



Azeer Intensive Care Ventilators Elisa Family



elisa 300
elisa 500

Instructions for Use
Supplement A

Manoeuvres, Functions, Ventilation Modes

The device operates according to the accompanying documentation and the equipment labelling, provided that it is assembled, operated, maintained and repaired according to the accompanying documentation. The device must be inspected at regular intervals. The device must not be used if found to be defective. Damaged, missing, clearly worn out, warped or contaminated parts must be replaced immediately. If a repair is necessary, the manufacturer and distributor recommend requesting advice via telephone or in writing from the nearest regional service centre. Maintenance and repairs must only be carried out at the service centre or by specialists authorised by the manufacturer. The user of the device shall have sole responsibility for any malfunction or damage which is due to improper use, poor maintenance, improper service, improper repairs or modifications carried out by unauthorised persons.

Each device has either a serial number or a UDI (Unique Device Identification).

Serial number system:

The coding system contains the code for the product group (03 or 05), the year of manufacture (YY) and a 4-digit numeric code (ZZZZ) for unique identification.

elisa 300	03YYZZZZ
elisa 500	05YYZZZZ

UDI system:

The coding system contains the Global Trade Identification Number (GTIN), the code for the product group (03 or 05), the year of manufacture (YY) and a 4-digit numeric code (ZZZZ) for unique identification. The system complies with the requirements for the GSI standard.

elisa 300	(01)04260192090319(21)03YYZZZZ
elisa 500	(01)04260192090326(21)05YYZZZZ

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A I.1 Information about the “Manoeuvres, Functions, Ventilation Modes” manual

These instructions for use describe the manoeuvres, functions and ventilation modes of the following products:

elisa 300 | Intensive care ventilator | Software version 2.09.x
elisa 500 | Intensive care ventilator | Software version 2.09.x

The software version installed in your device is displayed on the standby screen.

The present document “Manoeuvres, Functions, Ventilation Modes” is Supplement A to the Instructions for Use of the intensive care ventilators mentioned above.

For **specific details** concerning the devices elisa 300 / elisa 500, please refer to the separate document “Basic Instructions for Use – elisa 300 / elisa 500”.

The **configuration** of the devices elisa 300 and elisa 500 will be carried out by your Service engineer.

Remark

Depending on the configuration of your device, on purchased options and on the country of use, not all manoeuvres, functions and ventilation modes described in this manual may be available. If you would like to use a function not currently available in your device, please contact your Service engineer.

The manufacturer reserves the right to further develop the device and/or carry out changes in terms of technical progress.

The manufacturer's and distributor's contact details are stated on the back cover.

A I.2 Safety information in these instructions for use

All warnings and precautions must be read and observed!

The symbols below identify dangerous situations which may occur when users fail to observe these instructions for use:



Refers to dangerous situations which may occur when failing to observe the present instructions for use.

Warning

“Warning” refers to a situation which may cause injuries to the user or the patient.

Caution

“Caution” refers to a situation which may cause damage to the equipment.

A I.3 General safety instructions

Reference

These instructions for use describe the manoeuvres, functions and ventilation modes of the following products:

elisa 300 | Intensive care ventilator | Software version 2.09.x
elisa 500 | Intensive care ventilator | Software version 2.09.x

Safe operation

In order to guarantee the safe operation of elisa 300 / elisa 500, the system must only be used as described. Before putting the system into operation, users must familiarise themselves with the following instructions for use:

- Basic Instructions for Use elisa 300 elisa 500
- Supplement A “Manoeuvres, Functions, Ventilation Modes”
- and, depending on the functions used, with the relevant supplements.

As a matter of principle, all guidelines in these instructions for use as well as applicable legal provisions for the use of a ventilator must be observed.

Patient safety

elisa 300 / elisa 500 may only be operated by qualified medical staff (physicians, certified nursing staff, nursing staff specializing in intensive care medicine, respiratory therapists) in order to guarantee an adequate intervention in the event of a device malfunction.

Patients connected to the device require continuous surveillance by specialist staff. If a patient is connected to the system, make sure that the alarm limits are adapted to the patient condition and the alarms are activated.



Warning

When setting up the device and adjusting the inclination of the control unit, make sure that the alarm light at the top of the control unit remains visible from all directions.



Warning

Keep a manual resuscitation bag ready to be able to continue ventilation in the event of a device malfunction.

A I.4 Options matrix

Software options	elisa 300	elisa 500
Paux I: Cuffscout function	not available	standard
Paux II: oesophageal pressure measurement Peso	not available	standard
Paux II: IAP (intra-abdominal pressure)	not available	standard

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A 2.1 Manoeuvre availability

The availability of the manoeuvres and their order in the submenu depend on the settings on the configuration level of your ventilator (e.g., whether or not a particular manoeuvre has been enabled). Up to 8 manoeuvres can be assigned to the manoeuvre buttons.

Please contact your Service engineer if a particular manoeuvre is not available.

A 2.1.1 Availability for the different patient categories

Manoeuvre	Adults	Children
Inspiratory hold	X	X
Expiratory hold	X	X
Sigh (inspiratory and expiratory)	X	X
Manual breath	X	X
MIP	X	X
Sigh	X	X
Recruitment manoeuvre	X	---
PEEPfinder	X	---

A 2.2 HOLD manoeuvres

A 2.2.1 Inspiratory Hold (Insp. Hold)

You reach all the Hold manoeuvres by pressing the “Manoeuvres” button.

The inspiratory hold manoeuvre is a function to extend and hold the inspiratory pressure (e.g., for hyperinflation) for up to 30 seconds at the end of the inspiration phase. Set the desired hold time and finally start the manoeuvre. The remaining time of the manoeuvre is displayed in a bar chart. The manoeuvre can be terminated prematurely at any time.

Please note that the inspiratory hold manoeuvre will be aborted when the set maximum tidal volume V_T max is reached. This means that the time can be considerably shorter.

With the parameter “Flow active On/Off”, the inspiratory hold manoeuvre can be used for diagnostic (e.g., measurement of plateau pressure) as well as for therapeutic purposes (e.g., recruitment).

- Flow active “On” means that for therapeutic purposes an active flow is switched on to stabilize the set inspiratory pressure.
- Flow active “Off” means that the valves are closed for the diagnosis and the pressure situation can be assessed directly without any additional flow.

Remark | The Pplateau, ΔP and Cstat values are measured more frequently during the I-Hold manoeuvre and displayed. The last measured values are stored in the Workbench.

So, after deactivation of the flow compensation (Flow active “Off”), the measured values are determined under static conditions.

Remark | After a manoeuvre, the function is blocked for 15 seconds.

A 2.2.2 Expiratory Hold (Exp. Hold)

The expiratory hold manoeuvre is a function to extend and hold the expiration for up to 20 seconds. The intrinsic PEEP (PEEPi), trapping volume (Vtrap) and the Maximum Inspiratory Pressure (MIP) value are determined during the manoeuvre. The measured values are presented on the extended screen display.

Set the desired hold time and finally start the manoeuvre. The remaining time of the manoeuvre is displayed in a bar chart. The manoeuvre can be terminated prematurely at any time.

Remark | During the E-Hold manoeuvre the measured PEEPi and Vtrap values are displayed in the Workbench. The last measured values are stored in the Workbench.

Remark | After a manoeuvre, the function is blocked for 15 seconds.

A 2.2.3 Manual breath

The “Manual breath” manoeuvre is a function used to immediately deliver a single manual machine breath.

Press “Start”, then press and hold the appropriate button to apply a manual breath for up to 15 seconds, which is similar to ventilation with a manual resuscitation bag. A progress bar indicates the duration of the breath. The currently selected ventilation settings are retained for the manual breath.

The manoeuvre stops when the set maximum tidal volume V_T max or the set maximum pressure Plimit is reached.

A 2.3 Maximum Inspiratory Pressure (MIP)

The maximum inspiratory pressure corresponds to the negative inspiratory force that the patient can exert. The negative value is determined during the expiratory hold manoeuvre and terminates it. The measured value is presented on the extended screen display.

A 2.4 Sigh

You reach the manoeuvre by pressing the “Manoeuvres” button and then by selecting the “Sigh” tab.

Remark

The manoeuvre is not available for NIV and with the ventilation modes HFOT, CPAP, PC-APRV and proportional PSV.

The Sigh function regularly applies breaths with increased PEEP, pressure, or volume that are intended to ventilate little-used regions of the lung. The deeper breaths are intended to prevent atelectasis and protect non-ventilated regions of the lung from collapsing. The user can define the frequency, number of breaths with activated sigh function, and level of increase.

The function and its mode of operation (inspiratory or expiratory sigh) are defined at the configuration level.

If both sigh modes are enabled in the configuration menu, either the inspiratory sigh or the expiratory sigh can be selected.

A 2.4.1 Inspiratory sigh

With the inspiratory sigh function, the machine delivered breaths are intensified regularly as follows:

- in volume-controlled or pressure-controlled modes: by increasing the tidal volume by the set factor
- in pressure-controlled modes: by increasing the inspiratory pressure (P_{insp}) by the set factor

The user can define the following settings:

- Interval: Number of machine breaths between two sigh intervals
- Cycle: Number of breaths with activated sigh function
- Factor: Multiplier by which the tidal volume or P_{insp} increases



A 2.4.2 Expiratory sigh

With the expiratory sigh function, the machine delivered breaths are intensified regularly by increasing the PEEP by the set factor.

The user can define the following settings:

- Interval: Number of breaths with activated sigh function
- Cycle: Number of breaths with activated sigh function
- Factor: Multiplier by which PEEP increases



In order to prevent volutraumas and barotraumas, the set alarm limits remain active during delivery of breaths with activated sigh function.

A 2.5 Recruitment manoeuvre

You reach the manoeuvre by pressing the “Manoeuvres” button and then by selecting the “Recruitment” tab.

This function provides a manoeuvre that allows non-ventilated portions of the lung to be re-opened by elevated ventilation pressures and to keep them open. The level of invasiveness of the ventilation should be reduced afterwards.

Touch the “Recruitment” tab to open the associated menu.

The user can define the following settings:

- **Recruitment time:** set time for recruitment after reaching the inspiratory pressure (0 to 45 seconds)
- **Pinsp:** effective recruitment pressure added to the PEEP (1 to 50 mbar)
- **Recr. PEEP:** positive end-expiratory pressure during the recruitment manoeuvre (0.5 to 50 mbar)

Remark

By directly entering the delta pressure, the manoeuvre can also be used to implement an open lung strategy. Only the PEEP needs to be increased for this purpose.

Once the manoeuvre has started, the ventilator waits for the next expiration and then adjusts the set recruitment PEEP. With the next regular inspiration, the extended inspiration begins based on the set value for $P_{\text{Insp}} + \text{PEEP}$ and the configured manoeuvre time (recruitment time). The remaining time of the manoeuvre is displayed in a bar chart.



Remark

The manoeuvre can be terminated prematurely at any time with the “Stop” and Enter buttons.

After the manoeuvre, ventilation continues with the configured ventilation parameters.

By activating and confirming the “Apply the recruitment PEEP for ventilation” button, the PEEP set for the recruitment manoeuvre can also be adopted for the ongoing ventilation procedure.

Remark | After 5 manoeuvres, the function is blocked for 60 seconds.

Remark | The manoeuvre cannot be started in the 60 seconds immediately after starting the ventilation.

Remark | The recruitment manoeuvre cannot be restarted in the 60 seconds immediately after terminating a PEEPfinder manoeuvre.

Remark | The manoeuvre is not available in NIV modes, during HFOT and in purely spontaneous breathing modes (dimmed – message in info box).

Remark | The recruitment manoeuvre cannot be combined with any other manoeuvre.



Warning

No ventilation occurs during the recruitment manoeuvre. By taking suitable measures and through close monitoring, the user needs to protect the ventilated patient from possible complications.



Warning

The recruitment manoeuvre causes a ventilation pause. In cases of severe hypercapnia or oxygenation problems in particular, the user is required to clinically evaluate the potential repercussions and whether or not this manoeuvre is suitable for the patient.



Warning

The recruitment manoeuvre may be associated with special risks for the patient, such as pneumothorax or cardiovascular depression. The safety parameters need to be adapted to the clinical situation; close monitoring must be ensured.

A 2.6 PEEPfinder manoeuvre

With the PEEPfinder, the device offers a respiratory mechanics manoeuvre during which a quasi-static P/V graph (pressure/volume) is recorded at the bedside and which assists in determining a secure window for the ventilation settings. The PEEPfinder can optionally be used as a recruitment tool.

Remark

The extent of the manoeuvre (only inspiratory measurement, only expiratory measurement, or inspiratory and expiratory measurement) can be set on the configuration level.

A pre-oxygenation function with an adjustable oxygen concentration can be activated to prevent inadequate oxygen supply during the manoeuvre.

Depending on the configuration, the manoeuvre covers only the inspiratory portion, only the expiratory portion, or the entire breath.

The measured data may prove very useful for the clinical diagnosis as well as for optimizing the ventilation settings.

A 2.6.1 Prerequisites

Conditions for using PEEPfinders are:

- The patient must be intubated or tracheotomized and ventilated.
- The device passed the system test successfully (including measurement of the breathing circuit).
- Only mandatory ventilation is applied, the patient is not breathing spontaneously. In spontaneous breathing modes, during HFOT or non-invasive ventilation, the PEEPfinder function is deactivated.
- The overall leakage is low.

A 2.6.2 Contraindications

Possible **contraindications** for using PEEPfinder:

- Patients breathing spontaneously or with phases of spontaneous respiration
- Patients whose cardiovascular condition is unstable
- Hypovolaemic patients
- Patients with suspected or confirmed intracranial pressure problems
- Patients unable to tolerate elevated intrapulmonary pressures for other reasons
- Patients unable to tolerate extended ventilation pauses
- Patients susceptible to barotrauma or volutrauma
- Patients with an inadequate depth of sedation and level of relaxation

A 2.6.3 Warnings and remarks



With PEEPfinder, high pressures can be applied over an extended period of time.



No ventilation occurs during the PEEPfinder manoeuvre. By taking suitable measures and through close monitoring, the user needs to protect the ventilated patient from possible complications.



All patient alarms are deactivated for the PEEPfinder manoeuvre.



When using PEEPfinder in patients with severe COPD, there is a risk of elevated volumes. The safety parameter Vmax needs to be adapted to the clinical situation.



During the manoeuvre, a relatively high intrathoracic pressure may occur for a relatively long period of time. Before activating the manoeuvre, the user needs to assess the ventilated patient as haemodynamically stable, and close monitoring of the vital signs must be ensured during the manoeuvre.



A sudden drop of the intrathoracic pressure may lead to an overload of the heart in certain circumstances.



The PEEPfinder manoeuvre may be associated with special risks for the patient, such as pneumothorax or cardiovascular depression. The safety parameters need to be adapted to the clinical situation and close monitoring must be ensured.

Remark

PEEPfinder cannot be started if a system test was not carried out, if the patient breathes spontaneously, and immediately after onset of ventilation.

Remark

Activating the PEEPfinder will disable some of the elisa 300 / elisa 500 functions (e.g., drug nebulizer, hold manoeuvre, etc.) because they may influence the PEEPfinder manoeuvre.

Remark | The PEEPFinder manoeuvre will be blocked for 60 seconds immediately after onset of ventilation, upon termination of a PEEPFinder manoeuvre or after recruitment.

Remark | When the respiratory rate is below 6 breaths/min, it is not possible to start the PEEPFinder manoeuvre.

A 2.6.4 Settings

You reach the PEEPFinder manoeuvre by pressing the “Manoeuvres” button, and then by selecting the “PEEPfinder” tab.

The PEEPFinder records the pressure vs. volume relation of the lung in a quasi-static state without ventilation.

Using the subsequent safety settings, define a secure framework for the pending PEEPFinder manoeuvre:

- **P Low:** lower measuring range for the manoeuvre
- **P Top:** upper measuring range for the manoeuvre or maximum allowed pressure which will cause the manoeuvre to be aborted (if the option “Insp. Phase” is configured)
- **V Stop:** maximum allowed tidal volume which will cause the manoeuvre to be aborted
- **I Flow:** gas flow rate for slow filling and, if applicable, deflation of the lung during the measuring manoeuvre
- **O2:** oxygen concentration for the pre-oxygenation function
- **Recr. time:** time for recruitment after reaching P Top

Insp. Hold	Exp. Hold	Manual Breath	Sigh	Recruitment	PEEPfinder	Functions
		O2 100 %	I Flow 2.0 l/min	P Low 3.0 mbar	Pre-oxygenation	Start
		Recr. time 2 s	V Stop 800 ml	P Top 25 mbar		Stop
						System
						←

Remark | The manoeuvre can be started with or without the pre-oxygenation function.

Remark | The manoeuvre can be started with or without the recruitment function.

Remark | The user is required to adapt the safety settings to the different clinical situations.

Remark | The manoeuvre ends when the set PEEP is reached (see Set ventilation parameters).

A 2.6.5 Performing the PEEPfinder manoeuvre (inspiratory and expiratory)

The ventilation alarms are disabled during the manoeuvre, and the ventilation mode window indicates “PEEPfinder”.

The PEEPfinder can be started directly or, alternatively, via the optional pre-oxygenation function with an adjustable oxygen concentration.

- Upon starting the PEEPfinder, the system first determines the respiratory situation (leakage, trapping, ...) and initiates a prolonged expiratory phase if needed.
- Then, the quasi-static manoeuvre begins at the set starting point and proceeds as configured (inspiration only, expiration only, or inspiration and expiration).
- For the duration of the recruitment, between inspiration and expiration, the valves are closed. At the end of the recruitment time, the expiratory valve opens and the expiratory phase begins (no bias flow (Byflow) is added).
- Upon termination of the PEEPfinder manoeuvre, ventilation continues.

Remark | If, during the manoeuvre, a situation occurs which makes it impossible to determine a valid pressure situation (onset of spontaneous breathing, high leakage, reaching the limit volume, high recruitment effects, ...), the manoeuvre will be aborted and the graphic and numeric evaluation will not be displayed.

Remark | The manoeuvre can be terminated prematurely at any time with the “Stop” and “Enter” buttons.

Remark | Duration of the manoeuvre: 2.5 minutes maximum

A 2.6.6 Evaluation

When the manoeuvre has been successfully completed, the user can analyse and evaluate the measurement results at different levels:



The displayed PEEPfinder curve shows the inflection points as well as the corresponding measured values:

LIP: lower inflection point

UIP: upper inflection point

PMC: point of maximum curvature

The recruitment time is registered as the plateau phase between inspiratory phase and expiratory phase (colour of the recruitment phase trace = colour of the inspiratory phase curve).

A 2.6.7 Additional views / indices

The PEEPfinder manoeuvre provides two more views. The first view shows the PEEPfinder loop together with the ventilation curve.

The second view shows the **Indices**, the static overall compliance, and the C20/C index.

The C20/C index represents the proportion of the last 20 % of compliance to the overall compliance as determined with the PEEPfinder manoeuvre.

A C20/C value below 0.8 may be indicative of lung over-distension.



Warning

During a manoeuvre you determine measuring values with the PEEPfinder, which may form the basis for adapting the ventilator settings.

The interpretation and clinical evaluation of the graphic and numeric measurement results and the classification of each individual case must be referred to an experienced physician.

A 2.6.8 Recruitment with PEEPfinder

If you intend to perform a **recruitment** manoeuvre, adapt the **recruitment time** (45 seconds max.).



Warning

The recruitment manoeuvre performed with PEEPfinder additionally extends the ventilation pause by the set recruitment time. In cases of severe hypercapnia or oxygenation problems in particular, the user is required to clinically evaluate the potential repercussions and whether or not this manoeuvre is suitable for the patient.

Remark

After 5 manoeuvres, the function is blocked for 60 seconds.

Remark

The manoeuvre cannot be started in the 60 seconds immediately after starting the ventilation.

Remark

The recruitment manoeuvre cannot be restarted in the 60 seconds immediately after terminating a PEEPfinder manoeuvre.

Remark

The manoeuvre is not available in NIV modes, during HFOT and in purely spontaneous breathing modes (dimmed – message in info box).

Remark

The recruitment manoeuvre cannot be combined with any other manoeuvre.

**Warning**

No ventilation occurs during the recruitment manoeuvre. By taking suitable measures and through close monitoring, the user needs to protect the ventilated patient from possible complications.

**Warning**

The recruitment manoeuvre causes a ventilation pause. In cases of severe hypercapnia or oxygenation problems in particular, the user is required to clinically evaluate the potential repercussions and whether or not this manoeuvre is suitable for the patient.

**Warning**

The recruitment manoeuvre may be associated with special risks for the patient, such as pneumothorax or cardiovascular depression. The safety parameters need to be adapted to the clinical situation; close monitoring must be ensured.

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A 3.1 Availability of the functions

Functions	Adults	Children
O ₂ Flush	X	X
Automatic Suction Routine ASR	X	X
Cuffscout (elisa 500 only)	X	X
Oesophageal pressure measurement Peso (elisa 500 only)	X	X
IAP (intra-abdominal pressure) (elisa 500 only)	X	X
Pneumatic nebulizer	X	X
Hygiene	X	X
Reference loops	X	X
CO ₂ sensor	X	X
Multi-gas sensor	X	X
SpO ₂ sensor	X	X
AnaConDa	X	X
Bronchoscopy	X	X
Nurse call	X	X

The availability of the functions and their order in the submenu depend on the settings on the configuration level of your ventilator (e.g., whether or not a particular function has been enabled). Up to 8 functions can be assigned to the function buttons.

