STEPHAN®

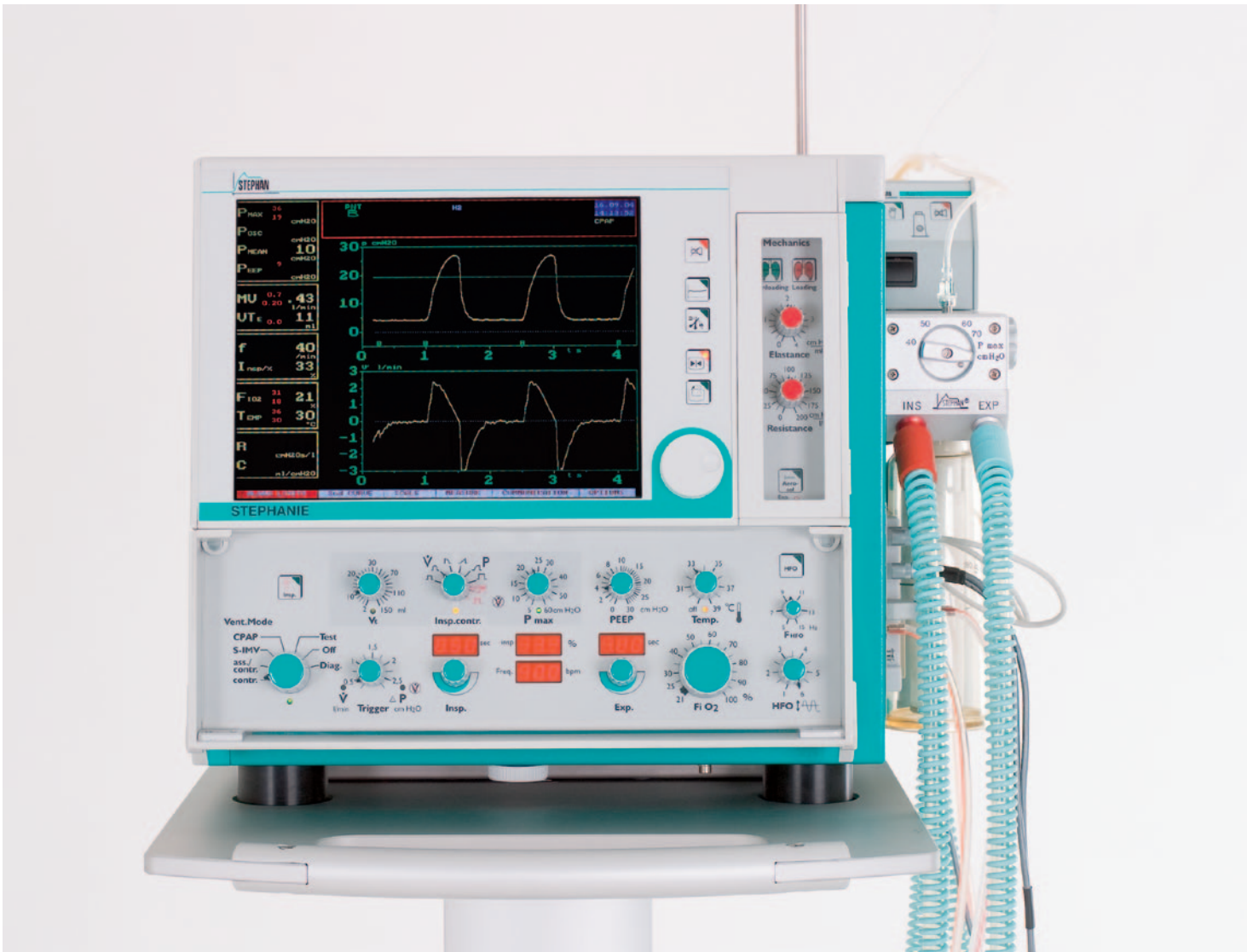
Pediatrics

Clinical Experience
Technical Competence

Stephanie

The ventilation system for neonatology

+ Conventional ventilator
+ High-frequency oscillator
+ Proportional Assist Ventilation (PAV)
+ Integrated patient gas humidifier
+ Minimum volume guarantee
+ Innovative „Closed Loop Ventilation“
+ Dead space free ventilation control with external respiration sensor
+ Synchronized, non-invasive ventilation



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Success in the area of top-class medical technology lies in the details. And it is in these details that the STEPHANIE neonatal ventilation system excels. From the outset, Fritz Stephan GmbH has specialized in solutions associated with ventilation in the area of neonatology and pediatrics. Through its many years of working closely with hospitals, Fritz Stephan GmbH is well aware of the demands medical personnel place on their "tools". The unique combination of ventilator, patient gas humidifier, oscillator and monitor available for the first time in this unit opens previously unimagined possibilities with regards to diagnostics and treatment. STEPHANIE is an excellent example of how clinical experience and technical expertise can lead to an outstanding product.

