

GIULIA

Neonatal Ventilator



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neo-tech for life

A multipurpose ventilator

Giulia Ventilator is a next-generation ventilator designed to give the best respiratory support at every step of the clinical treatment of the respiratory diseases of premature infants and newborns. With Giulia it is possible to shift rapidly from the most effective and safest mode of conventional triggered invasive ventilation, the Volume Targeted Ventilation (VTV), to non-invasive techniques as the unique Flow-Synchronized Nasal Intermittent Positive Pressure Ventilation (Flow-SNIPPV) or the simpler Heated High Flow Nasal Cannula (HHFNC)

Flow-SNIPPV – a new challenge in neonatal respiratory care

In the multifactorial pathogenesis of Broncho-Pulmonary Dysplasia (BPD), ventilator induced lung-injury (VILI) is considered to be a significant factor. This prompted the development of new non-invasive respiratory techniques, which would be more effective than nasal CPAP, for the treatment of the newborn with RDS. Nasal intermittent positive pressure ventilation is a non-invasive mode of ventilation that combines nasal CPAP with some intermittent mandatory breaths. It may be non-synchronized (NIPPV), or synchronized (NSIPPV) with the infant's breathing efforts. At GINEVRI we have developed a revolutionary flow-sensor to carry out NSIPPV. Figure 1 shows this flow sensor being used for the treatment of a baby of 650 grams. The device is very reliable, comfortable and easy to fit.

Several clinical trials favor NSIPPV, probably because delivering the inspiratory pressure immediately after the start of a respiratory effort, when the glottis is open, allows pressure to be transmitted effectively to the lungs. Figures 2 and 3 show the different ways that NIPPV and flow-NSIPPV interact with the spontaneous breathing of a VLBW infant (1).



Fig 1. The GIULIA Flow-sensor

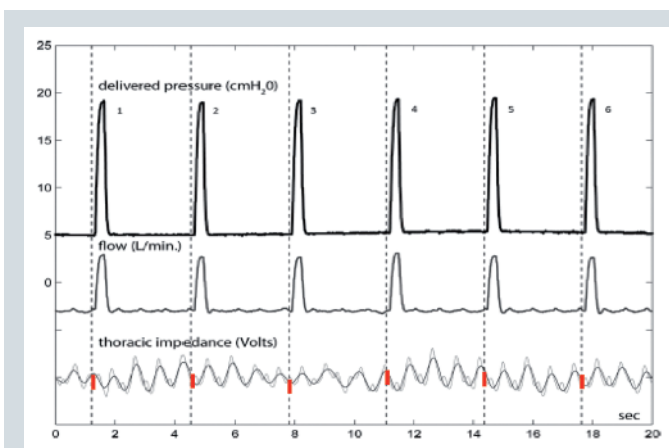


Fig 2. Reading from the top, this recording shows the delivered pressure, flow and thoracic impedance of a VLBW infant treated with NIPPV. Note the interactions of NIPPV mandatory cycles (back-up rate of 20 breaths/min) with the spontaneous respiratory rhythm of the patient. The infant is not entrained with the ventilator and the mechanical cycles start (red lines) at different stages of the spontaneous breathing cycle: 1 peak of breath, 2 mid-expiration, 3 late expiration, 4 peak of breath, 5 early expiration, 6 mid-expiration.

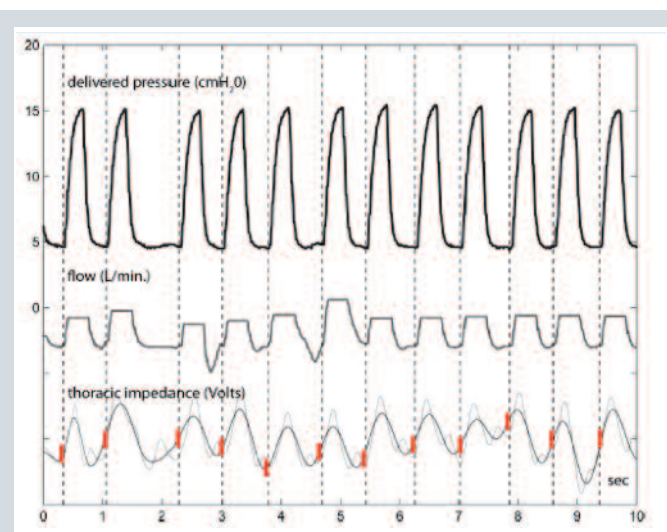


Fig 3. This recording shows the interactions of flow-NSIPPV with spontaneous breathing of the newborn. The infant is now well entrained with the ventilator and mechanical breaths start (red lines) immediately after the beginning of the patient's spontaneous ones.