Please contact your Service engineer if a particular function is not available.

Remark

Individual functions may not be available in all countries or may have to be purchased as options.

A 3.2 O2 Flush

You reach the “O2 Flush” function by pressing the “Functions” button and then by selecting the “O2 Flush” tab. Selecting and confirming the “On” button will briefly increase the inspiratory oxygen concentration to 100% for 180 seconds. After the 180-second period or when the Cancel button is pressed, ventilation continues with the previously set oxygen concentration.



A 3.3 Automatic Suction Routine (ASR)

The devices elisa 300 / elisa 500 offer suction manoeuvres for open or for closed suction systems to prevent conditions of hypoxia during endotracheal suctioning and to assist in performing the suction procedure.

To perform a suction manoeuvre, select the “Functions” button, and then select the “ASR” tab.

A 3.3.1 Suction with open suction systems

The manoeuvre consists of three phases:

Pre-oxygenation	Suctioning	Post-oxygenation
2:00 min	2:00 min	2:00 min

Start the manoeuvre by pressing the “Pre-oxygenation” button.

Once the suction routine has been started, it can be terminated during any phase and at any time by pressing and confirming the “Stop” function button.

A 3.3.1.1 Preoxygenation phase

The user can change the default O_2 concentration value to any desired O_2 value. The set O_2 concentration is stored and automatically applied when the ASR manoeuvre is accessed again. The setting is valid until a new system test is carried out and the default value is set again.

Once the pre-oxygenation phase has started, the remaining time is displayed by a count-down timer in the form of a bar chart.

The pre-oxygenation phase can be terminated at any time with the “Stop” function button, or the suction phase can be started prematurely with the “Suction” function button.

Remark

If the breathing circuit is opened during the pre-oxygenation phase, the intensive care ventilator switches to the suction phase after detecting the open circuit.

A 3.3.1.2 Suction phase

Upon completion of the pre-oxygenation phase, the ventilator emits a short acoustic signal and switches to the suction phase.

The remaining time of the suction phase is displayed by a count-down timer in the form of a bar chart. The gas supply valves are closed and the expiratory valve is opened at the start of the suction phase. Thus, the pressure in the breathing circuit is relieved and the patient tube connection can be opened without any risk for contamination.



Warning

All patient alarms are deactivated once the breathing circuit has been opened. A short acoustic signal is repeated every 10 seconds to remind the user that ventilation is not active.

The inspiratory flow and the expiratory valve are reconnected 10 seconds after starting the suction phase.

A 3.3.1.3 Postoxygenation phase

If a closed breathing circuit is detected, the suction phase is terminated and ventilation in the post-oxygenation phase starts. Ventilation will also start if the patient is still not disconnected after 10 seconds.

Alternatively, the ventilator switches to the post-oxygenation phase once the suction phase has been completed and starts ventilation. If this is not possible because the breathing circuit is still open, a corresponding alarm is triggered.

Once ventilation is resumed, the ventilation parameters and alarm limits of the pre-oxygenation phase are applied. Even a modified O_2 value is maintained but it can be changed at any time.

The post-oxygenation phase is terminated after 2 minutes. The O_2 value is automatically reset to the value which was set prior to starting the automatic suction routine. The automatic suction routine switches off automatically.

A 3.3.2 Suction with closed suction systems

When performing the suction routine with a closed suction system, the set oxygen concentration is applied as complementary oxygenation for 120 seconds, the byflow is adapted, and at the same time some of the audible alarms are disabled.

Remark

The BiLevel ventilation mode should be selected for suction with closed suction systems because negative pressures may occur or control algorithms may be altered in other modes.

Remark

The previously selected settings are retained during closed suction. The O_2 supply is increased during the manoeuvre.

A 3.4 Cuffscout

Remark

The Cuffscout function is not available for elisa 300.

A 3.4.1 Device setup

Two different Cuffscout lines are available and either type can be used.



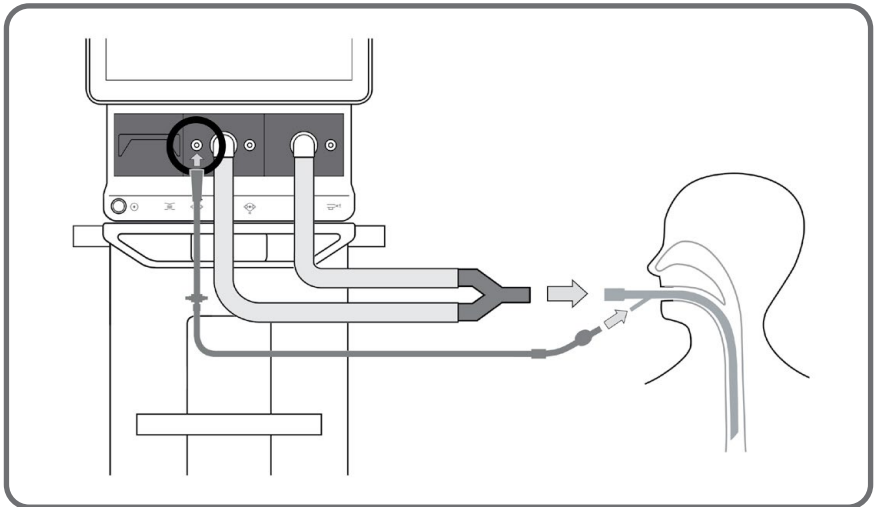
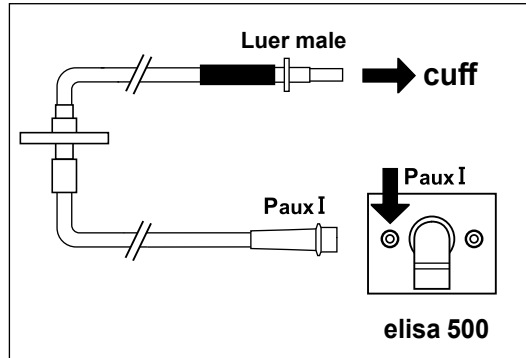
Warning

Only the Cuffscout connecting lines included in the accessory list are approved for use with the Cuffscout function (see illustration).

Remark

Check that the Cuffscout line fits the Paux I port. If it doesn't, your device was probably not yet upgraded to the new Paux ports. Please contact your service technician.

A 3.4.1.1 Cuffscout line



Slip the end with the non-return valve onto the Paux I port of elisa 500. The valve allows gas to flow through in only one direction. Therefore, the cuff pressure is maintained even if the Cuffscout line becomes disconnected.



Warning

Be sure to connect the Cuffscout line to **Paux I**. Connecting the line to any other port may jeopardise the safety of the patient.



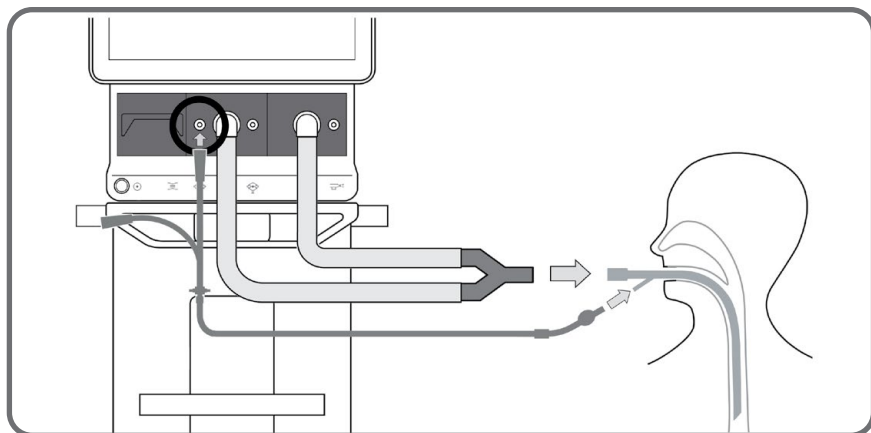
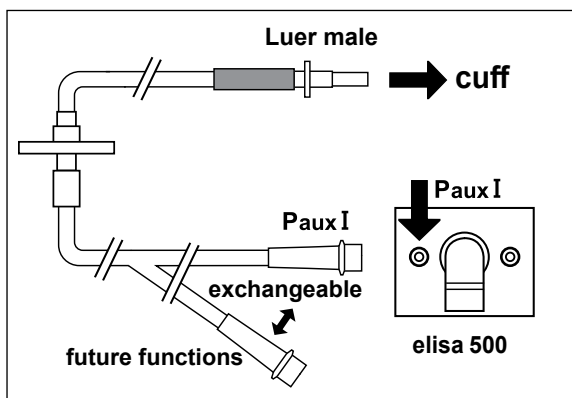
Warning

Cuffscout lines are single-use items which must be disposed of after use. Use a new Cuffscout line for each new patient.

Remark

The maximum service life of the Cuffscout connecting line is 29 days.

A 3.4.1.2 Cuffscout and test line



Slip one of the two ends of the Y-piece onto the Paux I port of elisa 500. The two ends of the Y-piece are identical, they are both closed with a non-return valve. The valve allows gas to flow through in only one direction. Therefore, the cuff pressure is maintained even if the Cuffscout line becomes disconnected.



Be sure to connect the Cuffscout line to **Paux I**. Connecting the line to any other port may jeopardise the safety of the patient.



Cuffscout lines are single-use items which must be disposed of after use. Use a new Cuffscout line for each new patient.

Remark

The maximum service life of the Cuffscout connecting line is 29 days.

A 3.4.2 Cuffscout function

You can choose between two modes: “**static**” and “**automatic**”.

At the configuration level, the cuff modes can be enabled and disabled and the parameters for the automatic cuff mode can be defined according to the ward-specific protocols.

You reach the Cuffscout menu by pressing the “Functions” button, followed by selection of the “Cuffscout” tab.

The following parameters can be adjusted:

Cuff const.	Specified value for the static cuff pressure.
Cuff max	Safety window for the maximum cuff pressure or setting for the maximum block manoeuvre.
Cuff min	Minimum cuff pressure

Remark

Initially, the cuff needs to be blocked manually.

Remark

You cannot switch off elisa 500 while the Cuffscout function is active.

A 3.4.2.1 Cuff pressure in the standby mode

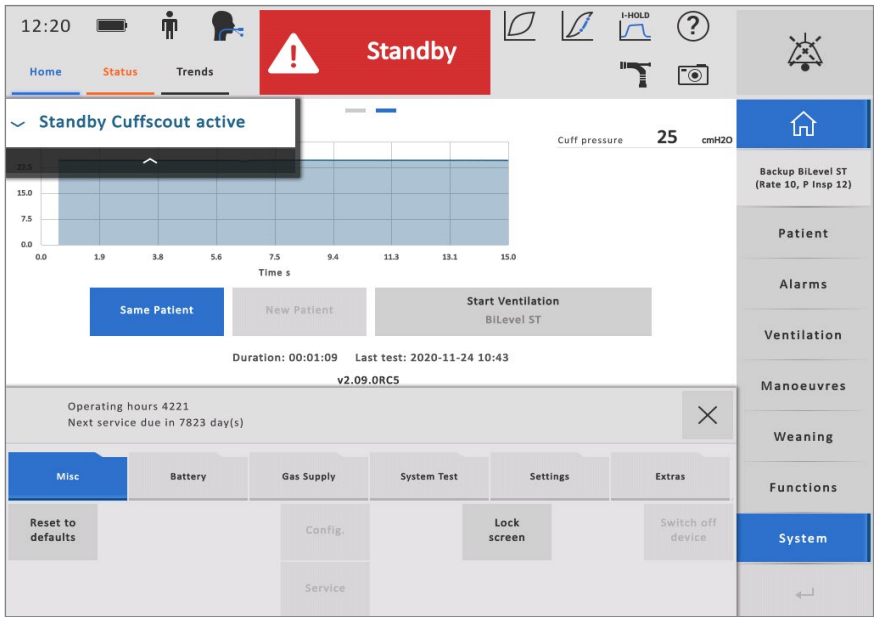
On completion of the ventilation procedure, the monitoring and control of the cuff pressure can be continued, e.g., for tracheotomised patients. For this function,

the static control mode needs to be selected and set.
For safety and to prevent that elisa is switched off inadvertently while the Cuffscout function is active, the Standby mode is indicated in large letters and a warning is displayed stating that the cuff pressure is activated.

Another standby view is available which displays the cuff pressure as a live graph.

Remark | The Cuffscout needs to be deactivated before you can switch off the ventilator.

Remark | This function is only available for the user if enabled on the configuration level and preset for the standby view.



When this view is selected, the Cuffscout graph is also displayed on the night screen (see chapter “7.4.5.2 Display brightness” in the Basic Instructions for Use).

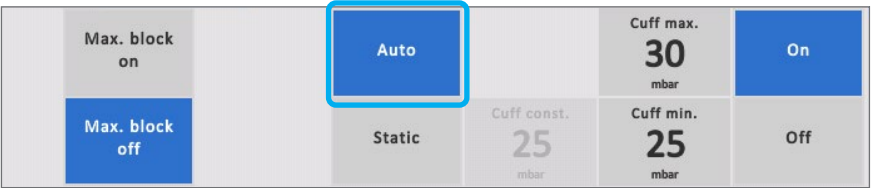
A 3.4.2.2 “Static” mode

The set cuff pressure is monitored and maintained.



A 3.4.2.3 “Automatic” mode

The cuff pressure is monitored and adapted on the basis of the set differential pressure via the plateau pressure. Whether or not the function is available depends on the installed hardware and configuration settings.



A 3.4.2.4 Max. block function

For manipulations at the tube (subglottic suctioning, repositioning of the tube, ...) a period of time can be specified in which the cuff pressure will be increased (Cuff max.).



Start Cuffscout by pressing either the “Static” or the “Auto” button, then press Enter.

The “Max. block” function is only available after activation of the Cuffscout.

A 3.5 Oesophageal pressure measurement (Peso)

An oesophageal catheter can be connected to the ventilator via the additional pressure port P_{aux II}. The changing oesophageal pressure may reflect the changing pleural pressure during the respiratory cycle and it enables transpulmonary pressure monitoring.



Warning

To ensure the validity of the measurement, connect the oesophageal catheter to the intensive care ventilators elisa 300 elisa 500 only by means of the pressure-tested Peso adapter (see separate accessory list).



Warning

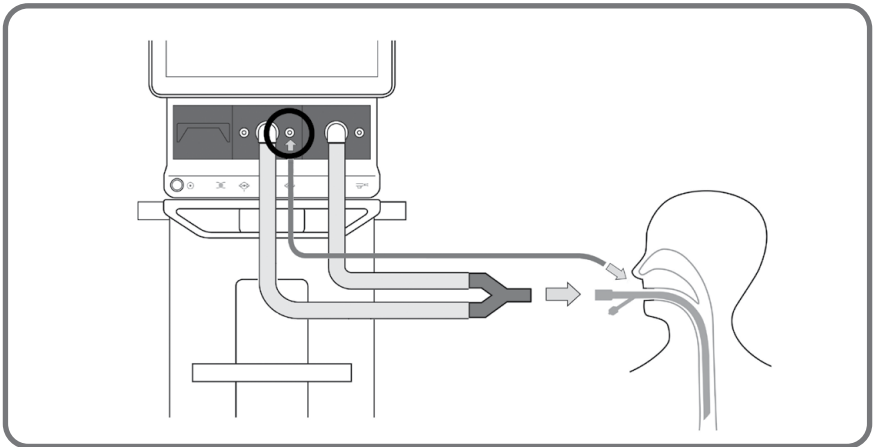
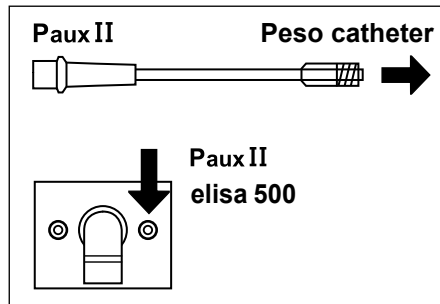
Observe the instructions for use supplied with the oesophageal catheter and the accessories used.

Remark

In elisa 300 ventilators, the oesophageal pressure measurement is not available.

A 3.5.1 Connecting the oesophageal catheter

Use the Peso adapter to connect the oesophageal pressure measuring line to the P_{aux II} port of elisa 500 (see separate accessory list).



Be sure to properly connect the line for the oesophageal pressure measurement to **Paux II**. Connecting the line to any other port may jeopardise the safety of the patient.

A 3.5.2 Peso function

Access to the “Peso” function depends on the configuration: either on the “Peso” tab displayed with the “Functions” button, or via the “Peso” shortcut.



It is absolutely essential that you activate the Peso function for measuring the oesophageal pressure. Other pressure measurement procedures, such as the IAP function, use different pressure ranges and apply special calculation algorithms. If the wrong pressure measurement procedure is activated by mistake, the displayed readings are useless.

The measured Peso values can be displayed in the different data tables as configured; some of them are also available in Fastprotect:

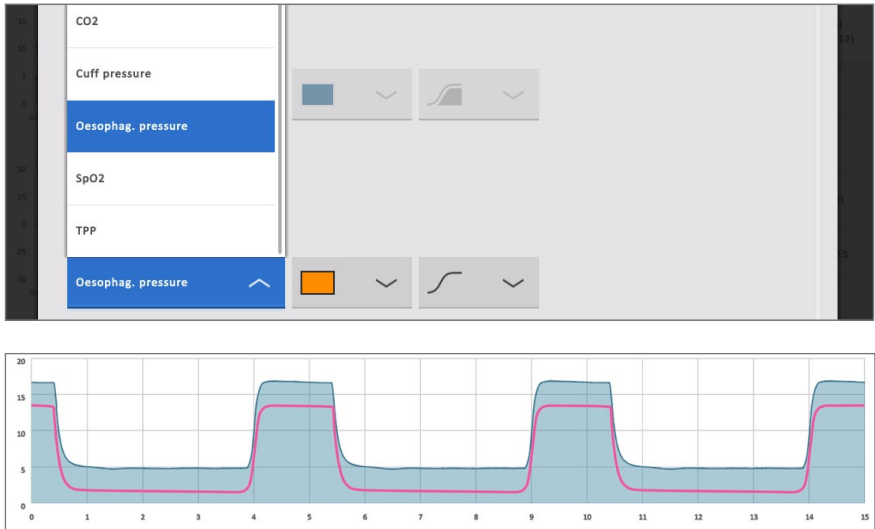
- P exp. (es)
- P insp. (es)
- TPP e (es)
- TPP i (es)
- ΔTPP (es)
- Peak (es)
- Pmin (es)
- ΔP (es)
- ΔPeso/ΔPAW

Additional values are measured or calculated for spontaneously breathing patients:

- Inspiratory work of breathing: WOB (es)
- Power of Breathing: POB spont. (es)
- Intrinsic PEEP: PEEPi (es)



At the same time, the user decides whether to display an oesophageal or a transpulmonary pressure curve (TPP). The colour for the additional pressure curve can also be selected.



Transpulmonary pressure curve TPP

A 3.5.3 Occlusion manoeuvre

The occlusion manoeuvre is offered as a simple method for checking the position of the oesophageal catheter. After selecting the Occlusion button, press and hold the Enter button. The inspiratory and expiratory valves will be closed. In this state of occlusion, you can visually assess and evaluate the position of the catheter by means of the ventilation pressure and oesophageal pressure curves. The maximum remaining time of the manoeuvre is displayed in a bar chart. Upon termination of the manoeuvre, ventilation continues.

After five manoeuvres, the button is blocked for 30 seconds. Another occlusion manoeuvre can be performed after the lockout time.

Remark

The maximum duration of an occlusion manoeuvre is 15 seconds.



Warning

No ventilation occurs during the manoeuvre. By taking suitable measures and through close monitoring, the user needs to protect the ventilated patient from possible complications.

A 3.5.4 Manual HOLD manoeuvre

The device offers a manual hold manoeuvre, which facilitates the determination of the end-inspiratory pressure situation. After selecting the manual hold button and simultaneously pressing the Enter button, a prolonged inspiration of up to 15 seconds is applied at the pressure level of the respective ventilation settings, and TPP insp. is continuously measured.

The remaining time of the manoeuvre is displayed in a bar chart. Upon termination of the manoeuvre, ventilation continues.

After five manoeuvres, the button is blocked for 30 seconds. Another manual hold manoeuvre can be performed after the lockout time.

Remark

The maximum duration of the manual hold manoeuvre is 15 seconds.

A 3.6 IAP (Intra-abdominal pressure)

A kit for measurement of the intravesical pressure can be connected to the ventilator via the additional pressure port Paux II. This allows the acquisition of the intra-abdominal pressure, using intravesical pressure (IVP) as a surrogate parameter. Intra-abdominal hypertension (IAH) is defined as an intra-abdominal pressure (IAP) equal to or above 12 mmHg, and abdominal compartment syndrome (ACS) is defined as an IAP above 20 mmHg with evidence of organ dysfunction/failure. Both levels of increased intra-abdominal pressure cause significant morbidity and mortality among intensive care patients. This includes acute renal failure, pulmonary impairment, and reduced blood flow to the gastro-intestinal organs. In addition, increased IAP can cause elevation of the diaphragm with consequent increase in intra-thoracic pressure, which has a major effect on pulmonary compliance. The high intra-thoracic pressure may interfere with the cerebral venous return via the jugular venous system leading to intra-cranial congestion and brain dysfunction. Clinically, significant intra-abdominal hypertension may be present in the absence of abdominal distension. Therefore, increased IAP is commonly measured by recording intravesical pressure (IVP).

