

WHITEPAPER:

The Next Frontier in Wearable Health: Unlocking the Power of Cough Monitoring

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Overview

Recent advances in wearable technology have made once-exotic metrics (like heart rate variability or oxygen saturation) widely available. Yet one vital indicator - cough - remains mostly untracked. Cough is a key marker for respiratory infections, immune stress, and chronic conditions such as asthma, COPD, and heart failure. It is also the *leading reason people seek medical help*. Historically, measuring cough continuously was very difficult, even in clinical settings.

Al-driven solutions now address this gap. Passive cough detection on wearables and smart devices is both accurate and scalable. These platforms can now easily integrate cough data with other health signals (e.g., sleep quality, heart rate variability, and environmental factors) to offer deeper, more valuable health and wellness insights. Early findings show that subtle changes in cough frequency can foreshadow infections, detect stress-related immune suppression, and flag worsening symptoms in chronic disease.

Adding cough metrics helps wearable and smart devices providers stand out in a saturated market. Many users would benefit:

- Athletes could anticipate immune strain before it affects performance
- Individuals with chronic disease might catch exacerbations early and seek timely treatment
- Older adults could receive alerts at the first sign of an infection

In research settings, continuous cough monitoring provides objective data that do not rely on self-reporting. This creates new clinical endpoints for studies on respiratory conditions, cardiac health, and infectious diseases.

Several challenges have emerged, but solutions are in place. The best cough detection models run efficiently on-device, minimizing battery drain. Privacy concerns are addressed by processing data locally,



storing no audio, and transmitting only cough timestamps. Clinical trials in multiple regions confirm that specificity and sensitivity for lead technologies can exceed 90%, showing real-world feasibility.

Looking ahead, standardizing cough-monitoring protocols will encourage broader adoption and fuel research into immune health, respiratory disease, and personalized preventive care. As integration becomes simpler and clinical evidence builds, cough tracking is poised to become a core feature of next-generation health platforms. For scientists, clinicians, and technology developers, it represents a powerful new dimension in wearable health and a major opportunity for innovation.



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Executive Summary

Wearable health technology has transformed how individuals monitor their health and well-being. Features that only a few years ago were considered highly specialized (like heart rate variability - HRV, oxygen saturation - SpO2, and even ECG) becoming standard¹.

Yet, one critical health metric remains untapped: cough.

Cough is a fundamental biomarker with relevance for respiratory health, immune function and overall well-being. It serves as an early indicator of infections, chronic conditions, and even stress-induced immune suppression. Despite its clinical significance, cough has historically been difficult to measure even in advanced clinical settings².

However, advancements in Al-driven, real-time cough monitoring are changing this space fastly. Validated, passive, and scalable cough tracking technology now exists, which enables continuous monitoring on wearables and other smart devices, unlocking new insights for wellness, chronic disease management, athletic performance, and clinical research.

For pharma and clinical trials, cough monitoring provides an objective, real-time endpoint, improving disease tracking, drug efficacy assessment, and patient monitoring. For wearable and other smart device companies, integrating cough into existing biometrics enhances user engagement, increases product differentiation, and expands market opportunities.

The future of digital health lies in multimodal biometrics - and cough is the next frontier. Wearables that incorporate cough tracking will gain a

¹ Leo et al, 2022, Coutu et all, 2023, Shah et all, 2023

² Birring et al, 2015



competitive advantage, offering deeper insights into health, unlocking new business models, and driving innovation in personalized medicine and preventive care. Companies that pioneer cough monitoring now, will lead the next wave of wearable health innovation.

Introduction

Context: Evolution of Wearable Health Technology

Wearable technology has evolved from niche gadgets to indispensable tools for health, fitness, and wellness monitoring. Companies like Apple, Garmin, Samsung, Fitbit (now owned by Google), and Oura have transformed the industry by integrating advanced medical functionalities into consumer devices. Features such as electrocardiograms (ECG), heart rate variability (HRV), resting Heart Rate, Respiratory Rate or oxygen saturation (SpO2) monitoring are now commonplace, empowering users with actionable insights into their health.

This evolution is not slowing down. Apple's recent launch of the "holistic Apple Health Study," in collaboration with Brigham and Women's Hospital³, exemplifies the industry's shift toward leveraging wearable data for long-term health research. By collecting data across devices like iPhones, Apple Watches, and AirPods, the study aims to uncover new insights into how physical activity, mental well-being, and other factors interrelate over time. This initiative underscores a broader trend: wearable technology is increasingly bridging the gap between consumer wellness and clinical healthcare.

