Strados Labs: An Efficient Process to Acquire and Characterize Clinically Validated Respiratory System Information Using a Non-Invasive Bio-Sensor

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Patients with respiratory diseases are often rushed to the emergency room with acute decompensation. If not managed properly, chronic respiratory disease prolongs the episode of care or leads to hospital readmissions that are costly and burdensome to the patient. The current standard of care, in an inpatient setting, relies on labor-intensive, eSpisodic clinical assessments to detect signs of worsening disease progression. In the outpatient setting, disease monitoring relies solely on self-reporting by patients. Occasionally, patients have the aid of an instrument, such as a peak flow meter, but these aids are prone to user error and cannot always accurately report critical data 0. Additionally, patients with COPD (Chronic Obstructive Pulmonary Disease) and asthma often receive inadequate treatment due to poor communication between the patient and clinician [2] - [3], poor disease status assessment by the clinician, inconsistent use of medication [4] - [5], or the unreliability of peak flow measurements 0. A system capable of continuously and remotely monitoring a patient's respiratory health could address this disconnect in patient care. Utilizing an intelligent patient monitoring system could improve patient care triage, reduce the length of hospital stay, lower the healthcare costs incurred by expensive pulmonary complications, and standardize the objective assessment of a patient's respiratory health.

Strados Labs has developed a clinically validated medical device system aimed toward providing remote monitoring for outpatient settings as well as delivering respiratory monitoring to inpatient clinical teams throughout the duration of care. This non-invasive device captures lung sounds and chest wall motions that are wirelessly transmitted through a mobile app to a web application to be analyzed for changes in respiratory health. Utilizing proprietary predictive models, this system is capable of generating reports within minutes of data acquisition that can help in diagnosing a patient's respiratory health.

The system differs from current technologies in that it allows monitoring of the lung sounds required to diagnosis and treat respiratory diseases, with or without a clinician present. Trained annotators segment key symptoms such as coughing, wheezing, and other adventitious breath sounds, which are then validated by medically trained professionals. Longitudinal analysis of these characteristic lung sounds reveals key trends and provides greater insights into a patient's respiratory condition, which can then be utilized by clinicians to better manage a patient's care.

Proprietary machine learning techniques, derived from state-of-the-art speech recognition algorithms, utilize this data to train models that automatically label region of interest. Preliminary results on over 13,000 lung sound samples show that the data can be automatically labeled with a sensitivity of 93% and a specificity of 97% using a held-out evaluation data set. This process creates a closed loop system that eliminates the delay between data acquisition and classification.

The described device and system have been implemented in a feasibility trial at NY Metropolitan Hospital in Harlem. Nearly 24 hours of lung sound data has been collected across 51 patients with respiratory disease accounting for over 4,500 different labeled events to date. The aim of this study was to show that continuous monitoring is superior to auscultation spot checks in identifying respiratory pathology signs.

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NYC HEALTH + HOSPITALS

ABSTRACT

Current standard of care practices in both inpatient and outpatient settings have been shown to be inconsistent, subjective, and ineffective in diagnosing and treating respiratory disease. Strados Labs has developed a clinically validated medical device system[1] aimed toward providing remote respiratory monitoring for outpatient settings as well as delivering respiratory monitoring to inpatient clinical teams throughout the duration of care. The non-invasive device captures lung sounds and chest wall motions that are segmented into key respiratory symptoms leveraged by clinicians to better manage a patient's respiratory health.

[1]   The Strados Respiratory Monitoring System is not yet cleared by the FDA

CHRONIC RESPIRATORY DISEASES (CRDs)

The most frequent CRDs are Asthma and Chronic Obstructive Pulmonary Disease (COPD). Symptoms of these diseases can be controlled through proper assessment, management, and education. Studies show that it is critical to adhere to the following guidelines in order to properly treat these diseases.

- Assess severity of disease by measuring lung health
- Control Environmental factors to avoid triggers
- Establish education plan with healthcare team
- Pharmacological therapy for long-term disease care

ISSUES WITH STANDARD OF CARE

The standard of care as described above is not always a reliable method of treating CRDs. Contributing factors to inadequate treatment of patients with CRDs include, inaccurate assessment of disease status, inconsistent medication usage, and unreliable measurement tools. These issues become more apparent when studying the differences between Inpatient and Outpatient treatment practices.

Inpatient care requires labor-intensive, episodic clinical assessments susceptible to subjective decisions by professionals.

