

EXECUTIVE SUMMARY

Sanso Health is a US-based healthcare technology company founded with the vision of creating game-changing solutions for patients requiring short or long-term supplemental oxygen (O₂). The company's first commercial product, Sanso Via™, is in the final stage of development and an application is being prepared for submission to the FDA (Food and Drug Administration) for approval to go to market. Sanso Via utilizes the patented AccuO₂™ algorithm to analyze the patient's real-time O₂ need and automatically deliver O₂ doses via nasal cannula. The device connects to a standard O₂ tank and monitors the patient's blood oxygen saturation (SpO₂), pulse rate, respiration rate, O₂ consumption, and activity level for transmission to the Cloud so caregivers, payers, and family members can collaborate in the therapeutic management of the patient to optimize their health and wellness.

THE PROBLEM

Using the best methods available today, a lung disease patient's oxygen saturation level is manually measured periodically using a pulse oximeter. From this periodic information their fixed O₂ flow rate is periodically manually adjusted via mechanical regulator dial. These fixed flow rates are unable to keep up with changes in the patient's O₂ demand associated with their activity, illness, sleep apnea, etc. While numerous products have been introduced to make O₂ therapy more portable and longer lasting by conserving O₂, none have addressed the real problem: the failure to "close the loop" between the prescribed drug therapy (oxygen), a desired clinical measurement (oxygen saturation level), patient outcome (better oxygenation), and cost-reduction (fewer exacerbations and hospitalizations). Sanso has solved this problem by creating a closed-loop feedback control system that continuously monitors a patient's oxygen saturation and automatically and instantaneously adjusts O₂ dosage delivered to achieve and maintain the desired oxygen saturation level for that patient's immediate needs.

THE SOLUTION

Simply put, Sanso integrates patient monitoring with O₂ dosing to deliver as much O₂ as needed, but only when it is actually needed. There is currently no commercially available system of this kind and the company has been told by possible strategic partners that there will be a strong demand from its target customers (the patients who benefit from the system, caregivers who prescribe it, and the payers who pay for its use).

Sanso's Breakthrough Technology Reinvents Supplemental O₂ Therapy

- replaces spot-check fingertip pulse oximeter with an always-on ear sensor integrated with a nasal cannula
- replaces mechanical regulator with a Cloud-based intelligent control module regulator
- automatically conserves or optimizes O₂ output based on each patient's individual physiological demand
- delivers a pulsed dose of O₂ in a brief puff when the patient inhales, delivering up to an equivalent of 15 liters per minute as needed
- wirelessly transmits oxygen saturation, pulse rate, respiration rate, and O₂ consumption to caregivers along with additional biometrics (activity, blood pressure, weight, temperature, etc.) from third party devices connected via Bluetooth

Sanso products are designed for use in the home and long-term care facilities where COPD (Chronic Obstructive Pulmonary Disease) and CHF patients are often under-oxygenated, become sedentary, and are at risk for exacerbations and costly hospitalizations. Sanso products will be used in hospitals for lung disease patients, but also for non-COPD patients who are traditionally given fixed high-flow O₂ in emergency care, surgery, general ward, ICU, etc. and are at significant risk of over-oxygenation.

Sanso's mission is to help patients requiring supplemental O₂ live more active, healthier, and longer lives by optimizing their O₂ therapy. The implementation of Sanso's breakthrough technology wherever supplemental O₂ is administered will help to improve patient outcomes and reduce costly hospital readmissions.

BUSINESS MODEL

OUR CUSTOMERS: Sanso's O₂ optimization solutions have broad appeal in several market segments worldwide. Our initial target customers are in Acute Care and Home Care healthcare segments primarily in the United States, Europe, Japan, Australia, and Canada.

Acute Care: Acute Care settings use O₂ therapy both in the hospital setting (e.g. emergency department, surgical post-op, ICU / CCU (intensive care / cardiac care), and pulmonary rehabilitation) and by first responders, while a patient is being treated or is in transit (e.g. ambulance, military battlefield theater, and basic life support - fire, police, airlines, cruise ships, etc). In these pre-hospital settings, high flow O₂ therapy may be administered as part of resuscitation or in the case of anaphylaxis, major trauma, seizure or hypothermia. In cases where injury or illness has caused hypoxemia (low oxygen in the blood), O₂ therapy may be used to increase the availability of oxygen to bodily tissues until target oxygen saturation levels are achieved (see Appendix I Clinical Information).

Sanso's primary value proposition is a reduction in hospital readmissions of lung disease "frequent fliers" (patients that are admitted to hospital two or more times each year). Nearly 20% of COPD patients hospitalized in the US are readmitted within 30 days, accounting for \$17 billion in annual expenditures (Jencks, 2009). By focusing on these patients Sanso demonstrates to its customers a healthy return on investment as the average hospitalization for one COPD admission can quickly surpass \$15,000. Sanso's solution to help prevent hospital readmissions will cost \$1,200 to \$2,400 per year, an excellent value for patients that cost health insurance carriers and at-risk care delivery organizations hundreds of thousands of dollars annually.

In October 2014, the U.S. Centers for Medicare and Medicaid Services (CMS) expanded its Hospital Readmission Reduction Program (HRRP) to include COPD. Under the new policy, hospitals are penalized with reduced reimbursement for the treatment of Medicare beneficiaries (Au., 2014). The CMS financial penalties can be 3% of hospital-specific Medicare payments for all discharges, not just payments related to the excess readmissions. Sanso products are ideal solutions for helping hospitals reduce COPD readmissions in accordance with US government initiatives. This is consistent with the overall goal of Sanso Health - to improve patient outcomes, decrease hospital readmissions, and reduce overall healthcare costs.

Long-Term Care: Long-term O₂ therapy (LTOT) in home care faces very different problems than acute care O₂ therapy. In acute care settings there is much less demand for patient mobility and the O₂ supply is plentiful (with the notable exception in military and other critical care transport where payload must be optimized). Because acute care O₂ supply is relatively inexpensive and readily available while the patients are immobile and present for only short time periods, caregivers have traditionally given maximum O₂ supply under the belief that it was never too much. In the long term care facility or the home, patients need to be mobile but their O₂ supply is limited. In order to properly oxygenate a home care patient, there are times when short bursts of high flow O₂ are required. Current O₂ delivery devices are designed for low cost, portability and to maximize battery life – and cannot deliver the higher flow of O₂ required by most COPD patients.

