

## **Counting Coughs: ERS 2025 Highlights on Objective Cough Monitoring**

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Disclosure:	Galvosas and Small are employees at and stock option holders of Hyfe, Inc.
Keywords:	Cough, cough monitoring, digital health.
Citation:	EMJ Respir. 2025;13[1]:24-29. https://doi.org/10.33590/emjrespir/GIAS3063

THE EUROPEAN Respiratory Society (ERS) Congress 2025 showcased continuous cough monitoring across sensor modalities, a pragmatic 7-day monitoring standard, and early signals for efficacy and tolerability in real studies, positioning cough as a scalable biomarker and clinical endpoint for respiratory care.

#### WHY COUGH, WHY NOW

In precision health, clinically meaningful parameters are quantified to individualise therapies and track response. Cough, one of the most common reasons for seeking care and a key respiratory sign, has historically been hard to measure reliably: 24-hour 'snapshots' are noisy, day-to-day variability is high, and manual annotation is slow, inconsistent, and privacy-intrusive. The ERS Congress 2025 highlighted how continuous, largely automated, and privacy-preserving technologies now enable objective, at-scale cough measurement suitable for clinical research and care.

# AUTOMATED APPROACHES SIGNAL RAPID PROGRESS IN COUGH DETECTION AND QUANTIFICATION

The Automated Cough Counting Algorithm (ACCA) demonstrated strong agreement with ground truth, showing high sensitivity (97%) and a positive predictive value exceeding 75% across heterogeneous

clinical conditions (refractory chronic cough, COPD, idiopathic pulmonary fibrosis, interstitial lung disease, and asthma), along with a low median absolute error compared to human-annotated counts.¹ Presenters noted that such models may surpass human annotators in consistency by eliminating inter-rater variability and enabling faster data analysis.¹ Such validated automated algorithms for cough counting can greatly accelerate clinical development and further expand the use of cough monitoring in trials.

Another signal processing algorithm for identifying coughs in respiratory audio recordings was presented during the Congress. The RESP biosensor-based algorithm (Strados Labs, Philadelphia, Pennsylvania, USA), trained on audio recordings from multiple chronic cough conditions (cough variant asthma, atopic cough, eosinophilic bronchitis, and reflux-related cough), demonstrated high precision (94.9%) and sensitivity (95%), and strong correlation with human annotation, with a mean absolute error of 3.26 coughs/hour.<sup>2</sup>





A new cough monitoring wearable device (C-mo, Caparica, Portugal) validation reported the performance of an automated cough monitoring algorithm against expertannotated reference, adding another modality to the growing objective cough monitoring ecosystem. The wearable chest-patch device uses electromyography to trigger audio recording during cough events and was evaluated for feasibility in patients with acute cough wearing the device for up to 4 hours, showing 93.7% sensitivity for detecting cough events in real-world environments.3 The same poster featured another group of study subjects wearing the device for 24 hours, showing 95% sensitivity in cough detection performance.3

A smartwatch-based, automated, and fully privacy-preserving cough-counting monitor (Hyfe Inc., Delaware, USA) was also featured across multiple posters. As shown earlier this year by Chaccour et al., 4 the correlation between manually annotated (human) and cough-counting monitor-measured hourly cough counts was very high, with a Pearson correlation coefficient of 0.99. The monitor's on-device algorithm achieved an overall sensitivity of 90.4% with 1.03 false positives per hour as users went about their usual activities. 4

It was evident at ERS 2025 that presented cough monitoring approaches differ in sensor placement, acoustic and

accelerometric features used to enhance adherence, and in whether they rely on post-processed audio or fully privacy-preserving on-device processing with no audio recordings, with several technologies now showing strong agreement with human annotations and readiness for scaled use.

### FROM RAW COUNTS TO ENDPOINTS: ANALYTICS THAT DETECT CHANGE

This year's event also emphasised the importance of how cough counts (e.g., cough timestamps) are analysed after detection. Patients with cough often report that periods of intense coughing (termed bouts or epochs) are the most distressing aspect, as "everyone notices that you've got a cough," and derived measures such as cough bouts and cough-free time remain exploratory endpoints in many clinical trials.

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In a TRPM8-agonist (AX-8) study<sup>5</sup> using an audio recording system with humanannotated cough events (Vitalograph, Ennis, Ireland), investigators categorised cough bout metrics into count- and duration-based hierarchies to assess treatment-induced changes in cough patterns. Placebo reduced mean coughs per bout while maintaining bout frequency, whereas treatment reduced bout frequency while maintaining mean coughs per bout. Similarly, placebo shortened the mean bout duration without affecting frequency, while treatment reduced frequency without altering duration, suggesting that countbased metrics might provide detailed granularity, whereas duration-based metrics may yield complementary insights in specific clinical contexts.5

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Another group presented a head-to-head comparison between a log-transformed linear mixed model and a negative binomial generalised linear mixed-effects model (GLMM) for handling skewed and overdispersed cough frequency data, and

assessing their impact on treatment interpretation. Using 24-hour cough frequency data collected with an audio recording system, the analysis showed that log-transformation reduced skewness and produced more precise estimates than assuming a negative binomial distribution, without altering the overall interpretation of treatment effects.<sup>6</sup>

