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
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.

Sophie The flexible neonatology ventilaton 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.
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.
### Technical Specifications

#### General specification

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<th>Patient range</th>
<th>Neonates and pediatric patients up to 25 kg bodyweight</th>
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<td>Class according to 93/42 ECC</td>
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<tr>
<td>Dimensions</td>
<td>470 x 342 x 332 mm (WxHxD)</td>
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<tr>
<td>Weight</td>
<td>26 / 42 kg (w/o /with trolley)</td>
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<td>Function principle</td>
<td>Time cycled, pressure controlled</td>
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#### Ventilation modes

- PC-IMV, PC-Ass./Cont., PC-SIMV, PC-HFO (opt.), PC-IMV-HFO (opt.), PC-Ass./Cont.-ITT, PC-SIMV-ITT, nCPAP, NIPPV, SNIPPV (opt.)

#### Modifications

<table>
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<tr>
<th>Volume guarantee (VtLim/VtTar)</th>
<th>Inspiratory Time Termination (ITT) (PSV)</th>
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<td>Preoxygenation</td>
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#### Ventilation parameters

- **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 cmH₂O
  - PEEP: 0 - 30 cmH₂O
  - Pmin: PEEP-Pmax
  - Inspiration pattern: Rectangle, sinusoidal, linear

- **Trigger sensitivity**
  - Flow: 0.2 - 2.9 l/min
  - Pressure: 0.2 - 2.9 cmH₂O
  - Abdominal movement: 0.2 - 2.9 Arbs
  - NIV MaxFlow: Off/20 - 6 l/min
  - Breathing gas temp.: 33 - 39 °C
  - FiO₂: 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 cmH₂O
    - Amplitude Vosc: max. 24 ml @ 10 Hz

- **Inspiration Hold / Manual**
  - Max. Hold Time: Tinsp./1 - 7 s

#### Medication nebulization

- **Aerosol time**: 30 - 420 s

#### Preoxygenation

- **FiO₂**: FiO₂ - 100%

- **Preoxy time**: 0 - 420 s

#### Measured values

- **Pressure measurement**
  - Insp. press.: -20 - 99 cmH₂O (Pmax)
  - End-Expir. press.: -20 - 99 cmH₂O (PEEP)
  - Mean airway press.: -20 - 99 cmH₂O (Pmean)
  - Osc.-amplitude: 0 - 120 cmH₂O (Posc)

- **Volume measurement**
  - Exp. tidal volume: 0 - 999 l (VTins)
  - Exp. minute volume: 0 - 999 l/min (MV)
  - Exp. tidal volume: 0 - 999 l/min (MVo)

- **Ventilation time parameters**
  - Breathing frequency: 0 - 999/min (F)
  - Inspiration: 0,1 - 100% (Insp%)
  - O₂ measurement
    - FiO₂: 0 - 100%

- **Breathing gas temperature**
  - Proximal measurem.: 12 - 60 °C

- **Lung mechanics**
  - Resistance (R): 0 - 999 H₂O/l/s
  - Compliance (C): 0 - 999 ml/cmH₂O
  - 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)

- **Inspiratory Time Termination (ITT) PSV**
  - PSV

- **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 (Vo)

- **Osc. minute volume**
  - high/low (MVo)

- **Disconnection**
  - Water level humidifier bottle

#### Interface

- **TreeLink/PDMS**

#### User interface

- **Display screen**
  - 10,4” Color-TFT

- **Color-Schemes**
  - Day view / Night view

- **Input devices**
  - Buttons + Turn-Push-Button