The Underexplored Metric: Cough

However, one critical health metric remains underexplored in the wearable ecosystem: **cough**. Cough is a universal symptom, often

³ New holistic Apple Health Study launches today in the Research app, February 12, 2025



serving as an early warning sign for respiratory infections, chronic conditions, and even systemic diseases. Despite its clinical significance, cough has historically been difficult to measure objectively, even in clinical settings⁴.

Purpose of This Paper

This white paper explores the transformative potential of integrating cough monitoring and cough intelligence into wearable data streams, creating unique value for users and unlocking new opportunities across wellness, lifestyle, athletic performance and health in general.

Why Cough Matters

Physiological and Clinical Relevance of Cough

Cough is a fundamental defensive reflex that prevents aspiration and clears excessive secretions or foreign material from the airways. It is among the most common symptoms across a broad spectrum of conditions, from acute infections to chronic diseases such as asthma, chronic obstructive pulmonary disease (COPD), and congestive heart failure. It is the No. 1 reason why people seek medical care⁵ and serves as a primary symptom in conditions like asthma and allergies, a persistent secondary symptom in chronic diseases and cancer treatments (including chemotherapy and radiotherapy-induced lung damage), and a hallmark of non-idiopathic interstitial pulmonary fibrosis. It can also signal non-respiratory issues, such as gastroesophageal reflux disease (GERD) or medication side effects.

Cough is mediated by a complex neural network involving airway receptors, the vagus nerve, and the brainstem cough center. In many

⁴ Birring et al, 2015

⁵ CDC: National Hospital Ambulatory Medical Care Survey, November 22, 2024



chronic conditions, alterations in cough dynamics emerge early, providing predictive markers for disease exacerbations and guiding timely interventions⁶. There is also emerging evidence of a relationship between cough and heart dysfunction^{7 8}.

Objective measurement of cough frequency and characteristics offers critical clinical insights often overlooked by patient-reported outcomes or brief assessments. Robust evidence supports the role of continuous cough monitoring in improving disease management and patient outcomes⁹.

Historical Barriers to Cough Tracking & Al-Driven Breakthroughs

Despite cough being the most common reason for people to visit healthcare providers¹⁰ and its prevalence across many illnesses, cough has been largely overlooked across healthcare and our current understanding of cough remains limited, mostly because it has been historically very difficult to quantify.

<u>Hyfe's</u> AI-driven cough tracking technology addresses this gap by enabling continuous, unobtrusive, and highly accurate cough monitoring on wearable devices.

The technology is now proven at scale and used <u>extensively in dozens of</u> <u>clinical trials</u>. Its implementation is robust and highly efficient - Hyfe's cough monitoring currently runs continuously, on device, requiring minimal infrastructure - and proven both in Hyfe's highly scalable pharma grade <u>CoughMonitor Suite</u> as well as in third party integrations such as with <u>Actigraph's LEAP platform</u>.

⁶ Song et al, 2015

⁷ Grabczak et al. 2020

⁸ White Paper: The Pulse of a Cough: Exploring Correlations Between Cough Frequency and Heart Rate

⁹ Morice et al 2020

¹⁰ https://pmc.ncbi.nlm.nih.gov/articles/PMC6234945/ ,

https://healthnewshub.org/the-top-10-reasons-people-visit-their-primary-care-physician/



By integrating this capability into existing wearables and health tracking platforms, consumer companies can boost the value they provide to their users and increase precision - and usefulness - of existing data.

Recent advances in cough detection and monitoring have enabled long-term, passive data collection in real-world settings¹¹. These methods capture valuable patterns in cough over time. For example, one study found that cough trends can predict acute exacerbations of COPD up to 3.4 days before hospitalization¹². In heart failure, <u>increased</u> <u>cough can signal fluid overload</u>. In conditions like lung cancer, persistent and worsening cough might indicate progression or signal the early development of treatment-related complications such as pneumonitis¹³.

