AN ASSESSMENT OF SLEEP DISORDERED BREATHING DIAGNOSIS USING

LEVEL I VERSUS LEVEL III SLEEP STUDIES

FINAL REPORT

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Alberta Health Technologies Decision Process

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Abbreviations

AHI = apnea hypopnea index

AHTDP = Alberta Health Technologies Decision Process

AHW = Alberta Health and Wellness

AI = apnea index

BMI = body mass index

BiPAP = bilevel positive airway pressure

CA = central apneas

COPD = chronic obstructive pulmonary disease

CPAP = continuous positive airway pressure

EDS = excessive daytime sleepiness

ESS = Epworth Sleepiness Scale

HI = hypopnea index

HTA = health technology assessment

ICER = incremental cost-effectiveness ratio; the additional cost of an intervention compared to the less expensive intervention (or to no intervention), divided by the difference in effect or patient outcome (e.g., QALY)

MA = mixed apneas

MeSH = Medical Subject Headings; the controlled vocabulary used by the US National Library of Medicine

OA = obstructive apneas

OSA = obstructive sleep apnea; also called obstructive sleep apnea syndrome (OSAS) or obstructive sleep apnea-hypopnea syndrome (OSAHS)

pCO_2 = partial pressure of carbon dioxide in blood

PSG = polysomnography

QALY = quality-adjusted life year; a measure of health care outcomes that adjusts gains (or losses) in years of life subsequent to an intervention by the quality of life during those years

RDI = respiratory disturbance index

ROC = receiver operating characteristics

UARS = upper airway resistance syndrome

Glossary

Apnea = temporary cessation of breathing that lasts at least 10 seconds.

Apnea-hypopnea index = an American Academy of Sleep Medicine formula calculated as the total number of apneas and hypopneas divided by the number of hours of sleep.

Bariatric surgery = various surgical procedures used to treat morbid obesity.

Bilevel positive airway pressure = a continuous positive airway pressure device that gives two pressures of airflow: a higher level for inhalation and a lower one for exhalation.

Body Mass Index (BMI) = a mathematical formula that takes into account both the person's weight and height (kg/m^2) to derive a statistical measurement of body weight. Normal BMI (weight) ranges from 18.5-24.9 kg/m^2.

Bronchospasm = abnormal contraction of the bronchi causing airway obstruction.

Central sleep apnea-hypopnea syndrome = temporary cessation of breathing (no respiratory effort and no airflow for at least 10 seconds); mainly caused by cardiac and neurological disorders.

Cheyne-Stokes breathing syndrome (also called Cheyne-Stokes respiration) = abnormal respiration characterized by a repetitive crescendo-decrescendo respiratory pattern, followed by periods of apnea.

Continuous positive airway pressure = often called CPAP, a treatment device that generates a continuous air pressure flow to keep the airways open during sleep; used to treat moderate to severe obstructive sleep apnea.

Dyspnea = difficult or laboured breathing.

Epworth Sleepiness Scale = a questionnaire used to measure daytime sleepiness based on responses to 8 questions.

Expiration = exhalation of breath.

Hyper = a prefix meaning excessive or higher than normal.

Hypercapnia = abnormally high levels of carbon dioxide in the blood.

Hypersomnia = excessive sleepiness or sleep.

Hyperventilation = rapid and deep breathing.

Hypo = a prefix meaning low or less than normal.

Hypopnea = reduced airflow or shallow breathing that lasts at least 10 seconds.

Hypoxemia = lack of oxygen in the blood.

Hypoxia = lack of oxygen.

Hypotonia = reduced muscle tone.

Hypoventilation = insufficient respiration.

Inspiration = inhalation of breath.

Level I sleep study = an in-laboratory (overnight) polysomnogram with a health care professional in attendance; level I sleep studies measure sleep stages and many other physiological parameters. They are required to diagnose many non-respiratory sleep disorders and involve monitoring multiple channels. They provide more comprehensive information on sleep disordered breathing than level III studies.

Level III sleep study = an in-home, unattended sleep study using a portable monitoring device that monitors at least 4 channels, including at least 2 respiratory channels, heart rate or electrocardiogram, and oxygen saturation. These studies do not measure the presence of sleep or sleep stages, and they cannot detect non-respiratory sleep disorders.

Likelihood ratios = how much a given diagnostic test result will raise or lower the odds of having a disease relative to the prior probability of disease.

Mixed sleep apnea = apnea in which both central and obstructive components are present.

Negative likelihood ratio = the odds of having the disease if the test result is negative.

Obstructive sleep apnea (also called obstructive sleep apnea syndrome or obstructive sleep apnea-hypopnea syndrome) = collapse of the airway during sleep that causes breathing cessation for at least 10 seconds (apnea) and partial arousal from sleep. The frequency of episodes of breathing cessation indicates the level of OSA (i.e., mild, moderate or severe).

Polysomnography = a level I sleep study.

Positive likelihood ratio = the odds of having the disease if the test result is positive.

Receiver operating characteristic (ROC) = a graph used to compare the ability of diagnostic tests to accurately distinguish the presence or absence of a condition.

Respiration = breathing (inspiration and expiration).

Respiratory disturbance index = the average number of apneas, hypopneas, and breathing-related arousals per hour of sleep; when assessing the severity of OSA, RDI definitions are: <5 events per

hour = no OSA, 5 - 14.9 events per hour = mild OSA, 15 - 29.9 events per hour = moderate OSA, >30 events per hour = severe OSA.

Sensitivity = the ability of a test to correctly identify those who have the disease. It is the number of subjects with a positive test who have the disease divided by all subjects who have the disease.

Sleep disordered breathing = includes various conditions, all of which are characterized by abnormal respiration during sleep; obstructive sleep apnea (OSA) is the most common type of SDB.

Sleep disorders = a broad category of disorders that includes over 80 different conditions that affect the ability to fall asleep, physiological processes that occur during sleep, or that affect daily activities due to fatigue, sleepiness, or inability to stay awake.

Specificity = the ability of a test to correctly identify those who do not have the disease. It is the number of subjects who have a negative test and who do not have the disease divided by the number of subjects who do not have the disease.

Upper airway resistance syndrome = repeated and increasing airflow resistance that causes brief arousal from sleep and daytime fatigue.

Executive Summary

- Sleep disordered breathing (SDB) includes various conditions, all of which involve abnormal respiration during sleep. Obstructive sleep apnea is the most common of these disorders, but other types of SDB include central sleep apnea (caused by cardiac or neurological malfunction that affects breathing), and disorders caused by other medical conditions, for example, Cheyne-Stokes respiration, which affects many patients with heart failure.

- There is no reliable information on the overall prevalence of SDB, or on the prevalence of SDB in Alberta. Based on literature from the US and elsewhere, estimates of prevalence for the most common condition, OSA range from 3 to 7% of men and 2 to 5% of women. Central sleep apnea is far less common and is estimated to affect less than 1% of the general population. The prevalence of other types of SDB varies depending on the underlying medical condition.

- Conditions associated with an increased risk for SDB include obesity, age, male gender, and certain medical conditions, such as cardiovascular and respiratory diseases. Rising obesity rates are reflected in the increasing incidence of OSA.

- Level I sleep studies involve overnight polysomnography in a sleep laboratory, with health care staff in attendance. The level I equipment has a minimum of 7 channels (though 16 or more channels are typically used) and captures various physiological measurements (including cardiac, respiratory and neurological, and sleep duration and stages).

- Level III sleep studies also involve overnight monitoring, but with portable devices that are used in the patient's home (or elsewhere). They may also be used in a sleep lab with a technician in attendance. Level III devices have a minimum of 4 channels, but they do not capture neurological data, sleep staging or duration of sleep. These studies are used to diagnose sleep apnea based on an algorithm to predict the presence and severity of apneas and hypopneas.

- Currently, there are 6 clinics (3 public and 3 private) providing level I sleep studies in Alberta. Last year, these centres performed approximately 5,500 level I sleep studies.

- Five of the 6 centres that offer level I sleep studies (2 public and 3 private) also offer ambulatory level III testing. Several private vendors also provide ambulatory level III studies in Alberta.

- In addition, at least one Alberta centre (Wetaskawin General Hospital) offers overnight, in-facility, attended level III sleep studies.

- An attempt to estimate the number of level III tests performed in Alberta each year, based on an earlier Calgary study, yielded a value of 8,679. Another estimate, from an informal survey of private vendors in the province, estimated that about 15,000 level III tests were performed in the past year.

- A systematic review of clinical evidence was undertaken to assess the diagnostic accuracy of level III sleep studies compared to level I studies in patients suspected of SDB.

- Thirty-four studies totalling 1,952 patients were included in the clinical review. All of these studies were comparative and used level I polysomnography as the reference standard. Most studies included only patients with uncomplicated OSA (i.e., patients without other medical problems or non-respiratory sleep disorders).

- No adverse events raising safety concerns were reported.

- In otherwise healthy patients with suspected OSA, the average sensitivity and specificity of in-home level III tests were approximately 89% and 64%, respectively.

- None of the studies reported on the relative effectiveness of in-home level III sleep studies for patients with suspected OSA and medical comorbidities (such as congestive heart failure).

- There were no significant differences in the effectiveness of in-home level III tests for the diagnosis of OSA associated with gender (3 studies) or age (1 study), when compared to pooled results for mild, moderate and severe AHI.

- Evidence on the diagnostic accuracy of in-home level III tests in patients with suspected SDB was limited to 10 studies, and only 5 of these studies included other SDB conditions (i.e., not just OSA).

- The sensitivity and specificity of in-home level III tests reported in the 1 study that measured other (non-OSA) SDB conditions in otherwise healthy patients, were 93.8% and 25.0%, respectively.

- Two studies assessed the effectiveness of in-home level III tests in patients with stable congestive heart failure and suspected SDB. One study reported 100% sensitivity and specificity for detection of other SDB conditions (central apnea).

- Based upon limited published economic evidence for the diagnosis of uncomplicated OSA (1 study), level III tests appear to be almost as effective as (measured in quality-adjusted life years), and less expensive than level I tests.

- Depending on the decision pathway for the provision of level I and in-home level III tests in Alberta, the estimated annual costs would range from $6,570,793 to $11,475,209.

Introduction

Purpose of Assessment

This assessment was commissioned by Alberta Health and Wellness to support the Alberta Health Technologies Decision Process (AHTDP). The AHTDP was established in response to recommendations of the Expert Advisory Panel to Review Publicly Funded Health Services. The intent of the AHTDP is to improve decision-making on the public funding of health technologies and services in Alberta.[1]

This assessment considers the evidence on using level I (in-laboratory polysomnography) versus level III (ambulatory, in-home*) sleep studies for the differential diagnosis of sleep disordered breathing (SDB) and specific conditions that fall within this disorder.†

Project objectives

1. To determine the sub-populations of patients suspected of SDB who are most appropriately diagnosed with level I sleep studies.

2. To determine the sub-populations of patients suspected of SDB who are most appropriately diagnosed with level III sleep studies.

3. To review the effectiveness, efficacy and safety of level I and level III sleep studies for the diagnosis of SDB-specific conditions.

4. To review the social, ethical and legal considerations for the provision of level I and III sleep studies for the diagnosis of SDB-specific conditions.

5. To review the fiscal and economic considerations for the provision of level I and III sleep studies for the diagnosis of SDB-specific conditions.

Research Questions

The main research question posed in the Project Charter for this assessment was:

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* Level III devices may also be used outside of the patient's home, for example, in longterm care facilities.

† As listed in the Project Charter for this assessment, these sleep disordered breathing conditions include: obstructive breathing disorders (including obstructive sleep apnea and upper airway resistance syndrome), central sleep apnea, Cheyne-Stokes respiration, primary pulmonary disorders that cause transient episodes of severe nocturnal hypoxia, nocturnal hypoxia/hypoventilation, and bronchospasm causing nocturnal bronchial constriction.

What is the role of sleep studies in Alberta in the diagnosis of SDB and the different conditions within this disorder?

The assessment was also to address:

1. How do level I and level III sleep studies compare with respect to the diagnosis of SDB-specific conditions across relevant sub-groups of patients suspected of SDB?

2. What are the indications for level I and level III testing?

Background

Sleep disordered breathing affects many adults, and the prevalence of some SDB conditions is increasing as the population ages and obesity rates rise.[2] The increasing prevalence of SDB, and a greater awareness of the associated health risks, have resulted in a high demand for testing and waiting lists for sleep studies.

Because it can diagnose other sleep disorders in addition to OSA, level I (in-lab, overnight) polysomnography is considered the standard test for sleep disorders. But level I polysomnography is an imperfect test.[3-5] Level I sleep studies are costly due to the staff, equipment costs and time required.[6] The requirement to stay overnight in a sleep clinic may also be inconvenient or impossible for some patients.

There is also variability in the test results of the level I polysomnograms between physicians, centres, and in individual patients from one night to the next.[3,7,8] This variability may be greater than differences between level I and level III test results.[9] The clinical importance of this variability is not known, but a difference of 10% on a level I or level III test will not affect clinical management or practice.[9]

Various apnea-hypopnea index (AHI) cut-off points are used to categorize the severity of OSA but the clinical importance of these cut-off points has not been substantiated.[4]

For OSA, the most common type of SDB, response to trial treatment with continuous positive airway pressure (CPAP) has been suggested as a preferable "gold" standard to level I testing.[7]

Level III devices monitor a minimum of 4 channels, including at least 2 respiratory channels, heart rate or electrocardiogram, and oxygen saturation. These devices do not measure the presence of sleep or sleep stages, and they cannot detect non-respiratory sleep disorders.

In-home diagnosis with a level III device provides a more natural and convenient setting for a sleep study, and may give patients improved access to diagnosis and treatment. But, the many level III devices available for at home testing measure various SDB parameters and analyse these parameters using different algorithms.[7] Level III devices used at home have also been associated with higher

rates of repeat studies due to user error, artifact or problems with the data recording (this is not an issue for level III testing performed in attended sleep centres).[5] The need for repeat tests with level III studies may offset some of the potential cost savings from the use of ambulatory testing.[10] These problems do not apply to level III devices used in a sleep lab with trained personnel in attendance.

Condition Definition

Sleep disordered breathing is an umbrella term that covers many conditions - all of which involve impaired airflow, resulting in reduced oxygen saturation levels, during sleep.

Accepted definitions of the conditions included in SDB differ, complicating clinical diagnosis and comparisons between research studies.[11-15] The definitions that best reflect the conditions specified in the Project Charter for this assessment are those described in the *Clinical Manual for Evaluation and Treatment of Sleep Disorders*, which includes six main sub-types of SDB:[12]

1. Obstructive breathing disorders: involve differing degrees of upper airway obstruction causing reduced oxygen saturation levels and fragmented sleep. Respiratory effort occurs but airflow is reduced or insufficient. Snoring, gasping for breath, sleep-related hypopnea (reduced airflow), and excessive daytime sleepiness are typical symptoms of obstructive breathing disorders.

> **Obstructive sleep apnea (OSA):** collapse of the airway during sleep that causes breathing cessation for at least 10 seconds (apnea) and partial arousal from sleep. The airway collapse may be caused by sleep-related loss of muscle tone (hypotonia) in the upper airway. It may also be due to, or exacerbated by, other conditions, such as small oropharyngeal (upper airway) passages; micrognathia (small jaw); retrognathia (receeding jaw); enlarged adenoids, tonsils, tongue (macroglossia) or uvula; nasal obstruction, or oropharyngeal cancer. Aging and obesity also affect upper airway patency during sleep.[12,16] Obstructive sleep apnea is the most common type of SDB.
>
> **Upper airway resistance syndrome (UARS):** partial sleep arousal caused by an increased level of respiratory effort, but without the frequency of apnea episodes or oxygen desaturation levels seen with OSA.[15] Upper airway resistance may be considered a mild form on a spectrum of conditions.[12]

2. Central sleep apnea: is caused by neurological malfunctioning affecting the muscles that control breathing. In central sleep apnea breathing stops or respiratory effort is insufficient. It can be caused by many conditions, including neuromuscular disorders (such as amyotrophic lateral sclerosis, myasthenia gravis, and postpolio syndrome), the use of opiod drugs, tumours, trauma to the brainstem, or obesity hypoventilation syndrome. Ascending to high altitudes may also cause a form of central sleep apnea.[12,17,18] Less than 10% of patients undergoing sleep studies have central sleep apnea.[18] This percentage may vary depending on the patient population at different sleep centres [Personal communication, Dr. Larry Pawluk, University of Alberta, May 20, 2010].

A combination of conditions occurs when both obstructive and central sleep apnea are present.

3. Cheyne-Stokes respiration: is sometimes considered another type of central sleep apnea. This condition is most common in patients with congestive heart failure, but it may also be caused by opioid drugs or neurological disorders. The respiratory pattern is often called "waxing and waning", with brief periods of rapid, deep breathing followed by shallow breathing or a pause in breathing.

4. Primary pulmonary disorders: conditions such as cystic fibrosis or chronic obstructive pulmonary disease often cause temporary episodes of severe hypoxemia (lack of oxygen) during sleep.

5. Nocturnal hypoxemia / hypoventilation: may be due to primary pulmonary or neuromuscular disorders that cause nocturnal hypoxemia (lack of oxygen) or hypoventilation (decreased oxygen and increased carbon dioxide levels due to slow or shallow breathing).

6. Bronchospasm: occurs in individuals with asthma who experience nocturnal bronchochronstriction due to exposure to an allergen, the effects of medication scheduling, or changes in airway patency during sleep.

Indications of possible SDB include patient complaints of fatigue and inability to concentrate, or partner reports of snoring or choking. Scores on questionnaires (such as the Epworth Sleepiness Scale) and symptom checklists are also used to assess patients for SDB. Other indications of possible SDB include, physical signs (such as neck circumference or body mass index (BMI)), and health conditions associated with an increased risk for SDB, such as cardiovascular or pulmonary disease.[19]

Technology Definition

Several types of diagnostic devices are used for sleep studies. These devices are commonly categorized in levels devised by the American Sleep Disorders Association: level I through level IV. The definitions of these devices vary between agencies and research studies; categorizing some studies can be difficult. Advances in these technologies have also blurred the distinction between some devices, particularly those in the Level III and Level IV categories. Moreover, the devices within each category differ and are not necessarily equivalent.[5] With these caveats in mind, this assessment uses the following definitions:

Level I: full night, overnight polysomnography in a sleep laboratory with a health care professional (sleep technician) in attendance. A level I sleep study takes both cardiorespiratory and neurological measurements, measures sleep duration and sleep stages, and detects other, non-respiratory sleep disorders. A minimum of 7 channels (but typically at least 16 channels) are used to measure various physiological parameters, including: respiratory effort, oxygen saturation, airflow, heart rate, brain waves, and body movements.[20]

A split-night sleep study is a variation of level I testing where the patient undergoes in-laboratory polysomnography for the first part of the night. If the testing indicates OSA, the remainder of the night is used to titrate the CPAP unit for therapy.

Level II: similar to a level I sleep study in the equipment and channels (both respiratory and sleep staging) used, but without a health care professional in attendance.

Level III: portable devices, usually intended for use at home, that record various sleep parameters (Figure 1). In this assessment, level III devices are defined as units that have a minimum of 4 channels, including at least 2 respiratory channels, heart rate or electrocardiogram, and oxygen saturation. Level III devices vary in measurement capabilities and quality. They do not measure sleep stages or duration, and cannot detect non-respiratory sleep disorders.[21] Because sleep duration is not measured, level III studies cannot calculate AHI, and instead measure the respiratory disturbance index (RDI). Level III devices can detect episodes of apnea and hypopnea, but as they do not include electroencephalography they may underestimate the severity of episodes, and arousals due to respiratory effort may not be identified.[19]

Level IV: these devices are also intended for unattended use at home, but they take only 1 or 2 measurements, such as oxygen saturation or airflow (though some newer devices take additional measurements). Level IV devices are used mainly for screening, rather than for diagnosing OSA. An example of a level IV device is the SleepStrip®. (Note, level IV devices were not included in the Project Charter for this assessment.)

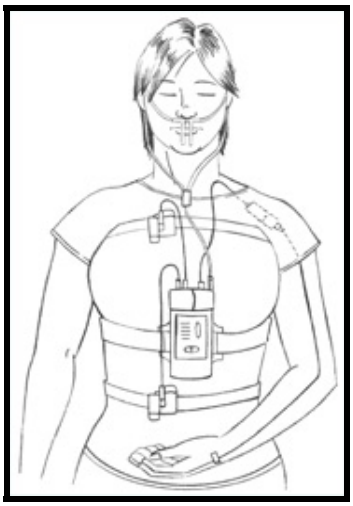


Figure 1. Woman wearing a home monitoring device.
(Reproduced with permission from the website of the Canadian Lung Association, www.lung.ca. All rights reserved.)

Health Canada Approval

Many different manufacturers of sleep study units of all levels (I through IV) have received Health Canada licensing approval. The approved indications for each device vary. For example, some (but not all) indicate the physiological variables the device can capture, and specify whether it is intended for use by a health care professional or by a patient at home. Note that Health Canada licensing does not specify the level of device. Some devices can be considered as level I, II, III or IV, depending on

whether they are used in an attended setting or at home, and on how many channels of data are available. Some examples of approved Health Canada indications for these devices are shown below.

Level I: The Alice 5 system (Respironics) is "...a polysomnography system that is intended to record, display and print physiologic information to clinicians / physicians. Provides documentation of various sleep or other physiological disorders..."

Level III: The Apnea Risk Evaluation System (also called the ARES Unicorder, Watermark Medical) is indicated for use "... in the diagnostic evaluation of adult patients with possible sleep apnea. The ARES can record and score obstructive respiratory events (e.g. apneas, hypopneas, mixed apneas and flow limiting events). The device is designed for in-home screening of adults with possible sleep disorders..."

Level IV: The SleepStrip Disposable Sleep Apnea Screener (S.L.P. Ltd) "is specifically indicated to obtain a quantitative measure of respiratory airflow, which correlates with the Apnea Hypopnea Index..." [Personal communication, Daniel Yoon, Health Canada, November 26, 2009].

Manufacturers frequently bring out new models of devices and discontinue older models; companies merge and product names change. A list of the devices available in Canada will inevitably be out-of-date. With this caveat, the tables below list the devices that we were able to identify as currently licensed in Canada. The table of level III devices was developed from a list in a 2009 review by the Canadian Agency for Drugs and Technologies in Health (CADTH),[20] with additional information from the manufacturers, and device license dates from the Health Canada Medical Devices Active Licence Listing database (www.mdall.ca). Several US product guides identify other devices that are not currently licensed by Health Canada.[22-25]

Table 1. Level I sleep studies devices licensed in Canada

Device name	Company name (manufacturer / Canadian distributor)	Health Canada license
Alice 5 Alice LE	Respironics	2004 2008
AURA PSG AURA PSG Lite	Astro-Med, Inc. / Grass Technologies	2008
Comet XL PSG System	Astro-Med / Grass Technologies	2004
Easy II & Easy II Ambulatory (can be used as Level I through IV)	Cadwell Laboratories	2005
Embla TITANIUM (can be used as Level I or Level III)	Embla Systems	2008
Harmonie (also called MESA-II) system	Stellate Systems / Natus Medical	1999
MediPalm (can be used as Level I through IV)	Braebon Medical Corp.	2003
Nihon Kohden PSG	Nihon Kohden	2002
Sandman Sleep Diagnostic Systems	Embla Systems	1999
Sleepscan XLTEK (also called SleepWorks Sleep System / Connex) Sleepscan Netlink Traveller Trex Home Sleep (level II)	Natus Medical	2002 2005 2007 2009
SOMNOScreen	SOMNOmedics	2007
SomnoStar	CareFusion	2000
Suzanne Sleep Recorder (discontinued product)	Was Nellcor Puritan Bennett, taken over by Embla	1999
Vitaport	Temec Instruments	2003

Table 2. Level III sleep studies devices licensed in Canada

Device name	Company name (manufacturer / Canadian distributor)	Health Canada license
Alice PDx Diagnostic System (level II through IV)	Philips Respironics	2008
ApneaLink Plus	ResMed	2009
ApnoeScreen Pro	Cardinal Health	2004
ARES Unicorder (also called Apnea Risk Evaluation System)	Watermark Medical	2007
Easy Net (8 channels, geared to use by pulmonologists, but can be used in the clinic or at home)	Cadwell Laboratories	2008
Embletta (X100, etc. being discontinued)	Embla Systems	2005
Embletta GOLD	Embla Systems	2008
MediByte	Braebon Medical Corp.	2006
Nomad System	G & B Electronic Designs / Provincial Medical	In process
Remmers Sleep Recorder (formerly called SnoreSat)	SagaTech	2001
Sandman Pocket (being discontinued)	Nellcor Puritan Bennett, taken over by Covidien, taken over by Embla	2006
SleepTrek 3 System	Astro-Med, Inc. / Grass Technologies	2008
SmartRecorder	Philips Respironics	1999
Somte Somte PSG	Compumedics / Northern Optotronics	2004 In process
Stardust II Sleep Recorder	Philips Respironics	2004
Trackit Sleep Walker (level II or III)	G & B Electronic Designs / Lifelines Medical (UK) / Provincial Medical	2008

Methodology

Literature

Literature Search

The literature search included controlled vocabulary terms, such as the Medical Subject Headings (MeSH), and additional keywords to capture the diagnosis of SDB (e.g., sleep disorders/diagnosis, sleep apnea syndromes/diagnosis, Cheyne-Stokes respiration/diagnosis, polysomnography, etc.). Two main searches were undertaken – one for the clinical assessment and the other for the review of economic literature. Publications identified by both searches, and from additional sources, including systematic reviews and health technology assessments, were used for the background and Social Systems and Demographics sections of the assessment. The databases searched were PubMed (where several search strategies were applied), The Cochrane Library, the Centre for Reviews and Dissemination databases (DARE, HTA, and NHS EED), EMBASE, CINAHL, Web of Science, and EconLit.

The grey literature search for unpublished reports, guidelines, clinical trials and other assessments used various Internet web sites. Proceedings from meetings of key associations were handsearched for recent conference abstracts, and the reference lists of relevant papers were scanned to identify additional studies. Manufacturers of the level III devices available in Canada, and members of the Expert Advisory Group for this assessment were also contacted for information. Appendix A details the search strategies and sources used.

Searches were run in November 2009, and were limited to English language publications from 2004 to date. The date limit was determined based on previous assessments that review the earlier literature.[5,20,26-29] Automated monthly update searches were run in PubMed to capture new publications throughout the project. Search results from the clinical and economic searches were merged into one bibliographic database (using Reference Manager®) once the researchers had completed their selection of papers for review.

Selection of Literature

The search results were imported into Reference Manager®, a software program for managing bibliographic citations. Duplicate citations were removed, and the references (titles, and abstracts where available) were independently reviewed by 2 researchers. The full papers of potentially relevant studies were retrieved and independently assessed by the researchers using pre-defined study inclusion criteria (Table 3). Where study details were unclear the authors were contacted for further information. When multiple citations from the same investigators reported on the same study populations, only the most recent study report was included. At both stages of review, discrepancies between reviewers were resolved through discussion, and no third party adjudication was required. Consensus between reviewers was assessed using the Kappa statistic.[30]

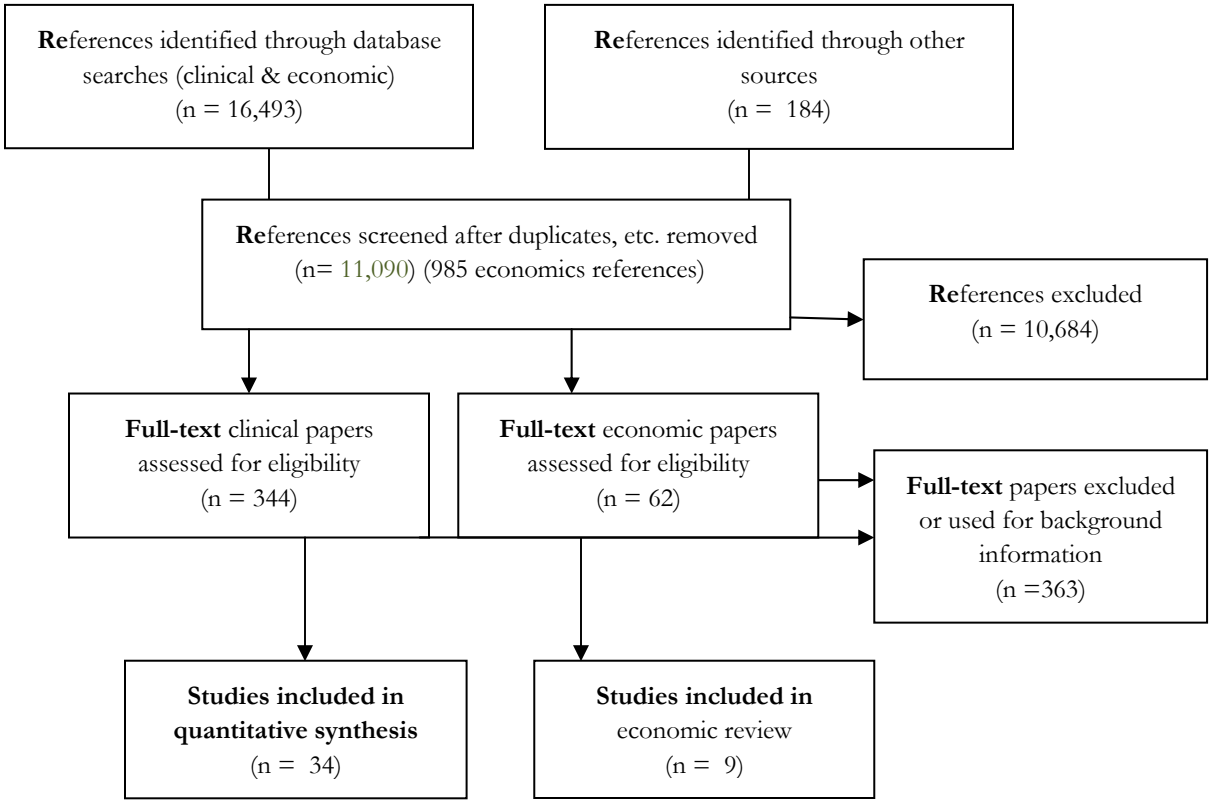
Table 3. Study inclusion criteria

Parameter	Inclusion Criteria	Exclusion Criteria
Study Design	Randomized controlled trials Non-randomized controlled trials Clinical trials Before-and-after studies Retrospective, prospective, or concurrent cohort studies Case or clinical series Cross sectional studies that distinguish between sleep disordered patients with and without SDB	Case reports Editorials & opinion pieces
Patients	Adult sleep disordered patients with suspected SDB requiring confirmation of diagnosis for treatment Adults with comorbidities potentially related to SDB Adults deemed medically stable	Adults with previous SDB related surgery Patients under 18 years of age
Intervention	Level III sleep study	
Comparator	Level I sleep study (polysomnography)	
Outcomes	Degree of concordance between level III and level I reports in patients who underwent both studies Degree to which therapeutic decisions changed in patients who underwent level III studies compared to those who underwent level I studies Adverse effects or complications related to the use of level III/level I studies in the diagnosis or misdiagnosis of SDB among sleep disordered patients	

Results of Literature Search

From the total literature search results (over 16,000 references), 406 papers were selected for full review. Of these papers, 34 studies met the selection criteria for the clinical component of the review (Figure 2. Flow diagram of study selection). The included studies are summarized in the evidence tables in Appendix B. Of the 34 included studies, 10 studies had recruited patients with any suspected SDB condition, but only 2 of these studies reported on conditions other than obstructive SDB. In the 24 studies of patients with suspected OSA, only 2 studies reported on respiratory events other than obstructive SDB. Both of these studies reported on patients with central sleep apnea. Data for all types of SDB were extracted from the studies where possible.

Figure 2. Flow diagram of study selection



Data Extraction

Clinical studies: Three researchers extracted data from the studies. Each researcher reviewed two-thirds of the papers and abstracts, resulting in 3 pairs of reviewers (i.e., A & B, B & C, and A & C). By using this method, each study was independently reviewed by 2 researchers.

Data was extracted using a pre-tested data extraction form (Table 4) and a set of decision rules. The form contained elements for assessing the purpose and methods of each study, and the validity of study results. When needed, missing data were sought from the study authors. Consensus within pairs of reviewers was assessed using the Kappa statistic.

Table 4. Elements in the data extraction form

Parameter	Description of information collected
Condition	SDB, OSA, upper airway resistance syndrome, central sleep apnea, Cheyne-Stokes respiration, primary pulmonary disorders, nocturnal hypoxia/hypoventilation, bronchospasm
Study Design	Setting, country, study type (e.g., case series, cohort studies, clinical trials, retrospective or prospective), methods of allocation, interpretation blinding, order of sleep study type, funding sources
Patients	Number of patients recruited, randomized or assigned to diagnostic arm (where possible), number of patients censored due to incomplete studies or loss to follow-up, age, gender, BMI, neck size, pre-test probability (Epworth Sleepiness Scale or Berlin Questionnaire), relevant co-morbidities, source of patient referral, inclusion and/or exclusion criteria
Diagnosis	Details of the diagnostic tests (location, manufacturer, number of channels monitored order of testing, simultaneous and/or separate studies, scoring method, study interpreter), interval between studies, indexes reported, diagnostic cutoff points reported
Outcomes	Diagnostic accuracy; described diagnoses; diagnostic agreement between studies; reported indexes by study type; adverse events; technical or human related complications encountered leading to study errors
Study Quality	Oxford level of evidence, QUADAS checklist, The Cochrane Collaboration risk of bias tool for RCTs (if applicable)[31]

The researchers also assessed the quality of each study they were assigned for data extraction. Quality was assessed using the Oxford levels of evidence, a validated, widely used critical appraisal tool that permits comparisons across different experimental designs (Table 5). The QUADAS checklist, a validated tool used to assess the quality of diagnostic studies, was also used.[32]

Measures of accuracy included sensitivity and specificity, positive and negative predictive values, positive and negative likelihood ratios, and receiver operating characteristic (ROC) curves (where available) (Table 4). For the purposes of this review, these values represent the mean difference in sleep indexes (apnea-hypopnea index (AHI)or respiratory disturbance index (RDI)) when comparing level I and level III results. The absolute values of various sleep indexes (AHI/RDI, apnea index (AI), hypopnea index (HI), obstructive apneas (OA), central apneas (CA) and mixed apneas (MA)) were collected and tabulated across the studies.

Table 5. Oxford levels of evidence: Diagnosis

Level	Diagnosis
1a	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres
1b	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre
1c	Absolute SpPins and SnNouts††
2a	SR (with homogeneity*) of Level >2 diagnostic studies
2b	Exploratory** cohort study with good††† reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases
3a	SR (with homogeneity*) of 3b and better studies
3b	Non-consecutive study; or without consistently applied reference standards
4	Case-control study, poor or non-independent reference standard
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

* systematic review free of "worrisome variations" (heterogeneity); ** validating studies test the quality of a diagnostic test, based on prior evidence; †clinical decision rule (algorithms or scoring systems which lead to a prognostic estimation or a diagnostic category); †† an "absolute SpPin" is a diagnostic finding whose **S**pecificity is so high that a **P**ositive result rules-**in** the diagnosis. An "absolute SnNout" is a diagnostic finding whose **S**ensivity is so high that a **N**egative result rules-**out** the diagnosis; ††† good reference standards are independent of the test, and applied blindly or objectively applied to all patients...; §§§ Spit-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into "derivation" and "validation" samples. (Source: *Oxford Centre for Evidence-based Medicine Levels of evidence).*[33]

Economic studies: The economic studies were appraised using the criteria developed by Drummond et al.[34] These criteria assess both the validity of the study results and the appropriateness of the methodological approach used. The critical appraisal tool includes 10 questions that allow the assessor to evaluate the rigor with which the methodology was undertaken and whether the results were appropriately reported. Each question is answered using 1 of 3 possible responses ("Yes", "No", or "Can't tell"). The results of the economic evaluations were then abstracted from each paper.

Social Systems and Demographics (S) Approach to Analysis

Information for the social and demographic aspects of this assessment was extracted by one reviewer from papers identified through the clinical and economic database and grey literature searches, and from other health technology assessments (see previous description under the

Literature Search section and Appendix A for details of the search terms and sources used). Additional searching was made for some topics (using PubMed and Google.ca), for example, on risk factors for SDB. Contact with researchers and health care providers in this field identified further information on the prevalence, burden of illness, current clinical practices for diagnosing SDB, and utilization of sleep studies in Alberta and elsewhere in Canada. Where possible, studies relevant to Alberta or Canada were used. Systematic reviews and health technology assessments were used when available, but there was otherwise no formal quality assessment of the studies used to prepare this section of the review. It is a descriptive summary of the information in the material reviewed.

Technology Effects and Effectiveness (T) Approach to Analysis

Methods for assessing the comparative effectiveness of level I and level III sleep studies were based on internationally recognized, published guidelines for the systematic review of diagnostic technologies.[35] These guidelines assess 'effectiveness' using a 'linked approach', which considers evidence regarding safety, accuracy, and impact on therapeutic decisions (i.e., change in management).

Selection of relevant studies

All citations were imported into a bibliographic software program (Reference Manager®), which was used to remove duplicate references and manage citations. The search results (titles and abstracts, where available) were independently assessed for relevance by 2 researchers. The full papers of potentially relevant references were retrieved and assessed for inclusion in the review using the inclusion criteria (Table 3).

Synthesis and critical appraisal of selected studies

As described in the Data Extraction section above, 2 researchers independently extracted information from individual selected studies using a standard, pre-tested data abstraction form and a set of decision rules established at the outset of this assessment. The form captured information on the objectives, methods, and results of each study. For example, it included elements such as: study type, patients, sampling methods, prior tests for SDB, pre-test probability of SDB, details of the devices used in the level I or level III studies, setting of the sleep study, information on signal or data loss, agreement between level I and level III study results, changes in treatment decisions between sleep study types, and adverse events or complications, as shown in the evidence tables in Appendix B.

Two researchers also independently appraised each study using the QUADAS checklist[32] and the Oxford levels of evidence (Table 5). The degree of agreement between researchers was assessed using the Kappa statistic.

Data analysis

Data extracted from studies were summarized in tabular form to facilitate qualitative analyses of trends or patterns in the findings across studies. Level I polysomnography was used as the reference standard, as specified in the Project Charter. Where possible, the sensitivity, specificity, likelihood ratio, and diagnostic odds ratio were calculated and compared for level I and level III sleep studies. A summary receiver operating characteristic curve (ROC), which plots paired estimates of sensitivity and specificity for individual studies, was also generated in order to compare the accuracy of the two types of sleep studies. (Note: the test which has the largest area of the summary curve is considered the most accurate).

Qualitative

Information was summarized in tabular form to more easily identify trends and patterns in findings across studies. Diagnostic accuracy was determined by the use of sensitivity/specificity, positive and negative predictive values, positive and negative likelihood ratios, and receiver operating characteristic (ROC) curves. Post-test diagnoses was recorded (where available) for each sleep study type. Index values for both level I and level III sleep study arms were recorded to evaluate differences reported by sleep study type.

Quantitative

Subgroup analysis was conducted by study design (simultaneous level I/III versus separate level I/III sleep study protocols), index cut-off points (AHI ≥ 5, AHI ≥ 10, AHI ≥ 15 etc) recruitment diagnosis (e.g., OSA, sleep apnea-hypopnea syndrome (SAHS), SDB), level III device type, and interval between sleep studies. All quantitative analyses were conducted in accordance with intention-to-diagnose principles (i.e., all patients are included in the analyses, irrespective of sleep study quality or the ability to complete the diagnostic test) where possible. [36,37] Where values for any of the outcome measures did not appear in the study, manual calculation was made using the raw data. All results were reported as quantitative values as it was not possible to calculate pooled weighted mean values for these measures.

Economic Evaluation (E) Approach to Analysis

Search results from both the clinical and economic literature searches were independently reviewed by 2 researchers.

Selection of relevant studies

From the total search results, 62 papers were selected for full review. Inclusion criteria for the economic studies were English language papers published within the last 5 years that reported on both costs and outcomes.

Synthesis and critical appraisal of selected studies

Qualitative

Following an approach similar to that outlined above for the review of clinical effectiveness, the quality of each study was independently assessed by 2 reviewers using published economic evaluation guidelines.[34] The degree of agreement between researchers was assessed using the Kappa statistic. Each study's compliance with the guidelines was examined and tabulated. Costs, outcomes (in QALYs) and ICERs were also tabulated (when reported).

Quantitative

A decision model was developed. In the model, patients with suspected SDB are treated with one of three possible scenarios. In the first scenario, all patients receive level I polysomnography in a lab. In the other two scenarios, patients start with a home-based level III test, and depending on the results, they may have subsequent level I or level III tests. The costs and outcomes associated with each scenario and a budget impact were calculated.

Social Systems and Demographics (S)

Patterns of Illness

Reliable information on the overall prevalence of clinically significant SDB is not available. No Alberta data on the prevalence of any type of SDB, including OSA, were found. Most studies cite the Wisconsin Sleep Cohort Study, conducted about 20 years ago, which reported prevalence rates for SDB of 24% in men and 9% in women (using a cut-off of AHI≥5 episodes per hour).[26,38] But using this cut-off would include many individuals with mild apnea who do not need treatment. The most common type of SDB is obstructive sleep apnea. Based on estimates from the literature, 3 to 7% of adult males and 2 to 5% of adult females have OSA.[38-40]

Many individuals with OSA remain undiagnosed. One US study, part of the Wisconsin Sleep Cohort Study, estimated that over 80% of middle-aged (aged 30 – 60 years) men and women with moderate to severe sleep apnea have not been diagnosed with this condition – something the researchers referred to as the "tip of the iceberg" phenomenon.[40,41] This study included only government employees with health insurance and local access to a sleep laboratory. Those who had been diagnosed with sleep apnea were more likely to be male, older, Caucasian, with higher educational levels and comorbid cardiovascular disease. Rates of undiagnosed sleep apnea in other groups, such as women, individuals with lower incomes, and the elderly, are probably higher.[40,42]

Central sleep apnea is less common than OSA and estimated to affect less than 1% of the general population.[18,43] A US study of men aged 20 to 100 found a general prevalence of 3.3% for OSA versus 0.4% for central sleep apnea.[44] Primary central sleep apnea is most common in middle and old age, with an increase in prevalence after 60 years of age.[18]

Individuals with cardiovascular conditions have an increased risk for SDB. For example, Cheyne-Stokes breathing or central sleep apnea is estimated to affect from 25-50% of patients with heart failure, and about 10% of stroke patients.[18,45] Many heart failure patients also have OSA. A German study of 700 heart failure patients found that 76% had SDB (40% had central apnea and 36% had OSA).[46‡]

Patients with chronic obstructive pulmonary disease (COPD), another relatively common condition, may also have coexisting OSA.[47] A recent study analyzed the medical records of veterans who had undergone polysomnography and had a pulmonary function test. This study found that, of 73 patient records analysed, 14 patients (19%) had neither COPD nor OSA, 7 patients (10%) had COPD alone, 23 patients (31%) had OSA alone, and 29 patients (39%) had both COPD and OSA.[48]

Burden of Illness

Patients with SDB may experience a variety of symptoms, including snoring, excessive fatigue or daytime sleepiness, inability to concentrate, headaches, sexual dysfunction, depression and mood swings. Sleep disordered breathing has a detrimental effect on quality of life,[25,49-51] and carries an increased risk for hypertension, stroke and cardiovascular disease, type 2 diabetes, obesity and premature death.[6,39,42,50,52,53] The bed partners of individuals with SDB also experience impaired quality of life as a result of disrupted sleep caused by their partners snoring and restlessness.[54] A Swedish study found that SDB was associated with a divorce rate three times that of those without OSA or daytime sleepiness.[54]

Motor vehicle accidents and occupational safety

A recent study from British Columbia found that individuals with OSA have a risk of motor vehicle collisions involving serious injury that is over 3 times that of those without OSA.[55] These findings confirm those of other studies, including a Canadian systematic review, which found that, compared to the general population, those with OSA have 2 to 3 times the risk for automobile accidents.[56]

One US study found that 17.6% of commercial truck drivers had mild sleep apnea, 5.8% had moderate sleep apnea, and 4.7% had severe sleep apnea.[57]

Excessive daytime sleepiness is also associated with an increased risk for occupational injuries and accidents (beyond commercial motor vehicle accidents), cognitive dysfunction, fatigue, absenteeism and decreased productivity.[3,54,58,59] An Australian study concluded that sleep disorders (including non-SDB conditions) caused an estimated 9.1% of work-related injuries.[60]

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‡ Note that some studies include Cheyne-Stokes breathing within the broader category of central sleep apnea.

