



Azeer Intensive Care Ventilators Elisa Family



elisa 300
elisa 500

Instructions for Use Compendium

Basic Manual
Supplement A
Supplement B
Supplement C

Supplement D
Supplement E
Supplement F



elisa 300
elisa 500

Instructions for Use
Basic Manual

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

0 Contents

1 About this manual	9
1.1 About this manual	10
1.2 Safety information in these instructions for use	10
2 Use	13
2.1 Intended use	14
2.2 Areas of application	14
2.3 Differences between elisa 300 and elisa 500	15
3 General safety instructions	17
3.1 General safety instructions	18
3.1.1 Safety standards	22
3.1.2 Safety functions	23
3.1.3 Work carried out on the device	25
4 Components and assembly	27
4.1 System overview	28
4.2 Main components and views	29
4.2.1 Front view	29
4.2.2 Back	30
4.2.3 Side view	31
4.2.4 Valve bar	32
4.2.4.1 Valve bar modules	32
4.2.4.2 Removing the valve bar	34
4.2.4.3 Installing the valve bar	34
4.2.5 Battery	34
4.3 Cart (option)	35
4.4 Breathing circuit	36
4.5 Tube hanger	37

4.6 Respiratory gas humidification	37
4.6.1 Connection with an active respiratory gas humidifier	38
4.6.2 Connection with a passive HME filter	39
5 General information	41
5.1 General description of the equipment functions	42
5.1.1 Layout of the ventilation screen	43
5.1.2 General operations	44
5.1.2.1 Open/close windows	44
5.1.2.2 Confirmation (Enter)	44
5.1.2.3 Edit parameters	44
5.1.2.4 Selector	44
5.1.2.5 Views	46
5.1.2.6 Stop graphs	46
5.1.2.7 Home	46
5.1.2.8 Symbols / Functions	47
5.1.2.9 Help function	47
5.1.3 Adjust the ventilation screen	48
5.2 Configuration	50
5.3 Symbols	50
5.4 Abbreviations and terms used in the instructions for use and in the user guidance	52
6 Preparing the system for use	61
6.1 Power supply	62
6.1.1 Mains supply	62
6.1.2 Internal power supply (rechargeable battery)	62
6.2 Gas supply	64
6.3 Switching power on and off	65
6.3.1 Automatic patient detection APD	65
6.4 Power up test	65
6.5 System test	67
6.5.1 Select the patient category	67
6.5.2 Performing a system test	68
6.6 Leakage test	70
7 Operation	71
7.1 Standby mode	73
7.1.1 Battery symbol	75
7.1.2 Patient symbol	75
7.1.3 Select patient interface	75
7.1.3.1 Tube compensation	76
7.1.4 Dynamic view of the lung	78
7.1.5 Shortcuts: Toolbox	78
7.1.5.1 Help function	79
7.1.5.2 Screenshot	79
7.1.6 Home	79

7.1.7 Status	80
7.1.8 Trend view 1	80
7.1.8.1 Search function to define a time window	81
7.1.8.2 Graphic trend of selected measurements (configurable)	81
7.1.8.3 Parameters (configurable)	82
7.1.8.4 Tabular trend (configurable)	82
7.1.8.5 Trend update	83
7.1.9 Trend view 2	83
7.2 Selection “Same Patient” / “New Patient”	84
7.2.1 Default ventilation	85
7.3 Ventilation	86
7.3.1 Set ventilation mode	87
7.3.2 Change ventilation mode	87
7.3.3 Set ventilation parameters	88
7.3.4 Trigger	89
7.3.5 Backup ventilation	89
7.3.6 Set alarm limits	90
7.3.7 Overview of alarm limits	91
7.3.7.1 Ventilation alarms	91
7.3.7.2 Gas	91
7.3.7.3 Other alarms	92
7.3.7.4 Alarm limits for non-invasive ventilation	92
7.3.8 Drug nebulization	93
7.3.9 Start ventilation / Stop ventilation	93
7.3.10 Configuration options on the ventilation screen (end user)	94
7.3.10.1 Curve display (unit of measurement as configured)	94
7.3.10.2 Trend graphs / compressed trend graphs	95
7.3.10.3 Data table / short data table	95
7.3.10.4 Loops	95
7.3.10.5 Fastwean / Fastprotect	95
7.4 Settings under “System”	96
7.4.1 Reset to defaults	96
7.4.2 Lock and unlock the screen	96
7.4.3 Battery	96
7.4.4 System test	97
7.4.5 Settings	97
7.4.5.1 Date / Time	97
7.4.5.2 Display brightness	97
7.4.5.3 Alarm volume / brightness	98
7.4.5.4 Extras	99
7.5 Service	99
8 Measurements and graphics	101
8.1 Curve presentation	102
8.2 Instant View window	103

8.3	Loop view	104
8.4	Data table or short data table	105
8.5	Fastwean	106
8.6	Fastprotect	107
9	Errors, alarms and troubleshooting	109
9.1	Problems – causes – corrective measures	110
9.2	Alarm system	111
9.2.1	Alarm messages	111
9.2.2	Alarm pause	112
9.2.3	Verification of the signalling devices	113
9.2.4	Alarm verification in the presence of a blocked breathing circuit	113
9.2.5	Alarm verification in the presence of a partially blocked breathing circuit	113
9.3	Alarm priorities	114
9.4	Alarm messages during operation	114
9.5	Error messages during power up test	161
9.6	Error messages during system test	164
10	Cleaning, disinfection and sterilisation, disposal	169
10.1	General information	170
10.1.1	Initial operation	170
10.2	Cleaning and disinfection	171
10.2.1	Intensive care ventilator	171
10.2.2	Valve bar	172
10.3	Disposal of elisa 300 / elisa 500	177
11	Maintenance	179
11.1	General	180
11.2	Oxygen measurement (O₂)	180
11.2.1	Calibration of the paramagnetic O ₂ sensor	181
11.3	Air filter cassette for turbine	181
11.3.1	Exchanging the air filter cassette	182
11.4	Maintenance intervals	183
11.4.1	Annual maintenance	183
11.4.2	Maintenance every 6 years	183
11.4.3	Maintenance every 12 years	183
11.5	Additional maintenance and repair information	184
12	Technical specifications	185
12.1	Function chart of the elisa 300 / elisa 500 ventilator	186
12.2	General	186
12.3	Supply	189
12.4	Technical data	190
12.5	Control unit	191
12.6	Default parameters	192

12.7	Increments and maximum performance range	192
12.8	InstantView window / data table(s)	196
12.9	Data transmission with terminal devices	200
12.10	Guidance and manufacturer's declaration	202
13	Default parameters	207
13.1	Default parameters (factory settings)	208
13.1.1	Default parameters	208
13.1.2	Adjustment ranges	209
13.1.3	Default alarm limits	209
13.1.3.1	Default alarm limits of the ALPV mode	211
13.1.3.2	Default alarm limits of the WOBOV mode	211
13.1.3.3	Default alarm limits of the CPR mode	212

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I About this manual

I.1 About this manual	10
I.2 Safety information in these instructions for use	10

I.1 About this manual

These instructions for use describe the intended use and the operation 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 “Basic Instructions for Use” describes the intensive care ventilators mentioned above.

The following supplements to these instructions for use are available as separate documents:

Title	For devices	Content
IFU Supplement A	elisa 600, elisa 800 / elisa 300, elisa 500	Manoeuvres, Functions, Ventilation Modes
IFU Supplement B	elisa 300 to elisa 800VIT	LeoCap
IFU Supplement C	elisa 300 to elisa 800VIT	LeoLyzer
IFU Supplement D	elisa 300 to elisa 800VIT	Pulse oximetry and LeoClac
IFU Supplement E	elisa 300 to elisa 800VIT	External interfaces
IFU Supplement F	elisa 300 to elisa 800VIT	elisa@megs

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.

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.

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2 Use

2.1	Intended use	14
2.2	Areas of application	14
2.3	Differences between elisa 300 and elisa 500	15

2.1 Intended use

elisa 300 / elisa 500 ventilators are designed for adult and paediatric patients requiring ventilation support. The range of application covers invasive and non-invasive ventilation as well as HFOT (high-flow oxygen therapy).

Patient category	Weight
Adults	30–500 kg
Children	8 - 150 kg

There are no known contraindications. It is the user's responsibility to select appropriate settings in consideration of the clinical situation of the ventilated patient, periodically review these settings and adapt them when necessary.

When combined with an application system for volatile anaesthetic agents, elisa 300 / elisa 500 can also be used as an anaesthesia workstation. For more details, please refer to the separate document “Instructions for Use – Supplement A – Manoeuvres, Functions, Ventilation Modes”.

For a description of the device functions, please refer to chapter “5.1 General description of the equipment functions”.

2.2 Areas of application

elisa 300 / elisa 500 is approved for stationary use and patient transport within health care facilities.



Warning

The ventilator must not be used:

- in close proximity to nuclear magnetic resonance equipment (MRI, NMR DEVICES)
- in close proximity to electrosurgical devices
- simultaneously with a defibrillator
- in potentially explosive areas
- in the presence of flammable anaesthetics or highly flammable substances
- in hyperbaric chambers
- during out-of-hospital transport of patients
- in EMS settings and ambulances
- in aircrafts or helicopters

2.3 Differences between elisa 300 and elisa 500

Hardware options	elisa 300	elisa 500
Screen diagonal	12.1 "	15 "
BF interfaces	2 x BF interface	4 x BF interface

Software options	elisa 300	elisa 500
Cuffscout function	not available	standard
Peso function	not available	standard
IAP function	not available	standard

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3 General safety instructions

3.1 General safety instructions	18
3.1.1 Safety standards	22
3.1.2 Safety functions	23
3.1.3 Work carried out on the device	25

3.1 General safety instructions

Reference

These basic instructions for use describe the 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 these instructions for use and with Supplement A (Manoeuvres, Functions, Ventilation Modes).

Depending on the functions used, users must also familiarise themselves with the relevant supplements (see section 1.1).

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.

Users must be trained in the use of the equipment to ensure safe operation. Please contact your sales organization to receive the required training.

Secure positioning

Verify the secure positioning of the device which must not be tilted or set up at an angle.

Moving the cart with the device

Check that the device is securely fastened on the cart. Release the locking brakes on the cart wheels.

When moving the cart over thresholds or when entering a lift, for example, slightly lift the cart.



Warning

Always manoeuvre the device using the handles on the sides, do not apply force to the device or the control unit – risk of tipping over!

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.

Only one patient may be connected to a ventilator at a time.



Warning

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

Remark

At an ambient temperature of 40°C, the respiratory gas may reach a maximum temperature of 42.5°C at the patient. This fact is to be considered in the individual patient management situation.

Reporting obligation

The manufacturer and the competent authority of the member state where the user and/or patient resides must be notified of all serious incidents involving the product.

Accessories

Only use accessories and accessory components specified in the list of accessories; these products have been tested by the manufacturer and are approved for use with the device. If employing different accessories, the user is required to test and demonstrate the safety of the system prior to its use. Restrictions regarding the application of the breathing circuits used must be observed (drug nebulization). In order to prevent adverse effects on the ventilator performance (prolonged mean expiration time, AutoPEEP, false triggering, flow-generated noise, ...) the tube-in-tube systems (coaxial breathing systems) must be designed for low flow resistance.



Warning

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. The device shall only be applied within the scope of its intended use.



Warning

Use of accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and cause incorrect operation.



Warning

Do not reuse components intended for single use.

Classification

elisa 300 / elisa 500 is a Class IIb device according to Directive 93/42/EEC concerning medical devices, Annex IX, section 3.1, rule 9 and section 3.2, rule 11, as well as according to Regulation (EU) 2017/745 on medical devices, Annex VIII, rule 12.

Classification according to EN 60601-1 Medical electrical equipment - General requirements for basic safety and essential performance:

DEVICE OF PROTECTION CLASS II, with internal power supply. Protection against electric shock hazards by protective earth terminal.

APPLIED PARTS with an electrical connection (type BF):

- CO₂ sensor IRMA / ISA
- CO₂ sensor LeoCap
- Multi-gas sensor LeoLyzer
- SpO₂ sensor
- Nurse call
- elisa@megs (medical device interface)



Warning

Only accessories included in the accessory list may be connected to the type “BF” connection ports.



Warning

Always connect type BF equipment to the device before connecting it to the patient.



Warning

Be sure to connect the equipment to the appropriate interfaces on the back of the device. Check that all connectors are properly secured.

APPLIED PARTS that conduct patient gases:

- Parts integrated in the elisa 300 / elisa 500 system (such as assemblies or modules) are inspected by the manufacturer.
- External parts conducting patient gases, which are connected to the elisa 300 / elisa 500 system, are inspected by the manufacturers of the parts concerned. For details, please refer to the documents enclosed with these parts.

CONTINUOUS OPERATION if applied in compliance with the intended use and within the indicated temperature limits.

Electrical hazard

elisa 300 / elisa 500 is exclusively designed for use in an electrical environment according to VDE 0100 part 710 or EN 60601-1. elisa 300 / elisa 500 must not be used if there are doubts concerning the quality and function of the protective earthing of the electrical installation.

Remark

The construction of elisa 300 and 500 fulfils the requirements of protection class II (as specified in the above standards). The devices do not have a safety connection to electrical earth (ground).

Remark

All metal accessible parts are insulated with plastic. This means that they cannot carry any potential (not even in the event of a fault) that would have to be equalised, and that is why a potential equalisation connection is not provided.



Warning

All approved accessories and the sockets in our devices where they are connected are not defibrillation-proof. It is mandatory to remove these accessories from the patient during defibrillation.

The housing must be dry before the device is connected to the mains supply. It must be ensured that the supply voltage corresponds to the ratings on the type plate on the back panel of the device.

The system must be stored and operated at the temperature and humidity levels indicated in chapter 12.4 "Technical specifications".

The system must always be disconnected from the power supply before cleaning, repair or maintenance work.

Fire hazard

elisa 300 / elisa 500 must not be used in potentially explosive atmospheres or in the presence of flammable anaesthetics.

Risk of electromagnetic disturbance

Devices that generate electromagnetic disturbance at levels exceeding the values of EN 60601-1-2 can affect the safe operation of the device and endanger the patient.

Devices that generate high frequency fields and are installed close to the system can affect the safe operation of elisa 300 / elisa 500 and endanger the patient.



Warning

The use of mobile communications equipment at a distance of less than 30 cm from the device, its accessories and cables can affect the safe operation of elisa 300 / elisa 500 and endanger the patient.



Warning

elisa 300 / elisa 500 must not be used in close proximity to nuclear magnetic resonance equipment (MRI, NMR devices).

Electromagnetic compatibility:

elisa 300 / elisa 500 is only intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The users of elisa 300 / elisa 500 can contribute towards avoiding electromagnetic interference by maintaining the minimum distance between portable and mobile high frequency communications equipment (transmitter) and elisa 300 / elisa 500.



Warning

The use of other electrical devices, e.g., power cords, may result in increased emissions or decreased immunity performance of elisa 300 / elisa 500. This may put the patient at risk.



Warning

Using other electrical devices with elisa 300 / elisa 500 or in its vicinity can cause interference. The correct performance of elisa 300 / elisa 500 must be verified prior to connecting the patient to the device.

Remark

All the elisa 300 / elisa 500 features are fully functional if the place of use meets the EMC requirements set forth in the applicable regulations. Detailed information on electromagnetic compatibility can be found in chapter 12.10 "Guidance and manufacturer's declaration".

Remark

In certain EMC environments, some functions of the device may fail briefly (e.g., restart of the display). These functions will automatically be reset. The ventilation functions of the device are not affected at all by these occurrences.

3.1.1 Safety standards

The intensive care ventilator was developed and manufactured according to the following safety standards:

EN 60601-1

Medical electrical equipment – General requirements for basic safety and essential performance

EN 60601-1-2

Medical electrical equipment – General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and testing

EN 60601-1-6

Medical electrical equipment – General requirements for basic safety and essential performance – Collateral standard: Usability

EN 60601-1-8

Medical electrical equipment – General requirements for basic safety and essential performance – Collateral standard: Alarm systems: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

EN 80601-2-12

Medical electrical equipment – Particular requirements for basic safety and essential performance of critical care ventilators

EN 80601-2-55

Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors

EN 62304

Medical device software – Software life-cycle processes

EN 62366

Medical devices – Application of usability engineering to medical devices

ISO 14971

Medical devices – Application of risk management to medical devices

DIN EN ISO 80601-2-13

Particular requirements for basic safety and essential performance of an anaesthetic workstation

3.1.2 Safety functions

Power up test

When switched on, the device performs the power-on self-test: the hardware and software modules whose function is relevant for the safety concept and the supply are checked. For safety reasons it is not possible to bypass this test.

Remark

For a list of all alarm messages during the power up test, please refer to chapter 9.5 “Error messages during power up test”.

Alarms were implemented in the ventilator as safety functions in order to warn the user if the patient is at risk.

Device alarms

Monitoring
Gas supply
Electrical supply
Sensors
Turbine
User interface
Device control system
Visual and audible alarms
External components (if available): CO ₂ sensor, multi-gas sensor, Cuffscout, etc.

All device alarms are evaluated during ventilation, in standby mode and when the automatic patient detection function does not detect a patient. An alarm is triggered when applicable.

Patient alarms

Monitoring
Airway pressures
Tidal volume / minute volume
Respiratory rates (overall/spontaneous)
Leakage
O ₂ concentration
In combination with the appropriate sensors: gas concentration of CO ₂ , sevoflurane, isoflurane

Patient alarms are only evaluated during ventilation and when the automatic patient detection function detects a patient. An alarm is triggered when applicable.

System test

As a matter of principle, a system test must be carried out before the ventilator is used.

**Warning**

Never carry out a system test if a patient is connected to the device.

The system test ensures that all safety-related functions and components are tested before the ventilator is used. The system test can be bypassed in the event of an emergency.

If the system test was bypassed, the system cannot determine the correct values of the currently used breathing circuit which are necessary for optimal compliance and resistance compensation. In this case, the measurement values of the last

system test are used.

If accessories were modified or the breathing circuit was exchanged, the system may not be operating within the specified accuracy and tolerance ranges.

Remark

After changing the patient category, it is not possible to skip the system test.

3.1.3 Work carried out on the device

Repairs, service and maintenance on the device must only be carried out by authorised personnel. The maintenance intervals and measures are described in chapter 11 “Maintenance”.

**Warning**

Never carry out repair, service or maintenance work if a patient is connected to the device.

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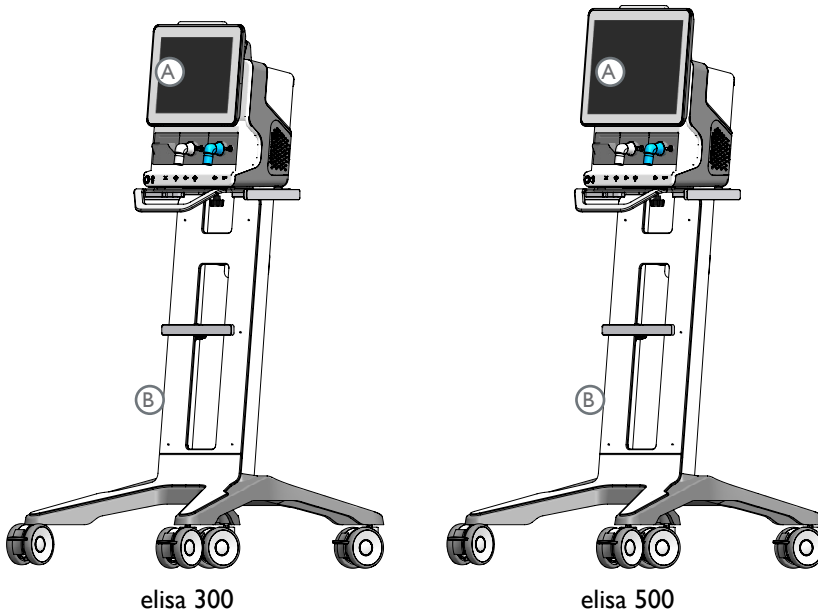
4 Components and assembly

4.1	System overview	28
4.2	Main components and views	29
4.2.1	Front view	29
4.2.2	Back	30
4.2.3	Side view	31
4.2.4	Valve bar	32
4.2.4.1	Valve bar modules	32
4.2.4.2	Removing the valve bar	34
4.2.4.3	Installing the valve bar	34
4.2.5	Battery	34
4.3	Cart (option)	35
4.4	Breathing circuit	36
4.5	Tube hanger	37
4.6	Respiratory gas humidification	37
4.6.1	Connection with an active respiratory gas humidifier	38
4.6.2	Connection with a passive HME filter	39

4.1 System overview

The standard components of the intensive care ventilator elisa 300 / elisa 500 are:

- A Intensive care ventilator with integrated control unit including the valve bar and the rechargeable battery

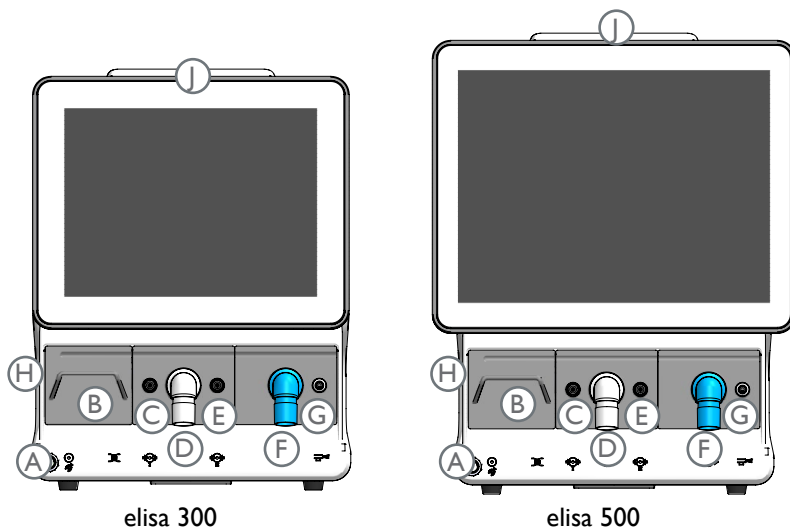


Furthermore, the ventilation system can be expanded to include the following options:

- B Cart with 2 standard rails on the sides and a standard rail in the middle whose height is adjustable
 - Tube hanger (not shown)

4.2 Main components and views

4.2.1 Front view



- A Power ON button
- B Expiratory flow sensor
- C $P_{aux I}$
- D Expiratory port
- E $P_{aux II}$
- F Inspiratory port
- G Pneumatic nebulizer connection
- H Exhaust gas port (on the side of the device)
- J Alarm LED



The ventilator and the connected accessories must not be covered during operation or while the internal power supply system is charging.

4.2.2 Back



elisa 300



elisa 500

- | | | | |
|---|--|---|------------------------------|
| A | 2 x USB port | E | Type plate |
| B | DVI port | F | Fan |
| C | Interfaces
(see “Detailed view of the inter-
faces”) | G | Battery compartment I and II |
| D | Button to release turbine filter
cover | H | Power input |
| | | J | Oxygen supply |

Detailed view of the interfaces:

Picture	Designation	Assignment
	A and B	PDMS/Monitor interface (configurable)
	1 and 2	Serial interface, type BF (configurable)
	3 and 4	Serial interface, type BF (configurable) (elisa 500 only)



Only approved accessories may be connected to the USB interfaces (refer to separate accessory list).



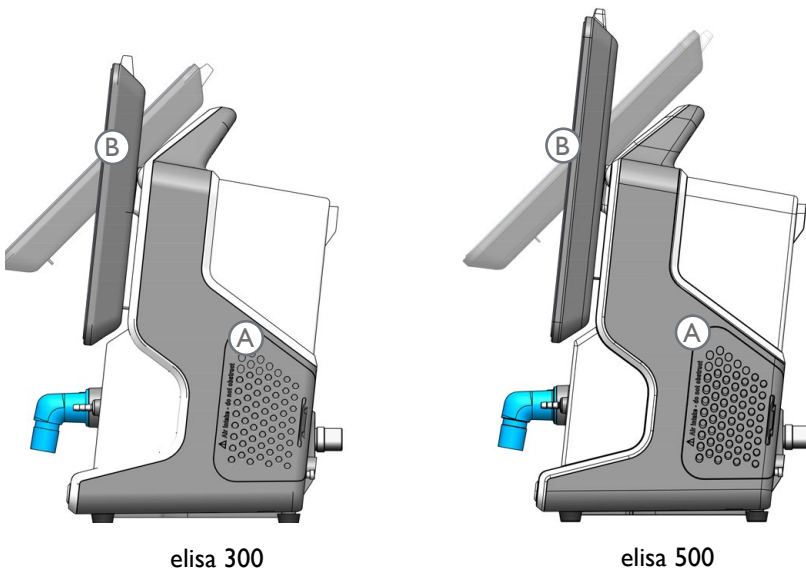
Only devices which comply with the EN 60601-1 and/or EN 60950 standard may be connected to the interfaces of elisa 300 / elisa 500.

Remark

Do not touch interfaces A or B or C and the patient at the same time.

4.2.3 Side view

The elisa 300 / elisa 500 control unit can be tilted manually by approx. 30°.

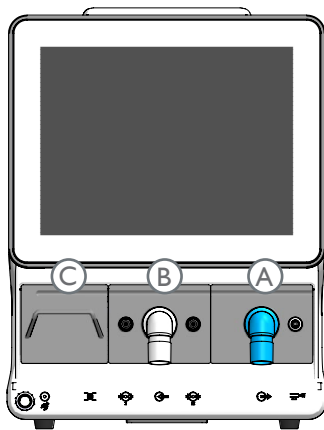


- A Cover of the turbine air filter
- B Tilting the control unit

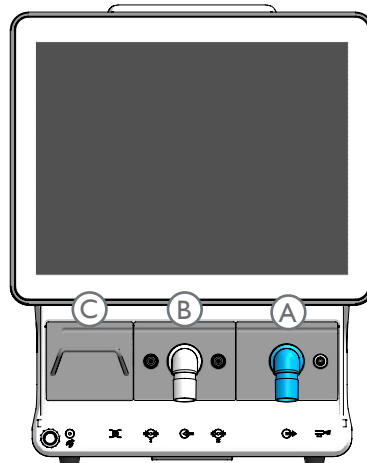
4.2.4 Valve bar

The elisa 300 / elisa 500 valve bar enables a quick exchange of all patient-side connections and is composed of the 3 following elements:

- A Inspiratory valve
- B Expiratory valve
- C Expiratory flow sensor



elisa 300



elisa 500

4.2.4.1 Valve bar modules



Warning

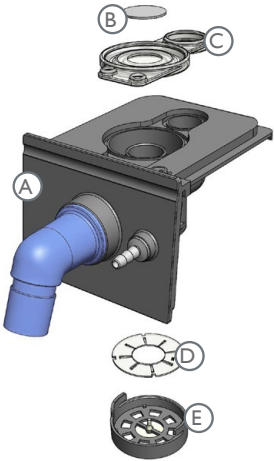
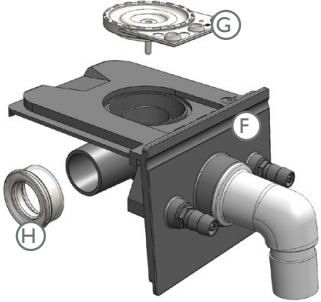
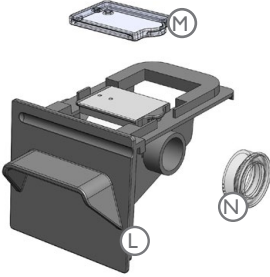
The modules used need to be reprocessed before each use (see chapter 10).



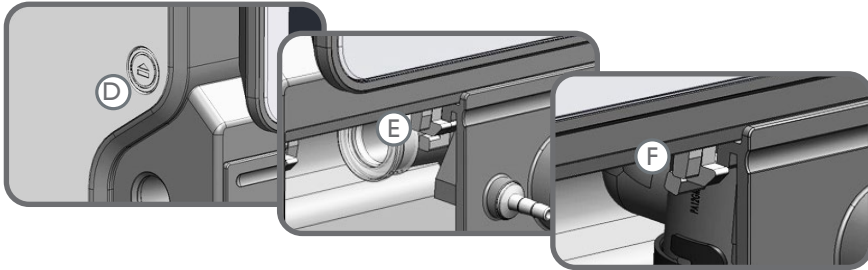
Warning

Before each use of the valve bar modules, visually check each module for damage. Make sure that components are intact and complete. Do not use a module that is damaged or incomplete.

Description of the modules and their components

A	Inspiratory valve	
B	Metal disc	
C	Inspiratory valve membrane	
D	Free breathing membrane	
E	Valve basket with mushroom valve	
F	Expiratory valve	
G	PEEP membrane (3 parts), consisting of silicone membrane, disc and silicone disc	
H	Sealing ring expiratory valve	
L	Expiratory flow sensor	
M	Sealing plate	
N	Sealing ring expiratory flow sensor	

4.2.4.2 Removing the valve bar



Actuate the respective release lever to be able to remove the individual elements one after another (push release levers **E** and **F** backwards).

- D Release lever for expiratory flow sensor
- E Release lever for expiratory valve
- F Release lever for inspiratory valve

4.2.4.3 Installing the valve bar

The valve bar is assembled in reverse order. Introduce the modules into their respective slots at a slight angle from below and push them upwards. Make sure that the mechanical locks engage.



Warning

All valve bar modules must be reprocessed before a patient may be connected to the ventilator.

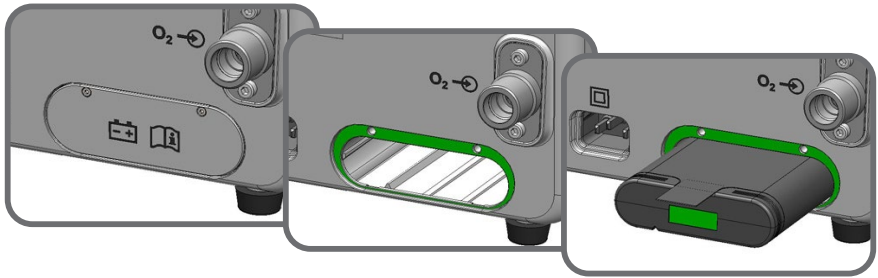
Remark

Observe the correct sequence when inserting the inspiratory and expiratory valve!

4.2.5 Battery

elisa 300 / elisa 500 can be equipped with a maximum of two batteries. One battery is usually included in the delivery.

To insert or change a battery, remove the battery compartment cover on the back of the ventilator. To do so, open the screws manually.



Remove the new battery from its packaging and push it into the compartment **all the way**. The guides allow the battery to be inserted only in one orientation. The capacity indicator faces out.

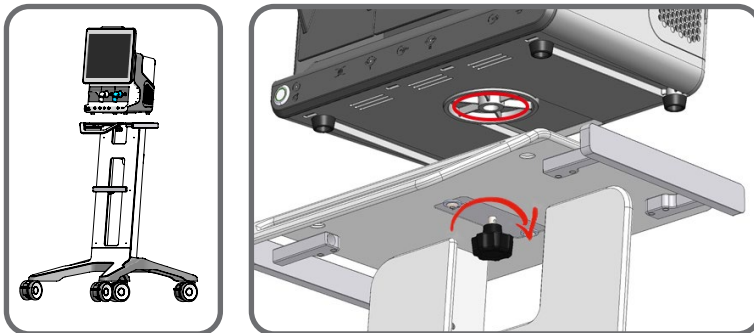
Remark

If you use only one battery, you can place it in any of the two battery compartments.

Close the battery compartment with the cover. Further information on battery usage can be found in chapter 6.1.2 “Internal supply system (rechargeable battery)”

4.3 Cart (option)

Place the ventilator on the cart. Be sure to hold it only at the carrying handle at the top of the device. Fasten the ventilator using the locking mechanism on the bottom of the platform.



Accessories can be attached to the rails on the sides as well as to the height-adjustable standard rail in the middle.

**Warning**

Do not use the cart in case of apparent damage.

**Warning**

All devices and accessories must be securely fastened to the cart and checked for tightness. Insufficient fastening can result in damage to the device and/or personal injury.

**Caution**

The user must apply the brakes on the cart wheels during stationary use of the ventilator.

**Caution**

Do not sit or stand on the cart!

**Caution**

In addition to elisa 300 / elisa 500, the cart accepts a maximum load of 10 kg, which is limited to 5 kg per standard rail.

4.4 Breathing circuit

Operate elisa 300 / elisa 500 only in conjunction with breathing circuits and accessories that meet the requirements specified in chapter 3.1 “General safety instructions”. Compliance, resistance and leakage of the tubing system used are measured individually in the system test.

Patient category	Adults	Children
Tube diameter	22 mm	15 mm

**Warning**

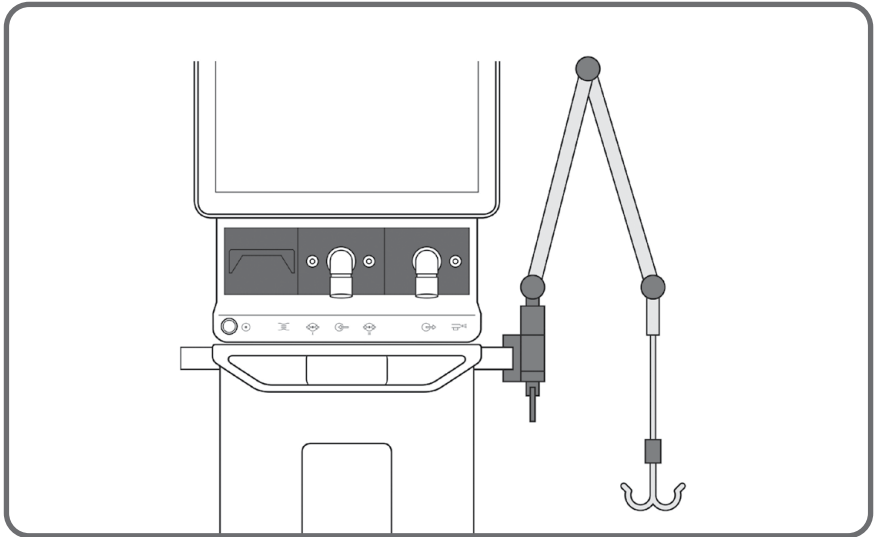
Do not use any anti-static or conductive tubes or breathing circuits as they may pose an electrical hazard to the patient!

Remark

Using a tube hanger is recommended in order to guide the tubing system between the ventilator and the patient.

4.5 Tube hanger

A tube hanger is optionally available as a strain relief for the ventilation tubes. You can fasten the hanger to one of the two side handles on the cart.



4.6 Respiratory gas humidification

For warming and humidifying the respiratory gases, elisa 300 / elisa 500 can be combined with various accessories for respiratory gas conditioning. Use only equipment that meets the requirements specified in chapter 3.1 “General safety instructions”.



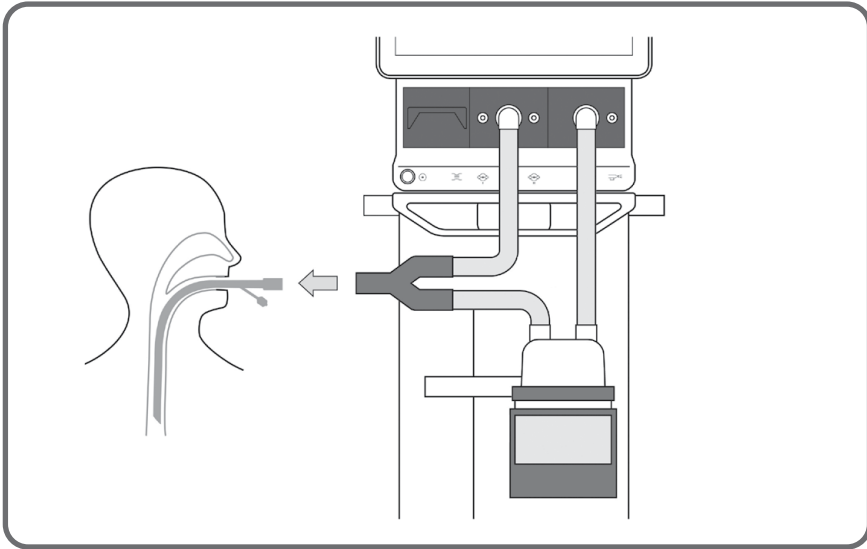
To avoid additional flow resistances, filter systems (e.g. HME) should not be used at the same time as active humidifiers!

4.6.1 Connection with an active respiratory gas humidifier

Fasten the active humidifier to the standard rail of the cart and integrate it into the ventilation system.

Remark

For additional information on connecting the breathing circuit to the active respiratory gas humidifier, refer to the information provided by the manufacturer.



Warning

Active humidifiers increase the resistance of the ventilation system!



Warning

To guarantee proper channelling of water condensation, the humidifier must be positioned well below the inspiratory or expiratory port.



Warning

Do not fasten the respiratory gas humidifier to the handles on the side of the ventilator unit.

4.6.2 Connection with a passive HME filter

Connect the passive HME filter between the Y-connector and the patient.

Remark

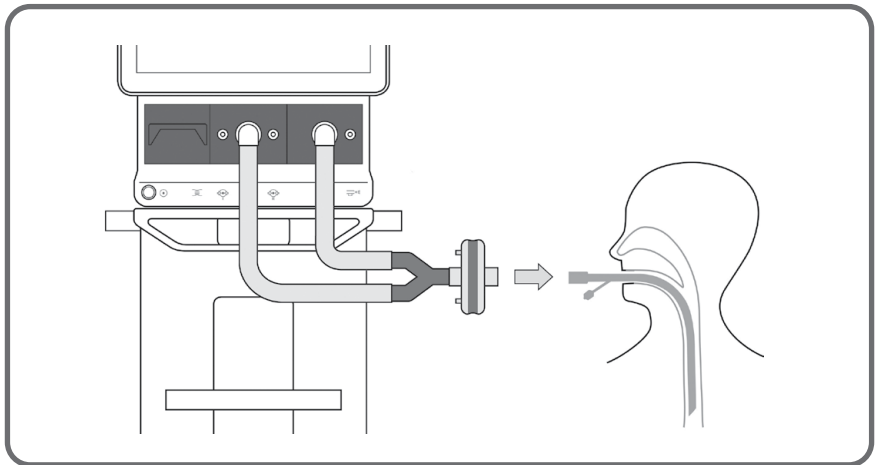
Filters increase the dead space volume and the resistance of the ventilation system.

**Warning**

Residual drug build-up from nebulization may cause high flow resistance, which may eventually block ventilation.

**Warning**

Regularly check the filter for increased resistance or clogging.



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5 General information

5.1	General description of the equipment functions	42
5.1.1	Layout of the ventilation screen	43
5.1.2	General operations	44
5.1.2.1	Open/close windows	44
5.1.2.2	Confirmation (Enter)	44
5.1.2.3	Edit parameters	44
5.1.2.4	Selector	44
5.1.2.5	Views	46
5.1.2.6	Stop graphs	46
5.1.2.7	Home	46
5.1.2.8	Symbols / Functions	47
5.1.2.9	Help function	47
5.1.3	Adjust the ventilation screen	48
5.2	Configuration	50
5.3	Symbols	50
5.4	Abbreviations and terms used in the instructions for use and in the user guidance	52

5.1 General description of the equipment functions

The main purpose of the ventilator is to perform the entire work of breathing, or part of it, in order to ensure adequate oxygenation and CO₂ elimination and to detect conditions of insufficient ventilation. This section describes the essential elements and functions of the ventilator.

- The ventilator consists of the **ventilator unit** and the **control unit**.
- The **ventilator unit** accommodates the entire pneumatic ventilation system which is controlled by hardware and software. A turbine generates the necessary air pressure (AIR).
- The **control unit** is the user interface for data input and displays the actual ventilation situation.
- **The ventilator unit operates independently of the control unit**, which ensures that the patient continues to be ventilated even under adverse conditions.

elisa 300 / elisa 500 units are equipped with various **alarm signalling devices**. The ventilator unit features an independent **watchdog function** for monitoring purposes which outputs an alarm when the electric or pneumatic components of the ventilation system fail. In this extreme situation the patient can breathe room air via the free breathing valve. The free breathing valve is integrated in the inspiratory valve.

Power supply is assured by connection to mains power and the integrated battery. The battery powers the ventilator in case of mains failure and mains power fluctuations as well as during patient transport within the health care facility.

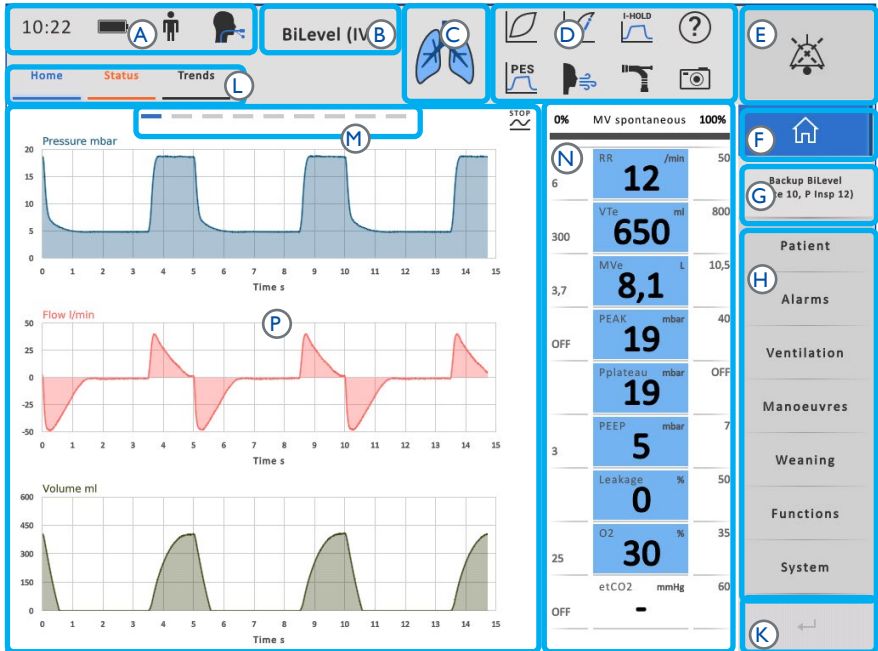
Oxygen (O₂) is supplied via a wall outlet or from a gas cylinder. AIR is supplied by the integrated turbine.

Software functions are provided for the **input of instructions and settings**. All settings are performed via the touch screen of the control unit. Your inputs instruct the pneumatic system of the ventilator to provide the patient with an accurately controlled gas mixture. At the same time the ventilator continuously determines the actual ventilation situation by means of the integrated flow and pressure sensors. Based on your inputs and on the data provided by the sensors, the device adapts the mixture of gases supplied to the patient. All these data are displayed in various windows on the graphical user interface of the control unit. The ventilator will output alarms when it is no longer able to ventilate the patient according to your settings.

During the ventilation procedure, the delivery of the gas mixture and the measuring functions are permanently monitored by an **alarm control system**. The proper functioning of the alarm control system is verified as part of the power up test and the system test of the ventilator. Please refer to chapter 12.1 “Function chart of the elisa 300 / elisa 500 ventilator” for a function chart.

5.1.1 Layout of the ventilation screen

The information displayed on the screen varies with the configuration. The basic layout of the screen display, however, remains unchanged:



- A** Status line
- B** Selected ventilation mode
- C** Dynamic view of the lung
- D** “Toolbox” with shortcuts (7 of them are user-configurable)
- E** Alarm pause button
- F** Home button (back to main screen)
- G** Backup mode button
- H** Button bar (if a value has been selected: selector)
- K** Enter button (confirms selected actions or parameters)
- L** Home, Status and Trends tabs
- M** Number of configured views (max. 9 views)
- N** Instant View window
- P** Ventilation screen

5.1.2 General operations

5.1.2.1 Open/close windows

The intensive care ventilator is controlled via the capacitive multi-touch display screen. Windows or menus are opened by touching the appropriate button. You close windows by selecting the X button or the Home button.



5.1.2.2 Confirmation (Enter)

Changes, such as entering a parameter, changing the ventilation mode or starting and stopping a function, must always be confirmed with the Enter button. In this case, the Enter button is coloured and blinks.



5.1.2.3 Edit parameters

To change a parameter, select the corresponding button. The selector is shown on the right-hand side of the screen. Turn the selector by swiping to the new value and confirm the selection with the Enter button.

To cancel the input and return to the main screen, press the button of the selected parameter once again or touch the screen anywhere outside the selector.

5.1.2.4 Selector

You open the selector by selecting an editable parameter.

The selector displays the following information and can be used for the following operations:

- A** Selection by vertical swipe over the displayed numerals
- B** Selection by vertical swipe on the side bar for faster scrolling (selected in Figure 2)
- C** Currently selected value
- D** Coloured marker identifying a threshold to a critical range
- E** Indication of the magnitude of the available range of values and of the position within this range
- F** “Critical” range of values (Figure 3), displayed with a different colour.

Figure 1

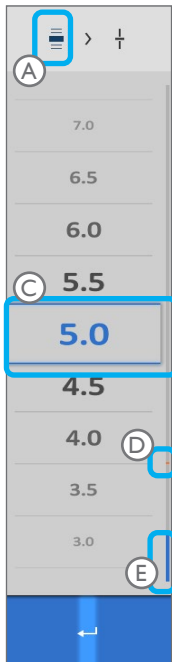
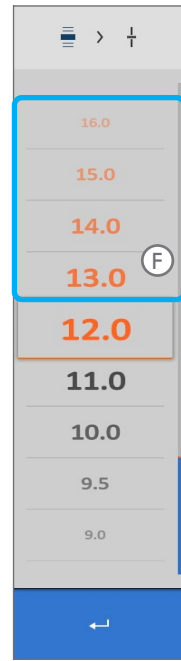


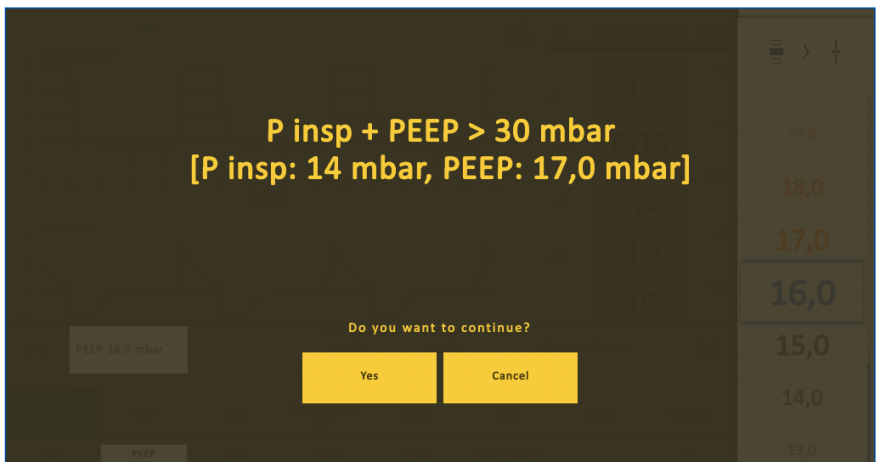
Figure 2



Figure 3

**Remark**

To prevent the adjustment of potentially hazardous settings, a warning is displayed, which must be acknowledged separately.



5.1.2.5 Views

The views available on the ventilation screen depends on the configuration (maximum: 9 views). The number of available views is indicated by the number of dashes displayed in the header of the main window. You scroll through the views by horizontal swiping. A total of 9 views is available for the displayed ventilation window.



5.1.2.6 Stop graphs

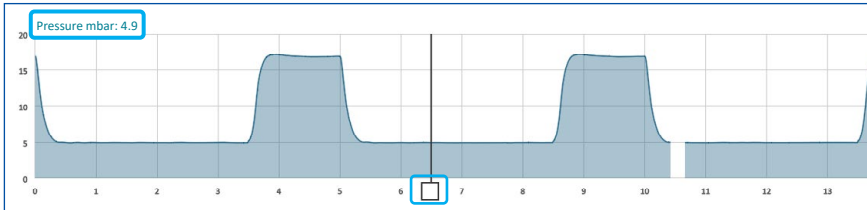
A STOP button is provided in the upper right hand corner of the graph window.



When you touch this button, the following will happen:

- All the active graphs will freeze.
- A “Restart Graphs” button will appear to unfreeze the graphs.
- Movable cursors will appear which can be used to perform measurements on the graphs.

By moving a cursor, you can view the corresponding measured values.



Tapping the “Restart Graphs” button will unfreeze the graphs. Alternatively, you can swipe to select another view or you can select the Home, Status or Trends tab.

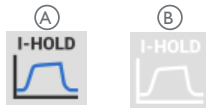
5.1.2.7 Home

With the Home button, you return to the main screen.

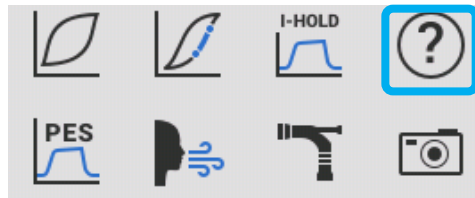


5.1.2.8 Symbols / Functions

The configured symbols in the Toolbox are represented in the passive state (A). When they are selected, they change their appearance to indicate the active state (B).

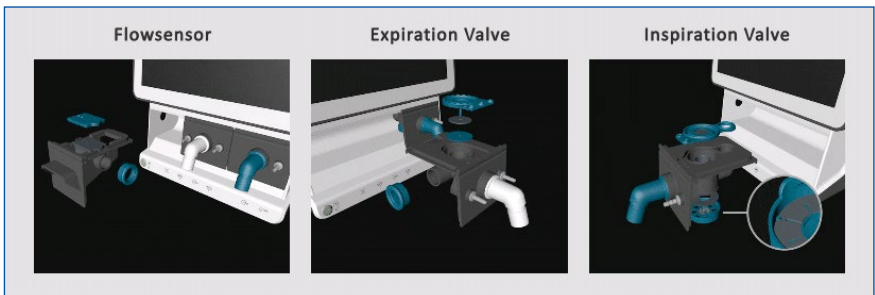


5.1.2.9 Help function



You can press the Help button to view additional information.

On the **power up test** screen and the **system test** screen, you will find a Help button which can be pressed to view pictures illustrating the correct assembly and positioning of the valve bar components. Tap a valve to obtain interactive instructions for the valve concerned.



In the standby mode and during ventilation, you can use the Help function to obtain information about the different ventilation modes, parameter settings, and alarm limits.

To view Help, touch the Help button: the button colour changes. Next, tap the function/parameter for which you need additional information.

Close the Help window with the “X” button or by tapping anywhere on the screen.

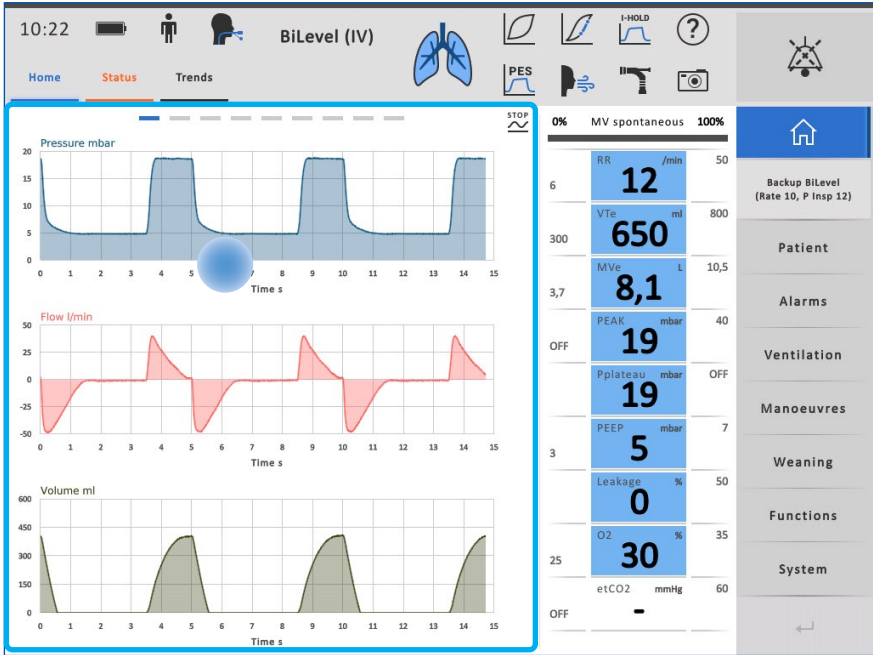
5.1.3 Adjust the ventilation screen

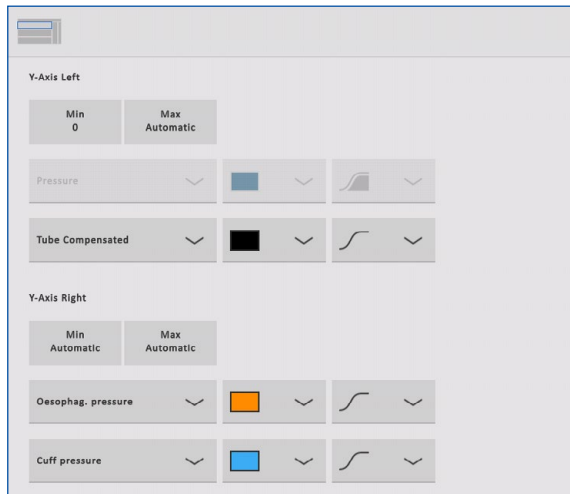
Additional adjustment options are available for numerous views and functions on the ventilation screen, even during ventilation.

Remark

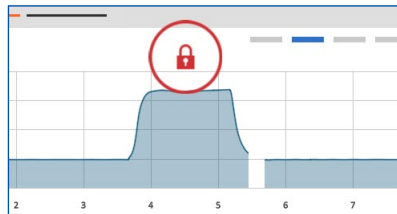
Adjustments performed in this window will be restored to the ward defaults by selecting “New Patient”.

Tap and hold a view/function to display an additional window where you can adjust specific parameters.
The window opened in this way can be closed with the “X” button or by tapping anywhere on the screen outside the new window.

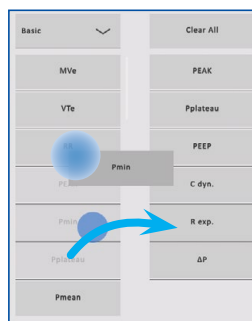




Individual elements or entire views locked on the configuration level are identified with the “padlock” symbol.



Some of the sub-menus support the “Drag and Drop” feature for configuration. To make a parameter “draggable”, touch it with your finger until a coloured circle appears. Then drag the parameter to its new position on the screen.



5.2 Configuration

Via the “Configuration” button on the standby screen and on the system test screen, the system can be configured to comply with the ward policy. If adjustments are required on the configuration level, please contact your service technician or the responsible person in your ward.

5.3 Symbols

Front panel



Power ON button



Power indicator



Gas outlet



Gas inlet



Paux I & II



Expiratory flow sensor



Nebulizer port

Side panel



Release lever for valve bar



Caution: exhaust gas port

Rear panel



HDMI port for connection of projector



Network interface



USB interface (2x)



Type BF applied part

	Serial interface
	Battery compartment
	Power input
	O ₂ inlet
	Observe instructions for use!
	Weight in kg
IP22	Protection class according to DIN EN 60529
	elisa 300 and elisa 500 fulfil the requirements of Directive 93/42/EEC concerning medical devices and of Regulation (EU) 2017/745, provided they are operated according to the instructions for use. "XXXX" is the identification number of the notified body.
	Manufacturer and date of manufacture
	This symbol identifies electrical and electronic devices that must not be disposed of with ordinary, unsorted household waste but must be treated separately. Please contact the manufacturer for more information regarding the disposal of the device.
	Unique Device Identification
	Medical Device
Cart	
	Do not step onto surface!
	Do not sit!
	Follow the instructions for use!