Outpatient care relies on proper usage of medication, self-reported information from patients, and devices prone to user-error.

STRADOS RESPIRATORY MONITORING

The Strados Respiratory Monitoring system provides continuous, remote respiratory monitoring enabling automatic clinical assessments and removing patient dependant practices.
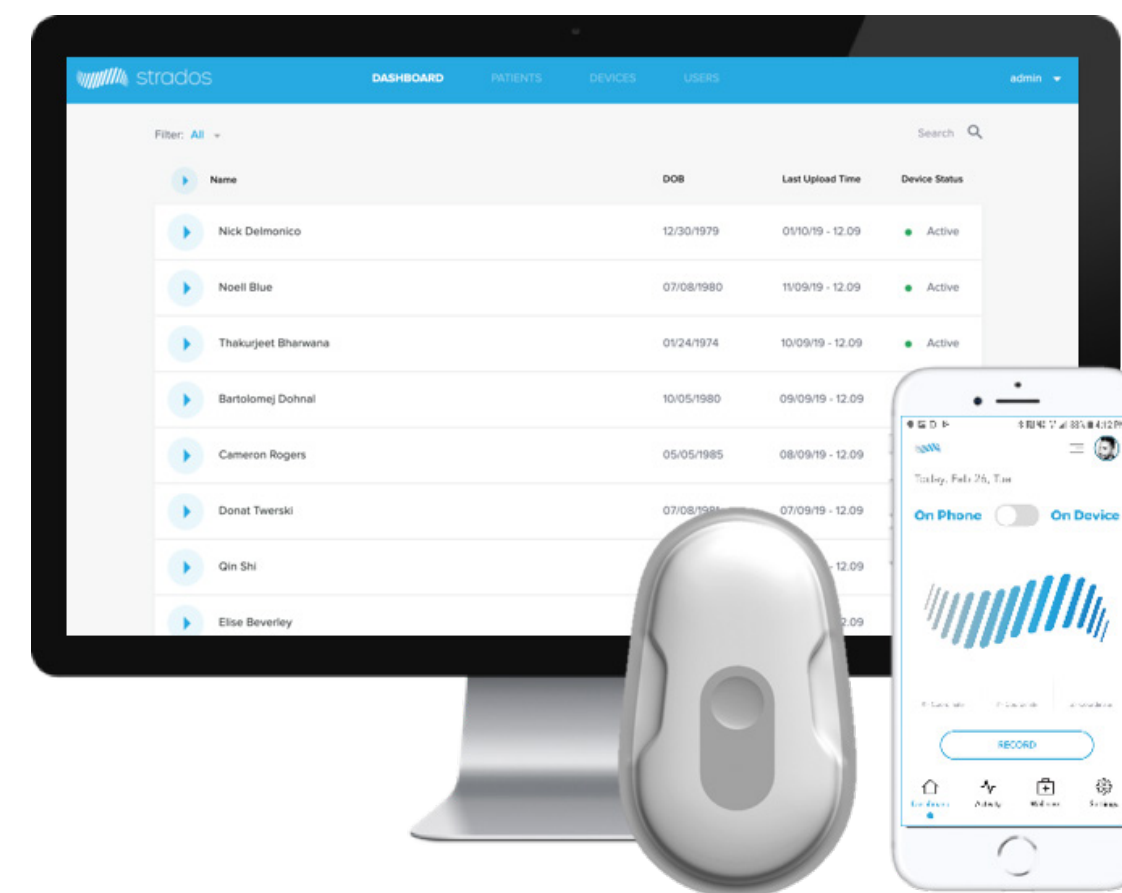
The device is easily placed on the surface of the skin using a medical grade adhesive.

Utilizing multiple microphones and sensors, the device records lung sounds and chest wall motions. The data quality is improved through Active/Passive Noise Cancelling and de-noising algorithms.


