LÖWENSTEIN
medical

leoni*plus*
leoni*plus transport*

User Manual

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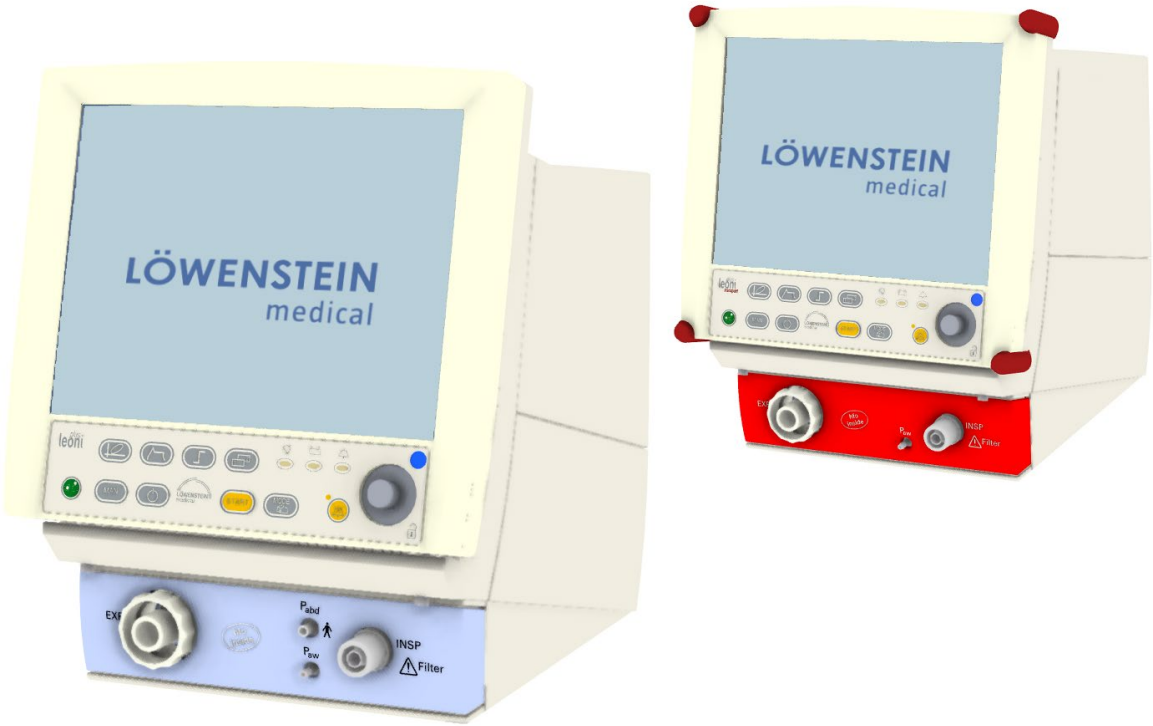


plus leoni

plus leoni transport

1. About this user manual

Validity of the user manual

This user manual is valid for the following products:

- LeoniPlus
- LeoniPlus transport

This user manual is also valid for all devices with the Heinen + Löwenstein manufacturer specification.

Important topics in the user manual

This user manual describes the components of the device and its operation.

It includes:

- information on safety measures that must be observed when working with the device
- an overview of all device components
- instructions for operating the device
- a detailed description of the monitor controls
- information on service, cleaning and sterilisation

Structure and purpose of user manual

The user manual laid out to help you become familiar with the operation of your ventilator step by step. Frequently used functions are described.

Read the user manual carefully before starting to use the ventilator.

Later, when you are familiar with the basic operation of the ventilator, the user manual will be useful as a reference for answering more detailed questions. Use the table of contents and the index to find a topic quickly.

Tips and safety notices

Tips

Tips are provided to supplement the instructions for actions.

Tips suggest actions that can make it easier and more efficient to operate the ventilator.

Notice

NOTICE

NOTICE indicates important information which, if not heeded, may result in damage to the equipment.

Caution

CAUTION

CAUTION indicates potential danger, which may not be immediate but if not avoided may result in injury.

Warning

WARNING

WARNING indicates direct danger, which if not avoided may result in serious injury or death.

Description of options

This user manual contains descriptions of standard and optionally available device equipment and functions. Description of an option does not provide create a legal claim to that option. You can find out which options are available on your system from your Löwenstein Medical dealer.

Storage of documentation

Keep the documentation available for reference in an accessible place near the device.

Additional information

If you have any questions or information on this user manual or our ventilator, please contact your authorised regional dealer or the manufacturer directly.

2. General safety instructions

The liability for proper function of the device is irrevocably transferred to the owner or operator of the device if it is serviced or repaired by persons who are not employed by *Löwenstein Medical* Service department or are not authorised by *Löwenstein Medical* or if it is operated in a manner contrary to its intended use.

Löwenstein Medical cannot be held responsible for damage caused by non-compliance with the above stipulations. The warranty and liability provisions of the terms of sale and delivery of *Löwenstein Medical* are also not modified by the following recommendations.

Intended use

Area of application

LeoniPlus: Ventilator for invasive and non-invasive ventilation of premature babies, neonates and infants up to 30 kg body weight for stationary use.

LeoniPlus transport: Ventilator for premature babies, neonates and infants up to 30 kg body weight in the following application areas:

- in the intensive care ward, in intermediate care wards, in emergency wards, in care facilities, or in the recovery room
- during transport inside and outside the hospital with a connection comprising a safety system according to EN 1789:2010 (for emergency vehicles in road transport)
- during transport in aircraft with connection by means of a fastening system according to EN 13718-1 and RTCA/DO1 60G

Use only with an alternative ventilator available

When in use an alternative ventilator (e.g. manual resuscitator) must always be available.

Ventilation modes

The ventilator is designed for the following ventilation modes:

- Intermittent Positive Pressure Ventilation / Intermittent Mandatory Ventilation (IPPV / IMV)
- Synchronized Intermittent Positive Pressure Ventilation (S-IPPV)
- Synchronized Intermittent Mandatory Ventilation (S-IMV)
- Pressure Support Ventilation (PSV) combined with SIMV or SIPPV
- Continuous Positive Airway Pressure (CPAP)
- High Frequency Oscillation (HFO)
- Nasal Intermittent Positive Pressure Ventilation (nIPPV)
- Nasal Continuous Positive Airway Pressure (nCPAP)
- Nasal High Frequency Oscillation (nHFO)
- Synchronized Nasal Intermittent Positive Pressure Ventilation (S-nIPPV)
- Synchronized Nasal Continuous Positive Airway Pressure (S-nCPAP)
- HiFlow (O_2 therapy)

Approved operators

The device is operated by a physician or a person trained and qualified to operate the device under the direction of a physician. Every user must be trained on the device and must be familiar with the user manual and the operation of the device.

Check regular oxygen saturation and CO_2 concentration

Incorrect ventilation parameters may result in incorrect oxygen supply to the patient over the long term. This means that the oxygen and CO_2 values must be checked regularly.

Check the oxygen saturation and the CO_2 concentration regularly by pulse oximetry and capnometry or blood-gas analysis.

CO_2 monitoring device for non-invasive ventilation

For non-invasive ventilation, an additional CO_2 monitoring device should be used to monitor the CO_2 concentration continuously.

Do not use the abdomen sensor during transportation

During ventilation with the abdomen sensor, triggers can be set off by shocks occurring in a transportation situation.

Modifications to the device

Modifications to the device may not be performed without the authorization of the manufacturer.

Combination with other devices Combination with other devices that are not mentioned in the user manual is permitted only in consultation with the manufacturer.

Approved gases The ventilator is approved for the connection of oxygen and air. It must not be used with helium or gas compounds containing helium.

LeoniPlus is suitable for administering NO ventilation; conformance with the relevant devices is confirmed. You can find out which devices are compatible from your authorized regional dealer or directly from the manufacturer.

Approved medicinal product As a medicinal product, medicinal oxygen is administered by inhalation and is approved for ventilation.

Contraindications

All contraindications resulting from the safety notices in Chapter "General safety instructions" must be observed (for the limitations that apply to pulse oximetry, see *Additional advices for Masimo pulse oximetry, P. 15*).

During non-invasive ventilation and O_2 therapy, certain monitoring functions are switched off or can be switched off.

Further contraindications are not known.

Maintenance and correct operating condition

Maintenance The device is a ventilator classified as a medical device class IIb under the European Directive.

The device must be serviced and safety checked every 12 months as specified by the manufacturer.

Only technicians trained by the manufacturer are authorised to carry out the service. Service technicians must have suitable instrumentation and test devices.

Only original parts from Löwenstein Medical may be used for maintenance.

Correct operating condition If a fault is detected during the self–test or the device check, the ventilator must not be attached to a patient.

Suitable installation and ambient conditions

Do not use in explosive atmospheres or near flammable substances Ventilator, batteries and charging station with all accessories must not be operated in environments where there is a danger of explosion or in the vicinity of flammable substances.

Do not use in areas exposed to water spray The ventilator must not be operated in the vicinity of bathtubs, showers or any places it might be exposed to water spray.

Not for use in rooms with overpressure The ventilator must not be used in an overpressure chamber.

Do not cover or place in an unsuitable position The ventilator must not be covered or positioned where it could negatively affect operation or working.

EMC precautions

Not MR Safe Do not use in the vicinity of magnetic resonance tomographs (MRT).

In the MR environment, the static magnetic field poses an impermissible danger for the patient, the medical personnel and other persons who are present.

Impairment of function due to EMC-relevant devices The correct functioning of the device may be impaired by the operation of instruments used in radiofrequency surgery, microwaves, short waves, or strong magnetic fields in the direct vicinity.

Protection against electrostatic discharge Observe the precautionary measures regarding electrostatic discharging (ESD) and electromagnetic interference (EMI) to and from the ventilator and to and from all connected devices and accessories.

Approved accessories only Using accessories, pressure sensors, and cables that are not specified or provided by the manufacturer of this equipment can lead to increased electromagnetic emissions or reduced electromagnetic immunity and result in operational malfunctions.

Sufficient distance from RF telecommunications devices

Portable RF telecommunications devices, including peripherals such as antenna cables and external antennas, should be positioned at a distance of at least 30 cm from all parts of the ventilator. This also includes all cables specified by the manufacturer. Otherwise, the performance of this equipment may be adversely affected.

Portable and mobile DRF telecommunications devices can have an effect on the ventilator and all electrical medical devices!

Electromagnetic emission protection

Due to its radio-frequency disturbance characteristics, the equipment is suitable for use in industrial environments and in hospitals (CISPR 11, Class A).

If used in a residential area (for which CISPR 11, Class B is normally required), this equipment may not provide adequate protection for radio-frequency communications services. The user might have to take mitigation measures, such as relocating or re-orienting the equipment

Accessories and consumables

Only approved accessories

The ventilator must only be operated with approved accessories.

Use with unauthorised accessory components will endanger the safety of the patient and/or the user and proper functioning of the device.

No antistatic or electrically conductive tubing

Antistatic or electrically conductive tubing may give the patient and/or user an electric shock. Never use tubing of this type.

Increased pressure drop by attachment of accessory components or by long tubing

The pressure drop in the ventilation system may be increased if accessory components or other components are attached to the ventilation system. The tube must be no longer than 1.8 m.

Safe working with the ventilator

Device check before operation

Device malfunctions may cause death or permanent injury to the patient.

Always check the ventilator before operation.

Check sensors regularly

Sensor malfunctions may cause death or permanent injury to the patient.

Calibrate the flow sensor regularly:
- after switching on
- after every sensor change

Sterility

The device must be sterilised before first use and after every time it is used on a patient.

Checking settings before connection to patient

Incorrect ventilation parameters may cause permanent damage to the patient's lungs.

Check the ventilation parameters before connecting the patient to the ventilator.

Avoid touch currents

Never touch the patient and the device at the same time.

No defibrillation during ventilation

The ventilator does not provide defibrillation protection.

Note battery charge

When the battery is discharged the device switches off automatically.

We recommend not operating the device until the battery is discharged.

The exhaled and measured volume differ

In non-invasive ventilation, the volume exhaled by the patient may differ from the measured volume due to leaks around the mask.

Check gas bottles

During operation of the ventilation device with gas bottles, they must first be checked for the quantity with which they are filled.

Patient monitoring

The LeoniPlus user is solely responsible for choosing the most suitable form of patient monitoring and patient monitoring system that will provide informative data about the functioning of the device and patient condition.

A guarantee of patient safety can be achieved in various ways, for example, by specialist personnel monitoring clinical symptoms or by electronic monitoring of the functioning of the device and patient condition.

Additional advices for Masimo pulse oximetry*

Intended use The Masimo pulse oximeter is used to measure SpO_2 and pulse rate during ventilation with the LeoniPlus.

Limitations A pulse oximeter should not be used as an apnea monitor.

Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.

A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analysed by a laboratory co-oximeter to completely understand the patient's condition.

Do not use the Masimo pulse oximeter or oximetry sensors during MRI scanning. Induced current could potentially cause burns. The pulse oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.

Interfering substances Carboxyhemoglobin may erroneously increase readings. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

* not for LeoniPlus transport

Operation

The Masimo pulse oximeter is to be operated by qualified personnel only.

Use only Masimo oximetry sensors for SpO_2 measurements. Tissue damage can occur due to incorrect placement of sensor. Read the Masimo sensor directions for use.

Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

Do not use damaged sensors or cables.

Check alarm limits each time the Masimo pulse oximeter is used to ensure that they are appropriate for the patient being monitored.

3. Technical data and equipment

Technical data

The device has been developed in accordance with the EN60601-1-4 guidelines. All parameters that could cause danger to the patient are redundantly monitored by hardware safety components.

Technical documentation must be requested from the manufacturer, if required.

Adjustment ranges of ventilation parameters – IV

	IPPV/IMV	S-IPPV	S-IMV
Inspiratory pressure **P Insp [mbar]**	4 .. 60	4 .. 60	4 .. 60
Pressure for supporting spontaneous breathing **P Support [mbar]**	-	-	Off, 6 .. 60
Positive, end expiratory pressure **PEEP [mbar]**	0 .. 30	0 .. 30	0 .. 30
Inspiratory flow **Flow Insp [l/min]**	1 .. 32	1 .. 32	1 .. 32
Expiratory flow **Flow Exp [l/min]**	2 .. 10	2 .. 10	2 .. 10
Volume trigger for detection of spontaneous breathing **Trig Vol [% VTi]**	-	5 .. 30	5 .. 30
Flow trigger for detection of spontaneous breathing **Trigger [l/min]**	-	0,1 .. 1	0,1 ..1
Breath frequency **Freq / [1] Freq Backup [bpm]**	6 .. 200	2 .. 100 [1]	2 .. 100
Inspiratory time **T Insp**	0.10 .. 2.00	0.10 .. 2.00	0.10 .. 2.00
Expiratory volume guarantee **VTG [ml]**	-	Off; 0.1 .. 200	Off; 0.1 .. 200

	IPPV/IMV	S-IPPV	S-IMV
Inspiratory volume limitation **VT Limit [ml]**	Off; 1 ..200	Off; 1 .. 200	Off; 1 .. 200
O_2 concentration **O_2 [%]**	21 .. 100	21 .. 100	21 .. 100
Manual breath time (Inspiration hold) **Maximum manual breath time [sec] ***	2 .. 10	2 .. 10	2 .. 10

	PSV-SIMV	PSV-SIPPV
Inspiratory pressure **P Insp [mbar]**	4 .. 60	4 .. 60
Pressure for supporting spontaneous breathing **P Support [mbar]**	Off, 6 .. 60	-
Positive, end expiratory pressure **PEEP [mbar]**	0 .. 30	0 .. 30
Inspiratory flow **Flow Insp [l/min]**	1 .. 32	1 .. 32
Expiratory flow **Flow Exp [l/min]**	1 .. 20	1 .. 20
Maximum inspiration time **T Insp max [sec]**	0.10 .. 2.00	0.10 .. 2.00
Volume trigger for detection of spontaneous breathing **Trig Vol [% VTi]**	5 .. 30	5 .. 30
Flow trigger for detection of spontaneous breathing **Trigger [l/min]**	0.1 .. 1	0.1 .. 1
Backup respiration frequency **Freq / [2] Freq Backup [bpm]**	2 .. 100	[2] 2 .. 100
Backup inspiration time **T I Backup [sec]**	0.10 .. 2.00	0.10 .. 2.00
Expiratory volume guarantee **VTG [ml]**	Off; 0.1 .. 200	Off; 0.1 .. 200
Inspiratory volume limitation **VT Limit [ml]**	Off; 1 ..200	Off; 1 .. 200
O_2 concentration **O_2 [%]**	21 .. 100	21 .. 100

* can be configured in the presettings

	PSV-SIMV	PSV-SIPPV
Manual breath time (Inspiration hold) **Maximum manual breath time [sec] ***	2 .. 10	2 .. 10

	CPAP	HFO
Minimum flow **Flow [l/min] / [3)] Flow CPAP [l/min]**	[3)] 2 .. 16	-
Manual breath flow **Flow Man [l/min]**	-	-
CPAP Pressure **CPAP [mbar]**	1 .. 20	-
Backup breaths **Backup [l/min]**	Off; 1 .. 5	-
Backup inspiration pressure **P Insp [mbar]**	4 .. 60	-
Apnea time **T Apnea [sec]**	6 .. 20	-
Pressure manual expiratory impulse **P Man [mbar]**	-	1 ..40
Mean pressure **P Mean [mbar]**	-	0 .. 40
Oscillation frequency **HF Freq [Hz]**	-	5 .. 20
Pressure amplitude, peak - peak **HF Ampl [mbar]**	-	5 .. 100
Inspiration to expiration ratio **I:E**	-	25:75 .. 50:50
Recruitment frequency **Freq Rec [1/std]** **[1/min]**	-	Off, 1 .. 59 1 .. 60
Recruitment inspiration time **T Rec [s]**	-	0,1 .. 5
Recruitment pressure level **P Rec [mbar]**	-	1 .. 40

* can be configured in the presettings

	CPAP	HFO
Expiratory volume guarantee **VTG [ml]**	-	Off, 0.1 .. 30
O_2 concentration **O_2 [%]**	21 .. 100	21 .. 100
Manual breath time (Inspiration hold) **Maximum manual breath time [sec] ***	2 .. 10	2 .. 10

Adjustment ranges of ventilation parameters –NIV

	nCPAP	S-nCPAP	nIPPV	S-nIPPV
CPAP Pressure **CPAP [mbar]**	1 .. 15	1 .. 15	-	-
Backup breaths **Backup [l/min]**		Off; 1 .. 5		
Backup inspiration pressure **P Insp [mbar]**		6 .. 30		
Apnea time **T Apnea [sec]**		6 .. 20		
Pressure manual expiratory impulse **P Man [mbar]**	6 .. 30		-	-
Inspiratory pressure **P Insp [mbar]**	-	-	5 .. 30	5 .. 30
Positive, end expiratory pressure **PEEP [mbar]**	-	-	0 .. 15	0 .. 15
Manual breath flow **Flow Man [l/min]**	4 .. 32	4 .. 32	-	-
Minimum flow **Flow CPAP [l/min]**	2 .. 20	2 .. 20	-	-
Inspiratory flow **Flow Insp [l/min]**	-	-	1 .. 32	1 .. 32
Expiratory flow **Flow Exp [l/min]**	-	-	2 .. 20	2 .. 20
Breath frequency **Freq [1/min]**	-	-	2 .. 200	2 .. 130

* can be configured in the presettings

	nCPAP	S-nCPAP	nIPPV	S-nIPPV
Inspiration time **T Insp [sec]**	-	-	0.1 .. 15	0.25 .. 15
Abdomen trigger **Trigger**		Off; 1 .. 30		Off; 1 .. 30
O_2 concentration **O_2 [%]**	21 .. 100	21 .. 100	21 .. 100	21 .. 100
Manual breath time (Inspiration hold) **Maximum manual breath time [sec] ***	2 .. 10	2 .. 10	2 .. 10	2 .. 10

	nHFO	HiFlow
Pressure manual expiratory impulse **P Man [mbar]**	2 .. 20	-
Mean pressure **P Mean [mbar]**	0 .. 20	-
Maximaler Druck **P Max [mbar]**	-	10 .. 35
Flow **Flow [l/min]**	-	2 .. 30
Oscillation frequency **HF Freq [Hz]**	5 .. 20	-
Pressure amplitude, peak - peak **HF Ampl [mbar]**	2 .. 50	-
Inspiration to expiration ratio **I:E**	25:75 .. 50:50	-
O_2 concentration **O_2 [%]**	21 .. 100	21 .. 100
Manual breath time (Inspiration hold) **Maximum manual breath time [sec]** *	2 .. 10	-

* can be configured in the presettings

Safety equipment

Pressure limitation	
mechanical excess pressure valve	P_{limMax} = 100 mbar
Software pressure limitation	> 10 mbar above adjusted Pinsp, emergency air valve opens

Alarm volumes

Volume setting	Sound pressure level measurement according to ISO 3744
minimum alarm volume at 50%	68,7 ± 2 dB (A)
maximum alarm volume at 100%	84,1 ± 2dB (A)
Operating volume	
maximum operating volume (HFO)	65,1 ± 2 dB (A)

The alarm volume is automatically set to 100% in HFO mode. *

NOTICE

* 100% refers here to the maximum alarm volume set in the Service menu.

Complementary values

	IPPV/IMV	S-IPPV	S-IMV
Expiration time **T_{EXP} [sec]**	0.2 .. 9,90	0.2 .. 29.9	0.2 .. 29.9
Inspiration to expiration ratio **I:E**	9:1 .. 1:99	9:1 .. 1:299	9:1 .. 1:299
Volume trigger for detecting spontaneous breathing **Trig Vol [ml]**	-	0 .. 300	0 .. 300

	PSV-SIMV	PSV-SIPPV	CPAP	HFO
Expiration time **T_{EXP} [sec]**	0,2 .. 29.9	0,2 .. 29.9	-	-
Inspiration to expiration ratio **I:E**	9:1 .. 1:299	9:1 .. 1:299	-	-
Volume trigger for detecting spontaneous breathing **Trig Vol [ml]**	0 .. 300	0 .. 300	-	-
Base flow **BaseFlow [L/min]**	-	-	-	7

	nIPPV	S-nIPPV	nCPAP	S-nCPAP
Expiration time **T_{EXP} [sec]**	0,2 .. 29.9	0,2 .. 15	-	-
Inspiration to expiration ratio **I:E**	74:1 .. 1:299	74:1 .. 1:199	-	-
Base flow (Neojet H+L) **BaseFlow [L/min]**	5 .. 20	5 .. 20	6 .. 20	6 .. 20
Base flow (Closed Systems) **BaseFlow [L/min]**	2 .. 8	2 .. 8	2.4 .. 8	2.4 .. 8

	nHFO	HiFlow
Base flow (Neojet H+L) **BaseFlow [L/min]**	15 .. 20	-
Base flow (Closed Systems) **BaseFlow [L/min]**	7	-

Resistance values

Resistance values	
System resistance at 30 l/min	< 20 mbar/l/s
System resistance at 5 l/min	< 12 mbar/l/s
Inspiratory resistance	< 12 mbar/l/s
Expiratory resistance	< 8 mbar/l/s

Accuracy of value display (BTPS*)

Accuracy of value display	
Peak pressure (Ppeak)	
Measurement range	-60 - 100 mbar
Resolution	0.1 mbar
Accuracy	±4 % of set value or 0,5 mbar, greater value is valid
Mean pressure (Pmean)	
Measurement range	-60 - 100 mbar
Resolution	0.1 mbar
Accuracy	±4 % of set value or 0,5 mbar, greater value is valid
Positive endexpiratory pressure (PEEP)	
Measurement range	-60 - 100 mbar
Resolution	0.1 mbar
Accuracy	±4 % of set value or 0,5 mbar, greater value is valid
Minute volume (MV)	
Measurement range	0 – 99.99 l/min
Resolution	10 ml/min
Accuracy	±8 %

* 37°C, ambient pressure, 100% air humidity

Accuracy of value display	
Tidal volume (VTi, VTe)	
Measurement range	0 – 999.9 ml
Resolution	0.1 ml
Accuracy	±8 % of set value or 0,5 mL, greater value is valid
Tube leakage (Leak)	
Measurement range	0; 10 - 100 %
Resolution	1 %
Accuracy	±10 %
Dynamic compliance (Cdyn)	
Measurement range	0 - 100 ml/mbar
Resolution	0.1 ml/mbar
Accuracy	±8 %
Airway resistance (R)	
Measurement range	0 - 1000 mbar/l/s
Resolution	1 mbar/l/s
Accuracy	±8 %
Oxygen concentration (O_2)	
Measurement range	0 - 100 %
Resolution	1 %
Accuracy	±2.5 % (Vol.) Partial pressure compensated measurement

Dimensions and weight

Dimensions / weight	
W x H x D	30.5 cm x 38.5 cm x 39 cm
Weight	20 kg (with Li-ion battery), 22 kg (with Pb battery)
Display	12.1 inch

Operating Data

Operating Data	
Power supply	100 V_{AC} +10% / -15%, 50/60 Hz 240 V_{AC} +10% / -15%, 50/60 Hz
Current consumption for 240 V for 100 V	 0.85 A 2.0 A
Power input	Max. 200 VA
Fuse at 240 V at 100 V	 T2.5A DIN 41571 (2x) T2.5A DIN 41571 (2x)
Protection against electric shock Device Abdomen sensor SpO_2 sensor according to DIN EN 60601-1	 Class I Type B  Type B: = „Body“ applied part for use on body but not on opened heart. Type BF  Type BF = „Body floating“ applied part for use on body but not on opened heart, electrically isolated from protective earth.
Classification according to Council Directive 93/42/EEC Appendix IX	Class II b
IP classification LeoniPlus LeoniPlus transport	 IPX1 Protection against dripping water IPX4 Protection from splashwater

Gas connections

Connections	
Compressed air supply	
Pressure range	2.0 – 6.5 hPa x 1000 (bar)
Quality	Medical grade air, dry, oil and particle free
Oxygen supply	
Pressure range	2.0 – 6.5 hPa x 1000 (bar)
Quality	Medical grade oxygen, dry, oil and particle free

Sensors

Flow sensor	
measurement method	hot-wire anemometry
death spot enlargement	0.6 ml
measurement range	up to 32 l/min
Accuracy	±8 % of the setting value or 0.5 ml, depending on which value is higher
Oxygen sensor	
Type	fuel cell
T0..90	<12s at 1l/min flow
Drift	1% (vol.) /month (without calibration)
SpO_2 sensors	
Masimo LNCS® NeoPt	adhesive, single patient use, <1kg
Masimo LNCS® Neo	adhesive, single patient use, <3kg or >40kg
Masimo LNCS® Inf	adhesive, single patient use, 3-20kg
Abdomen sensor	
measurement method	pressure measurement

Material

Component	
Housing Interior of device Internal tubing	Latex-free

Interfaces

Interfaces	
serial connection COM 1 (RS 232)	HULBUS (serial connection; for sending data to any other unit) *See separate installation instruction!*
serial connection COM 2 (RS 232)	VueLink (serial connection; connection to Phillips VueLink module) *See separate installation instruction*
serial connection SpO_2 (RS 232)	Masimo SpO_2 (serial connection to $uSpO_2$™ Masimo SET® Oximetry module)
Ethernet interface	only for service tasks
USB interface	only to be used for service purposes and for data analysis (monitoring data can be recorded for study purposes).

Environmental conditions

LeoniPlus	
During operation	
Temperature	-10 – 35°C
Air pressure	700 – 1060 hPa
Relative humidity	30 – 90 %, non-condensing
During storage and transport	
Temperature	-20 – 60°C
Air pressure	500 – 1060 hPa
Relative humidity	10 – 90 %, non-condensing
LeoniPlus transport	
During operation	
Temperature	-10 – 45°C
Air pressure	700 – 1060 hPa
Relative humidity	30 – 90 %, non-condensing
During storage and transport	
Temperature	-20 – 60°C
Air pressure	500 – 1060 hPa
Relative humidity	10 – 100 %, non-condensing
Short-term operating conditions (<20min)	
Temperature	-20 – 60°C
Air pressure	700 – 1060 hPa
Relative humidity	10 – 90 %, non-condensing

Device service life

- 8 years

Ventilation filter

Ventilation filter	
Expiration	**PALL BB100**
Internal volume	90 ml
Resistance	approx. 1 cmH_2O at 60 l/min
	Disposable
Filtration	Bacteria/viruses
Separation performance	99,99%
Water permeability	Hydrophobic membrane
	HEPA filter
Connections	ISO 22 mm (OD), ISO 15 mm (ID)
Inspiration	
Internal volume	37 ml
Resistance	0,9 mbar at 30 l/min
Filtration	Bacteria/viruses
Separation performance	99,9%
Connections	22M/15F and 22F/15M
Filtration type	Electrostatic/mechanical filter

Specification of uSpO$_2$™ Masimo SET® Oximetry module

Range	
Saturation (%SpO$_2$)	1 – 100 Vol%
Pulse Rate (bpm)	25 – 240
Perfusion	0.02 – 20 Vol%
Accuracy	
Saturation (% SpO$_2$) – During No Motion Conditions [1]	
Adults, Pediatrics	70 – 100 Vol% ± 2 Vol%
	0 – 69 Vol% unspecified
Neonates	70 – 100 Vol% ± 3 Vol%
	0 – 69 Vol% unspecified
Saturation (%SpO$_2$) – During Motion Conditions [2, 3]	
Adults, Pediatrics [2]	70 – 100 Vol% ± 3 Vol%
	0 – 69 Vol% unspecified
Neonates[3]	70 – 100 Vol% ± 3 Vol%
	0 – 69 Vol% unspecified
Pulse Rate (bpm) – During No Motion Conditions [1]	
Adults, Pediatrics, Neonates	25 to 240 ± 3
Pulse Rate (bpm) – During Motion Conditions [2, 3]	
Adults, Pediatrics, Neonates	25 to 240 ± 5

[1] The Masimo SET® MS board pulse oximeter with LNOP-Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70 – 100 % SpO$_2$ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[2] The Masimo SET® MS board pulse oximeter with LNOP-Adt sensors has been validated for motion accuracy in human blood studies on healthy volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70 – 100 % SpO$_2$ against laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[3] The Masimo SET® MS board pulse oximeter with LNOP-Neo and Neo Pt sensors has been validated for motion and no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70 - 100–% SpO$_2$ against laboratory co-oximeter and ECG monitor. 1 % has been added to the results to account for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Resolution	
Saturation (% SpO2) Pulse Rate (bpm)	1 Vol% 1

Low Perfusion Performance [4]	
> 0.02 % Pulse Amplitude and % Transmission > 5%	Saturation (%SpO_2) ± 2 Vol% Pulse Rate ±3

Interfering Substances	
Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.	

[4] The Masimo SET® MS board pulse oximeter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02 % and a % transmission of greater than 5 % for saturations ranging from 70 to 100 %. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68 % of the population.

Electromagnetic compatibility

Guidelines and Manufacturer's Declaration- Electromagnetic Immunity

LeoniPlus is intended for operation in the electromagnetic environment specified below. The customer or the user of LeoniPlus must ensure that it is used in such an environment.

Electromagnetic environment- Guidelines

Portable, mobile and permanently installed radio devices should not be operated any closer to LeoniPlus including its cables than the recommended protection ratio calculated according to the equation that applies to the transmission frequency.

Guidance and manufacturer's declaration – Electromagnetic immunity			
Radio interference test	**IEC 60601 test level**	**Conformity level**	**Electromagnetic environment – Guidance**
Static electrical discharge acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or furnished with ceramic tiles. If the floor is furnished with synthetic material, the relative air humidity must be at least 30 %.
Bursts acc. to IEC 61000-4-4	± 2 kV for power cables ± 1 kV for input and output cables	± 2 kV for power cables ± 1 kV for input and output cables	The quality of the supply voltage should correspond to that required for a typical business or hospital environment.
Surges acc. to IEC 61000-4-5	± 1 kV normal-mode voltage ± 2 kV common-mode voltage	± 1 kV normal-mode voltage ± 2 kV common-mode voltage	The quality of the supply voltage should correspond to that required for a typical business or hospital environment.
Voltage dips, short interruptions, and fluctuations of the supply voltage according to IEC 61000-4-11	< 5 % U for ½ cycle (> 95 % dip) 40 % U for 5 cycles (60 % dip) 70 % U for 25 cycles (30 % dip) < 5 % U for 5 s (> 95 % dip)	< 5 % U for ½ cycle (> 95 % dip) 40 % U for 5 cycles (60 % dip) 70 % U for 25 cycles (30 % dip) < 5 % U for 5 s (> 95 % dip)	The quality of the supply voltage should correspond to that required for a typical business or hospital environment. The battery life stated in the documentation must be observed.

Guidance and manufacturer's declaration – Electromagnetic immunity			
Radio interference test	**IEC 60601 test level**	**Conformity level**	**Electromagnetic environment – Guidance**
Power-frequency magnetic field (50/60 Hz) acc. to IEC 61000-4-8	3 A/m	3 A/m	Power-frequency magnetic fields should correspond to typical values that prevail in business and hospital environments.
Interference emission test		**Conformity**	**Electromagnetic environment – Guidance**
RF emission acc. to CISPR 11		Class A	LeoniPlus is suitable for use in all environments except residential environments and areas that are directly connected to a public supply network that also supplies buildings used for residential purposes.

Equation for protection distance depending on the transmission frequency			
Radio interference test	**IEC 60601 test level**	**Conformity level**	**Electromagnetic environment – Guidance**
Conducted RF disturbances acc. to IEC 61000-4-6	3 V_{rms} 150 kHz − 80 MHz outside the ISM ranges [a)]	3 Vrms	Recommended protection distance $d = (3.5 / U) \sqrt{P}$
	10 V_{rms} 150 kHz − 80 MHz inside the ISM ranges [a)]	10 Vrms	Recommended protection distance $d = (12 / U) \sqrt{P}$
Radiated RF disturbances acc. to IEC 61000-4-3	10 V/m 80 MHz − 2.5 GHz	10 V/m 80 MHz − 2.5 GHz	Recommended protection distance $d = (12 / E) \sqrt{P}$ for 80 MHz − 800 MHz $d = (23 / E) \sqrt{P}$ for 800 MHz − 2.5 GHz
P = maximum nominal power of the transmitter in watt [W] acc. to data of the transmitter manufacturer *d* = recommended protection distance in meters [m]. [b)]			
COMMENT 1:	In the case of 80 MHz and 800 MHz, the higher frequency range applies		
COMMENT 2:	These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorption and reflection by buildings, objects, and people.		

The field strength of stationary radio transmitters must be lower than the conformity level across all frequencies as determined by an electromagnetic site [c] survey.[d] [e]

Disturbances can occur in the environment of devices that bear this mark.

a) The ISM radio bands (for industrial, scientific, and medical applications) 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 LEVEL in the ISM radio bands between 150 kHz and 80 MHz and in the frequency range between 80 MHz and 2.5 GHz is intended to reduce the probability that mobile/portable communications equipment can cause interference if unintentionally taken into the PATIENT environment. For this reason, the additional factor of 10/3 is applied in the calculation of recommended protection distances in these frequency ranges.

c) The field strength of stationary transmitters, such as, for example, base stations of radiotelephones and land mobile services, amateur stations, AM and FM radio and television transmitters, cannot theoretically be precisely determined. An inspection of the location should be considered to assess the electromagnetic environment resulting from stationary RF transmitters. If the measured field strength at the location in which the LeoniPlus device is used exceeds the compliance level specified above, the LeoniPlus device should be observed to verify normal operation in every installation site. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LeoniPlus device.

d) Above the frequency range 150 kHz to 80MHz, the field strength should be less than 3 V/m.

e) Above the frequency range 430 MHz to 940 MHz, the field strength should be less than 10 V/m.

Protection distance depending on the transmission frequency				
Nominal power of the transmitter [W]	**Protection distance depending on the transmission frequency [m]**			
	150 kHz − 80 MHz outside the ISM ranges	150 kHz − 80 MHz in the ISM ranges	80 MHz – 800 MHz	800 MHz − 2.5 GHz
	$d = 1.16 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.16	1.20	1.20	2.30
2	1.64	1.70	1.70	3.25
10	3.67	3.79	3.79	7.27
100	11.6	12.0	12.0	23.0
For transmitters whose rated output power is not listed in the table above, the protection distance *d* in meters [m] can be estimated using the equation specified in each column, where P is the rated output power of the transmitter in watts [W] according to the transmitter manufacturer.				
COMMENT 1:	In the case of 80 MHz and 800 MHz, the higher frequency range applies			
COMMENT 2:	These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorption and reflection by buildings, objects, and people.			

Scope of delivery

- LeoniPlus ventilator
- Power cord
- Test lung
- User manual
- Short user guide
- Flow sensor + flow sensor cable
- Additional exhalatory valve

Configurations

Ventilation mode HFO

The unit is available with and without HFO (high frequency oscillation). Devices with ventilation mode HFO have "*hfo inside"* printed on the front panel.

LeoniPlus transport

LeoniPlus transport is based on the hardware and software of LeoniPlus. LeoniPlus transport differs in the following respects:

- Display corner protection, cover on the patient part, both red
- Front film with wording LeoniPlus transport
- Splash protection on the ventilation slots
- Power input module/line filter
- All screws are secured with screw locking elements
- Sealing strip between housing sections
- Display mounted in a different way

LeoniPlus transport, unlike LeoniPlus, is approved for mobile use (acc. to DIN 794-3 and RTCO DO-160 F).

Options

SpO_2 *

With option "SpO_2," ongoing monitoring of the saturation of oxygen in the patient during ventilation is possible.