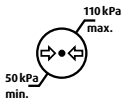
Packaging



Medical device, handle with care



Humidity from 0 to 99%, no condensation



Atmospheric pressure from 50 kPa to 110 kPa



Fragile, handle with care



Transport and storage at temperatures from -20°C to +60°C



This side up



Box supports a maximum load of 30 kg



Keep dry



Protect from heat and radioactive radiation

5.4 Abbreviations and terms used in the instructions for use and in the user guidance

Ventilation modes

VCV	Volume-controlled ventilation
PLV	Pressure limited ventilation (VCV with pressure limitation)
VC-SIMV	Synchronised intermittent mandatory ventilation – volume controlled
Optional VCV	Optional VCV
Flexible VCV	Flexible VCV
PCV	Pressure-controlled ventilation

PC-SIMV	Synchronised intermittent mandatory ventilation – pressure controlled
PC-APRV	BiLevel airway pressure release ventilation
BiLevel	Pressure-controlled BiLevel ventilation
BiLevel ST	Pressure-controlled BiLevel ventilation (spontaneous/timed)
Dynamic BiLevel ST	Pressure-controlled BiLevel ST ventilation, dynamic
Dual BiLevel ST	Dual pressure-controlled BiLevel ST ventilation
Mandatory BiLevel	Mandatory BiLevel ventilation
Optional BiLevel	Optional BiLevel ventilation
Dynamic BiLevel	Pressure-controlled BiLevel ventilation with volume guarantee
Dual BiLevel	Dual BiLevel ventilation
Flexible BiLevel	Flexible BiLevel ventilation
VA BiLevel	Volume-adaptive BiLevel ventilation
CPAP	Continuous positive airway pressure
PSV	Pressure-supported spontaneous breathing
Dyn. PSV	Dynamic pressure support
Prop. PSV	Proportional pressure support
PAPS	Proportional Adaptive Pressure Support
ALPV	Adaptive Lung Protection Ventilation
WOBOV	Work Of Breathing Optimized Ventilation
CPR	Reanimation mode
HFOT	High flow oxygen therapy (respiratory therapy)

Further abbreviations and terms

AIR 40 ... 90 PSI	Inlet AIR gas supply with a pressure range from 40 to 90 PSI
Adult	Patient category: Adults
APD	Automatic patient detection
Apnoea	Maximum time without inspirations, adjustable alarm limit
ASR	Automatic suction routine
ByFlow	Bias flow, configured value
C	Compliance of the respiratory system plus the patient, measured value
C20/Cstat	Ratio of the last 20% of the compliance to the overall compliance during inspiration (determined by a PEEPfinder manoeuvre)
CO ₂	Carbon dioxide

CO ₂ - V Loop	'CO ₂ vs. volume' loop
Cdyn	Dynamic compliance measured at the beginning of the inspiratory phase
Cstat	Static compliance (determined with the PEEPfinder manoeuvre)
Delta P (ΔP)	Pressure difference between Pplateau and PEEP, measured value
Delta P (es) (ΔP (es))	Amplitude of the oesophageal pressure (ΔPeso): Indicator of the higher respiratory muscle effort of spontaneously breathing patients
Delta Peso/Delta PAW (ΔPeso/ΔPAW)	Ratio between the changes in airway pressure and oesophageal pressure as an indicator of the position verification of the Peso catheter (Baydur test)
E	Expiratory time, configured value
Endot.	Endotracheal tube
etCO ₂	End-tidal carbon dioxide
etCO ₂ max	Maximum expiratory CO ₂ concentration, adjustable alarm limit
etCO ₂ min	Minimum expiratory CO ₂ concentration, adjustable alarm limit
exISO	Expiratory isoflurane
exISO max	Maximum expiratory isoflurane concentration, adjustable alarm limit
exISO min	Minimum expiratory isoflurane concentration, adjustable alarm limit
exSEV	Expiratory sevoflurane
exSEV max	Maximum expiratory sevoflurane concentration, adjustable alarm limit
exSEV min	Minimum expiratory sevoflurane concentration, adjustable alarm limit
Expirat.	(here) expiratory tube compensation
Exp. Hold	Duration of the Expiratory Hold manoeuvre, configured value
Exp Ramp mand	In pressure-controlled modes, the rate at which the pressure is reduced to the PEEP level, configured value
Exp Ramp spont	In pressure-support modes, the rate at which the pressure is reduced to the PEEP level, configured value
Exp Trigger	Trigger option for synchronisation of expiration in pressure-controlled ventilation modes
RR	Respiratory rate, breaths per minute, measured value
Flow	Flow in general, measured value
Flow insp.	Maximum flow measured during inspiration in L/min
Flow exp.	Maximum flow measured during expiration in L/min

Flow insp.	Maximum flow measured during inspiration in L/s
Flow exp.	Maximum flow measured during expiration in L/s
Flow - Paw Loop	'Flow vs. pressure' loop
RR mand.	Mandatory respiratory rate measured per minute, measured value
RR max	Maximum rate, adjustable alarm limit
RR min	Minimum rate, adjustable alarm limit
RR max spont	Maximum spontaneous breathing rate, adjustable alarm limit
RR min spont	Minimum spontaneous breathing rate, adjustable alarm limit
Rate	Respiratory rate, breaths per minute, configured value
RR spont.	Respiratory rate per minute, spontaneous, measured value
HR	Heart beats per minute, measured value
HW y/x	Hardware revision number
I	Inspiratory time, configured value
IAP	Intra-abdominal pressure
I:E	Inspiratory to expiratory time ratio, configured value
I Flow	Inspiratory flow, configured value
inCO ₂	Inspiratory carbon dioxide (ambient conditions)
inCO ₂ max	Maximum inspiratory CO ₂ concentration, adjustable alarm limit
inISO	Inspiratory isoflurane
inISO max	Maximum inspiratory isoflurane concentration, adjustable alarm limit
inISO min	Minimum inspiratory isoflurane concentration, adjustable alarm limit
Insp. Hold	Duration of the Inspiratory Hold manoeuvre, configured value
inSEV	Inspiratory sevoflurane
inSEV max	Maximum inspiratory sevoflurane concentration, adjustable alarm limit
inSEV min	Minimum inspiratory sevoflurane concentration, adjustable alarm limit
IV	Invasive ventilation
Paediatric	Patient category: Children
Compensat.	Tube compensation level
Compens. C	Extent of the compliance compensation
Compens. R	Extent of the resistance compensation

Leakage	Leakage rate (determined overall leakage in percent), measured value in table and maximum allowed leakage, adjustable alarm limit
LIP	Lower inflection point
MIP	Negative inspiratory force generated by the patient during an expiratory hold manoeuvre (Maximum Inspiratory Pressure), measured value
MVe	Overall expiratory minute volume, measured value
MVe spont.	Share of spontaneous breathing in the minute volume
MVe spont. %	Percentage of spontaneous breathing in the minute volume
MV target	Multiplier for determination of the target minute volume
MVe mand.	Minute volume of mandatory ventilation (without spontaneous breathing)
MV Leakage	Leakage measured per minute, measured value
MV max	Maximum minute volume, adjustable alarm limit
MV min	Minimum minute volume, adjustable alarm limit
MVsp	Spontaneous minute volume, measured value
MVsp%	Spontaneous minute volume in percent of the overall minute volume, measured value
NIV	Non-invasive ventilation
O ₂	Inspiratory O ₂ concentration, configured value
O ₂ 40 ... 90 PSI	Inlet O ₂ gas supply with a pressure range from 40 to 90 PSI
O ₂ max	Maximum inspiratory O ₂ concentration, adjustable alarm limit
O ₂ min	Minimum inspiratory O ₂ concentration, adjustable alarm limit
P	Inspiratory pause as a percentage of the inspiratory time, configured value
P0.I	Occlusion pressure of the P0.I manoeuvre, measured value
Paw	Airway pressure in general, measured value
Paw - V Loop	'Pressure vs. volume' loop
Paw - Peso Loop	'Pressure vs. Peso' loop
PEAK	Peak ventilation pressure
PEEP	Positive end-expiratory pressure, configured value
PEEPfinder	Low-flow PV manoeuvre to determine a secure window for the ventilator settings
PEEP max	Maximum positive end-expiratory pressure, adjustable alarm limit
PEEP min	minimum positive end-expiratory pressure, adjustable alarm limit

PEEPi	Intrinsic PEEP during spontaneous breathing, measured value
PEEPi (es)	Intrinsic PEEP (determined by means of oesophageal pressure measurement in the spontaneously breathing patient)
P exp. (es)	(expiratory) oesophageal pressure, measured value
P insp. (es)	(inspiratory) oesophageal pressure, measured value
Peak (es)	(maximum) oesophageal pressure, measured value
Pmin (es)	(minimum) oesophageal pressure, measured value
PMC	Point of maximum curvature
Pmax	Upper pressure limit, configured value
Pmin	Lower pressure limit, configured value
Pmean	Mean airway pressure, measured value
Pmin	Minimum airway pressure of the last breath, measured value
Plimit	Safety pressure and adjustable alarm limit
Pmean max	Maximum mean airway pressure, adjustable alarm limit
Pmean min	Minimum mean airway pressure, adjustable alarm limit
Pinsp	Inspiratory pressure, configured value
POB	Power of Breathing, total work of breathing done in one minute (work performed by the ventilator and by the patient): similar to WOB per minute
POB spont. (es)	Power of Breathing combined with the Peso measurement, measured value, work expected to be done by the patient in one minute (determined by an end-inspiratory manoeuvre): similar to WOB spont. per minute
POB spont.	Power of spontaneous breathing combined with the PAPS mode, work expected to be done by the patient in one minute (determined by an end-inspiratory manoeuvre): similar to WOB spont. per minute
Ppeak	Peak pressure of the last breath, measured value
Pplateau	Plateau pressure, measured value
Pplateau max	Plateau pressure, adjustable alarm limit
PpEEP	Positive end-expiratory pressure, measured value
PS	Pressure support, configured value
PS Endflow	Criterion for stopping the inspiratory phase of the spontaneous breathing activity, configured value
PS Ramp	Time between PEEP and PS pressure level, configured value
PS TImax	maximum inspiratory time with pressure support
R	Resistance of the respiratory system plus the patient, measured value

Ramp	Time between lower and upper BiLevel, configured value
RCexp	Expiratory time constant, measured value
R exp.	Resistance
Ref. Loop	Reference loop
Recr. PEEP	PEEP during recruitment, configured value
Recr. time	Recruitment time, configured value
RSBI	Rapid shallow breathing index
SAT	Spontaneous awakening trial
SBT	Spontaneous breathing trial
Ser. No.	Serial number
SpO ₂	Non-invasive measurement of blood oxygen level, measured value
SW y.z.z.x	Software revision number
SwitchFlow	Optional switching criterion for auto release with PC-APRV
t	Time in general
T _{insp}	Inspiratory time, configured value
T Flow	Duration of the active inspiratory phase
T _{plateau}	Duration of the plateau during the inspiratory phase (No-flow phase)
Trach.	Tracheal tube
Trigg	Flow or pressure trigger required for synchronisation of a breath, configured value
TPP (es)	Transpulmonary pressure, measured value (airway pressure in cmH ₂ O minus oesophageal pressure measurement)
TPP i (es)	Transoesophageal pressure at the end of the inspiration phase (Plateau minus P _{insp} (es)), measured value
TPP e (es)	Transoesophageal pressure at the end of the expiration phase (PEEP minus P _{exp} (es)), measured value
Δ TPP (es)	Transpulmonary Driving Pressure (mbar)
VT _{alv}	Alveolar volume as part of the expiratory tidal volume
VT _{alv} (%)	Alveolar volume as a percentage of the expiratory tidal volume
VT _{ds}	Anatomical dead space as part of the expiratory tidal volume
VT _{ds} (%)	Anatomical dead space as a percentage of the expiratory tidal volume
V'CO ₂	Measured volume of the eliminated CO ₂ per minute
VT	Tidal volume, configured value
UIP	Upper inflection point

Vtrap	Calculated trapping volume with prolonged exhalation (expiratory hold manoeuvre)
Vol	Volume in general, measured value
Vt max	Maximum tidal volume, adjustable alarm limit
Vt min	Minimum tidal volume, adjustable alarm limit
VT _e	Expiratory tidal volume, measured value
VT _e spont.	Share of spontaneous breathing in expiratory tidal volume, measured value
VT _i	Inspiratory tidal volume, measured value
VT/IBW	Calculated, ideal body weight
V - Flow Loop	'Volume vs. flow' loop
WOB	Work Of Breathing, weaning manoeuvre
WOB (es)	Work of breathing (inspiration), measured value
WOB spont.	Work of breathing performed by the patient (share of the total work of breathing)
WOB vent	Work of breathing performed by the ventilator (share of the total work of breathing)
 or AC	Alternating current
 or DC	Direct current

6 Preparing the system for use

6.1	Power supply	62
6.1.1	Mains supply	62
6.1.2	Internal power supply (rechargeable battery)	62
6.2	Gas supply	64
6.3	Switching power on and off	65
6.3.1	Automatic patient detection APD	65
6.4	Power up test	65
6.5	System test	67
6.5.1	Select the patient category	67
6.5.2	Performing a system test	68
6.6	Leakage test	70

6.1 Power supply

6.1.1 Mains supply

Connect the ventilator to the mains supply. The power indicator of the ON button on the front panel turns green.

Remark | Only use the original power cord.

Remark | Set up the ventilator so that it can be easily disconnected from the mains supply at any time.

Remark | The fan is always switched on whenever the device is connected to the mains supply (safety precaution because oxygen leakage may occur).



Warning

Do not use the power cable if it is damaged.



Warning

For safety reasons operation with an extension cable and/or a multiple socket outlet is not permitted.



Warning

To avoid the risk of electric shock, this device must only be connected to a power supply with a protective earth conductor.

The power cord is protected against accidental disconnection. This retainer closes automatically when the cord is plugged into the power input.

To disconnect elisa 300 / elisa 500 from the power supply, first release the red locking mechanism at the mains plug. Then remove the mains plug.

6.1.2 Internal power supply (rechargeable battery)

elisa 300 / elisa 500 is equipped with an internal power supply which ensures continued operation if the mains supply fails or during intra-hospital patient transports. If the mains supply fails, a low-priority alarm is triggered. The operating time on battery power depends on the number of inserted batteries, on the accessories in use, and on the selected ventilation parameters. Please refer to chapter 12.3 “Supply” for more information.

The integrity and capacity of the internal power supply are monitored and integrated in the alarm management. When the remaining operating time on battery power is less than 10 minutes, a low-priority alarm will be released (yellow), which is followed by a high-priority alarm (red) for a battery run time of less than 5 minutes (also refer to chapter 9.4 “Alarm messages during operation”).

To extend the operating time, the screen brightness is automatically reduced when the ventilator runs off battery power.

If the device is connected to the mains supply, the inserted batteries are automatically charged.

Remark

Battery charging while the ventilator is operating does not affect the ventilation.

Remark

A battery that has not been fully charged is also charged when the device is switched off but connected to the mains supply. In this case, the fan in the device is switched on.



Warning

Improper handling of the battery can pose a risk to the user and/or patient!



Warning

Protect the battery against heat, direct sunlight, and contact with liquids.



Caution

Only use original batteries.



Warning

Patient transport may only be carried out if the internal power supply is sufficiently charged! Replace the battery if its capacity is insufficient!

Remark

Battery life can vary depending on the operational demand (respiratory rate, ventilation mode, etc.).

Remark

For test purposes of the internal supply system, the ventilator can be operated with a test lung. After disconnection from the mains, ventilation must continue without interruption and the “power failure” alarm must be triggered.

Remark | The batteries used have a service life of 500 charge cycles.

6.2 Gas supply

Connect the elisa 300 / elisa 500 O_2 gas inlet to an O_2 gas supply that meets the requirements indicated in the technical specifications.

Remark | Technical details on gas supply can be found in chapter 12.3 “Supply”.

The current data of the connected gas supply can be reviewed any time during ventilator operation.



Warning

Only use gas supply tubes that meet the local standards. A faulty O_2 supply can pose a risk to the patient.



Warning

Ensure that only dry and clean gas is used. Water, oil or particles entering the device can damage the device and endanger the patient.

If in doubt, provide suitable water traps and/or oil separators.

elisa 300 / elisa 500 has been designed to allow operation without O_2 supply at any time. In this case, AIR will be supplied by the turbine integrated in the device.

If O_2 is not available for the system test, the absence of O_2 can be confirmed and the system test can be carried out all the same. The test steps for the missing O_2 are skipped. After a system test without oxygen, the value for FiO_2 is automatically set at 21%.

If FiO_2 is set to a value greater than 21% during the ventilation procedure, an alarm will be displayed to indicate that O_2 is missing.

To view information about the available gases, press the “System” button and select the “Gases” tab.

Remark

If the missing O_2 is connected during operation, the device automatically switches to operation with oxygen.

The information that the system test was carried out without O_2 remains displayed until the system test is repeated.

6.3 Switching power on and off

Switching power on

If elisa 300 / elisa 500 is connected to the mains supply, the ON button is green. The device can be switched on at any time if the power supply is sufficient.

Switching power off

elisa 300 / elisa 500 can only be switched off while the system test screen is displayed or when it is in standby mode. To terminate a ventilation procedure, first touch the buttons “Ventilation”, “Stop ventilation” and “Enter”; finally confirm the displayed prompt. The device is in standby mode now. Then, to definitely switch off elisa 300 / elisa 500, press the “Enter” button.

6.3.1 Automatic patient detection APD

Switching off during ventilation (APD)

The APD function, if enabled, prevents activation of the “Stop ventilation” button while the patient is ventilated. The tubing system must be disconnected first. The ventilator detects the disconnection and the dimmed “Stop ventilation” button is enabled. Press this button and the “Enter” button, and then confirm the following prompt to terminate ventilation; this puts the device in standby mode. Then, to definitely switch off elisa 300 / elisa 500, press the “Enter” button.

Remark

If the ventilation is performed without PEEP or with a low PEEP, the APD function may be technically limited. It may be necessary to increase the byflow or PEEP before the device can be switched off.

6.4 Power up test

The power up test is a test of the hardware and software modules whose function is relevant for the safety concept and the supply. For safety reasons it is not possible to bypass this test.

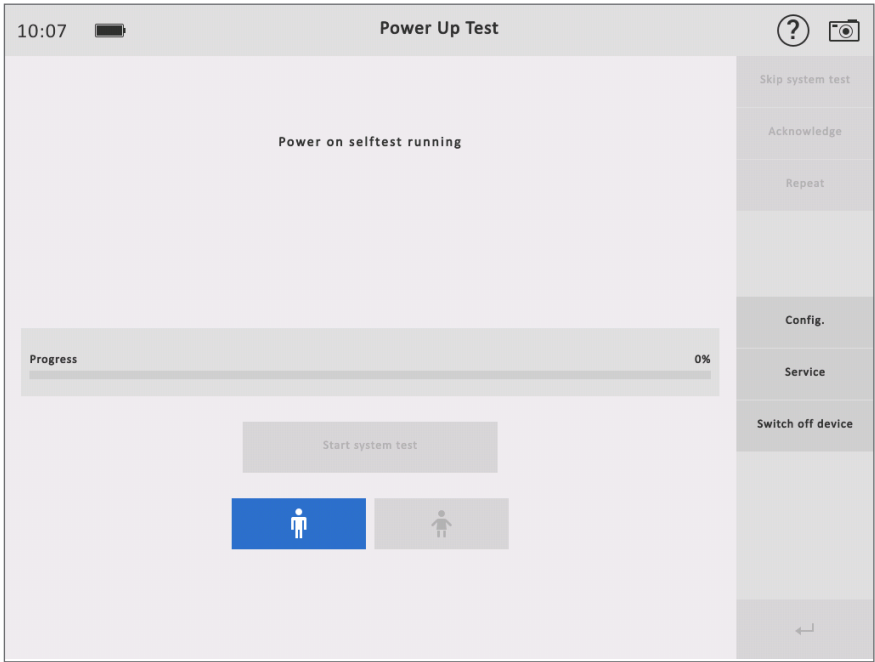
During the power up test the device checks the signalling devices:

Audible: The device emits two consecutive alarm tones.

Visual: The alarm indicator of the control unit blinks briefly yellow and red.

If a malfunction is identified during the power up test, a message with an error code and short instructions is displayed. If you acknowledge the error (“Acknowledge” button), the power up test will be repeated. If you decide not to use the device, press the “Switch OFF device” button to switch the device off.

All entries must be confirmed with the Enter button.



The “Configuration” and “Service” functions are also available.

The system test screen appears after a successful power up test.

Remark | For a list of all alarm messages during the power up test, please refer to chapter 9.5 “Error messages during power up test”.

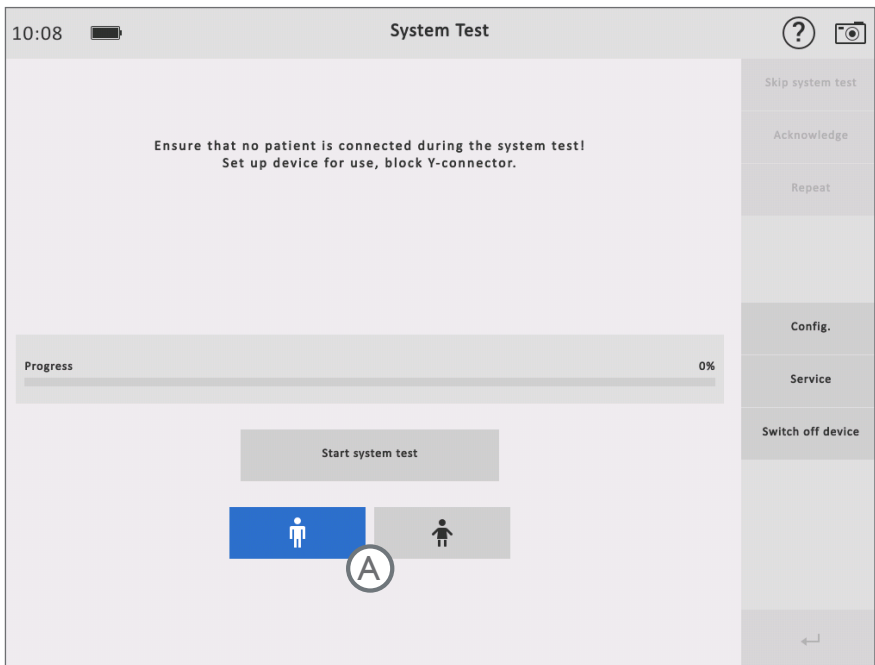
6.5 System test

During the system test, the device checks the ventilation functions and the alarm system. For the system test, the device must be equipped with the breathing circuit and components required for the planned ventilation procedure.

From the system test screen, you can also access the functions “Configuration”, “Service” and “Switch off device”.

6.5.1 Select the patient category

Select the patient category (A). You can choose between “Adults” and “Children”.



The choice of the patient category affects the following functions:

- default parameters
- alarm limits
- dynamic behaviour of the ventilation control

Please refer to chapter 13 “Default parameters” for details on parameters and limit values.

The ventilation procedure must be stopped before the patient category can be changed. Then press the “Functions” button, select the system test menu on the “System test” tab and tap the “Start system test” button.

The device performs the power up test and after that, you can select another patient category. Connect the appropriate breathing circuit and components and perform the system test. Then you can start ventilating a patient of the new patient category.

6.5.2 Performing a system test

Set up elisa 300 / elisa 500 with the breathing circuit and all accessories used during ventilation.



Caution

Check the secure fit of the installed valve bar before performing the system test.



Warning

Before starting the system test, check that the breathing circuit appropriate for the selected patient category is connected to elisa 300 / elisa 500. Otherwise, the ventilation parameter settings may be inappropriate, which may pose a risk to the patient.

Close the Y-connector of the ventilation tube and start the system test by tapping the “Start system test” button.

The system test lasts approx. 45 seconds. The remaining test time is displayed on the screen.

Open the Y-connector when instructed to do so. The device automatically recognises when the Y-connector has been opened and continues the system test.



Caution

Always open the circuit directly at the Y-connector to avoid an incorrect evaluation of the expiratory resistance.



Warning

Never carry out a system test if a patient is connected to the device.

After a successful system test, a summary of the measured compliance, resistance, leakage and nebulizer flow values is displayed for a few seconds. Then the display automatically enters the standby mode.

To review the system test information at any time, tap the “System” button and select the “System test” tab.

Remark

If a pneumatic nebulizer set was not connected during the system test, the most recently measured nebulizer flow with the notification “last value” is displayed. The values for the nebulizer flow depend on the type of nebulizer set used.

If a malfunction is identified during the system test, a message with an error code and further information as well as short instructions appear. Either press the “Acknowledge” button to continue the system test, or correct the malfunction and press the “Repeat” button. Alternatively, you can press the “Switch off device” button.

All entries must be confirmed with the Enter button.

After the system test, the ventilator switches to the standby mode.

In emergencies, when there is no time for the system test, you can skip it (“Skip system test” button). Ventilation can be started within approx. 15 seconds of switching the device on (i.e., on completion of the power up test) in this case.



Warning

If a system test is skipped, the ventilator will use the measurements of the most recent system test. If the installed accessories are very different from the components of the last setup, the ventilation parameters may deviate. This may pose a risk to the patient!

Remark

After changing the patient category, it is not possible to skip the system test.

Remark

The compliance and resistance of the connected breathing circuit are determined during a system test and compensated during ventilation. If the resistance exceeds 6 mbar/l/s and/or the compliance exceeds 3 l/mbar, the system test is terminated with an error message.

Remark

For a list of all alarm messages during the system test, please refer to chapter 9.6 “Error messages during system test”.

6.6 Leakage test

After replacing the breathing circuit, this test can be carried out without switching the device off; the characteristics of the breathing circuit are determined in this test and the appropriate compensation is activated. In the “System” submenu, select the “Leakage test” tab. This tab can only be selected when the device is in standby.

The device starts the power up test; the system test can be started afterwards. The results are presented in the “System” menu on the “System test” tab.

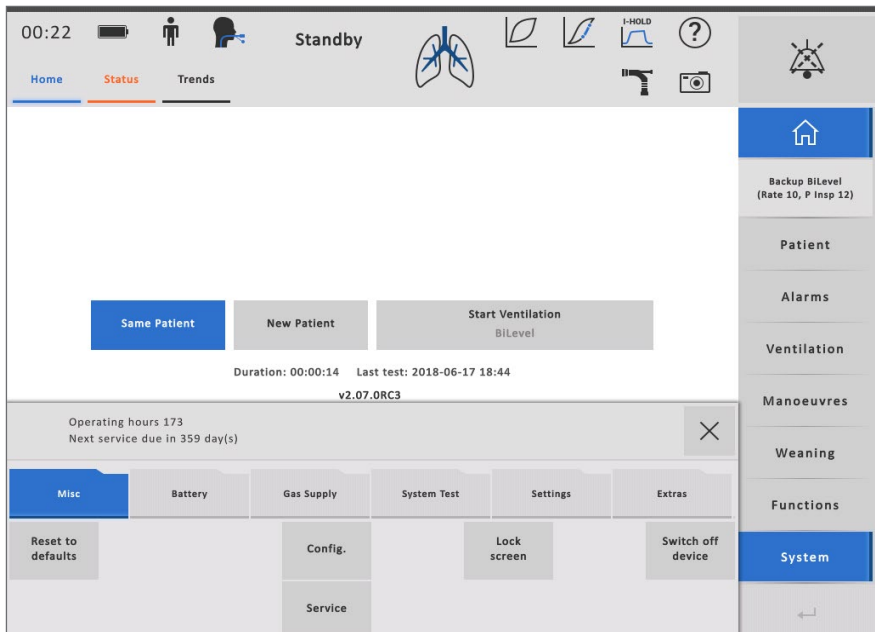
7 Operation

7.1 Standby mode	73
7.1.1 Battery symbol	75
7.1.2 Patient symbol	75
7.1.3 Select patient interface	75
7.1.3.1 Tube compensation	76
7.1.4 Dynamic view of the lung	78
7.1.5 Shortcuts:Toolbox	78
7.1.5.1 Help function	79
7.1.5.2 Screenshot	79
7.1.6 Home	79
7.1.7 Status	80
7.1.8 Trend view 1	80
7.1.8.1 Search function to define a time window	81
7.1.8.2 Graphic trend of selected measurements (configurable)	81
7.1.8.3 Parameters (configurable)	82
7.1.8.4 Tabular trend (configurable)	82
7.1.8.5 Trend update	83
7.1.9 Trend view 2	83
7.2 Selection “Same Patient” / “New Patient”	84
7.2.1 Default ventilation	85
7.3 Ventilation	86
7.3.1 Set ventilation mode	87
7.3.2 Change ventilation mode	87
7.3.3 Set ventilation parameters	88
7.3.4 Trigger	89
7.3.5 Backup ventilation	89
7.3.6 Set alarm limits	90
7.3.7 Overview of alarm limits	91

7.3.7.1 Ventilation alarms	91
7.3.7.2 Gas	91
7.3.7.3 Other alarms	92
7.3.7.4 Alarm limits for non-invasive ventilation	92
7.3.8 Drug nebulization	93
7.3.9 Start ventilation / Stop ventilation	93
7.3.10 Configuration options on the ventilation screen (end user)	94
7.3.10.1 Curve display (unit of measurement as configured)	94
7.3.10.2 Trend graphs / compressed trend graphs	95
7.3.10.3 Data table / short data table	95
7.3.10.4 Loops	95
7.3.10.5 Fastwean / Fastprotect	95
7.4 Settings under “System”	96
7.4.1 Reset to defaults	96
7.4.2 Lock and unlock the screen	96
7.4.3 Battery	96
7.4.4 System test	97
7.4.5 Settings	97
7.4.5.1 Date / Time	97
7.4.5.2 Display brightness	97
7.4.5.3 Alarm volume / brightness	98
7.4.5.4 Extras	99
7.5 Service	99

7.1 Standby mode

The entire patient ventilation protocol can be pre-configured and the procedure started in the standby mode.



Remark

All ventilation-relevant alarms are inactive in the standby mode. Supply and device alarms are suppressed in the standby mode and are only displayed as a message with the alarm-pause symbol in the alarm window. However, these alarm management provisions do not include the power supply alarms.

Depending on the configuration of your device, you have access to the following settings/parameters/manoeuvres:

Header (symbols)

Battery	Number of batteries, charge level
Patient	Patient data
Interface	Interface options, tube compensation
Ventilation mode	Currently selected ventilation mode
Lung icon	Dynamic view of the lung
Toolbox	Panel with up to 7 user-configured functions/manoeuvres and the Help function

Header of ventilation screen

Home	Main screen Additional views depending on configuration
Status	Status messages of the device Current interface configuration
Trends	Trend data of the device

Side bar (buttons)

Patient	Patient data Interface options
Alarms	Ventilation alarms Sensor alarms Additional alarms Delays
Ventilation	Ventilation modes (depending on configuration) Ventilation parameters Stop ventilation Change mode
Manoeuvre	Insp. Hold Exp. Hold Sigh Manual breath Recruitment PEEPfinder
Weaning	SAT SBT P0.I WOB
Functions	Nebulizer CO ₂ sensor (Masimo or LeoCap) Multi-gas sensor LeoLyzer AnaConDa Cuffscout (elisa 500 only) Peso (elisa 500 only) IAP (elisa 500 only) ASR O ₂ flush Hygiene SpO ₂ sensor
System	Miscellaneous Battery Gas supply System test Settings Extras

7.1.1 Battery symbol

You open the “Battery” information window by tapping the symbol in the header. For more information, please refer to chapter 7.4.2 “Battery”.

7.1.2 Patient symbol

Open the menu for input of the patient data by tapping the symbol in the header or by selecting the “Patient” button in the button bar.

In the “Data” menu, enter the following data for the patient to be ventilated:

- Height
- Weight
- Age
- Gender

You can also access the “Patient interface” menu; see next chapter.

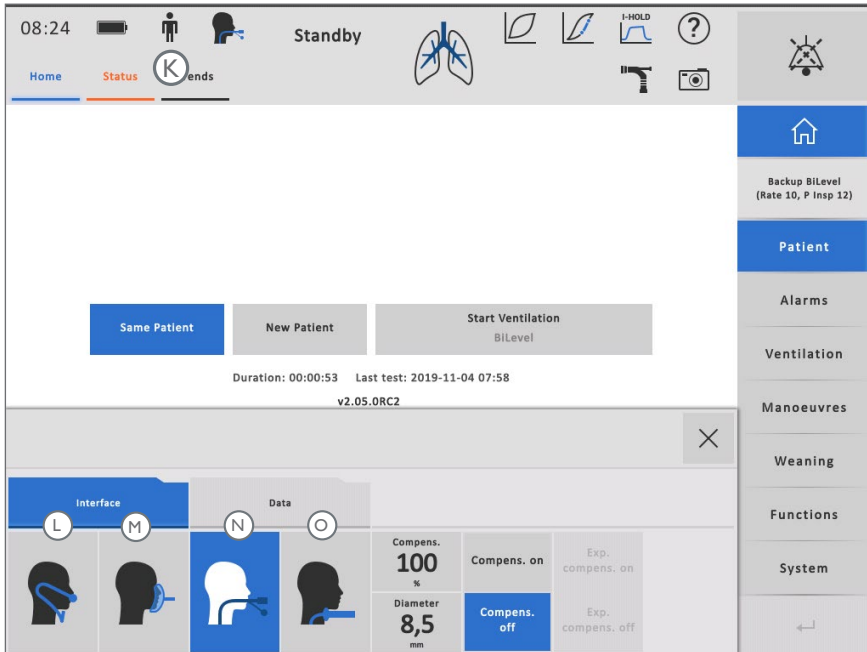
7.1.3 Select patient interface

By touching the “Patient interface” symbol in the header (**K**) you can open the patient interface menu at any time and select a different patient interface. Options that were deactivated on the configuration level are unavailable.

These are your options:

- L** HFOT (nasal CPAP: non-invasive)
- M** Mask (non-invasive)
- N** Endotracheal tube (invasive)
- O** Tracheostomy tube (invasive)

To switch between invasive and non-invasive ventilation, however, you have to enter the standby mode first. First terminate the ventilation procedure by pressing the “Ventilation” button and selecting “Stop ventilation”. Press “Enter” and then confirm the displayed prompt. This puts the device in standby mode and you can choose between invasive and non-invasive ventilation.



In the case of non-invasive ventilation, the displayed expiratory volume may differ from the actual volume applied due to leakage.

7.1.3.1 Tube compensation

elisa 300 / elisa 500 offers a tube compensation feature which can be activated to reduce the increased tube-related work of breathing of the spontaneously breathing patient.

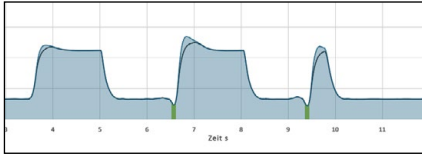
Tube compensation is adjustable by entering the tube size, by the degree of compensation and by switching the expiratory tube compensation on or off.

Tube compensation reduces the tube-related work of breathing during spontaneous breathing by compensating the inspiratory and (alternatively) expiratory resistance.

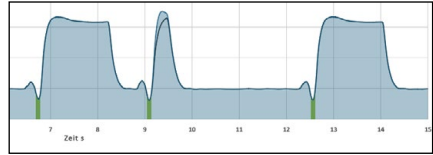
Remark

Tube compensation is deactivated and cannot be accessed when mask ventilation is selected.

Depending on the configured option, the compensation applies only to the spontaneous breaths or also to the pressure-controlled mandatory breaths.



Tube compensation for pressure-controlled and spontaneous breaths



Tube compensation only for spontaneous breaths

Remark

In the ventilation of neonates and infants, the compensation of the tube-related work of breathing activated for the mandatory breaths may increase the tidal volume.

Set the desired degree of compensation in percent and the internal diameter of the tube in millimetres.



Warning

The tube diameter must always be set to the size of the tube used. A tube diameter that is too small can lead to overcompensation and oscillation during ventilation.

Remark

The internal diameter is printed on the outside of the tube or its packaging.

Inspiratory or expiratory tube compensation can be activated once the degree of compensation and tube diameter have been set.

When the tube compensation is activated, the device calculates the tracheal pressure at the Y-piece before the tube and the pressure is displayed by an additional curve. If the curve is not visible, it may have been deactivated in the configuration menu.

Remark

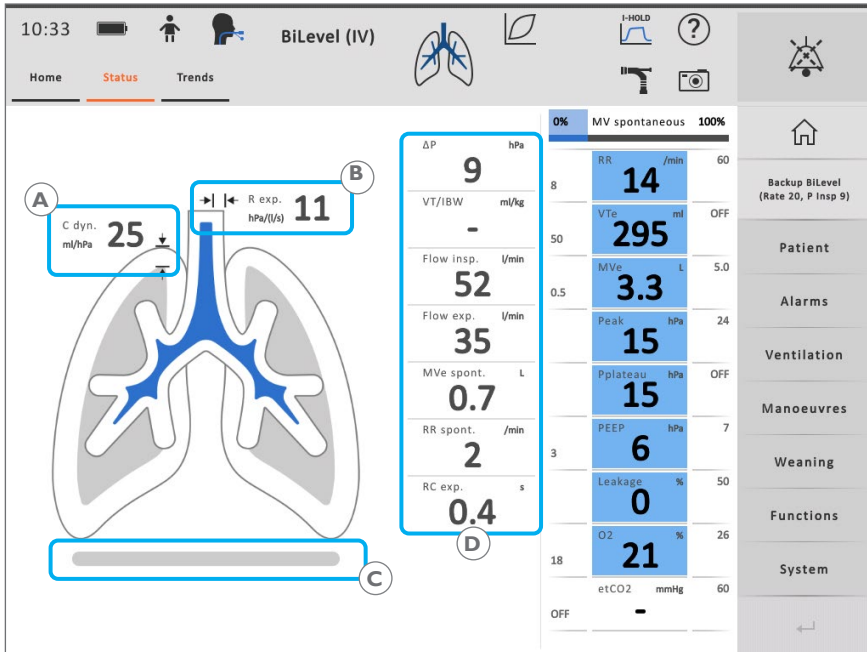
If the compensation values are high, the activation of expiratory compensation can lead to auto-triggering of the pressure support. In this case, a higher trigger sensitivity should be selected.

Remark

Visible overshoots and undershoots are not transferred to the patient via the tube.

7.1.4 Dynamic view of the lung

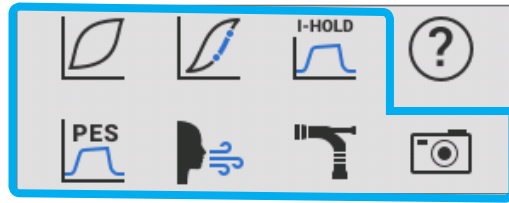
By tapping the lung icon in the header, you open the dynamic view of the lung. This view allows the compliance, resistance and trigger behaviour to be assessed easily and quickly.



- A Dynamic compliance C dyn.
- B Resistance R exp.
- C Representation of the diaphragm
- D Tabular data (configurable, see chap. 7.3.10.3 Data table for values)

7.1.5 Shortcuts:Toolbox

Via the shortcuts in the Toolbox you have direct access to individual functions of elisa 300 / elisa 500. On the configuration level, functions can be assigned to 7 buttons in the Toolbox; this does not affect the Help function.



7.1.5.1 Help function

View information on ventilation modes and parameters (see chapter 5.1.2.9 “Help function”).



7.1.5.2 Screenshot

The Screenshot function allows you to make a copy of the visible items displayed on the screen in the form of a digital image. A USB stick is needed for using the function.



The USB stick is plugged into one of the USB ports on the underside of the device. The device will detect the USB stick and activate the button. When the button is pressed, an audible feedback signal confirms that the screenshot has been made and saved on the flash drive.

If another USB stick is connected to the second USB port, a window opens where the USB stick to be used can be selected.



Only approved accessories may be connected to the USB interface (refer to separate accessory list).

7.1.6 Home

Touch this button to return to the main screen.



7.1.7 Status

Touch this button to view the status messages of the device. These messages provide up-to-date information regarding active manoeuvres, the results of the last system test, and general status information.

Whenever a new event is added to the status list, the tab turns yellow:

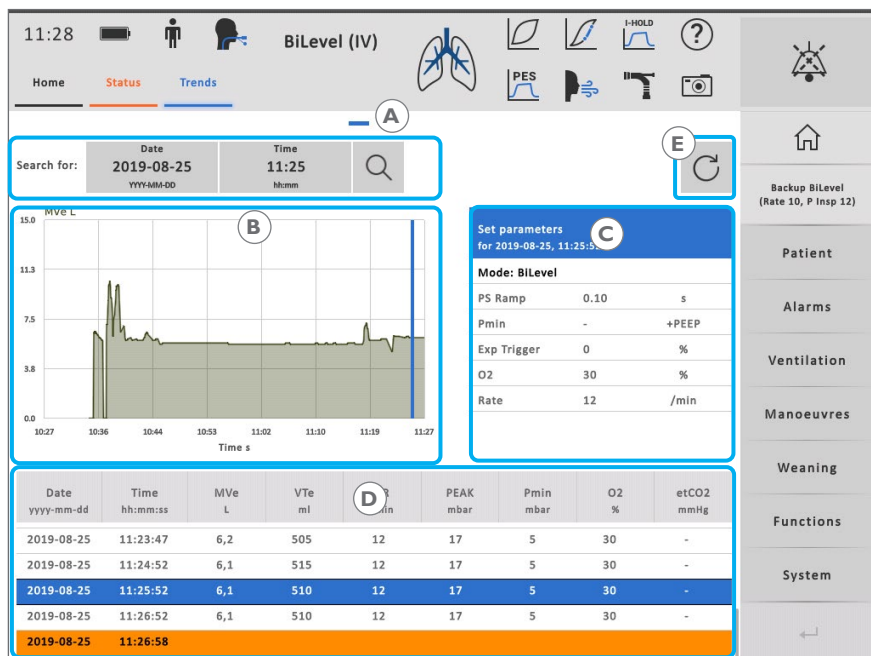
The second “Status” view (accessible by swiping) shows the current configuration of the external interfaces.

7.1.8 Trend view I

The trend data can be retrieved via the “Trends” tab.

The first trend view provides the following information/functions:

- A** Search function to define a time window.
- B** Graphic trend of selected parameters (configurable)
- C** Measured values (configurable)
- D** Tabular trend (configurable)
- E** Trend update



7.1.8.1 Search function to define a time window

Area **(A)**: Enter date and time, then touch the “Magnifying glass” to view the trend data of a given time window.

You can also review the values for a particular time by tapping in the range on the displayed curve.

7.1.8.2 Graphic trend of selected measurements (configurable)

Area **(B)**: By tapping and holding any point in the trend range, you open the configuration menu. Measurements can be assigned to the following axes.

Y-axis left: 1st parameter

Y-axis left: 2nd parameter

Y-axis right: 1st parameter

Possible measurements (unit of measurement as configured)

none	Pplateau	Leakage	P exp. (es)
MVe	Pmean	R exp.	P insp. (es)
VT _e	PEEP	C dyn	TPP e (es)
RR	PEEP _i	I:E	TPP i (es)
RR spont.	V _{trap}	RSBI	Δ TPP (es)
PEAK	MVe spont.	VT _e spont.	Δ P
etCO ₂	C. stat	VT/IBW	MVe mand.
Flow insp.	Tplateau	VT _{ds}	P min
Flow exp.	WOB spont.	VT _{ds}	VT _i
Flow insp.	WOB vent	VT _{alv}	MVe spont. %
Flow exp.	Cuff pressure	VT _{alv}	PEEP _i (es)
O ₂	inCO ₂	P min (es)	V _{trap} spont.
MIP	Peak (es)	WOB (es)	inISO
P0.1	V'CO ₂	POB spont.	exISO
RC exp.	IAP	POB spont. (es)	inSEV
RR mand.	MV Leakage	POB	exSEV
Δ P (es)	Δ Peso/Δ PAW	HR	SpO ₂

The following settings for the X-axis scaling are available:

1 hour	4 hours	12 hours	2 days
2 hours	8 hours	1 day	7 days

7.1.8.3 Parameters (configurable)

Area (C): Choose up to 7 parameters for display from the following options:

Rate	PEEP	Trigger	PS Endflow	SwitchFlow
T insp	P insp	PS Ramp	Byflow	Tplateau
VT	Insp. Ramp	Pmin	T exp	MV target
I-Flow	PS	O ₂	Vol. supp.	VT/IBW
Pmax	PS Tlmax	Exp. trigger	Flow supp.	Compens. C
Compens. R	Exp Ramp mand	Exp Ramp spont		

7.1.8.4 Tabular trend (configurable)

Area (D): Depending on the configuration, this view presents the ventilator settings, the logged changes to the ventilator settings, status information, active alarms and the measured patient parameters in tabular form.

By default, the tabular trend is displayed with a resolution of one minute. The trend display can be configured for different user requirements. By touching and holding any point on the value bar, you open a menu where the following parameters can be configured:

- **Resolution**

Every breath;

1, 5, 15, 30 or 60 minutes;

2, 4, 12 or 24 hours.

- **Screen**

Show / Hide Measurements

Show / Hide Events

Show / Hide Alarms

- **Ventilation parameters**

Choose up to 7 parameters for display from the following options:

General parameters (unit of measurement as configured)

MVe	Pmean	Leakage	VT/IBW
VT _e	PEEP	R exp.	Δ P
RR	VT _i	C stat.	Flow insp.
PEAK	MVe spont.	RC exp.	Flow exp.
P min	MVe spont. %	RSBI	MVe mand.
Pplateau	RR spont.	VT _e spont.	I:E
Flow insp.	Flow exp.	C dyn.	MIP
Tplateau	MV Leakage	P0.1	RR mand.
Cuff pressure	HR	SpO ₂	

Gas (unit of measurement as configured)

O ₂	etCO ₂	inCO ₂	VTalv (ml)
VTds (ml)	VTds (%)	VTalv (%)	inISO
inSEV	exSEV	V'CO ₂	exISO

Index (unit of measurement as configured)

PEEPi	P exp. (es)	TPP e (es)	PEEPi (es)
Vtrap	P insp. (es)	TPP i (es)	Δ TPP (es)
POB	POB spont. (es)	POB spont.	IAP
WOB (es)	WOB spont.	WOB vent	Pmin (es)
Peak (es)	Δ P (es)	Δ Peso/Δ PAW	

7.1.8.5 Trend update

Area (E): When you press the Update button, you update the displayed trend data with the continuously acquired data and values.

7.1.9 Trend view 2

Trend view 2 continues the tabular trend of view 1. Any modifications of the configuration of this view also affects the first trend view. You scroll through the measured values by a vertical swiping gesture.

11:28 BiLevel (IV)

Home Status Trends

Search for: Date 2019-08-25 Time 11:26

Date	Time	MVE	VTe	RR	PEAK	Pmin	O2	etCO2
yyyy-mm-dd	hh:mm:ss	L	ml	/min	mbar	mbar	%	mmHg
2019-08-25	11:21:48	Recruitment started						
2019-08-25	11:22:47	5,4	515	12	17	5	30	-
2019-08-25	11:23:47	6,2	505	12	17	5	30	-
2019-08-25	11:24:47	6,1	515	12	17	5	30	-
2019-08-25	11:25:47	6,1	510	12	17	5	30	-
2019-08-25	11:26:47	6,1	510	12	17	5	30	-
2019-08-25	11:26:58							
2019-08-25	11:27:47	6,1	510	12	17	5	30	-

Backup BiLevel (Rate 10, P Insp 12)

Patient

Alarms

Ventilation

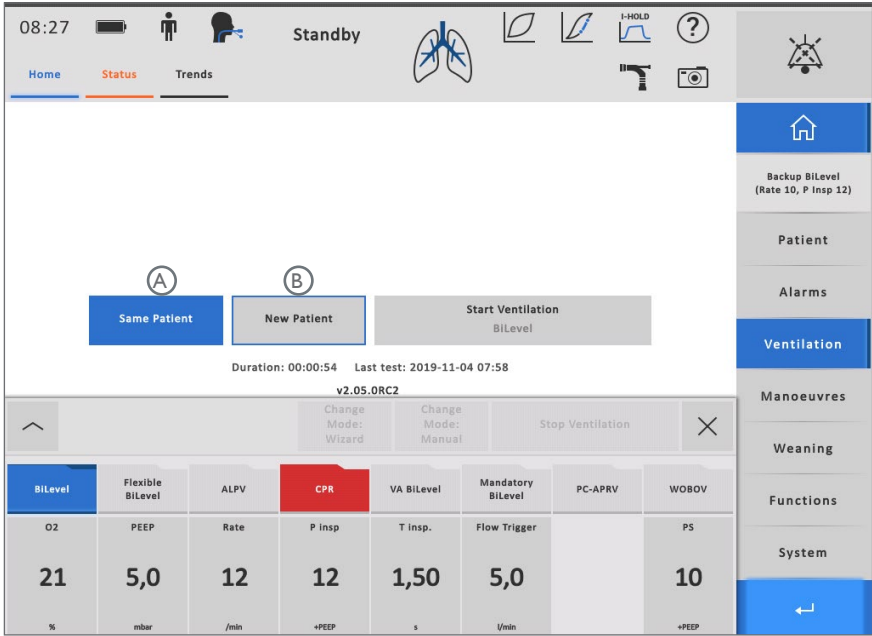
Manoeuvres

Weaning

Functions

System

7.2 Selection “Same Patient” / “New Patient”



By selecting “Same Patient” (A), you continue with the previously selected ventilation mode including all ventilation parameters and alarm limits.

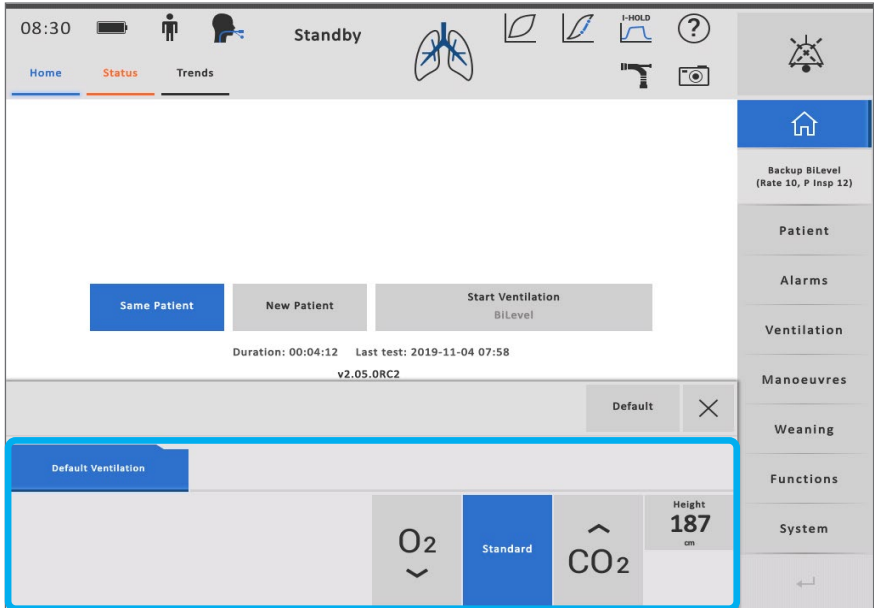
If “New Patient” (B) is selected, the alarm limits, ventilation mode and the ventilation parameters are all reset to the elisa 300 / elisa 500 default values. The automatically activated default ventilation mode is the first mode on the tab bar.

Remark | If the default parameters are adapted to the patient condition prior to starting ventilation, these will be reset to the defaults when “New Patient” (B) is selected.

Remark | After selection of the “New patient”, the alarm tone volume will be set to the level adjusted at the configuration level. The user needs to make sure that the set alarm tone volume is adequate for the clinical setting.

7.2.1 Default ventilation

With the “Default Ventilation” function, parameters will automatically adapt to the patient's clinical requirements at the beginning of the ventilation session. The function is available when you confirm the “New Patient” selection:



Depending on the configuration setting, you enter either the actual weight or the body height. In the configuration menu, you also adjust the target tidal volume in millilitres per kilogram of body weight.

The activated ventilation mode is the mode assigned to the first tab during configuration. The following rules apply:

- For volume-controlled modes: adjustment of the tidal volume based on the entered body weight
- For pressure-controlled modes with a guaranteed volume: adjustment of the tidal volume based on the entered body weight
- For pressure-controlled modes with analysis function activated at the configuration level: adjustment of P_{insp} after a 30-second analysis phase to guarantee the appropriate tidal volume
- For pressure-controlled modes with analysis function deactivated at the configuration level: adjustment of P_{insp} to a fixed value of 10 mbar

The following options and associated values are additionally available for the initial adjustment of PEEP, rate, inspiratory time, and O₂:

	O ₂ ▼	Standard	CO ₂ ▲
	Disease-related hypoxia	Normal ventilation situation	Disease-related hypercapnia
Rate	12 /min	12 /min	16 /min
Tinsp	2.0 s	1.5 s	1.2 s
PEEP	8 mbar	5 mbar	5 mbar
O ₂	100%	50%	50%

Tapping the “Default” button will reset the values: to “Standard” if one of the other two buttons was selected, and to “None” for “Height” and “Weight”).



Warning

Please review the parameters and alarm limits set with the default ventilation function.



Warning

When the analysis function is deactivated, the necessary pressure is not determined. Instead, a fixed delta pressure of 10 mbar will be applied.

Remark

For defining the default ventilation parameters in the patient category “Children”, the actual weight needs to be entered. No other options are available in this case.

7.3 Ventilation

The availability of the ventilation modes is determined by the software version and the configuration of your device.

A backup ventilation mode, which completely takes over the patient's ventilation in case of apnoea, is associated with each ventilation mode.



Warning

Make sure that the device appropriate for the respective ventilation modes is used:

Invasive: Endotracheal tube or tracheostomy tube
Non-invasive: Mask
HFOT: Nasal device

Remark

For a detailed description of the ventilation modes, please refer to the separate document “Instructions for Use A – Manoeuvres, Functions, Ventilation Modes”.

7.3.1 Set ventilation mode

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

The backup mode is indicated in the backup mode window.

Open the menu for selection of the ventilation mode with the “Ventilation” button in the button bar. Select one of the preconfigured ventilation modes and adapt the ventilation parameters to the patient's needs (also refer to chapter 7.3.3 “Set ventilation parameters”).

7.3.2 Change ventilation mode

To switch between ventilation modes during ventilation, select the “Ventilation” button in the button bar. Activate the new ventilation mode in the ventilation mode bar, then press the “Change Mode: Manual” button or the “Change Mode: Wizard” button, and confirm the change with the Enter button.

A wizard is available for switching between volume-controlled and pressure-controlled ventilation modes. On the basis of the measured values, the assistant recommends a pressure or a volume setting.

The plateau pressure values measured last, for example, are used to set P_{insp}. With the arrow button  you display the advanced parameters. The number of advanced parameters available depends on the configuration settings.