Sanso creates value by collecting and analyzing remote monitoring data that has never been available before, resulting in decreased costs and improved patient clinical outcomes. Sanso technology can help to decrease costs by conserving O₂ gas when the patient does not need it; transmit wireless biometric data to intervene and prevent exacerbations and hospitalizations; improve the logistics of home O₂ gas tank delivery; and collect data for longer-term outcomes analysis and economic modeling.

HOW WE MAKE MONEY: Sanso's business model is to design, develop and commercialize several technology solutions utilizing our patented AccuO₂ algorithm to healthcare environments worldwide, and to monetize all potential from the company's proprietary capital equipment, software applications, disposables, and remote data management services.

Each Sanso product has significant revenue generating possibilities allowing the company to create customized pricing solutions that include the following:

- Capital Equipment:** Sanso Via / Versa devices, reusable sensors (oximeters replaced 1 – 2 years)
- Software Applications:** Sanso Visi PT (patient), Sanso Visi CG (caregiver)
- Monitoring Services:** Transmission and data sharing - Sanso WS (webserver)
- Data Services:** Enterprise software licensing / data warehousing / analytics
- Disposables:** Sanso nasal cannula (replaced with each patient in acute care and typically replaced twice monthly in home care)

Sanso predicts long-term average gross margins of 50% to 70% on equipment, sensors, and disposables with its product solutions and 90% gross margin on data management services.

OUR KEY PARTNERS: Sanso relies heavily on contracted services with consultants for product development, certification testing, manufacturing, regulatory, and distribution:

- Product Development: Kablooe Design, Sparton Corporation, Festo
- Certification Testing: Element, Piper Medical, American Pre-Clinical Services, Specialty Labs, Clinimark
- Key Suppliers: Essex Industries, Nonin Medical, ITEC Engineering
- Manufacturing: Sparton Corporation
- Regulatory Services: ProMedic
- Distribution: Teijin, Air Liquide, McKesson, National Medical Sales Associates

THE PROGRESS WE HAVE MADE: Sanso began researching and developing a closed-loop oximeter-controlled oxygen delivery system in 2014 after obtaining a license on the AccuO₂ intellectual property from the original inventors and patent holders. Development of the Sanso Via began in early 2015 after Sanso received non-dilutive funding of \$460,000 from Teijin, a Japanese strategic commercialization partner. During product development the company used highly specialized contract engineers and manufacturing consultants with an emphasis on the highest quality parts from world-class suppliers. 3D printing and rapid prototype tooling were used to create early working models for the Sanso Via regulator module and ear lobe oximeter sensor. Pre-clinical testing with IRB (Independent Review Board) approval on the first generation ear oximeter sensor was performed at an independent laboratory comparing oximeter readings to drawn arterial blood. Development on this proprietary ear sensor continues and is planned for implementation in the second generation Sanso devices.

Ten pre-production Sanso Via systems are complete and in the final round of medical device testing certification, which includes biocompatibility, particulate matter testing, and all applicable elements of the IEC-60601 Medical Electrical Equipment standard. Sanso is currently preparing its US FDA 510k application for the Sanso Via system. Simultaneously, the company is completing a technical file for CE Mark certification in order to distribute into Europe. Sanso will begin seeking its first capital investment from outside investors after completing the FDA submission. The Sanso Via product launch into the US and Europe is projected for 2018.

SANSO VIA

The first commercial device to be introduced into the market is the Sanso Via. The device is designed for home use, emergency transport, and the hospital emergency department and connects to the most common oxygen tank configuration in the US and Asia. Additional regulator designs will be developed to adapt to other cylinder tank configurations around the world as demand dictates.





To use a Sanso Via system the patient simply attaches the device to the top of their existing oxygen cylinder (the same as a standard regulator), connects the nasal cannula (the same as a standard cannula), and attaches the oximeter sensor to either ear lobe. Once activated the system will detect a breath and deliver a pulse dose of O₂ as needed. The threshold to determine how much O₂ to deliver is based on the oximeter setting programmed by the caregiver. If data communication is desired and activated, the built-in Bluetooth® radio periodically transmits the recorded data through the patient's smartphone to the Cloud for interpretation and management. The caregiver can also be notified if the patient stops using the system or if oxygenation targets cannot be maintained.

Each delivered system includes one Sanso Via regulator, two disposable cannulas, and one reusable ear sensor pulse oximeter. The device has a sealed rechargeable lithium-ion battery that is charged via USB each night. LED indicators on the keypad help the patient adjust the device if the cannula or ear sensor are not positioned correctly and notifications are available when O₂ supply or battery level is getting low. A Boost button allows the patient to let the system know in advance to increase flow prior to activity (e.g. getting up from a chair).

SANSO VERSA

The Sanso Versa will be the second product introduced and is designed as a universal device for use with any O₂ source, not just tanks. This allows the Sanso Versa to work with facility central O₂ supply, home stationary oxygen concentrators, portable oxygen concentrators (POC), and liquid oxygen systems.

Medical gas supply systems are found in hospitals and most other healthcare facilities (and many ambulances), and are used for supplying piped O₂ and other medical gases to various parts of a facility, in particular areas such as general wards, operating theaters, ICU/ITU/CCU/NICU, recovery, major treatment rooms, etc. Oxygen delivery masks or cannula are connected to the medical gas supply system via a flow meter connected to station wall outlets. The Sanso Versa will connect to these outlets via adapters with built-in pressure regulators. These simple and inexpensive mechanical adapters enable the Sanso Versa to be connected directly to the wall outlets providing optimized O₂ therapy for every bed in the hospital. These adapters allow for additional mounting options including bed rails and a holster for travelling with the patient as they are moved off central O₂ supply to a portable O₂ tank (when going to pulmonary rehabilitation for example).

While Sanso Versa can integrate with any POC, Sanso's technology should help encourage development of new POCs with higher flow rates that use the AccuO₂ algorithm to conserve O₂ for when it is actually needed. The company will offer POC manufacturers an OEM (Original Equipment Manufacturer) module or a sublicense on the algorithms so they can integrate the technology directly inside their next generation POC devices. This is what is currently being done with Teijin in Japan.

SANSO VISI

Sanso Visi is the company's line of software applications and web services. Each Sanso device is equipped with built-in wireless communication capability serving as two-way communications to the Cloud either through short-range wireless with a smartphone or Internet gateway, or built-in cellular radio.

