Enhancing Pulmonary Diagnostics with the Ambulatory Lung Diagnostic System ALDS

LOTHAR MEDICAL

Ambulatory Lung Diagnostic System

The Ambulatory Lung Diagnostic System (ALDS) is a two-in-one device designed to perform both Airway Oscillometry and Forced Spirometry. This innovative system leverages a cloud-based algorithm to analyze test results, integrating clinical outcome parameters with patient history to deliver a clear physiological interpretation of lung function for healthcare providers.

The system algorithm identifies obstructive and restrictive patterns, helping clinicians detect and understand corresponding respiratory limitations.

Engineered for mobility, durability, and efficiency, the ALDS supports high patient throughput with each test typically taking just a few minutes.

By combining both diagnostic methods in daily diagnostic routines, the ALDS offers a comprehensive, multidimensional assessment of lung function, enhancing pulmonary diagnostics.

ALDS

Ambulatory Lung Diagnostic

Airway Oscillometry

Airway Oscillometry is a simple, non-invasive technique that measures the mechanical impedance of the lungs - a combination of respiratory resistance (airway openness) and reactance (elasticity and inertance of the airways).

During the test, the patient breathes normally and calmly through the ALDS device. While doing so, the system delivers gentle pressure oscillation to the lung. These sound waves travel through the airways, and the device captures the resulting pressure and airflow at the mouth.

The system then calculates clinically relevant, frequency-dependent impedance parameters, providing valuable insights into lung mechanics without requiring forced breathing maneuvers.

SPIRO

Advanced Spirometry for Comprehensive Lung Health Monitoring

Forced Spirometry

Forced Spirometry is a diagnostic technique used to measure airflow during a forced breathing maneuver. During this test, the patient performs a spirometry maneuver - taking a deep breath and then exhaling forcefully through the ALDS device. The system captures the airflow and calculates clinically relevant flow and volume parameters, offering valuable insights into the patient's pulmonary function.

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TWO METHODS - ONE MISSION
Smarter Lung Function Diagnostics

Spirometry

Spirometry remains the most widely used and validated method for assessing pulmonary function. The ALDS measures key parameters such as:

- Forced Vital Capacity (FVC)
- Forced Expiratory Volume in 1 second (FEV1)
- FEV1/FVC ratio
- PEF

These values are key for diagnosing lung diseases, assessing severity, and tracking treatment. Spirometry is recommended by major guidelines such as GINA and GOLD.

However, spirometry has notable limitations that underscore the need for complementary tools that can provide additional insights into lung function, particularly in challenging patient populations:

- Effort-dependence: Requires maximal inhalation and forceful exhalation, which can be challenging for young children, elderly patients, or those with neuromuscular disorders.
- Limited sensitivity to small airway dysfunction: Spirometry primarily reflects large airway function and may not detect early changes in peripheral airways.
- Variability: Results can vary based on patient effort and technician skill.

Oscillometry

During Oscillometry the ALDS measures respiratory impedance by superimposing pressure oscillations on normal tidal breathing. It quantifies:

- Resistance (R): Reflects airflow obstruction in central and peripheral airways.
- Reactance (X): Indicates elastic and inertive properties of the lung, sensitive to small airway dysfunction.
- Resonant frequency (Fres) and area under the reactance curve (AX): Provide further insight into lung mechanics.

Advantages of Oscillometry

- Effort - independent: Requires only quiet tidal breathing, making it ideal for children, elderly patients, and those with cognitive or physical impairments.
- Sensitive to small airway dysfunction: Detects early changes in distal airways, often missed by spirometry.
- Useful in bronchodilator testing: Can reveal reversibility not evident in spirometry, aiding in asthma and COPD management.

Clinical Applications

- Asthma: Oscillometry can detect small airway hyper-responsiveness and assess bronchodilator response, even when spirometry is normal.
- COPD: Helps in phenotyping patients and monitoring disease progression.
- Pediatrics and geriatrics: Offers a non-invasive, low-effort alternative for populations where spirometry is impractical

Best Practices for Combined Use of Spirometry and Oscillometry

To harness the full potential of both tools, clinicians should adopt a structured approach to their combined use:

Sequential Testing Protocol

1. Perform oscillometry first: Since it is sensitive to airway tone, it should be done before any forced maneuvers that might alter lung mechanics.
2. Follow with spirometry: To assess forced expiratory volumes and flow rates.

