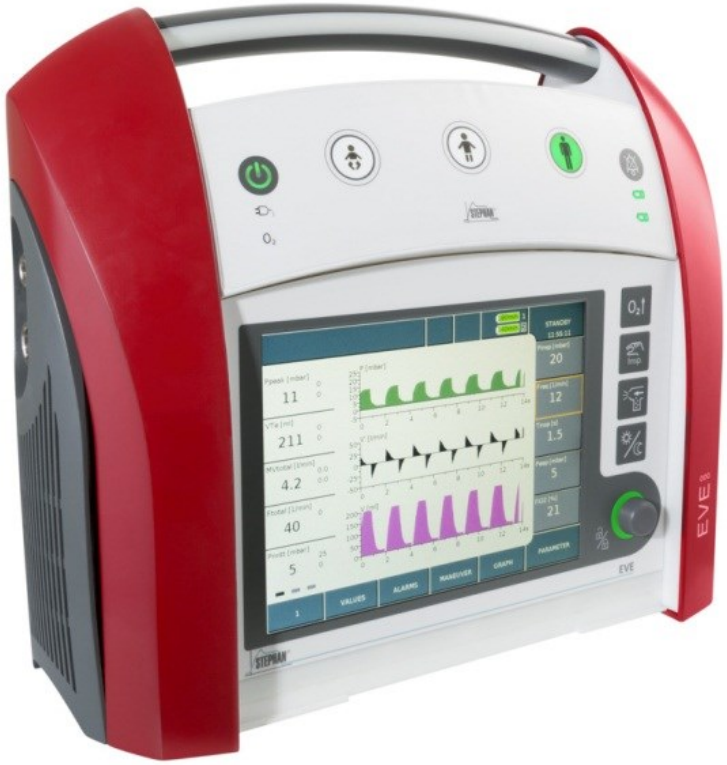
STEPHAN®

Clinical Experience
Technical Competence

EVE$_{TR}$

Transport Ventilator



Instructions for use

CE 0482

This manual aims to provide clear answers to your questions about the operation and care of the **EVE$_{TR}$**. It does not contain any information about repairs, installation or hazards that are clearly observable by the user or caused by the non-intended use of or non-authorized modifications to the device.

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 **EVE$_{TR}$** when it is operated according to the manual.

NOTE

For information about the maintenance and care of the **EVE$_{TR}$**, please see the service manual. This also contains detailed information about the device design and function as well as its individual components.

NOTE

Fritz Stephan GmbH offers training on the safe and efficient use of the **EVE** ventilator. Training material can also be requested. Please contact info@stephan-gmbh.com for more information.

Fritz Stephan GmbH
- Medizintechnik -
Kirchstraße 19

D-56412 Gackenbach

Art. no.: 107090011

Equipment is subject to technical modification.

Valid as of:	May 2018
Version:	V2.7
From software version:	V2.2

Table of contents

1 General information

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.

ATTENTION

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.

ATTENTION

The sole responsibility for selecting a suitable patient monitoring system that provides reliable data about the correct functioning of the medical device and the condition of the patient lies with the user of the ventilator. Different techniques can be used to monitor patient safety, from the electronic monitoring of the correct functioning of the medical device and the condition of the patient to simple direct observation of the patient. The sole responsibility for selecting a suitable patient monitoring technique lies with the user.

ATTENTION

All electrical cables and gas connections connected to the medical device must comply with applicable standards.

NOTE

The applied parts of the EVE (CO_2 sensor, SpO_2 sensor and ventilator breathing system (VBS)) are protected against defibrillation.

For the SpO_2 and CO_2 module, the recovery time is under 5 seconds.

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. Medication nebulizer

- Pneumatic medication nebulizer 22m/22f
  Manufacturer: GaleMed

2. Flow sensors

- Flow sensor, adults
  Manufacturer: Fritz Stephan GmbH
- Flow sensor, children
  Manufacturer: Fritz Stephan GmbH
- Pneumotachograph, preterm infants and newborns, type B for ventilator **EVE**
  Manufacturer: Fritz Stephan GmbH
- Pressure measuring adapter nCPAP
  Manufacturer: Fritz Stephan GmbH

3. Disposable patient tube systems

- EVE adult emergency
  Manufacturer: Fritz Stephan GmbH
- EVE paediatrics
  Manufacturer: Fritz Stephan GmbH
- EVE adult ICU
  Manufacturer: Fritz Stephan GmbH
- Patient tube system 10 mm, newborn, heated
  Manufacturer: WILAmed
- Patient tube system 15 mm, child, heated
  Manufacturer: WILAmed
- Patient tube system 22 mm, adult, heated
  Manufacturer: WILAmed
- Patient tube system RT 265, child, heated
  Manufacturer: Fisher & Paykel
- Patient tube system RT 380, adult, heated
  Manufacturer: Fisher & Paykel
- Patient tube system RT330 Optiflow Junior, heated
  Manufacturer: Fisher & Paykel
- Ventilation tube RT024
  Manufacturer: Fisher & Paykel

4. NCPAP patient interfaces
   - EasyFlow NCPAP system
     Manufacturer: Fritz Stephan GmbH
5. Expiration valve
   Manufacturer: Fritz Stephan GmbH
   CO_2 sensor
   Manufacturer: Masimo
6. Masimo Rainbow
   Manufacturer: Masimo
7. Optiflow Junior Nasal Cannula
   Manufacturer: Fisher & Paykel
8. Optiflow + Nasal Cannula
   Manufacturer: Fisher & Paykel

NOTE

Further information on the accessories for the ventilator can be found in chapter 13.

1.2 Optional components

1.2.1 Software components

On customer request, **EVE$_{TR}$** can also be equipped with the following software components:

- License graphic (loops & trends), art. no.: 107061451
- License Neo mode, art. no.: 107061460
- License Niv / Duopap, art. no.: 107061450
- License ACV+/nACV+, art. no.: 107061452

1.2.2 Hardware components

The **EVE$_{TR}$** can optionally be equipped with a CO_2 measurement using the mainstream or sidestream technique (see chapter 8) as well as a pulse oximeter for measuring the Masimo Rainbow® parameters Pulse, PVI, PI, SpMet, SpCO, and SpOC (see supplemental pulse oximetry manual).

1.3 Device name and manufacturer

Device name **EVE$_{TR}$**

Manufacturer

Fritz Stephan GmbH
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1.4 Intended use

The **EVE$_{TR}$** is used for invasive and non-invasive ventilation in emergency and transport settings. The **EVE$_{TR}$** is suitable for long-term ventilation. The ventilator is available in different feature levels and can be used by first responders as well as for ground, water, or air transport. The **EVE$_{TR}$** is suitable for the ventilation of children and adults weighing up to 200 kg. It is also possible to ventilate preterm infants and newborns.

The **EVE$_{TR}$** supports the following types of ventilation:

Therapeutic scope

Ventilation mode	Standard	Optional
PC-CMV	X	-
PC-SIMV	X	-
PC-ACV	X	-
PC-ACV+	-	License ACV+/nACV+ required
CPAP	X	-
VC-CMV	X	-
VC-SIMV	X	-
O_2 therapy	X	-
High flow O_2 therapy	-	License Neo mode required
DUOPAP	-	License Neo mode or NIV-DUOPAP required
nPCMV	-	License Neo mode required
nPC-SIMV	-	License Neo mode required
nPC-ACV	-	License Neo mode required
nPC-ACV+	-	License ACV+/nACV+ required
nDUOPAP	-	License Neo mode or NIV-DUOPAP required
nCPAP	-	License Neo mode required

Tab. 1: Therapeutic scope

1.5 Contraindications

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 type of ventilation based on the patient's medical condition. The continuous monitoring of the patient's condition must be assured at all times.

Non-invasive ventilation is contraindicated in the following cases:

- No spontaneous breathing
- Fixed or functional airway obstruction
- Gastrointestinal bleeding or ileus

1.6 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!

1.7 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.

NOTE

The **EVE$_{TR}$** must be operated from the front side. The operator must have a sufficient visual angle of the control and display elements.

Warranty The manufacturer does not accept any warranty claims resulting from incorrect operation or inadequate care and maintenance.

The manufacturer only guarantees the safety and reliability of the device if it is operated in compliance with the operating manual.

1.8 Abbreviations, definitions, and pictograms

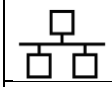
Abbreviation/ technical term	Term	Meaning
Battery		Device for storing electrical energy in the form of chemical energy
Apnea		Respiratory arrest
BTPS	Body Temperature Pressure Saturated	Measuring condition at body temperature, current ambient pressure and saturated gas
CPAP	Continuous Positive Airway 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.
Distal		Away from the patient
DUOPAP		Ventilation support at two different pressure levels
ETT		Endotracheal tube
Exp	Expiration (exhalation)	Time period from the onset of the expiration flow until the onset of the inspiration flow
Flow limit	Flow limitation	Limitation of the flow for non-invasive ventilation in NEO mode
HEPA	High Efficiency Particulate Air Filter	High-performance particle filter
HME	Heat and Moisture Exchanger	Heat and moisture exchanger
HP	High priority	An alarm indicating that the user should intervene without delay. (IEC 60601-1-8)
HW		Notification
IGR	Incremental encoder	Control knob for device operation
Insp	Inspiration (inhalation)	Time period from the onset of the inspiration flow until the onset of the expiration flow
MP	Medium priority	An alarm indicating that the user should intervene immediately. (IEC 60601-1-8).

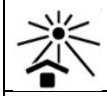
Abbreviation/ technical term	Term	Meaning
nCPAP	Non-invasive continuous positive airway pressure	Non-invasive spontaneous breathing with continuous positive airway pressure. When breathing under CPAP, the device keeps the pressure constant on the endotracheal tube's connection piece.
nPC-CMV	Non-invasive pressure-controlled mandatory ventilation	Non-invasive pressure-controlled mandatory ventilation
nPC-SIMV	Non-invasive pressure-controlled synchronized intermittent mandatory ventilation	Non-invasive pressure-controlled synchronized intermittent mandatory ventilation
nPC-ACV	Non-invasive pressure-controlled – Assist Control Ventilation	Non-invasive pressure-controlled assist/control ventilation
nPC-ACV+	Non-invasive pressure-controlled – Assist Control Ventilation with expiration trigger	Non-invasive pressure-controlled assist/control ventilation with expiration trigger
nDUOPAP		Non-invasive ventilation support at two different pressure levels
NIST	Non-interchangeable screw thread	Non-interchangeable screw thread
O_2		Oxygen level
PC-CMV	Pressure controlled mandatory ventilation	Pressure controlled mandatory ventilation
PC-SIMV	Pressure controlled synchronized intermittent mandatory ventilation	Pressure-controlled synchronized intermittent mandatory ventilation
PC-ACV+	Pressure Controlled – Assist Control Ventilation with expiration trigger	Pressure-controlled assist/control ventilation with expiration trigger
PC-ACV	Pressure Controlled – Assist Control Ventilation	Pressure-controlled assist/control ventilation
PI		Perfusion index
PRVC	Pressure regulated volume control	Pressure-controlled and volume-regulated ventilation
PSV	Pressure support ventilation	Pressure support ventilation
PVI™	Pleth Variability Index	Plethysmographic variability index
PEEP	Positive End Expiratory Pressure	Positive end expiratory pressure
Pinsp		Inspiratory pressure

Abbreviation/ technical term	Term	Meaning
PAW		Airway pressure
Pmean		Mean airway pressure
PNT	Pneumotachograph	Flow sensor
Proximal		Close to the patient
Resistive		Creates a pneumatic resistance
SIMV	Synchronized Intermittent Mandatory Ventilation	Form of ventilation synchronized to the patient
SpCO®	Carboxyhemoglobin measurement	Index for CO level in arterial blood
SpMet™	Methemoglobin measurement	Index for methemoglobin level in arterial blood
SpHb®	Hemoglobin measurement	Index for hemoglobin level in arterial blood
SpOC®	Oxygen level measurement	Index for oxygen level in arterial blood
Standby		The device is ready for use
STPD	Standard temperature, pressure, dry	Measuring condition at standard temperature (20 C), standard pressure (1013 mm Hg absolute), dry
TA		Technical alarm
TC	Tube compensation	Tube compensation
V´	Flow	Volume flow
VC-CMV	Volume-controlled continuous mandatory ventilation	Volume-controlled continuous mandatory ventilation
VC-SIMV	Volume-controlled synchronized intermittent mechanical ventilation	Volume-controlled synchronized intermittent mechanical ventilation
PU		Packaging unit
VT	Tidal volume	Breathing volume
VTe	Expiratory breathing volume	Expiratory tidal volume
CGS		Central gas supply
V		Volume

Tab. 2: Abbreviations and technical terms

Pictogram	Meaning
	Standard ventilation parameter for premature infants and newborns (see chapter 3.1.2)
	Standard ventilation parameter for children (see chapter 3.1.2)
	Standard ventilation parameter for adults (see chapter 3.1.2)
O_2	O_2 supply indicator (see chapter 3.1.2)
	Mains power indicator (see chapter 3.1.2)
	Charge indicator for battery 1 (see chapter 3.1.2)
	Charge indicator for battery 2 (see chapter 3.1.2)
	Inspiration hold (see chapter 3.1.3)
	Pre-oxygenation (see chapter 3.1.3)
	Activate aerosol nebulization (see chapter 3.1.3)
	Day/Night toggle switch (see chapter 3.1.3)
	Lock/unlock touchscreen (see chapter 3.1.3)
	Scroll (see chapter 3.2.3)
	Return (see chapter 3.2.1.3)
	Save settings (see chapter 3.2.1.3)
	Ventilation settings for adults pre-selected (see chapter 3.2.5)
	Ventilation settings for children pre-selected (see chapter 3.2.5)
	Ventilation settings for preterm infants and newborns preselected (see chapter 3.2.5)
	Non-invasive ventilation (see chapter 3.2.5)
	Invasive ventilation (see chapter 3.2.5)

Pictogram	Meaning
	PNT (see chapter 3.2.5)
	Alarm history contains unacknowledged alarms (see chapter 3.2.8)
	Alarm suppression switched on (see chapter 3.2.8)
	Pre-oxygenation activated (see chapter 3.2.8)
	Aerosol nebulization activated (see chapter 3.2.8)
	Touchscreen locked (see chapter 3.2.7)
	Mains power (see chapter 3.2.6)
	Charge level for battery 1 (see chapter 3.2.6)
	Charge level for battery 2 (see chapter 3.2.6)
	Contains conventional or rechargeable batteries and must not be disposed of as domestic waste.
	DC
	Protective conductor
	Ethernet port
	Type BF applied part, defibrillator-protected
	The instructions in the operating manual must be observed
	Read operating manual
	Equipotential bonding
	Hazard symbol for ESD-sensitive parts
	Push lever up to unlock
	Manufacturer
	Manufacturing date
	Serial number

Pictogram	Meaning
	Product number
	Expiration date
	Do not reuse
	Keep dry
	Keep away from sunlight
	Temperature limits for storage and transport
	Humidity limits for storage and transport
	Atmospheric pressure limits for storage and transport
	Warning
	Do not use if the packaging is damaged
	Recyclable materials
	CE marking, indicates compliance with Directive 93/42/EEC concerning medical devices

Tab. 3: Pictograms

1.9 Specifications

Ambient conditions

Operation	Temperature	−10 – 40° C
	Relative humidity	5 – 95% (non-condensing)
	Air pressure	540 – 1100 hPa
Storage	Temperature	−20 – 50° C
	Relative humidity	10 – 80% (non-condensing)
	Air pressure	540 – 1100 hPa
	Store in a protected, dust-free location protected from humidity.	

General information

Class according to 93/42/EEC	II b	
Protection type	IP 44 Protection against contact with tools, conductive parts with a diameter > 1.0 mm; protection against foreign objects with a diameter > 1.0 mm Protected against splash water from any direction	
UMDNS code	18-098	
GMDN code	36289	
Inspection/ maintenance cycle	Annually	
Dimensions	(WxHxD)	360 x 320 x 155 mm
Weight	Main device without external battery	6.3 kg
	Main device with external battery	6.9 kg
Sound pressure level		46 dB (A)
Sound power level		56 dB
Maximum pressure limit	$P_{LIM,}$ max	100 mbar (SFC)

Energy supply	Mains	Connection	100 – 240 V AC 50 – 60 Hz
	Protection class	II according to IEC 60601-1	
		Supply line	Power supply
		Power consumption	Max. 150 W
		Current consumption	1.667 – 0.625 A
	Battery	Type	Lithium-ion
		Nominal voltage	25.2 V DC
		Nominal capacity	2.1 Ah
		Operating time (with optional external battery) (new batteries, fully charged)	Max. 6 hours/ min. 3.5 hours
		Battery 1 (internal)	Max. 3 hours
		Battery 2 (external), optional	Max. 3 hours
		Charge time battery 1	Approx. 3 hours
		Charge time battery 2	Approx. 4 hours
		Batteries 1 and 2 are only charged at a battery temperature of 0 – 40° C.	

NOTE

The battery life of the ventilator is reduced at extreme temperatures.

Brackets	Ambulance bracket	
	Dimensions	380 x 360 x 118 mm (W x H x D)
	Weight	3.5 kg
	Connections:	12 – 28 V DC

Helicopter bracket	
Dimensions	426 x 360 x 150 mm (W x H x D)
Weight	3.3 kg
Connections:	12 – 28 V DC

Carry system without gas cylinder and pressure regulator	
Dimensions	470 x 335 x 260 mm (W x H x D)
Weight	2.7 kg

Gas supply

Supply pressure High pressure	O_2	280 – 600 kPa
Flow rate	Max. 200 l/min	
Gas consumption	Conventional (see chapter 5.1.2 for more information about O_2 gas consumption)	
	Aerosol	Approx. 7 l/min at 2.8 bar
The gases must be dry and free of oil and dust.		

Available ventilation modes

PC-CMV	Pressure-controlled continuous mandatory ventilation
PC-SIMV	Pressure-controlled synchronized intermittent mandatory ventilation
PC-ACV	Pressure-controlled assist/control ventilation
PC-ACV+	Pressure-controlled assist/control ventilation with expiration trigger
CPAP	Spontaneous respiration with continuous positive airway pressure
DUOPAP	Ventilation support at two different pressure levels
VC-CMV	Volume-controlled continuous mandatory ventilation
VC-SIMV	Volume-controlled synchronized intermittent mechanical ventilation
nPC-CMV	Non-invasive pressure-controlled mandatory ventilation
nPC-SIMV	Non-invasive pressure-controlled synchronized intermittent mandatory ventilation

nPC-ACV	Non-invasive pressure-controlled assist/control ventilation
nPC-ACV+	Non-invasive pressure-controlled assist/control ventilation with expiration trigger
nDUOPAP	Non-invasive ventilation support at two different pressure levels
nCPAP	Non-invasive spontaneous breathing with continuous positive airway pressure

Function keys

Parameter	Setting range	Resolution
Pre-oxygenation (time)	10 – 180 s	1
Pre-oxygenation (concentration)	21 – 100%	1
Insp. Hold	Max. 15 s	1
Aerosol	5 – 30 min	5

Ventilation parameters

Parameter	Meaning	Setting range	Resolution
PEEP	Positive end expiratory pressure	0 – 25 mbar	1
Pinsp*	Inspiratory pressure	6 – 55 mbar	1
ΔPsupp	Support pressure	1 – 55 mbar	
Phigh*	Inspiratory pressure under DUOPAP	6 – 55 mbar	1
VT	Tidal volume (PC mode / PRVC)	2 – 150 ml 150 – 500 ml 500 – 1000 ml 1000 – 2000 ml	1 5 10 50
VT	Tidal volume (volume-controlled ventilation)	100 – 150 ml 150 – 500 ml 500 – 1000 ml 1000 – 2000 ml	1 5 10 50
Flow limit	Flow limitation	5 -30 / Off l/min	1
Tinsp	Inspiration time	0.2 – 30 s	0.1
Texp	Expiration time	0.2 – 30 s	0.1

Parameter	Meaning	Setting range	Resolution
I:E	Inspiration/ expiration ratio	1:150, 150:1	1
f	Frequency	1 – 150 1/min	1
Apnea	Apnea duration	1 – 60 s	1
O_2	O_2 ratio of breathing air	21 – 100%	1
Trigger	Flow trigger	0.2 – 15 l/min	0.1
Ramp time	Ramp time	0.06 – 30 s	0.01
Flow	Flow O_2 therapy	2 – 20 l/min	1
ETS	Expiration trigger sensitivity	5 – 70%	1
Tube compensation	Intensity of tubus compensation	0 – 100%	1
Tube Ø	Tube diameter	2 – 12 mm	0.5

* Ensured by using a redundant pressure measurement and limitation

Monitoring

Measured value	Unit	Resolution	Display range
Pressure (accuracy[1]: ΔP = ±2 mbar + 4% of displayed value)			
Ppeak	mbar	1	−20 – 99
Pplat	mbar	1	−20 – 99
Pmean	mbar	1	−20 – 99
PEEP	mbar	1	−20 – 99
Flow (STPD, accuracy[1]: ΔV` = ±15%)			
V´min	l/min	0.1	−200 – 200
V´max	l/min	0.1	−200 – 200
Volume $V = \int V'(t)$ (STPD, accuracy[1]: ΔV = ±4.0 ml +15%)			
VTe	ml	1	0 – 3000
VTspon	ml	1	0 – 3000
VTleak	ml	1	0 – 100
MVe	l/min	0.01	0 – 999
MVspon	l/min	0.01	0 – 999

[1] Accuracy assumes an ambient temperature of 0 – 40° C.

Measured value	Unit	Resolution	Display range
Time (accuracy[1]: Δt` = ±5%)			
Tinsp	s	0.1	0 – 60
Texp	s	0.1	0 – 60
ftotal	1/min	1	0 – 300
fspon	1/min	1	0 – 300
I:E	I:E	0.1	1:150 – 150:1
O_2 (calculation accuracy[1]: ±2.5 Vol.% + 2.5% of displayed value)			
O_2	%	1	21 – 100
Rise time of O_2 level from 21% to 90%		58 s (VT = 30 ml) 37 s (VT = 150 ml) 22 s (VT = 500 ml)	
$EtCO_2$ (see manufacturer data sheet for sensor accuracy)			
$EtCO_2$	Vol% mmHg kPa	0.1 1 0.1	0 – 90 0 – 12 0 – 999
Lung dynamics			
R	mbar/l/s	1	0 – 1000
C	ml/mbar	0.1	0 – 650
Diagnostic			
P0.1	mbar	1	0 – -25
Time constant	s	0.1	0 – 20
RSB	1/min*L	1	0 – 9999
PTP	mbar x s	0.1	0 – 999
MASIMO® parameters (see manufacturer data sheet for accuracy of MASIMO® sensors)			
Pulse	bpm	1	0 – 239 (above "---")
PVI	%	1	0 – 100%
PI	%	0.01 0.1 1	0.02 – 0.99 1 – 9.9% 10 – 20%
SpM et	%	0.1	0 – 100
SpCO	%	0.1	0 – 100
SpOC	ml/dl	0.1	0 – 35

Measured value	Unit	Resolution	Display range
SpHb	g/dl	0.1	2 – 24.5
Curves			
Curve representation	P(t), V(t), V'(t), CO_2(t), plethysmography		
Loops	V(P), V'(V), V'(P)		
Trends	Ppeak, Pplat, Pmean, PEEP, Vte, Vtspon, Vtleak, MVe, MVespon, ftotal, fspon, O_2, R, C, RSB, PTP, $EtCO_2$, Pulse, PVI, PI, SPO_2, SPMet, SPCO, SPOC, FiO_2,Pplat/PEEP, MVe/MVespon, ftotal/fspon		

NOTE

The **EVE** ventilator features a multi-computer design with mutual monitoring and redundancy. In addition, ventilation pressures are limited by the hardware.

Auto-scaling

Parameter		Scale values
P (mbar)	[mbar]	−5/ 0/ +20/ +40/ +60/ +80/ +100 −5/ 0/ +15/ +30/ +45/ +60/ +75 −5/ 0/ +10/ +20/ +30/ +40/ +50 −5/ 0/ +5/ +10/ +15/ +20/ +25
t (s)	[s]	0/ 4/ 8/ 12/ 16/ 20 (adult and child) 0/ 2/ 4/ 6/ 8 (preterm infants and newborns)
V (ml)	[ml]	0/ 500/ 1000/ 1500/ 2000 0/ 250/ 500/ 750/ 1000 0/ 50/ 100/ 150/ 200 0/ 25/ 50/ 75/ 100
V' (l/min)	[l/min]	−200/ −100/ 0/ +100/ +200 −100/ −50/ 0/ +50/ +100 −50/ −25/ 0/ +25/ +50 −25/ −12.5/ 0/ +12.5/ +25

Setting ranges Alarm limit

Parameter	Unit	Lower limit	Upper limit	Resolution
PAW	mbar	2 – 59	11 – 60	1
PEEP	mbar	0 – 29	1 – 30	1
MVe	l/min	0.01 – 0.9	0.2 – 1.0	0.01
		0.9 – 41	1.0 – 42	0.1
f	1/min	-	5 – 120/Off	1
Apnea	s		4 – 60	1
VT	ml	0 – 99	1 – 100	1
		99 – 495	100 – 500	5
		490 – 990	500 – 2000	10
$EtCO_2$	Vol.%	0.0 – 11.9	0.1 – 12	0.1
	mmHg	0 – 89	1 – 90	1
	kPa	0.0 – 11.9	0.1 – 12	0.1
O_2	Vol.%	18 – 99	22 – 100	1
SpO_2	%	88 – 98	91 – 99/Off	1
Pulse	bpm	30 – 230	35 – 235/Off	1
PI	%	0.03 – 0.1/Off	0.04 – 0.1	0.01
		0.1 – 1	0.1 – 1	0.1
		1 – 18	1 – 19/Off	1
PVI	%	1 – 97/Off	2 – 99/Off	1
SpMet	%	0.1 – 2/Off	1 – 2	0.1
		2 – 99	2 – 99.5/Off	0.5
SpCO	%	1 – 97	2 – 98/Off	1
SpOC	ml O_2/dl	1 – 33	2 – 34, Off	1
SpHb	g/dl		2 – 24.5	0.1

Alarms	Visual, acoustic, plain text message

Sound	Minimum setting	72 dB(A)
	Maximum setting	80 dB(A)

Sensors

Flow/ volume	Flow sensor	Dead space
	Children	2.7 ml
	Adults	11 ml
	Preterm infants and newborns (PNT B)	0.6 ml
	Proximal measurement of flow (pressure difference) and pressure.	
CO_2	IRMA™ airway adapter	Dead space
	Preterm infants and newborns	≤ 1 ml
	Adults/children	≤ 6 ml

HME filter Children	Air filter volume	8 ml
	Connections	15f patient-side 15m machine-side Luer lock
	Pressure drop at 5 l/min	0.48 cmH_2O
	7.5 l/min	0.63 cmH_2O
	10 l/min	0.78 cmH_2O
HME filter Adults	Air filter volume	50 ml
	Connections	22m/15f patient-side 22f/15m machine-side Luer lock
	Pressure drop at 50 l/min	0.2 kpa
O_2 (EVE_{TR})	Consumption-free measurement	

Single-use tube systems	Adult emergency 1.8 m, art. no.: 107061120	Compliance	1.05 ml/hPa
		Insp. resistance (30 l/min)	0.0156 hPa/l/min
		Insp. resistance (15 l/min)	0.0126 hPa/l/min
		Insp. resistance (2.5 l/min)	0.008 hPa/l/min
		Exp. resistance (30 l/min)	0.051 hPa/l/min
		Exp. resistance (15 l/min)	0.0486 hPa/l/min
		Exp. resistance (2.5 l/min)	0.064 hPa/l/min
	Adult emergency 2.4 m, art. no.: 107061140	Compliance	1.48 ml/hPa
		Insp. resistance (30 l/min)	0.0327 hPa/l/min
		Insp. resistance (15 l/min)	0.022 hPa/l/min
		Insp. resistance (2.5 l/min)	0.016 hPa/l/min
		Exp. resistance (30 l/min)	0.06 hPa/l/min
		Exp. resistance (15 l/min)	0.0743 hPa/l/min
		Exp. resistance (2.5 l/min)	0.068 hPa/l/min
	Adult emergency 3 m, art. no.: 107061141	Insp. compliance	1.88 ml/hPa
		Insp. resistance (30 l/min)	0.0337 hPa/l/min
		Insp. resistance (15 l/min)	0.0226 hPa/l/min
		Exp. resistance (30 l/min)	0.053 hPa/l/min
		Exp. resistance (15 l/min)	0.0633 hPa/l/min
	Pediatrics art. no.: 107061124	Compliance	1.03 ml/hPa
		Insp. resistance (15 l/min)	0.116 hPa/l/min
		Insp. resistance (2.5 l/min)	0.076 hPa/l/min
		Exp. resistance (15 l/min)	0.12 hPa/l/min
		Exp. resistance (2.5 l/min)	0.1 hPa/l/min

2 Safety instructions

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.

ATTENTION

Identifies potentially dangerous situations that may result in minor or moderate injury to the patient or user or damage to the medical device if not avoided.

NOTE

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

2.1 Danger

DANGER

The device must only be operated by authorized and properly trained professional staff. The device must be operated according to the instructions in this operating manual.

DANGER

The device is not certified for use in potentially explosive environments!

DANGER

The device must not be used in areas with contaminated air.

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.

2.2 Warning

WARNING

Lack of an alternative ventilation method, such as a self-priming operator-powered resuscitator (according to ISO 10651-4), may result in patient death if the ventilator fails. Always have a separate manual breathing bag handy.

WARNING

Only authorized customer service staff of FRITZ STEPHAN GMBH are permitted to alter, modify, repair, or open the device, or to replace the internal battery. Only use spare parts from FRITZ STEPHAN GMBH for maintenance.

WARNING

Do not operate the device outside the specified ambient conditions (see chapter 1.9). Otherwise, device functionality may be impaired.

WARNING

The ventilator suctions ambient air to create compressed air. It must therefore never be covered during operation or placed so that its operation or performance is impaired. Failure to comply may result in device failure or damage and therefore pose a risk to the patient.

WARNING

If the ventilator is to be operated with additional O_2, the O_2 supply pressure must be 2.8 – 6 bar (see chapter 1.9).

WARNING

The displayed O_2 concentration is not a measurement. Instead, the gas concentration is calculated from the flow rates.

WARNING

Connecting a different type of gas instead of O_2 (such as compressed air) will falsify the displayed O_2 concentration.

WARNING

Using the ventilator in a contaminated environment may be dangerous.

WARNING

Excessive ventilation modes can increase the temperature of the patient's breathing air up to 43° C. Normal ambient temperatures counterbalance this effect.

WARNING

Only use patient tubing and accessories listed in chapters 1.2 (Product combination) and 12 (List of accessories). Using other patient tubing or accessories not intended for use with the ventilator may impair device performance and safety.

WARNING

When operating normally or in the event of the first fault, the tube system can be contaminated with body fluids or exhaled gases by the ventilator up to the expiration valve.

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 pull on patient tubing or electrical cables. This may cause the device to tip over or drop.

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

Never use the ventilator in a hyperbaric chamber.

WARNING

Never operate the ventilator with nitric oxide, helium, or mixtures containing helium.

WARNING

During non-invasive ventilation, a CO_2 monitor for measuring the expiratory CO_2 level must be used. The **EVE$_{TR}$** can be optionally equipped with an internal CO_2 measuring unit. Otherwise, an external measuring unit must be used.

WARNING

During non-invasive ventilation, the exhaled volume may differ from the measured exhaled volume if the mask is not fully sealed.

WARNING

FRITZ STEPHAN GMBH recommends using the pressure-controlled ventilation method PC-CMV in the case of suction. To prevent the occurrence of negative pressures, the PEEP must be set to a minimum of 4 mbar.

WARNING

Treat the individual parts carefully to avoid mechanical damage.
Only use correctly prepared parts to operate the device.

WARNING

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

WARNING

Check that no condensation accumulates near the Y piece of the inspiration tube which could leak into the flow sensor.

WARNING

Make sure that there are no water droplets in the pressure measurement lines.

WARNING

After using the special alarm suppression state, make sure that the alarm is reactivated before leaving the patient.

WARNING

FRITZ STEPHAN GMBH recommends that the ventilator is not operated with a low battery (capacity <10%) because the device will switch off immediately in the event of a power failure.

WARNING

Incorrectly selected trigger thresholds and large leaks may cause auto-triggering! In this case, the trigger threshold has to be manually adjusted.

WARNING

When adding system components or sub-assemblies to the ventilation system of the ventilator, the pressure gradient across the ventilation system, measured at the patient connection port, may negatively affect the performance data of the ventilator.

WARNING

The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the medical electrical equipment or system as replacement parts for internal components, may result in increased emission or decreased immunity of the medical electrical equipment or system.

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

No modifications to the **EVE$_{TR}$** are permitted without the manufacturer's authorization!

3 Design and functional description

3.1 Front view

Fig. 1: Front view

1	Touchscreen display	4	Function buttons
2	Transport handle with alarm indicator	5	Control knob
3	Control panel	6	Removable display cover

Fig. 2: Front view with display cover

3.1.1 Alarm indicator

The alarm indicator in the transport handle notifies the user about alarm occurrences. It flashes yellow for medium priority alarms and red for high priority alarms.

3.1.2 Control panel

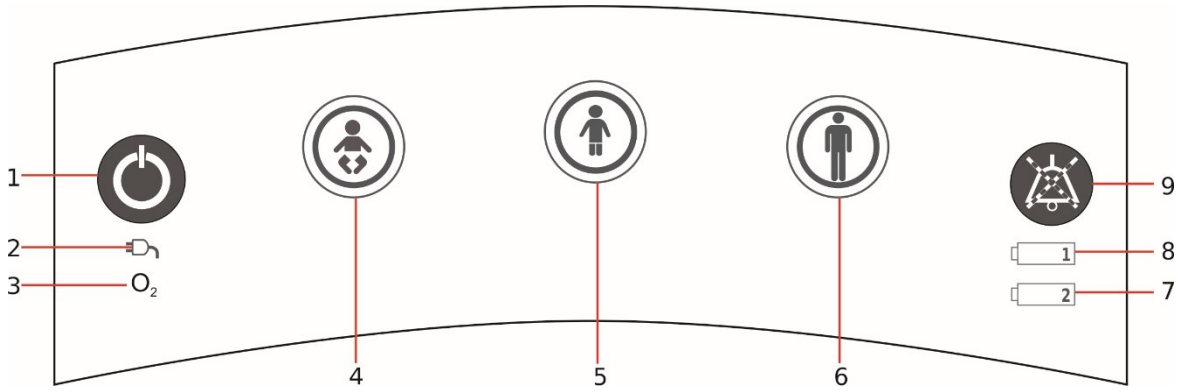


Fig. 3: Control panel

1	On/Off button	6	Adult fast tracking key
2	Mains power indicator		
3	O_2 supply indicator	7	Battery 2 charge indicator
4	Fast tracking key Preterm infants and newborns	8	Battery 1 charge indicator
5	Child fast tracking key	9	Acoustic alarm suppression

On/Off/Standby button

Press this button to switch the **EVE$_{TR}$** on/off or, in the case of ongoing ventilation, to switch it to Standby mode (see chapter 6.2).

Fast tracking keys

To prevent operator errors, the desired fast tracking key must be pressed for 0.5 s, after which it starts to flash green. Pressing the key again for 0.5 s will then start or switch to the selected ventilation mode.

Fast tracking key for preterm infants and newborns

Pressing this key will start ventilation using the standard parameters for preterm infants and newborns (see chapter 6.6).

NOTE

For safety reasons, the volume-controlled ventilation modes cannot be selected in the mode for preterm infants and newborns.

Child fast tracking key

Pressing this key will start ventilation using the standard parameters for children (see chapter 6.6).

Adult fast tracking key

Pressing this key will start ventilation using the standard parameters for adults (see chapter 6.6).

Acoustic alarm suppression

Pressing this key will suppress acoustic alarms for 2 min. If the key is pressed again within 5 s, the alarm suppression is canceled again. Pressing the key again after 5 s has passed will start a new 2 minute countdown.

NOTE

During therapeutic procedures, the acoustic alarm can be completely suppressed for 2 min by pressing the alarm suppression button before the occurrence of the first alarm.

Battery 1 charge indicator

The charge indicator tells you the remaining capacity of the internal battery 1.

Green	Capacity between 75 – 100%
Yellow	Capacity between 40 – 74%
Red	Capacity between 1 – 39%
Flashing red	Capacity 0% or error

Battery 2 charge indicator

The charge indicator tells you the remaining capacity of the external battery 2 (optional).

Green	Capacity between 75 – 100%
Yellow	Capacity between 40 – 74%
Red	Capacity between 1 – 39%
Flashing red	Capacity 0% or error

Mains power indicator

When connected to the energy supply, the mains power indicator is green. The internal batteries are charged automatically as needed. The battery charge indicators tell you the current battery level.

Oxygen supply indicator

O_2

The indicator is green when an oxygen cylinder with sufficient fill pressure is connected.

3.1.3 Function buttons

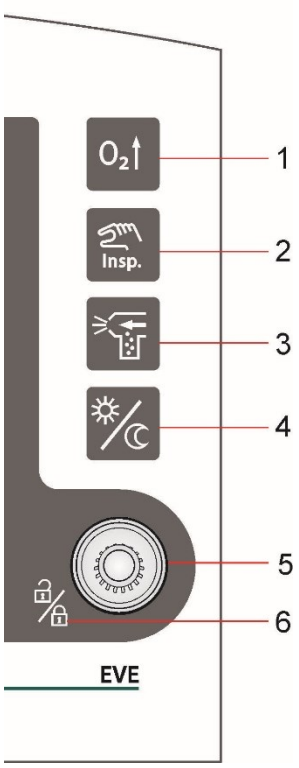


Fig. 4: Function buttons

1	»Preoxy« button	4	»Day/Night« toggle button
2	»Inspiration Hold« button	5	Control knob
3	»Aerosol« button	6	Lock/unlock touchscreen

»Preoxy« button

Press the »Preoxy« button to administer a pre-adjustable inspiratory oxygen concentration for a certain preset interval. These settings can be configured in the "System Settings/Function" menu (see chapter 4.1.4). At the same time, the display for the set oxygen concentration changes to the pre-set “Preoxy” value. The alarm limits for oxygen concentration are adjusted automatically. The button is green while pre-oxygenation is in progress.

»Inspiration Hold« button

Pressing this button during inspiration will hold inspiration at the end of the normal inspiration phase for the duration for which the button is pressed (maximum 15 s). Pressing the button during expiration will trigger a mandatory inspiration using the set ventilation parameters.

NOTE

This function is not available for the CPAP, VCV and PRVC ventilation modes. The key is then not illuminated.

»Day/Night« toggle button

This button lets you toggle the display, alarm indicator and patient/function buttons between day and night mode.

»Aerosol« button

Press the »Aerosol« button to switch on aerosol nebulization. The medication nebulization duration can be set to between 5 and 30 min in the "System Settings/Function" menu (see chapter 4.1.4). The nebulization ends automatically at the end of the set time or when pressing the button again. The button is green while nebulization is in progress.