		Change Mode: Wizard		Change Mode: Manual		Stop Ventilation				Weaning Functions System
BiLevel	VCV	PCV	Proportional PSV	ALPV	CPAP	PAP5	WOBOV			
O2	PEEP	Rate	Vt	T insp	Flow Trigger	Pmax	I-Flow			
30	5,0	12	420	1,50	5,0	35	40,0			
%	mbar	/min	ml	s	l/min	mbar	l/min			

Remark

The “Change Mode: Wizard” function is not available when the current measured values cannot be used as the basis for an automatic switchover. The button is inactive.

Remark

During ventilation, the new ventilation mode becomes active with the start of the next inspiration.


Warning

If the new ventilation mode has more parameters than the previous mode, these will be displayed on a yellow button. Default values are activated for these parameters.
Adapt the parameters to the current patient condition!

7.3.3 Set ventilation parameters



To set the ventilation parameters, open the menu with the “Ventilation” button. Select the parameter that you would like to change. Adjust the value with the selector and confirm your entry with the Enter button.
Use the arrow button  to display more parameters. The number of advanced parameters available depends on the configuration settings.

Remark

For a detailed description of the different ventilation parameters, please refer to the separate document “Instructions for Use A – Manoeuvres, Functions, Ventilation Modes”.

Remark

The adjustment ranges of the ventilation parameters can limit each other and may vary, depending on the situation.
The selector indicates the parameter which is limiting an adjustment range.

To cancel the entry, press the button of the selected parameter once again.

7.3.4 Trigger

The trigger function synchronises the ventilator and the patient. Depending on the selected ventilation mode and patient activities, mandatory ventilation strokes can be initiated via a flow or a pressure trigger, or the pressure support PS can be activated to enable deeper spontaneous breaths. The ventilator detects the patient's attempts to breathe in via the trigger, and the 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 sensitivities, the elasticity of the ventilation tubes could cause a trigger signal (auto-triggering).

Inspirations initiated by the trigger variable are coloured on the pressure curve. Different colours are assigned to mandatory and spontaneous triggers for differentiation.

If the triggered breaths are not coloured, the function may not have been activated. Change the configuration accordingly (to open the menu, tap and keep your finger on the curve) or contact your service technician.

Switching between flow and pressure trigger is done with the selector at the minimum trigger value or at OFF. The indication "Flow" and "Press." is displayed as appropriate. The desired trigger function is available after selection and confirmation.

Remark

When the trigger function is switched off, no pressure support is available in any of the modes to assist spontaneous breathing.

7.3.5 Backup ventilation

A backup ventilation mode, which completely takes over the patient's ventilation in case of apnoea, is associated with each ventilation mode.

Tap the "Backup" button to configure the backup ventilation parameters.

Backup BiLevel
(Rate 10, P Insp 12)

For a list of ventilation modes and their associated backup modes, please refer to the Instructions for Use – Supplement A, chapter A 5.1.1 Backup modes.

The button shows the selected backup mode, the set rate and tidal volume or inspiratory pressure.

By selecting the “No Backup” tab and then “Manual” and Enter, you deactivate the backup ventilation function. When the backup ventilation function is deactivated, the “No backup ventilation” button is highlighted.

Remark

Only some specific parameters can be set in the backup ventilation mode. The other parameters depend on the settings for the normal ventilation mode.

Remark

The apnoea interval, i.e., the time after which backup ventilation is activated, can be set in the ventilation alarms under “Backup ventilation”.

The backup ventilation function can be terminated as follows:

- **manual:** press the backup button again, then press “Manual” and Enter
- **automatic:** set the “Trigger counter” function. With this function, the user specifies the number of successfully triggered spontaneous breaths after which the backup ventilation mode will be terminated and the selected ventilation mode resumed.

7.3.6 Set alarm limits

Several alarms with variable alarm limits are available for adequate monitoring of the patient's ventilation and of the ventilator function.



Warning

Continuously adapt the alarm limits to the therapeutic measures that you need to take for the patient at hand. Particularly when switching between ventilation modes or changing parameters and after using the bronchoscopy function, you need to check the set alarm limits and adjust them when necessary.

Open the menu with the “Alarms” button. The menu is divided into ventilation alarms, sensor alarms, and other alarms. Select the alarm limit that you would like to change. Adapt the value by using the selector and confirm your entry with the Enter button.

To cancel the entry, press the button of the selected parameter once again.

7.3.7 Overview of alarm limits

7.3.7.1 Ventilation alarms

MV max	Upper alarm limit for the expiratory minute volume
MV min	Lower alarm limit for the expiratory minute volume
Vt max	Upper alarm limit for the expiratory tidal volume
Vt min	Lower alarm limit for the expiratory tidal volume
Leakage	Criterion for the "Leakage high" alarm. The percentage describes the leakage rate which is calculated from the total values ($100 \times (TV_i - TV_e) / TV_i$).
Plimit (relative or absolute)	Maximum peak airway pressure
P min	Minimum pressure within a breath
PEEP max	Upper alarm limit for the measured PEEP
PEEP min	Lower alarm limit for the measured PEEP
RR max	Upper alarm limit for the measured respiratory rate
RR min	Lower alarm limit for the measured respiratory rate

Remark

Depending on the selected configuration, the alarm limit for the maximum peak airway pressure PLimit can be set manually or it is linked with the Pinsp setting and adjusted automatically.

7.3.7.2 Gas

+ O ₂ max	Upper alarm limit for the inspiratory oxygen concentration. The difference between the alarm limit and set inspiratory oxygen concentration (O ₂) is maintained if the O ₂ value changes. The alarm criterion can be switched off at the upper end of the adjustment range. In this case, the "O ₂ limit values?" message appears.
– O ₂ min	Lower alarm limit for the inspiratory oxygen concentration. The difference between the alarm limit and set inspiratory oxygen concentration (O ₂) is maintained if the O ₂ value changes. The alarm criterion can be switched off at the lower end of the adjustment range. In this case, the "O ₂ limit values?" message appears.
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

7.3.7.3 Other alarms

RR max_spontan	Upper alarm limit for the measured spontaneous respiratory rate
RR min_spontan	Lower alarm limit for the measured spontaneous respiratory rate
Pmean max	Upper alarm limit for the measured mean airway pressure
Pmean min	Lower alarm limit for the measured mean airway pressure
Pplateau max	Upper alarm limit for the measured plateau pressure
HR (pulse) max	Upper alarm limit for the measured heart rate
HR (pulse) min	Lower alarm limit for the measured heart rate
SpO ₂ max	Upper alarm limit for the measured SpO ₂ concentration
SpO ₂ min	Lower alarm limit for the measured SpO ₂ concentration

7.3.7.4 Alarm limits for non-invasive ventilation

In an effort to prevent false alarms, to reduce the stress level for the ventilated patient due to alarm sounds and to maintain reliable monitoring, the alarm limits need to be adapted to the patient's individual situation.

For the alarms listed below, a delay can be defined, which should take the clinical situation into account. This will cause a delay of the audible and visual alarms:

Alarm delay	Default value	Adjustment range
TVT max	5 s	0–15 s
TVT min	5 s	0–15 s
T P min	10 s	0–30 s
T Backup ventilation	30 s	5–120 s
T Apnoea alarm	20 s	5–60 s
T Leakage high	5 s	0–15 s
T Disconnection	10 s	0–30 s

**Warning**

Depending on the clinical situation, users need to verify the appropriateness of the set alarm limits and delay times, if any, and consider additional monitoring methods (e.g., pulse oximetry).

7.3.8 Drug nebulization

Medication can be nebulized with elisa 300 / elisa 500 by means of a pneumatic nebulizer. The nebulizer can be activated in all ventilation modes. .

Remark

For a detailed description of the nebulizer application, please refer to the separate document “Instructions for Use – Supplement A – Manoeuvres, Functions, Ventilation Modes”.

**Warning**

The use of an externally driven nebulizer can affect the accuracy of the ventilator.

Remark

If the compensation values are high, the activation of expiratory compensation can lead to auto-triggering of the pressure support. In this case, a higher trigger sensitivity should be selected.

7.3.9 Start ventilation / Stop ventilation

To start the configured ventilation mode, select and confirm “Start Ventilation” in the standby mode.

To terminate the ventilation procedure, touch the “Ventilation” button and then select “Stop ventilation”. Confirm with “Enter”. To prevent that the ventilation procedure is terminated inadvertently, a warning is displayed, which must be acknowledged separately.

If configured, the **APD** function prevents the activation of the “Stop Ventilation” button during a ventilation procedure. The tubing system must be disconnected first. The ventilator detects the disconnection and the dimmed “Stop ventilation” button is enabled.

7.3.10 Configuration options on the ventilation screen (end user)

Unless locked on the configuration level, the individual elements of the ventilation screen can also be adapted by the end user.

By selecting “New Patient” and by pressing the “Reset to defaults” button in the “System” menu, all settings will be restored to the values defined on the configuration level.

Open the respective configuration menu by pressing and holding the element you want to adjust.

A colour (11 options) and a style (3 options) can be assigned to each curve. It is also possible to adapt the scales of the X-axis and of the Y-axis.

Different Y-axis scales can be selected for the first and second curves, but the scale of the first curve can also be applied to the second curve.

You can display the following curves:

7.3.10.1 Curve display (unit of measurement as configured)

Y-axis left

Curve 1	Pressure *
	Flow
	Volume
	CO ₂
	Cuff pressure
	Oesophag. pressure
	Pleth
	TPP
	IAP

Curve 2 **	none
	Tube Compensated
	Cuff pressure
	Oesophag. pressure
	TPP

Y-axis right

Curve 1	Pressure
	Flow
	Volume
	CO ₂
	Cuff pressure
	Oesophag. pressure
	Pleth
	TPP
	IAP

Curve 2	none
	Pressure
	Cuff pressure
	Oesophag. pressure
	TPP

* Exception: For the first view (3 live curves), the parameter “Pressure” for the upper curve and the associated colour and style are fixed; they cannot be changed.

** A second curve can only be configured for the upper live curve (pressure).

7.3.10.2 Trend graphs / compressed trend graphs

Configurable values for Y-axis left and Y-axis right: see section 7.1.8.2 under “Possible measurements”

It is also possible to configure the time interval for the X-axis.

The selected time interval will be applied to all trend graphs in all views.

Configuration options:

30 minutes	2 hours	12 hours
1 hour	6 hours	24 hours

7.3.10.3 Data table / short data table

Up to 24 values (up to 6 values for the short data table) can be selected (unit of measurement as configured).

For configurable values, see section 7.1.8.4.

7.3.10.4 Loops

You can display the following loops:

Paw - V	V - Flow	CO ₂ - V	Flow - Ptrach
Flow - Paw	Paw - Peso		

7.3.10.5 Fastwean / Fastprotect

The table below shows the values selectable for the “Fastwean” and the “Fastprotect” display fields:

P0.I	etCO ₂	TPP i (es)
RR spont.	Δ P	TPP e (es)
VT _{spont.}	VT/IBW	Δ TPP (es)
RSBI	Pplateau	WOB spont.
SpO ₂		

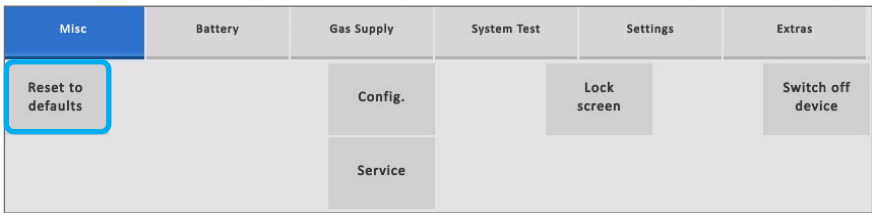
However, it is recommended to choose the following values:

Fastwean:	Fastprotect:
P0.I	Δ P
RR spont.	VT/ IBW
VTe spont.	Pplateau
RSBI	TPP i (es)
	TPP e (es)

7.4 Settings under “System”

7.4.1 Reset to defaults

With “Reset to defaults”, all adjustments made by the end user will be restored to the ward defaults.



7.4.2 Lock and unlock the screen

You can lock the screen (press “Lock screen” button and confirm) in order to prevent unintentional entries.

To unlock the screen, select the padlock symbol; then move it to the coloured circle as prompted.

7.4.3 Battery

Touch the “Battery” tab to open the associated information menu. It provides information about the availability of power sources (one battery or two), capacity of batteries, and the remaining operating time on the internal power supply. A coloured icon (blue or green, depending on the selected screen colour) represent a battery in use.

Remark

In the first 2 minutes after switching on elisa 300 / elisa 500, a minimum operating time on the internal power supply is indicated. Finally, an exact calculation of the remaining time is made on the basis of the current load.

Remark

The remaining time can vary depending on the load. The information is updated in intervals of one minute.

7.4.4 System test

Information about the most recent system test is displayed. Furthermore, you can perform a system test by pressing the “Start system test” button.

7.4.5 Settings

The “Settings” menu is available in the standby mode.

To change a setting, touch the appropriate button, set the new value with the selector, and confirm the new value with the Enter button.

7.4.5.1 Date / Time

Manual setting of date and time. This function is not available during ventilation when the field is dimmed.

7.4.5.2 Display brightness

Misc	Battery	Gas Supply	System Test	Settings	Extras
Date 2018-06-21 YYYY-MM-DD Time 00:46:51 hh:mm:ss	Day brightness 80 % Night brightn. 20 %	Day mode Night mode	Night screen on Night screen off	Alarm brightn. 20 % Volume 40 %	

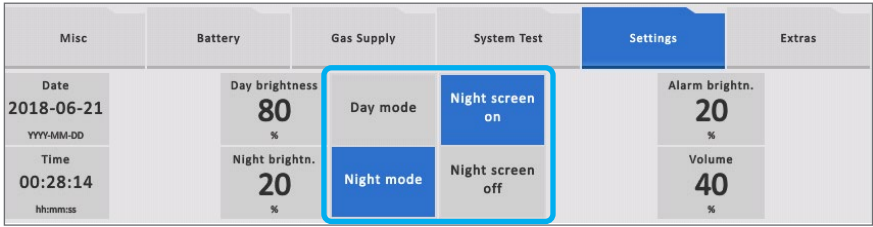
The device offers three options for adjusting the screen brightness:

- **Day mode**
- **Night mode**
- **Night screen**

Using the selector, you can preset a brightness level for the day mode and for the night mode: the day brightness and the night brightness. By selecting the day or night mode you activate the corresponding brightness level.

If an alarm of medium priority or above occurs, the display brightness is automatically set to the level of the day brightness.

In addition, the “Night screen on” option activates a dimmed screen display with a reduced number of data. This option can be selected only when the device is in the night mode.



After activation of the “Night screen on” button, the night view will come on within 30 seconds. The display switches back from the night screen to the night mode if one of the following conditions occurs:

Tapping the screen	30 seconds after the last input the display switches back from the night mode to the night screen.
Active alarms	If, after acknowledging an alarm, no alarm occurs for 30 seconds, the display switches back from the night mode to the night screen.
Manoeuvre in progress (The night screen remains active during automatic manoeuvres such as “P01” or “Sigh”.)	30 seconds after the end of the manoeuvre the display switches back from the night mode to the night screen.

The night view can only be activated during a ventilation procedure. If no ventilation is in progress, the Night screen button is dimmed and cannot be selected.

7.4.5.3 Alarm volume / brightness

Alarm volume

During normal operation (no alarms), elisa 300 / elisa 500 continuously measures the ambient noise level. When the ambient noise is very loud and an alarm occurs, the volume of the alarm tone is automatically adapted to the ambient noise level (Auto Volume ON). The maximum value is 20% above the set value in this case, but not more than 100%.

However, the volume of the alarm tone will never drop below the preset value. (A default value for the alarm volume can be preset at the configuration level. If no alarm volume is preset at the configuration level, the default value will be set at 80%.)

When you adjust the alarm tone volume, the ventilator will emit a tone with the actual volume so that a volume suitable for the environment can be selected.

Misc	Battery	Gas Supply	System Test	Settings	Extras
Date 2018-06-21 YYYY-MM-DD	Day brightness 80 %	Day mode	Night screen on	Alarm brightn. 20 %	
Time 00:46:51 hh:mm:ss	Night brightn. 20 %	Night mode	Night screen off	Volume 40 %	



Be sure to select an alarm tone volume that allows you to distinguish between alarm tones and the background noise.

Alarm brightness

With the “Alarm brightness” button, you can adjust the brightness of the alarm indicator.

7.4.5.4 Extras

On the “Extras” tab, you can activate and deactivate the “Bronchoscopy” function (see Supplement A “Functions”).

The tab also contains the button for manual calibration of the paramagnetic O₂ sensor.

7.5 Service

The service menu is available in the system test screen and in the standby mode. It is only intended for authorised service technicians and secured with an access code.

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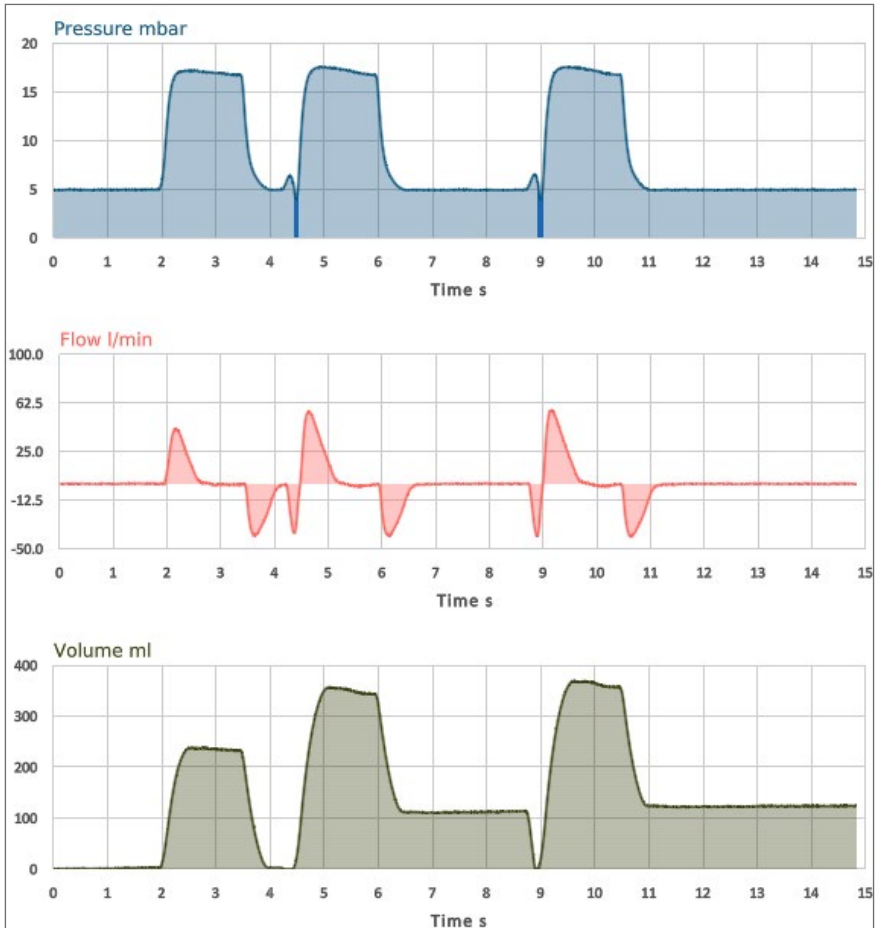
8 Measurements and graphics

8.1	Curve presentation	102
8.2	Instant View window	103
8.3	Loop view	104
8.4	Data table or short data table	105
8.5	Fastwean	106
8.6	Fastprotect	107

8.1 Curve presentation

The conventional curve display shows pressure, flow, and volume over time. The display will be scaled to the selected time axis.

The actual information displayed on your elisa 300 / elisa 500 depends on the configuration.



All trigger points reached are identified by corresponding markers. (If you do not see these coloured markers, the function may have been disabled at the configuration level. Please contact your service technician.)

Remark

When the tube compensation is activated, the device calculates the tracheal pressure at the Y-piece before the tube and the pressure is displayed by an additional curve.

8.2 InstantView window

The following measurement values and the corresponding alarm limits are displayed in the InstantView window by default:

- Respiratory rate: RR
- Expiratory tidal volume: VTe
- Expiratory minute volume: MVe
- Peak pressure of the last breath: PEAK
- Plateau pressure: P Plateau
- Positive end-expiratory pressure: PEEP
- Leakage in %
- Oxygen concentration: O₂
- End-tidal CO₂ measurement: etCO₂

0% MV spontaneous 100%		
6	RR /min	18
	12	
150	VTe ml	760
	720	
6,9	MVe L	12,0
	6,5	
OFF	PEAK mbar	40
	17	
	Pplateau mbar	OFF
	15	
3	PEEP mbar	7
	5	
	Leakage %	50
	0	
25	O ₂ %	35
	30	
	etCO ₂ mmHg	60
OFF	-	

In addition to the numeric values, colour codes are used to alert the user to measurements approaching alarm limits.

A value currently stabilising is displayed on a white background.

If a measured value reaches or exceeds an alarm limit, the display field of the measured value turns red and the appropriate alarm is triggered. A measurement value getting close to a defined alarm limit is identified by an orange display field. The threshold values of the individual alarm limits are summarised in the following table:

	Adults		Children	
	≤ lower limit	≥ upper limit	≤ lower limit	≥ upper limit
PEAK	none	2 mbar	none	1 mbar
Pplateau	none	2 mbar	none	1 mbar
PEEP	0 mbar	0 mbar	0 mbar	0 mbar
RR	1 /min	5 /min	1 /min	5 /min
VT_e	50 ml	50 ml	5 ml	5 ml
MV_e	500 ml	500 ml	100 ml	100 ml
Leakage	none	5%	none	5%
etCO₂	2 mmHg	2 mmHg	2 mmHg	2 mmHg

Remark | A threshold range for oxygen concentration is not displayed.

In addition to the measurement values, a bar chart shows the ratio of the spontaneous to the mandatory breathing portions in graphical form. In the graphic, the spontaneous part is shown in green and the mandatory part in white.



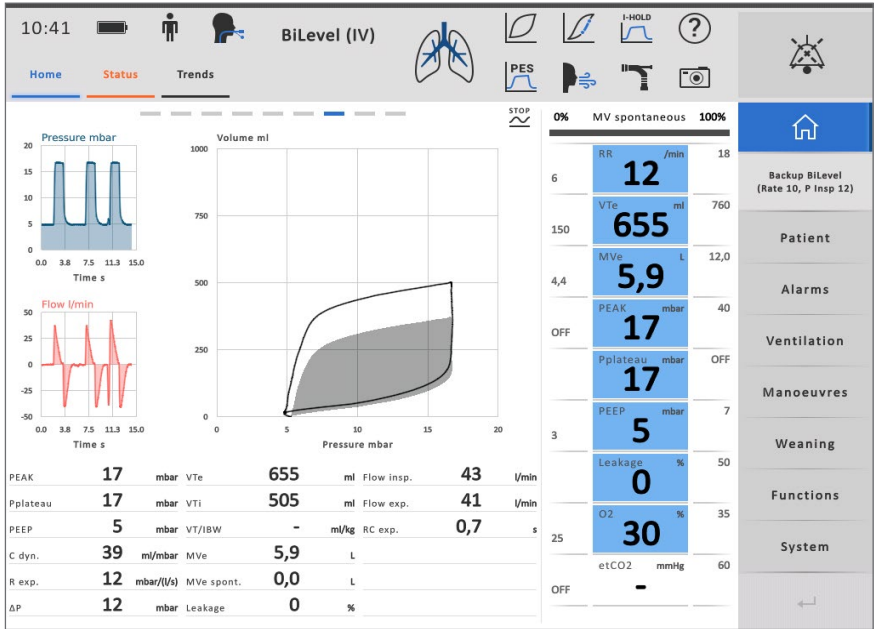
8.3 Loop view

Depending on the configuration, you can display the Loop view by swiping the window from right to left. To select the loop to be displayed, touch and hold a point on the displayed loop.

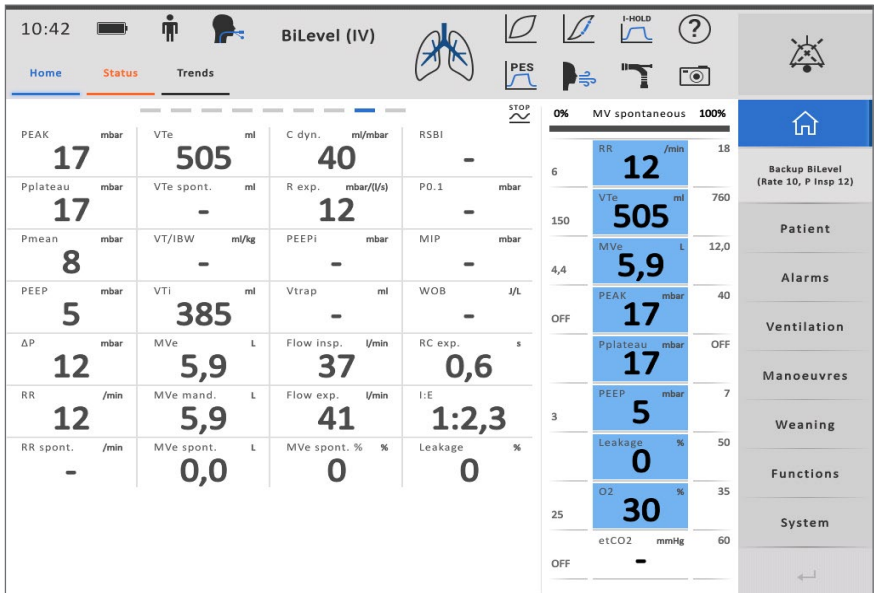
Selectable loops are:

- pressure – volume (Paw – V)
- volume – flow (V – Flow)
- flow – pressure (Flow – Paw)
- pressure – Peso (Paw – Peso)
- CO₂ – volume (CO₂ – V)
- Flow – Ptrach

The loop of the current breath is represented with a black line, the loop of the previous breath is displayed as a grey area. The scales of the loop view adapt automatically.



8.4 Data table or short data table



Depending on the settings on the configuration level, further views with the pre-configured measurements will be available.

Remark

The expiratory time constant is a measure of the complete expiration while avoiding an auto-PEEP situation. For this measurement, the expiratory flow is determined at 75% of the expiratory vital volume and the necessary expiration time is calculated.

The following standard values are applicable for the necessary expiration time:

- 1 x RCexp 63%
- 2 x RCexp 86.5%
- 3 x RCexp 95%
- 4 x RCexp 98%

8.5 Fastwean

Measurement values and indexes relevant for the weaning procedure can be monitored in the “Fastwean” weaning window. Values in the “safe window” are displayed in green, values outside the limits are displayed in yellow (the displayed values as well as the limits may be different, depending on the configuration):

	Yellow	Green	Yellow
P0.1 (mbar)	< -5	-5-0	-
RR spont. (/min)	< 9	9-16	> 16
VT _{spont.} (ml)	< 200	200-450	> 450
RSBI	-	0-105	> 105

Touch the upper limit or the lower limit and adjust the corresponding value with the selector.

These limits only apply to Fastwean, they do not affect other display elements, such as Fastprotect.

The general alarms are also not affected.



The timer counts from 00:00 to 23:59 (hh:mm), then it starts counting days (1 to 999 days).

After 999 days, the timer restarts from 00:00 hh:mm.

8.6 Fastprotect

For improved monitoring of lung-protective ventilation strategies, the “Fast-protect” window provides an overview of measured values and indices that are relevant for lung-protective ventilation. Values in the “safe window” are displayed in green, values outside the limits are displayed in yellow (the displayed values as well as the limits may be different, depending on the configuration):

	Yellow	Green	Yellow
ΔP (mbar)	-	0–15	> 15
VT/ IBW (ml/kg)	< 4.4	4.4–7	> 7
Plateau (mbar)	-	0–30	> 30
TPP i (es) (mbar)		0–20	> 20
TPP e (es) (mbar)		0–10	> 10

Remark

The value VT/IBW is only calculated for the “Adult” patient category.

Touch the upper limit or the lower limit and adjust the corresponding value with the selector.

These limits only apply to Fastprotect, they do not affect other display elements, such as Fastwear.

The general alarms are also not affected.

15	8.0	30	20	10
	4.4			
ΔP	VT/IBW	Pplateau	TPP Insp.	TPP exp.
12 mbar	7.6 ml/kg	17 mbar	16.6 mbar	4.8 mbar
00:06 hh:mm	00:00 hh:mm	00:07 hh:mm	00:00 hh:mm	00:00 hh:mm

The timer counts from 00:00 to 23:59 (hh:mm), then it starts counting days (1 to 999 days).

After 999 days, the timer restarts from 00:00 hh:mm.

9 Errors, alarms and troubleshooting

9.1 Problems – causes – corrective measures	110
9.2 Alarm system	111
9.2.1 Alarm messages	111
9.2.2 Alarm pause	112
9.2.3 Verification of the signalling devices	113
9.2.4 Alarm verification in the presence of a blocked breathing circuit	113
9.2.5 Alarm verification in the presence of a partially blocked breathing circuit	113
9.3 Alarm priorities	114
9.4 Alarm messages during operation	114
9.5 Error messages during power up test	161
9.6 Error messages during system test	164

9.1 Problems – causes – corrective measures

Error:	Possible causes:	Corrective measure:
Required reading, ventilation mode, function (e.g., Peso), parameter or curve is not displayed.	The desired function or display has not been configured for the user on the configuration level.	Please contact the responsible person in your ward or your service technician.
One of the connected accessories (CO ₂ sensor, SpO ₂ sensor, elisa@megs) does not work.	The desired function has not been configured for the user on the configuration level or it has been configured for another interface.	You can review the current interface configuration on the “Status” tab by selecting the second view. If in doubt, please contact the responsible person in your ward or your service technician.
Measured PEEP value is different from set value.	Valve bar or breathing circuit were exchanged but no system test was carried out	Carry out a system test.
Measured PEEP value is different from set value.	The PEEP membrane is contaminated with medication residue after a drug nebulization procedure (the expiratory filter is missing or unsuitable, or the selected replacement interval is too long considering the nebulization intensity or osmolarity of the applied medication.)	Exchange expiratory valve Install suitable expiratory filter for drug nebulization or choose a shorter replacement interval.
Ventilation pressure implausibly high	Accessories or combination with accessories increases the flow resistance	Exchange breathing circuit, exchange filter, remove / prevent condensate in breathing circuit
USB stick is not detected	Incorrect or implausible formatting.	The elisa 300 / elisa 500 devices support only a FAT32-formatted USB stick. The USB stick needs to be formatted with a standard operating system (e.g., Windows).

9.2 Alarm system

The intensive care ventilator is equipped with alarms to support patient safety.

The functions of the alarm system are automatically verified as part of the power up test and the system test.

When an alarm condition occurs, it is indicated in the alarm window and it also triggers the audible and visual signalling devices.

The system classifies the alarms in 7 different priority levels which can also escalate and de-escalate.

The alarm messages in the alarm window are sorted according to activity, priority and time of occurrence. If more than 4 alarms occur at the same time, the 4 alarm messages with the greatest importance will be shown.

The audible and visual alarms from the signalling devices are always those of the active alarm with the highest priority.

After switching between invasive and non-invasive ventilation or between ventilation modes, check the alarm limits and ventilation settings and adjust them so that the ventilation can be fully monitored. Extreme alarm limit settings may render the alarm system useless.

The user is required to review the alarm limits to determine their appropriateness for the individual ventilation situations and to adjust them if necessary.



Warning

Switch off alarm limits only if the missing alarm does not constitute a safety hazard for the patient!

9.2.1 Alarm messages

When you touch an alarm message in the alarm window, the window expands and shows information on the cause and possible corrective measures. If an alarm becomes inactive, the audible and visual signalling devices are also deactivated. The alarm message text, however, remains visible in the alarm window for informational purposes until it is acknowledged with the alarm pause button (A).

By touching the respective arrows, the alarm window can be closed horizontally or vertically. In this case, the alarm with the highest priority and the number of additional alarms will be displayed. After 20 seconds all alarms are displayed again in full size.

Remark	It is not possible to deactivate the alarm system as a whole. The system saves the times of deactivation of individual alarms in a log file.
Remark	The ventilator logs all alarms that occur, and authorised service technicians can access this alarm log even after a device failure.
Remark	If the storage capacity of the internal memory is exhausted, the oldest data of the alarm history is overwritten.
Remark	The set alarm limits are stored in a non-volatile memory and can be accessed at any time after switching on the ventilator and selecting “Same Patient”. This also applies after a power failure.
Remark	At the beginning of the ventilation procedure, audible alarms are disabled for 120 seconds. During this period, ventilator settings can be adjusted without annoying alarms, and the first measurements can be performed. This measure is intended to reduce the number of unnecessary alarms and the associated stress.
Remark	While parameters are being adjusted with the selector, alarms are also visualised by a different background colour of the screen display: A “red” alarm condition is indicated by a reddish background, a “yellow” alarm by a yellowish background.

9.2.2 Alarm pause

An alarm can be suppressed for a maximum of 2 minutes. Pressing the alarm pause button (A) deactivates the acoustic and visual alarms. The alarm message remains visible in the alarm window and an alarm pause symbol is additionally shown. The remaining alarm suppression time is displayed in the alarm pause button (B).

Remark	New alarms occurring during an alarm pause will trigger a new alarm!
Remark	During absence of alarms, all alarms can be suppressed in advance (C) for 2 minutes.



(A)



(B)



(C)

9.2.3 Verification of the signalling devices

During the power up test the device checks the signalling devices:

Audible signals:	The device emits two different, consecutive alarm tones. When you hear these tones, the acoustic signalling devices work perfectly.
Visual signals:	The alarm indicators of the ventilator unit blink briefly red and yellow. If the alarm indicators light up during the power up test, the visual signalling devices work perfectly.

9.2.4 Alarm verification in the presence of a blocked breathing circuit

A blocked breathing circuit triggers the “Insufficient volume” or “High pressure” alarm.

Follow these steps to verify the alarm function:

- Perform a system test with a successful result.
- Connect a test lung to the breathing circuit.
- Activate the “Dynamic BiLevel” ventilation mode.
- Start ventilation.
- Disconnect the Y-piece from the test lung.
- Block the open connection of the Y-piece.
- The “Insufficient volume” alarm must be triggered after 2 breaths.

9.2.5 Alarm verification in the presence of a partially blocked breathing circuit

When the breathing circuit is partially blocked, the “Airway pressure high” alarm will be output.

The alarm condition is detected by a permanent plausibility monitoring of the PEEP valve.

A system test can be carried out to verify the alarm detection function: When the system test does not reveal any faults, the plausibility monitoring function of the PEEP valve works properly.

9.3 Alarm priorities

The different alarm priorities are displayed in different forms:

Alarm priority	Alarm text	Alarm LED	Alarm sound
1 - information	Blue on a white background	OFF	OFF
2 - low priority	Blue on a yellow background	Yellow	ON
3 - low priority	Blue on a yellow background	Yellow	ON
4 - medium priority	Black on a yellow background	Yellow flashing	ON
5 - medium priority	Black on a yellow background	Yellow flashing	ON
6 - high priority	White on a red background	Red flashing	ON
7 - high priority	White on a red background (flashing in reverse video)	Red flashing	ON

Remark | Alarm priority 1 is purely advisory, no risk potential.

9.4 Alarm messages during operation

In the following tables, you will find an overview of the different alarm messages, their error codes, priorities, causes with delay times and possible corrective measures.

Remark | Please note down the displayed error codes for service purposes.

The alarm messages are sorted numerically in ascending order.

The following rules apply:

(*) only elisa 300 elisa 500

(**) only elisa 600 elisa 800

Patient alarms

Code	Prior-ity	Alarm message	Cause	Corrective measure
#101	6 7	MV high	Expiratory minute volume > Alarm limit	Please check: - Patient condition and breathing pattern - That Auto triggering is not the cause - Water condensation in breathing circuit - Ventilator settings Consider: - Adjusting alarm limits or ventilator settings
#102	6 7	MV low	Expiratory minute volume < Alarm limit	Please check: - Patient condition and breathing pattern - Correct assembly of breathing circuit - Breathing circuit, tube connector and humidifier for leaks - Whether the tube is blocked - The expiratory flow sensor for contamination Consider: - Adjusting alarm limits or ventilator settings
#103	6 7	VT high	Tidal volume > Alarm limit	Please check: - Patient condition and breathing pattern - Ventilation mode - Ventilator settings Consider: - Adjusting alarm limits or ventilator settings
#104	6 7	VT low	Tidal volume < Alarm limit	Please check: - Patient condition and breathing pattern - Breathing circuit, tube connector and humidifier for leaks - Correct mask position, if used - Correct assembly of breathing circuit Consider: - Adjusting alarm limits or ventilator settings
#105	2	Leakage high	Leakage > Alarm limit	Please check: - Patient condition and breathing pattern - Breathing circuit, tube connector and humidifier for leaks - Correct mask position, if used - Correct assembly of breathing circuit - and, if necessary: connections for CO₂ side-stream measurement Consider: - Adjusting alarm limits or ventilator settings
#107	4	Rate high	Respiratory rate > Alarm limit	Please check: - Patient condition and breathing pattern - That Auto triggering is not the cause - Water condensation in breathing circuit Consider: - Reviewing sedation protocol - Adjusting alarm limits or ventilator settings

Code	Priority	Alarm message	Cause	Corrective measure
#108	4 6	Rate low	Respiratory rate < Alarm limit	Please check: - Patient condition and breathing pattern - Correct ventilation mode - Correct ventilator settings Consider: - Reviewing sedation protocol - Adjusting alarm limits or ventilator settings
#109	7	Backup ventilation	Apnoea: Backup ventilation is enabled.	Please check: - Patient condition and breathing pattern - Correct ventilation mode - Correct ventilator settings - Appropriateness of alarm settings Consider: - Changing ventilation mode - Adjusting ventilator settings - Adjusting alarm limits
#110	7	Apnoea	Apnoea	Please check: - Patient condition and breathing pattern - Correct ventilation mode - Correct ventilator settings - Appropriateness of alarm settings Consider: - Changing ventilation mode - Adjusting ventilator settings - Adjusting alarm limits
#111	6	Airway pressure high	Airway pressure > Plimit	Please check: - Patient condition and breathing pattern - Breathing circuit, tube connector and tube for kinks - Whether the patient is fighting the ventilator (increased resistance of the filter caused by humidity or medication nebulization) Consider: - Reviewing sedation protocol - Adjusting alarm limits or ventilator settings Information: - This condition aborts the current breath
#112	7	Airway pressure high	Airway pressure > 2 mbar over Plimit	Please check: - Patient condition and breathing pattern - Breathing circuit, tube connector and tube for kinks - Whether the patient is fighting the ventilator (increased resistance of the filter caused by humidity or medication nebulization) Consider: - Reviewing sedation protocol - Adjusting alarm limits or ventilator settings Information: - The safety valve is open

Code	Prior- ity	Alarm message	Cause	Corrective measure
#113	1 2 4	Airway pres- sure high	Airway pressure > PLimit	Please check: - Patient condition and breathing pattern - Breathing circuit, tube connector and tube for kinks - Whether the patient is fighting the ventilator - Correct tube placement Consider: - Performing bronchial toilet - Reviewing sedation protocol Adjusting alarm limits or ventilator settings Information: - PLimit limits the pressure in current breath
#114	7	Airway pres- sure high	Airway pressure > 10 mbar over PLimit	Please check: - Patient condition and breathing pattern - Breathing circuit, tube connector and tube for kinks - Whether the patient is fighting the ventilator Consider: - Reviewing sedation protocol Adjusting alarm limits or ventilator settings Information: - The safety valve is open
#115	4	Airway pres- sure low	Airway Pressure < Alarm Limit	Please check: - Patient condition and breathing pattern - Breathing circuit, tube connector and tube for kinks - Whether the tube is blocked - Correct assembly of breathing circuit Consider: - Adjusting alarm limits or ventilator settings
#116	4	Mean airway pressure high	Mean Airway Pressure Pmean > Alarm Limit	Please check: - Patient condition and breathing pattern Consider: - Adjusting alarm limits or ventilator settings
#117	4	Mean airway pressure low	Mean Airway Pressure Pmean < Alarm Limit	Please check: - Patient condition and breathing pattern Consider: - Adjusting alarm limits or ventilator settings
#118	7	PEEP high	PEEP > Alarm Limit	Please check: - Patient condition and breathing pattern - Expiratory limb of breathing circuit including accessories for kinks - That the expiratory flow sensor is free of liquid and medication residues (increased resistance of the filter caused by humidity or medication nebulization) Consider: - Changing the expiratory flow sensor

Code	Prior- ity	Alarm message	Cause	Corrective measure
#119	7	PEEP low	PEEP < Alarm Limit Delay: 2 breaths max.	Please check: - Patient condition and breathing pattern - Breathing circuit, tube connector and tube for kinks - Whether the tube is blocked - Correct assembly of breathing circuit - That the PEEP valve is not jammed (May be caused by medication residues on the PEEP membrane of the expiration valve) Consider: - Adjusting alarm limits or ventilator settings
#120	5	O ₂ high	O ₂ Concentration > Alarm Limit Delay: 15 seconds max.	Please check: - Appropriateness of alarm settings - Whether O ₂ sensor needs calibration - O ₂ concentrator, if used - O ₂ delivery setting at O ₂ concentrator, if used
#121	5 7	O ₂ low	O ₂ Concentration < Alarm Limit Delay: 15 seconds max.	Information: - FiO ₂ sensor has to be calibrated in service menu If wrong O ₂ concentration persists after a calibration: Contact authorised service agent.
#122	4	etCO ₂ high	etCO ₂ Concen- tration > Alarm Limit	Please check: - Patient condition and breathing pattern - Respiratory minute volume, tidal volume and rate - All additional dead space due to accessories - Contamination of CO ₂ cuvette
#123	4	etCO ₂ low	etCO ₂ Concen- tration < Alarm Limit	Consider: - Performing a CO ₂ zero adjustment - Adjusting alarm limits or ventilator settings
#124	4	inCO ₂ high	inCO ₂ Concen- tration > Alarm Limit	Please check: - Appropriateness of alarm settings - Possibility of CO ₂ rebreathing - That gas supply is within working range Consider: - Performing a CO ₂ zero adjustment - Adjusting alarm limits - Correcting gas supply
#125	4	SpO ₂ low	The arterial oxygen saturation is below the set alarm limit.	Please check: - Patient condition and breathing pattern Consider: - Adjusting alarm limits or ventilator settings
#126	3	SpO ₂ high	The arterial oxygen saturation is above the set alarm limit.	Please check: - Patient condition and breathing pattern Consider: - Adjusting alarm limits or ventilator settings

Code	Prior-ity	Alarm message	Cause	Corrective measure
#127	3	Heart rate low	The heart rate is below the set alarm limit.	Please check: - Patient condition and breathing pattern Consider: - Adjusting alarm limits or ventilator settings
#128	3	Heart rate high	The heart rate is above the set alarm limit.	Please check: - Patient condition and breathing pattern Consider: - Adjusting alarm limits or ventilator settings
#131	1 4	Airway pressure negative	Paw < -1 mbar (for multiple breaths)	Please check: - Supply pressures of the gas supplies - Correct ventilation mode - Adapt parameters to the patient's spontaneous breathing Consider: - Increasing the byflow If negative pressure persists: Contact an authorised service agent
#132	7	Airway pressure negative	Paw < -1 mbar (for more than 5 s)	
#133	1 2	Pressure limitation	Airway Pressure ≥ Ventilation Parameter Pmax	Please check: - Patient condition and breathing pattern - Breathing circuit, tube connector and tube for kinks - Whether the patient is fighting the ventilator Consider: - Reviewing sedation protocol - Adjusting alarm limits or ventilator settings
#134	7	Disconnection	High leakage or tube disconnected Delay: 15 seconds max.	Please check: - Correct assembly of breathing circuit - Correct patient mask position, if used (eliminate leakage)
#135	7	Insufficient volume	It is not possible to apply the adequate volume Delay: 2 breaths max.	Please check: - Patient condition and breathing pattern - Whether tube or breathing circuit is blocked - Correct patient mask position, if used (eliminate leakage) - Whether the patient is fighting the ventilator Consider: - Performing bronchial toilet - Reviewing sedation protocol - Adjusting alarm limits or ventilator settings
#136	1	O ₂ alarm limits?	The O ₂ alarms are disabled or an O ₂ alarm limit deviates more than 5% from set ventilation parameter.	Adapt: - O ₂ alarm settings Consider: - Alternative FiO ₂ measurement method

Code	Priority	Alarm message	Cause	Corrective measure
#137	7	Expiratory sensor?	No expiratory flow can be measured. The expiratory flow sensor is missing or the measurement is implausible.	Information: - Volume measurement not possible - No trigger detection possible - No leak compensation possible - No tube compensation possible Please check: - Expiratory flow sensor for proper placement - That the expiratory flow sensor is clean and dry - Whether the expiratory valve needs to be replaced If the alarm recurs or persists: Contact authorised service agent.
#138	I	Closed suction	The suction routine for closed suction systems is activated	To terminate the suction phase of the device, press the <Post-oxygen> button or the <Stop> button.
#139	5	Open suction	The suction routine for open suction systems is activated	To terminate the suction phase of the device, reconnect the patient.
#140	4	Rate spont. high	Rate of spontaneous breathing > Alarm limit	Please check: - Patient condition and breathing pattern - That Auto triggering is not the cause Consider: - Adjusting alarm limits or ventilator settings - Reviewing sedation protocol
#141	4-6	Rate spont. low	Rate of spontaneous breathing < Alarm limit	Please check: - Patient condition and breathing pattern - Suitability of the selected ventilation mode Consider: - Adjusting alarm limits or ventilator settings - Reviewing sedation protocol
#142	4	Pplateau high	Pplateau > Alarm Limit	Please check: - Patient condition and breathing pattern Consider: - Adjusting alarm limits or ventilator settings
#143	I	Some alarm limits deactivated	Some of the audible alarms are deactivated.	Information: Ensure close monitoring!
#144	I	Ventilation alarms inactive	All ventilation alarms are deactivated.	Information: - The alarm management was adapted because of an active manoeuvre. Ensure close monitoring!
#145	I	Risk of trapping	Expiration time > 2 x RCexp	Information: - Ventilator will not adapt inspiratory time and PS-Endflow
#146	I	Continuous nebulization enabled	Continuous nebulization is enabled.	Information: - Switchover to continuous nebulization due to high respiratory rate

Code	Prior-ity	Alarm message	Cause	Corrective measure
#147	I	WOBOV settings implausible	WOBOV target values cannot be reached.	Information: - Tidal volume is high Consider: - Adjusting alarm limits or ventilation settings of WOBOV
#148	I	WOBOV settings implausible	WOBOV target values cannot be reached.	Information: - Tidal volume is low Consider: - Adjusting alarm limits or ventilation settings of WOBOV
#149	I	WOBOV settings implausible	WOBOV target values cannot be reached.	Information: - Respiratory rate is high Consider: - Adjusting alarm limits or ventilation settings of WOBOV
#150	I	WOBOV settings implausible	WOBOV target values cannot be reached.	Information: - Respiratory rate is low Consider: - Adjusting alarm limits or ventilation settings of WOBOV
#151	2	Cuff leakage	There is a leakage in the cuff or the cuff connection. The device compensates the cuff leakage. The set pressure can be reached.	Please check: - Defects at tube, tracheostomy tube and its connectors - Defects at cuff, e.g., caused during intubation - Defects at Cuffscout line and its connections Consider: - Replacing the pressure measuring line - Revising intubation - Exchanging tracheostomy tube
#152	6-7	Defective cuff	The set cuff pressure cannot be reached.	Please check: - That the cuff is blocked sufficiently - Defects at tube, tracheostomy tube and its connectors - Defects at cuff, e.g., caused during intubation - Defects at Cuffscout line and its connections Consider: - Replacing the pressure measuring line - Revising intubation - Exchanging tracheostomy tube

Code	Priority	Alarm message	Cause	Corrective measure
#153	1	Cuff pressure high	The actual cuff pressure is greater than the set value.	Please check: - That cuff pressure is normal - That the cuff pressure line is not kinked No further action necessary.
	2			Please check: - That cuff pressure is normal - That the cuff pressure line is not kinked The cuff function can be continued. If the alarm recurs or persists: Contact an authorised service agent.
	6			Please check: - That cuff pressure is normal - That the cuff pressure line is not kinked Block the cuff manually. If the alarm recurs or persists: Contact an authorised service agent.
#154	1	Standby Cuffscout active	The Cuffscout function is active in standby mode.	Information: - The following menus and functions are not available: - Switch off device - Carry out system test - Config. - Service - New patient Consider: - Switching off Cuffscout to access the listed menus and functions.
#155	1	SBT manoeuvre is running	SBT (Spontaneous Breathing Trial) is running.	Information: - The spontaneous breathing trial runs over the set period of time. - You can stop the spontaneous breathing trial at any time. Please check: - The set alarm limits and if necessary adjust the SBT to the clinical needs
#156	4	inISO high	inISO concentration > Alarm limit	Please check: - Appropriateness of alarm settings - Possibility of ISO/SEV rebreathing - That gas supply is within working range - Contamination of LeoLyzer cuvette Consider: - Performing a LeoLyzer zero adjustment - Adjusting alarm limits - Correcting gas supply

Code	Prior- ity	Alarm message	Cause	Corrective measure
#157	4	inISO low	inISO concentra- tion < Alarm limit	Please check: - Appropriateness of alarm settings - That gas supply is within working range • Contamination of Leolyzer cuvette - System for leakage Consider: - Performing a Leolyzer zero adjustment - Adjusting alarm limits - Correcting gas supply
#158	4	exISO high	exISO concentra- tion > Alarm limit	Please check: - Patient condition and breathing pattern - Respiratory minute volume, tidal volume and rate - All additional dead space due to accessories - Contamination of Leolyzer cuvette Consider: - Performing a Leolyzer zero adjustment - Adjusting alarm limits or ventilator settings
#159	4	exISO low	exISO concentra- tion < Alarm limit	Please check: - Patient condition and breathing pattern - Respiratory minute volume, tidal volume and rate - All additional dead space due to accessories - Contamination of Leolyzer cuvette - System for leakage Consider: - Performing a Leolyzer zero adjustment - Adjusting alarm limits or ventilator settings
#160	3	PAPS implau- sible	Resistance and compliance implausible.	Information: - The basic parameters Resistance and Compli- ance cannot be determined Please check: - The set diameter of the tube for correctness - That the breathing circuit and tube have no leaks - That the breathing circuit and tube are not kinked Decide: - If this error occurs frequently, the ventilation mode should be changed
#161	3	Resistance low	Respiratory re- sistance is low.	Please check: - The set diameter of the tube for correctness - That the breathing circuit and tube have no leaks
#162	3	Resistance high	Respiratory re- sistance is high.	Please check: - The set diameter of the tube for correctness - That the breathing circuit and tube have no leaks

Code	Priority	Alarm message	Cause	Corrective measure
#163	1	Pneumatic nebulization active	In volume-controlled ventilation modes, pneumatic nebulization can impact the set tidal volume and oxygen concentration.	Please check: - That the ventilation volume is in a safe range for the patient Decide if measured values are not in a safe range for the patient: - Deactivate pneumatic nebulization - Change the ventilation mode
#165	1 3 5	O2 control stopped	SpO2 signal is low	Information: - As long as the signal is low, no SpO2 measured values are displayed - Ventilation is continued with the last valid O2 value Please check: - That the sensor is positioned correctly - That the skin is not too strongly pigmented - Patient condition and breathing pattern If the alarm recurs or persists: Consider to stop O2 monitoring Delay: max. 60 s
#166	5	SpO2 ctrl. high	SpO2 > upper SpO2 control value	Please check: - Patient condition and breathing pattern Consider: - Adjusting alarm limits or ventilator settings Delay: max. 30 s
#167	5	SpO2 ctrl. low	SpO2 < lower SpO2 control value	Please check: - That the sensor is positioned correctly - That the skin is not too strongly pigmented - Patient condition and breathing pattern Consider: - Adjusting alarm limits or ventilator settings Delay: max. 30 s
#168	3 5	O2 ctrl. high	O2 > upper O2 control value	Please check: - Appropriateness of alarm settings - Whether O2 sensor needs calibration - O2 concentrator, if used - O2 delivery setting at O2 concentrator, if used Consider: - Adjusting alarm limits or ventilator settings Delay: max. 30 s
#169	3 5	O2 ctrl. low	O2 < lower O2 control value	Please check: - Appropriateness of alarm settings - Whether O2 sensor needs calibration - O2 concentrator, if used - O2 delivery setting at O2 concentrator, if used Consider: - Adjusting alarm limits or ventilator settings Delay: max. 30 s

Code	Prior- ity	Alarm message	Cause	Corrective measure
#170	I	Some alarms deactivated	Some of the alarms and alarm limits are deactivated	Close monitoring must be ensured
#171	4	inSEV high	inSEV concentration > Alarm limit	Please check: - Appropriateness of alarm settings - Possibility of ISO/SEV rebreathing - That gas supply is within working range - Contamination of Leolyzer cuvette Consider: - Performing a Leolyzer zero adjustment - Adjusting alarm limits - Correcting gas supply
#172	4	inSEV low	inSEV concentration < Alarm limit	Please check: - Appropriateness of alarm settings - That gas supply is within working range - Contamination of Leolyzer cuvette - System for leakage Consider: - Performing a Leolyzer zero adjustment - Adjusting alarm limits - Correcting gas supply
#173	4	exSEV high	exSEV concentration > Alarm limit	Please check: - Patient condition and breathing pattern - Respiratory minute volume, tidal volume and rate - All additional dead space due to accessories - Contamination of Leolyzer cuvette Consider: - Performing a Leolyzer zero adjustment - Adjusting alarm limits or ventilator settings
#174	4	exSEV low	exSEV concentration < Alarm limit	Please check: - Patient condition and breathing pattern - Respiratory minute volume, tidal volume and rate - All additional dead space due to accessories - Contamination of Leolyzer cuvette - System for leakage Consider: - Performing a Leolyzer zero adjustment - Adjusting alarm limits or ventilator settings
#175	2	Alarm limits have been reset	Alarm limits have been reset to default after bronchoscopy mode was stopped.	Do the following: - Re-evaluate and adapt alarm limits

Ventilator Unit Alarms

Code	Prior-ity	Alarm message	Cause	Corrective measure
#201	3	O2 flow error	O2 flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected Ventilator is operating safely.
#201	7	O2 flow error	O2 flow sensor error	Information: - The O2 flow sensor system is defective. - Ventilation is now only possible with air Monitor: - O2 concentration Decide: If ventilation with low oxygen is a hazard: - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#202	3	Air flow error	Air flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected Ventilator is operating safely.
	7			Information: - The air flow sensor system is defective - Ventilation is now only possible with pure oxygen Decide: If pure oxygen concentration is a hazard: - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#203	3	Paux reservoir pressure error	Paux reservoir - Defective pressure sensor	Information: - All Paux functions are disabled - Other device functions are not affected Ventilator is operating safely. - Contact an authorised service agent.
#204	3	O2 flow error	O2 flow sensor error	Information: - A redundant sensor is defective - The O2 flow is limited to 80 l/min Ventilator is operating safely.
	7			Information: - The O2 flow sensor system is defective. - Ventilation is now only possible with air Monitor: - O2 concentration Decide: if ventilation with low oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.

