

neumovent ts



Technical Specifications

GraphNet ts

Software Version 14.03

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 13485:2016 - Medical devices. Quality management systems. Requirements for regulatory purposes (ISO 13485:2016).
- 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/Transport	- 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

ADULT AND PEDIATRIC

- VCV – Volume Control (Assisted/Controlled).
- PCV – Pressure Control (Assisted/Controlled).
- PSV – Pressure Support.
- CPAP – Continuous Positive Airway Pressure.
- SIMV (VCV) + PSV – Synchronized Intermittent Mandatory Ventilation.
- SIMV (PCV) + PSV – Synchronized Intermittent Mandatory Ventilation.
- 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) – Synchronized Intermittent Mandatory Ventilation.

NEONATES-INFANTS (Optional category)

- VCV – Volume Control (Assisted/Controlled).
- PCV – Pressure Control (Assisted/Controlled).
- PSV – Pressure Support.
- CPAP – Continuous Positive Airway Pressure.
- TCPL – Time Cycled Pressure Limited.
- SIMV (VCV) + PSV – Synchronized Intermittent Mandatory Ventilation.
- SIMV (PCV) + PSV – Synchronized Intermittent Mandatory Ventilation.
- SIMV (TCPL) + PSV – Synchronized Intermittent Mandatory Ventilation.
- 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) – Synchronized Intermittent Mandatory Ventilation.

Parameter selection (according to operative mode and patient category)

Parameter	Range
Tidal volume [L]	ADL: 0,050 – 2,500 PED: 0,020 – 0,300 NEO-INF: 0,005 – 0,150 (with the option of neonatal category)
Programable minute volume (MMV + PSV) [L/min]	ADL: 1,0 – 50 PED: 1,0 – 50 NEO-INF: N/A
Maximum resulting minute volume [L/min]	ADL: 130 PED: 40 NEO-INF: 17
Inspiratory time [s] (in assist-control modes)	0,1 – 10
Inspiratory time [s] (APRV)	Low time: 0,2 – 30 High time: 0,5 – 30
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
Oxygen concentration [%]	21 – 100
Inspiratory sensitivity	Triggering by flow [L/min]: 0,2 – 15 Triggering by pressure [cmH ₂ O]: 0,5 – 20 below the PEEP
Expiratory sensitivity (for modes with PSV)	5% – 80% of the 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
Programmable inspiratory pause (in VCV) [s]	0 – 2
Inspiratory flow waveform	Descending and constant ramp (rectangular)
Inspiratory flow [L/min]	0,2 – 180
Continuous flow (NEO-INF) [L/min]	2 – 40
Limited pressure in TCPL (NEO-INF) [cmH ₂ O]	3 – 70
Maximum pressure limited [safety limits] [cmH ₂ 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 ₂ O]	Peak
Plateau pressure [cmH ₂ O]	Plateau
Mean pressure [cmH ₂ O]	Mean
PEEP [cmH ₂ O]	PEEP
Inspiratory peak flow [L/min]	Peak Flow
Expiratory peak flow [L/min]	Exp. peak flow
Inspiratory time [s]	Ti
Expiratory time [s]	Te
I:E ratio	I:E
Total rate [rpm]	f _{total}
Expired tidal volume [L] for ADL/PED - [mL] for NEO/INF	VT
Inspired tidal volume [L] for ADL/PED - [mL] for NEO/INF	VTi
Expired minute volume [L/min]	VE
Inspired minute volume [L/min]	VEi
Oxygen monitor [%]	Oxygen
Ideal body weight [kg]	IBW
Tidal volume per kg of patient weight [mL/kg]	Vt/kg
Mandatory minute volume [L/min]	VE Mandat
Spontaneous minute volume [L/min]	VE Spont
Spontaneous respiratory rate [rpm]	F spont
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 (Tobin 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
High inspiratory pressure [cmH ₂ O]	10 (or > min - 120)
Low inspiratory pressure [cmH ₂ O]	1 - 99 (or < max)
High tidal volume [L]	ADL: >VTmin - 3,0 PED: >VTmin - 0,500 NEO-INF: >VTmin - 0,250
Low tidal volume [L]	ADL: 0 - < VTmax PED: 0 - < VTmax NEO-INF: 0 - < VTmax
High minute volume (exhaled) [L/min]	ADL: >VMmin - 55 PED: >VMmin - 55 NEO-INF: >VMmin - 55
Low minute volume (exhaled) [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 [rpm]	3 - 160
SBT finalized [min] (*)	10 - 120
High f/Vt [bpm/L] (*)	65 - 900

