

Vyntus™ ONE Technical Data Sheet

all-in-one system for pulmonary function and cardiopulmonary stress testing

vyaire™ MEDICAL

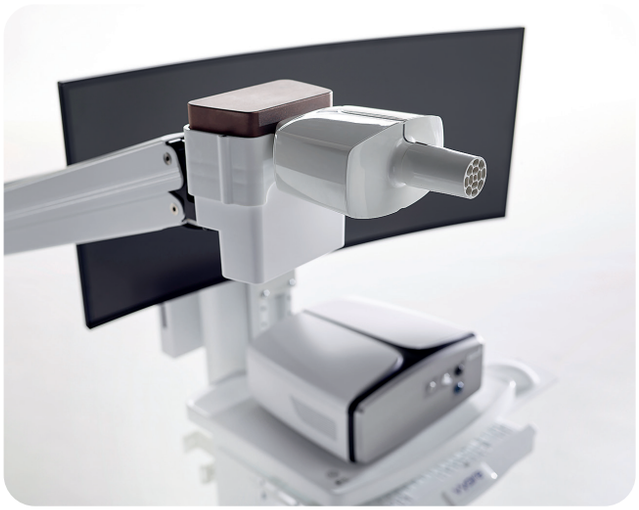
Vyntus™ ONE technical specifications

Measurement

Dynamic lung volumes:	FVC, FEV1, FEV1/FVC, MFEF 25-75, FEF 75, PEFand others
Static lung volumes:	Absolute lung volumes: TLC, FRCpleth, RV, RV/TLC and others; Static lung volumes: VC IN, VC EX, VC MAX, IC, ERV and others; Lung homogenity: LCI (lung clearance index)
Cardiopulmonary exercise-testing:	$V'O_2$, $V'CO_2$, RER, $V'O_2/kg$, $V'E$, BF, VTex, EqO_2, $EqCO_2$, BR FEV %, $PETO_2$, $PETCO_2$, REE, FAT, CHO, PROT and others
CO-diffusion real-time and CO-diffuison intra-breath:	DLCO, KCO, VA, TLC, FRCSB, RV and others
Options:	– Respiratory muscle strength (MIP/MEP) – Respiratory muscle strength (SNIP) – Respiratory drive (P0.1) – Airway resistance (Rocc/Rint) – Rhinomanometry – Compliance – Body plethysmography – Resting ECG – Stress ECG - SpO_2

Components

- Vyntus ONE module with fast reliable gas analyzers and container for easy O2 cell replacement
- Calibration-free and waterproof ultrasonic flow sensor
- Easy-to-clean Flow Path Valve with eDemand valve for test gas supply
- Digital Volume Transducer (DVT) for the exact CPET ventilation measurement
- PC with hygienic keyboard/mouse, printer and flatscreen monitor.
- Ergonomic, smooth-running cart with optional height adjustable keyboard/ mouse drawer, isolation transformer and flexible 3D arm.
- Set of accessories
- Complete software package for measurement and report generation plus extended infrastructure for data management



Vyntus™ ONE with ultrasonic flow sensor and eDemand valve for pulmonary function testing



