





# Azeer Anesthesia Workstation



# leon *plus*

user manual

Rev. 3.11.0

from software version 3.11.x

As at 01.07.2017



Please read this instruction manual carefully before using the device and keep it to hand at all times!



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Subject to change 01.07.2017

Löwenstein Medical GmbH & Co. KG Arzbacher Straße 80 56130 Bad Ems/Germany P: +49 2603/9600-0 F: +49 2603/9600-50

Web: www.hul.de

user manual leonplus 3.11.0 Order no.: Ba-0301v311



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## 1. List of abbreviations

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Abbreviation, Term	Description	
A	Breath-by-breath window	
Agent	Volatile anaesthetic	
AGSS	Anaesthetic gas scavenging system	
VSF	Ventilation system filter	
AIR	Medical compressed air	
No. charts	Number of real-time charts (minimum 1, maximum 4)	
APL valve	Adjustable Pressure Limitation Adjustable pressure-relief valve	
TV	Tidal volume	
BTPS	Body, Temperature, Pressure, Saturated  Measured values standardised to BTPS requirements refer to 37°C (body temperature), current atmospheric pressure and 100% steam saturation.	
C <sub>stat.</sub>	Compliance (static)	
C <sub>dyn</sub>	Compliance (dynamic)	
C20/C	Compliance during the last 20% of the inspiration phase compared with total compliance (Measurement for overdistention of the lungs ≤1)	
CO <sub>2</sub>	Carbon dioxide	
Compliance	Lung elasticity	
CPAP	Continuous Positive Airway Pressure Constant positive airway pressure	
Des.	Volatile anaesthetic – desflurane	

Table 1: Abbreviations and Terms				
Abbreviation, Term	Description			
Pressure units	<ul> <li>100 kPa = 1 bar = approx. 1 atm</li> <li>1 atm = approx. 1 kg/cm² (kp/cm²)</li> <li>1 hPa = 100 Pa = approx. 1 cm H₂O</li> <li>1 kPa = approx. 10 cm H₂O</li> <li>1 bar = 1 kPa × 100</li> <li>1 mbar = approx. 1 cm H₂O</li> <li>1 mm Hg = approx. 133 Pa</li> </ul>			
Pressure units (standard)	<ul> <li>1 kPa × 100 = 1 bar</li> <li>1 Pa × 100 = 1 mbar = approx. 1 cm H<sub>2</sub>O</li> </ul>			
E	Expiration			
Enf.	Volatile anaesthetic – enflurane			
Fresh gas flow	Sum of O <sub>2</sub> gas flows and carrier gas into the anaesthetic system			
f, Freq.	Frequency, number of breaths per minute			
Hal.	Volatile anaesthetic – halothane			
HLM	Heart-lung device			
1	Inspiration			
IBW	Ideal body weight			
I:E	Inspiration to expiration ratio			
IMV	Intermittent mandatory ventilation Volume-controlled ventilation			
Insp. Flow	Inspiratory flow			
Insp. vol	Inspiratory volume			
lso.	Volatile anaesthetic – isoflurane			
Calibration	To calibrate an analyser, the analyser is checked and the deviation from a standard (that is known to be correct) is determined.			
HIS	Hospital information system			
Leak	Difference between inspiratory and expiratory breath volume (ventilation gas lost in ventilation tubes, on seals, cross-over points and on the tube)			
Loop	Displays of flow over pressure, volume over pressure or flow over volume measured values in a coordinates system			

Table 1: Abbreviations and Terms		
Abbreviation, Term	Description	
Low flow	Fresh gas flow ≤ 1000 ml/min and > 500 ml/min	
LWL	Optical fibre cable	
MAC	Minimum alveolar concentration	
Minimal flow	Fresh gas flow ≤ 500 ml/min	
MV	Minute volume	
MON	Monitoring mode (to monitor sufficient spontaneously breathing patients)	
N <sub>2</sub> O	Dinitrogen monoxide (laughing gas)	
NGA	Anaesthetic gas aspiration	
O <sub>2</sub>	Oxygen	
O <sub>2</sub> flush	Oxygen flush	
Patient category Adult	Fast selection of preconfigured ventilation parameter settings and alarm limits for adult ventilation	
Patient category Child	Fast selection of preconfigured ventilation parameter settings and alarm limits for ventilation in children	
Patient category IBW	Fast selection of preconfigured ventilation pattern parameter settings and alarm limits on entry of the ideal bodyweight (child alarm limits)	
P <sub>aw</sub>	Ventilation pressure	
PCV	Pressure Controlled Ventilation Pressure-controlled ventilation	
PDMS	Patient Data Management System	
PEEP	Positive End Exspiratory Pressure Positive end-expiratory pressure	
P <sub>insp.</sub>	PCV to be reached	
Plat./Plateau	Percentage length of plateau during inspiration	
P <sub>Mean</sub>	Mean ventilation pressure	
P <sub>Peak</sub>	Maximum ventilation pressure	
P <sub>Plat.</sub> /P <sub>Plateau</sub>	Ventilation plateau pressure	

Table 1: Abbreviations and Terms		
Abbreviation, Term	Description	
PSV	Pressure Support Ventilation Pressure-supported ventilation	
R/Resistance	Airway resistance	
Ratio system	With $N_2O$ as the carrier gas, the minimum concentration setting for $O_2$ = 25%	
Settings	Settings	
Sev.	Volatile anaesthetic – sevoflurane	
S-IMV	Synchronised intermittent mandatory ventilation Triggered form of ventilation	
S-PCV	Synchronised pressure-controlled ventilation Triggered form of ventilation	
t	Time	
Carrier gas	Gas that is used as a fresh gas along with $O_2$ General AIR or $N_2 O$	
Trig. Flow	Flow needed to release the trigger	
Trig. vol.	Volume needed to release the trigger	
Trigger	Option of synchronising the ventilator device with spontaneous patient ventilation activity	
UPS	Uninterrupted power supply	
V	Volume	
Ÿ	Flow	
Vapour	anaesthetic vaporiser	
VGA	Video graphics array (computer graphics standard)	
$V_{Te}$	Tidal volume expiry	
$V_{TG}$	Tidal volume guarantee	
V <sub>Ti</sub>	Tidal volume inspiration	
ZGA	Central gas system (supply) for O <sub>2</sub> , N <sub>2</sub> O and AIR	

#### 2. About this user manual

#### Validity of this instruction manual

This instruction manual applies to the following products:

leon plus



These operating instructions also apply for all devices with Heinen + Löwenstein specified as the manufacturer.

# Essential information covered by the instruction manual

This user manual describes the leon *plus* ventilator and its operation. It contains:

- Information on the safe handling of the ventilation device
- An overview of all of the device components
- A description of how to operate the device
- A description of the monitor control elements
- Information on
  - Installation
  - Start-up
  - Operation
  - Monitoring and alarms
  - Errors and troubleshooting
  - Servicing
  - Accessories

The documentation for the leon *plus* anaesthesia system comprises:

- leon plus operating instructions
- leon plus service instructions
- leon plus short checklist/short instructions before start-up
- leon plus spare parts ordering (forms)
- leon plus Technical safety controls checklist
- The checklist, short instructions and copyable forms can be found at the end of the document.

#### Structure and purpose of the user manual

The user manual will familiarise you, step-by-step, with the operation of your ventilator. All of the available features are described.

Read through the user manual carefully, before you begin to work with the ventilator. Continue to consult the user manual for your work until you are perfectly sure of how to handle the device and have completed all of the training sessions successfully.

If you have detailed questions, the contents and index will help you to find a subject quickly.

Tips supplement the handling instructions. They suggest methods of operating the ventilator more efficiently and more simply under proper safety conditions.

#### **Description of options**

This user manual contains descriptions of standard and optional device equipment and features. No legal claim may be derived from the description of this option. You can find out which options are available in your system from your Löwenstein Medical sales partner.

#### **Retention of documentation**

Keep the documentation to hand at all times, in a complete and readable condition, near to the device. If the device is passed on, it must be accompanied by the documentation. In the event of loss, contact Löwenstein Medical customer services immediately.

#### **Further information**

If you have any questions or remarks regarding this instruction manual or the device, please contact your authorised regional specialist vendor or the manufacturer directly.

#### 3. Safety for you and the patient

#### user manual compliance



#### WARNING

Non-compliance with the user manual

#### Danger of harm to patients

- Precise knowledge and compliance with this user manual is required each time the device is used.
- The device is intended for the described use only.

This user manual is designed to help you, step-bystep, to become familiar with the operation of your ventilator. Frequently used features are described.



Read through the user manual carefully, before you begin to work with the ventilator.

Later on, when you are familiar with the basic operation of the ventilator, the user manual will serve as a reference for detailed questions. The contents and keywords index will help you to find a subject quickly.

#### Warnings



**ATTENTION** indicates important information, non-compliance with which could lead to damage to the device.

#### **ATTENTION**



**CAUTION** indicates a latent hazard that does not represent a direct threat but can lead to physical injury if not avoided.

#### **CAUTION**



**WARNING** indicates a hazard that represents a direct threat and can lead to severe injury or death if not avoided.

#### **WARNING**

#### Residual hazards

# Observe safety instructions and warnings

For the proper and safe operation and use of the device, it is absolutely essential that the safety instructions and warnings, (→ "Warnings" p. 16) in addition to this user manual, are read, understood and fully observed by every user before the initial start-up.

#### Operation by qualified staff

The leon *plus* anaesthesia device may be operated only by qualified specialist medical staff who have been instructed how to operate the device, so that they are able to take immediate action in the event of malfunction.



#### Device malfunctions!

#### Death of or permanent injury to the patient

#### **WARNING**

- During the use of the leon plus an alternative ventilation system, e.g. ventilation bag with mask, must always be available; preferably with an O<sub>2</sub> tube connector.
- If, in the event of a recognisable fault in the leon plusanaesthesia
  device, it can no longer be guaranteed that life can be sustained, the
  ventilation of the patient must be started promptly with independent
  ventilation equipment, e.g. ventilation bag with mask.
- A device check must be carried out beforehand each time the ventilator is used.
- If a fault is established during the self check or the device check, the ventilator must not be attached to a patient under any circumstances!



#### Working with live components!

#### Risk of injury through electrocution.

- Unplug the device from the mains before opening the housing.
- Ensure it is not plugged in again without authorisation!

#### WARNING



**WARNING** 

Flammable narcotic gases

#### Fire risk

Do not use any flammable anaesthetics!

Use only the following anaesthetics:

- halothane
- enflurane
- isoflurane
- sevoflurane
- desflurane



**WARNING** 

Lack of hygiene!

#### Risk of infection

- Prepare the device before first use.
- Use suitable ventilation system filters (VSF).
- Do not use single-use products more than once.

#### Liability and guarantee

- Liability for the functioning of the device transfers in every instance to the owner or operator,
  - if the device is maintained or commissioned by persons who are not associated to Löwenstein Medical or are not authorised by Löwenstein Medical,
  - if the device is handled in a way that does not correspond to the intended use.
- Löwenstein Medical is not liable for damage arising from non-compliance with the abovementioned instructions.
- Guarantee and liability provisions of the sale and delivery conditions of Löwenstein Medical are supplemented by the following instructions.

#### Combination with other devices

Electrical coupling with devices that are not mentioned in this user manual may only be carried out after consultation with the manufacturers or an expert.

## position

Do not cover or place in an unfavourable The device must not be covered or positioned in such a way that its operation or functioning is influenced negatively.

#### Alarms and troubleshooting

- The ventilator distinguishes between three types of alarms: patient alarms, system alarms and technical alarms.
- The alarms are allocated, according to the urgency of different priorities and are displayed in the alarm window according to the level of urgency (→ "Display of current alarms" p. 190).
- The alarm limits for patient alarms can be set by the user (→ "Setting patient alarm limits manually" p. 197).
- They have the option of seeing all of the alarms that have appeared in the alarm log.

#### **Cross-infections**

The following conditions ensure that the risk of crossinfection is reduced to a tenable risk under normal conditions and in the first fault instance:

- Appropriate use (ventilation gas filter close to the patient)
- Design of the water trap
- Return of the test gas before the CO<sub>2</sub> absorber

#### Classification of the device

Table 2: Classification		
Device group in accordance with 93/42/EEC Appendix IX	IIb	
Protection class It. EN 60601-1	I Туре В	
Operation type	suitable for permanent use	

#### **Maintenance instructions**

- a technical safety check and servicing must be carried out every 12 months, which must be executed in accordance with the instructions of Löwenstein Medical.
- every 3 years, at the latest every 10,000 operating hours, 10,000 hour servicing must be carried out, which must be executed in accordance with the manufacturer's instructions.
- every 6 years, at the latest every 20,000 operating hours, 20,000 hour servicing must be carried out, which must be executed in accordance with the manufacturer's instructions.
- the servicing may only be carried out by Löwenstein Medical-trained specialist staff, who have at their disposal suitable measuring methods and testing devices.

We recommend that you take out a service and repairs contract with a Löwenstein Medical-authorised service technician.

Use only original parts by Löwenstein Medical for maintenance.

- $\bigcirc$  Also note ( $\rightarrow$  "Maintenance and servicing" p. 257).
- Openition of maintenance in accordance with DIN 31 501:
  - Inspection: Establishing of actual state
  - Servicing: Methods for retaining the desired state
  - Repairs: Methods for restoring the desired state
  - Maintenance: Inspection, servicing and repairs

#### 4. Device overview

#### Intended use

- The leon *plus* is an anaesthesia workstation for adults, children, infants and premature babies.
- It enables controlled, manual ventilation as well as spontaneous breathing.

#### **Operating requirements**

It is recommended that the leon *plus* is operated only as described below:

- with AGSS
- with VSF
- in well-ventilated spaces
  - with reserve gas bottles

Only the following volatile anaesthetics may be used:

- halothane
- enflurane
- isoflurane
- sevoflurane
- desflurane
- O

If you have any questions, contact the manufacturer!

#### Forms of ventilation

The leon *plus* provides the following forms of ventilation:

- intermittent mandatory ventilation (IMV)
- pressure-controlled ventilation (PCV)
- synchronised intermittent mandatory ventilation (S-IMV)
- synchronised pressure-controlled ventilation (S-PCV)
- pressure-supported ventilation (PSV)
- ventilation mode using a heart-lung machine (HLM)
- manual ventilation (MAN)
- spontaneous ventilation (SPONT)
- monitoring (MON)

#### Anaesthesia systems

The leon *plus* supports the following systems:

- inhalation anaesthetics in the rebreathing system
- inhalation anaesthetics in semi-closed systems
  - in the low flow area
  - in the minimal flow area
- inhalation anaesthetics with non-rebreathing systems via fresh gas outlet e.g.
  - Bain
  - Magill
  - Jackson Rees
  - Kuhn

#### **Contraindications**

Never use the leon plus as follows:

- on the MRT
- at temperatures and under ambient pressure outside of the permissible area

 $(\rightarrow$  "Technical data" p. 301)

# Guidelines and manufacturer's declaration – Electromagnetic transmission

The leon *plus* is intended for operation in the electromagnetic environment given below. The customer or user of the leon *plus* must ensure that the leon *plus* is used in such an environment.

Table 3: Guidelines and manufacturer's declaration – Electromagnetic transmission

Transmission measurements	Compliance	Electromagnetic environment – Guidelines	
HF transmissions in accordance with CISPR 11	Group 1	The leon <i>plus</i> uses HF energy exclusively for its internal functioning. Its HF transmission is therefore very small and it is unlikely that neighbouring devices are disturbed.	
HF transmissions in accordance with CISPR 11	Class B with VGA output Class A	The leon <i>plus</i> is intended for use in facilities other than residential environments. In addition, the device is suitable for use in facilities	
Harmonics in accordance with IEC 61000-3-2	Class A	that are directly connected to a public mains network, which also supplies buildings that are used for	
Voltage variations / flickers in accordance with IEC 61000-3-3	Fulfilled	residential purposes.	

# Guidelines and manufacturer's declaration – Electromagnetic immunity

The leon *plus* is intended for operation in the electromagnetic environment given below. The customer or user of the leon *plus* must ensure that the leon *plus* is used in such an environment.

Table 4: Guidelines and manufacturer's declaration – Electromagnetic immunity

Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment – Guidelines
Discharge of static electricity in accordance with EIEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should consist of wood or concrete or be covered in ceramic tiles. If the floor is covered with synthetic material, the relative air humidity must amount to at least 30%.
Quick transient electrical interference / bursts in accordance with IEC 61000-4-4	± 2 kV for mains ± 1 kV for inlet and outlet pipes	± 2 kV for mains ± 1 kV for inlet and outlet pipes	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges in accordance with IEC 61000-4-5	± 1 kV push-pull voltage ± 2 kV push-pull voltage	± 1 kV push-pull voltage ± 2 kV push-pull voltage	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations in the supply voltage in accordance with IEC 61000-4-11.	< 5% U for ½ period (> 95% dip) 40% U for 5 periods (> 60% dip) 70 % U for 25 periods (> 30 % dip) < 5% U for 5 (> 95% dip)	< 5% U for ½ period (> 95% dip) 40% U for 5 periods (> 60 % dip) 70 % U for 25 periods (> 30 % dip) < 5% U for 5 (> 95% dip)	The quality of the supply voltage should correspond to that of a typical business or hospital environment. The battery life given in the documentation must be respected.
Magnetic field at supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields in the mains frequency must correspond to the typical values as found in a business or hospital environment.

#### **Electromagnetic environment – Guidelines**

The leon plus is intended for operation in the electromagnetic environment given below. The customer or user of the leon plus must ensure that the leon plus is used in such an environment.

Portable and mobile radio devices are not used at a shorter distance than the recommended protective distance from the leon plus including the cables, which is calculated according to the transmission frequency for the appropriate equivalence:

Table 5: Equivalence for protective distance depending on the transmitter frequency

Immunity test	IEC 60601-test level	Compliance level	Electromagne environment	
Conducted HF-interference in accordance with IEC 61000- 4-6	3 V <sub>eff</sub> 150 kHz – 80 MHz outside of the ISM-bands*	20 V <sub>eff</sub>	$d = \frac{3.5}{U} \times \sqrt{P}$	
	10 V <sub>eff</sub> 150 kHz - 80 MHz within the ISM-bands	20 V <sub>eff</sub>	$d = \frac{12}{U} \times \sqrt{P}$	
Radiated HF-interference in accordance with IEC 61000- 4-3	10 V/m 80 MHz – 2.5 GHz	40 V/m 80 MHz – 2.5 GHz	$d = \frac{12}{E} \times \sqrt{P}$	80 MHz - 800 MHz
			$d = \frac{23}{E} \times \sqrt{P}$	800 MHz – 2.5 GHz

P = rated power of the transmitter in watts [W] in accordance with the instructions of the transmitter manufacturer.

d = recommended protective distance in metres [m].



(((e))) The field strength of stationary radio transmitters is for all frequencies in accordance with an examination on site lower than the compliance level.

Interference is possible in the environment of devices that bear this icon.

The field strengths of stationary transmitters, such as the basic stations of radio telephones and mobile landline services, amateur stations, AM and FM radio broadcasting and television transmitters can theoretically not be predetermined precisely. To investigate the electromagnetic environment as a result of stationary HF transmitters, an examination of the site is recommended. If the investigated field strengths at the site of the leon plus exceed the compliance level given above, the leon plus must be observed with regard to its normal operation at each application location. If unusual performance characteristics are observed, it may be necessary to adopt additional measures, such as a change of direction or positioning the leon plusat another site.

Over a frequency area of 150 kHz to 80 MHz, the field strengths must be lower than 10 V/m.

NOTE 1: At 80 MHz and 800 MHz, the higher value applies.

NOTE 2: These guidelines may not apply to every situation. The distribution of

electromagnetic variables is influenced by absorption and reflections from

buildings, objects and human beings.

# Recommended protective distances between portable, mobile and landline HF telecommunications devices and the leon plus

The leon *plus* is intended for operation in an electromagnetic environment in which radiated HF interference is controlled. The customer or user of the leon *plus* can help to prevent electromagnetic interference by observing the minimum distances between portable and mobile HF communications equipment (transmitters) and the leon *plus*, as below corresponding to the maximum output performance of the communications equipment.

Table 6: Protective distance depending on the transmitter frequency

Rated power of the transmitter [W]	Protective distance depending on the transmitter frequency [m]			
	150 kHz – 80 MHz outside of the ISM bands	150 kHz - 80 MHz within the ISM bands	80 MHz – 800 MHz	800 MHz - 2.5 GHz
	$d = 0,18 \times \sqrt{P}$	$d = 0.8 \times \sqrt{P}$	$d = 0.3 \times \sqrt{P}$	$d = 0.6 \times \sqrt{P}$
0.01	0.02	0.06	0.03	0.06
0.1	0.06	0.19	0.09	0.19
1	0.18	0.6	0.3	0.6
2	0.25	0.85	0.42	0.85
10	0.57	1.9	0.5	1.9
100	1.8	6.0	3.0	6.0

For transmitters whose power rating in the above table is not given, the distance can be determined in metres using the equivalence, which belongs to each column, whereby P is the power rating in watts [W] in accordance with the instructions of the transmitter manufacturer.

**NOTE 1:** At 80 MHz and 800 MHz, the higher value applies.

**NOTE 2:** These guidelines may not be applicable in every situation. The distribution of

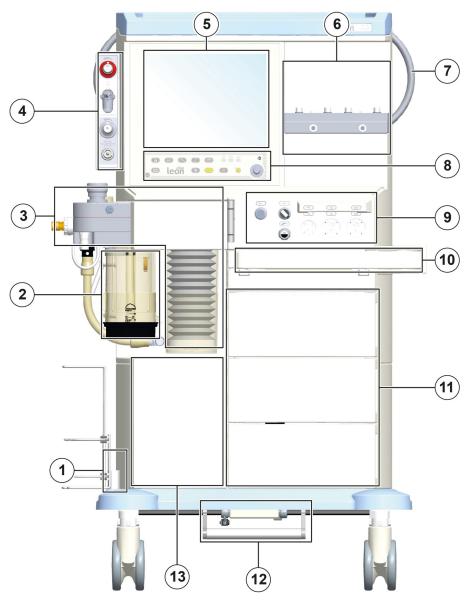
electromagnetic waves is influenced by absorption and reflections from

buildings, objects and human beings.

## **Device description**

#### **Overview**

#### **Front**

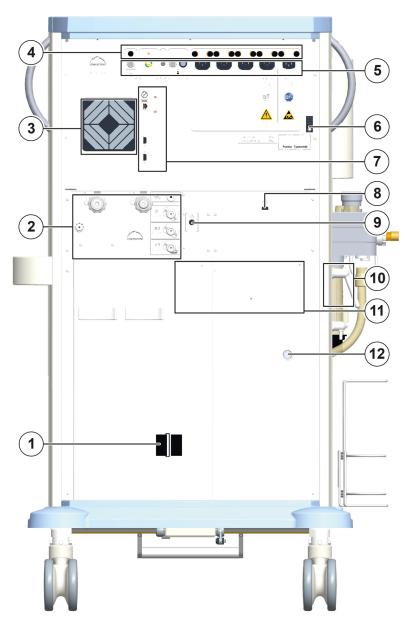


- (1) bronchial aspiration mounting
- (2) CO<sub>2</sub> absorber
- (3) patient module
- (4) options board
- (5) 15" touchscreen display
- (6) anaesthetic vaporiser mounting
- (7) manoeuvring handle

- (8) keypad with encoder
- (9) display and control elements
- (10) writing shelf
- (11) drawers
- (12) brakes (optional)
- (13) cupboard with drawer

000430

#### Rear



- (1) Pressure tube mounting (Velcro fastener)
- (2) Pneumatic connectors
- (3) Fans
- (4) Fuses
- (5) Electrical connectors

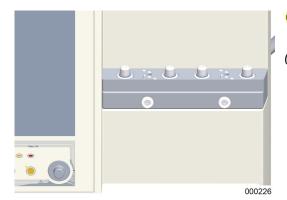
- (6) Clip for mains cable for additional display
- (7) Data connections
- (8) VGA or LWL connection (optional)
- (9) Heating fuse
- (10) Patient module locking mechanism
- (11) 10L bottle retainer (optional)
- (12) AGSS connector (optional)

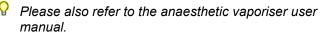
000431

#### Patient module

- decoupled fresh gas
- brought to the right temperature to avoid the buildup of condensation and to prevent the ventilation gases warming up
- decoupled APL during mechanical ventilation
- one inspiratory and one expiratory flow sensor
- absorber, which can be changed during operation
- fully sterilisable

#### **Anaesthetic vaporiser mounting**





(→ "Setting up the anaesthetic vaporiser" p. 85)

#### **Ventilator**

- pneumatic drive (O<sub>2</sub> or medical air)
- hanging bellows
- compliance-compensated
- pressure-limited

#### Railing system

The leon *plus* has a railing system on the right and on the left that can be adapted using accessories, e.g.:

#### **Device rails**

- Max. load: 5 kg
- available in different lengths

#### Support arms

- tube support arm
- monitor support arm
- adapter
- O

Please also refer to the individual user manuals of the adapted systems.

Mounting of over-heavy monitors on the support arms!

#### Damage to the device through overloading

• For stability reasons, the total weight of the monitors mounted on the support arm (maximum length: 500 mm) may not exceed 15 kg.

#### Lighting

- Workstation light (is switched off when the battery is on)
- Workstation light over writing shelf (is not switched off when the battery is on)

#### **Shelving**

(→ "Mounting additional monitors" p. 280)



You should also observe the maximum installation height of < 1.80 m (clearance height of doors).

Mounting of over-heavy monitors on the shelving!

#### Damage to the device through overloading

 For stability reasons, the total weight of the monitors on the shelving may not exceed 15 kg. The monitors must be secured so that they cannot fall.





**ATTENTION** 

#### Writing shelf, drawers, storage compartment

- storage compartment 31 cm x 20 cm x 28 cm with door
- pull-out writing shelf 42 cm x 60 cm
- three drawers 8 cm x 25 cm x 24 cm
- model without writing shelf, drawers, storage compartment



**ATTENTION** 

Improper loading of the writing shelf!

#### Damage to the device itself and to the writing shelf

The total weight to be placed on the writing shelf may not exceed 15 kg.

Improper loading of the drawers!

#### Damage to the device itself and to the drawers

The total load in the drawers may not exceed 5 kg.

#### Tube and cable guides

#### Tube and cable openings

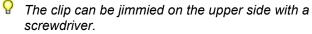


On both sides and on the back there are openings available at the top and bottom through which the cables or tubes can be led outside to the supply connections.

(1) Cable opening, side

#### Guide mains table additional monitors

The mains cable of the additional monitors, which are supplied with power from the four auxiliary outlets, can be guided over two clips (right and left in the upper third of the rear wall) through the cable openings out of the device to the monitors.



(→ "Rear" p. 28)

(→ "Connection of auxiliary devices" p. 87)

#### **Tube holder**

The Velcro fastener on the lower third of the rear wall of the device allows the pressure tubes to be brought together towards the ZGA and guided backwards away from the device. Opening of the rear wall doors by pulling the tubes is prevented.

(→ "Rear wall" p. 59)

#### **Delivery contents**

Transportation may only be carried out professionally by a specialist courier or by Löwenstein Medical themselves. The angle of inclination of the device may not exceed 10°.

The delivery contents (basic equipment) of the leon *plus* include the following items:

- anaesthesia workstationleon plus
  - gas measurement
  - integrated vacuum connector for bronchial aspiration
  - external O<sub>2</sub> outlet
- integrated battery buffering
- rear wall doors, drawers, writing shelf, storage compartment with door
- mains cable

The following items are not included in the basic equipment:

- pressure tubes (NIST adapter) in accordance with ISO 32 including supply plug for
  - O<sub>2</sub>
  - N<sub>2</sub>O
  - AIR
- waste hose with coupling and AGSS adapter
- potential equalisation cable
- patient tube system
- bronchial aspiration
- anaesthetic vaporiser

### **Operating instructions**

#### Permissible operating staff

The device is operated by a doctor or, on his/her instruction, by a person who is specifically trained and qualified for this task, whereby every user must be introduced to the device and familiar with the user manual and the operation of the device.

#### **Patient monitoring**

The device is equipped with a gas measurement ( $FiO_2$  or  $O_2$ ,  $CO_2$ ,  $N_2O$ , volatile anaesthetics) as standard. If this measurement is not available or is faulty, the following concentrations at least must be monitored by an external monitor.

- O<sub>2</sub> concentration
- anaesthetic gas concentration
- CO<sub>2</sub> concentration

Upper and lower alarm limits must be adjustable and in the event of an upper/lower deviation from these limits, an audible alarm must sound.

The gas measurement must fulfil the requirements of DIN EN ISO 80601-2-55.

#### **Proper condition**

If a fault is established during the self check or the device check, the anaesthesia device must not be attached to a patient under any circumstances!

#### Operation type

leon *plus* is designed for use at in-patient facilities only.

## 5. Operating concept

## **Function levels**



Every time the device is turned on, the boot process of the leon *plus runs a* self test.

The self check (starts when the device is turned on) must be carried out once a day.

The operating concept of the leon *plus* is built on three main levels, which are further divided into sublevels within which the actual functions ultimately start

Selection of a form of ventilation with the corresponding ventilation parameters  Display of alarm limits and gas supply pressures  Stopwatch  Reset to default settings  System test  Ventilation level  Selection of tab  Real-time curves  Trend curves  Tabular trend  Alarm log  Extras  O				
incl. FiO <sub>2</sub> calibration (for option "external O <sub>2</sub> fuel cells" only)  skip the system test (not recommended)> Quick start  Standby  Selection of patient category  Selection of tab  Selection of tab  Selection of a form of ventilation with the corresponding ventilation parameters  Display of alarm limits and gas supply pressures  Stopwatch  Reset to default settings  System test  Ventilation level  Selection of a form of ventilation with the corresponding ventilation parameters  Fresh gas settings  Selection of a form of ventilation with the corresponding ventilation parameters  Fresh gas settings  Selection of monitoring values page 1/2  Display of gas measurement measured values  Display of alarm limits and gas supply pressures	System test	Start of complete system test		
Standby  Selection of patient category  Selection of patient category  Selection of tab  Selection of tab  Selection of a form of ventilation with the corresponding ventilating System test  Ventilation level  Selection of a form of ventilation with the corresponding ventilation parameters  Display of alarm limits and gas supply pressures  Stopwatch  Reset to default settings  System test  Ventilation level  Selection of a form of ventilation with the corresponding ventilation with the corresponding ventilation with the corresponding ventilation with the corresponding ventilation parameters  Fresh gas settings  Selection of monitoring values page 1/2  Display of gas measurement measured values  Display of alarm limits and gas supply pressures		Start of individual system test blocks		
Standby  Selection of patient category  Child Adult IBW  Selection of tab  Selection of tab  Selection of tab  Selection of a form of ventilation with the corresponding ventilation parameters  Display of alarm limits and gas supply pressures  Stopwatch Reset to default settings System test  Ventilation level  Selection of tab  Real-time curves Trend curves Trend curves Trend curves Trabular trend Alarm log Extras  Selection of a form of ventilation with the corresponding ventilation parameters  Fresh gas settings  Selection of monitoring values page 1/2 Display of gas measurement measured values  Display of alarm limits and gas supply pressures				
Selection of tab  Selection of tab  Standby Trend charts Tabular trend Event log Extras  Selection of a form of ventilation with the corresponding ventilation parameters Display of alarm limits and gas supply pressures Stopwatch Reset to default settings System test  Ventilation level  Selection of tab  Real-time curves Trend curves Trend curves Trend curves Trend curves Trend curves Tabular trend Alarm log Extras  Selection of a form of ventilation with the corresponding ventilation parameters Fresh gas settings Selection of monitoring values page 1/2 Display of gas measurement measured values  Display of alarm limits and gas supply pressures				
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corresponding ventilation parameters  Display of alarm limits and gas supply pressures  Stopwatch Reset to default settings System test  Ventilation level  Selection of tab  Real-time curves Trend curves Trend curves Tabular trend Alarm log Extras  Selection of a form of ventilation with the corresponding ventilation parameters  Fresh gas settings  Selection of monitoring values page 1/2 Display of gas measurement measured values  Display of alarm limits and gas supply pressures		Selection of tab	Trend charts Tabular trend Event log	Config Volume System time Option
pressures Stopwatch Reset to default settings System test  Ventilation level  Selection of tab  Real-time curves Trend curves Trabular trend Alarm log Extras  Selection of a form of ventilation with the corresponding ventilation parameters Fresh gas settings Selection of monitoring values page 1/2 Display of gas measurement measured values  Display of alarm limits and gas supply pressures				
Reset to default settings System test  Ventilation level  Selection of tab  Real-time curves Trend curves Tabular trend Alarm log Extras  Selection of a form of ventilation with the corresponding ventilation parameters Fresh gas settings Selection of monitoring values page 1/2 Display of gas measurement measured values  Display of alarm limits and gas supply pressures				
System test  Ventilation level  Selection of tab  Real-time curves Trend curves Tabular trend Alarm log Extras  Selection of a form of ventilation with the corresponding ventilation parameters Fresh gas settings Selection of monitoring values page 1/2 Display of gas measurement measured values  Display of alarm limits and gas supply pressures		Stopwatch		
Ventilation level  Selection of tab  Real-time curves Trend curves Tabular trend Alarm log Extras  Selection of a form of ventilation with the corresponding ventilation parameters Fresh gas settings Selection of monitoring values page 1/2 Display of gas measurement measured values  Display of alarm limits and gas supply pressures		Reset to default settings		
Selection of tab  Trend curves Tabular trend Alarm log Extras  Selection of a form of ventilation with the corresponding ventilation parameters  Fresh gas settings  Selection of monitoring values page 1/2 Display of gas measurement measured values  Display of alarm limits and gas supply pressures		System test		
corresponding ventilation parameters  Fresh gas settings  Selection of monitoring values page 1/2 Display of gas measurement measured values  Display of alarm limits and gas supply pressures	Ventilation level	Selection of tab	Trend curves Tabular trend Alarm log	Config Volume Option
Selection of monitoring values page 1/2 Display of gas measurement measured values  Display of alarm limits and gas supply pressures				
Display of gas measurement measured values  Display of alarm limits and gas supply pressures		Fresh gas settings		
pressures		Display of gas measurement measured		
Stopwatch				
		Stopwatch		

## Icons

Table 7: Icons/labels						
	Warning of a danger point					
4	Warning of electrical voltage					
	Electrostatically endangered components					
	Charging of mobile phones, Smartphones, tablets prohibited					
<b>**</b> /**	Device may only be moved in the transport position					
	Follow the instructions					
	Unplug from mains before opening					
<u></u>	Type B applied part (applied part for use on the body, but not on an open heart)					
((n))	Non-ionised electromagnetic radiation					
	Icon for the separated collection of electrical and electronic devices					
<b>CE</b> 0044	CE with ID number of the notified place – confirmation of fulfilment of EU requirements					

Table 7: Icons/labels	
2005	Date of manufacture
$\downarrow$	Equipotential
	Fuse
$\bigcirc_2$	Manometer for O <sub>2</sub> reserve gas bottle pressure
N <sub>2</sub> O	Manometer for N <sub>2</sub> O reserve gas bottle pressure
VAC	Manometer for vacuum pressure
0 max	Suction switch – adjustable to:  • 0 = Off  • adjustable  • max
	Change a value by turning
000	Change a value in stages by turning
O <sub>2</sub> +	Button for O <sub>2</sub> flush (on the front)
	Outlet (pneumatic)
	Inlet (pneumatic)
0	Outlet (for energy and signals)

Table 7: Icons/labels	
<u>O</u>	Inlet (for energy and signals)
<u>O</u> +	Inlet/outlet (for energy and signals)
1	Block, general
1	Unblock, general
EXT O <sub>2</sub>	External O <sub>2</sub> outlet
EXT FG Pmax = 1,2 kPa x 100	External fresh gas outlet giving maximum P <sub>max</sub> pressure
⊕→ ETH	Ethernet interface
COM I COM 2	1st and 2nd Serial interface
	VGA outlet (for additional VGA monitor)
⊕ USB	USB interface
	Lamp; light; lighting
<b>←</b> <b>○ →</b> I ≤ 2 A	Auxiliary sockets charge with max. 2 A
<b>?</b>	Connection for high-pressure sensors

Table 8: Icons/button	S						
	ON/OFF	ON/OFF button					
	Selection	Selection button fresh gas blender window					
	Selection	button real	-time chart	s window			
	Selection	button forn	n of ventila	tion, ventilati	on parame	eters window	
	Selection form of v		N/SPONT (	(manual ven	tilation/spo	entaneous bre	eathing)
	Selection	button ope	n forward/f	ocus loops v	vindow		
	Selection	Selection button alarm limits window					
	Button for switching between the following windows						
	on stand	on standby during a ventilation procedure					
	Standby				Real-tim	ne curves	
	trend cur	trend curves Trend curves					
	Tabular t	rend			Tabular	trend	
	Event log	J			Alarm lo	og	
	Extras				Extras		
	Config	Volume	System time	Option	Config	Volume	Option
START	Button to start ventilation						
	Standby button (stop ventilation and change to standby)						
	Mute ala	Mute alarm for two or ten minutes button (10 minutes only in MAN/SPONT)					

Table 9: Icons/LEDs						
	LED mains voltage available (green light)					
-+	LED battery operation (yellow light)					
<u></u>	LED visual alarm display (red light)					
Table 10: Icons/scree	en (display only)					
50 min.	Screen icon/display: Remaining battery life					
<u>-</u> + 70 %	Screen icon/display: Battery charging control display					
10 min.	Screen icon/display: Battery low					
0 min.	Screen icon/display: Battery faulty					
×	Screen icon/display: No batteries available					
₽-	Screen icon/display: Mains voltage available					
⊅-	Screen icon/display: Mains voltage not available					
丁	Screen icon/display: Upper and lower alarm limits					
<b>0</b> —₽	Screen icon/display: ZGA pressures					
Ĩ	Screen icon/display: 10 L bottle pressures					

Table 11: Icons/screen (control elements)					
‡ Q +	Screen icon/control element of real-time charts  O point shift Zoom in Y direction Autoscale ON/OFF				
# of Charts: 4	Screen icon/control element: Number of real-time charts that should be displayed				
10 s	Screen icon/control element: Scaling of X-axis				
P <sub>aw</sub> cmH <sub>2</sub> O	Screen icon/control element: Selection of which measured value should be displayed as the real-time curve				
	Screen icon/control element: Display loop window in full screen				
	Screen icon/control element: Set limit values (alarm limits)				
MV 7.1	Screen icon/control element: Determine monitor value				
Table 12: Icons/scree	en (buttons)				
्र	Button Zoom loop in X direction				
+	Button Shift 0 point in X direction				
Q.\$	Button Zoom loop in Y direction				
<b>‡</b>	Button Shift 0 point in Y direction				
	Button Autoscale loops ON				
<b>♦</b>	Button Autoscale loops OFF				
×	Close window button				
•	Button Scroll list				

Table 12: Icons/screen (buttons)					
*	Button Scroll list (fast)				
Autoset	Adapt alarm button automatically				
Pause	Freeze loop				
Continue	Start loop				
Save	Save loop as reference loop				
Activate	Display reference loop and start current loop (activate comparison mode)				
Deactivate	Delete reference loop and start current loop (deactivate comparison mode)				

Table 13: Icons/screen (tabs)							
	on standby				during a ventilation procedure		
Standby	Standby window Real-time curve window						
Curves	(dark blue when active) (dark blue when active)					ctive)	
Trend Curves			Т	rend curv	e window		
Trend Tab			Ta	abular tre	nd window		
Event Log	Event log Alarm log						
Alarm log							
Extras		Extras					
Config							
Volume	Config	Volume	System time	Option	Config	Volume	Option
System time	Connig						
Option							
1 2	Monitoring values page 1 or 2						
Page 1	Tab with further pages						

## **User interface**

The user interface of the leon *plus* consists of three components:

- screen (TFT) with touchscreen (touch)
- keypad
- rotary switch (encoder)

The main control element is the touchscreen, but the device can also be fully operated by the keypad and rotary switch.

## Concepts

### Safety concept

#### **Modules**

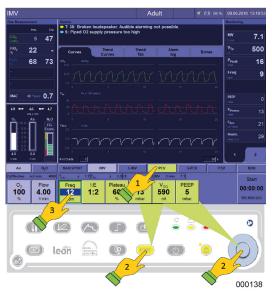
In the leon *plus* the ventilation unit, user interface and monitoring system are separate, independent modules. If the ventilation unit fails, this does not lead to a limitation in the functioning of other modules. Manual ventilation with full monitoring scope is then possible.

If the user interface and the monitoring system fail, the ventilation procedure continues to run using the last fresh gas settings and ventilation parameters set.

#### **User interface**

One function only is allocated to each control element. Any device function can also be accessed and carried out using the keypad buttons and the rotary switch. A faulty touchscreen does not lead to functionality limitations.

#### Colour concept



The outline of an active window is pale blue; the outline of an inactive window is dark blue.

(→ "Touchscreen" p. 47)

The button of the active form of ventilation (IMVhere) is displayed in pale blue. A newly selected breathing type (PCV here) and its buttons for setting the ventilation parameters are yellow (1).

When selecting a new form of ventilation, its buttons for presetting the ventilation parameters are shown above the buttons of the active form of ventilation. The newly selected form of ventilation can be started by the yellow "START" button on the keypad or by the rotary switch (2).

If a ventilation parameter unlocks, the button is outlined in green and the value to be entered is highlighted in dark blue (3).

If not confirmed, the form of ventilation presets (yellow) are closed again after 10 seconds and the previous active form of ventilation and its parameters are retained.

(→ "Control element functions" p. 48)

## **Keypad**

## Operation of keypad

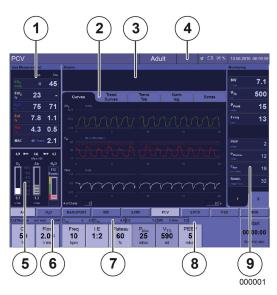


Various functions are carried out using the keypad (→ "Table 8: Icons/buttons" p. 40)

Operating states are visualised through LEDs.

(→ "Table 9: Icons/LEDs" p. 41)

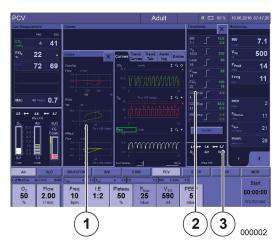
## **Touchscreen**



#### Basic screen

The basic information and control elements are displayed on the screen with a title bar and eight windows.

- (1) Display of gas measurement measured values
- (2) Tab system
- (3) Display of current alarms
- (→ "Display of current alarms" p. 190)
- (4) Title bar
- (5) Operation and display of the fresh gas blender
- (6) Display of effective O2 shortage
- (7) display T<sub>insp.</sub>, T<sub>exsp.</sub>, I:E
- (8) Setting and display of ventilation types and ventilation parameters
- (9) Display of ventilation measured value



#### **Extended monitor**

If desired, two further windows can be shown.