The SpO_2 values are continuously measured via the oximeter cable "uSpO_2™ Masimo SET® Oximetry" connected to the Masimo sensor and displayed as a monitoring value on the LeoniPlus.

* not for LeoniPlus transport

Closed Loop *

With the option “Closed Loop,” pulse-oximetric closed-loop-controlled ventilation is possible.

The ventilation parameter **O_2** is set such that the continuously defined SpO_2 value is within the target range defined by the user.

The option “Closed Loop” includes the option “SpO_2.”

Closed Loop 2.0/emergency control * §

The “emergency control” option expands the “Closed Loop” option with further closed-loop controls in the limit ranges of oxygen saturation (hypoxemia and hyperoxemia).

Neojet H+L

The "Neojet" option extends the application possibilities for the ventilation equipment by the non-invasive variants of ventilation modes CPAP, IPTV and HFO.

The pressure is also maintained by control of the expiration valve in relevant modes nCPAP, nIPPV and nHFO.

Closed Systems

With the option “Closed Systems,” non-invasive ventilation using generators without leak is possible.

HiFlow H+L

The option “HiFlow H+L” allows support of spontaneous ventilation of the patient in the form of O_2 therapy using a suitable nasal cannula.

Abdomen sensor * §

The “abdomen sensor” option expands the NIV with two further types of ventilation S-nCPAP and S-nIPPV with the possibility of non-invasive triggering.

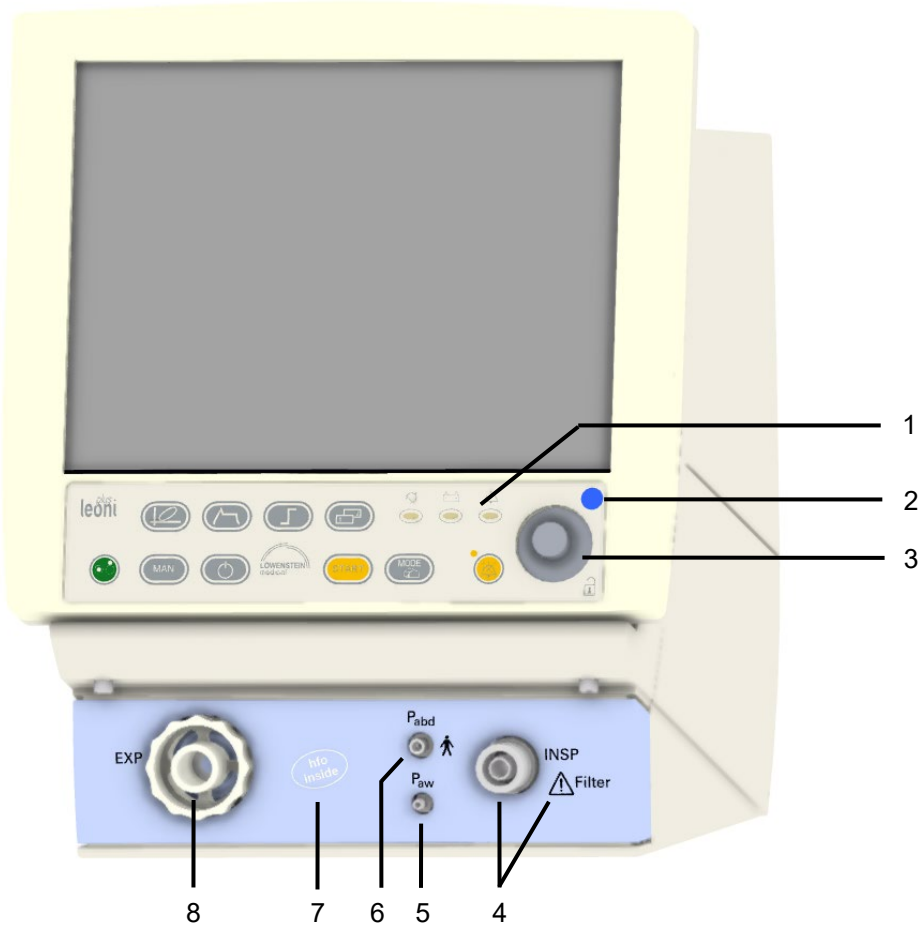
* not for LeoniPlus transport

§ The options Closed Loop 2.0 and abdomen sensor are available as of software version 3.2.x, incl. the relevant descriptions in this User Manual

4. Device Overview

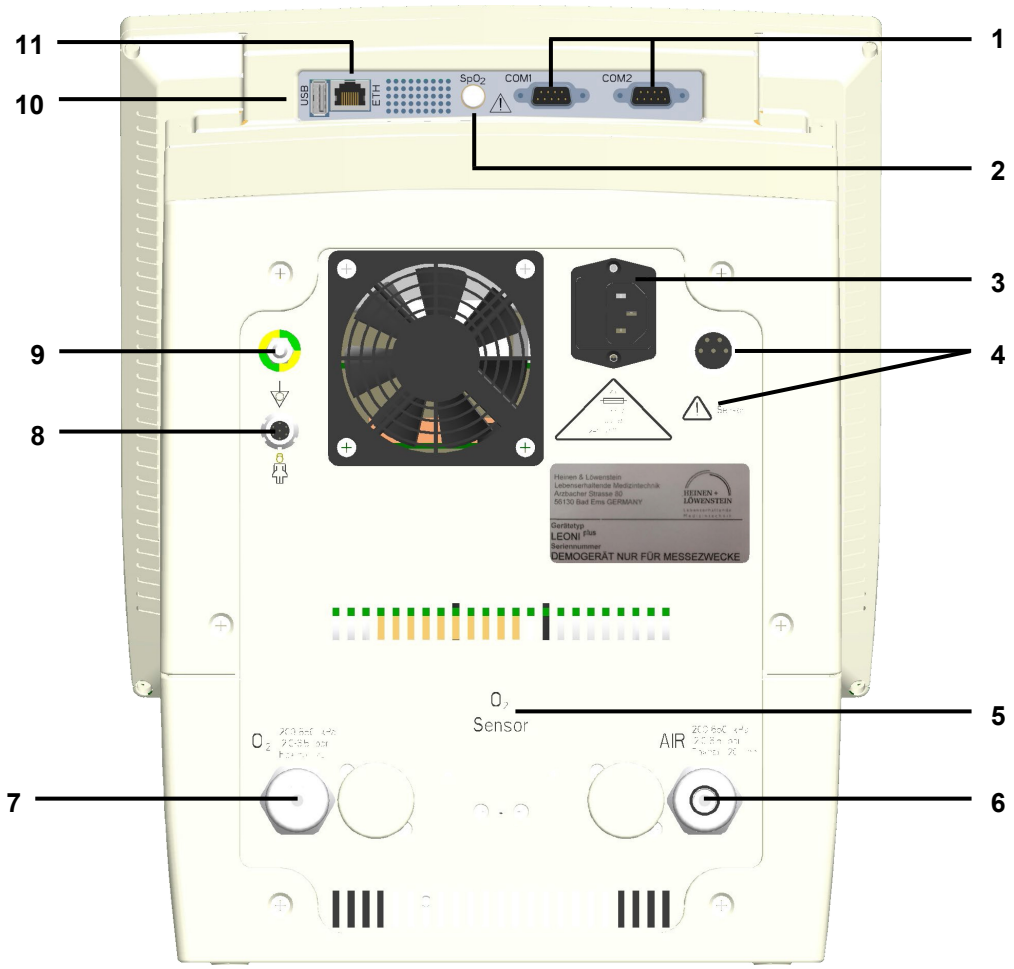
The ventilator

Front of LeoniPlus



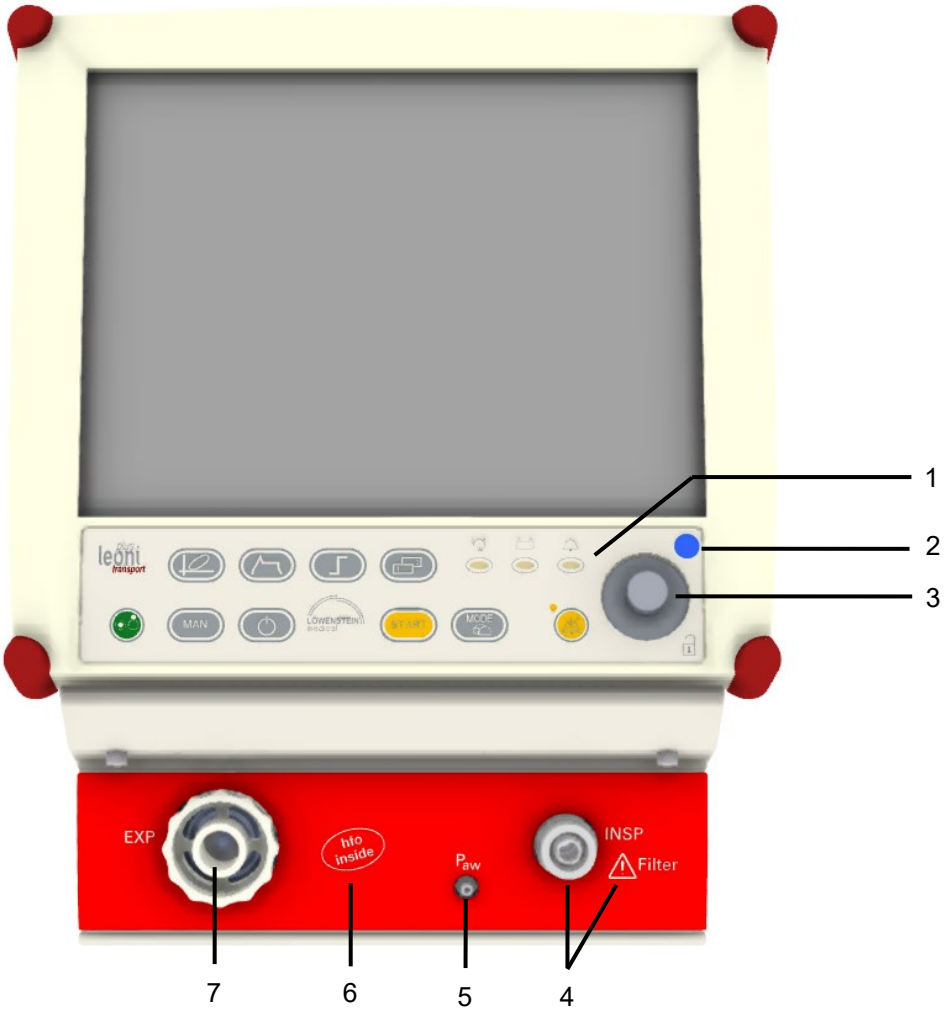
(1) Keypad
(2) Symbol “Read user manual”
(3) Rotary pulse encoder
(4) Inspiration connection, instruction plate "Use filter"
(5) Pressure tube connection
(6) Abdomen sensor connection
(7) Label “*hfo inside*”
(only on devices with ventilation mode HFO)
(8) Expiration connection

Rear of LeoniPlus



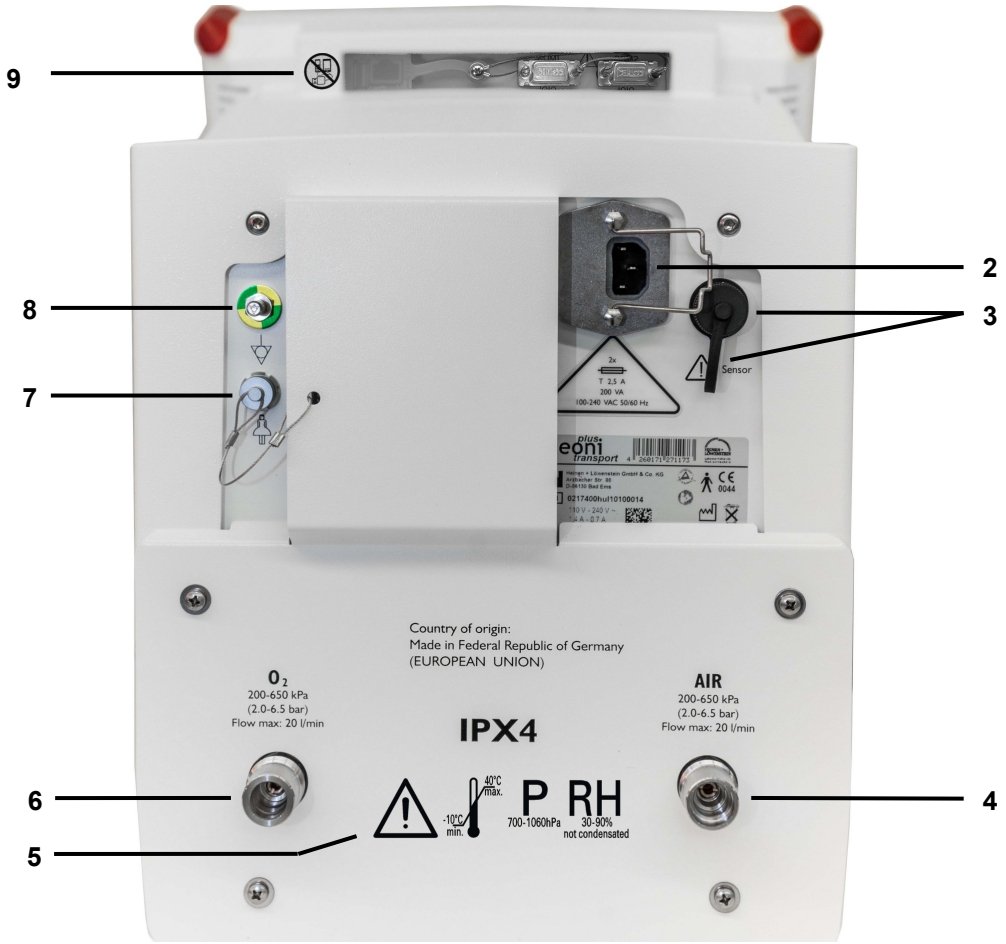
(1) Serial ports (RS232)
(2) SpO_2 sensor connection
(3) Mains power connection (100-240V, AC)
(4) Flow sensor connection, instruction plate "Sensor"
(5) Access to O_2 sensor
(6) Compressed air connection (air)
(7) Oxygen connection (O_2)
(8) Nurse call connector
(9) Earth connection
(10) USB port
(11) Ethernet port

Front of LeoniPlus transport



(1) Keypad
(2) Symbol “Read user manual”
(3) Rotary pulse encoder
(4) Inspiration connection, instruction plate "Use filter"
(5) Pressure tube connection
(6) Label "*hfo inside*"
(7) Expiration connection

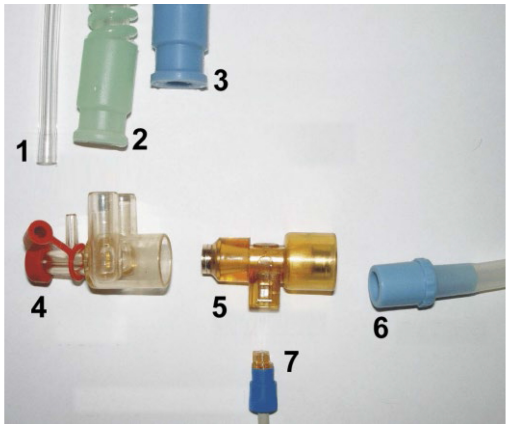
Rear of LeoniPlus transport



(1) Serial ports (RS232)
(2) Mains power connection (100-240V, AC)
(3) Flow sensor connection, instruction plate "Sensor"
(4) Compressed air connection (air)
(5) Instruction plates "Operating conditions"
(6) Oxygen connection (O_2)
(7) Nurse call connector
(8) Earth connection
(9) USB port, instruction plate "Do not connect portables"
(10) Ethernet port

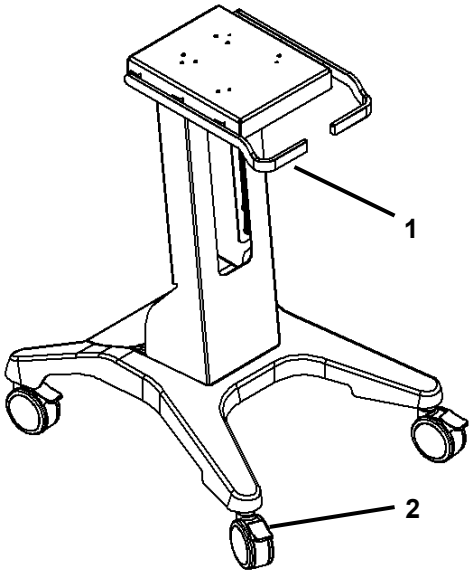
Accessories

For ventilation



(1) Pressure measurement tube
(2) Expiratory tubing
(3) Inspiratory tubing
(4) Y-piece
(5) Flow sensor
(6) Test lung
(7) Flow sensor cable

Mobile stand



(1) Handles
(2) Castor lock levers

Moving the mobile stand:

- Fold any extended mounts with equipment inwards to prevent collisions with other equipment, walls, doorways, and patients or personnel.
- Move the mobile stand by hand.

Only use the designated handles (1) for moving the mobile stand.

Parking the mobile stand:

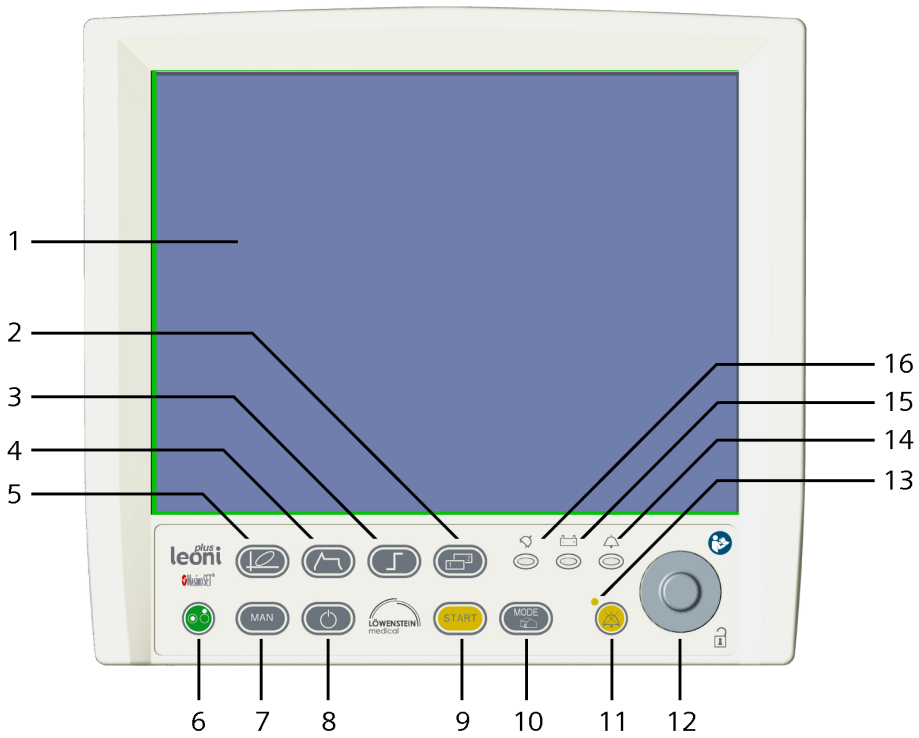
- Always lock the wheels by pressing the castor lock levers downward (2) when the mobile stand is not in use.

Cleaning and disinfecting the mobile stand:

→ *Cleaning the mobile stand P. 175*

Control panel and display

Control panel



(1) Monitor
with integrated touchscreen.

(2) Monitoring
alternates between the two numeric tables
In the start screen: toggles between the menu items and menu bar.

(3) Alarm limit values
Opens and closes the alarm limit values window.

(4) Charts
Opens the chart window.

(5) Loops
Opens and closes the loop window.

(6) ON / OFF / Start screen
Switches the unit on/off and opens the start screen.

(7) Manual breath (Inspiration hold)
Triggers a manual breath.

(8) Pause
Starts a ventilation pause.

(9) Start
Starts ventilation.

(10) Mode
Positions the selection frame on the ventilation modes.

(11) Alarm mute
Acknowledges or mutes alarms.

(12) Rotary pulse encoder
The rotary pulse encoder combines a pushbutton and a dial knob. The lock symbol indicates the safety function that prevents parameters from being changed by unintentional rotation of the rotary pulse encoder. A change is only applied after final confirmation.

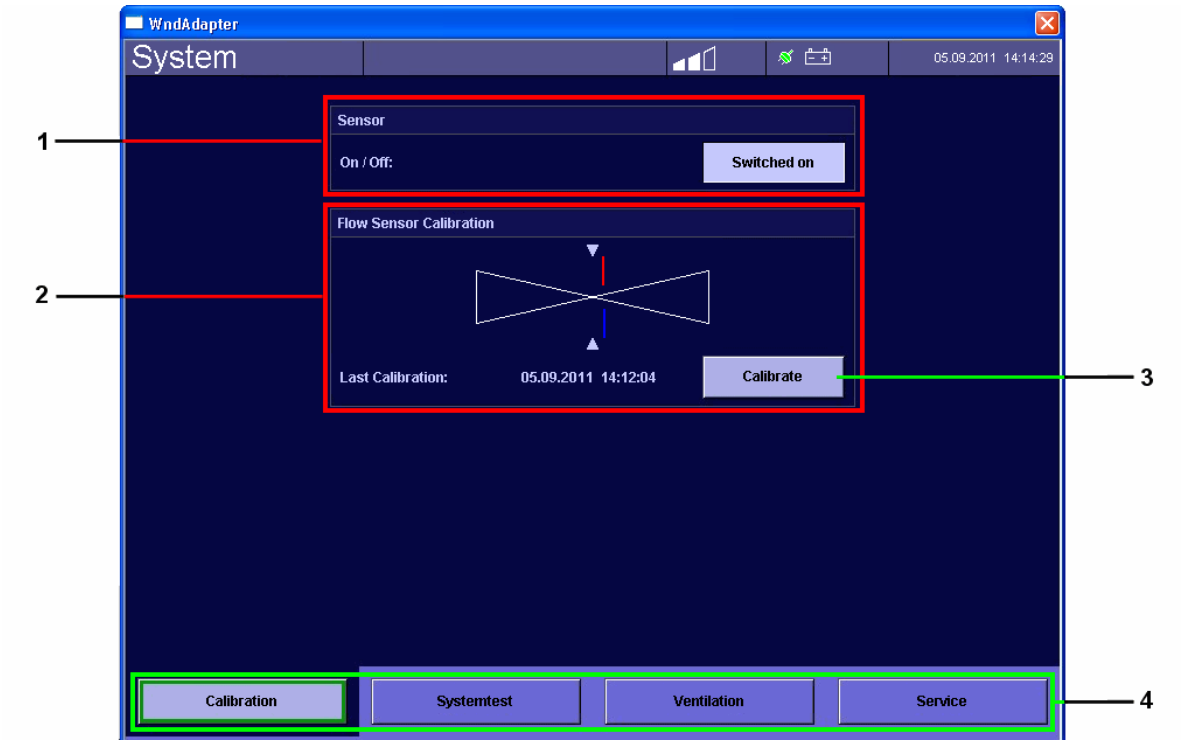
(13) Alarm mute LED
Yellow lamp indicator on as long as acoustic alarm is muted.

(14) Alarm LED
Lights up red when an alarm is triggered.

(15) Battery LED
Lights ups yellow during battery operation.

(16) Mains LED
Lights up green during mains operation.

Start screen



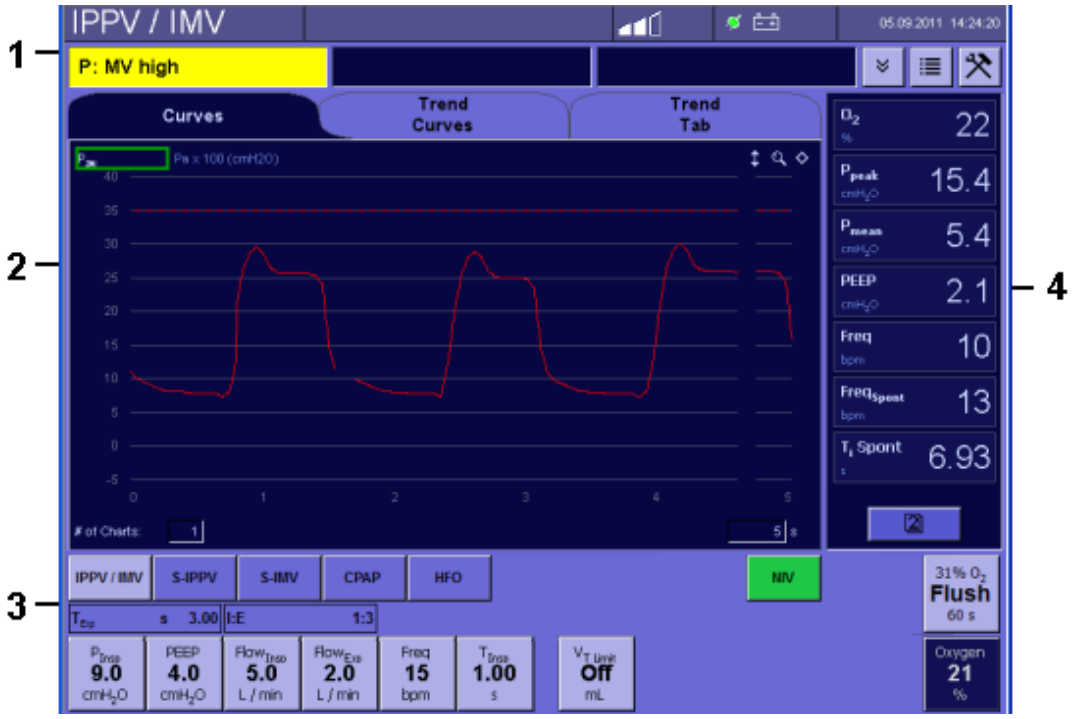
(1) Sensor
Permits switch-on/switch-off of the flow sensor

(2) Flow Sensor Calibration
Shows the accuracy and time of calibration

(3) Calibration buttons
Starts calibration of the flow sensor

(4) Menu bar
Allows direct selection of a submenu

Main display



(1) Alarm bar
Displays active alarms.

(2) Chart monitor
Displays real-time charts.

(3) Ventilation modes / ventilation parameters
Ventilation modes with current ventilation parameters and complimentary values.

(4) Monitoring
Numeric display of measured ventilation values.

5. Operating the Unit

You can operate the unit in various ways: via the integrated touchscreen, the rotary pulse encoder, the hard keys, or a combination of these elements. You can also operate the unit exclusively with the rotary pulse encoder and the hard keys.

WARNING

Muted alarms!

Danger of insufficient oxygen supply

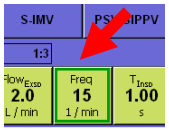
The alarm function is muted for 30 seconds every time the ventilation mode is changed.

- Monitor the breathing while the alarms are muted.

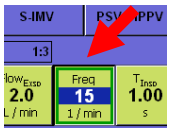
Operating the rotary pulse encoder

You can operate all menus, parameters and screen buttons with the rotary pulse encoder.

Changing parameter values with the rotary pulse encoder

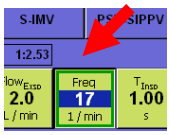


1. Rotate the rotary pulse encoder to highlight the desired parameter with the green frame.



2. Press the rotary pulse encoder to edit the parameter.

The parameter now has a coloured background.



3. Turn the rotary pulse encoder to change the parameter value.

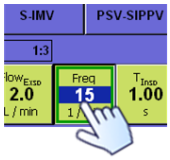
4. Press the rotary pulse encoder to accept the value.

Automatically reset to the initial value if not operated for 1 minute.

Operation via the touchscreen

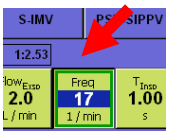
You can operate all the menus and action fields by pressing the relevant parts of the touchscreen.

Changing parameter values via touchscreen

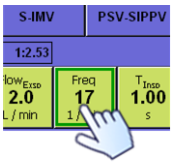


1. Press one of the parameters on the screen in order to edit it.

The parameter now has a coloured background.



2. Turn the rotary pulse encoder to change the parameter value.



3. Press the selected parameter on the screen to accept the value.

*Press anywhere outside the parameter or on another parameter to **reject** the changed value and retain the original value.*

Automatically reset to the initial value if not operated for 1 minute.

Hard keys

The hard keys can be used to operate the device more easily and faster and to support the user during operation.

Overview of hard keys

Loops

- Open the loop window
- Place a selection frame in the loop window
- Close the loop window

Charts

- Display the charts window
- Place a selection frame in the chart window

Alarm limit values

- Open the alarm limit values window
- Place a selection frame in the alarm limit values window
- Close the alarm limit values window

Monitoring

- Toggle between the two numeric tables
- Place a selection frame in the monitoring window
- On the start screen: changes between the items *Calibration*, *System test*, *Ventilation*, and *Service* of the menu bar.
- In standby: displays the start screen and changes between the items *Calibration*, *System test*, *Ventilation*, and *Service* of the menu bar.

On/Off

- Switch on device
- Stop ventilation, switch to the start screen
- Switch off device

Manual breath (Inspiration hold)

- Trigger manual breath
- Stop active manual breath

Pause

- Start ventilation pause

Start

- Start ventilation
- Confirm change of ventilation mode
- Stop pause early

Mode

- Place selection frame on ventilation modes/ventilation parameters

Mute alarms

- Switch alarms to mute
- Confirm info alarms

6. Commissioning

CAUTION

Poor hygiene!

Danger of infection

- Prepare the device and the tube system before first use and after every change of patient.

Installations

All installation work with the exception of the tasks described below may only be performed by specialist personnel who have been trained by us.

The device is operated with a separate display (optional) *

!

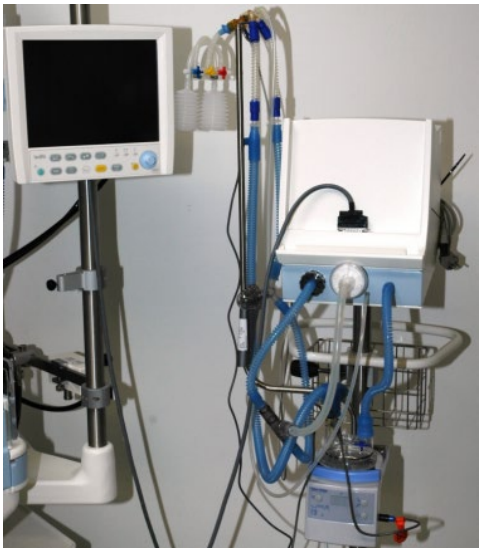
NOTICE

Incorrect mounting of the display!

Damage to the device by splashwater

- Mount the display tilted slightly backward. It must not be tilted forward; at most it must be installed in the vertical position.
- The display may only be replaced by an authorized technician because the display and device are specifically adapted to each other.

* not for LeoniPlus transport



The display and device are connected to each other via a data cable.

For this option, only the cable supplied must ever be used.

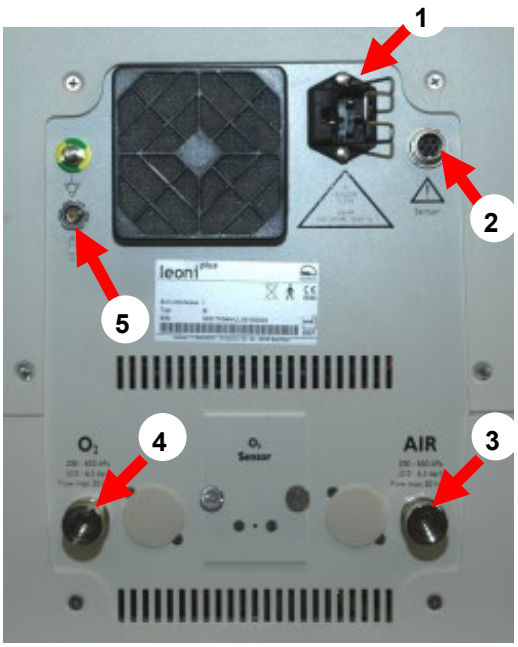
Connecting supply lines (power, gas)

WARNUNG

Connector without protective conductor!

Danger of electric shock

- Only connect the device to a supply network with protective conductor.



Use only the Löwenstein Medical power connection cable.

→ *Other accessories/spare parts P.203*

1. Connect the power cable to the device and to a suitable mains power socket.

   The device can be operated at 100 VAC to 240 VAC and it automatically adapts to the current voltage. A manual adjustment is not required.

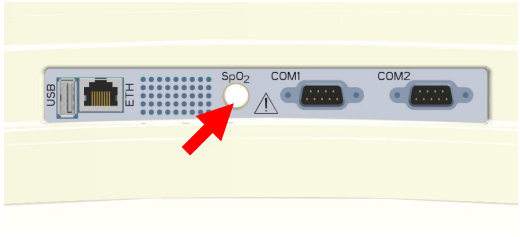
2. Connect the flow sensor.

A supply pressure of 2.0 to 6.5 kPa x 100 (bar) is required.
The inputs are coded to prevent confusion.

3. Connect the compressed air tubing.
4. Connect the oxygen tubing.
5. If one exists, connect the nurse call cable.

6. In order to establish equipotential bonding, join a designated connection point at the installation position to the equipotential bonding point provided on the device using a suitable conductor (equipotential bonding cable H+L product no. 0170501).
This additional equipotential bonding serves to compensate differences in potential between different metal parts which can be touched at the same time, thus protecting the patient, users and third parties against contact voltages.

Connecting the SpO_2 sensor*



1. Connect the uSpO$_2$™ Masimo SET® Oximetry cable to the SpO_2 socket..
2. Connect the SpO_2 sensor.

To connect the sensor on the uSpO$_2$™ Masimo SET® Oximetry cable and on the patient, refer to the separate operating instructions for the sensor.

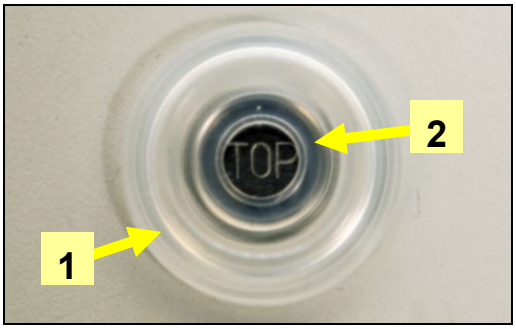
Attaching the expiration valve membrane

Installation of the exhalation valve membrane backwards

Device malfunction

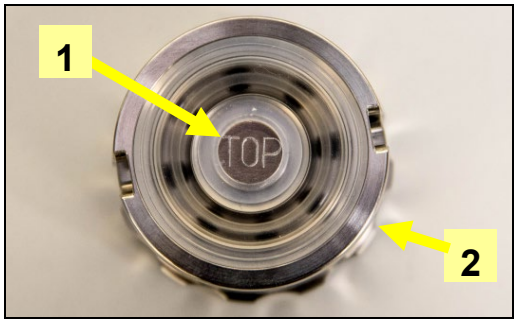
- Make sure that the membrane is correctly aligned: **TOP** is up.
- Always check that the membrane operates correctly immediately after installation!

NOTICE



1. Check if there is a metal disk (2) in the middle of the exhalation valve membrane (1).

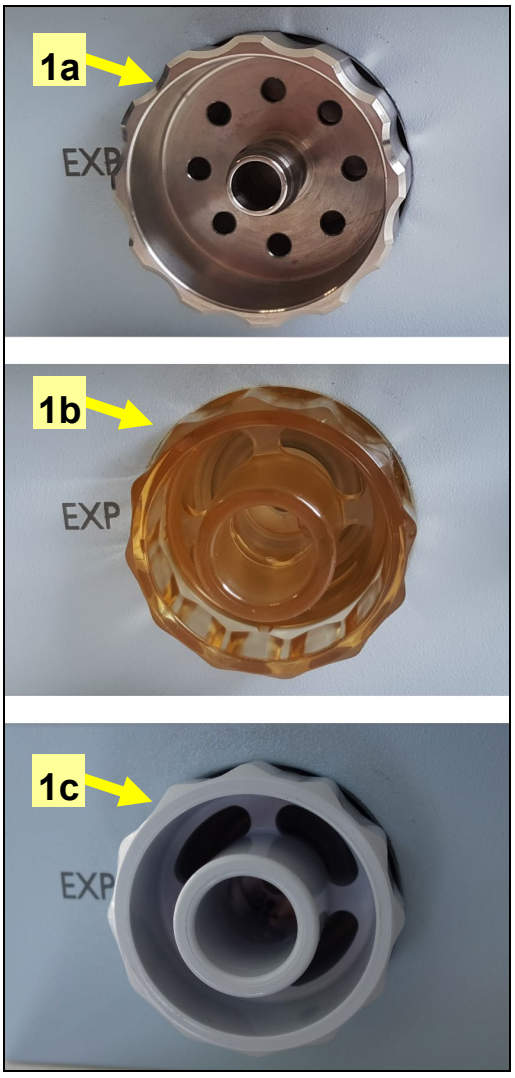
* not for LeoniPlus transport



2. Insert the membrane (1) into the membrane holder (2).

The top of the membrane is marked "TOP".

3. Tap on the label "TOP". You should hear a "Click".



4. Insert the exhalation valve (1) in the device and fasten by turning it slightly clockwise (to the stop).

Figure above: VA expiration valve (1a)

Figure center: Plastic expiration valve set, disposable (1b)

Figure below: Plastic expiration valve set, reusable (1c)

NOTE

If the new plastic expiration valves are used, the devices must be calibrated with these valves. Combined use of metal and plastic valves should be avoided as this can adversely affect the performance of the system.

