A Growing Clinical Need

Sleep apnoea is a common sleep disorder which effects approximately 2-4% of the world’s population between the ages of 30-60 years [1]. In Ireland alone, there are an estimated 60,000 people who are currently affected, with over 90% of these being undiagnosed [2].

Apnoic events are characterised by either pauses in breathing (apnoea) or episodes of shallow breathing during sleep (hypopnoea). Apnoic events can last from a few seconds to several minutes and may occur 5 to 30 times or more in a single hour.

The delayed diagnosis of sleep apnoea can increase:

- the risk of high blood pressure, heart attack, stroke, obesity, and diabetes
- the risk of, or worsening, heart failure
- the risk of arrhythmias or irregular heartbeats
- the chance of having work-related accidents
- the risk of road traffic accidents

The cost to the Irish healthcare system from delayed diagnosis of sleep apnoea can cost the Irish Healthcare system up to 0.8% of Ireland’s Gross Domestic Product (valued at €1.9 billion in 2014 [3]).

Addressing the Need

The two main challenges, when attempting to address the growing undiagnosed population using today’s sleep apnoea monitoring techniques, are:

- the large expense of undertaking the “gold standard” full sleep lab study to both the patient and the healthcare system, and
- the waiting time for patients to undertake the test (> 1 year)

As only a small percentage of the subjects tested each year are found to suffer from sleep apnoea, a more cost effective first stage Home Sleep Test (HST) screening is required.

Current available screening solutions are intrusive, minimally invasive and only supply simple apnoic counts.

PMD’s RS Sleep Screener (Figure 1) is being designed to supply apnoic event counting as a non-intrusive, non-invasive, remote home screening solution, along with:

- an apnoea hypopnea index (AHI) score
- an insight into body position during events
- levels of subject activity during sleep cycles
- a cloud based reporting platform

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A novel approach to increasing your patient coverage by 200%

RS Sleep Screener – A Population Screener

The RS Sleep Screener works by directly measuring the mechanics of respiration – the displacements of the gut and thorax - using a PMD’s proprietary Modified Respiratory Inductance Plethysmography (M-RIP) technique.

Using piezo-electric film sensors in PMD’s novel configuration, as a replacement for the traditional respiratory effort belts, PMD has achieved a discrete, patient friendly solution that does not suffer from slippage – a key factor in repeated HST testing.

The novel body worn device is pre-programed with the patient details, testing start and end times, details of clinical personnel, and unique patient identifiers. This is accomplished using PMD’s preparatory software application housed on a discrete gateway device that requires no patient interaction.

The calculated results of the PMD HST can be viewed on any computer by utilising PMDs web based platform. Patient data security is PMD’s highest priority. Each physician will have unique log-in credentials which will enable them to only examine those patients under their direct care. The physician will then have access to both the complete HST report and the raw data file while also having the ability to annotate the report and having print/email privileges. All this is available within 24 hours of the patient completing the Home Sleep Test.
Detection of Sleep Apnoea

Respiratory effort
By virtue of the verified accuracy of the CE marked RespiraSense module, very slight variations in abdominal movement of the subject can be detected. This allows for the detection of both hypopnoea and apnoea events enabling the calculation of the commonly employed apnoea-hypopnoea index (AHI).

Subject posture
The RS Sleep Screener module contains an on-board tri-axial accelerometer that can be used to accurately determine the subject’s real-time body position. This information has often been shown to be important, especially in position dependent sleep apnoea [4].

Subject activity level (arousal)
The available on-board accelerometer can also be employed to determine subject activity levels during sleep. This information will allow for the analysis of respiratory-effort related arousals (RERA’s), which are in turn used to calculate the commonly referenced respiratory disturbance index (RDI).

Indications of Efficacy
In June 2015, PMD began to evaluate the efficacy of its sensor platform with respect to event detection in comparison to the ‘gold standard’ Polysomnography (PSG).

Figure 2 provides an example output from the RS Sleep Screener during a period of apnoea as determined from the PSG.

![Figure 2 - Example RS Sleep Screener output (top) during PSG determined apnoea event (bottom)](image)

12 patients were initially recruited and the AHI from the RS Sleep Screener was compared to the AHI determined manually (by a trained clinician) from the PSG (Table 1). RS Sleep Screener was evaluated against PSG and compared against a combination of RS Sleep Screener+SpO2 and against SpO2 on its own.

<table>
<thead>
<tr>
<th>PSG AHI (Banded)</th>
<th>Mean Error</th>
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<tbody>
<tr>
<td></td>
<td>RS Sleep Screener &amp; SpO2</td>
</tr>
<tr>
<td>0-5</td>
<td>0.14</td>
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<tr>
<td>5-10</td>
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<tr>
<td>10-15</td>
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<td>15-20</td>
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<tr>
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<td>0.42</td>
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<td>0</td>
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</table>

The novel RS Sleep Screener has the potential to quickly, simply and effectively screen the greater population suspected of having a moderate or higher severity of sleep apnoea, therefore developing a new 3-tiered efficient and cost-effective approach to support PSG and Home Limited Studies.

Contact
If you are interested in reducing costs and increasing the number of tests per year in your sleep lab, PMD would be interested to support.

References:
2. Colten HR, Altevogt BM. "Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem", 2006, Chapter 4