



# Sophie

The innovative ventilation system for neonatology

- + Dead space free ventilation control with external respiration sensor
- + Synchronized, non-invasive ventilation
- + Integrated respiratory gas humidifier
- + High Frequency Oscillation (HFO)
- + Ergonomic design



## Sophie The flexible neonatology ventilation system

In intensive cooperation with renowned physicians, Fritz Stephan GmbH has succeeded in developing SOPHIE as a neonatology ventilator system based on the proven cutting-edge technology of STEPHANIE thus ensuring highest levels of efficiency, design and operability. With its flexibility and performance, SOPHIE can be adapted easily and reliably to the individually required ventilation situation for premature and newborn infants.

In addition to conventional and high frequency ventilation strategies it also allows non-invasive ventilation. This system sets new standards of non-invasive ventilation of premature and newborn infants by combining the innovative patient interface „EasyFlow nCPAP“ with dead space free ventilation control via external respiration sensor.



### **Ventilation modes**

SOPHIE offers all established conventional pressure controlled ventilation forms. Convenient undelayed change between various ventilation modes are possible by simple menu selection.

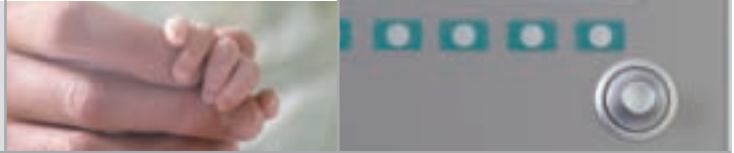
As a matter of course, our well proven volume guarantee is included in the range of features. It controls ventilation pressure of the subsequent inspiration according to the previously measured expiratory tidal volume.

### **High Frequency Ventilation HFOV**

SOPHIE is a ventilator that combines high-frequency oscillation and conventional ventilation strategies in one unit. The HFOV, which is available by pressing a button, can be carried out without any delay or need to change the patient tubes. The integration of the heated humidifier avoids any additional compressible volumes that would reduce the HFOV performance.

### **Optimum respiratory gas conditioning**

The integrated respiratory gas humidifier provides the patient simply and safely with ideally heated and humidified respiratory gas through molecular humidification. The intelligent control system prevents any condensation in the heated, temperature-monitored patient tubes. SOPHIE thus needs absolutely no additional equipment to condition the respiratory gas.



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

The benefits of a non-invasive ventilation therapy for newborn or prematurely born babies have been established by several scientific studies (e.g. COIN study). The application of NIV permits lung-protective ventilation strategies thus helping reduce the occurrence of air leak syndromes and BPD.

The use of NIPPV reduces the danger of ventilation failure after extubation and therefore significantly reduces the incidence of reintubation. A newly developed system of Fritz Stephan GmbH detects the abdominal movement of patients by means of an external respiration sensor. This is then converted into a stable, fast-reacting (<30ms) trigger signal, thus allowing SNIPPV which can further improve the efficiency of ventilation.

Although the BPD rate has the tendency to be lowered by an early application of NIV, the risk of pneumothorax may increase (especially in very prematurely born babies) since exogenous surfactants can only be safely applied to an intubated patient. Due to its innovative control system, SOPHIE allows swift changes between invasive and non-invasive

ventilation thus allowing the optimal support of the so-called INSURE method (INTubation-SURfactant-Extubation).

### **Innovative design**

SOPHIE's innovative design combines top quality aluminium and glass surfaces to produce an aesthetic whole.

SOPHIE's compatibility with STEPHANIE is another advantage: patient components, tubes and sensors are identical thus allowing an easy exchange between the two units.

### **Intuitive operation concept**

All settings can be adjusted with just one single knob. The user is guided systematically through the ventilation menu, with the display only showing the relevant parameters for the chosen ventilation form. The parameters can be adapted easily to the patient's needs even before starting ventilation. Efficient monitoring permits safe control at all times. Clearly allocated buttons make it much easier to separately adapt the relevant parameters during ventilation.