Health care utilization and the costs of sleep disordered breathing

Sleep disordered breathing is also associated with increased health care utilization and costs.[61] [54,59] One US study found that individuals who scored in the highest quartile on the Epworth Sleepiness Scale (scores of ≥11) used health care resources about 11% more than those with the lowest quartile scores.[62] Increased health care utilization includes physician visits, hospitalization and emergency visit costs, drug and other treatment costs.[61] Costs are highest in OSA patients with high BMI, heart disease, hypertension, and pulmonary disease.[47,63,64] Diagnosing and treating OSA in these patients reduces health care costs.[64,65]

The Australian study cited above estimated both direct and indirect costs of sleep disorders - from lost productivity to the costs of diagnosing and treating sleep disorders. This study concluded that the overall costs of sleep disorders in Australia (with a population of 20.1 million at the time of the study) was US$7,494 million.[60] Similarly, Canadian researchers who conducted a literature review of the costs of OSA found that it imposed a considerable economic burden, similar to that of other chronic conditions, which they roughly estimated as "billions of dollars per year". These costs were due to the effect of OSA on work (e.g., difficulty concentrating and performing work-related tasks, interpersonal relationships, and lost productivity), occupational injuries, traffic accidents, and health care costs – both for the treatment of OSA and for the costs resulting from untreated OSA.[59]

Treating patients with OSA (with CPAP or dental appliances) is effective in reducing daytime sleepiness and improving work performance.[59,66] There is good evidence that treatment of OSA with CPAP reduces the risk of motor vehicle accidents, but many patients refuse or cannot tolerate CPAP therapy.[56] There is less good evidence (from smaller, older, uncontrolled studies) that uvulopalatopharyngoplasty reduces automobile accidents.[56,67]

Social, legal and ethical issues

The main ethical issues surrounding SDB diagnosis in Alberta are: timely access to diagnostic services and public funding of effective treatments to reduce the burden of disease.

As summarized above, the consequences and health care costs of undiagnosed and untreated SDB are substantial.[42,68] Treating OSA has been shown to reduce overall health care costs and some countries and health insurers provide full coverage of CPAP therapy.[69] Despite the demonstrated cost-effectiveness of treating OSA with CPAP, most Canadian provinces do not provide coverage for this therapy.[59]

Recent papers have called for harmonization of reporting requirements for sleep disorders in driving license regulations across Europe.[70] In some European countries, OSA or excessive daytime sleepiness (due to or unrelated to SDB) are cited as medical conditions that affect driving ability. But, many licensing requirements don't list these conditions.[71] As in Canada, who – the individual or their physician – should report medical conditions that may impair driving ability is also an issue. The Canadian Medical Association recommends that if a physician believes their patient has a sleep

disorder, and the patient refuses a sleep study or refuses to comply with treatment, the patient should not drive any type of motor vehicle.[67] In some Canadian jurisdictions physicians are required to report patients who are considered medically unfit to drive.[72] In Alberta, it is the responsibility of the individual, rather than the physician, to report medical conditions that may interfere with their ability to drive safely.[73] Self-reports of daytime sleepiness, such as the Epworth Sleepiness Scale, do not accurately indicate driving impairment as some patients underestimate their daytime sleepiness out of fear that they will lose their driving privileges.[55] This may be particularly true for truck drivers and others whose livelihood would be affected by the loss of their license.[56]

The increasing prevalence of OSA is linked to rising obesity rates. The association between OSA and obesity may cause it to be seen as a "lifestyle" disease, possibly biasing attitudes towards funding diagnostic tests and treatments for this condition.

As with obesity, many of the risk factors for OSA are associated with lower socioeconomic status. The ability to comply with treatment may also be more of a problem for individuals in economically marginalized populations. Researchers in Israel examined the link between CPAP compliance and income, and found a clear link between lower incomes and non-compliance.[69,74] Co-payments for CPAP therapy were cited as one of several barriers to compliance. The researchers also identified a need for educational programs to improve compliance in marginalized groups, for example, training geared to individuals who may have lower literacy levels.[69,74]

Population Dynamics

Because body fat around the neck puts pressure on the airway, obesity is a common cause of OSA, and OSA prevalence rates are affected by rates of obesity.[50,57,75-77] A body mass index (BMI) ≥30 kg/m^2 is considered obese. Rates of obesity and overweight in Canadian adults have more than doubled over the past 20 years.[78] A 2000-2001 population health survey, based on self-reported data (considered an underestimate), found that over 6 million Canadians were overweight, and about 3 million Canadians were obese.[78] The 2007 Canadian Community Health Survey, also based on self-reported data, found that 17% of Canadian adults were obese.[79]A 2009 report from the US Sleep Heart Health Study, which followed 2,470 adults over a period of 5 years, found that BMI, rather than the apnea-hypopnea index (AHI), was a better indicator for the risk of developing hypertension in individuals with SDB.[80]An Ontario assessment of polysomnography estimated that up to 75% of those with OSA are obese.[4] Neck and waist circumference (or waist-to-hip ratio) are also used as markers of obesity and possible OSA. Gender is also a factor - men develop OSA more frequently than women (at a ratio of about 2:1).[50]

Many other conditions are associated with an increased risk for SDB. These include:

- congestive heart failure, cerebrovascular disease (stroke) and kidney failure (associated with Cheyne-Stokes breathing)[18]

- cerebrovascular disease, hypothroidism; Parkinson's disease, post-polio syndrome, muscular dystrophy, myasthenia gravis, Prader-Willi syndrome, acromegaly, idiopathic cardiomyopathy, neuromuscular disease and pulmonary disease (associated with central sleep apneas)[18]

- diabetes, polycystic ovarian syndrome (associated with obstructive and central sleep apneas)[18,77,81,82]

- individuals taking opioids or methadone, or using drugs that depress the central nervous system (such as anti-anxiety drugs and anti-seizure medications) (associated with central sleep apneas)[18]

- age and age-related diseases (associated with OSA, and with Cheyne-Stokes breathing caused by congestive heart failure, which is most common in those over the age of 60)[18,57,83]

- snoring (reported in 94% of patients with OSA)[4]

- menopause, family history, abnormalities of the jaw, and lifestyle factors, such as smoking and alcohol use (associated with OSA).[3,77,84]

Patterns of Care

History

Sleep disordered breathing has been described in the scientific and popular literature for several centuries, but a clinically accepted definition of sleep apnea syndrome was only developed in the mid 1960s. At that time the only treatment available for OSA was tracheotomy (surgical removal of the trachea), and this invasive procedure was considered only for patients with severe disease. With the introduction of CPAP therapy, in the early 1980s, patients had a more acceptable treatment option.[42]

Throughout the 1980s a group of US researchers lobbied for funding to address problems associated with sleep disorders. As a result, the US National Institutes of Health allocated funds for research in this field, part of which went to the Wisconsin Sleep Cohort Study on the epidemiology of SDB. Publications from the Wisconsin researchers demonstrated the prevalence of SDB, and around the same time several studies linked SDB to motor vehicle accidents.[70] As a result, SDB was acknowledged as a public health burden and interest in the diagnosis and treatment of sleep disorders has grown since then.[38,85,86]

Technology to record sleep developed alongside research to categorize the stages of normal sleep and the different kinds of sleep disorders.[87] Overnight sleep recordings were introduced in the late 1950s, and soon after the technology began to be used in the study of sleep disorders.[87] The term polysomnogram was first coined in 1974, to refer to "measurement of multiple physiologic parameters during sleep".[87]

Portable sleep monitoring also began in the 1970s, made possible by improvements in ambulatory electroencephalography (EEG).[88] The early units had only a few channels, but portable level III devices have developed rapidly and some devices now offer capabilities similar to those of level I, in-lab polysomnography.[7,88]

Procedures Overview and Trends

The general treatment pathway for a patient suspected of having a sleep disorder is an initial assessment by a general practitioner. At this point the clinical pathway used in Alberta varies between regions. General practitioners may either refer patients directly for ambulatory testing with a level III device or to a sleep specialist [Personal communication, Dawn Filewych, Alberta Health Services, Lethbridge, April 28, 2010]. Other health care specialists, for example, dentists, psychiatrists, cardiologists, internists, respirologists, and ear nose and throat specialists also refer patients for sleep testing [Personal communication, Dr. Larry Pawluk, University of Alberta, May 20, 2010].

A sleep specialist takes a comprehensive sleep history in order to develop a differential diagnosis (i.e., the likelihood of OSA, more complex SDB, or the possibility of other sleep disorders) [Personal communication, Dr. Larry Pawluk, University of Alberta, March 18, 2010].

Patients with complex medical conditions and comorbidities, or those suspected of having sleep disorders other than SDB, are scheduled for overnight level I testing in a sleep centre. Patients considered likely to have uncomplicated OSA and no indication of other SDB or sleep disorders may be referred for either ambulatory level III testing or for level I in-lab testing [Personal communications, Dr. Larry Pawluk, University of Alberta, March 18, 2010; Dr. Irvin Mayer, University of Alberta, March 30, 2010; Dr. Paul Easton, Chinook Healthcare Region Sleep Clinic, April 27, 2010].[19]According to a recent paper by Calgary researchers, most Calgary patients suspected of having OSA undergo level III ambulatory testing first.[81]

Lifestyle changes

Obstructive sleep apnea is a common, chronic condition that requires long-term management.[89,90] Lifestyle interventions, such as weight loss, exercise, reduced alcohol consumption, and modification of sleep practices may alleviate OSA in some patients.[49,84]

Continuous positive airway pressure (CPAP)

According to American Academy of Sleep Medicine practice parameters, CPAP is recommended for moderate to severe OSA.[91] The CPAP unit keeps the airway open by blowing in air. Although it is also used to treat mild OSA, upper airway resistance syndrome and snoring, there is inconclusive evidence that CPAP is effective for these conditions.[91]

Patients often stop using their CPAP unit and many patients who do use the device use it less than they should. Reasons for non-compliance with CPAP therapy include the cost to the patient of the

devices and accessories, discomfort, and lack of understanding of the health risks associated with untreated sleep apnea.[20] Follow-up health care visits, particularly in the initial weeks of use, can address problems with the use of CPAP and increase compliance.[91] CPAP may also be used to treat some patients with Cheyne-Stokes breathing, central or mixed sleep apneas.[18]

Bilevel positive airway pressure (BiPAP)

BiPAP units deliver 2 levels of air pressure, one level for inspiration and a lower pressure for expiration. They are used to treat some patients with central sleep apneas related to lung diseases or hypoventilation causing hypercapnia (excess carbon dioxide).[18,91]

Oral appliances

Custom made devices that reposition the jaw or tongue to reduce airway obstruction while the patient sleeps may be useful for some patients with OSA, particularly for patients with mild or moderate OSA, or for patients who cannot tolerate CPAP therapy, but they are less effective than CPAP, and patient compliance is also an issue.[72,92,93]

Surgical interventions

Uvulopalatopharyngoplasty and uvulopalatoplasty are surgical interventions for OSA. These procedures involve removing tissue in the palate, airways or nasal passages to relieve airway obstruction. Jaw realignment and orthodontic surgery may also be used to treat OSA. There is only limited evidence to support surgical interventions for OSA and adverse events and post-operative pain are common.[28,94] Some surgical procedures, for example, laser-assisted uvulopalatoplasty are no longer recommended for the treatment of OSA.[90] Despite this, there has been an increase in the use of surgical procedures for OSA in some countries.[94]

The effectiveness of several new treatments for OSA has not yet been determined. These include palatal implants, radiofrequency ablation of the palate and nasal passages, injection snoreplasty (the use of a sclerosing agent to stiffen the soft palate), and nasal surgery.[92] Bariatric surgery may be an effective treatment option for morbidly obese patients with OSA.[90,95]

Other therapies

Various drug therapies may be used to treat central sleep apneas and Cheyne-Stokes breathing.[18] Sleep disordered breathing in patients with comorbid conditions may be improved by treatment for their primary condition, for example, dialysis for kidney failure, or optimal medical management for patients with heart failure.[18]

Access to Sleep Studies in Alberta

A 2004 survey that compared access to sleep studies in 5 countries, and across Canada, found that the number of sleep studies per 100,000 people, and the wait lists for studies varied considerably. In Canada, the waiting list for a consult with a sleep specialist was typically from 4 to 6 months (though

in some areas it was over a year). The wait for completion of a level 1 sleep study ranged from 8 to 30 months. Wait lists for a specialist consult and level I studies were shorter in Ontario (about 2 months for each).[96]

The wait time to see a sleep specialist in Edmonton is about 6 months [Personal communication, Paul Vaillancourt, Sleep Medix, Edmonton, November 17, 2009]. Once referred for level I testing, the wait time is currently about 4 months. In early 2010, just over 700 patients were waiting for level I testing in Edmonton. The University of Alberta sleep laboratory operates 5 days per week and can accommodate 6 patients per night. During the past fiscal year (as of February 28, 2010), the centre completed 1,328 level I tests [Personal communication, Susan Derks, Alberta Health Services, Edmonton, March 30, 2010]. Level III studies are not presently done by the University of Alberta centre, but sleep specialists provide the clinical assessment and refer appropriate patients for level III studies to private vendors [Personal communication, Dr. Larry Pawluk, University of Alberta, May 20, 2010]. Once the patient has a prescription from a physician, there is virtually no wait for level III testing through private vendors. The privately operated sleep clinic in Edmonton provides about 41 level I tests and about 60 attended level III tests each month. [Personal communication, Northern Alberta Sleep Clinic, Edmonton, April 29, 2010]. The Merrill Clinic, an Edmonton dental clinic, also offers level III testing [Personal communication, Dr. Larry Pawluk, University of Alberta, June 22, 2010].

In Edmonton, unless they have private insurance that covers these tests, patients pay out-of-pocket for all level III testing through the private vendors, and also for a portion of level I test costs in the University of Alberta sleep lab. [Personal communication, Dr. Larry Pawluk, University of Alberta, May 20, 2010].

At the Southern Alberta Sleep Clinic, in Lethbridge, the wait time for a level I study is about 9 months, and there are currently 543 patients on the waiting list. The centre operates 4 beds per night (one bed is currently down for repair), and 2 beds per day, 5 days of the week, for a total of 30 sleep studies per week. The centre provided 1,186 level I tests over the past year. Both level I in-lab sleep studies and level III in-home studies are available through the centre and both types of testing are wholly publicly funded. [Personal communication, Dawn Filewych, Alberta Health Services, Lethbridge, April 28, 2010].

Over the past 3 years (April 2006 – March 2009), the Foothills Hospital Centre, in Calgary, performed 2,862 level I sleep studies (not including multiple sleep latency tests or research studies), and 4,482 level III studies. The level III tests were performed for various reasons, including new appointments, repeat tests for technical problems, and for patient follow-up [Personal communication, Dr. Ward Flemons, University of Calgary, Calgary, April 24, 2010]. Both level I and level III testing provided through the Foothills Hospital is publicly funded through the hospital's operating funds.

Several private companies in Alberta offer level III testing. An estimated 15,000 level III tests are performed by private vendors in Alberta per year. The number of tests performed varies widely between vendors, with some companies providing up to 250 tests per month, and others providing only 30-40 per year [Personal Communication, Connie Brooks, Alberta Aids to Daily Living, Edmonton, June 8, 2010].

Table 6. Level I sleep labs in Alberta

City	Centre	# of beds	Public / Private
Edmonton	University of Alberta	6	Public
Edmonton	Northern Alberta Sleep Clinic	2	Private
Lethbridge	Southern Alberta Sleep Clinic	4	Public
Calgary	Foothills Hospital	5	Public
Calgary	Canadian Sleep Institute	4	Private
Calgary	Centre for Sleep and Human Performance	3	Private

* The sleep clinic at Wetaskiwin General Hospital has 4 beds for in-laboratory, attended, level III sleep studies. ** This list does not include pediatric sleep laboratories.

A 2009 assessment from the Canadian Agency for Drugs and Technologies in Health (CADTH) included a survey of funding for OSA diagnostic and therapeutic devices.[20] No provinces directly cover the use of level III ambulatory sleep studies.[20] In Alberta, there are some exceptions (for example, in Calgary and Lethbridge) where individual centres fund the level III testing through their global operating funds.

Public funding for CPAP therapy varies across Canada. According to the 2004 survey, CPAP was fully publicly funded in some provinces, but in most provinces patients without private insurance paid the costs.[96] Some provincial programs, such as Alberta Aids to Daily Living (AADL) and Assured Income for Severely Handicapped (AISH), provide partial or full coverage for beneficiaries who require CPAP therapy. AISH currently requires a level 1 sleep study for the diagnosis SDB (including uncomplicated OSA).

No information on patient access to sleep studies in the different regions of Alberta, or for various sub-groups of the population was found.

Diffusion and Demand

A greater awareness of the health effects of sleep disorders among physicians and the general public may be responsible for the increased demand for sleep studies.[97] In one BC study, 62% of patients tested with level I polysomnography indicated they would have preferred ambulatory testing, whereas only 6% of patients in the in-home testing group would have preferred in-lab testing.[52]

Information on trends in the use of level I versus level III sleep studies was not available, nor was Alberta information on the diffusion or utilization of sleep studies over time. In Ontario, for example, the numbers of level I sleep studies more than doubled over a 10-year period, from just

under 60,000 tests in 1999 to over 120,000 tests in 2008 [Personal communication, Dr. Walter Wodchis, University of Toronto / Institute for Clinical and Evaluative Sciences, January 4, 2010].

Health System Capacity

Workforce & Infrastructural Capacity

Various health care professionals provide sleep studies in Alberta. These include respiratory therapists, respiratory technologists, and physician sleep specialists. According to the College of Physicians and Surgeons of Alberta, respiratory therapists registered with the College and Association of Respiratory Therapists of Alberta, and other health care professionals with appropriate training may perform sleep apnea testing. These tests should be performed only at the request of a physician. The interpretation of test results and prescribed treatments should be made by a physician with specialist qualifications (for example, in neurology, otolaryngology, internal medicine, pediatrics, respiratory medicine, psychiatry or anesthesiology) and additional training in sleep disorders.[98] Guidelines available from the College of Physicians and Surgeons of Alberta cover standards for private sleep medicine facilities in this province.[99] In some Alberta sleep centres a respiratory therapist or technologist (with additional training in reading polysomnography tests) scores the sleep test and the specialist physician interprets the results.

A 2009 UK Department of Health guide to good practice for respiratory and sleep services outlines issues to be tackled in response to their 18 week patient pathway initiative.[100] The guide describes four areas that must be addressed to improve service delivery:

- systems and process (for example, using efficient scheduling and appointment management services to clear wait lists, and capturing administrative data to allow for better planning and management of services)
- technology (for example, taking advantage of developments in information technologies that allow for remote provision of diagnostic studies)
- workforce (in particular, the use of multidisciplinary teams for service provision, offering longer hours of service, and training and using staff appropriately for the tasks involved)
- new service models (such as "one stop clinics" for provision of services).[100]

Technology Effects and Effectiveness (T)

Other Jurisdictional Guidelines

Current Canadian guidelines suggest that level III studies are an accepted diagnostic tool for patients suspected of having uncomplicated OSA. The patient's pre-test probability of this condition should first be determined by the referring physician following a complete patient history and physical exam.

The 2008 Canadian Thoracic Society guidelines for the diagnosis of OSA recommend that patients complete an assessment of daytime sleepiness (such as the Epworth Sleepiness Scale questionnaire), after which they should be assessed and triaged into either urgent, semi-urgent or elective categories according to severity of daytime sleepiness, the presence or absence of comorbidities, and whether the patient had a "safety critical occupation" (for example, commercial drivers).[101] The guidelines recommend level I in-lab polysomnography as the preferred diagnostic test, but found that level II or level III testing was acceptable for diagnosing patients with a moderate to high pre-test likelihood of OSA.[101]

The 2005 British Columbia Guidelines & Protocols Advisory Committee guidelines on the assessment and management of OSA in adults recommend that following a comprehensive patient history and physical exam, patients who do not have excessive daytime sleepiness should be referred for overnight home oximetry to rule out OSA. Patients who have excessive daytime sleepiness, and those with abnormal home oximetry tests should be referred to a sleep specialist.[16]

In British Columbia, Dr. Frank Ryan and colleagues have developed a diagnostic strategy to expedite care for patients with uncomplicated OSA. Their strategy is based on ambulatory diagnosis and auto-CPAP titration.[52§] This clinical pathway is used by their Vancouver sleep centre, but has not yet been adopted at a regional or provincial level [Personal communication, Dr. Frank Ryan, University of British Columbia, June 21, 2010]. A recent paper from this research group further describes their diagnostic algorithm.[102]

The Canadian Sleep Society is finalizing a position paper on level III sleep studies. This is expected to be published in the *Canadian Respiratory Journal* but the date of publication is not yet known [Personal communication, Dr. Helen Driver, Canadian Sleep Society, June 21, 2010].

Dr. Robert Skomro and colleagues at the Sleep Research Laboatory, Saskatoon Health Region, are working on a provincial diagnostic strategy for OSA in Saskachewan [Personal communication, Dr. Robert Skomro, Saskatoon City Hospital, June 19, 2010].

In 2007, the American Academy of Sleep Medicine reviewed the literature and issued guidelines on the use of portable (level III) devices for diagnosing OSA in adults.[103] These guidelines stipulate that a comprehensive sleep evaluation by a board certified sleep specialist, followed by ambulatory testing, can be used to diagnose patients with a high pre-test probability for OSA and no significant comorbidities. However, level III testing should not be used for population screening, or for patients with comorbidities or those who are suspected of having other types of sleep disorders. The raw data from level III tests should be reviewed, rather than relying on automated test scoring.

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§ This clinical trial was not included in this assessment because although it involved a level III device, only the oximetry data from the device was used in the study. In other words, the level III device was used as a level IV device.

Patients who have negative or inadequate test results from portable monitoring should be referred for in-lab level I testing.[103]

Guidelines on the management of OSA from the Scottish Intercollegiate Guidelines Network, and endorsed by the British Thoracic Society, concluded that full polysomnography (i.e., level I) is not necessary to diagnose OSA in most patients.[104] Level I testing is recommended only for patients with excessive daytime sleepiness who have no other signs suggestive of OSA. A 2009 review of the evidence since these guidelines were first issued (in 2003) concluded that the current evidence did not warrant changes to the guidelines at this time.[104]

Despite these guidelines, the appropriate use of level III sleep studies is difficult to control because of the lack of regulations covering these tests [Personal communication, Dr. Larry Pawluk, University of Alberta, May 28, 2010].

Summary of Other Recent Assessments of the Diagnosis of Sleep Disordered Breathing

Earlier health technology assessments have all focussed on the diagnosis and treatment of OSA.

A 2009 Canadian assessment concluded that "…among patients with a high pretest probability of moderate-to-severe OSA, portable monitoring devices can be used at home for diagnosis when there is limited access to laboratory sleep studies and sleep specialists."[20] Although some studies found that level III devices and CPAP autotitration may be less accurate than in-laboratory PSG and titration, this may not affect patient compliance and response to CPAP therapy.[20] The assessment also noted that current guidelines recommend the use of level III sleep studies be limited to those with a high likelihood of having OSA, without other sleep disorders or comorbidities. Sleep studies (both level I and level III) should meet common standards as part of a comprehensive program that includes access to sleep specialists, in-laboratory and in-home testing, and trained therapists to monitor CPAP therapy.[20]

The California Technology Assessment Forum also reviewed the use of level III testing for OSA in a 2009 update to their 2005 assessment.[7] This assessment concluded that:

> *The validation [of] trials of home portable monitoring devices are difficult because of known night to night variability in the AHI measured by full PSG [i.e., level I], known first night effects when patients are monitored, probable differences between sleep patterns in the laboratory and at home, and the limited correlation of AHI with health outcomes and response to CPAP. In fact, portable home testing may be better at predicting which patients will respond to treatment with CPAP or other interventions for OSA. Published reports of diagnostic accuracy are difficult to compare as they use many different recording devices and different definitions of RDI to define OSA...*[7]

The California review found that there was evidence to support the use of two portable devices (the level III Remmers Sleep Recorder and the level IV WatchPat) for the diagnosis of patients with a high likelihood of OSA who are unlikely to have daytime sleepiness due to other conditions.[7]

In 2009, the US Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination that stipulates level I, or unattended level II, III or IV sleep studies (with some conditions regarding the number of channels of data captured) will be covered for the diagnosis of OSA in patients with signs and symptoms indicative of OSA.[8] The coverage decision was based on a 2007 assessment and decision model prepared for the Agency for Healthcare Quality and Research.[5,26] The AHRQ assessment found that level I testing did not result in better diagnosis or outcomes (i.e., CPAP titration) for individuals with a high pre-test probability of OSA.[5]

A 2007 joint health technology assessment by Nordic agencies evaluated diagnostic and treatment technologies for OSA. This concluded that manually scored level III devices which included airflow, respiratory movement and oximetry had high sensitivity and specificity for detecting OSA when compared to level I polysomnography. Automatic scoring of level III sleep studies had high sensitivity for OSA, but low specificity. As level III devices do not record actual sleep time, it was not clear whether they would be able to distinguish between OSA and central apneas.[28]

In 2006, the Ontario Medical Advisory Secretariat's review of polysomnography for OSA concluded that individuals with a high pre-test probability for OSA (based on 2 criteria: snoring and excessive daytime sleepiness) could be offered a trial of CPAP therapy, rather than level I polysomnography. The review also advised that weight loss was a valid treatment option – either using personalized weight loss programs or bariatric surgery for morbidly obese patients.[4]

The Danish Centre for Evaluation and Health Technology Assessment also published a 2006 assessment which compared the use of level I, level III and ambulatory oximetry in the diagnosis of OSA. It concluded that providing sufficient level I in-lab polysomnography beds was not a practical option for diagnosing patients with uncomplicated OSA. Ambulatory oximetry did not offer a diagnostic or economic advantage. Level III ambulatory testing and auto-titrating CPAP was recommended as the preferred option for diagnosing and managing uncomplicated OSA.[105]

Forthcoming assessments

An assessment on level III, home-based diagnosis of SDB, prepared for the Australian government's Medical Services Advisory Committee was expected to be published in June 2010.

The Washington State Health Technology Assessment Program is just starting an assessment on the diagnosis and treatment of sleep apnea. The expected publication date for this review is not yet known.

Results

Description of Included Studies

Thirty-four studies totalling 1,952 patients were included in the review (Table 15). Twenty-four studies recruited patients with suspected OSA, and 10 recruited patients with suspected SDB (Table 16). The studies originated from centres in North America (n=16), South America (n=3), Asia (n=5), Australia (n=1), and Europe (n=8). Five were from Canada, and one of these studies reported on SDB.[106]

Demographic information

Twenty-five studies included demographic information (Table 27). The age of patients ranged from 18 to 80 years, with a pooled average of 50.8 years. There was a greater proportion of males than females (2.7:1). Three of the studies recruited patients based on gender; 2 recruited only male patients[107,108] and 1 recruited only female patients.[109] One study included only patients older than 65 years of age.[110]

Body Mass Index (BMI) was the most common anatomical pre-test probability indicator reported (in 23 of 33 studies). Many patients were overweight (BMI of 25-29.9kg/m^2), with a pooled mean of 29.7 kg/m^2.

The Epworth Sleepiness Scale (ESS) was the most commonly reported measure of excessive daytime sleepiness (in 14 of 33 studies). Mean ESS values ranged from 8.1 to 12.0, indicating that patients were considered "sleepy" during the day and in need of assessment and/or treatment.

Six of the studies (3 SDB and 3 OSA) included patients with stable cardiovascular disease (a comorbidity associated with SDB). One study included patients awaiting surgery.

Inclusion/exclusion criteria

The most commonly cited inclusion criterion was the presence of suspected OSA based on patient reported presentation/symptoms or clinical assessment. Commonly cited exclusion criteria included those patients suspected of having non-respiratory based sleep disorders.

Study Design

There were three general protocols used in the studies:

- Simultaneous in-lab level I and level III tests and separate in-home level III tests (9 studies totalling 569 patients)
- Simultaneous in-lab level I and level III tests (10 studies totalling 683 patients)
- Separate in-lab level I and in-home level III tests (14 studies totalling 640 patients)

In all of the studies, the same patients had both level I and level III tests, regardless of study protocol. Seven studies with an in-home arm used random allocation methods to assign test order. All but one of the studies were prospective. The one retrospective study was a chart review of patients with SDB.[106] Most studies (21 of 33) reported consecutive recruitment of patients as they were referred to a sleep specialist.

Sample sizes of the studies ranged from 5 to 175 patients. Only 2 studies made reference to the use of sample size calculations and statistical power. [111,112]

Study Devices and Location

Across the studies, there were 12 different level I devices and 15 different level III devices. One study, a multisite study, included the use of 4 different level I devices.[113] In 15 of the 33 studies, there were no details on the type of level I device used. Three studies did not provide details on the type of level III device used. All but one of the separate level III studies took place in the patient's home.[114] Most of the separate studies occurred within 2 weeks of each other (range 1 day to 1 year).

Scoring of Study

All level I sleep studies were scored manually. Level III studies involved either manual and/or automated scoring. Only half reported some form of outcome "blinding". Diagnostic apnea/hypopnea thresholds for a positive diagnosis, including Apnea Hypopnea Index (AHI) and Respiratory Disturbance Index (RDI) varied across studies. The most commonly used threshold was an AHI > 5 events per hour (18 of 33 studies), with a range of AHI/RDI > 5 to AHI/RDI > 30 events per hour. Data loss due to either technical or human (patient) error, was higher among level III studies than level I studies. Where this occurred, the study investigators typically excluded those patients from their analysis.

Quality of included studies

Using the Oxford Centre for Evidence-based Medicine levels of evidence (Table 5), 23/33 of the studies were graded either 1b or 1c with only one study graded below a level 3. Thus, the grade of recommendation was considered to be good to excellent. Based on results from the QUADAS tool for determining the quality of diagnostic studies,[32] studies scored well on measures of bias (internal validity) with a mean result of 7 (range of 4-9) of a possible 9 points. With respect to external validity and reporting, studies scored an average of 1 out of a possible points (range: 0-2) and 1.5 out of a possible 3 points (range: 0-3), respectively (Table 27).

Selection bias

Two thirds of the studies (21 of 33) reported consecutive recruitmentof patients – this considered ideal for diagnostic tests.[115] The patients recruited to the studies were likely representative of those who would be seen in clinical practice and referred for a level III test (i.e. patients suspected of OSA or SDB who were referred to a sleep specialist and who were without significant comorbidity).

However, less than one third of the studies gave details on the source of patient referrals, limiting this conclusion.

Most studies focused on OSA, reflecting the higher prevalence of this condition compared to other types of SDB. Therefore, the results are most applicable to patients with suspected OSA, rather than those with other SDB conditions.

Reporting bias

Details on study sampling, patient demographics, pre-test probability, study design, and study outcomes were lacking in many of the studies (16 of 34 studies were conference abstracts).

Measurement bias

Ten studies used simultaneous in-lab tests only (level I and level III). An in-lab level III test may not be a valid surrogate for an in-home test due to environmental differences. Also, simultaneous studies introduce a source of bias as they are not conducted independently of one another. In such studies, the level III test may show inflated accuracy compared to a separate level III test.

All studies used Level I tests as the single reference standard. Ideally, in diagnostic studies, more than one reference standard is used and patients are also followed up over time (for example, to assess their response to treatment – for patients with OSA this would include an assessment of their response to CPAP).[115]

Observer Bias

Half of the studies reported some form of outcome blinding. It was not clear if the blinding was associated with participants' test scores or with interpretation of test results from the other study arm. It is important to note that unblinded studies are more likely to overestimate diagnostic accuracy.

Other sources of bias in diagnostic studies

One factor that can inflate accuracy statistics is the exclusion of "test failures" in the analysis. This was common practice in the studies with indeterminate results. However, all studies controlled for verification bias by using the same level I test regardless of the results of the level III test (and vice versa). Treatment paradox (i.e., the patient is cured before the second test is conducted) was controlled for in all studies by limiting the time between tests and not implementing treatment before both were completed.

External validity

There were a number of threats to external validity in these studies. First, the extent to which the sample was representative could not be accurately determined because of the limited patient demographic information. Second, the broad range of devices used limits the generalizability of

results to other level III devices. It was not possible to determine whether some level III devices were more accurate than others because of the lack of studies on each device. Third the results of in-lab level III studies may not be generalizable to those of the same device used in-home due to important environmental differences.

Safety

Adverse events reported by sleep study type appear in Table 21. Across all studies there were no fatalities and few non-fatal adverse events reported, possibly due to the non-invasive nature of these diagnostic tests. There were two studies that each reported a single adverse event, both of which occurred during the simultaneous level I/III study arms.[113,116] One patient, in a group of stable heart failure patients being studied for SDB, experienced severe pacemaker inference. For the other patient, who experienced a hypertensive crisis, no additional patient details were provided.

Among those studies that included a level III in-home study, adverse events were reported in only one study; these included skin redness and irritation associated with sensor attachment among 27 of 50 patients.[113]

The literature search for this assessment did not identify any reports of serious adverse events from the use of level III devices. However, safety issues may occur if a patient with a comorbid health condition inappropriately receives a level III sleep study. For example, a level III sleep study, followed by at-home auto-CPAP titration in a patient with unstable or unsuspected chronic obstructive pulmonary disease could result in CO_2 narcosis [personal communication, Dr. Larry Pawluk, University of Alberta, May 20, 2010].

Failure

One study attributed the higher rates of test failure observed early in the study to the lack of experience of those involved in instructing patients on how to carry out the level III test at home.[117]

Due to the comorbidities associated with SDB (as outlined in the Burden of Illness section) it is likely that untreated SDB – whether undiagnosed or misdiagnosed - incurs health risks. A 2007 BC study, by Mulgrew et al, that examined the use of oximetry and ambulatory auto-titratiing CPAP versus in-lab level I polysomnography for patients with a high likelihood of OSA found that adherence to CPAP use was higher in the ambulatory group.[52] In this study, one patient with Cheyne-Stokes respiration was initially misdiagnosed as having OSA, but this was corrected when their condition did not improve during the 2-week trial of CPAP therapy. Although the device used in this study was a level III device, only oximetry data was used – in short, the device was used as a level IV device and the study was therefore excluded from this review.[9]

Efficacy / Effectiveness

Evidence related to efficacy/effectiveness of the level I and level III devices was analysed according to outcomes of diagnostic accuracy. Evidence pertaining to these outcomes was collected separately

for studies that reported on simultaneous level I/III sleep studies and those that reported on separate level I/III studies (Table 16). This was done to help assess differences in level III accuracy outcome measures attributable to studies performed in the patient's home versus in a sleep laboratory, as well as differences in accuracy associated with the time lag between level I and level III sleep studies. As there were 9 studies that included both a simulataneous in-lab and a separate in-home level III sleep study, the outcomes from these studies appear in 2 separate tables (Table 17 and Table 18). [110,112,113,116-121]

Outcomes

Outcomes data from all studies are presented in Table 16, Table 17, Table 18, Table 19, Table 20. Sleep indexes reported: OSA studiesTable 20, Table 21, Table 22, Table 23, Table 24, and Table 25.

Obstructive Sleep Apnea (OSA)

Studies that included both simultaneous in-lab level I and level III sleep studies plus a separate in-home level III sleep study

Eight studies reported on OSA, with a total of 549 patients, most of whom had no significant medical comorbidities.[108,110,112,113,116-118,120] However, 2 of the studies included patients with significant comorbidities, one stable chronic heart failure,[113]and the other general cardiovascular conditions.[112] Outcomes included sensitivity and specificity values, positive and negative likelihood ratios, and ROC values for 3 studies.[112,116,117]

The reported sensitivity and specificity values reported varied across the studies. Six studies[110,112,113,116-118] reported these values across several AHI threshold cut-off points. Four of these studies[113,116-118] reported decreasing sensitivity and increasing specificity with increasing AHI thresholds. (Table 18, Table 20). In other words, as the severity of OSA increased the sensitivity (i.e., the ability of level III testing to identify OSA) decreased and the specificity (i.e., the ability of level III testing to rule out OSA) increased.

In all 6 studies,[110,112,113,116-118] in-home level III sensitivity values at each AHI cut-off point were lower than those reported for the in-lab level III studies. There was no evidence to suggest that the time interval between in-home and in-lab studies, patient comorbidities, or the order in which sleep studies occurred affected these results.

Positive likelihood ratios in the 6 studies showed a general pattern of increasing ratios associated with increasing AHI cut-off points. The pattern associated with negative likelihood ratios varied: 4 studies[113,116-118] demonstrated a converse pattern associated with increasing AHI cut-off points, while 2 studies[110,112] demonstrated an inverse pattern. Positive likelihood ratio values across all AHI cut-offs were higher among in-lab level III sleep studies, while negative likelihood ratios were lower.

Positive and negative likelihood ratios were similar for in-lab and in-home level III devices, While in-home ratios were slightly lower than those in-lab, there was no information reported on either the clinical or statistical significance of this difference. There was evidence indicating better odds of

detecting disease as cut-off points increased. This finding also appeared independent of potential confounders. Ratios for severe OSA (AHI≥30/hour) indicated mixed results. Two studies[116,117] reported higher positive likelihood ratio values compared to lower cut-off points, while 2 studies[110,112] reported higher values compared to lower cut-offs.

ROC values reported[112,116,117] indicate high diagnostic agreement for both in-home and in-lab level III sleep studies. Across all cut-off points (including severe OSA) high ROC values (≥0.90) were reported for both in-home and in-lab sleep studies, which indicates that level III sleep studies are acceptable tests for OSA.

Pooled cut-off points for in-home level III sleep studies

Results were pooled to determine the diagnostic performance of in-home level III studies in identifying OSA. Sensitivity and specificity values from the studies that included both simultaneous in-lab testing and in-lab versus in-home testing were used in this calculation. Values were pooled and assessed using 4 cut-off points for OSA (i.e., mild AHI≥5 and AHI≥10 per hour; moderate AHI≥15; severe AHI≥30). The results suggest a pattern of lower sensitivity and higher specificity associated with increasing severity disease of OSA. Pooled sensitivity values were: 0.91 (based on 10 studies) and 0.86 (7 studies) for mild OSA, 0.83 (11 studies) for moderate OSA, and 0.81 (5 studies) for severe OSA. The specificity values were: 0.75 and 0.89 for mild OSA, 0.86 for moderate OSA, and 0.90 for severe OSA.

Three studies assessed diagnostic accuracy of level III devices according to gender: 2 male only studies,[107,108] and 1 female[109] only study. Sensitivity and specificity at different AHI cut-offs were reported by only 2 of studies. One (male) study reported a sensitivity of 0.78 and a specificity of 0.87 for moderate OSA (AHI≥15 per hour). The second (female) study reported sensitivity of 0.77 and specificity of 0.85 for mild OSA (AHI≥5). When these values are compared to the pooled results above there does not seem to be a difference in the diagnostic effectiveness of level III sleep studies associated with gender.

One study included only participants aged 65 years and over.[110] Sensitivity values reported were 0.70 for mild OSA (AHI≥5), 0.81 for moderate OSA (AHI≥15), and 0.81 for severe OSA (AHI≥30). Specificity values were 1.0 for mild OSA, 0.90 for moderate OSA, and 0.85 for severe OSA. Compared to the pooled values above, there appears to be a significant difference in the sensitivity and specificity values for mild disease, however, the diagnostic effectiveness for moderate and severe disease is comparable to that of the pooled study values.

Three studies assessed the diagnostic effectiveness of level III tests in patients with chronic heart failure.[113,119,122] Two of these studies reported sensitivity and specificity for moderate OSA (AHI≥15).[119,122] Sensitivity values from the 2 studies were 0.68 and 0.58. These values are significantly lower than the pooled values for this level of disease (0.83). The specificity values for moderate OSA were 0.95 and 0.62, compared to the pooled value of 0.86.

Table 7. Pooled performance of in-home level III testing at different levels of OSA severity

AHI cut-off	≥ 5 / hour Mild OSA	≥ 10 / hour Mild OSA	≥ 15 / hour Moderate OSA	≥ 30 / hour Severe OSA
True Positive	473	304	366	120
False Positive	47	27	50	24
False Negative	49	51	77	28
True Negative	140	215	298	219
Sensitivity	0.91	0.86	0.83	0.81
Specificity	0.75	0.89	0.86	0.90
Positive predictive value	0.91	0.92	0.88	0.83
Negative predictive value	0.74	0.81	0.79	0.89
Number of studies	10	7	11	5

Simultaneous in-lab level I and level III sleep studies

Eight studies[121,123-129] reported on OSA, with a total of 498 patients. One of these studies included 75 patients who had stable major medical conditions, including hypertension.[123] Outcomes data included sensitivity and specificity, positive and negative likelihood ratios, and ROC curve values.[123,126] Overall, the quantity of data from these studies were limited.

There was significant variation among the sensitivity and specificity values reported across all studies. Across studies reporting these values for various AHI cut-off points, sensitivity decreased, and specificity increased, with increasing cut-off points of AHI ≥5/hour to AHI ≥15/hour. [121,125,126,128,129] Two studies reported larger declines that may have been clinically significant.[128,129] There were no obvious confounding factors to account for these differences. Values from 5 studies reporting on severe disease (AHI ≥30/hour), were mixed and there was no pattern of either increased or decreased sensitivity or specificity. [121,125,126,128,129]

Across all studies, positive likelihood ratios ranged from 3.07 (AHI ≥ 5/hour) [129] to 49.0 (AHI ≥ 30/hour).[126] Positive likelihood ratios were higher overall for severe disease (AHI ≥ 30/hour). Statistical data verifying the significance of these higher ratios was not reported. Negative likelihood ratios reported did not indicate any consistent pattern of either increasing or decreasing values associated with increasing AHI cut-off points. There did not appear to be any within-study confounding factors that accounted for this variablity. Across all studies and all cut-off points, negative likelihood ratios ranged from 0.020 to 0.49 indicating better than chance odds of a negative result being correct.

ROC curve values ranged from 0.96 (AHI ≥ 5/hour)[123] to 0.996 (AHI ≥ 30/hour).[126] These ROC values indicate a high degree of performance in diagnosing OSA correctly across all cut-off points for these in-lab level III sleep studies.

Separate in-lab level I and in-home level III sleep studies

Twelve studies reported on OSA, with a total of 506 patients, a portion of which included subjects with stable cardiovascular comorbidities.[106,107,109,111,114,130-136] Limited outcomes data were reported for these patients. Outcomes included sensitivity and specificity, positive and negative likelihood ratios and an ROC curve value.[132]

No studies in this group reported sensitivity and specificity values for more than one threshold cut-point. Five studies reported values for an AHI ≥ 5/hour cut-off point.[106,109,130,134,135] Sensitivity ranged from 80% to 95%, while specificity ranged from 33.3% to 100%. Across the 3 studies reporting values for a cut-off point of AHI ≥ 10/hour sensitivity ranged from 61.9% to 100%, and specificity ranged from 78.9% to 100%.[114,131,132] The lowest sensitivity value at this cut-off point was reported for the study that included patients with comorbidities.[132] Overall, sensitivity and specificity values varied significantly, independent of patient characteristics, interval between studies, or sequence of studies.

Higher positive and negative likelihood ratios were reported among the studies reporting on AHI ≥ 10 cut-off points (range 3.95 to 14.78, and 0 to 0.4, respectively), compared to the AHI ≥ 5 cut-point studies (range 1.42 to 3.65, and 0.12 to 0.21, respectively). However, the variation in reported values did not indicate a pattern of improved odds of correct diagnosis, or correct non-diagnosis at different cut-off points. Overall, the in-home level III devices performed better than would be expected by chance.

The ROC value of 0.875 was reported for a cut-off point of AHI ≥10/hour. This value was lower than that cited by other studies that used the same AHI cut-off point, indicating a lower degree of diagnostic performance for mild OSA. [90,95,103]

Sleep Disordered Breathing (SDB) Conditions Other Than OSA

Studies that included both simultaneous in-lab level I and level III sleep studies plus a separate in-home level III sleep study

One study reported on SDB conditions other than OSA.[119] It recruited 20 patients, all of whom had stable chronic heart failure (CHF), a condition associated with a higher pre-test probability of SDB conditions. Outcomes included sensitivity and specificity, and positive and negative likelihood ratios (Table 17, Table 19).

