

TwinStream[™] EVO

User Manual



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1. Abbreviations and Symbols

1.1 Abbreviations

Abbreviation	Description
1/2/3/4 LUM	1/2/3/4 Lumen Catheter mode
bar	Kilopascal / cm^2
BRO	Bronchoscopy mode
BW	Body Weight
$^{\circ}\text{C}$	Degree Celsius
cCO ₂	continuous CO ₂ Concentration
CGS	Central Gas Supply
cm	Centimetre
CPAP	Continuous Positive Airway Pressure
COPD	Chronic Obstructive Pulmonary Disease
CPM / BPM	Cycles Per Minute / Breaths Per Minute
DISS / NIST	Standard for gas inlet
DM	DiaMeter
ECG	Electrocardiogram
ETT/LMA	Endotracheal Tube/Laryngeal Mask mode
etCO ₂	End-tidal CO ₂ concentration (mmHg)
F, f:	Frequency
FiO ₂	Fraction Inspiratory Oxygen
FiCO ₂	Fraction inspiratory carbon dioxide
FiO ₂ AW	Oxygen concentration in the Airway
FiO ₂ jet	Inspiratory oxygen in the jet line
FRC	Functional Residual Capacity
HF	High-Frequency ventilation
HFV	High-Frequency Ventilation
i:e	Ratio insp. to expir. HF
I:E	Ratio insp. to expir. NF
kg	Kilogram
kPa	KiloPascal (1kPa = 10mbar)
L	Litre
L/min (STPD)	Litre per minute
LAN	Network connection (Local Area Network)

Abbreviation	Description
LAR	Laryngoscopy mode
L _{WA}	A-weighted sound power level
LSM	Laser Safe Mode
MP _{AW}	Mean Airway pressure
mbar	Millibar (1mbar = 0,1kPa)
min	Minute
mm	Millimetre
mmHg	Millimetres of mercury
MMI	Men Machine Interface
ME-Device	Medical Electrical Device
MLS	Micro-laryngeal Surgery
NF	Normal-Frequency ventilation
P _{AW}	Airway pressure
PDMS	Patient Data Management System
PE	Potential Equalisation
PEEP	Positive End-Expiratory Pressure
P _{HF}	Emission pressure HF
PIP (PEAK)	Peak pressure (Peak Inspiratory Pressure)
P _{NF}	Emission pressure NF
PP	Pause Pressure
PPE	Personal Protective Equipment
RJ-45	Interface standard
RS 232	Interface standard
S-HFJV	Superimposed High-Frequency Jet Ventilation
STPD	Standard Temperature Pressure Dry
TIVA	Total IntraVenous Anaesthesia
TSI	Technical Safety Inspection
tcCO ₂	Transcutaneous CO ₂ measurement
USB	Interface standard
V	Volt
WD	Weight dependend

1.2 Symbols

Standardized symbols according to EN ISO 7000, EN ISO 7010 and IEC 60417

	Refer to instruction manual/booklet	SN	LOT	Serial number LOT batch number
	Application section BF: Jet Endoscope, Jet Catheter, Y-piece of the disposable tubing system	UDI		Unique device identification
	Production date Manufacturer	REF		Reference or Catalog
	CE marking European Conformity			Fragile; handle with care
	Warning			This way up
	Caution			Keep away from rain
	Total weight of the device including payload			Keep away from sunlight
	Potential Equalisation			Temperature limit
	No household waste			Humidity limitation
MD	Medical Device			Operator's Manual; operating instructions
	Do not sit here			

CARL REINER® Symbols

	LAR mode		3 LUM mode
	BRO mode		2 LUM mode
	ETT/LMA mode		1 LUM mode
	Expert mode		Laser Safe Mode
	4 LUM mode		

2. Safety Information

This chapter provides safety information related to setting up and operating the ventilator.

 Be sure to read the Instructions for Use before using the ventilator and any devices and accessories used with the ventilator.

Carefully review all sections of this safety chapter before setting up the ventilator and accessories, and ventilating the patient.