Example Applications Across Disease States

- COPD: Over 70% of COPD patients have chronic cough. Monitoring cough trends can predict exacerbations and reduce readmissions.
- 2. Heart Failure: "Cardiac cough" reflects pulmonary congestion. Studies show that 30% of patients experience a rise in cough one week before hospitalization. Monitoring cough might predict decompensation periods and reduce readmissions.
- 3. Asthma: Cough is a common symptom, can occur even when spirometry is normal. Monitoring cough has improved early detection of attacks and guided management¹⁴. Monitoring cough can predict exacerbations and guide personalized asthma management approaches.

¹¹ Morice et al. 2014

¹² Crooks et all, 2021.

¹³ Naidoo et all, 2017

¹⁴ Hughes et al 2022



- Lung Cancer: About 60% of patients present with cough.
 Objective data can assist in detecting adverse events such as radiotherapy-induced pneumonitis¹⁵.
- 5. Infectious disease (COVID-19, Tuberculosis, Flu): Cough is often the earliest or the most significant indicator. Passive surveillance has shown promise in predicting severe outcomes in COVID-19¹⁶, and monitoring adherence in TB therapy. Cough monitoring might detect new onset respiratory infections early.

Emerging Opportunities in Home and Wellness Monitoring

Advancements in wearables and smartphone-based technology have made continuous cough tracking feasible outside clinical settings. Al-powered platforms (such as those built by Hyfe) enable passive, longitudinal cough monitoring in real-world environments without requiring additional infrastructure or user action.

This unlocks a wide range of applications in wellness and preventive care, integrating cough as a meaningful health metric alongside other physiological and environmental data.

Correlating Cough with Other Health Metrics

- Allergy Management: Tracking cough frequency alongside diet logs and geolocation data helps identify potential triggers, such as specific foods or allergen-dense areas. These correlations support targeted avoidance strategies, reducing symptom severity¹⁷.
- Asthma Control: Continuous cough monitoring combined with environmental data (temperature, humidity, air quality) can

¹⁵ Harle et al 2018

¹⁶ Ali et al 2020

¹⁷ Bielory 2004



identify conditions that precipitate or mitigate bronchospasm. Real-time alerts empower patients to take timely action.

Holistic Personal Health Insights

- Sleep and Heart Rate Variability (HRV): Integrating cough frequency with HRV and sleep quality can provide early indicators of stress responses or new infection onset. New onset or increased nocturnal cough paired with HRV decline may signal worsening respiratory health in both acute and chronic cases.¹⁸
- Athletic Performance and Overtraining: Excessive physical exertion can transiently suppress immunity, increasing susceptibility to respiratory infections. Subtle increases in cough frequency may indicate early immune stress, allowing athletes to optimize training loads and prevent overtraining syndrome.

Elderly Care and Chronic Disease Prevention

- Infection and Exacerbation Detection: In older adults, early changes in cough frequency can signal emerging infections like pneumonia, bronchitis or flu. Connected health solutions can alert clinicians or caregivers before symptoms escalate, and preventative measures can be taken to prevent infectious spread.
- Chronic Condition Management: Many older individuals with comorbidities (hypertension, diabetes, COPD) experience subtle but significant cough variations that may indicate disease flares or infections. Continuous monitoring enables timely, targeted interventions¹⁹.

The following sections will explore these applications in greater detail.

¹⁸ Suarez-Roca et al. 2021

¹⁹ Song et al., 2017



Cough Monitoring as a Sentinel for Immune System Weakening

The human immune system is influenced by numerous physiological and environmental factors, many of which are difficult to quantify in real time²⁰. While traditionally assessed through infections and chronic diseases, it is increasingly evident that lifestyle variables - chronic stress, sleep deprivation, and overtraining - can suppress immune function, increasing susceptibility to illness²¹.

Detecting immune suppression early is crucial for mitigating health risks, optimizing performance, and preventing the spread of infectious diseases. However, conventional methods, such as blood biomarkers (e.g., cytokine levels, white blood cell counts), are invasive and impractical for continuous monitoring. Indirect markers like heart rate variability (HRV) and sleep patterns offer valuable insights but lack infection-specific real-time sensitivity.

Cough, a fundamental reflex of the respiratory system, frequently presents as an early symptom of new onset viral and bacterial infections. An increase in cough frequency often precedes symptomatic illness, suggesting that continuous cough monitoring could act as an early sentinel for immune weakening. Integrating cough data with widely available biometric streams – HRV, resting heart rate (RHR), and sleep metrics – may enhance the sensitivity of immune suppression detection.

