The Wild West of Home Sleep Apnea Testing

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Conflict of Interest Disclosures for Speakers

Mohan Dutt, MD has no relevant financial relationships with ineligible companies to disclose.

Learning objectives

After listening to this lecture participants should be able to

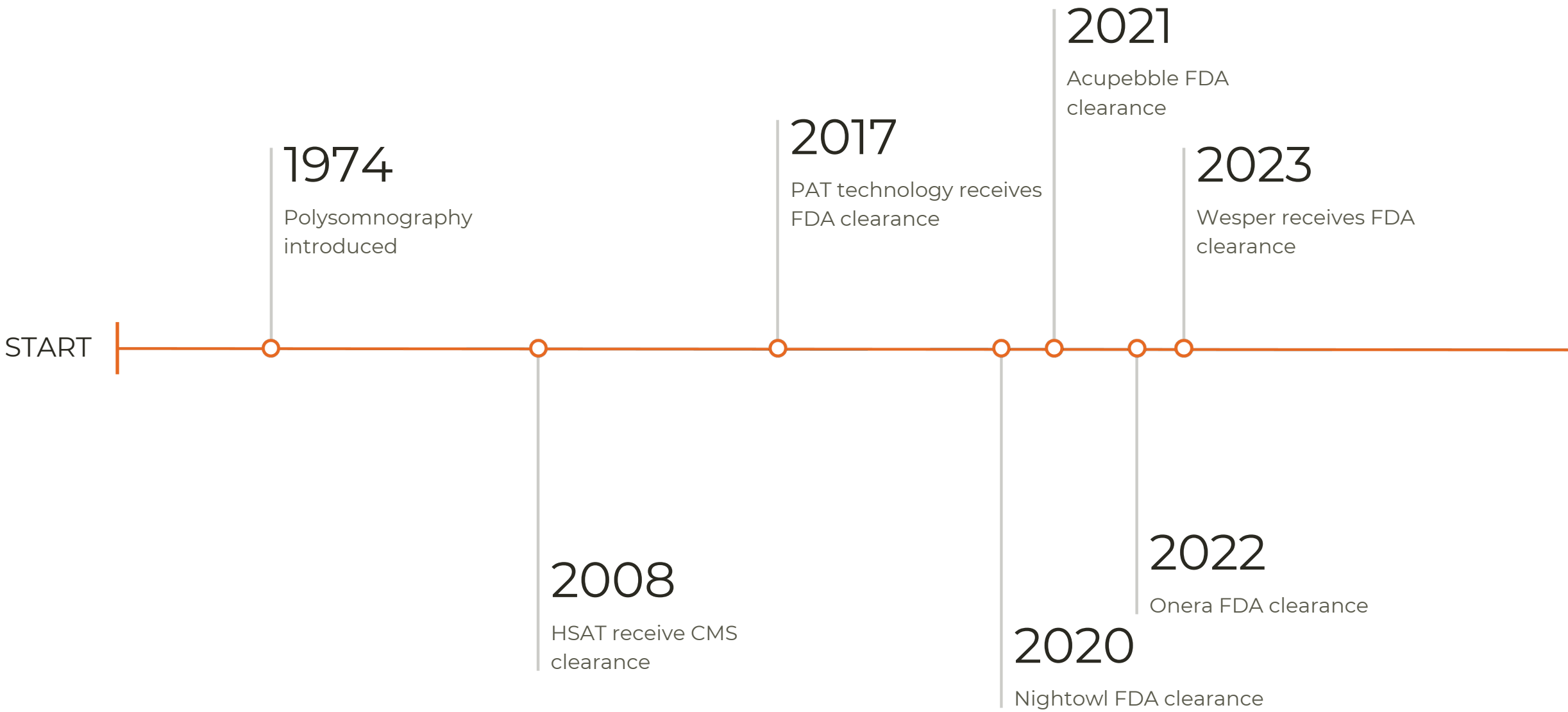
Discern between the different types of home sleep testing modalities

Explain the functional mechanism of newer modalities of home sleep apnea testing

Choose home sleep testing devices that best fits their unique patient population

Objectives

1. History
2. State of sleep medicine
3. Watch PAT update
4. New devices
5. Conclude


START
1974
Polysomnography introduced
2008
HSAT receive CMS clearance
2017
PAT technology receives FDA clearance
2020
Nightowl FDA clearance
2021
Acupebble FDA clearance
2022
Onera FDA clearance
2023
Wesper receives FDA clearance

Reasons for growth of sleep medicine market

Increasing prevalence of sleep disorders

Rising cases of insomnia, sleep apnea, narcolepsy etc. is boosting demand for diagnosis and treatment

Growing awareness about ill effects of sleep deprivation

People are more conscious about maintaining healthy sleep patterns and addressing disorders

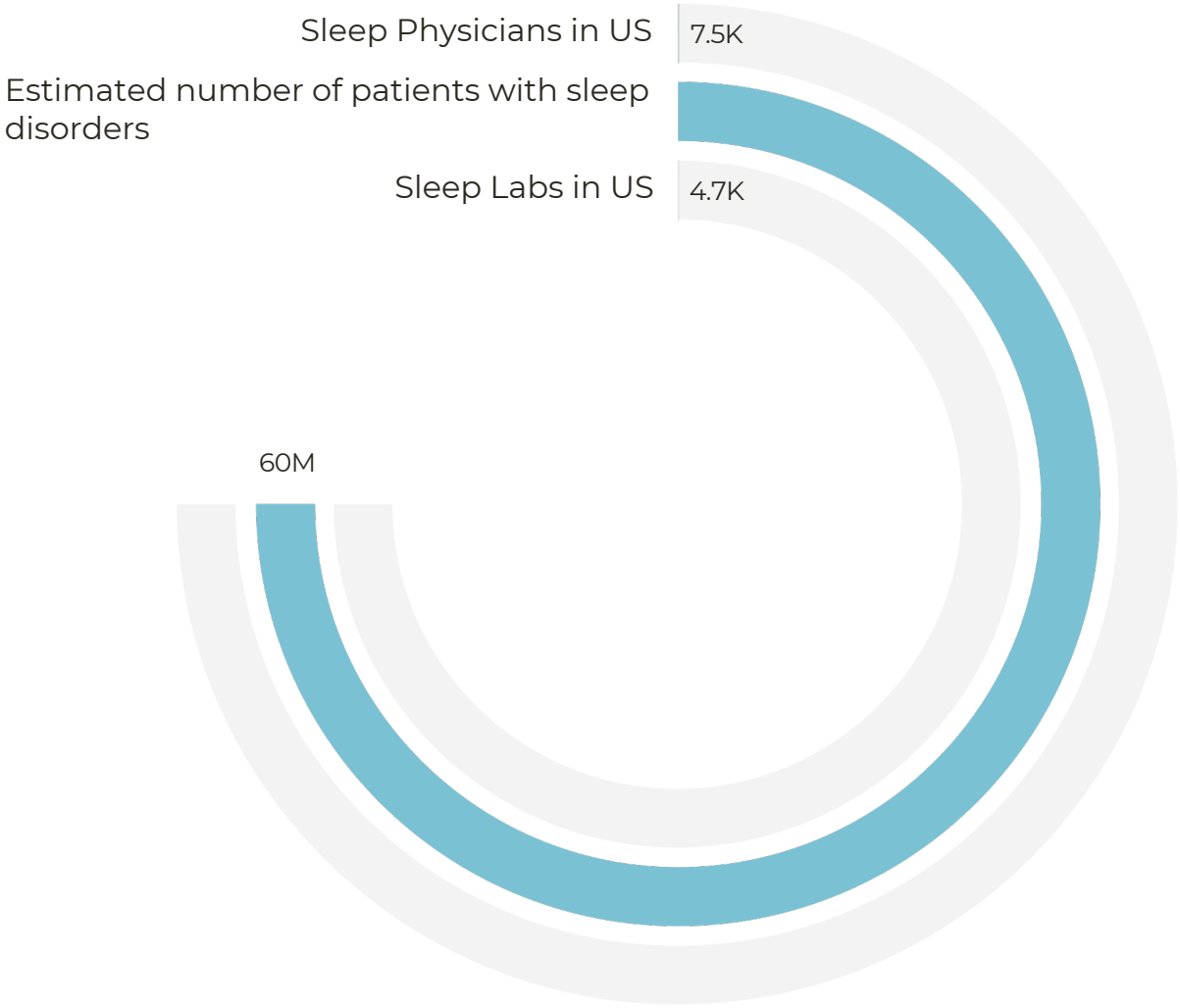
Advancements in sleep medicine technology

New diagnostic tools and treatments are being developed

The sleep medicine market is rapidly expanding due to rising prevalence of sleep disorders, growing public awareness and technological advancements in diagnosis and treatment.