Sanso will develop two Visi smartphone applications, one for the patient and one for the caregiver. A web-server application will be offered on a subscription to patients and authorized caregivers, family members, payers, and employers. Visi applications will also be compatible with other Bluetooth LE devices deployed in the home to better monitor and manage the patient (e.g. activity sensor, peak flow meter, blood pressure monitor, weight scale, or glucometer).

MARKET

There are an estimated 1.5 million long-term O₂ therapy users in the US and 4.5 million worldwide. Each year in home care, hospital, and pre-hospital transport, tens of millions of people receive O₂ therapy. All of these patient encounters could utilize Sanso devices, software, disposables, and data services to improve outcomes and reduce costs. With every O₂ tank and healthcare facility bed as a potential placement, equating to a market opportunity worth several billion dollars annually, Sanso solutions could change the standard of care with respect to O₂ delivery worldwide.

Transparency Market Research (TMR) estimates the global oxygen therapy devices market overall value to be US\$2.80 billion by 2020, expanding at a CAGR of 5.7% during the period from 2014 to 2020. Sanso predicts capturing 5% of the global oxygen therapy market within 10 years. There is no market data on the new market Sanso is creating for bedside intelligent O₂ delivery in hospitals, transitional care, long-term care and hospice. The current global medical gases market is projected to be US\$20 billion by 2021 according to Market And Markets. Medical oxygen equipment and accessories (manifolds, regulators, flowmeters, etc.) is a subset of this total market, which is predicted to grow at a CAGR of 8.0% from 2016 to 2021.

Geographically, the global medical gases market is segmented into North America, Europe, Asia-Pacific, Latin America, and the Middle East & Africa. In 2015, North America accounted for the largest share of the global medical gases market, followed by Europe. However, the Asia-Pacific region is expected to grow at the highest CAGR during the forecast period, owing to the increasing healthcare awareness, growth in the aging population, rising healthcare expenditures, and growth in per capita income.

VOICE OF THE CUSTOMER: Sanso has conducted end-user focus groups with an average of 15 participants each with home oxygen patients and acute care nurses independently to test human factors and usability of the Sanso Via. The results confirmed a large unmet need among COPD patients, many of whom described their high interest level and how they felt it would be beneficial to them and improve their quality of life. Nurses confirmed specific interest in acute care settings where they described a lack of time to monitor patients' oxygen saturation levels and manually adjust O₂ flow. The nurses also voiced opinions on the benefit for the system to automatically measure patients' respiration rate, a vital sign that is still determined by counting breathes manually, especially if respiration rate and O₂ consumption could be wirelessly integrated into the hospital's existing monitoring/telemetry systems.

PROGRESS WITH INITIAL CUSTOMERS: Sanso has recently engaged in discussions with a large local ACO (Accountable Care Organization) with thousands of home oxygen patients under its care. The meetings produced valuable market feedback and has helped Sanso refine its product, pricing, and business model. Certain provider sites have expressed interest in evaluating the system after FDA clearance. In addition to the distribution and licensing agreement entered into in 2014 with Teijin, the largest O₂ therapy supplier in Japan, negotiations began in 2016 with two additional multi-billion dollar global healthcare companies that each expressed interest in an OEM supplier relationship whereby Sanso would design and produce customized versions of the product to align with their respective distribution and service offerings. These market leaders came to Sanso because they need to find solutions for their customers that will help reduce costs associated with O₂ therapy and help them reduce hospital readmissions of their COPD patients.

MARKETING STRATEGY / COMPETITION: Currently there are no commercially available closed-loop O₂ therapy system available in the United States, however, there are competitors, including Dima Italia, SRL in Bologna, Italy. The company's device has CE Mark and is commercially available in Europe to hospitals, O₂ therapy patients, and athletes. The company does not have US FDA clearance on any product at this time. Sanso's respiration based dosing is the primary and obvious advantage over Dima Italia's products which are continuous flow – meaning their system will waste large quantities of O₂. Sanso devices only deliver O₂ doses during a patient's inhalation, pausing delivery when it is impossible for the gas to enter the patient's lungs.

OxyNov, Inc. Québec, QC, Canada has developed the FreeO₂ device, which is designed as a hospital bedside monitor. It reads oxygen saturation data and delivers titrated O₂ to the patient similar to Sanso's devices. The company's stated goal is to commercialize in European hospitals and there is no FDA cleared at this time. Sanso believes OxyNov's device is cost-prohibitive and will have difficulty achieving market penetration competing against well-established bedside monitoring equipment in the hospital. The system is not portable and is not designed for use outside acute care facilities.

Oxygen Mobility Solutions, Inc., from Riverside California appears to be developing a respiration and activity based system for O₂ delivery with plans to add a pulse oximeter to a future version. This differs from the Sanso technology platform in that Sanso uses pulse oximetry and oxygen saturation data, the clinical gold standard for determining the need and the amount of the supplemental O₂ dose. Oxygen Mobility Solutions has not introduced a product to any market and does not have FDA clearance at this time.

Sanso has an early-mover advantage having a previous iteration of its licensed technology already approved by FDA. Sanso also has the only system with an integrated ear sensor making the product practical and convenient to wear during normal daily activity. The Sanso Via is the only system that replaces a regulator directly on the O₂ tank and offers wireless connectivity. Sanso is positioned as the only developer of low-cost, portable solutions that can be used everywhere O₂ is prescribed and that can connect to any O₂ source.

SALES DISTRIBUTION: Sanso will sell directly to US-based ACOs and IDNs (Integrated Delivery Networks – e.g. HealthPartners, Kaiser Permanente, Veterans Administration, etc.) through full-time Regional Sales Managers (RSMs). These RSMs will negotiate contracts directly with the C-suite in these at-risk organizations promoting the cost savings of hospital readmission reduction and improved patient outcomes. RSMs will also sell to B2B to Home Care / Disease Management companies that will bundle Sanso solutions with their own non-competitive care management services. In order to sell to traditional hospitals that are at less risk than ACOs and IDNs, long-term care chains, and other non-acute care facilities, the company intends to contract with large wholesale distributors (e.g. McKesson, Henry Schein, Cardinal Health, and Medline) and to support these thousands of salespeople with a nationwide salesforce of independent manufacturer representatives.

Distribution, co-op marketing, and private-label arrangements will be sought with health data management and remote patient monitoring companies. Sanso products and services can be bundled with solutions for managing other diseases (cardiac rhythm, heart failure, diabetes, etc.) from companies such as Medtronic, Optum, WebMD Health, and Healthsmart. No other remote COPD therapy technology solution exists and Sanso expects strong demand for its solution, enabling these companies to expand services to millions of new patients. Sales outside the US will be managed by exclusive strategic partners / distributors in each country.

