

Appendices

Appendix A- Evidence Tables

Author/ Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments									
Type II Device	Study, inclusion/exclusion	n, age, sex,												
Orr, 1994 Simultaneous PSG and portable studies performed in the laboratory	<p>Dates of data collection: not specified</p> <p>Study Design: not specified</p> <p>Inclusion/Exclusion Criteria: not specified</p> <p>Type II Portable Device: Sleep I/T multi-channel device(8) measurements could be obtained channel device</p> <p>Data analysis-automatic</p>	<p>n= 40 20 pts each from 2 laboratories</p> <p>Age/Gender: not specified</p>	<p>Primary outcome: Correlation of the following sleep parameters</p> <ul style="list-style-type: none"> • Sleep efficiency • Desaturation index • RDI • PLM index 	<p align="center">Sleep Lab</p> <table border="1" data-bbox="1089 711 1333 877"> <tr> <td></td> <td>RDI ≥ 15</td> <td>RDI ≤ 15</td> </tr> <tr> <td>RDI ≥ 15</td> <td>25</td> <td>1</td> </tr> <tr> <td>RDI < 15</td> <td>0</td> <td>14</td> </tr> </table> <p>Portable Device Sensitivity: 100% Specificity: 93%</p> <p>Spearman correlation coefficients: RDI: 0.93 (p<0.0001)</p> <p>Desat Index: 0.96 (p<0.0001)</p>		RDI ≥ 15	RDI ≤ 15	RDI ≥ 15	25	1	RDI < 15	0	14	
	RDI ≥ 15	RDI ≤ 15												
RDI ≥ 15	25	1												
RDI < 15	0	14												

Author/ Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type II Device	Study, inclusion/excl usion	n, age, sex,			
Portier, 2000 Laborator y based PSG and unattended portable home study	Study Design: Inclusion/Excl usion Criteria: Patients excluded if they lived to far from the sleep laboratory, unable to give consent, or had a disability that precluded their participation. Type II Portable Device: 10-18 channel Minisomno	Patients referred to a sleep lab for work-up of sleep apnea n= 103 *n=78 patients had data available for analysis Mean Age: 52 Gender: 82% male BMI: 31	Outcome measures: <ul style="list-style-type: none">• Data quality• Patient perception evaluation• Diagnosis of OSA based on RDI \geq 15	For RDI \geq 15: Sensitivity 30/37= 81% Specificity 40/41= 98% Quality of Data: 26/103 pts (25%) were excluded based on poor quality data 20/103 (20%) had poor quality data with the home unattended study	

Author/ Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type II Device	Study, inclusion/exclu sion	N, age, sex,			
Mykytyn, 1999 Simultaneous PSG and portable study	Study design: 2 groups of 10 patients randomly assigned to receive simultaneous PSG and attended portable study or simultaneous PSG and unattended portable study Inclusion/Excl usion Criteria: Not specified Type II Portable Device: Compumedics PS1 Blinded test reviewer	Male patients referred to a sleep lab for work-up of sleep apnea N= 20	Outcome Measures: Correlation of the portable device with lab based polysomnography in terms of <ul style="list-style-type: none"> • Technical quality of data • Derived sleep indices (ex. AHI) • Final interpretiv e result performed by a clinician 	For AHI >10: Sensitivity: 80% Specificity: 90% For AHI >20: Sensitivity: 100% Specificity: 100% 2/20 pts (10%) had discordant AHI results that would have led to a change in diagnosis Signal Quality: EMG signaling and airflow signaling seemed to present the greatest problems for portable monitoring in the attended and unattended setting Sleep Scoring: (percentage of time the signals were inadequate for scoring sleep) Unattended portable device group: 1.5% Standard	

				<p>polysomnography group: <1%</p> <p>Attended portable device group: 5%</p> <p>Standard polysomnography group: Approx 1%</p> <p>the difference in these was not statistically significant</p> <p>Respiratory event Analysis: Unattended portable device group: 7%</p> <p>Standard polysomnography group: 1%</p> <p>Attended portable device group: Approx 2.5%</p> <p>Standard polysomnography group: <1%</p> <p>the values approached statistical significance for both groups</p> <p>Derived Values: Total sleep time, sleep efficiency, and frequency of arousals did not differ between groups</p>	
--	--	--	--	---	--

