Ambulatory Lung Diagnostic System ALDS Professional

LOTHAR MEDICAL

Ambulatory Lung Diagnostic System Professional

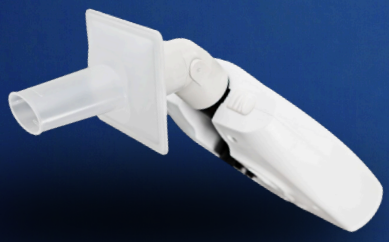
The Ambulatory Lung Diagnostic System Professional (ALDS PRO) is a single-device instrument for measuring Airway Oscillometry, Forced Spirometry and Exhaled Nitric Oxide (FeNO). The system's cloud-based algorithm evaluates the readings and uses the resulting clinical outcome parameters along with patient history data to provide physicians with a physiological interpretation of the results. The algorithm is based on published concepts for interpreting obstructive and restrictive patterns that indicate corresponding limitations. The ALDS is specifically designed for general practitioners.
The system fulfills modern requirements for mobility and robustness to efficiently examine many patients per day. The typical duration of an examination is only a few minutes per patient and implements a guided clinical pathway including airway resistances, forced expiratory flows and the fractional concentration of exhaled NO. The opportunity to combine these tests provides a comprehensive and multidimensional evaluation of the lung function.

ALDS Pro

Advanced Pulmonary Function Assessment

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.



FeNO

Fractional Exhaled Nitric Oxide

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.

Exhaled Nitric Oxide (FeNO)

Exhaled nitric oxide (NO) is measured when asthma or other respiratory conditions involving airway inflammation are suspected. Nitric oxide (NO) is a gas produced by certain cells during an inflammatory response. The fraction of exhaled NO (FeNO) serves as a biomarker for diagnosing, monitoring, and guiding treatment in both adults and children with asthma. FeNO is particularly useful in diagnosing asthma and determining which patients are likely to benefit from inhaled corticosteroids. Additionally, FeNO helps predict exacerbations and assess the potential for successful reduction or discontinuation of corticosteroid therapy.

