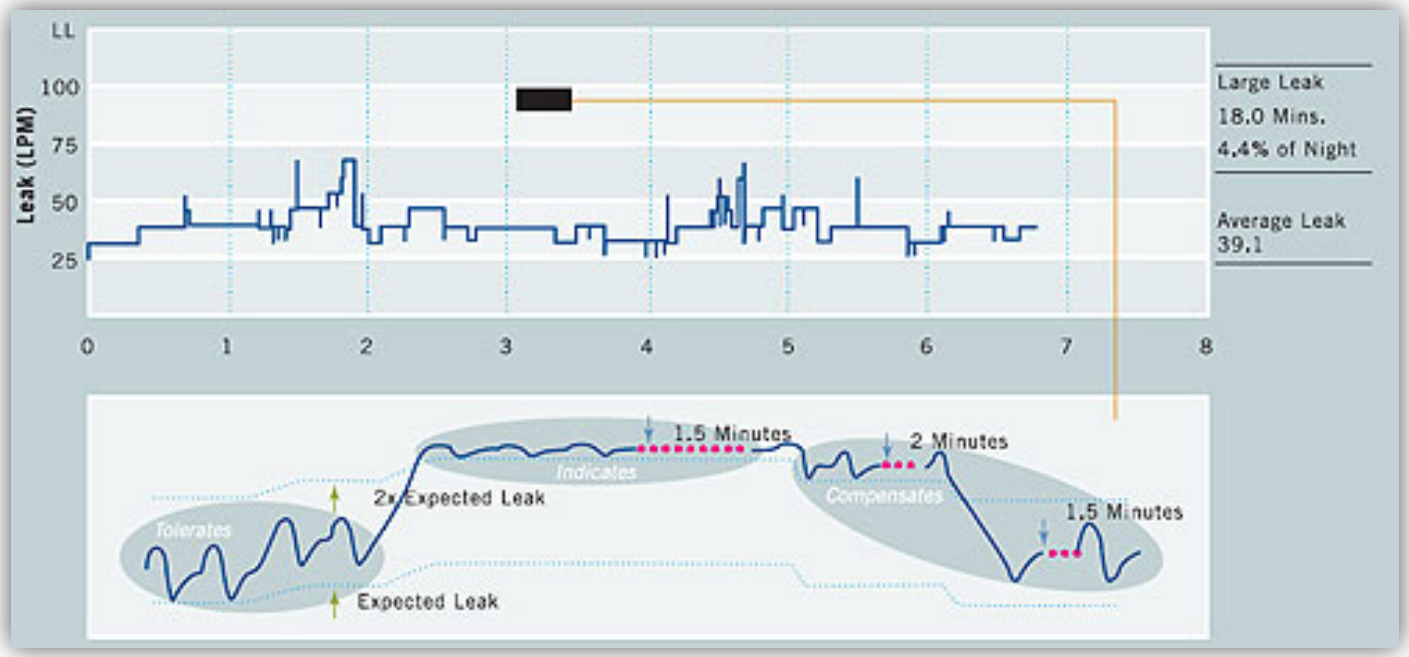
Pressure (cm H_2O)								
4	19.2	19.2		20.3	20.3			22.1
6	23.7	23.7	24.1	25.2	25.2	27.6	27.6	27.6
8	27.7	27.7	29.4	29.4	29.4	32.3	32.3	32.3
10	31.2	31.2	34.3	33.2	33.2	36.6	36.6	36.6
12	34.4	34.4	38.4	36.7	36.7	40.5	40.5	40.5
14	37.4	37.4	42.6	39.9	39.9	43.5	43.5	43.5
16	40.2	40.2	46.3	42.9	42.9	47.8	47.8	47.8
18	42.8	42.8	49.9	45.8	45.8	51.1	51.1	51.1
20	45.4	45.4	53.1	48.6	48.6	54.3	54.3	54.3

Expected flow rates (Liters/min)

www.cpaptalk.com

AutoPAP Leak Management

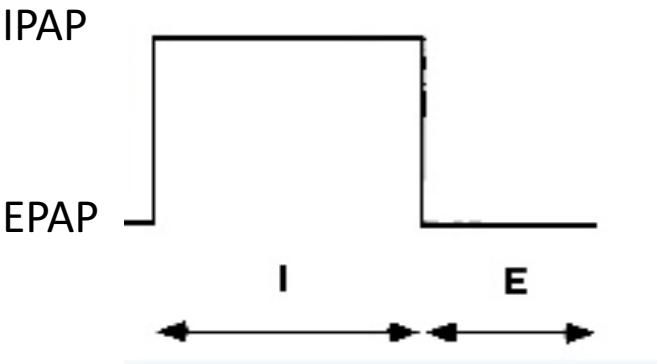
- Calculates large leaks by comparing measured to expected leak
- Compensates by decreasing pressure to “re-seal” mask
- “Auto-Trak” (Respironics) automatically adjusts trigger and cycle thresholds