Inhale/Cough   Wheeze
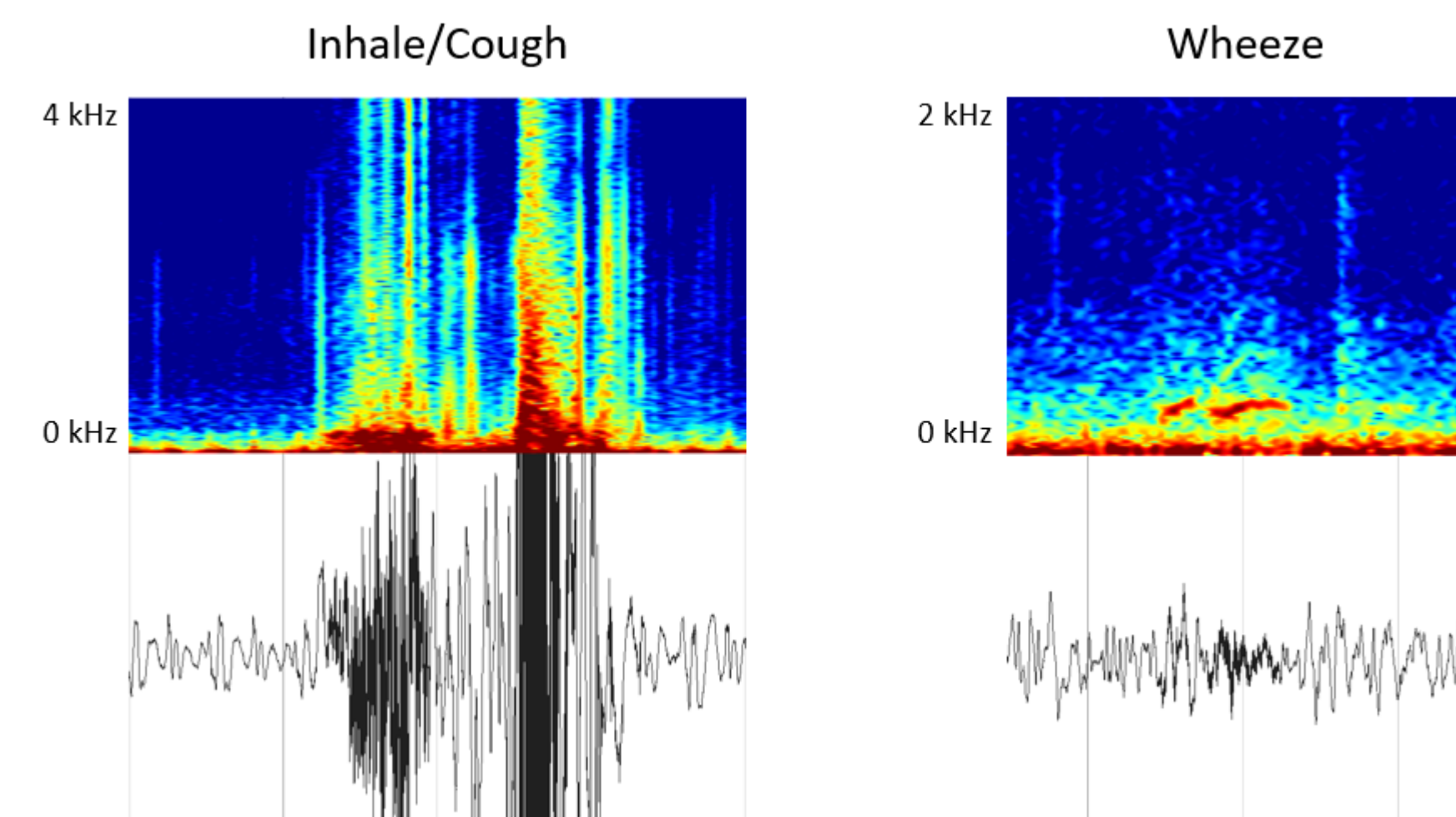
Captured data is first cached on the device, then streamed and stored on a cloud-based web application through which clinicians can assess patient health.