Sensitivity and specificity values based upon a diagnostic threshold cut-point of AHI ≥ 15/hour for the in-home level III sleep studies were 58.3% and 62.5%, respectively. These corresponded to positive and negative likelihood ratios of 1.55 and 0.67, respectively. Thus, the probability of detecting disease in a diseased patient using the in-home level III device was only slightly greater than chance. The probability of detecting no disease in a disease free patient was slightly less than chance. Receiver operating characteristic (ROC) values were not reported.

There were no diagnostic accuracy data provided for the in-lab level III studies.

Simultaneous in-lab level I and level III sleep studies

Two studies reported on SDB conditions other than OSA using simultaneous in-lab level I and level III sleep studies.[137,138] None of the 185 patients in these studies had significant comorbidities. Outcomes included sensitivity and specificity, positive and negative likelihood ratios, and ROC values for one study.[138]

Sensitivity and specificity were reported for multiple cut-off points in each study. One study[137] used the following 2 cut-off points: AHI ≥ 5/hour and AHI ≥ 15/hour; while the other applied the following four cut-off points: AHI ≥ 5/hour, AHI ≥ 10/hour, AHI ≥ 15/hour , and AHI ≥ 20/hour. Across all cut-off points there was a trend of decreasing sensitivity and increasing specificity. The cut-off point of AHI ≥ 20/hour had the lowest sensitivity and highest specificity. The clinical or statistical significance of these findings could not be determined.

Positive and negative likelihood ratios increased as threshold cut-points increased. The probability of making a positive diagnosis was highest among patients with severe disease; with a ratio of 19.84 for a cut-off of AHI ≥ 20/hour. However, the likelihood of misdiagnosis was highest for lower cut-off points.

ROC values were high (0.998 to 1.0) across all 4 cut-off points indicating that the in-lab level III device performed as well diagnostically, at each point, as the level I sleep study.[138]

Separate in-lab level I and in-home level III sleep studies

Two studies compared in-lab level I to an in-home level III.[122,139] One study[139]included 44 patients without medical comorbidities, while the other[122] included 90 patients with stable chronic heart failure. Outcomes included sensitivity and specificity, positive and negative likelihood ratios, and ROC values for one study.[122]

Each study reported on multiple diagnostic threshold cut-off points. For AHI ≥ 5/hour the sensitivity was 100% (for the healthy patients) and 82.5% for the stable CHF patients. A lower number of patients were correctly identified with having disease at higher cut-off points across both studies (AHI ≥ 15/hour sensitivity 93.8% and 68.4%, respectfully). CHF patients (those with a higher risk of SDB) were misdiagnosed as "disease free" more often as these cut-off points increased. Sensitivity decreased with increasing threshold cut-off points, except in extreme cases of disease (AHI ≥ 50/hour), where there was a "rebound" increase. Specificity values increased in both studies as the threshold cut-off points increased. Specificity and sensitivity values did not appear to be affected by the order in which the studies took place, nor the time interval between studies.

The single study presenting values for central sleep apnea reported 100% sensitivity and specificity for the identification of central apneas using a threshold cut-off point of AHI ≥ 15.[122]

Positive likelihood ratios increased with increasing threshold cut-off points. The diagnostic performance of level III devices among patients with disease was lowest at a cut-off point of AHI ≥ 5/hour (7.24 and 1.0). The device performed best in correctly diagnosing disease among more severe cases with AHI ≥50/hour (31.03).[139] Higher positive and negative likelihood ratios were reported for the CHF patients at both AHI ≥ 5 and AHI ≥ 15/hour cut-off points, compared to the medically stable patients. While negative likelihood ratios were low (0.103 to 0.33) for both studies, the values indicate higher odds of a negative test result being correct for higher cut-offs. The clinical and statistical significance of these values was not discussed.

The ROC value (0.862) was lowest for the AHI ≥ 15/hour cut-off point, indicating that the level III device performed better when using lower cut-off points of diagnosis.[122]

Comparative Benefits and Risks

Of the studies that reported patient preferences, most patients preferred the in-home level III sleep study over in-lab level I or in-lab level III sleep studies. Patient preference may be an important factor to consider, but missing data as a result of equipment or human error, or due to patient intolerance of the test was higher in in-home level III sleep studies (Table 22). Data loss occurred in approximately 8% of patients using a level III device at home, compared to 1% for in-lab level I and 5% for in-lab level III sleep studies. For both in-home and in-lab level III sleep studies, equipment errors caused most of the lost data. Human error and patient intolerance accounted for over one third of the lost data reported during in-home level III studies.

Delivery Considerations

It is important to note that level I sleep studies are also used to diagnose other sleep disorders, and to titrate CPAP therapy. Some patients may require 2 overnight sessions in the sleep centre – one for diagnosis and the second for CPAP titration, though autotitrating CPAP units now allow many patients to be titrated at home. Current evidence and guidelines support the use of home-based CPAP autotitration.[7]

No studies were found on the effect of patient training (i.e., in reducing data loss and the need for repeat testing) with level III devices. However, one study noted reduced data loss in level III test results as health care providers gained experience in providing patient instruction.[117]

Economic Evaluation (E)

Literature Review Findings

There are relatively few published economic evaluations of the diagnosis of SDB with level I or level III sleep studies technologies. Because there were so few relevant economic evaluations published in this area during the past 5 years, 2 further studies (published in 1999 and 2001), identified through the reference lists of selected papers, were also included. A total of 9 studies were identified and reviewed. The studies were quite heterogeneous, and used different study designs and treatment algorithms.

Study designs included:

- no sleep study (immediate treatment)
- sleep lab-based level I *versus* sleep lab-based level III
- sleep lab-based level I *versus* in-home level III with technician set-up (attended partial sleep monitoring)
- sleep lab-based level I *versus* in-home patient set-up level III (unattended partial sleep monitoring).

Treatment algorithms included:

- no treatment
- a trial of CPAP
- lifelong CPAP
- bariatric surgery.

The economic studies focussed on OSA or sleep apnea-hypopnea syndrome. None of the studies dealt with the broader category of SDB or with other conditions within this spectrum of disorders. Few of the studies meet the standards of a good quality economic evaluation (Table 8).[34]

Table 8. Quality of economic evaluations

Author Country, Year	Well defined analysis question	Comprehensive description of alternatives	Established program effectiveness	Identified all relevant costs and consequences	Accurately measured costs and consequences	Accurately valued costs and consequences	Discounting of costs and consequences	Incremental analysis of costs and consequences	Allowance for uncertainty in costs and consequences	Comprehensive presentation and discussion
Deutsch et al.[140] USA, 2006	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	No
Chervin et al.[141] USA, 1999	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Medical Advisory Secretariat of Ontario[4] Canada, 2006	No	Yes	Yes	No	No	No	Yes	Yes	Yes	No
Brown et al.[142] USA, 2005	Yes	Yes	No	Yes	Yes	No	No	Yes	Yes	No
Abdelghani, et al.[143] France, 2004	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No
Jurado-Gamez, et al.[144] Spain, 2007	Yes	Yes	Yes	No	No	No	No	No	No	No
Alonso Alvarez et al.[132] Spain, 2008	Yes	Yes	Yes	No	No	No	No	No	No	No
Ghegan et al.[10] Various, 2006	Yes	No	Yes	No	No	No	No	No	No	No
Reuveni et al.[145] Israel, 2001	Yes	Yes	No	No	Yes	No	No	No	No	No

Unit cost estimates

The factors included in the cost estimates produced in these studies varied widely (Table 9). While the studies provide a picture of the costing elements likely to be required for a comprehensive, Alberta-based analysis, there are several reasons why a separate costing of diagnosis and treatment from an Alberta perspective is needed in order to obtain credible cost estimates. First, the only Canadian study provided total cost estimates for diagnosis (and treatment), but this study did not include a level III diagnostic.[4] This precludes a direct cost comparison that would be applicable to Alberta. Furthermore, of the papers reporting studies from publicly financed health care systems, none included treatment of sleep-disordered breathing as part of the study. Finally, the studies that provided disaggregated treatment costs were from the US, where cost estimates tend to be much higher than in Alberta. Thus, while the studies cover many cost factors, none of them provide comprehensive costing information and no combination of these studies could be credibly translated to the Alberta system.

Table 9. Unit costs included in each study

				Disaggregated costs							
Author Country, Year	**Publicly funded system**	**Total cost of level 1 or level 3 diagnosis only**	**Total cost of CPAP**	**Cost of diagnostic equipment**	**Salary costs**	**Room / bed costs**	**Travel costs for home studies**	**Cost of CPAP equipment**	**Cost of CPAP titration**	**Cost of CPAP disposables**	**Cost of office visits**
Deutsch et al.[140] USA, 2006		+						+	+	+	+
Chervin et al.[141] USA, 1999		+						+	+		+
Medical Advisory Secretariat of Ontario[4] Canada, 2006	+	+	+								
Brown et al.[142] USA, 2005		+						+	+	+	
Abdelghani et al.[143] France, 2004	+			+	+	+	+				
Jurado-Gamez et al.[144] Spain, 2007	+				+	+	+				
Alonso Alvarez et al.[132] Spain, 2008	+		+	+							
Ghegan et al.[10] Various, 2006	+/-	+									
Reuveni et al.[145] Israel, 2001				+	+		+				

Costs of services avoided within a reasonable period of time

Two of the studies reported that untreated OSA has been linked to excessive daytime sleepiness,[141,143] increased risk for motor vehicle accidents,[140,143-145] cardiovascular complications,[140,141,143,144] increased mortality,[132,141,143-145] decreased quality of life,[4,132,140,144,145] and increased use of health-care resources.[4,141,144] However, none attempted to quantify the life-years gained or the cost-savings from diagnosis and subsequent treatment of OSA with CPAP. Furthermore, the reported small cost and effectiveness differences between the level I and level III studies did not take into account patient demand and access to sleep studies.

Cost comparisons

Incremental analysis of costs and consequences was undertaken in 4 of the 9 studies (Table 10).[4,140-142] One study[4] presented costs and consequences, but an incremental cost-effectiveness ratio (ICER) was not calculated. Only the studies by Deutsch et al.[140] and Chervin et al.[141] reported incremental cost-effectiveness ratios (ICERs) for level I versus level III studies, but these were limited to OSA patients. The ICERs ($US/quality-adjusted life-year) for full night level I compared to level III were $7,383/QALY[140] and $13,431/QALY.[141] The remaining studies presented only cost comparisons between the various treatment alternatives (Table 11) and found that the cost of a level III study varied between 35% and 88% of a level I study.[10,132,143-145]

The ICERs ($US/quality-adjusted life-year) for full night level I compared to level III studies were $7,383/QALY[140] and $13,431/QALY.[141] These are well below conventional thresholds for ICERs, such as the £20,000/QALY to £30,000/QALY that the UK's National Institute for Health and Clinical Excellence (NICE) uses.[146] As such, level I studies would be considered cost-effective. The remaining studies presented only cost comparisons between the various treatment alternatives (Table 10).[10,132,143-145]

Table 10. Summary of studies with costs, outcomes & incremental cost-effectiveness ratios

Study	Comparators	Cost	Outcomes (QALYs)	ICER ($/QALY)	Comments
Deutsch et al.[140] USA, 2006	Full night-level I	$4,886	2.33	7,383 vs. level III	FN: full night
	Split night-level I	$4,565	2.31	5,932 vs. level III	SN: split night
	Level III	$4,096	2.23	-	-
Chervin et al.[141] USA, 1999	Level I	$3,799	4.02	13,431 vs. level III 9,615 vs. no diagnosis	Time horizon of 5 yrs. CPAP may or not be provided in this time
	Level III	$2,939	3.96	-	-
	No diagnosis	$3,020	3.93	-	-
Medical Advisory Secretariat of Ontario[4] Canada, 2006	Level I+ CPAP	$5,734	32.9	-705	Patients with OSA on life-long CPAP; yearly sleep tests
	Level I+ CPAP+ surgery	$5,593	33.1	-8,377	As above, but morbidly obese patients (8% of total) offered surgery
	CPAP+ surgery	$3,221	33.2	-	
Brown et al.[142] USA, 2005	Level I +CPAP	$1,757	0.146	49,421 vs. no diagnosis or CPAP	-
	No diagnosis or CPAP	$0	0.1105	-	-

Estimates of patient and public demand, including prevalence and incidence of conditions

All of the studies that provided estimates of the prevalence of SDB referenced a common source: The Wisconsin Sleep Cohort Study.[38] It reported prevalence rates of 9% in women and 24% in men. But, these estimates include individuals with mild forms of SDB that would not usually require treatment (AHI >5 per hour).[7] The Wisconsin study also provided estimates for the prevalence of moderate to severe OSA (using a cut-off of AHI >15 per hour): 2% for women and 4% for men.[38] One Canadian study estimated prevalence using administrative data from Ontario.[4] It reported that, in 2004, 769 sleep studies were performed per 100,000 people in Ontario, totalling 96,134 studies at a cost of $47 million. At that time, there were 97 licensed sleep laboratories in Ontario and SDB was diagnosed using level I studies only.[4]

Table 11. Summary of cost analysis studies

Study	Comparators	Cost	Comments
Abdelghani, et al.[143] France, 2004	Level I (lab) Level I (home)	€303 €193	- €220 (with failures)
	Respiratory polygraphy (lab) Respiratory polygraphy (home)	€144 €86	- €95 (with failures)
Jurado-Gamez et al.[144] Spain, 2007	Level I Level III	€255 €153	- -
Alonso Alvarez et al.[132] Spain, 2008	Level I Level III	€179 €69	- -
Ghegan et al.[10] Various, 2006	Level I (US) Level III (US)	$434 - $1800 $149 - $890	-
	Level I (UK) Level III (UK)	£210 - £250 £29 - £46	-
	Level I (France) Level III (France)	€307 - €308 €123 - €152	-
	Level I (Spain) Level III (Spain)	€143 €93	-
Reuveni et al.[145] Israel, 2001	Level I Attended partial sleep monitoring Unattended partial sleep monitoring	$250 US $178 US $179 US	- - -

Summary of published economic evaluations

Existing economic evaluations are of limited value for an Alberta assessment on SDB. These evaluations focus on OSA and do not include the broader category of SDB conditions described in the Project Charter for this review. The two economic evaluations that compared level I to level III sleep studies found that the level I studies generated more quality-adjusted life years. While the ICER values found in the studies suggest that level I sleep studies offer good value for money, these

studies did not take into account the additional capital costs required to ensure timely access to level I sleep laboratories or other factors particular to the delivery of these services in Alberta.

All of the studies confirmed that level III sleep studies are less costly than level I in-lab polysomnography – something that was obvious from the outset. However, the economic evaluations report a range of values for level I and level III studies, and these differ depending on the location and the types of costs included.

Economic Analysis

Unit Costs

No current per-case cost estimates were available, however, fee information from the private clinic in Edmonton was used: $800 per level I test and $150 per level III test. Ontario reimburses level I tests at a total of $508.55 (technical and professional fees) [Personal communication, Dr. Walter Wodchis, University of Toronto, January 4, 2010].

Costs of Services Avoided

No estimates regarding the costs of services avoided could be made based on the available evidence.

Demand Estimates

The following assumptions were used to estimate the demand for sleep studies:

a. Annual average of 1,494 level III tests performed through the Foothills Hospital (calculated using a value of 4,482 tests performed between April 1, 2006 and March 31, 2009).

b. Assumes the proportion of level III to level I tests performed across the province is the same as in the Foothills Hospital (1,494 level III tests to 954 level I tests, for a ratio of 1.57).

c. This is likely an underestimate, given that there are several private vendors of level III tests in Alberta, who will be providing additional tests.

The level I test estimates refer to testing for SDB and do not include level I tests done for other sleep disorders or conditions. Based on these assumptions the number of level I tests performed per year in Alberta is 5,542 (Table 12). The number of level III tests performed per year in Alberta is 8,679.

Table 12. Number of level I sleep studies performed in Alberta per year

City	Centre	Public / Private	# of Level I tests/yr	Source/Assumptions
Edmonton	University of Alberta	Public	1,328	- Personal communication - Time period: April 1, 2009 to February 28, 2010)
Edmonton	Northern Alberta Sleep Clinic	Private	492	- Personal communication - Based on an average of 41 tests performed per month
Lethbridge	Southern Alberta Sleep Clinic	Public	1,186	- Personal communication - Time period: April 1, 2009 to March 31, 2010
Calgary	Foothills Hospital	Public	954	- Personal communication - Average calculated from 3 year value (April 1, 2006 to March 31, 2009)
Calgary	Canadian Sleep Institute Centre for Sleep and Human Performance	Private (both clinics)	1,582 (both clinics)	- Based on value from private clinic in Edmonton, and assuming the ratio of no. of tests per bed is the same as in the Northern Alberta Sleep Clinic: 492 tests with 2 beds, ratio is 246 tests per bed. The Calgary labs have a total of 7 beds

Modelling

In order to estimate the costs of level I and level III testing, a decision model was constructed, in consultation with the Expert Advisory Group, based on the American Academy of Sleep Medicine clinical guidelines.[103] In the model, patients with suspected SDB are treated according to one of three different scenarios using 2 different sets of model inputs (A and B) (see Table 13). The sets differ only in the physician fee for interpreting the results of each test. In the first scenario, all patients receive level I polysomnography in a sleep lab. Those patients diagnosed with SDB receive treatment whereas those without SDB do not. A small percentage of patients will drop-out following the level I test. This model assumes that level I testing is definitive in diagnostic accuracy with respect to SDB.

In the second scenario, all patients initially receive home-based level III sleep testing. Those patients testing positive for SDB receive treatment whereas those who do not test positive receive level I polysomnography in a sleep lab. Those patients diagnosed with SDB receive treatment whereas those without SDB do not. In the event of an unsuccessful level III test (data missing, equipment failure etc.), a second level III test is performed. If this test is also unsuccessful, the patient receives level I polysomnography in a sleep lab. At each stage, a small percentage of patients will drop out following the level I or level III tests. This model assumes that diagnostic accuracy of level III testing is less than 100% and that both false positive and false negative results are possible.

The third scenario incorporates the conditions of the second scenario except that level I testing is only performed following level III testing when the level III tests yield an ambiguous result or when 2 unsuccessful attempts at a level III test have been performed. The fraction of patients with successfully administered level III tests with ambiguous results (those requiring level I testing) was estimated as being equivalent to the false negative rate of the level III test. The model inputs are shown in the following table.

Table 13. Model inputs

Variable Name	Variable Description	Mean	Low	High	Distribution	Reference
Model A						
costLI	Total cost of a level I study	$800				Personal communication
costLIII	Total cost of a level III study	$150				Includes physician interpretation fee of $50/test (based on rates currently paid by private vendors in Alberta)[147]
NPV	Negative predictive value of a level III study	0.745	0.715	0.776	Beta(1.46, 1.51)	Included studies in evidence tables
pDropoutLI	Probability of patient dropout following a level I study	0.00058	0	0.02	Beta(3.70, 125.07)	Included studies in evidence tables
pDropoutLIII	Probability of patient dropout following a level III study	0.0057	0	0.049	Beta(3.28, 25.16)	Included studies in evidence tables
pFailLevelI	Probability of a level I study not being successful	0.0086	0	0.074	Beta(3.28, 24.96)	Included studies in evidence tables
pFailFirstLIII	Probability of a level III study not being successful	0.064	0	0.4	Beta(3.07, 16.07)	Included studies in evidence tables
pFailSecondLI	Probability of a second level III study not being successful	0.56				Included studies in evidence tables
pOSA	Fraction of SDB accounted for by OSA	0.945	0.9	0.99	Beta(1.42, 1.42)	Included studies in evidence tables
PPV	Positive predictive value of level III test	0.889	0.859	0.916	Beta(1.72, 1.55)	Included studies in evidence tables
pSDB	Pre-test probability of having SDB	0.42				Included studies in evidence tables
Model B						
costLI	Total cost of a level I study	$800				Personal communication
costLIII	Total cost of a level III study	$115				Assumes physician interpretation fee of $15/test (based on BC values (Personal communication, Dr. Irvin Mayers, University of Alberta, October 28, 2010)
NPV	Negative predictive value of a level III	0.745	0.715	0.776	Beta(1.46, 1.51)	Included studies in

	study					evidence tables
pDropoutLI	Probability of patient dropout following a level I study	0.00058	0	0.02	Beta(3.70, 125.07)	Included studies in evidence tables
pDropoutLIII	Probability of patient dropout following a level III study	0.0057	0	0.049	Beta(3.28, 25.16)	Included studies in evidence tables
pFailLevelI	Probability of a level I study not being successful	0.0086	0	0.074	Beta(3.28, 24.96)	Included studies in evidence tables
pFailFirstLIII	Probability of a level III study not being successful	0.064	0	0.4	Beta(3.07, 16.07)	Included studies in evidence tables
pFailSecondLI	Probability of a second level III study not being successful	0.56				Included studies in evidence tables
pOSA	Fraction of SDB accounted for by OSA	0.945	0.9	0.99	Beta(1.42, 1.42)	Included studies in evidence tables
PPV	Positive predictive value of level III test	0.889	0.859	0.916	Beta(1.72, 1.55)	Included studies in evidence tables
pSDB	Pre-test probability of having SDB	0.42				Included studies in evidence tables

Case costs

Using the model inputs from the table, the following case data were generated for each of the scenarios.

Table 14. Predicted case costs based on the decision model

Scenario	Case Cost	Level III Tests/Patient	Level 1 Tests/Patient
Model A			
1. Level I testing of all patients	$ 806.92	0	1.009
2. Level III testing of all patients + Level I testing for all negative Level III tests	$ 580.48	1.064	0.522
3. Level III testing of all patients + Level I testing for Level III tests with ambiguous results	$ 241.83	1.064	0.102
Model B			
1. Level I testing of all patients	$ 806.92	0	1.009
2. Level III testing of all patients + Level I testing for all negative Level III tests	$ 543.24	1.064	0.522
3. Level III testing of all patients + Level I testing for Level III tests with ambiguous results	$ 204.59	1.064	0.102

Figure 3. Scenario 1 - All patients receive level I testing

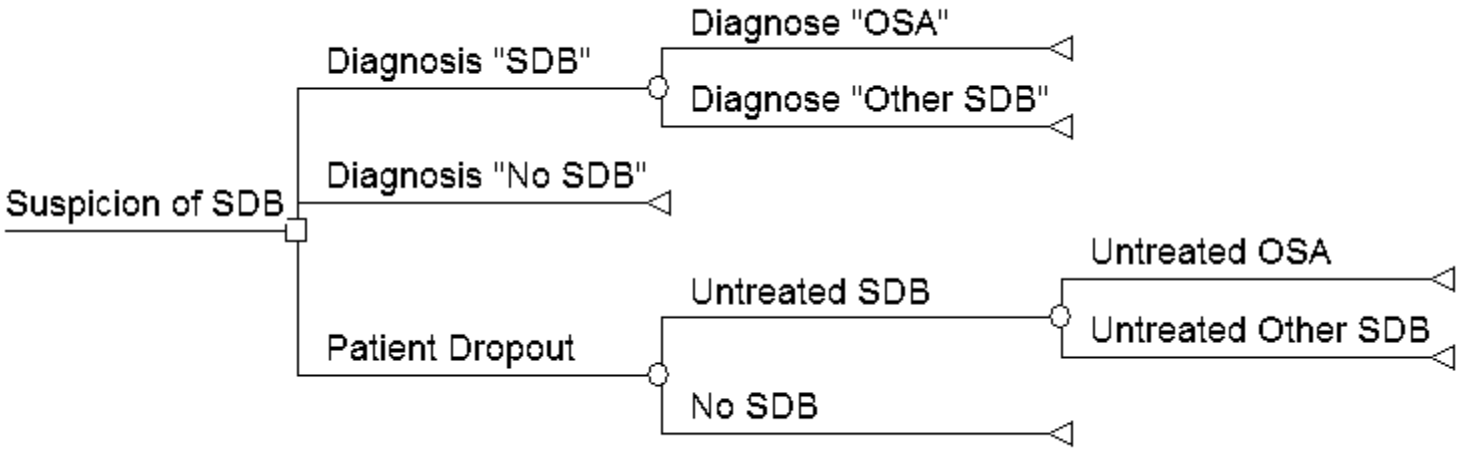


Figure 4. Scenario 2 - All patients receive level III testing + level I testing after 2 failed level III tests, a diagnosis of "No SDB" or an ambiguous level III test result

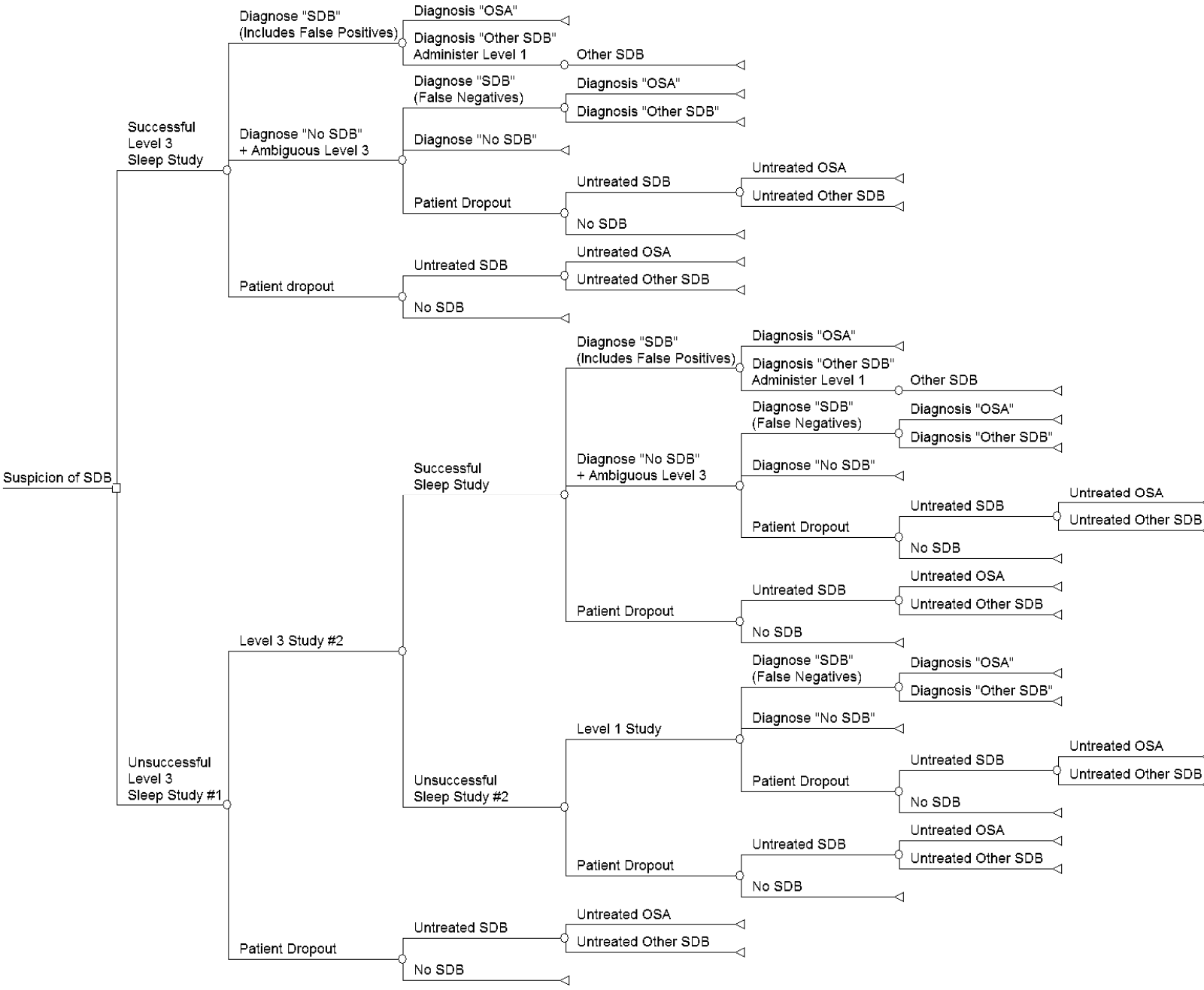
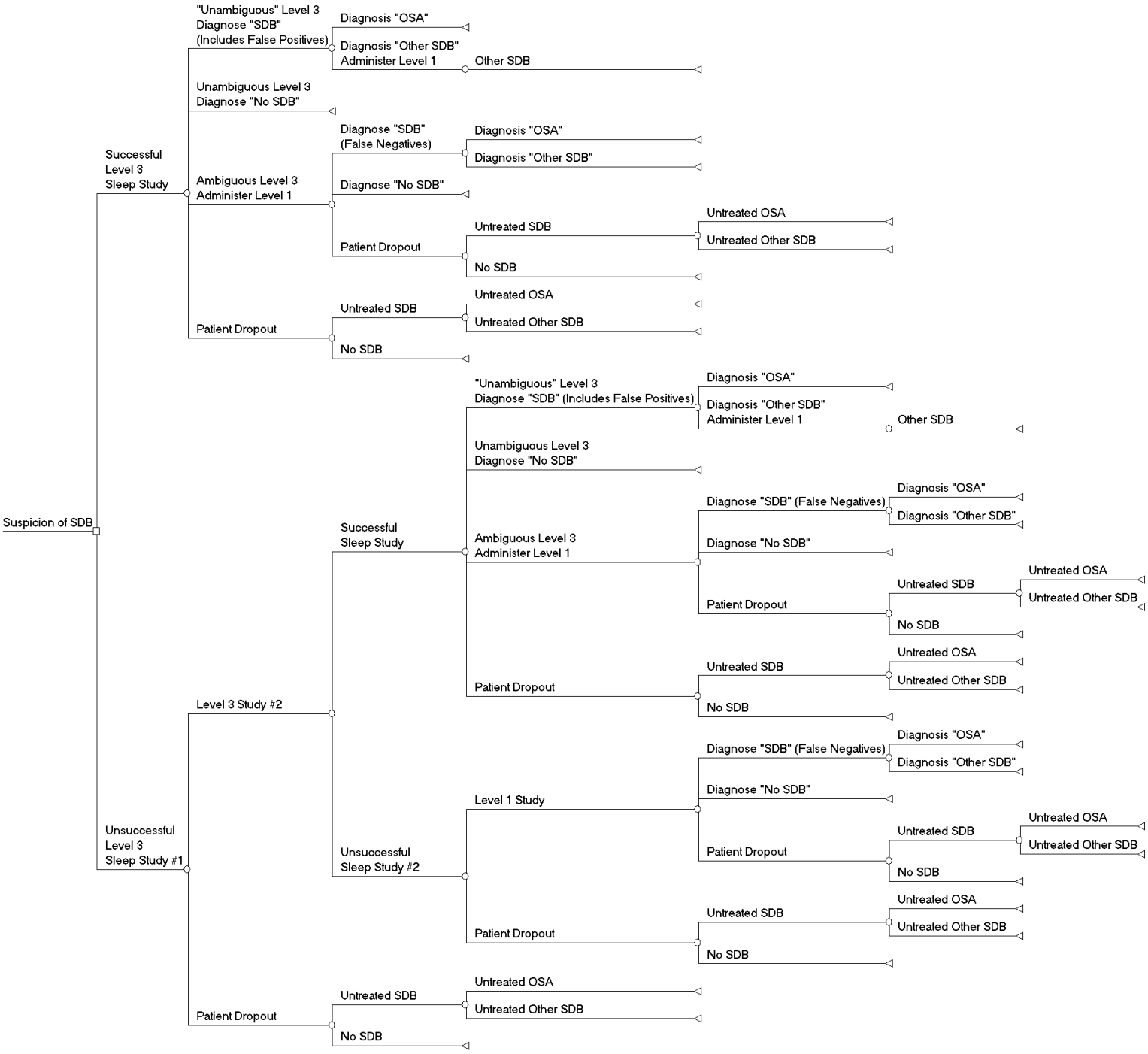


Figure 5. Scenario 3 - All patients receive level III testing + level I testing after 2 failed level III tests or an ambiguous level III test result



Budget Impact Analysis

Using per case costs from the decision model and the annual demand for level I tests of 5,542 and for level III tests of 8,679, it is estimated that the scenario with level I testing for all patients would cost (5,542 + 8,679) x $806.92 = $11,475,209. For the scenario where all negative level III tests were followed with a level I test, the estimated cost would be (5,542 x $806.92) + (8,679 x $580.48) = $9,509,937 if the physician interpretation fee remained at $50/test or (5,542 x $806.92) + (8,679 x $543.25) = $9,186,817 if the physician interpretation fee were similar to that in BC ($15/test). The scenario where only ambiguous level III tests were followed with a level I test would cost (5,542 x $806.92) + (8,679 x $241.83) = $6,570,793 if the physician interpretation fee remained at $50/test or (5,542 x $806.92) + (8,679 x $204.59) = $6,247,587 if the physician interpretation fee were similar to that in BC ($15/test).

Conclusions

Based on the findings of this review, the following conclusions can be drawn:

• Most of the evidence available on the diagnostic accuracy of in-home level III tests relates to uncomplicated OSA. Only one study provided evidence on the diagnostic accuracy of in-home level III tests in otherwise healthy patients with suspected non-OSA SDB.

• Based on the published literature, no safety issues were associated with either level I or in-home level III tests.

• In otherwise healthy patients with suspected OSA, the accuracy of in-home level III tests was considered to be good (average sensitivity ~ 89%; average specificity ~ 64%).

• The risk of a false negative (patient has OSA but the test is negative) appears to be low, given the high sensitivity.

• Diagnostic accuracy appears to improve when those who train patients to use level III devices at home gain experience in providing this training.

• Pooled diagnostic performance values for in-home level III sleep studies show they have a lower sensitivity and higher specificity depending on the severity of OSA.

• Given the wide variety of in-home level III devices used, no conclusions could be drawn about the relative effectiveness of one model compared to another.

• There were no significant differences in the effectiveness of in-home level III tests for the diagnosis of OSA associated with gender (3 studies) or age (1 study), when compared to pooled results for mild, moderate and severe AHI.

• Evidence on the effectiveness of in-home level III tests for the diagnosis of non-OSA SDB is limited.

• Limited evidence on the effectiveness of in-home level III tests in patients with non-OSA SDB who had stable, chronic heart failure suggests that level III tests are less accurate in these patients than in patients with uncomplicated OSA.

• Two studies assessed the effectiveness of in-home level III tests in patients with stable chronic heart failure and suspected SDB. One study reported 100% sensitivity and specificity for detection of other SDB conditions (central apnea).

• Based upon limited published economic evidence (1 study) for the diagnosis of uncomplicated OSA, level III tests are almost as effective as, and are less expensive than level I tests.

• Depending on the decision pathway for the provision of level I and in-home level III tests in Alberta, and the physician interpretation fee for Level III tests, the estimated annual costs would range from $6,247,587 to $11,475,209.

Appendices

Appendix A – Literature Search

Part A: Clinical search

1. PubMed

#112	Search #110 OR #111	2401
#111	Search ("2004/01/01"[Publication Date] : "3000"[Publication Date]) AND (#109) Limits: Humans, English, All Adult: 19+ years	2181
#110	Search #109 AND (in process [sb] OR publisher [sb])	220
#109	Search #99 AND #108	7821
#108	Search #100 OR #101 OR #102 OR #103 OR #104 OR #105 OR #106 OR #107	803168
#107	Search reproducibility of results	191260
#106	Search sensitivity and specificity	342161
#105	Search predictive value of tests	99253
#104	Search (portable [ti] OR home [ti] OR ambulatory [ti])	62515
#103	Search monitoring, ambulatory	22504
#102	Search diagnosis [ti]	263801
#101	Search oximetry	11811
#100	Search polysomnography	11293
#99	Search #86 OR #87 OR #88 OR #89 OR #90 OR #91 OR #92 OR #93 OR #94 OR #95 OR #96 OR #97 OR #98	17975
#98	Search hypoventilation [ti] AND (sleep [ti] OR apnea* [ti] OR apnoea* [ti])	82
#97	Search "sleep disordered breathing" [ti]	1151
#96	Search "nocturnal hypoventilation*" [ti]	17
#95	Search "nocturnal hypoxia*" [ti]	32
#94	Search "sleep apnea*" [ti] OR "sleep apnoea*" [ti]	9375
#93	Search "sleep related breathing disorder*" [ti]	26
#92	Search cheyne-stokes respiration/diagnosis	93
#91	Search sleep apnea, central/diagnosis	173
#90	Search sleep apnea, obstructive/diagnosis	2389
#89	Search sleep apnea syndromes/diagnosis	5653
#88	Search dyssomnias/diagnosis	8726
#87	Search sleep disorders, intrinsic/diagnosis	8339
#86	Search sleep disorders/diagnosis	10925

1a. PubMed

#29	Search #27 OR #28	3425
#28	Search #26 Limits: Humans, English	3238
#27	Search #26 AND (in process [sb] OR publisher [sb])	187
#26	Search ("2004"[Publication Date] : "3000"[Publication Date]) AND (#25)	3858
#25	Search #14 AND #24	7873
#24	Search #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23	846489
#23	Search reproducibility of results	191453
#22	Search sensitivity and specificity	342409
#21	Search predictive value of tests	99347
#20	Search portable [ti] OR home [ti] OR ambulatory [ti]	62544
#19	Search ambulatory care	61569
#18	Search monitoring, ambulatory	22516
#17	Search diagnosis [ti]	263888
#16	Search oximetry	11813
#15	Search polysomnography	11301

#14	Search #1 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13	17990
#13	Search hypoventilation [ti] AND (sleep [ti] OR apnea* [ti] OR apnoea* [ti])	82
#12	Search "sleep disordered breathing" [ti]	1155
#11	Search "nocturnal hypoventilation*" [ti]	17
#10	Search "nocturnal hypoxia*" [ti]	32
#9	Search "sleep apnea*" [ti] OR "sleep apnoea*" [ti]	9378
#8	Search "sleep related breathing disorder*" [ti]	26
#7	Search cheyne-stokes respiration/diagnosis	93
#6	Search sleep apnea, obstructive/diagnosis	2391
#5	Search sleep apnea syndromes/diagnosis	5657
#4	Search dyssomnias/diagnosis	8732
#3	Search sleep disorders, intrinsic/diagnosis	8344
#1	Search sleep disorders/diagnosis	10937

1b. PubMed (additional search terms from Dr. Pawluk)

#28 Search ((((sleep disorders/diagnosis) OR (sleep disorders, intrinsic/diagnosis) OR (dyssomnias/diagnosis) OR (sleep apnea syndromes/diagnosis) OR (sleep apnea, obstructive/diagnosis) OR (sleep apnea, central/diagnosis) OR (cheyne-stokes respiration/diagnosis) OR ("sleep related breathing disorder*"[ti]) OR ("sleep apnea*"[ti] OR "sleep apnoea*"[ti]) OR ("nocturnal hypoxia*"[ti]) OR ("nocturnal hypoventilation*"[ti]) OR ("sleep disordered breathing"[ti]) OR (hypoventilation[ti] AND (sleep[ti] OR apnea*[ti] OR apnoea*[ti]))) AND ((polysomnography) OR (oximetry) OR (diagnosis[ti]) OR (monitoring, ambulatory) OR (portable[ti] OR home[ti] OR ambulatory[ti]) OR (predictive value of tests) OR (sensitivity and specificity) OR (reproducibility of results))) AND (in process[sb] OR publisher[sb])) OR (("2004/01/01"[Publication Date] : "3000"[Publication Date]) AND ((((sleep disorders/diagnosis) OR (sleep disorders, intrinsic/diagnosis) OR (dyssomnias/diagnosis) OR (sleep apnea syndromes/diagnosis) OR (sleep apnea, obstructive/diagnosis) OR (sleep apnea, central/diagnosis) OR (cheyne-stokes respiration/diagnosis) OR ("sleep related breathing disorder*"[ti]) OR ("sleep apnea*"[ti] OR "sleep apnoea*"[ti]) OR ("nocturnal hypoxia*"[ti]) OR ("nocturnal hypoventilation*"[ti]) OR ("sleep disordered breathing"[ti]) OR (hypoventilation[ti] AND (sleep[ti] OR apnea*[ti] OR apnoea*[ti]))) AND ((polysomnography) OR (oximetry) OR (diagnosis[ti]) OR (monitoring, ambulatory) OR (portable[ti] OR home[ti] OR ambulatory[ti]) OR (predictive value of tests) OR (sensitivity and specificity) OR (reproducibility of results)))) AND (Humans[Mesh] AND English[lang] AND adult[MeSH])) 2436

#29	Search #27 NOT #28	6367
#27	Search ("2004"[Publication Date] : "3000"[Publication Date]) AND (#26)	7992
#26	Search #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25	16737
#25	Search "type 3 sleep studies"	773
#24	Search "type 1 sleep studies"	905
#23	Search "level 3 sleep studies"	1283
#22	Search "level 1 sleep studies"	1441
#21	Search "type 3 sleep study"	976
#20	Search "type 1 sleep study"	1144
#19	Search "level 3 sleep study"	1639
#18	Search "level 1 sleep study"	1840
#17	Search "portable sleep"	460
#16	Search "portable sleep monitor*"	7
#15	Search "cardio-respiratory monitoring"	17
#14	Search "cardiopulmonary monitoring"	72
#13	Search "sleep related hypoxemia"	13
#12	Search "breathing related sleep disorders"	7
#11	Search "nonobstructive alveolar hypoventilation"	4
#10	Search "sleep related nonobstructive alveolar hypoventilation"	0
#9	Search "sleep related hypoventilation"	18
#8	Search "periodic breathing"	662
#7	Search "cheyne stokes breathing"	80
#6	Search "central sleep apnea"	755

#5	Search "hypopnea syndrome"	752
#4	Search "osa syndrome"	136
#3	Search OSA	3795
#2	Search "obstructive sleep apnea"	10116

2. The Cochrane Library (issue 4, 2009)

Cochrane Reviews [5] | Other Reviews [10] | Clinical Trials [652] | Methods Studies [1] | Technology Assessments [11] | Economic Evaluations [24] | Cochrane Groups [0]

#1	(sleep disorders):ti,ab,kw	3282
#2	(dyssomnias):ti,ab,kw	12
#3	(sleep apnea syndromes):ti,ab,kw	766
#4	(sleep apnea):ti,ab,kw	1523
#5	(cheyne-stokes respiration):ti,ab,kw	46
#6	"sleep related breathing disorder*":ti,ab,kw	5
#7	"nocturnal hypoxia*":ti,ab,kw	9
#8	"nocturnal hypoventilation":ti,ab,kw	14
#9	"sleep disordered breathing":ti,ab,kw	157
#10	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9), from 2004 to 2009	1619
#11	(diagnosis):ti,ab,kw or (polysomnography):ti,ab,kw or (monitor*):ti,ab,kw or (ambulatory):ti,ab,kw or (oximetry):ti,ab,kw or (home):ti,ab,kw, from 2004 to 2009	28065
#12	(#10 AND #11)	703

3. Centre for Reviews and Dissemination (CRD) – DARE, HTA, NHS EED databases

1	"sleep apnea*" OR "sleep disorder*"	129
2	diagnosis OR polysomnography OR oximetry OR monitor* OR ambulatory OR home OR portable	8380
3	#1 AND #2	60
4	MeSH Sleep Disorders QUALIFIERS DI EXPLODE 1 2 3	55
5	MeSH Sleep Apnea Syndromes QUALIFIERS DI EXPLODE 1 2	40
6	#3 OR #4 OR #5 RESTRICT YR 2004 2010	48

4. EMBASE ((Ovid) 1980 to 2009 Week 44)

1	exp sleep disordered breathing/di [Diagnosis]	3994
2	exp sleep apnea syndrome/di [Diagnosis]	3777
3	exp central sleep apnea syndrome/di [Diagnosis]	59
4	exp obesity hypoventilation syndrome/di [Diagnosis]	43
5	exp upper airway resistance syndrome/di [Diagnosis]	31
6	4 or 1 or 3 or 2 or 5	3994
7	exp polysomnography/	9521
8	exp oximetry/	8653
9	exp ambulatory monitoring/	5465
10	exp home monitoring/	2012
11	exp "sensitivity and specificity"/	56821
12	exp diagnostic value/	105180
13	exp reproducibility/	37602
14	8 or 11 or 7 or 13 or 10 or 9 or 12	208435
15	6 and 14	2486
16	limit 15 to (human and english language and yr="2004 -Current" and adult <18 to 64 years>)	533
17	limit 15 to (human and english language and yr="2004 -Current" and aged <65+ years>)	223
18	16 or 17	567

5. CINAHL (EbscoHost)

S10 S9 Limiters - Publication Year from: 2004-2009; English Language;

