

Initiation of Coverage

25 June, 2019



Company Overview

Itamar Medical LTD. (NASDAQ and TASE: ITMR) is a publicly traded medical device company that focuses on leading the integration of Sleep Apnea management into the cardiac patient care pathway. The company has one HQ based in Israel's Caesarea Industrial Park and another in Atlanta Georgia. Since its foundation in 1997, the Company has engaged in research and development of non-invasive medical devices for the diagnosis of various medical conditions, including cardiovascular disease and respiratory disorders. Itamar Medical's main product family is based on the PAT signal and includes the WatchPAT™ home sleep apnea diagnosis device and the accompanying digital health care continuum management tools, the CloudPAT™ and SleepPath™ platforms. The company also sells the EndoPAT™, a device approved by the FDA for testing endothelial (arterial) function for predicting the risk of coronary artery disease and other cardiovascular diseases.

Revolutionary technology enables cardiologists to make better decisions and results in 30% assumed revenue growth by the end of 2019; Itamar Medical has a \$6.8B addressable market with limited competition; we start our coverage with a price target of 1.51 NIS.

Stock Exchange: NASDAQ, TASE

Symbol: ITMR

Sector: Health Care

Sub-sector: Medical Device

Stock Target Price: 1.51 NIS

As of June 25, 2019

Closing Price: 1.22 NIS

Market Cap: 405.8 million NIS

of Shares: 334 million

Stock Performance (last 12 months): 14%

Average Daily Trading Volume: NIS 275k

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Highlights

- Itamar Medical operates in the U.S. sleep market worth \$28.6 billion in 2017 with a 3.3% CAGR. Itamar Medical's technology has an addressable market of \$6.8 Billion.
- Itamar Medical's technology is better than the currently available alternative solutions for Home Sleep Apnea Tests: 3 points of contact and no facial and nasal interface, comprehensive sleep stage analysis, positional sleep and snoring level, accurate with true sleep time, cost effective, automatic scoring, and immediate and easy to read results. These features promote patient adherence and satisfaction.
- Itamar Medical offers a Total Sleep Solution™ (TSS) platform which provides complete sleep apnea management to cardiology customers.
- The platform has several advantages: For patients, it offers a simple and convenient solution from the comfort of their own home. For the doctors and clinics, the company's clients, it offers a unique business model with diagnostics and therapy all on the cloud.
- Financially, revenues in 2018 increased by 16.8% to \$24.2 million; as of March 31, 2019, Itamar has marketable securities of approximately \$19.9 million, enough to support its growth plans to 2020.

We view Itamar Medical as a growth company with investment potential.

We evaluate Itamar Medical's equity value at \$139.8M/502.8M NIS; price target to be in the range of 1.56 NIS to 1.45 NIS with a mean of 1.51 NIS.

Below are our main assumptions and forecast for 2019-2022:

	2018A	2019E	2020E	2021E	2022E
No. of US territories	19	26	36	51	71
Revenues (000, k)	24,190	31,497	43,634	60,585	83,105
Operating profit (loss), (000,k)	-3,121	-4,640	-5,628	-2,763	1,868

Stock overview YTD (Source: TASE website)



Executive Summary

Investment Thesis

Itamar Medical is engaged in research, development, sales and marketing of non-invasive medical devices for the diagnosis of respiratory sleep disorders with a focus on the cardiology market. The company offers a Total Sleep Solution™ (TSS) to help physicians provide comprehensive sleep apnea management in a variety of clinical environments to optimize patient care and reduce healthcare costs. Its flagship PAT-based product, the WatchPAT™ device, is a home-use diagnostic device for sleep breathing disorders. Its CloudPAT™ and SleePath™ digital health platform enable seamless care continuum for cardiology patients throughout their entire user journey. It also offers the EndoPAT™ system, an FDA cleared device to test endothelial dysfunction and to evaluate the risk of heart disease and other cardiovascular diseases.

Sleep apnea is a sleep disorder in which breathing is briefly and repeatedly interrupted during sleep. Obstructive sleep apnea (OSA) occurs when the muscles in the back of the throat fail to keep the airway open, despite efforts to breathe. Another form of sleep apnea is central sleep apnea, in which the brain fails to properly control breathing during sleep. Obstructive sleep apnea is far more common than central sleep apnea; however, some forms of central sleep apnea are common with patients with cardiac disease such as heart failure and atrial fibrillation.

Common symptoms include excessive daytime sleepiness, fatigue, non-refreshing sleep, nocturia, morning headache, irritability, and memory loss. Untreated OSA is also associated with lost productivity in the workplace and motor vehicle accidents resulting in injury and fatality. The costs of untreated OSA and sleep loss are substantial. Untreated OSA is associated with long-term health consequences including metabolic disorders, cognitive impairment, depression and cardiovascular disease.

The connection between sleep apnea and heart disease is rapidly being strengthened by continued research publications. People with cardiovascular problems such as atrial fibrillation, diabetes, high blood pressure, heart failure, and stroke have a high prevalence of sleep apnea.¹

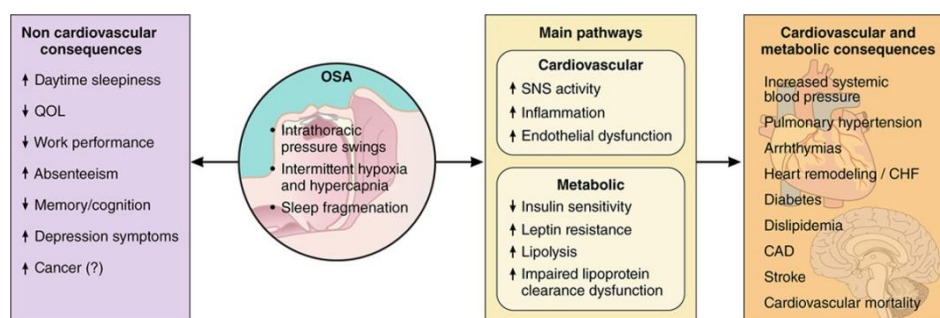


Figure 1: Proposed consequences of obstructive sleep apnea²

Itamar Medical PAT™ based technology is implemented in a non-invasive wrist worn device called WatchPAT. This simplistic device uses a finger mount bio-sensor to measure and record the PAT signal, which is then transferred to either local (zzzPAT) or cloud-based (CloudPAT) software for analysis and reporting of the sleep apnea diagnosis. (The PAT signal measures changes in the patient's peripheral arterial pulse volumes as well as various parameters of arterial activity. These arterial activity parameters accurately reflect the patient's sympathetic nervous system (autonomous (involuntary) nervous system) activity. The WatchPAT product is designed to enable patients to easily

¹ <https://www.sleepfoundation.org/articles/sleep-apnea-and-heart-disease-0>

² <https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.117.029400>

conduct sleep tests in the comfort of their home while delivering the treating physicians with accurate and reliable results for diagnosis of sleep apnea.

Itamar Medical's technology is better than the currently available alternatives solution for Home Sleep Apnea Tests. It is easy to use with only 3 points of contact and no facial and nasal interface, comprehensive sleep stage analysis, positional sleep and snoring level, accurate with true sleep time, cost effective, automatic scoring, and immediate and easy to read results. These features promote patient adherence and satisfaction.

Itamar Medical offers a Total Sleep Solution (TSS) platform which provides complete sleep apnea management to cardiology customers. The platform has several advantages: for patients, it offers a simple and convenient solution from the comfort of their own home. For the doctors and clinics, the company's clients, it offers a unique business model with diagnostics and therapy all on the cloud.

The company had made a strategic decision to focus its marketing and sales efforts on reaching out to cardiologists and offer the sleep apnea tests as a preventative measure for many diseases such as stroke and heart disease. We believe that this new business model will commercialize with rapid growth in 2019-2020.

Upside scenarios	Downside scenarios
Rapid growth within U.S territories may have great impact on Itamar's value. We assume 26 territories by the end of 2019.	Failure to grow at a rapid pace in the U.S may harm company value.
Technology acceptance by cardiologists may be higher than expectations.	Technology acceptance by cardiologists may be lower than expectations.

Valuation Methodology

Growth company valuations are challenging due to a non-cash / limited cash flow valuation with a long time-to-market in most cases. Methods typically used for company valuations, such as asset valuation or multiplier methods, are incompatible with the valuation of growth companies. In such companies, the current status of business cannot be analyzed by the capital in the balance sheet, and in most cases cannot be compared to similar companies due to their uniqueness, in both technological and financial aspects.

As part of a discounted cash flow (DCF), the accepted method used in financial valuations, there are several modifications to a growth company's valuation. In general, there are three primary methods within the DCF method:

1. **Real Options** - valuation method designated for pre-clinical and early-stage clinical programs/companies where the assessment is binary during the initial phases and based upon scientific-regulatory assessment only (binomial model with certain adjustments).
2. **Pipeline assessment** - valuation method used for programs/companies prior to the market stage. The company's value is the total discounted cash flow plus unallocated costs and assessment of future technological basis. The assessment of the future technological basis is established based on the company's ability to "produce" new clinical and pre-clinical projects and their feed rate potential.
3. **DCF valuation** - similar to companies not operating in the life sciences field, this method applies to companies with products that have a positive cash flow from operations.
4. **Multiples** – growth companies valuation by multiples, revenues multiples to cash flow multiples, can serve as a benchmark for similar companies in a comparable growth stages.

Itamar Medical's valuation was conducted under the DCF valuation method, while also using benchmarks from the medical devices industry.

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Company Overview

Itamar Medical Ltd. is a publicly traded medical device company (Nasdaq, TASE: ITMR) HQ in Israel's Caesarea Industrial Park and Atlanta Georgia USA that develops non-invasive medical devices using the proprietary PAT™ (Peripheral Arterial Tone) signal. The company was established on 1997 by Peretz Lavie and Giora Yaron and went public in 2007 (TASE).

Itamar Medical is engaged in research, designs, development, manufactures, sales and marketing of non-invasive medical devices for the diagnosis of respiratory sleep disorders with a focus on the cardiology market. The company focused on leading the integration of Sleep Apnea management into the cardiac patient care pathway. Their main scope is in the development, manufacturing and sales of the WatchPAT™ diagnostic product line based on the proprietary PAT® signal; and by offering Total Sleep Solution (TSS) – a product that includes a field support organization, partnerships, as well as core and supporting technologies that enable all physicians in general and cardiologists in particular to provide a seamless and full continuum of care to Sleep Apnea patients as part of their health care pathway.

A key factor that differentiates Itamar Medical from competition is the use of the Peripheral Arterial Tone (PAT) biological signal along with measurements, such as actigraphy, heart rate, chest motion, body position and snoring. The PAT-based technology is implemented in a user-friendly wrist worn device called WatchPAT that uses a finger mount bio-sensor to measure and record the PAT signal, which is then transferred to either a local (zzzPAT) or cloud-based (CloudPAT) software for analysis and reporting of sleep apnea diagnosis. The results of their proprietary analysis are automatically populated into a cohesive report that allows physicians to make accurate diagnosis of sleep apnea.

Itamar Medical's Total Sleep Solution (TSS) offers a comprehensive marketing program to physicians that combines products and services, including their proprietary diagnostic test, data analytics, a network of independent diagnostics testing facilities (IDTFs), and durable mobile equipment (DMEs) providers. TSS is designed to allow any medical practice or physician that is not a sleep physician by specialty, easy access to a comprehensive suite of products and services for the diagnosis, treatment and management of patients they suspect suffer from sleep apnea.

Furthermore, the company has developed and is also selling the EndoPAT™ system – an endothelial function assessment tool for risk classification used by clinicians, researchers and pharma companies to reliably quantify and track arterial health. The EndoPAT™ is the only device approved by the U.S. FDA for testing endothelial (arterial) function and assessing the risk of coronary artery disease and other cardiovascular diseases.

