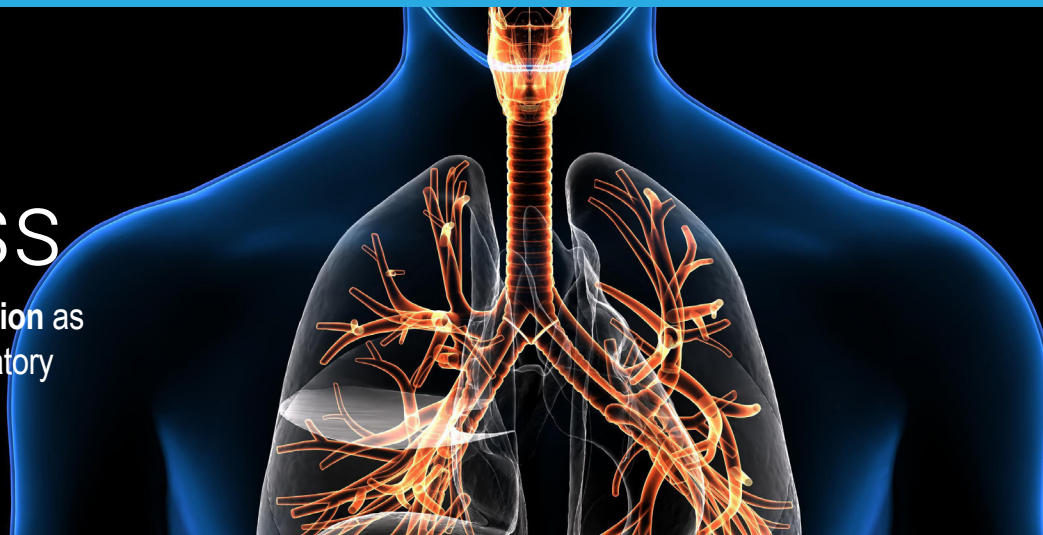


# Respiratory Wellness

The Use of **Forced Cough Vocalization** as a Biometric Marker to Assess Respiratory Changes and Diagnose Diseases



Changes to airway mucus in reaction to external stimuli are a measurable biomarker during the physical activity of Forced Cough Vocalization (FCV) – that is, an intentional cough.

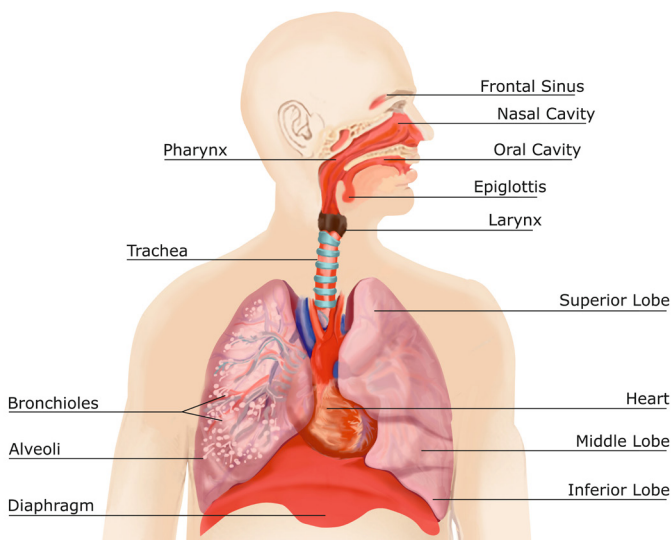


## Overview

The human respiratory system is the network of organs and tissues that allow us to breathe by helping the body absorb oxygen from the air and clean waste gases like carbon dioxide from the blood. The airways, consisting of the mouth and nose, sinuses, throat, trachea, and bronchial tubes deliver air to the lungs, extract oxygen from the air and move it to the bloodstream. The bloodstream delivers oxygen to all the organs and tissues of the body.