MARKETING: Sanso will rely heavily on internet marketing to create awareness for its product solutions. There is a very active online community of patients with respiratory disease that seek out solutions to their problems and share their personal experiences with care treatment and new technology. The company has contracted with a local marketing consultant who, upon FDA clearance, will create the company's marketing program, which will include search engine optimization, social media email campaigns (e.g. Facebook, Twitter, Linked-In, etc.), blogger content, and website referral programs.

Sanso intends to create a brand exposure campaign that will include advertisements in disease management journals helping to drive traffic to Sanso's website in order to convert inquiries into sales opportunities. An inside sales team will process the leads and set face-to-face meetings for the company's field RSMs and manufacturer reps. Sanso will be very aggressive in promoting initial trial programs that will lower the barrier for its customers to prove cost savings from the use of Sanso products. Discussions with potential customers have indicated that home care trials will require three to four months in order to determine the savings while acute care facilities will be able to verify the benefits much faster.

PRICING STRATEGY: Initial cost and pricing estimates are provided below. As new versions of the Sanso Via and the Sanso Versa are developed the Cost of Goods Sold (COGS) are expected to lower significantly.

Cost / Pricing Estimates (at product launch)	Cost	Wholesale Cost	Average Selling Price
Sanso Via System (with Sanso proprietary ear sensor and cannula)	350	800	1,000
Sanso Versa System (with Sanso proprietary ear sensor and cannula)	200	400	500
SpO ₂ Ear Sensor (Sanso proprietary) – reusable	20	80	100
Nasal Cannula (Sanso proprietary) – disposable	.50	4.80	6.00
Sanso VISI PT App Subscription (per user per month)	1.00	N/A	5.00
Remote Patient Monitoring Enrollment (one time per patient)	350	N/A	750
Remote Patient Monitoring Service (per patient per month)	10	80	100
Remote Patient Monitoring Enterprise Licensing (per site)		N/A	250,000
Remote Patient Monitoring Enterprise License Maintenance (per year)		N/A	30,000

REVENUE PROJECTIONS

Once the Sanso Via system is cleared by FDA for market release, the company will begin the pilot phase of its sales and distribution strategy. During the first year of commercializing the Sanso Via system, Sanso will focus its efforts on pilot projects with provider organizations to prove the capability of reducing costs and readmissions. The company is prepared to offer its capital equipment at cost or include remote monitoring services at no charge as an incentive for early adopters to conduct these pilot projects and share the results. After the first year pilot projects are completed Sanso will implement an aggressive sales and marketing strategy, expanding its global footprint, and continue to form strategic partnerships with market leaders. As the company grows its distribution network and revenue increases, the founders believe it will become an attractive acquisition candidate.

Revenue Forecast Estimates (First Five Years):

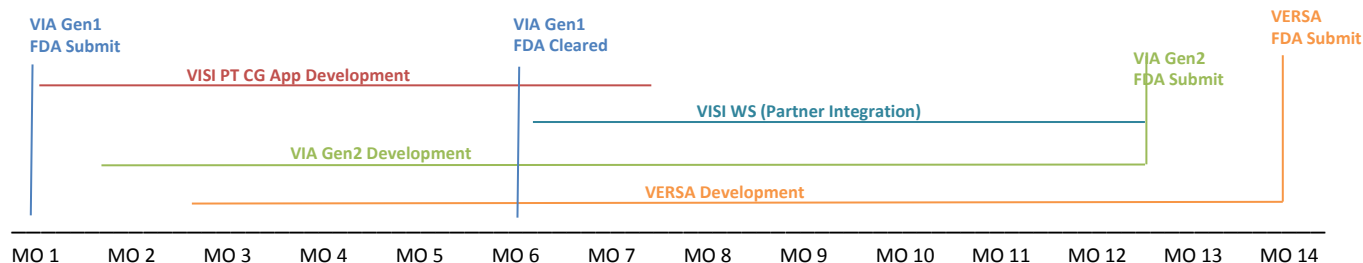
REVENUE (USD)	Year 1	Year 2	Year 3	Year 4	Year 5
Equipment	220,000	3,301,250	7,228,000	14,247,500	21,371,250
Supplies	0	479,250	1,415,250	3,260,250	6,027,750
Remote Patient Monitoring / Data Services	0	2,044,800	6,038,400	13,910,400	25,718,400
TOTAL PROJECTED REVENUE	220,000	5,825,300	14,681,650	31,418,150	53,117,400

Sanso is forecasting profitability in the third year from initial commercial launch. This assumes the market accepts the new technology and the savings to its customers are quantifiable. In order to meet the demand, the company will then need to build internal infrastructure of sales, marketing, support, development, and compliance staff, which will require additional capital investment.

PRODUCT ROADMAP AND BUDGET

Sanso's Series A round of financing is to be \$2.5 million and will begin after the submission of the Sanso Via to FDA. If the company is not acquired within two years of product launch, the Series B round of \$10 - \$15 million is planned to fully market and commercialize the company's products and services globally. Since its inception Sanso has raised \$600,000 in capital, the majority in a non-dilutive transaction with a strategic distribution partner. Additional funds have come from the founders who also currently finance company operations.

Sanso Health is forecasting the product schedule / roadmap as shown below assuming the company is fully funded at the start of the timeline:



Development Projects Budget Total	\$829,000
Working Capital – Parts/Inventory (Initial Builds)	\$400,000
Personnel, Royalties, General Admin / Payables	\$600,000
Intellectual Property – patents / trademarks	\$ 50,000
Optional – Potential Acquisition of OptiSat	<u>\$300,000</u>
TOTAL	\$2,179,000

OPERATIONS

MANUFACTURING: Production of Sanso devices and supplies is outsourced to Sparton Corporation, a FDA-registered, ISO 13485 certified contract manufacturer. Sparton will ship finished product and supply orders directly to the company's customers, distributors, and end-users in the home. In certain situations, select strategic partners around the world may have the option to produce Sanso products and supplies in their country in order to meet demand and provide the additional marketing benefit of being produced locally.