Asynchronous mechanical breaths may induce laryngeal closure, alter spontaneous respiratory rhythm, increase WOB, increase abdominal distention, cause volutrauma and pneumothorax and have harmful effects on BP and CBF (2, 3). Synchronous mechanical breaths may reduce inspiratory effort, increase ventilation, reduce breathing frequency, reduce thoraco-abdominal asynchrony and decrease WOB (3-8). A common objection to the use of a flow sensor for non-invasive ventilation is that its reliability can be affected by the continuous flow passing through it due to the variable leaks from the infant's nostrils and mouth. To show that this objection is not valid, we used a simulated neonatal model to demonstrate both the reliability of our flow-sensor with different measured

leaks through it and the performance of the GIULIA ventilator (9-11). The GIULIA flow-sensor detected 100% of the simulated spontaneous breaths in presence of any tested amount of leak from the prongs. The mean response time, measured from the beginning of inspiration to the beginning of the inspiratory pressure rise in the circuit, was $64 \pm (SD) 7$ ms (range 46-77 ms). These data prove that the GIULIA flow-sensor can detect very small inspiratory volumes and flows, and that its performance is not influenced by the amount of leakage. Another potential disadvantage of this device is the increase of dead volume, but this is only a theoretical problem since expiratory flow vents mainly from the patient's mouth.

GIULIA

Evidence from clinical trials indicates NSIPPV is more effective than NCPAP:

- in improving the success rate of extubation (8, 12, 13)
- in reducing the need for intubation in the acute phase of RDS after surfactant (8, 14, 15)
- in infants with apnoea (1)

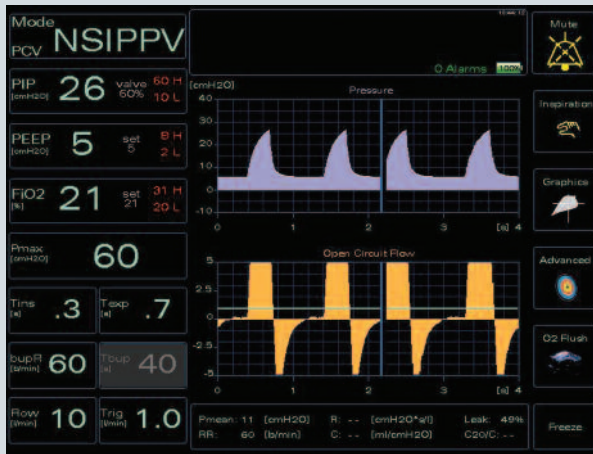


Fig 4. The GIULIA ventilator with its color touch-screen.



CHARACTERISTICS

- Invasive and non-invasive ventilation modes
- Dedicated invasive and non-invasive high-performance flow-sensors
- Two different models of patient interfaces for non-invasive ventilation
- Treatment of patients up to 5 kg of weight
- Encoder and color 10.4" Touch-Screen Digital Settings
- Manual and Automatic Alarms
- Pressure, Flow, Volume and Loop Graphical Trends
- Measurements of Compliance and Resistance
- Acoustic Signal of Trigger Activation
- Standby Mode
- O₂ Flush
- Data export

CONVENTIONAL INVASIVE AND NON-INVASIVE VENTILATION MODES

- CPAP – NCPAP
- SIMV – NSIMV
- IPPV – NIPPV
- SIPPV – NSIPPV
- VTV (invasive only)
- HHFNC (non-invasive only)

FLOW SENSOR FOR INVASIVE VENTILATION

The flow sensor for invasive ventilation is a differential pressure transducer without any electrical components, which guarantees a response time of less than 80 ms. It is autoclavable and reusable.