Code	Prior- ity	Alarm message	Cause	Corrective measure
#205	3	Air flow error	Air flow sen- sor error	Information: - A redundant sensor is defective - The air flow is limited to 80 l/min Ventilator is operating safely.
#205	7			Information: - The air flow sensor system is defective - Ventilation is now only possible with oxygen Decide: If pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#206	7	Inspiratory flow sensor error	Inspiratory flow sensor error	Information: - The air flow sensor system is defective - Ventilation is now only possible with oxygen Decide: If pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#207	3	Exp. flow error	Expiratory flow sensor error	Information: - A redundant sensor is defective - The expiratory flow is only measured up to 80 l/min - The tidal and minute volume displayed may be incorrect Ventilator is operating safely.
	7			Information: - The expiratory flow sensor system is defective - Tidal and minute volume cannot be measured - Ventilator now operates in emergency ventilation mode Decide: If emergency ventilation mode is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#208	3	Exp. pres- sure error	Expiratory pressure sensor error	Information: - The expiratory pressure sensor is defective - Patient pressure is measured and controlled only by the inspiratory pressure sensor Ventilator is operating safely. Contact an authorised service agent.
	7			Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator Contact an authorised service agent.

Code	Priority	Alarm message	Cause	Corrective measure
#209	3	Paux1 pressure error	Paux1 pressure sensor error	Information: - The Paux1 function is disabled - Other device functions are not affected Ventilator is operating safely. Contact an authorised service agent.
#210	3	Insp. pressure error	Inspiration pressure sensor error	Information: - The inspiratory pressure sensor is defective - Patient pressure is measured and controlled only by the expiratory pressure sensor Ventilator is operating safely. - Contact an authorised service agent.
	7			Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#211	3	Exp. flow error	Expiratory flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected Ventilator is operating safely.
#211	7			Information: - The expiratory flow sensor system is defective - Tidal and minute volume cannot be measured - Ventilator now operates in emergency ventilation mode Decide: If emergency ventilation mode is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#212	3	Paux2 pressure error	Paux2 pressure sensor error	Information: - The Paux2 function is disabled - Other device functions are not affected Ventilator is operating safely. - Contact an authorised service agent.
#213	3	O2 inlet pressure	O2 inlet pressure sensor error	Information: - The pressure of the O2 gas supply is not monitored - Failure of O2 gas supply is only detected in case of flow deviation Ventilator is operating safely. - Contact an authorised service agent.
#214	3	Air inlet pressure	Air inlet pressure sensor error	Information: - The pressure of the AIR gas supply is not monitored - Failure of AIR gas supply is only detected in case of flow deviation Ventilator is operating safely. - Contact an authorised service agent.

Code	Prior- ity	Alarm message	Cause	Corrective measure
#215 (*)	3	Filter pressure error	Filter pressure sensor error	Information: - The condition of the turbine intake filter is not monitored - A faulty intake filter can cause turbine malfunctions Ventilator is operating safely. Check visually every day: - That the filter is inserted - That the filter is clean - Contact an authorised service agent.
#217	3	O2 flow error	O2 flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected Ventilator is operating safely.
	7			Information: - The O2 flow sensor system is defective. - Ventilation is now only possible with air Monitor: - O2 concentration Decide: If ventilation with low oxygen is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#218	3	Air flow error	Air flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected Ventilator is operating safely.
	7			Information: - The air flow sensor system is defective - Ventilation is now only possible with oxygen Decide: If pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#220	3	O2 flow error	O2 flow sensor error	Information: - A redundant sensor is defective. - The oxygen flow is limited to 80 l/min Ventilator is operating safely.
#220	7			Information: - The O2 flow sensor system is defective. - Ventilation is now only possible with air Monitor: - O2 concentration Decide: If ventilation with low oxygen is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.

Code	Priority	Alarm message	Cause	Corrective measure
#221	3	Air flow error	Air flow sensor error	Information: - A redundant sensor is defective - Air flow is limited to 80 l/min Ventilator is operating safely.
	7			Information: - The air flow sensor system is defective. - Ventilation is now only possible with oxygen Decide: If pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#222	7	Inspiratory flow sensor error	Inspiratory flow sensor error	Information: - The air flow sensor system is defective - Ventilation is now only possible with oxygen Decide: If pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#223	3	Exp. flow error	Expiratory flow sensor error	Information: - A redundant sensor is defective - The expiratory flow is only measured up to 80 l/min - The tidal and minute volume displayed may be incorrect Ventilator is operating safely.
	7			Information: - The expiratory flow sensor system is defective - Tidal and minute volume cannot be measured - Ventilator now operates in emergency ventilation mode Decide: If emergency ventilation mode is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#224	3	Exp. pressure error	Expiratory pressure sensor error	Information: - The expiratory pressure sensor is defective - Patient pressure is measured and controlled only by the inspiratory pressure sensor Ventilator is operating safely. - Contact an authorised service agent.
	7			Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.

Code	Prior-ity	Alarm message	Cause	Corrective measure
#225	3	Paux1 pres-sure error	Paux1 pres-sure sensor error	Information: - The Paux1 function is disabled - Other device functions are not affected Ventilator is operating safely. Contact an authorised service agent.
#226	3	Insp. pres-sure error	Inspiration pressure sensor error	Information: - The inspiratory pressure sensor is defective - Patient pressure is measured and controlled only by the expiratory pressure sensor Ventilator is operating safely. - Contact an authorised service agent.
	7			Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#227	3	Exp. flow error	Expiratory flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected - The tidal and minute volume displayed may be incorrect Ventilator is operating safely.
	7			Information: - The expiratory flow sensor system is defective - Tidal and minute volume cannot be measured - Ventilator now operates in emergency ventilation mode Decide: If emergency ventilation mode is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#228	3	Paux2 pres-sure error	Paux2 pres-sure sensor error	Information: - The Paux2 function is disabled - Other device functions are not affected. Ventilator is operating safely. - Contact an authorised service agent.

Code	Priority	Alarm message	Cause	Corrective measure
#230	3	O2 flow error	O2 flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected Ventilator is operating safely.
	7			Information: - The O2 flow sensor system is defective. - Ventilation is now only possible with air Monitor: - O2 concentration Decide: If ventilation with low oxygen is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#231	3	Air flow error	Air flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected Ventilator is operating safely.
	7			Information: - The air flow sensor system is defective - Ventilation is now only possible with oxygen Decide: If pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#233	3	O2 flow error	O2 flow sensor error	Information: - A redundant sensor is defective - The oxygen flow is limited to 80 l/min Ventilator is operating safely.
	7			Information: - The O2 flow sensor system is defective. - Ventilation is now only possible with air Monitor: - O2 concentration Decide: If ventilation with low oxygen is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.

Code	Prior- ity	Alarm message	Cause	Corrective measure
#234	3	Air flow error	Air flow sensor error	Information: - A redundant sensor is defective - Air flow is limited to 80 l/min Ventilator is operating safely.
	7			Information: - The air flow sensor system is defective. - Ventilation is now only possible with oxygen Decide: If pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#235	7	Insp. flow error	Inspiratory flow sensor error	Information: - The air flow sensor system is defective - Ventilation is now only possible with oxygen Decide: If pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#236	3	Exp. flow error	Expiratory flow sensor error	Information: - A redundant sensor is defective - The expiratory flow is only measured up to 80 l/min - The tidal and minute volume displayed may be incorrect Ventilator is operating safely.
	7			Information: - The expiratory flow sensor system is defective - Tidal and minute volume cannot be measured - Ventilator now operates in emergency ventilation mode Decide: If emergency ventilation mode is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#237	3	Exp. pres- sure error	Expiratory pressure sensor error	Information: - The expiratory pressure sensor is defective - Patient pressure is measured and controlled only by the inspiratory pressure sensor Ventilator is operating safely. - Contact an authorised service agent.
#237	7	Exp. pres- sure error	Expiratory pressure sensor error	Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.

Code	Priority	Alarm message	Cause	Corrective measure
#238	3	Paux1 pressure error	Paux1 pressure sensor error	Information: - The Paux1 function is disabled - Other device functions are not affected Ventilator is operating safely. Contact an authorised service agent.
#239	3	Insp. pressure error	Inspiration pressure sensor error	Information: - The inspiratory pressure sensor is defective - Patient pressure is measured and controlled only by the expiratory pressure sensor Ventilator is operating safely. Contact an authorised service agent.
	7			Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator Contact an authorised service agent.
#240	3	Exp. flow error	Expiratory flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected Ventilator is operating safely.
	7			Information: - The expiratory flow sensor system is defective - Tidal and minute volume cannot be measured - Ventilator now operates in emergency ventilation mode Decide: If emergency ventilation mode is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator Contact an authorised service agent.
#241	3	Paux2 pressure error	Paux2 pressure sensor error	Information: - The Paux2 function is disabled - Other device functions are not affected Ventilator is operating safely. Contact an authorised service agent.
#243	3	O2 flow error	O2 flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected Ventilator is operating safely.
#243	7	O2 flow error	O2 flow sensor error	Information: - The O2 flow sensor system is defective. - Ventilation is now only possible with air Monitor: - O2 concentration Decide: If ventilation with low oxygen is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator Contact an authorised service agent.

Code	Prior-ity	Alarm message	Cause	Corrective measure
#244	3	Air flow error	Air flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected Ventilator is operating safely.
	7			Information: - The air flow sensor system is defective - Ventilation is now only possible with oxygen Ventilator is operating safely. Decide: If pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#246	3	O2 flow error	O2 flow sensor error	Information: - A redundant sensor is defective - The oxygen flow is limited to 80 l/min Ventilator is operating safely.
	7			Information: - The O2 flow sensor system is defective. - Ventilation is now only possible with air Monitor: - O2 concentration Decide: If ventilation with low oxygen is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#247	3	Air flow error	Air flow sensor error	Information: - A redundant sensor is defective - The air flow is limited to 80 l/min Ventilator is operating safely.
#247	7	Air flow error	Air flow sensor error	Information: - The air flow sensor system is defective - Ventilation is now only possible with oxygen Ventilator is operating safely. Decide: If pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.

Code	Prior- ity	Alarm message	Cause	Corrective measure
#248	7	Insp. flow error	Inspiratory flow sensor error	Information: - The air flow sensor system is defective - Ventilation is now only possible with oxygen Decide: If pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator Contact an authorised service agent. Decide: If emergency ventilation mode is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#249	3	Exp. flow error	Expiratory flow sensor error	Information: - The expiratory flow is only measured up to 80 l/min - The tidal and minute volume displayed may be incorrect Ventilator is operating safely.
	7			Information: - The expiratory flow sensor system is defective - Tidal and minute volume cannot be measured - Ventilator now operates in emergency ventilation mode.
#253	3	Exp. flow error	Expiratory flow sensor error	Information: - A redundant sensor is defective - The accuracy of low readings can be affected Ventilator is operating safely.
#253	7	Exp. flow error	Expiratory flow sensor error	Information: - The expiratory flow sensor system is defective - Tidal and minute volume cannot be measured - Ventilator operates in emergency ventilation mode Decide: If emergency ventilation mode is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#259	3	O2 flow error	O2 flow sensor error	Information: - Two redundant sensors measure implausible values - The accuracy of the measured values may be impaired Ventilator is operating safely. - Contact an authorised service agent.
#260	3	Air flow error	Air flow sensor error	Information: - Two redundant sensors measure implausible values - The accuracy of the measured values may be impaired Ventilator is operating safely. - Contact an authorised service agent.

Code	Prior- ity	Alarm message	Cause	Corrective measure
#262	3	O2 flow error	O2 flow sensor error	Information: - Two redundant sensors measure implausible values - The accuracy of the measured values may be impaired Ventilator is operating safely. - Contact an authorised service agent.
#263	3	Air flow error	Air flow sensor error	Information: - Two redundant sensors measure implausible values - The accuracy of the measured values may be impaired Ventilator is operating safely. - Contact an authorised service agent.
#265	3	Exp. flow error	Expiratory flow sensor error	Information: - Two redundant sensors measure implausible values - The accuracy of the measured values may be impaired Ventilator is operating safely. - Contact an authorised service agent.
#266	3	Exp. flow error	Expiratory flow sensor error	Information: - Two redundant sensors measure implausible values - The accuracy of the measured values may be impaired Ventilator is operating safely. Contact an authorised service agent.
#267	7	Sensor Voltage	Sensor Voltage Error	Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#268	7	Sensor Voltage	Sensor Voltage Error	Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#269	7	Sensor Voltage	Sensor Voltage Error	Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.

(*) elisa 300 elisa 500 only (**) elisa 600 elisa 800 only

Control Unit Alarms ()**

Code	Priority	Alarm message	Cause	Corrective measure
#301	3	Control unit	The internal communication with the control unit is disturbed.	Information: - This error does not affect the ventilation function - The control unit was automatically restarted. Ventilator is operating safely. Check that: - The connection cable to the ventilator is intact - The connector is securely plugged into the ventilator unit If the alarm recurs or persists: - Contact an authorised service agent.
#303	3	Control unit	The internal communication with the control unit is disturbed.	Information: - This error does not affect the ventilation function - The control unit was automatically restarted. Ventilator is operating safely. If the alarm recurs or persists: Contact an authorised service agent.
#306	3	Temperature Sensor	The temperature sensor in the control unit is defective.	Information: - This error does not affect the ventilation function - The fan in the control unit now runs at max speed. Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#307	3	Temperature Sensor	The temperature in the control unit is outside the operating range.	Information: - This error does not affect the ventilation function - The control unit may work slower - If the temperature gets too high, the control unit will switch off. Ventilator is operating safely. Check that: - The room temperature is not too high - The control unit is not covered by blankets - There is enough free space around the control unit for heat dissipation If the alarm recurs or persists: - Contact an authorised service agent.
#308	3	Fan failure	The fan sensor or the fan is defective.	Information: - This error does not affect the ventilation function - The fan within the control unit is defective - The control unit may work slower - If the temperature gets too high, the control unit will switch off. Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.

Code	Prior-ity	Alarm message	Cause	Corrective measure
#309	3	Loudspeaker error	The loud-speaker in the control unit is defective.	Information: - This error does not affect the ventilation function - The loudspeaker cannot generate the acoustic alarms - Now the buzzer in the ventilator unit generates the acoustic alarm Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#311	3	Visual alarm	The alarm indicators of the control unit failed.	Information: - This error does not affect the ventilation function - The alarm indicators of the control unit cannot generate the visual alarms - Now the display and the ventilator unit generate the visual alarms Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#312	3	Backlighting	The back-lighting of the control unit is defective.	Information: - This error does not affect the ventilation function - Ventilation will continue during change of control unit Do the following: - Exchange the control unit The new control unit will initialize automatically. If the alarm recurs or persists: - Contact an authorised service agent.
#313	3	Power failure	The internal power supply of the control unit is defective.	Information: - This error does not affect the ventilation function - Ventilation will continue during change of control unit Do the following: - Exchange the control unit The new control unit will initialize automatically. If the alarm recurs or persists: - Contact an authorised service agent.
#314	3 5	Power failure	The internal power supply of the control unit is defective.	Information: - This error does not affect the ventilation function - Ventilation will continue during change of control unit Do the following: - Exchange the control unit The new control unit will initialize automatically. If the alarm recurs or persists: - Contact an authorised service agent.

Code	Priority	Alarm message	Cause	Corrective measure
#315	3 5	Power failure	The internal power supply of the control unit is defective.	Information: - This error does not affect the ventilation function - Ventilation will continue during change of control unit Do the following: - Exchange the control unit The new control unit will initialize automatically. If the alarm recurs or persists: - Contact an authorised service agent.
#316	3 5	Power failure	The internal power supply of the control unit is defective.	Information: - This error does not affect the ventilation function - Ventilation will continue during change of control unit Do the following: - Exchange the control unit The new control unit will initialize automatically. If the alarm recurs or persists: - Contact an authorised service agent.
#317	3 5	Power failure	The internal power supply of the control unit is defective.	Information: - This error does not affect the ventilation function - Ventilation will continue during change of control unit Do the following: - Exchange the control unit The new control unit will initialize automatically. If the alarm recurs or persists: - Contact an authorised service agent.

(*) elisa 300 elisa 500 only (**) elisa 600 elisa 800 only

Power Management Alarms

Code	Priority	Alarm message	Cause	Corrective measure
#356	3	SpO ₂ sensor defective	The SpO ₂ sensor reports an error or is missing.	Information: - Sensor cannot be activated
#357	3	SpO ₂ signal quality low	Poor SpO ₂ sensor signal quality.	Information: - Inadequate SpO₂ signal quality. The measured values may be implausible Please check: - That the sensor is correctly applied to the finger - That the skin is not too strongly pigmented If the alarm recurs or persists: - Contact an authorised service agent.

Code	Prior- ity	Alarm message	Cause	Corrective measure
#401	7	Internal fault	No communi- cation between ventilator unit and power supply module Delay: 15 seconds max.	Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#402	2	Mains failure	Mains power failure occurred Delay: 15 seconds max.	Do immediately: - Restore mains power supply Check that: - Mains plug is connected - Power supply is given If required: - Contact an authorised service agent.
#403	7	No battery	There is no bat- tery available Delay: 15 seconds max.	Information: - Safe operation in the event of a power failure cannot be guaranteed without the battery Decide: - Insert battery - Put this ventilator out of service
#404	2	Battery >I< defective	The battery in compartment >I< is defective. Delay: 15 seconds max.	Do immediately: - Replace battery >I< If the alarm recurs or persists: - Contact an authorised service agent.
#405	2	Battery >II< defec- tive	The battery in compartment >II< is defective. Delay: 15 seconds max.	Do immediately: - Replace battery >II< If the alarm recurs or persists: - Contact an authorised service agent.
#406	2	Battery overload	The battery is overloaded Delay: 15 seconds max.	Information: - Additional functions be may disabled Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#407	2	Power supply overload	AC Adapter Overload Delay: 15 seconds max.	Information: - Additional functions be may disabled Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.

Code	Prior- ity	Alarm message	Cause	Corrective measure
#408	1 2 3 4 6 7	Battery >I< discharged	The battery in compart- ment >I< is discharged. Delay: 15 seconds max.	Information: - Battery power is on reserve capacity - Remaining ventilation time is less than 15 minutes Do one of the following: - Restore mains power supply - Install an additional battery in battery compart- ment >I<
#409	1 2 3 4 6 7	Battery >II< dis- charged	The battery in compart- ment >II< is discharged. Delay: 15 seconds max.	Information: - Remaining operating time on battery power is less than 15 minutes Do one of the following: - Restore mains power supply - Install an additional battery in battery compart- ment >I<
#410	5	Fan failure	The fan in the ventilator unit failed	Do the following: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service If the alarm recurs or persists: - Contact an authorised service agent.
#411	3	Internal fault	Communication error between ventilator unit and power sup- ply module. The device cannot be switched off. Delay: 15 seconds max.	Information: - Device cannot be switched off To switch off ventilator: - Disconnect the mains plug and - Remove the batteries If the alarm recurs or persists: - Contact an authorised service agent.
#412 and #413	1	Battery electronics	The battery>I< (>II<) cannot be charged. Delay: 15 seconds max.	Check that: - Battery is connected correctly - Battery temperature is not too high Do the following: - Reconnecting battery >I< (>II<) - Wait a few minutes until the battery has reinitialized itself and the charging process starts again automatically. If the alarm recurs or persists: - Replace the battery in compartment >I< (>II<)
#414 and #415	1	Battery electronics	The charging circuit of battery >I< (>II<) is de- fective. Charging is not possible. Delay: 15 seconds max.	Check that: - Battery is connected correctly If the alarm recurs or persists: - Contact an authorised service agent.

Code	Prior- ity	Alarm message	Cause	Corrective measure
#416 and #417	6	Battery tempera- ture	The battery in compartment >I< (>II<) is overheated. Delay: 15 seconds max.	Check that: - Mains plug is connected Do the following: - Replace the battery in compartment >I< (>II<) If the alarm recurs or persists: - Contact an authorised service agent.
#419	I	Battery electronics	Charging circuit failure. Delay: 15 seconds max.	Information: - Battery in compartment >I< will not be charged. Do the following: - Make sure that the mains plug is connected - Replace the battery in compartment >I< - Insert battery in compartment >II< If the alarm recurs or persists: - Contact an authorised service agent.
#420	I	Battery electronics	Charging circuit failure. Delay: 15 seconds max.	Information: - Battery in compartment >II< will not be charged. Do the following: - Make sure that the mains plug is connected - Replace the battery in compartment >II< - Insert battery in compartment >I< If the alarm recurs or persists: - Contact an authorised service agent.
#421	7	Battery electronics	Battery electronics is defective. Delay: 15 seconds max.	Information: - Ventilator cannot switch to backup battery - Ventilation is running on mains power only - Safe operation cannot be guaranteed Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#422	3	Internal fault	Internal monitoring of power supply is defective. Delay: 15 seconds max.	- Information: - Batteries cannot be charged - The current measurement in the power supply module is implausible If the alarm recurs or persists: - Contact an authorised service agent.

Intensive Care Ventilator Alarms

Code	Prior-ity	Alarm message	Cause	Corrective measure
#501	4	Expiratory flow sensor	The heater for the expiratory flow sensor is defective. Delay: 30 seconds max.	- Information: - Water condensation may be inside the expiratory flow sensor - Expiratory measuring values may be incorrect Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#502	5	Device temperature	Temperature of expiratory flow sensor is outside the operating range. Delay: 10 seconds max.	Information: - Expiratory measuring values may be incorrect Ventilator is operating safely. Check that: - Ambient temperature is within range - There are no external sources which are causing a temperature change - After transport: let the ventilator adapt to environmental conditions If the alarm recurs or persists: - Contact an authorised service agent.
#503	5	Device temperature	Temperature inside the gas mixer is outside the operating range. Delay: 10 seconds max.	Ventilator is operating safely. Check that: - Ambient temperature is within range - There are no external sources which are causing a temperature change - Temperature of supplied gases are within operating range of ventilator - After transport: let the ventilator adapt to environmental conditions If the alarm recurs or persists: - Contact an authorised service agent.
#504	4	ON button error	The ON button is stuck or was pressed too long Delay: 5 seconds max.	Information: - Do not press the ON switch longer than 10 seconds Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#505 (**)	3	Visual alarm	The alarm indicators of the ventilator unit failed.	Information: - This error does not affect the ventilation function - The alarm indicators of the ventilator unit cannot generate the visual alarms - Now the control unit generates the visual alarms Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.

Code	Prior- ity	Alarm message	Cause	Corrective measure
#506	7	Buzzer fault	The buzzer in the ventilator unit is defective	Information: - This error does not affect the ventilation function - The loudspeaker cannot generate the acoustic alarms - Now the loudspeaker in the control unit generates the acoustic alarm Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#507	3	Oxygen sensor	The O₂ measurement in the gas mixer is disturbed. Delay: 5 seconds max.	Information: - FiO₂ sensor calibration in the service menu may correct the error If the alarm recurs or persists: - Contact an authorised service agent.
#508	7	Internal device failure	A sensor communication failure occurred.	Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#509	2	Memory error	An error occurred while reading the default configuration	Do the following: - Check all ventilator settings and alarm limits and adapt them if required Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#510	7	Internal device failure	An internal voltage supply has failed	Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#511	3	CO ₂ sensor defect	The CO₂ sensor reports an error. Delay: 30 seconds max.	Information: - Sensor cannot be activated Do the following: - Disconnect CO₂ sensor from serial interface, then reconnect - Replace defective CO₂ sensor if applicable - Use external CO₂ monitoring if required If the alarm recurs or persists: - Contact an authorised service agent.

Code	Priority	Alarm message	Cause	Corrective measure
#512	3	CO ₂ sensor defect	The CO ₂ sensor reports an error or is missing. Delay: 30 seconds max.	Information: - Sensor cannot be activated Do the following: - Use external CO ₂ monitoring if required If the alarm recurs or persists: - Contact an authorised service agent.
#513	3	CO ₂ calibration	The CO ₂ sensor needs to be calibrated. Delay: 30 seconds max.	Do the following: - Rule out contamination of CO ₂ sensor - Perform calibration
#514	3	CO ₂ sensor defect	The CO ₂ sensor reports an error. Delay: 30 seconds max.	Information: - Sensor cannot be activated Do the following: - Disconnect CO ₂ sensor from serial interface, then reconnect - Replace defective CO ₂ sensor if applicable - Use external CO ₂ monitoring if required If the alarm recurs or persists: - Contact an authorised service agent.
#515	3	Invalid CO ₂ measurement	The end-tidal range or the breath cannot be reliably detected. Delay: 30 seconds max.	Do the following: - Rule out leak in breathing circuit and sampling tube - Watch patient to determine pathological breathing patterns - Check ventilator settings
#516	3	CO ₂ sensor adapter	No reliable readings from the measuring cell.	Do the following: - Check the measuring cell of the CO ₂ sensor or the sampling line - Replace defective CO ₂ sensor if applicable - Use external CO ₂ monitoring if required If the alarm recurs or persists: - Contact an authorised service agent.
#517	1	CO ₂ sensor temperature	Wait for sensor temperature to stabilize.	Do the following: - Wait until CO ₂ sensor temperature is within operating range.
#521	1 5	Setup error	Loading the trend data and setup file failed.	Information: - Safe operation of the ventilator is ensured - Default setup configuration is displayed - Ventilator tries loading trend data and your individual screen configuration automatically - A restart may solve the problem Do the following, if alarm recurs or persists: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.

Mesh Nebulizer Alarms

Code	Priority	Alarm message	Cause	Corrective measure
#530	3	Mesh nebulizer	The inhalation unit of the mesh nebulizer is defective. Delay: 30 seconds max.	Do the following: - Change inhalation unit, or - Use alternative nebulizer technique If the alarm recurs or persists: - Contact an authorised service agent.
#532	1 2	Mesh nebulizer	The fill level in the inhalation unit of the mesh nebulizer is below the minimum. Delay: 30 seconds max.	Do the following: - Switch off nebulizer - Check the position of the nebulizer cable - Check medication level - Refill inhalation solution if applicable - Switch on nebulizer and check for proper functioning
534	3	Wrong inhalation unit	There is no inhalation unit connected to the mesh nebulizer, or it is not an approved type. Delay: 30 seconds max.	- Connect approved nebulizer unit
#535	5	Pneumatic nebulizer has failed	Nebulization has stopped because the O ₂ gas supply is interrupted.	Do the following: - Check gas wall outlet for reliability - Open valve of pressure cylinder if applicable - Replace pressure cylinder if required - Check gas supply hoses for leaks if applicable
#536	3	SpO ₂ sensor defective	The SpO ₂ sensor reports an error or is missing.	Do the following: - Check the status of SpO ₂ sensor
#537	3	SpO ₂ Sensor not Connected	The SpO ₂ sensor is not connected to the Patient.	Information: - The SpO ₂ sensor is unable to measure correct values Please check: - That the sensor is correctly applied to the finger - That the skin is not too strongly pigmented If the alarm recurs or persists: Contact an authorised service agent.

Code	Priority	Alarm message	Cause	Corrective measure
540	3	Device temperature	The temperature inside the ventilator unit is outside the approved operating range.	- Check ambient temperature - Rule out presence of external heat sources causing rise in temperature - After transport in cold environment, allow device to warm up - If alarm condition persists, device should be removed from service as a precaution - Consider contacting an authorised service agent

Hygiene Management Messages

Code	Priority	Alarm message	Cause	Corrective measure
#550	I	Installed life: tubes	The ventilation tubes have reached the maximum period of service.	Do the following: - Replace the ventilation tubes - Document the replacement in the hygiene management
#551	I	Installed life: suction system	The suction system has reached the maximum period of service.	Do the following: - Replace the suction system - Document the replacement in the hygiene management
#552	I	Installed life: HME	The HME has reached the maximum period of service.	Do the following: - Replace the HME - Document the replacement in the hygiene management
#553	I	Installed life: valve bar	The valve bar has reached the maximum period of service.	Do the following: - Replace the valve bar - Document the replacement in the hygiene management
#554	I	Installed life: nebulizer	The nebulizer has reached the maximum period of service.	Do the following: - Replace the nebulizer - Document the replacement in the hygiene management
#555	I	Installed life: heated tube system	The ventilation tubes have reached the maximum period of service.	Do the following: - Replace the ventilation tubes - Document the replacement in the hygiene management
#556 (*)	I	Installed life: turbine intake filter	The turbine intake filter has reached the maximum period of service.	Do the following: - Replace the filter - Document the replacement in the hygiene management

(*) elisa 300 elisa 500 only (**) elisa 600 elisa 800 only

Intensive Care Ventilator Alarms

Code	Prior-ity	Alarm message	Cause	Corrective measure
#560	3	Conflict Plimit	The expected ventilation pressure (PS, P _{insp} , P _{max}) can be affected by the set value of Plimit.	Information: - Ventilation can be interrupted due to conflicts in the parameter settings. Do the following: - Adapt parameters in the way that PS, P_{insp}, P_{max} are at least 5 cmH₂O lower than Plimit That means reduce ventilation pressure settings or increase Plimit.
#570	3	Extension slots defective	Extension slots on the back of the device are not usable.	Information: - The PDMS data interface is defective and not available. - Equipment connected to the defective slots is not usable. If the alarm recurs or persists: Contact an authorised service agent.
#577	3	Nurse call Adapter Dis-connected	The nurse call adapter is not connected.	Information: - The nurse call adapter is not connected. Please check: - That the nurse call adapter is connected correctly. If the alarm recurs or persists: Contact an authorised service agent.
#578	3	LeoLyzer communication error	Unable to connect to LeoLyzer sensor	Please check: - That the sensor is connected correctly. If the alarm recurs or persists: - Replace the sensor - Contact an authorised service agent.
#579	1	LeoLyzer zeroing	LeoLyzer is currently zeroing	Do the following: - Wait until zeroing was performed correctly If the alarm persists: - Reconnect sensor - Replace the sensor - Contact an authorised service agent.
#581	2	LeoLyzer sensor temperature	Wait for sensor temperature to stabilize.	Do the following: - Wait until LeoLyzer temperature is within operating range

Code	Priority	Alarm message	Cause	Corrective measure
#582	3	LeoLyzer occlusion	Occlusion in sampling line	Please check: - That the sampling line is clear of occlusions. - That the sampling line is connected correctly to the sensor and patient. Do the following: Switch LeoLyzer off and on after the occlusions have been removed. If the alarm recurs or persists: - Replace the sensor - Contact an authorised service agent.
#583	3	Invalid LeoLyzer measurement	The end-tidal range or the breath cannot be reliably detected.	Do the following: - Rule out leak in breathing circuit and sampling line - Check that the sampling line is connected correctly to the sensor and patient - Closely monitor patient to determine pathological breathing patterns - Check ventilator settings
#584	1	LeoLyzer anaesthetic selection	LeoLyzer anaesthetic was not selected correctly.	Do the following: - Ensure the correct anaesthetic is selected.
#640	7	Valve error	NIF valve fault	Information: - The NIF valve is defective Check that: - Applied volume, flow and pressure are correct for the patient if OK, you can continue using the ventilator. Do, if required: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put the ventilator out of service - Contact an authorised service agent.
#641	7	Valve error	Security valve error.	Information: - The security valve is defective Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put the ventilator out of service - Contact an authorised service agent.

Code	Prior- ity	Alarm message	Cause	Corrective measure
#640	7	Valve error	NIF valve error.	Information: - The NIF valve is defective Check that: - Applied volume, flow and pressure are correct for the patient if OK, you can continue using the ventilator. Do, if required: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#641	7	Valve error	Security valve error.	Information: - The security valve is defective Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#642	7	Valve error	Turbine non-return valve error.	Information: - The turbine non-return valve is defective Check that: - Applied volume, flow and pressure are correct for the patient if OK, you can continue using the ventilator. Do, if required: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#649	7	Pressure implausible	The difference between inspiratory and expiratory pressure value is out of range.	Check that: - Tubes of breathing circuit have no kinks, water condensation or other restrictions Do, if required: - Replace tubing set and run system test If the alarm recurs or persists: - Put the ventilator out of service - Contact an authorised service agent.
#650	2	Flow measurement error	The measurements from the expiratory flow sensor are incorrect. Delay: 30 seconds max.	Information: - The sensor may be contaminated or defective Do the following: - Remove and clean expiratory flow sensor - Check measuring cell in expiratory flow sensor for damage - Replace expiratory flow sensor if required If the alarm recurs or persists: - Contact an authorised service agent.

Code	Priority	Alarm message	Cause	Corrective measure
#654	3	O ₂ supply	The pressure at the oxygen inlet is low.	Check that: - Pressure of gas wall outlet is in operating range - Gas supply lines and connections have no leaks Do the following: - Open valve of pressure cylinder if applicable - Replace pressure cylinder if required
	7			Information: - O₂ supply is not available Ventilation is now only possible with air Monitor: - O₂ concentration Decide: If ventilation with low oxygen is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#655	3 5	O ₂ supply	The pressure at the oxygen inlet is high.	Check that: - Applied volume, flow and pressure are correct for the patient if OK, you can continue using the ventilator. Do, if required: - Carry out the system test at the next opportunity (system test analyses the problem exactly and can solve it) If alarm recurs or persists in system test: - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.

Code	Prior- ity	Alarm message	Cause	Corrective measure
#656	3	Air supply	The pressure at the compressed air inlet is low.	Check that: - Pressure of gas wall outlet is in operating range - Gas supply lines and connections have no leaks Do the following: - Open valve of pressure cylinder if applicable - Replace pressure cylinder if required
	7			Information: - Air supply is not available - Ventilation is now only possible with oxygen Check that: - Pressure of gas wall outlet is in operating range - Gas supply lines and connections have no leaks Decide: If pressure supply is ok and pure oxygen concentration is a hazard: - Disconnect the patient from this ventilator - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#657	3 5	Air supply	The pressure at the compressed air inlet is high.	Check that: - Applied volume, flow and pressure are correct for the patient if OK, you can continue using the ventilator. Do, if required: - Carry out the system test at the next opportunity (system test analyses the problem exactly and can solve it) If alarm recurs or persists in system test: - Put this ventilator out of service - Continue ventilation with another ventilator - Contact an authorised service agent.
#660	7	Internal fault	The regulation of the O ₂ flow control valve is disturbed.	Information: - High flow volumes cannot be reliably provided - Safe operation cannot be guaranteed Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.

Code	Priority	Alarm message	Cause	Corrective measure
#661	7	Internal fault	The regulation of the Air flow control valve is disturbed.	Information: - High flow volumes cannot be reliably provided - Safe operation cannot be guaranteed Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#663	7	Internal fault	The regulation of the O2 flow control valve is disturbed.	Information: - Low flow volumes cannot be reliably provided - Safe operation cannot be guaranteed Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#664	7	Internal fault	The regulation of the Air flow control valve is disturbed.	Information: - Low flow volumes cannot be reliably provided - Safe operation cannot be guaranteed Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#666	7	Internal fault	A watchdog security error occurred.	Information: - Safe operation cannot be guaranteed Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#668	I	Simulation mode	No ventilation is running.	Information: - To terminate the simulation mode, switch the device off and switch it on again
#669 (**)	7	Control unit	The software versions of control unit and of the ventilator unit are incompatible.	Information: - Panel software version mismatch. Do immediately: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.

Code	Prior-ity	Alarm message	Cause	Corrective measure
#671	3	Reinitialisa-tion	The ventilator was reinitialized.	Information: - Ventilator performed a restart to solve an error Do the following: - Check the ventilation behaviour of the device - Restart interrupted manoeuvres if appropriate If the alarm recurs or persists: - Contact an authorised service agent.
#672	I	Alarm vol-ume low	The set alarm volume is below 40%.	Information: - Alarm sound can be too quiet to be heard from a far distance or in noisy environment Check that: - You can hear alarms at every workplace - You can hear alarms in noisy environment

(*) elisa 300 elisa 500 only (**) elisa 600 elisa 800 only

elisa 800 VIT Alarms

Code	Prior-ity	Alarm mes-sage	Cause	Corrective measure
#701	I	SensorBelt Defect	The SensorBelt reports implausi-ble values.	Do the following: - Check the placement of the SensorBelt - Apply ContactAgent to improve signal quality - Replace the SensorBelt if appropriate If the alarm recurs or persists: - Contact an authorised service agent.
#702	I	SensorBelt adapter defective	The SensorBelt-Connector re-ports implausible values.	Do the following: - Disconnect, then reconnect the SensorBelt-Connector - Check the SensorBeltConnector for me-chanical damage - Replace the SensorBeltConnector, if the problem recurs If the alarm recurs or persists: - Contact an authorised service agent.
#703	I	VIT defective	The VIT sends no or incorrect data.	Do the following: - Restart the ventilator to resolve the problem If the alarm recurs or persists: - Contact an authorised service agent.
#704	I	VIT error	Communication error between ventilator unit and VIT.	Do the following: - Restart the ventilator to resolve the problem If the alarm recurs or persists: - Contact an authorised service agent.

elisa 300 elisa 500 – Control Unit Alarms

Code	Pri- ority	Alarm message	Cause	Corrective measure
#711	3	Power failure	The internal power supply of the control unit is defective.	Information: - Control unit was automatically re-started Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#712	3	Power failure	The internal power supply of the control unit is defective.	Information: - Control unit was automatically re-started Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#713	3	Power failure	The internal power supply of the control unit is defective.	Information: - Control unit was automatically restarted Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#714	3	Control unit	The internal communication with the control unit is disturbed.	Information: - Control unit was automatically restarted Ventilator is operating safely. If the alarm recurs or persists: - Contact an authorised service agent.
#715	3	Loudspeaker failure	The loudspeaker is defective.	Information: - The redundant buzzer in the ventilator unit generates the acoustic alarm If the alarm recurs or persists: - Contact an authorised service agent.
#716	7	Visual alarm	The Alarm indicator is defective.	Information: - Visual alarm is still indicated on the display - Ensure good display visibility If the alarm recurs or persists: - Contact an authorised service agent.

elisa 300 elisa 500 – Turbine Alarms

Code	Priority	Alarm message	Cause	Corrective measure
#731	1 7	Turbine Error	A turbine error was detected during the power up test.	Information: - Only single-gas operation with oxygen is possible - Oxygen supply must be stable and powerful Check that: - Ventilator is connected to oxygen gas supply - No other alarms occur during ventilation due to a weak oxygen supply If no oxygen gas is connected and alarm recurs or persists: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#732	3	Turbine Error	The turbine power supply is defective.	Information: - Ventilation may fail shortly - In this case, only single-gas operation with oxygen is possible - Oxygen supply must be stable and powerful Check that: - Ventilator is connected to oxygen gas supply - No other alarms occur during ventilation due to a weak oxygen supply If no oxygen gas is connected and alarm recurs or persists: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#733	3	Turbine Error	The current consumption of the turbine is outside the permitted range.	Information: - Ventilation may fail shortly - In this case, only single-gas operation with oxygen is possible - Oxygen supply must be stable and powerful Check that: - Ventilator is connected to oxygen gas supply - No other alarms occur during ventilation due to a weak oxygen supply If no oxygen gas is connected and alarm recurs or persists: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.

Code	Pri- ority	Alarm message	Cause	Corrective measure
#734	1 7	Turbine Error	The turbine speed is outside the permitted range.	Information: - Only single-gas operation with oxygen is possible - Oxygen supply must be stable and powerful Check that: - Ventilator is connected to oxygen gas supply - No other alarms occur during ventilation due to a weak oxygen supply If no oxygen gas is connected and alarm recurs or persists: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#735	3	Turbine Error	The turbine temper- ature is outside the permitted range	Information: - Ventilation may fail shortly - In this case, only single-gas operation with oxygen is possible - Oxygen supply must be stable and powerful Check that: - Ventilator is connected to oxygen gas supply - No other alarms occur during ventilation due to a weak oxygen supply - Ambient temperature is within range - Ventilator and ventilation slots on the back of device are not covered - Ventilator unit has enough space for heat dissipation - After transport: let the ventilator adapt to environmental conditions If the alarm recurs or persists: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.

Code	Pri- ority	Alarm message	Cause	Corrective measure
#736	1 7	Turbine Error	internal communi- cation with the turbine controller is disturbed.	Information: - Ventilation may fail shortly - In this case, only single-gas operation with oxygen is possible - Oxygen supply must be stable and powerful Check that: - Ventilator is connected to oxygen gas supply - No other alarms occur during ventilation due to a weak oxygen supply If no oxygen gas is connected and alarm recurs or persists: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#737	3	Turbine Error	Power supply of turbine controller is defective.	Information: - Ventilation may fail shortly - In this case, only single-gas operation with oxygen is possible - Oxygen supply must be stable and powerful Check that: - Ventilator is connected to oxygen gas supply - No other alarms occur during ventilation due to a weak oxygen supply If no oxygen gas is connected and alarm recurs or persists: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#738	3	Turbine intake filter	Turbine intake filter is polluted.	Check that: - The filter is correctly inserted - The filter is clean Do, if required: - Insert a new turbine intake filter If the alarm recurs or persists: - Contact an authorised service agent.

Code	Pri- ority	Alarm message	Cause	Corrective measure
#739	1 7	Turbine Error	The backflow limit was reached.	Information: - Only single-gas operation with oxygen is possible - Oxygen supply must be stable and powerful Check that: - Ventilator is connected to oxygen gas supply - No other alarms occur during ventilation due to a weak oxygen supply If no oxygen gas is connected and alarm recurs or persists: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#740	1 7	Turbine error	The turbine flow is outside the permitted range.	Information: - Only single-gas operation with oxygen is possible - Oxygen supply must be stable and powerful Check that: - Ventilator is connected to oxygen gas supply - No other alarms occur during ventilation due to a weak oxygen supply If no oxygen gas is connected and alarm recurs or persists: - Disconnect patient from ventilator - Continue ventilation with another ventilator - Put this ventilator out of service - Contact an authorised service agent.
#741	5	No turbine intake filter	The turbine intake filter is loose or missing.	Information: - Without a filter, the inside of the ventilator can become contaminated Do immediately: - insert turbine intake filter correctly

Paux Alarms

Code	Prior-ity	Alarm message	Cause	Corrective measure
#751	I	Paux Error	The power supply of the Paux pump is defective	Information: - Any Paux function is only available when oxygen is connected. If the alarm recurs or persists: Contact an authorised service agent.
	5			Information: - Any Paux function is only available when oxygen is connected. Do immediately: - Connect ventilator to oxygen gas supply If the alarm recurs or persists: Contact an authorised service agent.
#752	I	Paux Error	The current consumption of the Paux pump is outside the permitted range	Information: - Any Paux function is only available when oxygen is connected. If the alarm recurs or persists: - Contact an authorised service agent.
#752	5	Paux Error	The current consumption of the Paux pump is outside the permitted range	Information: - Any Paux function is only available when oxygen is connected. Do immediately: - Connect ventilator to oxygen gas supply If the alarm recurs or persists: - Contact an authorised service agent.
#753	5	Paux error	Paux supply pressure is high.	Information: - All Paux functions are disabled If the alarm recurs or persists: - Contact an authorised service agent.
#754	5	Paux error	Paux supply pressure is low.	Information: - All Paux functions are disabled If the alarm recurs or persists: - Contact an authorised service agent.

9.5 Error messages during power up test

Remark | Please note down the displayed error codes for service purposes.

Code	Error message	Corrective measure
#201 to #269	Pressure, flow or voltage measurement error (sensor problem)	Do not use ventilator, switch OFF, contact authorised service agent

Code	Error message	Corrective measure
#654	O ₂ supply Low oxygen inlet pressure	Correct or acknowledge error; contact authorised service agent
#801 to #805	Various alarm LED errors (ventilator unit)	Do not use ventilator; switch OFF; contact authorised service agent
#811 and #812	Various buzzer errors (ventilator unit)	Do not use ventilator; switch OFF; contact authorised service agent
#813 and #814	Various power supply errors in the main controller	Do not use ventilator; switch OFF; contact authorised service agent
#815 and #816	Various power supply errors in the sensor controller	Do not use ventilator; switch OFF; contact authorised service agent
#817 to #826	Various power supply errors in the main board	Do not use ventilator; switch OFF; contact authorised service agent
#827	Buffer battery RTC drained	Set date and time Ventilator may be used contact authorised service agent
#831 and #833	Measurement of ventilator unit temperature < 5°C	Allow device to warm up
#832 and #834	Check ambient temperature	Rule out presence of external heat sources causing rise in temperature
#835 to #837	Various errors due to defective heating of expiratory flow sensor	Do not use ventilator; switch OFF; contact authorised service agent
#841 to #847	Various “internal memory” errors	Acknowledge error; Check all ventilator settings and alarm limits, adapt if required contact authorised service agent
#851 to #855	Internal Safety Circuit Error	Do not use ventilator; switch OFF; contact authorised service agent
#861 to #867	Various battery errors Battery compartment 1	Replace battery or insert additional battery in compartment 2
#868	Remaining usage time on battery 1 < 5 min	Connect device to the mains
#869	Capacity of battery 1 is insufficient for number of accessory devices	Connect device to the mains

Code	Error message	Corrective measure
#870 to #876	Various battery errors Battery compartment 1	Replace battery or insert additional battery in compartment 2
#877 to #883	Various battery errors Battery compartment 2	Replace battery or insert additional battery in compartment 1
#884	Remaining usage time on battery 2 < 5 min	Connect device to the mains
#885	Capacity of battery 2 is insufficient for number of accessory devices	Connect device to the mains
#886 to #892	Various battery errors Battery compartment 2	Replace battery or insert additional battery in compartment 1
#893	No mains voltage	Connect device to the mains
#894	Mains connection cannot be established	Acknowledge error, contact service agent
#895	Internal power supply safety circuit error	Do not use ventilator; switch OFF, contact authorised service agent
#896	Power supply error - voltage from 3.3 V power controller is incorrect	Do not use ventilator; switch OFF, contact authorised service agent
#897	Fault: charging circuit defect	Acknowledge error, contact authorised service agent
#898	Power supply error - voltage from 24 V power controller is incorrect	Do not use ventilator; switch OFF, contact authorised service agent
#899	No battery ready for use	Acknowledge error, contact authorised service agent
#900	Insufficient battery charge level	Acknowledge error, contact authorised service agent
#901	AC adapter in ventilator unit defective	Acknowledge error, contact authorised service agent
#902	Battery charge circuit defect	Acknowledge error, contact authorised service agent
#903	Fan failure Ventilator Unit	Do not use ventilator; switch OFF, contact authorised service agent
#904	Battery charge circuit defect	Acknowledge error, contact authorised service agent
#905	Power supply error - voltage from 24 V power controller of ventilator unit is incorrect	Do not use ventilator; switch OFF, contact authorised service agent
#906 to #910	Various power manager errors	Do not use ventilator; switch OFF, contact authorised service agent

Code	Error message	Corrective measure
#911 to #915	Internal communication error	Do not use ventilator; switch OFF; contact authorised service agent
#921	O ₂ sensor defect	Do not use ventilator; switch OFF; contact authorised service agent
#922 and #923	O ₂ sensor fault Implausible values	Calibrate O ₂ sensor; if problem persists, contact authorised service agent
#931 to #939	Trend memory error	Disable trending or overwrite trend memory
#951	Restart after severe exception	Recommendation: do not use with patient, contact authorised service agent
#952	Device was switched off automatically after 5 minutes running on battery in system test/service mode	---
#953	Device was switched off because of a failed battery test.	Replace defective battery.
#961	Maintenance overdue	Contact authorised service agent
#971	Firmware update of ventilator unit failed. Please repeat firmware update	Repeat firmware update

9.6 Error messages during system test

Remark | Please note down the displayed error codes for service purposes.

Code	Error message	Corrective measure
#654	O ₂ supply Low oxygen inlet pressure	System test continues when error has been acknowledged
#1001 to #1004	Fault of the internal O ₂ flow measurement Flow measurement outside operating range	Repeat system test
#1005	Low O ₂ gas supply maximum flow cannot be reached	Press <Acknowledge> to continue with a reduced maximum flow
#1006	Fault of the internal O ₂ flow measurement Flow measurement outside operating range	Repeat system test

Code	Error message	Corrective measure
#1007 to #1010	Fault of the internal AIR flow measurement Flow measurement outside operating range	Repeat system test
#1011	Low air supply maximum flow cannot be reached	Press <Acknowledge> to continue with a reduced maximum flow
#1012	Fault of the internal air flow measurement in the ventilator unit Flow measurement outside operating range	Repeat system test
#1013 to #1017	Fault of the internal expiratory flow measurement in the ventilator unit	Repeat system test - Check breathing circuit - Check correct assembly and order of inspiratory and expiratory valves - Check expiratory flow sensor - Check humidifier if applicable
1018	Expiratory flow sensor not properly engaged	Check expiratory flow sensor
#1031 and #1036	Deviating expiratory pressure	Repeat system test - Check breathing circuit - Check correct assembly of expiratory valve - Check expiratory flow sensor
#1041 and #1043	Fault of the internal expiratory pressure measurement in the ventilator unit	Repeat system test
#1042 and #1046	Leak in pneumatic system	Repeat system test - Check breathing circuit - Check correct assembly and order of inspiratory and expiratory valves - Check expiratory flow sensor - Check humidifier if applicable
#1044 and #1048	Deviating expiratory pressure	Repeat system test - Check breathing circuit - Check correct assembly of expiratory valve - Check expiratory flow sensor
#1045 and #1047	Fault of the internal inspiratory pressure measurement Pressure measurement outside operating range	Repeat system test
#1052 to #1055	Internal fault process gas valve	Repeat system test

Code	Error message	Corrective measure
#1051 and #1061	Leak in pneumatic system	Repeat system test - Check breathing circuit - Check correct assembly and order of inspiratory and expiratory valves - Check expiratory flow sensor - Check humidifier if applicable
#1056	Fault safety valve	Repeat system test - Check correct assembly inspiratory valve, or replace valve - If problem persists, contact service agent
#1062	Internal fault proportional valves	Repeat system test
#1063	Major leakage in breathing circuit	Repeat system test - Check Y-connector, breathing circuit, expiratory valve, and expiratory flow sensor for leaks
#1071 to #1074	Pneumatic nebulizer fault	Repeat system test
#1075 to #1078	Fault of the internal expiratory pressure measurement in the ventilator unit Flow measurement outside operating range	Repeat system test - Check breathing circuit - Check correct assembly and order of inspiratory and expiratory valves - Check expiratory flow sensor - Check humidifier if applicable - Calibrate oxygen sensor if applicable
#1079 and #1080	O ₂ measurement outside measuring range	Repeat system test - Calibrate oxygen sensor
#1091	Measured overall resistance high	Repeat system test - Check patient category - Rule out use of coaxial breathing circuits - Check breathing circuit for kinks - Check correct assembly and order of inspiratory and expiratory valves - Check expiratory flow sensor - Check humidifier if applicable
#1092	Oscillation Due to High Resistance	Repeat system test - Check patient category - Rule out use of coaxial breathing circuits - Check breathing circuit for kinks
#1093	Measured inspiratory resistance too high. Resistance : <value> [mbar/l/s]	Repeat system test - Check patient category - Rule out use of coaxial breathing circuits - Check breathing circuit for kinks
#1101 and #1102	CO ₂ sensor reports error and cannot be activated	Repeat system test

Code	Error message	Corrective measure
#1103	CO ₂ sensor calibration required	Repeat system test - Calibrate CO ₂ sensor
#1104	CO ₂ sensor reports error and cannot be activated	Repeat system test
#1111 to #1114	Fault safety valve	- Repeat system test - Check correct assembly inspiratory valve, or replace valve - If the problem persists, contact an authorised service agent

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10 Cleaning, disinfection and sterilisation, disposal

10.1	General information	170
10.1.1	Initial operation	170
10.2	Cleaning and disinfection	171
10.2.1	Intensive care ventilator	171
10.2.2	Valve bar	172
10.2.2.1	Removing the three parts of the valve bar	172
10.2.2.2	Machine cleaning with disinfection	172
10.2.2.3	Sterilisation of the valve bar	174
10.2.2.4	Visual inspection of the valve bar	175
10.2.2.5	Components of the valve bar	176
10.3	Disposal of elisa 300 / elisa 500	177

10.1 General information



Warning

Important safety precautions:

- Observe the instructions for use and data sheets of the cleaning agents and disinfectants.
- Wear protective gloves and safety goggles.
- Do not inhale fumes.



Caution

Avoid damage:

- Do not use any organic, halogenated or mineral oil based solvents, volatile anaesthetics, glass cleaners, acetone, sharp or abrasive cleaning agents, e.g., steel wool, silver polish or silver cleaners.
- Do not allow liquids to enter into the housing.
- Keep liquids away from electronic components.
- Only autoclave parts that have been declared as detachable and autoclavable in these instructions for use.
- Contact the manufacturer if you have questions concerning cleaning agents or disinfectants.



Warning

Avoid patient contamination:

- Clean elisa 300 / elisa 500 and sterilise the connected accessories after each patient.
- Comply with the general hygiene regulations of the hospital or the national hygiene recommendations.
- Do not reuse components intended for single use.

10.1.1 Initial operation

At the time of delivery the ventilator is not sterilised or cleaned by the manufacturer in the clinical sense. Prior to initial operation on a patient, the device must be processed appropriately.

10.2 Cleaning and disinfection

Switch the device off and disconnect it from the power supply.

Remove all tubes and other accessories from the device.

Discard all disposable items in compliance with the hygiene regulations of your hospital or institution.

Process all reusable items for reuse in compliance with the corresponding instructions for use.

10.2.1 Intensive care ventilator

Use a soft cloth and mild cleaning agent to clean the surface of the housing and of the control unit.

Remark

It is the task of the physician responsible for hygiene or of the hygiene specialist to ascertain that the cleaning agents used are suitable for the pathogen spectra that may be encountered in the different areas and applications. The products recommended below are essentially compatible with the intensive care ventilators.

The following disinfectants are recommended for disinfection of the surface. Use the products according to the manufacturer's instructions. Do not allow liquid to enter the housing.

- Schülke mikrozyd® sensitive liquid
- Schülke mikrozyd® sensitive wipes
- Schülke mikrozyd® universal liquid
- Schülke mikrozyd® universal wipes
- Schülke perform
- BODE Mikrobac® basic
- BODE Mikrobac® Tissues
- BODE Dismozon® plus
- Ecolab SANI-CLOTH® ACTIVE

Remark

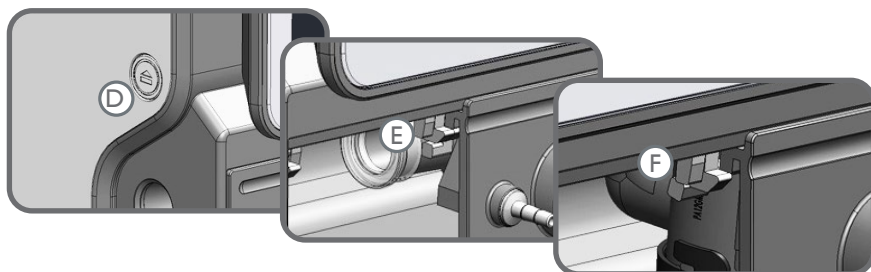
If you want to disinfect the display surface during operation, lock the screen first.
For further information, please refer to chapter 7.4.1 "Lock and unlock the screen".



Caution

Check that the device has thoroughly dried before using it again.

10.2.2 Valve bar



10.2.2.1 Removing the three parts of the valve bar

Actuate the respective release lever to remove the individual elements of the valve bar one after another (push release levers **E** and **F** backwards).

D Release lever for expiratory flow sensor

E Release lever for expiratory valve

F Release lever for inspiratory valve

10.2.2.2 Machine cleaning with disinfection

For machine cleaning and disinfection of the reusable modules of the valve bar, an EN ISO 15883 compliant washer disinfectant can be used. It is suggested to use the cart for anaesthesia and ventilation accessories for loading the item into the machine.



