



'Defining Life's Signals'



Designed and Manufactured in Victoria, Australia



Somfit®
Somfit^{PRO}
A breakthrough for
Primary Care Sleep Testing.



Somfit® is a wearable device for collecting patients' physiological data, primarily for use in assisting medical professionals to diagnose sleep disorders.

Somfit can be used as a single-night screening device if the GP suspects OSA but the patient does not meet the criteria for Medicare Benefits Schedule Item 12250. Somfit® is a non-Medicare Australia reimbursed device.

Somfit® can also be used for a seven-night investigation (non Medicare reimbursed) where Insomnia or a Circadian Rhythm disorder is suspected. This investigation is reviewed and reported by an Australian Sleep Physician.

Small, simple to use and comfortable

Ease of use and comfort were the main considerations in the design of the Somfit®.

The Somfit® system comprises of the Somfit® device, a disposable adhesive electrode and a phone app.



A single-use adhesive-gel electrode. This is worn on the patient's forehead and collects the physiological data.



The Somfit® device, is pressed onto the electrode. The Somfit houses the sensors and transmits the data to the Somfit App via Bluetooth. Somfit can collect up to 12 hours of data.



The Somfit® App
This is used to control the Somfit and to transmit the study data to be processed.



The Profusion Nexus360™ cloud-based data management and reporting system.
Data is HIPPA compliant, stored securely in Australia. Sleep reports are reviewed by Australian Sleep Physicians.
• Reports available within 48 hours of study completion.



Measure sleep directly - only possible with direct measurement of EEG

Exact data about sleep habits can only be achieved through the measurement of brain dynamics or electroencephalography (EEG) required to analyse the stages of sleep.

Somfit® Measures

Automatic Hypnogram

EEG (1ch)

EMG (1ch, measured)

EOG (2ch, measured)

Blood Oxygen Sat (SpO₂)

Pulse (Heart Rate) & HRV

Peripheral Arterial Tone (PAT)

Movement

Head Position

Snore

Ambient Light

Automatic Stage Light Off/On

Somfit® PRO

Somfit® PRO is a system that adds the RespiFit™ module to the Somfit® to provide additional clinical data.

Somfit® PRO is used as a single-night study device if the GP suspects OSA, using Medicare billing code 12250.

The study is reviewed and reported by an Australian Sleep Physician.



Somfit® Pro Additional Measures

ECG (1 channel - optional)

Thoracic respiratory effort (inductive band)

Abdominal respiratory effort (inductive band- optional)

Airflow

Respiration Rate

Body position

Movement

Somfit® and Somfit® Pro Comparison chart

| | Medicare Benefits Schedule Item 12250 OSA Study | Single-night Study (Non-Medicare) | Seven-night Study (Non-Medicare) |
|---|---|---|---|
| Applicable Device | | | |
| Medicare Reimbursed | ✓ | ✗ | ✗ |
| Sleep Physician Reviewed & Reported | ✓ | ✗ | ✓ |
| Duration | Overnight - at least 8 hours of sleep | 4 to 8 hours of sleep | 7 nights of 4 to 8 hours of sleep per night |
| Self-applied | ✓ | ✓ | ✓ |
| Home-based | ✓ | ✓ | ✓ |
| Used for the following Main Sleep Disorders | OSA | Suspected OSA | Insomnia Circadian Rhythm Disorder |

Costs of Inadequate Sleep in Australia¹

Australia Economic Costs of Inadequate Sleep:



Primary care focused approach to OSA management

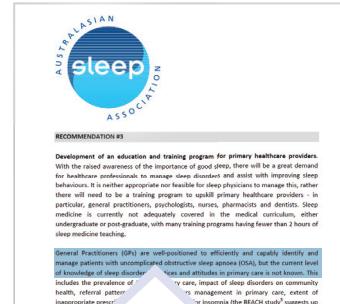
GPs are now required to provide preliminary assessment of individuals that they suspect of having OSA prior to patient referral for a Medicare Benefits Schedule subsidised PSG.

Increasing OSA prevalence has significantly increased waiting times for both assessment and care, further diminishing the fair and equitable access especially for those impacted by socioeconomic and geographic factors in the Australian health system.

Interest is thus growing for the role of primary care in the management of OSA.³



'Randomised controlled trials^{4,5,6,7} have demonstrated primary care management of OSA is not inferior to specialist-led care, promoting a more primary care focused approach to OSA management – a domain currently managed within a sleep specialist setting.'



'General practitioners (GPs) are best placed to manage the sleep health of patients, along with the comorbidities that are often associated and present. It is important that an evidence-based, patient-centred approach is used for diagnosis and management.'

'General Practitioners (GPs) are well-positioned to efficiently and capably identify and manage patients with uncomplicated obstructive sleep apnoea (OSA), but the current level of knowledge of sleep disorders, practices and attitudes in primary care is not known.'

'The management of uncomplicated sleep issues and disorders must more closely involve primary care and allied and community health workers. However, in order to do this there is an urgent need for improved education and training, as well as clear clinical guidelines for health professionals working in primary care and the community. This will ensure efficient and effective management of this major health problem in Australia.'

1. https://www.sleephealthfoundation.org.au/files/Asleep_on_the_job/Asleep_on_the_Job_SHF_report-WEB_small.pdf
2. Heinzer R, Vat S, Marques-Vidal P, Martí-Soler H, Andries D, Tobback N, et al. Prevalence of sleep-disordered breathing in the general population: the HypnoLaus study. Lancet Respir Med. 2015;3(4):310–8
3. Grivell N, Haycock J, Redman A, et al. Assessment, referral and management of obstructive sleep apnea by Australian general practitioners: a qualitative analysis. BMC Health Serv Res. 2021; 1248 (2021). <https://doi.org/10.1186/s12913-021-07274-7>

4. Chai-Coetzer CL, Antic NA, Rowland LS, Reed RL, Esterman A, Catchpole PG, et al. Primary care vs specialist sleep center management of obstructive sleep apnea and daytime sleepiness and quality of life: a randomized trial. JAMA. 2013;309(10):997–1004.
5. Sanchez-de-la-Torre M, Nadal N, Cortijo A, Masa JF, Duran-Cantolla J, Valls J, et al. Role of primary care in the follow-up of patients with obstructive sleep apnoea undergoing CPAP treatment: a randomised controlled trial. Thorax. 2015;70(4):346–52.

6. Tarraubella N, Sánchez-de-la-Torre M, Nadal N, De Battie J, Benitez I, Cortijo A, et al. Management of obstructive sleep apnoea in a primary care vs sleep unit setting: a randomised controlled trial. Thorax. 2018;73(12):1152.
7. Sánchez-Quiroga M, Barbe F, Barca J, Masa J, Corral J, Gómez-de-Terreros F, et al. Primary Care Physicians Can Comprehensively Manage Patients with Sleep Apnea: A Noninferiority Randomized Controlled Trial. Am J Respir Crit Care Med. 2018;198(5):648–56.

