



neumovent[®]
GraphNet advance

Committed to life

INTENDED USE

The GraphNet advance ventilator was 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.

CLASSIFICATION

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:

- EN ISO 13485:2012/AC:2012 - Medical devices. Quality management systems. Requirements for regulatory purposes (ISO 13485:2003).
- EN 60601-1:2006 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005).
- EN ISO 80601-2-12:2011/AC:2011 - Medical electrical equipment. Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO 80601-2-12:2011/Cor 1: 2011).
- EN 60601-1-2:2007/AC:2010 - Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007).
- EN 60601-1-6:2010 - Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability (IEC 60601-1-6:2010).
- EN 60601-1-8:2007/AC:2010 - 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 60601-1-8:2006).
- EN 60601-1-9:2008/AC:2013 - Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design (IEC 60601-1-9:2007/A1:2013).
- EN 62304:2006/AC:2008 - Medical device software. Software life cycle processes (IEC 62304:2006).
- EN 62366:2008 - Medical devices. Application of usability engineering to medical devices (IEC 62366:2007).

PHYSICAL CHARACTERISTICS

- 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).

OPERATING CONDITIONS

	Temperature	Ambient Pressure	Humidity
Operation	15 - 35 °C	560 - 1030 hPa	15%-95% non-condensing
Storage	- 10 °C - 55 °C	500 - 1060 hPa	< 95 % non-condensing

SCREEN

- Type: Resistive sensitive Touch Screen / color TFT-LED.
- Size: 12, 1".
- Resolution: 800x600.

GRAPHICS

GraphNet advance has 7 different screens to organize different curves and patient information.

- Five Curves: Pressure, volume and flow; and pressure/volume and flow/volume loops.
- Two Curves: Pressure and flow.
- Three Curves: Pressure, flow and volume.
- Loops: Pressure/volume, flow/volume and flow/pressure loops.
- Patient's Data: Pressure, volume and flow curves with patient data sheet.
- Capnography: Pressure, volume, flow and partial CO₂ pressure curves. Capnography data sheet and CO₂/volume curve.
- Numerical data: Numerical control of the following ventilation parameters:
Peak pressure, PEEP, volume per minute, tidal volume, respiratory rate, oxygen concentration.

OPERATIVE MODES

ADULTS AND PEDIATRICS:

- VCV – Volume Control (Assisted/Controlled).
- PCV – Pressure Control (Assisted/Controlled).
- PSV – Pressure Support.
- VSV – Volume Support.
- PRVC – Pressure Regulated Volume Control.
- CPAP – Continuous Positive Airway Pressure.
- SIMV (VCV) + PSV.
- SIMV (PCV) + PSV.
- SIMV (PRVC) + PSV.
- MMV + PSV – Mandatory Minute Ventilation.
- PSV + Tidal Volume Assured.
- APRV – Airway Pressure Release Ventilation.
- NIV – Non-Invasive Ventilation.
- High Flow Oxygen Therapy.

NEONATES-INFANTS:

- VCV – Volume Control (Assisted/Controlled).
- PCV – Pressure Control (Assisted/Controlled).
- PSV – Pressure Support.
- VSV – Volume Support.
- PRVC – Pressure Regulated Volume Control.
- CPAP – Continuous Positive Airway Pressure.
- SIMV (VCV) + PSV.
- SIMV (PCV) + PSV.
- SIMV (PRVC) + PSV.
- TCPL – Time Cycled Pressure Limited.
- SIMV (TCPL) + PSV.
- CPAP with Continuous Flow (with leak compensation for NIV).
- APRV – Airway Pressure Release Ventilation.
- High Flow Oxygen Therapy.

PARAMETER SELECTION (according to operative mode and patient category)

