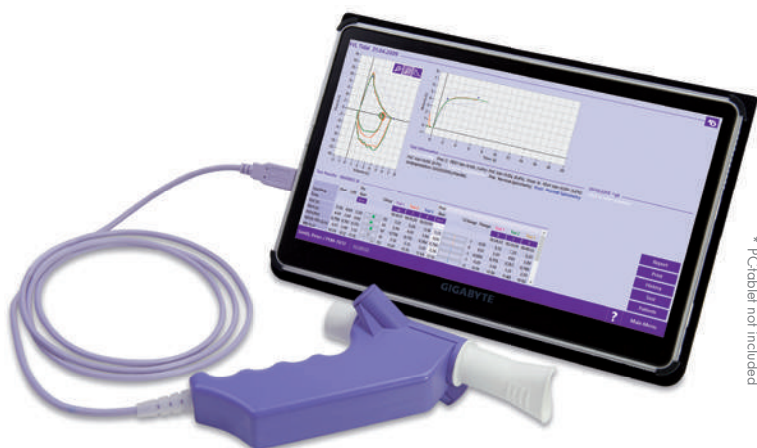




Spirometry (FVC, FVL, SVC, MVV, Provocation)



* PC/tablet not included

The proven ultrasound technology
n d d TrueFlow

no calibration, no warm-up time, no moving parts

Real time curves and pediatric incentives

Intuitive PC-based solution

Automated user guidance throughout maneuvers based on current ATS/ERS standards

Reproducible results ensure comparability in multicenter studies

Immediate test quality feedback in accordance with ATS/ERS criteria

Z-score, LLN and %predicted for fast interpretation of results

Export of pdf files and raw data

Flexible HL7 and XML interface for easy EMR integration

Absolute hygienic solution with Spirette consumable eliminates the risk of cross-contamination

Customizable reports

Powerful data-management



The original ultrasonic flow measurement is highly accurate in all flow ranges, independent of gas composition, pressure, temperature and humidity and does not require calibration during its life-time. The sensor is never in direct contact with the patient's flow. n d d TrueFlow is a hygienic and resistance-free solution.

Standards & Recommendations

Quality, Medical Devices & Electrical EN ISO 9001 , EN ISO 13485 , EN ISO 14971 , EN 62366 , EN 62304 , EN ISO 26782 , EN ISO 23747 , IEC 60601-1, IEC 60601-1-2

FDA 510(k) market clearance

MDD 93/42/EEC CE marked

Associations & Institutes ATS/ERS 2005, NIOSH/ OSHA, SSA Disability

Languages

English, French, German, Spanish, Italian, Brazilian-portuguese, Dutch, Russian, Vietnamese, Turkish, Chinese

Technical

Printing options direct to printer or over network

Data management EasyWare Pro (SQLite, MS SQL Server)

Interface HL7, XML, GDT

No. of tests > 10'000 tests

Age range Spirometry > 4 years

Device classification Type BF applied part

Operating conditions Temp 0 - 40 °C/32 - 104 °F
Rel. Humidity 5 - 95 %
Atmosph. Pressure 500 - 1060 hPA

Requirements PC/ Laptop

Hard disk capacity Installation/ system 1 GB
Data up to 4 GB

RAM 2 GB

Operating system Windows 7, Windows 8 and 8.1 (32 and 64 bit), Windows 10 (32 and 64 Bit)

Parameters

FVC	ATI, BEV, 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/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, to, 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, to, VCext, VCmax
SVC	ERV, IC, IRV, Rf, VC, VCex, VCext, VCin, VCmax, VT
MVV	MVV, MVV6, MVVtime, VT

Predicted normal values Spirometry

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	Hedenström 1985 & 1986, Gulsvik (Norway) 1985, Berglund Birath (Sweden) 1963, Langhammer (Norway) 2001, Finnish 1982 (1998), Nystad 2002
Australia	Hibbert 1989, Gore Crockett 1995
Asia	Chhabra (India) 2014, Dejsomritrutai (Thailand) 2000, Indonesia 1992, IP (China, HongKong) 2000 & 2006, JRS 2001 & 2014
Africa	Ethiopia 1985

Flow/Volume Sensor

Type	Ultrasonic transit time
Flow Range	± 16 l/s
Flow Resolution	4 ml/s
Flow Accuracy (except PEF)	± 2% or 0.02 l/s
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	~ 0.3 cm H ₂ O/l/s at 16 l/s
Sample Rate	400 Hz