				<p>Physician Interpretation of Data:</p> <p>13/20 (65%) portable studies ranked as good or excellent quality of recordings</p> <p>2/20 (10%) of portable studies considered inadequate for interpretation, repeat study recommended</p> <p>20/20 (100%) standard studies ranked as good or excellent</p> <p>Physician Interpretation of Data:</p> <p>Diagnostic concordance in 16/18 (89%) portable studies</p> <p>2 study pairs could not be evaluated secondary to technical quality</p>	
--	--	--	--	--	--

Author/ Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type II Device	Study, inclusion/exclusion	N, age, sex,			
<p>Fry, 1998</p> <p>Simultaneous in laboratory PSG and portable device studies</p>	<p>Study design:</p> <p>Part 1: randomized cross-over trial with all participants scheduled to receive both lab and home based studies</p> <p>Part 2: concurrent study with participants receiving portable and lab based testing simultaneously</p> <p>Inclusion: patients referred for evaluation of sleep-related complaints</p> <p>Exclusion: unable to give informed consent, disabling</p>	<p>Patients referred to a sleep lab for work-up of sleep apnea</p> <p>Part 1: N=95 *N=77 participants who completed both lab and home based study and included in the analysis</p> <p>Mean Age: 49.3</p> <p>Part 2: N=16 Mean Age: 49.9</p>	<p>Outcome Measures:</p> <p>Correlation of the following sleep parameters</p> <ul style="list-style-type: none"> • Sleep efficiency • Desaturation index • RDI • PLM index 	<p>Quality of Data:</p> <p>95% of all epochs were scorable for all parameters recorded</p> <p>Range of correlational values for sleep parameters r = 0.775-0.999</p> <p>Range of correlational values for respiratory parameters r = 0.923-0.999</p> <p>Range of correlational values for limb movement parameters r = 0.907-0.972</p>	

	<p>condition making it difficult to carry out the home procedure, regarding specific recording not part of the standard recording device</p> <p>Portable device: DHHS, in-lab technician initiated home recordings 10 measurements (18 channels)</p> <p>Blinded reviewer</p>				
--	--	--	--	--	--

Author/ Year Device Type	Study Design	Demographic s	Intervention, outcome measures; instruments	Results	Methodological Comments
Type II Device	Study, inclusion/ex clusion	N, age, sex,			
Iber, 2003 Laboratory PSG with unattended in home study	<p>Study design: multicenter trial</p> <p>Inclusion: volunteer subjects without preexisting sleep clinic evaluations not already participating in the Sleep Heart Health</p> <p>Exclusion: Not specified</p> <p>Portable device: Compumedics PS2</p> <p>Recording Analysis: Automatic with manual editing capability</p> <p>Blinding: not specified</p>	<p>N=76</p> <p>N=64, number of participants with analyzable data</p>	<p>Outcome Measures:</p> <p>Sleep parameters</p> <p>Effect of monitoring location on sleep and respiration</p> <p>RDI classification</p>	<p>Intraclass correlation ranges for RDI $r = 0.75-0.9=83$</p> <p>12/76 (16%) participants were excluded from analysis secondary to poor quality data</p>	

Author/ Year Device Type	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Ancoli- Israel 1997	<p>In-Home Unattended portable device and standard monitoring in the laboratory setting</p> <p>In-Home study performed first in all patients followed by PSG</p> <p>Inclusion: volunteer subjects already participating in a larger study; chosen based on an interview specifically suggestive of OSA or likely not to have OSA</p> <p>Exclusion: Not specified</p> <p>Portable device: Nightwatch System</p> <p>Recording Analysis: Automatic with manual editing capability</p> <p>Blinding: not specified</p>	<p>Patient volunteers enrolled in another study</p> <p>N=36 Men- 34/36 Women- 2/36</p> <p>Age: 33-60 Mean 48.5</p>	<p>Outcome Measure: diagnosis of OSA</p>	<p>Results based on n=34</p> <p>For RDI \geq 10</p> <p>Sensitivity: 25/25= 100%</p> <p>Specificity: 5/8= 63%</p> <p>Data Loss: Portable Device 1/36 (3%) PSG 1/36 (3%)</p>	