NOTE

Aerosol nebulization is only possible if O_2 is connected to the ventilator.

Lock/unlock touchscreen

Pressing the control knob for three seconds will lock the touchscreen. Press the control knob again for three seconds to unlock the touchscreen. When you tap the locked touchscreen, a lock icon appears in the "System Settings" field (see chapter 3.2.7).

Control knob

Use the control knob to select and activate all indirect **EVE$_{TR}$** functions.

The control knob has the following functions:

- Switching within the menus
- Selecting and executing menu functions
- Setting parameters
- Confirming parameter settings

Turn the control knob clockwise or counterclockwise to scroll through the available menus, function fields and parameter fields. You can also use the touchscreen. When using the control knob for navigation, the field in focus has an orange border. It can be selected using the touchscreen or by pressing the control knob again. When changing a numeric parameter, the control knob must be used to confirm this in order to accept the modified value.

3.2 Touchscreen monitor

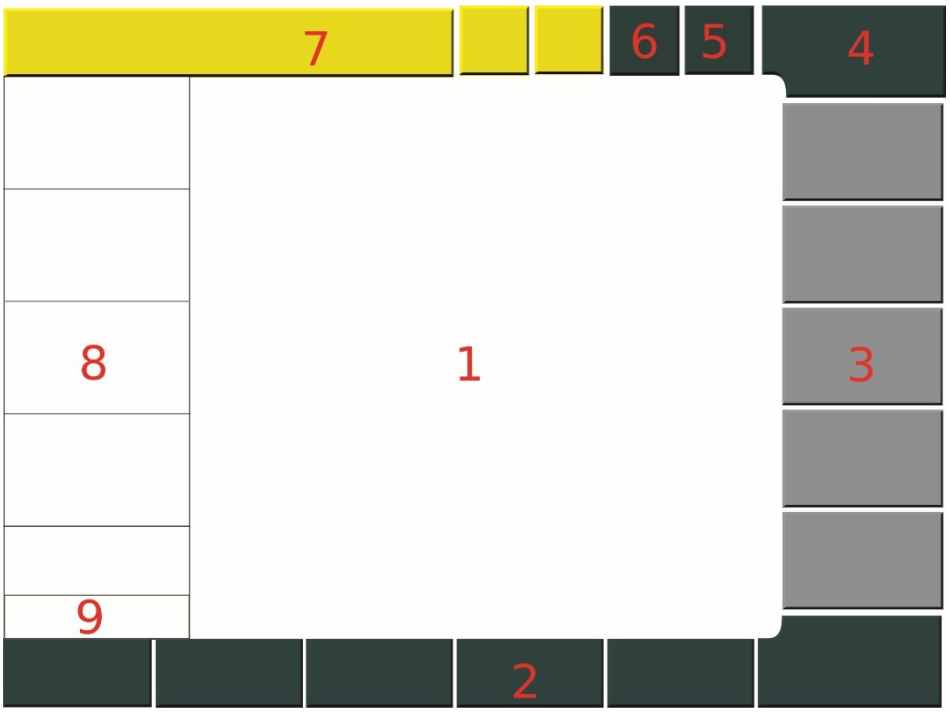


Fig. 5: Monitor unit

1 Graphic display, adjust graphic display
2 Function fields
3 Adjustable parameter display
4 Ventilation menu (ventilation mode and flow sensor display and selection)
5 System field (Access system settings / touchscreen lock state indicator)
6 System field (Energy supply indicator)
7 Status/alarm indicators and notifications, Change to alarm limits, preoxygenation, trigger
8 Measurement value display with alarm limits
9 Time display

3.2.1 General information about touchscreen navigation

The **EVE$_{TR}$** is controlled using a combination of touchscreen fields and the control knob. Both the touchscreen and the control knob can be used to select parameters or fields. When changing a numeric parameter, the control knob must be used to confirm this in order to accept the modified value.

3.2.1.1 Selecting a function field

Setting the focus When navigating the display using the control knob, the focus is indicated by an orange border. The field is "in focus" and can be selected using the touchscreen or by pressing the control knob again.

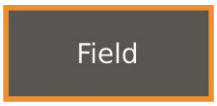


Fig. 6: Focus

Selection When selected, the color of a function field/tab changes from green to white. In case of navigation, no further confirmation is necessary. For safety-relevant functions (e.g. when changing the ventilation mode), a second button appears for confirming the selection.

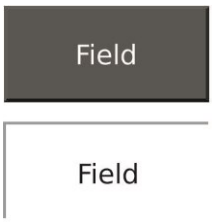


Fig. 7: Selecting a function field

3.2.1.2 Setting options and parameters

Pressing an option field places a green checkmark.
This will select the corresponding option.

Options

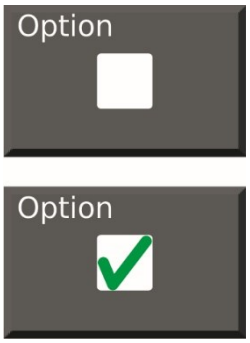


Fig. 8: Option deselected/selected

Parameter Selecting a parameter field changes its color to yellow. The value can now be changed using the control knob. Pressing the control knob again will accept the value, and the field color changes back to gray.

Fig. 9: Changing values

3.2.1.3 Functions in the System Settings menu

Return The "Return" field takes you to the higher menu level.

Fig. 10: "Return" field

Single drop-down box Pressing a drop-down box opens a list of possible options below the box. Use the control knob or touchscreen to make a selection.

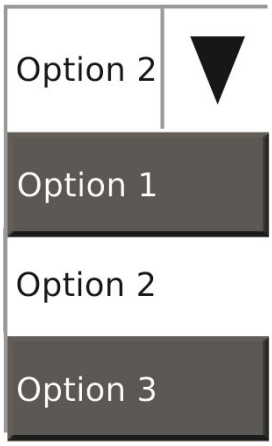


Fig. 11: Single drop-down box

Multiple drop-down box

Pressing the multiple drop-down box opens multiple options below the box. In addition, a navigation area opens on the right. Use the arrow buttons to navigate the menu. The bar indicates the position within the menu. Use the control knob or touchscreen to make a selection.

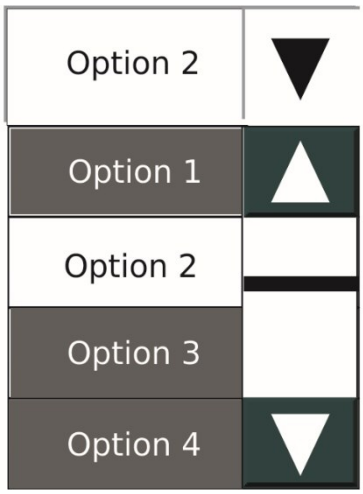


Fig. 12: Multiple drop-down box

Close

Select the X field to close a menu window. This field is always located at the top left corner of the open menu. If a parameter is selected and modified, but not yet confirmed when pressing this field, the action is canceled. The change is discarded.

Fig. 13: "Close" field

NOTE

Except for the menu for setting the ventilation parameters (see chapter 3.2.3.6), a menu can also be closed by selecting any other menu or a field on the touchscreen.

3.2.2 Measured value display

This display gives a quick view of the relevant measured values together with the alarm limits shown after the measured value.

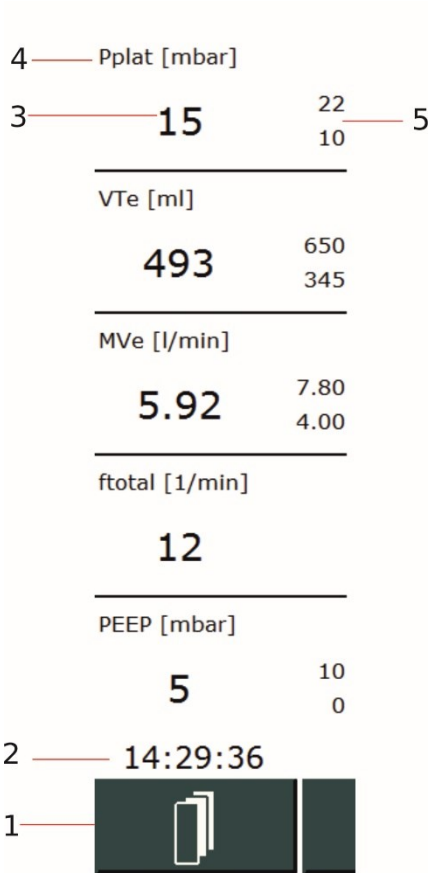


Fig. 14: Measured value display

1	Function field for toggling between the measured value display and the display of the active measured value block	4	Name of measured value including unit
2	Time display	5	Alarm limits display
3	Measured value		

Five measured values are displayed. Three sets of 5 measured values each are available. Only one set can be displayed at a time. Use the function field to switch between the sets (see chapter 3.2.3.1).

Item	Set 1	Set 2	Set 3
1	Pplat (cannot be configured)	O_2	Pmean
2	VTe	VTe	VTe
3	MVe	EtCO2	VTespon
4	ftotal	SpO2	Ppeak
5	PEEP	Pulse	VTleak

Tab. 4: Basic configuration of the measured value indicator's three sets

With the exception of Pplat, the user can freely configure the type and sort order of measured values in the three sets in the control panel (see chapter 4.3.1). The measured values listed in the following table are determined by the ventilator and can be displayed:

Category	Measured value	Description	Unit
Pressure	Ppeak	Inspiratory peak pressure	mbar
	Pplat	Plateau pressure	mbar
	Pmean	Mean airway pressure	mbar
	PEEP	Positive end expiratory pressure	mbar
Volume	MVe	Expiratory respiratory minute volume	l/min
	MVespon	Spontaneous expiratory respiratory minute volume	l/min
	VTe	Expiratory tidal volume	ml
	VTespon	Spontaneous expiratory tidal volume	ml
	VTleak	Leak	ml
Flow	V´min	Minimum flow	l/min
	V´max	Maximum flow	l/min
Time	Tinsp	Inspiration time	s
	Texp	Expiration	s
	ftotal	Total respiratory rate (mechanical + spontaneous respiratory rate)	1/min
	fspon	Spontaneous respiratory rate	1/min
	I:E	Inspiration time ratio	-

Category	Measured value	Description	Unit
Gas	O_2	Inspiratory oxygen concentration	%
	$EtCO_2$	End expiratory CO_2 concentration	mmHg/kPa/ Vol.%
Diagnostic	R	Patient and tube resistance	mbar l/s
	C	Patient compliance	ml / mbar
	P0.1	Oral occlusion pressure after 100 ms	mbar
	PTP	Pressure time product	mbar x s
	Time constant	Product from resistance and compliance	s
	RSB	Quotient from frequency and VT (Rapid shallow breathing index)	1/min*l
Masimo	SpO_2	Oxygen saturation	%
	Pulse		bpm
	PI	Perfusion index	%
	PVI	Pleth Variability Index	%
	SpMet	Methemoglobin	%
	SpCO	Carboxyhemoglobin	%

Tab. 5: Measured values

Alarm limits If a value breaches the upper or lower active alarm limit, the corresponding field is highlighted in red (HP alarm) or yellow (MP alarm), depending on the alarm priority. In addition, an error message appears in the status, alarm, and info display.

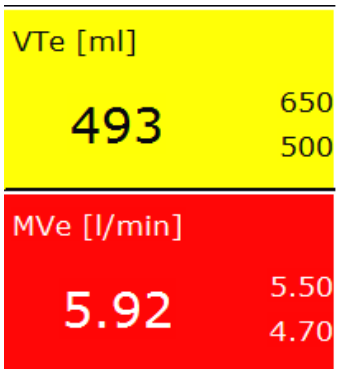


Fig. 15: Color change when alarm limits are breached

3.2.3 Function fields

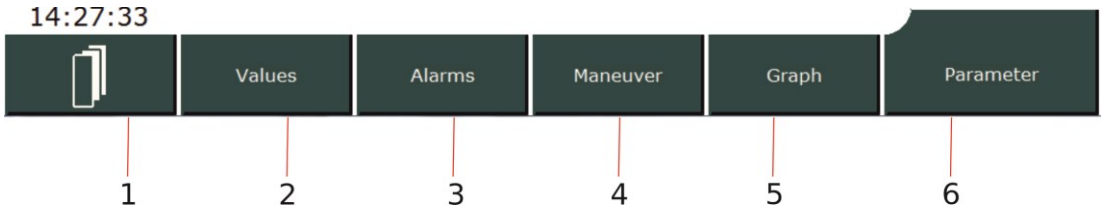


Fig. 16: Function fields

1	Measured value indicator switch	4	Maneuver
2	Values	5	Graphs
3	Alarms	6	Parameters

3.2.3.1 Measured value indicator switch

Pressing this function field toggles between the three sets of measured values (see chapter 3.2.2). The active set is indicated by a number in the function field.

3.2.3.2 Values

Pressing this function field opens the "Values" sub-menu. This provides an overview of the measured values currently determined by the ventilator.

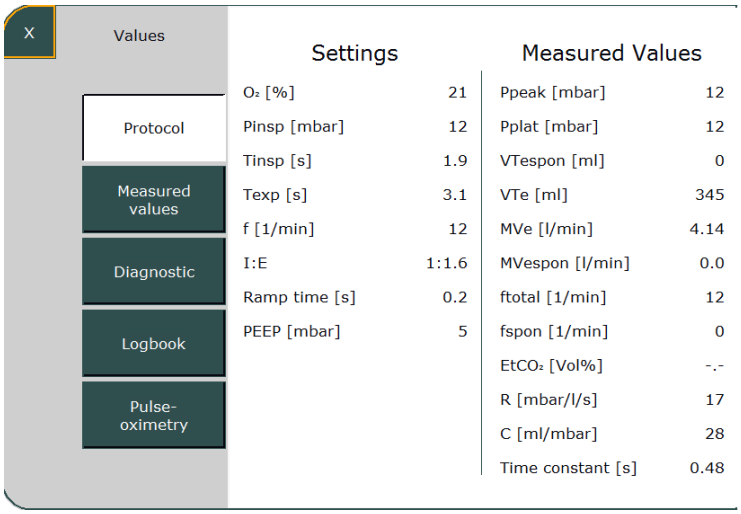


Fig. 17: Values sub-menu

The various measured values can be viewed by selecting the »Protocol«, »Measured Values«, and »Pulse oximetry« fields.

Logbook The following data is automatically archived in the logbook with the associated time in hours and minutes. This data can be viewed by selecting the »Logbook« field.

The following events are saved:

- Start / Stop/Standby
- Settings and change to the settings
- Execution of special actions and maneuvers
- Occurring alarms (ON/OFF)

The last 1000 values can be displayed on the monitor. In total up to 1100 entries can be saved in the device. If this value is exceeded, the oldest entries are automatically overwritten.

NOTE

The logbook data can be saved on the internal SD card (see chapter 4.4.9).

3.2.3.3 Alarms

The "Alarms" sub-menu shows the »Alarm History« and all measured values that are monitored by alarm limits.

Alarm history

Pressing the »Alarm History« field or the alarm indicator (see chapter 3.2.8) opens a list of the seven most recent alarms.

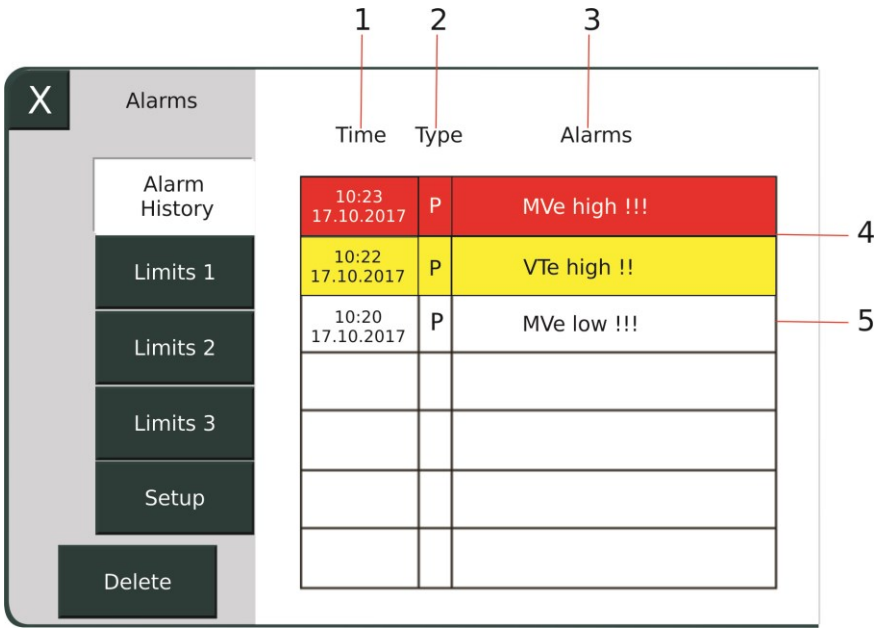


Fig. 18: "Alarm History" sub-menu

1	Time and date when the alarm occurred	3	Alarm text
2	Alarm category	4	Active alarms
		5	Inactive alarm

The system shows the date and time when the alarm occurred, the category (P = patient alarm, T = technical alarm), and the alarm text. The color indicates the priority (red = HP alarm; yellow = MP alarm; white = alarm no longer active).

All active and inactive alarms are stored internally. However, the alarm history only shows the 7 most recent alarms in chronological order. Once the cause of the alarm has been eliminated, the message remains, but is no longer highlighted in color. If an inactive alarm recurs, it becomes current and appears in the alarm history.

Manually deleting an inactive alarm from the alarm history moves the next internally stored alarm into the on-screen alarm history.

NOTE

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

NOTE

The alarm history 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 case of a total power failure, all entries are deleted from the alarm history.

Limits Pressing the »Limits 1-3« fields lets you view all the alarm limits and adjust them to the patient's needs. If limits are breached during the current ventilation, the corresponding parameter field turns yellow or red, depending on the alarm priority.

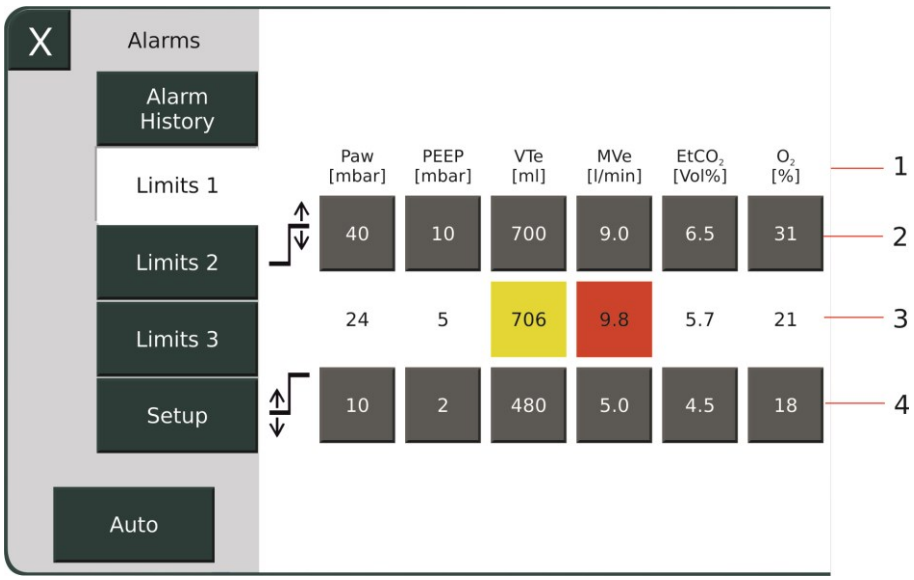


Fig. 19: Alarms sub-menu

1 Name and unit
2 Upper limit
3 Current measured value
4 Lower limit

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 **EVE$_{TR}$** always starts with the following preset alarm limits:

Parameter	Unit	Lower limit	Upper limit
PAW	mbar	-	Pinsp+10 (maximum 60 mbar)
PEEP	mbar	Set value -2-	Set value + 2
VTe (VC mode)	ml	Set value VT −30%	Set value VT +30%
VTe (PC mode)	ml	Adult: 350 Child: 140 Preterm infants and newborns: 14	Adult: 650 Child: 260 Preterm infants and newborns: 26
MVe (VC mode)	ml	(Set values VT·f) −30%	(Set values VT·f) +30%
MVe (PC mode)	ml	Adult: 4.2 Child: 2.8 Preterm infants and newborns: 0.42	Adult: 7.8 Child: 5.2 Preterm infants and newborns: 0.78
fspon	1/min	-	50
Apnea	s	-	15
$EtCO_2$	mmHg Vol.% kPa	30 4 4	45 6 6
O_2	%	Set value −10% minimum 21%	Set value +10% maximum 100%

Tab. 6: Preset alarm limits

Changing alarm limits

To change the alarm limits, select the corresponding upper or lower limit on the touchscreen. The field opens and is illuminated yellow. Use the control knob to adjust the value within the preset limits.

Parameter	Unit	Lower limit	Upper limit	Resolution
PAW	mbar	-	11 – 60	1
PEEP	mbar	0 – 29	1 – 30	1
VTe	ml	0 – 100	1 – 100	1
		100 – 490	100 – 500	5
		490 – 990	500 – 2000	10
$EtCO_2$	Vol.%	0.0 – 11.9	0.1 – 12.0	0.1
	mmHg	0 – 89	1 – 90	1
	kPa	0 – 11.9	0.1 – 12.0	0.1
PI	%	Off, 0.03 – 0.1	0.04 – 0.1	0.01
		0.1 – 1	0.1 – 1	0.1
		1 – 18	1 – 19, Off	1
PVI	%	1 – 98/Off	2 – 99/Off	1
SpO_2	%	88 – 98	91 – 99/Off	1
SpCO	%	1 – 97	2 – 98/Off	1
fspon	1/min		5 – 120/Off	1
Apnea	s		4 – 60	1
Pulse	bpm	30 – 230	35 – 235/Off	1

Tab. 7: Adjustable alarm limits

Auto

Pressing the »Auto« field sets the PAW, MVe, VTe, $EtCO_2$ and PEEP limits to the system's automatic alarm limit presets.

Parameter	Unit	Lower limit	Upper limit
PAW (VC mode)	mbar	-	Pplat+10 measurement value maximum 35 mbar, no less than PEEP+5
PAW (PC mode)	mbar	-	Pinsp + 10 maximum 35 mbar
PAW (PC mode+PRVC)	mbar	No Auto button available	No Auto button available
PEEP	mbar	Set value -2-	Set value + 2
VTe	mbar	−30%	+30%
$EtCO_2$	mbar	−10% minimum 35 mmHg	+10% maximum 45 mmHg

Tab. 8: Automatic alarm limits

If configured in the setup menu, the alarm limits for FiO_2, PAW LOW and PEEP are always set automatically.

Parameter	Unit	Lower limit	Upper limit
O_2	%	Set value −10 minimum 21%	Set value +10 maximum 100%
PEEP	mbar	-	Set value + 5

Setup

You configure certain alarm settings in this menu.

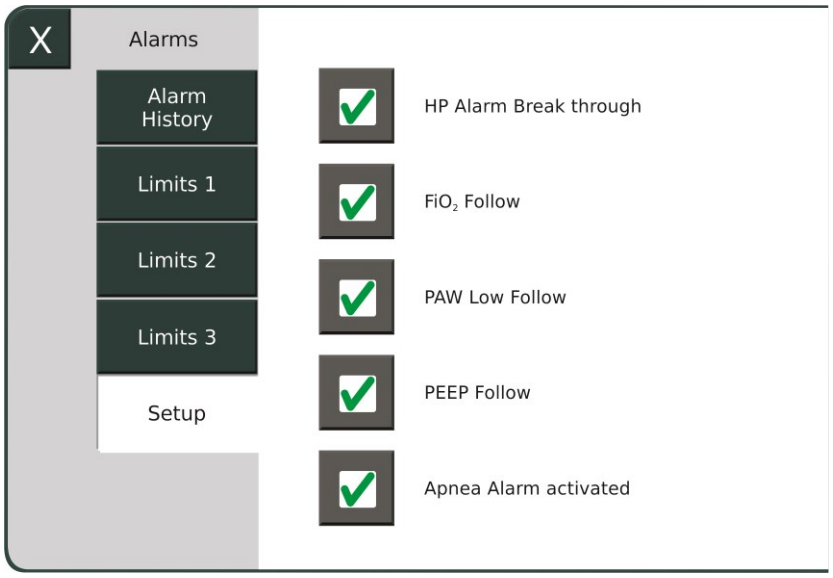


Fig. 20: Alarms/Setup sub-menu

HP Alarm Break through

If the "HP Alarm Break through" option is activated, an acoustic alarming of all HP alarms occurs even if acoustic alarm suppression is switched on.

"PAW Low Follow"

If you activate the "PAW Low Follow" option, the lower PAW alarm limit is automatically updated. However, it can also be manually set. If you deactivate this function, it is only possible to make the setting manually.

"FiO2 Follow"

If you activate the "FiO_2 Follow" option, the FiO_2 alarm limits are automatically updated. However, they can also be manually set. If you deactivate this function, it is only possible to make the setting manually.

PEEP Follow"

If the "PEEP Follow" option is activated, the PEEP alarm limits are automatically updated. You can also set them manually. If you deactivate this function, it is only possible to make the setting manually.

NOTE

The settings are automatically saved when shutting down the device and are retained when restarting the device. When the mainboard software is updated, all settings in the menu are reset and may need to be manually reactivated.

"Apnea alarm activated"

If the "Apnea alarm activated" option is selected, the device displays the apnea alarm. If the option is deactivated, the system does not issue an apnea alarm. The "Apnea alarm deactivated" icon is then displayed in the status, alarm, and info display (see chapter 3.2.8).

Fig. 21: Status, alarm, and info display, "Apnea alarm deactivated"

NOTE

The "Apnea alarm deactivated" symbol is only displayed if alarm suppression is not activated.

NOTE

The "Apnea alarm activated" setting switches on each time the device is started and cannot be saved as the default value. Fritz Stephan GmbH recommends supplementing patient monitoring with external monitoring if the apnea alarm is deactivated.

3.2.3.4 Maneuver

Maneuver

This sub-menu lets you perform the following maneuvers.

- P0.1
- SpHb measurement

To start a maneuver, select and press the corresponding field. This opens a sub-menu listing the main parameters. Press the »Start« field to trigger the maneuver. The following section provides a brief description and explanation of the various maneuvers:

P0.1 maneuver

The respiratory tract occlusion pressure (P0.1) is a measured parameter of the patient's respiratory drive. It is an index for the inspiration breathing effort by the patient against a closed system in the first 100 ms.

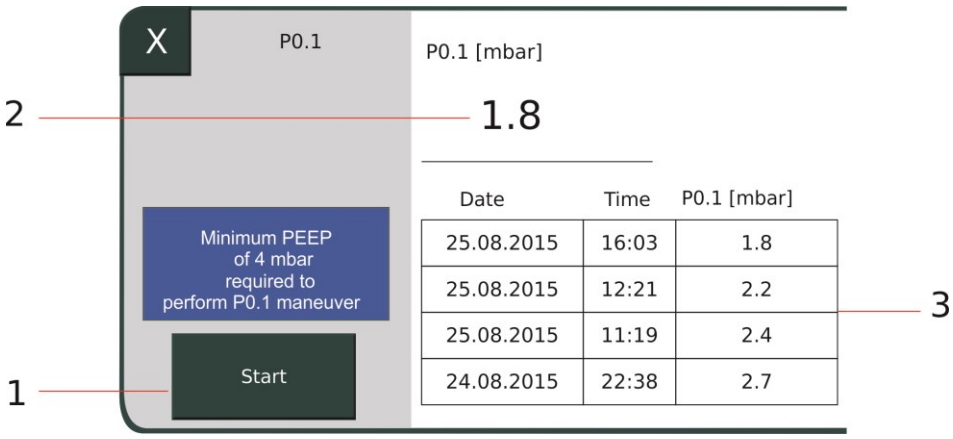


Fig. 22: Maneuver P0.1

1 »Start« field
2 Current measured value
3 Measured value history

A PEEP of minimum 4 mbar must be present for measurement of the P0.1 value. Then select the »Start« field. At the patient's next inspiration, **EVE** now automatically detects the spontaneous breathing effort by the patient, closes the system and measures the P0.1 value. When the measurement is complete, the determined value appears in the display. The three most recent measured values are saved and displayed for reference purposes.

SpHb measurement

This lets you measure a single hemoglobin value. This allows early detection of possible internal patient bleeding without having to wait for lab results.

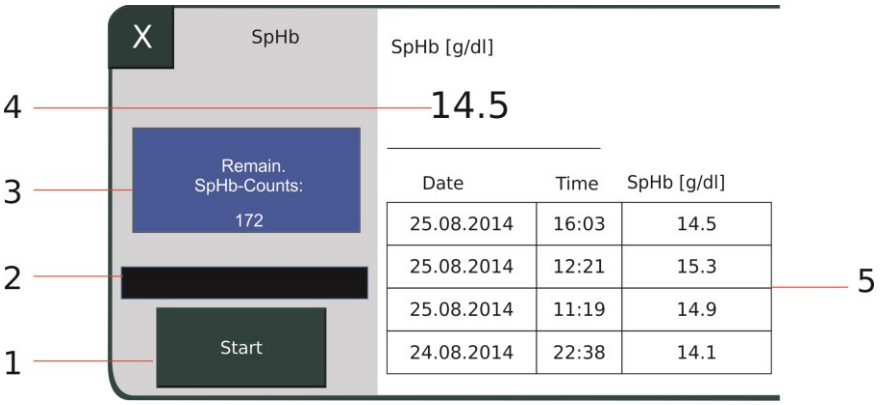


Fig. 23: SpHb measurement

1 »Start« field
2 Bar graph
3 Remaining SpHb measurements
4 Current measured value
5 Measured value history

The sensor requires a brief warm-up phase, indicated by the black bar graph. When the bar graph is completely filled, the SpHb measurement can be performed by pressing the »Start« field. When the measurement is complete, the measured value appears on the display. The three most recent measured values are saved and displayed for reference purposes.

3.2.3.5 Graph

Graph

The "Graph" sub-menu lets you configure the appearance of the graphic display (see chapter 3.2.9).

3.2.3.6 Parameter

Parameter

Pressing this function field opens a sub-menu with all configurable parameters and additional functions for the currently active ventilation mode.

Fig. 24: Configurable parameters for standard SIMV ventilation

1 Optionally selectable additional functions for the ventilation mode

2 Current ventilation mode indicator

3 Ventilation parameters

To change a parameter, select the corresponding field. The field then turns yellow. You can now change the value using the control knob.

If additional functions exist for the currently active ventilation mode, these can also be activated from this menu. Press the »Confirm« field to save the new settings and close the sub-menu.

3.2.4 Parameter display

The display provides an overview of the five most important ventilation parameters for the currently active ventilation mode.

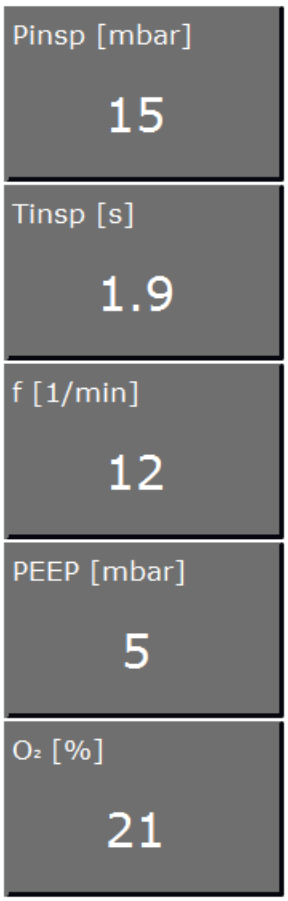


Fig. 25: Parameter display for PC-CMV ventilation mode

To change a parameter, select the corresponding field. The field then turns yellow. You can now change the value using the control knob.

3.2.5 Ventilation mode display

This display indicates the current ventilation mode, the active additional functions, the patient type and the flow sensor type. Selecting a non-invasive ventilation mode causes the display to turn orange. In addition, the icon for non-invasive ventilation appears.

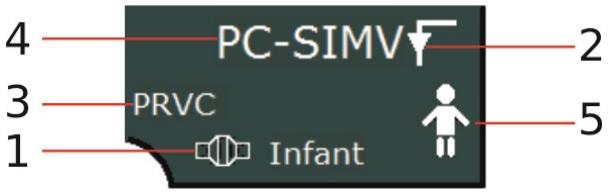


Fig. 26: Invasive ventilation mode

Fig. 27: Non-invasive ventilation

1	Flow sensor type	4	Ventilation mode
2	Icon for invasive ventilation	5	Patient type
3	Additional function for ventilation mode	6	Icon for non-invasive ventilation

Selecting this field opens a ventilation menu (see chapter 6.8) where you can adjust the settings to the current ventilation scenario.

3.2.6 Energy supply indicator

This indicator informs the user about the current state of the internal and external battery. Tap the field to open the "Battery" sub-menu. It contains detailed information about the status of the energy supply.

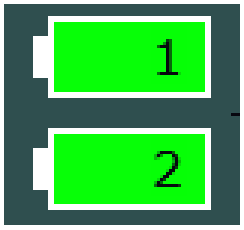


Fig. 28: Energy supply indicator

1 Battery 1 charge indicator 2 Battery 2 charge indicator

NOTE

To ensure the correct function of the battery charge indicator, both the internal and external battery must be calibrated every six months (see chapter 11.11).

Battery charge indicator

To allow for battery changes during operation, the **EVE$_{TR}$** can be equipped with two independent batteries. Their charge levels are indicated on the display by two icons. The remaining capacity is indicated by color. In addition, the battery icon shows the remaining battery level in percent during mains operation and the remaining operating time in minutes during battery operation.

Pictogram	Meaning	
	Green	Capacity between 75 – 100%
	Yellow	Capacity between 40 – 74%
	Red	Capacity between 1 – 39%

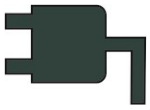
Tab. 9: Charge level indicator

"Batteries" sub-menu

It displays the following parameters for the internal and external battery:

- Charge status (%)
- Battery life (min)
- Charge time (min)
- Charge cycles

Mains power

Pictogram	Meaning
	The plug icon appears in front of both battery indicators when mains power is connected. The icon disappears from the display when mains power is disconnected.

Tab. 10: Mains power indicator

NOTE

If mains power is not connected, the battery providing power is shown with a blue border.

3.2.7 System settings

Fig. 29: "System Settings" field

Pressing this field opens the "System Settings" sub-menu (see chapter 4).

NOTE

This field contains a lock icon if the touchscreen is locked (see chapter 3.1.3).

3.2.8 Status, alarm and info display

Fig. 30: Status, alarm, and info display with active alarm

1	Alarm display	4	Trigger display
2	Alarm suppression time display	5	Nebulization time display
3	Pre-oxygenation time display	6	Alarm history icon

Fig. 31: Status, alarm, and info display, alarm history display

Alarm display and alarm history

The alarm display always shows the active alarm with the highest priority (notification = blue, MP alarm = yellow, HP alarm = red). Pressing the alarm display opens the alarm history (see chapter 3.2.3.3). If there are no active alarms, but a non-acknowledged alarm history exists, the corresponding icon appears on the alarm display. The icon disappears after deleting the alarm history.

Alarm suppression display

Pressing the »Alarm suppression« button (see chapter 3.1.2) mutes all alarms for a duration of two minutes. The corresponding icon appears on the display, and a countdown timer indicates the remaining alarm suppression time.

Preoxygenation display

Pressing the »Preoxy« button (see chapter 3.1.3) displays the corresponding icon, and the preset preoxygenation time starts to count down.

Nebulization display

Pressing the »Aerosol« button (see chapter 3.1.3) displays the corresponding icon, and the preset nebulization time starts to count down.

Trigger display Displays the type of trigger used (see chapter 4.2.3).

3.2.9 Graphic display

Pressing the »Graph« button (see chapter 3.2.3.5) opens the graphic display, which can be customized. The initial layout can be pre-configured in the system settings (see chapter 4.1.2). Three different layout versions are available.

1. Display of three curves
2. Display of two curves
3. Display of one curve, loop or trend

.

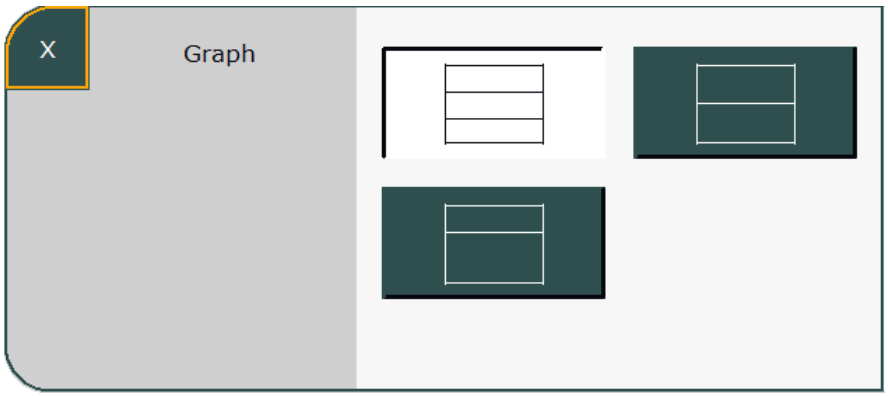


Fig. 32: Graphic display configuration

The top field of the graphic display always shows the pressure curve. The remaining fields can be freely configured by selecting them.

NOTE

The system automatically adapts the scaling of the curves and scales to the current measured values.

3.2.9.1 Configuring the measurement curves

Select a measurement curve on the display to change it.

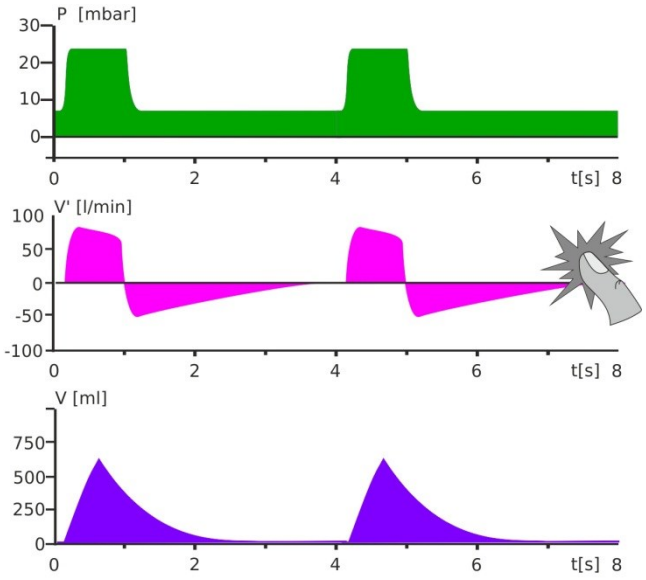


Fig. 33: Graphic display, changing the display

A window with all available measurement curves (volume, flow, CO_2 and plethysmogram) opens. You can now select the desired option.