The other parts of the respiratory system include:

- **Alveoli:** Tiny air sacs in the lungs where oxygen and carbon dioxide exchange occurs..
- **Bronchioles:** Small branches of the bronchial tubes that lead to the alveoli.
- **Capillaries:** Blood vessels in the alveoli walls that move oxygen and carbon dioxide.
- **Lung lobes:** Sections of the lungs – three lobes in the right lung and two in the left lung.
- **Pleura:** Thin sacs that surround each lung lobe and separate the lungs from the chest wall.
- **Cilia:** Tiny hairs that move in a wave-like motion to filter dust and other irritants out of airways.
- **Epiglottis:** Tissue flap at the entrance to the trachea that closes when swallowing to keep food and liquids out of the airway.
- **Larynx (voice box):** Hollow organ that allows us to talk and make sounds when air moves in and out.



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RAlsonance specializes in the artificial intelligence-powered analysis of Forced Cough Vocalizations (FCV) to achieve a range of health-related outcomes.

Normal airway mucus lines the epithelial surfaces (the cells that line the internal and external surfaces of the body) of the respiratory system. These surfaces are continuously exposed to the outside environment by breathing, eating, and speaking. Changes to airway mucus in reaction to external stimuli are a measurable biomarker during the physical activity of Forced Cough Vocalization (FCV) – that is, an intentional cough. This is the biomarker that Raisonance technology captures, digitizes, and analyzes.

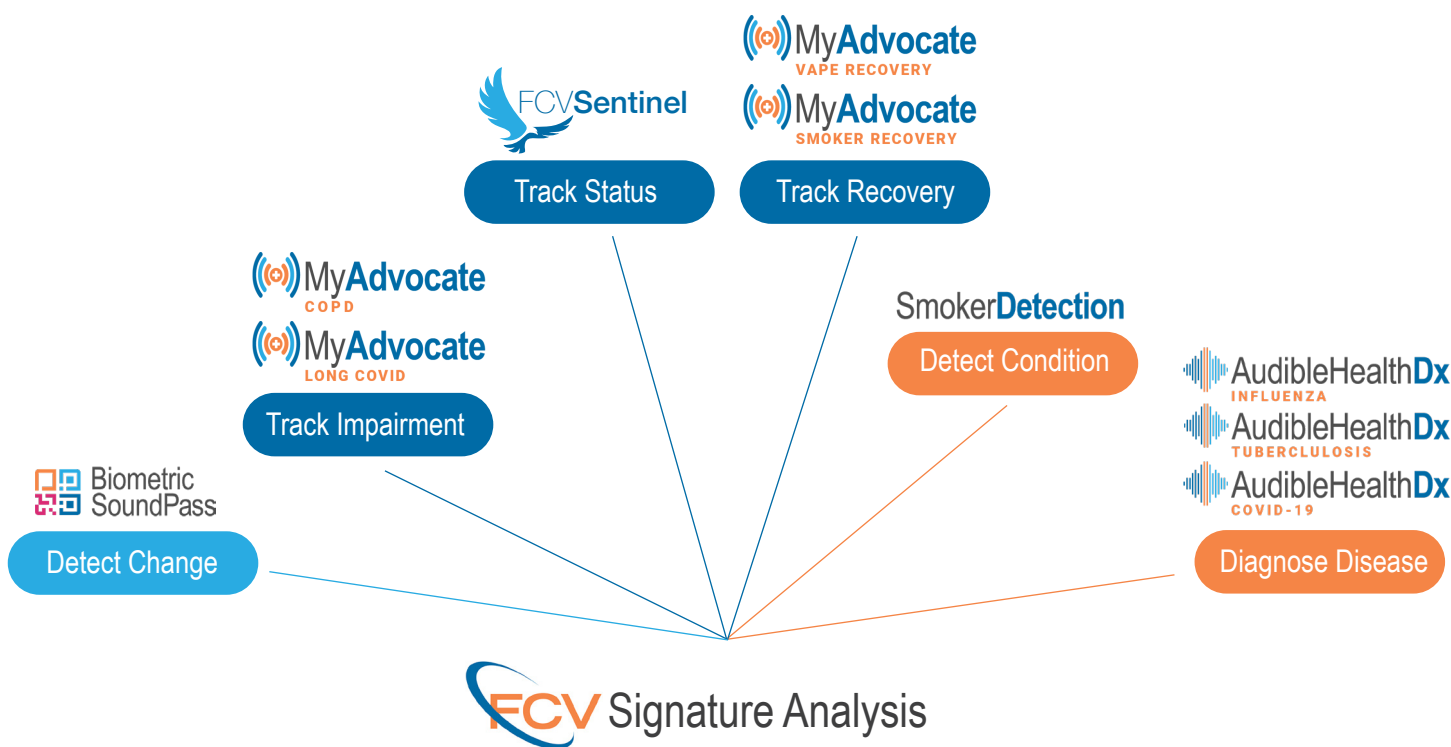
The primary defense used by airway epithelium is the secretion and clearance of mucus. Over time, humans evolved adaptations that created physiologic or biochemical methods to protect against airborne environmental hazards. Irritation of the respiratory tract causes changes in blood flow, mucus secretion, and the caliber – or diameter – of the airway. Toxins can interact with secretions directly and can lower viscosity, while sensory receptors in the body react to lung irritation or pulmonary inflammation. This inflammation changes both the quantitative and qualitative features of the sensory nerves.