Respironics

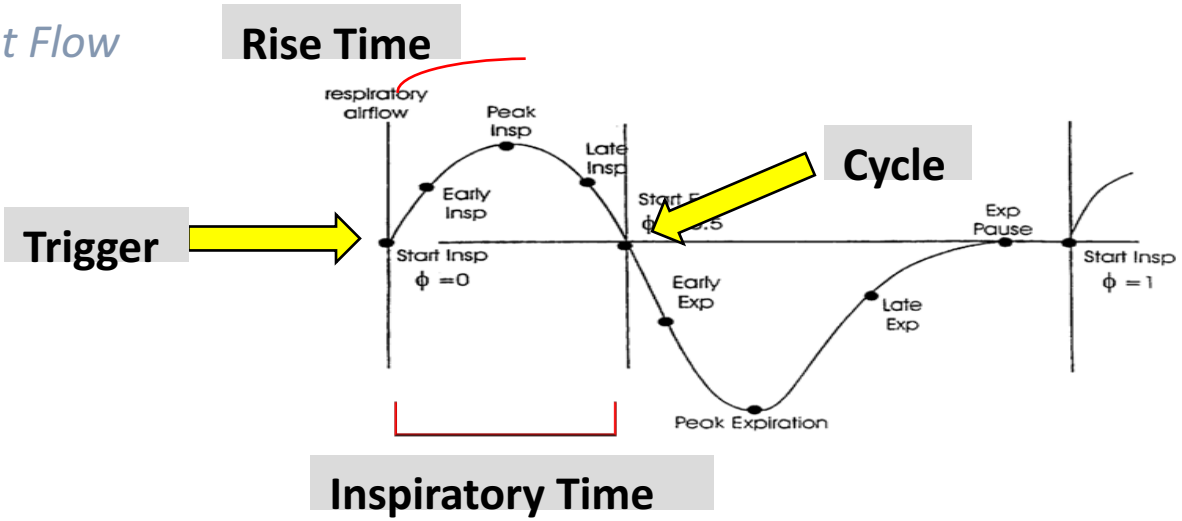
Bilevel PAP for pressure intolerance

Pressure

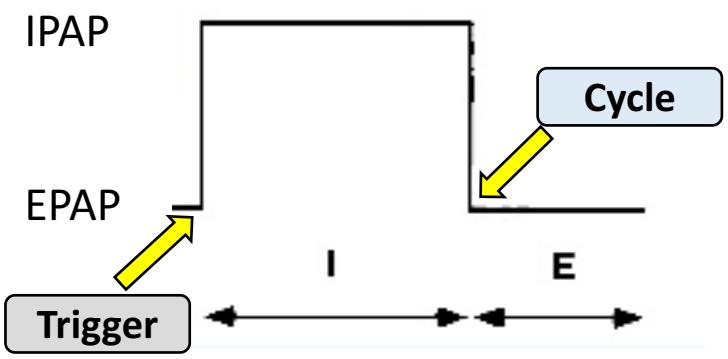


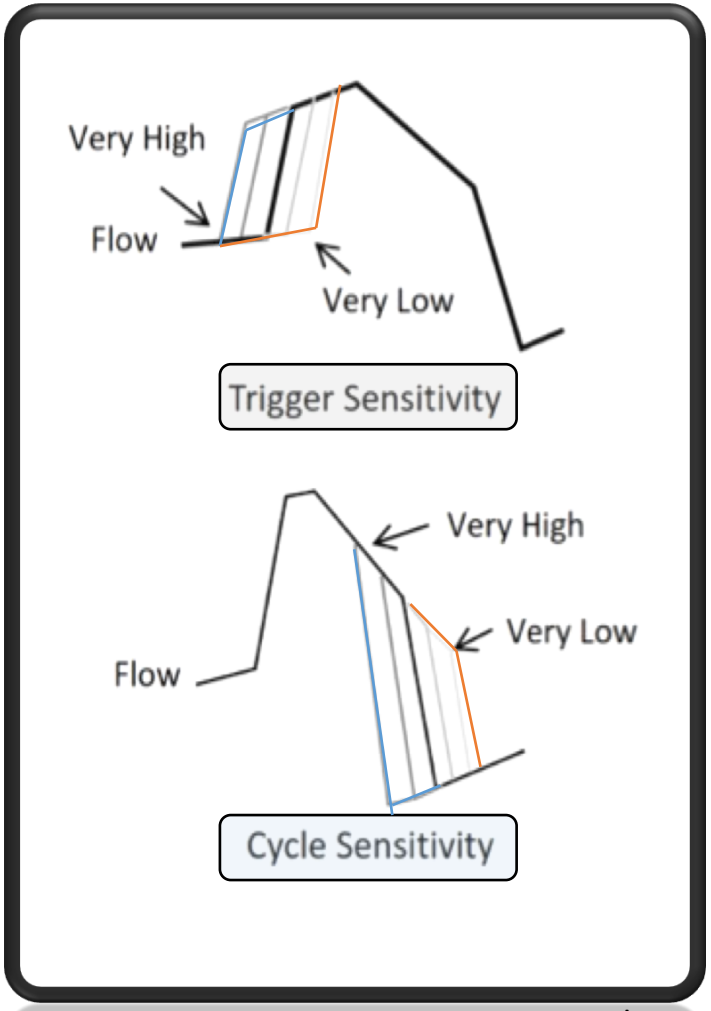
- Bilevel pressures may improve tolerance or help with ventilation
- A backup rate can be added to give a breath with weak or absent respiratory effort.