- (1) Show window for loops with the **loop window** button
- (2) Show window for limit values (alarm limits) with the **alarm limits window** button
- (3) Show display pressures ZGA and 10 L bottles with the **alarm limits window** button

5

#### Touchscreen operation

The device functions are operated primarily via the touch screen. The following functions, however, can be carried out via the keypad only:

- ON/OFF button
- Show loop window button
- Show alarm limits, display pressures ZGA, 10 L bottles window
- Button for switching between screens
- Start ventilation button
- Standby button, stop ventilation and change to standby
- Mute alarm for two or ten minutes button (10 minutes only in MAN/SPONT)



(→ "Table 8: Icons/buttons" p. 40)

Table 14: Control element functions (touchscreen)

#### control element selected preset active By touching a button with a function (e.g. selection of a form of ventilation), it unlocks independently and PCV PCV **PCV** is outlined in green. A setting value (e.g. ventilation parameter) is Plateau Plateau Plateau unlocked, outlined in green and the value to be 20 20 20 entered is highlighted in blue (change is possible only % % with the rotary switch). An icon with a function (e.g. control element of realtime charts) is outlined in green in a window and highlighted in pale blue. Q + Trend Curves A tab is highlighted in dark blue. Curves Scrolling data in the window slow/fast close open window

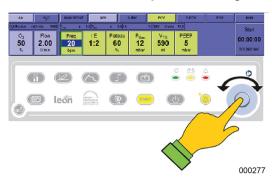
## **Rotary switch**



The button is turned for selection; press the rotary switch for confirmation:

- The rotary switch enables you to move to a button or a window
- The rotary switch confirms a button with a function
- This setting value is changed and confirmed via the rotary switch or by pressing the button again.
- The rotary switch confirms an icon with a function
- A form of ventilation can be started via the rotary switch

## Operation using the keypad exclusively



Without using the touchscreen, a button must be first of all focused on the relevant window through the keypad.

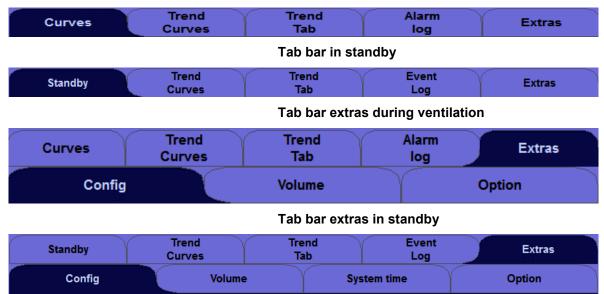
(→ "Operation of keypad" p. 46)

The shifting of the input focus to a button is carried out inside a window by turning the rotary switch. A ventilation parameter is unlocked by pressing the rotary switch, changed by turning and confirmed by pressing once more.

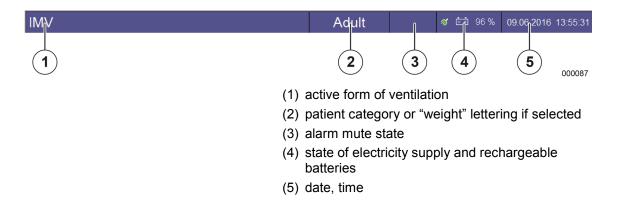
## Tab system

The centrally arranged window in the centre of the user interface consists of five tabs, which are partially assigned to different functions when on standby and during an ongoing ventilation procedure. The active tab is highlighted in dark blue.

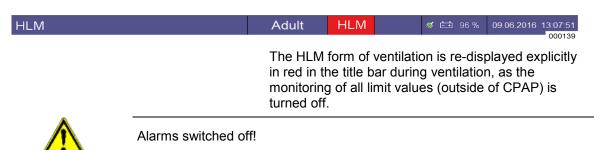
## Tab bar during ventilation



#### Title bar



## **HLM** form of ventilation

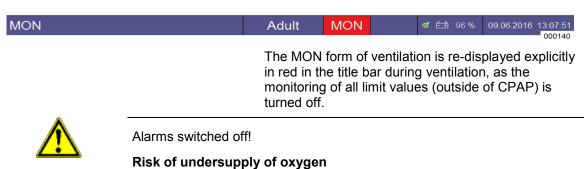


**WARNING** 

### Risk of undersupply of oxygen

Be extra vigilant during the ventilation.

## MON form of ventilation



## WARNING

Mak of undersupply of oxygen

Be extra vigilant during the ventilation.

P

In the MON form of ventilation, fresh gas administration is switched off.

## Monitoring of muting of alarm

#### Mute 2 min.



The **Mute** button is positioned on the bottom right of the keypad. By pressing **Mute**, the audible alarm for all currently pending alarms is muted for two minutes.



A minute counter appears in the title bar in mm:ss format, which displays the remaining mute time.

(→ "Alarm muting 2 minutes" p. 194)

#### Mute 10 min.



In the **MAN/SPONT** form of ventilation, a screen dialogue appears, if the **Mute** button is pressed for longer than 2 seconds.

 $(\rightarrow$  "10 minute alarm muting" p. 195).

If the dialogue is confirmed with **Yes**, all alarms are muted for 10 minutes. A minute counter appears in the title bar in mm:ss format, highlighted in red, which displays the remaining mute time.

The **Mute** function is only available in the MAN/SPONT form of ventilation.



#### Alarms muted!

#### Risk of undersupply of oxygen

Any alarms that occur are only displayed visually.

WARNING

• Watch the ventilation, while the alarms are muted.

This function should only be used when patients are disconnected from the device.

## **Screensaver**

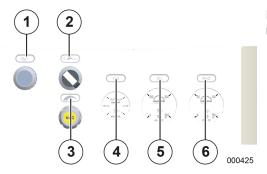
A screensaver can be set up in the configuration menu.

It should only be set up by trained specialist staff or by Löwenstein Medical-authorised service technicians.

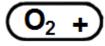
## **Control elements and displays**

### **Front**

## O<sub>2</sub>, flush, vacuum, manometers



Display and control elements are displayed on the right above the drawer block on the front:



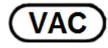
(1) Button for  $O_2$  flush ( $\geq 35$  l/min)



- (2) Switch for aspiration adjustable to:
  - 0 = Off
  - adjustable
  - max



(3) Rotary switch for vacuum dosage (turn anticlockwise to increase the vacuum)



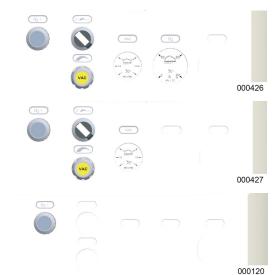
(4) Manometer for vacuum pressure



(5) Manometer for O2 bottle pressure



(6) Manometer for N<sub>2</sub>O bottle pressure



#### **Variants**

Display and control elements on the front, O<sub>2</sub> reserve gas bottle operation only

Display and control elements on the front, without reserve gas bottle operation

Display and control elements on the front, without reserve gas bottle operation without integrated bronchial aspirator

## Production and dosage of the vacuum

The vacuum can be turned on and off via a switch. The strength can be regulated between 0 and - 0.7 bar.



The switch has three settings:

- off
- regulated value
- max

If the max setting is selected, it switches immediately to maximum aspiration performance, without the regulating valve having to be fully turned on.

There are two variants for producing the vacuum for the bronchial aspirator:



injector principle



vacuum (wall connection)



## **Options board**



This device variant is optional for leon plus.

The options board is situated on the top of the left side wall of the device.

## External fresh gas outlet options board version



- (1) O<sub>2</sub> emergency dosing (red ring)
- (2) Water trap receptacle
- (3) Switch for external fresh gas outlet 1/0 (On/Off); displayed setting is  $0 \rightarrow$  Off
- (4) External pressure gas outlet; ISO cone 22 mm outside, 15 mm inside

## External O<sub>2</sub> outlet options board version

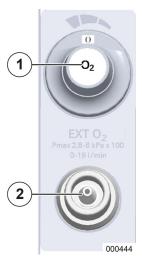


- (1) O<sub>2</sub> emergency dosing (red ring)
- (2) Water trap receptacle
- (3) Flowmeter for external O2 outlet
- (4) External O<sub>2</sub> outlet; ISO cone 22 mm outside, 15 mm inside

## **Device connections**

## **Description of device connections**

## External O<sub>2</sub> outlet

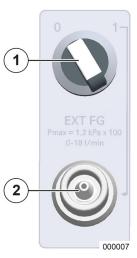


- (1) flowmeter for external O<sub>2</sub> outlet
- (2) external  $O_2$  outlet: ISO cone, 22 mm outside, 15 mm inside

The dosage and closing (OFF) of the external  $O_2$  outlet is carried out by the flowmeter.

The gas from the  $O_2$  fresh gas outlet consists of 100%  $O_2$ .

## External fresh gas outlet



- (1) Switch for fresh gas outlet 1/0; displayed setting is  $0 \rightarrow \text{OFF}$
- (2) Fresh gas outlet: ISO cone, 22 mm outside, 15 mm inside

The maximum pressure on the external fresh gas outlet is given with  $P_{max} = 1.2 \text{ kPa} \times 100$ .

The external fresh gas outlet serves as the connection to semi-opened systems e.g.

- Bain
- Jackson Rees systems
- The concentrations of gases from the fresh gas outlet are set as follows: Narcotic gases on the anaesthetic vaporiser; O<sub>2</sub>, N<sub>2</sub>O, AIR on the fresh gas blender

## Operation of the device connections

#### External O<sub>2</sub> outlet



The flowmeter for the external  $O_2$  outlet has a setting range of 0 (OFF) – 15 l/min. Setting values are: 0, 1, 2, 3, 4, 5, 6, 9, 12, 15 l/min.

The external  $O_2$  outlet can be used for  $O_2$  insufflation during local anaesthesia, for example.



Take care that the set flow can be seen in the display window of the flowmeter and the switch is not in an intermediate position.

## External fresh gas outlet



The fresh gas outlet has two switch positions; the position shown is  $0 \rightarrow OFF$ .

#### Switch positions:

- $1 \rightarrow ON \rightarrow$  fresh gas flows towards the external outlet
- $0 \to \text{OFF} \to \text{fresh}$  gas flows into the patient module

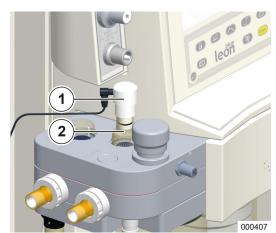
## Operation of emergency O<sub>2</sub> dosing



The  $O_2$  emergency dosing is located on the option board. It is marked by a red ring. It is a flowmeter with a setting range of 0 (OFF) – 15 l/min. Setting values are: 0, 4, 5, 6, 7, 8, 9, 10, 12, 15 l/min.

The  $O_2$  emergency dosing is only released during the ongoing system test and not released during an ongoing ventilation. (The label can vary and be called " $O_2$  CE 0044" or " $O_2$  SAFETY FLOW" .)

#### Gas measurement

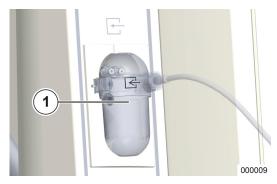


The leon plus is equipped with a side flow meter as standard. An FiO<sub>2</sub> meter is optional. The corresponding configuration occurs in servicing and may only be carried out by Löwenstein Medical-authorised service technicians.

#### FiO<sub>2</sub> meter

(only possible for the "external  $O_2$  fuel cells" option) The FiO<sub>2</sub> meter sensor is situated in an adapter, which replaces the inspiratory inspection glass from the patient module. Only the inspiratory  $O_2$  concentrations are measured.

- (1) FiO<sub>2</sub> sensor
- (2) adapter

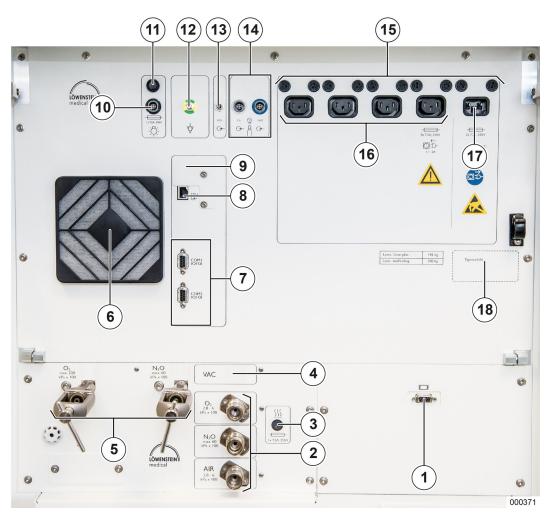


#### Side flow meter

The water trap of the side flow meter with a luer lock for the sample line is situated on the options board or options panel.

- (→ "Changing or emptying of the water trap" p. 258)
- If the leon plus is on standby, the gas measurement runs independently of the screensaver configuration for another 20 to 90 minutes. After this, it too switches to standby. If a button or the touchscreen is used, the gas measurement goes back into operation. The display is then delayed briefly.
- (1) Water trap

## Rear wall

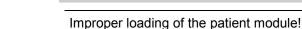


- (1) 1 x D-Sub, 15-pin socket, VGA outlet (optional with LWL connection)
- (2) Connections for ZGA
- (3) Patient module heating fuse
- (4) Vacuum or O<sub>2</sub> high-pressure outlet
- (5) Reserve gas bottle connection
- (6) Fans
- (7) 2 x D-sub, 9-pin socket, serial connection
- (8) 1 x RJ 45 Ethernet connection
- (9) 1 x USB connection (covered, for service purposes only)
- (10) Workstation light connection
- (11) Workstation light connection fuse

- (12) Connection for potential equalisation
- (13) Socket for FiO<sub>2</sub> meter (for "external O<sub>2</sub> fuel cells" option only)
- (14) Pressure sensor inlets for 10 I bottles: socket coded with white ring:  $O_2$  pressure sensor; socket coded with black or blue ring: AIR or  $N_2O$  pressure sensor
- (15) Mains connection and auxiliary power point fuses
- (16) Four auxiliary outlets
- (17) Mains: 100-240 VAC
- (18) Type plate

**ATTENTION** 

## **Patient module**



#### Damage to the device itself and to the patient module

Do not load the patient module improperly on the docking station:

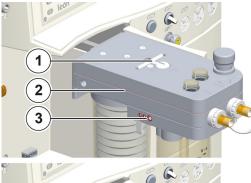
- do not lean on it
- do not use the APL valve as a manoeuvring handle
- do not handle the device with the docking station open
- avoid loading by moving the operating table up and down

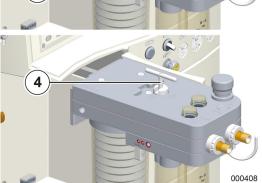
## Removing the patient module



To remove the patient module from the device, the docking station must first be unlocked by turning the lever towards anticlockwise (or back).

- (1) Docking station
- (2) Lever for locking the docking station to the patient module on the device
- (3) Open in the direction of the arrow





After unlocking, the docking station can be swivelled forwards to the side. The illustration shows the catch in locked position (lying at an angle to the longitudinal axis of the patient module).

- (1) Fold-out handle of the catch
- (2) Patient module in folded-out position
- (3) Orings
- (4) Handle in vertical position
- The patient module cannot be lifted off the docking station without removing the CO<sub>2</sub> absorber.
- Turn the handle of the catch up into vertical position. Turning anticlockwise releases the link, while pressing down and turning clockwise closes the link to the docking station.
- 2. Lift off the patient module vertically upwards.



Docking station locked incorrectly!

#### Damage to the device itself and to the patient module

 Before locking the docking station, it is vital to ensure that the docking station and the patient module are swivelled in fully.

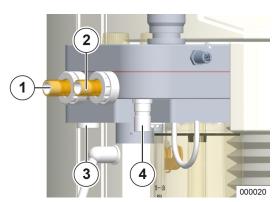


Patient module inserted incorrectly!

#### Damage to the device itself and to the patient module

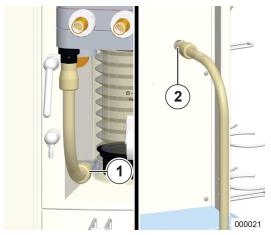
• The housing can be damaged if the handle of the catch is not shut when the patient module is shut.

# Connection for ventilation tubes, anaesthesia gas scavenging system and ventilation bag



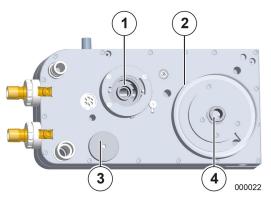
- (1) Patient expiration connection cone (Ø 22 mm)
- (2) Patient expiration connection cone (Ø 22 mm)
- (3) AGSS connection cone (Ø 30 mm)
- (4) AGSS connection cone (Ø 22 mm)

### Connection of the AGSS on the rear of the device

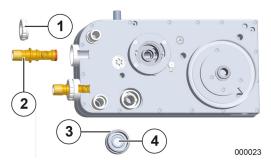


- (1) AGSS connection on the front of the casing (Ø 22 mm)
- (2) AGSS connection on the front of the casing (Ø 22 mm)
- Please also refer to the AGSS user manual.

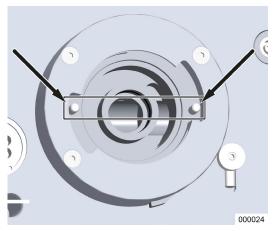
# Connection for respiratory bellows, dome and CO<sub>2</sub> absorber, PEEP valve diaphragm cover, flow sensors



- (1) Carrier CO<sub>2</sub> absorber
- (2) Carrier dome
- (3) PEEP valve diaphragm cover
- (4) Respiratory bellows connection

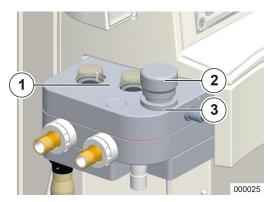


- (1) Lock nut
- (2) Flow sensor
- (3) PEEP valve diaphragm cover
- (4) PEEP valve diaphragm



Without the  $CO_2$  absorber, the two pins must be in place as shown in the illustration.

## **APL** valve

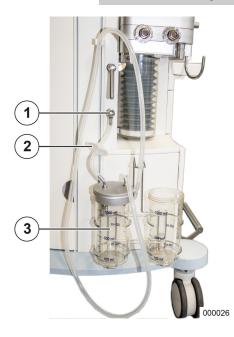


The ventilation pressure during the MAN/SPONT, HLM and MON forms of ventilation is limited by the APL valve (adjustable pressure limitation), which can be set manually between the two end positions SP (spontaneous breathing fully opened) 90 Pa × 100 (mbar).

The pressure limit is increased by turning the valve to the right and decreased by turning it to the left, whereby engagement is noticeable from 40 Pa × 100 (mbar). The marked settings are SP (spontaneous), 10, 20, 30, 50, 70, 90 Pa × 100 (mbar).

- (1) Inspiratory and expiratory valve diaphragm of sight glasses
- (2) APL
- (3) APL locking mechanism (bayonet catch)

## **Bronchial aspiration**



There are two variants for producing the vacuum:

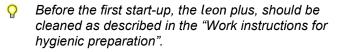
- injector principal
- vacuum wall connection
- Please also refer to the bronchial aspiration user manual.
- (1) Vacuum connection for bronchial aspiration
- (2) Filter
- (3) Bronchial aspiration glass

## 6. Preparations

## **First installation**

## **Adaptation to ambient conditions**

If the leon *plus* is subject to extreme ambient conditions (temperature, moisture) during transport or storage, give the device, while switched off, the opportunity to adapt to the conditions at the installation site. Connect the device as soon as possible to the mains supply.



# Customer requirements at the application site (leon *plus* – Standard configuration)



## Class I device!

## Risk of injury through electrocution.

• The mains to which the device is connected must be earthed.

## **WARNING**

Table 15: Customer requirements at the application site (leon <i>plus</i> – Standard configuration)				
Voltage	Supply	240 $V_{AC}$ + 10%/-15%, 50/60 Hz 115 $V_{AC}$ + 10%/-15%, 50/60 Hz The maximum internal resistance may not lead to an upper/lower deviation of the supply voltage of 240 V + 10/-15% or 115 V + 10/-15% at the mains socket.		
	Wall connection	in accordance with EN 60601-1 for earthed devices (Schuko plug)		
Potential equalisation	Wall connection	for POAG-KBT6DIN socket in accordance with DIN42801		
ZGA	Pressure	2.8-6.0 kPa × 100 (bar)		
	Wall connection	for supply plug DIN 13260-2 shape-coded with Ø 7.5 mm connecting nipple		
	Gas quality	dry, oil and particle-free (medical)		
Waste disposal system	Aspiration performance	55-60 l/min		
(AGSS)	Wall connection	in accordance with EN 737		
Climatic conditions		temperature, moisture, ambient pressure ( $\rightarrow$ "Technica data" p. 301) adequate ventilation		
Additional monitors		max. current consumption (switch-on surge) (→ "Connection of auxiliary devices" p. 87) and weight (→ "Mounting additional monitors" p. 280)		

## **Emergency power supply**



When selecting the installation site, take care that access to the mains plug is always guaranteed. The device must be able to be separated from the mains easily and at any time.

The leon *plus* has an uninterrupted power supply, which in the event of voltage variations in the mains current or total power failure maintains the operational readiness or operation of the device. Independent of the setting of the ventilation parameters, battery operation of at least 100 minutes is guaranteed.

## **Charging batteries**

The leon *plus* has two emergency power batteries. Connect the leon *plus* to a suitable mains socket via a mains cable. The device recognises the voltage of 240  $V_{AC}$  + 10%/-15%, 50/60 Hz or 115  $V_{AC}$  + 10%/-15%, 50/60 Hz automatically. A manual switch-over is not necessary. For the batteries to fully charge before first operation and after replacement, the device must be connected to the mains for at least 8 hours. If the mains plug is plugged in, the batteries charge automatically. The batteries charge even if the device is turned off.

## Out-of-operation for a longer period



If the leon *plus* is not used for a longer period, it should remain plugged into the mains to avoid the batteries discharging.

The green LED below the plug icon on the keypad shows that mains voltage is available.

## **Preparation for start-up**

#### Gas connections



Bottle valves, high pressure regulator and connected fittings! **Explosion risk** 

## WARNING

- Do not use any kind of tool to open the bottle valves.
- Oil and fats can react violently with some gases under pressure (O<sub>2</sub>, N<sub>2</sub>O (laughing gas), compressed air and their mixtures).
  - Do not grease or oil the connections for reserve gas bottles.
  - Avoid contact between hand cream and the fittings.

## Operating with reserve gas bottles

#### Reserve gas bottles start-up

- 1. Open the valve of the pressure gas bottle slowly.
- P

Ensure proper use with the patient in mind. If no gas is removed, close the valve of the pressure gas bottle.

#### Decommissioning reserve gas bottles

# When changing the pressure gas bottle or the high pressure regulator:

- **1.** Close the valve of the pressure gas bottle.
- **2.** Use up or bleed the remaining gas in the high pressure regulator and in the tube pipe.

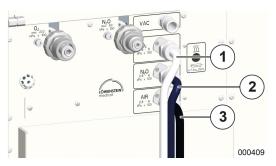


Do not unscrew the high pressure regulator while it is under pressure. The seals can be damaged.

- **3.** Release the screw fixing between the pressure gas bottle and the high pressure regulator.
- **4.** Put the protective cap on the connections. Store the device in dry and clean conditions.

## Connection to the central gas supply (ZGA)

Please also refer to the ZGA user manual.



The connections (the standard is NIST) for the central gas supply are situated on the rear left of the device. The supply pressure on the device connection must be between 2.8 and 6,0 kPa × 100 (bar).

Use ISO 32-compliant colour-coded pressure tubes:

(1) O<sub>2</sub>: white (2) N<sub>2</sub>O: blue

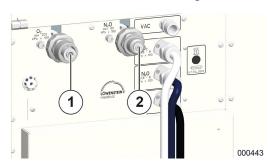
(3) AIR: black-and-white

Vacuum: yellow (not illustrated)

#### **Short ZGA check**

- 1. Check the ZGA pressures.
- 2. Check the seals on the connections.

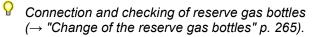
## Reserve gas bottle connection (2I or 3I)



The connections (the standard is DIN) for the reserve gas bottles are situated on the rear of the device. The connections are shape-coded so they cannot be confused.

- (1)  $O_2$
- (2)  $N_2O$

The bottle pressure is displayed on the pressure manometers on the front.

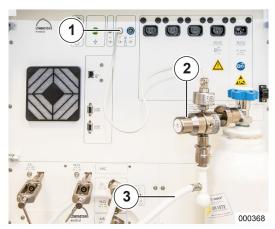


Reserve gas bottles should also be connected to the device for gas supply through the ZGA.

## Short check of reserve gas bottles

- 1. Make sure that the bottles are filled. Pressure
  - O<sub>2</sub>, AIR > 120 kPa × 100 (bar)
  - N<sub>2</sub>O > 40 kPa × 100 (bar)
- 2. Check the seals on the connections.
- **3.** Make sure that the bottle valves are closed.

#### 10 L bottle connection instead of ZGA



Instead of the central gas supply, the leon *plus* can also be supplied with fresh gas from two 10 L bottles. The gases available are  $O_2$  and optionally either AIR or  $N_2O$ . If  $N_2O$  is selected, AIR is replaced by  $O_2$  as a drive gas. The supply pressures on the device connection must be between 2.8 and 6,0 kPa × 100 (bar).

- **1.** Screw the high pressure regulator onto the particular bottle connection.
- Place the bottle(s) on the right next to each other at the back inside the device in the holder provided.
- Turn the bottle(s) until the high pressure regulators show towards the front slightly towards the left (it must be possible to close the rear wall doors).
- **4.** Secure the bottle(s) with the lashing straps.
- **5.** Connect the outlets of the high pressure regulator with the appropriate connections (the standard is NIST) via pressure tubes on the device.
- **6.** Plug the high-pressure sensors into the ISO 32-compliant (coloured ring) coded sockets in the rear wall of the device.
  - O<sub>2</sub>: white ring
  - AIR: black ring
  - N<sub>2</sub>O: blue ring

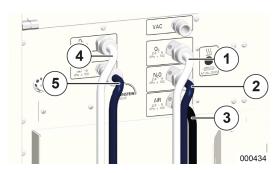
The bottle pressures are displayed in the limit values window.

- (→ "Pressure display when supply from 10 L bottles" p. 186)
- (1) pressure sensor connection
- (2) pressure regulator
- (3) pressure tube
- Use the 4 kPa x 100 (bar) pressure regulator prescribed by Löwenstein Medical.
- The type of gas contained in the 10 L bottles must be configured in the service. O₂ is always available, while AIR and N₂O are optional.
- Connection and checking of 10 L reserve gas bottles
   (→ "Change of the reserve gas bottles" p. 265).

#### Short check of 10 L bottles:

- Make sure that the bottles are filled (O<sub>2</sub>pressure, AIR > 120 kPa × 100 (bar) N<sub>2</sub>O > 40 kPa × 100 (bar)).
- 2. Check the seals on the connections.
- 3. Make sure that the bottle valves are opened (does not apply to AIR and ZGA 10 L bottle connection).
  (→ "AIR and ZGA 10 L bottle connection" p. 72)
- **4.** Check that the bottles are secure in the holder.
- **5.** Make sure that the high pressure sensors are plugged into the sockets in the rear wall of the device.

#### 10 L bottle connection as reserve bottles



Two 10 L bottles can also be attached to the leon *plus* as reserve gas bottles.

The two device connections are situated vertically one on top of the other on the rear left of the device instead of the device attachments for the 2 L or 3 L reserve gas bottles.

The supply pressures on the device connection must be between 1.8 and 2.0 kPa × 100 (bar).

The procedure for attaching the bottles and the short check are carried out as described above ( $\rightarrow$  "10 L bottle connection instead of ZGA" p. 70).



Use colour-coded pressure tubes in accordance with ISO 32:

(1) O<sub>2</sub> (ZGA): white

(2) N<sub>2</sub>O (ZGA): blue

(3) AIR (ZGA): black-and-white

Vacuum: yellow (not illustrated)

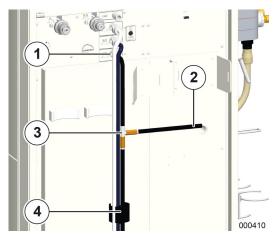
(4) O<sub>2</sub> (10 L reserve)

(5) N<sub>2</sub>O (10 L reserve)

#### Short ZGA check

- 1. Check the ZGA pressures.
- **2.** Check the tightness on the connections (→ "Short check of 10 L bottles" p. 71).
- Use the 1.9 kPa x 100 (bar) pressure reducer prescribed by Löwenstein Medical.

#### AIR and ZGA 10 L bottle connection



For AIR there is the option of parallel connection to a 10 L bottle and the ZGA. This requires a pressure tube with a T-connector.

- $(\rightarrow$  "leon plus Spare parts ordering options and replacement" p. 300)
- 1. Screw the pressure tube with the NIST screw fixing to the T-connector on the NIST connector on the device.
- **2.** Join one exit (long pressure tube) of the T-connector to the ZGA and the other, shorter one to the high-pressure reducer on the 10 L bottle.
- **3.** Plug the high-pressure sensor into the ISO 32-compliant (black) coded sockets on the rear wall of the device.
- The bottle pressure is displayed in the limit values window (→ "Pressure display when supply from 10 L bottles" p. 186).
- (1) NIST screw fixing
- (2) to the bottle
- (3) AIR pressure tube with T-connector
- (4) to the ZGA

#### Short ZGA check

- 1. Check the ZGA pressures.
- Check the tightness on the connections (→ "Short check of 10 L bottles" p. 71).

#### Connection to the AGSS!

# ATTENTION

#### Connection to the rear wall not possible

- The connection must be made directly to the patient module
- The intake system must be hung on the side of the device.

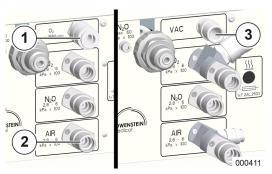


It is recommended that the AIR 10 L bottle is closed if the leon plus is supplied via the ZGA.

It is recommended that the pressure tubes are guided through the Velcro fastener in the lower third of the rear wall of the device.

(→ "Tube holder" p. 32)

#### Vacuum and external high-pressure gas outlet connection



There is either a connection for vacuum (alternative to compressed air) to drive the internal bronchial aspiration or an  $O_2$  high-pressure outlet to connect to an additional  $O_2$  flow meter via the connections to the ZGA

An AGSS can be connected to the ZGA connection for AIR via an AIR high-pressure outlet.

- (1) O<sub>2</sub> high-pressure outlet
- (2) AIR high-pressure outlet
- (3) Vacuum



The decrease at the  $O_2$  high-pressure outlet may not exceed 15 NI/min, and on the AIR high-pressure outlet 75 NI/min.

#### **Electrical connections**

#### Connection to the mains



The connection for the voltage supply is situated on the top right on the rear of the device.

This is an IEC socket.

- (1) Voltage supply
- When the IEC device is unplugged, the device is cut off from the mains completely.
- On not use voltage supply cables longer than a metres.

Possible voltage supplies at the following frequencies are:

- 240 V<sub>AC</sub> + 10%/-15% V<sub>AC</sub> 50/60 Hz
- 115 V<sub>AC</sub> + 10%/-15% V<sub>AC</sub> 50/60 Hz



The green LED below the plug icon on the keypad shows that mains voltage is available.



The plug icon appears in green in the title bar on the right if mains voltage is available. The battery icon appears in white with the display of the charging state shown as a percentage.

#### Connection of the equipotential bonding



To produce potential equalisation, join a connection provided for this purpose at the installation site via a suitable conductor (potential equalisation conductor HuL item number 0170501) to the potential equalisation provided on the device.

- The additional potential equalisation has the task of balancing potential differences between different simultaneously exposed metal components to protect the patient, user and third parties from contact voltages.
- (1) Potential equalisation

#### Mains connection fuses



If the device reports "Mains failure. Device running on battery", the fuses on the IEC socket of the leon *plus* may be faulty.

(1) Fuses

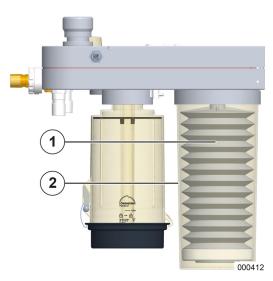
#### Connection of the workstation light



The voltage supply cable of the light is pulled through the left upper cable opening and plugged into the socket provided (coded by shape and black ring). The light fuse is situated above the socket.

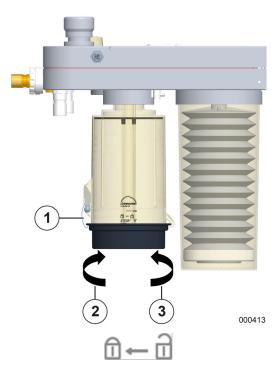
- (1) Workstation light fuse
- (2) Workstation light socket
- These are inert 2A fuses. The attachments for the fuses are released with a size 1.2 x 6.5 slot screwdriver.
- The lamp is turned off during battery operation.

## Connection of the respiratory bellows and the dome



- **1.** To fix the respiratory bellows and the dome, take off the patient module and place it upside down on a firm base.
- **2.** Pull the respiratory bellows onto the joining supports.
- **3.** Turn the dome into the carrier on the patient module (anticlockwise).
- $(\rightarrow$  "Connection for respiratory bellows, dome and  $CO_2$  absorber, PEEP valve diaphragm cover, flow sensors" p. 62)
- (1) Respiratory bellows
- (2) Dome

## Removing and installing the CO<sub>2</sub> absorber



A filled CO<sub>2</sub> absorber can only be removed or installed if the patient module is situated on the docking station.

Unlock the CO<sub>2</sub> absorber by turning in a clockwise direction and take it out of the carrier.

- (1) clamp
- (2) close
- (3) open

 The CO₂ absorber can also be changed when the device is in operation, as in the removed state the outlet and inlet of the CO₂absorber are shortcircuited. The alarm notification "CO₂ absorber removed. Circle system short-circuited" appears on the screen.

To reinstall the  $CO_2$  absorber in the carrier, the clamp must be visible on the front of the absorber jar. The  $CO_2$  absorber is unlocked by turning in an anticlockwise direction.



Changing the CO<sub>2</sub> absorber!

## Risk of CO<sub>2</sub> rebreathing

If the CO<sub>2</sub> absorber is changed during ventilation, it should be done rapidly, as CO<sub>2</sub> rebreathing could occur due to the short circuit when the CO<sub>2</sub> absorber is removed.

**WARNING** 

## Changing, emptying, filling the CO<sub>2</sub> absorber

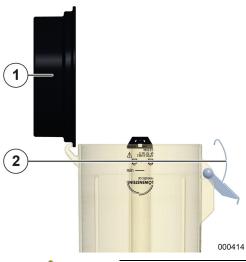


**CAUTION** 

Discolouration of the soda lime!

#### Risk of oxygen deficiency

- Discolouration of the soda lime or an increased inspired CO<sub>2</sub> measured value indicates inadequate CO<sub>2</sub> absorption capacity.
- The lime should be changed.



#### Opening the CO<sub>2</sub> absorber

- **1.** Turn the CO<sub>2</sub> absorber with the lid upwards.
- **2.** Open the lid by pulling the clamp on the absorber jar outwards.
- **3.** First lift up the lid in the guide into a vertical position, then take it out.
- **4.** Empty the CO<sub>2</sub> absorber jar and have the CO<sub>2</sub> absorber hygienically prepared.
- (1) lid
- (2) clamp



**WARNING** 

Eye contact with soda lime!

#### Risk of serious eye injury

- Avoid soda lime contact with the eyes.
- Get medical help immediately.
- Rinse thoroughly with water (for at least 30 minutes).



**WARNING** 

Skin contact with soda lime!

#### Risk of skin irritation

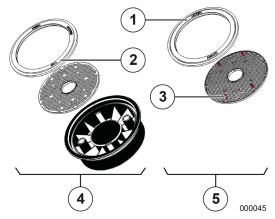
- Avoid soda lime contact with the skin or clothing.
- Get medical help immediately.
  - Rinse thoroughly with water for at least 15 minutes.
  - Take off, remove and clean clothing and shoes to avoid further exposure.



Inhalation or swallowing of soda lime!

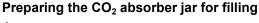
#### Risk of poisoning and irritation of the skin and respiratory tract

- Get medical help immediately.
- After swallowing, do not induce vomiting; drink plenty of water.
- After inhalation, get into fresh air immediately.



#### Assembling the CO<sub>2</sub> absorber lid

- **1.** Take the lid of an hygienically prepared CO<sub>2</sub> absorber.
- **2.** Make sure the sieve and seal in the lid are present and installed correctly. The top side must show upwards.
- (1) Seal with **BOTTOM** labelling
- (2) Seal with BOTTOM labelling
- (3) Underside of sieve with spacers
- (4) Top sides (correct)
- (5) Bottom sides (wrong)
- The top side of the seal is labelled **TOP**, while the bottom side of the sieve can be recognised by the missing spacers. Ensure that the seal is fitted cleanly and correctly.



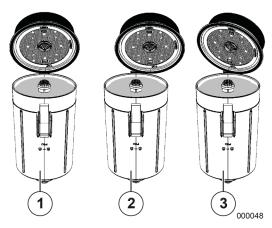
- **1.** Place the lid with the inner side down on a firm, disinfected base.
- **2.** Place the CO<sub>2</sub> absorber jar in the hollow provided in the lid.
- Ensure that the lid is exactly in line with the CO<sub>2</sub> absorber jar and is not offset to the side or twisted when suspended in the guide.
- **3.** Make sure that the protective cap is on the gas feed.
- (1) protective cap
- (2) gas feed

#### Filling the CO<sub>2</sub> absorber jar

- **1.** Fill the absorber jar up to at least the **min** filling mark and to the **max** filling mark at most.
- (1) max
- (2) min





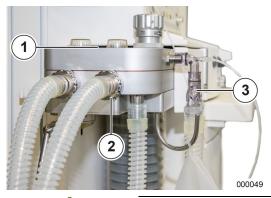


#### Closing the CO<sub>2</sub> absorber jar

- **1.** Take the CO<sub>2</sub> absorber jar out of the hollow provided in the lid.
- **2.** Close the CO<sub>2</sub> absorber jar by hanging the lid vertically in the guide, turning it downwards and closing with the help of the clamp.
- (1) correct
- (2) wrong
- (3) wrong
- O Eno

Ensure that the lid is exactly in line with the CO<sub>2</sub> absorber jar and is not offset to the side or twisted when suspended in the guide.

#### Connection of the ventilation tubes



- **1.** Put the ventilation tubes onto the two cones (Ø 22 mm) on the front of the patient module.
- **2.** Connect the ventilation tubes on the other end (the patient's side) using a y-piece.
- (1) insp./exp. labelling
- (2) cones Ø 22 mm
- (3) y-piece
- P Avoid using "tube-in-tube" systems.



Use of antistatic or conductive tubes and high-frequency electrosurgical devices!

#### Risk of burning

**WARNING** 

Do not use any antistatic or conductive tubes.



No unauthorised auxiliary parts!

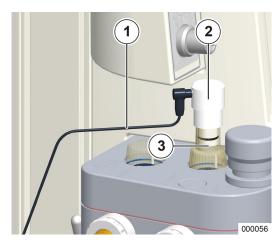
#### Electrical risk to the patient

Use authorised accessories only.

#### **WARNING**

#### Gas measurement

#### FiO<sub>2</sub> measurement



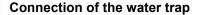
- 1. Use an adapter instead of the inspiratory sight glass to place the FiO<sub>2</sub> sensor on the patient module.
- **2.** Connect the sensor via a cable on the rear wall.
- (→ "Rear wall" p. 59)
- (1) Cable
- (2) FiO<sub>2</sub> sensor
- (3) Adapter

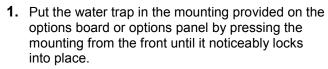
#### Side flow meter

The connector for the side flow meter is situated on the options board or options panel.

The device is fitted with automatic balancing for the barometer pressure. Before the multi gas analyser carries out calculations, the raw absorption data for air pressure and temperature are automatically corrected to the ideal gas law.

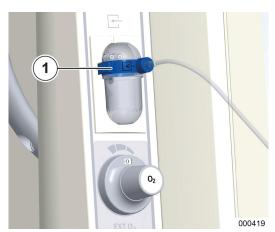
(→ "Gas measurement servicing" p. 258)





- (1) Water trap without coding
- Regularly check the fill level. When emptying or changing the water trap, observe(→ "Changing or emptying of the water trap" p. 258).
- The water trap should be changed once a month.







#### Connection of the sampling line

- **2.** Connect the sampling line to the connection provided (luer lock) on the water trap.
- (1) Water trap and sampling line with blue coding
- When ventilating neonates, please use the water trap and the sampling line for neonates (blue coding). For children and adults, use the water trap and sampling line for adults (without blue coding). If there is a requirement to use only one type of water trap (e.g. for logistical reasons), the type with blue coding is to be used.
- Use authorised accessories only.

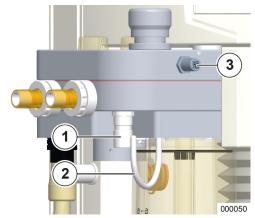
#### Connection of the patient adapter

- **3.** Connect the sample line to the connection provided (luer lock) on the patient adapter.
- **4.** Put the patient adapter on the patient's side onto the Y-piece.
- (1) Patient adapter (angled)

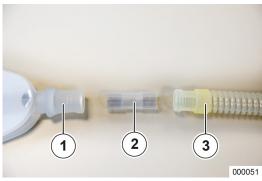
000059

- Insert suitable VSF (on the patient's side on the patient adapter).
- Patient adapters and y-pieces as listed in the appendix "Consumables" must be used, as otherwise distorted CO₂ measured values could occur.

## Connection of the ventilation bag



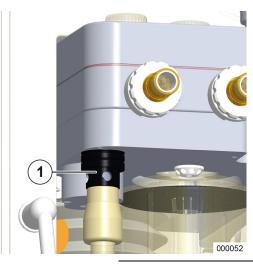
- **1.** Connect a ventilation tube to the cone (Ø 22 mm) on the underside of the patient module.
- (1) cone Ø 22 mm
- (2) suspension bracket for the ventilation bag
- (3) test adapter



- **2.** Join the ventilation bag via an adapter to the ventilation tube.
- **3.** Hang the ventilation bag to the suspension bracket provided.
- (1) ventilation bag
- (2) disposable tube connector
- (3) tube

## Connection to the anaesthesia gas scavenging system

### Connection of the AGSS directly to the patient module



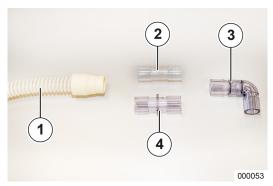
- **1.** Join the waste hose to the cone (Ø 30 mm) on the underside of the patient module via the adapter.
  - **2.** Join the other end of the waste hose to the waste disposal system via an appropriate coupling.
  - (1) AGSS adapter
  - The AGSS must comply with ISO 80601-2-13.
  - Please also refer to the waste disposal system user manual.



If an intake system is not used, it is imperative that this adapter (with four drill-holes as additional air intake) is used.

The aspiration performance of the waste removal system must be between 55 and 66 l/min.

#### Connection of the AGSS across the rear of the device



- **1.** Assemble the tube connector following the illustration adjacent.
- 2. Join the AGSS tube via the AGSS adapter to the cone (Ø 30 mm) on the underside of the patient module.
- $(\rightarrow$  "Connection of the AGSS on the rear of the device" p. 61)
- **3.** Place the adapter at an angle on the AGSS connector at the front of the casing.
- $(\rightarrow$  "Connection of the AGSS on the rear of the device" p. 61)
- **4.** Join the waste hose via the disposable tube connector to the AGSS connector on the rear of the device.
- $(\rightarrow$  "Connection of the AGSS on the rear of the device" p. 61)
- **5.** Join the waste hose via an appropriate coupling to the waste disposal system.
- (1) AGSS tube
- (2) disposable tube connector
- (3) angled adapter
- (4) ISO 22/22 plug adapter
- $(\rightarrow$  "leon plus Spare parts ordering options and replacement" p. 300)

# Suspension bracket of the intake system on the rear of the device

The intake system is suspended on a standard rail on the rear of the leon *plus*. To connect, use the construction described in ( $\rightarrow$  "Connection of the AGSS on the rear of the device" p. 61).



