

SLEEP CYCLE LAUNCHES CLINICAL STUDY FOR AI-POWERED SLEEP APNEA SCREENING, TARGETING A BILLION-DOLLAR MARKET

Exploring Medical-Grade Sleep Apnea Detection — Powered by Your iPhone

Sleep Cycle, the leading sleep technology company, today announced the start of a clinical study to validate its upcoming smartphone-based feature for screening and monitoring obstructive sleep apnea (OSA) with no additional hardware or wearables required. This milestone underscores the company's commitment to pioneering accessible, technology-driven health solutions that empower users to better understand and manage their sleep, unlocking a new era of sleep health.

"Sleep is the next frontier in preventive health, and we're here to lead it. By enabling sleep apnea screening using nothing but an iPhone, we're not just breaking clinical barriers—we're unlocking a scalable opportunity to transform lives and redefine the digital health market. This isn't just an app update; it's a strategic leap into a multi-billion dollar category ripe for innovation," said Erik Jivmark, Chief Executive Officer at Sleep Cycle.

Addressing a Global Health Challenge

Obstructive sleep apnea affects an estimated 950 million adults aged 30–69 worldwide, with nearly 80% of cases remaining undiagnosed. This silent epidemic contributes to numerous health complications, including cardiovascular disease, cognitive decline, and reduced quality of life. The global home testing market for sleep apnea is projected to grow from USD 712 million in 2025 to USD 966 million by 2035, highlighting the urgent demand for scalable, cost-efficient, and accessible solutions.*

By leveraging widely available smartphone technology and its proprietary algorithms, Sleep Cycle's upcoming sleep apnea feature aims to help users bridge this gap. With an intuitive interface and competitive pricing, the new solution is designed to democratize sleep health and improve early detection, particularly in underserved populations who may not have access to specialized sleep clinics or expensive testing equipment.

Leading the Way in Sleep Science

The clinical study is led by Dr. Mike Gradisar, Head of Sleep Science at Sleep Cycle, as Principal Investigator of the study, along with Dr. Mikael Kågebäck, Chief Technology Officer and PhD in AI and Machine Learning. Together, they bring deep expertise in behavioral sleep medicine and applied AI, reinforcing Sleep Cycle's evidence-based approach to innovation.

"Our AI-powered audio analysis is built on a proprietary sound model trained to identify subtle sleep-related breathing patterns in real-world environments," explained Dr. Kågebäck. "Unlike traditional methods, our solution analyzes sound in a context-aware manner, enabling detection of potential sleep apnea signs without intrusive wearables or sensors. This marks a new frontier in accessible sleep diagnostics."



Ethical Oversight and Regulatory Alignment

The clinical study has received formal ethical approval and is being conducted in compliance with international clinical research standards. Sleep Cycle has also completed a pre-submission dialogue with the U.S. FDA, ensuring alignment on trial design, methods, and intended outcomes. These regulatory engagements highlight Sleep Cycle's strategic commitment to compliance and transparency.

The study is set to begin on June 2 and will be conducted by the Sleep Testing Australia clinic in Brisbane and Adelaide. Consisting of approximately 700 participants, the study aims to track the precision of Sleep Cycle's new screening algorithm in detecting obstructive sleep apnea.

Commenting on the study, Mason Vozzo, Diagnostic Services Manager at Sleep Testing Australia, stated:

"I'm fascinated by the application of machine learning to deepen the analysis and comparison between PSG studies and Sleep Cycle's algorithm. It's great to see this technology applied in sleep research, especially given how data-rich traditional PSG is. We've likely only scratched the surface of the insights it can offer."

Backed by external regulatory counsel and strong in-house machine learning capabilities, Sleep Cycle is confident in the scientific rigor and technological robustness of this screening feature. This interdisciplinary approach strengthens the credibility of the study and the long-term impact of the technology.

For those interested in learning more about Sleep Cycle's approach to sleep apnea, visit https:// sleepcycle.com/sleep-apnea-news.

*https://aasm.org/new-national-indicator-report-details-importance-prompt-sleep-apneadiagnosis-treatment/

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About Sleep Cycle

Sleep Cycle is dedicated to making healthy sleep accessible to everyone. Our app helps users to build hero habits, identify potential sleep issues, and gain valuable insights into their sleep patterns. Leveraging patented sound technology and over 3 billion analyzed sleep sessions, Sleep Cycle provides unparalleled accuracy and personalized guidance. As part of its broader partnership program, Sleep Cycle offers company partnerships including in-app promotions, tailored SDK solutions, and an extensive data library, enabling businesses to expand their offerings with sleep solutions and insights. Sleep Cycle is listed on Nasdaq Stockholm under the ticker SLEEP, with its headquarters in Gothenburg, Sweden.

Image Attachments Sleep Cycle Sleep Apnea