

Accuracy and Equity of Pulse Oximetry in Sleep Medicine

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Conflicts of Interest

I have NO financial disclosure or conflicts of interest with the presented material in this presentation



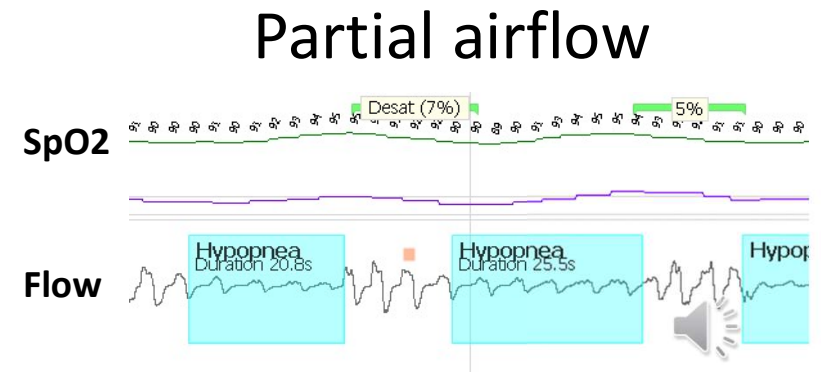
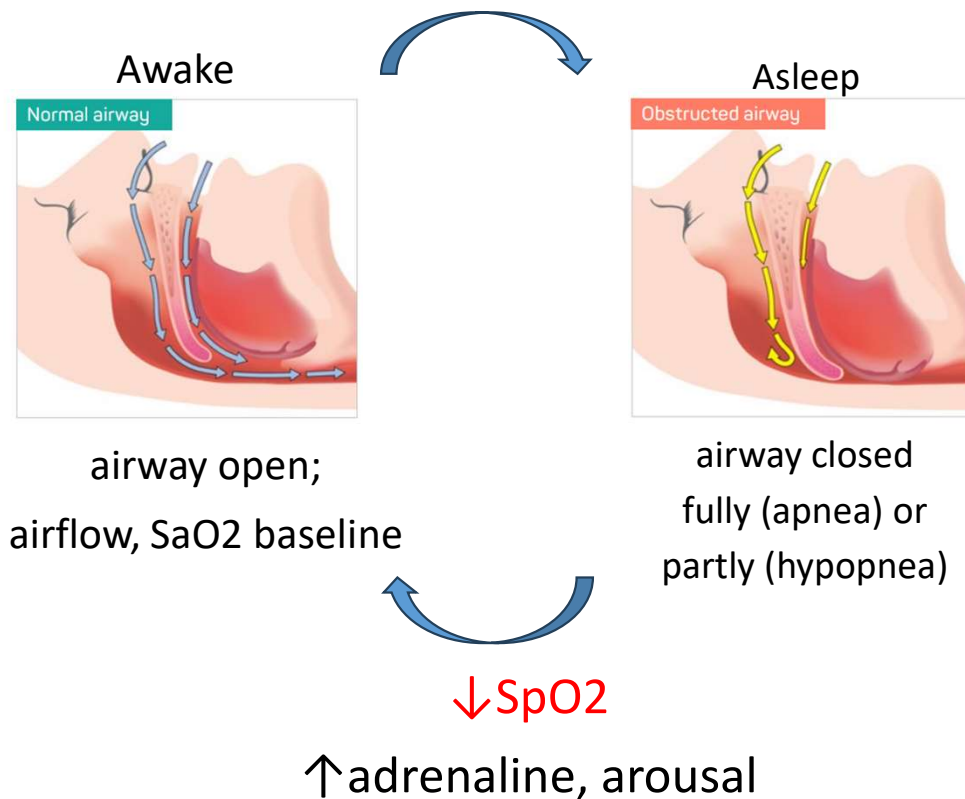
Disparities exist in how well oximetry works

- Among people with darker skin pigmentation, oximeters
 - **overestimate** oxygen saturation (“occult hypoxemia”)
 - show **greater within-subject variability (>4%)** over time

in critically ill or hospitalized

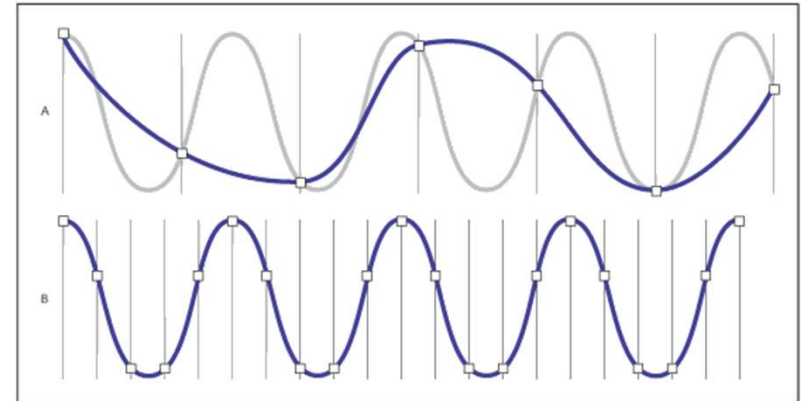
We do not have data about sleep center patients

