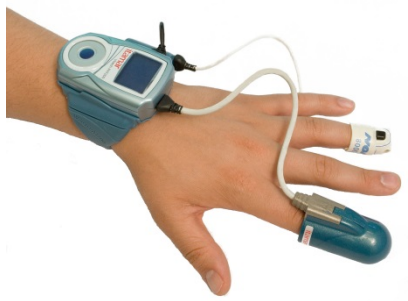
Diagnostic Accuracy of Level IV Portable Sleep Monitors Versus Polysomnography for Obstructive Sleep Apnea: A Systematic Review & Meta-Analysis

Abrahamyan L, Sahakyan Y, Chung S, Pechlivanoglou P, Bielecki J, Carcone SC, Rac VE, Fitzpatrick M, Krahn M



AIM OF THE SYSTEMATIC REVIEW

- To assess the diagnostic ability of Type IV portable monitor (PM) devices compared to polysomnography (PSG) in diagnosing patients with suspected OSA.

(Protocol registration number: CRD42016037470 (PROSPERO)

Classifying OSA Diagnostic Devices

Latest review: conducted by the Tufts Evidence-based Practice Center (commissioned by the AHRQ), covering the period up to September 2010

Table 1. Delineation of operational rules used to classify monitors in sleep studies

Type	Portability	Number of Channels	Indicative signals	≥2 airflow/ effort channels	Identifies sleep/ wake	Measures AHI
I	Facility-based	~14-16	EEG, EOG, EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
II	Portable	≥7	May have EEG, HR*, EOG, chin EMG, ECG/HR, airflow, effort, SaO2	Yes	Yes	Yes
III	Portable	≥4	Airflow and/or effort, ECG/HR, SaO2	Yes	No	No
IV	Portable	~1-3†	[All monitors not qualifying for Type III]	No	No‡	No

AHI = apnea-hypopnea index, ECG = electrocardiography, EEG = electroencephalography, EMG = electromyography, EOG = electro-oculography, HR = heart rate, SaO2 = arterial O2 saturation.

* Heart rate is allowed instead of EEG in Type II monitors. Essentially, many Type II monitors gather the same signals as Type I monitors.

† May have more than three channels, provided that criteria for Type III are not met

‡ May include monitors that measure signals that are in principle able to identify arousals from sleep.

Methods

Study selection criteria	
Participants	**Included**: ≥16 years old patients with symptoms suggestive of OSA. **Excluded**: if >20% of study population had a neuromuscular disease, congenital skeletal abnormalities, narcolepsy, narcotic addiction, dementia/epilepsy/disabling stroke; studies with only healthy general population or established SA/other sleep disorders.
Intervention	**Included**: Type IV PM applied at home/in laboratory for diagnosis of OSA **Excluded**: Type II or Type III monitors; PMs that used only heart rate, heart rate variability, actigraphy or clinical features for diagnosis of OSA.
Comparator	In laboratory PSG study.
Outcomes	Diagnostic performance: sensitivity, specificity, area under the curve, level of agreement of clinical diagnosis or AHI/RDI from Type IV monitors against PSG.
Studies	**Included**: cross-sectional, prospective experimental/quasi-experimental studies, prospective observational studies **Excluded**: <10 study participants for each test; retrospective analysis of clinical databases.

Methods

Information sources

- Ovid MEDLINE(R), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, and Cochrane library from January 1st 2010 to May1st 2016
- Limited to human subjects & English language.

Selection of studies & data extraction

- All stages conducted by two independent reviewers
- Data entered into a structured Excel database