By leveraging real-time, multimodal data, it becomes possible to identify periods of heightened vulnerability due to stress, sleep disruption, or physical overexertion.

We propose that:

²⁰ Mair, McNeilly et al. 2021

²¹ Marsland, Walshet al. 2017



- Cough frequency increases as an early indicator of immune suppression following stress, sleep deprivation, or overtraining.
- A rise in cough frequency precedes symptomatic infections, providing a non-invasive, real-time biomarker of immune dysfunction.
- Cough frequency correlates with established physiological and behavioral markers of immune health, including HRV, RHR, sleep quality, and training load.

By combining cough monitoring with multimodal biometric data, an early warning system for immune suppression could be developed, enabling proactive interventions before clinical symptoms emerge.

Early Signs of Immune Suppression

Subtle physiological shifts often signal immune weakening before overt illness. These include increased susceptibility to infections, prolonged recovery times, and inflammatory markers (e.g., C-reactive protein [CRP]) alongside autonomic nervous system dysregulation. We propose that cough frequency, when analyzed alongside HRV, RHR, and inflammatory biomarkers, could serve as a key early indicator of immune dysfunction.

Stress and Immune Suppression

Chronic stress disrupts immune function by elevating cortisol levels, which suppress T-cell proliferation, impair natural killer (NK) cell activity, and dysregulate cytokine production, thereby increasing infection susceptibility. Individuals under chronic stress exhibit:

- Lower HRV
- Elevated inflammatory markers (CRP, IL-6)
- Disrupted sleep cycles



These factors contribute to weakened immune responses and heightened risk of viral infections.

Sleep Deprivation and Immune Dysfunction

Sleep is essential for immune regulation, particularly through cytokine production (e.g., IL-1, TNF- α). Sleep deprivation disrupts this process, leading to:

- Increased inflammatory markers (CRP, IL-6, TNF-α)
- Impaired T-cell function and antibody response
- Reduced HRV and heightened sympathetic nervous system activity
- Greater susceptibility to upper respiratory infections

A 2022 study found that individuals with sleep deprivation exhibited lower HRV, increased inflammatory markers, and heightened viral susceptibility, reinforcing the role of sleep quality in immune defense²².

Overtraining and Immune Suppression

Overtraining syndrome (OTS) results from excessive exercise without adequate recovery, leading to systemic physiological stress and immune suppression. Symptoms include:

- Chronic fatigue and muscle soreness
- Increased infection susceptibility
- Elevated cortisol and inflammatory cytokines
- Depressed HRV and autonomic imbalance

Athletes engaging in high-intensity training without sufficient recovery demonstrate temporary reductions in white blood cell counts, increased upper respiratory infections, and cytokine imbalances (IL-6/IL-10).

²² Liu, Yu et al. 2022



Continuous biometric monitoring, including cough frequency, may provide an early signal of overtraining-induced immune suppression.

Cough as an Early Biomarker of Immune Stress

Cough is triggered by airway inflammation and irritation, mediated by sensory nerves (vagal afferents) and inflammatory cytokines (IL-1ß, IL-6, TNF-a). Research suggests that increased cough frequency often precedes symptomatic viral and bacterial infections:

- A study in *CHEST* found that **cough frequency rose up to 48 hours before fever or respiratory symptoms** in individuals exposed to viral pathogens.
- Al-driven cough monitoring systems, such as those developed by Hyfe, have demonstrated strong correlations between cough frequency and infection severity, enabling passive, real-time detection of early immune stress.

Implications and Future Directions

If validated, integrating cough monitoring with multimodal biometric data could revolutionize immune health assessment, providing an early warning system for athletes, healthcare workers, high-performance professionals, and the general population. By detecting immune suppression before clinical symptoms appear, individuals could take proactive measures - adjusting training loads, improving sleep hygiene, or managing stress - to prevent illness and maintain optimal health.



The Missing Data Stream: Why Cough Monitoring Belongs in Wearable Health Platforms

Expanding the Capabilities of Wearables

Advances in consumer-grade wearable technology have transformed personal health monitoring. Devices now track heart rate variability (HRV), resting heart rate (RHR), sleep patterns, physical activity, and respiratory rate - enabling users to detect stress, poor sleep, and physiological imbalances in real time. Integrating **cough frequency** into this ecosystem introduces a powerful, novel biomarker for **immune** health, respiratory conditions, and environmental sensitivity.