Vyntus™ ONE with DVT and option Vyntus™ ECG for cardiopulmonary exercise testing

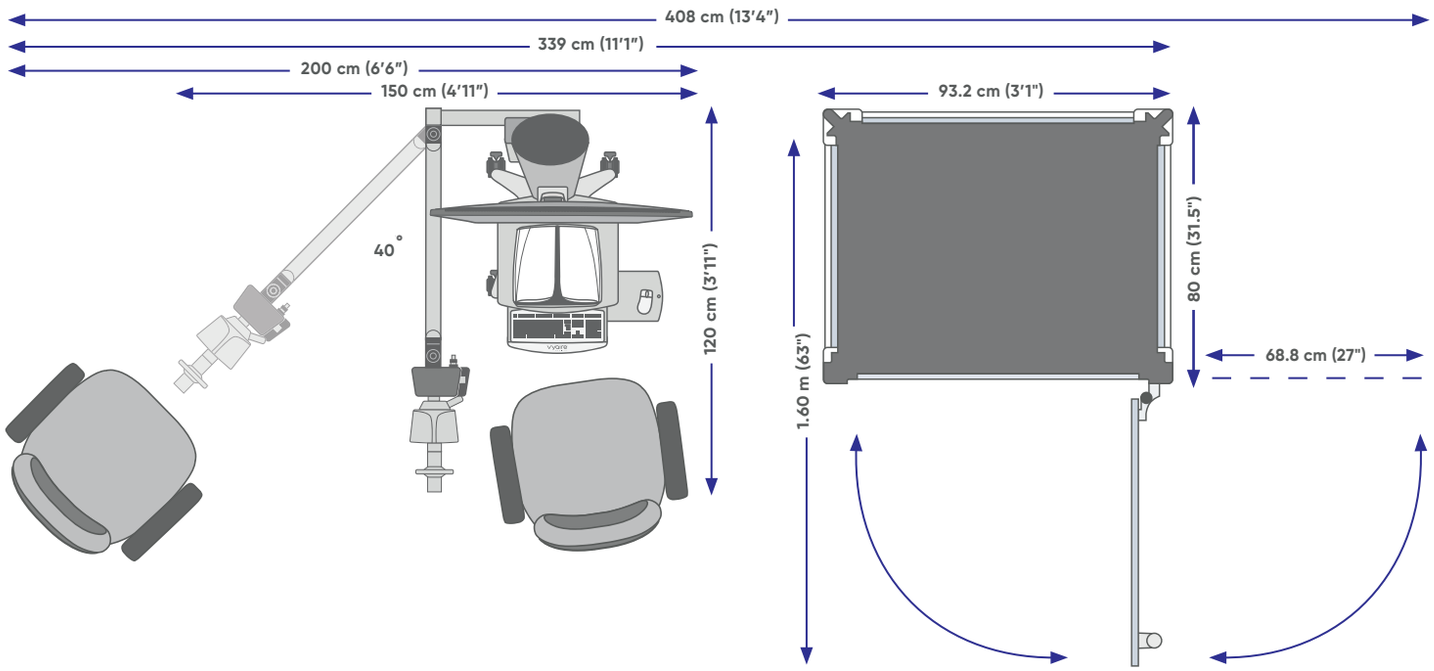
Required space

Vyntus ONE with Vyntus CART

200 x 160 cm (6’6” x 5’3”)

Vyntus ONE and Vyntus BODY with Vyntus CART

Space requirements with door 180 degrees open: 408 x 160 cm (13’4” x 5’3”).
With door 90 degrees open: 339 x 160 cm (11’1” x 5’3”)



Additional information

- The example layout is shown with 46 cm (1’6”) between the devices only as a suggestion.
- The USB cable connecting the box to the computer on the cart is 200 cm (6’6”)
- Hose length to reach gas tanks or wall gas supply is 300 cm (9’10”)
- For customers who purchase the Vyntus ONE which can also be used for exercise testing with a bike or treadmill. This would typically sit on the left side of this diagram but could be arranged in different ways depending on equipment and needs. The bike or treadmill will connect to the computer which sits on the back of the cart. Please refer to the space requirements for any bike or treadmill you may be using.