Deficiency in workforce

One physician for every 8000 patients



What role do HSATs fill?

- Quick
- Cost effective
- May be useful in underserved populations
- Generally reliable
- Useful for patients unable to come to sleep lab
- Quicker diagnosis and treatment

FDA Approval and Clearance

FDA approval

FDA approval is required before a drug or class III medical device can be marketed in the United States. The process includes clinical trials to test safety and efficacy.

FDA clearance

FDA clearance is required for medical devices to demonstrate they are substantially equivalent to a legally marketed device. Less data required than for approval.

22.5

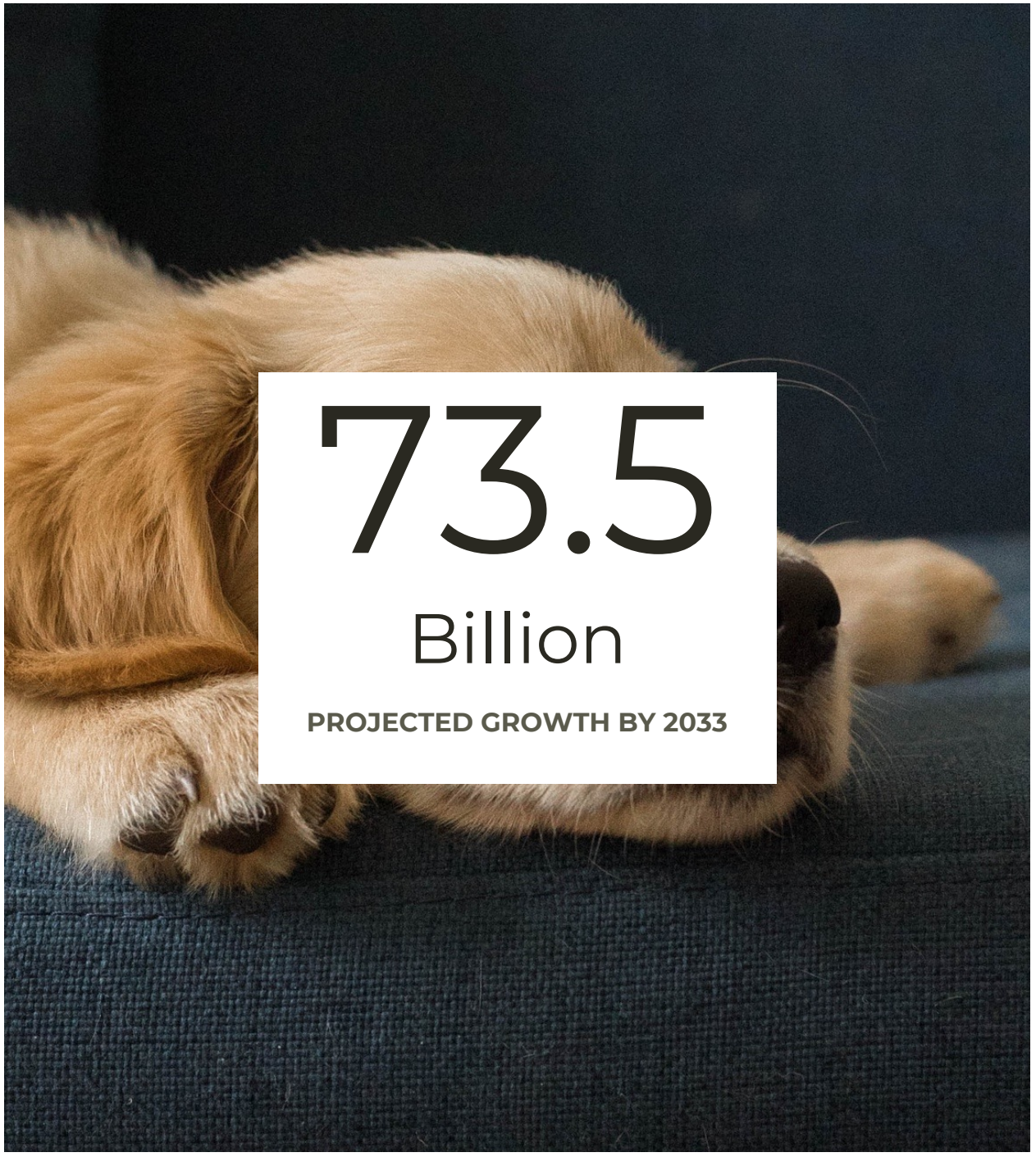
Billion

SLEEP MARKET SIZE (2022)

12%

CAGR

COMPOUND ANNUAL GROWTH RATE

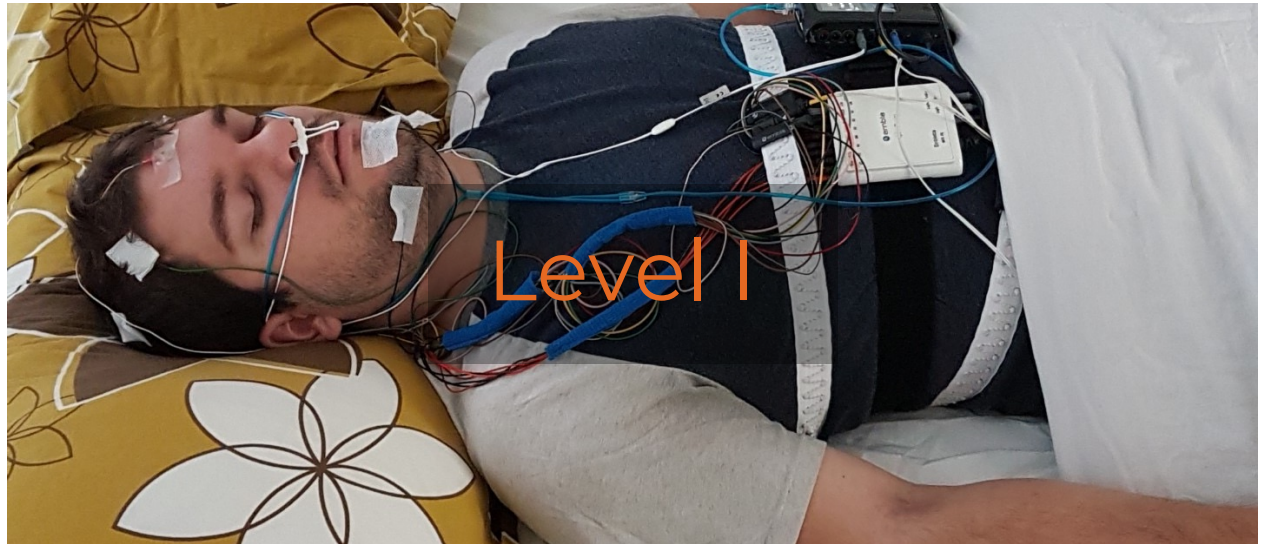


73.5

Billion

PROJECTED GROWTH BY 2033

Types of sleep testing



Testing Devices

Level I

- PSG

Level II

- Embletta
- ARES 620
- SOMNOtouch RESP
- Sleep Profiler and PSG2
- Apnea Track
- Cerebra Sleep System
- Onera STS
- Zmahine