Author/ Year Device Type	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Whittle 1997	<p>Two part study: 1. Validation study with laboratory PSG and unattended home studies to determine portable device AHI to be used in the prospective trial as diagnostic of OSA 2. Prospective trial with all subjects receiving home studies</p> <p>Inclusion: consecutive patients referred for evaluation of OSA; physician chose participants to receive a sleep study Exclusion: Physical or mental difficulty that would not allow the patient to operate the equipment unsupervised. Clinical suspicion of cataplexy or PLM disorder.</p> <p>Portable device: EdenTrace</p> <p>Recording Analysis: Automatic with manual editing capability</p> <p>Blinding: blinded reviewer</p>	<p>validation study n=23</p> <p>prospective trial n=149</p> <p>mean age=49 BMI= 33 Sex 75% male</p>	<p>Outcome Measures: Diagnosis of OSA Time to diagnosis Cost</p> <p>12</p>	<p>AHI >15 for PSG and AHI >30 for the portable device</p> <p>Sensitivity: 75% Specificity: 58%</p> <p>Data loss 27/149 (18%) of portable studies were not analyzable</p>	

Author/ Year Device Type	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Parra 1997	<p>In-Home Unattended portable device and standard monitoring in the laboratory setting</p> <p>Inclusion: consecutive patients referred for evaluation of OSA; physician chose participants to receive a sleep study</p> <p>Exclusion: Not specified</p> <p>Portable device: EdenTec</p> <p>Recording Analysis: Automatic with manual editing capability</p> <p>Blinding: blinded reviewer</p>	<p>N=89</p> <p>Mean age= 54 Men=73 Women=16</p> <p>BMI=29</p>	<p>Outcome Measure: diagnosis of OSA</p> <p>concordance for clinical decision making based on study results</p>	<p>AHI >10 for PSG and AHI >18 for the portable device</p> <p>Sensitivity: 73% Specificity: 80%</p> <p>AHI>10 for PSG and AHI >23 for the portable device</p> <p>Sensitivity: 63% Specificity: 93%</p> <p>Clinical decision making: 89% concordance</p>	

Author/ Year Device Type	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Redline 1991	<p>Inclusion: health volunteers, relatives of apneic patients, patients with sleep related complaints, patients with pulmonary disease</p> <p>Exclusion: not specified</p> <p>Portable device: EdenTec</p> <p>Reviewer: Blinded</p>	<p>N=51</p> <p>* results were reported for n=25 N=20, participants who underwent simultaneous PSG and portable studies</p> <p>N=5, participants who underwent PSG and unattended home portable studies</p> <p>mean age range: 33-59</p> <p>BMI: 26-31</p> <p>Sex: 56-83% male</p>	<p>Outcome Measures:</p> <p>Comparison of RDI</p> <p>Reproducibility of respiratory parameters</p>	<p>Correlation data for RDI ≥ 10 r = 0.96</p> <p>Diagnostic agreement 20/21 (95%)</p>	

Author/ Year Device Type	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
White 1995	<p>Inclusion: consecutive patients referred for evaluation of OSA; physician chose participants to receive a sleep study</p> <p>Exclusion: Physical or mental difficulty that would not allow the patient to operate the equipment unsupervised. Clinical suspicion of cataplexy or PLM disorder.</p> <p>Portable device: Nightwatch System</p> <p>Recording Analysis: Automatic with manual editing capability</p> <p>Blinding: blinded reviewer</p>	<p>N=100</p> <p>N=30, participants undergoing simultaneous laboratory based PSG and portable studies</p> <p>N=70, lab PSG and home unattended portable studies</p>	<p>Outcome Measures:</p> <p>Diagnosis of OSA</p> <p>Comparison of various parameters of sleep</p>	<p>AHI >10 for portable device studies in the laboratory Sensitivity: 100% Specificity: 64%</p> <p>AHI >20 for portable device studies in the laboratory Sensitivity: 77% Specificity: 88%</p> <p>AHI >10 for portable device studies at home Sensitivity: 91% Specificity: 71%</p> <p>AHI >20 for portable device studies at home Sensitivity: 86% Specificity: 83%</p> <p>Data loss 2.8% of portable studies were not analyzable</p>	

