

# ERT 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

The ERT MasterScope™ helps you overcome the challenges of working with various diagnostic technologies while following a complex clinical trial protocol. MasterScope's highly intuitive multi-language user interface, customized protocol workflows and many smart features such as biometric user identification (21 CFR Part 11 compliance) make it the preferred choice for your centralized studies. With a unique multi-protocol device reuse option, MasterScope also minimizes equipment costs and logistics, speeds trial start-up and eases investigative site burden.

MasterScope's integrated platform helps your sites to better focus on patient safety and data quality. It offers complete spirometry capabilities leveraging the ERT Wireless Spirometry Sensor, integrates home monitoring and patient-reported outcomes (PROs) electronic diary (eDiary) data from our AM3™ device family, and offers an optional 12-lead digital ECG utilizing the ERT HES™ algorithm. With third-party integrations like the Circassia NIOX VERO® for collecting fractional exhaled nitric oxide (FeNO), Thorasys tremoflo® for collecting oscillometry data and other advanced features, MasterScope will become your central diagnostic workstation.

## PUT MASTERSCOPE TO WORK FOR YOU

- > Integrate Spirometry, 12-lead ECG, FeNO, oscillometry and home spirometric monitoring with PROs eDiary data in one high-performance system
- > Leverage a wireless spirometry sensor with pre-calibrated, disposable pneumotach tubes that is easy to use (along with an ambient sensor for automatic room temperature, humidity and pressure data capture)
- > Simplify the most complex of trials with customizable, protocol-specific workflows
- > Minimize equipment costs and logistics with a unique multi-protocol option that allows one device to support multiple studies
- > Drive site performance with software designed with site needs in mind, including multi-language support

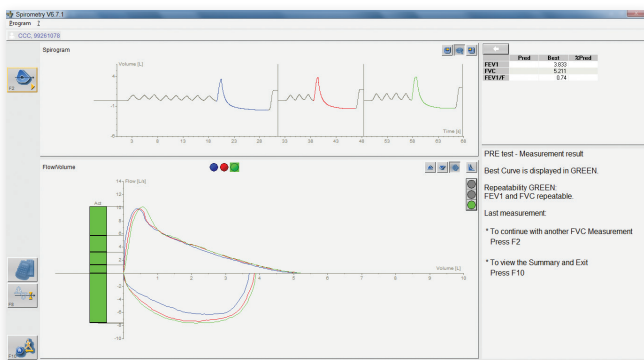


**ERT MASTERSCOPE INTEGRATES SPIROMETRY, ECGs, PROs AND OTHER ENDPOINTS**



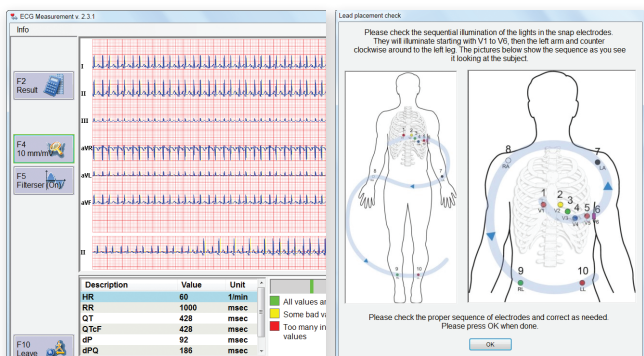
## MASTERSCOPE FEATURES

- > Spirometry according to ATS/ERS standards
- > Wireless (Bluetooth), calibration-free spirometry sensor, easy to use and clean
- > Wireless (Bluetooth) ambient sensor for automatic ambient conditions (temperature, pressure, humidity) data capture
- > Supports Quanjer-Global Lungs Initiative (GLI)-2012 reference values
- > Automated error detection:
  - Back extrapolated volume
  - Late peak flow
  - Coughing
  - Expiration time  $< 6$  s ( $< 3$  s for children), including graphical visualization during measurement
  - "No plateau detection" at the end of expiration, including graphical visualization during measurement
- > Automated acceptability and repeatability checks, including visualization by traffic light indicator
- > Enforced resting time for the patients between measurements
- > Volume/time and Tiffeneau views
- > Smart control for manual selection and deselection of loops by the user, including user comments (deselected loops will be stored, transmitted and reviewed by ERT's pulmonary overread experts)
- > Automated scoring and alerting calculation (e.g. FEV1 variation)
- > Automated calculation of inclusion, randomization, exclusion or alert criteria
- > Waiting Room function for easy multi-subject management on a single visit day
- > eLearning with local and online training videos and documentation
- > User verification by biometric fingerprint detection
- > Electronic submission and management of data correction requests
- > Protocol amendments and new features deployed via automatic online updates
- > Secure Ethernet (LAN), Wi-Fi or web upload (via USB Stick/SD Card) data transmission
- > Fully functional offline operation
- > Online setup for initial protocol software setup
- > Connects to our EXPERT® platform for centralized overread with optional data access and analytics
- > Online portal for near real-time data management and reporting



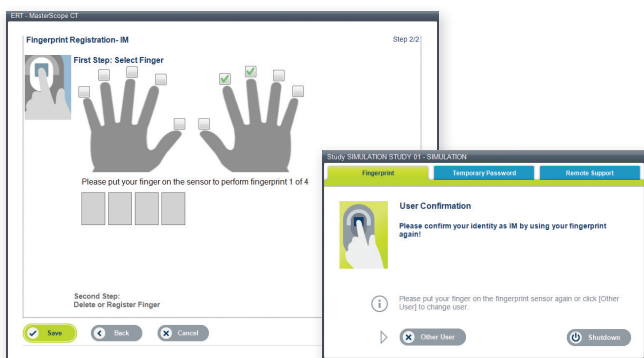
## Drive high-quality spirometry data

MasterScope's advanced logic delivers the highest-quality spirometry data. An intelligent traffic light indication for automated acceptability and repeatability checks provides site operators with immediate feedback on data quality. Other smart features, such as control of the resting time between maneuvers, help to achieve the best spirometry results from each patient.