REGULATORY: The first generation AccuO₂ product from MITI/OptiSat was cleared for marketing by the US FDA as a Class II medical device in June of 2005 (see Appendix III Clinical Validation). The Sanso Via device that utilizes the licensed AccuO₂ technology will require submitting a new 510k application to FDA in order to include new features not designed in the original product. Sanso will also expand the indications for use to market its products into all healthcare facilities, instead of only for home use as per the original FDA clearance.

CE Mark certification is expected to be completed during the time frame the company waits for FDA clearance. The CE Mark process will coincide with the preparation for production of the initial build of Sanso Via devices and will be completed by Sanso's contract manufacturer. Regulatory clearances are intended for each major market country outside the US and EU and will be completed by, or working in conjunction with, strategic partners that serve each respective market.

INTELLECTUAL PROPERTY

Exclusively Licensed US Patents	Number	Issued
Control Device for Supplying Supplemental Respiratory Oxygen	6,371,114	April 2002
Automated Control and Conservation of Supplemental Respiratory Oxygen	6,532,958	March 2003
Control of Supplemental Respiratory Oxygen	6,561,187	May 2003
Control of Supplemental Respiratory Oxygen	7,331,343	Feb 2008

Additional opportunities for new patent applications exist and are being explored.

MANAGEMENT TEAM

CEO: Spencer Lien has 30 years of experience in the medical technology industry and has developed highly-tuned skills in creating winning strategies. Spencer became a Vice President and part-owner in a medical sales distribution company within one year of graduating from the University of South Dakota. Spencer was a National Sales Manager at the age of 25 and soon after founded his first medical device startup. He has served on numerous advisory boards including the University of Minnesota's VALUE Advisory Board in the Department of Biomedical Engineering. He has been a guest speaker at the University of Minnesota's

Department of Health Services, St. Thomas University Graduate School of Business, and the Minnesota Venture Capital Conference. In 2008, he founded SALUS, a life science advisory firm located in Minneapolis. In recent years he served as a Mobile Health Strategist for a Fortune 500 company.

CTO: Greg Ingersoll, PhD is an experienced engineer, scientist, and product designer with over 17 years in practice. He has spent the majority of his career engineering complex systems in highly regulated markets including medical devices and industrial safety systems. Before launching his own consultancy, Convolution Research, in 2012, he worked for both a well-known Minnesota OEM and an influential product design company in Minneapolis where he managed a team of electrical engineers. Greg's formal education includes a Bachelor of Science degree in Electrical Engineering and Computer Science from the University of Wisconsin - Madison, and Master's and Ph.D. degrees in Electrical Engineering from the University of Minnesota. where his research focused on optical and laser systems. He has presented at multiple conferences and published peer-reviewed research in the journal Applied Optics.

OPERATIONS MANAGER: Mary Riebe has over 20 years of experience in small and large organizations in bookkeeping, logistics, and sales administration management roles. She spent 15 years with a national retail services company and transitioned into medical device technology services in 2015. Mary currently manages all internal operations, accounting, and purchasing functions while assisting Sanso's product development staff in project management and quality systems documentation.

CLINICAL MARKETING: Robert McCoy, BS, RRT, FAARC has spent over 25 years in the medical industry as a clinician, entrepreneur, and consultant. He is known as a tireless patient advocate and well-known respiratory care expert and author. Bob has served in numerous roles in the industry having been a Product Manager, Marketing Manager, and finally a Director of Marketing for a large respiratory manufacturer before founding Valley Inspired Products. He is active in his professional organizations and is currently the American Academy of Respiratory Care (AARC) Home Care Section Chairman and served on the AARC Board of Directors. He has published numerous peer-reviewed articles, written for trade magazines, lectured at both state and national meetings, and has participated in numerous Long-Term Oxygen Therapy Consensus Conferences.

PRODUCT DEVELOPMENT: Peter Bliss has over 30 years of experience in the design of medical oxygen devices having been a senior executive at multiple early stage design and manufacturing companies and a principal engineer at a Fortune 500 medical device company. He was a liquid oxygen systems product engineer at Caire (formerly Minnesota Valley Engineering) and was President of Wair Products, a manufacturer of specialty control valves. Peter was Chief Technical Officer of Oxytec Medical, a portable oxygen concentrator startup that was later acquired by Philips/Respironics where he served as a Principal Engineer after the acquisition. Peter holds a Bachelor's degree in Mechanical Engineering from the University of Minnesota and is the author of several research articles in peer reviewed medical journals. He has been issued 18 patents. Peter currently is a consultant for companies with emerging technologies and has been an owner in and an advisor to Sanso Health since 2015.

CLINICAL ADVISOR: Matt Mesnik, MD is an accomplished Healthcare Executive with 29 years of healthcare management experience. Matt was the emergency department medical director at Midway Hospital in St. Paul, MN. Matt served as the urgent care medical director for Aspen Medical Group, a 10 site, 180 provider, multi-specialty group in the Twin Cities of Minnesota. He went on to become the first Chief Medical Officer of Aprima Medical Software, an electronic health records and practice management software company. More recently, Matt served as the Chief Medical Officer of MinuteClinic, the originator of retail healthcare with over 1200 clinics in 34 states. He continues to consult for several health IT and medical device manufacturers and has published articles on electronic health records and urgent care medicine.

RISKS AND MITIGATION

PRODUCT RISK: There is a risk that Sanso's solution will not achieve a favorable return on investment for customers who acquired it to reduce hospital readmissions. To mitigate this risk the company has designed its product to ensure patient compliance, including (i) ease-of-use to ensure the patient uses the product; (ii) wireless notification service to ensure caregivers can be notified in real-time when the patient stops use; and (iii) a reward service to entice payers to provide incentives for the patient to use the product. If the patient uses the product as prescribed and the caregiver intervenes when it is not being used, the odds are significantly increased that exacerbations / hospitalizations can be reduced.

MARKET / LEGISLATION RISK: There is a risk that US Government could reverse or reduce the current penalties for hospitals failing to reduce their readmissions, significantly affecting the market for cost-saving technologies. **REIMBURSEMENT RISK:** There is also a risk that US reimbursement from healthcare payers for chronic care management services or other remote monitoring or equipment payment would be reduced significantly or eliminated (see Appendix III – US Reimbursement). In these events, caregivers could lose the incentive to invest in new technologies for helping patients remain well at home and Sanso may not have enough resources to implement a direct to consumer marketing and distribution campaign to convince customers to pay for Sanso technology on their own. To mitigate these risks the company has developed a regulatory approval and distribution strategy that targets leading markets globally so as to not be subject to any one countries' legislation or unforeseen change in the underlying stability of any one market.

