

# Introduction to Hypoglossal Nerve Stimulation (HGNS) and How It Works

An Alternative Therapy for  
Obstructive Sleep Apnea (OSA)

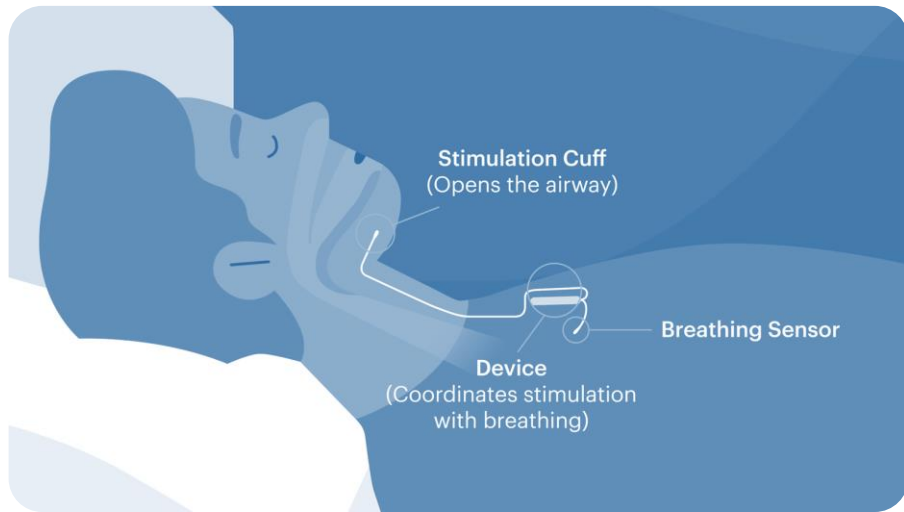
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# Hypoglossal Nerve Stimulation (HGNS)

A Treatment for Obstructive Sleep Apnea Patients Who Are Unable to Use CPAP

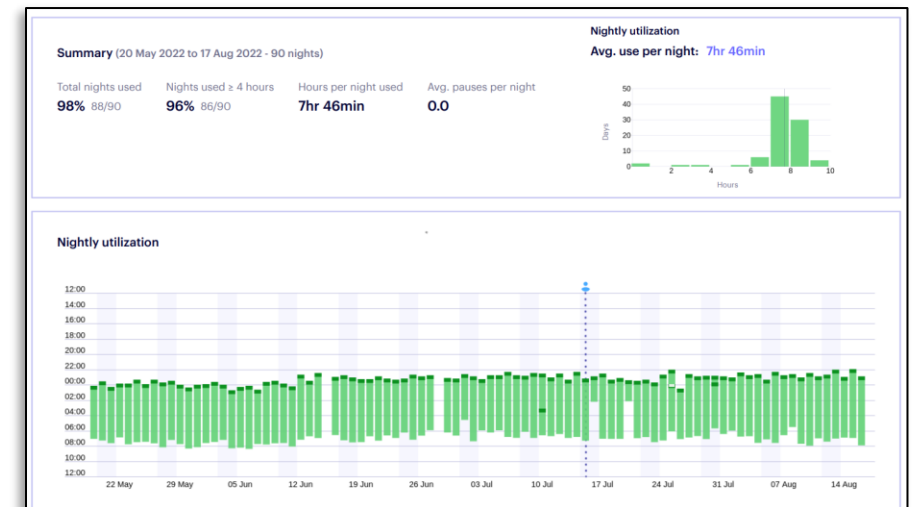
## Safe Outpatient Procedure



## Sleep Remote



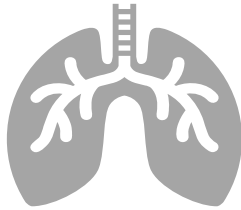
## Nightly Adherence Monitoring (Quality Measures)



# HGNS Patient Selection



Adults 18 years of age and older



Diagnosed with Moderate to Severe OSA  
(AHI 15-100)

