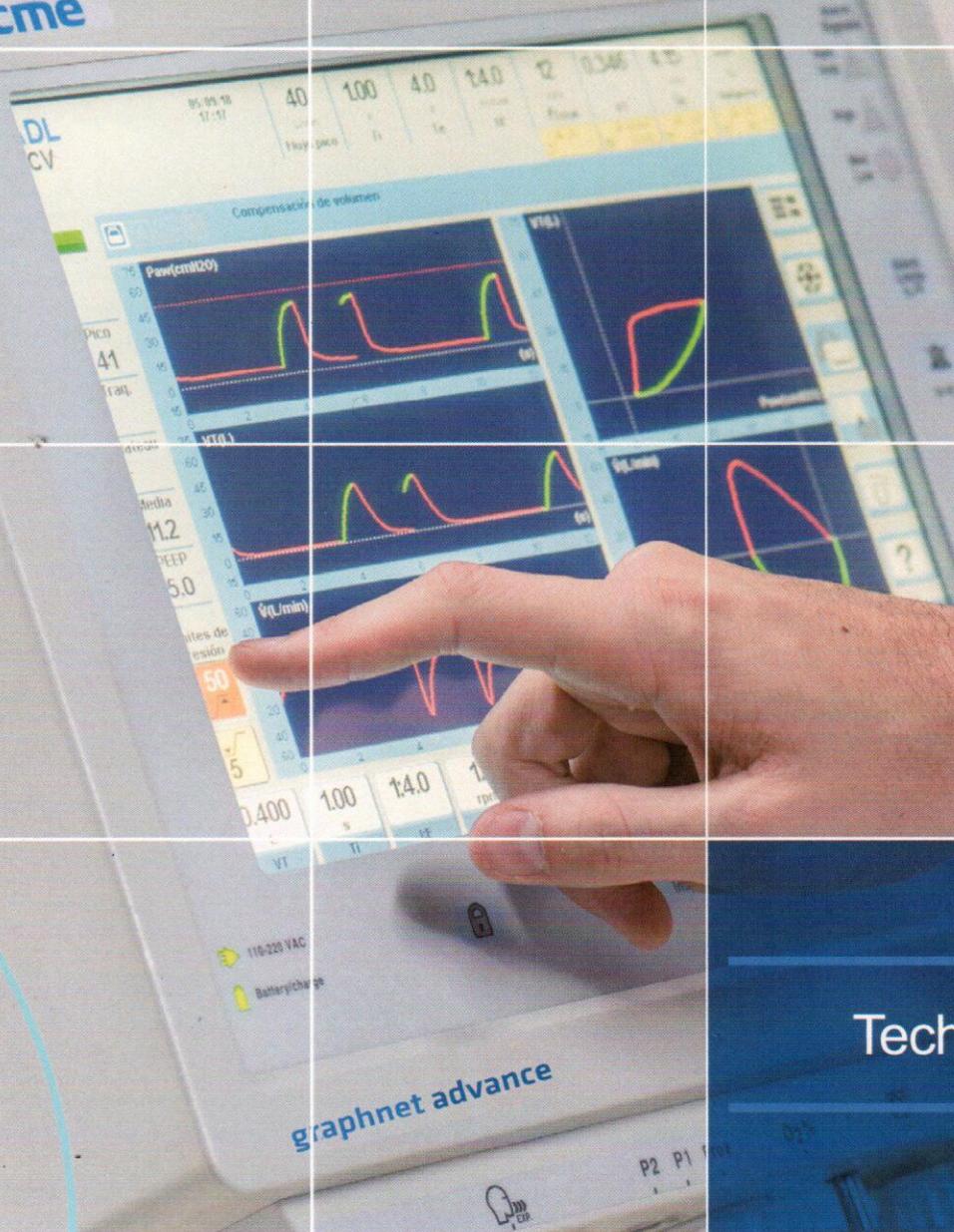


Tecme



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Technical Data Sheet

Tecme

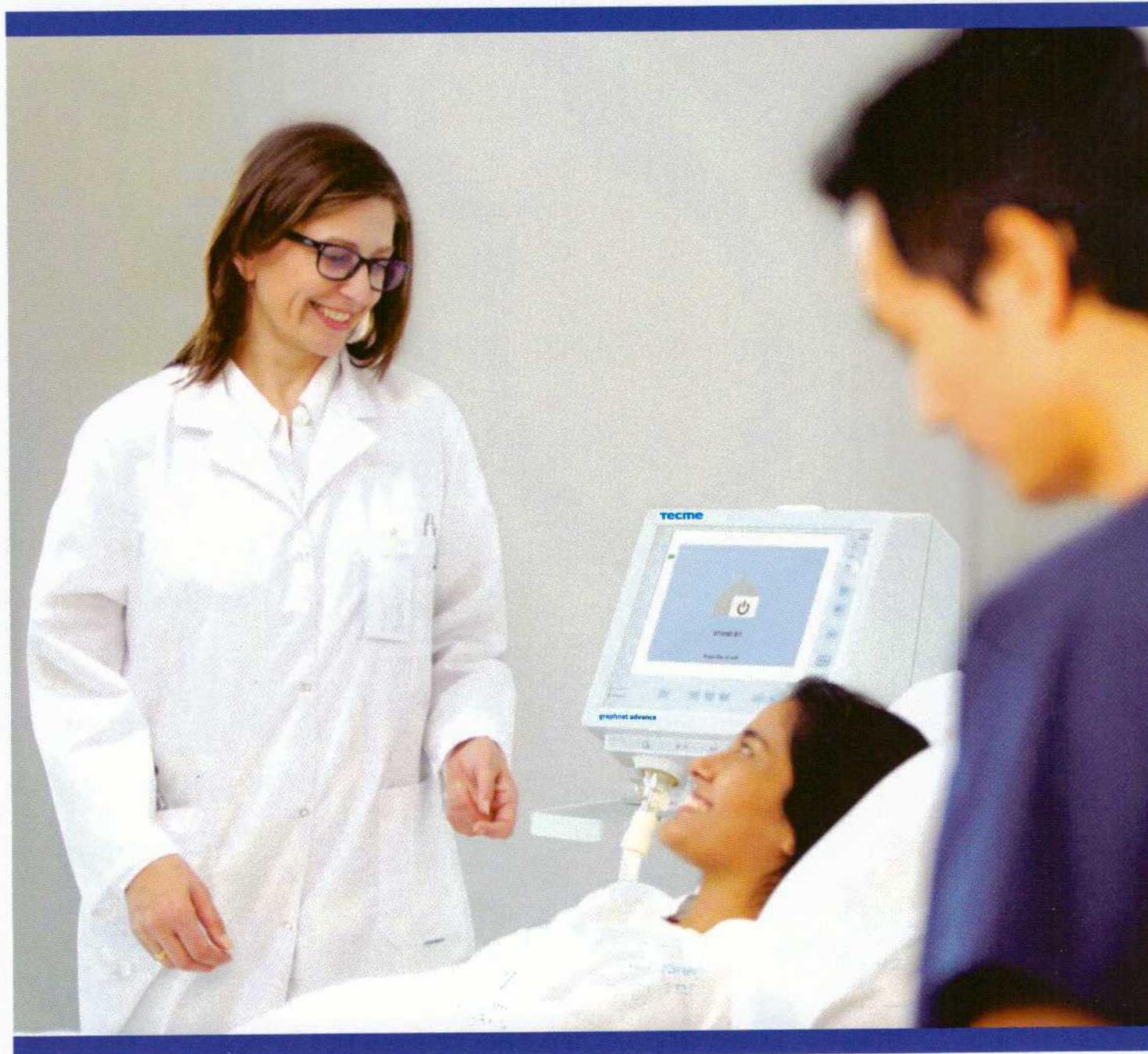
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— INTENDED USE

The microprocessed GraphNet advance ventilator is designed to be used with all types of patients: adult, pediatric, and neonatal infants requiring invasive and noninvasive ventilatory support, for a short or long period, allowing monitoring of the main ventilatory parameters.

The equipment provides care for patients able or unable to make their own breathing efforts.