2.1 Definition of Safety Information

Warning Symbol	Signal Wort	Definition
	Danger	Important information about a potential hazard that could result in death or serious injury to the patient, user or third party if it is not prevented.
	Warning	Important information about a potentially situation that could result in minor or moderate injury to the user, patient or damage to the medical device or other property if it is not prevented.
	Caution	Notes contain special information of important explanations or to avoid difficulties in operating the medical device.

2.2 General Safety Information

Danger:

Do not use in presence of explosive materials! The ventilator is not intended for use in areas where there is a danger of explosion. Where explosive gases are used, the apparatus must not to be operated in the danger area.

Warning:

- It is prohibited to place or store liquid containers on top of the housing. Liquid ingress can damage the equipment permanently.
- Do not cover the device. Keep the gas outlets of the device free!
- The operating instructions of the laser must be followed. The prescribed Personal Protective Equipment (PPE) and smoke evacuation must be used to prevent the risk of infection to the operating theater team. The smoke evacuation prevents the backflow of the laser smog even with the open ventilation system.
- No unauthorised changes may be made to the TwinStream™ EVO or its accessories. All unauthorised changes can endanger the health of the patient or the operator as well as third parties.
- The single-use accessories of device must not be processed and reused, as this can lead to damage to or malfunction of the medical devices and present a risk for the patient.
- Do not use greases or oils as sealants or lubricants on the connections of the connection hoses for oxygen and compressed air - risk of explosion!
- In all forms of high frequency ventilation exists an increased risk of infection by airborne diseases. Therefore, personal protective equipment must be used.
- When combining medical devices of various manufacturers without a compatibility certificate, the user takes on legal responsibility of a manufacturer according to the Medical Devices Regulation. We recommend that you obtain certification of compatibility from the concerned manufacturers before using the composite ventilation system on the patient.
- The supraglottic as well as infraglottic ventilation method with the endoscope requires an “open” ventilation system. Therefore, the distal opening of the Jet Endoscope must never be closed.
- Do not add any attachments or accessories to the ventilator that are not listed as intended for use in combination with the ventilator in the instructions of the ventilator or accessory, as the ventilator might not function correctly and lead to the risk of patient death or serious deterioration of health.
- Sound pressure levels of the audible alarm signal, which are lower than the ambient levels, may prevent the operator from detecting alarm conditions!
- Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or serious deterioration of health.

Caution:

- The TwinStream™ EVO is not intended for use with more than one patient at the same time.

2.3 Electromagnetic Susceptibility

Warning:

- Use of this product next to other equipment or stacked with other equipment should be avoided, as this could result in improper operation. If use is still necessary in the manner described above, this device and the other

devices should be observed to make sure they are working properly.

- PORTABLE RF communications equipment (including radios) (including their accessories, such as antenna cables and external antennas) should not be used closer than 30 cm (or 12 inches) to those of the TwinStream™ EVO and its cables. Failure to do so may result in a reduction in the performance of the device
- Leads of active electrosurgical equipment must be at least 30cm away from the TwinStream™ EVO. Using the TwinStream™ EVO immediately adjacent to the RF surgical leads should be avoided, as this could result in improper operation.
- Devices that may cause electromagnetic disturbances should not be operated in the vicinity of the ventilator (e.g., mobile phones etc.).
- Device should not be used in combination with an MRI or in MRI premises and not in a pressure chamber or hyperbaric therapy!

Caution:

- Use of accessories, cables, or transducers other than those specified herein with the TwinStream™ EVO may increase the emissions and reduce the electromagnetic immunity of the TwinStream™ EVO.
- The EMC characteristics of this equipment, permit its use in industrial and hospital environments (CISPR 11, Class A). When used in a residential environment (for which Class B is usually required by CISPR 11), this equipment may not provide adequate protection of radio services. The user may need to take corrective action such as relocation or re-orientation of the equipment.

