



 **neumovent**<sup>®</sup>  
GraphNet ts

Committed to life

## INTENDED USE

The GraphNet ts ventilator was designed to be used with all types of patients: adult, pediatric, and neonatal infants (optionally with the NEO-INF module) 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 ts has 6 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.
- 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.
- CPAP – Continuous Positive Airway Pressure.
- SIMV (VCV) + PSV.
- SIMV (PCV) + PSV.
- MMV + PSV – Mandatory Minute Ventilation.
- PSV + Tidal Volume Assured.
- APRV – Airway Pressure Release Ventilation.
- NIV – Non-Invasive Ventilation.
- High Flow Oxygen Therapy (Optional).
- VSV – Volume Support (Optional).
- PRVC – Pressure Regulated Volume Control (Optional).
- SIMV (PRVC) + PSV (Optional).

### NEONATES-INFANTS (Optional category)

- VCV – Volume Control (Assisted/Controlled).
- PCV – Pressure Control (Assisted/Controlled).
- PSV – Pressure Support.
- CPAP – Continuous Positive Airway Pressure.
- SIMV (VCV) + PSV.
- SIMV (PCV) + 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 (Optional).
- VSV – Volume Support (Optional).
- PRVC – Pressure Regulated Volume Control (Optional).
- SIMV (PRVC) + PSV (Optional).

## PARAMETER SELECTION (according to operative mode and patient category)

Parameter	Range
Tidal Volume [ml]	20-2500 mL (from 5 ml with the option of neonatal category)
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 (in assist/control modes) 150:1-1:60 (APRV)
Respiratory Rate [rpm]	ADL: 1 - 100 PED/NEO-INF: 1 - 150
FIO <sub>2</sub> [%]	21 - 100
Inspiratory Sensitivity	Flow Triggered [L/min]: 0.2 - 15 Pressure Triggered [cmH <sub>2</sub> O]: 0.5 - 20 below the PEEP value
Expiratory Sensitivity for PSV [% of Peak Flow]	5-80 of the initial peak flow, in steps of 5%.
PEEP/CPAP [cmH <sub>2</sub> O]	0-50
Controlled Pressure (PCV) [cmH <sub>2</sub> O]	2-100
Support Pressure (PSV) [cmH <sub>2</sub> 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
Limited Pressure in TCPL (NEO-INF) [cmH <sub>2</sub> O]	3-70
Maximum pressure limited (safety limits) [cmH <sub>2</sub> O]	Up to 120
Continuous Flow in Oxygen Therapy [L/min] (*)	ADL: 1 - 80 PED: 1 - 60 NEO-INF: 1 - 20 (*)
Oxygen concentration in oxygen therapy [%]	21 - 100