Respiratory health reports can be automatically generated by this system to provide further assistance in Asthma/COPD status assessments.
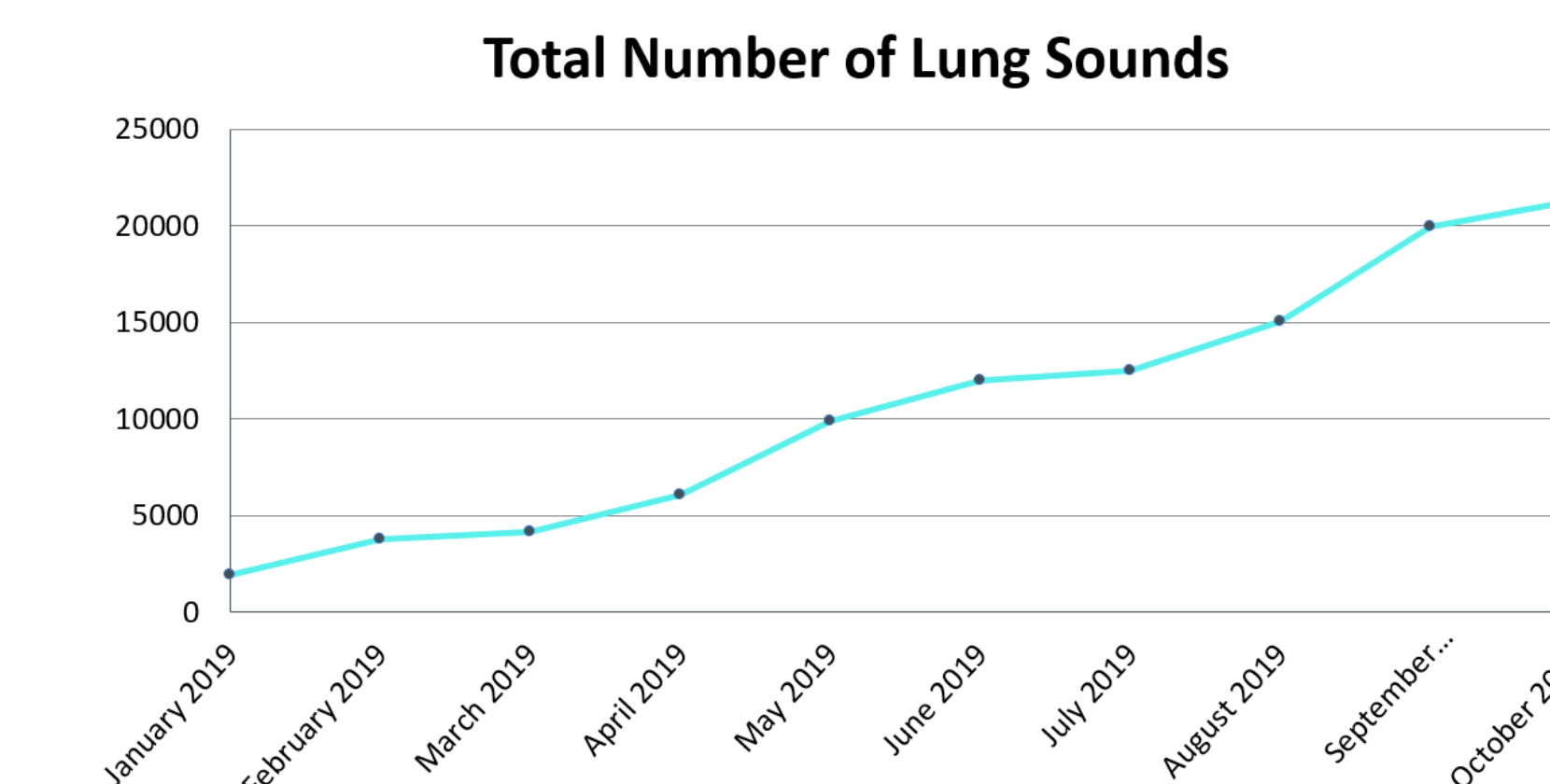
DATA ANNOTATION

Professional annotators are trained to segment the clinically captured data into key respiratory symptoms used to diagnose and assess patient health. Respiratory symptoms such as Cough, Wheeze, and other adventitious breath sounds (Ronchi, Crackles, etc.) are among the sounds that are segmented in this process.