The AGSS adapter described in ( $\rightarrow$  "Connection of the AGSS directly to the patient module" p. 82) may not have any drill-holes (additional air intake is guaranteed through the intake system).

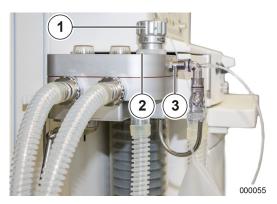


- 1. Join the inlet of the intake system to the AGSS connection on the rear of the leon *plus* with the help of a disposable tube connector and an AGSS tube.
- **2.** Join the outlet of the intake system to the waste disposal system via a waste hose and an appropriate coupling.
- (1) outlet
- (2) inlet
- (3) intake system
- (4) AGSS connection
  - Please also refer to the intake system user manual.



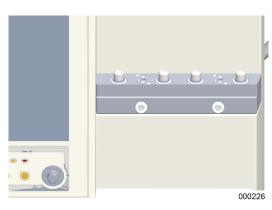
If using an intake system, it is imperative to use the "white" adapter (without drill-holes).

## **APL** valve



- **1.** Lock the APL valve with a bayonet catch on to the patient module
- (1) APL
- (2) APL bayonet catch
- (3) test adapter

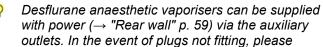
## Setting up the anaesthetic vaporiser



The leon *plus* provides a mounting for two anaesthetic vaporisers.

The anaesthetic vaporisers have a transportation safety catch, which must be removed before start-up (the arrow on the adjusting ring must lie over the arrow on the housing).

The anaesthetic vaporisers are interlocked so that just one of them can be operated if desired.



Adapt, fill, check and operate the anaesthetic vaporisers in accordance with their user manual.

contact a Löwenstein Medical representative.

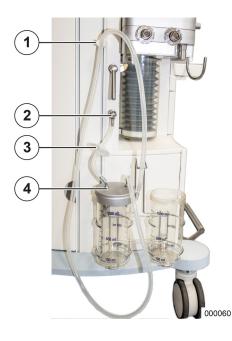


The auxiliary outlets are switched off during battery operation!

#### No power supply to the desflurane anaesthetic vaporiser

- supply via an external socket
- connect the anaesthesia device to mains power

## Connection of the bronchial aspiration



The connection of the bronchial aspiration is suitable for vacuum-driven modes only and is designed for  $\mathcal{Q}_{\text{inside}}$  6 mm tubes.

- Use a filter (follow the flow direction) to join the connection on the device to the connection on the lid of the absorber glass, which has a one-way valve on the inside.
- **2.** Join the other connection on the lid of the absorber glass to the suctioning tube and the spout to the connection of the aspiration catheter.
- 3. Hang the tube in the provided bracket.
- (1) aspiration tube holder
- (2) bronchial aspiration connection
- (3) filter
- (4) lid connection
- For connection and checking, refer to the bronchial aspiration manual.
- Observe correct connections on the lid of the absorber glass.

## Connection of auxiliary devices



A maximum of four auxiliary devices can be connected to the socket board at the back.

- (1) auxiliary outlets
- The connection of electrical devices to the multiplug socket leads to the formation of an ME system.
- The auxiliary outlets are switched off during battery operation.
- If an an auxiliary device reports no mains voltage, also check the correct position of the plug and then the fuses on the cold device socket on the leon plus.
- Please note that the switch-on surge can be higher than the current consumption shown on the auxiliary device.
- The workstation may not contain more than these four auxiliary outlets.
- In the event of a faulty earth wire, the values of the patient leakage currents can increase to values which exceed the permissible values when connecting devices. Measuring is recommended.



WARNING

Higher total earth leakage current!

#### Risk of electric shock for the user

The total earth leakage current may not exceed 5 mA for connected auxiliary devices.

Measure the total earth leakage current of the combination.

Overloading of auxiliary outlets!

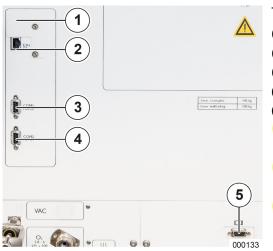


#### **Fuses blow**

The total power consumption of the device including the 4 auxiliary outlets may not exceed 9 A.

Follow the instructions of the accessory when installing.

## **Connection of data communication**



The leon *plus* provides the following interfaces:

- (1) USB (for service purposes only)
- (2) Ethernet: RJ-45
- (3) Serial (COM 1): D-sub, 9-pin
- (4) Serial (COM 2): D-sub, 9-pin
- (5) VGA: D-Sub, 15-pin or LWL: LC socket
- Only one data output is provided via the VGA and LWL interfaces.
- The two serial and the VGA interfaces are galvanically separated. (3 kV, VGA 5 kV).
- The USB connection is covered and serves exclusively for service purposes.



Charging mobile phones, Smartphones or tablets on the USB connection is prohibited.

**CAUTION** 

The USB connection is intended only for updates and reading log files.

## 7. Start-up

Ensure that you have checked the leon *plus* properly, in accordance with the "Short checklist before start-up" ( $\rightarrow$  "leon *plus* Short checklist before start-up" p. 300).

The execution of a system test is strongly recommended.

It is also strongly recommended that a "circuit system" system test block is executed after changing the patient tube system.

The device is not operable during the system test. However, the test can be interrupted (not recommended).

If the system test is skipped, low or minimal flow may not be operated.

If the system test is not carried out, it must be executed at the next opportunity.

## **Configuration (in standby)**

## Config tab

#### **General information**



To call up the **Config** tab, proceed as follows:

- **1.** Activate the tab in the **Extras** tab in the 1st row.
- **2.** Activate the corresponding tab of the tab in the 2nd row.

The following settings are available:

- settings
  - brightness (TFT)
  - illumination (is only shown if configured in the service)
- service
- (1) Config tab
- (2) Extras tab

### Illumination of the writing shelf

On the **Config** tab you can switch the light ON and OFF (only if configured in the service).

Lighting: ON/OFF



1. Select the **Lighting** button.



- 2. Unlock the function.
- 3. Select a value for the lighting.
- 4. Confirm the value.

## **Brightness of the screen (TFT)**

The brightness of the TFT can be set on the **Config** tab.

■ brightness: 0 – 100

increment: 5

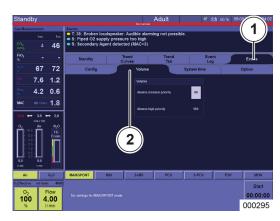


1. Select the **Display Brightness** button.



- 2. Unlock the function.
- **3.** Select a value for the brightness of the screen (TFT)).
- **4.** Confirm the value.

#### Volume tab



The volume can be changed on the **Volume** tab.

- volume: 50-100
- increment: 5
- (1) Extras tab
- (2) Volume tab
- Only the volume of medium-priority alarms can be changed. The fact that the volume of high-priority alarms may not be changed by the user is a normative requirement, in accordance with DIN EN ISO 60601-1-8.
- 1. In **Settings** select the **Volume** tab.
- **2.** Select the numeric keypad on the right adjacent to the **medium-priority alarms**.





- 3. Unlock the function.
- 4. Select a value for the volume.
- 5. Confirm the value.
- If a red alarm is active, the alarm value cannot be changed (numeric keypad "medium-priority alarms" is inactive).

## **System Time tab**

#### **General information**



To call up the **System Time** tab, proceed as follows:

- 1. Activate the tab in the Extras tab in the 1st row.
- **2.** Activate the corresponding tab of the tab in the 2nd row.

The following settings are available:

- settings
  - date
  - time
- (1) System Time tab
- (2) Extras tab

#### Date, time



**1.** Select the entry to be changed in the **Date** or **Time** fields (day, month, year, or hour, minute, second).



**2.** Unlock (day, month, year, or our, minute, second), set and confirm.

## **Option tab**



To call up the **Option** tab, proceed as follows:

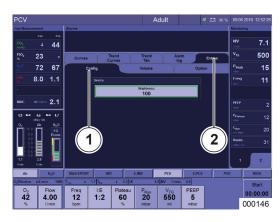
- 1. Activate the tab in the Extras tab in the 1st row.
- **2.** Activate the corresponding tab of the tab in the 2nd row.

The following information and settings are available:

- Information
  - System test result
- (1) Extras tab
- (2) Option tab

## **Configuration (during ventilation)**

## Config tab



The following settings are available:

- settings
  - brightness (TFT)
  - Lighting (is only shown if configured in the service)
- (1) Config tab
- (2) Extras tab

#### Volume tab

(→ "Volume tab" p. 91)

### **Option tab**

 $(\rightarrow$  "Option tab" p. 93)

## System configuration of the user interface

#### **General information**

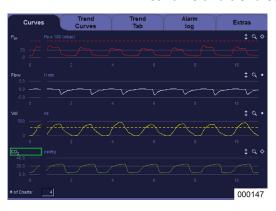
The following changes to the configuration can also be carried out while the device is in operation. However, they continue to apply only until the device is turned off.

The following setting can be reset by the **Reset To Default Settings** button, if desired.

- Alarms and ventilation parameters
- Curves, trend curves, tabular trend
- All settings (1st and 2nd)
- Only the settings of the currently selected patient category are reset.

(→ "Load default settings" p. 132)

#### Real-time and trend curves



#### Configuration of real time

Real-time and trend curves can be configured as follows:

- Selection of which measured value is displayed
- Shifting of 0 point in the window
- Scaling of the Y-axis
- ON/OFF autoscaling
- Number (minimum 1, maximum four) of the displayed real-time curves
- Scaling of the X-axis (4–30 seconds)

(→ "Table 11: Icons/screen (control elements)" p. 42)

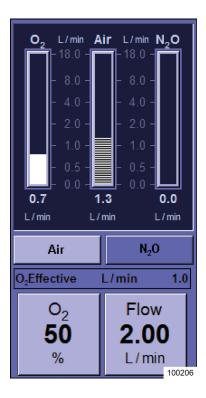


#### Configuration of trend curves

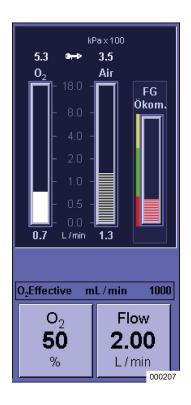
- Selection of which measured value is displayed
- Shifting of 0 point in the window
- Scaling of the Y-axis
- ON/OFF autoscaling
- Number (minimum 1, maximum four) of the displayed trend curves
- Scaling of the X-axis (10 min 72 hours)

### Configuration fresh gas blender

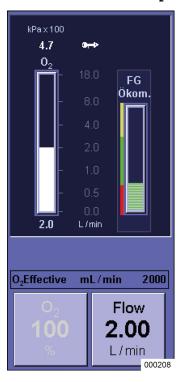
#### Option with N<sub>2</sub>O



Option without N<sub>2</sub>O



Option without AIR and  $N_2O$ 





The gas quantities of the fresh gas are displayed as bar graphs. The following start values of the fresh gas blender can be configured:

- Carrier gas (N<sub>2</sub>O or AIR )
- O<sub>2</sub> concentration
- Fresh gas flow
- (→ "Fresh gas setting" p. 134)

## Limit values configuration



You can configure the upper and lower alarm limits manually.

(→ "Setting patient alarm limits manually" p. 197)

#### Monitoring ventilation measured value configuration, calculated value I

8 values are displayed on each of two pages, if desired (configurable). 4 values in the upper section of the monitoring window are displayed larger. This is where the important measured values should be positioned. These 4 measured values are the same on both pages.

(→ "Monitoring ventilation measured values and calculated values I" p. 173)





### Configuration of form of ventilation

The following ventilation parameters can be configured as starting values per form of ventilation:

 $(\rightarrow$  "Buttons for setting ventilation parameters" p. 147)

## Service



To call up the Service screen

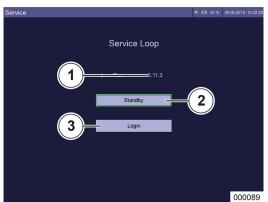
1. Change to the **Extras** tab.



**2.** Then change to the **Config** tab.



3. Activate the **Service** button on the touchscreen.



- **4.** The **Standby** button takes you back to the standby screen.
- This screen can only be called up from standby. Information:
- (1) Software version Selection buttons:
- (2) Standby
- (3) Login

#### Information

#### **Software version**

The current software version is shown in the **Version**: line. This information is useful when seeking phone support from a Löwenstein Medical representative.

## Login



Certain functions in the service are only available to Löwenstein Medical-authorised service technicians or trained staff. Access is only possible via a login with password.

There are two password-protected user names, which differentiate between the scope of your system rights:

- Administrator
- Service technician



#### WARNING

Changing settings!

#### Death of or permanent injury to the patient

Depending on the scope of your rights, changes to settings and calibration data can mean that the life-sustaining device functions are no longer guaranteed.

Contact a Löwenstein Medical-authorised service technician for information.



1. Select the **Login** button.



- 2. Unlock.
- Select a field
- **4.** With the help of the rotary button, enter one figure of your 4-character password per field (a clockwise turn increases the figure, an anticlockwise turn lowers the figure).
- 5. Confirm.



**6.** Confirm the whole password.



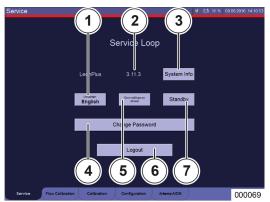
Do not leave the device in a logged-in state, as unauthorised persons could change settings and calibration data.

Restart the device if you were logged in.



As long as you are logged into the service, a red line under the title bar with the message **Service Mode** makes you aware of this.

## Service tab



The following configuration can be carried out when you are logged in:

#### Settings

- (1) Language Information
- (2) Software version
- (3) System information

Selection buttons

- (4) Change password
- (5) Save settings as default
- (6) Logout
- (7) Standby
- P

You will find a more detailed explanation of individual points in the service manual of the leon plus.

#### **Service information**

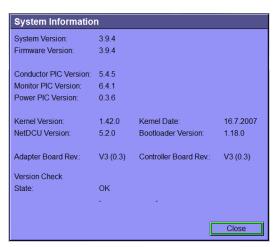


#### **System information**

1. Select the **System Information** button.



**2.** Confirm the entry.



The versions of the software components are in the left-hand column. The versions of the hardware components are in the right-hand column. If the system discovers an unknown component or incompatibilities between hardware and software versions, this is displayed.

This information is useful when seeking telephone support from a Löwenstein Medical representative.

### **Service settings**



#### Language

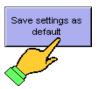
1. Select the **Select Language** button.



- 2. Unlock.
- 3. Select a language.
- 4. Confirm.

### Saving the current system configuration

In the service menu, the current changed system configuration can be saved as the default via the **Save Settings As Default** button. The basic settings are designated as default (standard) settings, which the device shows when it is switched on.



 Select the Save Current Settings As Default button.



2. Confirm.

- Access to this Service feature is only possible via a login with password.
- You should consult a Löwenstein Medical-authorised service technician for these settings.

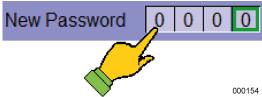
# User Service Engineer New Password 0 0 0 0 Ok Cancel 000153

#### Change password

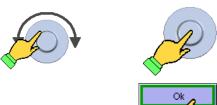
1. Select the User field.



- 2. Select the User.
- 3. Confirm.



4. Select the New Password field.



- 5. Select a password.
- **6.** Confirm.
- **7.** Confirm with OK.

## Configuration tab/page 1

## Measuring unit of the measured ${\rm CO_2}$ value



In the service menu, the unit of the measured endexpiratory CO<sub>2</sub> value can be selected under **Configuration/Page 1**.

The following are available:

- 0/2
- mmHg
- hPa
- kPa

Access to this Service feature is only possible via a login with password.

- (1) Tab page 1
- (2) Configuration tab



These changes are only visible when the device is turned OFF and then ON again. You should consult a Löwenstein Medical-authorised service technician for these settings.



In the service menu the limits  $x_1$  and  $x_2$  for the ecometer can be set under **Configuration/Page 1**.

X <sub>1</sub>	Minimum lower level of the ratio:				
	$O_2$ consumption Pat. + $O_2$ leak closed $O_2$ fresh gas flow.				
12.9	closed				
	O <sub>2</sub> fresh gas flow.				
<b>X</b> <sub>2</sub>					
	Economic upper limit of the ratio: O <sub>2</sub> consumption Pat. + O <sub>2</sub> leak				
1.1 3	closed				
	closed O <sub>2</sub> fresh gas flow				

Access to this feature of the service is only possible via a login with password.

You should refer to a Löwenstein Medicalauthorised service technician for these settings.

Table 16: Example for the setting of the limit between pressure gas shortage and economic consumption factor  $\mathbf{x}_1$ 

<b>X</b> <sub>1</sub>	Ratio O <sub>2</sub> consumption + O <sub>2</sub> leak to O <sub>2</sub> fresh gas flow	Ecometer turns red if	Ecometer turns green if
1	1:1	the set O <sub>2</sub> fresh gas flow is lower than the O <sub>2</sub> consumption + O <sub>2</sub> leak. (Patient undersupplied)	the set O <sub>2</sub> fresh gas flow is equal to or higher than the O <sub>2</sub> consumption + O <sub>2</sub> leak. (Maximum is limit to yellow)
2	2:1	the set O <sub>2</sub> fresh gas flow is lower than double the O <sub>2</sub> consumption	the set O <sub>2</sub> fresh gas flow is equal to or higher than double the O <sub>2</sub> consumption (maximum is limit to yellow)

Table 17: Example for the setting of the limit between economic consumption and uneconomic consumption factor  $\mathbf{x}_2$ 

<b>X</b> <sub>2</sub>	Ratio O <sub>2</sub> consumption + O <sub>2</sub> leak to O <sub>2</sub> fresh gas flow	Ecometer turns green if	Ecometer turns yellow if
1.1	1.1:1	the set O <sub>2</sub> fresh gas flow is lower than 1.1 times O <sub>2</sub> consumption + O <sub>2</sub> leak (minimum is limit to red).	the set $O_2$ fresh gas flow is equal to or higher than the 1.1 times $O_2$ consumption + $O_2$ leak.
2	2:1	the set O <sub>2</sub> fresh gas flow is lower than double the O <sub>2</sub> consumption + O <sub>2</sub> leak (minimum is limit to red).	the set $O_2$ fresh gas flow is equal to or higher than double the $O_2$ consumption + $O_2$ leak.

## Configuration tab/page 2

#### Gas supply





In the service menu, the gas supply for the device can be set under **Configuration**/page 2.

- (1) Tab page 2
- (2) Configuration tab

The following parameters are available for selection: Drive gas

- air
- O<sub>2</sub>

#### N<sub>2</sub>O

- ZGA
- bottle (10 L)
- not available

#### $O_2$

- ZGA
- bottle (10 L)

#### AIR

- ZGA
- bottle (10 L)
- not available

Gas type check (in the system test)

- ON
- OFF



The AIR selection **not available** is available only if  $O_2$  was selected as the drive gas.

In the service menu, the lighting of the writing shelf can be configured to available or not available under **configuration/page 2.** A corresponding **Lighting** button appears in standby on the **Config** tab.

Access to this feature of the service is only possible via a login with password.



You should refer to a Löwenstein Medicalauthorised service technician for these settings.

#### Lighting



## Procedure for saving the system configuration

- 1. Turn on the leon plus as follows:
- **2.** Switch to Service.
- 3. Log in.

### **General settings**

- **1.** Set the language.
- 2. Set the brightness, volume, date and time.
- **3.** Change to Configuration (tab).
- **4.** Set the measurement unit of the measured CO<sub>2</sub> value.
- **5.** Switch to standby (do not log out).
- 6. Start MAN/SPONT.
- **7.** Configure the real-time charts.

## Setting dependent on the patient category

- 1. Switch to standby.
- 2. Select a patient category (adult, child or weight).
- 3. Start MAN/SPONT.
- **4.** Configure monitoring and alarms.
- **5.** Switch to standby.

#### Settings dependent on patient category and form of ventilation

Carry out the following for each form of ventilation in this patient category:

- 1. Start the form of ventilation.
- Configure the presets of the ventilation parameters (only for adult and child; presets are calculated if weight is entered).
- Always switch back to MAN/SPONT before you configure the presets of the next form of ventilation.

After configuring the presets of all of the forms of ventilation in this patient category:

**3.** Select the form of ventilation that should be active at system start-up when this patient category is selected.

#### **Store configuration**

- 1. Switch to Service.
- **2.** Save the current settings as default (button).
- Switch to standby and restart with point
   (→ "Setting dependent on the patient category"
   p. 107) to configure the other patient categories.

# Active configuration after system start-up

- 1. Switch to standby.
- **2.** Select the patient category that should be active at system start-up.
- **3.** Select the form of ventilation that should be active at system start-up.
- **4.** Save the current settings as default (button).
- **5.** Restart the system.

#### **Device check**

- Run the selftest and the system test in **all** of the following situations:
  - Once a day
  - Before the first start-up
  - After every servicing and/or repair
  - After the device has been moved to a different location
  - After work on the central gas supply
- Make sure that you have carried out all work properly in accordance with (→ "Preparations" p. 64).



# WARNING

Device malfunctions!

#### Death or permanent injury of the patient

A device check must be run once a day.



#### **WARNING**

Proper state of the device is not monitored, system test and self test not executed/skipped!

#### Death or permanent injury of the patient

Run the self test and the system test:



#### **WARNING**

Alarms at system start-up: Device malfunction!

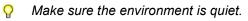
#### Death or permanent injury of the patient

Make sure no alarms are triggered at start-up.

### Selftest

This test is executed automatically when the device is turned on.

(→ "Turn on" p. 111)



The selftest (starts when the device is turned on) and the associated hardware check must be run once a day.

#### System test

After the device has passed the selftest, the system test screen appears.



**WARNING** 

#### System test not passed!

# Death or permanent injury of the patient

- Fix errors
- Rerun the system test
  - no oyotom toot
    - If the system test is not passed, the operational readiness of the device is limited and may be operated only in the event of an emergency and not in the low or minimal flow range.
      - The cause of the failed system test must be remedied at the earliest opportunity.
    - The system test can be skipped a maximum of 15 times. After this, it is no longer possible to start a ventilation and the cause of the failed system test must be remedied.

# Short checklist before start-up

This list is chained to the right side of the leon *plus*, but is also available as a copyable text "Short checklist before start-up". You will find the text at the end of this document.

This list must be processed manually. A description of the alarm tests required in the short checklist are available here:

 $(\rightarrow$  "Test of alarm functions" p. 125)

# **Limited start-up option**



The device can be put into limited operation:

- if only AIR or only O<sub>2</sub> are available.
- a system test block is passed with yellow.

You should not put the device into operation if the  $O_2$  supply gas pressure is below 2,8 kPa × 100 (bar).

#### Turn on



The green LED below the plug icon on the keypad shows that mains voltage is available.



The emergency dosing of theleon plus is only **not** released during the ongoing system test and during an ongoing ventilation.



 Keep the ON/OFF button on the keypad pressed down until the device confirms the entry with a sound signal.



The boot screen appears after approx. 2 seconds. A selftest of the hardware is run and the software is loaded.

State:

Selftest OK

After approx. 50 seconds the **Status** message appears: Shows **Selftest OK**. If the selftest is not passed, the relevant message follows:



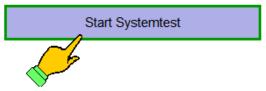
Please make a note of the error number and notify a Löwenstein Medical-authorised service technician.

After approx. 55 seconds, the system test screen appears and the device is ready for operation.



It is strongly recommended that the system test is executed.

The system test screen appears with the following functions for selection:



- Start of the full system test (→ "External fresh gas outlet before the system test" p. 116)
- Skip (NOT RECOMMENDED)

  000161
- Switch directly to standby (Skip system test Quick start
  - (→ "Quick start" p. 138)

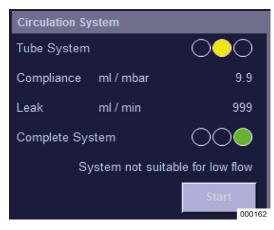


Start individual system test block.

# System test

#### **General information**

#### System test blocks



The system test screen consists of six blocks.

The first block is produced in the selftest. The rerun of the test can only take place through a new selftest (device restart).

The **gas supply** block is continually renewed.

The remaining system test blocks can be started together or individually.

A system test block consists of:

- test name
- test content
- test result
  - traffic light display
  - alphanumeric value
- test start/stop button
- P

The system test blocks can be started individually only if the system test has been run completely once before.

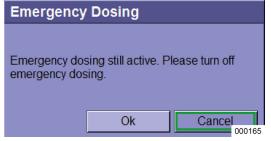
# Operating states of the system test block

Table 18: Operating states of the system test					
Operating state	Traffic light		Button		
Not run	000	Traffic light fields empty	Start	Test can be started individually	
Running Traffic light fields are alternately filled		Stop	Test can be aborted		
		in white		Test cannot be started	
Result	$\bigcirc\bigcirc\bigcirc$	Completed, passed	Start	Test can be started individually	
	$\bigcirc\bigcirc\bigcirc$	Completed, operation possible			
	$\bigcirc\bigcirc\bigcirc$	Completed, not passed			

#### Results of the selftest

Table 19: Results of the selftest **Test name** Description Gas supply (also ZGA pressures control: Gas supply updated in the system AIR, O<sub>2</sub>, N<sub>2</sub>O Pipeline supply kPa x 100 test) Traffic light: red, yellow or green possible 3.5 Air 10 L bottles control: O<sub>2</sub>, 37.5 0, N<sub>2</sub>O or AIR N<sub>2</sub>O 2.5 Traffic light: red, yellow or green possible Is only displayed if configured in the service (→ "Gas supply" p. 106) Selftest Check: Loudspeaker, battery, gas meter traffic Loudspeaker light: red, yellow or green possible Battery Gas Measuring

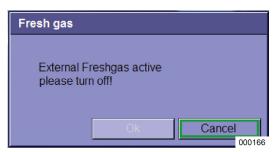
#### O<sub>2</sub> emergency dosing during the system test



Before the complete system test is started, a check of whether the O<sub>2</sub> emergency dosing is switched off is carried out.

During the ongoing system test the O<sub>2</sub> emergency dosing is switched off internally and cannot be activated

#### External fresh gas outlet before the system test



Before the full system test is started, a check verifies whether the external fresh gas outlet is active.

It is not possible to start the system test if the fresh gas outlet is open.

#### Start of the system test



- **1.** Activate the **Start** button on the bottom right of the system test screen and follow the prompts.
- 2. Put the y piece on the test adapter.
- (→ "Connection of the ventilation bag" p. 81)
- 3. Set the APL valve to 20 mbar.
- 4. Check the expiratory valve diaphragm.
- (→ "Change (dismantling) of the insp./exp. valve diaphragms" p. 262)
- **5.** Set the fresh gas outlet to position 0, if available.
- **6.** Confirm with **OK**.

The button label switches from **Start** to **Stop**. The system test can now be aborted by repressing the button.

#### Skip/cancel system test (Quick start)



#### To skip:

**1.** Activate the **Skip** button (**NOT RECOMMENDED**) on the bottom right of the system test screen.

#### Cancel:

 Activate the **Stop** button on the bottom right of the system test screen while the system test is running.

The results of the last passed system test are reproduced.

Standby Adult System 12:44:22
System 14:42
S

If the system test is skipped or the system has switched into standby, despite the system test not having been passed, a red bar with the label **system test skipped** is displayed below the title bar.

- The system test can be skipped a maximum of 15 times. After this, it must be executed and passed.

  Access to the service menu is possible.

If the system test is not executed or is cancelled, it must be carried out at the next opportunity.

## Back to the system test from standby

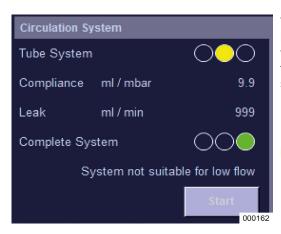


To get back to the system test from standby, use the **system test** button on the bottom left.

## **Execution of the system test**

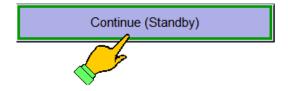
Table 20: System test blocks Test name Description **Execution** Gastype Check Gastype check (is Check of authenticity of AIR, O2, N2O only active if N<sub>2</sub>O N<sub>2</sub>O Check as carrier gas is Traffic light: red, yellow or green activated in the O, Check possible service and the Air Check gastype check) This test can be switched off if configured 000175 correspondingly in the service ( $\rightarrow$  "Gas supply" p. 106). Flow Measuring Calibration of the flow sensors measurement Traffic light: only red or green Flow Calibration possible 000172 Respirator Respirator Check of the fresh gas blender Traffic light: red, yellow or green Freshgas Blender Check 000 possible Propellant Blender Check Test of the drive gas generator: Traffic light: only red or green possible Circuit system Determination of compliance Circulation System Traffic light: red, yellow or green Tube System possible 9.9 Compliance ml / mbar Determination of leakage Traffic light: red, yellow or green Leak ml / min 999 possible Complete System System not suitable for low flow 000162

# Passed system test and display of values for compliance and leakage rate



The time of the last passed test is displayed on the bottom right of the system test screen. Next to the values for compliance and leakage rates, the system test block for the circuit system displays whether the system is suitable for heavy, minimal or low flow.

- 1. Activate the **Continue (Standby)** button on the bottom right of the system test screen to switch the device to standby.
- Even if the traffic light shows yellow (tube system leakage rate > 300 ml or circuit system leakage rate > 1000 ml), the system remains ready for operation. However, it is recommended that you remove the leak and repeat the test.



# System test not passed and detailed error display



If a test fails, the description of the error that occurred in the test appears on the bottom left of the system test screen. Suggestions for troubleshooting the error are displayed in a window.

- The Repeat button in the error window repeats the full system test.
- The **Start** button in the failed system test block will only repeat the actual system test block.
- If the system test is not passed, the cause must be fixed and the test repeated.
- ✓ If system test blocks are repeated individually, as they have not been passed, a system test that has not been passed with the subsequent passed system test blocks can be seen in the event log.

#### Display of values for compliance and leakage rate



The values for compliance and leakage rate with date and time can be seen at any time in standby.

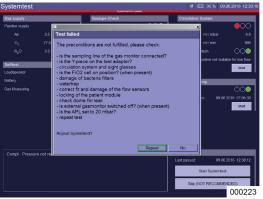
The date of the last passed system test and the number of skipped system tests is always displayed. In addition, the date and the results of the last system test executed is displayed.

If the system is not suitable for low or minimal flow, this is displayed stating the determined leakage rate.

## Repeating individual system test blocks



If the system test is not passed, the system test blocks that have not passed can be repeated in individual tests. If they are subsequently passed, the full system test counts as having passed. If a system test block does not pass, the red bar remains.



If a switch is made from standby to the system test screen (e.g. to redetermine compliance after changing the patient tube system), an individual test is started and not passed, a yellow bar with the label "Individual Test Not Passed" appears.

>1000

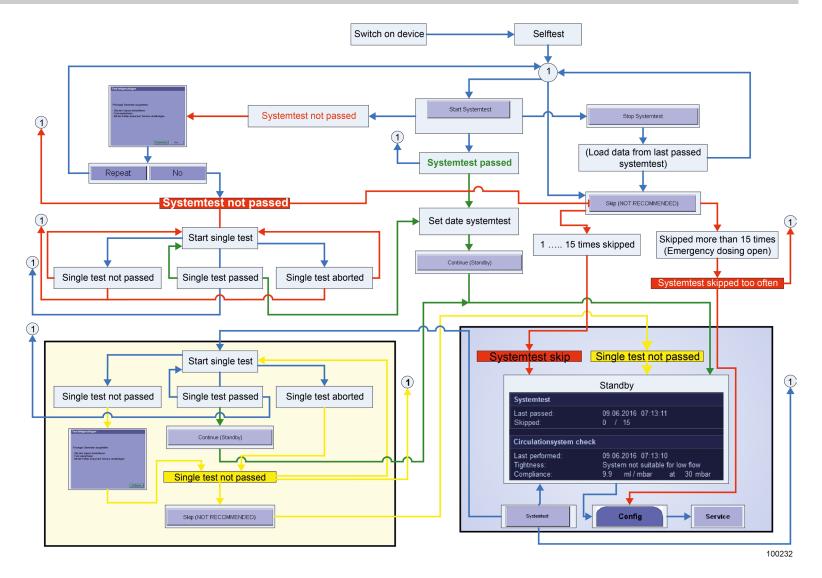
# Tightness of tube system and full system

Table 21: Tube system tightness					
Value in ml/min	Status	Traffic light			
<150	Tight	Green			
≤300	Not suitable for minimal flow	Green			
>300	Not suitable for low flow	Yellow			
Table 22: Total system tightness					
Value in ml/min	Status	Traffic light			
<500	Tight	Green			
≤1000	Not suitable for minimal flow	Green			

Yellow

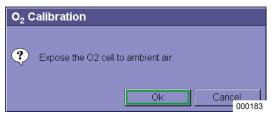
Not suitable for low flow

# System test procedure



# FiO<sub>2</sub> calibration

## Start of FiO<sub>2</sub> calibration



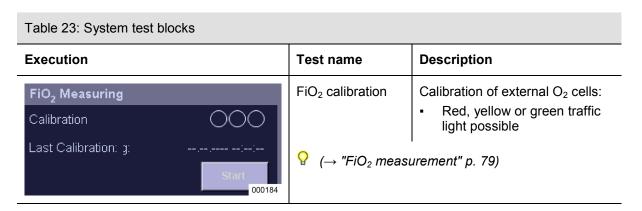
If you press the "**Start**" button on the bottom right of the system testscreen or in the FiO<sub>2</sub> calibration system test block, this prompt appears:

"Stop the  $O_2$  sensor of the ambient pressure." Follow the instruction and confirm with **OK**.

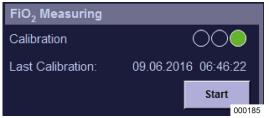


This system test block is only shown if an external  $O_2$  analyser ( $O_2$  fuel cell via the inspiratory valve diaphragm ( $\rightarrow$  "Fi $O_2$  measurement" p. 79)) is displayed and appropriately configured in the service menu.

#### Execution of the FiO<sub>2</sub> calibration



#### Passed FiO<sub>2</sub> calibration



If the test is successfully executed, the "traffic light" remains on green and no error message is given.

## FiO<sub>2</sub> calibration not passed



If the test is failed, the "traffic light" remains on red and the exact description of the error that occurred in the test appears on the bottom left of the system test screen.

♀ FiO₂ calibration error messages

 $(\rightarrow$  "Error search FiO<sub>2</sub> calibration" p. 243)

#### **Alarm test**

#### **General information**



The manufacturer recommends a daily check for proper functioning.

- once a day for routine daily work
- for each planned operation in standby time
- if possible, also in an emergency and in the event of unplanned, fast deployment.
- **1.** Set the alarm limits of the monitored data in accordance with the following table.
- 2. Start the given test.

All of the triggered alarms are stored in the alarm log and can ( $\rightarrow$  "Alarm log" p. 196) be seen here.

# **Test of alarm functions**

Table 24: Checking th	e alarm functions	
Alarm	Alarm limit settings	Test
		1. Set the alarm limit (low).
		2. Start the MAN/SPONT form of ventilation
insp. O <sub>2</sub> [%] low	>50 %	<b>3.</b> Put the patient adapter of the gas meter on the ypiece, which is linked to the patient module via the ventilation tubes.
FiO <sub>2</sub> [%] low	>50 %	<b>4.</b> Set a fresh gas flow of 5 I and 25% O <sub>2</sub> .
		5. Wait until the alarm is triggered.
exp. CO <sub>2</sub> [%] low	>7.0 %	3. Put a ventilation filter on the patient adapter of the gas meter and exhale several times into the filter.
		<b>4.</b> Wait until the alarm is triggered.
Volatile anaesthetics	[%] low	Check the anaesthetic vaporiser in accordance with its user manual.
		1. Set the alarm limit (high).
		2. Start the MAN/SPONT form of ventilation.
O <sub>2</sub> insp. [%] high	<50 %	<b>3.</b> Put the patient adapter of the gas meter on the y-piece, which is linked to the patient module via the ventilation tubes.
FiO <sub>2</sub> [%] high	<50 %	<b>4.</b> Set a fresh gas flow of 5 I and 100 % O <sub>2</sub> .
		5. Wait until the alarm is triggered.
insp. CO <sub>2</sub> [%] high	<0.5 %	3. Put a ventilation filter on the patient adapter of the gas meter and exhale several times into the filter.
exp. CO <sub>2</sub> [%] high	<1.0 %	4. Wait until the alarms are triggered.
Volatile anaesthetics	[%] high	Check the anaesthetic vaporiser in accordance with its user manual.
Apnoea		After the test of the alarm limits (high), wait until the alarm is triggered.

Alarm	Setting the alarm limits	Test
		<ol> <li>Switch to standby.</li> <li>Activate the Reset To Default Settings button.</li> <li>"Load default settings" p. 132)</li> <li>Set the alarm limit (low).</li> <li>Start the MAN/SPONT form of ventilation.</li> </ol>
MV [l/min] low	>5 l/min	5. Connect a commercial artificial lung to the y-piece.
VTe [ml] low	>1000 ml	<b>6.</b> Start volume-controlled ventilation with = 5/min,
Set the alarm limit (	high)	V <sub>Ti</sub> = 500 ml. <b>7.</b> Wait until the alarms are triggered.
MV [l/min] high	<2 l/min	
PPeak [mbar]	<20 mbar	
		<ol> <li>Switch to standby.</li> <li>Activate the Reset To Default Settings button.</li> <li>(→ "Load default settings" p. 132)</li> </ol>
Disconnection	/	<ol> <li>Connect a commercial artificial lung to the y-piece.</li> <li>Start mechanical ventilation and withdraw the artificial lung.</li> <li>Wait until the alarm is triggered.</li> </ol>
Decompression during expiration	/	<ol> <li>Connect a commercial artificial lung to the y-piece.</li> <li>Set a fresh gas flow of 5 L, close the connection to the AGSS on the patient module and start pressure-controlled ventilation.</li> <li>Wait until the alarm is triggered.</li> </ol>
ZGA	/	<ul> <li>3. Pull the supply plug for AIR, O<sub>2</sub> and N<sub>2</sub>O from the supply couplings.</li> <li>4. Wait until the alarms are triggered.</li> </ul>

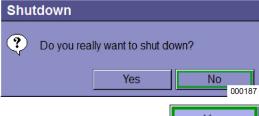
7

#### **Power off**

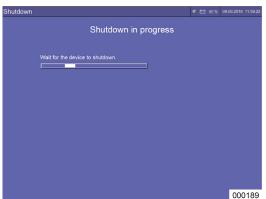


The device can only be turned off from standby.

- Keep the ON/OFF button on the keypad pressed down until the device confirms the entry with a sound signal.
- **2.** Confirm the screen dialogue on the touchscreen with **YES**.

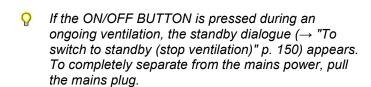




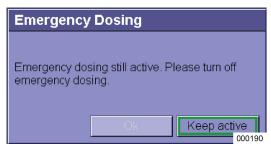


While system data are saved in the background, a running bar appears on the screen.

- 3. Wait until the device switches itself off.
- 4. Separate the device from the central gas supply (disconnect the supply plug from the wall connection or put it into park position) to prevent the possibility of the piping system becoming dirty.



# O<sub>2</sub> emergency dosing during shutdown of the device



If the device shuts down and the emergency dosing is switched on the following dialogue appears:

"Emergency dosing still active. Please turn off emergency dosing." The OK button is inactive.

1. If you wish to continue to ventilate the patient with the device switched off, confirmed the dialogue with the **keep active** button. Otherwise, close the emergency dosing.

The **OK** button becomes active.

**2.** Confirm the dialogue with the **OK** button. In both cases the further shutdown process takes place.

#### 8. Ventilation

## **General information**

#### **Compliance compensation**

Part of the tidal volume, called compliance volume, does not reach the patient due to compression in the patient module and into the patient tubes during inspiration. In volume-controlled ventilation, the leon *plus* therefore carries out a compliance compensation of the tidal volume by adding the compliance volume to the set tidal volume. The compliance volume in the patient tubes is taken into account during volume measurement. During pressure-controlled ventilation, the compliance volume during expiration is taken into account.

## **Patient categories**



You can choose between two patient categories:

- child
- adult

Different default settings are stored for particular categories. Some ventilation parameter setting options are limited, depending on the category.

The lower the tidal volume, the bigger the constant share of the compliance volume becomes.

Therefore, use child tube systems for children to lower the total gas volume of the system, if necessary.

# Weight (IBW)



You can enter the ideal body weight [kg] of the patient. The presets for the following ventilation parameters are calculated according to the entry:

- Minute volume MV [l/min]
- Breath volume (insp.) VTi, VTG [ml]
- Frequency f [1/min]

Table 25: Setting range and increments of the weight entry

	Range	Increment
Weight	1-5	0.1
	5-50	1
	50-99	5



The lower the tidal volume, the bigger the constant share of the compliance volume becomes. Therefore, use child tube systems for children to lower the total gas volume of the system, if necessary.

#### Ventilation parameters with weight entry

If the ventilation parameters are preset by entering the weight, the restrictions of the setting options of the ventilation parameters through the patient categories are lifted.

Table 26: Setting range and increment of the ventilation parameter with weight entry

Ventilation parameters	Ventilation			
	volume-controlled		pressure-controlled	
	Range	Increment	Range	Increment
	3-20	1	OFF, 3-20	1
	20-50	2	20-50	2
$V_{Ti}$ , $V_{TG}$ (optional for leon plus) [ml]	50-100	5	50-100	5
pido) [iiii]	600-1000	10	600-1000	10
	1000-1600	50	1000-1600	50
P <sub>max</sub> [mbar]	10-80	1	5-60	1
P <sub>insp.</sub> [mbar]	5-60	1	5-60	1
Frequency [1/min]	4-80 (100)	1	4-80 (100)	1
I:E	1:4-4:1	0.1	1:4-4:1	0.1
T <sub>insp.</sub> [s]	0.2-10	0.1	0.2-10	0.1
PEEP [mbar]	OFF, 1-20	1	OFF, 1-20	1
Plateau [%]	OFF, 10-50	5	10-90	5
	0.1-0.5	0.1	0.1-0.5	0.1
Trigger [l/min]	0.6-5	0.5	0.6-5	0.5
	6-10	1	6-10	1
	4-10	2	4-10	2
Backup [s]	10-15	5	10-15	5
	15-45	15	15-45	15

The frequency range up to 100 [1/min] is optional with the leon plus

Table 27: Calculation of the IBW					
IBW	Size [cm]	IBW [kg] calculation formula			
IBW children	50171	= 2,05 × $e^{(0,02 \times Size [cm])}$			
IBW adult male	152250	= 50 + 2,3 × (Size [cm] - 152,4) ÷ 2,54			
IBW adult female	152250	= 45,5 + 2,3 × (Size [cm] - 152,4) ÷ 2,54			

Calculation formulas according to:

- Traub SL, Comparison of methods of estimating creatine clearance in children
- Pai MP, The origin of the "ideal" body weight equations

### Load default settings

Reset default settings

In standby, the **Reset Default Settings** button is located on the bottom right of the screen.

The basic settings are designated as default settings, which the device shows when it is switched on.

The following can be reset to default:

- Alarms and ventilation parameters
- Charts, trend charts, tabular trend
- All settings
- P

Only the settings of the currently selected patient category are reset.



# Behaviour of the $P_{\text{insp.}}$ Setting upon change to the PEEP settings

Changing the PEEP setting does not influence the set  $P_{\text{insp.}}$  Setting (in the PCV form of ventilation). Minimum difference between PEEP and  $P_{\text{insp.}}$  is 5 mbar.