FLOW SENSORS AND KIT FOR NON-INVASIVE VENTILATION

Non-invasive ventilation can be performed with two different single-use sets:

- “Sync Flow Cannula, the new interface, is most comfortable for the patient and easiest to use for nurses.

- “Smart-Flow Kit NIV”, the classic interface, with nasal prongs and bonnets.

Both these devices have a dedicated flow-sensor, a very simple and light differential pressure transducer that guarantees a response time of less than 80 ms, and prongs of different sizes.

NASAL CANNULA FOR HHFNC

The single-use “High-Flow Nasal Cannula” for High-Flow therapy with heated and humidified gas are available in three different sizes.

ALARM SYSTEM

The GIULIA ventilator has all the alarms for correct and safe management of invasive and non-invasive respiratory care. The alarms are both visual and acoustic and are color-coded for priority.

HUMIDIFIER

The GIULIA ventilator is compatible with all commercial humidifiers, however GINEVRI strongly recommends using it with the new WETTY humidifier, which ensures a high level of humidity in the respiratory circuit with a very low quantity of moisture.

O₂ FLUSH

The O₂ flush delivers a preset oxygen concentration for a predetermined time.

Accessories



WETTY

WETTY is a humidifier for heating and humidifying the gas in the patient's respiratory circuit. The gas temperature and the humidity are regulated by a servo-controlled system. The humidity can be set at five different levels. Code number 8049.



TROLLEY

The trolley is designed to make GiULIA easy to use and move around. Code number 11472A70

OPTIONAL TROLLEY EXTRAS:



DRAWERS

Code number 11401A70



EXTRACTABLE SHELF

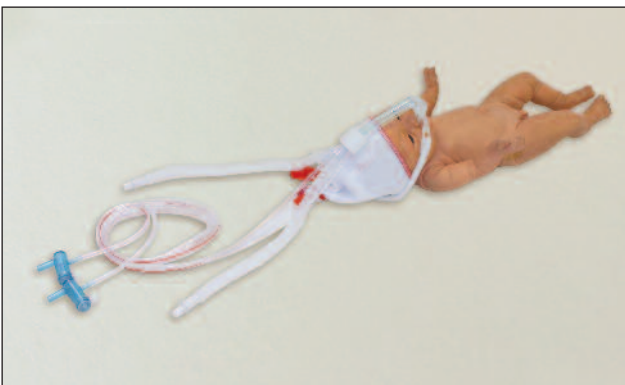
Code number 11405A70



IV POLE

Code number 6922

Consumables



SMART FLOW KIT NIV

(Disposable) Four different sizes, color coded:

RED KIT EXTRA-SMALL: Nasal prongs Ø 2 mm, length 8 mm + Flow-sensor, Ø 2.5 mm + Bonnet 25 cm.

Code number 12898A08

GREEN KIT SMALL: Nasal prongs Ø 2 mm, length 10 mm + Flow-sensor, Ø 2.5 mm + Bonnet 25 cm.

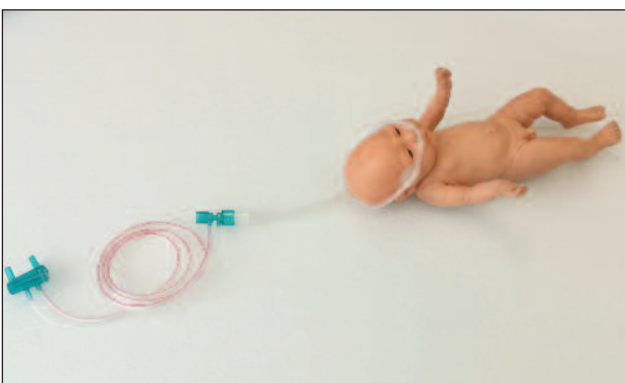
Code number 12898B08

WHITE KIT MEDIUM: Nasal prongs Ø 3 mm, length 12 mm + Flow-sensor, Ø 2.5 mm + Bonnet 30 cm.

