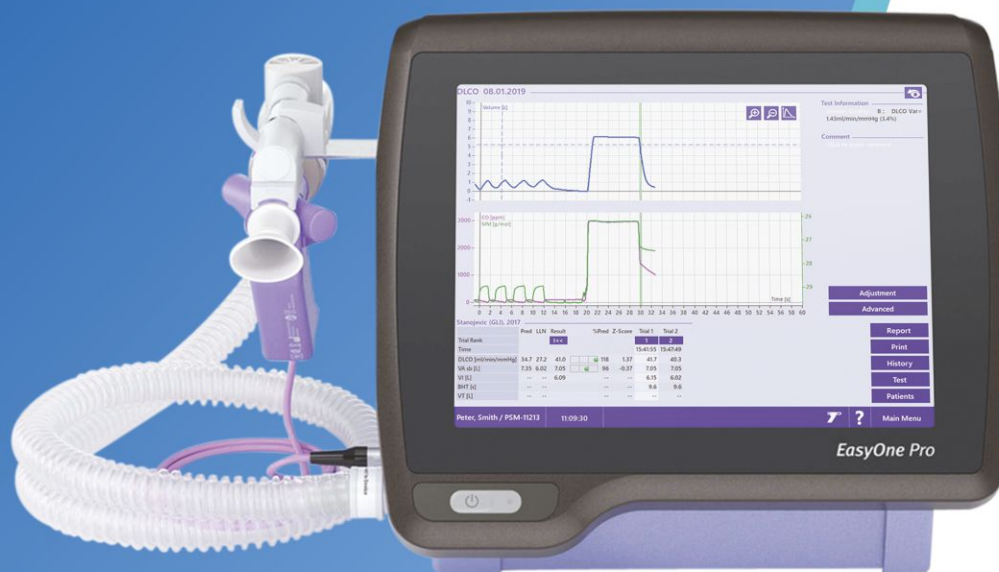


# EasyOne Pro

Advanced lung function testing with DLCO in a portable solution



## The Proven Ultrasound Technology

- No Calibration, No warm-up time, No moving parts
- Automated user guidance throughout maneuvers based on current ATS/ERS standards
- Z-score, LLN and % predicted for the fast interpretation of results
- Reproducible results ensure comparability in multicenter studies
- Real-time curves and pediatric incentives
- Immediate test quality feedback in accordance with ATS/ERS criteria
- Export of pdf files and raw data
- Flexible HL7 and XML interface for easy EMR integration
- Only 1 gas for DLCO, no calibration gas required
- Absolute hygienic solution with Filteratte consumables eliminates the risk of cross-contamination
- Compact device with smooth surface for easy and thorough cleaning
- Ungradable to N<sub>2</sub> washout FRC lung volume studies LCI and FeNO measurement

## Technical

Printing options	PCL standard, direct to printer or over network
Data Management	EasyWare Pro (SQLite, MS SQL Server)
Export	HL7, XML, GDT, via USB, LAN Network
Data links	Ethernet port, USB, possibility to upgrade to upgrade to WLAN
No. of tests	> 1 0,000 tests
Age range	Spirometry > 4 years DLCO > 6 years
Dimensions	27x33.5x27cm <sup>3</sup> (HxWxD), 8 kg
Device Classifications	Protection class I Type BF applied part
Operating Conditions	Temp 5-40°C / 41-104°F Rel. Humidity 15-95% No condensation Athmosph. Pressure 700-1060 hPa
Power Consumption	50 VA

## Gas Specification

DLCO	10% helium, ± 10% 0.3% carbon monoxide, ± 10% 18 to 25% oxygen (normally 21%) balance nitrogen
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## Standards & Recommendations

Quality, Medical Devices & Electrical	EN ISO 9001, EN ISO13485 EN ISO 14971, EN 62366, EN 62304, EN ISO 26782, EN ISO 23747, IEC 60601-1, IEC60601-1-2
FDA	510(k) market clearance
MDD 93/42/EEC	CE marked
Associations & Institutes	ATS / ERS 2005, NIOSH / OSHA SSA Disability