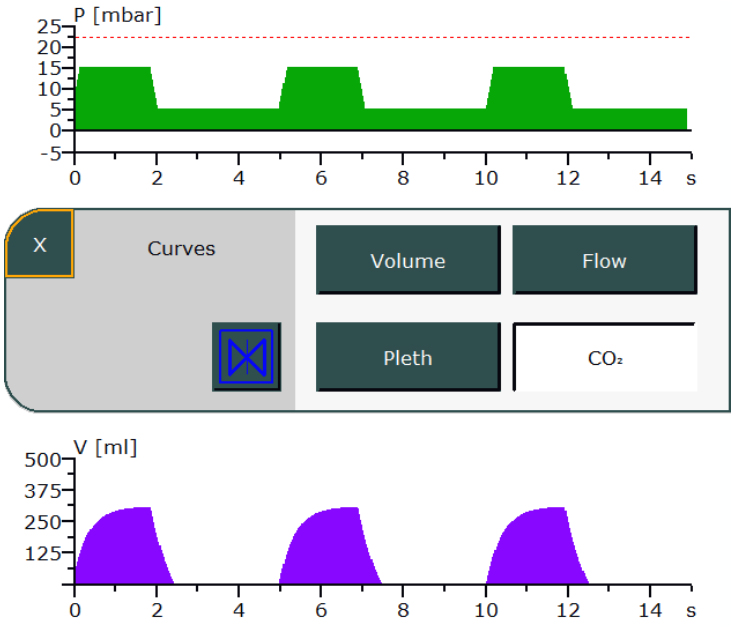


Fig. 34: Selecting the measurement curve

Pressing the »X« field closes the selection window and updates the graphic display with the new setting.

For a better view, the measurement curves can be frozen on the display. To do this, press the "Stop" field in the selection window. After activation, the measurement curves run until the end of the scale and are then frozen. This mode is ended by pressing the "Stop" field or automatically after 20 s have passed.

3.2.9.2 Configuration of loops and trends

Layout 3 provides the option of displaying loops and trends.
The lower field of the graphic display must be pressed for this. A sub-menu opens and the user can choose between loops and trends by selecting the corresponding field.

Loops If the »Loops« field is selected, available options are displayed on the right. Pressing the corresponding field lets you display the desired loop in the graphic display.

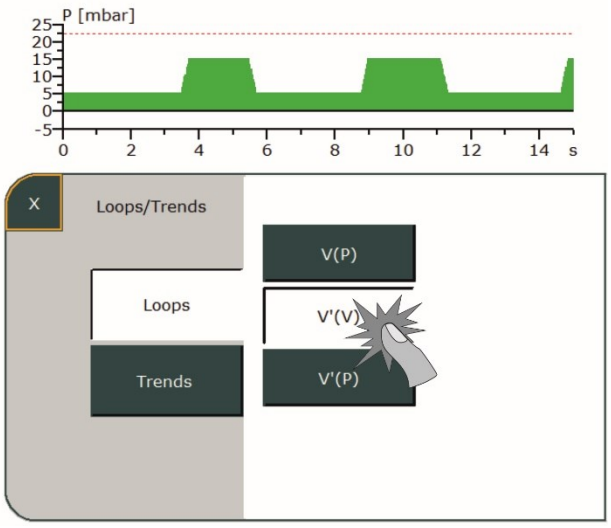


Fig. 35: Selecting loops

Pressing the »X« field closes the selection window and shows the loop including its measured values in the graphic display.

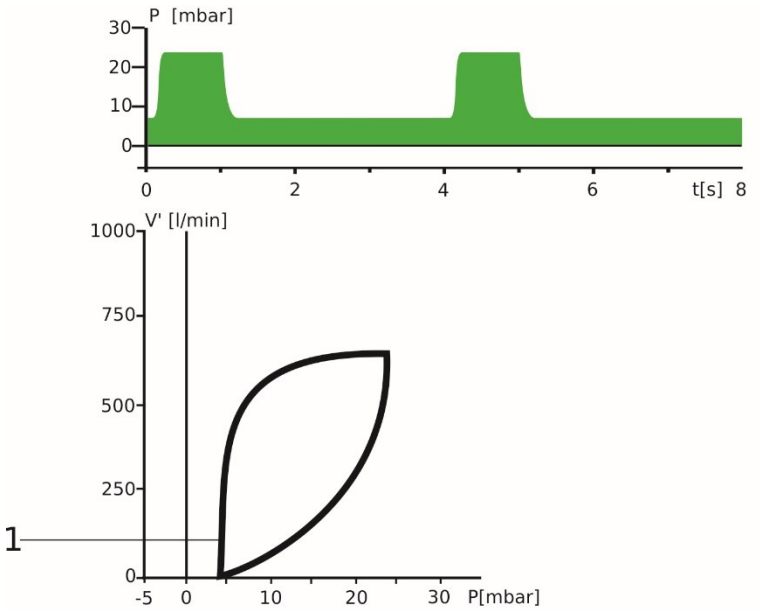


Fig. 36: Loop (here V‘(P))

1 Loop

Trends If the »Trends« field is selected, available options are displayed on the right.

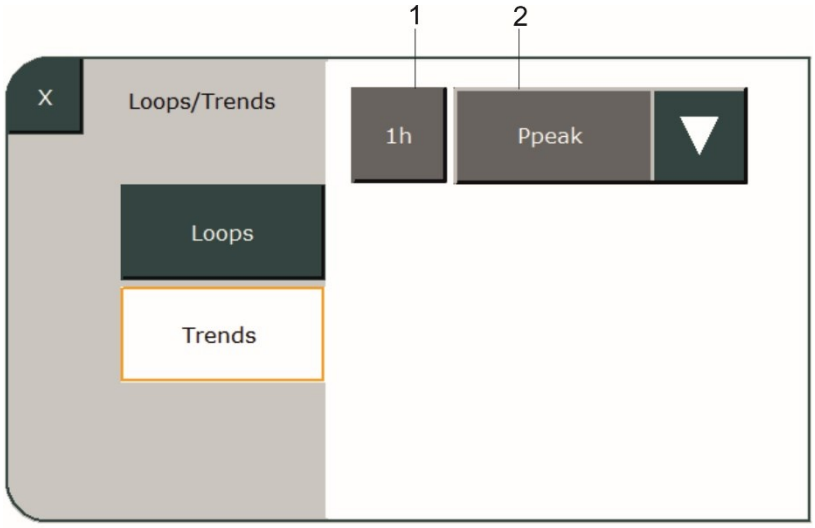


Fig. 37: Trends selection

1 Monitoring time setting 2 Trend selection

After selecting the first field, the observation time period can be set via the "IGR" control knob in the levels 1, 6, 12, 24, 48 and 72 h. Pressing the arrow key in the second window opens a dropdown menu. Here you can select the required trend. Up to two trends can be displayed at the same time for pressure, minute volume and frequency.

Selectable trends

Ppeak	Vte	MVespon	R	SPMet	SPO_2	FiO_2
Pplat	Vt spon	ftotal	C	Pulse	SPMet	Pplat/ PEEP
Pmean	Vt leak	fspon	RSB	PVI	SPCO	Mve/ Mvespon
PEEP	MVe	O_2	PTP	PI	SPOC	ftotal/ fspon

Tab. 11: Displayable trends

3.3 Left side view

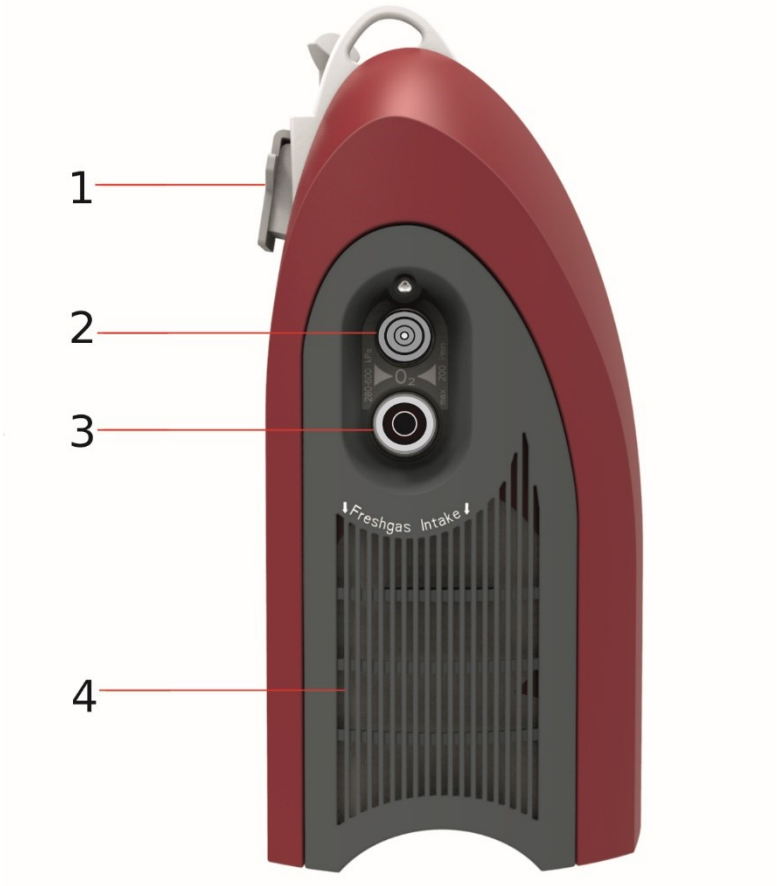


Fig. 38: Left side view

1	Attachment hook	3	O_2 input
2	O_2 input quick coupling	4	Air filter grille (coarse and HEPA filter)

Attachment hook

The maximum load of the attachment hook is 15 kg.
It can be used to attach the **EVE$_{TR}$** to

- a standard rail (10 x 25 mm)
- hospital beds (Ø 38 mm)
- Stretchers

3.4 Right side view

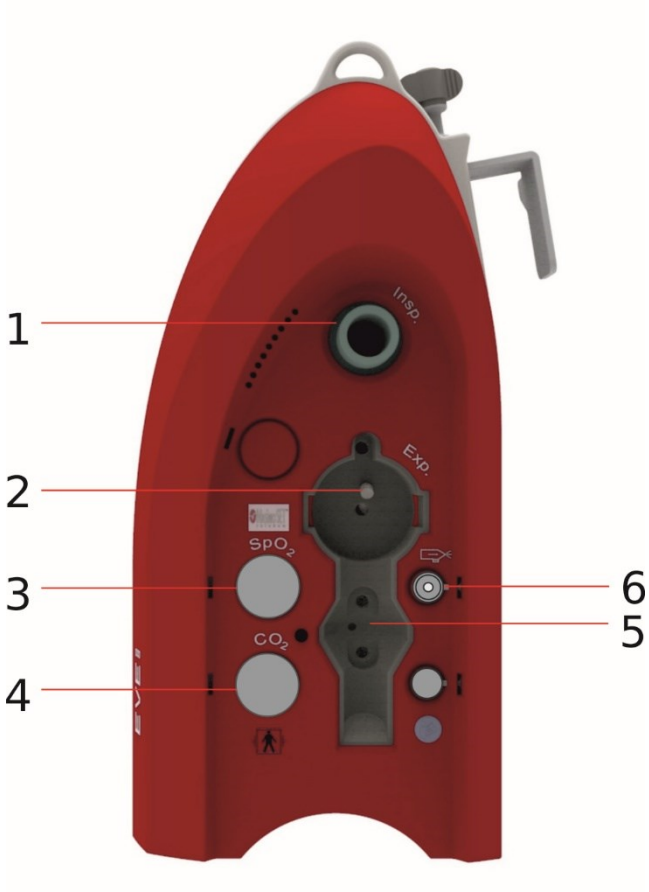


Fig. 39: Right side view

1 Insp. = gas outlet opening
Inspiration tube connection

2 Exp. = gas return opening
Expiration tube connection

3 SpO_2 sensor connection

4 CO_2 sensor connection

5 Flow sensor connection

6 Aerosol nebulizer connection

3.5 Bottom view

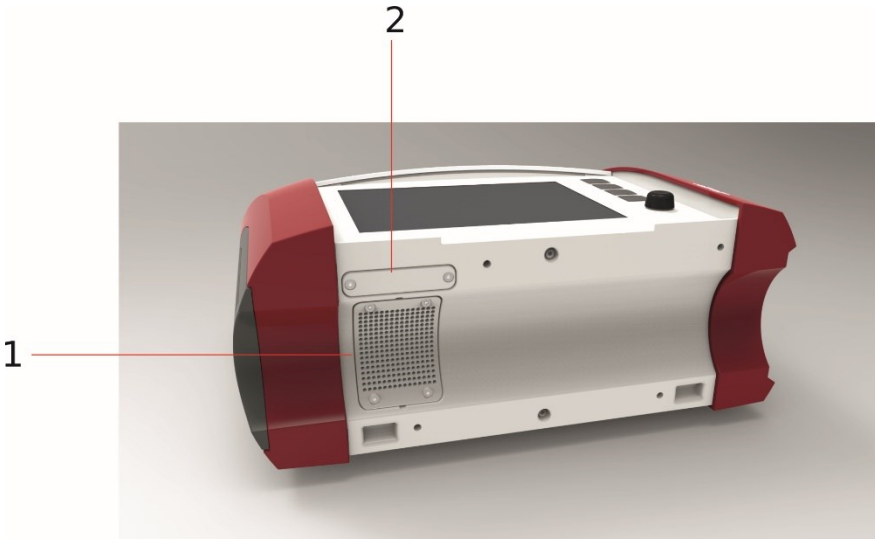


Fig. 40: Bottom view

1	Fan	2	Cover for the SD card slot

3.6 Rear view

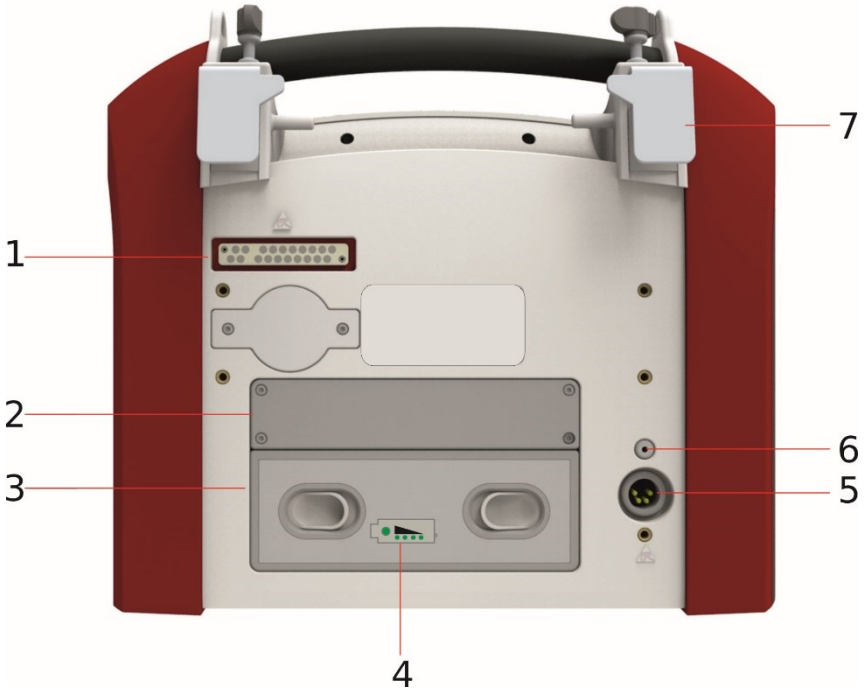


Fig. 41: Rear view

1	Docking station interface	5	Power supply input
2	Internal battery 1	6	Reset button
3	External battery 2 (optional)	7	Adjustable bracket
4	External battery charge level indicator		

External battery charge level indicator

The charge level indicator lets you check the external battery (optional) even when the device is switched off. Pressing the field shows the current charge level using LEDs.

Reset button

Pressing the Reset button causes the **EVE$_{TR}$** to restart. However, it does not reset the ventilator to factory settings.

3.7 Brackets

WARNING

When inserting the **EVE$_{TR}$** into the bracket, never place your hands or fingers between the device and the bracket. Otherwise, injuries due to crushing may result. Make sure the device locks into place!

CAUTION

The safety catch of the brackets must be checked at least every four weeks for intactness and correct functioning.

3.7.1 Ambulance bracket

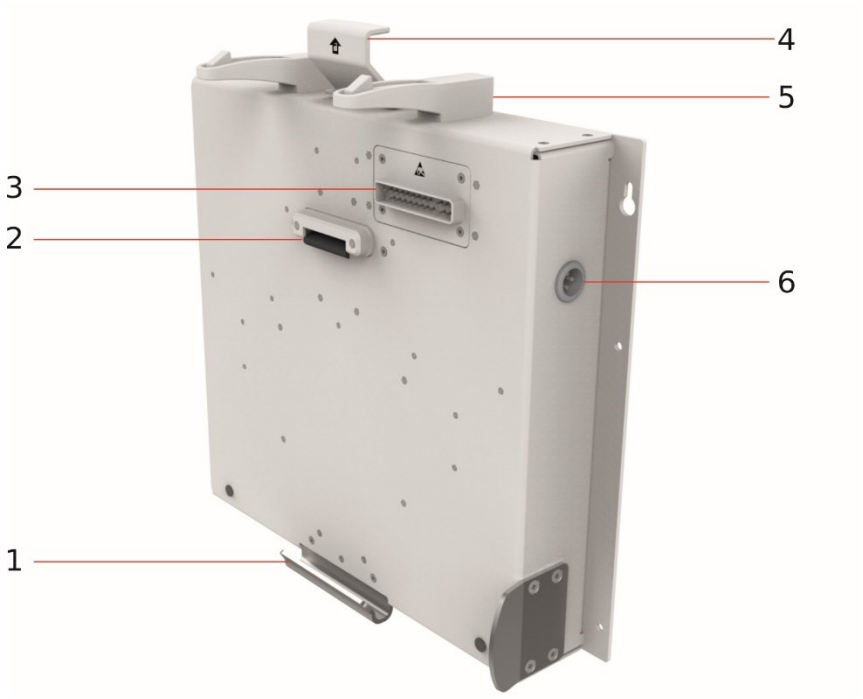


Fig. 42: Ambulance bracket

1	**EVE$_{TR}$** attachment hook	4	Lock/unlock latch
2	**EVE$_{TR}$** bracket	5	**EVE$_{TR}$** safety catch
3	**EVE$_{TR}$** interface	6	12/24 V on-board power supply input

Place the **EVE$_{TR}$**, including carry system (see chapter 3.7.3), into the attachment hooks (item 1) and push toward the ambulance bracket until first the safety catch (item 5) and then the bracket (item 2) lock into place with a click.

To remove the ventilator, press the lock/unlock latch (item 4). The device releases and can be removed from the bracket.

3.7.2 Helicopter bracket

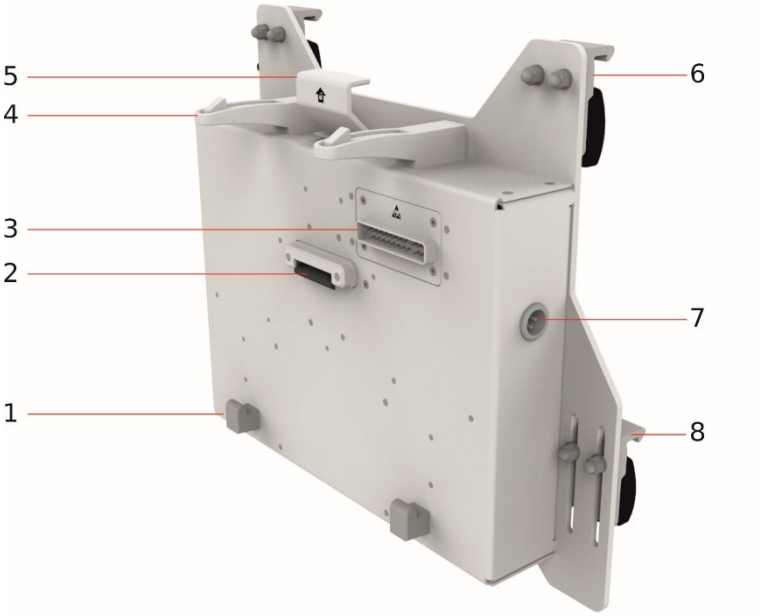


Fig. 43: Helicopter bracket

1	**EVE$_{TR}$** attachment hook	5	Lock/unlock latch
2	**EVE$_{TR}$** bracket	6	Standard rail bracket
3	**EVE$_{TR}$** interface	7	12/24 V on-board power supply input
4	**EVE$_{TR}$** safety catch	8	Height-adjustable rail system bracket

Place the **EVE$_{TR}$** into the attachment hooks (item 1) and push toward the helicopter bracket until first the safety catch (item 6) and then the bracket (item 2) lock into place with a click.

To remove the ventilator, press the lock/unlock latch (item 5). The device releases and can be removed from the bracket.

3.7.3 Carry system

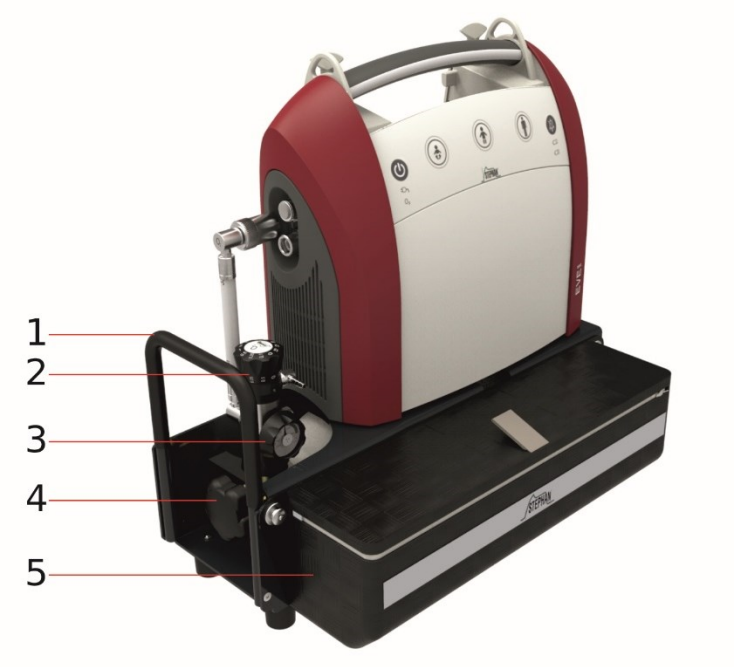


Fig. 44: **EVE$_{TR}$** carry system

1	Safety guard	4	Oxygen cylinder
2	Pressure regulator	5	Bag for tube system and accessories
3	Manometer		

WARNING

Only use the original carry system from FRITZ STEPHAN GMBH, otherwise device damage may result.

3.7.3.1 Built-in pressure regulator

NOTE

Observe the manufacturer's service and operating manuals!

4 System Settings

Pressing the System field opens the "System Settings" menu.

Fig. 45: System field

All the fields in the various menus can be touch-activated. Turn the control knob to change the parameters. Complete your input by pressing the control knob or touching the field again.

The "System Settings" menu is divided into the following sub-menus:

- System
- Sensors
- Display
- Setup

They are described below.

NOTE

Changes are automatically saved when exiting a sub-menu and remain in effect when restarting the device, with the exception of the Masimo Rainbow SET® parameters.

4.1 System

This lets you access the following sub-menus:

- Info
- Display
- Time
- Function

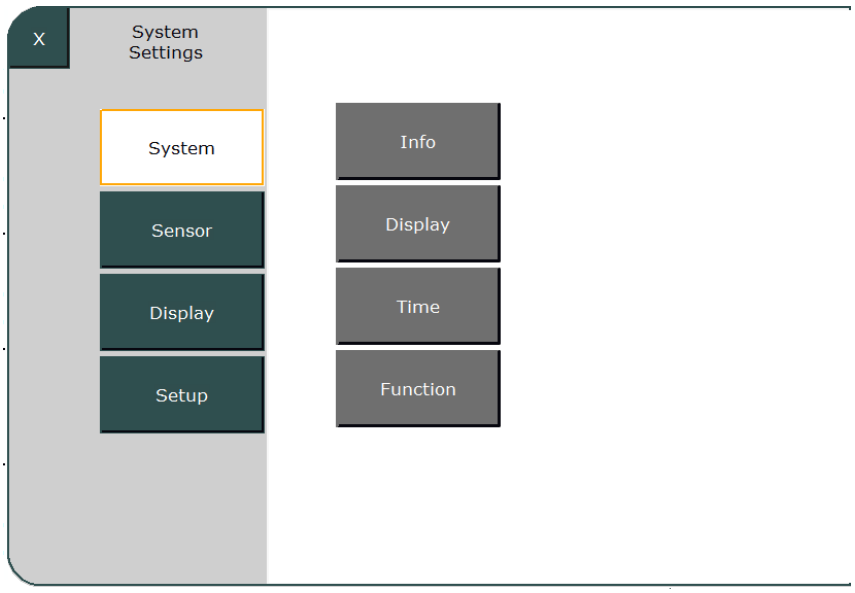


Fig. 46: System

4.1.1 Info

This sub-menu lets you access the following device-specific data:

Mainboard SW	Device serial number (ID-Number)	Mainboard SW
	Operating hours	Bootloader SW
	Date	MAC address
	Service date	Masimo module (optional)
Blower SW	Blower module	Bootloader Blower
	Blower SW	Bootloader motor
	Blower SW motor	
PSU SW (power supply)	PSU SW (power supply)	Akkupack2 SW (battery pack 2)
	Battery SW	Bootloader PSU
	Akkupack1 SW (battery pack 1)	Bootloader battery

4.1.2 Display

This sub-menu lets you separately adjust the display brightness for day and night operation in the range of 20 – 100%. You can also determine a start time for both operating modes. Use the »Settings activated« box to activate/deactivate the configured settings.

NOTE

Settings made in the "Display" sub-menu are also used when switching manually between day/night mode in the function area (see chapter 3.1.3).

4.1.3 Time and Date

This sub-menu lets you set the date and time.

4.1.4 Function

This sub-menu lets you configure the parameters for the »Aerosol« and »Preoxy«, buttons in the function area (see chapter 3.1.3).

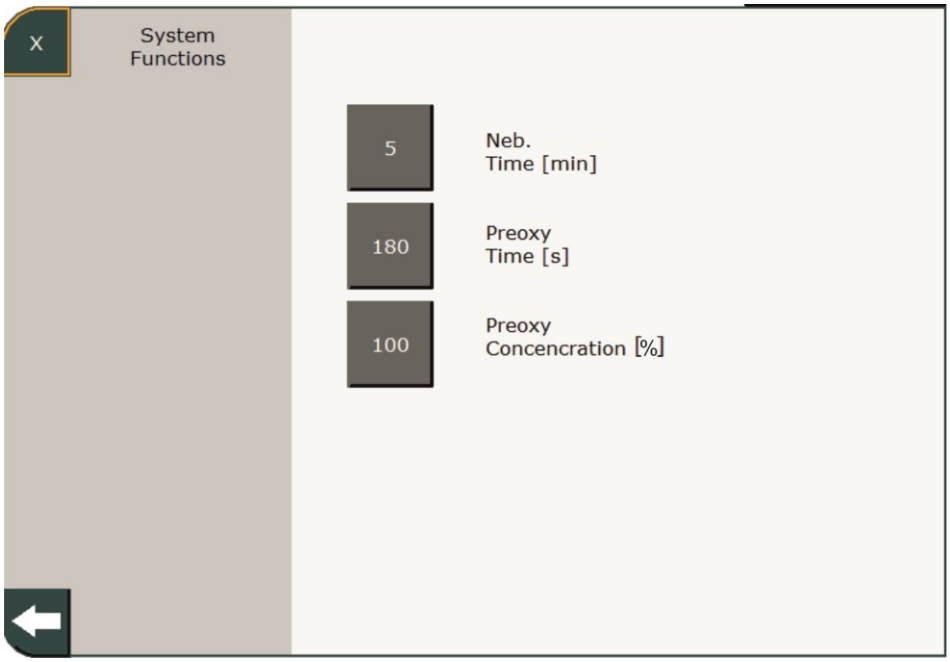


Fig. 47: Function

Aerosol time Lets you set the aerosol nebulization time (5 – 30 min). Aerosol nebulization is triggered by pressing the »Aerosol« button.

Preoxy time Lets you set duration of the preoxygenation (10 – 180 s) that is triggered when the »Preoxy« button is pressed.

Preoxy % Setting for the inspiratory oxygen concentration administered when the »Preoxy« button is pressed. You can select an inspiratory oxygen concentration between 21 and 100%.

4.2 Sensors

Selecting the corresponding fields in the sub-menu lets you activate or configure the sensors for pulse oximetry, capnometry, and flow. The tube system used is configured here.

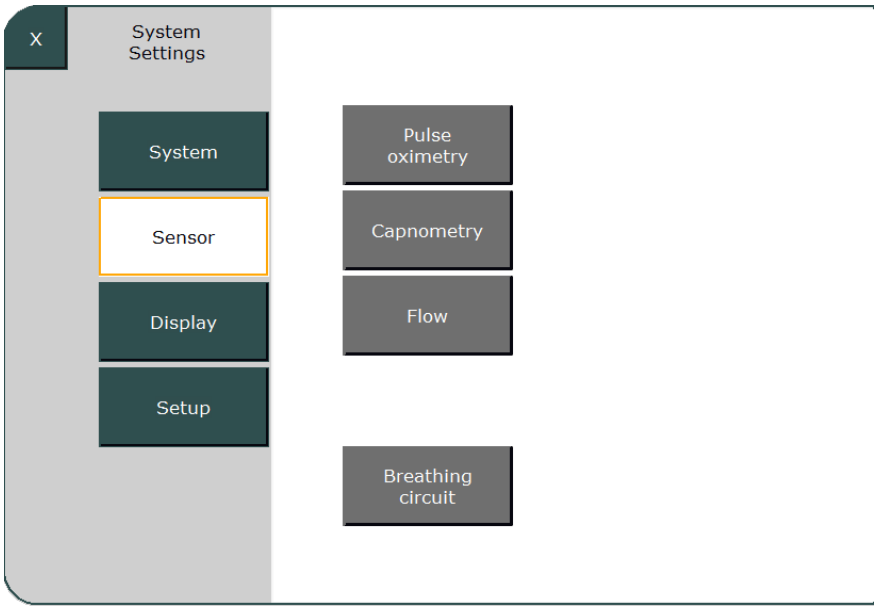


Fig. 48: Sensor sub-menu

4.2.1 Pulse oximetry

This sub-menu lets you configure the sensors for pulse oximetry.

NOTE

The configured settings are used for the current ventilation process when exiting the menu. The user-defined configuration for the Masimo sensors is not permanently saved. Restarting the ventilator will reset it to the factory settings.

4.2.1.1 Settings

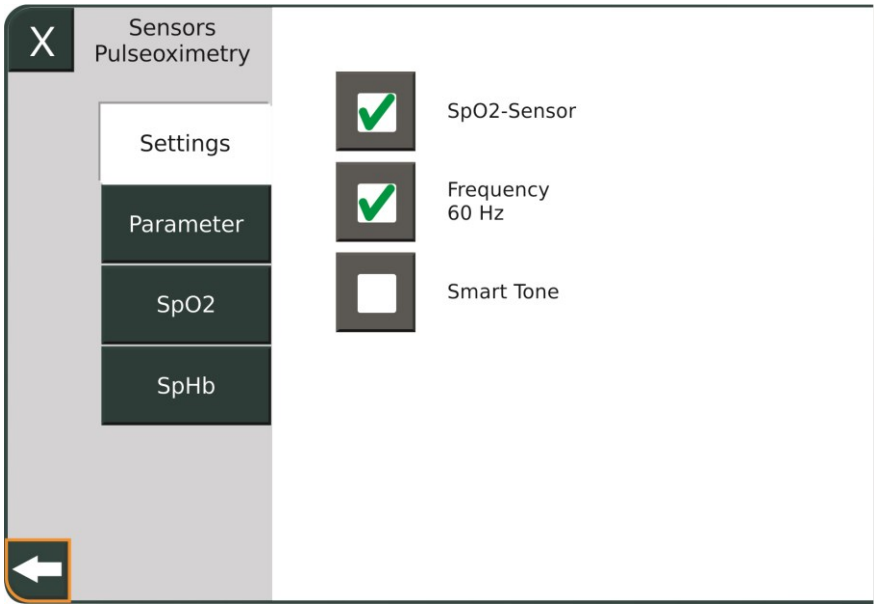


Fig. 49: Settings sub-menu

SpO_2-Sensor Turns the SpO_2 sensor on/off

Frequency setting This lets you switch the frequency of the sensor from 50 Hz (default value) to 60 Hz.

Smart Tone Selecting this function enables the acoustic pulse signal. Otherwise, the Smart Tone is disabled.

4.2.1.2 Parameter

When the SpO_2 sensor is activated (see chapter 4.2.1.1), this menu lets you turn on/off the measurement of the Pulse, PI, SpHb, SpMet, SpCO, SpOC, and PVI parameters.

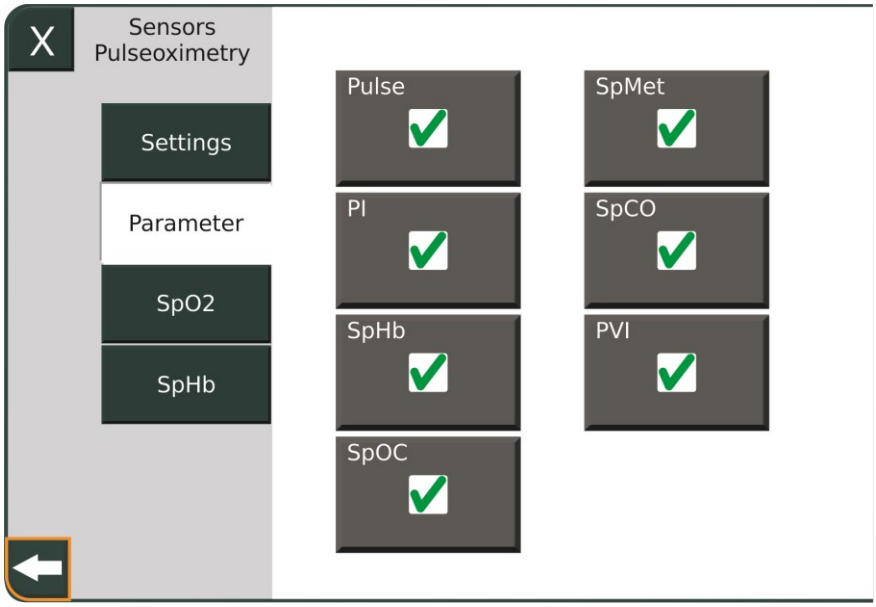


Fig. 50: Activating the measured values

NOTE

The number of measurement parameters is optional and can be configured upon customer request. Parameters not contained in the package are grayed out and not selectable.

NOTE

The SpOC parameter can only be selected if SpHb is activated.

4.2.1.3 SpO_2

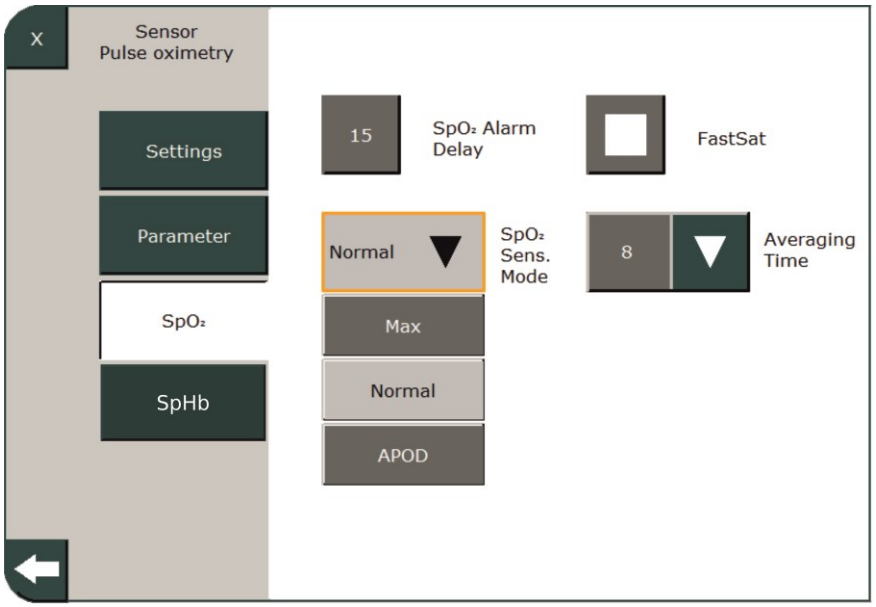


Fig. 51: SPO_2

SpO_2 Alarm Delay This lets you set a delay for the SpO_2 alarm. Possible settings are 0 s, 5 s, 10 s, and 15 s. The default is 15 s.

SpO_2 Sensor Sensitivity This sub-menu lets you configure the sensitivity of the SpO_2 sensor at the following levels: Normal, Max, and APOD™ (Adaptive Probe-Off Detection Technology). APOD™ offers the best detection of the three sensitivity levels if the sensor becomes detached from the patient.

FastSat® This lets you activate/deactivate FastSat® mode. This function monitors rapid changes of the arterial O_2 level.

NOTE

When FastSat® mode is activated, the averaging time depends on the input signal. If a range is specified for the averaging time of 2-4 s or 4-6 s, the averaging time will be within the selected range.

Averaging Time The signal averaging time can be set to 2 – 4, 4 – 6, 8, 10, 12, 14, or 16 s. The oximeter continuously measures the values over the preset time and then displays the mean value.

4.2.1.4 SpHb

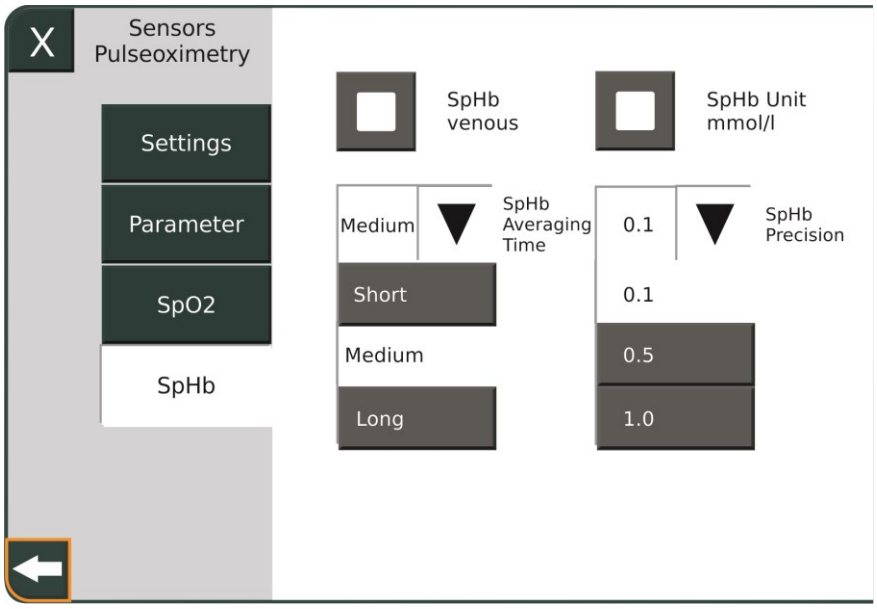


Fig. 52: SpHb

SpHb venous Select this option for venous instead of arterial measurement of the SpHb value. It is disabled by default.