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INTENDED USE

The microprocessor based GraphNet Advance ventilator is designed for Invasive and Non-invasive ventilation to be used with all types of patients: adult, pediatric, and neonatal infants (including premature weighing from 300 Gms) requiring invasive and noninvasive ventilatory support, for a short or long period, allowing monitoring of the main ventilatory parameters. The equipment provides care for patients able or unable to make their own breathing efforts

OPERATIVE MODES

ADULTS AND PEDIATRICS

- VCV – Volume Control (Assisted/Controlled).
- PCV – Pressure Control (Assisted/Controlled).
- PSV – Pressure Support.
- CPAP – Continuous Positive Airway Pressure.
- SIMV (VCV) + PSV.
- SIMV (PCV) + PSV.
- SIMV (PRVC) + PSV (*# Optional and Up-gradable*)
- MMV + PSV – Mandatory Minute Ventilation.
- PSV + Tidal Volume Assured.
- VSV - Volume Support Ventilation (*# Optional and Up-gradable*)
- APRV – Airway Pressure Release Ventilation (with BIPAP/Bi-level capability & Inverse Ratio Ventilating)
- PRVC – Pressure Regulated Volume Control.
- NIV – Non-Invasive Ventilation (Spontaneous & Bi-level (PCV)
- AVA – Adaptive Ventilatory Assistance (*# Optional and Up-gradable*)
- HFNC – High Flow Nasal cannula O₂ Therapy (*# Optional and Up-gradable*)

NEONATES-INFANTS

- VCV – Volume Control (Assisted/Controlled).
- PCV – Pressure Control (Assisted/Controlled).
- PSV/CPAP – Pressure Support / Continuous Positive Airway Pressure.
- SIMV (VCV) + PSV.
- SIMV (PCV) + PSV.
- SIMV (PRVC) + PSV (*# Optional and Up-gradable*)
- TCPL – Time Cycled Pressure Limited.
- SIMV (TCPL) + PSV.
- Nasal CPAP with Continuous Flow (with leak compensation for NIV).
- NIV – Non-Invasive Ventilation
- VSV - Volume Support Ventilation (*# Optional and Up-gradable*)
- APRV – Airway Pressure Release Ventilation with bi-phasic capability
- PRVC – Pressure Regulated Volume Control.
- HFNC – High Flow Nasal cannula O₂ Therapy (*# Optional and Up-gradable*)

(All modes are with Volume and leakage compensation.

All Spontaneous Modes are with Bi-directional (Auto-Switch over) Apnea back up ventilation mode)

PARAMETER SELECTION

(according to operative mode and patient category)

- Tidal Volume: 2 - 4000 mL
- Programmable Minute Volume (MMV + PSV): 1.0-50 L/min.
- Resulting Minute Volume: 0.01-130 L/min.
- Inspiratory Time: 0.1-10 s (30 s in APRV).
Minimum time: 0.1 to Timax and Maximum time: Timin to 10
- I: E Ratio: 5:1 - 1:599.
- Respiratory Rate (Contr. Mode): ADL: 1-100 bpm. PED/NEO-INF: 1-150 bpm.
- Respiratory Rate (SIMV) ADL: 1-100 bpm. PED/NEO-INF: 1-150 bpm.

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- FiO₂: 0.21-1.0.
- Inspiratory sensitivity: Flow Triggered: 0.2-15 L/min. Pressure Triggered: 0.2-20 cmH₂O below PEEP.
- Expiratory sensitivity for Spontaneous breaths: 5%-80% of the initial peak flow (flow cycle)
- PEEP/CPAP: 0-50 cmH₂O.
- Rise Time (Pressure Ramp) – Graphical representation (5 adjustments available which depends on Inspiratory time).
- Controlled Pressure (PCV): 2-100 cmH₂O.
- Support Pressure (PSV): 0-100 cmH₂O.
- Inspiratory Pause (programmable in VCV): 0 - 10 s or 0 – 80% of Ti
- Expiratory Pause: 0 - 20 s (manual)
- Inspiratory Flow Waveform (in VCV): Rectangular and Descending Ramp.
- Inspiratory Flow: 0.2-180 L/min.
- Continuous Flow in O₂ therapy:

Adult	1 – 80 LPM
Pediatric	1 – 60 LPM
Neonatal	1 – 20 LPM

- Continuous Flow (NEO-INF): 2-40 L/min in TCPL & N CPAP mode
- Limited Pressure in TCPL (NEO-INF): 2-70 cmH₂O.
- Maximum pressure limited (safety limits): up to 120 cmH₂O.
- Automatic Bias Flow.

