Giulia

Neonatal Ventilator

GINEVRI

Quality for life

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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

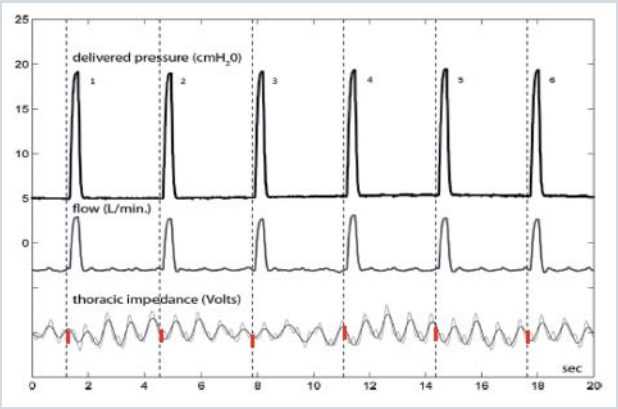

Fig 2. Reading from the top, this recording shows the delivered pressure, flow and thoracic impedance of a VLBW infant treated with NIPPV. Note the interactions of NIPPV mandatory cycles (back-up rate of 20 breaths/min) with the spontaneous respiratory rhythm of the patient. The infant is not entrained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

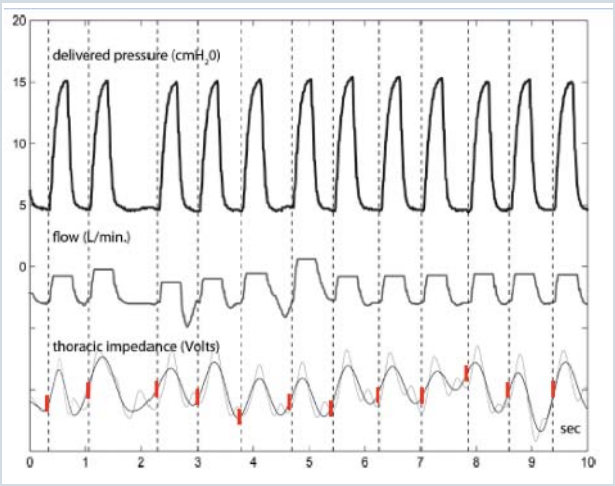

Fig 3. This recording shows the interactions of flow-SNIPPV with spontaneous breathing of the newborn. The infant is now well entrained with the ventilator and mechanical breaths start (red lines) immediately after the beginning of the patient's spontaneous ones.

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 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 ± (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).

