

ASX Release
4th September 2025

Somfit®D – FDA Cleared, Doubles Addressable U.S. Market for Somfit®

Key Highlights

- **Somfit®D (single-use) FDA-cleared**, immediately doubling the addressable U.S. market for Somfit®
- **Expands Compumedics' access to an estimated US\$240M annual U.S. Home Sleep Testing market** (~4 million studies per year), which has shifted rapidly to single-use devices. CMP is targeting 10% to 30% penetration by FY27
- **Complements the reusable Somfit®, creating the only EEG-based platform** serving both high-volume single-use and multi-night reusable diagnostic markets
- **Purpose-built as a single-use Home Sleep Testing (HST) solution**, targeting one of the fastest growing segments of U.S. sleep diagnostics
- **U.S. salesforce in place, providers already engaged**, and commercial rollout commencing immediately
- **Reinforces CMP's recurring revenue growth model** across SaaS, consumables, and devices
- **Somfit®D is now cleared in Australia, New Zealand, the EU, and the USA** with global reach
- **Company affirms FY 26 guidance** of at least \$70M revenues and A\$9M EBITDA

Compumedics Limited (ASX: CMP) ("Compumedics" or "Company") today announced that the U.S. Food & Drug Administration (FDA) has granted 510(k) clearance for the Somfit®D device (K252383), authorising its sale in the United States.

Somfit®D is a single-use Home Sleep Testing device engineered for national scale. It addresses the U.S. market's demand for single-use(disposable) solutions that reduce infection risk, shorten turnaround times, and enable high-throughput testing. In combination with the reusable Somfit®, Compumedics now delivers the only EEG-based platform that spans both single-use and reusable markets, offering true sleep architecture where competitors rely on indirect measures. This dual-platform strategy creates a defensible competitive advantage, expands Compumedics' addressable market, and positions the Company to capture market share across the entire spectrum of Home Sleep Testing.

The U.S. Home Sleep Testing market is worth up to US\$240M annually, representing approximately 4 million studies each year, with growth estimated at up to 25 percent per annum. With Somfit®D now FDA-cleared, Compumedics will immediately commence commercialisation, leveraging a dedicated U.S. salesforce already in place, established relationships with Independent Diagnostic Testing Facilities (IDTFs) and sleep centres that prioritise single-use workflows, and a proven recurring revenue engine spanning SaaS subscriptions, consumables, and device sales.

Dr. David Burton, Executive Chairman and CEO, said:

“The FDA clearance of Somfit®D is a transformational milestone for Compumedics. With a single-use device engineered for scale, we are entering the U.S. sleep diagnostics market with a disruptive solution that directly addresses provider needs. Together with the reusable Somfit®, we are positioned to capture meaningful share of a market worth up to US\$240M annually and to accelerate our recurring revenue growth for years to come.”

The Somfit® platform is designed to disrupt traditional sleep diagnostics by offering scalable SaaS economics with high-margin recurring revenue, clinical-grade data in the home with EEG signals equivalent to in-lab studies, convenience for patients by reducing reliance on hospital-based testing, and lower costs for providers by streamlining operations and improving capacity.



Somfit®D is now cleared in Australia, New Zealand, the EU, and the USA, providing Compumedics with global reach and multiple incremental revenue streams. Compumedics anticipates progressive revenue contribution from Somfit®D beginning in FY26 as adoption accelerates across the U.S.

The Company reaffirms FY26 guidance of at least A\$70M revenues and A\$9M EBITDA.

About Compumedics Limited

Compumedics Limited [ASX: CMP] is a leading global medical device company that develops, manufactures, and commercialises diagnostic technology for sleep, brain, and ultrasonic blood flow monitoring applications. The Company owns Neuroscan, based in the US, and DWL Elektronische GmbH, based in Germany. In conjunction with these two subsidiaries, Compumedics has a broad international reach, including the Americas, Australia and Asia Pacific, Europe, and the Middle East.

Executive Chairman Dr. David Burton founded Compumedics in 1987. The same year, the Company successfully designed and installed the first fully computerised Australian sleep clinic at Epworth Hospital in Melbourne. Following this early success, Compumedics focused on developing products for the growing international sleep clinic and home monitoring markets.

Compumedics listed on the Australian Securities Exchange in 2000. Over the years, Compumedics has received numerous awards, including Australia’s Exporter of the Year, and has been recognised as a Top 100 Innovator by both German and Australian Governments.

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Authorised for lodgement by Compumedics Limited’s Board of Directors