During the past few years, Itamar Medical has signed a number of strategic marketing agreements for its products, including agreements with Medtronic (2014)³ and DeVilbiss (the fourth largest continuous positive airway pressure, CPAP manufacturer in the US) in the US, and Philips Respironics & Nihon Kohden in Japan (2014)^{4 5}.

Additionally, Itamar Medical and BioTel Heart, a division of BioTelemetry, agreed to collaborate to make the company's Total Sleep Solution (TSS) and WatchPAT™ Home Sleep Apnea Tests available to select BioTel Heart cardiology customers in the U.S. The companies have conducted a successful pilot program with several of BioTel Heart's customers and are now making the service available in additional target regions⁶.

³ <https://en.globes.co.il/en/article-itamar-signs-medtronic-distribution-deal-for-sleep-device--1000925010>

⁴ <https://en.globes.co.il/en/article-itamar-medical-signs-distribution-agreement-in-japan-1000947940>

⁵ <https://www.marketwatch.com/press-release/itamar-medical-ltd-signs-strategic-marketing-and-distribution-agreement-for-its-endopat-device-with-premier-medical-device-maker-nihon-kohden-japan-2014-06-23>

⁶ https://www.itamar-medical.com/wp-content/uploads/2019/05/tv522322_ITAMAR-MEDICAL-LTD._6k_as-filed-bannerless.pdf

On May 2, 2019, Itamar Medical entered into a data integration agreement with ResMed Corp., the owner and developer of AirView™, a cloud based and compliance platform. Under the agreement, the company will obtain access to information entered by durable medical equipment providers who have agreed to share compliance data from AirView and its customers using the company's sleep management software. The data will be provided to customers through the company's SleepPath™, an integrated cloud-based sleep apnea patient care pathway management tool for non-sleep physicians⁷.

Itamar Medical's aim is to improve cardiac patient care through the integration of innovative and clinically efficient Sleep Apnea management solutions to the chronic disease care continuum that reduce overall healthcare costs⁸.

Itamar Medical received approximately \$25 million investment from Viola in November 2015 for about 25% of the company in addition to approximately \$5M from other existing investors. In Jan. 17, 2019, Itamar Medical entered into definitive agreements for a \$14.7 million private placement at a purchase price of NIS 1.1693 per ordinary share of the company, or \$9.55 per American Depositary Share (ADSs), each representing 30 ordinary shares⁹. Of the \$14.7 million, \$11.2 million will be made through purchases of ADSs (the "U.S. Tranche"), consisting among others of a fund managed by Deerfield Management Company, L.P. as well as Triple Gate Capital, L.P., West Elk Partners, L.P. and Alpha Capital Anstalt, and the balance of \$3.5 million will be by way of issuing ordinary shares to More Investment House (the "Israeli Tranche").

⁷ <https://maya.tase.co.il/reports/details/1228079/2/0>

⁸ <https://www.itamar-medical.com/mission-and-vision/>

⁹ <https://www.globenewswire.com/news-release/2019/01/17/1701350/0/en/Itamar-Medical-Announces-Definitive-Agreements-for-11-5-Million-Private-Placement.html>

Products and Services

Products

WatchPAT is an innovative diagnostic Home Sleep Apnea Test (HSAT) that utilizes the peripheral arterial tone signal (PAT) to enable simple and accurate obstructive sleep apnea (OSA) and central sleep apnea diagnosis while avoiding the complexity and discomfort associated with traditional air-flow based systems.

The PAT signal measures the changes in the patient's peripheral arterial pulse volumes as well as various parameters of arterial activity. These arterial activity parameters accurately reflect the patient's autonomous nervous system activity. The WatchPAT continuously records and interprets the autonomic nervous system activity during sleep, including that which occurs upon every sleep breathing disorder, as measured through the PAT signal. The PAT probe uses optical sensors to non-invasively measure the changes in arterial blood volume while applying sub-diastolic pressure on the distal two thirds of the finger, including the tip. The pressure fields reduce the arterial wall tension and generate a greater dynamic range of the measured PAT signal and improved sensitivity to changes in the signal amplitude. WatchPAT is designed to measure seven unique parameters, including the PAT signal, heart rate, oximetry, actigraphy, body position, snoring, and chest motion by three points of contact.

The first generation of WatchPAT (2001) is a watch-like device with one or two single-use disposable bio-sensors connected to the patient's fingers. It is designed to non-invasively record, measure and analyze digital pulse volume change, or changes in arterial blood volume, primarily in a patient's finger along with an additional oximetry sensor attached to another finger for blood oxygen saturation. In 2014, the company introduced WatchPAT 200 Unified, which allows the sleep apnea test to be performed using only a single finger to collect both oximetry and PAT data in a unified probe. In March 2019, Itamar Medical introduced the WatchPAT300 which is a new generation of the WatchPAT line of products, which, among others, is designed to expedite data transfer and allow the use of a lighter and smaller watch¹⁰.



Source: Itamar Medical's website¹¹

WatchPAT™ device leverages the EndoPAT™ system, to test endothelial dysfunction and to evaluate the risk of heart disease and other cardiovascular diseases¹². WatchPAT 300 was granted 510(k) clearance by the U.S. Food and Drug Administration on August 17, 2018 and will gradually replace the current WatchPAT 200 platform¹³.

The offered treatment today for sleep apnea detection is by polysomnogram (sleep study), which is a multiple-component test that electronically transmits and records specific physical activities while you sleep. During the sleep

¹⁰ Itamar Medical 20F, p.33

¹¹ <https://www.itamar-medical.com/watchpat-home-sleep-testing-made-simple/>

¹² <https://www.globenewswire.com/news-release/2019/03/20/1757811/0/en/Itamar-Medical-Advances-Simple-Accurate-and-Reliable-Home-Sleep-Apnea-Testing-with-Launch-of-WatchPAT-300.html>

¹³ <https://www.news-medical.net/news/20190321/Itamar-Medical-launches-next-generation-WatchPAT-system-for-home-sleep-apnea-testing.aspx>

study, surface electrodes will be placed on your face and scalp and belts will be placed around your chest and abdomen. These procedures will measure your breathing and a bandage-like oximeter probe will be put on your finger to measure the amount of oxygen in your blood¹⁴ (Figure 2). However, Itamar Medical's detection test is easier, much comfortable but also more expensive. The main cost is the thimble, which is single use and is discarded at the end of the examination. This is the company's profit model, as the watch itself can be used long-term for many years.



Figure 2: The traditional sleep test (left) versus Itamar Medical's WatchPAT technology (right)

EndoPAT is the only FDA-cleared non-invasive assessment of Endothelial Dysfunction (arterial health). The EndoPAT was designed to diagnose endothelial function by measuring the ability of blood vessels to dilate as a response to shear stress, or other stimuli, in order to accommodate increased blood flow. The endothelium is the inner lining of all blood vessels regulating their function and ability to dilate or constrict. The EndoPAT device uses PAT-based technology to measure the ability of blood vessels to dilate after an artificially created ischemic situation. Endothelial dysfunction is a proven independent functional marker for most types of cardiovascular disease.



EndoPAT is a key indicator for all major cardiovascular disease states, ranging from unexplained chest pains to atherosclerosis and coronary artery disease. As the ultimate non-invasive diagnostic cardiac tool, the EndoPAT test has the potential to become the “heart’s mammogram” by helping assess heart disease risk and alerting patients to initiate preventive steps to keep it from progressing.

The EndoPAT measures changes in pressure that indicate changes in arterial blood volume and result in a value called EndoScore. The test is uniquely performed at the fingertip and proven to be accurate, sensitive and reproducible.

¹⁴ <https://www.webmd.com/sleep-disorders/sleep-apnea/diagnosing-sleep-apnea>

WatchPAT One is the first and only fully disposable Home Sleep Apnea Test which recently (June 2019) received clearance 510(k) from the FDA¹⁵. WatchPAT One offers patients and physicians the same simplicity, accuracy and reliability as WatchPAT 300 without the need for return shipping, downloading, cleaning or preparation for the next study. The availability of a disposable WatchPAT system will improve patient access by increasing the number physicians able to offer the technology to their patients¹⁶. With WatchPAT One, patients pair the WatchPAT device to their smartphone using Itamar's proprietary app. Sleep study data are collected during the test and automatically sent to CloudPAT™, Itamar's secure server. Once the test is complete, a comprehensive report using WatchPAT's True Sleep Time, Sleep Architecture and Central Plus algorithms is automatically generated and sent to the prescribing physician. The patient then disposes the WatchPAT device.



SleePath. In May 2018, Itamar Medical launched SleePath, a digital sleep apnea management tool that helps cardiologists monitor patients with atrial fibrillation. The platform allows doctors to check their patients' sleep apnea management status and compliance with continuous positive airway pressure (CPAP) devices.

The product includes a cardio sleep dashboard that lets doctors track multiple aspects of a patient's sleep apnea status using data that comes from the Philips Respironics CPAP machines. It also lets clinicians see care pathway progress, diagnosis status and results, CPAP compliance, and the number of days and hours a patient spends on CPAP. Users can then see the data and how they are living up to their treatment goals¹⁷.

WatchPAT Related Services

Total Sleep Solutions™ (TSS)

Total Sleep Solution is a sleep apnea management service for cardiology practice, providing diagnosis and treatment to millions of cardiac patients with undiagnosed sleep apnea comorbidity. The rationale behind this service is to enable accessible sleep apnea testing for a large cardiac patient population, which will help overcome the large number of undiagnosed sleep apnea patients and help improve clinical outcomes.



Screening



Diagnosing



Treatment

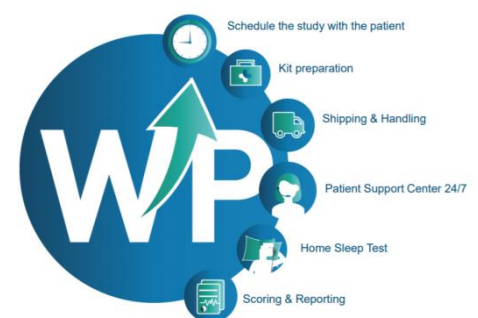


Reporting

WatchPAT Direct

WatchPAT Direct is a mail-order service which allows healthcare professionals/clinics/health institutes to scale up HSAT programs, with no upfront costs and with minimal time and effort. WatchPAT Direct includes coordination, delivery and collection of WatchPAT devices, based on orders of prescribed sleep tests, from a customer to the patient and back. (WatchPAT Direct is currently offered only in the mainland of the United States).

CloudPAT Platform



¹⁵ <https://www.nasdaq.com/press-release/itamar-medicals-watchpat-one-the-first-and-only-fully-disposable-home-sleep-apnea-test-receives-fd-20190606-00172>

¹⁶ <https://www.globenewswire.com/news-release/2019/06/06/1865142/0/en/Itamar-Medical-s-WatchPAT-One-the-First-and-Only-Fully-Disposable-Home-Sleep-Apnea-Test-Receives-FDA-510-k-Clearance.html>

¹⁷ <https://www.mobihealthnews.com/content/itamar-medical-launches-sleepath-track-sleep-apnea-afib-patients>

CloudPAT is a cloud-based information technology (IT) platform, designed to allow customers to transfer the WatchPAT test results primarily to board-certified sleep physicians, IDTF and DMEs. The board-certified sleep physicians receive and interpret the test results, make a diagnosis and potentially prescribe therapy.

zzzPAT Software

The zzzPAT is a proprietary PC or server-based analysis software used with the WatchPAT device. The software's advanced algorithm is automatic, eliminating the need for subjective manual scoring of respiratory events. If needed, the software also enables manual scoring for compliance with AASM standards. A comprehensive sleep study report is generated within minutes after downloading the study data, allowing patients to initiate treatment without delay¹⁸.

