Australian Government

Department of Health and Ageing

Australia and New Zealand Horizon Scanning Network

ANZHSN

AN INITIATIVE OF THE NATIONAL, STATE AND TERRITORY GOVERNMENTS OF AUSTRALIA AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

SleepStrip® for diagnosis of obstructive sleep apnoea

August 2008

AHTA

Adelaide Health Technology Assessment

ISBN
Publications Approval Number:

Electronic copies can be obtained from http://www.horizonscanning.gov.au

Enquiries about the content of the report should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

DISCLAIMER: This report is based on information available at the time of research cannot be expected to cover any developments arising from subsequent improvements health technologies. This report is based on a limited literature search and is not a definitive statement on the safety, effectiveness or cost-effectiveness of the health technology covered.

The Commonwealth does not guarantee the accuracy, currency or completeness of the information in this report. This report is not intended to be used as medical advice and intended to be used to diagnose, treat, cure or prevent any disease, nor should it be used therapeutic purposes or as a substitute for a health professional's advice. The Commonwealth does not accept any liability for any injury, loss or damage incurred by use of or reliance the information.

The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from departments in all states and territories, the Australia and New Zealand governments; and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by Adrian Purins, Linda Mundy and Professor Janet Hiller from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Discipline of Public Health, School of Population Health and Clinical Practice, Mail Drop 545, University of Adelaide, Adelaide, SA, 5005.

PRIORITISING SUMMARY

REGISTER ID: **000394**

NAME OF TECHNOLOGY: **SLEEPSTRIP® FOR DIAGNOSIS OF OBSTRUCTIVE SLEEP APNOEA**

PURPOSE AND TARGET GROUP: **HOME TESTING OF PATIENTS FOR OBSTRUCTIVE SLEEP APNOEA (OSA)**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☒	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number[1]
☐	No	
☐	Not applicable	

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Israel	✓		
Belgium	✓		
Germany	✓		
USA	✓		
UK	✓		

IMPACT SUMMARY:

Accutest markets the SleepStrip® for the purpose of home testing for obstructive sleep apnoea. The device is available from several Australian distributors through website based ordering. General practitioners direct their patients to the supplier's website to order the device and the patient performs the test at home. Results are analysed by the GP and further action taken if necessary.**BACKGROUND**

Obstructive sleep apnoea (OSA) is a common disorder that is under-diagnosed in the Australian population (Grunstein & Phillips 2008). OSA is defined as more than five

[1] The Australian distributor website claims the device is TGA approved. No entry in the TGA register could be found for this device.

obstructed breathing events per hour of sleep. These breathing interruptions cause arousals from sleep affecting the quality of sleep obtained.

The gold standard of OSA diagnosis is overnight polysomnography (PSG) in a sleep laboratory. Given the large undiagnosed OSA population, the demand for laboratory PSG exceeds availability. Additionally given the resources and time required the cost of these tests is high. Therefore there is a demand for cheap, easy to perform and accurate sleep analyses.

The apnoea/hypopnoea index (AHI) is a commonly used measure for diagnosing OSA. Apnoea is a period of breathing cessation and hypopnoea is a period of reduced breathing. AHI is the number of apnoea and hypopnoea events that occur per hour of sleep. An AHI of ≤5 is considered normal. OSA is defined as an AHI level of >5 (Grunstein & Phillips 2008).

The SleepStrip is a small self contained electronic device that can measure the flow of air from the mouth and nose. Electronics embedded within the device record breathing and any periods of apnoea or hyponoea are registered. The SleepStrip is attached to the face by adhesive pads and the subject sleeps in their own bed as usual (Figures 1 and 2).

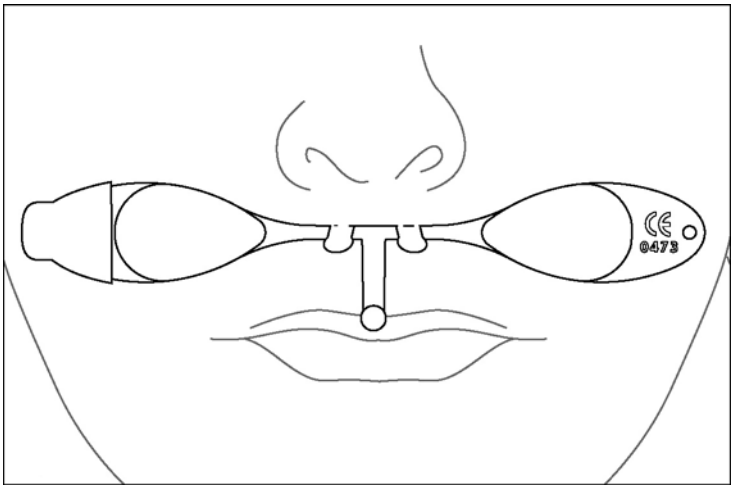

Figure 1 SleepStrip positioned on the face (NUTECH Pty Ltd 2008)