Remark

The IAP (intra-abdominal pressure) function is not available for elisa 300.



Warning

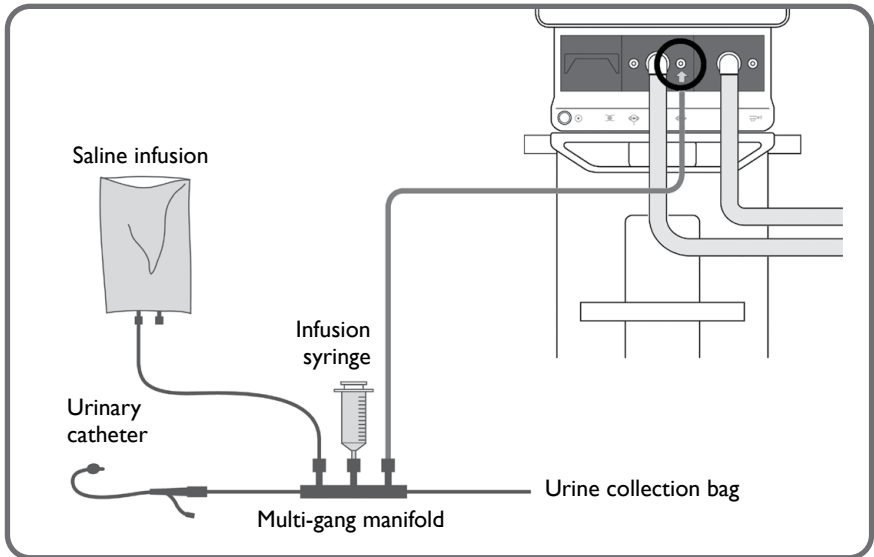
Check that the intravesical pressure measurement kit is connected to the correct port and familiarise yourself with intravesical pressure measurement with a closed system.



Observe the instructions for use supplied with the measurement kit and the accessories used.

A 3.6.1 Connecting the intravesical pressure measuring kit

Connect the intravesical pressure measuring kit to the Paux II port of elisa 500.



Check that the intravesical pressure measurement kit is connected to the correct Paux port. The intra-abdominal pressure cannot be measured when the kit is connected to any other port; furthermore, this may jeopardise the safety of the patient.

A 3.6.2 IAP function

Remark

IAP is available to the end user only if it was enabled on the configuration level.

Open the IAP workspace by pressing the “Functions” button and then by selecting the “IAP” tab. If configured accordingly, the intra-abdominal pressure measurement can also be selected via the shortcut “IAP”.

Activate and deactivate the function with the “On” and “Off” buttons. IAP is displayed as a numeric value and as a graphic trend.



Warning

It is absolutely essential that you activate the IAP function if you want to monitor the intra-abdominal pressure. Other pressure measurement procedures, such as oesophageal pressure measurement, use different pressure ranges and apply special calculation algorithms. If the wrong pressure measurement procedure is activated by mistake, the displayed readings are useless.

Remark

For more information about intravesical pressure measurement and the corresponding Guideline of the World Society of the Abdominal Compartment Syndrome, please go to:
<http://www.wsacs.org/images/2013%20Guidelines%20slide%20set.pdf>

A 3.7 Drug nebulization

A 3.7.1 Intended use

When the pneumatic nebulizer function is used, the patient receives medical aerosol via the breathing circuit during ventilation.

Depending on the set O_2 concentration, the nebulizer operates with AIR or with O_2 :

O_2 concentration $< 60\%$ = operation with AIR

O_2 concentration $\geq 60\%$ = operation with O_2

Algorithms are implemented to compensate variations in the inspiratory oxygen concentration during pneumatic drug nebulization.

Observe the intended use of the elisa 300 / elisa 500 instructions for use and the instructions for use of the nebulizer.

A 3.7.2 Nebulization

In each ventilation mode, medication can be nebulized with elisa 300 / elisa 500 by means of a pneumatic nebulizer.

Nebulizer	Peso	ASR	O2 Flush	Reference Loops	Hygiene	F
			Pneumatic nebulizer 	Time 30 min	On Off	

Remark

Ensure that all connections are secure and tight.

Remark | The nebulizer can be used within the patient environment.



HME or bacteria filters between the nebulizer set and the patient must not be used during drug nebulization. There is a risk of increasing the airway resistance!



Filters with an internal connecting rib (e.g., Pall Ultipor) do not allow a secure connection with the valve bar. Therefore, do not use these filters as device protection filters.



Nebulized aerosols and medication residue may adversely affect the function of the expiratory valve and the expiratory flow measurement.



To prevent deposits and contamination of the expiratory valve and impairment of the expiratory flow measurement, the use of device protection filters is mandatory. The replacement intervals of the device protection filter depend on the medications used, on the number of applications and on the specifications of the filter manufacturer.



If the filters or the filter replacement intervals are unsuitable, the expiratory limb may become clogged, which causes a considerable rise in flow resistance and reduces ventilation efficiency.



The filter (e.g., RT019) supplied with Fisher & Paykel breathing circuits is an approved bacterial and viral filter; it is not suitable for use as a device protection filter. Do not use this filter as a device protection filter.



When using HME filters at the Y-piece, medication residue in the exhaled air may cause flow resistances and reduce ventilation efficiency. Replace HME filters as appropriate, considering the medications used, the number of applications and the specifications of the HME filter manufacturer and/or monitor the patient closely.

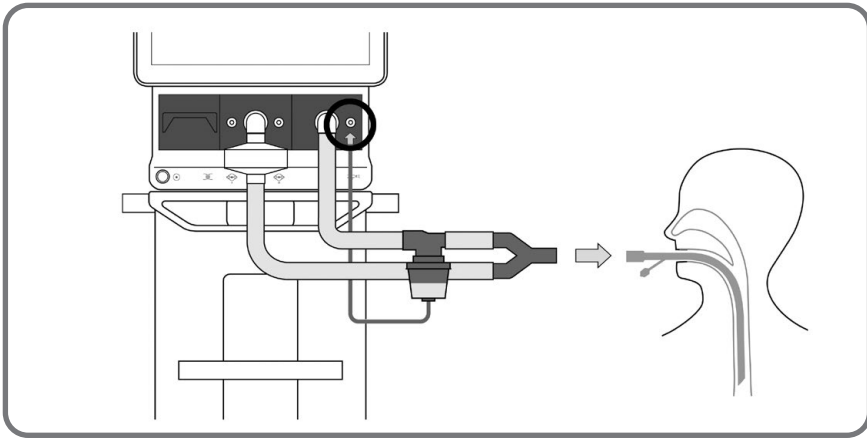
Remark | It is not possible to start nebulization while the AnaConDa function is active; the nebulization function is disabled.

A 3.7.3 Pneumatic nebulization

A 3.7.3.1 Connecting the pneumatic nebulizer set

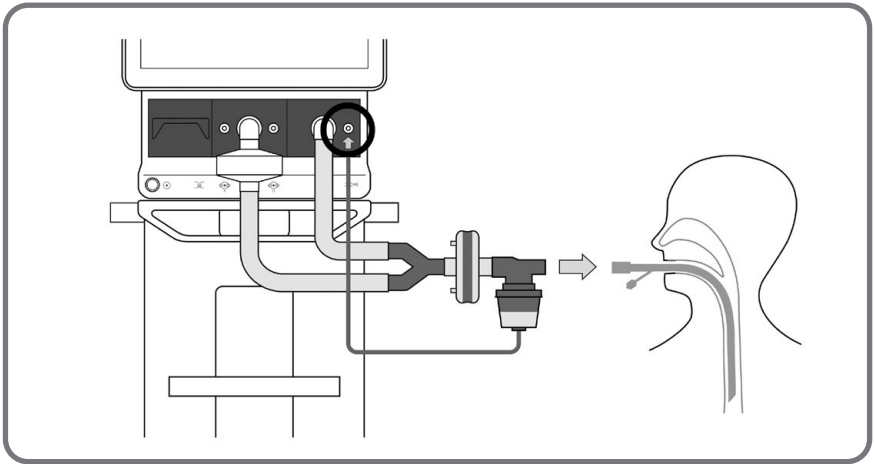
Remark | In volume-controlled modes, the pneumatic drug nebulization is not available for the patient category “Children”.

To avoid additional dead space volume, the nebulizer set is integrated on the inspiratory side of the breathing circuit. Install the device protection filter in front of the expiratory valve to protect the ventilator from medication residues.



Remark | Make sure that the nebulizer set is in an upright position.

Alternatively, the nebulizer set can be integrated between the HME filter and the tube.

**Remark**

The pneumatic nebulizer set should be measured in the system test before use for the best possible application of oxygen, volume, and pressure during nebulization. This helps achieve an almost complete compensation for all parameters.

A 3.7.3.2 General information

The nebulizer sets used for pneumatic drug nebulization should meet the following minimum requirements:

- Nebulizer flow between 4 and 12 l/min at a supply pressure of 130 kPa
- Pressure-stable up to a breath pressure of 80 mbar
- Leakage less than 200 ml/min at an airway pressure up to 50 mbar

Remark

The tested nebulizer sets are listed in the “elisa 300 / elisa 500 accessories list”.

Remark

In case of drug nebulization procedures requiring a defined aerosol output and/or a defined particle size distribution, the manufacturer of the nebulizer set must be contacted.

Remark

The components are intended for single use in order to prevent cross-contamination.

To achieve the best possible application of oxygen, volume and pressure during nebulization, the pneumatic nebulizer set should be included in the system test before use. This helps achieve an almost complete compensation for all parameters.

If the system test is performed without the nebulizer, the nebulizer data of the last system test are used to calculate the compensation.

Remark

Fill the medication chamber of the nebulizer set according to the manufacturer's instructions. Observe the maximum filling level.



Warning

When the nebulizer is switched on, no HME filters or bacteria filters should be used between the nebulizer and the patient. There is a risk of increasing the airway resistance.



Caution

Nebulized aerosols can be deposited in the expiratory flow sensor and can have a severe impact on the measuring accuracy. A bacteria filter in front of the expiratory valve can protect the flow sensor.



Warning

Check the proper functioning of the nebulizer set used. The ventilator does not monitor the nebulizer function.

A 3.7.3.3 Procedure

Integrate the nebulizer set in the breathing circuit as explained.

Open the configuration menu for drug nebulization by selecting the “Functions” button; then select the “Nebulizer” tab.

Start the pneumatic nebulization procedure by selecting the “On” button and confirm with the Enter button. During active nebulization the remaining nebulization period is shown in the nebulizer symbol.

Once the set application time has been reached, the nebulizer switches off automatically. The procedure can be stopped at any time (with “Off” and Enter).

A 3.7.3.4 Synchronisation

The nebulizer function is synchronised with the inspiratory flow at respiratory rates ≤ 25 /min.

The nebulizer is permanently active at respiratory rates > 25 /min.

In spontaneously breathing patients, the respiratory rate can fluctuate around a value of 25/min. In order to prevent frequent switching between inspiratory synchronised and permanent nebulization, the device will analyse three consecutive breaths to determine whether the respiratory rate is above or below the value of 25/min.

A 3.7.3.5 Pneumatic nebulization and O₂ concentration

Remark | When the O₂ supply is not connected, the pneumatic nebulizer cannot be started.

The nebulizer is operated with air at a set oxygen concentration (FiO₂) ≤ 60 % and with oxygen at a concentration > 60%.

The oxygen concentration of the inspiratory flow and the byflow are adapted such that the set oxygen concentration (FiO₂) at the Y-connector is guaranteed within a tolerance range of +/- 4%.

If the pneumatic nebulizer is switched on, the Instant View window no longer shows the measured FiO₂ value but rather the value calculated at the Y-connector. In this case the colour coding of the display field is hidden.

A 3.8 Hygiene function

After selecting the hygiene function via the “Functions” button, you have the following options:

- you can activate and deactivate the currently used accessories with “On” and “Off”, respectively;
- you can view the remaining times of use of the accessories;
- you can confirm the replacement of an accessory.

Nebulizer		Peso	ASR	O2 Flush	Reference Loops	Hygiene		Functions
Tube	Tube Heated	Turbine filter	Valve bar	Nebulizer	Suction System	Accessory changed	On	System
Remaining 1d 0h	Remaining Off	Remaining Off	Remaining 4d 0h	Remaining Off	Remaining Off		Off	

The following components are monitored:

- Breathing circuit
- Heated breathing circuit
- turbine filter
- valve bar
- nebulizer
- suction system

Remark | Components which were set to “Off” at the configuration level are not visible in this screen.

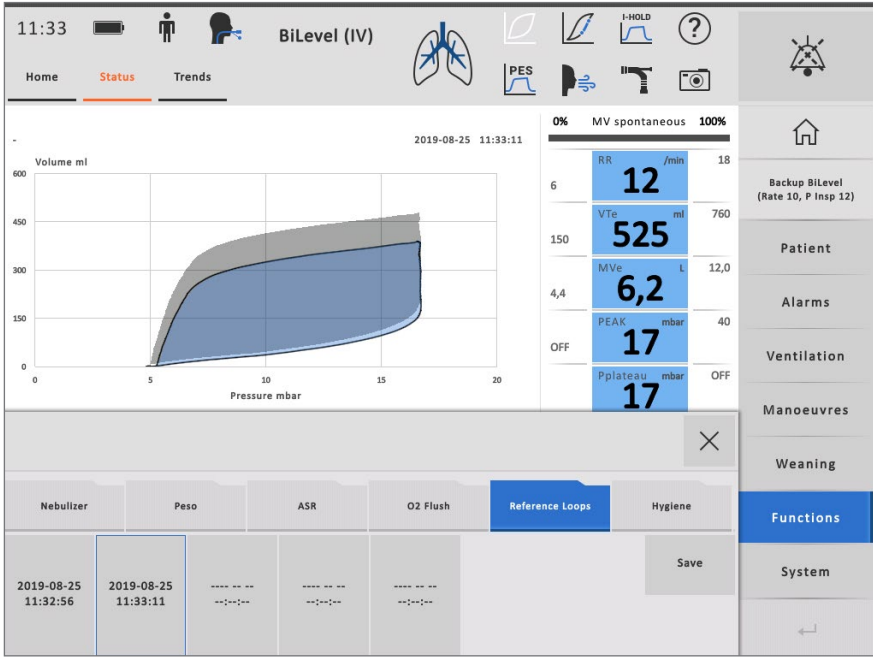
When the period of service of an accessory has expired, the alarm window will display a message.

The change of an accessory is also documented in the trend data.
Selecting a new patient in the standby mode will set all accessories to the “Off” status.

A 3.9 Reference loops

On the Reference loops tab, up to five reference loops can be saved with the corresponding times:

- First select the button to which you want to assign the loop.
- The selected button changes its colour when touched.
- Tap the Save button, and then tap Enter to save the reference loop; the date and time will be displayed in the designated button.
- When you touch the designated button again, the stored reference loop will be shown as a coloured area under the current loop (grey).



You can overwrite stored reference loops by selecting the corresponding button and saving another loop.
The stored reference loops will be deleted when you select a new patient.

A 3.10 Capnometry

A 3.10.1 Intended use

A CO₂ sensor can be connected to the intensive care ventilators elisa 300 / elisa 500, which adds the respiratory gas monitoring function for CO₂ when the sensor is activated.

The following sensors are available

- Mainstream CO₂ sensor LeoCap
- Mainstream CO₂ sensor IRMA CO₂
- Sidestream CO₂ sensor ISA CO₂
- Multi-gas sensor LeoLyzer

The CO₂ sensor LeoCap also provides volumetric capnometry.

Remark	Observe and adhere to the intended use of the elisa 300 / elisa 500 and to the instructions for use of the respective CO ₂ sensors.
---------------	--

Remark	CO ₂ monitoring is not available in the HFOT mode.
---------------	---

Remark	CO₂ measurement during NIV: During non-invasive ventilation, leakage of varying degrees and dependent on the ventilation pressure occurs regularly. This means that the volume expired by the patient and the measured expiratory volume will not be the same, which has a considerable effect on the accuracy of the CO₂ measurement. Therefore, it is necessary to critically review the measured CO₂ values and to evaluate them in the clinical context.
---------------	--

Remark	The CO ₂ sensor used must be configured on the configuration level of elisa 300 / elisa 500 in order to be available for CO ₂ measurement. You can review the current interface configuration on the standby or ventilation screen under the "Status" tab by selecting the second view with a horizontal swipe. If in doubt, contact your service technician.
---------------	---

A 3.10.1.1 Display priorities for curves and measured values

A CO₂ sensor and the multi-gas sensor LeoLyzer can be operated simultaneously. In this case, the displayed CO₂ values and curves are those from the **CO₂ sensor**.

A 3.10.2 Measuring principle

The CO₂ sensor sends infra-red light of a specific wavelength through the respiratory air. The absorbed portion of transmitted light is determined with a light-sensitive detector and it is used for calculation of the end-tidal CO₂ concentration.

A 3.10.3 Power supply

The CO₂ sensor is powered via the serial interface.

If the main power supply fails, the sensor continues to be powered from the elisa 300 / elisa 500 unit as long as the elisa 300 / elisa 500 battery maintains the ventilation function.

A 3.10.4 Breathing circuit

The CO₂ sensor is compatible with all approved breathing circuits.

A 3.10.5 Connecting a CO₂ sensor

Remark | The CO₂ sensor can be used within the patient environment.



Warning

First connect the CO₂ sensor to the device (power supply) before you allow it to come into contact with the patient.

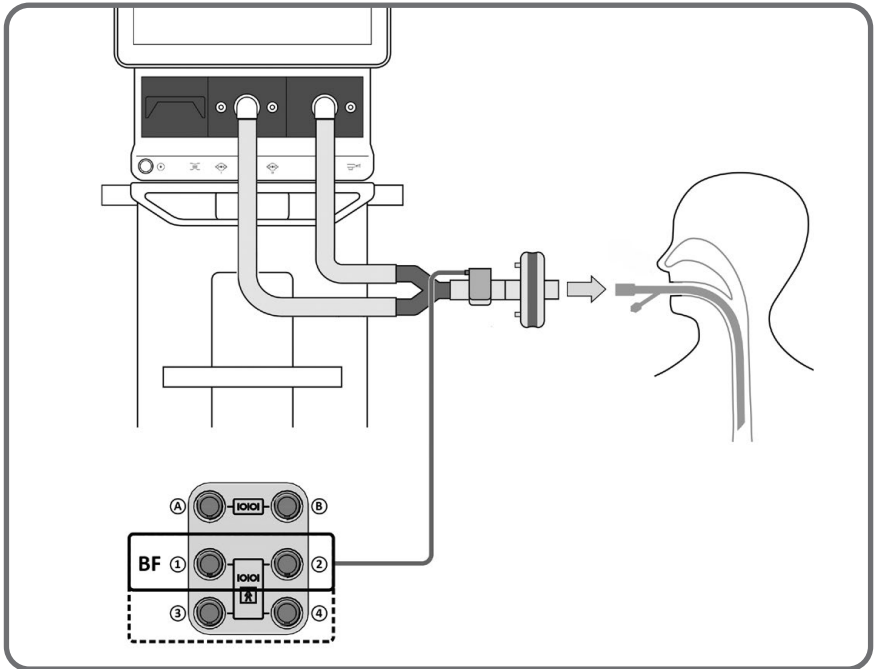


Warning

Be sure to connect the CO₂ sensor to one of the BF interfaces on the back of the device.

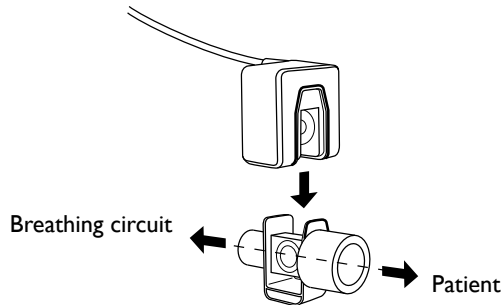
A 3.10.6 Connecting the LeoCap CO₂ sensor

Connect the LeoCap CO₂ sensor to the configured BF interface on the back of the ventilator using the connection cable.



Attach the CO₂ sensor to the measuring cuvette.

Remark | Check the correct orientation.



Remark | Check the temperature of the measuring cuvette. Cold cuvettes may cause fogging of the windows, which may have an adverse effect on the measurement results.

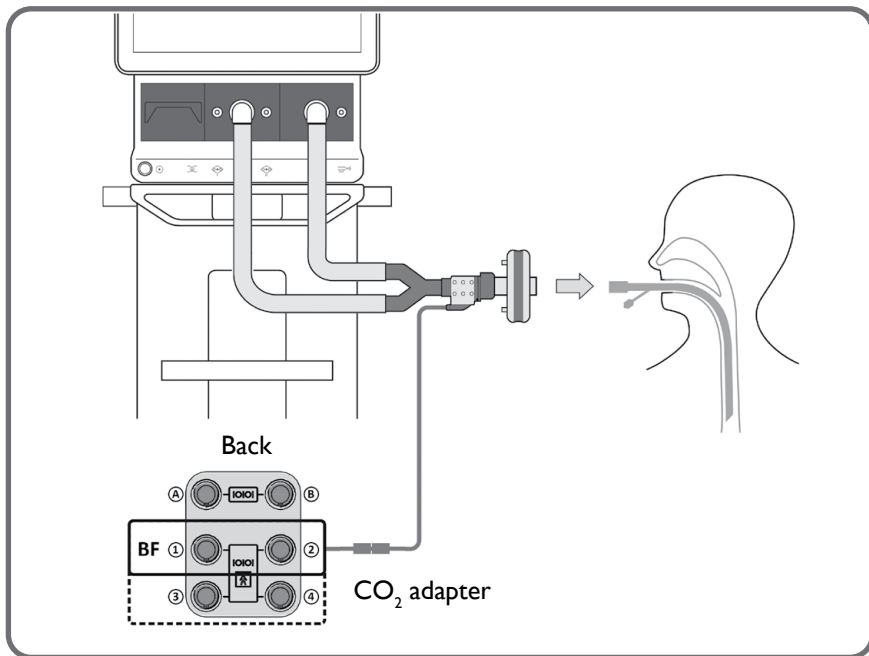


Do not touch the windows of the measuring cuvette. Finger prints may also lead to incorrect measurement results.