Author/ Year Device Type	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Dingli 2003	<p>Inclusion: consecutive patients referred for evaluation of OSA</p> <p>Exclusion: Participant residence greater than 50 miles from the sleep center.</p> <p>Portable device: Embletta</p> <p>Recording Analysis: Automatic with manual editing capability</p> <p>Blinding: blinded reviewer</p>	<p>N=101</p> <p>N=40, participants undergoing simultaneous laboratory based PSG and portable studies</p> <p>N=61, lab PSG and home unattended portable studies</p> <p>Mean BMI: 31/32</p> <p>Mean Age: 46/50</p>	<p>Outcome Measures:</p> <p>Diagnosis of OSA</p> <p>Comparison of various parameters of sleep</p>	<p>PSG AHI ≥ 15 and AHI ≥ 20 for portable device studies (based on the results of 50 studies) Sensitivity: 61% Specificity: 75</p> <p>Diagnostic accuracy for ruling out disease 9/9=100%</p> <p>Diagnostic accuracy for ruling in disease 23/23=100%</p> <p>Data loss 11/61 (18%) of portable studies were not analyzable</p>	

Author/ Year Device Type	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Reichert 2003	<p>Inclusion: consecutive patients referred for evaluation of OSA</p> <p>Exclusion: not specified</p> <p>Portable device: NovaSom QSG</p> <p>Blinding: blinded reviewer</p> <p>Patients underwent simultaneous laboratory PSG and portable device studies and, 3 separate nights of home unattended portable device studies</p>	<p>N=51</p> <p>N=45, participants who completed both studies</p> <p>N=61, lab PSG and home unattended portable studies</p> <p>Mean BMI: 30</p> <p>Mean Age: 52</p> <p>Gender 75% male</p>	<p>Outcome Measures:</p> <p>Diagnosis of OSA</p> <p>Comparison of various parameters of sleep</p>	<p>Results for the portable device as compared to PSG:</p> <p>AHI ≥ 15 for attended portable studies Sensitivity: 95 \pm 5% Specificity: 91 \pm 6%</p> <p>AHI ≥ 15 for unattended portable studies Sensitivity: 91 \pm 6% Specificity: 83 \pm 8%</p> <p>Results for portable device studies performed in the home versus those performed in the laboratory:</p> <p>AHI ≥ 15 for attended portable studies Sensitivity: 94 \pm 5% Specificity: 90 \pm 6%</p> <p>AHI ≥ 15 for unattended portable studies Sensitivity: 89 \pm 7% Specificity: 80 \pm 9%</p> <p>Data loss: 6.25% of portable studies were not</p>	

Author	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Ficker, 2001	<p>Study design: not specified</p> <p>Inclusion: consecutive patients referred to a sleep disorder center for suspected OSA</p> <p>Portable Device: Somnocheck</p> <p>Results analysis: blinded reviewer</p>	<p>N=51</p> <p>86% males</p> <p>Mean age: 53.4</p> <p>Mean BMI: 29</p>	<p>Outcome measures: Desaturations</p> <p>Apnoeas index</p> <p>Hypopnea index</p> <p>Apnoea-Hypopnea Index</p>	<p>Manual scoring vs. Automatic Scoring:</p> <p>AHI>5 Sensitivity: 94%/83% Specificity: 100% vs. 87% PPV: 100% NPV: 88% Accuracy: 96% vs. 84%</p> <p>AHI>10 Sensitivity: 97% vs. 83% Specificity: 100% vs. 95% PPV: 100% NPV: 96% Accuracy: 98% vs. 88%</p> <p>AHI >20 Sensitivity: 76% vs. 71% Specificity: 100% vs. 93% PPV: 100% NPV: 86%</p>	<p>Noted limitations of the study included the fact that the test was performed in a sleep lab and sensors were applied by trained staff. This will not be available to those using this diagnostic test in the home setting. The study also noted that diagnostic accuracy is dependent upon pre-test probability; for those patient requiring PSG based on symptoms, using such a portable</p>