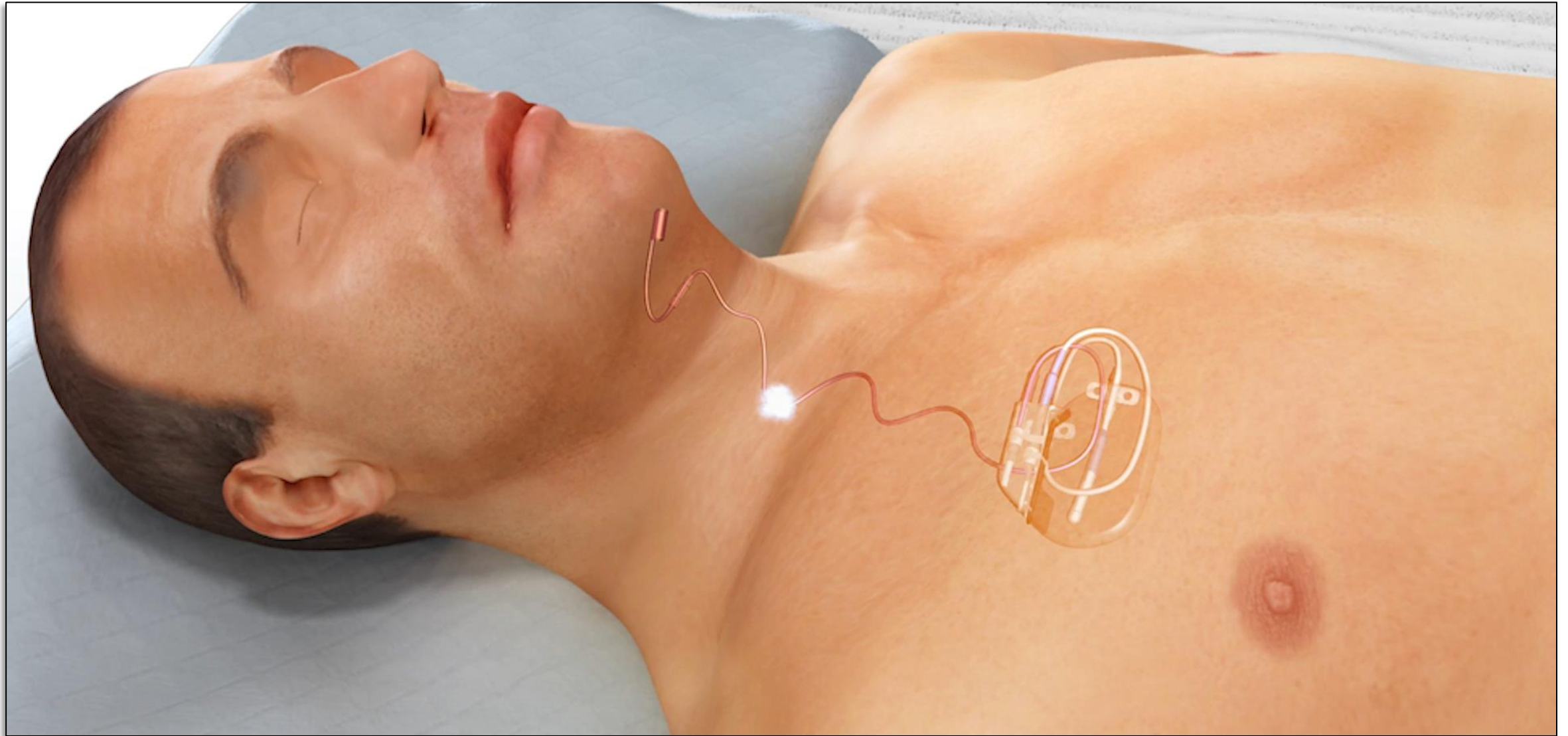


CPAP failure or inability to tolerate CPAP



Appropriate airway anatomy &  
< 25% Central + Mixed Sleep Apnea

# Hypoglossal Nerve stimulation – How It Works



# Hypoglossal Nerve Stimulation – targets mechanism of airway collapse

**No Stimulation**



**Mild Stimulation**



**Base of Tongue**

**Palate**



**Base of Tongue**

**Palate**



# Rigorous Clinical Evidence

Over 8 years of data, 200+ publications

## PHASE 1

Foundational data for therapy approval

## PHASE 2

Long-term outcomes, post-market studies

## PHASE 3

Real world data, indications, comparisons

STAR Trial – New England Journal of Medicine

2014

German Post-market 6-mo  
Single-center studies (UPMC, UPenn)

2016

STAR Trial – 5 Year Data  
ADHERE Registry 500  
UAS vs Sleep surgery Comparisons

2018

2015

STAR 3-year follow-up

2017

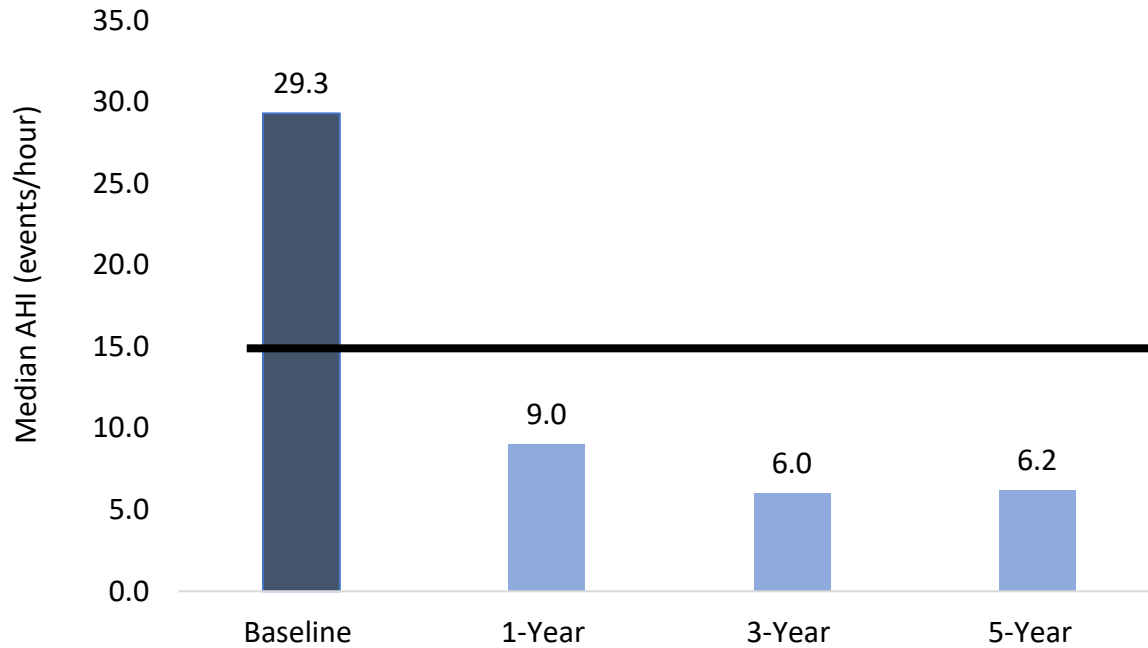
STAR 4 year  
German Post-market 1-year  
Single-center studies (Munich, TJU, UPMC)  
Down Syndrome Feasibility Trial