Warning

Please note that all valve bar parts may be contaminated by bodily fluids or exhaled gases!



Warning

Perfect functioning of the valve bar can be guaranteed only if each individual element is intact. The contact areas of the silicon membranes, in particular, must be carefully checked before each use; the valves must be replaced if required.

Remark

The three-part **PEEP membrane** (expiratory valve) remains assembled for reprocessing.

Remark

Observe the manufacturer's instructions for use of the cleaning agents and disinfectants.

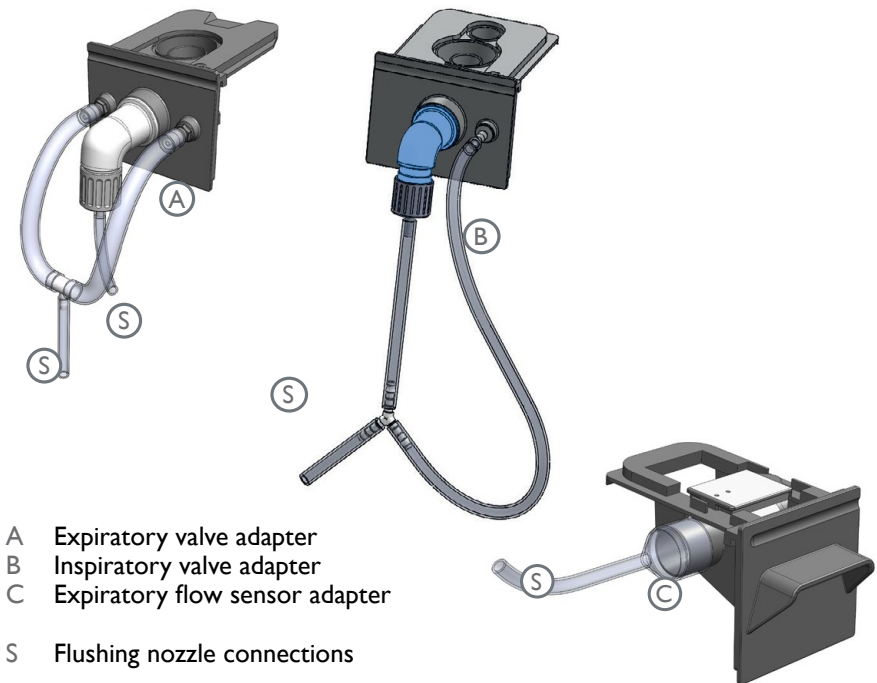
First remove all silicone parts of the valve bar.

Place the individual silicone parts **flat on a horizontal grid** in a separate preparation container for small parts.

Position all elements on the cart for anaesthesia and ventilation accessories so that all interior spaces and surfaces are completely rinsed.

Use the special cleaning adapters for the expiratory valve, the inspiratory valve and the expiratory flow sensor (refer to separate accessory list). These will ensure that the gas-conveying interior spaces are completely flushed and the water can run off freely.

The cleaning adapters are connected to the washer disinfector via four rinsing nozzles and connected to the valve bar elements according to the following images:

**Remark**

Observe the instructions for use of the washer disinfector.

Remark | Use a cleaning agent suitable for anaesthesia accessories.

For machine cleaning with disinfection, “neodisher MediClean forte” by “Chemische Fabrik Dr. Weigert GmbH & Co. KG” and Schülke thermosept® X.tra, applied according to the manufacturer's instructions, is recommended.

Select a programme for anaesthesia accessories (e.g. Vario TD). Cleaning is performed at 55°C (131°F) for a minimum of 10 minutes and thermal disinfection at 93°C (199.4°F) for a minimum of 5 minutes.

The final rinse must be carried out with demineralised water.

After cleaning and disinfection take the components of the valve bar out of the washer disinfector and carry out a visual inspection.

Subsequently, allow the parts to dry for at least 40 minutes.

10.2.2.3 Sterilisation of the valve bar

The valve bar can be steam sterilised at 134°C (273.2°F).

Minimum sterilisation period is 3 minutes.

Alternative: The A_0 value must be at least 3000.

Use DIN EN 285 compliant vacuum steam sterilisers for sterilisation, preferably with fractional vacuum.

Remark | Observe the instructions for use of the autoclave.

Remark | Autoclave the expiratory flow sensor, expiratory and inspiratory valves assembled.



Warning

Ethylene oxide diffusing into the components of the valve bar pose a health hazard to the patient. Therefore, do not sterilise the valve bar with ethylene oxide.

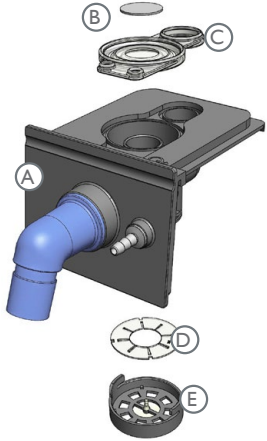
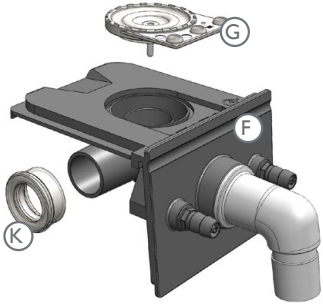


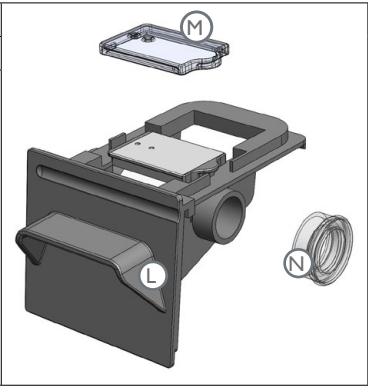
Warning

All silicone parts of the valve bar must be replaced after 500 sterilisation cycles or during annual maintenance, whichever occurs first.

10.2.2.4 Visual inspection of the valve bar

After reprocessing, the components of the valve bar must be checked to ensure that they are in perfect condition. Check that the following components are available and intact after reprocessing:

A	Inspiratory valve	
B	Metal disc	
C	Inspiratory valve membrane	
D	Free breathing membrane	
E	Valve basket with mushroom valve	
F	Expiratory valve	
G	PEEP membrane (3 parts), consisting of silicone membrane, disc and silicone disc	
K	Sealing ring expiratory valve	
	 Do not disassemble the PEEP membrane. This is neither allowed nor necessary.	
	 Check the proper fit of the sealing ring.	

L	Expiratory flow sensor	
M	Sealing plate	
N	Sealing ring expiratory flow sensor	

 Check the proper fit of the sealing ring.



Check that the valve bar does not exhibit signs of damage. Particularly check the contact surfaces of the silicone membranes. Replace damaged valves.



Please ensure that all individual parts are completely dry.

10.2.2.5 Components of the valve bar

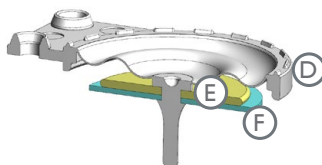
PEEP membrane

Check that the three-part PEEP membrane is complete and that the three components are intact (sectional view).

Remark

Do not disassemble the PEEP membrane. This is neither allowed nor necessary.

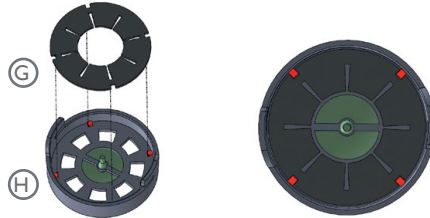
- D Expiratory valve membrane
- E Disc
- F Silicone disc



Free breathing membrane

Check that the free breathing membrane is placed in the valve basket with the proper orientation of the cut-outs.

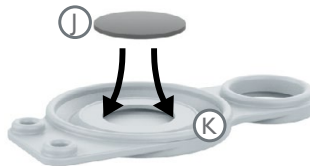
- G Free breathing membrane
- H Valve basket with mushroom valve



Inspiratory valve membrane

Check that the metal disc is correctly inserted in the corresponding space in the silicone membrane when assembling the **inspiratory valve** membrane.

- J Metal disc
- K Silicone membrane



Expiratory flow sensor

Pay attention to the correct orientation of the sealing disc when assembling the **expiratory flow sensor**.

10.3 Disposal of elisa 300 / elisa 500

Before disposing of the elisa 300 / elisa 500 ventilator, the device must be cleaned and disinfected according to chapter 10.2.

Do not dispose of the elisa 300 / elisa 500 and of the rechargeable batteries with the domestic waste. Consult an authorized, certified electronic waste recycling company for the proper disposal. Please contact the Environmental Officer of your facility or your town hall for the appropriate address.

The outer packaging (box) can be disposed of in the waste paper.

The foam inserts of the device packaging can be disposed of with the domestic waste.

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II Maintenance

II.1	General	180
II.2	Oxygen measurement (O₂)	180
II.2.1	Calibration of the paramagnetic O ₂ sensor	181
II.3	Air filter cassette for turbine	181
II.3.1	Exchanging the air filter cassette	182
II.4	Maintenance intervals	183
II.4.1	Annual maintenance	183
II.4.2	Maintenance every 6 years	183
II.4.3	Maintenance every 12 years	183
II.5	Additional maintenance and repair information	184

II.1 General

elisa 300 / elisa 500 has been designed as an intensive care ventilator that requires little maintenance. The user does not have to perform any calibration. Maintenance of the elisa 300 / elisa 500 must be performed annually by an authorised service technician according to the service interval indication. Detailed information can be found in the current elisa 300 / elisa 500 Technical Manual.

Before and during maintenance or repair, it must be ensured that:

- elisa 300 / elisa 500 is switched off and the power plug has been removed
- the batteries have been removed
- all tube components have been removed
- all additional components have been removed

These conditions do not apply for the technical safety inspections.



Warning

Reprocessing of the valve bar is mandatory after any service intervention involving the valve bar.

II.2 Oxygen measurement (O₂)

A paramagnetic O₂ sensor without consumables is used to monitor the inspiratory oxygen concentration. The sensor is calibrated by the authorised service technician as part of the annual maintenance procedure.



Warning

When using oxygen concentrators or when the oxygen concentration from the central gas supply is insufficient, the sensor calibration may not be correct.

Remark

The maintenance-free, paramagnetic oxygen sensor has an automatic compensation for the barometric pressure.

Remark

Measurement accuracy of the O₂ value:
2.5% volume per cent + 2.5% gas concentration

Remark

Long-term drift of the O₂ measurement values:
0.4% in the first month and 0.2% for each additional month



Reprocessing of the valve bar is mandatory after any service intervention involving the valve bar.

11.2.1 Calibration of the paramagnetic O₂ sensor

The user may have to perform a manual calibration of the paramagnetic O₂ sensor when there is a significant difference between the measured and the set inspiratory oxygen concentration or when the #1079 error message is displayed after the system test, which is indicative of a major difference.

The sensor can be calibrated after the power-up test or in the standby mode.

In the standby mode, the required button is accessed via “System” (button bar) and the “Extras” tab.

Select the “O₂ sensor calibration” button to open the corresponding window. Tap the button to start the calibration procedure. A progress bar is displayed indicating the process. The result will be displayed after the successful calibration. Close the window.

Remark

Note: The ventilator must be connected to the oxygen supply for calibration of the O₂ sensor.

11.3 Air filter cassette for turbine

elisa 300 / elisa 500 is a device with turbine technology that draws in room air to deliver patient ventilation.

The air entering the turbine is conducted through a HEPA quality fine filter. The filter efficiency of the fine filter meets the requirements of the HEPA H13 filter class, which means that 99.95% of all particles in the aspirated room air are captured. This guarantees that only ultra-clean air reaches the patient through the ventilator.

The air filter cassette for the turbine inlet air needs to be replaced at regular intervals. The ward standards for this interval are defined at the configuration level.

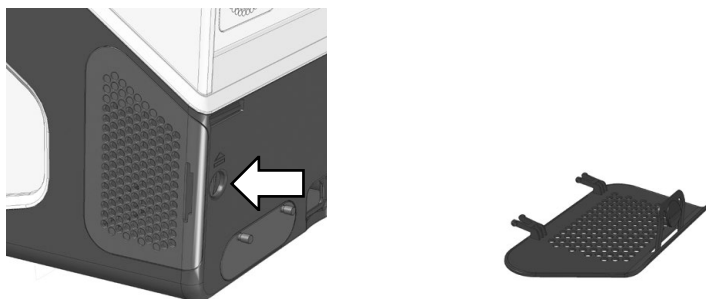


Always replace the turbine filter cassette in these situations:

- when prompted by a warning from the hygiene management
- when prompted by a warning in the system test
- when an appropriate alarm occurs during ventilation (see also “Turbine Alarms”)
- during the annual maintenance at the latest.

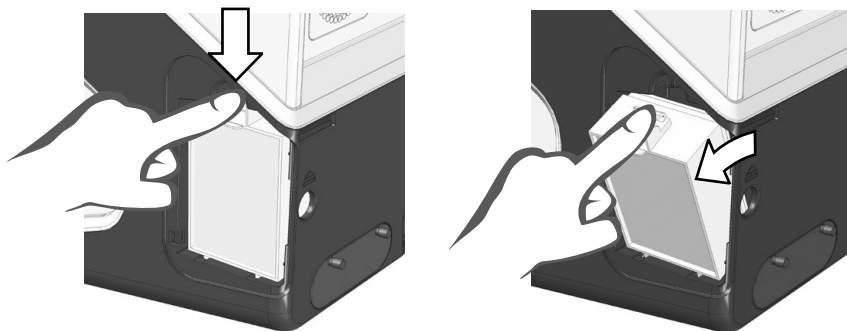
II.3.1 Exchanging the air filter cassette

Open the cover of the turbine filter on the side of the device by pressing on the release button at the back of the device .



Remove the cover and put it aside.

Remove the turbine filter cassette. To do this, press on the tab at the top of the filter cartridge and tilt it forward.



Dispose of the turbine filter cassette in compliance with the hygiene policy of your facility.

Remove the new filter cartridge from its packaging and check it for integrity. Do not use the filter cartridge if damaged.

Install the cartridge in the device. To do this, introduce the cartridge into the device at an angle so that the hooks at the bottom engage in the recesses in the device. Then push the filter cartridge into the device until you feel it lock into place. Finally introduce the snap arms of the turbine filter cover on the left and close it by pressing on the right side of the cover until you feel it lock into place.

**Warning**

- Use only turbine filter cassettes approved by the manufacturer (refer to separate accessory list).
- Replace the filter cassette only in standby mode or when the device is switched off.
- Run a system test each time after replacing a filter.

**Warning**

Do not use the intensive care ventilator without the turbine filter cassette or without the filter cover.

11.4 Maintenance intervals

11.4.1 Annual maintenance

Annual maintenance includes:

- a technical safety inspection
- the replacement of filters and seals/gaskets
- the replacement of membranes and valve bar seals
- the calibration of the O₂ sensor

11.4.2 Maintenance every 6 years

In addition to the annual maintenance measures, maintenance every six years includes:

- the replacement of the Lithium coin cell battery CR2032

11.4.3 Maintenance every 12 years

After 12 years or 50,000 hours of operation: Have preventive maintenance performed by a service technician authorised by the manufacturer.

II.5 Additional maintenance and repair information

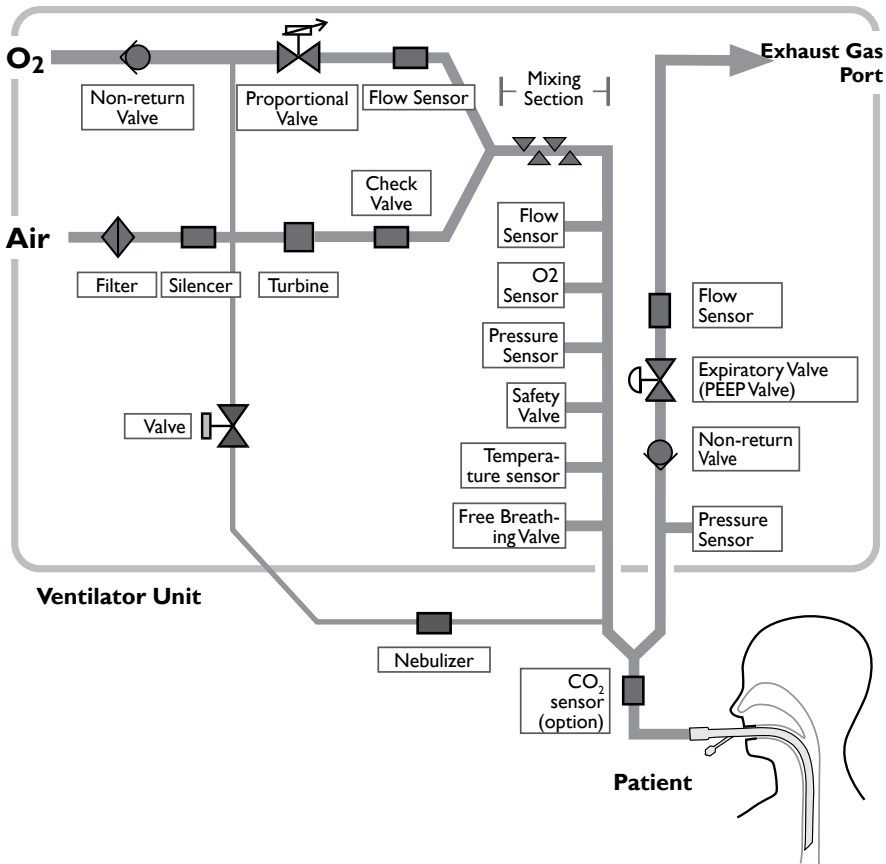
For further information about maintenance and repair, please refer to the elisa 300 / elisa 500 Technical Manual.

The Technical Manual is available for use by your service technician. This manual is available in English and German.

12 Technical specifications

12.1	Function chart of the elisa 300 / elisa 500 ventilator	186
12.2	General	186
12.3	Supply	189
12.4	Technical data	190
12.5	Control unit	191
12.6	Default parameters	192
12.7	Increments and maximum performance range	192
12.8	Instant View window / data table(s)	196
12.9	Data transmission with terminal devices	200
12.10	Guidance and manufacturer's declaration	202

12.1 Function chart of the elisa 300 / elisa 500 ventilator



12.2 General

Application

Medical application:	Invasive and non-invasive ventilation of humans	
Area:	Intensive care, recovery room, general ventilation, patient transport within health care facilities	
Use:	stationary, intra-hospital transport	
Patient category:	Adults	30 kg–500 kg
	Children	8 kg–150 kg

Dimensions and weight

Ventilator	
W x D x H	elisa 300: 315 x 245 x 405 mm elisa 500: 360 x 245 x 455 mm
Weight, net:	10 kg
Cart	
W x D x H	585 x 704 x 922 mm
Weight, net:	17 kg
Overall dimensions	
W x D x H	elisa 300: 585 x 704 x 1327 mm elisa 500: 585 x 704 x 1377 mm
Max. load:	10 kg

Operation

Menu control	Touchscreen
Menu languages:	German, English, French, Italian, Dutch, Norwegian, Swedish, Polish, Slovenian, Turkish, Spanish, Russian, Serbian, Finnish, Portuguese, Danish, Czech, Chinese, Hungarian, Greek, Japanese

Classification

Device class:	II b according to Directive 93/42/EEC, Annex IX, and according to Regulation (EU) 2017/745, Annex VIII
Protection class:	II (protection by double or reinforced insulation)
Duration of use:	Continuous operation
Protection class:	IP22

Remark

IP22: Protected against solid objects with a diameter over 12.5 mm and against falling drops of water when the housing is tilted at an angle up to 15°.

Interfaces

4 x BF interface (elisa 300: 2 x BF interface)	For the connection of applied parts with an electrical connection (type BF), configurable for: • CO₂ sensor Masimo IRMA / ISA • CO₂ sensor LeoCap • Multi-gas sensor LeoLyzer • SpO₂ sensor • Nurse call • elisa@megs (medical device interface) • Salvia / NO-A • Philips
2 x serial interface for PDMS	for transmission of patient data, configurable for • Salvia / NO-A • Philips
2 USB	for saving screenshots and short-term trends
DVI port	For connection of a projector for service purposes

Electromagnetic compatibility

Tested according to:	IEC/EN 60601-1-2
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Noise emission

Sound pressure level:	≤ 50 dB(A)
Sound power level:	≤ 10 ⁻⁶ W

Environmental conditions

During operation	
Temperature:	10 to 40°C
Atmospheric pressure:	60 to 106 kPa
Relative humidity:	0 to 95% (without condensation)
During storage and transport	
Temperature:	-20 to 60°C
Atmospheric pressure:	50 to 110 kPa
Relative humidity:	0 to 99% (without condensation)



Caution

At high humidity levels, it is not possible to completely rule out condensation. If the device is constantly operated at high humidity levels, corrosion can be expected.

12.3 Supply

Electrical supply

Main supply	
Supply voltage:	100–240 VAC, 50/60 Hz
Power consumption:	< 170 VA
Emergency supply	
Battery type:	Lithium-ion, rated capacity: 6200mAh, 89Wh rated voltage: 14.4V
Quantity:	1 (+1 optional battery)
Activation:	automatic when the mains supply fails (replacement possible during operation)
Operating time:	120 minutes (depending on device configuration, the operating time can be extended by reducing the screen brightness)
Duration of charge	< 4h for one battery

Remark

The charge cycle may take significantly longer at temperatures > 35°C.

Gas supply

Oxygen supply (O ₂)	
Pressure range:	200 to 600 kPa (29 to 87 PSI) > 270 kPa (for flows greater than 100 l/min)
Max. overpressure:	1000 kPa (145 PSI)
Quality:	medical gas, dry, oil-free and particle-free
Connection:	NIST

Remark

The operating pressure is set via the electromechanical expiratory valve.

Remark

All volume, flow and leakage data on the patient side refer to BTPS, all others refer to STPD.

Remark

The maximum period for the O₂ concentration to change its volume fraction from 21% to 90% in the specified volume is:

12 s for a respired volume of 500 ml

13 s for a respired volume of 150 ml

15 s for a respired volume of 30 ml

12.4 Technical data

Ventilation

Ventilation modes:	depending on software revision and device configuration
--------------------	---

Safety functions

Free breathing valve:	mechanical
Safety valve:	electric, pneumatic The safety valve limits the maximum allowed airway pressure at 140 hPa.
Patient category:	Adults, Children
Max. inspiratory pressure:	100 mbar
Max. inspiratory flow:	Adults: 180 l/min for each gas (elisa 300: 150 l/min) Children: 120 l/min for each gas
Device compliance:	< 2.0 ml/mbar*
Insp. resistance:	< 1.5 mbar/l/s*
Exp. resistance:	< 4.5 mbar/l/s*

* with patient circuit, adults, 2 x 22 mm, length 1.8 m

12.5 Control unit

General

Screen type	4:3 LCD display
Screen diagonal	elisa 300: 12.1" elisa 500: 15"
Input system	Touchscreen (capacitive multi-touch)
Support	can be tilted by approx. 35°

Screen display

Curve presentation	configurable
Curve parameters	configurable
Curves	synchronised
Curve scale	automatic/fixed (configurable)
Measurement value table	configurable

Display brightness

Brightness	adjustable
Adjustment range	5 to 100%
In alarm condition	100%, independent of the setting

Acoustic alarm

Alarm volume	adjustable
Adjustment range	Default volume: 20 to 100% (55 to 95 dbA) Minimum volume: 10 to 100% (configurable)

Visual alarm

Screen	Alarm messages on screen
Intensive care ventilator	Alarm bar at the top of the monitor (yellow or red, depending on severity)
Adjustment range	20–100%

Power indicator

Mains supply	green LED of ON button
--------------	------------------------

12.6 Default parameters

The default parameters depend on the software version and the configuration of your device. An authorised service technician can switch to another configuration (password-protected).

Remark | A detailed overview of the default parameters can be found in chapter 13 “Default parameters”.

12.7 Increments and maximum performance range

Parameters

Parameter	Patient category	Increment	Min. value	Max. value
O₂	all	1%	21%	100%
Rate	Adults	l /min	0 /min	100 /min
	Children	l /min	0 /min	120 /min
T_{insp}	all	0.01 @ 0.0–1.0 s 0.05 @ 1.0–1.5 s 0.10 @ 1.5–20 s	0.2 s	20 s
Inspiratory ramp	all	0.05 s	0.05 s	3.00 s or 0.8 * T _{insp}
PS Ramp	all	0.05 s	0.05 s	2.00 s
Expiratory ramp (mandatory)	Adults	20 @ –120 to –80 mbar/s	OFF, –100 mbar/s	–20 mbar/l/s
	Children	30 @ –80 to –20 mbar/s		
Expiratory ramp (spontaneous)	Adults	20 @ –120 to –80 mbar/s	OFF, –100 mbar/s	–20 mbar/l/s
	Children	30 @ –80 to –20 mbar/s		
P_{max}	all	l mbar	10 mbar	102 mbar
P_{max} (HFOT)	all	l mbar	10 mbar	50 mbar
P_{min}	all	l mbar	0 mbar	60 mbar
P_{insp}	all	l (+PEEP) mbar	0 mbar	102 – (2 mbar) – PEEP
PEEP	all	0.5 @ 0.5–10 mbar 1.0 @ 10–50 mbar	OFF, 0.5 mbar	50 mbar
PS	all	l mbar	0 mbar	102 – (2 mbar) – PEEP
Flow trigger	all	0.1 @ 0.1–3.5 l/min 0.5 @ 3.5–20.0 l/min	OFF, 0.1 l/min	20.0 l/min

Parameter	Patient category	Increment	Min. value	Max. value
Pressure trigger	all	0.1 @ -0.1 to -3.5 mbar 0.5 @ -3.5 to -10.0 mbar	OFF, -0.1 mbar	-10 mbar
Exp. trigger	all	1%	0	25%
VT	Adults	1 @ 0–20 ml 2 @ 20–50 ml 5 @ 50–100 ml 10 @ 100–300 ml	50 ml	2600 ml
	Children	20 @ 300–1000 ml 50 @ 1000–1500 ml 100 @ 1500–2600 ml	10 ml	1000 ml
I-Flow	Adults	0.1 @ 1.0–10.0 l/min 0.5 @ 10.0–30.0 l/min	12.0 l/min	120.0 l/min
	Children	1.0 @ 30.0–120.0 l/min	12.0 l/min	
I-Flow (HFOT)	Adults	0.1 @ 1.0–10.0 l/min 0.5 @ 10.0–30.0 l/min	10.0 l/min	70.0 l/min
	Children	1 @ 30.0–70.0 l/min	7.0 l/min	70.0 l/min
T Plateau	all	0.01 @ 0.0–1.0 0.05 @ 1.0–1.5 0.10 @ 1.5–15	0.00 s	< T _{insp}
SwitchFlow	all	1%	OFF, 1%	80%
ByFlow	all	0.5 l/min	10.0 l/min	30.0 l/min
PS Endflow	all	5%	5%	70%
PSTI max	all	0.5 s	1.0 s	5.0 s
Insp. Hold	all	0.25 @ 0.25–0.5 s 0.5 @ 0.5–1 s 1 @ 1–30 s	0.25 s	30 s
Exp. Hold	all	1 s	2 s	20 s
Texp	all	1 s	0.10 s	15 s
Flow support	all	0.5 mbar/(l/s)	0.0 mbar/(l/s)	30 mbar/(l/s)
Vol. support	all	0.1 mbar/l	0.0 mbar/l	25 mbar/l
Compens. R	all	5%	5%	95%
Compens. C	all	5%	5%	95%
MV target (ALPV, WOB _{OV} only)	Adults	5 ml/kg/min	50 ml/kg/min	350 ml/kg/min
VT/IBW	Adults	1 ml/kg	5 ml/kg	15 ml/kg
Acoustic alarm	all	5%	30%	100%
Alarm brightness	all	5%	20%	100%
Display brightness	all	5%	5%	100%

Alarm limits

Designation	Patient category	Increment	Min. value	Max. value
MV max	Adults	0.1 @ 0.6–10.0 0.5 @ 10.0–20.0 1.0 @ 20.0–60.0	0.6 L, MV min + 1 increment	60 L, OFF
	Children	0.1 @ 0.6–10.0 0.5 @ 10.0–20.0	0.6 L, MV min + 1 increment	20 L, OFF
MV min	Adults	0.1 @ 0.5–10.0 0.5 @ 10.0–20.0 1.0 @ 20.0–60.0	OFF or 0.5 L	59 L, MV max – 1 increment
	Children	0.1 @ 0.5–10.0 0.5 @ 10.0–20.0	OFF or 0.5 L	19.5 L, MV max – 1 increment
Vt max Pressure modes	Adults	1 @ 2–10 2 @ 10–50 5 @ 50–100 10 @ 100–300	2, VT min + 1 increment	4000 ml, OFF
	Children	20 @ 300–1000 50 @ 1000–1500 100 @ 1500–4000	2, VT min + 1 increment	1000 ml, OFF
Vt min	Adults	1 @ 1–10 2 @ 10–50 5 @ 50–100 10 @ 100–300	OFF, 2	Vt max – 1 increment
	Children	20 @ 300–1000 50 @ 1000–1500 100 @ 1500–4000	OFF, 2	Vt max – 1 increment
Vt min Volume modes	Adults	5%	OFF, –20%	–95%
	Children	1%		
Leakage	all	5%	5%	95%
Apnoea alarm	all	5 @ 5–60	5 s	60 s, ≤ backup ventilation
Backup ventilation	all	5 @ 5–120	5 s, apnoea alarm	120 s
RRmax	all	1 @ 3–100 /min 5 @ 100–250 /min	3 /min, RRmin + 1 increment	250 /min
RRmin	all	1 @ 2–100 /min 5 @ 100–245 /min	2 /min	245 /min, RRmax – 1 increment
RRmax spont	all	1 @ 3–100 /min 5 @ 100–250 /min	3 /min, RRmin + 1 increment	250 /min
RRmin spont	all	1 @ 2–100 /min 5 @ 100–245 /min	OFF, 2 /min	245 /min, RRmax – 1 increment
Plimit (absolute mode)	all	1 mbar	10 mbar	120 mbar

Designation	Patient category	Increment	Min. value	Max. value
Plimit (relative mode)	all	1 mbar	5 mbar	20 mbar
Pmin	all	1 mbar	OFF, 1 mbar	50 mbar, Plimit absolute – 1 increment
Pplateau max	all	1 mbar	1 mbar	80 mbar, OFF
Pmean max	all	1 mbar	Pmean min + 1 mbar	80 mbar, OFF
Pmean min	all	1 mbar	1 mbar	80 mbar, Pmean max – 1 increment
PEEP max	all	1 mbar, relative to PEEP	1 mbar	+ 20 mbar, OFF
PEEP min	all	1 mbar, relative to PEEP	OFF, –20 mbar	–1 mbar
O₂ max (relative to FiO₂)	all	1%	1%	20%, OFF
O₂ min (relative to FiO₂)	all	1%	–20%, OFF	–1%
etCO₂ max	all	0.1 vol%, kPa	0.1 + etCO ₂ min	15.0; OFF
		1 mmHg	1 mmHg + etCO ₂ min	115, OFF
etCO₂ min	all	0.1 vol%, kPa	OFF, 0.0	etCO ₂ max – 0.1
		1 mmHg	OFF, 0	etCO ₂ max – 1 mmHg
inCO₂ max	all	0.1 vol%, kPa	OFF, 0.0	15.0
		1 mmHg	OFF, 0	115
exISO min	all	0.1 vol%, kPa	OFF, 0.1	7.0
		1 mmHg	OFF, 1	55
exISO max	all	0.1 vol%, kPa	0.1	7.0, OFF
		1 mmHg	1	55, OFF
inISO min	all	0.1 vol%, kPa	OFF, 0.1	7.0
		1 mmHg	OFF, 1	55
inISO max	all	0.1 vol%, kPa	0.1	7.0, OFF
		1 mmHg	1	55, OFF

Designation	Patient category	Increment	Min. value	Max. value
exSEV min	all	0.1 vol%, kPa	OFF, 0.1	9.9
		1 mmHg	OFF, 1	75
exSEV max	all	0.1 vol%, kPa	0.1	9.9, OFF
		1 mmHg	1	75, OFF
inSEV min	all	0.1 vol%, kPa	OFF, 0.1	9.9
		1 mmHg	OFF, 1	75
inSEV max	all	0.1 vol%, kPa	0.1	9.9, OFF
		1 mmHg	1	75, OFF

Tube compensation

Designation	Patient category	Increment	Min. value	Max. value
Diameter	Adults, Children	0.5 mm	4.0 mm	12.0 mm
Compensation	Adults, Children	5%	25%	100%

12.8 Instant View window / data table(s)

Depending on the configuration, either all or only some of the following measuring values and indices will be displayed:

Measuring values

Designation	Patient category	Range	Resolution	Accuracy
MVe	all	0.0–50 l	0.1 l	±10% or ±150 ml (greater value)
MVe spont.	all	0.0–50 l	0.1 l	±10% or ±150 ml (greater value)
MVe mand.	all	0–50 l	0.1 l	±10% or ±150 ml (greater value)
MVe spont. %	all	0–100%	1%	±10%
VT _e	all	0–4000 ml	1 @ 0–100 5 @ 100–4000	±10% or ±10 ml (greater value)
VT _e spont.	all	0–4000 ml	1 @ 0–100 5 @ 100–4000	±10% or ±10 ml (greater value)

Designation	Patient category	Range	Resolution	Accuracy
VTi	Adults	50–5000 ml	1 @ 0–100	±10% or ±15 ml (greater value)
	Children	20–5000 ml	5 @ 100–5000	
PEAK	all	–50 to 150 mbar	1 mbar	± (0.5 mbar + 2%)
PEEP	all	–50 to 150 mbar	1 mbar	± (0.5 mbar + 2%)
ΔP (Delta P)	all	0–90 mbar	1 mbar	± (0.5 mbar + 2%)
Pplateau	all	–50 to 150 mbar	1 mbar	± (0.5 mbar + 2%)
Pmean	all	–50 to 150 mbar	1 mbar	± (0.5 mbar + 2%)
Pmin	all	–50 to 150 mbar	1 mbar	± (0.5 mbar + 2%)
RR	all	0–200 /min	1 /min	± 1 /min
RR spont.	all	0–200 /min	1 /min	± 1 /min
RR mand.	all	0 to 200 /min	1 /min	± 0.01s
R exp.	all	0–500 mbar/(l/s)	1 mbar/(l/s)	±40%
C dyn.	all	0–500 ml/mbar	1 ml/mbar	±20%
C stat.	all	0–500 ml/mbar	1 ml/mbar	±20%
Flow insp.	all	0–180 l/min	1 l/min	± 0.1 l/min
Flow insp.	all	0–3 l/s	0.01 l/s	-
Flow exp.	all	0–180 l/min	1 l/min	± 0.1 l/min
Flow exp.	all	0–3 l/s	0.01 l/s	-
I:E	all	0.0–9.9	0.1	± 0.1
RC exp.	all	0.1–6.0 s	0.1 s	± 0.1 s
RSBI	all	0–999	1	±10%
MIP	all	0.0 to –50.0 mbar	0.1 mbar	± (0.5 mbar + 2%)
P0.1	all	0.0 to –20 mbar	0.1 mbar	0.5 mbar
VT/IBW	Adults	0.0–99.9 ml/kgBW	0.1 ml/kgBW	±10% or ±15 ml/kg (greater value)
Leakage	all	0–100%	1%	±10%
MV Leakage	all	0.0–50.0 l/min	1 l/min	±10% or ±150 ml (greater value)
T Plateau	all	0.0–99.9 s	0.1 s	± 0.1 s

Designation	Patient category	Range	Resolution	Accuracy
HR	all	18–321 /min	1 /min	Each pulse wave is counted and averaged over one minute
SpO ₂	all	0–99%	1%	according to manufacturer's specifications

Gases

Designation	Patient category	Range	Resolution	Accuracy
O ₂ *	all	0–100%	1%	±2.0% The O₂ measurement accuracy is independent of the respiratory rate, ambient pressure and I:E ratio. The deviation from the calibrated value is: < ±0.4% O₂ in the first 24 hours < ±0.4% O₂ in the subsequent week (additional deviation) < ±0.2% O₂ in each of the subsequent months (additional deviation)
etCO ₂	all	0–25 vol%	0.1 vol%	according to manufacturer's specifications
		0–25 kPa	0.1 kPa	
		0–185 mmHg	1 mmHg	
		Response time		Main stream CO₂ sensor Response time: < 4s, Rise time: < 0.4s Side stream CO₂ sensor: Response time: < 1 s
inCO ₂	all	0–25 vol%	0.1 vol%	according to manufacturer's specifications
		0–25 kPa	0.1 kPa	
		0–185 mmHg	1 mmHg	
VTds	all	0–9999 ml	1 ml	according to manufacturer's specifications
VTds%	all	0–100%	1%	according to manufacturer's specifications
VTalv	all	0–9999 ml	1 ml	according to manufacturer's specifications
VTalv%	all	0–100%	1%	according to manufacturer's specifications

V̇CO₂	all	0 – 9999 ml/min	1 ml/min	according to manufacturer's specifications
exISO (LeoLyzer)	all	0–7.0 vol%	0.1 vol%	according to manufacturer's specifications
		0–7.0 kPa	0.1 kPa	
		0–55 mmHg	0.1 mmHg	
inISO (LeoLyzer)	all	0–7.0 vol%	0.1 vol%	according to manufacturer's specifications
		0–7.0 kPa	0.1 kPa	
		0–55 mmHg	0.1 mmHg	
exSEV (LeoLyzer)	all	0–9.9 vol%	0.1 vol%	according to manufacturer's specifications
		0–9.9 kPa	0.1 kPa	
		0–75 mmHg	0.1 mmHg	
inSEV (LeoLyzer)	all	0–9.9 vol%	0.1 vol%	according to manufacturer's specifications
		0–9.9 kPa	0.1 kPa	
		0–75 mmHg	0.1 mmHg	
etCO₂ (LeoLyzer)	all	0–15 vol%	0.1 vol%	according to manufacturer's specifications
		0–15 kPa	0.1 kPa	
		0–115 mmHg	0.1 mmHg	
inCO₂ (LeoLyzer)	all	0–2.6 vol%	0.1 vol%	according to manufacturer's specifications
		0–2.6 kPa	0.1 kPa	
		0–20 mmHg	0.1 mmHg	

* All tolerances were determined with a maximum measurement uncertainty of +/-10%.

Indices

Designation	Patient category	Range	Resolution	Accuracy
PEEPi	all	0.0 to 99.9 mbar	0.1 mbar	± (0.5 + PEEP + 2%)
PEEPi (es)	all	0.0 to 99.9 mbar	0.1 mbar	± (0.5 + PEEP + 2%)
Vtrap	all	0 to 1000 ml	1 ml	±20%
TPP i (es)	all	-10.0 to 99.9 mbar	0.1 mbar	± (0.5 mbar + 2%)
TPP e (es)	all	-10.0 to 99.9 mbar	0.1 mbar	± (0.5 mbar + 2%)
P insp. (es)	all	-10.0 to 99.9 mbar	0.1 mbar	± (0.5 mbar + 2%)
P exp. (es)	all	-10.0 to 99.9 mbar	0.1 mbar	± (0.5 mbar + 2%)
Peak (es)	all	0.0 to 99.9 mbar	0.1 mbar	± (0.5 mbar + 2%)
Pmin (es)	all	-10.0 to 99.9 mbar	0.1 mbar	± (0.5 mbar + 2%)
WOB (es)	all	0–99.9 J/L	0.1 J/L	±20%

Designation	Patient category	Range	Resolution	Accuracy
WOB vent	Adults	0–99.9 J/L	0.1 J/L	±20%
WOB spont.	Adults	0–99.9 J/L	0.1 J/L	±20%
POB spont.	all	0–999.9 J/min	0.1 J/min	±20%
POB spont. (es)	all	0–999.9 J/min	0.1 J/min	±20%
POB	all	0–999.9 J/min	0.1 J/min	±20%
IAP	all	0–70 mmHg	1 mmHg	± (0.5 mbar + 2%)
Δ TPP (es)	all	-10.0 to 99.9 mbar	0.1 mbar	± (0.5 mbar + 2%)
C20/C stat.	all	0.0–9.9	0.1	±20%
ΔP (es)	all	-10.0 to 99.9 mbar	0.01 mbar	± (0.5 mbar + 2%)
ΔPeso/ΔPAW	all	0.00–9.99 mbar	0.01 mbar	-

12.9 Data transmission with terminal devices

PDMS interfaces

If you would like to operate elisa 300 / elisa 500 in combination with a terminal device, please contact your service technician. The service technician will also inform you about the terminal devices compatible with elisa 300 / elisa 500. Via the PDMS interfaces, data are sent from the ventilator to terminal devices such as:

- Patient monitoring systems
- Patient data management systems

The 2 PDMS interfaces can be configured at the configuration level as needed: these are the configuration options: - PDMS Interface “Salvia / NO-A”
- PDMS interface “Philips”

The available BF interfaces can also be configured for PDMS communication at the configuration level when needed:

- PDMS Interface “Salvia / NO-A”
- PDMS interface “Philips”

You can review the current interface configuration on the standby or ventilation screen under the “Status” tab by selecting the second view.

The interface is **not** intended to change ventilator settings.

The transmitted data include:

- physiological alarms
- technical alarms

- configured ventilation parameters
- measured ventilation parameters
- equipment data

When applying the ventilator and the terminal device on a patient for medical purposes, you are required to observe the following notes and warnings:

Remark	The communication only takes place between the ventilator and a single terminal device.
Remark	After the initial installation, perform a functional test by checking whether the communication link between the ventilator and the terminal device meets the requirements of your facility. Perform a functional test every time a communication component is replaced or modified.
Warning	It is not permitted to connect the ventilator to the terminal device via a network.
Warning	Do not make any treatment-related decisions solely on the basis of the transmitted parameters. Always refer to the parameters on the display of the ventilator in addition.
Warning	If the terminal device indicates ventilation alarms, you need to determine and eliminate the root cause at the patient.
Warning	The patient monitor and the ventilator may present alarms in different ways. Not all patient monitors display detailed alarm messages.
Remark	The control of the ventilation procedure is independent of the data communication between ventilator and terminal device. This means that the ventilator continues ventilating the patient if a data communication problem occurs.

12.10 Guidance and manufacturer's declaration

Electromagnetic emissions:

Based on the device characteristics determined by its EMISSIONS, the device can be used in industrial areas and hospitals (CISPR 11 class A). If used in a residential environment (for which CISPR 11 class B is normally required), this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.

Emission tests	Compliance	Electromagnetic environment – guidance
RF emissions to CISPR 11	Class A, group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions to IEC 61000-3-3	Complies	

Electromagnetic immunity:

elisa 300 / elisa 500 is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that elisa 300 / elisa 500 is operated in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) to IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/bursts to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	The mains power quality should be that of a typical commercial or hospital environment.
Surges to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines to IEC 61000-4-11	100% dip in U_T for 10 ms 100% dip in U_T for 20 ms 30% dip in U_T for 500 ms 100% dip in U_T for 5000 ms	100% dip in U_T for 10 ms 100% dip in U_T for 20 ms 30% dip in U_T for 500 ms 100% dip in U_T for 5000 ms	The mains power quality should be that of a typical commercial or hospital environment. If the user of elisa 300 / elisa 500 requires continued operation during power mains interruptions, it is recommended that elisa 300 / elisa 500 be powered from an uninterruptible power supply (UPS).
Power frequency (50 Hz) magnetic field to IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test levels.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Portable and mobile RF communications equipment should be used no closer to elisa 300 / elisa 500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF to IEC 61000-4-6	3 V rms 150 kHz to 80 MHz outside ISM bands ^a	8 V (Mainstream sensor IRMA 6V)	$d = 1.2\sqrt{P}$
	6 V rms 150 kHz to 80 MHz inside ISM bands ^a	8 V (Mainstream sensor IRMA 6V)	$d = 0.6\sqrt{P}$
Radiated RF to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	8 V/m	$d = 1.2\sqrt{P}$ for 80 MHz to 500 MHz
			$d = 2.3\sqrt{P}$ for 500 MHz to 2.7 GHz

Recommended separation distance: where P is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^c, should be less than the compliance level in each frequency range.^d Interference may occur in the vicinity of equipment marked with the following symbol.



Note 1 | At 80 MHz and 500 MHz, the higher frequency range applies.

Note 2 | These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a

The ISM bands (for industrial, scientific and medical application) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.

b

The compliance level in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2.5 GHz is intended to reduce the probability that portable communications equipment could cause interference if it is inadvertently brought into patient areas.

This is why an additional factor of 10/3 is used in order to calculate the recommended distance for transmitters in these frequency ranges.

c

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.

d

Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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I 3 Default parameters

13.1	Default parameters (factory settings)	208
13.1.1	Default parameters	208
13.1.2	Adjustment ranges	209
13.1.3	Default alarm limits	209
13.1.3.1	Default alarm limits of the ALPV mode	211
13.1.3.2	Default alarm limits of the WOBOV mode	211
13.1.3.3	Default alarm limits of the CPR mode	212

13.1 Default parameters (factory settings)

13.1.1 Default parameters

Patient category	Adults	Children
Ventilation mode at start-up	BiLevel	BiLevel
Tube compensation	Comp.: 100% Diam.: 7.5 mm Insp.: On Exp.: Off	Comp.: 50% Diam.: 6.0 mm Insp.: Off Exp.: Off
O ₂	50%	50%
P insp	12 mbar + PEEP	9 mbar + PEEP
PEEP	5 mbar	5 mbar
Insp. Ramp	0.10 s	0.10 s
Exp Ramp mand	OFF	OFF
Exp Ramp spont	OFF	OFF
Rate	12 /min	20 /min
T insp	1.5 s	1.0 s
Vt	400 ml	150 ml
I-Flow	40 l/min	25 l/min
T Plateau	0.5 s	0.5 s
Trigger (Flow)	5.0 l/min	3.0 l/min
Exp. trigger	0%	0%
PS	10 mbar + PEEP	9 mbar + PEEP
PS Endflow	25%	25%
PS Ramp	0.10 s	0.10 s
PS Tlmax	4.0 s	3.0 s
T_exp	4.0 s	2.0 s
P min	5 mbar	5 mbar
P max	35 mbar	30 mbar
Byflow	3.0 l/min	3.0 l/min

13.1.2 Adjustment ranges

O ₂	21–100%
Flow trigger	0.1–20 l/min
Pressure trigger	0.1–10 mbar
PEEP	0–50 mbar
P insp	0–60 mbar
V _t	10–2300 ml
PS	0–100 mbar
P _{max}	10–100 mbar
Insp. Ramp	0.05–3 s
Exp Ramp mand	OFF; –100; –80; –50; –20 mbar/s
Exp Ramp spont	OFF; –100; –80; –50; –20 mbar/s
PS Ramp	0.05–2 s
Exp. trigger	0–25%
PS Endflow	5–70%
SwitchFlow	1–80%
Rate	Adults 0–100 /min Children 0–120 /min Neonates 0–180 /min

13.1.3 Default alarm limits

When selecting the factory settings, all alarm limits will be set to the least sensitive value.

In the CPR and ALPV modes, different alarm limits are automatically activated. Refer to the separate tables for the exact values.