MONITORED PARAMETERS

- Peak Inspiratory Pressure
- Plateau Pressure
- Tracheal Pressure
- Mean Airway Pressure
- PEEP/ CPAP
- Inspired & Expired Tidal Volume
- Minute Volume (Inspired & Expired) & Spontaneous Minute Volume
- Inspiratory Flow, Expiratory Peak flow (End Exp. Flow)
- Respiratory Rate (Total & spontaneous rate)
- Inspiratory & Expiratory Time, I: E Ratio
- Leak Volume (lpm) & leak in %
- O₂ concentration (FiO₂ real time)
- Ratio C20/C
- EtCO₂ measurement in mmHg (optional)

MONITORING WAVEFORM & LOOPS

- Pressure Vs Time
 - Volume Vs Time
 - Tracheal Pressure Vs time
 - Flow Vs Time
 - EtCO₂ Vs Time (Optionally available with Capnography)
 - Pressure Vs Volume
 - Flow Vs Volume
 - Pressure Vs Flow
 - Tracheal Pressure Vs Volume
 - EtCO₂ Vs Volume (Optionally available with Capnography)
 - Maximum 5 graphs can be viewed simultaneously (Combination of Waveforms and loops)
- Four loops can be saved as reference loops and can be recalled at any time. Maximum 4 loops or 4 graphs can be viewed simultaneously. Facility of Automatic and Manual scaling for all waveforms and loops

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MONITORED PARAMETER ACCURACY

Parameter Accuracy

Peak Pressure	±2 cmH ₂ O or ±10%
Plateau pressure	±2 cmH ₂ O or ±10%
Mean Pressure	±2 cmH ₂ O or ±10%
Base pressure	±2 cmH ₂ O or ±10%
Expired tidal volume	±10% if VT < 20 mL; ±2 mL + 10% if VT > 20 mL
Minute volume	±10%
Inspiratory flow	±10%
Respiratory rate	±1 rpm
Inspiratory time	±0.06 s
Expiratory time	±0.06 s
O ₂ concentration	±3%

RESPIRATORY MECHANICS

Selection by onscreen menu & depending on patient category

- Auto PEEP (Intrinsic PEEP)
- Dynamic and static compliance
- Inspiratory and Expiratory Resistance
- Slow Vital Capacity (Non-forced)
- P0.1.Occlusion Pressure
- PV Flex - Inflections Points (UIP & LIP measurement)
- Pi max (Maximum Inspiratory Pressure -MIP/ Negative inspiratory Force NIF)
- Trapped volume measurement
- Physiological Dead Space
- F/VT Index (Rapid Shallow breathing index) and RVR [rpm/L/kg] for NEO/INF
- Oxygenation Measurement of Oxygenation index and PaO₂/FiO₂
- WOBi (imposed work of breathing)
- TCexp (expiratory time constant)
- Exhaled tidal volume per kg of patient weight
- Stress Index
- SBT - Spontaneous breathing trial with cursor for measurement (*# Optional and Up-gradable*)

CAPNOGRAPHY (ETCO₂)

- Capnography (EtCo₂) Curves of CO₂/Time and Volumetric Capnography (CO₂/VT).
- Measurements of ETCO₂ (partial pressure of CO₂ at the end of expiration),
- Derive values (Alveolar Ventilation, Dead Space, CO₂ Elimination (VCO₂), VD/VT Ratio, CO₂ expired volume (VTCO₂), etc.)
- Estimated physiological dead space (Bohr estimated)
- Monitoring Range: 0.1 – 150 mmHg

The capnograph (sensor) is an optional accessory.

ALARMS

Visual and audible signals according to priority and messages on the screen. The system keeps a record of the occurred events with name, date, and time. This record is printable and cannot be deleted. The system allows the deactivation of Tidal Volume alarms in NIV and Apnea alarm in CPAP Continuous Flow (NEO-INF)

Adjustable

Inspiratory pressure	High	Low
Tidal Volume (with Volume limit and ml/kg of ideal body weight limit feature)	High	Low
Minute Volume (Expired)	High	Low