2019

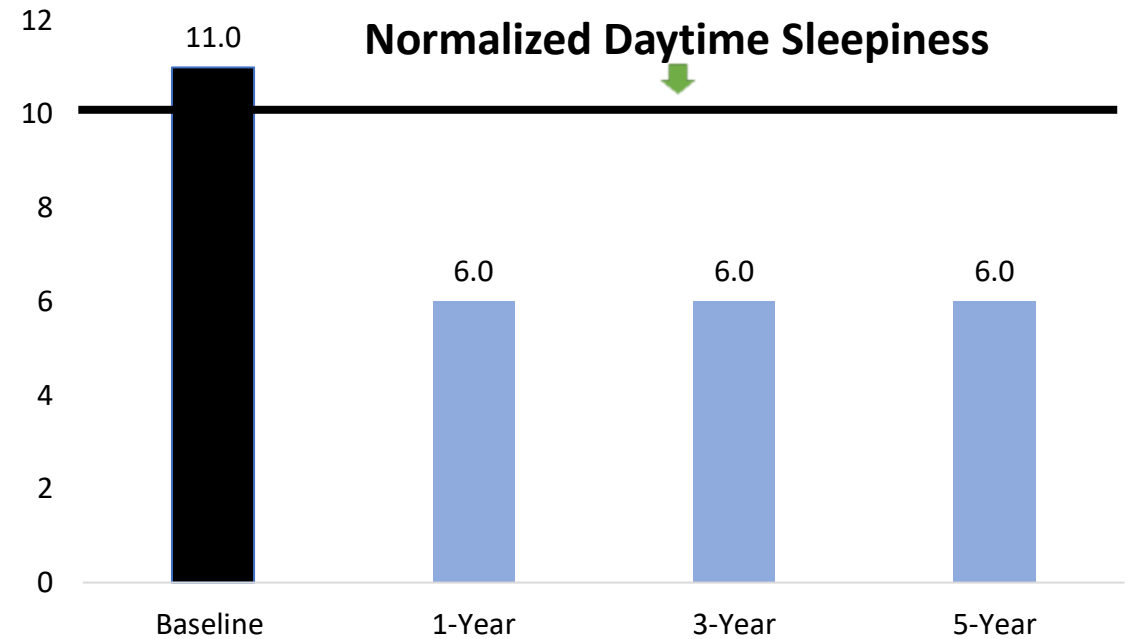
ADHERE Registry 1000  
German Post-market 3-year  
UAS in older patients  
Down Syndrome 1-year follow-up

# Stimulation Therapy for Apnea Reduction (STAR) Trial

## Apnea Hypopnea Index (AHI)



## Epworth Sleepiness Scale (ESS)



Multi-Center Prospective, 126 Patients, Randomized Control Tx, Withdrawal ARM

Strollo et al NEJM 2014; Woodson et al  
Heise et al ERJ 2019  
Pietzsch et Marin; 2018;

# Patient Outcomes in Clinical Practice

## ADHERE Registry

3,741 Enrolled

3,630 Implanted

2,485 Post Titration

1,883 Completed 12-month Visit

58 centers from US and Europe, total enrollment goal of 5,000

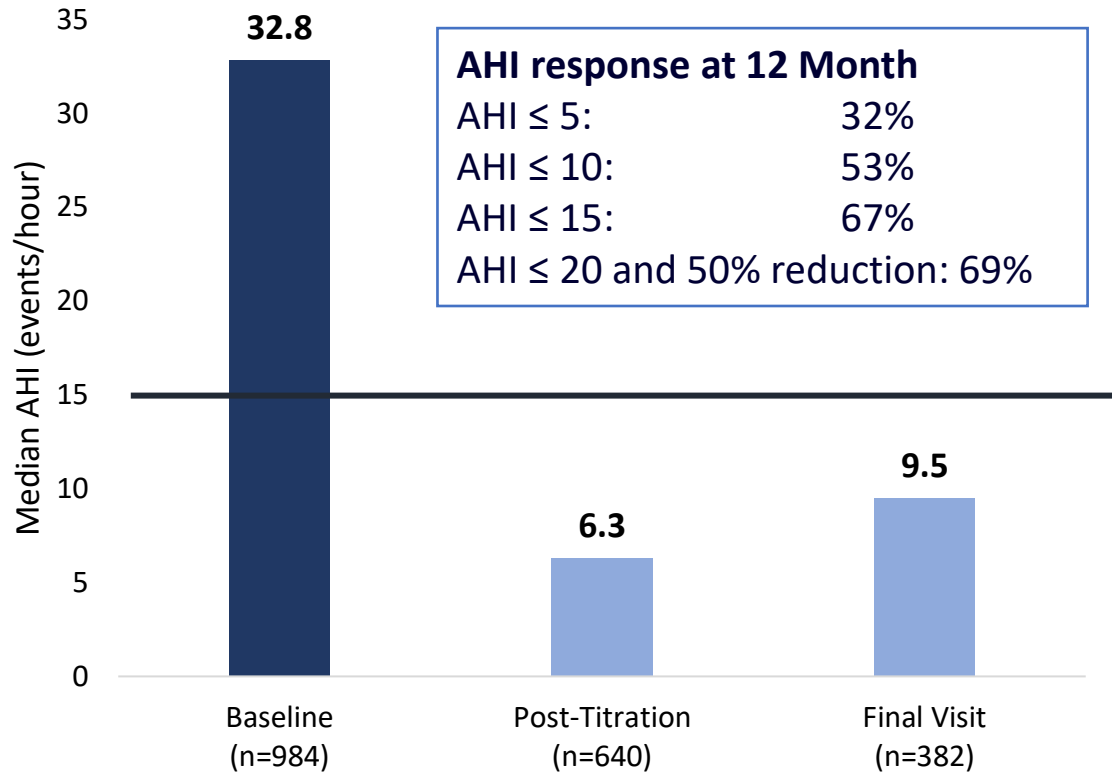
Patient Characteristics <sup>1</sup>	Value
Age	60 ± 11 (22-86)
Sex	73% Male
Ethnicity	94% Caucasian
Body Mass Index	29.2 ± 3.8
Baseline AHI	33.0
Baseline Co-morbidities <sup>2</sup>	Value
Hypertension	47%
Depression	23%
Diabetes	14%
Atrial Fibrillation	6%
Heart Attack	4%
Stroke	4%