	Exclude MEDLINE records; Age Groups: Adult, 19-44 years, Middle Age, 45-64 years, Aged, 65+ years, Aged, 80 and over	222
S9	S9 S7 and S8	5925
S8	S8 S3 or S4 or S5 or S6	640551
S7	S7 S1 or S2	11708
S6	TI home or portable or monitor* or ambulatory	41625
S5	(MH "Home Health Care+") or (MH "Home Care Equipment and Supplies")	25279
S4	("polysomnography") or (MH "Polysomnography")	2669
S3	("diagnosis") or (MH "Diagnosis+")	600925
S2	(MH "Sleep Apnea, Obstructive") or (MH "Sleep Apnea Syndromes+")	4095
S1	(MH "Sleep Disorders+") or (MH "Sleep Disorders, Intrinsic+") or (MH "Sleep Apnea, Central") or (MH "Dyssomnias+")	11674

6. Web of Science (Science Citation Index and Social Sciences Citation Index)

# 1 TI=("sleep disorder*" OR dyssomnia* OR "sleep apnea*" OR "sleep apnoea*" OR hypoventilation OR "cheyne stokes respiration" OR "sleep related breathing" OR "nocturnal hypoxia" OR "nocturnal hypoventilation") AND TI=(diagnosis OR polysomnography OR oximetry OR monitor* OR ambulatory OR portable OR home) AND Language=(English)
Databases=SCI-EXPANDED, SSCI Timespan=2004-2009 318

7. PsycINFO (Ovid)

1	exp Sleep Disorders/	3811
2	exp Sleep Apnea/	768
3	exp Polysomnography/	337
4	diagnosis.mp. or exp Diagnosis/	56628
5	ambulatory.mp.	1654
6	portable.mp.	548
7	home.mp.	24739
8	1 or 2	4379
9	6 or 4 or 3 or 7 or 5	82147
10	8 and 9	1013
11	limit 10 to (human and English language and yr="2004-Current")	740

Part B: Economics search

1. MEDLINE(R) Daily and Ovid MEDLINE(R) 1950 to Present

*used the NHS QIS brief economics search filter

1	exp economics/	416587
2	quality of life/	80054
3	value of life/	5086
4	quality-adjusted life years/	4159
5	models, economic/	3750
6	markov chains/	6014
7	monte carlo method/	13224
8	decision tree/	7093
9	ec.fs.	264204
10	economic$.tw.	107525
11	(cost? or costing? or costly or costed).tw.	236948
12	(price? or pricing?).tw.	18108
13	(pharmacoeconomic? or (pharmaco adj economic?)).tw.	2409
14	budget$.tw.	14167
15	expenditure$.tw.	27494
16	(value adj1 (money or monetary)).tw.	247
17	(fee or fees).tw.	9778
18	"quality of life".tw.	91730
19	qol$.tw.	11585

20	hrqol$.tw.	3902
21	"quality adjusted life year$".tw.	3370
22	qaly$.tw.	2918
23	cba.tw.	8016
24	cea.tw.	13712
25	cua.tw.	660
26	utilit$.tw.	80358
27	markov$.tw.	8519
28	monte carlo.tw.	18976
29	(decision adj2 (tree$ or analys$ or model$)).tw.	8143
30	((clinical or critical or patient) adj (path? or pathway?)).tw.	2689
31	(managed adj2 (care or network?)).tw.	15631
32	or/1-31	949706
33	letter.pt.	693529
34	editorial.pt.	262754
35	historical article.pt.	279000
36	animals/ not humans/	3383364
37	33 or 34 or 35 or 36	4571096
38	32 not 37	837796
39	exp Sleep Disorders/	47223
40	exp Sleep Disorders, Intrinsic/	30215
41	exp Dyssomnias/	36369
42	exp Sleep Apnea Syndromes/	18088
43	exp Sleep Apnea, Obstructive/	7000
44	exp Sleep Apnea, Central/	521
45	exp Cheyne-Stokes Respiration/	532
46	42 or 39 or 40 or 45 or 43 or 44 or 41	47516
47	38 and 46	3306
48	limit 47 to (english language and humans and yr="2004 -Current" and "all adult (19 plus years)")	1097

2. Centre for Reviews and Dissemination (CRD) – DARE, HTA, NHS EED databases

1	"sleep apnea*" OR "sleep disorder*"	129
2	MeSH Polysomnography EXPLODE 1	38
3	MeSH Sleep Disorders EXPLODE 1 2 3	232
4	MeSH Sleep Apnea Syndromes EXPLODE 1 2	115
5	#1 OR #2 OR #3 OR #4	254
6	cost* OR economic*	32699
7	MeSH Quality of Life EXPLODE 1 2	2391
8	#6 OR #7	33052
9	#5 AND #8 RESTRICT YR 2004 2010	74

3. EMBASE (Ovid)

1	exp health economics/	243626
2	exp health care cost/	111096
3	exp quality of life/	107983
4	economic$.tw.	74733
5	(cost? or costing? or costly or costed).tw.	178949
6	(price? or pricing?).tw.	12356
7	(pharmacoeconomic? or (pharmaco adj economic?)).tw.	3164
8	budget$.tw.	9136
9	expenditure$.tw.	21311
10	(value adj1 (money or monetary)).tw.	192
11	(fee or fees).tw.	5552
12	"quality of life".tw.	77390
13	qol$.tw.	9801

14	hrqol$.tw.	3204
15	"quality adjusted life year$".tw.	2874
16	qaly$.tw.	2467
17	cba.tw.	5677
18	cea.tw.	11099
19	cua.tw.	395
20	utilit$.tw.	67974
21	markov$.tw.	5530
22	monte carlo.tw.	12558
23	(decision adj2 (tree$ or analys$ or model$)).tw.	6517
24	((clinical or critical or patient) adj (path? or pathway?)).tw.	1778
25	(managed adj2 (care or network?)).tw.	8664
26	or/1-25	594093
27	exp sleep disordered breathing/	17219
28	exp sleep apnea syndrome/	16335
29	exp central sleep apnea syndrome/	290
30	exp obesity hypoventilation syndrome/	293
31	exp upper airway resistance syndrome/	107
32	exp polysomnography/	9521
33	or/27-32	21635
34	33 and 26	2155
35	limit 34 to (human and english language and yr="2004 -Current" and adult <18 to 64 years>)	364
36	limit 35 to (human and yr="2004 -Current" and aged <65+ years>)	143
37	35 or 36	364

4. Web of Science (Science Citation Index and Social Sciences Citation Index)

4 #3 AND #2 *Databases=SCI-EXPANDED, SSCI Timespan=2004-2009* 148

3 TI=(economic* OR cost OR costs OR costing OR "quality of life") AND Language=(English) *Databases=SCI-EXPANDED, SSCI Timespan=2004-2009* 69,289

# 2 TI=("sleep disorder*" OR dyssomnia* OR "sleep apnea*" OR "sleep apnoea*" OR hypoventilation OR "cheyne stokes respiration" OR "sleep related breathing" OR "nocturnal hypoxia" OR "nocturnal hypoventilation" OR polysomnography) AND Language=(English)
Databases=SCI-EXPANDED, SSCI Timespan=2004-2009 6,754

5. EconLit (EBSCOhost)

S2 TX sleep apnea* or TX sleep disorder* or TX dyssomnia* or TX apnea* or TX apnoea* Limiters – Published Date from: 20040101-20100131 19

Part C: Grey literature

** unless otherwise noted search terms were apnea or sleep

1. Guidelines

Canadian Medical Association CMA Infobase
http://www.cma.ca/index.cfm?la_id=1&ci_id=54294&keywords=barrett
Ontario Guidelines Advisory Committee (GAC) http://www.gacguidelines.ca/
BC Ministry of Health Guidelines & Protocols Advisory Committee
http://www.bcguidelines.ca/gpac/alphabetical.html
Alberta Medical Association Towards Optimized Practice (TOP) http://www.topalbertadoctors.org/cpg.html
Aetna Clinical Policy Bulletins http://www.aetna.com/cpb
Institute for Clinical Systems Improvement (ICSI) http://www.icsi.org
Intute http://www.intute.ac.uk
Guidelines.Gov http://www.guidelines.gov ** sleep apnea OR sleep disorders OR dyssomnias
NHS Evidence – National Library of Guidelines http://www.library.nhs.uk/guidelinesfinder/default.aspx ** sleep OR apnea OR apnoea
New Zealand Guidelines Group http://www.nzgg.org.nz/index.cfm ** sleep OR apnea OR apnoea

National Institute for Health and Clinical Excellence (NICE) http://www.nice.org.uk **sleep OR apnoea OR apnea OR dyssomnia OR "sleep disorders"
Scottish Intercollegiate Guidelines Network (SIGN) http://www.sign.ac.uk/guidelines/published/index.html ** scanned list of guidelines

2. Clinical trials
ClinicalTrials.gov http://www.clinicaltrials.gov
**polysomnography OR oximetry OR actigraphy OR "level 1" OR "level 3" OR portable OR home OR ambulatory | sleep disorders OR sleep apnea syndromes OR sleep apnea, obstructive OR dyssomnias
CCT Current Controlled Trials http://www.controlled-trials.com
(searched only ISRCTN Register, Action Medical Research, Medical Research Council (UK), National Health Service Research and Development HealthTechnology Assessment Programme (HTA), The Wellcome Trust, and the UK Clinical Trials Gateway)
**polysomnography OR oximetry OR actigraphy OR "level 1" OR "level 3" OR portable OR home OR ambulatory | sleep disorders OR sleep apnea syndromes OR sleep apnea, obstructive OR dyssomnias
CenterWatch http://www.centerwatch.com/clinical-trials/**searched under categories: sleep apnea syndromes, sleep disorders)

3. HTA agency web sites
Canada
Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS)
http://www.aetmis.gouv.qc.ca/site/home.phtml
Canadian Agency for Drugs and Technologies in Health (CADTH) http://www.cadth.ca
Institute for Clinical and Evaluative Sciences (ICES) http://www.ices.on.ca
Institute of Health Economics (IHE) http://www.ihe.ca
McGill University Health Centre Technology Assessment Unit http://www.mcgill.ca/tau/publications/
Ontario Health Technology Advisory Committee (OHTAC)
http://www.health.gov.on.ca/english/providers/program/ohtac/tech/recommend/rec_mn.html
Ontario Medical Advisory Secretariat (MAS)
http://www.health.gov.on.ca/english/providers/program/mas/tech/ohtas_mn.html
Programs for Assessment of Technology in Health (PATH Research Institute)
http://www.path-hta.ca/report.htm
University of British Columbia Centre for Health Services and Policy Research (CHSPR) http://www.chspr.ubc.ca/
US
California Technology Assessment Forum (CTAF) http://www.ctaf.org/

4. Health economics
Centre for Health Economics Research & Evaluation (CHERE)
http://datasearch.uts.edu.au/chere/research/research_reports.cfm
Cost-effectiveness Analysis (CEA) Registry
https://research.tufts-nemc.org/cear/default.aspx
Brunel University Health Economics Research Group (HERG)
http://www.brunel.ac.uk/about/acad/herg
McMaster University Centre for Health Economics and Policy Analysis (CHEPA)
http://www.chepa.org/
University of Aberdeen Health Economics Research Unit (HERU)
http://www.abdn.ac.uk/heru/

5. Other
Bandolier http://www.medicine.ox.ac.uk/bandolier/
New York Academy of Medicine Grey Literature collection
http://www.nyam.org/library/pages/grey_literature_report
ProQuest Dissertations and Theses
(sleep apnea OR sleep disorders OR dyssomnias) AND TI(portable OR home OR ambulatory OR diagnosis)

6. Google http://www.google.ca
= 1,600,000 English pages for | sleep-apnoea-* | sleep-disorder-* AND diagnosis | polysomnography | portable | ambulatory | home "sleep apnea * ".
** reviewed only first 700+ references

7. Conference proceedings
Sleep: annual meeting of the Associated Professional Sleep Societies (2004-2009 conference abstracts)
http://www.sleepmeeting.org/Abstracts.aspx
Chest: annual meeting of the American College of Chest Physicians (2004-2009 conference abstracts)
http://chestjournal.chestpubs.org/site/misc/mtg_abstract.xhtml (*search term sleep)
European Sleep Research Society: bi-annual meeting, published in supplements to J Sleep Res (scanned 2004, 2006, and 2008 supplements)
Canadian Sleep Society: bi-annual meeting published in Vigilance (scanned 2007 & 2009 supplements)
World Association of Sleep Medicine (WASM): bi-annual meeting, published in supplements to Sleep Med (scanned 2005, 2007 & 2009 supplements)

Appendix B – Evidence Tables

Table 15. Included studies

Primary Author	Year Published	Country	Conference Abstract	Full Published Study	Simultaneous Level I/III Study	Level III Device Used
Abraham, WT.[113]	2006	USA/UK		X		CPS ***
Alonso Alvarez, ML.[132]	2008	Spain		X		EMS *
Ayappa, I.[118]	2008	USA		X		ARES Unicorder
Bajwa, I.[127]	2009	USA	X		X	Alice PDx
Candela, A.[126]	2005	Spain		X	X	BITMED NGP140
Churchward, TJ.[131]	2006	Australia	X			Somté
Cilli, A.[134]	2006	Turkey	X			Embletta
Driver, HS.[129]	2008	Canada	X		X	Medibyte
Ferre, A.[125]	2008	Spain	X		X	Somté
Finkel, KJ.[130]	2009	USA		X		ARES Unicorder
Fordyce, L.[106]	2009	Canada	X			Not Reported
Garcia-Diaz, E.[112]	2007	Spain		X	X + separately	Apnoescreen II
Gjevre, J.[109]	2007	Canada	X			Embletta
Grant, B.[137]	2009	USA	X			Embletta
Grover, S.[133]	2009	USA	X			Alice PDx
Hernandez, L.[114]	2007	Spain		X		Respiratory Polygraphy
Kuna, ST.[108]	2005	USA	X			Stardust II
Kushida, CA.[120]	2009	USA	X			PMP-300E
Levendowski, D.[111]	2009	USA		X		ARES Unicorder
Miyata, S.[107]	2007	Japan		X		LT-200
Ng, S.[138]	2010	China		X	X	Embletta PDS
Orr, WC.[121]	2006	USA	X		X	Lifeshirt
Polese, JF.[110]	2009	Spain	X		X + separately	Stardust II
Quintana-Gallego, E.[122]	2004	Spain		X		Apnoescreen II
Santos-Silva, R.[116]	2009	Brazil		X		Stardust II
Shrivastava, D.[136]	2006	USA	X			Eden Trace PlusII
Skomro, R.[135]	2005	Canada	X			Embletta
Smith, LA.[119]	2007	UK		X		Embletta
Su, S.[148]	2004	USA		X	X	SNAP
Sullivan, GE.[128]	2009	Canada	X		X	Stardust
To, KW.[123]	2009	Hong Kong		X	X	ARES Unicorder
Tonelli de Oliveira, A.[117]	2009	Brazil		X		Somnocheck
Yagi, H.[124]	2009	Japan		X	X	Apnomonitor 5
Yin, M.[139]	2006	Japan		X		Stardust II

*EMS – Edentec Monitoring System polygraphy; **PSG – Lead limited at home PSG (respiratory polygraphy); ***CPS – ClearPath System Nx-301

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
Studies of simultaneous and separate Level I and Level III study						
Abraham WT.[113] 2006 USA/UK Full Study Funding sources: Not Reported	Academic teaching hospital No. of sites: 4 Cohort study Prospective Patient allocation: Not Reported Simultaneous and separate level I and level III study Non-randomized allocation to separate study arm, simultaneous in-lab study first followed by Level III at home study.	No. of patients enrolled in study: N= 50 Suspected diagnosis: Sleep disordered breathing: n=50 Gender: Male: 34 Female: 16 Age: Mean: 55.5 yrs SD: ±12.8 Range: 23-78 years Comorbidities: Stable New York Health Association Class III systolic heart failure (LVEF ≤ 35%): Mean: 26.4% SD: ±13.5 (Ischemic n=23, Dilated n=21, Hypertrophic n=2, Viral n=1) Body Mass Index: Mean: 32.6 kg/m² SD: ±6.5 Range: 19-48 kg/m² Neck circumference (cm): Not Reported SDB pre-test probability: Epworth Sleepiness Scale (n=46)	<u>Simultaneous level I and level III study</u> *Level I* Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: Trained sleep medicine registered polysomnographer Scoring methods: Manual Study interpreters: Sleep medicine physician Device name: Alice 3/Alice 4 (Respironics, USA), Sandman (Mallinchrodt, USA) or Embla (ResMed, USA) *Level III* Location of study: Sleep Laboratory Total No. of channels: 3+ (no nasal flow channel) Study operators: Trained sleep nurse	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *Diagnostic agreement* *Level I adjusted RDI values reported (mean±SD or median or range/sleep study type)* *Level III RDI values reported (mean±SD or median or range/sleep study type)* *Adverse events* *Complications*	<u>Simultaneous in lab Level I and Level III study</u> *Diagnostic accuracy:* Cut-point used: **RDI ≥ 5** · Sensitivity: 95.2% (95% CI 77.3, 99.2%) · Specificity: 52.2% (95% CI 33.0, 70.8%) · PPV: 64.5% (95% CI 46.9, 78.9%) · NPV: 92.3% (95% CI 66.7, 98.6%) · LR+: 1.99 (95% CI 1.286 to 3.084) · LR-: 0.09 (95% CI 0.013 to 0.643) · Area under the ROC curve: Not Reported Cut-point used: **RDI ≥ 10** · Sensitivity: 88.2% (95% CI 65.7, 96.7%) · Specificity: 63.0% (95% CI 44.2, 78.5%) · PPV: 60.0% (95% CI 40.7, 76.6%) · NPV: 89.5% (95% CI 68.6, 97.1%) · LR+: 2.38	Oxford: 3b QUADAS: *Internal Validity* **Yes**: 3,4,5, 7,10,11,12, 14 **No**: 6 **Unclear**: none *External Validity* **Yes**: none **No**: 1 **Unclear**: 2 *Reporting* **Yes**: 8,9,13 **No**: none **Unclear**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Mean: 10.6 SD: ±4.4 Range: 1-23 Berlin Risk (Low:High): Not Reported Source of referrals: Heart failure specialist Blinding: Study interpreter <u>Simultaneous level I and level III study</u> N=50 Withdrawal/dropout: n=6 Reason for withdraw/dropout: Level III in-lab technical error n=3 Intolerant to Level I study n=1 Severe pacemaker interference n=1 Premature patient withdrawal n=1 <u>Separate level III study at home</u> N=44 Withdrawal/dropout: n=2 Reason for withdraw/dropout: Level III at home technical failure: n=2	Scoring methods: Automated with limited manual editing by a certified EEG or sleep technician Study interpreters: Sleep medicine physician Device name: ClearPath System Nx-301 (Nexan Inc, USA) <u>Separate level III study</u> *Level III* Location of study: At home Total No. of channels: 3+ (no nasal flow channel ??) Study operators: Patient after instructions from trained sleep nurse in the sleep laboratory Scoring methods: Automated with limited manual editing by a certified EEG or sleep technician Study interpreters: Sleep medicine physician Device name: ClearPath System Nx-301 (Nexan Inc, USA) *Interval between study arms*:		(95% CI 1.414 to 4.013) · LR-: 0.19 (95% CI 0.049 to 0.709) · Area under the ROC curve: Not Reported Cut-point used: **RDI ≥ 15** · Sensitivity: 66.7% (95% CI 39.1, 86.2%) · Specificity: 78.1% (95% CI 61.2, 89.0%) · PPV: 53.3% (95% CI 30.1, 75.2%) · NPV: 86.2% (95% CI 69.4, 94.5%) · LR+: 3.05 (95% CI 1.415 to 6.565) · LR-: 0.43 (95% CI 0.188 to 0.97) · Area under the ROC curve: Not Reported *Diagnoses made* Not Reported *RDI values (mean±SD)* Level I: Not Reported Level III: Not Reported *Diagnostic agreement* · Correlation (Level I &	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Inclusion criteria: New York Health Association Class III heart failure patients LVEF ≤35% Stable heart failure with no change in medication for 2 weeks prior to study entry No change of diuretics during the first week of study entry No anticipated need to change medications during the study *Exclusion criteria:* Presence of cerebrovascular, neurovascular or terminal disease Severe chronic obstructive pulmonary disease Presence of known dermatologic condition or allergy to sensors or medical adhesives Documented myocardial infarction within 6 weeks of study	≤ 3 nights Level I index used: RDI (TST) Level III index used: RDI (total recording time in bed) Cut point used indicating diagnosis and/or treatment : RDI ≥ 15		III RDI/RDI): Not Reported · Bland and Altman Values: Not Reported *Adverse events:* Severe pacemaker interference n=1 *Complications:* Level III in-lab technical error n=3 Intolerant to Level I study n=1 <u>Separate at home Level III study</u> *Diagnostic accuracy:* Not Reported for N=44 *Diagnoses made* Not Reported *RDI values (mean±SD)* Level I: Not Reported Level III: Not Reported *AHI values on Level III device(mean±SD)* Level III: Not Reported *Diagnostic agreement* · Correlation (Level I &	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					Level III at home RDI/RDI): Not Reported · Bland and Altman Values: Not Reported *Adverse events* Sensors irritation: Very red skin n=1 Some redness n=8 Minimal redness n=10 Itchiness n=6 Sender irritation: Itchiness n=3 *Complications:* Level III at home technical failure: n=2	
Ayappa I.[118] 2008 USA Full Study Funding sources: Government (National Institute of Health) Private	Academic teaching hospital No. of sites: 1 Cohort study Prospective Consecutive Simultaneous and separate level I and level III study	No. of patients enrolled in study: N= 102 (demographic data reported only on n=97 who had either home or lab Level III study) Suspected diagnosis: Sleep disordered breathing: n=77 Healthy Controls: n=20 Gender: Male: 69 Female: 28 Age (Pooled): Mean: 44 years	<u>Separate level III study</u> *Level III* Location of study: Home Total No. of channels: 4+ Study operators: Patient Scoring methods: Automated with limited manual options Study interpreters: Sleep Technician Device name: ARES Unicorder	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *Diagnostic agreement* *Level I adjusted RDI values reported (mean±SD or median or range/sleep study type)*	<u>Separate at home Level III study</u> *Diagnostic accuracy:* Cut-point used: **AHI ≥ 5** · Sensitivity: 90% (95% CI 78-96%) · Specificity: 79% (95% CI 62-91%) · PPV: 87.0% · NPV: 79.0% · LR+: 4.29 · LR-: 0.13 · Area under the ROC curve:	Oxford: 1b QUADAS: *Internal Validity* **Yes**: 3,4,5,6, 7,10,12,14 **No**: none **Unclear**: 11 *External Validity*

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
(Advanced Brain Monitoring)	Non-randomized allocation to separate study arm, Level III study at home first followed by simultaneous in-lab study.	SD: Not Reported Range: 19-74 years Comorbidities: Not Reported Body Mass Index (Pooled): Mean: 29 kg/m² SD: Not Reported Range: 19-70 kg/m² Neck circumference (cm): Not Reported SDB pre-test probability: Epworth Sleepiness Scale Not Reported Berlin Risk (Low:High): Not Reported Source of referrals: SDB patients: NYU sleep disorders centre Controls: Word of mouth Blinding to study arms: Not Reported <u>Separate level III study at home</u> N=102 Withdrawal/dropout: n=14	(Advanced Brain Monitoring, USA) <u>Simultaneous level I and level III study</u> *Level I* Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: Sleep Technician Scoring methods: Manual Study interpreters: Sleep Technician Device name: Nocturnal PSG (Not specified) *Level III* Location of study: Sleep Lab Total No. of channels: 4+ Study operators: Sleep Technician Scoring methods: Automated with limited manual options Study interpreters: Sleep Technician	*Level III AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	Not Reported Cut-point used: **AHI ≥ 10** · Sensitivity: 86% (95% CI 70-95%) · Specificity: 82% (95% CI 67-91%) · PPV: 78% · NPV: 89% · LR+: 4.78 · LR-: 0.17 · Area under the ROC curve: Not Reported Cut-point used: **AHI ≥ 15** · Sensitivity: 74% (95% CI 56-87%) · Specificity: 88% (95% CI 75-95%) · PPV: 80% · NPV: 84% · LR+: 6.17 · LR-: 0.30 · Area under the ROC curve: Not Reported *Diagnoses made* Not Reported *AHI values on Level III*	**Yes**: 1,2 **No**: none **Unclear**: none *Reporting* **Yes**: 8,9,13 **No**: none **Unclear**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Reason for withdraw/dropout: Withdrawn prior to study start: n=2 Did not initiate Level III at home due to "lack of time": n=6 Could not tolerate the Unicorder: n=5 Technical failure: n=1 <u>Simultaneous level I and level III study</u> N=100 Withdrawal/dropout: n=8 Reason for withdraw/dropout: Withdrawn (not specified): n=4 Level III in lab technical failure: n=2 Level III device not started: n=1 Failed PSG: n=1 *Inclusion criteria:* Suspected SDB Health volunteers for control *Exclusion criteria:* Inability to read English Inability to wear Level III device on forehead	Device name: ARES Unicorder (Advanced Brain Monitoring, USA) *Interval between study arms*: ≤2 weeks Level I index used: AHI and adjusted RDI (TST) Level III index used: "AHI" (valid recording time) Cut point used indicating diagnosis and/or treatment: Adjusted RDI on PSG ≥ 15		*device(mean±SD)* At home Level III: AHI 4%: 16/hr(not reported) AHI 1%: 23/hr(not reported) *Diagnostic agreement* · Correlation (Level I & III RDI/AHI): Interclass correlation coefficient Home Level III vs Level I = 0.8 · Bland and Altman Values: Level I vs Home Level III = 4.1/hr (95% CI 0.8, 7.3/hr) *Adverse events:* Not Reported *Complications:* Did not initiate Level III recording n=6 Could not tolerate Level III device n=5 Technical failure n=1 <u>Simultaneous in lab Level I and Level III study</u> *Diagnostic accuracy:*	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					Cut-point used*:* **AHI ≥ 5** · Sensitivity: 98% (95% CI 89-100%) · Specificity: 84% (95% CI 67-93%) · PPV: 90.0% · NPV: 97.0% · LR+: 6.05 · LR-: 0.02 · Area under the ROC curve: Not Reported Cut-point used: **AHI ≥ 10** · Sensitivity: 97% (95% CI 85-100%) · Specificity: 85% (95% CI 72-93%) · PPV: 82.0% · NPV: 98.0% · LR+: 6.46 · LR-: 0.03 · Area under the ROC curve: Not Reported Cut-point used: **AHI ≥ 15** · Sensitivity: 92% (95% CI 76-98%) · Specificity: 95% (95% CI 84-99%)	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					· PPV: 92.0% · NPV: 95.0% · LR+: 17.11 · LR-: 0.09 · Area under the ROC curve: Not Reported *Diagnoses made* Not Reported *AHI values on Level I and Level III device(mean±SD)* In-lab Level I: Not reported In-lab Level III: AHI 4%: 19/hr (not reported) AHI 1%: 27/hr (not reported) *Diagnostic agreement* · Correlation (Level I & III RDI/AHI): Interclass correlation coefficient In-lab Level III vs Level I = 0.96 · Bland and Altman Values: Level I vs In-lab Level III = 0.5/hr (95% CI -1.0,	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					2.0/hr) *Adverse events:* Not Reported *Complications:* Level III in lab technical failure n=2 Level III device not started n=1 Failed PSG n=1	
Garcia-Diaz E.[112] 2007 Spain Full study Funding sources: Not Reported	Academic teaching hospital No. of sites: 1 Cohort study Consecutive Prospective Simultaneous level I and level III study, and level III home study Random allocation to simultaneous Level I/III and level III study	No. of patients enrolled in study: N= 65 (62 valid recordings) Suspected diagnosis: SAHS: n=62 Gender: Male: 54 Female: 8 Age: Mean: 54 years SD: 10.4 Comorbidities: Hypertension: 27 (43.5% of 62 patients) Cardiovascular comorbidity: 9 (14.5% of 62 patitnes) Body Mass Index: Mean: 30.1 kg/m² SD: 3.9	<u>Simultaneous level I and level III study</u> *Level I* Location of study: sleep lab Total No. of channels: 7+ Study operators: Not Reported Scoring methods: manual Study interpreters: technician Device name: Somnostar 4100 (SensorMedics Corporation, Yorba Linda, CA) *Level III* Location of study: sleep lab Total No. of channels: 4+	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *RDI/RDITRT values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	<u>Simultaneous in lab Level I and Level III study</u> *Diagnostic accuracy:* Cut-point used: **AHI ≥ 10** · Sensitivity: 94.6% (95% CI: 87.3%, 100%) · Specificity: 96% (95% CI: 88.3%, 100%) · PPV: 97.0% · NPV: 92.0% · LR+: 23.64 (95% CI: 3.5, 161.6) · LR-: 0.06 (95% CI: 0.01, 0.22) · Area under the ROC curve: 0.977 (95% CI: 0.937, 1.0) · Correctly classified proportion: 95.1% (RDI/AHI≥ 10)	Oxford: 1c QUADAS: *Internal Validity* Yes: 3, 4, 5, 6, 7, 10, 11, 12, 14 No: none Unclear: none *External Validity* Yes: 1 & 2 No: none Unclear: none *Reporting* Yes: 13 No: none Unclear: 8

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Neck circumference (cm): Not Reported SDB pre-test probability: Epworth Sleepiness Scale Mean: 12 SD: 3.7 Source of referrals: Not Reported Blinding to study arms: Study interpreter <u>Simultaneous level I and level III study</u> N=62 valid recordings <u>Level III home study</u> N= 62 valid recordings Withdrawal/dropout: n= 3 Reason for withdraw/dropout: Incomplete study protocol (n=2) Technical failure in level I device (n=1) *Inclusion criteria:* Not Reported *Exclusion criteria:* Physical or mental impairment that ruled out the use of the equipment	Study operators: Not Reported Scoring methods: manual Study interpreters: two researchers (independent from each other and level I reviewer) Device name: Apnoescreen II (Erich Jaeger GMBH and Cokg; Wuerzburg, Germany) <u>Level III home study</u> *Level III* Location of study: home Total No. of channels: 4+ Study operators: technicians Scoring methods: manual Study interpreters: two researchers (independent from each other and level I reviewer) Device name: Apnoescreen II (Erich Jaeger GMBH and Cokg; Wuerzburg, Germany) *Interval between studies*: < 15 days Level I index used:	Notes: Only findings of observer A reported in this table	Cut-point used: **AHI ≥ 15** · Sensitivity: 100% · Specificity: 96.7% (95% CI: 90.2%, 100%) · PPV: 97.0% · NPV: 100% · LR+: 30 (95% CI: 4.37, 206.08) · LR-: 0 · Area under the ROC curve: 0.998 (95% CI: 0.992, 1.0) · Correctly classified proportion: 98.4% (RDI/AHI≥ 15) Cut-point used: **AHI ≥ 30** · Sensitivity: 95.8% (95% CI: 87.8%, 100%) · Specificity: 94.7% (95% CI: 87.6%, 100%)) · PPV: 92.0% · NPV: 97.0% · LR+: 18.2 (95% CI: 4.7, 70.3) · LR-: 0.04 (95% CI: 0.01, 0.3) · Area under the ROC curve: 0.986 (95% CI: 0.964, 1.0) · Correctly classified proportion: 95.1%	& 9

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
			AHI (Total Sleep Time) Level III index used: RDI (Total Sleep Time) RDITRT (Total Recording Time) Cut point used indicating diagnosis and/or treatment: AHI ≥ 5		(RDI/AHI≥ 30) *Diagnoses made:* AHI ≥5: n=44 AHI ≥10: n=37 AHI ≥15: n=32 AHI ≥30: n=24 *AHI values (mean±SD):* Level I: 30.3/hr ± 33 *RDI values (mean±SD):* Level III: 27.5/hr ± 26.9 Level III(TRT): 26.1/hr ±25.9 *Diagnostic agreement:* · Correlation: Not Reported · Bland and Altman Values: Mean difference (Level I AHI – Level III RDI, mean±SD): 2.8±10.5, 95% CI: 0.13, 5.5 *Adverse events:* Not Reported *Complications:* Level I technical failure n=1 <u>Separate at home Level III study</u>	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					Diagnostic accuracy: Cut-point used**: AHI ≥ 10***:* · Sensitivity: 86.4% (95% CI: 75.4, 97.5) · Specificity: 100% · PPV: 100% · NPV: 84% · LR+: ∞ · LR-: 0.14 (95% CI: 0.06, 0.31) · Area under the ROC curve: 0.969 (95% CI: 0.934, 1.0) · Correctly classified proportion: 91.9% (RDI/AHI ≥10) Cut-point used: **AHI ≥ 15** · Sensitivity: 87.5% (95% CI: 76, 98.9) · Specificity: 96.7% (95% CI: 90.2, 100)) · PPV: 97% · NPV: 88% · LR+: 27.0 (95% CI: 3.8, 181.1) · LR-: 0.13 (95% CI:0.05, 0.32) · Area under the ROC curve: 0.972 (95% CI: 0.936, 1.0) · Correctly classified	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					proportion: 91.9% (RDI/AHI ≥ 15) Cut-point used: **AHI ≥ 30** · Sensitivity: 91.7% (95% CI: 80.6, 100) · Specificity: 94.7% (95% CI: 87.6, 100) · PPV: 92% · NPV: 95% · LR+: 17.0 (95% CI: 4.5, 67) · LR-: 0.09 (95% CI: 0.02, 0.33) · Area under the ROC curve: 0.986 (95% CI: 0.964, 1.0) · Correctly classified proportion: 93.5% (RDI/AHI ≥ 30) *Diagnoses made:* Not Reported *RDI values (mean±SD):* Level III: 27.3/hr±28.4 Level III(TRT): 25.5/hr±26.8 *Diagnostic agreement*: · Correlation: Not Reported	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					· Bland and Altman Values: Mean difference (level I AHI – level III RDI, mean±SD): 3.1±17, 95% CI: -1.1, 7.5 *Adverse events:* Not Reported *Complications:* Not Reported	
Kuna ST. [108] 2005 USA Abstract Funding sources: Government (CHERP) Private (Respironics, Inc)	Academic teaching hospital No. of sites: 1 Cohort study Prospective Patient Recruitment: Not Reported Separate at home Level III study followed by simultaneous in lab Level I and Level III study Non-randomized allocation to	No. of patients enrolled in study: N=39 Suspected diagnosis: Sleep Apnea: n=39 Gender: Male: 39 Female: 0 Age: Mean: 54.0 years SD: ±9.6 Range: Not Reported Comorbidities: Not Reported Body Mass Index: Mean: 35.8 kg/m² SD: ±7.0 Neck circumference (cm):	<u>Separate level III study</u> *Level III* Location of study: Home Total No. of channels: 4+ (Nasal pressure used as surrogate marker for airflow) Study operators: Patient Scoring methods: Manual Study interpreters: Not Reported Device name: Stardust II (Respironics Inc., USA) <u>Simultaneous Level I and Level III study</u> *Level I* Location of study: Sleep Laboratory	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *Level I AHI values reported (mean±SD or median or range/sleep study type)* *Level III AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events*	<u>Separate at home Level III study</u> *Diagnostic accuracy* Cut-point used: **AHI ≥ 15** · Sensitivity: 86.7% (95% CI Not Reported) · Specificity: 77.8% (95% CI Not Reported) · PPV: 93% · NPV: 64% · LR+: 3.90 (95% CI 1.14, 13) · LR-: 0.17 (95% CI 0.06, 0.45) · Area under the ROC curve: Not Reported *Diagnoses made* Level III Not Reported	Oxford: 1c QUADAS: *Internal Validity* **Yes**: 3,4,5,6, 7, 14 **No**: none **Unclear**: 10, 11,12 *External Validity* **Yes**: none **No**: 1, 2 **Unclear**: none *Reporting* **Yes**: 13 **No**: 9

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
	separate study arm, Level III study at home first followed by simultaneous in-lab study.	Not Reported SDB pre-test probability: Epworth Sleepiness Scale Not Reported Berlin Risk (Low:High): Not Reported Source of referrals: Not Reported <u>Separate Level III study</u> N= 39 Withdrawal/dropout: n=0 Reason for withdraw/dropout: Not Applicable <u>Simultaneous Level I and Level III study</u> N=39 Withdrawal/dropout: n=0 Reason for withdraw/dropout: Not Applicable Blinding: Not Reported	Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Manual Study interpreters: Not Reported Device name: Polysomnography (Not specified) *Level III* Location of study: Sleep Laboratory Total No. of channels: 4+ (Nasal pressure used as surrogate marker for airflow) Study operators: Not Reported Scoring methods: Manual Study interpreters: Not Reported Device name: Stardust II (Respironics Inc., USA) *Interval between studies*: 1 day Level I index used: AHI Level III index used: "AHI"	*Complications*	*AHI values (mean±SD)* Mean: 32.1/hr SD: ±27.4 *Diagnostic agreement* · Correlation (Level III & I AHIs): correlation coefficient 0.75 · Bland and Altman Values (level I –level III): Not Reported *Adverse events:* Not Reported *Complications:* Not Reported <u>Simultaneous in lab Level I and Level III study</u> *Diagnostic accuracy* Cut-point used: **AHI ≥ 15** · Sensitivity: 96.6% (95% CI Not Reported) · Specificity: 100% (95% CI Not Reported) · PPV: 100% · NPV: 90.0% · LR+: Infinity (95% CI 1.28, 284)	**Unclear**: 8

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Inclusion criteria: Suspected Sleep Apnea *Exclusion criteria:* Not Reported	(recording time) Cut point used indicating diagnosis and/or treatment: AHI: ≥15		· LR-: 0.03 (95% CI 0.01, 0.24) · Area under the ROC curve: Not Reported *Diagnoses made* Level I: OSA n=30 Level III: OSA not reported *AHI values (mean±SD)* Level I: 40.6/hr ±35.5 Level III: 36.4/hr: ±27.7 *Diagnostic agreement* · Correlation (Level III & I AHIs): correlation coefficient 0.92 · Bland and Altman Values (level I –level III): Not Reported *Adverse events:* Not Reported *Complications:* Not Reported	
Kushida CA.[120] 2009	Academic teaching hospital No. of sites: 1	No. of patients enrolled in study: N=11 Suspected diagnosis: OSA: n=11	Separate level III study *Level III* Location of study: Home	Outcomes of diagnostic test: *Diagnostic accuracy*	Separate at home Level III study *Diagnostic accuracy* Not Reported	Oxford: 3b QUADAS:

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
USA Abstract Funding sources: Private (Pacifico Medico Co., Ltd)	Cohort study Prospective Patient Recruitment: Not Reported Separate at home Level III study followed by simultaneous in lab Level I and Level III study Non-randomized allocation to separate study arm, Level III study at home first followed by simultaneous in-lab study.	Gender: Male: 7 Female: 4 Age:(Pooled): Mean: 42.1 years SD: Not Reported Range: Not Reported Comorbidities: Not Reported Body Mass Index (Pooled): Mean: 25.96 kg/m² SD: Not Reported Neck circumference (cm): Not Reported SDB pre-test probability: Epworth Sleepiness Scale Mean: 8.1 SD: Not Reported Berlin Risk (Low:High): Not Reported Source of referrals: Not Reported <u>Separate Level III study</u> N= 11 Withdrawal/dropout:	Total No. of channels: 4+ Study operators: Patient Scoring methods: Automated Study interpreters: Not Reported Device name: PMP-300E (Pacific Medico Co., LTD. Japan) <u>Simultaneous level I and level III study</u> *Level I* Location of study: Sleep Laboratory Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Manual Study interpreters: Sleep Technician Device name: Polysomnography (Not specified) *Level III* Location of study: Sleep Laboratory	*Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *Level I AHI values reported (mean±SD or median or range/sleep study type)* *Level III AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic agreement* Not Reported *Diagnoses made* Not Reported *AHI/AI/HI values (mean±SD)* Not Reported *Adverse events:* Not Reported *Complications:* Not Reported <u>Simultaneous in lab Level I and Level III study</u> *Diagnostic accuracy* Not Reported *Diagnoses made* Not Reported *AHI/AI/HI values (mean±SD)* Level I: AHI: 22.4/hr (not reported) AI: 8.7/hr (not reported) HI:13.6/hr (not	*Internal Validity* **Yes**: 5,6, 7, 12, 14 **No**: none **Unclear**: 3,4, 10,11 *External Validity* **Yes**: 1 **No**: none **Unclear**: 2 *Reporting* **Yes**: 13 **No**: 9 **Unclear**: 8

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		n=0 Reason for withdraw/dropout: Not Applicable <u>Simultaneous Level I and Level III study</u> N=11 Withdrawal/dropout: n=0 Reason for withdraw/dropout: Not Applicable Blinding: Not Reported *Inclusion criteria:* Age ≥ 18 yrs Suspected OSA *Exclusion criteria:* Not Reported	Total No. of channels: 4+ Study operators: Not Reported Scoring methods: Automated Study interpreters: Not Reported Device name: PMP-300E (Pacific Medico Co., LTD. Japan) *Interval between studies*: Not Reported Level I index used: AHI Level III index used: "AHI" Cut point used indicating diagnosis and/or treatment: AHI: Not Reported		reported) Level III: AHI: 15.2/hr (not reported) AI: 10/hr (not reported) HI: 3.6/hr (not reported) *Diagnostic agreement* · Correlation (Level I & III AHIs): Not Reported · Bland and Altman Values (Level III vs Level I): -8.6/hr ($p<0.05$) *Adverse events:* Not Reported *Complications:* Not Reported	
Polese JF.[110] 2009 Brazil Abstract Funding sources:	Academic teaching hospital No. of sites: 1 Cohort study Consecutive Prospective	No. of patients enrolled in study: N= 43 Suspected diagnosis: OSA: n=43 Gender: Male: 19 Female: 24 Age:	<u>Simultaneous level I and level III study</u> *Level I* Location of study: Sleep Laboratory Total No. of channels: Not Reported Study operators: Not Reported	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed / conditions)* *Level I & Level III*	<u>Simultaneous in lab Level I and Level III study</u> *Diagnostic accuracy* Cut-point used*:* **AHI ≥ 5** · Sensitivity: 93.9% · Specificity: 100% · PPV: 100% · NPV: 59.0%	Oxford: 1c QUADAS: *Internal Validity* **Yes**: 3,4,5,6, 7,10,11,12, 14 **No**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
Not Reported	Simultaneous and separate level I and level III study Random allocation to simultaneous Level I/III and level III study	Mean: 70 years SD: ±5 Range: Not Reported Comorbidities: Not Reported Body Mass Index: Mean: 30 kg/m² SD: ±6 Neck circumference (cm): Not Reported SDB pre-test probability: Epworth Sleepiness Scale Mean: 9 SD: ±7 Berlin Risk (Low:High): Not Reported Source of referrals: Not Reported <u>Simultaneous level I and level III study</u> N=43 Withdrawal/dropout: n=0 Reason for withdraw/dropout: Not Applicable	Scoring methods: Not Reported Study interpreters: Sleep Technician Device name: Embla N7000 (Embla systems Inc., USA) *Level III* Location of study: Sleep Lab Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Not Reported Study interpreters: Sleep Technician Device name: Stardust II (Respironics, Inc. USA) <u>Separate level III study</u> *Level III* Location of study: Home Total No. of channels: Not Reported Study operators: Not Reported	*AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	· LR+: Infinity · LR-: 0.061 · Area under the ROC curve: Not Reported Cut-point used: **AHI ≥ 15** · Sensitivity: 96.2% · Specificity: 100% · PPV: 100 % · NPV: 91.0% · LR+: Infinity · LR-: 0.038 · Area under the ROC curve: Not Reported Cut-point used: **AHI ≥ 30** · Sensitivity: 93.7% · Specificity: 78.9% · PPV: 71 % · NPV: 92% · LR+: 4.44 · LR-: 0.080 · Area under the ROC curve: Not Reported *Diagnoses made* Not Reported *AHI values (mean±SD)*	**Unclear**: none *External Validity* **Yes**: 2 **No**: 1 **Unclear**: none *Reporting* **Yes**: 8,9,13 **No**: none **Unclear**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Blinding: Study interpreter <u>Separate level III study</u> N= 43 Withdrawal/dropout: n=0 Reason for withdraw/dropout: Not Applicable Blinding: Study interpreter *Inclusion criteria:* Age ≥ 65 yrs Suspected OSA *Exclusion criteria:* Not Reported	Scoring methods: Not Reported Study interpreters: Sleep Technician Device name: Stardust II (Respironics, Inc. USA) *Interval between studies*: ≤1 week Level I index used: AHI Level III index used: "AHI" Cut point used indicating diagnosis and/or treatment: AHI > 5		Level I: AHI: 32.7/hr ±25.7 HI: 16.4/hr ±11.4 Level III: AHI: 33.7/hr ±18.8 HI: 18.3/hr ±9.4 *Diagnostic agreement* · Correlation (Level I & III AHIs): pearson correlation r=0.84 · Bland and Altman Values (level I –level III): "Strong Agreement" *Adverse events:* Not Reported *Complications:* Not Reported <u>Separate at home Level III study</u> *Diagnostic accuracy* Cut-point used: **AHI ≥ 5** · Sensitivity: 69.7% · Specificity: 100% · PPV: 94% · NPV: 50% · LR+: Infinity · LR-: 0.303 · Area under the ROC	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					curve: Not Reported Cut-point used: **AHI ≥ 15** · Sensitivity: 80.8% · Specificity: 90% · PPV: 85% · NPV: 60% · LR+: 8.08 · LR-: 0.213 · Area under the ROC curve: Not Reported Cut-point used: **AHI ≥ 30** · Sensitivity: 81.2% · Specificity: 85% · PPV: 76% · NPV: 84% · LR+: 5.41 · LR-: 0.221 · Area under the ROC curve: Not Reported *Diagnoses made* Not Reported *AHI values (mean±SD)* Level III: AHI: 23.0/hr ±24.0 HI: 9.0/hr ±6.0	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					Diagnostic agreement · Correlation (Level I & III AHIs): pearson correlation r=0.67 · Bland and Altman Values (level I –level III): Strong Agreement *Adverse events:* Not Reported *Complications:* Not Reported	
Santos-Silva R.[116] 2009 Brazil Full study Funding sources: Associacao fundo de incentive a psico-farmacologia & private	Academic teaching hospital No. of sites: 1 Cohort study Consecutive Prospective Simultaneous and separate level I and level III study Random allocation to simultaneous	No. of patients enrolled in study: N=82 Suspected diagnosis: OSA: n=72 Non-suspected SDB: 10 Gender: Male: 46 Female: 34 Age: Mean: 47 years SD: ±14 Range: Not Reported Comorbidities: Not Reported	<u>Simultaneous level I and level III study</u> *Level I* Location of study: Sleep Lab Total No. of channels: 10+ Study operators: Sleep Technician Scoring methods: Manual Study interpreters: Registered Technologist Device name: Embla S7000 (Embla systems, Inc., Broomfield, CO, USA)	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed / conditions)* *Level I and Level III AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events*	<u>Simultaneous in lab Level I and Level III study</u> *Diagnostic accuracy* Cut-point used*:* **AHI ≥ 5** · Sensitivity: 98% · Specificity: 62% · PPV: 87% · NPV: 93% · LR+:2.58 · LR-: 0.032 · Area under the ROC curve: 0.97 Cut-point used: **AHI ≥**	Oxford: 1b QUADAS: *Internal Validity* **Yes**: 3, 4,5, 6, 7, 10, 11, 12, 14 **No**: none **Unclear**: none *External Validity* **Yes**: 1 & 2

