STEPHAN

Clinical Experience
Technical Competence

Sophie

Neonatology Ventilator

Operating manual

CE 0482

Operating manual

This manual provides clear answers to your questions about the operation and care of the **SOPHIE**. This manual does not contain any information about repairs or installation.

If any malfunctions occur while operating the device, please contact the authorized FRITZ STEPHAN GMBH customer service team or the authorized specialist dealer who supplied the device and familiarized you with its function and operation.

The manufacturer only guarantees the safety and reliability of the **SOPHIE** when it is operated according to this manual.

Fritz Stephan GmbH
- Medizintechnik -
Kirchstraße 19

56412 Gackenbach
Germany

Equipment is subject to technical modification.

Valid as of:	April 2020
Version:	V5.3
From software version PC:	2.7.x
From software version Sophie MC:	2.1.x

Table of contents

1 General information

1.1 Product combination

FRITZ STEPHAN GMBH disclaims any warranty with respect to the operation of unauthorized device combinations with products not approved by the manufacturer or without certified compatibility.

Certified product combinations

1. Pneumatic medication nebulizer
   Manufacturer: Dräger AG Lübeck
   Art. no.: 8405000
   - Medication nebulizer set
     Manufacturer: Fritz Stephan GmbH
     Art. no.: 171060120
2. Ultrasonic nebulizer
   Manufacturer: Schill GmbH & Co. KG
   Art. no.: MN81100
   - Medication nebulizer set
     Manufacturer: Fritz Stephan GmbH
     Art. no.: 103560800
3. Medication nebulizer Aeroneb® Solo system
   Manufacturer: Aerogen Ltd.
   Art. no.: AG-AS3000-NE
4. Flow sensors
   - Type A pneumotachograph
     Manufacturer: Fritz Stephan GmbH
     Art. no.: 103561303
   - Type B pneumotachograph
     Manufacturer: Fritz Stephan GmbH
     Art. no.: 103561300
   - Type C pneumotachograph
     Manufacturer: Fritz Stephan GmbH
     Art. no.: 103561301
   - Type DP NEO pneumotachograph
     Manufacturer: Fritz Stephan GmbH
     Art. no.: 103861141

5. Abdominal respiration sensor (external trigger), disposable, length: 150 cm
   Manufacturer: Vio Healthcare
   Art. no.: 103560103

   (Only for Sophie ventilators with an external respiration sensor)

6. Abdominal respiration sensor (external trigger), disposable, length: 200 cm
   Manufacturer: Vio Healthcare
   Art. no.: 103560203

   (Only for Sophie ventilators with an external respiration sensor)

7. Reusable patient tube system

   - Heated with Y piece, pressure measuring tube, and connecting plug for incubator, length 1200 mm, of which 800 mm are heated
     Manufacturer: Fritz Stephan GmbH
     Art. no.: 100761500
   - Heated with Y piece, pressure measuring tube, and connecting plug for warming beds, length 1300 mm, of which 1200 mm are heated
     Manufacturer: Fritz Stephan GmbH
     Art. no.: 100761550

8. Disposable patient tube systems

   - Heated with Y piece, pressure measuring tube, and NO adapter
     Manufacturer: Fritz Stephan GmbH
     Art. no.: 100761300

9. NCPAP patient interfaces

   - EasyFlow NCPAP system
     Manufacturer: J. Söllner GmbH
     Art. no.: See accessories list in chapter 15
   - Bonnets for EasyFlow NCPAP system
     Manufacturer: Fritz Stephan GmbH
     Art. no.: See accessories list in chapter 15

10. Device for regulating the metered dosing of NO to inhaled air
    Name: Pulmonox mini
    Manufacturer: Messer, Austria
    Marketed by: Mallinckrodt – Nellcor – Puritan – Benett

    The following accessories must be used:

    - Flow box for measuring and dosing NO for connecting to the patient component with RS 232 to reduce dead space including PNT
      Art. no.: 170561000

- NO dosing adapter
  Art. no.: 103560067
- NO analysis adapter
  Art. no.: 103561314
- Pneumotachograph – type NO with plug and silicone tubes, can be autoclaved at 140°C, type B for determination of the flow using the flow box
  Art. no.: 1 035 61 302
- Adapter for NO suction
  Art. no.: 100753082
- Adapter for INO flow box
  Art. no.: 195361003

11. Device for regulating the metered dosing of NO to inhaled air
    Name: Inovent
    Manufacturer: Datex Ohmeda
12. Device for regulating the metered dosing and measurement of NO
    Name: NoxBox
    Manufacturer: Bedfont Scientific Ltd

    The following accessories must be used:

    - Single-use kit for administration and sampling 10 mm
      Art. no.: Noxkit-1-10
    - Single-use plug-in connector, straight, 22f–15 mm
      Art. no.: Noxflow-Con
    - Heating adapter for NoxBox connection
      Art. no.: 170561006

CAUTION

Do not reuse disposable accessories!
The necessary reconditioning may lead to the deterioration of mechanical and biological product properties, posing a significant risk to the patient. In addition, reusing such accessories dangerously increases the risk of contamination for the patient.

1.2 Device name and manufacturer

Device name **SOPHIE**

Manufacturer

Fritz Stephan GmbH
- Medizintechnik -
Kirchstraße 19
56412 Gackenbach
Germany

☎ (+)49 (6439) 9125 – 0
🖷 (+)49 (6439) 9125 – 111
✉ info@stephan-gmbh.com
🖳 www.stephan-gmbh.com

1.3 Intended use

The **SOPHIE** is suitable for the invasive and non-invasive ventilation of preterm infants, infants, and small children up to 25 kg, but especially for the ventilation of immature preterm infants with a very low birth weight.

Therapeutic scope

The **SOPHIE** can be used for all approved conventional ventilation modes:

- Non-invasive ventilation with continuous positive airway pressure (NCPAP) with or without backup ventilation
- Synchronized intermittent mandatory ventilation (SIMV) with or without inspiratory time termination (ITT)
- Synchronized intermittent mandatory ventilation (SIMV) with ITT and additional pressure support for spontaneous breathing
- Controlled ventilation (IMV)
- Assisted controlled ventilation (patient-triggered) with or without ITT
- Non-invasive positive pressure ventilation (NIPPV)
- Controlled and synchronized non-invasive positive pressure ventilation (SNIPPV)
- Optional: high frequency oscillation (HFO) in combination with IMV and CPAP ventilation options up to a body weight of 12 kg
- Optional: controlled and synchronized non-invasive positive pressure ventilation (SNIPPV) with expiratory trigger

Contraindication

The safety instructions provided in chapter 2 must be observed.
No additional contraindications exist.

It is the sole responsibility of the user to select the most appropriate ventilation mode based on the patient's medical condition.
The continuous monitoring of the patient's condition must be assured at all times.

Area of use

The ventilator's areas of use comprise interdisciplinary and discipline-specific intensive care units, primary care units for newborns, and the intra-hospital transportation between units or departments.

The ventilator may only be used by authorized personnel such as physicians, qualified medical specialists, health workers, nurses, and respiratory therapists.

The prescribed safety checks and preventative maintenance must only be conducted by the manufacturer or personnel qualified in line with the German Medical Devices Operator Ordinance (MPBetriebV).

The **SOPHIE** must not be used:

- in the vicinity of magnetic resonance imaging systems (MRT, NMR, NMI)
- in potentially explosive environments
- in positive pressure (hyperbaric) chambers

1.4 Disposal

Disposal of the packaging

The device packaging largely consists of recyclable or reusable materials.

The cardboard packaging can be reused or disposed of as used paper.

Disposal of the device and the battery

FRITZ STEPHAN GMBH will accept the return of any used devices from our company free of charge and dispose of these correctly, thus making a contribution to the environment.

Used batteries and the device itself must not be disposed of as domestic waste. Proper disposal must be conducted by a certified electrical and electronic waste recycling company. Disposal via municipal collection points for waste electrical equipment is not permitted!

WARNING

Risk of explosion!

Do not throw the battery into a fire or open it with force!

NOTE

Before disposing of the device or any of its components, these must be cleaned and disinfected.

Infectious disposable accessories must be disposed of as specified in the operating manual!

1.5 Introduction

Device setup, operation, and maintenance is only permitted by trained personnel. All relevant national laws, guidelines, and regulations as well as the following instructions must be observed:

- The device must be operated by trained personnel only. Thorough knowledge of the operating manual is required.
- Only use the device for the intended purpose described in the operating manual.
- Read the operating manual carefully and comply with its instructions; lasting safety for the patient and user is only ensured when the device is operated correctly.
- The operating manual must be kept readily available at the place of use.
- Inadequate care and incorrect operation can cause downtime and accidents.

Warranty The manufacturer does not accept any warranty claims resulting from incorrect operation or inadequate care and maintenance.
The manufacturer guarantees the safety and reliability of the device only when it is operated in compliance with operating instructions.

1.6 Abbreviations, definitions, and pictograms

Abbreviation/ technical term	Term	Meaning
ApD		Apnea duration
Apnea		Respiratory arrest
Aqua dest.	Aqua destilata (lat.)	Distilled, demineralized water
Arb	Arbitrary unit	Free parameter of the abdominal respiration sensor for the external trigger (graphical display)
Ass./Co.	assisted controlled (patient activated)	With this ventilation mode, the device delivers a mandatory breath whenever the inspiratory volume flow exceeds the preset trigger threshold.
Bar		Unit of measurement for pressure 1000 hpa = 1 bar
Bat.	Battery	Device for storing electrical energy in the form of chemical energy
Bpm	Breaths per minute	Breaths per minute
BTPS	Body temperature and ambient pressure saturated	Measuring condition at body temperature, current ambient pressure, and saturated gas
BU	Backup	Standard backup ventilation mode
CGS		Central gas supply
cmH_2O		Unit of measurement for pressure 1 cmH_2O = 0.9806 hPa
COM		Serial interface
Communic.		Communication
Connection		Connection
Cont.		Continuous
contr.	Controlled	With this ventilation mode, the device controls the ventilation pressure on the Y piece and the periodic process for the cyclic changes of this pressure. Controlled ventilation modes: • time controlled, pressure controlled • time controlled, volume controlled

Abbreviation/ technical term	Term	Meaning
CPAP	Continuous positive airway pressure	Spontaneous breathing with continuous positive airway pressure. When breathing under CPAP, the device keeps the pressure constant on the endotracheal tube's connection piece.
Diathermia HF diathermia	High frequency diathermia	Therapy where high frequency currents heat through the tissues within the body.
DIN		German Institute for Standardization
Disc.	Disconnection	Interruption (pneumatic) of a connection
Distal		Away from the patient
DP-NEO PNT	Pneumotachograph	Flow sensor for measuring the inspiratory and expiratory flow
EN		European Standard
ETT		Endotracheal tube
Exp.	Expiration	Exhalation
FBU	Frequency-controlled backup	Frequency-controlled backup ventilation
F_{HFO}		Frequency of high frequency oscillation
FiO_2		Inspiratory oxygen fraction
Flow	Symbol: $\dot{V}$	Volume flow
HP	High priority	An alarm indicating the need for prompt intervention by the user (IEC 60601-1-8).
hPa	Hectopascal	Unit of measurement for pressure 1 hPa = 1 mbar
Hz	Hertz	Unit of measurement for frequency
IGR	Incremental encoder	Push and turn knob for device operation
IMV	Intermittent mandatory ventilation	Intermittent mandatory ventilation
Insp	Inspiration	Inhalation
IP	International protection code	Code indicating the degree of protection against dust and moisture
ITT	Inspiratory time termination	Inspiratory time termination
LED	Light emitting diode	Light emitting diode
Linear		Pressure curve pattern: 

Abbreviation/ technical term	Term	Meaning
LP	Low priority alarm	An alarm indicating that the user should be aware of the situation.
MAP	Mean airway pressure	Mean airway pressure
mbar		Unit of measurement for pressure
MHP	Alarm of at least medium priority	An alarm of at least medium priority is evaluated as a medium priority alarm (MP) when the alarm situation occurs; it progresses to a high priority alarm (HP) 30 seconds later.
Min	Minute	Unit of measurement for time
MP	Medium priority	An alarm indicating the need for prompt intervention by the user (IEC 60601-1-8).
ms	Millisecond	Unit of measurement for time
NCPAP	Non-invasive CPAP	Non-invasive (nasal) CPAP
NCPAP-B	Non-invasive CPAP with backup	Non-invasive (nasal) CPAP with backup ventilation
NIPPV		Non-invasive positive pressure ventilation
NIST		Non-interchangeable screw thread
PEEP		Positive end expiratory pressure
Pmax		Peak pressure
Pmean		Mean airway pressure
PNT	Pneumotachograph	Flow sensor
Proximal		Close to the patient
PU		Packaging unit
Rectangle		Pressure curve pattern: 
Resistive		Creates a pneumatic resistance
Resp.		Respiration
s	Second	Unit of measurement for time
SIMV	Synchronized intermittent mandatory ventilation	Ventilation mode synchronized to the patient
Sinus		Pressure curve pattern: 

Abbreviation/ technical term	Term	Meaning
SNIPPV		Synchronized non-invasive positive pressure ventilation
SNIPPV-B		Synchronized non-invasive positive pressure ventilation with backup
Standby		The device is ready for use
TA		Technical alarm
Temp.		Temperature
V		Volume
V′		Flow
Vo		Oscillatory tidal volume
VT	Tidal volume	Breathing volume
VTe	Expiratory breathing volume	Expiratory tidal volume
VTi	Inspiratory breathing volume	Inspiratory tidal volume
WB	Water bath	Humidifier bottle filled with water

Tab. 1: Abbreviations and technical terms

Pictogram	Meaning
	Alarm suppression (see chapter 3.1.2)
	Alarm menu (see chapter 3.1.2)
	Stop (screen display frozen; see chapter 3.1.2)
	Aerosol nebulization (see chapter 3.1.2)
	Pre-oxygenation (see chapter 3.1.2)
	Hold inspiration (see chapter 3.1.2)
	Main menu (see chapter 3.1.2)
	Remaining duration of alarm suppression (see chapter 3.2.7)
	Charge indicator for internal battery (see chapter 3.2.7)
	Heating switched off (see chapter 3.2.7)
	Standard backup active (see chapters 9.7.1 and 9.8.1)

Pictogram	Meaning
	Frequency backup active (see chapters 9.7.1 and 9.8.1)
	External trigger active
	Flow trigger active
	Flow measurement switched off (see chapter 5.4)
	Indication of the active PNT (A, B, or C, see chapter 4.2.7.1)
	PNT DP NEO active
	Contains conventional or rechargeable batteries and must not be disposed of as domestic waste.
	Pressure curve pattern, sinus
	Pressure curve pattern, linear
	Pressure curve pattern, rectangular
	Protective conductor
	Equipotential bonding
	24 V DC
	Button in »Off« position
	Button in »On« position
	Type B applied part
	Mains power
	Battery status
	On-board power supply (24 V DC)
	Compressed air membrane dryer
	Observe the operating manual
	Never lift or carry the device from the drip strip.

Tab. 2: Pictograms

1.7 Specifications

1.7.1 General information

Classification according to 93/42/EEC	II b	
Protection class	IP 21 Protected against solid foreign bodies with a diameter of 12.5 mm or above and water droplets	
Sound pressure level	47.5 dB(A) during ventilation	
	70 dB(A) during acoustic alarm	
Sound power level	58.5 dB(A)	
UMDNS code	14-361	
GMDN code	14361	
Safety checks	Every 6 months	
Dimensions	470 × 342 × 332 mm	(W × H × D)
Weight	Basic device with patient component	26 kg
	Mobile stand	16.2 kg
Display	Color – TFT	10.4″

1.7.2 Ambient conditions

Operation	Temperature	15–40°C
	Rel. humidity	10–80%
	Air pressure	700–1060 hPa
	Allow to reach room temperature before using device.	
Storage	Temperature	5–40°C
	Relative humidity	10–80%
	Air pressure	700–1060 hPa
	Store in a dust-free place protected from humidity and frost.	

1.7.3 Power supply

Mains	Connection	100–240 V AC; 50–60 Hz
	Protection class	I type B according to IEC 60601-1
	Supply line	Safety plug with device socket
	Power consumption	210 VA
	Current consumption	2.1–0.87 A
	Fuses	2× T3.15 AH/250 V; DIN 41571
Battery with nominal capacity of 2.1 Ah	Type	Lithium-ion
	Nominal voltage	25.2 V DC
	Nominal capacity	2.1 Ah
	Battery life (new/100% charge)	At least 60 min (without heating)
	Charge time	At least 6 h to 100%
	Max. no. of charge cycles	500
Battery with nominal capacity of 3.12 Ah (from 10/2018 on)	Type	Lithium-ion
	Nominal voltage	25.2 V DC
	Nominal capacity	3.12 Ah
	Battery life (new/100% charge)	At least 80 min (without heating)
	Charge time	At least 9 h to 100%
	Max. no. of charge cycles	500

1.7.4 Interface

WARNING

Only cables with a length < 3 m may be connected to the Sophie interface!

Serial interface	Type	RS-232-C Sub D 9-pin (male)
	Isolation	5 kV
	Pin assignment	2 RxD
		3 TxD
		5 GND
Port configuration	Baud rate	9600–115200
	Data bits	8
	Start bits	1
	Stop bits	1
	Parity	None
Logs	VueLink, IntelliBridge, PDMS or Stephan log	

1.7.5 Gas supply

Supply pressure	AIR	3–6 +0.5 bar
	O_2	3–6 +0.5 bar
Gas consumption	Conventional	Min. 4 l/min*
	HFO	Min. 18 l/min*
	HFO transport	Min. 14 l/min*
	Aerosol	Approx. 9 l/min
	* + MV (max. 25 l/min)	
System pressures	System pre-pressure	Max. 150 cmH_2O
	At max V‘ 20 l/min	Ca. 116 cmH_2O
	At max V‘ 12 l/min	Ca. 51 cmH_2O
	At max V‘ 6 l/min	Ca. 20 cmH_2O
	Active expiration	Max. –30 cmH_2O
	Pneumatic medication nebulizer	1.5 bar

1.7.6 Sensors

Flow/volume	Sensor	Max. flow	Dead space*
	PNT type A	±5 l/min	0.5 ml
	PNT type B	±12 l/min	0.6 ml
	PNT type C	±25 l/min	0.9 ml
	PNT type Neo	±25 l/min	1.3 ml
* Dead space may differ depending on which tube adapter is used.			
Abdominal movement	Type	Graseby respiration sensor	
FiO_2	Type	Electrochemical oxygen sensor, type M-11	
	$T_{21–90}$	< 15 s	

1.7.7 Operating modes

Pressure-controlled	Pressure pattern	Linear
		Sinus
		Rectangle
Pressure-controlled/ volume-controlled	Adjustment to expiratory tidal volume	

1.7.8 Pneumatic properties

Inspiration resistance during operation (PNT B)		Max. 1 cmH_2O at 5 l/min
Expiration resistance during operation (PNT B)		Max. 1 cmH_2O at 5 l/min
Inspiration resistance on device failure	No PNT	Max. 0.09 cmH_2O at 5 l/min
	PNT B	Max. 1.54 cmH_2O at 5 l/min
	PNT C	Max. 1.32 cmH_2O at 5 l/min
Expiration resistance on device failure	No PNT	Max. 0.08 cmH_2O at 5 l/min
	PNT B	Max. 1.52 cmH_2O at 5 l/min
	PNT C	Max. 1.34 cmH_2O at 5 l/min
Patient tube system compliance	P7	0.12 ml/cmH_2O

1.7.9 Humidifier performance

Recommended ambient temperature	18–26°C		
Liquid reservoir for humidifier	Max. 144 ml		
Flow rate	5–25 l/min		
Chamber temperature	26–45°C		
Humidifier release at 38°C (proximal)	Humidity level	Flow	aH[1] (rH[2])
	0	6 l/min	> 33 mg/l (> 75%)
	+ + +	10 l/min	> 33 mg/l (> 75%)
	+ + + + +	15 l/min	> 33 mg/l (> 75%)
	+ + + + + +	17 l/min	> 33 mg/l (> 75%)
	- - - -	25 l/min	> 10 mg/l (> 23%)
Warm-up time	~0 min		
Displayed temperature	Temperature at the end of the inspiration tube		

[1] Absolute humidity
[2] Relative humidity based on 37°C (BTPS)

1.7.10 Automatic refill system (optional)

Initial filling periods	Conventional ventilation		Max. 79,2 s
	HFO		Max. 67,2 s
	NIV	MaxV‘ OFF	Max. 74 s
		MaxV‘ 20 l/min	Max. 52,2 s
		MaxV‘ 12 l/min	Max. 30,6 s
		MaxV‘ 6 l/min	Max. 22 s
Normal filling periods	Conventional ventilation		17.6 s
	HFO		14.2 s
	NIV	MaxV‘ OFF	19 s
		MaxV‘ 20 l/min	11.5 s
		MaxV‘ 12 l/min	5.6 s
		MaxV‘ 6 l/min	4 s

1.7.11 Ventilation modes

NCPAP	Spontaneous breathing using non-invasive patient interface (prong/nasal mask) with continuous positive airway pressure
NCPAP B	Non-invasive (nasal) CPAP with backup ventilation
SIMV	Synchronized intermittent mandatory ventilation
Ass./Co.	Assisted controlled mandatory ventilation
IMV (contr.)	Controlled mandatory ventilation
ITT	Inspiratory time termination in addition to the ventilation modes SIMV and Ass./Co. For SIMV, with additional pressure support
VG	Volume guarantee in addition to all conventional ventilation modes through VtTar/VtLim
HFO	High frequency oscillation
NIPPV	Non-invasive intermittent mandatory ventilation
SNIPPV	Synchronized non-invasive intermittent mandatory ventilation
SNIPPV B	Synchronized non-invasive intermittent mandatory ventilation with backup ventilation
CPAP (optional)	Spontaneous breathing at continuous positive airway pressure
CPAP B (optional)	CPAP with backup ventilation

1.7.12 Reusable tube systems

Tube system	**P7 tube system for incubators (art. no. 100761500)**	**P7 tube system for warming beds (art. no. 100761550)**
Total length	1.225 m	1.300 m
Length of cold section	425 mm	125 mm
Resistance	< 2 mbar @ 22 l/min	< 2 mbar @ 22 l/min
Compliance	< 0.1 ml/mbar	< 0.1 ml/mbar
Volume	191 ml	191 ml
Inner diameter	10 mm	10 mm

1.7.13 Disposable patient tube system

NOTE

For information about using the device as intended, about warnings and safety instructions, as well as technical data, refer to the operating manual provided with the tube system.

1.7.14 Adjustable parameters

Parameter	Meaning	Range	Resolution	Default	Hospital-specific
Insp	Inspiration time	0.1–2.00 s	0.01 s	0.35 s	
Exp[1]	Expiration time	0.10–2.00 s 2.00–6.00 s 6.00–60.00 s	0.01 s 0.10 s 1.00 s	1.15 s	
Freq[1]	Frequency	1–300/min	l/min	40/min	
Pmax*	Inspiratory peak pressure	5–10 cmH_2O 10–60 cmH_2O	0.5 cmH_2O 1.0 cmH_2O	15 cmH_2O	
FiO_2	Inspiratory oxygen fraction	21–100%	1%	21%	
PEEP*	Positive end expiratory pressure	0–5 cmH_2O 5–10 cmH_2O 10–30 cmH_2O	0.1 cmH_2O 0.5 cmH_2O 1.0 cmH_2O	5 cmH_2O	
MAP*	Mean airway pressure	0–5 cmH_2O 5–10 cmH_2O 10–30 cmH_2O	0.1 cmH_2O 0.5 cmH_2O 1.0 cmH_2O	Pmean +2	---
PPSV%*	Pressure support level for SIMV – ITT (PSV)	0–100%	5%	20%	
MaxV‘	Maximum gas flow (flow limitation)	6–20 l/min / OFF	1 l/min	12 l/min	
Trig	Trigger threshold (sensitivity)	0.2–2.9 / OFF l/min cmH_2O Arb	0.1 l/min cmH_2O Arb	1.2 l/min 1.2 cmH_2O 0.5 Arb	
VtTar	Target volume under ITT(PSV)	2–5 ml 5–10 ml 10–150 ml OFF	0.1 ml 0.5 ml 1.0 ml	OFF	---

Parameter	Meaning		Range	Resolution	Default	Hospital-specific
VtLim	Tidal volume limitation		2–5 ml 5–10 ml 10–150 ml OFF	0.1 ml 0.5 ml 1.0 ml	OFF	---
KV'	Factor of the inspiratory peak flow, for inspiration end		5–40%	1%	5%	
ApD	Apnea duration		4–16 s / OFF	1 s	4 s	
HF freq	Oscillation frequency for HFO		5–15 Hz	0.5 Hz	10 Hz	
HF-IE	Inspiration ratio for HFO		33–50%	1%	40%	
HF-AM	Oscillation pressure amplitude for HFO		5–100%	1%	20%	
HFO-INSP	Switches oscillation "on" or "off" during inspiration		ON/OFF	---	OFF	
Temp	Respiratory gas temperature		30–40°C	0.5°C	38°C	
Humidity	Difference between the humidifier temperature and the respiratory gas temperature	Conv: HFO NCPAP	–4 ... +6	1	0 +2 +2	
FBU	Interval of the frequency-controlled backup ventilation		10/30/60 s / OFF	---	OFF	
Preoxy % (can be configured, see chapter 4.2.6)	FiO_2 for preoxygenation					
	Preoxy % (direct setting)		21–100%	1%	80%	
	Delta (FiO_2+Preoxy %)		1–79%	1%	20%	
	FiO_2 X (FiO_2 x Preoxy %)		1.1–2.0 × FiO_2	0.1 × FiO_2	1.2	
Preoxy T	Duration of the preoxygenation		OFF / 30–420 s	30 s	180 s	

Parameter	Meaning	Range	Resolution	Default	Hospital-specific
Insp Hold	Maximum insp. hold time	Insp / 1–7 s	1 s	Insp	
Aerosol T	Medication nebulization duration	30–420 s	30 s	300 s	
Pressure limit for patient component*		40–70 / 125 cmH_2O	Infinite	---	---
* Setting accuracy of all pressure-based setting values: $\Delta P = \pm (4\% \cdot P + 2\ cmH_2O)$					

NOTE

[1] Depending on the customer's wishes, the Sophie can be delivered with either a selectable expiration time or a selectable breathing frequency. The selection does not affect the inspiration time setting.

1.7.15 Curves displayed

Real-time curves	Airway pressure P(t)	–5...15 / –10...30 / –20...60 / –30...90 cmH_2O
	Volume V(t)	–1...5 / –5...15 / –5...45 / –30...150 / –50...450 ml
	Flow V'(t),	±3/6/15/45 l/min
	Abdominal movement E(t)	±3/6/9/24 Arb
	Time axis	4 s / 8 s / 16 s*
Loops	Volume/pressure V(P) Flow/volume V'(V) Flow/pressure V'(P)	
Trends	Airway pressure Pmean(t)	–5...15 / –10...30 / –20...60 / –30...90 cmH_2O
	Minute volume MV(t)	0–1 / 0–2 / 0–5 / 0–10 l/min
	Tidal volume Vt(t)	–1...5 / –5...15 / –5...45 / –30...150 / –50...450 ml
	Time axis	30 min / 1 h / 2 h / 4 h / 12 h / 24 h

* For trend display, the time axis is automatically halved

1.7.16 Measured values displayed

Pressure	Pmax	–20...99 cmH_2O
	Pmean	–20...99 cmH_2O
	PEEP	–20...99 cmH_2O
	P_{OSC}	–20...99 cmH_2O
	Accuracy:	$\Delta P = \pm (4\% \cdot P + 2\ cmH_2O)$
Volume (BTPS)	MV	0–999 l/min
	Vte	0–999 ml
	VTi	0–999 ml
	Vleak	0–999 ml
	MVo	0–999 l/min
	Vo	0–999 l/min
	Accuracy:	$\Delta V = \pm (15\% \cdot V + 4\ ml)$

Breathing rate		0–999/min
Inspiration ratio		0.1–100%
FiO_2		0–100%
	Accuracy:	±5 Vol %
Respiratory gas temperature		12–60°C
Resistance		0–999 $cmH_2O/l/s$
Compliance		0–999 ml/cmH_2O
DCO_2		0–999 ml^2/s

NOTE

- The values displayed are generated from mean values. The number of measurement points used depends on the measured value.
- The measured values are recorded every 2 ms.
- The values for the pressure and volume flow are averaged over a period of 10 ms.
- The values for the temperature measurement are averaged over a period of 100 ms.
- The values for the oxygen concentration measurement are averaged over a period of 500 ms.
- The pressure and volume flow measured variables are subjected to 15 Hz low pass filtering using an IIR filter to prevent interference.
- These filtered measured variables are used in the graphical representation and to determine the ventilation-related parameters PEEP, Pmax, Pmean, inspiratory and expiratory Vt and leakage volume.
- The parameters under HFO are determined using the non-filtered pressure and volume flow measured variables with subsequent exponential smoothing of the ventilation-related measured values determined for Posc and Vosc.
- Exponential smoothing is also used to smooth the measured values for the minute volume, frequency, and I:E.

1.7.17 Monitored measured values

Parameter	Unit	Lower limit	Upper limit	Resolution	Default lower limit	Default upper limit
Pmax	cmH_2O	1–60	2–70	1	12	25
Posc	cmH_2O	0–149	1–150	1	10	30
Pmean[1]	cmH_2O	0–27	3–33	1	---	---
PEEP[1]	cmH_2O	–	5–35	1	---	---
MV, MVo	l/min	OFF–0.10	–	0.01	0.10	2
		0.10–9.90	–	0.05		
		–	0.2–19.9	0.1		
VT_E	ml	0–10	2–10	0.5	0	20
		10–50	10–50	2		
		50–150	50–225	5		
Vo	ml	0–10	–	0.5	0	–
		10–50	–	2		
		50–150	–	5		
FiO_2	%	18–99	21–100	1	20	40
f	l/min	–	Off / 5–150	1	---	Off
T_{EMP}	°C	29–40	36–41	1	33	39
Flim[2]	l/min	Off / 0.2–10	–	0.1	1.0	--

[1] Cannot be set manually

[2] Is not shown in the measured value display

1.7.18 Automatic alarm limits

Parameter	Unit	Lower limit	Upper limit
Pmax	cmH_2O	PEEP +0.7 × (Pmax – PEEP)[a] +0.5 × (Pmax – PEEP)[b] +3[c] +0.3 × (Pmax – PEEP)[d]	Pmax + 10
Posc	cmH_2O	0.7 × Posc[e]	1.3 × Posc[e]
Pmean	cmH_2O	PEEP – 3 MAP – 3[b]	PEEP + 3 MAP + 3[b]
PEEP	cmH_2O	-	PEEP + 5
MV	l/min	0,25 × MV[e]	1,75 × MV[e]
MVo	l/min	0.25 × MVo[e]	1.75 × MVo[e]
Vo	ml	0.25 × Vo[e]	-
VTe	ml	0.25 × VTe[e] 0.25 × VtLim (VtTar)[c]	- 1.5 × VtLim (VtTar)[c]
FiO_2	%	FiO_2 – 10	FiO_2 + 10
TEMP	°C	TEMP – 3	TEMP + 3

[a] Conventional ventilation. [b] HFO ventilation. [c] With activated VtLim (VtTar) function. [d] Non-invasive ventilation (NIV).

[e] Measured value.

1.7.19 Materials used

Patient valve	Housing Piston	Nickel silver PEEK
Humidifier bottle		Polysulfone (PSU), yellow
Patient component	Block, inspiration, and expiration nozzles	Anodized aluminum
	Humidifier tube	PTFE (Teflon)
Patient tube (reusable)		Silicone rubber, transparent, green, red
Y piece (reusable)		Polysulfone (PSU), yellow
Pneumotachograph	Body Centering tubes	PEEK, green Stainless steel V4A
Pressure measurement lines (reusable)	Pressure, pressure difference	Silicone rubber, transparent
Safety valves	Valve disks	Stainless steel X5CrNi18-10 Glass filament fabric Hgw 2372.1

2 Safety instructions

NOTE

Identifies additional information that is useful for device operation and intended to avoid problems during use.

The following safety instructions are repeated at relevant points in the operating manual and must be observed at all times.

DANGER

Identifies potentially dangerous situations that result in death or life-threatening injury if not avoided.

WARNING

Identifies potentially dangerous situations that may result in death or serious injury if not avoided.

CAUTION

Identifies potentially dangerous situations that may result in minor or moderate injury if not avoided.

2.1 General safety instructions

The following general safety instructions relate to the operation of this ventilator. Special safety instructions for functions or components of the ventilator can be found in the corresponding chapters of this operating manual.

DANGER

The ventilator may only be used by trained and authorized medical specialists.

The device must be operated according to the instructions in this operating manual.

DANGER

Risk of explosion!

Do not use any combustible or anesthetic gases.

DANGER

Use of the device in the vicinity of magnetic resonance imaging systems may degrade its functionality, which can potentially put the patient and operator at risk.

DANGER

Never close the ventilation outlet behind the silencer. This may cause the device to malfunction and put the patient at great risk.

DANGER

Always have a separate manual breathing bag handy.

Lack of an alternative ventilation method may result in patient death if the ventilator fails.

DANGER

If the “Battery fail” alarm message is displayed on the device, do not press the power switch on Sophie or disconnect power when connected to a patient.
Interrupting the power supply when the battery is defective results in the device switching off immediately.

DANGER

Only use original pressure measurement lines from FRITZ STEPHAN GMBH.
The use of pressure measurement lines made from different materials, of different lengths or diameters, or with different compliance to those/that intended by the ventilator's manufacturer can impair the pressure measurement. This can sometimes lead to the safety valve opening and ventilation being interrupted.

WARNING

The ventilator must not be covered or positioned so as to impair its operation or performance.

WARNING

Burns may be caused by antistatic or electro-conductive patient tubing when using electrical high-frequency surgical instruments at the same time. Therefore, do not use antistatic or electro-conductive patient tubing or lines.

WARNING

Never operate the ventilator with helium or mixtures containing helium.

WARNING

Only use the patient tubing and accessories listed in chapters 1.1 (Product combination) and 15 (List of accessories). Using other patient tubing or accessories not intended for use with the ventilator may impair device performance and safety.

WARNING

Do not operate the ventilator outside the specified ambient conditions (see chapter 1.7). Its functionality may otherwise be impaired.

WARNING

Short wave therapy devices, RF diathermy devices, defibrillators, and similar equipment in close proximity of the device may impair device functionality. In such cases, the patient and device must be monitored continuously.

WARNING

WARNING

Non-invasive ventilation is not intended for patients without sufficient spontaneous breathing (e.g. diaphragm or abdominal wall defects, meconium aspiration, or high grades of postpartal asphyxia).

WARNING

IEC 60601-1 and IEC 62353 must be observed specifically for medical devices with an electrical connection. According to these directives, such devices must only be repaired by the manufacturer or an entity explicitly authorized by the manufacturer for this purpose.

WARNING

Never use the ventilator in a hyperbaric chamber.

This can impair the operation of the device and thereby pose a risk to the patient's safety.

WARNING

Only authorized customer service staff of FRITZ STEPHAN GMBH are permitted to alter, modify, repair, or open the device, or to replace the battery. This does not include the intended dismantling of the patient component according to the operating instructions. When servicing the device, only use spare parts from FRITZ STEPHAN GMBH.

WARNING

When analyzing the composition of the respiratory gas for research purposes, please note:

- The respiratory gas outlet behind the silencer must not be closed!
- The device must only be operated under the permanent monitoring of appropriately trained staff.
- The outlet tube must be rated with a tube diameter of > 1 cm and a length of < 20 cm.

WARNING

The device must be secured using a supporting bracket when attached to wall rails.

WARNING

WARNING

Medical electrical equipment or systems should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the medical electrical equipment or system should be monitored to verify its intended operation in the configuration in which it is used.

WARNING

Adding system parts or other components or sub-assemblies to the ventilator's ventilation system can negatively affect the pressure gradient across the ventilator's ventilation system, measured at the patient connection port.

3 Design and functional description

3.1 Front view

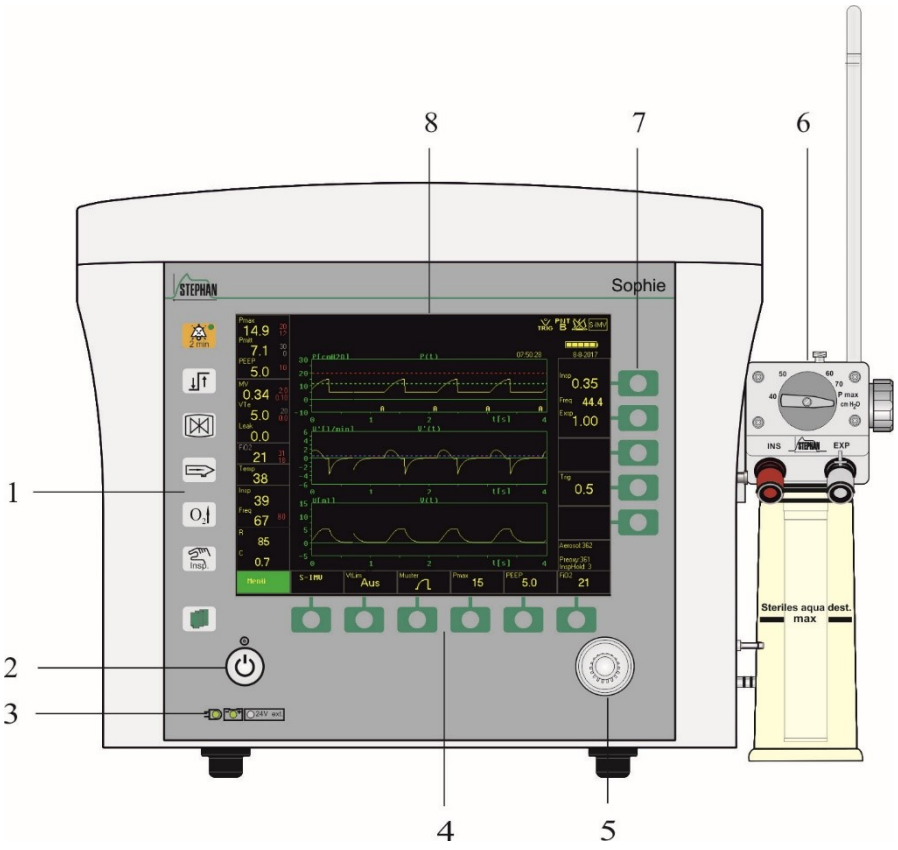


Fig. 1: Front view

1 Function buttons
2 »ON« button
3 Power source indicator
4 Selection buttons (bottom parameter display)
5 »IGR« control knob
6 Patient component
7 Selection buttons (right-hand parameter display)
8 Monitor unit

»ON« button

Press »ON« to start the ventilator. The **SOPHIE** performs a system selftest and automatically calibrates the pressure and O_2 sensors. The “Ventilation” menu then opens and enables the user to select the desired ventilation mode.

The LED above the »ON« button is lit only when it can be used to switch on the ventilator. It is not lit during operation or in standby, test, or break mode.

NOTE

»ON« button

For units with touch-sensitive buttons (manufactured until 2010), the design of the »ON« button differs from the model described here, but their function is identical.

»IGR« control knob

Use the »IGR« push and turn knob to select and activate all indirect functions on the **SOPHIE**.

The »IGR« can be used to:

- Switch within the menus
- Select and execute menu functions
- Parameter settings

Turn the »IGR« clockwise or counterclockwise to scroll through the available menu options. While scrolling, the individual options are highlighted in succession. Press a menu option to execute the corresponding function or open a sub-menu.

»Selection« buttons

»Selection« buttons are located along the right and bottom edge of the monitor. Pressing them triggers a short acoustic signal and opens the corresponding menu or parameter field. Turn the »IGR« knob to change the value. Finish your input by clicking with the »IGR« knob or pressing the selection button again.

NOTE

More information on using the »IGR« and the »selection« buttons can be found in chapters 4.1 and 5.1.

NOTE

»-/+« buttons

Only available on devices with touch-sensitive buttons (manufactured until 2010).
Alternately, use the »-« and »+« buttons instead of the »IGR« to scroll through the menu options or switch between parameter fields.

3.1.1 Power source indicator

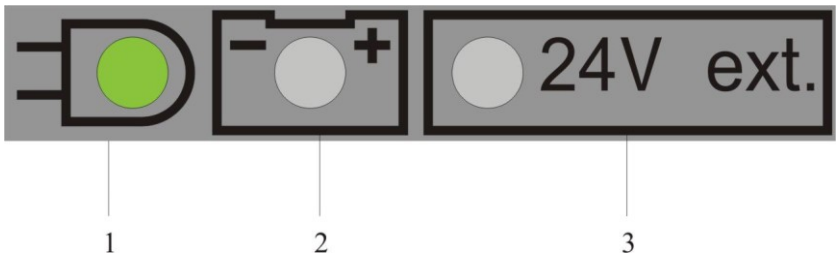


Fig. 2: Power source indicator

1	Mains power indicator	3	External DC power source indicator (optional)
2	Internal battery indicator		

If the ventilator is connected to a power source and the power switch is switched on (see chapter 3.4.2), the display indicates which power source is active and shows the charge status of the internal battery as follows:

- Green LED — Battery level between 50–100%
- Yellow LED — Battery level between 20–50%
- Red LED — Battery level between 0–20%

Mains power (100–240 V) — The mains power indicator lights up green. The internal battery is recharged automatically as needed. The current battery level is shown by the internal battery indicator.

Battery operation — Only the internal battery indicator lights up and indicates the current battery level.

NOTE

NOTE

FRITZ STEPHAN GMBH does not recommend operating the ventilator with a low battery (capacity < 20%), as the run time of the device will be very short.

External power source (24 V) (optional)

The external power source indicator lights up green. The internal battery is recharged automatically as needed. The current battery level is shown by the internal battery indicator.

DANGER

If the "Battery fail" alarm message is displayed on the device, do not press the power switch on Sophie or disconnect power when connected to a patient. Interrupting the power supply when the battery is defective results in the device switching off immediately.

WARNING

In case of a power failure, the internal battery supplies power to the device. The battery must be recharged at least every 14 days. A safety circuit prevents the battery from being overcharged.

WARNING

If the maximum number of charge cycles has been reached, the battery must be replaced. This can only be done by the authorized FRITZ STEPHAN GMBH customer service team.

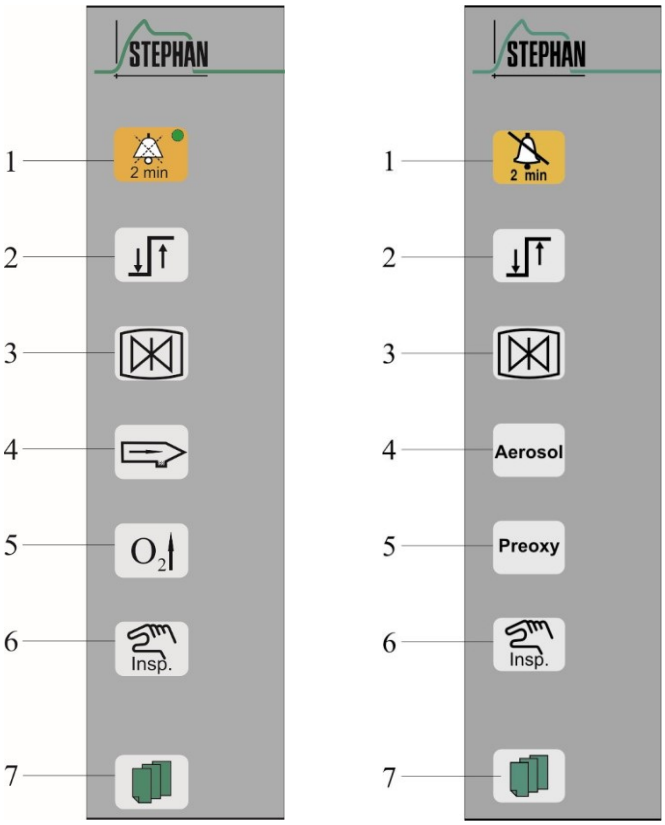
WARNING

The humidity must not exceed 80% during storage and operation, otherwise the battery may be damaged.

WARNING

The ambient temperature must not exceed 40°C during storage and operation, otherwise the battery may be damaged.

3.1.2 Function buttons



a b

Fig. 3: Function buttons

1 »Alarm suppression« button
2 »Alarm menu« button
3 »Stop« button
4 »Aerosol« button
5 »Preoxy« button
6 »Inspiration hold« button
7 »Main menu« button

NOTE

A short acoustic signal can be heard when one of the function buttons is pressed.

NOTE

For devices with touch-sensitive buttons (manufactured until 2010), the design of some keys in the function area is different (see Fig. 3b), but their function is identical.

»Alarm suppression« button

Briefly pressing this button will suppress acoustic alarms for 120 s. This is indicated by a yellow symbol in the status, alarm, and info display (see chapter 3.2.7). Acoustic alarm suppression only applies to the current alarm. Every new alarm immediately cancels the acoustic alarm suppression again. Alarm suppression can also be canceled by pressing the button again.

If the »alarm suppression« button is pressed twice within a period of three seconds, all incoming acoustic alarms are suppressed completely for 120 s. This is indicated by a red symbol in the status, alarm, and info display. Alarm suppression can also be canceled by pressing the button again.

Fig. 4: Status, alarm, and info display with activated alarm suppression

The LED on the »Alarm suppression« button also indicates the current alarm status:*

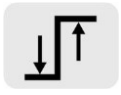
• Green		No alarm
• Yellow		Low-priority alarm
• Yellow	Flashing	Medium-priority alarm
• Red	Flashing rapidly	High priority alarm
• Red		Acoustic alarm suppressed

After eliminating the causes of an alarm, the alarm remains stored in the **SOPHIE** alarm history and displayed in green font.

WARNING

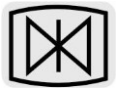
When using the special alarm suppression mode, ensure that the alarm is reactivated before leaving the patient.

»Alarm menu« button



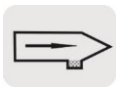
Opens the “Alarmlimits” menu for setting the alarm limits during ongoing ventilation. Use the »IGR« to select the settings (see also chapter 4.2.1).

»Stop« button



Press the »Stop« button to freeze the graphic display for better observation of a ventilation event. This also opens the Measure menu for measuring the curves. The status, alarm, and info display together with the measured value display continue to provide information about the current ventilation situation. Press the button again to cancel this function. If the function is activated, the special functions area lights up blue and the “**S**” symbol appears (see chapter 3.2.6).

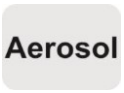
»Aerosol« button



Press the »Aerosol« button to switch on aerosol nebulization. The aerosol nebulization duration can be set between 30–420 s under “Extra-func.” ➔ “Aerosol-time” in the Main menu (see chapter 4.2.6).

The nebulization ends automatically at the end of the set time or when the button is pressed again. The current time setting is displayed in the special functions area of the monitor (see Fig. 5/item 5). If the function is activated, the special functions area lights up blue, the “**A**” symbol appears, and the countdown starts (see chapter 3.2.6).

NOTE



»Aerosol« button

For devices with touch-sensitive buttons (manufactured until 2010), the design of the »Aerosol« button differs from the model described here, but their function is identical.

WARNING

Aerosols can impair or damage the patient component and thus pose a risk to the patient! When administering medication using nebulization, an expiration filter must always be fitted between the EXP connection piece and the expiration tube.

»Preoxy« button

Press the »Preoxy« button to administer a pre-adjustable inspiratory oxygen concentration for a certain preset interval. The time can be set between 30 and 420 s in the Main menu under “Extra-func.” ➔ “Preoxy time” or switched off entirely. The current time setting is displayed in the special functions area of the monitor (see Fig. 5/item 5).

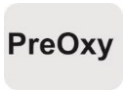
The inspiratory oxygen concentration can be set in the Main menu under “Extra-func.” ➔ “Preoxy %” (see chapter 4.2.6). If the function is activated, the special functions area lights up blue, the “**P**” symbol appears, and the countdown starts (see chapter 3.2.6). At the same time, the display of the set oxygen concentration changes to the pre-set “preoxy” value. The oxygen concentration alarm limits are adjusted automatically.

NOTE

If the “Pmean high” alarm is activated, the »Insp. hold« button is automatically deactivated.

NOTE

NOTE



»Preoxy« button

For devices with touch-sensitive buttons (manufactured until 2010), the design of the "Preoxy" button differs from the model described here, but their function is identical.

»Insp. hold« button

Press the »Insp. hold« button during:

Inspiration: To hold inspiration at the final inspiration pressure level after the end of normal inspiration for the duration of the set inspiration time (when selecting the option »Tinsp«) or for 1 to 7 s.

Expiration: To trigger mandatory inspiration with the set ventilation parameters.

Set the required time or the »Tinsp« option in the Main menu under "Extra-func." ➔ "Insp. hold" (see chapter 4.2.6). The current time setting is displayed in seconds in the special functions area of the monitor (see Fig. 5/item 5).
If the function is activated, the special functions area lights up blue, the "**I**" symbol appears, and the countdown starts (see chapter 3.2.6).

NOTE

If the "Pmean high" alarm is activated, the »Insp. hold« button is automatically deactivated.

»Main menu« button

Press this button to open the Main menu. Use the »IGR« to scroll through the menu options. Activate the menu options by clicking with the »IGR« or by pressing the »Main menu« button again (see chapter 4.1). Pressing this button while in the Ventilation menu or parameter settings closes them. In this case, changed settings are not applied.

NOTE

A detailed description of the Main menu and its corresponding functions can be found in chapter 4.

3.2 Monitor unit

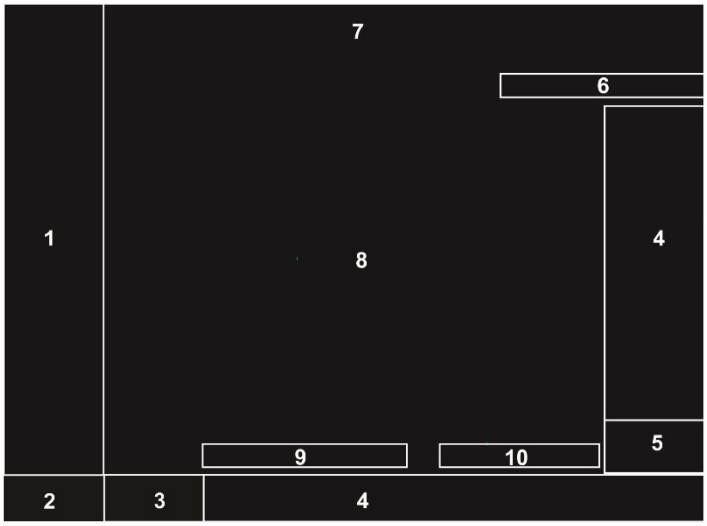
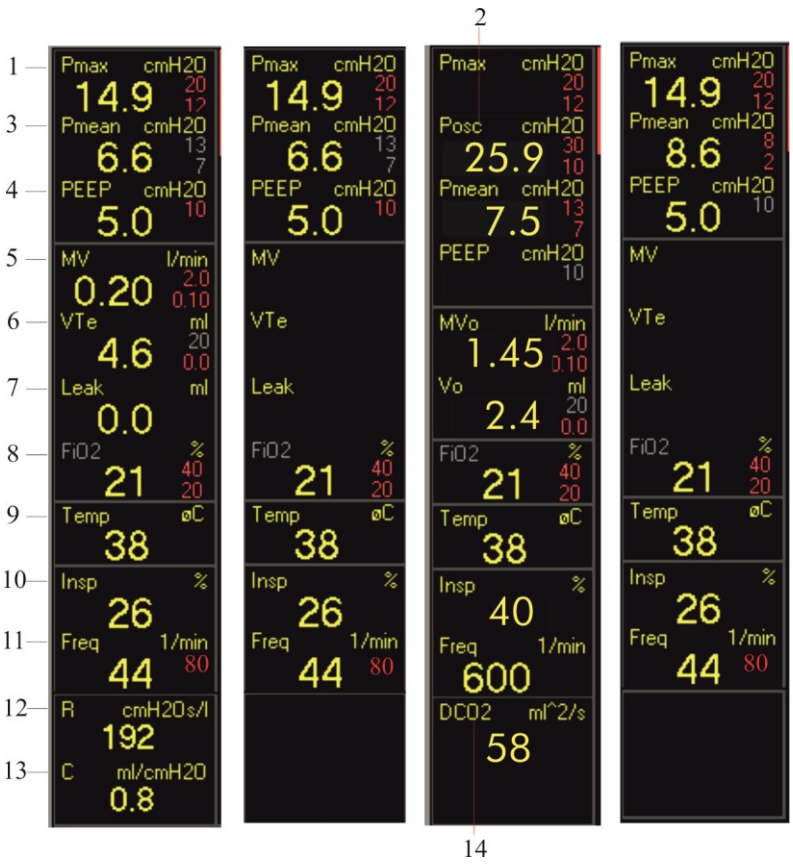


Fig. 5: Monitor unit

1	Measured value display with configurable alarm limits	6	Date and time display
2	Main menu	7	Status, alarm, and info display
3	Ventilation menu (ventilation mode indication and selection)	8	Graphic display
4	Parameter display	9	Expiratory trigger status (if an external trigger is activated)
5	Special functions display	10	Apnea counter for non-invasive ventilation and CPAP

3.2.1 Measured value display

This display provides a quick view of the relevant measured values together with the alarm limits shown after the measured value. The alarm limits can be adjusted manually in the Main menu or by pressing the »Alarm menu« button (see chapter 3.1.2). A detailed description of how to set the alarm limits can be found in chapter 4.2.1.



a) b) c) d)

Fig. 6: Measured value displays

a) Measured value display with PNT

b) Measured value display without PNT

c) Measured value display CPAP with HFO

d) Measured value display NCPAP

NOTE

If a value violates the upper or lower active alarm limit, the corresponding measured value field is highlighted in red. In addition, an error message appears in the status, alarm, and info display.