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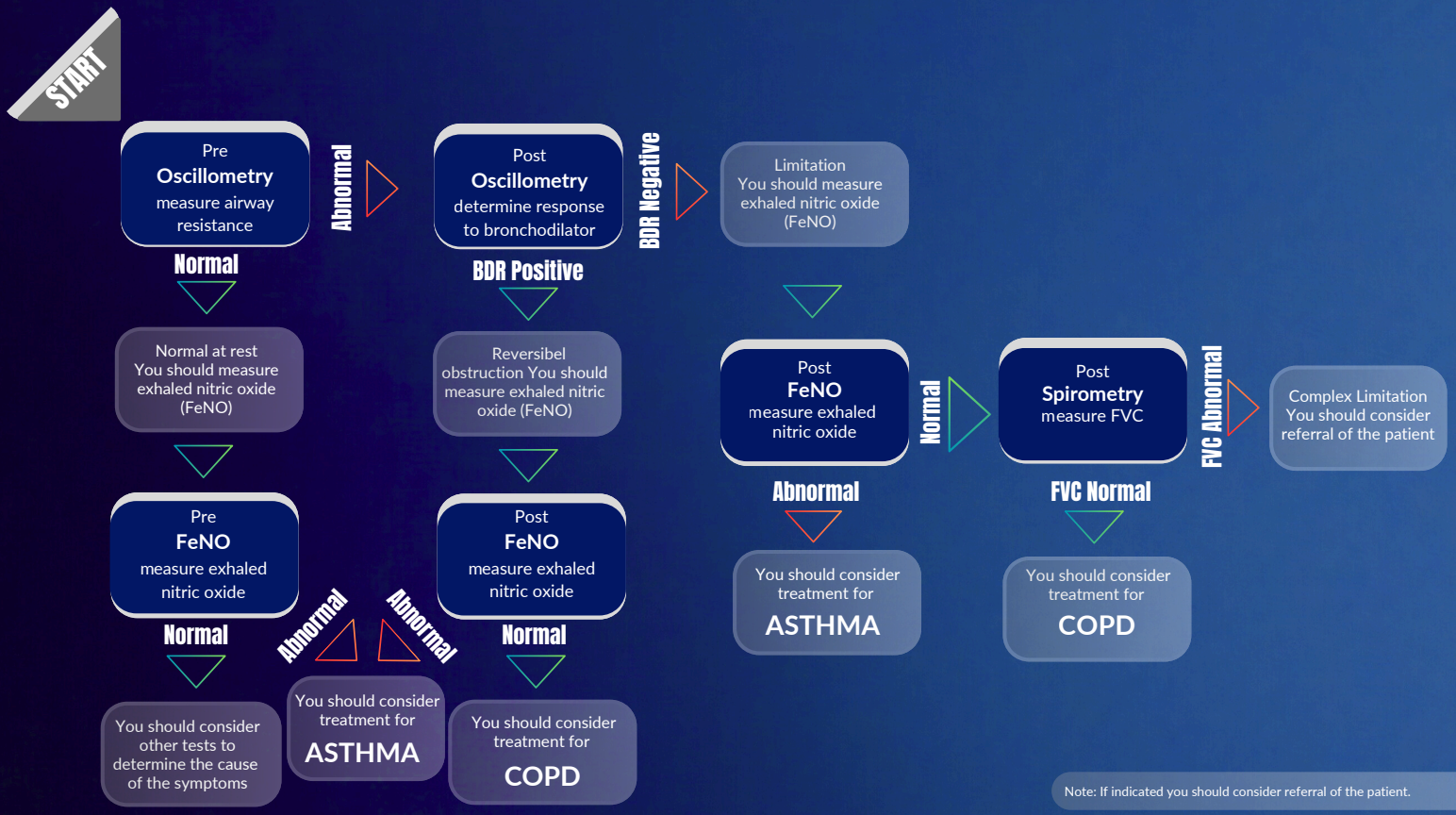
Clinical Pathway



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

Device Specification

Technical Parameters

Measurement Principle	Aay Oscillometry, Forced Oscillation Technique	Forced Spirometry	Exhaled Nitric Oxide (FENO)
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)	Nitric oxide gas sensor Nitric Oxide (NO) measurement: electrochemical FENO Range: 1 - 300 ppb FENO resolution: 0.3 ppb FENO accuracy: ±2 ppb below 50 ppb ± 10% 50 ppb and above Subtraction of ambient concentration of chemical NitricOxide-Scrubber to consider ambient nitric oxide for analysis.
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	none
Dead Space	40 mL(effective)	n.a.	n.a.
Data acquisition	Digital Resolution: 16 Bit Sampling rate: 500 Hz (pressure, flow)	Digital Resolution: 16 Bit Sampling rate: 500 Hz (flow)	Analogue
Calibration	No calibration needed Optional device check with 1.5 kPa*s/L reference test load (hardware included)	No calibration needed Optional device check with 3L calibration syringe (hardware not included)	Factory re-calibration Devices are regularly exchanged
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)	American Thoracic Society 2011
System requirements app	Cross-platform, Bluetooth Low Energy Operating systems: Windows 10, Windows 11, iOS14+ 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): 14x20x9 cm 6x9x4 in Weight: 600 g / 1.2 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

Class IIa Medical Device	Medical Device Regulation 2017/745 of the European Commission
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
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 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.

Exhaled Nitric Oxide (FENO)			
Clinical Outcome	Fractional concentration of Exhaled Nitric Oxide	FENO50	The fractional concentration of exhaled nitric oxide is a noninvasive marker of airway inflammation in asthma and many other disease entities, including COPD and cystic fibrosis.
Quality	Mean Exhalation Flow Rate	MEFR	Parameter indicating mean exhalation flow rate is 0.05 L/second (±10%) during the time of the exhalation.

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