Code number 12898C08

BLUE KIT LARGE: Nasal prongs Ø 4 mm, length 14 mm + Flow-sensor, Ø 3.5 mm + Bonnet 35 cm.

Code number 12898D08



SYNC-FLOW NASAL CANNULA

(Disposable)

XXS: Øe 2,2 mm, Interaxis 4,2 mm, length 8 mm.

Code number 13226A73

XS: Øe 2,5 mm, Interaxis 5,5 mm, length 9 mm.

Code number 13226B73

S: Øe 3 mm, Interaxis 7 mm, length 10 mm.

Code number 13226C73

M: Øe 3,5 mm, Interaxis 8,5 mm, length 11 mm.

Code number 13226D73

Consumables



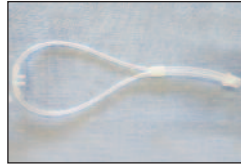
NASAL PRONGS

(Disposable)
EXTRA-SMALL: Ø 2 mm, length 8 mm.
Code number 12251A08
SMALL: Ø 2 mm, length 10 mm.
Code number 6968A08
MEDIUM: Ø 3 mm, length 12 mm.
Code number 6969A08
LARGE: Ø 4 mm, length 14 mm.
Code number 12205A08



BONNETS

(Disposable)
RED EXTRA-SMALL: 25 cm.
Code number 11659A08
GREEN SMALL: 25 cm.
Code number 11659B08
WHITE MEDIUM: 30 cm.
Code number 11659C08
BLUE LARGE: 35 cm.
Code number 11659D08



HEATED HIGH-FLOW NASAL CANNULA

(Disposable)
PEDIATRIC
Code number AEC030013
INFANT
Code number AEC030014
NEONATE
Code number AEC030015



PATIENT CIRCUIT

(Disposable) Heated inspiratory pipes, with humidification chamber and water trap.
Code number 13213A73



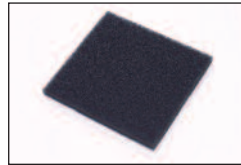
TRACHEAL TEST-LUNG

Code number 11574A70



NASAL PRONGS TEST-LUNG

Code number 11953A70



DUST FILTER

Code number 12340A73



O₂ SENSOR

Code number 10267A73



EXPIRATORY VALVE MEMBRANE

Code number 11654A08



TRACHEAL FLOW-SENSOR

(Autoclavable)
Code number S103561300



CONNECTION CIRCUIT FOR TRACHEAL FLOW-SENSOR

(Disposable)
Code number 12936A08

Patent invention No:

USA US 7,814,906 B2;
India 264045;
Cina 200610077819.3;
Europe EP 1719536.

