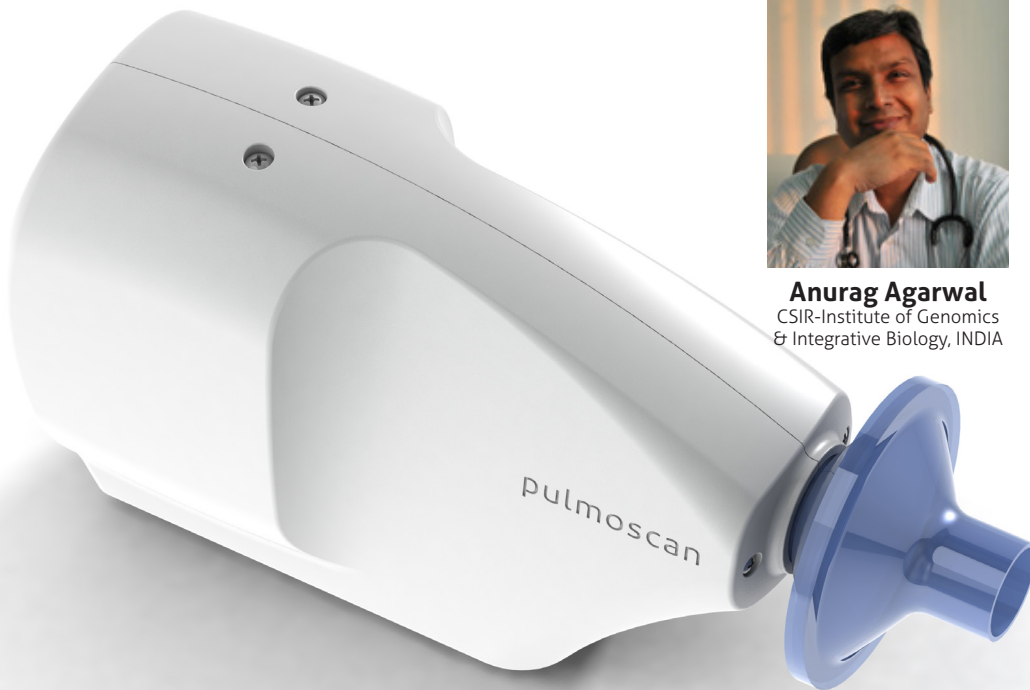
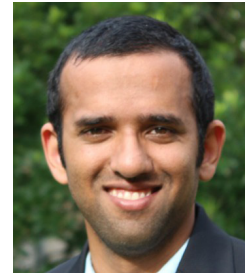


Pulmoscan®

# BREATHING EASY



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**Chronic lung diseases are amongst the top three threats to global health. Of these, Chronic Obstructive Pulmonary Disease (COPD) and asthma are not just the most common, but also increasing in prevalence.**

**T**he clinical presentation of COPD may be as innocuous as a chronic cough that won't go away and as severe as acute respiratory failure. Clinical diagnosis can often be wrong in absence of objective tests of lung function. Spirometry, the commonest and most well accepted test, requires coordinated sharp forced expiratory effort by patients and takes time and training to be done properly. It requires comprehension on part of the test subject, making it unsuitable for a large number of young children with asthma, and is hard to do, making it poorly suited for elderly people with COPD. The class of tests known as Forced Oscillation Technique (FOT) has shown the most promise as an alternative to spirometry, requiring minimal instruction and training and therefore suitable for all ages. Such oscillometric devices are more sensitive than spirometry for early small airway disease and all such devices can additionally be used to perform spirometry. The currently poor penetration of oscillometric devices into the international market is almost entirely attributable to bulkiness, non-portability, cost

of currently available solutions (USD 25000 for an oscillometer versus USD 3000 for high-quality spirometers). The insurance coverage of oscillometric tests in the U.S. is also inconsistent, leading to financial disincentives in the U.S. market for physicians who choose to use oscillometry. However, a handheld, portable, battery operated oscillometer with automated analysis would be very suitable for high volume practices in India, where the time-efficiency and ease of use of oscillometers would make up for reasonable additional input costs.

Our group thus set out to build a new generation oscillometer with novel design and analysis elements to improve ease of use and reduce costs.

We had a clear scientific and business plan, uniquely strengthened by the complementarity and synergy between the Indian and U.S. partners. Cognita Labs is a spinoff from Rice University with a strong background in engineering sciences. Its mission is to develop novel healthcare products with innovative deployment models. Cognita Labs had already built an advanced easy to use spirometer, **UltraSpiro**, with an assistive coaching tablet application and a cloud support to allow minimally trained medical professionals to conduct accurate spirometry. The experience and partnerships created during building and testing **UltraSpiro** provided a strong technological head-start for building **Pulmoscan**<sup>®</sup>. The experience in clinical applications of oscillometry at the CSIR-IGIB CoE for Translational Research in Asthma & Lung disease provided unique knowledge resources. The synergy led to a successful application to USISTEF for building a novel portable forced oscillation based device for simple yet more sensitive detection of airway disease. A lot was learnt in the process of applying and much useful feedback was gained, with the project taking full shape by 2016.

Over the last 2 years, we have seen **Pulmoscan**<sup>®</sup> go to an actual two-hand bulky prototype running off a tablet, to a sleek one handed standalone version with visual cues for correct use and automated test completion. New engineering and design was required to come this far



and IP protection has been applied for. The prototype was tested in over 1000 subjects, getting operational feedback from clinical partners. Many of these partners now anxiously await a market version that they can recommend to their friends for purchase. The results from the initial testing against in-market models have been promising with broad agreement with existing brands.

There have been challenges as well. It has become obvious to users that while all devices provide ability to distinguish normal and diseased subjects, there is fundamental variability in the absolute values and cutoffs between oscillometric devices, due to different approaches to a complex mathematical problem; unlike spirometers that are inherently simple in their design and principle. This can be confusing to clinicians. We have recently become part of an international group of oscillometer manufacturers and users that aims to best standardize the outputs across devices in a way that would make it uniform and more convenient for physicians.

We now expect to get **Pulmoscan**<sup>®</sup> into the market in 2019, a bit later than originally envisioned, but very much past the steepest part of the climb. Many people, including those at USISTEF who saw its potential, deserve the credit for getting us as far as we have come, and we take the opportunity to thank them. We would strongly encourage device developers to take this opportunity and apply for the USISTEF Program. ●