Calibration must always be performed by a trained technician. Please contact service!

5. Check that the membrane operates correctly.

→ *System test – Function tests P. 68*

Connecting the tubing system

WARNING

Non-approved accessories!

Patient hazard
Danger from low pressure

- Use approved accessories only.

WARNING

Tubing system without inspiratory bacteria filter!

Infection of subsequent patient
Contamination of the device

- Always use a bacteria filter at the inspiratory connector.

CAUTION

HFO and nHFO with wrong tube system!

Danger for patient
Danger of too high pressure

- Use only tube systems without a non-return valve for HFO and nHFO ventilation modes.

!

NOTICE

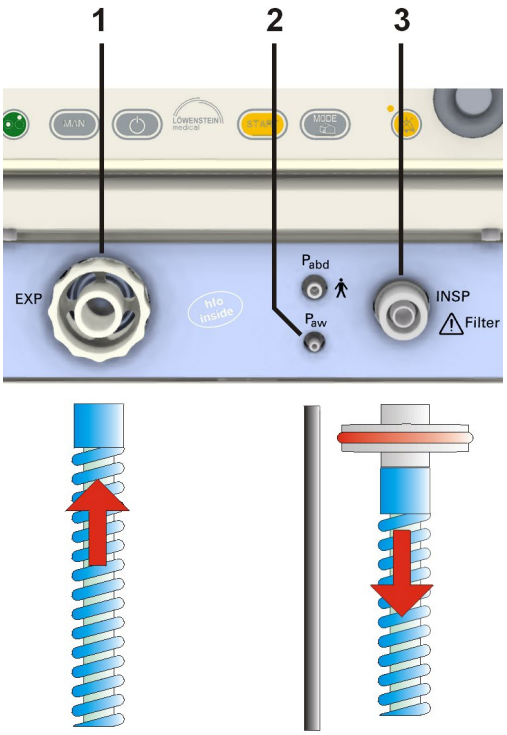
Careless connection and disconnection of tubing!

Damage to tubing

- Always grip tubing by the connector to connect and disconnect it. Otherwise it may be damaged.

Connections on the device side

Connection for all ventilation modes



1. Connect the exhalatory tube to (1).
2. Connect the pressure measurement tube to (2).

For NIV ventilation modes: Connect the pressure measurement tube adaptation set.

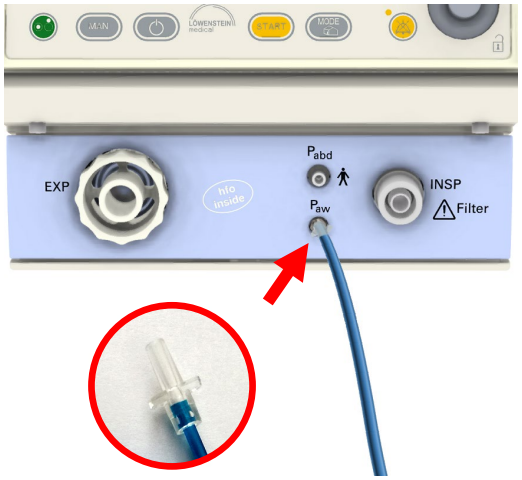
3. Connect the inspiration tube via the bacteria filter to (3).

   Connect only tube systems without a non-return valve for HFO and nHFO ventilation modes.

Always use a bacteria filter on the inspiration side to rule out contamination of the device and possible infection of subsequent patients.

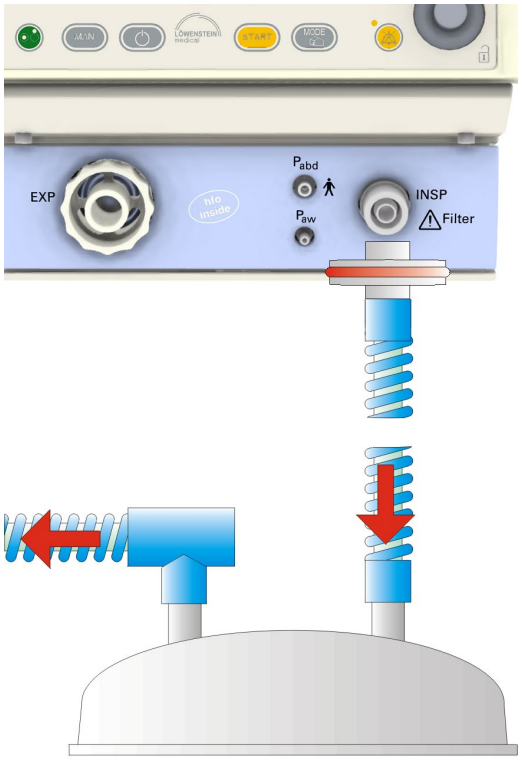
If the HFO is contaminated after performing HFO and nHFO ventilation without a bacteria filter, the HFO must be conditioned. This task cannot be performed by the user. Please contact the relevant service personnel.

Connection for abdomen sensor (device side)



1. If the optional abdomen sensor is used, connect the blue tube.

Connecting the respiratory humidifier



1. *Follow the manufacturer's directions in the next step:*
   Prepare the respiratory humidifier and connect it to the tubing system.
2. If the respiratory gas humidifier only has an inspiration tube heater: mount a water trap on the expiration side.
3. If the respiratory humidifier does not have an inspiratory heater:
   install water traps in the inspiratory and expiratory tubing.

Make sure that the flow sensor is not exposed to excessive moisture.

Caution during nebulization

If filters that are unsuitable for nebulization are used in the expiration side, they may become blocked, resulting in a significant increase in the flow resistance and ventilation hindrance. On the other hand, dispensing with the filters in the case of clouding with higher NaCl concentrations (e.g. 3%) results in increased salt deposits in the hose system and in the expiration valve.

- Remove the flow sensor before performing nebulization.
- Only use the filter PALL BB100, which is suitable for nebulization, in the ventilation tubing system of the patient. Regularly check the filter for increased resistance and blockages.
- To prevent the expiratory valve from sticking due to the use of nebulized medications, you must only use medications that are approved for nebulization.
- Regularly inspect and clean the expiratory valve.
- Remember that the precision of the ventilation device might be impaired by the gas introduced by the nebulizer.

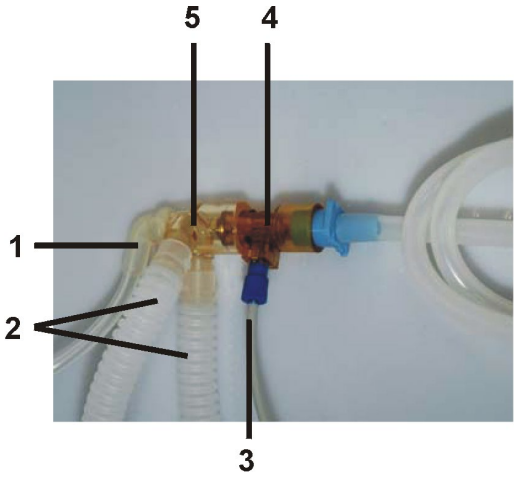
Using water chambers with HFO

In the case of large water chambers, the compressible volume is very large and the output of HFO is reduced.

- For very large amplitudes (above 80 mbar) use an infant water chamber to utilise the full output of HFO.

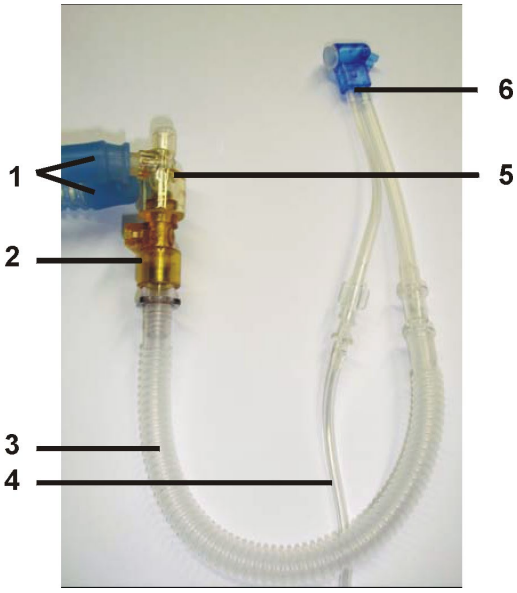
Connections on the patient side

Connection for all IV ventilation modes (patient side)

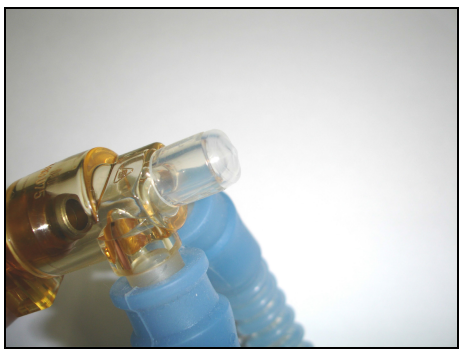


1. Connect the following to the Y-piece (5):
   - Pressure tube (1)
   - Inspiratory/expiratory tubes (2)
   - Flow sensor (4)
2. Connect the flow sensor cable (3) to the flow sensor (4).
3. Connect the test lung to the flow sensor.

Connection for NIV ventilation modes, Neojet H+L (patient side)

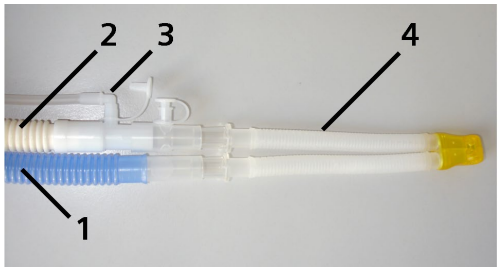


1. Connect the following to the nCPAP generator (6):
   - Ventilation tube adaptation set (3)
   - Pressure measurement tube adaptation set (4)
2. Connect the following to the Y-piece (5):
   - Inspiratory/expiratory tubes (1)
   - Flow sensor (2) with ventilation tube adaptation set (3)
     OR
     only breathing tube adaptation set (3)



3. Close the conventional connection of the pressure measurement tube at the Y-piece using the supplied plug.

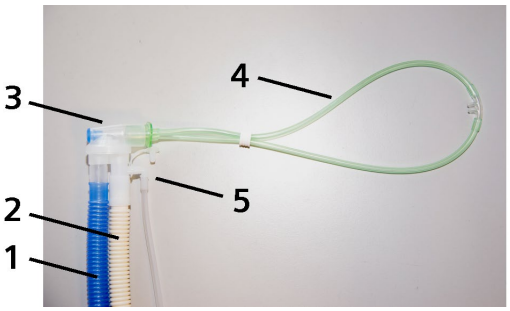
Connection for NIV ventilation modes, closed systems (patient side)



1. Connect the following directly to the closed NIV generator (4):
   - Inspiratory tube (1)
   - Expiratory tube (2)
2. Connect the pressure measurement tube (3) to the expiratory tube (2).

In some tube systems, an adapter must be used, which is included with the tube set.

Connection for NIV ventilation, HiFlow H+L (patient side)



1. Connect the following to the Y-piece (3):
   - Inspiratory tube (1)
   - Expiratory tube (2)
   - HiFlow nasal cannula (4)
2. Connect the pressure measurement tube (5) to the expiratory tube (2).

Connection for abdomen sensor (patient side)

For attachment of the abdomen sensor to the patient, see *Connecting the abdomen sensor P. 128.*

Switching on

Switching the device on

When all preparations for operation have been completed, the ventilator can be switched on.

WARNING

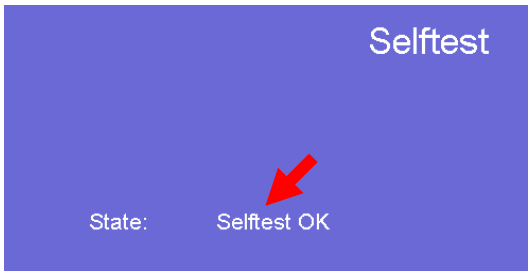
Alarms at system start: Malfunctioning of the device!

Death or permanent injury to the patient

- Check that no alarms were triggered when starting the ventilator.

1. Switch on the ventilator with the **On/Off** switch.

When the ventilator starts up the start screen is displayed, during which the device runs a system self-test routine.



2. Check the status.

If a value other than `Selftest OK` is displayed, do not continue to use the device. In this case consult a specialist who has been trained by us.

After a successful self-test, the device performs a system test. If errors are found, the system test screen will be displayed, showing the results and providing help with correcting the errors.

→ *System test – device status P. 68*

CAUTION

In long-term service the state of the device is seldom examined!

Deteriorating health of the patient

- Switch off the device after each change of patient and after each conditioning and then on again in order for the device to have the device examined by means of a self-test.

7. Preparing ventilation

Calibration

O_2 sensor calibration and flow sensor calibration can also be performed while ventilation is running.

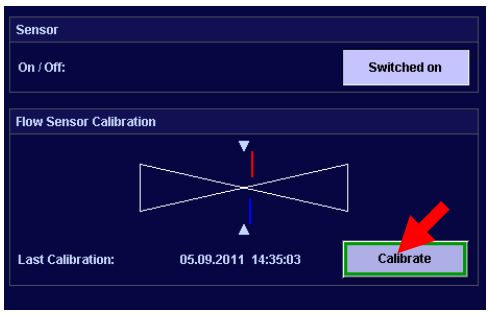
Calibrating the flow sensor

WARNING

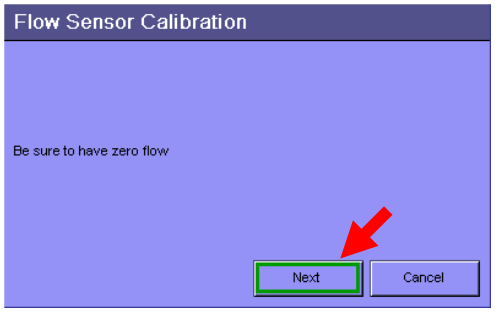
Malfunction of sensors!

Danger of insufficient or excessive oxygen supply

- Calibrate the flow sensor regularly:
  - every time the device is switched on
  - after every sensor change

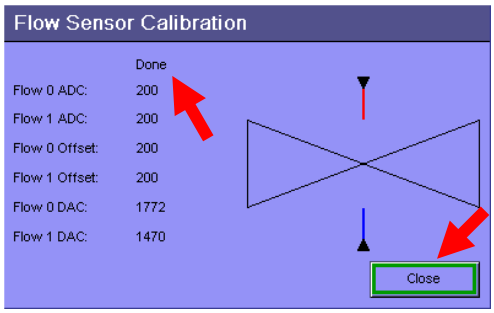


1. Select the **Calibration** menu on the Start screen.
2. In the **Flow Sensor Calibration** window press the **Calibrate** button.



3. Make sure that there is no flow.

   Press **Next.**



4. A status window opens.

   Wait until the **Done** status appears.

5. Press **Close** to exit calibration.

*Press **Cancel** to stop the procedure and the data remain unchanged.*

Calibrating the flow sensor during ventilation

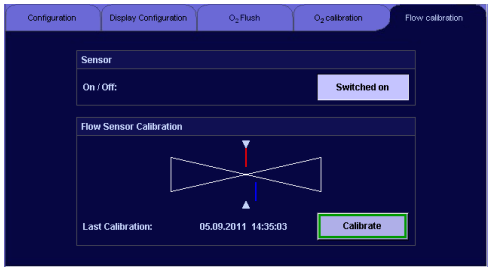
WARNING

Stopping ventilation during flow sensor calibration!

Danger of lung damage

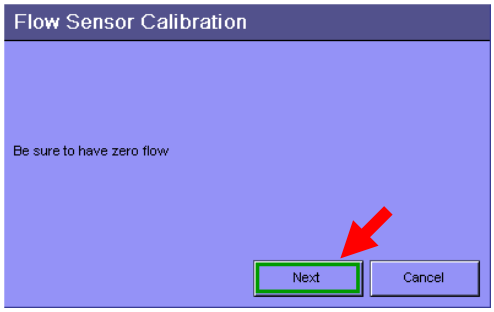
- Use an alternative ventilation system (e.g. manual resuscitator) when performing calibration.

1. Select the **Settings** menu on the Ventilation screen.



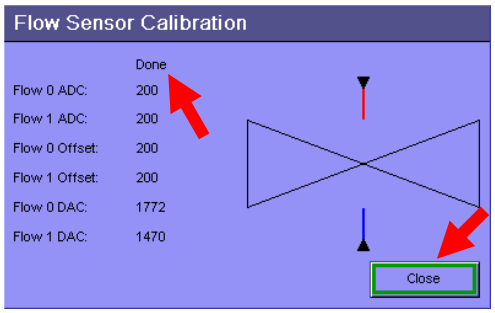
2. Select the **Flow calibration** tab card.
3. Press the **Calibrate** button.

   The acoustic alarm is suppressed.



4. Disconnect the flow sensor from the tube system.
5. Make sure there is no flow.

   Press **Next**.



6. A status window opens.

Wait until the status **Done** is displayed.

An audible signal is output to indicate that calibration is complete and ventilation restarts.

Press **Close** to end calibration.

The system returns to the ventilation mode active before calibration.

*Pressing **Cancel** cancels the action without changing the calibration data.*

The flow sensor can be replaced without deactivating the device.

→ *Replacing the flow sensor P. 188*

Calibrating the O_2 sensor

WARNING

Malfunction of sensors!

Danger of insufficient or excessive oxygen supply

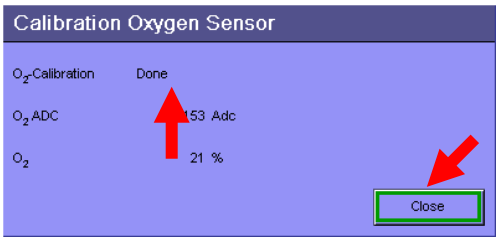
- Calibrate the O_2 sensors regularly:
- after every sensor change

The O_2 sensor is automatically calibrated each time the device is started (after 10 minutes, after 30 minutes, after 1 hour and after 6 hours) and every 24 hours. Calibration is automatically activated if no action has been performed by the user for over 5 minutes.

If the measured O_2 values deviate from the set O_2 concentrations, calibration can additionally be performed manually.

1. Select the **Settings** menu on the Ventilation screen.

2. Select the **O_2 calibration** tab card.
3. Press the **Calibrate** button.



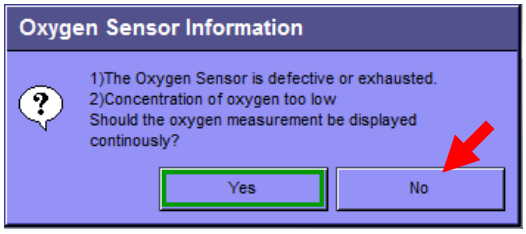
4. A status window shows you how calibration is progressing.

   Wait until the **Done** status appears.
5. Press **Close** to exit calibration.

*Press **Cancel** to stop the procedure and the calibration data remain unchanged.*

O_2 sensor defective

If the sensor is defective, you can deactivate the O_2 sensor in the message box that is displayed.



1. Press **No** to switch the O_2 sensor off.

   The value "-" will be shown for O_2 in the value display.
2. Replace the O_2 sensor.

   → *Replacing the O_2 sensor P. 189*

*Press **Yes** if you wish to continue displaying the O_2 measurement. However, the measured values may be incorrect.*

Device check

WARNING

Device malfunctions!

Death or permanent injury to the patient

- A device check must be conducted before every use of the ventilator.

Perform the following steps:

- Check the connections and error-free device starting using the device checklist.
- Check the device status in the system test and function tests.
- Perform checks before commissioning

For more information on the device check see the short instructions on the device.

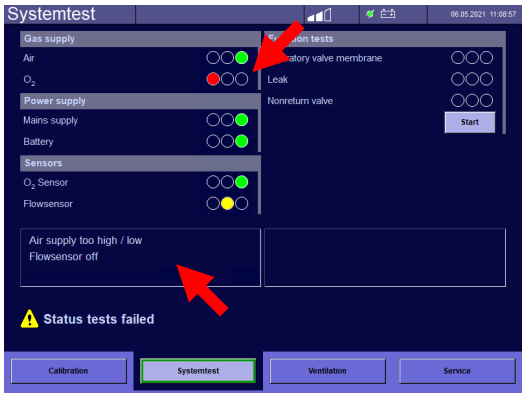
Device checklist

Test	Description	Passed Yes	Passed No
System status	`State = Selftest Ok`? → *Switching on P. 62*		
Gas supply	Compressed air and oxygen tubing tightly attached		
Ventilation system	Expiratory valve is tight		
	Ventilation tubing complete		
	Water traps at lowest point in vertical position		
	Flow sensor correctly connected		
	Test lung connected		
Sensor function	Calibration of O_2 sensor (automatic)		
	Calibration of flow sensor		

System test – device status

While the device is operating, a status test of the connections and sensors regularly runs in the background. You can display the current results, e.g. after alarms, on the system test screen.

*If the status test fails during device start-up, the system test will be displayed automatically. Access to the menu bar of the start screen is blocked. If you do not correct the error, you can only release the menu bar by clicking the **Continue anyway** button, which is displayed in such cases.*

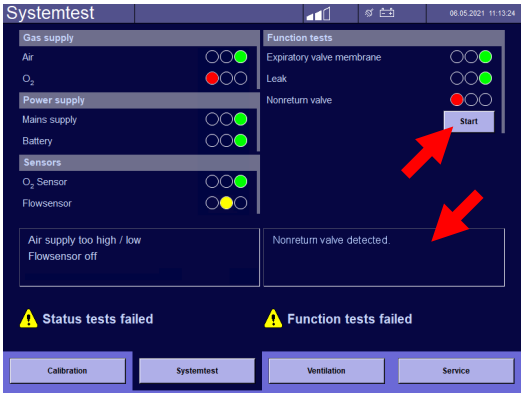


1. Select the **Systemtest** menu on the Start screen.
2. Check the status traffic lights in the left half of the screen.
   - *Green*: Status correct
   - *Yellow*: Status not correct Check the cause and correct it if necessary
   - *Red*: Status not correct Correct the error before continuing
3. Examine and correct errors that have occurred using the help text shown in the lower area and the device checklist.

System test – Function tests

The function tests are started manually. They include a function test of the expiration valve, a leakage test of the complete installed tube system as well as a test that no non-return valve is inserted in the tube system or on the humidifier chamber.

1. Select the **Systemtest** menu on the Start screen.
2. Connect a complete tubing system and test lung.



3. Press the **Start** button.
4. Confirm the safety query that all components are connected properly.

   The function test (expiration valve) is started first, followed by a leakage test and the non-return valve test. The status lights on the right-hand side of the screen show the results.
5. Examine and correct errors that have occurred using the help text shown in the lower area.

   If the non-return valve test fails, check whether a non-return valve is inserted in the tube system or on the humidifier chamber. Remove it or replace the tube system.

   If a function test is passed, the traffic light is green.

If a function test is failed, ventilation can only be started by acknowledging the message "Warning function tests", which is then displayed.

Checking the alarm for partial blockage

The device has two pressure sensors located at two different positions. In this way, a blockage on the exhalation side can be detected.

1. Disconnect the exhalation tube.
2. The error message "Excess pressure Exsp. Tube" must be displayed.

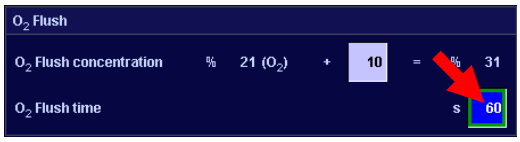
Checks before commissioning

→ *Performing checks before commissioning P. 214*

Settings

Setting O_2 flush time

1. Select the **Settings** menu on the Ventilation screen.
2. Select the **O_2 Flush** tab card.



3. Select the **O_2 Flush time** parameter field.
4. Select the desired flush time.

Setting O_2 flush concentration

1. Select the **Settings** menu on the Ventilation screen.
2. Select the **O_2 Flush** tab card.

3. Select the **O_2 Flush concentration** parameter field.

There are two setting methods by which the O_2 flush concentration (in percent) can be defined:
O_2 value x 1.1 ≤ 100 %
O_2 value + min. 2% ≤ 100 %

4. Select the desired flush concentration.

Setting the maximum manual breath time (Inspiration hold)

1. Select the **Settings** menu on the Ventilation screen.
2. Select the **Configuration** tab card.

3. Select the **Maximum Manual Breath Time** parameter field.
4. Select the maximum manual expiratory impulse time.

!

NOTICE

If an inspiration pressure greater than 30 mbar is chosen for ventilation, the manual expiratory impulse time will be limited to 5 seconds. This also applies if a greater maximum manual expiratory impulse time as been selected.

Setting insp./exp. flow equal

1. Select the **Settings** menu on the Ventilation screen.
2. Select the **Configuration** tab card.

3. Select the **Insp./Exp. Flow equal** parameter field.
4. Select the desired function.

*The **inspiration flow** parameter is not available in all ventilation modes.*

Setting SpO_2 monitoring*

The oximeter cable with sensor must be connected to the LeoniPlus.

1. Select the **Settings** menu on the Ventilation screen.
2. Select the **SpO_2** tab card.

3. Select the **SpO_2 sensor** parameter field.
4. Activate or deactivate the function.

If activated, SpO_2 and pulse rates can be represented as a trend curve during monitoring.

Setting Closed Loop*

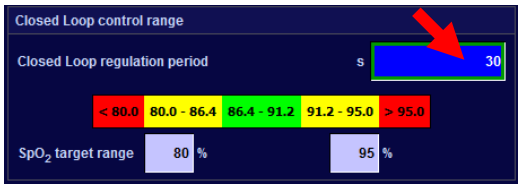
The SpO_2 sensor must be switched on.

1. Select the **Settings** menu on the Ventilation screen.
2. Select the **SpO_2** tab card.

3. Select the **Closed Loop** parameter field.
4. Activate or deactivate the function.

After the function has been activated, the input fields for the Closed Loop control range are displayed.

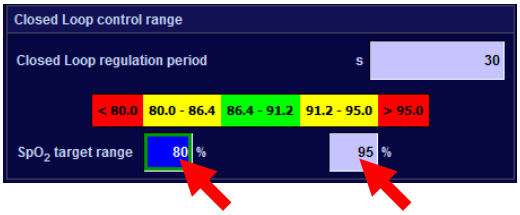
5. Select the **Closed Loop regulation period** parameter field.



6. Set the desired time (range: 30 - 180 sec. in steps of 15 sec.).

The Closed Loop regulation period can be defined as fixed default in Service ranging from 30 to 180 sec. In this case, the defined value is displayed and cannot be changed..

* not for LeoniPlus transport



7. Set the lower and upper limit for the SpO_2 target range (max. range: 80.0 – 100.0%).

*During ventilation, parameter **O_2** is automatically adjusted to regulate oxygen saturation to the target range.*

*The setting of the **SpO_2** therapy range is divided into three fields yellow - green – yellow and weighting is applied to the range in relation to the hemoglobin saturation curve.*

Setting display brightness

1. Select the **Settings** menu on the Ventilation screen.
2. Select the **Display Configuration** tab card

3. Select **Brightness**.
4. Select the desired brightness.

Setting nightmode

1. Select the **Settings** menu on the Ventilation screen.
2. Select the **Display Configuration** tab card.

3. Select **Nightmode**.
4. Activate or deactivate the function.
5. If the function is activated: Select the desired **Nightmode Brightness**.

If nightmode is activated, the display will be dimmed after 1 minute if no user inputs are made. For alarms or device operation, the display is reset to normal brightness.

Configuration of alarm presets

VORSICHT

The use of different alarm presets on devices in one station (e.g. tone, delay time) can lead to misunderstandings.

Alarm conditions might not be recognized.

- Have all the devices in your station configured with the same presets..

1. The alarm presets are configured in the Service menu and are only to be performed by authorized, qualified personnel. All modifications are to be recorded in the event log.

Please contact your service engineer for modifications to the alarm presets.

2. The following presets are configurable:
   - Minimum and maximum volume
   - Different tone sequences for alarms with high priority (red) and medium priority (amber)
   - Trigger delay for specific alarms
3. The minimum and maximum volume values are used to automatically adjust the alarm volume depending on the selected ambient noise level.

An icon in the upper window bar on the screen indicates if values other than the default alarm sequences have been configured.

The icon is not displayed for default settings or muted alarm.

VORSICHT

An acoustic alarm might not be heard in a noisy environment if the alarm volume is set to low.

Alarm conditions might not be recognized.

- Have the alarm presets coordinated to the local ambient conditions.
- Select the appropriate environmental sound level to adequately adapt the acoustic alarm to the ambient noise level.

Setting the environmental sound level

Selection of the environmental sound level achieves a qualitative adjustment of alarm volume to the ambient noise level for the device.

1. Select the **Settings** menu on the Ventilation screen.
2. Select the **Configuration** tab card.

3. Select the **Environmental Sound Level** parameters field.

4. Select the appropriate noise level for the location of the device.
   - **Low**
   - **Medium**
   - **High**

When a key is selected, an audible signal sequence is emitted at the volume configured for the specific noise level.

Setting tube system

1. The LeoniPlus can be set on following tube types:
   - **Disposable**:
     For **disposable** tubes
     the maximum RF amplitude is 80 mbar.
   - **Silicone**:
     For reusable tubes and any of the humidifiers
     the maximum RF amplitude is 100 mbar.
   - **Silicone Gründler**:
     For reusable tubes and Gründler humidifiers
     the maximum RF amplitude is 100 mbar.
2. The setting is made in the Service menu and may only be performed by authorized service personnel.

Setting trigger

1. Two different types of triggers are available.
   - Volume trigger
   - Flow trigger
2. The trigger type is set in the Service menu and may only be performed by authorized service personnel.

Setting flow control/AutomaticFlow

1. LeoniPlus features two different types of flow control in the **NIV** ventilation modes:
   - **AutomaticFlow On**: Flow is automatically controlled by the device
   - **AutomaticFlow Off**: Flow can be set manually

2. Select the **Settings** menu on the Ventilation screen.
3. Select the **Configuration** tab card.

4. Activate or deactivate the function.

__AutomaticFlow__ can also be activated or deactivated during ventilation. There is no need to interrupt ventilation.

8. Ventilation modes, parameters and measured values

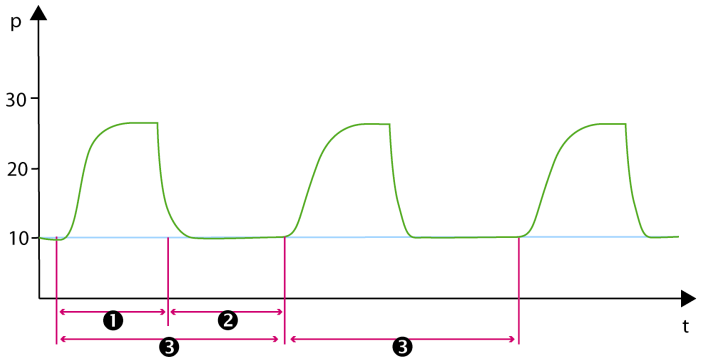
The ventilation modes

IPPV / IMV

In IPPV/IMV ventilation mode you will either be in IPPV or IMV mode depending on your settings. If an expiration time of more than 1.5 seconds is derived from the set inspiration time and the frequency, the device will be in IMV mode; otherwise it will be in IPPV mode.

The two ventilation modes are described below.

IPPV



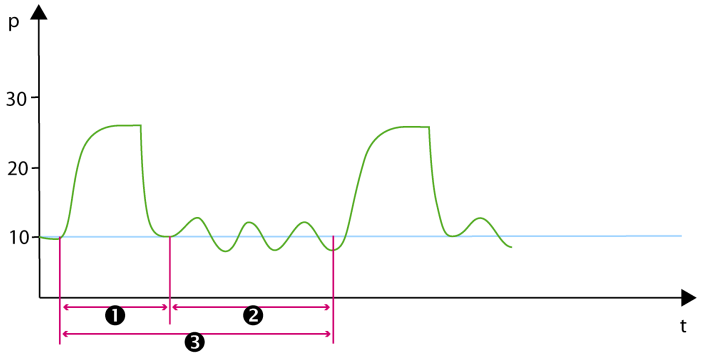
❶ Specified inspiration time

❷ Specified expiration time (< 1.5 s)

❸ Assisted breathing

In IPPV ventilation mode (***I**ntermittent **P**ositive **P**ressure **V**entilation*) ventilation follows a pattern set in the device without reference to any spontaneous breathing by the patient. An excess pressure is generated in the inspiratory phase while the expiration is passive.

IMV



❶ Specified inspiration time

❷ Specified expiration time (≥ 1.5 s) with time for spontaneous breathing

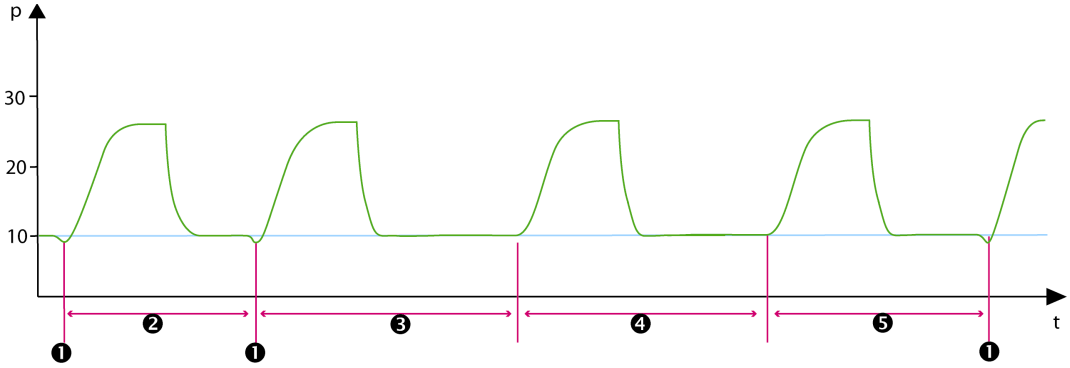
❸ Assisted breathing

In IMV ventilation mode (***I**ntermittent **M**andatory **V**entilation*) the patient is allowed the option of spontaneous breathing between the ventilation strokes.

This means that the expiration time must be set (possibly via the frequency) to allow an E Time greater than 1.5 seconds.

IMV ventilation mode is a special case of IPPV ventilation mode.

S-IPPV



❶ Spontaneous inspiration

❷ Interval with triggered breath expiration time ended by spontaneous inspiration ❶

❸ Interval with triggered breath expiration time ended by specified time interval

❹ Interval with controlled breath triggered by expiry of interval ❸

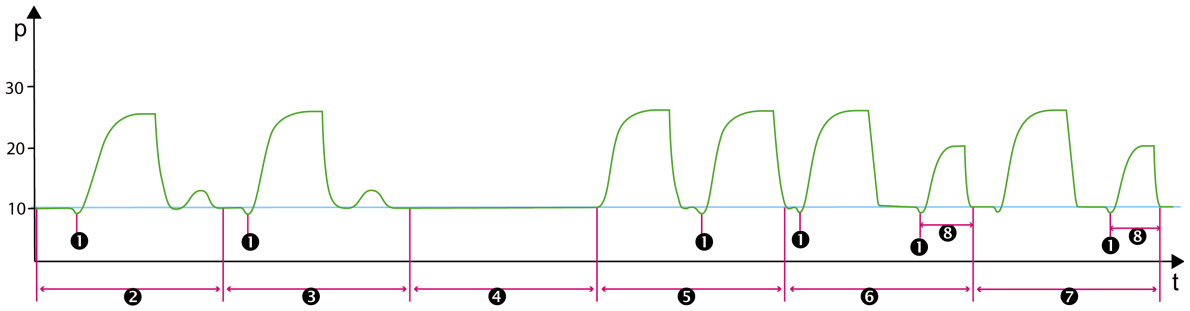
❺ Interval with controlled breath triggered by expiry of interval ❹ expiration time ended by spontaneous inspiration ❶

In SIPPV mode (***S**ynchronized **I**ntermittent **P**ositive **P**ressure **V**entilation*) every spontaneous breath of the patient activates a mechanical breathing stroke by the ventilator at the specified ventilation parameters for inspiration time and pressure.

The number of strokes per minute supported by the ventilator is regulated by the spontaneously breathing patient. The inspiration time corresponds to the time set in the ventilator. The expiration time is variable depending on the frequency of spontaneous breathing.

If the patient is no longer breathing independently, the minimum number of controlled breaths is identical to the values set on the ventilator for the frequency.

S-IMV



❶ Spontaneous inspiration

❷ Interval with triggered breath ❶
$P_{Support}$ OFF

❸ Interval with triggered breath ❶
$P_{Support}$ OFF

❹ Interval with no breath as a function of the I:E ratio

❺ Interval with controlled breath triggered by breathing stop ❹
A triggered breath is also allowed.

❻ Interval with triggered breath ❶ and one spontaneous breath supported at $P_{Support}$ level ❽

❼ Interval with triggered breath ❶ and one spontaneous breath supported at $P_{Support}$ level ❽

❽ Spontaneous breath supported at $P_{Support}$ level

In SIMV mode (***S**ynchronized **I**ntermittent **M**andatory Ventilation*) the patient can breathe spontaneously between the mandatory (supported) breathing strokes of the ventilator. The ventilator is also synchronised with the patient's breathing pattern. The time intervals are determined by the frequency set on the ventilator.