2.4 Gas Supply

Warning:

- The ventilator shall not be used with inlet gases that are not specified for use (e.g. helium or mixtures with helium). Such use might cause the ventilator not function correctly and cause patient death or serious deterioration of health.
- It is the responsibility of the organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the ventilator and indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health.
- The device is not suitable for operation with oxygen 93.
- The TwinStream™ EVO must not be used with nitric oxide, such use could cause the ventilator to malfunction and result in death or significant deterioration of the patient's health.
- The ventilator must not be used with injected gases . If applicable, such use could cause the ventilator to malfunction and result in the patient's death or significant health deterioration.
- The TwinStream™ EVO is a high-volume flow device and should be connected only to a central gas supply installation designed on the basis of a simultaneity factor that allows the specified high flow at a specified number of sampling points, thereby avoiding exceeding the designed flow of the central gas supply and minimizing the risk of the ventilator interfering with the operation of adjacent equipment.

2.5 Operation

Warning:

- In all forms of high frequency ventilation, clinical monitoring of the patient by auscultation of the lung and observation of thoracic excursion is critical to avoid endobronchial misalignment or dislocation.
- The patient must receive only TIVA, because inhalation anaesthetics in the conventional sense (e.g. mixture of nitrous oxide and oxygen, admixture of inhalation anaesthetics) are not compatible with the device or the use of an open ventilation system!
- Nebulization breathing system filters and heat and moisture exchangers must not be used with the ventilator, as these become clogged with increasing humidity and block the open system, which can lead to over pressure.
- Disconnect patient from the device during selftest!
- Antistatic or electrically conductive hoses or tubing are not to be used in the HFV breathing system.
- To prevent increased patient leakage currents, the device and the patient must not be touched at the same time.

Caution:

- Always choose the correct ventilation mode and current patient weight to make sure alarm presettings are set adequate.
- the device is not intended to be used with closed suction systems.

2.6 Alarms and Alarm Settings

Warning:

- Sound pressure levels of the audible alarm signal, which are lower than the ambient levels, may prevent the operator from detecting alarm conditions!
- The use of medical equipment with similar sounding alarms may pose a risk. Operator should note and differentiate alarm priority settings of TwinStream™ EVO and other equipment, which can be located in the same Operation Room.

Caution:

When setting the upper and lower alarm limits, care must be taken to avoid extreme settings so as not to disable the alarm system.

2.7 Electrical: Power and Battery

Warning:

- To avoid the RISK of electric shock, device must only be connected to a POWER SUPPLY with a protective earth conductor. INTERNAL POWER SUPPLY should be used if the proper condition of the protective earth conductor is in doubt.
- When using a multiple socket, the additional equipotential bonding must be used. Equipotential bonding prevents an electrically different potential between devices from leading to uncontrolled discharges.

Caution:

Remove the rechargeable batteries if the device will be stored more than half a year and put in new batteries cells before reuse.

2.8 Cleaning and Disinfection

Warning:

- Cleaning and disinfection work may only be carried out if the mains plug is disconnected from the power supply!
- The device itself must not be immersed in liquid disinfectants or autoclaved!

Caution:

Do not introduce large quantities of disinfectant into the front panel outlets of the device, liquid ingress might damage the device.

2.9 Storage and Transportation

Warning:

- Avoid direct sunlight!
- Water ingress during transport or storage can lead to functional impairment or even damage!
- Use only original packaging! Inadequate packaging may cause damage during transport.
- Do not turn over the device! Incorrect handling may cause damage of the device during transportation.
- In the event of the packaging being damaged, unintentionally opened or exposed to environmental conditions out of this specification, please contact Carl Reiner before use. The authorised person will test device conditions.

Caution:

If the temperature, air pressure and humidity are too high or too low, the service life of the used materials may be shortened.

2.10 Maintenance

Warning:

- Repair and maintenance must not be performed when the unit is used on the patient.
- The ventilator is delivered in an oxygen-compatible state after a comprehensive test run has been performed. No grease or oil should be used during repair or maintenance work in order to avoid malfunction of the apparatus, which may be as serious as explosions when the apparatus is used with oxygen.
- Make sure that the maintenance interval is observed.
- To make sure the device works properly in case of a power outage, replace the battery cells every 24 months.