Patient Flow



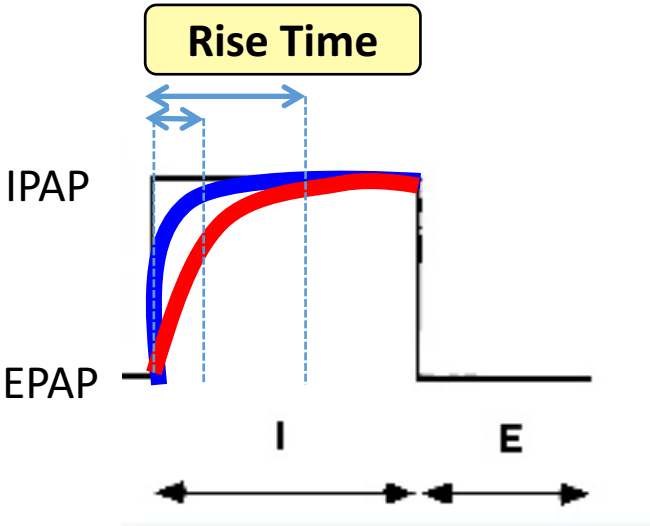
Bilevel PAP: Coordinated breathing

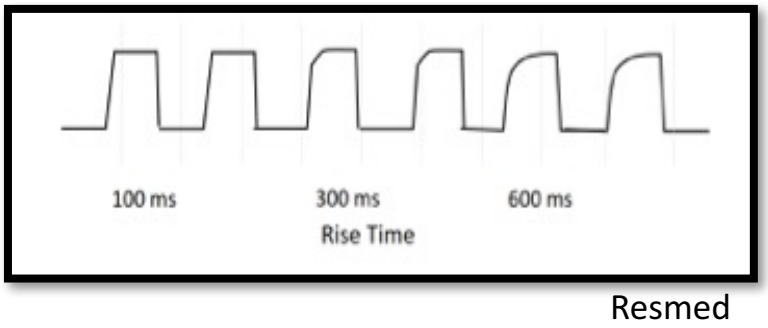




Resmed

Bilevel PAP: Supporting pulmonary physiology





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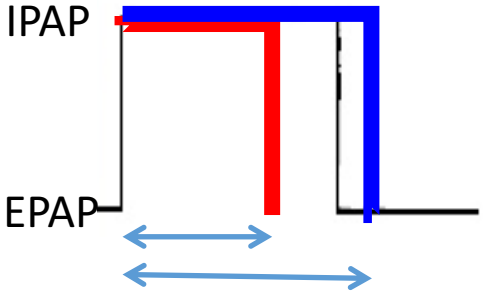
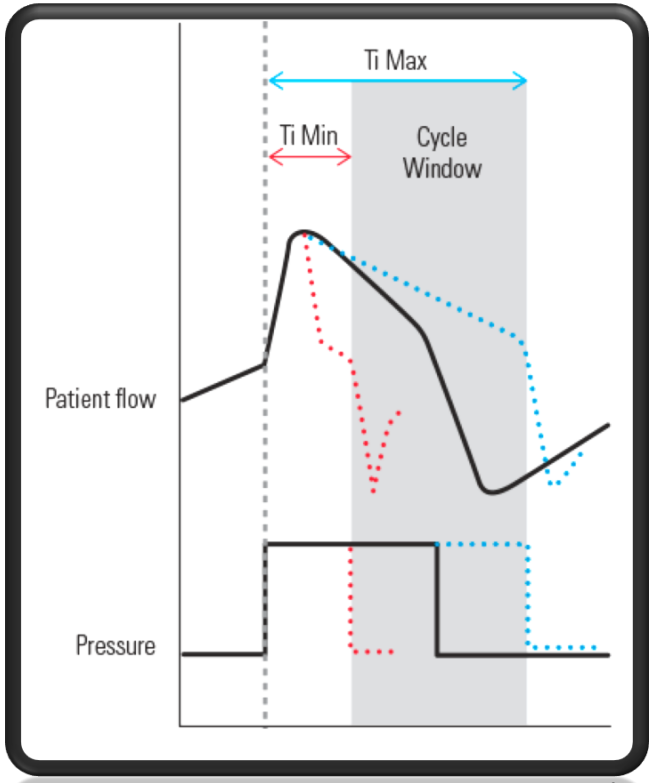


Inspiratory Time (Ti)



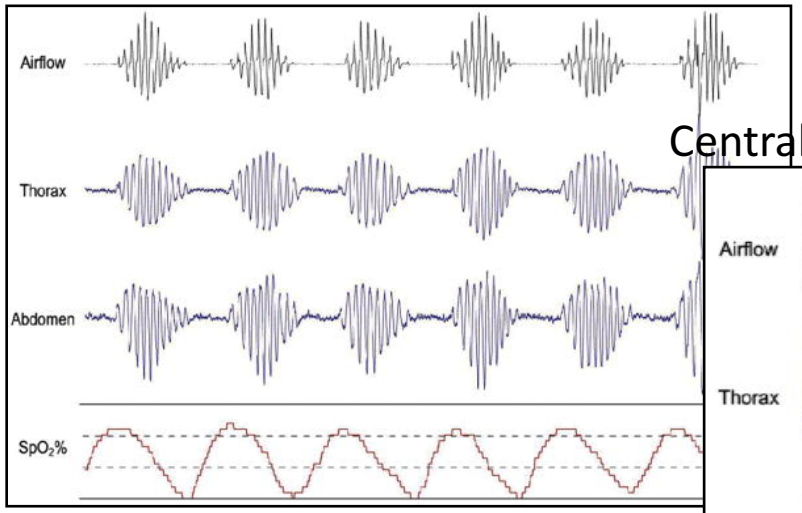
Resmed

BPAP-ST recommendations

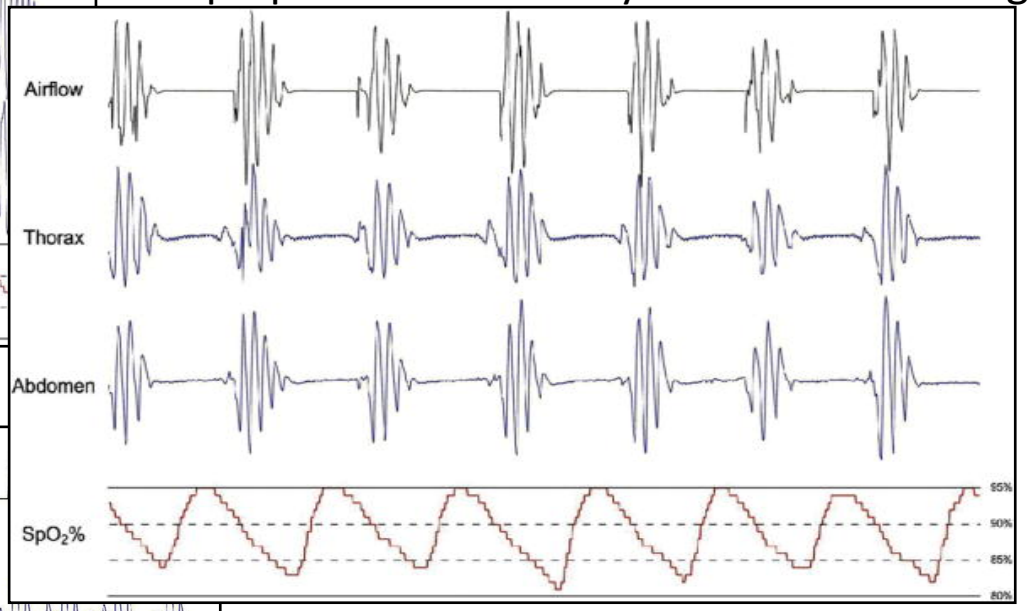
	OSA	COPD	OHS	NMD	ILD
PS	For hypopneas or comfort	TcCO2 TV	TcCO2 TV	TcCO2 TV	WOB
EPAP	For obstructive apneas	For obstructive apneas WOB TBM	For obstructive apneas Hypoxemia TBM	For obstructive apneas Hypoxemia	For obstructive apneas
Trigger	Medium	Medium	High	High	Medium
Cycle	Medium	High	Low	Low	Low
Ti (sec)	0.3-2	0.3-1	0.8-1.5	0.8-1.5	0.8-1.5
Rise Time (sec)	300	150	300	300	300
RR			For central apneas	For central apneas	