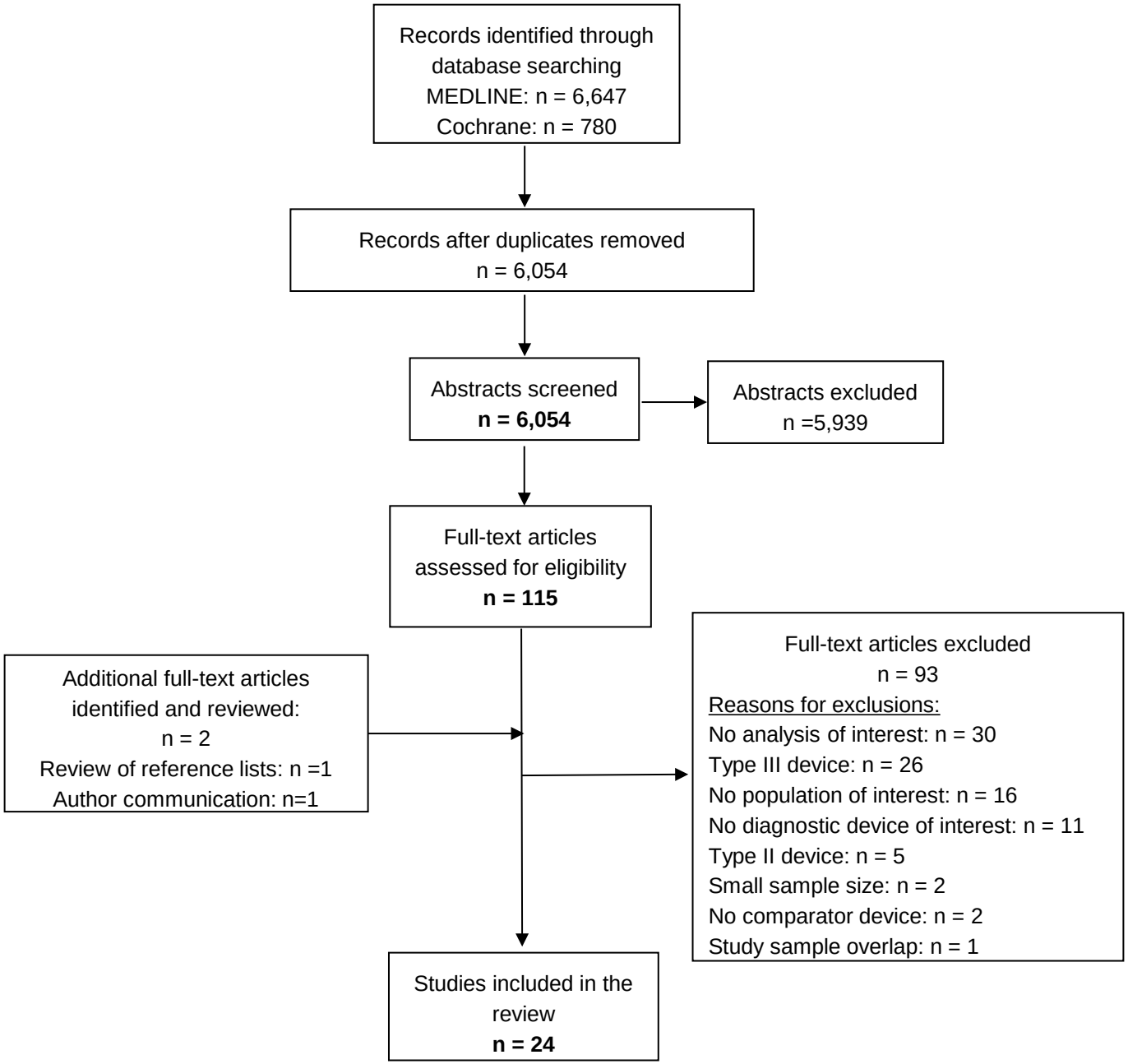
Quality assessment

- Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) tool

Data analysis

- Descriptive summary tables
- Use of a plot digitizer program when needed
- Meta-analysis including all PMs together not considered
- Meta-analysis to obtain average sensitivity and specificity, using bivariate mixed-effects binary regression models
  - If sufficient data was reported to allow calculations, and
  - > 3 studies assessed the same PM