The highlights

Conventional respiraiton

STEPHANIE provides all conventional ventilation modes such as CPAP, S-IMV, A/C (assisted/controlled ventilation), V-CMV (volume-controlled ventilation) with various inspiration flow patterns as well as P-CMV (pressure-controlled ventilation) with various inspiratory pressure pattern. The V-CMV mode is equipped with leak-gas compensation with which the inspiratory leakage frequently associated with premature infants can, to a great extent, be offset. STEPHANIE now also offers PSV for patient-triggered ventilation procedures.

Volume-limited ventilation

Premature infants undergoing controlled ventilation tend to synchronize their respiration to the ventilator's rhythm, resulting in so-called "entrainment". This can result in an undesirably high inspiration tidal volume and a possible volume trauma. In order to counteract this tendency, the P-CMV of the new STEPHANIE provides volume limitation. Once the expiration volume reaches the volume limit, the pressure of the sub-sequent inspiration is limited or applied at the lowest possible ventilation pressure, thus safely and quickly preventing an excessively high tidal volume. We refer to this as the „minimum volume guarantee".

HFO
The integrated high-frequency oscillation ventilation (HFOV) can be initiated at the push of a button and without any delay or the necessity of changing patient tubes. The unique patient ventilator means that there are no additional compressible volumes which can reduce the performance of the HFO.

Patient gas conditioning
The integrated, heated patient gas humidification system generates saturated and warmed respiration gas ahead of the inspiration valve, in other words, "within" the ventilator so to speak. The heated patient tubes provide temperature monitoring when carrying the gas to the patient. Intelligent sensors compensate any temperature differences. This helps avoid both frequent patient tube changes as well as preventing the ormation of condensation in the tubes, thus increasing the hygienic standard.

Monitor
Optimal monitoring by means of the integrated 10.4" TFT monitor visualizes all relevant respiratory parameters. The patient's overall vital signs can be quickly and comprehensively assessed.

PAV
An additional special feature offered by STEPHANIE lies in the expansion of the conventional ventilation modes to include "Proportional Assist Ventilation" (PAV), which reduces obstructive or resistive stresses on natal lungs in a volume- or flow-proportional manner, thus aiding in compensating for these deficiencies.