No.	Measured value	Description	Unit
1	Pmax	Maximum end inspiratory breathing pressure	cmH_2O
2	Posc	Pressure amplitude during oscillation	cmH_2O
3	Pmean	Mean airway pressure	cmH_2O
4	P_{EEP}	Positive end expiratory pressure	cmH_2O
5	MV	Respiratory minute volume	l/min
	MV_O	Respiratory minute volume during oscillation	l/min
6	VT_I	Inspiratory tidal volume	ml
	VT_E	Expiratory tidal volume	ml
	VT_O	Tidal volume during oscillation	ml
7	Leak	Leak volume	ml
8	FiO_2	Inspiratory oxygen concentration	%
9	Temp	Proximal respiratory gas temperature	°C
10	Insp%	Relative inspiration time	%
11	f	Breathing frequency	/min
12	R	Patient and tube resistance	cmH_2O l/s
13	C	Patient compliance	ml/cmH_2O
14	DCO_2	Gas transport coefficient	ml^2/s

Tab. 3: Measured value display

NOTE

Active alarm limits are shown in red font behind the measured values. If the alarm limits are not active, they are shown in gray in night mode and in yellow in day mode.

3.2.2 Main menu

Fig. 7: Main menu opened

Select the Main menu using the »IGR«. The field turns green. Click with the »IGR« or press the »Main menu« button to open the menu (see chapter 3.1.2).

NOTE

A detailed description of the Main menu and its corresponding functions can be found in chapter 4.

3.2.3 Ventilation menu

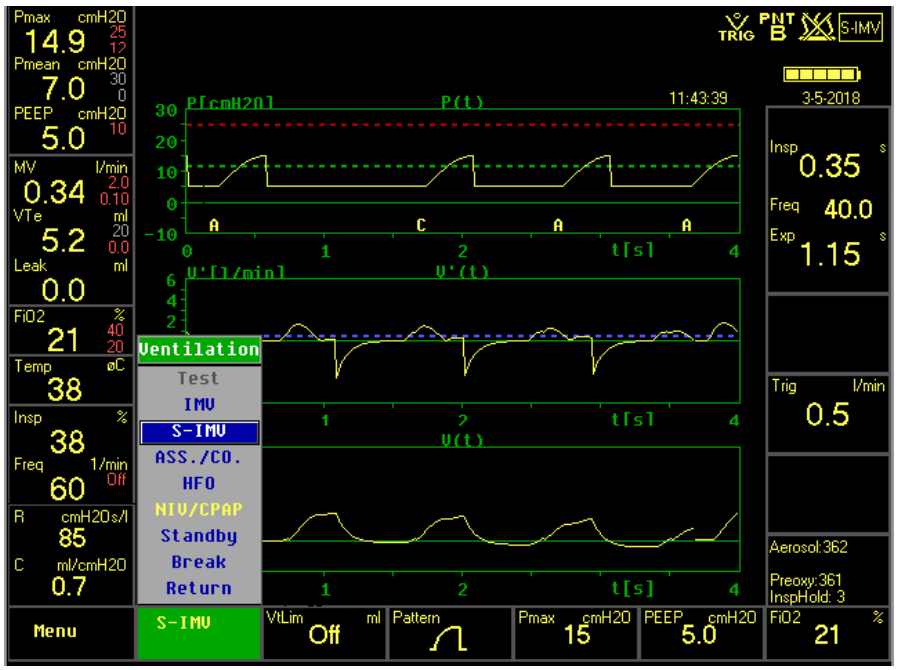


Fig. 8: Ventilation menu opened

Open the Ventilation menu using the »IGR« or the corresponding selection button. The field turns green. In the Ventilation menu, use the »IGR« to select the ventilation mode. The selected field is highlighted in blue. Click with the »IGR« or press the selection button to confirm the selection.

NOTE

A detailed description of the Ventilation menu can be found in chapter 5.

3.2.4 Ventilation parameter display

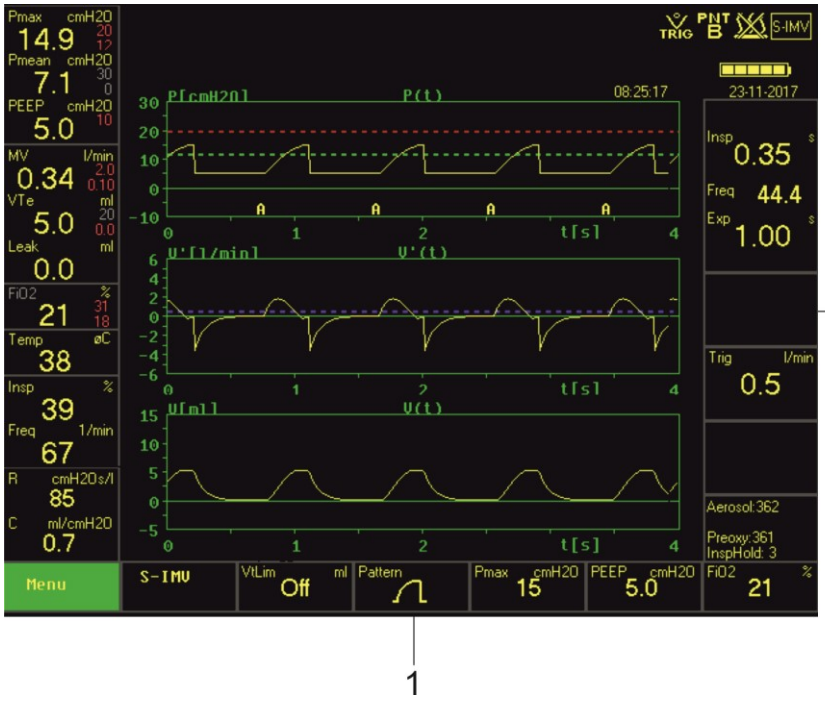


Fig. 9: Parameter display

1	Parameter display (bottom edge of monitor)	2	Parameter display (right edge of monitor)

The parameter setting fields are located along the right and bottom edge of the monitor. When selecting a ventilation mode, a pop-up menu appears listing all the necessary parameters.

To change a ventilation parameter during ongoing ventilation, open the corresponding parameter field using the »IGR« or directly using the corresponding »selection« button.
Use the »IGR« to make the adjustment. Click with the »IGR« or press the corresponding »selection« button to save and exit the setting (see chapter 3.1).

NOTE

More information on setting the ventilation parameters can be found in chapter 5.

3.2.5 Date and time display

The current date (DD-MM-YY) and time are shown in the first two lines of the parameter display on the right side of monitor (see Fig. 5).

NOTE

If the trend display is activated in the curve area, the time is not displayed.

3.2.6 Special functions display

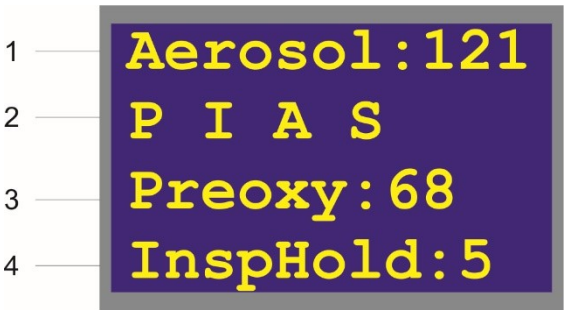


Fig. 10: Special functions display

1	Aerosol nebulization display	3	Preoxygenation display
2	Active special functions display	4	Inspiration hold display

The special functions display constantly shows the current time settings for aerosol nebulization, preoxygenation, and inspiration hold in seconds.

If the »Preoxy«, »Insp. hold«, »Aerosol«, or »Stop« buttons are pressed (see chapter 3.1.2), the color of the special functions display changes to blue while in use; the corresponding symbol appears and the set time starts to count down.

The following symbols are used:

»Preoxy«	**P**
»Insp. hold«	**I**
»Aerosol«	**A**
»Stop«	**S**

3.2.7 Status, alarm, and info display

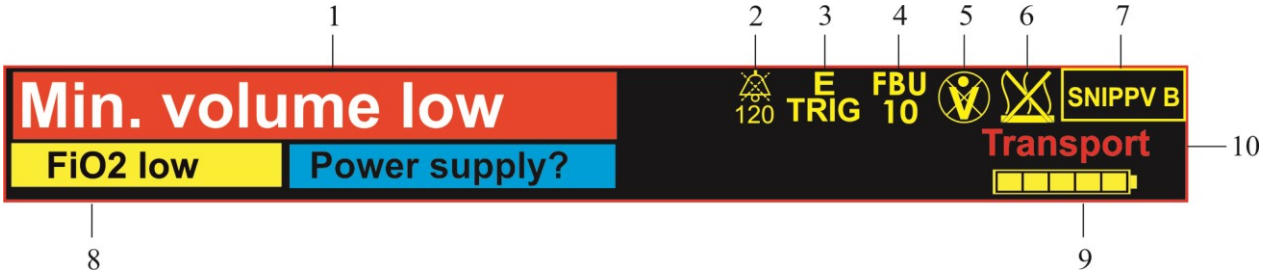


Fig. 11: Status, alarm, and info display

1	Latest alarm according to priority (e.g. Min. volume low)	6	Heating on/off
2	Acoustic alarm suppression	7	Ventilation mode
3	Trigger type	8	Other alarm messages (in order of priority/chronological)
4	Backup ventilation mode	9	Charge indicator for the internal battery or remaining run time
5	PNT type	10	Transport mode on

Tab. 4: Status, alarm, and info display

3.2.7.1 Alarm messages

The **SOPHIE** has several alarms that protect the patient and inform the user about changes in the patient's condition or possible faults with the device. The alarm display can show up to three active alarms simultaneously. If more than three alarms are active, the three alarms with the highest priority are displayed. The remaining active and inactive alarms are listed in the alarm list (see chapter 3.2.7.2).

The visual and acoustic alarms are compliant with IEC 60601-1-8.
All alarms are emitted not only acoustically, but also visually in plain text format with color coding depending on their priority.

High priority alarm

An alarm indicating that the user must respond immediately.

Color: Red

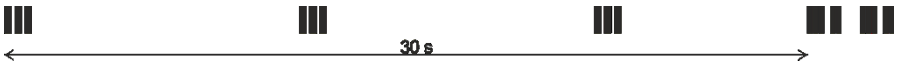
Sequence:

Alarm of at least medium priority

An alarm that escalates from medium to high priority after 30 s if the cause of the alarm has not been eliminated.

Color: Yellow/red (after 30 s)

Sequence:



Medium-priority alarm

An alarm indicating that the user must respond quickly.

Color: Yellow

Sequence:

Low priority alarm

An alarm indicating that the user should be aware of the situation and attentive.

Color: Cyan

Sequence: (no repetition)

NOTE

A mainboard with a serial number below S81018191000030 (prior to September 2018) has no acoustic components for a low-priority alarm.

NOTE

All notification and alarm messages, together with their causes and remedies, can be found in chapter 12.

3.2.7.2 Alarm list

The alarm list shows the active and inactive alarms with time and priority. It can be accessed by selecting the alarm display using the »IGR« control knob and opened by pressing the »IGR«. Alternatively, the alarm list can also be accessed from the Main menu. To do so, open the “Alarmlimits” sub-menu and choose the “Alarm list” option (see chapter 4.2.1.5).

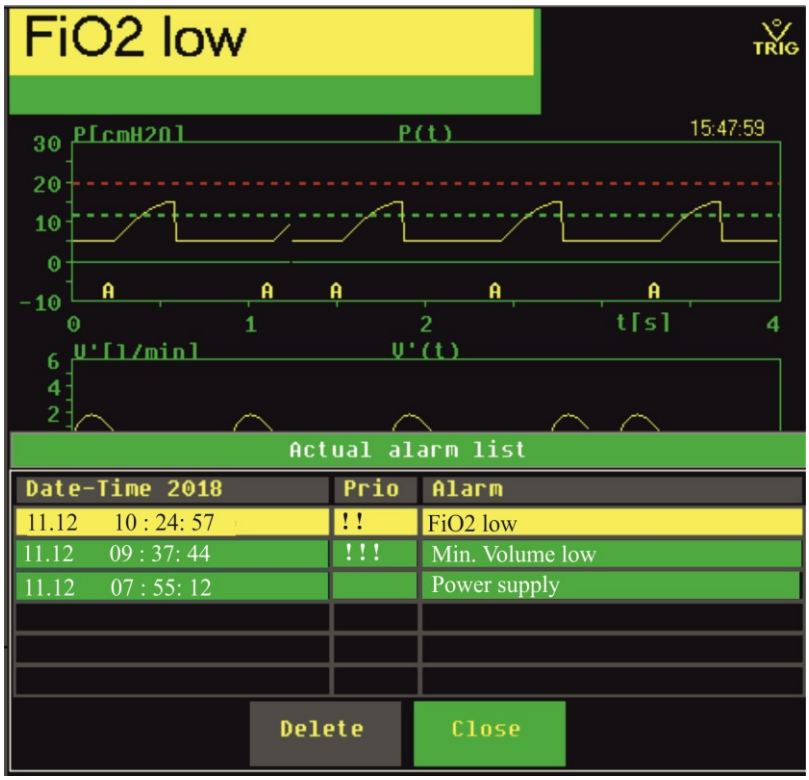


Fig. 12: Opened alarm list

Each alarm can be displayed only once, together with the date and time it last occurred.

The alarms are displayed in the following sequence according to the following criteria:

1. Status (active before inactive)
2. Priority (HP before MP before LP)
3. Date and time of last occurrence (new before old)

Present inactive alarms

If there are no active alarms, the symbol  in the alarm display indicates that unconfirmed inactive alarms exist. They can be checked by accessing the alarm list and confirmed if necessary.

Deleting the alarm list

Active alarms are displayed in the color of their priority and can be neither confirmed nor deleted. Inactive alarms are shown in green. By choosing the “Delete” field, all visible inactive alarms are confirmed and deleted. If other inactive alarms are present, they are now shown and can also be confirmed.

NOTE

Switching off the device completely will automatically delete all entries from the alarm list.

NOTE

The alarm list is retained in the event of a power outage of less than 30 s. In this case, energy is supplied by the internal battery.

NOTE

In the event of a total power failure, all entries are deleted from the alarm list.

3.2.7.3 Internal battery level indicator

When the device is running on mains power, the battery level is depicted by a bar graph. If the Sophie switches to battery power, the display shows the ventilator’s remaining run time in minutes.

Display	Battery level
	80–100%
	60–80%
	40–60%
	20–40%
	0–20%
	Remaining run time

Tab. 5: Battery level

NOTE

NOTE

The power source indicator on the front of the **SOPHIE** housing also shows the internal battery level (see chapter 3.1.1).

NOTE

The battery should be completely charged, discharged, and recharged at least once every 12 months. This re-calibrates the calculation of the battery capacity to ensure maximum accuracy of the battery level indicator.

3.2.8 Graphic display

You can choose to display two or three curves. This can be set in the Main menu under “Curves” (see chapter 4.2.2.1).

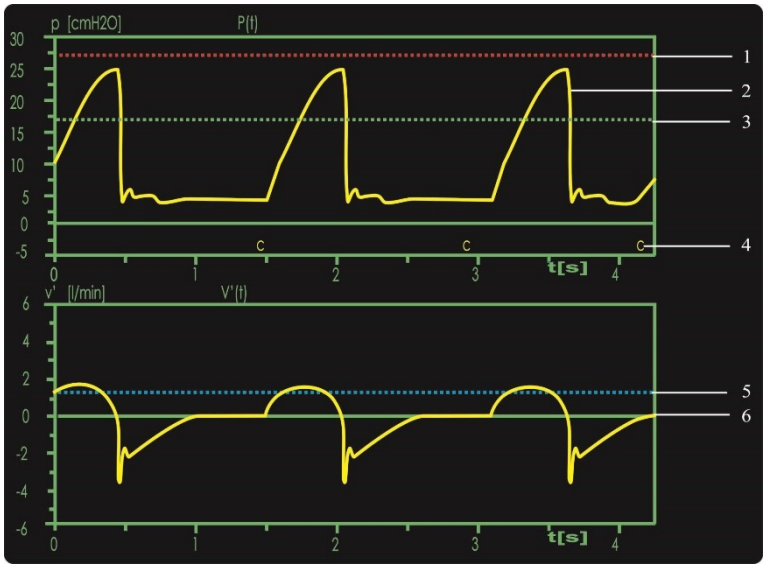


Fig. 13: Default graphic display (two curves)

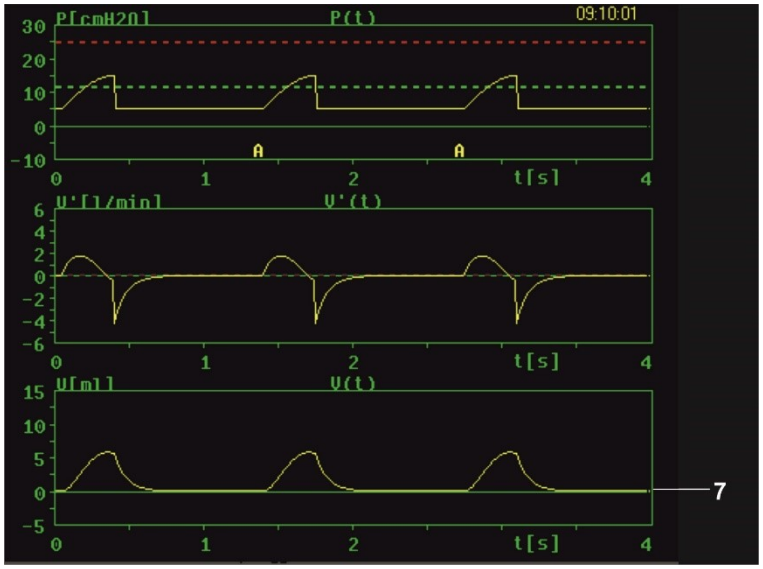


Fig. 14: Alternate graphic display (three curves)

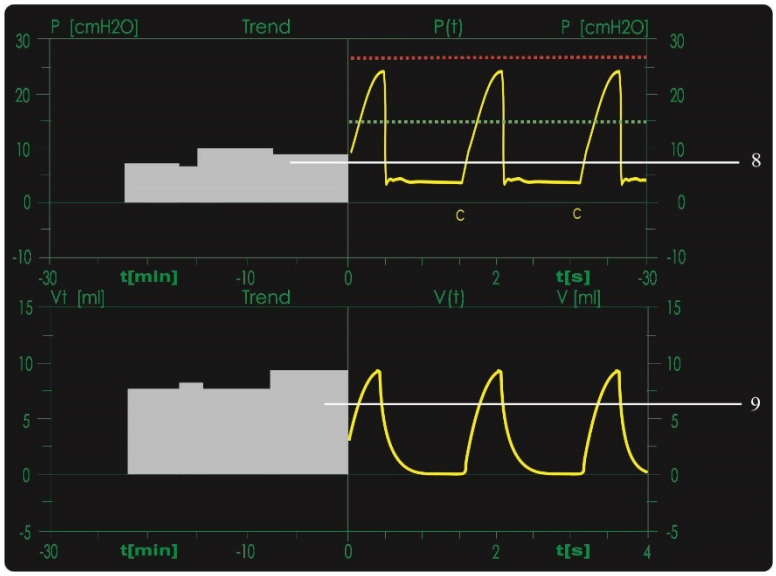


Fig. 15: Graphic display with activated trend

NOTE

If curves 2 and 3 (panels 2 and 3) show the same information, the two displays are automatically combined into an enlarged screen for better readability (see Fig. 16). This view is particularly useful for loops and trends.

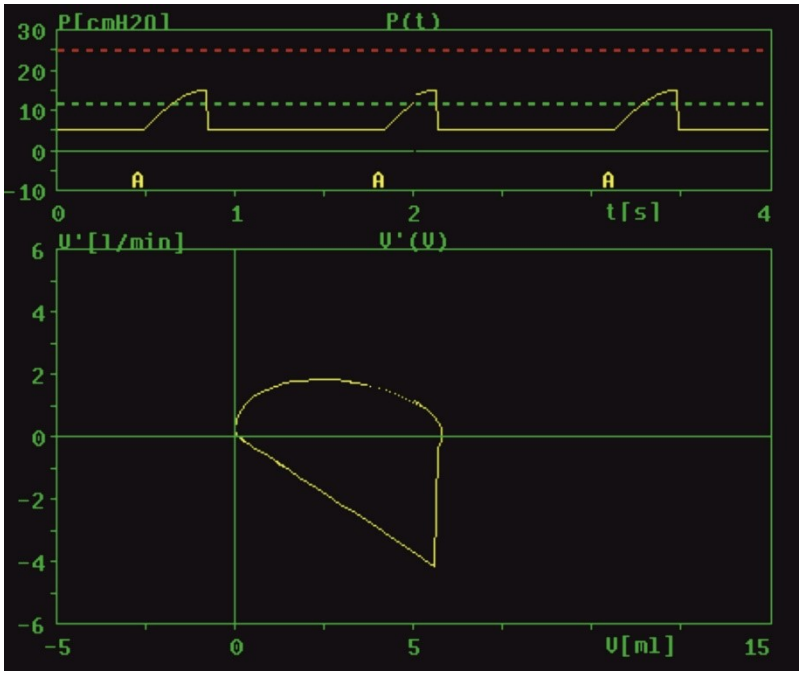


Fig. 16: Enlarged window showing identical information for curves 2 and 3 (panels 2 and 3)

No.	Display		Description
1	P_{MAX} UL (red)		Displays the upper limit for the alarm limit value P_{MAX}
2	Pressure curve (yellow)		Mean value of the inspiration and expiration tube pressures of the ventilation tube To monitor the pressure alarm limit value, the inspiration and expiration pressures are measured.
3	P_{MAX} LL (green)		Displays the lower limit for the alarm limit value P_{MAX}
4	C		Controlled breath
	Ax		Assisted breath / x: backup stage (1–5)
	Bx		Backup breath / x: backup stage (1–5)
	S		Spontaneous breath without pressure support
5	Trigger (blue)		Corresponds to the settings in the “Trigger” menu (see chapter 4.2.7.3): Flow trigger Light blue trigger line in the curve V’(t) Pressure trigger Light blue trigger line in the curve P(t) Ext. trigger Light blue trigger line in the curve E(t)
	Flow limit line (blue)		The flow limit line can be set in the Ventilation menu by selecting HFO ventilation (see chapters 5.4.2 and 5.4.7). It monitors the mean flow (see chapter 9.6).
6	Panel 2		The second curve can be selected in the “Curves” menu (see chapter 4.2.2.1). You can select the curves for volume flow V’(t), volume V(t), and external trigger E(t), as well as the loops V(P), V’(P), and V’(V).
7	Panel 3		The third curve can be selected in the “Curves” menu (see chapter 4.2.2.1). You can select the curves for volume flow V’(t), volume V(t), and external trigger E(t), as well as the loops V(P), V’(P), and V’(V).
8	Trend Pmean		Displays the progress of the mean airway pressure over a defined period
9	Trend volume		Displays the progress of the respiratory minute volume or the tidal volume, depending on the selected option for panel 2 or panel 3. Panel 2/3 V’(t): respiratory minute volume trend Panel 2/3 V(t): tidal volume trend

Tab. 6: Graphic display

3.2.9 External expiratory trigger status

When selecting the external trigger, the respiration sensor can also be used to record the inspiration end. The status of the expiratory trigger is then displayed on the left, below the bottom graphic display.

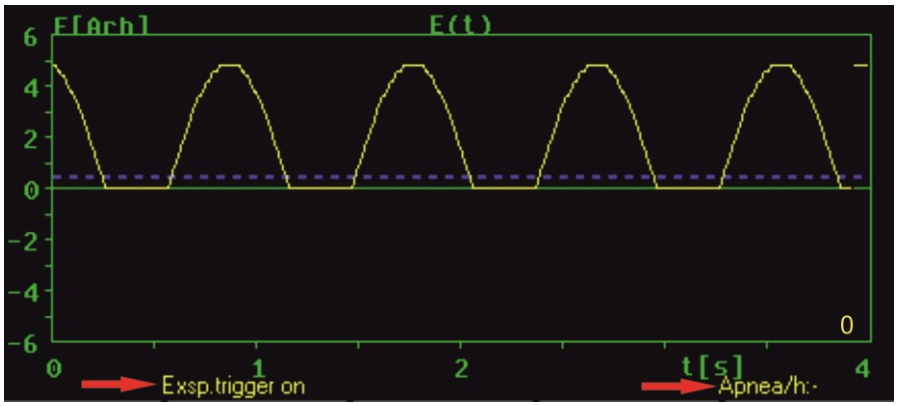


Fig. 17: External expiratory trigger status and apnea counter

3.2.10 Apnea counter

During non-invasive ventilation and CPAP, an apnea counter is displayed to the right and below the bottom graphic display (see Fig. 17). It indicates how often backup ventilation with full frequency has been started within the last hour.

3.3 Right side view

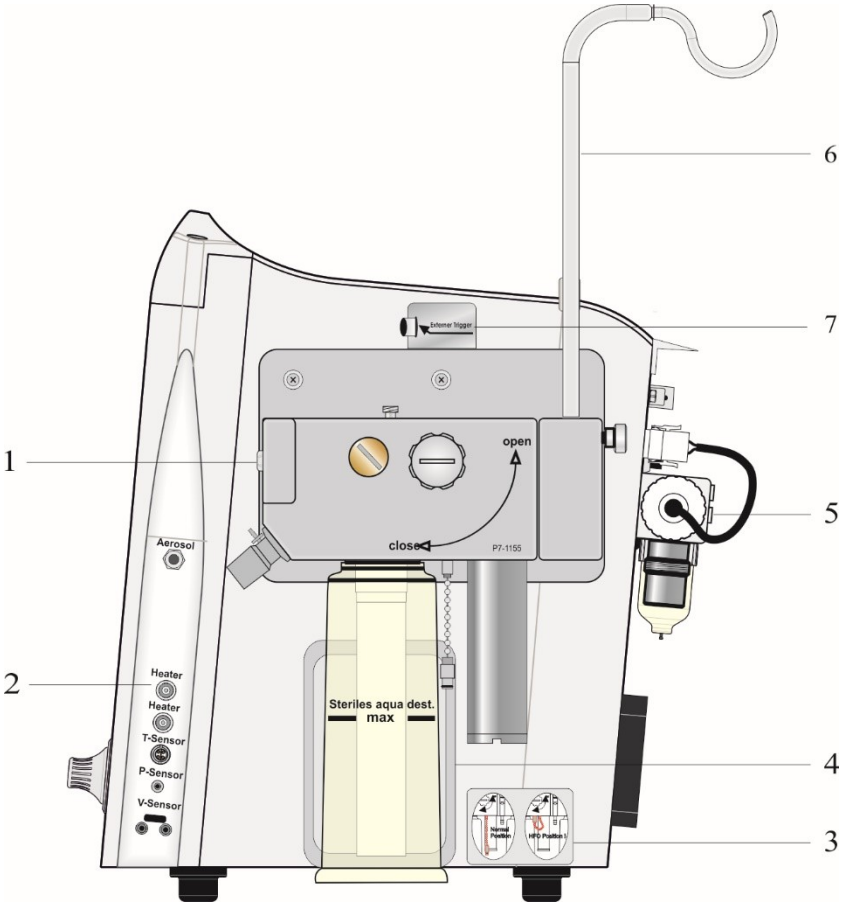


Fig. 18: Right side view

1	Patient component	5	Gas supply connections
2	Connection panel	6	Sterile water bag holder
3	HFO label	7	Respiration sensor connection (optional)
4	Fill level sensor for humidifier bottle		

HFO label Detailed descriptions for using the »HFO« sealing plug can be found in chapter 9.6.

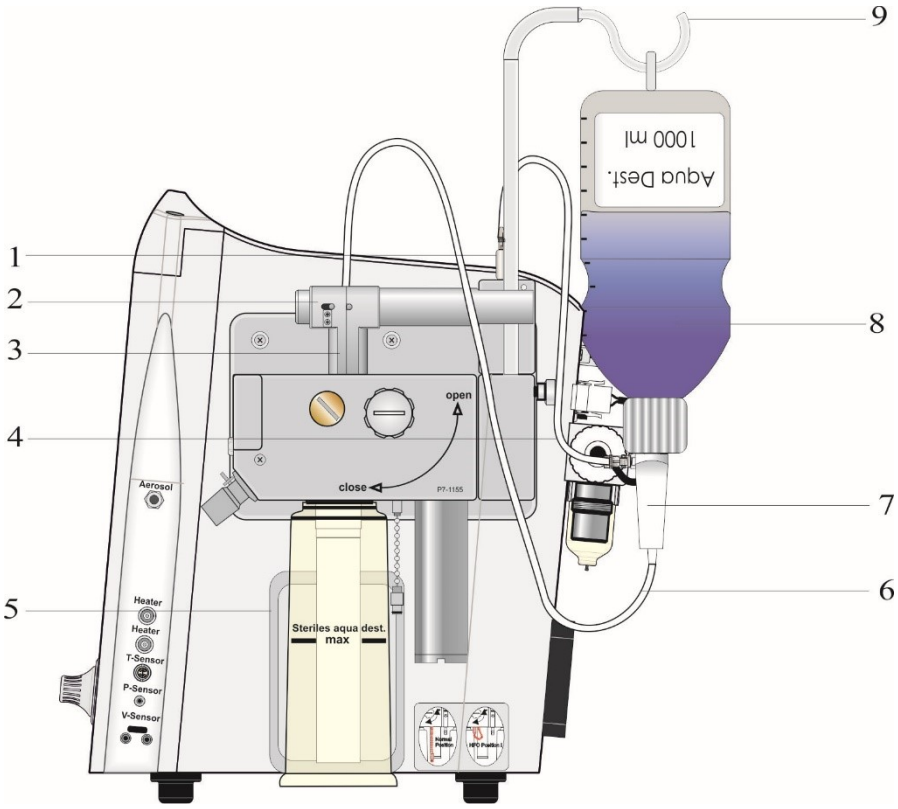


Fig. 19: Sophie with automatic refill system

1	Driving gas outlet	6	Aqua dest. tube
2	Tube pinch valve	7	Transfer spike
3	Aqua dest. inlet	8	Aqua dest. bottle
4	Driving gas tube	9	Bottle holder
5	Fill level sensors		

Automatic refill system

A detailed description on the use and functions of the automatic refill system is found in chapters 6.3.3 and 11.1.2.

3.3.2 Patient component

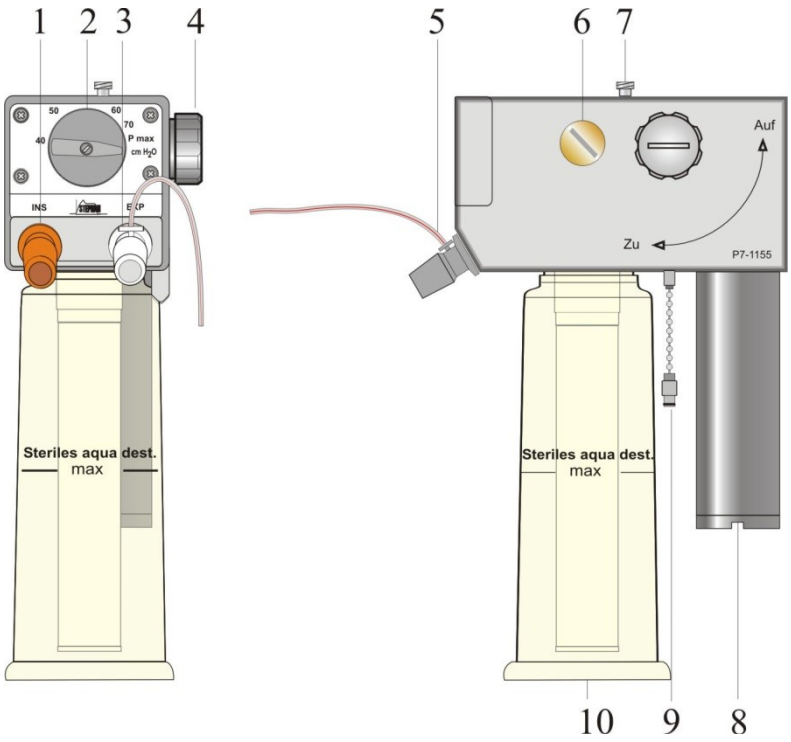


Fig. 20: Front and side views of the patient component

1 Inspiration tube connection
2 Positive pressure safety valve Pmax
3 Expiration tube connection
4 Locking screw
5 Pressure measurement nozzle with pressure measurement line
6 Patient valve
7 Luer lock connection Intake fitting for filling the humidifier bottle
8 Silencer
9 »HFO« sealing plug
10 Humidifier bottle

DANGER

Only use original pressure measurement lines from FRITZ STEPHAN GMBH.
The use of pressure measurement lines made from different materials, of different lengths or diameters, or with different compliance to those/that intended by the ventilator's manufacturer can impair the pressure measurement. This can sometimes lead to the safety valve opening and ventilation being interrupted.

DANGER

Never close the ventilation outlet behind the silencer.
This may cause the device to malfunction and put the patient at great risk.

WARNING

Never unscrew the humidifier bottle during operation! The humidifier chamber is pressurized.

NOTE

Make sure that the pressure measurement line is connected correctly.

HFO sealing plug Instructions for using the HFO sealing plug can be found in chapter 9.6.

Positive pressure safety valve Pmax

Name:	Pmax
Setting range:	40–70
Unit:	cmH_2O

WARNING

The set value for the positive pressure safety valve Pmax must always be higher than the value for inspiratory peak pressure Pmax set via »IGR« in the Ventilation menu (see chapter 5.3).

3.3.3 Reusable patient tube systems

Intended use Heated tube systems used to deliver and return the patient's respiratory gas in connection with the ICU respirators **STEPHANIE** and **SOPHIE** from Fritz Stephan GmbH. This patient tube system is reusable (see chapter 13.4).

CAUTION

Always hold the patient tube by the sleeve when connecting and disconnecting it to prevent damage.

Do not stretch, compress or twist the tube system!

CAUTION

Do not cover the tube system with blankets, towels or similar items! This could cause the tube system to overheat.

CAUTION

Do not use tube supports that are too narrow or have sharp edges!

CAUTION

If the gas supply is interrupted or deactivated, the heating function must be switched off!

CAUTION

Before using the tube system, check that all connection plug screws are tight!

CAUTION

Avoid prolonged direct contact with the patient's skin!

CAUTION

CAUTION

Check the tube system for the accumulation of condensation at short intervals over the course of its use.

3.3.3.1 Tube system for incubators

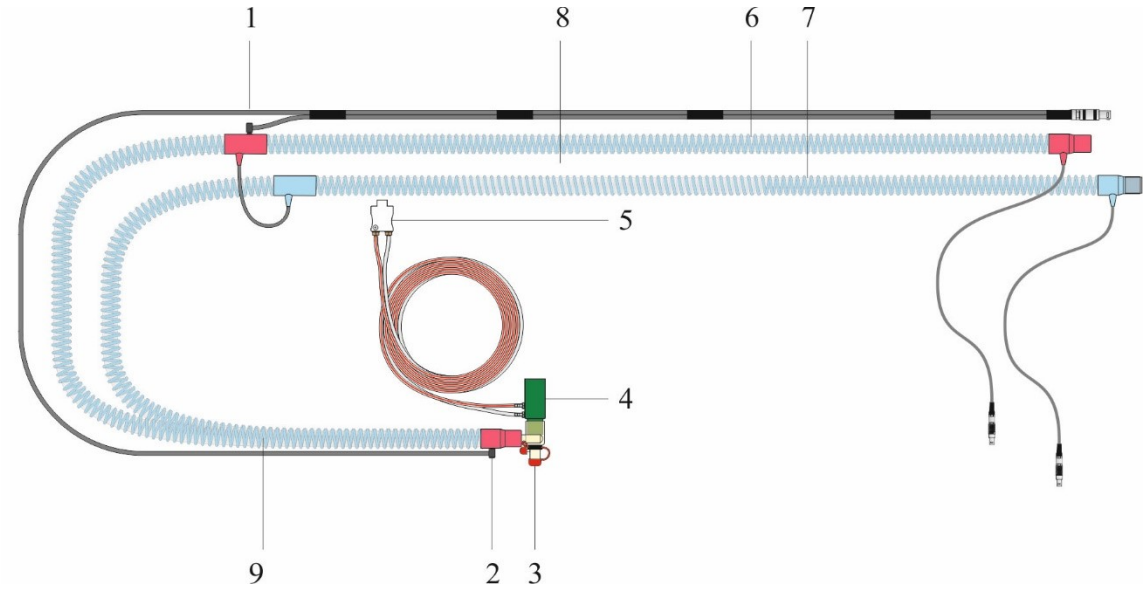


Fig. 21: Tube system for incubators (art. no. 100761500)

1	Distal temperature sensor	6	Inspiration tube
2	Proximal temperature sensor	7	Expiration tube
3	Y piece	8	Heated part
4	Pneumotachograph	9	Unheated part
5	Pneumotachograph plug		

3.3.3.2 Tube system for warming beds

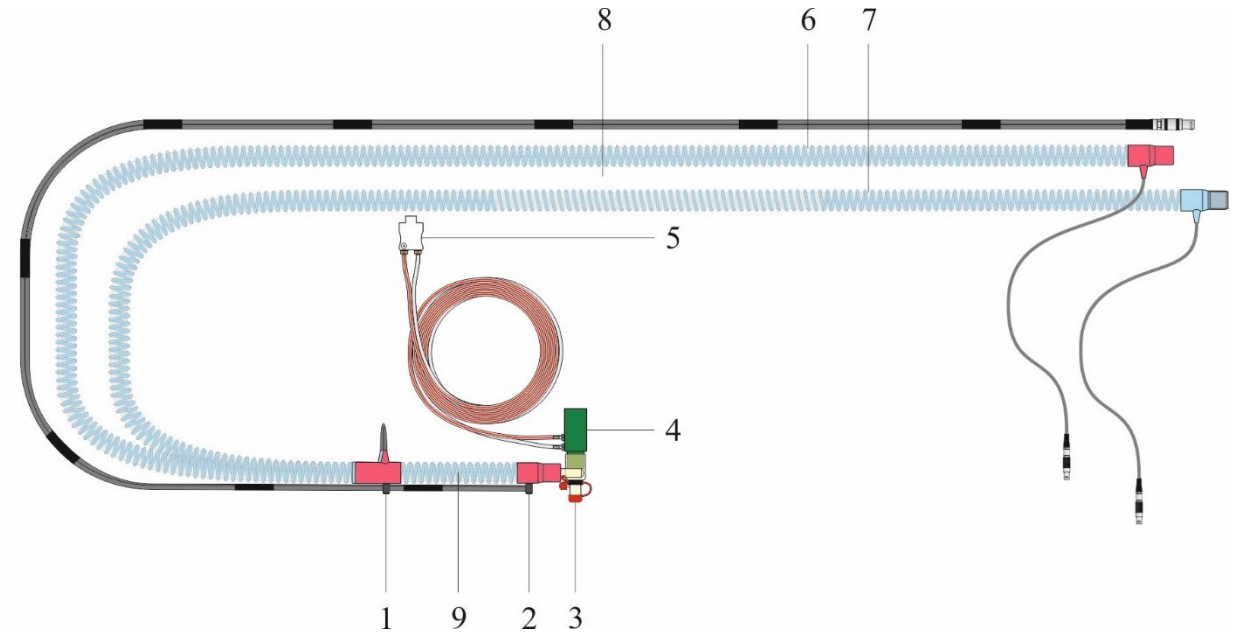


Fig. 22: Tube system for warming beds (art. no. 100761550)

1	Distal temperature sensor	6	Inspiration tube
2	Proximal temperature sensor	7	Expiration tube
3	Y piece	8	Heated part
4	Pneumotachograph	9	Unheated part
5	Pneumotachograph plug		

3.3.4 Disposable patient tube system

NOTE

For information about using the device as intended, about warnings and safety instructions, as well as technical data, refer to the operating manual provided with the tube system.

CAUTION

Always hold the patient tube by the sleeve when connecting and disconnecting it to prevent damage.

Do not stretch, compress or twist the tube system!

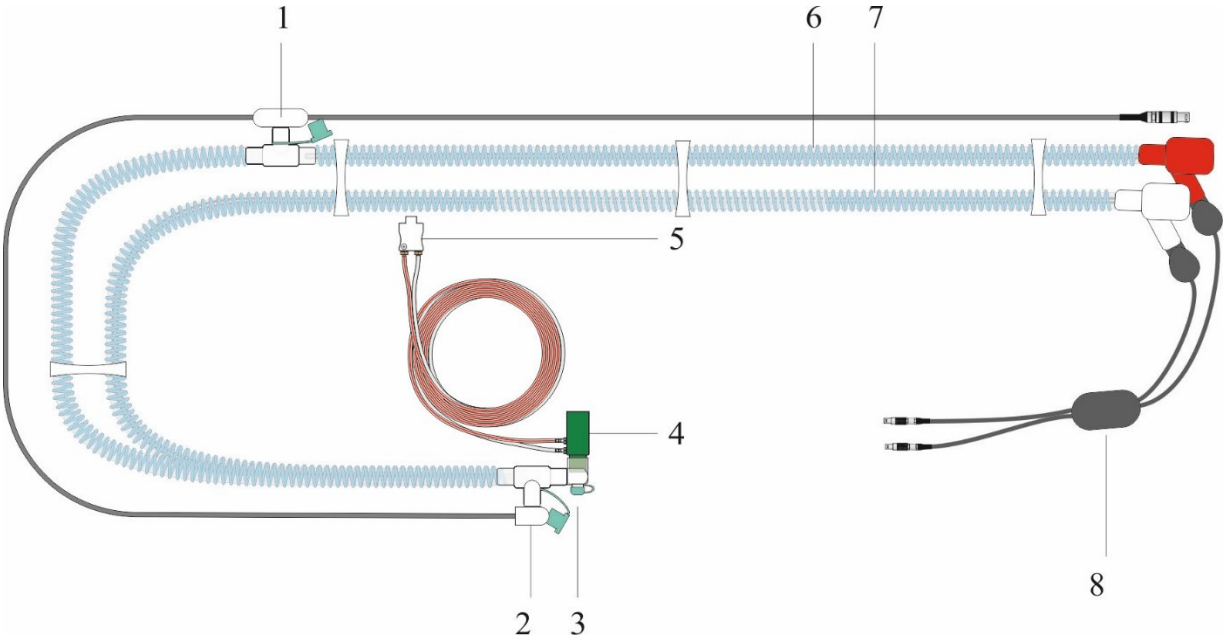


Fig. 23: Disposable tube system P3/P7 (art. no. 100761300)

1	Distal temperature sensor for disposable patient tube system (art. no. 100761300)	5	Pneumotachograph plug (reusable)
2	Proximal temperature sensor for disposable patient tube system (art. no. 100761300)	6	Inspiration tube
3	Y piece	7	Expiration tube
4	Pneumotachograph (reusable)	8	Tube heater adapter (reusable)

3.3.5 Connection panel

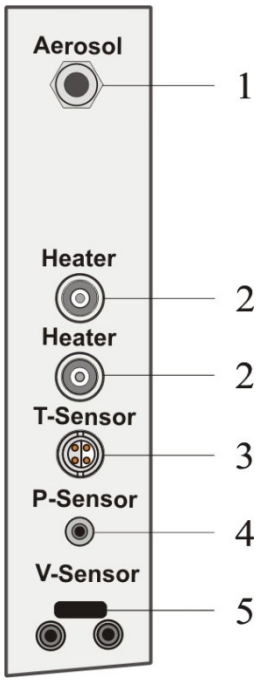


Fig. 24: Connection panel

1 Aerosol nebulizer
2 Tube heater
3 Temperature sensor
4 Pressure measurement line
5 Pneumotachograph

3.4 Rear view

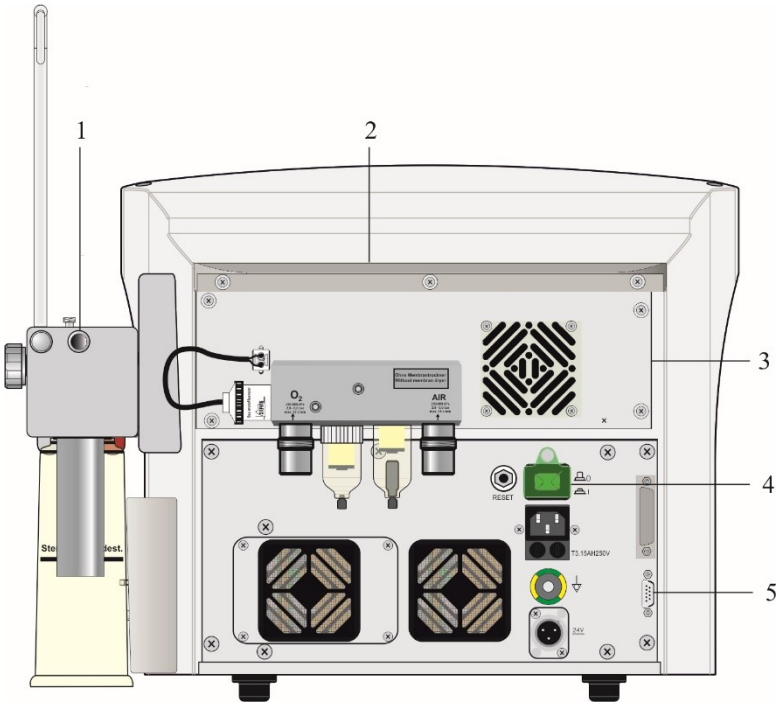


Fig. 25: Rear view

1	Y piece park position	2	Drip strip
3	Pneumatic module	4	Power supply module
5	RS232 interface		

DANGER


Risk of injury! Never lift or carry the device from the drip strip. The strip could break.

NOTE

Depending on the design, the power supply module can vary and differ from the type shown. Further information can be found in chapter 3.4.2.

NOTE

In order to be able to use the DP NEO PNT (from SW version PC 2.7x), the park position (item 1/Fig. 25) on the back of the patient component has to be modified. Otherwise a test of this PNT is not possible.

3.4.1 Pneumatic module

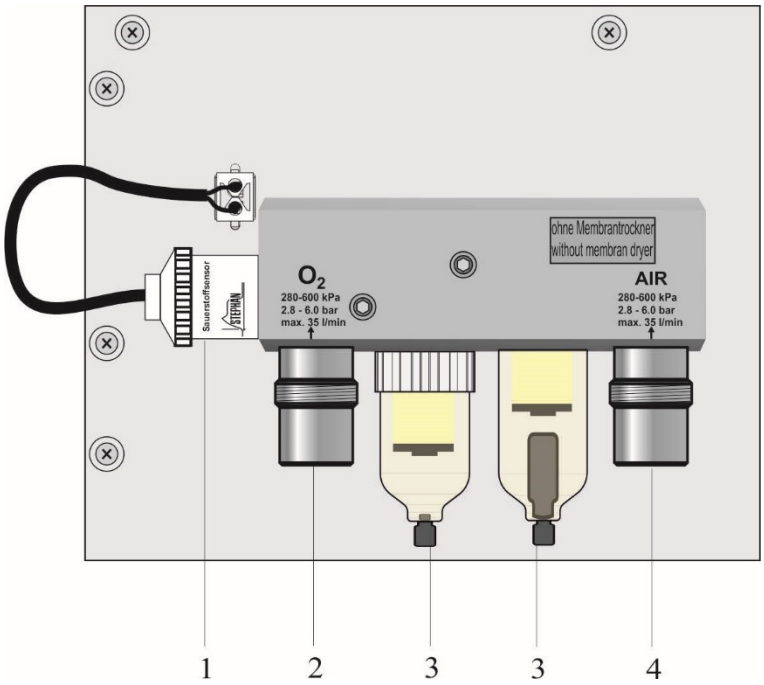


Fig. 26: Pneumatic module

1	Oxygen sensor	3	Water separator with filter
2	O_2 connection (NIST)	4	AIR connection (NIST)

3.4.2 Power supply module and interfaces

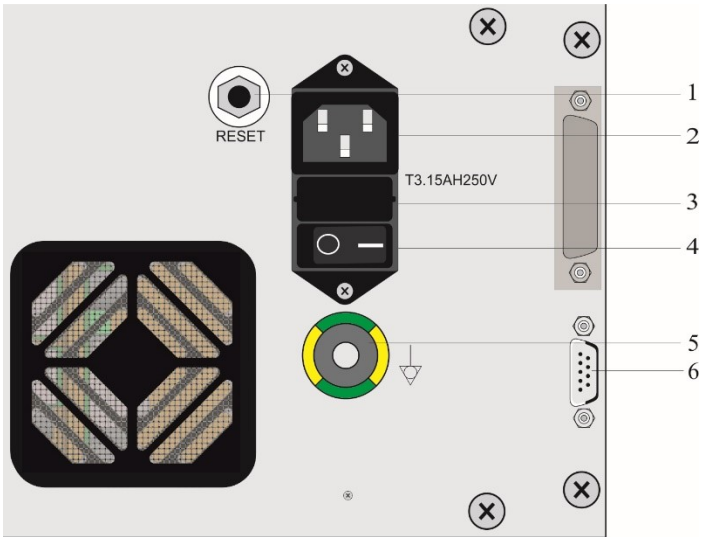


Fig. 27: Power supply module (art. no. 103861075)

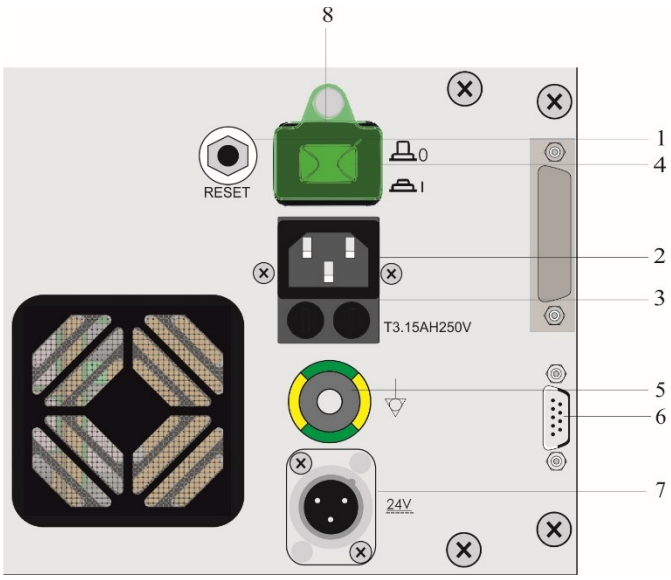


Fig. 28: Power supply module (art. no. 10386120 and art. no. 103861080)

1	»Reset« button	5	Equipotential bonding
2	Power socket	6	Serial interface RS 232 (galvanically isolated)
3	Mains fuses	7	On-board power supply (24 V DC) (optional)
4	»ON/OFF« power switch	8	Power switch cover

WARNING

Only devices compliant with IEC 60601-1 or IEC 60950-1 with protective extra-low voltage may be connected to the serial interfaces.

»Reset« button

The **SOPHIE** is typically shut down by activating the »Standby/OFF« special function in the "Ventilation" menu (see chapter 5.2.1). If the Sophie does not shut down due to a malfunction, proceed as follows:

1. Switch off the »ON/OFF« power switch.
2. Use a pen to press the »Reset« button to shut down the unit.

CAUTION

If this situation arises, contact the FRITZ STEPHAN GMBH customer service team.