When increasing the PEEP settings, the  $P_{insp.}$  setting must also be increased correspondingly, as otherwise it would lead to a lowering of the  $V_{Ti}$  or MV.

#### Moisture in the ventilation system

If long anaesthesias are predominantly carried out in the minimal and low flow range, increased moisture from the patient gases and water freed during CO<sub>2</sub> absorption gathers in the ventilation system.

The excess moisture condenses at the coldest points in the ventilation system. As the patient module is heated, this is the tube to the ventilation bag and bellows. The water in the tube can also be removed during operation by briefly pulling it out and emptying it. The bellows can only be emptied when the patient module is folded down.

By interposing water traps in the ventilation tubes, some of the moisture can be trapped. The water traps must be suspended at the lowest point (between the y-piece, the patient and the patient module) of the ventilation tubes. To ensure this, use ventilation tubes of different lengths, if necessary.



Extreme moisture in the ventilation system can falsify the gas measurement.

#### Low flow and minimal flow

Table 28: Conditions for low or minimal flow suitability

now suitability					
Range	Settable fresh gas flow	Leakage rate of the tube system			
Low flow	≤1000 l/min	≤300 ml/min			
Minimal flow	≤500 ml/min	≤150 ml/min			

A system is described as suitable for low or minimal flow if the following conditions are fulfilled:

If the sum of the gas intake of the patient and the leakage rate of the ventilation system is bigger than the fresh gas flow, the ventilation system empties itself. The fresh gas flow must then be adapted accordingly. A fresh gas flow that is too high escapes through the excess diaphragm in the AGSS. The fill state of the ventilation system corresponds to the fill state of the ventilation bag serving as a reservoir.

# Fresh gas setting



Here, the following occurs:

- the selection of the carrier gases AIR or N<sub>2</sub>O
- the setting of the percentage share of oxygen on the fresh gas flow
- the setting of the fresh gas flow
- econometer

#### Features:

- the setting range is 0.2 l/min-18 l/min (except for HLM1)
- AIR or N<sub>2</sub>O are available as carrier gas
- ensuring of an O<sub>2</sub> minimum flow of 0.2 l/min (except for HLM1)
- ensuring of an O<sub>2</sub> concentration in the O<sub>2</sub>/N<sub>2</sub>O blend of at least 25% (ratio system)
- N<sub>2</sub>O block in the event of O<sub>2</sub> shortage
- automatic switch to 100% AIR with O<sub>2</sub> shortage with fresh gas flow remaining the same
- automatic switch to O<sub>2</sub> with AIR shortage with fresh gas flow remaining the same
- automatic switch to 100% O<sub>2</sub> with N<sub>2</sub>O shortage with fresh gas flow remaining the same
- audible and visual alarm in the event of O<sub>2</sub>, AIR or N<sub>2</sub>O shortage
- O<sub>2</sub> effective [ml/min] or [l/min] (quantity 100% oxygen in the set fresh gas)
- display of an economic fresh gas flow

The set gas amount is displayed under the relevant tube in I/min. There is a graphic display of the amount in the tube as a bar graph.

If not confirmed, presets (yellow) are closed again after 10 seconds



1. Select the fresh gas blender button in the window to implement the settings.



1. Select the button for the **carrier gas** (AIR or  $N_2O$ ) in the fresh gas blender window.





2. Confirm the entry.



3. Select the O<sub>2</sub> button.





**4.** Set the **percentage share of O<sub>2</sub>** to the fresh gas flow.





**6.** Select the **flow** button.





- 7. Set the fresh gas flow.
- **8.** Confirm the entry.
- P

The fill state of the ventilation system corresponds to the fill state of the ventilation bag serving as a reservoir. If the ventilation bag empties, the fresh gas supply must be increased accordingly.

Presetting the fresh gas is also possible in standby. If the fresh gas blender fails its control elements become inactive. Then ensure the fresh gas flow through the O<sub>2</sub> emergency supply

# Fresh gas ecometer



On the right of the fresh gas blender window there is a three-part tube. Depending on the height of the  $O_2$  fresh gas flow, the tube is filled in red, green or yellow.

#### Fresh gas shortage (red):

 $O_2$ Effektiv <  $\dot{V}_{O2eff} \times X_1$ 

The set  $O_2$  fresh gas flow is lower than the total oxygen consumption in the system multiplied by a factor  $x_1$ .

#### Fresh gas economic (green):

 $O_2$ Effektiv  $> = \dot{V}_{O2eff} \times X_1$ 

The set  $O_2$  fresh gas flow is the same or higher than the total oxygen consumption in the system multiplied by a factor  $x_1$ .

(Maximum is limit to yellow)

#### Fresh gas uneconomic (yellow):

 $O_2$ Effektiv >  $\dot{V}_{O2eff} \times X_2$ 

The set  $O_2$  fresh gas flow is higher than the total oxygen consumption in the system multiplied by a factor  $x_2$ .

 $\dot{V}_{O2eff}$  = total oxygen consumption in the system (sum from  $O_2$  uptake of the patient and leakage of the system)

 $x_1$  and  $x_2$  = factors that can be changed in the service to individually adjust the threshold from red to green and from green to yellow

### **Borderline fresh gas settings**

- P
- For **borderline settings** or in the event of a shortage of supply gases (ZGA), consider:
  - smallest flow that can be set is 0.2 l/min (except for HLM)
  - minimum O<sub>2</sub> flow in the fresh gas is 0.2 l/min (except for HLM)
  - the  $O_2$  concentration in the  $O_2/N_2O$  blend is  $\geq 25$  % (ratio system)
  - for the reasons given above, the O<sub>2</sub> increases over the N<sub>2</sub>O concentration for a fresh gas flow under 0.8 l/min.
  - for the reasons given above, the dosing of 21% O₂ (AIR only) is not possible below 1 l/min
  - N<sub>2</sub>O block in the event of O<sub>2</sub> shortage
     0.6-0.8 kPa × 100 (bar)
  - with O<sub>2</sub> shortage <2.8 kPa × 100 (bar) automatic switch to AIR with the fresh gas flow remaining the same
  - with AIR shortage <2.8 kPa × 100 (bar) automatic switch to O<sub>2</sub> (100 %) with the fresh gas flow remaining the same
  - with N<sub>2</sub>O shortage <2.8 kPa × 100 (bar)
     automatic switch to O<sub>2</sub> (100%) with the fresh gas
     flow remaining the same

# Setting of the anaesthetic vaporiser



Please operate the anaesthetic vaporiser in accordance with its user manual.

#### **Quick start**

In the case of emergency, the device is ready for ventilation immediately without the execution of the system test.



Quick start, system test is not executed.

#### Some functions not checked

Pay greater attention.

CAUTION

A red bar is shown in the title bar with the message "System test skipped"



Quick start: System test is not executed

#### Some functions not checked

Low or minimal flow are not allowed to run



The  $O_2$  emergency dosing of the leon plus is active in the turned-off state. If it is opened before the start and if the system test is skipped, it remains active until a ventilation is started.

The  $O_2$  emergency dosing is **not** active during the ongoing system test.

**1.** Turn on the leon *plus* as follows:

# Manual operation during the boot process and the selftest



- **1.** Set the APL valve to the maximum desired ventilation pressure.
- 2. Set the O<sub>2</sub> emergency dosing to the desired fresh gas flow.
- **3.** Set the anaesthetic vaporiser to the desired concentration.
- **4.** Ventilate the patient manually for a short time.

After approx. 1 minute, monitoring and the controlled form of ventilation of theleon *plus* are available.

Skip (NOT RECOMMENDED)

You can switch from the system test screen directly to standby (skip system test)

- Skipping the system test is not recommended.
- Set the O<sub>2</sub> emergency dosing to 0.

# **Execute quick start**

Child

Adult



- **1.** To **quick start mechanical ventilation**, first select the patient category:
  - Child
  - Adult
  - Weight
- 2. Set the fresh gas as described in the chapter (→ "Fresh gas setting" p. 134).



3. Select the Form Of Ventilation button.



4. Confirm the selection.



5. Select the Ventilation Parameters button.





- 6. Set the parameter.
- **7.** Confirm the entry.



**8.** Set the anaesthetic vaporiser to the desired concentration.



9. Start ventilation.

# Forms of ventilation

#### **Manual ventilation**

#### Start a MAN/SPONT manual/spontaneous ventilation

Child

Adult



- **1.** To start a manual ventilation or spontaneous breathing, first select the patient category:
  - Child
  - Adult
  - Weight
- 2. Carry out the fresh gas setting, as described in the chapter (→ "Fresh gas setting" p. 134).



**3.** Select the **MAN/SPONT** button in the form of ventilation window.



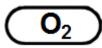
 Set the APL on the patient module to a value corresponding to the pressure limit (e.g. 20 Pa × 100 (mbar).



Set the anaesthetic vaporiser to the desired concentration.



**6.** Start the monitoring and ventilate the patient with the ventilation bag.



**7.** Activate the O<sub>2</sub> flush on the front of the device to fill the system quickly.

Table 29: Setting parameters, setting range and increment of the MAN/SPONT form of ventilation.

Ventilation parameters	Child		Adult	
	Range	Increment	Range	Increment
Fresh gas flow [l/min]	0.2-1	0.05	0.2-1	0.05
	1-18	0.1	1-18	0.1
Fresh gas O2 [% from fresh gas flow]	25(21)-100	1	25(21)-100	1
V <sub>Ti</sub> [ml]	1	1	/	1
V <sub>TG</sub> [ml]	1	1	/	1
P <sub>max</sub> [mbar]	1	1	/	1
P <sub>insp.</sub> [mbar] (is set over APL)	0-90	free	0-90	free
Frequency [1/min]	I	1	/	1
I:E	1	1	/	1
T <sub>insp.</sub> [s]	1	1	/	1
PEEP [mbar]	1	1	/	1
Plateau [%]	I	1	1	1
Trigger [l/min]	I	1	1	1
Backup [s]	1	1	1	1

 $O_2$  fresh gas parameters [% of fresh gas flows], minimal  $O_2$  concentration fresh gas blender:

- with carrier gas AIR 21 %
- with carrier gas N<sub>2</sub>O 25 %

#### **HLM** (ventilation using a heart-lung machine)

If the leon *plus* is operated together with a heart-lung machine, the HLM form of ventilation is available. The HLM form of ventilation is the equivalent of the MAN/SPONT form of ventilation, except that here the monitoring of all of the limit values (except for CPAP) is switched off. Along with the CPAP (continuous positive airway pressure) five further measured values are displayed:

- Minute volume MV
- Breath volume (exp.) V<sub>Te</sub>
- Ventilation pressure P<sub>Peak</sub>
- Plateau pressure P<sub>Plateau</sub>
- Freq.<sub>CO2</sub>



WARNING

#### Alarms switched off!

#### Risk of undersupply of oxygen

• Be extra vigilant during the ventilation.



If no breath can be detected for 30 seconds, change the monitoring value to --.- (except for CPAP).



- Set the APL on the patient module to a value corresponding to the pressure limit (e.g. 10 PaPa × 100 (mbar)10).
- Carry out the fresh gas setting, as described in the chapter (→ "Fresh gas setting" p. 134) (0 l/min possible).



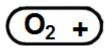
Select the HLM button in the form of ventilation window.



- Start the monitoring.
  - The CPAP sets itself.



5. Set the CPAP alarm.



**6.** Activate the O<sub>2</sub> flush on the front of the device to reach the CPAP quickly.

Table 30: Setting parameters, setting range and increment of the HLM form of ventilation.

Ventilation parameters	Child		Adult	
	Range	Increment	Range	Increment
Fresh gas flow [l/min]	OFF above 0.2-	0.05	OFF above 0.2-	0.05
	1-18	0.1	1-18	0.1
Fresh gas O <sub>2</sub> [% from fresh gas flow]	25(21)-100	1	25(21)-100	1
V <sub>Ti</sub> [ml]	/	1	/	1
V <sub>TG</sub> [ml]	/	1	/	1
P <sub>max</sub> [mbar]	/	I	/	1
P <sub>insp.</sub> [mbar] (is set over APL)	0-90	free	0-90	free
Frequency [1/min]	/	I	/	1
I:E	/	I	/	1
T <sub>insp.</sub> [s]	/	I	/	1
PEEP [mbar]	/	I	/	1
Plateau [%]	1	I	1	1
Trigger [I/min]	1	I	1	1
Backup [s]	1	1	1	1

O<sub>2</sub> fresh gas parameters [% of fresh gas flows], minimal O<sub>2</sub> concentration fresh gas blender:

- with carrier gas AIR 21%
- with carrier gas N<sub>2</sub>O 25%

### **MON** mode

For regional anaesthesias (with adequate spontaneous breathing) or when monitoring an awake patient, the leon *plus* provides the MON (monitoring) form of ventilation. The patient can be supplied with  $O_2$  via a mask and the internal  $O_2$  outlet or an external  $O_2$  outlet. Fresh gas cannot be given via the blender. The monitoring of all of the limit values (except for CPAP, insp. $O_2$ , exp.  $CO_2$  and  $Freq_{CO_2}$ ) is switched off. Connecting the gas meter of the device to the ventilation mask is a prerequisite for monitoring and displaying the monitoring values (except CPAP).

Six measured values are displayed:

- Minute volume MV
- Breath volume (exp.) V<sub>Te</sub>
- Ventilation pressure P<sub>Peak</sub>
- Plateau pressure P<sub>Plateau</sub>
- Freq.<sub>CO2</sub>
- CPAP



In the MON form of ventilation it is not possible to set ventilation parameters.



**WARNING** 

Various patient alarms switched off!

### Risk of undersupply of oxygen

Be extra vigilant during the ventilation.





If no CO<sub>2</sub> has not yet been measured, the monitoring values (except for CPAP) display --.-.



1. Select the MON button in the form of ventilation window.



2. Start the monitoring.

# No Freshgas

000192

- Presh gas cannot be given via the fresh gas blender.
- **3.** Follow the prompts on the screen:
  - Connect the multi gas analyser to the respiratory mask.
  - Connect the respiratory mask to an O<sub>2</sub> outlet.
  - Open the O<sub>2</sub> outlet.

## **Mechanical ventilation**

### Selection of a mechanical form of ventilation

The leon *plus* provides the following mechanical forms of ventilation:

- volume-controlled ventilation: IMV
- pressure-controlled ventilation: PCV
- synchronised intermittent mandatory ventilation: S-IMV
- pressure-controlled synchronised ventilation: S-PCV
- pressure-supported ventilation: PSV



1. Select the Form Of Ventilation button.

# Ventilation parameters



### Setting the ventilation parameters

1. Select the Ventilation Parameters button.





- **2.** Set the parameters.
- **3.** Confirm the entry.

Pressure limit from which the plateau is developed (optional)

<b>Buttons fo</b>	r setting ve	entilation p	arameters				
General IM	General IMV, PCV						
Freq I:E		Plateau	PEEP	Freq.	Ventilation frequency		
10	1:2	10	5	I:E	Time ratio of inspiration to expiration		
bpm		%	mbar	Plateau	percentage share of inspiration time in		
					which the ventilation pressure in the patient's lungs is kept constant		
				PEEP	Positive pressure that is maintained in the patient tube system during expiration		
IMV (additi	ional)						
V <sub>Ti</sub> P <sub>Max</sub>			P <sub>Max</sub>	V <sub>Ti</sub>	inspiratory ventilation volume that should be reached per breath		
0.71 50 cmH <sub>2</sub> O		P <sub>max</sub>	Pressure limit from which the plateau is developed				
PCV (addit	ional)						
	P <sub>In</sub>	ısp	$V_{TG}$	P <sub>insp.</sub>	inspiratory pressure that should be reached per breath		
	14	4	Off	$V_{TG}$	Tidal volume guarantee (optional)		
	mb	ar	mL				

 $P_{\text{max}}$ 

V<sub>TG</sub> **500** 

mL

## General S-IMV, S-PCV, PSV

P<sub>Max</sub> **21** 

mbar

-,,			
PEEP	Trigger	Trigger	flow produced by the patient from which a mechanical breath is triggered
<b>5</b> mbar	<b>0.5</b> L/min	PEEP	positive pressure that is maintained in the patient tube system during expiration

- 1-
8

S-IMV (a	S-IMV (additional)					
Freq	T <sub>Insp</sub>	Plateau	$V_{Ti}$	P <sub>Max</sub>	Freq.	Ventilation frequency
10 bpm	<b>2.0</b>	50	0.71	<b>22</b> mbar	T <sub>insp.</sub>	Time for the inspiration
		,		mbai	Plateau	percentage share of inspiration time in which the ventilation pressure in the patient's lungs is kept constant
					$V_{Ti}$	inspiratory ventilation volume that should be reached per breath
					$P_{\text{max}}$	Pressure limit from which the plateau is developed
S-PCV (a	dditiona	ıl)				
Freq	T <sub>Ins</sub>	en Pla	ateau	P <sub>Insp</sub>	Freq.	Ventilation frequency
10	2.0		40	12	T <sub>insp.</sub>	Time for the inspiration
bpm	S		%	mbar	P <sub>insp.</sub>	inspiratory pressure that should be reached per breath
					Plateau	percentage share of inspiration time in which the ventilation pressure in the patient's lungs is kept constant
PSV (add	ditional)					
P <sub>Insp</sub>	Ba	ackup			P <sub>insp.</sub>	inspiratory pressure that should be reached per breath
10 mbai		Manual Breath		Backup	Length of apnoea period until the leon <i>plus</i> triggers a mechanical breath independently	
					Manual breath	the user can trigger a mechanical breath him/herself

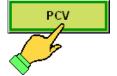
### Start of a mechanical ventilation







- **1.** To start a mechanical ventilation, first select the patient category:
  - Child
  - Adult
  - Weight
- **2.** Carry out the fresh gas setting, as described in the chapter (→ "Fresh gas setting" p. 134).



3. Select the Form Of Ventilation button.



4. Confirm the selection.



**5.** Select the **Ventilation Parameters** button in the form of ventilation/parameters window.





- **6.** Set the parameters.
- 7. Confirm the entry.

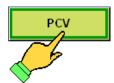


**8.** Set the anaesthetic vaporiser to the desired concentration.



**9.** Start the ventilation.

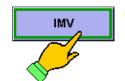
## To change a form of ventilation



Select the button of the new form of ventilation (highlighted in yellow)



Start the new form of ventilation with the unchanged parameter settings.



Alternatively, you can keep the active form of ventilation (pale blue)

## To change a ventilation parameter





1. Select the **Ventilation Parameter**s button (highlighted in pale blue for active or in yellow for a new form of ventilation).





- 2. Set the parameters.
- 3. Confirm the entry.



**4.** If a parameter was changed to a new form of ventilation, start this new form of ventilation with the changed ventilation parameter settings (yellow).

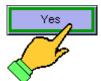


If not confirmed, the form of ventilation presets are closed again after 45 seconds and the previous active parameters are retained.

## To switch to standby (stop ventilation)

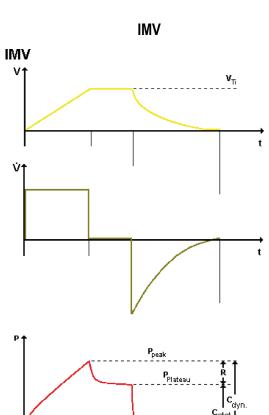


**1.** Activate the **Standby** button on the keyboard.



**2.** Confirm the screen dialogue on the touchscreen with **Yes**.

## **Description of the forms of ventilation**



Plat.

f/60

E

The IMV (intermittent mandatory ventilation) is a volume-controlled ventilation. A constant volume is sought.

In this form of ventilation, the respirator setting of the leon *plus* establishes the  $V_{Ti}$  breath volume and the **I:E** ratio timing and ventilation **frequency**. The setting of a **PEEP** and a **plateau** phase as a percentage share of the inspiration time is available.

If the pressure reaches the P<sub>Peak</sub> alarm limit, the mechanical breath breaks off.

P

If the alarm message " $P_{max}$  reached too early" appears, the  $V_{Ti}$  selected is so big that the ventilation pressure  $P_{aw}$  exceeds the set  $P_{max}$  limit. As the mechanical breath is not completely executed (in exceeding  $P_{ma}$ the plateau is developed) the set  $V_{Ti}$  and the MV resulting from it is not reached. This could possibly lead to volume alarms that cannot be fixed by increasing  $V_{Ti}$ , but through a raising of the  $P_{max}$  limit and/or the ventilation frequency and/or changing the I:E ratio.

P<sub>Max</sub> **50** mbar

PEEP,

000227

### P<sub>max</sub> pressure limit in the IMV

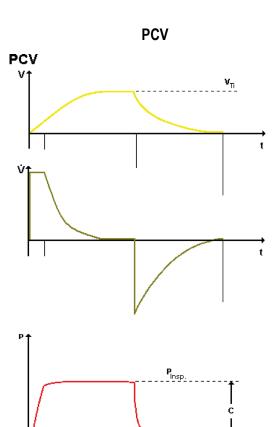
In the IMV form of ventilation a maximum  $P_{max}$  limit can be set for safety. If this maximum desired  $P_{max}$  pressure limit is exceeded, the plateau phase is started too early and the set tidal volume is not completely administered. It then becomes a volume-controlled, pressure-limited form of ventilation.

Table 31: Setting parameters, setting range and increment of the IMV form of ventilation.

Ventilation parameters	Ch	nild	Adult		
	Range	Increment	Range	Increment	
Fresh gas flow [l/min]	0.2-1	0.05	0.2-1	0.05	
	1-18	0.1	1-18	0.1	
Fresh gas O2 [% from fresh gas flow]	25(21)-100	1	25(21)-100	1	
V <sub>Ti</sub> [ml]	3-20	1	300-1000	10	
	20-50	2	300-1000	10	
	50-100	5	1000 1000	50	
	100-600	10	1000-1600	50	
V <sub>TG</sub> [ml]	1	1	1	1	
P <sub>max</sub> [mbar]	10-80	1	10-80	1	
P <sub>insp.</sub> [mbar]	/	1	/	/	
Frequency [1/min]	14-80 (100)	1	4-40	1	
I:E	1:4-4:1	0.1	1:4-4:1	0.1	
T <sub>insp.</sub> [s]	/	1	/	/	
PEEP [mbar]	OFF, 1-15	1	OFF, 1-20	1	
Plateau [%]	OFF, 10-50	10	OFF, 10-50	10	
Trigger [I/min]	1	1	1	1	
Backup [s]	1	1	1	1	

O<sub>2</sub> fresh gas parameters [% of fresh gas flows], minimal O<sub>2</sub> concentration fresh gas blender:

- with carrier gas AIR 21 %
- with carrier gas N<sub>2</sub>O 25 %



Plat.

Ī

PEEP

000228

Ε

f/60

The PCV is a pressure-controlled ventilation. With this form of ventilation, the optimal ventilation pressures of the patient are of paramount importance.

In this form of ventilation, the respirator setting of the leon plus establishes the maximum  $\mathbf{P}_{insp.}$  ventilation pressure and the I:E timing ratio and ventilation **frequency**. The setting of a **PEEP** and a **plateau** phase as a percentage share of the inspiration time is available.

The leon *plus* first ventilates the patient with a high, constant flow until the set  $P_{insp.}$  inspiration pressure is reached and then with a decelerated flow to keep the reached set ventilation pressure constant.

It is important to monitor the breath minute volume.

Borderline settings occur if the inspiration time is too short to reach the desired P<sub>insp.</sub> ventilation pressure.



### Volume guarantee V<sub>TG</sub> in the PCV

In the PCV the ventilation parameter  $V_{TG}$  (volume title guarantee) is available. At the start of the PCV,  $V_{TG}$  is OFF by default. If the  $V_{TG}$  is switched on, the ventilation parameter  $\mathbf{P}_{insp.}$  changes to  $\mathbf{P}_{max.}$ . The  $\mathbf{P}_{max.}$  setting is set to  $\mathbf{P}_{insp.}$  Setting + 5 mbar.  $V_{TG}$  is allocated as the start value with the monitoring value  $V_{TE}$ .

After a  $V_{TG}$  is set as breath volume and a  $P_{max.}$  is corrected and confirmed as the pressure limit, this volume is administered to the patient under pressure control. If the maximum desired  $P_{max}$  pressure limit is exceeded, the plateau phase is initiated prematurely and the set tidal volume is not completely administered

(→ "IMV" p. 151).

Therefore, this pressure-limited, pressure-regulated, tidal volume-guaranteed form of ventilation should not be deployed but the ventilation parameters should be adjusted so that a  $P_{\text{max}}$  is not reached if possible.

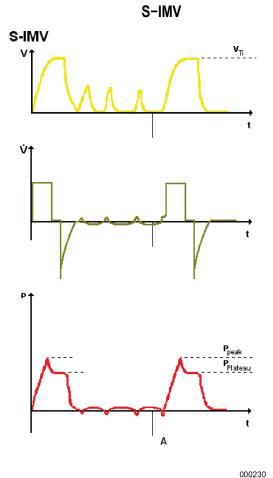
If  $V_{TG}$  switched off, the ventilation parameter  $P_{max}$ . changes back to  $P_{insp.}$  and  $P_{insp.}$  is allocated as start value with the monitoring value  $P_{peak}$ .

Table 32: Setting parameters, setting range and increment of the PCV form of ventilation

Ventilation parameters	Ch	nild	Adult		
	Range	Increment	Range	Increment	
Fresh gas flow [l/min]	0.2-1	0.05	0.2-1	0.05	
	1-18	0.1	1-18	0.1	
Fresh gas O2 [% from fresh gas flow]	25(21) - 100	1	25(21) - 100	1	
V <sub>Ti</sub> [ml]	1	1	/	1	
	OFF, 3-20	1	OFF 200 4000	40	
\/ [mal] (antiqual)	20-50	2	OFF, 300-1000	10	
V <sub>TG</sub> [ml] (optional)	50-100	5	1000 1000	50	
	100-600	10	1000-1600	50	
P <sub>max</sub> [mbar]	5-60	1	5-60 1		
P <sub>insp.</sub> [mbar]	5-60	1	5-60 1		
Frequency [1/min]	14-80 (100)	1	4-40 1		
I:E	1:4-4:1	0.1	1:4-4:1 0.1		
T <sub>insp.</sub> [s]	1	1	/	1	
PEEP [mbar]	OFF, 1-15	1	OFF, 1-20	1	
Plateau [%]	10-90	5	10-90	5	
Trigger [I/min]	1	1	/	1	
Backup [s]	1	1	/	1	

O2 fresh gas parameters [% of fresh gas flow], minimal O2concentration fresh gas blender:

- with carrier gas AIR 21 %
- with carrier gas N<sub>2</sub>O 25 %



In S-IMV (**S**ynchronized Intermittend **M**andatory **V**entilation) mechanical breaths are combined with spontaneous breathing. The patient can breathe at his/her own respiratory rhythm and nevertheless receive a preset number of mechanical breaths dependent of the set ventilation **frequency**, which are synchronised by the leon *plus* after triggering by the patient.

With the **S-IMV** the mechanical breath is administered via volume-controlled  $V_{\text{Ti}}$ . The setting of the  $T_{\text{insp.}}$  inspiration time of a **PEEP** and a **plateau** phase as a percentage share of the inspiration time is available.

When the time has come for the mechanical breath according to the set frequency, a "trigger" is activated by the leon *plus* (the patient can release the trigger). The next inspiration effort by the patient leads to administration of the mechanical breath. The time from half of the entire breath period ( $T_{insp.} + T_{exsp.}$ ) until the end of the expiration time (but at least 500 ms after the start of the inspiration time) that is available for the trigger activation is called a "breath-by-breath" window. If the trigger was not activated by the end of this breath-by-breath window, the breath is administered unsynchronised. Finally, a period follows with the option of spontaneous breathing until the start of the next "breath-by-breath" window.

P

It must be ensured that adequate volume monitoring takes place.

P

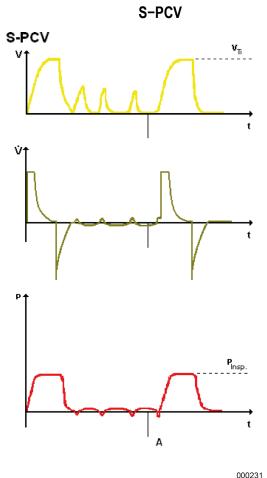
With this form of ventilation the duration of the controlled phases is fixed, i.e. an expiration of the patient during the mechanical breath is not possible. This can lead to pressure increases if the patient makes expiration attempts, which are, however, limited by the  $P_{Peak}$  alarm

Table 33: Setting parameters, setting range and increment of the S-IMV form of ventilation.

Ventilation parameters	Cr	nild	Adult		
	Range	Increment	Range	Increment	
Fresh gas flow [l/min]	0.2-1	0.05	0.2-1	0.05	
	1-18	0.1	1-18	0.1	
Fresh gas O2 [% from fresh gas flow]	25(21)-100	1	25(21)-100	1	
V <sub>Ti</sub> [ml]	3-20	1	300-1000	10	
	20-50	2	300-1000	10	
	50-100	5	1000-1600	F0	
	100-600	10	- 1000-1600	50	
V <sub>TG</sub> [ml]	1	1	/	1	
P <sub>max</sub> [mbar]	10-80	1	10-80	1	
P <sub>insp.</sub> [mbar]	1	1	/	1	
Frequency [1/min]	6-60	1	4-40	1	
I:E	1	1	/	1	
T <sub>insp.</sub> [s]	0.2-2.9	0.1	0.3-10	0.1	
PEEP [mbar]	OFF, 1-15	1	OFF, 1-20	1	
Plateau [%]	OFF, 10-50	10	OFF, 10-50	10	
Trigger [l/min]	0.1-0.5	0.1	0.1-0.5	0.1	
	0.6-5	0.5	0.6-5	0.5	
	6-10	1	6-10	1	
Backup [s]	1	1	1	I	

 $\mbox{O}_2$  fresh gas parameters [% of fresh gas flow], minimal  $\mbox{O}_2$  concentration fresh gas blender:

- with carrier gas AIR 21 %
- with carrier gas N<sub>2</sub>O 25 %



In S-PCV (Synchronized Pressure Controlled Ventilation) mechanically controlled mechanical breaths are combined with spontaneous breathing. The patient can breathe at his/her own respiratory rhythm and nevertheless receive a preset number of mechanical breaths dependent of the set ventilation frequency, which are synchronised by the leon *plus* after triggering by the patient.

With the **S-PCV** the mechanical breath is administered via pressure-controlled  $P_{insp.}$  The setting of the  $T_{insp.}$  inspiration time of a **PEEP** and a **plateau** phase as a percentage share of the inspiration time is available.

When the time has come for the mechanical breath according to the set frequency, a **"Trigger"** is activated by the leon *plus* (the patient can release the trigger). The next inspiration effort by the patient leads to administration of the mechanical breath. The time from half of the entire breath period ( $T_{insp.} + T_{exsp.}$ ) until the end of the expiration time (but at least 500 ms after the start of the inspiration time) that is available for the trigger activation is called a "breath-by-breath" window. If the trigger was not activated by the end of this breath-by-breath window, the breath is administered unsynchronised. Finally, a period follows with the option of spontaneous breathing until the start of the next "breath-by-breath" window.

P

It must be ensured that adequate volume monitoring takes place.

limited by the P<sub>Peak</sub> alarm.

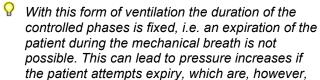
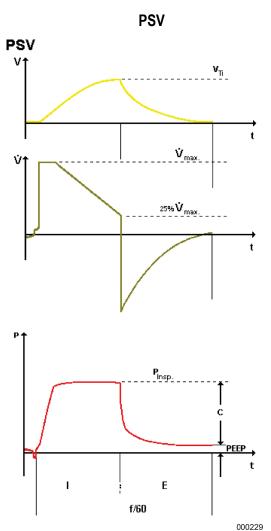


Table 34: Setting parameters, setting range and increment of the S-PCV form of ventilation.

Ventilation parameters	Child		Adult	
	Range	Increment	Range	Increment
Fresh gas flow [l/min]	0.2-1	0.05	0.2-1	0.05
	1-18	0.1	1-18	0.1
Fresh gas O <sub>2</sub> [% from fresh gas flow]	25 (21)-100	1	25(21)-100	1
V <sub>Ti</sub> [ml]	1	1	1	1
V <sub>TG</sub> [ml]	1	1	/	1
P <sub>max</sub> [mbar]	1	1	1	1
P <sub>insp.</sub> [mbar]	5-60	1	5-60	1
Frequency [1/min]	6-60	1	4-40	1
I:E	1	1	1	1
T <sub>insp.</sub> [s]	0.2-2.9	0.1	0.3-10	0.1
PEEP [mbar]	OFF, 1-15	1	OFF, 1-20	1
Plateau [%]	10-90	5	10-90	5
Trigger [I/min]	0.1-0.5	0.1	0.1-0.5	0.1
	0.6-5	0.5	0.6-5	0.5
	6-10	1	6-10	1
Backup [s]	1	1	1	1



The PSV (**P**ressure **S**upport **V**entilation) serves as pressure support of insufficient spontaneous breathing. The breath frequency is determined by the patient, while the leon *plus* takes over an adjustable share of the ventilation work. Each spontaneous inspiration attempt is supported with the aid of technical equipment (accessible **trigger**) by an adjustable positive  $\mathbf{P}_{\text{insp.}}$  pressure. While the patient triggers the inspiration, the leon *plus* starts the expiration if the inspiration flow has dropped 25% of the previously reached maximum value.

The setting of a **PEEP** is possible.

If the leon *plus* is not triggered by an adjustable apnoea time (backup) of the patient, the leon *plus* starts an inspiration independently.

In addition, a **manual breath** can be started by means of a button not activated by the patient.

If an inspiration time of 4 s is exceeded, the leon plus starts the expiration independently.

Table 35: Setting parameters, setting range and increment of the PSV form of ventilation.

Ventilation parameters	Cr	nild	Adult		
	Range	Increment	Range	Increment	
Fresh and flow [l/min]	0.2-1	0.05	0.2-1	0.05	
Fresh gas flow [l/min]	1-18	0.1	1-18	0.1	
Fresh gas O2 [% from fresh gas flow]	25(21)-100	1	25(21)-100	1	
V <sub>Ti</sub> [ml]	1	1	1	1	
V <sub>TG</sub> [ml]	1	1	/	1	
P <sub>max</sub> [mbar]	1	1	/	1	
P <sub>insp.</sub> [mbar]	5-60	1	5-60	1	
Frequency [1/min]	1	1	/	1	
I:E	1	1	/	1	
T <sub>insp.</sub> [s]	1	1	/	1	
PEEP [mbar]	OFF, 1-15	1	OFF, 1-20	1	
Plateau [%]	1	1	/	1	
	0.1-0.5	0.1	0.1-0.5	0.1	
Trigger [I/min]	0.6-5	0.5	0.6-5	0.5	
	6-10	1	6-10	1	
	4-10	2	4-10	2	
Backup [s]	10-15	5	10-15	5	
	15-45	15	15-45	15	

### Locked ventilation parameters

#### Display of a lock

If the setting of a ventilation parameter is not possible due to its lock, this is symbolised by an arrow on the button of the ventilation parameter that is preventing the setting. To release the lock, the ventilation parameter concerned must be changed to "arrow direction".

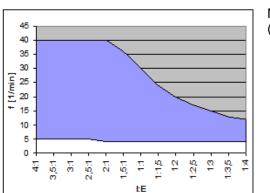
#### 

## Display of a lock through too-low frequency

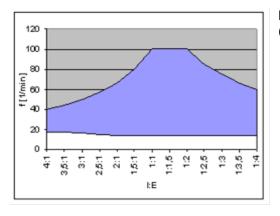
To increase the I share of a 2:1 I:E ratio, the ventilation frequency must first be raised.

# Display of a lock by too-high PEEP compared with $P_{\text{insp.}}$ in the PCV

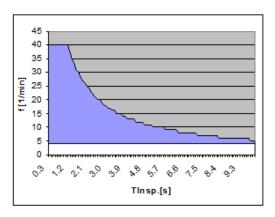
To achieve in the PCV a PRRP greater than 11 with a set  $P_{insp.}$  inspiration pressure of 16, the  $P_{insp.}$  must first of all be increased.



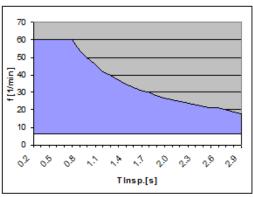
Maximum ventilation frequency with a given I:E ratio (adult)



Maximum ventilation frequency with a given I:E ratio (child)



Maximum ventilation frequency with a given  $T_{\text{insp.}}$  (Adult)



Maximum ventilation frequency with a given  $T_{\text{insp}}$  (child)

## Takeover of ventilation parameters

- When switching from a pressure-controlled ventilation to a volume-controlled ventilation, the reached volume is taken over as a preset for V<sub>Ti</sub>.
- When switching from a volume-controlled ventilation to a pressure-controlled ventilation,  $P_{Plat.}$  is taken over as a pre-set for  $P_{ins.}$
- The plateau setting is not taken over from a volumecontrolled ventilation to a pressure-controlled ventilation and vice versa.
- No parameters are taken over or transferred in and out of the PSV and HLM forms of ventilation.
- Other parameters are taken over only if they are available and valid as settings in the new form of ventilation.

9

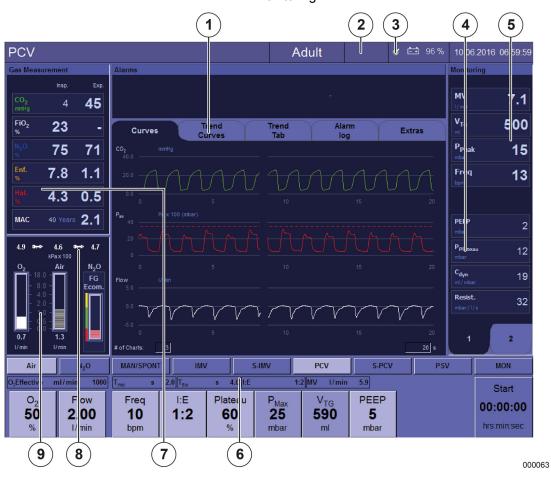
# 9. Monitoring

# **General information**

All measured values are administered for BTPS. Flow, pressure and concentrations are measured by sensors. All other sizes are derived from these measured values.

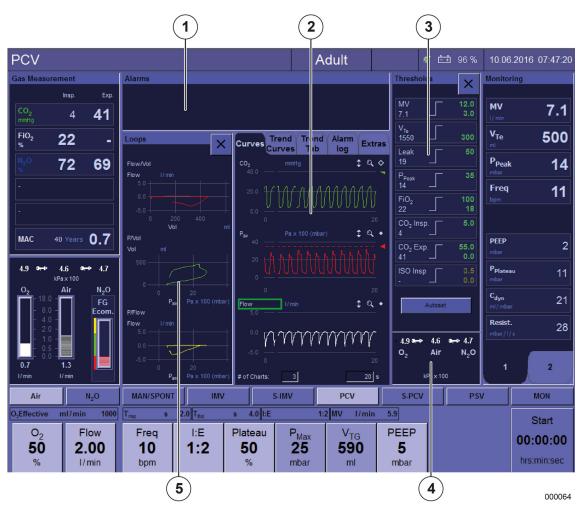
## **Data**

The following data are displayed on the screen for monitoring:



- (1) tabs
- (2) alarm muting
- (3) batteries
- (4) calculated values I
  - Leak
  - %Spont.
  - MAC
  - Compliance (static, dynamic)
  - C20/C
  - Resistance
- (5) measured values
  - value as a graphical display (realtime, trend)
  - value as a numerical display (monitoring, tabular)

- (6) calculated values II
  - T<sub>insp.</sub>
  - T<sub>exp.</sub>
  - I:E
  - MV
- (7) Gas concentration
  - Values as graphical display
  - Values as numerical display
- (8) Pressures
  - ZGA
  - 10 L bottles
- (9) Bar graphs
  - Fresh gas amount (O<sub>2</sub>, N<sub>2</sub>O, AIR)



- (1) alarm messages
- (2) real-time graphs
- (3) limit values
- (4) supply pressures
  - ZGA
  - 10 L bottles

- (5) Loops
  - Volume over pressure
  - Flow over pressure
  - Flow over volume

# Alarm muting (mute)

(→ "Alarm muting" p. 194)

# **Limit values**

(→ "Limit values (patient alarm limits)" p. 197)

## Alarm messages

(→ "List of alarm messages" p. 204)

## **Batteries**

(→ "Batteries" p. 189)

## **Device functions**

(→ "Monitoring of device functions" p. 182)

# **Monitored data**

# Measured values as graphical display

## Data as real-time curves



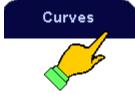
The following measured values for monitoring are displayed as curves (a minimum of one or maximum four measured values can be displayed as curve(s):

Airway pressure [mbar]

Flow [l/min]

Volume (inspiratory) [ml] patient gases

- O<sub>2</sub> [%]
- CO<sub>2</sub> [%, mmHg, hPa, kPa]
- N<sub>2</sub>O [%]
- volatile anaesthetics
  - halothane [%]
  - enflurane [%]
  - isoflurane [%]
  - sevoflurane [%]
  - desflurane [%]



1. Select the Curves tab.



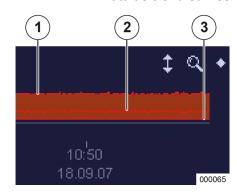
- 2. Select the button in the window.
- (→ "Table 11: Icons/screen (control elements)" p. 42)





- **3.** Set the parameters.
- **4.** Confirm the entry.

### Data as trend curves



The following measured values for monitoring are displayed as trend curves (a minimum of one or maximum four measured values can be displayed as curve(s): The values are stored every five seconds: airway pressures [mbar]

aliway pressures [ilibar

minute volume [ml] frequency

patient gases

- O<sub>2</sub> [%]/FiO<sub>2</sub> [%]
- CO<sub>2</sub> [%, mmHg, hPa, kPa]
- N<sub>2</sub>O [%]
- volatile anaesthetics
  - halothane [%]
  - enflurane [%]
  - isoflurane [%]
  - sevoflurane [%]
  - desflurane [%]

## Calculated values I

- MAC
- Compliance
  - static [ml/mbar]
  - dynamic [ml/mbar]
- resistance [mbar/l/s]
- (1) P<sub>Peak</sub>
- (2) P<sub>Mean</sub>
- (3) PEEP



1. Select the Trend Curves tab.

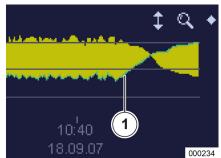


- 2. Select the button in the window.
- (→ "Table 11: Icons/screen (control elements)" p. 42)





- 3. Set the parameters.
- **4.** Confirm the entry.