Attach the sensor to the measuring cuvette and integrate the assembly between the HME filter and the patient (at the patient end of the circuit).

When not in use, the sensor should be stored in the optional holder which can be mounted on either of the two handles on the sides of the ventilator unit.

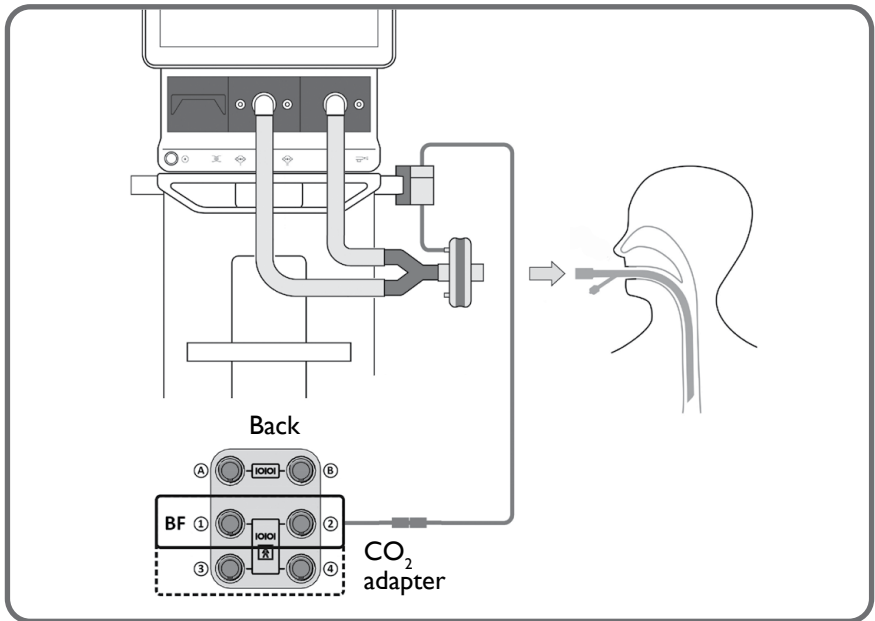
A 3.10.7 Connecting the mainstream sensor IRMA CO₂



Connect the CO₂ sensor IRMA CO₂ to the configured BF interface on the back of the ventilator using the connection cable and the CO₂ adapter (see separate accessory list).

Integrate the measuring cuvette between the Y-connector and HME filter close to the patient. After zeroing of the CO₂ sensor, push it on to the measuring cuvette.

A 3.10.8 Connecting the sidestream sensor ISA CO₂



Connect the CO₂ sensor ISA CO₂ to the configured BF interface on the back of the ventilator using the connection cable and the CO₂ adapter (see separate accessory list).

Using the approved support, fasten the sidestream sensor to one of the two side handles of the ventilator. Using a sampling line, connect the sensor to the appropriate port of the HME filter.



The sampling line must be replaced after each patient to avoid cross-contamination.

When using a sidestream CO₂ sensor, you can choose between sampling lines with Luer-Lock connectors (such as on the HME filter) or with a tube adapter (e.g., for combination with heated tubing systems). The respective sampling line is first connected to the gas inlet of the sidestream CO₂ sensor and then to the corresponding connection in the breathing circuit.

A 3.10.8.1 Respiratory gas humidification

The CO₂ sensor can be combined with active and passive humidifiers.

Remark

The use of heated tubes is recommended when using the CO₂ sensor with an active humidifier.

Remark

The windows of the CO₂ measuring cuvette may be contaminated with condensation and nebulized drugs, which affects the measurement results and can render them useless. The CO₂ sensor should always be placed with the cuvette windows in a perpendicular position, never horizontally. This helps prevent patient secretions from contaminating the windows.

A 3.10.8.2 Drug nebulization

Remark

The windows of the CO₂ measuring cuvette may be contaminated with condensation and nebulized drugs, which affects the measurement results and can render them useless. The CO₂ sensor should always be placed with the cuvette windows in a perpendicular position, never horizontally. This helps prevent patient secretions from contaminating the windows.

A 3.10.9 Performing capnometry

A 3.10.9.1 Zeroing of the CO₂ sensor (only IRMA or ISA)

Before use, the sensor should be calibrated with ambient air. To do so connect the sidestream sensor to the measuring line or place the mainstream sensor on the measuring cuvette.

After a warm-up phase of 15 seconds, the “Zero Adjust” button in the “CO₂ Sensor” menu will be enabled and the sensor can be zeroed.



Warning

A ventilated patient must not be connected while the sensor is being zeroed.



Warning

Mainstream method:
For zeroing, no CO₂ is allowed in the ventilation system.



Sidestream method:

It must be ensured that the ambient air inlet of the CO₂ sensor is positioned in a well ventilated location.

Avoid breathing in close proximity to the sensor during zeroing.

Remark

Sidestream method:

During long-term applications, the sidestream CO₂ sensor automatically performs zero adjustments at least once every 24 hours.

Remark

If the CO₂ sensor is connected at the time of the system test, its function is tested and a zero adjustment is automatically carried out.

After the zero adjustment, the CO₂ measurement is performed continuously and the result is displayed in the Instant View window.

A 3.10.9.2 CO₂ measurement

Open the CO₂ measurement menu by selecting the “Functions” button; then select the “CO₂ sensor” tab.

The device automatically identifies the connected sensor.

Nebulizer	AnaConDa	Cuffscout	ASR	O2 Flush	Reference Loops	Leolyzer	CO2 Sensor	Functions
							Mean value 5 breaths	On
							Zero adjust	Off
								System
								←

Set the number of breaths for averaging of the etCO₂ value. Start the measurement of the CO₂ sensor by selecting the “On” button and confirm with the Enter button.

Remark

By touching the “On” button, you activate the sensor. After activation, please bear the following information in mind:

- The first etCO_2 value and the corresponding waveform will not be displayed before the end of the warm-up phase, which may take up to 10 seconds.
- The accuracy of the CO_2 measurement is reduced in the first 2 minutes because the sensor is still warming up. During this warm-up phase, you will see the alarm message “ CO_2 sensor temperature”.
- In the first 2 minutes, the accuracy of the CO_2 measurement is very much dependent on the temperature of the measuring cuvette. Low temperatures of the cuvette lead to strong fluctuations of the measured CO_2 values.

Remark

The intensive care ventilator may be configured to activate the CO_2 sensor when switched on. If this is the case, the warm-up phase of the CO_2 sensor begins immediately after the intensive care ventilator is switched on.

The CO_2 measurement can be terminated by switching off the CO_2 sensor. The end-expiratory CO_2 concentration (end tidal) is constantly measured and shown along with the associated alarm limits in the Instant View window. Depending on the configuration, the CO_2 curve is displayed in the area of the volume curve.

Interrupting the ventilation (“Standby”) also stops the CO_2 measurement. If ventilation continues with the “Same patient”, the set alarm limits for the CO_2 concentration are retained.

When the “New patient” function is selected, the alarm limits for the CO_2 concentration are set to the default values.

Remark

If the measured end-tidal values or the CO_2 waveform do not seem plausible, check the CO_2 measuring cuvette and exchange if necessary.

Remark

LeoCap auto-calibrates continuously. The user is not required to perform calibrations.

Remark

There are two configuration options for CO_2 measurements: the measurement starts when activated by the user or the measurement is activated by default.

A 3.10.9.3 Volumetric capnography

Volumetric capnography (VC) provides valuable insights into the ventilation situations and reflects the current CO_2 elimination. It is, therefore, a suitable tool for non-invasive, real-time monitoring of cyclic recruitment manoeuvres and for assessment of the collapse recruitment physiology at the bedside. The information obtained non-invasively can be separated into the particular effects that lung recruitment exerts on lung perfusion, gas exchange, ventilation, and gas transport, whereby each VC variable carries a particular physiological meaning. The sensitivity and specificity of non-invasive VC can be verified and/or enhanced by supplemental measurements of gas exchange.

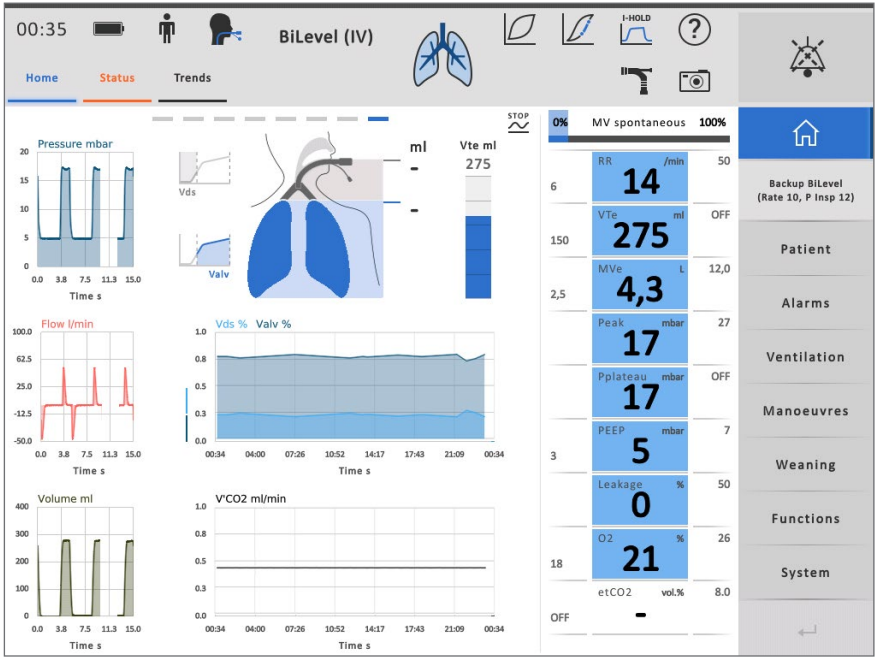
Remark

Volumetric capnography can only be performed with the high-resolution CO_2 mainstream sensor LeoCap.

The ventilator monitors the following volumetric capnography measurements, among others:

- CO_2 elimination (VCO_2): enables assessment of the metabolic situation (e.g., increase in the case of sepsis) and the effect of ventilator settings on CO_2 elimination
- end-tidal CO_2 : correlation with blood gas analysis (taking into account the respective ventilation/perfusion ratios V/Q)
- anatomical dead space as part of the expiratory tidal volume (VTds)
- anatomical dead space as a percentage of the expiratory tidal volume ($\text{VTds} \%$)
- alveolar dead space as part of the expiratory tidal volume (VTalv)
- alveolar dead space as a percentage of the expiratory tidal volume ($\text{VTalv} \%$)

For the continuous assessment of volumetric capnometry, a special template can be configured which includes the trend data of the determined dead spaces as percentages of the tidal volume and of VCO_2 .



- Remark

For display of the volumetric capnography information, a special template must be selected on the configuration level. Please contact the equipment officer of your institution or an authorized service agent.
- Remark

VCO₂ reflects the measured CO₂ elimination which may be different from the CO₂ production because it is influenced by the clinical situation.

A 3.10.10 Alarm limits

The following alarm limits are available for an adequate monitoring of the CO₂ measurement:

etCO ₂ max	Upper alarm limit for the expiratory CO ₂ concentration
etCO ₂ min	Lower alarm limit for the expiratory CO ₂ concentration
inCO ₂ max	Upper alarm limit for the inspiratory CO ₂ concentration

A 3.10.11 Status indicator of the CO₂ sensors IRMA and ISA

The CO₂ sensors IRMA and ISA each have a status light which indicates the following system statuses:

Green static	System OK
Green flashing	Zeroing in progress
Red static	Sensor problem
Red flashing	Check adapter or sampling line

A 3.11 Multi-gas sensor LeoLyzer

A 3.11.1 Intended use

By connecting and activating the LeoLyzer multi-gas sensor, you expand the functionality of the elisa 300 / elisa 500 intensive care ventilator by multi-gas measurement.

The gas measurement options are

- CO₂ + sevoflurane
- CO₂ + isoflurane
- only CO₂

Remark

The multi-gas sensor LeoLyzer does not support volumetric capnometry.

Remark

Observe and adhere to the intended use of the elisa 300 / elisa 500 and the instructions for use of the LeoLyzer multi-gas sensor (see separate Instructions for Use, Supplement C).

Remark

Multi-gas measurement is not available in the HFOT mode.

Remark

Multi-gas measurement during NIV:

During non-invasive ventilation, leakage of varying degrees and dependent on the ventilation pressure occurs regularly. This means that the volume expired by the patient and the measured expiratory volume will not be the same, which has a considerable effect on the accuracy of the measurement. Therefore, it is necessary to critically review the measured values and to evaluate them in the clinical context.

Remark

The multi-gas sensor LeoLyzer must be configured on the configuration level of elisa 300 / elisa 500 in order to be available for multi-gas measurement. You can review the current interface configuration on the standby or ventilation screen under the "Status" tab by selecting the second view with a horizontal swipe. If in doubt, contact your service technician.

A 3.11.2 Measuring principle

The method is based on the measurement of infrared light absorption at wavelengths of 4.2 μm , 7.85 μm , and 8.3 μm . The measured amount of light that passes through the gas to the photo sensor serves as the calculation basis. The concentration of CO_2 and anaesthetic gas is calculated from the partial pressure at atmospheric pressure conditions.

A 3.11.3 Power supply

The multi-gas sensor is powered via the serial (BF) interface of the intensive care ventilator.

If the main power supply fails, the sensor continues to be powered from the intensive care ventilator as long as the battery of the intensive care ventilator maintains the ventilation function.

A 3.11.4 Breathing circuit

The CO_2 sensor is compatible with all approved breathing circuits.

A 3.11.5 Integrating the multi-gas sensor LeoLyzer

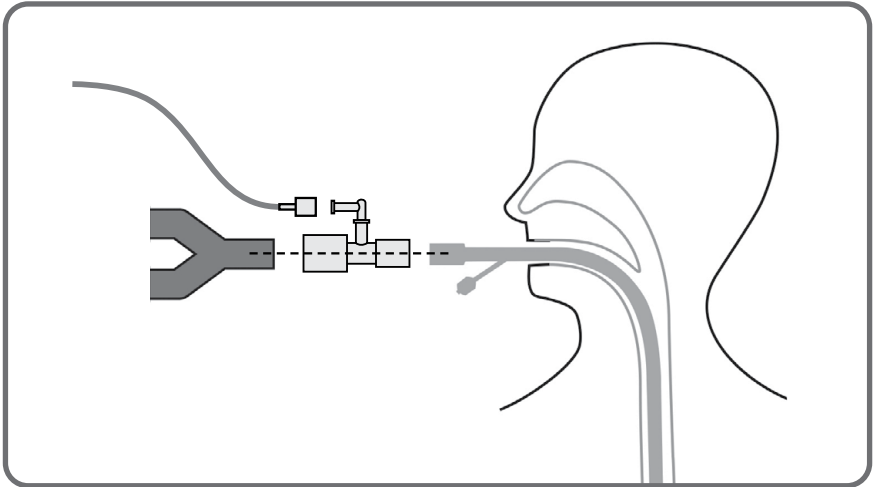
Insert the airway adapter between the Y-piece and the tube of the breathing circuit.

Connect the sampling line to the airway adapter by turning the line clockwise.

Connect the sampling line to the water trap by turning the line clockwise.



Suspend the middle part of the sampling line above the level of its ends to drain the condensate formed in the sampling line. To prevent moisture accumulation in the airway adapter, it should be positioned so that the port where the sampling line is connected points UP.



- The maximum performance is reached after about 10 minutes. The indicator flashes green during the warm-up phase.
- Check whether the screen of the intensive care ventilator displays readings.
- The device is ready for operation when the indicator is green.
- The device is not ready for operation when the indicator is red. Check the device function.

A 3.11.6 Sample gas outlet

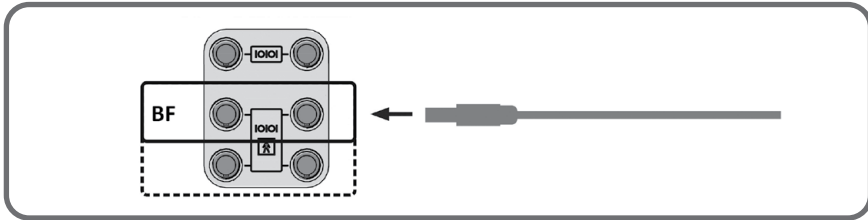
The sample gas outlet is located on the back of the device.

Via the sample gas outlet, the gas sample can be returned to the breathing circuit or disposed of in the residual gas filter or in the anaesthetic gas scavenging system.

Please contact our field service department for the required accessories.

A 3.11.7 Connecting the multi-gas sensor LeoLyzer

Connect the multi-gas sensor LeoLyzer to the configured BF interface on the back of the ventilator using the connection cable.



Remark | The multi-gas sensor can be used within the patient environment.



First connect the multi-gas sensor to the device (power supply) before you allow it to come into contact with the patient.



Be sure to connect the multi-gas sensor to one of the BF interfaces on the back of the device.

A 3.11.8 Performing a multi-gas measurement

A 3.11.8.1 Multi-gas measurement

Open the multi-gas measurement menu by selecting the “Functions” button; then select the “LeoLyzer” tab.

Select the gas or gases to be measured by pressing the appropriate buttons and confirm the selection:

- SEV (sevoflurane and CO₂ will be measured)
- ISO (isoflurane and CO₂ will be measured)
- CO₂ only (only CO₂ will be measured)

Set the number of breaths for averaging of the measured value / values. Start the measurement with LeoLyzer by selecting the “On” button and confirm with the Enter button.

Nebulizer	AnaConDa	Cuffscout	ASR	O2 Flush	Reference Loops	Leolyzer	CO2 Sensor	Functions
					Gas type	Mean value	On	System
					CO2 only	5 breaths		
						Zero adjust	Off	←

Remark

By touching the “On” button, you activate the device. After activation, please bear the following information in mind:

- The first measured value and the corresponding waveform will not be displayed before the end of the warm-up phase, which may take up to 10 seconds.
- The accuracy of the measurement is reduced in the first 10 minutes because the sensor is still warming up. During this warm-up phase, you will see the alarm message “LeoLyzer sensor temperature”.
- In the first 10 minutes, the accuracy of the measurement is very much dependent on the device temperature. Low temperatures of the device lead to strong fluctuations of the measured values.

Stop the multi-gas measurement by activating the “Off” button in the LeoLyzer Workbench.

The concentration of the selected gas / gases is measured continuously. The measured values will be displayed only if previously configured in one of the views (for details, please refer to chapter 5 General information in the Basic Manual of the instructions for use).

The measured values can be displayed in the following formats:

- Data Table
- Short Trend Graph
- Trend Table
- Trend Graph

Interrupting the ventilation (“Standby”) also stops the multi-gas measurement. If ventilation continues with the “Same patient”, the set alarm limits for the multi-gas concentration are retained.

When the “New patient” function is selected, the alarm limits for the multi-gas concentration are set to the default values.

Remark

LeoLyzer auto-calibrates continuously. The user is not required to perform calibrations.

A 3.12 SpO₂ sensor

A 3.12.1 Connecting the SpO₂ sensor (with adapter)



Warning

First connect the SpO₂ finger sensor adapter to the device (power supply) before you allow it to come into contact with the patient.

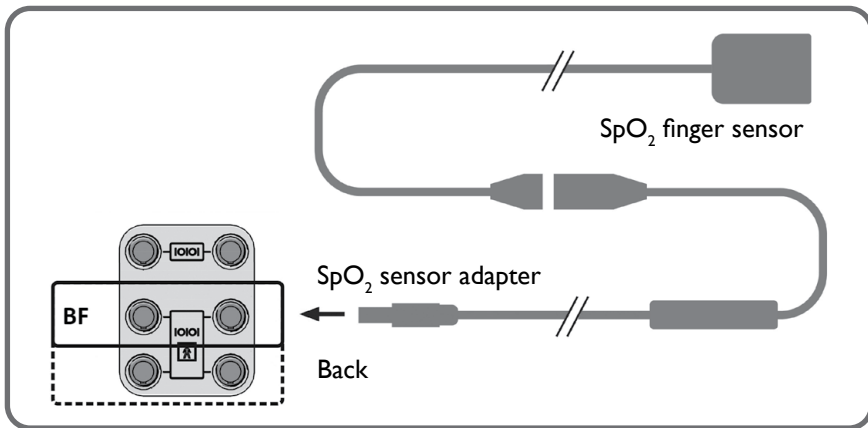


Warning

Be sure to connect the SpO₂ finger sensor adapter to one of the BF interfaces on the back of the device.

Remark

The SpO₂ finger sensor can be used within the patient environment.



