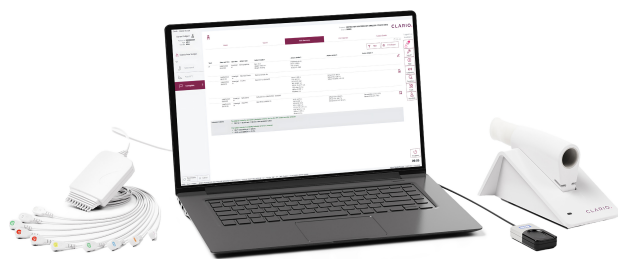


# MasterScope™

Minimize risk and uncertainty with our centralized spirometry, ECG, patient-reported outcomes and multi-endpoint platform

## Your first choice for centralized, integrated respiratory trials

Working with various diagnostic technologies while following a complex clinical trial protocol makes it challenging for sites to focus on patient safety and data quality.



MasterScope Wireless Spirometry Sensor combines a high-quality, pre-calibrated pneumotach with smart technology.

MasterScope's highly intuitive multi-language user interface, customized protocol workflows and many smart features make it the preferred choice for your centralized studies.

With a multi-protocol device reuse option, MasterScope minimizes equipment costs and logistics, speeds trial start-up and eases investigative site burden.

Data is synchronized via Wi-Fi, Ethernet or web upload networks with the EXPERT® platform for central data management, quality analysis, business intelligence and portal access.

## Benefits of putting MasterScope to work for you

**Drive high-quality spirometry data** with an algorithm for automated acceptability and repeatability checks and controlled resting time between maneuvers.

**Speed time-to-approval with integrated cardiac safety** to collect, interpret and distribute ECG data, with LED electrode placement guides and automatic lead connectivity check.

**Boost site efficiency and focus on data quality** with software interface in the site's native language with user-friendly features, such as a waiting room function to manage multiple patients on the same visit day and a dashboard with notifications on when the next action needs to be performed by each patient.

**Centralize other endpoints and boost efficiency** with a fully integrated solution that visualizes and centralizes parameter data such as home monitoring with PROs eDiary, FeNO or Oscillometry, completes regular quality checks, reviews calibration efforts and updates software.

**Simplified daily calibrations** with compliant pneumotach tubes pre-calibrated to simplify daily actions while capturing highly-accurate data. MasterScope supports ATS/ERS guidance by providing a calibration check.

**Ensure patient safety and hygiene** by simply cleaning the sensor and replacing the disposable, single-patient use pneumotach tube. Additional bacterial filters are available for added safety and protection.

## MasterScope features

MasterScope's centralized diagnostic workstation offers complete spirometry capabilities (according to ATS / ERS 2005 or ATS/ERS 2019 standards) leveraging the Wireless Spirometry Sensor and integrates with:

- Home monitoring and patient-reported outcomes (PROs) electronic diary (eDiary) data from our AM3™ device family
- Optional 12-lead digital ECG utilizing the HES™ algorithm
- Third-party technologies like Circassia NIOX VERO® for collecting fractional exhaled nitric oxide (FeNO) and Thorasys tremoflo® for collecting oscillometry data

### Other features include:

- Wireless (Bluetooth) spirometry sensor
- Wireless (Bluetooth) ambient sensor for automatic ambient conditions
- Automatic online updates of protocol amendments and new features
- Secure Ethernet (LAN), Wi-Fi or web upload (via USB Stick) data transmission
- Online setup for initial protocol software setup
- Connection to our EXPERT® platform for centralized overread with optional data access and analytics
- Online portal for near real-time data management and reporting
- MasterScope on Windows 10 security using the kiosk mode, Bitlocker encryption, Windows Defender anti-virus software and firewall

## Spirometry specifications

Flow measurement	High-quality pneumotach
Measuring range	PEF: 0.1 to 16 L/s FEV1 and FVC: 0.1 to 8 L
Resolution	PEF: < 5 mL/s FEV1 and FVC: 1 mL
Accuracy	PEF: 0.1 to 16 L/s $\pm$ 10% of reading or $\pm$ 0.3 L/s FEV1 and FVC: 0.1 to 8L: $\pm$ 2.5% of reading or $\pm$ 0.050 L
Resistance Spirometer	max. 135 Pa/L/s at 14 L/s
Instantaneous Flow	0.1 – 14 L/s: $\pm$ 5% or 0.2 L/s

## ECG specifications

Active contact test	LED indicator snap
Sampling rate	1000 Hz per channel
Pacemaker detection	4000 Hz sampling, detection in amplifier
Resolution	2.6 $\mu$ V/bit ECG, 19 bit
Interpretation	Hannover ECG System ("HES")

## Optional devices

MasterScope™ 12-lead digital ECG  
 AM3™ electronic PEF/FEV1 meter and diary  
 Circassia NIOX VERO®  
 Thorasys tremoflo®

## Optional accessories

Pneumotach sensors

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QUALITY AND SAFETY: eResearchTechnology GmbH operates a Quality Management System according to EN ISO 13485 and 21 CFR Part 820. The device complies with the applicable standards and regulations. The device is CE-marked (according to Medical Device Regulation) and US FDA cleared (510(k)).

Clario generates the richest clinical evidence. Fusing our deep scientific expertise and global scale into the broadest endpoint technology platform, we empower our partners to transform lives.



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