

David Lee, Founder and CEO, Singular Wings medical from Taiwan.
"Find the invisible health killer during sleep, Singular Wings"

Obstructive Sleep Apnea, is associated with increases in the incidence and progression of coronary heart disease, heart failure, stroke, and atrial fibrillation. It is a common disorder that has all of the characteristics of the chronic condition, as with other chronic conditions. OSA requires ongoing management of treatment.

Nearly 1 billion adults aged 30 to 69 years old worldwide were estimated to have obstructive sleep apnea with or without symptoms. In some highly stressed societies, like Japan, the percentage may climb even higher like 20 to 30%. The problem is that almost 90% of them are not diagnosed meaning they themselves don't even know this is a disease. 60% of patients don't have a good reaction to drug treatment.

In Japan or any other highly developed society, seniors who live alone are threatened by all kinds of chronic conditions. Such as sudden heart attacks. Their health problems deserve to be taken care of in a better and smarter way, like remote or technical assistance.

The usual condition of an OSA is recurrent pauses in breathing during their sleep. The conventional way of diagnosis requires the patient to sleep overnight in the lab or in the hospital attended by professional personnel. We are working on an innovative way to change it. Taking a PSG test in the lab or hospital usually is a pain. It is very expensive, extremely uncomfortable, and a very long waiting time to get one. FDA has approved a type three home sleep test method, which uses fewer devices and allows users to conduct a test and stay at home. But as you can see, this is still very complex work to do for most of the people.

[Technology of Singular Wings]

This is an alternative proposed by Singular Wings. Just by putting the one patch sensor to the chest they can collect all the necessary data with just one night of sleep at home. The solution is a tiny device attached to the chest skin. It simultaneously collects EKG, respiration, temperature, chest movement, HRV, and the sleep stages. All data is collected and analyzed by one of our proprietary cloud based algorithms. A sleep and analysis report can be available in the morning.

The core advantage is that we can take a few key vital signs with perfect accuracy. We are able to identify sleep stages with extremely high accuracy, precision, and a callback rate.

Let's look at the market. The sleep test market in the US is over 11 billion dollars per year. And the market in Japan, according to the data I can check from the internet, is over 400 million US dollars per year. So this is a really big market to look at.

[What is Single Wings?]

This is a company with 19 dedicated engineers, certified by ISO 13485. Six patents granted from the US and Taiwan. Unfortunately, there is no one from Japan yet. We are preparing our FDA 510(K) and TFDA clearance submission by November this year and hopefully will get cleared by Mid of 2022.

[What are we looking for?]

We are looking for partners and investment from Japan to join us to develop this great market in Japan.

[Q & A]

Q.

I didn't put up the last pages. So how about the situation for 510 K and the CE mark and also ISO 13485? So have you already got all of them or just you're applying for the 510 K now?

A.

We are now working on the preparation of submission presently. We are working on track. And we can submit it in November this year for FDA 510(k) and TFDA. CE we put it on the next year. ISO13485 we have been certified.

Q.

You already saw in the traction. You said five hospital tests already done and maybe present a little bit data. But can you explain a little bit more about how many patients and then what do you did you discover the superiority against existing devices?

A.

No, you have already noticed that there are five hospitals tested our devices and solutions and but we have only conducted two IRB only. And two IRB ongoing project. So far one IRB is planned to receive 120 patients and the other one is 60 and is going all the way so we are still continuing collecting patients so far. Among the studies, we have achieved fully automatic sleep stage labeling by using solely our wearable device (i.e. without EEG presence) with accuracy 88.69%, precision 88.98% and recall 88.44% from over 2.85 million data sets obtained from hospital PSG data base.

Q.

Did you compared with other devices or do you have any data?

A.

Yes. For example this one, respiration data From our device. This is the respiration graph collected from our device. This is the data collected from PSG in the hospital, we put them on the same time axis and they are perfectly compatible. And here this is the respiration collected from our device and the blue line is from EDR (EKG Derived Respiration, a kind of algorithm) calculated result. And the red line is the direct measurement from our device. They are also perfectly compatible. And here, this is the heart rate through the time axis from 10 o'clock the night before, continuously till five o'clock in the morning. At the heart rate extracted from EKG, the blue line is our data. And the red line is from the PSG from the hospital through the whole night, they are awfully the same.

Q.

Do you have any comparison with the other wearable device like a Fitbit or Apple watch?

A.

Most of the wrist worn devices, including Apple Watch and Fitbit use PPG instead of EKG. The PPG is based on LED and can give you only heart rate – if the measurement is performed carefully – but it is still just a less informative number. Not like EKG, heart rate is a very much truncated information and does not contain meaningful physiological sense, not even mentioning diseases symptoms. Some latest Apple watch versions do allow EKG but it requires user to put both hands contacting the watch electrodes so to activate the measurement. This fundamental design concept prevents the possibility of continuous, long term detection. So it is not possible to get EKG during sleep or exercises. Another difference is, the wrist worn devices do not collect respirational signal either. It is very difficult to get breathing data from wrist area. The last point is, the motion sensor put on wrist is meaningless. The hand gestures just don't represent anything about body movement, e.g. fall detection or sleep quality related body movement. For the reasons listed above, we put the EKG, respiration and motion sensors in one device attached to the chest surface plus a temperature sensor which Apple Watch and Fitbit do not provide.