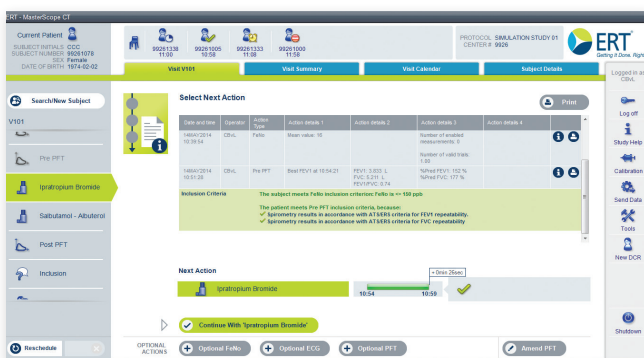
## Speed time-to-approval with integrated cardiac safety

Capturing the highest-quality safety data on time and in the correct format is critical for new drug approvals. MasterScope integrates an optional solution to centrally collect, interpret and distribute ECG data. To ensure proper placement of ECG electrodes, LEDs guide users by flashing in the appropriate sequence, a unique feature. Prior to testing, MasterScope also automatically checks the connectivity of each lead to ensure the best quality signal.



## Ensure quality control and compliance oversight

MasterScope is the first diagnostic platform that provides biometric fingerprint identification for site operators in compliance with 21 CFR Part 11 requirements — no passwords are required. The system also automatically creates a comprehensive audit trail log, simplifying quality and compliance monitoring.



## Sites never lose focus on data quality

With MasterScope, you can offer site users a software interface in their native language to boost their efficiency. User-friendly features, such as a waiting room function, make it easier to manage multiple patients on the same visit day. This enables site users to view a dashboard that includes notifications on when the next action needs to be performed by each patient (e.g., the next serial spirometry measurement). Users can also seamlessly switch between patient profiles with a single click.



## Centralize other endpoints and boost efficiency

If your protocol requires collection of additional parameters such as home monitoring with PROs eDiaries, FeNO or oscillometry data, we offer fully integrated solutions that visualize and centralize such data. MasterScope also completes regular automated quality checks, reviews calibration efforts and automatically updates software to ensure the latest protocol amendments and features are being used at each site, reducing burden on site personnel while increasing trial efficiency.

## TECHNICAL SPECIFICATIONS

### SPIROMETRY SPECIFICATIONS

<b>Measuring range</b>	PEF: 0.1 to 16 L/s	FEV1 and FVC: 0.1 to 8 L
<b>Resolution</b>	PEF: < 5 mL/s	FEV1 and FVC: 1 mL
<b>Accuracy</b>	PEF: 0.1 to 16 L/s: $\pm 10\%$ of reading or $\pm 0.3$ L/s	FEV1 and FVC: 0.1 to 8 L: $\pm 3\%$ of reading or $\pm 0.050$ L
<b>Resistance spirometer</b>	max. 135 Pa/L/s at 14 L/s	
<b>Instantaneous flow</b>	0.1 - 14 L/s: $\pm 5\%$ or 0.2 L/s	
<b>Applied part</b>	ERT PT, WSSU	
<b>Dimensions</b>	Wireless spirometry sensor unit: 11 x 8 x 4 cm (L x W x H)	Charging station: 19 x 13 x 7 cm (L x W x H)
<b>Weight</b>	Wireless spirometry sensor unit: 0.15 kg	Charging station: 0.27 kg
<b>Medical power supply</b>	Model: GTM41134-0606-1.0 Input / Output: 100 - 240V 50-60 Hz 0.6 A / 5V 1.2 A 6W Cable length: 1.5 m	
<b>Battery</b>	Wireless spirometry sensor unit: Built in rechargeable Lithium Ion battery 3.7 V, 640 mAh. Battery will last under standard operating conditions for about 3 days in standby mode and 2.5 h for constant measurements.	Full charging: 2 h Cycle life: 70% of rated capacity after 500 charging cycles
<b>Protection class</b>	Wireless spirometry sensor unit: Internally powered	Charging station: N/A
<b>Mode of operation</b>	Continuous	
<b>Moisture protection</b>	Power supply charging station: IP21	Wireless spirometry sensor unit: IP20
<b>Measuring principle</b>	High quality pneumotach	
<b>Operating ambient</b>	Temperature: +10° C to +35° C Relative humidity: 15% to 90% Barometric pressure: 700 to 1070 hPa	
<b>Transport/storage</b>	Temperature: -20° to +50° C Relative humidity: 15% to 90% Barometric pressure: 600 to 1200 hPa	

### ECG SPECIFICATIONS

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

### OPTIONAL DEVICES

12-lead digital ECG
ERT AM3™ electronic PEF/FEV1 meter and diary
Circassia NIOX VERO® (FeNO)
Thorasys tremoflo® (Oscillometry)

### OPTIONAL ACCESSORIES

Nose clips with nose pads
Pneumotach tubes
ECG electrodes

### QUALITY AND SAFETY

ERT 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 device is CE-marked (according to Medical Device Directive) and US FDA registered (510(k)).



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