Parameter	Range
Tidal Volume [ml]	2-2500 (*) (*) Available from N11-ADV-01.12.00
Minute Volume (MMV + PSV setting) [L/min]	1.0-50
Maximum resulting minute volume [L/min]	130 (Not a direct user setting)
Inspiratory Time [s]	0.1 - 10 (in assist/controlled modes) 0.2 - 30 (Low Time in APRV) 0.5 - 30 (High time in APRV)
I:E Ratio	5:1 - 1:599.
Respiratory Rate [rpm]	ADL: 1 - 100 PED/NEO-INF: 1 - 150
FIO ₂ [%]	21 - 100
Inspiratory Sensitivity	Flow Triggered [L/min]: 0.2 - 15 Pressure Triggered [cmH ₂ O]: 0.5 - 20 below the PEEP.
Expiratory Sensitivity for PSV and VSV [% of Peak Flow]	5-80 of the initial peak flow, in steps of 5%.
PEEP/CPAP [cmH ₂ O]	0-50
Controlled Pressure (PCV) [cmH ₂ O]	2-100
Support Pressure (PSV) [cmH ₂ O]	0-100
Rise Time	Modifications to rise time can be seen graphically as a rise or decline in the tracing of the initial segment of the inspiratory pressure curve
Inspiratory Pause (programmable in VCV) [s]	0-2
Inspiratory Flow Waveform (VCV)	Rectangular – Descending Ramp
Inspiratory Flow [L/min]	0.2-180
Continuous Flow (NEO-INF) [L/min]	2-40
Continuous Flow in Oxygen Therapy [L/min]	ADL: 1 - 80 PED: 1 - 60 NEO-INF: 1 - 20
Limited Pressure in TCPL (NEO-INF) [cmH ₂ O]	3-70
Maximum pressure limited (safety limits) [cmH ₂ O]	Up to 120
Oxygen concentration in oxygen therapy [%]	21 - 100

MONITORED PARAMETERS

Parameter	Reference
Peak Pressure [cmH ₂ O]	Peak
Plateau Pressure [cmH ₂ O]	Plateau
Mean Pressure [cmH ₂ O]	Mean
Tracheal Pressure [cmH ₂ O]	Trach
PEEP [cmH ₂ O]	PEEP
Inspiratory Peak Flow [L/min]	Peak Flow
Inspiratory Time [s]	Ti
Expiratory Time [s]	Te
I:E Ratio	I:E
Total Rate [rpm]	ftotal
Expired Tidal Volume [L] for ADL/PED - [mL] for NEO/INF	VT
Inspired Tidal Volume	VTi
Expired Minute Volume [L/min]	VE
FIO ₂ [%]	%Oxygen
Ideal body weight	IBW
Tidal volume per kg of patient weight	Vt/kg
Mandatory Minute Volume [L/min]	VE Mandat
Spontaneous Minute Volume [L/min]	VE Spont
Spontaneous Respiratory Rate [rpm]	Fspont
Expiratory Time Constant [s]	TCexp
Dynamic Compliance [ml/cmH ₂ O]	Cdyn
Static Compliance [ml/cmH ₂ O]	Cest
Inspiratory Resistance [cmH ₂ O/L/s]	Ri
Expiratory Resistance [cmH ₂ O/L/s]	Re
Leak [L/min]	Leak
Percentage of Leak [%]	Leak %
f/Vt Index [rpm/L]	f/Vt
Ratio between the inspiration time and the time needed for a full breath.	Ti/Ttot
Imposed Work of Breathing [mL/min]	WOBi
End of Inspiration CO ₂ [mmHg]	ETCO ₂
Elimination of CO ₂ [mL/min]	VCO ₂
Ratio of dead space and tidal volume	VD/VT
Anatomical Dead Space [mL]	VD
Current Alveolar Volume [mL]	Va
Alveolar Minute Volume [mL/min]	Va min
Current Volume of CO ₂ [mL]	VTCO ₂
Stress Index	Stress Index

ALARMS

Light 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 and Minute Volume alarms in NIV.

Alarm Adjustment

Parameter	Range
Maximum Inspiratory Pressure [cmH ₂ O]	10 (or > min – 120)
Minimum Inspiratory Pressure [cmH ₂ O]	1-99 (or < max)
Maximum Tidal Volume [L]	ADL: >VTmin - 3,0 PED: >VTmin - 0.500 NEO-INF: >VTmin -0,250
Minimum Tidal Volume [L]	ADL: 0 - <VTmax PED: 0 - <VTmax NEO-INF: 0 - <VTmax
Maximum Minute Volume (Expired) [L/min]	ADL: >VMmin - 55 PED: >VMmin - 55 NEO-INF: >VMmin- 55
Minimum Minute Volume (Expired) [L/min]	ADL: 0 – <VMmax PED: 0 – <VMmax NEO-INF: 0 – <VMmax
High/Low O ₂ concentration [%]	High: 25 - 110 Low: 19 - 95
Apnea Condition [s]	5-60
PEEP loss [cmH ₂ O]	0-6
High rate [bpm]	3-160
Maximum and Minimum ETCO ₂ [mmHg]	Max: >Min - 150 Min 1 to <Max
SBT finalized [min]	10 - 120
High f/Vt [bpm/L]	65 - 200

Non-Configurable Alarms

Emergency Ventilation
Continuous high pressure
Low air and oxygen pressure
Low oxygen (or air) pressure
Defective Battery
Low Battery
Power loss
Fan failure
Target volume not reached
Nebulization interrupted
Transporting
Standby
Inadequate oxygen [%]
Disconnection
Leakage out of range
Sound Controller Failure
Maximum proximal flow
SBT aborted