# Trend curves display bigger for expiratory values than inspiratory values

- Under certain conditions (e.g. anaesthetics drainage) expiratory gas values can be bigger than inspiratory values. To mark this trend, the expiratory side of the bar chart is marked with a line in a different colour.
- (1) Expiration value

Table 36: Resolution and autoscaling range of the real-timecurves

Real-time curves	Range max.	Resolution max.	Autoscaling		
		illax.	Lower limit	Upper limit	
P <sub>aw</sub> [mbar]	-10 - +100	5	-5	Alarm P <sub>peak</sub> + 5	
Flow [I/min]	-200 - +200	5	0	Flow max. × 1,25	
Volume [ml]	0 - + 2000	10	0	V <sub>Te</sub> max. × 1,25	
O <sub>2</sub> [%]	0 - +100	5	15	insp. O <sub>2</sub> alarm high	
CO <sub>2</sub> [%]	0 - +10	0.5	0	exp. O <sub>2</sub> alarm high	
volatile anaesthetics [%] (except for desflurane)	0 - +10	0.1	0	insp. volatile anaesthetics high	
DES [%]	0 - +22	1	0	insp. DES alarm high	
N <sub>2</sub> O [%]	0 - +100	1	0	Concentration in the FG	

CO<sub>2</sub> curve value setting: autoscaling=OFF, X-axis range=0-40 mmHg

## **Tabular trend**



Up to 12 values, as desired (configurable), updated every five seconds, can be displayed as a table:

- date
- time
- event
  - start and stop of a ventilation
  - change of anaesthetic gas
- measured value
  - insp./exp. CO<sub>2</sub> [%, mmHg, hPa, kPa]
  - insp./exp. O<sub>2</sub> [%] /FiO<sub>2</sub> [%]
  - insp./exp. N<sub>2</sub>O [%]
  - insp./exp. agent [%]
  - P<sub>Peak</sub>/PEEP [mbar]
  - P<sub>Mean</sub> [mbar]
  - MV [l/min]
  - Freq [1/min]
- calculated values I
  - MAC
  - static/dynamic compliance [ml/mbar]
  - resistance [mbar/l/s]

9

# **Event log**



All of the settings made, occurring alarms and events on the leon *plus* are displayed in the event log. Events can be displayed in a detailed view:

- display
  - coding
  - date
  - time
  - time difference to current time
  - event
- coding
  - alarms
- (→ "Alarm priorities" p. 191)
  - events

#### Possible events



Turning device on/off



Start/stop of a ventilation



Change of form of ventilation



Change of ventilation parameters



Change of alarm limits



Fresh gas, carrier gas changes (only for the leon *plus*)



Calibrations

P

The event log can only be viewed in standby.

# Measured values in a numerical display

### Monitoring ventilation measured values and calculated values I





The following measured values of the ventilation are displayed for monitoring:

- pressures
  - peak pressure P<sub>Peak</sub> [mbar]
  - mean pressure P<sub>Mean</sub> [mbar]
  - plateau pressure P<sub>Plateau</sub> [mbar]
  - PEEP [mbar]
  - CPAP [mbar]
- Volumina
  - exp. breath minute volume [l/min]
  - insp. breath volume V<sub>Ti</sub> [ml]
  - exp. breath volume V<sub>Te</sub> [ml]
- frequencies
  - ventilation frequency Freq. [1/min]
  - breath frequency via CO<sub>2</sub> Freq.<sub>CO2</sub> [1/min]
  - breath frequency spontaneous Freq.<sub>Spont.</sub>[1/min]
  - share of spontaneous breaths %Spont. [%]
  - inspiration time of spontaneous breaths  $T_i \, \text{Spont.} \, [s]$
- calculated values I
  - leak [%]
  - MAC
  - compliance (static [mbar/ml], dynamic [mbar/ml])
  - C20/C
  - resistance [mbar/l/s]

8 values are displayed on each of two pages, if desired (configurable). 4 values in the upper section of the monitoring window are displayed larger. This is where the important measured values should be positioned. These 4 measured values are the same on both pages.

 In MAN/SPONT the monitoring values after elapse of the apnoea time switch to −−.−.

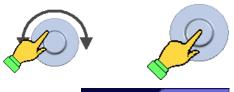


# Control element Monitoring ventilation and calculated values I

**1.** Focus the window.



2. Select the measured value in the window.



- 3. Change the value.
- 4. Confirm the entry.



- **5.** Call up the measured values on page 1 or 2.
- The monitoring window can only be selected via the touchscreen.

Table 37: Range and resolution of the numerically displayed measured values

		, , ,			
Measured value		Range	Resolution		
MV [l/min]		0-50	0.1		
	A 1 11 15)A/	0-1000	10		
.,	Adult, IBW	1000-5000	50		
$V_{Ti}$ [ml] and $V_{Te}$ [ml]	2	0-100	1		
	Child	100-5000	10		
P <sub>peak</sub> [mbar]		-50-200	1		
P <sub>Plateau</sub> [mbar]		-50-200	1		
P <sub>mean</sub> [mbar]		-50-200	1		
PEEP [mbar]		-50-200	1		
CPAP [mbar]		-50-200	1		
Freq. [1/min]		0-300	1		
Freq. <sub>Spont.</sub> [1/min]		0-300	1		
Freq. <sub>CO2</sub> [1/min]		0-100	1		
T <sub>i</sub> Spont [s]		0-10	0.1		
MAC		0-10	0.1		
Compl. stat. [ml/mba	r]	0-1000	1		
Compl. dyn. [ml/mba	r]	0-1000	1		
C20/C		0-200	1		
Resist. [mbar/l/s]		0-1000	1		
%Spont. [%]		0-100	1		
Leak [%]		10-100	1		

## monitoring:calculated values II

The following ventilation values that are calculated via the settings are displayed:



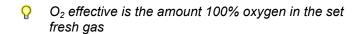
- Blender
  - O<sub>2</sub> effective [ml/min] o. [l/min]



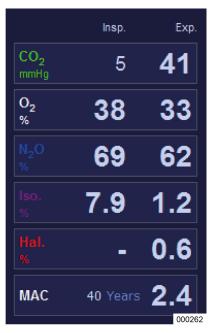
- I:E ratio
  - T<sub>insp.</sub> [s]
  - T<sub>exp.</sub> [s]
  - I:E



- Volume
  - MV (only if a V<sub>Ti</sub> can be adjusted as a



#### Gas measurement



The following inspiratory and expiratory gas measured values are displayed for monitoring:

- $CO_2$
- O<sub>2</sub> or FiO<sub>2</sub>
  - $N_2O$
- volatile anaesthetics
  - halothane
  - enflurane
  - isoflurane
  - sevoflurane
  - desflurane

The measurement of O<sub>2</sub>, N<sub>2</sub>O and volatile anaesthetics is optional.

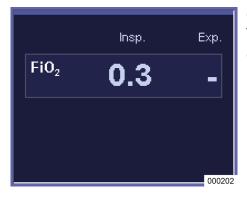
Volatile anaesthetics (inspiratory and expiratory) can be optionally detected and displayed automatically from a concentration of 0.15% (auto ID automatic anaesthesia gas measurement.)

In the gas measurement window the age for the MAC value calculation is given.

Anaesthesia gases are colour-coded:

halothane: red
enflurane: orange
isoflurane: purple
sevoflurane: yellow
desflurane: blue

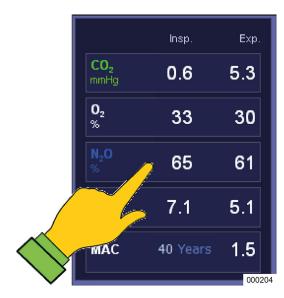
- The detection of a second narcotic gas only happens if the gas measurements is equipped with an automatic narcotic gas identification.
- It is possible that the gas measurement displays wrong measured values for halothane, even though it is not deployed as a volatile anaesthetic. This phenomenon appears with greater frequency during low-flow anaesthesia. Methane is produced through microbial fermentation of carbohydrates and is expelled from the body via the lungs. Methane absorbs at the same wavelength as halothane and thus has an influence on the determination of the halothane concentration.
- The deployment of alcohol-containing cleaning products can also falsify the measurement.



# Gas measurement only with FiO<sub>2</sub> measurement window

Only inspiratory FiO<sub>2</sub> is displayed for monitoring.

# **Entry of age for MAC calculation**



The display of the MAC value and the age entry to be calculated take place in the gas measurement window.

1. Focus the gas measurement window.



- $\textbf{2.} \ \ \text{Select the } \textbf{MAC} \ \text{field in the window}.$
- 3. Change the value.
- **4.** Confirm the entry.

# Manual selection of the narcotic gas

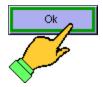


If the multi gas analyser is not equipped with an automatic narcotic gas identification, the selection is carried out via the gas measurement window. The adjacent dialogue opens by touching the field in which the narcotic gas concentration is displayed. The last narcotic gas set is displayed in the gas measurement window by default.

**1.** Focus the gas measurement window (field narcotic gas concentration display).



2. Select the narcotic gas button in the window.



**3.** Confirm the entry with the **OK** button.



Wrong selection of narcotic gas!

#### Death or permanent injury of the patient

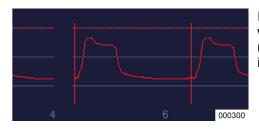
#### **CAUTION**

Through wrong manual selection, the narcotic gas concentration is no longer correct.

• Be sure to make the precisely correct selection!

9

## **Detection of triggered breaths**



In the S-IMV, S-PCV and PSV forms of ventilation, in which the patient can trigger a mechanical breath, the moment of triggering can be marked by a vertical line in the real-time charts in the relevant chart colour.

## **Loops (monitoring of lung function)**

#### Three loops window



To monitor the lung function, three loops can be displayed at the same time:

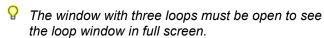
- Flow over volume
- Volume over pressure
- Flow over pressure



With this button, you can open or close the window with three loops, or close the full screen with one loop.



With this button, you can open one of the three loop windows in full screen.





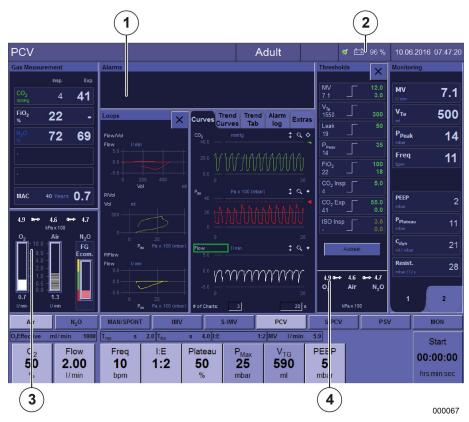
With this button, you can close the full screen window or the window with three loops.

Other control elements:

(→ "Table 11: Icons/screen (control elements)" p. 42)

(→ "Table 12: Icons/screen (buttons)" p. 42)

## 10. Monitoring of device functions

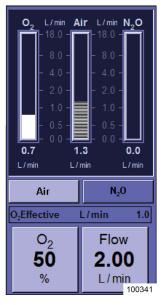


The following functions are displayed on the screen for monitoring:

- fresh gas blender
- batteries
- drive gas supply
- gas supply pressures
- supply pressures 10 L bottles
- reserve gas bottle operation (only as alarm message)
- drive gas generator (only as alarm message)
- gas measurement (only as alarm message)
- fresh gas shortage (only as alarm message)
- patient module (only as alarm message)
- CO<sub>2</sub> absorber (only as alarm message)
- fans (only as alarm message)
- (1) alarm messages
- (2) batteries
- (3) fresh gas blender
- (4) gas supply pressures
- (→ "Errors and measures" p. 228)

## Fresh gas blender

### Intact fresh gas blender

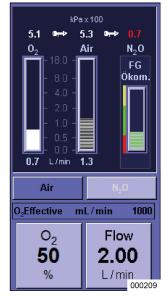


With an intact fresh gas blender there is a graphic display within the tube of the flowing  $O_2$ , AIR and  $N_2O$  amounts.

The following buttons are active:

- Selection of carrier gas
- Setting of the percentage share of oxygen on the fresh gas flow
- · Fresh gas flow
- The inlet pressures of the gases for the fresh gas blender must be at least 1.1 kPa × 100 (bar). Otherwise, the gas is deactivated.

# Fresh gas blender in the event of failure of a carrier gas



The button for the selection of the failed gas ( $N_2O$  here) as carrier gas is greyed out. The gas must no longer be used as a carrier gas. In the event of ZGA failure,  $N_2O$  and  $O_2$  can be made available via reserve gas bottles. If AIR fails,  $O_2$  is used as carrier gas.

- P Requirement for reserve gas bottle operation:
  - Reserve gas bottles available
  - Reserve gas bottles sufficiently filled
  - Reserve gas bottles opened

## Display of damaged fresh gas blender



If the blender fails, the buttons for the selection of AIR or  $N_2O$  as carrier gas, the button to set the flow and the button to set the percentage  $O_2$  share in the fresh gas are greyed out. AIR and  $N_2O$  must no longer be used as carrier gases.

- the buttons to set the percentage share of O<sub>2</sub> in the fresh gas flow and the fresh gas flow are inactive
- the fresh gas flow to the system, consists of 100% O<sub>2</sub>, can only be regulated via O<sub>2</sub> emergency dosing
- If the blender fails: Set the O₂ emergency dosing to the desired fresh gas flow. Check the anaesthetic vaporiser setting, as the fresh gas flow has changed
- The button on the keyboard for focusing the fresh gas blender window is inactive.

## Gas supply pressures



The gas supply pressures are displayed in the lower section of the **Threshold** window In addition, there is a display in the fresh gas blender window.

(→ "Fresh gas blender" p. 183)



You can open the **Threshold** window with this button.





You can close the **Threshold** window with both of these buttons.

## **Central gas supply pressures**



WARNING

No central gas supply

## Risk of undersupply of oxygen

- Open the reserve gas bottles on the rear.
- Switch to manual ventilation.



#### Pressure display with intact central gas supply

With an intact ZGA the pressures of the central gas supply are displayed in white on the bottom of the Threshold window.

The supply plug icon marks that the pressure of the ZGA is displayed.



An ZGA gas is judged available if its pressure is over 1.1 kPa × 100 (bar). Below 2.5 kPa × 100 (bar) counts as too low.



#### Pressure display when no central gas supply

With no ZGA the pressures of the central gas supply are displayed in red.

If the leon *plus* is supplied with fresh gas from 2 L or 3 L gas bottles only, this is only marked by a message in the alarm window.



If only 2 L or 3 L reserve gas bottles are attached, AIR is not available as a drive gas. Ventilation is only possible in the MAN/SPONT form of ventilation. The reserve bottle pressure can be read from the manometers on the front of the leon plus.



 $\{ ( \rightarrow "O_2, flush, vacuum, manometers" p. 53). \}$ 

## Pressure display when supply from 10 L bottles



If the leon *plus* is supplied with gas by 10 L gas bottles and the pressure of the bottles is monitored, this is marked by a gas bottle icon ( $\rightarrow$  "10 L bottle connection instead of ZGA" p. 70). The value (40 kPa × 100 (bar)) next to the bottle icon is the pressure of the 10 L bottle. The value next to the supply plug icon (4.0 kPa × 100 (bar)) displays the pressure at the gas inlet of the leon *plus*.

The following combinations can be attached as 10 L bottles:

- O<sub>2</sub> only
- N<sub>2</sub>O only
- AIR only
- O<sub>2</sub>, AIR
- O<sub>2</sub>, N<sub>2</sub>O
- If attached 10 L bottles do not contain any AIR, O₂
   is used as the drive gas.
- An AIR or  $O_2$  bottle is judged full if its pressure is over 120 kPa × 100 (bar), and the  $N_2O$  over 40kPa × 100 (bar).
- The bottle icon with pressure of the 10 L bottle is only displayed if it is configured in the service (→ "Gas supply" p. 106).

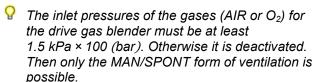
## **Drive gas generator**

If the drive gas generator fails, the buttons for selecting mechanical forms of ventilation are inactive. The device switches automatically to the MAN/SPONT form of ventilation. Alarm message "Driving gas blender failed. Only Man/Spont possible" is given.



#### AIR as drive gas

AIR is used as the drive gas by default (fresh gas supply via the ZGA. If the leon *plus* is supplied with fresh gas via  $10 L O_2$  gas bottles and AIR, AIR is used as the drive gas.





#### O<sub>2</sub> as drive gas

If AIR fails as the drive gas (fault in the ZGA), or if the leon plus is supplied with fresh gas via 10 L  $O_2$  and  $N_2O$  gas bottles,  $O_2$  is used as the drive gas.

If AIR is not available as the drive gas and O<sub>2</sub> runs in the reserve gas bottle operation, only one ventilation is possible in the MAN/SPONT form of ventilation.

#### Gas measurement

The following are monitored:

- gas measurement failure
- O<sub>2</sub> calibration
- occlusion of gas measurement bag
- change of water trap



Calibration is carried out automatically during operation.



Gas measurement failure

## Undersupply of oxygen

CAUTION

 External monitoring, monitoring of the O<sub>2</sub>, CO<sub>2</sub> and anaesthesia gas concentration

## Fresh gas shortage

The filling of the system is monitored visually. In the event of a fresh gas shortage (the "System running empty" due to a leak or because the patient needs more fresh gas than supplied), the alarm message "Fresh gas supply too small" is given.

## Docking station with patient module

The correct locking of the patient module on the device is monitored electrically. If the patient module on the docking station is not locked properly to the device, the alarm message "Patient module not locked. Ventilation stopped" is given.

## CO<sub>2</sub> absorber

The position of the CO<sub>2</sub> absorber is monitored electrically. If the absorber is not turned all the way to the stop, the alarm message "CO<sub>2</sub> absorber removed or not locked. Circulation system short-circuited" is given.

#### **Fans**

The maximum  ${\rm O_2}$  concentration in the housing of the leon *plus* should not exceed 25%. To guarantee this, the housing is ventilated with a fan. A useful side-effect is the cooling of the inside of the housing. If the fan fails, the alarm message "Fan failed" is given.

#### **Batteries**



#### Charging batteries (mains voltage available)

On the right of the title bar the plug icon appears in green as "Mains voltage available", the battery icon appears in white with the display of the charging status of the battery as a percentage.



#### **Battery operation**

On the right of the title bar the plug icon appears in white as "No mains voltage available", the battery icon appears in green with the display of the remaining life of the battery in minutes.



#### **Battery low**

In the title bar on the right the battery icon appears in yellow with the display of the remaining life as 10 minutes.



#### **Battery failure**

In the title bar on the right the battery icon appears in red as "Battery failure".



#### **Batteries not connected**

In the title bar on the right the battery icon appears struck through in red as "Battery not connected" or "Battery not available".



(→ "Mains supply failure" p. 247)

## Stopwatch



Stop 00:02:40 hrs:min:sec Reset 00:04:41 hrs:min:sec

The ope

Stopwatch Stopwatch Stopwatch start running stopped

There is a stopwatch on the right in the forms of ventilation and ventilation parameters window. The time measurement is carried out in hh:mm:ss format. The maximum clockable time is 99:59:59. The operation is as follows:

- Start: Briefly touch the stopwatch on the touchscreen
- Stop: Briefly touch the stopwatch on the touchscreen again
- Reset: Keep the stopwatch on the touchscreen pressed down for longer than two seconds
- Onfirmation is also possible via the rotary button.

### 11. Alarms

## **General information**



Caution! - The device may have other possible alarm limit settings or configurations as similar devices or the same type of device.

## Display of current alarms

#### Display of alarms on the screen



A maximum of four alarms can be displayed at the same time. The alarms have the following features:

- Priority
- Type
- Text
- Tone

They are arranged in priority sequence, corresponding to their effect on the function of the device within the same priority, in a window displayed above the tab system. Technical alarms and system alarms also have error numbers.





If there are more than four alarms at the same time, to display the others, the list can be scrolled down via buttons in the window.



The alarm limits of the measured values displayed as real-time curves are marked in a broken line in the curve colour concerned.

#### **Alarm priorities**

Table 38: Identification of alarm priorities

Priority	Colour Oval	Audible coding
high	red	continuous intermittent tone sequence
medium	yellow	intermittent tone sequence every 30 seconds
informative	pale blue	no tone sequence

The alarms are divided into three priorities. Each alarm is identified according to the priority by:

- a prefixed coloured oval
- tone (except for informative)

The alarms are arranged in a further six priorities within the same priority, according to their effect on the function of the device.

There are four alarms, which have an **informal** character in standby but have **high priority** during ventilation:

- O<sub>2</sub> emergency dosing active
- CO<sub>2</sub> absorber short-circuited
- no water trap
- patient module not locked

#### Alarm types

Table 39:	Alarm	types						
Туре	Code	triggered by	fixable by					
Patient P		Patient	- User					
System	S	Technical	User					
Techno- logy	Т	fault	Löwenstein Medical					

The alarms are divided into three types, depending on the cause and its fixability. Technical alarms and system alarms also have error numbers.



Please make a note of the error number before you notify a Löwenstein Medical-authorised service technician.

#### Alarm volume

(→ "Volume tab" p. 91)

### Saving alarm messages

All alarm messages are saved when the device is shut down (turned off). In the event of a power failure, the device switches automatically to battery operation and, if the power supply is not restored after a further 100 minutes, powers down independently with a message.

## **Factory settings of the alarms**

Table 40: Factory settings of the alarms

			Form of ventilation Child Adult													
				Ch	ild							Ad	lult			
Alarm	IMV	S-IMV	PCV	S-PCV	PSV	MAN/SPONT	HLM	MON	IMV	S-IMV	PCV	S-PCV	PSV	MAN/SPONT	НГМ	MON
insp. O <sub>2</sub> [%] high								10	00							
insp. O <sub>2</sub> [%] low								2	5							
insp. CO <sub>2</sub> [mmHg] high			5	.0				/			5	.0				1
exp. CO <sub>2</sub> [mmHg] high			50	.0							55	.0				
exp. CO <sub>2</sub> [mmHg] low				0								0				
insp. HAL [%] high			3	.0				/			3	.0			1	
insp. HAL [%] low				0 /					0							/
insp. ENF [%] high			5	.0				/			5	.0				/
insp. ENF [%] low				0				/				0				/
insp. ISO [%] high			3	.5				/			3	.5				/
insp. ISO [%] low				0				/	0							/
insp. SEV [%] high		3.5						/	3.5							/
Insp. SEV [%] low		0						/				0				/
insp. DES [%] high		10.0						/			10	.0				/
insp. DES [%] low				0				/	0 /							

Table 40: Factory settings of the alarms

	90 01	Form of ventilation														
						I	Form	of v	entil	latior	า					
				Cr	nild							Ad	lult			
Alarm	NM V	S-IMV	PCV	S-PCV	PSV	MAN/SPONT	HLM	MON	IMV	S-IMV	PCV	S-PCV	PSV	MAN/SPONT	HLM	MOM
FiO <sub>2</sub> [%] high			10	00	•	•		/		•	10	00	•	•	•	/
FiO <sub>2</sub> [%] low			2	25				/			2	25				/
Leak [%]			ţ	50				/			5	50			/	
Apnoea [s]				1		30	1	/		/ 30						/
MV [l/min] high			9	.0		/	1	/			12	.0		/	/	/
MV [l/min] low			2	.0		/	/	/			3	.0		/	/	/
V <sub>Te</sub> [ml] low			10	00				/				300				/
P <sub>Peak</sub> [mbar]	P <sub>max</sub>	P <sub>max</sub> + 5 P <sub>insp.</sub> + 10				35	/	/	P <sub>max</sub>	<sub>x</sub> + 5	Pir	nsp. +	10	40	/	/
CPAP [mbar]		1					20	/				/			20	/
Freq <sub>CO2</sub> high		1						100				1				100
Freq <sub>CO2</sub> low				/	_			4	1							4

## **Alarm muting**

### Alarm muting 2 minutes



Alarms muted!

#### Risk of undersupply of oxygen

Any alarms that occur are only displayed visually.

- Watch the ventilation, while the alarms are muted.
- Be extra vigilant.



The **Mute** button is positioned on the bottom right of the keypad. By pressing **Mute**, the audible alarm for all currently pending alarms is muted for two minutes. Re-pressing deactivates mute.



If Mute is activated, a minute counter appears in the title bar in mm:ss format, which displays the remaining mute time.

(→ "Mute 2 min." p. 52)

- High or medium-prioritised alarms are audibly renewed every 120 seconds.
- If during the mute time a new alarm with higher priority than the existing alarm appears the alarm sounds immediately. Mute is lifted.
- If during the mute time a new alarm with the same or lower priority than the existing alarm appears the alarm does not sound until the mute time has elapsed. This behaviour applies only to alarms of medium and informative priority. Higher priority alarms always go through. Mute is then lifted.
- If during the mute time there is no alarm the mute function is cancelled early. The next alarm to appear sounds according to its priority.
- Informative priority alarms are deleted from the alarm window if the Mute button is pressed.

## 10 minute alarm muting



#### Alarms muted!

#### Risk of undersupply of oxygen

Any alarms that occur are only displayed visually.

- Watch the ventilation, while the alarms are muted.
- Be extra vigilant.



In the MAN/SPONT form of ventilation, an adjacent screen dialogue appears, if the Mute button is pressed for longer than 2 seconds. If the dialogue is confirmed with Yes, all alarms are muted for 10 minutes. Re-pressing of the button deactivates mute.



In the title bar ( $\rightarrow$  "Mute 10 min." p. 52) a minute counter appears in the title bar in mm:ss format, highlighted in red, which displays the remaining mute time.



System alarms and technical alarms are audibly sounded and mute is reset.

## **Alarm log**



- **1.** Select the appropriate tab to call up the alarm log. All alarms are stored and saved chronologically in the alarm log. Before each alarm text the appearance and time difference to the current time are displayed. They are given a coloured oval according to their priority (→ "Alarm priorities" p. 191) and a suffix according to their type (→ "Alarm types" p. 191). The window can be scrolled if its size is not sufficient to display all of the occurring alarms.
- If the device is shut down properly, the data are kept and available on restart. The shutdown time of the device is also logged. In the event of a complete mains failure, data that have been added since the last proper shutdown are not lost.
- If the capacity limit of the alarm log store is reached, the oldest data are deleted (fifo)
- The alarm log can only be seen during the ventilation. In standby it is part of the event log.

**Alarms** 

## **Limit values (patient alarm limits)**

## Setting patient alarm limits manually

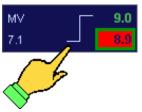


This window can only be opened via a button on the keyboard. After opening, the current active alarm is selected. If an alarm is active and the window is already open, this alarm must be manually selected.

- (1) Medium priority alarm exceeded (value in yellow)
- (2) High priority alarm exceeded (value in red)
- (3) Currently selected alarm (highlighted according to the colour of its priority)
- (4) Unexceeded alarm (value in green)
- (5) Inactive alarm (value in brown)
- (→ "Active alarms" p. 202)



**1.** To edit alarm limits, open the Thresholds window.



If the window is already open, focus it, select an alarm in the window and set the upper and lower alarm limits.



- **3.** Set the parameters.
- 4. Confirm the entry.



5. Close the window.



## Further control elements in the Thresholds window:

Adapting active alarms to the current measured value. (→ "Adjusting alarm limits to current measured value (autoset)" p. 201)

## Adjustable alarm limits

The following alarm limits can be adjusted in the window:

#### Pressures

- P<sub>aw</sub> ventilation pressure
- CPAF

#### Volume

- expiratory MV breath minute volume
- expiratory V<sub>Te</sub> breath volume

#### Patient gases

- CO<sub>2</sub> (inspiratory and expiratory)
- O<sub>2</sub> (inspiratory)/ FiO<sub>2</sub>
- volatile anaesthetics (inspiratory)
  - halothane
  - enflurane
  - isoflurane
  - sevoflurane
  - desflurane

#### Leak

#### Apnoea

Freq<sub>CO2</sub>

## Display of apnoea duration



In the MAN/SPONT form of ventilation, the time that has passed since the last breath (apnoea duration) is shown at the bottom left of the Limit Values window under the entry "Apnoea".

The adjustable alarm limit for "Apnoea" is on the bottom right.

P

In the MAN/SPONT form of ventilation, the MV minute volume is not displayed as a limit value.

## Application area and increment of alarm

Table 41: Application area and increment of alarm

			Form of ventilation  Child Adult														
					Ch	ild							Ad	lult			
Alarm	Increment	IMV	S-IMV	PCV	S-PCV	PSV	MAN/SPONT	MON	HLM	NM.	S-IMV	PCV	S-PCV	PSV	MAN/SPONT	MON	HLM
insp. O <sub>2</sub> [%] high	1			1	19–99	9			1				19–9	9			1
insp. O <sub>2</sub> [%] low	1			1	18–98	8			1				18–9	8			1
insp. CO <sub>2</sub> [%] high	0.1			0-	1.5			1	1			0–	1.5			1	1
exp. CO <sub>2</sub> [%] high	0.1			0	).1–1	0			1			1					
exp. CO <sub>2</sub> [%] low	0.1			(	0–9.9	)			/			1	1				
insp. HAL [%] high	0.1			0.1	-10			1	/			0.1	<b>–10</b>			1	1
insp. HAL [%] low	0.1			0-	9.9			1	/			0-	9.9			1	1
insp. ENF [%] high	0.1			0-	10			1	/			0-	-10			1	1
insp. ENF [%] low	0.1			0-	9.9			1	/			1	1				
insp. ISO [%] high	0.1			0.1	-10			1	1			0.1	-10			1	1
insp. ISO [%] low	0.1			0-	9.9			1	1			0-	9.9			1	1
insp. SEV [%] high	0.1			0.1	-10			1	/			0.1	-10			1	1
insp. SEV [%] low	0.1			0-	9.9			1	/			0-	9.9			1	1
insp. DES [%] high	0.1		0.1–22						/	0.1–22							1
insp. DES [%] low	0.1		0–21.9						/	0–21.9 /							1
FiO <sub>2</sub> [%] high	1		19–99						/			19-	-99			1	1
FiO <sub>2</sub> [%] low	1		18–98						/			18-	-98			1	1
Leak [%]	1			10-	100			1	/		1	1					

Table 41: Application area and increment of alarm

		Form of ventilation  Child Adult															
					Cł	nild							Ad	lult			
Alarm	Increment	IMV	S-IMV	PCV	S-PCV	PSV	MAN/SPONT	MON	HLM	IMV	S-IMV	PCV	S-PCV	PSV	MAN/SPONT	MON	HLM
Apnoea [s]	1		1					/	1			/			10-60	/	/
MV [l/min] high	0.1		0.2–30					1	1	0.2–30					1	1	/
MV [l/min] low	0.1		0.	1–19	.9		1	1	1	0.1–19.9						1	/
V <sub>Te</sub> [ml] low	10		1	0–60	0		1	1	1	50–1600					1	1	/
P <sub>Peak</sub> [mbar]	1	P <sub>max</sub> + 5	- 85	PEEP + 5		P <sub>insp.</sub> + 10	10–85	1	1	Pmax + 5 - 85 - 85 PEEP + 5 - 7					10–85	1	/
CPAP [mbar]	1			ı	/			2-60	2-60			,	/			2-60	2-60
Freq <sub>CO2</sub> high	1							1-100		5						1–100	
Freq <sub>CO2</sub> low	1							66-0								66-0	

# Adjusting alarm limits to current measured value (autoset)

The alarm limits for the following measured values can be adjusted via autoset:

Table 42: Autoset alarms

					Foi	m of v	entilat	ion				
			Ch	ild					Ad	lult		
Alarm	IMV	S-IMV	PCV	S-PCV	PSV	MAN/SPONT, MON, HLM	IMV	S-IMV	PCV	S-PCV	PSV	MAN/SPONT, MON, HLM
MV [l/min] high	V <sub>Te</sub> ×	f × 1,4	MV × 1,4			/	V <sub>Te</sub> ×	f × 1,4	N	/IV × 1,	4	,
at least	2	.0		2.0		1	2	.0		2.0		,
MV [l/min] low	V <sub>Te</sub> ×	f × 0,6	N	/IV × 0,0	6	/	V <sub>Te</sub> ×	f × 0,6	N	/IV × 0,0	6	,
at least	0	.5		0.5		,	0	.5		0.5		,
V <sub>Te</sub> [ml] low		\	√ <sub>Ti</sub> × 0,6	6		1		\	/ <sub>Ti</sub> × 0,6	6		/
P <sub>peak</sub> [mbar]	P <sub>max</sub> + 5		5 P <sub>plateau</sub> + 10 /				P <sub>max</sub> + 5 P <sub>plateau</sub> + 10					1

O

The alarm limit is automatically adjusted only if the set alarm limit is exceeded.

## Alarm limits that are automatically followed

Table 43:	automatically followed	d alarms
Alarm	Range (adjustable in the service)	Increment
P <sub>Peak</sub> [cm H <sub>2</sub> O]	P <sub>insp.</sub> + 5 - P <sub>insp.</sub> + 30	1

To avoid alarms being triggered by deliberate settings, the pressure-controlled form of ventilation of the  $P_{\text{Peak}}$  pressure alarm is automatically followed:

P<sub>Peak</sub> airway pressure alarm during changes of P<sub>insp.</sub> with pressure-controlled forms of ventilation

#### **Active alarms**

Only certain alarms are active depending on whether the ventilation is mechanical or manual, or the patient breathes spontaneously. Inactive alarms are displayed as brown in the Threshold window.

(→ "Setting patient alarm limits manually" p. 197) To mute alarms see:

(→ "Alarm muting" p. 194)

Table 44: active alarms

		active										
Alarm	IMV, PCV, S-IMV, S-PCV, PSV	MAN/SPONT	HLM	MON								
insp. O <sub>2</sub> [%] high	immediately after the start of a ventilation	immediately after the start of the ventilation	no	immediately after the start of the ventilation								
insp. O <sub>2</sub> [%] low	30 seconds after the start of a ventilation	30 seconds after the start of the ventilation	no	30 seconds after the start of the ventilation								
insp. CO <sub>2</sub> [%] high	after the first detection of a breath	after the first detection of a breath	no	is not displayed								
exp. CO <sub>2</sub> [%] high/low	immediately after the start of a ventilation	immediately after the start of the ventilation	no	immediately after the start of the ventilation								
vol. insp. anaesthetic [%] high/low	after the first detection of a breath	after the first detection of a breath	no	is not displayed								
FiO <sub>2</sub> [%] high	immediately after the start of a ventilation	immediately after the start of the ventilation	no	is not displayed								

## Table 44: active alarms

		active				
Alarm	IMV, PCV, S-IMV, S-PCV, PSV	MAN/SPONT	HLM	MON		
FiO <sub>2</sub> [%] low	30 seconds after the start of a ventilation	30 seconds after the start of the ventilation	no	is not displayed		
MV [l/min] low	30 seconds after the start of a ventilation	is not displayed	is not displayed	is not displayed		
MV [l/min] high	immediately after the start of a ventilation	is not displayed	is not displayed	is not displayed		
V <sub>Te</sub> [ml] low	30 seconds after the start of a ventilation	no	no	is not displayed		
P <sub>peak</sub> [mbar]	immediately after the start of a ventilation	immediately after the start of the ventilation	is not displayed	is not displayed		
CPAP [mbar]	is not displayed	is not displayed	immediatel y after the start of the ventilation	immediately after the start of the ventilation		
Leak [%]	30 seconds after the start of a ventilation	30 seconds after the start of a ventilation	no	is not displayed		
Apnoea [s]	is not displayed  30 seconds a the start of the ventilation		is not displayed	is not displayed		
Freq <sub>CO2</sub> high/low	is not displayed	is not displayed	is not displayed	immediately after the start of the ventilation		

## List of alarm messages

Table 45: List of all alarm message (alphabetical)

					<b>D</b>			1/0		) = in 1 = a an be	ctive		ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue Medium, High)	Code (Patient, Technical, System)
Air failed. Fresh gas at 100% O <sub>2</sub>	177	Air supply failed	Restore air supply ZGA	< 1.1 bar	2 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	I	S
Air and N <sub>2</sub> O failed Fresh gas O <sub>2</sub>	183		Restore air and N <sub>2</sub> O supply	AIR < 1.1 bar N₂O < 1.1 bar	2 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	I	S
Air supply failed	178		Restore air supply ZGA	AIR < 1.1 bar	2 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	I	S
Air ZGA input pressure too high	160		Check ZGA compressed air	AIR > 7.5 bar	> 10 s	0	1	1	1	1	1	1	1	1	1	I	S
Battery empty	133	0 min. reached	Restore mains supply. Not possible during operation. Only resettable via reboot	1 min	-	0	1	1	1	1	1	1	1	1	1	Н	S

Table 49. List of all	alali	ii iiiessaye (aipiiabei	ioai)														
					<u> 6</u>			1/0		1 = a	active ctive deac		ed			jue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue, Info, Medium, High)	Code (Patient, Technical, System)
Battery empty	134	Battery voltage < 21V	Battery empty, only MAN/SPONT possible	22.1 V	> 20 s	0	1	1	1	1	1	1	1	1	1	Н	S
Battery fail. Please	1	Battery erroneous	Replace / repair	-	-	0	1	1	1	1	1	1	1	1	1	М	T
replace.	2	Battery charge / monitoring hardware fail				0	1	1	1	1	1	1	1	1	1	M	Т
Batteries erroneously connected or damaged	3	Batteries not correctly connected	Batteries correctly connected	-	-	0	1	1	1	1	1	1	1	1	1	M	T
Batteries almost	131	Battery life < 10 Min	Restore mains	11 min	-	0	1	1	1	1	1	1	1	1	1	М	S
empty	132	Battery voltage too low	supply.	22.5 V	> 20 s	0	1	1	1	1	1	1	1	1	1	М	S
Batteries deep discharged. Please calibrate.	41	Battery deep discharged/damaged (capacity reduced)	Change batteries	-	-	1	0	0	0	0	0	0	0	0	0	М	Т
Alarm log full. Oldest entries deleted.	191	-	-	1000	-	1	1	1	1	1	1	1	1	1	1	I	S

Table 45: List of all alarm message (alphabetical)

					5)			1/0		) = in: 1 = a an be	ctive		ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MOM	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
Apnoea	354	No breath detected for a long period	Check ventilation tube system	(→ "Application area and increment of alarm" p. 199)	-	0	0	1	0	0	0	0	0	0	0	Н	Р
Apnoea backup breath was triggered		Backup breath in the PSV mode was emitted (apnoea)	Patient not triggered, forced breath is triggered by machine	-	-	0	0	0	0	0	0	0	1	0	0	I	Р
Apnoea CO <sub>2</sub>	353	Disconnection AION/IRMA	Check tube system gas measurement	-	-	0	0	1	0	0	0	0	0	0	1	Н	Р
Gas measurement calibration needed	81	Measurement (probably) wrong	Not possible during operation. Can only be reset via reboot (possible replacement/ repair)	-	-	0	1	1	1	1	1	1	1	1	1	Н	T

Table 45: List of all alarm message (alphabetical)

					ĵ.			1/0		1 = a	active ctive dead		ed			<b>(D</b> ialogue, <b>I</b> nfo, , <b>H</b> igh)	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialog Medium, High)	Code (Patient, Technical, System)
FiO <sub>2</sub> Sensor Fail. Please change cell.	18	Voltage O <sub>2</sub> cell too small. Old cell	Change cell	75 ADC	6 s	0	1	1	1	1	1	1	1	1	1	Н	Т
Gas measurement failed	82	Broken Artema AION	Replace / repair	-	-	1	1	1	1	1	1	1	1	1	1	Н	Т
Blender failed. Turn on emergency dosing!	72	Fresh gas flow too high	Successful check in system test	170 (not for V < 2 % // min)	120 s	0	1	1	1	1	1	1	1	1	1	Н	Т
uosiiig:	73	Fresh gas flow too low		30 (not for $\dot{V}$ < 2 I/ % min)	120 s	0	1	1	1	1	1	1	1	1	1	Н	Т
	76	FG blender check O <sub>2</sub> in system test failed		-	-	0	1	1	1	1	1	1	1	1	1	Н	T
	80	FG flow measurement disconnected. Cable for FG blender valves probably also pulled out -> fail FG dosing		< 20 ADC	30 s	0	1	1	1	1	1	1	1	1	1	Н	Т
O <sub>2</sub> measurement failed. Please calibrate O <sub>2</sub> Cell.	135	The Servomex sensor must be calibrated (together with the gas measuring bench)	measurement	-	-	0	1	1	1	1	1	1	1	1	1	Н	S

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Table 45: List of all alarm message (alphabetical)

Table 45. List of all	alall	n message (alphabet	ilcai)	T	1	ı											
					Bu		T	1/0		) = ina 1 = a in be	ctive		ed			gue, Info,	tem)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue, Info, Medium, High)	Code (Patient, Technical, System)
No driving gas. Only MAN/SPONT possible	165	No driving gas for mechanical ventilation	Successful check in system test	O <sub>2</sub> < 1.5 Bar AIR < 1.5 bar	2 s	0	1	1	1	1	1	1	1	1	1	Ι	S
pocoibie	166	No driving gas for mechanical ventilation		O <sub>2</sub> < 1.1 bar	2 s	0	1	0	1	1	1	1	1	0	0	Н	S
No driving gas. Only MAN/SPONT possible.	69	Drive gas blender check in system test failed	Successful check in system test	-	-	0	1	1	1	1	1	1	1	1	1	Н	Т
No driving gas blender. Only MAN/SPONT possible.	79	No driving gas supplied (drive gas blender failed, disconnected/dropped off drive gas tube, blockage drive gas channel)	Successful drive gas blender check in system test	$\begin{aligned} V_{Ti} < 3 \text{ mI} \\ \dot{V}_{max,} < 500 \text{ mI/min} \\ P_{max}\text{-}p_{Peep} < 1 \text{ mbar} \\ V_{Te} \ge V_{Ti} \times 0,5 \text{ \%} \end{aligned}$	5 breaths	0	0	0	1	1	1	1	1	0	0	Ι	Т
Ventilation and fresh gas stopped.	45	If the error is not fixed by a restart or it is repeated, make a note of the error number and notify a Löwenstein Medical- authorised technician	Not possible during operation. Only resettable via reboot Use the O <sub>2</sub> emergency dosing		-	1	1	1	1	1	1	1	1	1	1	Н	T
Checksum error	84	Wrong or erroneous file	Reinstall software	-	-	1	1	1	1	1	1	1	1	1	1	Н	Т

Table 45: List of all alarm message (alphabetical)

					5			1/0		1 = a	active ctive dead	_	ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	нгм	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
CO <sub>2</sub> absorber removed. Circle	148	CO <sub>2</sub> absorber was removed. Circle	Fit absorber	-	-	0	0	1	1	1	1	1	1	1	1	Н	S
system short- circuited.	149	system short-circuited				0	1	0	0	0	0	0	0	0	0	I	S
Expiratory CO <sub>2</sub> high	312		Change ventilation	(→ "Application area and increment of alarm" p. 199)	3 breaths	0	0	1	1	1	1	1	1	0	1	Н	Р
Expiratory CO <sub>2</sub> low	313	Expiratory CO <sub>2</sub> too low	parameters			0	0	1	1	1	1	1	1	0	1	М	Р
Inspiratory CO <sub>2</sub> high	311	Inspiratory CO <sub>2</sub> too high				0	0	1	1	1	1	1	1	0	1	Н	Р
Insp. DES too high	322	Inspiratory desflurane too high	Change vaporiser setting			0	0	1	1	1	1	1	1	0	1	Н	Р
Insp. DES too low	323	Inspiratory desflurane too low				0	0	1	1	1	1	1	1	0	1	М	Р

Table 45: List of all alarm message (alphabetical)

					5			1/0		1 = a	active ctive dead		ed			ue, Info,	(me
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	нгм	MOM	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
Disconnection. Check circulation system.	350	Circulation system not connected (inspiratory)	Check ventilation circulation system	3 mbar	2 breaths	0	0	0	1	1	1	1	1	0	0	Н	Р
	351	Circulation system not connected (expiratory)		<peep +2="" mbar<="" setting="" td=""><td>2 breaths</td><td>0</td><td>0</td><td>0</td><td>1</td><td>1</td><td>1</td><td>1</td><td>1</td><td>0</td><td>0</td><td>Н</td><td>Р</td></peep>	2 breaths	0	0	0	1	1	1	1	1	0	0	Н	Р
	352	Circulation system not connected (between y-piece and tube or between tube and patient)		V > 2000 (adult) ml V > 700 (child) if (p <sub>peak</sub> − PEEP setting) < 7 mbar	2 breaths	0	0	0	0	0	1	1	1	0	0	Н	Р
	357	Circulation system not connected (Flow)		V <sub>Te</sub> < 25% of V <sub>Ti</sub> % PEEP < 2 mbar	-	0	0	0	1	1	1	1	1	0	0	Н	Р
Encoder without function	85	Encoder is without function	Not possible during operation. Only resettable via reboot	-		1	1	1	1	1	1	1	1	1	1	Н	T