Ultrasonic flow sensor – PFT application

Flow measurement

Type	Ultrasound
Methodological peculiarities	Simultaneous measurement of ultrasound transit time in and against flow direction
Sample rate	True 1000 Hz for flow, achieved by 2000 ultrasound transit time measurements (double shot technology)
Range	0 to 18 L/s bidirectional
Accuracy	Exhalation 0 to 14 L/s: 1.5 % or 0.05 L/s (whichever is greater) Inhalation 0 to 14 L/s: 2.0 % or 0.05 L/s (whichever is greater)
Precision	1 % or 0.1 L/s (whichever is greater)
Resolution	0.001 L/s
Total resistance (MicroGard II filter + USS Module + FPV block eDemand)	< 0.150 kPa*s/L (< 1.53 cmH20*s/L) at 14 L/s
Dead space USS Module	66 mL

Volume integration

Principle	Software volume integration of flow signal (ultrasound)
Range	30 L (software limited)
Accuracy	Exhalation and inhalation 0.5 to 14 L/s: 2.5% or 0.075 L (75 mL)
Precision	1 % or 50 mL (whichever is greater)
Interface to PC	Resolution



Calibration-free and waterproof ultrasonic sensor

Mouth pressure measurement

Type	piezo resistive
Range	± 30 kPa (± 225 mmHg)
Accuracy	0 to ±2 kPa: ± 2 % or 0.02 kPa (0.150 mmHg) (whichever is greater)
Resolution	Polypropylene

O2 analyzer

Type	Fully digital, high speed analyzer, based on electrochemical principle
Measurement	0 – 100 vol %
Accuracy	0.05 vol % or 0.2 %
Resolution	0.01 vol %
Typical rise time (T10 – 90)*	75 ms
Service life	Typically 2 years

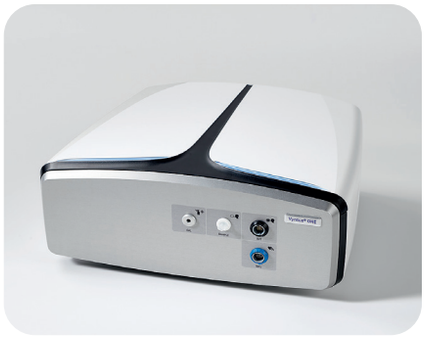


Vyntus ONE fits all kind of patients – also the little ones

CO_2 analyzer

Type	Fully digital, high speed analyzer, based on infrared absorption
Measurement	0 – 15 vol %
Accuracy	0.05 vol % or 1 %
Resolution	0.01 vol %
Typical rise time (T10 – 90)*	75 ms

* Rise time after digital filtering. During every gas calibration the filter coefficients are specifically optimized for the sensors.



Vyntus ONE main unit equipped with all PFT and CPET gas analyzers

Multigas analyzer ($CO/CH_4/C2H_2$) – Diffusion measurement

Type	Infrared
Range	0 – 0.4 vol %
Accuracy	0.003 vol % or 2 % relative (whichever is greater)
Resolution	0.0005 vol %
Maximum nonlinearity	±1 % of full scale
Response time	≤ 145 ms

Gas exchange CPET (physiological measurement)

Parameter	Measurement range	Accuracy
Ventilation (V'E)	0 to 300 L/min	2 % or 0.5 L/min
O_2 uptake (V'O2)	0 to 7 L/min	3 % or 0.05 L/min
CO_2 Production ($V'CO_2$)	0 to 7 L/min	3 % or 0.05 L/min
RER	0.6 to 2.0	4 % or 0.04



Vyntus ONE CPET application with bike or treadmill

Volume sensor CPET DVT (physiological measurement)

Type	Flat vane system
Weight	45 g
Dead space	30 mL
Resolution	3 mL
Resistance	< 0.1 kPa/L/s (0.75 mmHg/L/s) at 15 L/s
ATS	Compliant

Parameter	Measurement range	Accuracy
Volume	0 – 10 L	2 % or 0.05 L
Flow	0 – 15 L/s	3 % or 0.07 L/s