<sup>1</sup>Boschieter et al. JCSM 2022



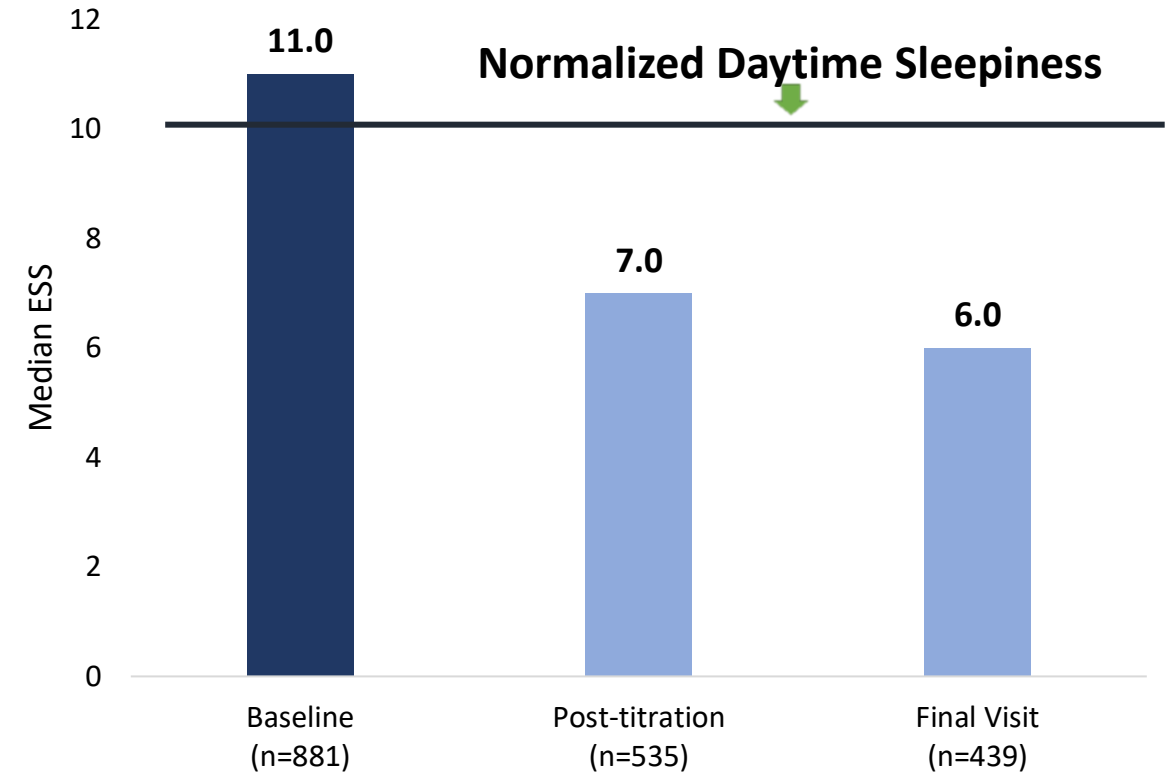
# ADHERE Registry: Consistent effectiveness

## Apnea Hypopnea Index (AHI)



Mean AHI reduced from baseline of  $35.8 \pm 15.4$  to  $14.2 \pm 15.0$  at 12 months ( $p < 0.001$ )

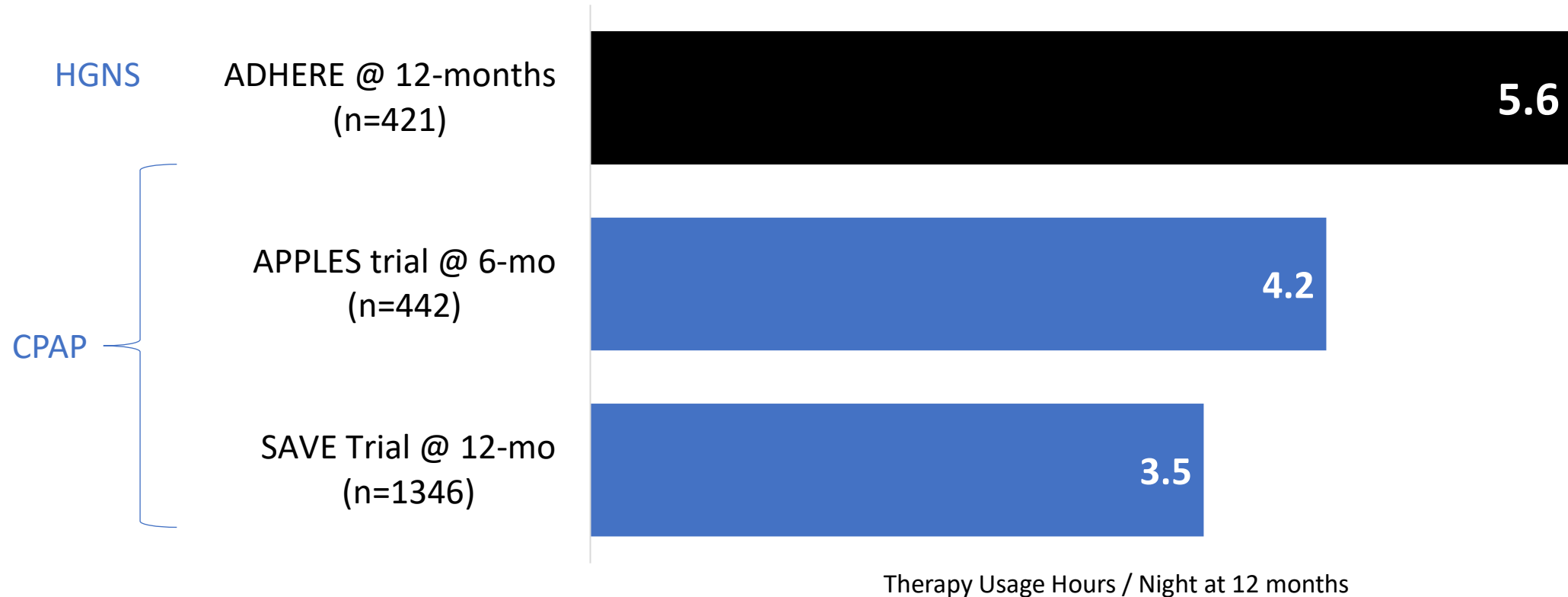
## Epworth Sleepiness Scale (ESS)



Mean ESS reduced from baseline of  $11.4 \pm 5.6$  to  $7.2 \pm 4.8$  at 12 months  
Reference: ESS < 10 considered free of symptoms for excessive daytime sleepiness

# High Patient Adherence

Usage of 5.6 hours/night exceeds most CPAP clinical trials



1. ADHERE-1000: Thaler, Laryngoscope 2019
2. APPLES: Kushida, Sleep 2012
3. SAVE: McEvoy, NEJM 2016

# Possible Surgical Adverse Events

*Each approx. <1% with current implant techniques & products*

- Stimulation lead tethering
- Neurapraxia of the HGN
- Inappropriate lead connection with generator
- Pneumothorax
- Marginal mandibular nerve weakness
- Failure to place stimulation lead cuff around HGN
- Blood vessel damage during tunneling
- Hematoma
- Device-related infection