Table 40: Elst of all	aiaii	ii iiiessage (alpiiabet	lioui)														
					5			1/0		) = ina 1 = a in be	ctive		ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MOM	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
Set pressure P <sub>insp</sub> not reachable.	307	Pressure not reached	Change ventilation	-	2 breaths	0	0	0	0	0	1	1	1	0	0	М	Р
Set volume V <sub>Ti</sub> not reachable.	305	Volume not reached	parameters			0	0	0	1	1	0	0	0	0	0	М	Р
ENF insp. too high	316	Inspiratory enflurane too high	Change vaporiser setting/	(→ "Application area and increment of alarm" p. 199)	3 breaths	0	0	1	1	1	1	1	1	0	1	Н	Р
Insp. ENF too low	317	Inspiratory enflurane too low				0	0	1	1	1	1	1	1	0	1	М	Р
Exhalation condition not reached	302	in the PSV not	Change ventilation parameters	25% of V <sub>max</sub> .	2 breaths	0	0	0	0	0	0	0	1	0	0	1	Р
External fresh gas active	112	Manual switch-over of external Fresh gas	Set external fresh	-	-	0	1	1	0	0	0	0	0	1	1	I	S
active	113	outlet	yas io o			0	0	0	1/0	1/0	1/0	1/0	1/0	0	0	Н	S

Table 45: List of all alarm message (alphabetical)

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					ත			1/0		) = ina 1 = a in be	ctive		ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
Check external O <sub>2</sub> measurement	229	No oxygen measurement patient	Enable external O <sub>2</sub> measurement (fit O <sub>2</sub> cell)	-	30 s	1	0	0	0	0	0	0	0	0	0	I	S
Failure during communication with VueLink	193	VueLink connection available but data incorrectly transferred	Receive valid requests/ VueLink deactivated	-	-	0	1	1	1	1	1	1	1	1	1	I	S
Calibrate FiO <sub>2</sub> cell	140	FiO <sub>2</sub> sensor uncalibrated or incorrectly calibrated	Calibrate cells	105 %	> 3 s	0	1	1	1	1	1	1	1	1	1	Н	S
FiO₂ too high	331	Insp. Oxygen concentration too high		(→ "Application area and increment of alarm" p. 199)	3 breaths	0	0	1	1	1	1	1	1	0	0	М	Р
FiO₂ too low	330	Inspiratory oxygen concentration too low	parameters			0	0	1	1	1	1	1	1	0	0	Н	Р
Flow and volume measurement not possible.	66		Successful check in system test	V < = 15 ADC	90 s	0	0	0	1	1	1	1	1	0	0	Н	Т

					<del>ن</del>			1/0		) = in 1 = a an be	ctive		ed			( <b>D</b> ialogue, Info, , High)	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialog Medium, High)	Code (Patient, Technical, System)
FreqCO <sub>2</sub> too high	360	Resp. rate too high	-	100 1/min	-	0	0	0	0	0	0	0	0	0	1	Н	Р
FreqCO <sub>2</sub> too low	361	Resp. rate too low	-	0 1/min	-	0	0	0	0	0	0	0	0	0	1	Н	Р
Fresh gas shortage	341		Increase fresh gas flow	-	5 breaths	0	0	0	1	1	1	1	1	0	0	Н	Р
Gas measurement unreliable	136	be guaranteed.	Not possible during operation. Can only be reset via reboot (possible replacement/ repair)	-	-	0	1	1	1	1	1	1	1	1	1	М	S
Insp. HAL too high	314	Inspiratory halothane too high	Change vaporiser setting	(→ "Application area and increment of alarm" p. 199)	3 breaths	0	0	1	1	1	1	1	1	0	1	Н	Р
Insp. HAL too low	315	Inspiratory halothane too low				0	0	1	1	1	1	1	1	0	1	M	Р
Insp. ISO high	318	Inspiratory isoflurane too high				0	0	1	1	1	1	1	1	0	1	Н	Р
Insp. ISO too low	319	Inspiratory isoflurane too low				0	0	1	1	1	1	1	1	1	1	М	Р

Table 45: List of all alarm message (alphabetical)

					6			1/0		) = ina 1 = a in be	ctive		ed			ue, Info,	m)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue, Info, Medium, High)	Code (Patient, Technical, System)
No anaesthetic gas recognised.	122	Narcotic gas no longer recognised	-	-	-	0	1	1	1	1	1	1	1	1	1	I	S
No N <sub>2</sub> O recognised in system test	75	FG blender check N₂O in system test failed	Successful check in system test	-	-	0	1	1	1	1	1	1	1	1	1	I	Т
No secondary anaesthetic gas recognised.	124	Narcotic gas no longer recognised	-	-	-	0	1	1	1	1	1	1	1	1	1	I	S
Audible alarming not possible.	38	Broken loudspeaker	Replace / repair	-	-	1	1	1	1	1	1	1	1	1	1	M	Т
No decompression during expiration	190	Pressure cannot be reduced in the system (valve clips)	Check PEEP valve	PEEP Setting + 5 mbar	> = 16 s	0	0	0	1	1	1	1	1	0	0	Н	S
No expiratory volume measurement	65	Erroneous expiratory flow sensor	Successful check in system test	V const.< = 15 ADC	90 s	0	0	0	1	1	1	1	1	0	0	Н	Т
	118	ADC at stop for a long time	Clean flow sensor	> 2750 ADC	4 s	0	1	1	1	1	1	1	1	1	1	Н	S

					ð			1/0		1 = a	active ctive dead	_	ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
No insp. volume measurement	64	Erroneous insp. flow sensor	Successful check in system test	V const. < = 15 ADC	90 s	0	0	0	1	1	1	1	1	0	0	Н	Т
	117	ADC value at stop for a long time	Clean flow sensor	> 2750 ADC	4 s	0	1	1	1	1	1	1	1	1	1	Н	S
No check of audible alarming	83	Broken microphone	Replace / repair	-	-	1	0	0	0	0	0	0	0	0	0	M	Т
No volume measurement. Execute system test.	130	Zero adjustment flow sensor not calibrated	Successful calibration in system test	V <sub>Offset.</sub> > 0.5 l/m -0.5 l/m	> 2 s	0	1	0	0	0	0	0	0	0	0	Н	S
No water trap	127	No water trap	Fit water trap	-	-	0	0	1	1	1	1	1	1	1	1	Н	S
	128	available				0	1	0	0	0	0	0	0	0	0	I	S
Leak too high	358	2 × V <sub>Ti</sub> > V <sub>Te</sub>	Look for leak	(→ "Application area and increment of alarm" p. 199)	3 breaths	0	0	1	1	1	1	1	1	0	0	M	Р

Table 45: List of all alarm message (alphabetical)

					б			1/0		) = in: 1 = a an be	ctive		ed			ue, Info,	(me
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
Fan fail	5	Fan fault	Replace / repair	-	-	0	1	1	1	1	1	1	1	1	1	I	Т
Gas measurement occlusion	126	Sampling line occluded	Remove sampling line obstruction	-	-	0	1	1	1	1	1	1	1	1	1	Н	S
Blender fail. Fresh gas at 100% O <sub>2</sub>	19	Voltage O <sub>2</sub> cell too small. Old cell	Change cell	75 ADC	30 s	0	0	1	1	1	1	1	1	1	1	Н	Т
Blender fail. Fresh gas at 100% O <sub>2</sub>	70	Oxy desired state deviation on blender outlet	Successful check in system test	< 20 %	30 s downwar ds 120 s upwards	0	0	1	1	1	1	1	1	1	1	Н	Т
	71	FG O <sub>2</sub> calibration in		-	-	0	1	1	1	1	1	1	1	1	1	Н	Т
	74	system test failed				0	1	1	1	1	1	1	1	1	1	Н	Т
	141	FG O <sub>2</sub> sensor uncalibrated resp. incorrectly calibrated		< 16 %	> 30 s	0	1	1	1	1	1	1	1	1	1	Н	S

					ත			1/0		1 = a	active ctive dead		ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	нгм	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
MV high	334	Minute volume too high	Change ventilation	(→ "Application area and increment of alarm" p. 199)	3 breaths	0	0	1/0	1/0	1/0	1/0		1/0	0	0	M	Р
MV low	333	Minute volume too low	parameters			0	0	1/0	1	1	1	1	1	0	0	Н	Р
N <sub>2</sub> O fail Fresh gas at 100% O <sub>2</sub>	179	N₂O (ZGA and reserve) supply fail	Restore N <sub>2</sub> O supply (ZGA or reserve)	< 1.1 bar	2 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	I	S
N₂O supply from reserve	182	N₂O ZGA supply fail. Reserve ok	Restore N₂O supply ZGA	PS5 > 1.1 bar PS4 < PS5 u, PS4 < 2.5	10 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	I	S
N₂O supply fail.	180	N₂O (ZGA and reserve) supply fail	Restore N <sub>2</sub> O supply (ZGA or reserve)	< 1.1 bar	2 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	I	S
N₂O ZGA input pressure too high	161	N₂O ZGA supply pressure too high	Check pressure N₂O ZGA	> 7.5 bar	> 10 s	0	1	1	1	1	1	1	1	1	1	I	S

Table 45: List of all alarm message (alphabetical)

					<u>5</u>			1/0		) = in: 1 = a an be	ctive		ed			lue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
N₂O ZGA too low	181	N <sub>2</sub> O ZGA supply has low input pressure but still supplies gas	Check N₂O supply ZGA	$1.1 < PS4 < 2.5$ at bar $N_2O$ consumption $> 0$ $PS4 < 2.5$ with $N_2O$ consumption $= 0$	10 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1	S
Mains fail. Device running on batteries	101		Restore mains supply.	-	1 s	0	1	1	1	1	1	1	1	1	1	Ι	S
Emergency dosing active	102	Active emergency dosing was recognised during the boot process	Turn off emergency dosing	> 2 lpm	-	0	1	0	0	0	0	0	0	0	0	-	S
	103		Successful fresh gas blender check in system test			0	0	1	1	1	1	1	1	1	1	1	S
Emergency dosing still active. Please turn off emergency dosing.	104		Turn off emergency dosing or confirm with "Yes"	> 2 lpm	-	0	1	0	0	0	0	0	0	0	0	D	S

Table 10: Elector at	· alaii	ii iiiessage (aipiiabei															
					<b>5</b>			1/0		1 = a	active ctive deac		ed			ue, Info,	(me
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
O <sub>2</sub> fail. Fresh gas with air.	170	O <sub>2</sub> (ZGA and reserve) supply fail, air ok	Restore O <sub>2</sub> supply (ZGA or reserve)	O <sub>2</sub> < 1.1 bar reserve > = 1.1 bar	2 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	Н	S
	172					0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	Н	S
Inspiratory O <sub>2</sub> high	309	Inspiratory O <sub>2</sub> too high	Change ventilation parameters		3 breaths	0	0	1	1	1	1	1	1	0	1	M	Р
Inspiratory O <sub>2</sub> low	310	Inspiratory O <sub>2</sub> too low	Change ventilation parameters	(→ "Application area and increment of alarm" p. 199)	3 breaths	0	0	1	1	1	1	1	1	0	1	Н	Р
O <sub>2</sub> calibration necessary: remove water trap briefly	125	Oxygen calibration is necessary	Calibration	-	-	0	1	1	1	1	1	1	1	1	1	Н	S
O <sub>2</sub> and air fail. No	171	O <sub>2</sub> (ZGA and reserve)		O <sub>2</sub> < 1.1 bar	2 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	Н	S
fresh gas.	173	-supply fail, air fail also	or reserve) and air supply	AIR < 1.1 bar		0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	Н	S
O <sub>2</sub> supply from reserve	176	O <sub>2</sub> ZGA supply fail. Reserve ok	Restore O <sub>2</sub> supply ZGA	PS3 > 1.1 bar PS2 < PS3 u, PS2 < 2.5	10 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	I	S

Table 45: List of all alarm message (alphabetical)

					g			1/0		) = in: 1 = a an be	ctive		ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
O <sub>2</sub> supply fail.	174	O <sub>2</sub> supply fail but not needed at present	Restore O <sub>2</sub> supply (ZGA or reserve)	< 1.1 bar	2 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1	Н	S
O <sub>2</sub> ZGA input pressure too high	162		Check pressure O <sub>2</sub> ZGA	> 7.5 bar	> 10 s	0	1	1	1	1	1	1	1	1	1	I	S
O <sub>2</sub> ZGA supply too high	175	O <sub>2</sub> ZGA supply has low input pressure but still supplies gas	Check O <sub>2</sub> supply ZGA	$\begin{array}{l} 1.1 < PS2 < 2.5 \text{ at bar} \\ O_2 \text{ consumption } > \\ 0 \\ PS2 < 2.5 \text{ with } O_2 \\ \text{consumption } = 0 \end{array}$	10 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	Н	S
Patient module not locked. Ventilation stopped	111	-	Lock patient module	-	-	0	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	Н	S
in	110	-	Lock patient module	-	-	0	1	0	0	0	0	0	0	0	0	I	S
Patientsafe: Reboot the device	55	Device cannot be operated. Ventilation continues				1	1	1	1	1	1	1	1	1	1	Н	Т

Table 45. List of all	alan	ii iiiessage (aipiiabei	licai)														
					б			1/0		) = ina 1 = a in be	ctive		ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	НГМ	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
Paw < -10 mbar	362	Ventilation pressure < -10 mbar	Change ventilation parameters	10 mbar		0	0	1	1	1	1	1	1	0	0	Н	Р
Paw > alarm limit CPAP	359	Ventilation pressure > alarm limit	Change APL setting	20 mbar	-	0	0	0	0	0	0	0	0	1	1	Н	Р
Paw > alarm limit pPeak	304	Ventilation pressure > alarm limit	Change ventilation parameters	IMV, SIMV: mbar P <sub>max</sub> + 5 PCV, SPCV: Pinsp + 10 Manspont: 20	-	0	0	1/0	1	1	1	1	1	0	0	Н	Р
	337			IMV, SIMV: P <sub>max</sub> + mbar 10 PCV, SPCV: Pinsp + 10 Manspont: Adult 40 Child 35	3 breaths	0	0	1/0	1	1	1	1	1	0	0	Н	Р
PEEP not reached	335	The PEEP set is not reached	Change ventilation	PEEP setting - 2 mbar	5 breaths	0	0	0	1	1	1	1	1	0	0	М	Р
P <sub>max</sub> setting reached too early.	306	Plateau pressure reached too early	parameters Increase P <sub>max</sub>	-	2 breaths	0	0	0	1	1	0	0	0	0	0	М	Р

					5			1/0		1 = a	active ctive dead		ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	нгм	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
Primary anaesthetic gas recognised.	120	Narcotic gas discovered (previously: none)	-	-	-	0	1	1	1	1	1	1	1	1	1	I	S
	121	Narcotic gas     discovered     (previously: other)				0	1	1	1	1	1	1	1	1	1	I	S
Secondary narcotic gas discovered (MAC<3)	123	Narcotic gas blend recognised with MAC<3	-	-	-	0	1	1	1	1	1	1	1	1	1	I	S
Secondary narcotic gas recognised (MAC>3)	129	Narcotic gas blend recognised with MAC>3	-	-	-	0	1	1	1	1	1	1	1	1	1	I	М
Sensor fail, only MAN/SPONT possible	4	Erroneous pressure sensor or not calibrated	Not possible during operation. Only resettable via reboot	+/- 5 mbar	-	0	1	1	1	1	1	1	1	1	1	Н	Т

		m meesage (aipmase															
					<u> </u>		0 = inactive 1 = active 1/0 = can be deactivated    NAW/SBON1				jue, Info,	em)					
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
Sensor fail, only MAN/SPONT possible	77	Pressure valve from drive gas blender frozen (sensor tube off or disconnected, sensor fail)	Successful compliance test in system test	-	3 breaths	0	0	1	1	1	1	1	1	1	1	Н	Т
	78	Pressure valve from mainboard frozen (sensor tube off or disconnected, sensor fail)				0	0	1	1	1	1	1	1	1	1	Н	Т
Insp. SEVO high	320	Inspiratory sevoflurane too high	Change vaporiser setting	(→ "Application area and increment of alarm" p. 199)	3 breaths	0	0	1	1	1	1	1	1	0	1	Н	Р
Insp. SEVO too low	321	Inspiratory sevoflurane too low				0	0	1	1	1	1	1	1	0	1	М	Р

Table 45. List of al	ı alalı	n message (alphabet	licai)													1	
					50			1/0		) = in: 1 = a in be	ctive		ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	\MI	S-IMV	ΛϽd	S-PCV	PSV	МЈН	NOW	Priority (Dialogue, Info, Medium, High)	Code (Patient, Technical, System)
Technical failure	7	If the error is not fixed		-	-	1	0	0	0	0	0	0	0	0	0	Н	Т
	8	repeated, make a	during operation. Only resettable via			1	0	0	0	0	0	0	0	0	0	Н	Т
	9	note of the error number and notify a	reboot Use the O <sub>2</sub> emergency dosing			1	1	1	1	1	1	1	1	1	1	Н	Т
	10	Löwenstein Medical- authorised technician				1	1	1	1	1	1	1	1	1	1	Н	Т
	11					1	1	1	1	1	1	1	1	1	1	Н	Т
	12	1				1	1	1	1	1	1	1	1	1	1	Н	Т
	13	1				0	1	1	1	1	1	1	1	1	1	Н	Т
	15	1				1	0	0	0	0	0	0	0	0	0	Н	Т
	16					0	1	1	1	1	1	1	1	1	1	Н	Т
	17	1				0	1	1	1	1	1	1	1	1	1	Н	Т
	20	1				0	1	1	1	1	1	1	1	1	1	Н	Т
	21	1				1	0	0	0	0	0	0	0	0	1	Н	Т

Table 45: List of all alarm message (alphabetical)

					ත			1/0		) = in: 1 = a in be	ctive		ed			ue, Info,	(me
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MOM	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
Technical failure	22	repeated, make a	during operation. Only resettable via	-	-	1	1	1	1	1	1	1	1	1	1	Н	Т
	23	number and notify a	reboot Use the O <sub>2</sub> emergency dosing			1	0	0	0	0	0	0	0	0	0	Н	Т
	30		Replace/repair			1	1	1	1	1	1	1	1	1	1	Н	Т
	31		Use the O <sub>2</sub> emergency dosing			1	1	1	1	1	1	1	1	1	1	Н	Т
	32					1	1	1	1	1	1	1	1	1	1	Н	Т
	33					1	1	1	1	1	1	1	1	1	1	Н	Т
	34					1	1	1	1	1	1	1	1	1	1	Н	Т
	35					1	1	1	1	1	1	1	1	1	1	Н	Т
	36					1	1	1	1	1	1	1	1	1	1	Н	Т
	37					1	1	1	1	1	1	1	1	1	1	Н	Т
	44					0	1	1	1	1	1	1	1	1	1	Н	Т

Table 45: List of all alarm message (alphabetical)

					50			1/0		= ina 1 = a in be	ctive		ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	нгм	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
Technical failure	46	If the error is not fixed by a restart or it is	Replace/repair use the O <sub>2</sub>	-	-	1	1	1	1	1	1	1	1	1	1	Н	Т
	47	repeated, make a	emergency dosing			1	1	1	1	1	1	1	1	1	1	Н	Т
	60	number and notify a Löwenstein Medical-	Not possible			0	0	1	1	1	1	1	1	1	1	Н	Т
	61	authorised technician	during operation. Only resettable via			1	0	0	0	0	1	0	0	0	0	Н	Т
	62		reboot Use the O <sub>2</sub> emergency dosing			1	1	1	1	1	1	1	1	1	1	Н	Т
	63					1	1	1	1	1	1	1	1	1	1	Н	Т
Drive gas switched to air	167	O <sub>2</sub> supply ZGA fail. Switching to air	Restore O <sub>2</sub> supply ZGA	-	2 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	I	S
Drive gas switched to O <sub>2</sub>	168		Restore air supply ZGA	-	2 s	0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	1/0	I	S
Versions not compatible.	40	VersionsCheck shows incompatibility	Replace / repair	-	-	1	1	1	1	1	1	1	1	1	1	Н	Т

					5			1/0		1 = a	active ctive dead		ed			ue, Info,	em)
Alarm message	No.	Description	Removal	Limit value	Filtering	Selftest	Standby	MAN/SPONT	IMV	S-IMV	PCV	S-PCV	PSV	HLM	MON	Priority (Dialogue, Medium, High)	Code (Patient, Technical, System)
V <sub>Te</sub> low	332	Tidal volume too low	Change ventilation parameters	(→ "Application area and increment of alarm" p. 199)	3 breaths	0	0	1/0	1	1	1	1	1	0	0	М	Р
VueLink not connected	192	VueLink is not connected/incorrectly connected	Receive valid requests/ VueLink deactivated	-	60 s	0	1	1	1	1	1	1	1	1	1	I	S
Change water trap gas measurement	129	Water trap blocked or full	Change water trap	-	-	0	1	1	1	1	1	1	1	1	1	М	S

## 12. Errors and measures

## **General information**

## **Patient monitoring**

System and technical errors have error numbers.
System errors can generally be fixed by the user. To fix a technical error, you should refer to a Löwenstein Medical-authorised service technician.

### Pressure relief valve

mechanical ventilation

Excess fresh

gas leaks

Table 46: Pressure relief valve				
Valve (short description) (→ "Gas flow plans" p. 284)	Description	Maximum work pressure [Pa × 100] (mbar)	Driving	Status of malfunction
APL (APL)	Control of the airway pressure in the MAN/SPONT, HLM and MON forms of ventilation.	90	manual	manually adjustable
PEEP valve (VC2)	Control of the airway pressure in mechanical ventilation	125	electric	open without current
plateau valve (VC1)	Production of an inspiratory plateau during	125	electric	open without current

2

The electrically controlled valves are opened when the device is shut down (without power). In the accessed state an airway pressure of a maximum of 125 Pa × 100 (mbar) can be produced, depending on the build (through power limitation).

open without

pressure

pneumatic

In the MAN/SPONT, HLM and MON forms of ventilation the control of the airway pressure is carried out purely through the APL. During mechanical ventilation, the APL is decoupled. Excess fresh gas leaks through the excess diaphragm. If the valves malfunction, pressures that could endanger the patient can leak through the plateau and PEEP valve.

Excess diaphragm

(PV)

### **Defined safe state**

In the leon *plus* the ventilation unit, user interface and monitoring system are separate, independent modules. Two safe states are defined:

- Patientsafe: If the user interface with monitoring fails, the ventilation unit continues to run.
- Failsafe: If the ventilation unit and user interface with monitoring fail, manual ventilation is possible with the leon plus.

For a defined safe state it is required that the leon *plus* can no longer be operated in its proper state.

Depending on the extent of the failure, the leon *plus* then falls automatically into one of two defined safe states.

If the user deliberately shuts down manually, the leon *plus* goes into the **second** defined safe state.

(→ "Power off" p. 127)

### Patientsafe defined safe state

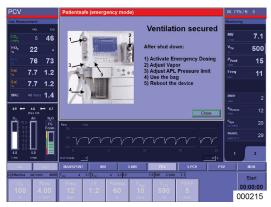
- the device can no longer be operated with the touchscreen and keyboard (other than to turn off)
- ventilation continues with the last ventilation parameters set
- fresh gas supply is carried out according to the last settings of the fresh gas blender
- AIR, N<sub>2</sub>O are available
- O<sub>2</sub> flush is available
- anaesthetic vaporiser available

### Failsafe defined safe state

- the device can no longer be operated with the touchscreen and keyboard (other than to turn off)
- ventilation and gas monitoring are not possible
- all electric valves are without power
- all pneumatic valves are without pressure
- the mechanical ventilation is stopped, the patient must be manually ventilated with the leon plus
- fresh gas is supplies in accordance with the O<sub>2</sub>emergency dose settings
- O<sub>2</sub> flush is available
- anaesthetic vaporisers available

### Inoperability or failure of the device

Reaction of the system and measures in the event of inoperability of the device (Patientsafe)



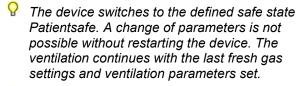
## Messages/measures (Patientsafe (emergency operation)):

After shutdown:

- 1) open emergency dosing
- 2) adjust vapour settings
- 3) set APL
- 4) use manual ventilation
- 5) restart device

The device should be restarted as soon as possible.

## Points 1) and 5) must be carried out after shutdown.



 $\bigcirc$  The O<sub>2</sub> emergency dosing is released.



Close the **Patientsafe** error dialogue (**emergency operation**).

- Ventilation continues with the last fresh gas settings and ventilation parameters set. The O₂ emergency dosing is released.
- $\bigcirc$  ( $\rightarrow$  "Execute quick start" p. 139)

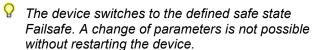
# Reaction of the system and measures in the event of failure of the device (Failsafe)

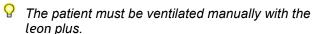


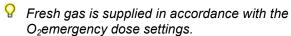
#### Messages/measures (technical errors: Failsafe):

- 1) open emergency dosing
- 2) set APL
- 3) adjust vapour settings
- 4) use manual ventilation
- 5) restart device

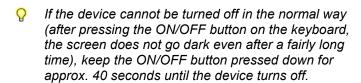
#### Points 1) and 5) must be carried out immediately.







See also manual ventilation presentation (→ "Start a MAN/SPONT manual/spontaneous ventilation" p. 140).





### WARNING

#### Failure of the device

### Death or permanent injury of the patient

- Use an alternative ventilation system
- Use an external gas monitor
- Check for a possible alternative continuation of the narcotic gas
  - If you are unable to fix the error yourself, notify a Löwenstein Medical-authorised technician.

## Self check error search

## Gas supply error search

Table 47: Gas supply error messages			
Test	Error message	Description	Possible cause
AIR			<ul><li>ZGA not attached</li><li>ZGA pressure too low</li></ul>
O <sub>2</sub>	Traffic light is red	1	<ul><li>ZGA not attached</li><li>ZGA pressure too low</li></ul>
N <sub>2</sub> O			<ul><li>ZGA not attached</li><li>ZGA pressure too low</li></ul>

### Self check error search

Table 48: Self check error messages			
Test	Error message	Description	Possible cause
Loudspeaker	Traffic light is red		<ul><li>damaged</li><li>cabling damaged</li></ul>
Battery	Traffic light is red		<ul><li>damaged</li><li>cabling damaged</li></ul>
	Traffic light is yellow	/	battery voltage low
Gas measurement	Traffic light is red		<ul><li>damaged</li><li>cabling damaged</li><li>tubing damaged</li></ul>

## **Error search system test**

## Error search gas type check

Table 49: Gas t	ype check		
Test	Error message	Description	Possible cause
N <sub>2</sub> O check	N <sub>2</sub> O check: Not executed due to previous error	Error from previous test not fixed	1
	N <sub>2</sub> O check: No N <sub>2</sub> O detected	Oxygen concentration not < 10% if nitrous oxide flows	N <sub>2</sub> O incorrectly connected
	N <sub>2</sub> O check:N <sub>2</sub> O input pressure outside of permitted range	ZGA pressure too high or too low	check N₂O ZGA wall connection
	N <sub>2</sub> O check:O <sub>2</sub> input pressure outside of permitted range	ZGA pressure too high or too low	<ul> <li>check O<sub>2</sub> ZGA wall connection</li> </ul>
	N <sub>2</sub> O check: N <sub>2</sub> O and O <sub>2</sub> input pressure outside of permitted range	ZGA pressure too high or too low	<ul> <li>check N<sub>2</sub>O and O<sub>2</sub> ZGA wall connection</li> </ul>
O <sub>2</sub> check	O <sub>2</sub> check: No O <sub>2</sub> detected	Oxygen concentration not > 35% if oxygen flows	O <sub>2</sub> incorrectly connected
	O <sub>2</sub> check:O <sub>2</sub> input pressure outside of permitted range	ZGA pressure too high or too low	<ul> <li>check O<sub>2</sub> ZGA wall connection</li> </ul>
AIR check	AIR check: No AIR detected	Oxygen concentration > 35% or < 10% if AIR flows	AIR incorrectly connected
	AIR check: AIR input pressure outside of permissible range	ZGA pressure too high or too low	check AIR ZGA wall connection

## Error search fresh gas blender

Table 50: Error messages fresh gas blender			
Test	Error message	Description	Possible cause
Calibration O <sub>2</sub> cell	Not executed due to previous error	Error from previous test not fixed	/
fresh gas blender 21% or 100%	O <sub>2</sub> calibration: AIR and O <sub>2</sub> not available	no O <sub>2</sub> and AIR detected in gas type check	O <sub>2</sub> and AIR incorrectly connected
	O <sub>2</sub> calibration: System under pressure	Pressure during oxygen calibration > 4 mbar	fresh gas blender untight
	O <sub>2</sub> calibration: O <sub>2</sub> cell soon exhausted	at calibration 21% and 100% value too low (yellow traffic light)	O <sub>2</sub> cell soon exhausted
	O <sub>2</sub> calibration: Signal too low	at calibration 21% or 100% value considerably too low	<ul> <li>O<sub>2</sub> cell fail</li> <li>no O<sub>2</sub> detected</li> </ul>
	O <sub>2</sub> calibration: Signal too high	at calibration 21% or 100% value considerably too high	<ul> <li>O<sub>2</sub> cell fail</li> <li>fresh gas blender untight</li> </ul>
	O <sub>2</sub> calibration: Data not stable	Signal not stable	O <sub>2</sub> cell fail

Table 50: Error messages fresh gas blender

Test	Error message	Description	Possible cause
O <sub>2</sub> check	Fresh gas blender: O <sub>2</sub> not available	no O <sub>2</sub> detected in gas type check	O <sub>2</sub> incorrectly connected
	Fresh gas blender: Flow out of permissible range	Flow of a valve out of permissible range or obstruction	<ul> <li>valve fresh gas blender fail</li> <li>O<sub>2</sub> emergency dosing untight</li> <li>ZGA not connected or pressure too low</li> <li>occlusion in the fresh gas branch</li> </ul>
Check AIR, N <sub>2</sub> O	Fresh gas blender: AIR and N <sub>2</sub> O not available	no AIR, N <sub>2</sub> O detected in gas type check	N <sub>2</sub> O, AIR incorrectly connected
	Fresh gas blender: Flow out of permissible range	Flow of a valve out of permissible range or obstruction	<ul> <li>valve fresh gas blender fail</li> <li>O<sub>2</sub> emergency dosing untight</li> <li>ZGA not connected or pressure too low</li> <li>occlusion in the fresh gas branch</li> </ul>

## **Error search respirator**

Table 51: Error messages respirator

Test	Error message	Description	Possible cause
Drive gas blender	Drive gas blender: not executed due to previous error	Error from previous test not fixed	/
	Drive gas blender: Flow out of range	Drive gas flow of a valve out of range or obstruction	<ul> <li>emergency air valve untight</li> <li>insp. flow sensor untight</li> <li>insp. flow sensor fail</li> <li>valve drive gas generator fail</li> <li>plateau valve fail</li> <li>decoupling diaphragm untight</li> <li>insp. inspection glass untight</li> <li>O-ring on the drive gas port failed or defective</li> <li>patient module not locked</li> <li>dome not correctly adapted</li> <li>ZGA not attached</li> <li>vaporiser</li> </ul>
	Drive gas blender: insp./exp. differ insp. and exp. flow differs, leak	insp. and exp. flow differs, leak	<ul> <li>flow sensor, insp., exp. fail</li> <li>Y-piece not on the test adapter</li> </ul>
	Drive gas blender: Pressure too high	Blockage	<ul><li>high resistance after inspiration Flow sensor</li><li>PEEP valve hangs</li></ul>
	Drive gas blender: AIR, O <sub>2</sub> not available (only with leon <i>plus</i> )	Drive gas blender: AIR, O <sub>2</sub> not available	O <sub>2</sub> and/or AIR erroneously or not connected

## **Error search flow sensors**

Table 52: Error messages flow measurement
---

Test	Error message	Description	Possible cause
Flow calibration	Flow not 0	a flow was detected during calibration	<ul><li>fresh gas blender untight</li><li>flow sensor fail</li></ul>
	Disconnected	1	plug or cabling to the flow sensor fail
	Contaminated (insp. wire)	1	Flow sensor contaminated (insp.)
	Sensor contaminated (exp. wire)	1	Flow sensor contaminated (exp.)
	Failed (insp. wire)	1	Flow sensor fail (insp.)
	Failed (exp. wire)	1	Flow sensor fail (exp.)

## **Error search circulation system**

Table 53: Error messages circulation system

Test	Error message	Description	Possible cause
Tube system	Compl.:not executed due to previous error	Error from previous test not fixed	1
	Compl.:pressure not reached  Compl.:leak too big	heavy leak	<ul> <li>emergency air valve untight</li> <li>flow sensor untight</li> <li>ventilation tubes untight</li> <li>exp. inspection glass untight</li> <li>patient module not locked</li> <li>dome not correctly adapted</li> <li>dome seal not correctly fitted or damaged</li> <li>gas measurement cable not connected (only with gas meter)</li> <li>y-piece not on the test adapter</li> <li>PEEP valve untight</li> <li>decoupling diaphragm untight</li> </ul>
	Compl.:pressure rise on zero flow	Pressure rise although flow turned off	<ul><li>drive gas blender untight</li><li>slide valve auto/manual untight</li></ul>
	Compl.:compliance too low/high	Compliance too high	inspiration shank occluded
	Compl.:inspiratory non-return valve untight	blue inspiratory valve diaphragm untight	blue insp. valve diaphragm, not available damaged, fits incorrectly
	Compl.:insp. Valve: Pressure not reached	blue inspiratory valve diaphragm untight	blue insp. valve diaphragm, not available damaged, fits incorrectly

### Table 53: Error messages circulation system

Test	Error message	Description	Possible cause
	Compl.:drive gas blender not available	I	See error search respirator
	Compl.:drive gas not available (only with the leon <i>plus</i> )	no AIR, O <sub>2</sub> recognised	O <sub>2</sub> and/or AIR incorrectly connected or not connected
Complete system	Compl.:not executed due to previous error	Error from previous test not fixed	I
	Leak:filling the bag not possible		bag no longer suitable, change
	Compl.:pressure not reached	heavy leak	ventilation bag/tube to bag untight
	Compl.:leak too big	1	<ul> <li>Plateau valve untight</li> <li>CO<sub>2</sub> absorber untight or not properly adapted</li> <li>excess diaphragm untight</li> <li>APL untight</li> <li>O-ring on the slide valve auto/manual damaged</li> </ul>
	Compl.:pressure rise on zero flow	Pressure rise although flow turned off	<ul> <li>fresh gas blender untight</li> <li>pressure port on the excess diaphragm untight</li> <li>slide valve APL</li> </ul>

Table 53: Error messages circulation system

Test	Error message	Description	Possible cause
APL	Leak, APL:start pressure not reached	Leak, inlet pressure, bag filling not reached	see error search circulation     system/complete     system/Compl.:pressure not reached
	Leak, APL:end pressure not reached	Leak, pressure > 20 mbar not reached	<ul> <li>see error search circulation system/complete system/Compl.:pressure not reached</li> <li>APL not set to 20 mbar</li> </ul>
	Leak, APL:check valve	APL too tight or untight	<ul> <li>APL defective</li> <li>slide valve auto/manual</li> <li>ventilation bag too old</li> <li>leak complete system too big</li> <li>vapour or vapour suspension bracket untight</li> </ul>
Bellows	Leak, bellows:minimum flow not reached	Bellows does not move up	<ul> <li>drive gas blender fail</li> <li>insp. flow sensor fail</li> <li>dome untight or not properly screwed on</li> <li>O-ring dome carrier damaged or failed</li> </ul>
	Leak, bellows:not available	Bellows not recognised	Bellows not available or dropped off

## Error search FiO<sub>2</sub> calibration

Table 54: Error messages	O <sub>2</sub> calibration
--------------------------	----------------------------

Test	Error message	Description	Possible cause	
Calibration	O <sub>2</sub> calibration:not executed due to previous error	Error from previous test not fixed	/	
	O <sub>2</sub> calibration: O <sub>2</sub> cell soon exhausted	at calibration 21% and 100% value too low (yellow traffic light)	O <sub>2</sub> cell soon exhausted	
	O <sub>2</sub> calibration:signal too low	at calibration 21% and 100% value considerably too low	O <sub>2</sub> cell fail	
	O <sub>2</sub> calibration:signal too high	at calibration 21% and 100% value considerably too high	O <sub>2</sub> cell fail	
	O <sub>2</sub> calibration.:data not stable	Signal not stable	O <sub>2</sub> cell fail	

(only for option "external O<sub>2</sub> fuel cells")

## **External supply units failure**

### No central gas supply



We recommend that  $O_2$  and  $N_2O$  reserve gas bottles are kept available connected to the device.

If the pressure of the central gas supply falls below  $2.3 \pm 0.3$  kPa × 100 (bar), this is judged by the system as a failure of the gas supply and it switches to reserve gas bottle operation. Depending on whether reserve gas bottles are attached and whether they are filled, the system reacts according to the following table:

### Reaction of the system when no central gas supply

Table 55: Gas supply when ZGA fails

ZGA		Reserve		O <sub>2</sub> concentration if carrier gas:		Drive gas	Possible messages		
AIR	O <sub>2</sub>	N₂O	O <sub>2</sub>	N₂O	AIR	N₂O		(see following table)	
ОК	OK	OK	closed	closed	Blender setting	Blender setting	AIR	None	
ОК	OK	failed	closed	open	Blender setting	Blender setting	AIR	3.2, 3.3	
ОК	OK	failed	closed	empty	Blender setting	100%	AIR	3.2, 3.3	
failed	ОК	ОК	closed	closed	100%	Blender setting	O <sub>2</sub>	1.1, 1.2	
failed	OK	failed	closed	closed	100%		$O_2$	3.4	
ОК	failed	OK	closed	closed	Blender setting	Blender setting	AIR	2.1	
ОК	failed	OK	open	closed	Blender setting	Blender setting	AIR	2.2	
OK	failed	OK	empty	closed	21%	(AIR)	AIR	2.2, 2.3	

Table 55:	Gas	supply	when	ZGA fails
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Table 33. Gas supply when 20% falls								
ZGA	GA		Reserve		O <sub>2</sub> concentration if carrier gas:		Drive gas	Possible messages (see
AIR	O <sub>2</sub>	N <sub>2</sub> O	O <sub>2</sub>	N <sub>2</sub> O	AIR	N <sub>2</sub> O		following table)
ОК	failed	failed	open	open	Blender setting	Blender setting	AIR	2.2, 3.2
ОК	failed	failed	open	empty	Blender setting	100%	AIR	2.2, 3.2
OK	failed	failed	empty	open	21%	(AIR)	AIR	2.2, 2.3, 3.2
OK	failed	failed	empty	empty	21% (AIR)		AIR	2.2, 2.3, 3.2
failed	failed	ОК	closed	closed	operation not possible		operation not possible	4
failed	failed	ОК	open	closed	100%	Blender setting	mechanical ventilation not possible	1.2, 2.2
failed	failed	ОК	empty	closed	operation not possible		operation not possible	4
failed	failed	failed	open	open	100%	Blender setting	mechanical ventilation not possible	1.2, 2.2, 3.2
failed	failed	failed	open	empty	100%		mechanical ventilation not possible	2, 3.2
failed	failed	failed	empty	open	operation not possible		operation not possible	4, 3.2
failed	failed	failed	empty	empty	operation not possible		operation not possible	4

Table 56: Possible messages				
1.1	Drive gas switched to O <sub>2</sub>			
1.2	AIR failed. Fresh gas 100% O <sub>2</sub> (only with the leon <i>plus</i> )			
2.1	O <sub>2</sub> supply fail			
2.2	O <sub>2</sub> fail. Fresh gas on AIR (only with the leon <i>plus</i> )			
2.3	O <sub>2</sub> supply on reserve			
2.4	Drive gas switched to AIR			
3.1	N₂O supply fail			
3.2	N₂O supply on reserve			
3.3	N <sub>2</sub> O fail. Fresh gas 100% O <sub>2</sub> (only with the leon <i>plus</i> )			
3.4	Air and N <sub>2</sub> O failed Fresh gas 100% O <sub>2</sub> (only with the leon <i>plus</i> )			
4	O <sub>2</sub> and AIR fail. Fresh gas stopped (only with the leon <i>plus</i> )			



#### Failure of the device

### Death or permanent injury of the patient

### **WARNING**

- Use an alternative ventilation system
- Use an external gas monitor
- Check for a possible alternative continuation of the narcotic gas



### Failure of the device

### **WARNING**

#### Death or permanent injury of the patient

Only if the following errors occur at the same time should theleon *plus* no longer be operated: O<sub>2</sub> supply pressure of the ZGA failed, O<sub>2</sub>reserve gas bottles not available or empty and AIR supply pressure of the ZGA failed



A mechanical ventilation is only possible with a pressure air supply through  $O_2$  or AIR of the ZGA, or through  $O_2$  or AIR from the 10 L bottle. Otherwise the system switches automatically to the MAN/SPONT form of ventilation and the patient can continue to be ventilated with the ventilation bag.

The buttons to select the forms of ventilation are inactive.

### Measures when no central gas supply

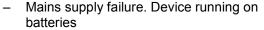
- Open the reserve gas bottles on the rear of the device.
- 2. If you are unable to fix the error yourself, make a note of the error number and notify a Löwenstein Medical-authorised technician.

### Mains supply failure



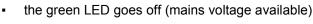
Possible messages:







- automatic switch-over to battery operation
- the yellow LED under the battery icon on the keyboard lit



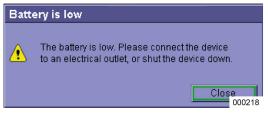


On the right of the title bar the plug icon appears in white as "No mains voltage available", the battery icon appears in green with the display of the remaining life of the battery in minutes.

If the batteries are fully charged, a running time of a further 100 minutes is available. After this time, the device switches off into a defined safe state.



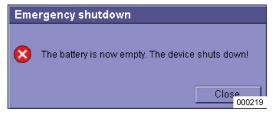
If the mains supply cannot be restored, when there is a remaining life of 10 minutes the following message appears:



 The remaining life of the battery is short. Please connect the device to an external power supply or turn it off.



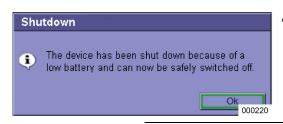
Shortly before the batteries can no longer guarantee power supply and the leon *plus* shuts down independently, the following dialogue appears:



The battery is now empty. The device shuts down.



Finally, the dialogue appears:



The device has been shut down because of a low battery and can now be safely switched off.



Mains supply failure!

### Automatic switch-over to battery operation

The following units are no longer supplied with voltage:

- auxiliary outlets on the rear of the device
- heating of the patient module
- workstation light

### Measures for mains supply failure

With full batteries, all functions of the leon plus are available without restriction for a further 100 minutes.

If you are unable to fix the error yourself, make a note of the error number and notify a Löwenstein Medicalauthorised technician.



If the device reports "Mains failure. Device running on batteries" also check the fuses of the cold device plug of the leon plus.