## MONITORED PARAMETERS

Parameter	Reference
Peak Pressure [cmH <sub>2</sub> O]	Peak
Plateau Pressure [cmH <sub>2</sub> O]	Plateau
Mean Pressure [cmH <sub>2</sub> O]	Mean
PEEP [cmH <sub>2</sub> 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]	f <sub>total</sub>
Expired Tidal Volume [L] for ADL/PED - [mL] for NEO/INF	VT
Inspired Tidal Volume	VTi
Expired Minute Volume [L/min]	V <sub>E</sub>
FIO <sub>2</sub> [%]	%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]	F <sub>spont</sub>
Expiratory Time Constant [s]	TC <sub>exp</sub>
Dynamic Compliance [ml/cmH <sub>2</sub> O]	C <sub>dyn</sub>
Static Compliance [ml/cmH <sub>2</sub> O]	C <sub>est</sub>
Inspiratory Resistance [cmH <sub>2</sub> O/L/s]	Ri
Expiratory Resistance [cmH <sub>2</sub> 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
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 <sub>2</sub> O]	10 (or > min - 120)
Minimum Inspiratory Pressure [cmH <sub>2</sub> O]	1-99 (or < max)
Maximum Tidal Volume [L]	ADL: >VTmín - 3,0 PED: >VTmín - 0.500 NEO-INF: >VTmín - 0,250
Minimum Tidal Volume [L]	ADL: 0 - <VTmáx PED: 0 - <VTmáx NEO-INF: 0 - <VTmáx
Maximum Minute Volume (Expired) [L/min]	ADL: >VMmín - 55 PED: >VMmín - 55 NEO-INF: >VMmín - 55
Minimum Minute Volume (Expired) [L/min]	ADL: 0 - <VMmáx PED: 0 - <VMmáx NEO-INF: 0 - <VMmáx
High/Low O <sub>2</sub> concentration [%]	Alta: 25 - 110 Baja: 19 - 95
Apnea Condition [s]	5-60
PEEP loss [cmH <sub>2</sub> O]	0-6
High rate [rpm]	3-160
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	<b>Enabled by default</b> Leak Compensation: ADL: up to 50 L/min PED: up to 30 L/min NEO: up to 10 L/min
Leak Compensation – Remaining Modes	<b>Activated / Deactivated</b> Leak Compensation: ADL: up to 15 L/min PED: up to 15 L/min NEO-INF: up to 10 L/min.
Volume Compensation (Based on the compliance of the patient circuit)	Activated/Deactivated
Trends	Up to 72 hours

## OTHER FEATURES AND CONTROLS

### Function

Backup Ventilation

Sighs

Sound Volume

Suction %O<sub>2</sub>

Inspired Oxygen Sensor

### Clarifications

Mandatory Setting:

ADL/PED	PSV/CPAP – VSV – MMV + PSV – PSV + Assured VT
NEO/INF	PSV/CPAP – VSV

Optional Setting:

ADL/PED	SIMV(VCV)+PSV SIMV(PRVC)+PSV SIMV(PCV)+PSV - APRV
NEO/INF	SIMV(VCV)+PSV SIMV(PV)+PSV SIMV(TCPL)+PSV SIMV(PRVC)+PSV CPAP continuous flow APRV

In VCV mode

40 % - 100%

Sequence for aspiration with variable O<sub>2</sub>  
concentration and time,  
greater than or equal to 2 minutes

## 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 <sub>2</sub> 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 bottles
Extended event log	<ul style="list-style-type: none"> <li>• Record up to 5000 events</li> <li>• Alarms / warnings: activated alarms during the ventilation and warnings shown during the self-test</li> <li>• Adjustments: operative mode, settings and ventilatory adjuncts.</li> <li>• States: Turn on, turn off, Standby, transport, calibrations and battery charge.</li> </ul>

## 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
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.

## OPTIONALS

- Module 1: High Flow Oxygen Therapy.
- Module 2: PRVC: Pressure Regulated Volume Control, VSV: Volume Support, SIMV(PRVC)+PSV.
- Module 3: Stress Index and Spontaneous Breathing Trial (SBT).
- Module 4: Neonatal Category.

## ACCESSORIES

- **Two expiratory ensembles.**
- **Water filter for compressed air inlet.**
- **Air supply high pressure hose (3 meters) with 3/4"-16H connectors.**
- **O<sub>2</sub> supply high pressure hose (3 meters) with 9/16"-18H DISS connectors.**
- **Nebulizer (complete kit).**
- **Adult test lung.**
- **Power cord.**
- **O<sub>2</sub> Sensor.**



## OPTIONAL ACCESORIES

- **Reusable Patient Circuit:** Reusable circuits (Hytrek and Silicone) for ADL (22 mm), PED (15 mm) and NEO-INF (10mm) patient categories.
- **Heater-Humidifier.**
- **Compressor:** Allows using the ventilator 24 hours, supplying the absence of air of the central source.
- **Neonatal test lung.**
- **Flexible arm with tubes holder.**
- **Four-wheel cart (with brakes).**

Manufactured by  **TECME**

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