Results: Flow Diagram of Selection of Studies



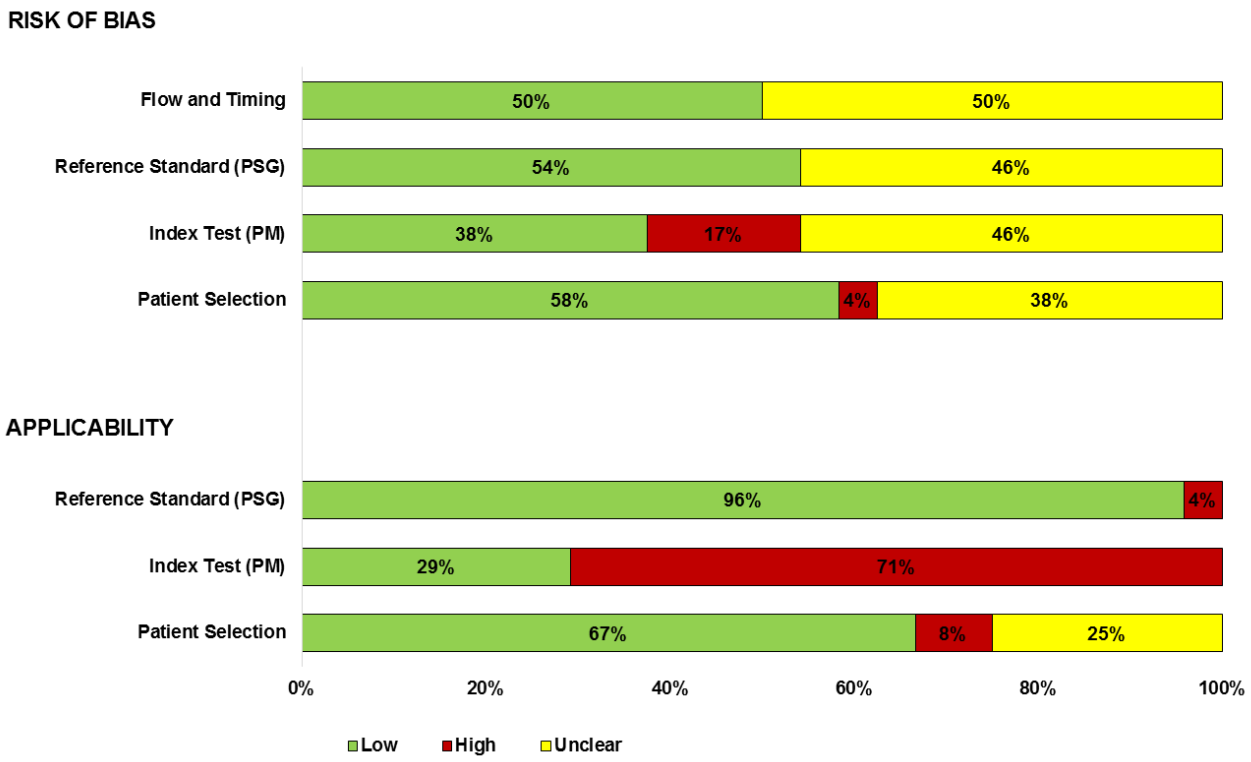
Characteristics of Included Studies (n = 24)

Countries	US (6), Argentina (3), Australia (3), Canada (2), Japan (2), China (2), France (1), Germany (1), Ireland (1), Republic of Korea (1), Saudi Arabia (1), Turkey (1)
Sample size	Varied from 25 to 198 patients
Mean age	Varied from 40.9 to 64.6 years
Males	Varied from 24.0 to 88.4% of study population
Mean BMI	Varied from 25.5 to 36.6 kg/m^2
Mean AHI	Varied from 8.0 to 42.7 events/hour of sleep
Comorbidities	• Hypertension: 20 to 55% of patient population • Coronary heart disease: 7 to 50% • Diabetes: 5 to 30% • Asthma: 6 to 16%
Setting	• 17 compared in-lab PM vs PSG (simultaneous) • 6 tested both in-lab & in-home PM vs PSG • 1 tested in-home PM vs in-lab PSG

