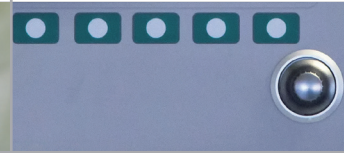




Pediatrics

Clinical Experience  
+ Technical Competence



# Sophie



The innovative Ventilation System for Neonatology

- + SpO<sub>2</sub>-Controller "SPOC" controlled Oxygen Saturation  
automatic FiO<sub>2</sub> Adjustment  
adaptive Increase of Ventilation
- + Synchronized, non-invasive Ventilation through external Respiration Sensor
- + Integrated Respiratory Gas Humidification
- + High Frequency Oscillation



# Sophie The flexible Neonatology Ventilation System

The requirements for sensitive ventilation units in neonatology are growing continuously. To meet those requirements, Fritz Stephan GmbH has developed the SOPHIE ventilation system based on state-of-the-art ventilation technology. By using SOPHIE, the individual ventilation strategy for the premature and newborn infant can be implemented easily and reliably. Modern trigger technology permits flexible synchronization of invasive and non-invasive ventilation. With **SPOC**, Fritz Stephan GmbH offers an adaptive controller SpO<sub>2</sub> controller which, for the first time, incorporates additional non-invasive ventilation into oxygen saturation control strategy.

## Oxygen Saturation Control **SPOC**

In cooperation with Ulm University Hospital/Germany, Fritz Stephan GmbH has developed an automatic SpO<sub>2</sub> control system for stabilizing oxygen saturation (SpO<sub>2</sub>). By combining the existing pulse oximetry of your clinic with SOPHIE, double measurement can be avoided.



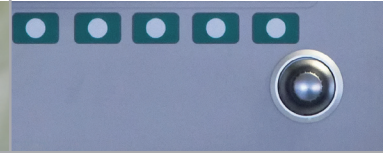
How does **SPOC** react to desaturation?

- + under NIV, the synchronized mechanical ventilation is intensified and helps to positively influence oxygen uptake (VO<sub>2</sub>).
- + Increase of FiO<sub>2</sub> is not uniform, previous and current events are taken into account.
- + In case of hyperoxia **SPOC** reduces FiO<sub>2</sub> to below 25% within a very short time.

**SPOC** operates independently of the selected ventilation form.

**SPOC** helps to:

- + prevent hyperoxia, to reduce oxidative stress
- + prevent hypoxia, to avoid hemorrhage and damage to brain tissue
- + reduce SpO<sub>2</sub> fluctuation
- + increase the period within the SpO<sub>2</sub> target range



### **Ventilation forms**

Easy accelerated change between all established, conventional and pressure controlled ventilation forms is possible with just a single menu selection. Also included is the volume guarantee feature, which controls respiratory pressure of the subsequent inspiration corresponding to the previously measured expiratory tidal volume.

### **High Frequency Oscillation HFOV**

SOPHIE combines High Frequency Oscillation and conventional ventilation forms in one device. HFOV can be activated immediately without replacing the patient tube by the push of just a single button. The application of an integrated, active respiratory humidifier does not create any additional compressible volumes which may affect HFOV performance.

### **Optimum respiratory gas conditioning**

The integrated active respiratory humidification system supplies the patient by nebulizing optimally warmed and humidified respiratory gas. The intelligent control system prevents the formation of condensate in the heated, temperature controlled patient tubes. SOPHIE thus conditions respiratory gas independently of auxiliary devices.

### **Non-invasive Ventilation (NIV)**

NIV allows lung protective ventilation strategies thus reducing the occurrence of air leak syndromes and BPD. NIPPV minimizes both the risk of respiratory failure after extubation and the frequency of reintubation significantly. By using an external respiration sensor, patient abdominal movements are converted to a stable, responsive (<30ms) trigger signal. This synchronized non-invasive ventilation (SnIPPV) increases effectiveness and reduces reintubation rates.

### **Intuitive Operation Concept**

Relevant ventilation parameters can easily be adjusted to the patient requirements prior to commencing ventilation. Effective monitoring allows safe supervision at all times.

Separate adjustment of relevant parameters during ventilation is simplified by clearly assigned buttons.