Patient category	Adults	Children
MVmin	2.5 l	0.5 l
MVmax	12.0 l	5.0 l
V _t min (pressure modes)	150 ml	50 ml
V _t max	OFF	OFF
Leakage (IV)	50%	50%
Leakage (NIV)	95%	95%

RRmin	6 /min	14 /min
RRmax	50 /min	60 /min
Apnoea Alarm	20 s	20 s
Backup ventilation	30 s	30 s
Plimit absolute VCV, SIMV, Dynamic BiLevel	40 mbar	20 mbar
Plimit absolute BiLevel, CPAP / PS	40 mbar	20 mbar
Plimit relative VCV, SIMV, Dynamic BiLevel	10 mbar	10 mbar
Plimit relative BiLevel, CPAP / PS	10 mbar	10 mbar
Pmin	OFF	OFF
Pmean max	OFF	OFF
Pmean min	OFF	OFF
Pplateau max	OFF	OFF
PEEPmax	+ 2 mbar	+ 2 mbar
PEEPmin	-2 mbar	-2 mbar
O ₂ max	set FiO ₂ + 5%	set FiO ₂ + 5%
O ₂ min	set FiO ₂ - 5% or 18%	set FiO ₂ - 5% or 18%
etCO ₂ max	8.0 vol% or 8 kPa	8.0 vol% or 8 kPa
etCO ₂ min	OFF	OFF
inCO ₂ max	OFF	OFF
RR spont. max	OFF	OFF
RR spont. min	OFF	OFF

13.1.3.1 Default alarm limits of the ALPV mode

Patient category	Adults
MVmin	$= 0.5 * MV_i$ $= 0.5 * (IBW * \%MV) / 1000$
MVmax	$= 2.0 * MV_i$ $= 2.0 * (IBW * \%MV) / 1000$
Vtmin	$= 0.75 * VT_i$ $= 0.75 * IBW * 6.0 \text{ ml / kgBW}$ $= 0.75 * IBW * VGF$
Vtmax	$= 1.60 * VT_i$ $= 1.60 * IBW * 6.0 \text{ ml / kgBW}$ $= 1.60 * IBW * VGF$
RRmin	$= 0.7 * \text{rate}$ $= 0.7 * (\%MV / 6.0)$ $= 0.7 * (\%MV / VGF)$
RRmax	$= 2.0 * \text{rate}$ $= 2.0 * (\%MV / 6.0)$ $= 2.0 * (\%MV / VGF)$

13.1.3.2 Default alarm limits of the WOBOV mode

Patient category	Adults
Plimit WOBOV	$P_{\text{max}} + 10 \text{ mbar}$

13.1.3.3 Default alarm limits of the CPR mode

Patient category	Adults
MVmin	1.5 l
MVmax	20.0 l
Vtmin	50 ml
Vtmax	1500 ml
Leakage	95%
RRmin	5 /min
RRmax	40 /min
Apnoea Alarm	20 s
Backup ventilation	30 s
Plimit	40 mbar or P _{insp} + PEEP + 10
Pmin	OFF
Pmean max	OFF
Pmean min	OFF
Pplateau max	OFF
PEEPmax	OFF
PEEPmin	OFF
O ₂ max	set FiO ₂ + 5%
O ₂ min	set FiO ₂ – 5% or 18%
etCO ₂ max	OFF
etCO ₂ min	OFF
inCO ₂ max	OFF
RR spont. max	OFF
RR spont. min	OFF
technical CO ₂ alarms	inactive

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

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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

A 0 Contents

A 1	About this manual	7
A 1.1	Information about the “Manoeuvres, Functions, Ventilation Modes” manual	8
A 1.2	Safety information in these instructions for use	9
A 1.3	General safety instructions	9
A 1.4	Options matrix	10
A 2	Manoeuvres	11
A 2.1	Manoeuvre availability	12
A 2.1.1	Availability for the different patient categories	12
A 2.2	HOLD manoeuvres	12
A 2.2.1	Inspiratory Hold (Insp. Hold)	12
A 2.2.2	Expiratory Hold (Exp. Hold)	13
A 2.2.3	Manual breath	13
A 2.3	Maximum Inspiratory Pressure (MIP)	14
A 2.4	Sigh	14
A 2.4.1	Inspiratory sigh	14
A 2.4.2	Expiratory sigh	15
A 2.5	Recruitment manoeuvre	16
A 2.6	PEEPfinder manoeuvre	19
A 2.6.1	Prerequisites	19
A 2.6.2	Contraindications	19
A 2.6.3	Warnings and remarks	20
A 2.6.4	Settings	21
A 2.6.5	Performing the PEEPfinder manoeuvre (inspiratory and expiratory)	22
A 2.6.6	Evaluation	23
A 2.6.7	Additional views / indices	23
A 2.6.8	Recruitment with PEEPfinder	24
A 3	Functions	27
A 3.1	Availability of the functions	31
A 3.2	O2 Flush	32
A 3.3	Automatic Suction Routine (ASR)	32
A 3.3.1	Suction with open suction systems	33

A 3.3.1.1 Preoxygenation phase	33
A 3.3.1.2 Suction phase	33
A 3.3.1.3 Postoxygenation phase	34
A 3.3.2 Suction with closed suction systems	34
A 3.4 Cuffscout	34
A 3.4.1 Device setup	34
A 3.4.1.1 Cuffscout line	35
A 3.4.1.2 Cuffscout and test line	36
A 3.4.2 Cuffscout function	37
A 3.4.2.1 Cuff pressure in the standby mode	37
A 3.4.2.2 "Static" mode	39
A 3.4.2.3 "Automatic" mode	39
A 3.4.2.4 Max. block function	39
A 3.5 Oesophageal pressure measurement (Peso)	40
A 3.5.1 Connecting the oesophageal catheter	40
A 3.5.2 Peso function	41
A 3.5.3 Occlusion manoeuvre	43
A 3.5.4 Manual HOLD manoeuvre	44
A 3.6 IAP (Intra-abdominal pressure)	44
A 3.6.1 Connecting the intravesical pressure measuring kit	45
A 3.6.2 IAP function	45
A 3.7 Drug nebulization	46
A 3.7.1 Intended use	46
A 3.7.2 Nebulization	46
A 3.7.3 Pneumatic nebulization	48
A 3.7.3.1 Connecting the pneumatic nebulizer set	48
A 3.7.3.2 General information	49
A 3.7.3.3 Procedure	50
A 3.7.3.4 Synchronisation	50
A 3.7.3.5 Pneumatic nebulization and O ₂ concentration	51
A 3.8 Hygiene function	51
A 3.9 Reference loops	52
A 3.10 Capnometry	52
A 3.10.1 Intended use	53
A 3.10.1.1 Display priorities for curves and measured values	53
A 3.10.2 Measuring principle	54
A 3.10.3 Power supply	54
A 3.10.4 Breathing circuit	54
A 3.10.5 Connecting a CO ₂ sensor	54
A 3.10.6 Connecting the LeoCap CO ₂ sensor	54
A 3.10.7 Connecting the mainstream sensor IRMA CO ₂	56
A 3.10.8 Connecting the sidestream sensor ISA CO ₂	57
A 3.10.8.1 Respiratory gas humidification	58
A 3.10.8.2 Drug nebulization	58
A 3.10.9 Performing capnometry	58

A 3.10.9.1 Zeroing of the CO ₂ sensor (only IRMA or ISA)	58
A 3.10.9.2 CO ₂ measurement	59
A 3.10.9.3 Volumetric capnography	61
A 3.10.10 Alarm limits	62
A 3.10.11 Status indicator of the CO ₂ sensors IRMA and ISA	63
A 3.11 Multi-gas sensor LeoLyzer	63
A 3.11.1 Intended use	63
A 3.11.2 Measuring principle	64
A 3.11.3 Power supply	64
A 3.11.4 Breathing circuit	64
A 3.11.5 Integrating the multi-gas sensor LeoLyzer	64
A 3.11.6 Sample gas outlet	65
A 3.11.7 Connecting the multi-gas sensor LeoLyzer	66
A 3.11.8 Performing a multi-gas measurement	66
A 3.11.8.1 Multi-gas measurement	66
A 3.12 SpO₂ sensor	68
A 3.12.1 Connecting the SpO ₂ sensor (with adapter)	68
A 3.12.1.1 SpO ₂ Measurement	68
A 3.12.2 Alarm limits	69
A 3.13 AnaConDa function	69
A 3.13.1 Intended use	69
A 3.13.2 Safety instructions	70
A 3.13.2.1 Safe operation	70
A 3.13.2.2 Patient safety	71
A 3.13.3 Technical requirements	71
A 3.13.4 Assembly	73
A 3.13.4.1 Anaesthetic gas elimination	73
A 3.13.4.2 Elimination via Flurabsorb	73
A 3.13.4.3 Connection to an anaesthetic gas scavenging system (AGSS)	75
A 3.13.4.4 Connecting the AnaConDa system to elisa 300 / elisa 500	77
A 3.13.5 Ventilation with AnaConDa function	78
A 3.13.6 Checklist for verification of the entire elisa 300 / elisa 500 system with the AnaConDa system	79
A 3.14 Bronchoscopy	80
A 3.15 Nurse call	81
A 3.15.1 Intended use	81
A 3.15.2 Connection	81
A 3.15.3 Function	82
A 4 Weaning analyzer	83
A 4.1 Weaning analyzer	84
A 4.2 Availability of the weaning procedure	84
A 4.2.1 Availability for the different patient categories	84
A 4.3 SAT	84
A 4.3.1 SAT test (Spontaneous Awakening Trial)	84

A 4.4 SBT (Spontaneous Breathing Trial)	85
A 4.4.1 SBT procedure	86
A 4.5 P0.I	87
A 4.6 WOB	88
A 5 Ventilation modes and parameters	89
A 5.1 Default settings	91
A 5.1.1 The modes are named in compliance with the ISO standard 19223:2019-07	91
A 5.1.2 Backup modes	92
A 5.2 Default ventilation	92
A 5.3 Ventilation modes	92
A 5.3.1 Special information regarding volume-controlled modes	94
A 5.4 Ventilation parameters	95
A 5.4.1 Expiratory ramps	99
A 5.5 Modes	100
A 5.5.1 BiLevel ST	101
A 5.5.2 Dynamic BiLevel ST	102
A 5.5.3 Dual BiLevel ST	103
A 5.5.4 BiLevel	104
A 5.5.5 Mandatory BiLevel	105
A 5.5.6 Dynamic BiLevel	106
A 5.5.7 Dual BiLevel	107
A 5.5.8 Optional BiLevel	108
A 5.5.9 Flexible BiLevel	109
A 5.5.10 PC-SIMV	110
A 5.5.11 PSV	112
A 5.5.12 Dynamic PSV	113
A 5.5.13 Proportional PSV	114
A 5.5.14 PAPS (Proportional Adaptive Pressure Support)	116
A 5.5.15 CPAP	118
A 5.5.16 VCV	119
A 5.5.17 PLV	120
A 5.5.18 VC-SIMV	121
A 5.5.19 Optional VCV	122
A 5.5.20 Flexible VCV	123
A 5.5.21 Volume-adaptive BiLevel	124
A 5.5.22 PC-APRV	125
A 5.5.23 PCV	126
A 5.5.24 ALPV (Adaptive Lung Protection Ventilation)	128
A 5.5.25 WOBOW (Work Of Breathing Optimized Ventilation)	129
A 5.5.26 CPR	131
A 5.5.27 HFOT	133

A I About this manual

A I.1 Information about the “Manoeuvres, Functions, Ventilation Modes” manual	8
A I.2 Safety information in these instructions for use	9
A I.3 General safety instructions	9
A I.4 Options matrix	10

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

A 2 Manoeuvres

A 2.1	Manoeuvre availability	12
A 2.1.1	Availability for the different patient categories	12
A 2.2	HOLD manoeuvres	12
A 2.2.1	Inspiratory Hold (Insp. Hold)	12
A 2.2.2	Expiratory Hold (Exp. Hold)	13
A 2.2.3	Manual breath	13
A 2.3	Maximum Inspiratory Pressure (MIP)	14
A 2.4	Sigh	14
A 2.4.1	Inspiratory sigh	14
A 2.4.2	Expiratory sigh	15
A 2.5	Recruitment manoeuvre	16
A 2.6	PEEPfinder manoeuvre	19
A 2.6.1	Prerequisites	19
A 2.6.2	Contraindications	19
A 2.6.3	Warnings and remarks	20
A 2.6.4	Settings	21
A 2.6.5	Performing the PEEPfinder manoeuvre (inspiratory and expiratory)	22
A 2.6.6	Evaluation	23
A 2.6.7	Additional views / indices	23
A 2.6.8	Recruitment with PEEPfinder	24

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 Functions

A 3.1	Availability of the functions	31
A 3.2	O ₂ Flush	32
A 3.3	Automatic Suction Routine (ASR)	32
A 3.3.1	Suction with open suction systems	33
A 3.3.1.1	Preoxygenation phase	33
A 3.3.1.2	Suction phase	33
A 3.3.1.3	Postoxygenation phase	34
A 3.3.2	Suction with closed suction systems	34
A 3.4	Cuffscout	34
A 3.4.1	Device setup	34
A 3.4.1.1	Cuffscout line	35
A 3.4.1.2	Cuffscout and test line	36
A 3.4.2	Cuffscout function	37
A 3.4.2.1	Cuff pressure in the standby mode	37
A 3.4.2.2	“Static” mode	39
A 3.4.2.3	“Automatic” mode	39
A 3.4.2.4	Max. block function	39
A 3.5	Oesophageal pressure measurement (Peso)	40
A 3.5.1	Connecting the oesophageal catheter	40
A 3.5.2	Peso function	41
A 3.5.3	Occlusion manoeuvre	43
A 3.5.4	Manual HOLD manoeuvre	44
A 3.6	IAP (Intra-abdominal pressure)	44
A 3.6.1	Connecting the intravesical pressure measuring kit	45
A 3.6.2	IAP function	45
A 3.7	Drug nebulization	46
A 3.7.1	Intended use	46
A 3.7.2	Nebulization	46
A 3.7.3	Pneumatic nebulization	48

A 3.7.3.1 Connecting the pneumatic nebulizer set	48
A 3.7.3.2 General information	49
A 3.7.3.3 Procedure	50
A 3.7.3.4 Synchronisation	50
A 3.7.3.5 Pneumatic nebulization and O ₂ concentration	51
A 3.8 Hygiene function	51
A 3.9 Reference loops	52
A 3.10 Capnometry	52
A 3.10.1 Intended use	53
A 3.10.1.1 Display priorities for curves and measured values	53
A 3.10.2 Measuring principle	54
A 3.10.3 Power supply	54
A 3.10.4 Breathing circuit	54
A 3.10.5 Connecting a CO ₂ sensor	54
A 3.10.6 Connecting the LeoCap CO ₂ sensor	54
A 3.10.7 Connecting the mainstream sensor IRMA CO ₂	56
A 3.10.8 Connecting the sidestream sensor ISA CO ₂	57
A 3.10.8.1 Respiratory gas humidification	58
A 3.10.8.2 Drug nebulization	58
A 3.10.9 Performing capnometry	58
A 3.10.9.1 Zeroing of the CO ₂ sensor (only IRMA or ISA)	58
A 3.10.9.2 CO ₂ measurement	59
A 3.10.9.3 Volumetric capnography	61
A 3.10.10 Alarm limits	62
A 3.10.11 Status indicator of the CO ₂ sensors IRMA and ISA	63
A 3.11 Multi-gas sensor LeoLyzer	63
A 3.11.1 Intended use	63
A 3.11.2 Measuring principle	64
A 3.11.3 Power supply	64
A 3.11.4 Breathing circuit	64
A 3.11.5 Integrating the multi-gas sensor LeoLyzer	64
A 3.11.6 Sample gas outlet	65
A 3.11.7 Connecting the multi-gas sensor LeoLyzer	66
A 3.11.8 Performing a multi-gas measurement	66
A 3.11.8.1 Multi-gas measurement	66

A 3.12	SpO₂ sensor	68
A 3.12.1	Connecting the SpO ₂ sensor (with adapter)	68
A 3.12.1.1	SpO ₂ Measurement	68
A 3.12.2	Alarm limits	69
A 3.13	AnaConDa function	69
A 3.13.1	Intended use	69
A 3.13.2	Safety instructions	70
A 3.13.2.1	Safe operation	70
A 3.13.2.2	Patient safety	71
A 3.13.3	Technical requirements	71
A 3.13.4	Assembly	73
A 3.13.4.1	Anaesthetic gas elimination	73
A 3.13.4.2	Elimination via Flurabsorb	73
A 3.13.4.3	Connection to an anaesthetic gas scavenging system (AGSS)	75
A 3.13.4.4	Connecting the AnaConDa system to elisa 300 / elisa 500	77
A 3.13.5	Ventilation with AnaConDa function	78
A 3.13.6	Checklist for verification of the entire elisa 300 / elisa 500 system with the AnaConDa system	79
A 3.14	Bronchoscopy	80
A 3.15	Nurse call	81
A 3.15.1	Intended use	81
A 3.15.2	Connection	81
A 3.15.3	Function	82

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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.

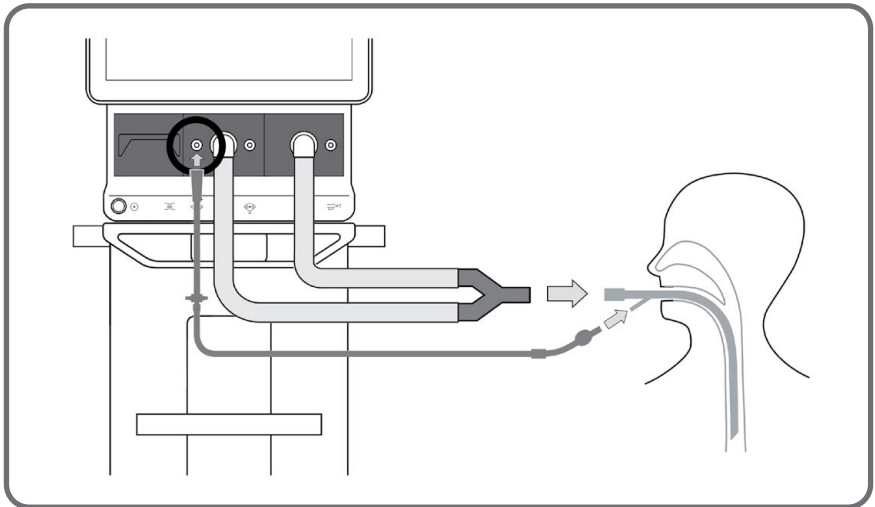
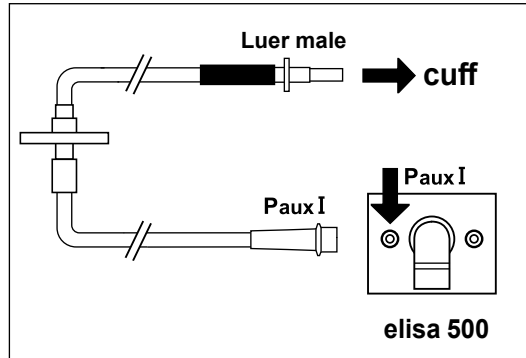


Warning

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.



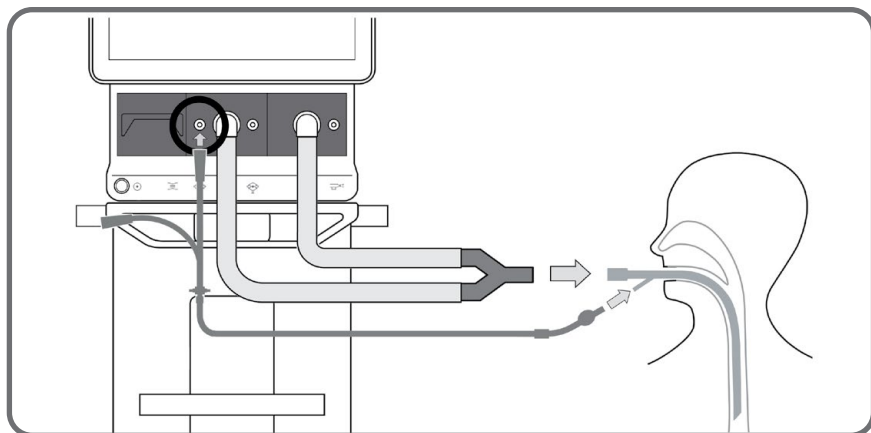
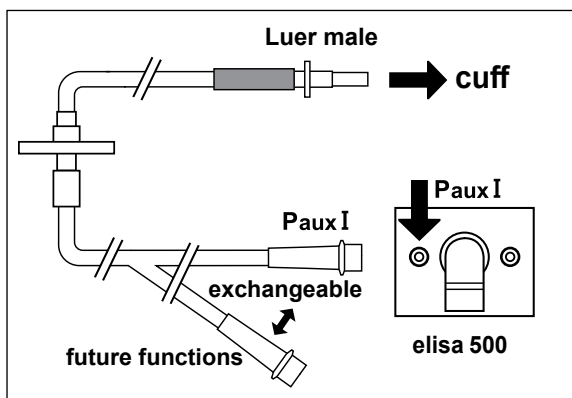
Warning

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

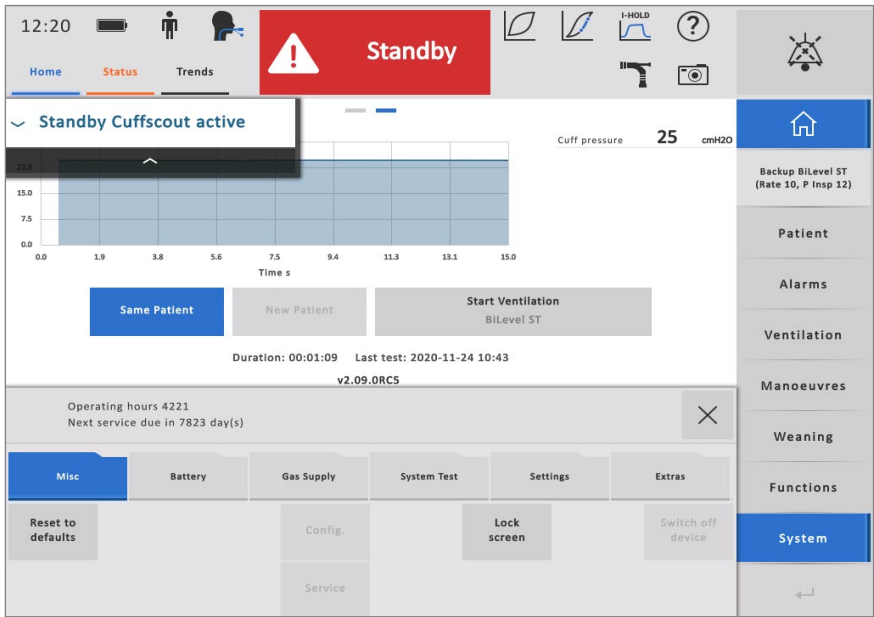
On completion of the ventilation procedure, the monitoring and control of the cuff pressure can be continued, e.g., for tracheotomised patients. For this function,

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).

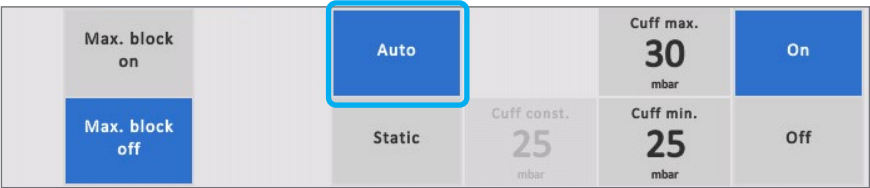
A 3.4.2.2 “Static” mode

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.



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).



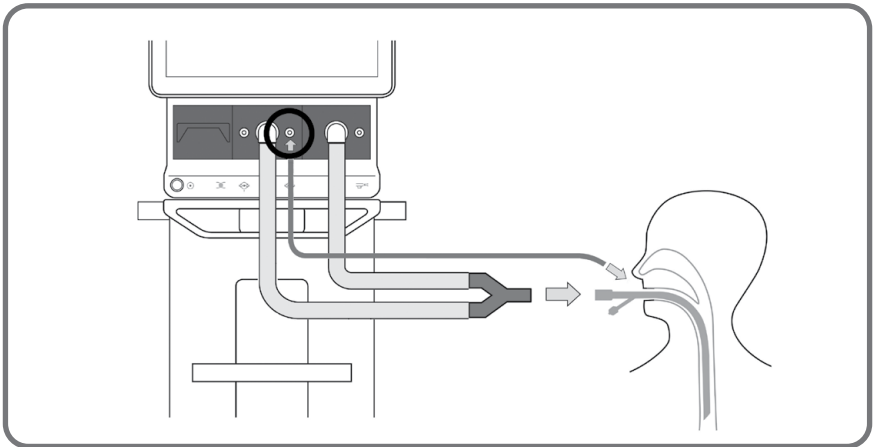
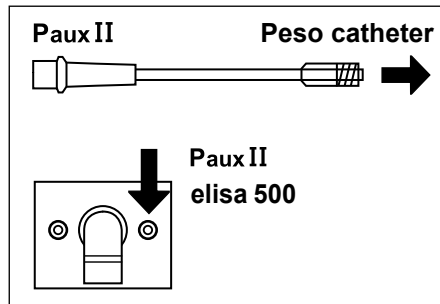
Observe the instructions for use supplied with the oesophageal catheter and the accessories used.

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:

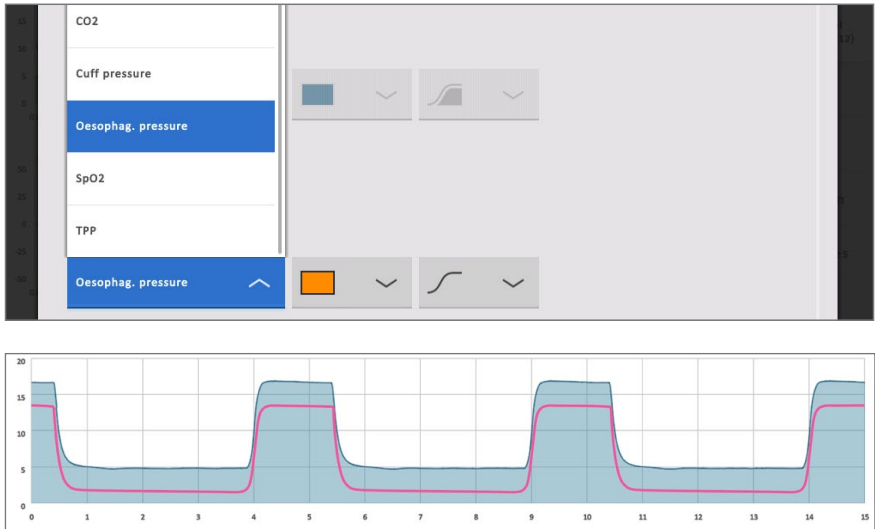
- P exp. (es)
- P insp. (es)
- TPP e (es)
- TPP i (es)
- ΔTPP (es)
- Peak (es)
- Pmin (es)
- ΔP (es)
- ΔPeso/ΔPAW

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

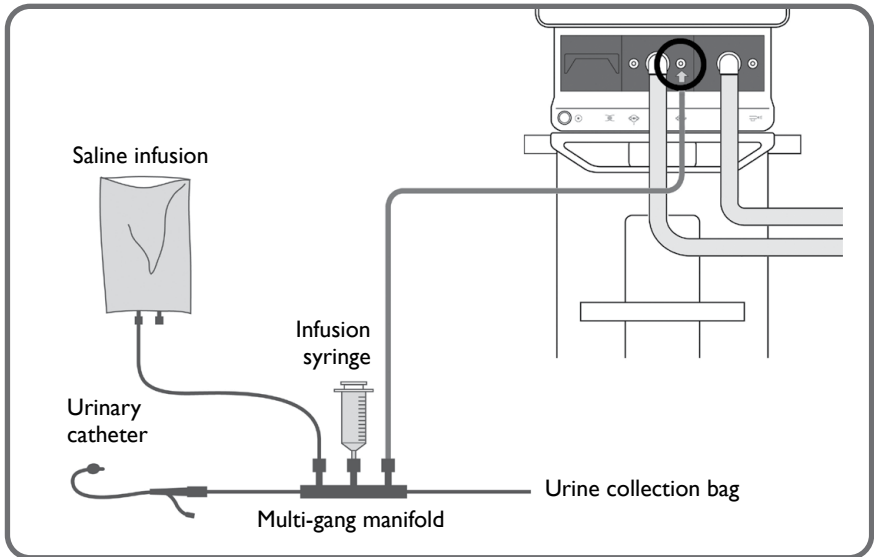
Check that the intravesical pressure measurement kit is connected to the correct port and familiarise yourself with intravesical pressure measurement with a closed system.



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
				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.

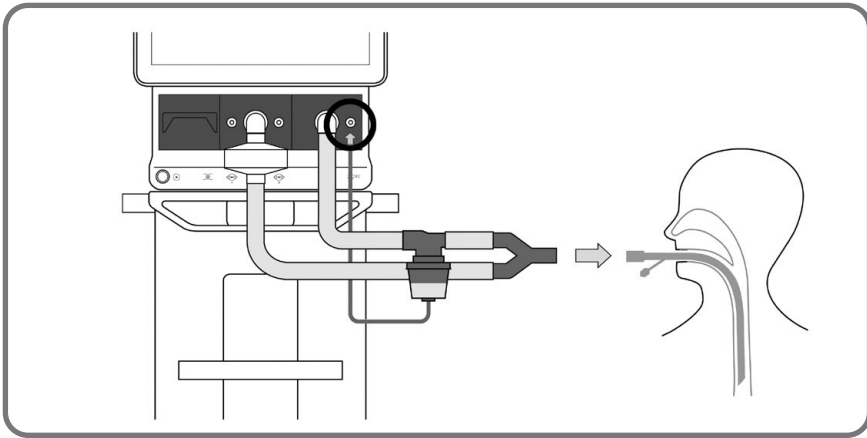
Remark | It is not possible to start nebulization while the AnaConDa function is active; the nebulization function is disabled.

A 3.7.3 Pneumatic nebulization

A 3.7.3.1 Connecting the pneumatic nebulizer set

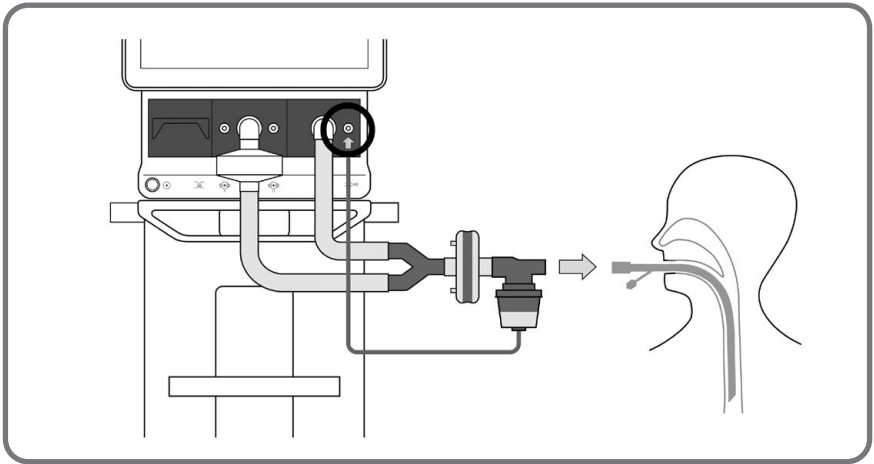
Remark | In volume-controlled modes, the pneumatic drug nebulization is not available for the patient category “Children”.

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.

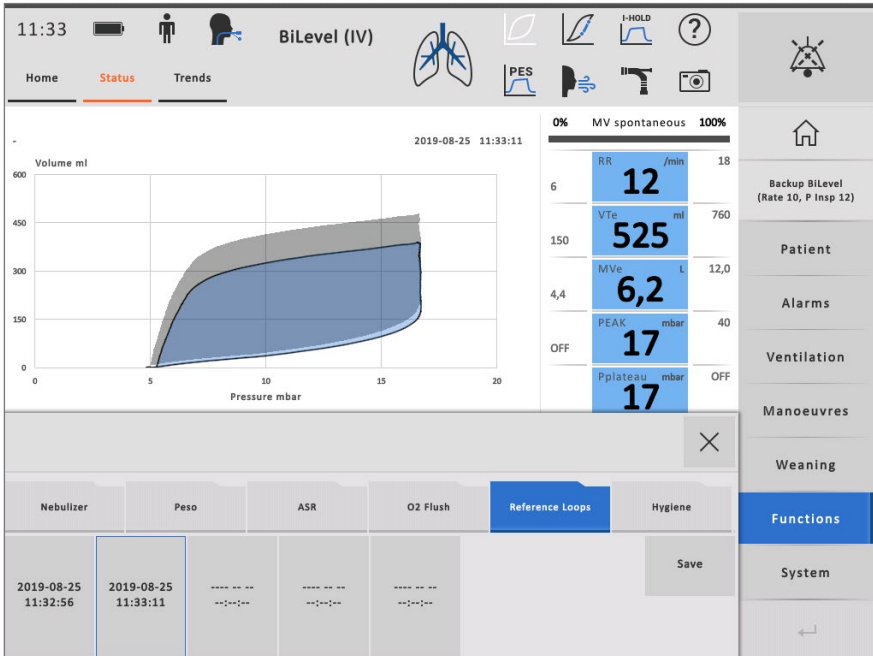
When the period of service of an accessory has expired, the alarm window will display a message.

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.

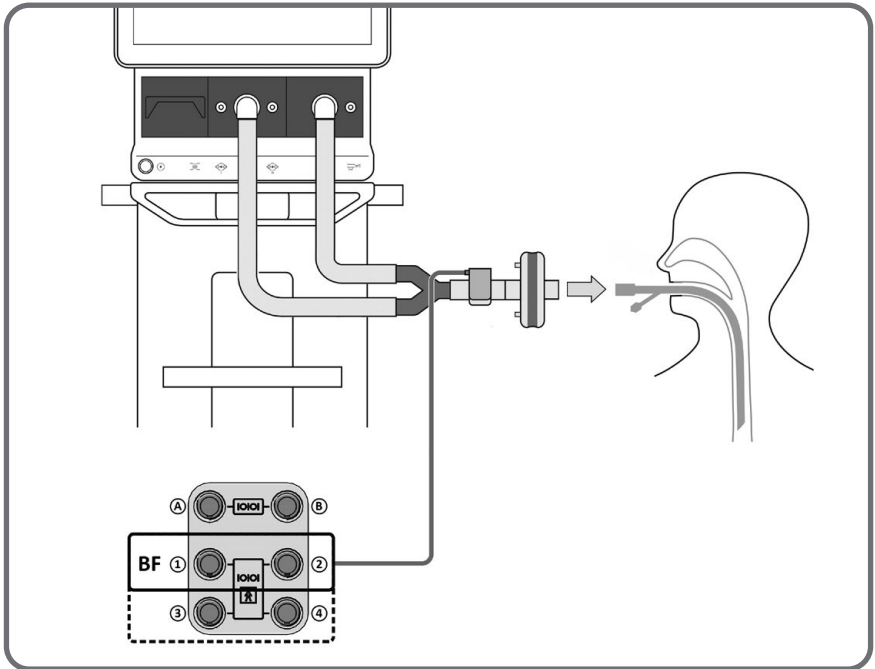


Warning

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

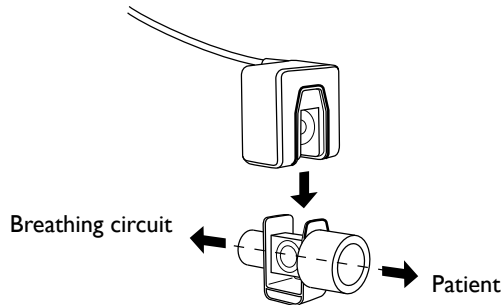
A 3.10.6 Connecting the LeoCap CO₂ sensor

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.

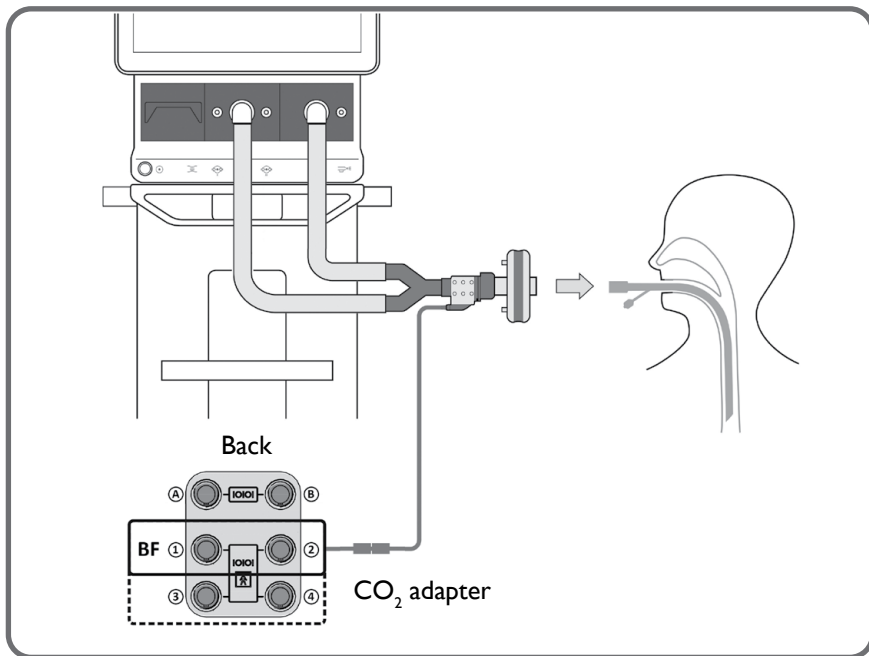


Do not touch the windows of the measuring cuvette. Finger prints may also lead to incorrect measurement results.

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.

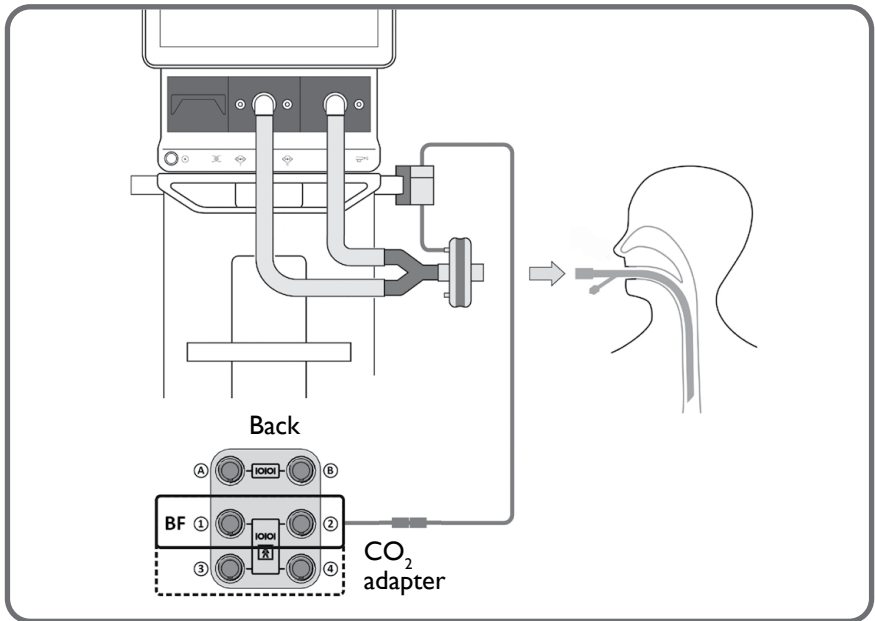
A 3.10.7 Connecting the mainstream sensor IRMA CO₂



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.

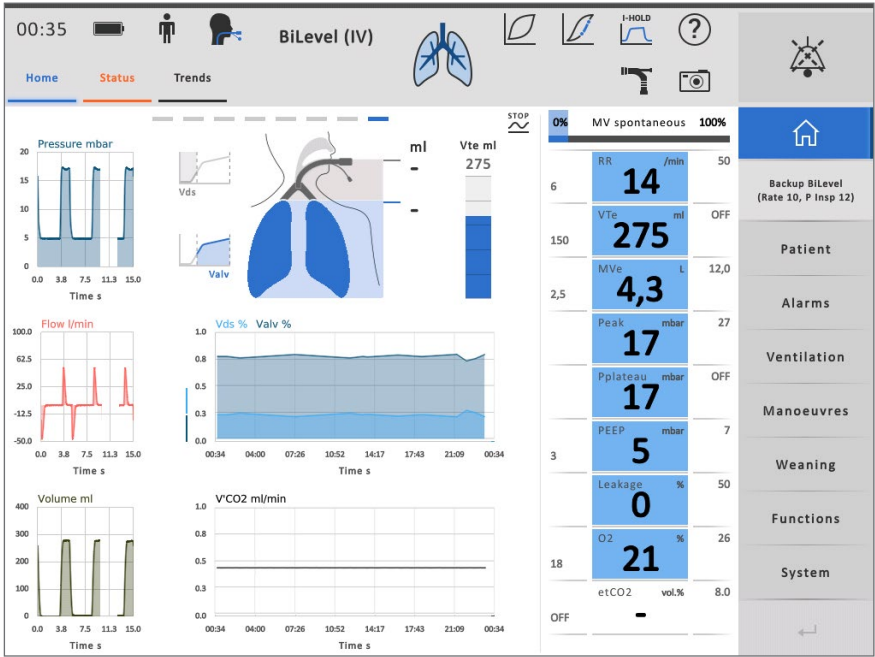
Remark

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

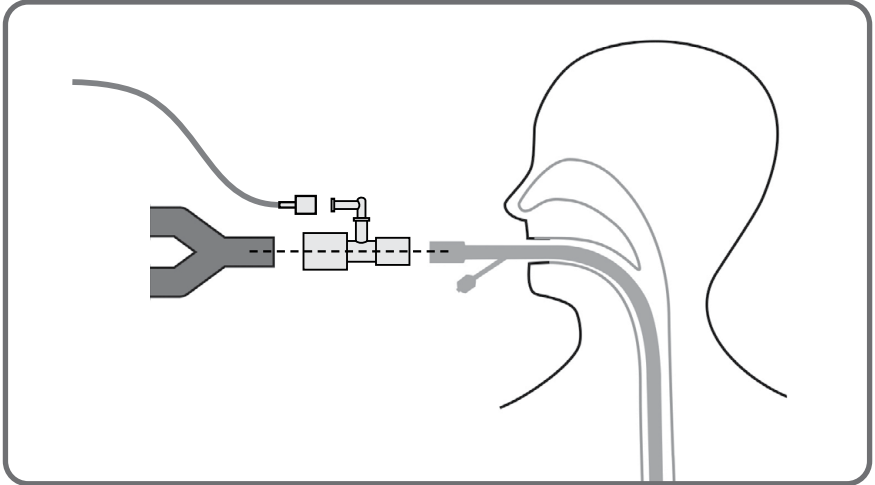
Insert the airway adapter between the Y-piece and the tube of the breathing circuit.

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

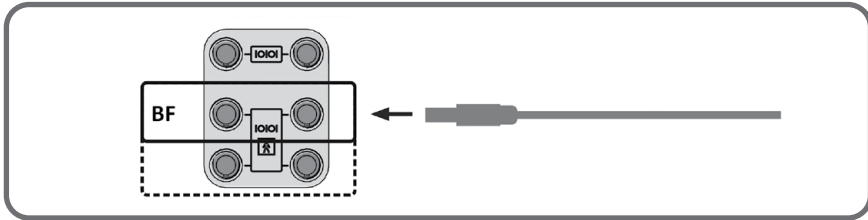
The sample gas outlet is located on the back of the device.

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.

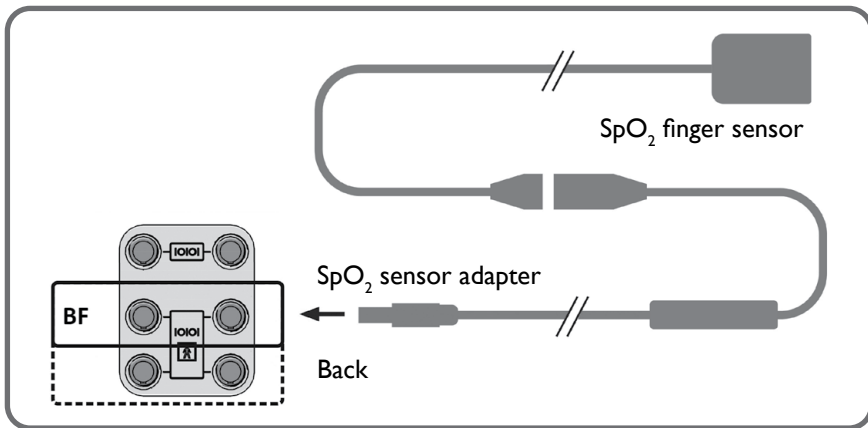


Warning

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.

**Warning**

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.

**Warning**

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

**Warning**

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:

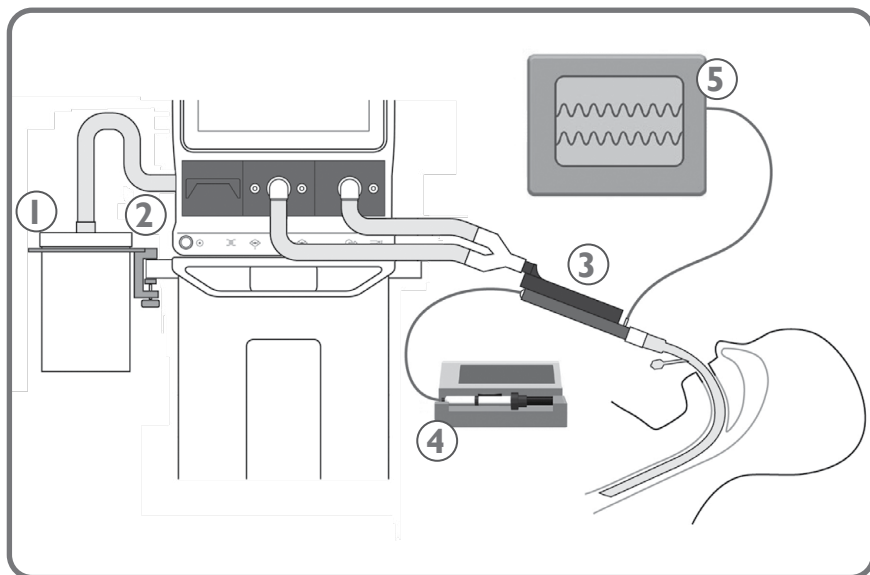
- Disconnect AnaConDa or AnaConDa-S from the patient tube or tracheostomy tube
- connect a resuscitation bag to the patient tube or tracheostomy tube.
- Ventilate the patient manually, if necessary with oxygen supply and PEEP valve.
- Stop administering the anaesthetic agent with the syringe pump.
-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

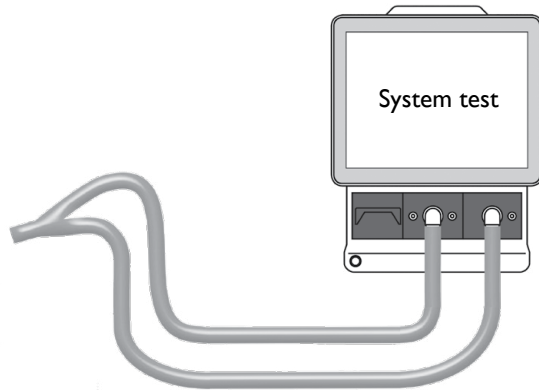
Accessories approved for use with elisa 300 / elisa 500 are specified in the “elisa 300 / elisa 500 list of accessories”. If employing different accessories, the user is required to test and demonstrate the safety of the system prior to its use. All accessories used must have an EC declaration of conformity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

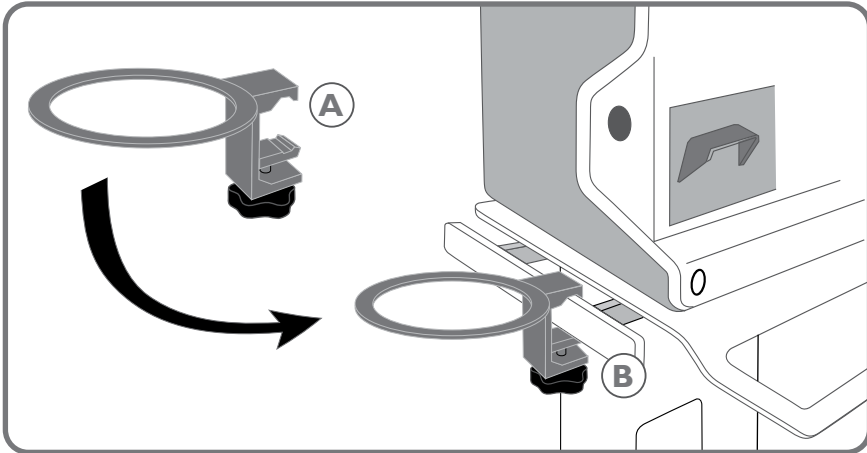
Decide if you want to eliminate the anaesthetic gas via the hospital gas scavenging system or through the anaesthetic gas filter. You will need the corresponding accessories (see separate list of accessories).

A 3.13.4.2 Elimination via Flurabsorb

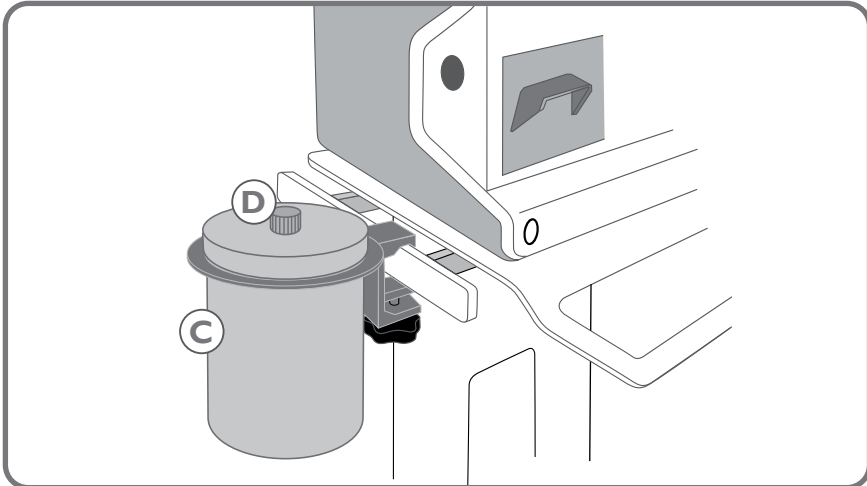
Obtain the following accessories (see separate list of accessories):

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

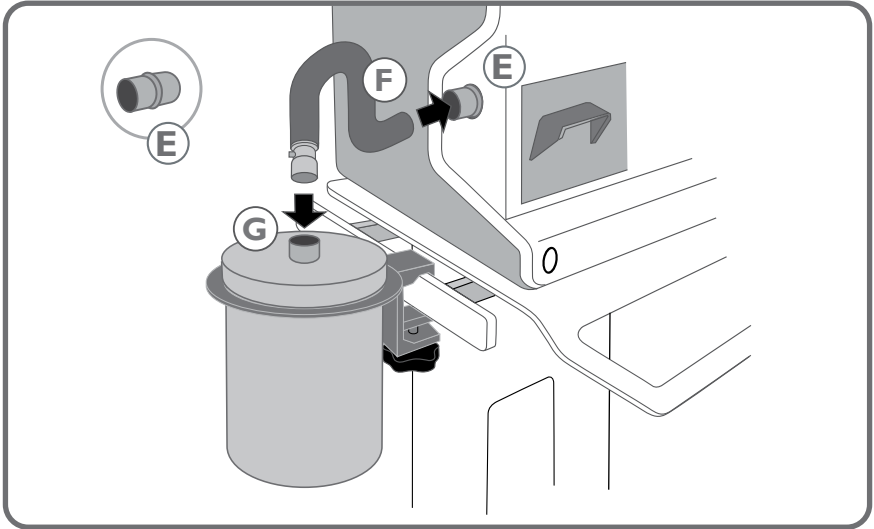
1.) Attach the holder for the anaesthetic gas filter (A) to the handle or standard rail on the left of the elisa 300 / elisa 500 cart (B).



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)



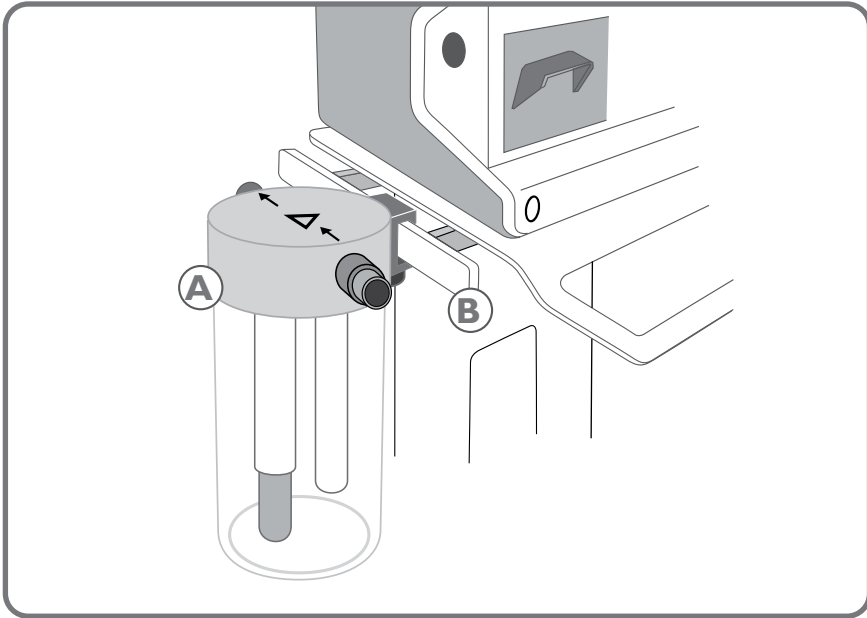
Warning

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).

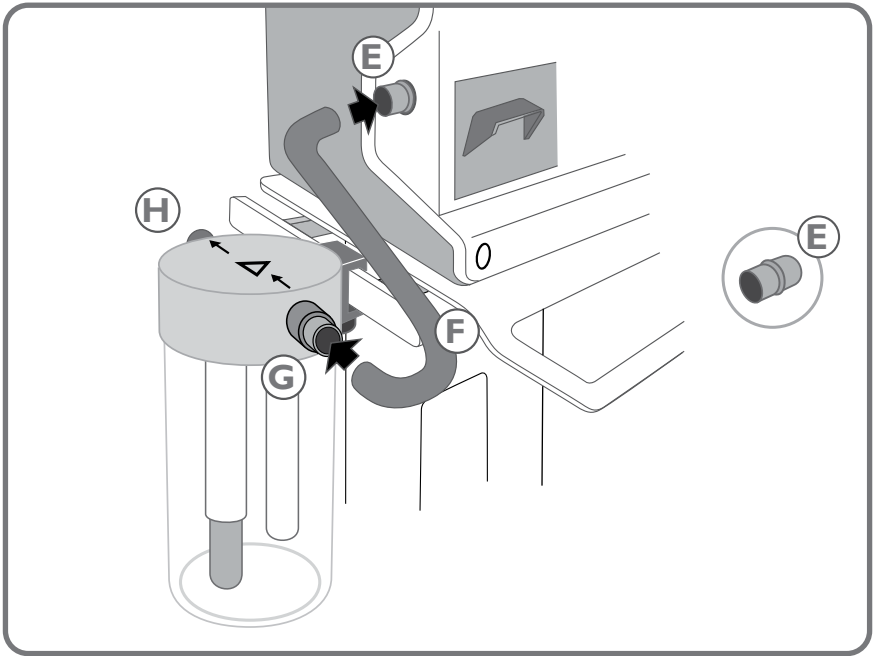


2.) Attach the 22 mm/22 mm adapter (E) to the exhaust gas port of elisa 300 / elisa 500. Slip the AGSS transfer hose onto the adapter (F). Attach the other end of the hose to the inlet port of the receiving container (G). Check that the tube is securely attached and tight.



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

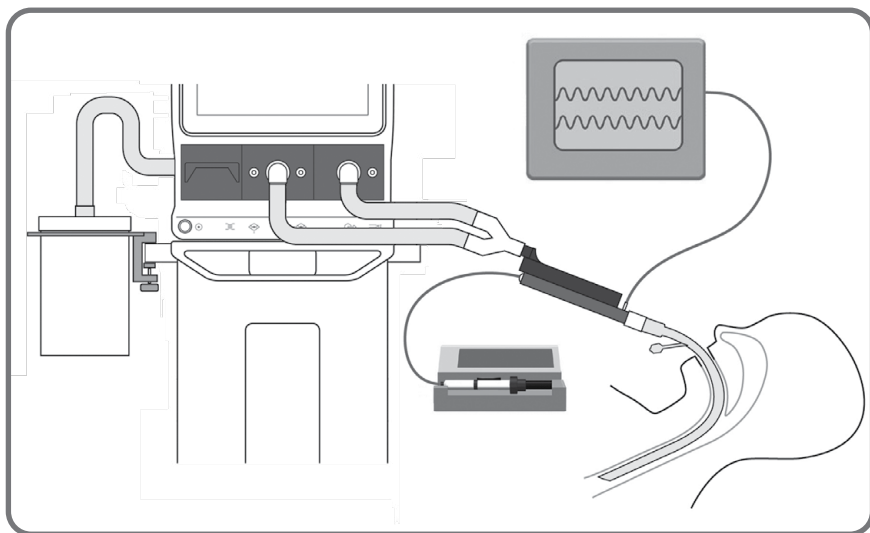
Finally assemble all components of the AnaConDa system (AnaConDa device, syringe pump with AnaConDa syringe and the anaesthetic gas monitor) as described in the AnaConDa instructions for use.



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.



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.

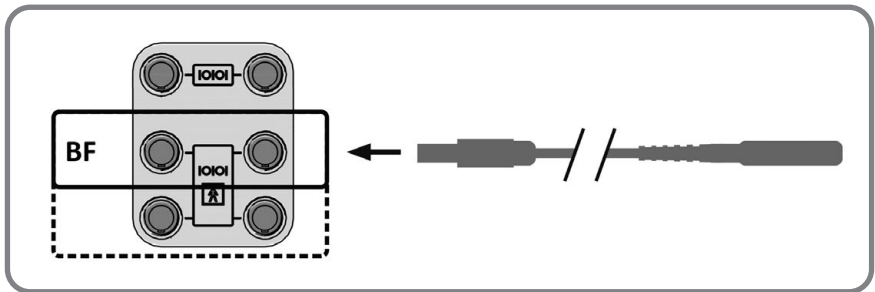
A 3.15 Nurse call

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

A 4.1	Weaninganalyzer	84
A 4.2	Availability of the weaning procedure	84
A 4.2.1	Availability for the different patient categories	84
A 4.3	SAT	84
A 4.3.1	SAT test (Spontaneous Awakening Trial)	84
A 4.4	SBT (Spontaneous Breathing Trial)	85
A 4.4.1	SBT procedure	86
A 4.5	P0.1	87
A 4.6	WOB	88

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

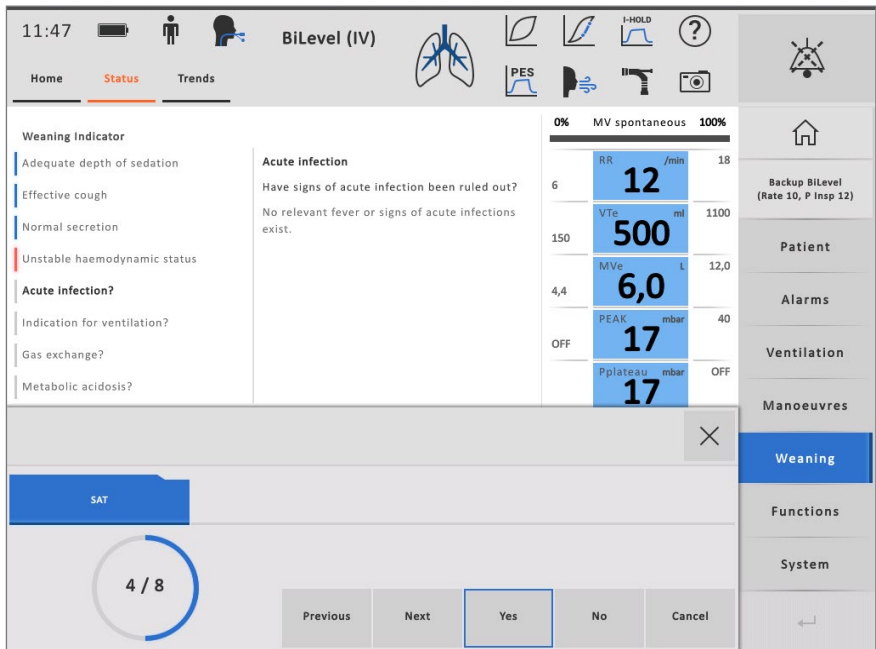
Weaning	Adults	Children
SAT	X	X
SBT	X	X
P0.I	X	X
WOB	X	X

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.

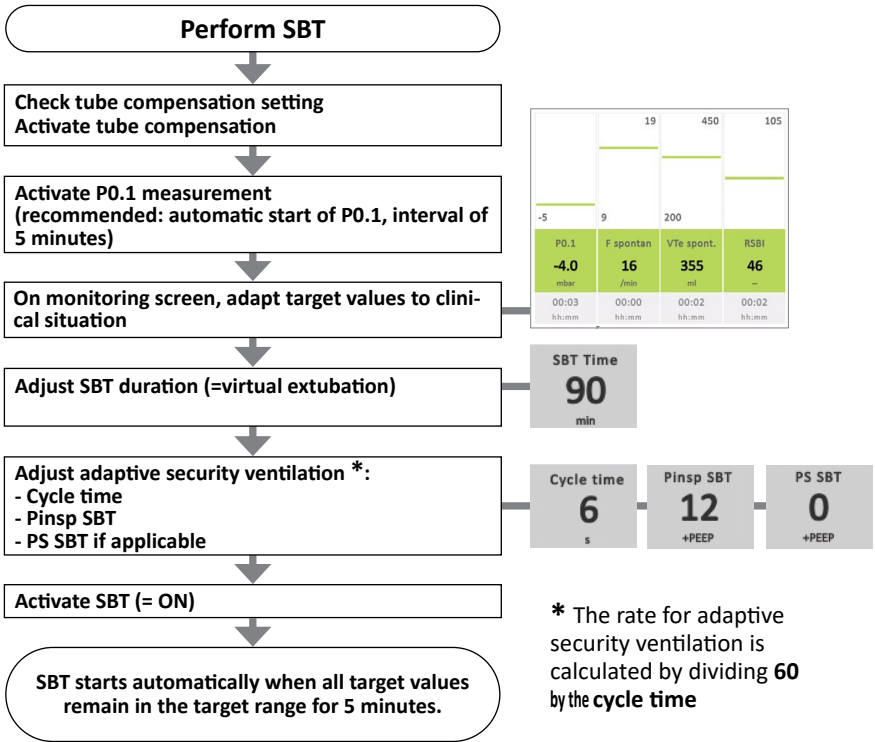
On the monitoring screen, adapt the target values to the patient's clinical situation:

	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	Compens. C	Stop	
					8,5 mm	10 %		

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

A 5.1	Default settings	91
A 5.1.1	The modes are named in compliance with the ISO standard 19223:2019-07	91
A 5.1.2	Backup modes	92
A 5.2	Default ventilation	92
A 5.3	Ventilation modes	92
A 5.3.1	Special information regarding volume-controlled modes	94
A 5.4	Ventilation parameters	95
A 5.4.1	Expiratory ramps	99
A 5.5	Modes	100
A 5.5.1	BiLevel ST	101
A 5.5.2	Dynamic BiLevel ST	102
A 5.5.3	Dual BiLevel ST	103
A 5.5.4	BiLevel	104
A 5.5.5	Mandatory BiLevel	105
A 5.5.6	Dynamic BiLevel	106
A 5.5.7	Dual BiLevel	107
A 5.5.8	Optional BiLevel	108
A 5.5.9	Flexible BiLevel	109
A 5.5.10	PC-SIMV	110
A 5.5.11	PSV	112
A 5.5.12	Dynamic PSV	113
A 5.5.13	Proportional PSV	114
A 5.5.14	PAPS (Proportional Adaptive Pressure Support)	116
A 5.5.15	CPAP	118

A 5.5.16 VCV	119
A 5.5.17 PLV	120
A 5.5.18 VC-SIMV	121
A 5.5.19 Optional VCV	122
A 5.5.20 Flexible VCV	123
A 5.5.21 Volume-adaptive BiLevel	124
A 5.5.22 PC-APRV	125
A 5.5.23 PCV	126
A 5.5.24 ALPV (Adaptive Lung Protection Ventilation)	128
A 5.5.25 WOBOV (Work Of Breathing Optimized Ventilation)	129
A 5.5.26 CPR	131
A 5.5.27 HFOT	133

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.