Central Sleep Apnea

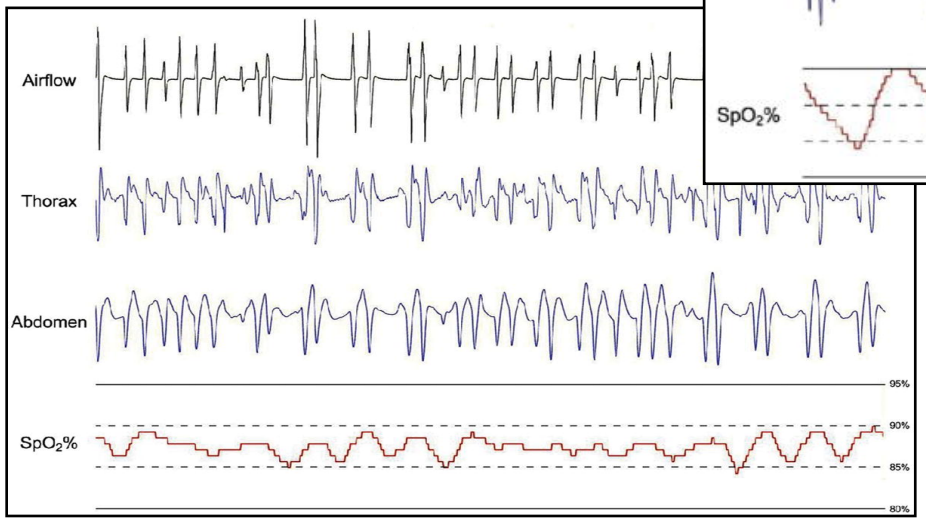
Cheyne-Stokes Breathing



Central Sleep Apnea without Cheyne-Stokes Breathing



Biot's or Ataxic Breathing

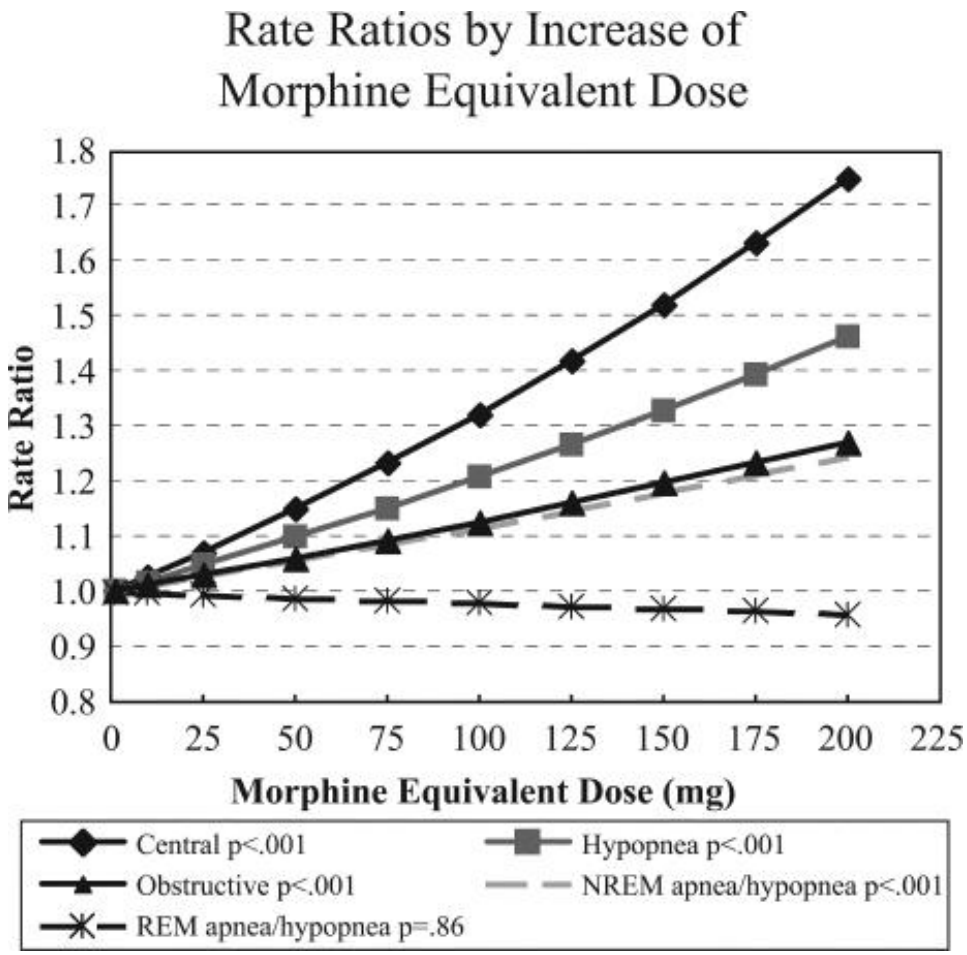


Correa et al, Anesthesia & Analgesia 2015

Opioid-induced central sleep apnea (Op-CSA)

A spectrum of sleep breathing disorders may be observed with opioid use

- Obstructive apneas/hypopneas
- Central apneas/hypopneas
- Hypoventilation, hypoxemia
- Ataxic or irregular breathing patterns



Walker et al, JCSM 2007

- Morphine equivalent daily dosing (MEDD) >200 mg/d was associated with increased CSA severity and ataxic breathing
- Each 100 mg MEDD increased CAI by 2.8 events/hr compared to patients not taking opioids

Op-CSA: Treatment

No clear consensus on how best to manage opioid-induced SDB, apart from using the lowest effective opioid dose

