

Giulia

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Neonatal Ventilator



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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 (SNIPPV) with the infant's breathing efforts. At GINEVRI we have developed a revolutionary flow-sensor to carry out SNIPPV. 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 SNIPPV, 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-SNIPPV interact with the spontaneous breathing of a VLBW infant (1).



Fig 1. The GIULIA Flow-sensor

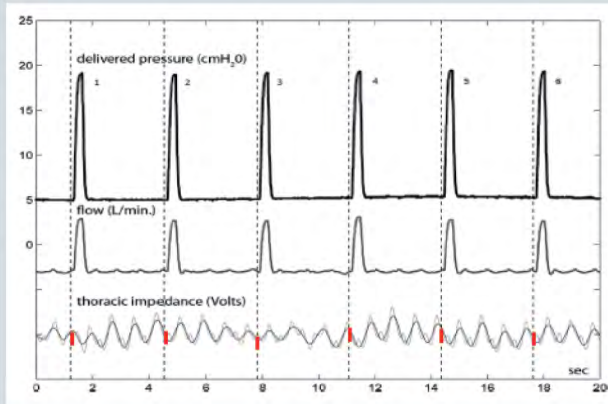


Fig 2. Reading from the top, this recording shows the delivered pressure, flow and thoracic impedance of a VLBW infant treated with NIPPV. Note the interactions of NIPPV mandatory cycles (back-up rate of 20 breaths/min) with the spontaneous respiratory rhythm of the patient. The infant is not entrained 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.

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 (3-7).

A common objection to the use of a flow sensor for non-invasive ventilation is that its reliability can be altered 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

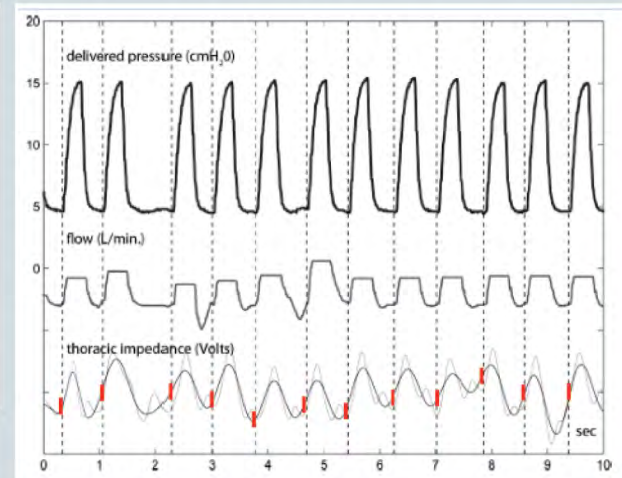


Fig 3. This recording shows the interactions of flow-SNIPPV with spontaneous breathing of the newborn. The infant is now well entrained with the ventilator and mechanical breaths start (red lines) immediately after the beginning of the patient's spontaneous ones.

demonstrate both the reliability of our flow-sensor with different measured leaks through it and the performance of the GIULIA ventilator (8). 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 affected by the amount of leaks. 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.

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Evidence from clinical trials indicates SNIPPV is more effective than nasal CPAP:

- in improving the success rate of extubation (9, 10)
- in reducing the need for intubation in the acute phase of RDS after surfactant (10-13)
- in infants with apnoea (1)

The GIULIA ventilator, initially developed only to carry out flow-SNIPPV, has recently been improved to perform also all the invasive ventilation modes (Fig 4).