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
	Level I/III and level III study	Body Mass Index: Mean: 28 kg/m² SD: ±5 Neck circumference (cm): Mean: 36.6 cm SD: ±4.9 SDB pre-test probability: Epworth Sleepiness Scale Mean: 10.4 SD: ±5.8 Berlin Risk (Low:High): 26 : 54 Source of referrals: Not Report Blinding: Study interpreter <u>Simultaneous level I and level III study</u> N=82 Withdrawal/dropout: n=2 (from simultaneous arm) Reason for withdraw/dropout: Incomplete study protocol (n=1) Hypertensive crisis during study (n=1) <u>Separate level I and level III study</u>	*Level III* Location of study: Sleep Lab Total No. of channels: 4+ Study operators: Sleep Technician Scoring methods: Manual Study interpreters: Registered Technologist (independent from Level I reviewer) Device name: Stardust II (Respironics, Inc. USA) <u>Separate level I and level III study</u> *Level III* Location of study: Home Total No. of channels: 4+ Study operators: Patients Scoring methods: Manual Study interpreters: Registered Technologist (independent from Level I reviewer)· Device name: Stardust II (Respironics, Inc. USA)	*Complications* *Reporting*	**15** · Sensitivity: 97% · Specificity: 74% · PPV:78 % · NPV: 96% · LR+: 3.73 · LR-: 0.041 · Area under the ROC curve: 0.98 Cut-point used: **AHI ≥ 30** · Sensitivity: 96% · Specificity: 92% · PPV: 87 % · NPV: 98% · LR+: 12.0 · LR-: 0.043 · Area under the ROC curve: 0.98 *Diagnoses made* Not Reported *AHI/AI/HI values (mean±SD)* Level I: AHI: 26/hr ±28 AI: 15/hr ±22 HI: 11/hr ±14 Level III: AHI: 27/hr ±23	**No**: none **Unclear**: none **Yes**: 8, 9 & 13 **No**: none **Unclear**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		N= 80 Withdrawal/dropout: n=2 (from level III arm) Reason for withdraw/dropout: Level III equipment malfunction (n=2) *Inclusion criteria:* Age ≥ 21 yrs Suspected OSA *Exclusion criteria:* Suspected other non-OSA sleep disorders Severe or unstable comorbid conditions Receiving oxygen or mechanical ventilation Neurological disorders Sedative, hypnotics or stimulants use Alcohol or drugs abuse	*Interval between studies*: Within 2 weeks Level I index used: AHI (TRT) Level III index used: AHI (TRT) Cut point used indicating diagnosis and/or treatment: AHI ≥ 5		AI: 15/hr ±20 HI: 11/hr ±8 *Diagnostic agreement* · Correlation (Level I & III AHIs): pearson correlation r=0.892 (p<0.0001, 95% CI: 0.83, 0.93) · Bland and Altman Values (level I –level III): - 1.1/hr (95% CI: -24.9, 22.8) *Adverse events:* Hypertensive crisis during study n=1 *Complications:* Not Reported <u>Separate at home Level III study</u> *Diagnostic accuracy* Cut-point used: **AHI ≥ 5** · Sensitivity: 93% · Specificity: 59% · PPV: 85% · NPV: 76% · LR+: 2.27 · LR-: 0.12 · Area under the ROC	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					curve: 0.90 Cut-point used: **AHI ≥ 15** · Sensitivity: 85% · Specificity: 80% · PPV:80 % · NPV: 84% · LR+: 4.25 · LR-: 0.19 · Area under the ROC curve: 0.92 Cut-point used: **AHI ≥ 30** · Sensitivity: 77% · Specificity: 93% · PPV: 81% · NPV: 91% · LR+: 11.0 · LR-: 0.25 · Area under the ROC curve: 0.95 *Diagnostic agreement* Level I vs. Level III = 83% *AHI/AI/HI values (mean±SD)* Level I:	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					AHI: 23/hr ±24 AI: 12/hr ±19 HI: 11/hr ±11 Level III: AHI: 23/hr ±24 AI: 13/hr ±20 HI: 9/hr ±6 *Diagnostic agreement* · Correlation (Level I & III AHIs): pearson correlation r=0.876 (p<0.0001, (95% CI: 0.81, 0.91) · Bland and Altman Values (level I –level III): - 0.7/hr (95% CI -24.0, 22.6) *Adverse events:* Not Reported *Complications:* Level III: Equipment malfunction n=2	
Smith LA.[119] 2007 UK Full study	Academic teaching hospital No. of sites: 1 Cohort Study	No. of patients enrolled in study: N=20 Suspected diagnosis: Sleep Disorder Breathing: n=20 Gender: Male: 14	<u>Simultaneous level I and level III study</u> *Level I* Location of study: Sleep Laboratory Total No. of channels: 10+	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients*	<u>Simultaneous in lab Level I and Level III study</u> *Diagnostic accuracy:* Not Reported *Diagnoses made:*	Oxford: 1b QUADAS: *Internal Validity* Yes: 3, 4,

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
Funding sources: British heart foundation	Consecutive Prospective Simultaneous level I and level III study; separate level III home study Non random allocation to simultaneous level I/ level III study and level III home study	Female: 6 Age: Mean: 61 years SD: ±10 Range: 18-20 years Comorbidities: (CHF) Ischaemic heart disease: n=13 Dilated cardiomyopathy: n=7 Atrial fibrillation: 3 Left ventricular ejection fraction (mean±SD): 33±12 Body Mass Index: Mean: 29 kg/m² SD: ±6 Neck circumference (cm): Not Reported SDB pre-test probability: Epworth Sleepiness Scale Mean: 8 SD: ±4 Source of referrals: Not Reported Blinding: Not Reported <u>Simultaneous level I and level III study</u> N=20	Study operators: Not Reported Scoring methods: manual Study interpreters: experienced sleep technician Device name: Compumedics (Abbotsford, Australia) *Level III* Location of study: Sleep Laboratory Total No. of channels: 4+ Study operators: Not Reported Scoring methods: manual Study interpreters: experienced sleep technician Device name: Embletta (Flaga, Iceland) <u>Level III home study</u> *Level III* Location of study: Home Total No. of channels: 4+ Study operators: patient	*diagnosed / conditions)* *AHI values reported (mean±SD or median or range/ sleep study type)* *A+H values reported (mean±SD or median or range/ sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	Level I AHI>15: OSA n=10 CSA n=1 *AHI values (mean±SD):* Level I: AHI: 25.7/hr ± 22.2 HI: 16.4/hr ±13.5 MA: 0.0/hr ±0.0 CA: 2.8/hr ±9.6 OA: 6.3/hr ±13.4 Level III: AHI: Not Reported HI: 14.4/hr ±10.0 MA: 0.0/hr ±0.1 CA: 0.6/hr ±1.8 OA: 4.5/hr ±8.1 *A+H values (mean±SD):* Level I: 24.2 ± 16.8 Level III: 19.5 ±16.0 (difference between Level I and Level III A+H statistically significant, p< 0.01) *Diagnostic agreement:* · Correlation (Pearson's): between level I and III A+H: r= 0.92 (p<0.01); between level III A+H and level I AHI: r=0.94 (p<0.01) · Bland and Altman	5, 6, 7, 10, 11, 12, 14 No: none Unclear: none *External Validity* Yes: 1 & 2 No: none Unclear: none *Reporting* Yes: 13 No: none Unclear: 8 & 9

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Withdrawal/dropout: n= 0 (from simultaneous arms) <u>Level III home study</u> N= 20 Withdrawal/dropout: n= 0 *Inclusion criteria:* Consenting CHF patients Age between 18 and 80 years Symptomatic but stable CHF for at least one month on medical therapy Objective evidence of left ventricular systolic dysfunction *Exclusion criteria:* Acute coronary syndrome within the preceding three months Primary valvular heart disease Stroke with residual neurological deficit	Scoring methods: manual Study interpreters: experienced sleep technician Device name: Embletta (Flaga, Iceland) *Interval between studies*: Median: 2 days Range: 1-7 days Level I index used: AHI (TST) and A+H (TIB) Level III index used: A+H (TIB) Cut point used indicating diagnosis and/or treatment: A+H ≥ 10		Values: Mean difference (level I A+H - level III A+H, mean±SD): 5 ± 7; (95% CI: -8, 18) Mean difference (level I AHI - level III A+H, mean±SD): 6 ±9; (95% CI: -11, 24) · Diagnostic accuracy agreement between level I and level III A+H: Kappa coefficient = 0.63, p<0.01 *Adverse events:* Not Reported *Complications:* Not Reported <u>Separate at home Level III study</u> *Diagnostic accuracy* Cut-point used: **AHI ≥ 15** · Sensitivity: 58.3% · Specificity: 62.5% · PPV: 70% · NPV: 50% · LR+: 1.55 · LR-: 0.67 · Area under the ROC curve: Not Reported	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					Diagnoses made: Not Reported *AHI values (mean±SD):* AHI: Not Reported HI: 10.6/hr ±8.9 MA: 0.0/hr ±0.0 CA: 0.2/hr ±0.6 OA: 2.9/hr ±5.1 *A+H values (mean±SD):* Level III: 13.7 ± 12.6 (difference between level I and level III A+H statistically significant, p< 0.01) *Diagnostic agreement:* · Correlation (Pearson's, between level I and III A+H): r=0.54 (p=0.01) · Bland and Altman Values: Mean difference (level I A+H-level III A+H, mean±SD): 10±15; (95% CI: -18, 39) Mean difference (level I AHI-level III A+H, mean±SD): 12±19;(95% CI: -25, 49) · Diagnostic accuracy	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					agreement between level I AHI and level III A+H: Kappa coefficient = 0.27, p=0.06 *Adverse events:* Not Reported *Complications:* Level III; Poor nasal pressure trace n=2 Poor PSO^2 trace n=2 Patient error requiring repeat study n=1	
Tonelli de Oliveria AC.[117] 2009 Brazil Full Study Funding sources: government	Academic teaching hospital No. of sites: 1 Cohort study Consecutive Prospective Simultaneous level I and level III study, and level III home study Random allocation to simultaneous level I/ level III	No. of patients enrolled in study: N=157 (149 valid recordings) Suspected diagnosis: OSAS: n=149 Gender: Male: 111 Female: 38 Age: Mean: 45 years SD: ±12 Comorbidities: Not Reported Body Mass Index: Mean: 29.2 kg/m^2	<u>Simultaneous Level I and Level III study</u> *Level I* Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: technician Scoring methods: manual Study interpreters: sleep specialist (one author) Device name: Not Reported *Level III*	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *Level I & Level III AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	<u>Simultaneous in lab Level I and Level III study</u> *Diagnostic accuracy:* Cut-point used: **AHI <5** · Sensitivity: 95.3% (95% CI: 91.7, 99.0) · Specificity: 75% (95% CI: 56, 94) · PPV: Not Reported · NPV: Not Reported · LR+: 3.81 · LR-: 0.06 · Area under the ROC curve: Not Reported *Diagnoses made:* Not Reported	Oxford: 1b QUADAS: *Internal Validity* Yes: 3, 4, 5, 6, 7, 10, 11, 12, 14 No: none Unclear: none *External Validity* Yes: 1 & 2 No: none Unclear: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
	study and level III home study	SD: ±5.5 Neck circumference (cm): Not Reported SDB pre-test probability: Epworth Sleepiness Scale Mean: 11 SD: ±5 Source of referrals: Not Reported Blinding: Study Interpreter <u>Simultaneous level I and level III study</u> N= 149 valid recordings Withdrawal/dropout: n= 8 (from simultaneous arm) Reason for withdraw/dropout: Level III: < 4 hours recording n=6 Lost airflow signal n=1 Lost oximetry n=1 <u>Level III home study</u> N= 141 valid recordings Withdrawal/dropout: n= 36	Location of study: Sleep Laboratory Total No. of channels: 4+ Study operators: technician Scoring methods: automated/manual Study interpreters: sleep specialist (one author different from level I reviewer) Device name: Somnocheck (Weinmann GmbH, Hamburg, Germany) <u>Level III home study</u> *Level III* Location of study: Home Total No. of channels: 4+ Study operators: patients Scoring methods: automated/manual Study interpreters: sleep specialist (one author different from level I reviewer) Device name: Somnocheck		*AHI values (mean±SD):* Level I: 30.2±27.8 Level III: 27.5±24.7 *Diagnostic agreement:* · Concordance (Kappa statistics, Level I & III AHIs): AHI<5: 0.69 (95% CI: 0.52, 0.84) 5≤AHI<15: 0.51 (95% CI: 0.35, 0.67) 15≤AHI<30: 0.55 (95% CI: 0.4, 0.71) 30≤AHI: 0.79 (95% CI: 0.63, 0.95) Overall: 0.64 (95% CI: 0.55, 0.74) · Bland and Altman Values: 95% CI (level I AHI-level III AHI): +2.6/hr (95% CI-17.7, 22.8) *Adverse events:* Not Reported *Complications:* Level III: < 4 hours recording n=6 Lost airflow signal n=1 Lost oximetry n=1	*Reporting* Yes: 8 & 13 No: 9 Unclear: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Reason for withdraw/dropout: Level III: Absent from study n=13 < 4 hours recording n=12 Lost oximetry n=5 Lost airflow signal n=4 Intolerant of level III device n=1 Forgot to wear level III device n=1 *Inclusion criteria:* Age > 18 years Referred for evaluation of suspected OSAS *Exclusion criteria:* Pregnant Severe comorbidities (cancer, heart failure, etc.) Difficulties that would interfere with examinations Patients outside of Porto Alegre	(Weinmann GmbH, Hamburg, Germany) *Interval between studies*: maximum 48 hours interval between simultaneous studies and level III home study Level I index used: AHI (Not Reported) Level III index used: AHI (denominator: total artifact-free recording time) Cut point used indicating diagnosis and/or treatment: AHI ≥ 5		<u>Separate at home Level III study</u> *Diagnostic accuracy:* Cut-point used: **AHI ≥ 5** · Sensitivity: 96.15% (95% CI: 92.5, 99.8) · Specificity: 64.7% (95% CI: 42.0, 87.4) · PPV: 94.3% (95% CI: 89.9, 98.7) · NPV: 73.3% (95% CI: 51.0, 95.7) · LR+: 2.7 · LR-: 0.05 · Area under the ROC curve: 0.96 (95% CI: 0.91, 0.99) Cut-point used: **AHI ≥ 10** (Best cut point for level III AHI=9) · Sensitivity: 90.7% (95% CI: 82.7, 95.2) · Specificity: 82.9% (95% CI: 67.3, 91.9) · PPV: 92.9% (95% CI: 85.3, 96.7) · NPV: 68.4% (95% CI: 62.8, 88.6) · LR+: 5.2 · LR-: 0.11 · Area under the ROC curve: 0.92 (95% CI: 0.85, 0.96)	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					Cut-point used: **AHI ≥ 15** (Best cut point for level III AHI=9) · Sensitivity: 81.3% (95% CI: 71.1, 88.5) · Specificity: 82.6% (95% CI: 69.3, 90.9) · PPV: 88.4% (95% CI: 78.8, 94.0) · NPV: 73.1% (95% CI: 59.7, 83.2) · LR+: 4.6 · LR-: 0.22 · Area under the ROC curve:0.91 (95% CI: 0.85, 0.96) Cut-point used: **AHI ≥ 30** (Best cut point for level III AHI=33) · Sensitivity: 80.0% (95% CI: 68.3, 91.7) · Specificity: 92.1% (95% CI: 86.0, 98.2) · PPV: 85.7% (95% CI: 75.1, 96.3) · NPV: 88.6%, (95% CI: 81.6, 95.6) · LR+: 10.1 · LR-: 0.21 · Area under the ROC curve:0.92 (95% CI: 0.86, 0.96)	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					Diagnoses made: Correctly exclusion of OSAS: 91.7%; Correctly diagnose severe OSAS: 87.6% *AHI values (mean±SD):* Level III: 25.9±22.5 *Diagnostic agreement:* · Concordance (Kappa statistics, Level I & III AHIs): AHI<5: 0.64 (95% CI: 0.46, 0.81) 5≤AHI<15: 0.37 (95% CI: 0.20, 0.55) 15≤AHI<30: 0.38 (95% CI: 0.20, 0.55) 30≤AHI: 0.73 (95% CI: 0.55, 0.90) Overall: 0.53 (95% CI: 0.42, 0.63) · Bland and Altman Values: 95% CI (level I AHI-level III AHI): +3.2/hr (95% CI-28.0, 34.3) *Adverse events:* Not Reported *Complications:*	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					Level III: < 4 hours recording n=12 Lost oximetry n=5 Lost airflow signal n=4 Intolerant of level III device n=1 Forgot to wear level III device n=1	
Studies of simultaneous level I and level III studies only						
Bajwa I.[127] 2009 USA Abstract Funding: Not Reported	General Hospital No. of sites: 1 Cohort Study Prospective Study Recruitment: Not Reported Simultaneous level I and level III study	No. of patients enrolled in study: N=7 Suspected diagnosis: Not Reported Gender: Male: Not Reported Female: Not Reported Age: Not Reported Comorbidities: Not Reported Body Mass Index: Not Reported Neck circumference: Not Reported SDB pre-test probability Epworth Sleepiness Scale:	*Level I* Location of study: Sleep Laboratory Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Manual Study interpreters: Sleep Technician Device name: Alice 5 PSG (Philips Respironics Inc, USA) *Level III* Location of study: Sleep Laboratory Total No. of channels: 4+	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed / conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *RDI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy* Not Reported *Diagnoses made* Level I: Not Reported Level III: Not reported *AHI values (range)* Level I: 4.3-103.5 *RDI values (range)* Level III: 4.8-104.8 *Diagnostic agreement:* · Correlation (Level I & Level III AHI): r=0.949 (p=0.001) · Correlation (Level I & Level III RDI): r=0.953 (p=0.001) · Bland and Altman Values: Not Reported	Oxford : 3b QUADAS: *Internal Validity* **Yes:** 3,4,5,6, 7,12,14 **No:** None **Unclear:** 10,11 *External Validity* **Yes:** none **No:** 2 **Unclear:** 1

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Not Reported Berlin Risk (Low:High)%: Not Reported Source of referrals: Not Reported Withdrawal/dropout: Not Reported Reason for withdraw/dropout: Not Reported Blinding: Not Reported *Inclusion criteria:* Not Reported *Exclusion criteria:* Not Reported	Study operators: Not Reported Scoring methods: Manual Study interpreters: Sleep Technician Device name: Alice PDx (Philips Respironics Inc, USA) Level I index used: AHI Level III index used: RDI Cut point used indicating diagnosis and/or treatment: Not Reported		*Adverse events:* Not Reported *Complications:* Not Reported	*Reporting* **Yes:** 13 **No:** none **Unclear:** 8,9
Candela A.[126] 2005 Spain Full Study Funding: Government	Academic hospital No. of sites: 1 Cohort Study Prospective Consecutive Simultaneous level I and level III	No. of patients enrolled in study: N= 103 (92 valid recordings) Suspected diagnosis: Sleep Related-breathing disturbances: n=92 Gender: Male: 72 Female: 20 Age:	*Level I* Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: Experienced sleep technicians Scoring methods: Manual Study interpreters: Independent	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI/A+H values reported (medians IQR or range/sleep study type)*	*Diagnostic accuracy* Cut-point used: **AHI ≥ 10** (manual (automated)) · Sensitivity: 97% (97%) · Specificity: 82% (85%) · PPV: 93% (94%) · NPV: 92% (92%) · LR+: 5.39 (6.47) · LR-: 0.037 (0.035) · Area under the ROC curve (95% CI): 0.971 (95% CI 0.943,	Oxford: 1b QUADAS: *Internal Validity* **Yes:** 3,4,5,6, 10,11 12,14 **No:**

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
	study	Mean: 52.4 years SD: ±11.8 Range: 24-77 years Comorbidities: Arterial Hypertension: n= 37 COPD: n=8 Body Mass Index: Mean: 31.8 kg/m² SD: ±6.6 Range: 21.9-59.2 Neck circumference: Mean: 41.2 cm SD: ±3.6 Range: 33-50 SDB pre-test probability: Epworth Sleepiness Scale Mean: 11.2 SD: ±4.8 Range: 2-22 Berlin Risk (Low:High)% Not Reported Source of referrals: Outpatient Pneumology Clinic Withdrawal/dropout: N=103 patients entered the study but data is only reported on n=92	experienced pneumologist Device name: Somnostar α System (Sensor Medics Co, USA) *Level III* Location of study: Sleep Laboratory Total No. of channels: 4+ Study operators: Not Reported Scoring methods: Manual and Automated Study interpreters: Independent experienced pneumologist Device name: BITMED NGP140 (Meditel Ingenieria Medica, Spain) Level I index used: AHI (TST) Level III index used: REI (TIB) Cut point used indicating diagnosis and/or treatment: AHI ≥10	*REI values reported (medians IQR median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	0.999) (0.969 (95% CI 0.936, 1)) Cut-point used: **AHI ≥ 15** (manual (automated)) · Sensitivity: 96% (92%) · Specificity: 94% (97%) · PPV: 96% (98%) · NPV: 94% (90%) · LR+: 16 (30.67) · LR-: 0.042 (0.082) · Area under the ROC curve (95% CI): 0.975 (95% CI 0.947, 1) (0.986 (95% CI 0.969, 1)) Cut-point used: **AHI ≥ 20** (manual (automated)) · Sensitivity: 96% (92%) · Specificity: 97% (97%) · PPV: 98% (98%) · NPV: 95% (90%) · LR+: 32 (30.67) · LR-: 0.041 (0.082) · Area under the ROC curve (95% CI): 0.995 (95% CI 0.987, 1) (0.987 (95% CI 0.970, 1)) Cut-point used: **AHI ≥ 30** (manual (automated)) · Sensitivity: 98% (98%) · Specificity: 98% (93%) · PPV: 98% (94%)	None **Unclear:** 7 *External Validity* **Yes:** 1, 2 **No:** none **Unclear:** none *Reporting* **Yes:** 8,9,13 **No:** none **Unclear:** none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Reason for withdraw/dropout: (from the original N=103) TST < 148 minutes n=7 Level III technical errors n=3 Failure of airflow signal n=1 Blinding: Sleep study interpreter *Inclusion criteria:* Suspected Sleep Related-Breathing disturbances *Exclusion criteria:* Not Reported			· NPV: 98% (98%) · LR+: 49 (14) · LR-: 0.020 (0.021) · Area under the ROC curve (95% CI): 0.996 (95% CI 0.989, 1) (0.989 (95% CI 0.975, 1)) *Diagnoses made* Level I: SAHS n=65 Level III: Not reported *AHI values (median, IQR)* Level I: A+H: 31.8/hr (7-72) AI: 22.3/hr (3-53) HI: 4.8/hr (2-20) *REI values (median, IQR)* (manual (automated)) Level III: A+H: 30/hr (7-52) (20/hr (5-46)) AI: 12.4/hr (2-34) (8/hr(1-27)) HI:8.7/hr (4-20) (6/hr(3-14)) *Diagnostic agreement:* · Correlation (Level I AHI & III REIs): Interclass correlation coefficient (manual) r=0.945 (95% CI 0.917,	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					0.963) · Bland and Altman Values: (manual (automated)) 7.6 (95% CI -4.9, 10.4) (12.1 (95% CI -8.8, 15.3)) *Adverse events:* Not Reported *Complications:* Level III reporting errors: n=4	
Driver HS.[129] 2009 Canada Abstract Funding: Private (Braebon Medical Corporation)	Academic Teaching Hospital No. of sites: 1 Cohort Study Prospective Consecutive Simultaneous level I and level III study	No. of patients enrolled in study: N=72 Suspected diagnosis: Suspected OSA n=72 Gender: Male: 30 Female: 42 Age: Mean: 53 years SD: ±12 Range: 20-71 Comorbidities: Not Reported Body Mass Index: Mean: 32.2 kg/m² SD: ±6.2 Neck circumference:	*Level I* Location of study: Sleep Laboratory Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Manual Study interpreters: Not Reported Device name: Attended PSG (Not specified) *Level III* Location of study: Sleep Laboratory Total No. of channels: Not Reported	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *RDI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy* Cut-point used: **AHI>5** · Sensitivity: 92% · Specificity: 70% · PPV: 92% · NPV: 59% · LR+: 3.07 · LR-: 0.114 · Area under the ROC curve: Not Reported Cut-point used: **AHI>10** · Sensitivity: 92% · Specificity: 86% · PPV: 94% · NPV: 83% · LR+: 6.57 · LR-: 0.093 · Area under the ROC curve: Not Reported	Oxford: 1c QUADAS: *Internal Validity* **Yes:** 3,4,5,7,12,14 **No:** none **Unclear:** 6, 10, 11 *External Validity* **Yes:** 1 **No:** 2 **Unclea**

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Not Reported SDB pre-test probability Epworth Sleepiness Scale: Not Reported Berlin Risk (Low:High)%: Not Reported Source of referrals: Not Reported Withdrawal/dropout: (N=79 entered the study) n=7 dropped from study Reason for withdraw/dropout: Missing data (low battery, poor airflow signal, faulty pressure transducers) Blinding: Not Reported *Inclusion criteria:* Suspected OSA *Exclusion criteria:* Not Reported	Study operators: Not Reported Scoring methods: Manual Study interpreters: Not Reported Device name: MediByte (Braebon Medical Corp, Canada) Level I index used: AHI Level III index used: RDI Cut point used indicating diagnosis and/or treatment: AHI ≥10		Cut-point used: **AHI>15** · Sensitivity: 79% · Specificity: 97% · PPV: 98% · NPV: 76% · LR+: 26.0 · LR-: 0.22 · Area under the ROC curve: Not Reported Cut-point used: **AHI>20** · Sensitivity: 89% · Specificity: 97% · PPV: 97% · NPV: 90% · LR+: 30.0 · LR-: 0.11 · Area under the ROC curve: Not Reported Cut-point used: **AHI>30** · Sensitivity: 73% · Specificity: 100% · PPV: 100% · NPV: 89% · LR+: Infinity · LR-: 0.27 · Area under the ROC curve: Not Reported	**r:** none *Reporting* **Yes:** 13 **No:** none **Unclear:** 8,9

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					Diagnoses made Level I: Not Reported Level III: Not reported *AHI values (mean ±SD)* Level I: Mean: 26.0/hr ±25.9 *RDI values(mean ±SD)* Level III: Mean: 20.1/hr ±18.8 *Diagnostic agreement:* · Correlation (Level I AHI & Level III RDI): Pearson Correlation r =0.92 · Bland and Altman Values: -6/hr (±11.3) *Adverse events:* Not Reported *Complications:* Level III n=7 Missing data (low battery, poor airflow signal, faulty pressure transducers)	
Ferre A.[125] 2008 Spain Abstract	General hospital No. of sites: 1 Cohort Study Prospective	No. of patients enrolled in study: N =37 Suspected diagnosis: SDB: n=37 Gender: Male: 24	*Level I* Location of study: Not Reported Total No. of channels: Not Reported Study operators: Not Reported	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients*	*Diagnostic accuracy:* Cut-point used: **AHI >5** · Sensitivity: 93.3% · Specificity: 86.7% · PPV: Not Reported · NPV: Not Reported · LR+: 7.01	Oxford: 1C QUADAS: *Internal Validity*

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
Funding sources: Not Reported	Study Recruitment: Not Reported Simultaneous level I and level III study	Female: 13 Age: Mean: 55.1 years SD: ±11.5 Comorbidities: Not Reported Body Mass Index: Mean: 27.3 kg/m² SD:± 3.9 Neck circumference (cm): Not Reported SDB pre-test probability: Epworth Sleepiness Scale Mean: 10 SD: ±8.0 Source of referrals: Not Reported Blinding: Not Reported Withdrawal/dropout: n= 0 *Inclusion criteria:* Suspected SDB *Exclusion criteria:*	Scoring methods: manual Study interpreters: Not Reported Device name: Not Reported *Level III* Location of study: Not Reported Total No. of channels: 4+ Study operators: Not Reported Scoring methods: manual Study interpreters: Not Reported Device name: Somte Level I index used: AHI (Not Reported) Level III index used: AHI (Not Reported) Cut point used indicating diagnosis and/or treatment: Not Reported	*diagnosed / conditions)* *AHI values reported (mean±SD or median or range/ sleep study type)* *Diagnostic agreement* *Adverse events* *Complications* Notes: outcomes of 1st observer tabulated	· LR-: 0.08 · Area under the ROC curve: Not Reported Cut-point used: **AHI >15** · Sensitivity: 84.2% · Specificity: 100% · PPV: Not Reported · NPV: Not Reported · LR+: Infinity · LR-: 0.16 · Area under the ROC curve: Not Reported Cut-point used: **AHI >30** · Sensitivity: 55.6% · Specificity: 96.4% · PPV: Not Reported · NPV: Not Reported · LR+: 15.44 · LR-: 0.46 · Area under the ROC curve: Not Reported *Diagnoses made:* Not Reported *AHI values (mean±SD):* Level I: 20.5±18.0 Level III: 17.7±16.6 *Diagnostic agreement:* · Correlation (Level I & III AHIs): Not Reported	Yes: 4, 5, 6, 7, 12 No: none Unclear: 3, 10, 11, 14 *External Validity* Yes: 1 No: none Unclear: 2 *Reporting* Yes: 13 No: 8 & 9 Unclear: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Not Reported			· Bland and Altman Values: Not Reported *Adverse events:* Not Reported *Complications:* Not Reported	
Grant B.[137] 2009 USA Abstract Funding: Not Reported **This study eliminated all but the Embletta channels from the PSG and called this a "separate limited study"**	General Hospital No. of sites: 1 Cohort Prospective Consecutive Simultaneous level I and level III study	No. of patients enrolled in study:N= 95 Suspected diagnosis: Sleep apnea: n=95 Gender: Male: Not Reported Female: Not Reported Age: Mean: Not Reported SD: Not Reported Range: Not Reported Comorbidities: Not Reported Body Mass Index: Not Reported Neck circumference: Not Reported SDB pre-test probability: Epworth Sleepiness Scale Not Reported	*Level I* Location of study: Sleep Laboratory Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Manual Study interpreters: Sleep technician Device name: Rembrandt (Embla, USA) *Level III* Location of study: Sleep Laboratory Total No. of channels: 4+ Study operators: Not Reported Scoring methods: Manual	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy* Cut-point used: **AHI ≥ 5** · Sensitivity: 99% · Specificity: 73% · PPV: 76% · NPV: 99% · LR+: 3.6 (95% CI 2.3, 5.5) · LR-: 0.015 (95% CI 0.001, 0.24) · Area under the ROC curve: Not Reported Cut-point used: **CAI ≥ 5 (Central Apnea Index)** · Sensitivity: Not Reported · Specificity: Not Reported · PPV: Not Reported · NPV: Not Reported · LR+: 15 (95% CI 6.5, 35) · LR-: 0.089 (95% CI 0.006, 1.2) · Area under the ROC curve (95% CI):	Oxford: 4 QUADAS: *Internal Validity* **Yes:** 3,4,5,6, 10, 14 **No:** 7 **Unclear:**11,12 *External Validity* **Yes:** none **No:** none **Unclear:** 1, 2 *Reporting*

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Berlin Risk (Low:High)% Not Reported Source of referrals: Not Reported Withdrawal/dropout: n=0 Reason for withdraw/dropout: Not Applicable Blinding: Sleep study interpreter Comorbidities: Not Reported *Inclusion criteria:* Not Reported *Exclusion criteria:* Not Reported	Study interpreters: Sleep technician Device name: Embletta (Embla, USA) Level I index used: AHI Level III index used: AHI Cut point used indicating diagnosis and/or treatment: AHI >5		Not Reported Cut-point used: **AHI ≥ 15** · Sensitivity: 97% · Specificity: 81% · PPV: 47% · NPV: 99% · LR+: 5.1 (95% CI 3.2, 8.1) · LR-: 0.041 (95% CI 0.003, 0.63) · Area under the ROC curve Not Reported *Diagnoses made* Level I: Not sleep apnea (AHI <5) n=51 Mild sleep apnea (>5 AHI <15) n=30 Moderate sleep apnea (>15 AHI <30) n=10 Severe sleep apnea (AHI>30) n=4 Level III: Not reported *Level I AHI values:* Not reported *Level III AHI values:* Not reported *Diagnostic agreement:*	**Yes:** 13 **No:** 9 **Unclear:** 8

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					· Correlation (Level I AHI & III AHIs): Not Reported · Bland and Altman Values: Level I vs Level III AHIs 35% (95% CI 22, 49%) overestimation by Level III device Level I vs Level III **CAIs** -5.7% (95% CI -21, +12%) underestimation by Level III device *Adverse events:* Not Reported *Complications:* Not Reported	
Ng S.[138] 2010 China Full Study Funding: Academic (Respiratory Research Fund, The Chinese University of Hong Kong)	Academic hospital No. of sites: 1 Cohort Prospective Consecutive Simultaneous level I and level III study	No. of patients enrolled in study: N=90 (data reported on n=80 due to lost data) Suspected diagnosis: OSAS: n=90 Gender: (n=80) Male: 63 Female: 17 Age: Mean: 51.4 years SD: ±11.9 Range: Not Reported Comorbidities: Not Reported	*Level I* Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: Not Reported Scoring methods: Manual Study interpreters: Not Reported Device name: Alice 4 (Healthdyne, USA) *Level III* Location of study: Sleep	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed / conditions)* *Level I AHI values reported (mean±SD or median or range/sleep study type)* *Level III AHI values reported (mean±SD or median or range/sleep*	*Diagnostic accuracy* Cut-point used: **AHI ≥ 5** · Sensitivity: 92.4% · Specificity: 85.7% · PPV: 96.8% · NPV: 70.6% · LR+: 6.462 · LR-: 0.089 · Area under the ROC curve (95% CI): 1.00(Not Reported) Cut-point used: **AHI ≥ 10** · Sensitivity: 90.0% · Specificity: 86.7% · PPV: 91.8% · NPV: 83.9%	Oxford : 1b QUADAS: *Internal Validity* **Yes:** 3,4,5,6, 7,10,11, 12,14 **No:** none **Unclear:** none *Externa*

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Body Mass Index: Mean: 27.1 kg/m² SD: ±4.2 Range: Not Reported Neck circumference: Mean: 38.6 cm SD: ±3.6 Range: Not Reported SDB pre-test probability: Epworth Sleepiness Scale Mean: 9.7 SD: ±5.3 Range: Not Reported Berlin Risk (Low:High)% Not Reported Source of referrals: Hospital based respiratory clinic Withdrawal/dropout: n=10 Reason for withdraw/dropout: (from the original N=90) Lost oximetry on Level III device (n=6) Nasal signal loss on Level III device (n=3) Less than 4 hours interpretable data on Level III device (n=1)	Laboratory Total No. of channels: 4+ Study operators: Not Reported Scoring methods: Automated Study interpreters: Not Reported Device name: Embletta PDS (Medcare, Iceland) Level I index used: AHI (TST) Level III index used: AHI (Total Recording Time) Cut point used indicating diagnosis and/or treatment: Not Reported	*study type)* *Diagnostic agreement* *Adverse events* *Complications*	· LR+: 6.767 · LR-: 0.115 · Area under the ROC curve (95% CI): 1.00(Not Reported) Cut-point used: **AHI ≥ 15** · Sensitivity: 87.8% · Specificity: 94.9% · PPV: 94.7% · NPV: 88.1% · LR+: 17.216 · LR-: 0.126 · Area under the ROC curve (95% CI): 0.998 (Not Reported) Cut-point used: **AHI ≥ 20** · Sensitivity: 85.3% · Specificity: 95.7% · PPV: 93.5% · NPV: 89.8% · LR+: 19.837 · LR-: 0.154 · Area under the ROC curve (95% CI): 1.00(Not Reported) *Diagnoses made* Level I: Not reported Level III: Not reported *AHI values (mean ±SD)* Level I:	*l* *Validity* **Yes:** 1, 2 **No:** none **Unclear:** none *Reporting* **Yes:** 13 **No:** none **Unclear:** 8,9

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Blinding: "double blinded to PSG and Embletta records" *Inclusion criteria:* Suspected OSAS Self reported daytime sleepiness interfering with daytime function OR 2 of the following: a) Choking during sleep b) Gasping during sleep c) Recurrent awakenings from sleep d) Unrefreshed sleep e) Daytime fatigue f) Impaired concentration *Exclusion criteria:* Not Reported			AHI: 21.6/hr ±19.1 HI: 4.2/hr ±4.1 OA: 15.7/ ±16.7 CA: 1.1/hr ±2.2 Level III: AHI: 20.8/hr ±18.7 HI: 4.3/hr ±4.5 OA: 14.0/ ±15.7 CA: 1.0/hr ±1.9 *Diagnostic agreement:* · Correlation (Level I AHI & III AHIs): Pearson's r=0.979 ($p<0.05$) · Bland and Altman Values: (Level III to Level I) +0.91 (95% CI -6.82, 8.54) *Adverse events:* Not Reported *Complications:* Level III: Lost oximetry n=6 Nasal signal loss n=3 Less than 4 hours interpretable data n=1	
Orr WC.[121] 2006 USA Abstract	Academic Teaching Hospital No. of sites: 1 Cohort Study	No. of patients enrolled in study: N=48 Suspected diagnosis: Not Reported Gender: Male: Not Reported	*Level I* Location of study: Sleep Laboratory Total No. of channels: Not Reported	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients*	*Diagnostic accuracy* Cut-point used: **AHI≥5** · Sensitivity: Not Reported · Specificity: 81% · PPV: Not Reported · NPV: Not Reported · LR+: Not Reported	Oxford: 3b QUADAS: *Internal Validity*

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
Funding: Not Reported	Prospective Patient selection: Not Reported Simultaneous level I and level III study	Female: Not Reported Age: Not Reported Comorbidities: Not Reported Body Mass Index: Not Reported Neck circumference: Not Reported SDB pre-test probability Epworth Sleepiness Scale: Not Reported Berlin Risk (Low:High)%: Not Reported Source of referrals: Not Reported Withdrawal/dropout: Not Reported Reason for withdraw/dropout: Not Reported Blinding: Not Reported *Inclusion criteria:*	Study operators: Sleep technicians Scoring methods: Manual Study interpreters: "Trained personnel" Device name: PSG (Not specified) *Level III* Location of study: Sleep Laboratory Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Automated Study interpreters: Automated analysis Device name: Lifeshirt (VivoMetrics, USA) Level I index used: AHI Level III index used: AHI Cut point used indicating diagnosis and/or treatment: AHI ≥5	*diagnosed / conditions)* *Level I & III AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	· LR-: Not Reported · Area under the ROC curve: Not Reported Cut-point used: **AHI≥10** · Sensitivity: 83% · Specificity: 87% · PPV: Not Reported · NPV: Not Reported · LR+: 6.38 · LR-: 0.195 · Area under the ROC curve: Not Reported Cut-point used: **AHI≥15** · Sensitivity: 82% · Specificity: Not Reported · PPV: Not Reported · NPV: Not Reported · LR+: Not Reported · LR-: Not Reported · Area under the ROC curve: Not Reported Cut-point used: **AHI≥25** · Sensitivity: 100% · Specificity: Not Reported · PPV: Not Reported · NPV: Not Reported · LR+: Not Reported · LR-: Not Reported	**Yes:** 4,5,6,7, 10,11,12,14 **No:** none **Unclear:** 3 *External Validity* **Yes:** none **No:** 2 **Unclear:** 1 *Reporting* **Yes:** 13 **No:** none **Unclear:** 8,9