REGULATORY RISK: There is a risk that there will be a delay in Sanso's FDA clearance process. While the company expects clearance to market within three to six months, it is possible that new clinical trials requirements for closed-loop technologies such as in the Sanso products could be required, which would require several years to complete. In that event, Sanso may not be able to raise the resources to comply with the requirements. To mitigate this risk, Sanso is intending to achieve CE Mark status while applying for FDA clearance, which will ensure a sizable market and profitability for the company even if Sanso decides to forego the US market.

KEY PERSONNEL RISK: There is a risk that Sanso will not be able to retain its current employees vital to the company's future success. To mitigate this risk, Sanso utilizes several contractors and consultants who are not likely to leave the services of the company and if so could be supplanted by similarly competent replacements. Sanso also has provided ownership incentive for key staff to entice them into to stay with the company on a long-term basis.

FINANCING RISK: There is a risk that Sanso will not be able to raise the significant capital required to continue product development and commercialize its planned product line. In this event, Sanso may not have the resources to continue operations, maintain its licensed intellectual property, or stay competitive. To mitigate this risk, the company has very limited fixed expenses allowing Sanso to maintain operations even if funding takes longer than expected. In addition, all of the founders and most of the management team has deferred all compensation until a successful completion of the first round of outside funding.

COMPETITION RISK: There is a risk that an existing or presently unknown competitor will develop new technology that is superior to that of Sanso's and offer a better value proposition to the market, which would severely hinder the company's ability to achieve profitability. To mitigate this risk, the company has and continues to perform competitive research so as to not be caught off-guard. In addition, Sanso's business and pricing model is based on the expectation of significant competition from unknown sources and therefore its second and third generation products will be designed for cost reduction and expansion into new markets. The company also plans to file new patent applications in order to create and maintain barriers for new competitors in the most appealing markets.

APPENDIX I Clinical Information

Sanso's AccuO₂ product solutions work to prevent both hypoxia and hyperoxia. Hypoxemia (low oxygen in blood) can cause hypoxia (low oxygen in tissues) when blood doesn't carry enough oxygen to tissues to meet the body's needs. Hypoxia is frequently encountered in COPD (Chronic Obstructive Pulmonary Disease) and is responsible for a reduction in exercise tolerance and causes severe complications. When patients with COPD experience chronic hypoxemia at rest, long term oxygen therapy (LTOT) has been proven to reduce complications and mortality. However, patients' needs are variable and episodes of oxygen desaturation may occur during daily activities, from day to day, and in nearly half of patients during the night, despite the use of oxygen therapy.

To prevent low oxygen in blood (hypoxemia), the flow of oxygen needs to be adjusted so that the SpO₂ level of the patient is maintained at or above 90%. Another problem is that between manual adjustments, lower values of SpO₂ may result from lower ventilation reflecting changes in body position or arousal (sleep), or result from increased demand for oxygen reflecting changes in physical activity or emotional state. Such periods of lower SpO₂ levels may contribute to progressive declines in health. Improved maintenance of SpO₂ above 90% by more frequent adjustments of oxygen flow rate would improve supplemental oxygen treatment and may improve survival and health-related quality of life.

By automatically adjusting the oxygen level administered to patients, research shows they will spend more time within the desired oxygen saturation (SpO₂) range as well as experience fewer hypoxic events. (M. G. Iobbi, 2007) One study found that when continuous oxygen monitoring was used to adjust a patient's oxygen prescription, **there was a significant increase in the percentage of time the patient spent between the targeted 88% and 92% SpO₂. In addition, there was a 50% decrease in the amount of oxygen delivered without a significant increase in the time of desaturation.** (Z. Zhu, 2005)

High level of oxygen in the blood (hyperoxemia) and can result in hyperoxia (increased level of oxygen in tissues). It has been shown that the vast majority of patients hospitalized for exacerbations of chronic respiratory disease receive oxygen at high flows. (Hale KE, 2008) For these reasons, tailoring oxygen therapy to the needs of patients is desirable and should meet several objectives:

- Minimize episodes of desaturation
- Avoid excessive oxygen administration that may be responsible for respiratory acidosis
- Customize oxygen flow to the patient's needs, especially during activity and sleep (F. Lellouche, 2012)

In other populations, such as acute coronary syndrome or traumatic brain injury, there are also risks associated with oxygen desaturation (Dewitt DS, 2009) (Galatius-Jensen S, 1994) and hyperO₂ia. (Farquhar H, 2009) (Floyd TF, 2003) (Wijesinghe M P. K., 2009) Closed-loop adjustment of oxygen administration based on SpO₂ is designed to optimize oxygen therapy and improve patient safety. The target SpO₂ level for most patients is 94-98% and for those with COPD, the level is 88-92%.

Results of a new trial suggest supplemental oxygen therapy in patients with ST-elevation MI (STEMI) may actually be harmful for patients who are not hypoxic (Stub, 2015). The Air Versus Oxygen in ST-Elevation Myocardial Infarction (AVOID) trial compared supplemental oxygen versus no oxygen unless SpO₂ fell below 94%.

"The AVOID study found that in patients with ST-elevation myocardial infarction who were not hypoxic, **there was this suggestion that, potentially, oxygen is increasing myocardial injury, recurrent myocardial infarction, and major cardiac arrhythmia and may be associated with greater infarct size at 6 months,**" said lead author

Dr. Dion Stub. “These findings certainly need to be confirmed in larger randomized trials that are powered for hard clinical end points, but **the AVOID study investigators would really question the current practice of giving oxygen to all patients and certainly to those who have normal oxygen levels to begin with.**”

Austin and colleagues compared high flow oxygen versus titrated oxygen treatment in a group of patients with COPD exacerbation in Tasmania. (Austin MA, 2010) They evaluated 214 patients with a diagnosis of COPD exacerbation, of whom 117 received high flow oxygen and 97 received titrated oxygen therapy. **In this group the mortality was 9% in the high flow oxygen group, and 2% in the titrated oxygen group.** Patients receiving titrated oxygen were far less likely to have acidosis or hypercapnia. Other authors have made similar findings in this group of patients. (Wijesinghe M P. K., 2011)

The key to Sanso’s AccuO₂ technology is that it has the opportunity to allow caregivers to deploy new standards in the use of oxygen therapy. **Data strongly suggests a reversal is needed regarding the use of high flow oxygen in acute care settings for specific clinical conditions (post myocardial infarction, stroke, cardiac arrest, COPD, congestive heart failure, pulmonary edema, traumatic injury, sickle cell crisis, and breathlessness) in favor of titrating to SpO₂ levels.** Sanso’s AccuO₂ algorithm allows caregivers to make the transition away from the use of high-flow oxygen by allowing SpO₂ measurements to automatically determine how much oxygen to deliver once it is programmed with basic thresholds.