Select the finger sensor size suitable for the patient. Connect the SpO₂ finger sensor to the configured BF interface on the back of the ventilator using the SpO₂ adapter.

Attach the SpO₂ finger sensor to the patient's finger.

A 3.12.1.1 SpO₂ Measurement

For details of the SpO₂ measurement, refer to the Instructions for Use, Supplement D – Pulse oximetry and LeoClac.

A 3.12.2 Alarm limits

The following alarm limits are available for an adequate monitoring of the multi-gas measurement:

etCO ₂ max	Upper alarm limit for the expiratory CO ₂ concentration
etCO ₂ min	Lower alarm limit for the expiratory CO ₂ concentration
inCO ₂ max	Upper alarm limit for the inspiratory CO ₂ concentration
inISO max	Upper alarm limit for the inspiratory isoflurane concentration
inISO min	Lower alarm limit for the inspiratory isoflurane concentration
exISO max	Upper alarm limit for the expiratory isoflurane concentration
exISO min	Lower alarm limit for the expiratory isoflurane concentration
inSEV max	Upper alarm limit for the inspiratory sevoflurane concentration
inSEV min	Lower alarm limit for the inspiratory sevoflurane concentration
exSEV max	Upper alarm limit for the expiratory sevoflurane concentration
exSEV min	Lower alarm limit for the expiratory sevoflurane concentration

A 3.13 AnaConDa function

A 3.13.1 Intended use

elisa 300 / elisa 500 is also suitable for use as an anaesthesia workstation. For the delivery of volatile anaesthetic agents during ventilation, the AnaConDa function is implemented in the device. The AnaConDa function can be enabled at the configuration level.

After activation of the AnaConDa function (by touching the “On” button in the AnaConDa menu), the intensive care ventilator will compensate the flow resistances of the AnaConDa system at the patient end and of the anaesthetic gas filter (FlurAbsorb).

Remark	To use the AnaConDa function, it must be enabled at the configuration level of elisa 300 / elisa 500.
Remark	The AnaConDa function is not available for neonates and not in all countries.
Remark	It is not possible to start nebulization while the AnaConDa function is active; the nebulization functions are disabled.



The AnaConDa device contains a hydrophobic bacterial/viral filter. This means that humidification of the inspired gases will increase the ventilation pressures. Humidification of the inspired gases while using the AnaConDa system is therefore contraindicated.

The system is composed of

- elisa 300 or elisa 500
- AnaConDa and AnaConDa-S (Anaesthetic Conserving Device)
- syringe pump
- anaesthetic gas monitor and
- anaesthetic gas absorption/scavenging (anaesthetic gas filter or AGSS)

It is intended for administering the volatile anaesthetic agents isoflurane and sevoflurane to patients through mechanical ventilation.

When working with the AnaConDa system, the minimum tidal volume applied may not be less than 350 ml.

When working with the AnaConDa-S system, the minimum tidal volume applied may not be less than 300 ml.

Continuous operation of elisa 300 / elisa 500 is allowed in combination with isoflurane and sevoflurane.



elisa 300 / elisa 500 may only be operated in conjunction with the anaesthetic agents sevoflurane and isoflurane.



Only the AnaConDa or the AnaConDa-S device may be utilized for delivery and recirculation of the anaesthetic agents sevoflurane and isoflurane in conjunction with elisa 300 / elisa 500.

A 3.13.2 Safety instructions

A 3.13.2.1 Safe operation

In order to guarantee the safe operation of the intensive care ventilator with the AnaConDa function, the system may only be used as described in this manual. Before putting the system into operation, users must familiarise themselves with these instructions for use and with the instructions for use of the AnaConDa system.

Remark

The AnaConDa system must be set up and applied as described in the instructions for use provided by its manufacturer Sedana.

Remark

Using the AnaConDa function requires permanent monitoring of the anaesthetic gas concentration by means of an appropriate gas monitor.

**Warning**

Furthermore, observe and follow the instructions given in the documents supplied with each system component.

A 3.13.2.2 Patient safety

elisa 300 / elisa 500 with AnaConDa may only be operated by qualified medical staff in order to guarantee an adequate intervention in the event of a device malfunction.

**Warning**

You must undergo training for each system component before you are allowed to use the system for patient treatment. Please contact your sales partner for information about training programs for AnaConDa or AnaConDa-S in combination with elisa 300 / elisa 500.

**Warning**

If the gas or power supply fails, the ventilator may not be able to maintain the ventilation function.

In this situation, perform emergency ventilation immediately by following these steps:

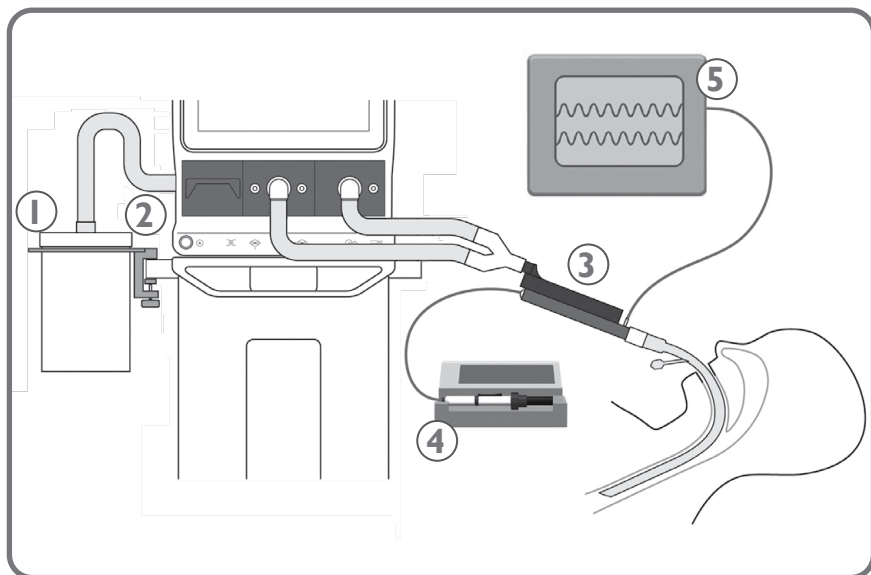
- Disconnect AnaConDa or AnaConDa-S from the patient tube or tracheostomy tube
- connect a resuscitation bag to the patient tube or tracheostomy tube.
- Ventilate the patient manually, if necessary with oxygen supply and PEEP valve.
- Stop administering the anaesthetic agent with the syringe pump.
- Choose an alternative method if a sedative needs to be administered.

A 3.13.3 Technical requirements

Remark

Before you can use the AnaConDa function, it must be enabled at the configuration level of elisa 300 / elisa 500.

The following additional accessories are required for use of the AnaConDa function of elisa 300 / elisa 500:



- 1.) Anaesthetic gas filter with holder **or** a scavenging system for the anaesthetic gas with reservoir (not shown)
- 2.) Accessories for the selected anaesthetic gas filtering/scavenging method
- 3.) AnaConDa or AnaConDa®-S device
- 4.) Syringe pump with AnaConDa syringe
- 5.) Anaesthetic gas monitor for display of the concentrations of the anaesthetic gases and CO₂
- 6.) Filling adapter (REF 26042, 26064) (not shown)

Remark

For use of the AnaConDa function, the elisa 300 / elisa 500 device must be installed on a cart (optional accessory) with handles or standard rails on the side. Only in this configuration is it possible to securely mount all the required accessories.



Warning

Electrical connections between the devices are not allowed.

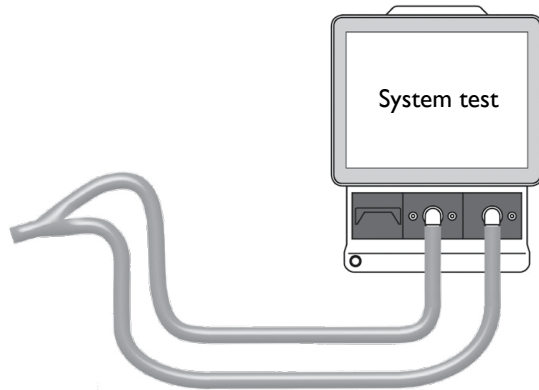
Accessories approved for use with elisa 300 / elisa 500 are specified in the “elisa 300 / elisa 500 list of accessories”. If employing different accessories, the user is required to test and demonstrate the safety of the system prior to its use. All accessories used must have an EC declaration of conformity in compliance with the medical device directive 93/42/EEC and they must have passed the elisa 300

/ elisa 500 system test.

All components shall only be applied within the scope of their respective intended use.

A 3.13.4 Assembly

First of all, perform a system test of the elisa 300 / elisa 500.



A 3.13.4.1 Anaesthetic gas elimination

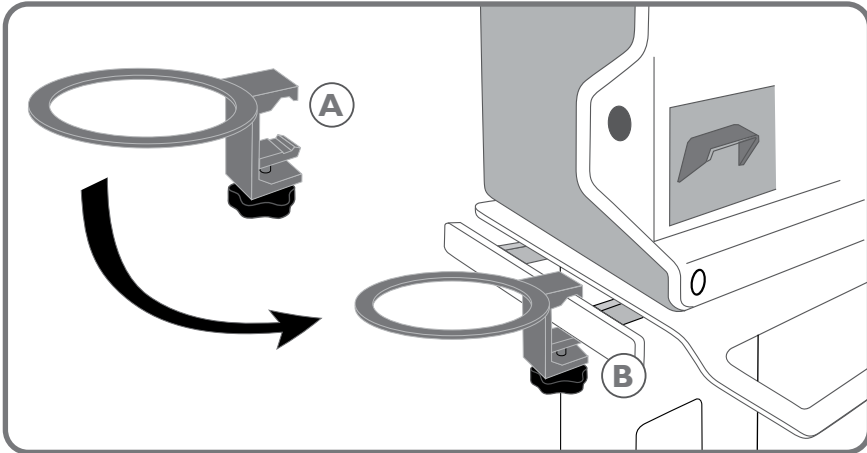
Decide if you want to eliminate the anaesthetic gas via the hospital gas scavenging system or through the anaesthetic gas filter. You will need the corresponding accessories (see separate list of accessories).

A 3.13.4.2 Elimination via Flurabsorb

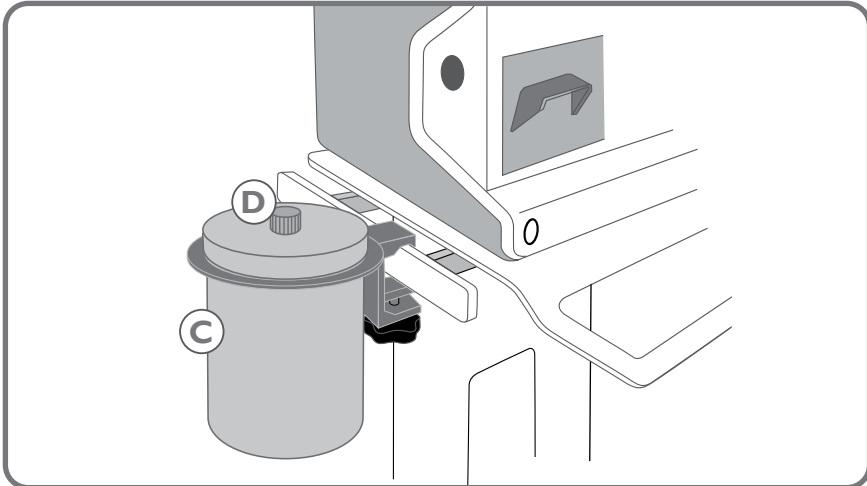
Obtain the following accessories (see separate list of accessories):

- Anaesthetic gas filter holder
- Anaesthetic gas filter accessory kit
- Adapter 22mm/22mm for elisa 300 / 500
- Anaesthetic gas filter

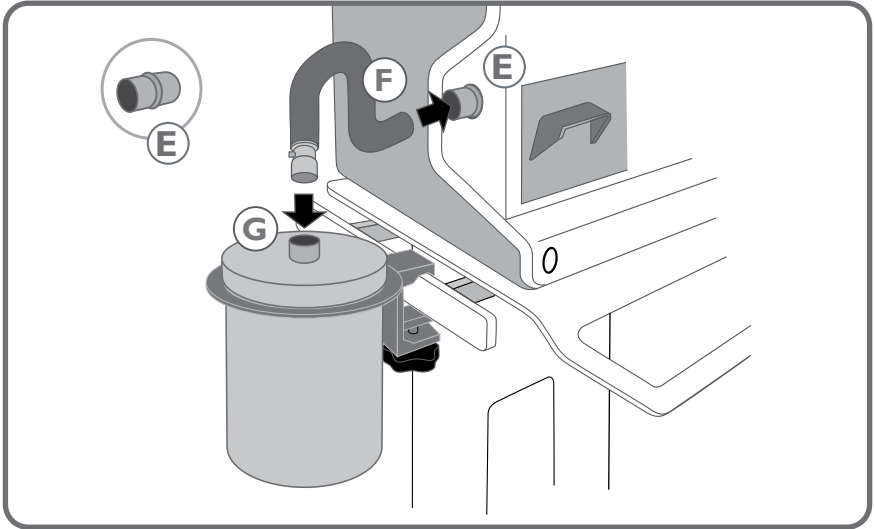
1.) Attach the holder for the anaesthetic gas filter (A) to the handle or standard rail on the left of the elisa 300 / elisa 500 cart (B).



2.) Place the anaesthetic gas filter (C) in the holder and unscrew the cap (D).



3.) Attach the 22mm/22mm adapter (E) to the exhaust gas port of elisa 300 / elisa 500. Then slip the 22-mm tube from the accessory kit (F) onto the adapter. To do this, remove the 22mm/30mm adapter from the tube; it is not needed. Using the adapter provided for this purpose, attach the other end of the tube to the aperture of the anaesthetic gas filter (G). Check that the tube is securely attached and tight.



A 3.13.4.3 Connection to an anaesthetic gas scavenging system (AGSS)



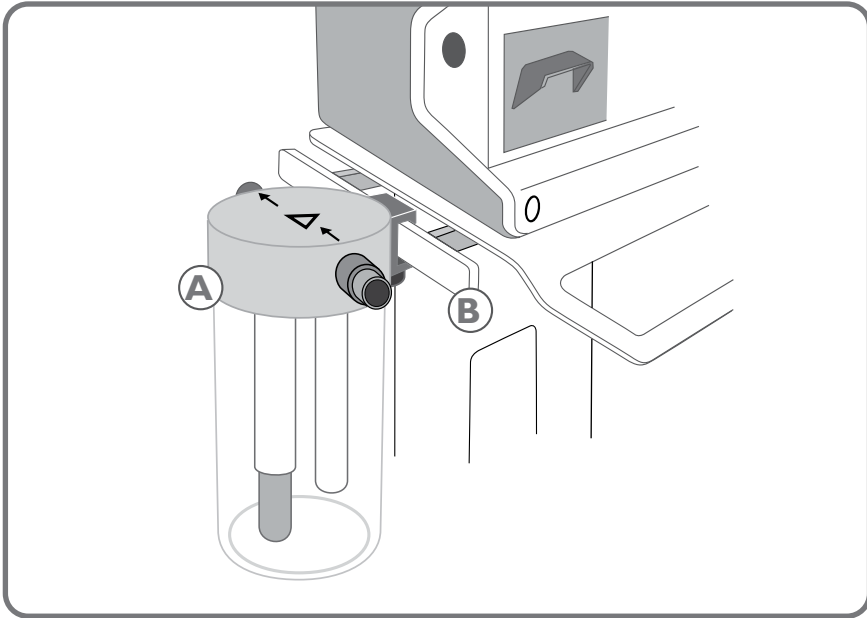
Warning

Before using the AGSS, read the corresponding instructions for use.

Obtain the following accessories (see separate list of accessories):

- AGSS receiving container with AGSS adapter
- AGSS transfer hose
- 22mm/22 mm adapter
- Connection hose, 5 metres
- AGSS coupler for terminal port

1.) Attach the receiving container (A) to the handle or standard rail on the left of the cart (B).

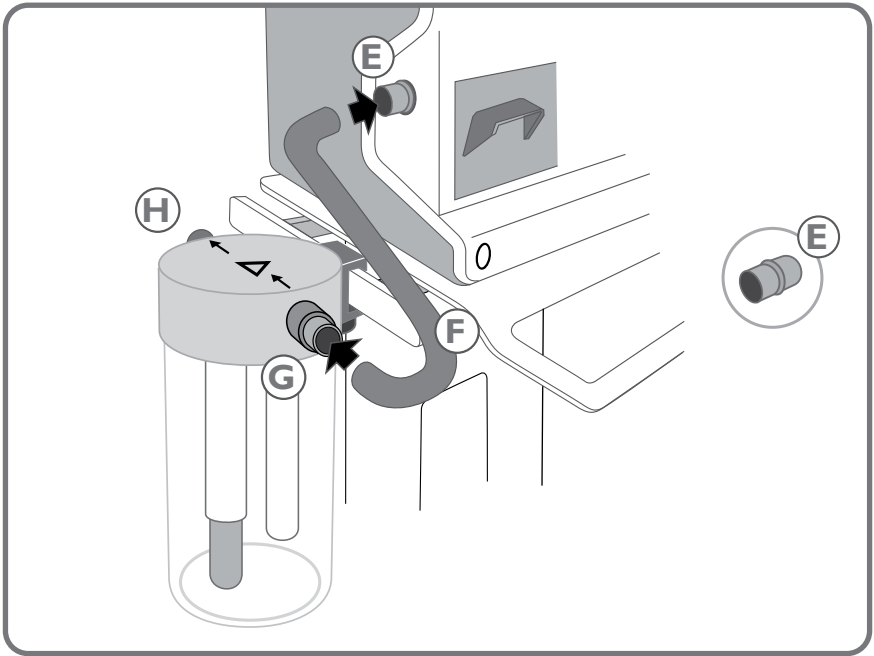


2.) Attach the 22 mm/22 mm adapter (E) to the exhaust gas port of elisa 300 / elisa 500. Slip the AGSS transfer hose onto the adapter (F). Attach the other end of the hose to the inlet port of the receiving container (G). Check that the tube is securely attached and tight.



Warning

Observe the flow direction of the gas indicated by the arrows on the lid.



3.) Plug one end of the 5-metre hose to the outlet port of the receiving container (H). Plug the other end to the AGSS coupler. Connect the coupler to the terminal port.

A 3.13.4.4 Connecting the AnaConDa system to elisa 300 / elisa 500

Finally assemble all components of the AnaConDa system (AnaConDa device, syringe pump with AnaConDa syringe and the anaesthetic gas monitor) as described in the AnaConDa instructions for use.



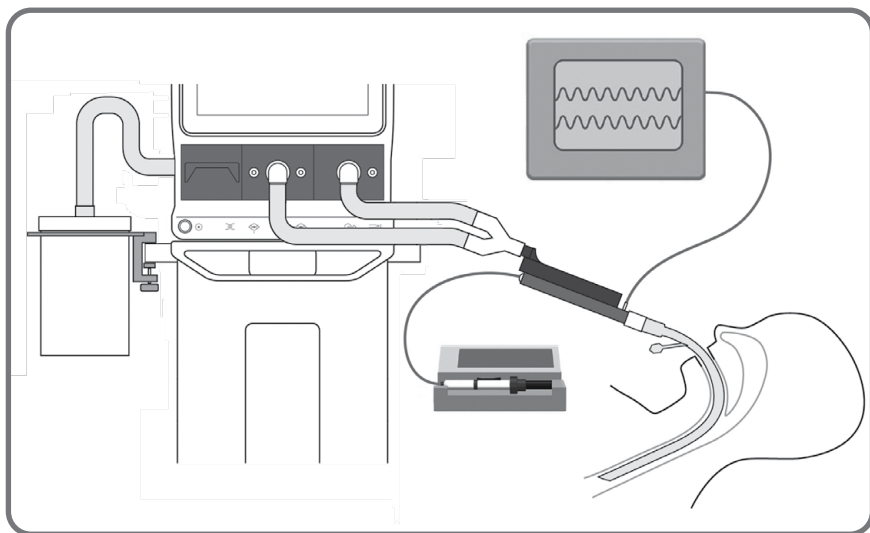
Warning

If you are using a power strip to connect the devices to mains power, the power strip must comply with the particular electrical safety requirements of EN 60601-1.



Warning

Check that all connections are secure.



Warning

Before starting ventilation with the anaesthetic delivery function, check the system by means of the checklist in the following chapter.

A 3.13.5 Ventilation with AnaConDa function

You reach the anaesthetic delivery function by pressing the “Functions” button and then by selecting the “AnaConDa” tab.

In the menu, choose AnaConDa or AnaConDa-S, touch the “On” button and confirm with “Enter”.



Warning

If the AnaConDa function is activated while the AnaConDa (or AnaConDa-S) device and/or the residual gas filter are not connected, flow control and pressure control of the ventilation will be impaired.

A 3.13.6 Checklist for verification of the entire elisa 300 / elisa 500 system with the AnaConDa system

Check point:	Yes	No
System:		
System test successfully completed according to chapter 6.5?		
AnaConDa system securely connected between ventilation tube / tracheostomy tube and Y-piece of the breathing circuit?		
Anaesthetic gas filter or anaesthetic gas scavenging system connected to expiratory flow sensor via adapter?		
All tube connections checked for leaks and all plug connections verified?		
Anaesthetic gas monitor connected via sidestream port and ready for operation?		
AnaConDa system filled according to manufacturer's instructions and prepared for use?		
Syringe pump ready for operation and properly connected?		
Is a bag valve mask available for emergency ventilation? Can the resuscitation bag be connected to the patient's tube / tracheostomy tube?		
elisa 300 / elisa 500 device:		
Is the internal battery fully charged?		
Correct AnaConDa system (AnaConDa or AnaConDa-S) selected?		
Activate the AnaConDa function and perform sedation with AnaConDa (or AnaConDa-S) according to the manufacturer's instructions and clinical circumstances.		