# ADHERE Registry: Strong safety profile

Type	Post-Titration		Final Visit	
	# of Events	% of Patients	# of Events	% of Patients
Tongue Weakness	3	<1%	0	-
Swallowing or speech related	4	1%	1	<1%
Infection	2	<1%	0	-
Revision interventions (including explant)	1	<1%	2	<1%
<b>Total</b>	<b>10</b>	<b>3%</b>	<b>3</b>	<b>&lt;1%</b>

Type	Post-Titration		Final Visit	
	# of Events	% of Patients	# of Events	% of Patients
Discomfort (incision/scar)	14	4%	8	2%
Discomfort (device)	10	3%	5	1%
Stimulation related discomfort	41	12%	28	8%
Other Discomfort	12	3%	8	2%
Post-Op – Other	14	4%	6	2%
Tongue abrasion	12	3%	14	4%
Insomnia/Arousal	10	3%	17	5%
Activation - Other	37	3%	23	7%
<b>Total</b>	<b>151</b>	<b>43%</b>	<b>110</b>	<b>31%</b>

# Favorable Physician & Patient Satisfaction @ 12-months

## 92% of physicians reported patient improvement



Q: How much the patient's OSA has improved or worsened relative to Baseline/prior to HGNS Therapy?

## More than 9 out of 10 patients are satisfied

95%

of patients said HGNS was better than CPAP (n=378)

94%

of patients said they would choose HGNS again (n=390)

96%

of patients said they would recommend HGNS to a friend or family member (n=390)

93%

of patients said they were satisfied with HGNS (n=391)



Patient  
Screening

Airway Exam

HGNS  
Procedure

Incision Check

# Patient Journey – Pre-Implant

# A Proven Patient Care Pathway

AT LEAST 90 DAYS

## IMPLANT



30 DAYS>

- Allow healing
- System validation

## ACTIVATION



30 DAYS>

- Configure Initial Settings

## CHECK-IN



30 DAYS>

- Confirm patient is stepping up levels once per week

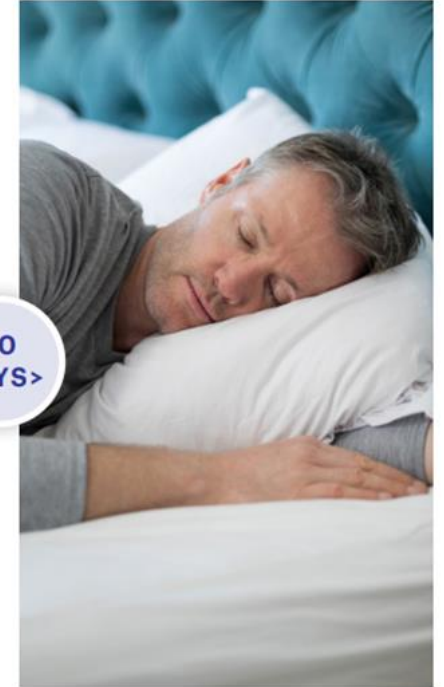
## OFFICE VISIT



30 DAYS>

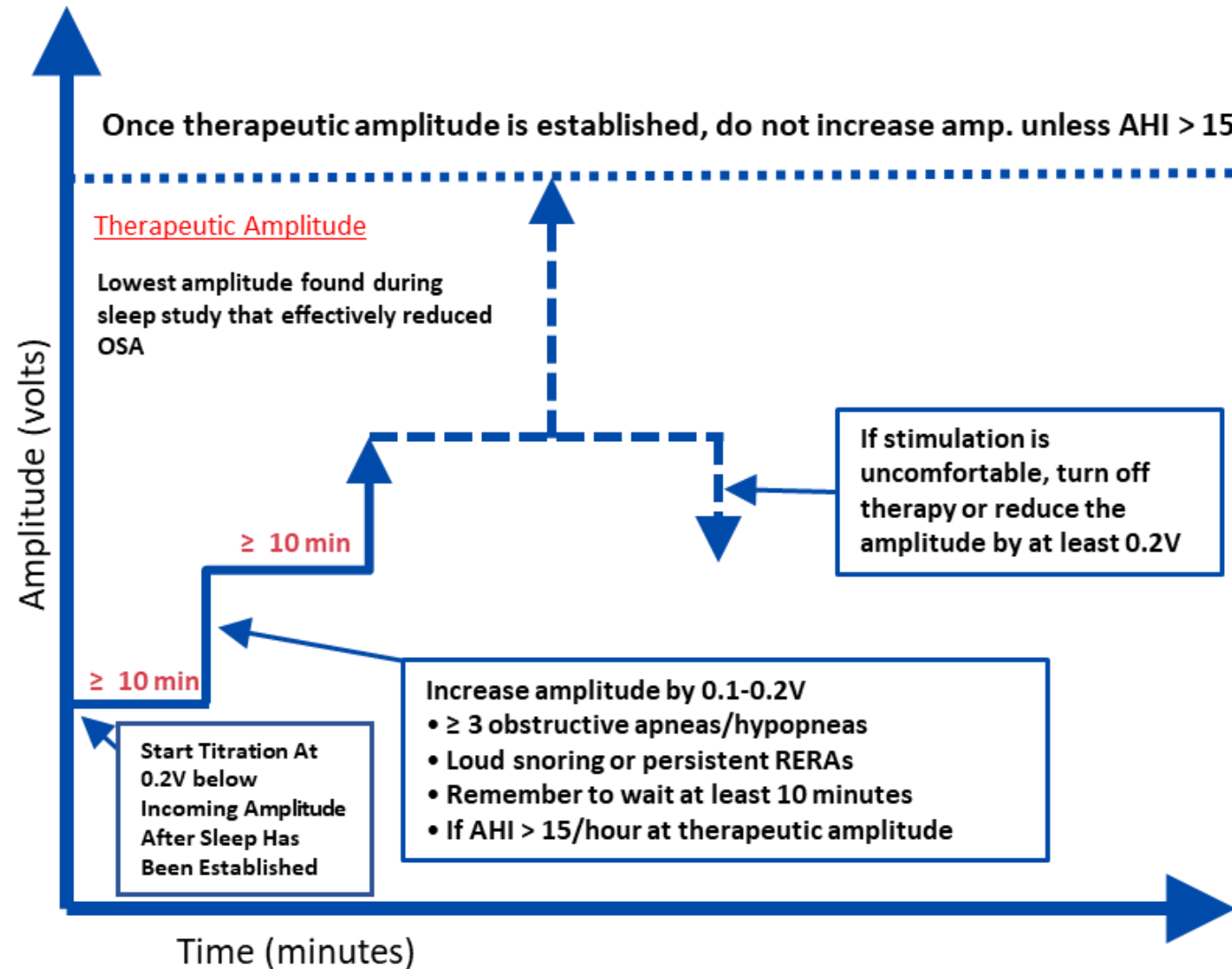
- Confirm usage >4 hours/night
- As needed:** Make office adjustments to increase adherence

