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Resmed Receives FDA Clearance for Personalized Therapy Comfort Settings, to be Marketed as Smart Comfort, an AI-Enabled, Digital Medical Device That Helps Personalize CPAP Therapy

Technology uses real-world sleep data and machine learning to help people with sleep apnea start and stay on therapy

SAN DIEGO, Dec. 08, 2025 (GLOBE NEWSWIRE) -- Resmed (NYSE: RMD, ASX: RMD), the leading health technology company focused on sleep, breathing and care delivered in the home, today announced it has received U.S. Food and Drug Administration (FDA) clearance for Personalized Therapy Comfort Settings (PTCS), to be marketed as Smart Comfort.

Smart Comfort is the first FDA-cleared AI-enabled medical device that recommends personalized comfort settings to help people with obstructive sleep apnea (OSA) start and stay on CPAP therapy. Smart Comfort will launch in early 2026 in a limited U.S. beta version for new users of myAir™, Resmed's consumer sleep companion app, paired with a Resmed AirSense™ 11 device. It will be followed by a broader U.S. rollout to new myAir users later in 2026.

CPAP therapy is not one-size-fits-all. Addressing common therapy issues, like comfort and mask fit, early can promote long-term adherence. Smart Comfort leverages Resmed's proprietary machine-learning algorithms, drawing on more than 100 million nights of de-identified, real-world sleep data and user information, such as age, gender and Apnea-Hypopnea Index (AHI), to recommend individualized comfort settings for CPAP therapy delivered by Resmed's market leading AirSense 11 devices. These include settings that help ease users into therapy, adjust how gradually an AirSense 11 increases pressure and reduce pressure on exhale. Smart Comfort was developed with clinical oversight and ethical data use in compliance with privacy laws, considering quality and patient safety at every stage.

"For people new to CPAP therapy, personalized comfort settings can help them adjust faster and more comfortably, improving confidence and overall health," said Justin Leong, Chief Product Officer at Resmed. "Smart Comfort's FDA clearance marks an important milestone for the future of personalized, data-driven care. It's another example of how we're using

technology and real-world evidence to make sleep health more personal, accessible and effective.”

The FDA submission was supported by retrospective real-world evidence showing that Resmed AirSense 10 and 11 users whose comfort settings matched Smart Comfort recommendations had higher engagement and sustained therapy adherence compared to those using default settings. These findings demonstrate that personalized comfort adjustments can help improve the therapy experience without compromising efficacy.

In the U.S., OSA impacts an estimated 61 million people and is expected to rise to nearly 77 million by 2050.¹ Left untreated, OSA can significantly impact health and quality of life, increasing the risk of high blood pressure, heart disease, type 2 diabetes and stroke.² CPAP therapy, the gold standard treatment for sleep apnea, can significantly reduce the risk of death in people with OSA.³

For healthcare providers, Smart Comfort offers a solution to help streamline user setup and follow-up and reduce manual adjustments so clinicians can devote more attention to clinical decision-making and patient support. By getting people engaged in their therapy from day one, Smart Comfort helps standardize the comfort settings workflow and builds user confidence that their settings are personalized for them. These non-prescription comfort settings are designed to support CPAP therapy device usage – not alter prescribed therapy settings or therapy efficacy.

Smart Comfort is part of Resmed’s connected, personalized sleep-health ecosystem – combining AI, cloud-connected Resmed devices and digital tools to help make sleep health more personal and support therapy efficacy. Together with other myAir features, including Dawn™, Therapy Control and Streaks, these innovations demonstrate Resmed’s commitment to responsible, data-driven innovation that helps more people start and stay on therapy.

About Resmed

Resmed (NYSE: RMD, ASX: RMD) creates life-changing health technologies that people love. We’re relentlessly committed to pioneering innovative technology to empower millions of people in 140 countries to live happier, healthier lives. Our AI-powered digital health solutions, cloud-connected devices and intelligent software make home healthcare more personalized, accessible and effective. Ultimately, Resmed envisions a world where every person can achieve their full potential through better sleep and breathing, with care delivered in their own home. Learn more about how we’re redefining sleep health at Resmed.com and follow @Resmed.

For Media

Caela Shay

Caela.shay@resmed.com

[news@resmed.com](https://news.resmed.com)

For Investors

Salli Schwartz

Salli.Schwartz@resmed.com

investorrelations@resmed.com

¹ Boers E, et al. *Lancet Respir Med*. 2025;13(12):1078–1086.

² Yeghiazarians Y, et al. *Circulation*. 2021;144(3):E56–E67.

³ Benjafield AV, et al. *Lancet Respir Med*. 2025;13(5):403–413.



Source: Resmed, Inc.