A 3.14 Bronchoscopy

You reach the “Bronchoscopy” function by pressing the “System” button and then by selecting the “Extras” tab.

During bronchoscopy and similar therapeutic measures, which are associated with high leakage, frequent audible alarms cannot be prevented. To reduce the stress level during the intervention, audible alarms are often permanently muted. Activation of the bronchoscopy function will automatically silence the audible ventilation alarms. In this situation, it is essential to watch the patient closely or use other suitable means of patient monitoring.

Remark

When the bronchoscopy function is activated, you will see the “Bronchoscopy” label in the display area of the ventilation mode concerned.



Warning

Activating bronchoscopy will disable all audible and visual ventilation alarms. Technical alarms, however, are still reported.



Warning

To rule out any risk for the patient, the bronchoscopy function may only be activated when close patient monitoring is ensured. The extent of direct observation of the patient or additional monitoring methods (pulse oximetry, end-tidal CO₂ measurement, ...) depend on the patient's clinical condition.



Warning

After deactivation of the bronchoscopy function, the default alarm limits will automatically be restored. To rule out any risk for the patient, adapt the alarm limits of the device to the alarm limits of the therapeutic measures that you need to take for the patient at hand.

Remark

After deactivation of the bronchoscopy function, an audible alarm will be emitted to remind the user of the necessity to adapt the alarm limits. When adjusting the first alarm limit, the alarm criterion will be deactivated.

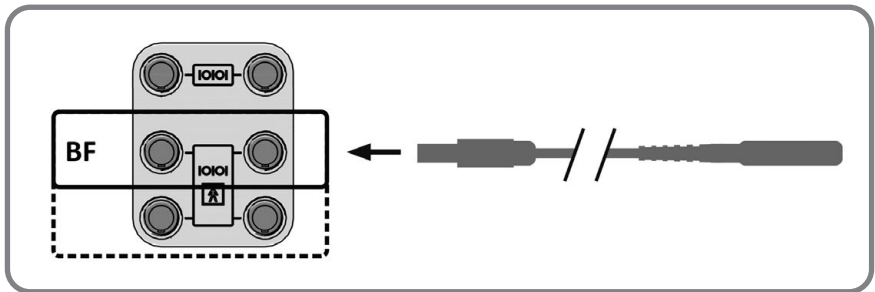
A 3.15 Nurse call

A 3.15.1 Intended use

The nurse call function is used to connect elisa to the hospital nurse call system. Alarms of categories 6 and 7 (“red” alarms) are transmitted.

A 3.15.2 Connection

Connect the nurse call adapter to one of the BF interfaces on the back of the elisa. Connect the other end to the appropriate nurse call system.



Remark

The nurse call function must be configured on the configuration level of elisa 300 / elisa 500 in order to be available for the transmission of alarms. Please contact your service technician for details.

Remark

If the nurse call function is enabled on the configuration level but no nurse call adapter is connected, an alarm will be displayed. Connect the nurse call adapter to the configured BF interface. You can review the current interface configuration on the standby or ventilation screen under the “Status” tab by selecting the second view with a horizontal swipe.

Verify the proper functioning of the nurse call by triggering a “red” alarm at the intensive care ventilator. Check whether the alarm signal is transmitted.

A 3.15.3 Function

When the nurse call adapter is connected to elisa 300 / elisa 500 and the BF interface has been configured accordingly, elisa will send alarms of categories 6 and 7 ("red" alarms) to the hospital nurse call system.

There is a delay of less than 200 ms between the occurrence of the ALARM CONDITION and the time the ALARM CONDITION leaves the SIGNAL OUTPUT PART and is displayed.



Warning

A disturbance in one of the components can cause a failure of the nurse call function. In this case, the alarms from the intensive care ventilator will not be transmitted.



Warning

Regular surveillance of the patient on the ventilation screen of the intensive care ventilator is mandatory, even when the ventilator is connected to the nurse call system. Check the ventilation screen regularly.

A 4 Weaninganalyzer

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A 4.1 Weaninganalyzer

The Weaninganalyzer comprises two standardised test procedures:

- the spontaneous awakening trial SAT to determine whether the patient is capable of spontaneous breathing
- the spontaneous breathing trial SBT to determine the earliest possible point in time for extubation

Both tests as well as the occlusion manoeuvre P0.I can be accessed via the Weaning button.

A 4.2 Availability of the weaning procedure

On the configuration level, you activate and set up the functions and procedures available for weaning and define the order of the tabs.

Please contact your service technician if needed.

A 4.2.1 Availability for the different patient categories

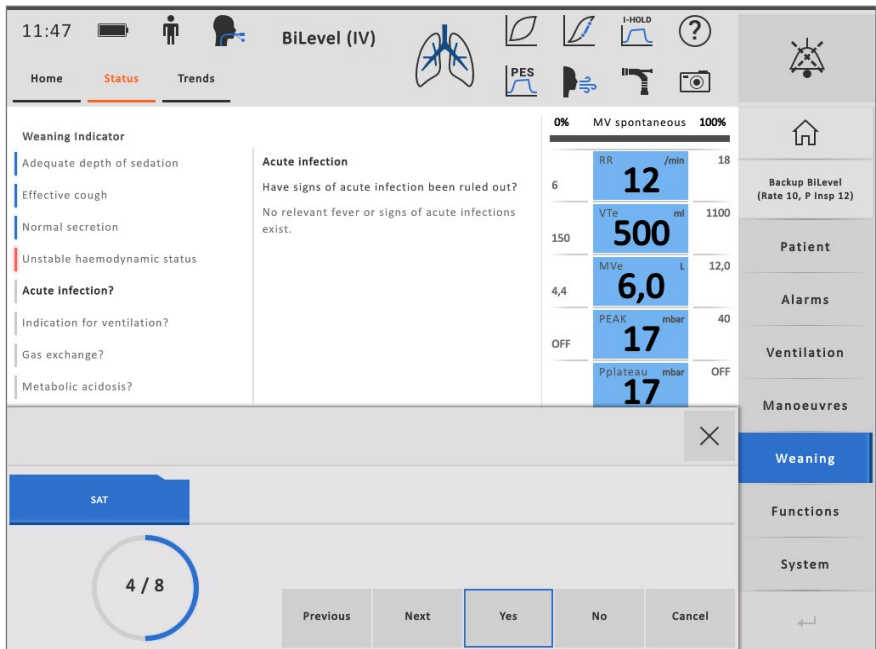
Weaning	Adults	Children
SAT	X	X
SBT	X	X
P0.I	X	X
WOB	X	X

A 4.3 SAT

You reach the “SAT” function by pressing the “Weaning” button and then by selecting the “SAT” tab.

A 4.3.1 SAT test (Spontaneous Awakening Trial)

The SAT test collects the data for the weanability criteria, supporting the daily screening of the respiratory situation as part of the weaning protocol. Eight questions have to be answered with YES or NO.



Remark

The parameters shown are only an orientation. In each individual case, the clinical situation of the ventilated patient needs to be analysed carefully.

The final representation of the SAT status and a colour-coded evaluation give orientation to the health care providers how to proceed and which measures to take.

A 4.4 SBT (Spontaneous Breathing Trial)

SBT is a standardised test procedure that can be combined with all spontaneous and augmenting ventilation modes. It starts automatically when the user-configured target values are reached and maintained for 5 minutes. For the duration of the test defined by the user the patient breathes spontaneously at the PEEP level. The tube-related work of breathing is compensated by activation of the tube compensation function. Throughout the SBT the patient is monitored and the weaning indicators are trended. On completion of the SBT, the trend values are frozen and can be referred to and evaluated until the next SBT starts.

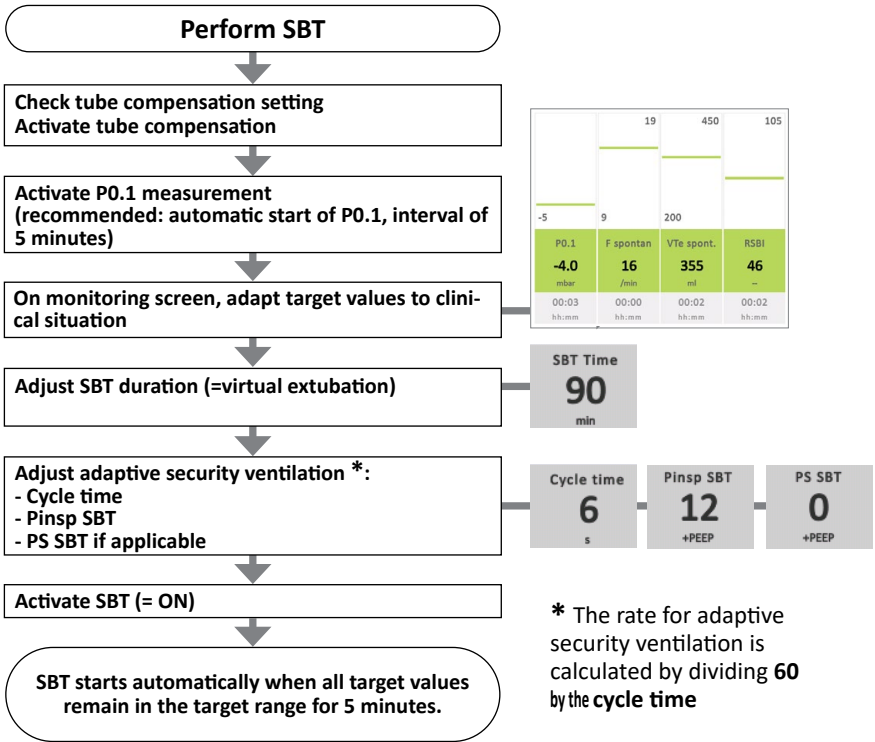
On the monitoring screen, adapt the target values to the patient's clinical situation:

	Cycle time 6 s	PS SBT 0 +PEEP	SBT Time 90 min	On	System
	Pinsp SBT 12 +PEEP			Off	←

An adaptive security ventilation mode is active during the SBT manoeuvre. This feature supplements the ventilation within the cycle time in the event of missed spontaneous breaths; audible alarms are not released in these situations. Before activating the SBT, adjust the cycle time and the required pressure difference (Pin-sp SBT) to the clinical situation. When necessary, pressure support (PS SBT) can be added during an SBT manoeuvre.

Beginning and end of the most recent SBT are displayed in the upper left hand corner of the SBT Workbench.

A 4.4.1 SBT procedure



A 4.5 P0.1

P0.1 occlusion pressure identifies the negative value which is established in the first 100 milliseconds (0.1 s) of an inspiration phase (with closed valves) and represents a measure for the neuromuscular respiratory drive of the spontaneously breathing patient.

The values in a patient with healthy lungs who is breathing calmly are up to -3 and -4 mbar. Values below -6 mbar indicate imminent respiratory fatigue.



The manoeuvre can be started in all ventilation modes. The only condition is the patient being able to reach the trigger value.

The manoeuvre can be activated as a manual single measurement or for regular monitoring at defined intervals (0.5 up to 120 minutes maximum). After the manoeuvre, the respective measured value (if configured) is displayed in the measurement value table.

Depending on the configuration, P0.1 can also be displayed and assessed in the "Fastwean" display.

	19	450	105
-5	9	200	
P0.1	F spontan	VTe spont.	RSBI
-4.0	16	355	46
mbar	/min	ml	—
00:03	00:00	00:02	00:02
hh:mm	hh:mm	hh:mm	hh:mm

A 4.6 WOB

The work of breathing (WOB) can be acquired as an additional weaning indicator in the form of a periodic manoeuvre. The energy expended for respiration ($\int \text{pressure} \times \text{volume}$) is normally determined by means of a properly located oesophageal catheter. Similar to the determination of WOB in the spontaneous respiration mode PAPS, an approximate WOB value can also be determined without oesophageal pressure measurement and its course over time can be assessed. After activation of the manoeuvre, its frequency and the diameter of the endotracheal tube or tracheostomy tube need to be specified. The percentage for compensation of the flow and airway resistances can be adjusted to match the clinical situation.

Published guidance values:
Adults: 0.3–0.6 J/litre

SAT		SBT		P0.1		WOB		Functions
WOB spont.	WOB vent.	POB spont	POB		Interval	Compens. R	Start	System
0,1	0,1	0,2	0,4		10 l/min	80 %		
J/L	J/L	J/min	J/min		Diameter 8,5 mm	Compens. C 10 %	Stop	←

The parameters POB, POB spont., WOB vent. and WOB spont. are permanently measured and the value measured last is always displayed. (However, this applies to POB and POB spont. only in the PAPS ventilation mode)

A 5 Ventilation modes and parameters

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A 5.1 Default settings

Once a new patient has been selected in the standby mode, the default ventilation mode including all default parameters is automatically activated. The default settings can be configured as needed (see section 13.1 in the Basic Instructions for Use – elisa 300 / elisa 500). The automatically activated default ventilation mode is the first mode on the tab bar.

A narrow coloured bar at the top of the screen identifies the active ventilation mode.

NIV (non-invasive) Depending on selected screen colour:	green or blue
IV (invasive)	grey
Backup ventilation	yellow
Resuscitation (or CPR) mode	red

A 5.1.1 The modes are named in compliance with the ISO standard 19223:2019-07

You can review the names of the ventilation modes as defined in the ISO standard 19223:2019-07 by using the Help function. Tap the Help icon, then select the mode of interest. Under “Detailed Description” you will find the name as defined in the ISO standard 19223:2019-07.

A 5.1.2 Backup modes

A backup ventilation mode is associated with each ventilation mode (also refer to Basic Instructions for Use, chapter 7.3.5).

Mode	Backup mode	Mode	Backup mode
BiLevel	BiLevel	PLV	PLV
Dyn. BiLevel	Dyn. BiLevel	PCV	PCV
Dual BiLevel	Dual BiLevel	PC-SIMV	PC-SIMV
Optional BiLevel	Optional BiLevel	PC-APRV	Mand. BiLevel
Flexible BiLevel	Flexible BiLevel	CPAP	Mand. BiLevel
Mand. BiLevel	Mand. BiLevel	PSV	BiLevel
BiLevel ST	BiLevel ST	Dyn. PSV	Dual BiLevel
Dyn. BiLevel ST	Dyn. BiLevel ST	Prop. PSV	VA BiLevel
Dual BiLevel ST	Dual BiLevel ST	ALPV	VA BiLevel
VA BiLevel	VA BiLevel	PAPS	VA BiLevel
VCV	VCV	WOBOV	VA BiLevel
VC-SIMV	VC-SIMV	CPR	No backup
Optional VCV	Optional VCV	HFOT	No backup
Flexible VCV	Flexible VCV		

A 5.2 Default ventilation

(see Basic Instructions for Use – elisa 300 / elisa 500, section 7.2.1).

A 5.3 Ventilation modes

The ventilation modes available depend on the software revision, the device configuration and the selected patient settings (e.g., mask, tube, HFOT, etc.).

	IV		NIV		HFOT	
	Adults	Children	Adults	Children	Adults	Children
BiLevel ST	✓	✓	✓	✓		
Dynamic BiLevel ST	✓	✓	✓	✓		
Dual BiLevel ST	✓	✓	✓	✓		
BiLevel	✓	✓	✓	✓		
Mandatory BiLevel	✓	✓	✓	✓		
Dynamic BiLevel	✓	✓	✓	✓		
Dual BiLevel	✓	✓	✓	✓		
Optional BiLevel	✓	✓	✓	✓		
Flexible BiLevel	✓	✓				
PC-SIMV	✓	✓				
PSV	✓	✓	✓	✓		
Dynamic PSV	✓	✓	✓	✓		
Proportional PSV	✓	✓				
CPAP	✓	✓	✓	✓		
VCV	✓	✓				
PLV	✓	✓				
VC-SIMV	✓	✓				
Optional VCV	✓	✓				
Flexible VCV	✓	✓				
VA BiLevel	✓	✓	✓	✓		
PC APRV	✓	✓				
PCV	✓	✓	✓	✓		
CPR	✓	✓				
ALPV	✓					
WOBOV	✓					
PAPS	✓					
HFOT					✓	✓

A 5.3.1 Special information regarding volume-controlled modes

Volume-controlled modes:

- VCV
- PLV
- VC-SIMV
- Optional VCV
- Flexible VCV

For the volume-controlled modes listed above, the Workbench either shows the parameter Tplateau or the parameter I-Flow, depending on your choices in the configuration.

BiLevel	VCV	PCV	Proportional PSV	ALPV	CPAP	PAPS	PC-SIMV	Functions
O2	PEEP	Rate	Vt	T insp	Flow Trigger	Pmax	I-Flow	System
30	5,0	12	360	1,50	5,0	35	40,0	
%	mbar	/min	ml	s	l/min	mbar	l/min	

When adapting certain parameters, the header of the Workbench will display the resulting Tplateau or I-Flow value as well as the T Flow value, which is the resulting duration of the inspiration phase.

Adjustment on config. level	Tplateau	I-Flow
Adaptation of the depending parameters	RR	RR
	Vt	Vt
	Tinsp	Tinsp
	Tplateau	I-Flow
Value displayed in Workbench	I-Flow, T Flow	Tplateau, T Flow

If Tplateau is too short for the system to reliably determine the value (< 0.1 s), the Instant View window will not show any plateau measurement. The reading will be presented as “-”.

Remark

In volume-controlled modes, the pneumatic drug nebulization is not available for the patient category “Children”.

A 5.4 Ventilation parameters

Different parameters are available to set the ventilation modes:

O ₂	Inspiratory O ₂ concentration
PEEP	Positive end-expiratory pressure
Insp. Ramp	Inspiratory time ramp between PEEP and P _{insp}
PS Ramp	Time ramp between PEEP and PS
P _{insp}	Inspiratory pressure
PS	Pressure support
T _{insp}	Inspiratory time, inspiratory/expiratory ratio I:E is also shown
PS T _{lmax}	Maximum duration of inspiratory phase with pressure support
Exp. trigger	Expiratory trigger with pressure-controlled ventilation Percentage of the trigger expectation window for the synchronised switch to expiration
PS Endflow	Stop criterion of inspiratory phase with pressure support
Rate	Respiratory rate
Trigger	The ventilator detects the patient's attempts to breathe in via the trigger. Trigger sensitivity can be individually adapted to the patient. The lower the set value the more sensitive the ventilator is to patient's attempts at inhaling. At very low settings, even the elasticity of the ventilation tubes might cause a trigger signal (auto-triggering).
V _t	Tidal volume
Byflow	As bias flow, the Byflow provides the set trigger flow and simultaneously presents a kind of "flow reservoir" for the spontaneously breathing patient. The Byflow function is available in all ventilation modes. The setting can be increased if the dynamic behaviour of the device is unsatisfactory during or after triggering when using endotracheal tubes with a deflated cuff, or if rebreathing of CO ₂ is to be prevented when a ventilation helmet is used.
P _{max}	A pressure limit can be set in order to rule out excessively high pressure values in case of an acute worsening of the mechanics of breathing. No further pressure adjustments are carried out if the pressure limit has been reached. The "Pressure limitation" alarm is triggered. The V _{tmin} alarm limit must be set in order to be able to recognise that the set tidal volume has not been reached. For volume-controlled modes, the pressure limitation P _{max} can be deactivated on the configuration level.
P _{min}	In pressure-controlled or pressure-supported ventilation modes with specified volumes, P _{min} represents the lower pressure adaptation window. If the required pressure drops below this setting, the automatic pressure adaptation is suspended. To prevent unintended high tidal volumes, it is necessary to set the V _{tmax} alarm limit.
I-Flow	Inspiratory gas flow rate
T _{plateau}	Duration of the plateau during the inspiratory phase (No-flow phase)
Flow support	Extent of the resistance compensation

Volume support	Extent of the compliance compensation
Height	Input of the patient's height
%MV	Target minimum minute volume in percent
SwitchFlow	Optional switching criterion for auto release with PC-APRV
Compens. R	Extent of the resistance compensation
Compens. C	Extent of the compliance compensation
MV target	Target minute volume (together with the ideal body weight, it forms the multiplication factor for setting the target minute volume)
Diameter	Diameter of the endotracheal tube or tracheal cannula
Exp Ramp mand	In pressure-controlled modes, the rate at which the pressure is reduced to the PEEP level, in mbar per second
Exp Ramp spont	In pressure-support modes, the rate at which the pressure is reduced to the PEEP level, in mbar per second

Remark

The following applies to PS (pressure support) modes: If a value greater than 30 mbar is adjusted, a prompt for confirmation will be displayed.