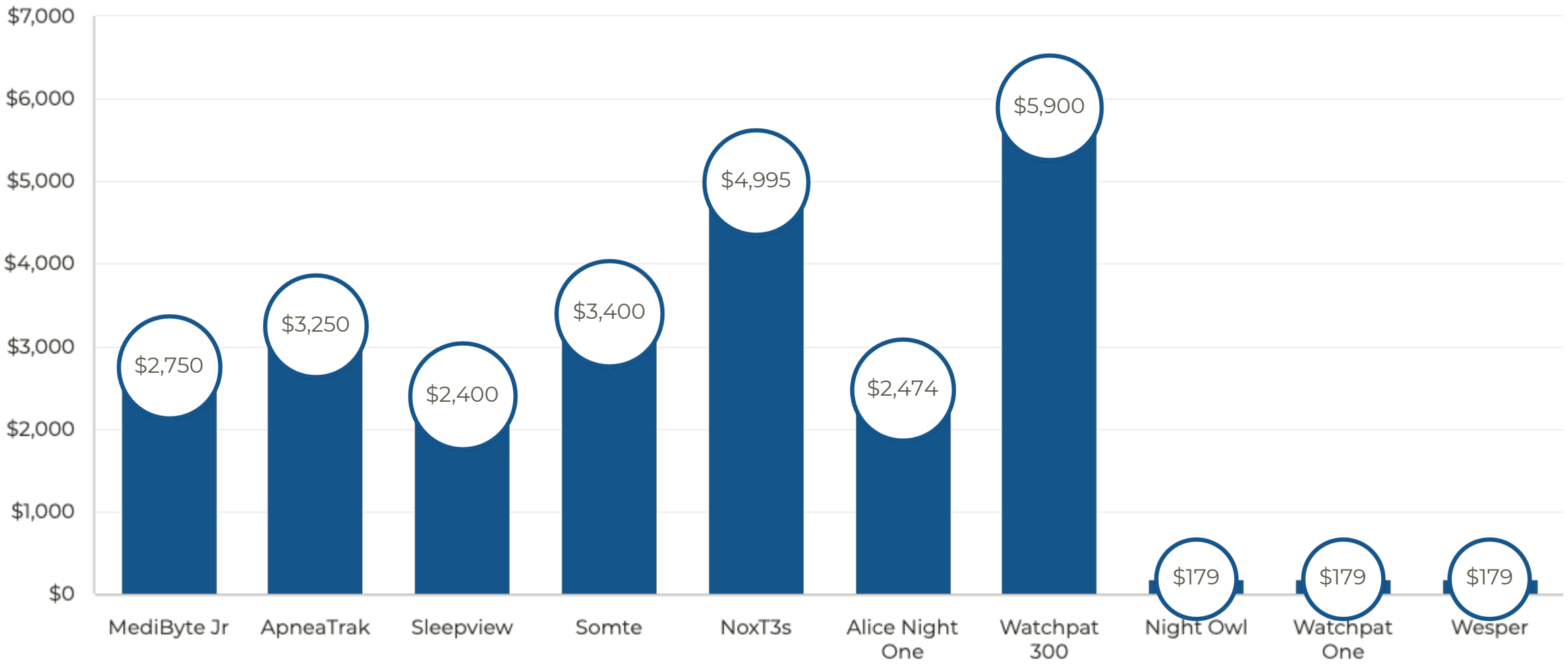
Level III

- WatchPat
- ApneaLink Air
- Wesper
- Somte
- BWMini HST Compass
- Nox T3
- Accusom
- Alice Night one

Level IV

- Nightowl
- Sunrise

Cost of HSAT devices



Quick Refresher on PAT

Respiratory event → Sympathetic activation → Increase in peripheral arterial tone

Contraindications

- Alpha Blockers
- Nitrites
- Pacemaker
- Non Sinus cardiac arrhythmias

Updates to PAT therapy

2022 meta analysis

- Clinically significant discordance in quantifying AHI in comparison to PSG
- Authors recommend follow up PSG if mild OSA.

Watchpat and afib

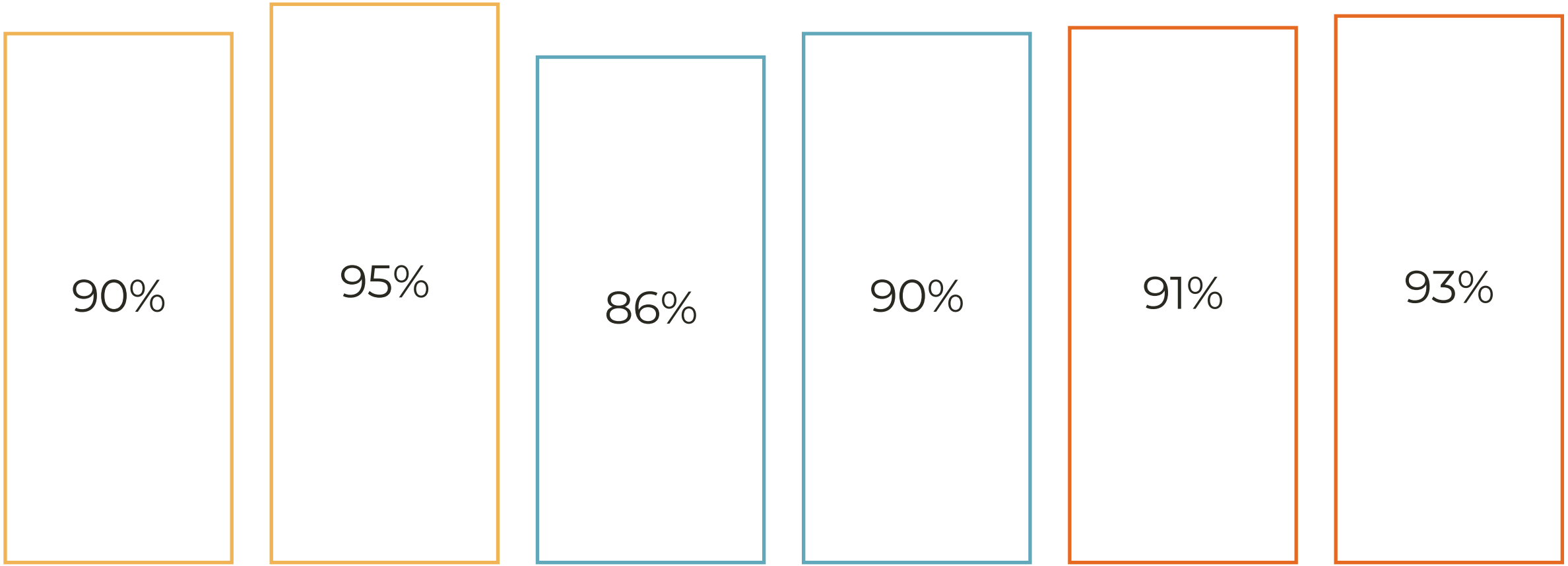
- Study evaluating effectiveness in afib
- Correlation 0.80 (p<0.0001)
- Sensitivity 0.88
- Specificity 0.63

	Sensitivity	Specificity	DOR	LR+	LR–
AHI ≥ 5 events/h	94.11%; SE, 2.6%	43.47%; SE, 12.9%	12.30; SE, 3.62	1.66; SE, 0.34	0.13; SE, 0.03
AHI ≥ 15 events/h	92.21%; SE, 2.4%	72.39%; SE, 7.8%	31.08; SE, 17.97	3.34; SE, 0.97	0.10; SE, 0.03
AHI ≥ 30 events/h	74.11%; SE, 5.6%	87.10; SE, 3.4%	19.33; SE, 6.46	5.74; SE, 1.41	0.29; SE, 0.06

Nightowl

- FDA cleared
- Level IV study
- Outputs
  - PAT
  - Actigraphy
  - Oximetry
  - Pulse
- Validated against PSG

