STEPHAN®




# SOPHIE

SPO2C inside

## THE INNOVATIVE NEONATAL VENTILATION SYSTEM

# SO PRECISE. SO PERFECT. SOPHIE.

Sophie was developed to meet the demand of neonatologists for a sensitive ventilator. SOPHIE offers state-of-the-art ventilation technology with the option of using customized ventilation strategies for premature and newborn babies. Its high-tech trigger technology provides you with flexible synchronization for both invasive and non-invasive ventilation.
The major challenge in non-invasive ventilation (NIV) of newborn and premature infants is the adjustment of ventilation and oxygen saturation to the current, frequently changing patient situation.

This is one of SOPHIE's strengths; thanks to innovative sensor technology, the device immediately recognizes changes and adjusts therapy parameters accordingly. In addition, you have the option of activating high-frequency oscillation at the touch of a single button if the situation so requires. Plus: SOPHIE allows effective monitoring at every stage during therapy to ensure optimal supervision.



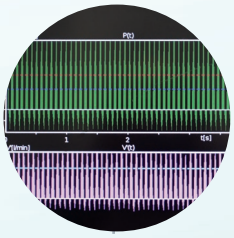


# DEMONSTRATED TO PROLONG TIME IN OPTIMAL OXYGEN SATURATION.

SOPHIE uses $SPO_2C$, an integrated oxygen saturation controller, which automatically maintains optimum oxygen saturation. By adjusting saturation in real time, SOPHIE helps to prolong the proportion of time spent in the predefined $SPO_2C$ target range and to reduce hypoxemic episodes.

Monitoring the course of therapy is also simplified considerably, as all relevant parameters are continuously recorded and can be accessed in trend view at any time.

# THESE FEATURES MAKE SOPHIE UNIQUE.



Integrated high-frequency oscillation



External respiration sensor for synchronized non-invasive ventilation and apnea detection



Automatic integrated respiratory humidification




Clearly arranged, user friendly touch panel



Heated electronic flow sensor




$SpO_2$ controller $SPO_2C$ for optimum oxygen saturation



# SOPHIE

SPO2C inside






## SO INNOVATIVE. SO INTELLIGENT. SOPHIE.

SOPHIE not only automatically adapts the therapy to the patient's needs but also documents the entire course of therapy. This relieves the strain from care staff and creates space for the important aspects of care which cannot be automated. The advantages in everyday hospital life are obvious:

- No manual recording of oxygen saturation
- Reduction of manual therapy adjustments
- Optimal ventilation of the little patients at all times

If required, simply activate high-frequency oscillation at the push of a button. Thanks to the integrated solution, there is no need for changing patient tubes.

Because little patients change their breathing pattern with every movement, SOPHIE is particularly flexible. The respiratory sensor converts abdominal movements into a trigger signal and ventilation is adapted automatically. The child's breathing and NIV ventilation are synchronized in real time. Recent studies have shown that this synchronized intermittent positive pressure ventilation is the most effective mode of support in preventing reintubation and reducing the risk of CLD or pulmonary air leaks.

Another major advantage of SOPHIE is its electronic flow sensor. It allows accurate measurement of flow rates to record tidal volume (Vt) and flow with minimal dead space. The sensor is heated to prevent condensation. Respiratory gas is optimally humidified thanks to the integrated humidification system, which heats and humidifies respiratory gas for the little patients.

# TECHNICAL DATA

| General | |
|---|---|
| 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 |
| Battery backup | min. 80 min. (with internal, rechargeable Li-Ion-Battery) |
| Gas supply | |
| AIR | 2.7 - 6.5 bar |
| $O_2$ | 2.7 - 6.5 bar |

| Ventilation parameters | |
|---|---|
| Ventilation modes | |
| Invasive | CPAP, PC-IMV, PC-Ass./Cont., PC-SIMV, PC-HFO, PC-sHFO |
| | PC-IMV-HFO, PC-Ass./Con.-ITT, PC-SIMV-ITT |
| Non-invasive | nCPAP, NIPPV, SNIPPV (opt.), NIVA, PC-HFO, PC-sHFO, |
| | PC-IMV-HFO, HighFlow |
| Modifications | Volume guarantee (VtLim/VtTar), Volume guarantee |
| | (HFO/Vosc), nspiratory Time Termination (ITT) PSV |
| Maneuver functions | Inspiration Hold / Manual, Pre-oxygenation, |
| | Medication nebulization |

| Flow sensor | |
|---|---|
| Single use or reusable, electronical, heated | |
| PDFS | dead-space-free flow sensor |

| Ventilation settings | |
|---|---|
| Frequency | 1 - 300/min |
| Insp.-time/Exsp.-time | 0.1 - 2 s / 0.1 - 60 s |
| Tidal volume | 2 - 150 ml (VtTar/VtLim) |
| Pmax / PEEP | 5 - 60 mbar / 0 - 30 mbar |
| Inspiration pattern | Rectangle, sinusoidal, linear |
| Trigger sensitivity | |
| Flow (High Flow) | 1–25 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 |
| $FiO_2$ | 21 - 100% |
| 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 mbar |
| Amplitude Posc | 5 - 100% |
| Amplitude Vosc | max. 24 ml @ 10 Hz |
| Base $FiO_2$ | 21 - 100% |
| Backup $FiO_2$ | Base, 21 - 100% |
| $SpO_2$ UL | 84 - 100% |
| $SpO_2$ LL | 80 - 96% |
| Inspiration | Hold / Manual |
| Max. hold time | Tinsp 1 - 7 s |
| Medication nebulization | |
| Aerosol time | 30 - 420 s |
| Pre-Oxygenation | |
| $FiO_2$ | $FiO_2$ - 100% |
| Preoxy time | 0 - 420 s |
| HFO Vosc | Off / 0.1–40 l/min |
| NIVA Gain | Auto / 1–99 % |

| Parameters | |
|---|---|
| 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 (Posc) |
| Volume measurement | |
| Insp. tidal volume | 0 - 999 ml (VTins) |
| Exp. tidal volume | 0 - 999 ml (VTexsp) |
| Leak volume | 0 - 999 ml (VTleak) |
| Exp. minute volume | 0 - 999 l/min (MV) |
| Osc. minute volume | 0 - 999 l/min (MVo) |
| Ventilation time parameters | |
| Breathing frequency (F) | 0 - 999 /min |
| Inspiration | 0 - 100% (Insp%) |
| $O_2$ measurement | |
| $FiO_2$ | 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 |
| $SpO_2$ | 0 - 100% |
| Base$FiO_2$ | 0 - 100% |
| Curve display | Paw(t), V'(t), V(t), V(P), V'(V), V'(P), Arbs(t) |
| Trend display | Pmean(t), MV(t), VT(t), $FiO_2$(t), |
| | Base$FiO_2$(t), $SpO_2$(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. $O_2$Conc. $FiO_2$ | high/low |
| Breathing gas temp. | 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) |
| Base $FiO_2$ | high |
| $FiO_2$Limit | |
| Disconnection | |
| Water level humidifier bottle | |
| Apnea | |

| Features |
|---|
| Abdominal trigger (external) |
| $SPO_2$C ($SpO_2$-Controller) |
| Refill-System (automatically) for integrated humidification |

| Interfaces / Monitore | |
|---|---|
| RS232 (Vue Link, PDMS, IntelliBridge), USB, Ethernet, HL7 | |
| GE Healthcare | Patient monitor DASH, SOLAR, CARESCAPE |
| | 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 | 12.1" Colour Touchscreen |
| Color scheme | Day view / night view |
| Input devices | Buttons + Turn-Push-Button, Touchscreen |

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