Each of these responses to irritants changes the frequency and energy pattern of the FCV. Repeated or prolonged exposures to irritating gases, vapors, pathogens, and fumes can lead to the development of irritant-induced changes in the FCV. Laboratory studies confirm that airway inflammation creates cellular and tissue damage and can also lead to FCV changes.

### Our FCV Analysis

Raisonance specializes in the artificial intelligence-powered analysis of Forced Cough Vocalizations (FCV) to achieve a range of health-related outcomes, as presented in Figure 1 below. One product line, called AudibleHealth Dx, is a Diagnostic Software as a Medical Device (SaMD) designed to diagnose dozens of respiratory conditions including COVID-19, Tuberculosis, RSV, and Influenza. The other is a biometric wellness tracking line of products, called SoundPass and MyAdvocate, that capture a user’s “normal” baseline and provide ongoing analysis and feedback about changes detected to a user’s FCV signature.

Figure 1  
Range of FCV Analysis Capabilities



To conduct the analysis, each of the acceptable coughs are first converted into three different image types, each designed to communicate dozens of complex features to the artificial intelligence engine beings used.

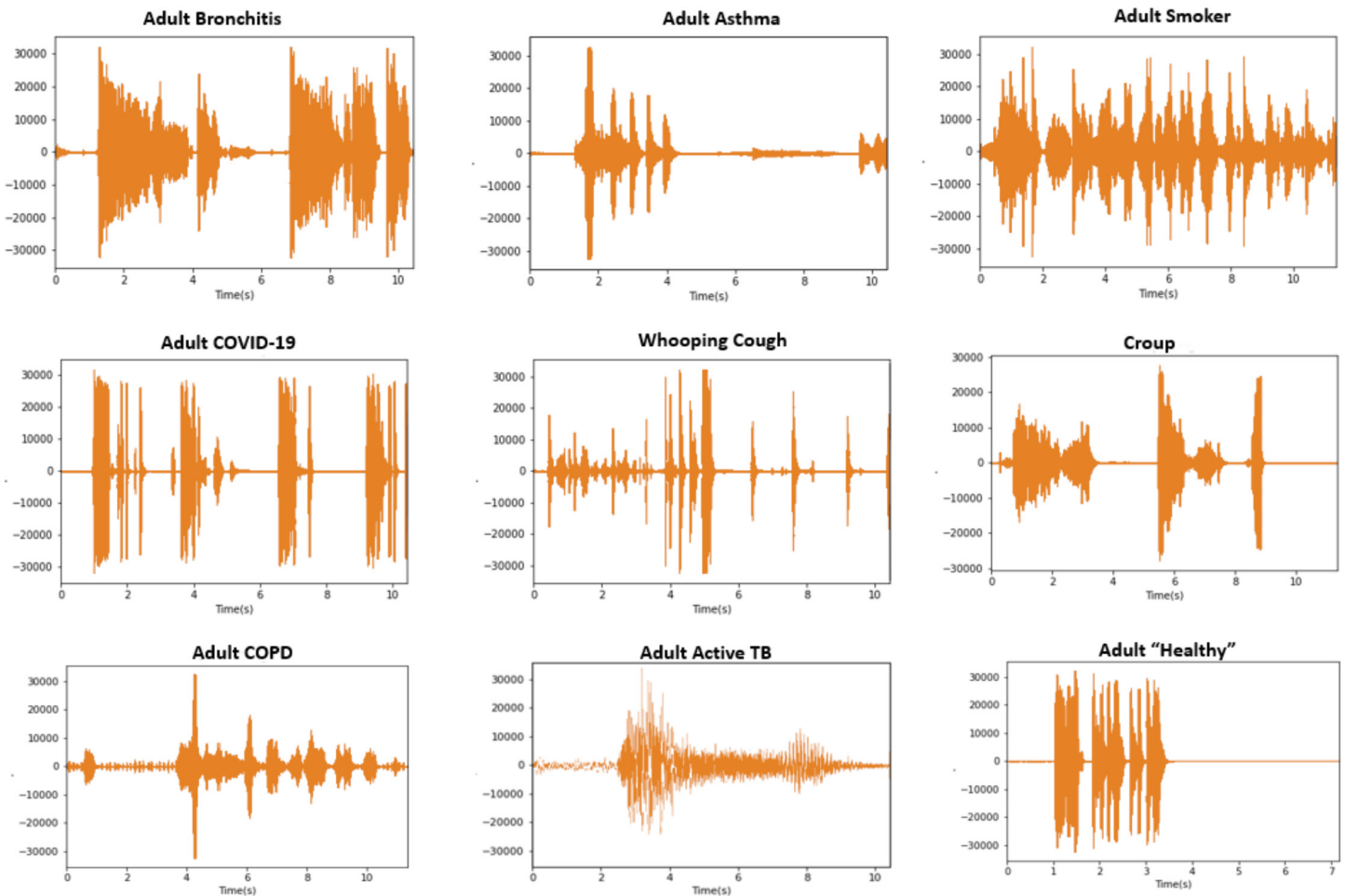
To conduct an FCV analysis, Raisonance technology conducts a multi-step, sophisticated sound processing operation to prepare the inbound cough recording. This proprietary process detects overall sound quality, screens for problematic background noise, and rejects coughs that are inadequate in any number of ways.

More specifically, the incoming cough recording is split into distinct cough events, using a proprietary, dual-layer, hidden Markov model (HMM) cough splitter. This extensively trained and highly accurate tool removes the silence or sound between coughs, and “listens” to detect the three phases of the cough. Once it detects the beginning and end of each cough, that cough is split apart from other coughs, to produce a collection of individual coughs for analysis.

To conduct the analysis, each of the acceptable coughs are first converted into three different image types, each designed to communicate dozens of complex features to the artificial intelligence engine being used. Each cough type produces completely different images based on mucus conditions, inflammation, energy envelope, cough pattern, and the like. Illnesses like COVID-19 Tuberculosis and Smoker’s Cough produce a distinct cough “signature” – a set of features that represent the respiratory dysfunction created by a given pathogen.

The waveform images gallery in Figure 2 demonstrates the obvious differences between various types of coughs. Although this visualization format is informative for the human eye, artificial intelligence classifiers perform better using different visualization formats such as MFCCs, FFTs, and Mel spectrograms.

Figure 2  
Cough Types



Once collected and analyzed, this group of data points becomes the user's baseline FCV signature — an exceptionally detailed compilation imprint of their respiratory system that is as unique to them as a fingerprint or retina scan.

