SCIENCE BRIEF

# AI–enabled forced spirometry quality control

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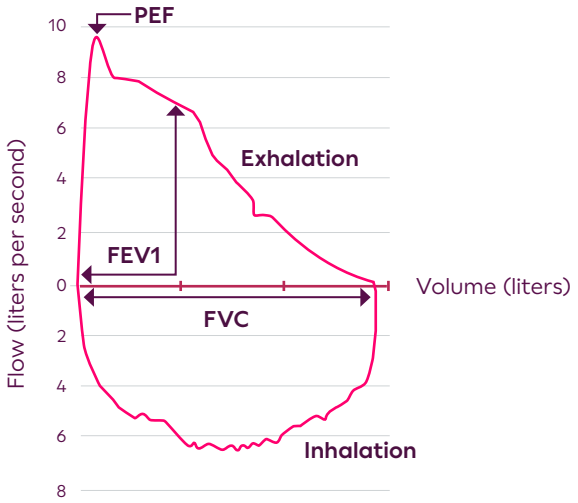
# Clinical overview

## Spirometry

Spirometry is a fundamental pulmonary function test designed to assess how well the lungs function by measuring the volume and speed of inhaled and exhaled air. This non-invasive diagnostic tool helps healthcare professionals evaluate respiratory conditions, such as asthma, chronic obstructive pulmonary disease (COPD) and other lung disorders.[1,2] During a spirometry test, individuals exhale forcefully into a device called a spirometer, producing essential data that aid in the diagnosis and management of various respiratory issues.

Spirometry generates data that are presented in several formats, most commonly as a flow-volume loop that provides a visual representation of the breathing maneuver, helping to identify characteristic patterns of obstructive, restrictive or mixed ventilatory defects. Together, these data allow clinicians to quantify lung function, diagnose disease, monitor progression and assess response to treatment.

The most important parameters obtained include forced vital capacity (FVC), which represents the maximum volume of air that can be exhaled after a full inhalation, and forced expiratory volume in one second ($FEV_1$), the volume exhaled during the first second of forced expiration. The $FEV_1$/FVC ratio is central for detecting airflow obstruction, while the peak expiratory flow (PEF) reflects the maximum speed of exhalation.




In trials of asthma, COPD, interstitial lung disease and other disorders that affect the respiratory system, spirometry-derived parameters such as $FEV_1$, FVC and the $FEV_1$/FVC ratio are routinely used as primary or secondary endpoints. Beyond efficacy, spirometry also plays a critical role in safety monitoring, enabling the detection of treatment-related bronchospasm and restrictive ventilatory changes, and generating evidence of potentially developing drug-induced pulmonary toxicity.

## Challenges with spirometry

Ensuring high-quality spirometry data is a fundamental tenet in respiratory clinical trials, as lung function measurements often serve as primary endpoints. Quality spirometry performance requires optimal coaching by the operator and is heavily dependent on optimized effort by the study participant. As a result, a quality review process or "over-reading" of spirometry data is critical to ensuring compliance with ATS/ERS standards, an initial step for assuring the quality of the measures and allowing correct interpretation of the lung function. Centralized overreading has historically been applied (and continues) to support a correct and consistent overreading of the data, which is typically done within 24 or 48 hours.

## Home spirometry

Spirometry has traditionally been administered as a hospital or clinic-based procedure with trained operators used to instruct and coach a participant through the testing process. Recent experience and supportive literature confirm that spirometry can be performed at home. Home spirometry is transforming respiratory care and research by enabling patients to conveniently monitor lung function at home, reducing clinic visits and supporting early detection of chronic conditions. In clinical trials, at-home testing provides participant-friendly data collection that enhances understanding of treatment effects, improves efficiency and accelerates respiratory research and drug development. Unlike clinical settings where professionals closely supervise tests, at-home measurements may be more prone to variations influenced by factors like technique errors or environmental conditions without proper monitoring and associated feedback.[3] To further enhance at-home spirometry quality, Clario offers remote testing with real-time coaching by clinical site staff with the ability to assure highest quality efforts are attained, given potential challenges of the setting.

## Artificial intelligence for near real-time spirometry over-reading: ArtiQ.QC

Artificial intelligence (AI) has emerged as a transformative solution to the challenge of maintaining high-quality data in spirometry.

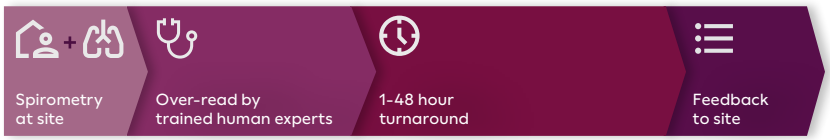
ArtiQ.QC is an AI–based software solution developed to automatically assess the quality of spirometry efforts in accordance with ATS/ERS Spirometry 2005 and 2019 standards.[1,2] The tool analyzes the flow–volume and volume-time curves of each maneuver and provides objective feedback on key quality criteria. By means of AI, ArtiQ.QC is able to not only assess numerical criteria (e.g., back extrapolated volume) but also perform visual inspection of the curves to detect artefacts (e.g., cough and obstructed mouthpiece).

By analyzing the data collected, ArtiQ.QC's AI algorithm can offer near real-time feedback on the quality of spirometry maneuvers and has been validated to be as accurate as human over-readers.[4,5] This reduces participant burden and ensures immediate operator education by highlighting suboptimal techniques, allowing for timely intervention and correction of potential errors. Practically, such contemporaneous feedback can inform the need to pursue additional testing to attain optimal quality when home/remote testing is pursued and can help avoid potential need for return of study participants for retesting on a subsequent day for clinic-based assessments.

## How does it work?

- Clario offers near real-time AI over-reading services in various combinations with human oversight by clinical experts.

**Expert over-read only**




**AI-based over-read only**


**AI + human touch or x% random review**


**AI + human touch + x% random review**


x% random review: Optional expert review of x% of processed data to verify that AI-based algorithms meet protocol requirements; the specific percentage chosen for random review decided per study

Borderline/unacceptable: Optional expert review of rejected data to determine potential use for study inclusion

- ArtiQ.QC can be configured to follow the study-specific protocol per sponsor/CRO agreement and is communicated and approved by means of the QC Guidelines.
- The output of ArtiQ.QC is provided via the existing PFT Analysis Report, accessible through the Clario Portal in near real time or sent by email (depending on the study-specific configuration). The resulting report and audit trail clearly indicate when the over-reading was performed by ArtiQ.QC.
- ArtiQ.QC is a closed system that is not self-learning and that has been developed in accordance with ICH GCP and IEC 62304 best practices.

A combined approach using ArtiQ.QC AI along with Clario's expertise and human oversight offers the most advanced and complete spirometry QC solution available.



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## References


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## About Clario

Clario is a leading provider of endpoint data solutions to the clinical trials industry, generating high-quality clinical evidence for life sciences companies. We offer comprehensive evidence-generation solutions that combine medical imaging, eCOA, precision motion, cardiac and respiratory endpoints.

For more than 50 years, Clario has delivered deep scientific expertise and broad endpoint technologies to help transform lives around the world. Our endpoint data solutions have been deployed over 30,000 times to support clinical trials in more than 100 countries. Our global team of science, technology, and operational experts have supported over 70% of all FDA drug approvals since 2012.