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"Neurodetector" - Finding the minds of patients with disorder of consciousness"

What is a Neuro Detector?
This device has been developed towards an accurate diagnosis of locked-in patients for their better care and rehabilitation.
The unmet medical need that we focused on is the misdiagnosis of the locked-in state as a vegetative state. A vegetative state is the first persistent form of consciousness with loss of cognitive functions. These patients still have their eyes open while having sleep and wake cycles. Martin Pistorius, was a patient who was diagnosed as vegetative at the age of 12. But in fact, he was conscious and locked inside his own body for 13 years. Martin was luckily discovered later by a therapist and he received proper rehabilitation. After his miraculous recovery, he revealed his unspoken experience of being locked in with his artificial voice. He said that people abused him physically, verbally, and sexually. His mother turned to him and told him that he should die. Some studies like Martin's even show that up to 43% of patients diagnosed as vegetative are reassessed as having at least some level of consciousness such as the locked-in and minimally conscious states.
. So, these Locked-in state patients have healthy sensory and cognitive functions, but they're often misdiagnosed because they have severe motor dysfunctions.

[Our vision]
Our vision is to take these patients back to the social world by directly detecting cognition. By allowing them to mentally respond. We believe that this accurate diagnosis is the most important first step for these patients to re-socialize. Because unless these patients are found out, they will not get sufficient support and appropriate rehabilitation for them to be socialized.

[Our technology and strength]
We focused on a signal called the event-related potentials (ERP) that reflects an instant change of attention. This signal typically requires long-term recordings of over 50 trials to get a legitimate signal. We have been developing an ERP-based communication aid "Neurocommunicator®" for patients with severe motor deficits, who could be in a locked-in state when the disease is progressed. This system has been verified by clinical trials with over 40 subjects mostly ALS patients who typically have healthy cognitive functions. These core technologies of Neurocommunicator were used for the development of Neurodetector.

The raw data of the ERPs obtained are multivariable and very difficult to analyze. However, by using our pattern matching algorithm, we can use these ERP waveforms to determine whether the subjects succeeded in responding to the cognitive task or not. And by doing so, we can calculate an individual score called Task Success Rate, which will eventually be the biomarker quality tasks. We are still at the development stage for this, but we will be using the database of healthy patients to diagnose disorders of consciousness for patients with stroke and trauma. The database of healthy patients can be referred to diagnose new patients into different levels of consciousness, from truly vegetative to locked-in. If a patient could conduct these tasks with the mind switch, as successful as healthy patients, that means the patient is in the locked-in state, with high consciousness levels.

We have obtained 11 patents in Japan. 5 of which are also taken in the US, 1 in the EU. Comparing our technology with the other advanced technologies, the main point we would like to stress out is that the Neurodetector stands out in terms of locked-in detectability, which means the sensitivity for accurate diagnosis. Therefore, we can test the amount of communicability the patient has. Our technology is also superior for decoding speed, convenience, independence of eye movement, price,

and market size. We believe that these will also be factors that will affect our promotion sales in the future.

[Estimated Market Size]
In Japan there are about 700,000 patients and 2.5 million in the US. Our estimated market size for our service for the first year is about 120 million yen, and we estimate to sell our devices to about 100 hospitals in Japan, who have these patients. The serviceable available market is around 750 million yen per year, and hopefully sold to 626 big hospitals around the time that may need this device.

[What we are looking for]
We look for HVC Kyoto to get advice about clinical evaluation, obtaining funds and making connections with partners for clinical evaluation. Our team is very small so we look for new members for business management and perhaps medical approval.

[Q & A]
Q.
You explain about the Locked-in State but can you explain about your technology itself? So what is your technology and why you can use your technology for these symptoms?
A.
The strength of our technology is the ability to conduct to analyze raw data of the brain waves that is ERPs effectively. These signals are very small, like five micro-volts. And they are very difficult to extract from the chaotic raw data of our various signals. But our technology allows us to specifically take out these signals and use them as a virtual switch for internal decisions, that is, the Mind Switch for the locked-in patients to respond to others. And since these patients have healthy cognitive functions, by detecting their cognitive ability, we can tell if the patient is whether if they are in a vegetative or lock-in state.

Q.
How many points you put on your headgear to take the signals?
A.
Our headgears have 8 electrodes around the top of the head.

Q.
It's an interesting program and project. And if you want to expand the use of this headgear to different disease or states, I was thinking about ADHD, for example, like kids with ADHD might overreact to certain signals. And I guess this can be a good diagnosis tool. Just as a suggestion, but you might want to consider about that.
A.
Thank you for your suggestion. We are also interested in it. The application might be a good use-case for device. And we are thinking of other options right now.

Q.
What is the way of differentiate the healthy vs negative patients? Can you explain how did you come up with this? This graph and this distribution? Or what is the key parameter showed in your device to come up with this? Just allocation?
A.
The cognitive task has several trials, and we can calculate the score of how well they can do by Mind Switch. We only have the results about distribution from 40 healthy subjects, and still have to conduct clinical trials to confirm our hypothesis. The average score of healthy subjects was about

77%. If the score of a tested patient is close to this average. He/she could be in a locked-in state. If the score is lower, the state may be minimally conscious or truly vegetative. This logic is still our hypothesis, and needs to be verified.