¹⁸ https://www.itamar-medical.com/wp-content/uploads/2017/05/TotalSleepSolution_tts_bro.pdf

Market Overview

Market Structure

Sleep market

The sleep market is made up of five major segments: Sleep equipment (beds, pillows, blankets), Sleep labs (Hospitals, Clinics and home), Sleep devices (Diagnostic and Therapeutic), Sleep medication (OTC and Prescription), and Retail Sleep Aids (Earplugs, Clocks, Lights, Eye masks, Sound conditioning machines).

Sleep disorder is defined as a sleep problem, which is characterized by snoring, insomnia, depression, and sleep apnea. It is found that approximately more than 75% of Americans from the age of 25 to 59 suffer from sleep disorder in the U.S.

The U.S. sleep market was worth \$28.6 billion in 2017 while the sleep disorder part was anticipated to reach over \$1.31 billion by 2017¹⁹. In 2017, the sleep apnea devices dominated the global market, in terms of revenue. For 2018, the sleep market should grow by 3.3%. To 2023, we forecast 4.7% average annual growth²⁰. Asia Pacific is estimated to be the fastest growing region in terms of revenue. Growing awareness about sleep disorders and developing healthcare infrastructure are some of the factors that are projected to generate lucrative opportunities for the market in APAC¹⁵.

The prescription insomnia drugs market in the U.S. can be valued at an estimated \$1.4 billion, whereas the OTC sleeping pills market, valued at \$576 million, is growing at a faster rate.

There are approximately 4,700 U.S. sleep centers or labs which perform studies (polysomnograms) to diagnose sleep disorders. The typical lab has revenues of \$920,000 and a bed count of about 7-8. Labs are located in hospitals, MD practices, universities, or are independent. This segment was worth \$4.3 billion in 2017. There has been consolidation and closures due to reimbursement pressure from competing portable home testing devices approved by Medicare.

CPAP devices (continuous positive airway pressure) are a \$4.3 billion market that is growing 7.2% per year. It is dominated by ResMed and Respireonics. The market is largely untapped — only 12% penetrated in the U.S. It has major potential, as more people, especially the obese, are diagnosed with obstructive sleep apnea²¹.

Sleep devices includes devices, sensors, peripherals, and applications that can be used for monitoring, understanding, and improving sleep for both clinical/disease studies and wellness reasons. The sleep device segment may be further sub-segmented according to;

1. Technology: sleep-tracking devices (monitoring and recording of sleep patterns) – wearables, bed-based sensors, mobile apps, software platforms or sleep aid devices (help in curing/improving sleep issues) – wearables, ambient devices, mobile apps.
2. Purpose: diagnostic devices aim to diagnose and monitor sleep patterns and identify sleep disorders such as Polysomnography, oximeters, PAT™ (Peripheral Arterial Tone) signal whereas, therapeutic devices aim to treat patients with sleep disorders, especially apnea related conditions. Examples include PAP/CPAP, Facial interfaces (mask), Oxygen concentrators, Adaptive Servo-Ventilation (ASV), Airway clearance systems.

Of a total population of 327 million Americans, 58% are estimated to experience insomnia symptoms or sleep disorders. Companies across America are trying to sell us a perfect night's sleep with medications, premium

¹⁹ <https://www.reuters.com/brandfeatures/venture-capital/article?id=113590>

²⁰ <https://www.webwire.com/ViewPressRel.asp?ald=222385>

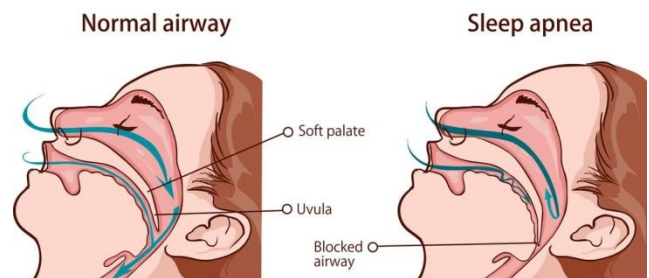
²¹ <https://blog.marketresearch.com/top-6-things-to-know-about-the-28-billion-sleep-market>

mattresses, high tech pillows, CPAP devices, white noise machines, smartphone apps, and more. All of this has become a \$28.6 billion a year industry²².

Sleep Apnea

Sleep apnea is a common but serious sleep disorder where your breathing is briefly interrupted when you're asleep²³. The "apnea" in sleep apnea refers to a breathing pause that lasts at least ten seconds. The main types of sleep apnea are:

- **Obstructive sleep apnea (OSA)**, the more common form that occurs when the muscles in the back of the throat fail to keep the airway open, despite efforts to breathe²⁴
- **Central sleep apnea**, which occurs when your brain doesn't send proper signals to the muscles that control breathing
- **Complex sleep apnea syndrome**, also known as treatment-emergent central sleep apnea, which occurs when someone has both obstructive sleep apnea and central sleep apnea²⁵



More than 18 million American adults have sleep apnea and nearly 1 billion people worldwide²⁶. It is very difficult at present to estimate the prevalence of childhood OSA because of widely varying monitoring techniques, but a minimum prevalence of 2 to 3% is likely, with prevalence as high as 10 to 20% in habitually snoring children. OSA occurs in all age groups and both sexes¹⁴

According to a study published a year ago by the American Journal of Respiratory and Critical Care Medicine, the prevalence of sleep apnea impacts more than 936 million people worldwide. At the same time, and despite the growing awareness of the consequences of OSA, it was estimated that over 80% of patients with clinically significant and treatable OSA have never been diagnosed.

The annual economic costs (including the cost of diagnosis and treatment, public safety costs from OSA-related traffic accidents, and the incremental medical costs of OSA co-morbidities) of untreated moderate to severe OSA in the U.S. to be between \$65 billion and \$165 billion annually, potentially greater than the cost of asthma, heart failure, stroke or hypertensive disease, which range from \$20 billion to \$80 billion according to estimates.

Life-threatening conditions associated with OSA range from chronic daytime fatigue to heart disease, stroke, type 2 diabetes, depression, and more. Previous studies have suggested that undiagnosed sleep apnea costs nearly \$150 billion in the United States alone as a result of related lost productivity, motor vehicle accidents and workplace accidents – an economic impact that's likely much greater, given a higher prevalence total¹⁶.

The signs and symptoms of obstructive and central sleep apneas overlap and include the following: loud snoring, episodes in which you stop breathing during sleep, gasping for air during sleep, awakening with a dry mouth, morning headache, insomnia, excessive daytime sleepiness (hypersomnia), difficulty paying attention while awake and irritability.

There are a number of factors that increase risk, including having a small upper airway (or large tongue, tonsils or uvula), being overweight, having a recessed chin, small jaw or a large overbite, a large neck size (17 inches or greater

²² <https://www.researchandmarkets.com/reports/4516634/the-u-s-sleep-market-2018-competitive-and>

²³ <https://www.helpguide.org/articles/sleep/sleep-apnea.htm>

²⁴ <https://www.sleepfoundation.org/sleep-apnea>

²⁵ <https://www.mayoclinic.org/diseases-conditions/sleep-apnea/symptoms-causes/syc-20377631>

²⁶ <https://www.businesswire.com/news/home/20180521005096/en/>

in a man, or 16 inches or greater in a woman), smoking and alcohol use, being age 40 or older, and ethnicity (African-Americans, Pacific-Islanders and Hispanics). Also, OSA seems to run in some families, suggesting a possible genetic basis.

Central sleep apnea is more common in males and people over the age of 65. However, unlike obstructive sleep apnea, central sleep apnea is often associated with serious illness, such as heart disease, stroke, neurological disease, or spinal or brainstem injury. The first step in treating central sleep apnea is to treat the existing medical conditions that are causing it.

Lifestyle changes to reduce sleep apnea symptoms

- Lose weight. People who are overweight have extra tissue in the back of their throat, which can fall down over the airway and block the flow of air into the lungs during sleep. Even a small amount of weight loss can expand your throat and improve sleep apnea symptoms.
- Quit smoking. Smoking contributes to sleep apnea by increasing inflammation and fluid retention in your throat and upper airway.
- Avoid alcohol, sleeping pills, and sedatives, especially before bedtime, because they relax the muscles in the throat and interfere with breathing.
- Exercise regularly. As well as helping you lose weight, regular exercise can have a major effect on the duration and quality of sleep. Aerobic and resistance training can help reduce sleep apnea symptoms, while yoga is also good for strengthening the muscles in your airways and improving breathing.
- Avoid caffeine and heavy meals within two hours of going to bed.
- Maintain regular sleep hours. Sticking to a steady sleep schedule will help you relax and sleep better. Sleep apnea episodes decrease when you get plenty of sleep¹³

The severity of sleep apnea is typically measured by the number of partial or complete airway blockages that a patient experiences in an hour (which also referred to as the apnea-hypopnea index or AHI) or the average number of respiratory disturbances and related arousals (RERAs) per hour of sleep, referred to as the respiratory disturbance index, or RDI.

Apnea-Hypopnea Index (AHI)	
Mild	5-15
Moderate	15.1-30
Severe	>30

The currently offered treatments for obstructive sleep apnea include: Continuous Positive Airflow Pressure (CPAP), other breathing devices, dental devices, implants and surgery.

Continuous Positive Airflow Pressure (CPAP) is the most common treatment for moderate to severe obstructive sleep apnea. The CPAP device is a mask-like machine that covers your nose and mouth, providing a constant stream of air that keeps your breathing passages open while you sleep.

In addition to CPAP, there are **other devices** that a sleep specialist may recommend for sleep apnea treatment: Expiratory positive airway pressure (EPAP) is a single-use device which fit over the nostrils to help keep the airway open and are smaller and less intrusive than CPAP machines; Bilevel positive airway pressure (BiPAP or BPAP) devices can be used for those who



are unable to adapt to using CPAP, or for central sleep apnea sufferers who need assistance for a weak breathing pattern. This device automatically adjusts the pressure while you're sleeping, providing more pressure when you inhale, less when you exhale; Adaptive servo-ventilation (ASV) device stores information about your normal breathing pattern and automatically uses airflow pressure to prevent pauses in your breathing while you're asleep.

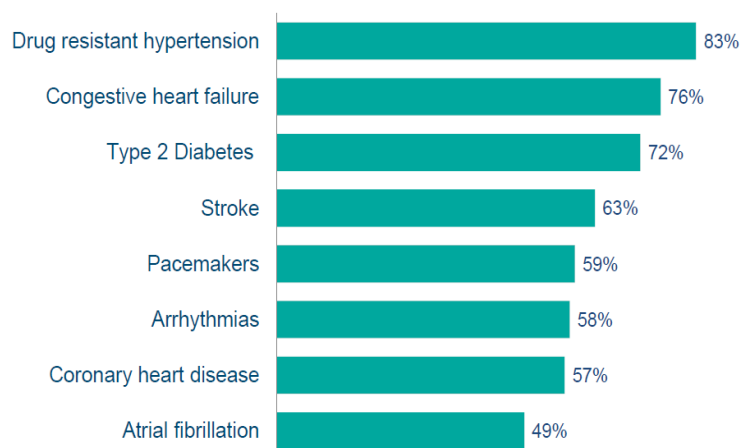
Most of the offered **dental devices** are acrylic and fit inside your mouth; others fit around your head and chin to adjust the position of your lower jaw. Two common oral devices are the mandibular repositioning device and the tongue retaining device. These devices open your airway by bringing your lower jaw or your tongue forward during sleep.

One of the newest treatments for sleep apnea involves the **insertion of a pacemaker system** that stimulates muscles to keep airways open so you can breathe during sleep. The new treatment has been approved by the FDA in the U.S. for people with moderate to severe obstructive sleep apnea (Although the technology is relatively new (and expensive), studies suggest it may also benefit people with central sleep apnea).

Surgery is another option for treatment which can increase the size of the patient's airways, thus reducing episodes of sleep apnea. The surgeon may remove tonsils, adenoids, or excess tissue at the back of the throat or inside the nose, reconstruct the jaw to enlarge the upper airway, or implant plastic rods into the soft palate. Surgery carries risks of complications and infections, and in some rare cases, symptoms can become worse after surgery.