3.5 Mobile stand

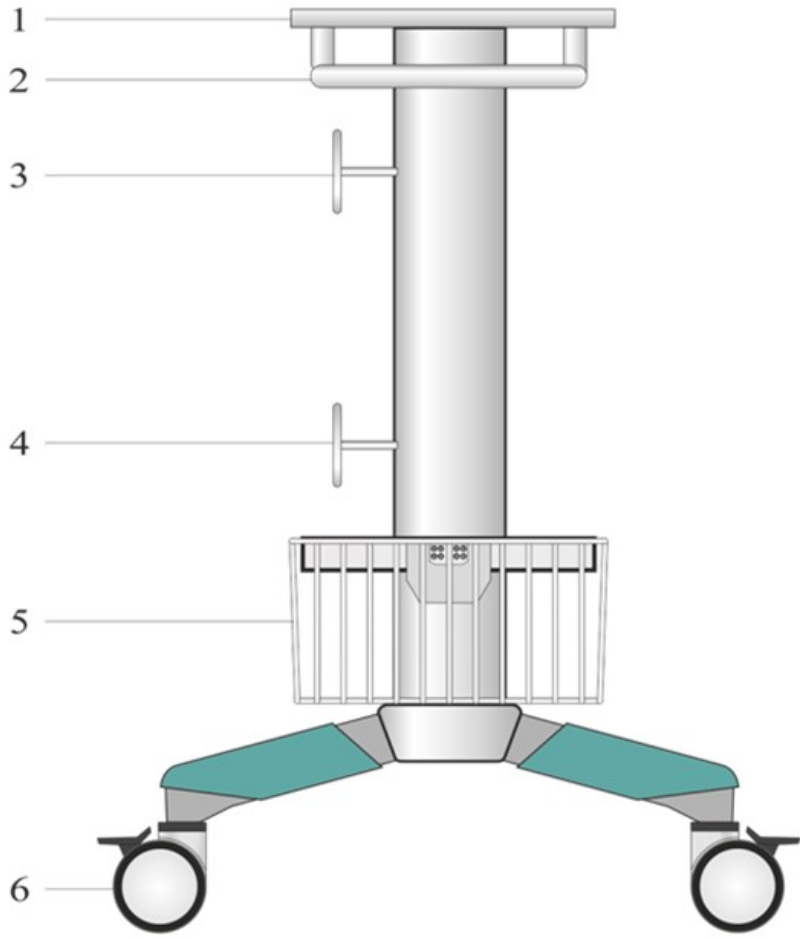


Fig. 29: Mobile stand

1	Support for the SOPHIE	4	Tube holder (optional)
2	Handle	5	Storage basket (optional)
3	Tube holder (optional)	6	Castors (4, 2 with brakes)

4 Main menu

The Main menu contains six sub-menus, some of them branching into as many as five sub-levels.

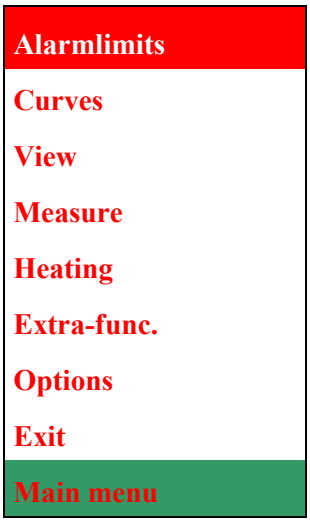


Fig. 30: Main menu opened

The following section provides a brief description and explanation of the operating concept and all sub-menus.

4.1 Operating concept

Operation using »IGR«

The entire Main menu can be controlled using the central »IGR« push and turn knob:

1. Turn the »IGR« to select the “Main menu” field. The field turns green.
2. Click (press) the »IGR« to open the Main menu.
3. Turn the »IGR« clockwise or counterclockwise to scroll through the available menu options. The selected option is highlighted in red.
4. Click the »IGR« to carry out the corresponding function or open a sub-menu.
5. Set parameters or switch functions on and off by turning the »IGR«.
6. Click the »IGR« to exit the setting.

NOTE

The Main menu can also be opened and closed using the »Main menu« button. Detailed information on the »Main menu« button can be found in chapter 3.1.2.

NOTE

Detailed information on the »IGR« control knob can be found in chapter 3.1.

Switching functions on and off/setting numerical values

Some functions in the Main menu (e.g. Heating) can be switched on and off, while others require numerical values to be set (e.g. Temperature). To do so, select and open the function. Above the menu, a yellow field shows the current status or current numerical value of the function. Turn the »IGR« to select the desired setting, then press the »IGR« knob to confirm the new entry.

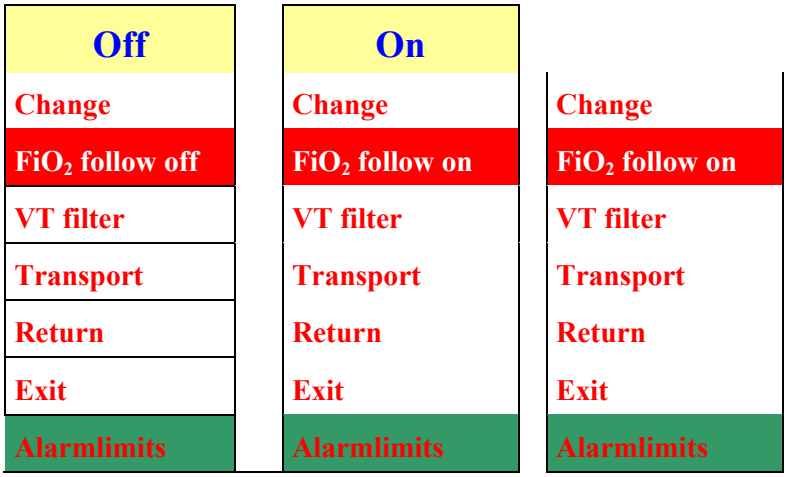


Fig. 31: Setting the function "FIO$_2$ follow on/off"

NOTE

"On" or "off" after a function always indicates the current function status. For example, if "FiO$_2$ follow on" is displayed, this indicates that the function "FiO$_2$ follow" is activated. For clarity purposes, the functions with a status indicator are always shown with both options in the operating manual (e.g.: "FiO$_2$ follow on/off").

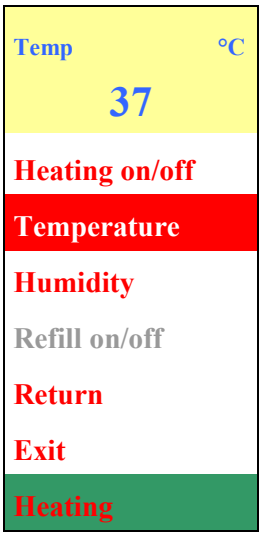


Fig. 32: Setting the respiratory gas temperature

“Return” function

The “Return” function can be found in every sub-menu. When activated, it takes the user back to the next higher menu. The next higher menu is always shown in the bottom green field of every sub-menu.

“Exit” function

The “Exit“ function can be found in every menu. When activated, the Main menu closes and previously changed settings are applied.

Non-selectable functions

The Sophie has several optional components such as the refill system. Depending on the device version, this means that it may not be possible to select some of the menu functions. These functions are grayed out (see the “Refill” function in Fig. 32).

4.2 Menu structure

4.2.1 “Alarmlimits” menu

The “Alarmlimits” sub-menu offers the following functions which are explained below:

Fig. 33: “Alarmlimits” menu

4.2.1.1 "Change"

WARNING

The alarm limits must be verified by medical personnel and possibly adapted to the current patient situation. The alarm limits must always be based on the patient's needs. Using extreme settings that are not medically indicated may render the alarm system useless and put the patient at risk.

The "Change" function in the "Alarmlimits" menu lets you adjust the alarm limits to the specific needs of the patient during ongoing ventilation. This can also be done by pressing the »Alarm menu« button (see chapter 3.1.2).

In both cases, a pop-up menu opens, showing the effective upper and lower alarm limits together with the current measured values. To change the alarm limits:

1. Use the »IGR« to select the desired alarm limit and click to open the setting. The alarm limit is highlighted in yellow.
2. Adjust the value by turning the »IGR«. Click again to exit. The new value takes effect immediately for the ongoing ventilation.
3. Proceed accordingly to adjust the next value.
4. Once all settings have been made, you can close the pop-up menu by selecting the »Close« field.

Fig. 34: "Alarmlimits" pop-up menu

NOTE

If the MAP or PEEP levels are changed, the alarm limits for the mean airway pressure (only CPAP-HFO/NCPAP) will be adjusted automatically.

Mode / Limit	IMV	HFO IMV	HFO CPAP	SIMV	Ass./Con	NIPPV	SNIPPV	NCPAP	CPAP
Pmax	**X**	**X**		**X**	**X**	**X**	**X**	**X**	**X**
Posc		**X**							
MV	**X**			**X**	**X**				**X**
MVo		**X**							
VT_E	**X**	**X**		**X**	**X**				**X**
Vo									
FiO_2	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
f				**X**	**X**	**X**	**X**	**X**	**X**
T_{EMP}	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
F_{lim}		**X**	**X**						

Tab. 7: Adjustable alarm limits

»Auto« Selecting the »Auto« field will automatically fix the alarm limits within the limits above and below the current settings/measured values and immediately apply them for the ongoing ventilation. The calculated limit values are rounded up or down according to their resolution and incrementation.

The algorithms for calculating the alarm limits are described in chapter 1.7.18.

NOTE

The automatic setting of the alarm limits cannot cover all conceivable ventilation situations. To ensure optimal patient safety, all alarm limits must be checked before starting ventilation.

NOTE

If the alarm limits are set automatically, the default minimum value for VT and MV is 0.1 ml. Values below 0.1 ml have to be set manually.

WARNING

The alarm limits are not saved permanently.

If the device is switched off completely or if the device switches off automatically because the battery is completely discharged, the alarm limits are automatically reset to the default settings.

The alarm limits must be continuously verified by medical personnel and possibly adapted to the current patient situation.

4.2.1.2 "FiO_2 follow on/off"

Switches the function for automatically adjusting the FiO_2 alarm limit value following changes to the »FiO_2« parameter on or off.

Parameter	Unit	Lower limit	Upper limit
FiO_2	%	FiO_2 – 10	FiO_2 + 10

4.2.1.3 "VT filter"

This function can be used to set the minimum tidal volume for SIMV ventilation between 0.2 and 10 ml. This determines the threshold value for the tidal volume above which a spontaneous breath is evaluated as complete and is thus taken into account for alarm generation and frequency determination.

4.2.1.4 "Transport on/off"

This function activates transport mode, in which specific functions for patient transport are optimized to the special requirements of the situation.

WARNING

The "Transport" function should not be used in stationary operation with normal power and gas supply.

Temporary deactivation of the power supply alarm can lead to an undetected discharge and premature depletion of the internal battery.

If only one gas supply source is available, the alarm that is activated because the second source is missing can be temporarily deactivated by confirming it in the alarm list (see chapter 3.2.7.2).

In addition, when using HFO ventilation in transport mode, gas consumption can be reduced by up to 20% by setting the amplitude to < 50% or the frequency to < 12 Hz.

If an external gas supply source is not available for patient transport, the power failure alarm can be temporarily deactivated by confirming it in the alarm list (see chapter 3.2.7.2).

The alarms will be re-activated if the cause of the alarm is eliminated i.e. the supply of power or gas is restored or the „transport“ function is switched off.

WARNING

Prior to transportation, always verify that the **SOPHIE** fresh gas reservoir (compressed gas cylinder) and the battery level of the internal battery is sufficient for the duration of transport.

If the Transport function is activated, this is shown in the status, alarm and info display.

Fig. 35: Transport function display

NOTE

In case of simultaneous failure of both the O_2 and AIR supplies, the “Gas supply” alarm is triggered automatically. This alarm cannot be permanently silenced.

4.2.1.5 Alarm list

This function is used to access the alarm list (see chapter 3.2.7.2).

4.2.2 "Curves" menu

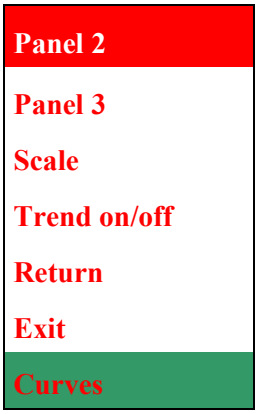
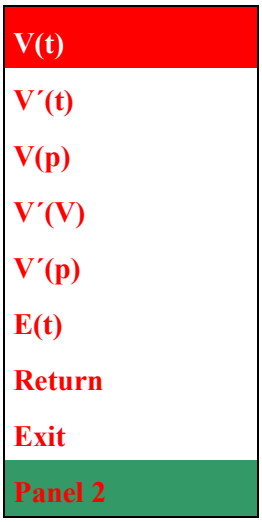


Fig. 36: "Curves" menu

In the "Curves" menu, the second and third reference curve in the graphic display can be selected and the trend display can be switched on or off. The scale of the graphic displays can also be adjusted.

4.2.2.1 "Panel 2"



Volume time curve

Flow time curve

Volume pressure loop

Flow volume loop

Flow pressure loop

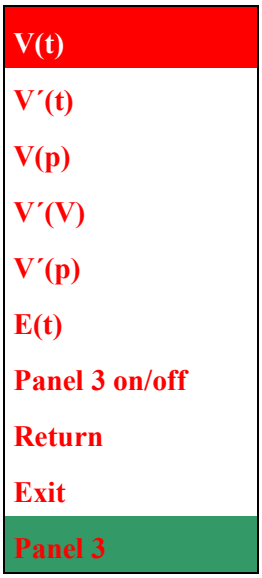
Respiration sensor signal

Fig. 37: "Panel 2" sub-menu

The "Panel 2" sub-menu can be used to select the third reference curve in the graphic display (see chapter 3.2.8).

The currently selected curve is highlighted in blue when opening the menu.

4.2.2.2 "Panel 3"



Volume time curve
Flow time curve
Volume pressure loop
Flow volume loop
Flow pressure loop
Respiration sensor signal
Switches the third reference curve on or off

Fig. 38: "Panel 3" sub-menu

The "Panel 3" sub-menu can be used to select the third reference curve in the graphic display (see chapter 3.2.8).
The currently selected curve is highlighted in blue when opening the menu.

NOTE

If curves 2 and 3 (panels 2 and 3) show the same information, the two displays are automatically combined into an enlarged screen for better readability (see Fig. 16). This view is particularly useful for loops and trends.

4.2.2.3 "Scale"

Use the »IGR« to select all the scale values and change them according to the following table.

Scale value		Possible settings
P	**[cmH$_2$O]**	15, 30, 60, 90
t	**[s]**	4, 8, 16 (2, 4, 8 with activated trend display)
V	**[ml]**	5, 15, 45, 150, 450
V'	**[l/min]**	3, 6, 15, 45
E	**Arb**	3, 6, 15, 45
P Trend	**[cmH$_2$O]**	15, 30, 60, 90
MV Trend	**[l/min]**	1.0, 2.0, 5.0, 10
VT Trend	**[ml]**	5, 15, 45, 150, 450
t Trend	**[min]/[h]**	30 min, 1 h, 2 h, 4 h, 12 h, 24 h

Tab. 8: Scale

NOTE

The "Scale" function can only be activated during ongoing ventilation. If there is no ongoing ventilation, the function is grayed out and cannot be selected.

Scale value		Scale from–to					
P/P Trend	**[cmH$_2$O]**	–5...15	–10...30		–20...60	–30...90	-
t	**[s]**	0–2	0–4		0–8	0–16	-
V/Vt Trend	**[ml]**	–1...5	–5...15		–5...45	–30...150	–50...450
V'	**[l/min]**	–3...3	–6...6		–15...15	–45...45	-
E	**Arb**	–3...3	–6...6		–15...15	–45...45	-
MV Trend	**[l/min]**	0–1.0	0–2.0		0–5.0	0–10	-
t Trend	**[min]/[h]**	–30 min	–1 h	–2 h	–4 h	–12 h	–24 h

Tab. 9: Scaling

4.2.2.4 "Trend on/off"

This function switches the trend display on and off.

4.2.3 "View" menu

Fig. 39: "View" menu

The "View" menu can be used to select the graphic options for the monitor or to switch them "ON" and "OFF". You can also choose between day and night view. The individual functions are described below.

4.2.3.1 "Units on/off"

These functions switch the monitor units on and off.

4.2.3.2 "Display VT"

Use this function to select the type of tidal volume to appear in the measured value display.

Fig. 40: "Display VT" sub-menu

VT insp The measured value display shows the inspiratory tidal volume VTi (see chapter 0).

VT exp The measured value display shows the expiratory tidal volume Vte (see chapter 0).

The currently selected VT is highlighted in blue when opening the menu.

NOTE

The “Display VT” menu cannot be selected during ventilation modes without PNT or high frequency oscillation.

4.2.3.3 “Limits on/off”

Use this function to switch the alarm limits display on and off in the measured value display.

NOTE

The alarm limits continue to be monitored even when the display is switched off.

4.2.3.4 "Day/Night" view

Use this function to switch to day or night view.

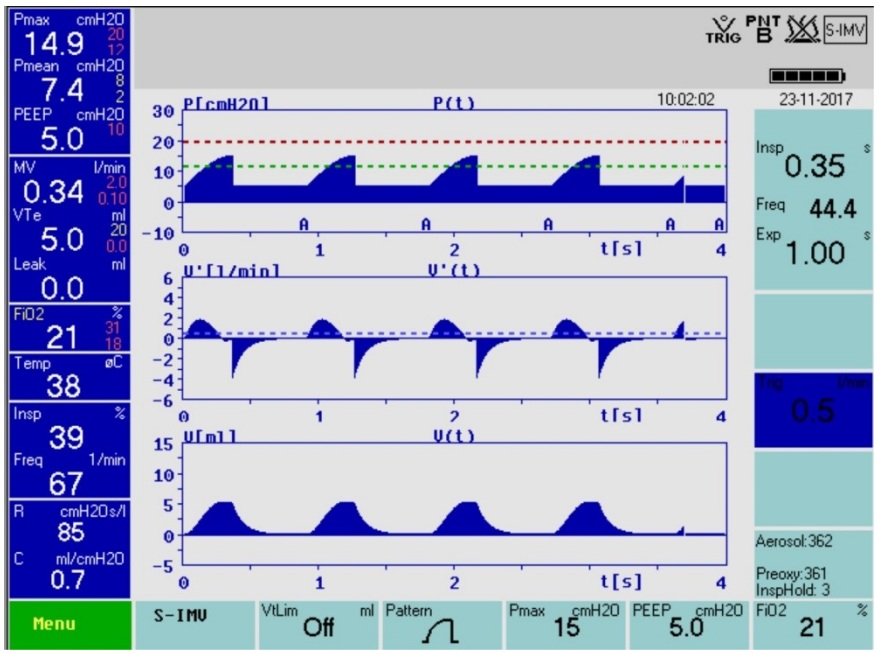


Fig. 41: Day view

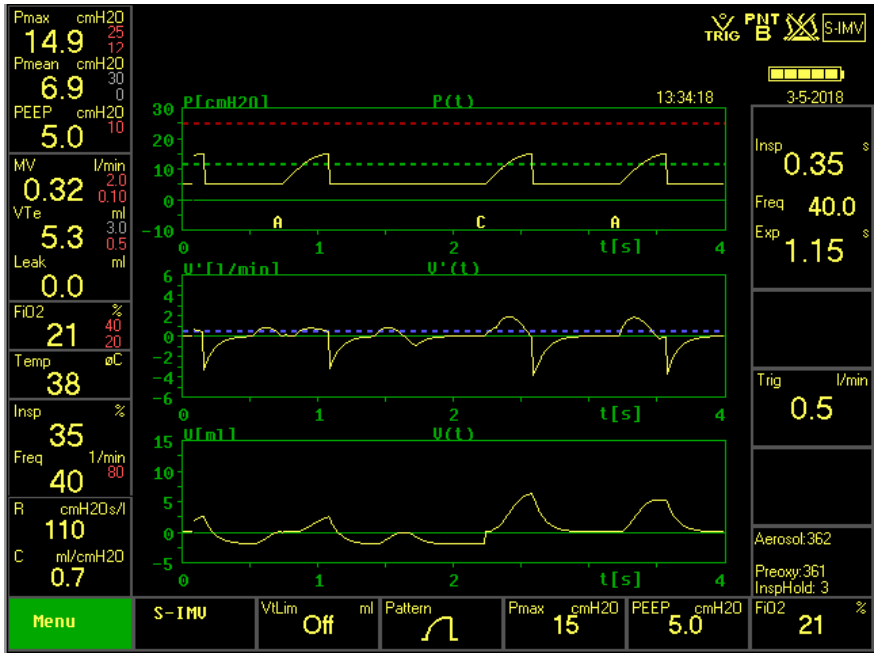


Fig. 42: Night view

4.2.4 "Measure" menu

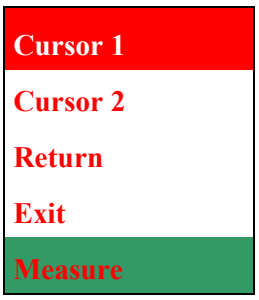


Fig. 43: Measure

The Measure function freezes the curves in the graphic display. Ventilation continues in the background.

"Cursor 1" and "Cursor 2" can be used to select two points on the curve. The absolute values and the differences between the points are displayed on the right-hand side of the screen.

Select "Return" to close the menu.

Cursor 1 Press the function to show a red crosshair on the graphic display, which can be navigated on both curves using the »IGR«.

Cursor 2 Press the function to show a green crosshair in the graphic display, which can be navigated on both curves using the »IGR«.

Reference x,y	x and y value of the red cursor 1
Meas x,y	x and y value of the green cursor 2
Δx, Δy	$\Delta x = x_{MEAS} - x_{REF}$
	$\Delta y = y_{MEAS} - y_{REF}$
Δy/Δx	$\frac{\Delta y}{\Delta x}$

NOTE

The Measure menu can only be selected with ongoing ventilation. If there is no ongoing ventilation, the menu is grayed out and cannot be selected.

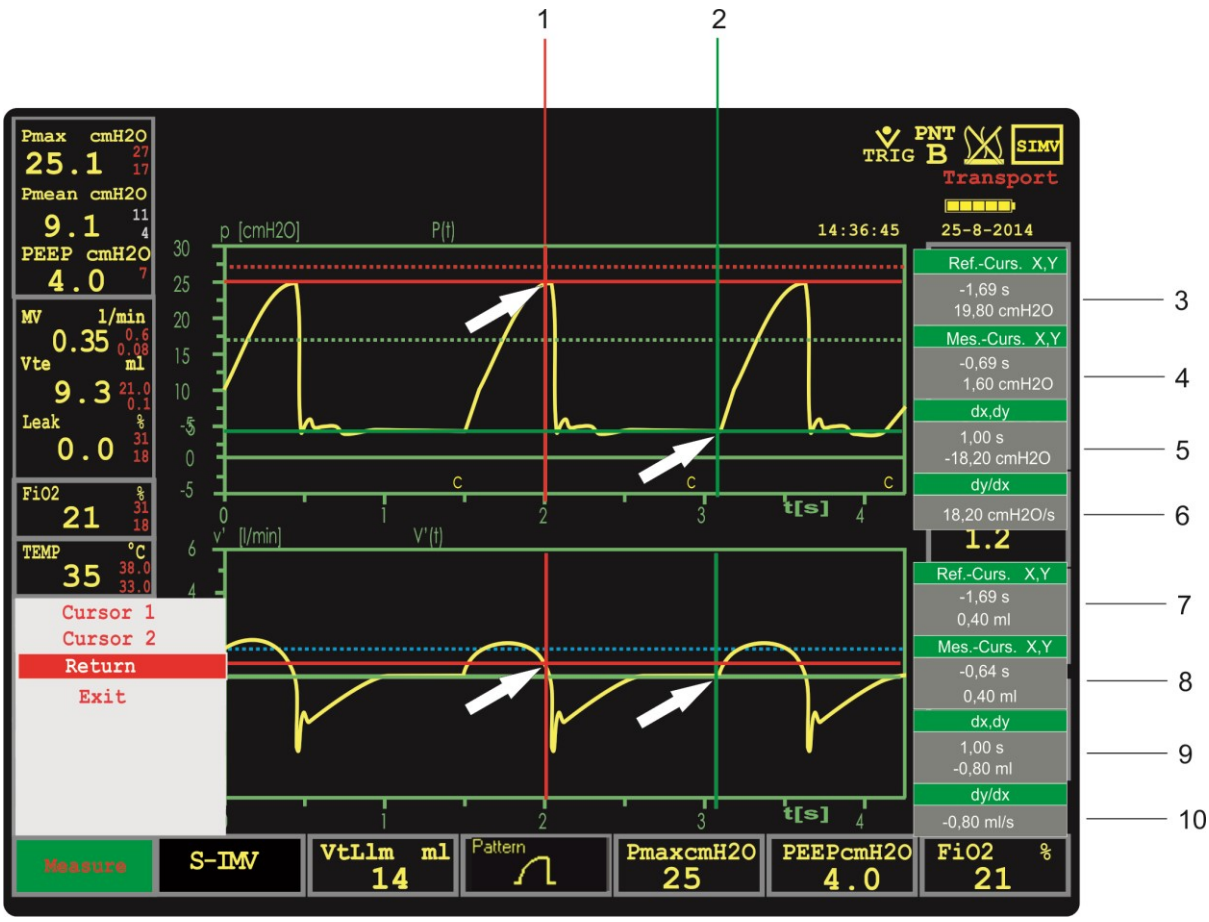


Fig. 44: Measure menu (arrows show the measured points)

1 Cursor 1

2 Cursor 2

3 Measured values of cursor 1 from curve 1

4 Measured values of cursor 2 from curve 1

5 Difference between cursor 2 and cursor 1 from curve 1

6 Quotient of differences between cursor 2 and cursor 1 from curve 1

7 Measured values of cursor 1 from curve 2

8 Measured values of cursor 2 from curve 2

9 Difference between cursor 2 and cursor 1 from curve 2

10 Quotient of differences between cursor 2 and cursor 1 from curve 2

NOTE

The Measure menu should only be used with the 2-curve view to eliminate screen clutter.

4.2.5 "Heating" menu

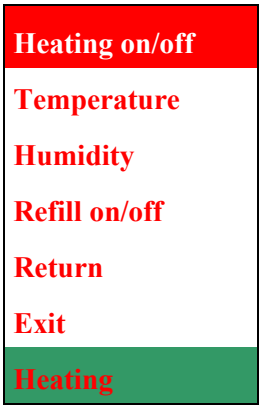


Fig. 45: Heating menu

Heating on/off This function switches the humidifier system's heater on or off.

Temperature Temperature setting for the respiratory gas at the Y piece. A temperature of between 30 and 40°C can be selected.

NOTE

The heater switches off automatically if the level of the water bath in the humidifier bottle is too low. In this case, an MP alarm "Waterlevel low" is generated and the message "Heating off" is displayed.

NOTE

The water bath in the humidifier bottle needs a certain amount of time to heat up after the heater has been switched on. During this time, the acoustic alarms for the "Temperature low" and "Temp. wb" alarms are suppressed for 30 minutes.

Humidity Use this sub-menu to increase or reduce the humidity of the respiratory gas using the slider if necessary.

NOTE

To reach a saturation of 90–95% relative humidity, the default setting should generally be adequate in all ventilation modes. Depending on the ventilation situation, an adjustment of the humidity may, however, be necessary.

If this function is activated, a humidity slider is displayed. It can be adjusted in ten steps between –4 and +6 using the »IGR« knob. The vertical bar marks the default setting for the current ventilation mode.

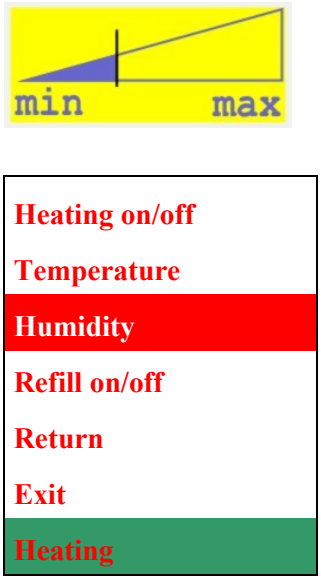


Fig. 46: Setting the humidity using the slider

The selected humidity level is shown in the box below the temperature display. The number of plus (+) and minus (–) symbols indicates the set level of humidity in the positive and negative direction. If the humidity level differs from the standard setting, the temperature and humidity display is shown with a yellow background.

Fig. 47: Humidity level 0

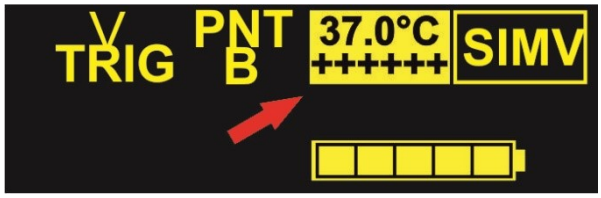


Fig. 48: Humidity level +6 (maximum humidity)

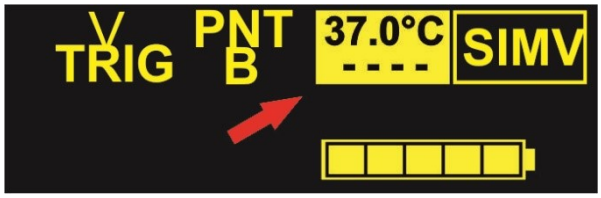


Fig. 49: Humidity level –4 (lowest humidity)

NOTE

A humidity level of 0 is the default preset for conventional ventilation modes. If the humidity level is changed during conventional ventilation, this value is saved for the ongoing ventilation and will be retained if switching to another conventional mode of ventilation.

Ventilation modes with high flow levels (HFO, NCPAP, and SNIPPV) require a higher humidity level to ensure optimum humidification. In these ventilation modes, the default humidity level has therefore been preset to +2.

The default humidity levels can be individually adjusted. To do so, contact the authorized FRITZ STEPHAN GMBH customer service team.

NOTE

If the humidity is changed during HFO ventilation, this value is saved for the ongoing ventilation and will be retained if switching to another HFO ventilation mode.

NOTE

If the humidity is changed during non-invasive ventilation, this value is saved for the ongoing ventilation.

NOTE

Changes to the humidity are saved in all ventilation modes for the ongoing ventilation only. Re-starting the ventilator will automatically restore the factory defaults.

Refill on/off (optional)

The automatic refill system is optional. It retains an almost constant fill level in the humidifier bottle to allow for optional breathing gas conditioning.

This function switches the Sophie automatic refill system on or off (see chapter 11.1.2).

4.2.6 "Extra-func." menu

This menu can be used to adjust the parameters for the »Aerosol«, »Preoxy«, and »Insp. hold« function buttons (see chapter 3.1.2).

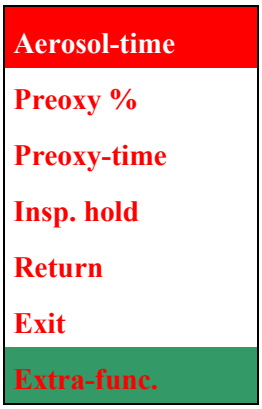


Fig. 50: Extra-func. menu

Aerosol-time Setting for the aerosol nebulization time (30–420 s). Aerosol nebulization is triggered by pressing the »Aerosol« button.

Preoxy % Setting for the inspiratory oxygen concentration administered when pressing the »Preoxy« button. An inspiratory oxygen concentration between 21 and 100% can be selected.

NOTE

The setting of the inspiratory oxygen concentration during preoxygenation can be configured at the factory upon request. Three setting modes are available:

- Set absolute value in % (default setting). The set oxygen concentration is delivered during preoxygenation. Selecting "Preoxy %" from the menu will display "Preoxy" in the adjuster.
- Set as summand for current FiO_2 concentration. The set value is added to the FiO_2 value for preoxygenation. Selecting "Preoxy %" from the menu will display "Delta" in the adjuster.
- Set as factor of current FiO_2 concentration. The set factor is multiplied by the current FiO_2 value and delivered during preoxygenation. Selecting "Preoxy %" from the menu will display "FiO_2x" in the adjuster.

Preoxy-time Lets you set the duration of the preoxygenation (30–420 s) that is triggered when the »Preoxy« button is pressed. The menu can also be used to completely switch off preoxygenation.

Insp. hold Lets you set the maximum time for which inspiration is maintained at the end expiratory pressure level when pressing the »Insp. hold« button.

The selectable time interval is 1–7 s. When using the »Tinsp« option, the inspiration time setting is automatically applied.

Inspiration ends immediately when the »Insp. hold« button is pressed again.

The settings made can be viewed in the special functions area of the monitor (see chapters 3.2 and 4.2.6).

4.2.7 "Options" menu

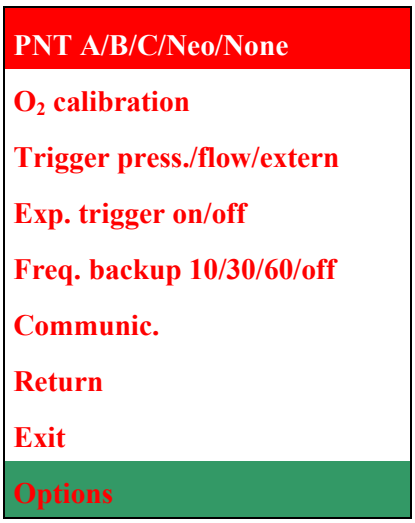


Fig. 51: Options menu

4.2.7.1 PNT A/B/C/Neo/None

The PNT type can be changed in this sub-menu. The following options are possible:

PNT A Selection of PNT type A (flow up to 10 l/min / deadspace: 0.5 ml)

PNT B Selection of PNT type B (flow up to 15 l/min / deadspace: 0.6 ml)

PNT C Selection of PNT type C (flow up to 25 l/min / deadspace: 0.9 ml)

PNT Neo Selection of PNT type Neo (flow up to 25 l/min / deadspace: 1.3 ml)

None No PNT is selected.

CAUTION

Always check if the PNT which has been set in the menu matches the PNT type which is actually connected. Setting the PNT type incorrectly leads to inaccurate measurements.

4.2.7.2 "O2 calibration"

When "O_2 calibration" is selected, O_2 calibration starts automatically. "CAL" flashes conspicuously in the FiO_2 measured value display on the left side of the monitor (see chapter 0).

Fig. 52: FiO_2 display

NOTE

The "O_2 calibration" function cannot be selected again while a calibration is in progress! It is therefore grayed out in the menu during calibration.

If the O_2 sensor is defective or not connected, the "O_2 sensor fail" alarm appears in the alarm display. If this situation arises, check the O_2 sensor, replace it if necessary, and repeat the calibration.

Fig. 53: "O_2 sensor fail" alarm

4.2.7.3 "Trigger press./flow/extern"

Use this sub-menu to select the type of trigger.

Pressure Selects the pressure-controlled trigger. It acts as differential pressure trigger (relative to PEEP).

Flow Selects the flow-controlled trigger. Activated when the inspiratory flow exceeds the trigger threshold set.

NOTE

The flow trigger can only be used for the "S-IMV" and "Ass./Co." ventilation modes. When switching to a non-invasive ventilation mode, the flow sensor is automatically disabled.

NOTE

The Sophie flow trigger is a relative trigger. The trigger threshold can automatically adapt to the measured leak.

Extern (optional) Selects the external trigger. Activated when the abdominal movements measured by the respiration sensor exceed the trigger threshold set.

WARNING

Incorrectly selected trigger thresholds or major leaks can cause auto-triggering! In this case, the trigger threshold has to be manually adjusted.

4.2.7.4 "Exp. trigger on/off"

This sub-menu can be used to activate or deactivate the expiratory trigger.

Expiratory trigger

The expiratory trigger synchronizes the start of the expiration phase with mechanical ventilation with the end of the spontaneous inspiration based on the patient's respiratory movements recorded by the respiration sensor.

If no expiration effort of the patient is detected, expiration is automatically triggered at the end of the specified inspiration time.

NOTE

The expiratory trigger deactivates the termination criterion »KV'%« in ventilation modes with inspiratory time termination. In this case, ITT is fully controlled by the expiratory trigger.
The default setting for the expiratory trigger in non-invasive ventilation modes is »On«.

With linear and sinusoidal pressure patterns, the set inflation pressure (Pmax) is typically not reached until the set inflation time has elapsed. If the inflation is terminated by the expiratory trigger before the set inflation time has elapsed, the applied inflation pressure drops as well. Consequently, the applied inflation pressure also depends on the duration of the spontaneous inspiration of the patient. Further information on the expiratory trigger can be found in chapter 9.2.

4.2.7.5 Freq. backup 10/30/60/Off

Use this sub-menu to set the backup ventilation mode for the ventilation modes NCPAP B and SNIPPV B. If set to "Off", the **SOPHIE** automatically uses standard backup ventilation, which immediately stops mandatory backup ventilation upon restoration of spontaneous breathing. If set to 10, 30 or 60 s, frequency-controlled backup ventilation is activated. In this case, mandatory backup ventilation is not stopped immediately upon restoration of spontaneous breathing, but is instead reduced incrementally. The set interval of 10, 30 or 60 s determines the duration of the individual backup stages. Detailed information on the two backup ventilation options can be found in chapters 5.4.8.1 and 9.7.1.

4.2.7.6 "Communication"

Use this sub-menu to select the transmission speed for the interface and the system language. It also shows the system data.

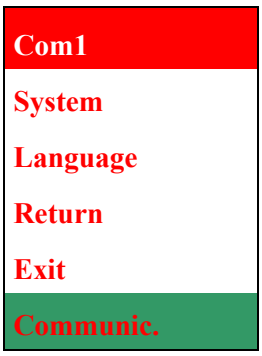


Fig. 54: Communication menu

"Com1" Configuration of the transmission speed for the **SOPHIE** serial RS232 interface. The sub-menu offers the following transmission speeds.

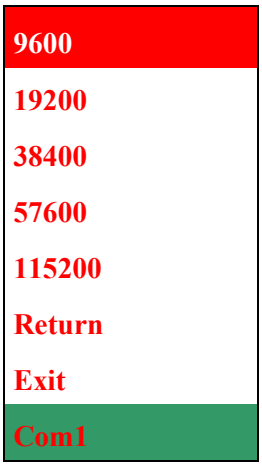


Fig. 55: Selecting the transmission speed

The currently selected transmission speed is highlighted in blue when you open the menu.

“System” Selecting this function opens a screen with the following data:

- Date and time
- Software and device version
- Operation and service time
- Serial number

“Language” Use this sub-menu to set the **SOPHIE** menu and system language. English is pre-installed on the ventilator. The second language can be optionally selected on request.

Fig. 56: Language sub-menu

5 “Ventilation” menu

5.1 Operating concept

Fig. 57: Ventilation menu opened

The entire “Ventilation” menu can be controlled using the central »IGR« push and turn knob:

- Turn the »IGR« to select the “Ventilation” menu. The field turns green.
- Click (press) the »IGR« to open the “Ventilation” menu.
- Turn the »IGR« clockwise or counterclockwise to scroll through the available menu options. The selected option is highlighted in blue.
- Click the »IGR« to carry out the corresponding function or open a sub-menu.
- After selecting the required ventilation mode, a pop-up menu appears with the necessary ventilation parameters.

NOTE

The pop-up menu control makes it far easier to adjust the ventilation parameters. The user only sees the parameters relevant to the chosen ventilation mode and can adapt these quickly and easily to the patient’s needs.

- Turn the »IGR« clockwise or counterclockwise to scroll through the ventilation parameters; the selected field turns green.
- Click to open the selected field (the field turns yellow), then turn the »IGR« to set the ventilation parameter.
- Click again to finish the entry; the field turns green again. Selecting the »Start« field and clicking to activate it now starts ventilation.

NOTE

Alternatively, the »Ventilation« menu and the corresponding ventilation parameters can also be opened or closed using the corresponding selection buttons. Detailed information on the »IGR« and the selection buttons can be found in chapter 3.1.

Direct setting mode

In addition to the “Push/turn/push” method, a direct setting mode can also be used for the parameters »PEEP«, »MAP«, and »HFO-AM«. This mode allows real-time value changes like when using a standard turning knob. Proceed as follows:

- Select the desired parameter using the button or »IGR«; the field turns green.
- Push and hold the »IGR« for approx. 2 seconds. The parameter field now begins to flash.
- Turn the »IGR« to continuously increase or decrease the value. The ventilator immediately applies the selected oscillation amplitude.
- Push and hold the »IGR« again to finish the direct setting mode.

The direct setting mode automatically exits after 30 s without any user interaction or when pushing another button.

5.1.1 Setting the ventilation mode after system start-up

After the **SOPHIE** has been switched on or rebooted and a successful system test has been carried out, the Ventilation menu opens automatically. Proceed as follows to configure the settings:

- Select the ventilation mode; the selected field is highlighted in blue.
- Confirm the selection by clicking the »IGR« or pressing the selection button.
- A sub-menu appears, listing all available ventilation options (e.g. ITT) for the selected ventilation mode. Select the desired option and confirm by clicking the »IGR« or pressing the selection button.

NOTE

If the ventilator is not ventilating, the »Break« field cannot be selected and is grayed out. The “Standby” function will appear in the menu as soon as ventilation begins.

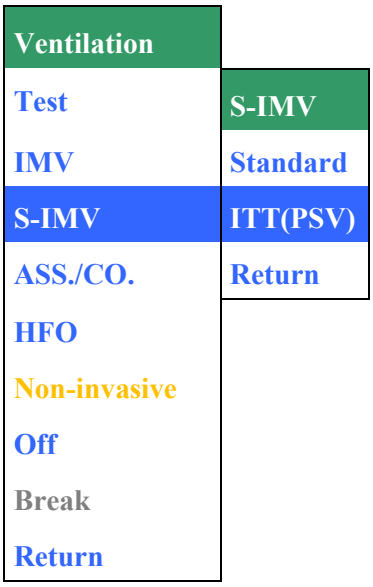


Fig. 58: Ventilation options S-IMV

- A pop-up menu appears, listing all parameters required for the selected ventilation mode.

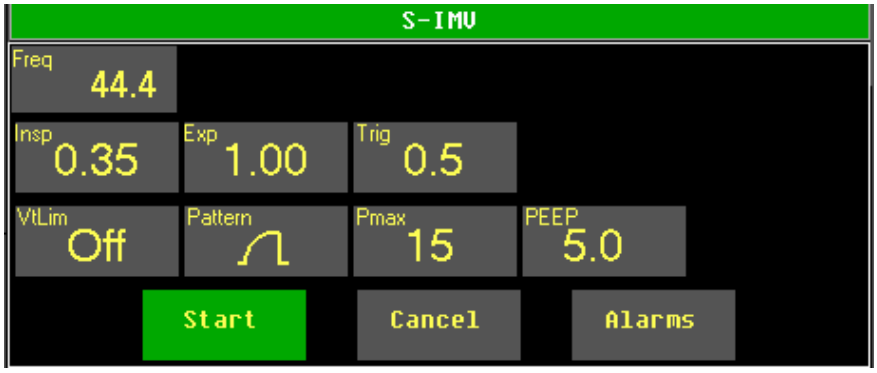


Fig. 59: Pop-up menu for S-IMV ventilation

NOTE

When opening the “Ventilation” menu, the second and third curves (Panels 2 and 3) are frozen.

NOTE

After ventilation has started, the values in the two upper rows of the pop-up menu are shown in the parameter bar on the right edge of the monitor. The values of the lower row are shown in the parameter bar at the bottom edge of the monitor (see chapter 3.2.4).

- To change a value, select it using the »IGR«. The selected field turns green.

Fig. 60: Pop-up menu for S-IMV – selecting the expiration time

- Click or press the selection button to open the corresponding field. It is highlighted in yellow.
- Turn the »IGR« to change the value. Click again or press the selection button to finish the entry. The other values can be changed the same way.

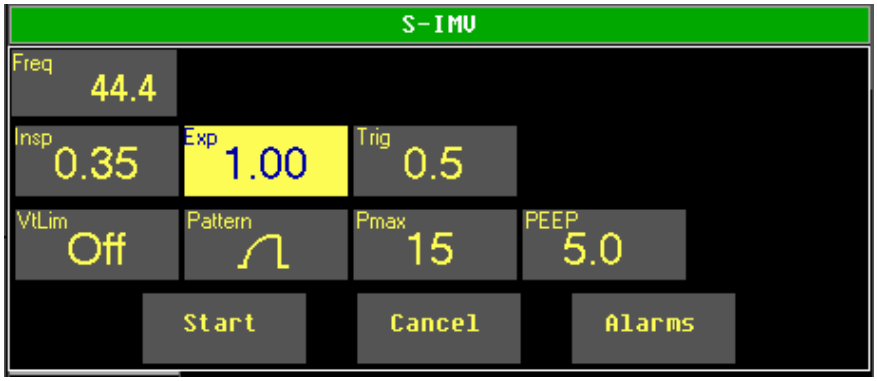


Fig. 61: Pop-up menu – setting the expiration time

- After correctly making all the necessary settings, you have the option of setting the default alarm limits for the selected ventilation mode using the “Alarms” field (see chapter 5.1.2).
- To start the ventilation mode, select the »Start« field and activate it by clicking the »IGR« or pressing the selection button. The pop-up menu closes and ventilation begins.

Fig. 62: Starting ventilation

5.1.2 Presetting alarm limits

The “Alarms” field lets you manually adjust the alarm limits before starting ventilation.

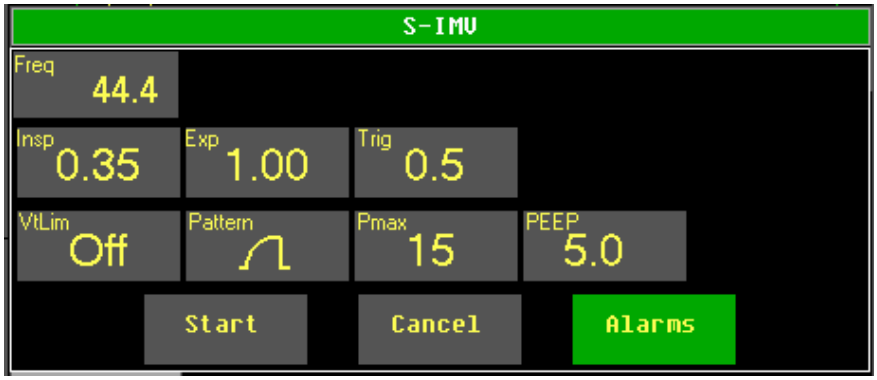


Fig. 63: Selecting the “Alarms” field

Selecting the “Alarms” field opens a pop-up menu, showing all the alarm limits for the relevant ventilation mode. These alarm limits can be adjusted using the »IGR« control knob (just like the ventilation parameters).

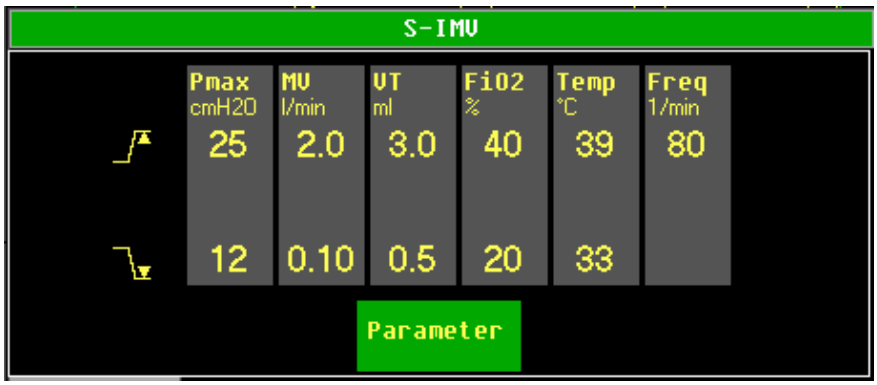


Fig. 64: Setting alarm limits

Selecting the »Parameter« field completes the entry of alarm limits and returns you to the screen for setting the ventilation parameters. Ventilation can be started as usual.

NOTE

Unlike the alarm limit settings made in the Main menu (see chapter 4.2.1.1) or using the »Alarm menu« button (see chapter 3.1.2), the settings made in the Ventilation menu do not take effect until the selected ventilation mode is started.

5.1.3 Changing the ventilation mode during operation

Proceed as follows to change the ventilation mode during ongoing ventilation:

- Open the Ventilation menu.
- Select the desired ventilation mode from the menu. Select available ventilation options (e.g. ITT/PSV) for the chosen ventilation mode from the sub-menu and confirm with the »IGR« or selection button.

NOTE

While setting a new ventilation mode and its parameters, the ongoing ventilation continues unchanged. The ventilator only switches to the new ventilation mode after the “Start” function is activated in the pop-up menu for the new ventilation mode.

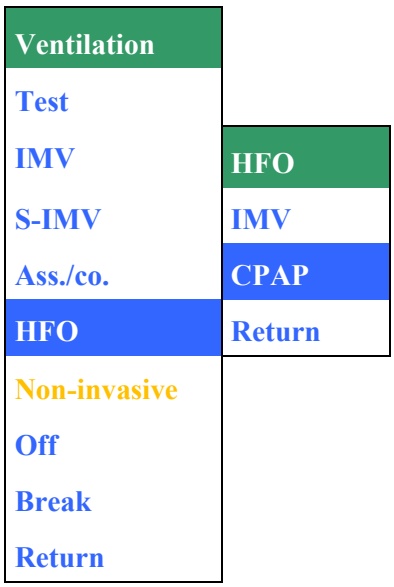


Fig. 65: Changing the ventilation mode during ongoing ventilation

NOTE

For safety reasons, the “Off” and “Test” functions can only be selected in “Standby” mode (see chapter 5.2).

- A pop-up menu appears, listing all the parameters needed for ventilation (see Fig. 59). To change a value, select it using the »IGR«. The selected field turns green.
- Click or press the selection button to open the corresponding field. It is now highlighted in yellow and the set value flashes.
- Turn the »IGR« to change the value. Click again or press the selection button to finish the entry. The other values can be changed the same way.
- Once all the settings have been correctly selected, ventilation can begin. Select the »Start« field and activate ventilation with the »IGR« or by pressing the selection button in the menu.
- The pop-up menu is closed and the ventilator switches to the new ventilation mode.

NOTE

After ventilation has started, the values in the upper row of the pop-up menu are shown in the parameter bar on the right edge of the monitor. The values of the lower row are shown in the parameter bar at the bottom edge of the monitor (see chapter 3.2.4).

NOTE

To change a ventilation parameter during ongoing ventilation, open the corresponding parameter field directly with the corresponding selection button or the »IGR«. Use the »IGR« to make the adjustment. Click with the »IGR« or press the corresponding »selection« button to save and exit the setting (see chapter 3.1).

5.2 Special functions in the Ventilation menu

5.2.1 “Standby” and “Off”

The “Standby” function ends the current ventilation process and puts the ventilator into standby mode or shuts it down completely. Proceed as follows:

- Open the Ventilation menu using the »IGR« or selection button.
- Select and activate the “Standby” function.
- The confirmation prompt “Exit ventilation?” appears.

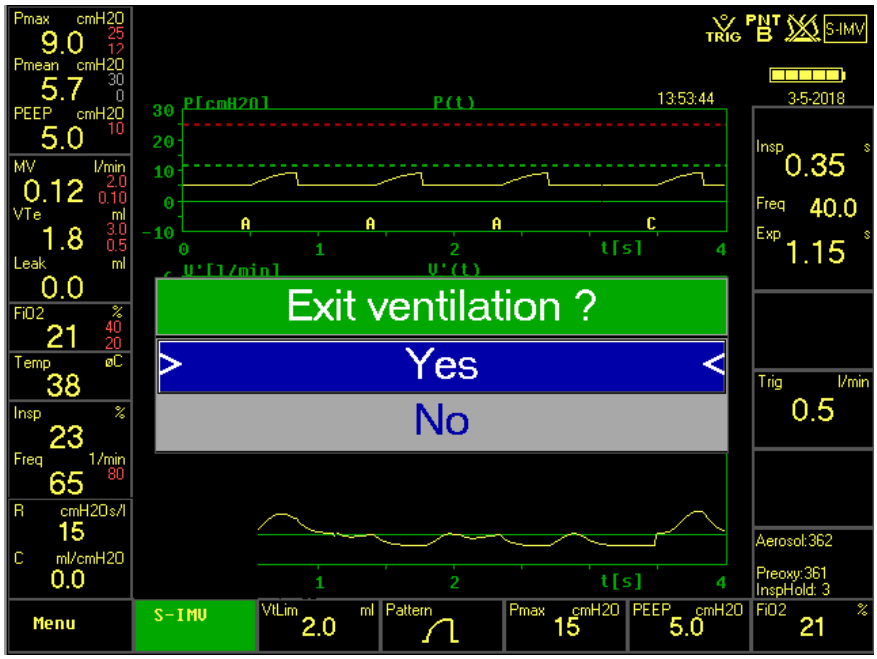


Fig. 66: Confirmation prompt “Exit ventilation?”

NOTE

The selected confirmation prompt field is highlighted in blue and indicated by two inside facing arrows.