Inhale   Cough
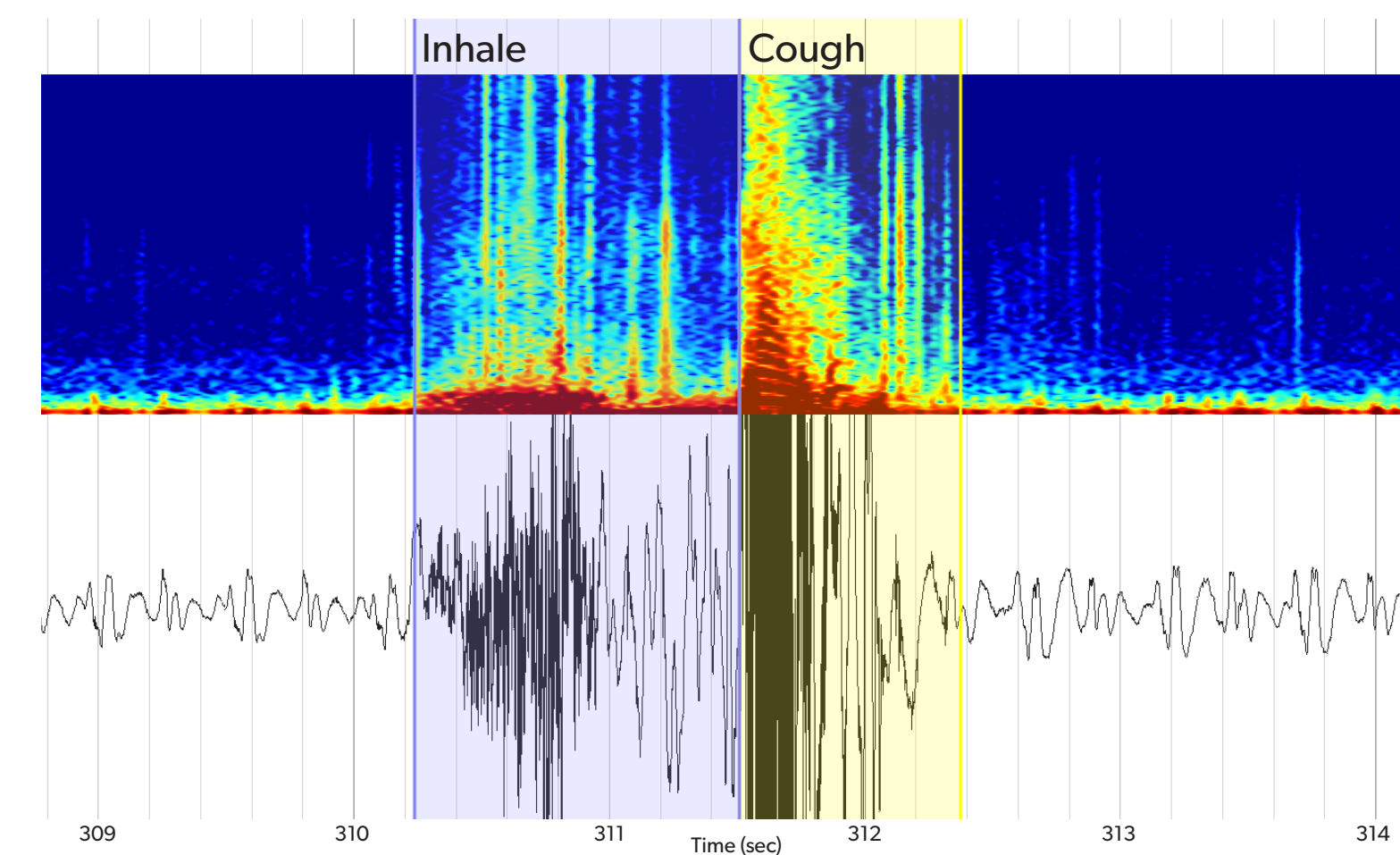
Custom software has been developed to efficiently and accurately segment the data. It provides data visualizations and annotation capabilities that sync to the previously captured cloud-stored data.

DATA VALIDATION

Segmented data samples are reviewed by certified clinicians to validate the accuracy of our data segments. Validators listen to the audio and revise the onsets, offsets, and label of the previously segmented events as necessary.

Total Number of Lung Sounds

LONGITUDINAL HEALTH ANALYSIS

The process of continuous data acquisition, professional annotation, and clinical validation, enables longitudinal analysis that tracks respiratory symptoms over time.

Clinical results show that performing a continuous auscultation is more effective in diagnosing a patient's respiratory health than performing episodic spot auscultations.

NYC HEALTH + HOSPITALS

In collaboration with NYC Health + Hospitals, a clinical study was implemented in the Emergency Department with the following goals.

- Primary Goal: Test the effectiveness of continuous auscultations (Strados Device) against the spot auscultations (Electronic Stethoscope)

- Secondary Goal: Test the feasibility of the Strados Respiratory Device System in a clinical environment.

Over 11,000 Lung Sounds from 48 Patients were successfully recorded, annotated, and validated through the Strados System.