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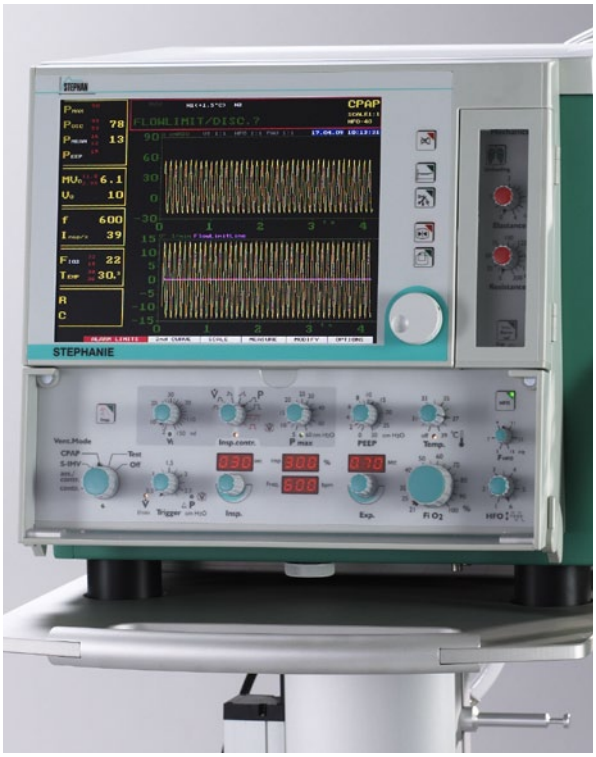
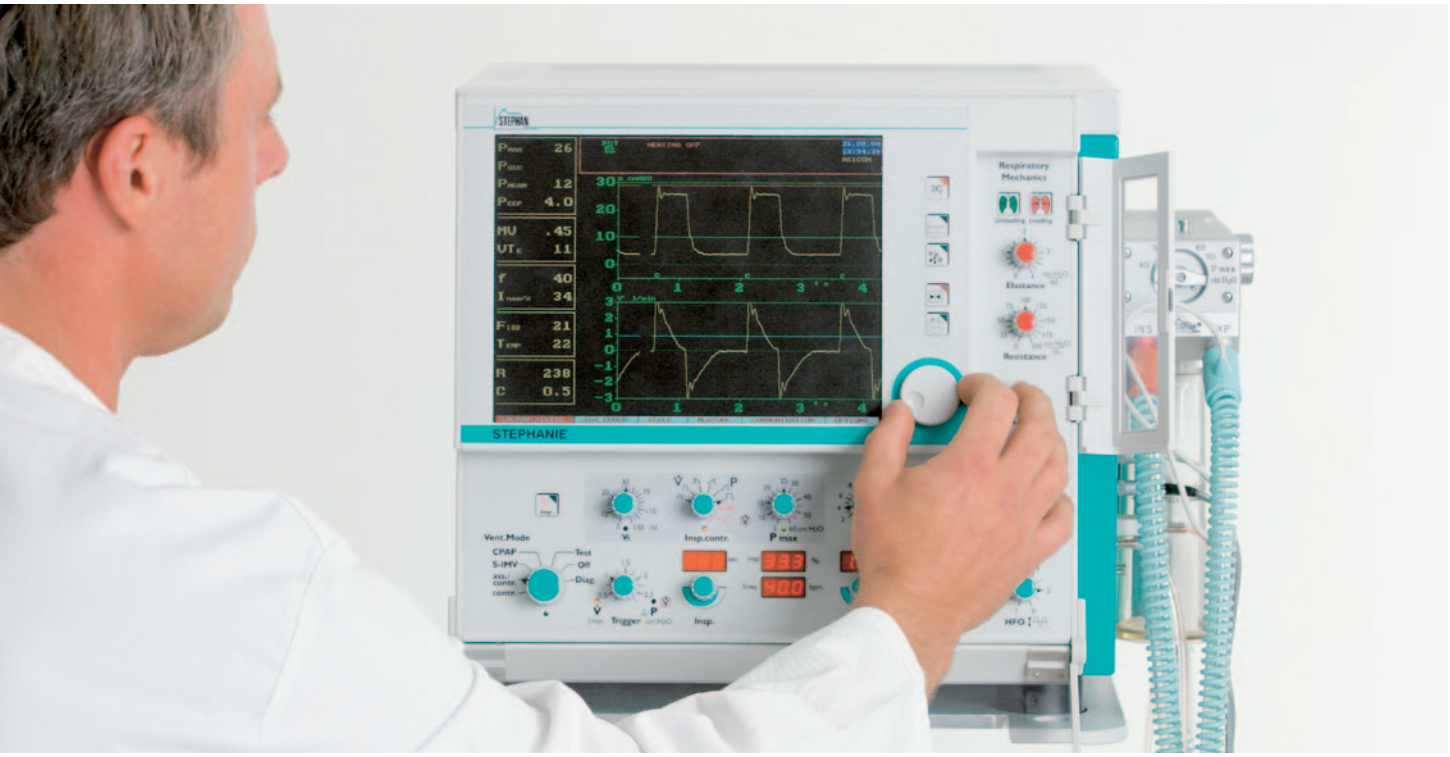


High-frequency oscillation
The integrated high-frequency oscillation represents one of the characteristics which sets this system apart. It can be activated at the push of a button, and frequency, amplitude as well as the I/E ratio are all ad-justable. The wide adjustment range of the Mean Airway Pressure (MAP) up to 30 cmH2O provides reliable oxygenation. The precision monitoring fully developed for STEPHANIE permits even the smallest volumes to be measured during HFOV, even at very high frequencies. Thanks to the effective amplitude (stroke volume: approx. 24 ml), patients weighing up to 10 kg can be reliably oscillated.

"Proportional Assist Ventilation" (PAV)
The integrated "elastic and resistive relief" procedure allows medical personnel to employ the so-called "Proportional Assist Ventilation" (PAV) method. This respiration treatment achieves a reduction in the resistive and elastic respiration stresses while fully maintaining the spontaneous breathing pattern. The goal of "Proportional Assist Ventilation" lies in the determination and selective support of the patient's breathing effort. In doing this, the pressure during inspiration increases proportionally with the tidal volume breathed in and/or the respiration gas flow. Thus, neither ventilation times nor inspiration pressures or tidal volumes are predefi ned. Instead, STEPHANIE adapts itself to the patient's own biological breathing regulation. In their effect, the pressure increases overlay the respiratory path resistance and the lung compliance, thus producing a reduction in the overall effort required for breathing. What this means is that, at a given level of lung effort, greater breath-minute volumes can be breathed: "Proportional Assist Ventilation" thus reduces the stress on spontaneously breathing patients.