Digital Volume Transducer (DVT) for the exact CPET ventilation measurement

Ambient measurement

Sensor	Measurement range	Accuracy
Temperature sensor	– 10 to 50 °C (14 to 122 °F)	± 0.5 °C at 20 °C (68 °F) ± 1 °C at 10 to 34 °C (50 to 93.2 °F)
Humidity sensor	0 – 100 % relative humidity	4 % relative humidity at 20 – 80 % relative humidity
Air pressure sensor	500 to 1100 hPa (375 to 825 mmHg)	± 2.5 hPa (1.88 mmHg) at 700 to 1060 hPa (525 to 795 mmHg)

SpO_2 sensors

Displayed oxygen saturation range (SpO_2)	0 to 100 %
Displayed pulse rate range	18 to 321 beats per minute (BPM)
SpO_2 accuracy (Arms*)	± 3 digits @ 70 to 100 %

* ± 1 Arms represents approximately 68 % of measurements.



Vyntus™ ECG

Application	ECG recording	
ECG leads	According to Einthoven, Wilson, Goldberger	
Bandwidth	0.05 – 150 Hz digital	
Sampling rate per channel	500 Hz	
Pacemaker detection	4000 Hz	
Resolution	< 2.5 µV/bit	
Connection to the PC	Wireless, Bluetooth®	
Connection of the electrodes	4 mm snap, gilded or suction electrode	
Bluetooth®	Bluetooth® module	Panasonic PAN 1322
	Bluetooth® standard V2.1, class 2 device	V2.1, class 2 device
	Output power	2.5 dBm, max. 4.5 dBm
	Frequency range	2400 – 2483.5 MHz
	FCC identifier	T7VEBMU
	IC identifier	216QEBMU
	Bluetooth® QD ID	B021246

Gas concentrations

Diffusion gas

Methane (CH4)	0.3 % ± 0.021 %
Carbon Monoxide (CO)	0.3 % ± 0.021 %
Acetylene (C2H2) (optional)	0.3 % ± 0.021 %
Oxygen (O2)	21 % ± 1.47 %
Nitrogen	Rest



Oxygen O_2 gas

Oxygen (O2), medically pure	100 %

Calibration gas

Oxygen (O2)	16 % ± 0.8 %
Carbon dioxide (CO2)	5 % ± 0.3 % with accuracy of 1 % (relative)
Methane (CH4)	0.3 % ± 0.021 %
Carbon Monoxide (CO)	0.3 % ± 0.021 %
Acethylene (C2H2) (optional)	0.3 % ± 0.021 %
Nitrogen	Rest



Dimensions / Weight

Vyntus™ ONE module

Dimensions	33 cm W × 28.5 cm D × 13.5 cm H (13″ × 11.2″ × 5.3″)
Weight	3.99 kg (8.796 lbs)

Vyntus™ CART 3.0N/3.1N

Dimensions total		145 cm W × 118 cm D × 175 cm H (57.1″ × 46.5″ × 68.9″)
Weight total		71 kg (156.5 lbs) inclusive 24″ Monitor
Castors		4 twin swivel castors Ø 10 cm (3.9″), lockable, non marking grey polyurethane tyred
Shelves	Number	2
	Platform area	45 cm W × 36 cm D (17.7″ × 14.2″)
	Load capacity	20 kg (44 lbs) distributed load
Keyboard drawer with mousepad (left/right)	Keyboard platform area	40 cm W × 20 cm D (15.7″ × 7.9″)
	Load capacity	3 kg (6.6 lbs) distributed load
Mechanical height adjustment for keyboard/mouse and monitor (CART 3.1N only)	Type	Gas spring
	Range	30 cm (11.81″)
	Load capacity during height adjustment	10 – 16 kg (22 – 35.2 lbs)

Vyntus™ CART 3.0N/3.1N (continued)		
Computer holder for Dell OptiPlex Micro on the backside	Size inside	3.6 cm W × 17.8 cm D × 18.2 H (1.4″ × 7.0″ × 7.2″)
	Load capacity	1.5 kg (3.3 lbs)
Monitor mount	Load capacity	8.5 kg (18.7 lbs)
	Compatible with	VESA 75 and 100
34'' curved monitor as dual screen application (option)	Dimensions	ca. 82.5 cm W × 8.8 cm D × 36.1 cm H (32.5'' × 3.5'' × 14.2'')
	Weight	ca. 6.2 kg (13.7 lbs)
Dual gas bottle mount (option)	Load capacity	2 × 6.5 kg (14.3 lbs)
	Bottle diameter	max. 111 mm