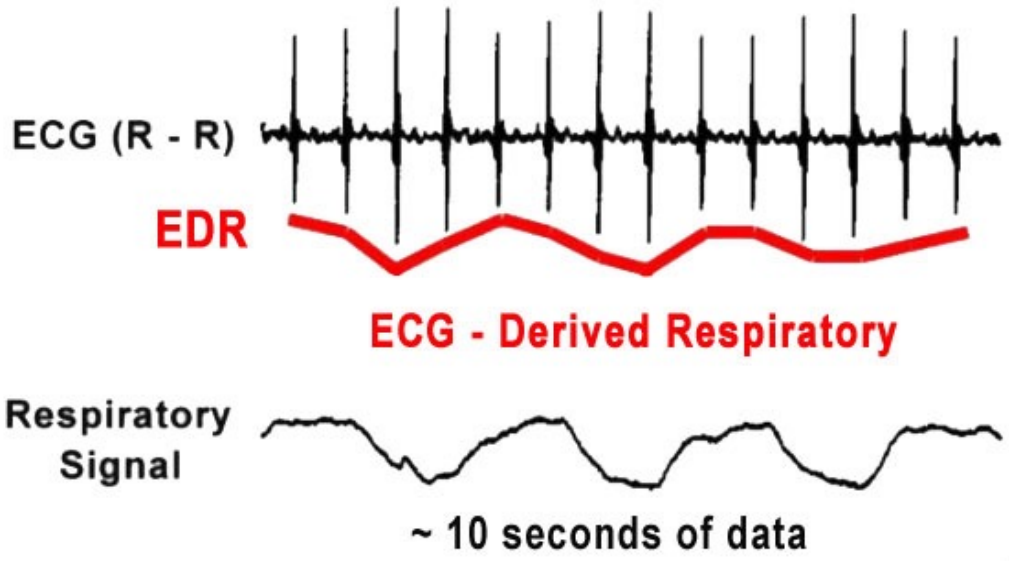
Validation Data



Sleep Image

- Level IV device
- Cardiopulmonary coupling
- FDA cleared 2022
  - Software as a medical device
- Validated in adults and children

Sleep Image



Cardiopulmonary Coupling

- Coherence of heart rate variability and ECG derived respiration

Sleep Image

Outputs

- Plethysmography
- Actigraphy
- Oximetry
- Heart rate variability
- Pulse Rate
- Respiration

Sleep Image

Limitations

- Arrythmia
- Chronic pain disorders

Cardiopulmonary coupling relationship to sleep staging

High frequency coupling	Low Frequency Coupling	Very low frequency coupling
NREM	Unstable NREM	REM