- Answering “No” causes ventilation to continue unchanged. Selecting “Yes” causes the ventilator to switch to standby mode and displays the following message:

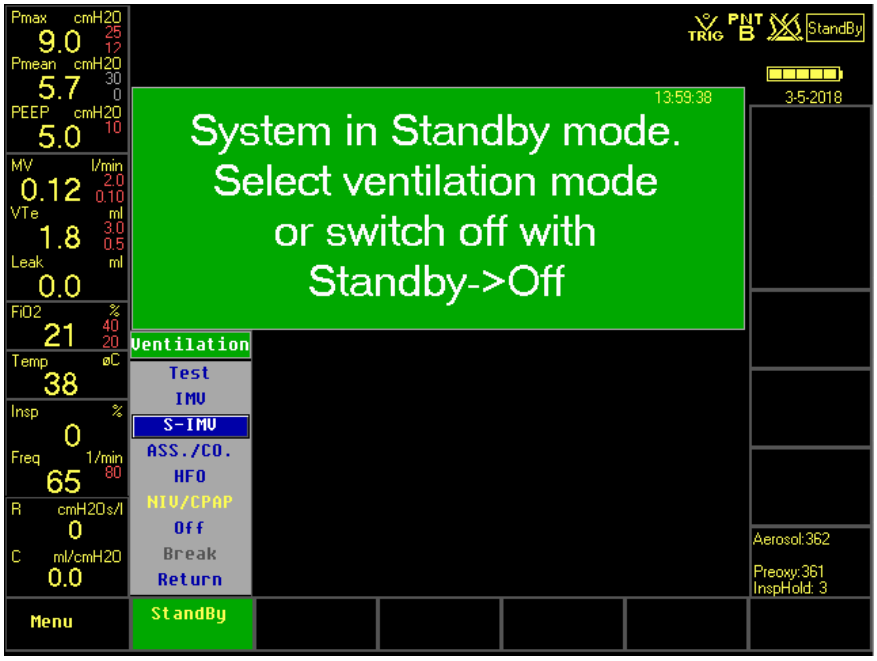


Fig. 67: Standby mode

- Selecting “Off” will completely shut down the device.
- Another confirmation prompt appears.

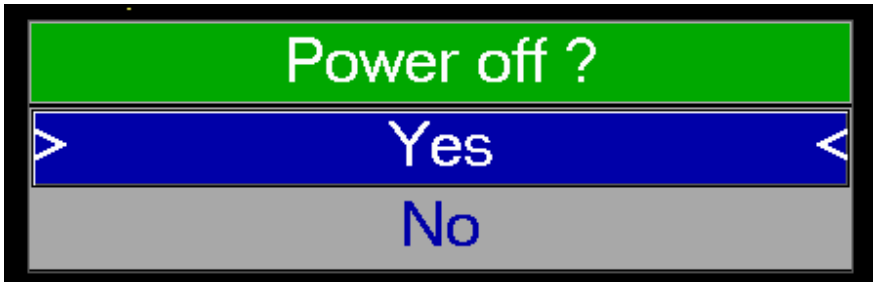


Fig. 68: Confirmation prompt before shutting down

- If the confirmation prompt is answered “Yes”, the device shuts down completely.
- The message “System shut down” appears and the ventilator saves the internal logbook.

Fig. 69: Shutting down the Sophie

After saving the logbook, the ventilator shuts down and can only be switched on again by pressing the »On« button (see chapter 3.1).

NOTE

If there is no ongoing ventilation, e.g. after completing the system test or in standby mode, the ventilator can be turned off directly by selecting the “Off” function in the Ventilation menu.

5.2.2 “Break”

The “Break” function stops the current ventilation. It is intended to briefly interrupt the operation of the device. The monitor remains on and the selected ventilation parameters are preserved as long as ventilation continues in the same mode after the break. The “Break” function can only be selected during ongoing ventilation. Proceed as follows to switch the device to the “Break“ mode:

- Open the Ventilation menu using the »IGR« or selection button.
- Select and activate the “Break” function.
- The confirmation prompt “Break ventilation?” appears.

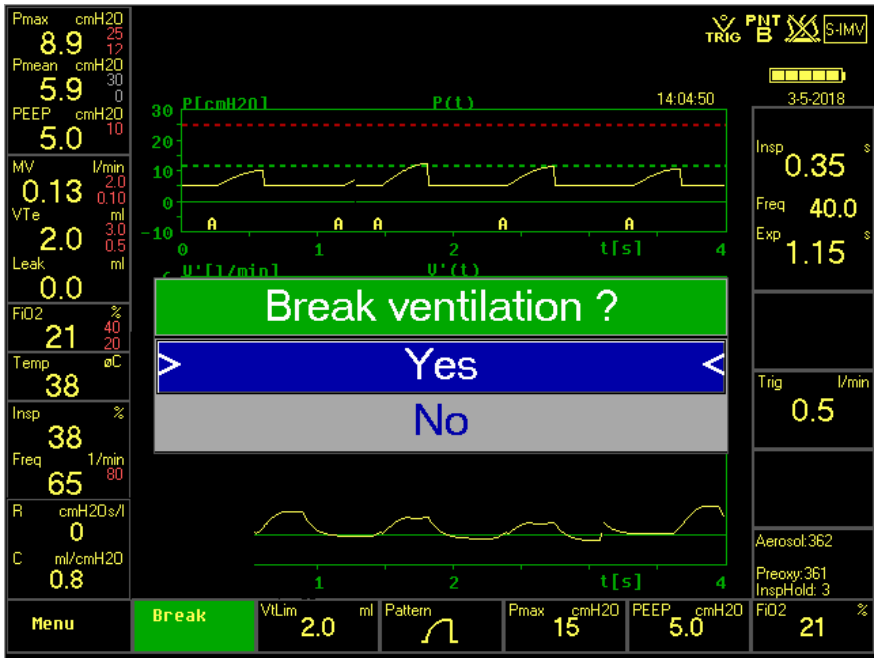


Fig. 70: Confirmation prompt “Break ventilation?”

- Select “Yes” and confirm.
- The ventilator now ends the ongoing ventilation and switches to “Break” mode.
- The screen remains switched on. “Break” appears in the field of the Ventilation menu.

Press the »IGR« or selection button to re-open the “Ventilation” menu. Click on the “Continue” function to continue the ventilation using the same mode as before the break; the ventilation parameters remain the same. To continue with a different ventilation mode, this can simply be selected in the “Ventilation” menu.

NOTE

“Break” can only be selected during ongoing ventilation.

5.2.3 “Test”

If the “Test” function is selected, the ventilator proceeds with an internal selftest. For safety reasons, this function is only available in “Standby” mode. A system test can be carried out after ventilation as follows:

- Open the Ventilation menu using the »IGR« or selection button.
- Select and click on “Standby”.
- The confirmation prompt “Exit ventilation?” appears.
- Select “Yes” and confirm.
- The Sophie now ends the ongoing ventilation and switches to “Standby” mode.
- Re-open the Ventilation menu and select “Test”.
- The ventilator carries out an internal selftest; the pressure and O_2 sensors are automatically calibrated.

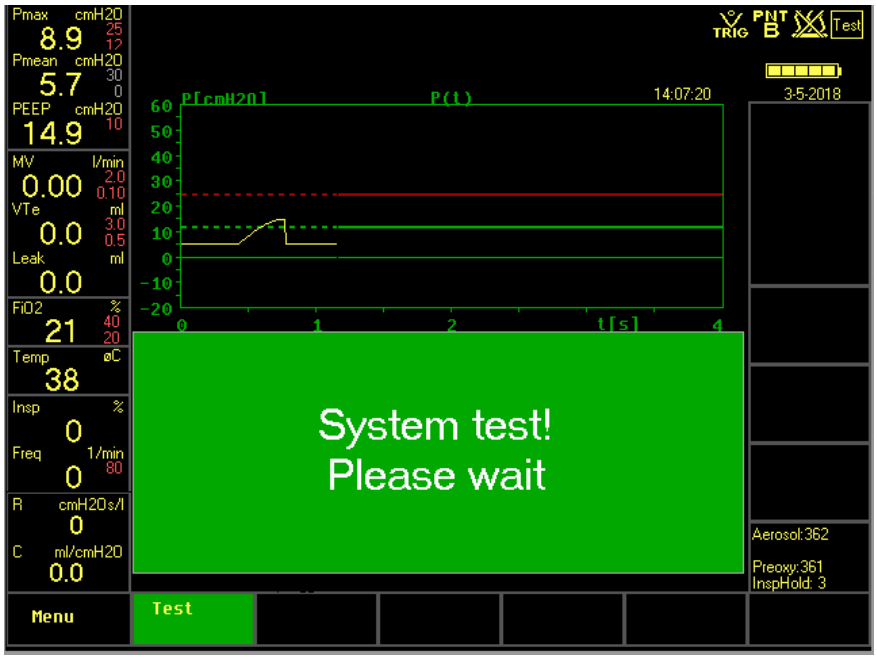


Fig. 71: System test

- This completes the system test. A message appears on the monitor. A new ventilation can now begin.

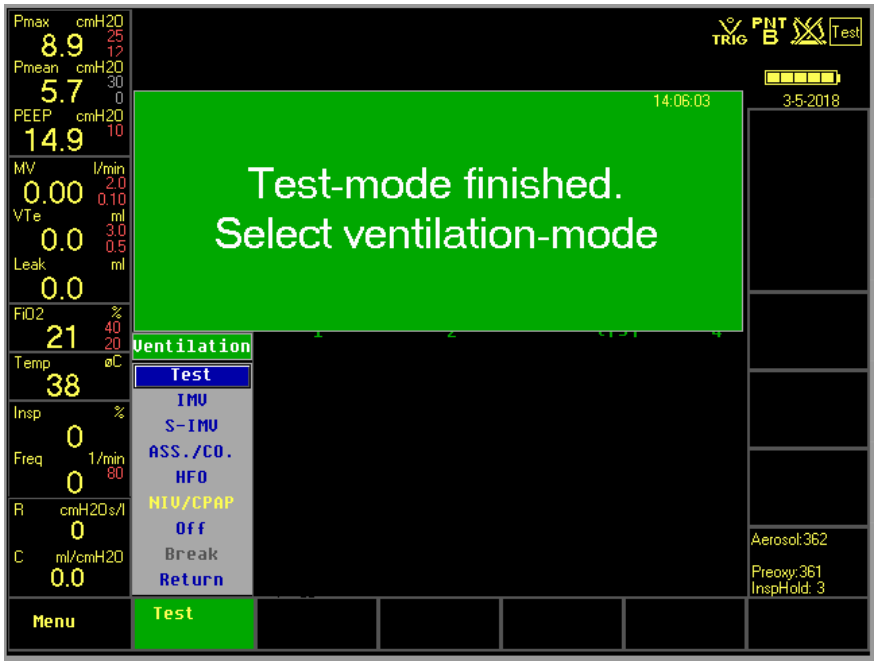


Fig. 72: Test mode completed successfully

If errors occur during the system test, the current alarm list opens automatically to display the errors.

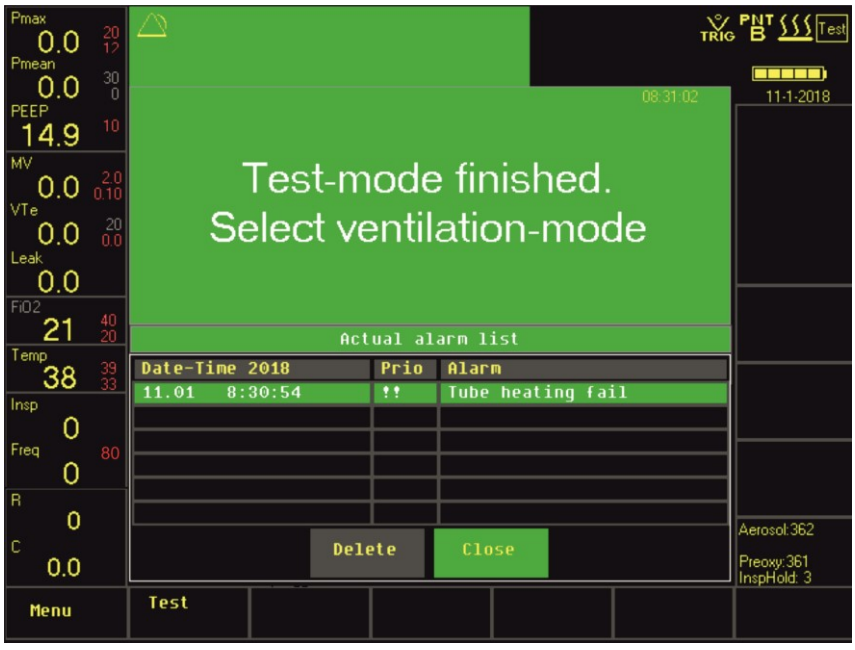


Fig. 73: Test-mode finished, alarms sounded are automatically displayed

CAUTION

If the system test is not passed, the ventilator must be shut down and re-started (possible causes can be found in Tab. 10).
If the device fails the test again, it must be decommissioned (see chapter 8.6) and the Fritz Stephan GmbH customer service team must be notified immediately.

Message	Color	Meaning	Remedy
Test mode finished **Select ventilation mode**	**GREEN**	• No errors	
Test mode finished **System not ok**	**RED**	• Safety-related errors have occurred during the selftest System not operational!	• Check connection lines, patient component and type system. • Contact FRITZ STEPHAN GMBH customer service
PC-MC version mismatch. **System not ok**	**RED**	• The installed software is not compatible System not operational!	• Check the software version and repeat installation if necessary • Contact FRITZ STEPHAN GMBH customer service
Configuration error **System limited ok!**	**YELLOW**	• Configuration file corrupted or not available • Product key does not match serial number System operational with default settings!	• Check the configuration file and repeat the installation process if necessary • Contact FRITZ STEPHAN GMBH customer service

Tab. 10: System test overview table

5.3 Adjustable ventilation parameters

Parameter	IMV	HFO IMV	SIMV	SIMV ITT	Ass./ Con	Ass./ Con ITT	SNIPPV	HFO CPAP	NCPAP
Tinsp	X	X	X	X	X	X	X	X	X
Texp (Freq)	X	X	X	X	X	X	X		X[1]
Trigger			X	X	X	X	X		X
Pmax	X	X	X	X	X	X	X	X	X
PEEP	X	X	X	X	X	X	X		X
PPSV%				X					
MAP								X	
VtLim	X		X		X				
VtTar				X		X			
Pattern	X		X	X	X	X	X		X[1]
KV%				X		X			
ApD							X		X
HF Freq		X						X	
Exp. Trigger			X	X	X	X	X[2]		X[2]
HF Am		X						X	
HF IE		X						X	
FLim		X						X	
MaxV‘							X		X
HFO-INSP		X							

[1] With the backup function switched on only. [2] With an external respiration sensor only (ext. trigger).

Tab. 11: Adjustable ventilation parameters

Name in menu	Meaning	Adjustable in the range of
Insp	Inspiration time	0.1–2 s
Exp*	Expiration time	0.1–60 s
Freq*	Frequency	1–300/min
Pmax	Inspiratory peak pressure	5–60 cmH_2O
PPSV%	Pressure support level for spontaneous breathing under SIMV – ITT(PSV)	0–100%
PEEP	Positive end expiratory pressure	0–30 cmH_2O
MAP	Mean airway pressure	0–30 cmH_2O
MaxV‘	Maximum gas flow (flow limitation)	6–20 l/min / Off
FiO_2	Inspiratory oxygen fraction	21–100%
Trig	Trigger threshold (sensitivity)	0.2–2.9 l/min 0.2–2.9 cmH_2O 0.2–2.9 Arb / Off
VtTar	Target volume under ITT(PSV)	2–150 ml / Off
VtLim	Tidal volume limitation	2–150 ml / Off
KV’	Factor of the insp. peak flow at which inspiration is ended	5–40%
ApD	Apnea duration – time after which backup ventilation occurs according to the set ventilation parameters once spontaneous breathing fails (apnea).	4–16 s / Off
HF freq	Oscillation frequency for HFO	5–15 Hz
HF-IE	Inspiration ratio for HFO	33–50%
HF-AM	Oscillation pressure amplitude for HFO	5–100%
HFO-INSP	Switches oscillation “on” or “off” during inspiration	On/Off
FLim	Flow limit line setting for HFO	0.2–10 l/min / Off
Pattern	Ventilation pressure pattern setting	Linear, Sinus Rectangle
* Depending on the customer’s wishes, the Sophie can be delivered with either a selectable expiration time or a selectable breathing frequency. The selection does not affect the inspiration time setting!		

Tab. 12: Setting the ventilation parameters

CAUTION

When using a closed suction procedure during pressure-controlled ventilation, the PEEP should be at least 5 cmH_2O to prevent excessive negative pressure during suction. When using a closed suction procedure, the trigger threshold should be temporarily disabled to prevent auto-triggering.

5.3.1 Special aspects of setting the VtLim/VtTar

Setting the VtLim or VtTar parameter activates the “Volume guarantee” function. This automatically reduces the inspiratory pressure if the measured expiratory tidal volume exceeds the set volume limit/volume target.

For safety reasons, the pressure cannot drop lower than the set PEEP + 4 cmH_2O.

NOTE

For VtLim and VtTar, the volume is limited by the pressure “Pmax”. If VtLim or VtTar is exceeded, the set inspiratory pressure Pmax can therefore no longer be reached.

CAUTION

When using a closed suction catheter with VtLim or VtTar, the effect on the volume measurement can cause inspiration to be stopped due to the volume limitation and pose a risk to the patient.

5.3.2 Setting the expiration time or frequency

Depending on the customer’s wishes, the Sophie can be delivered with either a selectable expiration time or a selectable breathing frequency. The selection does not affect the inspiration time setting!

Fig. 74: Version with selectable expiration time

Fig. 75: Version with selectable breathing frequency

5.4 Choosing the ventilation mode

The following section explains how to select the ventilation mode and shows the corresponding pop-up windows and their parameters. The innovative pop-up menu control is extremely convenient to use and makes it far easier to adjust the ventilation parameters. The user only sees the parameters relevant to the chosen ventilation mode and can adapt these quickly and easily to the patient’s needs.

NOTE

More information about the ventilation modes can be found in chapter 9. More details about the ventilation parameters can be found in chapter 5.3.

NOTE

High frequency oscillation (HFO) is an optional **SOPHIE** component. This option cannot be selected on versions without HFO; it is grayed out in the menu.

NOTE

The external trigger is an optional **SOPHIE** component. It allows the connection of an external respiration sensor for detecting spontaneous breathing efforts of the patient. This trigger mode cannot be selected on versions without external triggering and is grayed out in the menu. If the external trigger is available, selecting a non-invasive ventilation mode automatically activates the respiration sensor as trigger mode. The PNT setting is automatically set to “No PNT”. The external respiration sensor’s curve is shown in the graphic display as the second curve.

If the external trigger is not available, selecting a non-invasive ventilation mode automatically activates the pressure trigger as trigger mode.

WARNING

If the external respiration sensor is used, volume monitoring is automatically disabled.

In this case, the patient should be monitored using additional SpO_2 and transcutaneous CO_2 measurement.

5.4.1 IMV – intermittent mandatory ventilation

Fig. 76: Selecting IMV

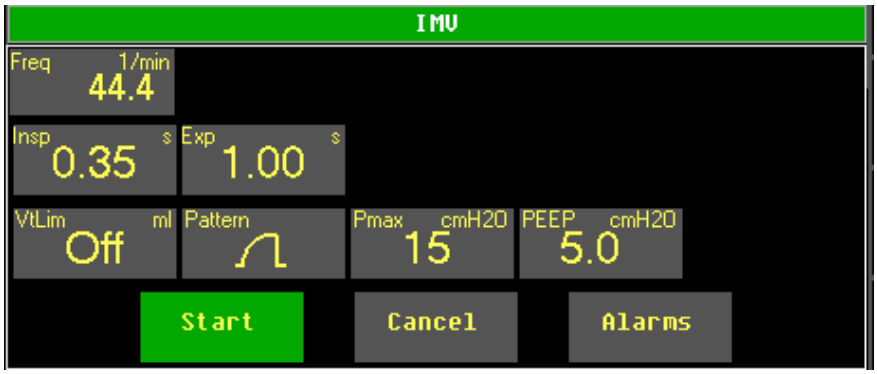


Fig. 77: Parameter settings for IMV

5.4.2 S-IMV – synchronized IMV ventilation

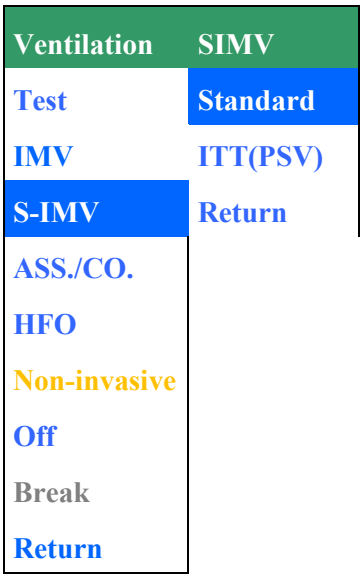


Fig. 78: Selecting S-IMV

Fig. 79: Parameter settings for S-IMV

5.4.3 S-IMV with inspiratory time termination (ITT)

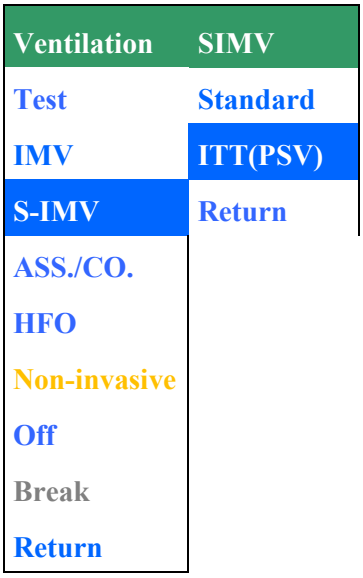


Fig. 80: Selecting S-IMV with ITT (PSV)

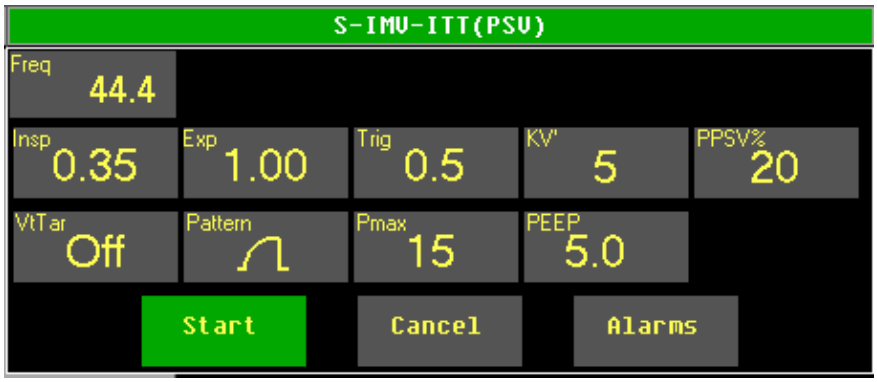


Fig. 81: Parameter settings for S-IMV-ITT (PSV)

5.4.4 Ass./Co. – assist-controlled ventilation

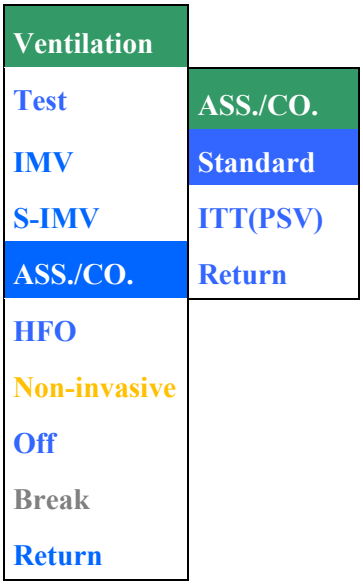


Fig. 82: Selecting ASS./CO.

Fig. 83: Parameter settings for ASS./CO

5.4.5 Ass./Co. with inspiratory time termination (ITT/PSV)

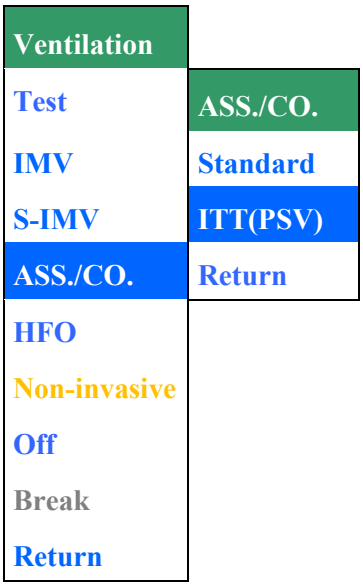


Fig. 84: Selecting Ass./Co. with ITT (PSV)

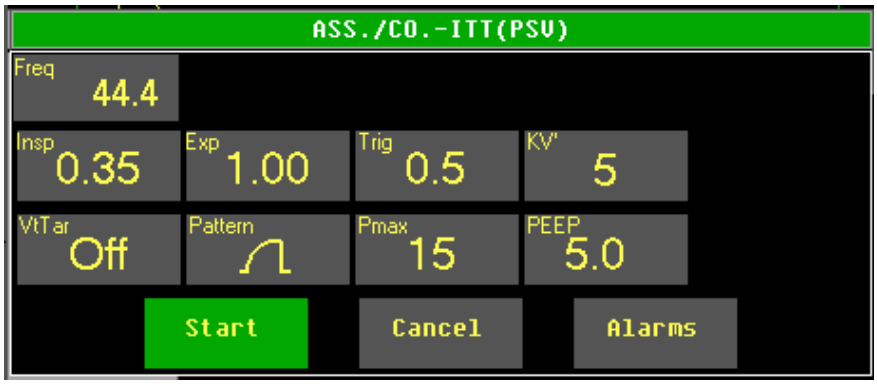


Fig. 85: Parameter settings for Ass./Co. with ITT (PSV)

5.4.6 High frequency oscillation with IMV (optional)

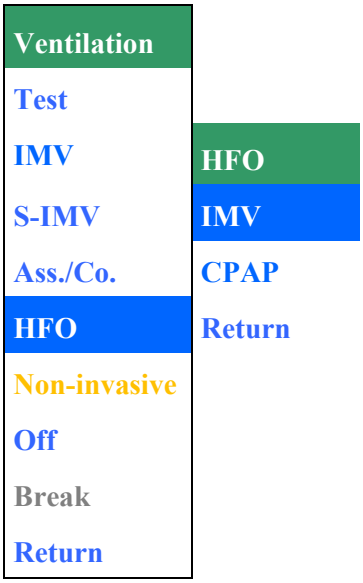


Fig. 86: Selecting high frequency oscillation (HFO) with IMV

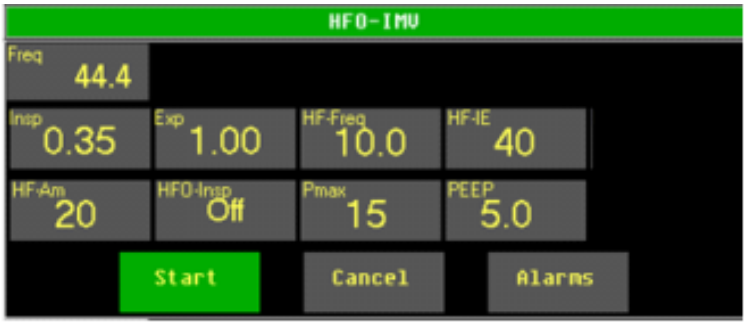


Fig. 87: Parameter settings for HFO with IMV

NOTE

When switching from a conventional ventilation mode to an HFO ventilation mode, the most recent Pmax and PEEP settings are saved. When switching from the HFO ventilation mode to a conventional ventilation mode, the previously saved values are suggested for ongoing ventilation.

Always check all ventilation settings prior to starting the new ventilation!

NOTE

The alarms limit for PEEP are adjusted automatically after changing the PEEP. If the alarm limit was previously set manually, this setting will be automatically overwritten!

WARNING

When using HFO ventilation in transport mode, gas consumption can be reduced by up to 20% by setting the amplitude to < 50% or the frequency to < 12 Hz.

5.4.7 High frequency oscillation with CPAP (optional)

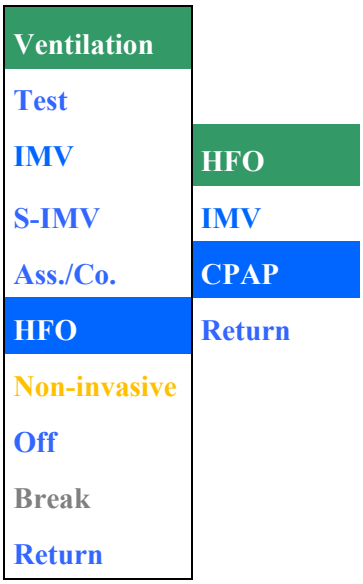


Fig. 88: Selecting HFO with CPAP

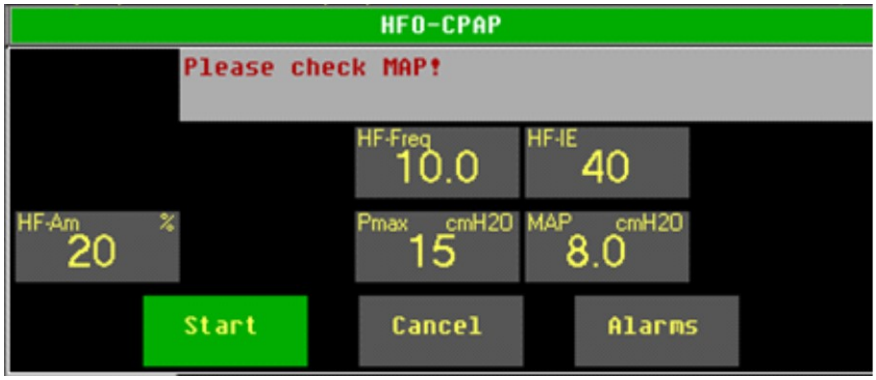


Fig. 89: Parameter settings for HFO CPAP

MAP – mean airway pressure

The PEEP start value is used as reference setting for MAP when selecting the ventilation mode “HFO-CPAP” from “Test”, “Break”, or “Standby” modes. When switching from another ventilation mode to “HFO+CPAP”, the measured mean airway pressure (Pmean) + 2 cmH_2O is used.

Gas transport coefficient DCO_2

For the “HFO-CPAP” ventilation mode, the system displays the gas transport coefficient DCO_2 instead of the resistance (R) and compliance (C). It uses ml^2/s for the unit.

NOTE

When switching from a conventional ventilation mode to an HFO ventilation mode, the most recent Pmax and PEEP settings are saved. When switching from the HFO ventilation mode to a conventional ventilation mode, the previously saved values are suggested for ongoing ventilation.

Always check all ventilation settings prior to starting the new ventilation!

NOTE

The alarm limits for the mean airway pressure are adjusted automatically after changing the MAP. If the alarm limit was previously set manually, this setting will be automatically overwritten!

NOTE

The two parameters »Insp.« and »Pmax« are shown in the parameter display, but hidden in the parameter settings because they are only relevant to the “HFO-CPAP” ventilation mode if the special function »Insp. hold« is used (see chapter 3.1.2). In this case, »Pmax« determines the inflation pressure and »Insp.« the duration of the manual inflation if the setting »Tinsp« is used instead of a specific time. Both values, »Insp.« and »Pmax«, can be selected in the parameter display via the selection button and changed using the »IGR«.

NOTE

When using HFO ventilation in transport mode, gas consumption can be reduced by up to 20% by setting the amplitude to < 50% or the frequency to < 12 Hz.

5.4.8 NCPAP – non-invasive (nasal) CPAP

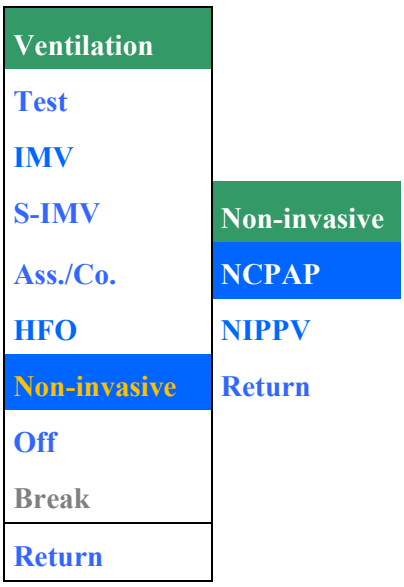


Fig. 90: Selecting NCPAP

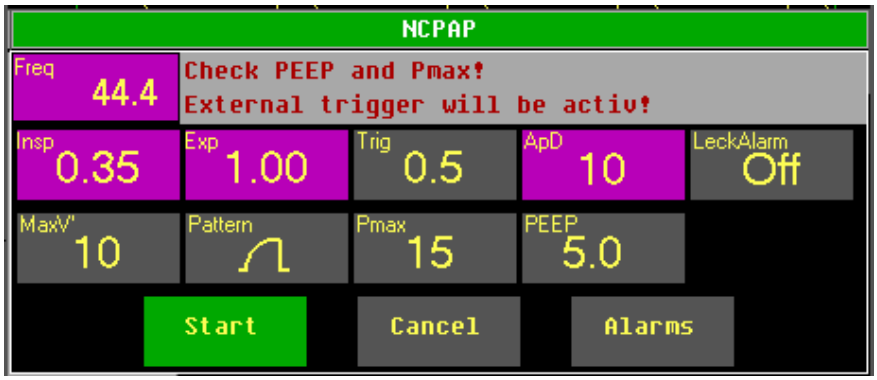


Fig. 91: Parameter settings for NCPAP (with frequency-controlled backup ventilation)

NOTE

Non-invasive ventilation must not be used with intubated patients.

WARNING

When switching from non-invasive to invasive ventilation modes, the flow measurement and flow trigger will be automatically activated! Always check all ventilation parameters prior to starting the new ventilation!

If the ventilation mode is changed to NCPAP, the ventilation pattern »SINUS« is preset automatically, but only used for the special function »Insp. Hold« and for optional backup ventilation. The pattern can still be modified if needed.

The CPAP pressure level is set by the parameter »PEEP«. The alarm limits for the mean airway pressure are adjusted automatically after changing the parameter »PEEP«. If the alarm limits were previously set manually, these settings will be overwritten automatically!

Leak alarm

When the function »Leak alarm« is switched on, the actual leak situation is determined. The determined leak is the basis for the generation of a combined leakage/disconnection alarm if the leak increases by more than 50%.

NOTE

Only use masks and prongs that fit properly! Poorly fitting masks and prongs can lead to major leaks.

If the leak situation changes, e.g. when switching out the prong, the alarm threshold for the leak alarm may need to be reset by switching the »Leak alarm« function off and back on.

Flow limitation (MaxV’)

By setting a flow limitation, the maximum flow available for the compensation of leaks can be limited.

The flow limitation can be set between 20 and 6 l/min or switched off completely.

WARNING

If flow limitation is activated, it may not be possible to reach the set ventilation pressures, depending on the amount of leakage. Therefore, set the flow limitation to a value at which the desired pressures are just reached.

Trigger threshold (Trig)

By setting a trigger threshold using the pressure trigger or an external respiration sensor, spontaneous breathing of the patient can be monitored when using NCPAP ventilation. The trigger threshold can be set between 0.2 and 2.9 or switched off completely.

WARNING

When the trigger threshold »Trigger« is switched off, the patient’s spontaneous breathing activity is not monitored. Apnea monitoring must be ensured by independent monitoring devices.

WARNING

If non-invasive ventilation is used, the patient should be monitored using additional SpO_2 and transcutaneous CO_2 measurement.

5.4.8.1 NCPAP-B

Advanced apnea monitoring is available when using the ventilation mode NCPAP B. It starts mechanical backup ventilation “BU” in the absence of spontaneous breathing. To activate apnea monitoring, an apnea duration in the range of 4 to 16 s must be set for the »ApD« parameter.
The suffix “B” for backup ventilation is shown in the status display for the ventilation mode. At the same time, the backup ventilation mode is indicated by a corresponding backup symbol (BU for standard backup, FBU 10/30/60 s for frequency-controlled backup).

Fig. 92: NCPAP with activated standard backup ventilation

In addition, the parameters »ApD«, »Insp«, »Exp«, and »Freq« are colored orange for standard backup or purple for frequency-controlled backup for better clarity.

If the apnea duration interval is switched off, backup ventilation is deactivated and the parameters »Exp« (»Freq«) and »Pattern« are automatically hidden.

The parameters «Insp« and «Pmax« are only relevant if the special function «Insp. hold« is used.

Without backup ventilation, the »Apnoe« alarm is triggered after 15 s without spontaneous breathing activity by the patient.

Backup modes

A differentiation is made between the following backup options:

- Standard backup (BU)
- Frequency-controlled backup (FBU)

If no spontaneous breath is detected, mandatory backup ventilation starts automatically in both modes with the parameter settings for »Pmax«, »Insp«, »Exp« (»Freq«), and »Pattern«. The apnea counter increases.

Detailed information on the two backup ventilation options can be found in chapters 9.7.1 and 9.8.1.

The backup mode is selected in the »Options« menu (see chapter 4.2.7.5).

5.4.9 NIPPV – non-invasive positive pressure ventilation

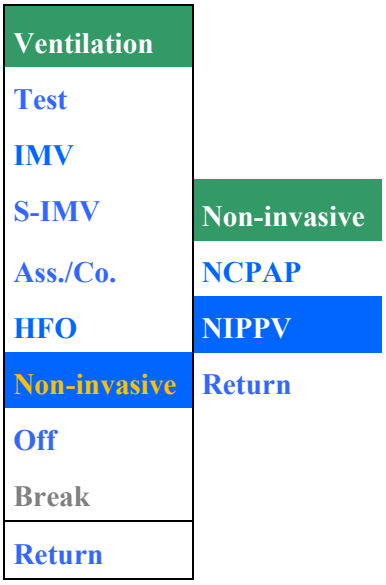


Fig. 93: Selecting NIPPV

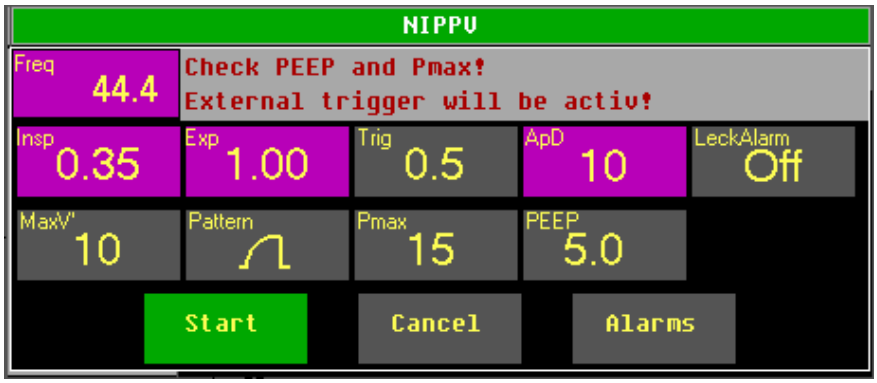


Fig. 94: Parameter settings for NIPPV (with frequency-controlled backup ventilation)

NOTE

Non-invasive ventilation must not be used with intubated patients.

WARNING

When switching from non-invasive to invasive ventilation modes, the flow measurement and flow trigger will be automatically activated! Always check all ventilation parameters prior to starting the new ventilation!

If the ventilation mode is changed to NIPPV, the ventilation pattern »SINUS« is preset automatically. It can still be changed if needed.

The PEEP level is set by the corresponding parameter. The PEEP alarm limits are adjusted automatically after changing the parameter. If the alarm limits were previously set manually, these settings will be overwritten automatically. The level of pressure support is set by the parameter »Pmax«.

Leak alarm

When the function »Leak alarm« is switched on, the actual leak situation is determined. The determined leak is the basis for the generation of a combined leakage/disconnection alarm if the leak increases by more than 50%.

NOTE

Only use masks and prongs that fit properly! Poorly fitting masks and prongs can lead to major leaks. If the leak situation changes, e.g. when switching out the prong, the alarm threshold for the leak alarm may need to be reset by switching the »Leak alarm« function off and back on.

Flow limitation (MaxV’)

By setting a flow limitation, the maximum flow available for the compensation of leaks can be limited. The flow limitation can be set between 20 and 6 l/min or switched off completely.

WARNING

If flow limitation is activated, it may not be possible to reach the set ventilation pressures, depending on the amount of leakage.

Therefore, set the flow limitation to a value at which the desired pressures are just reached.

5.4.9.1 SNIPPV

By setting a trigger level for the pressure trigger or external respiration sensor it is possible to synchronize the spontaneous breathing of the patient with the mechanical pressure support in NIPPV ventilation.
To activate the synchronization, the parameter »Trig« must be used to set the trigger threshold between 0.2 and 2.9. This ventilation mode now corresponds to an SNIPPV ventilation. This is also indicated by showing the ventilation mode in the status display.

Fig. 95: SNIPPV ventilation

5.4.9.2 SNIPPV-B

With SNIPPV backup, **SOPHIE** enables the patient to achieve better control of the ventilation frequency. This function can be activated by switching on apnea monitoring. Therefore, the parameter »ApD« must be set between 4 and 16 s.

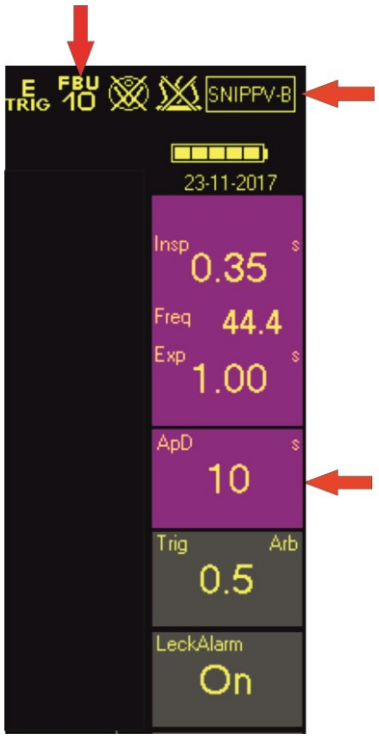


Fig. 96: SNIPPV with frequency-controlled backup ventilation

The expiration time is now deactivated as long as the apnea monitoring detects sufficient spontaneous breathing. The patient is able to independently control the ventilation frequency. If the optional expiratory trigger is activated, the inspiration time is also deactivated.

The suffix “B” for backup ventilation is shown in the status display for the ventilation mode. At the same time, the backup ventilation mode is indicated by a corresponding backup symbol (BU for standard backup, FBU 10/30/60 s for frequency-controlled backup). In addition, the parameters »ApD«, »Insp«, »Exp«, and »Freq« are automatically colored orange for standard backup or purple for frequency-controlled backup.

Backup modes

A differentiation is made between the following backup options:

- Standard backup (BU)
- Frequency-controlled backup (FBU)

If no spontaneous breath is detected, mandatory backup ventilation starts automatically in both modes with the parameter settings for »Pmax«, »Insp«, »Exp« (»Freq«), and »Pattern«. The apnea counter increases.

Detailed information on the two backup ventilation options can be found in chapter 9.8.1.

The backup mode is selected in the »Options« menu (see chapter 4.2.7.5).

WARNING

If non-invasive ventilation is used, the patient should be monitored using additional SpO_2 and transcutaneous CO_2 measurement.

5.4.10 Invasive CPAP (optional)

NOTE

An optional invasive CPAP mode can be pre-configured on the device at the request of the customer. This results in a change to the Ventilation menu (see Fig. 97).

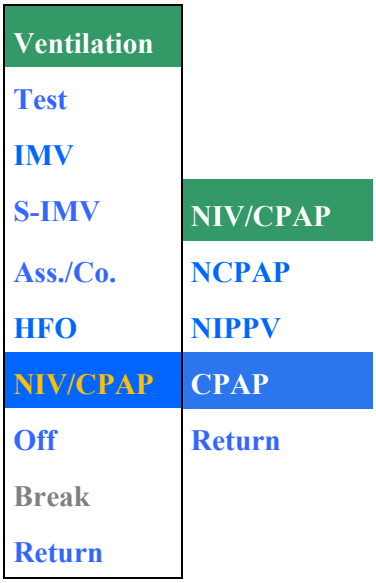
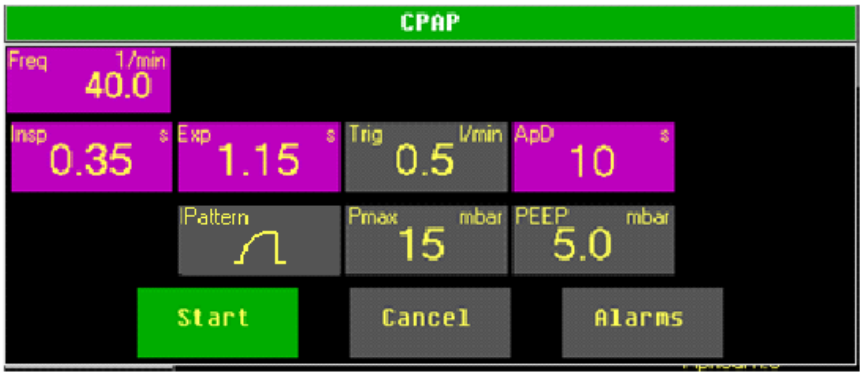


Fig. 97: Selecting CPAP

Fig. 98: Parameter settings for CPAP (with frequency-controlled backup ventilation)



If the ventilation mode is changed to CPAP, the ventilation pattern »SINUS« is preset automatically, but only used for the special function »Insp. Hold« and for optional backup ventilation. The pattern can still be modified if needed.

The CPAP pressure level is set by the parameter »PEEP«. The alarm limits for the mean airway pressure are adjusted automatically after changing the parameter »PEEP«. If the alarm limits were previously set manually, these settings will be overwritten automatically!

Trigger threshold (Trig)

By setting a trigger threshold using the pressure trigger or an external respiration sensor, spontaneous breathing of the patient can be monitored when using CPAP ventilation. The trigger threshold can be set between 0.2 and 2.9 or switched off completely.

WARNING

When the trigger threshold »Trigger« is switched off, the patient’s spontaneous breathing activity is not monitored. Apnea monitoring must be ensured by independent monitoring devices.

5.4.10.1 CPAP-B

Advanced apnea monitoring is available when using the ventilation mode CPAP B. It starts mechanical backup ventilation “BU” in the absence of spontaneous breathing. To activate apnea monitoring, an apnea duration in the range of 4 to 16 s must be set for the »ApD« parameter.
The suffix “B” for backup ventilation is shown in the status display for the ventilation mode. At the same time, the backup ventilation mode is indicated by a corresponding backup symbol (BU for standard backup, FBU 10/30/60 s for frequency-controlled backup).

Fig. 99: CPAP with activated standard backup ventilation

In addition, the parameters »ApD«, »Insp«, »Exp«, and »Freq« are colored orange for standard backup or purple for frequency-controlled backup for better clarity.

If the apnea duration interval is switched off, backup ventilation is deactivated and the parameters »Exp« (»Freq«) and »Pattern« are automatically hidden.

The parameters «Insp« and «Pmax« are only relevant if the special function «Insp. hold« is used.

Without backup ventilation, the »Apnoe« alarm is triggered after 15 s without spontaneous breathing activity by the patient.

Backup modes

A differentiation is made between the following backup options:

- Standard backup (BU)
- Frequency-controlled backup (FBU)

If no spontaneous breath is detected, mandatory backup ventilation starts automatically in both modes with the parameter settings for »Pmax«, »Insp«, »Exp« (»Freq«), and »Pattern«. The apnea counter increases.

Detailed information on the two backup ventilation options can be found in chapters 9.7.1 and 9.8.1.

The backup mode is selected in the »Options« menu (see chapter 4.2.7.5).

6 Preparation for use

WARNING

Only use correctly prepared parts for operation (see chapter 13).

6.1 Setting up the device

The **SOPHIE** must be placed in the middle of the support on the mobile stand.

The front castors of the mobile stand are equipped with brakes to prevent any unintended movement of the **SOPHIE**.

Press the brake lever down with your foot to apply the brake and stop the castors from moving. Lift the brake lever with your foot to release the brake again.

CAUTION

Risk of tipping over: when moving the device trolley, ensure that the brakes are released. Reapply the brakes when the device is in position.

6.2 Connecting the gas and power supplies

6.2.1 Gas supply

DANGER

Risk of explosion: do not use flammable gases.

WARNING

Only use dry compressed air! Humidity in the gas line can lead to technical malfunctions of the device. If compressed air of the required quality is not present, a special membrane dryer (art. no. 1 60060214) available from FRITZ STEPHAN GMBH must be used.

Central gas supply (CGS)

1. Connect the O_2 tube to the O_2 connection on the back of the device and the CGS wall outlet.
2. Connect the AIR tube to the AIR connection on the back of the device and the CGS wall outlet.

6.2.2 Power supply

Mains power

The **SOPHIE** can be operated with mains voltages of 100–240 V AC.

1. Check whether the mains voltage corresponds to the voltage range stated on the nameplate.
2. Connect the power cable to the power socket on the back of the device. Connect the other end of the power cable to the wall socket.
3. Switch on the ON/OFF power switch on the back of the device. The power supply indicator on the front of the Sophie lights up (see chapter 3.1.1). The battery is now being charged and the **SOPHIE** can be switched on with the “ON” switch.

Optional 24 V on-board power supply

In the “Transport” version, the **SOPHIE** can be operated (optional) with an on-board power supply with a voltage range of 20–36 V DC.

1. Check whether the on-board power supply corresponds to the specified voltage range.
2. Connect the on-board power cable to the 24 V DC input on the back of the device. Connect the other side of the connecting cable with the vehicle's on-board socket.

   The external DC power source indicator on the front of the Sophie lights up (see chapter 3.1.1). The battery is now being charged and the **SOPHIE** can be switched on with the “ON” switch.

Battery operation

Alternately, the **SOPHIE** can be operated for transport without a mains power supply.

An alarm indicates that there is no mains power supply. This alarm can be temporarily deactivated in "Transport" mode.

WARNING

The “Transport” function should not be used in stationary operation with normal power and gas supply.

Temporary deactivation of the power supply alarm can lead to an undetected discharge and premature depletion of the internal battery.

CAUTION

Depending on the device design, the humidifier system’s heater automatically switches off immediately or if the remaining capacity is < 50% when operated in battery mode.

Up to generation 2.2.0 of the power supply, the Sophie cannot be operated when the battery is completely discharged. As of generation 2.2.0 of the power supply, the confirmation prompt “Low state of charge ok?” indicates that the battery is low. Answering “Yes” allows you to continue operating the device despite the lower battery. Answering “No” causes the device to power off.

You can check the power supply version in the Communic./System menu (see chapter 4.2.7.6).

The device's internal battery should always be fully charged. To this end, when not in use:

1. The device should be continually connected to mains power.
2. The mains switch on the back of the device should be in the »On« position. The battery indicator on the front of the Sophie lights up (see chapter 3.1.1).

If this is not possible, the battery must be fully charged at least every two weeks.

A safety circuit prevents the battery from being overcharged.

CAUTION

Failure to comply can cause total discharge of the battery so that it no longer functions. Failure to comply with this safety instruction is considered to be an operating error on the part of the user.

NOTE

FRITZ STEPHAN GMBH does not recommend operating the ventilator with a low battery (capacity < 20%), as the run time of the device will be very short.

If the maximum number of charge cycles has been reached, the battery must be replaced. This can only be done by the authorized FRITZ STEPHAN GMBH customer service team.

Equipotential bonding

If equipotential bonding is necessary, a ground wire for equipotential bonding has to be connected to the socket provided on the back of the device. Connect the other end to the point provided inside the ICU.

6.3 Preparing the patient component

6.3.1 Preparing the patient gas humidifier

1. Take the disposable humidifier fleece (100761131) from its packaging and place it over the tool used to insert the fleece. Do not cover the cut-out with fleece.
2. Push the fleece inserting tool with the humidifier fleece into the humidifier tube until the fleece is no longer visible in the cut-out of the outer tube.
3. Push in the locking ring and tighten it counterclockwise.

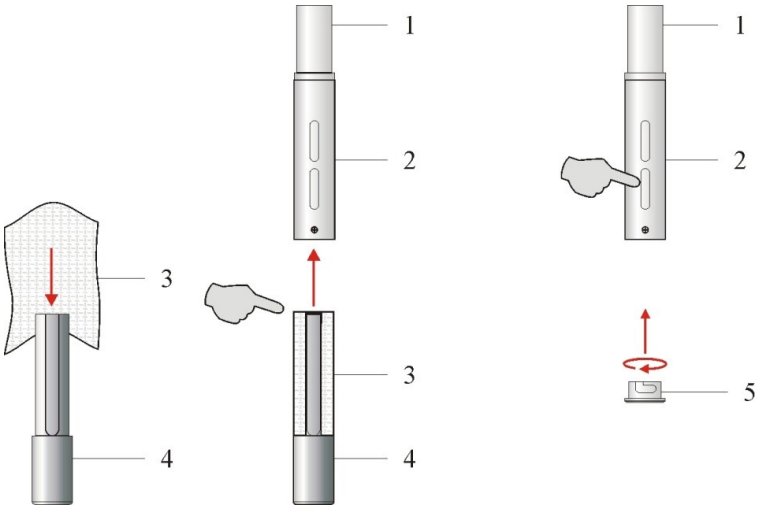


Fig. 100: Inserting the humidifier fleece

1	Inner tube	4	Fleece inserting tool
2	Outer tube	5	Locking ring
3	Humidifier fleece		

4. Push the humidifier tube above the heating tube of the patient component onto the holding bush.
5. Insert the silencer element in the silencer and lock with the cover.
6. Push the humidifier bottle over the humidifier tube and screw tight clockwise.
7. Connect the patient component to the right-side panel of the Sophie and use the locking screw to firmly attach it to the side panel.

6.3.2 Filling the humidifier bottle manually

WARNING

Never unscrew the humidifier bottle during operation. The humidifier bottle is pressurized. Make sure that the pressure does not force the plunger out of the syringe.

CAUTION

Check the water level of the humidifier bottle regularly during operation.