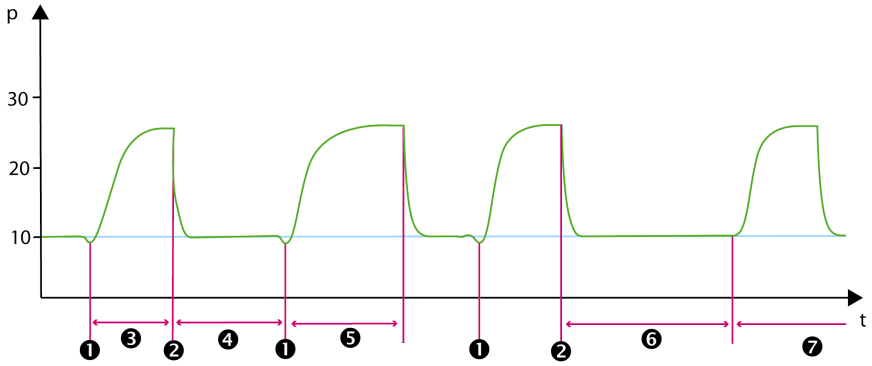
$P_{Support}$ OFF: If the patient breathes spontaneously (❶), one assisted, synchronised breath is triggered per time interval. All subsequent spontaneous breaths in this time interval are not assisted and are performed at the set PEEP level (❷,❸,❺).

$P_{Support}$ ON: If the patient breathes spontaneously (❶), one assisted, synchronised breath is performed per time interval. All subsequent spontaneous breaths (❽) in this time interval are supported at Psupport level (❻,❼). These breaths are supported according to the PSV pattern. Inspiration is triggered by a laboured breath of the patient. Expiration occurs as soon as the inspiratory flow has fallen to 25 % of the maximum value.

If the patient does not breathe spontaneously (Apnoe), a controlled breath is triggered at the end of a time interval (❺). In this special case, the patient's first spontaneous breath is still assisted. (❺).

If the patient is no longer breathing independently, the minimum number of controlled breaths is identical to the values set on the ventilator for the frequency.

PSV-SIPPV



❶ Spontaneous inspiration

❷ Start expiration by reduction to 25% of the maximum flow

❸ Inspiration ended by triggered expiration

❹ Expiration ended by spontaneous inspiration

❺ Inspiration ended by time expiry

❻ Expiration ended by time expiry

❼ Controlled breath triggered by time expiry

In PSV-SIPPV mode (***P**ressure **S**upport **V**entilation - **S**ynchronized **I**ntermittent **P**ositive **P**ressure **V**entilation)*, inspiration and expiration is triggered by spontaneous breathing. The breathing frequency and the inspiration and expiration time are set by the patient.

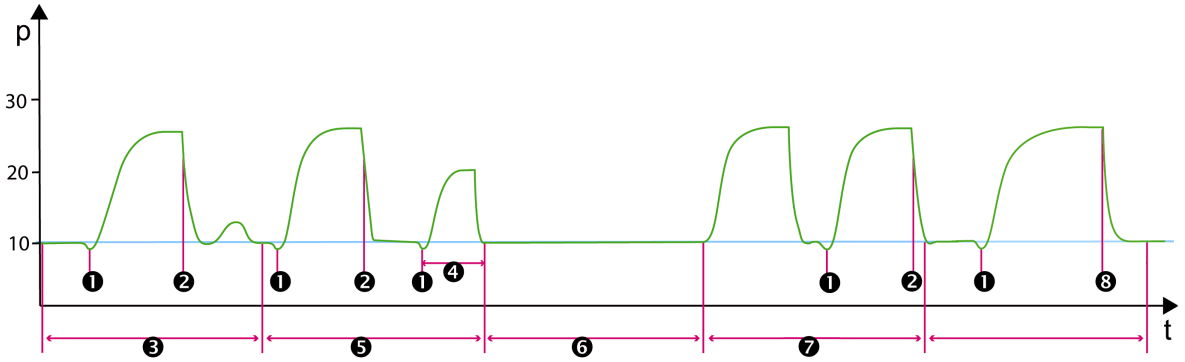
All breaths are machine-supported in combination with PSV in the same way as with S-IPPV.

The inspiration is initiated by a laboured breath (❶) by the patient. The expiration occurs as soon as the inspiratory flow has fallen to 25% of the maximum value (❷).

If the spontaneous inspiration time exceeds the inspiration time set at the ventilator, a controlled expiration is initiated (❺).

If a spontaneous breathing attempt is not initiated by the patient on expiry of the time interval set by the frequency, a controlled inspiration is initiated (❻).

PSV-SIMV



❶ Spontaneous inspiration

❷ Start expiration by reduction to 25% of the maximum flow

❸ Interval with triggered breath ❶
$P_{Support}$ OFF

❹ Spontaneous breath supported at $P_{Support}$ level

❺ Interval with triggered breath ❶ and spontaneous breath supported at $P_{Support}$ level ❹ (**$P_{Support}$ ON**)

❻ Interval with no breath as a function of the I:E ratio

❼ Interval with controlled breath, triggered by breathing stop ❻, a triggered breath is additionally allowed

❽ Inspiration ended by time expiry

In PSV-SIMV mode (***P**ressure **S**upport **V**entilation - **S**ynchronized **I**ntermittent **M**andatory **V**entilation)*, inspiration and expiration is triggered by spontaneous breathing. The breathing frequency and the inspiration and expiration time are set by the patient.

Like with S-IMV, only certain spontaneous breaths are supported within the time interval derived from the set frequency.

The inspiration is initiated by a laboured breath (❶) by the patient. The expiration occurs as soon as the inspiratory flow has fallen to 25% of the maximum value (❷).

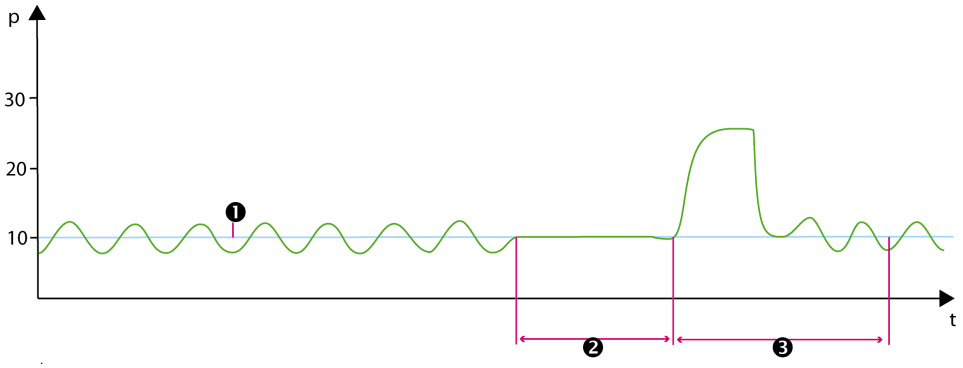
$P_{Support}$ OFF: If the patient breathes spontaneously (❶), an assisted synchronised breath per time interval is generated. All other spontaneous breaths in this interval are not supported by the ventilator and occur at the specified PEEP level (❸).

$P_{Support}$ ON: If the patient breathes spontaneously (❶), an assisted synchronised breath per time interval is generated. All further spontaneous breaths (❹) in this interval are supported at the Psupport level (❺).

If the patient does not breathe spontaneously (apnoea), a controlled breath is triggered on expiry of an interval (❼).In this special case, the patient's first spontaneous breath is still supported by the ventilator (❼).

If the spontaneous inspiration time exceeds the inspiration time set at the ventilator, a controlled expiration is initiated (❽).

CPAP – spontaneous breathing under continuous positive airway pressure



❶ Positive pressure (CPAP)

❷ Interval without a breath (APNEA)

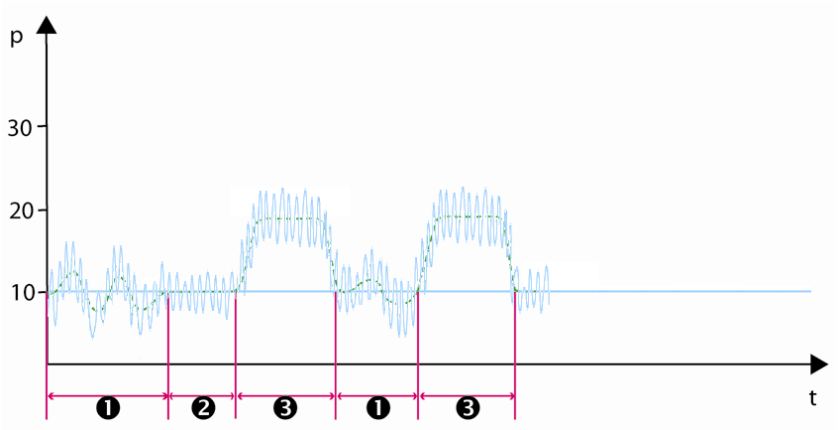
❸ Assisted breath (triggered by breathing stop ❷ if backup ventilation is active)

In CPAP ventilation mode (***C**ontinuous **P**ositive **A**irway **P**ressure*) the patient breathes spontaneously.

Only a positive pressure (similar to PEEP) is generated for inspiration and expiration, which significantly reduces the effort to breathe required by the patient.

If the patient stops breathing spontaneously, the ventilator activates a backup respiration to stimulate spontaneous breathing with the specified ventilation parameters, if the Backup option has been enabled.

HFO – high frequency oscillation ventilation



❶ Spontaneous breathing with HFO

❷ Pure HFO respiration

❸ Recruitment breath or manual breath (triggered by user with set inspiration pressure)

In HFO ventilation mode (***H**igh **F**requency **O**scillation*) the breathing air is made to produce high-frequency oscillations, which makes it easier to eliminate CO_2. If the patient breathes spontaneously, the ventilation device does not assist breathing. Only a positive pressure (similar to PEEP) can be generated for inspiration and expiration, which significantly reduces the effort to breathe required by the patient.

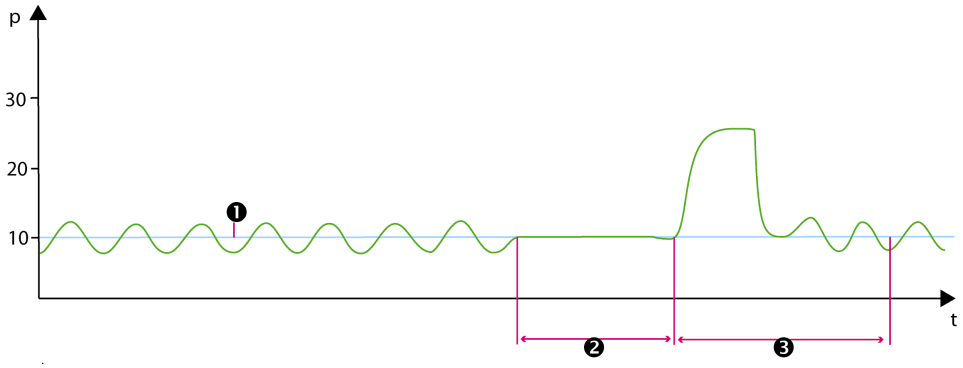
The ventilation pressure may be negative during the exhalation phase (maximum underpressure -50mbar).

The HFO ventilation mode is also possible when the flow sensor is switched off.

For leakage detection, make sure that the P_{Mean} alarm is correctly set.

→ *Alarm settings P. 151*

nCPAP – spontaneous breathing under positive airway pressure without intubation



❶ Positive pressure (CPAP)

❷ Interval without a breath (APNEA)

❸ Manual breath (triggered by user, with set inspiration pressure)

In nCPAP ventilation mode (nasal ***C**ontinuous **P**ositive **A**irway **P**ressure*) the patient breathes spontaneously. A positive pressure (similar to PEEP) is generated for both inspiration and expiration, which significantly reduces the effort to breathe required by the patient.

When the nCPAP function is active it is now only possible to set the required CPAP pressure. If **AutomaticFlow On** is set the set pressure is automatically generated by regulated flow. A fixed flow is automatically assigned to the set pressure, which is shown under the pressure value. If **AutomaticFlow Off** is set, $Flow_{man}$ and $Flow_{CPAP}$ need to be set manually.

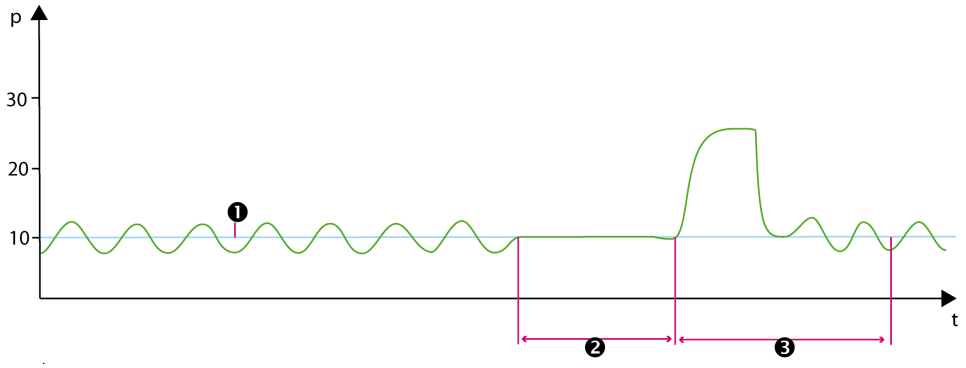
→ *Setting flow control/AutomaticFlow P. 76*

The ventilation device is adapted to the patient via the nasal connection on the tubing system (generator).

When the operator switches to nCPAP mode, the flow sensor is automatically switched off.

In nCPAP mode the flow sensor is automatically switched off because with the expected high leakage rate volume control would produce incorrect information.
The flow does not change in response to leaks. However, the device is able to maintain the pressure even with high leakage rates by controlling the expiratory valve.

S-nCPAP



❶ Positive pressure (CPAP)

❷ Interval without a breath (APNEA)

❸ Assisted breath (triggered by breathing stop ❷ if backup ventilation is active)

In S-nCPAP ventilation mode (***S**ynchronized **n**asal **C**ontinuous **P**ositive **A**irway **P**ressure*) the patient breathes spontaneously. A positive pressure (similar to PEEP) is generated for both inspiration and expiration, which significantly reduces the effort to breathe required by the patient.

If the patient stops breathing spontaneously, the ventilator activates a backup respiration to stimulate spontaneous breathing with the specified ventilation parameters, if the Backup option has been enabled.

When the S-nCPAP function is active it is now only possible to set the required CPAP pressure. If **AutomaticFlow On** is set the set pressure is automatically generated by regulated flow. A fixed flow is automatically assigned to the set pressure, which is shown under the pressure value. If **AutomaticFlow Off** is set, $Flow_{man}$ and $Flow_{CPAP}$ need to be set manually.

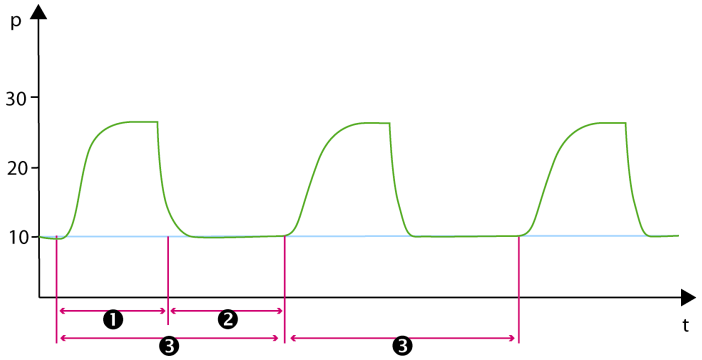
→ *Setting flow control/AutomaticFlow P. 76*

The ventilation device is adapted to the patient via the nasal connection on the tubing system (generator).

When the operator switches to S-nCPAP mode, the flow sensor is automatically switched off.

In S-nCPAP mode the flow sensor is automatically switched off because with the expected high leakage rate volume control would produce incorrect information.
The flow does not change in response to leaks. However, the device is able to maintain the pressure even with high leakage rates by controlling the expiratory valve.

nIPPV – spontaneous breathing under positive airway pressure without intubation



❶ Specified inspiration time

❷ Specified expiration time (< 1.5 s)

❸ Assisted breath

With nIPPV ventilation mode (***n**asal **I**ntermittent **P**ositive **P**ressure **V**entilation*), ventilation is performed with the pattern set and specified by the device, without taking account of a possible spontaneous breath by the patient. Overpressure is generated in the inspiration phase and expiration occurs passively. This ventilation mode is designed for use of the Neojet generator, which allows the patient to breathe spontaneously at both pressure levels.

With nIPPV ventilation mode, it is possible to generate the specified pressure automatically by means of regulated flow (**AutomaticFlow On**) or for the user to set the flows.

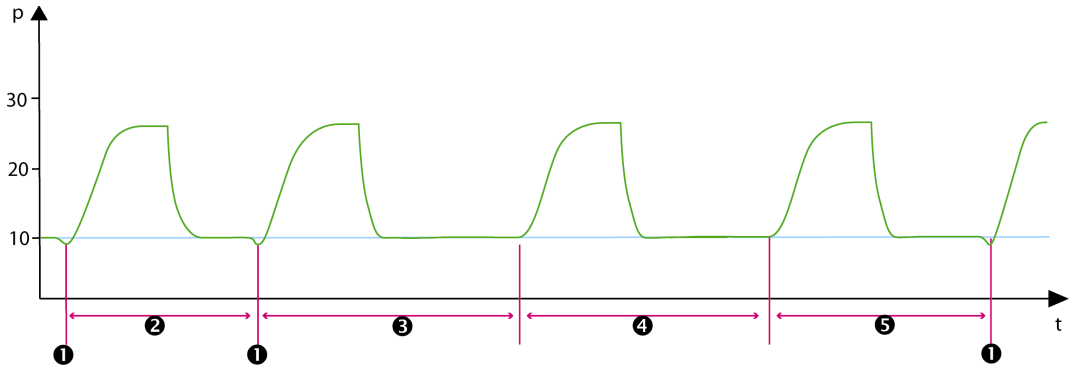
→ *Setting flow control/AutomaticFlow P. 76*

The ventilation device is adapted to the patient via the nasal connection on the tubing system (Neojet Generator).

When the operator switches to nIPPV mode, the flow sensor is automatically switched off.

In nIPPV mode the flow sensor is automatically switched off because with the expected high leakage rate, volume control would produce incorrect information. The flow does not change in response to leaks. However, the device is able to maintain the pressure even with high leakage rates by controlling the expiratory valve.

S-nIPPV



❶ Spontaneous inspiration

❷ Interval with triggered breath expiration time ended by spontaneous inspiration ❶

❸ Interval with triggered breath expiration time ended by specified time interval

❹ Interval with controlled breath triggered by expiry of interval ❸

❺ Interval with controlled breath triggered by expiry of interval ❹ expiration time ended by spontaneous inspiration ❶

In S-nIPPV mode (***S**ynchronized **n**asal **I**ntermittent **P**ositive **P**ressure **V**entilation*) every spontaneous breath of the patient activates a mechanical breathing stroke by the ventilator at the specified ventilation parameters for inspiration time and pressure.

The number of strokes per minute supported by the ventilator is regulated by the spontaneously breathing patient. The inspiration time corresponds to the time set in the ventilator. The expiration time is variable depending on the frequency of spontaneous breathing.

If the patient is no longer breathing independently, the minimum number of controlled breaths is identical to the values set on the ventilator for the frequency.

With S-nIPPV ventilation mode, it is possible to generate the specified pressure automatically by means of regulated flow (**AutomaticFlow On**) or for the user to set the flows.

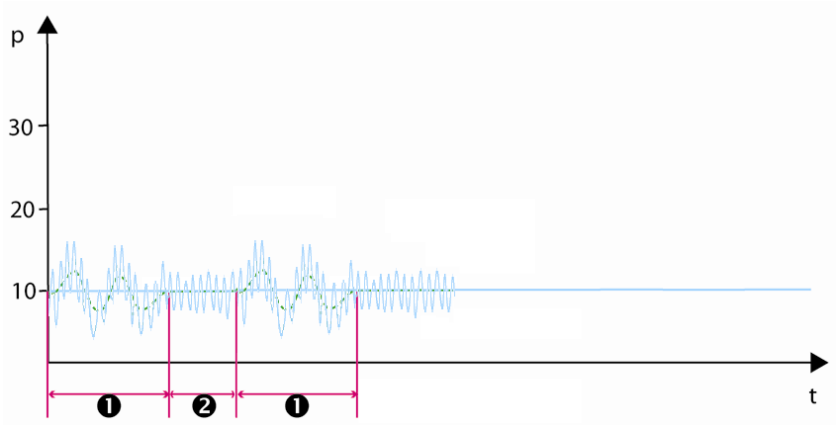
→ *Setting flow control/AutomaticFlow P. 76*

The ventilation device is adapted to the patient via the nasal connection on the tubing system (Neojet Generator).

When the operator switches to S-nIPPV mode, the flow sensor is automatically switched off.

In S-nIPPV mode the flow sensor is automatically switched off because with the expected high leakage rate, volume control would produce incorrect information. The flow does not change in response to leaks. However, the device is able to maintain the pressure even with high leakage rates by controlling the expiratory valve.

nHFO – high frequency oscillation ventilation without intubation



❶ Spontaneous breathing with nHFO

❷ Pure nHFO respiration

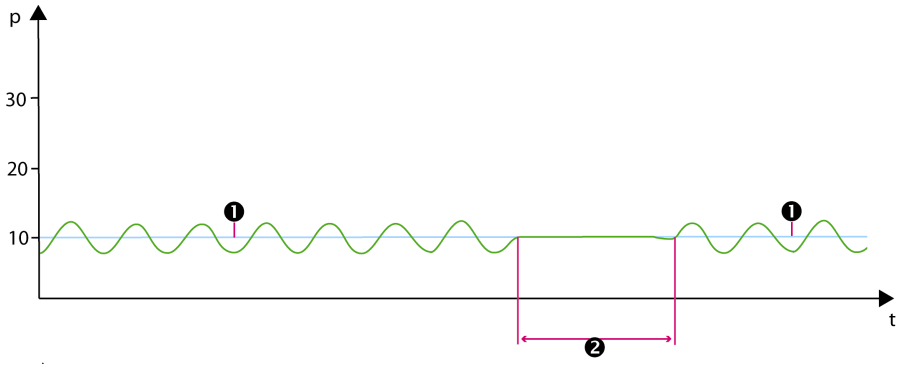
In nHFO ventilation mode (***n**asal **H**igh **F**requency **O**scillation*) the breathing air is made to produce high-frequency oscillations, which makes it easier to eliminate CO_2. If the patient breathes spontaneously, the ventilation device does not assist breathing. Only a positive pressure (similar to PEEP) can be generated for inspiration and expiration, which significantly reduces the effort to breathe required by the patient.

- *The ventilation pressure may be negative during the exhalation phase (maximum underpressure -25mbar).*
- *For leakage detection, make sure that the P_{Mean} alarm is correctly set.*

  → *Alarm settings P. 151*
- *When the operator switches to nHFO mode, the flow sensor is automatically switched off.*

In nHFO mode the flow sensor is automatically switched off because with the expected high leakage rate, volume control would produce incorrect information. The flow does not change in response to leaks. However, the device is able to maintain the pressure even with high leakage rates by controlling the expiratory valve.

HiFlow – spontaneous breathing under positive airway pressure without intubation



❶ Positive pressure = effective pressure (Peff)

❷ Interval without any breath (apnea)

In HiFlow mode, the patient breathes spontaneously using a nasal cannula.

The anatomical dead space in the upper airways is rinsed with a high flow rate using a nasal cannula. This provides a reservoir of fresh gas for each breath that the patient takes.

Volume-limited ventilation

Structural damage to the lung can result if the ventilation volume is too high. Volume-limiting ventilation can be used to counteract volume trauma on changes to the condition of lung. The maximum respiration volume is fixed.

If the condition of the lung changes (for example as the result of medication) which would result in an increased inspiratory volume, then the volume limitation function is activated.

The user can now reduce the inspiration pressure, if necessary, to prevent the set volume from being exceeded.

→ *$V_{T\ Limit}$ (Volume limit) P. 107*

Volume guarantee

The volume guarantee ensures that at least a guaranteed volume is applied to the patient on each breath.

→ *V_{TG} (volume guarantee) P. 108*

Backup ventilation

Backup ventilation is only activated when the device detects cessation of breathing (apnea).

The backup function triggers one or several breaths mechanically to ensure the patient is supplied with oxygen.

A message on the display indicates that backup ventilation has been triggered.

Backup breathing is only available for triggered ventilation modes and for CPAP.

→ *Backup breaths P. 98*
→ *$Freq_{Backup}$ P. 100*
→ *$T_{I\ Backup}$ P. 105*

Pulse oxymetric controlled ventilation (Closed Loop)* CLAC 1.1®

When the Closed Loop function is activated, the ventilation parameter **O_2** is set such that the continuously defined SpO_2 value is within the target range defined by the user.

→ *Setting Closed Loop P. 72*

Applicable ventilation modes

Closed Loop is suitable for all available ventilation modes (IV as well as NIV).

Calculation

The incoming SpO_2 values are used to permanently calculate the deviation from the target range as well as the trend of the value curve:

- Deviation from the target range is calculated based on the last max. 180 measured data (depending on the set control period).
- The control period can be set between 30 and 180 seconds.
  This expectation window can be adjusted during operation or defined in service mode.
- If 80% of the measured data are below the limit for low/very low, the current SpO_2 is classified as "low"/"very low". Similarly, SpO_2 is considered "high"/"very high" if 80% of the measured data exceed the limit for high/very high.
- A straight line is plotted by averaging the last max. 60 measured values (depending on the set control period). Above an inclination of +/- 0.1 (SpO_2 change in % per second), the trend is interpreted as rising/falling.

Closed Loop basic control CLAC 1.1

Depending on the classification of the current SpO_2 value, the ventilation parameter **O_2** is changed by +5, +2, 0 (SpO_2 within target range), -1, -2.

No adjustment is made in the following cases:

- The most recent change occurred less than three minutes ago.
- The SpO_2 trend is falling and **O_2** should be reduced.
- The SpO_2 trend is rising and **O_2** should be increased.
- The current SpO_2 value is invalid or below the desaturation limit.
- The measured-value spread is too large.

* not for LeoniPlus transport

- Fewer than 80% of the measured values taken in the last three minutes are valid.
- The controller has been suspended by the user.

Control process

Case:

Oversaturation in the SpO_2 control range after manual FiO_2 increase

Objective:

Excess SpO_2 due to manual FiO_2 increase is to be brought back into the "normal" range by automatic reduction of the FiO_2.

Precondition:

SpO_2 increase due to manual FiO_2 increase beyond the defined SpO_2 target range.

Control:

If the measurement results within the set control period of 100% is SpO_2, the reduction in the FiO_2 is half of the last manual increase step.

- If the measurement result is still 100% SpO_2, this step is repeated after the set control period, up to SpO_2 < 100%.
- If the measurement result is less than 100% or the upper limit of the yellow range is reached, closed-loop control is performed in the normal CLAC algorithm (reduction in steps of -1 % or -2 %)

The manual control of the FiO_2 always has priority over automated control of CLAC.

Desaturation limit

The desaturation limit is the lower limit of the SpO_2 control range (<70%). If the SpO_2 value falls below this limit, the value is not used for the closed-loop control and the controller waits until the SpO_2 values are above the desaturation limit again.

Undershooting the desaturation limit is not a fallback mode. The closed-loop control merely pauses until the SpO_2 values are above 70% again.

Irrespective of the desaturation limit, LeoniPlus outputs an alarm at the limits of the SpO_2 target range.

→ *Setting Closed Loop P. 72*

Pulse oxymetric controlled ventilation (Closed Loop)* CLAC 2.0® emergency control

When the closed loop function is activated, the ventilation parameter **O_2** is set in such a way that the continuously determined SpO_2 value is within the target range defined by the user.

→ *Setting Closed Loop P. 72*

Ventilation modes that can be used

Closed loop is suitable for all available ventilation modes, both IV and NIV.

Control process (after manual FiO_2 increase)

Case:

Oversaturation in the SpO_2 control range after manual FiO_2 increase

Objective:

Excess SpO_2 due to manual FiO_2 increase is to be brought back into the "normal" range by automatic reduction of the FiO_2.

Precondition:

SpO_2 increase due to manual FiO_2 increase beyond the defined SpO_2 target range.

Control:

- Info alarm "SpO_2 too high – fast O_2 reduction"
- The set control period is shortened to 30 seconds.
- The 30 second control period is divided into measuring ranges of 10 seconds:
  1. Period (10 sec.), accepted SpO_2 measurement results between 95% and 100%.
  2. Period (10 sec.), accepted SpO_2 measurement results between 98% and 100%.
  3. Period (10 sec.) depending on the current therapy period, accepted SpO_2 measuring results 99% - 100%.

a) For a measuring result 99% - 100% SpO_2

- The reduction in FiO_2 is half the last manual increase step.
- If the measurement result is then still > 99% SpO_2, this step is repeated every 30 sec. until SpO_2 < 99% or the upper limit of the yellow range is reached or the originally set FiO_2 is reached before the manual increased due to reduction.

* not for LeoniPlus transport

b) If the measurement result is < 99% or if the upper limit of the yellow range is reached, control is performed in the normal CLAC.
Algorithm:

- Stop the control on reaching the upper limit (green range)
- The control period shortened to 30 sec. is reset to the originally set value.
- Return to the normal CLAC control.

Control process (for SpO_2 < 70%)

Case:

Desaturation in the SpO_2 control range less than 70%.

Objective:

A fast drop in SpO_2 is to be brought into the set target range by a fast FiO_2 increase.

Precondition:

Drop in SpO_2 below 70% SpO_2 within the set control period.

Control:

On fast desaturation (sudden drop in SpO_2 below 70%), the closed loop basic control is replaced by the following closed loop control:

- The set control period is shortened to 30 sec.
- Initially, the ventilation parameter O_2 is increased by +10 within 30 sec.
- The therapy control time is automatically changed to 30 sec.
- Then, O_2 is further increased every 30 sec. by +10 until O_2 = 100% is reached.
- "Alarm SpO2 too low – emergency control active" is signaled as a high-priority alarm.
- The O_2 button flashes red in addition to the red alarm.
- This sequence is only ended when the measured SpO_2 measured values are in the normal control range yellow/green/yellow again. In this case, resetting to the originally set control period is performed.

The set control period is shortened to 30 sec.

The FiO_2 limits defined by the user can be exceeded by the emergency control in CLAC 2.0. In this case, a high-priority alarm is output.

Control process (for SpO_2 > 70%)

Case:
Desaturation in the SpO_2 control range down to 70%.

Objective:
A fast drop in SpO_2 is brought into the set target range by a fast FiO_2 increase.

Precondition:
SpO_2 drop of at least 5% within 10 sec. down to 70% SpO_2.

Control:
- On a drop of 5% SpO_2, the closed-loop control increases the ventilation parameter **O_2** by +5.
- On a drop of >5%-10% SpO_2, **O_2** is increased by +8.
- On a drop of >10% SpO_2, **O_2** is increased by +10.
- Then, after the set therapy control time has finished, **O_2** is increased further by an additional amount calculated once, of 5, 8 or 10%, until **O_2** =100% is reached. The set therapy control time is retained (not shortened).
- An alarm with high priority (red alarm “Dyn. O2 increasing”) signals the intervention of the emergency control.
- If the drop in the SpO_2 value is stopped and the normal closed-loop control range yellow/green/yellow is reached, basic control is resumed.
- This closed-loop control has priority over the Closed Loop basic control and is only applied if the emergency control is activated in Service!

Control process (after dynamic FiO_2 increase)

Case:
SpO_2 oversaturation after dynamic control (SpO_2 greater than 70%).

Objective:
Excess SpO_2 due to dynamic FiO_2 increase is to be brought back into the "normal" range by dynamic reduction of the FiO_2.

Precondition:
SpO_2 increase due to dynamic control beyond the defined SpO_2 target range.

Control:

- Info alarm "SpO_2 too high – fast O_2 reduction"
- Reduction of the FiO_2 by the last step made in the dynamic increase (5, 8 or 10%)
- The algorithm is stopped on reaching the upper set SpO_2 limit (green range).
- Return to the normal CLAC control CLAC 2.0.

Control process (after emergency control)

Case:

SpO_2 oversaturation after emergency control (SpO_2 less than 70%).

Objective:

Excess SpO_2 due to fast FiO_2 increase is to be brought back into the "normal" range by fast reduction of the FiO_2.

Precondition:

Fast SpO_2 increase due to emergency control beyond the defined SpO_2 target range.

Control:

- Info alarm "SpO_2 too high – fast O_2 reduction"
- The set control period is shortened to 30 sec.
- Reduction of the FiO_2 by -10% every 30 sec.
- The algorithm is stopped on reaching the upper set SpO_2 limit (green range).
- The control period shortened is reset to the originally set value.
- Return to the normal CLAC control CLAC 2.0.

Volume trigger

Volume trigger supports a breathing effort if the adjusted volume is reached.

The setting is in % of measured inspiratory tidal volume VTi.

→ *TrigVol P. 106*

Flow trigger

Flow trigger supports a breathing effort if the adjusted flow is reached.

The setting is in L/min and is independent of other measurement values.

→ *Trigger (for flow triggering) P. 107*

Non-invasive trigger (abdomen trigger)

In the case of the abdomen trigger, respiratory effort is supported when the set trigger threshold is crossed.

The trigger threshold is set independently of other measured values and is dimensionless.

→ *Trigger P. 107.*

The ventilation parameters

Backup breaths

WARNING

No backup ventilation!

Danger of insufficient oxygen supply

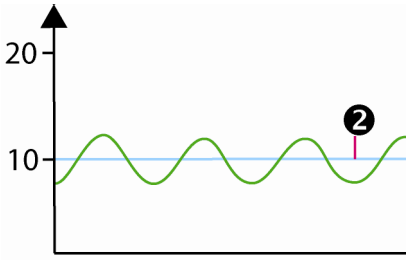
- Activate backup breaths under Backup breaths in CPAP mode.

For ventilation mode CPAP only

Backup breaths define the number of breaths that are automatically triggered when the APNEA time is exceeded.

The backup breath is performed with the specified inspiration pressure (P_{Insp}) and with a permanently set inspiration and expiration time.

CPAP



CPAP (❷) specifies the continuous positive airway pressure for CPAP ventilation.

CPAP is only available for CPAP and nCPAP ventilation mode.

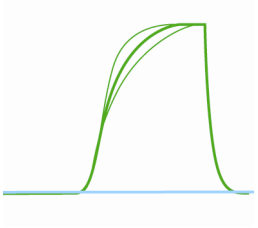
$Flow_{Exp}$ / Flow / $Flow_{CPAP}$

FlowExp defines the expiration flow. This continuous flow flushes the CO_2 out of the tubing system and builds up the PEEP/CPAP.

Flow is available for CPAP and HiFlow ventilation modes only

$Flow_{CPAP}$ is only available for nCPAP ventilation mode

$Flow_{Insp}$ / $Flow_{man}$

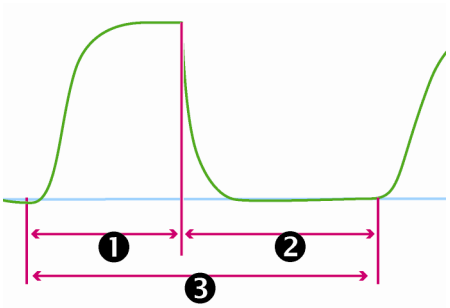


$Flow_{Insp}$ specifies the inspiratory flow. This value determines the rise in the breathing chart during inspiration.

If $Flow_{Insp}$ is too low the maximum inspiratory pressure (P_{Insp}) cannot be reached.

$Flow_{man}$ is only available for nCPAP ventilation mode.

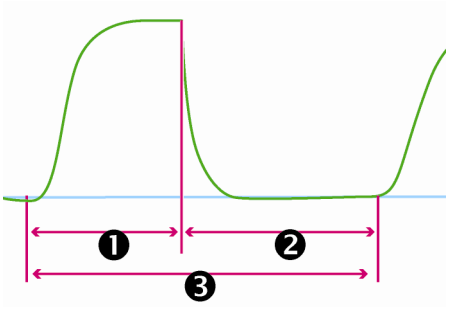
Freq



Freq (❸) sets the breathing frequency.

Freq is only available for ventilation modes IMV / IPPV, SIMV, PSV-SIMV and nIPPV.

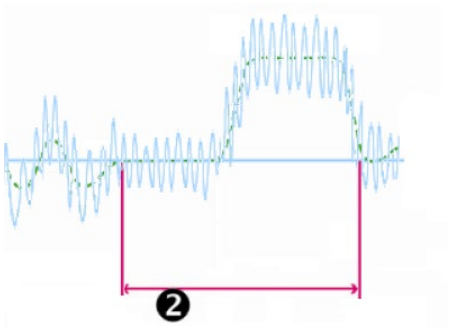
$Freq_{Backup}$



$Freq_{Backup}$ (❸) specifies the backup frequency.

$Freq_{Backup}$ is only available for ventilation modes S-IPPV and PSV-SIPPV.

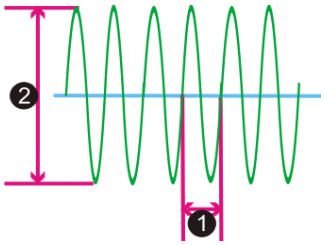
$Freq_{Rec}$



$Freq_{Rec}$ specifies the frequency of the recruitment breaths.

$Freq_{Rec}$ is only available for ventilation mode HFO.

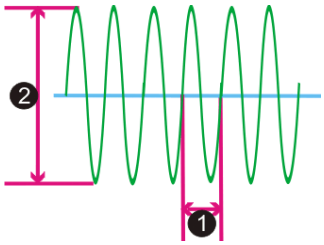
HF Am_{max}



$HFAm_{max}$ (❷) is the maximum limit value that the amplitude is allowed to reach.