### Failure of the anaesthesia gas scavenging system

### Reaction of the system when the AGSS fails

As the output of the patient module to the AGSS from the device is not monitored, a failure is not noticed and not reported. The monitoring must be guaranteed through the implementation of a suitable AGSS with display of the suction performance.

#### Measures for AGSS failure

- Check whether the tubes of the AGSS are kinked or have dropped off.
- Check whether the suction performance on the AGSS is sufficient.
- Check whether the suction system is functioning (green mark on the supply plug).
- If you are unable to fix it yourself, notify your technical department or the AGSS manufacturer.
- Remember that N₂O and volatile narcotics get into the ambient air and could impair your consciousness. Please also refer to the AGSS user manual.

### Failure of internal units

### Touchscreen failure

### Reaction of the system to failure of the touchscreen

If the touchscreen fails, any device function can also be accessed and carried out using the keypad buttons and the rotary switch. This guarantees that safe operation is always possible.

### Measures for touchscreen failure

Operate the device via the buttons on the keyboard and the rotary button. These operating processes are described in the relevant chapters. You are now in the right column of the particular table.

### Fresh gas dosing failure

### Fresh gas blender failure



## Reaction of the system to failure of the fresh gas blender

Possible messages:

- Blender failed. Turn on emergency dosing!
- Blender failed. Fresh gas with 100% O<sub>2</sub>

audible and visual alarm

The current form of ventilation remains active.

The fresh gas blender window becomes inactive.

The button on the keyboard for focusing the fresh gas blender window is inactive.

### Measures for fresh gas blender failure

Appears with message: **Blender failed. Turn on emergency dosing!** 

- **1.** Set the O<sub>2</sub> emergency dosing to the desired fresh gas flow.
- **2.** Check the anaesthetic vaporiser setting, as the fresh flow has changed.
- **3.** Bring the anaesthesia to an end.

Appears with message: Blender failed. Fresh gas with 100%  $O_2$ 

- **1.** Execute a system test at the next available opportunity.
- **2.** Check the O<sub>2</sub> gas supply.
- **3.** Notify your technical department or the ZGA manufacturer.
- If you are unable to fix the error yourself, make a note of the error number and notify a Löwenstein Medical-authorised technician.

### Failure of monitoring of fresh gas blender



## Reaction of the system to failure of the fresh gas blender monitoring

Possible messages:

- failure blender fresh gas 100% O<sub>2</sub>
- No N<sub>2</sub>O recognised in system test

audible and visual alarm

The current form of ventilation remains active.

## Measures for monitoring of fresh gas blender failure

Appears with message: failure blender fresh gas  $100\% O_2$ 

**1.** Execute a system test at the next available opportunity.

Appears with message: No  $N_2O$  detected in system test

- **1.** Check the  $O_2$  gas supply.
- **2.** Notify your technical department or the ZGA manufacturer.



If you are unable to fix the error yourself, make a note of the error number and notify a Löwenstein Medical-authorised technician.

### Ventilator failure

### Reaction of the system to failure of the ventilator



- Possible messages:
  - No driving gas. Only MAN/SPONT possible
- The system switches automatically to the MAN/SPONT form of ventilation
- The buttons to select mechanical forms of ventilation are inactive.
- audible and visual alarm
- semi-open operation is not possible.

#### Measures for ventilator failure

The patient can continue to be ventilated with the ventilation bag.



If you are unable to fix the error yourself, make a note of the error number and notify a Löwenstein Medical-authorised technician.

#### Gas measurement failed

### Reaction of the system to failure of the gas measurement

Possible messages:

- Gas measurement failed
- O<sub>2</sub> calibration needed: Remove water trap briefly
- Gas measurement tube occlusion
- Change gas measurement water trap

#### Measures for gas measurement failure

P

The functioning of the device is not impaired.

Gas measurement failed:

- Connect an external gas monitor to monitor the:
  - O<sub>2</sub> concentration
  - anaesthesia gas concentration
  - CO<sub>2</sub> concentration

O<sub>2</sub> calibration needed: remove water trap briefly:

 Remove the water trap briefly and put it back on to force a calibration.

Gas measurement occlusion:

- Check whether the sample line is kinked or jammed.
- If necessary, change the sample line.

Change water trap gas measurement:

- Empty the water trap.
- If necessary, change the water trap.
- If you are unable to fix the error yourself, make a note of the error number and notify a Löwenstein Medical-authorised technician.

### Flow measurement failure

### Reaction of the system to failure of the inspiratory flow measurement



- Possible messages:
  - No inspiratory volume measurement possible
- the device continues to ventilate in the current ventilation mode
- audible and visual alarm
- only the buttons to select the MAN/SPONT and PCV forms of ventilation are still active

#### Measures for failure of the inspiratory flow measurement

Switch to the pressure-controlled PCV form of ventilation or ventilate the patient with the ventilation bag.

- No inspiratory volume measurement possible: Check the inspiratory flow sensor for soiling and damage at the next available opportunity. If necessary, change the inspiratory flow sensor.
- Execute a system test at the next available opportunity.
- If you are unable to fix the error yourself, make a note of the error number and notify a Löwenstein Medical-authorised technician.

#### Reaction of the system to failure of the expiratory flow measurement

- Possible messages:
  - Exp. volume measurement no longer possible
- The device continues to ventilate in the current ventilation mode
- Audible and visual alarm

#### Measures for failure of the expiratory flow measurement

The device continues to ventilate in the current ventilation mode (no display for MV and  $V_{Te}$ , only inspiratory flow and volume curve).

- Check the expiratory flow sensor for soiling and damage at the next available opportunity. If necessary, change the expiratory flow sensor.
- Execute a system test at the next available opportunity.
- If you are unable to fix the error yourself, make a note of the error number and notify a Löwenstein Medical-authorised technician.

### Pressure measurement failure

#### Reaction of the system to failure of the pressure measurement

- Possible messages:
  - Sensor fail, only MAN/SPONT possible
- The system switches automatically to the MAN/SPONT form of ventilation.
- The buttons to select the forms of ventilation are inactive.

#### Measures for pressure measurement failure

The patient can continue to be ventilated with the ventilation bag.



If you are unable to fix the error yourself, make a note of the error number and notify a Löwenstein Medical-authorised technician.



WARNING

Pressure measurement failure!

#### Too-high ventilation pressures lead to lung damage

- The patient can continue to be ventilated with the ventilation bag.
- Set an alternative ventilation pressure measurement.

## 13. Maintenance and servicing

## **General information**



WARNING

Device malfunctions during maintenance and servicing work!

Death or permanent injury of the patient

 Do not carry out any servicing or maintenance work while the device is being used on a patient.

The leon *plus* must be serviced (→ "Servicing interval" p. 270) regularly by a Löwenstein Medical-authorised service technician. All maintenance measures must be entered in a logbook which is prepared in accordance with the relevant statutory legislation. We recommend that servicing should be carried out as part of a servicing and maintenance contract with Löwenstein Medical. The guarantee is terminated if interventions, changes or repairs to the device are made by persons who are not authorised to do so or if the device is used with auxiliary accessories or spare parts of third-party origin.

## Servicing by hospital staff

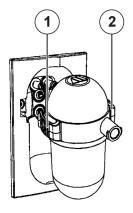
## Change CO<sub>2</sub> absorber

 $(\rightarrow$  "Removing and installing the CO $_2$  absorber" p. 75)

## Change bronchial aspiration filter

(→ "Connection of the bronchial aspiration" p. 86)

## Gas measurement servicing



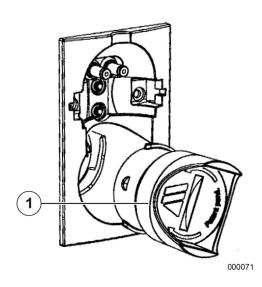


#### Changing or emptying of the water trap

- **1.** Press the flaps on the right and left of the water trap inwards and take it out.
- **2.** Open the water trap by removing the lid.
- **3.** Empty the water trap and replace the lid or dispose of it if it has been used for longer than a month.
- **4.** Replace the water trap by pressing it into the mounting from the front until it has noticeably engaged on both sides.
- (1) strap
- (2) strap
- (3) lid
- When ventilating neonates, please use the water trap for neonates (blue coding (→ "Connection of the sampling line" p. 80)).

The maximum permissible intervals between necessary interventions of the user in the drainage system

- with a minimum specified test gas flow (120 or 70 ml/min)
  - adults: 28 hneonates: 34 h
- with a maximum specified test gas flow (200 or 120 ml/min)
  - adults: 17 hneonates: 20 h



## Change (calibration) O<sub>2</sub> cell (side current measurement)

- **1.** Turn on the leon *plus* as follows:
- **2.** Let a ventilation run for at least two minutes. Then stop the ventilation.
- **3.** Remove the sample line from the patient adapter.
- **4.** Remove the water trap.
- **5.** Remove the  $O_2$  cell (use a coin and turn the  $O_2$  cell anticlockwise).
- **6.** Insert the (possibly new) O<sub>2</sub> cell.
- 7. Insert the water trap with connected sample line.
- 8. Wait approx.10 seconds.
- **9.** Carry out a 100% O<sub>2</sub> calibration (see service instructions).
- (1) O<sub>2</sub> cell

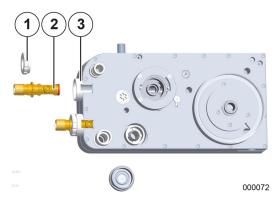
## Flow sensor servicing

At every system test the flow sensors are checked and calibrated. If the check or calibration could not be executed successfully, check:

- soiling
- faulty connection of the plug
- damage (measuring wire ripped, housing breaks, plug broken off, O-ring)

Before cleaning and disinfection the flow sensors must be dismantled and changed if they are damaged.

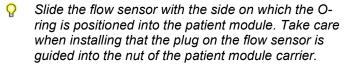
#### Change (dismantling) flow sensors



- **1.** Remove the CO<sub>2</sub> absorber.
- **2.** Take the patient module from the docking station on the device.
- 3. Place the patient module onto a firm base.
- **4.** Remove the lock nuts (turn anticlockwise) that hold the flow sensors in the patient module.
- **5.** Pull the flow sensors out of the carrier.
- (1) lock nut
- (2) flow sensor
- (3) flow sensor carrier

Installation is carried out in reverse sequence.

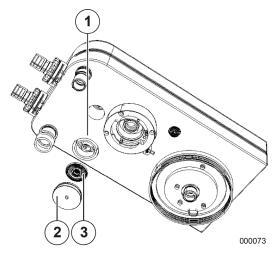
(→ "Connection for respiratory bellows, dome and CO<sub>2</sub> absorber, PEEP valve diaphragm cover, flow sensors" p. 62)



## PEEP valve diaphragm servicing

Before cleaning and disinfection the PEEP valve diaphragm must be dismantled and changed if damaged.

### Change (dismantling) PEEP valve diaphragm

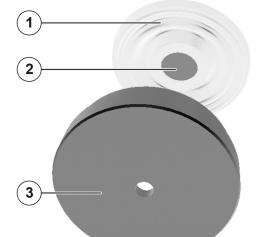


#### Remove the PEEP valve diaphragm

- **1.** Remove the CO<sub>2</sub> absorber.
- **2.** Take the patient module from the docking station on the device.
- **3.** Place the patient module onto a firm base.
- **4.** Remove the PEEP valve membrane cover (turn bayonet catch anticlockwise) that holds the PEEP valve diaphragm in the patient module.
- **5.** Remove the PEEP valve membrane.
- (1) PEEP valve diaphragm carrier
- (2) PEEP valve diaphragm cover
- (3) PEEP valve diaphragm

Installation is carried out in reverse sequence.

( $\rightarrow$  "Connection for respiratory bellows, dome and CO<sub>2</sub> absorber, PEEP valve diaphragm cover, flow sensors" p. 62)



## Installation of the PEEP valve diaphragm

- (1) PEEP valve diaphragm
- (2) metal disc

000074

(3) PEEP valve diaphragm cover



Faulty installation of the PEEP valve diaphragm!

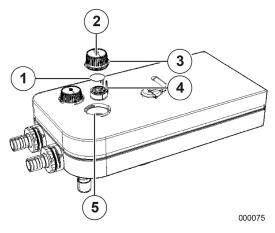
#### **Device malfunction**

 Place the diaphragm in the diaphragm cover so that the metal disc in the diaphragm can be seen through the hole in the cover.

## Servicing of the insp./exp. valve diaphragms

Before cleaning and disinfection the insp./exp. valve diaphragm(s) must be dismantled and changed if damaged.

#### Change (dismantling) of the insp./exp. valve diaphragms



#### Changing the valve diaphragm

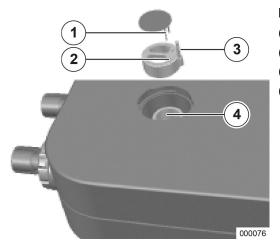
- **1.** Remove the inspection glass by turning anticlockwise and lift it out.
- **2.** Put the valve diaphragm holder on the peg provided for it from its seat in the patient module.
- Tear the old valve diaphragm from the valve diaphragm holder. Remove any remnants from the valve diaphragm holder.
- **4.** Pull the two flag rods of the new valve diaphragm through the drill-holes provided in the valve diaphragm holder until the valve diaphragm lies evenly all over the valve diaphragm holder.
- **5.** Cut the two flag rods sticking out from the valve diaphragm holder as short as possible.
- (1) valve diaphragm
- (2) inspection glass
- (3) O-ring
- (4) peg
- (5) seat in the patient module



Faulty installation of the valve diaphragm!

#### **Device malfunction**

- Cut off the two flag rods sticking out from the inside of the valve diaphragm holder.
- If the valve diaphragms are removed from the diaphragm holder, these valve diaphragms may not be used again and must be replaced by new valve diaphragms.



#### Installation of the valve diaphragm

- (1) valve diaphragm flag rods
- (2) valve diaphragm holder drill-holes
- (3) valve diaphragm holder peg
- (4) valve diaphragm holder seat

## Servicing of fans

Change the fan filter pad on the rear of the housing if soiling is detected.

- **1.** Pull the protective grid vertically from the mounting.
- **2.** Change the filter pad.
- 3. Press the protective grid back into the mounting.

## Servicing of reserve gas bottles and 10 L bottles

#### Regular checks of the reserve gas bottles and 10 L bottles



(→ "10 L bottle connection instead of ZGA" p. 70)

#### Safety



WARNING

Bottle valves, high pressure regulator and connected fittings!

## Explosion risk

- Do not use any kind of tool to open the bottle valves.
- Oil and fats can react violently with some gases under pressure (O<sub>2</sub>, N<sub>2</sub>O (laughing gas), compressed air and their mixtures).
  - Do not grease or oil the connections for reserve gas bottles.
  - Avoid contact between hand cream and the fittings.



 $O_2$  strongly encourages burning when in contact or mixed with flammable materials.

#### Risk of burning

WARNING

- Before connection it is essential that the compatibility of the gas type of the high-pressure regulator and the supply is ensured.
- Ensure good ventilation.
- No smoking and no bare flames.



 $N_2\text{O}$  has a strong anaesthetic effect and increases the flammability of all flammable substances.

#### Danger of O<sub>2</sub> shortage and respiratory standstill

- WARNING
- Before connection it is essential that the compatibility of the gas type of the high-pressure regulator and the supply is ensured.
- Ensure good ventilation.
- No smoking and no bare flames.



It must be insured through special guards that no dangerous pressure can build up in devices that are connected to the high-pressure regulator. The poppet valve of the high-pressure regulator is not suitable as protection for this device.

The high-pressure regulator is not fitted with a back pressure manometer. If monitoring of the back pressure in operation is desired, it is monitored by the connected device.

#### Change of the reserve gas bottles

#### Preparation of reserve gas bottles

For the high-pressure regulator to function perfectly it is required that the bottle valve is in a clean condition and that dust-free and dry gases are used.

- Check the label to see whether the available highpressure regulator is suitable for the intended application purpose (gas type, pressure). The maximum permissible inlet pressure of the highpressure regulator should be equal to or higher than the full pressure of the bottle.
- (→ "Technical data" p. 301)
- In well-ventilated rooms or in the fresh air: Before connecting the high-pressure regulator, open the valve of the pressure gas bottle slowly but briefly to blow off contaminants.
- Take off the protective caps from the connections of the high-pressure regulator and keep them to one side.
- **4.** Screw the pressure bottle to the high-pressure regulator.
  - The connections must fit to each other directly.
  - Do not use any adapter pieces!
- All connections must be clean, as well as free from oil and grease! Do not use any lubricants!

  These could soil the high-pressure regulator. Also, when using O<sub>2</sub> or N<sub>2</sub>O there is a risk of burning.
- **5.** Plug the high-pressure sensors into the sockets in the rear wall of the device (only with 10 L bottles).
- (→ "Technical data" p. 301)



WARNING

Pressure surges through quick opening!

Do not direct gas jet at people.

**Explosion risk** 

## Manual connection of the high-pressure regulator

To facilitate joining the high-pressure regulator to the bottle valve, the high-pressure regulator is fitted with a manual connector.

When connecting, be sure not to use a tool to screw it on.

The connection must be removed without pressure. The removal of the connection under pressure and using a tool may only be carried out in an emergency. The seal ring is destroyed by this procedure.

## 13

## Cleaning and disinfection of the high-pressure regulator

**Before cleaning and disinfection**Close the inlet connection with suitable caps if the

high-pressure regulator is not connected to a gas

bottle.

Cleaning of the high-pressure regulator 
Clean the surface of the high-pressure regulator with

a disposable cloth.

Disinfection of the high-pressure

regulator

For disinfection, use permitted, commercial preparations from the group of surface disinfectants. Observe the manufacturer's instructions for use.

The high-pressure regulator may not be immersed in

fluids and may not be sterilised!

Maintenance of the high-pressure

regulator

 $(\rightarrow$  "Maintenance of the high-pressure regulator"

p. 272)

#### Troubleshooting the high-pressure regulator and reserve gas bottles

Table 57: Faults and fault-fixing				
	Problem	Possible cause	Remedy	
Case 1	Link between bottle and high- pressure regulator is untight	Seal ring damaged	Replace seal ring	
Case 2	Back pressure increases, poppet valve discharges	Valve seat soiled or damaged	Repair by a Löwenstein Medical- authorised service technician	
Case 3	Untightness in the area of the spring bonnet	Valve damaged	Repair by a Löwenstein Medical- authorised service technician	
Case 4	Maximum flow is not reached	Filter in the inlet pressure connection blocked	Repair by a Löwenstein Medical- authorised service technician	

## Disposal



For the professional removal of separated fluids (e.g. fluids from reusable water traps) please refer to the hygiene guidelines of your hospital.

## Disposal of gas

Proper discharge of calibration gases

Carry out the calibration in well-ventilated rooms only. Refer to the hygiene guidelines of your hospital.

Proper discharge of sampled gases

Connect the device to a narcotic gas aspiration hose to remove the sampled gas.

## Disposal of soda lime

The soda lime can be contaminated by patient gas. For disposal please refer to the hygiene guidelines of your hospital.

## Disposal of bronchial aspiration filter

The filter can be contaminated by patient gas, blood, stomach and tracheal secretions. For disposal please refer to the hygiene guidelines of your hospital.

## Disposal of water trap and sample line

Water trap and sample line can be contaminated by patient gas. For disposal please refer to the hygiene guidelines of your hospital.

## Disposal of O<sub>2</sub> sensor

The O<sub>2</sub> sensor contains lead. It may therefore not be disposed of with household waste. For disposal please refer to the hygiene guidelines of your hospital.

## Disposal of flow sensor

The flow sensors can be contaminated by patient gas. A repair of the flow sensor is not possible. For disposal please refer to the hygiene guidelines of your hospital.

## Disposal of valve diaphragm

The valve diaphragms can be contaminated by patient gas. For disposal please refer to the hygiene guidelines of your hospital.

## Disposal of fan filter pad

May not be disposed of with household waste.

# Disposal of electric and electronic components of the device

In general, electric and electronic components of the device are only disposed of during servicing.

Otherwise, dispose of this material according to the label if marked. If in doubt, please proceed in accordance with the disposal guidelines of your hospital or contact a Löwenstein Medical representative.

## **Disposal of battery**

Dispose of this material according to the label if marked. If in doubt, please proceed in accordance with the disposal guidelines of your hospital or contact a Löwenstein Medical representative.

## Changing and filling reserve gas bottles or 10 L bottles

Please refer to the guidelines of your hospital.

## Maintenance by authorised service technicians

#### **General information**

A maintenance service contract should be taken out. Please contact a Löwenstein Medical-authorised service technician or another Löwenstein Medical representative.

Use only original components by Löwenstein Medical for maintenance.

Before beginning maintenance an inspection is required (establishment of actual state). The inspection establishes whether along with the actual maintenance other measures are needed to maintain or restore the proper operational state of the device.

## **Servicing interval**

#### Every 12 months (servicing):

- STC (to establish faults)
- annual service
- system adjustment/system calibration
- STC (check of work carried out)

## Every 3 years or every 10,000 operating hours (general overhaul):

- STC (to establish faults)
- annual service
- 3-year service
- system adjustment/system calibration
- STC (check of work carried out)

## Every 6 years or every 20,000 operating hours (general overhaul):

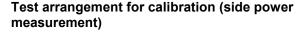
- STC (to establish faults)
- annual service
- 3-year service
- 6-year service
- system adjustment/system calibration
- STC (check of work carried out)

#### Side power measurement servicing

#### **Calibration (side power measurement)**

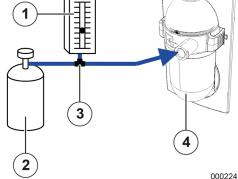
A calibration is recommended.

- annually (during service)
- in the event of suspicion of extreme deviation from a measured value



#### Required:

- (1) Flow meter: (measuring range 0-200 ml/min)
- (2) Calibration gas: (Scott Medical recommended)
- (3) Y-piece: (for inner tube diameter 2 mm)
- (4) Water trap



The flow meter is needed to ensure that the multi gas analyser does not draw in any air from the room in parallel.

Table 58: Calibration gas concentration

Gas	Concentration [%]	Tolerance [%]
CO <sub>2</sub>	6	±0.2
N <sub>2</sub> O	45	±3.0
O <sub>2</sub>	45	±2.0
desflurane	4	±0.2

The components of the used calibration gas must have the accompanying concentrations:

## Execution of the calibration (side power measurement)

- 1. Put the test arrangement together
- (→ "Test arrangement for calibration (side power measurement)" p. 270).
- 2. Turn on the device.
- 3. Start the MAN/SPONT form of ventilation.
- **4.** Open the valve of the calibration gas bottle until a value between 0–10 ml/min can be read on the flow meter (to ensure that the multi gas analyser is drawing in calibration gas only).
- **5.** Wait 30 seconds for the system to stabilise.
- **6.** Compare the measured value including tolerance with the values given on the calibration gas bottle.



#### Storing of the calibration gas

The storage temperature is between 18 °C and 25 °C.

If a storage temperature of 5  $^{\circ}$ C is exceeded a 1-hour mixture (at 18  $^{\circ}$ C to 25  $^{\circ}$ C) is required before the given concentrations are reliable.

Twist or turn the container



If the values are outside of the tolerance, notify a Löwenstein Medical-authorised service technician.

## Maintenance of the high-pressure regulator

Maintenance may be carried out only by trained specialist staff and with original Löwenstein Medical spare parts!

Under normal demands an inspection is carried out every 12 months, during which the device is inspected for external damage and its functionality is checked.

In addition, a general overhaul must be carried out every 6 years, which includes the replacement of all worn components.

In the event of unusually high demand shorter servicing intervals may be required.

## **Technical safety controls**

#### General information

Scope and periods of technical safety controls in accordance with the German Medical Devices Act (MPG)/Medical Devices Operator Ordinance (MPBetreib V) Section 6.



The controls listed here must be carried out in this scope as a minimum.

The following controls must be carried out on this device at least every 12 months. They may be carried out only by persons who, due to their education, knowledge and experience gained from practical activity, provide the guarantee for a proper execution of the technical safety controls that, with regard to this controlled activity, are subject to no court orders and have suitable measuring and test facilities.

#### Scope of the tests and documentation

All test and measuring results must be logged in the medical product book.

**Periods** 

## **Mechanical safety**

Table 59: Tests – mechanical safety			
Gas connection tubes	Check the gas connection tubes for O <sub>2</sub> , AIR and N <sub>2</sub> O with regard to mechanical damage and untightness.		
Keypad	Check for mechanical damage, legibility and function		
Touchscreen	Check for mechanical damage and function		
Patient module	Check for mechanical damage		
Bag-in-bottle unit	Check for mechanical damage		
CO <sub>2</sub> absorber	Check for mechanical damage		
Anaesthetic vaporiser (if available)	Check brakes and check for mechanical damage		
Monitor support arm (if available)	Check for perfect mechanical state		
Tube support arm (if available)	Check for perfect mechanical state		
Cable support arm (if available)	Check for perfect mechanical state		
Workstation illumination (if available)	Check for perfect mechanical state and functionality		
Trolley	Check wheels and brakes for perfect mechanical state		

## **Electrical safety**

## **General requirements (STC)**

Check, assessment of results and documentation of the process/results must be carried out in accordance with DIN EN 62353; measuring devices must also meet these requirements!

Table 60: STC (measured values)				
Electrical cables	Check the condition of all of the cables for intactness, brittleness and strain relief.			
Protective conductor resistance leon <i>plus</i>	The protective conductor resistance between the protective contact of the device plug and all exposed metal components of the leon <i>plus</i> , which in the case of a fault can receive direct mains voltage, may not exceed:	0.2 Ohm		
Reserve device earth leakage on the leon <i>plus</i>	The reserve device earth leakage on the leon <i>plus</i> must be checked with an appropriate IEC 60601-1 earth leakage measurement device. It is measured on the protective earth conductor or on the components joined to the protective earth conductor, including any connectable units, and may not exceed:	1.0 mA		
Insulation resistance	The insulation resistance must be measured between L + N against the protective conductor and may not exceed:	> 2.0 MOhm		

## **Functional safety**

Table 61: Establish functional safety					
Check for tightness		1.	Execute a system test. (→ "System test" p. 110)		
Alarms			Check the alarm functions. (→ "Test of alarm functions" p. 125)		
PEEP valve			Connect an external pressure meter to the y-piece followed by a commercial artificial lung.		
		4.	Start controlled ventilation.		
			<b>5.</b> Set the various PEEP values and compare the displayed values with the external pressure meter.		
Ventilation pressure		6.	Connect an external pressure meter to the y-piece followed by a commercial artificial lung.		
		7.	Start controlled ventilation.		
		8.	Set the various pressure values on the leon <i>plus</i> and compare the displayed values with the external pressure meter.		
Fresh gas blender	Flow	9.	Connect an external flow meter to the connection pin for fresh gas.		
		10	Set the various föow values on the leon <i>plus</i> and compare the displayed values with the external flow meter.		
	Gas concentrations	11	. Connect an external gas meter to the connection pin for fresh gas.		
		12	. Set a flow of 2 l/min for $O_2$ on the leon <i>plus</i> .		
		13. Set various O <sub>2</sub> concentrations on the leon plus.			
		14	Compare the set values with the external gas meter.		
Anaesthetic vaporisers		15	Connect an external gas meter to the connection pin for fresh gas.		
		16	. Set a flow of 2 I/min on the leon plus.		
		17	Set the various concentrations and compare the set values with the external gas meter.		

Table 61: Establish functional safety				
Gas measurement		<b>18.</b> Check the calibration. (→ "Calibration (side power measurement)" p. 270)		
	Ratio system	19. Start controlled ventilation.		
		<b>20.</b> Select AIR as carrier gas and set an O <sub>2</sub> concentration of 21%.		
		<b>21.</b> Select N <sub>2</sub> O as carrier gas.  The setting of the O <sub>2</sub> concentration jumps to 25%.		
	N2O cut-off	22. Start controlled ventilation.		
O <sub>2</sub>		<b>23.</b> Pull out the $O_2$ supply plug from the ZGA and wait until the $O_2$ pressure has dropped to <0.6 kPa × 100 (bar). It is no longer possible to administer $N_2O$ .		
	Flush	<ul> <li>24. Proceed according to the leon plus short checklist before start-up.</li> <li>(→ "leon plus Short checklist before start-up" p. 300)</li> </ul>		
	Switch-over	25. Start controlled ventilation.		
		<b>26.</b> Unplug the $O_2$ and $N_2O$ supply plugs from the ZGA and wait until the $O_2$ and $N_2O$ pressure has dropped to <2.5 kPa × 100 (bar).		
Reserve		27. Open the reserve gas bottles.		
	Backflow	<b>28.</b> When connected to the ZGA, connect an external flow meter to the O <sub>2</sub> and the N <sub>2</sub> O reserve gas bottles connection, as desired. No gas may flow from the connections.		
APL		(→ "APL valve" p. 63)		
Batteries		<ul> <li>29. Proceed according to the leon <i>plus</i> short checklist before start-up.</li> <li>(→ "leon <i>plus</i> Short checklist before start-up"</li> <li>p. 300)</li> </ul>		

#### **Miscellaneous**

- Visual check of external changes of the device/system. After changing a system, measured values must be documented as firstmeasured values.
- Visual check of external faults or damage.
- User manual must be present and correspond to the installed software version.
- Warnings in the German language must be present.
- Medical product book must be present.

#### Assessment and documentation

If the earth leakage measurement values exceed 0.9 times the permissible values, they must be compared with the previous first measured values. If these are not present, a shortening of the checking interval may be required. If the safety of an external device/system is not given, e.g. through not passing tests, this must be identified by informing the user in writing of the emanating threats.

### Checklist leon plus Technical safety controls

A suggestion for a copyable text "Checklist of technical safety controls" for the leon *plus* is located in the final pages of this document.

### 14. Accessories

## **General information**

Only the following listed accessories and consumables may be used with the leon *plus*:

- leon *plus* Spare parts ordering consumables
- leon plus Spare parts ordering options and replacement

The use of accessories and consumables other than those specified can limit the performance and safety system. The accessories and units that are used with the leon *plus*, must nevertheless comply with the requirements of DIN EN 60601-1 or DIN EN ISO 80601-2-13.



The user is responsible for ensuring that all accessories and units are compatible with the system and that their deployment does not impair the normal functionality of the system.

If in doubt, contact a Löwenstein Medical representative.

Nothing may be affixed to the system (e.g. stickers). This could lead to important information being concealed, which could lead to an impairment of the patient's safety.

### **Accessories Consumables**

 $(\rightarrow$  "leon plus Spare parts ordering consumables" p. 300)

## Accessories options and replacements

 $(\rightarrow$  "leon plus Spare parts ordering options and replacement" p. 300)

## **O-ring**

(→ "O-ring" p. 299)

## 15. Product combinations

## **General information**

Only the following listed auxiliary devices may be used with the leon *plus*. The use of auxiliary devices other than those specified can limit the performance and safety of the system. The accessories and units that are used with the leon *plus*, must nevertheless comply with the requirements of DIN EN 606011 or DIN EN ISO 80601-2-13.



The user is responsible for ensuring that all auxiliary devices are compatible with the system and that their deployment does not impair the normal functionality of the system.

If in doubt, contact a Löwenstein Medical representative.

## **Auxiliary devices**

If devices from other manufacturers are connected to the leon *plus*, the safety of this equipment must fulfil the requirements of the following standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 80601-2-13

The total power consumption of the device including the 4 auxiliary outlets may not exceed 9 A.

The workstation may not contain more than these four auxiliary outlets.

The total earth leakage current may not exceed 5 mA in the normal state for connected auxiliary devices. Measuring is recommended.

#### **ATTENTION**

When connecting devices to the auxiliary outlets, the values of the patient leakage currents can increase to values which exceed the permissible value of 10 mA in the event of a faulty earth wire.

The total weight of the monitor mounted on the top shelf of a support arm is restricted.

With gas monitors with side power measurement processes, ensure that the gas measurement sample is not conducted into the room

If in doubt, contact a Löwenstein Medical representative.

## Mounting additional monitors

Additional monitors should only be mounted on the top shelf or fixed to a support arm mounted on the side of the device. Monitors that are mounted on the top shelf must be secured to ensure they do not fall off. For stability reasons, the total weight of the display units on the shelving may not exceed 20 kg. You should also observe the maximum installation height of < 1800 mm (clearance height of doors). For stability reasons, the total weight of the monitors mounted on the support arm (max. Length 500 mm) may not exceed 15 kg.

If in doubt, contact a Löwenstein Medical representative.

## **Anaesthetic vaporiser**

All anaesthetic vaporisers can be used with Selectatec or Dräger-compatible mounting, which comply with the following standards:

- ISO 5358
- ISO 80601-2-13
- ISO 5360
- ISO 5356-1
- 93/42/EEC

If in doubt, contact a Löwenstein Medical representative.

## **Bronchial aspiration**

Only vacuum-driven bronchial aspirations may be connected.

If in doubt, contact a Löwenstein Medical representative.

## **Support arms**

Only use support arms approved by Löwenstein Medical.

- monitor support arm
- cable support arm
- tube support arm
- PC support arm

If in doubt, contact a Löwenstein Medical representative.

## **PDMS**

On request.

### HIS

On request.

## **AGSS**

The AGSS used must comply with the requirements of DIN EN ISO 80601-2-13.

If in doubt, contact a Löwenstein Medical representative.

## 16. Appendix

## Notes

Table 62: Notes			
Number	Entry		

Table 62: Notes				
Number	Entry			

## Gas flow plans

## Legend gas flow plans

Table 63: Legend for gas flow plans 1			
<b>\$</b>	Non-return valve open		
•	Non-return return valve closed		
Voice Coil	Electrically controlled valve open		
Voice Coil	Electrically controlled valve closed		
-	Gas flow with direction		
	Tube system under pressure		
=>=	Excess gas		

Table 64: Legend for gas flow plans 2			
PM	Patient module	В	Ventilation bag
G1	Fresh gas	AV	Anaesthetic vaporiser
G2	O <sub>2</sub> flush	AB	CO <sub>2</sub> absorber
G3	Drive gas	Paw	Ventilation pressure
RV1	Decoupling valve	D	Dome
RV2	Emergency air valve	FG	Fresh gas outlet
RV3	Inspiratory valve diaphragm	SV1	Slide valve auto/manual 1
RV4	Expiratory valve diaphragm	SV2	Slide valve auto/manual 2
RV5	Absorber decoupling valve	SV3	Slide valve of open system
VC1	Plateau valve	SV4	Fresh gas outlet change-over valve
VC2	PEEPvalve	F1	Inspiratory flow sensor
APL	Manual overdrive valve	F2	Expiratory flow sensor
PV	Excess valve	AGSS	Connection to the anaesthesia gas scavenging system

## Inspiration (manual)

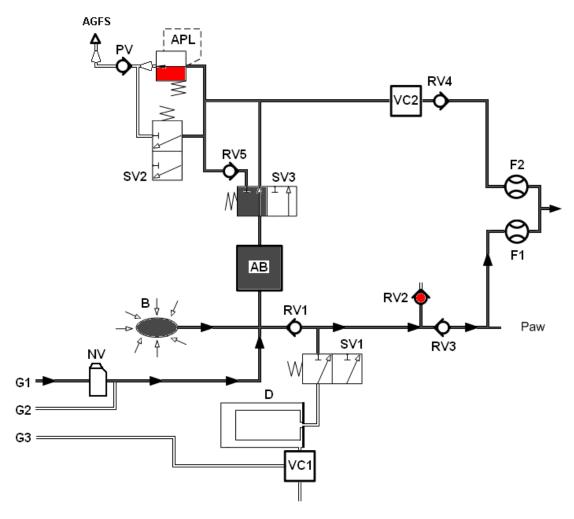


Fig.1: manual ventilation, inspiration

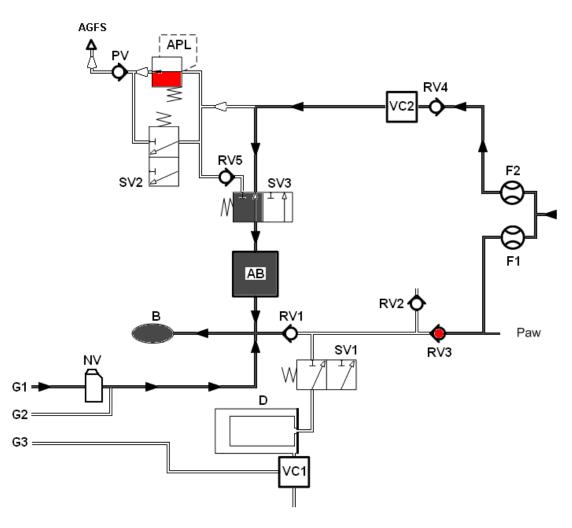


Fig.2: manual ventilation, expiration

## **Mechanical ventilation**

## Inspiration (semi-closed)

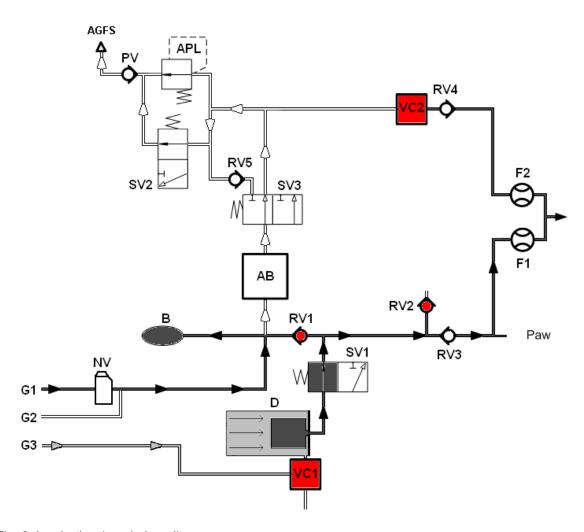


Fig. 3: inspiration (semi-closed)

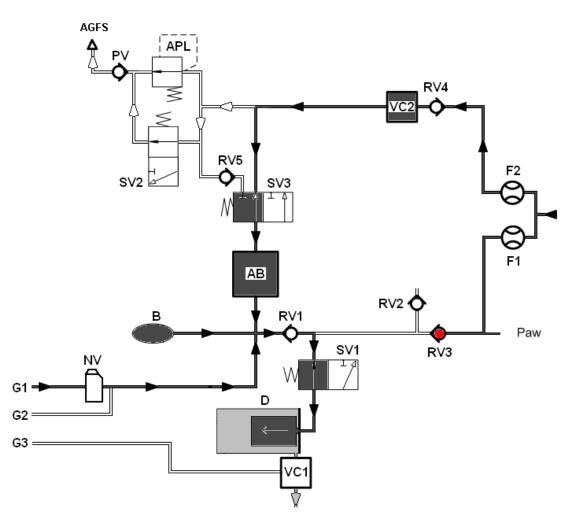


Fig. 4: Expiration (semi-closed)

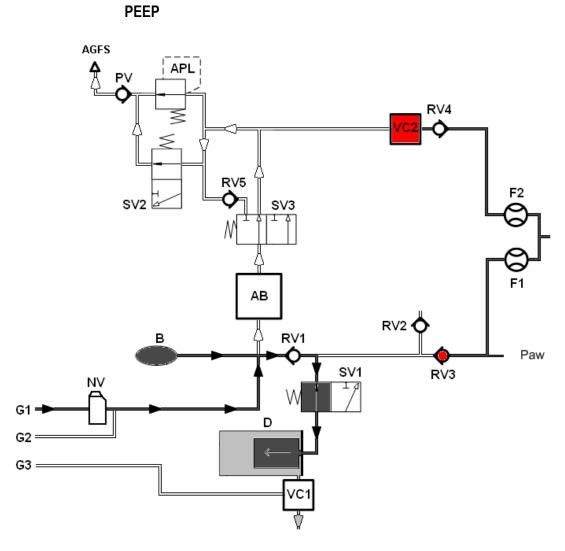
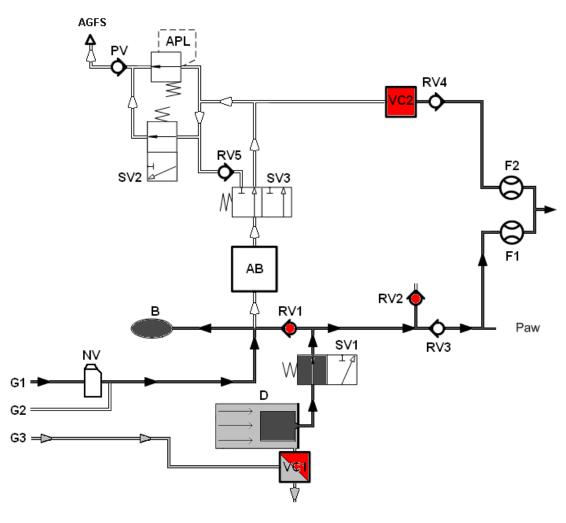


Fig. 5: PEEP



III. 6: Plateau

### **Calculation methods**

Table 65: alveolar concentration for MAC = 1

AA	MAC <sub>40</sub> [%]
N <sub>2</sub> O	100.00
halothane	0.75
enflurane	1.70
isoflurane	1.15
sevoflurane	2.05
desflurane	6.00

MAC= 
$$\frac{\text{EtAA}_{1}[\%]}{\text{xAA}_{1}} + \frac{\text{EtAA}_{2}[\%]}{\text{xAA}_{2}} + \frac{\text{EtN}_{2}O[\%]}{\text{xN}_{2}O}$$

 $AA_{1,2}$  = inhalation anaesthetic Et = end-expiratory concentration  $AA_{1,2}$  =  $ABC_{40} \times AB_{1,2} \times AB_{1,2}$ 

$$Freq_{Spont} = AZV_{trig} + AZV_{spont}$$

AZV <sub>trig</sub>	= number of triggered, supported breaths
AZV <sub>spont</sub>	= number of spontaneous breaths

# $\%Spont.[\%] = \frac{100 \times \left(AZV_{trig} + AZV_{spont}\right)}{AZV_{trig} + AZV_{spont} + AZV_{mech}}$

AZV <sub>trig</sub>	<ul><li>number of triggered, supported breaths</li></ul>
AZV <sub>spont</sub>	= number of spontaneous breaths
AZV <sub>mech</sub>	<ul><li>number of mechanical breaths (untriggered)</li></ul>

# $Leak[\%] = \frac{MV_i - MV_e}{MV_i} \times 100$

MV <sub>e</sub>	= exp. minute volume
$MV_i$	= insp. minute volume

**MAC** = minimum alveolar concentration;

Definition:

minimum alveolar concentration;

MAC is the alveolar concentration of an inhalation anaesthetic to which 50% of all patients no longer react defensively to the surgical skin incision. MAC is a direct measure for the potency of an anaesthetic.

The MAC value is an empirically raised value. MAC depends on age.

The displayed minimum alveolar concentration is calculated according to the accompanying formula and only applies to patients of an age of >1 year. (Calculation according to W. W. Mapleson)

If  $N_2O$  is administered at the same time, the minimum alveolar concentration (MAC) is reduced.

#### Freq<sub>Spont:</sub>

Number of spontaneous breaths.

#### %Spont.:

Number of spontaneous breaths to the total frequency.

#### Leak:

Difference between inspiratory and expiratory minute volume.