Clinical Experience  
Technical Competence

## Technical Specifications

General specification	
Patient range	Neonates and pediatric patients up to 25 kg bodyweight
Class according to 93/42 ECC	II b
Dimensions	470 x 342 x 332 mm (WxHxD)
Weight	26 / 42 kg (w/o /with trolley)
Function principle	Time cycled, pressure controlled
Operational specification	
Power supply	100 - 240 V AC, 50 - 60 Hz, 210 VA, 24V DC (opt.)
Battery backup	min. 60 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, nCPAP, NIPPV, SNIPPV (opt.)
Modifications	Volume guarantee (VtLim/VtTar)
	Inspiratory Time Termination ITT (PSV)
Maneuver functions	Inspiration Hold / Manual Medication nebulization Preoxygenation
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 cmH <sub>2</sub> O
PEEP	0 - 30 cmH <sub>2</sub> O
Pmin	PEEP-Pmax
Inspiration pattern	Rectangle, sinusoidal, linear
Trigger sensitivity	
Flow	0.2 - 2.9 l/min
Pressure	0.2 - 2.9 cmH <sub>2</sub> O
Abdominal movem.	0.2 - 2.9 Arbs
NIV MaxFlow	Off/20 - 6 l/min
Breathing gas temp.	33 - 39 °C
FiO <sub>2</sub>	21 - 99 %
Inspiratory Time Termination (ITT) PSV	
Exp.-Trigger KV%	5 - 40 % V' Peak
High Frequency Oscillation HFO	
Frequency	5 - 15 Hz
Inspiration	33 - 50%
MAP	0 - 30 cmH <sub>2</sub> O
Amplitude Vosc	max. 24 ml @ 10 Hz
Inspiration Hold / manual	
Max. Hold Time	T <sub>insp./1</sub> - 7 s

Ventilation settings	
Medication nebulization	
Aerosol time	30 - 420 s
Preoxygenation	
FiO <sub>2</sub>	FiO <sub>2</sub> - 100%
Preoxy time	0 - 420 s
Measured values	
Pressure measurement	
Insp. press.	-20 - 99 cmH <sub>2</sub> O (Pmax)
End-Expir. press.	-20 - 99 cmH <sub>2</sub> O (PEEP)
Mean airway press.	-20 - 99 cmH <sub>2</sub> O (Pmean)
Osc.-amplitude	0 - 120 cmH <sub>2</sub> O (Posc)
Volume measurement	
Insp. tidal volume	0 - 999 l (VT <sub>ins</sub> )
Exp. tidal volume	0 - 999 l (VT <sub>exp</sub> )
Leak volume	0 - 999 l (VT <sub>leak</sub> )
Exp. minute volume	0 - 999 l/min (MV)
Osc. minute volume	0 - 999 l/min (MV <sub>o</sub> )
Ventilation time parameters	
Breathing frequency	0 - 999/min (F)
Inspiration	0,1 - 100% (Insp%)
O <sub>2</sub> measurement	
FiO <sub>2</sub>	0 - 100%
Breathing gas temperature	
Proximal measur.	12 - 60 °C
Lung mechanics	
Resistance (R)	0 - 999 H <sub>2</sub> O/l/s
Compliance (C)	0 - 999 ml/cmH <sub>2</sub> O
Curve display	Paw(t), V'(t), V(t), P(V), P(V'), V(V'), Arbs(t)
Trend display	Pmean(t), MV(t), VT(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	low (VT)
Insp.O <sub>2</sub> -Concentr. FiO <sub>2</sub>	high/low
Breathing gas temp.	high/low
End-Exp. pressure	high (PEEP)
Mean airway pressure	high/low (Pmean)
Oscillatory amplitude	high/low (Posc)
Osc. tidal volume	high/low (V <sub>o</sub> )
Osc. minute volume	high/low (MV <sub>o</sub> )
Disconnection	
Water level humidifier bottle	
Apnea	
Interface	
RS232: VueLink/PDMS	
User interface	
Display screen	10,4" Color-TFT
Color-Schemes	Day view / Night view
Input devices	Buttons + Turn-Push-Button