SpHb Units This sub-menu lets you select the units for the SpHb value. The following settings are available:

- g/dl (default)
- mmol/l

SpHb Averaging Time The signal averaging time can be set to the following levels: Short, Medium (default), and Long. The oximeter continuously measures the values over the preset period and then displays the mean value.

SpHb Precision This lets you set the signal precision to the following levels: 0.1 (default), 0.5, and 1.0.

4.2.2 Capnometry

This lets you activate/deactivate CO_2 monitoring (optional).

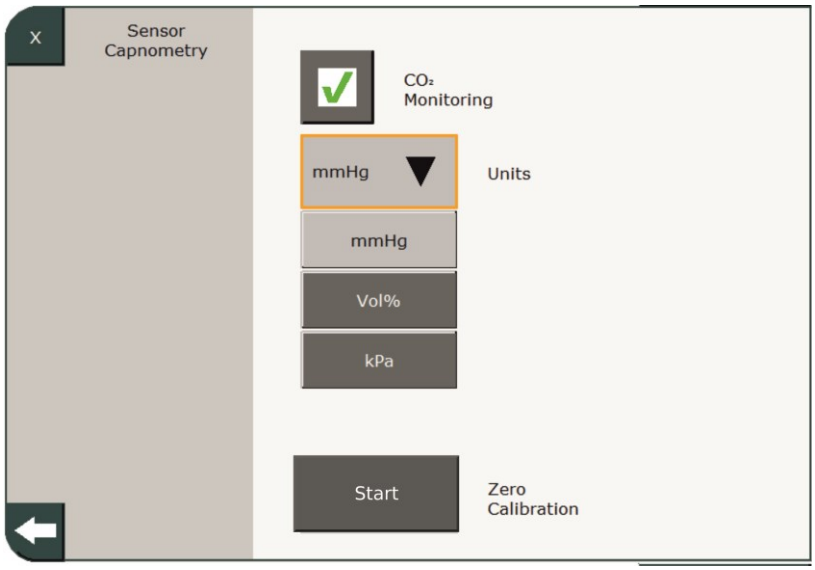


Fig. 53: Capnometry

In addition, you can select the unit (mmHg, kPa, and Vol.%) and choose to run zero calibration on the sensor (see chapters 8.1.5 and 8.2.5).

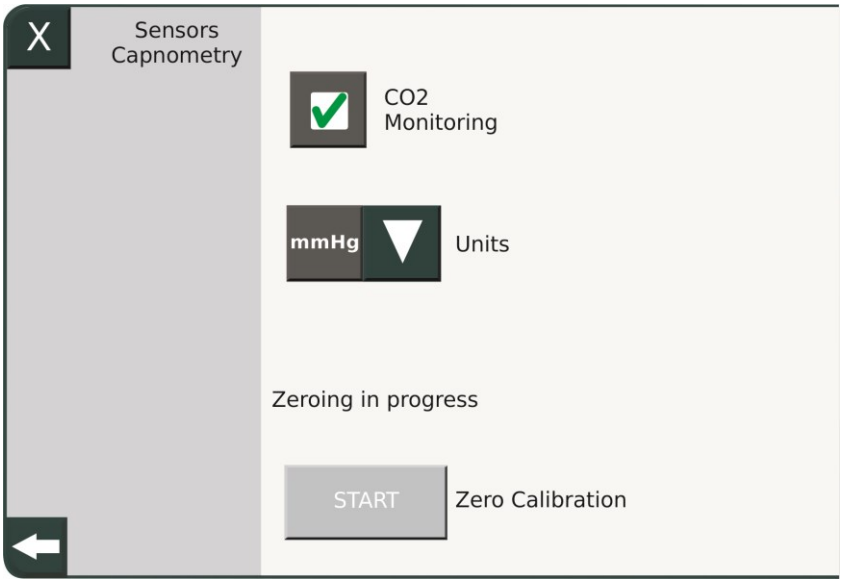


Fig. 54: Running zero calibration

4.2.3 Flow

This sub-menu lets you configure the flow sensor.

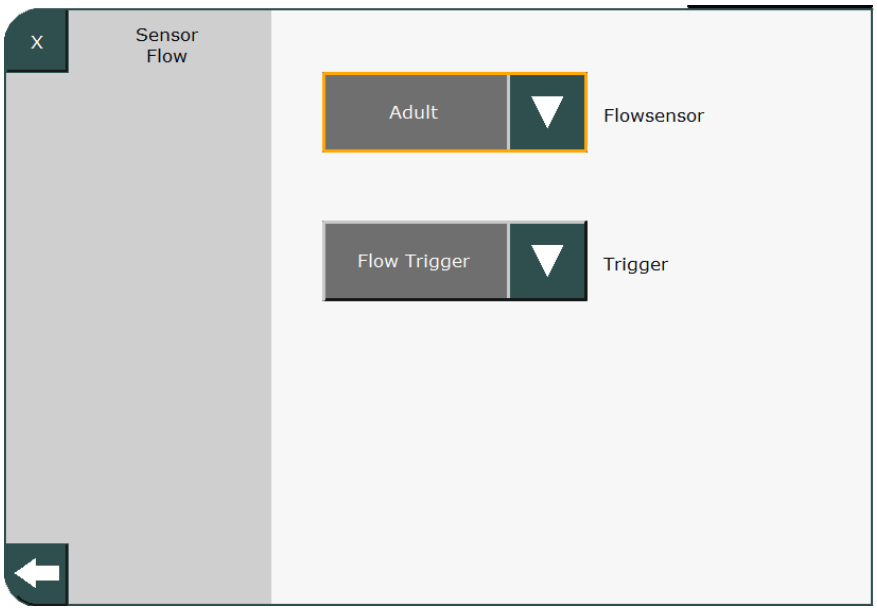


Fig. 55: Configuring the flow sensor

Select from the following settings for the flow sensor:

- Adult
- Infant (child)
- PNT B
- OFF

Furthermore, the flow trigger can be switched on or off here.

4.2.4 Ventilation tube system

Standard tube systems are preconfigured for the various patient groups. If other tube systems are used, make the appropriate settings in this menu or in the Ventilation Breathing System menu (see chapter 6.7). The corresponding tube system must be selected for this based on the type designation or a pictogram.

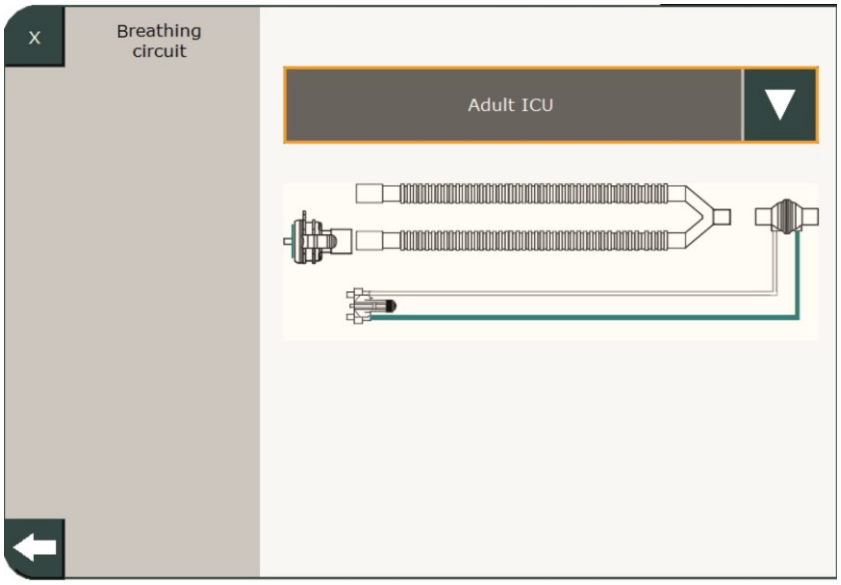


Fig. 56: Presetting for the patient tube system

ATTENTION

Fritz Stephan GmbH explicitly recommends that only patient tube systems included in the list of accessories are used. Otherwise, ventilator function may be impaired!

If it is necessary to use a non-standardized tube system that has not been tested by FRITZ STEPHAN GMBH, select the "Other Tube System" option. Then enter the tube system's parameters manually.

4.3 Display

This sub-menu lets you configure the measured value display.

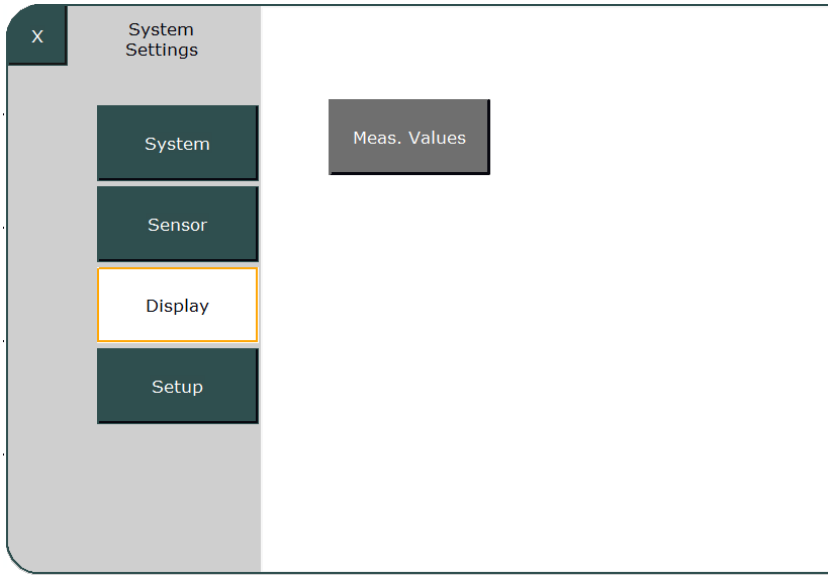


Fig. 57: Display sub-menu

4.3.1 Measured values

The three sets of the measured value display (see chapter 3.2.2) can be freely configured by the user in this sub-menu.

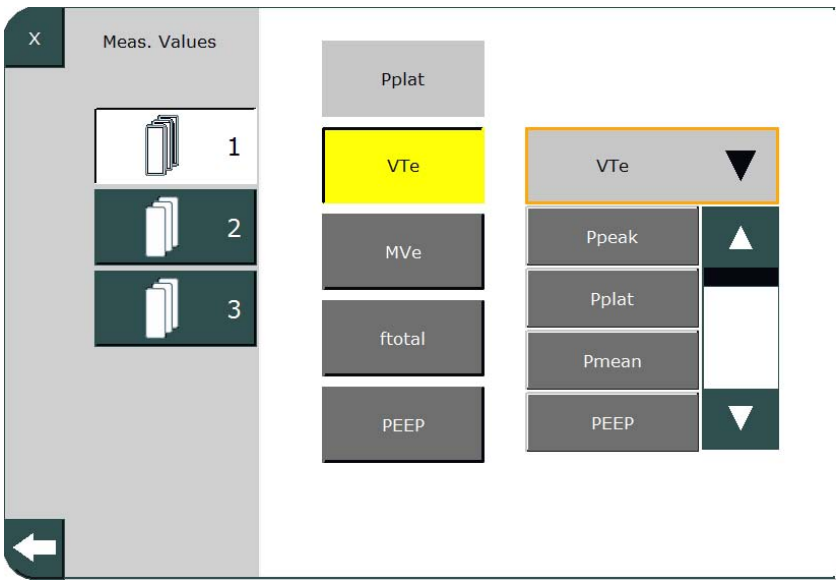


Fig. 58: Configuring the measured values

Start by selecting the desired set. The current measurement fields appear on the right side. Next, select the value to be changed. This is illuminated yellow.
Next, use the touchscreen or control knob to open a drop-down menu with all available measurement fields on the left side. Use the arrow buttons to select and the touchscreen or control knob to activate the desired field, which is immediately added to the measured value bar. Repeat as necessary until configuration is complete. Changes are automatically saved when exiting the menu and remain in effect after restarting the **EVE$_{TR}$**.

4.4 Setup

The Setup menu lets you make changes and configure settings that directly affect the ventilator's therapy settings. For this reason, this area is protected by a 4-digit code **1948** to be entered on the touchscreen.

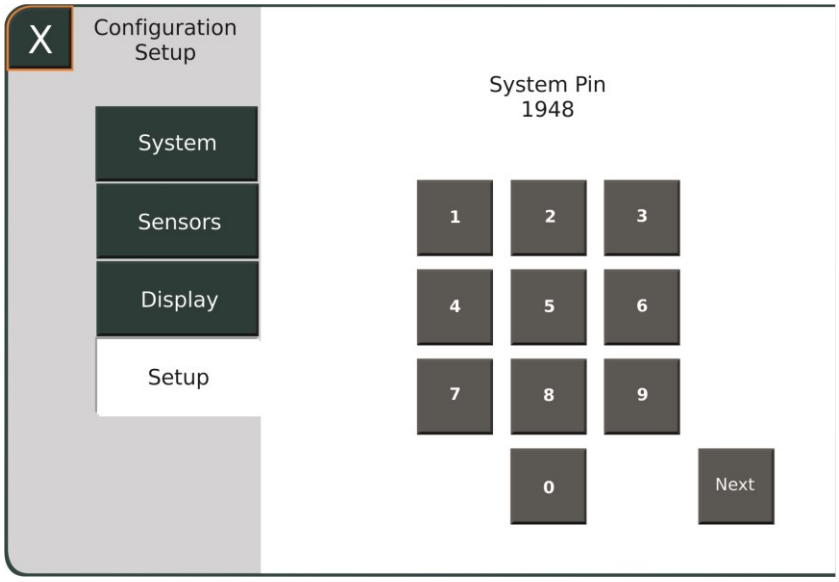


Fig. 59: Entering the code

Correctly entering the code opens the following sub-menu:

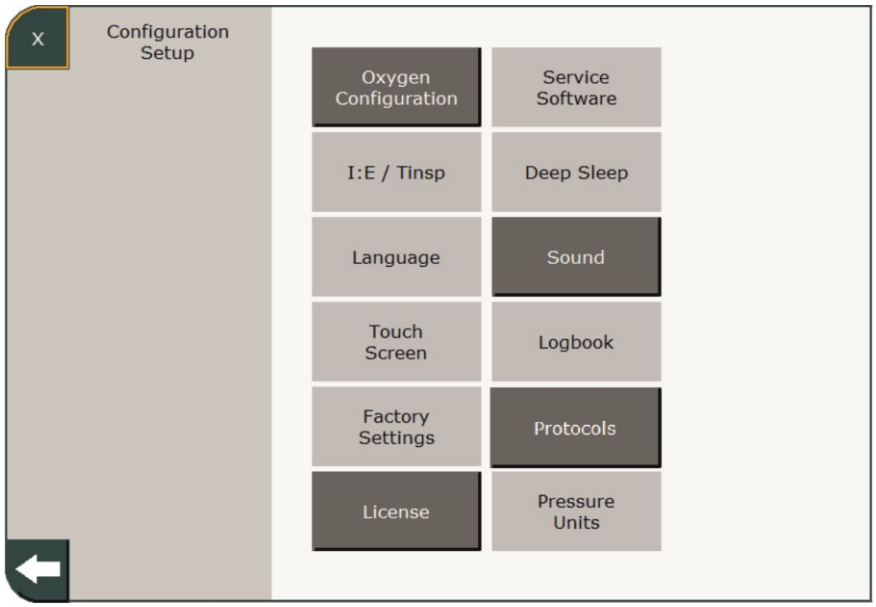


Fig. 60: Setup menu

NOTE

The "I:E/Tinsp," "Language," "Touchscreen," "Factory Settings," "Service Software," "Deep Sleep," "Logbook," and "Pressure units" fields are only available in Standby mode.

4.4.1 Oxygen configuration

Oxygen93 Select this option when using oxygen with a concentration of 93%.

4.4.2 I:E/Tinsp

This lets you pre-select the type of breathing cycling. The following options are possible:

- Inspiration time/expiration time (Tinsp/Texp)
- Breathing time ratio/frequency (I:E/Frequency)
- Inspiration time/frequency (Tinsp/Frequency)

The settings remain stored and are only overwritten when resetting the device to factory settings.

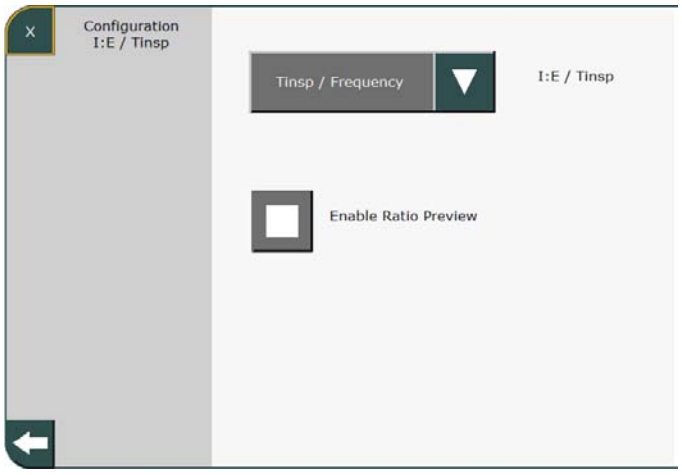


Fig. 61: I:E/Tinsp configuration

When you activate the "Display All Parameters" field, all current breathing cycling values are shown in the parameter display.

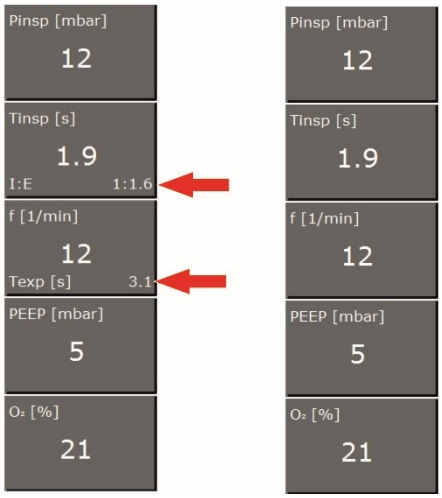


Fig. 62: Parameter display with and without activated breathing cycling display

4.4.3 Language

This lets you select the system language. Use the arrow buttons to select the desired language. Press the »Save« field to save the selection. After saving, the **EVE$_{TR}$** must be restarted for the language change to take effect.

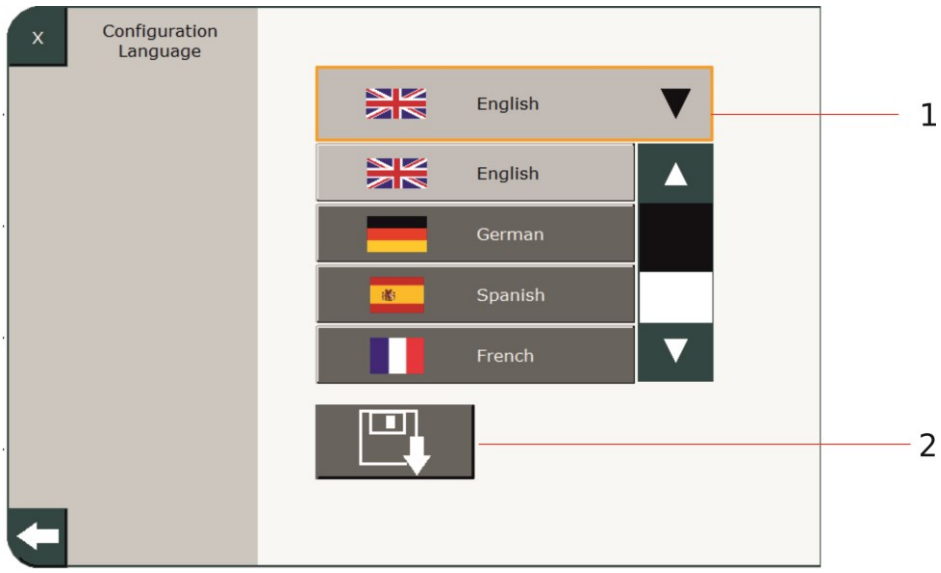


Fig. 63: Setting the system language

1 Language selection 2 »Save« button

4.4.4 Touchscreen calibration

This sub-menu lets you calibrate the touchscreen by pressing the corresponding field.

4.4.5 Factory Settings

This sub-menu lets you reset the **EVE$_{TR}$** to factory settings by pressing the corresponding field followed by a restart.

4.4.6 Service Software

Pressing the Start button will start the service software from the SD card.

4.4.7 Deep Sleep mode

Pressing the Start button will put the EVE into Deep Sleep mode for transport.

NOTE

After putting the **EVE$_{TR}$** into Deep Sleep mode, the device must be connected to the mains supply in order to be powered on.

4.4.8 Sound

This sub-menu lets you separately adjust the alarm volume for day and night operation in the range of 30 – 100%. You can also determine a start time for both operating modes.

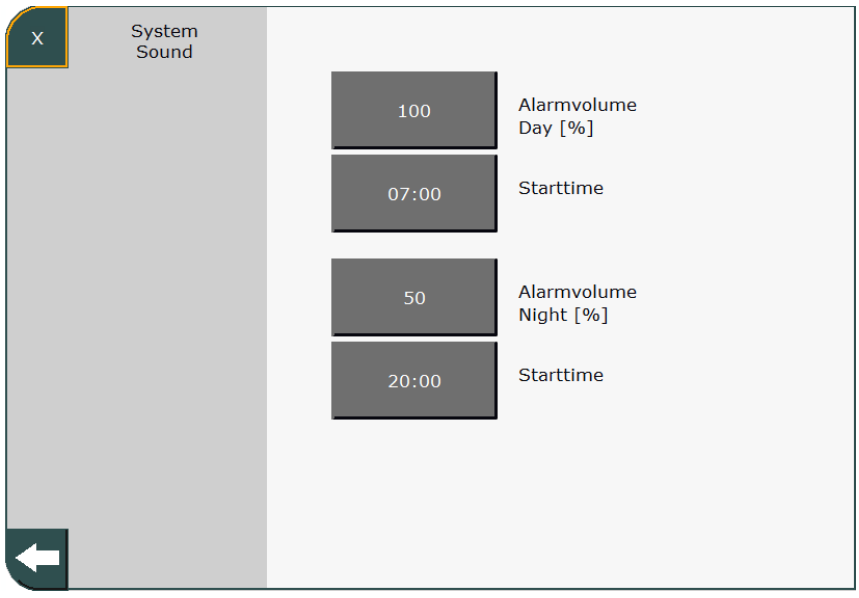


Fig. 64: Setting the alarm volume

WARNING

The alarm volume must be selected so it can be heard over ambient noise. Otherwise, the patient may be put at risk because the user may not be able to hear acoustic indicators for existing alarms.

4.4.9 Logbook

The system and logbook data can be transferred to the internal SD card here. Furthermore, the space available on the SD card and the size of the data to be transferred are displayed.

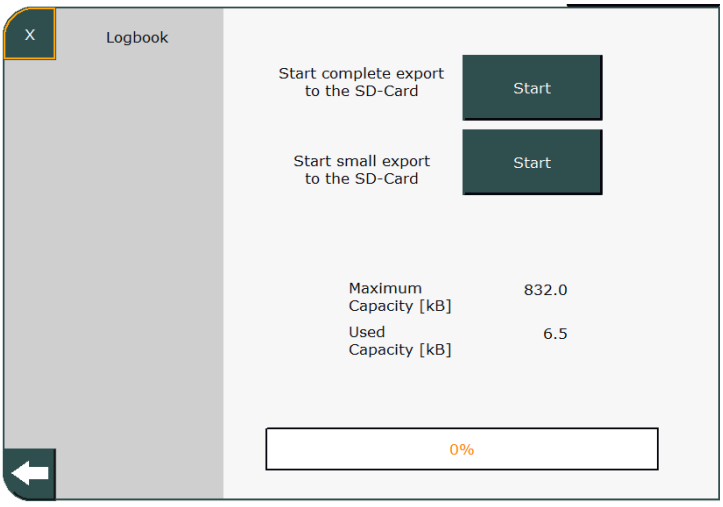


Fig. 65: Logbook

4.4.10 License

This menu displays which optional software licenses have been purchased (see chapter 1.2.1).

4.4.11 Protocol

You can switch the protocol for the Patient Data Management System (PDMS) on or off here.

4.4.12 Pressure units

The unit for the displayed pressure can be selected here. The following options are possible:

- cmH_2O
- mbar
- hPA

5 Preparation for use

5.1 Connecting the oxygen supply

CAUTION

Only trained or instructed personnel may handle oxygen.

CAUTION

Smoking and handling ignition sources and open flames are prohibited when handling oxygen.

CAUTION

Never let oxygen that is not being used escape into closed rooms.

CAUTION

Particles such as adhesive residue from band aids may ignite flowing oxygen.

CAUTION

Keep equipment, fittings, and valves for oxygen free from oil and grease (this includes not using ointments or gels) and protect from contamination. Never use oil or grease to lubricate parts or connections of cylinder valves and oxygen equipment.

CAUTION

Immediately degrease equipment and facilities for oxygen that are contaminated by oil and grease using suitable solvents. Never work on oxygen equipment or facilities with dirty hands, gloves, or cloths.

5.1.1 Connecting the oxygen cylinder

Oxygen cylinders are pressurized and filled with highly compressed oxygen. Typical sizes are 1, 2, or 10 liters. Observe the following safety information when connecting oxygen cylinders:

CAUTION

Pressurized gas cylinders may only be used by instructed and experienced personnel.

CAUTION

Pressurized gas cylinders may not be thrown and must be protected from tipping over during storage and use.

CAUTION

Use oxygen cylinders only with a pressure regulator approved for oxygen (look for "Oil and grease free" labeling!). Only approved pressure regulators according to DIN EN ISO 10524 or ones with special approval may be used together with oxygen. Only approved (original) seals and metal connectors may be used when connecting pressure regulators.

CAUTION

Adjustable pressure regulators must always be relieved (pressure adjustment screw all the way turned out) before applying pressurized oxygen.

CAUTION

Pressurized gas cylinders must be protected from dangerous heating (> 50° C), e.g. from heaters or open flames.

CAUTION

Handle the valves of oxygen cylinders manually only and open them slowly. Always point the valve opening and handwheel away from the body.

CAUTION

Do not fill pressurized gas cylinders from another pressurized gas cylinder.

CAUTION

Do not damage, modify, or remove labeling (embossings, labels).

CAUTION

For safety reasons, valves of pressurized gas cylinders, in particular their connecting threads, as well as pressure regulators must be kept free of oil and grease and protected against contamination. Wash hands before use. Oil, grease, rubbing alcohol, hand lotion, or band aids may cause explosive reactions.

CAUTION

Keep valves of pressurized gas cylinders closed while no gas is used. Handle the valves of pressurized gas cylinders manually only and open them slowly. Do not use wrenches.

CAUTION

Only use approved pressurized gas cylinders!

Only use filled pressurized gas cylinders!

Do not use damaged pressurized gas cylinders!

CAUTION

Except during use, oxygen cylinders may only be transported with an approved valve protector (e.g. cylinder cap) and if sufficiently protected against sliding or rolling.

CAUTION

Change the pressurized gas cylinder in time to ensure sufficient operating time.

To connect the oxygen cylinder:

- Install the oxygen cylinder inside support frame and secure it in place.
- Connect the pressure regulator.
- Connect the O_2 hose to the O_2 input on the left side of the **EVE$_{TR}$** (see chapter 3.3).
- Slowly open the valve and then slowly release it completely.

5.1.2 Sample calculation: O_2 oxygen consumption

The oxygen in the pressurized gas cylinder is highly pressurized. Due to the pressure, the volume in the cylinder is significantly reduced. The oxygen content of a pressurized gas cylinder (O_2 content) is calculated by multiplying the oxygen cylinder pressure (P_{cyl}) with the oxygen cylinder volume (V_{cyl}).

For **EVE$_{TR}$**, the basic flow for the adult and pediatric range is at 2 l/min, and at 3 l/min for the Neo range. It is active only during expiration and when the inspiration plateau phase has been reached.
This results in the following consumption:

Calculating the O_2 cylinder content

$$O_2\ content = P_{cyl} * V_{cyl}$$

Example

P_{cyl} = 200 bar

V_{cyl} = 10 liters:

$$O_2\ content = 10\ l * 200\ bar \cong 2000\ l$$

The cylinder contains 2000 l of oxygen.

Sample calculation: adult patient supplied with 95% oxygen

Tidal volume VT = 500 ml

Respiratory rate f = 12 1/m

T_{insp} = 1.9 s

T_{Ramp} = 1.9 s

Basic flow at 95% oxygen = 2 l/min

The minute volume is calculated by multiplying the tidal volume with the respiratory rate: $MV = Vt * f = 500\ ml * 12\ 1/min = 6\frac{l}{m}$

$$Consumption = \left(MV + 2\ \frac{l}{min} * \frac{Tinsp - TRamp + Texp}{Tinsp + Texp}\right) * \frac{(FiO2 - 20.9\%)}{79.1\%}$$

$$Consumption = \left(6\ \frac{l}{min} + 2\frac{l}{min} * \frac{0\ s + 3.1\ s}{3.1\ s + 1.9\ s}\right) * \frac{(95\% - 20.9\%)}{79.1\%} = 6.77\ \frac{l}{min}$$

$$Operating\ time = \frac{Cylinder\ content}{Consumption} = \frac{2000\ l}{6.77\ l/m} = 295.4\ min$$

Sample calculation: Neo patient supplied with 95% oxygen

Tidal volume Vt = 10 ml

Respiratory rate f = 40 1/m

T_{insp} = 0.4 s

T_{Ramp} = 0.4 s

Basic flow at 40% oxygen = 3 l/min

The minute volume is calculated by multiplying the tidal volume with the respiratory rate: $MV = Vt * f = 10ml * 40\ 1/min = 0{,}4\frac{l}{m}$

$$Consumption = \left(MV + 3\ \frac{l}{min} * \frac{Tinsp - TRamp + Texp}{Tinsp + Texp}\right) * \frac{(FiO2 - 20.9\%)}{79.1\%}$$

$$Consumption = \left(0.4\ \frac{l}{min} + 3\frac{l}{min} * \frac{0\ s + 1.1\ s}{0.4\ s + 1.1\ s}\right) * \frac{(95\% - 20.9\%)}{79.1\%} = 2.43\ \frac{l}{min}$$

$$Operating\ time = \frac{Cylinder\ content}{Consumption} = \frac{2000\ l}{2.43\ l/m} = 823\ min$$

NOTE

At very high temperatures the basic flow may rise, but due to the blower module the **EVE$_{TR}$** can provide ventilation without any added oxygen at any time.

5.1.3 Changing the oxygen cylinder

NOTE

Before changing the pressurized gas cylinder, refer to the operating manual of the pressure regulator.

CAUTION

Before changing the pressurized gas cylinder, its valve must be hand-tightened!

- Drain any residual gas from the pressure regulator via the output until the pressure gauge on the pressure regulator shows "0".
- Loosen the O_2 NIST screw connector from the O_2 input on the **EVE$_{TR}$**.
- Loosen the fastening buckles on the support frame and carefully remove the oxygen cylinder.
- Remove the pressure regulator from the valve by turning the screw connector counter-clockwise and connect to the new cylinder.
- Place the new cylinder in the support frame and close the fastening buckles.
- Fit the O_2 NIST screw connector to the O_2 input on the **EVE$_{TR}$**.
- Open the pressurized gas cylinder's valve.

This completes the cylinder replacement.

CAUTION

After changing the pressurized gas cylinder, a leakage test according to manufacturer instructions must be carried out.

5.1.4 Connection to the central gas supply

If the device is not operated with an oxygen cylinder, it must be connected to the CGS. Connect the O_2 hose to the O_2 connector on the left side of the **EVE$_{TR}$** device (see chapter 3.3) and to the CGS wall outlet.

5.1.5 Connecting to an oxygen concentrator

The device can also be operated with an oxygen concentrator. Connect the O_2 hose to the O_2 quick coupling on the left side of the **EVE$_{TR}$** device (see chapter 3.3) and to the oxygen concentrator in accordance with the manufacturer instructions.

5.2 Energy supply connection

NOTE

The device, including its external power supply, must be positioned so that it can be disconnected from the mains power at all times.

5.2.1 Mains power supply

Power supply operation

Connect the power supply to the corresponding socket (see chapter 3.6) on the back of the **EVE$_{TR}$**. Connect the power supply cable of the power supply unit to the mains (80 – 240 V) and switch on the power supply unit.

WARNING

According to IEC 60601-1-1, the energy supply must only be connected to energy supply grids with adequate protective conductor connection.

WARNING

The power supply is part of the system. Only use original power supplies from FRITZ STEPHAN GMBH, otherwise damage to the **EVE$_{TR}$** may result.

5.2.2 12/24 V mains power supply

The **EVE$_{TR}$** can be operated directly at 12 V or 24 V using the ambulance or helicopter bracket. Connect the power plug to the 12/24 V socket on the back of the corresponding ambulance bracket (see chapters 3.7.1 and 3.7.2).

5.2.3 Internal energy supply

CAUTION

FRITZ STEPHAN GMBH recommends that the ventilator is not operated without a battery or with low batteries (capacity < 10%) because the device will switch off immediately in the event of a power failure.

CAUTION

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

CAUTION

If the battery is completely discharged, recharging may no longer be possible and replacement may be required. The internal battery (battery 1) may only be replaced by the authorized FRITZ STEPHAN GMBH customer service team.

The primary supply of the ventilator is mains voltage. In case of a power failure or if the device is disconnected from the external voltage source (e.g. during patient transport), energy is supplied by the internal voltage source. This is indicated by a text message in the alarm field.

The device is equipped with an internal battery with a battery life of 3 hours. An external battery may be used (optional); it extends the run time by an additional three hours. The type of energy supply is indicated both on the monitor (see chapter 3.2.6) and on the housing (see chapter 3.1.2).

NOTE

The specified run time assumes a new battery with a capacity of 100%. The operating time can be affected by the age of the battery, the charging cycles, and the charge level and can therefore deviate from specifications.

Battery	Operating time	Charge time
Internal battery 1 (built in)	Max. 180 min	Approx.180 min
External battery 2 (optional)	Max. 180 min	Approx. 240 min

Tab. 12: Operating time

NOTE

The charge level of the battery is indicated by a pictogram during mains operation (see chapter 3.2.6). When the **EVE$_{TR}$** is running on a battery, the charge level in % on the display automatically changes to remaining run time in minutes.

5.2.4 Charging the external battery

The external battery (optional) can be charged directly inside the device or externally using a separate power supply.

NOTE

We recommend fully charging both the internal and the external battery before starting a new ventilation.

5.3 Connecting the patient tube system

CAUTION

Installing additional components may cause increased dead space, resistance, and compliance in the ventilation tube system.

CAUTION

A patient filter (HME filter) should not be used together with an external patient gas humidification system because this causes increased resistance.

WARNING

Only use patient tube systems included in the list of accessories. Otherwise, ventilator function may be impaired!

WARNING

The patient tube systems are labelled with an expiration date. The expiration date must be checked before use.

5.3.1 EVE adults emergency single-use tube system

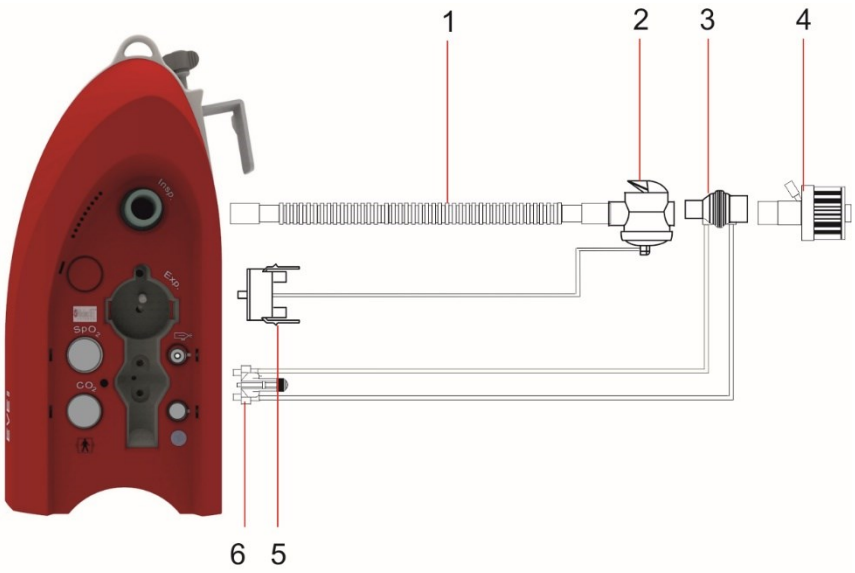


Fig. 66: EVE adult emergency single-use tube system

1	Tube system	4	Patient filter (optional)
2	Proximal expiration valve	5	Expiration valve adapter
3	Flow sensor for adults	6	Flow sensor adapter

5.3.2 EVE pediatric single-use tube system

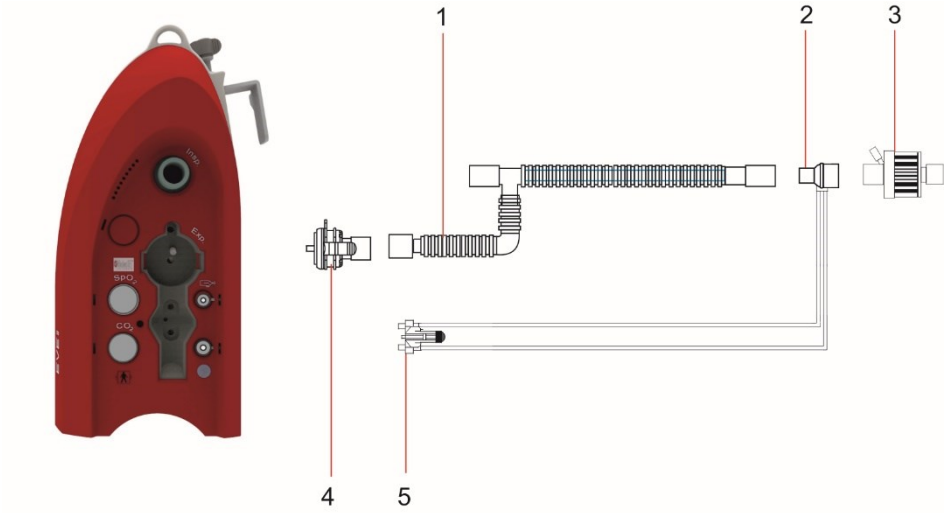


Fig. 67: EVE pediatric single-use tube system

1 Tube system
2 Flow sensor for children
3 Patient filter (optional)
4 Distal expiration valve
5 Flow sensor adapter

5.3.3 Configuration for use of the EasyFlow nCPAP system

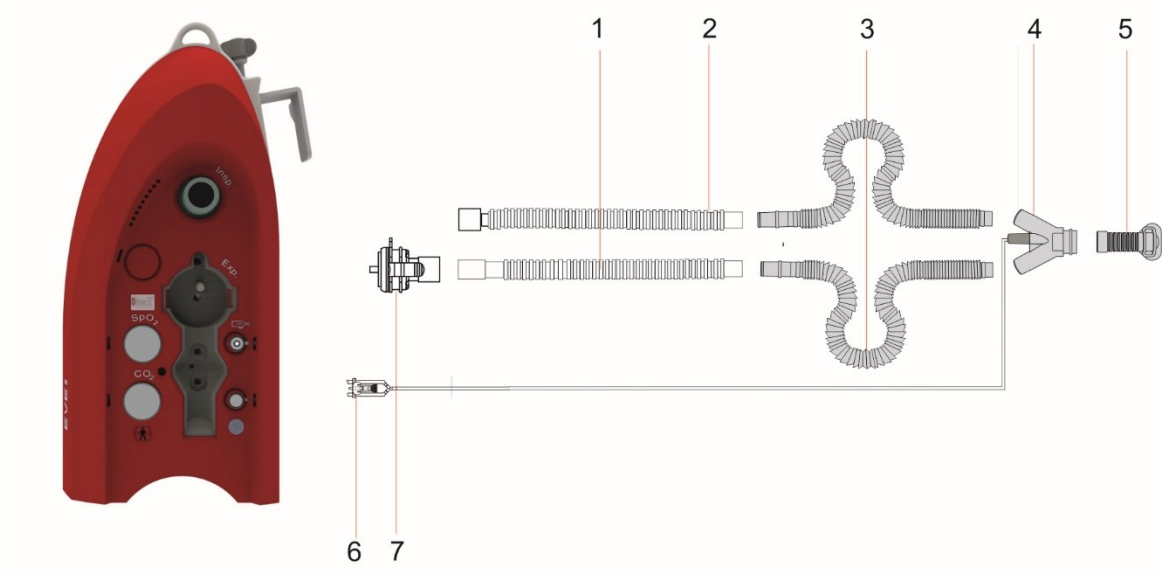


Fig. 68: Configuration with EasyFlow nCPAP system

1	Humidifier chamber filling connection	5	Prong / Mask
2	Tube system	6	Flow sensor adapter
3	Decoupling tube	7	Distal expiration valve
4	Applicator		

5.4 Installing the expiration valve

CAUTION

Carefully insert the expiration valve in the corresponding connection on the right side panel and allow to engage. Do not tilt the expiration valve or press it in with force. Danger of breakage!