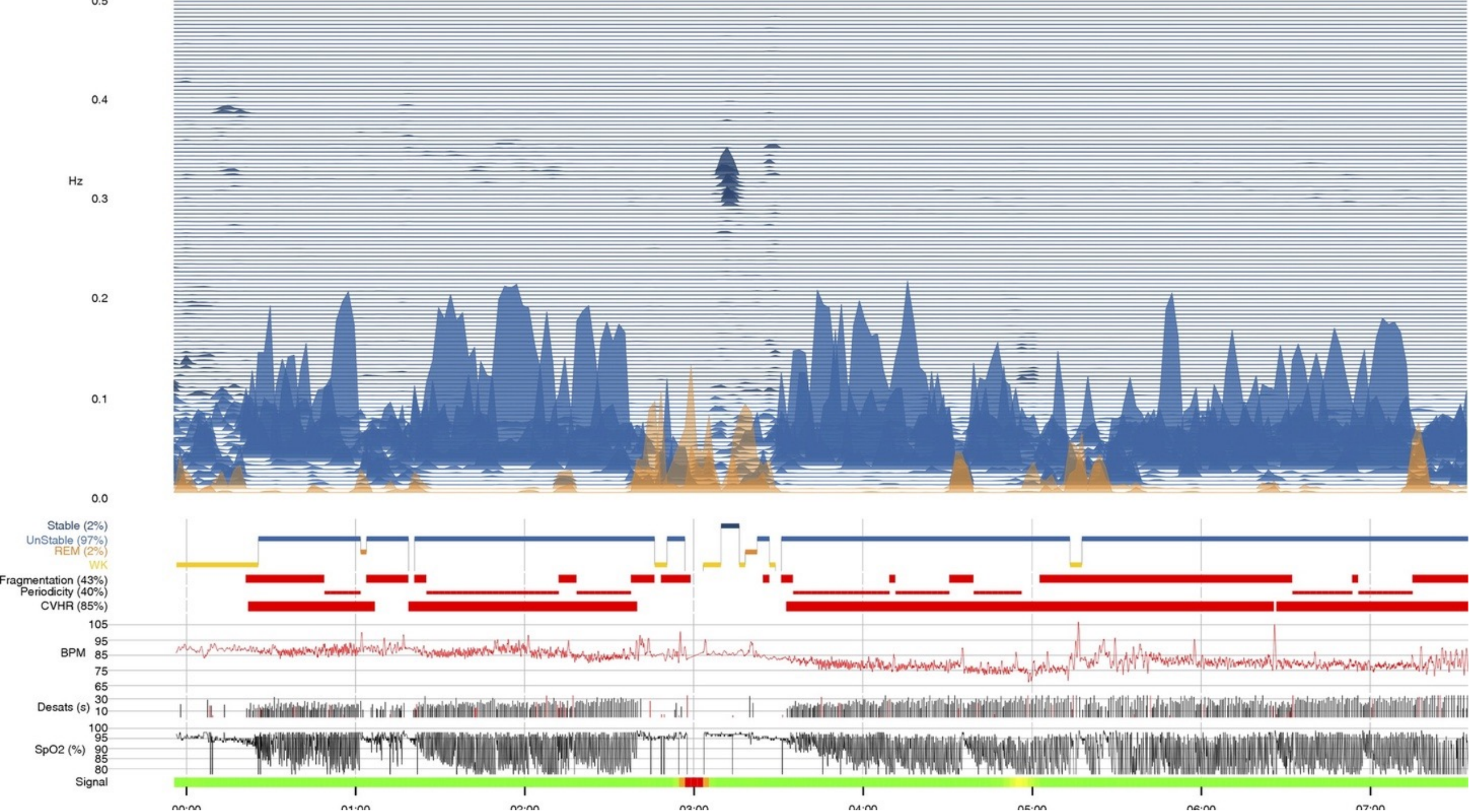
Sleep Image Validation Data

Mild OSA

Moderate OSA

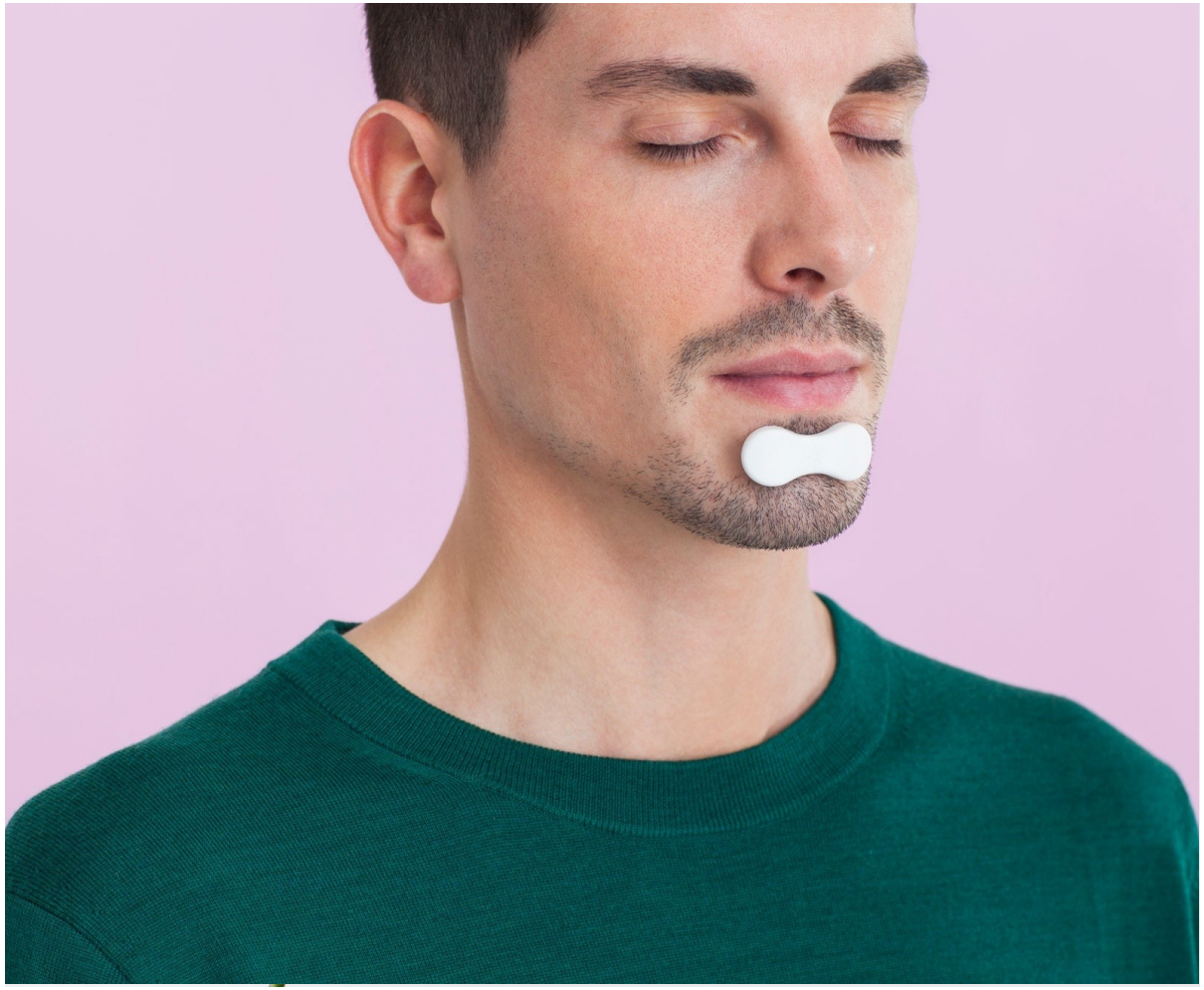
Severe OSA

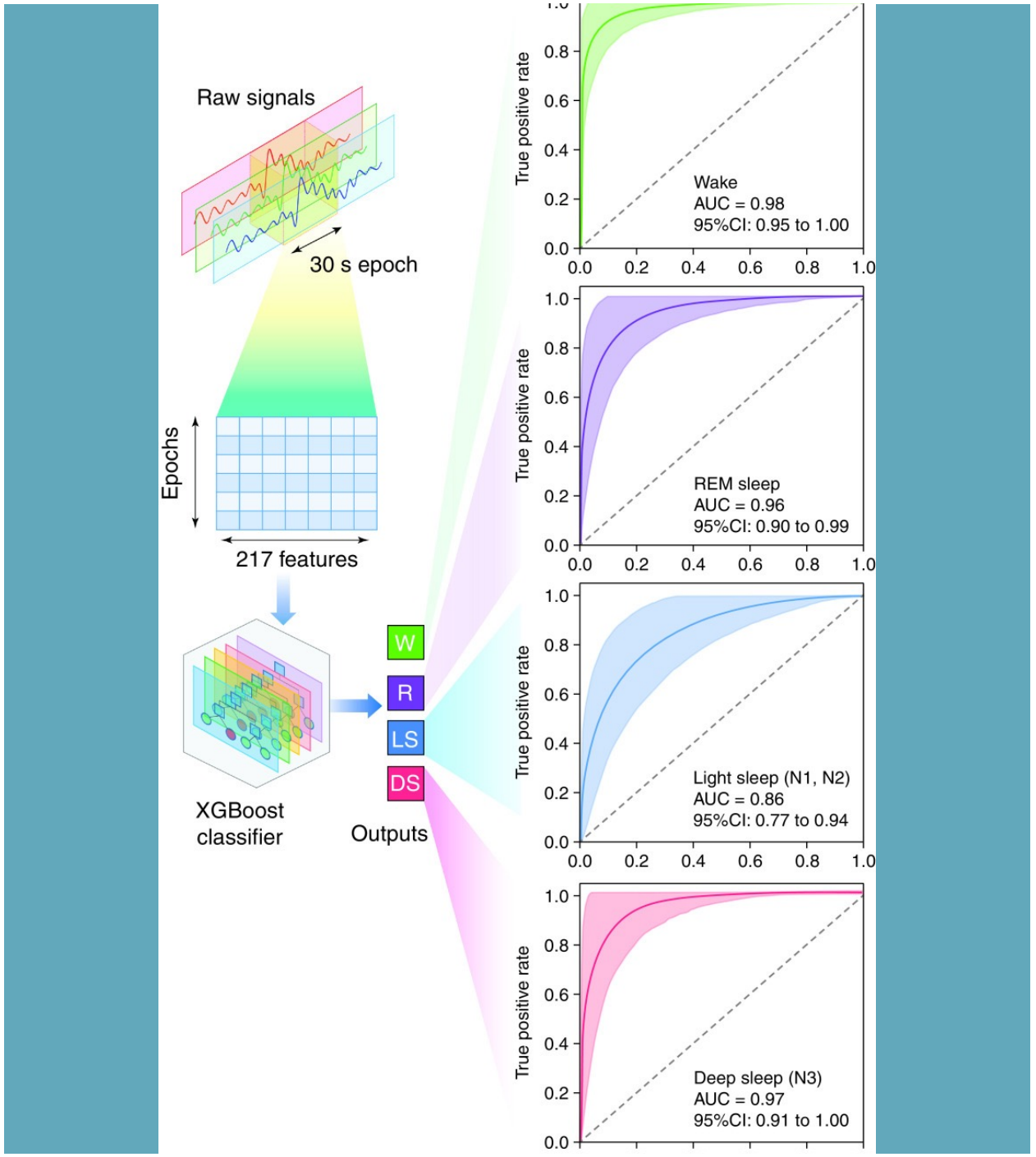
Accuracy comparison of DAHI to 3%AHI using APPLES database

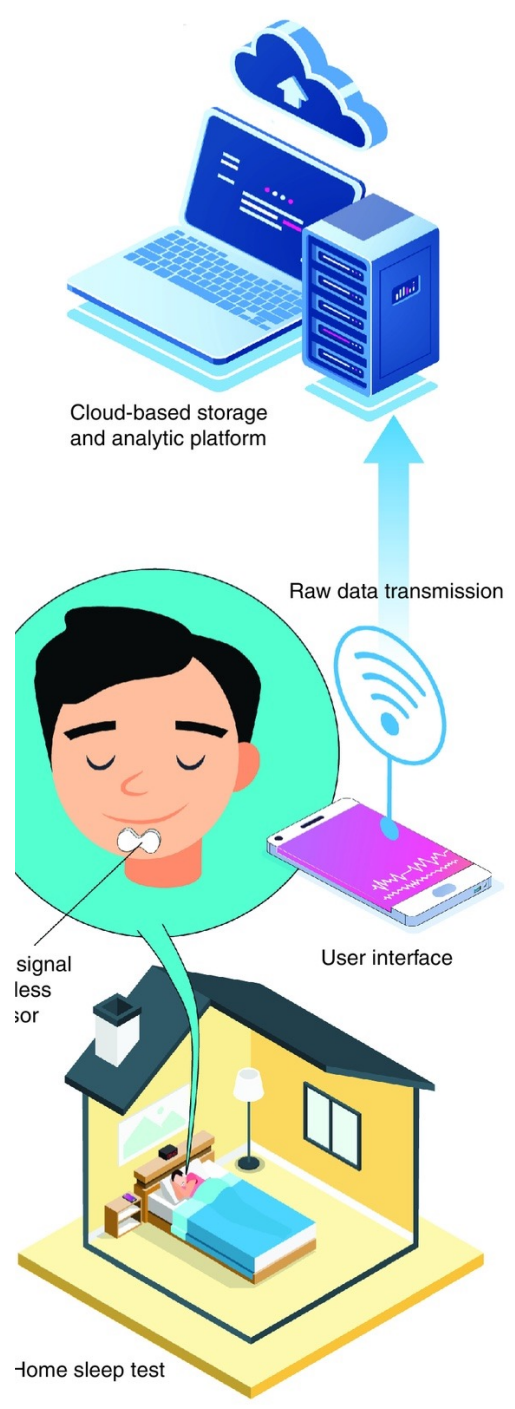

0.5
0.4
Hz
0.3
0.2
0.1
0.0
Stable (2%)
UnStable (97%)
REM (2%)
WK
Fragmentation (43%)
Periodicity (40%)
CVHR (85%)
105
95
BPM
85
75
65
30
Desats (s)
10
100
95
SpO2 (%)
90
85
80
Signal
00:00
01:00
02:00
03:00
04:00
05:00
06:00
07:00