Options include:

- Withdrawal opioids, using non-opioid analgesics
- reducing opioid dose
- selecting an opioid that may have less toxicity (e.g. buprenorphine instead of methadone)
- avoidance of potentially aggravating concurrent drugs
- supplemental oxygen
- PAP
- pharmacologic therapy (e.g. acetazolamide, theophylline, carbon dioxide)

Op-CSA: Summary

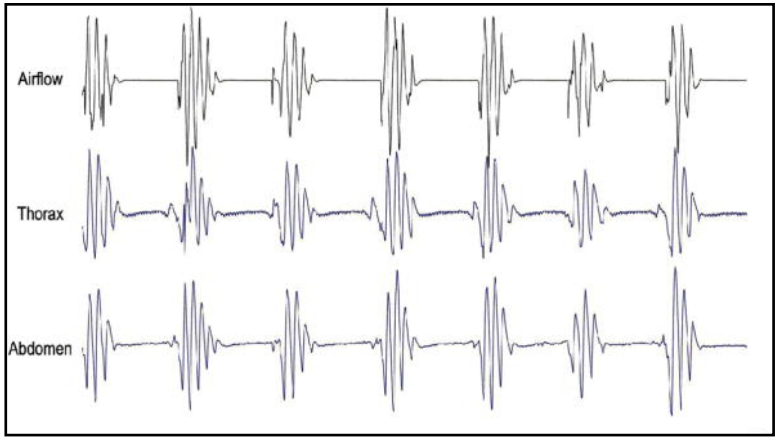
Prevalence

- Reports vary between studies due to small numbers, different sampling (sleep labs vs pain centers, etc), but likely 14-60%
- Op-CSA more commonly take the forms of ataxic breathing or CSA non-CSR, and less commonly CSR
- Many patients may have concurrent OSA
- Risk factors include: opioid dose, female, non-obese, concurrent BZD, anti-depressants, and other sedating medications

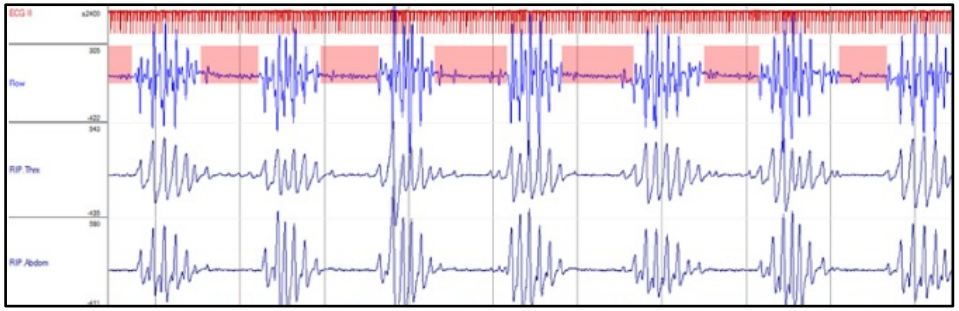
Treatment

- Current data regarding PAP therapy is inconclusive
- CPAP appears to be mostly ineffective in reducing central apneas
- BPAP-ST may eliminate Op-CSA in as many as 60%
- ASV has produced some conflicting results
- Presence of ataxic breathing predicts poor response to any of these PAP modes

TE-CSA: Polysomnographic Features



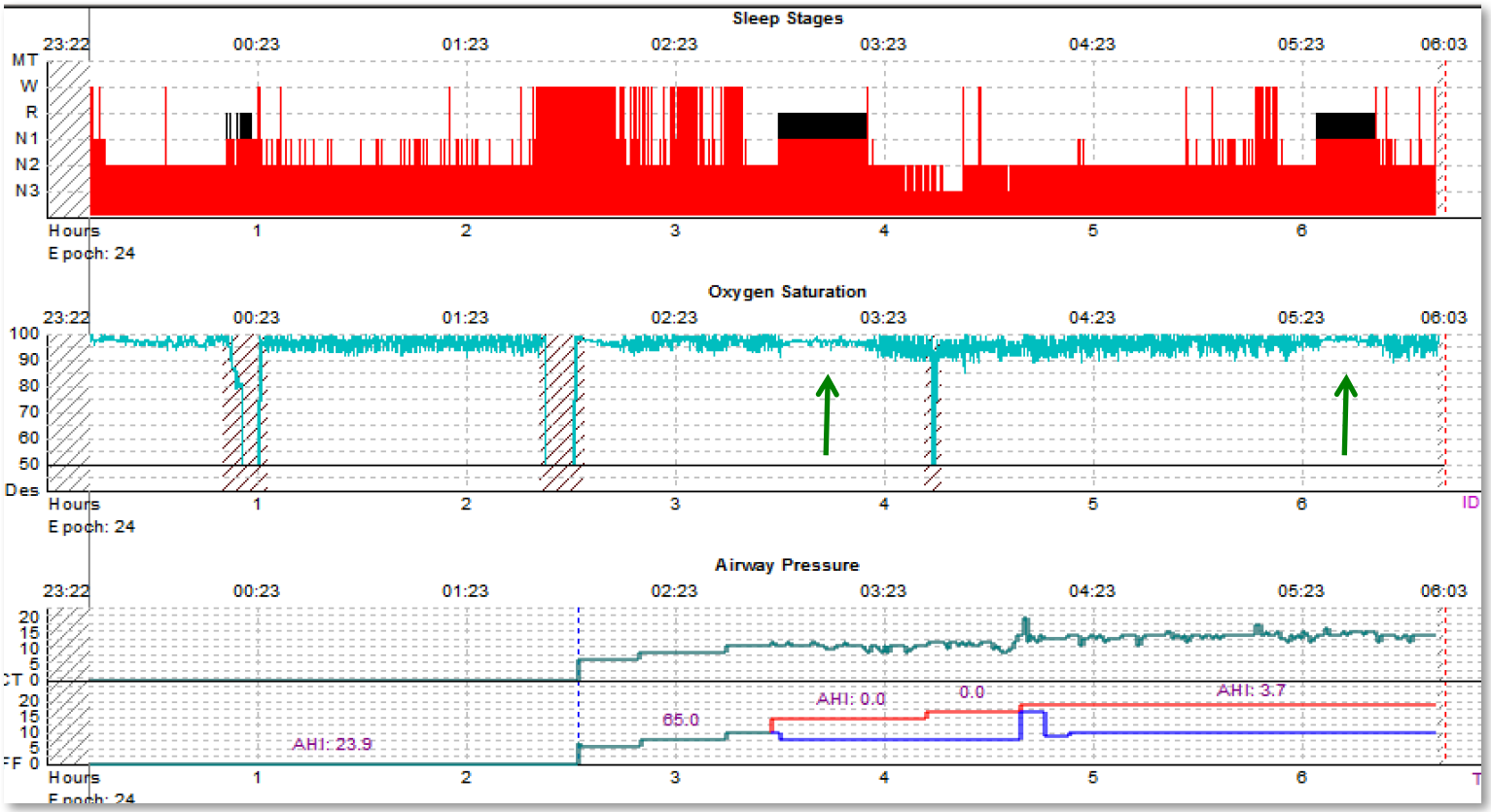
Correa et al, Anesthesia & Analgesia 2015