The **EVE$_{TR}$** lets you use both distal (away from the patient) and proximal (close to the patient) expiration valves.

Distal expiration valves are used with the

- **EVE** pediatric single-use tube system
- Fisher & Paykel single-use tube system
- WILAmed single-use tube system

A proximal expiration valve is used with the **EVE** adult emergency single-use tube system.

5.4.1 Connecting the distal expiration valve

The distal expiration valve is connected directly to the expiration port and linked to the tube system (see Fig. 67).

5.4.2 Connecting the proximal expiration valve

The proximal expiration valve is connected between the flow sensor and the tube system. The control line of the valve is connected to the expiration outlet of the device using an adapter (see Fig. 66).

5.5 Installing the flow sensor

EVE$_{TR}$ measures pressure and flow via the flow sensor (PNT).
The measurement is taken proximally between the Y piece and the tube connector. For this purpose, a flow sensor head is fitted between the two parts. The differential pressure resulting from the flow sensor head's resistor is a measure of the volume flow. Separate flow sensors are available for adults and children.

Specifications

Flow sensor type	Dead space
Flow sensor for preterm infants and newborns (PNT B) (optional)	0.6 ml
Flow sensor, child	2.7 ml
Flow sensor, adult	11 ml

The flow sensor is connected between the expiration valve and the endotracheal tube (ETT). Fig. 69 and Fig. 70 show the additional connection of a CO_2 sensor and a bacterial filter.

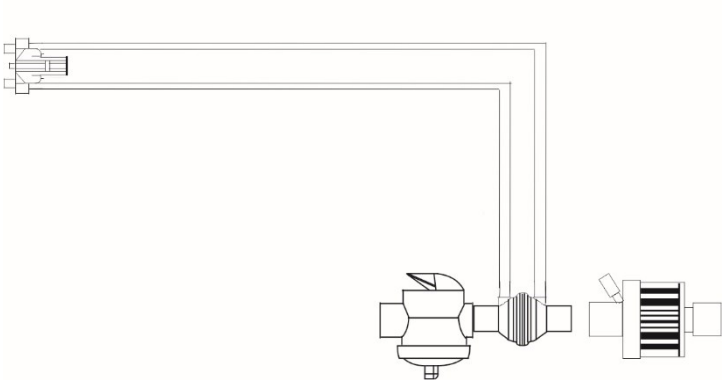


Fig. 69: Flow sensor connection with proximal expiration valve

Fig. 70: Flow sensor connection with distal expiration valve

NOTE

Turn the flow sensor measurement line connectors upward to prevent condensate from entering the measurement lines.

The flow sensor settings can be pre-selected in the system configuration in the "Sensors/Flow" menu (see chapter 4.2.3).

5.6 Installing the patient filter

CAUTION

Using a patient filter (HME filter) may increase (airway) resistance. In addition, the increased dead space volume when connecting a filter must be taken into account.

CAUTION

Use only approved patient filters. Otherwise, the patient may be at risk. Always follow the manufacturer's operating manual!

5.7 Installing the SpO_2 sensor

The SpO_2 sensor for measuring the Masimo-SET Rainbow® parameters is connected to the SpO_2 input on the right side of the **EVE_{TR}** device (see chapter 3.4).

5.8 Aerosol nebulization

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, especially in case of children.

WARNING

Nebulization and humidification may increase the resistance of patient filters. The user must regularly inspect the patient filter for increased resistance or blockage.

CAUTION

Select the medication dose carefully. If the medication dose is too high, it may negatively affect the ambient air.

CAUTION

The accuracy of the ventilator may be impaired by the gas added by the nebulizer.

CAUTION

The measurement of the minute volume (MV) may be affected by the medication nebulization.

CAUTION

Remove the medication nebulizer after use. Unintended nebulization may put the patient at risk and impair breathing.

CAUTION

The **EVE$_{TR}$** features built-in automatic compensation. As a result, the Aerosol button (see chapter 3.1.3) should be pressed only when a medication nebulizer is connected. Otherwise, the resulting breathing volume is too low.

NOTE

Aerosol nebulization is only possible if O_2 is connected to the ventilator.

NOTE

Aerosol nebulization is automatically synchronized with inspiration.

NOTE

In volume-controlled mode, the volume is automatically compensated for during nebulization.

For medication nebulization, install the nebulizer as shown in Fig. 71 and fill according to the operating manual provided with the nebulizer.

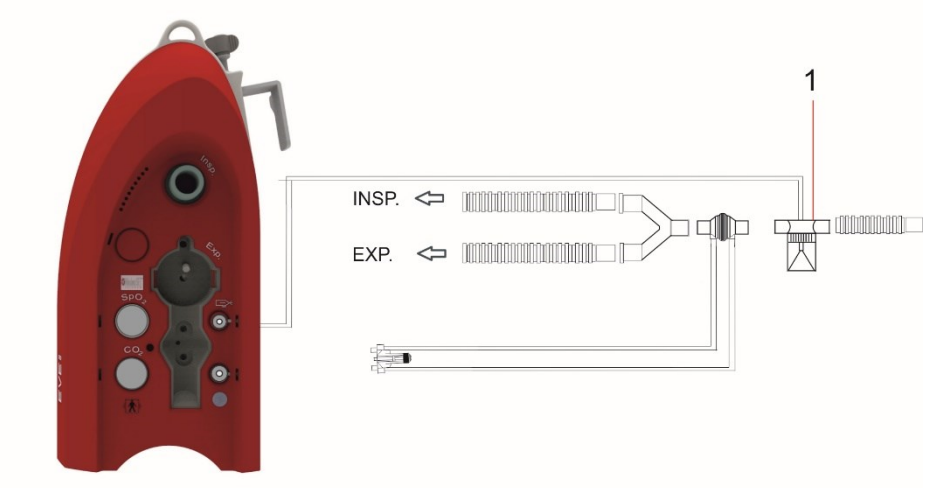


Fig. 71: Nebulizer connection

1 Nebulizer

Press the »Aerosol« button to switch on aerosol nebulization. The aerosol nebulization duration can be set to between 5 and 30 min in the "Function" menu (see chapter 4.1.4) in the system configuration. The nebulization ends automatically at the end of the set time or when pressing the button again.

NOTE

Follow the operating manual provided with the nebulizer for installation and filling!

6 Operation

6.1 Test before every 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.

6.1.1 Testing requirements

- The last safety check must have been carried out as scheduled. Visual check of the safety check sticker.
- The device is completely assembled and connected.
- The internal battery must be fully charged.

DANGER

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

6.1.2 Test list

Device type: _____		**Date:** _____	
SN: _____		**Signature:** _____	
WHAT	**HOW**	**TARGET**	**AC-TUAL**
Operating manual	The operating manual is part of the device and must always be kept with the device.	Available	☐
CGS Gas connection lines	Visual check of color-coding of gas types	ISO color code O_2 (oxygen) white	☐
	Unique mechanical features of the angled connector and gas connections	O_2 (oxygen) ⬡	☐
O_2 pressurized gas cylinders		Leak tightness Residual pressure	☐ ☐
Mains power supply	Visual check of the mains connection	Undamaged Mains switch »On/Off« to "On" »On« button illuminated	☐ ☐ ☐
Patient connections (All patient components must be connected properly)	Check the patient tube system	Connected properly	☐
	Check the SpO_2 sensor (optional)	Connected properly	☐
	Check the CO_2 sensor (optional)	Connected properly	☐
	Check the flow sensor (PNT)	Connected properly	☐
	Check the expiration valve	Connected properly	☐
Manual breathing bag	Self-filling, present, within reach	Functions correctly	☐
Bracket	Function test	Correct function	☐
Switch on the device			
Selftest	Perform selftest	Selftest completed successfully	☐
Internal energy supply	Disconnect the device from the external energy supply	Battery sufficiently charged	☐
Acoustic alarm	Check if the acoustic alarm is triggered during the selftest	Acoustic alarm is triggered during the selftest	☐
Alarm: Power failure	Disconnect the device from the external energy supply	"Powersupply?" notification appears.	☐
Alarm: Disconnection	Disconnect the patient tube system from the ventilator	"Disconnection!!!" HP alarm appears	☐
Alarm: O_2 level low	Close O_2 pressure regulator, set O_2 level to 30%.	After 30 s, "O2 low!!" MP alarm appears	☐
Alarm: High pressure	Connect test lung, set PAW UL to minimum, trigger peak pressure	Airway pressure high!!! HP alarm appears.	☐

Tab. 13: Test list

6.2 Switching the device on/off

On/Off/Standby button

Pressing the On/Off switch (see chapter 3.1.2) switches the **EVE$_{TR}$** on.

With display cover:

- Press and hold the button for three seconds
- The device ends the current ventilation process and switches to standby mode. The button flashes
- Press and hold the button for another three seconds
- The device now switches off.

6.3 Selftest

6.3.1 Selftest passed

After switching on the device, the **EVE$_{TR}$** performs an automatic selftest. If the selftest is successful, the **EVE$_{TR}$** automatically switches to Standby mode.

The following functions are checked during the selftest:

Power supply test	Battery charge level	12 V supply
	Battery voltage	5 V supply
	Battery temperature	
Valve test	Flow valve 1	O_2 calibration valve
	Flow valve 2	Nebulizer valve
Sensor test	External ADC channel 2	External ADC channel 9
	External ADC channel 5	Difference between ADC channels 0 and 1
	External ADC channel 7	Internal ADC channel 0
Turbine test	Test of the blower module	

Selftest passed

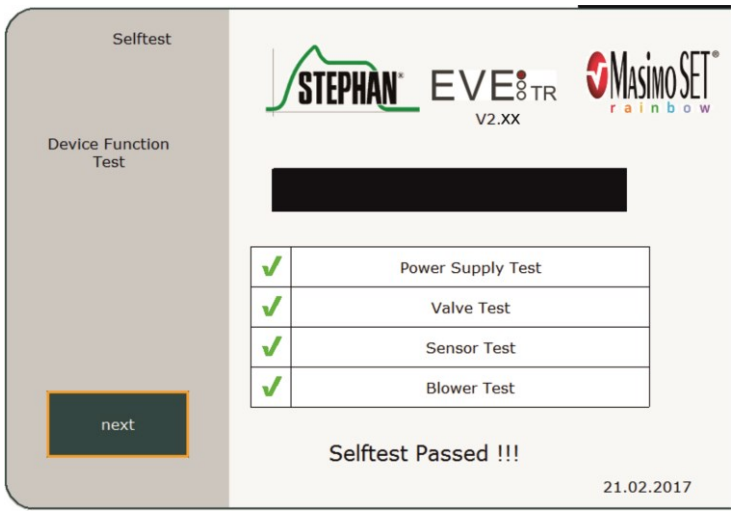


Fig. 72: Selftest passed

After the selftest is passed, press the »Next« field to open the standby screen.

6.3.2 Selftest failed

A failed selftest means that the ventilator cannot currently be used. An error code appears. See chapter 10.2 for causes and information on troubleshooting. After the malfunction has been corrected, the selftest can be repeated.

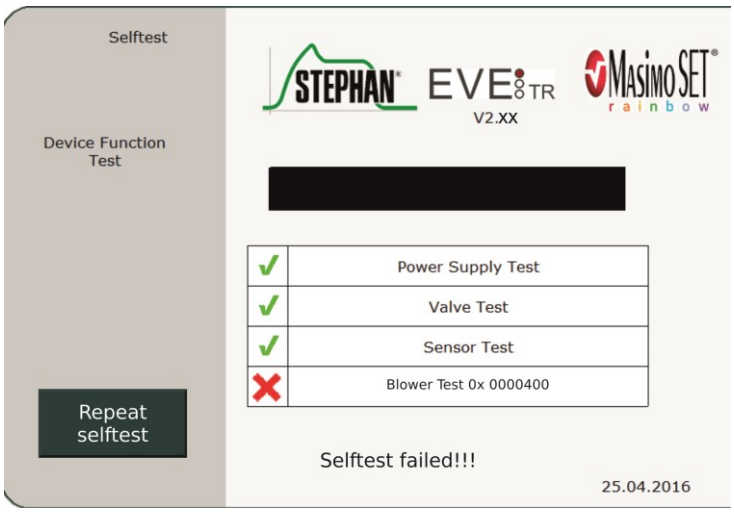


Fig. 73: Selftest failed

6.4 Standby mode

If the selftest is passed, the standby screen appears. Initially, it always shows the ventilation mode and settings for the most recent ventilated patient.

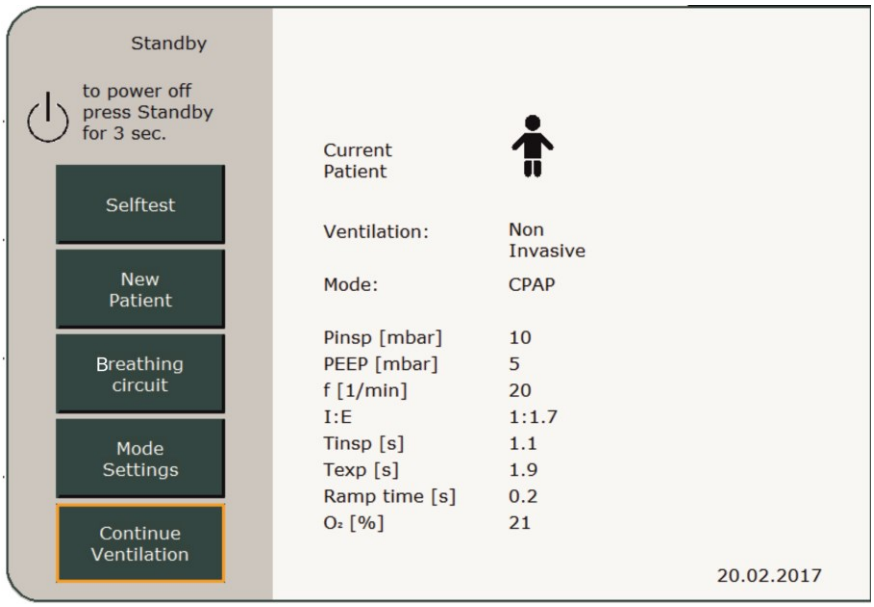


Fig. 74: Standby mode

To keep these settings, press the »Continue Ventilation« field to activate ventilation. Press the »New Patient« field to create a new patient.

Activate Standby mode

To switch to Standby mode from a current ventilation process, press and hold the On/Off/Standby button for 3 s (see chapter 6.2).

6.5 Using fast tracking keys

The easiest way to start a new ventilation process is by using the fast tracking keys on the front panel of the ventilator (see chapter 3.1.2). These provide a quick and easy way to select the default ventilation parameters for preterm infants and newborns, children, and adults (see chapter 6.7.1).

To prevent operator errors, the desired fast tracking key must initially be pressed for 0.5 s, after which it starts to flash green. Pressing the key again for 0.5 s will then start or switch to the selected ventilation mode.

6.6 New Patient

This menu lets the user switch between settings for preterm infants and newborns, children, and adults. This selection corresponds to the function of the fast tracking keys (see chapter 6.5). After selecting the patient type, the system suggests a PC-CMV ventilation with default ventilation parameters adapted to the corresponding patient type.

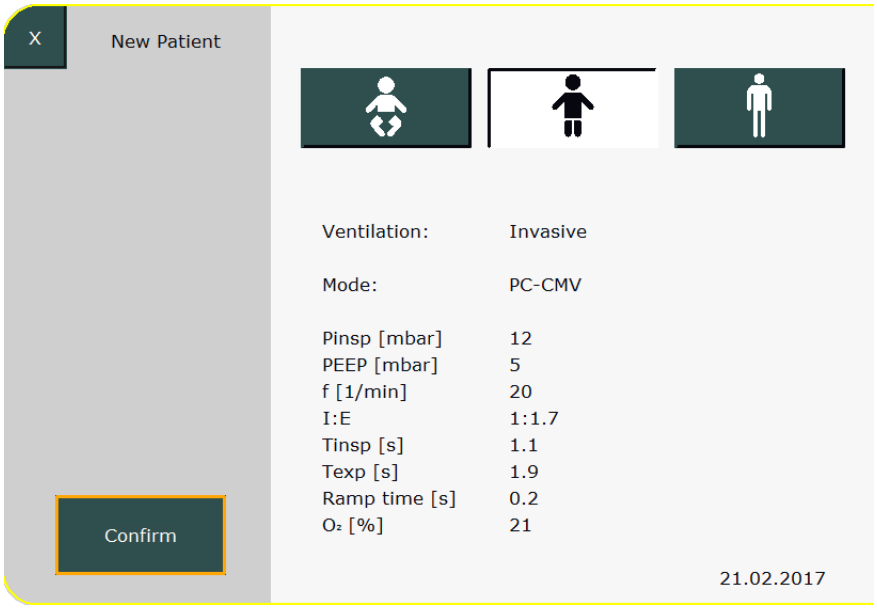


Fig. 75: Selecting the patient type

Press the »Confirm« button to save the settings and return the ventilator to the Standby screen. You can now select the »Start Ventilation« field. Press the »Mode Settings« field to change the ventilation mode.

6.7 Ventilation tube system

Standard tube systems are preconfigured for the various patient groups. If other tube systems are used, make the appropriate settings in this menu or in the System Settings/Sensors/Tube system menu (see chapter 4.2.4). The corresponding tube system must be selected for this based on the type designation or a pictogram.

If no new patient is displayed, the presetting for the tube system of the last ventilation is adopted.

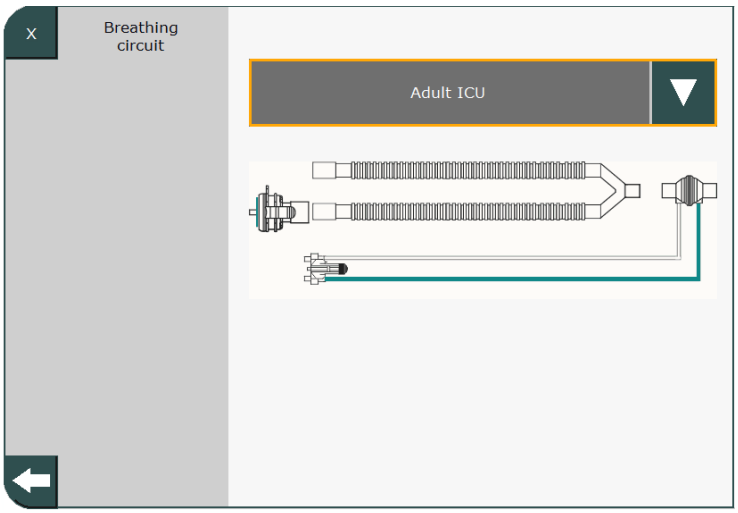


Fig. 76: Presetting for the patient tube system

ATTENTION

FRITZ STEPHAN GMBH explicitly recommends that only patient tube systems included in the list of accessories are used. Otherwise, ventilator function may be impaired!

If it is necessary to use a non-standardized tube system that has not been tested by FRITZ STEPHAN GMBH, select the "Other Tube System" option. Then enter the tube system's parameters manually.

6.7.1 Default ventilation parameters

The ventilator offers default ventilation parameters for all ventilation modes for the three patient types. These parameters are activated after selecting the type. They can be adapted to the corresponding patient in the Mode Settings menu.

Parameter	Preterm infants and newborns (optional)	Child	Adult
Apnea	4 s	4 s	4 s
ETS	25%	25%	25%
O_2	21%	21%	21%
f	40	20	12
I:E	1:2.7	1:1.7	1:1.7
PEEP	5 mbar	5 mbar	5 mbar
Phigh	18 mbar	12 mbar	12 mbar
Pinsp	18 mbar	12 mbar	12 mbar
ΔPsupp	1 mbar	10 mbar	10 mbar
Ramp time	0.1 s	0.2 s	0.2 s
VT	5 ml	200 ml	500 ml
Trigger	0.5	3.0	4.0
Flow limit	9 l/min	--	--

Tab. 14: Default ventilation parameters

6.8 Mode Settings

WARNING

When selecting the suitable ventilation mode, the indications and contraindications in particular must be observed (see chapter 1.5).

WARNING

Disconnection alarm is activated in all non-invasive ventilation forms only if the tube system is disconnected from the device. If the patient interface is disconnected (prong, mask) or has a leakage, the disconnection alarm will not be triggered.

NOTE

For safety reasons, the volume-controlled ventilation modes cannot be selected in the mode for preterm infants and newborns.

NOTE

Volume alarms are not active during non-invasive ventilation methods.

The "Mode Settings" menu first lets the user decide between invasive or non-invasive ventilation.

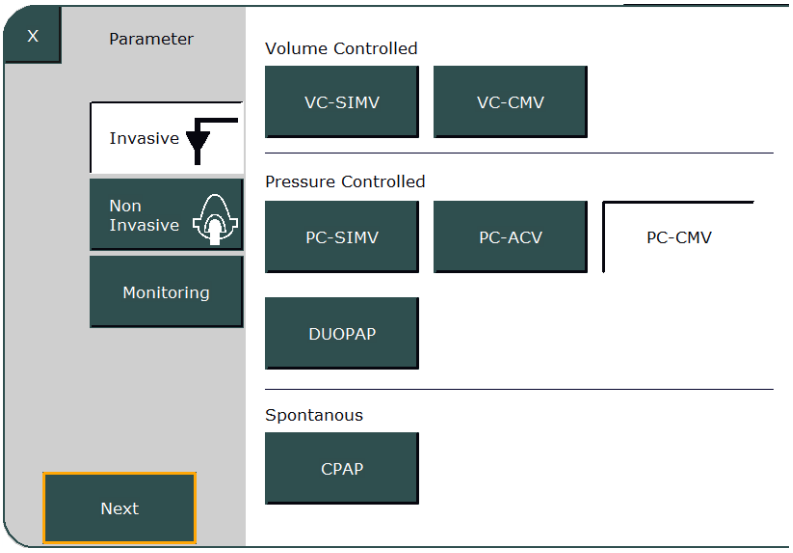


Fig. 77: Mode Settings menu

Depending on the license package, the following ventilation modes are available:

Ventilation mode	License	Invasive	Non-invasive
Volume Controlled			
VC-SIMV	Standard	X	-
VC-CMV	Standard	X	-
Pressure Controlled			
PC-SIMV	Standard	X	X
nPC-SIMV	License Neo mode required	-	X
PC-ACV	Standard	X	X
PC-ACV+	License ACV+/nACV+ required	X	X
nPC-ACV	License Neo mode required	-	X
nPC-ACV+	License ACV+/nACV+ required	-	X
PC-CMV	Standard	X	X
nPC-CMV	License Neo mode required	-	X
nDUOPAP	License Neo mode required	-	X
DUOPAP	License Neo mode or NIV/DUOPAP required	X	X
Spontaneous			
CPAP	Standard	X	X
nCPAP	License Neo mode required	-	X
Other			
O_2 therapy	Standard	-	X
High flow – O_2 therapy	Standard	-	X

Tab. 15: Ventilation modes

6.8.1 Monitoring

If the ventilation functions of the **EVE** are not required, the device can also be used as a pulse oximeter. For this purpose, the "Monitoring" field must be selected in the "Ventilation Settings" menu and the "SPO_2" field activated in the subsequent sub-menu. The Pleth and Pulse values are then displayed graphically.

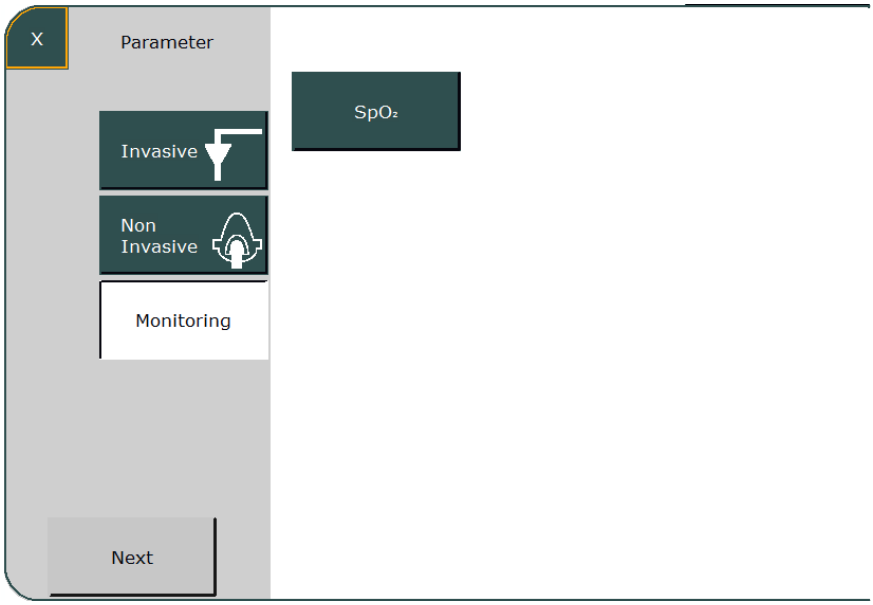


Fig. 78: Setting for SPO_2 monitoring

6.8.2 Selecting the ventilation mode

This example uses invasive PC-SIMV to describe the selection of the ventilation mode. Proceed as follows:

- Press the »Invasive« field in the menu. All available ventilation modes are displayed.
- Select »PC-SIMV« and press the »Next« field.

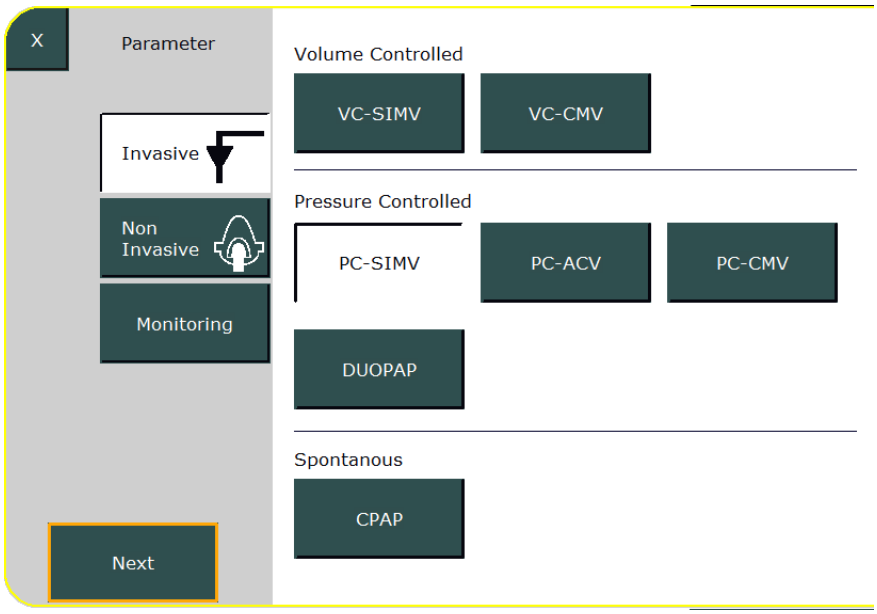


Fig. 79: Selecting the ventilation mode

The configuration menu for PC-SIMV opens.

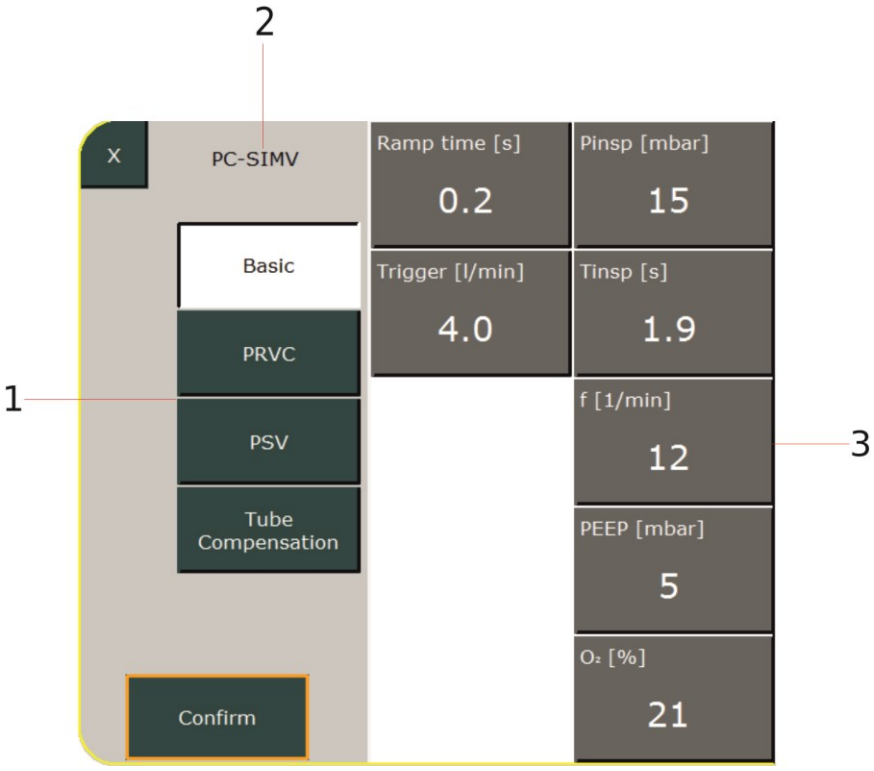


Fig. 80: PC-SIMV configuration menu

1 Additional functions for the selected ventilation mode

2 Current ventilation mode

3 Configurable ventilation parameters

Possible additional options for PC-SIMV (here PRVC and PSV) and tube compensation are listed on the left side. The relevant configurable ventilation parameters are listed on the right side. After the user selects the desired PC-SIMV option, the corresponding ventilation parameters are displayed and can be adapted to the patient's needs.

Select a parameter. The parameter turns yellow. The value can now be changed using the control knob. Press the control knob or the »Confirm« field to complete your entry. Proceed analogously to configure the other ventilation parameters.

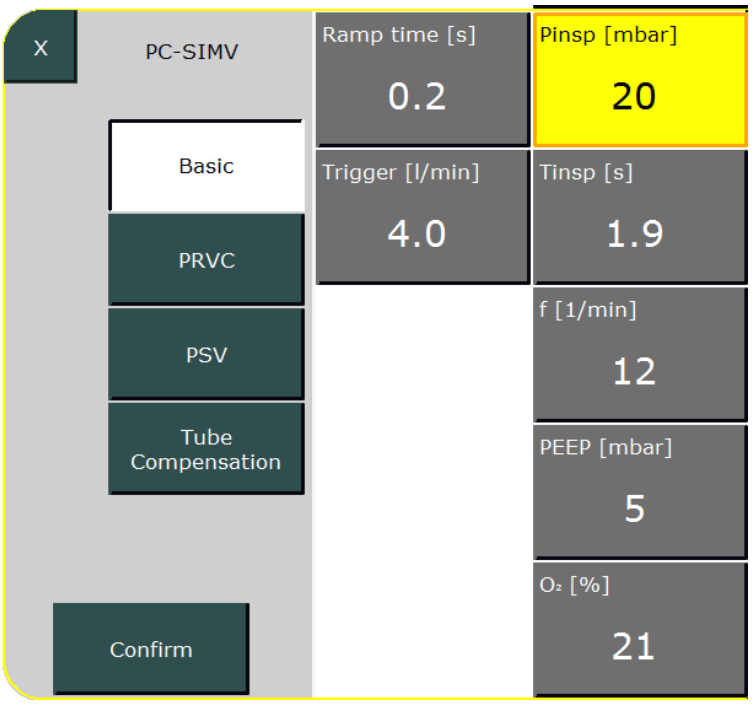


Fig. 81: Setting parameters

Press the »Confirm« button to save the settings and return the ventilator to the "Standby" menu. Select »Continue Ventilation« to activate the ventilation.

NOTE

See chapter 7 for a detailed description of all the ventilation modes and configurable ventilation parameter settings provided by the **EVE$_{TR}$**.

6.9 Ending ventilation

To end the current ventilation process and switch to Standby mode, press and hold the »On/Off/Standby« button for 3 s (see chapter 6.2). Pressing the button for another 3 s turns the ventilator off.

7 Ventilation modes

7.1 Invasive and non-invasive ventilation modes

The **EVE$_{TR}$** provides both invasive and non-invasive (NIV) ventilation modes. Whereas all volume-controlled ventilation modes (VC-CMV, VC-SIMV, see chapter 7.3.1) are only suitable for invasive ventilation, the pressure-controlled ventilation modes (PC-SIMV, PC-CMV, PC-ACV, PC-ACV+ (optional), CPAP, and DUOPAP, see chapter 7.3.2) can be used for non-invasive ventilation.

The non-invasive ventilation modes nCPAP, nPC-SIMV, nPC-ACV, nPC-ACV+, nDUOPAP, and nPC-CMV are used for the ventilation of preterm infants and newborns. In this case, ventilation is carried out without a flow sensor because pressure measurement is performed proximally via an adapter.

NOTE

The ventilation modes for preterm infants and newborns, as well as for PC-ACV+ and nPC-ACV+, are not included in the scope of supply and available only with a corresponding license (see chapter 1.2.1).

A flow limit is available in NEO mode for non-invasive ventilation modes. The preset flow limit is 9 l/min. It can be set within a range of 5-30 l/min in the corresponding field or switched off completely.

Fig. 82:Flow limit

Invasive ventilation involves positive pressure ventilation via the endotracheal tube (ETT). NIV involves ventilation without intubation or endotracheal access using masks or binasal prongs.

The benefits of non-invasive ventilation are a reduced risk of nosocomial infections and their complications as well as avoiding sedation and its negative side effects. However, it requires sufficient spontaneous breathing of the patient. NIV ventilation is contraindicated in the following cases:

- No spontaneous breathing
- Fixed or functional airway obstruction
- Gastrointestinal bleeding or ileus

Invasive ventilation is generally indicated when the airways MUST be secured, e.g. in coma patients, in case of risk of aspiration, or with complete sedation.

Additional options

Some ventilation modes provide additional options, such as

- Pressure-regulated and volume-controlled ventilation (PRVC)
- Pressure support ventilation (PSV)
- Backup ventilation
- Tube compensation

The following table provides an overview of the available additional options for the various ventilation modes:

Ventilation mode	PRVC	PSV	Backup	Tube compensation
VC-CMV	-	-	-	X
VC-SIMV	-	X	-	X
PC-CMV	X	-	-	X
nPC-CMV	-	-	-	-
PC-SIMV	X	X	-	X
nPC-SIMV	-	X	-	-
PC-ACV	X	-	-	X
PC-ACV+	X	-	-	X
nPC-ACV	-	-	-	-
nPC-ACV+	-	-	-	-
CPAP	-	X	X	X
nCPAP	-	X	X	-
DUOPAP	X	X	-	X
nDUOPAP	-	X	-	-
O_2 therapy	-	-	-	-

Tab. 16: Overview of selectable additional options

When selecting a ventilation mode, the available additional options appear as fields along the right edge of the screen (see Fig. 80). Select the corresponding field to use an additional option. This will open the configurable parameters for this ventilation mode. Chapter 7.4 describes the function of the additional options.

Points to note in relation to the visualization of spontaneous breathing

Spontaneous breathing is visualized in the curve display by a color change in the ventilation curve. The color of the flow curve changes from magenta to orange.

7.2 Trigger functionality

7.2.1 Flow trigger

The flow sensor enables the **EVE$_{TR}$** to measure the patient's inspiratory flow. If the inspiratory flow exceeds the value set by the user, a mandatory breath is triggered. This "trigger threshold" is set in the »Trigger« field as flow in l/min.

NOTE

The flow trigger level for spontaneous breathing detection is preset in the device and cannot be changed by the user. It is independent of the setting for inspiration flow detection.

The present trigger levels are

- approx. 10 l/min (adults)
- approx. 2 l/min (children)
- approx. 0.8 l/min (preterm infants and newborns)

7.2.2 Internal flow trigger

The internal flow trigger is active for all non-invasive neonatal ventilation forms (optional). The "trigger threshold" is set in the »Trigger« field as flow in l/min.

NOTE

The internal flow trigger can be activated for all ventilation forms. The external flow sensor must first be switched off in the "Sensors/Flow" menu (see chapter 4.2.3).

7.3 Mandatory ventilation

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 (Tinsp). During this inspiration time, an inspiratory tidal volume (VT) is provided to sustain the exchange of gas within the lungs.

At the end of the inspiration time (Tinsp), the ventilator switches to a preset expiration time (Texp). The elastic restoring forces of the lung are now responsible for passive expiration, during which pressure between the lungs and ventilator is equalized. The exhaled expiratory breathing volume is called the tidal volume and measured by the flow sensor (PNT) and shown on the display.

