Datasheet

Servo-air Ventilator System v4.6

GETINGE

1 Available modes and functions

X = standard — = not applicable O = option

Modes/Functions	Configuration
PC	X
PRVC	O
VC	X
Bi-Vent/APRV	O
PS/CPAP	X
VS	O
Automode	O
SIMV (PC) + PS (PRVC) + PS (VC) + PS	 X O X
NIV PC	O
NIV PS	O
High Flow therapy	O
CO_2 analyzer	O
Servo Compass	O
Nebulizer	X
Alarm output connection	O

2 System

General	
Standards	▪ IEC 60601-1: 2005 + A1:2012 + A2:2020, Class I, continuous operation Applied parts – Equipment making physical contact with the patient and the gas path ways. Type B – Nebulizer patient unit and cable. Type BF – CO_2 sensor. Type BF ▪ ISO 80601-2-12:2020 ▪ ISO 80601-2-55:2018 ▪ ISO 80601-2-90:2021 ▪ EN 13544-1:2007 + A1:2009
Electromagnetic disturbance	According to IEC 60601-1-2:2014 + A1:2020.

General	
Patient category	**Tidal volume** ▪ Pediatric: 20 - 400 ml ▪ Adult: 100 - 2000 ml **Patient weight** ▪ Pediatric: 5 - 50 kg ▪ Adult: 15 kg and above
Ingress protection	IP 21
Noise	▪ A-weighted sound power level (LWA): <61 dB

Operating conditions	
Operating temperature range	10 to 40°C
Relative humidity	15 to 95 % non-condensing
Atmospheric pressure	660 to 1060 hPa
Lowest pressure in patient circuit	-400 cmH_2O

Non operating conditions	
Storage temperature	5 to 40°C
Storage relative humidity	5 to 85% non-condensing
Storage atmospheric pressure	660 to 1060 hPa

Power supply	
Power supply, automatic range selection	Rated input power ▪ 100 - 240 V AC ±10%, 50-60 Hz
Typical mean power consumption, range	30 - 100 W
External 12 V battery	12.0 V lead acid battery, minimum 7 Ah Applicable standard: UL 1989
Battery module	▪ 1 - 2 battery modules rechargeable 14.4 V ▪ Battery backup time factory new battery 2 h fully charged. ▪ Typical recharge time approximately 2 h/battery (90%), up to 4 h (100%) if battery is completely discharged. Usable backup time depends on set mode and selected ventilation settings.

3 Ventilator system

General	
Dimensions	▪ User interface: W 300 x D 34 x H 248 mm ▪ Patient unit: W 375 x D 350 x H 275 mm
Weight	Approx. weight: 17 kg

Gas supply	
Ambient air	Dust and HEPA filtered ambient air.
Gas quality, O_2	Supplied gas must meet the requirements for medical grade gases according to applicable standards.
Inlet gas, O_2	▪ Pressure: 2.0 – 6.0 kPa x 100 (29 – 87 psi)
Connection standards available	AGA, DISS, NIST, or French

Patient system connectors	
Conical fittings	Nominal 22 mm and 15 mm, in accordance with ISO 5356-1
Gas exhaust port	Male 30 mm cone

4 Inspiratory channel

Inspiratory channel	
Pressure drop	Maximum: 6 cmH_2O at a flow of 60 l/min
Gas delivery system	Air turbine and O_2 valve
Gas delivery device	▪ Flow range: – Pediatric: 0 - 240 l/min – Adult: 0 - 240 l/min ▪ Maximum pressure setting: – Pediatric: 80 cmH_2O – Adult: 100 cmH_2O
NIV max. leakage compensation level	▪ Pediatric: Inspiratory leakage up to max inspiratory flow. Expiratory leakage up to 25 l/min. ▪ Adult: Inspiratory leakage up to max inspiratory flow. Expiratory leakage up to 65 l/min.
Inspiratory tidal volume	Air/O_2 Setting range: ▪ Pediatric: 20 - 400 ml ▪ Adult: 100 - 2000 ml
High Flow therapy	Flow setting range: ▪ Pediatric: 2 - 50 l/min. ▪ Adult: 5 - 60 l/min. Inaccuracy: ±(0.5 l/min + 8% of set value)