OTHER FEATURES AND CONTROLS

Function	Clarifications
Manual Inspiration	The ventilator should initiate a mandatory breath.
Manual Inspiratory / Expiratory Pause	Inspiratory Pause: 0-7 s Expiratory Pause: 0-20 s
Nebulization	30 min - Synchronized with the Inspiration / Deactivated
Leak Compensation – NIV and Continuous Flow CPAP	Enabled by default Leak Compensation: ADL: up to 50 L/min PED: up to 30 L/min NEO: up to 10 L/min
Leak Compensation – Remaining Modes	Activated / Deactivated Leak Compensation: ADL: up to 15 L/min PED: up 15 L/min NEO-INF: up 10 L/min
Volume Compensation (Based on the compliance of the patient circuit)	Activated/Deactivated
Trends	Up to 72 hours

Backup Ventilation	Mandatory Setting:				
	<table border="1"> <tr> <td>ADL/PED</td> <td>PSV/CPAP – VSV – MMV + PSV – PSV + Assured VT</td> </tr> <tr> <td>NEO/INF</td> <td>PSV/CPAP – VSV</td> </tr> </table>	ADL/PED	PSV/CPAP – VSV – MMV + PSV – PSV + Assured VT	NEO/INF	PSV/CPAP – VSV
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NEO/INF	PSV/CPAP – VSV				
	Optional Setting:				
	<table border="1"> <tr> <td>ADL/PED</td> <td>SIMV(VCV)+PSV SIMV(PRVC)+PSV SIMV(PCV)+PSV - APRV</td> </tr> <tr> <td>NEO/INF</td> <td>SIMV(VCV)+PSV SIMV(PRVC)+PSV SIMV(PSV)+PSV SIMV(TCPL)+PSV CPAP Continuous flow APRV</td> </tr> </table>	ADL/PED	SIMV(VCV)+PSV SIMV(PRVC)+PSV SIMV(PCV)+PSV - APRV	NEO/INF	SIMV(VCV)+PSV SIMV(PRVC)+PSV SIMV(PSV)+PSV SIMV(TCPL)+PSV CPAP Continuous flow APRV
ADL/PED	SIMV(VCV)+PSV SIMV(PRVC)+PSV SIMV(PCV)+PSV - APRV				
NEO/INF	SIMV(VCV)+PSV SIMV(PRVC)+PSV SIMV(PSV)+PSV SIMV(TCPL)+PSV CPAP Continuous flow APRV				
Tube compensation (Endotracheal o Tracheostomy Tube)	Compensation of 10%-100% for Ø 4-12 mm				
Sighs	In VCV mode				
Sound Volume	40 % - 100%				
Suction %O ₂	Sequence for aspiration with variable O ₂ concentration and time, greater than or equal to 2 minutes.				
Inspired Oxygen Sensor					

SAFETY MECHANISMS

Mechanisms	Clarifications
Screen Lock	If the screen is locked when an alarm is triggered, it is automatically unlocked.
Standby	
Emergency Ventilation	Mechanism that is activated in conditions of extreme necessity to provide temporary ventilation to the patient until measures are taken to replace the ventilator with an alternative ventilatory mechanism
Pressure Relief Valve	This valve allows the patient to breathe ambient air, under the following conditions: When the equipment is de-energized, when the ventilator is out of order, when air pressure and oxygen pressure are simultaneously low, on standby.
Operating Gas Leakage	The gas that can seep into the unit is collected in a common manifold, and directed towards the outside.
Auto-Zeroing	Every 10 minutes or when the operator enables it, the pressure sensors are zeroed.
Circuit Purge	To avoid obstruction and humidity leakage in the pressure sensors.
Safety Valve	120 cmH ₂ O (±5).

COMPLEMENTARY FUNCTIONS

Function	Clarifications
Altitude compensation for volume correction	
Body temperature volume correction (BTPS)	Volume correction according to the selected type of humidifier
Pressure correction according to patient circuit resistance	
Tidal Volume Setting based on Ideal Body Weight (IBW)	ml/kg of patient weight
Possibility to set the VCV mode as Tidal volume + Inspiratory time or tidal volume + Peak flow	
Intra-hospital transport	Facilitates the mobilization when the ventilator can only be supplied with oxygen tubes. <ul style="list-style-type: none"> Record up to 5000 events Alarms / warnings: activated alarms during the ventilation and warnings shown during the self-test Adjustments: operative mode, settings and ventilatory adjuncts States: Turn on, turn off, Standby, transport, calibrations and battery charge.
Extended event log	
Capnography	Curves of CO ₂ /Time and Volumetric Capnography (CO ₂ /VT). Measurements of ETCO ₂ (partial pressure of CO ₂ at the end of expiration), and their derivatives variables (Alveolar Ventilation, Dead Space, CO ₂ Elimination (VCO ₂), VD/VT Ratio, CO ₂ expired volume (VTCO ₂), etc.) (According to patient category).