The ventilation rate within one minute is called breathing frequency. 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 invasive mandatory ventilation, the patient has a virtually "pressure-tight" connection to the ventilator through the endotracheal tube (ETT) and the tube system. His breathing therefore depends on the flexibility and efficiency of the ventilator. The ETT positioned in the intubated patient's trachea prevents him from breathing. The smaller the diameter of the ETT, the more difficult it is to breathe in and out.

Increased air tube pressure during expiration (PEEP = positive end expiratory pressure) improves alveolar ventilation/the pulmonary exchange of gases.

For the patient to breathe in spontaneously, he first has to overcome the resistance of the ETT before respiratory gas can flow into his 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 the patient's spontaneous breathing depends on the inner resistance. This ability is significant for the quality of the ventilator.

Depending on the selected ventilation mode (pressure or volume-controlled ventilation), the inner resistance can also be used to specifically react to a given ventilation scenario. The **EVE$_{TR}$** makes a basic distinction between pressure-controlled and volume-controlled ventilation.

7.3.1 Volume-controlled ventilation

NOTE

Never use volume-controlled ventilation modes with unattended patients.

NOTE

Volume-controlled ventilation modes are only available for tidal volumes of 100 ml or more.

7.3.1.1 Volume-controlled continuous mandatory ventilation (VC-CMV)

Volume-controlled continuous mandatory ventilation (VC-CMV) "forces" the delivery of a preset inspiratory tidal volume. The ventilation pressure delivered changes with the mechanical parameters of the lungs. If compliance improves, the ventilation pressure needed to reach the selected tidal volume adjust to the lowest possible value.

However, if the compliance of the lungs worsens, the ventilation pressure needed to maintain the selected tidal volume may increase. The ventilation pressure may even exceed the upper pressure limit.

In this case, the tidal volume actually delivered may be less than the target volume set by the user. The ventilation pressure limit and/or respiratory rate may then have to be adjusted to maintain an adequate respiratory minute volume. If the patient breathes "against" the ventilator during the inspiration phase, the ventilation pressure increases within the selected maximum pressure limit until the selected tidal volume has been safely delivered.

However, ETT leakage may prevent the total ventilator-delivered volume from reaching the lungs.

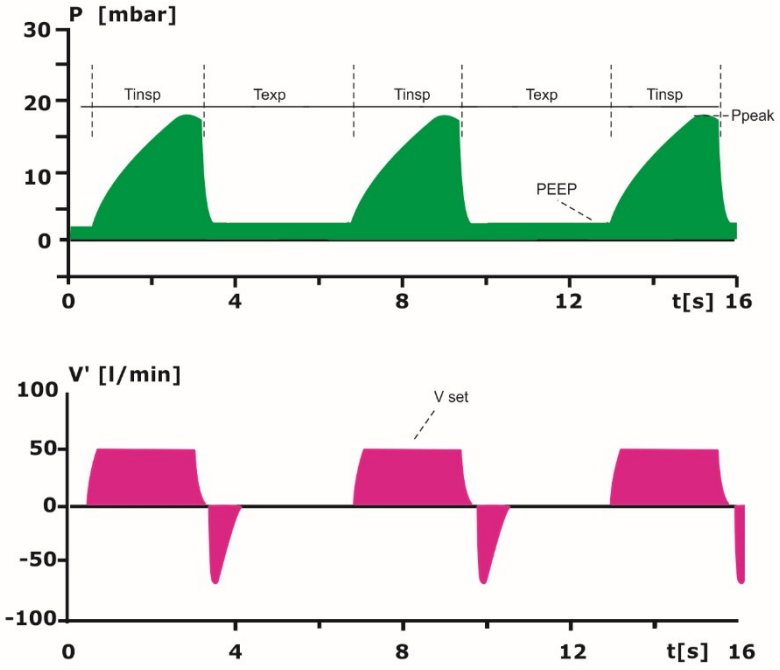


Fig. 83: Volume-controlled ventilation VC-CMV

Adjustable ventilation parameters

Ventilation mode	Adjustable parameters
VC-CMV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Tidal volume (VT)

Tab. 17: VC-CMV

NOTE

The VC-CMV ventilation mode includes an option for tube compensation (see chapter 7.4.3).

7.3.1.2 Volume-controlled synchronized intermittent mandatory ventilation (VC-SIMV)

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 **EVE$_{TR}$** uses the flow sensor's patient gas flow signal as a synchronization trigger. The flow sensor enables the **EVE$_{TR}$** to measure the patient’s inspiratory flow. If the inspiratory flow exceeds the value set by the user, a mandatory breath is triggered. This "trigger threshold" is set in the »Trigger« field as flow in l/min. The trigger threshold appears as a light blue line in the respiratory gas flow signal window. The higher the setting for this trigger threshold above the respiratory gas flow signal in the expiratory phase, the more the patient has to breathe in to activate the trigger. In turn, too little distance to the respiratory gas flow signal can cause unintended triggering due to artifacts or leakage flows. For VC-SIMV, the **EVE$_{TR}$** delivers a mandatory breath once an inspiratory flow reaches the preset trigger threshold.

The trigger is only active within a so-called trigger expectation window. The length of this expectation window and the time gap between the windows vary depending on the set expiration time.

The expiration time is divided into two phases.
In the first phase ($Texp_{spon}$ = 50% of Texp), the patient can only breathe spontaneously. Even when the trigger threshold is crossed, there is no mandatory support from the ventilator. If the patient breathes spontaneously during the second phase of the expiration time, the **EVE_{TR}** now delivers a mandatory breath.

Selecting the inspiration and expiration time or frequency lets the user specify a mandatory base frequency that does not change. It applies even if the patient exhibits active spontaneous breathing that could theoretically trigger a lot more mandatory breaths. As a result, the time by which the expiration time was reduced is added to the next following expiration times after each trigger event. This means that the average matches the mandatory base frequency set by the user.
The actual total breathing frequency is shown in the "ftotal" measured value display of the monitor. This also shows the minute volume measurement as "MVtotal".

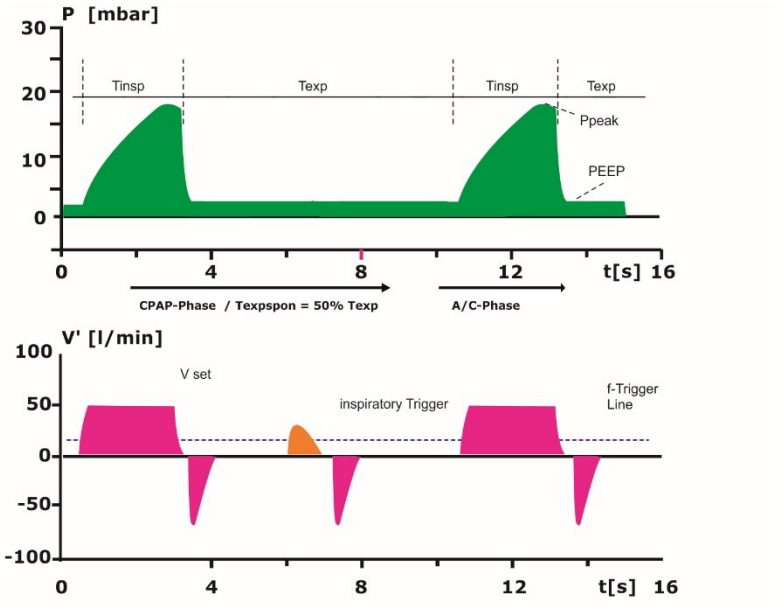


Fig. 84: VC-SIMV

Adjustable parameters:

Ventilation mode	Adjustable parameters
VC-SIMV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Tidal volume (VT) ▪ Trigger

Tab. 18: VC-SIMV

NOTE

The VC-SIMV ventilation mode can be used with optional pressure support (PSV) (see chapter 7.4.2). It also includes an option for tube compensation (see chapter 7.4.3).

Ventilation mode	Adjustable parameters
VC-SIMV with PSV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Tidal volume (VT) ▪ Pressure support (ΔPsupp) (relative set value with reference to PEEP) ▪ Expiration trigger sensitivity (ETS)

Tab. 19: VC-SIMV with PSV

7.3.2 Pressure-controlled ventilation modes

NOTE

The device can compensate for a leakage of up to 50 l/min when pressure-controlled ventilation modes are in use.

7.3.2.1 Pressure-controlled continuous mandatory ventilation (PC-CMV)

The ventilation pressure is the key factor for pressure-controlled ventilation. It compares the preset nominal parameters such as inspiratory peak pressure »Pinsp« and positive end expiratory pressure »PEEP« with the pressure values measured during inspiration (Pinsp) and expiration (PEEP). Any deviations caused, for example, by spontaneous breathing activity are compensated quickly.

Under PC-CMV, the time required for mandatory insufflation is adjusted in the »Tinsp« field. The set inspiratory peak pressure »Pinsp« 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 »Pinsp« settings. Spontaneous breathing attempts by the patient during inspiration are not restricted by PC-CMV. The patient can breathe in and out freely at every pressure level. The pressure is controlled, that is, it remains constant.

At the start of every inspiration phase, the 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 lungs. There is no further flow between the Y piece and the lungs due to the pressure gradient.

The lungs have now been filled within the time indicated on the time axis. The inspiratory pressure increase which can be set in the »Ramp time« field determines how the ventilation pressure reaches its maximum value within the inspiration time »Tinsp.«.

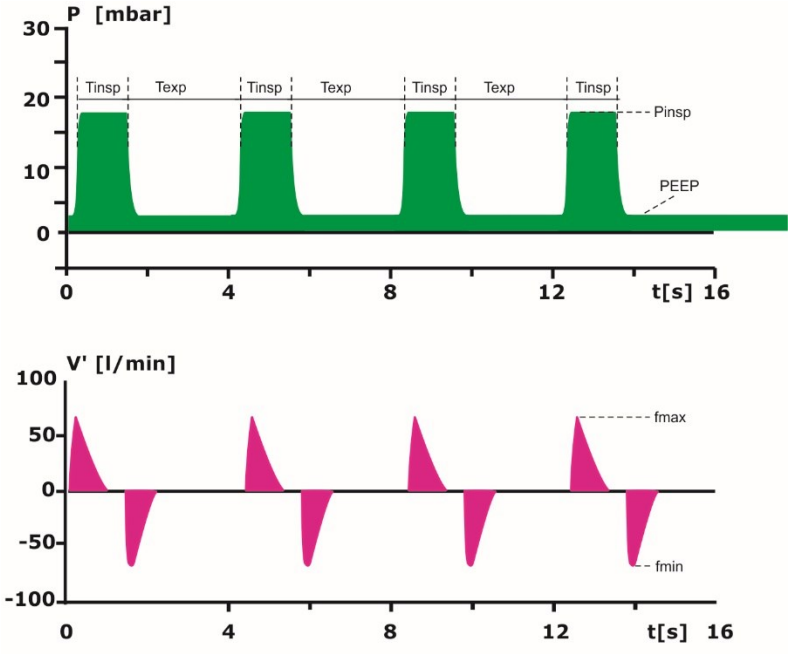


Fig. 85: PC-CMV

Adjustable parameters

Ventilation mode	Adjustable parameters
PC-CMV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Inspiration pressure (Pinsp)

Tab. 20: PC-CMV

NOTE

The PC-CMV ventilation mode can be used with volume guarantee (PRVC) (see chapter 7.4.1). It also includes an option for tube compensation (see chapter 7.4.3).

Adjustable parameters

Ventilation mode	Adjustable parameters
PC-CMV with PRVC	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Target volume (VT)

Tab. 21: PC-CMV with PRVC

7.3.2.2 Non-invasive pressure-controlled mandatory ventilation (nPC-CMV)

The nPC-CMV corresponds to the behavior of the PC-CMV. It is only available in non-invasive Neo mode. The device is operated without a flow sensor (PNT) in this mode. The pressure is measured proximally via the pressure measurement adapter set.

Adjustable parameters

Ventilation mode	Adjustable parameters
nPC-CMV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Inspiration pressure (Pinsp) ▪ Flow limitation (in NEO mode only)

Tab. 22: nPC-CMV

7.3.2.3 Pressure-controlled synchronized intermittent mandatory ventilation (PC-SIMV)

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 **EVE$_{TR}$** uses the flow sensor's patient gas flow signal as a synchronization trigger. The flow sensor enables the **EVE$_{TR}$** to measure the patient's inspiratory flow. If the inspiratory flow exceeds the value set by the user, a mandatory breath is triggered. This "trigger threshold" is set in the »Trigger« field as flow in l/min. The trigger threshold appears as a light blue line in the respiratory gas flow signal window. The higher the setting for this trigger threshold above the respiratory gas flow signal in the expiratory pause, the more the patient has to breathe in to activate the trigger. In turn, too little distance to the respiratory gas flow signal can cause unintended triggering due to artifacts or leakage flows.

For PC-SIMV, the **EVE$_{TR}$** delivers a mandatory breath once an inspiratory flow reaches the preset trigger threshold. The trigger is only active within a so-called trigger expectation window. The length of this expectation window and the time gap between the windows vary depending on the set expiration time.

The expiration time is divided into two phases.
In the first phase ($Texp_{spon}$ = 50% of Texp), the patient can only breathe spontaneously. Even when the trigger threshold is crossed, there is no mandatory support from the ventilator. If the patient breathes spontaneously during the second phase of the expiration time, the **EVE$_{TR}$** now delivers a mandatory breath.

Selecting the inspiration and expiration time or frequency lets the user specify a mandatory base frequency that does not change. It applies even if the patient exhibits active spontaneous breathing that could theoretically trigger a lot more mandatory breaths. As a result, the time by which the expiration time was reduced is added to the next following expiration times after each trigger event. This means that the average matches the mandatory base frequency set by the user.

The actual total breathing frequency is shown in the "ftotal" measured value display of the monitor. This also shows the minute volume measurement as "MVtotal".

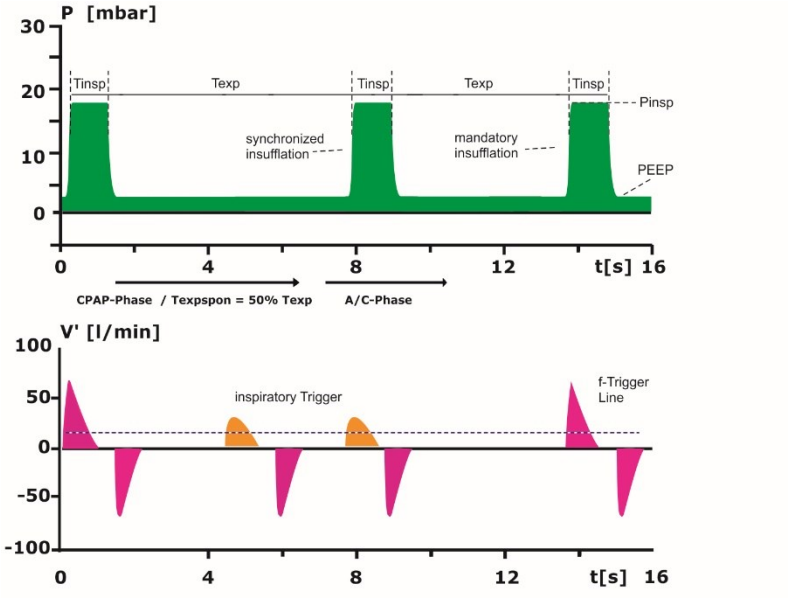


Fig. 86: PC-SIMV

Adjustable parameters

Ventilation mode	Adjustable parameters
PC-SIMV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Inspiration pressure (Pinsp) ▪ Trigger

Tab. 23: PC-SIMV

NOTE

The PC-SIMV ventilation mode can be used with volume guarantee (PRVC) or pressure support (PSV) (see chapters 7.4.1 and 7.4.2).
It also includes an option for tube compensation (see chapter 7.4.3).

Ventilation mode	Adjustable parameters
PC-SIMV with PRVC	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Target volume (VT)

Tab. 24: PC-SIMV with PRVC

Ventilation mode	Adjustable parameters
PC-SIMV with PSV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Inspiration pressure (Pinsp) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Pressure support (ΔPsupp) (relative set value with reference to PEEP) ▪ Trigger ▪ Expiratory trigger sensitivity (ETS)

Tab. 25: PC-SIMV with PSV

7.3.2.4 Non-invasive pressure-controlled synchronized intermittent mandatory ventilation (nPC-SIMV)

The nPC-SIMV corresponds to the behavior of the PC-SIMV. It is only available in non-invasive Neo mode. The device is operated without a flow sensor (PNT) in this mode. The pressure is measured proximally via the pressure measurement adapter set.

Adjustable parameters

Ventilation mode	Adjustable parameters
nPC-SIMV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Inspiration pressure (Pinsp) ▪ Trigger ▪ Flow limitation (in NEO mode only)

Tab. 26: nPC-SIMV

Ventilation mode	Adjustable parameters
nPC-SIMV with PSV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Inspiration pressure (Pinsp) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Pressure support (ΔPsupp) (relative set value with reference to PEEP) ▪ Trigger ▪ Expiratory trigger sensitivity (ETS)

Tab. 27: nPC-SIMV with PSV

7.3.2.5 Pressure-controlled assist/control ventilation (PC-ACV)

Like PC-SIMV, the assist/control mode is a synchronized ventilation mode. In PC-ACV mode, however, the ventilator supports all of the patient's own breathing efforts that exceed the preset trigger threshold with a mechanical breath. This triggers the patient's mandatory inspiration, but its characteristic is controlled by the device. The patient cannot trigger a new mandatory breath until this time has elapsed.

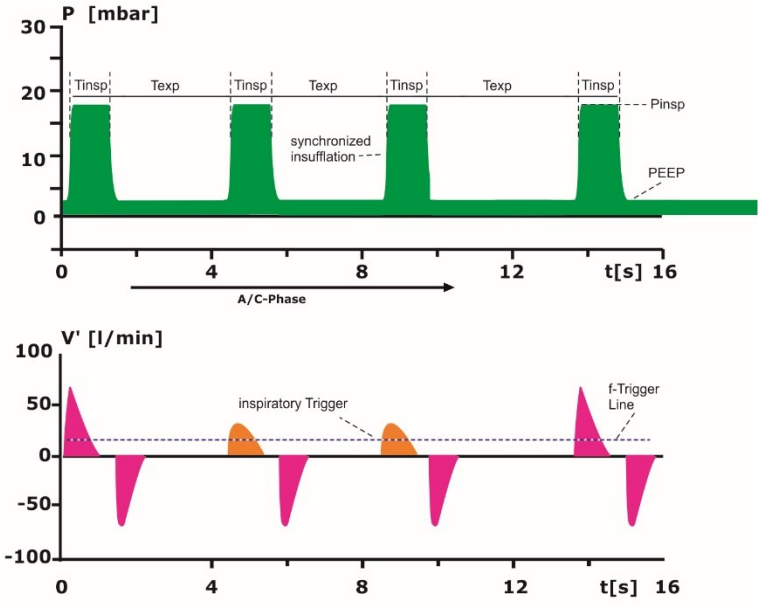


Fig. 87: PC-ACV

Ventilation mode	Adjustable parameters
PC-ACV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Inspiration pressure (Pinsp) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Trigger

Tab. 28: PC-ACV

NOTE

NOTE

The PC-ACV ventilation mode can be used with volume guarantee (PRVC) (see chapter 7.4.1). It also includes an option for tube compensation (see chapter 7.4.3).

Ventilation mode	Adjustable parameters
PC-ACV with PRVC	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Target volume (VT) ▪ Trigger

Tab. 29: PC-ACV with PRVC

7.3.2.6 Non-invasive pressure-controlled assist/control ventilation (nPC-ACV)

The nPC-ACV corresponds to the behavior of the PC-ACV. It is only available in non-invasive Neo mode. The device is operated without a flow sensor (PNT) in this mode. The pressure is measured proximally via the pressure measurement adapter set.

Ventilation mode	Adjustable parameters
nPC-ACV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Trigger ▪ Flow limitation (in NEO mode only)

Tab. 30: nPC-ACV

7.3.2.7 Pressure-controlled assist/control ventilation + (PC-ACV+)

The PC-ACV+ corresponds to the behavior of the PC-ACV. The expiration trigger is active in this mode.

The change to the PEEP level takes place either upon expiration of the set inspiration time or is patient triggered at incipient expiration by the patient. As a result, the patient controls the beginning, progress, and volume of the mechanically supported breath.

Ventilation mode	Adjustable parameters
nPC-ACV	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Target volume (VT) ▪ Trigger ▪ Flow limitation (in NEO mode only)

Tab. 31: PC-ACV+

7.3.2.8 Non-invasive pressure-controlled assist/control ventilation plus (nPC-ACV+)

The nPC-ACV+ corresponds to the behavior of the PC-ACV. It is only available in non-invasive Neo mode. The expiration trigger is active in this mode (see chapter 7.2). If the device is operated without a flow sensor (PNT), pressure is measured proximally via the pressure measurement adapter set.

The change to the PEEP level takes place either upon expiration of the set inspiration time or is patient triggered at incipient expiration by the patient. As a result, the patient controls the beginning, progress, and volume of the mechanically supported breath.

Ventilation mode	Adjustable parameters
nPC-ACV+	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Trigger ▪ Flow limitation (in NEO mode only)

Tab. 32: nPC-ACV+

7.3.2.9 DUOPAP

DUOPAP is a pressure-controlled, timed ventilation support mode for both mandatory and synchronized ventilation. This ventilation mode features two freely selectable time windows Tinsp and Texp (the parameters for breathing cycling can be configured, see chapter 4.4.2) and two independently selectable pressure levels that allow the patient to breathe freely at any time.

Due to the special regulating characteristics of the integrated turbine, the flow is regulated when spontaneous breathing activity of the patient is detected. This is to keep the selected airway pressure constant while simultaneously allowing spontaneous breathing. The mechanical ventilation portion is the result of the pressure difference between the two selected levels and the resulting breathing volume. The resulting pressure difference Δp causes patient gas flow. The inspiratory pressure increase which can be set in the »Ramp time« field determines how the ventilation pressure reaches its maximum value within the inspiration time »Tinsp«. To adapt the patient's spontaneous breathing activity even better, the corresponding pressure changeovers can be synchronized both from the lower to the upper or from the upper to the lower pressure level.

For this purpose, the »Trigger« field is used to set the trigger function. The flow trigger is used to initiate the changeover from the lower to the upper pressure level within a trigger window.

The trigger is only active within a so-called trigger expectation window. The length of this expectation window and the time gap between the windows vary depending on the set expiration time. The expiration time is divided into two phases.
In the first phase ($Texp_{spon}$ = 50% of Texp), the patient can only breathe spontaneously. Even when the trigger threshold is crossed, there is no mandatory support from the ventilator. If the patient breathes spontaneously during the second phase of the expiration time, the **EVE_{TR}** now delivers a mandatory breath.

The expiration time is divided into two phases. In the first phase ($Texp_{spon}$ = 50% of Texp), the patient can only breathe spontaneously. Even when the trigger threshold is crossed, there is no mandatory support from the ventilator. If the patient breathes spontaneously during the second phase of the expiration time, the **EVE_{TR}** now delivers a mandatory breath. The change from the upper to the lower level is either upon expiration of the set inspiration time or is patient triggered at incipient expiration by the patient. After the first inspiration phase has passed ($Tinsp_{spon}$ = 50% of Tinsp). As a result, the patient controls the beginning, progress, and volume of the mechanically supported breath.

This differentiates DUOPAP from other mixed ventilation modes where spontaneous and controlled breaths follow one after another. In addition, mechanical ventilation and spontaneous breathing can be combined simultaneously.

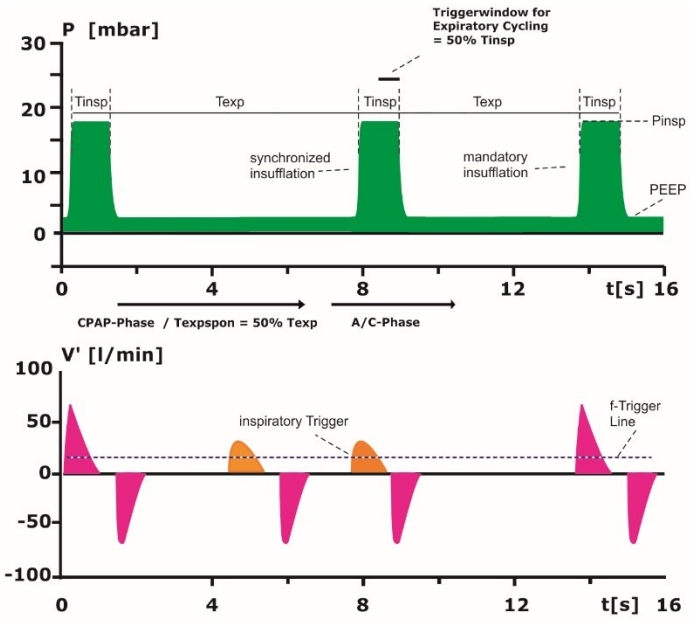


Fig. 88: DUOPAP

NOTE

The DUOPAP ventilation mode can be used with volume guarantee (PRVC) or pressure support (PSV) (see chapters 7.4.1 and 7.4.2). It also includes an option for tube compensation (see chapter 7.4.3).

Ventilation mode	Adjustable parameters
DUOPAP with PVRC	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Inspiration pressure (Pinsp) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Target volume (VT)

Tab. 33: DUOPAP with PRVC

Ventilation mode	Adjustable parameters
DUOPAP with PSV	▪ O_2 ▪ Upper pressure level (Phigh) ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Pressure support (ΔPsupp) (relative set value with reference to PEEP) ▪ Trigger ▪ Expiratory trigger sensitivity (ETS)

Tab. 34: DUOPAP with PSV

7.3.2.10 Non-invasive DUOPAP (nDUOPAP)

nDUOPAP corresponds to the behavior of the DUOPAP. It is only available in non-invasive Neo mode. The device is operated without a flow sensor (PNT) in this mode. The pressure is measured proximally via the pressure measurement adapter set.

Ventilation mode	Adjustable parameters
nDUOPAP	▪ O_2 ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Trigger ▪ Flow limitation (in NEO mode only)

Tab. 35: nDUOPAP

Ventilation mode	Adjustable parameters
nDUOPAP with PSV	▪ O_2 ▪ Upper pressure level (Phigh) ▪ Inspiration time (Tinsp) and breathing frequency (f) (the parameters for breathing cycling can be configured, see chapter 4.4.2) ▪ Positive end expiratory pressure (PEEP) ▪ Ramp time ▪ Pressure support (ΔPsupp) (relative set value with reference to PEEP) ▪ Trigger

Tab. 36: nDUOPAP with PSV

7.3.3 Spontaneous breathing

7.3.3.1 CPAP

The CPAP ventilation mode requires the full spontaneous breathing of the patient. The patient can breathe in and out freely at the set CPAP level. The CPAP level can be set in the »PEEP« field. The inspiratory and expiratory breathing effort is the sole responsibility of the patient. The only support provided by the ventilator is rapid compensation of the patient-inhaled inspiratory flow during pressure-regulated CPAP.

Spontaneous breathing activity can be monitored via the corresponding trigger signal. If spontaneous breathing stops (apnea), the ventilator issues an apnea alarm.

CPAP can be combined with backup ventilation. The user can set the maximum desired apnea duration in the »Apnea« field. If there is no spontaneous breathing during this time, the ventilator begins mandatory ventilation using the preset parameters. The parameter settings for backup ventilation are comparable to PC-SIMV ventilation (see chapter 7.3.2.3).

To return to normal CPAP ventilation, the following criteria must be fulfilled:

- Once backup ventilation starts, the locking time of 3x (Tinsp + Texp) must be run.
- Once the spontaneous breathing activity of the patient has exceeded the flow trigger threshold (see chapter 7.2), a time window of 10 s opens. If an additional sufficient spontaneous breathing takes place during this time window, the respirator returns to normal CPAP ventilation.

Ventilation mode	Adjustable parameters
CPAP	▪ O_2 ▪ PEEP ▪ Trigger ▪ Backup

Tab. 37: CPAP

Ventilation mode	Adjustable parameters
CPAP with backup	▪ Ramp time ▪ Trigger ▪ Apnea ▪ Backup ▪ Phigh ▪ Tinsp ▪ f ▪ PEEP ▪ O_2

Tab. 38: CPAP with backup

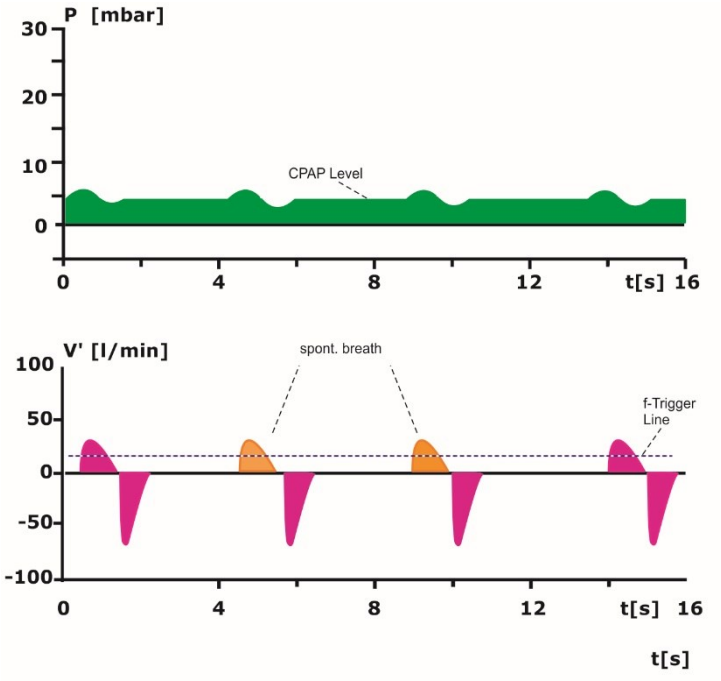


Fig. 89: CPAP

NOTE

The CPAP ventilation mode can be used with pressure support (PSV) (see chapters 7.4.1 and 7.4.2). It also includes an option for tube compensation (see chapter 7.4.3).

NOTE

A two-curve view is always active in the CPAP ventilation mode. The pressure curve as well as optionally the curve for flow, CO_2 or Pleth is displayed.

Ventilation mode	Adjustable parameters
CPAP with PSV	▪ O_2 ▪ PEEP ▪ Positive end expiratory pressure (PEEP) ▪ Pressure support (ΔPsupp) (relative set value with reference to PEEP) ▪ Expiratory trigger sensitivity (ETS)

Tab. 39: CPAP with PSV

7.3.3.2 nCPAP

The ventilation form nCPAP corresponds to the behavior of the CPAP. It is only available in non-invasive Neo mode. The device is operated without an external flow sensor (PNT) in this mode. The pressure is measured proximally via the pressure measurement adapter set.

Ventilation mode	Adjustable parameters
nCPAP	▪ O_2 ▪ PEEP ▪ Trigger ▪ Backup ▪ Flow limitation (in NEO mode only)

Tab. 40: nCPAP

7.3.4 O_2 therapy

O_2 therapy is not a ventilation mode in the strict sense. Its purpose is rather a dosed enrichment of the breathing air with oxygen in case of breathing problems and to increase the O_2 level in the arterial blood. The O_2 concentration and flow can be set on the ventilator. Monitoring by the **EVE$_{TR}$** requires the connection of an (optional) SpO_2 sensor. The oxygen is delivered by a nasal tube, nasal cannula, or oxygen mask.

NOTE

When using an O_2 nasal cannula, the set maximum flow 6 l/min should not be exceeded.

7.3.5 High flow O_2 therapy

High flow O_2 therapy is available only in Neo mode and is actually not a form of ventilation; instead it serves as ventilatory support. Oxygen is supplied using "high flow nasal cannula". O_2 concentration, flow, and operating pressure limit (PAW alarm limit) can be set on the ventilator The respirator monitors this only if an SpO_2 sensor (optional) is connected.

Ventilation mode	Adjustable parameters
High-Flow	▪ FiO_2 ▪ Flow ▪ Pressure limit (PAW alarm limit)

Tab. 41: High-Flow

ATTENTION

The operating pressure, not the patient's inspiration pressure, is displayed on the ventilator. If the operating pressure is decreased via the PAW alarm limit, the flow to the patient also decreases.

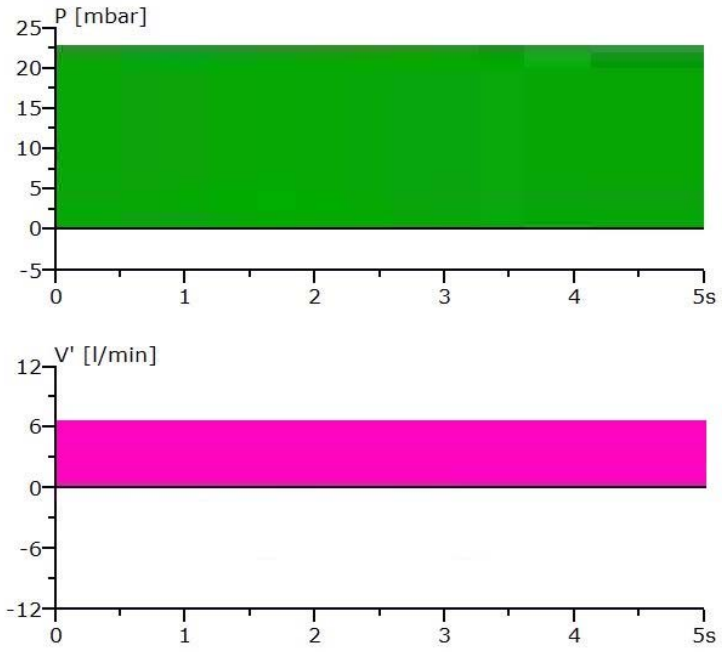


Fig. 90: Displayed operating pressure at High-Flow ventilation mode

7.4 Additional options for ventilation modes

7.4.1 Pressure-regulated and volume-controlled ventilation (PRVC)

PRVC (pressure regulated volume controlled) is an advanced setting for the following pressure-controlled ventilation modes: PC-CMV, PC-SIMV, PC-ACV, and DUOPAP. It combines pressure-controlled and volume-controlled ventilation.

This option lets the user select a target volume that guarantees a tidal volume with minimum required pressure during breaths. Depending on the patient's spontaneous breathing efforts and lung compliance, the inspiration pressure varies with the intention to apply the selected tidal volume with the minimum required pressure.

In order to use volume target ventilation, the positive end expiratory pressure »PEEP«, the inspiration time »Tinsp«, and the frequency »f« should be set as usual. In this case, however, the »VT« parameter field has special significance, because it is used to set the desired tidal volume.

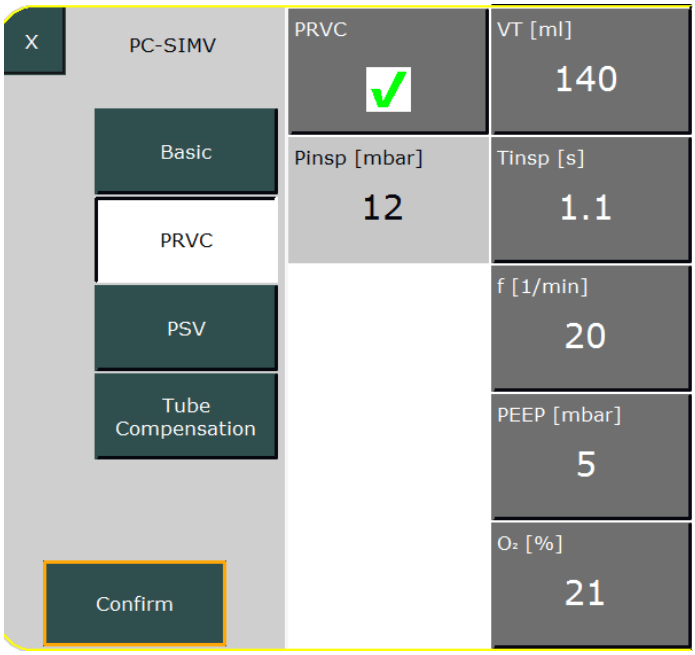


Fig. 91: PC-SIMV with PRVC parameter setting

The **EVE$_{TR}$** now changes the ventilation pressure accordingly in increments in order to reach the preselected tidal volume within five breathing cycles.

The »Pmax« pressure limit is automatically set to 5 mbar below the upper pressure alarm limit. However, to ensure a minimum pressure, it is not possible to reduce the inspiration pressure below the minimum limit of PEEP + 5 mbar.

The **EVE$_{TR}$** 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 automatically set »Pmax«.

As of this pressure, it will no longer be possible to apply the set tidal volume in full. The ventilator now reverts to pressure-controlled-only ventilation.

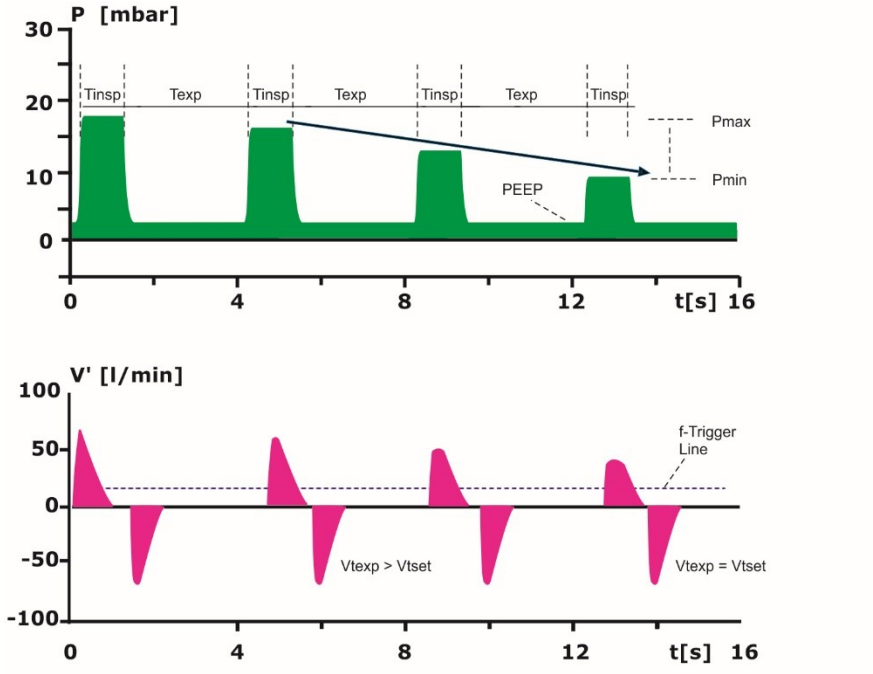


Fig. 92: PRVC

7.4.2 Pressure support ventilation (PSV)

The PC-SIMV, VC-SIMV, CPAP, and DUOPAP ventilation modes can be optionally used with PSV (pressure support ventilation).

PSV is designed to support insufficient spontaneous breathing. It combines the benefits of pressure-controlled ventilation with the patient's spontaneous breathing activity. It helps better adapt the ventilation control to the patient's physiological needs and helps the patient overcome flow resistance caused by the tracheal tube and tube system.

