neumovent®
GraphNet neo

Committed to life

INTENDED USE

The GraphNet neo ventilator was designed to be used with neonatal infants (including premature babies), and 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 ºC	560 - 1030 hPa	15%-95% non-condensing
Storage	- 10 ºC - 55 ºC	500 - 1060 hPa	< 95 % non-condensing

SCREEN

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

GRAPHICS

GraphNet neo 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

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

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PARAMETER SELECTION

Parameter	Range
Tidal Volume [ml]	2-350
Maximum resulting minute volume [L/min]	17 (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]	1-150
FIO_2 [%]	2 -100
Inspiratory Sensitivity	Flow Triggered [L/min]: 0.2 - 15 Pressure Triggered [cmH_2O]: 0.5 - 20 below the PEEP
Expiratory Sensitivity for PSV [% of Peak Flow]	5-80 of the initial peak flow, in steps of 5%
PEEP/CPAP [cmH_2O]	0-50
Controlled Pressure (PCV) [cmH_2O]	2-100
Support Pressure (PSV) [cmH_2O]	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]	0-1
Inspiratory Flow Waveform (VCV)	Rectangular - Descending Ramp
Inspiratory Flow [L/min]	0.2-40
Continuous Flow [L/min]	2-40
Limited Pressure in TCPL (NEO-INF) [cmH_2O]	3-70
Maximum pressure limited (safety limits) [cmH_2O]	Up to 120
Continuous Flow in Oxygen Therapy [L/min]	1-20
Oxygen concentration in oxygen therapy [%]	21-100

MONITORED PARAMETERS

Parameter	Reference
Peak Pressure [cmH_2O]	Peak
Plateau Pressure [cmH_2O]	Plateau
Mean Pressure [cmH_2O]	Mean
PEEP [cmH_2O]	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 [mL]	VT
Inspired Tidal Volume	VTi
Expired Minute Volume [L/min]	VE
FIO_2 [%]	%Oxigen
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_2O]	Cdyn
Static Compliance [ml/cmH_2O]	Cest
Inspiratory Resistance [cmH_2O/L/s]	Ri
Expiratory Resistance [cmH_2O/L/s]	Re
Leak [L/min]	Leak
Percentage of Leak [%]	% Leak
Ratio between the inspiration time and the time needed for a full breath	Ti/Ttot

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.

Alarm Adjustment

Parameter	Range
Maximum Inspiratory Pressure [cmH_2O]	10 (or > min – 120)
Minimum Inspiratory Pressure [cmH_2O]	1-99 (or < max)
Maximum Tidal Volume [L]	>VTmín - 250
Minimum Tidal Volume [L]	0 - <VTmáx
Maximum Minute Volume (Expired) [L/min]	>VMmín- 55
Minimum Minute Volume (Expired) [L/min]	0 – <VMmáx
High/Low O_2 concentration [%]	High: 25 - 110 Low: 19 - 95
Apnea Condition [s]	5-60
PEEP loss [cmH_2O]	0-6
High rate [rpm]	3-160

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
Maximum proximal flow
Sound controller failure

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	Leak Compensation: up to 10 L/min **Enabled by default in Continuous Flow CPAP**
Volume Compensation (Based on the compliance of the patient circuit)	Activated/Deactivated
Trends	Up to 72 hours
Backup Ventilation	**Mandatory Setting:** PSV/CPAP – VSV **Optional Setting:** SIMV(VCV)+PSV SIMV(PSV)+PSV SIMV(TCPL)+PSV SIMV(PRVC)+PSV CPAP continuous flow APRV
Sound Volume	40 % - 100%
Suction %O_2	Sequence for aspiration with variable O2 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_2O (±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	• 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.

RESPIRATORY MECHANICS

Parameters	Clarifications
AutoPEEP or intrinsic PEEP	Dynamic pulmonary hyperinflation
Static and Dynamic Compliance	
Inspiratory and Expiratory Resistance	
Trapped Volume	Air remaining within the lungs due to dynamic pulmonary hyperinflation

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.

ACCESSORIES

- **Two expiratory ensembles.**
- **Fixed orifice proximal pneumotachograph:** 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.**
- **O_2 supply high pressure hose (3 meters) with 9/16”-18H DISS connectors.**
- **Nebulizer (complete kit).**
- **Neonatal test lung.**
- **Power cord.**
- **O_2 Sensor.**

OPTIONAL ACCESORIES

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

Manufactured by TECME

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