## FCV Analysis for Biometric Monitoring

Biometrics is defined as the measurement and analysis of unique physical or behavioral characteristics (such as fingerprint or voice patterns), especially as a means of verifying personal identity. Biometric identifiers are distinctive, physiological characteristics that relate to a human individual.

Examples include palm prints, facial recognition, fingerprints, DNA, retina mapping, and iris recognition. New uses of biometric mapping include behavioral patterns of an individual, such as their typing rhythm, gait, keystroke pattern, written signature, and voiceprint, together sometimes referred to as "behaviormetrics".

To build a complete biometric FCV profile, users provide a series of FCVs over a prescribed period of time using the custom sound capture features found in Raisonance's line of mobile app-based products. Once collected and analyzed, this group of data points becomes the user's baseline FCV signature — an exceptionally detailed compilation imprint of their respiratory system that is as unique to them as a fingerprint or retina scan. Raisonance technology considers the upper body to be a complex and adaptable resonance chamber, and this imprint takes into account the current respiratory signature function from the diaphragm all the way up to the frontal sinuses.



Once a baseline is established, Raisonance's Biometric monitoring products provide several ways to evaluate a new FCV compared to this baseline:

- **SoundPass** is designed to detect minute changes that may be the result of a pathogen, chemical agent, or toxin, which have produced a notable change in the user's FCV. Like a "check engine light", SoundPass alerts the user that a change has been detected in about 2 minutes for status checks.
- The **MyAdvocate** product line tracks both FCV illness and recovery. For Long COVID sufferers, MyAdvocate tracks ongoing respiratory dysfunction. After creating their baseline, the user can cough again and receive an FCV Impairment Score to evaluate the degree of dysfunction from the current submission. For smokers, MyAdvocate starts with a user's profile once they've decided to quit, and thereafter tracks the smoker's journey from their prior respiratory status as a smoker, providing an FCV Improvement Score to document their improvement over time.
- **FCV Sentinel** is designed for both military and enterprise users. The mobile app tracks users' FCV scores over time to identify changes that could suggest decreased health. Scores are delivered in near real time to a sophisticated set of dashboards to track workforce readiness and the health of military forces.

This technology is possible because each respiratory-related illness creates a specific FCV signature in an individual, due to the unique ways in which each disease affects the human respiratory system.

## FCV Analysis for Diagnosis

Raisonance has also devised FCV analysis technology designed to detect a specific disease or condition from an individual's FCV using a mobile application interface, rendering a diagnosis in about 2 minutes. This investigational Software as a Medical Device (SaMD) is currently under review by FDA and by HealthCanada for Emergency Use Authorization for the diagnosis of COVID-19. Using specially trained artificial intelligence classifiers that have been tuned to recognize a specific disease signature in an FCV, this technology is a promising new frontier in non-invasive, highly scalable, lab-less diagnostics.

This technology is possible because each respiratory-related illness creates a specific FCV signature in an individual, due to the unique ways in which each disease affects the human respiratory system. Some diseases create additional mucus, cause changes in mucus viscosity, or cause dangerous inflammation throughout the respiratory system.



COVID-19 attacks the epithelial cells that line the airways, preventing them from performing their essential task of clearing the airways, and instead allowing them to be flooded with debris and fluids. COPD causes structural degeneration of the walls of the airways and the walls between the air sacs. This causes airways to collapse or narrow, allowing them to become inflamed and thick with mucus. This results in clogging and decreased airflow. RSV can cause conditions such as bronchiolitis, which is an inflammation of the small airways in the lung. RSV can also cause pneumonia, an infection of the lungs that may fill the air sacs with fluid, causing a cough with phlegm, fever, chills, and difficulty breathing.

This diagnostic FCV analysis does not require a "normal" baseline as does the Raisonance Biometric line of products. Instead, the AI/ML models used have been trained extensively to detect the unique signature of one respiratory disease. In addition to COVID-19, Raisonance is also training new models to add Tuberculosis, Influenza, and RSV indications to this digital diagnostic testing platform.

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