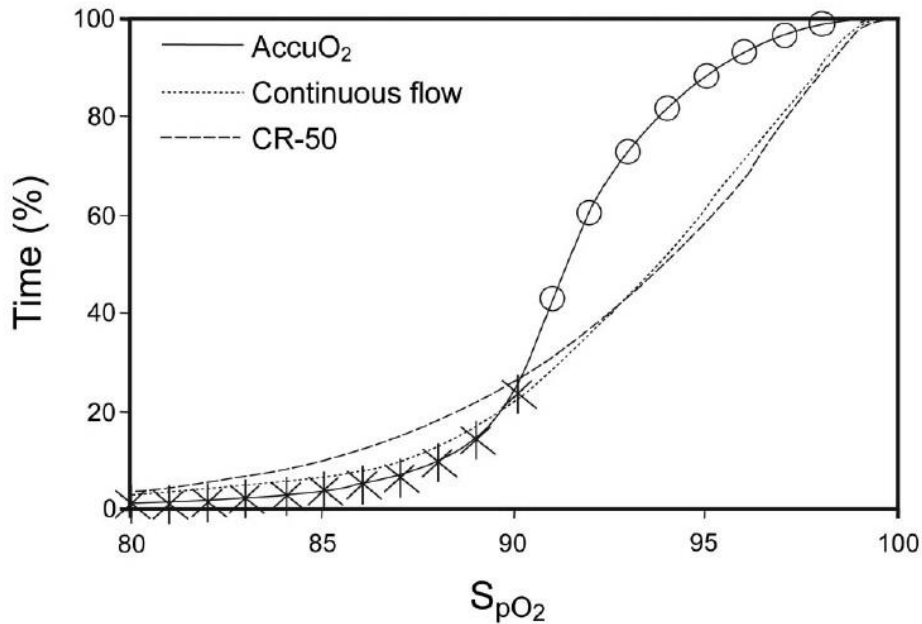
APPENDIX II
AccuO₂ Clinical Validation

In a 2011 article published in *Respiratory Care* (Rice, 2011), Rice et al reported a randomized trial of the first generation AccuO₂ system which they compared to standard continuous-flow oxygen and to another oxygen-conserving device (CR-50). They tested the three oxygen systems' ability to maintain SpO₂ at 90%, and compared the systems' oxygen consumption/conservation.

Their findings confirm data from a randomized controlled trial of a device that automatically adjusts the oxygen dose based on SpO₂ measurements during a constant-workload test, compared to manual titration by a respiratory therapist. The merits of the study by Rice et al are numerous, including their rigorous methods, the use of two controls (i.e. continuous flow and CR-50), and the real-life testing with patients. By keeping SpO₂ very constant, at a "desirable" value, AccuO₂ may be useful in patients with preexisting hypercapnia, in whom increasing PaO₂ (the actual oxygen content in arterial blood) above a certain limit causes deleterious changes to alveolar ventilation and gas exchange, thus worsening acidosis.

The AccuO₂ system had better oxygen conservation than the CR-50. This is very likely to be associated with a cost savings, which may be considered rather small in absolute terms per patient, but from a larger perspective may result in a quite impressive cost reduction. For example, Rice et al point out that 24 million Americans are affected by COPD, but in other parts of the world the COPD population is much larger: for example, in China it is estimated to be about 110 million.

Cumulative Time Spent Above or Below Target SpO₂



Cumulative percent of time under various SpO₂ levels during two 8-hour periods on 2 consecutive days at home. P values compared to continuous-flow O₂ for each 1% increment increase in SpO₂ are represented by open circles for P values < .05, and by Xs for P values > .05

APPENDIX III

US Reimbursement

There are potential payments to US physicians and reimbursement to patients for the use of the Sanso products and services.

Devices and Supplies Coverage

Many insurance carriers will cover the purchase of a pulse oximeter, replacement oximeter sensors, and cannula tubing for home use. Some carriers will cover the purchase of one pulse oximeter (HCPCS code E0445) every 12 months, when oxygen saturation is transient, variable and unpredictable, even in the presence of supplemental oxygen, and occurs on a frequent basis and requiring frequent changes in liter flow.

Carriers including many Blue Cross Blue Shield payers consider oximeters as medically proven to be effective and therefore, are considered medically appropriate for patients with chronic, progressive conditions who require continuous oxygen therapy and who have a change in clinical status necessitating assessment of oxygen dosing.

It is common for pulse oximeters for home use to be viewed as medically necessary durable medical equipment (DME) for members with any of the following indications:

- A. To determine appropriate home oxygen liter flow for ambulation, exercise, or sleep; or
- B. To monitor individuals on a ventilator at home; or
- C. When a change in the individual's physical condition requires an adjustment in the liter flow of their home oxygen needs; or
- D. When weaning the individual from home oxygen

Caregiver Services

Caregivers that utilize Sanso product and services may be able to bill insurance carriers for one of the following procedure codes that range from \$4 to \$36 on a national average:

- CPT: 94760 noninvasive ear or pulse oximetry for oxygen saturation; single determination
- CPT: 94761 multiple determinations (e.g. during exercise)
- CPT: 94762 continuous overnight monitoring (separate procedure)

In addition, there is the potential for a caregivers (including physicians, clinical nurse specialists, nurse practitioners, and physician assistants) to receive payment for managing the care of chronic patients who are using Sanso products under codes and rules for Chronic Care Management Services. According to Centers for Medicare & Medicaid Services, the codes cover chronic and complex care management on a monthly basis for non-face-to-face services provided to beneficiaries.

Code 99490 (average non-facility \$42.71): Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient
- Chronic conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline
- Comprehensive care plan established, implemented, revised, or monitored

CPT 99487 (average non-facility \$52.76): Complex chronic care management services, with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient
- Chronic conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline
- Establishment or substantial revision of a comprehensive care plan
- Moderate or high complexity medical decision making
- 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month

CPT 99489 (average non-facility \$47.14): Each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure).

Other codes that may be reimbursable include:

CPT 99090: Analysis of clinical data stored in computers (eg, ECGs, blood pressures, hematologic data)

CPT 99091: Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time.

