

# Withings Sleep Rx Receives FDA Clearance for the First Contactless Device to Aid for Sleep Apnea Diagnosis

**Boston, MA, September 9, 2024** – [Withings](#), a global leader in connected health, announces that its Sleep Rx Mat has received clearance from the U.S. Food and Drug Administration. Sleep Apnea is not only severely underdiagnosed worldwide - but also diagnosed using solutions that have shown limitations, in both access and accuracy. By addressing these challenges, the release of Sleep Rx in the US will mark a new era in sleep apnea diagnosis, paving the way to better health outcomes for millions of adults in the US.

## Addressing The Growing and Underdiagnosed Sleep Apnea Crisis

Obstructive Sleep Apnea (OSA) affects approximately 30 million adults in the U.S., with a staggering 80% of cases going undiagnosed<sup>1</sup>. Traditional diagnostic methods, such as Polysomnography (PSG), are limited to diagnosing only the most severe sleep disorders due to their low availability and high cost. PSG is also bulky and intrusive<sup>2</sup>, requiring an overnight stay in a sleep lab, which many patients find inconvenient. Moreover, a single-night assessment may not accurately represent the severity of OSA, as it can fluctuate from night to night, leading to potential error rates of up to 50%<sup>3</sup>.

The underdiagnosis of OSA is highly problematic because untreated OSA significantly increases cardiometabolic risks, including diabetes mellitus<sup>4</sup>, resistant hypertension<sup>5</sup>, atrial fibrillation<sup>6</sup>, stroke, and myocardial infarction<sup>7</sup>.

“We’re thrilled to bring Sleep Rx to the U.S. market,” said Antoine Robiliard, VP of Withings Health Solutions. “Enabling earlier and more precise diagnosis, Sleep Rx creates a new sleep apnea diagnosis and management paradigm. We know that a one-night assessment is not sufficient. By enabling more efficient and lower-cost home-based OSA diagnosis, Sleep Rx could not only reduce the staggering \$150 billion annual economic burden of undiagnosed sleep apnea but also significantly improve long-term health outcomes.”

## Advanced Sleep Insights at Home

Sleep Rx is an advanced sleep device clinically validated for use in home screening of adults with suspected sleep breathing disorders as an aid for diagnosis of OSA, sleep analysis, and heart rate

- 
1. What doctors wish patients knew about sleep apnea. *American Medical Association* <https://www.ama-assn.org/delivering-care/public-health/what-doctors-wish-patients-knew-about-sleep-apnea> (2022).
  2. M.k, S., S, S. P. & S, P. Detection of Obstructive Sleep Apnea Using Internet of Things: A Review. *Int. J. Sens. Wirel. Commun. Control* **11**, 263–270.
  3. Lechat, B. *et al.* Multinight Prevalence, Variability, and Diagnostic Misclassification of Obstructive Sleep Apnea. *Am. J. Respir. Crit. Care Med.* **205**, 563–569 (2022).
  4. Nannapaneni, S., Ramar, K. & Surani, S. Effect of obstructive sleep apnea on type 2 diabetes mellitus: A comprehensive literature review. *World J. Diabetes* **4**, 238–244 (2013).
  5. Ahmed, A. M., Nur, S. M. & Xiaochen, Y. Association between obstructive sleep apnea and resistant hypertension: systematic review and meta-analysis. *Front. Med.* **10**, 1200952 (2023).
  6. Marulanda-Londoño, E. & Chaturvedi, S. The Interplay between Obstructive Sleep Apnea and Atrial Fibrillation. *Front. Neurol.* **8**, 668 (2017).
  7. Shahar, E. *et al.* Sleep-disordered Breathing and Cardiovascular Disease. *Am. J. Respir. Crit. Care Med.* **163**, 19–25 (2001).
  8. Huyett, P. *et al.* Comparison of Home Sleep Devices and Sleep Study Testing in Hypoglossal Nerve Stimulation Patients. *The Laryngoscope* (2024) doi:10.1002/lary.31710.

estimation. The sleek, unobtrusive mat requires a one-time set up, fits under any mattress, eliminating the need for masks or cumbersome equipment. Once set up, it provides detailed analysis of sleep, breathing, and cardiovascular activity throughout the night.

Available in the U.S. by prescription as part of clinical sleep management or remote patient monitoring programs, Sleep Rx can be acquired by healthcare professionals through Withings Health Solutions. It represents a major advancement in the early diagnosis of sleep apnea, using a pneumatic sensor to measure respiratory rate, body movement, and continuous heart rate, along with tracking sleep cycles, duration, and interruptions. Sound and motion sensors detect snoring and breathing disturbances, key indicators of sleep apnea. Each morning, Sleep Rx provides a comprehensive sleep quality score, giving patients an easy-to-understand assessment of their rest.