				<p>Accuracy: 90% vs.84%</p> <p>AHI>40 Sensitivity: 69% vs. 61% Specificity: 100% vs. 100% PPV: 100% NPV: 90% Accuracy: 92% vs. 90%</p> <p>Correlational data for number of oxygen desaturations 0.93</p>	<p>recording device in a less well- selected group of patients must be expected to result in a lower level of specificity.</p>
--	--	--	--	--	--

Author	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodolog ical Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Zuconi , 1996	<p>Study design: not specified</p> <p>Inclusion: consecutive patients suspected of suffering from OSA</p> <p>Portable Device: Micro-Digitrapper</p>	<p>N=29</p> <p>38% males</p> <p>Mean age: 53</p>	<p>Outcome measures: AHI</p>	<p>Automatic vs. Semi- Automatic Scoring:</p> <p>AHI>10 Sensitivity: 100% vs. 100% Specificity: 100% vs. 100% PPV: 100% NPV: 100%</p>	<p>Small sample size, not generalizable to the Medicare population.</p>

				<p>AHI >20 Sensitivity: 94% vs. 94% Specificity: 100% vs. 92% PPV: 100% vs. 94% NPV: 93% vs. 92%</p> <p>AHI>40 Sensitivity: 55% vs. 91% Specificity: 95% vs. 94% PPV: 86% vs. 91% NPV: 94% vs. 77%</p>	
--	--	--	--	--	--

Author	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Claman, 2001	No specific research design noted, but simultaneous sleep monitoring was performed by formal PSG and Bedbugg. Inclusion criteria:	N=42 (consecutive sample of 42 volunteers were recruited from sample population who had been referred for PSG-31 males	Outcome measures: AHI (apnea/hypopnea index) (For PSG, AHI was determined based on sleep time.	Using Pearson's Correlation coefficient, the AHI correlation between PSG and Bedbugg was 0.96.	Instrumentation bias may exist (both diagnostic test used different ways of determining AHIs)

	<ul style="list-style-type: none"> • Age 18 and older • Clinical suspicion of uncomplicated OSA • Patients already scheduled for full PSG <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Exhibiting flu-like symptoms • Primary complaint of insomnia • Suspected respiratory failure or hypoventilation • Suspected narcolepsy or idiopathic hypersomnia 	and 11 females, mean age was 54	<p>For Bedbugg, AHI was determined based on total duration of recorded data.</p> <p>Correlation was determined AHI from PSG with AHI of Bedbugg.</p>	<p>Using PSG as a reference, for AHI>15, Bedbugg had a sensitivity of 85.7%; for AHI <15, Bedbugg had a specificity of 95.2%.</p> <p>Bedbugg had a PPV of 94%, and a NPV of 87.5%.</p>	<p>In the demographic characteristic section, study did not mention if AHI was not statistically different.</p> <p>Based on this study, very few patients in Medicare age group were included in the study, making this study difficult to generalize to the Medicare population</p>
--	---	---------------------------------	--	--	--

Author/Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Man, 1995	No specific research design was noted. 104 consecutive patients were referred to sleep	104 patients involved-81 males and 23 females, ranging in age from 17 to 68 (mean age 47).	Apnea Index (AI), Apnea/Hypopnea Index (AHI)	Correlation coefficient (CC) for AI was .94, and .97 for AHI For AI>5/h, sensitivity=83%,	Study does not address the question whether PolyG is appropriate for “unattended” home