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Not Reported *Exclusion criteria:* Not Reported			· Area under the ROC curve: Not Reported Cut-point used: **AHI≥30** · Sensitivity: Not Reported · Specificity: 100% · PPV: Not Reported · NPV: Not Reported · LR+: Not Reported · LR-: Not Reported · Area under the ROC curve: Not Reported *Diagnoses made* Level I: Not Reported Level III: Not reported *AHI values (range)* Level I: Not Reported Level III: Not Reported *Diagnostic agreement:* · Correlation (Level I & Level III AHI): Not Reported · Bland and Altman Values: 0.79 (±14.46) *Adverse evemts:* Not Reported *Complications:*	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					Not Reported	
Su S, et al.[148] 2004 USA Full Study Funding sources: Private (SNAP Corporation)	Academic teaching hospital No. of sites: 1 Cohort study Prospective Patient allocation: Not Reported Simultaneous level I and level III study	No. of patients enrolled in study: N= 60 Suspected diagnosis: OSAS: n=60 Gender: Male: 25 Female: 35 Age: Mean: 45.2 yrs SD: ±12.3 Range: 19-74 years Comorbidities: Hypertension (n = ??) Body Mass Index: Mean: 35.6 kg/m² SD: ±10.1 Range: 16.9-60.7 kg/m² Neck circumference (cm): Not Reported SDB pre-test probability: Epworth Sleepiness Scale: Not Reported Berlin Risk (Low:High): Not Reported Source of referrals:	<u>Simultaneous level I and level III study</u> *Level I* Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: Sleep disorder clinic technicians Scoring methods: Automated Study interpreters: Board certified neurologist Device name: Not reported *Level III* Location of study: Sleep Laboratory Total No. of channels: 4+ Study operators: Sleep disorder clinic technicians Scoring methods: Automated Study interpreters: PhD electrical engineer & computer scientist	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *Diagnostic agreement* *Level I RDI values reported (mean±SD or median or range/sleep study type)* *Level III RDI values reported (mean±SD or median or range/sleep study type)* *Adverse events* *Complications*	<u>Simultaneous in lab Level I and Level III study</u> *Diagnostic accuracy:* Cut-point used: **RDI ≥ 5** · Sensitivity: 98.0% (95% CI: not reported) · Specificity: 40.0% (95% CI: not reported) · PPV: 89.1% (95% CI: not reported) · NPV: 80.0% (95% CI: not reported) · LR+: not reported · LR-: not reported · Area under the ROC curve: 0.945 Cut-point used: **RDI ≥ 10** · Sensitivity: 87.8% (95% CI: not reported) · Specificity: 73.7% (95% CI: not reported) · PPV: 87.8% (95% CI: not reported) · NPV: 73.7% (95% CI: not reported) · LR+: not reported · LR-: not reported · Area under the ROC curve: 0.908	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Family Physician Blinding: Study interpreter <u>Simultaneous level I and level III study</u> N=60 Withdrawal/dropout: n=0 *Inclusion criteria:* Suspected OSAS Consecutive patient referrals *Exclusion criteria:* Not reported	(developer of SNAP) Device name: SNAP (SNAP Laboratoriesm International LLC, Wheeling, IL, USA) *Interval between study arms*: Simultaneous Level I index used: RDI (TST) Level III index used: RDI (TST) Cut point used indicating diagnosis and/or treatment : RDI ≥ 15		Cut-point used: **RDI ≥ 15** · Sensitivity: 83.9% (95% CI: not reported) · Specificity: 75.9% (95% CI: not reported) · PPV: 78.8% (95% CI: not reported) · NPV: 81.5% (95% CI: not reported) · LR+: not reported · LR-: not reported · Area under the ROC curve: 0.872 *Diagnoses made* Not Reported *RDI values (mean±SD)* Level I: 27.3/hr (±29.7/hr) Level III: 26.3/hr (±27.6/hr) *Diagnostic agreement* · Correlation (Level I & III RDI/RDI): 0.92 · Bland and Altman Values: Not Reported *Adverse events:* None *Complications:*	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					Level I in-lab technical error n=3 Level III in-lab technical error n=1	
Sullivan GE.[128] 2009 Canada Abstract Funding: Government (Atlantic Health Sciences research Fund) Private (Medigas, Praxair Canada Inc, Canada)	General Hospital No. of sites: 1 Cohort Prospective Patient selection: Not Reported Simultaneous Level I and Level III study	No. of patients enrolled in study: N=34 Suspected diagnosis: Not Reported Gender: Male: Not Reported Female: Not Reported Age: Not Reported Comorbidities: Not Reported Body Mass Index: Not Reported Neck circumference: Not Reported SDB pre-test probability Epworth Sleepiness Scale: Not Reported Berlin Risk (Low:High)%: Not Reported Source of referrals: Not Reported	*Level I* Location of study: Sleep Laboratory Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Not Reported Study interpreters: Not Reported Device name: Harmonie (Stellate, Canada) *Level III* Location of study: Sleep Laboratory Total No. of channels: 4+ Study operators: Not Reported Scoring methods: Manual Study interpreters: Sleep Technician Device name: Stardust	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed / conditions)* *Diagnostic agreement* *Level I RDI values reported (mean±SD or median or range/sleep study type)* *Level III RDI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy* Cut-point used: **AHI < 5** · Sensitivity: 70% · Specificity: 100% · PPV: Not Reported · NPV: Not Reported · LR+: Infinity · LR-: 0.3 · Area under the ROC curve: Not Reported Cut-point used: **AHI >5-15** · Sensitivity: 86% · Specificity: 82% · PPV: Not Reported · NPV: Not Reported · LR+: 4.78 · LR-: 0.17 · Area under the ROC curve: Not Reported Cut-point used: **AHI >15-30** · Sensitivity: 57% · Specificity: 88% · PPV: Not Reported · NPV: Not Reported · LR+: 4.75	Oxford: 3b QUADAS: *Internal Validity* **Yes:** 4,5,6,14 **No:** None **Unclear:** 3,7,10,11,12 *External Validity* **Yes:** none **No:** 2 **Unclear:** 1 *Reporting* **Yes:** 13 **No:**

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Withdrawal/dropout: Not Reported Reason for withdraw/dropout: Not Reported Blinding: Not Reported *Inclusion criteria:* Not Reported *Exclusion criteria:* Not Reported	(Respironics Inc, USA) Level I index used: RDI (TST) Level III index used: RDI (TIB) Cut point used indicating diagnosis and/or treatment: RDI >5/hr		· LR-: 0.49 · Area under the ROC curve: Not Reported Cut-point used: **AHI >30** · Sensitivity: 75% · Specificity: 97% · PPV: Not Reported · NPV: Not Reported · LR+: 25 · LR-: 0.26 · Area under the ROC curve: Not Reported *Diagnoses made* Level I: Not Reported Level III: Not reported *Level I RDI values* Level I: Not reported Level III: Not reported *Diagnostic agreement:* · Correlation (Level I & Level III RDI): Not Reported · Bland and Altman Values: (Level I vs Level III RDIs) -1.38/hr (95% CI -18.9, +16.1) Obstructive Apneas 4.64/hr	8,9 **Unclear:** none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					(95% CI -11.73, +21) Central Apneas 0.83/hr (95% CI -6.5, +8.14) Mixed Apneas -0.12/hr (95% CI -9.4, +9.1) Hypopneas -6.92/hr (95% CI -28.1, +14.27) *Adverse events:* Not Reported *Complications:* Not Reported	
To KW.[123] 2008 Hong Kong , China Full study Funding sources: academic + non-government	Academic teaching hospital No. of sites: 1 Cohort Study Prospective Study Recruitment: Not Reported Simultaneous level I and level III study	No. of patients enrolled in study: N=175 (N= 141 valid recordings) Suspected diagnosis: OSAS: n= 175 Gender: Male: 132 Female: 43 Age: Mean: male: 47.8 years, female: 52.3 years SD: male: 9.8, female: 12.2 Comorbidities: Hypertension: n=85 Diabetes: n=27	*Level I* Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: Not Reported Scoring methods: manual Study interpreters: technician Device name: Siesta (Compumedics, Australia) *Level III* Location of study: Sleep Laboratory	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy:* Cut-point used: Level I **AHI ≥ 5** & Level III desaturation level ≥ 4% · Sensitivity: 84% (95% CI: 77%, 90%) · Specificity: 100% · PPV: 100% · NPV: 27% · LR+: ∞ · LR-: 0.16 · Area under the ROC curve: 0.96 (95% CI: 0.93, 0.99) · False positive rate: 0 · False negative rate: 73% Cut-point used: Level I	Oxford : 1c QUADAS: *Internal Validity* Yes: 3, 4, 5, 6, 7, 10, 11, 12, 14 No: none Unclear: none *Externa*

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Hyperlipidaemia: n=25 Fatty liver: n=18 Cerebrovascular accident: n=11 Body Mass Index: Mean: male: 28.5 kg/m² female: 29.2 kg/m² SD: male: 4.9, female: 6.0 Neck circumference (cm): Not Reported SDB pre-test probability: Epworth Sleepiness Scale Mean: male: 9.8, female: 12.2 SD: male: 5.3, female: 5.0 Source of referrals: Specialist Blinding: Study Interpreter Withdrawal/dropout: n= 8 (from Level I arm alone) n= 21 (from Level III arm alone) n= 5 (from both level I and Level III arms) Reason for withdraw/dropout: Poor signal output from level III device (most common cause), very short total sleeping time, equipment malfunction *Inclusion criteria:* Significant sleepiness interfering with	Total No. of channels: 4+ Study operators: Not Reported Scoring methods: Automated Study interpreters: Service provider (ARES insight software) Device name: ARES Unicorder (Advanced Brain Monitoring, Inc., Carlsbad, CA, USA) Level I index used: AHI (Not Reported) Level III index used: AHI (Not Reported) Cut point used indicating diagnosis and/or treatment: AHI >5/hr		**AHI ≥ 5** & Level III desaturation level ≥ 3% · Sensitivity: 89% (95% CI: 84%, 94%) · Specificity: 100% · PPV: 100% · NPV: 35% · LR+: ∞ · LR-: 0.11 · Area under the ROC curve: 0.97 (95% CI: 0.95, 1.00) · False positive rate: 0 · False negative rate: 65.2% Cut-point used: Level I **AHI ≥ 5** & Level III desaturation level ≥ 1% · Sensitivity: 97% (95% CI: 94%, 99%) · Specificity: 63% (95% CI: 55%, 71%) · PPV: 98% · NPV: 56% · LR+: 2.61 · LR-: 0.05 · Area under the ROC curve: 0.98 (95% CI: 0.95, 1.00) *Diagnoses made:* Level III: moderate OSAS 141/141 patients	*l* *Validity* Yes: 1&2 No: none Unclear: none *Reporting* Yes: 13 No: none Unclear: 8 & 9

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		daily activities 2 of the following symptoms: Choking or grasping during sleep, recurrent awakenings, unrefreshed by sleep, daytime fatigue and impaired concentration *Exclusion criteria:* Pregnant Patients who declined to participate or could not comply with the set-up of the device			*AHI values (mean±SD):* Level I: male: 41.6±26.9, female: 32.2±22.9 Pooled : 39.3/hr (not reported) Level III: Not Reported Level III AHI < Level I AHI *Diagnostic agreement:* · Correlation (Level I & III AHIs): k coefficient=0.24 ($p<0.01$, oxygen desaturation level ≥4%); k coefficient = 0.3 ($p<0.01$, oxygen desaturation level ≥3%); k coefficient=0.55 ($p<0.01$, oxygen desaturation level ≥1%) (Level I AHI cut point not reported) · Bland and Altman: +7.5/hr (95% CI -9.6, 24.6) *Adverse events:* Not Reported *Complications:* Level I: Technical failures n= 13 Level III: Recording time < 4hrs n= 21 Technical failures n= 5	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
Yagi H.[124] 2009 Japan Full Study Funding: Not Reported	General hospital No. of sites: 1 Cohort Study Prospective Consecutive Simultaneous level I and level III study	No. of patients enrolled in study: N=22 Suspected diagnosis: Sleep Apnea Syndrome: n= 22 Gender: Male: 17 Female: 5 Age: Mean: 52.9 years SD: ±13.3 Range: 31-74 years Comorbidities: Not Reported Body Mass Index: Mean: 25.7 kg/m² SD: ±4.4 Range: 18.8-39.3 Neck circumference: Not Reported SDB pre-test probability: Epworth Sleepiness Scale Not Reported Berlin Risk (Low:High)% Not Reported Source of referrals: Not Reported	*Level I* Location of study: Inpatient Unit Total No. of channels: 10+ Study operators: Not Reported Scoring methods: Manual Study interpreters: Trained Polysomnographer Device name: Alice 4 device (Respironics Inc, Murrysville, PA, USA) *Level III* Location of study: Inpatient Unit Total No. of channels: 4+ Study operators: Not Reported Scoring methods: Manual Study interpreters: Trained Polysomnographer Device name: Apnomonitor 5 (Chest Co., Tokyo) Level I index used: AHI	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *Level I & III AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy* Cut-point used: **AHI ≥ 15** · Sensitivity: 95% · Specificity: Not Reported · PPV: 95% · NPV: Not Reported · LR+: Not Reported · LR-: Not Reported · Area under the ROC curve: Not Reported *Diagnoses made:* Not Reported *Level I & III AHI values (mean±SD):* Level I: AHI: 43.9/hr ±21.2 AI: 26.4/hr ±23.0 HI: 15.5/hr ±11.1 Level III: AHI: 46.0/hr ±20.4 AI: 23.7/hr ±22.1 HI: 22.2/hr ±11.5 *Diagnostic agreement:* · Correlation (Level I & III AHIs): pearson correlation r=0.96 · Bland and Altman Values: Not Reported *Adverse events:* Not Reported	Oxford : 1b QUADAS: *Internal Validity* **Yes:** 3,4,5,6, 7,10,11, 12 **No:** None **Unclear:** 14 *External Validity* **Yes:** 1 **No:** 2 **Unclear:** none *Reporting* **Yes:** 13 **No:** none **Unclear:** 8,9

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Withdrawal/dropout: Not Reported Reason for withdraw/dropout: Not Reported Blinding: Sleep study interpreter *Inclusion criteria:* Suspected Sleep Apnea Syndrome *Exclusion criteria:* Not Reported	Level III index used: "AHI" Cut point used indicating diagnosis and/or treatment: AHI ≥5		*Complications:* Not Reported	
Studies of separate Level I and Level III study only						
Alonso Alvarez M.[132] 2008 Spain Full study Funding sources: Not Reported	Academic teaching hospital No. of sites: 1 Cohort study Prospective Random Sampling Level III followed by Level I study	No. of patients enrolled in study: N=45 Suspected diagnosis: Sleep Apnea Hypopnea Syndrome: n= 45 Gender: Male: 39 Female: 6 Age: Mean: 52.3 yrs SD: ±11 yrs Range: Not Reported Comorbidities: Hypertension n=8	*Level I* Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: Not Reported Scoring methods: Manual Study interpreters: Not Reported Device name: Somnotrac 4250 (SensorMedics Corp, USA) *Level III* Location of study: Home	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed / conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *RDI values reported (mean±SD or median or range/sleep study type)*	*Diagnostic accuracy* Cut-point used: **AHI ≥10** · Sensitivity: 61.9% (95% CI 38, 85%) · Specificity: 95.8% (95% CI 85, 100%) · PPV: 92.9% (95% CI 75, 100%) · NPV: 74.2% (95% CI 57, 91%) · LR+: 14.78 · LR-: 0.40 · Area under the ROC curve: 87.5% (95% CI 74, 95%)	Oxford: 1b QUADAS: *Internal Validity* **Yes**: 3, 4, 5 6, 7, 10, 11, 12, 14 **No**: none **Unclear**: none *External Validity* **Yes**: 1, 2 **No**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Heart rhythm abnormalities n=5 Heart disease n=3 Cardiovascular accident n=1 Chronic obstructive pulmonary disorder n=1 Asthma n=1 Body Mass Index: Mean: 28.7kg/m² SD: ±4 kg/m² Neck circumference (cm): Mean: 40.2cm SD: ±2cm SDB pre-test probability: Epworth Sleepiness Scale Mean: 8.9 SD: ±3 Range: 0-19 Berlin Risk (Low:High): Not Reported Source of referrals: Respiratory Sleep Disorders Clinician Withdrawal/dropout: n= 0 Reason for withdraw/dropout: Not Applicable Blinding: Study Interpreter	Total No. of channels: 4+ Study operators: Trained sleep laboratory nurse Scoring methods: Automated and manual Study interpreters: Not Reported Device name: Edentrace II Model 3711 (Edentec Corp, USA) Interval between studies: < 2 weeks Level I index used: AHI (TST) Level III index used: RDI (Total study time) Cut point used indicating diagnosis and/or treatment: AHI ≥ 10	*Diagnostic agreement* *Adverse events* *Complications*	*Diagnoses made* Level I: OSA n=21 Level III: Not Reported *AHI values(mean±SD)* Level I Mean: 15.1/hr SD: ±18/hr *RDI values(mean±SD)* Level III Mean: 13.6/hr SD: ±11/hr *Diagnostic agreement:* · Correlation (Level I & III AHIs): 0.727 p < .001 · Bland and Altman Values: Not Reported *Adverse events* Not Reported *Complications:* Not Reported	**Unclear**: none *Reporting* **Yes**: 8, 9, 13 **No**: none **Unclear**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Inclusion criteria: Suspected sleep apnea hypopnea syndrome Residents of Burgos (Spain) metropolitan area Patient's home suitable for home sleep study *Exclusion criteria:* Severe concomitant illness Symptoms of sleep disorders other than SAHS Occupation in which SAHS would increase occupational risk Sleep related symptoms requiring urgent treatment				
Churchward TJ.[131] 2006 Australia Abstract Funding sources: Not Reported	General hospital No. of sites: 1 Cohort study Consecutive Prospective Random allocation to level I and level III study (2 level III home studies, 2 level I studies)	No. of patients enrolled in study: N=20 Suspected diagnosis: OSA: n=20 Gender: Male: 16 Female: 4 Age: Mean: 50 years SD: 13 Comorbidities: Not Reported Body Mass Index:	*Level I* Location of study: Sleep Laboratory Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Not Reported Study interpreters: Not Reported Device name:	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed / conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events*	*Diagnostic accuracy* Cut-point used: **AHI ≥ 10** · Sensitivity: 100% · Specificity: 100% · PPV: 100% · NPV: 100% · LR+: ∞ · LR-: 0 · Area under the ROC curve: Not Reported *Diagnoses made:* Not Reported *AHI values(mean±SD)* AHI values (mean±SD):	Oxford: 1C QUADAS: *Internal Validity* Yes: 5, 6, 7, 12 No: none Unclear: 3,4, 10, 11, 14 *External Validity* Yes: 1 No: 2

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Mean: 34 kg/m² SD: 8.3 Neck circumference (cm): Not Reported SDB pre-test probability: Not Reported Source of referrals: "sleep lab" Blinding: Study Interpreter Withdrawal/dropout: n= Not Reported (from both studies) Note: 20% of 40 home studies were technical failures. *Inclusion criteria:* Possible OSA *Exclusion criteria:* Not Reported	Not Reported *Level III* Location of study: Home Total No. of channels: Not Reported (using the same channels as in-lab device apart from EMG, and only 1 EEG and 1 EOG channel used) Study operators: Not Reported Scoring methods: Not Reported Study interpreters: Not Reported Device name: Somte (Compumedics, Abbotsford, Victoria) *Interval between studies*: Not Reported Level I index used: AHI (Not Reported) Level III index used: AHI (Not Reported) Cut point used indicating diagnosis/treatment:	*Complications*	Level I: 1st test: 30.3±20.3; 2nd test: 31.8 ±not reported (1st test AHI- 2nd test AHI: mean difference=-1.5, SD: 10.1, not statistically significant) Level III: 1st test 30.5±20.9; 2nd test: 30.3 ±not reported (1st test AHI- 2nd test AHI: mean difference=0.2, SD: 14.8, not statistically significant) *Diagnostic agreement*: · Correlation (Level I & III AHIs): Not Reported · Bland and Altman Values: Not Reported *Adverse events:* Not Reported *Complications:* Level III: Technical failures n=8 Note: Clinical passway assessment: 5% home	Unclear: none *Reporting* Yes: 13 No: 8 & 9 Unclear: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
			AHI ≥10/hr		study based assessments needed level I study to confirm diagnosis; 2.5% false positive. 65% patients preferred home study.	
Cilli A.[134] 2006 Turkey Abstract Funding sources: Not Reported	Academic teaching hospital No. of sites: 1 Cohort study Prospective Patient Recruitment: Not Reported Random allocation to level I and level III studies: Not Reported	No. of patients enrolled in study: N=55 Suspected diagnosis: OSA: n=55 Gender: Male: 49 Female: 6 Age: Mean: 46 years Comorbidities: Not Reported Body Mass Index: Not Reported Neck circumference (cm): Not Reported SDB pre-test probability: Not Reported Source of referrals: Not Reported Blinding:	*Level I* Location of study: Not Reported Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Not Reported Study interpreters: Not Reported Device name: Embla *Level III* Location of study: Not Reported Total No. of channels: Not Reported Study operators: Not Reported	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy* Cut-point used: **AHI >5** · Sensitivity: 93% · Specificity: 44.4% · PPV: 89.5% · NPV: 57.1% · LR+: 1.67 · LR-: 0.16 · Area under the ROC curve: Not Reported *Diagnoses made:* Not Reported *AHI values:* Not Reported *Diagnostic agreement:* · Correlation (Level I & III AHIs): Not Reported · Bland and Altman Values: Not Reported *Adverse events:* Not Reported *Complications:* Not Reported	Oxford: "1b" QUADAS: *Internal Validity* Yes: 5, 6, 7, 12 No: 14 Unclear: 3, 4, 10, 11 *External Validity* Yes: 1 No: 2 Unclear: none *Reporting* Yes: none No: 8, 9 Unclear: 13

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Not Reported Withdrawal/dropout: Not Reported *Inclusion criteria:* Not Reported *Exclusion criteria:* Not Reported	Scoring methods: Not Reported Study interpreters: Not Reported Device name: Embletta Interval between studies: Not Reported Level I index used: "AHI" (Not reported) Level III index used: "AHI" (Not reported) Cut point used indicating diagnosis/treatment: AHI > 5/hr			
Finkel KJ.[130] 2009 USA Full study Funding sources: Not Reported	Academic teaching hospital No. of sites: 1 Cohort study Prospective Consecutive Level III study followed by Level I study.	No. of patients enrolled in study: N=26 Suspected diagnosis: OSA: n= 26 (high risk) Gender: Male: Not Reported Female: Not Reported Age: Mean: Not Reported SD: Not Reported Range: Not Reported Comorbidities:	*Level I* Location of study: Sleep Lab Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Not Reported Study interpreters: Not Reported Device name: Not Reported *Level III*	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *RDI or REI values reported (mean±SD or*	*Diagnostic accuracy* Cut-point used: **AHI >5** · Sensitivity: 95% (73.1-99.7%) · Specificity: 33.3% (6.0-75.9%) · PPV: 82.6% · NPV: 66.7% · LR+: 1.42 · LR-: 0.15 · Area under the ROC curve: Not Reported *Diagnoses made* Level I: OSA n=19	Oxford: 1b QUADAS: *Internal Validity* **Yes**: 3, 6, 7, 12, 14 **No**: 4, 5 **Unclear**: 10,11 *External Validity* **Yes**: 2

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Not Reported Body Mass Index: Mean: Not Reported SD: Not Reported Neck circumference (cm): Mean: Not Reported SD: Not Reported SDB pre-test probability: Epworth Sleepiness Scale Mean: Not Reported SD: Not Reported Berlin Risk (Low:High): Not Reported Source of referrals: Not Reported Blinding: Not Reported Withdrawal/dropout: n= 0 Reason for withdraw/dropout: Not Applicable *Inclusion criteria:* Pre-operative patients ≥ 18 years *Exclusion criteria:* Prior OSA diagnosis	Location of study: Home Total No. of channels: 3+ (No respiratory effort channel ??) Study operators: Patient Scoring methods: Not Reported Study interpreters: Not Reported Device name: ARES Unicorder Interval between studies: ≤ 1 year Level I index used: AHI Level III index used: Not Reported Cut point used indicating diagnosis and/or treatment: AHI ≥ 5 (mild to severe OSA)	*median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	Level III: OSA n=26 *AHI values (mean±SD)* Level I: Not Reported Level III: Not Reported *RDI (or REI) values* Not Reported *Diagnostic agreement:* · Correlation (Level I & III AHIs): Not Reported · Bland and Altman Values: Not Reported *Adverse events* Not Reported *Complications* Not Reported	**No**: 1 **Unclear**: *Reporting* **Yes**: 13 **No**: 9 **Unclear**: 8

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Required home oxygen Allergy to synthetic material Intolerance to sleep apnea detection device				
Fordyce L.[106] 2009 Canada Abstract Funding sources: Not Reported	Academic teaching hospital No. of sites: 1 Cohort study Retrospective Non-consecutive Separate level I and level III study Non random allocation to Level III followed by Level I study	No. of patients enrolled in study: N=9 Suspected diagnosis: SDB: 9 Gender: Male: 6 Female: 3 Age: Mean: 40.3 years SD: Not Reported Comorbidities: Not Reported Body Mass Index: Mean: 25.4 kg/m² SD: Not Reported Adjusted neck circumference (cm): Mean: 38.2 cm SD: Not Reported SDB pre-test probability: Not Reported Source of referrals: sleep physician Blinding: Not Reported	*Level I* Location of study: Not Reported Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Not Reported Study interpreters: Not Reported Device name: Not Reported *Level III* Location of study: Not Reported Total No. of channels: Not Reported Study operators: Not Reported Scoring methods:	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed / conditions)* *RDI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy:* Cut-point used: **AHI ≥5** · Sensitivity: 80% · Specificity: 100% · PPV: 100% · NPV: 80.0% · LR+: Infinity · LR-: 0.20 · Area under the ROC curve: Not Reported *Diagnoses made:* 2 severe OSA (level I RDI>30) 1 moderate OSA (15≤level I RDI≤30) 2 mild OSA (5<level I RDI<15) *Notes:* level III RDI of these 5 patients ≤ 15 *RDI values (mean±SD)* Level I: mean= 20.3/hr (±28.9) Level III: mean= 6.5/hr (±5.2) *Diagnostic agreement:* · Correlation (Level I &	Oxford: 2b QUADAS: *Internal Validity* Yes: 5, 7, 12, 14 No: none Unclear: 3, 4, 6, 10, 11 *External Validity* Yes: 1 & 2 No: none Unclear: none *Reporting* Yes: none No: 8 & 9 Unclear: 13

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Withdrawal/dropout: n= 0 Reason for withdrawal: Not Applicable *Inclusion criteria:* Patients received both level I and level III testing and had history of snoring *Exclusion criteria:* Body mass index ≥ 30 Adjusted neck circumference ≥ 42 Level III RDI ≥ 15 Epworth sleepiness scale < 10	Not Reported Study interpreters: Not Reported Device name: Not Reported Interval between studies: Not Reported Level I index used: RDI (Not Reported) Level III index used: RDI (Not Reported) Cut point used indicating diagnosis and/or treatment: AHI ≥ 5 (mild to severe OSA)		III RDIs): r=0.837 (p=0.005) · Bland and Altman Values: 13.54/hr ±24.7 (95% CI -34.87, 61.95) *Adverse events:* Not Reported *Complications:* Not Reported	
Gjevre J.[109] 2007 Canada Abstract Funding sources: "government" (Saskatchewan Health Research Foundation)	Academic teaching hospital No. of sites: 1 Cohort study Consecutive Prospective Non random allocation to Level I followed by Level III study	No. of patients enrolled in study: N= 71 (45 valid recordings) Suspected diagnosis: OSA: n=71 Gender: Male: 0 Female: 45 Age: Mean: 52.24 years SD:±10.84 Comorbidities:	*Level I* Location of study: Not Reported Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: manual Study interpreters: sleep physicians Device name:	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *RDI values reported (mean±SD or median or*	*Diagnostic accuracy* Cut-point used: **AHI >5** · Sensitivity: 85% · Specificity: 73% · PPV: 90.6% · NPV: 61.5% · LR+: 3.13 · LR-: 0.20 · Area under the ROC curve: Not Reported · Overall accuracy: 82.2% Cut-point used: **AHI >**	Oxford: 1b QUADAS: *Internal Validity* Yes: 5, 6, 7, 10, 11, 12 No: 14 Unclear: 3 & 4 *External Validity*

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Not Reported Body Mass Index: Mean: 35.25 kg/m² SD: ±9.46 Neck circumference (cm): Not Reported SDB pre-test probability: Epworth Sleepiness Scale Mean: 9.56 SD: ±4.42 Average total Pittburg score: Mean: 8.35 SD: ±3.76 Source of referrals: Not Reported Blinding: Not Reported Withdrawal/dropout: n= 26 Reason for withdraw/dropout: Not Reported *Inclusion criteria:* Female Suspected OSA	Not Reported *Level III* Location of study: home Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: automated Study interpreters: Computer scored Device name: Embletta *Interval between studies*: Not Reported Level I index used: AHI (Not Reported) Level III index used: RDI (Not Reported) Cut point used indicating diagnosis and/or treatment: AHI > 5	*range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	**30** · Sensitivity: Not Reported · Specificity: Not Reported · PPV: 50% · NPV: Not Reported · LR+: Not Reported · LR-: Not Reported · Area under the ROC curve: Not Reported *Diagnoses made:* Level I AHI > 5: 32 OSA 13 normal Level I AHI > 30: 8 severe OSA Level III RDI >5: 30 OSA 15 normal *AHI values (mean±SD, range):* Level I: 16.01±16.26 (0.50-80.90) *RDI values (mean±SD, range):* Level III: 17.69±14.77, 1.0-68.60 Paired t-test: mean difference between level	Yes: 2 No: 1 Unclear: none *Reporting* Yes: none No: 8, 9, 13 Unclear: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Exclusion criteria: Not Reported			III RDI and level I AHI=1.69, p=0.442, 95% CI: -6.07, 2.70 *Diagnostic agreement:* · Correlation (Level I & III AHIs): Pearson's correlation r= 0.561 (p<0.001) · Bland and Altman Values: Not Reported Paired T-test mean difference: 1.69/hr (95% CI -6.07, 2.70) *Adverse events:* Not Reported *Complications:* Not Reported	
Grover S.[133] 2009 USA Abstract Funding sources: Not Reported	General Hospital No. of sites: 1 Cohort study Prospective Patient selection: Not Reported Non random allocation to study	No. of patients enrolled in study: N=5 Suspected diagnosis: Sleep related breathing disorders: n= 5 Gender: Male: Not Reported Female: Not Reported Age: Mean: Not Reported SD: Not Reported Range: 29-59 yrs	*Level I* Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: Patient and sleep professional Scoring methods: Not Reported Study interpreters: Not Reported	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI values reported (mean±SD or median or range/sleep study type)*	*Diagnostic accuracy* Not Reported *Diagnoses made* Level I: Not Reported Level III: Not Reported *AHI values(mean±SD)* Level I Not Reported *RDI values(mean±SD)* Level III	Oxford: 2b QUADAS: *Internal Validity* **Yes**: 3, 5, 6, 7, 12, 14 **No**: none **Unclear**: 4, 10, 11 *External*

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
	arm, Level III study followed by Level I study.	Comorbidities: Not Reported Body Mass Index: Mean: Not Reported SD: Not Reported Neck circumference (cm): Mean: Not Reported SD: Not Reported SDB pre-test probability: Epworth Sleepiness Scale Not Reported Berlin Risk (Low:High): Not Reported Source of referrals: Not Reported Withdrawal/dropout: n= 0 Reason for withdraw/dropout: Not Applicable Blinding: Sleep study interpreter *Inclusion criteria:* Polysomnography naïve subjects	Device name: Polysomnograph (not specified) *Level III* Location of study: Home Total No. of channels: 4+ Study operators: Patient Scoring methods: Not Reported Study interpreters: Not Reported Device name: Alice PDx (Philips Respironics Inc, USA) Interval between studies: 1 night Level I index used: AHI Level III index used: RDI Cut point used indicating diagnosis and/or treatment: AHI: Not Reported	*RDI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	Not Reported *Diagnostic agreement:*· Correlation (Level I & III AHI): Pearsons r=0.842 (p=0.073) · Correlation (Level I & III RDI): Pearsons r=0.852 (p=0.067) · Bland and Altman Values: Not Reported *Adverse events* Not Reported *Complications* Level III application error n=1	*Validity* **Yes**: none **No**: 2 **Unclear**: 1 *Reporting* **Yes**: 8, 13 **No**: 9 **Unclear**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Exclusion criteria: Not Reported				
Hernandez L.[114] 2007 Spain Full study Funding sources: Government	General Hospital No. of sites: 2 Cohort study Prospective Consecutive Random allocation to Level I or Level III study	No. of patients enrolled in study: N=88 Suspected diagnosis: Sleep Apnea Hypopnea Syndrome: n= 88 (after assessment screening) Gender: Male: 71 Female: 17 Age: Mean: 50.3 years SD: ±11.6 Range: Not Reported Comorbidities: Not Reported Body Mass Index: Mean: 29.6 kg/m² SD: ±4.2 Neck circumference (cm): Mean: Not Reported SD: Not Reported SDB pre-test probability Epworth Sleepiness Scale: Not Reported Berlin Risk (Low:High): Not Reported	*Level I* Location of study: Sleep Lab Total No. of channels: 10+ Study operators: Sleep Technician Scoring methods: Manual Study interpreters: Sleep physician Device name: PSG (not specified) *Level III* Location of study: Hospital Unit Total No. of channels: 4+ Study operators: Nurse or technician Scoring methods: Manual Study interpreters: Respiratory physician Device name: Respiratory polygraph (not specified) Interval between studies: ≤ 1 month	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *RDI reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy* Cut-point used: **AHI ≥10** · Sensitivity: 83.3% · Specificity: 78.9% · PPV: 91.8% · NPV: 62.5% · LR+: 3.95 · LR-: 0.21 · Area under the ROC curve: Not Reported *Diagnoses made* Level I: Severe SAHS n=32 Level III: Severe SAHS n=30 *AHI values (median, 25 and 75 percentiles)* Level I: 21.5/hr (8, 57.5) *RDI values(median, 25 and 75 percentiles)* Level III: 15/hr (4.5, 48.5) *Diagnostic agreement:* · Correlation (Level I & III AHIs): Lin coefficient 0.826 (95% CI 0.759,	Oxford: 1b QUADAS: *Internal Validity* **Yes**: 3, 5, 6, 7, 10, 11, 12, 14 **No**: none **Unclear**: 4 *External Validity* **Yes**: 1 **No**: 2 **Unclear**: none *Reporting* **Yes**: 13 **No**: none **Unclear**: 8, 9

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Source of referrals: Sleep physician or respiratory physician with sleep training. Withdrawal/dropout: n= 0 Reason for withdraw/dropout: Not Applicable Blinding: Referring physician Sleep study interpreter *Inclusion criteria:* Suspected Sleep Apnea Hypopnea Syndrome *Exclusion criteria:* Not Reported	Level I index used: AHI Level III index used: RDI Cut point used indicating treatment: AHI ≥10		0.894) · Bland and Altman Values: 4.6/hr (95% CI -25.0, 34.31) *Adverse events:* Not Reported *Complications:* Not Reported	
Levendowski D.[111] 2009 USA Full Study Funding sources: Not Reported	Academic Teaching Hospital & General Hospital No. of sites: 3 Cohort study Prospective Patients Selection: Not Report	No. of patients enrolled in study: N=37 Suspected diagnosis: OSA n= 37 Gender: Male: Not Report Female: Not Report Age: Mean: Not Report SD: Not Report Range: Not Reported	<u>*Level I*</u> Location of study: Sleep Laboratory or hospital unit Total No. of channels: Not Reported Study operators: Not Reported Scoring methods: Manual Study interpreters: Registered PSG technician	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *Level I AHI values reported (mean±SD or median or range/sleep study type)*	*Diagnostic accuracy* Not Reported *Diagnoses made* Level I: Not Reported Level III: Not Reported *AHI values* Level I: Not Reported Level III: Not Reported *Diagnostic agreement:* · Correlation (Level I & III AHIs): Not Reported	Oxford: 2b QUADAS: *Internal Validity* **Yes**: 3, 4, 5, 6, 7, 10, 12 **No**: **Unclear**: 11, 14

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
	Non random allocation to study arm, Level III study followed by Level I study	Comorbidities: Not Reported Body Mass Index: Not Report Neck circumference (cm): Not Reported SDB pre-test probability Epworth Sleepiness Scale: Not Report Berlin Risk (Low:High): Not Reported Source of referrals: Not Reported Withdrawal/dropout: n= 0 Reason for withdraw/dropout: Not Applicable Blinding: Double-blinded (not specified) *Inclusion criteria:* Placebo subjects from a placebo control study assessing the efficacy of palatal implants *Exclusion criteria:*	Device name: Attended PSG (not specified) *Level III* Location of study: Home Total No. of channels: 4+ Study operators: Patient Scoring methods: Automated Study interpreters: Not Reported Device name: ARES Unicorder (Advanced Brain Monitoring, USA) Interval between studies (initial Level III and Level I): Mean: 59 days SD: ±34days Level I index used: AHI (TST) Level III index used: "AHI" (TIB) Cut point used indicating diagnosis/treatment: AHI >10	*Level III AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	· Bland and Altman Values (mean, ±SD): Initial test: Mean: +1.8/hr (bias for Level III) SD: ±11 Retest: Mean: +5.6/hr (bias for Level I) SD: ±27 *Adverse events:* Not Reported *Complications:* Not Reported	*External Validity* **Yes**: none **No**: 2 **Unclear**: 1 *Reporting* **Yes**: 8, 13 **No**: 9 **Unclear**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		AHI <10 or > 40 based on in-home baseline study BMI >32kg/m² Non retro-palatal airway obstruction Prior airway surgery other than nasal, adenoid or tonsil Presence of other sleep disorders				
Miyata S.[107] 2007 Japan Full Study Funding sources: Not Reported	Academic Teaching Hospital No. of sites: 1 Cohort study Prospective Consecutive Non random allocation to study arm, Level I study followed by Level III study.	No. of patients enrolled in study: N=18 Suspected diagnosis: OSAS n= 18 Gender: Male: 18 Female: 0 Age: Mean: 51.0 years SD: ± 10.8 Range: Not Reported Comorbidities: Not Reported Body Mass Index: Mean: 25.1kg/m² SD: ±3.7 Neck circumference (cm): Not Reported SDB pre-test probability Epworth Sleepiness Scale: Not Reported	<u>*Level I*</u> Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: Not Reported Scoring methods: Not Reported Study interpreters: Not Reported Device name: Alice 3 (Respironics, USA) <u>*Level III*</u> Location of study: Home Total No. of channels: 4+ Study operators: Patient (after training by sleep technician) Scoring methods: Not Reported Study interpreters: Not Reported	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *Level I & Level III AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy* Not Reported *Diagnoses made* Level I: Not Reported Level III: Not Reported *AHI values (mean, ±SD)* Level I: 33.0/hr (±25.7) Level III: 28.1/hr (±20.6) *Diagnostic agreement:* · Correlation (Level I & III AHIs): Pearson's r=0.94 (p <0.0001) · Bland and Altman Values (Level I vs III AHIs): +4.3/hr (-4.4 to 13.1/hr) *Adverse events:* Not Reported *Complications:*	Oxford: 1b QUADAS: *Internal Validity* **Yes**: 3, 4, 5, 6, 7, 12, 14 **No**: none **Unclear**: 10, 11 *External Validity* **Yes**: none **No**: 1, 2 **Unclear**: none *Reporting* **Yes**: none **No**: none **Unclear**: 8, 9, 13

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Berlin Risk (Low:High): Not Reported Source of referrals: Not Reported Withdrawal/dropout: n= 0 Reason for withdraw/dropout: Not Applicable Blinding: Not Reported *Inclusion criteria:* Suspected OSAS *Exclusion criteria:* Not Reported	Device name: LT200 (Fukudadenshi, Japan) Interval between studies: 1 week Level I index used: AHI Level III index used: "AHI" Cut point used indicating diagnosis/treatment: AHI ≥5		Not Reported	
Quintana-Gallego E.[122] 2004 Spain Full Study Funding sources: Government	Academic Teaching Hospital No. of sites: 1 Cohort study Prospective Consecutive Random allocation to study	No. of patients enrolled in study: N=90 (Data reported only on the n=75 who completed the study) Suspected diagnosis: Sleep Disordered Breathing n= 75 Gender: Male: 65 Female: 10 Age: Mean: 56.1 years	<u>*Level I*</u> Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: Not Reported Scoring methods: Manual Study interpreters: Experienced Neurophysiologist	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI values reported (mean±SD or median or range/sleep study type)*	*Diagnostic accuracy* Cut-point used: **AHI ≥5** · Sensitivity: 82.5% (95% CI 70.7, 94.2) · Specificity: 88.6% (95% CI 74.1, 97.3) · PPV: 89% · NPV: 82% · LR+: 7.24 · LR-: 0.20 · Area under the ROC curve: 0.896 (95%CI 0.815, 0.977)	Oxford: 1b QUADAS: *Internal Validity* **Yes**: 3, 4, 5, 6, 7, 10, 11, 12, 14 **No**: none **Unclear**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
	arm, Level I/III followed by Level I/III	SD: ± 11.7 Range: Not Reported Comorbidities: (CHF) Stable heart failure due to systolic dysfunction (LVEF ≤ 45%) Ischaemic: 42.3% Idiopathic: 39.4% Other: 18.3% Body Mass Index: Mean: 28.6kg/m² SD: ±4.4 Neck circumference (cm): Not Reported SDB pre-test probability Epworth Sleepiness Scale: Not Reported Berlin Risk (Low:High): Not Reported Source of referrals: Cardiologist Withdrawal/dropout: n= 15 Reason for withdraw/dropout: Death n=1 Cardiac Transplant n=2	Device name: Somnostar 4100 (SensorMedics, USA) <u>*Level III*</u> Location of study: Home Total No. of channels: 4+ Study operators: Patient assisted by "experienced technician" in the home Scoring methods: Manual Study interpreters: Experienced pneumologist Device name: Apneoscreen II (Erich Jaeger Gmbh & Cokg, Germany) Interval between studies: Mean: 13.8 days SD: ±8.9days Level I index used: AHI Level III index used: RDI (per hour of recording) Cut point used indicating diagnosis/treatment: AHI ≥ 5	*RDI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	Cut-point used: **AHI ≥10** · Sensitivity: 79.3% (95% CI 64.5, 94) · Specificity: 97.8% (95% CI 93.7, 100) · PPV: 96% · NPV: 88% · LR+: 36.04 · LR-: 0.21 · Area under the ROC curve: 0.907 (95%CI 0.817, 0.998) Cut-point used: **AHI ≥15** · Sensitivity: 68.4% (95% CI 47.5, 89) · Specificity: 94.6% (95% CI 86.1, 99) · PPV: 81% · NPV: 90% · LR+: 12.67 · LR-: 0.33 · Area under the ROC curve: 0.862 (95%CI 0.730, 0.994) *Diagnoses made* Level I: AHI ≥5: n=40 AHI ≥10: n= 29 (OSA n=5; CSA-CSR	*External Validity* **Yes**: 2 **No**: 1 **Unclear**: none *Reporting* **Yes**: 8, 9, 13 **No**: none **Unclear**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Withdrew consent n=3 Decompensated heart failure n=9 Blinding: Sleep Study Interpreters *Inclusion criteria:* No change in signs or symptoms of congestive heart failure for 4 weeks prior to the study LVEF ≤ 45% No change in drug treatment doses for 4 weeks prior to the study *Exclusion criteria:* Instability of heart failure during the study Acute myocardial infarction in the previous 3 months Unstable angina Congenital heart disease Arterial oxygen tension < 8kPa (60mmHg)			n=24) AHI ≥15: n= 19 Level III: AHI ≥5: n=33 AHI ≥10: n= 23 (Sensitivity and specificity 100% in detecting an obstructive or central pattern of SDB) AHI ≥15: n= 13 *AHI/RDI value (mean, ±SD)* Level I: 11.6/hr (±14) Level III: 10.5/hr (±8.7) *Diagnostic agreement:* · Correlation (Level I AHI & III RDI): Not Reported · Bland and Altman Values (Level I AHI vs III RDIs): 1.58/hr (-0.57 to 3.73/hr) *Adverse events:* Not Reported *Complications:* Level III: Failure of bands n=4	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					TRT <3hrs n=2 Disconnected thermistor n=1	
Shrivastava D.[136] 2006 USA Abstract Funding sources: Not Reported	Academic teaching hospital No. of sites: 1 Cohort study Prospective Patients Selection: Not Report Non random allocation to study arm, Level III sleep study followed by Level I study	No. of patients enrolled in study: N= 99 Suspected diagnosis: Sleep Disordered Breathing: n= 99 Gender: Male: Not Report Female: Not Report Age: Mean: Not Report SD: Not Report Range: Not Reported Comorbidities: Not Report Body Mass Index: Mean: Not Report SD: Not Report Neck circumference (cm): Mean: Not Report SD: Not Report SDB pre-test probability: Epworth Sleepiness Scale Not Report Berlin Risk (Low:High): Low risk (n=99)	*Level I* Location of study: Sleep Laboratory Total No. of channels: Not Report Study operators: Not Reported Scoring methods: Not Report Study interpreters: Not Reported Device name: PSG (not specified) *Level III* Location of study: Home Total No. of channels: Not Report Study operators: Not Report Scoring methods: Not Report Study interpreters: Not Reported Device name: Edentrace Plus II (Edentec Corp, USA) Interval between studies: Not Report	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed / conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *RDI/REI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy* Cut-point used: **>5 AHI** · Sensitivity: 86.4% (95% CI Not Report) · Specificity: 80.8% (95% CI Not Report) · PPV: 95% · NPV: 59% · LR+: 4.50 · LR-: 0.17 · Area under the ROC curve: Not Report *Diagnoses made* Level I: SDB n=80 Level III: SDB n=99 *AHI /RDI values(mean±SD)* Level I: Not Reported Level III: Not Reported *Diagnostic agreement:* · Correlation (Level I & III AHIs): Not Reported · Bland and Altman Values: Not Reported	Oxford: 3b QUADAS: *Internal Validity* **Yes**: 5, 7, 10, 14 **No**: 6, 11 **Unclear**: 3, 4, 12 *External Validity* **Yes**: 1 **No**: none **Unclear**: 2 *Reporting* **Yes**: 13 **No**: 8, 9 **Unclear**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Source of referrals: Not Report Withdrawal/dropout: n= 0 Reason for withdraw/dropout: Not Applicable Blinding: Not Report *Inclusion criteria:* Community based primary care clinic population *Exclusion criteria:* Not Report	Level I index used: Not Report Level III index used: Not Report Cut point used indicating diagnosis and/or treatment: AHI >5/hr		*Adverse events:* Not Reported *Complications:* Not Reported	
Skomro R.[135] (supplemental data from ref #13669) 2005 Canada Abstract Funding sources: Regional and provinicial government (Saskatchewan,	Academic Teaching Hospital No. of sites: 1 Cohort study Prospective Consecutive Non random allocation to study arm, Level III study followed by Level I	No. of patients enrolled in study: N=33 Suspected diagnosis: OSA n= 33 Gender: Male: 27 Female: 6 Age: Mean: 48.3 years SD: ± 13.1 Range: Not Reported Comorbidities: Not Reported	<u>*Level I*</u> Location of study: Sleep Laboratory Total No. of channels: 10+ Study operators: Sleep laboratroy technologist Scoring methods: Manual Study interpreters: Not Reported Device name: Sandman PSG (Puritan Bennet, USA) <u>*Level III*</u>	Outcomes of diagnostic test: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *AHI values reported (mean±SD or median or range/sleep study type)* *RDI values reported (mean±SD or median or range/sleep study type)*	*Diagnostic accuracy* Cut-point used: **AHI >5** · Sensitivity: 92% · Specificity: 67% · PPV: 88% · NPV: 75% · LR+: 2.79 · LR-: 0.12 · Area under the ROC curve: Not Reported *Diagnoses made* Level I: Not Reported Level III: Not Reported *AHI values (mean, ±SD)* Level I: 29.4/hr (±28.4)	Oxford: 1b QUADAS: *Internal Validity* **Yes**: 6, 7, 12, 13, 14 **No**: 5 **Unclear**: 3, 4, 10, 11 *External Validity* **Yes**: 1, 2 **No**: none