HF Am_{max} is only available for ventilation mode HFO if parameter V_{TG} is activated.

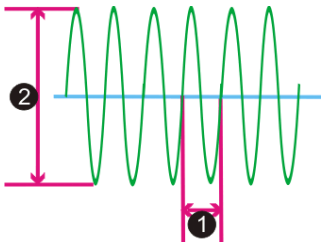
HF Ampl



HF Ampl (❷) specifies the amplitude for HFO ventilation (peak to peak)

HF Ampl is only available for ventilation modes HFO and nHFO.

HF Freq



HF Freq (❶) specifies the HFO frequency

HFFreq is only available for ventilation modes HFO and nHFO.

I:E

I:E defines the ratio of inspiration to expiration.

The following values can be set:

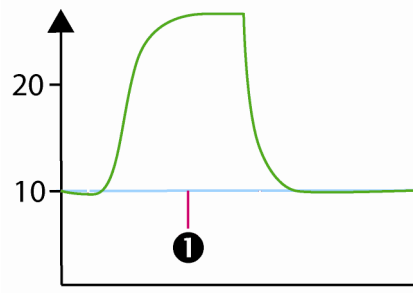
- 50:50
- 40:60
- 33:66
- 25:75

*Ventilation parameter **I:E** is only available for ventilation modes HFO and nHFO.*

O_2

O_2 sets the oxygen content of the breathing air.

PEEP



PEEP (❶) specifies the continuous end-expiration pressure.

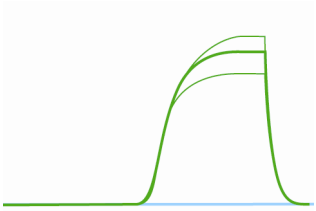
P_{Insp}

WARNING

P_{Insp} value too high!

Danger of permanent lung damage!

- Check the ventilation pressure.



P_{Insp} specifies the inspiratory pressure. This is the maximum pressure that can be achieved with inspiration.

P_{man}

P_{man} specifies the ventilation pressure of a manual breath (Inspiration hold).

P_{man} is only available for ventilation modes nCPAP, HFO, and nHFO.

P_{Max}

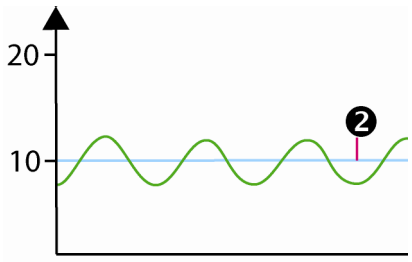
P_{Max} specifies the maximum ventilation pressure that may be reached in volume-guaranteed ventilation.

P_{Max} is only available for ventilation modes S-IPPV, S-IMV, PSV-SIPPV, PSV-SIMV.

In ventilation mode HiFlow:

P_{Max} in ventilation mode HiFlow is the maximum upper pressure limit at which the system vents.

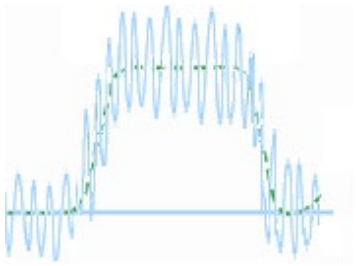
P_{Mean}



P_{Mean} specifies the continuous positive airway pressure for ventilation mode HFO.

- *P_{Mean} is automatically determined when the device switches from another ventilation mode to HFO: P_{Mean}(HFO) = (P_{Mean} (conventional) + 2).*
- *P_{Mean} is only available for ventilation modes HFO and nHFO.*

P_{Rec}



P_{Rec} defines the pressure level to which the P_{Mean} is raised during a recruitment manoeuvre.

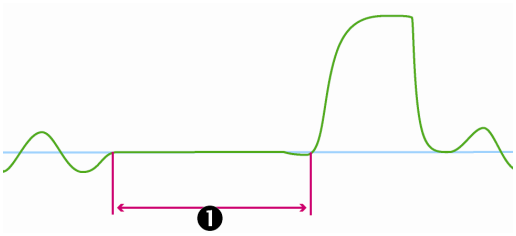
- *P_{Rec} is only available for ventilation mode HFO.*

$P_{Support}$

$P_{Support}$ defines the pressure for supporting spontaneous breathing.

- *For triggered breaths outside the SIMV rhythm, $P_{Support}$ can be selected between PEEP and P_{Insp}.*
- *If V_{TG} is used, the $P_{Support}$ breaths are not controlled as the set volume.*
- *$P_{Support}$ is only available for ventilation modes S-IMV and PSV-SIMV.*

T_{Apnoe}

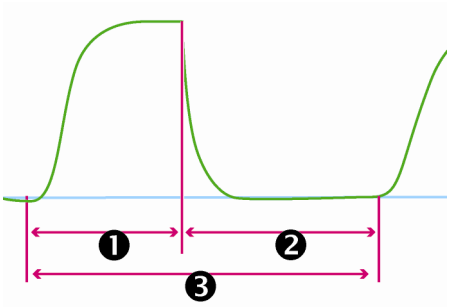


For ventilation mode CPAP only

T_{Apnoe} sets the permissible cessation of breathing (apnea) time (❶). If this time is exceeded, automatic backup breathing is triggered.

The number of automatic breaths triggered is defined in parameter Backup breaths.

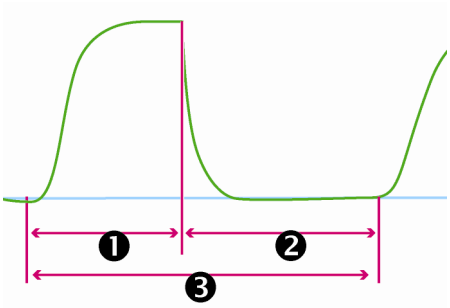
$T_{I\ Backup}$



$T_{I\ Backup}$ (❶) specifies the time for backup inspiration.

$T_{I\ Backup}$ is only available for ventilation modes PSV-SIPPV, PSV-SIMV.

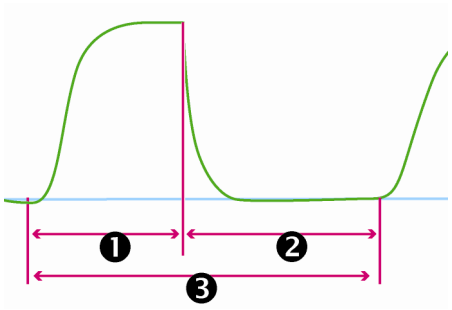
T_{Insp}



T_{Insp} (❶) specifies the time for inspiration.

T_{Insp} is only available for ventilation modes IMV / IPPV, S-IPPV, S-IMV and nIPPV.

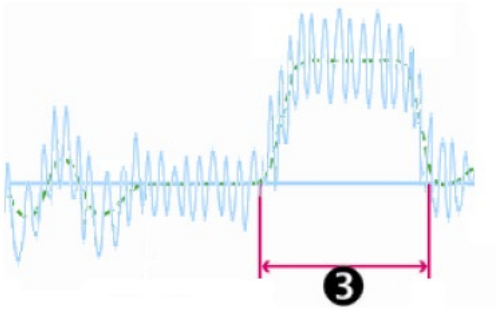
$T_{Insp\ max}$



$T_{Insp\ max}$ (❶) sets the maximum inspiration time for breaths controlled by the patient.

$T_{Insp\ max}$ is only available for ventilation modes PSV-SIPPV, PSV-SIMV.

T_{Rec}



T_{Rec} specifies the inspiration time for the recruitment manoeuvre.

T_{Rec} is only available for ventilation mode HFO.

TrigVol

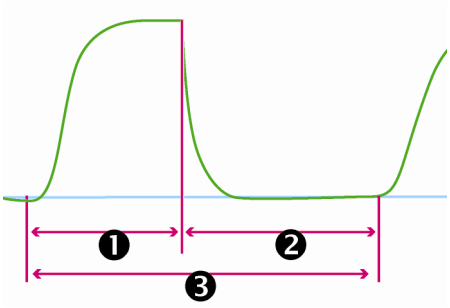
TrigVol (Trigger Volume) sets the volume of breath as from which a spontaneous breath can be detected.

This value is specified as a percentage of the measured tidal volume.

TrigVol is only available for ventilation modes S-IPPV, S-IMV, PSV-SIPPV, PSV-SIMV.

TrigVol is only available if volume trigger is chosen.

Trigger (for flow triggering)



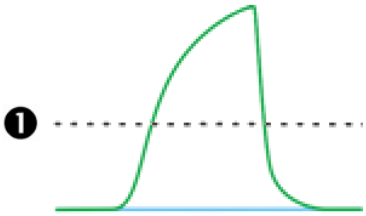
Trigger sets the flow as from which a spontaneous breath can be detected.

This value is specified as L/min of the measured flow.

Trigger (for flow triggering) is only available for ventilation modes S-IPPV, S-IMV, PSV-SIPPV, PSV-SIMV.

Trigger is only available if flow trigger is chosen.

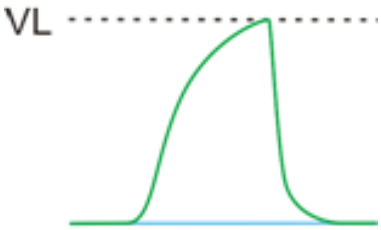
Trigger (for abdomen triggering)



With the trigger, a spontaneous breath is detected. The trigger threshold (❶) can be set in the range 1 - 30, where 1 is the most sensitive setting.

Trigger (for abdomen triggering) is only available for ventilation modes *S-nIPPV, S-nCPAP.*

$V_{T\ Limit}$ (Volume limit)

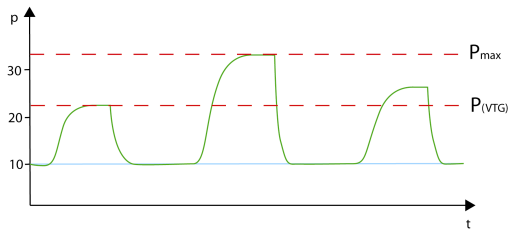


$V_{T\ Limit}$ specifies the maximum volume that may be reached.

If this value is reached, inspiration is aborted. A message is displayed indicating that this value has been reached.

$V_{T\ Limit}$ is only available for ventilation modes S-IPPV, S-IMV, PSV-SIPPV, PSV-SIMV.

V_{TG} (volume guarantee)



V_{TG} specifies the minimum volume that must be reached with ventilation (volume guarantee).

VTG is only available for ventilation modes S-IPPV, S-IMV, PSV-SIPPV, PSV-SIMV and HFO.

For all ventilation modes except HFO:

The device automatically generates the necessary pressure ($P_{(VTG)}$) to achieve this volume.

The ventilation pressure cannot exceed p_{max}.

The volume guarantee control does not apply to the $P_{Support}$ breaths..

When the volume guarantee is deactivated, the currently measured pressure value is applied as the new P_{Insp}. The message “Check pressure settings” appears.

For HFO:

The device automatically adjusts the required amplitude to obtain this volume.

The amplitude cannot exceed HF AM_{max}.

If increased spontaneous breathing effort appear an impairment of the amplitude control is possible.

When the volume guarantee in the HFO is deactivated, the currently measured amplitude pressure value is applied as the new amplitude. The message “Check pressure settings” appears.

On a mode change from/to HFO, the volume guarantee is automatically deactivated.

The measured values (numeric values)

% Spont [%]

Proportion of spontaneous breathing effort referred to the overall breathing assistance of the device.

C20/C

Measurement of overdistention of lung

Compliance during last 20% of the inspiration phase as a proportion of the total compliance.

Cdyn [ml/mbar]

Compliance: Expandability of lung (dynamic)

CPAP

CPAP: continous positive airway pressure

DCO_2 [ml*ml/s]

This parameter is termed the “gas transport coefficient” DCO_2. Increasing this coefficient lowers the CO_2.

In oscillation ventilation it has been shown that CO_2 elimination correlates well with $(Vt_{HFO})^2$ x f.

Here, Vt is the oscillation volume and f is the oscillation frequency.

Freq [1/min]

For all ventilation modes except HFO:

Breathing rate

For HFO: [Hz]

Oscillation frequency

The oscillation frequency is expressed in hertz (Hz) and influences the oscillation volume.

Freq Spont [1/min]

Frequency of the spontaneously breathing patient

HFO amplitude [mbar]

Measured actual amplitude, depends on the tube system configuration.

Leak [%]

Difference between inspiratory and expiratory volume.

MV [l/min]

Minute volume: Mean inspiratory volume per minute.

O_2 [%]

Oxygen content of the breathing air

PEEP [mbar]

Positive endexpiratory pressure, existing at the end of a breathing

PI [%]

Perfusion index indicating arterial pulse signal strength as the percentage of pulsatile signal to non-pulsatile signal (SpO_2 measurement, only).

PI allows clinicians to place sensors on optimal sites (the site with the highest PI value).

P_{Mean} [mbar]

For all ventilation modes except HFO:

Mean airway pressure, averaged over inspiration and expiration over time.

For HFO:

Mean airway pressure, calculated as an arithmetic mean value over an oscillation.

P_{eff} [mbar]

P_{eff} is the measured pressure in the tube system at the point of connection of the pressure measurement tube.

This pressure does not represent the pressure situation in the lung of the patient.

P_{peak} [mbar]

Upper maximum pressure peak value

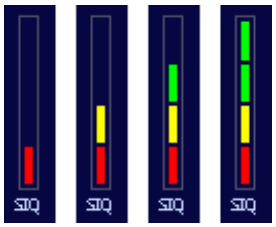
Pulse

Pulse rate determined with $uSpO_2$™ Masimo SET® Oximetry.

Resistance R [mbar/l/s]

Static inspiratory resistance of the lung and of the tube system/device.

SIQ



Signal IQ (bar display) indicating the acquired signal quality and the timing of the pulse relative to the Plethysmograph (SpO_2 measurement, only).

SpO_2 [%]

Oxygen saturation determined with $uSpO_2$™ Masimo SET® Oximetry.

Ti Spont [s]

Spontaneous inspiration time

Time constant τ [ms]

The time constant τ characterises all resistance occurring during expiration. It is calculated as the product of the resistance and the compliance.

For complete expiration, a duration of at least 3 time constants is required. If the expiration time is shorter, the end-expiratory lung volume will increase (air trapping). That affects the mechanical properties of the lungs (compliance), which depend on the end-expiratory lung volume.

Vt HFO [ml]

Measured tidal volume of an oscillation in ml.

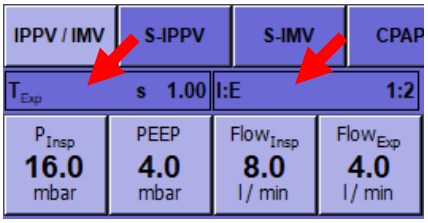
VTe [ml]

Expiratory tidal volume (measured volume that the patient breathes out on each breathing stroke)

VTi [ml]

Inspiratory tidal volume (measured volume that the patient is administered on each breathing stroke)

Complimentary values



The complimentary values are derived from the set ventilation parameters and are displayed between the ventilation modes and the parameters.

Which and how many complimentary values are displayed, depends on the ventilation mode.

I:E

Inspiration to expiration ratio (calculated by the breathing rate and the inspiration time)

T_{EXP} [s]

Expiration time (calculated by the breathing rate and the inspiration time)

TrigVol [ml]

TrigVol (Trigger volume) calculated breathing volume, detecting a spontaneous breath (calculated by the Trig Vol [%] and the measured tidal volume)

BaseFlow [L/min]

Baseflow HFO

BaseFlow is only available for ventilation modes HFO, nHFO, nCPAP, and nIPPV.

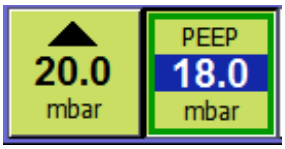
$Flow_{Insp}$ [l/min]

During NIV ventilation, the inspiratory flow that is used for the inspiratory breaths is displayed in addition to the BaseFlow. The two flows are calculated internally by a characteristic in the **AutomaticFlow** mode and set by the device.

Interdependency of ventilation parameters

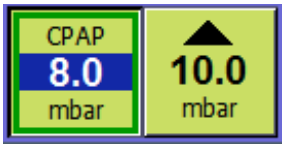
If parameters regulate each other, one parameter can initially be changed up to the limit of the regulated range. An arrow for the dependent parameter will then point in the direction in which it must be adjusted before a further change can be made to the initial parameter.

Interdependency of P_{Insp} and PEEP



There must always be a difference of 2 mbar between P_{Insp} and PEEP.

Interdependency of P_{man} and CPAP



There must always be a difference of 2 mbar between P_{man} and CPAP.

Interdependency of P_{Insp} and I-Flow

If P_{Insp} < 10 mbar, the I-Flow must not be set to more than 10 l/min.

Interdependency of frequency, I-Time and E-Time

The setting options of the three different parameters result in various interdependencies.

9. Ventilation

WARNING

Patient connected too soon!

Danger of lung damage

- Before connecting a patient to the ventilator:
- conduct a device check
- adapt the ventilation parameters to the patient.

Basic procedures

WARNING

Limited disconnection detection when the flow sensor is switched off!

Danger of insufficient oxygen supply

- Make sure that the device is not disconnected.

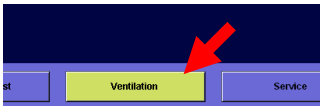
WARNING

Tubing system without inspiratory bacteria filter!

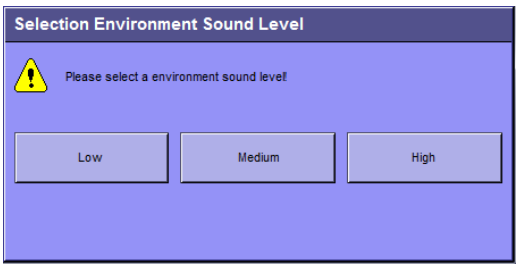
Infection of subsequent patient
Contamination of the device

- Always use a bacteria filter on the inspiration connection for all ventilation modes.

Starting ventilation



1. Press the **Start** hard key or select the **Ventilation** menu in the start screen.



A dialog box for selection of the environmental sound level will appear after switching the device on and starting respiration for the first time. This is to be taken into account in automatic adjustment of the alarm tone volume.

2. Select the appropriate volume for the surroundings – **Low**, **Medium** or **High**.

When a button is selected, an audible signal sequence is emitted at the volume configured for the specific noise level.

The currently set environmental sound level is indicated by a bar chart in the upper window bar of the screen.

The selected environmental sound level can be modified at any time via the presets.

→ *Setting the environmental sound level P. 75*

VORSICHT

An acoustic alarm might not be heard in a noisy environment if the alarm volume is set to low.

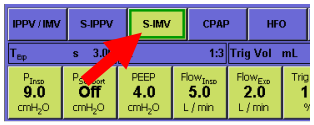
Alarm conditions might not be recognized.

- Have the alarm presets coordinated to the local ambient conditions.
- Select the appropriate environmental sound level to adequately adapt the acoustic alarm to the ambient noise level.

3. These buttons can be used to load the last selected respirator settings or the default settings when starting respiration for the first time after switching on the device.

4. Select **IV** (invasive) or **NIV** (non-invasive) ventilation.

With **NIV**, additionally select the ventilation system to be used (**Neojet H+L**, **HiFlow H+L**, **Closed Systems**).



5. Select a ventilation mode (not for **HiFlow**):

- For **IV** ventilation: **IPPV / IMV**, **S-IPPV**, **S-IMV**, **CPAP**, or **HFO (**optional).
- For **NIV** ventilation: **nCPAP**, **nIPPV**, or **nHFO (**optional).

Default settings have a yellow background and are not yet active.

The bacteria filter must be connected on the inspiration side when you start HFO or nHFO ventilation mode.

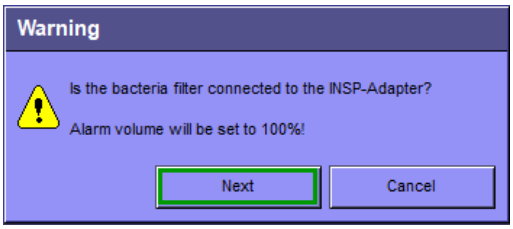
6. For **IV** ventilation, choose the **PSV** option to switch between ventilation modes with/without PSV (**SIPPV** / **PSV-SIPPV**, **SIMV** / **PSV-SIMV**).

7. Adapt the ventilation parameters of the default settings to the patient.

→ *Changing parameter values with the rotary pulse encoder P. 48*

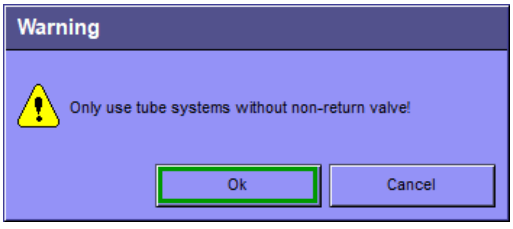
8. Press the **Start** hard key to start ventilation in the preselected ventilation mode.

If you start ventilation mode S-nCPAP or S-nIPPV, the trigger functionality is initially always set to "OFF". To activate the triggering, set the trigger threshold to any value.



Only when starting HFO/nHFO respiration mode: The security prompt about the connected inspiration filter appears and the alarm volume is increased to 100%.

9. Confirm with **Continue**.



Then you will be reminded that only tube systems without a non-return valve may be used.

10. Confirm with **OK**.

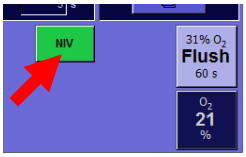
Switching the ventilation mode during ventilation

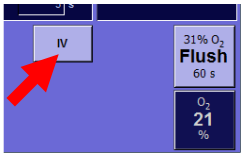
WARNING

Confusing the default settings with the active ventilation parameters!

Danger of lung damage

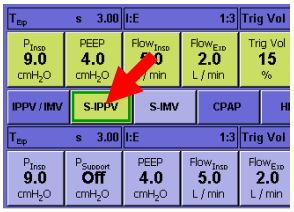
- Make sure that you do not accidentally edit the active ventilation parameters.





1. Click **NIV** or **IV** to change the ventilation.

With **NIV**, additionally select the ventilation system to be used (**Neojet H+L**, **HiFlow H+L**, **Closed Systems**).



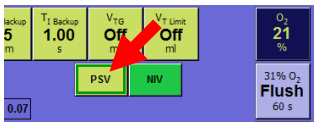
2. Preselect a ventilation mode (not for **HiFlow**):

- For **IV** ventilation: **IPPV / IMV**, **S-IPPV**, **S-IMV**, **CPAP**, or **HFO (**optional).
- For **NIV** ventilation: **nCPAP**, **nIPPV**, or **nHFO (**optional).

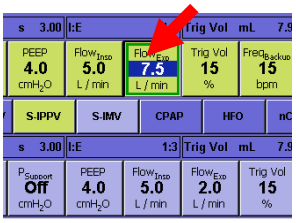
The ventilation parameters to be preset are displayed above the active ventilation parameters and are shown with a yellow background.

The parameter values from the current ventilation action are used as the default settings. On a change from/to HFO, the volume guarantee will be switched off automatically (V_{TG} off).

If > 1 min. (timeout) passes between selection of a new ventilation mode and confirmation of that selection, the preselected setting is reset.



3. Choose the **PSV** option to switch between ventilation modes with/without PSV (**SIPPV** / **PSV-SIPPV**, **SIMV** / **PSV-SIMV**).



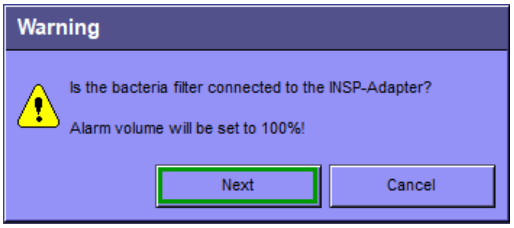
4. Adapt the ventilation parameters of the default settings to the patient.

→ *Changing parameter values with the rotary pulse encoder P. 48*

The bacteria filter must be connected on the inspiration side when you start HFO or nHFO ventilation mode.

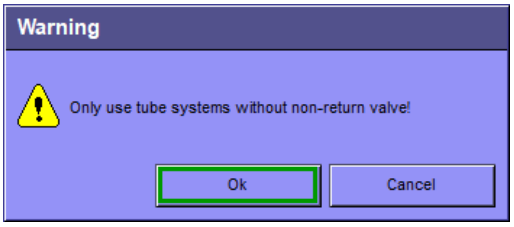
If you change to ventilation mode S-nCPAP or S-nIPPV, the trigger functionality is initially always set to "OFF". To activate the triggering, set the trigger threshold to any value.

5. Press the **Start** hard key to switch to the preselected ventilation mode.



Only when changing to the HFO/nHFO respiration mode:
The security prompt about the connected inspiration filter appears and the alarm volume is increased to 100%.

6. Confirm with **Continue**.



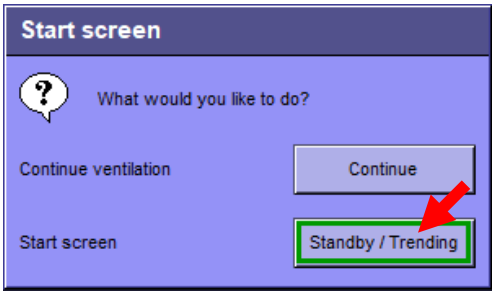
Then you will be reminded that only tube systems without a non-return valve may be used.

7. Confirm with **OK**.

The preselected ventilation mode is then applied with the pre-set respiration parameters.

Stopping ventilation

1. Press the **On/Off** hard key.



2. A safety prompt opens.

Select **Standby/Trending**.

Ventilation is stopped and “Device ready”/Standby screen is displayed.

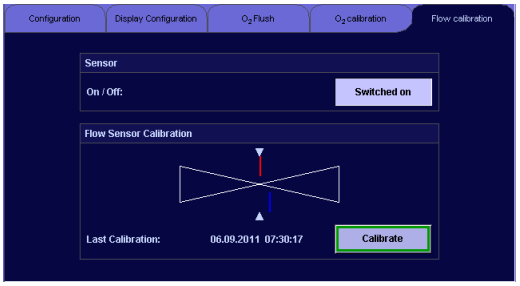
3. Press **monitoring** hard key to reach start screen resp. to toggle between the menu items of the menu bar.

*Press **Continue** to cancel the procedure and return to ventilation.*

Special procedures

Switching off the flow sensor

1. Select the **Settings** menu on the Ventilation screen.



2. Select the **Flow calibration** tab.

*As an alternative to the **Settings** menu, you can switch to the **Start screen** and deactivate the flow sensor in the same way there.*

3. Select the "**Switched on**" button in the sensor window.

4. You can now switch off the flow sensor by turning the encoder.

Switch-off is not possible during ventilation if the current ventilation mode requires a flow sensor. This is the case for all synchronised ventilation modes.

As soon as you switch off the flow sensor, the calibration area disappears.

5. Now open the ventilation screen.

6. By switching off the flow sensor, only **IV** ventilation modes IPPV / IMV, CPAP, HFO and **NIV** ventilation modes nCPAP, nIPPV nHFO, and HiFlow are selectable.

7. Now only pressure control is available.

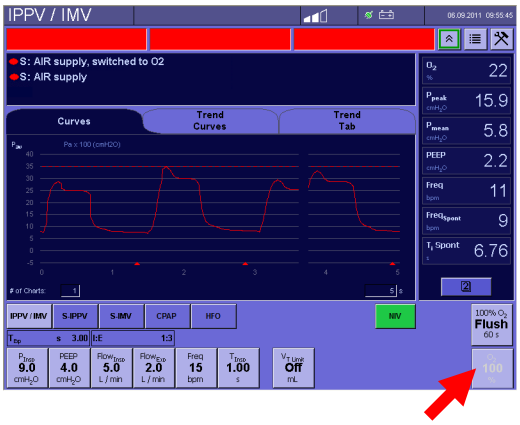
Ventilation if one gas supply fails

Switching to remaining gas by gas supply failure!

Danger of insufficient oxygen supply

- Check the oxygen saturation of the patient

WARNING



It is automatically switched to the remaining gas if one gas fails.

1. The alarming “O_2 supply“ resp. “Air supply“ implies that the pressure of the gas supply falls down.
2. The alarming “O_2 supply, switched to freshgas Air“ resp. “Air supply, switched to freshgas O_2” appears if the gas fails completely.

   It is switched to the remaining gas.
3. The ventilation parameter O_2 is displayed greyed out and can not be altered.

*The **O_2** button is set to 21 % O_2 if O_2 fails and switching to AIR, resp. to 100 % O_2 if Air fails and switching to O_2.*

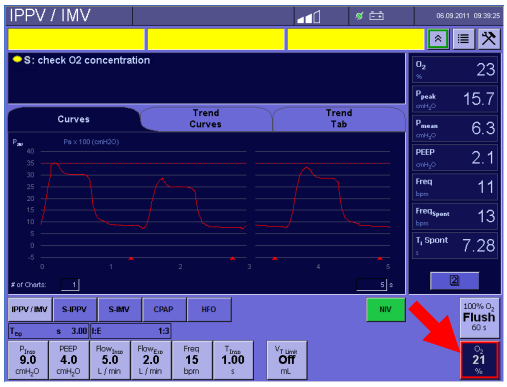
4. The ventilation can be continued with the remaining gas.
5. Check the oxygen saturation of the patient.

If the failed gas returns, the ventilator returns to the oxygen setting prior to the failure!

Danger of insufficient or excessive oxygen supply

- Closely monitor the oxygen supply to the patient.

WARNING



When the failed gas returns, it is switched back to the oxygen concentration used before the failure

1. The oxygen concentration returns to the previous used concentration.
2. The **O_2** button is displayed with a red blinking frame.

*The oxygen setting can be changed with the **O_2** button.*

3. The alarm “S: check O_2 concentration” is displayed.

The alarm “S: check O_2 concentration” shows switchover to both gases and cannot be acknowledged with the alarm mute button.

4. Confirm the preset concentration by pressing the **O_2** button.
5. The alarm is no longer active.

Ventilation by failure of entire gas supply

WARNING

Failure of entire gas supply!

Danger of insufficient oxygen supply

- Establish an alternative ventilation method (e.g. manual resuscitator).

If both gases fail during ventilation, the following message is displayed: „O2 and Air supply failed. Dosing fresh gas stopped.“

1. Ensure the oxygen supply to the patient with an alternative ventilation system (e.g. manual resuscitator).

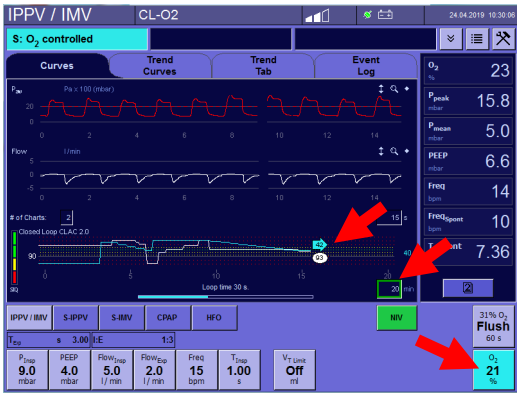
Closed Loop ventilation*

Starting Closed Loop

1. Select the **Settings** menu on the Ventilation screen.
2. Select the **SpO_2** tab card.

3. Activate **Closed Loop**.

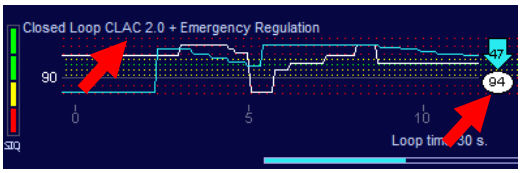
If ventilation is already running, it switches to Closed Loop mode. If the device is in standby, Closed Loop mode is activated when ventilation is started.



4. The patient status (current SpO_2 measured value) is represented in the monitoring by a trend curve.

   The time window of the trend curve can be set between 10 min and 12 h.

   During ventilation in Closed Loop mode, the **O_2** key is colored light blue.



In the trend curve, the CLAC version and the activated emergency control may be displayed.

The white line shows the curve for the SpO_2 measured values. The current SpO_2 value is displayed in the white bubble.

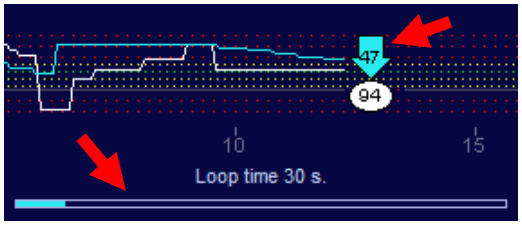
The curve of the SpO_2 line visualizes the actual value as referred to the set target range:

- Green dotted line = SpO_2 target range
- Yellow dotted line = normoxemia
- Red dotted line = SpO_2 outside the target range

*The lower and upper limit range for the SpO_2 target range is set in the **Settings** menu.*

→ *Setting Closed Loop P. 72*

* not for LeoniPlus transport



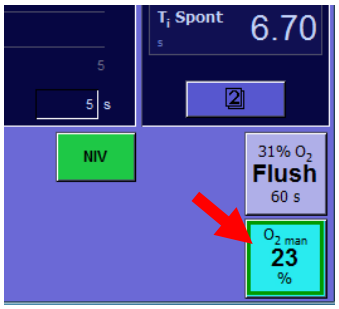
The arrow above the current SpO_2 value indicates whether the setting for **O_2** will be increased, maintained, or reduced on the next adjustment.

The progress bar below the trend curve visualizes the time to the next adjustment.

*The control period is set in the **Settings** menu. It can be changed even while ventilation is in progress.*

→ *Setting Closed Loop P. 72*

Pausing Closed Loop



1. Change the setting for **O_2** manually.

   The set value for **O_2** is applied immediately and Closed Loop control is interrupted for a control period. (You can set the control period in Service.)

   During the pause, the **O_2** button flashes.

2. After a pause (see progress bar below the SpO_2 bubble level), Closed Loop control automatically starts again.

Closed-loop control fallback mode

Closed-loop ventilation is aborted if no value is received from the SpO_2 sensor for 90 s. Ventilation is resumed without closed-loop control using the preset parameters.

An alarm of medium priority signals fallback mode ("O2 control aborted").

The O_2 button is no longer light blue.

As soon as values are received from the SpO_2 sensor, the Closed Loop control is automatically resumed.

Closed Loop emergency control

The emergency control includes expanded O2 control for different situation arising in clinical use.

See description of Closed Loop control.

→ *Pulse oxymetric controlled ventilation (Closed Loop) P. 92*

The emergency control is activated by default and can be deactivated in the Service menu. If emergency control is active, this is indicated by a relevant addition in the trend curve, e.g. "CLAC 2.0 + Emergency Regulation".

On severe desaturation below 70% SpO_2, in addition to a high priority alarm, the red flashing **O_2** button indicates the escalation from the (normal) basic control.

Terminating Closed Loop

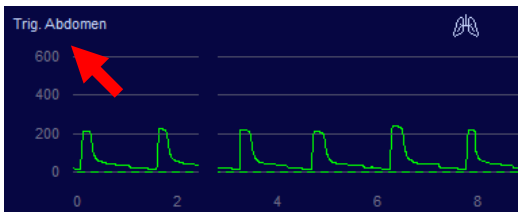
1. Select the **Settings** menu on the Ventilation screen.

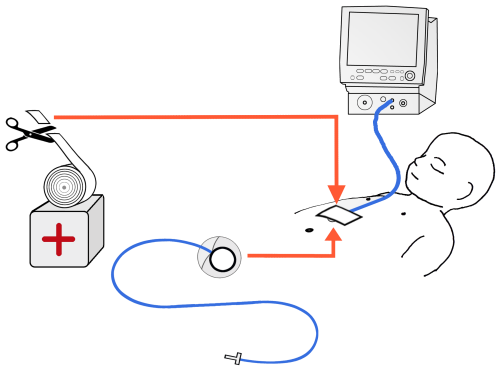
2. Select the **SpO_2** tab card.
3. Deactivate **Closed Loop**.

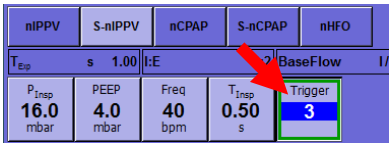
   Ventilation is continued in normal ventilation mode with the preset parameters.

Ventilation with abdomen sensor*§

Connecting the abdomen sensor







1. Connect the connector of the pressure tube (blue) to the ventilation device.

   → *Connection for abdomen sensor (device side) P. 58*

2. Start the ventilation mode S-nCPAP or S-nIPPV and select the curve "Trig. Abdomen".

3. Press the sensor carefully together.

   The curve of the abdomen sensor pressure signal is supposed to change.

4. Attach the sensor to the infant:
   - Affix the abdomen sensor using adhesive tape or other suitable fixing aids.
   - Position the sensor between the navel and the xiphoid process at the point of greatest expansion of the abdomen.
   - Alternatively, positioning on the side of the abdomen is also possible.

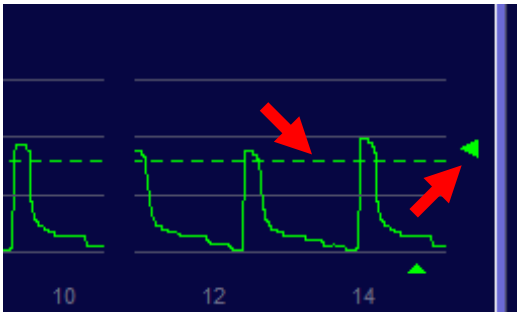
5. Check correct positioning.

