h2o Announces FDA Listing of Apple Watch-Based Cueing Feature 'Foggy'

Parkinson’s disease affects millions worldwide, presenting unique challenges to both patients and caregivers. Freezing of gait is when someone may have temporary episodes of an inability to step forward. This abnormal gait pattern, in particular, significantly impacts mobility and independence, often leading to falls and decreased quality of life.

Foggy uses the Taptic Engine in Apple Watch to provide vibrotactile stimulation for individuals experiencing freezing of gait, a debilitating symptom of Parkinson’s disease. Users can simply tap a complication on their Apple Watch to initiate haptic feedback that helps with the condition.

“Cueing strategies hold immense promise in aiding individuals with freezing of gait,” says Yagmur Selin Gulmus, founder of h2o therapeutics. “However, the key to their effectiveness lies in accessibility, individualization, and ease of use. Our introduction of Foggy marks a significant advancement in the field, offering patients a non-invasive solution by simply wearing their Apple Watch, designed to assist without adding cognitive load.”

h2o conducted two clinical studies to explore different cueing methods, including audio and visual cues using augmented reality. By collaborating closely with the Parkinson’s community, the company gained valuable insights into patients' specific needs and preferences. In response, h2o developed Foggy, a user-friendly app tailored to the unique requirements of people living with Parkinson’s disease.

“We're excited to launch Foggy on World Parkinson's Day, highlighting a major step in our fight against the tricky problem of freezing of gait, a condition full of unknowns," explains Gulmus. “Foggy is a starting point towards tackling this issue that only a wealth of real-world data can clarify. Besides haptic cue generation, Foggy also acts as a data platform. This allows us to better understand freezing of gait and individualize our technology to meet the specific needs of those experiencing it."

In 2022, h2o therapeutics obtained 510(k) marketing clearance from the U.S. Food and Drug Administration for its prescription mobile app, Parky, designed for monitoring Parkinson’s Disease. Integrated into Parky is the new Class II feature, Foggy, enhancing the app's capabilities with a holistic approach to manage Parkinson's symptoms. Parky app enables real-time monitoring of symptoms like tremors and dyskinesia through integration with Apple Watch using the Movement Disorder API; with the addition of Foggy, it now offers even more comprehensive support for patients. This innovation is a valuable tool for facilitating the exchange of meaningful and reliable data between patients and medical professionals, aiding in a better understanding and management of the disease.

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