5 Expiratory channel

Expiratory channel	
Pressure drop	Maximum: 3 cmH_2O at a flow of 60 l/min
Internal compressible factor	Maximum: 0.1 ml/cmH_2O
PEEP regulation	Microprocessor controlled valve
Expiratory flow measurements	▪ 0 - 192 l/min
Bias flow during expiration	2 l/min

6 Display

Views	▪ Basic ▪ Advanced ▪ Loops ▪ Distance ▪ Family ▪ Servo Compass (option)
Real time waveforms	▪ Pressure ▪ Flow ▪ Volume ▪ CO_2 (option)
Loops	▪ Pressure – Volume ▪ Volume – Flow A reference loop and three overlaying loops can be displayed.
Servo Compass	Visualizes volume (VT/PBW) and pressure (total or driving) in relation to set targets in invasive modes.

7 Ventilatory settings

Settings	Setting range	
		
Maximum apnea time in Automode (s)	3 – 15	7 - 12
Breath cycle time, SIMV (s)	0.5 - 15	1 - 15
Respiratory rate (b/min)	4 - 150	4 - 100
Respiratory rate (b/min) in NIV	4 - 150	4 - 100
Circuit compensation	ON/OFF	ON/OFF
Flow trigger level in invasive modes, (l/min)	0 - 2	0 - 2
I:E ratio	1:20 - 4:1	1:20 - 4:1
I:E ratio in backup	1:20 - 4:1	1:20 - 4:1
End inspiration (% of peak flow)	1 - 70	1 - 70
End inspiration (% of peak flow) in NIV	10 - 70	10 - 70

Settings	Setting range	
		
Inspiratory rise time (%)	0 - 20	0 - 20
Inspiratory rise time (s)	0 - 0.5	0 - 0.5
Inspiratory rise time (s) in NIV	0 - 0.5	0 - 0.5
Minute volume (l/min)	0.3 - 20	0.5-60
Nebulizer	ON/OFF	ON/OFF
Nebulizer time (min)	5 - 30, continuous nebulization	5 - 30, continuous nebulization
O_2 boost level (%)	0 - 79	0 - 79
O_2 concentration (%)	21 - 100	21 - 100
PEEP (cmH_2O)	0 - 50	0 - 50
PEEP in NIV (cmH_2O)	2 - 20	2 - 20
Phigh (cmH_2O)	2 - 50	2 - 50
Pressure trigger level (cmH_2O)	-1 - -20	-1 - -20
Pressure level above PEEP (cmH_2O)	0 - 80	0 - 100
Pressure level above PEEP in NIV (cmH_2O)	0 - 60	0 - 60
Pressure level above PEEP in backup (cmH_2O)	5 - 80	5 - 100
Pressure level above PEEP in NIV backup (cmH_2O)	5 - 60	5 - 60
PS above PEEP in Bi-Vent/APRV (cmH_2O)	0 - 80	0 - 100
PS above Phigh in Bi-Vent/APRV (cmH_2O)	0 - 78	0 - 98
Respiratory rate in backup (b/min)	4 - 150	4 - 100
SIMV frequency (b/min)	1 - 60	1 - 60
Thigh (s)	0.2 - 30	0.2 - 30
Ti (s)	0.1 - 5	0.1 - 5
Ti in backup (s)	0.1 - 5	0.1 - 5
Tidal volume (ml)	20 - 400	100 - 2000
Tidal volume in backup (ml)	20 - 400	100 - 2000
Tpause (%)	0 – 30	0 – 30
Tpause (s)	0 - 1.5	0 - 1.5
TPEEP (s)	0.1 - 10	0.1 - 10
VC Flow pattern (%)	0-100	0-100
Flow in High Flow therapy (l/min)	2 - 50	5 - 60