Vyntus™ ECG		
ECG housing	Dimensions	9.5 cm W × 8.5 cm D × 2 cm H (3.7″ × 3.3″ × 0.8″)
	Weight	0.2 kg (0.4 lbs)
Length of electrode cables	V1 – V6	60 cm (23.6″)
	LL	45 cm (17.7″)
	LA / RL	70 cm (27.6″)
	RA	80 cm (31.5″)

Ambient conditions

Temperature	+10 °C to +34 °C (+50 °F to 93.2 °F)
Relative humidity	20 to 80 % RH, non-condensing
Ambient pressure	700 to 1060 hPa (525 to 795 mmHg)
Altitude	≤ 3000 m (9842 ft)

Transport and storage conditions

Temperature	– 20 °C to + 50 °C (– 4 °F to 122 °F)
Rel. humidity	15 to 95 % RH, non-condensing
Ambient pressure	600 to 1200 hPa (450 to 900 mmHg)



Power supply

Vyntus™ ONE main unit

Mains voltage	The Vyntus ONE is supplied by the isolating transformer of the Vyntus CART
Power input	max. 80 VA
Electrical safety	Protection class I

Vyntus™ CART 3.0N and 3.1N with PC/Monitor/Printer

Mains voltage	100 - 120 V AC, 50 / 60 Hz 220 - 240 V AC, 50 / 60 Hz
Power input	Bottle diameter
Electrical safety	Protection class I
Mains plug	Used for isolating all poles simultaneously from supply mains
Primary Fuse 220 - 240 V	2 × T3.15 AH / 250 VAC
Primary Fuse 100 - 120 V	2 × T6.3 AH / 250 VAC

Vyntus™ ECG

Supply voltage	1.5 V DC AA battery or 1.2 V DC AA NiMH rechargeable battery, at least 2500 mAh
Power input (max.)	500 mA
Service life with fully charged battery	at least 6 hours

Moisture Protection

Vyntus ONE	IP 20
Vyntus CART 3.0N / 3.1N	No IP protection
Vyntus ECG	IP 20



Classification of applied parts

Vyntus ONE	Applied Part Type B
Vyntus ECG	Applied Part Type CF, defibrillator proof

Category according to MDD 93/42/EEC (2007)

Complete system	Active class IIa medical product

Operating mode

Complete system	Continuous operation

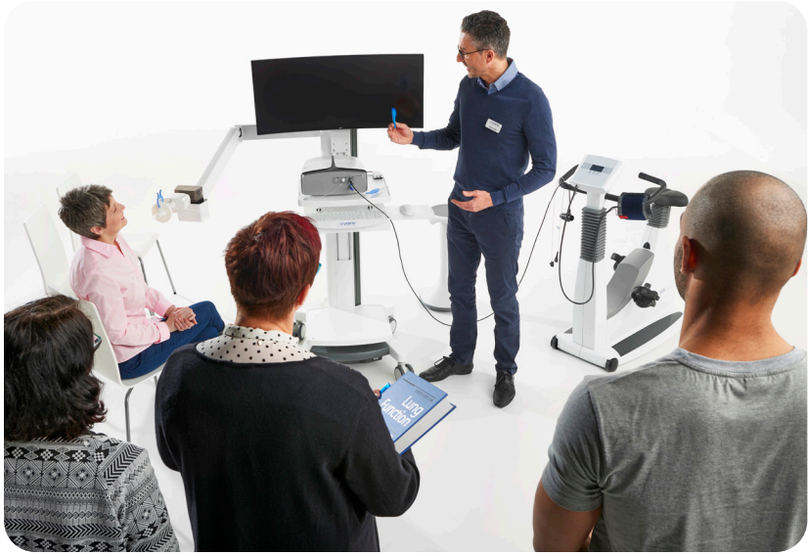
Standards, directives and market clearances