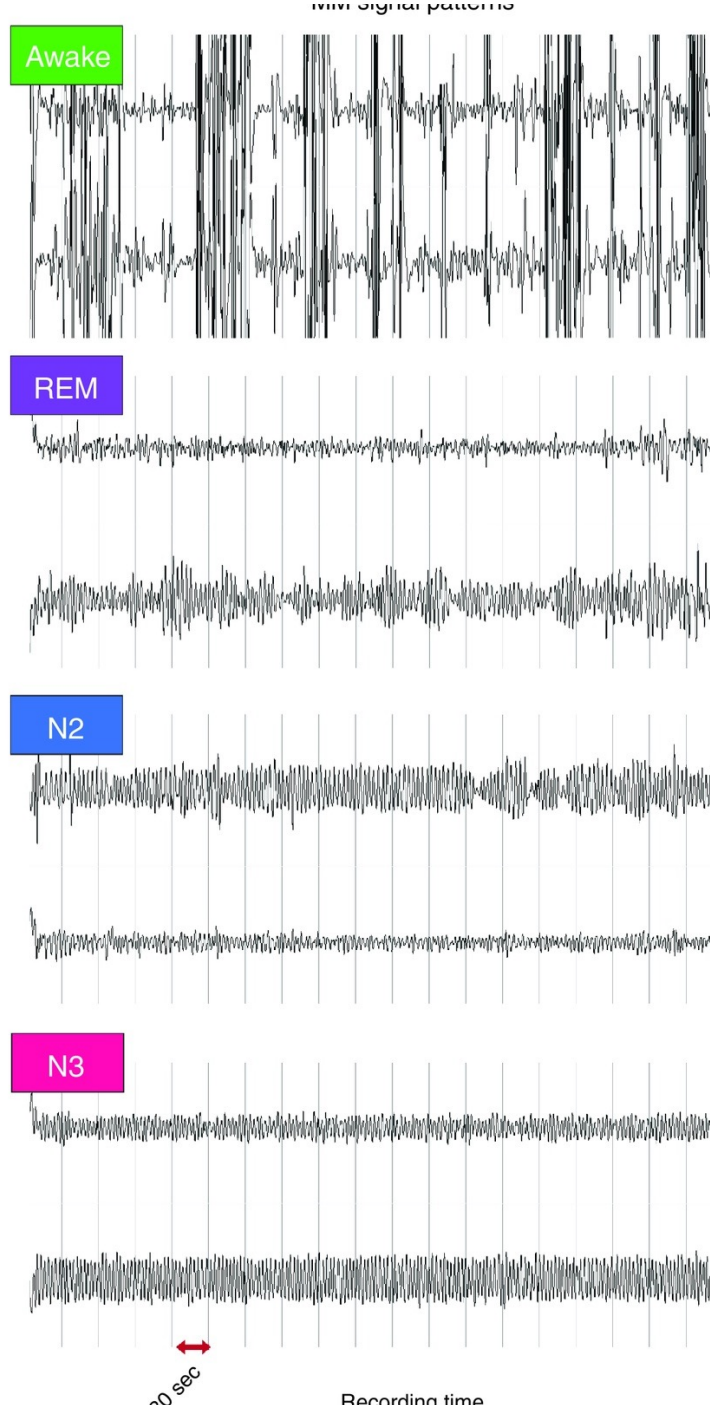
Sunrise Sleep System

- Received clearance February 2023
- Uses mandibular movements
- Validated in children
- Ongoing long term study estimated completion 2024
- 3 outputs
  - mandibular gyroscope
  - mandibular acceleration
  - position



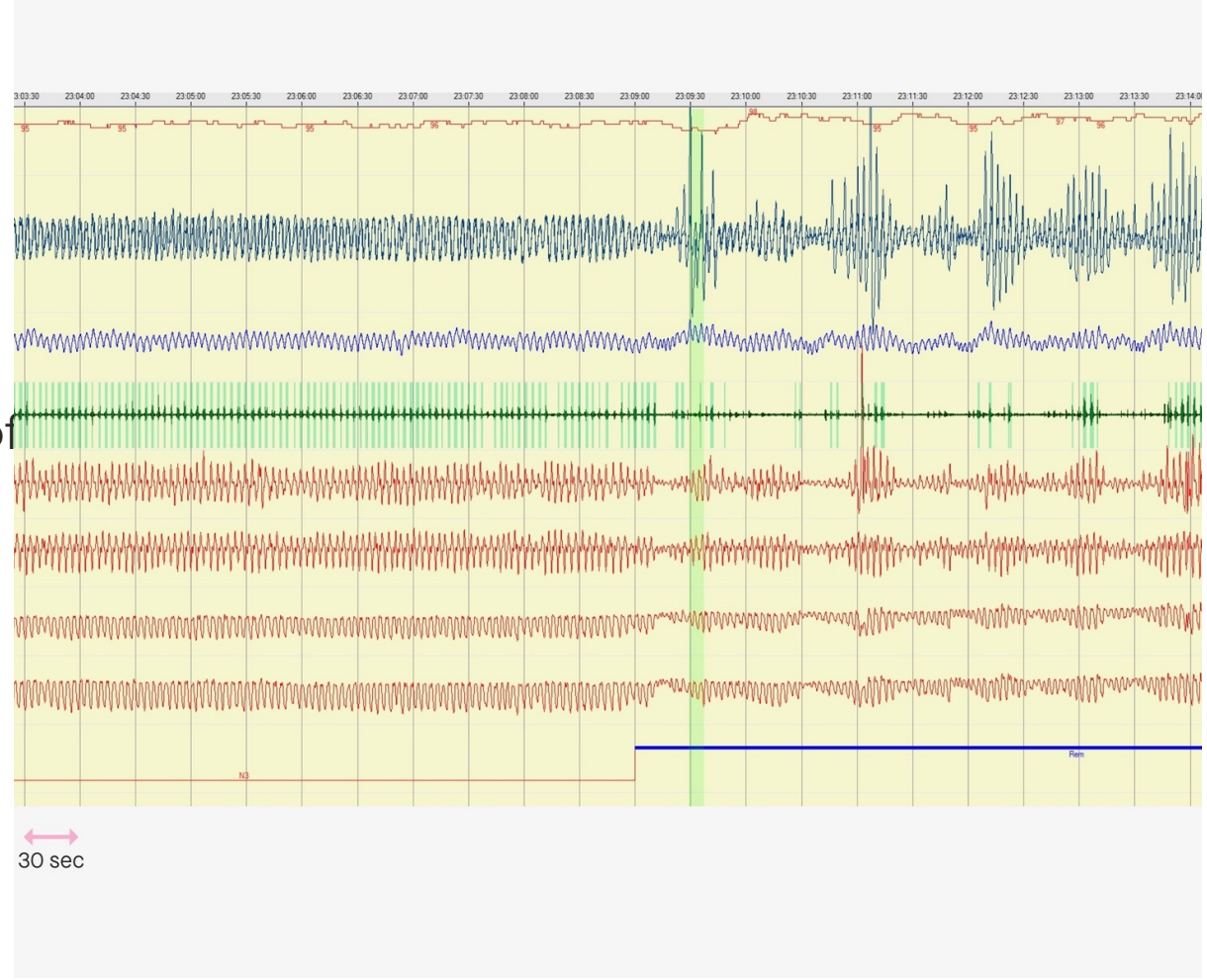

Raw signals
30 s epoch
Epochs
217 features
XGBoost classifier
W
R
LS
DS
Outputs
True positive rate
Wake
AUC = 0.98
95%CI: 0.95 to 1.00
REM sleep
AUC = 0.96
95%CI: 0.90 to 0.99
Light sleep (N1, N2)
AUC = 0.86
95%CI: 0.77 to 0.94
Deep sleep (N3)
AUC = 0.97
95%CI: 0.91 to 1.00

