



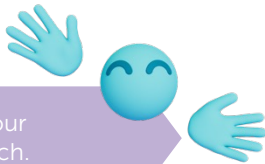
Medical Technologies

Inspiring innovation. Every day.

EasyOne Sky

Redefining spirometry with Buddy

Spirometry (FVC, FVL including pre/post testing)



Meet Buddy, your spirometry coach.

Buddy simplifies performing spirometry

- Encouraging incentives for patients
- Integrated coaching for better test results
- Immediate test feedback

n d d TrueFlow - The proven ultrasound technology

Simplifies high-quality spirometry

- Quickly and easily assess test quality and interpretation
- Calibration-free technology
- Accurate across broad flow ranges

n d d TrueFlow
makes the difference

n d d's unique ultrasonic flow measurement is highly accurate in all flow ranges, independent of gas composition, pressure, temperature and humidity.

n d d TrueFlow is a hygienic and resistance-free solution that does not require calibration during its lifetime.

n d d Cloud
simplifying workflows

n d d's modern and secure connectivity solution. Designed to connect to healthcare platforms and EHR/EMR systems.



Standards & Recommendations

Quality, electrical, medical devices

ISO 13485, ISO 14971, IEC 62366-1, IEC 60601-1, IEC 60601-1-2, 2012/19/EU, 2011/65/EU, 2015/863, 2006/66 EU, 2018/852, 2014/53/EU,

Market clearance e.g.

FDA 510(k)
EU MDR 2017/745

Standards

ATS/ERS 2019 Spirometry Standard

Languages – User Interface

English, Spanish

Users & Patients

User group

Healthcare professional

Age range (patient)

> 4 years

Technical Specifications

Dimensions

4.3 x 3.3 x 1.3" / 111 x 84 x 33 mm (L x H x W), 4.9 oz / 140 g (w/o battery)

Device classification

Type BF applied part

Operating conditions

Temperature:	41-104 °F 5-40 °C
Rel. humidity (non-condensing):	15-90%
Atmosph. pressure:	700-1060 hPa

Power source

2 x AA batteries (power consumption 0.3 W)

Communication interface

Bluetooth Low Energy V5.1 and higher

Data management

EasyOne Mobile

App compatibility

EasyOne Mobile app is compatible with



iOS and Android not available in all countries

Test	Test Description	Available Parameters
FVC	Forced expiratory vital capacity test	BEV, FEF ₂₅ , FEF ₂₅₋₇₅ , FEF ₅₀ , FEF ₇₅ , FET, FEV _{.75} *, FEV _{.75} /FVC*, FEV ₁ , FEV ₁ /FVC, FEV ₁ Q, FVC, PEF *only shown for children <6 yr
FVL	Flow volume loop test	BEV, FEF ₂₅ , FEF ₂₅₋₇₅ , FEF ₅₀ , FEF ₇₅ , FET, FEV _{.75} *, FEV _{.75} /FVC*, FEV ₁ , FEV ₁ /FVC, FEV ₁ Q, FVC, PEF, PIF *only shown for children <6 yr
Post	Post bronchodilator test	FVC %change, FEV ₁ %change

Predicted Normal Values – Spirometry

Global GLI (Bowerman) 2023, GLI (Quanjer) 2012, NHANES III (Hankinson) 1999

System Interpretation

ERS/ATS 2022, GOLD/Hardie

Flow/Volume Sensor

Type	Ultrasonic transit time
Flow range	± 16 l/s
Flow resolution	1 ml/s
Flow accuracy (except PEF)	± 2 % or 0.020 l/s
PEF accuracy	± 5 % or 0.2 l/s
Volume range	± 12 l
Volume accuracy	± 2 % or 0.050 l
Resistance	< 1.5 cm H ₂ O/l/s at 14 l/s

Order Information Accessories *

Part number	Product
5050-50	EasyOne FlowTube, individually wrapped, box of 50 pcs
5050-200	EasyOne FlowTube, individually wrapped, box of 200 pcs
5050-500	EasyOne FlowTube, individually wrapped, box of 500 pcs
2030-2	ndd calibration syringe 3L with EasyOne FlowTube Cal Check Adapter
5030-2	EasyOne FlowTube adapter
2800-50.1sp	EasyOne Sky Bluetooth dongle

Order Information Device *

Part number	Product
2800-1M	EasyOne Sky
2800-1D	EasyOne Sky incl. BLE dongle for PC use

* not available in all countries