The adjustable ventilation parameters for each mode are summarised in the following tables:

	BiLevel ST	Dynamic BiLevel ST	Dual BiLevel ST	BiLevel	Mandatory BiLevel	Dynamic BiLevel	Dual BiLevel	Optional BiLevel	PCV	VA BiLevel	PC-APRV
O ₂	x	x	x	x	x	x	x	x	x	x	x
PEEP	x	x	x	x	x	x	x	x	x	x	x
Insp. Ramp	x	x	x	x	x	x	x	x	x	x	x
PS Ramp	x	x	x	x		x	x	x	x	x	
Pinsp	x			x	x				x		x
PS	x	x		x		x		x			
Tinsp	x	x	x	x	x	x	x	x	x	x	x
Texp											x
PSTImax	x	x	x	x		x	x	x			
Exp. trigger	x	x	x	x		x	x	x	x	x	
PS Endflow	x	x	x	x		x	x	x			
Rate	x	x	x	x	x	x	x	x	x	x	
Trigger	x	x	x	x	x	x	x	x	x	x	x
Vt		x	x			x	x	x		x	

	BiLevel ST	Dynamic BiLevel ST	Dual BiLevel ST	BiLevel	Mandatory BiLevel	Dynamic BiLevel	Dual BiLevel	Optional BiLevel	PCV	VA BiLevel	PC-APRV
Byflow	x	x	x	x	x	x	x	x	x	x	x
Pmax		x	x			x	x	x		x	
Pmin		x	x			x	x	x		x	
SwitchFlow											x
Exp Ramp mand	x			x	x				x		
Exp Ramp spont	x			x							

	Flexible BiLevel	PC-SIMV	PSV	Dyn. PSV	Prop. PSV	PAPS	CPAP
O ₂	x	x	x	x	x	x	x
PEEP	x	x	x	x	x	x	x
Insp. Ramp	x	x					
PS Ramp	x	x	x	x			
Pinsp		x					
PS		x	x				
Tinsp	x	x	x	x			
Texp							
PS Tlmax	x	x	x	x	x	x	
Exp. trigger	x	x					
PS Endflow	x	x	x	x	x	x	
Rate	x	x					
Trigger	x	x	x	x			
Vt	x			x			
Byflow	x	x		x	x		x
Pmax	x			x	x	x	
Pmin	x			x			
Flow support					x		
Vol. support					x		
Diameter						x	
Compens. R						x	
Compens. C						x	

A 5 | Ventilation modes and parameters

	Flexible BiLevel	PC-SIMV	PSV	Dyn. PSV	Prop. PSV	PAPS	CPAP
Exp Ramp spont			x	x			

	VCV	VC-SIMV	Opt.VCV	Flex. VCV	PLV	ALPV	WOBOV	HFOT
O ₂	x	x	x	x	x	x	x	x
PEEP	x	x	x	x	x	x	x	
Insp. Ramp								
PS Ramp		x	x	x				
P insp								
PS		x	x					
Tinsp	x	x	x	x	x			
Texp								
PS Tlmax		x	x	x		x	x	
Exp Trigger						x	x	
PS Endflow		x	x	x				
Rate	x	x	x	x	x			
Trigger	x	x	x	x	x	x		
Vt	x	x	x	x	x			
I-Flow*	x	x	x	x	x			x
Tplateau*	x	x	x	x	x			
Byflow	x	x	x	x	x	x	x	
Pmax	x	x	x	x	x	x	x	x
Pmin				x		x	x	
Height						x	x	
VT/IBW						x		
Flow Trigger							x	
MV support						x	x	

* as configured I-Flow or Tplateau.

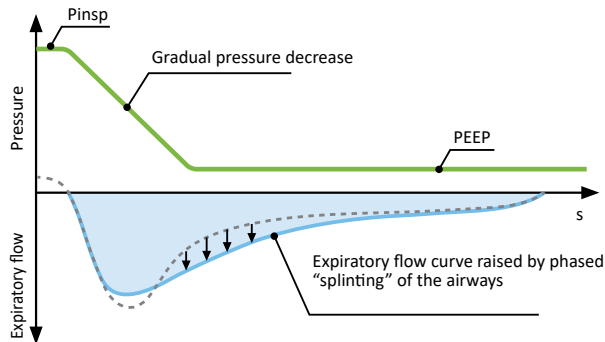
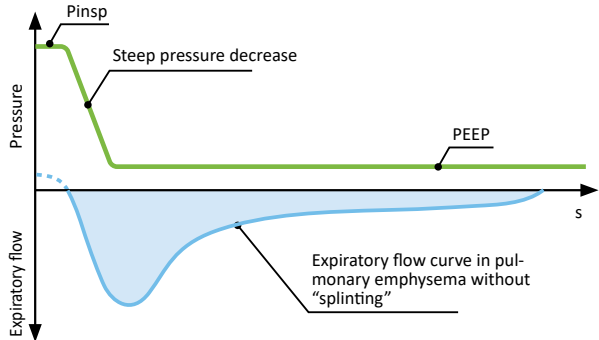
A 5.4.1 Expiratory ramps

Via the expiratory pressure ramp setting, you adapt the rate at which the pressure is reduced to PEEP level to the patient's needs.

In pressure-controlled modes -> mandatory expiratory ramp

In pressure-support modes -> spontaneous expiratory ramp

Both ramps can be adjusted separately in steps, or they can be deactivated.



An unrestrained transition from inspiration to the PEEP level can cause local collapse of airways in certain clinical conditions such as pulmonary emphysema. By setting an expiratory pressure ramp, however, it is basically possible to protect the small airways from collapse with a quickly acting pneumatic splint at the start of expiration. The risk of collapse in the early expiratory phase is very high; an expiratory ramp – similar to the effect of pursed lips breathing – is an effective countermeasure to achieve a very favourable pressure course.

Remark

The option of setting a mandatory and a spontaneous expiratory pressure ramp must be enabled on the configuration level.

Remark

Activating the mandatory or spontaneous expiratory pressure ramp will extend the expiration phase. Whether to use pressure ramps and which settings to choose needs to be evaluated based on the clinical situation and on the flow pattern, and the settings may have to be optimised accordingly.

Remark

By activating the mandatory or spontaneous expiratory pressure ramp, you deactivate the expiratory tube compensation, which may increase the tube-related work of breathing.

A 5.5 Modes

Remark

Depending on hospital policies, advanced adjustment parameters may be deactivated on the configuration level, which means they are not available for users in the ward.

A 5.5.1 BiLevel ST

BiLevel Spontaneous Timed.

Synchronised, pressure-controlled ventilation which allows the patient to breathe spontaneously during the entire respiratory cycle.



The patient has the option of unrestricted spontaneous breathing at both adjustable pressure levels. Switching between both pressure levels guarantees a mandatory minute volume and facilitates spontaneous breathing at PEEP level on the lower pressure level or pressure support. In contrast to conventional BiLevel ventilation, the ventilator calculates a cycle time on the basis of the set respiratory rate. If spontaneous breathing activity does not occur within the cycle time, a mandatory BiLevel breath is triggered.

A 5.5.2 Dynamic BiLevel ST

Dynamic BiLevel Spontaneous Timed.

Combination of BiLevel ST mode and dynamic BiLevel with dynamic adjustment of the mandatory ventilation pressure and the possibility of spontaneous breathing during the entire ventilation cycle.



Breath cycles are defined by setting a fixed respiratory rate (60/f). If spontaneous breathing results in the machine's trigger threshold being reached, the spontaneous breath will be supported with the set pressure. If the patient fails to breathe spontaneously during the cycle, the machine will initiate a conventional BiLevel breath with volume guarantee (= dynamic BiLevel) at the end of the calculated cycle time. In patients with no spontaneous breathing activity, ventilatory support is delivered in the form of the set mandatory minute volume ($f \times V_t$). In patients who stop breathing for short periods of time, the mandatory ventilation components provide an intelligent back-up system for apnoea ventilation.

A 5.5.3 Dual BiLevel ST

Dual BiLevel Spontaneous Timed.

Combination of BiLevel ST mode and dual BiLevel, allowing spontaneous breaths during the entire respiratory cycle. The dynamic adaption of the ventilation pressure refers to the mandatory and spontaneous portions of the respiratory cycle.



Breath cycles are defined by setting a fixed respiratory rate (60/f). If spontaneous breathing results in the machine's trigger threshold being reached, pressure support with volume guarantee (= dynamic PSV) will be provided for the spontaneous breath. If the patient fails to breathe spontaneously during the cycle, the machine will initiate a conventional BiLevel breath with volume guarantee (= dynamic BiLevel) at the end of the calculated cycle time. In patients with no spontaneous breathing activity, ventilatory support is delivered in the form of the set mandatory minute volume ($f \times V_t$). In patients who stop breathing for short periods of time, the mandatory ventilation components provide an intelligent back-up system for apnoea ventilation.

A 5.5.4 BiLevel

Synchronised, pressure-controlled ventilation which allows the patient to breathe spontaneously during the entire respiratory cycle.



The patient has the option of unrestricted spontaneous breathing at both adjustable pressure levels. Switching between both pressure levels guarantees a mandatory minute volume and facilitates spontaneous breathing at PEEP level on the lower pressure level or pressure support.

The desired minute volume is determined by the set pressure difference between the upper (P_{insp}) and lower CPAP level (PEEP) and the set respiratory rate (Rate). The tidal volume achieved depends mainly on the compliance and resistance of the patient's lungs. Inspiration and expiration times (I:E) and the ramp time between the lower and upper pressure level have an impact on the pressure and flow curves.

The base pressure level is set with the positive end-expiratory pressure (PEEP). Although this is a mandatory mode, the patient is allowed to breathe spontaneously during the inspiration and expiration phase. This enables the patient to increase the minute volume beyond the mandatory values set.

A 5.5.5 Mandatory BiLevel

Synchronised, pressure-controlled ventilation mode, allowing the patient to breathe spontaneously at the upper level and initiating a mandatory breath for each trigger variable.



In contrast to the conventional BiLevel mode, the ventilator performs the entire work of breathing. Consequently, BiLevel breaths are time-cycled via the set respiratory rate and also initiated via the trigger function.

This mode does not allow additional pressure support, nor does it allow mandatory inspiration time to be shortened in response to an expiratory trigger variable, which would relieve the patient significantly. The tidal volume delivered is determined by the difference between the lower pressure level (PEEP) and the upper pressure level (Pinsp), and is dependent upon lung elasticity (compliance).

A 5.5.6 Dynamic BiLevel

Synchronised, volume-targeted, pressure-controlled ventilation with dynamic adjustment of the mandatory ventilation pressure and spontaneous breaths during the entire ventilation cycle.



This enhancement of the conventional BiLevel mode reduces the need for adjustments and prevents overdistension of the lungs with improving mechanics of breathing. With dynamic BiLevel the advantages of pressure-controlled ventilation are combined with the possibility of unrestricted spontaneous breathing at both pressure levels with a constant volume.

Depending on the current lung situation, the ventilator adapts the upper pressure level so that the set tidal volume is applied with the lowest possible inspiratory pressure.

The Pmax and Pmin parameters determine a range in which the ventilator is allowed to automatically readjust the necessary pressure to achieve the desired tidal volume.

A 5.5.7 Dual BiLevel

Synchronised, volume-targeted, pressure-controlled ventilation with the possibility of spontaneous breaths during the entire ventilation cycle. The dynamic adaption of the ventilation pressure refers to the mandatory and spontaneous portions of the respiratory cycle.



With Dual BiLevel the advantages of pressure-controlled ventilation are combined with the possibility of unrestricted spontaneous breathing at both pressure levels with a constant volume.

Depending on the current lung situation, the ventilator adapts the upper pressure level or the necessary pressure support of spontaneous breathing so that the set tidal volume is applied with the lowest possible inspiratory pressure.

The P_{max} and P_{min} parameters determine a range in which the ventilator is allowed to automatically readjust the necessary pressure to achieve the desired tidal volume.

A 5.5.8 Optional BiLevel

Synchronised, pressure-controlled ventilation which allows the patient to breathe spontaneously during the entire respiratory cycle. If the measured minute volume is above the setting (Rate x Vt), the patient is able to breathe spontaneously. If the minute volume drops below the setting, BiLevel breaths are triggered.



This mixed form of ventilation combines a synchronised, pressure-controlled, volume-targeted ventilation mode to ensure a specified minute volume with the possibility of achieving deeper breaths using pressure support.

Depending on the current lung situation, the ventilator adapts the mandatory pressure level so that the set tidal volume is applied with the lowest possible inspiratory pressure.

The Pmax and Pmin parameters determine a range in which the ventilator is allowed to automatically readjust the necessary pressure to achieve the desired tidal volume.

In contrast to conventional SIMV ventilation, the user defines a minimum minute volume by setting the respiratory rate and tidal volume. No mandatory breaths are initiated if the minute volume can be achieved by the patient's spontaneous

breathing.

The ventilator continuously monitors the patient's respiratory activity. If the minute volume drops below the preselected value, a mandatory breath is initiated. If spontaneous breathing fails completely, the patient is ventilated with the selected mandatory respiratory rate.

A 5.5.9 Flexible BiLevel

Synchronised, pressure-controlled ventilation which allows the patient to breathe spontaneously during the entire respiratory cycle. If the measured minute volume is above the setting ($\text{Rate} \times V_t$), the patient is able to breathe spontaneously. BiLevel breaths are triggered with a dynamic adjustment of the mandatory ventilation pressure if the minute volume drops below the setting.



With flexible BiLevel the advantages of pressure-controlled ventilation are combined with the possibility of unrestricted spontaneous breathing at both pressure levels with a constant volume.

Depending on the current lung situation, the ventilator adapts the upper pressure level or the necessary pressure support of spontaneous breathing so that the set tidal volume is applied with the lowest possible inspiratory pressure.

The Pmax and Pmin parameters determine a range in which the ventilator is allowed to automatically readjust the necessary pressure to achieve the desired tidal volume.

In contrast to conventional SIMV ventilation, the user defines a minimum minute volume by setting the respiratory rate and tidal volume. No mandatory breaths are initiated if the minute volume can be achieved by the patient's spontaneous breathing.

The ventilator continuously monitors the patient's respiratory activity. If the minute volume drops below the preselected value, a mandatory breath is initiated. If spontaneous breathing fails completely, the patient is ventilated with the selected mandatory respiratory rate.

A 5.5.10 PC-SIMV

Pressure Controlled - Synchronised Intermittent Mandatory Ventilation. Synchronised, pressure-controlled ventilation with the possibility of spontaneous breathing between the controlled breaths.



This mixed form of ventilation combines a synchronised, pressure-controlled ventilation mode to ensure a specified minute volume with the possibility of achieving

deeper spontaneous breaths using pressure support.

The desired minute volume is determined by the set pressure difference between the upper (P_{insp}) and lower CPAP level (PEEP) and the set respiratory rate (Rate). The tidal volume achieved depends mainly on the compliance and resistance of the patient's lungs. Inspiration and expiration time (I:E) and the ramp time between the lower and upper pressure level have an impact on the pressure and flow curves.

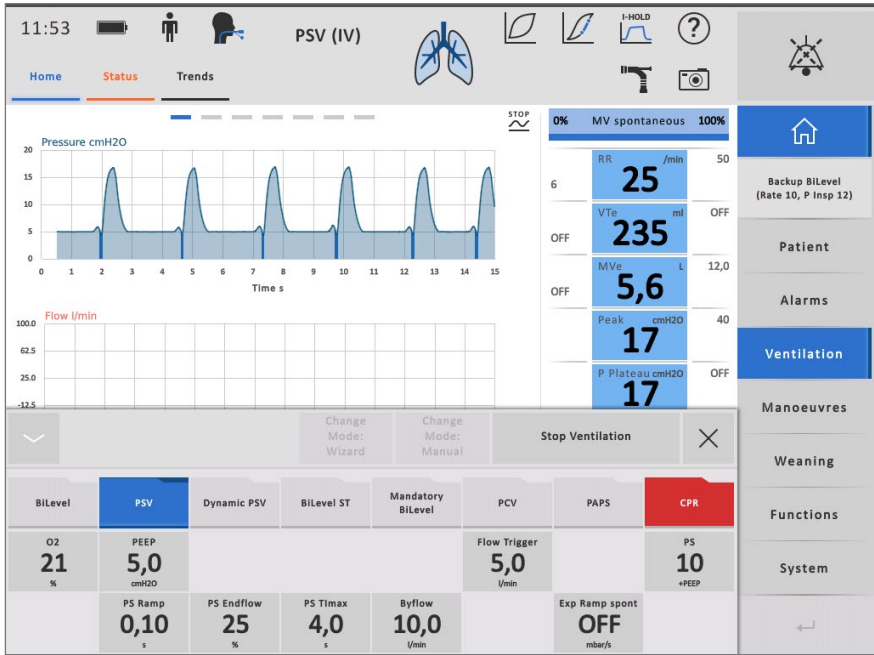
In this mixed form of ventilation the system permits spontaneous breathing at the lower pressure level. As a result, the minute volume may exceed the set mandatory value. By setting the PS pressure support, the patient's work of breathing at the lower pressure level can be reduced. Initiated by reaching the set trigger threshold, the ventilator delivers the required flow in order to increase the pressure to the specified PS pressure beyond the PEEP value.

The pressure-supported mandatory breath is terminated when the flow to the patient (measured as a percentage of the peak PS flow) drops to the specified PS end flow.

The pressure rise time from the PEEP value to the PS pressure (PS) can be set via the PS ramp time. The shorter the ramp time, the higher the initial PS flow.

A 5.5.11 PSV

Pressure Support Ventilation. Pressure-supported spontaneous breathing at the CPAP pressure level.



Pressure support reduces the patient's work of breathing by increasing the tidal volume. Initiated by reaching the set trigger threshold, the ventilator delivers the required flow in order to increase the pressure to the specified PS pressure beyond the PEEP value.

The pressure-supported mandatory breath is terminated when the flow to the patient (measured as a percentage of the peak PS flow) drops to the specified PS end flow. The pressure rise time from the PEEP value to the PS pressure (PS) can be set via the PS ramp time. The shorter the ramp time, the higher the initial PS flow.

A 5.5.12 Dynamic PSV

Dynamic Pressure Support Ventilation. Pressure-supported spontaneous breathing at the CPAP pressure level with dynamic adjustment of the pressure support.



Pressure support reduces the patient's work of breathing by increasing the tidal volume. Initiated by reaching the set trigger threshold, the ventilator delivers the required flow increase the pressure to the PS pressure beyond the PEEP value, which is required to achieve the specified tidal volume.

The PLimit alarm limit determines a range in which the ventilator is allowed to automatically readjust the necessary pressure to achieve the desired tidal volume.

The pressure-supported mandatory breath is terminated when the flow to the patient (measured as a percentage of the peak PS flow) drops to the specified PS end flow.

The pressure rise time from the PEEP value to the PS pressure (PS) can be set via the PS ramp time. The shorter the ramp time, the higher the initial PS flow.

A 5.5.13 Proportional PSV

Proportional Pressure Support Ventilation



A technological advancement over conventional PSV. In spontaneously breathing patients, pressure support is delivered at a level that is proportional to the degree of compensation required in relation to flow resistance (Flow Support) and airway resistance (Volume Support). This partially replaces the patient's work of breathing and allows deeper breaths. The level of pressure support delivered varies on a breath-by-breath basis and is dependent on flow and inspired volume.



Warning

This ventilation mode relies on a stable respiratory drive.



Warning

Before activating proportional pressure support, bronchopleural fistulas and endotracheal tubes with a deflated cuff must be ruled out.



Adapt the backup ventilation to the patient's individual ventilation situation.



Proportional PSV is only available for invasive ventilation. Leakage may lead to over-compensation of the flow resistances.



Check that the conditions for using the proportional PSV ventilation mode, such as an adequate respiratory drive, no hiccup, or absence of an inhomogeneous breathing pattern are met.



Consider the contraindications for the proportional PSV ventilation mode, such as central respiratory depression, quick change of respiratory mechanics, Cheyne-Stokes respiration, manifest or suspected elevated intracranial pressure.



As a measure to prevent pressure peaks resulting from potential overcompensation, both the upper pressure limit (P_{max}) and the alarm limits need to be adapted to the patient condition.

A 5.5.14 PAPS (Proportional Adaptive Pressure Support)

Contrary to the fixed pressure support in the PSV mode, the spontaneously breathing patient receives proportional pressure support in the PAPS mode. The effective pressure support in this mode adapts to the elevated elastic and restrictive resistances. Tyler (1962) and M.Younes (from 1987) in Winnipeg established the fundamentals of this method. A special algorithm cyclically determines the work of breathing due to higher flow and airway resistances and adapts the pressure support required for compensation. This involves regular end-inspiratory occlusion to determine the surrogate parameters for compliance and resistance and the determination of the work of breathing (WOB spont.).



In contrast to the PSV mode, there is no fixed, static pressure support for inspiration but patients receive pressure support in proportion to their own inspiratory efforts: The harder the patient tries to inhale, the more support is provided by the ventilator. This means that a positive airway pressure is generated, which remains in proportion to the flow and volume generated by the patient trying to inhale. The condition for an optimal adjustment is the assessment or measurement of the elastic and restrictive properties of the lung by the user. The PAPS mode resolves this issue by regular, automatic end-inspiratory measurements that form the basis for the pre-set percentages for compliance and resistance compensation. In contrast to the conventional PSV pressure support ASB, there is no minimum support in the presence of little respiratory efforts. That is why the PAPS

mode is only allowed for patients with an intact respiratory drive.

Remark

The PAPS ventilation mode is not available for paediatric patients (children and neonates).



PAPS is only available for invasive ventilation. Leakage may lead to over-compensation of the flow resistances.



Adapt the backup ventilation to the patient's individual ventilation situation.



The alarm limits need to be adapted to the patient's clinical situation. Individualised alarm limits for low and high tidal volumes are of particular importance so that a possible overestimation of the compliance will not cause insufficient assistance with an inadequate tidal volume.