Dellweg et al, Sleep 2013

- Generally, of the non-Cheyne-Stokes pattern
- Arousals occur at termination of apneas
- Worse in supine vs non-supine sleep
- OSA co-occurs
- Decreased inspiratory effort during an obstructive event
- Longer than expected obstructive apneas

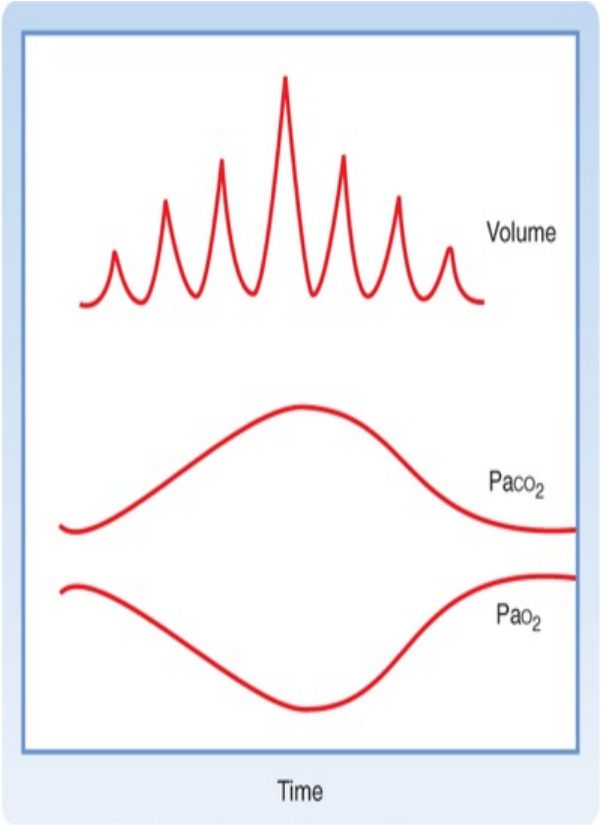
TE-CSA: Polysomnographic Features



TE-CSA occurs almost exclusively during NREM sleep

Why can CPAP and BiPAP worsen periodic breathing and Cheyne Stokes Respiration?

- High pressures may cause PB/CSR in NREM
- CPAP/BPAP may lower CO2, reach apneic threshold by:
  - increasing ventilation
  - increasing TV
  - increasing RR (with back up rate)
  - lowering upper airway resistance



TE-CSA: Natural Course

- 5-15% of patients with OSA will demonstrate TE-CSA **(emergent)** on initial titration
- Generally transitory: 50-80% resolve with chronic use of PAP (4-12 weeks)
- 1.5% of patients with OSA will have TE-CSA **(persistent)** (CAI ≥5)
- 7% may develop TE-CSA **(delayed emergent)** after chronic PAP use
- Those with TE-CSA tend to have more subjective sleepiness than those without CSA
- Long-term clinical consequences unknown

Kuzniar et al, Sleep Breath 2008; Javaheri et al, JCSM 2009; Lehman et al, JCSM 2007; Cassel et al, Eur Respir J 2011