Al-powered cough monitoring, such as Hyfe's continuous tracking technology, enables:

- Early detection of subtle increases in cough frequency a potential indicator of immune suppression or early respiratory illness.
- Correlations between cough data, HRV, sleep, and training metrics to improve predictive health models.
- Actionable insights for users to optimize performance, manage stress, and prevent illness.

By embedding cough monitoring into wearables, companies can enhance user engagement, improve health insights, and differentiate their platforms with real-time, passive respiratory tracking.

Use Cases: How Cough Monitoring Enhances Wearable Technology



1. Athletes and Fitness Enthusiasts

Wearable platforms from Garmin, Apple, Samsung, Wahoo, and Polar are essential tools for athletes, yet they lack a reliable indicator of immune suppression and overtraining. Cough frequency serves as an early, objective proxy for these conditions:

- Overtraining and Immune Function: Overtraining weakens the immune system, increasing susceptibility to viral infections. Subtle rises in cough frequency - particularly alongside HRV suppression
 may signal immune strain before symptoms emerge.
- Exercise-Induced Bronchoconstriction (EIB): Coughing is a common sign of airway irritation from cold air, dry air, or prolonged exertion. Wearables could detect early signs of EIB and prompt preemptive strategies, such as appropriate warm-ups, hydration, or inhaler use.
- Environmental Irritants and Performance Optimization: Cough frequency correlated with air quality data can help runners, cyclists, and outdoor athletes optimize training routes, reducing exposure to pollutants, allergens, and wildfire smoke.

2. Wellness and Lifestyle Users

The largest segment of wearable users focuses on **general wellness**, **sleep optimization**, **and proactive health tracking**. Cough monitoring expands the value of existing health metrics:

- Early Detection of Respiratory Issues: Unusual cough patterns may indicate early respiratory infections, allergies, or conditions like GERD or asthma before symptoms escalate.
- Personalized Health Insights: Correlating cough frequency with environmental factors (pollen, pollution, humidity) can help users identify triggers and optimize their daily routines.
- Tracking Recovery and Treatment Effectiveness: Wearables can objectively measure whether interventions such as lifestyle



changes, medications, or inhalers - are reducing cough frequency over time.

3. Chronic Disease Patients

For individuals managing asthma, COPD, GERD, or heart failure, cough frequency is a critical, yet often overlooked, biomarker. Continuous cough monitoring offers:

- Early detection of COPD exacerbations research shows cough frequency alone can predict COPD flare-ups days before they occur²³.
- Actionable insights for asthma and allergy sufferers, correlating symptoms with environmental triggers.
- A potential lung cancer early warning system, detecting cough patterns that warrant further screening.
- Personalized treatment adjustments allowing real-time medication optimization based on cough frequency trends.

4. Aging Populations and Caregivers

Cough monitoring is particularly valuable for **older adults** who may not recognize or report changes in their symptoms. Wearable integration provides **non-intrusive**, **passive tracking** to:

- Detecting early signs of infections, pneumonia, or medication side effects before hospitalization is necessary.
- Support congestive heart failure (CHF) management, where worsening cough is a key indicator of fluid buildup.
- Enable **remote monitoring for caregivers**, with alerts for sudden cough frequency increases.

5. Chronic Coughers

²³ Crooks et al. 2021



Chronic cough affects **10% of adults globally**²⁴, yet many sufferers remain undiagnosed or mismanaged. Wearable-based cough tracking provides **objective**, **real-world data** for:

- Identifying cough patterns overlooked in clinical evaluations.
- Supporting behavioral cough suppression therapy (BCST), delivering interventions in real time.
- Informing combination therapy strategies by assessing medication impact alongside behavioral modifications.

6. Mental Health and Stress Management

Emerging research suggests cough frequency may serve as a biomarker for stress and autonomic nervous system dysregulation. Wearables could integrate cough data into mental health monitoring by:

- Correlating cough with HRV trends, helping users identify stress-related cough patterns.
- Detecting psychosomatic cough, where coughing increases on high-stress days but subsides during sleep.
- Enhancing mindfulness and breathing exercises, using cough frequency as a biofeedback marker for stress resilience.