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
Canada) Non-government (Lung Association of Saskatchewan		Body Mass Index: Not Report Neck circumference (cm): Not Reported SDB pre-test probability Epworth Sleepiness Scale: Mean: 11.7 SD: ±4.2 Berlin Risk (Low:High): Not Reported Source of referrals: Not Reported Withdrawal/dropout: n= 0 Reason for withdraw/dropout: Not Applicable Blinding: Investigators *Inclusion criteria:* Referred to tertiary Sleep Disorders Centre for suspected OSA Age >18 years *Exclusion criteria:* Respiratory/cardiac failure Presence of other sleep disorders	Location of study: Home Total No. of channels: 4+ Study operators: Patient Scoring methods: Manual Study interpreters: Sleep Medicine Physician Device name: Embletta (Medcare Inc, USA) Interval between studies: Not Reported Level I index used: AHI Level III index used: RDI Cut point used indicating diagnosis/treatment: AHI >5 or RDI >5	*Diagnostic agreement* *Adverse events* *Complications*	*RDI values(mean, ±SD)* Level III: 28.9/hr (±23.9) *Diagnostic agreement:* · Correlation (Level I & III AHIs): R^2=0.79 · Bland and Altman Values: Not Reported *Adverse events:* Not Reported *Complications:* Level III: Failure requiring repeat study n=13	**Unclear**: none *Reporting* **Yes**: 13 **No**: 9 **Unclear**: 8

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Safety-sensitive occupation Use of hypnotics Upper airway surgery CPAP or oxygen therapy Pregnancy Inability to provide informed consent				
Yin M.[139] 2006 Japan Full study Funding sources: Not Reported	Academic Teaching Hospital No. of sites: 1 Cohort study Prospective Consecutive Non random allocation to study arm, Level III study followed by Level I	No. of patients enrolled in study: N= 90 Suspected diagnosis: OSA : n= 44 (with good Level III data) Gender: Male: 40 Female: 4 Age: Mean: 52.3 years SD: ± 13.5 Range: Not Reported Comorbidities: Not Reported Body Mass Index: Mean: 26.7 kg/m² SD: ±5.3 Neck circumference (cm): Mean: Not Reported SD: Not Reported SDB pre-test probability Epworth Sleepiness Scale: Not Reported	*Level I* Location of study: Not Reported Total No. of channels: 10+ Study operators: Not Reported Scoring methods: Manual Study interpreters: "experienced doctors" Device name: Rembrandt (Medcare Inc, Iceland) *Level III* Location of study: Home Total No. of channels: 4+ Study operators: Patient Scoring methods: Automated Study interpreters: Not Reported Device name: Stardust II (Respironics Inc, USA)	Outcomes of diagnostic tests: *Diagnostic accuracy* *Diagnoses made (Sleep study type/No. of patients diagnosed /conditions)* *Level I & Level III AHI values reported (mean±SD or median or range/sleep study type)* *Diagnostic agreement* *Adverse events* *Complications*	*Diagnostic accuracy* Cut-point used: **AHI ≥5** · Sensitivity: 100% · Specificity: Not Reported · PPV: 93.2% · NPV: Not Reported · LR+: 1.0 · LR-: Not Reported · Area under the ROC curve: Not Reported Cut-point used: **AHI ≥15** · Sensitivity: 93.8% · Specificity: 25.0% · PPV: 76.9% · NPV: 60.0% · LR+: 1.251 · LR-: 0.228 · Area under the ROC curve: Not Reported Cut-point used: **AHI ≥30** · Sensitivity: 79.2% · Specificity: 70.0% · PPV: 76.0%	Oxford: 1c QUADAS: *Internal Validity* **Yes**: 3, 5, 6, 7, 12, 14 **No**: none **Unclear**: 4, 10, 11 *External Validity* **Yes**: 1 **No**: 2 **Unclear**: none *Reporting* **Yes**: 13 **No**: none **Unclear**: 8, 9

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
		Berlin Risk (Low:High): Not Reported Source of referrals: Not Reported Withdrawal/dropout: n= 46 Reason for withdraw/dropout: Poor Level III data Blinding: Not Reported *Inclusion criteria:* Suspected OSA *Exclusion criteria:* Not Reported	Interval between studies (mean, SD, Range): 60.8 days ±27.7 (2-93) Level I index used: AHI (TST) Level III index used: AHI (TIB) Cut point used indicating diagnosis/treatment: AHI > 5/hr		· NPV: 73.7% · LR+: 2.64 · LR-: 0.297 · Area under the ROC curve: Not Reported Cut-point used: **AHI ≥50** · Sensitivity: 90.0% · Specificity: 97.1% · PPV: 90.0% · NPV: 97.1% · LR+: 31.034 · LR-: 0.103 · Area under the ROC curve: Not Reported *Diagnoses made* Level I: Not Reported Level III: Not Reported *AHI values (Mean, ±SD)* Level I: 33.6/hr (±24.9) Level III: 36.9/hr (±20.5) ($p<0.05$) *Diagnostic agreement:* · Correlation (Level I & III AHIs): r = 0.845 ($p<0.001$) 6· Bland and Altman (Level III – Level I AHI):	

Table 16. Studies comparing Level I with Level III sleep studies for sleep disordered breathing						
Primary author, year country, funding source	**Setting and study design**	**Patient population**	**Diagnosis**	**Outcome measures**	**Findings**	**Study quality**
					3.7/hr ±13.1 (95% CI -22.5, 29.9) *Adverse events*: Not Reported *Complications:* Not Reported	

Notes: AHI (apnea-hypopnea index), BMI (body mass index); 95% CI (95% confidence interval); HRQL (health related quality of life); IQR (interquartile range); LR+ (positive likelihood ratio); LR- (negative likelihood ratio); N/A (not available); No. (number); NPV (negative predictive value); NR (not reported); OSA (obstructive sleep apnea); OSAS (obstructive sleep apnea syndrome); PPV (positive predictive value); QUADAS (quality assessment of diagnostic accuracy studies); RCT (randomized controlled trial); RDI (respiratory disturbance index); REI (respiratory effort index); ROB (risk of bias); ROC (receiver-operating characteristic); SDB (sleep disordered breathing); TIB (time in bed); TRT (total recording time); TST (total sleep time).

Table 17. Diagnostic accuracy: SDB conditions other than OSA

Table 17. Diagnostic accuracy: SDB conditions other than OSA									
Simultaneous + Separate									
Primary author, reference, Year Country	**Diagnostic Accuracy Measure**	**Level I Sleep Study Apnea-Hypopnea Index Cutoff**							
		≤5/hr	**≥5/hr**	**≥10/hr**	**≥15/hr**	**≥20/hr**	**≥25/hr**	**≥30/hr**	**≥50/hr**
Smith LA.[119]	**Sensitivity**	-	-	-	-	-	-	-	-
2007	**Specificity**	-	-	-	-	-	-	-	-
UK	**PPV**	-	-	-	-	-	-	-	-
	NPV	-	-	-	-	-	-	-	-
IN LAB	**+ LR**	-	-	-	-	-	-	-	-
	- LR	-	-	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Smith LA.[119]	**Sensitivity**	-	-	-	58.3%	-	-	-	-
2007	**Specificity**	-	-	-	62.5%	-	-	-	-
UK	**PPV**	-	-	-	70.0%	-	-	-	-
	NPV	-	-	-	50.0%	-	-	-	-
AT HOME	**+ LR**	-	-	-	1.55	-	-	-	-
	- LR	-	-	-	0.67	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Simultaneous									
Grant B.[137]	**Sensitivity**	-	99.0%	-	97.0%	-	-	-	-
2009	**Specificity**	-	73.0%	-	81.0%	-	-	-	-
USA	**PPV**	-	76.0%	-	47.0%	-	-	-	-
	NPV	-	99.0%	-	99.0%	-	-	-	-
	+ LR	-	3.6	-	5.1	-	-	-	-
	- LR	-	0.015	-	0.041	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Ng S.[138]	**Sensitivity**	-	92.4%	90.0%	87.8%	85.3%	-	-	-
2010	**Specificity**	-	85.7%	86.7%	94.9%	95.7%	-	-	-
China	**PPV**	-	96.8%	91.8%	94.7%	93.5%	-	-	-
	NPV	-	70.6%	83.9%	88.1%	89.8%	-	-	-

Table 17. Diagnostic accuracy: SDB conditions other than OSA

Simultaneous + Separate

Primary author, reference, Year Country	Diagnostic Accuracy Measure	Level I Sleep Study Apnea-Hypopnea Index Cutoff							
		≤5/hr	≥5/hr	≥10/hr	≥15/hr	≥20/hr	≥25/hr	≥30/hr	≥50/hr
	+ LR	-	6.46	6.77	17.22	19.84	-	-	-
	- LR	-	0.089	0.115	0.126	0.154	-	-	-
	ROC	-	1.00	1.00	0.998	1.00	-	-	-

Separate

Author, year, reference number	Diagnostic Accuracy Measure	Level I Sleep Study Apnea-Hypopnea Index Cutoff							
		≤5/hr	≥5/hr	≥10/hr	≥15/hr	≥20/hr	≥25/hr	≥30/hr	≥50/hr
Quintana-Gallego E.[122]	**Sensitivity**	-	82.5%	79.3%	68.4%	-	-	-	-
2004	**Specificity**	-	88.6%	97.8%	94.6%	-	-	-	-
Spain	**PPV**	-	89.0%	96.0%	81.0%	-	-	-	-
	NPV	-	82.0%	88.0%	90.0%	-	-	-	-
	+ LR	-	7.24	36.04	12.67	-	-	-	-
	- LR	-	0.20	0.21	0.33	-	-	-	-
	ROC	-	0.896	0.907	0.862	-	-	-	-
Yin M.[139]	**Sensitivity**	-	100%	-	93.8%	-	-	79.2%	90.0%
2006	**Specificity**	-	-	-	25.0%	-	-	70.0%	97.1%
Japan	**PPV**	-	93.2%	-	76.9%	-	-	76.0%	90.0%
	NPV	-	-	-	60.0%	-	-	73.7%	97.1%
	+ LR	-	1.0	-	1.25	-	-	2.64	31.03
	- LR	-	-	-	0.228	-	-	0.297	0.103
	ROC	-	-	-	-	-	-	-	-

Table 18. Diagnostic accuracy: OSA studies

Table 18. Diagnostic accuracy: OSA studies									
Simultaneous + Separate									
Author, year, reference, country	**Diagnostic Accuracy Measure**	**Level I Sleep Study Apnea-Hypopnea Index Cutoff**							
		≤5/hr	**≥5/hr**	**≥10/hr**	**≥15/hr**	**≥20/hr**	**≥25/hr**	**≥30/hr**	**≥50/hr**
Abraham WT.[113]	**Sensitivity**	-	95.2%	88.2%	66.7%	-	-	-	-
2006	**Specificity**	-	52.2%	63.0%	78.1%	-	-	-	-
USA/UK	**PPV**	-	64.5%	60.0%	53.3%	-	-	-	-
	NPV	-	92.3%	89.5%	86.2%	-	-	-	-
	+ LR	-	1.99	2.38	3.05	-	-	-	-
IN LAB	**- LR**	-	0.09	0.19	0.43	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Abraham WT.[113]	**Sensitivity**	-	-	-	-	-	-	-	-
2006	**Specificity**	-	-	-	-	-	-	-	-
USA/UK	**PPV**	-	-	-	-	-	-	-	-
	NPV	-	-	-	-	-	-	-	-
	+ LR	-	-	-	-	-	-	-	-
AT HOME	**- LR**	-	-	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Ayappa I.[118]	**Sensitivity**	-	98.0%	97.0%	92.0%	-	-	-	-
2008	**Specificity**	-	84.0%	85.0%	95.0%	-	-	-	-
USA	**PPV**	-	90.0%	82.0%	92.0%	-	-	-	-
	NPV	-	97.0%	98.0%	95.0%	-	-	-	-
	+ LR	-	6.05	6.46	17.11	-	-	-	-
	- LR	-	0.02	0.03	0.09	-	-	-	-
IN LAB	**ROC**	-	-	-	-	-	-	-	-
Ayappa I.[118]	**Sensitivity**	-	90.0%	86.0%	74.0%	-	-	-	-
2008	**Specificity**	-	79.0%	82.0%	88.0%	-	-	-	-
USA	**PPV**	-	87.0%	78.0%	80.0%	-	-	-	-
	NPV	-	79.0%	89.0%	84.0%	-	-	-	-
	+ LR	-	4.29	4.78	6.17	-	-	-	-
AT HOME	**- LR**	-	0.13	0.17	0.30	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Garcia-Diaz E.[112]	**Sensitivity**	-	-	94.6%	100%	-	-	95.8%	-

Table 18. Diagnostic accuracy: OSA studies									
Simultaneous + Separate									
Author, year, reference, country	**Diagnostic Accuracy Measure**	**Level I Sleep Study Apnea-Hypopnea Index Cutoff**							
		≤5/hr	**≥5/hr**	**≥10/hr**	**≥15/hr**	**≥20/hr**	**≥25/hr**	**≥30/hr**	**≥50/hr**
2007	**Specificity**	-	-	96.0%	96.7%	-	-	94.7%	-
Spain	**PPV**	-	-	97.0%	97.0%	-	-	92.0%	-
	NPV	-	-	92.0%	100%	-	-	97.0%	-
	+ LR	-	-	23.64	30	-	-	18.2	-
IN LAB	**- LR**	-	-	0.06	0	-	-	0.04	-
	ROC	-	-	0.977	0.998	-	-	0.986	-
Garcia-Diaz E.[112]	**Sensitivity**	-	-	86.4%	87.5%	-	-	91.7%	-
2007	**Specificity**	-	-	100%	96.7%	-	-	94.7%	-
Spain	**PPV**	-	-	100%	97.0%	-	-	92.0%	-
	NPV	-	-	84.0%	88.0%	-	-	95.0%	-
	+ LR	-	-	Infinity	27.0	-	-	17.0	-
AT HOME	**- LR**	-	-	0.14	0.13	-	-	0.09	-
	ROC	-	-	0.969	0.972	-	-	0.986	-
Kuna ST.[108]	**Sensitivity**	-	-	-	96.9%	-	-	-	-
2005	**Specificity**	-	-	-	100%	-	-	-	-
USA	**PPV**	-	-	-	100%	-	-	-	-
	NPV	-	-	-	90.0%	-	-	-	-
IN LAB	**+ LR**	-	-	-	Infinity	-	-	-	-
	- LR	-	-	-	0.03	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Kuna ST.[108]	**Sensitivity**	-	-	-	86.7%	-	-	-	-
2005	**Specificity**	-	-	-	77.8%	-	-	-	-
USA	**PPV**	-	-	-	93.0%	-	-	-	-
	NPV	-	-	-	64.0%	-	-	-	-
AT HOME	**+ LR**	-	-	-	3.90	-	-	-	-
	- LR	-	-	-	0.17	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Kushida CA.[120]	**Sensitivity**	-	-	-	-	-	-	-	-
2009	**Specificity**	-	-	-	-	-	-	-	-
USA	**PPV**	-	-	-	-	-	-	-	-
	NPV	-	-	-	-	-	-	-	-
	+ LR	-	-	-	-	-	-	-	-
IN LAB	**- LR**	-	-	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-

Table 18. Diagnostic accuracy: OSA studies									
Simultaneous + Separate									
Author, year, reference, country	**Diagnostic Accuracy Measure**	**Level I Sleep Study Apnea-Hypopnea Index Cutoff**							
		≤5/hr	**≥5/hr**	**≥10/hr**	**≥15/hr**	**≥20/hr**	**≥25/hr**	**≥30/hr**	**≥50/hr**
Kushida CA.[120]	**Sensitivity**	-	-	-	-	-	-	-	-
2009	**Specificity**	-	-	-	-	-	-	-	-
USA	**PPV**	-	-	-	-	-	-	-	-
	NPV	-	-	-	-	-	-	-	-
	+ LR	-	-	-	-	-	-	-	-
AT HOME	**- LR**	-	-	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Polese JF.[110]	**Sensitivity**	-	93.9%	-	96.2%	-	-	93.7%	-
2009	**Specificity**	-	100%	-	100%	-	-	78.9%	-
Brazil	**PPV**	-	100%	-	100%	-	-	71%	-
	NPV	-	59.0%	-	91.0%	-	-	92%	-
	+ LR	-	Infinity	-	Infinity	-	-	4.44	-
IN LAB	**- LR**	-	0.061	-	0.038	-	-	0.08	-
	ROC	-	-	-	-	-	-	-	-
Polese JF.[110]	**Sensitivity**	-	69.7%	-	80.8%	-	-	81.2%	-
2009	**Specificity**	-	100%	-	90.0%	-	-	85.0%	-
Brazil	**PPV**	-	94.0%	-	85.0%	-	-	76.0%	-
	NPV	-	50.0%	-	60.0%	-	-	84.0%	-
	+ LR	-	Infinity	-	8.08	-	-	5.41	-
AT HOME	**- LR**	-	0.303	-	0.213	-	-	0.221	-
	ROC	-	-	-	-	-	-	-	-
Santos-Silva R.[116]	**Sensitivity**	-	98.0%	-	97.0%	-	-	96.0%	-
2009	**Specificity**	-	62.0%	-	74.0%	-	-	92.0%	-
Brazil	**PPV**	-	87.0%	-	78.0%	-	-	87.0%	-
	NPV	-	93.0%	-	96.0%	-	-	98.0%	-
	+ LR	-	2.58	-	3.73	-	-	12.0	-
IN LAB	**- LR**	-	0.032	-	0.041	-	-	0.043	-
	ROC	-	0.97	-	0.98	-	-	0.98	-
Santos-Silva R.[116]	**Sensitivity**	-	93.0%	-	85.0%	-	-	77.0%	-
2009	**Specificity**	-	59.0%	-	80.0%	-	-	93.0%	-
Brazil	**PPV**	-	85.0%	-	80.0%	-	-	81.0%	-
	NPV	-	76.0%	-	84.0%	-	-	91.0%	-
	+ LR	-	2.27	-	4.25	-	-	11.0	-
AT HOME	**- LR**	-	0.12	-	0.19	-	-	0.25	-
	ROC	-	0.90	-	0.92	-	-	0.95	-

Table 18. Diagnostic accuracy: OSA studies

Simultaneous + Separate

Author, year, reference, country	Diagnostic Accuracy Measure	Level I Sleep Study Apnea-Hypopnea Index Cutoff							
		≤5/hr	≥5/hr	≥10/hr	≥15/hr	≥20/hr	≥25/hr	≥30/hr	≥50/hr
Tonelli de Oliveria AC.[117]	**Sensitivity**	95.3%	-	-	-	-	-	-	-
2009	**Specificity**	75.0%	-	-	-	-	-	-	-
Brazil	**PPV**	-	-	-	-	-	-	-	-
	NPV	-	-	-	-	-	-	-	-
	+ LR	3.81	-	-	-	-	-	-	-
IN LAB	**- LR**	0.06	-	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Tonelli de Oliveria AC,.[117]	**Sensitivity**	-	96.2%	90.7%	81.3%	-	-	80.0%	-
2009	**Specificity**	-	64.6%	82.9%	82.6%	-	-	92.1%	-
Brazil	**PPV**	-	94.3%	92.9%	88.4%	-	-	85.7%	-
	NPV	-	73.3%	68.4%	73.1%	-	-	88.6%	-
	+ LR	-	2.7	5.2	4.6	-	-	10.1	-
AT HOME	**- LR**	-	0.05	0.11	0.22	-	-	0.21	-
	ROC	-	0.96	0.92	0.91	-	-	0.92	-

Simultaneous

Author, year, reference, country	Diagnostic Accuracy Measure	Level I Sleep Study Apnea-Hypopnea Index Cutoff							
		≤5/hr	≥5/hr	≥10/hr	≥15/hr	≥20/hr	≥25/hr	≥30/hr	≥50/hr
Bajwa I.[127]	**Sensitivity**	-	-	-	-	-	-	-	-
2009	**Specificity**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
USA	**PPV**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
	NPV	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
	+ LR	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
	- LR	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
	ROC	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Candela A.[126]	**Sensitivity**	-	-	97%	96%	96%	-	98%	-
2005	**Specificity**	**-**	**-**	82%	94%	97%	**-**	98%	**-**
Spain	**PPV**	**-**	**-**	93%	96%	98%	**-**	98%	**-**
	NPV	**-**	**-**	92%	94%	95%	**-**	98%	**-**
	+ LR	**-**	**-**	5.39	16	32.0	**-**	49.0	**-**

Simultaneous									
Author, year, reference, country	**Diagnostic Accuracy Measure**	**Level I Sleep Study Apnea-Hypopnea Index Cutoff**							
		≤5/hr	**≥5/hr**	**≥10/hr**	**≥15/hr**	**≥20/hr**	**≥25/hr**	**≥30/hr**	**≥50/hr**
	- LR	**-**	**-**	0.037	0.042	0.041	**-**	0.020	**-**
	ROC	**-**	**-**	0.971	0.975	0.995	**-**	0.996	**-**
Driver HS.[129]	**Sensitivity**	-	92.0%	92.0%	79.0%	89.0%	-	73.0%	-
2009	**Specificity**	**-**	70.0%	86.0%	97.0%	97.0%	**-**	100.0%	**-**
Canada	**PPV**	**-**	92.0%	94.0%	98.0%	97.0%	**-**	100.0%	**-**
	NPV	**-**	59.0%	83.0%	76.0%	90.0%	**-**	89.0%	**-**
	+ LR	**-**	3.07	6.57	26.0	30.0	**-**	Infinity	**-**
	- LR	**-**	0.114	0.093	0.22	0.11	**-**	0.27	**-**
	ROC	**-**	-	-	-	-	**-**	-	**-**
Ferre A.[125]	**Sensitivity**	-	93.3%	-	84.2%	-	-	55.6%	-
2008	**Specificity**	**-**	86.7%	**-**	100%	**-**	**-**	96.4%	**-**
Spain	**PPV**	**-**	-	**-**	-	**-**	**-**	-	**-**
	NPV	**-**	-	**-**	-	**-**	**-**	-	**-**
	+ LR	**-**	7.01	**-**	Infinity	**-**	**-**	15.44	**-**
	- LR	**-**	0.08	**-**	0.16	**-**	**-**	0.46	**-**
	ROC	**-**	-	**-**	-	**-**	**-**	-	**-**
Orr WC.[121]	**Sensitivity**	-	-	83.0%	82.0%	-	100%	-	-
2006	**Specificity**	-	81.0%	87.0%	-	-	-	100%	-
USA	**PPV**	-	-	-	-	-	-	-	-
	NPV	-	-	-	-	-	-	-	-
	+ LR	-	-	6.38	-	-	-	-	-
	- LR	-	-	0.195	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Su S, et al.[148]	**Sensitivity**	-	98.0%	87.8%	83.9%	-	-	-	-
2004	**Specificity**	**-**	40.0%	73.7%	75.9%	**-**	**-**	**-**	**-**
USA	**PPV**	**-**	89.1%	87.8%	78.8%	**-**	**-**	**-**	**-**
	NPV	**-**	80.0%	73.7%	81.5%	**-**	**-**	**-**	**-**
	+ LR	**-**	-	-	-	**-**	**-**	**-**	**-**
	- LR	**-**	-	-	-	**-**	**-**	**-**	**-**
	ROC	**-**	0.945	0.908	0.872	**-**	**-**	**-**	**-**
Sullivan GE.[128]	**Sensitivity**	70.0%	86.0%	-	57.0%	-	-	75.0%	-
2009	**Specificity**	100%	82.0%	-	88.0%	-	-	97.0%	-
Canada	**PPV**	-	-	-	-	-	-	-	-
	NPV	-	-	-	-	-	-	-	-
	+ LR	Infinity	4.78	-	4.75	-	-	25.0	-

Simultaneous									
Author, year, reference, country	**Diagnostic Accuracy Measure**	**Level I Sleep Study Apnea-Hypopnea Index Cutoff**							
		≤5/hr	**≥5/hr**	**≥10/hr**	**≥15/hr**	**≥20/hr**	**≥25/hr**	**≥30/hr**	**≥50/hr**
	- LR	0.3	0.17	-	0.49	-	-	0.26	-
	ROC	-	-	-	-	-	-	-	-
To KW.[123]	**Sensitivity**	-	84.0%	-	-	-	-	-	-
2008	**Specificity**	-	100%	-	-	-	-	-	-
Hong Kong/China	**PPV**	-	100%	-	-	-	-	-	-
	NPV	-	27%	-	-	-	-	-	-
	+ LR	-	Infinity	-	-	-	-	-	-
	- LR	-	0.16	-	-	-	-	-	-
	ROC	-	0.96	-	-	-	-	-	-
Yagi H.[124]	**Sensitivity**	-	-	-	95.0%	-	-	-	-
2009	**Specificity**	-	-	-	-	-	-	-	-
Japan	**PPV**	-	-	-	95.0%	-	-	-	-
	NPV	-	-	-	-	-	-	-	-
	+ LR	-	-	-	-	-	-	-	-
	- LR	-	-	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-

Separate									
Author, year, reference, country	**Diagnostic Accuracy Measure**	**Level I Sleep Study Apnea-Hypopnea Index Cutoff**							
		≤5/hr	**≥5/hr**	**≥10/hr**	**≥15/hr**	**≥20/hr**	**≥25/hr**	**≥30/hr**	**≥50/hr**
Alvarez M.[132]	**Sensitivity**	-	-	61.9%	-	-	-	-	-
2008	**Specificity**	-	-	95.8%	-	-	-	-	-
Spain	**PPV**	-	-	92.9%	-	-	-	-	-
	NPV	-	-	74.2%	-	-	-	-	-
	+ LR	-	-	14.78	-	-	-	-	-
	- LR	-	-	0.40	-	-	-	-	-
	ROC	-	-	0.875	-	-	-	-	-
Churchward TJ.[131]	**Sensitivity**	-	-	100%	-	-	-	-	-
2006	**Specificity**	-	-	100%	-	-	-	-	-
Australia	**PPV**	-	-	100%	-	-	-	-	-
	NPV	-	-	100%	-	-	-	-	-

Separate									
Author, year, reference, country	**Diagnostic Accuracy Measure**	**Level I Sleep Study Apnea-Hypopnea Index Cutoff**							
		≤5/hr	**≥5/hr**	**≥10/hr**	**≥15/hr**	**≥20/hr**	**≥25/hr**	**≥30/hr**	**≥50/hr**
	+ LR	-	-	Infinity	-	-	-	-	-
	- LR	-	-	0	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Cilli A.[134]	**Sensitivity**	-	93.0%	-	-	-	-	-	-
2006	**Specificity**	-	44.4%	-	-	-	-	-	-
Turkey	**PPV**	-	89.5%	-	-	-	-	-	-
	NPV	-	57.1%	-	-	-	-	-	-
	+ LR	-	1.67	-	-	-	-	-	-
	- LR	-	0.16	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Finkel KJ.[130]	**Sensitivity**	-	95.0%	-	-	-	-	-	-
2009	**Specificity**	-	33.3%	-	-	-	-	-	-
USA	**PPV**	-	83.0%	-	-	-	-	-	-
	NPV	-	67.0%	-	-	-	-	-	-
	+ LR	-	1.42	-	-	-	-	-	-
	- LR	-	0.15	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Fordyce L.[106]	**Sensitivity**	-	80.0%	-	-	-	-	-	-
2009	**Specificity**	-	100%	-	-	-	-	-	-
Canada	**PPV**	-	100%	-	-	-	-	-	-
	NPV	-	80.0%	-	-	-	-	-	-
	+ LR	-	Infinity	-	-	-	-	-	-
	- LR	-	0.20	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Gjevre JE.[109]	**Sensitivity**	-	84.4%	-	-	-	-	-	-
2007	**Specificity**	-	76.9%	-	-	-	-	-	-
Canada	**PPV**	-	90.6%	-	-	-	-	50.0%	-
	NPV	-	61.5%	-	-	-	-	-	-
	+ LR	-	3.65	-	-	-	-	-	-
	- LR	-	0.21	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Grover S.[133]	**Sensitivity**	-	-	-	-	-	-	-	-
2009	**Specificity**	-	-	-	-	-	-	-	-
USA	**PPV**	-	-	-	-	-	-	-	-
	NPV	-	-	-	-	-	-	-	-

Separate									
Author, year, reference, country	**Diagnostic Accuracy Measure**	**Level I Sleep Study Apnea-Hypopnea Index Cutoff**							
		≤5/hr	**≥5/hr**	**≥10/hr**	**≥15/hr**	**≥20/hr**	**≥25/hr**	**≥30/hr**	**≥50/hr**
	+ LR	-	-	-	-	-	-	-	-
	- LR	-	-	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Hernandez L.[114]	**Sensitivity**	-	-	83.3%	-	-	-	-	-
2007	**Specificity**	-	-	78.9%	-	-	-	-	-
Spain	**PPV**	-	-	91.8%	-	-	-	-	-
	NPV	-	-	62.5%	-	-	-	-	-
	+ LR	-	-	3.95	-	-	-	-	-
	- LR	-	-	0.21	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Levendowski D.[111]	**Sensitivity**	-	-	-	-	-	-	-	-
2009	**Specificity**	-	-	-	-	-	-	-	-
USA	**PPV**	-	-	-	-	-	-	-	-
	NPV	-	-	-	-	-	-	-	-
	+ LR	-	-	-	-	-	-	-	-
	- LR	-	-	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Miyata S.[107]	**Sensitivity**	-	-	-	-	-	-	-	-
2007	**Specificity**	-	-	-	-	-	-	-	-
Japan	**PPV**	-	-	-	-	-	-	-	-
	NPV	-	-	-	-	-	-	-	-
	+ LR	-	-	-	-	-	-	-	-
	- LR	-	-	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Shrivastava D.[136]	**Sensitivity**	-	-	-	86.4%	-	-	-	-
2006	**Specificity**	-	-	-	80.8%	-	-	-	-
USA	**PPV**	-	-	-	95.0%	-	-	-	-
	NPV	-	-	-	59.0%	-	-	-	-
	+ LR	-	-	-	4.50	-	-	-	-
	- LR	-	-	-	0.17	-	-	-	-
	ROC	-	-	-	-	-	-	-	-
Skomro R.[135]	**Sensitivity**	-	92.0%	-	-	-	-	-	-
2005	**Specificity**	-	67.0%	-	-	-	-	-	-
Canada	**PPV**	-	88.0%	-	-	-	-	-	-
	NPV	-	75.0%	-	-	-	-	-	-

Separate									
Author, year, reference, country	**Diagnostic Accuracy Measure**	**Level I Sleep Study Apnea-Hypopnea Index Cutoff**							
		≤5/hr	**≥5/hr**	**≥10/hr**	**≥15/hr**	**≥20/hr**	**≥25/hr**	**≥30/hr**	**≥50/hr**
	+ LR	-	2.79	-	-	-	-	-	-
	- LR	-	0.12	-	-	-	-	-	-
	ROC	-	-	-	-	-	-	-	-

Table 19. Sleep indexes reported: SDB conditions other than OSA

Table 19. Sleep indexes reported: SDB conditions other than OSA												
Simultaneous + Separate												
Primary author	**In Lab Level I Sleep Study**						**At Home Level III Sleep Study**					
	AHI	**AI**	**HI**	**OA**	**CA**	**MA**	**RDI/REI /AHI**	**AI**	**HI**	**OA**	**CA**	**MA**
Smith LA.[119]	24.2/hr† (±16.8)	_	16.4/hr (±13.5)	6.3/hr (±13.4)	2.8/hr (±9.6)	0.0/hr (±0.0)	13.7/hr† (±12.6)	_	10.6/hr (±8.9)	2.9/hr (±5.1)	0.2/hr (±0.6)	0.0/hr (±0.0)
							In Lab Level III Sleep Study					
	24.2/hr† (±16.8)	_	16.4/hr (±13.5)	6.3/hr (±13.4)	2.8/hr (±9.6)	0.0/hr (±0.0)	19.5/hr† (±16.0)	_	14.4/hr (±10.0)	4.5/hr (±8.1)	0.6/hr (±1.8)	0.0/hr (±0.1)
Simultaneous												
Primary author	**In Lab Level I Sleep Study**						**In Lab Level III Sleep Study**					
	AHI	**AI**	**HI**	**OA**	**CA**	**MA**	**RDI/REI /AHI**	**AI**	**HI**	**OA**	**CA**	**MA**
Grant B.[137]	_	_	_	_	_	_	_	_	_	_	_	_
Ng S.[138]	21.6/hr (±19.1)	_	4.2/hr (±4.1)	15.7/hr (±16.7)	1.1/hr (±2.2)	_	20.8/hr (±19.7)	_	4.3/hr (±4.5)	14.0/hr (±15.7)	1.0/hr (±1.9)	_
Separate												
Primary author	**In Lab Level I Sleep Study**						**At Home Level III Sleep Study**					
	AHI	**AI**	**HI**	**OA**	**CA**	**MA**	**RDI/REI /AHI**	**AI**	**HI**	**OA**	**CA**	**MA**
Quintana-Gallego E.[122]	11.6/hr (±14.0)	_	_	_	_	_	10.5/hr (±8.7)	_	_	_	_	_
Yin M.[139]	33.6/hr (±24.9)	29.8/hr (±25.2)	3.8/hr (±3.0)	27.4/hr§ (NR)	0.8/hr§ (NR)	1.7/hr§ (NR)	36.9/hr (±20.5)	31.5/hr (±21.8)	5.5/hr (±5.1)	26.1/hr§ (NR)	0.8/hr§ (NR)	2.4/hr § (NR)

Table 20. Sleep indexes reported: OSA studies

Table 20. Sleep indexes reported: OSA studies												
Simultaneous and Separate												
Primary author	**In Lab Level I Sleep Study**						**At Home Level III Sleep Study**					
	AHI	**AI**	**HI**	**OA**	**CA**	**MA**	**RDI/REI /AHI**	**AI**	**HI**	**OA**	**CA**	**MA**
Abraham WT.[113]	–	–	–	–	–	–	–	–	–	–	–	–
							In Lab Level III Sleep Study					
	–	–	–	–	–	–	–	–	–	–	–	–
							At Home Level III Sleep Study					
Ayappa I.[118]	–	–	–	–	–	–	16.0/hr (NR)	–	–	–	–	–
							In Lab Level III Sleep Study					
	–	–	–	–	–	–	19.0/hr (NR)	–	–	–	–	–
Garcia-Diaz E.[112] Spain	30.3/hr (±33.0)	–	–	–	–	–	27.3/hr (±28.4)	–	–	–	–	–
							In Lab Level III Sleep Study					
	30.3/hr (±33.0)	–	–	–	–	–	27.5/hr (±26.9)	–	–	–	–	–
							At Home Level III Sleep Study					
Kuna ST.[108]	40.6/hr (±35.5)	–	–	–	–	–	32.1/hr (±27.4)	–	–	–	–	–
							In Lab Level III Sleep Study					
	40.6/hr (±35.5)	–	–	–	–	–	36.4/hr (±27.7)	–	–	–	–	–
							At Home Level III Sleep Study					
Kushida CA.[120]	22.4/hr (NR)	8.7/hr (NR)	13.6/hr (NR)	–	–	–	–	–	–	–	–	–
							In Lab Level III Sleep Study					
	22.4/hr (NR)	8.7/hr (NR)	13.6/hr (NR)	–	–	–	15.2/hr (NR)	10.0/hr (NR)	3.6/hr (NR)	–	–	–

Table 20. Sleep indexes reported: OSA studies												
Simultaneous and Separate												
Primary author	**In Lab Level I Sleep Study**						**At Home Level III Sleep Study**					
	AHI	**AI**	**HI**	**OA**	**CA**	**MA**	**RDI/REI /AHI**	**AI**	**HI**	**OA**	**CA**	**MA**
							At Home Level III Sleep Study					
Polese JF.[110]	32.7/hr (±25.7)	_	16.4/hr (±11.4)	_	_	_	23.0/hr (±24.0)	_	9.0 (±6.0)	_	_	_
							In Lab Level III Sleep Study					
	32.7/hr (±25.7)	_	16.4/hr (±11.4)	_	_	_	33.7/hr (±18.8)	_	18.3/hr (±9.4)	_	_	_
							At Home Level III Sleep Study					
Santos-Silva R.[116]	23.0/hr (±24.0)	12.0/hr (±19.0)	11.0/hr (±11.0)	_	_	_	23.0/hr (±24.0)	13.0/hr (±20.0)	9.0/hr (±6.0)	_	_	_
							In Lab Level III Sleep Study					
	26.0/hr (±28.0)	15.0/hr (±22.0)	11.0/hr (±14.0)	_	_	_	27.0/hr (±23.0)	15.0/hr (±20.0)	11.0/hr (±8.0)	_	_	_
							At Home Level III Sleep Study					
Tonelli de Oliveria AC.[117]	30.2/hr (±27.8)	_	_	_	_	_	25.9/hr† (±22.5)	_	_	_	_	_
							In Lab Level III Sleep Study					
	30.2/hr (±27.8)	_	_	_	_	_	27.5/hr† (±24.7)	_	_	_	_	_

Simultaneous												
Primary author	**In Lab Level I Sleep Study**						**In Lab Level III Sleep Study**					
	AHI	**AI**	**HI**	**OA**	**CA**	**MA**	**RDI/REI/ AHI**	**AI**	**HI**	**OA**	**CA**	**MA**
Bajwa I.[127]	4.3-103.5§	_	_	_	_	_	4.8-104.8§	_	_	_	_	_
Candela A.[126] (manual)	31.8/hr†* (7-72)	22.3/hr* (3-53)	4.8/hr* (2-20)	_	_	_	30.0/hr†* (7-52)	12.4/hr* (2-34)	8.7/hr (4-20)	_	_	_
Driver HS.[129]	26.0/hr (±25.9)	_	_	_	_	_	20.1/hr (±18.8)	_	_	_	_	_
Ferre A.[125]	20.5/hr (±18.0)	_	_	_	_	_	17.7/hr (±16.6)	_	_	_	_	_

Simultaneous												
Primary author	**In Lab Level I Sleep Study**						**In Lab Level III Sleep Study**					
	AHI	**AI**	**HI**	**OA**	**CA**	**MA**	**RDI/REI/ AHI**	**AI**	**HI**	**OA**	**CA**	**MA**
Orr WC.[121]	–	–	–	–	–	–	–	–	–	–	–	–
Su S.[148]	27.3/hr (± 29.7)	28.2/hr (± 59.8)	69.6/hr (± 63.1)	–	–	–	26.3/hr (± 27.6)	34.4/hr (± 55.2)	63.7/hr (± 44.9)	–	–	–
Sullivan GE.[128]	–	–	–	–	–	–	–	–	–	–	–	–
To KW.[123]	39.3/hr¥ (NR)	–	–	–	–	–	↓ than Level I	–	–	–	–	–
Yagi H.[124]	43.9/hr (±21.2)	26.4/hr (±23.0)	15.5/hr (±11.1)	–	–	–	46.0/hr (±20.4)	23.7/hr (±22.1)	22.2/hr (±11.5)	–	–	–

Separate												
Primary author	**In Lab Level I Sleep Study**						**At Home Level III Sleep Study**					
	AHI	**AI**	**HI**	**OA**	**CA**	**MA**	**RDI/REI/ AHI**	**AI**	**HI**	**OA**	**CA**	**MA**
Alonso Alvarez M.[132]	15.1/hr (±18.0)	–	–	–	–	–	13.6/hr (±11.0)	–	–	–	–	–
Churchward TJ.[131]	30.3/hr (±20.3)	–	–	–	–	–	30.5/hr (±20.9)	–	–	–	–	–
Cilli A.[134]	–	–	–	–	–	–	–	–	–	–	–	–
Finkel KJ.[130]	–	–	–	–	–	–	–	–	–	–	–	–
Fordyce L.[106]	20.3/hr (±28.9)	–	–	–	–	–	6.5/hr (±5.2)	–	–	–	–	–
Gjevre JE.[109]	16.0/hr (±16.26)	–	–	–	–	–	17.7/hr (±14.8)	–	–	–	–	–

Separate												
Primary author	**In Lab Level I Sleep Study**						**At Home Level III Sleep Study**					
	AHI	**AI**	**HI**	**OA**	**CA**	**MA**	**RDI/REI/ AHI**	**AI**	**HI**	**OA**	**CA**	**MA**
Grover S.[133]	–	–	–	–	–	–	–	–	–	–	–	–
Hernandez L.[114]	21.5/hr* (8.0, 57.5)	–	–	–	–	–	15.0/hr* (4.5, 48.5)	–	–	–	–	–
Levendowski D.[111]	–	–	–	–	–	–	–	–	–	–	–	–
Miyata S.[107]	33.0/hr (±25.7)	–	–	–	–	–	28.1/hr (±20.6)	–	–	–	–	–
Shrivastava D.[136]	–	–	–	–	–	–	–	–	–	–	–	–
Skomro R.[135]	29.4/hr (±28.4)	–	–	–	–	–	28.9/hr (±23.9)	–	–	–	–	–

Table 21. Adverse events during sleep studies

Table 21. Adverse events during sleep studies									
Primary Author	**In Lab Level I**			**In Lab Level III**			**IAt Home Level III**		
	Sensor Irritation	**Medical health complication**	**Other**	**Sensor Irritation**	**Medical health complication**	**Other**	**Sensor Irritation**	**Medical health complication**	**Other**
Abraham WT.[113]	_	n =1*	_				**n=27**	_	_
Alonso Alvarez M.[132]	_	_	_				_	_	_
Ayappa I.[118]	_	_	_	_	_	_	_	_	_
Bajwa I.[127]	_	_	_	_	_	_			
Candela A. [126]	_	_	_	_	_	_			
Churchward TJ.[131]	_	_	_				_	_	_
Cilli A.[134]	_	_	_				_	_	_
Driver HS.[129]	_	_	_	_	_	_			
Ferre A.[125]	_	_	_	_	_	_			
Finkel KJ.[130]	_	_	_				_	_	_
Fordyce L.[106]	_	_	_				_	_	_
Garcia-Diaz E.[112]	_	_	_	_	_	_	_	_	_
Gjevre JE.[109]	_	_	_				_	_	_
Grant B.[137]	_	_	_	_	_	_			
Grover S.[133]	_	_	_				_	_	_
Hernandez L. §[114]	_	_	_				_	_	_
Kuna ST.[108]	_	_	_	_	_	_	_	_	_
Kushida CA.[120]	_	_	_	_	_	_	_	_	_
Levendowski D[111]	_	_	_				_	_	_
Miyata S.[107]	_	_	_				_	_	_
Ng S.[138]	_	_	_	_	_	_			
Orr WC.[121]	_	_	_	_	_	_			
Polese JF.[110]	_	_	_	_	_	_	_	_	_
Quintana-Gallego E.[122]	_	_	_				_	_	_
Santos-Silva R.[116]	_	n =1**	_	_	_	_	_	_	_
Shrivastava D.[136]	_	_	_				_	_	_
Skomro R.[135]	_	_	_				_	_	_
Smith LA.[119]	_	_	_	_	_	_	_	_	_
Su S.[148]	_	_	_	_	_	_			
Sullivan GE.[128]	_	_	_	_	_	_			
To KW.[123]	_	_	_	_	_	_			
Tonelli de Oliveria AC.[117]	_	_	_	_	_	_	_	_	_

