

SpiroSphere®

Take your spirometry and ECG collection to the next level with our smart, portable and affordable solution

Respiratory trials advanced

Smart, portable and affordable, SpiroSphere® is the latest system from Clario for the measurement, recording and assessment of accurate lung function parameters (FEV1, FVC, PEF, FEF25-75, VC, IC, ERV and others) and ECG collection.



Specially designed to simplify routine use in healthcare and clinical trials, this innovative system simplifies most challenges while improving pulmonary function testing (PFT) and the collection of ECGs. The compact, portable spirometer is ideal for use by a physician or healthcare professional, and provides maximum efficiency based on extensive feedback from sites participating in clinical trials.

SpiroSphere combines a high-quality, pre-calibrated, pneumotach sensor and optional 12-lead ECG with the latest wireless technology. A high-resolution, color touchscreen display and streamlined user interface **keeps the focus on the patient and data quality**. The built-in, reliable biometric fingerprint scanner allows only access to the system after successfully completing proficiency training and testing.

Intuitive software and unique features optimize and automate study-specific workflows to **improve protocol compliance and acceptability**. Collected data is synchronized via Wi-Fi or Ethernet with the EXPERT® platform for central data management, quality analysis, business intelligence and portal access. With training and instructions integrated into our devices, *Clario simplifies endpoint collection for patients*.

SpiroSphere measures, records and assesses accurate lung function parameters with optional ECG collection



Put SpiroSphere to work for you

Coach, collect and assess

Proper coaching is the key to precise, repeatable data, as patients often have challenges performing maneuvers. SpiroSphere is compact and truly portable with a built-in rechargeable battery. Smart icons deliver quality feedback in real time so patients can be guided to proper maneuvers adhering to the latest American Thoracic Society (ATS) and European Respiratory Society (ERS) standards. To ensure high quality cardiac data, our ECG software is tested according to the IEC 60601-2-25 standard and guides users on proper electrode placement with automatic lead connectivity confirmation.

Connect wirelessly

SpiroSphere's high-quality, wireless pneumotach sensor and wireless ECG device give users and patients full freedom of movement. Always connected, SpiroSphere supports Wi-Fi and Ethernet for mobility and seamless data transmission. After a patient is evaluated, reports can be emailed to other physicians, printed through any compatible printer, backed up locally to a USB stick and transmitted to the EXPERT platform.

Never calibrate again

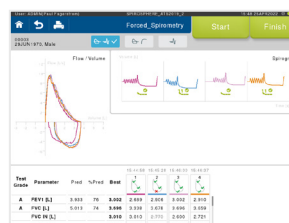
Why waste time on calibration? SpiroSphere comes with pre-calibrated pneumotach tubes, simplifying daily procedures while capturing highly-accurate data. Each pneumotach tube comes with an attached mouthpiece suitable for all ages. SpiroSphere supports the 2019 ATS/ERS guidance by providing a calibration check.

Clean and go

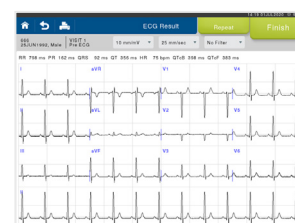
Hygiene is critical for safety, so SpiroSphere relies on a disposable, single-patient use pneumotach tube. Simply clean the handle and replace the tube, and SpiroSphere is ready for the next patient. Additional bacterial filters are available for added safety and protection.



Spirometry



ECG



SPIROSPHERE FEATURES

- Spirometry with pre-calibrated disposable pneumotach
- Optional digital 12-lead ECG
- Bluetooth®-connected
- Supports Wi-Fi and Ethernet for mobility and seamless data transmission
- Portable operation with rechargeable batteries in main and sensor unit
- Printing to PDF or through compatible USB printer
- Back up local data via USB stick
- Supplied with carrying case

Technical Specifications	
Flow measurement	High-quality pneumotach
Flow range (PEF)	0.1 to 16 L/s
Flow accuracy (PEF)	0.1 to 16 L/s: +/- 10% of reading or +/- 0.3 L/s
Flow resolution	< 5 mL/s
Resistance	Max 135 Pa/(L/s) at 14 L/s
Instantaneous flow	0.1 – 14 L/s: +/- 5% or 0.2 L/s
Volume measurement	Digital integration
Volume range	0.1 to 8 L
Volume accuracy	0.1 to 8L +/- 3% of reading or +/- 0.05 L
Volume resolution	1 mL
Display	High-resolution LCD touchscreen, backlit 16.2 cm x 12.2 cm, 1024 x 768 pixels
L x W x H	31.5 cm x 19.5 cm x 7.5 cm
Power supply input	100-240VAC, 50/60Hz, 1.5A
ECG leads	Acc. to Einthoven, Wilson, Goldberger
ECG bandwidth	0-150 Hz digital
ECG sampling rate per channel	500 Hz
Pacemaker detection	4000 Hz sampling rate
ECG resolution	1.94 μ V/bit ECG, 15 bit
ECG electrodes	Standard ECG electrodes, 4mm snap, gilded
ECG power supply	1 x AA battery
ECG electrode cable length	0.44 m/0.81 m
ECG algorithm	HES [®] Hannover ECG System

Take your respiratory trial to the next level with our smart, portable and affordable spirometer and optional ECG. For more information, go to clario.com or email info@clario.com

QUALITY AND SAFETY

ERT or eResearchTechnology GmbH operates a Quality Management System according to EN ISO 13485 and 21 CFR Part 820. The device complies to the applicable standards and regulations. The SpiroSphere spirometer is CE-marked (according to Medical Device Directive) and US FDA cleared (510(k)).



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