Standards	EN 60601-1, EN 60601-1-2, EN 60601-2-25 (for Vyntus ECG only) ,EN 62304, EN 62366, EN ISO 14971, EN ISO 10993-1
Directives	93/42/EEC amended by 2007/47/EC, RoHS 2011 / 65 / EU compliant
Market clearances	CE, FDA 510(k) clearance

Software			
Organization Programs	**Vyntus ONE DL**	**Vyntus ONE PFT**	**Vyntus ONE**
Slow/Forced Spirometry/MVV	✓	✓	✓
Spirometry Animation Programs for Forced Spirometry	✓	✓	✓
Single-Breath Diffusion Real-time	✓	✓	✓
Single-Breath Diffusion Intrabreath	✓	✓	✓
Noninvasive Cardiac Output C_2H_2*	o	o	o
Lung Volumes FRC N2 Washout and LCI	–	✓	o
Airways Resistance by R Occlusion	o	o	o
P 0.1	o	o	o
MIP / MEP	o	o	o
SNIP	o	o	o
Rhinomanometry	o	o	o
Compliance	o	o	o
Body plethysmography with Vyntus BODY	o	o	o
CPET breath by breath	–	–	✓
Resting ECG with Vyntus ECG	o	o	o
Stress ECG with Vyntus ECG	o	o	o
CardioSoft ECG GE Healthcare	–	–	–
Calibration Programs	**Vyntus ONE DL**	**Vyntus ONE PFT**	**Vyntus ONE**
Patient Data Management for advanced corrective actions	✓	✓	✓
Networking	–	–	✓
SentrySuite Mobile Review Web Application	✓	✓	✓

* Not available for the US

Legend: ✓ = standard | O = option | – = not possible



Software			
Organization Programs	Vyntus ONE DL	Vyntus ONE PFT	Vyntus ONE
SentrySuite™ home page (Settings, Export/Import)	✓	✓	✓
SentrySuite Review	✓	✓	✓
Patient Data	✓	✓	✓
Report Output (Print, View, Quick View, Save, PDF)	✓	✓	✓
Multiformat Output (JPG, TIFF, RTF and others)	✓	✓	✓
Auto Interpretation	✓	✓	✓
ATS / ERS Quality Check	✓	✓	✓
Comments / Physician Interpretation	✓	✓	✓
Report Designer for generating customized reports	✓	✓	✓
Predicted Values / Reference Sets Design / Editor	✓	✓	✓
Bronchial Challenge Generation	o	o	o
CPET Layout Editor	–	–	✓
CPET Profile Editor	–	–	✓
User Parameter Editor for customized parameters	o	o	o
Offline Data Input	✓	✓	✓
SentrySuite (SeS) Quality Management	✓	✓	✓
Log file viewer	✓	✓	✓
Backup/Restore	✓	✓	✓
InterConnectivity Manager for interface with JLAB / Vmax / SPCS platforms	✓	✓	✓
GDT connection (German standard)	✓	✓	✓
Questionnaire Designer for customized questionnaires	o	o	o
Security and User Administration	o	o	o
SentryConnect for HIS integration via HL7	o	o	o
Spirometer Data Transfer (FlowScreenTM, SpiroProTM, MicroLoop, MicroLab)	✓	✓	✓
Bloodgas Data Transfer	o	o	o
SeS SQL Database Interface Query / DataCube	o	o	o
Patient Data Management for advanced corrective actions	o	o	o
Networking	o	o	o
SentrySuite Mobile Review Web Application	o	o	o

Legend: ✓ = standard | O = option | – = not possible

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