If sleep apnea is left untreated, it increases the risk of serious chronic conditions, such as high blood pressure, cardiac arrhythmias (such as atrial fibrillation) and other cardiovascular disease, metabolic disease, adult type II diabetes and other life-threatening diseases. In particular, the risk of stroke or of death from sudden cardiac arrest doubles; the risk of death from CVD is five times greater and the risk of recurrence of atrial fibrillation following ablation increases by 42%.

A study which was published in *Anesthesiology Clinics* illustrates the following co-morbidities associated with sleep apnea: drug resistant hypertension (83%); congestive heart failure (76%); diabetes type 2 (72%); stroke (63%); pacemakers (59%); arrhythmias (58%); coronary heart disease (57%); and atrial fibrillation (49%).



Source: Itamar Medical's investor's presentation

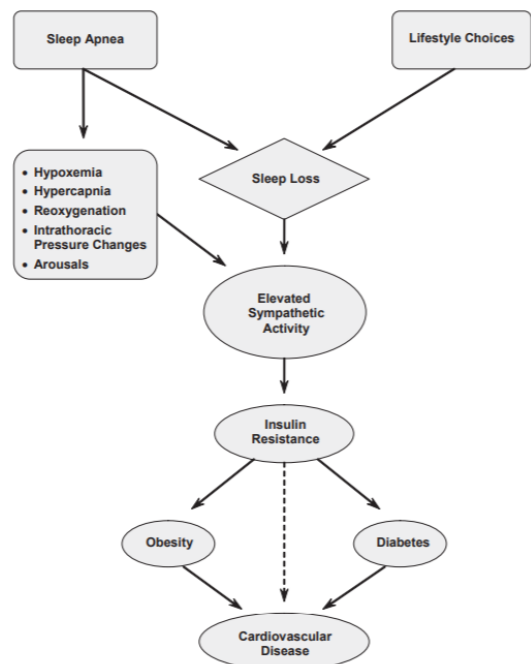
Sleep Apnea and Cardiovascular Disease (CVD)

The World Health Organization indicates that 31% (17.9 million) of annual global deaths can be attributed to CVDs. This chronic illness can be managed pharmacologically as well as using cardiac surgical interventions.

According to the Centers for Disease Control and Prevention, in United States, every year, 610,000 people die of heart disease, which translates to one in every four deaths. Every year, approximately 735,000 Americans have a heart attack. This high and growing disease burden needs effective treatment and management tools²⁷.

Synchronization of molecular, metabolic, and cardiovascular circadian oscillations is fundamental to human health. Sleep-disordered breathing, which disrupts such temporal congruence, elicits hemodynamic, autonomic, chemical, and inflammatory disturbances with acute and long-term consequences for heart, brain, and circulatory and metabolic functions. Each apneic episode ordinarily lasts a minute or less but when repeated hour by hour, night after night, for years or decades, the hemodynamic, autonomic, chemical, and inflammatory disturbances elicited can exert long-term aftereffects on the heart, brain, circulation, and metabolism.

Thus, apneas can trigger events during sleep, and cardiovascular events can accrue long after apneas cease on awakening. Mismatch between myocardial oxygen delivery during apnea and the metabolic requirements imposed by acute increases in intrathoracic and systemic arterial pressure render the heart vulnerable to nocturnal ischemia, myocardial infarction, and ventricular arrhythmias²⁸.



- During an apnea event (pause in breathing) the oxygen levels in your blood drop significantly. When this happens your brain partially wakes from sleep to send signals to the nervous system to constrict the blood vessels (tighten up) in order to increase the flow of oxygen to your heart and brain.
- When your blood pressure increases at night to keep oxygen flowing to your heart and brain, it causes high blood pressure during sleep.
- The increased blood pressure experienced during sleep often begins to overlap into periods of wakefulness. Even though your blood pressure only needs to be increased at night when you require extra respiratory effort to get oxygen, many people with sleep apnea end up with increased blood pressure at all times.
- High blood pressure is a major risk factor for heart disease, stroke, heart attack, and many other medical problems, and sleep apnea is a major risk for high blood pressure.



²⁷ Frost & Sullivan; Game-changing Innovations Transforming Cardiovascular Care; March 2019

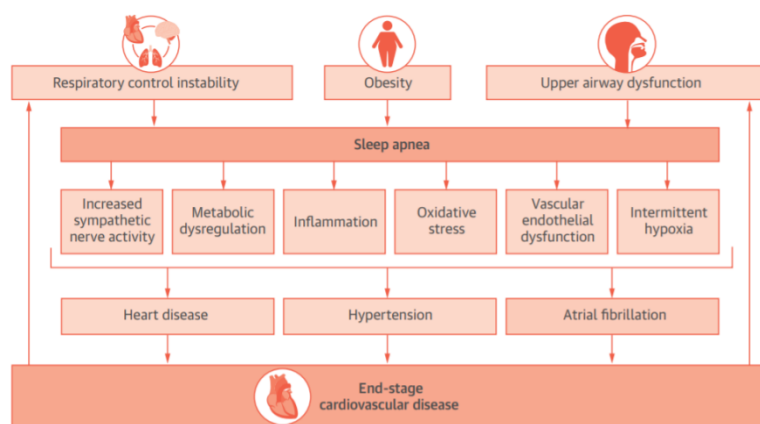
Figure : <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2546461/pdf/JCSM.4.3.261.pdf>

²⁸ <https://www.ahajournals.org/doi/10.1161/CIRCRESAHA.118.310783>

There is increasing awareness among cardiologists and the general population of the importance of sleep apnea in the causation or promotion of hypertension, coronary artery disease, heart failure, atrial arrhythmias, and stroke, and, consequently, as a predictor of premature cardiovascular death.

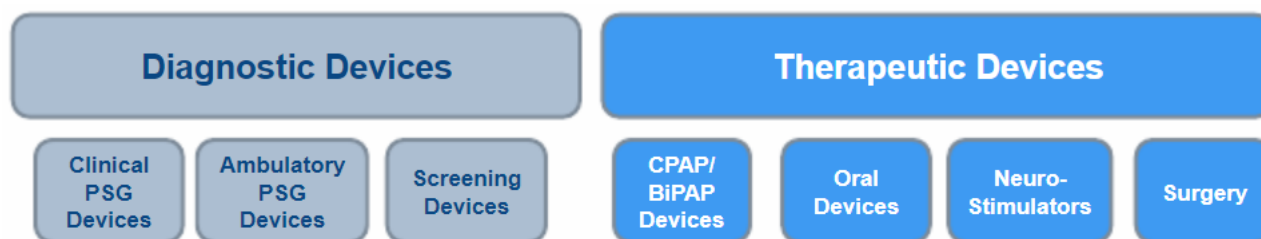
Linkage between obstructive sleep apnea and cardiovascular disease is corroborated by evidence that treatment of sleep apnea with continuous positive airway pressure reduces systolic blood pressure, improves left ventricular systolic function, and diminishes platelet activation²⁹.

Potential Etiological Risk Factors for Sleep Apnea and the Downstream Consequences³⁰:



Sleep apnea market

The global sleep apnea devices market is expected to reach \$7.5 Billion by 2024 from \$4.5 Billion in 2019 at a CAGR of 10.7%. The major factors driving the growth of the sleep apnea devices market are primarily a large pool of undiagnosed sleep apnea patients, growing awareness about the ill effects of untreated sleep apnea, growing usage of oral appliances, technological advancements in sleep apnea devices, considerable venture capital funding, and an increasing number of companies venturing into sleep apnea and oral appliances markets.



Source: Therapeutics Devices (Non-Drug) for Sleep Apnea; December 2015; Frost & Sullivan

The sleep apnea devices market has been segmented into therapeutic devices and diagnostic devices. The therapeutic devices segment accounted for the largest market share. The key factors contributing to this growth are the increasing number of undiagnosed sleep apnea patients across the globe, the improving reimbursement scenario for these devices³¹, technological developments and rising geriatric population³². U.S. led the sleep apnea devices market during 2016–2017, mainly due to the increasing cases of OSA, awareness-raising campaigns, and technological advancements in devices.

The North America sleep apnea devices market is expected to reach \$3.7 Billion in 2025 from \$ 2.1 Billion in 2017. The market is estimated to grow with a CAGR of 7.6% from 2018-2025³³. While the U.S. will still be the largest user of sleep apnea devices in 2018–2023, the Asia-Pacific (APAC) region, especially Japan, will witness the highest market

²⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2546461/pdf/JCSM.4.3.261.pdf>

³⁰ <http://www.onlinejacc.org/content/69/7/841>

³¹ <https://www.marketsandmarkets.com/PressReleases/sleep-apnea-devices.asp>

³² <https://www.globenewswire.com/news-release/2019/05/28/1851165/0/en/The-3-7-Billion-Sleep-Apnea-Devices-Market-in-North-America-2019-2025.html>

³³ https://www.researchandmarkets.com/reports/4769888/north-america-sleep-apnea-devices-market-to-2025?utm_source=GNDIY&utm_medium=PressRelease&utm_code=wfpqjr&utm_campaign=1248921+-The+%243.7+Billion+Sleep+Apnea+Devices+Market+in+North+America+2019-2025&utm_exec=joca220prd

growth globally. Factors such as increasing sleep disorder incidents, along with those of heart diseases and obesity that further result in sleep apnea, and awareness programs will keep the market stable in the U.S.^{34 35}.

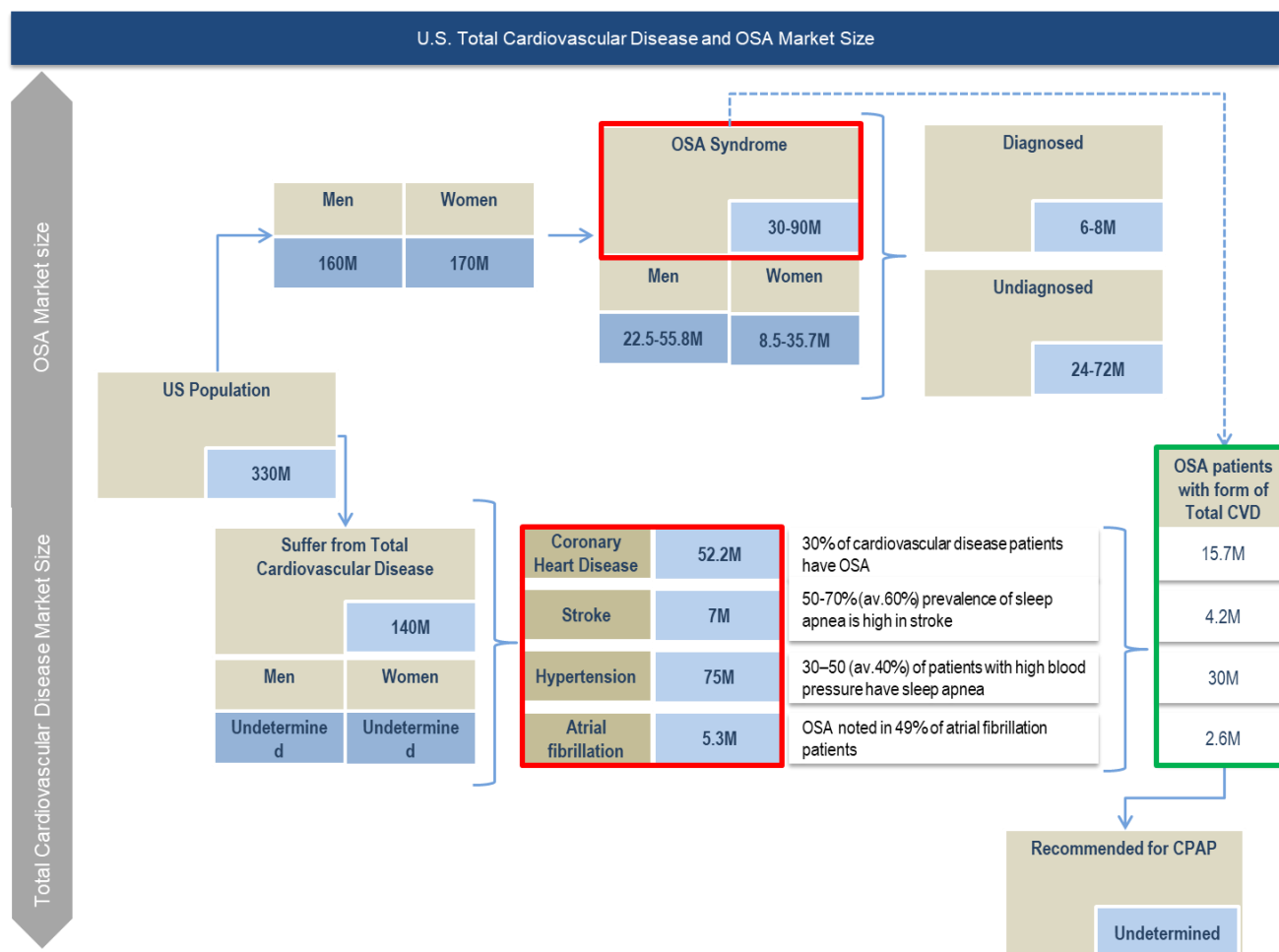


Figure 3: Market size for total cardiovascular disease and sleep apnea as well as potential number of OSA patients with a form of CVD disease in U.S.^{36 37 38}.