6. Set the trigger threshold (**Trigger**) from "OFF" to the desired value.

   The trigger threshold can be set in the range 1 - 30, where 1 is the most sensitive setting.

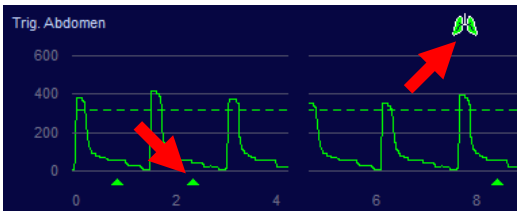
* not for LeoniPlus transport

§ Functionality above software version 3.2.x



The trigger threshold currently set is represented by the dashed line in the pressure curve "Trig. Abdomen".

A change in the trigger threshold is shown by the arrow at the right edge of the curve display.



The trigger visualization (lung symbol) flashes if a trigger is detected.

The triggered breaths are indicated by small arrows below the curve.

10. Special functions

Manual breath (Inspiration hold))

Manual breaths can be administered as an option in every ventilation mode except HFO.

The duration of a manual breath is limited to max. 10 s.

→ *Setting the maximum manual breath time P. 71*

Another manual breath cannot be triggered for another 0.2 s.

When a volume limit is set, the manual breath is automatically stopped when the volume limit is reached.

For a manual breath in volume-guaranteed ventilation (VTG), P_{Max} is used as the ventilation pressure.

WARNING

Danger of permanent lung damage!

- Make sure that P_{Max} is correctly set.

1. Press the **MAN** hard key to trigger a manual breath.

A manual breath is triggered as long as the hard key is held down.

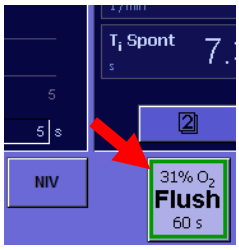
Triggering O_2 Flush (oxygen flush)

A short-term oxygen flush (O_2 Flush) with increased O_2 concentration is available in all ventilation modes. It is automatically stopped after a set time or the user can abort it prematurely.

The default O_2 flush concentration is 40%.

→ *Setting O_2 flush concentration P. 70*

The default O_2 flush duration is 60 seconds.
→ *Setting O_2 flush time P. 70*



1. Press **O_2 Flush** to trigger the O_2 flush.
2. Press the button again to abort O_2 flush prematurely.

Pausing ventilation

Ventilation can be paused in all ventilation modes. The pause is automatically stopped after maximum two minutes, but the user can also cancel it early.

WARNING

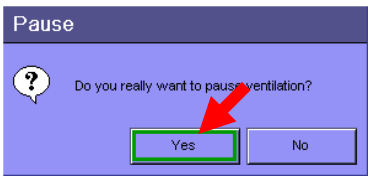
Improper use!

Danger of insufficient oxygen supply

- The standby function is not intended for the aspiration procedure. Disconnection or reconnection is not detected.

The function of the ventilation standby enables auscultation of the heart sounds or the recording of X-ray images.

1. Press the **Pause** hard key.



2. A safety prompt opens.

   Select **Yes**

Ventilation is interrupted for maximum 2 minutes.

*If you select **No**, the procedure will be aborted but ventilation will not be interrupted.*

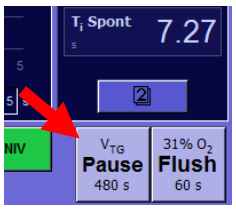
3. Press the **Start** hard key to end the pause prematurely.

   You return to ventilation.

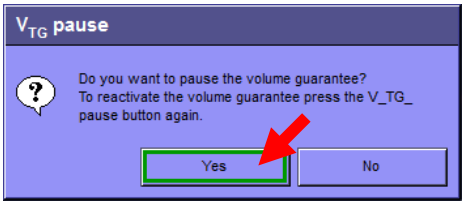
Pausing volume guarantee

During ventilation with volume guarantee (VTG), the **V_{TG} Pause** button is displayed, which can be used to switch to continue ventilation without VTG when needed.

The function "pausing volume guarantee" can be enabled in the Service menu by an authorized service technician.



1. Press **V_{TG} Pause** to pause volume guarantee.

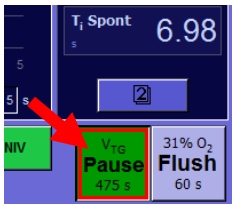


2. A safety prompt opens.

Select **Yes**

VTG is interrupted for maximum 8 minutes.

During the VTG pause, ventilation is continued at the last Ppeak under pressure control. The alarms "Volume not reached," "MV low," "Leak too high," "Ppeak low" are deactivated during this time.



3. Press **V_{TG} Pause** again to resume volume-guaranteed ventilation.

Closed aspiration

If you are using a closed aspiration system, a non-synchronized ventilation mode should be chosen to prevent counterregulation on synchronized breaths (auto triggering).

When the volume guarantee is activated, the function V_{TG} Pause can be used. This interrupts pressure regulation for a certain time and thus prevents counterregulation. During V_{TG} Pause, ventilation continues under pressure control using the pressure values last measured, to keep the volume as constant as possible.

Leakage compensation

Adaptive leakage compensation is available in synchronized ventilation modes to prevent automatic triggering, whereby pressure in the expiration valve is maintained by regulation during increased leakage.

Leakage compensation in CPAP mode is achieved by increasing the flow.

Pressure is similarly maintained in NIV ventilation by regulation of the expiration valve during leakage (exception HiFlow).

11. Monitoring

All values relevant to ventilation, such as flow, volume of breath and airway pressure, can be displayed in graphic form as time-dependent charts or as loops.

The measured values airway pressure, frequency, oxygen concentration, and minute volume can be displayed in tabular form every 5 minutes for monitoring purposes.

Additional measured values, such as positive, end expiratory pressure, mean pressure, spontaneous inspiration time etc., can be displayed numerically. Additional comparison options allow the user to assess the ventilation quality and set the ventilation parameters to the optimum values for the specific patient requirements.

WARNING

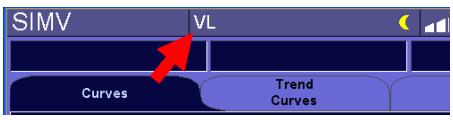
Inappropriate parameter settings!

Danger of insufficient oxygen supply

- Check the oxygen saturation and the CO_2 concentration regularly by pulse oximetry and capnometry or blood-gas analysis.

Display of active functions / options

Display



Currently selected functions and options are shown in the second field of the upper bar of the window:

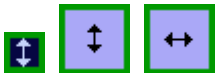
- Volume guarantee (**VG**)
- Pausing volume guarantee (**VG Pause**)
- Volume limit (**VL**)
- $P_{Support}$ (**Psupport**)
- Recruitment HFO (**REC**)
- Closed loop (**CL-O2**)
- Nightmode (yellow crescent moon)

Scaling

You can scale display of the curves and loops to adapt them to your current requirements.

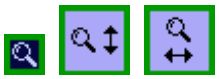
Controls

Different controls are available in the various views.



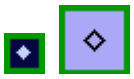
Shift

Shifts the coordinate system in the direction of the arrow.



Zoom

Magnifies or reduces the area of observation in the direction of the arrow.



Autoscale

Automatically adapts the chart and loop displays to the characteristics of the current ventilation.

Full screen

Allows magnification of the selected display in a larger window.

Close

Closes the current window.

Using the controls

1. Select a control in the main screen.

The control now has a coloured background.

2. Turn the rotary pulse encoder to change the view.

3. Confirm your input by pressing the encoder or by pressing the control.

The settings are also applied if you press another part of the screen.

Charts

The following charts displays can be selected:

- Flow
- P_{aw}
- Vol
- Trig. Abdomen
- Pleth

Charts view

(1) Chart type
switches between the different chart views

(2) Trigger visualisation
Lung symbol filled in for trigger event
Arrow icon to identify the triggered breaths

(3) Scale
shifts coordinate system up or down

(4) Zoom
magnifies or reduces view area

(5) Autoscale
automatic determination of the optimum viewing area

(6) Number of charts
indicates number of displayed charts

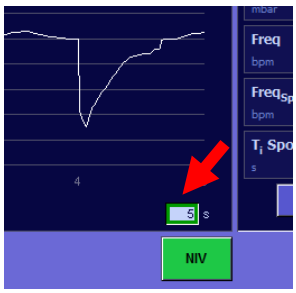
(7) Time axis
adjusts the time axis

Setting chart type

1. Select the **chart type** control.
2. Select a chart type:
   Flow, **P_{aw}**, **Vol**, or **Trig. Abdomen**

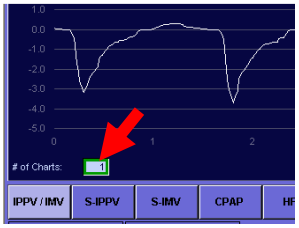
Triggered breaths are identified by an arrow icon.

Adjust time axis



1. Select the **time axis** control.
2. Select a time axis scale:
   2 – 30s

Adjust number of charts



1. Select the **# of Charts** control.
2. Select the number of charts that are to be displayed simultaneously.
   1 - 3

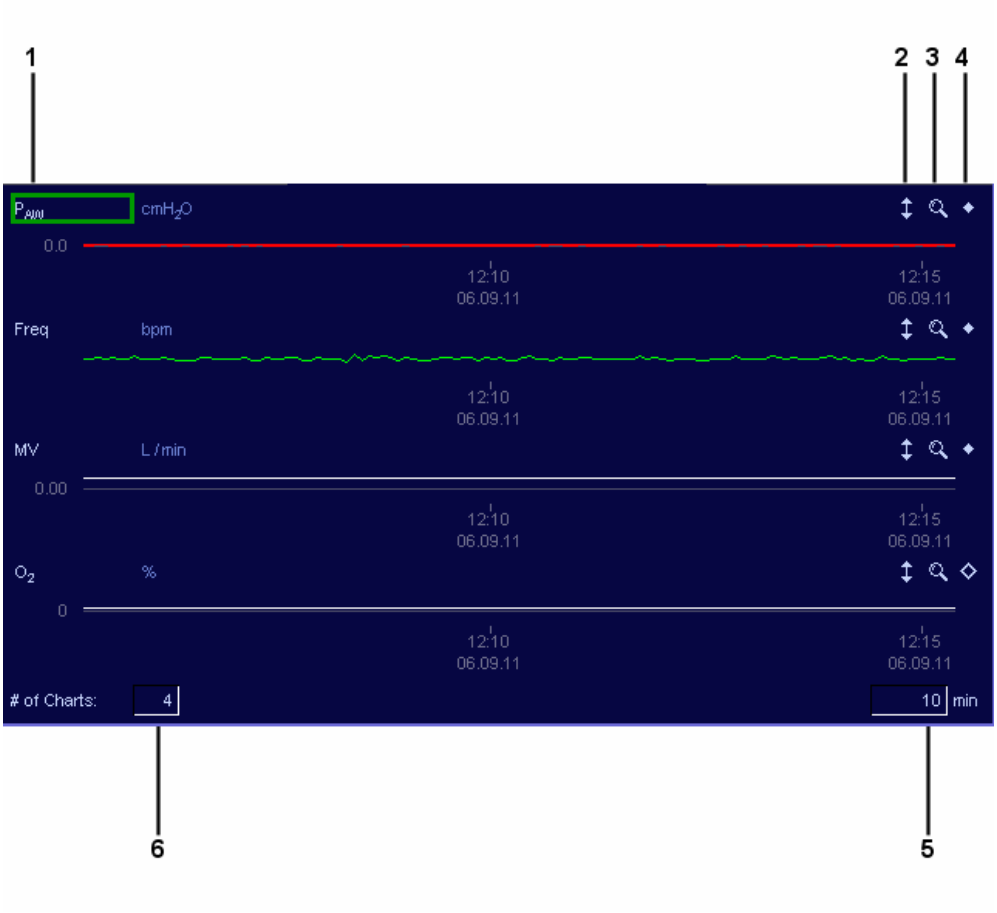
Trend charts

The following measured values can be visualized as trend charts for monitoring ventilation:

- P_{aw}
- Freq
- MV
- O_2
- DCO_2
- SpO_2

Up to 4 charts can be displayed at any one time. Displaying charts concurrently can be used to visualize correlations. The measured values are saved every 5 seconds.

Trend chart display



(1) Chart type
Switches between the various chart views

(2) Scaling
Moves coordinate system up or down

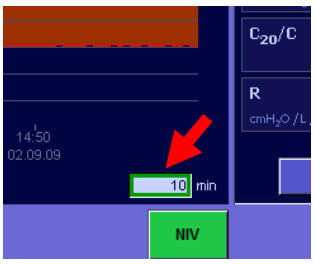
(3) Zoom
Magnifies or reduces the area of observation

(4) Autoscale
Automatic determination of the optimum area of observation

(5) Time axis
Scales the time axis

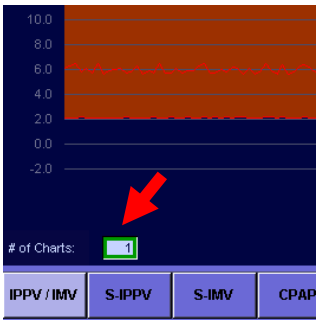
(6) Number of charts
Number of displayed charts

Adapting time axis trend charts



1. Select the **Time axis** control.
2. Select the desired time axis scale:
   10 min – 72h 00min

Adapting the number of trend charts



1. Select the **Number of charts** control.
2. Select the number of charts to be displayed concurrently:
   1 - 4

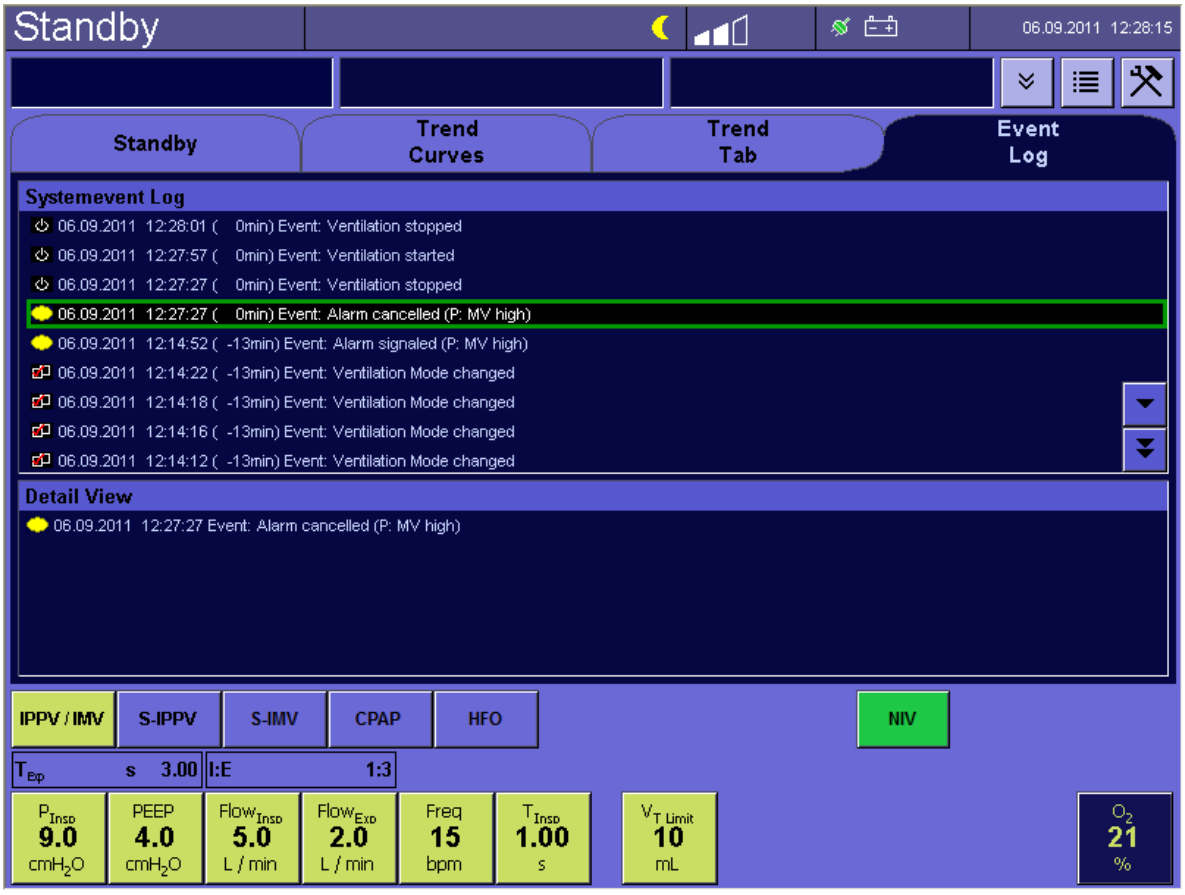
Tabular trend

The following measured values are displayed in tabular form every 5 minutes to monitor ventilation:

- Date/Time
- Event (start and stop of ventilation and ventilation mode)
- Measured values (Ppeak, Pmean, PEEP, MV, O_2, Freq)

Event Log

All settings, alarms and events made in LeoniPlus can be viewed, monitored and analysed in an event log. Events can be displayed in a detailed view.



The following events are displayed:

 Triggered alarms

 Device switched on and off

 Ventilation started and stopped

 Ventilation mode changed

 Ventilation parameters changed

 Calibration performed

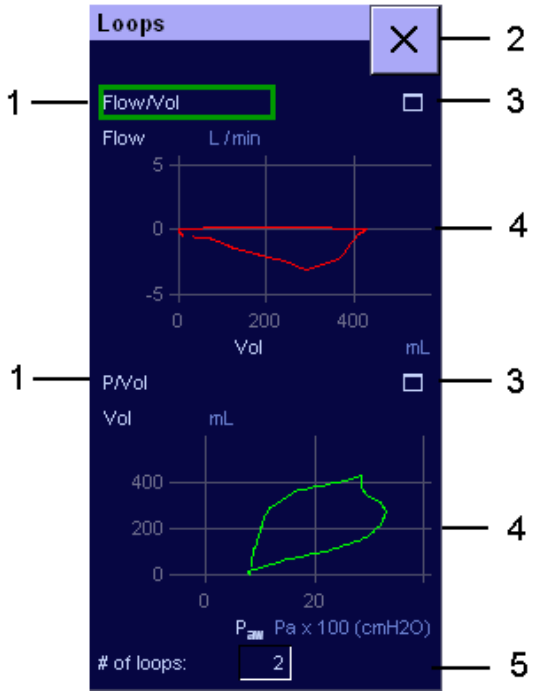
 Alarm limits changed

Loops

The following three loop displays can be selected:

- Flow / Vol
- P / Vol
- P / Flow

Loop view



(1) Loop type
switches between the various loop views

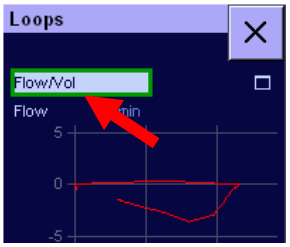
(2) Close window
closes the loop window

(3) Full screen
maximises the current loop view

(4) Loop view
press directly on the loop to open the full screen view

(5) Number of loops
number of simultaneously displayed loops

Set loop type



1. Select the **loop type** control.
2. Select a loop type:
   Flow / Vol, P / Vol or **P / Flow**

Adjust number of loops

1. Select the **# of loops** control.
2. Select the number of loops that are to be displayed simultaneously.
   1 or **2**

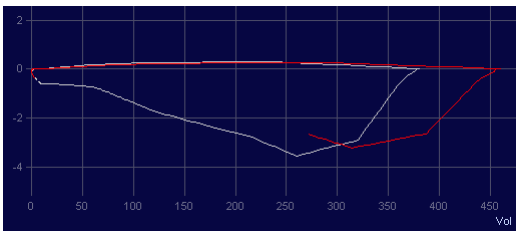
Storing a reference loop

You can store a loop and insert it as a reference loop.

1. Press **Pause** in the loop display.
   The chart display is frozen.

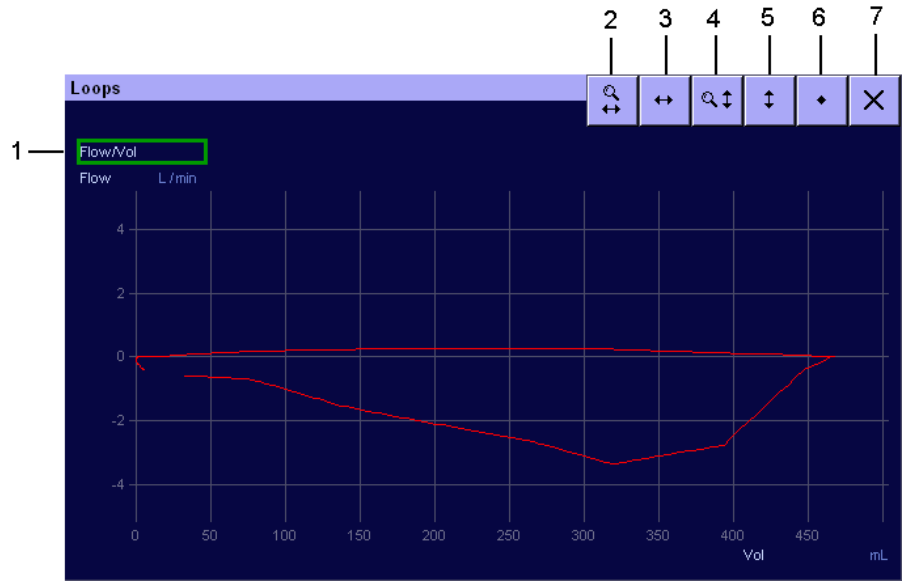
2. Press **Save**.
   The loop is stored

3. Press **Activate**.



The stored chart is displayed as a reference chart.

Loop view in full screen



(1) Loop type
switches between the various loop views

(2) Horizontal zoom
magnifies or reduces the viewing area in a horizontal direction

(3) Horizontal shift
shifts the coordinate system in the horizontal direction

(4) Vertical zoom
magnifies or reduces the viewing area in the vertical direction

(5) Vertical shift
shifts the coordinate system in the vertical direction

(6) Autoscale
automatically sets the optimum viewing area

(7) Close full screen window
returns to the normal view

Numerics

In the **NUMERICS** view a large number of measured values are displayed in numerical form. The “damped average values” are updated after every breath, but no more than once every second.

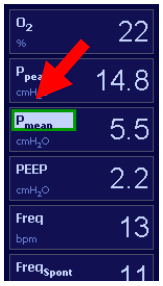
The scope of the calculated numeric values varies from ventilation mode to ventilation mode.

The **NUMERICS** view cannot be hidden.

Information about the measured values:

→ *The measured values (numeric values) P. 109*

Changing displayed measured value



1. Select a **measured value** from the numerics table.
2. Select the measured value that you want to display.

Measured values that have already been displayed cannot be displayed again.

Switching over the numeric table

1. Press the **Monitoring** hard key or press the **Switch table** button in the numeric table.

12. Battery mode

Battery mode

During battery operation the battery LED is yellow.

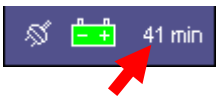
An information message is displayed. It can be acknowledged by pressing the **mute alarm** hard key.

The battery icon in the title bar is green.

The battery runs for different lengths of time depending on the type of battery installed.

For normal ventilation the battery will run for 60-200 minutes or longer.

Depending on the setting, the battery will run between 15 and 120 minutes in the case of HFO.



Pay attention to the residual operating time of the battery displayed. This is calculated for the respective current operational mode.

CAUTION

Reduction of battery life when switching modes!

Automatic shutoff of ventilator

Changing modes, for example, to HFO, may significantly reduce the battery life!

- Observe the remaining battery life when changing settings!
- Never leave device and patient unattended!
- Connect the device to a mains power source in time.

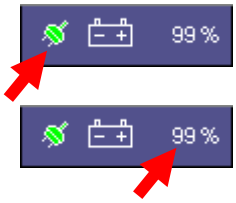
Charging the battery

To charge the batteries, connect the LeoniPlus to a suitable mains power socket using a power cable. The device automatically detects the voltage (100 – 240 VAC, 50 – 60 Hz). You do not have to switch over the device manually. To fully charge the battery before the device is operated for the first time or when the battery is replaced, leave the device connected to the mains power for at least 8 hours.

When the mains power plug is connected, the batteries are automatically recharged both in mains operation and when the device is switched off.

Mains operation

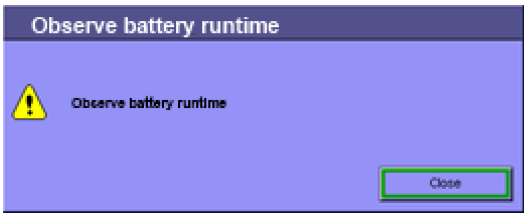
The mains operation LED is green.



The mains icon in the title bar is green.

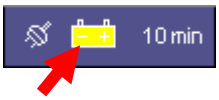
After about 10 seconds the charging condition of the battery is shown.

Warnings for low battery charge



When the remaining operating time is 20, 10 and 5 minutes a dialog is shown which prompts the operator to pay attention to the time the battery will continue to run.

In this case, if possible create a network-bound power supply!



When the residual battery operating time is only 10 more minutes, the battery icon turns yellow.

Below a residual battery operating time of 5 minutes, the residual operating time is signalised as "<5 min".

The alarm **`Battery almost empty`** is shown and an audible alarm sounds informing the user that the device is about to shut down.

If this happens, connect the device to a mains power source immediately.

Emergency shut-down when battery is empty

As soon as the residual battery operating time reaches 0 minutes the backup alarm of the device signalises it additionally. The device works until it reaches a critical voltage threshold. It then switches into a passive, safe state. After two more minutes the device automatically switches off in order to avoid exhaustive discharge.

CAUTION

Keeping within the residual operating time of the battery!

Automatic shutdown of the ventilator

- Never leave device and patient unattended during battery operation.
- Connect the device to a mains power source in time.

If the remaining run time of the battery falls below 0 minutes, the battery icon turns red.

The **`Battery empty`** alarm is shown and an audible alarm sounds.

The device stops all ventilation actions and switches to a passive, safe status that will not influence the patient during autonomous breathing.

This status can only be reset by a restart. Connect the device to a mains power source immediately and restart it!

NOTICE

Forced device operation after automatic shutoff!

Danger of exhaustive battery discharge

- Do not force the device to operate after an automatic shutoff.

13. Alarms & troubleshooting

The ventilator has three types of alarms: *patient alarms*, *system alarms* and *technical alarms*. Depending on their urgency they are assigned different priorities and are displayed in the alarm window according to that priority.

The user can set the alarm limits for patient alarms.

All alarms can be viewed in the alarm log.

Alarm settings

All alarms are muted for 30 seconds after starting ventilation.

NOTICE

Setting range & calculation method

Setting ranges of alarm limits	
MV [l] calculated minute volume	⚠: 0.05 – 10.0 ▽: 0.00 – 4.99
V_{Te} [ml] volume limit (range of possible tidal volume)	⚠: 2 – 250 ▽: 0 – 249
Leak [%] percentage breathing gas loss in ventilation hoses	⚠: 8 – 100
Freq [1/min] number of breaths per minute (breathing frequency)	⚠: 10 – 220
Apnea [sec] time in seconds after which a breathing stop triggers an alarm (can be deactivated)	⚠: OFF, 6 –60

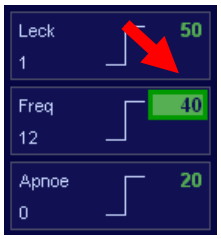
Setting ranges of alarm limits	
P_{Peak} [mbar] limits between which the inspiration pressure must be set	⚠: 5 - 90 ▽: -10 – 20
P_{mean} [mbar] limits between which the mean pressure in the HFO must be set	⚠: 1 - 50 ▽: -5 – 40
CPAP [mbar] level between which the CPAP level must be set	⚠: 2 - 50 ▽: 0 – 6
O_2 [%] range in which the oxygen concentration is allowed to vary. (can be set if this is configured in the Service menu)	⚠: 5 – 30 % above set O_2 ▽: 5 – 30 % below set O_2
O_2 Set [%] range between which the Closed Loop controlled O_2 setting is allowed.	⚠: 26 – 100 ▽: 18 – 23
SpO_2 [%] range between which the measured SpO_2 value is allowed. (Closed Loop defaults: upper and lower level of SpO_2 target range)	⚠: 71.0 – 100.0 ▽: 70.0 – 99.0

Calculation of the automatic alarm limits:	
MV [l] calculated minute volume	⚠: 85% above the measured minute volume ▽: 50% below the measured minute volume
V_{Te} [ml] range of the possible exp. tidal volume	⚠: 30% above measured tidal volume ▽: 30% below measured tidal volume
Leak [%] percentage breathing gas loss in ventilation hoses	⚠: 50% above the measured high leak to the maximum value of 50% high leak
Freq [1/min] number of breaths per minute (breathing frequency)	⚠: 50% above measured frequency
Apnea [sec] time in seconds after which a breathing stop triggers an alarm	⚠: 10 s

Calculation of the automatic alarm limits:	
P_{Peak} [mbar] limits between which the inspiration pressure must be set	: 3 points above set pressure : 3 points below set pressure
P_{mean} [mbar] limits between which the mean pressure in the HFO must be set	: 20% above set P_{Mean} : 20% below set P_{Mean}
CPAP [mbar] level between which the CPAP level must be set	: 3 mbar above set CPAP : 3 mbar below set CPAP
O_2 [%] range between which the oxygen concentration is allowed	: 5 % above set O_2 : 5 % below set O_2
Peff [mbar] range between which the Peff pressure is allowed	: 3 mbar above set CPAP : 3 mbar below set CPAP

Setting patient alarm limits manually

1. Press the **alarm limits** hard key to display the alarm limit values if they are not visible.



2. Select the desired limit value.
3. Set the desired limit value.
4. Confirm your entries.

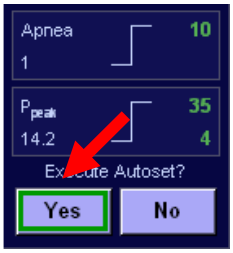
You can also use the button/rotary knob to set the alarm limits.

→ *Changing parameter values with the rotary pulse encoder P. 48*

Setting patient alarm limits automatically

1. Press the **alarm limits** hard key to display the alarm limit values if they are not visible.

2. Press **Autoset**.



3. A safety prompt opens.

Select **Yes**.

The alarm limits are automatically calculated and set for the current status.

→ *Setting range & calculation method P. 151*

*Press **No** to stop the procedure and the alarm limits will remain unchanged.*

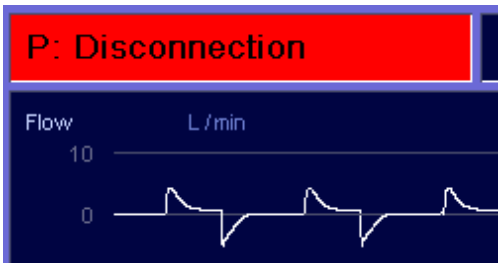
Setting the alarm volume

→ *Configuration of alarm presets P. 74*
→ *Setting the environmental sound level P. 75*

Alarm messages

Alarm priorities

The device has two priorities depending on the urgency of the alarm message. They are identified by a specific tone sequence and colour-coded alarm messages.



Priority high:

Requires immediate action to prevent a life-threatening event (such as disconnected tubing).

The tone sequence configured for high-priority alarms will sound.

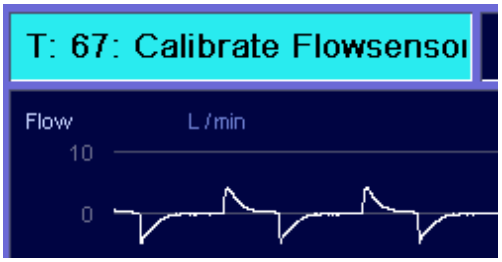
→ *Configuration of alarm presets P. 74*

Priority medium:

Requires quick action to prevent a life-threatening event (such as patient alarm).

The tone sequence configured for medium-priority alarms will sound.

→ *Configuration of alarm presets P. 74*



Info message:

Info messages provide information for the user. They do not require immediate action. However, the user must take precautions or appropriate action depending on the circumstances.

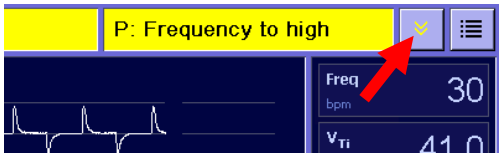
Info messages can be acknowledged by pressing the **mute alarm** hard key.

Viewing alarms

Pending alarms are displayed in the alarm bar. They are shown in order of priority.

If more than three alarms occur simultaneously, this is indicated by the yellow arrow icon in the alarm bar. Press the arrow to view a list of all current pending alarms.

The alarm is also signalled by a flashing red light (**alarm LED**) and an **audible alarm**.

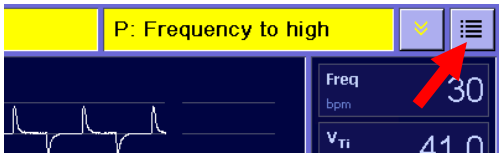


1. Press the arrow icon in the alarm bar to open the list of current alarms.

2. A list of all active alarms is shown.

You can scroll up and down in the list with the controls.

3. Press the arrow icon in the alarm list to close the list.



4. Press the **Alarm Log** icon to open the alarm log.

The alarm log contains all previous alarms in chronological order.

5. The yellow information icon prompts the user to view the alarms in the alarm log.

The prompt icon is shown if an alarm of high priority was reset without the user responding when the alarm occurred.

The icon is reset when the alarm log is opened.

Muting alarms

1. Press the **Mute alarm** hard key.

The patient alarms are muted for two minutes.

Does not include high-priority technical alarms and system alarms.

While it is muted, the LED on the hard key is yellow and the **alarm LED** remains red.

This icon in the display shows how long the alarm has been muted.

If no alarm is active, you can press the ***Mute alarm** hard key* to suppress alarms for the next two minutes, too.

The alarms will be acoustically suppressed for 2 minutes if the Mute alarm button is held pressed for longer than 3 seconds. This is possible both for active and non-active alarms.

WARNING

No audible alarms will be signaled after pressing the Mute alarm button for 3 seconds. Important alarms can go unnoticed.

Death or permanent damage to the patient is possible.

- It is essential to remain with patients or cancel this function by briefly pressing the Mute alarm button again.

Displaying the alarm log

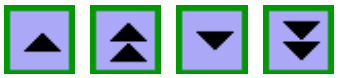
All alarm messages are placed and stored in the alarm log in chronological order. The data are retained on proper shutdown of the device and are available again on restarting. The switch-off time of the device is also recorded. On a complete power failure, data added since the last proper shutdown are lost.

When the capacity limit of the alarm log memory is reached, the oldest data are deleted.

1. Press the **alarm limits** hard key to display the alarm limit values if they are not visible.

2. Select **Log**

The alarm log window opens.



3. You can scroll up and down in the list with the controls.

*The alarm log can be displayed by pressing the **Alarm Log** icon in the alarm bar.*

Troubleshooting

Error messages – patient alarms

!

NOTICE

The tripping delay (filter) of some patient alarms can be amended in the Service menu.

The configurable areas are specified in brackets in the table's "Filtering" column.