Expanding Research and Clinical Applications

Wearables are rapidly expanding into clinical research and digital health, with first movers like Actigraph already integrating objective cough monitoring into pharmaceutical trials and real-world evidence (RWE) generation²⁵. The addition of cough monitoring strengthens:

• Clinical trial endpoints: Cough is a critical biomarker in respiratory and infectious disease research, yet traditional cough

²⁴ Song, Chang et al. 2015

²⁵ ActiGraph and Hyfe Announce Availability of New Digital Health Tool for Cough Monitoring, Jan 28 2025

⁻ https://blog.theactigraph.com/news/actigraph-hyfe-digital-health-tool-cough-monitoring



assessments rely on subjective patient-reported outcomes (PROs). Al-driven cough monitoring provides objective, continuous data for trials targeting chronic cough, COPD, asthma, IPF and other ILDs, lung cancer.

- Telehealth and virtual care: Real-time cough data enables remote monitoring, early intervention, and precision medicine strategies - reducing hospitalizations and improving disease management.
- Real-world evidence generation: Large-scale cough data streams can uncover treatment efficacy trends, patient subgroups, and early disease signals, accelerating drug development, regulatory approvals and post-market activities.

A New Era for Cough Monitoring in Digital Health

For decades, cough was an **underestimated and poorly quantified** symptom. Today, **AI-powered cough monitoring is transforming both consumer health and clinical research**. Cough is no longer just a symptom - it is an actionable, objective, and clinically meaningful biomarker.

By integrating cough tracking into wearable ecosystems, a new dimension of respiratory and immune health monitoring can be unlocked. Whether for athletes, chronic disease patients, or the general population, cough frequency adds unparalleled precision to wellness tracking, stress management, and early disease detection.

With advances in AI, real-world data collection, and clinical validation, continuous cough monitoring is positioned to become a core feature of next-generation health platforms.



Scientific Validation and Technological Readiness

Hyfe's cough monitoring technology has undergone rigorous validation in nearly 50 clinical and research studies. These investigations span diverse clinical indications and consistently demonstrate high sensitivity, exceeding 90%, with an average rate of one false positive per hour in real-world conditions²⁶.

Integration into existing digital health platforms is achieved via a robust software development kit (SDK). This approach simplifies adoption and supports diverse deployment scenarios. In addition, the technology shows strong correlations with other physiological signals, such as heart rate, in multiple disease states and clinical contexts²⁷.

Real-world use further underscores Hyfe's efficacy. It has been deployed in more than 50 studies and is utilized daily by hundreds of thousands of individuals. The scientific community has recognized these findings, with <u>20 peer reviewed publications</u> featuring results derived from Hyfe's platform.

The business case for consumer wearable companies - Integrating cough monitoring into consumer wellness wearables and smart devices presents a unique strategic opportunity. As respiratory health gains prominence in both medical and consumer markets, this innovation offers a competitive edge while unlocking new revenue streams and expanding market reach.

The Golden Era of Cough: A Growing Market Opportunity

²⁶ Chaccour, Sánchez-Olivieri et al. 2025

²⁷ The Pulse of a Cough: Exploring Correlations Between Cough Frequency and Heart Rate



Cough is emerging as a key biomarker in digital health, driven by advances in acoustic AI, growing clinical interest, and the development of new drugs and therapies targeting chronic cough and respiratory conditions. The market for cough-related healthcare solutions is expanding, fueled by increasing rates of respiratory diseases, air pollution concerns, and post-viral syndromes such as long COVID. Wearables with cough monitoring capabilities can position themselves at the forefront of this evolving landscape.

Unaddressed Market with High Incidence

The incidence of coughing is substantial – chronic coughing alone affects at least 10% of the adult population, with substantially higher rates among specific demographics, including older adults and individuals exposed to environmental irritants such as air pollution or occupational hazards. If adding other conditions such as asthma or allergies, the percentage of any given market segment with an active interest in cough would be at least 27%²⁸.

Yet, no major consumer wearable currently offers continuous cough monitoring, **presenting a unique opportunity for early adopters of this technology**.

First-Mover Advantage and Market Differentiation

Integrating continuous cough monitoring into a smartwatch platform would establish an entirely new category of health insights. The first company to introduce and refine this capability would hold a significant competitive edge—differentiating its devices in a mature market where most wearables offer near-identical health tracking features.