Sleep apnea can leave you tired throughout the day, increasing the likelihood of accidents, poor performance and judgment. OSA has also been linked to a host of serious cardiovascular problems. It occurs in about half of people with heart failure or atrial fibrillation and one-third of people with hypertension and coronary artery disease. The **total available market for Itamar Medical is \$52.2M**, which reflects all OSA patients with cardiovascular disease. The **average reimbursement** for sleep apnea diagnostics is \$130 (for technical component) which yields a Total Available Market (TAM) of approximately \$6.8 Billion (Figure 3).

Market drivers³⁹⁻⁴⁰

- Change in lifestyle: Lifestyle is becoming hectic and there is an increase in the number of people suffering from sleep disorders around the world. Increasing work pressure and stress has directly influenced sleeping

³⁴ <https://www.globenewswire.com/news-release/2019/03/04/1745679/0/en/U-S-Sleep-Apnea-Devices-Market-to-Lead-the-Global-Market-in-Coming-Years-P-S-Intelligence.html>

³⁵ <https://www.alliedmarketresearch.com/sleep-apnea-diagnostics-market>

³⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3721244/>

³⁷ <https://www.cardiosmart.org/news-and-events/2015/05/sleep-apnea-and-high-blood-pressure-a-dangerous-pair>

³⁸ <https://resindo.com/2018/09/19/sleep-apnea-facts-and-figures/>

³⁹ Therapeutics Devices (Non-Drug) for Sleep Apnea, December 2015; Frost & Sullivan

⁴⁰ Technology Breakthroughs in Sleep Apnea (Technical Insights); December 2013; Frost & Sullivan

patterns. Additionally, increasing night life and sedentary lifestyle have increased the risk of sleep problems that are helping the sleep apnea diagnostics and sleep services market to grow.

- Advances in technology: More companies are entering the sleep apnea market, replacing elaborate practices, targeting patient comfort and compliance, and driving acceptance of sleep monitoring devices. As a result of widespread acceptance, equipment prices will drop, making new technology platforms and products affordable.
- Increasing number of service providers: To meet the increasing end-user requirement an increasing number of service providers have cropped up.
- Increasing awareness of sleep apnea combined with rising awareness of diseases such as diabetes and obesity that are underlying issues associated with obstructive sleep apnea is constantly driving the market.
- Availability of sleep monitoring devices and home sleep testing devices that are user friendly and easy to use have led to an increase in the therapeutic segment to correct apnea.
- Persistent product modifications combined with introduction of novel technologies such as neuro-stimulators in this space is one of the major drivers for this market.

Market Restraints²⁹⁻³⁰

- Poor compliance with CPAP devices has resulted in sleep apnea and its associated illnesses recurring. (The negative side effects related to CPAP devices are noise arising from the device, nasal dryness or congestion, and breathing discomfort).
- Reimbursement policies: Sleep apnea costs are highly fragmented and touch many disconnected stakeholders. Reimbursement policies differ from country to country, leading to uncertainty over the regulations. Low funding for sleep diagnostics makes it a tough decision for the patient to go for diagnosis and further therapy as most of the cost would have to be borne by the patient. This negatively impacts the market and reduces the scope of market expansion.
- Shortage of qualified personnel such as pulmonologists and otolaryngologists have compromised the levels of standards across sleep diagnostic and monitoring services. Most patients are told that CPAP is their only option. Although CPAP therapy is clearly safer and more effective than any surgical therapy, there are a huge number of patients who cannot or will not use CPAP.
- High cost of surgery associated with neuro-stimulators is a major challenge that needs to be addressed by manufacturers developing neuro-stimulation devices.

Competitive Landscape

There is growing recognition of the widespread prevalence and impact of sleep-disordered breathing at a population level, while concurrently there is increasing societal and political attention being given to reducing health care costs. Home sleep apnea tests (HSAT) for obstructive sleep apnea (OSA) have been proposed as less costly alternatives to gold standard in-laboratory polysomnography (PSG) for both diagnostic purposes and for large scale screening of certain population⁴¹.

WatchPAT is an FDA-approved portable diagnostic device that uses the most innovative technology to ensure the accurate screening, detection, and follow-up of sleep apnea. Its ease of use is unparalleled in the marketplace and it is greatly complemented by the fact that WatchPAT testing is done in the comfort of your own bedroom; an environment that best reflects the pattern of your sleep habits⁴².

Itamar Medical's WatchPAT competes primarily with international and local vendors of home sleep apnea tests (HSAT) sleep tests, including in the following main categories: PSG (polysomnography) tests, HSATs

⁴¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5837829/>

⁴² <https://www.itamar-medical.com/patients-watchpat/>

(polysomnography – PSG), HSATs (Suppliers of home sleep testing for diagnostic purposes that offer ambulatory systems) and Pulse oximetry devices.

PSG (polysomnography) tests

Polysomnography (PSG) tests are procedures that diagnose sleep disorders. Polysomnogram (PSG) is a test that electronically transmits and records specific physical activities while you sleep. The recordings become data that a qualified sleep specialist analyzes to determine if you have a sleep disorder⁴³. Some companies are engaged in supplying these tests:

Nihon Kohden: Nihon Kohden offers the most comprehensive array of products and services in the world to address the sleep diagnostic market. The company is a pioneer in the first polysomnographs and continue to lead the way in developing cutting-edge smart solutions for home sleep apnea testing (HSAT), polysomnography, combined EEG and PSG multi-modality tools, data management and IT compatible solutions⁴⁴⁻⁴⁵.

Viasys Healthcare- SomnoStar™ z4 Sleep System is a full PSG sleep diagnostic system. SomnoStar z4 Sleep System offers a comprehensive feature set that allows for a complete and thorough diagnostic test. The company's integrated database allows for detailed tracking and reporting of patients through the arc of care⁴⁶.



Cleavemed: Cleveland Medical Devices Inc. is leading the way in services and devices for portable sleep disorders testing. Its various specialties include monitors for home sleep apnea testing (SleepView® and SleepScout™), systems for in-lab evaluation (Sapphire PSG™), and its fulfillment services directly to patients' homes (SleepView Direct). The company's aim is to expand the reach of sleep medicine⁴⁷.

Cadwell: Cadwell offer a broad range of PSG and HSAT offerings. The Easy Ambulatory 2 solution utilizes the same Easy III software as clinical PSG system. The Easy Ambulatory 2 is composed of a recorder, battery pack, 32-channel color-coded amplifier, respiratory belts, accessories and EasyNet™ modules for nasal pressure and snoring, oximetry, body position and limb movement⁴⁸. Cadwell have also released the ApneaTrak product line, which is an integrated sleep testing solution. The features include a nasal pressure/snore sensor, Oximeter, Body position sensor, thermistor, microphone, RIP/PVDF Thoracic and Abdominal sensors⁴⁹.

Additional companies includes: Puritan Bennett, Philips U.S. (part of Philips Medical), Stellate Healthcare, Embla and Grass Technologies (a subsidiary of Astro-Med Inc.).

The WatchPAT products are competitive in price and features and have certain advantages as compared to PSG tests.

HSATs (polysomnography - PSG)

Suppliers of home sleep testing for diagnostic purposes that offer devices that perform full PSG tests at home.

Aura-Grass: The AURA® PSG Ambulatory System is a powerful, easy-to-use polysomnography system consisting of a high quality 25-channel AURA PSG Amplifier



⁴³ <https://www.webmd.com/sleep-disorders/guide/polysomnogram>

⁴⁴ <https://us.nihonkohden.com/clinical/polysomnography/>

⁴⁵ https://us.nihonkohden.com/media/1301/psg-brochure_nmlb-004-f-co-0484_low-res.pdf

⁴⁶ <https://www.vyaire.com/intl/our-products/respiratory-care/sleep-diagnostics-and-therapy/somnostar-z4-sleep-system>

⁴⁷ <https://clevedmed.com/>

⁴⁸ <https://www.cadwell.com/easyambpsg/>

⁴⁹ <https://www.cadwell.com/apneatrak/>

System with built-in electrode/sensor inputs and built-in oximeter designed especially for PSG, and TWin PSG Record and Review Software⁵⁰.

An additional company that engages in the same field is Embla.

These tests typically do not provide a significant cost benefit relative to in-lab PSG tests.

HSATs: Suppliers of home sleep testing for diagnostic purposes that offer ambulatory systems

Embletta MPR (provided by Embla Systems): The Embletta MPR Sleep System is scalable from Type IV to Type I PSG testing. The foundation of the Embletta MPR Sleep System is the Embletta MPR, a fourth generation ambulatory sleep recorder designed to be reliable and easy to use that offers 7 channels of data. The LCD on the device facilitates signal quality checks bedside, without the need for a computer. The Embletta PG offers 12 channels of collected data and can be interfaced with the ST Proxy for 8 additional channels or the ST+ Proxy for 16 additional channels to meet Type II ambulatory recording requirements. Finally, the addition of the TX Proxy adds Differential Pressure and 6 DC channels with the ability to record online when used with RemLogic software⁵¹.

Philips U.S. (part of Philips Medical): The Philips home sleep test uses a simple device called Alice NightOne to provide overnight monitoring in the comfort of your own home. The results are analyzed by a team of sleep specialists, according to the NHS process. Using the Philips Home Sleep Test ensures you get your official sleep apnea diagnosis more quickly, through an efficient and convenient service bringing you one step closer to treatment⁵².



Nox Medical

The Nox A1 PSG System is a fully portable polysomnography system that includes head sensors to increase study robustness and save time during hook-up⁵³. The Nox T3 portable respiratory sleep monitor can monitor sleep apnea, PLMS, and sleep bruxism. The Nox T3 System uses Bluetooth® technology to create a wireless body area network to maximize patient comfort (chest sensor, wrist oximeter, nasal cannula). This saves time during patient hook-up, increases patient comfort, and saves cleaning costs. The Nox T3 has a built-in microphone, capable of recording high quality sound. This feature gives clinicians the ability to play the audio along with the other recorded signals, thereby giving new insights into sleep medicine⁵⁴.



Additional companies includes: Apnea Link Air (provided by ResMed Corp.) and ARES (provided by SleepMed Inc.), These devices typically measure four to five parameters (compared to the seven parameters measured by WatchPAT), and lack measurement of sleep stages or total sleep time (TST) when not used with EEG (which is used only by ARES, which provides total sleep time by a device placed on the forehead with built-in EEG electrodes) and all of which also require nasal cannula.