### **Revolutionizing Sleep Apnea Patient Journey**

Global studies have shown Sleep Rx's potential to impact every step of the patient's journey from diagnosis<sup>3</sup> to treatment efficacy<sup>8</sup>. By offering a scalable, accurate, and comprehensive diagnostic solution, Sleep Rx is set to profoundly improve the lives of millions of Americans. As a non-intrusive solution, Sleep Rx can provide longitudinal data. This is a game changer, given that a study of over 11 million nights by Flinders Health and Medical Research Institute using Withings Sleep tracking mats revealed significant variability in the apnea-hypopnea index (AHI) from night to night, highlighting the need for longer-term follow-up—something Sleep Rx now makes possible<sup>3</sup>.

### **Availability**

Sleep Rx is now available in the U.S. by prescription. For more information about Sleep Rx and Withings' ongoing commitment to digital health innovation, visit [www.withingshealthsolutions.com/connected-devices/sleep-rx](http://www.withingshealthsolutions.com/connected-devices/sleep-rx).

**-Ends-**

### **About Withings and Withings Health Solutions**

Withings Health Solutions is a dedicated division of global connected health leader Withings, serving healthcare professionals across chronic disease prevention and management, remote patient monitoring, clinical research and more. Its mission is to bridge the gap between patients and their care teams by continuously and effortlessly providing healthcare professionals with medical-grade data generated by patients from an ecosystem of connected devices.

- 
1. What doctors wish patients knew about sleep apnea. *American Medical Association* <https://www.ama-assn.org/delivering-care/public-health/what-doctors-wish-patients-knew-about-sleep-apnea> (2022).
  2. M.k, S., S, S. P. & S, P. Detection of Obstructive Sleep Apnea Using Internet of Things: A Review. *Int. J. Sens. Wirel. Commun. Control* **11**, 263–270.
  3. Lechat, B. *et al.* Multinight Prevalence, Variability, and Diagnostic Misclassification of Obstructive Sleep Apnea. *Am. J. Respir. Crit. Care Med.* **205**, 563–569 (2022).
  4. Nannapaneni, S., Ramar, K. & Surani, S. Effect of obstructive sleep apnea on type 2 diabetes mellitus: A comprehensive literature review. *World J. Diabetes* **4**, 238–244 (2013).
  5. Ahmed, A. M., Nur, S. M. & Xiaochen, Y. Association between obstructive sleep apnea and resistant hypertension: systematic review and meta-analysis. *Front. Med.* **10**, 1200952 (2023).
  6. Marulanda-Londoño, E. & Chaturvedi, S. The Interplay between Obstructive Sleep Apnea and Atrial Fibrillation. *Front. Neurol.* **8**, 668 (2017).
  7. Shahar, E. *et al.* Sleep-disordered Breathing and Cardiovascular Disease. *Am. J. Respir. Crit. Care Med.* **163**, 19–25 (2001).
  8. Huyett, P. *et al.* Comparison of Home Sleep Devices and Sleep Study Testing in Hypoglossal Nerve Stimulation Patients. *The Laryngoscope* (2024) doi:10.1002/lary.31710.

Withings created the first smart scale in 2009 and has been the pioneer in connected health ever since. Its clinically validated and multi-award-winning range is used by millions worldwide and include smart scales, hybrid watches, blood pressure monitors, sleep analyzers, and more. For more than 15 years, Withings has built expertise in user experience, engagement, and retention. Withings Health Solutions extends this expertise to the healthcare industry to remove friction in the patient's journey and allow digital health to expand. For more information, visit [www.withingshealthsolutions.com](http://www.withingshealthsolutions.com).

- 
1. What doctors wish patients knew about sleep apnea. *American Medical Association* <https://www.ama-assn.org/delivering-care/public-health/what-doctors-wish-patients-knew-about-sleep-apnea> (2022).
  2. M.k, S., S, S. P. & S, P. Detection of Obstructive Sleep Apnea Using Internet of Things: A Review. *Int. J. Sens. Wirel. Commun. Control* **11**, 263–270.
  3. Lechat, B. *et al.* Multinight Prevalence, Variability, and Diagnostic Misclassification of Obstructive Sleep Apnea. *Am. J. Respir. Crit. Care Med.* **205**, 563–569 (2022).
  4. Nannapaneni, S., Ramar, K. & Surani, S. Effect of obstructive sleep apnea on type 2 diabetes mellitus: A comprehensive literature review. *World J. Diabetes* **4**, 238–244 (2013).
  5. Ahmed, A. M., Nur, S. M. & Xiaochen, Y. Association between obstructive sleep apnea and resistant hypertension: systematic review and meta-analysis. *Front. Med.* **10**, 1200952 (2023).
  6. Marulanda-Londoño, E. & Chaturvedi, S. The Interplay between Obstructive Sleep Apnea and Atrial Fibrillation. *Front. Neurol.* **8**, 668 (2017).
  7. Shahar, E. *et al.* Sleep-disordered Breathing and Cardiovascular Disease. *Am. J. Respir. Crit. Care Med.* **163**, 19–25 (2001).
  8. Huyett, P. *et al.* Comparison of Home Sleep Devices and Sleep Study Testing in Hypoglossal Nerve Stimulation Patients. *The Laryngoscope* (2024) doi:10.1002/lary.31710.