Icelandic SME develops the best respiratory analyser to date

There is growing concern among sleep researchers that the current medical framework for ‘Obstructive sleep apnea’ (OSA) diagnosis is critically limited in scope. Icelandic company Nox Medical is offering to solve this problem with a technology that will assess the quality of each patient breath during the night.

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OSA, a condition where repeated episodes of partial or complete blockage of the airway occur during sleep, is on the rise. It has reached the staggering prevalence rate of over 35 % in people over 40 years old. Worse still, up to 82 % of men and 92 % of women who have moderate or severe OSA have not been diagnosed yet.

Other forms of ‘Sleep disordered breathing’ (SDB), such as snoring and laboured breathing, cannot even be detected. They continue to cause increases in cardiovascular disease, diabetes, stroke, cancer, risk of accidents, growth and mood disturbance, as well as a tiredness that can significantly decrease quality of life and functional capacity. Women, and in particular pregnant women, are especially sensitive. This all represents a huge financial burden for society which needs to be addressed.

Currently OSA is diagnosed by counting the number of times a patient stops breathing when breathing is severely reduced. Diagnosis is based on around 100 night breaths. For other, more subtle cases and to detect other forms of SDB, Nox Medical will soon provide a diagnosis using all of the approximately 8 000 times we breathe overnight. The technology can identify the underlying cause of SDB in patients, which could mark the end of current one-size-fits-all treatment.

Svenni Hoskuldsson, CTO at Nox Medical, details the technology’s status, as Phase

1 funding for the RESPIRATORY ANALYZER (Validation of calibrated RIP based biomarker for diagnosis of SDB and the identification of an accessible screening solution) project just came to an end.

How does your system work exactly?

The system is based around the current products offered by Nox Medical, the Nox A1 and Nox T3 sleep monitoring devices.

A fundamental part of the systems are the ‘Respiratory inductance plethysmography’ (RIP) belts. The RIP belts accurately measure the breathing movements of the thorax and abdomen. By analysing the breathing movements, the patient’s respiratory drive, the patient’s intention to breath can be measured. With further analysis, the respiratory drive can be divided into a flow contributing part, breathing, and breathing movements which are lost to overcome obstruction in the airway. The ratio of flow contributing breathing movements to the respiratory drive gives the breathing efficiency of each breath.

We have shown that, even when the Tidal Volume is maintained throughout the night, the breathing efficiency can be severely reduced during some parts of the night. These drops in breathing efficiency may indicate that the patient suffers from SDB even though he shows no signs of OSA.

What are your main target markets?

The main target market for the technology is traditional sleep clinics and specialists, where the technology can be used to augment current diagnosis schemes. The technology lends itself to being easy to use and it is easy to interpret the results, so expansions into new markets such as cardiologists, paediatricians and dentists — where sleep is important but not the main speciality of the practitioner — are envisioned.

Why opt for a pay-per-use solution?

The pay-per-use solution is tailored to the needs of the occasional user of sleep diagnostics. At Nox Medical, our mission is ‘Sleep for All’. It is our goal to bring sleep diagnostics and sleep medicine to anyone who needs them.

We are working towards this goal from two ends: On the one hand we are developing better diagnostics paradigms, and on the other hand we are working on improving access to sleep diagnostics devices. A key step in being able to offer sleep diagnostics to a larger user base is to have a diagnostics protocol than can be applied by practitioners who are not sleep specialists. This is where the new biomarker plays a key role. A second key step is offering a solution, device and

software that can be accessed without having to invest heavily in infrastructure.

How did you proceed to identify your biomarker for SDB screening?

The biomarker has been under development for some time. During the Phase 1 period of the project, we ran two pilot studies to test the feasibility of using the biomarker as a surrogate measure of SDB and to see if it had any clinical significance.

One pilot study compared the performance of the biomarker to a standard measure of SDB. This standard measure is based on threading a pressure sensor through the patient's nose into his oesophagus. The preliminary results show that the biomarker is correlated to the standard measure of SDB. Then, a second study was performed by comparing breathing efficiency to clinical outcomes in teenage patients. The results from the study show that the biomarker is a better predictor of clinical outcomes than standard OSA diagnosis methods.

What kind of reactions are you getting from stakeholders?

The results from these two pilot studies were presented at the WorldSleep 2015 conference organised by the World Sleep Federation and the European Sleep Research Society. The results from the pilot studies attracted much attention from leading scientists and physicians.

During the conference, Nox Medical formally started a collaboration with the best scientists and physicians in the field of sleep research and SDB. The research consortium that will carry out the clinical validation of the biomarker includes researchers from Harvard Medical School, Imperial College London, NeuroScience Australia, University of Sydney, Charité University in Berlin and others.

How else did you benefit from funding under Horizon 2020?

An important aspect of the Phase 1 project was that it forced us to think through the whole project, set up a plan, and really go for it. In the industrial environment, it can be difficult to carve out the resources needed to follow through with a large, long-term research project.

At Nox Medical, 50 % of the staff work on R&D and out of those 20 % work only on research. Even with this heavy R&D focus, starting a research project of this scale requires much support from the outside.

What are the next steps now that Phase 1 is completed? Will you be applying for Phase 2?

Nox Medical will now complete the clinical validation of the biomarker. We will apply for Phase 2 to finish the work we have started. Researchers and physicians are eagerly waiting to start the clinical validation and one way or another we will carry on with the project.

The feasibility study from Phase 1 sparked great interest in the technology, yet many questions are still to be answered.

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