8 Alarms

Parameter	Setting range	
		
Airway pressure, upper limit (cmH_2O)	16 - 90	16 - 100
Airway pressure, upper limit (cmH_2O) in NIV	16 - 70	16 - 70
Airway obstructed pressure limit (cmH_2O)	—	—
Apnea time to alarm (s)	2 - 45	15 - 45
Expiratory tidal volume low (ml)	5 - 440	50 - 1900
Expiratory tidal volume, high (ml)	6 - 450	60 - 2000
End expiratory pressure, upper limit (cmH_2O)	1 - 55	1 - 55
End expiratory pressure, lower limit (cmH_2O)	0 - 47	0 - 47
Expired minute volume, lower limit (l/min)	0.1-15	0.5 - 40
Expired minute volume, upper limit (l/min)	0.15 - 20	1 - 60
Respiratory rate, lower limit (b/min)	1 - 159	1 - 159
Respiratory rate, upper limit (b/min)	2 - 160	2 - 160
$etCO_2$ Lower alarm limit		
%	0.5 - 19.9	0.5 - 19.9
mmHg*	4 - 149	4 - 149
kPa*	0.5 - 19.9	0.5 - 19.9
$etCO_2$ Lower alarm limit in NIV		
%	0 - 19.9	0 - 19.9
mmHg*	0 - 149	0 - 149
kPa*	0 - 19.9	0 - 19.9
$etCO_2$ Upper alarm limit		
%	0.6 - 20	0.6 - 20
mmHg*	5 - 150	5 - 150
kPa*	0.6 - 20	0.6 - 20
$etCO_2$ Upper alarm limit in NIV		
%	0.5 - 20	0.5 - 20
mmHg*	4 - 150	4 - 150
kPa*	0.5 - 20	0.5 - 20

9 Trends

Peak airway pressure	Ppeak
Pause airway pressure	Pplat
Mean airway pressure	Pmean
Driving pressure	Pdrive
Positive end expiratory pressure	PEEP
Spontaneous breaths per minute	RRsp
Respiratory rate	RR
Spontaneous expiratory minute volume	MVe sp
Inspired minute volume	MVi
Expired minute volume	MVe
Leakage (%)	Leakage
Inspired tidal volume	VTi
Expired tidal volume	VTe
End expiratory flow	Flowee
Measured oxygen concentration	O_2 conc.
CO_2 end tidal concentration	etCO_2
CO_2 minute elimination	VCO_2
CO_2 tidal elimination	VTCO_2
Dynamic compliance	Cdyn
Static compliance	Cstatic
Inspiratory resistance	Ri
Expiratory resistance	Re
Work of breathing, ventilator	WOBvent
Work of breathing, patient	WOBpat
Elastance	E
P 0.1	P 0.1
Shallow Breathing Index	SBI
Ratio of expired tidal volume to predicted body weight	VT/PBW
Switch to backup (/minute)	Backup Σ
Backup (%/min)	Backup %
Ratio of tidal volume to predicted body weight *Based on VTe*	VT/PBW
Switch to backup (/minute)	Backup Σ
Backup (%/min)	Backup %

10 Aerogen nebulizer

10.1 Aerogen Solo nebulizer

Aerogen Solo nebulizer	
Weight	Approximate 13.5 g
Dimensions	W 48 x L 25 x H 67 mm
Operating temperature	10°C to 38°C
As measured with the Anderson Cascade Impactor:	
Specification range Average tested	1 - 5 µm. 3.1 µm
As measured with the Marple 298 Cascade Impactor:	
Specification range Average tested	1.5 - 6.2 µm. 3.9 µm
Flow rate	>0.2 (average: ~0.38) ml/min
Max volume, medication cup	6 ml
Residual volume	<0.1 ml for 3 ml dose
Control cable	1.8 m
Lifetime	▪ Intermittent use a maximum of 28 days based on a typical usage profile of four treatments per day. ▪ Continuous use a maximum of 7 days. Do not exceed the recommended usage time.

