respira labs

LOWELL • WORCESTER UMASS M2D2 Advancing Med Device & Biotech Innovations

CAPCaT Center for Advancing Point of Care Technologies

PROJECT TEAM

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MOTIVATION

Three months following hospitalization, up to 43% of COVID-19 patients report dyspnea. Respiratory symptoms left untreated can cause irreversible lung damage and progressive decline in lung function. Maintaining accurate post-acute COVID patient monitoring employing acoustic lung resonance for air trapping measurement can help **understand COVID-19 sequelae and new therapy development, efficacy, safety, and side effects.**

OUR PROPOSAL: SYLVEE

Today's tools are inadequate!

- $50K device
- >1 Hr duration
- Requires a technician
- Difficult to complete (blowing)
- Performed every other year

PLETHYSMOGRAPHY

- 70% error rates
- Issues with colored skin
- Could be normal with symptoms
- Need to stay still
- Doctors don't prescribed them

PULSE-OXIMETER

- $2M device
- >1 Hr duration
- Requires a technician
- Need to stay still
- Performed every other year

CT SCANNER

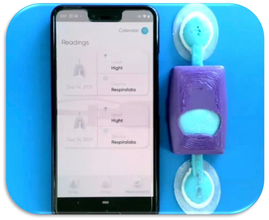
- 67% accurate
- Relies on subjective data
- Needs patients to complete it
- The **STATUS QUO** at home

QUESTIONNAIRE

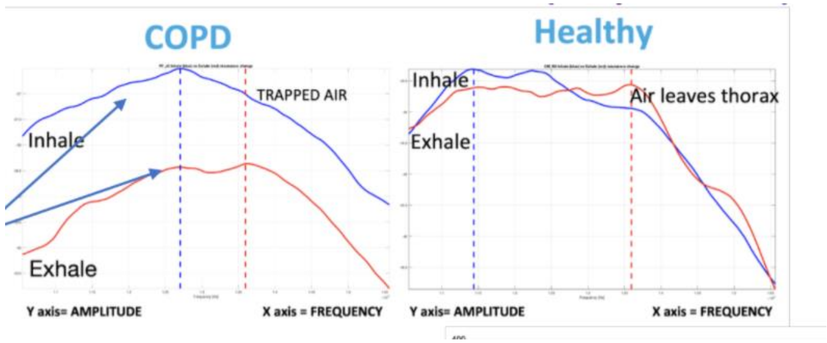
Preliminary results:

- ❑ Accuracy of >90% to detect respiratory rate when moving.
- ❑ Sylvee can consistently identify changes in lung resonance in COPD patients during exercise.
- ❑ The acoustic resonances and frequency shifts of patients with and without COPD differed.

Our device uses next-generation technology to **quantify air trapping**, a well-known biomarker of lung function decline. It monitors and analyzes acoustic resonance properties in real time or stores them for later processing.



Current prototype



DELIVERABLES

1) Clinical: Perform a semi-remote feasibility trial (n=25 COVID-19 survivors; n=25 healthy controls) to track changes in acoustic resonance properties using PFTs, metronome breathing, and the 6MWT. Also compare Sylvee's efficacy to chest CT scan imaging, standardized questionnaires, and other clinical parameters.

2) Academic: Publish in a respected peer-reviewed journal like American Journal of Respiratory and Critical Care Medicine, European Respiratory Journal or The Lancet Respiratory Medicine

3) Regulatory: Submit a pre-EUA package to the FDA for review before submitting an EUA.

4) Business: Conduct over 50 interviews with patients, healthcare providers and administrative staff to learn how to understand how our device fits into workflows and what economic data they need to see value (e.g., safety, savings, new revenue).

5) Fundraising: Secure 5 letters to support raising $4M from institutional investors.