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Apnoea		5 - 60 sec
PEEP	High 0-6 CmH ₂ O above PEEP set	Low 0-6 cmH ₂ O below PEEP Set
Respiratory Rate	High	3 - 160 B/min
O ₂ Percentage	High	Low
EtCO ₂	High	Low
(optional with capnography)	> Min to 150	1 < Max
F/VT	High	65 – 200 (bpm/litre)
SBT	Aborted	Finalised 10 – 120 Min
Non Adjustable		
Continuous high pressure	5 cmH ₂ O above set PEEP for over 15sec	
Main Power loss	Will automatically switch over to Battery operation (Indicator available)	
Dead Battery	Null or very low charge level	
Inop. Vent	Ventilator is inoperative	
Oxygen not adequate	If O ₂ % falls below 18	
Low battery		
Air Pressure	Low	
O ₂ Pressure	Low	
Disconnection		
Leak out of range		
Target volume not reached		
Emergency Ventilation		
Defective battery		
Nebulization interrupted		
Stand-by		
Transporting		
SBT aborted		
Technical Failure Alarms		
PEEP Valve fail		
Expiratory Valve fail		
Flow Sensor fail		
Fan Failure		
Sound Controller fail		

OTHER FEATURES AND CONTROLS

- Trends (up to 72 hrs.) with adjustable resolution from 1 min to 7 min
- Loops: Pressure vs Flow, Pressure vs Volume y Volume vs Flow. 4 loops can be saved as reference loops.
- Movable measurement cursor for PV loops in PV flex measurement
- In VCV mode selection of - Tidal Volume + Inspiratory Time or Tidal Volume + Inspiratory flow
- Sighs (in VCV) with Pressure limit
- Alarm sound volume regulation (Sound Level: 60.3 dBA to 74.7 dBA)
- The device can save more than 5000 different events. They are classified as follows:
 - i. Alarms / warnings: activated alarms during the ventilation and warnings shown during the self-test
 - ii. Adjustments: operative mode, settings and ventilatory adjuncts
 - iii. States: Turn on, turn off, Standby, transport, calibrations and battery charge

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- Suction %O₂: for suction sequence with variable FiO₂ and Suction time.
- Nebulizer- Volume, Pressure, & FiO₂ Compensated pneumatic Nebulizer
- Manual Inspiration
- Inspiratory/Expiratory Pause (manual with timer alert): Inspiratory Pause: 0 - 10 s or 0 – 80% of Ti (Inspiratory Time) and
Expiratory Pause: 0 - 20 s
- Adjustable Apnea back up ventilation mode as per user's choice with VCV/PCV/ TCPL depends on patient category selected
- Standby function
- Watchdog
- Inspiratory relief valve (anti-suffocation)
- Total Valve response time approx. 4.5 msec (+/-15%)
- Pneumatic safety valve: 120 cmH₂O (±5)

COMPLEMENTARY FUNCTIONS

- Altitude compensation for volume correction
- Apnea backup ventilation with user selectable backup modes and parameters (VCV/ PCV/ TCPL as per the patient category)
- Automatic calibration of all valve and sensor on start -up
- Body temperature volume correction (BTPS)
- Volume correction according to patient circuit compliance (Automatic Circuit Compliance compensation)
- Calculation of Patient circuit resistance for better estimation for pressure at Y piece
- Automatic detection of patient's disconnection during suction procedure
- Leak compensation available in all operative's modes and can be switched ON/OFF

Mode	Category		
	ADL	PED	NEO-INF
NIV	60 L/min	30 L/min	10 L/min
Remaining modes	15 L/min	15 L/min	10 L/min

- Cooling Mechanism: Internal Dual Cooling FAN assembly
- VCV mode protocol – Vt + Inspiratory time OR Vt + Peak flow setting.
- Endotracheal tube resistance compensation: compensation of 10%-100% for ET tube diameter Ø 2.5-12 mm.
- Tidal Volume setting based on Ideal Body Weight (IBW). IBW setting minimum 0.3 kg and onward
- Manual calibration of proximal flow sensor
- Intra-hospital transport: facilitates the mobilization when the ventilator can only be supplied with oxygen bottles

CONNECTIVITY

- RS-232C with DB-9 connector (With USB port available)
- VGA out for External / Additional Display
- HL7 compatible

DISPLAY

- 12.1" Resistive sensitive touch screen color TFT-LED, Resolution 800x600

DISPLAY INDICATOR

- Simultaneous view of - Set, Monitored & Alarm Parameters, Date & Time, Battery usage & Status, Main Power, Warning, Patient category & mode name

- **Direct Front Panel Access**

Alarm Signal

Priority Alarms

Alarm Limits

Set Alarm Limits

Pause Audio

Silence alarm 30 - 60 sec

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Menu	
Mode	
Lock Screen	
Suction O2	
Manual Insp.	Combination key
Insp/Exp Pause	
Ctrl	Escape
Esc	
Rotary Knob	
Electrical power source indicators	

PHYSICAL CHARACTERSTICS

Height 35 cm (13.8 in)

Width 36 cm (14.2 in)

Depth 32 cm (12.6 in)

Height including the pedestal 131 cm (51.6 in)

Weight not including the pedestal 9.8 kg (21.6 lb.)