CAUTION

Never fill the humidifier bottle with “aqua dest.” distilled water up to the “MAX” marking before screwing on the bottle, as the water may rise above the maximum permitted level when the humidifier tube is immersed.

CAUTION

During operation, only fill the humidifier bottle with the automatic refill system or through the Luer lock connection using a syringe.

NOTE

“Temperature low” and “Temp. wb” alarms potentially triggered by refilling cold water can be suppressed by selecting the »Heating« menu and briefly switching off the heater for approx. 1 second and then switching it back on. The acoustic alarm is then suppressed for 30 minutes (see chapter 4.2.5).

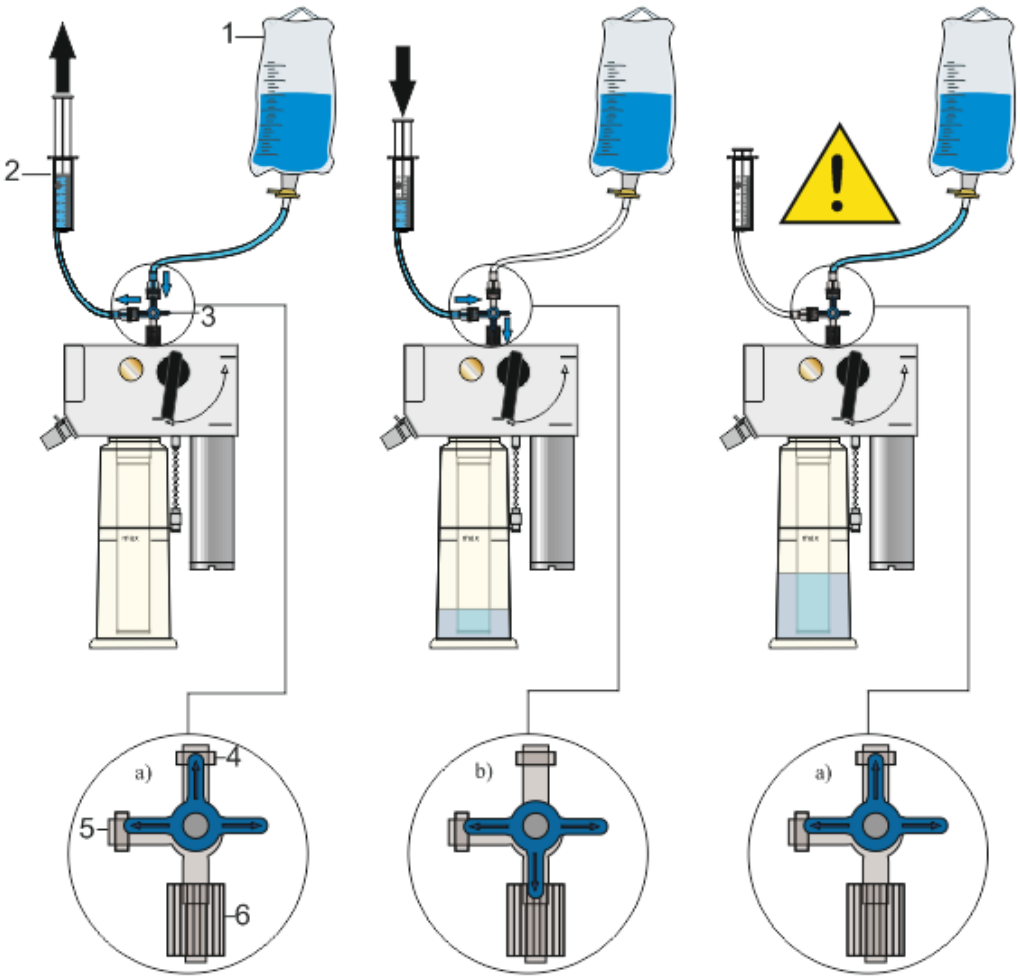


Fig. 101: Filling the humidifier bottle

1	Container with “aqua dest.” distilled water	4	Connection for container with distilled water
2	Syringe	5	Syringe connection
3	3-way valve	6	Luer lock patient component connection

1. Connect the 3-way valve to the Luer lock connection at the top of the patient component.
2. Connect the syringe to the 3-way valve using a tube.
3. Connect the container with the “aqua dest.” distilled water to the 3-way valve using a tube.
4. Move the 3-way valve into position (a) and fill the syringe with the appropriate amount of water from the container with distilled water “aqua dest”.

5. Move the 3-way valve into position (b) and fill the humidifier bottle of the patient component with distilled water up to “MAX” mark.

CAUTION

Always move the 3-way valve into position (a) when filling is complete! Otherwise, the system pressure of the humidifier may force the plunger out of the syringe, which may in turn cause a pressure drop in the system.

NOTE

Initial filling of the humidifier bottle can be done automatically for devices that have the refill system (optional) (see chapter 6.3.3).

6.3.3 Connecting the automatic refill system

CAUTION

Only fill the humidifier bottle with distilled demineralized water.

NOTE

The connection piece (art. no. 103860035) for the automatic refill system is only intended for single use.

CAUTION

Do not reuse disposable accessories! The necessary reconditioning may lead to the deterioration of mechanical and biological product properties, posing a significant risk to the patient. In addition, reusing such accessories dangerously increases the risk of contamination for the patient.

The optional automatic refill system is to be connected as shown below:

1. Insert the transfer spike (1) with the tubes for aqua dest. (2) and driving gas (3) into the bottle containing aqua dest. (4).
2. Attach the tube (3) to the driving gas outlet (5) on the patient component.

3. Connect aqua dest. tube (2) to aqua dest. inlet (6) on the patient component.
4. Push the slider on the tube pinch valve forward. The valve opens.
5. Insert the tube (2).
6. Push the tube pinch valve (7) down and let go of the slider.
7. Attach the aqua dest. bottle (4) to the holder (8).

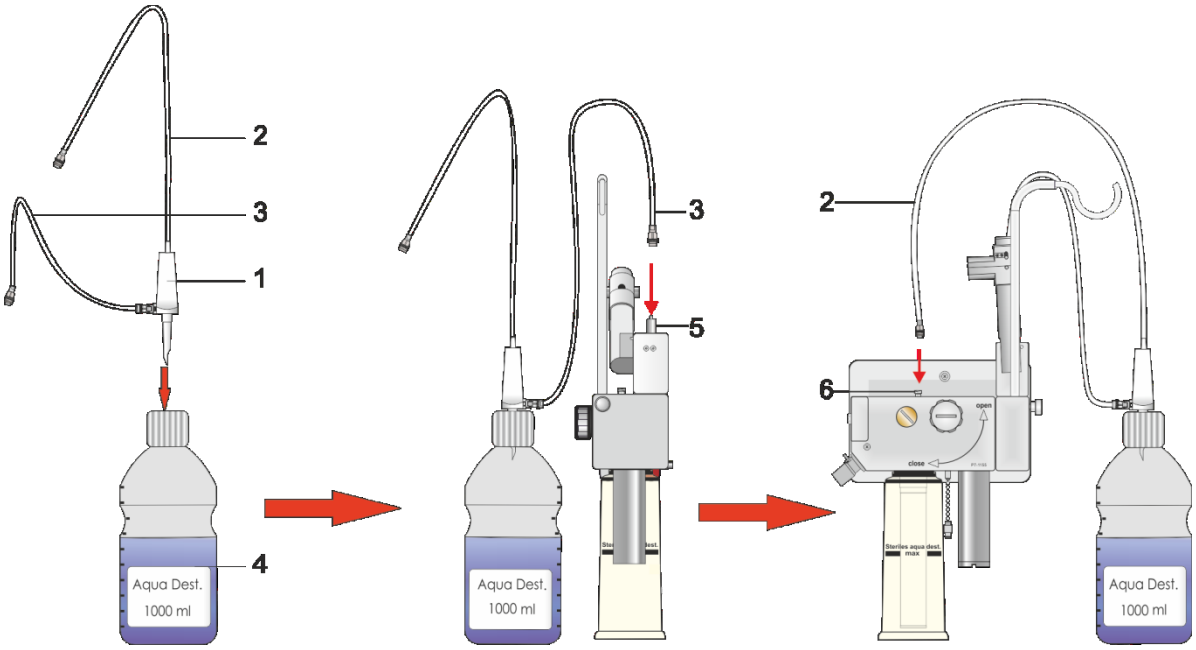


Fig. 102: Installing the water bottle and connection piece

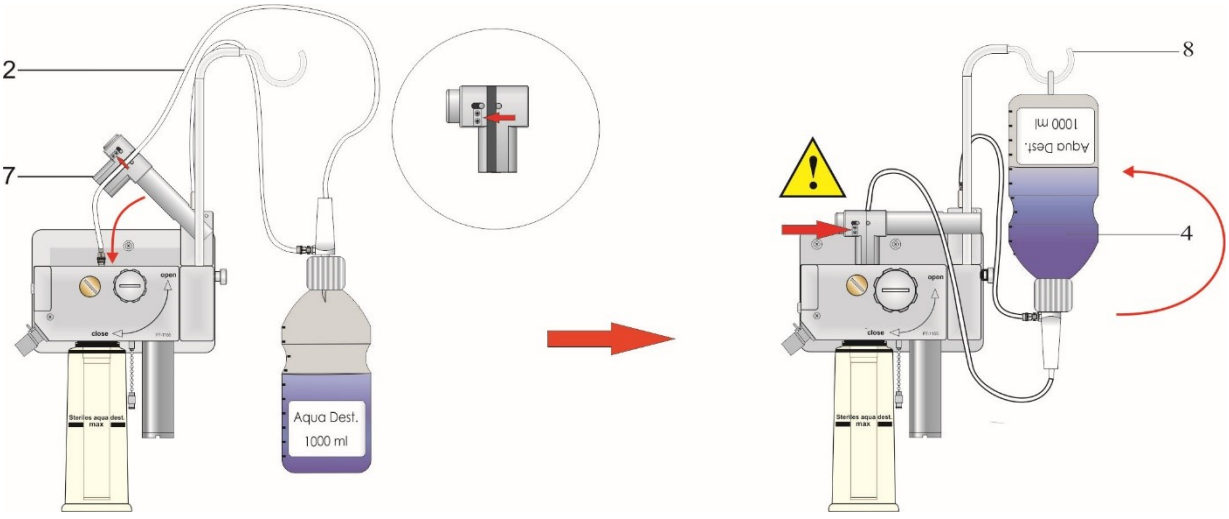


Fig. 103: Inserting the connection piece in the pinch valve

CAUTION

The water bottle is under pressure.

Residual water can escape from the refill tube when removing the connection piece. Before disconnecting the tubes, always first unhook and flip the water bottle to prevent an excess of water from escaping the water bottle.

6.4 Connecting the patient tube system

6.4.1 Reusable patient tube system for incubators

Art. no. 100761500

CAUTION

Always hold the patient tube by the sleeve when connecting and disconnecting it to prevent damage.

Do not stretch, compress or twist the tube system!

1. Connect the red inspiration tube to the red »INS« connection on the front of the patient component.
2. Connect the expiration tube to the »EXP« connection on the front of the patient component.
3. Connect the inspiration and expiration tube to the Y piece.
4. Attach the sealing cap to the Y piece and close the cap.
5. Connect the pneumotachograph (PNT) to the Y piece on the front.
6. Connect the PNT plug to the pneumotachograph connection on the right side of the **SOPHIE**.
7. Connect the tube heating plug to the tube heating connection on the right side of the **SOPHIE**.
8. Connect the temperature sensor plug to the temperature sensor connection on the right side of the **SOPHIE**.

WARNING

Only use temperature sensors for the reusable patient tube system for incubators (art. no. 100761110)!

Temperature sensors other than those intended for this tube system can impair the device's functioning and put the patient at risk!

9. Insert temperature sensor T1 at the end of the heated section of the inspiration tube (distal) into the intended port.

10. Insert temperature sensor T2 at the end of the inspiration tube (proximal) into the intended port.

11. Connect the pressure measurement line from the pressure measurement nozzle on the patient component to the pressure measurement line connection on the right side of the **SOPHIE**.

The patient tube system must be positioned for operation so that the heated part of the tube system is outside the incubator.

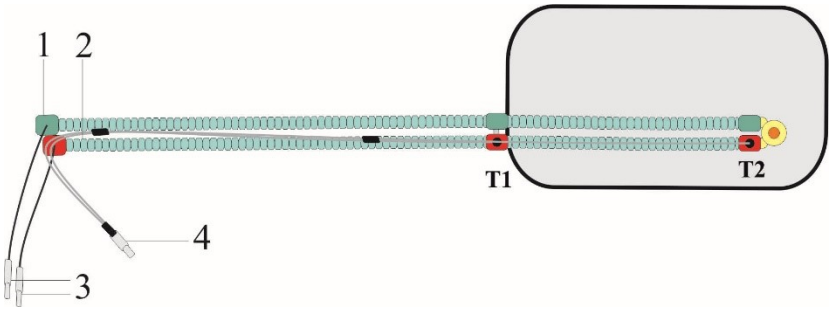


Fig. 104: Sensor position with tube system for incubator

1	Expiration tube	4	Temperature sensor connection
2	Inspiration tube	T1	Distal temperature sensor
3	Tube heating connections	T2	Proximal temperature sensor

CAUTION

To measure the temperature accurately, the distal temperature sensor (T1) must be positioned outside the incubator.

6.4.2 Reusable patient tube system for warming beds

Art. no. 100761550

CAUTION

Always hold the patient tube by the sleeve when connecting and disconnecting it to prevent damage.

Do not stretch, compress or twist the tube system!

1. Connect the red inspiration tube of the patient tube system to the red »INS« connection on the front of the patient component.
2. Connect the expiration tube of the patient tube system to the »EXP« connection on the front of the patient component.
3. Connect the inspiration and expiration tube to the Y piece.
4. Attach the sealing cap to the Y piece and close the cap.
5. Connect the pneumotachograph (PNT) to the Y piece on the front.
6. Connect the PNT plug to the pneumotachograph connection on the right side of the **SOPHIE**.
7. Connect the tube heating plug to the tube heating connection on the right side of the **SOPHIE**.
8. Connect the temperature sensor plug to the temperature sensor connection on the right side of the **SOPHIE**.

WARNING

Only use temperature sensors for the reusable patient tube system for warming beds (art. no. 100761100)!

Temperature sensors other than those intended for this tube system can impair the device’s functioning and put the patient at risk!

9. Insert temperature sensor T1 at the end of the heated section of the inspiration tube (distal) into the intended port.
10. Insert temperature sensor T2 at the end of the inspiration tube (proximal) into the intended port.
11. Connect the pressure measurement line from the pressure measurement nozzle of the patient component to the pressure measurement line connection on the side of the **SOPHIE**.

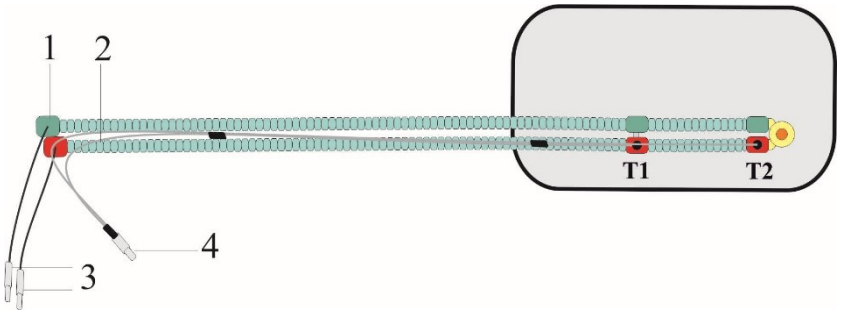


Fig. 105: Sensor position with tube system for warming bed

1	Expiration tube	4	Temperature sensor connection
2	Inspiration tube	T1	Distal temperature sensor
3	Tube heating connections	T2	Proximal temperature sensor

6.4.3 Disposable tube system P3/P7

Art. no. 100761300

CAUTION

Always hold the patient tube by the sleeve when connecting and disconnecting it to prevent damage.

Do not stretch, compress or twist the tube system!

1. Connect the red inspiration tube adapter to the red »INS« connection on the front of the patient component.
2. Connect the white expiration tube adapter to the colorless »EXP« connection on the front of the patient component.
3. Connect the pneumotachograph (PNT) to the Y piece on the front.
4. Connect the PNT plug to the pneumotachograph connection on the side of the **SOPHIE**. Connect the tube heating adapter to the tube heating connections on the right side of the **SOPHIE**.
5. Connect the tube heating adapter to the connections of both patient tubes.
6. Connect the pressure measurement line from the pressure measurement nozzle on the patient component to the pressure measurement line connection on the right side of the **SOPHIE**.
7. Connect the temperature sensor plug to the temperature sensor connection on the right side of the **SOPHIE**.

WARNING

Only use temperature sensors for disposable patient tube systems (art. no. 100763009)! Temperature sensors other than those intended for this tube system can impair the device's functioning and put the patient at risk!

8. Insert temperature sensor T1 at the end of the heated section of the inspiration tube (distal) into the intended adapter.
9. Insert temperature sensor T2 at the end of the inspiration tube (proximal) into the intended adapter.
10. Ensure that all of the tube system adapters are firmly connected to one another and the temperature sensors are fully inserted into the adapters.

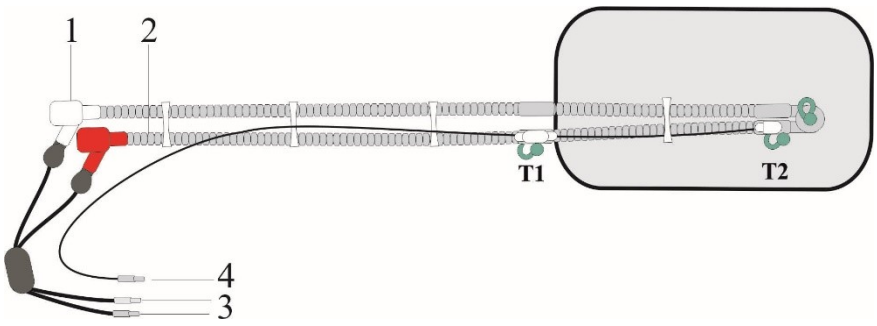


Fig. 106: Sensor position with disposable patient tube system (art. no. 100761300)

1	Expiration tube	4	Temperature sensor connection
2	Inspiration tube	T1	Distal temperature sensor
3	Tube heating connections	T2	Proximal temperature sensor

CAUTION

To measure the temperature accurately, the distal temperature sensor (T1) must be positioned outside the incubator.

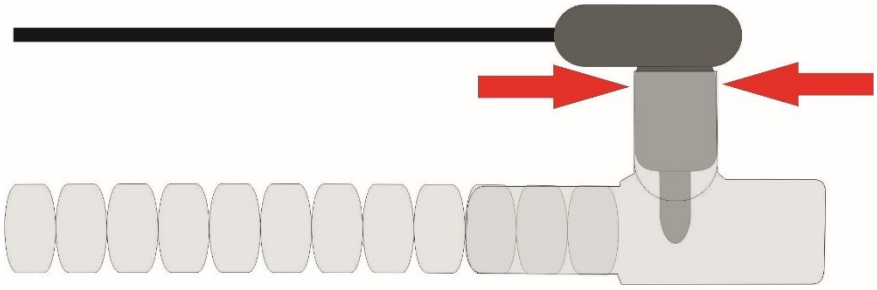


Fig. 107: Inserting the temperature sensor into the adapter

CAUTION

Do not reuse disposable accessories!
The necessary reconditioning may lead to the deterioration of mechanical and biological product properties, posing a significant risk to the patient. In addition, reusing such accessories dangerously increases the risk of contamination for the patient.

6.5 Using accessories

6.5.1 Tube adapter

WARNING

When selecting the tube adapter, make sure that the outlet openings inside the PNT are not blocked by the adapter!

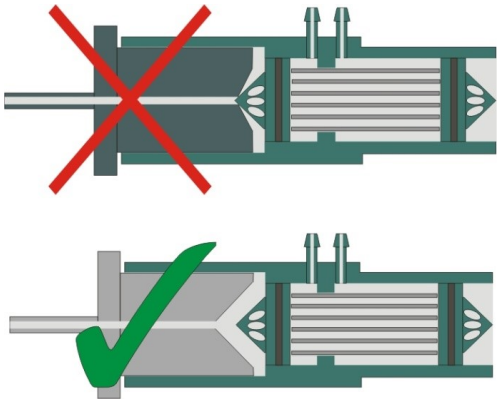


Fig. 108: Tube adapter

6.5.2 PNT A

Based on its special design, the PNT A must be locked manually before use. To do this, move the nose of the turning ring into the appropriate position.

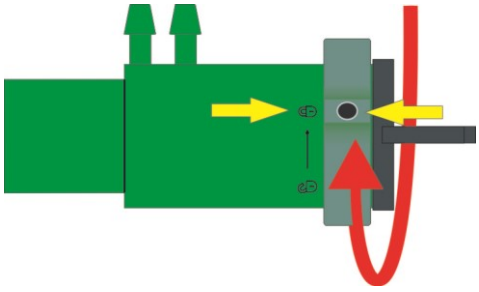


Fig. 109: Locking of PNT A

CAUTION

When using a PNT A, always ensure that it is correctly locked into place. If the PNT A is not correctly locked into place, the tube adapter can dislodge and cause disconnection.

6.5.3 EasyFlow NCPAP systems

1. Connect the mask or prong to the applicator.
2. Disconnect the two decoupling tubes from each other and create an arc (see Fig. 110).
3. Connect the smooth ends of the decoupling tubes to the applicator.
4. Remove the Y piece from the patient tube system.
5. Connect the decoupling tubes to the patient tube system.

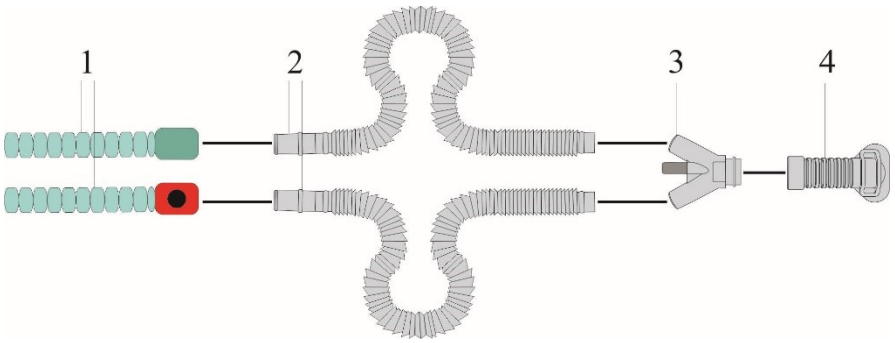


Fig. 110: Connecting an EasyFlow NCPAP

1	Patient tube system	3	Applicator
2	Decoupling tubes	4	Mask/prong

CAUTION

Do not reuse disposable accessories!
The necessary reconditioning may lead to the deterioration of mechanical and biological product properties, posing a significant risk to the patient. In addition, reusing such accessories dangerously increases the risk of contamination for the patient.

6.5.4 Pneumatic medication nebulizer

WARNING

Due to tolerances in the nebulizer flow, the minute and breathing volume displayed during medication nebulization may differ significantly from the actual values. As a result, FRITZ STEPHAN GMBH recommends using a pressure-controlled ventilation mode for nebulization.

WARNING

Aerosols can impair or damage the patient component and thus pose a risk to the patient!

When administering medication using nebulization, an expiration filter must always be fitted between the EXP connection piece and the expiration tube.

The pneumatic medication nebulizer is operated with a gas mixture in the preset O_2 concentration in order to retain a constant FiO_2.

Preparing the medication nebulizer

1. Assemble the medication nebulizer according to its operating manual.
2. Use the silicone plug supplied to seal the nebulizer input (1).
3. Use the silicone tube to connect the nebulizer output (2) to the connecting piece (3) of the reusable Y piece (art. no. 1 701 60 416).
4. Connect the driving gas tube to the bushing on the nebulizer housing.

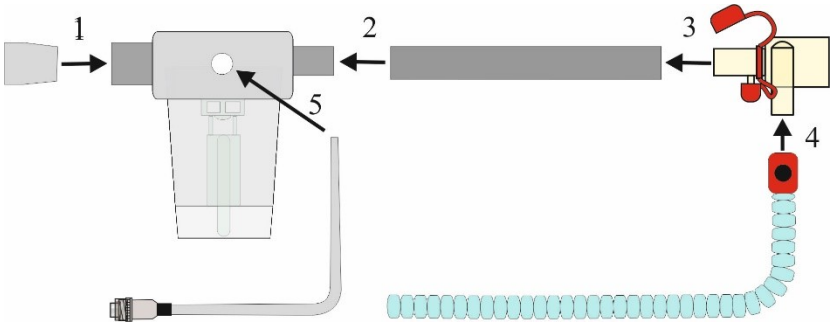


Fig. 111: Nebulizer in reusable tube system

5. Connect the Luer connector for the driving gas to the ventilator's "Aerosol" connecting piece.
6. Connect the Y piece to the patient tube system (4).
7. Insert the expiration filter into the expiration tube.
8. Position the medication nebulizer upright in the tube duct outside the incubator or in a tube bracket if using warming beds.

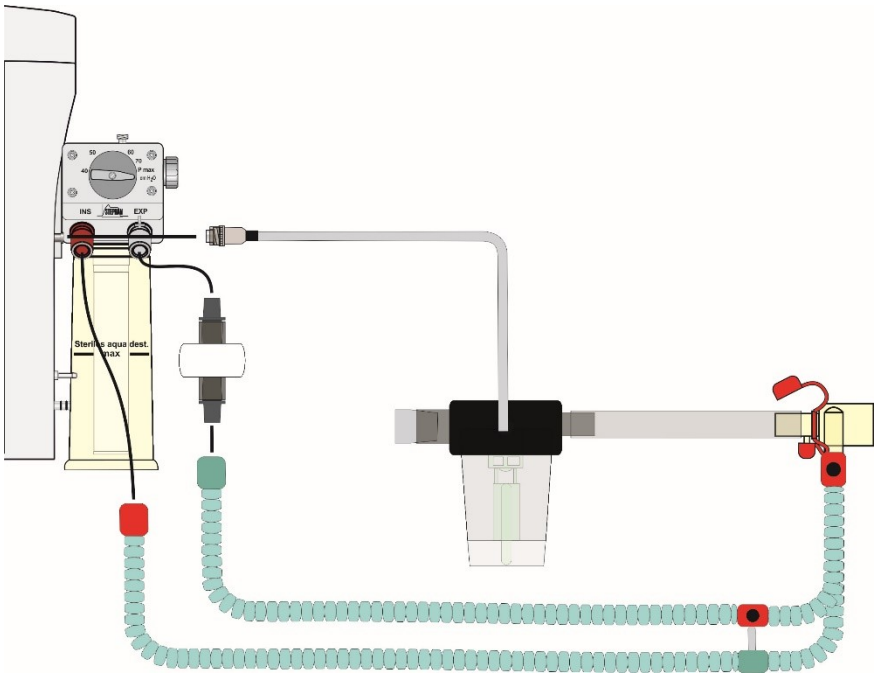


Fig. 112: Installing the pneumatic medication nebulizer

The salt crystals generated during the nebulization of medication in a saline solution environment are capable of destroying the patient component within just a few weeks.

For this reason, the special expiration filter must be fitted between the pressure measurement hose and the expiration hose connection of the patient component.

6.5.5 Aeroneb Solo medication nebulizer

WARNING

Aerosols can impair or damage the patient component and thus pose a risk to the patient!

When administering medication using nebulization, an expiration filter must always be fitted between the EXP connection piece and the expiration tube.

Installing the medication nebulizer

Install the medication nebulizer in the tube system according to the operating manual for the Aeroneb Solo nebulizer.

When operating the Aeroneb nebulizer, always observe the manufacturer's usage and safety instructions!

NOTE

Do not use the special »Aerosol« function with the Aeroneb nebulizer!

The Aeroneb medication nebulizer does not require any driving gas from the ventilator's aerosol connection.

6.5.6 Connection of the external respiration sensor (optional)

The external respiration sensor connection is on the right side, just above the **SOPHIE** patient component. The sensor simply plugs in.

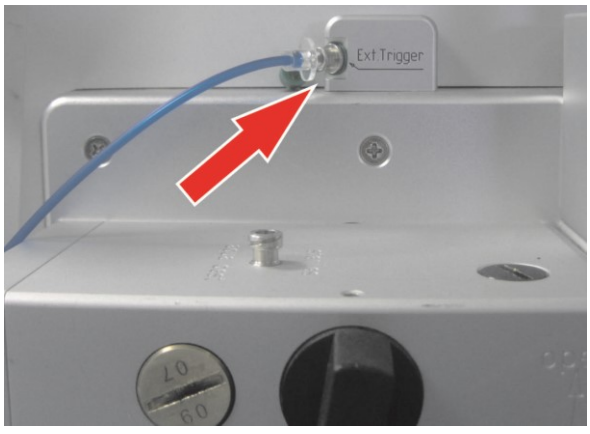


Fig. 113: Connection of the external respiration sensor

Positioning the sensor

1. For ideal positioning, the patient should be in the supine position.
2. Position the sensor in the abdominal area. Secure the sensor using medical tape. Fit tape across sensor and let it protrude at least 3 cm on both sides.

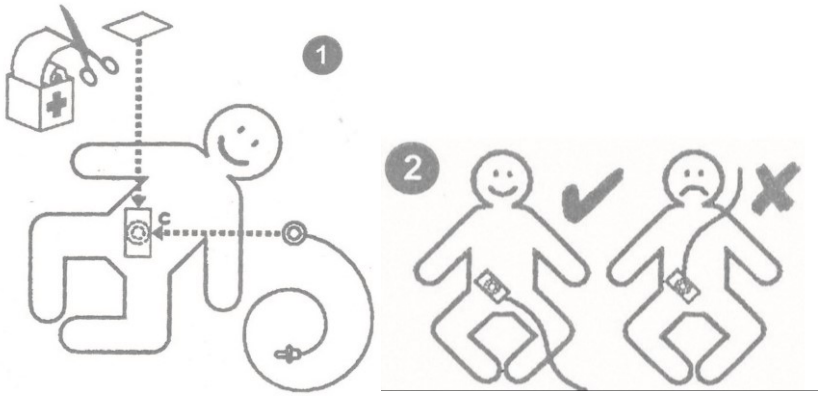


Fig. 114: Positioning of the sensor on the abdomen

3. Check that clear, strong signals from the patient are being displayed on the device (E(t) curve 2).
4. Verify that synchronization with the respiration sensor works in the prone and supine position of the patient.

7 Test before start-up

All tests must be carried out before the device is used. The staff carrying out the tests must be well acquainted with the operating manual.

7.1 Testing requirements

- The last safety check must have been carried out as scheduled.
  Visual check of the safety check label.
- The device is completely assembled and connected.

DANGER

Never operate device if it has failed one of the tests!

DANGER

Always switch on the device, use the test mode and test the alarms without a patient!

7.2 Checklist

Device type: _____		**Date:** _____	
Serial no.: _____		**Signature:** _____	
WHAT	**HOW**	**TARGET**	ACTUAL
Operating manual	The operating manual is part of the device and must always be kept with the device.	Manual is present.	☐
CGS Gas connection lines	Visual check of the color characteristics of the types of gases, observe poss. compliance with in-house regulations	ISO color code O_2 (oxygen) white AIR (compressed air) black-and-white	☐ ☐
	Unique mechanical features of the angled connectors and gas connections	O_2 (oxygen) ⬡ AIR (compressed air) ☐	☐ ☐
Mains power supply	Visual check of the mains connection	Undamaged and strain relief Mains switch »On/Off« set to “On” »On« button illuminated	☐ ☐ ☐
Patient connections	All patient components must be connected properly		
	Patient component	Firmly connected with humidifier fleece	☐ ☐
	Patient tube system	Connected properly	☐
	Temperature sensor	Connected properly	☐
	Pressure measurement line	Connected properly (expiration)	☐
	Pneumotachograph (PNT) (optional)	Connected properly (pressure measurement lines point upwards at the PNT button)	☐
	Ext. respiration sensor (optional)	Connected properly	☐
Test mode	Carry out test mode	Test mode completed successfully	☐
Alarm triggering	Check if alarms are triggered	“Low pressure/disc” and “Vt(exsp) low” are visually and acoustically triggered during the test mode	☐
Manual breathing bag	Self-filling, present, within reach	Functions correctly	☐

Tab. 13: Checklist

7.3 Alarm tests

During the system test, the visual and acoustic alarms are checked by generating HP and MP alarms (see chapter 8.2). The most important alarms can also be tested manually. To do this, prepare the device for operation (as described in the operating manual), connect the tube system and the test lung and switch the device on. Next, proceed as follows:

7.3.1 Peak pressure alarm

- Select pressure-controlled ventilation “IMV”
- Set the upper Pmax alarm limit below the Pmax measured
- Check whether the “Peak pressure” alarm is triggered
- Set the upper Pmax alarm limit above the Pmax measured
- Check whether the “Peak pressure” alarm is reset

7.3.2 Min. volume low alarm

- Select pressure-controlled ventilation “IMV”
- Set the lower MV alarm limit above the MV measured
- Check whether the “Min. volume low” alarm is triggered
- Set the lower MV alarm limit below the MV measured
- Check whether the “Min. volume low” alarm is reset

7.3.3 FiO_2 low alarm

- Select pressure-controlled ventilation “IMV”
- Set FiO_2 to 21%.
- Set the lower limit for FiO_2 above 21%
- Check whether the “FiO_2 low” alarm is triggered
- Set the lower limit for FiO_2 below 21%
- Check whether the “FiO_2 low” alarm is reset

7.3.4 Low pressure/disc alarm

- Select pressure-controlled ventilation “IMV”
- Disconnect the test lung
- Check whether the “Low pressure/disc” alarm is triggered
- Reconnect the test lung
- Check whether the “Low pressure/disc” alarm is reset

7.3.5 Pressure diff. alarm

- Select pressure-controlled ventilation “IMV”
- Carefully pinch the expiratory pressure measurement line
- Check whether the “Pressure diff.” alarm is triggered
- Release the expiratory pressure measurement line
- Check whether the “Pressure diff.” alarm is reset

7.3.6 Apnea alarm (“Apnoe”)

- Select pressure-controlled ventilation “NCPAP”
- Set the trigger to 1.5 Arb or cmH_2O
- Set ApD to “OFF”
- Do not activate the trigger
- Check whether the “Apnoe” alarm is triggered after 15 s
- Activate the trigger
- Check whether the “Apnoe” alarm is reset

8 Operation

DANGER

Always have a separate manual breathing bag handy.

Lack of an alternative ventilation method may result in patient death if the ventilator fails!

8.1 Switching on

Press »ON« to start the **SOPHIE**. The software version and release date are displayed and an automatic system test is then carried out.

NOTE

The Y piece must be closed before switching on the device, preferably by connecting it to the parking position on the back of the patient component.

When using non-invasive patient interfaces, the patient connection port must be sealed, for example by pinching it with a sterile glove.

8.2 Test mode

After switching on the Sophie, an automatic system test is carried out. This is indicated by the message “System test! Please wait”. During the system test, the pressure sensors are automatically calibrated.

NOTE

If the ventilator is in “Standby” mode, a system test can be carried out at any time by selecting the special function »Test« in the Ventilation menu (see 5).

The following checks are performed during the selftest:

1. Check of the humidifier and tube heating temperature sensors
2. Check of the oxygen sensor
3. Check of the humidifier and tube heating
4. Electrical check of the speaker
5. Check of the gas supply pressures
6. Check of the HP alarm – visual (Low pressure/disc) and acoustic
7. Calibration of the pressure sensors
8. Electrical check of the emergency air valve
9. Check of the MP alarm – visual (Vt(exsp) low) and acoustic
10. Leak check of the entire ventilation system
11. Check of the EDA measure
12. Check of the mechanical function of the emergency air valve
13. Check of the electronic blender
14. Check of the high frequency oscillation
15. Check of the system configuration and the SW versions

The alarm messages “Low pressure/disc” and “Vt(exsp) low” are solely used to check whether the alarms are triggered and are automatically cleared once the system test is complete.

WARNING

If the “Low pressure/disc” and “Vt(exsp) low” alarms are not visually or acoustically triggered, potentially hazardous situations for patients cannot be detected. Do not operate the device!

This completes the system test. A message appears on the monitor. If the system test was successful, the desired ventilation mode can be selected.

NOTE

Calibration of the O_2 sensor takes place automatically after a successful system test and is repeated automatically during operation. Manual calibration of the O_2 sensor is also possible using the Main menu (see chapter 4.2.7.2).

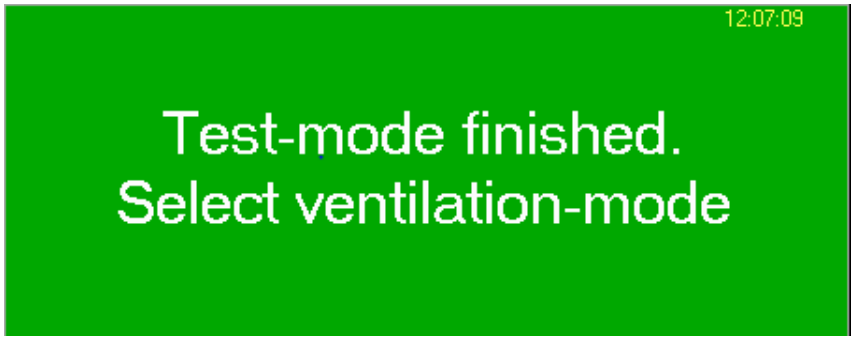


Fig. 115: System test successful

CAUTION

If an error message appears, the system test can be repeated or the device shut down. If the system test is not passed, the device is not ready for use and no ventilation mode can be selected!

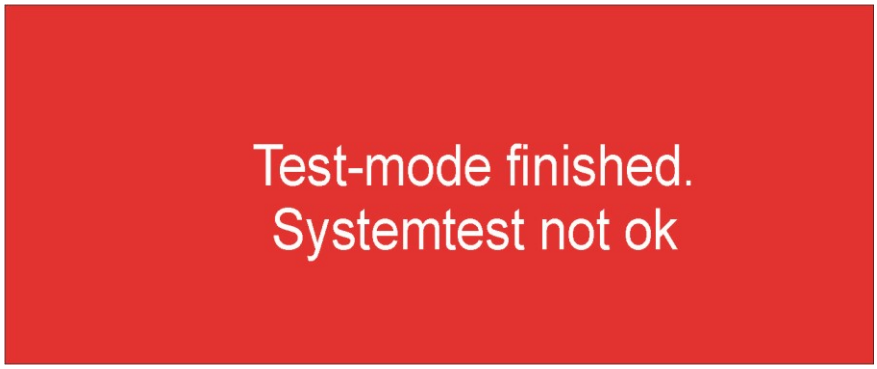


Fig. 116: System test not successful

DANGER

If the “Battery fail” alarm message is displayed on the device, do not press the power switch on Sophie or disconnect power when connected to a patient. Interrupting the power supply when the battery is defective results in the device switching off immediately.

CAUTION

Up to generation 2.2.0 of the power supply, the Sophie cannot be operated when the battery is completely discharged. As of generation 2.2.0 of the power supply, the confirmation prompt “Low state of charge ok?” indicates that the battery is low. Answering “Yes” allows you to continue operating the device despite the lower battery. Answering “No” causes the device to power off.

You can check the power supply version in the Communic./System menu (see chapter 4.2.7.6).

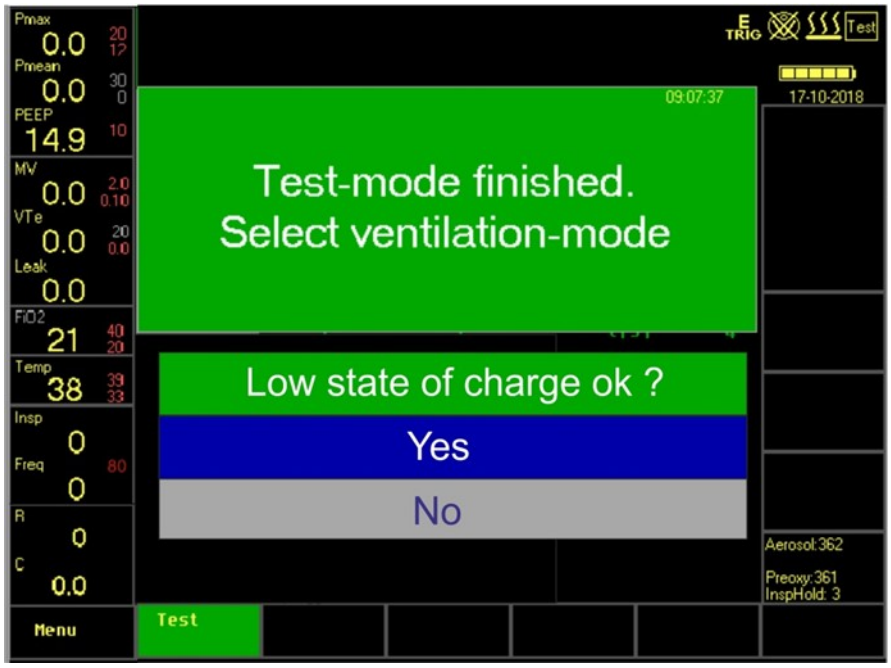


Fig. 117: Operation with low battery charge level

8.3 Choosing the ventilation mode

All ventilation modes can be selected in the Ventilation menu using the »IGR«. A pop-up menu then opens automatically with all parameters necessary for the ventilation mode. After configuring these parameters, select the »Start« field to start ventilation.

NOTE

Detailed information on the ventilation modes and their selection can be found in chapters 5 and 9.

Overview of the ventilation modes

Ventilation mode	IMV	S-IMV	Ass./Co.	HFO	Non Invasive
Standard	×	×	×		
HFO+IMV				×	
HFO+CPAP				×	
ITT (PSV)		×	×		
NCPAP					×
SNIPPV					×

Tab. 14: Possible combinations of the ventilation modes

8.4 Non-invasive ventilation

If a non-invasive ventilation mode has been selected, the parameter displays at the bottom and on the right side of the monitor are displayed in light gray to clearly indicate non-invasive ventilation mode.

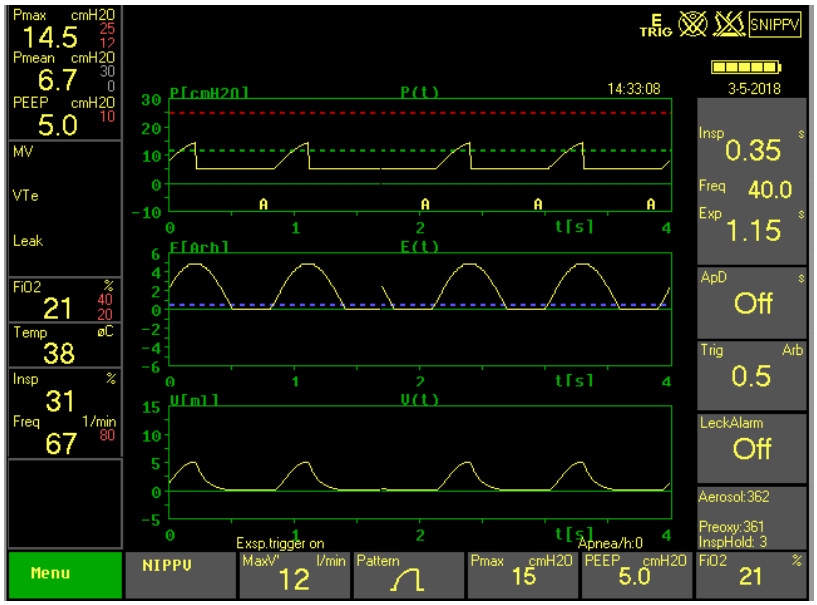


Fig. 118: Parameter display with non-invasive ventilation

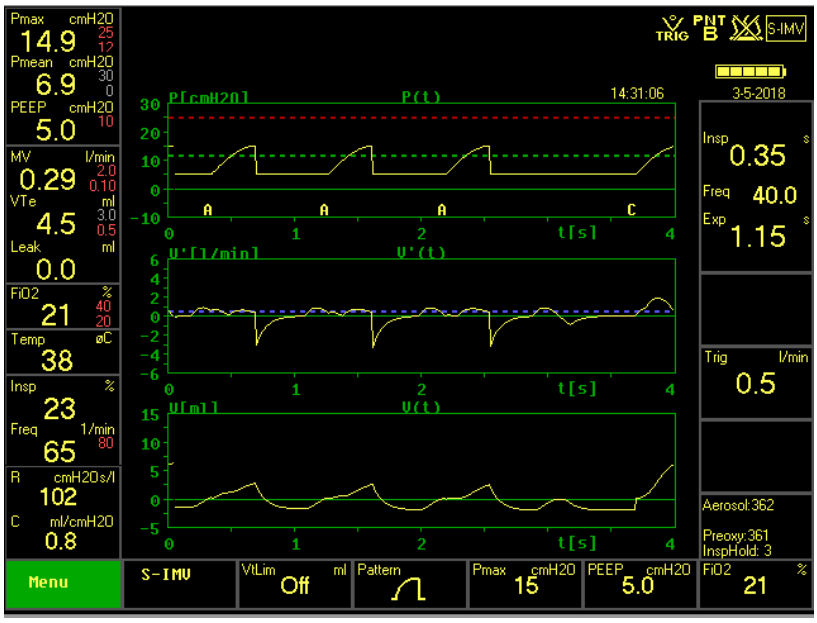


Fig. 119: Parameter display with invasive ventilation

8.5 Switching off

To switch off the Sophie, first select the »Standby« function in the Ventilation menu. The confirmation prompt “Exit ventilation?” is displayed. Answering “Yes” puts the **SOPHIE** into standby mode. If you then select the »Off« function, the confirmation prompt “Power off?” is displayed. Answering “Yes” again switches the device off completely, and it can only be switched on again using the »On« button (see chapter 5.2.1).

WARNING

In the event of a power failure or the failure of the optional 24 V DC supply, the internal battery supplies power to the ventilation system. The **SOPHIE** should therefore remain connected to the power supply with the power switch turned on so that the battery is charged and the device ready for use.

8.6 Decommissioning the device

1. Proceed in the same way as described in chapter 8.5.
2. After use, also disconnect **SOPHIE** from the central gas supply (CGS) to prevent any gas reflux or soiling of the pipe system.

8.6.1 Automatic refill system (optional)

CAUTION

The water bottle is under pressure.

Residual water can escape from the refill tube when removing the connection piece. Before disconnecting the tubes, always first unhook and flip the water bottle to prevent an excess of water from escaping the water bottle.

The connection piece should be removed from the automatic refill system after it is used as shown below:

1. Unhook the aqua dest. bottle (4) from the holder and then set it aside with the connection piece facing up.
2. Push the slider on the tube pinch valve (7) forward. The valve opens.
3. Push up the tube pinch valve (7) and remove the aqua dest. bottle (2) from the valve.
4. If the bottle is made of plastic, back siphon the residual water from the tube by pressing lightly on the bottle in the humidifier chamber.
5. Disconnect the aqua dest. tube (2) from the aqua dest. inlet on the patient component.
6. Disconnect the tube (3) from the driving gas outlet on the patient component.

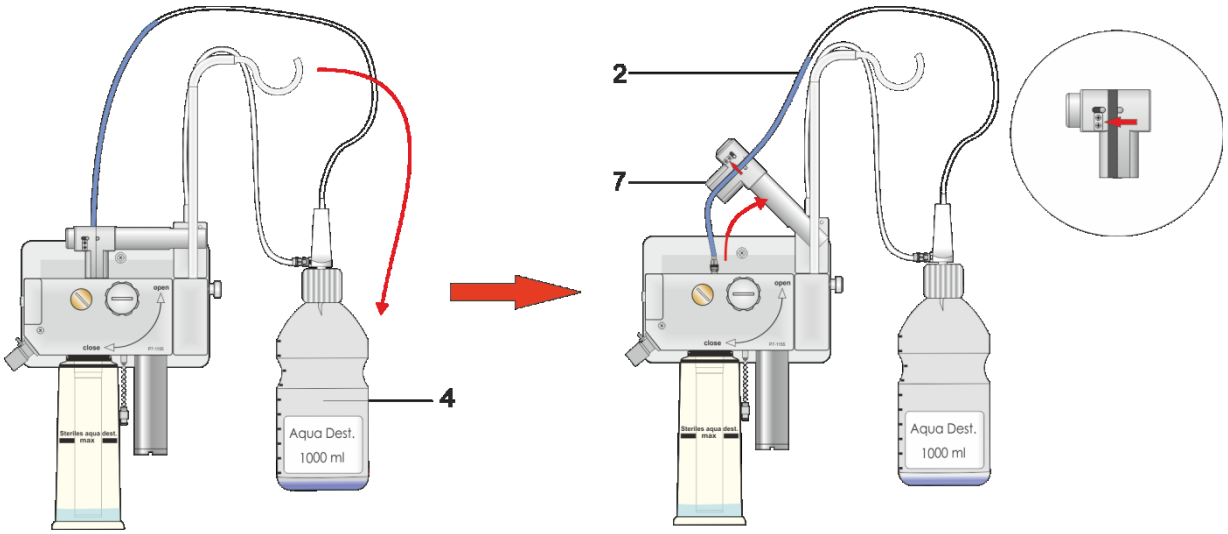


Fig. 120: Turning the water bottle and removing the connection piece

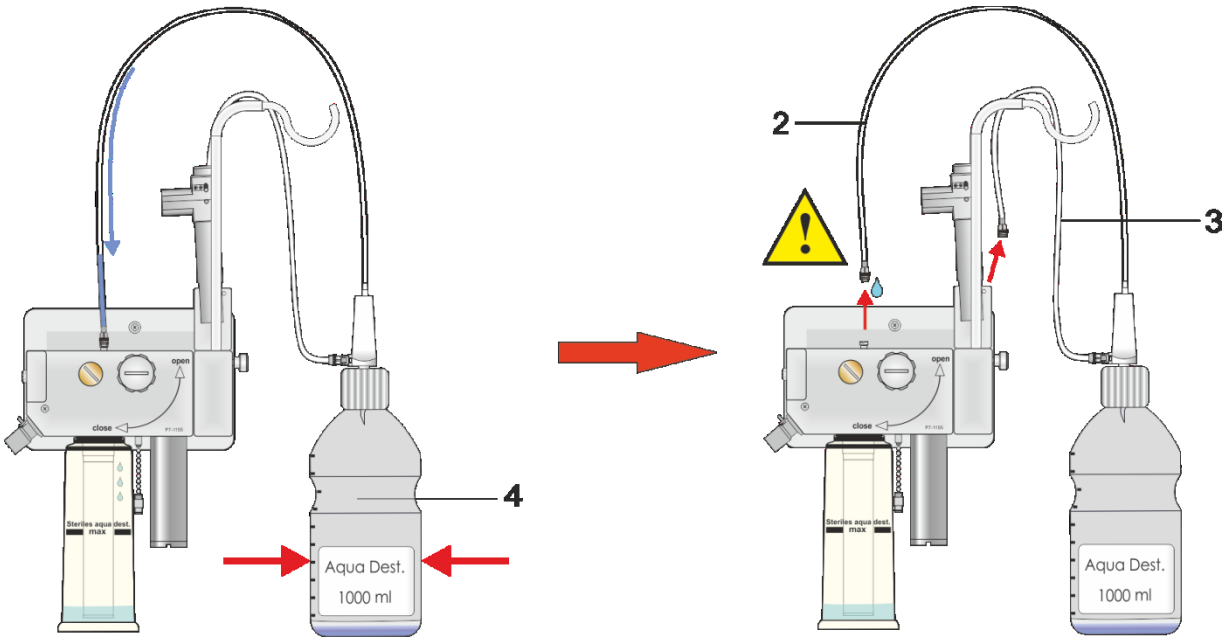


Fig. 121: Back siphoning the residual water and removing the connection piece

NOTE

The automatic refill system is switched off as soon as the tube pinch valve (2) is folded up.

NOTE

The connection piece (art. no. 103860035) for the automatic refill system is only intended for single use.

CAUTION

Do not reuse disposable accessories! The necessary reconditioning may lead to the deterioration of mechanical and biological product properties, posing a significant risk to the patient. In addition, reusing such accessories dangerously increases the risk of contamination for the patient.

9 Ventilation modes

9.1 General

CMV (controlled mandatory ventilation) means that the ventilator completely manages the breathing process. The patient has no influence on ventilation. Mandatory ventilation "forces" insufflation of the lungs for a preset inspiration time (T_{Insp}). During this inspiration time T_{Insp}, an inspiratory tidal volume (Vt) is provided to sustain the exchange of gas within the lungs.

At the end of the inspiration time T_{Insp}, the ventilator switches to a preset expiration time T_{Exp}. The elastic restoring forces of the lung are now responsible for passive expiration, during which the pressure between the lung and ventilator is equalized. The exhaled expiratory tidal volume is measured by the pneumotachograph PNT and shown on the display.

The expiratory breathing volume is defined as the tidal volume. Only the VT_E is used as basis for calculating the minute volume (MV).
The ventilation rate within one minute is referred to as the breathing frequency (BPM = breaths per minute or f = frequency). It is determined by the inspiration and expiration time. **SOPHIE** displays the ratio of the two breathing times as the percentage inspiratory ratio "Insp. %".
The patient's spontaneous breathing is not hindered during the expiration time, although the ventilator is not synced with the patient's spontaneous breathing.