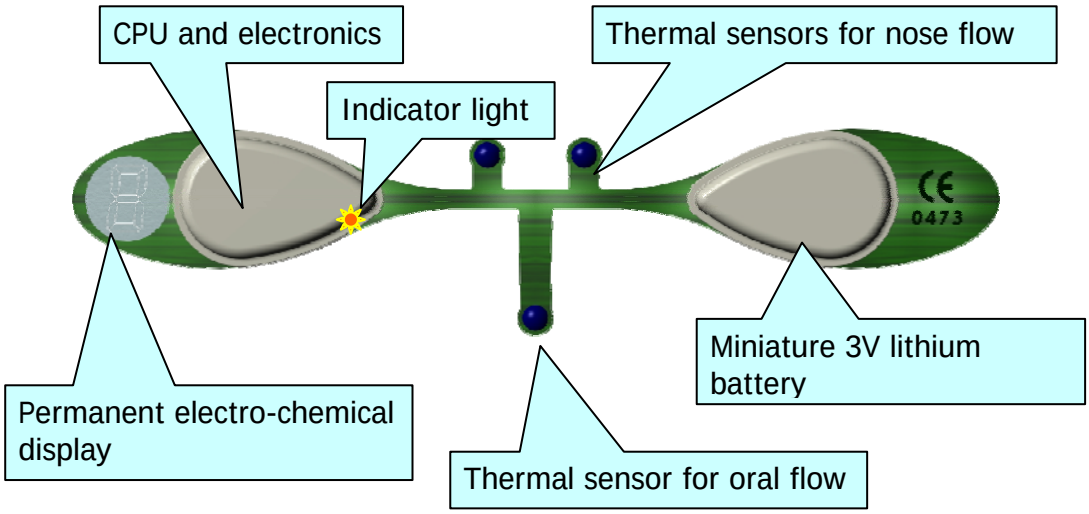

Figure 2 SleepStrip features (NUTECH Pty Ltd 2008)

In the first 20 minutes the patient is assumed to be awake and normal breathing rate is calibrated. After 20 minutes the study automatically begins and must continue for at least four hours. After the device is removed from the face, the SleepStrip registers what appears to be a long apnoea (ie no breathing) and this signals that the study has been terminated and recording stops. The device then displays a reading as shown in **Error! Reference source not found.**. The device can then be taken by the patient to their medical practitioner who will advise them on further action if necessary.

Table 1 Readout from SleepStrip after overnight usage

Reading	Meaning
0	< 15 AHI = Normal
1	15 ≤ AHI < 25 = Mild OSA
2	25 ≤ AHI < 40 = Mild OSA
3	40 ≤ AHI = Severe OSA
E	Study short or low flow error

CLINICAL NEED AND BURDEN OF DISEASE

If OSA is defined as ≥5 AHI, then 25 per cent of middle-aged men and 10 per cent of women have the disorder. In addition, 93 per cent of females and 82 per cent of males with moderate to severe SAS are undiagnosed (Young et al 1997; Young et al 2002). Being under-diagnosed, OSA prevalence is unknown but estimates of OSA syndrome[2] are around four per cent in men and two per cent in women (Stradling & Davies 2004). These estimates correlate to 427,400 men and 213,700 women in Australia being affected by this severe form of OSA[3]. The impact of OSA is large and may include links with excessive daytime sleepiness and impaired cognitive function,

[2] OSA syndrome is defined as an AHI >5 and significant daytime sleepiness
[3] Based on a December 2007 Australian population of 21,370,000 (ABS 2008)

which has many subsequent effects including workplace and traffic accidents. Additionally there are data that OSA is linked with a higher risk of cardiovascular disease (Grunstein & Phillips 2008). Estimated costs of sleep disorders in Australia, in which OSA plays a large role, are around $7 billion annually (Hillman et al 2006).