Table 21. Adverse events during sleep studies									
Primary Author	**In Lab Level I**			**In Lab Level III**			**IAt Home Level III**		
	Sensor Irritation	**Medical health complication**	**Other**	**Sensor Irritation**	**Medical health complication**	**Other**	**Sensor Irritation**	**Medical health complication**	**Other**
Yagi H.[124]	_	_	_	_	_	_			
Yin M.[139]	_	_	_				_	_	_
TOTAL	N = 0	N = 2	N = 0	N = 0	N = 0	N = 0	N = 27	N = 0	N = 0

* - severe pacemaker interference; ** - hypertensive crisis; § - level III study conducted in hospital

Table 22. "Failures"

Table 22. "Failures"									
Primary author	**In Lab Level I**			**In Lab Level III**			**At Home Level III**		
	Equipment related error	**Patient related error**	**Intolerant to device**	**Equipment related error**	**Patient related error**	**Intolerant to device**	**Equipment related error**	**Patient related error**	**Intolerant to device**
Abraham WT.[113]	_	_	n = 1	n = 3	_	_	n = 2	_	_
Alonso Alvarez M.[132]	_	_	_				_	_	_
Ayappa I.[118]	n = 1	_	_	n = 2	n = 1	_	n = 1	n = 6	n = 5
Bajwa I.[127]	_	_	_	_	_	_			
Candela A.[126] (manual)	_	_	_	n = 4	_	_			
Churchward TJ.[131]	_	_	_				n = 8	_	_
Cilli A.[134]	_	_	_				_	_	_
Driver HS.[129]	_	_	_	n = 7	_	_			
Ferre A.[125]	_	_	_	_	_	_			
Finkel KJ.[130]	_	_	_				_	_	_
Fordyce L.[106]	_	_	_				_	_	_
Garcia-Diaz E.[112]	n = 1	_	_	_	_	_	n = 2	_	_
Gjevre JE.[109]	_	_	_				_	_	_
Grant B.[137]	_	_	_	_	_	_			
Grover S.[133]	_	_	_				_	n = 1	_
Hernandez L.[114] §	_	_	_				_	_	_
Kuna ST.[108]	_	_	_	_	_	_	_	_	_
Kushida CA.[120]	_	_	_	_	_	_	_	_	_
Levendowski D.[111]	_	_	_				_	_	_
Miyata S.[107]	_	_	_				_	_	_
Ng S.[138]	_	_	_	n = 9	n = 1†	_			
Orr WC.[121]	_	_	_	_	_	_			
Polese JF.[110]	_	_	_	_	_	_	_	_	_
Quintana-Gallego E.[122]	_	_	_				n = 3	n = 2†	_
Santos-Silva R.[116]	_	_	_	_	_	_	n = 2	_	_
Shrivastava D.[136]	_	_	_				_	_	_
Skomro R.[135]	_	_	_				n = 13*	_	_

Table 22. "Failures"									
Primary author	**In Lab Level I**			**In Lab Level III**			**At Home Level III**		
	Equipment related error	**Patient related error**	**Intolerant to device**	**Equipment related error**	**Patient related error**	**Intolerant to device**	**Equipment related error**	**Patient related error**	**Intolerant to device**
Smith LA.[119]	_	_	_	_	_	_	n = 4	n = 2	_
Su S.[148]	n=3	_	_	n=1	_	_			
Sullivan GE.[128]	_	_	_	_	_	_			
To KW.[123]	n = 13	_	_	n = 26†	_	_			
Tonelli de Oliveria AC.[117]	_	_	_	n = 8†	_	_	n = 21†	n = 13	n = 1
Yagi H.[124]	_	_	_	_	_	_			
Yin M.[139]	_	_	_				_	_	_
TOTAL	N = 18	N = 0	N = 1	N = 60	N = 2	N = 0	N = 56	N = 24	N = 6
Total % lost data by population	**1.0% (19/1952)**			**4.8% (62/1290)**			**7.7% (86/1121)**		

† - Includes patients with less than 4 hours recording time; * - may include patients related error – author contacted for clarificiation; § - level III sleep study took place in hospital

Table 23. Bland & Altman mean differences: SDB conditions other than OSA

Simultaneous and Separate

Primary author	Simultaneous In Lab Level I vs Level III Sleep Study		Separate In Lab Level I vs Home Level III Sleep Study	
	Bland & Altman † (mean bias/hr (95% CI))	Correlation (Pearson's r, p or 95%CI)	Bland & Altman † (mean bias/hr (95% CI))	Correlation (Pearson's r, p or 95%CI)
Smith LA.[119]	+6.0/hr (95% CI -11.0, 24.0)	r=0.94 (p < 0.01)	+12.0/hr (95% CI -25.0, 49.0)	–

Simultaneous

Author	Simultaneous In Lab Level I vs Level III Sleep Study		Separate In Lab Level I vs Home Level III Sleep Study	
	Bland & Altman † (mean bias/hr (95% CI))	Correlation (Pearson's r, p or 95%CI)	Bland & Altman † (mean bias/hr (95% CI))	Correlation (Pearson's r, p or 95%CI)
Grant B.[137]	AWAITING RESPONSE	AWAITING RESPONSE	–	–
Ng S.[138]	+0.9/hr (95% CI -6.8, 8.5)	r=0.98 (p< 0.05)	–	–

Separate

Author	Simultaneous In Lab Level I vs Level III Sleep Study		Separate In Lab Level I vs Home Level III Sleep Study	
	Bland & Altman † (mean bias/hr (95% CI))	Correlation (Pearson's r, p or 95%CI)	Bland & Altman † (mean bias/hr (95% CI))	Correlation (Pearson's r, p or 95%CI)
Quintana-Gallego E.[122]	–	–	+1.6/hr (95% CI -0.57, 3.73)	–
Yin M.[139]	–	–	-3.7/hr (95% CI -29.4, 22.0)	r=0.84 (p < 0.001)

Table 24. Bland & Altman mean differences: OSA studies

Simultaneous and Separate				
Primary author	**Simultaneous In Lab Level I vs Level III Sleep Study**		**Separate In Lab Level I vs Home Level III Sleep Study**	
	Bland & Altman † (mean bias/hr (95% CI))	**Correlation (Pearson's r, p or 95%CI)**	**Bland & Altman † (mean bias/hr (95% CI))**	**Correlation (Pearson's r, p or 95%CI)**
Abraham WT.[113]	–	–	–	–
Ayappa I.[118]	+0.5/hr (95% CI -1.0, 2.0)	0.96§ (Not Reported)	+4.1/hr (95% CI 0.8, 7.3)	0.80§ (Not Reported)
Garcia-Diaz E.[112]	+2.8/hr (95% CI 0.13, 5.5)	–	+3.1/hr (95% CI -1.1, 7.5)	–
Kuna ST.[108]	–	r=0.92 (not reported)	–	r=0.75 (not reported)
Kushida CA.[120]	+8.6/hr (not reported)	–	–	–
Polese JF.[110]	–	r=0.84 (p = not reported)	–	r=0.67 (p = not reported)
Santos-Silva R.[116]	-1.1/hr (95% CI -24.9, 22.8)	r=0.89 (p < 0.0001)	-0.7/hr (95% CI -24.0, 22.6)	r=0.88 (p < 0.0001)
Tonelli de Oliveria AC, et al.	+2.6/hr (95% CI -17.7, 22.8)	0.64‡ (p < 0.001)	+3.2/hr (95% CI -28.0, 34.3)	0.53‡ (p < 0.001)

Simultaneous				
Primary author	**Simultaneous In Lab Level I vs Level III Sleep Study**		**Separate In Lab Level I vs Home Level III Sleep Study**	
	Bland & Altman † (mean bias/hr (95% CI))	**Correlation (Pearson's r, p or 95%CI)**	**Bland & Altman † (mean bias/hr (95% CI))**	**Correlation (Pearson's r, p or 95%CI)**
Bajwa I.[127]	–	r=0.95 (p = 0.001)	–	–
Candela A.[126] (manual)	+7.6/hr (95% CI -4.9, 10.4)	0.94§ (95% CI .92, 0.963)	–	–
Driver HS.[129]	+6.0/hr (Not Reported)	r=0.92 (Not Reported)	–	–
Ferre A.[125]	–	–	–	–

Simultaneous				
Primary author	**Simultaneous In Lab Level I vs Level III Sleep Study**		**Separate In Lab Level I vs Home Level III Sleep Study**	
	Bland & Altman † (mean bias/hr (95% CI))	**Correlation (Pearson's r, p or 95%CI)**	**Bland & Altman † (mean bias/hr (95% CI))**	**Correlation (Pearson's r, p or 95%CI)**
Grant B.[137]	AWAITING RESPONSE	AWAITING RESPONSE	_	_
Ng S.[138]	+0.9/hr (95% CI -6.8, 8.5)	r=0.98 (p< 0.05)	_	_
Orr WC.[121]	-0.8/hr (95% CI -29.1, 27.5)	_	_	_
Su S.[148]	-	r=0.92 (95% CI: NR)	-	-
Sullivan GE.[128]	-1.4/hr (95% CI -18.9, 16.1)	_	_	_
To KW.[123]	+7.5/hr (95% CI -9.6, 24.6)	0.24‡ (p < 0.01)	_	_
Yagi H.[124]	_	r=0.96 (not reported)	_	_

Separate				
Author	**Simultaneous In Lab Level I vs Level III Sleep Study**		**Separate In Lab Level I vs Home Level III Sleep Study**	
	Bland & Altman † (mean bias/hr (95% CI))	**Correlation (Pearson's r, p or 95%CI)**	**Bland & Altman † (mean bias/hr (95% CI))**	**Correlation (Pearson's r, p or 95%CI)**
Alonso Alvarez M.[132]	–	–	–	r=0.73 (p < .001)
Churchward TJ.[131]	–	–	–	–
Cilli A.[134]	–	–	–	–
Finkel KJ.[130]	–	–	–	–
Fordyce L.[106]	–	–	+13.5/hr (95% CI -34.9, 61.9)	r=0.84 (p = .005)
Gjevre JE.[109]	–	–	-1.7/hr¥ (95% CI -6.1, 2.7)	r=0.56 (p < .001)
Grover S.[133]	–	–	AWAITING RESPONSE	r=0.85 (p=0.067)
Hernandez L.[114]	–	–	+4.6/hr (95% CI -25.0, 34.3)	0.83* (95% CI 0.76, 0.89)
Levendowski D.[111]	–	–	-1.8/hr (95% CI -23.4, 19.8)	–
Miyata S.[107]	–	–	+4.3/hr (95% CI -4.4, 13.1)	r=0.94 (p< 0.0001)
Shrivastava D.[136]	–	–	–	–
Skomro R.[135]	–	–	–	–

Table 25. Diagnosis

Table 25. Diagnosis										
Primary Author Country	**Study Characteristics**				**Reported Respiratory events Made**					
	N	**Study Design**	**Recruitment diagnosis**	**Diagnostic Cut-off**	**Obstructive Breathing**	**Central Sleep Apnea**	**Cheyne-Stokes Respiration**	**Primary Pulmonary Disorder**	**Nocturnal Hypoxia/ Hypoventilation**	**Bronchospasm**
Abraham WT.[113] USA/UK	50	Simultaneous & Separate	SDB	RDI ≥ 15/hr	X	-	-	-	-	-
Alonso Alvarez M.[132] Spain	45	Separate	SAHS	AHI ≥ 10/hr	X	-	-	-	-	-
Ayappa I.[118] USA	102	Simultaneous & Separate	SDB	RDI ≥ 15/hr	X	-	-	-	-	-
Bajwa I.[127] USA	7	Simultaneous	SDB	-	-	-	-	-	-	-
Candela A.[126] (manual) Spain	103	Simultaneous	SRBD	AHI ≥ 10/hr	X	-	-	-	-	-
Churchward TJ.[131] Australia	20	Separate	OSA	AHI ≥ 10/hr	X	-	-	-	-	-
Cilli A.[134] Turkey	55	Separate	OSA	AHI > 5/hr	X	-	-	-	-	-
Driver HS.[129] Canada	72	Simultaneous	OSA	AHI ≥ 10/hr	X	-	-	-	-	-
Ferre A.[125] Spain	37	Simultaneous	SDB	_	X	-	-	-	-	-
Finkel KJ.[130] USA	26	Separate	OSA	AHI ≥ 5/hr	X	-	-	-	-	-
Fordyce L.[106] Canada	9	Separate	SDB	AHI ≥ 5/hr	X	-	-	-	-	-
Garcia-Diaz E.[112] Spain	65	Simultaneous & Separate	SAHS	AHI ≥ 5/hr	X	-	-	-	-	-
Gjevre JE.[109] Canada	71	Separate	OSA	AHI > 5/hr	X	-	-	-	-	-
Grant B.[137]										

Table 25. Diagnosis										
Primary Author Country	**Study Characteristics**				**Reported Respiratory events Made**					
	N	**Study Design**	**Recruitment diagnosis**	**Diagnostic Cut-off**	**Obstructive Breathing**	**Central Sleep Apnea**	**Cheyne-Stokes Respiration**	**Primary Pulmonary Disorder**	**Nocturnal Hypoxia/ Hypoventilation**	**Bronchospasm**
USA	95	Simultaneous	Sleep Apnea	AHI > 5/hr	X	X	-	-	-	-
Grover S.[133] USA	5	Separate	SRBD	_	X	-	-	-	-	-
Hernandez L.[114] Spain §	88	Separate	SAHS	AHI ≥ 10/hr	X†	-	-	-	-	-
Kuna ST.[108] USA	39	Simultaneous & Separate	Sleep Apnea	AHI ≥ 15/hr	X	-	-	-	-	-
Kushida CA.[120] USA	11	Simultaneous & Separate	OSA	-	X	-	-	-	-	-
Levendowski D.[111] USA	37	Separate	OSA	AHI > 10/hr	X	-	-	-	-	-
Miyata S.[107] Japan	18	Separate	OSAS	AHI > 5/hr	X	-	-	-	-	-
Ng S.[138] China	90	Simultaneous	OSAS	-	X	X	-	-	-	-
Orr WC.[121] USA	48	Simultaneous	-	AHI ≥ 5/hr	X	-	-	-	-	-
Polese JF.[110] Brazil	43	Simultaneous & Separate	OSA	AHI > 5/hr	X	-	-	-	-	-
Quintana-Gallego E.[122] Spain	90	Separate	SDB	AHI ≥ 5/hr	X	X	X	-	-	-
Santos-Silva R.[116] Brazil	82	Simultaneous & Separate	OSA	AHI ≥ 5/hr	X	-	-	-	-	-
Shrivastava D.[136] USA	99	Separate	SDB	AHI > 5/hr	-	-	-	-	-	-
Skomro R.[135] Canada	33	Separate	OSA	AHI > 5/hr	X	-	-	-	-	-

Table 25. Diagnosis

Primary Author Country	Study Characteristics				Reported Respiratory events Made					
	N	Study Design	Recruitment diagnosis	Diagnostic Cut-off	Obstructive Breathing	Central Sleep Apnea	Cheyne-Stokes Respiration	Primary Pulmonary Disorder	Nocturnal Hypoxia/ Hypoventilation	Bronchospasm
Smith LA.[119] UK	20	Simultaneous & Separate	SDB	A+H ≥ 10/hr	X	X	X*	-	-	-
Su S.[148] USA	60	Simultaneous (some hypertensive pts)	OSAS	RDI ≥ 15/hr	X	-	-	-	-	-
Sullivan GE.[128] Canada	34	Simultaneous	_	RDI > 5/hr	X	-	-	-	-	-
To KW.[123] Hong Kong/ China	175	Simultaneous	OSAS	AHI ≥ 5/hr	X	-	-	-	-	-
Tonelli de Oliveria AC.[117] Brazil	157	Simultaneous & Separate	OSAS	AHI ≥ 5/hr	X	-	-	-	-	-
Yagi H.[124] Japan	22	Simultaneous	SAS	AHI ≥ 5/hr	X	-	-	-	-	-
Yin M.[139] Japan	44	Separate	OSA	AHI > 5/hr	X	X	-	-	-	-
TOTAL	**1952**				**32**	**5**	**2**	**0**	**0**	**0**

OSA – Obstructive Sleep Apnea; OSAS – Obstructive Sleep Apnea Syndrome; SAHS- Sleep Apnea Hypopnea Syndrome; SAS – Sleep Apnea Syndrome; SDB – Sleep Disordered Breathing; SRBD – Sleep Related Breathing Disorder/Disturbances; * - Monitored for but n=0 diagnosed; † - Including Upper Airway Resistance Syndrome; § - Level III sleep study done in hospital.

Table 26. Patient demographics

Table 26. Patient demographics										
Primary author	**N**	**Recruitment diagnosis**	**MALE**	**FEMALE**	**AGE mean (range)**	**BMI mean (range)**	**NECK CIRCUMFERENCE**	**ESS mean (range)**	**BERLIN**	**COMORBIDITY**
Abraham WT.[113] USA/UK	50	SDB	34	16	55.5 yrs (23-78)	32.6 kg/m² (19-40 kg/m²)	-	10.6 (1-23)	-	CHF
Alonso Alvarez M.[132] Spain	45	SAHS	39	6	52.3 yrs (-)	28.7 kg/m² (-)	40.2 cm (-)	8.9 (0-19)	-	Cardiovascular Respiratory
Ayappa I.[118] USA	102	SDB	69*	28*	44.0 yrs* (19-74)	29.0 kg/m²* (19-70 kg/m²)	-	-	-	-
Bajwa I.[127] USA	7	SDB	-	-	-	-	-	-	-	-
Candela A.[126] Spain	103	SRBD	72*	20*	52.3 yrs* (24-77)	31.8 kg/m²* (22-59 kg/m²)	41.2 cm* (33-50 cm)	11.2* (2-22)	-	-
Churchward TJ.[131] Australia	20	OSA	16	4	50.0 yrs (-)	34.0 kg/m² (-)	-	-	-	-
Cilli A.[134] Turkey	55	OSA	49	6	46.0 yrs (-)	-	-	-	-	-
Driver HS.[129] Canada	72	OSA	30	42	53.0 yrs (20-71 yrs)	32.2 kg/m² (-)	-	-	-	-
Ferre A.[125] Spain	37	SDB	24	13	55.1 yrs (-)	27.3 kg/m² (-)	-	10.0 (-)	-	-
Finkel KJ.[130] USA	26	OSA	-	-	-	-	-	-	-	-
Fordyce L.[106] Canada	9	SDB	6	3	40.3 yrs (-)	25.4 kg/m² (-)	38.2 cm (-)	-	-	-
Garcia-Diaz E.[112] Spain	65	SAHS	54*	8*	54.0 yrs* (-)	30.1 kg/m²* (-)	-	12 (-)	-	Hypertension Cardiovascular
Gjevre JE.[109] Canada	71	OSA	0*	45*	52.2 yrs* (-)	35.2 kg/m²* (-)	-	9.6* (-)	-	-
Grant B.[137] USA	95	Sleep Apnea	-	-	-	-	-	-	-	-
Grover S.[133] USA	5	SRBD	-	-	- (29-59 yrs)	-	-	-	-	-
Hernandez L.[114]	88	SAHS	71	17	50.3 yrs (-)	29.6 kg/m² (-)	-	-	-	-

Table 26. Patient demographics

Primary author	N	Recruitment diagnosis	MALE	FEMALE	AGE mean (range)	BMI mean (range)	NECK CIRCUMFERENCE	ESS mean (range)	BERLIN	COMORBIDITY
Kuna ST.[108] USA	39	Sleep Apnea	39	0	54.0 yrs (-)	35.8 kg/m² (-)	-	-	-	-
Kushida CA.[120] USA	11	OSA	7	4	42.1 yrs (-)	25.96 kg/m² (-)	-	8.1 (-)	-	-
Levendowski D.[111] USA	37	OSA	-	-	-	-	-	-	-	-
Miyata S.[107] Japan	18	OSAS	18	0	51.0 yrs (-)	25.1 kg/m² (-)	-	-	-	-
Ng S.[138] China	90	OSAS	63*	17*	51.4 yrs* (-)	27.1 kg/m²* (-)	38.6 cm* (-)	9.7* (-)	-	-
Orr WC.[121] USA	48	-	-	-	-	-	-	-	-	-
Polese JF.[110]. Brazil	43	OSA	19	24	70.0 yrs (-)	30.0 kg/m² (-)	-	9.0 (-)	-	-
Quintana-Gallego E.[122] Spain	90	SDB	65*	10*	56.1 yrs* (-)	28.6 kg/m²* (-)	-	-	-	CHF
Santos-Silva R.[116] Brazil	82	OSA	46	34	47.0 yrs (-)	28.0 kg/m² (-)	36.6 cm (-)	10.4 (-)	Low: 26 High: 54	-
Shrivastava D.[136] USA	99	SDB	-	-	-	-	-	-	-	-
Skomro R.[135] Canada	33	OSA	27	5	48.3 yrs (-)	-	-	11.7 (-)	-	-
Smith LA.[119] UK	20	SDB	14	6	61.0 yrs (18-80)	29.0 kg/m² (-)	-	8.0 (-)	-	CHF
Su S.[148] USA	60	OSAS	25	35	45.2 yrs (19-74)	35.6 kg/m² (16.9-60.7 kg/m²)	-	-	-	Hypertension (n=?)
Sullivan GE.[128] Canada	34	-	-	-	-	-	-	-	-	-
To KW.[123] Hong Kong/China	175	OSAS	132	43	48.9 yrs (-)	28.7 kg/m² (-)	-	10.4 (-)	-	Hypertension Diabetes

Table 26. Patient demographics										
Primary author	**N**	**Recruitment diagnosis**	**MALE**	**FEMALE**	**AGE mean (range)**	**BMI mean (range)**	**NECK CIRCUMFERENCE**	**ESS mean (range)**	**BERLIN**	**COMORBIDITY**
Tonelli de Oliveria AC.[117] Brazil	157	OSAS	111*	38*	45.0 yrs* (-)	29.2 kg/m²* (-)	-	11.0 (-)	-	-
Yagi H.[124] Japan	22	SAS	17	5	52.9 yrs (31-74)	25.7 kg/m² (19-39kg/m²)	-	-	-	-
Yin M.[139] Japan	44	OSA	40	4	52.3 yrs (-)	26.7 kg/m² (-)	-	-	-	-
TOTAL (pooled mean)	1952		1087	433	50.8 yrs (19-78yrs)	29.7 kg/m² (16.9-70 kg/m²)	39.0 cm (33-50 cm)	10.4 (0-23)		

CHF – Stable chronic heart failure ; * - reported only for those patients who completed the study protocol

Table 27. Quality assessment tools

Table 27. Quality assessment tools					
Primary author	**Study design**	**Study Quality Assessment Tool**			
		Oxford	**QUADAS (yes)**		
			Internal validity	**External validity**	**Reporting**
Abraham WT.[113]	Simultaneous & Separate	3b	8/9	0/2	3/3
Alonso Alvarez M.[132]	Separate	1b	9/9	2/2	3/3
Ayappa I.[118]	Simultaneous & Separate	1b	8/9	2/2	3/3
Bajwa I.[127]	Simultaneous	3b	7/9	0/2	1/3
Candela A.[126] (manual)	Simultaneous	1b	8/9	2/2	3/3
Churchward TJ.[131]	Separate	1c	4/9	1/2	1/3
Cilli A.[134]	Separate	1b	4/9	1/2	0/3
Driver HS.[129]	Simultaneous	1c	6/9	1/2	1/3
Ferre A.[125]	Simultaneous	1c	5/9	1/2	1/3
Finkel KJ.[130]	Separate	1b	5/9	1/2	1/3
Fordyce L.[106]	Separate	2b	4/9	2/2	0/3
Garcia-Diaz E.[112]	Simultaneous & Separate	1c	9/9	2/2	1/3
Gjevre JE.[109]	Separate	1b	6/9	1/2	0/3

Grant B.[137]	Simultaneous	4	6/9	0/2	1/3
Grover S.[133]	Separate	2b	6/9	0/2	2/3
Hernandez L.[114]	Separate	1b	8/9	1/2	1/3
Kuna ST.[108]	Simultaneous & Separate	1c	6/9	0/2	1/3
Kushida CA.[120]	Simultaneous & Separate	3b	5/9	1/2	1/3
Levendowski D.[111]	Separate	2b	7/9	0/2	2/3
Miyata S.[107]	Separate	1b	7/9	0/2	0/3
Ng S.[138]	Simultaneous	1b	9/9	2/2	1/3
Orr WC.[121]	Simultaneous	3b	8/9	0/2	1/3
Polese JF.[110]	Simultaneous & Separate	1c	9/9	1/2	3/3
Quintana-Gallego E.[122]	Separate	1b	9/9	1/2	3/3
Santos-Silva R.[116]	Simultaneous & Separate	1b	9/9	2/2	3/3
Shrivastava D.[136]	Separate	3b	4/9	1/2	1/3
Skomro R.[135]	Separate	1b	4/9	2/2	1/3
Smith LA.[119]	Simultaneous & Separate	1b	9/9	2/2	1/3
Su S.[148]	Simultaneous	1b	9/9	2/2	2/3
Sullivan GE.[128]	Simultaneous	3b	4/9	0/2	1/3
To KW.[123]	Simultaneous	1c	9/9	2/2	1/3
Tonelli de Oliveria AC.[117]	Simultaneous & Separate	1b	9/9	2/2	2/3

Yagi H.[124]	Simultaneous	1b	8/9	1/2	1/3
Yin M.[139]	Separate	1c	6/9	1/2	1/3
TOTAL		Level 1 = 24 Level 2 = 3 Level 3 = 6 Level 4 = 4	6.9/9	1.1/2	1.4/3

Table 28. Excluded studies

Table 28. Excluded studies			
Author (Reference number)	**Year**	**Article type**	**Rationale for excluding**
Abdelghani A, Roisman G & Escourrou P.[149]	2007	Paper	Non-English language
Aetna[92]	2009	Bulletin	Background
Aetna[150]	2009	Bulletin	Background
Aetna[151]	2009	Bulletin	Background
Aetna[152]	2009	Bulletin	Background
Aetna[153]	2009	Bulletin	Background
Ahmed M, Patel N & Rosen I.[154]	2007	Paper	Background
Al Lawati N, et al.[155]	2008	Abstract	Background
Alvarez D, et al.[156]	2006	Paper	No level III device comparator
Amir O, et al.[157]	2007	Abstract	No in-lab Level I device comparator
American Thoracic Society[158]	2004	Paper	Review, background
Andrews A, et al.[159]	2005	Abstract	No in-lab Level I device comparator
Anwar A, et al.[160]	2007	Abstract	No in-lab Level I device comparator/No level III device comparator
ANZHSN[97]	2007	Paper	HTA, review, background
Ayappa I, et al.[161]	2006	Abstract	Duplicate data of included study
Bailes S, et al.[162]	2009	Paper	No in-lab Level I device comparator/No Level III device comparator
Barbanoj MJ, et al.[163]	2005	Abstract	No available outcome data
BC Health Services[164]	2004	Paper	Background
BC Health Services[16]	2005	Paper	Background
Berry R, Hill G & Kakkar R.[165]	2007	Abstract	No level III device comparator
Berry RB, et al.[166]	2008	Paper	No level III device comparator
Berthomier C, et al.[167]	2007	Abstract	No level III device comparator
BlueCross BlueShield[168]	2009	Policy	Background
Brandauer E, et al.[169]	2004	Abstract	No applicable diagnostic outcome data
Bravata, D.[170]	2009	Abstract	No applicable diagnostic outcome data
Brinkley A & de Weerd A.[171]	2004	Abstract	No level III device comparator
Brown L, et al.[172]	2008	Abstract	EEG channel validation study, no applicable diagnostic outcome data
Budhiraja R, et al.[173]	2009	Abstract	No level III device comparator
Cahan C, et al.[174]	2008	Abstract	No level III device comparator
Canadian Thoracic Society[175]	2008	Pamphlet	Background
Castronovo VE, et al.[176]	2005	Abstract	No in-lab level I device comparator
Castronovo VE, et al[176]	2005	Abstract	No in-lab level I device comparator/No level III device comparator

Table 28. Excluded studies			
Author (Reference number)	**Year**	**Article type**	**Rationale for excluding**
Cetel M & Erman MK.[177]	2005	Abstract	No level III device comparator
Champagne KA.[178]	2007	Abstract	No in-lab level I device comparator
Chen H, et al.[179]	2009	Paper	No level III device comparator
Chung F, et al.[180]	2009	Abstract	No in-lab level I device comparator/No level III device comparator
Chung F, et al[181]	2010	Paper	No level III device comparator
Cistulli P & Grunstein R.[182]	2005	Paper	Review, background
Clark AL, et al.[183]	2009	Paper	No level III device comparator
Collop N.[184]	2004	Letter	Editorial
Collop N.[185]	2006	Letter	Editorial
Collop N, et al.[103]	2007	Paper	Review, background
Collop N.[186]	2008	Paper	Review, background
Collop N.[187]	2009	Paper	Review, background
Craine BL.[188]	2009	Abstract	No applicable diagnostic outcome data
de Chazal P, et al.[189]	2007	Paper	No level III device comparator
de Chazal P, et al.[190]	2009	Paper	No level III device comparator
Delcour K, et al.[191]	2007	Abstract	No level III device comparator
Dhawan R, Liendo C & Pittman S.[192]	2004	Abstract	No in-lab level I device comparator
Dorffner G, et al.[193]	2005	Abstract	No available outcome data
Driver HS, et al.[194]	2008	Abstract	Duplicate data of included study
Driver HS, et al[195]	2009	Abstract	Duplicate data of included study
Eder DN.[196]	2008	Abstract	Background
Edinger J, et al.[197]	2004	Paper	No level III device comparator
El-kharoubi DA[198]	2007	Abstract	No level III device comparator
Enomoto M, et al.[199]	2008	Abstract	No level III device comparator
Espie CA, et al.[200]	2004	Abstract	No applicable diagnostic outcome data
Epstein L, et al.[90]	2009	Paper	Background
Escourrou P, et al.[201]	2008	Abstract	No applicable diagnostic outcome data
Ferini-Strambi L, et al[202]	2006	Abstract	No level III device comparator
Fietze IU, et al.[203]	2005	Abstract	No in-lab level I device comparator
Fleetham J, et al.[13]	2006	Paper	Background
Frassineti S, et al.[204]	2005	Abstract	No level III device comparator
Guidelines Advisory Committee[205]	2009	Paper	Background
Gay P, et al.[206]	2006	Paper	Review, background
Ghegan MD, et al.[10]	2006	Paper	Meta-analysis, review, background

Table 28. Excluded studies			
Author (Reference number)	**Year**	**Article type**	**Rationale for excluding**
Gonzalez M, et al.[207]	2008	Abstract	Respiratory effort channel validation study, no applicable diagnostic outcome data
Grewal RG, et al.[208]	2008	Abstract	No level III device comparator
Gschliesser V, et al.[209]	2004	Abstract	No applicable diagnostic outcome data
Hailey D, et al.[210]	2005	Paper	HTA, review, background
Hailey D, et al.[211]	2006	Paper	Review, background
Hamburger H, Suraiya S & Harten L.[212]	2005	Abstract	No in-lab level I device comparator/No level III device comparator
Hamburger H, Suraiya S & Harten L.[213]	2005	Abstract	No level III device comparator
Hamburger H, Suraiya S & Harten L.[214]	2005	Abstract	Duplicate
Harrell DB, Riggins MA & Swanson R.[215]	2005	Abstract	No in-lab level I device comparator
Hedner J, et al.[216]	2008	Abstract	No in-lab level I device comparator/No level III device comparator
Hein H, Warmuth R & Kuchler G.[217]	2007	Abstract	No in-lab level I device comparator
Heogh T, et al.[218]	2009	Abstract	No level III device comparator
Herscovici S, et al.[219]	2008	Abstract	No level III device comparator
Higgins S, et al.[220]	2008	Abstract	No level III device comparator
Hlavac M.[221]	2006	Paper	Background
Hong S, et al.[222]	2005	Abstract	No level III device comparator
Htwe ZW, et al.[223]	2008	Abstract	No in-lab level I device comparator/No level III device comparator
Institute for Clinical Systems Improvement[27]	2008	Paper	Background
Inoue A.[224]	2007	Abstract	No level III device comparator
Jelic S.[225]	2008	Paper	Review, background
Jobin V, et al.[226]	2007	Paper	No in-lab level I device comparator
Jokic R, et al.[227]	2007	Abstract	No applicable diagnostic outcome data
Joshi JM.[228]	2008	Paper	Review, background
Jennum P, et al.[229]	2004	Abstract	HTA, review, background
Jennum P, et al.[230]	2005	Abstract	Review, background
Jennum P, et al[231]	2007	Paper	Review, background
Jeroncic A, et al.[232]	2008	Abstract	Background
Kehoe TJ.[233]	2005	Letter	Editorial
Keller-Wossidlo H & Suter N.[234]	2004	Abstract	Background
Kemlink D, et al.[235]	2004	Abstract	No applicable diagnostic outcome data
Khan J, Shaman Z & Auckley D.[236]	2006	Abstract	Background
Kobayashi T, et al.[237]	2004	Abstract	No level III device comparator
Kohsaka M, Noguchi S & Fukuda N.[238]	2008	Abstract	No applicable diagnostic outcome data
Kosseifi SG, et al.[239]	2006	Abstract	No applicable diagnostic outcome data

Table 28. Excluded studies			
Author (Reference number)	**Year**	**Article type**	**Rationale for excluding**
Kushida CA, et al.[240]	2005	Paper	Background
Landon C.[241]	2006	Abstract	Background
Lee-Chiong TL & Magalang U.[242]	2005	Paper	Review, background
Levendowski D, et al.[243]	2007	Abstract	No level III device comparator
Levendowski DJ, et al.[244]	2008	Paper	No level III device comparator
Lieching TN, et al.[245]	2004	Paper	No level III device comparator
Littner MR.[246]	2005	Paper	Review, background
Littner MR, et al.[247]	2005	Paper	Background
Littner M, et al.[19]	2006	Paper	Background
Lubit RH, Bonds CL & Lucia MA.[248]	2009	Paper	Background
MacDermot SM, et al.[249]	2006	Abstract	No level III device comparator
MacDonald M, et al.[250]	2004	Abstract	No level III device comparator
Mack DC, et al.[251]	2006	Abstract	No level III device comparator
Madani M, et al.[252]	2007	Paper	Review, background
Madathil SC, et al.[253]	2008	Abstract	No in-lab level I device comparator
Makarie Rofail L, et al.[254]	2008	Abstract	No level III device comparator
Makarie Rofail L, et al.[255]	2008	Abstract	No level III device comparator
Masdeu MJ, et al.[256]	2008	Abstract	No applicable diagnostic outcome data
Masdeu MJ, et al.[257]	2010	Paper	No applicable diagnostic outcome data
Mattei A, Tabbia G & Baldi S.[258]	2004	Paper	Background
McEvoy RD, et al.[259]	2008	Abstract	No level III device comparator
McInrue E, et al[260]	2009	Abstract	No applicable diagnostic outcome data
McKinley M.[261]	2008	Abstract	Background
Means MK, et al.[262]	2004	Abstract	No applicable diagnostic outcome data
Means MK, et al.[263]	2005	Abstract	No applicable diagnostic outcome data
Michaelson PG, et al.[264]	2006	Paper	No level III device comparator
Middleton B, et al.[265]	2004	Abstract	No level III device comparator
Miles L, et al.[266]	2004	Abstract	No applicable diagnostic outcome data
Miyata S, et al.[267]	2007	Paper	No level III device comparator
Modarres-zadeh M, Johnson NL & Redline S.[268]	2006	Abstract	No level III device comparator
Morgenthaler T, et al.[269]	2007	Paper	Background
Moscovitch A, et al.[270]	2005	Abstract	No applicable diagnostic outcome data
Mueller A, et al.[271]	2006	Paper	No level III device comparator

Table 28. Excluded studies			
Author (Reference number)	**Year**	**Article type**	**Rationale for excluding**
Mulgrew AT, et al.[52]	2007	Paper	No level III device comparator
Murphie P, et al.[272]	2008	Abstract	No applicable diagnostic outcome data
Murphie P, Rafferty P & Little S.[273]	2009	Poster	No in-lab level I device comparator/No level III device comparator
Nakayama-Ashida Y, et al.[274]	2008	Paper	No in-lab level I device comparator
National Guideline Clearinghouse[275]	2009	Summary	Background
National Guideline Clearinghouse[276]	2009	Summary	Background
NICE[277]	2008	Paper	HTA, review, background
Nogueira F, et al.[278]	2008	Abstract	No in-lab level I device comparator
Nogueira F, et al.[279]	2009	Abstract	No in-lab level I device comparator
Norman M, Edwards N & Sullivan C.[280]	2007	Abstract	No in-lab level I device comparator
Overland B, et al.[281]	2004	Paper	No level III device comparator
Overland B, Arke H & Skatvedt O.[282]	2006	Abstract	No level III device comparator
OHTAC[283]	2006	Paper	HTA, review, background
Oldenburg O, Lamp B & Horstkotte D.[284]	2006	Letter	Editorial
Olsen EJ, Morgenthaler TI, Park JG.[285]	2004	Abstract	Background
Ontario Medical Advisory Secretariat[4]	2006	Paper	HTA, review, background
Palombini LO, Garbuio SA & Tufik S.[286]	2006	Abstract	No level III device comparator
Palombini LO, Garbuio SA & Tufik S.[287]	2007	Abstract	No level III device comparator
Passero M, et al.[288]	2007	Abstract	No level III device comparator
Patel MR, et al.[289]	2007	Paper	Case report
Patil SP, et al.[290]	2007	Paper	Review, background
Pelayo R, Yuen K & Slack S.[291]	2006	Abstract	No in-lab level I device comparator
Penders J, et al.[292]	2004	Abstract	No level III device comparator
Pepin JL, et al.[293]	2009	Paper	No level III device comparator
Peppard PE & Young T.[2]	2006	Abstract	Background
Phurrough S, et al.[294]	2008	Paper	Background
Pittman SD, et al.[295]	2004	Paper	No level III device comparator
Planes C, et al.[296]	2009	Paper	No in-lab level I device comparator
Popovic D, et al.[297]	2009	Paper	Respiratory effort channel validation study, no applicable diagnostic outcome data
Ramachandran SK & Josephs LA.[298]	2009	Paper	Meta-analysis, review, background
Raviv G.[299]	2006	Letter	Editorial
Rice KL, et al[300]	2006	Paper	No applicable diagnostic outcome data
Roebuck TJ, et al.[301]	2008	Abstract	No level III device comparator
Roehrs JD, Park K & Jacobs P.[302]	2009	Abstract	No level III device comparator

Table 28. Excluded studies			
Author (Reference number)	**Year**	**Article type**	**Rationale for excluding**
Rosenzweig E, et al.[303]	2004	Abstract	No in-lab level I device comparator/No level III device comparator
Roehrs JD, Raza MH & McHugh M.[304]	2005	Abstract	No level III device comparator
Roehrs JD, et al.[305]	2006	Abstract	No applicable diagnostic outcome data
Russo R, et al.[306]	2004	Abstract	No level III device comparator
Sadamoto Y, Miyazaki S & Yamaguchi Y.[307]	2009	Abstract	No level III device comparator
Schlosshan D & Elliot MW.[308]	2004	Paper	Review, background
Schneider H.[309]	2008	Abstract	Respiratory flow channel validation study, no applicable diagnostic outcome data
Schweitzer M, et al.[310]	2004	Abstract	No level III device comparator
Seelall V, et al.[311]	2007	Abstract	No in-lab level I device comparator
Shah N, Roux F & Mohsenin V.[312]	2006	Paper	Review, background
Shambroom J, Johnstone F & Fabregas SE.[313]	2009	Abstract	No level III device comparator
Sharif Z, et al.[314]	2007	Abstract	No level III device comparator
Siegel T, et al.[315]	2008	Abstract	No in-lab level I device comparator/No level III device comparator
Silber M.[316]	2007	Letter	Editorial
Singh A, et al.[317]	2008	Paper	No level III device comparator
Silva RS, et al.[318]	2008	Abstract	Duplicate data of included study
Skjodt NM, Wong EY & Mayers I.[319]	2005	Abstract	Background
Skomro R, et al.[320]	2006	Abstract	No applicable diagnostic outcome data
Skomro R, et al.[321]	2008	Abstract	No applicable diagnostic outcome data
Skomro R, et al.[322]	2010	Paper	No applicable diagnostic outcome data
Smith LA, et al[323]	2005	Abstract	Duplicate data of included study
Smits MG, et al.[324]	2005	Abstract	No level III device comparator
Spratt GK, et al.[325]	2008	Abstract	No in-lab level I device comparator
Sokolovsky A, et al.[326]	2008	Abstract	No level III device comparator
Stepnowsky CJ, Orr WC & Davidson TM.[327]	2004	Abstract	No in-lab level I device comparator
Stores G.[328]	2006	Paper	Background
Sun F, et al.[329]	2008	Abstract	No in-lab level I device comparator
Swartz S, et al.[330]	2007	Abstract	No applicable diagnostic outcome data
SzternakN & Szakacs Z.[331]	2008	Abstract	No level III device comparator
Szyszko A, et al.[332]	2009	Paper	No level III device comparator
Takaya H.[333]	2005	Abstract	No level III device comparator
Thakkar K & Yao M.[334]	2007	Paper	Background
Thurnheer R.[335]	2006	Letter	Editorial
Tice JA.[7]	2009	Paper	HTA, review, background

Table 28. Excluded studies			
Author (Reference number)	**Year**	**Article type**	**Rationale for excluding**
Tiihonen P, et al.[336]	2009	Paper	No in-lab level I device comparator
Tiihonen P, et al.[337]	2009	Paper	Level III device not commercially available
Tiihonen P, et al.[338]	2009	Paper	Level III device not commercially available
Todros K, et al[339]	2004	Abstract	No level III device comparator
Townsend D, et al.[340]	2005	Abstract	No level III device comparator
Townsend D, et al.[341]	2007	Paper	No level III device comparator
Trajanovic NN, et al.[342]	2004	Abstract	No level III device comparator
Turci M, van den Bossche RAS & de Weerd AW.[343]	2004	Abstract	No level III device comparator
Undevia NS, Giglio P & Spire JC.[344]	2004	Abstract	Background
Valerio TD & Zallek SN.[345]	2004	Abstract	No in-lab level I device comparator/No level III device comparator
Vetrugno R, et al.[346]	2004	Paper	No level III device comparator
Ward H & Dowson LJ.[347]	2008	Abstract	No in-lab level I device comparator/No level III device comparator
Watkins MR, et al.[348]	2009	Paper	No level III device comparator
Weimer S, et al.[349]	2006	Abstract	No level III device comparator
Weimer SM & Martin CS.[350]	2008	Abstract	No in-lab level I device comparator
Weinreich G, et al.[351]	2009	Paper	No level III device comparator
West S, McBeath H, & Stradling J.[352]	2009	Paper	Background
Westbrook PR, et al.[353]	2004	Abstract	No level III device comparator
Westbrook PR, et al.[354]	2005	Abstract	No level III device comparator
Westbrook P, et al.[355]	2007	Abstract	No in-lab level I device comparator
Westbrook PR, et al.[356]	2007	Paper	No level III device comparator
Whitelaw WA, Brant RF & Flemons WW.[357]	2005	Paper	No level III device comparator
Wright KP, et al.[358]	2008	Abstract	No level III device comparator
Yamaguchi Y & Taketa Y.[359]	2007	Paper	No level III device comparator
Yasuda Y, et al.[360]	2005	Paper	No in-lab level I device comparator/No level III device comparator
Yin M, et al[361]	2005	Paper	No in-lab level I device comparator
YounT & Yoon J.[362]	2008	Abstract	No level III device comparator
Zacharia A, et al.[363]	2007	Paper	No level III device comparator
Zoller R, et al.[364]	2008	Abstract	No level III device comparator
Zou D, et al.[365]	2005	Abstract	No level III device comparator
Zou D, et al.[366]	2006	Paper	No level III device comparator

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