## FINE TUNE SLEEP STUDY



- Goals:**
- Usage >4 hours/night
- Symptom improvement
- Estimated AHI <15/hour

# Standardized Sleep Study Algorithm for HGNS\*

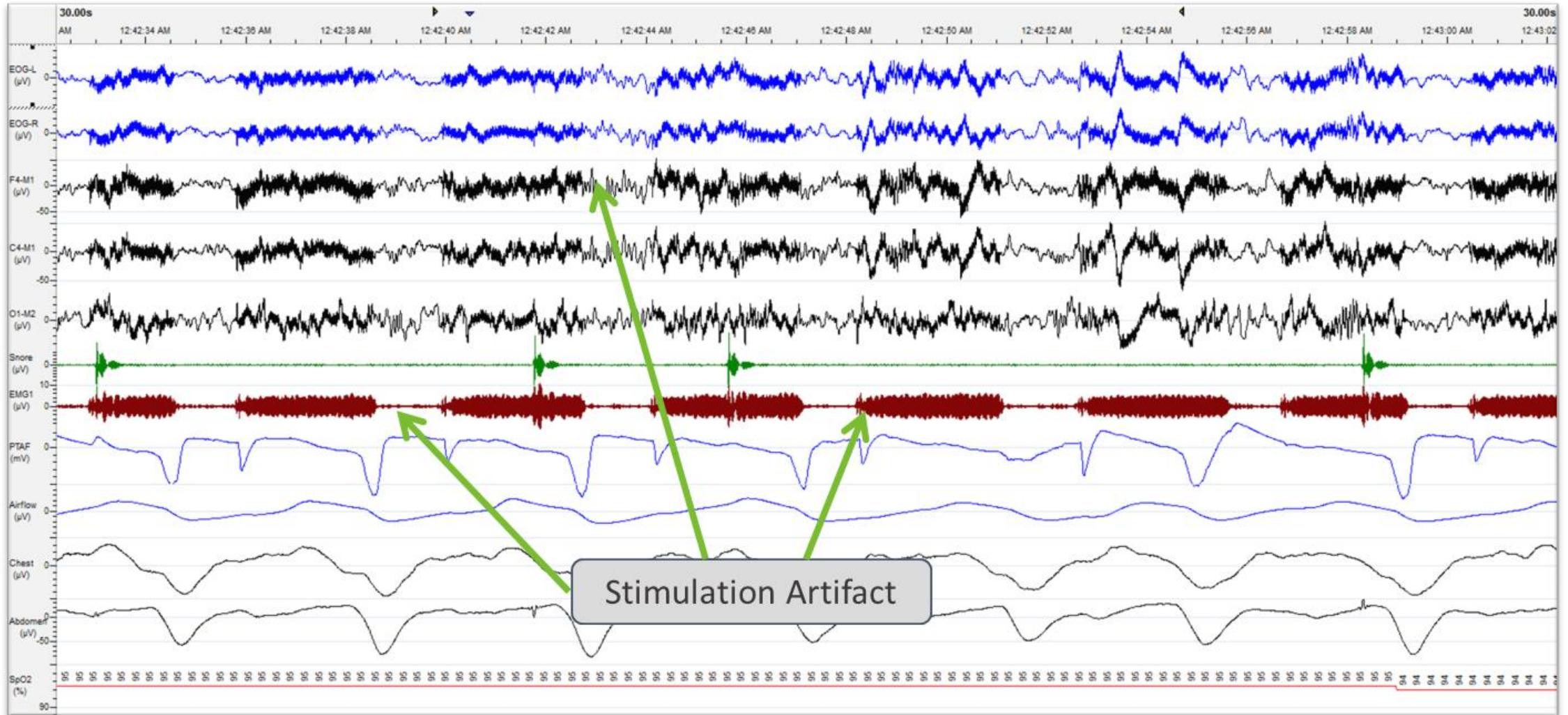


\*Adapted from current practice guidelines established for CPAP titration by the American Academy of Sleep Medicine, ref: Journal of Clinical Sleep Medicine, Vol. 4, No 2, 2008