Alarm message	Priority	Filtering	Possible causes	Possible remedies
Apnea	High	–	▪ Patient no longer breathes spontaneously ▪ Stenosis in/after tubing	▪ Change ventilation mode ▪ Remove stenosis
Set pressure not reachable	Medium	2 consecutive breaths (2 – 15 breaths)	▪ Leak in device-side tubing (before flow sensor, at y-piece) ▪ Leak at inspiration valve ▪ Leak at tube ▪ Flow too low	▪ Check inspiration tube and inspiration connection ▪ Check tube ▪ Increase flow
Frequency too high	Medium	3 consecutive breaths (3 – 15 breaths)	▪ Hyperventilation ▪ Additional spontaneous breathing by patient	▪ Reset alarm limits ▪ Reset breath frequency setting ▪ Reset ventilation mode
MV low	Medium	3 consecutive breaths (3 – 15 breaths)	▪ Change in lung compliance	▪ Increase P_{Insp} or adapt V_{TG}
MV high	Medium	3 consecutive breaths (3 – 15 breaths)	▪ Change in lung compliance	▪ Reduce P_{Insp} or adapt V_{TG}

Alarm message	Priority	Filtering	Possible causes	Possible remedies
PEEP too high	Medium	3 consecutive breaths (3 – 15 breaths)	▪ Inspiratory tube blocked or kinked ▪ PEEP membrane defective ▪ Poor fitting of expiratory valve ▪ Flow sensor defective	▪ Check pressure settings ▪ Calibrate flow sensor
PEEP pressure not reached	Medium	3 consecutive breaths (3 – 15 breaths)	▪ Peep pressure setting cannot be reached ▪ Leak too high	▪ Check tubing system ▪ Increase expiration flow
Volume not reached	High	> 15s	▪ Inspiration pressure setting is reached prematurely	▪ Change inspiration pressure setting ▪ Increase inspiration time ▪ Change volume preset
Volume limit reached	Info	–	▪ Breath discontinued as the set volume limit was reached	▪ Change inspiration pressure setting ▪ Change volume preset
Ppeak high	High	"HFO: > 3 s (3 – 15 s) all other vent. modes: 3 consecutive breaths (3 – 15 breaths)	▪ Inspiration pressure setting greater than Ppeak alarm limit	▪ Adapt Ppeak alarm limit
Ppeak low	High	"HFO: > 1 s (1 – 15 s) all other vent. modes: 3 consecutive breaths (3 – 15 breaths)	▪ Inspiration pressure setting cannot be reached, inspiration time too short	▪ Change inspiration pressure setting ▪ Adapt Ppeak alarm limit
Pmean too high	High	> 1 s (5 – 10 s)	▪ Expiratory valve defective	▪ Inspect inspiratory valve membrane
Pmean too low/ Disconnection?	High	> 1 s (5 – 10 s)	▪ Inspiratory flow missing	▪ Inspect inspiratory tube

Alarm message	Priority	Filtering	Possible causes	Possible remedies
Leak too high	Medium	3 consecutive breaths (3 – 15 breaths)	▪ Leakage in tubing between flow sensor and patient ▪ Tube too small ▪ Air leak in tube	▪ Check tubing between flow sensor and patient ▪ Replace tube ▪ Check blocking
Excess pressure Insp-Tube	High	–	▪ Inspiratory tube blocked or kinked	▪ Inspect inspiratory tube
Excess pressure Exsp-Tube	High	–	▪ Exhalatory tube blocked or kinked	▪ Inspect inspiratory tube
HFO amplitude not reached	High	(60 – 180 breaths)	▪ The set HFO amplitude cannot be reached	▪ Adapt HFO amplitude setting
Check pressure settings	Info	during VTG pause	▪ Inspiration pressure setting was changed when switching off volume guarantee	▪ Check inspiration pressure setting
Disconnection? (possibly with supplement "Pressure", "HiFlow pressure" or "Flow")	High	(4 – 7 s), (7 – 14 s), (13 – 20 s)	▪ Inspiratory tube disconnected ▪ Exhalatory tube disconnected ▪ Pressure tube disconnected ▪ Tubing disconnected	▪ Check tubing system
Tubus occluded	High	Resistance: 3 breaths (3 – 15 breaths) HFO Resistance: 10 s (10 – 30 s) Flow: 35 s (35 – 60 s)	▪ Tube blocked/bent	▪ Inspect tube
O_2 too low **O_2 too high**	High	6 s (6 – 18 s)	▪ The O_2 concentration deviates from the specified value	▪ Contact a technician ▪ Check the gas supply ▪ Calibrate the oxygen sensor

Alarm message	Priority	Filtering	Possible causes	Possible remedies
SpO2 too low	High	10 s (10 – 20 s)	▪ Oxygen saturation too low ▪ SpO_2 sensor fitted incorrectly	▪ Check O_2 setting ▪ Check SpO2 sensor
SpO2 too high	High	10 s (10 – 20 s)	▪ Oxygen saturation too high ▪ O_2 setting too high	▪ Check O_2 setting / O_2 concentration
SpO_2 too low – Emergency Regulation activated	High	–	▪ Desaturation of the patient below 70% SpO_2	▪ Check provision to the patient, fastening / positioning / function of the SpO_2 sensor
SpO_2 too low – Regulation paused	High	–	▪ Desaturation of the patient below 70% SpO_2	▪ Check provision to the patient, fastening / positioning / function of the SpO_2 sensor
SpO_2 too high – Quick O_2 Reduction	Info	–	▪ O_2 concentration too high	▪ Check provision to the patient, fastening / positioning / function of the SpO_2 sensor
Dyn. O_2 increasing	High	–	▪ O_2 concentration too low	▪ Check provision to the patient, fastening / positioning / function of the SpO_2 sensor
O_2 Set too low	Medium	6 s	▪ O_2 setting too low	▪ Check O_2 setting
O_2 Set too high	Medium	6 s	▪ O_2 setting too high	▪ Check O_2 setting
VTe too high	Medium	3 consecutive breaths (3 – 15 breaths)	▪ Inspiration pressure too high	▪ Check inspiration pressure
VTe too low	Medium	3 consecutive breaths (3 – 15 breaths)	▪ Inspiration pressure too low ▪ Flow sensor defective	▪ Check inspiration pressure ▪ Calibrate flow sensor

Alarm message	Priority	Filtering	Possible causes	Possible remedies
CPAP too high	High	(3 – 10 s)	▪ CPAP pressure too high ▪ Tubing system connected incorrectly	▪ Check CPAP pressure ▪ Check tubing system
CPAP too low	High	(3 – 10 s)	▪ CPAP pressure too low ▪ Tubing system connected incorrectly ▪ Leak present	▪ Check CPAP pressure ▪ Check tubing system
Peff too high	Medium	3 s (3 – 15 s)	▪ Flow set too high	▪ Reduce flow
Peff too low	Medium	3 s (3 – 15 s)	▪ Peff too low	▪ Increase flow
Pmax reached	High	3 s	▪ Flow set too high	▪ Reduce flow
Tidal volume too high	Medium	10 breaths	▪ Inspiration pressure too high	▪ Check inspiration pressure
Tidal volume too low	Medium	10 breaths	▪ Inspiration pressure too low	▪ Check inspiration pressure
Vt HFO high	Medium	10 – 20 consecutive breaths	▪ Amplitude too high	▪ Check the amplitude
Vt HFO low	Medium	10 – 20 consecutive breaths	▪ Amplitude too low ▪ Flow sensor faulty	▪ Check the amplitude ▪ Calibrate the flow sensor

Error messages – system alarms

Alarm message	Priority	Filtering	Possible causes	Possible remedies
O_2 supply	High	2 s	▪ Pressure in oxygen line too low or too high	▪ Check central gas supply
Air supply	High	2 s	▪ Pressure in oxygen line too low or too high	▪ Check central gas supply

CAUTION

Gas supply failure!

Switching to the remaining gas

- Check the oxygen saturation of the patient
  → *Ventilation if one gas supply fails P. 123*

Alarm message	Priority	Filtering	Possible causes	Possible remedies
Flowsensor contaminated	High	4.0 s (FW)	▪ The flow sensor is soiled or defective	▪ Check flow sensor ▪ Replace flow sensor
Check abdomen sensor	Info	10 s	▪ Abdomen sensor not connected ▪ Abdomen sensor defective	▪ Check connection ▪ Replace abdomen sensor ▪ Contact a technician
Check abdomen trigger setting	Info	–	▪ Trigger threshold is set to "OFF" by default	▪ Set the trigger threshold to a suitable value
Device running on batteries	Info	–	▪ Power supply not available	▪ Restore power supply
Observe battery runtime	Info	–	▪ Residual battery operating time is less than 20 minutes	▪ Restore power supply
Battery almost empty	Medium + High	– > 20 s	▪ The maximum battery life has almost been reached	▪ Restore power supply
Battery empty. Mechanical ventilation stopped.	High	–	▪ The battery is exhausted	▪ Restore power supply
Battery empty. Supply voltage too low	High	> 20 s	▪ The battery is exhausted	▪ Restore power supply
Check O2 concentration	Medium	–	▪ O_2 concentration was changed by the system	▪ Check O_2 concentration
O2 supply failed. Freshgas is Air	High	5 s	▪ Central oxygen supply failed	▪ Check central gas supply

Alarm message	Priority	Filtering	Possible causes	Possible remedies
Air supply failed. Freshgas is O2	High	5 s	▪ Central air supply failed	▪ Check central gas supply
O2 and Air supply failed. Dosing fresh gas stopped.	High	5 s	▪ Central oxygen and air supply failed	▪ Check central gas supply
Oximetry cable not connected	Medium	30 s	▪ Sensor cable disconnected	▪ Check sensor and cable
SpO_2 Sensor not connected	Medium	–	▪ Sensor cable disconnected	▪ Check sensor and cable
SpO_2 Communication error	Medium	–	▪ Sensor cable disconnected	▪ Check sensor and cable
SpO_2 sensor failure	Medium	10 s	▪ Sensor cable disconnected	▪ Check sensor and cable
SpO_2 change too big	Info	–	▪ Step changes in SpO_2 too large	▪ Check fastening of the SpO_2 sensor ▪ If necessary, chose another measuring point on the patient
SpO_2 change not permitted	Info	–	▪ Too little controller data available ▪ Data are not valid	▪ Check fastening of the SpO_2 sensor ▪ If necessary, chose another measuring point on the patient
Too few data	Info	–	▪ Too little controller data available	▪ Check fastening of the SpO_2 sensor ▪ If necessary, chose another measuring point on the patient
Trend to target range	Info	–	▪ The calculated trend of the controller runs counter to the current change	▪ Check fastening of the SpO_2 sensor ▪ If necessary, check the control via the trending
Oximetry cable failure	Medium	–	▪ Sensor cable disconnected	▪ Check sensor and cable

Alarm message	Priority	Filtering	Possible causes	Possible remedies
O_2 controlled	Info	–	▪ Closed Loop function activated. O_2 is controlled automatically	–
O_2 control aborted	Medium	90 s	▪ Closed Loop function aborted. O2 is not controlled automatically	▪ Check for poor SpO_2 signal ▪ Check for low signal strength ▪ Check for poor sensor fitting
Closed Loop pause	Info	–	▪ Closed Loop function pauses. O_2 setting was changed manually	–
Low Perfusion	Medium	–	▪ Sensor disconnected	▪ Check for poor sensor fitting
SpO_2: Sensor off patient	Medium	–	▪ Sensor disconnected	▪ Check for poor sensor fitting
SpO_2: No cable connected	Medium	–	▪ Sensor cable disconnected	▪ Check cable
SpO_2: No adhesive sensor connected	Medium	–	▪ Sensor disconnected	▪ Check sensor
Pulse search	Info	–	▪ Pulse signal	▪ Wait for correct pulse signal
SpO_2: Interference detected	Info	–		▪ Check for poor sensor fitting
SpO_2: Too much ambient light	Info	–	▪ Too much ambient light reaches the sensor	▪ Check for poor sensor fitting
Low Signal IQ	Info	–	▪ Confidence level of SpO_2 and pulse rate data is low	▪ Check for poor sensor fitting ▪ Reduce motion, environmental interferences
SpO_2: Demo mode	Info	–	▪ SpO_2 sensor is in demo mode	▪ Stop demo mode

Error messages – technical alarms

WARNING

Malfunction of sensors!

Danger of insufficient or excessive oxygen supply

- Calibrate the sensor after every change.

Alarm message	Priority	Filtering	Possible causes	Possible remedies
Technical Failure	High	–	▪ An internal device fault has been detected	▪ Contact a technician
Battery Fail **Battery not connected**	Medium	–	▪ The batteries are defective ▪ The batteries are incorrectly connected or not connected	▪ Contact a technician ▪ Replace the batteries
Deviation pressure sensors	High	–	▪ The pressure measurement tube is not correctly connected ▪ The pressure sensors are defective	▪ Check pressure measurement tube ▪ Contact a technician
Sensor Fail Blender/Patient Pressure	High	2 s	▪ Condensate in the tube system/ pressure measurement tube ▪ The pressure sensors are defective	▪ Check the tube system/ pressure measurement tube ▪ Contact a technician
Fan Fail: risk of overheating	Medium	–	▪ The fan has failed	▪ Switch off the device ▪ Contact a technician
Oxy Measurement Fail	High	On PIC	▪ The oxygen sensor is defective ▪ The oxygen sensor is expended	▪ Replace the oxygen sensor ▪ Contact a technician
Loudspeaker failure	Medium	–	▪ The acoustic alarm signal has failed	▪ Contact a technician
Failsafe	High	–	▪ The device has switched to a passive, safe status to protect the patient	▪ Restart ▪ Contact a technician

Alarm message	Priority	Filtering	Possible causes	Possible remedies
Patient safe	High	–	▪ The device has switched to a passive, safe state to protect the patient. It continues to ventilate with the last settings	▪ Restart ▪ Contact a technician
Flow sensor broken **Flow sensor fail**	High	14.0 s (FW)	▪ The flow sensor has been disconnected ▪ The flow sensor is defective	▪ Check the flow sensor ▪ Replace the flow sensor
Current consumption too high	High	> 1 s	▪ An internal device fault has been detected	▪ Restart device ▪ Contact a technician
Versions not compatible	High	–	▪ An internal device fault has been detected	▪ Contact a technician
Controllerboard EEPROM checksum failed	High	–	▪ An internal device fault has been detected	▪ Contact a technician
Controllerboard EEPROM not write protected	Info	–	▪ An internal device fault has been detected	▪ Contact a technician
O_2 Calibration failure	Medium	–	▪ Calibration of the oxygen sensor has failed	▪ Calibrate the oxygen sensor
Calibrate Flowsensor	Info	–	▪ Flow sensor has been replaced ▪ Flow sensor has been disconnected and reconnected	▪ Calibrate the Flowsensor
Checksum error	High	–	▪ An internal device fault has been detected	▪ Contact a technician
USB data storage finished	Info	–	▪ RAM memory use ≥ 90%	▪ Restart device

Errors related to pulse oximetry*

If the result of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the $uSpO_2$™ Masimo SET® Oximetry for proper functioning.

Inaccurate measurements

Inaccurate measurements may be caused by:

- Incorrect sensor application or use.
- Significant levels of dysfunctional hemoglobins, e.g., carboxyhemoglobin (COHb) or methemoglobin (MetHb).

When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.

- Intravascular dyes such as indocyanine green or methylene blue.
- Excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight. (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material).
- Excessive patient movement.
- Venous pulsations may cause erroneous low readings (e.g. tricuspid value regurgitation).
- Elevated levels of total bilirubin.
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

Loss of pulse signal

Loss of pulse signal can occur in any of the following situation:

- The sensor is too tight.
- There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight.
- A blood pressure cuff is inflated on the same extremity as the one with a SpO_2 sensor attached.
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- There is arterial occlusion proximal to the sensor.
- The patient suffers cardiac arrest or is in a state of shock.

* not for LeoniPlus transport

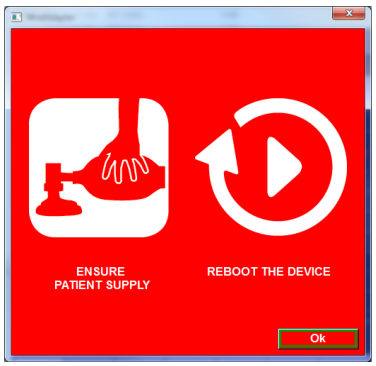
Failsafe and Patient Safe states

If, due to occurrence of a technical fault, the ventilation device can no longer be safely used to ventilate correctly, it switches to a passive state to ensure a safe state for the patient.

1. Ensure the oxygen supply to the patient with an alternative ventilation system (e.g. manual resuscitator).

2. Switch the device off and then switch it on again.
3. Contact a technician.

Patient Safe



If a non-critical/acceptable fault occurs that cannot be eliminated by the software, the device switches to the "Patient Safe" state.

Ventilation is maintained with the last parameters that were active.

It is not possible to change the parameters without restarting the device.

Failsafe

If a critical error occurs that cannot be corrected by the software, the device switches to the "Failsafe" state.

Ventilation is halted.

The device cannot be operated without restarting the device.

14. Switching off the device

WARNING

Working on live parts!

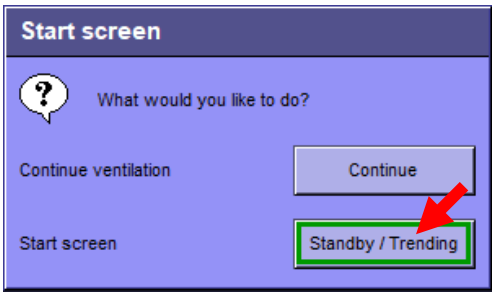
Danger of injury due to short circuit or electric shock

- Pull the power cord out of the socket to disconnect the ventilator from the power supply completely.

End ventilation

Active ventilation must be ended before the device can be switched off.

1. Press the **On/Off** hard key.



2. A safety prompt opens.

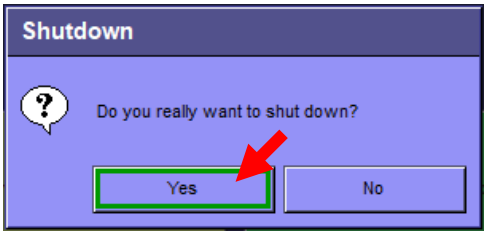
Select **Standby/Trending**.

The ventilation is ended and the device is set to the standby status. The "Device Ready"/Standby screen is displayed.

*By selecting **Continue**, the process is aborted and you return to ventilation.*

Switch Off

1. Press the **On/Off** hard key.



2. A safety prompt opens.

Press **Yes**.

The device is now switched off.

*If you press **No**, the process is aborted and the previous screen is displayed.*

15. Preparation, cleaning, sterilisation

General instructions

CAUTION

Poor hygiene!

Danger of infections

- Prepare the device and the tube system before first use and after every change of patient.
- Never use disposable products more than once (Example: The disposable filter will not function as well after conditioning).
- See the instructions for preparation of the manufacturers of the different products.

!

NOTICE

Incorrect cleaning and sterilisation!

Danger of damage to the device

- Ensure that personnel are trained accordingly (users and personnel of the central sterilization and supply department).
- Never sterilise the ventilator.
- Only disinfect the device by wiping it with the approved cleaning agents.
- When wiping the display with disinfectant, make sure that no drops form.

All medical devices contaminated with pathogens may be the source of human infections.

Re-use and handling of such medical devices requires comprehensive prior preparation. The measures described below are suitable for keeping the device hygienic and minimising the risk of infection as much as possible.

The procedures described below must be followed by appropriately trained and qualified persons to keep the device hygienic.

Read the following section completely before carrying out any of the steps described.

Proceed with the following steps to prepare the device and its components:

- Disassemble (for components only)
- Pretreatment
- Precleaning
- Cleaning
- Rinse, dry
- Disinfection/sterilisation
- Check that all surfaces are clean and undamaged
- Function test
- Sterilisation
- Transport and storage
- Commissioning

The tasks described here are generally compliant with the recommendations of the RKI and BfArM “Requirements for hygiene in the preparation of medical devices” with reference to the special requirements for ventilators, the recommendations of the SPECTARIS med association and, in particular, the materials used in this device.

Cleaning the device

WARNING

Working with electricity!

Danger of electric shock

- Before cleaning and disinfecting the device switch it off and remove the plug from the mains socket.

!

NOTICE

Water inside housing!

Danger of damage to the device

- Do not allow water to enter the interior of the device.
- Only wipe/clean the device with a wrung-dry cloth.

The outer housing of the device can be treated with standard cleaning agents. Do not use acidic, abrasive or corrosive agents.

The removable components of the LeoniPlus must be prepared with methods suitable for the material and contact with the patient.

There are three groups of components (TYPE A, TYPE B and TYPE C) that must be taken into account when preparing the device:

→ *The component groups (TYPE A, B and C) P. 176*

Cleaning the mobile stand

CAUTION

Löwenstein Medical makes no claims regarding the efficacy of the listed chemicals or processes as a means for controlling infection!

Danger of infection

- Consult your hospital's infection control officer or epidemiologist.

!

NOTICE

Use of unapproved substances or processes for cleaning and disinfecting the mobile stand!

Danger of damage to the device, which will not be covered by warranty.

- Do not use strong chemicals and solvents such as acetone and trichloroethylene, as this will permanently damage the surface.
- We recommend that you test any cleaning solution on a small area of the arm that is not visible to verify compatibility.
- Do not use steel wool or other abrasive material to clean the mounting assembly.

The cart may be cleaned with most mild, non-abrasive solutions commonly used in the hospital such as diluted bleach, ammonia, or alcohol solutions.

Wipe any cleaning agents off of the arm immediately using a water-dampened cloth. Dry the cart thoroughly after cleaning.

To clean or sterilize mounted instruments or accessory equipment, refer to the specific instructions delivered with those products

The component groups (TYPE A, B and C)

TYPE A:

The Type A sterilisable components installed near the patient with indirect contact to mucous membranes are the following:

- Expiratory valve (VA, Item No. 0217026-1)
- Expiratory valve (polysulfone, Item No. 0217026v2)
- Diaphragm for expiratory valve (silicone, Item No. 0217038v01bg)
- Ventilation tubes (reusable, see accessories)
- Baby test lung H+L (Item No. 0217043bg)

TYPE B:

The Type B sterilisable components installed near the patient and that can also be pretreated with protein-removal agents are the following:

- Multi-way flow sensor (Item No. 0217011)

TYPE C:

The type C components installed near the patient and with sensitive surfaces are the following:

- Flow sensor connection cable (Item No. 0217012)
- $uSpO_2$™ Masimo SET® Oximetry cable (Item No. 0217856hul102)

Sterilising TYPE A components

1. **Disassembly**

   Carefully remove the TYPE A components from the vicinity of the patient.

2. **Pretreatment**

   Remove surface contamination with a disposable cloth. Then rinse the components with water.

To prevent deposits we recommend treating TYPE A components immediately after use.

3. Precleaning

Additional precleaning of components is not required.

Very contaminated parts can be precleaned in an ultrasonic bath (max. 3 - 5 min).

Special feature of ventilation tubes:

Clean the inside lumen and the outside of the tubing system with warm water with detergent (solutions with surface-acting, non-foaming additives). Rinse the tubing with clear water. Allow the tubes to drip-dry.

4. Cleaning

a. Machine cleaning:

Machine cleaning is preferable to manual preparation because of work safety and reproducibility of work processes.

- Cleaning agent (cleaner concentration 0.5 %, cleaners are mildly alkali with PH value > 10)
- Place TYPE A components in the automatic cleaner and disinfectors so the cleaning agent can reach and flow out of the inside lumen.
- Set the cycle. It must reach a cleaning temperature of ≥ 55°C and a cleaning duration of at least 10 minute. Follow the cleaning agent manufacturer's directions for cleaning time.
- When removing the components inspect them for visible dirt.

The appropriate automatic program should be selected in accordance with the A0 3000 concept (DIN EN ISO 15883-1, Annex section 4).

b. Manual cleaning:

Note:

Use a suitable brush to clean holes and hollow spaces to reach every part of the component

Observe industrial safety, because cleaning performed before disinfection.

- Rinse surface contamination thoroughly from the components.
- Clean the exhalatory valve with a soft brush and surface-active, non-foaming detergents.

Make sure that all interior spaces are also cleaned.

- After cleaning rinse the valve under running water for two minutes. The interior lumen and holes must be thoroughly rinsed (several times).

Ensure that all detergent residues have been removed.

5. Disinfection (otherwise sterilisation, then continue with Section 6)

- After cleaning, place the component in a disinfectant solution or use a disinfector.
- Disinfectant (disinfectant concentration 0.5 %, disinfectants are mildly alkali with PH value > 10)
- Put the TYPE A components into the disinfector in such a way that the disinfectant can also reach the inner lumen and flow away again.
- Set the cycle. A disinfection temperature of > 55°C over a disinfection time of at least 10 minutes must be reached. Pay attention to the specifications from the validation relating to the rinsing time.
- Check the components for visible dirt on taking them out.

The appropriate automatic program should be selected in accordance with the A0 3000 concept (DIN EN ISO 15883-1, Annex section 4).

SECUSEPT and SECUSEPT FORTE S from ECOLAB are suitable disinfectants.

Make sure that there are no air bubbles in the interior lumen. All surfaces have to be bathed. The TYPE A components must be rinsed or completely filled with disinfectant.

Make sure that the components are immersed in the disinfectant for the time specified by the disinfectant manufacturer.

- Use deionised water for the final rinse.

6. Drying

It is very important that the components are dried thoroughly to prevent water from remaining in tubing and control tubes.

The drying temperature as part of the cleaning/disinfection cycle must not exceed 93 °C.

7. Check that all surfaces are clean and undamaged

- Carefully inspect all surfaces after cleaning and disinfection.
- Inspect the Type A components for obvious damage.
- Sort out damaged Type A components.

8. Packaging

- Pack TYPE A components individually in paper, foil or similar packaging as specified by DIN EN 868. Use the appropriate size of packaging material for the size of the component.
- Regardless of sterilisation method the packaging is generally:
  - mechanically protective packaging
  - outer packaging if required
- Do not use sterile packaging for disinfected products

Observe the storage periods for sterile goods as per DIN 58953 Part 8.

9. Sterilisation

- Observe DIN EN ISO 17665 as the basic requirement.
- Steam-sterilise the Type A components in an autoclave at, for example:
- ≥ 121°C, ≥ 15 min.
- ≥ 134°C, ≥ 5 min. and < 18 min.

10. Transport and storage

- Store the Type A components in a dry, dark place.

11. Function testing

- Check the function before it is next used as described in

→ *Calibration P. 63, Device check P. 67*

12. Commissioning

Preparation of TYPE B components (flow sensor)

Incorrect cleaning of the flow sensor!

NOTICE

Destruction of sensor wires

- **Never** clean the sensor with compressed air or strong water spray.
- **Never** place the sensor in a cleaning or disinfection machine.
- **Never** clean the sensor in an ultrasonic bath.

1. Disassembly

Carefully remove the TYPE B components from the vicinity of the patient.

2. Pretreatment

Carefully remove obvious residues on the sensor surface with a soft damp cloth or a disposable cloth.

3. Precleaning

Remove all electrical cables.
Otherwise deposits will form and the function of the sensor can no longer be guaranteed.

- Rinse TYPE B components immediately after use.

4. Cleaning

- Treat TYPE B components with protein-removal agents because of their closeness to the patient (solutions containing glutaraldehyde, such as Glutarex from Henkel).
- Additional precleaning of TYPE B components (flow sensor) is not required.

Do not use fixing agents.

5. Rinse, dry

After cleaning wipe the TYPE B components with a dry cloth. The components must be completely dried to ensure that they are effectively disinfected.

6. Disinfection (otherwise sterilisation, then continue with Section 7)

Immerse the component in a disinfectant solution after cleaning.

- Disinfectant (e.g. disinfectant concentration 0.5 %, disinfectants are mildly alkali with PH value > 10)

SECUSEPT and SECUSEPT FORTE S from ECOLAB are suitable disinfectants.
(If other disinfectants are used check that they are compatible with polysulfone and make sure that they have an antiviral, bactericidal and fungicidal effect.)

7. Check that all surfaces are clean and undamaged

- Carefully inspect all surfaces after cleaning and disinfection.
- Inspect the TYPE B components for obvious damage.
- Sort out damaged TYPE B components.

8. Sterilisation

- Observe DIN EN ISO 17665 as the basic requirement.
- Steam-sterilise (as required) the TYPE B components in an autoclave at, for example:
- ≥ 121°C, ≥ 15 min.
- ≥ 134°C, ≥ 5 min. and < 18 min.

9. Packaging

- Pack Type B components individually in paper, foil or similar packaging as specified by DIN EN ISO 11607-1.2006 in combination with DIN EN 868. Use the appropriate size of packaging material for the size of the component.
- Regardless of sterilisation method the packaging is generally:
  - mechanically protective packaging
  - outer packaging if required
- Do not use sterile packaging for disinfected products.

Observe the storage periods for sterile goods as per DIN 58953 Part 8.

10. **Transport and storage**

- Store the TYPE B components in a dry, dark place.

11. **Function testing**

Check the function before it is next used as described in

→ *Calibration P. 63, Device check P. 67*

12. **Commissioning**

Cleaning TYPE C components

1. **Disassembly**

Carefully remove the TYPE C components from the vicinity of the patient.

2. **Pretreatment**

Remove surface contamination with a disposable cloth.

To prevent deposits we recommend treating TYPE C components immediately after use.

3. **Precleaning**

Additional precleaning of components is not required.

4. **Cleaning**

5. **Disinfection**

Wipe the Type C components thoroughly with a disposable alcohol wipe or disinfect them with a spray disinfectant.

- Disinfectant (e.g. disinfectant concentration 0.5 %, disinfectants are mildly alkali with PH value > 10)

Do not use fixing agents

6. **Drying**

Make sure that the component is completely dry before it is next used.

7. Sterilisation

Type C components are NOT sterilised.

8. Check that all surfaces are clean and undamaged

- Carefully inspect all surfaces after cleaning and disinfection.
- Inspect the TYPE C components for obvious damage.
- Sort out damaged TYPE C components.

9. Packaging

- Pack Type C components individually in paper, foil or similar packaging as specified by DIN EN 868. Use the appropriate size of packaging material for the size of the component.
- Regardless of sterilisation method the packaging is generally:
  - mechanically protective packaging
  - outer packaging if required
- Do not use sterile packaging for disinfected products

10. Transport and storage

Store the Type C components in a dry, dark place.

11. Function testing

Check the function before it is next used as described in

→ *Calibration P. 63, Device check P. 67*

12. Commissioning

Approved cleaning and disinfection agents

We recommend using only the following cleaning agents and disinfectants.

Surface disinfection:

- Incidin Extra N (Henkel ECOLAB)

Observe the manufacturer's directions for use

If a different agent is used note the DGHM recommendations and the compatibility of the agent with plastics.

Disinfection of TYPE A:

- SECUSEPT or SECUSEPT FORTE S from ECOLAB

Observe the manufacturer's directions for use

If a different agent is used note the DGHM recommendations and the compatibility of the agent with plastics.

Disinfection of TYPE B:

- SECUSEPT or SECUSEPT FORTE S from ECOLAB
- Glutarex from Henkel

Observe the manufacturer's directions for use

If a different agent is used note the DGHM recommendations and the compatibility of the agent with plastics.

Cleaning the Masimo pulse oximeter*

Please observe the following advices for cleaning the Masimo pulse oximeter:

- Do not autoclave, pressure sterilise, or gas sterilise this oximeter.
- Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the oximeter. These substances attack the device's materials and device failure can result.

* not for LeoniPlus transport

16. Maintenance and repair

Intervals for maintenance

CAUTION

Maintenance, repair and return of contaminated devices!

Danger of infection

- Clean and disinfect the device or device components before every maintenance procedure – also when returning the device for repair.

!

NOTICE

Incorrect maintenance!

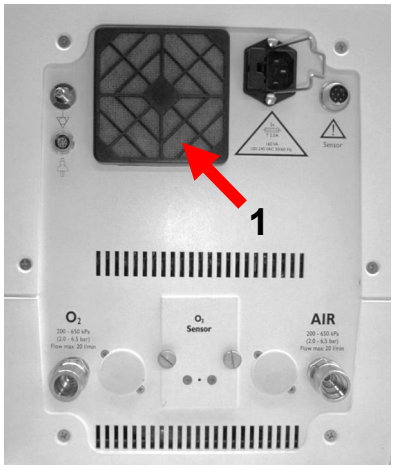
Danger of malfunction and damage to the device

- Only technicians trained by the manufacturer are authorised to carry out the service and safety checks.
- Suitable instruments and test equipment are required.
- Use only original parts from Löwenstein Medical.
- Regularly clear the dirt off the fan filter pad.
- Replace the fan filter pad every 3 months.

Every 3 months	**Next service:**
Replace fan filter pad ▪	
Every 12 months	**Next service:**
Maintenance and safety check as specified by regulations	
The following work is required: ▪ Check alarm and limit value functions ▪ Check pressure connections ▪ Check electrical connections ▪ Check safety shutoffs ▪ Calibration	

Replace the following components: ▪ Oxygen sensor ▪ Air filter and O_2 filter ▪ Expiration valve membrane	
Every 3 years	**Next service:**
▪ Replace lithium battery on the controller board for data backup (dispose of old battery correctly) ▪ Replace batteries	
Every 10 years	**Next service:**
Replace entire internal tube set	

Replacing the fan filter pad



1. Remove the fan cover (1).

2. Replace the filter pad of the cooling fan.

Replacing the flow sensor

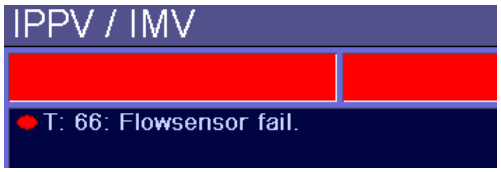
WARNING

Uncalibrated sensor!

Danger of insufficient or excessive oxygen supply

- Calibrate the sensor after replacement.

1. Disconnect the flow sensor cable from the flow sensor.

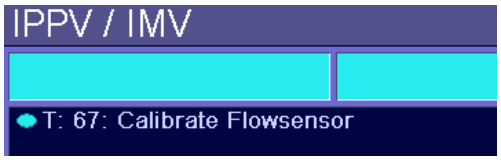


2. An alarm message `Flow sensor failed` appears on the alarm screen.

3. Replace the flow sensor as quickly as possible.

If no replacement sensor is available:
Connect the tube-side tube system directly to the y-piece. Switch off the flow sensor.

→ *Switching off the flow sensor P. 122*



4. After replacement a message `Calibrate flow sensor` appears on the alarm screen.

5. Calibrate the sensor.

→ *Calibrating the flow sensor P. 63*

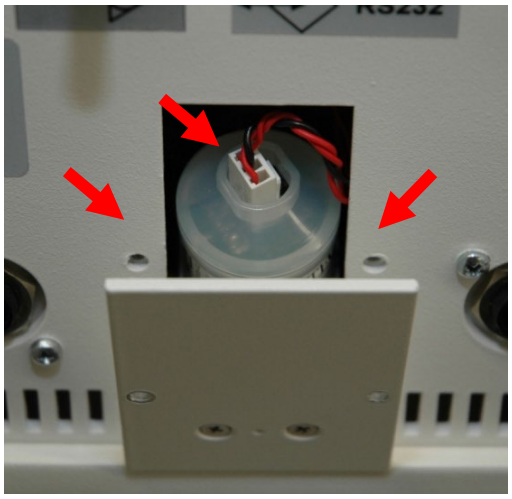
Replacing the O_2 sensor

WARNING

Malfunction of sensors!

Uncalibrated O_2 sensors may result in the patient receiving too much or too little oxygen

- Always calibrate the sensor before connecting it to the patient.
- Make sure that calibration is correctly completed.



1. Unscrew the cross-head screws around the O_2 sensor flap using a screwdriver.
2. Disconnect the cord from the O_2 sensor.
3. Unscrew the O_2 sensor.
4. Replace it with a new sensor.
5. Connect the O_2 sensor with the connector.
6. Close the O_2 sensor flap and tighten the screws.

When closing the O_2sensor flap make sure that no cables or other components are crushed.

Replacing a fuse

The fuses must be replaced by a technician only.

Fuse: 2 x T2.5A

17. Disposal of used materials

The used materials must be disposed of correctly.

WARNING

Improper disposal!

Explosion hazard, injury hazard

- Do not dispose of O_2 sensors in a fire.
- Do not open O_2 sensors by force.

O_2 sensor

- Dispose of O_2 sensors as required by local waste disposal regulations.

For more information contact the local environmental offices or law enforcement agencies and suitable waste disposal companies.

Flow sensor

- As long as they are not irreparably destroyed they can be sent for repair. If in doubt, contact a representative from Löwenstein Medical

Expiration valve membrane

- Valve membrane can become contaminated by patient gas. For disposal, follow the hygiene guidelines of your hospital

Batteries

- These materials must be disposed of in accordance with regulations. If in doubt, refer to the hygiene guidelines of your hospital or contact a representative of Löwenstein Medical

Electrical and electronic parts of system

- Electrical and electronic parts of the system generally only need to be disposed of during servicing. Otherwise these materials must be disposed of in accordance with regulations. If in doubt, refer to the hygiene guidelines of your hospital or contact a representative of Löwenstein Medical.

Bacteria filter

- The bacteria filter may be contaminated by patient gas and should not be thrown in the house waste. Please observe the hygiene regulations of your hospital.

Fan filter pads

- Dispose of fan filter pads as required by local waste disposal regulations.

For more information contact the local environmental offices or law enforcement agencies and suitable waste disposal companies.

Abdomen sensor

- The abdomen sensor can be contaminated by contact with the patient and should not be disposed of in general waste. Please follow the hygiene regulations of your hospital.