Alphabet soup of PAP technology

- CPAP
- APAP
- BPAP S/T
- Auto-BPAP

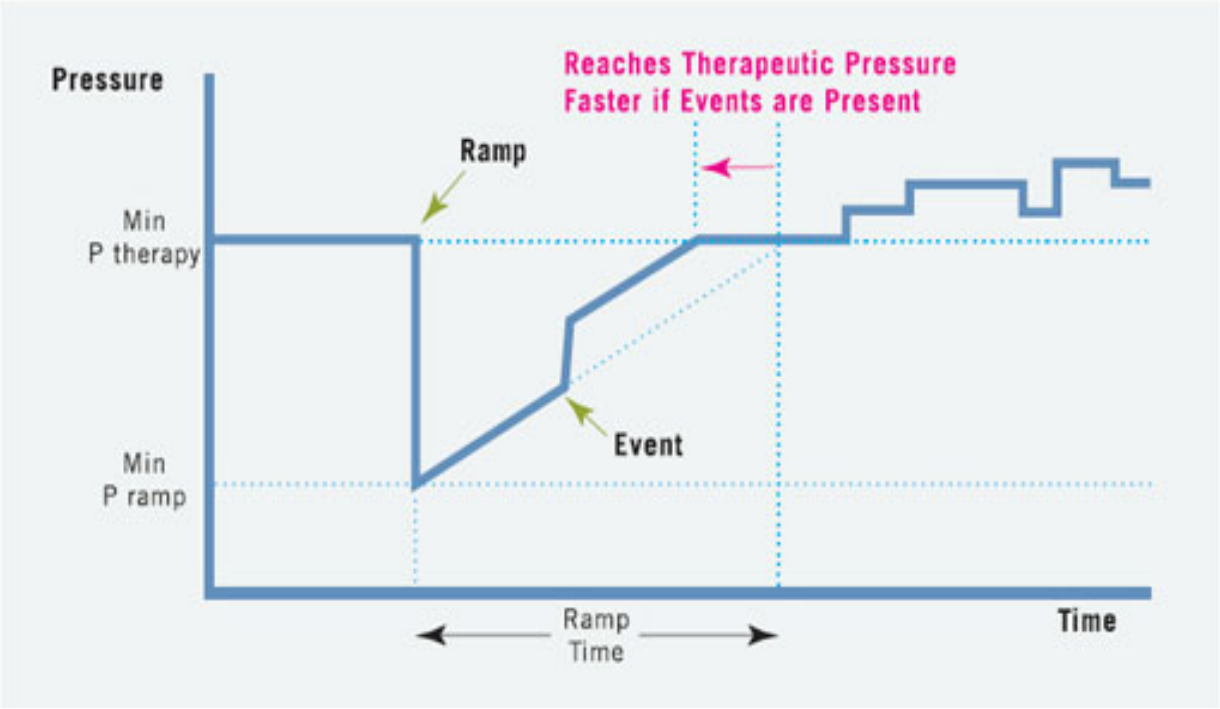
- VAPS (auto)
- ASV (auto)
- NIV

PAP adherence features

- Mask Technology
- Humification/ Heated tubing
- Ramp
- Auto Adjusting starting pressures
- Automatic start and turn off
- Expiratory Pressure Relief/Flex
- Data storage and retrieval
- Quieter CPAP
- Smaller CPAP

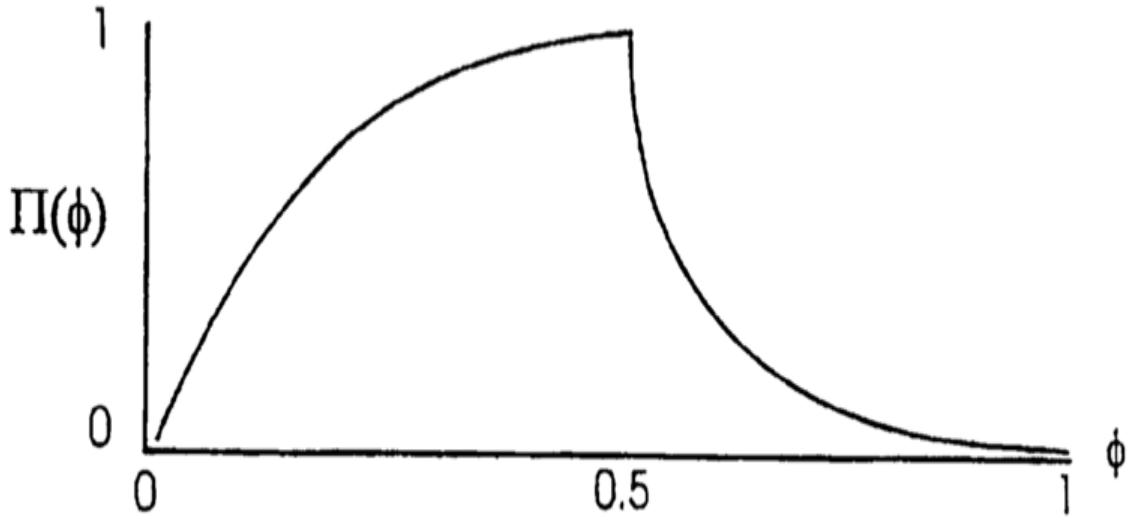
Smart Ramp

- Comfort feature
- Time to fall asleep at lower pressure
- Responds to events should they occur during ramp time