PAV is a safe respiration treatment since the spontaneous breathing efforts are continuously monitored and a backup ventilation utilizing conventional S-IMV automatically takes over if the tidal volumes being breathed become too low or if spontaneous respiration stops.

The backup ventilation permits a more subtle form of respiration support for children with breathing insufficiencies. Apneas or a large reduction of spontaneous breathing in premature infants are characterized by drops in oxygen saturation due to insufficient pulmonary aeration. If an apnea is followed by a resumption of spontaneous breathing, there is a time delay before the oxygen saturation of the blood increases. Because of this time delay, switching the backup ventilation off immediately upon the resumption of spontaneous breathing can result in a renewed reduction in the oxygen saturation level.
A slow “disengagement” of the backup ventilation therefore appears advisable. The new backup ventilation control provided by STEPHANIE does not allow the patient to completely switch the backup ventilation off once spontaneous breathing resumes, but instead, only permits a reduction in the mechanical respiration frequency.

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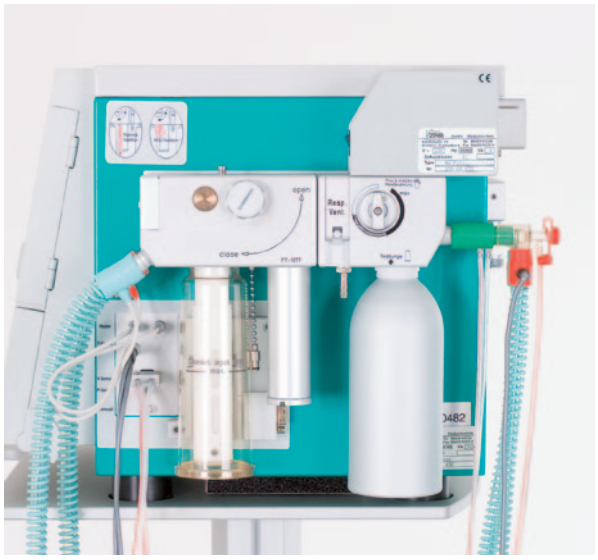

The integrated, heated humidification system
During normal, spontaneous breathing, the respiration gas is moistened and warmed in the upper respiratory tract. Insufficient moisture in the gas or gas which has not been adequately warmed will quickly lead to disruptions in the activities of the cilia in the bronchial epithelium, to an increase in the viscosity of the respiratory tract secretion and to an increased risk of a partial obstruction of smaller pulmonary path-ways due to a secretion build-up. The integrated, heated respiration air humidification system prevents this. Respiration gas humidification is achieved by evaporation on a molecular basis, thus completely avoiding the use of water traps. An intelligent sensor system prevents the formation of condensation in the heated patient tubes. The automatic water refill system maintains a constant fluid level and ensures the uniform humidification of the patient gas under the highest hygienic conditions. STEPHANIE therefore eliminates all the above-cited risks!

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, STEPHANIE allows swift changes between invasive and non-invasive ventilation thus allowing the optimal support of the so-called INSURE method (INtubation-SURfactant-Extubation).

„Closed Loop Ventilation“
STEPHANIE is equipped with an additional, safety-related innovation with regard to backup ventilation: the so-called “Closed Loop Ventilation”. The SpO2 data acquired by the NEOSID NOVA Pulsoximeter (Fritz Stephan GmbH) provide information regarding the oxygen saturation status. The frequency, duration and severity of decreases in the oxygen saturation level can be directly determined and can be independently corrected by the selective employment of the backup ventilation. This is an advance with life-saving relevance!

Optimal diagnostics with the 10.4" TFT color monitor
The availability of all relevant parameters on STEPHANIE means optimal mechanical respiration diagnostics on the part of the physician. The display methods (numeric/graphic) can be selected via a menu. The respiration pressure curve and the inspiration and expiration flow and tidal volumes are displayed in detail in the form of curves or respiration loops. Beyond this, a wide variety of other diagnostic tools such as the visualization of the intra-pulmonary pressure, inadvertent PEEP, or the pulmonary-time constant are available to the physician.

