

Comparison of Parameters for In-home Unattended Limited Channel Devices for the Diagnosis of OSA

The Ranks provided below were derived from responses to a questionnaire returned by 75 members of the American Academy of Sleep Medicine.

	Rank	ARES	Embletta	Nova-Som	Remmers Recorder	Snap	Star-dust II	Watch-Pat
SpO2	1	***	***	***	***	***	***	***
Ability to edit automated scoring or to fully manually score recording	2	***	***				***	***
Airflow – Nasal Pressure	3	***	***		***		***	
Detection and marking of periods of poor signal quality	4	***	***					
Full disclosure recording	5	***	***		***		***	***
Signals needed to visually differentiate obstructive/central events	6	***	***	***	***	***	***	
Pulse rate	7	***	***	***	***	***	***	***
Head/body position	8	***	***		***		***	***
User defined event criteria ¹	8	***	***				***	
Respiratory effort – qualitative (effort present or absent) ²	10	***	***	***	***	***	***	
Awake/Sleep – other indicators (e.g., actigraphy)	11	***	***					***
Arousal Indicators (behavioral) ³	12	***						***
Capability to routinely record two or more nights	13	***		***				
Respiratory effort – quantitative (amount of effort) ⁴	14	***	***		***		***	
Snoring level - qualitative	15	***	***	***	***	***	***	***
Airflow – other ⁵	16	***	***	***	***	***	***	
Monitor signal quality w/ feedback to patient in real time during data acquisition	17	***		***				
Automated differentiation of apnea/hypopnea/flow limitation events	18	***	***			***		
Integrate estimate of prior probability of OSA or other sleep disorder risk by questionnaire	19	***		***	***	***		***
Snoring level - quantitative	20	***				***		***
Battery powered	----	***	***				***	***

¹ SpO2 desaturation criteria can be adjusted, combination of signals required to call an event, etc.

² Single effort band, reliance on snoring or other indirect measure of effort

³ Integrates automatic detection of arousal indicators into the event detection algorithms

⁴ Calibrated effort bands

⁵ Thermistor, extracted from snoring signal, etc.

Quality of the Validation of the In-home Unattended Limited Channel Device

	Rank	ARES	Embletta	Nova-Som	Remmers Recorder	Snap	Stardust II	Watch - Pat
Less than 10% failure rate	1	***					***	***
PSG criteria/parameters used to assess accuracy	2	***	***	***	***	***	***	***
In-home to PSG sensitivity > 0.90, specificity > 0.80.	3	***	***	***				***
Clinical study - in-home vs. PSG > 100 (req'd if the study includes healthy controls)	4	***						***
Clinical study - portable device concurrent with PSG > 40	5	***		***	***	***		***
Clinical study - In-home vs. PSG > 40	6	***	***	***			***	***
Multi-site study	7	***						***
Includes subjects not referred to a sleep lab for a PSG	8	***					***	***
Greater than 20% healthy controls	9	***						
Self-applied by patient	10	***	***	***	***	***	***	***
Multiple night recordings	11	***		***				
Auto-scoring criteria described	----	***			***			

Device	Concurrent with PSG			PSG vs. in-home comparison			
	n	Sensitivity	Specificity	n	Sensitivity	Specificity	Failure Rate
ARES	284	97.4	85.6	187	91.5	85.7	2.0% (4/191)
ARES	92	97.0	85.0	86	86.0	82.0	3.0% (3/93)
Embletta	39 ³	85.2	83.3	50	100.0	81.2	18.0% (11/61)
NovasSom	86	90.4	93.1	45	91.0	83.0	11.7% (6/51)
Remmers Recorder	246	98.0	88.0	--	----	----	----
Snap	119 ^{4,5}	83.6	85.1	31 ⁶	73.3	56.3	----
Stardust II	39	96.6	100.0	39	86.7	77.8	----
Stardust II ⁷	----	----	----	44	93.8	25.0	6.7% (6/90)
Watch_PAT ⁸	29	96.0	100.0	29	82.0	100.0	0.0% (0/29)
Watch_PAT ⁹	----	----	----	98	89.9	92.0	8.1% (8/106)

To compare data assumptions were made about clinical cutoffs when multiple options were presented in the studies. The assumptions are shown immediately below with references on the following page

1 Clinical cutoff PSG AHI > 10

2 Clinical cutoff PSG AHI > 10 by Medicare AHI criteria

3 Estimated from correlation plot using Embletta Auto-scoring (Fig 1.g.)

4,5 Averaged sensitivity and specificity from two studies of equal sample size using PSG AHI > 15.

6. See article reference

7, Clinical cut-off PSG AHI > 15 applied

8 Chicago Criteria, clinical cut-off PSG AHI > 10 selected so results from studies 1 and 2 were comparable

9 Concurrent PSG and Watch_PAT in the home statistics with WP RDI and PSG AHI > 10 provided in personal communication from D. Zou and J. Hedner.

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⁸ Validation a Portable Monitoring Device for Sleep Apnea Diagnosis in a Population Base Cohort Using Synchronized Home Polysomnography, D. Zou et al., Sleep 2006: 29(3): 367-374.