Although it is difficult to determine the prevalence, it has been estimated that 2-4 per cent of the New Zealand population suffer from OSA. Between 0.5 -1 per cent will suffer from moderate to severe OSA and are therefore at increased risk of excessive daytime sleepiness, respiratory failure, cardiomyopathy, hypertension, ischaemic heart disease and cardiovascular disease. In addition, OSA appears to be more prevalent and severe in Maori and Pacific Island populations (TSANZ 2004).

DIFFUSION

The SleepStrip is available on several websites that market to Australia. Critical Assist distributes the device in the Australian market. Critical Assist is currently marketing to general practitioners who may direct their patients to the Critical Assist website to purchase the SleepStrip. Pharmacy based distribution was thought to be too costly by Critical Assist.

COMPARATORS

The gold standard for diagnosis of OSA is the laboratory-based, overnight polysomnography (PSG). The advantages of laboratory based studies versus home studies are the higher quality of data obtained (more data channels monitored and verification that the patient slept) and that alternative diagnoses can be made for conditions other than OSA. Additionally, split-night studies allow treatments to be tailored for the patient during the latter part of the night if a positive OSA diagnosis has occurred. The disadvantages of laboratory PSG are the high relative costs, the long waiting lists for access to a test, the artificial environment (which may alter the patients' sleep characteristics) and that patients often favour home based tests (Douglas 2003). The SleepStrip monitors only a single parameter (rate of breathing) and returns a single digit code depending on the internal calculations of the device. Despite this simplistic design, if shown to be effective, the low cost and easy home use would make the SleepStrip an attractive triage diagnostic device.

SAFETY AND EFFECTIVENESS ISSUES

The SleepStrip was compared to the gold standard, laboratory PSG, in three studies. Two were based on SleepStrip testing in sleep laboratories concurrent with PSG and the third study investigated home testing using postal delivery of the SleepStrip to patients followed by laboratory PSG.

The SleepStrip was used in a study on a population of 402 suspected OSA patients that was performed in three centres from Israel, Belgium and Germany. Of the 402 patients only 208 were eligible for analysis due to less than five hours of recording

with the SleepStrip (88 cases) or SleepStrip malfunctions (31 cases) or both malfunctions and insufficient recording (11 cases). The SleepStrip testing was performed at the same time as normal laboratory PSG. Conventional AHI scores were obtained from the laboratory PSG testing. In addition the AHI score was determined by the SleepStrip. The SleepStrip used in this study gave three grades of OSA severity: mild OSA (AHI > 10), moderate OSA (>20 AHI) and severe OSA (>40 AHI). The correlation between the AHI scores obtained from the SleepStrip and laboratory PSG is shown in Table 2.

Table 2 Correlation of the SleepStrip score to the laboratory PSG determined AHI[4]

SleepStrip score					
Mild OSA(AHI > 10)		Moderate OSA(>20 AHI)		Severe OSA(>40 AHI)	
Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
0.86	0.57	0.80	0.70	0.80	0.86

The overall correlation between SleepStrip AHI and laboratory PSG AHI was r = 0.73 (p<0.001). The SleepStrip was more accurate at diagnosing severe cases of OSA (Shochat et al 2002) (Level III-2 diagnostic evidence).

A second study comparing SleepStrip AHI to laboratory PSG was performed on 37 prospectively recruited subjects. In contrast to the above study Pang et al (2006) reported poor correlation between the AHIs from SleepStrip and Laboratory PSG as summarised in Table 3. In this study the SleepStrip used recorded three grades of OSA severity corresponding to mild OSA (AHI > 15), moderate OSA (>25 AHI) and severe OSA (>40 AHI). This corresponds to the current diagnostic parameters of the SleepStrip and is slightly modified from SleepStrip in the Shochat et al (2002) study. The small size of this study meant that the number of subjects diagnosed in each category was even smaller. The Sleep strip performed poorly when diagnosing severe OSA. The small study size meant there was no significant difference between the tests for diagnosing mild or moderate OSA, however, the sensitivity of the SleepStrip was poor for al cut-off levels. The SleepStrip was able to rule out those who did not have severe OSA (specificity 95%) (Level III-2 diagnostic evidence).