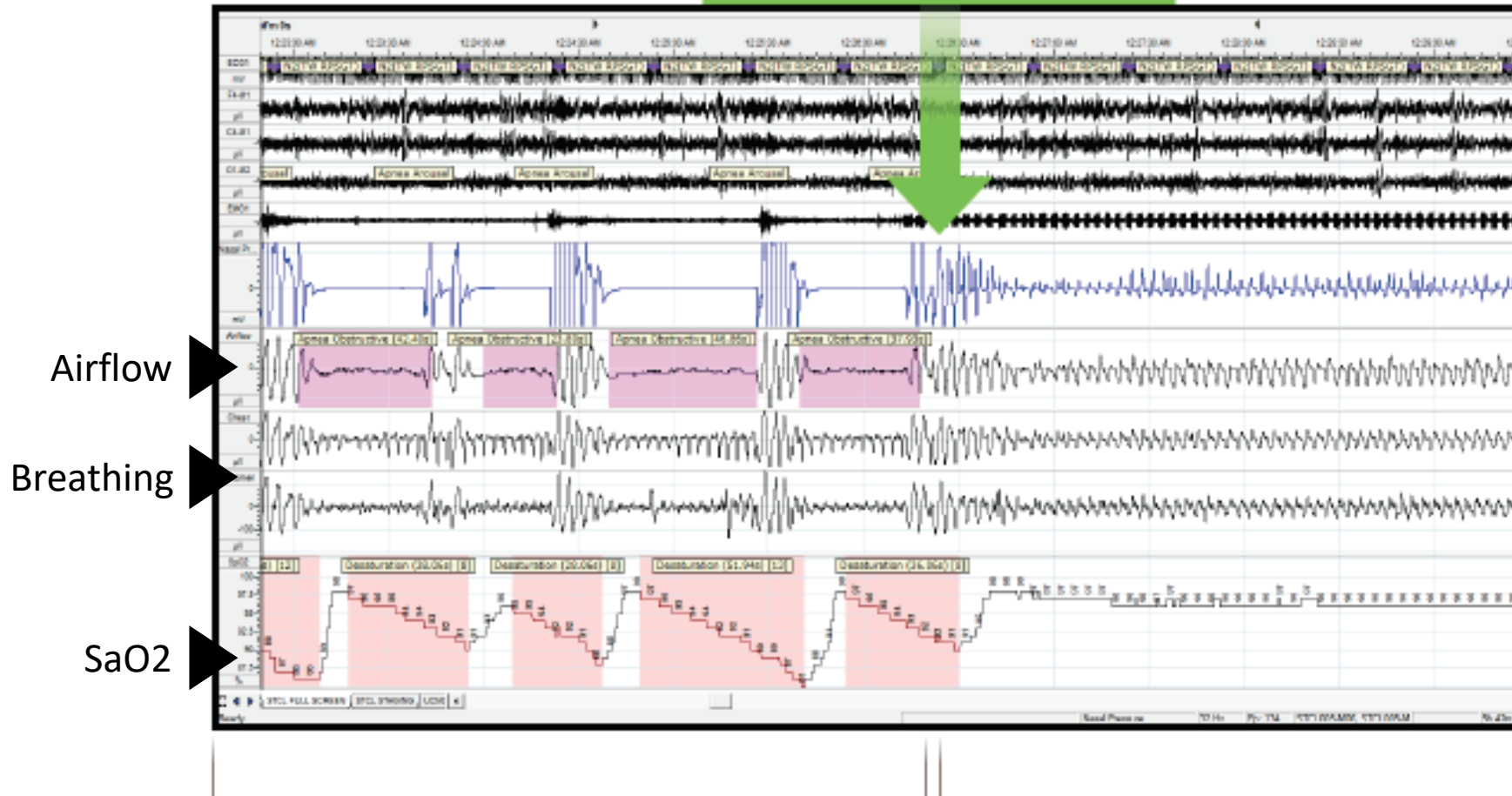
# HGNS Artifact

When therapy is on, stimulation artifact can be seen in some or many of the recording channels during polysomnography, especially the EEG.



