DATA SHEET

CLARIO.

Home spirometry and ePRO

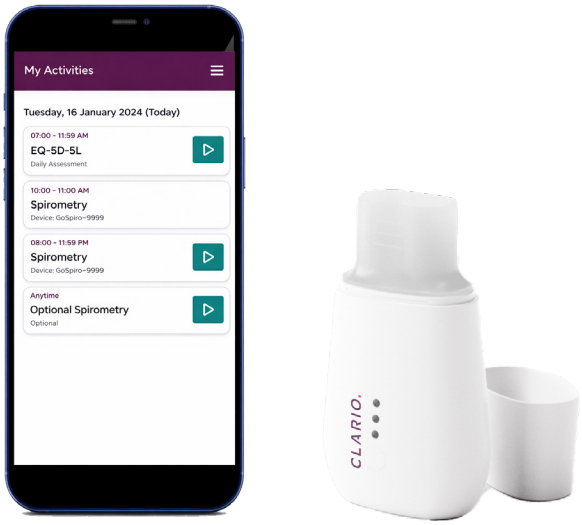
Complete at-home solution for capturing spirometry endpoints and electronic patient-reported outcomes (ePRO)

Clario Home Experience with spirometry and an ePRO solution

The integrated iSpiro® Ultrasonic Sensor and mobile application streamline the collection of high-quality spirometry and patient-reported data directly from the participant's home. By enabling participants to easily capture accurate lung function measurements and real-time symptom insights, you gain more robust data, greater engagement and the operational efficiency needed to accelerate trial outcomes.

The Clario Home Experience combines symptom diaries and an easy-to-use spirometer that:

- Enables spirometry at home to measure forced expiratory volume in 1 second (FEV_1) and peak expiratory flow (PEF).
- Provides a seamless participant journey through eDiary and spirometry.
- Combines a handheld sensor with the Clario Home App on a dedicated, locked-down mobile device.
- Includes a built-in training video, instant feedback on the testing effort and notifications to bolster compliance.
- Uses a high-quality, high-accuracy ultrasonic sensor for data capture.
- Delivers clinical grade accuracy at home.



More robust data, greater engagement and the operational efficiency needed to accelerate trial outcomes

Accurate, reliable and convenient spirometry assessments

Individuals with respiratory conditions, such as asthma, COPD, cystic fibrosis or idiopathic pulmonary fibrosis, often find it challenging to visit research sites for the necessary spirometry assessments.

At-home spirometry plus ePRO

Clario's at-home spirometry device makes it simple for sponsors, sites and participants to capture PEF or FEV_1 data alongside daily symptom diaries.

Our solution delivers a single, seamless interface, enhancing the participant's experience on a mobile device. We provide an easy-to-use, protocol-driven workflow that engages participants and supports high-quality outcomes and compliance.

- Daily symptom diaries and spirometry tests seamlessly integrate based on the protocol definition, making it easy for participants to follow the correct workflow.
- Data is automatically uploaded to Clario's database.
- Error-prone manual transcriptions are minimized.
- The solution includes a participant-facing application to drive both spirometry assessments and participant-reported outcomes.
- Training videos are included in the participant-facing application.

Enhanced compliance

- Notifications on the handheld device alert participants when assessments or symptom diaries are due.
- Sites are notified via email and/or reporting in the Clario portal when a participant misses an assessment or reading.
- At-home workflow guidance on when to complete symptom diaries and spirometry based on protocol requirements drives high protocol compliance and helps avoid missing evaluable data points.

High-quality spirometry and ePRO data

- The tutorial video enhances spirometry reading accuracy.
- Spirometry quality checks are based on ATS/ERS standards.

Near real-time data for fast decision-making

- Faster decisions on trial progress and key milestones are possible with close monitoring of the data captured.
- Sites can respond quickly regarding any concerning measurements.

Global availability

- It is approved for use across the U.S., Europe and select other locations (not currently available in China).
- Helpdesk support is available in native languages to reduce the site burden.

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Technical data for the iSpiro Ultrasonic Sensor

Characteristic	Performance
Device	
Dimensions (L x W x H)	110 x 63 x 41 mm
Weight	With batteries: 90 g Without batteries: 67 g
Power supply	2 x 1.5V AAA alkaline or rechargeable batteries
Protection class	Internally powered
Mode of operation	Continuous
Operating ambient conditions	
Temperature	+15°C to +35°C
Relative humidity	30% to 85%
Barometric pressure	700 hPa to 1060 hPa
Transport/storage conditions	
Temperature	-20°C to +60°C
Relative humidity	5% to 85%
Barometric pressure	700 hPa to 1060 hPa
Device lifetime	
iSpiro Ultrasonic Sensor (main unit)	5 years
SpiroWay mouthpiece (insert)	3 months
Moisture protection	IP22
Application	Measuring pulmonary function
Applied part	Type BF
Wireless connection	BLE 4.2
Measuring principle	Ultrasonic pulse transit-time measurement

Characteristic	Performance
Measuring range	
Flow (PEF)	0-14 L/s
Volume (FEV_1), maximum measured	10 L
Resolution	
Flow (PEF)	1 mL/s
Volume (FEV_1)	1 mL
Accuracy	
Flow (PEF)	± 10.00% or 170 mL/s
Volume (FEV_1)	± 2.50% or 0.05 L
Spirometer resistance/ highest impedance	48.54 Pa*s/L

Make your clinical trials easier, faster, more engaging and accessible to all.
To learn more, go to clario.com/solutions/respiratory/ or email respiratory@clario.com.

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, ePRO, precision motion, cardiac and respiratory endpoints.

Quality and Safety eResearchTechnology GmbH operates a Quality Management System according to EN ISO 13485:2016 and 21 CFR Part 820. Images of device and technical specifications are subject to change. Security: Certificate ISO/IEC 27001:2022

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