Weight including the pedestal 23.8 kg (52.5 lb.)

Width of the pedestal 51 cm (20.1 in) - 65 cm with lateral wheels (25.6 in).

Depth of the pedestal 52 cm (20.5 in) - 59 cm with in-line wheels (23.2 in)



ELECTRICAL REQUIREMENTS

- Main Power: 100-240 V / 50-60 Hz. Automatic voltage switching ($\pm 10\%$)
- Internal Battery: 11.1 V / 7.8 Ah. Automatic recharge. Estimated duration: 2.5 hrs. When fully charged. Charge level indicator onscreen.
- Maximum consumption 0.5 Amp. At 110 Volts – 0.3 Amp. At 220 Volts
- Protection: Replaceable Fuse at Mains inlet.

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PNEUMATIC REQUIREMENTS

- Gases supply:
 - Oxygen: Pressure 2.8-6 bar (approx. 41-87 psi). Connector: DISS 9/16"-18.
 - External Air: Pressure 2.8-6 bar (approx. 41-87psi). Connector: DISS 3/4"-16.
- (Additional wide range is available on request for inlet pressure)
- Automatic gas switching when one of them is absent in order to allow patient ventilation with the remaining gas.

CLEANING AND MAINTENANCE

- The equipment enclosure must be externally cleaned and disinfected, using any of the following products:
 - Hydro alcoholic / quaternary ammonium solvent-based cleaner (such as benzalkonium chloride).
 - Glutaraldehyde at 2%.
- The expiratory set is autoclavable. It supports 50 autoclaving cycles if the following parameters are selected: 20 minutes at 121 °C - 2 hours; or 15 minutes at 134 °C - 1.5 hours.

ENVIRONMENTAL REQUIREMENTS

Environmental Requirements			
Temperature	Ambient pressure	Humidity	
Operation	15 °C – 40 °C	560 – 1030 hPa	15 - 95% non-condensing
Storage	-5 °C – 70 °C	500 – 1060 hPa	< 95% non-condensing

CLASIFICATION & STANDARDS

Risk:

- Class IIb (Council Directive 93/42/EEC).
- Class III (MERCOSUR/GMC/RES. N° 40/00).

Electrical Insulation: • Class I – Type B (according to IEC 60601-1).

IP Protection: • IP21 (IEC 60529).

Operational mode: • Continuous Operation (IEC 60601-1).

Standards:

- IEC 60601-1 ed3.0 (2005-12) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- ISO 80601-2-12 ed1.0 (2011-05) Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators.
- IEC 60601-1-2 ed3.0 (2007-03) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -

Requirements and tests.

- IEC 60601-1-6 ed3.0 (2010-01) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 60601-1-8 ed2.0 (2006-10) Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- IEC 60601-1-9 ed1.1 (2013-06) Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design.
- IEC 62366 ed1.0 (2007-10) Medical devices - Application of usability engineering to medical devices.
- IEC 62304 ed1.0 (2006-05) Medical device software - Software life cycle processes.
- ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.
- IEC 60068-2-27 ed4.0 (2008-02) Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock.
- IEC 60068-2-64 ed2.0 (2008-04) Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance.
- IEC 60068-2-31 ed2.0 (2008-05) Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens.

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INCLUDED STANDARD ACCESSORIES

- Reusable patient circuit Adult
- Reusable and autoclavable expiratory valve with Differential Pressure sensing type flow sensor
- Flexible Support arm with tubes holder.
- Water filter for compressed air inlet.
- Air supply high pressure hose (3 meters) with 3/4"-16H DISS connectors.
- O₂ supply high pressure hose (3 meters) with 9/16"-18H DISS connectors.
- DispO. Pneumatic Nebulizer (complete kit).
- O₂ sensor (Galvanic) Life up to one year; operating life varies based on oxygen usage and ambient temperature).
- Test lung.
- Four-wheel cart (with brakes).