²⁸ Morice, Millqvist, et al. 2014, Kelsall, Decalmeret al. 2009



Expanding the Consumer Base

By addressing this unmet need, cough monitoring could serve as a gateway feature that brings new users into the ecosystem. Individuals who have never purchased a smartwatch may be drawn to a first mover company (and away from category leaders like Apple or Google) as the only brand providing this functionality, particularly if they have respiratory concerns or live in environments where air quality is a daily consideration. Furthermore, existing users would benefit from enhanced device value, strengthening retention and brand loyalty.

A Platform for Continuous Innovation

Beyond its initial adoption, cough monitoring presents a foundation for iterative advancements in respiratory health tracking, including Al-driven insights, integration with telehealth services, and predictive analytics for disease onset. Establishing leadership in this domain positions the company at the forefront of next-generation health technology while competitors remain locked into more traditional biometrics.

Market Expansion into Clinical Trials and Real-World Evidence Research

Beyond the consumer and wellness markets, integrating cough monitoring into wearables presents a significant opportunity in clinical trials and real-world evidence (RWE) research. Modern clinical trials increasingly incorporate consumer-grade devices – either as primary endpoints or as exploratory tools – to collect longitudinal health data in real-world settings. A wearable that includes validated, continuous cough tracking would offer a unique advantage in this growing sector, where remote, passive, and objective health monitoring is becoming essential.



Cough is a critical symptom in respiratory, infectious disease, and drug safety research, yet it remains largely unmeasured outside clinical settings. Traditional cough monitoring relies on subjective self-reports or impractical, time-limited audio recordings, making it nearly impossible to capture long-term, real-world data. A reliable consumer-grade wearable capable of tracking cough frequency over the duration of a study would bridge this gap, providing pharmaceutical companies and research organizations with a scalable, patient-friendly solution.

For a company integrating cough tracking into its wearable ecosystem, this would offer a direct pathway into the lucrative life sciences market. Sponsors of clinical trials and RWE studies would recognize the device as a valuable tool for decentralized and hybrid study designs, improving participant monitoring and data quality. By pioneering this capability, a wearable company could establish itself as the go-to platform for respiratory-related clinical research, further differentiating from competitors while opening new revenue streams beyond traditional consumer sales.

User Demand for Integrated Cough Metrics

Health-focused consumers are increasingly calling for more convenient, unobtrusive ways to monitor their wellness. From Hyfe's experience with <u>CoughPro</u> (leading cough monitoring app, part of the Hyfe family of cough monitoring solutions), a recurring theme among users has been the desire to integrate cough tracking directly into wearable devices. For many, a smartwatch-based solution offers several important advantages, including 24/7 wearability, easy access to real-time tracking data, and the possibility of collecting a more complete cough record.

In fact, CoughPro's feedback channels have been inundated with requests for integration - so much so that some individuals have



indicated they would be more inclined to purchase or upgrade to a smartwatch if it could provide continuous cough tracking. Such comments underline the perceived value of including wearables in a cough-monitoring ecosystem.

Several themes emerge from user feedback:

- <u>Constant Wear and Convenience</u>: The always-on nature of a smartwatch is highly appealing. Users who currently rely on a phone for cough monitoring report missing data when the phone is not nearby or when the app is inadvertently closed. As one user explained, "I've been using the cough tracker for about six weeks now and have discovered that I don't always have my phone with me. Is there an app for the Apple Watch that records also?"
- Potential for Expanded Market and Adoption: Some users who do not currently own a smartwatch express they would be more likely to purchase one if cough tracking were available. This suggests that, beyond meeting the needs of current smartwatch wearers, an integrated solution could expand the overall market for wearables. One potential adopter noted, "I don't have a smartwatch, but if I get one, I'd love to know if there's a way to integrate a smartwatch with the app to track coughs separate from my phone."
- <u>Uninterrupted Data Collection</u>: For individuals managing chronic respiratory conditions, a missed cough or a gap in continuous data can be significant. Wearable integration promises more consistent monitoring, which may lead to more accurate insights and better healthcare outcomes. As one user put it, "It doesn't appear I can add the app to my Apple Watch? That would be ideal, since my watch is always with me and always on."
- <u>Ease of Use and Real-Time Insights</u>: Several users referenced the value of a "light" version of the app on a watch, enabling them to switch cough tracking on and off and view recent data without needing to open a phone app. This streamlined functionality



could make cough monitoring more accessible and more widely used.