During mandatory ventilation, the patient has a virtually "pressure-tight" connection to the ventilator consisting of an endotracheal tube (ETT) and a tube system. His breathing therefore depends on the flexibility and efficiency of the ventilator. The endotracheal tube (ETT) positioned in the intubated patient's trachea prevents the patient from breathing.
The smaller the diameter of the ETT, the more difficult it is to breathe in (and breathe out). Increased airway pressure during expiration (PEEP = positive end expiratory pressure) improves alveolar ventilation/pulmonary exchange of gases.

For patients to breathe in spontaneously, they first have to overcome the resistance of the ETT before respiratory gas can flow into their lungs. The respiratory gas flowing into the lungs causes the pressure at the ETT inlet to decrease slightly. The faster the ventilator compensates for this

drop in pressure, the less effort the patient must make to breathe. The ability of the ventilator to react to these fluctuations in pressure resulting from spontaneous breathing activity by the patient depends on the inner resistance. This ability is the best measure for the quality of a ventilator.

NOTE

Detailed information on selecting the following ventilation modes and setting the corresponding parameters can be found in chapter 5.

9.2 External trigger (optional)

Spontaneous breathing efforts of a newborn or premature patient are typically accompanied by characteristic abdominal movements.
The abdominal movements can be easily detected by **SOPHIE** by means of a pressure capsule filled with soft foam (respiration sensor). During spontaneous breathing, the pressure inside the capsule changes according to the abdominal movement.

The foam inside the capsule allows it to return to its original pressure at end of the inspiration phase. A highly sensitive pressure sensor inside the ventilator detects these pressure changes. In addition, a software filter eliminates artifacts. This makes it possible to sync the mandatory inflation with the spontaneous efforts of the patient without “auto-trigger” interference. The abdominal movement can be graphically displayed as a second curve on the ventilator display. Its units are arbitrary units and dimensionless. The scale of the curve E(t) can be adjusted to the magnitude of the abdominal movement in increments of 0, 3, 6 and 9.

External inspiratory trigger

As with the conventional flow and pressure trigger methods, an external trigger threshold can be defined. This is adjusted to the spontaneous breathing efforts of the patient according to the E(t) curve. The **SOPHIE** detects spontaneous inspiration when the trigger threshold is exceeded.

For SNIPPV, this is used to sync mandatory inflation. For NCPAP, the trigger is used to monitor apnea and measure the breathing rate.

External expiratory trigger

The external trigger lets you detect both the start and the end of a spontaneous inspiration. As soon as the movement stops or the signal no longer rises, the ventilator acknowledges this as the start of expiration and automatically terminates the mechanical inflation. This enables the **SOPHIE** to sync both inflation and expiration. As a result, the patient is able to completely control the ventilation. With linear and sinusoidal

pressure patterns, the set inflation pressure (Pmax) is typically not reached until the set inflation time has elapsed. If the inflation is terminated by the expiratory trigger before the set inflation time has elapsed, the applied inflation pressure drops as well. Consequently, the applied inflation pressure also depends on the duration of the spontaneous inspiration of the patient.

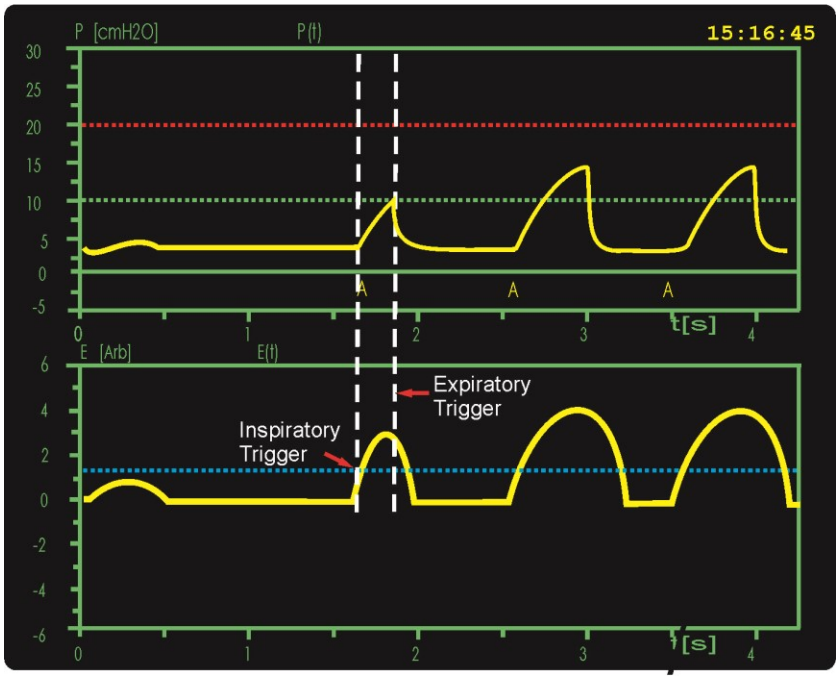


Fig. 122: Inspiratory and expiratory triggers

The abdominal movement signal has to drop below the trigger threshold before another assisted inflation can be triggered. For this purpose, triggers are suppressed for 150 ms at the end of the inflation. The external expiratory trigger can be switched off using the corresponding function in the »Options« menu.

9.3 Pressure-controlled ventilation (IMV)

During pressure-controlled ventilation, all respiratory phases are adjusted to the ventilation pressure. This is known as a pressure control loop and it compares the preset nominal parameters such as inspiratory peak pressure »Pmax« and positive end expiratory pressure »PEEP« with the pressure values measuring during inspiration (P_{MAX}) and expiration (P_{EEP}). Any deviations caused, for example, by spontaneous breathing activity during inspiration or expiration are compensated quickly. **SOPHIE** offers a very

fast control response time. As a result, the ventilator can be said to have a very low internal resistance which does not hinder spontaneous breathing.

Under IMV, the time required for mandatory insufflation is set in the »Insp« field in the pop-up menu (see chapters 5.4.1 and 5.4.2). The set inspiratory peak pressure »Pmax« is reached during this time. The magnitude of the tidal volume depends on the compliance of the patient's lungs and results from the »PEEP« and »Pmax« settings. Pressure-controlled ventilation is not affected by any tube leaks; only the tidal volume can fluctuate. Spontaneous breathing attempts by the patient during inspiration are not restricted by pressure-controlled ventilation IMV. The patient can breathe in and out freely at every pressure level. The pressure is controlled, that is, it remains constant.

The graphic display of flow over time V'(t) is useful when determining the corresponding inspiration time.

At the start of every inspiration phase, the inspiratory flow increases rapidly to a maximum value. At the end of inspiration, this flow decreases and approaches zero. At this point in time, there is a balance of pressure between the ventilator and the lung after which there is no further flow between the Y piece and the lung due to the pressure gradient. The lung has now been filled within the time indicated on the time axis. The configurable inspiratory patterns (linear, sinus, rectangle) determine how the ventilation pressure reaches its maximum value within the inspiration time »Insp«.

NOTE

Detailed information on selecting the ventilation mode »IMV« and setting the corresponding parameters can be found in chapters 5.4.1 and 5.4.2.

9.3.1 IMV with volume limitation

A principle characteristic of pressure-controlled ventilation is the comparatively uncontrolled tolerance of tidal volumes as lung compliance changes. Up to now, inadvertent increases in pressure were presumed to cause lung damage (barotrauma) in infant patients on ventilation systems. Today, it is presumed that uncontrolled supplied volume (volutrauma) is the real cause rather than an uncontrolled increase in pressure.

Entrainment phenomena

In the worst case, effects of syncing ventilated patients with the ventilator (Herin-Breuer reflex, Head's paradoxical reflex or negative feedback phenomena) in particular can be associated with major increases of tidal volume under pressure-controlled ventilation. Therefore, limitation to

the expiratory tidal volume can be activated during pressure-controlled ventilation.

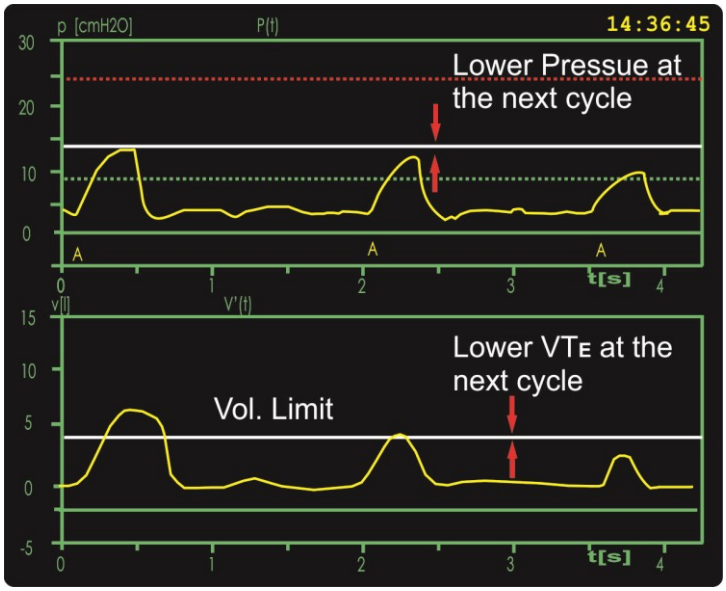


Fig. 123: IMV with VT_E limitation

IMV with volume limitation

This means of adjusting to the expiratory volume VT_E starts to limit pressure after the increased volume has been inhaled. The inspiration pressure of the following mandatory breath is selected lower than the previous breath. The benefit of this kind of control is that it reliably prevents too large a volume. Furthermore, limiting ventilation to the expiratory volume compensates for any possible inspiratory ETT leak.

Volume limitation safeguards the special benefits of pressure-controlled ventilation while the patient breathes spontaneously.

Procedure

In order to use volume limitation, the inspiratory peak pressure »Pmax«, the positive end expiratory pressure »PEEP«, the inspiration time »Insp.«, and the expiration time »Exp.« should be set as usual. In this case, however, the »VtLim« parameter field has special significance because it is used to adjust the expiratory volume limitation. Volume limitation should be set slightly above the expected or already breathed tidal volume. If the expiratory tidal volume now exceeds the volume limitation, pressure-controlled ventilation is limited starting with the next breath. However, to ensure a minimum pressure, it is not possible to reduce the inspiration pressure below the minimum limit of PEEP + 4 cmH_2O. Development of volume limitation based on the entrainment phenomena described above has revealed that volume limitation under pressure-controlled ventilation can be used as an ideal volume target.

Volume target

After setting the ideal tidal volume for a patient (5 ml/kg/bodyweight) in the »VtLim« parameter field and allowing for a max. ventilation pressure of »Pmax«, the preset tidal volume automatically adjusts to the lowest possible inspiratory ventilation pressure. In addition, there is also up to 50% leakage compensation.

Procedure

In order to use volume target ventilation, the positive end expiratory pressure »PEEP«, the inspiration time »Insp.«, and the expiration time »Exp.« should be set as usual. In this case, however, the »VtLim« parameter field has special significance because it is used to adjust the volume target. The desired tidal volume is set using the »IGR«.

The ventilation pressure »Pmax« is set to the anticipated peak pressure. Again, it is vital to know the lung compliance C. The **SOPHIE** now selects the ventilation pressure for every inspiration so that the expiratory tidal volume is delivered with the lowest possible pressure. If lung compliance deteriorates, the ventilation pressure increases at maximum to the »Pmax« setting. As of this pressure, it will no longer be possible to deliver the set tidal volume in full. The ventilator reverts to pressure-controlled-only ventilation.

CAUTION

When using a closed suction catheter with VtLim or VtTar, influencing the volume measurement can cause the inspiration to be canceled due to the volume limitation and put the patient at risk.

NOTE

With VtLim and VtTar, the volume is limited by the pressure “Pmax”. If VtLim or VtTar is exceeded, the set inspiratory pressure Pmax can therefore no longer be reached.

9.3.2 Pressure-controlled ventilation without PNT

To use pressure-controlled ventilation without PNT, first select the function “No PNT” by navigating to “Main menu” ➔ “Options” ➔ “PNT” (see chapter 4.2.7.1). During ventilation without PNT, tidal volumes, minute volumes, resistance, and compliance are no longer displayed and calculated.

Reasons for ventilation without PNT may include PNT dead space influence on alveolar ventilation.

The trigger required for syncing spontaneous breathing is automatically switched from the flow to the pressure signal.

If the “External trigger” option is available, syncing can also be based on the abdominal movement of the patient.

9.4 Synchronized mechanical ventilation

Controlled ventilation may result in asynchrony between the spontaneous breathing efforts of the patient and the fixed ventilation cycles of the ventilator. In this case, the mandatory breaths randomly coincide with different phases of spontaneous breathing. Due to the possible resulting adverse effects, syncing between a spontaneously breathing patient and the ventilator is especially important. The **SOPHIE** uses different trigger signals for syncing.

1. Respiratory gas flow signal of the pneumotachograph
2. Differential pressure signal of the pressure sensors
3. Abdominal movement from respiration sensor (optional)

The trigger threshold is set using the “Trigger” parameter field.
The higher the setting for this trigger threshold in the expiratory pause, the more the patient has to breathe in to activate the trigger.

Pneumotachograph

The **SOPHIE** uses the pneumotachograph (PNT) to measure the patient’s inspiratory flow. If the inspiratory flow exceeds a value set by the operator, a mandatory breath is triggered. The trigger threshold appears as a blue line in the respiratory gas flow window V‘(t).

Respiration sensor (optional)

The respiratory sensor is used to detect the patient’s abdominal movements. If the trigger threshold set by the operator is exceeded, a mandatory breath is triggered. The trigger threshold appears as a blue line in the external trigger window E(t).

Differential pressure sensor

The differential pressure trigger is only automatically activated when the “No PNT” function has been selected in “Main menu” ➔ “Options” ➔ “PNT” (see chapter 4.2.7.1). All displays, calculations, and signals belonging to the flow signal are now switched off automatically. The trigger signal then changes to a differential pressure trigger. The blue trigger line appears below the PEEP line in the ventilation pressure window. When the patient attempts to breathe spontaneously, the PEEP drops slightly.

The trigger threshold can detect the PEEP drop and trigger a mandatory breath. The lower the trigger threshold is positioned below the PEEP line, the more the patient has to breathe in to trigger a breath. In turn, too little distance to the PEEP line can cause unintended triggering due to artifacts.

9.4.1 Assisted controlled ventilation

The **SOPHIE** delivers a mandatory breath whenever the selected trigger threshold is exceeded. Mandatory inspiration is triggered by the patient, but the characteristics are controlled by the device.

After every inspiration, the trigger is suppressed for 200 milliseconds. The patient cannot request a new breath until the trigger suppression period has elapsed. Similar to IMV ventilation, assisted controlled ventilation supports volume limitation.

NOTE

Detailed information on selecting the ventilation mode “Ass./Co.” and setting the corresponding parameters can be found in chapters 5.4.4 and 5.4.5.

9.4.2 S-IMV

In this mode, the operator defines a maximum mandatory breathing frequency which the patient can sync with spontaneous breathing efforts. This breathing frequency should be significantly lower than the patient’s spontaneous breathing frequency to prevent asynchronies. For this purpose, a sufficiently long expiration time must be set during which the patient is able to “trigger” (i.e. request) mechanical pressure support. Spontaneous breaths outside the trigger expectation window (in the first half of the expiration time) are not mechanically supported.

The expiration time is divided into 2 equal halves. In the first half, the patient can only breathe spontaneously. Even when the trigger threshold is crossed, there is no mandatory support from the ventilator. However, a spontaneous breath which is greater than the trigger threshold is used to calculate the minute volume MV, breathing frequency, and inspiration ratio in %.

The actual total breathing frequency is shown in the “F” measured value display of the monitor. This is also where the measured values for the minute volume “MV” and the actual inspiratory ratio “Insp/%” are located. If the patient does not start to breathe spontaneously during the trigger expectation window, the ventilator performs a mandatory breath immediately after the end of the set expiration time. Similar to the previous ventilation modes, SIMV ventilation can also be combined with volume limitation.

Ignoring weak spontaneous breaths

If a patient breathes weakly in the CPAP phase of SIMV, the “VT low” alarm is triggered. Previously, this could only be prevented by setting the lower limit of the “Vt(exp) low” alarm to a very low value. However, this has the result that mandatory breaths with less than the desired tidal volume do not trigger alarms either. To enable optimal setting of the alarm limit while still preventing alarm triggering due to weak spontaneous breaths, a “VT filter” threshold with a configuration range of 0.2 to 10 ml has been incorporated. Only breaths that exceed the configured threshold are registered and taken into account for alarm generation and frequency determination (see chapter 4.2.1).

NOTE

Detailed information on selecting the ventilation mode “S-IMV” and setting the corresponding parameters can be found in chapter 5.4.2.

9.4.3 Inspiratory time termination (ITT/PSV)

NOTE

Inspiratory time termination (ITT) can be selected as an option for the ventilation modes S-IMV and ASS./CO. in the »Ventilation« menu (see chapters 5.4.3 and 5.4.5).

Inspiratory time termination (ITT)

A modified form of patient-triggered ventilation, known as inspiratory time termination (ITT), can be used to achieve greater sensitization and enhanced adjustment of the ventilation control to the patient’s physiological needs. This is designed to allow the patient to determine both the start and end of the inspiratory breath.

Using the set trigger threshold, the ventilator detects the patient’s inhalation effort.

The inspiratory peak flow is stored during inspiration. With increasing inspiration progress, the inspiratory flow drops and approaches zero towards the end when the lung has been filled completely.

This effect can be used for better syncing of the ventilation process. This new method of patient-synced ventilation lets you adjust the inspiratory peak flow value as a percentage (KV’ %). Inspiration ends when the value falls below this peak flow value.

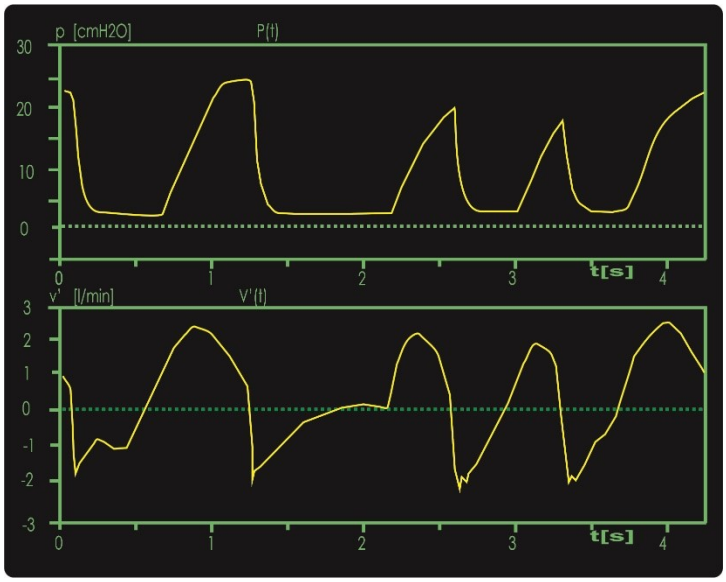


Fig. 124: Inspiratory time termination ITT

The abort criterion can be set between 5 and 40% of the peak inspiratory flow. This enables the ventilator to adjust the degree to which the lungs are filled to the physiological conditions. If the patient reduces or completely discontinues spontaneous breathing, the pre-set target volume (VtTar) is applied.

This function only works with the following ventilation methods:

- S-IMV
- Ass./Co.

The “KV’ %” function can be used to adjust the inspiratory peak flow factor as a percentage at which inspiration ends.

NOTE

More information on setting the parameters “KV’ %” and “VtTar” can be found in chapter 5.3 and in chapters 5.4.3 and 5.4.5.

9.5 S-IMV with ITT and pressure support

SIMV permits spontaneous breaths between the mandatory inflations, which can receive additional ventilator support.

PPSV% With spontaneous breathing between the mandatory inflations, the patient is responsible for part of the breathing effort. These spontaneous breaths receive pressure support according to the »PPSV%« setting. The »PPSV%« parameter sets the supporting pressure for the patient's spontaneous breaths in proportion to the actually applied inflation pressure. »PPSV%« is adjustable within the range of 0–100%.

NOTE

If PPSV% is set to 0%, the pressure support for the spontaneous breaths is switched off.

Pressure-supported spontaneous breaths are generally ITT inflations with inspiratory and expiratory syncing.

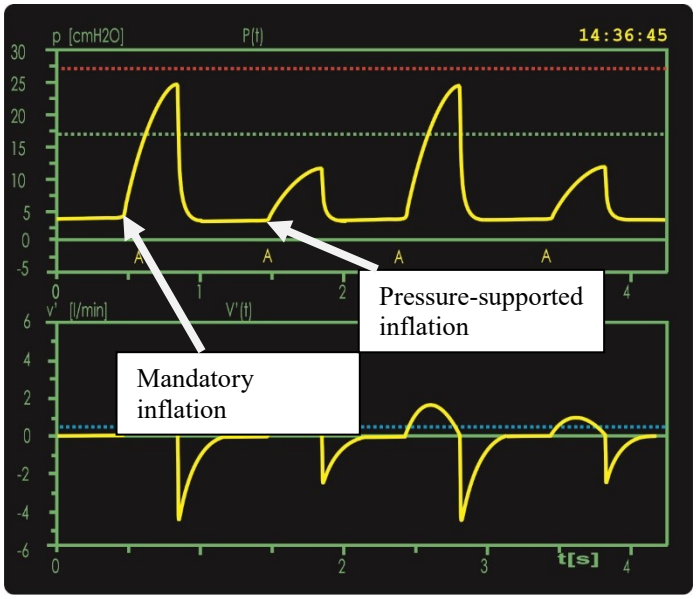


Fig. 125: SIMV with ITT and pressure support

If the pressure of the mandatory/assisted inflations is reduced by the VtTar volume control, the supporting pressure for spontaneous breaths is automatically adjusted to the new inflation pressure.

9.6 High frequency oscillation

NOTE

High frequency oscillation (HFO) is an optional **Sophie** component. For versions without HFO, the HFO option cannot be selected and is grayed out in the Ventilation menu.

Settings

High frequency oscillation is supported in the ventilation modes IMV and CPAP. It can be set in the Ventilation menu (see chapters 5.4.6 and 5.4.7).

High frequency oscillation (HFO) causes a sort of vibration in the lung by imposing pressure oscillation around a mean pressure at the tube connector. The oscillation is generated by the **SOPHIE**'s proportional valve, which oscillates between a positive and negative pressure source.

The following variables must be preset by the user:

- Mean airway pressure using the »MAP« parameter (for CPAP)
- Positive end expiratory pressure using the »PEEP« parameter (for IMV)
- Oscillation pressure amplitude
- Oscillation frequency
- I/E oscillation ratio
- Pressure limit and time period of the insp. hold function

HFO can be combined with the conventional ventilation modes IMV and CPAP in pressure-controlled mode. Typically, CPAP ventilation is selected as the basis for HFO.

The corresponding parameters can be set in the HFO pop-up menu, particularly the inspiration/expiration time ratios. HFO is monitored by an upper and lower alarm limit for the oscillating pressure amplitude, the mean airway pressure, and the oscillating minute volume together with a lower alarm limit for PEEP (IMV mode), MAP (CPAP mode), and tidal volume. The alarm limits can be changed automatically or manually.

A possible disconnection of the patient from the oscillation pressures is hardly detectably with HFO because of the strong influence of airway resistance. One of the greatest airway resistances in this system is the endotracheal tube. As a result, unintentional extubation of the child from the endotracheal tube cannot be detected reliably based on a change in the oscillation amplitude.

However, the mean oscillation flow shows a marked positive increase in the case of such a large leak or extubation. On the other hand, the oscillation amplitude remains nearly the same. Only the subsequent volume alarm informs the user of this critical situation.

The **SOPHIE** has a new monitoring method that can detect the mean flow during HFO.

If the mean flow shows a marked positive increase during HFO, that is, a very large portion of the flow exits the tube system without returning during expiration, this can be presumed to indicate disconnection. A blue line appears in the flow display under HFO.

The position of this line can be adjusted in the sub-menu of the selected HFO ventilation. The line is referred to as the flow limit line. If the determined mean flow rises above the blue flow limit line, the "Flowlimit/disc?" alarm is activated immediately.

NOTE

The sub-menu "Alarmlimits" can be accessed using the switch (see chapter 3.1.2) or using the menu "Alarmlimits" (see chapter 4.2.1).

Patient component preparation

The **SOPHIE** patient component has various safety features for the event of a device malfunction or gas supply failure. If the gas supply fails, the emergency air valve of the test block always switches the system so that there is no resistance between the patient and the atmosphere.

This safety feature is checked automatically every time the device starts up. In the unlikely event that this emergency air valve is blocked, the patient can breathe spontaneously by means of a mechanical safety valve. However, this valve does not open until a negative pressure of approx. –6 cmH_2O is reached.

When using HFO, larger amplitude settings result in a negative pressure, which quickly reaches the value of –6 cmH_2O at which the safety valve opens. To avoid losing the therapeutic benefits of large pressure amplitude due to the secondary safety function, the safety valve may be disabled during HFO therapy using the »HFO« sealing cap.

Always comply with the instructions on the warning label attached to the right side of the **SOPHIE**.

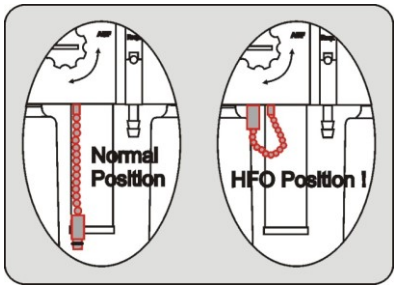


Fig. 126: HFO label

9.7 Non-invasive CPAP (NCPAP) and CPAP

The NCPAP and CPAP ventilation modes presume sufficient spontaneous breathing by the patient. The patient can breathe in and out freely at the set CPAP level. The CPAP level can be set using the »PEEP« parameter.

The **SOPHIE** ventilator generates a stable pressure level and compensates for pressure level changes due to leakage by automatically adjusting the amount of continuous flow characteristic of NCPAP and CPAP to the current ventilation situation.

By setting a flow limitation with NCPAP, the flow that is available for leakage compensation can be limited. The »MaxV'« flow limitation can be set between 20 and 6 l/min or switched off completely.

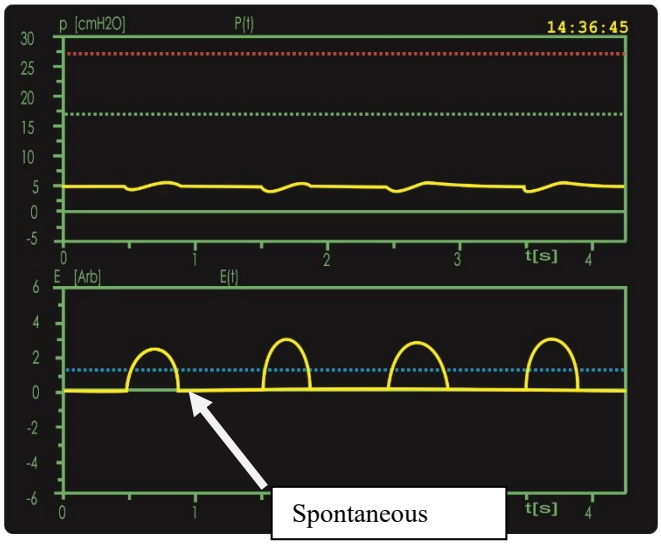


Fig. 127: Spontaneous breathing in NCPAP and CPAP

9.7.1 Backup ventilation

To activate enhanced apnea monitoring, the »ApD« parameter must be set to an interval between 4 and 16 s. This time should be set in accordance with the magnitude of the functional residual capacity (FRC), the oxygen reservoir of the patient.

The »ApD« parameter determines the time the ventilator waits for a detected spontaneous breath before it starts the backup ventilation. A spontaneous breath is detected as soon as an inspiratory effort of the patient, represented by the trigger signal, exceeds the preset trigger threshold.

If no spontaneous breath is detected within the apnea duration (ApD), the apnea counter increases. At the same time, a mandatory backup ventilation using the »Pmax«, »Insp«, »Exp« (»Freq«), and »Pattern« parameters is initiated.

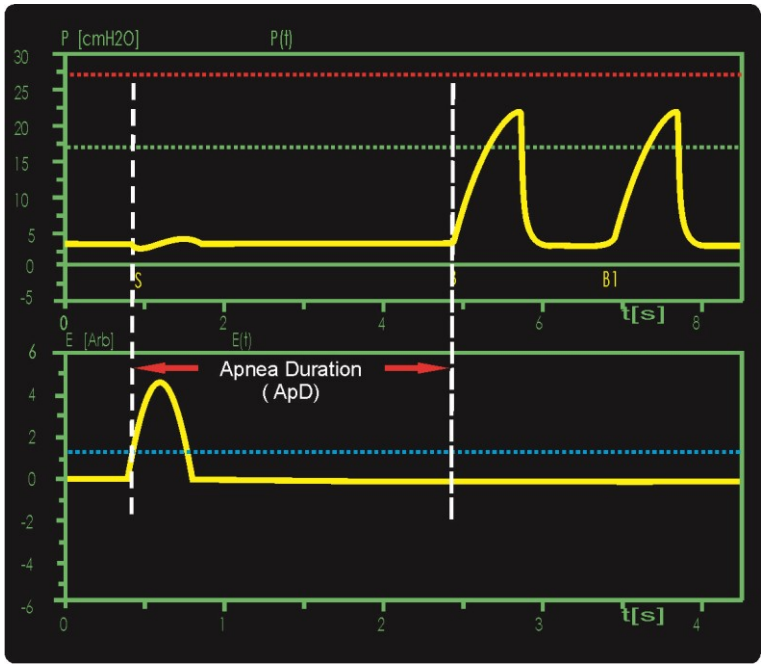


Fig. 128: NCPAP backup ventilation

These parameters must be set to ensure safe and sufficient ventilation in the case of an apnea event (discontinued spontaneous breathing).

Backup modes

A differentiation is made between the following backup options:

- Standard backup (BU)
- Frequency-controlled backup (FBU)

The backup mode is selected in the »Options« menu (see chapter 4.2.7.5).

9.7.1.1 Standard backup

The standard backup mode is indicated by the “BU” icon in the status bar. In addition, the »ApD«, »Insp«, »Exp«, and »Freq« parameters are automatically colored orange.

With the first spontaneous breath that exceeds the set trigger threshold, backup ventilation is stopped with an assisted breath.

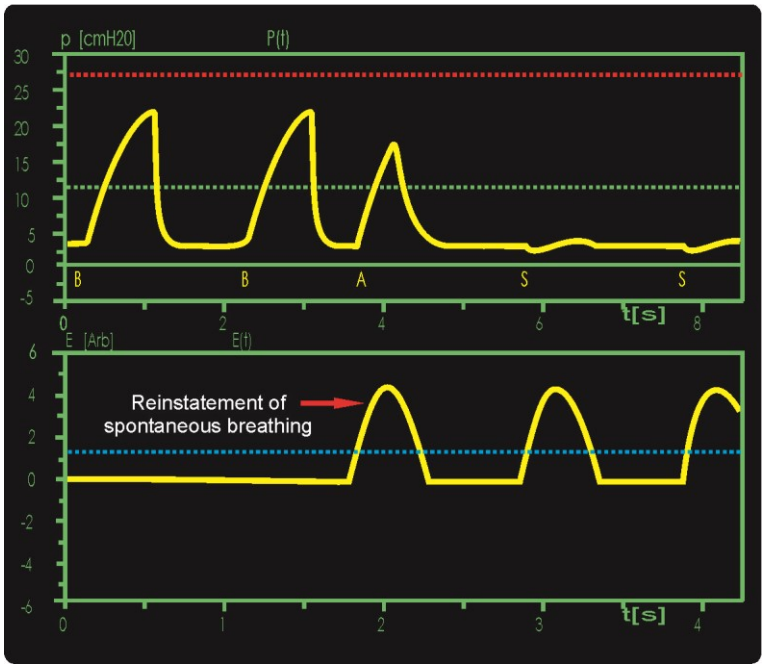


Fig. 129: NCPAP standard backup mode

9.7.1.2 Frequency-controlled backup ventilation

Frequency-controlled backup mode is indicated by the “FBU” icon and the associated interval (10, 30 or 60 s) in the status bar. In addition, the »ApD«, »Insp«, »Exp«, and »Freq« parameters are automatically colored purple.

If a spontaneous breath is detected after an apnea in frequency-controlled backup mode, backup ventilation is gradually reduced by 1/3 of the set backup frequency. The duration until the complete shutoff of backup ventilation is at least five times the duration of the set FBU interval (for example, 5 minutes with “FBU 60”). The apnea counter is reset when ApD is switched off, upon restart, or when the ventilation mode is changed.

The frequency of the backup ventilation should be set above the expected spontaneous frequency of the patient to eliminate the apnea-related accumulated excessive CO_2 during the first stage.

- In the first stage of the backup ventilation (B1), at least one spontaneous breath must be detected to enable the second stage, which will then start automatically once the first stage has elapsed.

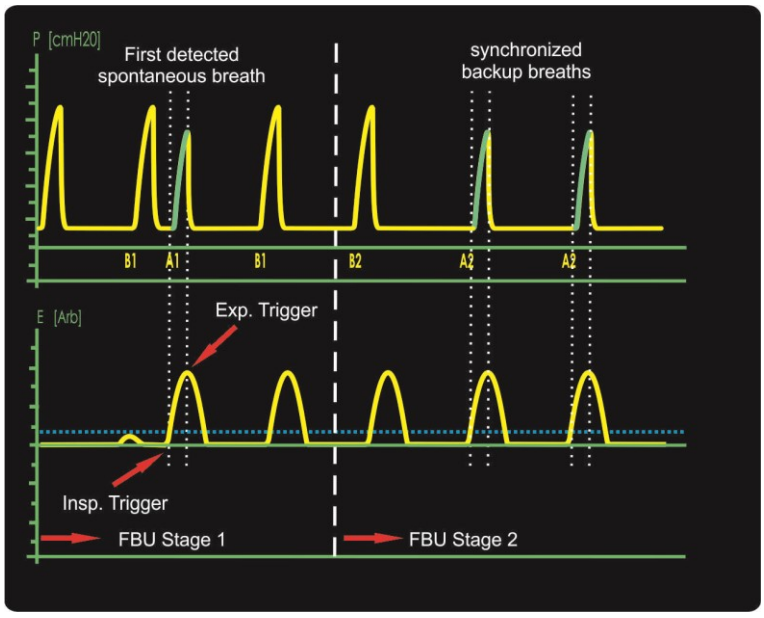


Fig. 130: Backup stages 1 and 2

- The second stage of the backup ventilation (B2) reduces the backup frequency by 1/3 by extending the expiration time. The extended expiration time allows patients to better sync their spontaneous breathing with the ventilator.

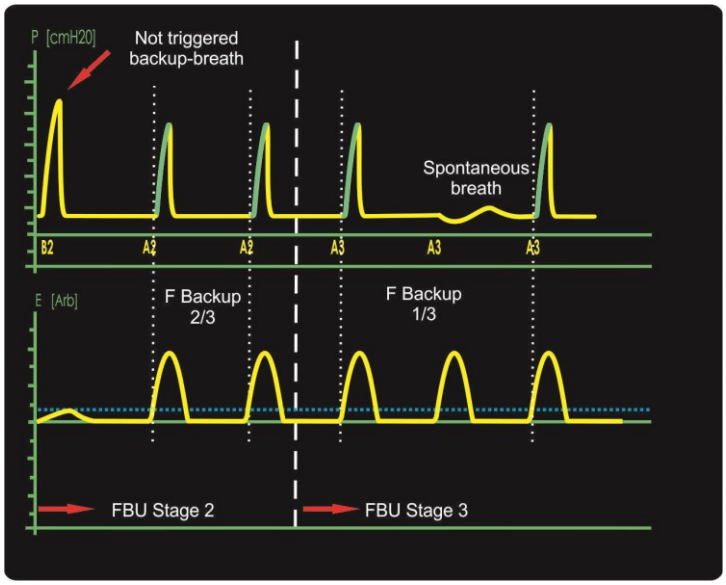


Fig. 131: Backup stages 2 and 3

- If no additional apnea is detected, the third stage of backup ventilation (B3) will be enabled, which will then start automatically once the second stage has elapsed. This reduces the backup frequency by another 1/3 by extending the expiration time. This allows the patient to breathe spontaneously between mandatory backup inspirations. From this stage of the backup ventilation, the ventilator also monitors the patient's average spontaneous respiration rate. The patient has to breathe spontaneously for at least 2/3 of the set backup frequency to enable the subsequent stage.

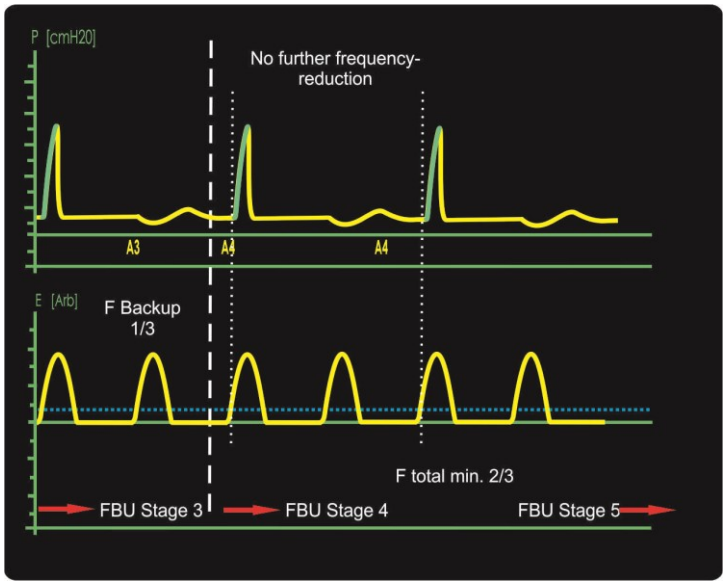


Fig. 132: Backup stages 3 and 4

- In stages four (B4) and five (B5) of the backup ventilation, there is no further reduction of the backup frequency. If the spontaneous breathing continues for at least 2/3 of the set backup frequency and no additional apnea is detected, the backup ventilation switches off automatically once the fifth stage has elapsed. The total duration of backup ventilation is therefore at least five times the duration of one FBU interval.
- If the conditions for enabling the next stage are not met within each stage (B1–B5), the backup ventilation automatically switches back to stage B1.

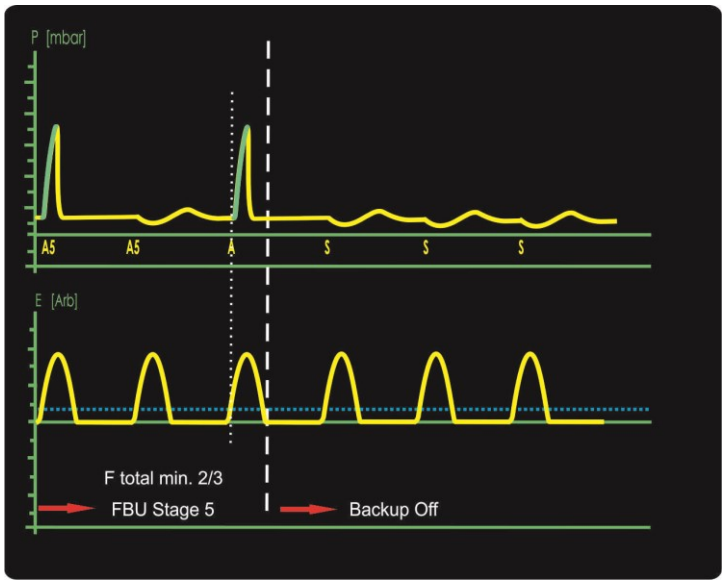


Fig. 133: Backup stage 5 and backup off

The current stage is indicated below the inflation pressure curve. A »B« indicates a controlled mandatory inflation and an »A« indicates an assisted inflation. The number after the character indicates the current stage. Pure spontaneous breaths are marked by a single »S«.

9.8 Synchronized NIPPV

SNIPPV ventilation presumes sufficient spontaneous breathing by the patient. Spontaneous breaths are supported by assisted mechanical inflation. The inflation is synced with the patient's inspiratory efforts using the inspiratory trigger (pressure trigger or, optionally, external trigger). If the external trigger was selected, the trigger signal also works as an expiratory trigger, syncing the end of the inspiration phase.

SNIPPV

To allow the patient maximum respiration control, the »Insp« and »Exp« (»Freq«) parameters can be inactivated by switching on apnea monitoring with the external respiration sensor activated. The parameters take effect only if no spontaneous breath was detected and backup ventilation is initiated after the apnea duration time (ApD) elapses.

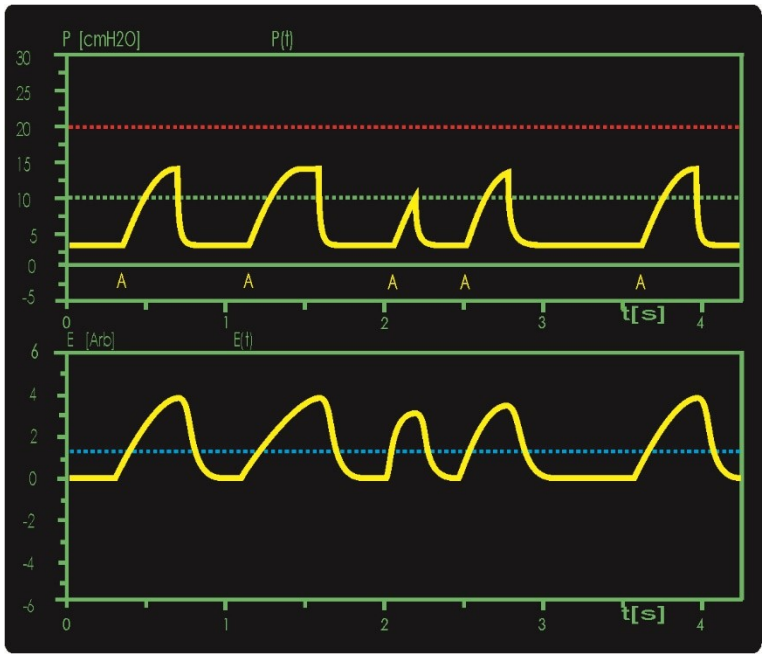


Fig. 134: Pressure support during SNIPPV

The inspiration time, and therefore the duration of pressure support, is determined by patients themselves when apnea monitoring is switched on.

The target duration of the linear and sinusoidal pressure pattern is still determined by the »Insp« parameter. If the spontaneous inspiration is longer than »Insp«, a pressure plateau forms until the start of expiration. For safety reasons, the inspiration is ended automatically after 700 ms.

If the spontaneous inspiration is shorter than »Insp«, the support pressure preset using the »Pmax« parameter is no longer reached with a linear or sinusoidal pressure pattern.

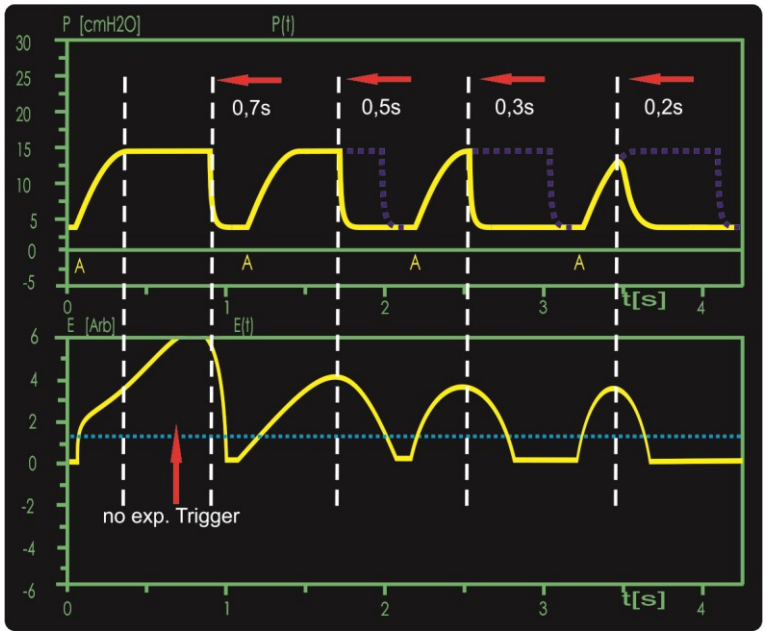


Fig. 135: Expiratory trigger during SNIPPV

9.8.1 Backup ventilation

To activate SNIPPV-B, the »ApD« parameter must be set to an interval between 4 and 16 s. This time should be set in accordance with the magnitude of the functional residual capacity (FRC), the oxygen reservoir of the patient. The »ApD« parameter determines the time the ventilator waits for a detected spontaneous breath before it starts the backup ventilation.

A spontaneous breath is detected as soon as an inspiratory effort of the patient, represented by the trigger signal, exceeds the preset trigger threshold.

If no spontaneous breath is detected within the apnea duration (ApD), the apnea counter increases. At the same time, a mandatory backup ventilation using the »Pmax«, »Insp«, »Exp« (»Freq«), and »Pattern« parameters is initiated.

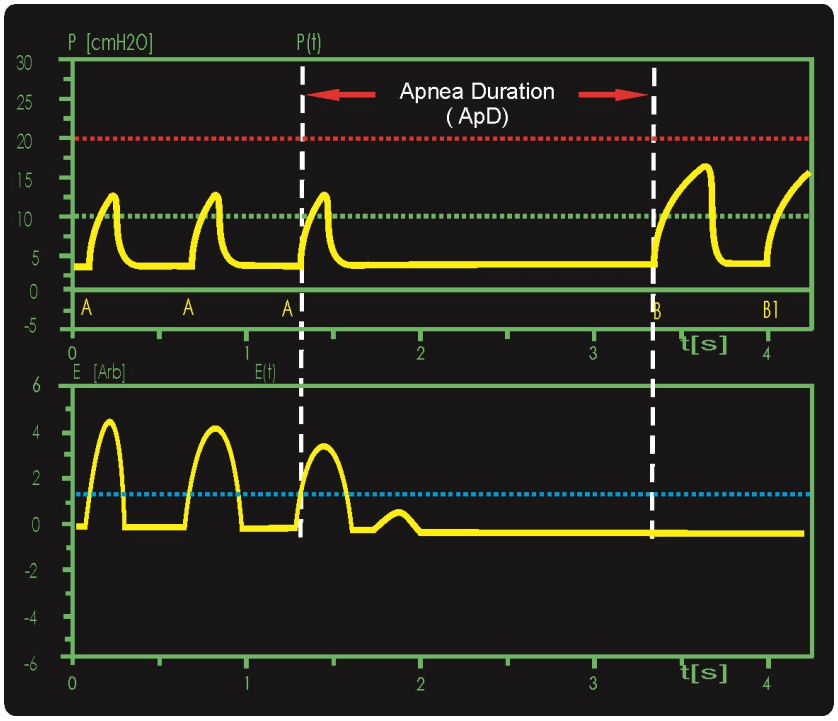


Fig. 136: SNIPPV with apnea monitoring

The »Pmax«, »Insp«, »Exp« (»Freq«), and »Pattern« parameters must be set to ensure safe and sufficient ventilation in the case of an apnea event (discontinued spontaneous breathing).

Backup modes

A differentiation is made between the following backup options:

- Standard backup (BU)
- Frequency-controlled backup (FBU)

The backup mode is selected in the »Options« menu (see chapter 4.2.7.5).

9.8.1.1 Standard backup

The standard backup mode is indicated by the “BU” icon in the status bar. In addition, the »ApD«, »Insp«, »Exp«, and »Freq« parameters are automatically colored orange.

On the first spontaneous breath that exceeds the set trigger threshold, backup ventilation is stopped.

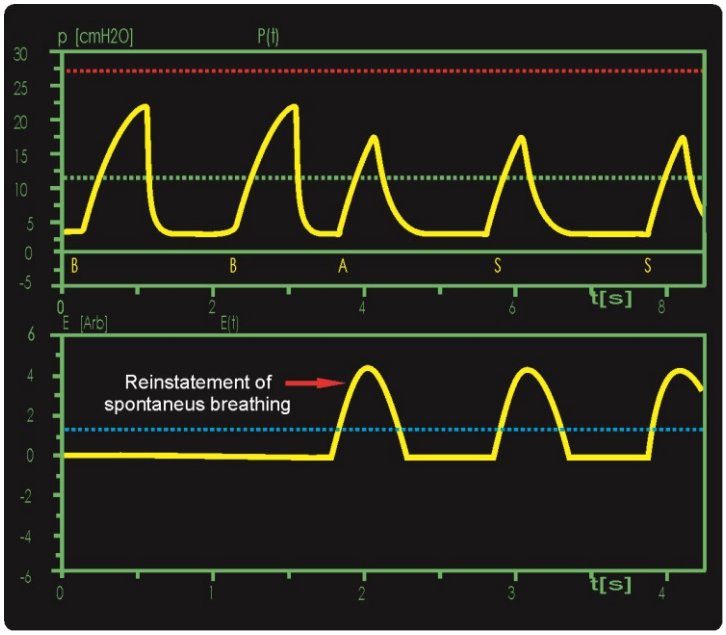


Fig. 137: SNIPPV standard backup mode

9.8.1.2 Frequency-controlled backup ventilation

Frequency-controlled backup mode is indicated by the “FBU” icon and the associated interval (10, 30 or 60 s) in the status bar. In addition, the »ApD«, »Insp«, »Exp«, and »Freq« parameters are automatically colored purple.

If a spontaneous breath is detected after an apnea in frequency-controlled backup mode, backup ventilation is gradually reduced by 1/3 of the set backup frequency. The duration until the complete shutoff of backup ventilation is at least five times the duration of the set FBU interval (for example, 5 minutes with “FBU 60”). The apnea counter is automatically reset when ApD is switched off, upon restart, or when the ventilation mode is changed. The frequency of the backup ventilation should be set above the expected spontaneous frequency of the patient to eliminate the apnea-related accumulated excessive CO_2 during the first stage.

- In the first stage of the backup ventilation (B1), at least one spontaneous breath must be detected to enable the second stage, which will then start automatically once the first stage has elapsed.

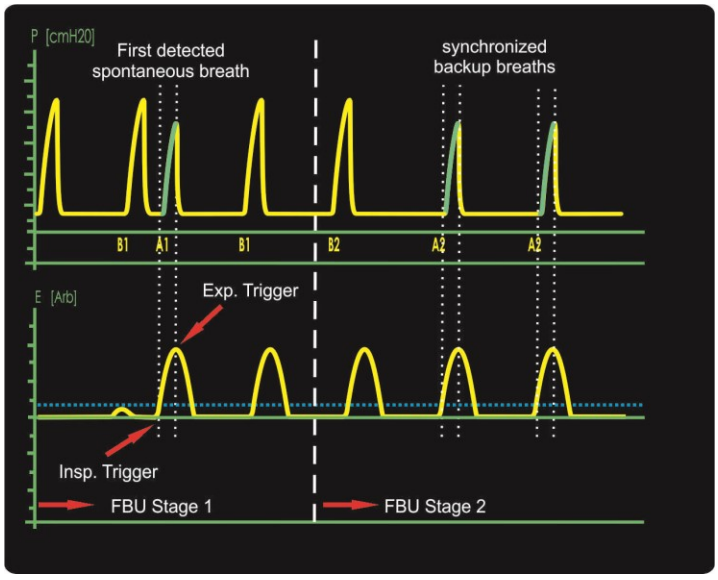


Fig. 138: Backup stages 1 and 2

- The second stage of the backup ventilation (B2) reduces the backup frequency by 1/3 by extending the expiration time. The extended expiration time allows patients to better sync their spontaneous breathing with the ventilator. If no additional apnea is detected, the third stage of backup ventilation (B3) will be enabled, which will then start automatically once the second stage has elapsed.

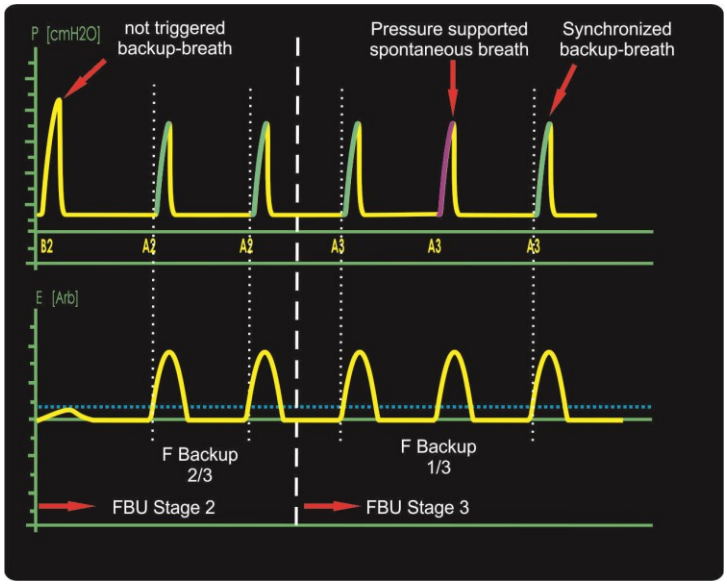


Fig. 139: Backup stages 2 and 3

- The third stage of the backup ventilation (B3) reduces the backup frequency by another 1/3 by extending the expiration time. This allows the patient to breathe spontaneously between mandatory backup inspirations.

