

What is the big idea?

Developed by Tidal Medical Technologies, InSee is a patented smart monitoring system that quantitatively tracks patient usage of existing incentive spirometers. Using the InSee system we are building the largest Spirometry EaaS platform with predictive analysis and machine learning techniques that can save thousands of lives and prevent hospitals from losing billions of dollars due to patient readmissions.

What Are We Building?

We are building an Expert as a Service (EaaS) platform for pulmonologists through Al-based solutions in order to simplify and streamline their complex and highly scrutinized evaluation processes.

In order to accomplish this goal, and collect sufficient pulmonary data, we are developing a smart, connected real-time monitoring system, called InSee. InSee is a patented device, with Emergency Use Authorization from the FDA that can quantitatively track patient usage of incentive spirometers (IS). The IS is an existing disposable mechanical ventilator that is used by thousands of patients in hospitals, skilled nursing facilities, extended care facilities, and at home-health settings. They help to optimize pulmonary function and promote deep breathing in order to reduce the risk of pneumonia.

InSee can also monitor the breath-hold, following a deep breath, and remind the patient to use the IS at the prescribed time intervals, thus coaching patients to improve lung expansion in those at risk for pulmonary complications.

All the data collected by InSee is sent and retained in our spirometry database. By utilizing artificial intelligence (AI) based on deep learning we intend to create the first EaaS platform that can potentially identify high risk patients, and provide a more effective treatment prior to discharge from hospitals or nursing facilities.

What is The Problem?

We believe our system can result in a significant net cost saving for hospitals and nursing facilities by improving their **pulmonary diagnostic** procedures, as well as the quality of their health care:



- A. The InSee system can help hospitals reduce their readmission rate and thus save money. There are nearly 140,000 hospital readmissions per year. Despite efforts to optimize inpatient care delivery, 30-day readmissions are estimated to occur in 17% to 25% of patients hospitalized for pneumonia. This costs hospitals upwards of \$10 billion a year due to penalties. Early discharge, while the patient still has an inadequate respiratory rate, is one of the main factors that leads to patient readmissions. InSee can track respiratory rates in real-time and thus help physicians to create a more effective data-driven discharge plan for patients, potentially saving hospitals millions of dollars.
- B. The InSee can reduce the current high cost of implementing a postoperative Incentive Spirometer. IS has been reported to be used in 95% of US hospitals after surgery. For the 9.7 million inpatient surgeries performed annually in the United States, the total annual cost of implementing postoperative IS is estimated to be \$1.04 billion. The majority of this cost is based on observing the patient using the device and monitoring lung sounds and respiratory status by skilled medical personnel. InSee can automate routine functions such as monitoring and data collection, which in turn can result in considerable time and cost savings. It also helps medical personnel gain insight into patient performance, and compliance.
- C. The InSee system is the key step to creating the first pulmonary EaaS platform. Such a platform can have great importance in diagnosis, managing, and determining the level and assessment processes of respiratory diseases. We believe once this platform is available, many research institutions and hospitals will be very interested to subscribe to it. By combining the pulmonary and other clinical data, such as chest X-rays, our EaaS platform can perform predictive analytics and help with early detection & risk stratification of respiratory conditions. This can lead to improved treatment and fewer readmissions.
- D. Aside from its financial opportunities and cost-saving advantages, InSee promotes patient compliance and accountability. It reminds and coaches patients to properly use the incentive spirometers and tracks their breathing exercises in real-time, without the need to modify the existing devices or protocols.

Our Team:

Our founder team consists of an **MD** Board Certified in Family Medicine with fellowship training in Emergency Medicine and over 9 years of experience as Director of Emergency Medicine for many ERs in Texas and surrounding states; another **MD** with extensive training in surgery, family medicine, and hospice/palliative care, as well as many years of experience as the regional medical director for a large physician staffing agency; a **PhD** electrical engineering professor at Sonoma State University, specializing in telecommunications and biomedical



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devices, and **a biomedical engineer** with over 15 years of experience in medical devices. Our development team includes a **cloud architect** (also a part-time lecturer at Sonoma State University) with more than a decade of experience with AWS cloud and cloud security, a hardware developer with more than 12 years of experience, specializing in sensors and the Internet of Things, and a database and security engineer, who is also an alumnus of Sonoma State University, with 15 years of experience working with major industries, including hospitals and financial institutions. Our interdisciplinary team has been working successfully on various projects together over the past several years in different capacities. Everyone on the team is extremely passionate about this project and strongly believes in the potential opportunities of InSee.

Our progress so far:

Our team started working on the InSee project about two years ago. The project took off at Sonoma State University as a student project, following the hospitalization of one of the engineering faculty members (full story here: <u>https://spectrum.ieee.org/infrared-device-helps-monitor-covid19-patients-breathing-therapy</u>).

Initially, we received a small grant from the California State University system to start the project with an undergraduate and a graduate student. As the project received more attention, we decided to turn it into a commercial medical device and sought new partners, creating a team of physicians, engineers, and medical device experts. So far, we have been fully self-funded, and our investors are mainly friends and colleagues. We have completed the first InSee prototype (with no connectivity capability) and manufactured 100 medical-graded units for the clinical trial. We have been awarded a U.S patent and an Emergency Use Authorization from FDA, which allows the use of our prototype on COVID patients.

We are currently collaborating with one researcher from Brown University to prepare our clinical trial protocol. We are also collaborating with the Medical Director at the Center for Critical Care at Houston Methodist Hospital in order to conduct the clinical trial on 50-75 patients. We are currently waiting to receive the Institutional Review Board (IRB) approval in order to begin the clinical trial. We have not had any sales, since the device is not fully approved by the FDA, yet.

Over the last 18 months we have completed our AWS-based cloud system. Using our cloud, we can receive and retain respiratory data from the InSee units. We have also completed the first working prototype version of the connected InSee (InSee-C). The InSee-C is one of the first medical devices which operates using LoRaWAN. The existing secure web-based user interface



allows the medical personnel to easily track the patient usage of the incentive spirometers. All alarms and event reports are currently handled by AWS Cloudwatch.