Tested Type IV PM devices

- **17** studies tested a single-channel PM, **4** tested a four-channel PM, and **3** tested a two-channel PM
- In total, 10 different PMs have been tested including:
  - **ApneaLink™** (n = 6): a single channel PM measuring nasal airflow; **ApneaLink Ox™** (n = 2): two-channels (ApneaLink with oximetry).
  - **BresoDx™** (n = 2): a single-channel breath sound recording PM
  - **Flow Wizard** (n = 2): a single-channel PM measuring nasal airflow
  - **Oximetry** (n = 4): a single-channel PM using oxymetry
  - **SD-101** (n = 2): a single-channel PM that uses an array of pressure sensors on a bed pad to collect information on respiration
  - **SleepMinder** (n = 1): a single-channel PM representing a non-contact, bedside bio-motion sensor which uses radio-waves to measure respiration and movement
  - **SleepView** (n = 1): a two-channel PM measuring oronasal airflow and oxymetry
  - **WatchPAT 100** (n = 1) & **WatchPAT 200** (n = 3): a four-channel PM (peripheral arterial tone, heart rate, pulse oximetry, and actigraphy)

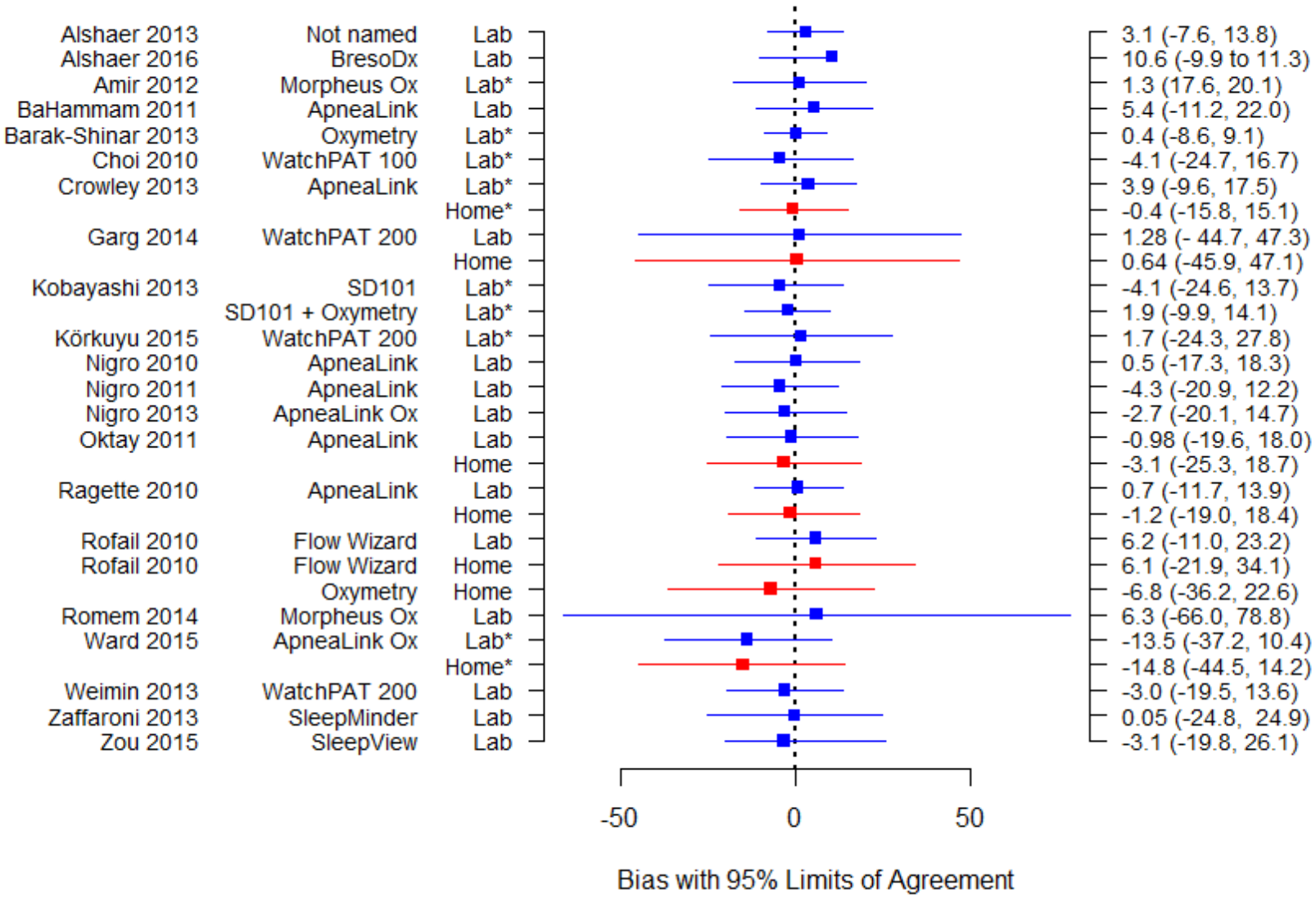
Assessment of Quality: QUADAS-2



- Interval b/in tests appropriate? All receive same reference standard? All patients included in analysis?