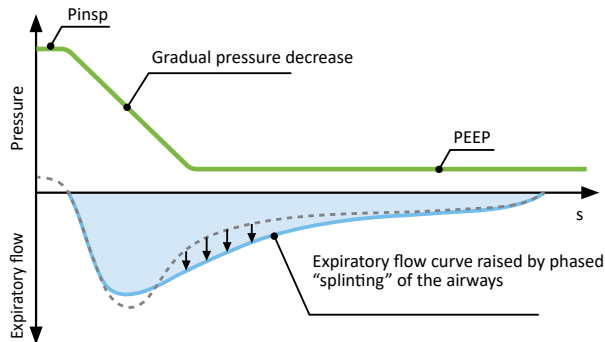
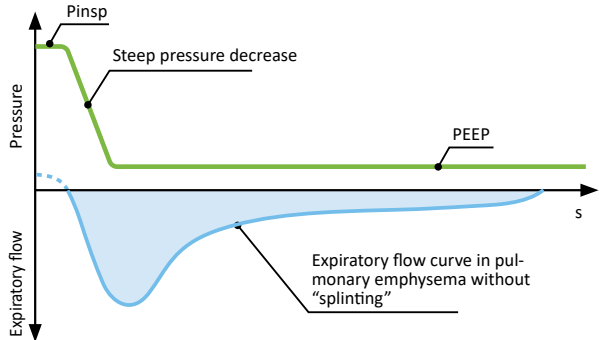
A 5.4.1 Expiratory ramps

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 (Pin_{sp}) 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.

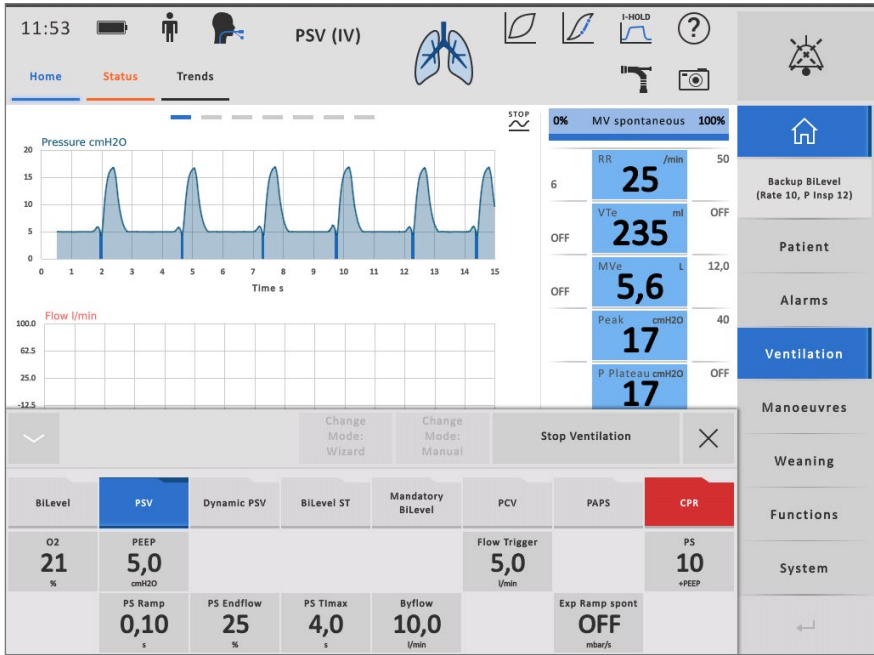
In this mixed form of ventilation the system permits spontaneous breathing at the lower pressure level. As a result, the minute volume may exceed the set mandatory value. By setting the PS pressure support, the patient's work of breathing at the lower pressure level can be reduced. Initiated by reaching 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

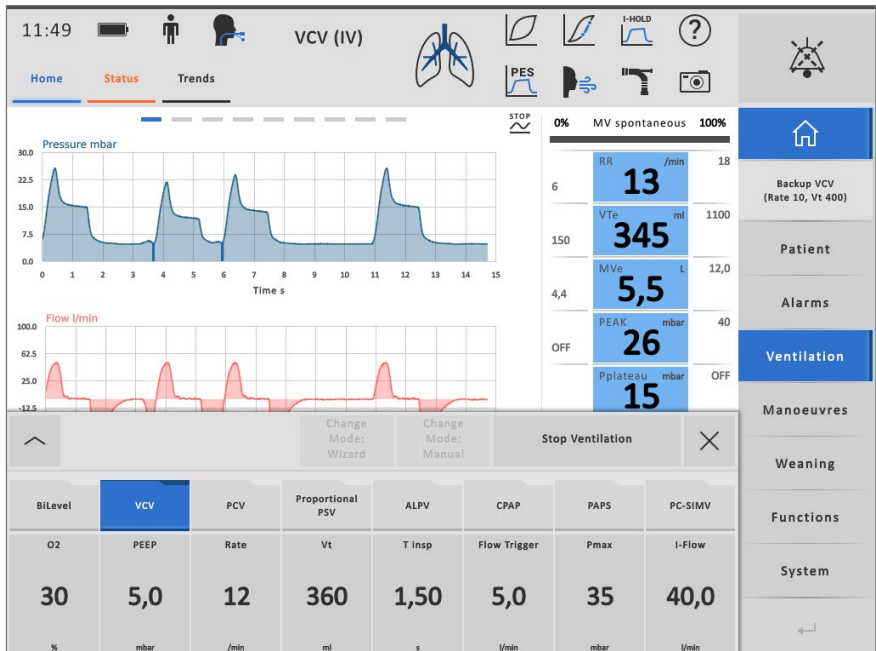
Continuous Positive Airway Pressure Spontaneous breathing at ambient pressure level or with continuous positive airway pressure (CPAP).



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

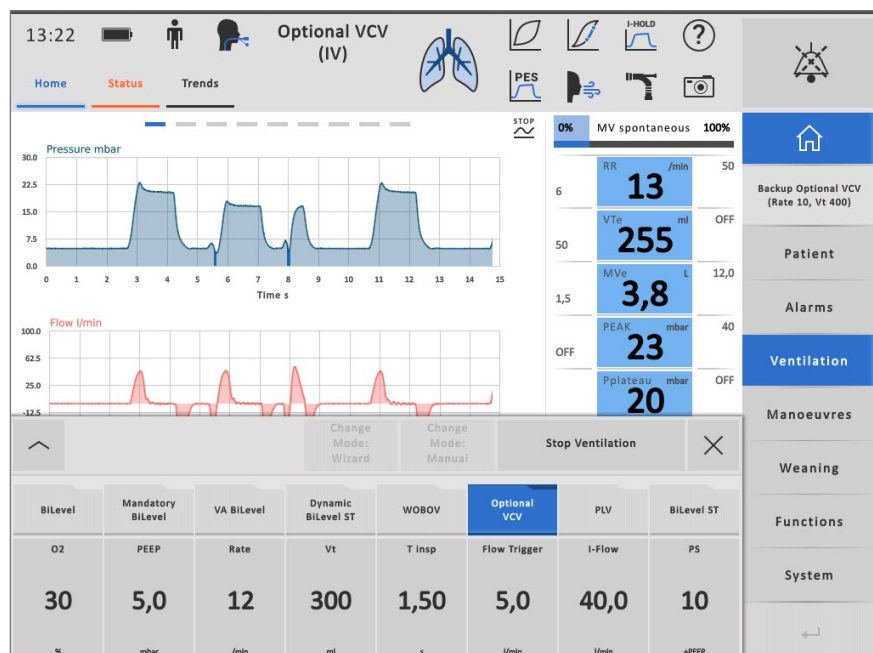
Volume Controlled - Synchronised Intermittent Mandatory Ventilation. Synchronised, volume-controlled ventilation with the possibility of spontaneous breathing between the controlled breaths.



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.

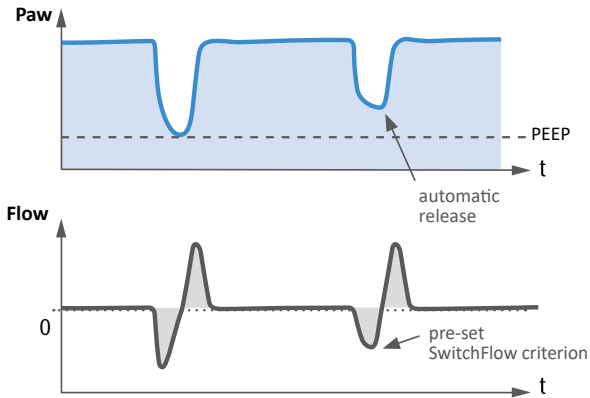
A 5.5.22 PC-APRV

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.

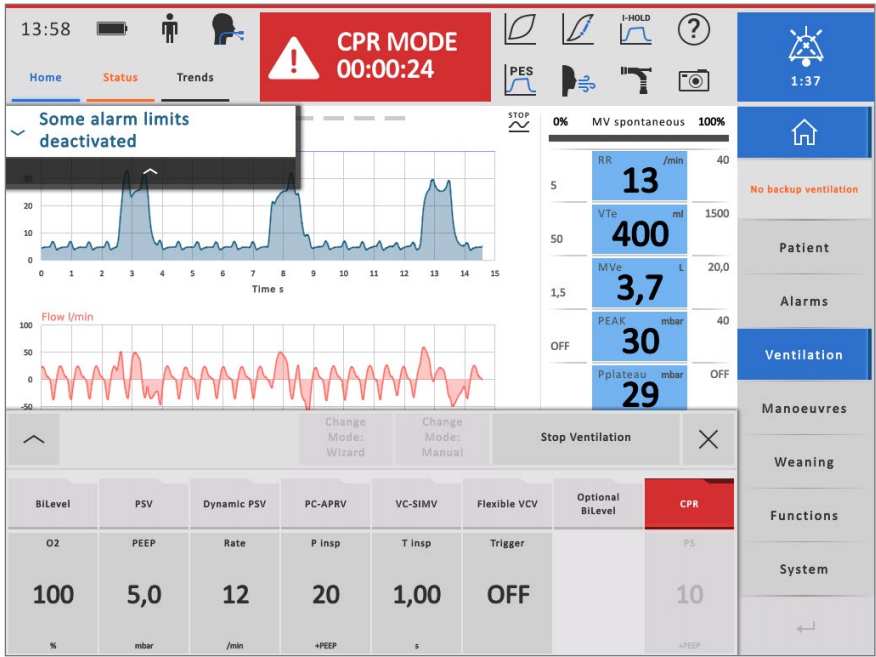

Warning

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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CO₂ Mainstream Sensor

LeoCap

Instructions for Use
Supplement B

The device operates according to the accompanying documentation and the equipment labelling if used 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.

0 Contents

1 General notes	5
1.1 About this manual	5
2 Use	5
2.1 Intended use	5
2.2 Order numbers	5
2.3 CO ₂ sensor – details	6
2.4 Theory of operation	7
3 General safety instructions	7
3.1 Safety information	8
3.2 Symbols on the device and on the packaging	10
4 Sensor operation	11
4.1 Installation	11
4.2 Connecting the sensor	11
4.3 Checking the CO ₂ data on the device	14
4.4 Functional description of the device	14
4.5 Removing the sensor from the patient	15
4.5.1 Separating the sensor from the airway adapter	15
4.5.2 Removing the airway adapter from the breathing circuit	15
4.6 Checks before and after use	15
4.7 Troubleshooting	16
5 Disinfection	16
5.1 Disinfection of the device	16
5.1.1 Recommended cleaning agents and disinfectants	17
5.1.2 Cleaning and disinfection	17
5.2 Disinfection of reusable airway adapters	18
5.2.1 Reprocessing procedure	18
5.2.2 Cleaning and disinfection	19
6 Storage	20

7 Disposal	21
8.1 Maintenance and repair	21
8.1.1 Device maintenance	21
8.1.2 Repair	21
9 Technical data	22
10 Guidance and manufacturer's declaration	24

I General notes

I.1 About this manual

These instructions for use describe the intended use and the operation of the following product:

LeoCap CO₂ mainstream sensor

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

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

2 Use

2.1 Intended use

The CO₂ mainstream sensor (hereinafter referred to as “sensor”) is used for the continuous measurement of the etCO₂ concentration in the patient's main respiratory airflow; it also measures the respiratory rate represented in a capnogram.

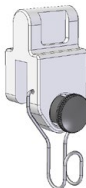
The sensor was developed for medical devices used for respiratory care, intensive care and patient monitoring.

The sensor is equipped with a reusable, sterilizable airway adapter (for adults/children, or children/neonates), sensor cable and connector.

The LeoCap sensor is only intended for use with the intensive care ventilators of the elisa family (elisa 300 – elisa 800VIT).

2.2 Order numbers

Description	Picture	Part no. LMI	Part no. LM
LeoCap CO ₂ mainstream sensor volumetric, for elisa 300 – elisa 800 for SW 2.05.x and higher		AZ-480100	0691530

Description	Picture	Part no. LMI	Part no. LM
Airway adapter for adults/children (sterilizable)		AZ-480110	0691531
Airway adapter for children/neonates (sterilizable)		AZ-480120	0691533
Holder LeoCap CO ₂ sensor “Classic” for attachment to a standard rail		AZ-540615	0691532
Holder LeoCap CO ₂ sensor “Standard” for attachment to a standard rail		AZ-540645	az-540645

2.3 CO₂ sensor – details

	LeoCap CO₂ sensor 1 Sensor 2 Connector (connects to intensive care ventilator) 3 Sensor cable 2.80 m 4 Type plate
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2.4 Theory of operation

The sensor allows the continuous measurement of the CO₂ concentration in the patient's respiratory airflow by infrared spectroscopy.

The method is based on measuring the absorption of infrared light with a certain wavelength by CO₂ molecules. The amount of measured light that passes through the respiratory gas to the sensor serves as the calculation basis. The concentration of CO₂ is calculated from the partial pressure at atmospheric pressure condition.

By means of appropriate accessories, the sensor is connected to the breathing circuit. The user can choose from different types of airway adapters for neonates, children and adults.

The sensor is equipped with a monochromatic infrared emitter and a photo detector. The adapter has two sapphire windows, transparent to the emitted infrared light. Through these windows, the light emitted from the infrared source passes through the gas mixture to be analysed and reaches the photo detector. Thus, the device measures the degree of absorption of infrared rays during their passage through the gas stream.

3 General safety instructions

These instructions for use are an integral part of the delivery. When the device changes ownership, the manual must also be handed over. Information contained in this document can be changed without notice.

The device 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.

Before working with the sensor, carefully read these instructions for use as well as the Basic Instructions for Use and Supplement A of the intensive care ventilator used. Improper use of the sensor can cause malfunction, loss of performance and it can create a hazard for the patient.

If malfunctions or unstable operation of the sensor occur, refer to the troubleshooting tips in section 4.7 and also to the appropriate sections of these instructions for use.

The following signs and symbols are used to identify important information in 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.

Reusable consumables have limited service life. Various operation conditions, cleaning, disinfection and sterilization can lead to the deterioration and the corresponding reduction of their service life. If signs of deterioration (cracks, deformation, discolouration, paint peeling off, etc.) are detected, you need to replace the consumables.

3.1 Safety information



Warning

Do not establish a diagnosis solely based on the data acquired with the sensor. A physician who understands the features, limitations and characteristics of the sensor and has access to biometric signals from other devices should provide the overall assessment.



Warning

If an emergency occurs during operation (fire, short circuit, etc.), immediately disconnect the device from the patient and continue monitoring with another device.



Warning

Use the sensor only with the specified intensive care ventilators. Using devices not explicitly mentioned may cause injuries and equipment damage.



Warning

Do not pull or bend the sensor or the adapter cable and do not roll equipment trolleys over any cables. Failure to follow these instructions may cause cable discontinuity, short circuits, skin burns on the patient due to elevated device or sensor temperatures resulting from the short circuit in the cable, and failed measurements. If the sensor or adapter is broken, replace it with a new one.

**Warning**

Sensor functions may be affected by equipment operated in the vicinity. Before use, check that the device operates normally when used in the vicinity of other equipment.

**Warning**

Keep magnetic objects away from the device. Magnetic objects may distort the waveform and cause incorrect readings.

**Warning**

Do not use the device in the vicinity of nuclear magnetic resonance equipment.

**Warning**

Measurements may not be performed correctly until several minutes after connection of the sensor because the temperature of the device is not yet stable.

**Warning**

Do not allow liquid to enter into the housing of the device during operation.

**Warning**

Do not immerse the device in liquids, such as water or disinfectant.

**Warning**

The CO₂ sensor is not defibrillation-proof. It is mandatory to remove the CO₂ sensor from the patient during defibrillation.

**Warning**

Use only the specified airway adapters. Otherwise, the maximum performance cannot be guaranteed due to larger dead space, leakage or an unsafe (electrical) connection, etc.

**Warning**

Do not use the adult/paediatric adapter on neonates because the dead space of the airway adapter is 5 ml.

**Warning**

Select the airway adapter taking into consideration the patient weight and ventilation volume. If an inappropriate airway adapter is used, the resistance in the breathing circuit increases, which leads to incorrect measurements.

**Warning**

Major changes of the operating temperature and considerable amounts of condensation in the airway adapter may lead to incorrect measurements.

**Warning**

Do not let the patient bite on the interface cable or sampling line. This may damage to the device and harm the patient.

**Caution**

It is strongly recommended to operate the device in an electromagnetic environment as specified in chapter 10. Otherwise, the maximum performance cannot be guaranteed due to electromagnetic disturbances.

**Caution**

Recommended separation distances between portable and mobile radio frequency (RF) communications equipment and the device are stated in chapter 10.

3.2 Symbols on the device and on the packaging

	Caution!
	Lot number
	Serial number
	Medical Device
	Unique Device Identification
	Manufacturer
	Date of manufacture

	The device fulfils the requirements of Directive 93/42/EEC concerning medical devices and of Regulation (EU) 2017/745, provided it is operated according to the instructions for use. 0123 is the notified body.
	Follow the instructions for use!
	Prohibition sign
IP44	Protection class according to DIN EN 60529
	The sensor must be disposed of in compliance with Directive 2002/96/EC.

4 Sensor operation

4.1 Installation

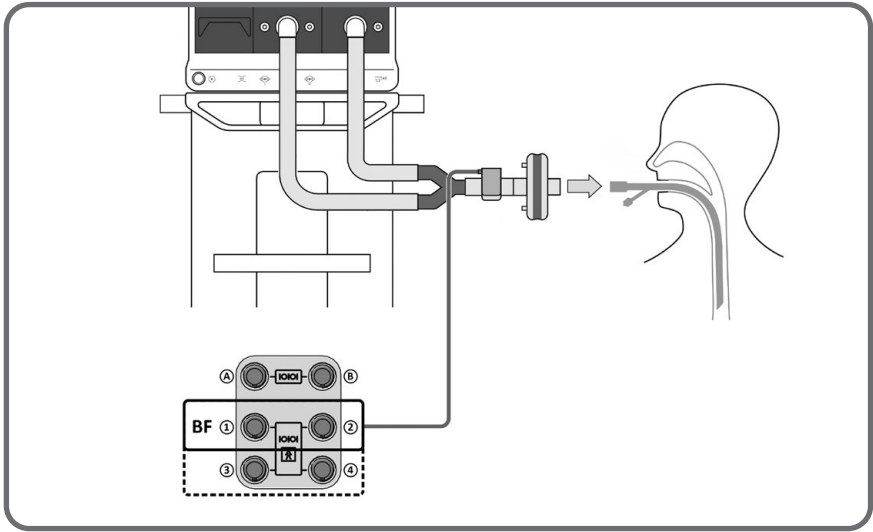
To ensure the best possible sensor performance, it needs to be correctly installed and connected. The sensor is to be treated like an electronic device and must be properly secured with the available accessories.

Communication to and from the device is via a serial connection (BF interface of the intensive care ventilator).

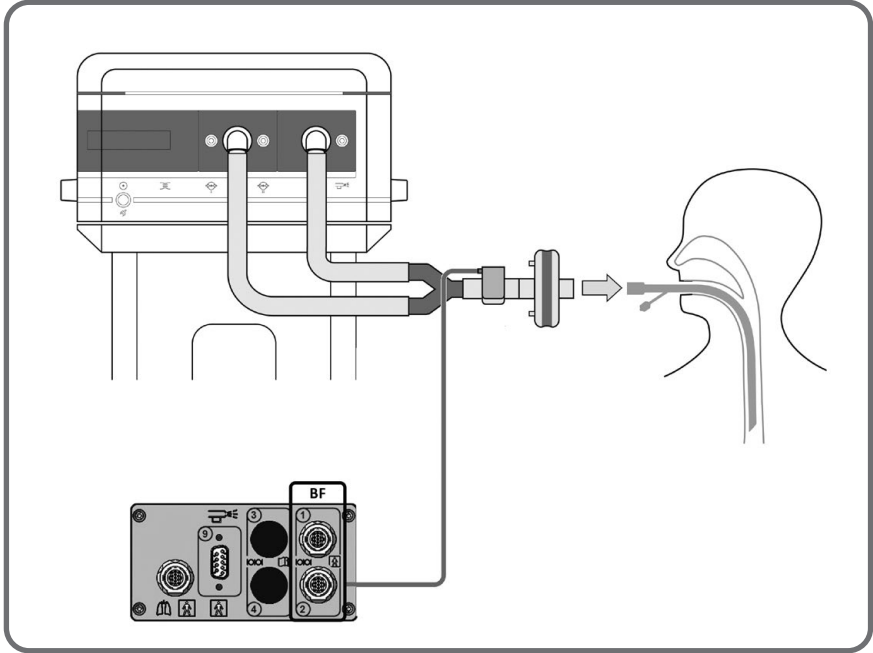
4.2 Connecting the sensor

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

elisa 300 / elisa 500



elisa 600 / elisa 800



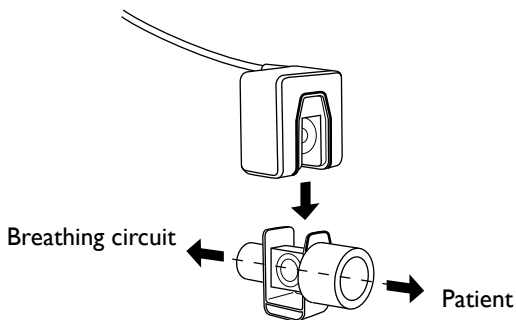
**Warning**

Always connect type BF equipment to the intensive care ventilator before connecting it to the patient.

**Warning**

Be sure to connect the equipment only to the interfaces on the back of the intensive care ventilator intended for the respective purposes.

- Check the windows in the sensor and in the airway adapter. They must be dry and clean. If necessary, clean or replace the airway adapter.
- Attach the CO₂ sensor to the measuring cuvette so that you hear it click into place.



- Integrate the assembled cuvette/sensor unit between the HME filter and the patient (at the patient end of the circuit).

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.

**Caution**

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



Warning

The windows in the airway adapter should be arranged vertically with respect to ground. This orientation reduces or completely prevents contamination of the adapter windows by the patient's secretions.



Caution

Follow the instructions for use (Basic Manual and Supplement A) of the respective intensive care ventilator.

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 or on the standard rail of the optional cart.

- The maximum performance is reached after a warm-up of about 2 minutes.
- Check whether the screen of the ventilator displays measurement results.

4.3 Checking the CO₂ data on the device

Check that the CO₂ data are correctly displayed on the intensive care ventilator. For further information, please refer to the instructions for use of the intensive care ventilator.

Periodically check the breathing circuit for water accumulation. Accumulated water should be removed immediately.

Especially when an uncuffed tracheal tube is used, the CO₂ partial pressure curve may be inaccurate due to leakage at the tracheal tube.

When using the airway adapter with a constant flow ventilator, the end-tidal CO₂ partial pressure curve may be unstable due to the low respiratory flow (depending on the settings at the intensive care ventilator).

4.4 Functional description of the device

During operation the connected intensive care ventilator displays the measured etCO₂ value and the capnogram. For further information, please refer to the instructions for use of the intensive care ventilator.

Depending on the configuration of the intensive care ventilator, the CO₂ concentration is displayed as a partial pressure (mmHg or kPa) and (or) as a percentage concentration (%).

If normal operation is not possible, the sensor will be disabled and an error message will be displayed. For further information about sensor messages, please refer to the instructions for use of the intensive care ventilator.

Remark | Calibration of the LeoCap sensor is an automatic routine function.

4.5 Removing the sensor from the patient



Caution

When removing the sensor, do not hold only the cable or only the sensor. The cable may break or the sensor may be damaged by excessive force.

4.5.1 Separating the sensor from the airway adapter

Hold the adapter in the breathing circuit with one hand and the sensor with the other hand. Lift off the sensor.

4.5.2 Removing the airway adapter from the breathing circuit

Disconnect the airway adapter from the breathing circuit without exerting excessive force.

4.6 Checks before and after use

After unpacking a new sensor, handle it with care because static electricity, water or chemical solutions may cause damage.

Before each use, check the sensor and the external surfaces of the reusable airway adapter (especially the optical elements) for contamination. Contamination and moisture can reduce the measuring accuracy of the CO₂ sensor. If necessary wipe the windows clean with a moist cloth.

Also make sure that the connectors and cables are intact.

A damaged airway adapter must be replaced with a new one.

If necessary, clean and disinfect the CO₂ sensor and the airway adapter according to chapter 5; all surfaces must be dry and clean.

4.7 Troubleshooting

Problem	Possible causes	Remedy
Measurement is not performed	Environment causes electromagnetic interference	Turn off the devices that cause strong electromagnetic interference
	BF interface was not configured	On the screen of the intensive care ventilator, select the “Status” tab and go the second view which shows the current configuration of the BF interfaces. If in doubt, contact your service technician.
The measured value is inaccurate	Rapid temperature change	Measurements may be incorrect when rapid temperature changes and condensation occur
	Water has accumulated in the airway adapter	Remove water from breathing circuit

5 Disinfection

5.1 Disinfection of the device

Disinfect the surface of the CO₂ mainstream sensor (including the windows) by wiping down with a damp cloth; wipe them again with a clean, lintfree cloth. The windows of the sensor should always be clean and dry.



Caution

The device shall be cleaned and disinfected after each use, before commissioning, maintenance or returning it to the manufacturer for repair.



Caution

Do not spill liquids on the device.



Caution

Application of high temperatures and chemical sterilization techniques, including immersion of the device in disinfecting solution is strictly prohibited!



Caution

Do not allow the pins of the device connector to become wet. This may cause a device failure. The interface cable may be damaged.



Caution

When disinfecting the interface cable by pulling it through a swab or cloth moistened with disinfectant, do not apply excess tension to the cable.

5.1.1 Recommended cleaning agents and disinfectants

- Hydrogen peroxide solution (3%) with 0.5% solution of ionic surface-active substances
- Alcohol solution (ethyl or isopropyl alcohol) 70%
- Chlorhexidine gluconate solution (0.5%)

It is possible to use other approved cleaning agents and disinfectants with similar active ingredients in the right concentration that are commonly used in hospitals.

5.1.2 Cleaning and disinfection

- Disconnect the sensor plug from the Intensive care ventilator; disconnect the airway adapter from the sensor.
- Clean and disinfect the surfaces of the sensor, which are not intended for sterilization, by wiping them down with a gauze swab or soft cloth moistened with one of the cleaning agents and disinfectants mentioned above. Squeeze the cloth before wiping down the device to prevent liquid from entering the device. Use only distilled water to prepare the cleaning and disinfection solution. Follow the instructions for use from the manufacturer's of the cleaning agents and disinfectants.
- Before the next application, check the sensor windows: they must be completely dry and clean. Also check the windows for stains from cleaning agents or water.

5.2 Disinfection of reusable airway adapters



Caution

Adapters are supplied non-sterile. Airway adapters must be reprocessed (resterilized) before and after use.



Caution

Do not use rough brushes, sharp tools and abrasive materials for manual cleaning!

The adapters withstand at least 100 reprocessing cycles (unless damaged during use). Use only distilled water to prepare the solution.

5.2.1 Reprocessing procedure

- Disconnect the adapter from the sensor.
- Clean and disinfect the adapter according to the following recommendations.
- Check the adapter for defects.
- Place the adapter into the special container for autoclaving.
- Sterilize the adapter by autoclaving according to the following recommendations.
- Check that the adapter is completely dry before packaging it after sterilization.
- Store the adapter in its packaging.
- Before use, check that the adapter windows are clean and dry. After connecting the adapter to the sensor, perform the necessary tests and calibrations.

5.2.2 Cleaning and disinfection

Recommended cleaning agents and disinfectants

Cleaning agents:

- Ionic, surface-active substances, 0.5% solution
- Neutral soap solution
- Neodisher Mediclean forte I %, manufacturer: Dr. Weigert

Disinfectants:

- Lysetol AF and Gigasept FF, manufacturer: Schülke & Mayr
- Sekusept PLUS, manufacturer: Henkel-Ecolab
- CIDEX, manufacturer: Johnson & Johnson or glutaraldehyde solution (concentration $\leq 3.6\%$)

It is possible to use other approved cleaning agents and disinfectants with similar active ingredients in the right concentration that are commonly used in hospitals.

Cleaning

- Disconnect the adapter from the sensor.
- Immerse the adapter in warm cleaning solution (temperature below 40 °C) prepared with one of the recommended cleaning agents. Put the adapter on the cleaning tray to soak it in the solution. Make sure that the adapter is completely covered by the solution and that there are no air bubbles in opening and cavities of the adapter. Use a soft plastic brush for removing solid particles from the surface of the adapter. Exposure time and cleaning method depend on the cleaning agent used. Observe the manufacturer's instructions.
- Rinse the adapter with clean, running water and follow the recommendations of the manufacturer of the cleaning agent.

Disinfection

- Immerse the adapter in disinfecting solution for disinfection. Put the adapter on the cleaning tray to soak it in the solution. Make sure that the adapter is completely covered by the solution and that there are no air bubbles. Exposure time and disinfection method depend on the disinfectant used. Observe the manufacturer's instructions.
- Allow the adapter to air dry. Do not wipe the adapter down while it is drying.
- Inspect the adapter and discard it if found to be defective.

Automated cleaning and disinfection

For automated cleaning and disinfection, use washer disinfectors that comply with the ISO 15883 standard. A suitable cleaning agent is Neodisher FA®, a suitable neutralizer, Neodisher Z®, both manufactured by Dr. Weigert. Observe the instructions for use of the washer disinfectant and of the cleaning agent. The table below provides a general guideline for cleaning/disinfection.

Recommended stages for automated cleaning and disinfection

Stage	Temperature	Duration
Pre-rinsing	Cold water	3 min
Cleaning	65 °C	5 min
Neutralizing	Hot water	1 min
Rinsing	Cold distilled water	3 min
Thermal disinfection	93 °C	44 min
Drying	120 °C	12 min

Packaging

After cleaning and disinfection, put the adapter in sterile packaging. The sterile packaging must fulfil the requirements of the ISO 11607 standard.

Sterilization

Sterilize the adapters in a hot steam sterilizer at 134 °C and 0.21 MPa. Minimum duration of a sterilization cycle: 5 minutes

6 Storage

Store the device in its original packaging in a closed, ventilated room at an air temperature between 5 °C and 40 °C and a maximum relative humidity of 80% at a temperature of 25 °C.

In case of temporary withdrawal from the packaging, store the device at an ambient temperature of 5 °C to 40 °C and a maximum relative humidity of 80% (at 25 °C). Devices should be stored on a rack in a single line. Do not store the device in places where acid vapours or other harmful vapours may occur.

In case of long-term storage after use, the device should be placed in a polyethylene case and, if possible, in the original packaging to protect it from mechanical damage.

The device may be transported in the original packing without any limitation of distance, according to the applicable transportation regulations. The temperature range for transport is from -50 °C to +50 °C.



Caution

After transport at temperatures below 0 °C, the device should be allowed to accommodate to the normal ambient conditions for 12 hours before unpacking.

7 Disposal

At the end of its service life or when its performance deteriorates, the device should be disposed of in compliance with the relevant applicable, local regulations for collection, storage and disposal of hospital waste.



Dispose of the packaging material according to the local guidelines and the disposal guidelines valid in your facility.



For countries covered by Directive 2002/96/EC (WEEE):
The device is not intended for household use and is not subject to disposal with standard electrical and electronic equipment.

For detailed information contact your local health or environmental authorities or your waste management company.

Prior to disposal, the device must be cleaned and disinfected as described in chapter 5.

8.1 Maintenance and repair

8.1.1 Device maintenance

For consistent measuring accuracy, check the measuring accuracy every six months.

When the device is removed from service and stored temporarily, its functionality should be checked every 12 months.

The device does not require routine calibration.

8.1.2 Repair

If a problem exists that can only be remedied by disassembling the electronic components, the device must be sent to an authorized service centre where repairs will be carried out by specialized technicians and with the appropriate equipment.

9 Technical data

Technical data

Sensor type	CO ₂ mainstream sensor
Functional principle	Non-dispersive infrared sensor (NDIR)
Initialization time	20 s (at an ambient temperature of 25 °C)
CO ₂ measuring range	0 – 20 vol% (0 – 150 mmHg)
CO ₂ measuring accuracy	±(0.2 vol% + 2 % of reading)* or ±(1.5 mmHg + 2 % of reading)*
CO ₂ measurement resolution	0.1 vol% or 0.1 mmHg
Response time	approx. 10 ms
Respiratory rate	0 – 200 breaths per minute
Accuracy of the respiratory rate measurement	±1 breath
Calibration	No user calibration required
Airway adapter	for adults / children (reusable), for children / neonates (reusable) Material: polysulphone Dead space volume: <5 ml (adult/pediatric), <1 ml (pediatric/neonate) Sterilization: ethylene oxide/autoclaving up to 100 times Compliance with ISO 5356-1:2015
Compensation	Atmospheric pressure: 390 – 900 mmHg Adjustable compensation for O ₂ , N ₂ O and anaesthetic gas

Electrotechnical data

Connector	RS232 4-pin Lemo Redel
Power	Voltage: 5.0 V ± 5% Power consumption: 1.3 W; less than 2 W during warm-up

Operating conditions

Ambient temperature	10 – 35 °C
Relative humidity	10 – 90% (at ambient temperature of 25 °C)

Storage conditions

Ambient temperature	5 – 40 °C
Relative humidity	<80 % (at ambient temperature of 25 °C)
Atmospheric pressure	390 – 900 mmHg

Transport conditions

Ambient temperature	-50 – 50 °C
Relative humidity	<80 % (at ambient temperature of 25 °C)

Standards compliance

- Safety: the device complies with IEC 60601-1, ISO 80601-2-55.
- Electromagnetic compatibility (EMC): the device meets the requirements of IEC 60601-1-2. The device is intended for use in the electromagnetic environment specified in chapter 10.

Remark

The following factors may impair the CO₂ measuring accuracy:

- mechanical damage of the device
- cyclical pressure peaks of up to 10 kPa (100 cmH₂O)
- high gas humidity or condensate
- leakage or internal venting of the sampled gas

Remark

The respiratory rate (RR) has no influence on the measuring accuracy of the CO₂ concentration within the specified RR measuring range and at an I:E ratio of 1:1.

Remark

There is no drift in the CO₂ measuring accuracy for at least 6 hours.

10 Guidance and manufacturer's declaration

Electromagnetic environment:

Refer to the appropriate chapter in the instructions for use of the connected intensive care ventilator.

Electromagnetic emissions

Emission tests	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11:2009	Group I	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic device.
RF emissions CISPR 11:2009	Class A	The device can be used in industrial areas and hospitals (CISPR 11 class A). If used in a residential environment (for which CISPR 11 class B is normally required), this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.
Harmonic emissions IEC 61000-3-2:2005	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3:95 +A1:2001	Complies	

Electromagnetic immunity:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2:2008	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4:2012	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	The mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5:2005	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	The mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:2004	$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 1 cycle $70\% U_T$ (30 % dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 s	$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 1 cycle $70\% U_T$ (30 % dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 s	The mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8:2009	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test levels.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6:2013	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3:2008	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d = 1.2\sqrt{P}$ (80 MHz to 800 MHz) $d = 2.3\sqrt{P}$ (800 MHz to 2.7 GHz), where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and dis the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a) should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.

If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

(b) Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, W	Separation distance according to frequency of transmitter, m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.7\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance D in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Instructions for Use Supplement B – CO₂ Sensor LeoCap

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Multi-Gas Sensor

LeoLyzer

Instructions for Use
Supplement C

The device operates according to the accompanying documentation and the equipment labelling if used 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.

0 Contents

1	General notes	5
1.1	About this manual	5
2	Use	5
2.1	Intended use	5
2.2	Scope of delivery	6
2.3	Illustrations	6
2.4	Theory of operation	7
3	General safety instructions	8
3.1	Safety information	9
3.2	Symbols on the device and on the packaging	12
3.3	Colour of the indicator lights and its meaning	13
4	Operation	13
4.1	Installation	13
4.2	Connecting the device	14
4.3	Sample gas outlet	15
4.4	Multi-gas measurement	15
4.5	Checking measurements	15
4.6	Functional description of the device	15
4.7	Zero adjustment	16
4.8	Removing the device from the patient	16
4.9	Emptying the water trap	16
4.10	Checks before and after use	16
4.11	Troubleshooting	17
5	Disinfection	17
5.1	Cleaning and disinfection of the device	17
5.2	Recommended cleaning agents and disinfectants	18
5.3	Cleaning and disinfection procedure	18

6	Storage and transport	19
7	Disposal	19
8	Maintenance and repair	21
8.1	Device maintenance	21
8.1.1	Maintenance schedule	21
8.1.2	Replacing the water trap	21
8.1.3	Replacing the rubber O-rings	21
8.2	Repair	22
9	Technical data	22
10	Guidance and manufacturer's declaration	24

I General notes

I.1 About this manual

These instructions for use describe the intended use and the operation of the following product:

Multi-gas sensor LeoLyzer

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

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

2 Use

2.1 Intended use

The LeoLyzer multi-gas sensor (hereinafter referred to as “device”) is used for non-invasive measurement of the following gas concentrations:

Inspiration:

- CO₂
- Isoflurane
- Sevoflurane

Expiration:

- CO₂
- Isoflurane
- Sevoflurane

The LeoLyzer multi-gas sensor is designed for use with medical devices for respiratory care, intensive care and patient monitoring.

The device is suitable for all patient categories.

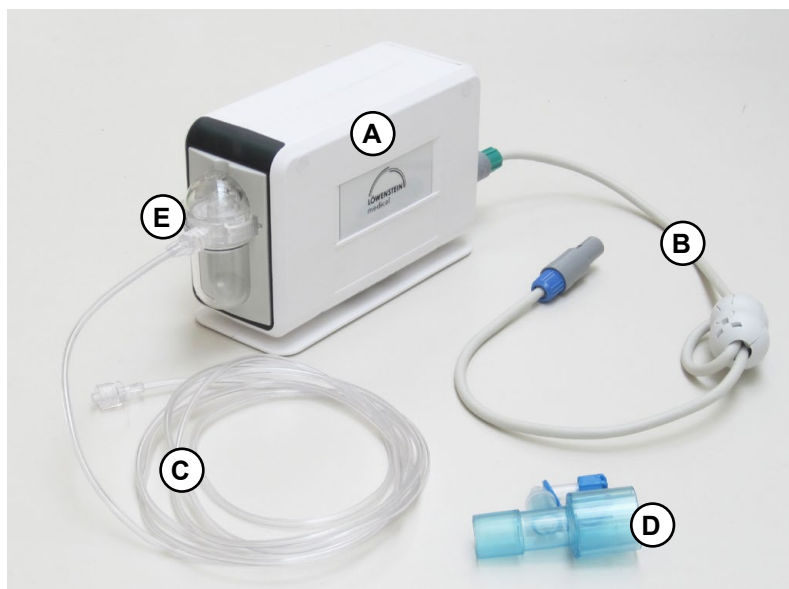
The device is only intended for use with the intensive care ventilators of the elisa family (elisa 300 – elisa 800VIT) (hereinafter referred to as “intensive care ventilator”).

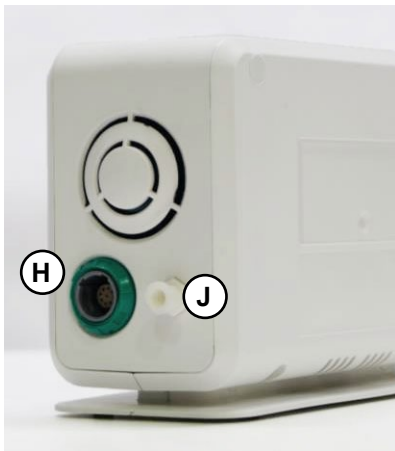
2.2 Scope of delivery

Content	
A	Multi-gas sensor Leolyzer
B	Connecting cable
C	Sampling line
D	Airway adapter
E	Water trap

2.3 Illustrations

Device components



Front view		
F G	O-rings LED display	
Rear view		
H J	Interface cable connector Sample gas outlet	

2.4 Theory of operation

The device allows the continuous measurement of CO₂, isoflurane and sevoflurane gas concentrations in the patient's respiratory air flow by infrared spectroscopy.

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 CO₂ and anaesthetic gas is calculated from the partial pressure at atmospheric pressure conditions.

The device is connected to the breathing circuit using the airway adapter and the sampling line.

An infrared light source and a photo sensor are integrated in the device. The gas mixture to be analysed is conducted through a measuring cell. The light emitted by the infrared light source reaches the photo sensor after passing through the measuring cell. Thus, the device measures the degree of absorption of infrared light during its passage through the gas stream.

3 General safety instructions

These instructions for use are an integral part of the delivery. When the device changes ownership, the manual must also be handed over. Information contained in this document can be changed without notice.

The device 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.

Before working with this device, carefully read these instructions for use as well as the Basic Instructions for Use and Supplement A of the intensive care ventilator used. Improper use of the device can cause malfunction, loss of performance and it can create a hazard for the patient.

If malfunctions or unstable operation of the device occur, refer to the troubleshooting tips in section 4.11.

The following signs and symbols are used to identify important information in 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.

Reusable consumables have a limited service life. Various operating conditions as well as cleaning, disinfection and sterilization procedures can adversely affect the material and reduce the service life. If signs of deterioration (cracks, deformation, discolouration, paint peeling off, etc.) are detected, you need to replace the consumables.

3.1 Safety information



Warning

If an emergency occurs during operation (fire, short circuit, etc.), immediately disconnect the device from the patient and continue monitoring with another device.



Warning

Use the device only with the specified intensive care ventilators. Using devices not explicitly mentioned may cause skin burns.



Warning

Do not pull or bend the interface cable of the device. Failure to follow these instructions may cause cable discontinuity, short circuits, failed measurements and skin burns on the patient due to elevated device temperatures resulting from the short circuit in the cable. Replace defective devices with new ones.



Warning

Do not let the patient bite on the interface cable or sampling line. This may damage to the device and harm the patient.



Warning

Keep magnetic objects away from the device. Magnetic objects may distort the waveform and cause incorrect readings.



Warning

The device is not defibrillation-proof. It is mandatory to remove the device from the patient during defibrillation.



Warning

Empty the water trap reservoir when it is half full. It should never be filled to the marked maximum fill level. Remember that liquid getting into the measuring path of the device will lead to malfunction.

**Warning**

Do not carry the device with a full water trap while in use, and do not remove the water trap while the device is operating to prevent liquid getting into the measuring path.

**Warning**

Do not turn the device even with a partially filled water trap. This can cause device malfunction.

**Warning**

Do not use the device in the vicinity of nuclear magnetic resonance equipment.

**Warning**

Do not blow into the sampling line while it is connected to the device. The high pressure may damage the components of the pneumatic circuit. Disconnect the sampling line before flushing.

**Warning**

Do not allow liquid to enter into the housing of the device during operation.

**Caution**

Do not establish a diagnosis solely based on the data acquired with the device. A physician who understands the features, limitations and characteristics of the device should provide the overall assessment.

**Caution**

The device functions may be affected by equipment operated in the vicinity. Before use, check that the device operates normally when used in the vicinity of other equipment.

**Caution**

The device cannot be used with high-frequency electrosurgical devices.

**Caution**

Keep magnetic objects away from the device. Magnetic objects may distort the waveform and cause incorrect readings.



Measurements may not be performed correctly until several minutes after connection of the device because the temperature of the device is not yet stable.



Use only the specified airway adapter. Otherwise, the maximum performance cannot be guaranteed due to larger dead space, leakage or an unsafe (electrical) connection, etc.



The measured value may be incorrect when the ambient temperature changes significantly during operation.



The gas mixture must be free from nitrous oxide.



It is strongly recommended to operate the device in an electromagnetic environment as specified in chapter 10. Otherwise, the maximum performance cannot be guaranteed due to electromagnetic disturbances.



Certain gases in the mixture can lead to measurement errors. See chapter 10.



Recommended separation distances between portable and mobile radio frequency (RF) communications equipment and the device are stated in chapter 10.



After each use, we recommended disconnecting the sampling line from the device and leaving the device on for another 10 to 30 minutes to allow the internal pneumatic path to dry. Do not switch off the intensive care ventilator or deactivate the multi-gas measurement function during this time.



Device, airway adapter, sampling line, water trap and packaging are not made with natural rubber latex.

Only healthcare personnel who have read these instructions for use and understand its content are allowed to use the device.

3.2 Symbols on the device and on the packaging

	Attention, read accompanying documents!
	Sample gas
	Serial number
REF	Part number
	Medical Device
	Unique Device Identification
	Transport and storage at temperatures from +5 °C to +40 °C
	This side up
	Keep dry
	Fragile, handle with care
	Manufacturer
	Date of manufacture
CE 0123	The device fulfils the requirements of Directive 93/42/EEC concerning medical devices and of Regulation (EU) 2017/745, provided it is operated according to the instructions for use. 0123 is the notified body.
IP22	Protection class according to DIN EN 60529
	The device must be disposed of in compliance with Directive 2002/96/EC

3.3 Colour of the indicator lights and its meaning

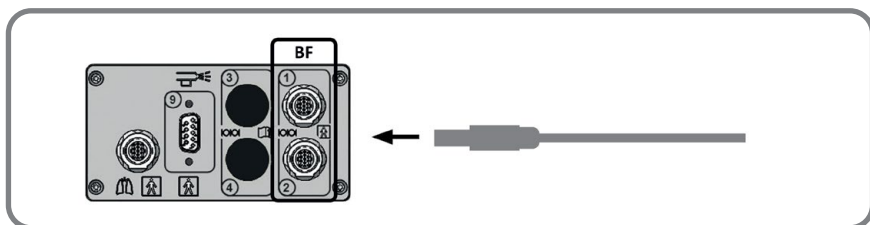
Colour	Meaning
Red	Device defect
Green flashing	The device is preparing for a measurement (warming up, calibration)
Green	Ready for use
Blue	The device is monitoring the respiratory rate and the CO ₂ concentration. The higher the CO ₂ concentration in the expired air, the brighter the indicator shines.

4 Operation

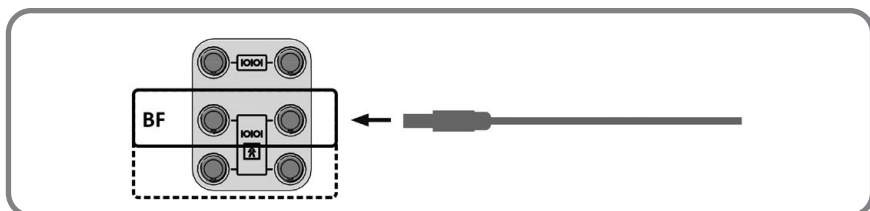
4.1 Installation

Using the connection cable, connect the device to the configured BF interface at the back of the intensive care ventilator.

elisa 600 elisa 800 – interfaces on the back



elisa 300 elisa 500 – interfaces on the back



On the screen of the intensive care ventilator, select the “Status” tab and go the second view which shows the current configuration of the interfaces.



Warning

Always connect type BF equipment to the intensive care ventilator before connecting it to the patient.



Warning

Be sure to connect the equipment only to the interfaces on the back of the intensive care ventilator intended for the respective purposes.

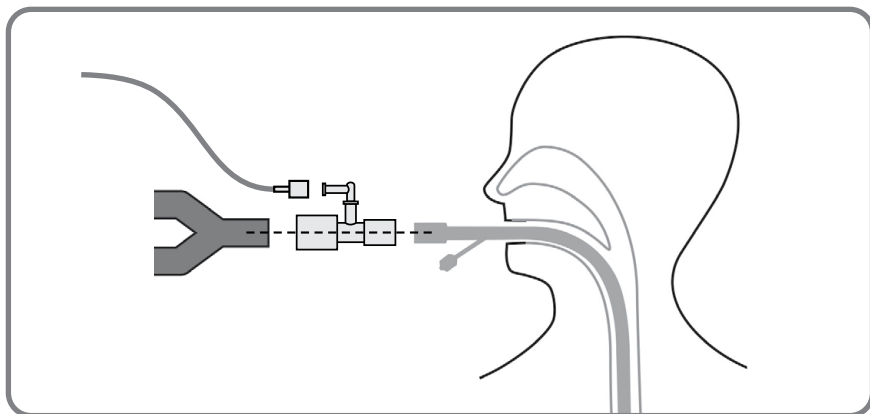
4.2 Connecting the device

- Check the sampling line. The sampling line must be dry and clean.
- Install the water trap: it must click into place.
- Insert the airway adapter between the Y-piece and the tube of the breathing circuit. (See illustration).
- 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.



Caution

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.



Follow the instructions for use of the respective intensive care ventilator.

4.3 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.

4.4 Multi-gas measurement

For details of the multi-gas measurement procedure, please refer to the appropriate chapter in the instructions for use of the intensive care ventilator used.

4.5 Checking measurements

Check that the CO_2 , sevoflurane and isoflurane data are displayed correctly on the connected intensive care ventilator. For further information, please refer to the instructions for use of the intensive care ventilator.

Especially when an uncuffed tracheal tube is used, the partial pressure curves of CO_2 , sevoflurane and isoflurane may be inaccurate due to leakage at the tracheal tube.

4.6 Functional description of the device

The measured values of etCO_2 , etISO , etSEV , inCO_2 , inISO , inSEV and respiratory rate, the capnogram and anaesthetic gas curves are displayed on the screen of the intensive care ventilator. For further information, please refer to the instructions for use of the intensive care ventilator.

Depending on the configuration of the intensive care ventilator, the CO_2 , sevoflurane or isoflurane concentration is displayed as a partial pressure (mmHg or kPa) and (or) as a percentage concentration (%).

If normal operation is not possible, the device will be disabled and an error message will be displayed on the intensive care ventilator. For further information about system messages, please refer to the instructions for use of the intensive care ventilator.

4.7 Zero adjustment

The device has an automatic zero calibration function. In the first 10 minutes after the device is switched on, calibrations are carried out every 90 seconds. After this time, zero calibration occurs if the device detects the need for it. In the first half hour after being switched on, the device automatically checks every 5 minutes whether a zero adjustment is required; afterwards, the interval is 15 minutes. Calibration takes less than 5 seconds.

Manual zero calibrations should be performed when conditions change significantly between automatic zero calibrations (pressure, temperature, etc.) and if the measured values do not seem plausible.

4.8 Removing the device from the patient



Caution

When removing the device, do not hold the interface cable or the sampling line. The interface cable and the sampling line may be damaged when subjected to excessive force.

Hold the breathing circuit firmly with one hand and disconnect the sampling line by turning it counter-clockwise with the other hand. If necessary, close the valve of the airway adapter.

4.9 Emptying the water trap

If you need to empty the water trap, press the two tabs on the sides of the water trap and pull it carefully forward, away from the device.



Warning

Empty the water trap when it is half full. It should never be filled to the marked maximum fill level. Please note that liquid getting into the measuring path of the device will lead to malfunction.

Open the water trap by pulling the top straight upward. Thoroughly rinse and dry the reservoir before putting the top back into place.

Attach the water trap to the device and push in until you hear the tabs lock into place.

4.10 Checks before and after use

After unpacking a new device, handle it with care because static electricity, water or chemical solutions may cause damage. Check the cleanliness of the device, the surface of the reusable water trap, the sampling line and the airway adapter.

If necessary clean and disinfect the device and reprocess the water trap (see chapter 5).

4.1.1 Troubleshooting

Problem	Possible causes	Remedy
Measurement is not performed	Unsuitable electromagnetic environment	Turn off the devices that cause strong electromagnetic interference
	BF interface was not configured	On the screen of the intensive care ventilator, select the "Status" tab and go the second view which shows the current configuration of the BF interfaces. If in doubt, contact your service technician.
The measured value is inaccurate	Rapid temperature change	Measurements may be incorrect when rapid temperature changes occur
	Water has accumulated in the water trap	Empty the water trap

5 Disinfection

5.1 Cleaning and disinfection of the device

The water trap and the sampling line must be regularly checked for contamination, defects and soiling. They must be replaced when necessary.

Applicable hygiene guidelines valid in the respective countries and facilities shall be observed.



It is mandatory to disconnect the device from the intensive care ventilator before disinfection.



Do not allow liquid to enter into the housing of the device during disinfection.

**Warning**

Do not reuse disposable accessories that are marked “single use”.

**Caution**

Do not sterilize.

**Caution**

Do not disinfect the cable by immersion in disinfecting solution.

**Caution**

Do not allow the pins of the device connector to become wet. This may cause a device failure. The interface cable may be damaged.

**Caution**

When disinfecting the interface cable by pulling it through a swab or cloth moistened with disinfectant, do not apply excess tension to the cable.

**Caution**

The device shall be cleaned and disinfected after each use, before commissioning, maintenance or returning it to the manufacturer for repair.

5.2 Recommended cleaning agents and disinfectants

- Hydrogen peroxide solution (3 %) with 0.5% solution of ionic, surface-active substances
- Alcohol solution (ethyl or isopropyl alcohol) 70%
- Chlorhexidine gluconate solution (0.5%)
- It is possible to use other approved cleaning agents and disinfectants with similar active ingredients in the right concentration that are commonly used in hospitals.