  From this stage of the backup ventilation, the ventilator also monitors the patient's average spontaneous respiration rate. The patient has to breathe spontaneously for at least 2/3 of the set backup frequency to enable the subsequent stage.

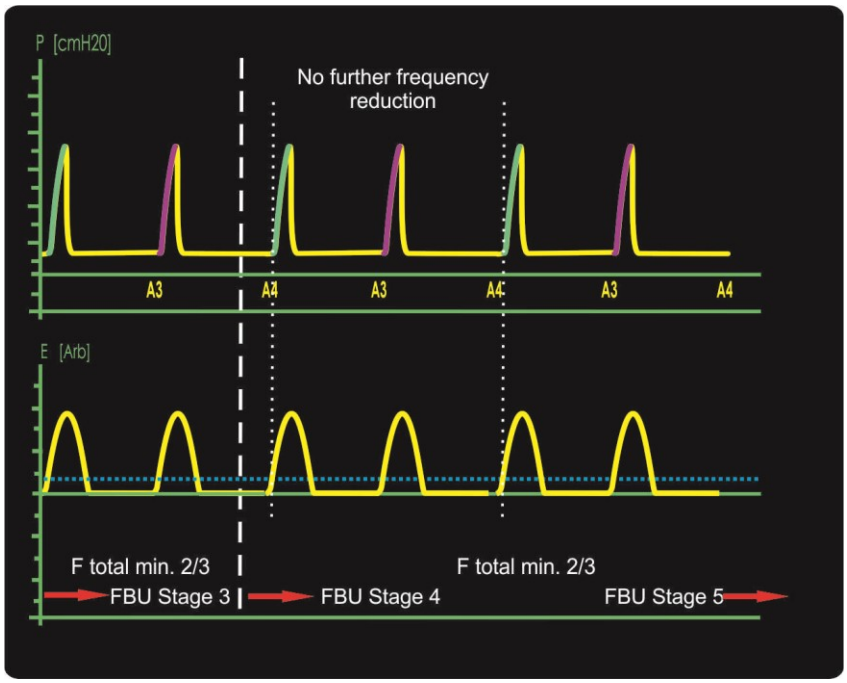


Fig. 140: Backup stages 3 and 4

- In stages four (B4) and five (B5) of the backup ventilation, there is no further reduction of the backup frequency. If the spontaneous breathing continues for at least 2/3 of the set backup frequency and no additional apnea is detected, the backup ventilation switches off automatically once the fifth stage has elapsed. The total duration of backup ventilation is at least five times the duration of the set FBU interval (for example, 5 minutes with "FBU 60").

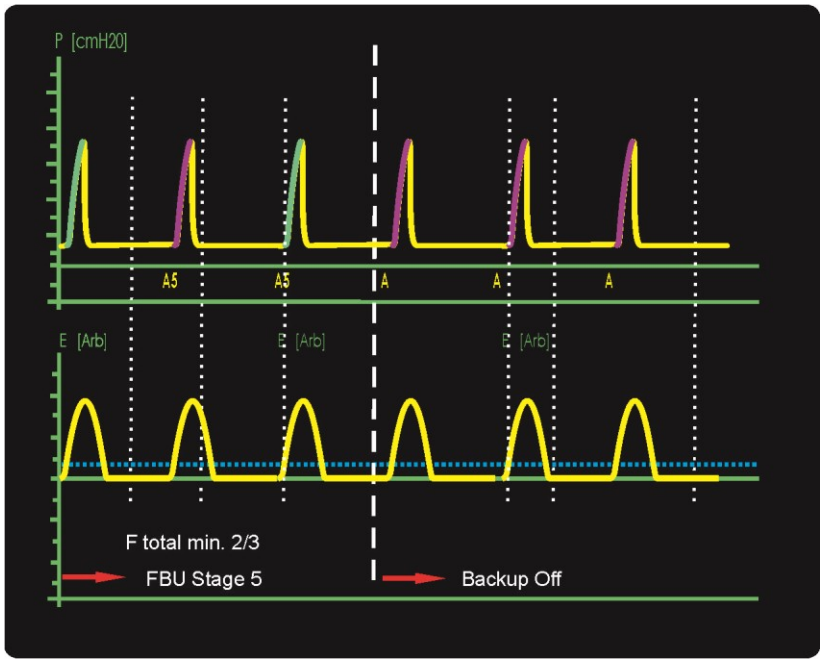


Fig. 141: Backup stage 5 and backup off

- If the conditions for enabling the next stage are not met within each stage (B1–B5), the backup ventilation automatically switches back to stage B1.

The current stage is indicated below the inflation pressure curve.
A »B« indicates a controlled mandatory inflation and an »A« indicates an assisted inflation. The number after the character indicates the current stage.

NOTE

The **SOPHIE** controls the ventilation pressure by continually adjusting the flow through the tube system to the current ventilation situation. By setting a flow limitation, this flow is limited. The desired ventilation pressure may no longer be reached. The flow limitation limit must therefore be set to a level where the target ventilation pressure is just reached.

10 Patient gas humidification

10.1 General

The patient gas temperature set in the heating menu is the target temperature that the patient gas should reach at the patient connection port. The measured temperature value displayed on the screen corresponds to the temperature measured at end of the inspiration tube (proximal). The built-in humidifier in the P7 patient system features an automatically regulated water bath heater. This allows you to modify the humidity of the patient gas. Setting the humidity level determines the temperature of the humidifier. Increasing the humidity level results in an increase of the temperature in the water bath relative to the set patient gas temperature. The humidity capacity of the gas, and therefore the humidity, is increased due to the increased temperature. Lowering the humidity level, in turn, reduces the humidity capacity, and therefore the humidity.

10.2 Special features of the P7 patient system

One of the unique features of the P7 system is the combined inspiration/expiration valve located downstream of the humidifier.

The humidification chamber therefore has no effect on the compressible volume of the system. This is especially useful when ventilating very small premature infants and in HFO.

Because of this valve arrangement, the humidification chamber is pressurized to the system pressure for the **SOPHIE**.

The pressurized gas is charged with a certain amount of water in the humidifier. When the patient gas expands to breathing pressure in the patient tube, its volume increases. However, the increased volume of patient gas still contains the same amount of water.

This means that a smaller amount of water is transported for every liter of patient gas. As a result, the gas becomes drier. The **SOPHIE** automatically compensates this effect by adjusting the humidifier temperature.

10.3 Humidity and flow

Like nearly all standard commercial humidifiers, the P7 is what is known as an evaporator. It uses the principle of evaporation and enriches the gas with water molecules. The quantity of water molecules depends on the temperature and the surface area available for evaporation. For conventional ventilation, the ventilation system has a continual flow of about 5 l/min. Under these flow conditions, the humidifier is capable of sufficiently saturating the gas for the patient. For special therapies, such as nasal “CPAP” or “HFO”, however, the flow can easily more than double. In order to compensate for a reduction in the humidity at high flow rates, more water molecules must be available in the humidifier. This can be compensated by a higher humidity level.

NOTE

The **SOPHIE** provides a separate humidity level for each of the three basic ventilation modes: “conventional”, “HFO”, and “NIV”. If the ventilation mode is changed, the corresponding level is automatically set.

The default humidity levels can be individually adjusted by the FRITZ STEPHAN GMBH customer service team.

10.4 Condensation in the tube system

Active patient gas humidifiers typically generate a relative humidity of close to 100%, that is, near the saturation limit. The amount of water that the gas can absorb depends on the temperature of the gas. The maximum amount of water in one liter of air at a temperature of 37°C is about 44 mg. The amount of water in the gas is also called the absolute humidity. The relative humidity is then 100%.

If the gas cools, the humidity capacity of the gas is also reduced. The gas can no longer retain the amount of water it has previously absorbed. The excess water condenses and forms a fine mist. This mist, in turn, precipitates on the walls of the patient tubes. In order to prevent the patient gas from cooling below this “dew point”, the patient tubes are electrically heated. There are situations, however, in which merely heating the tubes is not sufficient to stabilize the temperature in the tube system:

10.4.1 Air conditioned rooms

Air conditioners, conforming to international standards, generate laminar air flows along the walls. These cold air flows can negatively affect the heating performance of the reusable patient tube systems and promote condensation. The reusable patient tube systems can be protected with the following optional insulating tube warmers:

1 007 60 007 Length 730 mm for heated section of the incubator tube system

1 007 60 004 Length 1130 mm for heated section of the warming bed tube system

WARNING

Do not use tube warmers for reusable patient tube systems with the disposable patient tube system (art. no. 100761300)!

The insulation can cause heat buildup that weakens the material and can damage the tube!

The tube warmers are wrapped around the heated sections of the inspiration and expiration tubes like a jacket and fastened using a Velcro strip.

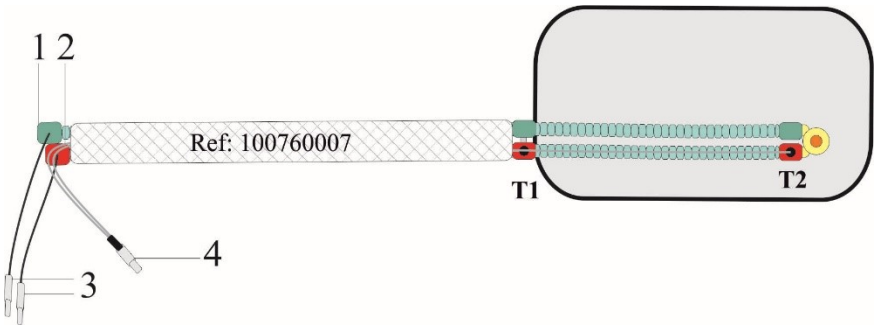


Fig. 142: Using the tube warmer 100760007

1 Expiration tube
2 Inspiration tube
3 Tube heating connections
4 Temperature sensor connection
T1 Distal temperature sensor
T2 Proximal temperature sensor

CAUTION

To measure the temperature accurately, the distal temperature sensor (T1) must be positioned outside the incubator.

10.4.2 Low incubator temperature

If the incubator temperature is more than 4°C below the set patient gas temperature, the heating system can no longer compensate for the difference in temperature. The target temperature for the patient gas at the Y piece is therefore no longer reached. If the patient gas temperature falls below the dew point, condensate forms.

The reusable patient tube system for incubators can be fitted with the optional insulated tube warmer:

1 007 60 003 Length 390 mm for cold section

to reduce the drop in temperature of the patient gas along the cold section in the incubator.

WARNING

Do not use tube warmers for reusable patient tube systems with the disposable patient tube system (art. no. 100761300)!

The insulation can cause heat buildup that weakens the material and can damage the tube!

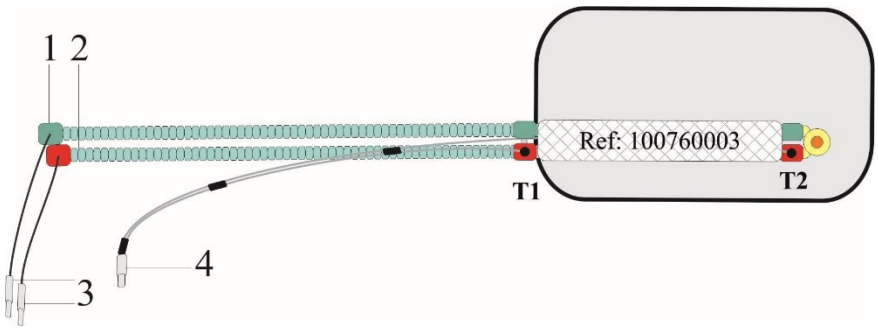


Fig. 143: Using the tube warmer 100760003

1 Expiration tube
2 Inspiration tube
3 Tube heating connections
4 Temperature sensor connection
T1 Distal temperature sensor
T2 Proximal temperature sensor

CAUTION

To measure the temperature accurately, the distal temperature sensor (T1) must be positioned outside the incubator.

The tube warmer is wrapped around the non-heated sections of the inspiration and expiration tubes like a jacket and fastened using a Velcro strip. The disposable patient tube system (art. no. 100761300) can be fitted with the optional insulated tube warmer:

1 007 60 507 Length 390 mm for cold section

to reduce the drop in temperature of the patient gas along the cold section in the incubator.

NOTE

The disposable patient tube system (art. no. 100761300) is heated along the entire expiration tube and does not require insulation. The tube warmer is only used for the inspiration tube!

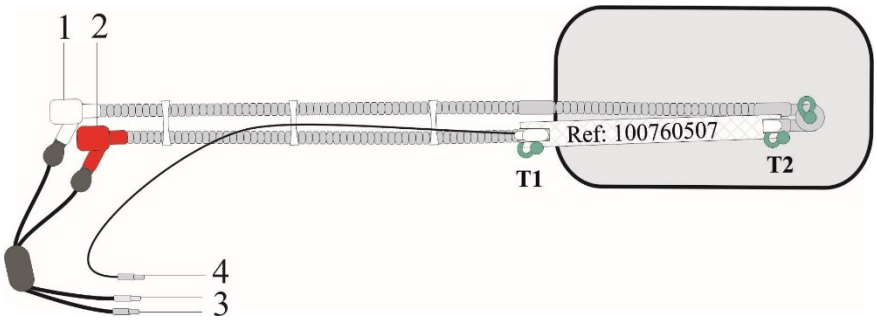


Fig. 144: Using the tube warmer 100760507

1	Expiration tube	4	Temperature sensor connection
2	Inspiration tube	T1	Distal temperature sensor
3	Tube heating connections	T2	Proximal temperature sensor

CAUTION

To measure the temperature accurately, the distal temperature sensor (T1) must be positioned outside the incubator.

NOTE

At differences of > 4°C between the incubator temperature and the patient gas temperature, use a tube warmer inside the incubator.

Alternatively, the reusable patient tube system for warming beds can be used in these types of situations. This tube system has a longer heating section, which was designed to prevent condensation in open warming beds.

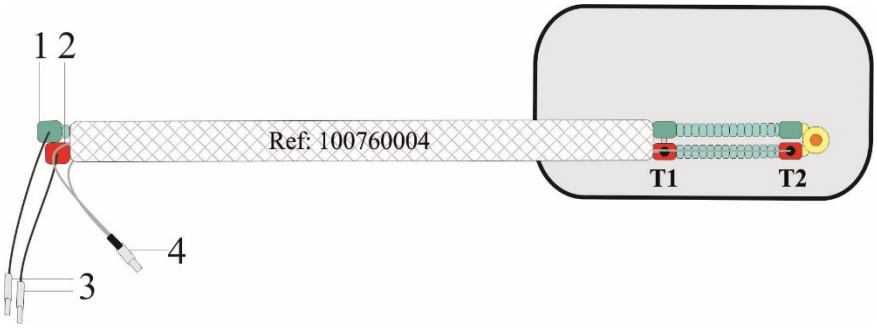


Fig. 145: Using the tube warmer 100760004

1	Expiration tube	4	Temperature sensor connection
2	Inspiration tube	T1	Distal temperature sensor
3	Tube heating connections	T2	Proximal temperature sensor

The heated section of the reusable tube system for warming beds can be insulated with an optional tube warmer if ambient conditions require it.

10.4.3 Sensor positioning

The temperatures of the P7 patient system are controlled by an intelligent temperature management program. It measures the patient gas temperature at the outlet of the water bath, at the end of the heating section, and at the end of the inspiration tube. Depending on the situation, the heaters for the humidifier and the patient tubes are regulated. If the distal sensor at the end of the heating section is accidentally positioned inside the incubator, then its temperature will cause a misreading.

Direct irradiation of the sensor by a heating lamp can also lead to the temperature reading being too high.

CAUTION

Avoid direct irradiation of temperature sensors!

Direct irradiation can negatively affect the temperature measurement and thus the humidity of the patient gas!

11 Functional description

11.1 General

Older ventilators are based on the constant flow principle: After configuring a constant basic flow, mechanical ventilation occurs by opening or closing an expiration valve. By altering the basic flow, the inspirational pressure pattern can be altered to a certain extent. The drawbacks of this method are a severely limited choice of desired inspiration patterns and unnecessarily high gas consumption.

SOPHIE, on the other hand, embodies a new generation of ventilators for infants, with a different ventilating principle that permits a choice of three different inspiration pressure patterns. This presents a new level of ventilation quality by offering the physician a much greater variety of options. There is no longer a need for variable basic flow setup.

For improved purging of the expired gases in the Y piece, the **SOPHIE** has a fixed basic flow of about 3–5 l/min.

11.1.1 Description of the pneumatic system

The **SOPHIE** ventilator is made up of several different pneumatic functional units, which are explained in this chapter.

Oxygen and compressed air are fed into the device via the gas inlet block sub-assembly (A). Safety valves (SV1/SV2) restrict the input pressures to a maximum of 7 bar. In addition to the inlet filters (F1/F2), the compressed air inlet can also be fitted with a membrane dryer (TR1). The O_2 sensor measures the inspiratory oxygen concentration using the sidestream technique. For calibration purposes, compressed air from the blender is directed at the sensor via the valve MV2.

The oxygen and compressed air are mixed in the EGB sub-assembly (B). The oxygen concentration is regulated by two proportional valves (PV1/PV2) while a further proportional valve (PV3) regulates the pressure in the buffer volume.

The gas mixture is then fed through two filters (F3/F4) to the connection block (C) on which the patient component (D) is docked.

Here, additional valves release the gas supply for the optional refill system (MV3) and control the emergency air valve (MV4).

When the device is in standby or in the event of a fault, the pneumatic emergency air valve (E) for the patient component opens to enable the patient free inspiration and expiration. The check valves RV1 and RV2 control the direction of the gas flow and reduce the level of CO_2 re-inhalation. The additional valve (RV3) prevents excessively high negative pressures. The adjustable positive pressure valve (ÜV1) limits the pressure in the inspiration tube.

The system is designed so that when operating normally or in the event of the first fault, only the patient component is contaminated. It can be fully decoupled from the ventilator for cleaning. At the patient component inlet (D), the fresh gas is fed through the integrated humidifier to the patient valve (double piston valve).

Patient valve

The patient valve controls both the inspiration and expiration of the mechanical ventilation. In essence, it consists of valve housing with slots for fresh gas intake, inspiration, expiration, and a patient gas outlet. A valve piston is fitted in this housing, which can be moved lengthwise. The valve piston is magnetically coupled to an electrodynamic drive used to move the piston.

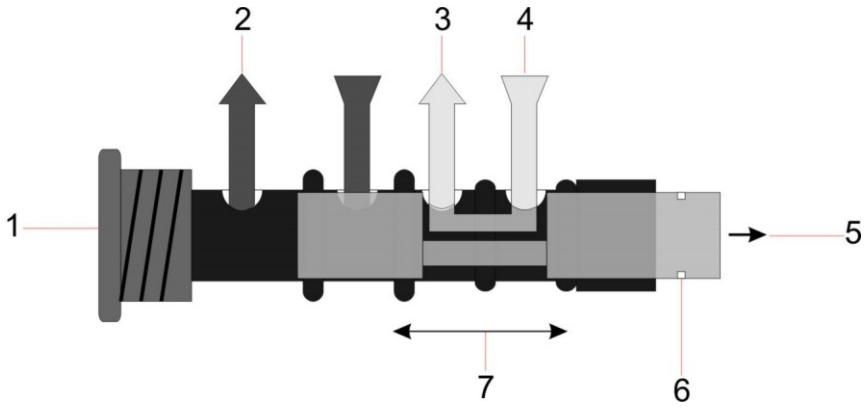


Fig. 146: Patient valve P7, valve piston in the inspiration position

1	Valve housing	5	Magnetic coupling
2	Outlet	6	Visual path measurement
3	Patient inspiration	7	Valve piston movement
4	Fresh gas		

During inspiration, the fresh gas is supplied to the patient at a continuous positive pressure via the inspiration path, causing the ventilation pressure to rise. When the setpoint value for the ventilation pressure is reached, the piston is retracted and the inspiration path for fresh gas is closed. When entering the expiration phase, the piston is moved to the expiration

position, which opens the expiration path and evacuates the expiration gas from the lungs.

During high frequency oscillation (HFO), an ejector in the patient component creates an additional negative pressure, which allows active expiration. The ejector is driven by the valves (MV8/MV9) at two levels.

During normal operation and with HFO, the expiration gases are expelled from the system via a silencer.

Pressure and flow measurement

Both the inspiratory and the expiratory pressure are measured using two separate pressure sensors (DS5/DS6). These values are used to calculate the airway pressure at the Y piece.

The volume flow to the patient is determined using a pneumotachograph (PNT) by means of a differential pressure measurement.

The valves MV5 and MV6 cyclically switch the differential pressure sensor (DDS1) to atmospheric pressure for zero point calibration.

The pressure measurement lines are continually purged with fresh gas via the chokes D2–D5 to remove any condensate from the lines.

Medication nebulization

A pneumatic medication nebulizer can be connected to the aerosol outlet. A gas mixture is used as the driving gas and supplied via the valve (MV10) with the same oxygen concentration as the inspiratory gas at the aerosol port. This has little impact on the inspiratory oxygen concentration.

Refill system

The optional refill system (A03861009) controls the water level in the humidifier to ensure steady humidification. The tube for the sterile water bag is inserted into a pinch valve (QV1), which releases the water flow into the humidifier. The pinch valve (QV1) is pneumatically controlled by the valve MV3.

The sterile water bag is additionally pressurized by a pressure regulator (DR1) to enable water inflow against the positive pressure of the humidifier. The check valve (RV4) prevents the water from flowing back into the ventilator.

External trigger

The use of an external trigger makes it possible to record spontaneous breaths without any contact with the ventilator’s gas system.

The pressure changes to the pressure capsule are recorded by the pressure sensor (DS7) in the “external trigger” sub-assembly (A03861099).
The valve (MV7) cyclically activates the capsule with respect to the atmosphere to calibrate the zero point.

11.1.2 Description of the automatic refill system

The advantage of the optional automatic refill system is that the humidifier bottle retains an almost constant fill level. This allows optimal breathing gas conditioning.

The automatic refill system can be switched on and off in the “Heating” menu (see chapter 4.2.5). When the system is active, it monitors the water level of the humidifier bottle via three sensors and refills it automatically if required.

The refill system is controlled by pre-defined filling periods, and, depending on the situation, also by the water level. The length of the filling periods depends on the situation (initial filling or refilling), the ventilation mode, and the pressure in the humidifier bottle.

See chapter 1.7.10 for information about the various filling periods.

If the water level cannot be detected once the refill system starts, “initial”filling starts and continues until water reaches the bottom water level sensor, however for no more than 93 s. For this purpose, driving gas is pumped into the sterile water bag and the pinch valve is opened.

This is the starting point for the “normal” refilling process.

NOTE

To prevent the humidifier from overheating, heating is deactivated until the minimum water level is reached.

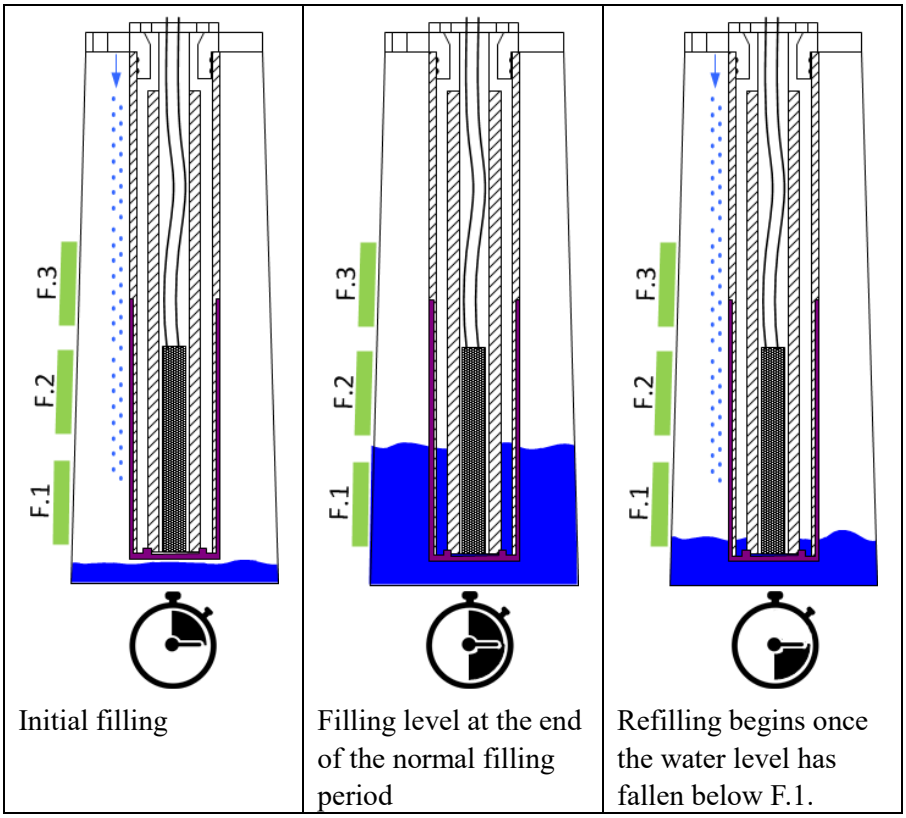
During “initial filling”, this is indicated after a delay of 15 s by two alarms: “Waterlevel low” and “Heating off”.

During “normal filling”, the delay equals the maximum fill time.

Depending on the ventilation mode, this ranges between 4 and 19 s.

Once the filling period expires or once the middle water level sensor is reached, the driving gas is switched off and the pinch valve is closed.

Refilling starts as soon as the water level falls below the minimum water level, which is detected by the bottom sensor.



Initial filling	Filling level at the end of the normal filling period	Refilling begins once the water level has fallen below F.1.

Fig. 147: Automatic refilling with the refill system

If the sensors cannot detect the water level within the permitted filling period, the “Waterlevel?” alarm is assigned medium priority and triggered to sound.

If the water level detected is not plausible, the “Refill fail?” alarm is assigned medium priority and triggered to sound.

The refilling system is deactivated when either alarm sounds.

CAUTION

The refilling system remains deactivated if the water level is not plausible or if the maximum filling period is exceeded, even if the reason for the alarm no longer exists.

To activate automatic refilling, the user must manually switch it off and then on again in the menu.

If the water level still exceeds the maximum allowed level, e.g. because of manual refilling, the alarm is escalated to “Waterlevel high” and assigned high priority.

11.2 Pneumatic diagram

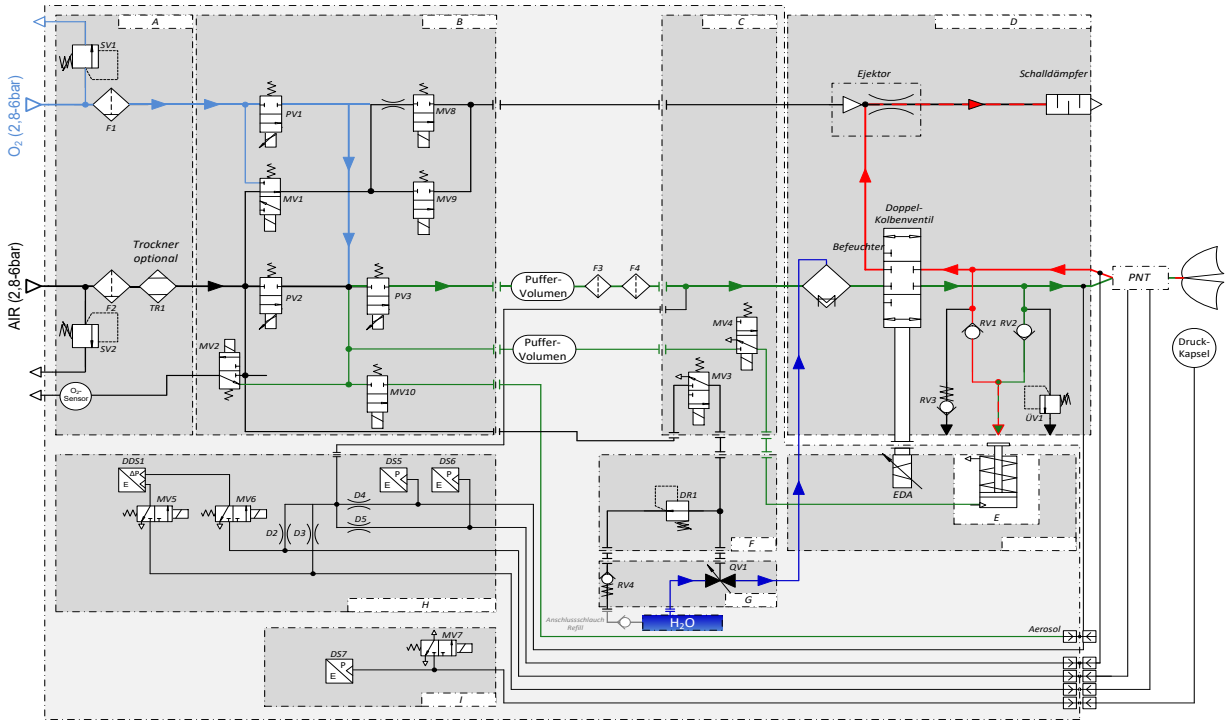


Fig. 148: Sophie, pneumatic diagram with patient component P7

	O_2 flow	SV1	O_2 safety valve	MV9	Ejector control valve
	AIR flow	SV2	AIR safety valve	MV10	Aerosol control valve
	Gas mixture	F1/F2	Inlet filter	F3/F4	Attenuation filter
	Exp. gas	TR1	Membrane dryer	RV1	Emergency air circuit valve (exp.)
	H_2O	PV1	O_2 proportional valve	RV2	Emergency air circuit valve (insp.)
	Measurement tube	PV2	AIR proportional valve	RV3	Negative pressure safety valve
A	Gas inlet block	PV3	Fresh gas proportional valve	RV4	Refill check valve
B	Electrical gas blender	MV1	Substitution valve	DR1	Refill pressure regulator
C	Connection block	MV2	O_2 calibration valve	QV1	Refill pinch valve
D	Patient component P7	MV3	Refill control valve	DDS1	Differential pressure sensor
E	Emergency air valve	MV4	Control valve for emergency air valve	DS5	Inspiration pressure sensor
F	Refill control block	MV5	Flow calibration valve	DS6	Expiration pressure sensor
G	Refill pinch arm	MV6	Flow calibration valve	DS7	Pressure capsule pressure sensor
H	Flow zeroing block	MV7	Pressure capsule calibration valve	ÜV1	Positive pressure safety valve
I	External trigger	MV8	Ejector control valve	D2-D5	Purge flow chokes

Tab. 15: Sophie pneumatic diagram key

12 Troubleshooting

12.1 List of errors

The **SOPHIE** has a monitoring concept which ensures patient safety and reacts immediately to errors.

Safety mode

The emergency air valve connects the patient tube system to the atmosphere – the patient can breathe spontaneously.

All valves are switched off, including the valves for the compressed air (AIR) and oxygen (O_2). The patient is connected to the atmosphere by the emergency air valve.

The patient valve control is switched off.

Ventilate the patient immediately with a separate ventilation alternative.

NOTE

In order to ensure optimal service, note the version number of the installed software before contacting the FRITZ STEPHAN GMBH customer service team. The version number can be found in the “Main menu” under “Options” ➔ “Communic.” ➔ “System”.

TA	Technical alarm	Alarm displays a technical error
HW	Test mode message	Alarm that is displayed only in test mode
LP	Low priority alarm	The user should be aware of the situation and attentive
MP	Medium-priority alarm	The user must respond quickly
MHP	Alarm of at least medium priority	Alarm that escalates from medium to high priority after 30 s if the cause of the alarm has not been eliminated.
HP	High priority alarm	The user must respond immediately

Tab. 16: Alarm types and priorities

Alarm text	Prio./ Type	Cause	Corrective action
EEPROM values?	HW	• Error in checksum of calibration data memory	• Reboot the device • Device may continue to be used only under continuous monitoring of device functions • Contact FRITZ STEPHAN GMBH customer service
Init MC xxxxxxxx	HW	• Microcontroller initialization error	• Check the sensor connections • Contact FRITZ STEPHAN GMBH customer service
Init PC xxxxxxxx	HW	• PC initialization error	• Check the sensor connections • Contact FRITZ STEPHAN GMBH customer service
Bat. Calibration	LP TA	• Battery > 12 months not calibrated • Max. number of charge/discharge cycles reached since the last calibration	• Calibrate the battery (completely charge, completely discharge, and recharge)
Speaker fail	LP TA	• Speaker malfunction	• Device may continue to be used only under continuous monitoring of device functions • Replace device as soon as the patient's situation permits • Replace speaker • Contact FRITZ STEPHAN GMBH customer service
Sound gen. fail	LP TA	• Sound generator detected as defective for more than 3 s	• Device may continue to be used only under continuous monitoring of device functions • Replace device as soon as the patient's situation permits • Contact FRITZ STEPHAN GMBH customer service
Power supply?	LP TA	• **SOPHIE** was disconnected from mains supply	• Check the mains supply

Alarm text	Prio./ Type	Cause	Corrective action
Battery low	MP TA	• Heating on: remaining battery life < 10 min • Heating off: remaining battery life < 20 min	• Check power supply and restore if necessary
Apnea	MP	• No inspiration detected for more than 15 s	• Check the patient's condition • Switch to a controlled ventilation mode as needed
			• Check trigger threshold • Check trigger method
Respiratory rate high	MP	• Patient is breathing for more than 15 s at a respiratory rate above the alarm limit setting	• Check the patient's condition! • Check the alarm limits • Check the trigger threshold and correct if necessary
Air inlet	MP TA	• Inlet pressure AIR < 3 bar and difference between FiO_2 setting and measured value > 30 vol% for more than 20 s • Inlet pressure AIR < 2 bar for more than 3 s	• Check the connection to the central gas supply (CGS)
		• Blender defective	• Contact FRITZ STEPHAN GMBH customer service
Pressure diff.?	MP TA	• Pressure difference too large between inspiratory and expiratory pressure sensor Safety mode if the pressure difference exceeds 20 cmH_2O for 20 ms or 10 cmH_2O for 400 ms	• Check and possibly replace the patient tube system and the pressure measurement line
		• Internal pressure measurement disrupted	• Ventilate the patient immediately with a separate ventilation alternative • Contact FRITZ STEPHAN GMBH customer service
EEPROM timeout	MP TA	• Write/read error in the calibration data memory	• Switch off the **SOPHIE** and contact the FRITZ STEPHAN GMBH customer service team

Alarm text	Prio./ Type	Cause	Corrective action
Ext. Trigger	MP TA	• Board for external trigger (optional) detected as defective for more than 5 s	• Disable external trigger and select a different suitable ventilation mode • Contact FRITZ STEPHAN GMBH customer service
FiO_2 high	MP	• Measured FiO_2 is above the set upper alarm limit for more than 6 s (after changing the FiO_2 alarm limits, the alarm is suppressed for 60 s)	• Check the FiO_2 upper limit and adjust if necessary
		• O_2 sensor not calibrated	• Start O_2 calibration
		• Blender defective	• Contact FRITZ STEPHAN GMBH customer service
FiO_2 low	MP	• Measured FiO_2 is below the set lower alarm limit for more than 6 s • (after changing the FiO_2 alarm limits, the alarm is suppressed for 60 s)	• Check the FiO_2 lower limit and adjust if necessary
		• O_2 sensor not calibrated	• Start O_2 calibration
		• Blender defective	• Contact FRITZ STEPHAN GMBH customer service
Heating H1 fail	MP TA	• Humidifier's heating element is defective	• Replace the patient component
Heating off	MP TA	• Battery capacity too low (< 20%) for more than 1 s	• Restore the mains power supply
		• Temperature sensors detected as defective for more than 1 s	• Check the temperature sensor and replace if necessary
		• Temperature > 41°C for more than 1 s	• Check the patient tube system for accidental covering.
		• Fill level of the humidifier bottle is too low for more than 1 s	• Fill the humidifier bottle
VT leak > 50%	MP	• The measured inspiratory volume (Vt insp) is at least twice the expiratory volume (Vt exp)	• Check the patient's condition • Check the patient tube system • Check the position of the tube/mask/prong

Alarm text	Prio./ Type	Cause	Corrective action
		• Measured PEEP more than 10% but at least 2 mbar (cmH_2O) below the PEEP setting (only when leakage alarm is ON)	• Check the tube system • Check MaxV' and increase if necessary • Check the position of the mask/prong
		• Current leak is at least double as high as the leak initially determined (only when leakage alarm is ON)	• Check the tube system • Check the position of the mask/prong • Adjust the leakage alarm to the new leakage situation by switching on and off again
Min. volume high	MP	• Expiratory breathing volume is above the set upper alarm limit for more than 9 s	• Check that the manual settings are correct and plausible, adjust if necessary
Blender	MP TA	• Gas blender detected as defective for more than 18 s	• Contact FRITZ STEPHAN GMBH customer service
Refill fail	MP TA	• Sensor error in the automatic refill system detected for more than 1 s	• Switch off the refill • Check the water level regularly and refill as needed • Contact FRITZ STEPHAN GMBH customer service
PSU temperature	MP TA	• PSU temperature increased with less than 50% battery capacity remaining. Battery charging stops	• Check the fan and ventilation openings • Replace the dust filter on the fan • Device may continue to be used only under continuous monitoring of device functions
O_2 sensor fail?	MP TA	• Oxygen sensor defective or depleted	• Monitor FiO_2 externally • Check the oxygen sensor and replace if necessary
P-Osc high	MP	• Measured P_{OSC} above the set upper alarm limit	• Check that the manual settings are correct and plausible, adjust if necessary
P-Osc low	MP	• Measured P_{OSC} below the set lower alarm limit	• Check that the manual settings are correct and plausible, adjust if necessary
P-Mean low	MP	• Measured Pmean below the set lower alarm limit for more than 4 s	• Check that the manual settings are correct and plausible, adjust if necessary

Alarm text	Prio./ Type	Cause	Corrective action
Oxygen inlet	MP	• Inlet pressure O_2 < 3 bar and difference between FiO_2 setting and measured value > 30 vol% for more than 20 s • Inlet pressure O_2 < 2 bar for more than 3 s	• Check the connection to the central gas supply (CGS)
		• Blender defective	• Contact FRITZ STEPHAN GMBH customer service
Tube heating fail	MP	• Tube heating defective or not plugged in	• Check whether the connector is securely connected • Replace the patient tube system
Low sys. pressure	MP TA	• Internal pre-pressure of the patient gas mixture below 10% of the nominal value for more than 5 s Ventilation only possible with lower ventilation pressure	• Check the patient tube system for disconnected parts • Check the gas supply • Ventilate the patient immediately with a separate ventilation alternative
Temperature high	MP	• Measured proximal temperature above the set upper alarm limit for more than 6 s	• Check that the manual settings are correct and plausible, adjust if necessary
		• Temperature sensor is defective	• Replace the temperature sensor
Waterlevel?	MP TA	• Water level not reached within the predefined time when automatically refilled.	• Check the sterile water bag • Check the water supply lines • Check the connections • Push the valve arm down • Switch off refill and switch back on again
Temp. sensor	MP TA	• Temperature sensor not connected or malfunctioning	• Check the temperature sensor connection • Replace the temperature sensor
Temp. wb	MP	• Water bath (WB) temperature sensor defective Heating deactivated	• Replace the patient component • Continue operation without heating, when possible

Alarm text	Prio./ Type	Cause	Corrective action
Temperature low	MP	• Measured proximal temperature below the set lower alarm limit for more than 6 s	• Check that the manual settings are correct and plausible, adjust if necessary
		• Incorrect patient tube system for the application	• Replace the patient tube system with one that has an extended heating section
		• Tube heating is defective	• Check the patient tube system's connections and replace the patient tube system if necessary
		• Temperature sensor is defective	• Replace the temperature sensor
VT low/Pmax?	MP	• Target volume (VtTar) cannot be reached with the set maximum pressure (Pmax) for more than 14.7 s (PSV only)	• Check the Pmax setting and adjust if necessary
Vt(exp) high	MP	• Measured breathing volume above the set upper alarm limit for more than Tinsp+Texp (max. 2 s)	• Check that the manual settings are correct and plausible, adjust if necessary
Waterlevel low	MP TA	• Water level in the humidifier too low for more than 10 ms	• Check the water level, top up if necessary
EDA measure	MP TA	• Error in monitoring the patient valve	• Device may continue to be used only under continuous monitoring of device functions • Contact FRITZ STEPHAN GMBH customer service
Min. volume low	MHP TA	• Expiratory breathing volume below the set alarm limit for more than 9 s	• Check that the manual settings are correct and plausible, adjust if necessary • Check the patient tube system for leakage • Check the flow sensor
		• Incorrect flow sensor type	• Set the flow sensor type

Alarm text	Prio./ Type	Cause	Corrective action
Negative pressure	MHP TA	• Pressure at the Y piece is below –7 cmH_2O for more than 0.5 s Safety mode is activated for 2 seconds	• Ventilate the patient immediately with a separate ventilation alternative • Replace the patient component • Contact FRITZ STEPHAN GMBH customer service
Temperature > 41°C	MHP	• Proximal temperature above 41°C	• Check the patient tube system for accidental covering.
Vt(exsp) low	MHP	• Measured breathing volume below the set lower alarm limit for more than 6 s	• Check that the manual settings are correct and plausible, adjust if necessary
		• Leakage in the patient tube system	• Check the patient tube system for leakage
		• Incorrect flow sensor type	• Set the flow sensor type
		• Tube blocked	• Check the tube
		• Inaccurate measurement of the flow sensor (PNT)	• Check the PNT measurement tubes (defective/length) • Remove water droplets from the PNT and measurement tubes
Battery low	HP TA	• remaining battery life < 5 min	• Restore the power supply immediately
Battery fail	HP TA	• Internal battery detected as defective for more than 20 s Does not take over ventilation in case of power failure	• Do not disconnect the device from the power supply during ongoing ventilation; device will shut off. In the status, alarm, and info display, a flashing message appears in place of the battery symbol. • Device may continue to be used only under continuous monitoring of device functions • Contact FRITZ STEPHAN GMBH customer service

Alarm text	Prio./ Type	Cause	Corrective action
Main control fail	HP TA	• System error detected for more than 0.5 s	• Ventilate the patient immediately with a separate ventilation alternative • Contact FRITZ STEPHAN GMBH customer service
Controller fail	HP TA	• Micro controller defective • Time monitoring circuit is not activated Alarm suppression is not possible Safety mode	• Ventilate the patient immediately with a separate ventilation alternative • Contact FRITZ STEPHAN GMBH customer service
Press.sensor fail	HP TA	• Measured value outside measuring range	• Check measuring line for stenosis • In the event of a persistent error, ventilate the patient with a separate ventilation alternative • Contact FRITZ STEPHAN GMBH customer service
FiO_2 < 18%	HP	• FiO_2 < 18% for more than 6 s • Oxygen cell defective	• Check and possibly replace the oxygen cell • Monitor FiO_2 externally
		• O_2 sensor not calibrated	• Start O_2 calibration
Low pressure/disc	HP	Patient tube system leakage or disconnection • End inspiratory pressure below the set limit for more than Tinsp+Texsp (min. 4 s) • Measured flow > 5 l/s for more than 5 s	• Check that the manual settings are correct and plausible, adjust if necessary • Check the patient tube system for leakage
Flowlimit/disc.?	HP	• For CPAP and HFO, the mean flow is higher than the set flow limit line for more than 1.9 s	• Check that the manual settings are correct and plausible, adjust if necessary
		• ETT disconnected	• Check the ETT
		• Flow > max. measuring range of PNT	• Use PNT type C
Waterlevel high	HP	• Water level in the humidifier is too high for longer than 1 s • Water droplets on the wall of the humidifier bottle	• Empty humidifier bottle up to the max. mark
		• Refill tube not inserted in the tube pinch	• Check the refill tube

Alarm text	Prio./ Type	Cause	Corrective action
		• Fill level sensor defective • Pinch valve stiff or defective	• Switch off the refill • Check the water level regularly and refill as needed • Contact FRITZ STEPHAN GMBH customer service
Hardware error	HP TA	• Internal selftest error Alarm suppression is not possible Safety mode	• Ventilate the patient immediately with a separate ventilation alternative • Contact FRITZ STEPHAN GMBH customer service
Prol. high press.	HP	• Pmean longer than 15 s above the upper alarm limit	• Check the upper Pmean limit setting and adjust if necessary
		• Expiration tube blocked	• Check the patient tube system • In the case of nebulization, replace the expiratory filter if necessary
PSU temperature	HP TA	• Power supply temperature too high Battery is switched off; does not take over ventilation in case of power failure	• Check the fan and ventilation openings • Replace the dust filter on the fan • Device may continue to be used only under continuous monitoring of device functions • Contact FRITZ STEPHAN GMBH customer service
Safety valve	HP TA	• Emergency air valve defective	• Contact FRITZ STEPHAN GMBH customer service
Safety valve open	HP TA	• Emergency air valve open Ventilation pressure is discharged to atmosphere The patient can breathe spontaneously	• Check that the manual settings are correct and plausible, adjust if necessary

Alarm text	Prio./ Type	Cause	Corrective action
Patient valve	HP TA	• Malfunction of the patient valve in the patient component Safety mode	• Check the seat of the patient valve and replace the patient component if necessary (it must be possible to move the black piston of the patient valve easily by approx. 6 mm) • Ventilate the patient immediately with a separate ventilation alternative • Contact FRITZ STEPHAN GMBH customer service
PC-failure	HP TA	• PC defective • Time monitoring circuit is not activated Alarm suppression is not possible Safety mode	• Ventilate the patient immediately with a separate ventilation alternative • Contact FRITZ STEPHAN GMBH customer service
Peep high	HP	• PEEP is above the set upper alarm limit for more than 4 s	• Check that the manual settings are correct and plausible, adjust if necessary
		• Expiration tube blocked • Elevated resistance in the expiration tube	• Check the patient tube system • In the case of nebulization, replace the expiratory filter if necessary
P-mean high	HP	• Pmean is above the set upper alarm limit for more than 4 s	• Check that the manual settings are correct and plausible, adjust if necessary
Software failure	HP TA	• System error	• Ventilate the patient immediately with a separate ventilation alternative • Contact FRITZ STEPHAN GMBH customer service
Peak pressure	HP	• Inspiratory pressure limit exceeded for longer than 50 ms Inspiration aborted Pressure regulated to PEEP	• Check that the manual settings are correct and plausible, adjust if necessary
Therapy startup	HP TA	• System error in start phase	• Contact FRITZ STEPHAN GMBH customer service

Alarm text	Prio./ Type	Cause	Corrective action
Gas supply	HP TA	• AIR and O_2 input pressure is below 2.8 bar for more than 3 s	• Check the connection to the central gas supply (CGS)
Peak press. > 0.3 s	HP	• Measured pressure is above the set upper alarm limit for more than 0.3 s Inspiration aborted Safety mode activated for 2 s	• Check that the manual settings are correct and plausible, adjust if necessary
PSU fail	HP TA	• Internal technical fault in the PSU	• Device may continue to be used only under continuous monitoring of device functions • Contact FRITZ STEPHAN GMBH customer service
Communication	HP TA	• Communication error between the micro controller and the PC Alarm limits that can be set on the monitor are not transmitted • Alarm suppression is not possible	• Ventilate the patient immediately with a separate ventilation alternative • Contact FRITZ STEPHAN GMBH customer service

Tab. 17: Troubleshooting

12.2 Heavily oscillating ventilation curves

12.2.1 Patient valve

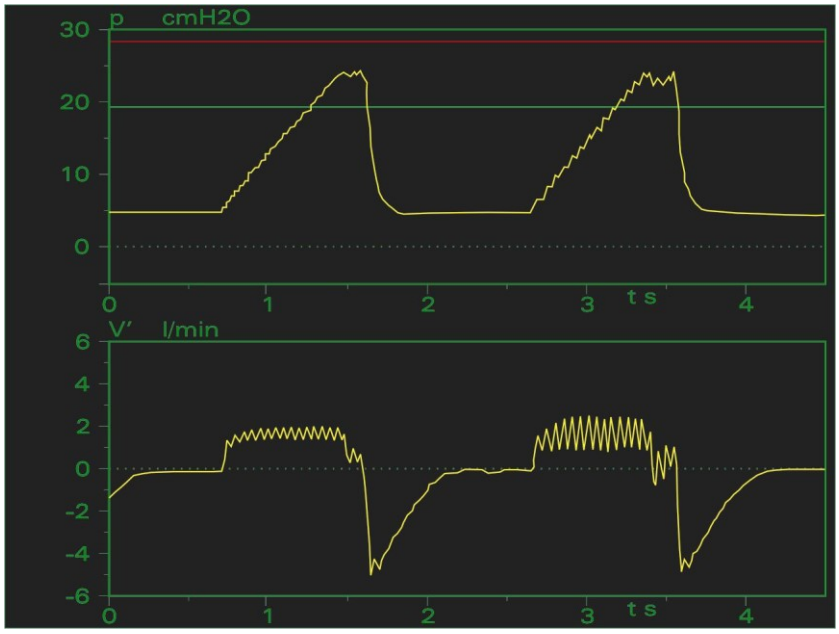


Fig. 149: Oscillating ventilation curves – patient valve

Corrective action

- Check that the patient component is properly connected to the side panel of the **SOPHIE**.
- Screw the patient valve into the patient component with the installation wrench, adjusting to the correct position if necessary with a half turn to the left or right.

12.2.2 Humidity in the pneumotachograph

Humidity or even water droplets in the pressure measurement lines of the pneumotachograph (PNT) can distort the volume flow measurement. The flow signals cross the border of the monitor display or begin to oscillate.

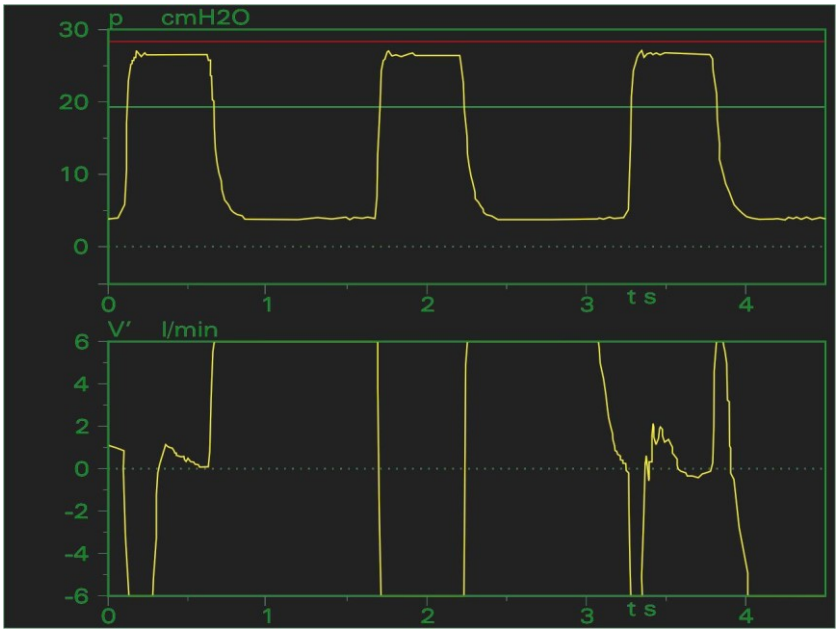


Fig. 150: Humidity in the pneumotachograph

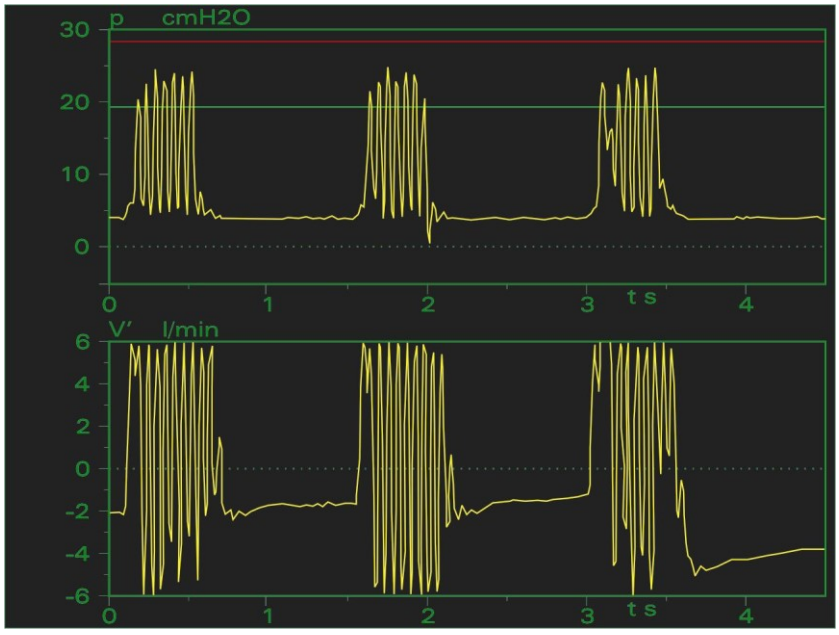


Fig. 151: Humidity in the PNT – measurement tube

Corrective action

- Switch the Sophie to standby mode.
- Remove the pneumotachograph from the Y piece and disconnect the plug from the side panel.
- Switch the Sophie back to ventilation mode.
- Press the »Aerosol« button.
- Hold the pneumotachograph itself or the pressure measurement lines to the aerosol nebulizer outlet (see chapter 0) to let any moisture escape.