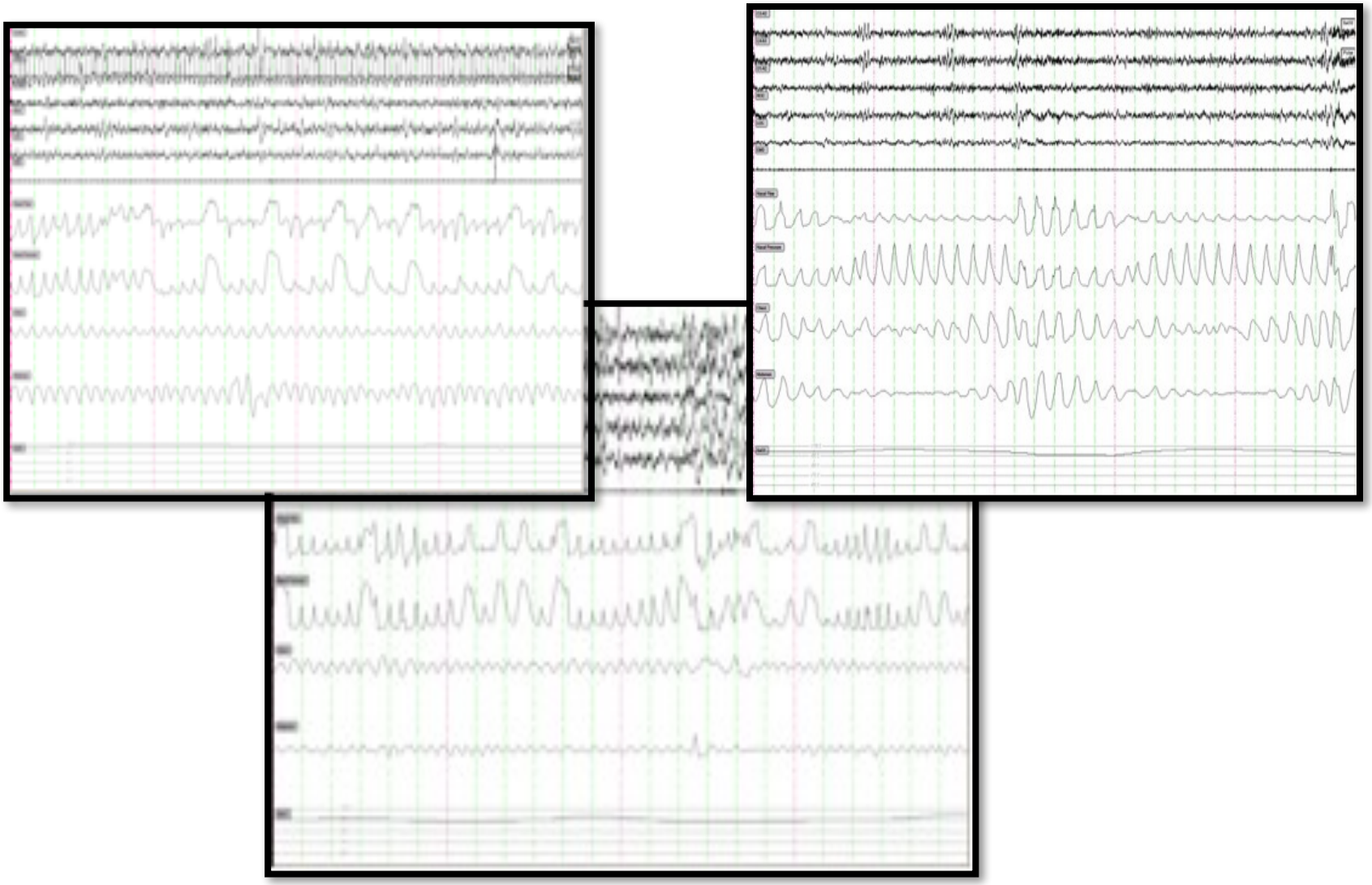
Respironics

“Easy breath” wave form (ResMed)

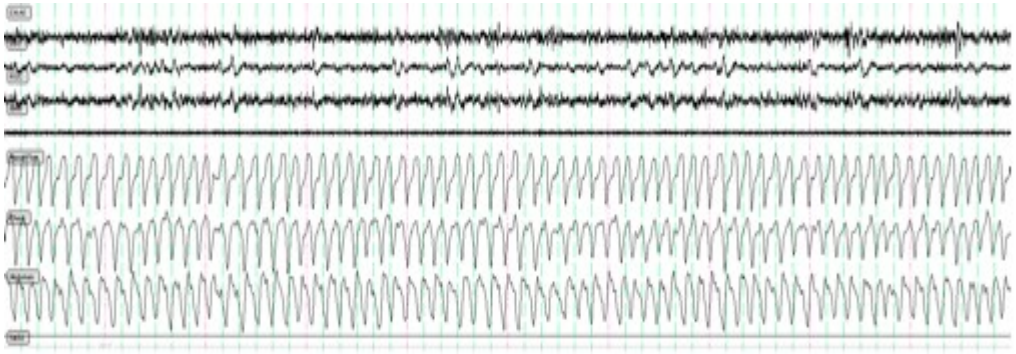


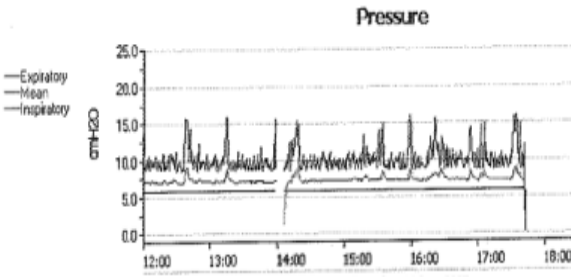
The pressure support is continuously changed throughout inspiration to get to target ventilation while achieving a shark fin shaped wave form.

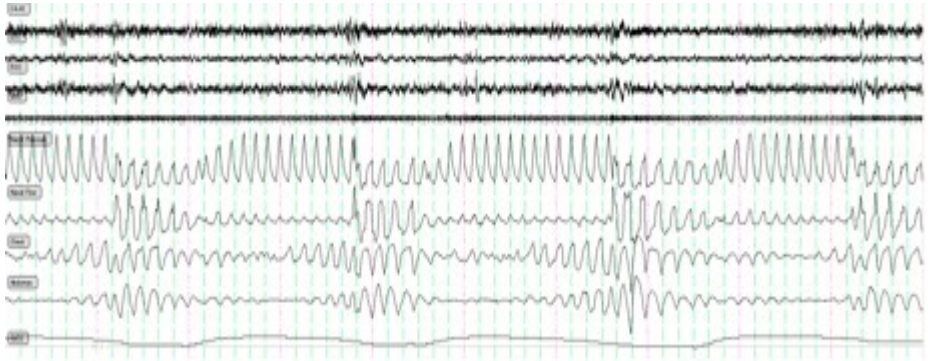
ASV dyssynchronous patterns

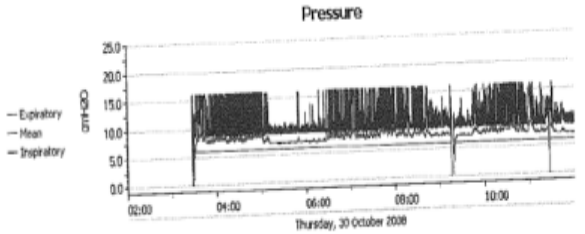


Assessing breathing stability and pressure fluctuations during ASV therapy





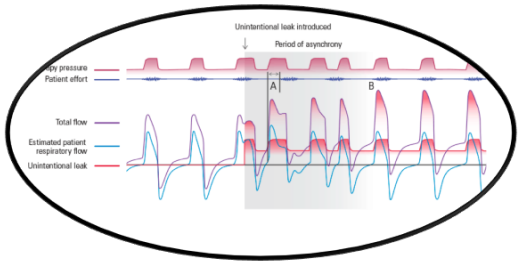


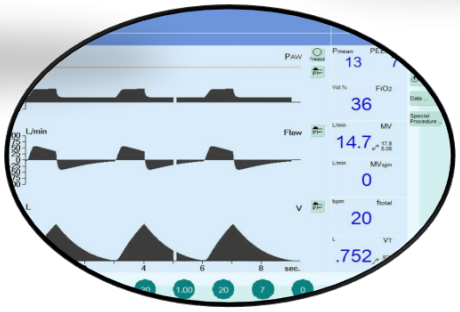


Personalized sleep medicine

Summary

Rapidly advancing PAP technology





Need more data: outcomes, titrations, phenotypes, health care delivery…


Thank you!
Questions?