Check that the conditions for using the PAPS ventilation mode, such as an adequate respiratory drive, no hiccup, or absence of an inhomogeneous breathing pattern are met.



Consider the contraindications for the PAPS ventilation mode, such as central respiratory depression, quick change of respiratory mechanics, Cheyne-Stokes respiration as well as manifest or suspected elevated intracranial pressure.



As a measure to prevent pressure peaks resulting from potential overcompensation, both the upper pressure limit (P_{max}) and the alarm limits need to be adapted to the patient condition.

Remark

PAPS regularly determines resistance and compliance. Resistance, in particular, is affected by numerous confounding elements, such as condensate, incrustation on the inside of the tube, or a used-up HME filter. Therefore, the ventilator first determines the resistance and then permanently calculates the deviation from this initial value. When the differences exceed a given limit, a yellow "Resistance high" or "Resistance low" alarm will be displayed.

Remark | The P0.I manoeuvre is not available in the PAPS mode.

Remark | It is possible to activate the nebulizer function in the PAPS mode, but the nebulizer will be switched off during manoeuvres for determination of compliance and resistance.

A 5.5.15 CPAP

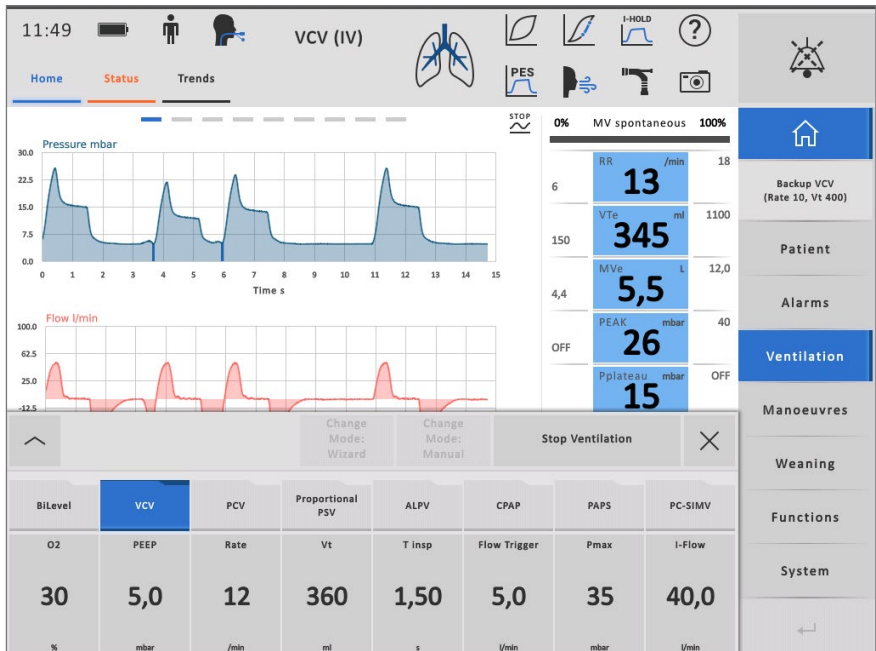
Continuous Positive Airway Pressure Spontaneous breathing at ambient pressure level or with continuous positive airway pressure (CPAP).



CPAP ventilation is a form of ventilation that combines the patient's spontaneous breathing with a constant overpressure (PEEP). The patients themselves can determine the depth of their respirations, the rate and the flow.

A 5.5.16 VCV

Volume controlled ventilation with constant mandatory minute volume (Volume Constant, Controlled Ventilation).



The desired mandatory minute volume is determined by the set tidal volume (V_t) and the set rate (Rate). Inspiration and expiration times (I:E) and the inspiratory flow (I-Flow) determine the pressure and flow curves. The system automatically generates an inspiratory pause (plateau) and its duration depends on the flow and times. The higher the I-Flow, the longer is the pause (plateau interval). Spontaneous breathing at PEEP level which can increase the respiratory minute volume is possible. The patient can trigger additional mandatory breaths once the set trigger criterion has been reached. This changes the actual respiratory rate and the respiratory minute volume.

A 5.5.17 PLV

Conventional volume-controlled ventilation (pressure limited ventilation) with optional pressure control.



By setting a pressure limit (Pmax), undesired pressure peaks can be prevented. When reaching the pressure limit, the flow velocity will drop and a decelerating flow pattern emerges. The resulting slower flow reduces the duration of the plateau interval within the set inspiratory time. The set tidal volume can be applied at a constant level as long as an arithmetical minimum plateau interval is available.

Remark | When the pressure limit is reached, a message rather than a medium priority alarm is output.

A 5.5.18 VC-SIMV

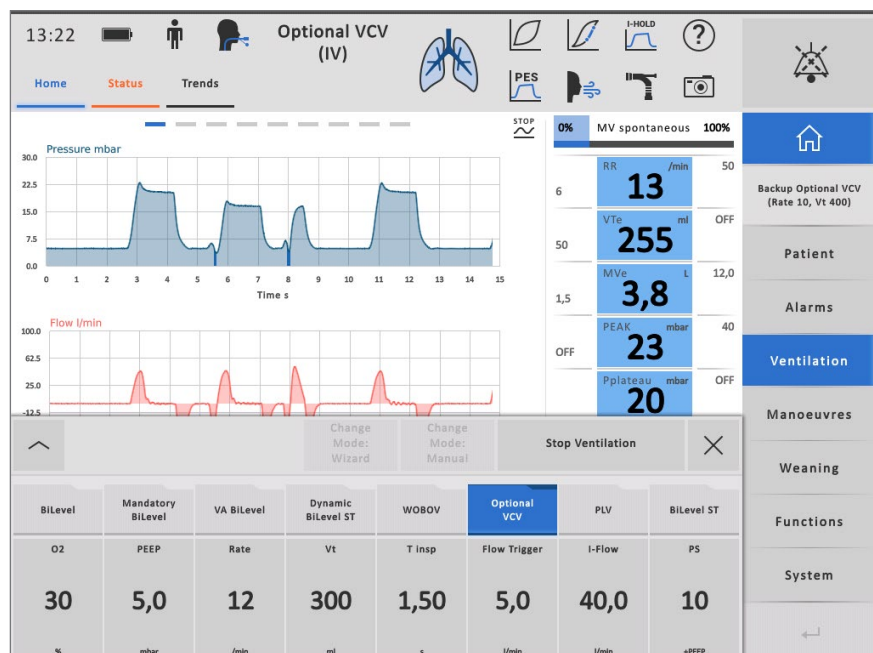
Volume Controlled - Synchronised Intermittent Mandatory Ventilation. Synchronised, volume-controlled ventilation with the possibility of spontaneous breathing between the controlled breaths.



This mixed form of ventilation combines a synchronised, volume-controlled ventilation mode to ensure a defined minute volume with the possibility of deepening the patient's spontaneous breaths by pressure support. The desired mandatory minute volume is determined by the set tidal volume (Vt) and the set rate (Rate). Inspiration and expiration times (I:E) and the inspiratory flow (I-Flow) determine the pressure and flow curves. The system automatically generates an inspiratory pause (plateau) and its duration depends on the flow and times. The higher the I-Flow, the longer is the pause (plateau interval).

A 5.5.19 Optional VCV

Synchronised, volume-controlled ventilation, allowing the patient to breathe spontaneously at PEEP level or with the set pressure support. If the measured minute volume is above the setting ($\text{Rate} \times V_t$), the patient is able to breathe spontaneously. If the minute volume drops below the setting, volume-controlled breaths are triggered.



Optional VCV combines the advantages of volume-controlled ventilation with the possibility of spontaneous breathing at PEEP level with a set pressure support. In contrast to conventional SIMV ventilation, the user defines a minimum minute volume by setting the respiratory rate and tidal volume. No mandatory breaths are initiated if the minute volume can be achieved by the patient's spontaneous breathing.

A 5.5.20 Flexible VCV

Synchronised, volume-controlled ventilation, allowing the patient to breathe spontaneously at PEEP level or with dynamic pressure support. If the measured minute volume is above the setting (Rate x Vt), the patient is able to breathe spontaneously. The dynamic adjustment of the pressure support corresponds with the set tidal volume. If the minute volume drops below the setting, volume-controlled breaths are triggered.



Flexible VCV combines the advantages of volume-controlled ventilation with the possibility of spontaneous breathing at PEEP level with a dynamic adjustment of the pressure support. In contrast to conventional SIMV ventilation, the user defines a minimum minute volume by setting the respiratory rate and tidal volume. No mandatory breaths are initiated if the minute volume can be achieved by the patient's spontaneous breathing.

A 5.5.2 | Volume-adaptive BiLevel

Synchronised, volume-targeted, pressure-controlled ventilation with dynamic adjustment of the mandatory ventilation pressure and spontaneous breaths during the entire ventilation cycle.

This enhancement of the conventional BiLevel mode reduces the need for adjustments and prevents overdistension of the lungs with improving mechanics of breathing.



With VA BiLevel the advantages of pressure-controlled ventilation are combined with the possibility of unrestricted spontaneous breathing at both pressure levels with a constant volume.

Each of the patient's inspiratory efforts (attaining the set trigger threshold) on the PEEP level will trigger a synchronised mandatory breath. This allows the patient to determine the timing and number of mandatory breaths.

Depending on the current lung situation, the ventilator adapts the upper pressure level so that the set tidal volume is applied with the lowest possible inspiratory pressure.

The Pmax and Pmin parameters determine a range in which the ventilator is allowed to automatically readjust the necessary pressure to achieve the desired tidal volume.

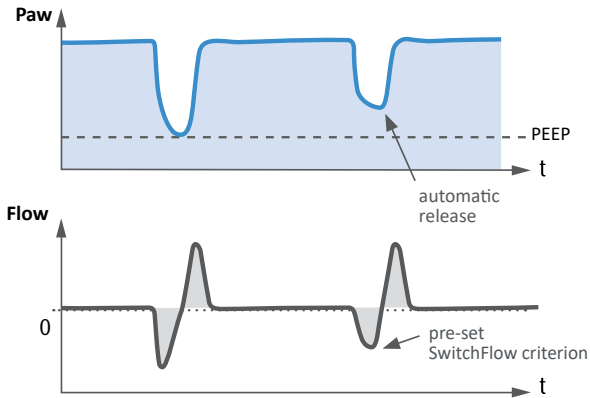
A 5.5.22 PC-APRV

Airway Pressure Release Ventilation is a modified BiLevel mode with inverse inspiratory to expiratory time ratio. Patients normally breathe spontaneously on the upper pressure level. CO₂ elimination is achieved by briefly lowering airway pressure to the lower pressure level (PEEP). At the same time, these short pressure release phases are intended to prevent the collapse of lung areas that are ventilated more slowly.



The automatic release function can be activated by adjusting the SwitchFlow parameter. SwitchFlow is the expiratory flow which is checked for plausibility and which serves as the criterion for automatic switching to the upper pressure level. The user can adapt this flow to the current clinical situation.

Reaching the pre-set SwitchFlow criterion → automatic release



The SwitchFlow algorithm permanently considers the inspiratory and expiratory flow and checks their plausibility. Using this trigger function, which can be switched off, the mandatory breaths can be synchronized.

A 5.5.23 PCV

Synchronised, time- and pressure-controlled ventilation mode with two adjustable pressure levels, allowing unimpeded spontaneous breathing on the lower pressure level. Switching between both pressure levels guarantees a mandatory minute volume and facilitates spontaneous breathing at PEEP level on the lower pressure level, which increases the respiratory volume. Additional triggers start additional mandatory breaths.



The desired minute volume is determined by the set pressure difference between the upper (Pinsp) and lower CPAP level (PEEP) and the set respiratory rate (Rate). The tidal volume achieved depends mainly on the compliance and resistance of the patient's lungs.

A 5.5.24 ALPV (Adaptive Lung Protection Ventilation)

ALPV is a closed-loop mode and can be considered as an enhanced version of the ASV mode. In contrast to the ASV mode, the ALPV mode is not based on the Otis equation but controls the ventilation according to the most recent guidelines for lung-protective ventilation strategies.



ALPV combines pressure-controlled ventilation with volume guarantee (dynamic BiLevel) and pressure-supported spontaneous breathing with volume guarantee (dynamic PSV). ALPV coordinates the necessary mandatory ventilation component with the spontaneous breathing activity. The alveolar minimum ventilation and the control of the respiratory rate and inspiratory pressures to ensure a lung-protective tidal volume are based on the parameter settings. Referred to the ideal body weight, the tidal volume can adapt to different clinical situations, which indirectly also affects the respiratory rate. To prevent auto-PEEP, the regulation of the inspiratory time is correlated with the expiratory time constant (RCexp).

Remark | When setting the parameters to ensure the alveolar minimum ventilation (“Height” or “%MV”), the calculated mandatory rate and the calculated minute volume are displayed in the info bar.

- Remark** | After input of the body height, the calculated IBW value is displayed in the Workbench.
- Remark** | The ALPV ventilation mode is not available for the treatment of paediatric patients.
- Remark** | Mode-specific default alarm limits are set in the ALPV ventilation mode. The alarm limits are listed in section “13.1.3.3 Default alarm limits of the ALPV mode”.

A 5.5.25 WOBOV (Work Of Breathing Optimized Ventilation)

WOBOV is a generalist mode that takes promoting spontaneous breathing, sufficient minute ventilation, an energetically optimal breathing pattern and compliance with specific lung protection rules into account. In this mode, the breathing pattern associated with the highest energy efficiency is continuously calculated and the ventilation control (modified Otis equation) adapted accordingly. This control is based on the insights of Rohrer (1925) and Otis et al. (1950), according to which an energetically optimal breathing pattern reduces negative work of breathing, promotes spontaneous breathing and prevents dead space ventilation. At the same time it supports spontaneous breathing by automatically reducing the assistance provided by the ventilator. In the case of insufficient ventilation, WOBOV will gradually increase ventilator support, i.e., the algorithm will compensate the deficit up to the pre-set minute ventilation when necessary. In this mode, both pressure-controlled ventilation with volume guarantee (comparable to dynamic BiLevel) and pressure-assisted spontaneous breathing with volume guarantee (dynamic PSV) are available.

In the WOBOV ventilation mode, an adaptive, closed-loop control system controls the ventilator. After input of the patient data (body height, MV support, ...), the ventilator automatically calculates a secure window (minimum and maximum tidal volume or respiratory rate).

- Remark** | After input of the body height, the calculated IBW value is displayed in the Workbench.

BiLevel	Flexible BiLevel	ALPV	CPR	VA BiLevel	Mandatory BiLevel	PC-APRV	WOBOV	Functions
O2	PEEP		Height	MV target	Flow Trigger	Pmax		System
30	5,0		187	100	5,0	35		
%	mbar		cm	ml/kg/min	l/min	mbar		

Referring to automatic measurements of resistance and compliance, the WOBOV

algorithm continuously calculates the optimal relationship between tidal volume and respiratory rate in order to keep the work of breathing as low as possible (Otis or Rohrer equation). When there is no spontaneous respiratory activity, a pressure-controlled mode with a guaranteed volume is activated, which continuously adapts the ventilation pressures, the respiratory rate and the I:E ratio. The expiration time is determined by the expiratory time constant (RC_{exp}) to prevent dynamic hyperinflation. For patients with spontaneous breathing activity, WOBOV activates a pressure support with a guaranteed volume. Since the pressure support is automatically reduced as the patient's respiratory efforts increase, this mode promotes weaning.



Remark The WOBOV ventilation mode is not available for paediatric patients (children and neonates).

Warning Always use the parameter MV support to adapt the minute volume setting. Do not adapt this setting by changing the patient's body height (IBW).

**Warning**

Check the depicted range for the adaptive ventilation and adjust the alarm limits accordingly.

A 5.5.26 CPR

In the CPR mode, the ventilation settings automatically adapt to the individual conditions of ventilated patients in need of resuscitation. Additionally, some of the audible alarms are deactivated, while measurement of the end-tidal CO₂ concentration is activated.

**Warning**

Some of the audible alarms are inactive, different alarm limits are set (refer to chapter “13.1.3.3 Default alarm limits of the CPR mode”). The CPR mode shall only be applied in the presence and under direct supervision of qualified health care professionals.

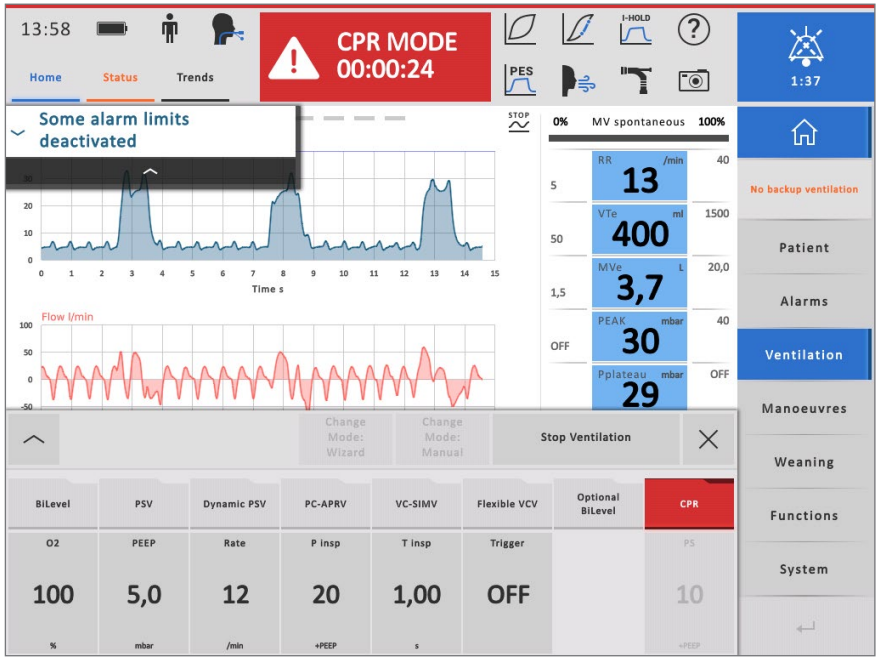
**Warning**

The compliance of the thorax changes during resuscitation measures, which is reflected by appropriate parameter settings in the CPR mode. The user is required to adapt these settings to the clinical situation when needed.

**Warning**

To continue ventilating the patient after the resuscitation intervention

- select another mode
- check the parameter settings and alarm limits and adapt them to the clinical situation.



The CPR mode is only available in the patient category “Adults” and can be enabled at the configuration level.

When you select and confirm the CPR mode, the patient will receive modified BiLevel ventilation with the following parameter settings:

O2: 100%
PEEP: 5 mbar
Pinsp: 20 (+PEEP) mbar
Tinsp: 1.0 s
Trigger: inactive

The window of the active ventilation mode is highlighted red.

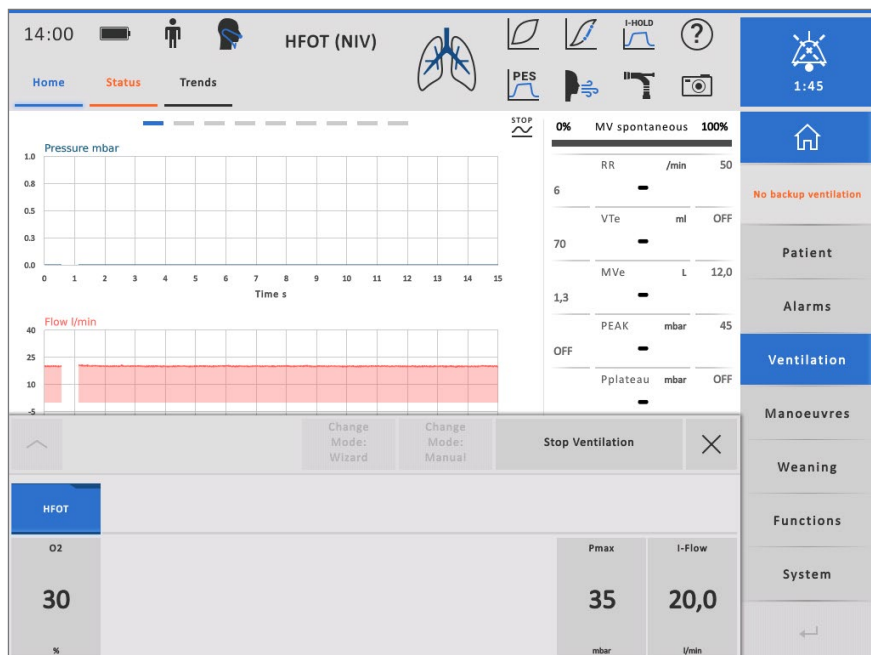
The end-tidal CO₂ measurement is activated automatically. The displayed measured values are based on the last calibration values. Audible alarms are deactivated to reduce the stress level; hence, the alarm limits in the Instant View window are highlighted red. At the same time, the info bar continuously indicates the duration of the CPR mode.

Beginning and end of the CPR ventilation are documented in the trend.

A 5.5.27 HFOT

In the High Flow Oxygen Therapy mode, elisa 300 / elisa 500 can also be used as a flow generator for nasal CPAP therapy. For this application, the flow setting determines the therapeutic CPAP level.

Select this mode with the “nasal cannula” button in the patient interface area.



The maximum adjustable flow value is 70 l/min. Whenever selecting values greater than 60 l/min, check that the gas supply is able to deliver this flow without adversely affecting other connected systems. In the critical range, the values on the selector are yellow.

Instructions for Use elisa 300-500 Supplement A | SW 2.09.x

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