Pulse oximetry devices: Suppliers of pulse oximetry devices, such as Nonin and Masimo.

In contrast to diagnostic devices, pulse oximetry devices only measure one or two physiological parameters (oxygen saturation and motion) and participate in the sleep space mostly as screening tools.

⁵⁰ <https://www.selectscience.net/products/aura-psg-ambulatory-systems/?prodID=171717#tab-2>

⁵¹ <https://neuro.natus.com/products-services/embletta-mpr-sleep-system>

⁵² <https://www.sleepapnea.com/diagnosis/in-home-testing/>

⁵³ <https://noxmedical.com/products/nox-a1-psg-system/>

⁵⁴ <https://noxmedical.com/products/nox-t3-sleep-monitor/>

Market Landscape

Remote or Home Monitoring

Cardiologists have always been early adopters of home-based and telemedicine applications and telehealth tools (for example, the Holter monitor). Consequently, cardiologists are already accustomed to remotely monitoring their patients through implantable cardiac devices such as pacemakers and defibrillators that continuously collect and transmit data back to clinicians together with their main tasks of keeping the heart beating.

Alongside the popularity of telemedicine for cardiac patients, lies the rising awareness of the link between Sleep apnea and heart disease. With concern growing for the effects of sleep apnea on patients' cardiovascular risk and cardiac disease progression, home sleep testing will serve as an ambulatory tool in the cardiologist's arsenal.

Remote or home monitoring systems are networked communication solutions allowing exchange of digitized data from implanted or wearable devices⁵⁵.

Geographically, during the historical period, North America held the largest share in the mHealth market, with 37.8% in 2017. This leading position of the regional market is mainly due to the increasing healthcare spending, growing geriatric population, rising prevalence of chronic and lifestyle associated disease and improving consumer accessibility to connected medical devices. The increasing elderly population with chronic diseases further adds to the demand of remote monitoring devices and different mobile health applications⁵⁶.





Home Monitoring			
Cardio		Sleep apnea	
Non-implantable (ECG, EKG)	Implantable (Pacemakers, ICDs, CRTs)	Diagnostics	Therapeutic
			

Figure 4: Cardiac and Sleep companies operating in the home monitoring space (non-exhaustive)

Home cardiac monitoring market

Remote cardiac monitoring is the continuous monitoring of electrical activities of the heart, which takes place outside hospitals. The monitoring can also be done while the patient is doing the day to day activities⁵⁷. Remote cardiac monitoring consists of cardiac monitors (ECG, EKG), pacemakers, implantable defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices (Figure 4).

The cardiac monitor segment has witnessed a number of recent technological breakthroughs and advancements, including the digitization of the electrocardiogram (ECG) signal, the miniaturization of electronic components, and propagation communication networks have made possible cardiac telemetry, the wireless transmission of ECG recordings to central servers, to be evaluated remotely by a physician or other trained personnel. Non-traditional

⁵⁵ <https://onlinelibrary.wiley.com/doi/full/10.1002/cce2.36>

⁵⁶ <https://www.alliedmarketresearch.com/sleep-apnea-diagnostics-market>

⁵⁷ <https://www.businesswire.com/news/home/20170109006186/en/Global-Remote-Cardiac-Monitoring-Market-Size-Trends>

health companies such as Apple and Withings along with new players to the market such as AliveCor and Cronovo have brought remote ECG monitoring to the masses.

However, the implantable devices segment such as pacemakers, ICDs and CRT devices, demonstrate restraint towards adoption. Remote monitoring is used routinely in way less than 50% of patients overall and in some cases 40% of patients are not even enrolled⁵⁸. For example, 64% of St. Jude Medical patients are enrolled in Merlin.net that monitors patients implanted with the company's cardiac devices⁵⁹. 60% of Medtronic's patients are enrolled in CareLink, the company's remote monitoring system⁶⁰. This prevents good management of cardiac patients because almost 25% of patients do not come for a follow up within the first year of being implanted with a cardiac device for a variety of reasons⁶¹.

Home sleep monitoring market

Sleep study or polysomnography is a type of test conducted to diagnose sleep disorders. Sleep study tests record brain waves, oxygen level in blood, heart rate, breathing, and eye and leg movements. A sleep study is usually conducted in a laboratory or clinic and in home care settings. A sleep study is conducted to diagnose various sleep disorder conditions such as sleep apnea, periodic limb movement disorder, narcolepsy, REM, sleep behavior disorder, and unexplained chronic insomnia⁶².

In 2017, the polysomnography (PSG) segment held the largest market share, 70.2%, of the sleep apnea devices market.⁶³ There are an estimated 4,700 U.S. sleep centers or labs which perform studies (polysomnography) to diagnose sleep disorders. The typical lab has revenues of \$920,000 and a bed count of about 7-8. Labs are located in hospitals, MD practices, universities, or are independent. This segment was worth \$4.3 billion in 2017.

Entering the sleep apnea market can be affected by several factors including acceptance by physicians, obtaining the adequate regulatory approvals, insurance reimbursements and the fact that the product should be innovative, efficient, safe and easy to use.

Clinical need

Sleep disorders and specifically obstructive sleep apnea (OSA) have been increasingly recognized as significant health problems in the last two decades. OSA is a condition in which repetitive episodes of airway occlusion occur during sleep, resulting in apnea's or hypopneas and related arousals. These events lead to intermittent hypoxemia, increased sympathetic tone, cytokine production, metabolic abnormalities, and abnormal sleep structure. OSA patients experience daytime sleepiness, decreased cognitive function and are at an increased risk for comorbidities and accidents. Studies have consistently found that OSA patients report lower quality of life than non-OSA patients. This abnormal physiology results in increased health risks, most notably those related to the cardiovascular and cerebrovascular systems. It also leads to neurocognitive abnormalities, which have significant societal consequences.

A diagnosis of OSA is generally derived from one of three diagnostic modalities: full-night polysomnography (PSG), split-night PSG, and unattended portable home monitoring. Unattended portable home sleep tests are being used with growing frequency, although full-night PSGs are still considered the gold standard for evaluation of OSA.

⁵⁸ <https://www.mddionline.com/pathetic-state-remote-cardiac-monitoring-today>

⁵⁹ <https://www.mddionline.com/pathetic-state-remote-cardiac-monitoring-today>

⁶⁰ <https://www.mddionline.com/pathetic-state-remote-cardiac-monitoring-today>

⁶¹ <https://www.mddionline.com/pathetic-state-remote-cardiac-monitoring-today>

⁶² <https://www.persistencemarketresearch.com/market-research/sleep-service-providers-market.asp>

⁶³ https://www.researchandmarkets.com/reports/4769888/north-america-sleep-apnea-devices-market-to-2025?utm_source=GNDIY&utm_medium=PressRelease&utm_code=wfpqjr&utm_campaign=1248921+-The+%243.7+Billion+Sleep+Apnea+Devices+Market+in+North+America+2019-2025&utm_exec=joca220prd

Continuous positive airway pressure (CPAP) is considered the gold standard of treatment for OSA. When adherence is optimal, CPAP improves sleep quality, reduces the risk of OSA-related co-morbidities, and improves patient quality of life. However, in spite of many technological advances of the CPAP apparatus and the patient device interface, adherence remains a significant problem. OSA surgeries often involve high morbidity, long recovery times, and low patient acceptance.

Research has established links between OSA patients and several important co-morbidities. OSA impact on cardiovascular disease (CVD) appears to be due to recurrent cardio metabolic perturbations experienced when repetitively attempting to breath against an occluded airway, during precipitating nightly episodes of hypoxia, sleep disturbance, and sympathetic nervous system surges, culminating in elevated blood pressure and heart rate, endothelial dysfunction, systemic inflammation, and insulin resistance, mechanisms which have been implicated in the pathogenesis of CVD.

Recent studies have shown a clear association of OSA with the development of hypertension, type II diabetes, stroke, congestive heart failure, coronary artery disease, cardiac arrhythmias and even early mortality. The prevalence of depression in this population has been cited to be as high as 50%.

Social need

Road safety - Sleep-related respiratory events interrupt physiological sleep structure and inhibit sleep-based functional recovery. This leads to excessive daytime sleepiness, impaired vigilance, decreased ability to adequately perform daily tasks and ultimately, accidents. In 2004, Sassani and colleagues estimated that 810,000 motor vehicle crashes a year are attributable to OSA patients, resulting in 1400 fatalities and costing roughly \$15.9 billion. Their research also concluded that treating the same OSA sufferers with CPAP, assuming 70% adherence would prevent roughly 500,000 collisions, save 1000 lives and reduce costs by \$11.1 billion.

Workplace productivity - OSA sufferers are also at an increased risk for workplace accidents. Respondents reporting both snoring and excessive daytime sleepiness over a ten-year period were at a greater risk for workplace accidents, odds ratio of 3.1. Admittedly, a limitation of the Lindberg study is that they only categorized subjects based on snoring and daytime sleepiness: PSG was not performed to confirm a diagnosis of OSA. Furthermore, another study found that individuals suffering from OSA and reporting excessive daytime sleepiness experience a significantly greater risk of workplace disability than those with no OSA and no daytime sleepiness, odds ratio of 13.7.

Economic - The increased risk of health complications, work-place errors, and traffic accidents in OSA patients conveys significant costs in terms of healthcare dollars and the overall economy. The cost of care for two of the most significant consequences of untreated OSA: stroke and myocardial infarction. The cost of coronary heart disease and stroke in the United States was estimated at roughly \$200 billion per year⁶⁴. The cost impact of OSA and have demonstrated that overall healthcare utilization costs are higher for undiagnosed OSA patients. It is estimated that increased healthcare spending to treat undiagnosed OSA patients is between \$1950 and \$3,899, per patient, per year.

⁶⁴ https://www.cdc.gov/dhdsdp/data_statistics/fact_sheets/fs_heart_disease.htm

Financial Valuation and Projections

Financial Analysis

Itamar's revenues consist primarily of sales of WatchPAT products (93% of 2018 revenues) and, to a lesser extent, Endo PAT products and related services to hospitals, clinics, and physicians practices, including health management organizations, or HMOs, directly as well as through distribution channels. The company offers these products mainly as a combination of TaaS ("Test as a Service") or CPT ("Cost Per Test") (as part of their TSS program in the cardiology field in the U.S.), in the form of capital equipment (which can be used for several years) and one-time disposable probes.

Revenues in 2018 increased by 16.8% to \$24.2 million, compared with \$20.7 million in 2017. The increase is mainly attributable to an increase of 23.6% in revenues from sales of the WatchPAT product mainly in the US, which was partially offset by a decrease of \$0.8 million, or 30.5%, in the revenues from sales of the Endo PAT product in 2018, compared with 2017.

The portion of revenues from the sale of disposables out of total revenues in 2018 slightly increased to 54.9%, from 54.8% in 2017 (within the U.S. this proportion slightly increased to 62.4% in 2018, from 61.7% in 2017), while the portion of revenues from the sale of devices out of total revenues in 2018 decreased to 33.9%, from 36.3% in 2017. The change in the ratio between revenues from sale of disposables and sale of devices in the comparison years was mainly attributed to an increase in the number of WatchPAT tests (and hence, use of disposables) conducted during such years, primarily in the U.S.

The decrease in revenues from sales of the Endo PAT product in 2018 (-30% in 2018) is primarily due to a continued decrease in sales and marketing efforts of this product, which is consistent with the trend of decreased volume of sales of the Endo PAT product in recent years.