Continuity of development
Future-oriented and ongoing development includes the continuous adaptation of STEPHANIE to meet new demands. In this regard, particular importance is placed on the ability of previous STEPHANIE generations to be upgraded. This provides the user with a cost effective means of profiting from our innovations and of working with the latest STEPHANIE generation.

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Technical Specifications

General specifications	
Patient range	Neonates and pediatric patients up to 25 kg bodyweight
Class according to 93/42 ECC	II b
Dimensions	455 x 360 x 420 mm (WxHxD)
Weight	33 / 53 kg (w/o with trolley)
Function principle	Time cycled, pressure controlled, flow controlled
Operational specifications	
Power supply	100 - 240 V AC, 50 - 60 Hz, 200 VA
Battery backup	min. 5 min. (with internal, rechargeable battery)
Gas supply	
AIR	3 - 6 (+0.5) Bar
O_2	3 - 6 (+0.5) Bar
Ventilation parameters	
Ventilation modes	
PC-IMV, PC-Ass./Cont., PC-S-IMV, PC-HFO, PC-IMV-HFO, PC-Ass./Con.-PSV, PC-S-IMV-PSV, VC-IMV, VC-Ass./Cont., VC-S-IMV, CPAP-PAV, S-IMV-PAV, CPAP-MVG, nCPAP, NIPPV, SNIPPV (opt.)	
Modifications	Volume guarantee (VtLim/VtTar) Leakage compensation, PSV
Maneuver functions	Inspiration Hold / Manual
	Medication nebulization Insp./Exp. Occlusion
Ventilation settings	
Inspiration time	0.1 - 2 s
Expiration time	0.1 - 60 s
Tidal volume	0.2 - 15/2 - 150 ml
Pmax	5 - 60 mbar
PEEP	0 - 30 mbar
Inspiration pattern	
Pressure controlled	Square wave, half sinus, linear
Flow controlled	Square ware, sinus, secelarating
Trigger sensitivy	
Flow	0.1 - 2.9 l/min
Pressure	0.1 - 2.9 cmH_2O
Abdominal movem.	0.1 - 2.9 Arbs
Breathing gas temp.	30 - 39 °C
FiO_2	21 - 100%
PSV	
Exp.-Trigger KV%	5 - 40% V‘ Peak
PPSV%	0 - 100% V‘ Pmax
Vmin	1 - 40 ml
High Frequency Oscillation HFO	
Frequency	5 - 15 Hz
Inspiration I	33 / 40 / 50% / Sinus
MAP	0 - 30 mbar
Amplitude Vosc	max. 24 ml @ 10 Hz
Inspiration Hold	1 - 7 s

Ventilation settings	
PAV	
Elastic	0 - 4 cmH_2O/ml
Resistive	0 - 200 cmH_2O/l/s
PAV-Volume limit	1 - 150 ml
Measured values	
Pressure measurement	
Insp. pressure	-20 - 99 mbar (Pmax)
End-exp. pressure	-20 - 99 mbar (PEEP)
Mean airway press.	-20 - 99 mbar (Pmean)
Osc.-amplitude	0 - 180 mbar (Posc)
Volume measurement	
Insp. tidal volume	0 - 999 l (VTins)
Exsp. tidal volume	0 - 999 l (VTexp)
Leak volume	0 - 999 l (VTleck)
Exp. minute volume	0 - 999 l/min (MV)
Osc. minute volume	0 - 999 l/min
Ventilation time parameters	
Breathing frequency	0 - 999/min (F)
Inspiration	0.1 - 100% (Insp%)
O_2 measurement	
FiO_2	0 - 100%
Breathing gas temperature	
Proximal measurem.	12 - 60 °C
Lung mechanics	
Resistance	0 - 999 mbar/l/s (R)
Compliance	0 - 999 ml/mbar (C)
Curve display	Paw(t), V‘(t), V(t), P(V), P(V‘), V(V‘), Arbs(t)
Trend display	P(t), V(t), V‘(t)
Trend duration	0.5, 1, 2, 4, 12, 24 (h)
Alarms/Monitoring	
Airway pressure	high/low (Pmax)
Exsp. Minute volume	high/low (MV)
Exp. Tidal volume	low (VT)
Insp.O_2-Concentr.	high/low (FiO_2)
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	
Apnea	
Interface	
RS232: VueLink/PDMS/Stephan protocol	
User interface	
Display screen	10.4" Color-TFT
Input devices	
Buttons + Turn-Push-Button	
Turn-Buttons + Potentiometer	