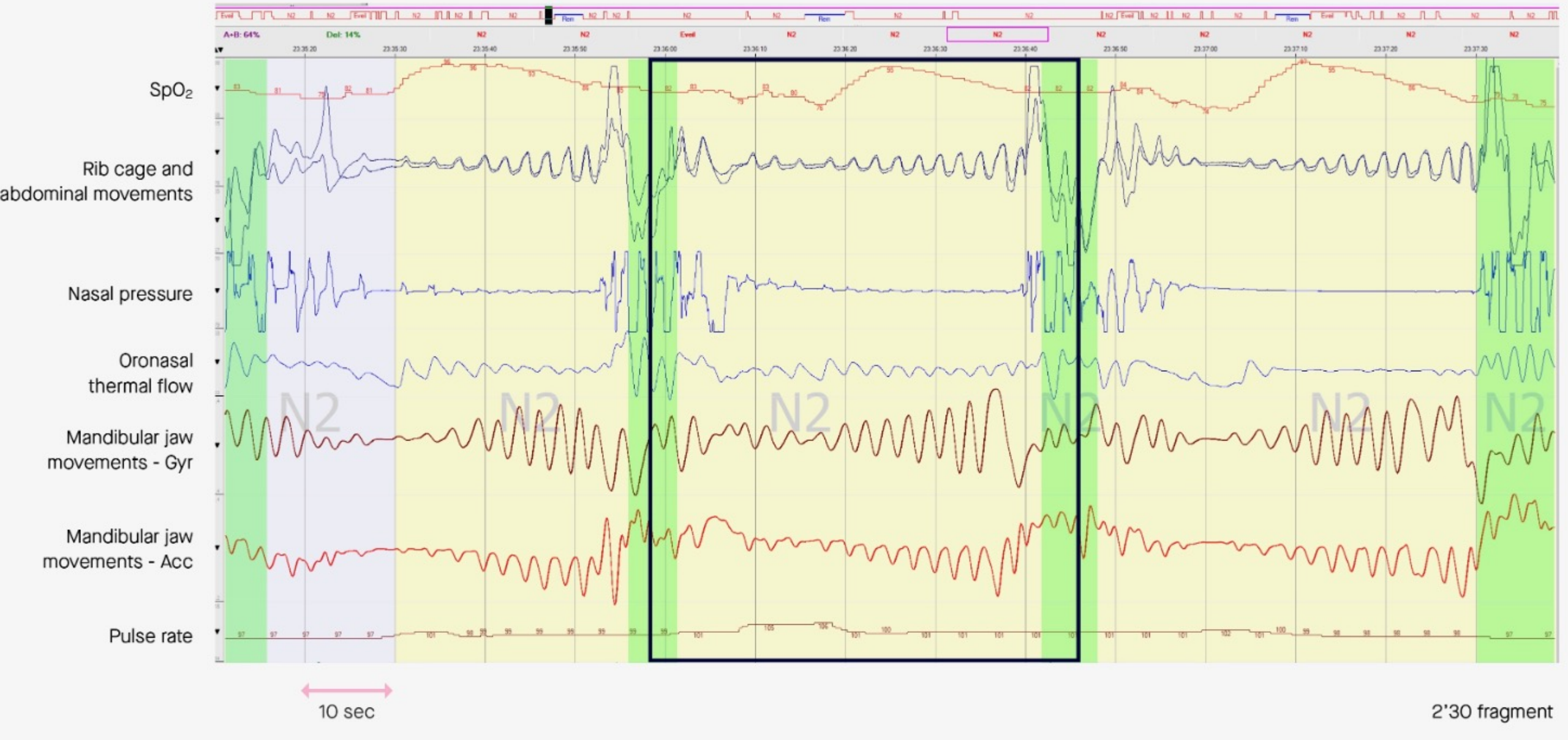

Cloud-based storage and analytic platform
Raw data transmission
User interface
signal
less
sor
Home sleep test

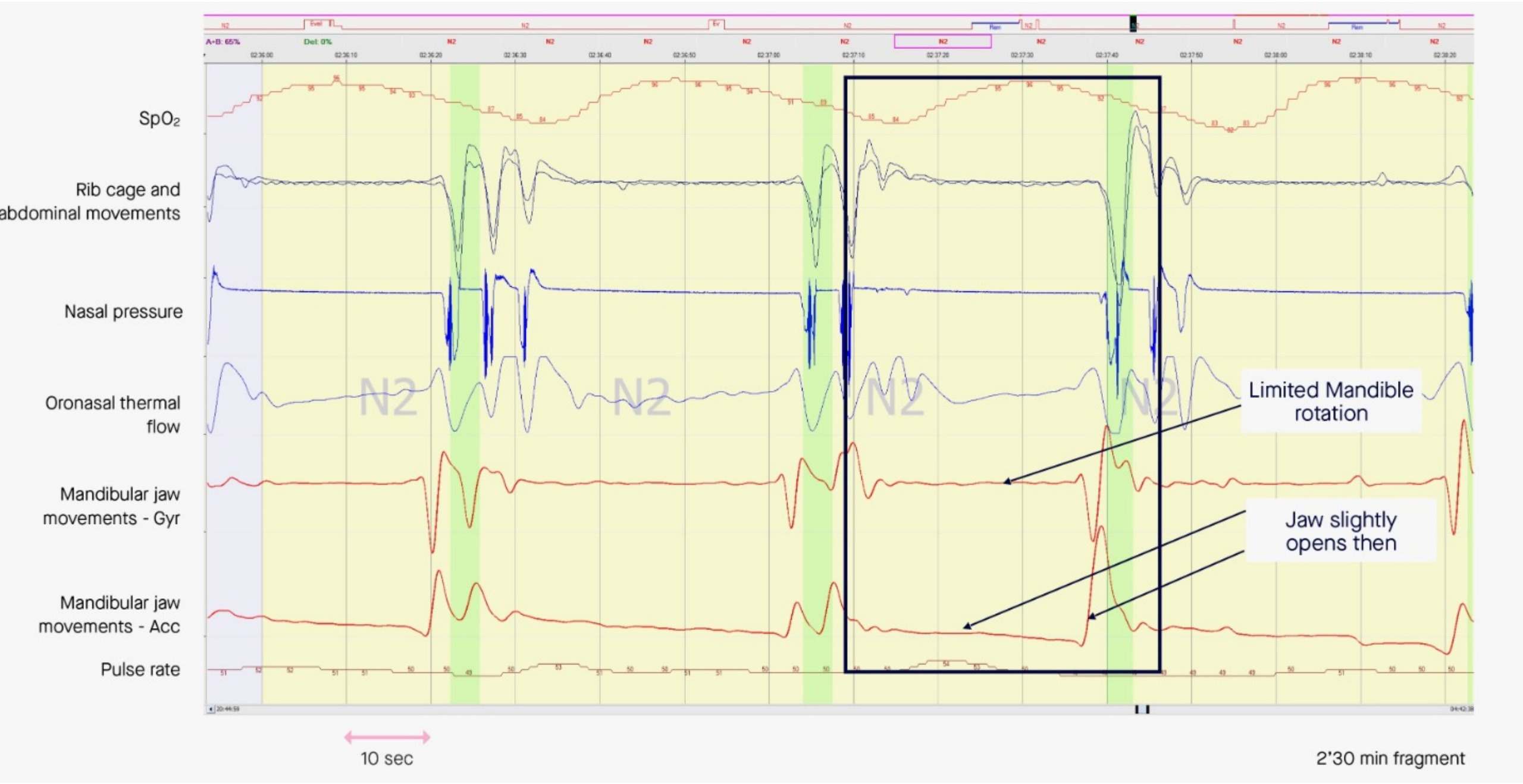

Awake
REM
N2
N3
Recording time

Mandibluar Movements

- Gyroscope
  - Measures displacement of mandible by rotational speed
- Accelerometer
  - measures position of mandible
- Normal displacement during sleep is tenths of mm
  - produced by rotation of mandibular condoyle