5.3 Cleaning and disinfection procedure

- Disconnect the interface cable of the device from the intensive care ventilator; disconnect the airway adapter from the breathing circuit, disconnect the water trap and the sampling line with the airway adapter from the device.
- Clean and disinfect the device housing by wiping it down with a gauze swab or

soft cloth moistened with a cleaning agent or disinfectant mentioned above. Squeeze the cloth before wiping down the device to prevent liquid from entering the device. Use only distilled water to prepare the cleaning and disinfection solution. Follow the instructions for use from the manufacturer's of the cleaning agents and disinfectants.

- Disinfect the interface cable by pulling it through a swab moistened with disinfectant.
- The water trap is not intended for sterilization. Clean the water trap only with a mild detergent or no detergent at all. Thoroughly rinse and dry the reservoir before use.

6 Storage and transport

Store the device in its original packaging in a closed, ventilated room at an air temperature between 5 °C and 40 °C and a maximum relative humidity of 80% at a temperature of 25 °C.

In case of temporary withdrawal from the packaging, store the device at an ambient temperature of 5 °C to 40 °C and a maximum relative humidity of 80% (at 25 °C). Devices should be stored on a rack in a single line. Do not store the device in places where acid vapours or other harmful vapours may occur.

In case of long-term storage after use, the device should be placed in a polyethylene case and, if possible, packaged in the original packaging to protect it from possible mechanical damage.

The device may be transported in the original packing without any limitation of distance, according to the applicable transportation regulations.

The temperature range for transport is from -50 °C to +50 °C



Caution

After transport at temperatures below 0 °C, the device should be allowed to accommodate to the normal ambient conditions for 12 hours before unpacking.

7 Disposal



Caution

Dispose of the packaging material of accessories and disposable items according to the local guidelines and the guidelines valid in your facility.



After use, disposable items must be disposed of according to the guidelines valid in the medical facility.



Dispose of accumulated fluids and sample gas according to the local guidelines and the guidelines valid in your facility.

At the end of its service life or when its performance deteriorates, the device should be disposed of in compliance with the relevant applicable, local regulations for collection, storage and disposal of hospital waste.



For countries covered by Directive 2002/96/EC (WEEE):
The device is not intended for household use and is not subject to disposal with standard electrical and electronic equipment.

For detailed information contact your local health or environmental authorities or your waste management company.
Prior to disposal, the device must be cleaned and disinfected as described in chapter 5.

8 Maintenance and repair

8.1 Device maintenance



Caution

Before performing any maintenance, ensure that the device and its accessories are properly disinfected.

To ensure the proper functioning of the device during its service life, perform regular maintenance.

The user of the device is responsible for proper maintenance. Maintenance work is not covered by the warranty of the manufacturer or supplier.

Maintenance work does not require special skills or knowledge; it is not necessary to disassemble and reassemble the electronic components for maintenance.

Even if the device is not used or temporarily stored, it must be checked for proper functioning at least once per year.

8.1.1 Maintenance schedule

No.	Task	Interval	Description
1.	Replace water trap	When necessary	Section 8.1.2
2.	Replace rubber O-rings	Annually	Section 8.1.3

8.1.2 Replacing the water trap

- Disconnect the interface cable of the device from the intensive care ventilator.
- Disconnect the airway adapter from the breathing circuit.
- Disconnect the sampling line from the water trap.
- Remove the water trap by pressing the two tabs on the sides of the water trap; then pull it carefully forward, away from the device.
- Install a new water trap: it must click into place.

8.1.3 Replacing the rubber O-rings

- Use tweezers to remove the rubber O-rings from the fittings.
- Again using tweezers, stretch the new rubber O-ring and place it on the fitting. Apply the second rubber O-ring in the same way.
- Rubber O-rings are usually easy to stretch without tearing.

8.2 Repair

If a problem exists that can only be remedied by disassembling the electronic components, the device must be sent to an authorized service centre where repairs will be carried out by specialized technicians and with the appropriate equipment.



Caution

Before sending the device to the service centre, check that it was properly disinfected.

9 Technical data

General data

Sensor type	Sidestream sensor
Functional principle	Infrared spectroscopy
Dimensions	150 x 62 x 96 mm (without cable)
Weight	400 g

Measurement

Measured gases	only CO ₂ CO ₂ and ISO CO ₂ and SEV
Initialization time	Accuracy according to ISO standard within 45 s Full accuracy within 10 min CO ₂ channel within 10 s
CO ₂ measuring range	CO ₂ 0 – 15 vol% or kPa (resolution 0.1) ISO 0 – 7 vol% (resolution 0.1) SEV 0 – 9.9 vol% (resolution 0.1)
CO ₂ measuring accuracy	CO ₂ ± (0.43 vol% + 8 % of reading) ISO ± (0.2 vol% + 15 % of reading) SEV ± (0.2 vol% + 15 % of reading)
Drift measurement: CO ₂ concentration	± (0.43 vol% + 8 % of reading)
Anaesthetic gas concentration	± (0.2 vol% + 15 % of reading)
Measured gas flow	50 – 250 mL/min

Response time (sampling line 200 cm, sample flow rate 250 ml/min)	2.5 s (may vary with sample flow rate)
Rise time	0.5 s
Respiratory rate	0 – 160 breaths per minute
Acceptable absolute accuracy of atmos- pheric pressure	± 2 mmHg
Calibration	No user calibration required

Electrotechnical data

Connector	4-pin Lemo Redel
Power consumption	2.5 W, < 5 W during warm-up
Power	5.0 V ± 5%
Power	5.0 V ± 5%

Operating conditions

Ambient temperature	10 – 35 °C
Relative humidity	10 – 90% (at ambient temperature of 25 °C)

Storage conditions

Ambient temperature	5 – 40 °C
Relative humidity	<80% (at ambient temperature of 25 °C)

Transportation conditions

Ambient temperature	(-50) – 50 °C
Relative humidity	<80% (at ambient temperature of 25 °C)

Data output

Interface	Interface: RS-232 Connector: 4-pin (LEMO-REDEL)
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Standards compliance

- Safety: the device complies with IEC 60601-1, ISO 80601-2-55.
- Electromagnetic compatibility (EMC): the device meets the requirements of IEC 60601-1-2. The device is intended for use in the electromagnetic environment specified in chapter 10.

Remark

The following factors may impair the CO₂, ISO and SEV measuring accuracy:

- mechanical damage of the device
- cyclical pressure peaks of up to 10 kPa (100 cmH₂O)
- leakage or internal venting of the sampled gas

Remark

The respiratory rate (RR) has no influence on the measuring accuracy of the CO₂, ISO and SEV concentration within the specified RR measuring range and at an I:E ratio of 1:1.

Remark

There is no drift in the CO₂, ISO and SEV measuring accuracy for at least 6 hours.

10 Guidance and manufacturer's declaration

Electromagnetic environment:

Refer to the appropriate chapter in the instructions for use of the connected intensive care ventilator.

Electromagnetic emissions

Emission tests	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11:2009	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic device.
RF emissions CISPR 11:2009	Class A	The device can be used in industrial areas and hospitals (CISPR 11 class A). If used in a residential environment (for which CISPR 11 class B is normally required), this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.
Harmonic emissions IEC 61000-3-2:2005	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3:95 +A1:2001	Complies	

Electromagnetic immunity:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2:2008	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8:2009	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test levels.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3:2008	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2\sqrt{P}$ (80 MHz to 800 MHz) $d = 2.3\sqrt{P}$ (800 MHz to 2.7 GHz) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a) should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.

If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

(b) Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, W	Separation distance according to frequency of transmitter, m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance D in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Interference from gas and vapour

Influence of interfering gas on the measured CO₂ value

Gas	Concentration (%)	Accuracy (%abs)
Sevoflurane	≤5	0.1
Isoflurane	≤5	0.1
Xenon	<100	0.1
Helium	<50	0.1
Ethanol	<0.1	0
Aceton	<1	0.1
Methane	<1	0.1

Influence of interfering gas on the value measured by the device

Gas	Concentration (%)	Quantitative effect (%abs)*	
		CO ₂	Anaesthetic gas
CO ₂	≤10	/	0.1
Anaesthetic gas	within the measurement limits	0	/
Xenon	<100%	0.1	0
Helium	<50%	0.1	
Ethanol	<0.1%	0	
Aceton	<1%	0.1	
Methane	<1%	0.1	

* – The maximum quantitative effect of each gas at concentrations within the specified error ranges for each gas. The total effect of all interfering substances usually does not exceed 5% of the gas concentration.

CE 0123

Instructions for Use Supplement C – Multi-Gas Sensor LeoLyzer

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Pulse Oximetry and LeoClac

Instructions for Use
Supplement D

The device operates according to the accompanying documentation and the equipment labelling if used 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.

Contents

1	About this manual	4
2	XPOD SpO ₂ sensor adapter	4
2.1	Intended use	4
2.2	Areas of application	5
2.3	General safety instructions	5
2.3.1	Safety information	5
2.4	Connection to the devices elisa 600 – elisa 800 (VIT)	6
2.5	Cleaning	7
2.6	Disposal	8
3	Nonin finger sensor	8
3.1	Intended use	8
3.2	Areas of application	8
3.3	General safety instructions	8
3.3.1	Safety information	9
3.4	Connection to the devices elisa 600 – elisa 800 (VIT)	9
3.5	Cleaning	10
3.6	Disposal	10
4	Pulse oximetry function	10
4.1	Patient safety	11
4.2	Prerequisites	11
4.3	Function	12
5	LeoClac (Closed-Loop Automatic Oxygen Control)	12
5.1	Prerequisites	12
5.2	Safety instructions	13
5.3	Function	13
5.4	Application	14

I About this manual

These instructions for use describe the **pulse oximetry** and the **LeoClac** functions.

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

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

If you intend to use the pulse oximetry function of intensive care ventilators elisa 600 - elisa 800 (VIT), you will need the **XPOD SpO₂ sensor adapter** and a **Nonin finger sensor**.

The **LeoClac** function can only be employed in combination with **pulse oximetry** (SpO₂ measurement).

2 XPOD SpO₂ sensor adapter

2.1 Intended use

The XPOD SpO₂ sensor adapter is intended for non-invasive spot-checking and/or continuous monitoring of the oxygen saturation of arterial blood (oximetry) and the heart rate (pulse) of adult and paediatric patients using the Nonin finger sensors.

Use only the Nonin SpO₂ finger sensors with the XPOD SpO₂ sensor adapter (see separate list of accessories for the intensive care ventilator).



Warning

The XPOD SpO₂ sensor adapter may only be operated in conjunction with the intensive care ventilators elisa 600 – elisa 800 (VIT).

Remark

Pulse oximetry is only available for the patient categories “Adults” and “Children”.

2.2 Areas of application



- Do not use during magnetic resonance imaging or in an MR environment.
- Do not use in hyperbaric oxygen therapy chambers.
- Do not use in an explosive atmosphere or in the presence of flammable anaesthetics or gases.
- During whole-body irradiation, remove from irradiated area.
- This device is not defibrillation-proof as per IEC 60601-1.

2.3 General safety instructions

The device 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.

Before working with the XPOD SpO₂ sensor adapter, carefully read these instructions for use, the instructions for use supplied with the Nonin finger sensor, as well as the Basic Instructions for Use and Supplement A of the intensive care ventilator used. Improper use of the sensor can cause malfunction, loss of performance and it can create a hazard for the patient.

The following signs and symbols are used to identify important information in these instructions for use:



“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.

2.3.1 Safety information



Always inspect the device before use. Do not use a damaged device.



Ensure that no other devices (e.g., a blood pressure cuff) hinder the measurements. Otherwise, proper monitoring cannot be guaranteed.

**Warning**

Carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.

**Caution**

A functional tester cannot be used to assess the accuracy of an SpO₂ finger sensor.

**Warning**

Always inspect the device before use. Do not use a damaged device.

Remark

For more information about required safety and regulatory requirements for pulse oximeters, refer to ISO 80601-2-61 and IEC 60601-1.

**Warning**

Use only the Nonin finger sensors (size L, M or S) with the XPOD SpO₂ sensor adapter (see separate list of accessories for the intensive care ventilator).

Remark

Additional safety information can be found in the documents provided with each SpO₂ finger sensor.

2.4 Connection to the devices elisa 600 – elisa 800 (VIT)

Remark

The XPOD SpO₂ sensor adapter can be used within the patient environment.

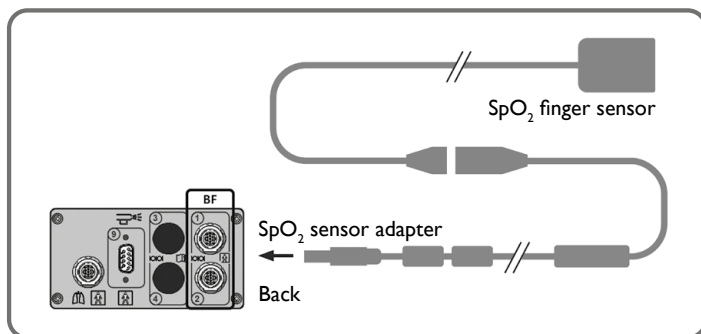
**Warning**

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

**Warning**

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

Connect the XPOD SpO₂ sensor adapter to the configured BF interface on the back of the ventilator.



Select the finger sensor size suitable for the patient. Connect the SpO₂ finger sensor to the XPOD SpO₂ sensor adapter.

The Nonin SpO₂ finger sensor is available in 3 sizes: L, M and S (see chapter 3 and the separate list of accessories for the intensive care ventilator).

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

2.5 Cleaning

Wipe the finger sensor clean with a soft cloth. Use one of the recommended disinfectants for disinfection:

- Chloroxylenol 3.0%
- Disinfectant wipes (Lysol)

Dry the finger sensor with a soft cloth or allow to air dry.



Do not sterilize, autoclave or immerse the device in liquid of any kind. Do not pour or spray any liquids onto the device.



Do not use caustic or abrasive cleaning agents on the device. Do not use any cleaning solutions other than those recommended here, as permanent damage could result.



Make sure that the XPOD SpO₂ sensor adapter is completely dry before application.

2.6 Disposal

In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste.

Observe the local regulations and recycling instructions regarding disposal and recycling of the XPOD SpO₂ sensor adapter.

This device contains WEEE materials; please contact your system manufacturer regarding take-back or recycling of the device.

3 Nonin finger sensor

3.1 Intended use

The soft, reusable sensors from Nonin are intended for non-invasive spot-checking and/or continuous monitoring of adult and paediatric patients who are well or poorly perfused.

They are intended for use in environments including operating room, surgical recovery, critical care, emergency room, long-term care, home use, and mobile environments.

The finger sensors are available in sizes L, M and S.

3.2 Areas of application



Warning

- Do not use during magnetic resonance imaging or in an MR environment.
- The sensors are not defibrillation-proof as per IEC 60601-1.

3.3 General safety instructions

The device 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.

Before working with the Nonin finger sensor, carefully read these instructions for use, the instructions for use supplied with the Nonin finger sensor, as well as the Basic Instructions for Use and Supplement A of the intensive care ventilator used. Improper use of the sensor can cause malfunction, loss of performance and it can create a hazard for the patient.

The following signs and symbols are used to identify important information in these 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.

3.3.1 Safety information



Warning

Always inspect the finger sensor before use. Do not use a damaged finger sensor.



Warning

Ensure that no other devices (e.g., a blood pressure cuff) hinder the measurements. Otherwise, proper monitoring cannot be guaranteed.



Warning

Use only the XPOD SpO₂ sensor adapter for connection to the intensive care ventilator (see separate list of accessories for the intensive care ventilator).



Warning

Carefully route patient cables and connections to reduce the possibility of entanglement or strangulation.

3.4 Connection to the devices elisa 600 – elisa 800 (VIT)

Remark

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

Select the finger sensor size suitable for the patient:

Finger diameter	Sensor size
12.5 to 25.5 mm	L
10 to 19 mm	M
7.5 to 12.5 mm	S

Use the XPOD SpO₂ sensor adapter to connect the finger sensor to the intensive care ventilator (see section 2.4).

3.5 Cleaning

Wipe the finger sensor clean with a soft cloth. Use one of the recommended disinfectants for disinfection:

- Chloroxylenol 3.0%
- Disinfectant wipes (Lysol)

Dry the finger sensor with a soft cloth or allow to air dry.



Warning

Do not sterilize, autoclave or immerse the device in liquid of any kind. Do not pour or spray any liquids onto the device.



Warning

Do not use caustic or abrasive cleaning agents on the device. Do not use any cleaning solutions other than those recommended here, as permanent damage could result.



Warning

Make sure that the finger sensor is completely dry before application.

3.6 Disposal

In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste.

Observe the local regulations and recycling instructions regarding disposal and recycling of the SpO₂ finger sensor.

This device contains WEEE materials; please contact your system manufacturer regarding take-back or recycling of the device.

4 Pulse oximetry function

Pulse oximetry is a non-invasive method to determine arterial oxygen saturation (oximetry) and heart rate (pulse).

4.1 Patient safety



The pulse oximetry function integrated in the elisa ventilator provides additional information for the assessment of the ventilated patient. This information is not suitable as the sole basis for establishing a diagnosis or making a therapeutic decision. The overall assessment with respect to diagnosis and therapy is the responsibility of the physician who is familiar with the possibilities and limitations of pulse oximetry and can interpret the results in the context of the clinical situation (e.g. blood gas analysis data, symptoms).



If the measured values seem implausible, check the patient's vital signs. Rule out potential causes such as poor peripheral perfusion, conditions of shock or hypothermia, nail polish, carbon monoxide poisoning, contrast agent (e.g. methylene blue) or motion artefact.



Check the condition of the patient's skin at the application site of the SpO₂ finger sensor regularly. In the case of patients at risk of bedsores and with delicate skin that reacts to the increased temperature at the finger clip, the skin must be inspected for alterations, reddening, burns and necrosis at least every 4 to 6 hours. Change the site if any compromise in skin quality occurs.



The patient's skin pigmentation may affect the absorbed amount of light and, thus, the measured SpO₂ value.

4.2 Prerequisites

Prerequisites on the configuration level:

- Configure one of the BF interfaces for the SpO₂ sensor
- Configure the SpO₂ function
- Add the measured values (SpO₂ and HR) to the data table(s) if desired
- Add the display of the plethysmogram if desired

4.3 Function

- Use the XPOD SpO₂ sensor adapter to connect the SpO₂ sensor to the intensive care ventilator (see chapter 4)
- Apply the finger clip to the patient at a suitable site
- Select the SpO₂ function
- Set pulse wave averaging
- Adapt the SpO₂ and HR alarm limits to the clinical situation
- Start SpO₂ measurement (“On”).

Nebulizer	AnaConDa	Cuffscout	ASR	O2 Flush	Reference Loops	Hygiene	SpO2 Sensor	Leo Clac	Functions
SPO2	HR						Average SpO2 3 pulse wave	On	System
99	80							Off	←
%	/min								

Alarm limits

HR (pulse) max	Upper alarm limit for the measured heart rate
HR (pulse) min	Lower alarm limit for the measured heart rate
SpO ₂ max	Upper alarm limit for the measured SpO ₂ concentration
SpO ₂ min	Lower alarm limit for the measured SpO ₂ concentration

5 LeoClac (Closed-Loop Automatic Oxygen Control)

Prerequisite for the LeoClac function is the activated pulse oximetry function (see chapter 4).



Warning

The LeoClac function is only available for the patient category “Adults”.

5.1 Prerequisites

Further prerequisites on the configuration level:

- Select the LeoClac template
- Configure the LeoClac function

5.2 Safety instructions



Observe the instructions and warning of the pulse oximetry chapter. Do not employ the automatic closed-loop control function if the clinical situation of the ventilated patient suggests a reduced significance or accuracy of the SpO₂ measurement.



Activate the LeoClac function only when the patient condition warrants the continued acquisition of the SpO₂ signal. Assess potential contraindications such as restlessness or reactive psychosis of the patient.



When using the LeoClac function, the user is required to ensure the plausibility of the SpO₂ measurement by means of additional, independent means (e.g. additional SpO₂ monitoring with a vital signs monitor, regular blood gas analysis, ...).



Make sure that the SpO₂ measurement is unimpeded. Do not apply the sensor on the same arm used for non-invasive blood pressure measurement or IABP therapy.



LeoClac may only be used in patients with sufficient minimum ventilation.

5.3 Function

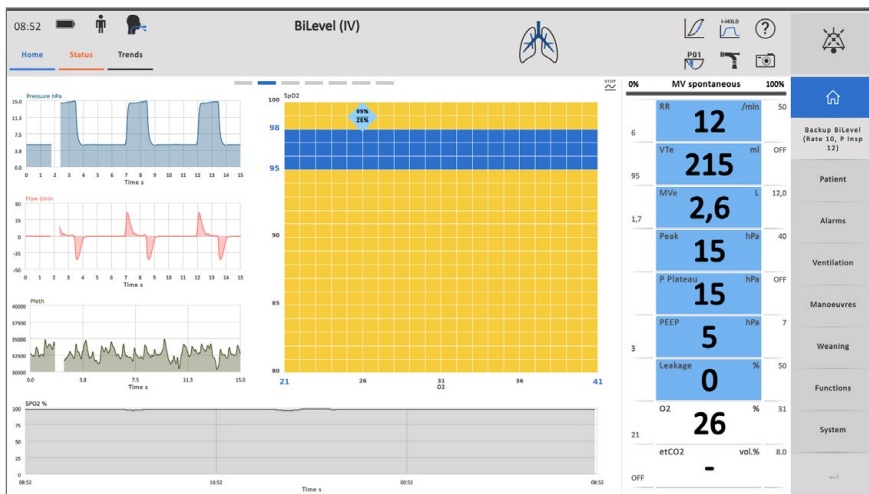
- Select and activate the SpO₂ function (see also chapter 5)
- Select the LeoClac function
- Enter the SpO₂ target range
- Adapt the alarm limits for “O₂ ctrl. min/max” to the clinical situation
- Adapt the alarm limits for “+SpO₂ ctrl. min/max” to the clinical situation
- Start the LeoClac function (“On”)

Nebulizer	AnaConDa	Cuffscout	ASR	O ₂ Flush	Reference Loops	Hygiene	SpO ₂ Sensor	Leo Clac	Functions
SP02	HR						Target SpO ₂ 94 - 97 %	On	System
98	72						Average SpO ₂ 3 pulse wave	Off	q-1
%	/min								

5.4 Application

Permanently adapting the inspired oxygen concentration to the patient requirements is of particular importance in ventilation medicine. To prevent conditions of hypoxia as well as hyperoxia, the user is normally guided by non-invasive pulse oximetry data and spot-check measurements of the gas exchange by BGA.

The LeoClac function assists clinical users in their routine tasks: they first define a range for the closed-loop control system regulating the inspiratory O_2 level, then LeoClac automatically controls this range and initiates the necessary adjustments. By specifying a target range, the user defines a window comprising the target range and the expanded control range. The user can view the status at any time with a cursor.



A special LeoClac algorithm adjusts the inspired oxygen concentration based on pulse oximetry and taking into account the following rules:

- Minor deviations from the defined SpO_2 target range are readjusted at fixed intervals by adapting the O_2 concentration in small steps.
- Major deviations from the defined SpO_2 target range are readjusted at fixed intervals by adapting the O_2 concentration in bigger steps.
- Conditions of hypoxia are prevented by a faster increase of the inspired oxygen concentration while a necessary decrease of the inspired oxygen concentration occurs with a delay.
- When the SpO_2 concentration is 10 to 20% below the target value, the O_2 concentration is immediately increased to 100%.

- When the SpO₂ signal is disturbed by low perfusion, artefacts or other problems, the LeoClac function stops immediately. The corresponding alarm enables the user to respond to the situation by analysing and resolving the problem. If necessary, the inspired oxygen concentration can be readjusted manually.



The user can define additional alarms for “O₂ ctrl. min/max” and is then alerted in case of major changes of the inspired oxygen concentration. The alarm limits refer to the inspired oxygen concentration defined in the set of parameters of the ventilation mode concerned.



Besides the absolute alarm limits for the SpO_2 value, the activated LeoClac function can provide the user with relevant information about impending major SpO_2 deviations when the alarm limits for “+ SpO_2 ctrl. min/max” are additionally defined.

Alarm limits

+ SpO_2 ctrl. max	Upper alarm limit referred to the parameter “Target SpO_2 ” (LeoClac)
– SpO_2 ctrl. min	Lower alarm limit referred to the parameter “Target SpO_2 ” (LeoClac)
O_2 ctrl. max	Upper O_2 alarm limit with LeoClac (absolute)
O_2 ctrl. min	Lower O_2 alarm limit with LeoClac (absolute)

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Instructions for Use Supplement D – Pulse Oximetry and LeoClac

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elisa 300
elisa 500
elisa 600
elisa 800
elisa 800 VIT

External Communication

Instructions for Use
Supplement E

0 Contents

I	General information	3
1.1	About this manual	3
1.2	General safety instructions	3
1.3	Schematic diagram elisa 600 – elisa 800 VIT	4
2	External communication interfaces with Salvia protocol	6
2.1	Introduction	6
2.2	Layout of the external communication interfaces	6
2.3	External medical equipment interface elisa@megs	9
2.4	Interface specification	10
2.4.1	Configuration of the external receiving interface	10
2.4.2	EC Interface SALVIA	10
2.4.3	EC Interface Philips	10
2.4.4	elisa@megs	10
2.5	Viewable information	11
2.5.1	Ventilation modes	11
2.5.2	Ventilation curves	11
2.5.3	Parameters	11
2.5.4	Alarms	11

I General information

I.1 About this manual

Reference

These instructions for use describe the external communication interfaces of the following products:

elisa 300 | intensive care ventilator
elisa 500 | intensive care ventilator
elisa 600 | intensive care ventilator
elisa 800 | intensive care ventilator
elisa 800VIT | intensive care ventilator

The present document “External Communication” is Supplement E to the Instructions for Use of the intensive care ventilators mentioned above.

For specific details of the devices elisa 300 – elisa 800VIT, please refer to the corresponding Basic Instructions for Use.

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

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

I.2 General safety instructions

Safe operation

In order to guarantee the safe operation, the system must only be used as described. Before putting the system into operation, users must familiarise themselves with these instructions for use. As a general rule, all instructions given in this manual and in the

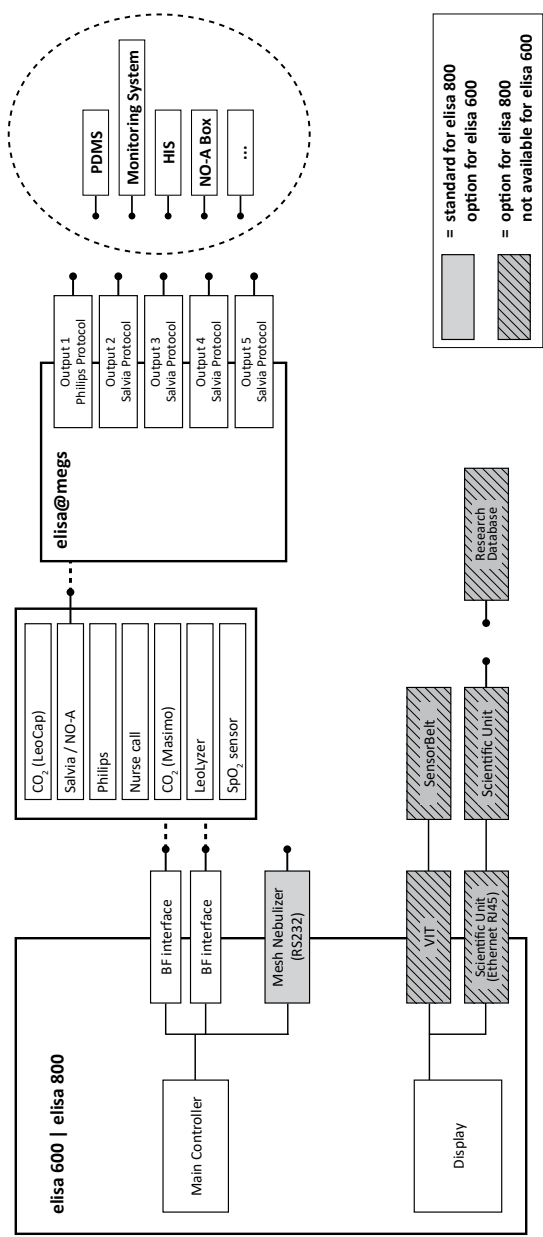
- Basic Instructions for Use elisa 600 / elisa 800
- Basic Instructions for Use elisa 300 / elisa 500

as well as further legal provisions for the use of ventilators must be observed.

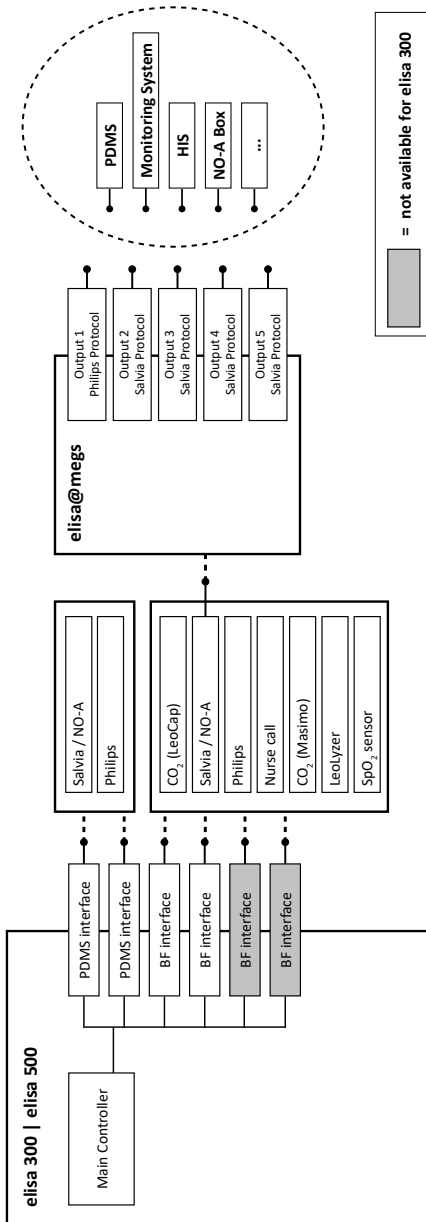


Subsequent changes to the IT network may induce new risks and require further analysis on the part of the equipment owner.

1.3 Schematic diagram elisa 600 – elisa 800 VIT



1.4 Schematic diagram elisa 300 – elisa 500



2 External communication interfaces with Salvia protocol

2.1 Introduction

This chapter describes the use of the communication interfaces with the Salvia protocol. These external communication interfaces are used by the devices elisa 300 – elisa 800 VIT for communication with various external devices and networks.

Remark

This document provides the necessary information for integrating elisa 300 – 800 VIT in an IT network and the additional information requested according to chapter 3.5 of the DIN EN 80001 standard.

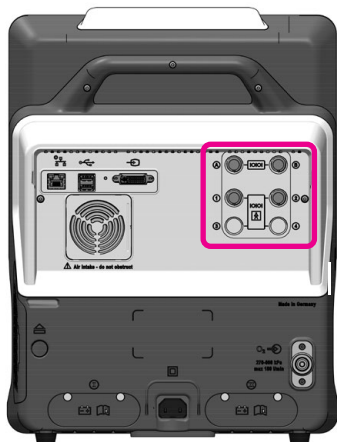
Remark

To enable the use of the interfaces with the Salvia protocol, the interfaces need to be preconfigured at the configuration level. Under “Status” on the standby or ventilation screen, go to the second view and check which interface is configured with the Salvia protocol. If in doubt, contact your service technician or the responsible person in your ward.

2.2 Layout of the external communication interfaces

The devices elisa 300 – 800 VIT are equipped with a number of different communication interfaces. The interfaces are located at the back of the devices.

Rear view of elisa 300 / elisa 500



elisa 300

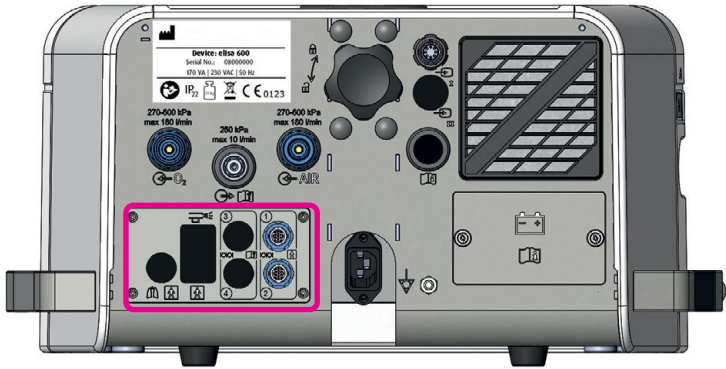


elisa 500

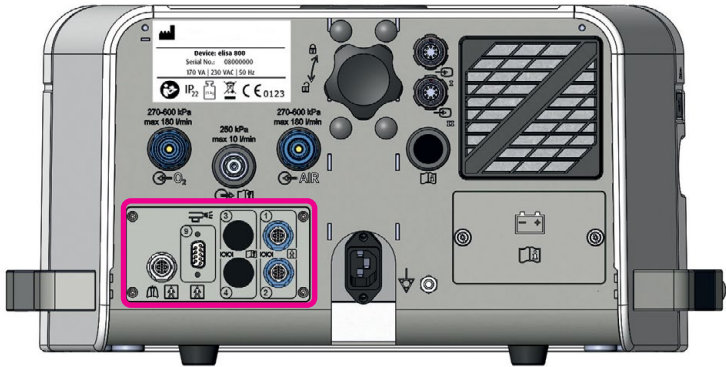
Detailed view of the interfaces:

Illustration	Designation	Assignment
	A and B	PDMS/Monitor configurable for PDMS Salvia protocol or PDMS Philips protocol
	1 and 2	Type BF serial interface configurable for PDMS Salvia protocol or PDMS Philips protocol
	3 and 4	Type BF serial interface configurable for PDMS Salvia protocol or PDMS Philips protocol (not available for elisa 300)

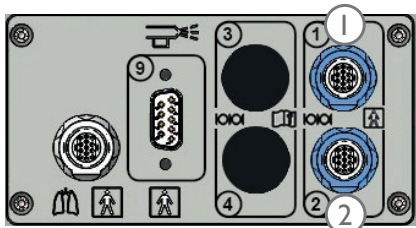
Rear view of elisa 600



Rear view of elisa 800

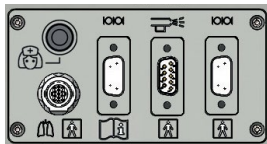


Detailed view of the interfaces:

Illustration	#	Assignment
	I and 2	Serial interface, type BF, configurable for PDMS Salvia protocol or PDMS Philips protocol

2.3 External medical equipment interface elisa@megs

By connecting an external medical equipment interface elisa@megs, elisa 300 – 800 VIT devices can be expanded with another 5 communication options.

Remark	elisa@megs must be connected to one of the BF interfaces with the Salvia protocol. This requires the configuration of the BF interface for the “Salvia” protocol in the configuration menu. Contact your service technician or the responsible person in your ward for this configuration change.
	Check the interfaces at the back of your elisa 600 / elisa 800. Devices with older serial numbers (SW 2.04.x) may not be equipped with the required BF interfaces.  It is not possible to use elisa@megs with these devices.

elisa@megs expands the communication options of elisa 300 – 800 VIT by another five external communication interfaces, four of which using the Salvia protocol and one using the Philips protocol. They can be used in parallel, which means, for example, that elisa 300 – 800 VIT can be integrated in a patient data management system and at the same time, measured values, configuration parameters and alarm data can be transferred to a patient monitor via one of the other interfaces. For details, please refer to the instructions for use of the external medical equipment interface elisa@megs.

2.4 Interface specification

2.4.1 Configuration of the external receiving interface

The receiving system must have a serial interface that corresponds to the specified communication interface of the elisa (or elisa@megs).

You may have to use an adapter for the 9-pin SUB-D socket (female) to connect the elisa (or elisa@megs) to the receiving system (hospital monitor or hospital information system).

For the serial interfaces for external communication, the Salvia protocol is standard. At the configuration level of elisa 600 – 800 VIT, the Philips protocol can optionally be preset.

2.4.2 EC Interface SALVIA

For a detailed specification of the SALVIA protocol, please refer to this document: [Salvia_Serial_Protocol_I_0_I_3.pdf](#)

2.4.3 EC Interface Philips

For a detailed specification of the Philips protocol, please refer to this document: [Salvia_Philips Protokoll.pdf](#)

2.4.4 elisa@megs

The medical equipment interface elisa@megs has one input interface and five output interfaces.

Four of these interfaces use the Salvia protocol, one interface uses the Philips protocol.

2.5 Viewable information

The scope of viewable information depends on whether you use the SALVIA protocol or the Philips protocol.

Remark

For a detailed specification of the SALVIA protocol with all the ventilation modes, parameters, measurements, ventilation curves, and alarms that can be transmitted, please refer to this document: [Salvia_Serial_Protocol_I_0_I_3.pdf](#)

Remark

For a detailed specification of the Philips protocol with all the ventilation modes, parameters, measurements, and alarms that can be transmitted, please refer to this document: [Salvia_Philips Protokoll.pdf](#)

2.5.1 Ventilation modes

See document: [Salvia_Serial_Protocol_I_0_I_3.pdf](#)

See document: [Salvia_Philips Protokoll.pdf](#)

2.5.2 Ventilation curves

See document: [Salvia_Serial_Protocol_I_0_I_3.pdf](#)

2.5.3 Parameters

See document: [Salvia_Serial_Protocol_I_0_I_3.pdf](#)

See document: [Salvia_Philips Protokoll.pdf](#)

2.5.4 Alarms

See document: [Salvia_Serial_Protocol_I_0_I_3.pdf](#)

See document: [Salvia_Philips Protokoll.pdf](#)

Instructions for Use Supplement E – External Communication

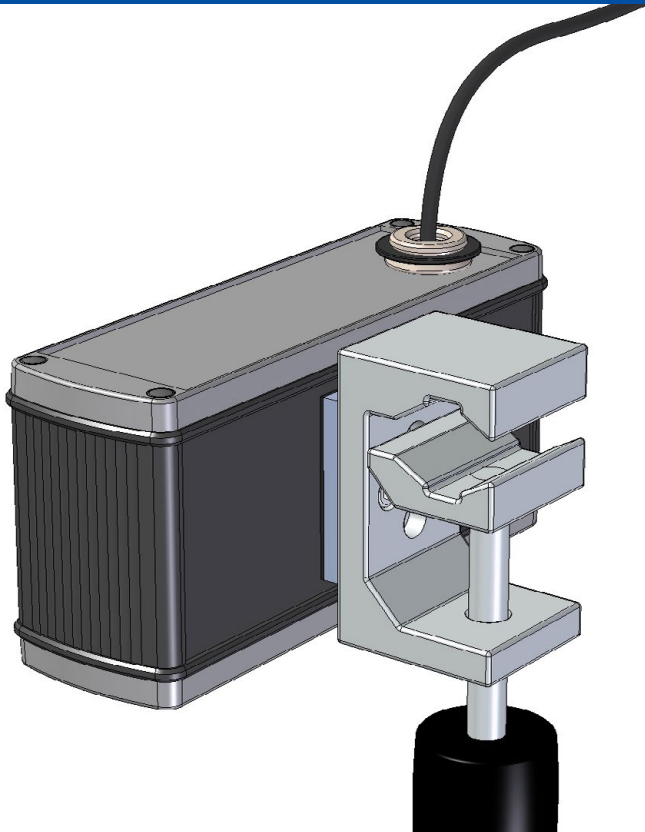
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Medical Equipment Interface

elisa@megs

Instructions for Use
Supplement F

The device operates according to the accompanying documentation and the equipment labelling if 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.

The devices are provided with serial numbers. Their code system includes the product group code (MEGS), year of manufacture and ascending production number for unique identification.

XX represents a number which indicates the year of manufacture:
20 = 2020, 21 = 2021, etc.

0 Contents

1 General notes	5
1.1 About this manual	5
1.2 Safety information in these instructions for use	5
2 Use	6
2.1 Intended use	6
3 Safety instructions	7
3.1 General safety instructions	7
3.1.1 Safety standards	8
4 Components and assembly	10
4.1 System overview	10
4.2 Mounting the device	10
4.3 Connection	11
5 Operating elisa@megs	13
5.1 Ports	13
5.2 Port using the Philips protocol	13
5.3 Port using the Salvia protocol	13
6 Cleaning, disinfection, disposal	14
6.1 General information	14
6.2 Cleaning and disinfection	14
6.3 Disposal of elisa@megs	15
7 Technical data	15
7.1 General	15
7.2 Guidance and manufacturer's declaration	16

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I General notes

I.1 About this manual

These instructions for use describe the intended use and the operation of the following product:

Medical equipment interface elisa@megs

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.

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.

2 Use

2.1 Intended use

The medical equipment interface elisa@megs is a data node and data hub for medical data.

Using a proprietary protocol, it communicates with the devices elisa 300 to 800 VIT and transmits control and status information, device parameters and measured values.

The data acquired from the devices elisa 300 to 800 VIT are made available to other medical devices or networks at five serial interfaces. All interfaces comply with the requirements of the RS232 standard. The maximum baud rate of the five serial interfaces is limited to 256 kBaud.

It is impossible to control the devices elisa 300 to 800 via the medical equipment interface elisa@megs.

The device is only approved for use with the devices elisa 300, 500, 600, 800 and 800 VIT.

3 Safety instructions

3.1 General safety instructions

Reference

These instructions for use describe the product:

Medical equipment interface elisa@megs

Safe operation

In order to guarantee the safe operation of elisa@megs, the system must only be used as described. Before putting the system into operation, users must familiarise themselves with these Instructions for Use, with the Basic Instructions for Use of elisa 300 to 500 or 600 to 800 and with the Instructions for Use Supplement E “External Communication”.

Secure mounting

Check that the device is securely mounted on a standard rail.

Classification

elisa@megs is a Class I device according to Directive 93/42/EEC concerning medical devices, Annex IX, section 3.3., rule 12.

Electrical hazard

The housing must be dry before the device is connected to elisa.

The system must be stored and operated at the temperature and humidity levels indicated in chapter 7 “Technical specifications”.

The system must always be disconnected from elisa before cleaning, repair or maintenance work.

Fire hazard

elisa@megs must not be used in potentially explosive atmospheres or in the presence of flammable anaesthetics.

Risk of electromagnetic disturbance

Devices that generate electromagnetic disturbance at levels exceeding the values of EN 60601-1-2 can affect the safe operation of the device.

Devices that generate high frequency fields and are installed close to the system can affect the safe operation of elisa@megs.



elisa@megs must not be used in close proximity to nuclear magnetic resonance equipment (MRI, NMR devices).

Electromagnetic compatibility:

elisa@megs is only intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of elisa@megs can contribute towards avoiding electromagnetic interference by maintaining the minimum distance between portable and mobile high frequency communications equipment (transmitter) and elisa@megs.



Warning

Using other electrical devices with elisa@megs or in its vicinity can cause interference. The correct performance of elisa@megs must be verified after putting the system into service.

Note

All the elisa@megs features are fully functional if the place of use meets the EMC requirements set forth in the applicable regulations. Detailed information on electromagnetic compatibility can be found in chapter 7.3 Guidance and manufacturer's declaration.

3.1.1 Safety standards

The device elisa@megs was developed and manufactured according to the following safety standards:

EN 60601-1

Medical electrical equipment – General requirements for basic safety and essential performance

EN 60601-1-2

Medical electrical equipment – General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and testing

When applying a ventilator and a terminal device on a patient for medical purposes, you are required to observe the following notes and warnings.

Note

The communication only takes place between one interface and a single terminal device.

Note

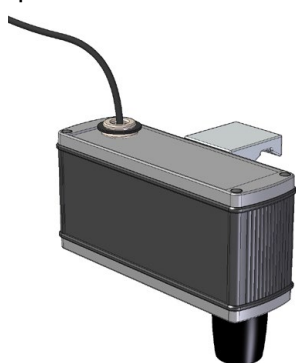
After the initial installation, perform a functional test by checking whether the communication link between the ventilator and the terminal device meets the requirements of your facility. Perform a functional test every time a communication component is replaced or modified.

Warning	It is not permitted to connect the ventilator to the terminal device via a network.
Warning	Do not make any treatment-related decisions solely on the basis of the transmitted parameters. Always refer to the parameters on the display of the ventilator in addition.
Warning	If the terminal device indicates ventilation alarms, you need to determine and eliminate the root cause at the patient.
Warning	The patient monitor and the ventilator may present alarms in different ways. Not all patient monitors display detailed alarm messages.
Note	The control of the ventilation procedure is independent of the data communication between ventilator and terminal device. This means that the ventilator continues ventilating the patient if a data communication problem occurs.

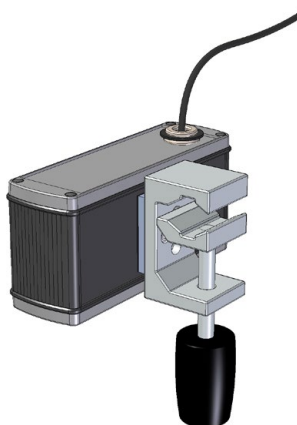
4 Components and assembly

4.1 System overview

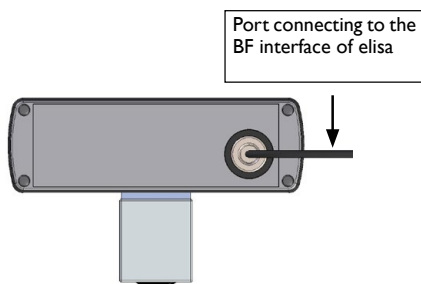
Perspective views



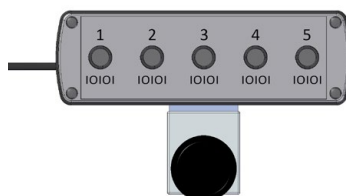
Front view



Rear view showing bracket for attachment to standard rail



Top view



Bottom view

4.2 Mounting the device

Use the bracket to secure the elisa@megs to the standard rail of the optional cart or to any other standard rail.



Check the correct orientation of elisa@megs. The five ports point **downwards**. Only this orientation guarantees the protection of category IP22.

4.3 Connection

Plug the elisa@megs connector into one of the BF-type data interfaces of your elisa device (300, 500, 600, 800, or 800VIT).

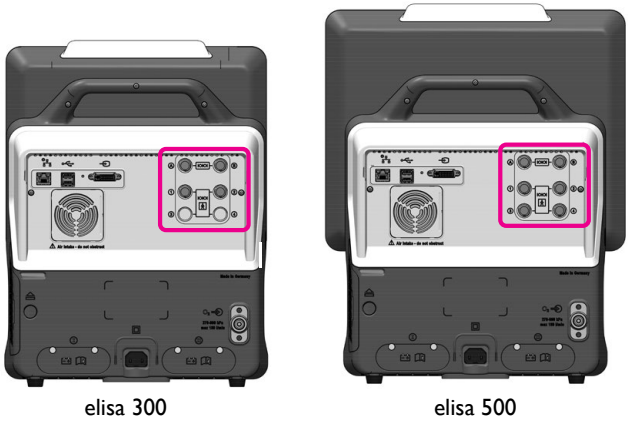
This functionality must be enabled on the configuration level of elisa in the “Protocols” submenu where the selected BF data interface must be set to “Salvia”. Contact your service technician or the responsible person in your ward for this configuration change.

The current interface configuration is illustrated on the standby or ventilation screen on the “Status” tab when you swipe to the second view.

Note

Use only one of the **type BF** data interfaces. Do not use one of the PDMS interfaces.

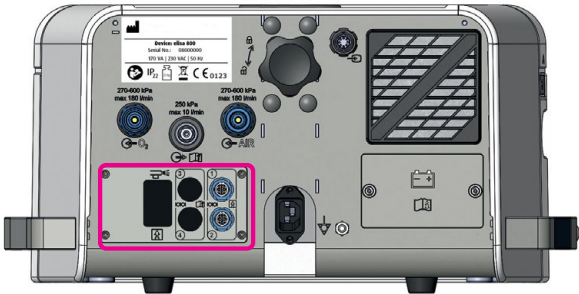
Rear view of elisa 300 / elisa 500



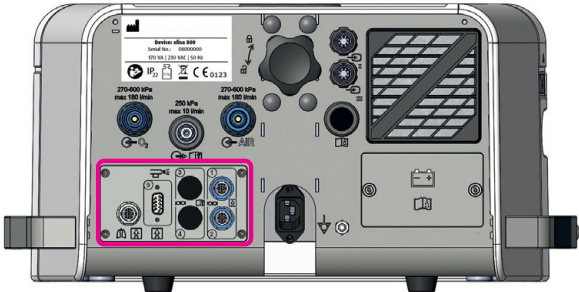
Detailed view of the interfaces:

Picture	Designation	Assignment
	A and B	PDMS/Monitor (configurable)
	1 and 2	Type BF serial interface (configurable)
	3 and 4	Type BF serial interface (configurable) (not on elisa 300)

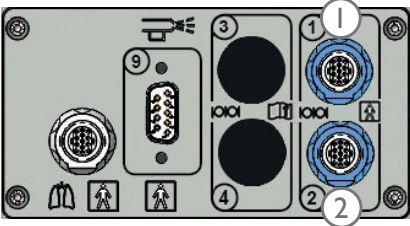
Rear view of elisa 600



Rear view of elisa 800

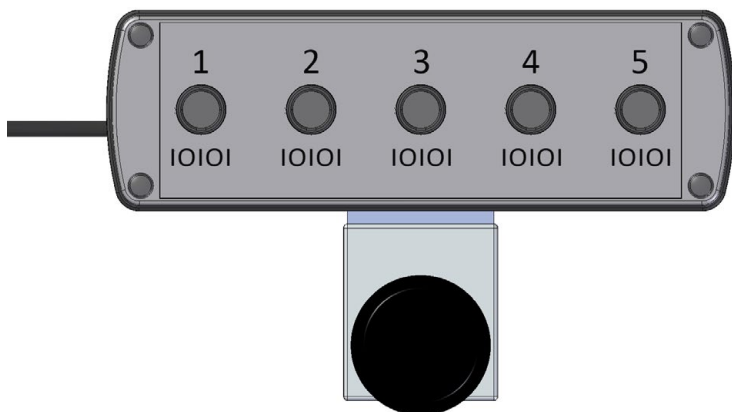


Detailed view of the interfaces:

Picture	#	Assignment
	I and 2	Type BF serial interface (blue colour coding) (configurable)

5 Operating elisa@megs

5.1 Ports



Port 1 = Philips protocol
Ports 2-5 = Salvia protocol

5.2 Port using the Philips protocol

Devices using the Philips protocol can be connected to **port 1**.

If you need more information, please contact your service technician or the manufacturer.

5.3 Port using the Salvia protocol

Devices using the Salvia protocol can be connected to **ports 2-5**.

If you need more information, please contact your service technician or the manufacturer.

6 Cleaning, disinfection, disposal

6.1 General information



Warning

Important safety precautions:

- Observe the instructions for use and data sheets of the cleaning agents and disinfectants.
- Wear protective gloves and safety goggles.
- Do not inhale fumes.



Caution

Avoid damage:

- Do not use any organic, halogenated or mineral oil based solvents, volatile anaesthetics, glass cleaners, acetone, sharp or abrasive cleaning agents, e.g., steel wool, silver polish or silver cleaners.
- Do not allow liquids to enter the housing.
- Contact the manufacturer if you have questions concerning cleaning agents or disinfectants.



Warning

Avoid patient contamination:

- Comply with the general hygiene regulations of the hospital or the national hygiene recommendations.

6.2 Cleaning and disinfection

Disconnect the device from elisa (300 to 800 VIT).

'mikrozid® sensitive liquid' by 'Schülke & Mayr GmbH' (www.schuelke.com) is recommended for disinfection of the surface (use per manufacturer's instructions).

Do not allow liquids to enter the housing.



Caution

Before putting the device into service, check that it is completely dry.

6.3 Disposal of elisa@megs

Do not dispose of elisa@megs with the domestic waste. Consult an authorized, certified electronic waste recycling company for the proper disposal. Please contact the Environmental Officer of your facility or your town hall for the appropriate address.

The outer packaging (box) can be disposed of in the waste paper.

7 Technical data

7.1 General

Application

Use:	Medical equipment interface for devices elisa 300 to elisa 800 VIT
Area:	Intensive care, recovery room, ventilation in general
Use:	stationary

Dimensions and weight

Device W x D x H	172 x 55 x 81 mm
Device incl. bracket W x D x H	172 x 110 x 163 mm
Weight, net:	800 g

Environmental conditions

Operating temperature	0 to 40°C
Storage temperature	0 to 60°C
Atmospheric pressure	60 to 106 kPa

Classification

Device class:	Class I (according to Directive 93/42/EEC concerning medical devices, Annex IX, section 3.3., rule 12)
Duration of use:	Continuous operation
Protection class:	IP22

Note

IP22: Protected against solid objects with a diameter over 12.5 mm and against falling drops of water when the housing is tilted at an angle up to 15°.

**Caution**

At high humidity levels, it is not possible to completely rule out condensation. If the device is constantly operated at high humidity levels, corrosion can be expected.

7.2 Guidance and manufacturer's declaration

Electromagnetic emissions:

elisa@megs is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user of elisa@megs to ensure that the device is operated in such an environment.

Emission tests	Compliance	Electromagnetic environment – guidance
RF emissions to CISPR 11	Class A	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions to IEC 61000-3-3	Complies	

Electromagnetic immunity:

elisa@megs is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that elisa@megs is operated in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) to IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/bursts to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	The mains power quality should be that of a typical commercial or hospital environment.
Surges to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations to IEC 61000-4-11	100% dip in U_T for 10 ms 100% dip in U_T for 20 ms 30% dip in U_T for 500 ms 100% dip in U_T for 5000 ms	100% dip in U_T for 10 ms 100% dip in U_T for 20 ms 30% dip in U_T for 500 ms 100% dip in U_T for 5000 ms	The mains power quality should be that of a typical commercial or hospital environment. If the user of elisa@megs requires continued operation during power mains interruptions, it is recommended that elisa@megs be powered from an uninterruptible power supply (UPS).
Power frequency (50 Hz) magnetic field to IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test levels.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Portable and mobile RF communications equipment should be used no closer to elisa@megs, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF to IEC 61000-4-6	3V rms 150 kHz to 80 MHz outside ISM bands ^a	10V	$d = 1.2\sqrt{P}$
	6V rms 150 kHz to 80 MHz inside ISM bands ^a	10V	$d = 0.6\sqrt{P}$
Radiated RF to IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ for 800 MHz to 2.7 GHz
		Recommended separation distance: where P is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^c, should be less than the compliance level in each frequency range.^dInterference may occur in the vicinity of equipment marked with the following symbol. 	

Note 1 | At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 | These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a
The ISM bands (for industrial, scientific and medical application) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.

b
The compliance level in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range of 80 MHz to 2.5 GHz is intended to reduce the probability that portable communications equipment could cause interference if it is inadvertently brought into the patient environment.

This is why an additional factor of 10/3 is used in order to calculate the recommended distance for transmitters in these frequency ranges.

c

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.

d

Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Instructions for Use Supplement F – elisa@megs

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