References

- 1) Gizzi C, Montecchia F, Panetta V, Castellano C, Mariani C, Campelli M, Papoff P, Moretti C, Agostino R. "Is synchronized NIPPV more effective than NIPPV and NCPAP in treating Apnoea of Prematurity (AOP)? A randomised crossover trial", Arch Dis Child Fetal Neonatal Ed Published Online First: 15 Oct 2014 doi:10.1136/archdischild-2013-305892.
- 2) Greenough Z, Dimitriou G, Prendergast M, and Milner AD. "Synchronized mechanical ventilation for respiratory support in newborn infants", Cochrane Database Syst Rev, no. 1, Article ID CD000456, 2008
- 3) Chang HY, Claire N, D'Ugard C, Torres J, Nwajei P, and Bancalari E. "Effects of synchronization during nasal ventilation in clinically stable preterm infants", Pediatric Research, vol. 69, no. 1, pp. 84-89, 2011.
- 4) Kiciman NM, Andr asson B, Bernstein G, Mannino FL, Rich W, Henderson C, Heldt GP. "Thoracoabdominal motion in newborns during ventilation delivered by endotracheal tube or nasal prongs", Pediatric Pulmonology, vol. 25, no. 3, pp. 175-181, 1998.
- 5) Owen LS, Morley CJ, Dawson JA, and Davis PG. "Effects of non-synchronised nasal intermittent positive pressure ventilation on spontaneous breathing in preterm infants", Archives of Disease in Childhood: Fetal and Neonatal Edition, vol. 96, no. 6, pp. F422-F428, 2011.
- 6) Moretti C, Gizzi C, Papoff P, Lampariello S, Capoferri M, Calcagnini G, Bucci G. "Comparing the effects of nasal synchronized intermittent positive pressure ventilation (nSIPPV) and nasal continuous positive airway pressure (nCPAP) after extubation in very low birth weight infants", Early Human Development, vol. 56, no. 2-3, pp. 167-177, 1999.
- 7) Aghai ZH, Saslow JG, Nakhla T, Milcarek B, Hart J, Lawrysh-Plunkett R, Stahl G, Habib RH, Pyon KH. "Synchronized nasal intermittent positive pressure ventilation (SNIPPV) decreases work of breathing (WOB) in premature infants with respiratory distress syndrome (RDS) compared to nasal continuous positive airway pressure (NCPAP)", Pediatric Pulmonology, vol. 41, no. 9, pp. 875-881, 2006.
- 8) Cummings JJ, Polin RA, AAP the Committee on Fetus and Newborn. Noninvasive Respiratory Support. Pediatrics 2016;137(1):e20153758
- 9) Moretti C, Papoff P, Gizzi C, Montecchia F, Giannini L, Fassi C, Midulla F, Agostino R, Sanchez-Luna M. "Flow-synchronized nasal intermittent positive pressure ventilation in the preterm infant: development of a project", J Pediatr Neonat Individual Med. 2013;2(2).
- 10) Moretti C, Gizzi C, Montecchia F, Barb ara CS, Midulla F, Sanchez-Luna M, Papoff P. Synchronized Nasal Intermittent Positive Pressure Ventilation of the Newborn: Technical Issues and Clinical Results. Neonatology. 2016;109(4):359-65. doi: 10.1159/000444898
- 11) Moretti C, Midulla F, Barbara CS, Nenna R, Di Lucchio L, Gizzi C. Precision non-invasive ventilation in newborns. J Pediatr Neonat Individual Med. 2017; 6(2): 16-18.
- 12) Moretti C, Giannini L, Fassi C, Gizzi C, Papoff P, Colarizi P. "Nasal flow-synchronized intermittent positive pressure ventilation to facilitate weaning in very low-birthweight infants: unmasked randomized controlled trial". Pediatr Int 2008; 50: 85-91.
- 13) Lemyre B, Davis PG, De Paoli AG, et al. Nasal intermittent positive pressure ventilation (NIPPV) versus nasal continuous positive airway pressure (NCPAP) for preterm neonates after extubation (Review). Cochrane Database of Syst Rev 2017;1;2:CD003212
- 14) Gizzi C, Papoff P, Giordano I, Massenzi L, Barb ara CS, Campelli M, Panetta V, Agostino R, Moretti C. "Flow-synchronized nasal intermittent positive pressure ventilation for infants <32 weeks' gestation with respiratory distress syndrome". Crit Care Res Pract. 2012; 2012:30181805384
- 15) Lemyre B, Laughon M, Bose C, Davis PG. Early nasal intermittent positive pressure ventilation (NIPPV) versus early nasal continuous positive airway pressure (NCPAP) for preterm infants. Cochrane Database Syst Rev. 2016 Dec 15;12:CD0

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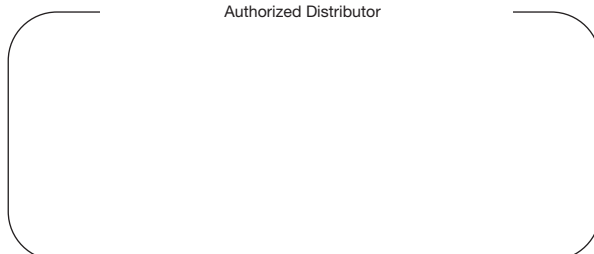
GINEVRI srl
Via Cancelliera, 25/b
00041 Albano Laziale (Rome) - Italy
Tel.: +39 06 93459 330
e-mail: export@ginevri.com
www.ginevri.com

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