



Progress in the USA

12th June 2013, SomnoMed last week attended the annual AADSM (American Association of Dental Sleep Medicine) and AASM (American Association of Sleep Medicine) conferences in Baltimore, Maryland. The AASM conference was attended by the major companies in the US sleep market, such as ResMed Inc., Respiroics and Fisher and Paykel.

Importantly, at the conferences SomnoMed was pleased to announce that FDA approval had just been granted for two new products, which should lead to increased future sales for SomnoMed in the United States and internationally, being the SomnoDent[®] Herbst MAS device and the DentiTrac[®] compliance system.

The SomnoDent[®] Herbst product line will allow SomnoMed to enter the mid-price market for oral appliances and offer this product as a Medicare reimbursed treatment solution, subject to PDAC approval by the national CMS. The SomnoDent[®] Herbst launch attracted strong interest from the SomnoMed Preferred Dental Network and other dentists at the AADSM.

The DentiTrac[®] compliance system manufactured by Braebon Medical Corporation is to be distributed by SomnoMed on a global basis. Importantly, a patient's compliance will now be able to be objectively measured by a micro recorder embedded in SomnoDent[®] oral appliances, which will monitor the wearing time of the SomnoDent[®] device, as well as gather other information (oral temperature, movements and head position) relating to the patient's sleep pattern during the night. The ability to prove compliance should broaden the acceptance from medical specialists of MAS treatment and gain greater support from insurers around the world, who require proof that sleep apnea patients are compliant in their treatment. Compliance remains a major issue with CPAP treatment and understandably insurers demand compliance measurement for reimbursement. DentiTrac[®] will now allow SomnoMed to enter into discussions with professional organisations, such as the US Trucker's Association (with over 11 million members), which insist on nightly treatment of their sleep apnea diagnosed members and demand proof of compliance. The DentiTrac[®] system was exhibited by SomnoMed at both exhibitions and met with strong interest, especially from physicians attending the medical conference.

During the medical sleep conference SomnoMed's recently appointed Chief Medical Officer Dr. Jagdeep Bijwadia, a leading sleep physician based in Minneapolis, hosted a symposium on new developments in the oral appliance treatment of sleep disordered patients, attended by over 100 physicians.

The presentations were led by Dr. Craig Phillips, one of the authors of a clinical research paper published in the prestigious American Journal of Respiratory and Critical Care Medicine in April 2013, which compared SomnoDent[®] MAS and Resmed's CPAP. He presented the results of research, which utilized a Randomized Controlled Clinical Trial of the health outcomes of CPAP vs. Oral Appliance Treatment for Obstructive Sleep Apnea. The research carried out over a three year period, with patients using both CPAP and SomnoDent[®] and funded by the Australian Federal Government, concluded that the outcome of treatment of both treatment methods was comparably successful for mild, moderate and severe patients after taking a range of factors into consideration.

Professor John Remmers, the inventor of APAP and the MATRx oral appliance titration test system and Dr. Rick Bonato, CEO of Braebon also made presentations. Professor Remmers discussed the measurement of the efficacy of oral appliance treatment using the MATRx system, distributed by SomnoMed and Dr Bonato presented the concept and features of the Braebon DentiTrac® compliance system.

During the dental sleep convention SomnoMed hosted its annual appreciation dinner attended by over 150 of its most important US practitioners at which awards were presented to SomnoMed's leading practitioners during the 2012/13 year. At the event Executive Chairman Dr. Peter Neustadt introduced SomnoMed's North American new and expanded management team under the leadership of Dr. Kien Nguyen and launched the expansion of SomnoMed's activities into the medical markets.

"The annual events this year served as launching platforms for new exciting products for which FDA approval had just been received and to introduce our new expanded Medical and Dental management teams. The operational problems we experienced during the transition period have been largely resolved and there are signs that our US business has turned. We will be able to give more detailed information in early July about the volumes achieved in Q4," commented Dr. Neustadt.

"The FDA approval of the SomnoDent® Herbst MAS device and the DentiTrac® compliance system is very exciting. Both products will be able to contribute to our anticipated growth in 2013/14. Programs implementing various programs in medical and dental education, marketing and sales are now underway and will shape the development of SomnoMed in the US in 2013/14 and beyond," said Dr. Neustadt.

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About SomnoMed

SomnoMed is a public company providing diagnostic and treatment solutions for Sleep-related Breathing Disorders including obstructive sleep apnea, snoring and bruxism. SomnoMed was commercialized on the basis of extensive clinical research. Supporting independent clinical research, continuous innovation and instituting medical manufacturing standards has resulted in SomnoDent® becoming the state-of-the-art and clinically proven medical oral appliance therapy for obstructive sleep apnea. SomnoDent® is the most comfortable and effective design and treatment solution for over 130,000 patients in 22 countries.

For additional information, visit SomnoMed at <http://www.somnomed.com.au>