Non-configurable alarms

Emergency ventilation
Continuous high pressure
Low air and oxygen pressure
Low oxygen (or air) pressure
High oxygen pressure (or air)
Defective battery
Low battery
Power loss
Fan failure
Target volume not reached
Nebulization interrupted
Transporting
Standby
Oxygen concentration below 18%
Disconnection
Non-compensable leak
Sound controller failure
Oxygen therapy disabled (*)
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 in NIV	Enabled by default Leak compensation: ADL: up to 60 L/min PED: up to 30 L/min
Leak compensation - remaining modes	Activated / Deactivated 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	Clarifications				
Backup ventilation	Mandatory Setting:				
	<table border="1"> <tr> <td data-bbox="820 389 1075 459">ADL/PED</td> <td data-bbox="1078 389 1439 459">PSV/CPAP – MMV + PSV - PSV + Assured VT – VSV</td> </tr> <tr> <td data-bbox="820 463 1075 533">NEO/INF</td> <td data-bbox="1078 463 1439 533">PSV/CPAP – VSV</td> </tr> </table>	ADL/PED	PSV/CPAP – MMV + PSV - PSV + Assured VT – VSV	NEO/INF	PSV/CPAP – VSV
	ADL/PED	PSV/CPAP – MMV + PSV - PSV + Assured VT – VSV			
	NEO/INF	PSV/CPAP – VSV			
Optional Setting:					
<table border="1"> <tr> <td data-bbox="820 602 1075 689">ADL/PED</td> <td data-bbox="1078 602 1439 689">SIMV(VCV)+PSV – SIMV(PCV)+PSV – SIMV(PRVC) + PSV - APRV</td> </tr> <tr> <td data-bbox="820 694 1075 824">NEO/INF</td> <td data-bbox="1078 694 1439 824">SIMV(VCV)+PSV SIMV(PSV)+PSV SIMV(TCPL)+PSV SIMV(PRVC)+PSV CPAP continuous flow APRV</td> </tr> </table>	ADL/PED	SIMV(VCV)+PSV – SIMV(PCV)+PSV – SIMV(PRVC) + PSV - APRV	NEO/INF	SIMV(VCV)+PSV SIMV(PSV)+PSV SIMV(TCPL)+PSV SIMV(PRVC)+PSV CPAP continuous flow APRV	
ADL/PED	SIMV(VCV)+PSV – SIMV(PCV)+PSV – SIMV(PRVC) + PSV - APRV				
NEO/INF	SIMV(VCV)+PSV SIMV(PSV)+PSV SIMV(TCPL)+PSV SIMV(PRVC)+PSV CPAP continuous flow APRV				
Sighs	In VCV mode.				
Sound volume	40 % - 100%.				
Suction %O ₂	Sequence for aspiration with variable O ₂ concentration and time, greater than 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: <ul style="list-style-type: none"> • When the equipment is de-energized. • When the ventilator is out of order. • When air pressure and oxygen pressure are simultaneously low. • On standby. • When the oxygen therapy mode is disabled
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 (BTSP)	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	Record up to 5000 events of the following: <ul style="list-style-type: none"> • Alarms / warnings: activated alarms during the ventilation and warnings shown during the self-test. • Adjustments: including device configuration changes such as patient category, ventilatory mode, parameter adjustment, ventilatory complements, among other adjustments. • States: Including states in which the equipment is (power on, calibration, during ventilation, Stand-By, Intra hospital transportation, Power off, recalibrations, battery charge level), as well as some complementary functions accessed through quick access.

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.

Conectivity

- 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.
- O₂ supply high pressure hose (3 meters) with 9/16"-18H DISS connectors.
- Nebulizer (complete kit).
- Adult test lung.
- Power cord.
- O₂ Sensor.

Optional accessories

- Reusable patient circuit: Reusable circuits (Hytrel and Silicone) for adult, pediatric and neonatal patient categories.
- Four-wheel cart (with brakes).
- Flexible arm with tubes holder.
- Heater-Humidifier.
- Compressor: Allows using the ventilator 24 hours, supplying the absence of air of the central source.

50 years of innovation and development in mechanical ventilators.

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