# HGNS Effect During Sleep

HGNS is turned on



Uninterrupted sleep continues without arousals

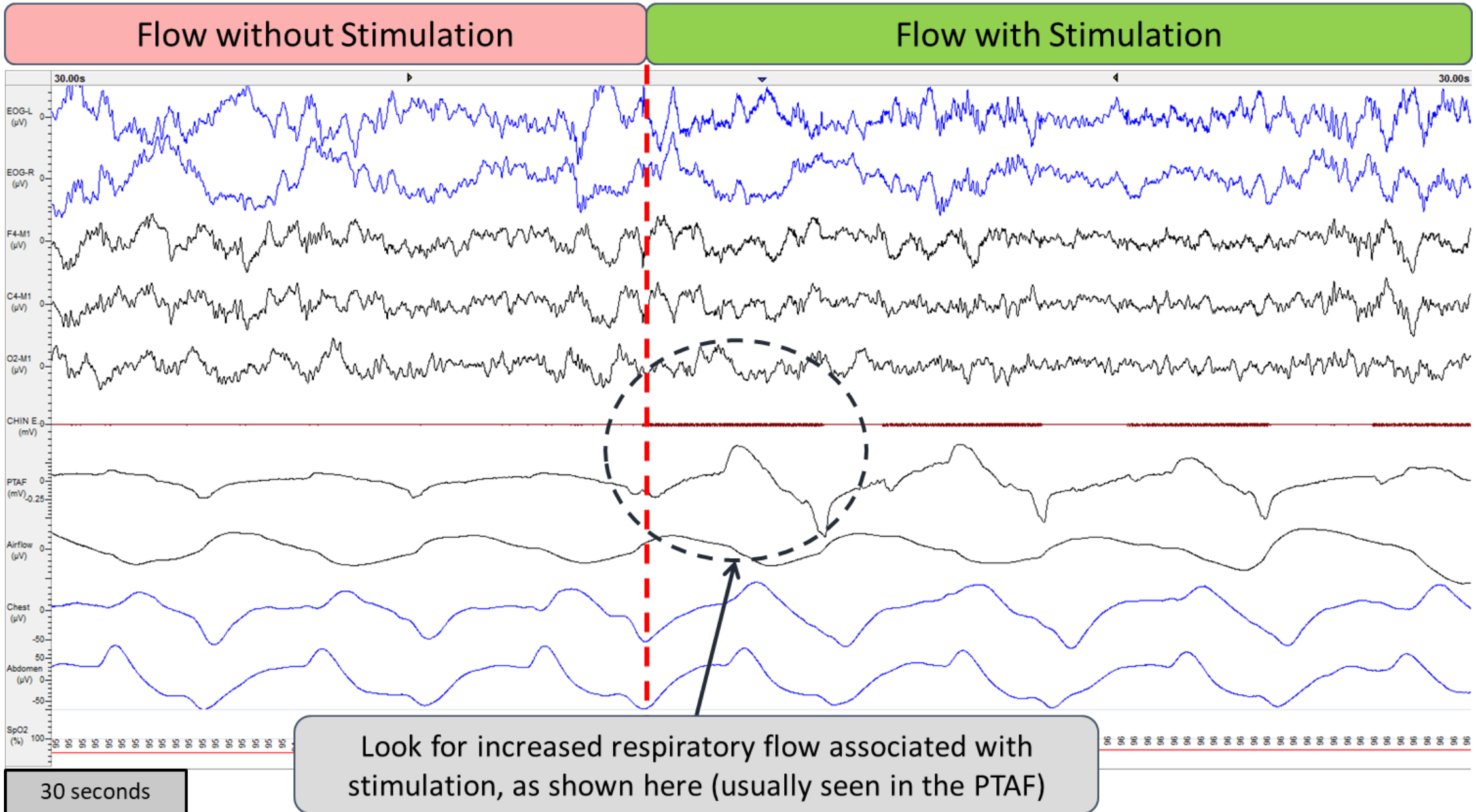
Airflow and breathing become stabilized

SaO2 levels are normalized

Severe OSA Events

OSA Events Resolved

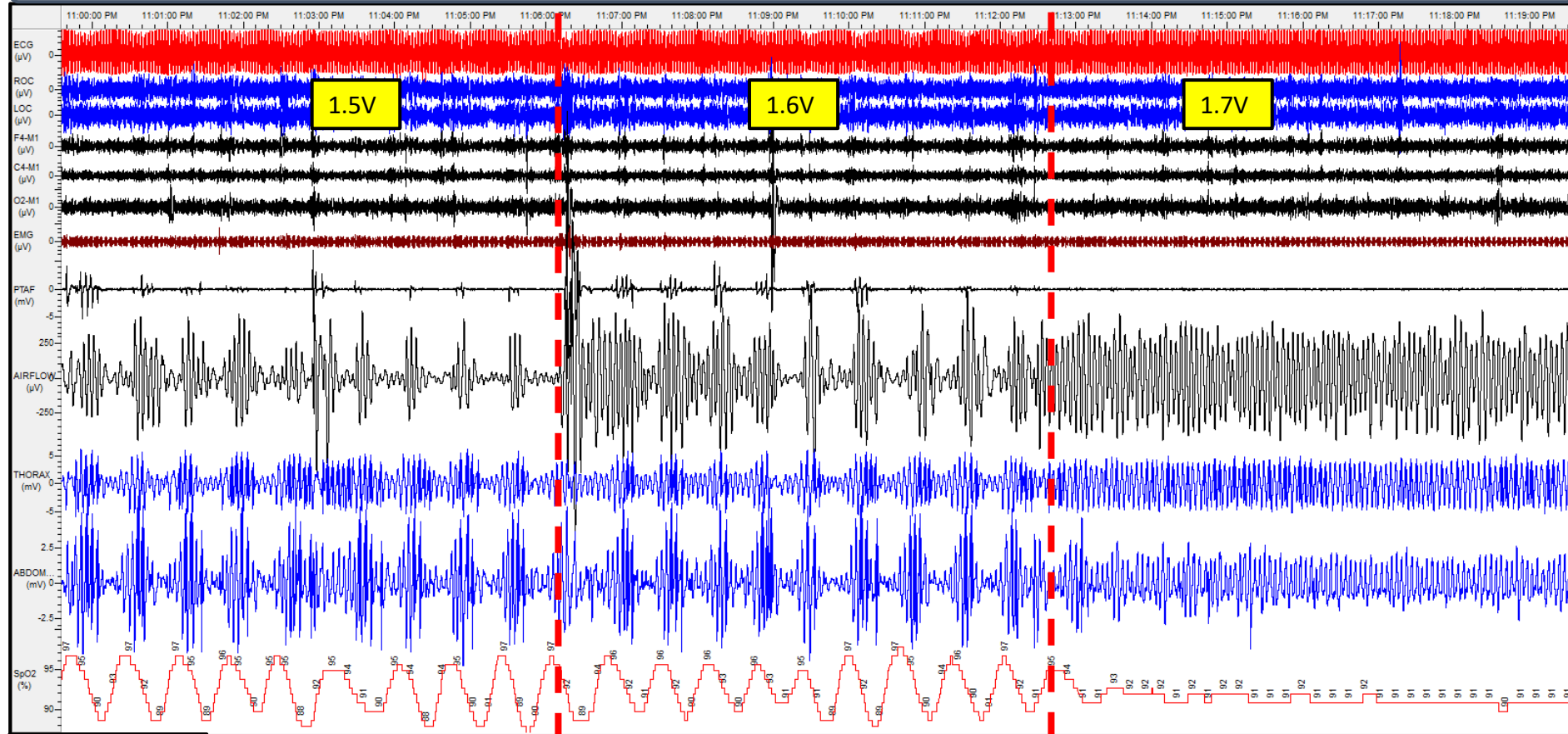
# HGNS Causes Positive Flow Effect in PTAF



# Fine Tuning Amplitude for Obstructive Events

## “10 Minute Rule”

Titrate slowly (0.1 volts every 10 minutes) to eliminate obstructive events.



30 Minutes

# WITHIN 4 WEEKS OF FINE TUNE PSG

office follow-up visit

## OFFICE VISIT AFTER FINE TUNE GREEN CARE PATHWAY

Good usage and good AHI reduction

- Review sleep study results
- Confirm adherence
- Confirm tongue motion & waveform
- Finalize Programming
- Discuss long-term follow-up

6 MONTHS >

### LONG-TERM FOLLOW UP



- Confirm usage, tongue motion, waveform and subjective benefit

6 MONTHS >

### OPTIONAL HOME SLEEP APNEA TEST (HSAT)



When optimal adherence and AHI are achieved the patient returns to the Green Care Pathway.



## OFFICE VISIT AFTER FINE TUNE YELLOW CARE PATHWAY

Sub-optimal AHI and/or sub-optimal usage

Make simple, office-based adjustments to help:

- Increase usage
- Decrease AHI

6 WEEKS >



- Confirm usage
- HSAT to assess AHI

6 WEEKS >



- Confirm usage
- HSAT to assess AHI

6 WEEKS >



Advanced settings assessment

>

### OFFICE VISIT

### AWAKE ENDOSCOPY

### ADVANCED FINE TUNE

### COMBINATION THERAPY

**Consider:**

- Positional therapy
- Airway surgery
- Oral appliance
- CPAP

Thank you!

We will now take a few moments to answer  
any questions you may have.