12.3 Prevention of condensate in PNT and tubes

In practice, a certain degree of condensation cannot be prevented. However, following these 5 suggestions can reduce it to an acceptable, non-interfering level.

1. Check the temperature settings

The difference between the incubator temperature and the patient gas temperature should not exceed 4–5°C. Should this be necessary for therapy, the cold section of the tube should be insulated using a tube warmer.

2. Check the temperature sensors

Should the distal sensor of the incubator tube system be placed inside the incubator or be directly exposed to a heating lamp (this also applies to the proximal sensor), the temperature may be overestimated.

Should the distal sensor be too far away from the incubator, condensate may form in the unheated section of the tube, especially in colder rooms.

3. Set the humidity

Gradually set the humidity level until the condensate disappears. Settings for high flow therapies such as NCPAP and HFO (++ to ++++++), settings for normal flow therapies (0).

4. Choose the correct tube system

When using warming beds or incubator temperatures of < 33°C, switch to the patient tube system with a long heated section.

5. Position the PNT

Turn the measurement tube connectors upward to prevent condensate from entering the measurement tubes.

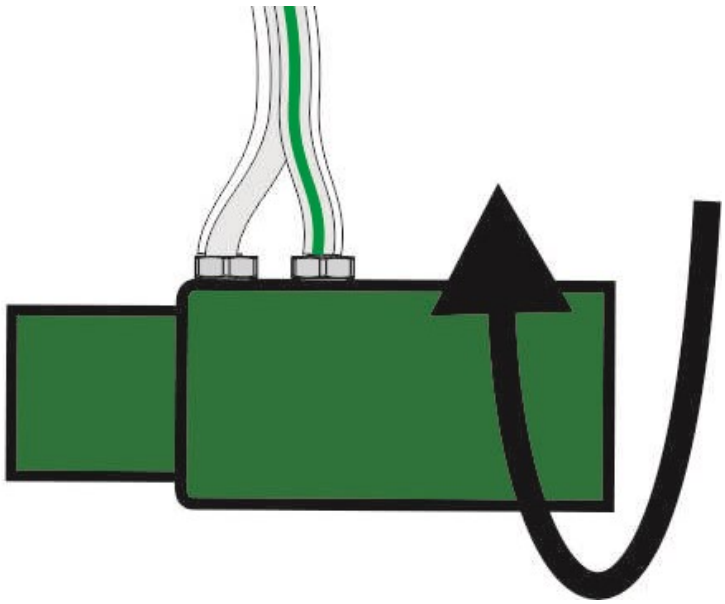


Fig. 152: Turning the measuring tube connectors upward

13 Care and maintenance

13.1 Treatment processes

NOTE

These instructions were formulated in accordance with DIN EN ISO 17664 and explain how to treat the P7 ventilation accessory for the **SOPHIE** device.

CAUTION

Cleaning and disinfection of the device must only be performed by trained employees.

CAUTION

The processes for the treatment of this medical device as described in this manual are recommendations only. The requirements regarding hygiene and workplace safety must always be observed during the treatment of medical products.

Routine cleaning must be carried out at regular intervals according to local hospital guidelines.

All disposable parts must be disposed of in an environmentally friendly manner according to local hospital guidelines.

NOTE

Automated thermal treatment should be used wherever possible.

13.1.1 Information about cleaning agents and disinfectants

CAUTION

When using cleaning agents and disinfectants, pay attention to the correct concentration and dwell time to prevent damage to the materials.

CAUTION

When using agents other than those specified, please contact the manufacturer of the disinfectant to confirm its compatibility.

CAUTION

Ask the manufacturer of the disinfectant you are using to provide information about compatibility with regard to use for ventilation and inhalation systems (safety data sheet, toxicity).

CAUTION

Disinfectants based on amines and their derivatives can damage silicone parts (e.g. patient tubes) and are therefore not suitable for use on the device.

CAUTION

When using cleaning agents and disinfectants, observe the rules established by the professional associations on the use of cleaning agents and disinfectants.

13.1.2 Automated cleaning and disinfection

For automated cleaning, configure the automated cleaning and disinfection equipment according to the manufacturer's operating instructions.

CAUTION

Use only automated cleaning and disinfection equipment that complies with DIN EN ISO 15883-1!

The parts to be cleaned must be disassembled according to the instructions in this operating manual before treatment. Load the automated cleaning and disinfection equipment in such a way that the inner and outer surfaces of the parts can be reached by the cleaning agent and no spots are missed.

All parts must be arranged to avoid the formation of water pockets, e.g. with slack or kinked tubing.

Select a suitable program (e.g. anesthesia program). Cleaning should take at least five minutes at 40–60°C.

Thermal disinfection

Cleaning is followed by thermal disinfection at 80–95°C. The dwell time depends on the temperature of the disinfection program as follows:

Efficacy ranges:

A: Suitable for killing vegetative bacteria (including mycobacteria) and fungi (including fungal spores)

AB: Same as A, and for the inactivation of viruses

	Efficacy range A	**Efficacy range AB**
Ao	600	3000
Disinfection at 80°C	10 min.	50 min.
Disinfection at 85°C	3.2 min.	15.8 min.
Disinfection at 90°C	1 min.	5 min.
Disinfection at 95°C	0.1 min.	0.5 min.

Tab. 18: Efficacy ranges according to EN ISO 15883-1

Demineralized water must be used for all interim rinses and the final rinse.

Once the disinfection program has finished, remove the parts from the automated cleaning and disinfection equipment and check the visible surfaces for visible residual contamination. If necessary, repeat the cleaning and disinfection process. After this, dry the treated parts thoroughly (in a drying cabinet if necessary).

Cleaning agents

With regard to material compatibility, suitable cleaning agents are enzymatic and mildly alkaline, such as neodisher® Mediclean from Dr. Weigert GmbH in Hamburg.

CAUTION

Do not use disinfectants in automated cleaning and disinfection equipment!

These could damage the parts to be treated.

CAUTION

Highly alkaline cleaning agents can severely corrode and damage anodized surfaces.
To neutralize alkaline cleaning agents, do not use phosphoric acid!
Phosphoric acid can severely corrode and damage anodized surfaces.

NOTE

Always closely follow the instructions of the cleaning agent manufacturer for using the cleaning agent!

Products based on the following are not suitable because they could possibly damage materials:

- Oxygen-releasing or chlorine-releasing compounds
- Halogen-releasing compounds
- Phenols and their derivatives
- Amines and their derivatives
- Strong organic acids

Products listed in the most current version of the DGHM list published by the Deutsche Gesellschaft für Hygiene und Mikrobiologie (German Society of Hygiene and Microbiology) (mhp-Verlag, Wiesbaden) are recommended for users in the Federal Republic of Germany.

13.1.3 Manual cleaning and disinfection

Manual cleaning

For manual cleaning, clean the individual parts carefully under running water using a standard commercial cleaning agent. All secretions and other visible deposits and contamination must be completely removed.

After cleaning, all parts must be thoroughly rinsed under running water until no more visible residues of the cleaning agent are present. Once manual cleaning is complete, check the visible parts for visible residual contamination. If necessary, repeat the manual cleaning process.

Manual disinfection

For manual disinfection of the individual parts, submerse them in the ready-to-use disinfectant solution (instrument disinfection agent). All of the parts must be fully covered by the disinfectant. The parts must be moved around in the solution several times until all air bubbles have been removed.

After the dwell time, the disinfectant must be completely rinsed off with aqua dest. Afterwards, the parts must be dried thoroughly.

CAUTION

Cleaning and disinfection may be affected by the water quality!

Use only demineralized water for all rinsing.

Once manual disinfection is complete, check the parts for visible residual contamination. If necessary, repeat the manual cleaning and disinfection process.

Cleaning agents

With regard to material compatibility, suitable cleaning agents and disinfectants are instrument disinfection agents that use alcohol and aldehydes as the active ingredient, such as gigasept® ff from Schülke & Mayr.

The efficacy of the disinfectant that is used must be proven.

NOTE

Always closely follow the instructions of the cleaning agent manufacturer for using the cleaning agent!

Products based on the following are not suitable because they could possibly damage materials:

- Oxygen-releasing or chlorine-releasing compounds
- Halogen-releasing compounds
- Phenols and their derivatives
- Amines and their derivatives
- Strong organic acids

Products listed in the most current version of the DGHM list published by the Deutsche Gesellschaft für Hygiene und Mikrobiologie (German Society of Hygiene and Microbiology) (mhp-Verlag, Wiesbaden) are recommended for users in the Federal Republic of Germany.

Disinfecting surfaces

Use ready-to-use disinfectant solution to disinfect the device surfaces. Completely wipe down the surfaces using the wiping cloth. The wiping cloth should only be moist.

WARNING

When using wipe disinfection, ensure that no liquid enters the device. Liquid ingress can impair the operation of the device and thereby pose a risk to the patient.

All disinfectant residue must be completely removed afterwards.

Disinfectants

With regard to material compatibility, suitable for wipe disinfection are aldehyde-free quick disinfecting wipes such as Bacillol® wipes or tissues from Paul Hartmann AG.

NOTE

Always closely follow the instructions of the cleaning agent manufacturer for using the cleaning agent!

13.1.4 Sterilization

Components labeled in this operating manual as suitable for sterilization can be sterilized with hot steam at temperatures of up to 134°C.

NOTE

NOTE

Only use vacuum steam sterilizers – preferably ones with a fractionated vacuum.

The hot steam sterilizer must be loaded according to the manufacturer's instructions for use and the corresponding program started.

Temperature	Hold/dwell time
134°C	3–18 min

Tab. 19: Standard procedure for steam sterilization*

* All standard steam sterilization procedures can be used.

13.2 Device overview

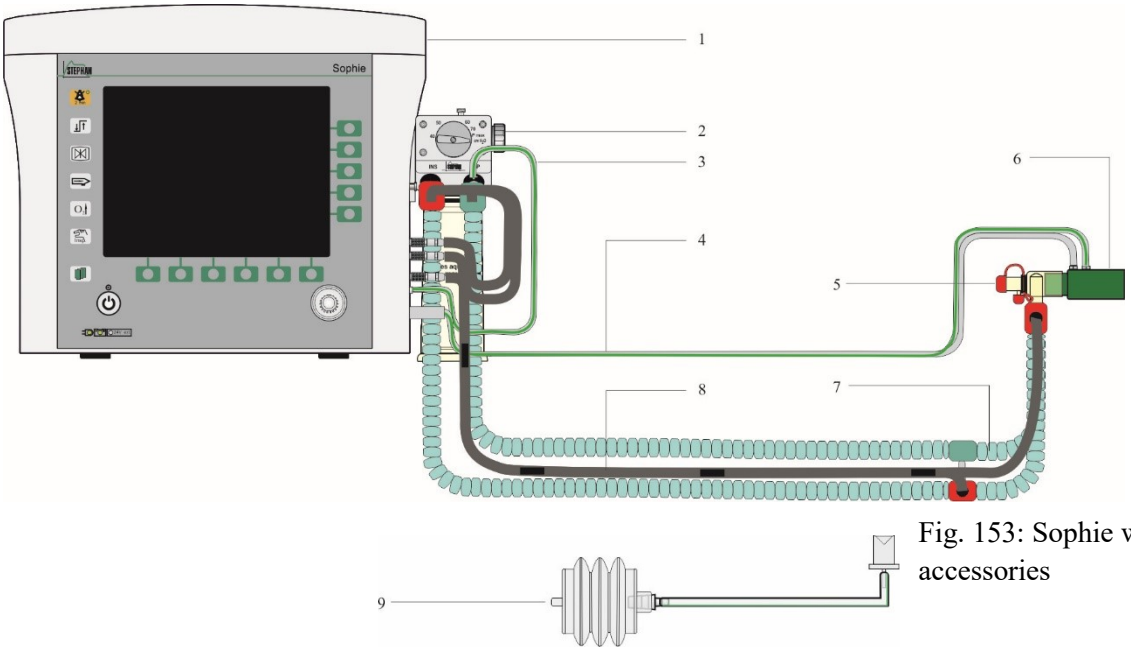


Fig. 153: Sophie with accessories

Fig. 154: Test lung

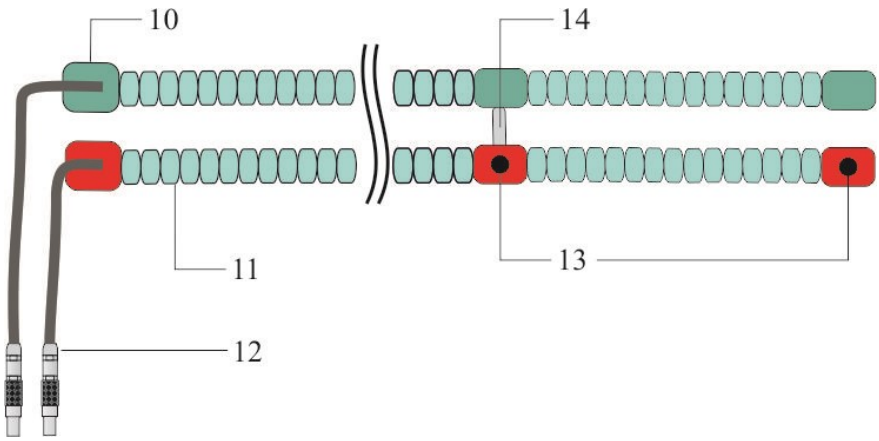


Fig. 155: Reusable tube system P7

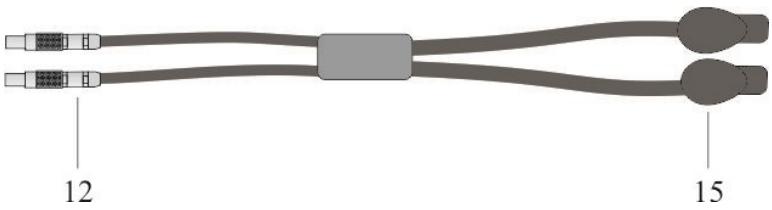


Fig. 156: Connection cable P3/P7 for disposable patient tube system

1 Sophie ventilator (main device)
2 Patient component P7
3 Expiratory pressure measurement line
4 Duplex pressure measurement line flow sensor
5 Y piece
6 Flow sensor (PNT)
7 Patient tube system P7
8 Temperature sensor system P7
9 Test lung with tube adapter
10 Connection sleeve
11 Support bracket with heating wire
12 Tube heating plug
13 Ports for temperature sensors
14 Tube heating cable bridge
15 Tube heating plug for disposable patient tube system

13.3 Device housing with park position, gas supply tubes, and power cable

CAUTION

Always hold the patient tube by the sleeve when connecting and disconnecting it to prevent damage.

Do not stretch, compress or twist the tube system!

Instructions	
Place of use	Remove surface dirt with a disposable cloth/paper towel.
Storage and transport	No particular requirements
Cleaning preparations	Remove the patient component, tube system, pressure measurement line, temperature sensor system, and flow sensor
Cleaning: automatic Cleaning: manual Disinfection Drying	Not possible Wipe the surfaces with ready-to-use disinfectant solution (surface disinfectant). Further information on manual cleaning and disinfection can be found in chapter 13.1.3.
Maintenance	Not necessary with cleaning
Inspection and functional checks	Before using the Sophie after cleaning, a functional check must be performed (see chapter 7 of the operating manual).
Packaging	Standardized packaging material can be used for the packable parts. The bag must be large enough for all components so that there is no strain on the seal.
Sterilization	Not possible
Storage	Store in a dry place free from dust and frost
Additional information	Ensure mains supply for keeping the battery charged

13.4 Reusable patient tube system

CAUTION

Always hold the patient tube by the sleeve when connecting and disconnecting it to prevent damage.

Do not stretch, compress or twist the tube system!

CAUTION

Do not allow the tubes from the tube system to twist around or catch on the cable bridge!

If the tubes become twisted or caught on the cable bridge, the tube heating may be damaged and not work properly.

Instructions

Place of use	Remove surface dirt with a disposable cloth/paper towel.
Storage and transport	Do not allow the patient tube system to catch on the cable bridge!
Cleaning preparations	Remove the Y piece. Remove large impurities immediately after use (within a maximum of 2 h). This also helps to prevent unwanted blood staining. Use only running water or aldehyde-free disinfectant solutions, which have been tested for effectiveness and are suitable for disinfecting silicone tubes. To manually remove contamination, use only a soft brush or a clean, soft cloth intended specifically for this purpose only. Rinse all lumina for at least 1 min. under running water. Disinfectants used for pretreatment are only for personal protection and do not replace the need for disinfection after cleaning is completed.
Cleaning: automatic	1. Place the ventilation tubes in the automated cleaning and disinfection equipment so that they do not touch one another for the most part. 2. Connect all ventilation tube lumina to the rinse connection of the cleaning and disinfection equipment.
	3. Start the program. 4. Once the program stops, remove the ventilation tubes from the cleaning and disinfection equipment. Further information on automatic cleaning can be found in chapter 13.1.2.

Instructions	
Cleaning: manual Disinfection Drying	1. Immerse the individual parts in ready-to-use disinfectant solution. All of the parts must be fully covered by the disinfectant. 2. Move the parts around in the solution several times until all air bubbles have been removed. 3. Clean the parts on the inside and outside with a **soft brush**. 4. After the dwell time, rinse off the disinfectant completely with aqua dest. 5. Dry the parts thoroughly. 6. After completion, check the parts for visible external residual contamination. If necessary, repeat the manual cleaning and disinfection process. Further information on manual cleaning and disinfection can be found in chapter 13.1.3.
Maintenance	No maintenance required for cleaning. Oils can damage silicone!
Inspection and functional checks	After disinfection and before each use, check all parts for damage (cracks, breaks, hardening, etc.) and ensure that the connection plug screw fitting is tight. Tighten the screw fitting if necessary. Do not reuse damaged parts.
Packaging	Standardized packaging material can be used for the packable parts. The bag must be large enough for all components so that there is no strain on the seal.
Sterilization	The reusable tube system can be autoclaved with steam at up to 134°C. Load the autoclave according to the manufacturer's instructions for use and start the appropriate program. Further information on sterilization can be found in chapter 13.1.4.
Storage	After sterilization, store the system in the sterilization packaging, first ensuring it is dry and free of contamination.
Additional information	Do not allow the tubes from the tube system to twist around or catch on the cable bridge! If the tubes become twisted or caught on the cable bridge, the tube heating may be damaged and not work properly.

13.5 Temperature sensor systems P7

CAUTION

The temperature sensor P7 for the patient tube system cannot be sterilized using hot steam. Sterilization with hot steam leads to the destruction of the sensor!

Instructions	
Place of use	Remove surface dirt with a disposable cloth/paper towel.
Storage and transport	No particular requirements
Cleaning preparations	1. Disconnect the temperature sensor system plug from the ventilator. 2. Remove the temperature sensors from the patient tube system.
Cleaning: automatic	Not possible
Cleaning: manual Disinfection Drying	Wipe the surfaces with ready-to-use disinfectant solution (surface disinfectant). Further information on manual cleaning and disinfection can be found in chapter 13.1.3.
Maintenance	No maintenance necessary
Inspection and functional checks	After disinfection and before each use, check all parts for damage (cracks, breaks, hardening, etc.) and ensure that the connection plug screw fitting is tight. Tighten the screw fitting if necessary. Do not reuse damaged parts.
Packaging	Standardized packaging material can be used for the packable parts. The bag must be large enough for all components so that there is no strain on the seal.
Sterilization	Not possible
Storage	Store in a dry place free from dust and frost and ensure low microbiological contamination.
Additional information	None

13.6 Connection cable P3/P7 for disposable patient tube system P3/P7

CAUTION

The connection cable P3/P7 for disposable patient tube systems is not suitable for automatic treatment or sterilization with hot steam.

Sterilization with hot steam leads to the destruction of the adapter!

Instructions	
Place of use	Remove surface dirt with a disposable cloth/paper towel.
Storage and transport	No particular requirements
Cleaning preparations	1. Disconnect the connection cable plug from the ventilator 2. Remove the connection cable from the patient tube system
Cleaning: automatic	Not possible
Cleaning: manual Disinfection Drying	Wipe the surfaces with ready-to-use disinfectant solution (surface disinfectant). Further information on manual cleaning and disinfection can be found in chapter 13.1.3.
Maintenance	No maintenance necessary
Inspection and functional checks	After disinfection and before each use, check all parts for damage (cracks, breaks, hardening, etc.) and ensure that the connection plug screw fitting is tight. Tighten the screw fitting if necessary. Do not reuse damaged parts.
Packaging	Standardized packaging material can be used for the packable parts. The bag must be large enough for all components so that there is no strain on the seal.
Sterilization	Not possible
Storage	Store in a dry place free from dust and frost and ensure low microbiological contamination.
Additional information	None

13.7 Flow sensor (PNT), Y piece, pressure measurement line

CAUTION

Only use the intended assembly tools to remove the flow sensor's vortex bodies!

The PNT's inner tubes and webs could be damaged during cleaning.

Instructions

Place of use	1. Remove surface dirt with a disposable cloth/paper towel. 2. Remove the flow sensor's pressure measurement line.
Storage and transport	No particular requirements
Cleaning preparations	1. Use the assembly tool to carefully pull out the vortex bodies on both sides of the PNT. 2. If there are large impurities in the PNT, soak it in a disinfectant solution and carefully remove the impurities using pointed tweezers. Do not damage or bend the centrally positioned tubes or the spacer plate! Further information on preparation can be found in chapter 13.7.1.
Cleaning: automatic	1. Connect the pressure measurement lines (silicone tubes) to the rinse connections on the automated cleaning and disinfection equipment. 2. Connect the PNT housing to a rinse connection on the automated cleaning and disinfection equipment. 3. Place the vortex bodies in a closed strainer. 4. Load the disinfector according to the manufacturer's instructions for use and start the program for anesthesia materials. 5. Dry the disinfected parts (in a drying cabinet if necessary), unless this happens inside the automated cleaning and disinfection equipment. Further information on automatic cleaning can be found in chapter 13.1.2.

Instructions

Cleaning: manual Disinfection Drying	1. Immerse the individual parts in ready-to-use disinfectant solution. All of the parts must be fully covered by the disinfectant. 2. Move the parts around in the solution several times until all air bubbles have been removed. 3. After the dwell time, rinse off the disinfectant completely with aqua dest. 4. Dry the parts thoroughly. 5. After completion, check the parts for visible external residual contamination or disinfectant. If necessary, repeat the manual cleaning and disinfection process. 6. Check for residual water and carefully purge with sterile compressed air if necessary. Further information on manual cleaning and disinfection can be found in chapter 13.1.3.
Maintenance	Pick up the vortex bodies (VK) with the flat end of the assembly tool and insert them into the PNT housing. The tip of the distal vortex body must not protrude over the edge of the outer cone. The visible ring face of the proximal vortex body must be flush with the indentation in the PNT housing. The vortex bodies must sit tightly in the housing and not fall out on their own. If they are too loose or too tight, either their O-rings or the vortex bodies in their entirety must be replaced. Grease the O-rings occasionally with silicone grease. Further information on post-treatment can be found in chapter 13.7.2.
Inspection and functional checks	Check all parts for damage (cracks, breaks, hardening, etc.) after disinfection and before each use. Do not reuse damaged parts.
Packaging	Standardized packaging material can be used for the packable parts. The bag must be large enough for all components so that there is no strain on the seal.
Sterilization	All flow sensor parts and the Y piece can be autoclaved with steam at 134°C. Load the autoclave according to the manufacturer's instructions for use and start the appropriate program. Further information on sterilization can be found in chapter 13.1.4.
Storage	After sterilization, store the system in the sterilization packaging, first ensuring it is dry and free of contamination.
Additional information	None

13.7.1 Preparing the flow sensor

1. Pull the pressure measurement lines off the PNT connectors.
2. Carefully pull both vortex bodies out on both sides of the flow sensor using the assembly tool.

Preparing the PNT B/C

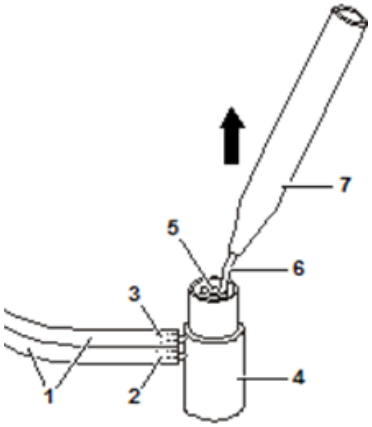


Fig. 157: Preparing the PNT B/C

1	Pressure measurement lines	5	Vortex body
2	Connector 1	6	Hook
3	Connector 2	7	PNT B/C assembly tool
4	Pneumotachograph		

Preparing the PNT A

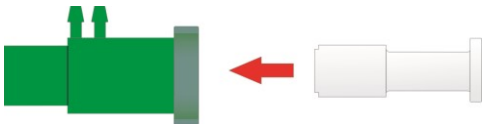


Fig. 158: Inserting the assembly tool into the PNT A

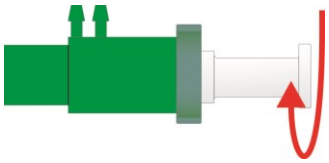


Fig. 159: Turning the assembly tool clockwise

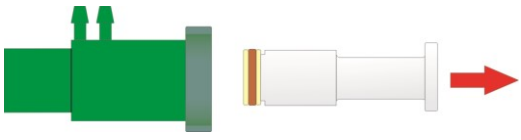


Fig. 160: Pulling out the assembly tool with the vortex body

13.7.2 Post-treatment

1. Check that all parts are mechanically undamaged and complete.
   - 2 vortex bodies with one O-ring each.
   - PNT housing with concentric tube system, held by three webs on each side.
     Check that the tube system is securely seated in the housing.
   - 2 connectors.
2. Carefully purge the parts with compressed air so that there is no water in the connectors.
3. Attaching the vortex body to the assembly tool

Post-treatment PNT B/C

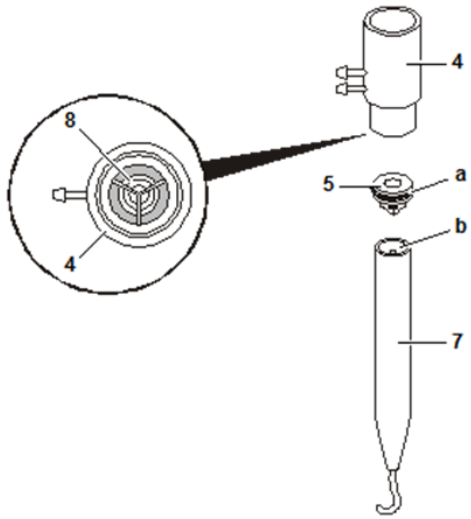


Fig. 161: Post-treatment PNT B/C

4	PNT housing		
5	Vortex body	a	O-ring of the vortex body
7	Assembly tool	b	Flat end of the assembly tool
8	Concentric tube system		

Post-treatment PNT A

Fig. 162: Attaching the vortex body to the assembly tool

4. Insert the assembly tool until the end stop, then rotate slightly until the vortex body locks into place.

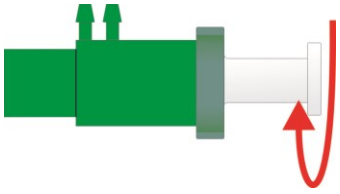


Fig. 163: Inserting the assembly tool and rotating slightly

Fig. 164: Repeating the procedure for the second vortex body

CAUTION

The pneumotachographs type A, B and C have different vortex bodies with different bore diameters. The vortex bodies are labeled with the letter of the relevant PNTs and must not be confused. Otherwise, significant measuring errors must be expected.

During assembly, ensure that the seals and O-rings are positioned correctly and not crushed.

Preparation for use

1. Connect the red pressure measurement line (proximal pressure measurement line) to connector 1 near the attachment fitting (wide port) of the PNT (marked by a black dot on the plug and PNT housing).
2. Connect the second pressure measurement line to connector 2.

Function test

Before using the flow sensor, leak and functional checks must be performed (see chapter 7 of the operating manual).

13.8 Test lung with tube adapter

Instructions

Place of use	Remove surface dirt with a disposable cloth/paper towel.
Storage and transport	No particular requirements
Cleaning preparations	1. Remove the connection tube from the test lung together with the tube adapter and tube sleeve. 2. Remove the tube adapter and tube sleeve from the silicone tube. Further information on preparation can be found in chapter 13.7.1.
Cleaning: automatic	1. Connect the silicone tube to the injector rail of the cleaning and disinfection equipment. 2. Position the test lung to ensure that the cavity will be fully rinsed and that no spots are missed. Excess water must be able to run off freely. 3. Place the tube sleeve in a small parts container. 4. Load the automated disinfection equipment according to the manufacturer's instructions for use and start the program for anesthesia materials. 5. Dry the disinfected parts (in a drying cabinet if necessary), unless this happens inside the automated disinfection equipment. Further information on automatic cleaning can be found in chapter 13.1.2.
Cleaning: manual Disinfection Drying	1. Immerse the individual parts in ready-to-use disinfectant solution. All of the parts must be fully covered by the disinfectant. 2. Move the parts around in the solution several times until all air bubbles have been removed. 3. After the dwell time, rinse off the disinfectant completely with aqua dest. 4. Dry the parts thoroughly. 5. After completion, check the parts for visible external residual contamination or disinfectant. If necessary, repeat the manual cleaning and disinfection process. Further information on manual cleaning and disinfection can be found in chapter 13.1.3.
Maintenance	1. Check for residual water and carefully purge with sterile compressed air if necessary. 2. Connect the tube adapter and tube sleeve to the silicone tube. 3. Connect the connection tube to the test lung together with the tube adapter and tube sleeve.

Instructions	
Inspection and functional checks	Check all parts for damage (cracks, breaks, hardening, etc.) after disinfection and before each use. Do not reuse damaged parts.
Packaging	Standardized packaging material can be used for the packable parts. The bag must be large enough for all components so that there is no strain on the seal.
Sterilization	All test lung parts can be autoclaved with steam at 134°C. Load the autoclave according to the manufacturer's instructions for use and start the appropriate program. Further information on sterilization can be found in chapter 13.1.4.
Storage	After sterilization, store the system in the sterilization packaging, first ensuring it is dry and free of contamination.
Additional information	None

13.8.1 Preparing the test lung with the tube adapter

1. Remove the connection tube from the test lung together with the tube adapter and tube sleeve.
2. Remove the tube adapter and tube sleeve from the silicone tube.

Preparing the test lung

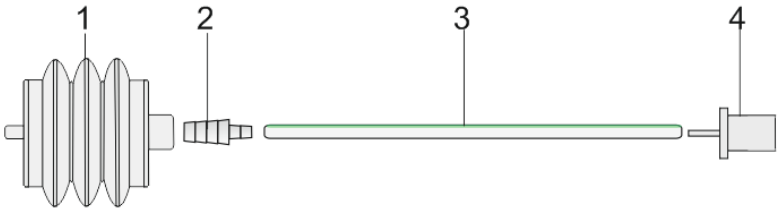


Fig. 165: Test lung with tube adapter

1	Pediatric test lung (silicone)	3	Silicone connection tube
2	Tube sleeve	4	Tube adapter

13.9 Patient component P7

Instructions

Instructions	
Place of use	1. Disconnect the patient component from the side panel of the ventilator 2. Unscrew and drain the humidifier bottle 3. Remove surface dirt with a disposable cloth/paper towel.
Storage and transport	No particular requirements
Cleaning preparations	1. Unscrew the silencer from the patient component 2. Disconnect the humidifier tube and remove and dispose of the humidifier fleece 3. Place the fixing sleeve on the proportional valve's piston Further information on preparing the patient component can be found in chapter 13.9.1.
Cleaning: automatic	1. Connect the expiration nozzle of the patient component to the rinse connection of the cleaning and disinfection equipment. 2. Position the patient component to ensure that it will be fully rinsed and that no spots are missed. Excess water must be able to run off freely. Only wipe-disinfect the silencer or first remove the foam core and dispose of it properly. 3. Load the automated disinfection equipment according to the manufacturer's instructions for use and start the program for anesthesia materials. Dry the disinfected parts (in a drying cabinet if necessary), unless this happens inside the automated disinfection equipment. Further information on automatic cleaning can be found in chapters 13.1.2 and 13.9.1.
Cleaning: manual Disinfection Drying	1. Immerse the individual parts in ready-to-use disinfectant solution. All of the parts must be fully covered by the disinfectant. 2. Move the parts around in the solution several times until all air bubbles have been removed. 3. After the dwell time, rinse off the disinfectant completely with aqua dest. Only wipe-disinfect the silencer or first remove the foam core and dispose of it properly. 4. Then dry it thoroughly. 5. After completion, check the parts for visible external residual contamination or disinfectant. If necessary, repeat the manual cleaning and disinfection process. Further information on manual cleaning and disinfection can be found in chapter 13.1.3.

Instructions

Maintenance	1. Mount the humidifier tube 2. Attach the silencer. Further information on post-treatment can be found in chapter 13.9.2.
Inspection and functional checks	Check all parts for damage (cracks, breaks, hardening, etc.) after disinfection and before each use. Do not reuse damaged parts.
Packaging	Standardized packaging material can be used for the packable parts. The bag must be large enough for all components so that there is no strain on the seal.
Sterilization	All patient component parts can be autoclaved with steam at up to 134°C. Load the autoclave according to the manufacturer's instructions for use and start the appropriate program. Further information on sterilizing the ventilation system can be found in chapters 13.1.4 and 13.9.2.1.
Storage	After sterilization, store the system in the sterilization packaging, first ensuring it is dry and free of contamination.
Additional information	None

13.9.1 Preparation

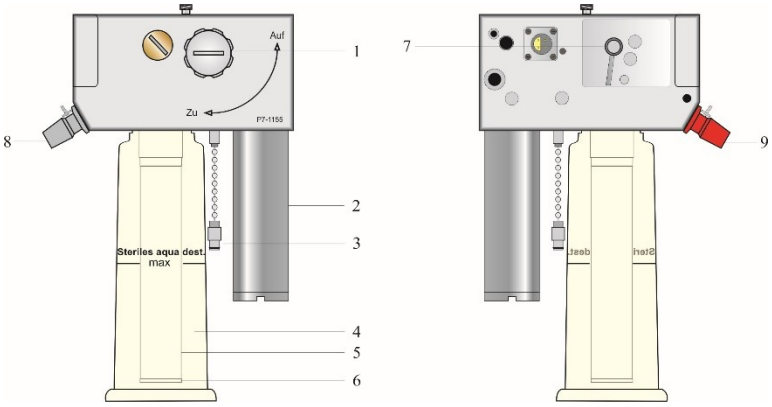


Fig. 166: Patient component P7

1 Locking lever
2 Silencer
3 HFO plug
4 Humidifier bottle
5 Humidifier tube
6 Humidifier tube locking ring
7 Patient valve piston
8 Expiration tube connection
9 Inspiration tube connection

Preparing the patient component P7

1. Disconnect the patient component from the side panel.
2. Unscrew the silencer.
3. Unscrew and drain the humidifier bottle.
4. Pull humidifier tube down and off.
5. Turn the locking ring of the humidifier tube (item 6) clockwise and remove.
6. Remove the humidifier fleece and dispose of it correctly.
7. Attach the proportional valve's piston using the fixing sleeve (art. no. 100761002).

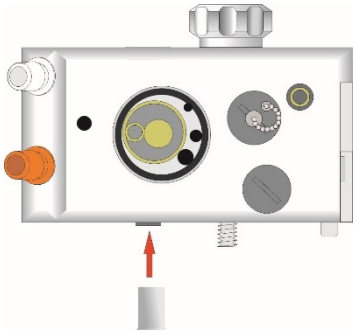


Fig. 167: Attaching the proportional valve's piston

8. Remove the HFO plug.
9. Attach the rinse tube (10) including rinse adapter (11) to the expiration tube connection.
10. Position the patient component to ensure that it will be fully rinsed and that no spots are missed.
11. Attach the rinse tube (10) (100761006) to one of the injector rail nozzles (13) on the drawer of the cleaning and disinfection equipment.

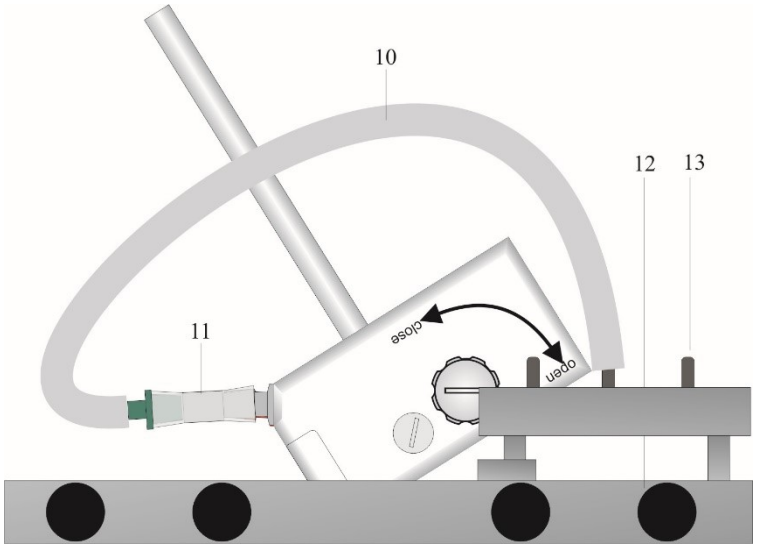


Fig. 168: Example for positioning on the drawer of the cleaning and disinfection equipment

12. Load the automated disinfection equipment according to the manufacturer's instructions for use and start the program. Dry the disinfected parts (in a drying cabinet if necessary), unless this happens inside the automated disinfection equipment.

CAUTION

After each manual or automated thermal treatment, any residual water must be removed from the patient component by purging with sterile compressed air.

13.9.1.1 Preparing the silencer

CAUTION

Do not clean the silencer automatically or by immersing it in disinfectant solution! Only wipe-disinfect or first remove the foam core and dispose of it properly.

Wipe the surfaces with ready-to-use disinfectant solution (surface disinfectant).

NOTE

Like all parts of the patient component, the silencer can be autoclaved with steam at up to 134°C. Load the autoclave according to the manufacturer's instructions for use and start the appropriate program.

13.9.2 Post-treatment

Post-treatment of the patient component P7

1. When using the disposable humidifier fleece art. no. 100753131 (PU: 25 pcs.), insert the humidifier fleece using the tool for inserting the fleece in the humidifier tube and secure with the locking ring (see also chapter 6.3).
2. Attach the complete humidifier tube to the holding bush at the bottom of the patient component.
3. Attach the silencer to the patient component.

13.9.2.1 Sterilizing the patient component

All patient component parts can be autoclaved with steam at up to 134°C. Load the autoclave according to the manufacturer's instructions for use and start the appropriate program.

Sterilization

1. Separately place the patient component and the humidifier bottle into autoclave.
2. Sterilize the patient component and humidifier bottle according to the instructions for the autoclave.
3. Allow the patient component and humidifier bottle sufficient time to dry following sterilization.

13.10 Assembly

Storage Store in a dry place free from dust and ensure low microbiological contamination for subsequent use.

Preparation for use Instructions on the preparation for use can be found in the respective chapters of the operating manual.

Function test Before the **SOPHIE** is used, a check must always be performed. Details of the check can be found in the respective chapters of the operating manual.

Procedures in the event of damage If you notice any damage on the device or accessories during or after treatment, please contact your medical technology department or the authorized FRITZ STEPHAN GMBH customer service team immediately.

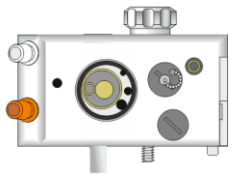
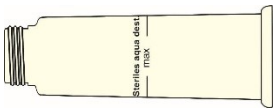
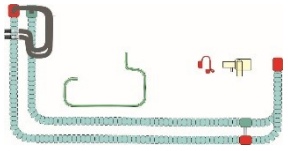
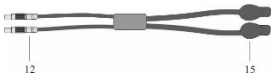
13.11 Treatment table

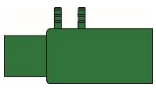
CAUTION

The processes for the treatment of the medical device described in this table are recommendations only.
Always observe the specific procedural instructions given by the responsible hygiene officer.

CAUTION

In case of infectious patients, all parts of the patient system carrying breathing gas must also be sterilized.

System components		Automated thermal treatment	Manual treatment	Sterilization
Patient component body with fixing sleeve, emergency valves, and patient valve		Yes	Yes	Yes
Humidifier bottle		Yes	Yes	Yes
Humidifier tube (without humidifier fleece)		Yes	Yes	Yes
Humidifier tube (with humidifier fleece)		No	No	Yes
Silencer		No	Surface	Yes
Patient tube system (reusable), Y piece, silicone cap, and pressure measurement line		Yes	Yes	Yes
Temperature sensor system		No	Surfaces	No
Connection cable P3/P7 for disposable patient tube system P3/P7		No	Surfaces	No

System components		Automated thermal treatment	Manual treatment	Sterilization
Pneumotachograph A, B, C		Yes	Yes	Yes
PNT connector with silicone tube		Yes	Yes	Yes
Test lung with tube adapter		Yes	Yes	Yes
Fleece inserting tool		No	Yes; surfaces	No

Tab. 20: Treatment table

13.12 Special tools and accessories

Item	Description	Art. no.
1	Humidifier fleece (PU: 25 pcs.)	100753131
2	Humidifier fleece P3/P7, packaged individually	100761131
3	Fixing sleeve for piston for mechanical treatment of the patient component P7	100761002
4	Connection tube for cleaning and disinfection equipment for mechanical treatment of the patient component P7	100761006
5	Fleece inserting tool for humidifier system P7	100753129
6	Pneumotachograph type A assembly tool	103553016
7	Pneumotachograph type B/C assembly tool	103553019

Tab. 21: Special tools and accessories for treatment

13.13 Servicing

WARNING

Only authorized customer service staff of FRITZ STEPHAN GMBH are permitted to alter, modify, repair, or open the device, or to replace the battery. This does not include the intended dismantling of the patient component according to the operating instructions. When servicing the device, only use spare parts from FRITZ STEPHAN GMBH.

CAUTION

The **SOPHIE** and all its accessories must be cleaned and disinfected before all servicing activities, as well as before being returned for repair.

13.13.1 Maintenance and inspection intervals

Interval	Tasks
Before each patient	Replace the humidifier fleece
Monthly	Clean the filter of the device fan on the back, replace if necessary
Every 6 months	Check the O-rings on the pressure measurement nipples P7 and PNT, replace if necessary
Every 6 months	Perform a safety check (see also chapter 13.13.2)
Annually	Completely charge, completely discharge and re-charge the internal battery (battery calibration)
Annually	Replace the filter of the device fan on the back
Annually	Maintenance and inspection by the authorized customer service team
Every 2 years	Have the internal battery replaced by the authorized customer service team

Tab. 22: Maintenance and inspection intervals

13.13.2 Safety checks

WARNING

If the safety checks are not performed, the safety of the device may be compromised!

The safety checks must always be performed at the specified intervals.

CAUTION

Safety checks must not be used as a substitute for the maintenance and replacement of wear parts as prescribed by the manufacturer.

Visual inspection

- Visible safety deficiencies on the device or accessories
- Lock on the patient component works correctly and securely
- All labeling and markings on the device are present and legible, operating manual available

Electrical safety

- Inspection according to DIN EN 62353

Checking the safety functions

- Perform an automatic selftest
- Function of the alarm speaker
- Function of control elements
- Function of the water level sensors
- Function of refill system (optional), crimper opens and closes smoothly
- Check of the differential pressure alarm, emergency air valve opens, pressure drops to 0 cmH_2O, no suction effect on restarting the device
- Check of the gas supply alarm and substitution, FiO_2 at 21% and > 98% with substitution

Checking the device functions

- Function test of the pressure measurement
- Function test of the volume measurement
- Function test of FiO_2
- Function test of the heating
- Function test of the external trigger (optional)
- Check of the internal battery

14 Electromagnetic emissions and immunity

NOTE

Electrical medical devices are subject to special precautions regarding electro-magnetic compatibility (EMC) and must be installed and put into service according to the EMC information provided in the accompanying documentation.

NOTE

Portable and mobile RF communications equipment can affect electrical medical devices.

14.1 Electromagnetic emissions

The **SOPHIE** ventilator is intended for operation in the electromagnetic environment specified below. The customer or user of the **SOPHIE** ventilator should assure that it is used in such an environment.

Emissions	Compliance	Electromagnetic environment guideline
RF emissions as defined in CISPR 11	Group 1	The **SOPHIE** ventilator uses RF energy for its internal function only. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions as defined in CISPR 11	Class B	The **SOPHIE** is suitable for use in establishments other than homes and those directly connected to the public low-voltage power supply network that also supplies buildings used for domestic purposes.
Harmonics as defined in IEC 61000-3-2	Class B	
Voltage fluctuations/flicker as defined in IEC 61000-3-3	Met	

Tab. 23: Electromagnetic emissions (IEC 60601-1-2)

WARNING

Portable and mobile RF communications equipment can affect electrical medical devices!

Electrical medical devices or systems should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the electrical medical device or system should be monitored to verify its intended operation in the configuration in which it will be used.

14.2 Electromagnetic immunity

The **SOPHIE** ventilator is intended for operation in the electromagnetic environment specified below. The customer or user of the **SOPHIE** ventilator should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guideline
Electrostatic discharge (ESD) as defined in IEC 61000-4-2	+6 kV (contact) +8 kV (air)	+6 kV (contact) +8 kV (air)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst as defined in IEC 61000-4-4	+2 kV for mains cables +1 kV for input and output cables	+2 kV for mains cables +1 kV for input and output cables	Mains power quality should be that of a typical commercial or hospital environment.
Surges as defined in IEC 61000-4-4	+1 kV Line-to-line +2 kV Line-to-earth	+1 kV Line-to-line +2 kV Line-to-earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short term interruptions and fluctuations in the supply voltage as defined in IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 seconds	< 5% UT (> 95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. The battery run time specified in the documentation must be taken into account.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guideline
Power frequency (50/60 Hz) magnetic field as defined in IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
UT is the AC mains voltage prior to application of the test level.			

Tab. 24: Electromagnetic immunity (IEC 60601-1-2)

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guideline
			Portable and mobile RF communications equipment should be used no closer to any part of the **SOPHIE** ventilator, including the cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF disturbances as defined in IEC 61000-4-6	3 $V_{effective\ value}$ 150 kHz to 80 MHz outside ISM bands[a]	3 $V_{effective\ value}$	Recommended separation distances: $d = 1{,}2\sqrt{P}$ $d = 4\sqrt{P}$ $d = 4\sqrt{P}$ for 80 MHz to 800 MHz
	10 $V_{effective\ value}$ 150 kHz to 80 MHz in ISM bands[a]	3 $V_{effective\ value}$	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guideline
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 7{,}7\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol. 
At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.			
b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance in these frequency ranges.			
c Field strengths from fixed transmitters, such as base stations for mobile telephones, mobile terrestrial radio equipment, amateur radio stations, AM and FM radio stations, and TV stations cannot theoretically be predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **SOPHIE** ventilator is used exceeds the compliance levels above, the **SOPHIE** ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **SOPHIE** ventilator.			
d Over the frequency range 150 kHz to 80 MHz, field strength is less than 10 V/m.			

14.3 Recommended separation distance

The SOPHIE ventilator is intended for operation in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or user of the SOPHIE ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SOPHIE ventilator as recommended below, according to the maximum output power of the communications equipment.

Recommended separation distances between portable and mobile RF communications equipment and the SOPHIE ventilator				
Maximum transmission power of the transmitter (W)	Distance based on the transmitter frequency (m)			
	150 kHz to 80 MHz outside ISM bands[a] $d = 1{,}2\sqrt{P}$	**150 kHz to 80 MHz in ISM bands[a]** $d = 4\sqrt{P}$	**80 MHz – 800 MHz** $d = 4\sqrt{P}$	**800 MHz – 2.5 GHz** $d = 7{,}7\sqrt{P}$
0.01	0.12 m	0.4 m	0.4 m	0.77 m
0.1	0.38 m	1.26 m	1.26 m	2.43 m
1	1.2 m	4 m	4 m	7.7 m
10	3.8 m	12.65 m	12.65 m	24.35 m
100	12 m	40 m	40 m	77m
For transmitters without a rated output listed in the table above, the distance can be determined using the equation in the corresponding column, where P is the transmitter's rated output in watts (W) according to the transmitter manufacturer.				
1	At 80 MHz and 800 MHz, the higher frequency range applies.			
2	The ISM bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.			
3	An additional factor of 10/3 has been incorporated into the formula and is used to calculate the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.			
4	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Tab. 25: Recommended separation distance (IEC 60601-1-2, Table 5)

15 Spare parts and accessories

Item	Description	Art. no.
1	Patient component P7 with heated respiratory gas humidifier	100761000
2	Humidifier fleece (PU: 25 pcs.)	100753131
3	Humidifier fleece P3/P7, packaged individually	100761131
4	Silencer element P7	100761025
5	Reusable patient tube system P7, heated, with Y piece, pressure measurement line, and connecting plug for: • Closed incubator Length 1200 mm, incl. 800 mm heated • Open incubator Length 1300 mm, incl. 1200 mm heated	 100761500 100761550
6	Temperature sensors for reusable patient tube system • Closed incubator • Open incubator	 100761110 100761100
7	Disposable patient tube system P3/P7, heated, with Y piece, pressure measurement line, and NO adapter	100761300
8	Connection cable P3/P7 for disposable patient tube system P3/P7 (100761300)	100760021
9	Temperature sensor P7 for disposable patient tube system P3/P7 (100761300)	100763009
10	External pneumotachographs • PNT type A neonatology • PNT type B neonatology • PNT type C pediatrics • DP PNT Neo	 103561303 103561300 103561301 103861141
11	Tube warmer to compensate for larger differences in temperature – For reusable patient tube systems: • Closed incubator for cold section (390 mm) • Closed incubator for heated section (730 mm) • Open incubator for heated section (1130 mm) – For disposable patient hose system (ref. no. 100761300): • For cold section (390 mm)	 100760003 100760007 100760004 100760507
12	Medication nebulizer set, pneumatic, autoclavable	171060120

Item	Description	Art. no.
13	Expiration filter for medication nebulizer	170160210
14	Y piece, autoclavable, with sealing cap	170160416
15	Breathing mask	
	• Silicone size 0	170060000
	• Silicone size 1	170060001
	• Silicone size 2	170060002
16	Self-filling breathing bag, silicone	
	• 250 cm^3 with breathing masks for newborns	170060038
	• 500 cm^3 with breathing masks for children	170060039
17	Connection piece for the automatic refill system	103860035
18	EasyFlow_n CPAP	
	Prongs (PU: 5)	
	• XS	170161006
	• S	170161001
	• M	170161002
	• L	170161003
	• XL	170161004
	Mask (PU: 5)	
	• XS	170161005
	• S	170161012
	• M	170161013
	• L	170161014
	• XL	170161015
	Applicator with magnet and pressure sealing cap (PU: 5)	170161161
	Decoupling tube set with connectors (Ø 10 mm) (PU: 5)	170163408
	Decoupling tube set with connectors (Ø 12 mm, F&P) (PU: 5)	170163409
	Bonnets including forehead pad and fixing straps (PU: 1)	
	• XS	170161019
	• S	170161020
	• M	170161021
	• L	170161022
	• XL	170161023
	• XXL	170161024
	• 3XL	170161025

Item	Description	Art. no.
	• 4XL	170161026
	• 5XL	170161027
	• 6XL	170161028
	• 7XL	170161029
	Headband complete with 2 fixing straps and forehead pad (PU: 1)	
	• micro	170161040
	• mini	170161041
	• maxi	170161042
19	Abdominal respiration sensor (external trigger), disposable Length: 150 cm	103560103
20	Abdominal respiration sensor (external trigger), disposable Length: 200 cm	103560203
21	Test lung with tube adapter	170060092
22	Fixing sleeve for piston for mechanical treatment of the patient component P7	100761002
23	Connection cable, 24 V DC, 2 m, on-board power supply for Sophie transport, with 4-pin plug	160561031
24	Connection tube for cleaning and disinfection equipment for mechanical treatment of the patient component P7	100761006
25	Fleece inserting tool for humidifier system P7	100753129
26	Pneumotachograph type A assembly tool	103553016
27	Pneumotachograph type B/C assembly tool	103553019
28	Sophie operating manual	103890000

Tab. 26: Accessory list

16 List of figures

17 List of tables

18 Notes

Fritz Stephan GmbH
- Medizintechnik -
Kirchstraße 19
56412 Gackenbach
Germany

☎ (+)49 (6439) 9125 – 0
🖹 (+)49 (6439) 9125 – 111
✉ info@stephan-gmbh.com
💻 www.stephan-gmbh.com