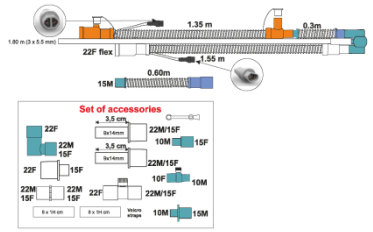
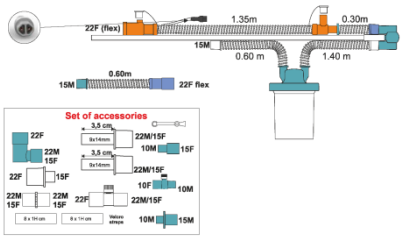
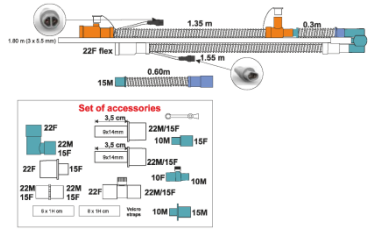
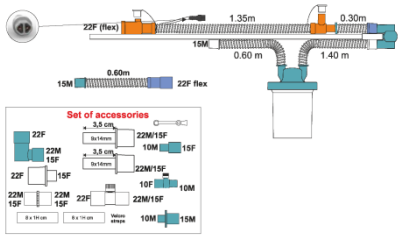
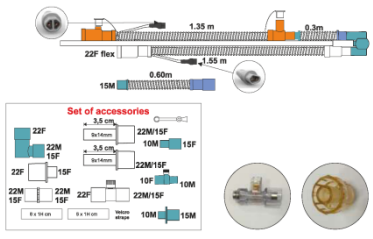
18. Accessories & spare parts

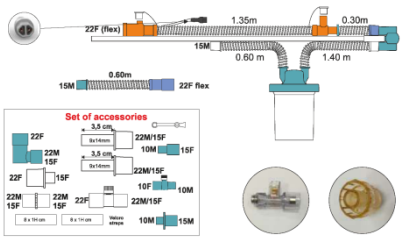
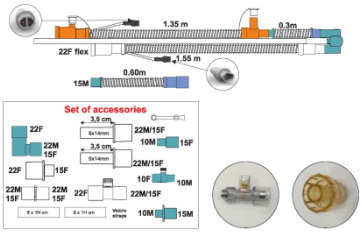
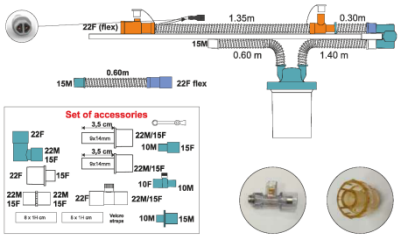
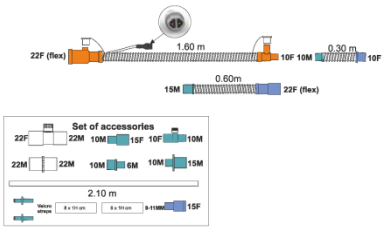
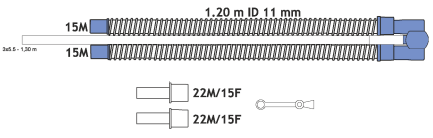
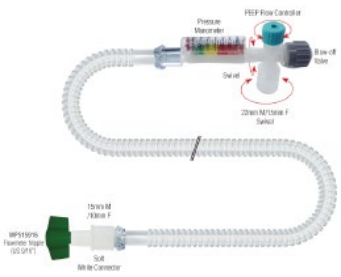
Löwenstein Medical Accessories * §

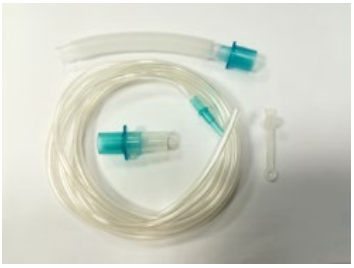
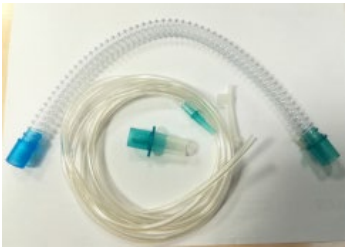
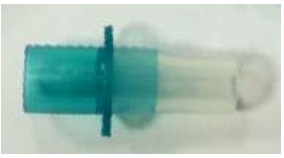
Article number	Description	Figure
0217105	Breathing gas humidifier LM2000, 230V, adult/paed., w/T-cable 1.80 m long, w/ i+e heating wire adapter, w/power cable EU	
0217121	Temperature probe 1.40 m for LM2000	
0217108	Tube heating adapter dual (i+e) for LM2000 humidifier/LM tube systems	
0217108-1	Tube heating adapter inspiratory (i) for LM2000 humidifier/LM tube systems	

* For information on the content substances, see the manufacturer's data

§ See the manufacturer's specifications for information about preparation/cleaning.

Article number	Description	Figure
n160v2c	Tube system, neonatology, disposable, length 1.60 m (incl. incubator extension 30 cm), IV, heated (i+e), incl. humidifier chamber, Vti ≤ 50 ml (SU 10 pieces)	
n160v1c	Tube system, neonatology, disposable, length 1.60 m (incl. Incubator extension 30 cm), IV, heated (i), incl. humidifier chamber, Vti ≤ 50 ml (SU 10 pieces)	
n160v2	Tube system, neonatology, disposable, length 1.60 m (incl. incubator extension 30 cm), IV, heated (i+e), without humidifier chamber, Vti ≤ 50 ml (SU 10 pieces)	
n160v1	Tube system, neonatology, disposable, length 1.60 m (incl. incubator extension 30 cm), IV, heated (i), without humidifier chamber, Vti ≤ 50 ml (SU 10 pieces)	
n160v2c-2	Tube system, neonatology, disposable, length 1.60 m (incl. incubator extension 35 cm), IV, heated (i+e), incl. humidifier chamber, Vti ≤ 50 ml, exp. valve, flow sensor (SU 10 pieces)	

Article number	Description	Figure
n160v1c-2	Tube system, neonatology, disposable, length 1.60 m (incl. incubator extension 35 cm), IV, heated (i), incl. humidifier chamber, Vti ≤ 50 ml, exp. valve, flow sensor (SU 10 pieces)	
n160v2-2	Tube system, neonatology, disposable, length 1.60 m (incl. incubator extension 30 cm), IV, heated (i+e), incl. exp. valve, flow sensor, without humidifier chamber, Vti ≤ 50 ml (SU 10 pieces)	
n160v1-2	Tube system, neonatology, disposable, length 1.60 m (incl. incubator extension 30 cm), IV, heated (i), incl. exp. valve, flow sensor, without humidifier chamber,Vti ≤ 50 ml (SU 10 pieces)	
n160nv1c	Tube system, neonatology, disposable, length 1.90 m (incl. incubator extension 30 cm), NIV, heated (i), incl. humidifier chamber, Vti ≤ 50 ml, (SU 10 pieces)	
0217081-1	Neonatal tube system 11 mm, disposable, length 1.60 m, IV, unheated for Leoni M, Leoni 2, Leoni plus, Vti ≤ 50ml (SU 10 pieces)	
0217086-1	Reanimation tube system for children, disposable, w/PEEP /PIP adjustable, NIV, (alternative for Perivent)	

Article number	Description	Figure
0217057v1	Test lung, neonatal, disposable 64 ml (SU 10 pieces)	
nj1250d	Connecting tube, extendible, disposable, neojet, neonatal, NIV, nCPAP (SU 10 pieces)	
nj1240d	Connecting tube, smoothbore, disposable, neojet, neonatal, NIV, nCPAP (SU 10 pieces)	
0217111v3	Adapter, disposable, for nj1240d for connection neo tube system Y-piece (SU 10 pieces)	
0217085-1	High Flow nasal cannula, disposable, neonatal, less than 750 g, white "giraffe"	
0217085-2	High Flow nasal cannula, disposable, neonatal, 750 g-1000 g, green "lion"	

Article number	Description	Figure
0217085-3	High Flow nasal cannula, disposable, neonatal, 1000 g-2500 g, blue "elephant"	
0217085-4	High Flow nasal cannula, disposable, neonatal, >2500 g, orange "panda"	

Accessories AIRcon * §

Item number	Description	Picture
0217016-10	Dual heated disposable tubing system supply line: 0.60 m insp./exp. tubing lengths: 1.20 m pressure measurement line: 1.20 m incubator extension: 0.40 m humidifying chamber: C200AF	
Ac100.900	AIRcon breathing gas humidifier, 230V (including temperature probe, heating wire distribution cable (i+e), power cable)	
Ac100.905	Respiratory humidifier AIRcon, 120V (incl. temperature probe, heating-wire distributor cable (i+e), power cord)	

* For information on the content substances, see the manufacturer's data

§ See the manufacturer's specifications for information about preparation/cleaning.

Item number	Description	Picture
Ac100.910	Temperature probe, reuseable	
Ac100.929	Heating-wire distributor cable (i+e)	
ac100.942	Heating wire distribution cable	
ac500.300e	Autofill Humidifier Chamber C200AF incl. Plate, max. filling volume 180ml	
ac500.350	Reusable humidifier chamber C200R, suitable for all patient groups	
0217081-1	Neo tubing system, unheated, 1,2m (pack à 10 pcs)	
0217082-1	Neo tubing system, dual heated, incl. humidification chamber, (pack à 10 pcs)	
07420	Dual Heating Cable Adapter for AirCon	

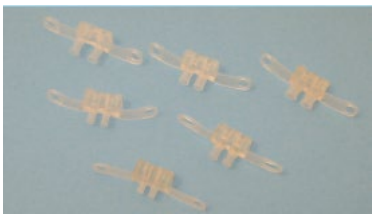
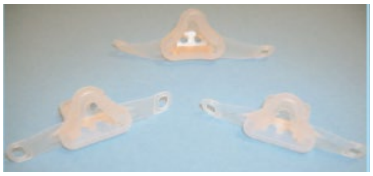
Hamilton H900 accessories * §

Item number	Description	Picture
950001	Hamilton H900 humidifier with fully digital user interface for invasive and noninvasive ventilation	
355234	2.5-m power cable for Hamilton H900 and battery charger	
260185	Ventilation tube set with two arms, neonatal, humidification chamber, incubator ext., universal connection, single-use (pack of 15), length approx. 1.65 m	
0400037bg	Holder for humidifier	

* For information on the content substances, see the manufacturer's data

§ See the manufacturer's specifications for information about preparation/cleaning.

Accessories NIV* §

Item number	Description	Picture
nj1500-01	Prong / PU 10 pieces Größe: micro	
nj1500-21	Prong / PU 10 pieces Size: s	
nj1500-02	Prong / PU 10 pieces Size: m	
nj1500-22	Prong / PU 10 pieces Size: l	
nj1500-03	Prong / PU 10 pieces Size: xl	
nj1500-32	Prong / PU 10 pieces medium width on the web	
nj1500-33	Prong / PU 10 pieces large width on the web	
nj1500-04	Mask / PU 10 pieces Size: s	
nj1500-05	Mask / PU 10 pieces Size: m	
nj1500-06	Mask / PU 10 pieces Size: l	
nj1500-07	Mask / PU 10 pieces Size: xl	
nj1500-08	Mask / PU 10 pieces Size: xs	
nj2150/1	Templates for determining the masks and prong size, piece	

* For information on the content substances, see the manufacturer's data

§ See the manufacturer's specifications for information about preparation/cleaning.

Item number	Description	Picture
nj1550	Cap set 7 caps / PU 1 piece	
nj1513-10	Cap / PU 10 pieces Size:XXS, colour: white	
nj1514-10	Cap / PU 10 pieces Size:XS, colour: white	
nj1515-10	Cap / PU 10 pieces Size:S, colour: yellow	
nj1516-10	Cap / PU 10 pieces Size:M, colour: red	
nj1517-10	Cap / PU 10 pieces Size:L, colour: light blue	
nj1518-10	Cap / PU 10 pieces Size:XL, colour: orange	
nj1519-10	Cap / PU 10 pieces Size:XXL, colour: light green	
nj1520-10	Cap / PU 10 pieces Size:XXXL, colour: white – black	
nj1212-15	Cap / PU 10 pieces holding straps extra short	
nj1212-18	Cap / PU 10 pieces holding straps extra medium	
nj1212-23	Cap / PU 10 pieces holding straps extra long	
nj2000HL/2	nCPAP generator / PU 1 piece, sterilised, disposable	
nj2000	nCPAP generator / PU 20 pieces, sterilised, disposable	
nj1010	nCPAP generator blue 60°/ PU 1 piece, reusable	
nj1020	nCPAP generator silver 45° / PU 1 piece, reusable	
nj1240e/1	Leoni adapter tube set, PU 1 piece, disposable	
nj1240/2	Leoni adapter tube set, PU 10 pieces, disposable	

Item number	Description	Picture
nj1024	Adapter 15 mm, PU 1 piece	
nj2000-10	NeoJet starter set for nCPAP	
nj1030	Foam padding NeoJet	
nj0164s nj0165l	CPAP Noise hydrocolloid dressing, PU 20 pieces, size S CPAP Noise hydrocolloid dressing, PU 20 pieces, size L	
0217080	NeoJet test lung set for simulation NeoJet	
nj1240d	Leoni adapter tube set, PU 10 pieces, disposable	
pf-n756 pf-n757	Mini EZ-Hold cannulas fixing hydrocolloid, PU 100 pieces EZ-Hold cannulas fixing hydrocolloid, PU 100 pieces	

Closed Systems

Item number	Description	Picture
nj4000	Miniflow nCPAP generator, PU 20 pieces	
nj1223	Extension Miniflow unheated, PU 20 pieces	
nj4010	Pressure measurement tube Miniflow, PU 10 pieces	
nj4030	Foam padding Miniflow, PU 10 pieces	

Accessories Aerogen * §

Item number	Description	Picture
Aeroneb.start	Nebulizer starterset Aeroneb Pro	
agap1020e	T-adapter for children (autoclavable), with silicone plugs for Aeroneb	
Agap1025e	Adapterkit newborn for Aeroneb, autoclavable	

Accessories Aeroneb * §

Item number	Description	Picture
153053000	LM-neb Pressure+ incl. 2 nebulizer units	
153053005	LM-neb Flow+ incl. 2 nebulizer, 2 T-pieces,	
153053101	LM-neb Nebulizer unit Pressure + and Flow+ with connection for intubated patients	
153053102	LM-neb nebulizer unit with mouth piece Pressure + Flow +	
153053104	LM-neb Connection cable	
153053106	LM-neb Trigger line	
153053107	LM-neb Adapter for Trigger Line, Luer Lock	

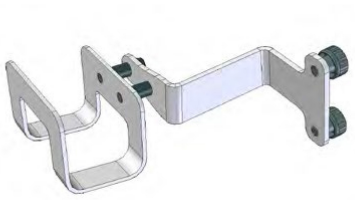
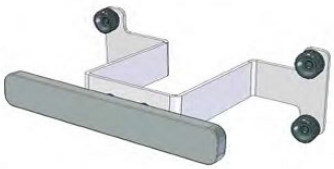
* For information on the content substances, see the manufacturer's data

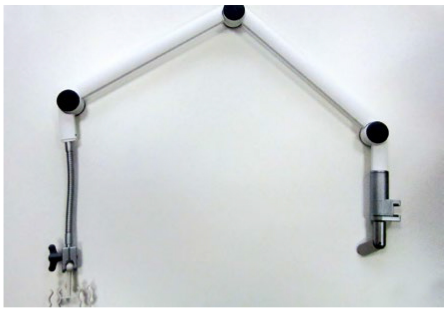
§ See the manufacturer's specifications for information about preparation/cleaning.

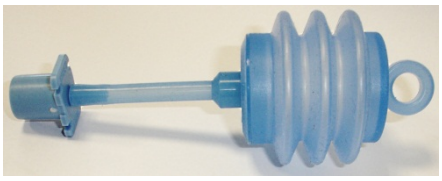
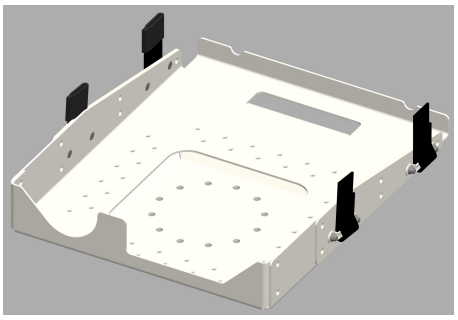
Item number	Description	Picture
153053108	LM-neb mains adapter for Pressure+ and Flow	
153053109	LM-neb device holder Pressure +	
153053110	LM-neb device holder Flow+	
153053111	LM-neb Mouth piece	

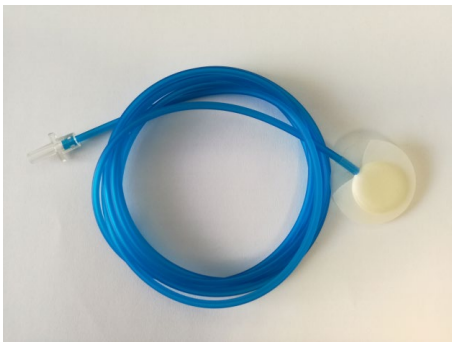
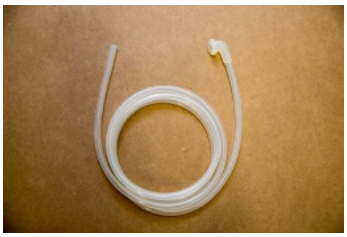
Other accessories/spare parts

Item number	Description	Picture
00.030	Power connection cable, 3 m long. Further country-specific power connection cables available on request	
00102000-111-300	O_2 pressure tubing with removable connector, neutral standard, black, 3m	
0012001-111-300	Air pressure tubing with removable connector, neutral standard, black, 3m	
0012000-211-300	O_2 pressure tubing with removable connector, ISO 32, white, 3m	
0012001-211-300	Air pressure tubing with removable connector, ISO 32, white, 3m	
0217021	Tube holder Leoni	
0209773-2	Tool rail 150mm, complete with screws for tube holder	
0122031	Filter PALL BB100 for nebulization	
0122030-1	Bacterial filter for insp. connection	

Item number	Description	Picture
0217023-1bg	Tube / cable holder Leoni with installation accessories	
0400016bg	Tool rail 200mm, complete with installation accessories	
0691000	Mobile stand for LeoniPlus	
0691003	Pressure hose holder for mobile stand	
0691005	DIN standard rail for mobile stand	
0691007set	Gas cylinder holder for 2l, 3l, 5l compressed gas cylinders	

Item number	Description	Picture
0691010	Device holder incl. standard rail Leoni plus for mobile stand 0691000	
0217038v01bg	Membrane for Expiration valve	
0217026v1/10	Expiration valve set for single use (incl. diaphragms 0217038v01bg), for Löwenstein Medical Leoni mobil / Leoni2 / LeoniPlus / LeoniPlus Transport, PU 10 pieces	
0217026v2bg	Expiration valve set, reusable (incl. diaphragms 0217038v01bg), for Löwenstein Medical Leoni mobil / Leoni2 / LeoniPlus / LeoniPlus Transport	
0217031	Oxygen measurement cell	

Item number	Description	Picture
0207169	Sinter filter for Nist connection	
0217755hul100	Filter pad for fan (80x80 mm)	
0217043bg	Baby test lung H+L	
0217011	Flow sensor	
0217012	Flow sensor connection cable	
0217450	Retainer LeoniPlus Transport (mounting plate for transport incubators)	

Item number	Description	Picture
0217116	Abdomen sensor, disposable, PU 50 pieces	
0217116e	Abdomen sensor, disposable, PU 1 pc	
910AG 138	Y-piece	
0217115/10	Disposable flow sensor, PU 10 pieces	
810AG150	Pressure measurement tubing, Length 1.5m	
0217794	Connection cable for external display, 3m	
0140048	Tube and rail holder for external display	
910BM 010	Tube adapter	

Maintenance kits

Item number	Description
0219700	Maintenance kit Leoni plus complete
0219700-1	Maintenance kit Leoni plus without O_2 cell
0219705	Maintenance kit internal tubing (10 years)

19. Glossary

General definitions	Description
Atelectasis	Collapsed lung section filled with little or no air, the alveolar walls are in contact
AutomaticFlow	Flow control type in nCPAP and nIPPV ventilation modes When AutomaticFlow is activated, the flow is automatically controlled by the ventilation device
Base Flow	Minimum flow that is circulated in the ventilation system during the exhalatory phase
BTPS	Customary pressure/temperature conditions in breathing physiology under which measurements are taken in the gas volume. Measured data standardised according to the BTPS conditions (body temperature, pressure, saturated) based on 37°C (body temperature), the current air pressure in the environment and 100% steam saturation.
C20/C	Dynamic compliance during the last 20% of the inspiratory phase in relationship to the total dynamic compliance.
Compliance	Expansion of the lung Compliance depends on how full the lung is. It is measured in volume increase per increase of the applied fill pressure [ml/mbar]. A reduction in compliance results in an increase in the effort required to breathe.
Decelerating Flow	The air volume per unit time decreases as time progresses (example: 1st second 30 l/min, 2nd second: 20 l/min)
Dynamic compliance	Expandability of the lung, measured based on the peak airway pressure during a breath. The difference between static and dynamic compliance can provide information on the flow-related airway resistance.
E Time	Duration of expiration
FiO_2	See O_2

General definitions	Description
Flow	Air flow [l/min] (including respiratory gas flow)
Hemoglobin saturation curve	The hemoglobin saturation curve is the graphical representation of the relationship between the arterial partial pressure of oxygen (P_aO_2) and the arterial oxygen saturation of the hemoglobin (S_aO_2).
HFO	High frequency oscillation, ventilation mode
Insp Time	Duration of inspiration
Inspection	Detection of the current status
Leak	Respiration gas loss in ventilation tubing
Maintenance	Actions for retaining the nominal status
Maintenance	inspection, maintenance, repair
MV total	Total minute volume generated by the ventilator and by the patient's spontaneous breathing
O_2	Fraction of oxygen = molecular proportion of oxygen in the total molecular occurrence per volume (in the ambient air: O_2 = 21%)
Oxygen	Oxygen concentration
P average	Average airway pressure
P Insp	Inspiratory pressure
P max	Maximum inspiratory pressure
P mean	Average airway pressure
P effective	The effective airway pressure is the pressure measured at the connection of the pressure measurement tube in the tube system. This pressure does not represent the pressure situation in the lung of the patient
p_ACO_2	Alveolar carbon dioxide partial pressure. Calculation: $p_ACO_2 = p \cdot Fi_ACO_2$, where Fi_ACO_2 describes the CO_2 fraction in the alveoli during exhalation. It is assumed that Fi_ACO_2 = 5%. Example at msl: p_ACO_2 = 1033 mbar * 0.05 = 51.6 mbar
p_aCO_2	Arterial carbon dioxide partial pressure

General definitions	Description
p_AO_2	Alveolar oxygen partial pressure As with p_iO_2 the CO_2 fraction in the alveoli is also taken into account. Calculation: $p_AO_2 = p_iO_2 - p_ACO_2 \cdot (FiO_2 + \frac{1 - FiO_2}{R})$ Example at msl, p_iO_2 = 202 mbar, p_ACO_2 = 51.6 mbar: pAO2 = 202 mbar – 51.6 mbar * (0.21+ 0.93) = 143.2 mbar
p_aO_2	Arterial oxygen partial pressure
PEEP	(positive end-expiratory pressure) artificially generated positive atmospheric pressure in the lung during breathing, remaining on completion of exhalation (expiration). A PEEP prevents the alveoli from collapsing and thus prevents atelectasis. In addition, this also improves oxygen saturation of the blood in many cases.
p_iO_2	Inspiratory oxygen partial pressure The partial vapour pressure that is generated when the respiratory air is humidified is taken into account here. It must be subtracted from the total atmospheric pressure when calculating the pO_2. Calculation: $p_iO_2 = (p - pH_2O) \cdot FiO_2$ Example at msl and 7% vapour pressure fraction: p_iO_2= [1033 mbar - (1033 mbar * 0.07)] * 0.21 = 202 mbar
pO_2	Inspiratory oxygen partial pressure = proportion of total pressure generated by the oxygen molecules. Calculation: $pO_2 = p \cdot FiO_2$ Example in ambient air at sea level: pO_2 = 1033 mbar * 0.21 = 212.73 mbar
p	Total atmospheric pressure At mean sea level (msl): p = 1033 mbar
PI	Perfusion index indicating arterial pulse signal strength as the percentage of pulsatile signal to non-pulsatile signal.
Plethysmograph	The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse.
Repair	Actions for restoration of the nominal status

General definitions	Description
Resistance	Scale for flow resistance (airway resistance) The narrower the airways the greater the resistance (e.g. increased resistance through the tubing). Increased resistance is found in an acute asthma attack, chronic obstructive lung diseases and displacement of the airways by secretions or foreign bodies. Pathologically increased resistance is also referred to as obstructive ventilation disorder. The resistance can be calculated by measuring the ventilation pressure required for a specified flow. The unit is [mbar/l/s].
RMV	Respiratory minute volume RM is calculated from the product of respiratory minute volume x frequency.
R	Respiratory quotient The respiratory quotient describes the ratio of CO_2 production to O_2 consumption. Normal value approx. 0.85
Recruitment	Recruitment produces a cyclic increase of the mean pressure (P_{Mean}). It is based on the values $Freq_{Rec,}$ P_{Rec} and $T_{I\ Rec}$. The decisive physiological effect of such an intermittently applied (expanding) pressure is to open the dystelectatic regions of the lung. This results in a considerable volume recruitment and thus improved oxygenation.
Servicing	Inspection, maintenance, repair
SIQ	Signal IQ indicating the acquired signal quality and the timing of the pulse relative to the Plethysmograph.
SpO_2	Oxygen saturation determined with $uSpO_2$™ Masimo SET® Oximetry.
Static Compliance	Expansion of the lung, measured during ventilation with plateau at the end of breath if there is pressure compensation between the ventilation system and alveoli.
Tidal volume	Breath volume, stroke volume (air volume per breath)
Trig Level	Sensitivity of trigger
Trig Vol	Height of inspiratory breath volume from which a trigger must occur.

General definitions	Description
VTe average	Average exhalatory breath volume
VTe	Exhalatory breath volume
VTi	Inspiratory breath volume

20. Short guide

Performing checks before commissioning

When the tubing system and test lung (item No. 0217043bg or disposable test lung 0217057) are connected set IPPV ventilation mode.

Default settings

Ventilation parameters		Alarm limits	
P_{Insp}:	20 mbar	MV high:	1.00 L
PEEP:	5 mbar	MV low:	0.02 L
Insp. Flow	12 L/min	Leak:	60%
Exp. Flow:	4 L/min	Frequency:	70 1/min
Frequency:	45 1/min	Apnea:	20
Insp Time:	0.5 sec	P high:	30 mbar
Oxygen:	30 %	P low:	0 mbar

Checking the connections + calibration

System status	Self-test successfully completed?
Gas supply	Pressure air and oxygen tubes firmly connected?
Ventilation system connections	Exhalatory valve tight? Membranes correctly inserted?
	Ventilation tubing complete?
	Water traps at lowest point in vertical position?
	Flow sensor correctly connected?
	Test lung connected?
Sensor functions	Calibration of O_2 sensor (runs automatically)
	Calibration of flow sensor

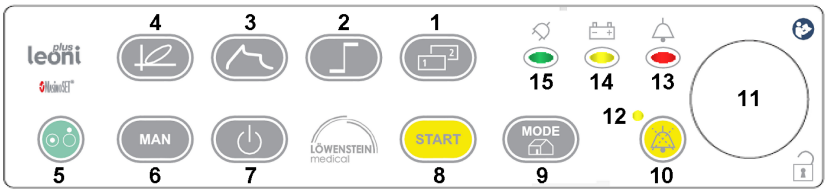
Ventilation test

Ventilation test	Setting	Result
Tightness	P_{Insp}: 60 mbar Insp Time: 1 sec Reset values to standard after test	P_{max}: 60 ± 3 mbar Leak: 0 + 1 %
PEEP / CPAP	PEEP: 1 mbar	PEEP display: 1 ± 1 mbar
PEEP / CPAP	PEEP: 10 mbar	PEEP display: 10 ± 1 mbar
Breath frequency	Frequency: 60 1/min	Display: 60 ± 2 1/min
Oxygen	30 %	Display: 30 ± 2 %
Tidal volume	Test with standard settings	VT_E: 13 ml ± 2 ml (0217043bg) VT_E: 5 ml ± 1 ml (0217057)

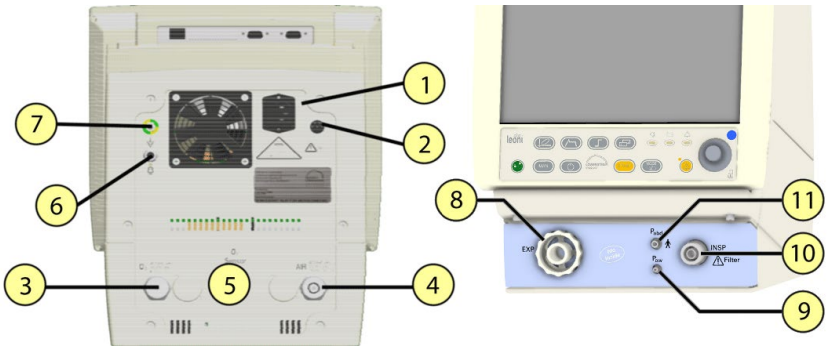
Alarm test

Alarm test	Setting	Result
Pressure	P_{Insp}: 40 mbar Reset to 28 mbar	after approx. 10 secs.: → Pressure alarm
Minute volume	Frequency: 80 1/min Reset to standard	after approx. 10 secs.: → MV alarm → Frequency alarm
Frequency		
Patient disconnect	Disconnect any tube from the device	→ Disconnection alarm
Apnea	Apnea alarm: 8 Sec. frequency: 6 1/min	after approx. 8 secs. → apnea alarm
Power loss	Disconnect mains power cable from device	→ Power loss alarm
Continued pressure	Disconnect pressure measurement tube	System alarm: → Pressure sensor deviation

Controls



(1) Monitoring
(2) Alarm limit values
(3) Charts
(4) Loops
(5) ON / OFF
(6) Manual breath (Inspiration hold)
(7) Pause
(8) Start
(9) Mode
(10) Mute alarms
(11) Rotary pulse encoder
(12) Mute alarm LED
(13) Alarm LED
(14) Battery operation LED
(15) Mains operation LED



1) Mains plug
2) Flow sensor connection
3) O2 pressure connection
4) AIR pressure connection
5) Access O_2 meas. cell
6) Nurse call
7) Earth connection
8) Expiratory connection
9) Flow sensor connection
10) Inspiration connection
11) Abdomen sensor connection

21. Appendix

SpO_2 measurement – principle of operation*

The Masimo SET® MS board pulse oximeter is based on the following principles:

- Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).
- The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse (plethysmography).
- Arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse.

The Masimo SET® MS board pulse oximeter as well as traditional pulse oximetry determines SpO_2 by passing red and infrared light into a capillary bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as the light sources, a photodiode serves as the photodetector.

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance (AC) to the mean absorbance (DC) at each of two wavelengths, 660 nm and 905 nm:

S(660) = AC(660)/DC(660)
S(905) = AC(905)/DC(905)

The oximeter then calculates the ratio of these two arterial pulse-added absorbance signals:

R = S(660)/S(905)

* not for LeoniPlus transport

This value of R is used to find the saturation SpO_2 in a look-up table built into the oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The Masimo SET® MS board pulse oximeter assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major component of noise during the pulse. MS board decomposes S(660) and S(905) into an arterial signal plus a noise component and calculates the ratio of the arterial signals without the noise:

S(660) = S1 + N1

S(905) = S2 + N2

R = S1/S2

Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO2 in an empirically derived equation into the oximeter's software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The above equations are combined and a noise reference (N') is determined:

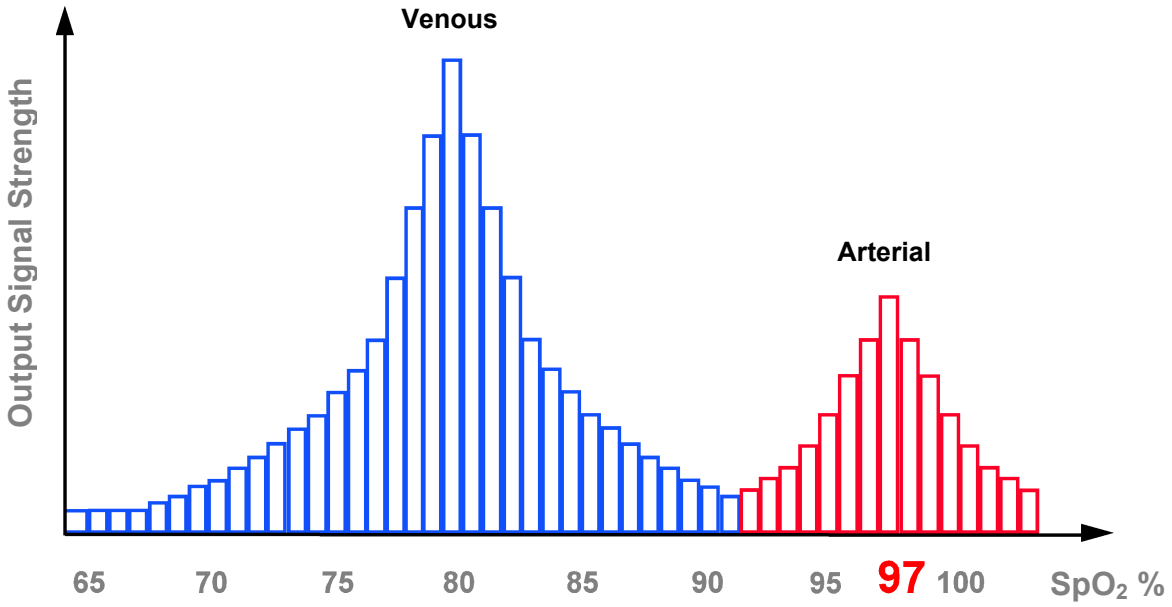
N' = S(660) - S(905) x R

If there is no noise N' = 0: then S(660) = S(905) x R which is the same relationship for the traditional pulse oximeter.

The equation for the noise reference is based on the value of R, the value being seeked to determine the SpO_2. The MS board software sweeps through possible values of R that correspond to SpO_2 values between 1% and 100% and generates an N' value for each of these R-values. The S(660) and S(905) signals are processed with each possible N' noise reference through an adaptive correlation canceler (ACC) which yields an output power for each possible value of R (i.e., each possible SpO_2 from 1% to 100%).

The result is a Discrete Saturation Transform (DST™) plot of relative output power versus possible SpO_2 value as shown in the following figure where R corresponds to SpO_2 = 97%:

Discrete Saturation Transform (DST™) Algorithm



The DST plot has two peaks: the peak corresponding to the higher saturation is selected as the SpO_2 value. This entire sequence is repeated once every two seconds on the most recent four seconds of raw data. The MS board SpO_2 therefore corresponds to a running average of arterial hemoglobin saturation that is updated every two seconds.

Pneumatic scheme

Legend

1 Sinter filter

2 Pressure regulator

3 Pressure transducer

4 Air/oxygen blender

5 Solenoid valve blender (10 x air, 10 x oxygen)

6 Sapphire nozzle (10 x air, 10 x oxygen)

7 Check valve (as required, e.g. the patient can breathe with this valve in case of gas failure; not included in more recent versions of the hardware)

8 Vent valve / emergency valve

9 Pneumatic overpressure valve (pop-off)

10 Double O_2 measuring cell (module for aut. O_2 calibration)

11 Pressure transducer in inspiration side

12 Proximal pressure transducer on Y-piece

13 Expiratory valve

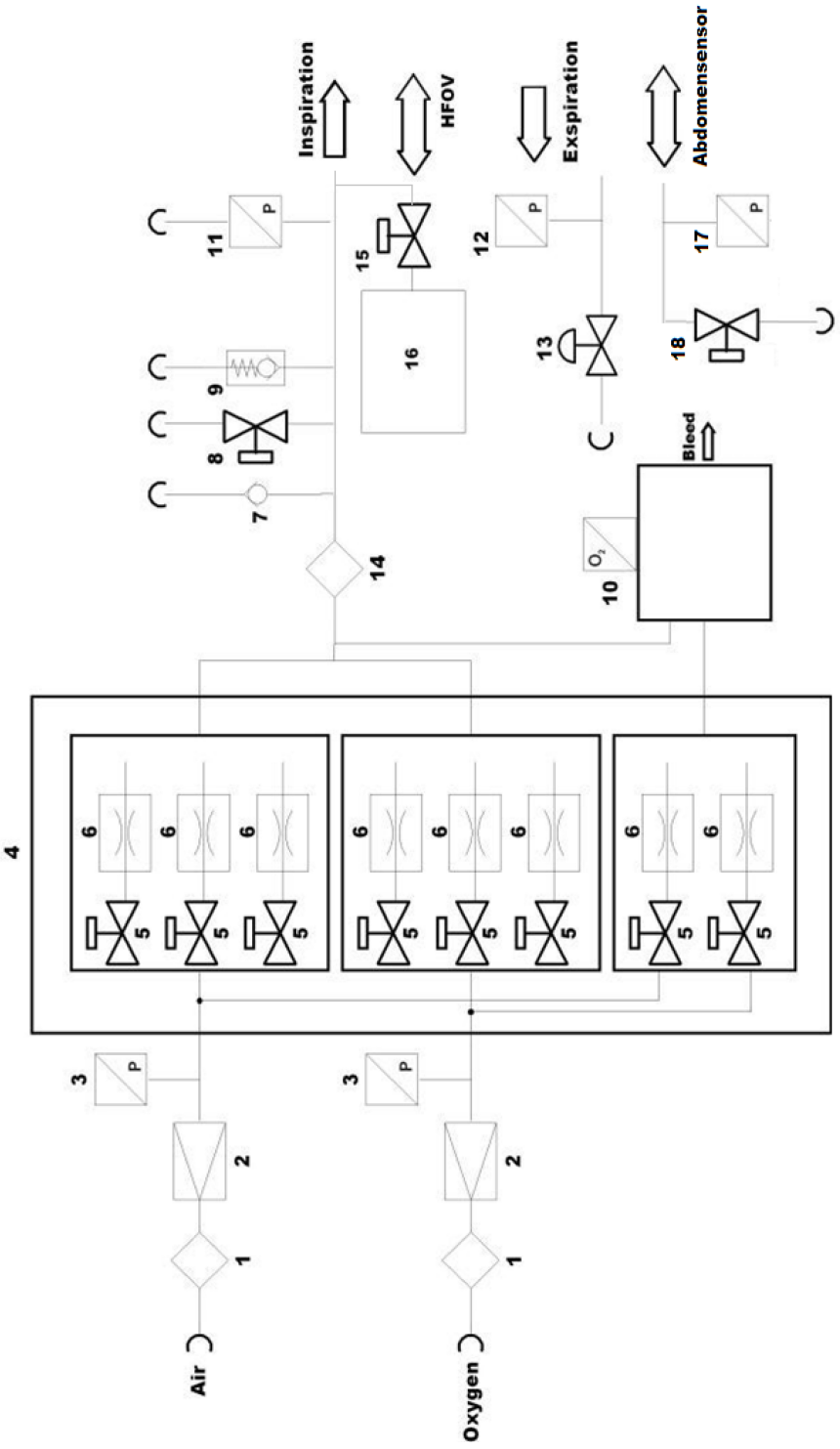
14 Microfilter

15 HFO shut-off valve

16 HFO module

17 Pressure sensor abdomen sensor

18 Vent valve abdomen sensor



22. Index

Subject to changes

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