Taken together, these user voices make it clear that integrating cough-tracking capabilities into smartwatches is not just a "nice to have" - it's a feature that consumers actively seek out and will use in their daily lives. By meeting this strong demand, device manufacturers stand to benefit from increased user engagement, broader market appeal, and the potential for richer health data sets that can fuel better individual and population-level health outcomes.

Challenges & Solutions

1. Challenge: Battery Drain and Device Performance

Wearables run on limited battery power. Adding any additional sensor - in particular one using the microphone - may raise concerns about power and memory use. However, Hyfe's Al detection models are highly optimized for low resource consumption. Its on-device inference uses minimal CPU cycles. Hyfe's internal tests show negligible impact on battery life.

2. Challenge: Privacy and Data Security

A live Microphone Recording or transmitting audio can rightfully be perceived as invasive. Users need reassurance that their data remains confidential. Hyfe processes cough detection locally on the device. There is no sound recording and it does not store any audio. Only anonymized timestamps (text files defining the exact time, to the millisecond, when a cough occurred) are transmitted, ensuring privacy and compliance with data regulations.



3. Challenge: Accuracy and False Positives

Users worry about false alerts or missed coughs. A misclassification could erode trust and limit user adoption. Hyfe's algorithms achieve high sensitivity and specificity, validated in multiple clinical trials. Real-world data show over 90% accuracy with very few false positives per hour. This is comparable with a human ear.

4. Challenge: Integration Complexity

Wearable ecosystems vary widely, and each has unique hardware and software constraints. Integrating new features risks time and resource overhead. Hyfe's SDK offers a modular, plug-and-play architecture. Developers can integrate cough monitoring with minimal coding effort, reducing deployment timelines.

5. Challenge: Clinical Validation and Regulatory Hurdles

Medical and wellness features often face scrutiny. Users need evidence of clinical benefit to navigate regulations.Hyfe is already validated in dozens of trials across chronic and acute conditions. This robust research base can support regulatory submissions and expedite market entry.

Next Steps

The integration of Al-driven cough monitoring into wearable platforms and other smart devices is offering unprecedented opportunities for personalized health insights, early disease detection and clinical



research advancements. To fully realize the potential of this technology, several critical next steps should be prioritized:

1. Validation and Standardization

- Conduct multicenter, longitudinal studies to validate the clinical utility of continuous cough monitoring across diverse populations and disease states.
- Develop standardized protocols for cough frequency analysis, ensuring consistency across different devices and healthcare applications.
- Establish regulatory pathways for cough monitoring as a validated biomarker in clinical trials and real-world evidence (RWE) studies.

2. Multimodal Data Integration

- Investigate the correlation between cough frequency and other physiological metrics, such as heart rate variability (HRV), respiratory rate, sleep patterns, and physical activity levels.
- Develop Al-driven predictive models that integrate cough trends with biometric data to enhance early detection of respiratory infections, immune suppression, and chronic disease exacerbations.
- Expand research on the intersection of cough monitoring and environmental variables, such as air quality, humidity, and allergen exposure, to refine personalized health recommendations.



3. Expanding Clinical Applications

- Continue to investigate the role of cough monitoring in early detection of respiratory illnesses, including COPD exacerbations, cardiac cough, and pulmonary complications in oncology patients.
- Develop real-world use cases in telemedicine, enabling remote monitoring of patients with chronic conditions through passive, continuous cough tracking.
- Continue to explore applications in behavioral cough suppression therapy (BCST) for chronic cough sufferers, leveraging real-time feedback mechanisms to improve patient adherence.

4. Commercialization and Market Adoption

- Engage with digital health and consumer wearable companies to drive adoption, highlighting the added value of cough monitoring in enhancing user engagement and differentiating products in the competitive health-tech market.
- Educate healthcare providers and policymakers on the benefits of continuous cough monitoring, advocating for its inclusion in remote patient monitoring and public health surveillance frameworks.

5. Future Research Directions

 Expand research into the relationship between cough patterns and immune system function, assessing its viability as an early biomarker for stress-induced immune suppression.



 Explore novel applications in sports science, assessing how cough frequency fluctuations correlate with overtraining syndrome and respiratory resilience in elite athletes.

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