APPENDIX IV COPD Statistics and Costs

In 2010 COPD cost the US an estimated \$29.5 billion in direct costs and \$20.4 billion in indirect costs. (NHLBI, 2007) About half of the estimated \$50 billion in annual health care expenditures for COPD has been attributed to costs associated with hospitalizations for COPD exacerbations. (Toy EL, 2010)

In the US:

- 14.8 million Americans diagnosed with COPD (CDC, CDC Fast Facts: COPD. <https://www.cdc.gov/nchs/fastats/copd.htm>, 2013)
- Percent of Residents of Assisted Living or other Resident Care with COPD: 10.8% (CDC, CDC Fast Facts: COPD. <https://www.cdc.gov/nchs/fastats/copd.htm>, 2013)
- 150 million days of work are lost annually (NHLBI, 2007)
- A person with COPD dies every 4-minutes in the US (CDC, CDC Data, 2005)
- 3rd leading of cause of death (CDC, Statistics, National Vital Reports Volume 59, Number 2)
- 2nd leading cause of disability (NHLBI, 2007)

COPD ranks #3 in acute hospital admissions in the US (DRG: 088):

- 700,000 COPD hospitalizations annually (NHLBI N. H., 2012)
- 1 in 5 (>20%) are readmitted within 30 days (NHLBI N. H., 2012)
- Average annual hospitalized days 8.18 (Schneider KM, 2009)
- Average length of stay 5.1 days (State, 2009)
- Average total cost/admission \$15,093 (Dalal AA, 2010)

Works Cited

- Au., L. F. (2014). Penalizing Hospitals for Chronic Obstructive Pulmonary Disease Readmissions. *American Journal of Respiratory Critical Care Medicine*, Vol 189, Iss 6, pp 634–639.
- Aubier M, M. D.-E. (1980). Effects of the administration of O₂ on ventilation and blood gases in patients with chronic obstructive pulmonary disease during acute respiratory failure. *American Review of Respiratory Disease*, 122(5):747-754.
- Austin MA, W. K.-B. (2010). Effect of high flow oxygen on mortality in chronic obstructive pulmonary disease patients in prehospital setting: randomised controlled trial. *British Medical Journal*, 341:c5462
10.1136/bmj.c5462.
- CDC. (2005). *CDC Data*.
- CDC. (2013). *CDC Fast Facts: COPD*. <https://www.cdc.gov/nchs/fastats/copd.htm>.
- CDC. (n.d.). *Statistics, National Vital Reports Volume 59, Number 2*.
- Dalal AA, C. L. (2010). Direct costs of chronic obstructive pulmonary disease among managed care patients. *International Journal of COPD*, 5:341-49.
- Dewitt DS, P. D. (2009). Blast-induced brain injury and posttraumatic hypotension and hypoxemia. *Journal Neurotrauma*, 26(6):877-887.
- Dunn WF, N. S. (1991). Oxygen-induced hypercarbia in obstructive pulmonary disease. *American Review Respiratory Disease*, 144(3 Pt 1):526-530.
- F. Lellouche, E. L. (2012). Automated Oxygen Flow Titration to Maintain Constant Oxygenation. *Respiratory Care*, August Vol 47 No 8.
- Farquhar H, W. M. (2009). Systematic review of studies of the effect of hyperoxia on coronary blood flow. *American Heart Journal*, 158(3):371-377.
- Floyd TF, C. J. (2003). Independent cerebral vasoconstrictive effects of hyperoxia and accompanying arterial hypocapnia at 1 ATA. *Journal Applied Physiology*, 95(6):2453-2461.
- Galatius-Jensen S, H. J. (1994). Nocturnal hypoxaemia after myocardial infarction: association with nocturnal myocardial ischaemia and arrhythmias. *British Heart Journal*, 72(1):23-30.
- Hale KE, G. C. (2008). Audit of oxygen use in emergency ambulances and in a hospital emergency department. *Emerg Med J*, 25(11); 773-776.
- Jencks, S. F. (2009). Rehospitalizations among Patients in the Medicare Fee-for-Service Program. *New England Journal of Medicine*, 360: 1418-1428.
- M. G. Iobbi, A. K. (2007). Oximetry feedback flow control simulation for oxygen therapy. *Journal of Clinical Monitoring and Computing*, Vol. 21, pp. 115–123.
- NHLBI. (2007). *Morbidity and Mortality: Chartbook on Cardiovascular, Lung and Blood Diseases*.
- NHLBI, N. H. (2012). *Fact Book Fiscal Year 2012, Chapter 4-Disease statistics*.
- R. D. Branson, J. J. (2013). Pre-Hospital Oxygen Therapy. *Respiratory Care*, January Vol 58 No 1.
- Rice, e. a. (2011). AccuO₂ Oximetry-Driven Oxygen-Conserving Device Versus Fixed-Dose Oxygen Devices in Stable COPD Patients. *Respiratory Care*, 56(12):1901–1905.
- Sassoon CS, H. K. (1987). Hyperoxic-induced hypercapnia in stable chronic obstructive pulmonary disease. *American Review Respiratory Disease*, 135(4):907-911.
- Schneider KM, O. B. (2009). Prevalence of multiple chronic conditions in the United States' Medicare population. *Health Qual Life Outcomes*, 7:82.
- State, D. o. (2009). *Average Length of Stays*.

- Stockinger ZT, M. N. (2004). Prehospital supplemental oxygen in trauma patients: its efficacy and implications for military medical care. *Military Medicine*, 169(8):609-612.
- Stub, e. a. (2015). AVOID Study. Air Versus Oxygen in ST-Segment Elevation Myocardial Infarction. *CIRCULATION AHA*, 114.014494.
- Toy EL, G. K. (2010). The economic impact of exacerbations of chronic obstructive pulmonary disease and exacerbation definition. *COPD*, 7: 214–228.
- Wijesinghe M, P. K. (2009). Routine use of oxygen in the treatment of myocardial infarction: systematic review. *Heart*, 95(3):198-202.
- Wijesinghe M, P. K. (2011). Pre-hospital oxygen therapy in acute exacerbations of chronic obstructive pulmonary disease. *Internal Medicine Journal*, 41(8):618-622.
- Z. Zhu, e. a. (2005). Continuous oxygen monitoring - better way to prescribe long-term oxygen therapy. *Respiratory Medicine*, Vol. 99, pp. 1386–1392.