

The Apnea Risk Evaluation System (ARES™) integrates physiological data acquired in-home with clinical history and anthropomorphic data to determine presence and severity Obstructive Sleep Apnea (OSA). The ARES has been cleared by the United States Food and Drug Administration (FDA) and was validated in a large multi-site clinical study.

Clinical Validation of the ARES vs. Polysomnography (PSG)

- ❖ The ARES was validated in a multi-site investigation with comparison of the ARES concurrently with PSG in 284 patients. The ARES was also evaluated when applied by the user and worn in-home in 187 studies.
- ❖ The ARES Validation Study meets the Sackett Evidence Level I: Blinded comparison, consecutive patients, reference standard performed on all patients.
- ❖ The ARES Validation Study meets all eight of the following quality indicators:
 - Prospective study
 - Device studied outside the sleep laboratory
 - Random order of subject allocation to PSG or portable test first
 - Low data loss: $\leq 10\%$ of SpO₂
 - High percentage of completions ($\geq 90\%$ of those entered)
 - PSG Methodologies fully described
 - Portable methodology fully described
 - Portable scoring fully described
- ❖ Highlights of the PSG vs. concurrent ARES study
 - PSG failure rate was 3% and ARES failure rate was 1%.
 - Over 30% of the subjects studied had NOT been referred to a sleep laboratory and were presumed to have no prior probability of OSA. 12.7% of the subjects were patients with general medical conditions (e.g., hypertension, diabetes, etc.) and 17.6% were presumably healthy individuals recruited from the community.
- ❖ Highlights of the PSG vs. In-home ARES study
 - ARES failure rate was 2.1%.
 - 25% of the subjects studied had NOT been referred to a sleep laboratory and were presumed to have no prior probability of OSA. 22.5% were presumably healthy individuals recruited from the community.

Clinical Results from In-Lab and In-Home ARES vs. PSG

ARES-RDI compared to PSG-AHI	In-Lab n = 285			In-Home n = 187		
	95% Conf. Int.			95% Conf. Int.		
	Low	Hi		Low	Hi	
Kappa Score	0.85	0.77	0.89	0.77	0.66	0.85
Sensitivity	97.4	95.0	98.8	91.5	87.3	94.4
Specificity	85.6	80.4	88.5	85.7	78.8	90.6
Positive Predictive Value	93.6	91.3	94.9	91.5	87.3	94.4
Negative Predictive Value	93.9	88.3	97.1	85.7	78.8	90.6

This data is excerpted from the following published study:

[Description and Validation of the Apnea Risk Evaluation System: A Novel method to Diagnose Sleep Apnea-Hypopnea in the Home.](#)

Westbrook, P.R., Levendowski, D.J., Cvetinovic, M., Zavora, T., Velimirovic, V., Henninger, D., Nicholason, D. *Chest*. 2005 Oct; 128: 2166-2175.