OPTIONAL ACCESSORIES

- Heated- Servo controlled /non- servo controlled Humidifier with all accessories and chamber
- Fix orifice proximal pneumotacograph flow sensor for NEO-INF. Sensing Position –Near patient Y piece
- Micro pump nebulizer Aeroneb®Pro from Aerogen.
- Non-Invasive Reusable & Autoclavable Mask with Ball & Socket headgear with Removable forehead
- NCPAP Kits
- Capnography (EtCO₂) - Capnostat 5® Mainstream or Loflow Side stream

	Capnostat 5 Sensor	Loflo Sensor
Transducer Type	Mainstream CO ₂ Sensor	SideStream CO ₂ Sensor
Principle of Operation	Non-dispersive infrared (NDIR) single beam optics, dual wavelength, no moving parts	Non-dispersive infrared (NDIR) single beam optics, dual wavelength, no moving parts
Sample Flow Rate	NA	50 mL/minute ±10 mL/minute
Initialization Time	Capnogram, displayed in less than 15 seconds at an ambient temperature of 25°C, full specifications within 2 minutes	Capnogram, displayed in less than 15 seconds at an ambient temperature of 25°C, full specifications within 2 minutes
CO ₂ Measurement Range	0 to 150 mm Hg, 0 to 19.7%, 0 to 20 kPa (at 760 mm Hg) Barometric Pressure supplied by host	1 to 150 mm Hg, 0 to 19.7%, 0 to 20 kPa (at 760 mm Hg) Barometric Pressure supplied by host
Rise Time	Less than 60 ms - Adult Reusable or Single-Patient-Use Airway Adapter Less than 60 ms - Infant Reusable or Single-Patient-Use Airway	Less than 60 ms
CO ₂ Resolution	0.1 mm Hg 0 to 69 mm Hg 0.25 mm Hg 70 to 150 mm Hg	0.1 mm Hg 0 to 69 mm Hg 0.25 mm Hg 70 to 150 mm Hg
CO ₂ Accuracy	0 – 40 mm Hg ±2 mm Hg	1 – 40 mm Hg ±2 mm Hg
	41 – 70 mm Hg ±5% of reading	42 – 70 mm Hg ±5% of reading
	71 – 100 mm Hg ±8% of reading	72 – 100 mm Hg ±8% of reading
	101 – 150 mm Hg ±10% of reading	102 – 150 mm Hg ±10% of reading
Respiration Rate	0 to 150 Breaths Per Minute (BPM)	1 to 150 Breaths Per Minute (BPM)
Respiration Rate Accuracy	±1 breath	±1 breath
Calibration	No routine user calibration required. An airway adapter zero is required when changing to a different style of airway adapter.	No routine user calibration required. An airway adapter zero is required when changing to a different style of airway adapter.

*Note: Modes & Features vary with the selected patient category.

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Optional Accessories

Medical Air compressor

The Neumovent Air Compressor provides clean and dry compressed air for medical ventilators. It can be used as a primary source of air or an automatic backup system, in case of a failure of the main source of air in the medical facility.

The Neumovent Air Compressor is available for use with all Neumovent Ventilators: Advance, Neo and Ts. Also, it's available the Compressor Trolley making a fully integrated system.

Features	Alarms	Indications
Small	Temperature	Outlet pressure
Compact	Pressure	Working hours
Advanced design	Power	Drying



486712V

Technical specification

	Neumovent Air Compressor
Nominal voltage and frequency (*)	230 V/50Hz - 115 V/60 Hz
Compressor efficiency	50 l.min ⁻¹ /3,5bar
Peak flow	200 l.min ⁻¹
Air tank capacity	2 lit.
Filtration of air to	5 µm
Dew point depression at 3 bar, 20°C	5°C under the ambient temperature
Dew point depression at 3 bar, 20°C, with membrane dryer.	10°C under the ambient temperature
Outlet connection	DISS 1160-A (3/4"-16 UNF)
Mode of the operation	Continuous - S1
Wall connection	yes
Classification according to	class II.b
MDD 93 / 42 / EEC, 2007 / 47 / EC	
Noise level	≤ 50 dB [A]
Dimensions (w x d x h) (**)	445 x 355 x 440 mm
Weight (**)	34 kg

specifications are subject to change without notice

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50 years of innovation and development in mechanical ventilators.

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