11 CO_2 analyzer

General - CO_2 analyzer	
Measured parameters	▪ CO_2 End Tidal Concentration ▪ CO_2 Minute Elimination ▪ CO_2 Tidal Elimination The End Tidal CO_2 Concentration is measured as the maximum CO_2 concentration during the expiration.
Measuring method	Mainstream, dual-wavelength, non-dispersive infrared.
Oxygen concentration compensation	Automatic. Values supplied from the ventilator system
Barometric pressure compensation	Automatic. Values supplied from the ventilator system

CAPNOSTAT 5 - CO_2 analyzer	
Size	Sensor: 32.0 x 47.0 x 21.6 mm
Weight	▪ Sensor: 20 g ▪ Airway adapter: 10 g
Sensor cable	2.8 m
Measuring range	▪ 0 to 100 mmHg CO_2 partial pressure ▪ 0 to 13.3 kPa CO_2 partial pressure ▪ 0 to 13.2 % CO_2 volume (at a barometric pressure of 1013 hPa)

CAPNOSTAT 5 - CO_2 analyzer	
Warm-up time	15 s to initial CO_2 indication maximum 2 minutes to full specification
Digitizing rate	100 Hz
Airway adapter dead space	▪ Pediatric: <1 cm^3 ▪ Adult: <6 cm^3

12 Communication/interface

Communication/interface	
Serial ports	Isolated RS-232C. For data communication via the Servo Communication Interface (SCI) Information regarding connector wiring is available from the manufacturer.
Servo Communication Interface (SCI)	A protocol for data communication with external devices
Alarm output connection (option)	Isolated 4-pin modular connector for communication of all active alarms Switching capability: Max 40 V DC, Max 500 mA, Max 20 W Information regarding connector wiring is available from the manufacturer.
Data Transfer via USB port	Non-isolated For transfer of trends, logs, screen shots and recordings to a USB memory stick

13 Accessories

To avoid instability, load the ventilator equipment symmetrically on the ventilator system.

Mobile cart (option)	
Weight	15.0 kg
Dimensions	W 647 x L 547 x H 860 mm

Storage bin (option)	
Weight	0.9 kg
Dimensions	W 331 x L 223 x H 104 mm
Load weight	2.5 kg

Humidifier holder (option)	
To avoid instability, mount the humidifier holder in the front part of the carrier.	
Weight	0.5 kg
Dimensions	W 76 x L 125 x H 140
Maximum load	5 kg (excluding water bag/IV pole)

Water bag/IV pole (option)	
Weight	0.4 kg
Dimensions	W 148 x L 26 x H 1007
Maximum load	1.5 kg

Support arm 179 (option)	
Weight	1.9 kg
Dimensions	Length 900 mm
Maximum load	0.5 kg

Gas cylinder restrainer kit (option)	
Weight	1.0 kg
Dimensions	Upper: W 104 x L 65 x H 48 Lower: W 106 x L 162 x H 76
Maximum load	Two 8 kg bottles

Shelf base (option)	
Make sure that the shelf base is securely fixed on the table or shelf.	
Weight	3.0 kg
Dimensions	W 340 x L 270 x H 43

Y piece holder (option)	
Dimensions	W 42 x L 52 x H 46

Cable holder for handle (option)	
Weight	0.1 kg
Dimensions	W 138 x L 92 x H 155
Maximum load	2.5 kg

Other accessories (option)	
Expiratory heater, Servo Duo Guard	Refer to the Expiratory heater, Servo Duo Guard User's Manual.
Servo Duo Guard	Refer to the Servo Duo Guard User's Manual.
Servo Guard	Refer to the Servo Guard User's Manual.
Fisher & Paykel Healthcare, MR850 Respiratory humidifier	Refer to the Fisher & Paykel Healthcare, MR850 Respiratory humidifier User's Manual.
Fisher & Paykel Healthcare, MR810 Respiratory humidifier	Refer to the Fisher & Paykel Healthcare, MR810 Respiratory humidifier User's Manual.
Fisher & Paykel Healthcare, F&P 950 Respiratory humidifier	Refer to the Fisher & Paykel Healthcare, F&P 950 Respiratory humidifier, User instructions.

Refer to Servo-air system flowchart for information regarding use of accessories to be used with the ventilator system.

14 Logs

14.1 Event log

The following events are logged:

- Activation/deactivation of clinical alarms
- Ventilator settings
- Apnea periods
- Manual breath
- O_2 boost
- Activation/deactivation of circuit compensation

14.2 Diagnostic log

The following items are logged:

- Technical information
- Test results
- Service records
- Software installation
- Configuration information

15 Service

Preventive maintenance must be performed by authorized personnel at least once every 5000 hours of operation or once every 12 months, whichever comes first.

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