Clinical Scenarios for Combined Use

- **Suspected early asthma or COPD: Oscillometry may detect changes before spirometry becomes abnormal.**
- **Monitoring treatment response: Especially in patients with poor spirometric technique.**
- **Evaluating unexplained symptoms: Such as chronic cough or exertional dyspnea with normal spirometry.**

Interpretation Strategy

- **Concordant results: Reinforce the diagnosis (e.g., both tests show obstruction).**
- **Discordant results: May indicate early or localized disease (e.g., normal spirometry but abnormal oscillometry suggests small airway involvement).**

Integration into Practice

- **Training: Technicians should be trained in both techniques to ensure accurate and reproducible results.**
- **Standardization: Use of reference values and quality control measures is essential for reliable interpretation.**
- **Patient education: Explaining the purpose and process of each test can improve cooperation and data quality.**

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Case Study: Early Detection of Small Airway Dysfunction in a Middle-aged Smoker

Patient Profile

- Age: 50
- Sex: Male
- History: 25-pack-year smoking history, occasional cough, mild exertional dyspnea
- No prior diagnosis of asthma or COPD

Clinical Presentation

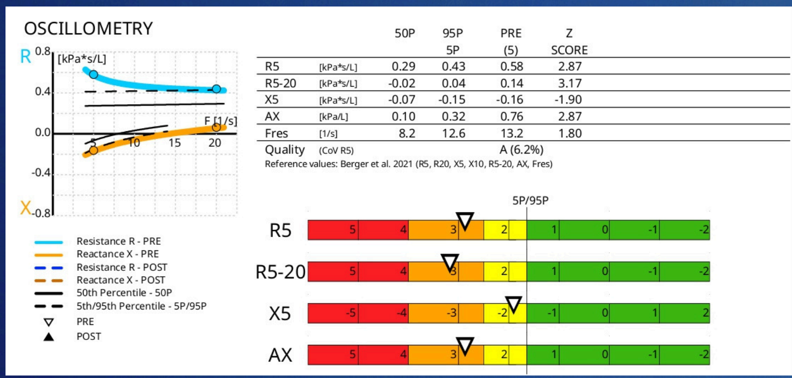
The patient presented for a routine health check-up. He reported mild shortness of breath during physical activity but denied wheezing or frequent respiratory infections. Given his smoking history, the clinician opted for a comprehensive lung function assessment.

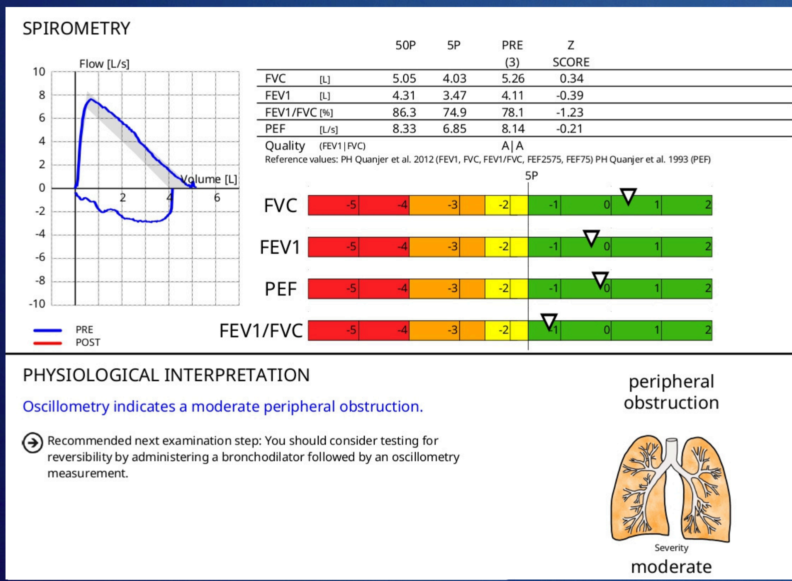
Spirometry Results

- FEV_1: 4.11 L (ca. 95% predicted)
- FVC: 5.26 L (ca. 104% predicted)
- FEV_1/FVC ratio: 0.78 (within normal limits)
- Interpretation: Normal spirometry, no evidence of obstruction or restriction.