Multi-day cough monitoring featured prominently during the Congress. Evidence supporting a 7-day standard showed that most participants with problematic cough reached accurate frequency estimates within 7 days.7 This duration captures inter- and intraindividual cough variability, enhancing the accuracy of cough-related endpoints in research, as well as variation that may result from daily habits. 'Metronomic' phenotypes stabilised sooner; highly variable phenotypes needed closer to 8 days, supporting 7 days as a pragmatic default balancing statistical stability and operational feasibility.6 While future work may explore tailored monitoring durations for specific populations, a 7-day period is recommended as the default for most studies involving cough frequency assessment.7



Future research should establish standardised definitions for cough bouts and other timestamp-derived clinical outcome assessments, as current presentations use varying definitions, which remains a significant limitation.

#### OPERATIONAL READINESS: ADHERENCE, PRACTICALITY, AND PRIVACY

Continuous endpoints are only as good as the time truly monitored. A poster presented at ERS 2025 highlighted that the use of an on-device photoplethysmography-based wear detector enabled the aforementioned smartwatch-based cough-counting monitor (Hyfe Inc., Delaware, USA) to achieve 98.93% overall accuracy for wear versus non-wear classification (sensitivity: 98.94%; specificity: 98.92%; negative predictive value: 99.45%; positive predictive value: 97.94%) across 28,185 5-minute observations.8 The study also found that accurate wear detection allows objective, device-verified adherence (including onwrist via photoplethysmography sensor and bedside charging), supports per-protocol and missing-data strategies, and reduces reliance on self-report.8

Given recent advancements in continuously evaluating adherence to cough monitoring, future studies could explore how adherence metrics correlate with participants' adherence to prescribed interventions. Additionally, researchers could examine whether adherence insights gathered during screening could be leveraged to train participants for improved compliance in subsequent study phases.

Several platforms presented privacypreserving designs (e.g., on-device processing and no storage of raw conversational audio). This directly addresses concerns from patients and Institutional Review Boards about audio data handling.

Future studies should compare adherence across various device form factors, such as smartwatches, pendants, and adhesive sensors placed on the abdomen or chest, and assess how adherence is influenced by user age and study duration.

### APPLICATIONS OF CONTINUOUS COUGH MONITORING: SIGNALS OF EFFICACY AND TOLERABILITY

Objective monitoring is already finding treatment signals and flagging tolerability issues. An open-label exploratory trial with azithromycin was presented at the event. In this trial, 30 patients with chronic respiratory disease who underwent continuous smartwatch monitoring (Hyfe



Inc., Delaware, USA), showed a significant reduction in median coughs/hour by Week 4 (p<0.01), alongside improvements in patient-reported outcomes and 'relief-of-cough' time.<sup>9</sup> Notably, the trajectory of change was visible from Week 1, supporting continuous cough endpoints for early signal detection.<sup>9</sup>

Continuous cough monitoring to assess tolerance to inhaled antibiotics in chronic bronchial infection was also presented by a group from Spain. Among eight participants monitored with a coughmonitor smartwatch (Hyfe Inc., Delaware, USA), individual cough trajectories across 'before-during-after' periods showed progressive increases in cough in those who did not tolerate treatment, followed by reductions after discontinuation, illustrating how continuous cough monitoring can serve as an objective tolerability marker complementing patient-reported symptoms.<sup>10</sup> In the future, continuous cough monitoring insights could help personalise treatment approaches by identifying those that are best tolerated and most effective for individual patients.

Lastly, a poster on patient-reported outcomes versus objective cough frequency was presented. This longitudinal analysis examined day-to-day variability in VAS/NRS and objective cough frequency captured via a cough monitoring pendant (SIVA Health, Zurich, Switzerland). Correlations were modest (0.42 for VAS and objective cough frequency; and 0.41 for NRS and objective cough frequency), and observations were patient-specific, underlining that PROs and objective counts are complementary.

To date, most work has focused on chronic cough, but there is growing interest in extending objective cough monitoring to additional respiratory and systemic conditions.

#### **CONCLUSIONS**

ERS 2025 data show that objective cough monitoring has crossed a practical threshold: algorithms now demonstrate high agreement with human annotation, devices are accessible and privacy-aware, adherence can be verified at scale, and week-scale windows yield stable, responsive endpoints. These capabilities are already implemented across observational studies and interventional drug trials in chronic cough and related conditions, and broader adoption of objective cough endpoints across therapeutic areas now appears both scientifically justified and operationally foreseeable.

In the future, clinical studies to compare and contrast the advantages and limitations of various devices, such as watches, pendants, and adhesives, in terms of accuracy and acceptability are needed. In addition, we can expect that continuous monitors may not only count coughs but also classify them; for example, distinguishing between dry and wet coughs. 'Coughomics' could further enable the endotyping of patients with chronic cough: some may display a neurogenic profile (high cough frequency, normal lung function, heightened cough reflex sensitivity), while others show an inflammatory profile (moderate cough frequency, abundant sputum, and airway inflammation). Once considered a background symptom, cough is now emerging as a valuable data stream, and continuous monitoring is what makes this transformation possible.

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