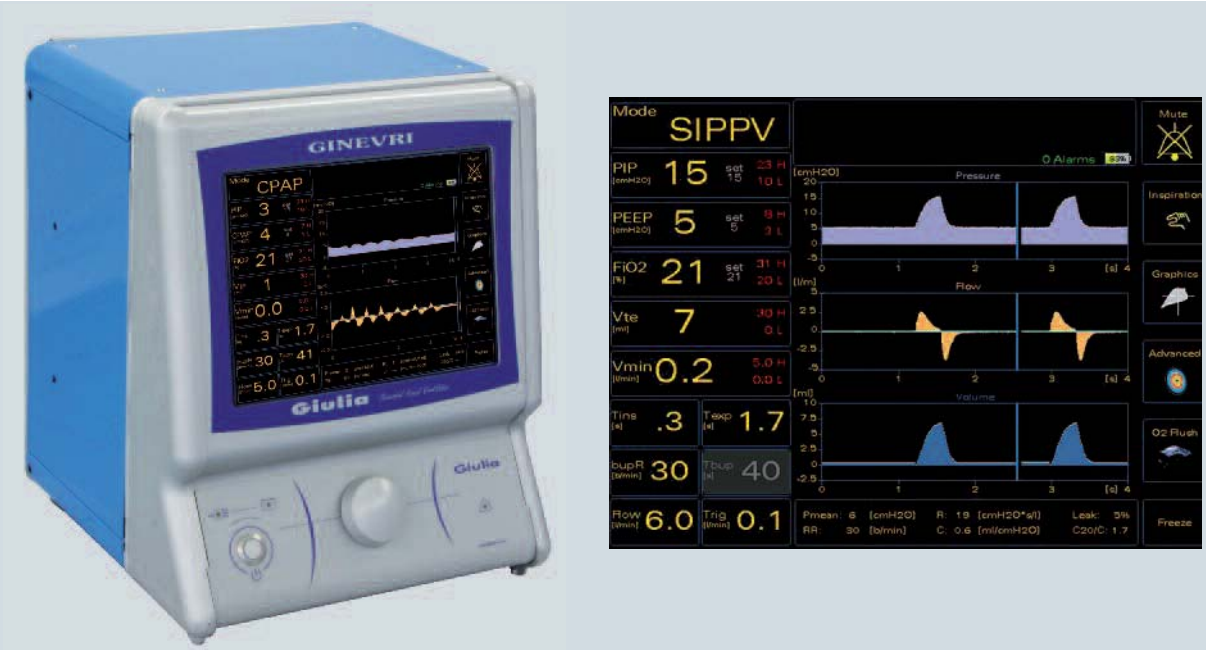

Fig 4. The new GIULIA with invasive and non-invasive ventilation modes and its color touch-screen

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
- O_2 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 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 condensation.

O_2 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 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

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: 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

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

O_2 SENSOR
Code number 10267A73

EXPIRATORY VALVE MEMBRANE
Code number 11654A08

DUST FILTER
Code number 12340A73

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Technical Specifications

General	MPG–Class	IIb	
	Dimensions (WxHxD)	38x33x38 cm	
	Weight	18 kg	
Power supply	Mains	230 V AC (50-60Hz),50VA	
		115 V AC (50- 60Hz),50VA	
	Battery	Voltage	24VDC, 45min
Gas supply		AIR	3–5 bar
		O_2	3–5 bar
Operating mode	Nasal	With Nasal prongs	
	Tracheal	With endotracheal tube	
Ventilation modes (INVASIVE & NON INVASIVE)		**SIMV, IMV ,SIPPV ,IPPV, PS, NCPAP,SNIPPV, NSIMV, NIPPV,BI-LEVEL**	
Parameters	Pmax	0–100 cm H2O	
	PIP	10–100 cm H2O	
	PEEP	0–50 cm H2O	
	CPAP	0–15 cm H2O	
	PSV	0 – 80 cm H2O	
	Flow	1-40 L/min	
	Inspiration time	0,1–5 s	
	Expiration time	0,4–60 s	
	FiO2	21–100%	
	Trigger	Flow & Pressure	
	Tapn	1–60s	
	Tbck	1–180s	
	Pre-oxygenation	21-100 % FiO2	
Monitoring	**Display**	10,4“ Color–TFT	
	Pressure	PIP	-20 ± 100 cmH2O
		PEEP	-20 ± 50 cmH2O
	Volume		
	Vte	0-500ml	
		MinuteVolume	0-25 l/min
	Respiration frequency	0–999 b/min	
	FiO2	0–100%	Accuracy: ± 5Vol
	Resistance	0–9999cmH2O/l/s	
	Compliance	0–999ml/cmH2O	
	Graph Display	pressure , Volume ,Flow	
	Data freeze and Loops	**P(t), V(t) , V’(t) , V(P) , V’(V), V’(P)**	

Alarms	**Parameter**	**Lower Limit**	**Upper limit**	**Unit**
	PIP	From (PEEP+3) to (set PIP)	From (set PIP) to 100	cmH_2O
	PEEP	From 0-50 or (PIP-2)	0-50	cmH_2O
	V min	0.0– 6.5	0.0 – 25	l/min
	VTE	0 – 20	0–500	ml
	FIO2	20–100	22–100	%
Data output	USB			

Flow Sensor	Tracheal	Pneumotachograph (Autoclavable / Reusablle)		500g–5Kg
	Nasal	Pneumotachograph (Reusable)	Diam.2.5	500g–2Kg
			Diam.3.5	2–5 Kg

Quality System

ISO 9001:2008
ISO 13485:2012

CE

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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