- Correctly identifies OSA? Blinded from index test results?
- Blinded from reference standard? Used pre-defined cut-off?
- Consecutive/random enrollment?

- Target condition diagnosed matches review question?
- Conduct and interpretation differ from review question?
- Included patients match review question (inclusion criteria, comorbidities)?

Concordance Between PM AHI/RDI & PSG AHI/RDI



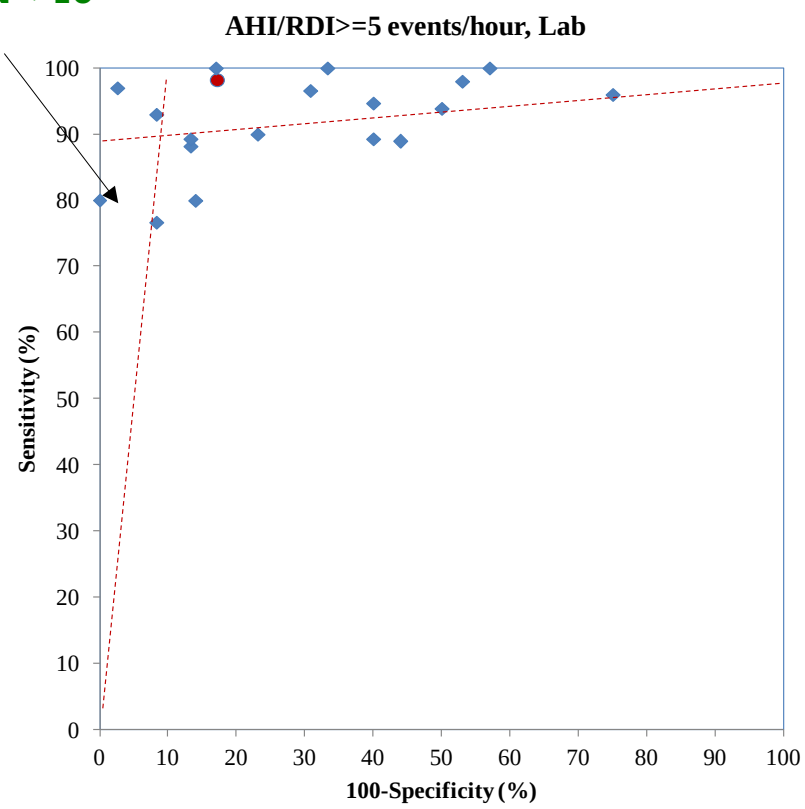
Sensitivity and specificity ranges of Type IV PMs: current and past systematic reviews*

AHI/RDI cut-off values	Single-channel PMs		Two-channel PMs		Three/more channel PMs	
	Sensitivity range	Specificity range	Sensitivity range	Specificity range	Sensitivity range	Specificity range
Current review (January 1st 2010 to May 10th 2016)						
	n = 13		n = 2		n = 3	
≥5	0.68 – 1.00	0.43 – 0.97	0.77 – 0.93	0.83 – 0.92	0.96 – 1.00	0.25 – 0.83
≥15	0.65 – 1.00	0.58 – 0.98	0.66 – 0.74	1.00	0.81 – 0.94	0.67 – 0.77
Past review (up to September 2010)						
	n = 12		n = 6		n = 6	
≥5	0.85 – 0.96	0.50 –1.00	0.92 – 0.98	0.50 – 1.00	0.85 – 1.00	0.67 – 1.00
≥15	0.43 –1.00	0.42 –1.00	0.67 – 0.91	0.78 – 0.96	0.75 – 0.92	0.50 – 1.00