Oscillometry Results

- R5 (total airway resistance): 0.58 kPa·s/L → Significantly elevated
- R5–R20 (peripheral airway resistance): 0.14 kPa·s/L → Significantly elevated
- X5 (reactance at 5 Hz): −0.16 kPa·s/L → Significantly abnormal
- AX (area under reactance curve): 0.76 kPa → Significantly increased
- Fres (resonant frequency): 13.2 Hz → Elevated (normal typically <10 Hz)
- Interpretation: Oscillometry indicates a moderate peripheral obstruction.





Interpretation

Despite normal spirometry, oscillometry revealed increased resistance and reactance in the small airways, suggesting early small airway dysfunction - often referred to as the “silent zone” of the lungs. These findings are consistent with early changes seen in smokers before spirometric abnormalities appear.

Conclusion

Combining oscillometry and spirometry offers a more complete and sensitive approach to lung function testing - capturing both large and small airway abnormalities. The Ambulatory Lung Diagnostic System (ALDS) by Lothar Medical streamlines this dual-pathway approach in a single, portable device. By integrating both diagnostic methods, ALDS enables clinicians to detect early disease, monitor progression, and tailor treatment with greater precision - all in one efficient workflow.

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Clinical Pathway

START

Pre
Oscillometry
measure airway resistance

Abnormal

Post
Oscillometry
determine response to bronchodilator

BDR Negative

Post
Spirometry
measure FVC

FVC Abnormal

Complex Limitation
You should consider referral of the patient

Normal

Normal at rest
You should measure post spirometry if COPD is suspected

Normal at rest
You should conduct a provocation test
if Asthma is suspected

BDR Positive

You should consider treatment for
COPD or Asthma

FVC Normal

You should consider treatment for
COPD

Note: If indicated you should consider referral of the patient.

Device Specification

Technical Parameters

Measurement Principle	Airway Oscillometry, Forced Oscillation Technique (FOT)	Forced Spirometry
Sensor Technology	Differential pressure Flow measurement: Lilly-type screen pneumotachograph Pressure measurement: Differential pressure to ambient Flow Range: ± 4 L/s Flow resolution: 2 mL/s Flow accuracy: ±2% or 0.020 L/s Pressure Range: ± 500 Pa Pressure resolution: 0.01 Pa Pressure accuracy: 3% Impedance Range: 0 – 2 kPa*s/L Impedance accuracy: 10% Resistance: ≤0.16 kPa*s/L at 5 Hz (system with accessories and filter)	Differential pressure Flow measurement: Lilly-type screen pneumotachograph Flow Range: ±14 L/s Flow resolution: 2 mL/s Flow accuracy: ±2% or 0.020 L/s (except peak flow) Flow accuracy: ±5% or 0.200 L/s (peak flow) Volume Range: 0 - 9 L Volume resolution: 1 mL Volume accuracy: ±2% or 0.050 L Resistance: ≤0.15 kPa*s/L up to 14 L/s (system with accessories and filter)
Actuator Technology	Loudspeaker Frequencies (single frequency): 5, 10, 20 Hz Frequencies (pseudo random noise): 5, 7, 11, 13, 17, 19, 23, 29, 31, 37 Hz Output pressure: ≤ 40 Pa (peak-to-peak)	none
Effective Dead Space	40 ml	n.a.
Data acquisition	Digital Resolution: 16 bit Sampling rate: 500 Hz (pressure, flow)	Digital Resolution: 16 bit Sampling rate: 500 Hz (flow)
Calibration	No calibration needed Optional device check with reference test load (hardware included)	No calibration needed Optional device check with 3L calibration syringe (hardware not included)
Hygiene	Two-level cross-infection prevention Level 1: Single-Use Pulmonary Filter Level 2: Airflow channel and other relevant accessories can be chemically disinfected, and steam sterilized	
Reference Models	Berger 2021 (adults) Nowowiejska 2008 (adolescents) Calogero 2013 (children)	GLI 2012 (Global Lung Initiative)
System requirements app	Cross-platform, Bluetooth Low Energy Operating systems: Windows 10+, iOS 13+ Bluetooth Low Energy: 4.2+	
Interoperability	All data can be shared in real-time in all standard data formats as well as custom data formats. Data types: Reports (pdf), individual clinical outcome parameters (see list above), graphs (png, svg), results of cloud-based physiological interpretation, artefacts, audit trail and other meta data Technology: cloud-based data endpoint, push model preferred (fire-and-forget) Markup: json, xml, custom Standards:, HL7, GDT, DICOM, CDISC, email and other	
Device properties	Desktop Dimensions (WxDxH): 20x14x45 cm 8x6x17 in Weight: 2 kg / 4.4 lb	Handheld Dimensions (WxDxH): 13x18x9 cm 5x7x4 in Weight: 200 g / 0.4 lb
Power supply	Battery powered Batteries: Li-Ion batteries (built-in) Charging: rechargeable, charger included (5V, min. 10W, USB-A connector) Charging cycle: typically optionally daily (overnight) or once per week (over the weekend)	

