# 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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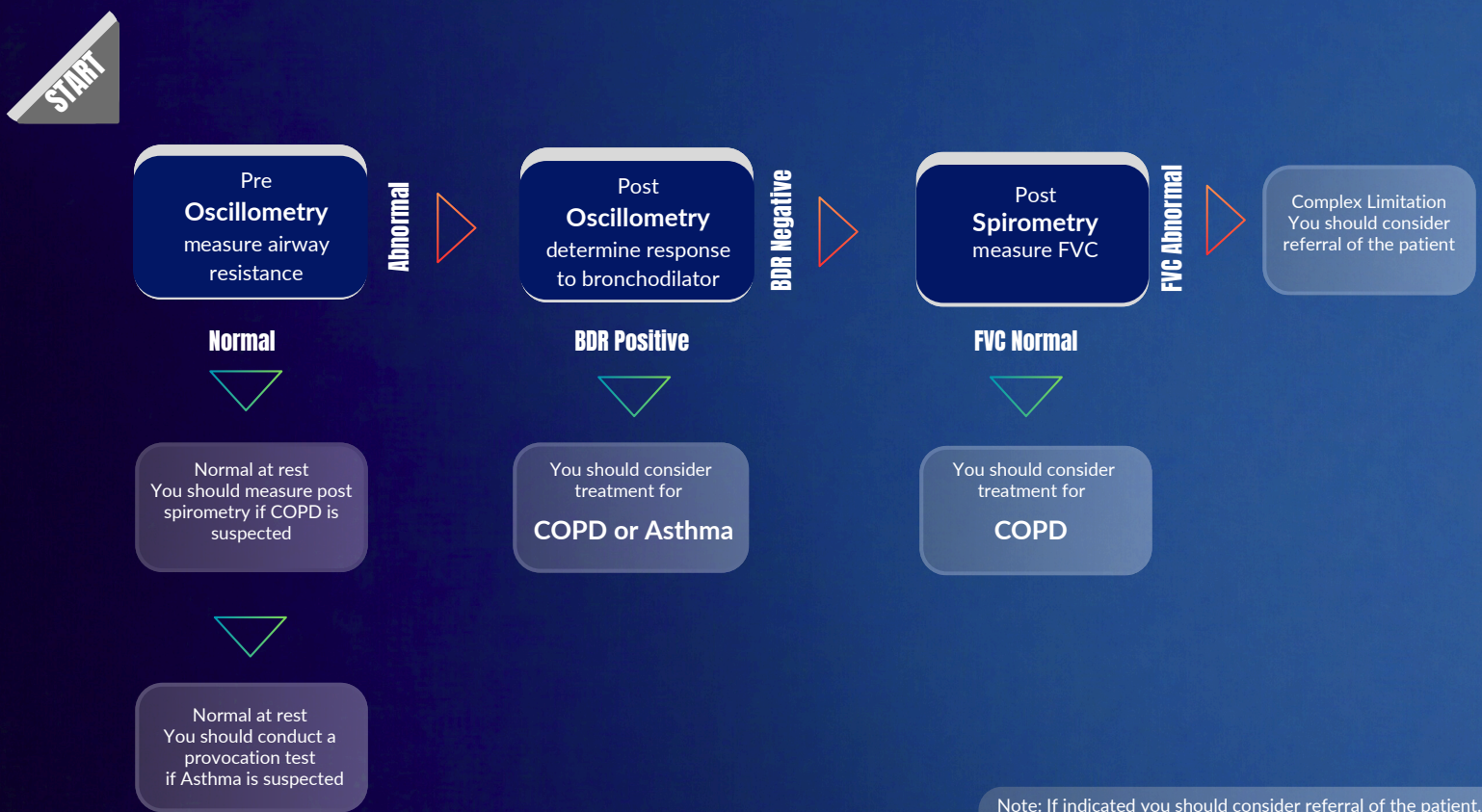
# Clinical Pathway




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

## Technical Standards

| | |
|---|---|
| Class IIa Medical Device | Medical Device Regulation 2017/745 of the European Commission |
| Airway Oscillometry | Technical standards for respiratory oscillometry<br>Official European Respiratory Society Technical Standard |
| Forced Spirometry | Standardization of Spirometry 2019 Update<br>Official American Thoracic Society and European Respiratory Society Technical Statement |
| Forced Spirometry | 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<br>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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