## Clinical Experience Technical Competence

General specifications	
Patient range	Neonates and pediatric patients up to 25 kg
Classification	II b (according to 93/42 ECC)
Dimensions	470 x 342 x 332 mm (WxHxD)
Weight	26 / 42 kg (without/with trolley)
Function principle	Time cycled, pressure controlled
Operational specifications	
Power supply	100-240 V AC, 50-60 Hz, 210 VA, 24 V DC (opt.)
Battery backup	min. 90 min. (with internal, rechargeable Li-Ion-Battery)
Gas supply	
AIR	2.7 - 6.5 bar
O <sub>2</sub>	2.7 - 6.5 bar
Ventilation parameters	
Ventilation modes	
PC-IMV, PC-Ass./Cont., PC-SIMV, PC-HFO (opt.), PC-IMV-HFO (opt.), PC-Ass./Con.-ITT, PC-SIMV-ITT, nCAP, NIPPV, SNIPPV (opt.)	
Modifications	Volume guarantee (VtLim/VtTar) Inspiratory Time Termination (ITT) PSV
Maneuver functions	Inspiration Hold / Manual, Pre-oxygenation, Medication nebulization
Ventilation settings	
Frequency	1 - 300/min
Inspiration time	0.1 - 2 s
Expiration time	0.1 - 60 s
Tidal volume	2 - 150 ml (VtTar/VtLim)
Pmax	5 - 60 mbar
PEEP	0 - 30 mbar
Inspiration pattern	Rectangle, sinusoidal, linear
Trigger sensitivity	
Flow	0.2 - 2.9 l/min
Pressure	0.2 - 2.9 mbar
Abdominal movement	0.2 - 2.9 Arbs
NIV MaxFlow	Off/20 - 6 l/min
Breathing gas temp.	30 - 40° C
FiO <sub>2</sub>	21 - 100%
Inspiratory Time Termination (ITT) PSV	
Exsp.-Trigger KV%	5 - 40% V' Peak
High frequency oscillation HFO	
Frequency	5 - 15 Hz
Inspiration	33 - 50%
MAP	0 - 30 mbar
Amplitude Posz	5 - 100%
Amplitude Vosz	max. 24 ml @ 10 Hz
Base FiO <sub>2</sub>	21 - 100%
Backup FiO <sub>2</sub>	Basis, 21 - 100%
SpO <sub>2</sub> UL	84 - 100%
SpO <sub>2</sub> LL	80 - 96%
Inspiration	Hold / Manual
Max. Hold time	T <sub>insp</sub> 1 - 7 s
Medication nebulization	
Aerosol time	30 - 420 s
Pre-oxygenation	
FiO <sub>2</sub>	FiO <sub>2</sub> - 100%
Preoxy time	0 - 420 s

Measured values	
Pressure measurement	
Insp. pressure	-20 - 99 mbar (Pmax)
End expiration pressure	-20 - 99 mbar (PEEP)
Mean airway pressure	-20 - 99 mbar (Pmean)
Osc. amplitude	0 - 120 mbar (Posz)
Volume measurement	
Insp. tidal volume	0 - 999 l (VTins)
Exp. tidal volume	0 - 999 l (VTexp)
Leck volume	0 - 999 l (VTleck)
Exp. minute volume	0 - 999 l/min (MV)
Osc. minute volume	0 - 999 l/min (MVo)
Ventilation time parameters	
Breathing frequency (F)	0 - 999 l/min
Inspiration	0 - 100% (Insp%)
O <sub>2</sub> measurement	
FiO <sub>2</sub>	0 - 100%
Breathing gas temperature	
Proximal measurement	12 - 60° C
Lung mechanics	
Resistance (R)	0 - 999 mbar/l/s
Compliance (C)	0 - 999 ml/mbar
SpO <sub>2</sub>	0 - 100%
Base FiO <sub>2</sub>	0 - 100%
Curve display	Paw(t), V'(t), V(t), V(P), V'(V), V'(P), Arbs(t)
Trend display	Pmitt(t), MV(t), VT(t), FiO <sub>2</sub> (t), BaseFiO <sub>2</sub> (t), SpO <sub>2</sub> (t)
Trend duration	0,5; 1; 2; 4; 12; 24 (h)
Alarms/Monitoring	
Airway pressure	high/low (Pmax)
Exp. minute volume	high/low (MV)
Exp. tidal volume	high/low (VT)
Insp. O <sub>2</sub> Concentr. FiO <sub>2</sub>	high/low
Breathing gas temperature	high/low
End exp. pressure	high (PEEP)
Mean airway pressure	high/low (Pmean)
Osc. amplitude	high/low (Posc)
Osc. tidal volume	high/low (Vosc)
Osc. minute volume	high/low (MVosc)
BasisFiO <sub>2</sub>	high
FiO <sub>2</sub> limit	
Disconnection	
Water level humidifier bottle	
Apnea	
Interfaces / Monitors	
RS232: Vue Link, PDMS, IntelliBridge	
GE Healthcare	Patient monitor DASH 2000/3000/4000/5000
	Patient monitor SOLAR 8000i/8000M/9500
	Unity Network Interface Device in connection with pulse oxymeter option
Masimo	Radical 7 Signal Extraction pulse CO oximeter
Philips	IntelliVue X2, MP series, MX series
Dräger	Infinity series
Operating unit	
Screen	10,4" color TFT
Color scheme	Day view / Night view
Input devices	Buttons + Turn-Push-Button