

DEVICE

Air Next is a hand-held, Bluetooth-connected diagnostic spirometer for basic lung-function and spirometry testing — measuring FEV₁ and FVC in a forced expiratory maneuver. The patient exhales into a single-use turbine; airflow rotates a propeller whose rotations are counted by a digital infrared sensor and converted to flow on-board. Turbine properties are verified at manufacture, so no routine device calibration is required. Results stream live to the Air Next app (iOS & Android) for guided testing, review and sharing. The Air Next is FDA cleared and clinically validated for home use.

TECHNICAL SPECIFICATION

Dimensions	98 × 62 × 26 mm
Weight	~75 g (with batteries)
Turbine / mouthpiece	Disposable single-use + mouthpiece
Power supply	2 × AAA 1.5 V alkaline
Connectivity	Bluetooth · iOS & Android
Display	Paired smartphone / tablet
Calibration	Not required
Data storage	Air Next mobile app
Operating env.	+10 to +40 °C · 10–95% RH

PATIENT POPULATION

Age	≥ 5 years
Weight / height	> 10 kg / ≥ 110 cm
Assistance	Competent adult may assist

COMPONENTS INCLUDED

Air Next device · 1 × single-use disposable turbine · 2 × AAA alkaline batteries · user manual · cotton carrying bag

APPLICABLE STANDARDS

Spirometry	ATS/ERS 2005; ISO 26782:2009
Electrical safety	IEC 60601-1
EMC	IEC 60601-1-2
Usability	IEC 60601-1-6 / IEC 62366
Biocompatibility	ISO 10993-1, -5, -10

SPIROMETRY

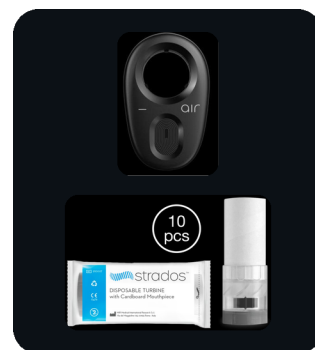
Flow sensor	Bi-directional digital turbine
Flow range	0–15 L/s
Volume range	Up to 10 L
Volume accuracy	±3% of reading / ±0.050 L*
Flow accuracy	±5% or 200 mL/s
Flow resistance	<0.5 cmH ₂ O/L/s
Test	Forced expiratory (FVC) · live coaching

MEASURED PARAMETERS

FEV₁, FVC, FEV₁/FVC, FEV_{0.75/3/6}, PEF, FEF_{25–75}, FEF_{25/50/75}, FEV₁/FEV₆, FIVC, FIV₁, PIF, FIF_{25–75}, FET — with flow-volume and volume-time curves and % predicted.

CERTIFICATES & REGISTRATIONS

FDA 510(k)	K231416
Regulation	21 CFR 868.1840
Regulatory class	Class II
Product code	BZG
Model	NVD-02
Predicate devices	K072979, K061712
Type of use	Prescription (Rx)



INDICATIONS FOR USE

The Air Next is intended to test lung function and spirometry in adults and children 5 years of age and older. It can be used in hospitals, in the clinical setting, and at home. The Air Next is not intended for use in an operating room. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.