## Parameters

FVC	ATI, BEV, EOTV, FEF10, FEF25, FEF 2575, FEF2575_6, FEF40, FEF50, FEF50/FVC, FEF50/VCmax, FEF60, FEF75, FEF75-85, FEF80, FET, FET25-75, FEV.25, FEV.5, FEV.5/FVC, FEV.75, FEV.75/FEV6, FEV.75/FVC, FEV.75/VCmax, FEV1, FEV1/ FEV6, FEV1/FVC, FEV1/FVC6, FEV1/VCmax, FEV1/VCext, FEV3/FVC, FEV3/VCmax, FEV3, FEV6, FVC, FVC6, MEF20, MEF25, MEF40, MEF50, MEF60, MEF75, MEF90, MMEF, MTC1, MTC2, MTC3, MTCR, PEF, PEFT, t0, VCext, VCmax
FVL	ATI, BEV, CVI, E50/150, EOTV, FEF10, FEF25, FEF2575, FEF2575_6, FEF40, FEF50, FEF50/FVC, FEF50/VCmax, FEF60, FEF75, FEF75-85, FEF80, FET, FET25-75, FEV.25, FEV.5, FEV.5/FVC, FEV.75, FEV.75/FEV6, FEV.75/FVC, FEV.75/VCmax, FEV1, FEV1/FEV6, FEV1/FIV1, FEV1/FVC, FEV1/VCmax, FEV1/VCext, FEV3/FVC, FEV3/VCmax, FEV3, FEV6, FIF25, FIF50, FIF50/FEF50, FIF75, FIV.25, FIV.5, FIV1, FIVC, FVC, MEF20, MEF25, MEF40, MEF50, MEF60, MEF75, MEF90, MIF25, MIF50, MIF75, MMEF, MTC1, MTC2, MTC3, MTCR, PEF, PEFT, PIF, t0, VCext, VCmax
SVC	ERV, IC, IRV, Rf, VC, VCex, VCext, VCin, VCmax, VT
MVV	MVV, MVV6, MVVtime, VT
DLCO	BHT, COHb, ColBarVol, CO Conc, HE Conc, O2 Conc, Anatomic Dead Space, System Dead Space, Discard Volume, DLadj, DLadj/VA, DLCO, DLCO/VA (KCO), FA CO, FA HE, FE CO, FEV1/FVC, FI CO, FI HE, FRC sb, FRC Cor, Hb, tl, Kroghs K, PA02, RV sb, RV Cor, RV/TLC, RV/TLC Cor, TLC sb, TLC Cor, TLCO, VA sb, VA Cor, VCext, VCmax, Vd, VI

## Flow / Volume Sensor

Type	Ultrasonic transit time
Flow Range	± 16 l/s
Flow Resolution	4 ml/s
Flow Accuracy	± 2% or 0.02 l/s (except PEF)
Volume Resolution	1 ml
Volume Accuracy	± 2% or 0.050 l
PEF Accuracy	± 5% or 0.200 l/s
MVV Accuracy	± 5% or 5 l/min
Resistance	~ 0.3cm H <sub>2</sub> O/l/s at 16 l/s
Sample Rate	400Hz

## Gas Sensor CO

Type	Non- dispersive infrared
Range	0 to 0.35%
Resolution	0.0001%
Accuracy	± 0.001%

## Gas Sensor Helium

Type	Ultrasonic transit time
Range	0 to 50%
Resolution	0.02%
Accuracy	0.05%

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## Predicted Normal Values Spirometry

Asia	<b>Chhabra (India) 2014</b> , Dejsomritrutai (Thailand) 2000, Indonesia 1992, IP (China, Hong Kong) 2000 & 2006, JRS 2001 & 2014
GLI	Stanojevic 2009, Quanjer 2012
North America	NHANES III (Hankinson) 1999, Knudson 1983, Knudson 1976, Crapo 1981, Morris 1971 & 1976, Hsu 1979, Dockery (Harvard) 1993, Polgar 1971, Gutierrez (Canada) 2004, Eigen 2001
Latin America	Pereira 1992, Perreira 2006 & 2008, Pérez-Padilla (PLATINO) 2006, Pérez-Padilla (Mexico) 2001, Pérez-Padilla (Mexico, Pediatrics) 2003, Chile 2010, Chile (Pediatrics) 1997
Europe	ERS (ECCS, EGKS, Quanjer) 1993, Zapletal 1977, Zapletal 2003, Rosenthal 1993, Austria 1988, Austria 1994, Sapaldia (Switzerland) 1996, Roca (Spain, SEPAR) 1982, Garcia-Rio (SEPAR) 2013, Vilozni 2005, Falaschetti 2004, Klement (Russia) 1986
Europe Scandinavia	Hedenstrom 1985 & 1986, Gulsvik (Norway) 1985, Berglund Birath (Sweden) 1963, Langhammer (Norway) 2001, Finnish 1982 (1998), Nystad 2002
Australia	Hibbert 1989, Gore Crockett 1995
Africa	Ethiopia 1985

## Predicted Normal Values DLCO

Asia	<b>Chhabra (India) 2015</b> , Pereira 2008, Thompson 2008, Kim 2012, Ip (China, HongKong) 2007, JRS (Japan) 2001
North America	Ayers 1975, Burrows 1961, Crapo 1981 & 1982, Goldman Becklake 1958, Knudson 1987, McGrath Thompson 1959, Miller 1980, Gutierrez (Canada) 2004, NHANES (Neas) 1996, Polgar 1971
Latin America	Vazquez Garcia (ALAT) 2016
Europe	ERS (Quanjer) 1993, Zapletal 1977, Roca 1990 & 1998, Hedenström 1985 & 1986, Gulsvik 1992, Klement (Russia) 1986

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