The ventilator uses the selected trigger threshold to detect the patient's inhalation efforts and then triggers a mandatory breath using the selected pressure support (ΔPsupp). Without patient triggering, however, the ventilator does not provide pressure support.

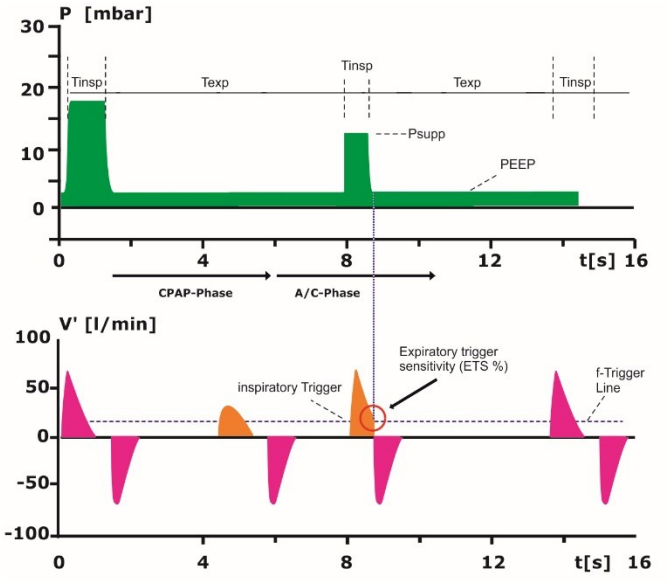


Fig. 93: PSV

With increasing inspiration progress, the flow delivered by the ventilator 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 as follows:

With PSV enabled, the ventilator stores the inspiratory peak flow during inhalation. Expiration is initiated as soon as the flow has dropped to the previously set percentage for the inspiratory peak flow. The Expiration Trigger Sensitivity (ETS %) is used for this setting.

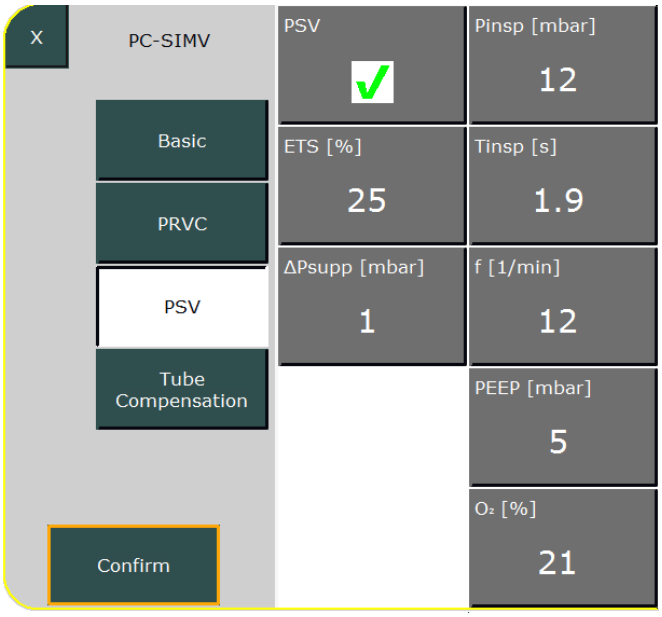


Fig. 94: PC-SIMV with PSV parameter setting

7.4.3 Tube compensation

All ventilation modes can be combined with tube compensation. This function lets you adjust the ventilation pressure to the resistance of the tracheal or endotracheal tube. During mandatory ventilation, increased airway resistance is of minor importance. However, during spontaneous breathing it makes breathing more difficult and requires more breathing effort.

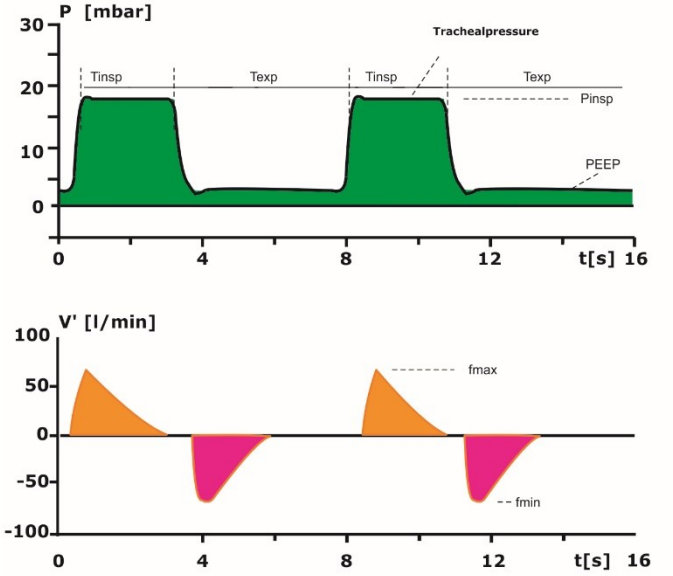


Fig. 95: Tube compensation

NOTE

If tube compensation is activated, the calculated tracheal pressure and pressure in the tube system are visualized simultaneously as a pressure curve. The pressure in the tube system is visualized as a filled curve, the tracheal pressure as a single black line.

Additional pressure support can significantly reduce the breathing effort for the patient. The following parameters must be set:

Adjustable parameters

- Compensation (%)
- Tube diameter (mm)

These settings can be configured directly in the respective ventilation menu.

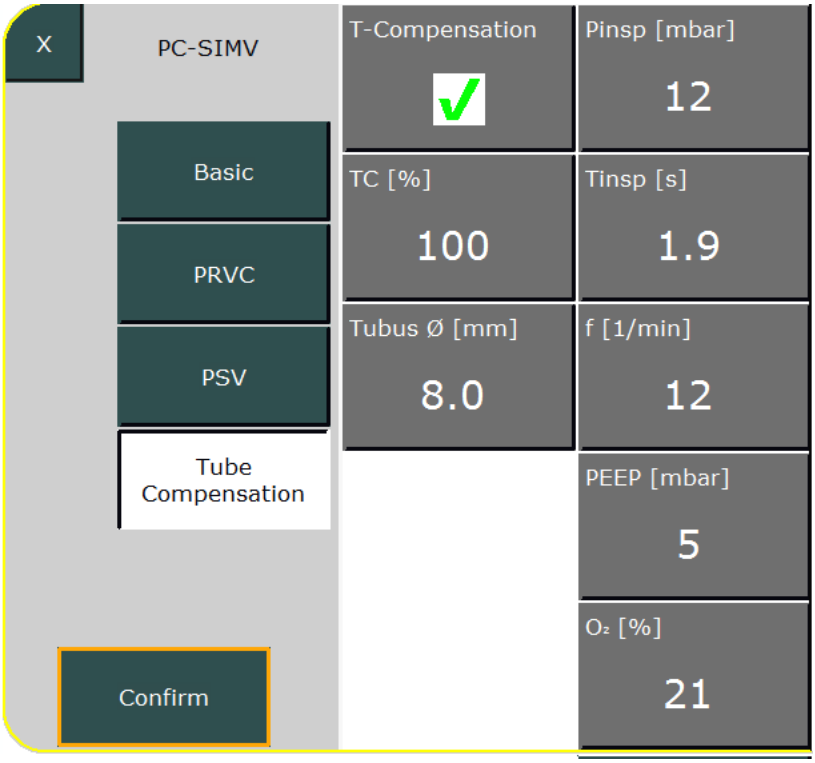


Fig. 96: Configuring tube compensation with PC-SIMV

8 CO_2 measurement (optional)

The CO_2 measurement with the **EVE$_{TR}$** can be performed using the mainstream or sidestream technique. The measurement principle is based on infrared spectroscopy. This means that infrared light is absorbed by CO_2 molecules. The higher the CO_2 level in the patient gas, the weaker the measurable infrared light at the end of the detector.

Data output The measuring data is output either numerically (see chapter 3.2.2) or graphically as curves on the display of the **EVE$_{TR}$** (see chapter 3.2.9).

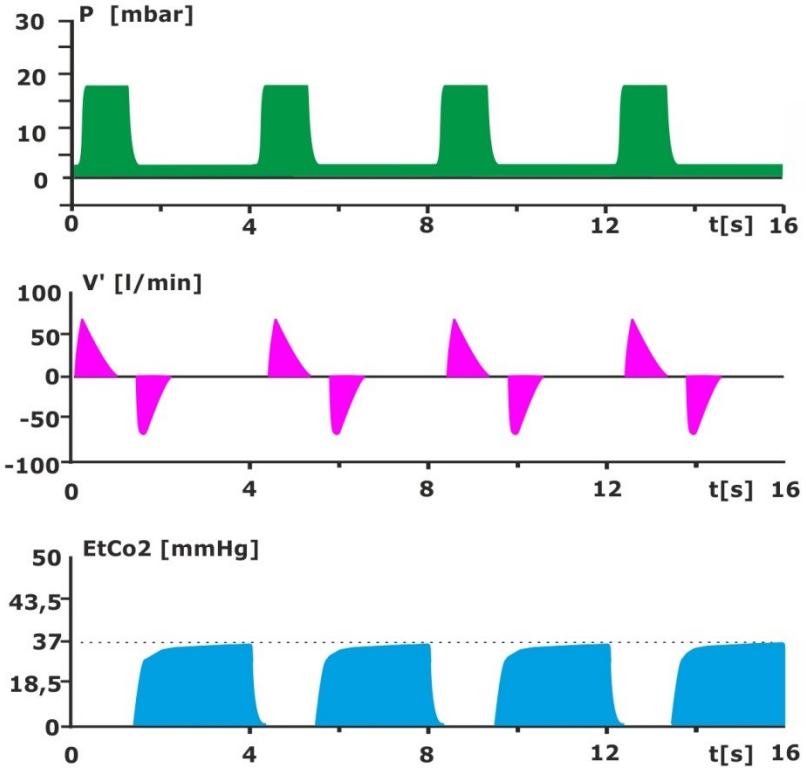


Fig. 97: CO_2 curve display

8.1 Measurement using the mainstream technique

To measure the CO_2 concentration using main stream technique, a MASIMO IRMA™ CO_2 measuring probe is inserted into the tube system. The advantage of this technique is that the entire air volume is measured without any volume loss. The mainstream technique uses a MASIMO IRMA™ CO_2 analyzer.

8.1.1 Intended use

The IRMA™ CO_2 analyzer can be connected to a patient ventilation system for real-time measurement of the CO_2 concentration. The probe is designed for use both in EMS and ICU settings. The device is suitable for adults, children, and infants and can be used in the OR, the ICU, the patient's room, and emergency medicine settings.

Fig. 98: IRMA CO_2 analyzer

The IRMA™ CO_2 analyzer is not designed for use as a standalone patient monitoring device. It must always be used in combination with other systems for monitoring the vital signs and/or together with professional patient observation.

8.1.2 Specifications

IRMA™ airway adapter	Infants	Dead space	≤ 1 ml
		Resistance	1.3 cmH_2O at 10 lpm
		ETT	≤ 4 mm
	Adults/children	Dead space	≤ 6 ml
		Resistance	0.3 cmH_2O at 30 lpm
		ETT	> 4 mm

NOTE

For detailed specifications about the MASIMO IRMA™ CO_2 analyzer, see the documentation included with the product.

8.1.3 Warnings

WARNING

Before using the IRMA™ CO_2 analyzer, carefully read the documentation provided with the product and observe the usage instructions and warnings it contains.

WARNING

The IRMA™ probe may only be used by authorized and properly trained healthcare professionals.

WARNING

The IRMA™ CO_2 analyzer is not designed for use as a standalone patient monitoring device. It must always be used in combination with other systems for monitoring the vital signs.

WARNING

The IRMA™ probe may not be used with flammable anesthetics.

WARNING

The IRMA™ airway adapter is a disposable product and not designed to be reused. Reuse of the disposable adapter may cause cross-infection.

WARNING

Do not use the IRMA™ airway adapter for adults and children with infants because the adapter increases the dead space in the patient's breathing system by 6 ml.

WARNING

Do not use the IRMA™ airway adapter for infants with adults because this may cause excessive flow resistance.

WARNING

Mobile and RF communication devices may impair the measurements. It must be ensured that the probe is used in an electromagnetic environment as specified in the operating instructions.

WARNING

The use of RF electrosurgical devices in the vicinity of the IRMA™ CO_2 analyzer or the **EVE$_{TR}$** may cause interference and erroneous measurements.

WARNING

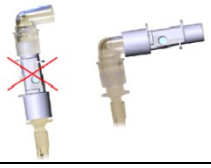
The IRMA™ CO_2 analyzer is not designed for use in MRI environments.

WARNING

Do not use the IRMA™ airway adapter together with metered-dose inhalers or medication nebulizers because this impairs the translucency of the adapter's view ports.

WARNING

Do not insert the IRMA™ airway adapter between the endotracheal tube and the bend because this may cause secretions to enter the adapter's view ports, resulting in distorted measurements.



WARNING

Only use the IRMA™ CO_2 analyzer in the upright position with the LED pointing up to prevent secretions and moisture from collecting on the sensor windows.

WARNING

The airway adapter must be replaced in case of moisture collection or condensation on the inside.

WARNING

Never make modifications to the device!

WARNING

Only use MASIMO brand IRMA™ airway adapters.

WARNING

Direct contact of the IRMA™ probe with the patient must be prevented.

WARNING

When connecting the IRMA™ probe to the system of an infant, direct contact of the probe with the infant's body must ALWAYS be prevented. If the probe comes in contact with the infant's body for whatever reason, insulating material must be used.

CAUTION

Do not use the IRMA™ probe outside the specified ambient temperature.

CAUTION

Do not expose the cable of the IRMA™ probe to tensile forces.

8.1.4 Installing the CO_2 measuring probe

To install the CO_2 measuring probe:

- Connect the IRMA™ connecting cable to the CO_2 sensor input on the right side of the **EVE$_{TR}$** (see Fig. 39). Switch on the **EVE$_{TR}$**.
- Before connecting the IRMA™ airway adapter to the patient system, the gas values and curves on the **EVE$_{TR}$** monitor must be checked.

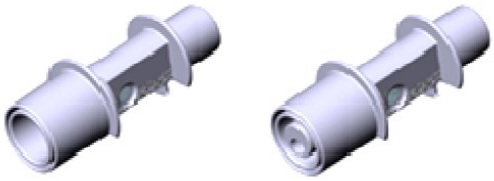


Fig. 99: Airway adapter for adults/children and infants

- Secure the IRMA™ probe to the IRMA™ airway adapter. The probe audibly locks into place when secured properly.

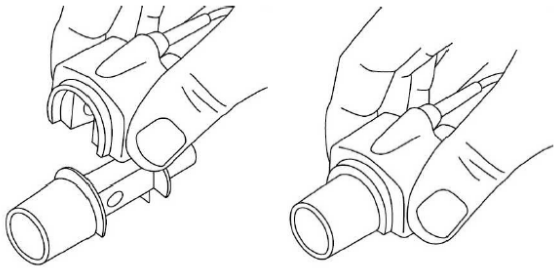


Fig. 100: Securing the probe to the airway adapter

- The probe must be placed so that its status indicator (see chapter 8.1.6) points up. The CO_2 analyzer is ready for use when the status indicator is green.

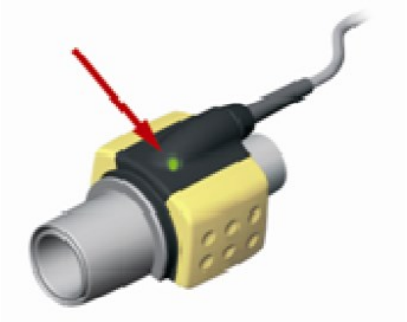


Fig. 101: Status indicator of the CO_2 analyzer

- Connect the socket of the airway adapter to the Y piece of the ventilation system.

Fig. 102: Connecting the airway adapter's socket to the Y piece

- Connect the socket of the airway adapter to the ETT tube.

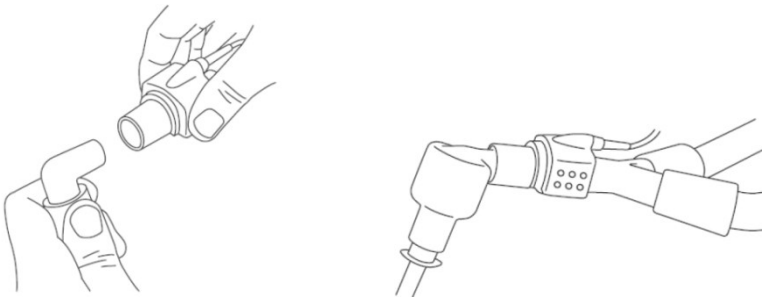


Fig. 103: Connecting the socket of the airway adapter to the ETT tube

NOTE

The use of an HME filter is recommended! In this case, place the measuring probe between the HME filter and the ventilator. The HME filter protects the airway adapter from secretions and water vapor so that the adapter does not have to be replaced.

NOTE

The measured gas values should be checked regularly for accuracy by conducting comparative measurements. The gas section should be tested annually.

NOTE

After inserting the probe, a leakage test of the **EVE$_{TR}$** patient system is recommended.

WARNING

The airway adapter must be replaced if moisture or condensation collect on the inside.

8.1.5 Running zero calibration

NOTE

Zero calibration is only necessary if deviations in gas values are observed or if the "CO_2 accuracy out of range!" alarm is displayed.

WARNING

Mistakes made during zero calibration cause erroneous measurements.

CAUTION

For correct zero calibration, the airway adapter MUST be surrounded by room air (0% CO_2). For this reason, it is particularly important not to breathe in the vicinity of the airway adapter before and during zero calibration.

CAUTION

When replacing the airway adapter, you have to wait at least 10 s before you can perform the zero calibration.

For highest measurement accuracy, the following recommendations for zero calibration should be followed:

- For zero calibration, connect the IRMA™ probe to the **EVE$_{TR}$** and attach to a new IRMA™ airway adapter. Do not connect the adapter to the ventilation system.
- Switch on the **EVE$_{TR}$** and wait approx. 10 s until the probe has reached its optimum measurement accuracy.
- Press the corresponding field in the **EVE$_{TR}$** "Capnometry" menu (see chapter 4.2.2) to start the zero calibration. The probe's LED flashes green during zero calibration.
- Every zero calibration must be followed by a functional test.

If zero calibration is immediately followed by a "CO_2 sensor zero calibration!" alarm, the procedure must be repeated.

8.1.6 Probe status indicator

The status indicator of the IRMA™ probe indicates the following operating states:

LED color	Meaning
Green	System ready for use
Flashing green	Zeroing in progress
Red	Sensor fault
Flashing red	Check adapter

Tab. 42: Status indicator

8.1.7 Cleaning the probe

To clean the IRMA™ probe, use a cloth moistened with alcohol or isopropyl alcohol (< 70%).

CAUTION

Do not sterilize the IRMA™ probe or submerge it in liquid.

CAUTION

The IRMA™ airway adapter is a non-sterile device. Do not autoclave it, otherwise it will be damaged.

8.2 Measurement using the sidestream technique

Measuring the CO_2 concentration using the sidestream technique involves the continuous suction of a small amount of air which is routed to the MASIMO ISA™ detector via a thin tube. This is where the measurement occurs. The benefit of this approach is that the weight near the ETT is not increased, reducing the risk of extubation. For this reason, this technique is particularly popular in pediatric and neonatal settings.

8.2.1 Intended use

The MASIMO ISA™ CO_2 analyzer can be connected to a patient ventilation system to measure the CO_2 concentration.
The analyzer is suitable for adults, children, and infants and can be used in the OR, the ICU, the patient's room, and suitable emergency medicine and emergency transport settings.

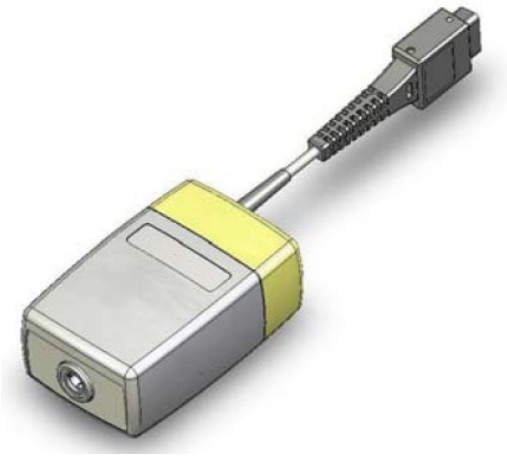


Fig. 104: MASIMO ISA CO_2 analyzer with connected communication cable (shown shortened)

The ISA™ CO_2 analyzer is not designed for use as a standalone patient monitoring device. It must always be used in combination with other systems for monitoring the vital signs and/or together with professional patient observation.

8.2.2 Specifications

NOTE

For detailed specifications about the MASIMO ISA™ CO_2 analyzer, see the documentation included with the product.

8.2.3 Warnings

WARNING

Before using the MASIMO ISA™ CO_2 analyzer, carefully read the documentation provided with the product and observe the usage instructions and warnings it contains.

WARNING

The ISA™ CO_2 analyzer may only be used by authorized and properly trained healthcare professionals.

WARNING

The ISA™ CO_2 analyzer is not designed for use as a standalone patient monitoring device. It must always be used in combination with other systems for monitoring the vital signs and/or together with professional patient observation.

WARNING

Only use Nomoline sample collection tubes made by MASIMO.

WARNING

Do not reuse disposable sample collection tubes!

WARNING

Used disposable sample collection tubes must be disposed of as medical waste according to local regulations.

WARNING

Do not lift the ISA™ CO_2 analyzer at the sample collection tube. This may cause the tube connection to detach, and the analyzer could drop onto the patient.

WARNING

The ISA™ CO_2 analyzer may not be used with flammable anesthetics.

WARNING

Make sure the sample collection tube is routed properly to prevent the risk of patient entanglement or strangulation.

WARNING

Do not use the sample collection tube configuration for adults and children with infants because this may add 7 ml of dead space to the patient system circuit.

WARNING

Do not use the sample collection tube configuration for infants with adults because this may cause excessive flow resistance.

WARNING

The Nomoline sample collection tube and its connections are non-sterile. To prevent damage, do not autoclave any part of the sample collection tube.

WARNING

The sample collection tube must be replaced if the tube input connector starts flashing red or a Nomoline locking message appears on the **EVE$_{TR}$** display.

WARNING

The ISA™ CO_2 analyzer is not designed for use in MRI environments. During MRI scans, the analyzer must remain outside the MRI room.

WARNING

Do not sterilize the ISA™ CO_2 analyzer or submerge it in liquids.

WARNING

Do not use the ISA™ CO_2 analyzer with metered-dose inhalers or medication nebulizers because this may clog the bacterial filter.

WARNING

Check that the gas sample flow is not too strong for the respective patient category.

WARNING

No modifications to the device are permitted without the manufacturer's authorization. If authorized modifications are made to the device, the device must be tested accordingly.

WARNING

Mobile and RF communication devices may impair the measurements. It must be ensured that the ISA™ CO_2 analyzer is used in an electromagnetic environment as specified in the ISA operating instructions.

WARNING

The use of RF electrosurgical devices in the vicinity of the ISA™ CO_2 analyzer or the **EVE$_{TR}$** may cause interference and erroneous measurements.

WARNING

Do not create negative pressure in the Nomoline tube (e.g. using a syringe) to remove water condensation.

WARNING

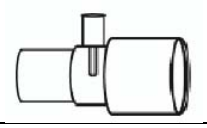
Excessive positive or negative pressure in the patient system circuit.

WARNING

Always use a bacterial filter on the waste gas side if the collected sample gas should be breathed back.

WARNING

Use only T adapters whose sample collection point is located in the middle of the adapter.



WARNING

Excessive scavenger system pressure may impact gas sample flow.

WARNING

Waste gas must be returned to the patient system circuit or a scavenger system.

WARNING

Do not position the ISA™ analyzer in a way where it is at risk of dropping onto the patient.

WARNING

Position the ISA™ analyzer securely to avoid device damage.

WARNING

Do not put strain on the ISA™ analyzer's cable.

CAUTION

Do not use the ISA™ analyzer outside the specified ambient temperature range.

8.2.4 Installing the ISA™ CO_2 analyzer

To install the ISA™ CO_2 analyzer:

- Connect the ISA™ communication cable to the CO_2 sensor input on the right side of the **EVE$_{TR}$** (see Fig. 39) using the adapter.
- Connect a Nomoline sample collection tube to the ISA™ analyzer's input connector.

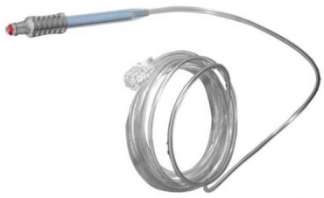


Fig. 105: Nomoline sample collection tube

NOTE

The Nomoline sample collection tube is not reusable! The Nomoline sample collection tube must be replaced according to good clinical practice or when the "CO_2 sampling line clogged!!" message appears on the **EVE$_{TR}$** display.

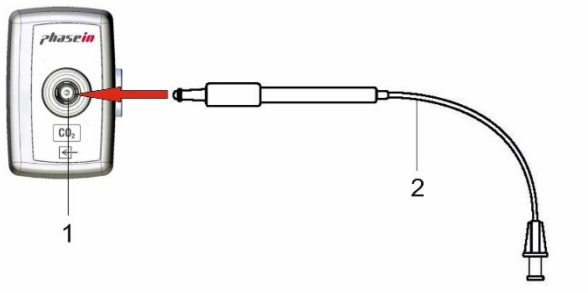


Fig. 106: Connecting the sample collection tube to the ISA™ CO_2 analyzer

1 CO_2 connection analysis adapter 2 Sample collection tube

- Switch on the **EVE$_{TR}$**. A green LED indicates that the ISA™ analysis adapter is ready for use.
- Blow into the sample collection tube and verify that the valid CO_2 curves and values are displayed by the **EVE$_{TR}$**.
- Close the sample collection tube with your fingertip and wait 10 s.
- Check if an occlusion alarm displays and for a red flashing light on the CO_2 analyzer.

Connect the sample collection tube to the patient tube system.

Connection via an airway adapter

- Attach the sample collection tube to the airway adapter.

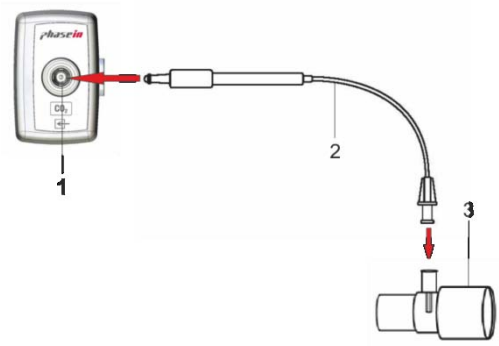


Fig. 107: Connecting the sample collection tube to the airway adapter

1 CO_2 connection analysis adapter 2 Sample collection tube
3 Adult airway adapter

- Connect the airway adapter socket to the ventilation system's Y piece.
- Connect the airway adapter socket to the ETT tube.

NOTE

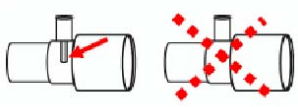
The measured gas values should be checked regularly for accuracy by conducting comparative measurements. The gas section should be tested annually.

NOTE

After connecting the ISA™ CO_2 analyzer, a leakage test of the **EVE$_{TR}$** patient system is recommended.

NOTE

Use only T adapters whose sample collection point is located in the middle of the adapter (see figure).



8.2.5 Running zero calibration

CAUTION

For correct zero calibration, the CO_2 analyzer MUST contain room air (0% CO_2). For this reason, it is particularly important to place the CO_2 analyzer in a well ventilated area and not to breathe in the vicinity of the analyzer before and during zero calibration.

The ISA™-CO_2 runs zero calibration automatically. For this purpose, gas sample collection switches from ventilation system to ambient air. Automatic zero calibration is performed every 24 hours and takes less than 3 s.

8.2.6 Status indicator of the analysis adapter

The status indicator of the ISA™ probe indicates the following operating states:

LED color	Meaning
Green	System ready for use
Flashing green	Zeroing in progress
Red	Sensor fault
Flashing red	Check sample collection tube

Tab. 43: Status indicator

8.2.7 Cleaning the CO_2 analyzer

The ISA™ CO_2 analyzer must be cleaned regularly. Use a cloth moistened with alcohol or isopropyl alcohol (< 70%) for cleaning.

While cleaning the analyzer, the Nomoline sample collection tube must remain connected to prevent cleaning liquid or dust from entering the analyzer via the CO_2 connection.

CAUTION

Do not sterilize the ISA™ CO_2 analyzer or submerge it in liquids.

CAUTION

The Nomoline sample collection tubes are not sterile. To prevent damage, do not autoclave any part of the sample collection tube.

9 Functional description

The **EVE$_{TR}$** is used for invasive and non-invasive ventilation in emergency and transport settings and is designed to support patients suffering from respiratory failure or apnea (see also respiration).

Ventilation can be delivered in both pressure-controlled and volume-controlled mode. For optimum patient therapy, the basic ventilation modes can be combined with additional options such as PRVC, PSV, and tube compensation.

The EVE$_{TR}$ consists of the following applied parts: CO_2 sensor, SpO_2 sensor and ventilation tube system (VBS).

The patient tube system is use to deliver and return patient gas. It is supplied complete with an expiration valve and flow sensor and can be connected directly to the device and the patient. Two different tube systems are available.

- EVE adult emergency single-use tube system
- EVE pediatric single-use tube system

All tube systems are pre-fitted with a flow sensor and expiration valve and can be equipped with an optional CO_2 measurement.

The ventilator has a built-in turbine and a battery capacity of three hours, which can be extended to six hours by an optional external battery. It therefore does not need an external power supply or gas supply. The device features a high-resolution 8.4" display and can be operated via touchscreen or a rotary knob.

The user can choose from three different, freely configurable curve views. In addition, the system can display 15 different ventilation parameters, as well as the inspiratory and expiratory CO_2 patient gas concentration. Optional MASIMO® technology integration provides all Rainbow parameters. Furthermore, an optional non-invasive SpCO measuring procedure can be integrated. This allows immediate diagnosis of carbon monoxide poisoning and supports the user in patient treatment and monitoring tasks.

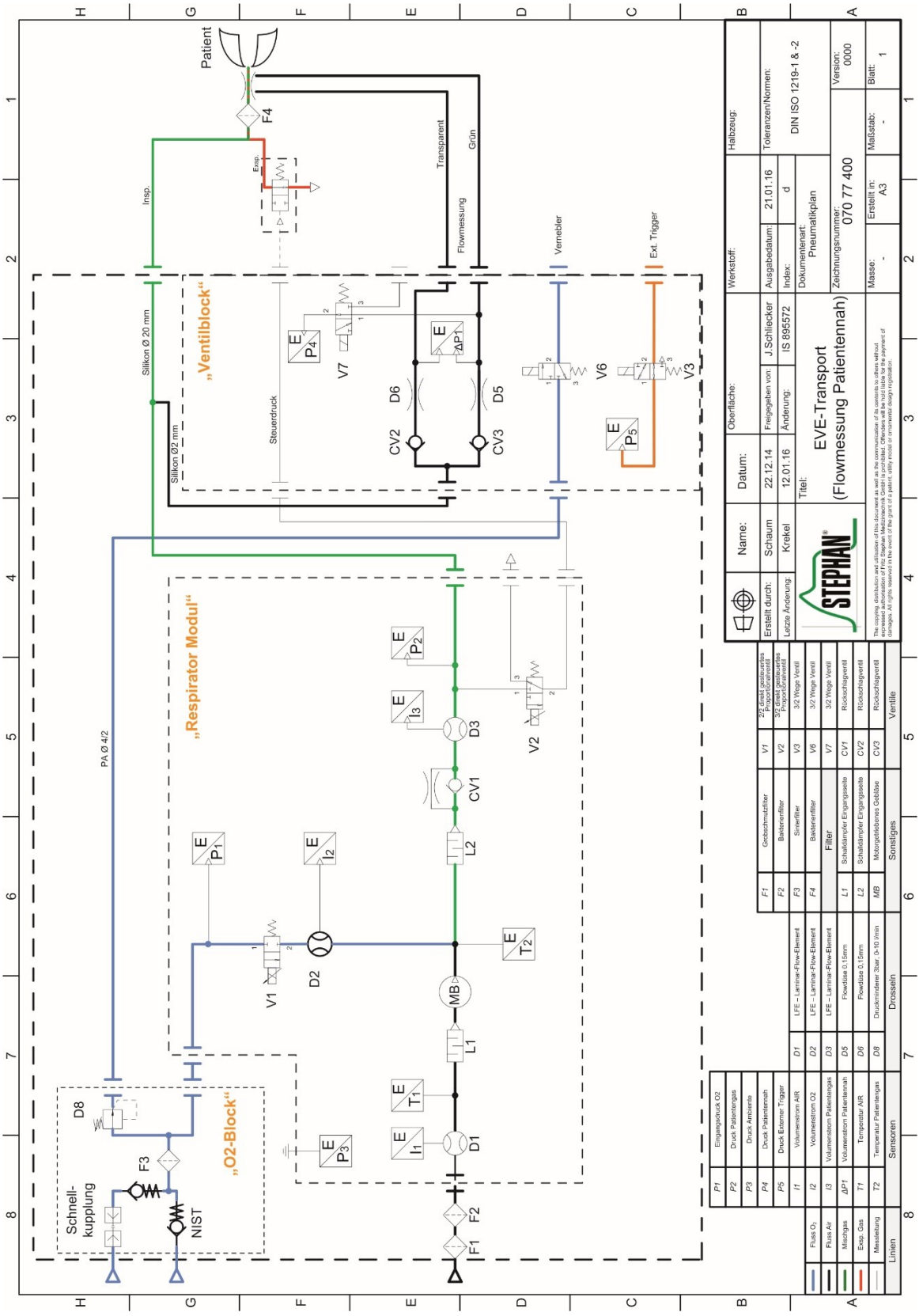


Fig. 108: **EVE$_{TR}$** pneumatics design

10 Troubleshooting

NOTE

All pulse oximetry-related alarms are listed in the corresponding supplemental operating manual.

NOTE

Volume alarms are not active during non-invasive ventilation methods.