	<p>study lab for assessment of sleep complaints. Patients underwent simultaneous PSG and PolyG overnight recordings.</p> <p>Data was screened and analyzed separately by 2 technicians without knowledge of the results of the other system. Though no inclusion/exclusion criteria noted in study, patients were stratified into high risk (n=23), medium risk (n=51), and low risk (n=30) groups.</p>			<p>specificity=91%, PPV=73%, NPV=95%, Accuracy=89%.</p> <p>For AHI>15/h sensitivity=86%, specificity=95%, PPV=86%, NPV=95%, Accuracy=92%.</p> <p>For risk-group analysis, accuracy was highest in the low-risk group (97% using either diagnostic criteria); for low and high risk groups, both sensitivity and negative predictive values were 100% regardless of which criteria were used.</p>	<p>monitoring.</p> <p>Average age patient is 47, results may not be applicable to the Medicare population</p>
--	---	--	--	--	---

Author/Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
	Study, inclusion/exclusion	N, age, sex,			
Verse, 2000	No specific research designed identified. Patients underwent	N=53 (49 males and 4 females with obstructive	Apnea-Hypopnea index (AHI), Apnea index	AHI correlation coefficient is .97, and AI correlation is .97.	Study says patients were randomly selected, but

	<p>simultaneous portable studies and PSG in a sleep lab.</p> <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Patients with COPD • Cardiac insufficiency (New York classification) <p>Evaluation of recordings were performed in a double-blind manner by examiners.</p>	<p>sleep-related breathing disorders of varying severity)</p> <p>Mean age of subject was 48.1 +/- 10.8 years</p>	<p>(AI), Hypopnea index (HI), Oxygen desaturation index (ODI)</p>	<p>AI >5 sensitivity: 91% specificity: 100%</p> <p>AI >10 sensitivity: 85% specificity: 100%</p> <p>AHI >10 sensitivity: 92% specificity: 96%</p> <p>AHI >15 sensitivity: 87% specificity: 97%</p> <p>AHI >20 sensitivity: 72% specificity: 97%</p>	<p>does not describe the process</p>
--	---	--	---	---	--------------------------------------

Author/ Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodologic Comments
	Study, inclusion/exclusion	N, age, sex,			
Calleja, 2002	<p>No specific research design was identified</p> <p>Study occurred in sleep lab overnight; PSG and MERLIN were performed simultaneously;</p>	<p>N=79 (89% were males, 11% were females; mean age was 52, (SD of 11.1) and BMI of 30.1 kg.m² (SD of 4.4)</p>	<p>Apnea/Hypopnea index (AHI);</p> <p>Respiratory Events index (REI) was assessed using the Bland and Altman method.</p> <p>Receiver Operator Curve (ROC) was used to determine the discriminatory ability of the cardiopulmonary polygraphical scores for the diagnosis of SAS</p>	<p>REI obtained by MERLIN automatic analysis in patients with AHI<10 was higher than values obtained via PSG 5.3+/-5.1 versus 3.1+/-2.1.</p> <p>REI obtained by MERLIN manual analysis in patients with AHI>10 was lower than values obtained via PSG 36.4+/-23.4 versus 41.8+/-27.7.</p> <p>For AHI>5, manual score had sensitivity and specificity of 97.1 and 90.9 respectively; For AHI>10, manual score had sensitivity and specificity of 90.6 and 86.7 respectively; For AHI>15, manual score had sensitivity and specificity of 90.6 and 80.8 respectively; For AHI>20, manual score had sensitivity and specificity of 91.1 and 85.3 respectively; For AHI>30, manual score had sensitivity and specificity of 88.6 and 90.9 respectively;</p> <p>ROC analysis revealed</p>	<p>Highly experienced neurophysiologist read PSG recordings, while different experienced neurophysiologist read the MERLIN recordings (could lead to bias).</p> <p>Study does note several limitations-small sample size, and prevalence of male subjects, makes it difficult to generalize to population.</p> <p>Also lack of Medicare aged patients makes it difficult to generalize to Medicare population.</p>

				that manual scores had greater discriminatory ability than automatic scoring for all AHI cut-off points ranging from > to >30. The area under the ROC for an AHI of >5 was .976 in the manual scoring versus 0.818 in the automatic scoring	
--	--	--	--	---	--