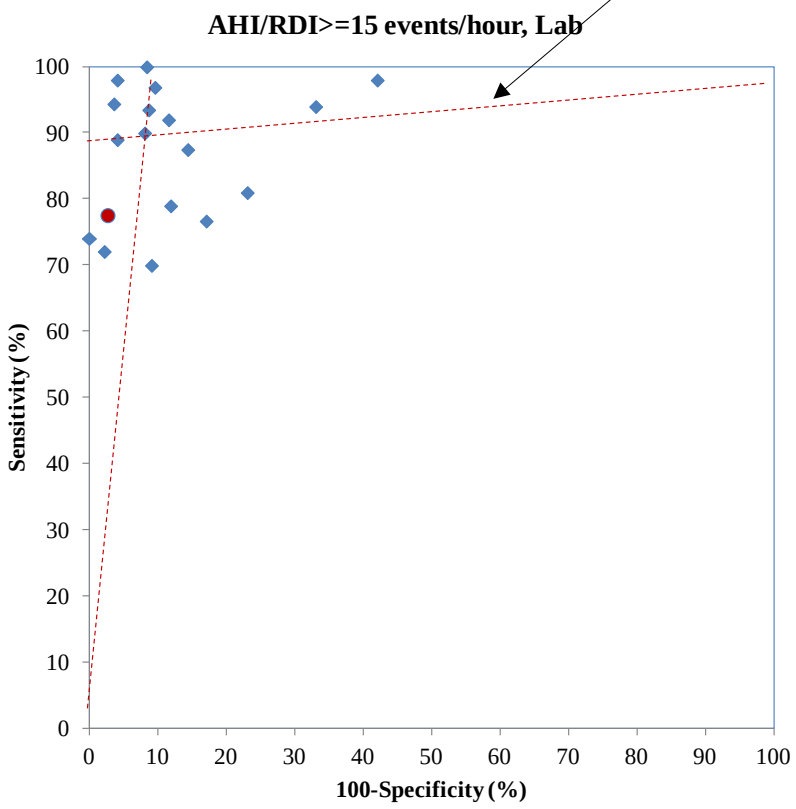
**Studies excluded (n = 6) from this table included: three studies testing single channel PMs and one study testing a two-channel PM that used other thresholds; one study testing a single-channel PM that reported measures other than AHI/RDI; and one study of a four-channel PM that did not report data on sensitivity and specificity.*

AHI: apnea hypopnea index; PM: portable monitor; PSG: polysomnography; RDI: respiratory disturbance index

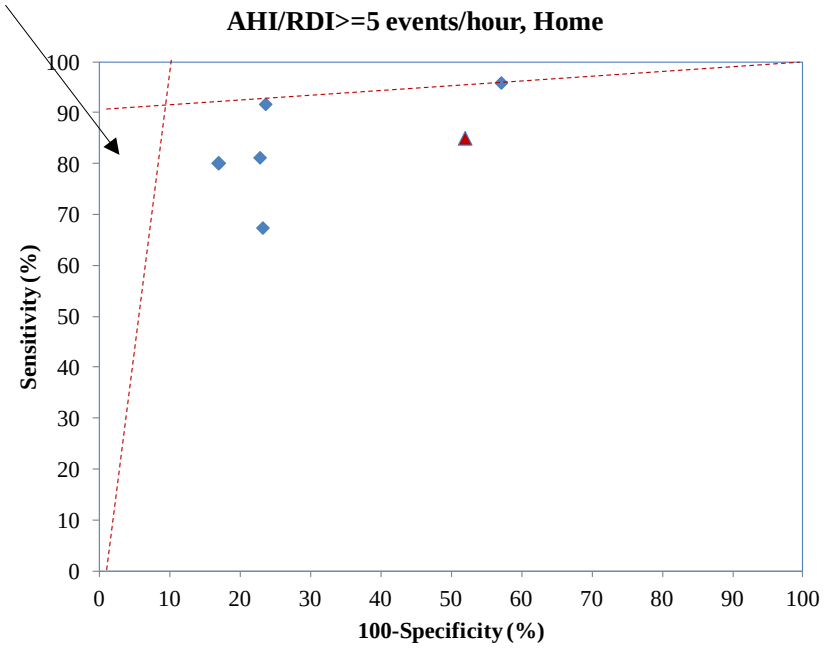
LR⁺ >10


AHI/RDI>=5 events/hour, Lab
Sensitivity (%)
100-Specificity (%)
0
10
20
30
40
50
60
70
80
90
100