Revenues for the first quarter of 2019 increased by 10.7% to \$6.1 million, compared to \$5.5 million in the same quarter in 2018. Revenue growth was mainly due to an increase in U.S. WatchPAT sales and offset due to sales seasonality in Japan. In the U.S. WatchPAT revenues for the first quarter of 2019 increased by 34.2% to \$4.3 million, compared to \$3.2 million for the same quarter in 2018. Sales from disposables and renewable products were approximately 65% of WatchPAT revenues in the U.S. in the first quarter of 2019, similar to the first quarter of 2018.

Below is a breakdown of Itamar Medical's sales by locations and products in 2017 and 2018:

Year Ended December 31,	2018	%	2017	%	YoY %
Revenues by products					
WatchPAT and other related services	22,384	93%	18,105	87%	24%
Endo PAT and other related services	1,805	7%	2,596	13%	-30%
Total	24,189	100%	20,701	100%	17%
Revenues by location					
United States and Canada	17,582	73%	14,764	71%	19%
Japan	3,374	14%	2,965	14%	14%
Europe	1,885	8%	1,746	8%	8%
Asia Pacific (excluding Japan)	849	4%	759	4%	12%
Other	499	2%	467	2%	7%
Total	24,189	100%	20,701	100%	17%

Cost of Revenues and Gross Profit respectively for 2018 increased by 14.5% to \$5.7 million, compared with \$5.0 million in 2017, whereas gross profit for 2018 increased by 17.6% to \$18.5 million, compared with \$15.7 million in 2017. The increase in absolute gross profit is primarily due to increased volume of sales. The increase in gross profit margin to 76.3% in 2018 from 75.8% in 2017, is primarily attributable to: (i) allocation of fixed costs and overhead expenses on a higher volume of sales; and (ii) increased efficiency and cost reduction in the production process. Gross profit for the first quarter of 2019 increased to \$4.7 million, compared to \$4.2 million in the same quarter in 2018. Gross profit margin for both the first quarter of 2019 and 2018 was approximately 77% of total revenues.

Selling and marketing expenses for 2018 increased by 4.6% to \$12.7 million, compared with \$12.1 million in 2017. This increase is primarily due to the following: (i) an increase in employee related costs (including payroll, share-based compensation, sales commissions and travel expenses), mostly related to recruitment of personnel in the U.S.; and (ii) an increase in consulting and legal expenses, mainly additional expenses related to efforts to increase the insurance coverage for reimbursement for use of the Company's products. This increase was partially offset by (i) a decrease of employee related costs (including payroll, share-based compensation, sales commissions and travel expenses), related to the Japanese subsidiary; and (ii) a decrease in advertising, public relations and sales promotion expenses, including expenses relating to marketing campaigns and trade shows. The headcount of selling and marketing personnel increased from 42 as of December 31, 2017 to 52 as of December 31, 2018.

Research and development expenses decreased by 11.9% to \$3.6 million in 2018, compared with \$4.1 million in 2017. This decrease is primarily due to the following: (i) a decrease in expenses associated with a clinical study in the U.S. carried out in 2017 and 2018 in order to expand the acquaintance of the medical community with the PAT signal technology; and (ii) a decrease in expenses related to consultants and subcontractors. This increase was partially offset by an increase in employee related costs related to recruitment of new R&D personnel. The headcount of R&D personnel increased from 14 as of December 31, 2017 to 17 as of December 31, 2018.

General and Administrative Expenses decreased to \$5.2 million in 2018, compared with \$5.3 million in 2017. This decrease is primarily attributable to a decrease of \$0.1 million in allowance for doubtful debts and a decrease in share-based compensation expenses that was partially offset by an increase in employee related costs. The headcount of G&A personnel increased from 20 as of December 31, 2017 to 21 as of December 31, 2018.

Operating Loss decreased from \$5.8 million in 2017 to \$3.1 million in 2018; **Net loss** for 2018 decreased by \$3.6 million, or 67.4%, to \$1.7 million, compared with a net loss of \$5.3 million in 2017. Operating loss for the first quarter of 2019 was \$1.3 million, compared to \$0.9 million in the same period in 2018. The increase in operating loss was mainly due to an increase of \$0.9 million in selling and marketing expenses as a result of an increase in employee-related costs, primarily related to the expansion of the of the U.S. sales team into new geographical territories, partially offset by the increase in revenues.

Cash and cash equivalents as of March 31, 2019, had the following breakdown. Marketable securities amounted to approximately \$19.9 million; net cash used for operations for the first quarter ended March 31, 2019 amounted to \$0.3 million compared to \$1.6 in Q1 2018.

Valuation

We see Itamar Medical as a growth firm. Thus we based our valuation on current and future market trends and the company's management activities. We analyzed Itamar Medical's revenues based on territory expansion. US revenues in 2017-2018 were approx. \$925K on average per territory as show below:

	2018	2017
# of US Territories	19	16
United States and Canada	17,582	14,764
Average per territories	925	923

*based on F&S analysis of 2017 and 2018 financial reports.

We assume Itamar Medical will witness a rapid growth in the number of territories it penetrates in the U.S. Territories can be a state or a specific region the company sees as a territory and the addition of every territory is coupled with a new sales force. We assume the company will reach 26 territories in 2019 (the company forecasts 27)⁶⁵ and 36 territories by 2020 as describe below.

As for Japan, representing 8% of total revenues, we forecast 10% growth during our forecast period. Europe has already shown revenues of \$0.7M in Q1 2019, thus we assume approx. \$2.6M for the year and then growth of 40% during the forecast period as the company will invest more in its EU activity. APAC and ROW - we assume slow increase in sales, similar to previous years.

Below is our estimation for Itamar Medical's revenues 2019 – 2026:

No. of territories	16	19	26	36	51	71	93	111	134	147
\$, 000	2017A	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
United States and Canada	14,764	17,582	24,060	33,683	47,157	66,019	85,825	102,990	123,588	135,947
YoY growth		19%	37%	40%	40%	40%	30%	20%	20%	10%
Japan	2,965	3,374	3,374	4,724	6,613	8,597	11,176	13,411	16,093	17,703
YoY growth		19%	37%	40%	40%	30%	30%	20%	20%	10%
Europe	1,746	1,885	2,579	3,611	5,056	6,572	8,544	10,253	12,304	13,534
YoY growth		19%	37%	40%	40%	30%	30%	20%	20%	10%
Asia Pacific (excluding Japan)	759	849	950	1,045	1,149	1,264	1,390	1,529	1,682	1,851
YoY growth		12%	12%	10%	10%	10%	10%	10%	10%	10%
Other	467	499	533	570	609	650	695	743	794	848
YoY growth		7%	7%	7%	7%	7%	7%	7%	7%	7%
Total revenues	20,701	24,190	31,497	43,634	60,585	83,105	107,632	128,928	154,462	169,883

Additional parameters used in our DCF:

- Cost of revenues – the Company showed some improvements in GP (76.3% of revenues in 2018). We assume it will reach 77% and will stay stable.
- Selling and marketing expenses – we assume the Company will increase its S&M in 2019 to 55% of revenues in order to support its rapid growth in the US. During 2021 to 2026 we assume the same linear growth (45%

⁶⁵ Company's Q1 2019 financial report

of revenue growth) with revenue growth. I.e as Itamar Medical is a growth firm, S&M should be linear to revenue growth.

- R&D expenses and G&A expenses – we maintain the same rates as in 2017-2018. We assume Itamar Medical will maintain its G&A, however S&M as described above will grow with the Company's revenues.
- Itamar has more than \$100M carry forward tax. Thus we assume no tax payments in our forecast model.
- CAPM discount rate – we assume 16.7% based on our CAPM model as elaborated in appendix B.

Itamar P&L forecast, 2019 – 2026:

\$, 000	2017A	2018A	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Total revenues	20,701	24,190	31,497	43,634	60,585	83,105	107,632	128,928	154,462	169,883
Revenues	20,701	24,189	31,497	43,634	60,585	83,105	107,632	128,928	154,462	169,883
YoY growth	12%	17%	30%	39%	39%	37%	30%	20%	20%	10%
Cost of revenues	5,002	5,726	7,244	10,036	13,934	19,114	24,755	29,653	35,526	39,073
Gross profit	15,699	18,463	24,253	33,598	46,650	63,990	82,877	99,274	118,936	130,810
% of GP	76%	76%	77%	77%	77%	77%	77%	77%	77%	77%
Operating expenses:										
Selling and marketing expenses	12,140	12,699	17,336	23,216	27,184	31,630	35,737	38,849	42,234	44,089
% of revenues	59%	52%	55%	53%	45%	38%	33%	30%	27%	26%
Research and development expenses	4,129	3,638	4,725	6,545	9,088	12,466	16,145	19,339	23,169	25,482
% of revenues	20%	15%	15%	15%	15%	15%	15%	15%	15%	15%
General and administrative expenses	5,278	5,247	6,832	9,465	13,142	18,027	23,347	27,967	33,505	36,851
% of revenues	25%	22%	22%	22%	22%	22%	22%	22%	22%	22%
Total operating expenses	21,547	21,584	28,893	39,226	49,414	62,122	75,229	86,154	98,909	106,422
% of revenues	104%	89%	92%	90%	82%	75%	70%	67%	64%	63%
Operating (loss) profit	-5,848	-3,121	-4,640	-5,628	-2,763	1,868	7,647	13,120	20,027	24,388

Equity Value

Non-operational assets/liabilities and unallocated costs

As of March 31, 2019, Itamar Medical has non-operational assets (cash) of approximately \$19.9M. The company has \$5M in loans as of March 31, 2019.

Based on the above parameters we evaluate Itamar Medical's equity value in \$139.8M/502.8M NIS.

Sensitivity Analysis

The table below presents Itamar Medical's equity value in relation to the capitalization rate. We set a range of 0.5% change from our CAPM model (see Appendix B).

Sensitivity Analysis - Capitalization Rate vs. Equity Value

Cap. rate	Target Price (NIS)
15.7%	1.63
16.2%	1.56
16.7%	1.51
17.2%	1.45
17.7%	1.40

We estimate Itamar Medical's price target to be in the range of 1.56 NIS to 1.45 NIS with a mean of 1.51 NIS.

Valuation by multiples

A revenue multiple measures the value of the equity or a business relative to the revenues that it generates. As with other multiples, other things remaining equal, firms that trade at low multiples of revenues are viewed as cheap relative to firms that trade at high multiples of revenues. The expectation for companies that are valued based on growth – to sustain high growth rates over a longer period, have a significant TAM with insignificant penetration and, significant competitive advantage over their competitors. The multiple used is often a function of the sustained growth rates. However, we do see the disadvantage of focusing on revenues, as this can lead to high values for firms that are generating high revenue growth while losing significant amounts of money and therefore need to keep raising more funds and dilute existing shareholders.

As long as the increase in valuation is based on high growth rates than the dilutive factor – shareholder value is sustained. As a general note, ultimately, a firm has to generate earnings and cash flows for it to have value. We examined the sector Itamar Medical operates in, healthcare products, using 251 firms as of the end of 2018.⁶⁶ We found that the average EV/EBITDA was 19.33.

We used the First Chicago Method, in which VCs can evaluate growth firms like Itamar Medical. Our forecast for the year 2026 (our 7th year of forecast), assuming the company will show operating profit of \$24.4M. Discounting Itamar Medical's EBITDA using our CAPM rate is \$8.2M in current prices. Thus, Itamar Medical's current valuation will be \$8.2M multiplied by 19.33, which equals \$158M.