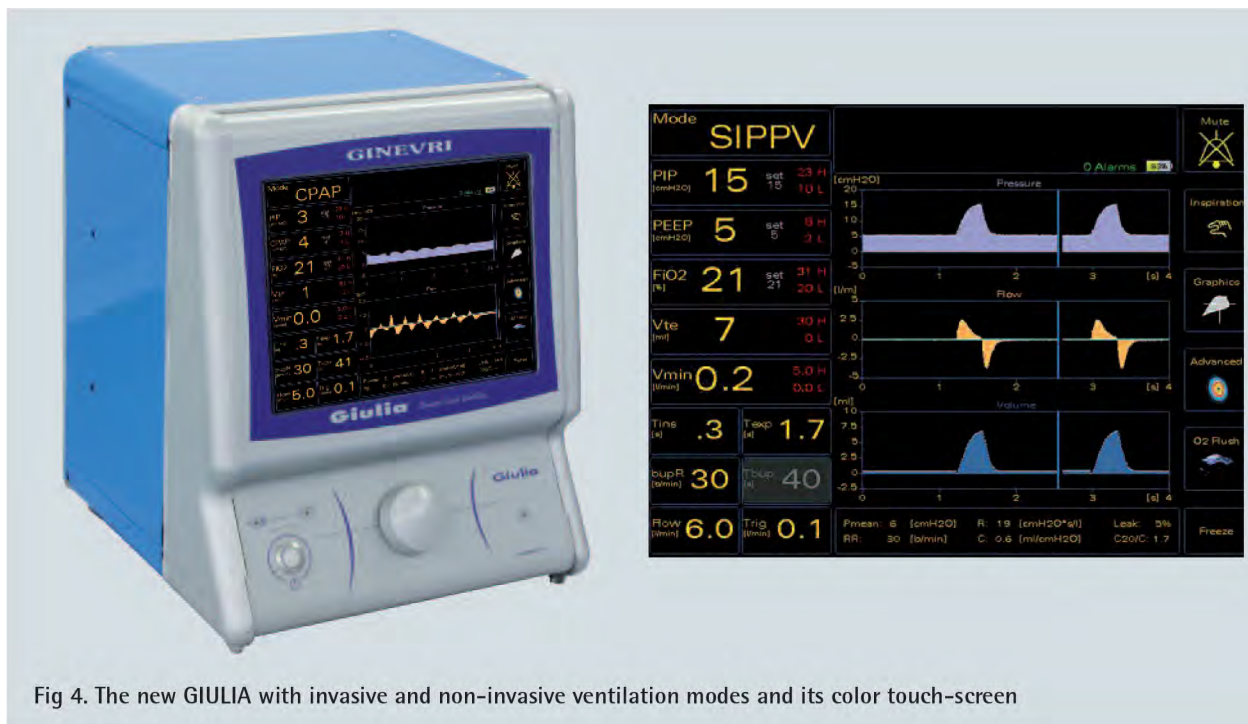


Fig 4. The new GIULIA with invasive and non-invasive ventilation modes and its color touch-screen

IMPROVEMENTS

The New GIULIA has been improved with:

- Invasive Ventilation Modes
- 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
- O₂ Flush
- Battery Level

CHARACTERISTICS

The New GIULIA can be used with patients of up to 5 kg of weight.

VENTILATION MODES

The following conventional invasive and non-invasive ventilation modes can be set:

- CPAP - NCPAP
- SIMV - SNIMV
- SIPPV - SNIPPV
- IPPV - NIPPV

FLOW SENSORS

GIULIA is supplied with two flow-sensors. Both are simple differential pressure transducers without any electrical components: one for invasive ventilation to calculate tidal volume, and the other for non-invasive ventilation, which comes in 2.5 and 3.5 mm sizes. The flow sensor for invasive ventilation guarantees a response time of less than 100 ms and is autoclavable and reusable.

SMART FLOW KIT NIV

The new flow-sensor for non-invasive ventilation gives maximum lightness and comfort for the patient. The single-use "Smart-Flow NIV Kit" for non-invasive ventilation includes nasal prongs and bonnets, and comes in four different sizes for infants of different weights.

NASAL PRONGS

The nasal prongs are made from a very soft material and are designed to adapt to the newborn's nostrils in the most comfortable way.

ALARM SYSTEM

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

O₂ FLUSH

This function 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

This dedicated trolley allows GIULIA to be used easily with its accessories.
Code number 11472A70

OPTIONAL TROLLEY EXTRAS:

DRAWERS.
Code number 11401A70
EXTRACTABLE SHELF.
Code number 11405A70
IV POLE.
Code number 6922



TRACHEAL TEST-LUNG
Code number 11574A70



NASAL PRONGS TEST-LUNG
Code number 11953A70



TRACHEAL FLOW-SENSOR
(Autoclavable)
Code number S103561300

Consumables



SMART FLOW KIT NIV

(Disposable)

Four different sizes, color coded:

RED KIT EXTRA-SMALL: Nasal prongs \varnothing 2 mm, length 8 mm
+ Flow-sensor, \varnothing 2.5 mm + Bonnet 25 cm. Code number 12898A08
GREEN KIT SMALL: Nasal prongs \varnothing 2 mm, length 10 mm
+ Flow-sensor, \varnothing 2.5 mm + Bonnet 25 cm. Code number 12898B08
WHITE KIT MEDIUM: Nasal prongs \varnothing 3 mm, length 12 mm
+ Flow-sensor, \varnothing 2.5 mm + Bonnet 30 cm. Code number 12898C08
BLUE KIT LARGE: Nasal prongs \varnothing 4 mm, length 14 mm
+ Flow-sensor, \varnothing 3.5 mm + Bonnet 35 cm. Code number 12898D08



CONNECTION CIRCUIT FOR TRACHEAL FLOW-SENSOR
(Disposable)
Code number 12936A08



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



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



PATIENT CIRCUIT
(Disposable) Heated inspiratory pipes, with humidification chamber and water trap.
Code number 12043A08



O₂ SENSOR
Code number 10267A73



EXPIRATORY VALVE MEMBRANE
Code number 11654A08



DUST FILTER
Code number 12340A73

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Quality System

ISO 9001:2008
ISO 13485:2012



The specifications in this catalogue are indicative. The company GINEVRI srl reserves the right to make changes, without further notice, to the products described within this catalogue in order to improve reliability, function or design.



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