Technical Standards

Airway Oscillometry	Technical standards for respiratory oscillometry Official European Respiratory Society Technical Standard
Forced Spirometry	Standardization of Spirometry 2019 Update Official American Thoracic Society and European Respiratory Society Technical Statement
Peak Flow	ISO 26782:2009 Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans
Physiological Interpretation	ERS/ATS technical standard on interpretive strategies for routine lung function tests Official European Respiratory Society Technical Standard

Clinical Parameters

Airway Oscillometry			
Clinical Outcome	Resistance	R5, R10, R20, R5-20	Resistance of the respiratory system, reflecting frictional losses both in gases as they flow along airways and in tissues of the lung and chest wall as they are stretched and deformed.
	Reactances	X5, X10, X20	Reactance of the respiratory system, reflecting respiratory system elastance due to the combined stiffnesses of the lung and chest wall tissues and respiratory system inertance due to the mass of gas in the central airways.
	Resonant frequency	Fres	Resonant frequency, where elastance and inertance make equal and opposite contributions to impedance.
	Area under the reactance curve	AX	The area under the reactance curve is the area inscribed by the X curve between the lowest measured frequency and Fres. AX is thus an integrative measure dominated by the lower frequency components of X, determined predominately by elastance, and affected by the point at which X crosses the frequency axis (X=0).
Quality	Coefficient of Variation	CoV	Within-session coefficient of variability (cutoffs: 10% adults and 15% children).

Forced Spirometry			
Clinical Outcome	Forced expiratory volumes	FEV1, FEV3, FEV6	Forced expiratory volumes are used to categorize the severity of obstructive lung diseases, such as asthma and chronic obstructive pulmonary disease.
	Forced expiratory flows	PEF, FEF25, FEF50, FEF75, FEF2575	Forced expiratory flows are used in the diagnosis of obstructive ventilatory patterns.
	Forced expiratory capacity	FVC	FVC is an indicator for restrictive lung diseases, such as chest wall deformities and idiopathic pulmonary fibrosis.
	Forced inspiratory capacity	IVC	Comparison of the IVC with the FVC provides feedback to the operator on whether the patient began the forced expiration from full inflation.
	FEV1/FVC ratio	FEV1/FVC	The ratio of FEV1 to FVC is used as indicator for obstructive ventilatory patterns.
Quality	Back-extrapolated volume	BEV	Volume of gas that has already been expired from maximal lung volume to the start of the forced expiration.
	End of forced expiration	EOFE	Parameter indicating whether at least one of the three recommended indicators of EOFE has been achieved.

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