Table 3 Correlation of the SleepStrip score to the laboratory PSG determined AHI

SleepStrip score					
Mild OSA (AHI > 15)		Moderate OSA (>25 AHI)		Severe OSA (>40 AHI)	
Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
0.546	0.700	0.438	0.813	0.330	0.950
p = 0.26		p = 0.25		p = 0.05	

[4] P values not given for this data

A third study investigated the feasibility of using the SleepStrip for home based testing using the postal service as the means for device delivery. A SleepStrip device, instructions, reply paid envelope, and a standard screening questionnaire were sent to 48 patients referred to a sleep centre for OSA diagnosis. Of the eligible subjects 30 returned their SleepStrip after testing. Of these, 17 (57 %) had valid SleepStrip determined AHI scores. Laboratory PSG was performed on 15/30 patients and home PSG was performed on the remaining 15. Moderate to severe OSA (AHI ≥ 20) was diagnosed in 12/30 patients by home or laboratory PSG. The SleepStrip recorded a valid reading for seven of these12 patients and only in two cases did the SleepStrip correctly diagnose the patient as having moderate to severe OSA (Hollingworth et al 2003) (Level III-2 diagnostic evidence).

The SleepStrip results reviewed here are disparate and this can partly be explained by the different study environments. Additionally, included studies used different AHI thresholds for diagnosing the OSA severity categories. This may be significant in the light of the conflicting efficacy evidence. The SleepStrip performed well in a controlled environment in a medium sized population. In contrast, the SleepStrip performed poorly in a smaller laboratory based study and when patients were self testing at home, patient compliance and test validity were very low.

COST IMPACT

The SleepStrip will be available for approximately $AUD50 plus GST with discounts for bulk orders. No other equipment is required to use the device (Critical Assist personal communication).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

No issues were identified/raised in the sources examined.

SUMMARY OF FINDINGS

All studies reviewed here compared the SleepStrip to Laboratory PSG. The results were disparate with the largest study concluding that the SleepStrip provided a positive solution to home sleep testing. The remaining two studies found that the device performed poorly. Further larger studies in the home environment need to be performed for the SleepStrip to be considered a viable option for patient administered OSA screening.

HEALTHPACT ACTION:

The MSAC are currently considering and application for the assessment of home sleep studies for the diagnosis of obstructive sleep apnoea. HealthPACT have

recommended that this summary be referred to the MSAC Advisory Panel and that further assessment of this technology by HealthPACT is no longer warranted.

NUMBER OF INCLUDED STUDIES

Total number of studies

Level III-2 diagnostic evidence 3

REFERENCES:

Douglas, N. J. (2003). 'Home diagnosis of the obstructive sleep apnoea/hypopnoea syndrome', *Sleep Med Rev,* 7 (1), 53-59.

Grunstein, R. R. & Phillips, C. L. (2008). 'Obstructive sleep apnoea--getting to the heart of the matter?' *Med J Aust,* 188 (6), 324-325.

Hillman, D. R., Murphy, A. S. & Pezzullo, L. (2006). 'The economic cost of sleep disorders', *Sleep,* 29 (3), 299-305.

Hollingworth, L., Tooby, M. et al (2003). 'Practicality of the Sleepstrip in postal screening for obstructive sleep apnoea', *J Sleep Res,* 12 (2), 157-159.

NUTECH Pty Ltd (2008). *Sleep strip presentation* [Internet]. Available from: [Accessed 22nd July].

Pang, K. P., Dillard, T. A. et al (2006). 'A comparison of polysomnography and the SleepStrip in the diagnosis of OSA', *Otolaryngol Head Neck Surg,* 135 (2), 265-268.

Shochat, T., Hadas, N. et al (2002). 'The SleepStrip: an apnoea screener for the early detection of sleep apnoea syndrome', *Eur Respir J,* 19 (1), 121-126.

Stradling, J. R. & Davies, R. J. (2004). 'Sleep. 1: Obstructive sleep apnoea/hypopnoea syndrome: definitions, epidemiology, and natural history', *Thorax,* 59 (1), 73-78.

TSANZ (2004). *Standards for adult respiratory and sleep services in New Zealand,* Thoracic Society of Australia and New Zealand (New Zealand Branch). http://www.moh.govt.nz/moh.nsf/pagesmh/3756.

Young, T., Evans, L. et al (1997). 'Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women', *Sleep,* 20 (9), 705-706.

Young, T., Peppard, P. E. & Gottlieb, D. J. (2002). 'Epidemiology of obstructive sleep apnea: a population health perspective', *Am J Respir Crit Care Med,* 165 (9), 1217-1239.

SEARCH CRITERIA TO BE USED:

Polysomnography
Prospective Studies
Sleep Apnea, Obstructive/ diagnosis