RESPIRATORY MECHANICS

Parameters	Clarifications
AutoPEEP or intrinsic PEEP	Dynamic pulmonary hyperinflation
Static and Dynamic Compliance	
Inspiratory and Expiratory Resistance	
Slow Vital Capacity	Amount of air that can be expired after a maximal inspiration
P0.1	Occlusion Pressure during the first 100 ms
P/V Flex (Inflection Points)	Insufflations with low flow (4L/min) in order to determine the lower inflection point (Lip) and upper inflection point (Uip). This tool can be used to assess recruitability and to set PEEP based on respiratory mechanics.
Pi max	Negative Inspiratory Effort
Trapped Volume	Air remaining within the lungs due to dynamic pulmonary hyperinflation
VD/VT Physiologic	Measurement of the Physiological Dead Space
Spontaneous breathing trial (SBT)	Tool to assess patient tolerance of breath with minimal ventilatory support, prior to extubation procedure.

CONNECTIVITY

- RS-232C with DB-9 connector.
- VGA output for an external monitor connection.

ELECTRICAL REQUIREMENTS

- Main Power: 100-240 V / 50-60 Hz. Automatic voltage switching.
- Internal Battery: 11.1 V / 7.8 Ah. Automatic recharge. Estimated duration: 2.5 hours when fully charged. Charge level indicator on screen.

PNEUMATIC REQUIREMENTS

- Working pressure: 2.0 bar (approx. 29 psi).
- Gases supply:
 - Oxygen: Pressure 2.8-6 bar (approx. 41-87 psi). Connector: DISS 9/16"-18.
 - Air: Pressure 2.8-6 bar (approx. 41-87 psi). Connector: DISS 3/4"-16.
- Automatic gas switching when one of them is absent in order to allow patient ventilation with the remaining gas.

ACCESSORIES

- **Two expiratory ensembles.**
- **Fixed orifice proximal pneumotachograph:** It is a disposable accessory used for measuring flow at a point close to the patient connection.

Parameters	Clarifications
Weight	12 grams.
Measuring Method	Fixed orifice pneumotachograph
Electric Power	Not required
Measured parameters	Airway pressure Expired and Inspired Flow Expired and Inspired Tidal Volume Trigger
Range	Must be used to ventilate with peak flows under or at 20 L/min only
Dead Space	< 1 mL

- **Water filter for compressed air inlet.**
- **Air supply high pressure hose (3 meters) with 3/4"-16H connectors.**
- **O₂ supply high pressure hose (3 meters) with 9/16"-18H DISS connectors.**
- **Nebulizer (complete kit).**
- **Adult test lung.**
- **Neonatal test lung.**
- **Power cord.**
- **O₂ Sensor.**

OPTIONAL ACCESORIES

- Reusable Patient Circuit: Reusable circuits (Hytrek and Silicone) for ADL (22 mm), PED (15 mm) and NEO-INF (10mm) patient categories.
- Four-wheel cart (with brakes).
- Flexible arm with tubes holder.
- CAPNOSTAT 5 CO₂ Sensor.

Parameters	Clarifications
Electric Power	Provided by the ventilator
Power Rating	1.1 W typical
Measuring Method	Mainstream, Non-dispersive infrared (NDIR) single beam optics, dual wavelength, no moving parts
Measured Parameters	End-Tidal CO ₂ (ETCO ₂), Expired Tidal Volume of CO ₂ (VCO ₂), volume of CO ₂ expired per minute (VCO ₂)
Measuring Range	Partial Pressure of CO ₂ : 0-150 mmHg Partial Pressure of CO ₂ : 0-20 kPa Volume of CO ₂ : 0- 19.7% (760 mm Hg)
Rise Time	< 60 ms
Warm-up time	Capnogram, displayed in less than 15 seconds at an ambient temperature of 25°C, full specifications within 2 minutes
Compensation of Oxygen Concentration	Automatic. Values are given by the ventilator
Compensation of barometric pressure	Automatic. Values are given by the ventilator
Dead Space	<5 mL

- Heater-Humidifier.
- Compressor: Allows using the ventilator 24 hours, supplying the absence of air of the central source.

Manufactured by  **TECME**

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