10.1 List of errors

Priority/type of alarm

TA	Technical alarm	
PA	Patient alarm	
HW	Notifications	
MP	MP alarms	Medium priority alarm Flash frequency: 0.625 Hz
HW MP	HW/MP alarms	Alarm starts out as a notification and becomes an MP alarm after 30 seconds.
MP/ HP	MP/HP alarms	Alarm starts out as an MP alarm and becomes an HP alarm under defined conditions.
HP	HP alarms	High priority alarm Flash frequency: 2 Hz

Sequence

Color code	HP	MP	Notifications
	C-A-F-A-F	C-A-F	-
	C2-B-A-G-F	C2-B-A	-
	C2-C-C-C2-C	C2-C-C	-
	C-C-C-C-C	C-C-C	E-C

Alarm text	Priority/ type of alarm	Sound	Possible cause	Corrective action
Battery 2 failure	HW		▪ Battery 2 malfunction during mains operation or during battery operation	▪ Check battery 2, replace if necessary
Battery 1 cal	HW		▪ Battery 1 requires calibration	▪ Completely discharge battery 1 and recharge
Battery 2 cal	HW		▪ Battery 2 requires calibration	▪ Completely discharge battery 2 and recharge
Battery 1 cycles > 500!	HW		▪ Battery 1 has been charged more than 500 times	▪ Replace battery 1
Battery 2 cycles > 500!	HW		▪ Battery 2 has been charged more than 500 times	▪ Replace battery 2
Alarm speaker failure	HW		▪ Speaker malfunction ▪ Only an acoustic auxiliary alarm sounds (Piezo)	▪ Check speaker, replace if necessary ▪ Contact FRITZ STEPHAN GMBH customer service
Blower failure 4	HW		▪ Internal temperature sensor malfunction	▪ Contact FRITZ STEPHAN GMBH customer service
CO_2 pressure out of range!	HW		▪ Ambient pressure out of range	▪ Check ambient pressure
CO_2 temp. out of range!	HW		▪ Internal sensor temperature is outside the operating range	▪ Check the outside temperature
CO_2 accuracy out of range!	HW		▪ The measured CO_2 concentration is outside the specified measuring range	▪ Disconnect the measuring probe and the adapter from the tube system, replace the adapter, and wait 10 s. Run zero calibration for the CO_2 sensor. ▪ Clean the CO_2 sensor; if necessary, replace the CO_2 adapter

Flow measurement failure!	HW		▪ Flow measurement outside range	▪ Contact FRITZ STEPHAN GMBH customer service
Device temp. high	HW		▪ Device temperature high	▪ Remove the device from direct sunlight or other heat source, if necessary ▪ Check the fan operation ▪ Check the coarse filter at the filter inlet ▪ Check the device ▪ If the error occurs despite a low ambient temperature, contact FRITZ STEPHAN GMBH customer service
Change HEPA filter	HW		▪ Service interval for the HEPA filter exceeded ▪ HEPA filter exhibits increased resistance	▪ Change the filter
Pressure limit!	HW		▪ The inspiration pressure needed to reach the preset tidal volume is higher than the PAW alarm limit setting	▪ Check the patient's condition! ▪ Correct the PAW alarm limit, if necessary ▪ Correct the target volume setting, if necessary
Paw limited by Pawlim	HW		▪ Paw alarm limit limited by Pawlim	▪ Check Paw alarm settings
Paw limited by Pinsp	HW		▪ Paw alarm limit limited by Pinsp	▪ Check Paw alarm settings
Paw limited by Δ Psupp	HW		▪ Paw limited by Δ Psupp	▪ Check Paw alarm settings ▪ Check Δ Psupp setting
Paw limited by PEEP	HW		▪ Paw limited by PEEP	▪ Check Paw alarm settings ▪ Check PEEP setting
PEEP limited by PEEPlim	HW		▪ PEEP limited by upper pressure alarm limit	▪ Check PEEP setting

PEEP limited by Δ Pinsp	HW		▪ PEEP limited by **Δ** Pinsp	▪ Check PEEP setting
PEEP limited by Pinsp	HW		▪ PEEP limited by Pinsp	▪ Check PEEP setting ▪ Check Pinsp setting
PEEP limited by Δ Psupp	HW		▪ PEEP limited by Δ Psupp	▪ Check PEEP setting ▪ Check Δ Psupp setting
PEEP limited by Paw	HW		▪ PEEP limited by Paw	▪ Check PEEP setting ▪ Check Paw alarm settings
Pinsp limited by Freq	HW		▪ Pinsp limited by the respiratory rate	▪ Check Pinsp setting ▪ Check respiratory rate setting
Pinsp limited by Plim	HW		▪ Pinsp limited by upper or lower limit pressure	▪ Check Pinsp setting
Pinsp limited by Paw	HW		▪ Pinsp limited by upper alarm limit	▪ Check Paw setting
Pinsp limited by PEEP	HW		▪ Pinsp limited by PEEP	▪ Check Pinsp setting ▪ Check PEEP setting
Pinsp limited by Δ PEEP	HW		▪ Pinsp limited by **Δ** PEEP	▪ Check Pinsp setting
Pinsp limited by Ramp	HW		▪ Pinsp limited by ramp time	▪ Check Pinsp setting ▪ Check ramp time setting
PSV limited by PSVlim	HW		▪ PSV limited by PSV limit pressure	▪ Check Δ Psupp setting
PSV limited by Paw	HW		▪ PSV limited by Paw alarm limit	▪ Check Δ Psupp setting ▪ Check Paw alarm limit
Ramp limited by Pinsp	HW		▪ Ramp time limited by Pinsp	▪ Check Pinsp setting ▪ Check ramp time setting
RTC error	HW		▪ Internal communication error	▪ Contact FRITZ STEPHAN GMBH customer service team

Powersupply?!	HW		▪ Device has been disconnected from the external energy supply	▪ If possible, connect the device to the external energy supply ▪ No device error if the device was deliberately disconnected from the energy supply (undocked from docking station, device bracket for patient transport). Notification can be acknowledged with the "Alarm Suppression" button.
Nebulizer inactive/ check O2!	HW		▪ Oxygen supply not connected or malfunctioning.	▪ Check oxygen supply, connect if necessary
Maintenance required	HW		▪ Maintenance interval reached	▪ Perform service ▪ Contact FRITZ STEPHAN GMBH customer service
VTe high	HW/MP PA		▪ The inspiratory breath volume is above the upper alarm limit for two breaths ▪ Escalates to MP after 60 s	▪ Check the patient's condition ▪ Check the settings and adjust if necessary ▪ Check the alarm limits and adjust if necessary
VTe low	HW/MP PA		▪ The expiratory breath volume is below the lower alarm limit for three breaths ▪ Escalates to MP after 60 s	▪ Check the patient's condition ▪ Check the settings and adjust if necessary ▪ Check the alarm limits and adjust if necessary ▪ Check the tube system for leakage or disconnected parts

Battery low	MP TA		▪ Battery voltage low	▪ Check the mains supply and charge the battery ▪ Have a spare battery at the ready ▪ If the battery cannot be charged, contact FRITZ STEPHAN GMBH customer service
Battery 1 temp. high	MP TA		▪ Battery 1 has overheated	▪ Check battery 1, replace if necessary ▪ Keep the device away from direct sunlight or other heat sources. ▪ Contact FRITZ STEPHAN GMBH customer service
Battery 2 temp. high	MP TA		▪ Battery 2 has overheated	▪ Check battery 2, replace if necessary ▪ Keep the device away from direct sunlight or other heat sources. ▪ Contact FRITZ STEPHAN GMBH customer service
Battery 1 temp. low	MP TA		▪ Battery 1 undercooled	▪ Check battery 1, replace if necessary ▪ Do not operate the device at temperatures outside ambient conditions (see chapter 1.9). ▪ Contact FRITZ STEPHAN GMBH customer service

Battery 2 temp. low	MP TA		▪ Battery 2 undercooled	▪ Check battery 2, replace if necessary ▪ Do not operate the device at temperatures outside ambient conditions (see chapter 1.9). ▪ Contact FRITZ STEPHAN GMBH customer service
Apnea	MP PA		▪ No inspiration within the set apnea alarm limits	▪ Check the patient's condition! Does the patient actually exhibit apnea? ▪ Switch to mandatory ventilation, if necessary ▪ Check the flow sensor ▪ Check the alarm limits
Respiratory rate high (Alarm delay: 15 s)	MP PA		▪ Patient is breathing 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
Airway pressure low	MP PA		▪ Volume measurement outside specified accuracy	▪ Flow sensor clogged ▪ Water buildup in flow sensor tube
Blower failure 1	MP TA		▪ Internal malfunction of the O_2 valve	▪ Check the measured and set the value for O_2 ▪ Contact FRITZ STEPHAN GMBH customer service
Blower failure 2	MP TA		▪ Malfunction of the internal flow sensor	▪ Contact FRITZ STEPHAN GMBH customer service
Replace CO_2 adapter	MP TA		▪ CO_2 adapter malfunction or contamination	▪ Replace the CO_2 adapter
CO_2 sampling line clogged	MP TA		▪ Sampling line is contaminated or clogged	▪ Check the sampling line ▪ Replace the sampling line

No CO_2 sampling line	MP TA		▪ Sampling line not connected	▪ Connect the sampling line
CO_2 sensor zeroing required	MP TA		▪ CO_2 calibration failed	▪ Repeat CO_2 calibration ▪ Check the CO_2 adapter and clean if necessary ▪ Replace the CO_2 adapter, if necessary ▪ Replace the CO_2 sensor, if necessary
CO_2 sensor reinsert	MP TA		▪ CO_2 measurement faulty	▪ Check the CO_2 sensor ▪ Reinsert the CO_2 sensor
$EtCO_2$ high	MP PA		▪ Measured $EtCO_2$ above the upper limit setting	▪ Check the patient's condition ▪ Check the $EtCO_2$ upper limit and adjust if necessary ▪ Check the ventilation settings ▪ Calibrate the CO_2 sensor, if necessary ▪ Clean the CO_2 sensor/ cuvette, if necessary
$EtCO_2$ low	MP PA		▪ Measured $EtCO_2$ below the lower limit setting	▪ Check the patient's condition ▪ Check the $EtCO_2$ lower limit and adjust if necessary ▪ Check the ventilation settings ▪ Calibrate the CO_2 sensor, if necessary ▪ Clean the CO_2 sensor/ cuvette, if necessary
CO_2 sensor error	MP TA		▪ CO_2 sensor is not detected ▪ CO_2 sensor or adapter contaminated. ▪ CO_2 sensor possibly incorrectly attached to the cuvette	▪ Check the CO_2 sensor ▪ Replace the CO_2 sensor if necessary ▪ Use external CO_2 monitoring if necessary

Leakage (Alarm delay: 3 s)	HP PA		▪ If the inspiratory tidal volume is 80% more than the expiratory tidal volume after three breaths	▪ Check the patient's condition ▪ Check the tube system ▪ Check the ETT
Fan failure	MP TA		▪ Fan malfunction	▪ Check the fan, replace if necessary
Low O_2 pressure	MP TA		▪ Oxygen delivery pressure from the gas cylinder or central gas supply too low (< 2.7 bar)	▪ Check the oxygen delivery pressure and replace the O_2 cylinder if necessary ▪ Check the oxygen pressure in CGS
O_2 high (Alarm delay: 30s)	MP PA		▪ Calculated O_2 value is above the automatic alarm limit value	▪ Compare the set O_2 value with the calculated value ▪ In case of larger deviations, contact FRITZ STEPHAN GMBH customer service
O_2 low (Alarm delay: 30s)	MP PA		▪ Calculated O_2 value is below the automatic alarm limit value	▪ Compare the set O_2 value with the calculated value ▪ In case of larger deviations, contact FRITZ STEPHAN GMBH customer service
Parameter error	MP TA		▪ Internal communication error	▪ Contact FRITZ STEPHAN GMBH customer service

PEEP high (Alarm delay: 3 s)	MP PA		▪ "PEEP" measured value is above upper PEEP alarm limit	▪ Check the PEEP setting and adapt to the selected ventilation mode if necessary ▪ Check inspiration and expiration times ▪ Check the tube system for blockages and water droplets ▪ Check the patient filter and replace if necessary ▪ Check the expiration valve and replace if necessary
Check CO_2 adapter	MP TA		▪ Incorrect CO_2 adapter ▪ CO_2 adapter malfunction ▪ CO_2 adapter contaminated	▪ Check the CO_2 adapter and clean if necessary ▪ Replace the CO_2 adapter if necessary
Standby	MP TA		▪ Device has been switched to Standby mode	▪ No action necessary
Temp. Gasoutlet high	MP TA		▪ The temperature at the blower module's gas outlet is too high	▪ Keep the device away from direct sunlight or other heat sources. ▪ Reduce ventilation pressures ▪ Contact FRITZ STEPHAN GMBH customer service if the temperature cannot be reduced.
Blower failure 7!!	MP/HP TA		▪ If the temperature in the blower is too high, an MP alarm is generated. ▪ If the blower overheats, an HP alarm is triggered	▪ Keep the device away from direct sunlight or other heat sources. ▪ Reduce ventilation frequency ▪ Reduce flow for O_2 therapy
Battery 1 & 2 failure	HP TA		▪ Battery 1 and 2 malfunction	▪ Check the batteries, replace if necessary

Battery 1 failure	HP TA		▪ Battery 1 malfunction during mains or battery operation	▪ Check the battery, replace if necessary
Battery low < 5 min	HP TA		▪ Battery voltage low ▪ Ventilator has a remaining run time of less than 5 minutes	▪ Check the mains supply and charge the battery ▪ Install the spare battery ▪ If the battery cannot be charged, contact FRITZ STEPHAN GMBH customer service
Battery 1 & 2 temp. high	HP TA		▪ Both batteries have overheated	▪ Check the batteries, replace if necessary ▪ Keep the device away from direct sunlight or other heat sources. ▪ Contact FRITZ STEPHAN GMBH customer service
Battery 1 & 2 cal	HP TA		▪ Both batteries require calibration	▪ Calibrate the batteries
Battery 1 & 2 temp. low	HP TA		▪ Both batteries undercooled	▪ Check battery 1 and 2, replace if necessary ▪ Do not operate the device at temperatures outside ambient conditions (see chapter 1.9). ▪ Contact FRITZ STEPHAN GMBH customer service
Airway pressure high	HP PA		▪ Measured inspiration pressure is above the upper PAW alarm limit ▪ Airway tube kinked	▪ The **EVE$_{TR}$** automatically reduces the pressure to PEEP level ▪ Check the patient's condition ▪ Check the pressure alarm limits ▪ Check the flow sensor and breathing tube ▪ Check the ETT or mask

Blower failure 3	HP TA		▪ Internal pressure sensor malfunction	▪ Contact FRITZ STEPHAN GMBH customer service
Blower failure 5	HP TA		▪ CAN bus communication fault	▪ Contact FRITZ STEPHAN GMBH customer service
Blower failure 6	HP TA		▪ Malfunction of the internal voltage supply	▪ Contact FRITZ STEPHAN GMBH customer service
Disconnection	HP PA		▪ If the "PAW low" limit is not breached during the entire breathing cycle, an alarm is issued after a 20 s delay ▪ Tube system leakage or disconnection	▪ Check the pressure alarm limits ▪ Check the patient tube system for disconnected parts ▪ Check that the manual settings are correct and plausible, adjust if necessary
EEPROM failure	HP TA		▪ EEPROM malfunction	▪ Contact FRITZ STEPHAN GMBH customer service
Measurement system error	HP TA		▪ Internal measuring error	▪ Contact FRITZ STEPHAN GMBH customer service
MVe high	HP PA		▪ Expiratory breathing volume above the upper alarm limit setting ▪ Flow sensor malfunction	▪ Check the patient's condition ▪ Check minute volume alarm limits ▪ Check that the manual settings are correct, adjust if necessary ▪ Check the flow sensor
MVe low	HP PA		▪ Expiratory breathing volume below the lower alarm limit setting ▪ Leak ▪ Flow sensor malfunction	▪ Check the patient's condition ▪ Check minute volume alarm limits ▪ Check patient tube system and connections for leakage ▪ Check that the manual settings are correct, adjust if necessary

Int. power supply failure (Alarm delay: 2 s)	HP TA		▪ Internal power supply malfunction	▪ Contact FRITZ STEPHAN GMBH customer service
Occlusion	HP TA		▪ Airway blockage ▪ Airway tube kinked ▪ ETT kinked	▪ The **EVE$_{TR}$** automatically reduces the pressure to PEEP level and then opens the expiration valve so that the patient can breathe freely. ▪ Check the airway tube ▪ Check the ETT
PEEP low	HP PA		▪ PEEP measured value is below lower PEEP alarm limit	▪ Check inspiration and expiration times ▪ Check ventilation tube system connections for possible leakage ▪ Check expiration valve for proper connection ▪ Check mask and tube for proper connection
P-Meas.: Check VBS	HP TA		▪ Pressure measurement failure	▪ Check patient tube system

Tab. 44: Troubleshooting

10.2 Selftest error

Error during power supply test	HW	▪ Battery malfunction ▪ Battery empty	▪ Check battery level, charge battery if necessary ▪ If the error cannot be corrected, contact FRITZ STEPHAN GMBH customer service, providing the error code displayed
Error during valve test	HW	▪ Valve malfunction	▪ Contact FRITZ STEPHAN GMBH customer service, providing the error code displayed
Error during sensor test	HW	▪ Sensor system malfunction	▪ Check secure connection of the patient tube system ▪ If the error cannot be corrected, contact FRITZ STEPHAN GMBH customer service, providing the error code displayed
Error during turbine test	HW	▪ Turbine malfunction	▪ Check secure connection of the patient tube system ▪ Check system for leakage ▪ Check sealing plug on Y piece ▪ If the error cannot be corrected, contact FRITZ STEPHAN GMBH customer service, providing the error code displayed

Tab. 45: Selftest error

10.3 Moisture in the PNT B (flow sensor)

Moisture or even water droplets in the pressure measurement lines of pneumotachograph B (flow sensor) can distort the volume flow measurement. If this is the case, you can proceed as follows:

- Switch EVE either to "Standby" mode or switch off the flow sensor in the system settings (see chapter 4.2.3).
- Remove the pneumotachograph from the Y piece and disconnect the plug from the side panel.
- Press the »Aerosol« button.
- Hold the pneumotachograph itself or the pressure measurement lines to the aerosol nebulizer outlet (see chapter 3.4) to let any moisture escape.

Position the PNT

Turn the measurement line connectors upward to prevent condensate from entering the measurement lines.

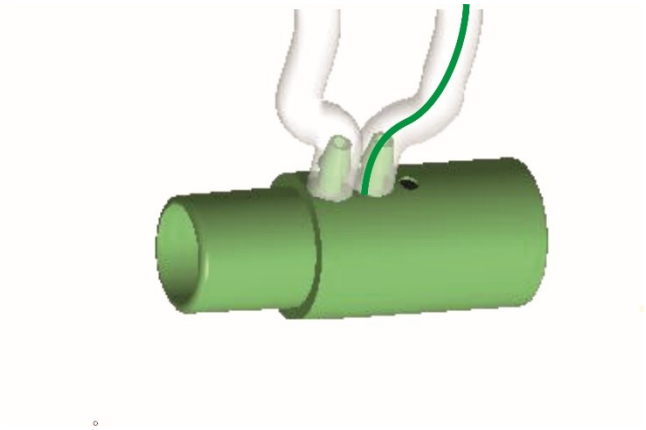


Fig. 109: Turning the measurement line connectors upward

11 Care and maintenance

WARNING

The device must be disconnected from the patient before performing any maintenance or service activities.

WARNING

Following maintenance or service activities, a function test as described in chapter 6.1 must be performed.

11.1 Disinfection and sterilization

CAUTION

Analogously to device operation, cleaning and disinfection work on the device may only be performed by trained specialist personnel.

CAUTION

The processes for the treatment of this medical product 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.

CAUTION

Routine cleaning must be carried out at regular intervals according to local hospital guidelines. Automated thermal treatment should be used wherever possible. All disposable parts must be disposed of in an environmentally friendly manner according to local hospital guidelines and hygiene regulations.

CAUTION

Do not sterilize the device in an autoclave, under pressure, or using ethylene oxide (EO). This will damage the device.

CAUTION

Do not immerse the device in liquids! Use cleaning solutions sparingly. Excess liquid may enter the housing and damage the device.

11.2 Information about cleaning agents and disinfectants

CAUTION

When using cleaning agents and disinfectants, pay attention to the correct concentration and dwell time to rule out any damage to the materials.

Always closely follow the instructions of the cleaning agent manufacturer for using the cleaning agent!

CAUTION

When using agents other than those specified, please contact the manufacturer of the disinfectant to confirm its compatibility with ventilation and inhalation systems (safety data sheet, toxicity).

CAUTION

When using cleaning agents and disinfectants, observe the rules established by the professional associations on the use of cleaning agents and disinfectants.

CAUTION

Do not use petroleum-based cleaning agents, acetone, or other harsh cleaning agents! These agents can damage the device material and cause malfunctions.

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

Do not use any disinfectants based on amines or their derivatives! These agents can damage the plastics and silicone in the device and cause malfunctions.

CAUTION

Do not use any disinfectants containing oxygen, chlorine or halogen donors or phenols and their derivatives! These agents can damage the material and cause malfunctions.

CAUTION

Do not use any highly alkaline cleaning agents (pH > 10.9)! These agents can damage the material and cause malfunctions.

CAUTION

Do not use any rinse aids or other drying agents!

11.3 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. 46: 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 cleaning agents, such as neodisher® Mediclean from Dr. Weigert GmbH in Hamburg.

Products based on the following are not suitable because they could possibly damage materials:

- Highly alkaline solutions
- Petroleum or acetone
- 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.

CAUTION

Do not use disinfectants in automated cleaning and disinfection equipment!

Do not use any rinse aids or other drying agents!

These could damage the parts to be treated.

For more information about using cleaning agents, see chapter 11.2.

11.4 Manual cleaning and disinfection

WARNING

Manual treatment cannot be validated and does not deliver reproducible results.

For this reason, automated treatment should be preferred where possible.

Manual cleaning

To manually clean the individual parts, pre-rinse them in warm water. Then clean the individual parts in the cleaning and disinfectant solution, if necessary using soft brushes or sponges. All secretions and other deposits and contamination must be completely removed.

Manual disinfection

To manually disinfect the individual parts, place them in the ready-to-use disinfectant solution (instrument disinfection agent). All of the parts must be fully covered by the disinfectant, and they must be free from bubbles.

After the dwell time, the disinfectant must be completely rinsed off using demineralized water. Afterwards, the parts must be dried thoroughly.

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.

Products based on the following are not suitable because they could possibly damage materials:

- Highly alkaline solutions
- Petroleum or acetone
- 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.

11.5 Cleaning and disinfection of device surfaces

Use ready-to-use disinfectant solution to disinfect the surfaces of the device. 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.

CAUTION

Do not use abrasive cleaners or brushes on the touchscreen. They can scratch the display.

Prior to cleaning the touchscreen during ongoing ventilation, ALWAYS press the Lock Touchscreen button (see chapter 3.1.3).

All disinfectant residue must be completely removed afterwards.

Disinfectants

Suitable cleaning agents with regard to material compatibility are aldehyde-free quick disinfecting wipes, such as Bacillol® wipes or tissues made by Paul Hartmann AG, Heidenheim or Mikrozid® PAA wipes made by Schülke, Norderstedt.

11.6 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

Only use vacuum steam sterilizers!

Sterilizers with a fractionated vacuum are preferable.

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. 47: Standard procedure for steam sterilization*

*All standard steam sterilization procedures can be used.

11.7 Carrying out the treatment

11.7.1 Type B Pneumotachograph (flow sensor)

	CAUTION
	Only use the assembly tools intended for this 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 11.7.1.1.
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 11.3.

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. 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 11.4.
Maintenance	▪ Pick up the vortex bodies 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.
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 parts of the flow sensor 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 11.6.
Storage	After sterilization, store the system in the sterilization packaging, first ensuring it is dry and free of contamination.
Additional information	None

11.7.1.1 Preparing the PNT B

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

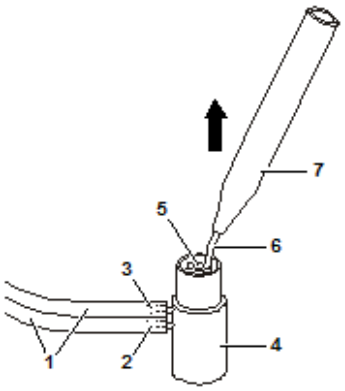


Fig. 110: Preparing the PNT B

1	Pressure measurement line	5	Vortex body
2	Connector 1	6	Hook
3	Connector 2	7	PNT B assembly tool
4	Pneumotachograph		

11.7.1.2 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 bodies to the assembly tool

Post-treatment PNT B

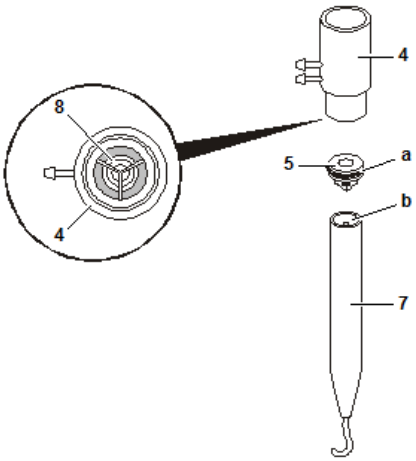


Fig. 111: Post-treatment PNT B

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		

CAUTION

During assembly, ensure that the seals and O-rings are positioned correctly and not crushed.

Preparation for PNT use

1. Connect the proximal pressure measurement line (green or marked in green) to connection 1 near the attachment fitting of the PNT (marked by a black dot on the plug and PNT housing).
2. Connect the second pressure measurement line to connection 2.

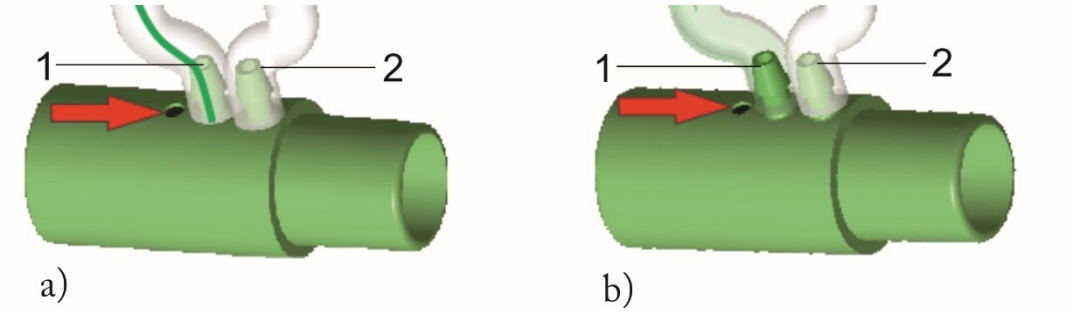


Fig. 112: Connecting the pressure measurement lines on the PNT

1	Connection 1 for proximal pressure measurement line	2	Connection 2
a	Reusable pressure measurement lines	b	Disposable pressure measurement lines

Preparation for use of the flow measurement adapter (reusable)

3. Connect the proximal pressure measurement line (green) to the connection (3) marked with "P" on the reusable flow sensor adapter.
4. Connect the second pressure measurement line to the second connection (4) on the reusable flow sensor adapter.

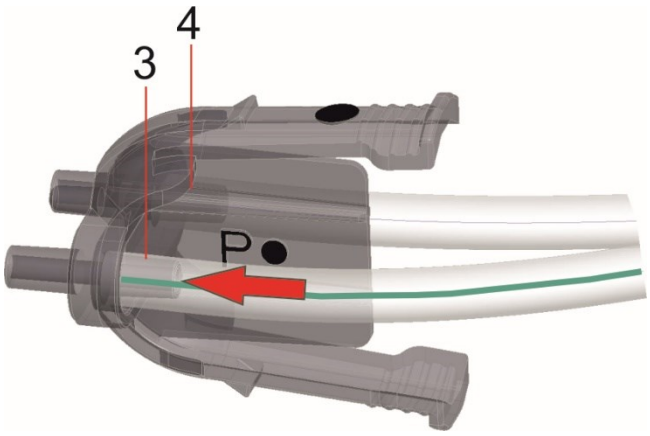


Fig. 113: Connecting the pressure measurement lines on the reusable flow measurement adapter

3 Connection 1 for proximal pressure measurement line

4 Connection 2

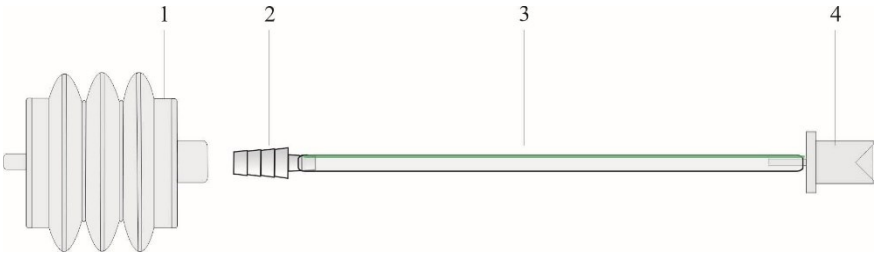
CAUTION

Ensure that all pressure measurement lines are mounted in the correct position. Any confusion between different pressure measurement lines may result in inverted measurements. If this occurs, the measurement results for tidal volumes and minute volumes will be incorrect.

Function test Before using the flow sensor, leak and functional checks must be performed (see chapter 7 of the operating manual).

11.7.2 Test lung Neo 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 (3) from the test lung (1) together with the tube adapter (4) and tube sleeve (2). 2. Remove the tube adapter and tube sleeve from the silicone tube.  Fig. 114: Test lung with tube adapter
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.
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, the disinfectant must be completely rinsed off using cold water (at least drinking water quality). 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.
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	Following disinfection, conduct a visual inspection. There must be no visible cracks or material damage.
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.
Storage	After sterilization, store the system in the sterilization packaging, first ensuring it is dry and free of contamination.
Additional information	None

11.8 Treatment table

CAUTION

The processes for the treatment of the medical device described in this table are recommendations only. Always observe the individual procedural instructions given by the responsible hygiene officer.

WARNING

In case of infectious patients, all reusable parts of the patient system carrying breathing gas must also be sterilized.

System components	Recommended treatment intervals	Automated thermal treatment	Manual treatment	Sterilization
Case, power cord, connection tubes	After every patient/ weekly	No	Surfaces	No
Touchscreen	After every patient/ weekly	No	Surfaces	No
Docking station	After every patient/ weekly	No	Surfaces	No
Ambulance bracket	If contaminated	No	Surfaces	No
Helicopter bracket	If contaminated	No	Surfaces	No
Carry system	If contaminated	No	Surfaces	No
Accessories bags (carry system)	If contaminated	No	Clean manually using a brush	No
Adult test lung	After every patient/ weekly	Observe the manufacturer's operating manual!		
Test lung Neo with tube adapter	After every patient/ weekly	Yes	Yes	Yes
Reusable expiration valve	After every patient/ weekly	Yes	Yes	Yes
Reusable patient tube system	After every patient/ weekly	Yes	Yes	Yes
Type B pneumotachograph	After every patient/ weekly	Yes	Yes	Yes

System components	Recommended treatment intervals	Automated thermal treatment	Manual treatment	Sterilization
Pressure measuring adapter NCPAP	After every patient/ weekly	Yes	Yes	Yes
SpO_2 sensor	After every patient/ weekly	No	Surfaces	No
		Observe the manufacturer's operating manual!		
CO_2 sensor	After every patient/ weekly	No	Surfaces	No
		Observe the manufacturer's operating manual!		
Mobile stand, brackets	After every patient/ weekly	No	Surfaces	No

Tab. 48: Treatment table

11.9 Safety checks

Safety checks must be carried out annually by the manufacturer or the authorized FRITZ STEPHAN GMBH customer service team.

11.10 Maintenance

For reasons of device safety, we recommend performing basic maintenance on the **EVE_{TR}** annually in connection with the safety checks. All maintenance

- Basic maintenance (annually)
- Major maintenance (every five years)

must be performed according to maintenance instructions by the authorized FRITZ STEPHAN GMBH customer service team.

11.11 Servicing

DANGER

Disconnect the ventilator from the power supply during all servicing work.

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. Only use spare parts from FRITZ STEPHAN GMBH for maintenance.

ATTENTION

Use only spare parts from FRITZ STEPHAN GMBH for servicing, otherwise device damage may result.

The following procedures must be performed regularly to ensure that the ventilator is operational at all times:

Affected parts	When to replace	Who is responsible?
Complete patient tube system including accessories	After every patient, otherwise according to hospital guidelines	User/operator
Coarse filter	As needed, but at least monthly	User/operator or authorized FRITZ STEPHAN GMBH customer service team
HEPA filter	As needed, but at least annually	User/operator or authorized FRITZ STEPHAN GMBH customer service team
External battery	To ensure the correct function of the battery charge indicator, both the internal and external battery must be calibrated every six months. This involves completely discharging and recharging battery twice in a row Replacement after 500 load cycles, or if the battery capacity is below 50% after full charging	User/operator or authorized FRITZ STEPHAN GMBH customer service team
Battery	To ensure the correct function of the battery charge indicator, both the internal and external battery must be calibrated every six months. This involves completely discharging and recharging battery twice in a row Replacement after 500 load cycles, or if the battery capacity is below 50% after full charging	User/operator or authorized FRITZ STEPHAN GMBH customer service team Authorized FRITZ STEPHAN GMBH customer service team

Tab. 49: Servicing

11.11.1 Procedure

11.11.1.1 Replacing the coarse filter

- Remove the screw on the left side panel.

Fig. 115: Removing the screw on the side panel

- Slightly lift the housing cover and remove.
- Replace the coarse filter.

Fig. 116: Replacing the coarse filter

- Replace the housing cover.

11.11.1.2 Replacing the HEPA filter

- Remove the side panel and coarse filter as described in chapter 11.11.1.1.
- Pull out the HEPA filter by carefully puncturing it using a sharp object or screwdriver.

Fig. 117: Replacing the HEPA filter

- Install the new HEPA filter.
- Replace side panel and coarse filter.

11.11.1.3 Replacing the fan filter

- Remove the screw on the right side panel.

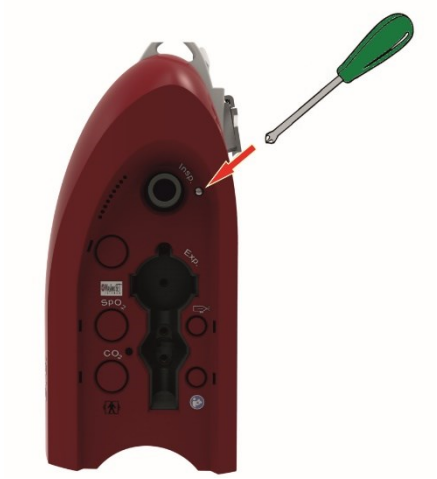


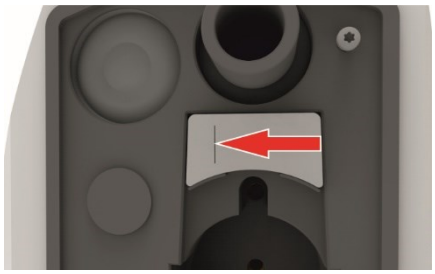
Fig. 118: Removing the screw on the side panel

- Slightly lift the housing cover and remove.
- Replace the filter element.

Fig. 119: Replacing the filter element

NOTE

When replacing the filter element, observe the correct installation direction. The filter has a slit on the front left side.



- Replace and screw on the fan cover.

11.11.1.4 Replacing the external battery

To replace the external battery 2 (optional), squeeze together the two tabs on the rear of the battery. This automatically releases the battery from the device for replacement.

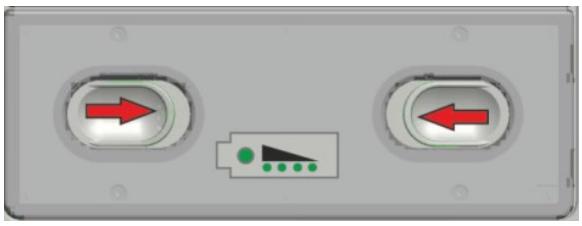


Fig. 120: Replacing the external battery

12 Electromagnetic emissions and immunity

NOTE

Electrical medical devices are subject to special precautions regarding electromagnetic 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.

12.1 Electromagnetic emissions

The **EVE** ventilator is intended for use in the electromagnetic environment specified below. The customer or user of the **EVE** ventilator should ensure that it is used in such an environment.

Emissions	Compliance	Electromagnetic environment guideline
RF emissions as defined in CISPR 11	Group 1	The **EVE** 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 A	The **EVE** 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. 50: 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.

12.2 Electromagnetic immunity

The **EVE** ventilator is intended for use in the electromagnetic environment specified below. The customer or user of the **EVE** ventilator should ensure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment guideline
Electrostatic discharge (ESD) as defined in IEC 61000-4-2:2008	+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 61000-4-4:2012	+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 61000-4-4:2012	+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.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment guideline
Voltage dips, short interruptions, and voltage variations as defined in IEC 61000-4-11:2004	< 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.
Power frequency (50/60 Hz) magnetic field as defined in IEC 61000-4-8:2009	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 A.C. mains voltage prior to application of the test level.			

Tab. 51: Electromagnetic immunity (IEC 60601-1-2)

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment guideline
			Portable and mobile RF communications equipment should be used no closer to any part of the **EVE** 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	10 $V_{effective\ value}$ 150 kHz to 80 MHz outside ISM bands [a]	10 $V_{effective\ value}$	Recommended separation distances: $d = 0{,}35\sqrt{P}$
	10 $V_{effective\ value}$ 150 kHz to 80 MHz in ISM bands [a]	10 $V_{effective\ value}$	$d = 1{,}2\sqrt{P}$ $d = 0{,}6\sqrt{P}$ for 80 MHz to 800 MHz

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment guideline
Radiated RF IEC 61000-4-3 (without docking station)	Without docking station		
	20 V/m 80 MHz to 2.5 GHz	20 V/m	$d = 1{,}2\sqrt{P}$ 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 **EVE** ventilator is used exceeds the compliance levels above, the **EVE** 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 **EVE** ventilator.			
d Over the frequency range 150 kHz to 80 MHz, field strength is less than 10 V/m.			

12.3 Recommended separation distance

The **EVE** ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the **EVE** ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **EVE** 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 EVE ventilator					
Maximum transmission power of the transmitter (W)	Distance based on the transmitter frequency (m)				
	150 kHz to 80 MHz outside ISM bands a	**150 kHz to 80 MHz in ISM bands [a]**	**80 MHz – 800 MHz**	**800 MHz – 2.5 GHz**	
				Without docking station	With docking station
	$d = 0{,}35\sqrt{P}$	$d = 1{,}2\sqrt{P}$	$d = 0{,}6\sqrt{P}$	$d = 1{,}2\sqrt{P}$	$d = 2{,}4\sqrt{P}$
0.01	0.001 m	0.12 m	0.06 m	0.12 m	0.24 m
0.1	0.11 m	0.38 m	0.19 m	0.38 m	0.76 m
1	0.35 m	1.2 m	0.6 m	1.2 m	2.4 m
10	1.1 m	3.8 m	1.9 m	3.8 m	7.6 m
100	3.5 m	12 m	6 m	12 m	24 m
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. 52: Recommended separation distance (IEC 60601-1-2, Table 5)

13 Accessory list

Description	Art. no.
EVE adult emergency single-use tube system, length: 180cm	107061120
EVE adult emergency single-use tube system, length: 300 cm	107061141
EVE pediatric single-use tube system, length: 180 cm	107061124
Disposable adult flow sensor, PU: 6	107061127
Disposable pediatric flow sensor, PU: 6	107061128
EVE NEO single-use tube system, length: 180 cm	107061189
Pneumotachograph B flow sensor for preterm infants and newborns (EVE)	107061129
Flow measurement adapter with line for PNT-B (disposable)	107061138
Pressure measuring adapter NCPAP	107061137
Disposable nebulizer set 22M/22F with O_2 safety tube	170460422
Disposable EVE distal expiration valve	107061072
EVE replacement battery, pluggable	107061037
EVE external power supply	107061041
EVE carry system	107061250
Ambulance bracket with carrying system	107061300
Ambulance bracket without carrying system	107061310
Ambulance bracket for attachment to standard rail	107061320
24-V ambulance bracket	107061380
24-V ambulance bracket with bracket set	107061390
Smart bracket	107061330
Helicopter bracket with DC /DC charging electronics	107061350
Helicopter bracket without charging electronics	107061360
Helicopter bracket with charging electronics 24 V DC	107061370
Docking station Light	107061660
EVE pressure regulator including connection tube	107063001
O_2 connection hose, 3 m, phthalate-free DIN-NIST, EN 5359	110261270
O_2 safety tube, 2 m	170460434

Description	Art. no.
Mainstream CO_2 sensor including adapter cable	107061050
IRMA airway adapter adult/pediatric, PU: 25	107060051
Disposable infant CO_2 measurement adapter, PU: 10	107060052
Sidestream CO_2 analyzer including adapter cable	107060053
Nomoline airway adapter set, length: 200 cm, PU: 20	107060056
Nomoline CO_2 sampling line, length: 200 cm, PU: 25	107060054
Nomoline adapter, length 15 cm, PU: 25	107060055
Nomo disposable extension sampling line including male Luer lock connector, length: 200 cm, PU: 25	107060057
Nomo disposable extension sampling line including male Luer lock connector, length: 300 cm, PU: 25	107060058
T airway adapter, PU: 25	107060059
Masimo Rainbow	
Masimo Rainbow® DCI SC-200 sensor, adult, reusable (SpHb, SpO_2, SpMet)	107060512
Masimo Rainbow® ReSposable R2-25 sensor system, adult (SpO_2, SpHb, SpMet)	107060514
Masimo Rainbow® DCI reusable sensor, adult (SpCO, SpMet. SpO_2)	107060510
Masimo Rainbow® RC-25-4RA patient cable	107060021
Masimo SpO_2 finger clip sensor M-LNCS DCI for adults B TR/IN	170460147
Adult HME filter	170060013
Pediatric HME filter	170060014
HEPA filter	170160207
O_2 safety tube, 2 m	170460434
O_2 mask adult, incl. O2 safety tube, 2 m	170060151
O_2 mask child, incl. O2 safety tube, 2 m	170060152
O_2 nasal cannula adult with O2 safety tube, 2 m	1 70460425
O_2 nasal cannula child, incl. O2 safety tube, 2 m	1 70060428
Headband for children's breathing mask	170060007
Headband for adult breathing mask	170060008
Small mask ring for breathing mask, size 0–1	170060005

Description	Art. no.
Large mask ring for breathing mask, size 2–5	170060006
Air-Soft breathing mask, size 0 (newborn)	170060048
Air-Soft breathing mask, size 1 (large newborn)	170060049
Air-Soft breathing mask, size 2 (infant)	170060050
Air-Soft breathing mask, size 3 (large child)	170060051
Air-Soft breathing mask, size 4 (adult)	170060052
Air-Soft breathing mask, size 5 (large adult)	170060037
Pediatric test lung, silicone, 30 ml, including tube adapter for connection to Y piece	170060092
Test lung GaleMed with adapter (Fritz Stephan GmbH)	107061207

Description	Art. no.
EasyFlow_nCPAP system	
Prongs (PU: 5)	
• 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

Description	Art. no.
• XXL	170161024
• 3XL	170161025
• 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

14 Warranty

The manufacturer, FRITZ STEPHAN GMBH, warrants the product for 24 months from the purchase date.
This assumes regular safety checks and device maintenance by the manufacturer or by personnel authorized by FRITZ STEPHAN GMBH.
See the corresponding chapters in this operating manual for additional information.

Only FRITZ STEPHAN GMBH or authorized professionals are allowed to manipulate or repair the device. Non-compliance voids the warranty.

Improper handling of the device also voids the warranty.

15 List of figures

16 List of tables

17 Notes

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