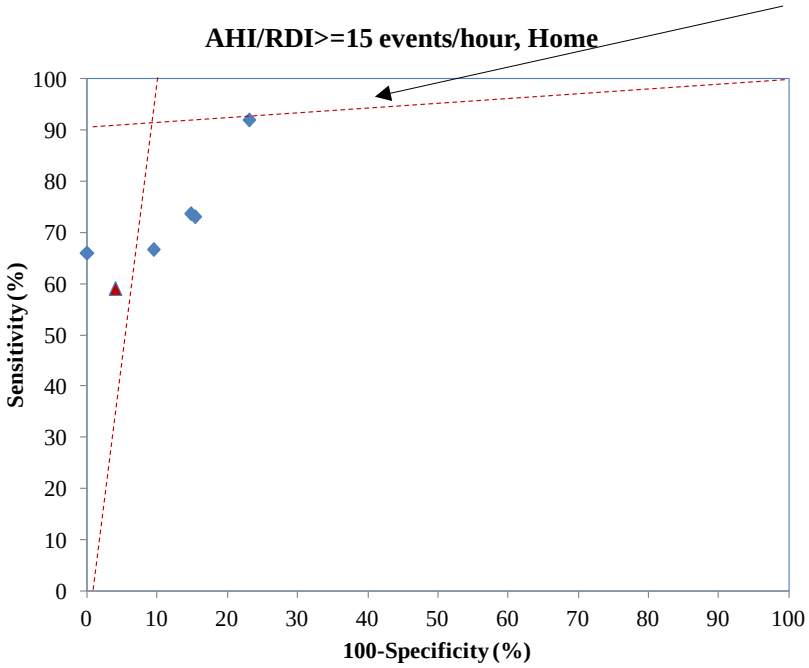
LR⁻ ≤0.1


AHI/RDI>=15 events/hour, Lab
Sensitivity (%)
100-Specificity (%)
0
10
20
30
40
50
60
70
80
90
100

LR^+ >10


AHI/RDI>=5 events/hour, Home
Sensitivity (%)
100-Specificity (%)
0
10
20
30
40
50
60
70
80
90
100

LR^- ≤0.1


AHI/RDI>=15 events/hour, Home
Sensitivity (%)
100-Specificity (%)
0
10
20
30
40
50
60
70
80
90
100

Meta-analysis of diagnostic accuracy of Type IV PM ApneaLink (laboratory setting)

PSG and PM AHI/RDI cut-off	**# of studies**	**Sensitivity (95% CI)**	**Specificity (95% CI)**	**Area under ROC curve**	**Positive LR (95% CI)**	**Negative LR (95% CI)**
≥5 events/hour	6[24-29]	0.88 (0.82, 0.92)	0.64 (0.52, 0.75)	0.842	2.53 (1.86, 3.46)	0.19 (0.12, 0.27)
≥15 events/hour	6[24-29]	0.82 (0.69, 0.90)	0.88 (0.83, 0.91)	0.888	6.61 (4.58, 9.42)	0.21 (0.11, 0.35)

Conclusions

- ✓ The diagnostic accuracy of Type IV PMs varies depending on the number of channels, setting and OSA severity levels.
  - ✓ The sensitivity and specificity estimates of PMs were generally better if they were done in a laboratory setting than at home.
  - ✓ Type IV devices should be tested at home as designed to give more real-world results.
- ✓ In selected patient population with high pre-test probability PMs may offer improved access to diagnostic testing and timely treatment.
- ✓ However, evidence is not strong for their stand-alone, single night use in routine clinical practice
- ✓ Policy recommendations regarding PM use should consider the health and societal implications of false positive and false negative diagnoses and its cost-effectiveness.