SpO2
Rib cage and abdominal movements
Nasal pressure
Oronasal thermal flow
Mandibular jaw movements - Gyr
Mandibular jaw movements - Acc
Pulse rate
N2
10 sec
2'30 fragment


SpO2
Rib cage and abdominal movements
Nasal pressure
Oronasal thermal flow
Mandibular jaw movements - Gyr
Mandibular jaw movements - Acc
Pulse rate
N2
N2
N2
N2
Limited Mandible rotation
Jaw slightly opens then
10 sec
2'30 min fragment

Validation data

Accuracy	False negative rate	
66%	47%	AHI >1 = Sr_RDI 5.75
85%	20%	AHI >5 = Sr_RDI 9.61
94%	12%	AHI >10 = Sr_RDI 13.07

sun✳rise

Sleep Study Report of Doe John

Summary

AHI 32.5

Respiratory Events

		Supine	Non-Sup.	REM	NREM
AHI	**32.5**	42.2	22.8	42.2	22.8
RDI	**46.4**				
OAHI	**32.2**				
CAHI	**0.1**				
ORDI	**46.3**	60.1	32.4	60.1	32.4

Above indices are calculated at 3%.

RERA Index	**13.9**
Respiratory Effort	**80% of TST**
AHI 4%	**30.7**

Awakenings and Arousals Events

Awakening Index	**4.1**
Arl	**45.7**

Oxygen Saturation

ODI 3%	**27.6**
ODI 4%	**18.4**
Mean	**97%**
Min	**85%**
Max	**100%**
Sleep Time < 90%	**8% of TST**
	34 min
Sleep Time < 88%	**5% of TST**
	21 min

Pulse Rate (bpm)

Mean	**52**
Min	**46**
Max	**73**

Position

Position Changes Index	**4.3**
Supine	**36% of TST**
Non-Supine	**64% of TST**

Acupebble

- Uses machine learning algorithm to determine respiratory events from physiological sounds
- Validated against level III HSAT
- FDA cleared
  - Used in Europe since 2021, not yet available in USA
- Sensitivity 92.7%
- Specificity 96.8%

Wesper

- FDA cleared 2023
  - Approved for long term data collection
- Type III device
- Validated against PSG
  - Pearson correlation 0.951 (p =0.0003)
- Channels
  - Abd, thorax
  - Air flow, pressure
  - Oximetry, Heart rate
  - Audio, body position
  - Skin temperature
  - sleep phases

Onera STS

Patch based Level II study

- Head sensor
- Chest Sensor
- Flow Sensor
- Leg Sensor

Validation Data

- 77% faster set up time than PSG
- Increased Total sleep time
- Higher recorded Sp02
- Near 100% correlation in AHI

The Good, the bad, and the ugly

The Good

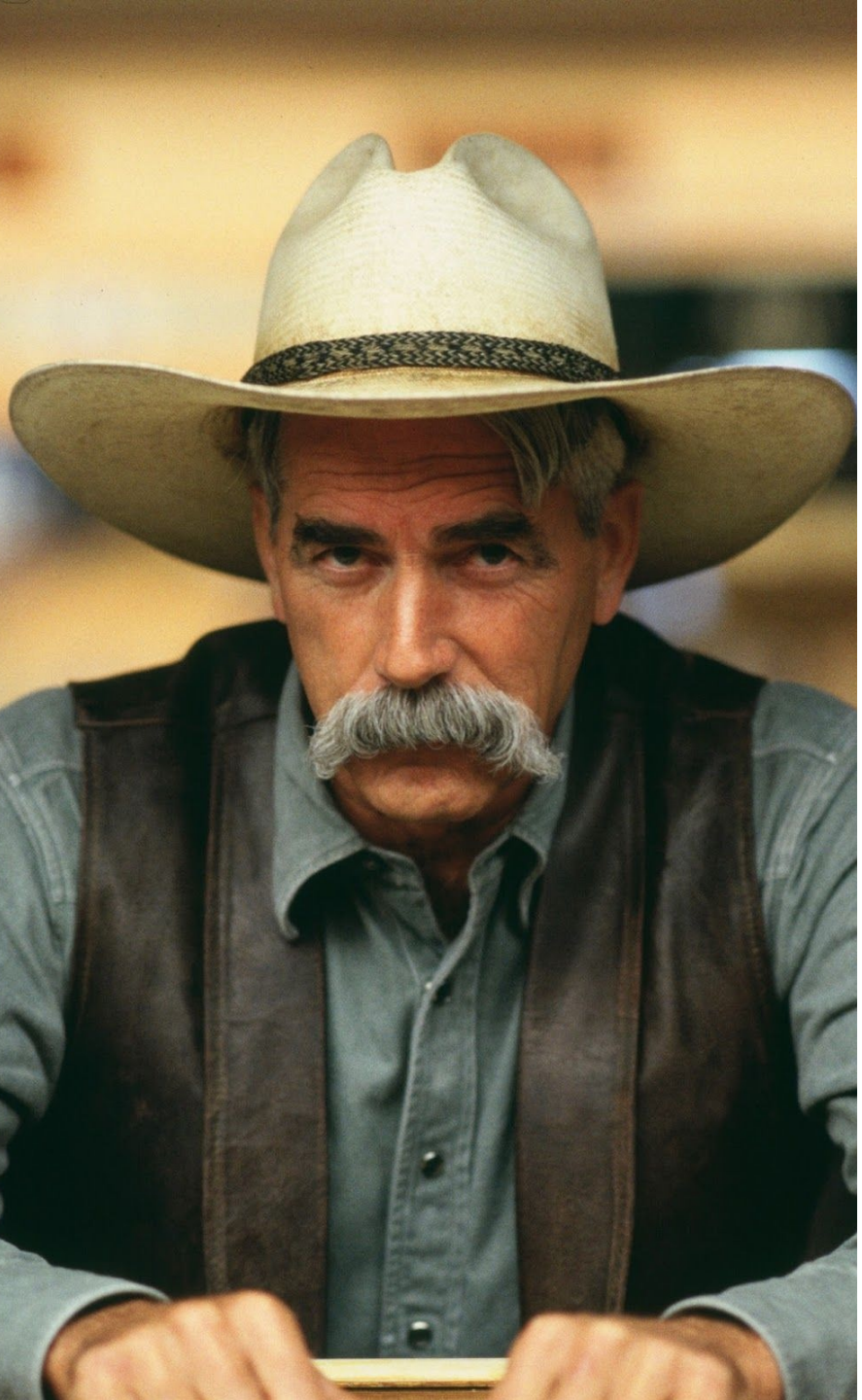
Increased availability for testing, lowering lab burden.

The Bad

Less accurate, increased operator error, less information.

The Ugly

Direct to consumer sleep testing.



So many devices, what to choose?

- New does not mean better
- Evaluate patient population
- Good mix of testing device types
- Is there a role for Level II testing
- Follow AASM HSAT recommendations

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