



Itamar™ Medical Announces Publication of COMPASS Study Validating First Scoring Guidelines for WatchPAT™ Device in Diagnosing Sleep Apnea

Two additional published studies highlight WatchPAT's accuracy and effectiveness in patients with Central Sleep Apnea (CSA) and Chronic Obstructive Pulmonary Disease (COPD)

CAESAREA, Israel, February 18, 2020 -- Itamar Medical Ltd. (Nasdaq: ITMR) (TASE: ITMR), a medical technology company focused on the development and commercialization of non-invasive medical devices to aid in the diagnosis of respiratory sleep disorders, today announced publication of results of the COMPASS study validating scoring guidelines that better enable physicians and respiratory technologists to review, verify and interpret WatchPAT automated scoring. The study also found that the use of those guidelines is reliable and improves agreement between WatchPAT and gold standard polysomnography (PSG)-derived sleep and breathing indices across age and gender subgroups. The study appears online in the [*Journal of Clinical Sleep Medicine*](#).¹

“WatchPAT significantly improves workflow by automatically rendering a fully scored report. This report is generated automatically from a unique set of signals, most notably the PAT™ Signal, which is used to stage sleep and recognize sleep disordered breathing events without requiring any sensors on the face or head to record electroencephalogram or airflow signals,” said Alan Schwartz, MD, Principal Investigator for the study, which was conducted at Johns Hopkins University. “Sleep physicians are accustomed to using scoring guidelines when interpreting sleep studies. This study takes the same concept a big step further. It provides the first validated scoring guidelines for physicians and technologists using PAT-based technologies. It should help sleep physicians unfamiliar with the PAT signal build confidence in WatchPAT as they incorporate this home sleep testing device into their diagnostic armamentarium.”

The prospective, blinded, nonrandomized clinical trial study had 262 participants, who underwent WatchPAT simultaneously with PSG to develop (n=30), optimize (n=62) and validate (n=170) scoring guidelines. Sleep physicians can use these guidelines to review and edit respiratory events and sleep architecture from WatchPAT automated scoring and recordings. The study concluded that manual review of WatchPAT's automatic scoring is reliable and improves the agreement with PSG-derived sleep and apnea/hypopnea indices.

Results from two other studies, which add to the growing body of clinical evidence demonstrating the accuracy and effectiveness of the WatchPAT in patients with CSA and COPD, have also been recently published.^{2,3}

Key findings from a [study](#) evaluating the use of WatchPAT when enhanced with the two new features, PAT signal upstroke analysis and the Respiratory Effort Snore & Body Position Sensor, can detect central sleep apnea in adult patients² by accurately measuring the apnea-hypopnea index (AHI) and central apnea-hypopnea index (AHIC), all with correlations of 0.80 or higher, as compared with in-lab PSG.



Additional findings from a [study](#) evaluating the accuracy of WatchPAT in diagnosing obstructive sleep apnea (OSA) in patients with chronic obstructive pulmonary disease³ include the presence of OSA and AHI as determined by WatchPAT has good agreement with PSG in COPD patients, and that WatchPAT AHI accuracy was not affected by COPD severity as measured by lung function. Given its lower cost and improved convenience, WatchPAT represents a viable option for speeding diagnosis of co-morbid OSA in at risk populations with COPD.

“Itamar Medical is committed to removing the obstacles that hinder accurate diagnosis and effective management of sleep apnea in the 80% of patients believed to suffer from this chronic disease and never been diagnosed,” said Gilad Glick, President and Chief Executive Officer of Itamar Medical. “We believe that making it easy for clinicians to interpret WatchPAT and providing them with robust clinical evidence of the accuracy and utility of WatchPAT in diverse patient populations and clinical indications is critical to driving adoption of WatchPAT. These three published studies add to the solid clinical evidence that the WatchPAT accurately diagnoses multiple forms of sleep disordered breathing across gender, age, and co-morbid conditions. We believe that publication of these studies will continue to raise awareness of and increase physician confidence in the benefits that WatchPAT and our digital healthcare platform provides to help them increased access to diagnosis and therapy to achieve optimal outcomes for their patients and reduce healthcare costs.”

References

¹ Zhang Z, Otvos T, Sanglard Sperandio L, et al. A comparison of automated and manual sleep staging and respiratory event recognition in a portable sleep diagnostic device with in-lab sleep study. *J Clin sleep Med*. 2020 Feb 5. doi: 10.5664/jcsm.8278. [Epub ahead of print]

² Pillar G, Berall M, Berry R, et al. Detecting central sleep apnea in adult patients using WatchPAT – a multicenter validation study. *Sleep Breath*. 2019 Aug 11. doi: 10.1007/s11325-019-01904-5. [Epub ahead of print]

³ Jen R, Orr JE, Li Y, et al. Accuracy of WatchPAT for the diagnosis of obstructive sleep apnea in patients with chronic obstructive pulmonary disease. *COPD: Journal of Chronic Obstructive Pulmonary Disease*, 17:1, 34-39, DOI: [10.1080/15412555.2019.1707789](https://doi.org/10.1080/15412555.2019.1707789)

About Itamar Medical Ltd.

Itamar Medical is a medical technology company focused on the development and commercialization of non-invasive medical devices to aid in the diagnosis of respiratory sleep disorders. Itamar Medical commercializes a digital healthcare platform to facilitate the continuum of care for effective sleep apnea management with a focus on the core sleep, cardiology and direct to consumer markets. Itamar Medical offers a Total Sleep Solution to help physicians provide comprehensive sleep apnea management in a variety of clinical environments to optimize patient care and reduce healthcare system costs.



Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other applicable securities laws. Statements preceded by, followed by, or that otherwise include the words "believes", "expects", "anticipates", "intends", "estimates", "plans", and similar expressions or future or conditional verbs such as "will", "should", "would", "may" and "could" are generally forward-looking in nature and not historical facts. For example, when we discuss driving increased adoption of WatchPAT, we are using forward-looking statements. Because such statements deal with future events, they are subject to various risks, uncertainties and assumptions, including events and circumstances out of the Company's control and actual results, expressed or implied by such forward-looking statements, could differ materially from the Company's current expectations. Factors that could cause or contribute to such differences include, but are not limited to, risks, uncertainties and assumptions discussed from time to time by the Company in reports filed with, or furnished to, the U.S. Securities and Exchange Commission ("SEC") and the Israel Securities Authority ("ISA"), including the Company's latest Form 20-F and its registration statement on Form F-1, which are each accessible on the SEC's website at www.sec.gov. Except as otherwise required by law, the Company undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

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