NY Health + Hospitals ED	Littmann Electronic Stethoscope	Strados Respiratory Device
Time Recorded	0.53 Hours	46.08 Hours
CABS	133	1408
Wheezes	607	3006
Coughs	85	531
Total Lung Sounds	1446	10141
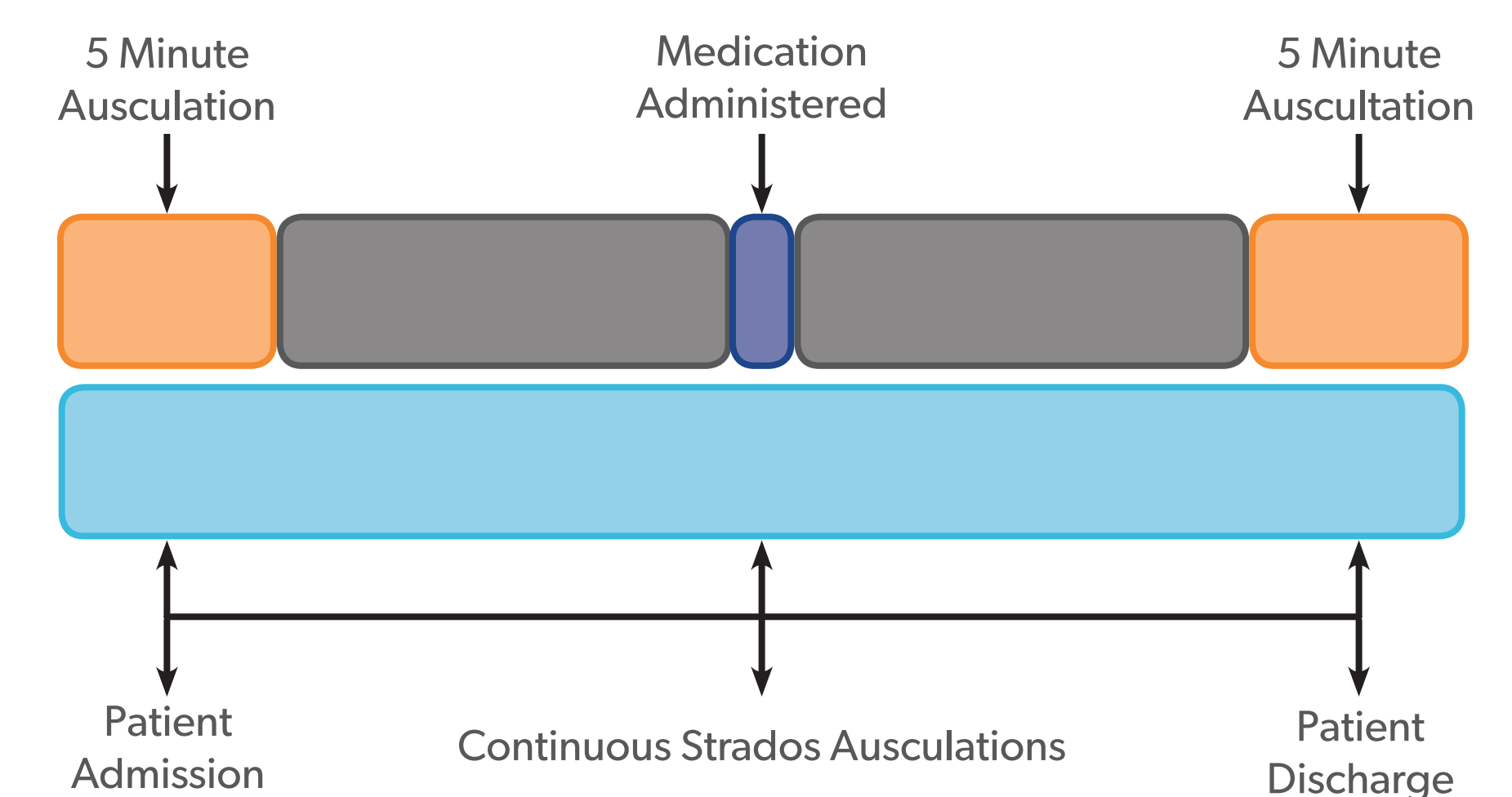
NEXT STEPS

The technology described has been shown through clinical results to perform accurate and reliable spot auscultations, while also providing continuous auscultations with the same level of accuracy.

Preliminary results of the machine learning algorithms developed with this system show that the acquired data can be classified with 93% sensitivity and 97% specificity based on a held-out discrete evaluation set.

Further improving these algorithms will provide a level of autonomy on top of the continuous, remote, and real-time respiratory monitoring system.