

ASX Release

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## **Falcon™ HST Receives FDA Clearance to Market in the USA – further underpins USA sleep business growth strategy**

### **Key Highlights:**

- **Significant addressable market in the USA between USD100m-200m in potential revenue, with Compumedics currently targeting 10% to 30% of that over the next 24 months**
- **USA has approximately 3,000 sleep centres & 15 major Independent Diagnostic Testing Facilities (IDTF's)**
- **Home sleep testing (HST) market in the USA is estimated at up to four million studies per annum**
- **Post-release success with Falcon™ HST in Australia to be leveraged to the ten times larger USA market**

**Compumedics Limited (ASX: CMP)** a global medical device company that develops, manufactures and commercialises diagnostic technology for sleep, brain, and ultrasonic blood flow monitoring is pleased to announce the US Food & Drug Administration (FDA) has cleared the **Falcon™ HST** device to be marketed in the USA. This marks the achievement of another significant strategic milestone for Compumedics USA HST market growth strategy with a second HST product, **Falcon™ HST** for the fast-growing USA HST market. The **Falcon™ HST** will complement the Somfit technology platform, which is currently gaining commercial traction in the USA HST market, one of the world's largest and fastest growing sleep markets.

The home sleep testing (HST) market in the USA, which the Somfit and now the **Falcon™ HST** are primarily targeted at, is estimated to be up to four million studies per annum. Given the market research activities undertaken by Compumedics, this represents a potential new addressable market of between USD100m and USD200m a year in new and incremental SaaS (software as a service) revenues for Compumedics. The revenue assumption is based on market research activities with existing HST providers in the USA market, which included potential pricing for the Somfit and **Falcon™ HST** platforms, should they switch to Somfit and/or **Falcon™ HST**. The revenue assumption is for the full market opportunity of about four million studies per year, using differing pricing points based on volumes of studies achieved. Compumedics is currently targeting to achieve between 10% and 30% of the addressable market over the next 24 months

and has already commenced sales of Somfit in the USA, where initial sales in the last six months were approximately \$1m.

As noted over the last six months in releases to the ASX, Compumedics has built a high-performance sales team in the USA focused on selling the Somfit HST platform and now the **Falcon™ HST** will be added to the product offering across the USA sleep sales team.

Following the **Falcon™ HST** release in Australia last October (2024) it has quickly gained traction selling more than 100 devices (about \$1.0m in total revenues), with a further 100 to 200 **Falcon™ HST** devices expected to be sold by end of FY25. Importantly one of the biggest sleep therapeutic home care providers in Australia, now uses **Falcon™ HST** exclusively, together with our Nexus 360 (SaaS) platform. Further, Compumedics is testing the **Falcon™ HST** in Australian markets that are adjacent to sleep, such as cardiac disease. These adjacent markets offer potentially significant and highly complimentary markets to grow in. Further, this early success in Australia augurs well for the much larger USA market, which is more than 10 times bigger than the Australian market, based on population.

**Falcon™ HST** offers a more clinically based technology platform that captures more data points than the Somfit for those customers whose sleep practice demands this. The **Falcon™ HST** is still very much a scalable product offering a clinical grade technology for use in the home, greater convenience and ease of use for the patients, along with an overall reduced cost.

**In commenting on this significant milestone for Compumedics, Executive Chairman & CEO, Dr David Burton said:**

“Following FDA clearance for the **Falcon™ HST** device in the USA, Compumedics can further accelerate our HST commercialisation strategy to capitalise on this high growth sleep market segment. The **Falcon™ HST** has already been on sale in the Australian market for six months now and we can take from our experience here that the product is highly regarded by both our existing and new customers, and this augurs well for the much larger USA market.”

Compumedics reaffirms FY25 guidance of revenues of at least \$55m and EBITDA of about \$5m.

#### **About Falcon HST®**

#### **Fully Integrated and Connected end-to-end Home Sleep Testing (HST) solution**

**Falcon™ HST is a fully integrated and connected end-to-end HST solution.** The solution is designed for fast and efficient patient self-setup without compromising signal quality. From data recording to study reporting, the Falcon™ HST is seamless – leveraging Compumedics deep experience and best-of diagnostic technologies.



### **About Compumedics Limited**

**Compumedics Limited (ASX: CMP)** is a medical device company involved in the development, manufacture, and commercialisation of diagnostics technology for sleep, brain, and ultrasonic blood flow monitoring applications. The Company owns US based Neuroscan, and Germany based DWL Elektronische GmbH. 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. In the same year the Company successfully designed and installed the first Australian, fully computerised sleep clinic at Epworth Hospital in Melbourne. Following this early success, Compumedics focused on the development of products that sold into 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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