#### O<sub>2</sub> uptake and CO<sub>2</sub> production

O<sub>2Uptake</sub>: O<sub>2</sub> uptake of the patient per minute

$$O_{2\mathsf{Uptake}}[\mathsf{mI/min}] = \int\limits_{\mathsf{t1}}^{\mathsf{t2}} \left( \dot{\mathsf{V}}_{(\mathsf{t})} \times O_{2\mathsf{Konz}(\mathsf{t})} \right) \mathsf{dt} + \int\limits_{\mathsf{t2}}^{\mathsf{t3}} \left( \dot{\mathsf{V}}_{(\mathsf{t})} \times O_{2\mathsf{Konz}(\mathsf{t})} \right) \mathsf{dt}$$

CO<sub>2Produktion</sub>: CO<sub>2</sub> uptake of the patient per minute

$$CO_{2Prod}[ml/min] = \int_{t2}^{t3} (\dot{V}_{(t)} \times CO_{2Konz(t)}) dt \times (-1) - \int_{t1}^{t2} (\dot{V}_{(t)} \times CO_{2Konz(t)}) dt$$

Ÿ = flow

t3

= O<sub>2</sub> concentration O<sub>2 Konz.</sub>

= CO<sub>2</sub> concentration CO<sub>2 Konz.</sub>

= Start of the inspiration t1 (flow > 0)

t2 = Start of the inspiration

(flow < 0)

= Start of the next inspiration (flow > 0)

$$C (stat.) = \frac{V_{Te}[ml]}{(P_{Plat.}[mbar] - PEEP[mbar])}$$

stat. = static

= expiratory mechanical breath  $V_{Te}$ 

volume

= Plateau pressure P<sub>Plat</sub>.

#### Compliance C<sub>stat.</sub>:

Lung elasticity (static)

$$C (dyn.) = \frac{V_{Te}[ml]}{(P_{Peak}[mbar] - PEEP[mbar])}$$

Compliance C<sub>dyn.</sub>:

Lung elasticity (dynamic)

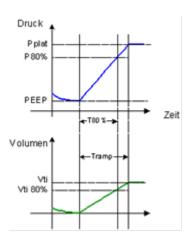
= dynamic dyn.

= expiratory mechanical breath volume

 $P_{\text{Peak}}$ = peak pressure

Compliance during the last 20% of the inspiration phase

16



#### C20/C:

Compliance during the last 20% of the inspiration phase in relation to total compliance (Measurement for overdistention of the lungs)

$$R (stat.) = \frac{(P_{Plat.}[mbar] - PEEP[mbar])}{\dot{V}_{max.}[ml/s]}$$

stat. = static

P<sub>Plat.</sub> = Plateau pressure

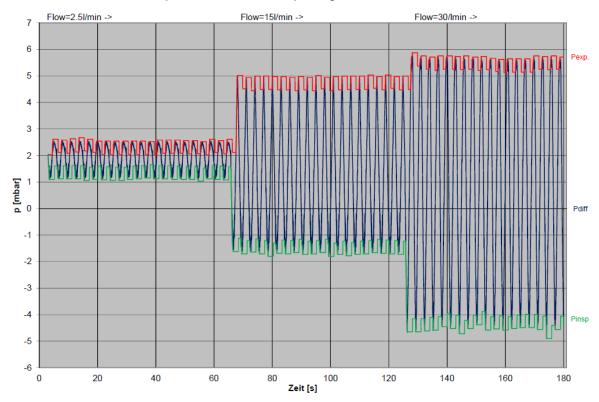
 $\dot{V}_{max.}$  = maximum expiratory flow

#### Resistance:

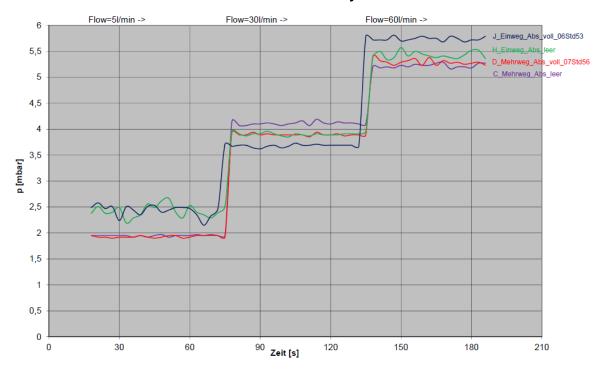
Static inspiratory resistance of the lungs and of the tube system/device

# **Pressure flow characteristics**

# Inspiratory and expiratory pressure flow characteristics of the system to the patient connection opening



# Inspiratory and expiratory pressure flow characteristics of the absorber module of the breath circulation system



# Life of consumables

#### Life of soda lime

- · change of colour of the soda lime
- increased insp. CO<sub>2</sub> Measured value

### Life of bronchial aspiration filter

- 2 months
- in the event of visible soiling
- slackening of aspiration performance
- damaged

#### **Gas measurement**

#### Life of water trap and sample line

- 1 month
- damaged

If the water trap and sample line are not changed at the prescribed interval (monthly), the multi analyser guarantee ceases.

#### Life O<sub>2</sub> cell (side power measurement)

- 12 months
- damaged

#### life:FiO<sub>2</sub> cell

- 12 months
- damaged

#### Life of the flow sensors

- soiling that cannot be removed
- damaged

A guarantee of 1 year or a maximum of 52 executed cleaning cycles is given for the housing of the flow sensor. Damage caused by neglect is excluded from this guarantee.

No guarantee is given for damage to electrical components of the flow sensor caused by improper handling, especially during cleaning.

#### Life of the PEEP valve diaphragm

- annual service
- untight
- damaged

### Life of the insp./exp. valve diaphragms

- annual service
- damaged

#### Life of the fan filter pad

- annual service
- soiled
- damaged

# O-ring

# Table 66: O-ring

Item number	Description	Number
0020201	APL (bayonet lock)	2
0020206	APL	1
0020170	Pin of docking station (large)	2
0020168	Pin of docking station (small)	6
0020156	Plateau valve on patient module	1
0020162	Inspiration, expiration inspection glass	2
0020119	Transition of housing to the docking station (small)	4
0020054	Transition of housing to the docking station fresh gas	1
0020005-1	Anaesthetic vaporiser mounting valves	4
0020166	Water trap receptacle	2
0020159	Damping of the base of the patient module on the docking station	7

#### **Inlet pressures**

#### leon plus Spare parts ordering consumables

A copyable text "Spare parts ordering consumables" for the leon *plus* is located in the final pages of this document.

# leon *plus* Spare parts ordering options and replacement

A copyable text "Spare parts ordering options and replacements" for the leon *plus* is located in the final pages of this document.

### leon plus Short checklist before start-up

A copyable text "Short checklist before start-up" for the leon *plus* is located in the final pages of this document.

## leon plus Short operating instructions

A copyable text "Short operating instructions" for the leon *plus* is located in the final pages of this document.

## leon plus Technical safety controls checklist

A suggestion for a copyable text "Checklist of technical safety controls" for the leon *plus* is located in the final pages of this document.

# 17. Technical data

The maximum equipment of the leon *plus* is described in the technical data. Basic equipment and options.

 $(\rightarrow$  "Device description" p. 27)

Table 67: Basic data, weight, dimensions			
Chassis	Trolley with 4 antistatic rollers		
	Brakes	All rollers can be locked	
		Central brake for all 4 rollers (optional)	
	Base weight	145 kg (with central brake and anaesthetic vaporiser)	
	Dimensions (H x W x D) 140 x 92 x 67 cm		
	Minimum clearance width = 70 cm		
	Removable writing shelf (W x D)	42 x 60 cm	
	3 drawers (H x W x D) 8 x 25 x 24 cm		
Wall device	Base weight 100 kg Dimensions (H x W x D) 93 x 85 x 48 cm		
Wall mounting	optional		
Ceiling mount	optional		
Sound level	standby 34.5 dBA, ventilation 40 dBA		
	alarm min. (50%) 50 dBA, alarm max. (100%) 70 dBA		
Life	10 years		

Table 68: Ambient conditions in operation			
Ambient temperature	+15 °C - +35 °C		
Relative humidity	20 - 80%, non-condensing		
Atmospheric pressure	700 - 1060 Pa × 100		
Table 69: Ambient conditions for storage and transport			
Ambient temperature	-15 °C - +60 °C O <sub>2</sub> sensor -15 °C - +50 °C Battery -15 °C - +40 °C		
Relative humidity	20 - 80%, non-condensing		
Atmospheric pressure	500 - 1060 Pa × 100		
Table 70: Electromagnetic compatibility			
Conforms to standard	EN 60601-1-2		
Table 71: protection class			
	I Type B in accordance with EN 60601-1		
Table 72: Classification			
	II b pursuant to 93/42/EEC Appendix IX		
Table 73: Mains voltage and power supply			
Mains voltage	240 V(AC) +10 %/-15 %, 50/60 Hz 115 V(AC) +10 %/-15 %, 50/60 Hz		
Power consumption	120 VA (including heating 20 W)		
Rechargeable battery supply	2 x 12 V(DC) each with 7.2 Ah		
Rechargeable battery life	At least 100 minutes (with fully charged batteries)		
Auxiliary outlets	4 units, each with 2 x T 2 A fuses		

Table 74: Gas connections		
Central gas supply	Connections for O <sub>2</sub> , N <sub>2</sub> O and AIR	
Reserve gas bottles	Connections for $O_2$ and $N_2O$ Display of reserve gas bottles pressure Permissible input pressures: $O_2$ , $N_2O$ : <5 - 200 kPa × 100 (bar)	
10 L bottles	O <sub>2</sub> , N <sub>2</sub> O or AIR  Monitoring of the supply pressures with display on the screen  Permissible input pressures:  O <sub>2</sub> , N <sub>2</sub> O, AIR: <5 - 200 kPa × 100 (bar)	
Supply pressure	2.8 - 6.0 kPa × 100 (bar)  Monitoring of the supply pressures with display on the screen	
Connection type (standard)	NIST standard	
Aspiration	Integrated vacuum source for bronchial aspiration with vacuum display	

Table 75: Gas control		
Fresh gas producer	Electronic fresh gas blender for 3 gases Selection of gas blend and flow settings via screen display	
= O <sub>2</sub> concentration	Setting range 21 – 100 vol. % with $N_2O$ as carrier gas 25 – 100 vol. % (ratio system) 100 % $O_2$ with fresh gas flow = 200 ml/min Accuracy $\pm 5$ %	
Fresh gas flow	Setting range	0.2 – 18 l/min
	Accuracy	<0.5 l/min ±0.05 l/min and >0.5 l/min ±10 %
O <sub>2</sub> flush	> 35 l/min	
O <sub>2</sub> emergency dosing	OFF, 4, 5, 6, 7, 8, 9, 10, 12 ,15 l/min	
Other connections	Fresh gas outlet	22 mm external/15 mm internal ISO cones
	Ext. O <sub>2</sub> outlet	22 mm external/15 mm internal ISO cones

Table 76: Patient module		
Conforms to standard	DIN EN ISO 80601-2-13	
Circuit system	Fresh gas decoupled, heated Complete, with absorber container (can be changed during operation) Inspiratory and expiratory flow measurement, decoupled APL	
Breath system	All components completely latex-free	
Patient connections	22 mm external/15 mm internal ISO cones	
Dimensions W x H x D	190 mm, 70 mm, 365 mm (height without APL)	
Weight	without absorber	9.3 kg
<b>Volume</b> (without ventilation tubes and bag, with absorber)	MAN/SPONT form of ventilation	approx. 2.6 I
	in mechanical ventilation	approx. 5.3 l
Compliance (without ventilation tubes and bag, with	MAN/SPONT form of ventilation	approx. 2.6 ml/Pa × 100
absorber)	in mechanical ventilation	approx. 5.3 ml/Pa × 100
Leakage	Conforms to DIN EN ISO 80601-2-13 <150 ml/min at 30 Pa × 100 (mbar)	
exp./insp. resistance with 2.5 l/min with 15 l/min with 30 l/min	Conforms to DIN EN ISO 80601-2-13 2.5 Pa × 100 5.0 Pa × 100 5.4 Pa × 100	
Table 77: APL valve		
Application area	Spontaneous breathing and adjupressures up to at least 90 Pa × screening	
<u> </u>	Accuracy ±5 %	

Table 78: Anaesthetic vaporiser mounting	
Connection type	Selectatec® or Dräger-compatible anaesthetic vaporiser mounting for 2 interlock-compatible anaesthetic vaporisers

Table 79: CO <sub>2</sub> absorber			
Dimensions	Ø 140 mm height 265 mm		
Weight	550 g		
Material	Polisulfon/PBT		
Volume	2000 ml (fillable 1750 ml)		
Guarantee	1 year or max. 52 cleaning cycles		
Material specification for sensitive absorbents	SofnoLime:	3 wt. % sodium hydroxide 75 wt. % sodium hydroxide White or coloured solids pH value 12 - 14	
	Sodasorb:	2 wt. % sodium hydroxide 80 wt. % sodium hydroxide White or coloured solids pH value 12 - 14	
	Spherasorb:	>2 wt. % sodium hydroxide 75 - 80 Gew% calcium hydroxide White, firm balls pH value alkaline solution	

Table 80: Anaesthetic ventilator			
Conforms to standard	DIN EN ISO 80601-2-13		
Ventilator	Pneumatically driven and electronically controlled hanging bellows pressure-limited compliance-compensated		
Drive gas consumption	≥minute volume MV		
Accuracy of drive gas generator	· ·	up to 150 ml ±10 % min. ±10 ml from 150 ml ±5 % min. ±15 ml	
	frequency	±10 % of set value or ±1	
Screen	15" TFT display, touchscreen		
Graphic displays	Selection of display of 4 real-time charts at the same time  Complete data management with trend display		

Table 80: Anaesthetic ventilator	
Charts display	Pressure Flow Volume $O_2$ $CO_2$ $N_2O$ Volatile anaesthetics
Respirator settings	2 volume-controlled forms ventilation (IMV, S-IMV) 2 pressure-controlled forms ventilation (PCV, S-PCV) 1 pressure/flow-controlled form of ventilation (PSV) 1 heart-lung machine form of ventilation (HLM) 1 manual ventilation/spontaneous breathing (MAN/SPONT) 1 monitoring (MON)
Inspiratory flow	maximum 180 l/min
MV	maximum 30 l/min
Rated value of breathing rate	2 – 100 1/min

Table 81: IMV volume-controlled ventilation		
V <sub>Ti</sub> tidal volume Numerical values in brackets: optional	20 (3) - 600 ml (children) 300 - 1600 ml (adults) 20 (3) - 1600 ml (IBW)	
Ventilation frequency Numerical values in brackets: optional	14 - 80 (100) 1/min (children) 4 - 40 1/min (adults) 4 - 80 (100) 1/min (IBW)	
I:E ratio	1:4 - 4:1 (incremental 0.1)	
PEEP	OFF, 1 - 20 Pa × 100 (mbar)	
Plateau	OFF, 10 - 50% (incremental 10%)	
Pressure limitation (P <sub>max</sub> )	10 - 80 Pa × 100 (mbar)	

Table 82: Volume-controlled synchronised ventilation S-IMV		
V <sub>Ti</sub> tidal volume Numerical values in brackets: optional	20 (3) - 600 ml (children) 300 - 1600 ml (adults) 20 (3) - 1600 ml (IBW)	
Inspiration time T <sub>insp.</sub>	0.2 - 2.9 s (children) 0.3 - 10 s (adults) 0.2 - 10 s (IBW)	
Ventilation frequency	6 - 60 1/min (children) 4 - 40 1/min (adults) 4 - 60 1/min (IBW)	
PEEP	OFF, 1 - 20 Pa × 100 (mbar)	
Plateau	OFF, 10 - 50% (incremental 10%)	
Pressure limitation (P <sub>max</sub> )	10 - 80 Pa × 100 (mbar)	
Trigger threshold	0.1 – 10 l/min	

Table 83: Pressure-controlled ventilation PCV			
Ventilation frequency Numerical values in brackets: optional	14 - 80 (100) 1/min (children) 4 - 40 1/min (adults) 4 - 80 (100) 1/min (IBW)		
I:E ratio	1:4 - 4:1 (incremental 0.1)		
Plateau	10 - 90 % (incremental 5%)		
Ventilation pressure P <sub>insp.</sub>	5 - 60 Pa × 100 (mbar)		
PEEP	OFF, 1 - 20 Pa × 100 (mbar)		
Volume guarantee V <sub>TG</sub> (optional)  Numerical values in brackets: optional	V <sub>TG</sub> tidal volume	OFF, 20 (3) - 600 ml (children) OFF, 300 - 1600 ml (adults) OFF, 20 (3) - 1600 ml (IBW)	
	Pressure limitation (P <sub>max</sub> )	5 - 60 Pa × 100 (mbar)	

Table 84: Pressure-controlled synchronised ventilation S-PCV		
Ventilation pressure P <sub>max</sub>	5 - 60 Pa × 100 (mbar)	
Inspiration time T <sub>insp.</sub>	0.2 - 2.9 s (children) 0.3 - 10 s (adults) 0.2 - 10 s (IBW)	
Ventilation frequency	6 - 60 1/min (children) 4 - 40 1/min (adults) 4 - 60 1/min (IBW)	
PEEP	OFF, 1 - 20 Pa × 100 (mbar)	
Plateau	10 - 90 % (incremental 5%)	
Trigger threshold	0.1 – 10 l/min	

Table 85: Pressure-supported spontaneous breathing PSV (ASSIST)		
Supporting pressure P <sub>insp.</sub> 5 – 60 Pa × 100 (mbar) (adults and children)		
PEEP	OFF, 1 - 20 Pa × 100 (mbar)	
Trigger threshold	0.1 – 10 l/min	
Backup	4, 6, 8, 10, 15, 30, 45 seconds	

Table 86: MAN/SPONT manual ventilation	
Ventilation bag	Manual ventilation is produced with the ventilation bag, which serves as a reservoir
	Display of apnoea duration

Table 87: Ventilation using a heart-lung machine HLM		
Ventilation bag	Manual ventilation is produced with the ventilation bag, which serves as a reservoir	
	CPAP via APL	
	Fresh gas settings at 0 l/min possible	

Table 88: Monitoring mode MON		
	Monitoring mode for adequately spontaneously breathing patients	
	Freq. <sub>CO2</sub> alarm	
Table 89: Safety equipment		
Minimum concentration O <sub>2</sub>	Electronic control of the fresh gas setting so that in an $O_2/N_2O$ gas blend, an $O_2$ concentration of 25% cannot be exceeded.	
	O <sub>2</sub> fresh gas (100%) of at least 200 ml/min is guaranteed (except for HLM)	
	N <sub>2</sub> O block in the event of O <sub>2</sub> shortage	
Safety valves	Valves with adjustable pressure relief	
	Automatic safety valve that prevents high-pressure hazards	
	Automatic safety valve that prevents low-pressure hazards	
Gas type check (can be activated in the service)	ZGA O <sub>2</sub> , N <sub>2</sub> O, AIR,	

Table 90: Ventilation monitoring		
Airway pressure	Peak, medium, PEEP, Plateau, CPAP	
	Туре	Piezo-resistant
	Range	-10 - 100 Pa × 100 (mbar)
	Accuracy	±4 % min. 2 Pa × 100 (mbar)
	Resolution of displays	1 mbar
Tidal volumes V <sub>Ti</sub> , V <sub>Te</sub>	Range	0 – 5000 ml/min
	Accuracy of displays	±10 % or 5 ml
	Resolution	1 ml
Minute volume	Range	0 – 5000 ml/min
	Accuracy of displays	±10 % or 50 ml
	Resolution	10 ml
Frequency (spontaneous)	Range	0 - 150 1/min
	Accuracy	± 1/min
	Resolution of displays	1/min

Table 90: Ventilation monitoring			
Flow measurement	Туре	Hot-wire anemometry	
	Range	-200 – 200 l/min	
	Accuracy	±10 %	
	Resolution of displays	0.1 l/min	
Lung function	Static/dynamic compliance C20/C Resistance Loops		
Other	Spontaneous breathing rate, share of spontaneous breaths, inspiration time of spontaneous breaths, $T_{\text{insp.}}$ , $T_{\text{exsp.}}$ , I:E, MV, effective		

Table 91: Gas supply monitoring		
ZGA pressure	Туре	Piezo-resistant
	Range	0 - 10 kPa × 100 (bar)
	Accuracy	±3 % min. 0.1 Pa × 100 (mbar)
	Resolution of displays	0.1 kPa × 100 (bar)
Bottle pressure	Туре	Metallic thin-film sensor
	Range	0 - 250 kPa × 100 (bar)
	Accuracy	±4 % or 2 kPa × 100 (bar)
	Resolution of displays	1 kPa × 100 (bar)

Table 92: Standard specifications (full accuracy)

Gas	Concentration <sup>1)</sup> [% <sub>rel</sub> ]	Deviation <sup>2), 3</sup> ) [% <sub>abs</sub> ]	Interference	<sup>4), 5)</sup> [% <sub>abs</sub> ]
CO <sub>2</sub>	0 - 1 1 - 5 5 - 7 7 - 10 >10	±0.1 ±0.2 ±0.3 ±0.5 Not specified	N <sub>2</sub> O O <sub>2</sub> each agent	0.1 0.1 0.1 <sup>6)</sup>
N₂O	0 – 20 20 – 100	±2 ±3	CO <sub>2</sub> O <sub>2</sub> each agent	0.1 0.1 0.1 <sup>6)</sup>
HAL <sup>9)</sup> , ENF <sup>9)</sup> , ISO <sup>9)</sup>	0 – 1 1 – 5 >5	±0.15 ±0.2 Not specified	$CO_2$ $N_2O$ $O_2$ 2, agent	0 0.1 0.1 0.1 (typical) <sup>7)</sup>
SEV <sup>9)</sup>	0 – 1 1 – 5 5 – 8 >8	±0.15 ±0.2 ±0.4 Not specified	$CO_2$ $N_2O$ $O_2$ 2, agent	0 0.1 0.1 0.1 (typical) <sup>7)</sup>
DES <sup>9)</sup>	0 - 1 1 - 5 5 - 10 10 - 15 15 - 18 >18	±0.15 ±0.2 ±0.4 ±0.6 ±1 Not specified	CO <sub>2</sub> N <sub>2</sub> O O <sub>2</sub> 2, agent	0.1
O <sub>2</sub> Hummingbird PM1111E (optional)	0 – 25 25 – 80 80 – 100	±1 ±2 ±3	CO <sub>2</sub> O <sub>2</sub> each agent	0.2 0.2 1.0
O₂ OXIMA™ (optional)	0 - 40 40 - 60 60 - 80 80 - 100	± (1%abs + 1%rel) ± (1%abs + +2 %rel) ± (1%abs + +3 %rel) ± (1%abs + +4 %rel)	0.38)	

#### Instructions

- (1) Gas data are shown as zero, if the measured concentration is more than three s under the established threshold level:  $CO_2$ -0.1/0.3 %;  $N_2O$  -3.3 %;  $O_2$ -0/0 %, Agent -0.15/0.3 % (for/ISO accuracy).
- (2) Using a DRYLINE ™ sampling system, the inaccuracy at 10 55°C operating temperature is specified and is compensated by H₂O partial pressure of 11 mbar as standard (i.e. 22 °C at 40% relative humidity ambient conditions.) For the automatic compensation of the effect of ambient humidity on the gas sample composition, the actual H₂O ambient partial pressure of the host can be given via the communication interface of the AION™.
- (3) Specifications of the inaccuracy comprise stability and drift.
- (4) Maximum interference by each gas at concentrations within the specified accuracy for each gas.
- (5) Multiple faults on  $CO_2$ ,  $N_2O$  and  $O_2$  are usually the same as individual faults.
- (6) For AION™ 02, 02 and 01 ERP: Required entry of the agent used.
- (7) Applies only to AION™ 02, 02 and 01 ERP
- (8) Maximum interference for gas concentrations up to 5%  $CO_2$ , 80%  $N_2O$  (bal N2), 5% HAL, 5% ISO, 5% ENF, 8% SEV, 18% DES.
- (9) Not applicable to AION™ 01.

Table 93:	Extended	specifications <sup>1, 2, 3, 4)</sup>	(full	accuracy)
Table 33.	LAIGHUGU	Specifications	(IUII	accuracy,

Gas	Range [%rel]	Deviation [% <sub>abs</sub> ]	Static [% <sub>abs</sub> ] <sup>5)</sup>	Interference [% <sub>abs</sub> ] <sup>6)</sup>
	<5	p. spec. normal range		
	5 – 6	±0.2	0.05	
ISO	6 – 10	±0.6	0.1	$N_2O + O_2 = 0.4$
	10 – 15 <sup>7)</sup>	±2.0	0.22	2. Agent Not specified
	>15	Not specified	Not specified	
	<8	p. spec. normal range		
	8 – 12	±0.6	0.09	
SEV	12 – 16	±1.0	0.12	$N_2O + O_2 = 0.4$
SEV	$16 - 20^{7}$	±2.0	0.17	2. Agent Not specified
	$20 - 24^{7)}$	±2.5	0.24	
	>24	Not specified	Not specified	
	<18	p. spec. normal range		
	18 – 24	±2.2	0.44	
DES	$24 - 30^{7}$	-2.2/+6.0	0.86	$N_2O + O_2 = 0.4$
	$30 - 32^{7)}$	-2.2/+8.0	1.10	2. Agent Not specified
	>32	Not specified	Not specified	

Table 94: Extended range pressure effects 8)

	[%abs]			
	@ 700 hPa	@ 850 hPa	@ 1013 hPa	@1100 hPa
@ 7.5 % ISO	-0.0 +0.6	-0.0 +0.2		-0.1 +0.2
@ 13 % SEV	-0.0 +0.2	-0.0 +0.3	See table above	-0.3 +0.0
@ 15 % DES	-1.0 +0.0	-0.5 +0.0		-0.0 +0.5

#### **Notes**

- (1) Extended specification not valid if in ISO mode
- (2) At ambient pressure of 1013 hPa
- (3) Extended range must be set with a special command, which also requires the entry of the used agent. NOTE: If the wrong agent is entered, the accuracy specification is invalid.
- (4) CO<sub>2</sub> and N<sub>2</sub>O data are not valid if the extended range is activated.
- (5) Typical static specification. Static is calculated as the standard deviation from 600 sample values (80 ms interval).
- (6) Interference is added to the specification of accuracy.
- (7) Ranges above 10% ISO, 16% and 24% SEV DES are not intended for normal or permanent operation but only for error conditions.
- (8) Ambient pressure effects are specified for 1.5 times the normal range of the maximum concentrations (except for DES). The effects are added to the specification of inaccuracy. Ambient pressure effects increase with increasing gas concentration and are specified for 1.5 times the normal range.

Not specified

Not specified

0.3

0.3

0.3

**Drive gas-operated** 

isopropanol steam

dosing aerosol

<0.1% ethanol

Saturated

<1% acetone

<1% methane

Table 95: Interference due to gas contamination

Not

specified

0

0.1

0.1

0.1

	Interference [% <sub>abs</sub> ]					
Contamination	CO <sub>2</sub>	N <sub>2</sub> O	Agents	O <sub>2</sub> Hummingbird PM1111E (optional)	O₂ OXIMA™ (optional)	
<100 % Xenon	0.1	0	0	0.5	0.3	
<50 % He	0.1	0	0	0.5	0.3	

Not

Not

specified

0

0

specified

0

0.5

0.5

0.5

0.5

0.5

Not

specified

0

0

0.1

0.1

Table 96: Gas me	asurement	
FiO <sub>2</sub>	optional	Inspiratory fuel cell
Side flow meter		standard
	O <sub>2</sub>	Measurement paramagnetic or fuel cell inspiratory/expiratory
	CO <sub>2</sub>	Measurement infrared spectrometry inspiratory/end-tidal
	N <sub>2</sub> O	Measurement infrared spectrometry inspiratory/end-tidal
	Anaesthetic gases	Measurement infrared spectrometry inspiratory/end-tidal Halothane, enflurane, isoflurane, sevoflurane and desflurane Auto ID
rate	e triggered breathing expiratory values	<ul> <li>60 1/min</li> <li>at 200 ml/min for Dryline water trap/gas sample tube type adults</li> <li>at 120 ml/min for Dryline water trap/gas sample tube type neonates</li> </ul>

Table 96: Gas measurement		
Rise time (t <sub>10</sub> -90%)	CO <sub>2</sub>	250 ms (fall time 200 ms)
@ 120 ml/min	N <sub>2</sub> O	250 ms
	O <sub>2</sub>	600 ms
	HAL, ISO, SEV, DES	300 ms
	ENF	350 ms
Rise time (t <sub>10</sub> -90%)	CO <sub>2</sub>	250 ms (fall time 200 ms)
@ 200 ml/min	N <sub>2</sub> O	250 ms
	$O_2$	500 ms
	HAL, ISO, SEV, DES	300 ms
	ENF	350 ms
Delay time		<4 s
Flow	Adults	120 - 200 ml/min
	Neonates	70 – 120 ml/min
Blockage alarm		Flow <40 ml/min
Water trap full		Flow <75 % of the set flow
Duration of zero phase		5 s, maximum 9 s every 4 hours
Accuracy		ISO (11196) after 45 s, full after 10 min
MAC		Establishment of the minimum alveolar concentration

Table 97: Interfaces	
Serial	COM1, COM2 D-SUB, socket (standard, 9-pin) galvanically separated, 3 kV
Ethernet	IEE 802.3, 100BaseT, CAT5
USB	1.0 (Update, Logfiles)
VGA	D-SUB, socket (standard, 15-pin) galvanically separated, 5 kV
LWL	LC socket
Table 98: protocols	
Phillips VueLink	COM1

Table 98: protocols	
Phillips VueLink	COM1
Philips Intellibridge	COM1
HuLBus	COM2
HL7	Ethernet

Table 99: Relevant standards	
93/42/EEC	RATES GUIDELINE dated 14 June 1993 on medical products
DIN EN 60601-1	Medical electrical devices – Section 1: General specifications for safety including essential performance features (IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012); German edition EN 60601-1:2006 + Cor.:2010 + A1:2013
DIN EN 60601-1-2	Medical electrical devices – Section 2: General specifications for safety including essential performance features – extended standard: Electromagnetic compatibility – requirements and tests (IEC 60601-1-2:2007, modified); German edition EN 60601-1-2:2007
DIN EN ISO 80601-2-13	Medical electrical devices – Section 2 – 13: General specifications for safety including essential performance features – anaesthesia workstations: (ISO 80601-2-13:2011); German edition EN ISO 80601-2-13:2012

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leo	leon plus Short checklist before start-up				
Tes	t	Description	Passe <b>Yes</b>	ed <b>No</b>	
1.	Visual monitoring	Technical monitoring of damage, completely correct set-up, hygienic cleanliness, suitable accessories, test seal			
Tur	n off device				
2.	Plug in ZGA, plug in r	nains cable			
3.	Mains supply	available (green LED mains connection control lit)			
4.	O <sub>2</sub> emergency dosing	O <sub>2</sub> emergency dosing at 15 l/min, audible inflow sound in the ventilation bag. O <sub>2</sub> emergency dosing at 0 l/min			
Tur	n on device				
5.	Potential equalisation*	connected (to device and to wall connection)			
6.	CO <sub>2</sub> absorber	Sieve with seal correctly placed, protective cap available,			
		filled, filling date, lime not coloured, locked			
7.	Breathing bellows in dome	Available and correctly adjusted			
8.	Dome	adjusted, finger-tight, tight			
9.	Patient module	Attachment parts completely and firmly adjusted, blue insp./exp. Valve diaphragm on carriers available, correctly inserted, docking station with patient module correctly locked onto the device			
	APL	available, at 20 mbar			
11.	Ventilation tubes	Correctly connected, (to Ø 22 mm cones on the front of the patient module), y-piece available and placed on the test adapter, new ventilation filter*			
	NGA, AGSS	Correctly connected (with adapter on Ø 30 mm cone to the underside of the patient module), aspiration performance monitored			
	Gas measurement (O <sub>2</sub> , CO <sub>2</sub> *, N <sub>2</sub> O*, NG*)	available (internally or externally), connected, (patient adapter*, measuring gas tube*, water trap*), ready for operation, check water trap for fill state and expiry date*			
14.	Anaesthetic vaporiser*	Correct fit, fill state, at 0, connected to electricity*			
15.	<b>Execute system test</b>				
	O <sub>2</sub> control	Unplug the patient adapter* of the gas meter with y-piece from the test adapter, start MAN/SPONT, set a fresh gas flow of 100% $O_2$ and 5 l/min. The $O_2$ measured value must rise recognisably. Replug the patient adapter* with y-piece into the test adapter			
	O <sub>2</sub> flush	Activate O <sub>2</sub> flush button, audible inflow sound in the ventilation bag, key resets			
18.	Ext. O <sub>2</sub> outlet*	Ext. O <sub>2</sub> flow meter at 15 l/min, gas flows audibly from the ext. O <sub>2</sub> outlet. Ext. O <sub>2</sub> flow meter at 0 l/min			
19.	Fresh gas outlet*	External fresh gas outlet switch at 1 (ON), activate O <sub>2</sub> flush key, gas flows audibly from the fresh gas outlet. External gas outlet switch at 0 (OFF)			
20.	Bronchial aspiration	connected, filter available, ready for operation -> VAC display ≤(-0.7) bar with locked aspiration tube			
21.	Charge battery	Unplug mains cable. Remaining life display = 100 min.			
22.	Reserve gas bottles*	Check tightness, connections and fill state			
23.	Visual alarm signal, audible	Trigger an alarm, LED lit on keyboard, alarm tone can be heard			
24.	Auxiliary devices*	Secured, check in accordance with their own user manuals			
	•	on equipment e.g. ventilation bag with mask available, checked			
	Test alarms (also on a				
*If a	ıvailable				

Signature

Name of checker

Check date

#### leon plus Short operating instructions

Keypad		Touchscreen	
	leon <i>plus</i> ON and OFF	57	Display mains operation / battery operation
	Standby (stop ventilation)	Child Adult BRW 30 kg	Select patient category
START	Start of a form of ventilation	IMV   S-IMV	Preset form of ventilation and parameters
		40 200 mL	
	Selection fresh gas blender	Air         N <sub>2</sub> O           O <sub>2</sub> Effective         ml/min         1000           O <sub>2</sub> Flow           50         2.00           %         l/min	Setting fresh gas blender
	Selection of form of ventilation and parameters	IMV   S-IMV	Setting of running form of ventilation and parameters
	Opening and closing alarm limits window	Autoset	Adjust alarm limits automatically
	Selection of MAN/SPONT form of ventilation	MAN / SPONT	Selection of MAN/SPONT form of ventilation
	Selection of real-time graphs	Paw Pa x 100 (mbar)	Real-time graphs control elements
	Opening and closing alarm limits window		Control elements loops
	Switch between windows	Curves Trend Trend Alarm Estras  Curves Tab leg Estras	Switch between windows
	Muting of alarm tone for 2 or 10 minutes	○ O1:53 O9:57	Mute display 2 or 10 minutes

Checklist of technical safety controls	
	Technical safety controls carried out in accordance with DIN EN 62353 by:
	Company / Department
	Name of checker
	Name of device (serial name / inventory number)

Machanical assets	Passed		
Mechanical safety		No	
Gas connection tubes			
Keypad			
Touchscreen			
Patient module			
Bag-in-bottle unit			
CO <sub>2</sub> absorber			
Anaesthetic vaporiser			
PC and other monitor support arms			
Tube support arm			
Cable support arm			
Workstation illumination			
Trolley			

Electrical safety		Passed	
Electrical Safety			No
Electric cables (state)			
		Measure	ed value:
Protective cable resistance	max. 0.2 Ohm		Ohm
Reserve device earth leakage	max. 1.0 mA		mA
Insulation resistance	>2 MOhm		MOhm

Eurotional aufatu		Passe	Passed	
Functional safety		Yes	N	
Check for tightness				
Alarms LEDs keyboard, audibl	e			
PEEP valve				
Ventilation pressure				
Fresh gas blender	Flow			
	Gas concentrations			
Anaesthetic vaporiser	•			
Gas measurement				
O <sub>2</sub>	Ratio system			
	N2O cut-off			
	Flush			
Reserve	Switch-over			
	Return flow			
APL				
Batteries				

Miscellaneous		i
Miscellarieous	Yes	No
Visual check of external changes		
Visual check of external faults or damage		
Check device combinations		
Labels complete and legible		
User manual must be present and correspond to the installed software version.		
Warnings in the German language must be present.		
Alarm and safety functions in accordance with the user manual		
Medical product book must be present		

Test device	Туре	Serial number	Calibrated up to

Result of check	Remarks on check	
No technical safety faults		
Faults were immediately fixed		
Faults that require servicing		
Fixable faults; this device may only be used after faults have been fixed. Danger for patients, users or third parties.		
Name of checker	Signature	Check date



### leon plus Spare parts ordering consumables



	Client:	
	Personal	
Löwenstein Medical GmbH & Co. KG	contact:	
Hospital Department	Department:	
Arzbacher Straße 80		
56130 Bad Ems/Germany	Street:	
	Town: _	
Tel.: +49 2603/9600-0	Tel.:	
Fax: +49 2603/9600-50	Fax:	
Internet: www.hul.de	Email:	

Accessories Consumables		Page 1/1
Item number	Description	Order
0205009	Insulation bag adults	
0122002	Ventilation filter	
0202015	CO <sub>2</sub> soda lime (5 l)	
0209410/6	CO <sub>2</sub> single-use absorber plus	
0209411/6	CO <sub>2</sub> single-use absorber premium	
0205029	Disposable tube system for children	
369-0343-00	Bronchial aspiration filter	
0209608	Fan filter pad	
0209106	Insp./exp. valve diaphragm (blue)	
0208610	Calibration gas	
0208632	Sample line adults	
0208633	Sample line neonates	
0230009	O <sub>2</sub> fuel cell (external O <sub>2</sub> measurement FiO <sub>2</sub> )	
0208622	O <sub>2</sub> fuel cell (OXIMA)	
0045003	Patient adapter for sample line, straight	
0045002	Patient for sample line, angled	
0205090	Patient tube system	
0208630	Water trap adults	
0208631	Water trap neonates	
0045001	Y-piece adults	
60-20-301	Y-piece neonates	
0209045	Spare parts accessories set leon plus	



Löwenstein Medical GmbH & Co. KG Arzbacher Straße 80 56130 Bad Ems/Germany

Tel.: +49 2603/9600-0 Fax: +49 2603/9600-50 Internet: www.hul.de

leon plus Spare parts ordering consumables

# leon plus Spare parts ordering options and replacement



			medicai	
		Client:		
Löwenstein Medica	l GmbH & Co. KG	Personal contact: _		
Hospital Departmen	nt	Department: _		
Arzbacher Straße 8	0			
56130 Bad Ems/Ge	ermany	Street:		
		Town:		
Tel.: +49 2603/9600	0-0	Tel.:		
Fax: +49 2603/9600-50		Fax: _		
Internet: www.hul.de		Email: _		
Accessories optio	ns and replacements			Page 1/3
Item number	Description			Order

Accessories options and replacements		Page 1/3
Item number	Description	Order
0011300	Waste hose 3 m	
0202005	AGSS adapter black 4 holes (patient module wall connection)	
0209581	AGSS adapter white without holes (patient module carrier system)	
900MR130	Adapter angled (AGSS)	
020870	Rechargeable battery (lead gel)	
0209130	APL	
0209455	Workstation illumination	
0209460	Carrier system (AGSS)	
0209352	Bellows	
ba-leon <i>plus</i> -en	User manual leon <i>plus</i>	
0140900	Bronchial aspiration collection bottle, rinsing bottle	
0209365	CO <sub>2</sub> absorber glass	
0209360	CO <sub>2</sub> absorber PSU (complete)	
0209590	CO <sub>2</sub> click adapter	
0209353	Dome	
0208611	Pressure reducer for calibration gas bottle	
0342002	Pressure regulator with pressure measurement cable for 10 L N <sub>2</sub> O bottles	
0342000	Pressure regulator with pressure measurement cable for 10 L O <sub>2</sub> bottles	
0011071-1 /-2	AIR pressure tube with supply plug and NIST plug ISO 32/transmission standard	
0011700-1	AIR pressure tube with T-connector, supply plug and NIST plug ISO 32/transmission standard	
0011072-1 /-2	N <sub>2</sub> O pressure tube with supply plug and NIST plug ISO 32/transmission standard	
0011070-1 /-2	O <sub>2</sub> pressure tube with supply plug and NIST plug ISO 32/transmission standard	

## leon plus Spare parts ordering options and replacement



	Client:	
	Personal	
Löwenstein Medical GmbH & Co. KG	contact:	
Hospital Department	Department:	
Arzbacher Straße 80		
56130 Bad Ems/Germany	Street:	
	」 Town: ַ	
Tel.: +49 2603/9600-0	Tel.:	
Fax: +49 2603/9600-50	Fax:	
Internet: www.hul.de	Email:	

Accessories opt	tions and replacements	Page 2/3
Item number	Description	Order
0011073-1/-2	Vacuum pressure tube with supply plug and NIST plug ISO 32/transmission standard	
0200518	Isoflurane filling adapter	
0045000	Disposable tube connector (AGSS)  Disposable tube connector (ventilation bag/ventilation tube adapter)	
0050011	10 L N <sub>2</sub> O bottles, empty	
0050010	10 L O <sub>2</sub> bottles, empty	
0209120	Flow sensor inspiratory, expiratory	
0208540	Device rails 25 x 10 (length on request)	
0208550 /-1	Support for 300 mm/400 mm monitors	
0208540	Support for PC and keyboard (including adapter disc)	
0209450	Tube support arm	
0209298	Bronchial aspiration mounting	
0208600	with agent auto ID	
0208601	without agent auto ID	
0208602	without agent	
ba-leons-hy-d	Hygiene instructions	
900MR534	ISO 22/22 plug adapter (AGSS)	
P accessory apnoea	Anaesthesia accessories catalogue	
0205010	Catheter receptacle with holding claw	
0140165	Catheter basket (150 x 100 x 480)	
06006832	Artificial lung	
0206024	Desflurane anaesthetic vaporiser, Selectatec®	

## leon plus Spare parts ordering options and replacement



Löwenstein Medical GmbH & Co. KG	Client: Personal contact:	
Hospital Department	Department:	
Arzbacher Straße 80		
56130 Bad Ems/Germany	Street:	
	Town: _	
Tel.: +49 2603/9600-0	Tel.:	
Fax: +49 2603/9600-50	Fax:	
Internet: www.hul.de	Email:	

Accessories options and replacements		Page 3/3
Item number	Description	Order
0206021	Isoflurane anaesthetic vaporiser, Selectatec®	
0206020	sevoflurane anaesthetic vaporiser, Selectatec®	
0208766	O <sub>2</sub> fuel cell (fresh gas blender)	
209100	Patient module complete (without CO <sub>2</sub> absorber)	
0170501	Potential equalization conductor	
0050003	N <sub>2</sub> O reserve gas bottles, 2L, empty	
0050002	O <sub>2</sub> reserve gas bottles, 2L, empty	
7520	AGSS tube (feeds through on the rear)	
0011050	Bronchial aspiration tube set	
0208552	Tube holder clips for tube support arm	
M103261699	Cable interface VueLink module	
0170024	Fuses 2 AT	
00.030	Voltage supply cable	
0170500	Voltage supply cable for auxiliary devices	
0209135	Dome inspection glass inspiration, expiration	
0205013-1	All connection plug AGSS EN 737	
208774	PEEP valve diaphragm	
0209990	VueLink module (complete with cabling)	
900MR139	Water trap patient tube system	



Löwenstein Medical GmbH & Co. KG Arzbacher Straße 80 56130 Bad Ems/Germany Tel.: +49 2603/9600-0

Fax: +49 2603/9600-50 Internet: www.hul.de

leon plus Spare parts ordering options and replacement



Subject to change

As at 01.07.2017



#### Löwenstein Medical GmbH & Co. KG

Arzbacher Straße 80 56130 Bad Ems/Germany

Tel.: +49 2603/9600-0 Fax: +49 2603/9600-50

Internet: www.hul.de

user manual leon plus

Order no.: Ba-0301v311