Author/ Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodologica l Comments
	Study, inclusion/exclusion	N, age, sex,			
Esnaola, 1996	A double-blind research design was identified, nocturnal PSG and MESAM IV recordings were performed simultaneously. Study used Receiver Operator Curve (ROC) to test the discriminatory ability of MESAM IV using cut-off points to exclude true disease, then used as a confirmation test Double-blind design was used	N=150 consecutive patients with clinically suspected OSA were included in the study (89% were males), mean age was 57, SD of 11)	Apnea Hypopnea Index (AHI) Intraclass Correlation Coefficient Heart rate variation index (HRVI), Oxygen desaturation index (ODI), and Intermittent snoring index (ISI) were ROC measurement used for ROC for MESAM IV	For AHI >10, sensitivity: 98% specificity: 78% For AHI > 15, sensitivity: 96% specificity: 76% For AHI >20, sensitivity: 96% specificity: 70%. Intraclass correlation agreement was 72%.	Study notes that the diagnostic accuracy of study is affected when subjects with other characteristics, or in other settings are used. Because of the absence of measurement for the direct determination of sleep staging, the calculated score refer to the selected recording time, which does not always correspond to

					the sleep stage.
--	--	--	--	--	------------------

Author/ Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Ballester, 2000	Specific research design not identified; subjects admitted to sleep lab and simultaneously received conventional PSG and PRRG; No information provided about inclusion/exclusion criteria Data obtained was blindly reviewed and analyzed	N=116 subjects recruited from the general population of an ongoing epidemiological study in the population of Mataro, Spain.	RDI (Respiratory Distress Index), AHI (Apnea-Hypoxia Index) Logistic regression used to estimate the chance per unit of RDI of apnoeas, and ROC used to obtain sensitivity and specificity profile for each observed RDI value obtained.	Bland and Altman analysis revealed high level of agreement between PSG and PRRG. For a full PSG cut-off point of 10, a PRRD of six showed a balanced sensitivity and specificity of 95% and 92% respectively. For a full PSG cut-off point of 30, a PRRD of sixteen showed a balanced sensitivity and specificity of 100% and 97% respectively.	Authors list a number of limitations of the study including sleep disorders other than SAHS may be missed, inability determine sleep time (due to absence of measurement of neurological variables, and lack of demonstration of this test in the home setting. Also a potential limitation of this study is this evaluation used patients currently involved in an epidemiological study. This group may be very different from the general population.

Author/ Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results	Methodological Comments
Type III Device	Study, inclusion/exclusion	N, age, sex,			
Marrone, 2002	<p>Subjects suspected for OSAS, were simultaneously studied by PSG in a sleep laboratory, along with POLYSAM system (PM);</p> <p>No specific research design stated; No inclusion/exclusion criteria stated in the study</p> <p>Study was performed in sleep lab, not in home setting; no specific information included about patients within the Medicare age group.</p>	50 consecutive patients were referred to sleep lab, 40 male, and 10 females. Aged 49.6+/- 10.2 years; BMI of 32.7+/- 6.1Kg/m ²	Durations and frequencies of Central apneas (Ac), Obstructive apneas (Ao), mixed apneas (Am), and hypopneas (H), were collected for both groups for time in bed (TIB)	<p>For AH/TIB >5 sensitivity 100%, specificity 71.%, PPV 95.5%, NPV 100%</p> <p>For AH/TIB >10 sensitivity 95.2%, specificity 100%, PPV 100%, NPV 80%</p> <p>No statistical difference between both groups for Ac/TIB, Am/TIB, AH/TIB, and AH duration.</p> <p>Ao/TIB was statistically less for PM versus PSG (25.1 vs. 25.1), and H/TIB was statistically lower for PSG than for PM (7.9 vs. 12.9).</p> <p>Significant correlation was found between values calculated for PSG and PM recordings (r</p>	Study reveals good agreement between the total number of nocturnal respiratory disorder events scored by the PM with those scored by the PSG; also a good agreement was found between mean AH durations scored with both systems as well as between indices relative to the rate of occurrences of some types of events (e.g., mixed and central apneas). The results show accuracy between PM and PSG.

				between .68 and .99, $p < .001$); Bland and Altman analysis showed very good agreement between Ac/TIB, Am/ TIB, AH/TIB, and AH duration values, but poor agreement between Ao/TIB, and H/TIB	
--	--	--	--	---	--