Observing similar firms operating in the medical devices area reveals the following revenues and R&D expenses multiples:

	Company	Market cap	Revenues (\$, 000)	Operating profit (\$, 000)	R&D expenses (\$, 000)	No. of employees	Market cap/revenues	Market cap/R&D expenses (\$k)
1	BioTelemetry, Inc. (BEAT)	1,624	377,250	64,473	11,206	16,000	4.3	144.9
2	iRhythm (IRTC)	1,717	147,293	Loss	20,750	748	11.7	82.7
3	Inspire Medical (INSP)	1,376	50,593	Loss	7,388	165	27.2	186.2
4	Semler (SMLR)	288	21,491	5,342	2,085	46	13.4	138.1
5	ResMed (RMD)	16,834	2,340,196	560,263	155,149	39,600	7.2	108.5
6	Masimo Corporation (MASI)	7,400	858,289	76,967	208,469	1,500	8.6	35.5
7	Ambu A/S (AMBU-B.CO)	24,564	2,606,000	563,000	111,000	2,700	9.4	221.3
8	Insulet Corporation (PODD)	6,648	563,823	40,023	88,606	1,169	11.8	75.0
9	Inogen, Inc. (INGN)	1,453	358,111	37,892	7,029	1,099	4.1	206.7
10	Tandem Diabetes Care, Inc. (TNDM)	4,163	183,866	Loss	29,227	653	22.6	142.4
11	Tactile Systems Technology, Inc. (TCMD)	990	143,751	4,790	5,289	499	6.9	187.2

⁶⁶ www.demodaran.com

Average							11.6	139.0
ST							7.3	59.0

*Market cap is as of June 7th, 2019; financial data as of December 31st, 2018. Data extracted from Yahoo Finance.

The revenues multiple is 11.6 (with high a standard deviation of 7.3) and an R&D multiple of \$139k (with standard deviation of 59). As Itamar Medical is a growth company, we assume revenue multiples will be more suitable as a benchmark than our DCF valuation. We assume Itamar Medical's revenues for 2019 will total \$31.5M, in 2020 will total \$42.8M and in 2021 will total \$58.3M.

The revenues' multiple is 11.6, however we take a more conservative revenue multiple of 5, at the lower level of standard deviation. Thus, based on this valuation method, we forecast Itamar Medical's current value to be \$158M in 2019 and \$213.9M in 2020.

	2019E	2020E	2021E
Revenues	31,556	42,772	58,245
X 5	157,782	213,860	291,223

Investment Thesis and Price Forecast Risks

Biotech or medical devices companies, particularly those in the research and development stage, are relatively high-risk companies. Key risks that may affect Itamar include:

Delay / postponement of marketing / regulatory approval decisions

In order for Itamar Medical to market or distribute its products, it is necessary for them to receive marketing approval from regulatory agencies, such as the FDA (US) and EMA (EU). Our estimates regarding time to market are based on the assumption that these products will successfully complete clinical phases and will receive regulatory approval. Failure to fulfill the clinical endpoints of these experiments will force the company to conduct additional clinical trials or abandon the development of certain projects. We consider this to be the main risk factor of the company's activity at this stage.

Risks involved in obtaining sources of financing and stock trading

Failure to raise funds, or fundraising under conditions that are not beneficial to the company, may affect its worth. In addition, the low level of tradability may deter some investors from buying Itamar Medical's stock.

General risks related to similar companies

The value of small companies in the biotech field could, to a relatively high degree, be affected by publications not related directly to their activities. Such publications may refer, for example, to competitors, macro-trends in the healthcare sector, and political events.

Appendices

Appendix A - Financial Reports

	March 31, 2019	December 31, 2018
	U.S. dollars in thousands	
Assets		
Current assets		
Cash and cash equivalents	\$ 19,887	\$ 6,471
Trade receivables	6,366	6,549
Other receivables	877	1,018
Inventories	2,426	2,235
Total current assets	29,556	16,273
Non-current assets		
Long-term restricted deposits and prepaid expenses	385	365
Long-term trade receivables	247	243
Property and equipment	1,243	1,213
Right-of-use assets	1,732	-
Intangible assets	338	298
Total non-current assets	3,945	2,119
Total assets	\$ 33,501	\$ 18,392
Liabilities		
Current liabilities		
Trade payables	\$ 1,869	\$ 1,517
Short-term employee benefits	302	222
Current maturities of lease liabilities	765	-
Short-term bank loan	5,000	5,000
Provisions	219	215
Accrued expenses	1,258	1,034
Other accounts payable	2,075	2,063
Total current liabilities	11,488	10,051
Non-current liabilities		
Lease liabilities	1,016	-
Derivative instruments	78	442
Long-term employee benefits	169	159
Other long-term liabilities	1,071	1,052
Total non-current liabilities	2,334	1,653
Total liabilities	13,822	11,704
Commitments		
Equity		
Ordinary share capital	874	748
Additional paid-in capital	125,338	111,486
Accumulated deficit	(106,533)	(105,546)
Total equity	19,679	6,688
Total liabilities and equity	\$ 33,501	\$ 18,392

	Three Months Ended March 31,	
	2019	2018
	U.S. dollars in thousands (except per share data)	
Revenues	\$ 6,056	\$ 5,470
Cost of revenues	1,402	1,249
Gross profit	4,654	4,221
Selling and marketing expenses	3,722	2,809
Research and development expenses	940	983
General and administrative expenses	1,287	1,313
Total operating expenses	5,949	5,105
Operating loss	(1,295)	(884)
Financial income from cash and investments	92	210
Financial expenses from leases, notes and loans	(298)	(578)
Gain from derivatives instruments, net	364	1,400
Financial income, net	158	1,032
Income (loss) before taxes on income	(1,137)	148
Taxes on income	(27)	(36)
Net income (loss)	\$ (1,164)	\$ 112
Earnings (loss) per share (in U.S. dollars):		
Basic	\$ (0.00)	\$ 0.00
Diluted	\$ (0.00)	\$ 0.00

Appendix B - Capitalization Rate

Itamar Medical

Cost of equity capital (k_e) represents the return required by investors. The capitalization rate is calculated using the CAPM (Capital Asset Pricing Model). It is based on a long-term 20-year T-bond with a market risk premium, and based on Professor Aswath Damodaran's (NY University) commonly used sample (www.damodaran.com). As of December 31, 2018, the US market risk is estimated at 5.69%. A three-year market regression Beta is 1.01, according to a sample of 248 companies representing the US pharmaceutical products. We used an unleveraged beta of this sample, which is higher than a leveraged beta, due to high rate of cash versus debt. The implied CAPM is 6.5%.

CAPM model (k_e) is estimated as follows: $k_e = r_f + \beta(r_m - r_f) + P$

Itamar is a small cap company, in which marketability and size premiums need to be considered. Duff and Phelps' data research in the years 1963-2018 indicates that a 10.24% premium needs to be added to the CAPM for small cap companies. We therefore estimate the company's CAPM to be 16.7%.

CAPM Model		Value	Source
Long-term (20 years) T-bond	R(f)	0.76%	US Department of the Treasury (20Y)
Market risk premium	R(m)- R(f)	5.69%	based on Professor Damodaran's sample (1/19)
Beta unleveraged	B	1.01	Beta sample of 248 Drugs (pharma products) firms (1/19)
Cost of Capital	k_e	6.4%	
Size Premium		10.24%	Duff and Phelps data, 10dz.
CAPM	CAPM	16.7%	

Appendix C – Key Team Bios

Dr. Tiran Rothman is the head of Frost & Sullivan Research & Consulting Ltd., a subsidiary of Frost & Sullivan in Israel. He has over 10 years of experience in research and economic analysis of capital and private markets, obtained through positions at a boutique office for economic valuations, as chief economist at the AMPAL group, and as co-founder and analyst at Bioassociate Biotech Consulting. Dr. Rothman also serves as the Economics & Management School Head at Wizo Academic College (Haifa). Tiran holds a PhD (Economics), MBA (Finance), and was a visiting scholar at Stern Business School, NYU.

Dr. Hadar Cohen Halevy, Ph.D is a healthcare consulting analyst at Frost & Sullivan. Formerly, Hadar worked at Teva Pharmaceutical as a scientist in the process development department and has extensive knowledge in biosimilar manufacturing and GMP regulation. Hadar holds a Ph.D in Biochemistry from the Weizmann Institute of Science and a M.Sc in Biotechnology and Nanotechnology from Tel Aviv University. Hadar has a broad scientific background in inter-disciplinary fields and over 10 years of experience conducting original research, with expertise in peptide synthesis and drug design.

Kobi Hazan is the Lead Analyst at Frost & Sullivan Research & Consulting Ltd., a subsidiary of Frost & Sullivan in Israel. He has over 14 years of experience in capital markets, including: research, analysis, investment advisory, and management. Mr. Hazan served as a Fund Manager for provident and mutual funds at Analyst Ltd. and, since 2012, he owns and manages the Amida Israel Fund, a hedge fund specializing in Israeli equities. Kobi holds an Economics and Management degree from The College of Management Academic Studies. He is licensed as an Investment Advisor in Israel.

Contact Details & Management

Itamar Medical Ltd.

Itamar Medical Ltd.

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Management

Mr. Gilad Glick, CEO and president: Mr. Glick holds 18 year career in Medical Devices spans across multiple countries in Europe and the US and a variety of functional areas including Sales, Marketing, Service and Research & Development. Until joining Itamar Medical, Mr. Glick held the position of Worldwide Vice President of Sales & Marketing of Biosense Webster, a Johnson & Johnson company, overseeing all strategic and commercial activities.

Dr. Koby Sheffy, Senior Vice President and CTO: Formerly Dr. Sheffy held senior positions in the Israeli Navy, The Division of Missiles at Rafa'el (The Armament Development Authority), was a research fellow in the School of Engineering at Oxford, UK . Prior to joining Itamar Medical Dr. Sheffy held a position as the R&D Director of the Sleep Medicine Center at the Technion, Haifa and also acted as the manager of one of its sleep labs.

Mr. Shy Basson, CFO: Mr. Basson brings over 15 years of experience in, Finance, Business and Operations in global organizations as well as startups. Before joining Itamar Medical, Mr. Basson was Chief Financial Officer, Business and Strategy for WeFi and previously served as Director of Business Development at AOL (a Time Warner Company). Prior to AOL, Mr. Basson filled the role of CFO of ICQ the world leader instant messenger.

Mr. Ira Prigat, President of Itamar Medical Japan, Vice President Itamar Medical Ltd.: prior to joining Itamar Mr. Prigat served as the CEO and President of of Light Instruments Ltd. (commercially known as Syneron Dental Lasers) since 2010. In 2013, Mr. Prigat was named a World Business Leader of the Year, by The Bizz. Previously, he co-founded and led KIMAX-International Ltd, a trade liaison firm located in Tokyo, Japan. Mr. Prigat also served as a member on the Board of Directors of the Israel-Japan Chamber of Commerce and Friendship Society from 2003 to 2012.

Ms. Efrat Litman, VP Research, Development and Technology: Ms. Litman has over twenty years of experience in R&D work. Prior to joining Itamar, she held several positions as a project and product manager and algorithm team leader in high-tech and bio-tech industries, including over eight years at Orbotech Ltd.

Mr. Itay Kariv, VP Advanced R&D: Mr. Kariv has over twenty five years of experience in research and development work. Mr. Kariv held several positions as research and development director in high-tech and medical devices industries as well as program management roles. Prior to joining Itamar Medical , Mr. Kariv served seven years at Johnson and Johnson followed by seven years at St. Jude Medical.

Mr. Shlomo Ayanot – Vice President Engineering and Operations: Mr. Ayanot serves as VP Engineering & Operations at Itamar Medical Ltd. Prior to joining Itamar Medical, Mr. Ayanot has over 30 years of experience in several High Tech companies including Medical Devices, Microelectronics Industries, as well as in several international Start-up companies. Mr. Ayanot covers a multi-discipline position at Itamar Medical Ltd., in charge of Supply Chain, Logistics, ERP system implementation, CRM, Documentation, QA Regulation and concurrent engineering.

Mr. Eilon Livne, President and CEO: Mr. Livne held 17 years career in international sales and marketing, in a variety of industries, mainly in consumer goods. Prior to joining Itamar, Mr. Livne was partner and CEO in a consumer goods marketing company in London, until it was sold in 2013. In his previous positions Mr. Livne specialized in markets development and establishment of sales operations.

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