Obstructive sleep apnea: repetitive airway closure, brief episodes of hypoxia



Sleep studies for diagnosing apnea

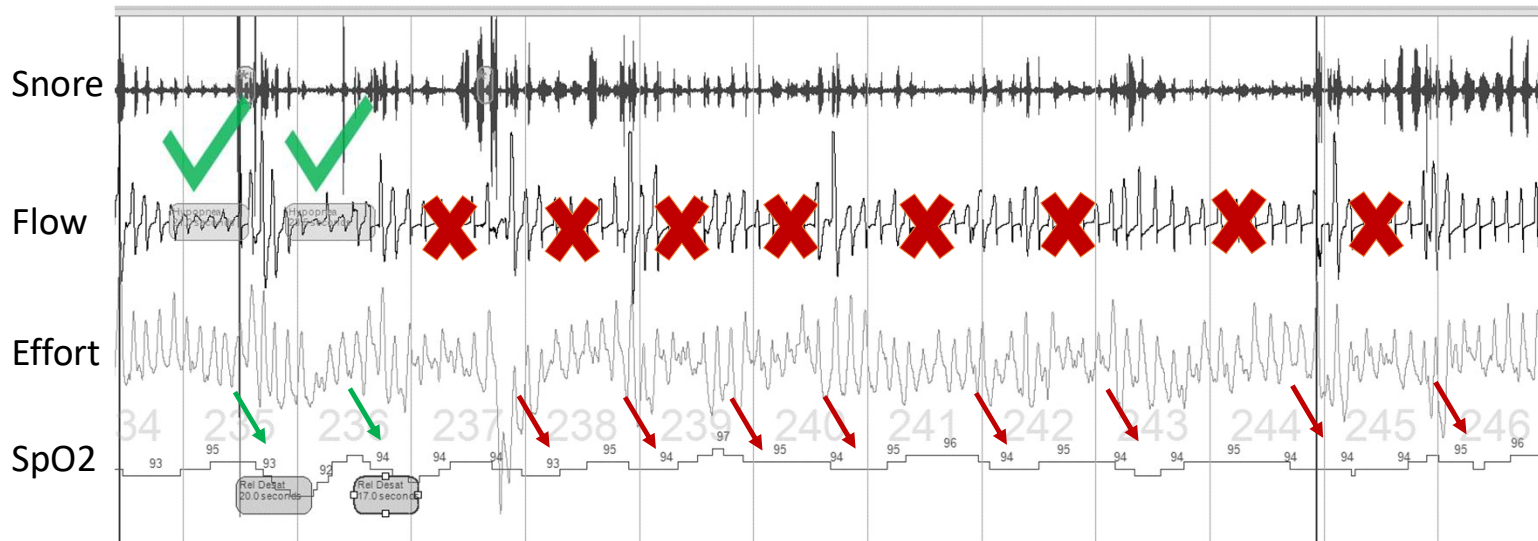
- **SpO2 is a core signal**
- In-lab, home and hospital studies
- Sampling frequency > 10 Hz
- **Thresholds for scoring hypopneas**
 - AASM standard: $\geq 3\%$ desaturation
 - CMS standard: $\geq 4\%$ desaturation



High sensitivity and low within-subject variance are needed.



Hypopneas with <4% desaturation not scored if treatment is to be covered by CMS



Are low values due to underestimation?
Is underestimation related to skin color?



FDA standard: calibration vs clinical environment

	FDA Standard	Sleep medicine
Patients	N=10, healthy	Comorbidities <ul style="list-style-type: none"> • Wide BMI • Heart failure, arrhythmias • Smoking, lung disease • Neuromuscular disease
Darker skin	Larger of N=2 or 15%	more apnea in Black patients
Accuracy	$A_{RMS} \pm 2-3\%$ of ABG values; 95% CI ± 5 to 6%	Need $<\pm 1\%$ in bias Low within-subject variance (trends)
Other		



ogy)

Missing the diagnosis of sleep apnea can have serious consequences

DAYTIME

- **Sleepiness**
 - ↑ **Crash risk**
- **Cognitive**
- ↓ memory, concentration, attention
- ↓ **Mood**
- **Physical**
 - Headache, Impotence
- **Occupational**
 - ↓ productivity
 - Absenteeism
 - Accidents

LONG-TERM

- Hypertension
- Heart disease, arrhythmias
- Stroke
- Alzheimer's
- Pre-diabetes
- Death



Metro-North engineer in fatal derailment had sleep apnea, NTSB says

April 9, 2014 • Metro Magazine Staff • □



Frost and Sullivan, JCSM, 2016

<https://sleepeducation.org/wp-content/uploads/2023/03/obstructive-sleep-apnea-indicator-report.pdf>

Recommendations

- **Calibration studies**

- Must reflect sleep center populations
- Be inclusive (color, race, gender, health conditions)
- Diversity of scientists
- Powered to detect small, within-subject trends

- **Approval standards**

- More accurate, precise trend data

- **Post-market studies**

- in array of settings

- **Clinically meaningful labeling**

- bias and within-subject variance

- **Education**

- clinicians, patients, payers, researchers



Thank you