⚠ Caution:

- All the service mentioned in this Manual (maintenance, repair, update/upgrade) must be carried out by the qualified personnel who is authorised by the manufacturer.
- The battery and oxygen sensors may only be changed by trained and factory authorised maintenance personnel.
- To prevent malfunction of the ventilator, only original CARL REINER® spare parts may be used for any maintenance work.
- TwinStream™ EVO ventilator or Jet accessories (Jet Endoscope, Jet Coupling) which do not function or do not meet the manufacturer's specifications may not be used until all necessary repairs have been completed.
- Maintenance and repair work on the ventilator, parts of the ventilator or original accessories such as Tubing Set or Jet Endoscopes can only be conducted if these have been cleaned and disinfected prior to their being collected or sent in. We reserve the right to return contaminated instruments, tube systems or ventilator to the sender.
- Make sure the ventilator is switched off and disconnected with the power supply cable before replacement of battery and sensor.

2.11 PDMS**⚠ Warning:**

- If the device is connected to another none medical device via an electrical connection (USB-B, RS232), it must be galvanically isolated e.g. by network isolator.
- No other electrical device may be connected to the USB interface during operation.
- The interface may only be activated by authorised personnel!

⚠ Caution:

- The integration of the device into an IT network that includes other devices could lead to risks for patients, operators or third parties that were not previously known.
- The responsible organisation should identify, analyse and manage these risks.
- Changes to the IT network could lead to new risks and therefore could require additional analyses. Changes to the IT network can include following:
 - Changes to the IT network configuration
 - Connecting additional elements to the IT network
 - Removing elements from the IT network
 - "Update" of devices that are connected to the IT network
 - "Upgrade" of devices that are connected to the IT network
- The use of non-validated PDMS can lead to wrong or falsely displayed patient data. The use of this data can cause harm to the patient.
- An interruption of the data line or connection can lead to data loss.
- The PDMS interface is not intended to remotely send alarm signals to the user on a communicator. The interface is intended only for external recording of data.
- The correct settings must be selected to validate the communication. In the event of an incorrect transmission, an information message is displayed.

2.12 Function**⚠ Caution:**

- Humidity in the gas sample higher than 95% relative or condensate can negatively effect the accuracy of the FiO₂ AW and etCO₂ measurement.
- Leaks in the measurement line negatively effect the accuracy of the measurement.
- Manipulation with surgical instruments or similar inside the instrument during measurement can effect the accuracy of the measurement.

2.13 Installation**⚠ Warning:**

Antistatic or electrically conductive hoses or tubing are not to be used in the HFV breathing system.

⚠ Caution:

- Do not install the device in a way which makes it difficult to disconnect the mains cable!
- Using screws which are too long to install the device can damage the housing and the unit!
- Make sure the device is switched off!

- When installing or replacing battery cells, pay attention to the polarity of the cells! If they are put in upside down (wrong polarity), damage can be caused!

3. Installation

Warning:

Antistatic or electrically conductive hoses or tubing are not to be used in the HFV breathing system.

Caution:

Do not install the device in a way which makes it difficult to disconnect the mains cable!

Notice:

Installation and commissioning at the premises of the client may only be undertaken by trained Carl Reiner or authorised personnel.

3.1 Fixed Mounting

The ventilator should be placed on a flat and stable surface like a tilt tested trolley (see Fig. 3) with an appropriate minimum bearing capacity .



Fig.1 TwinStream™ EVO S-HFJV



Fig.2 TwinStream™ EVO HFJV

3.2 Mounting the ventilator on the TwinStream™ EVO trolley

If you have purchased a TwinStream™ EVO trolley for the ventilator the apparatus should be installed on the trolley by an authorised customer service, at the provided holes, using the original screws delivered with the apparatus.

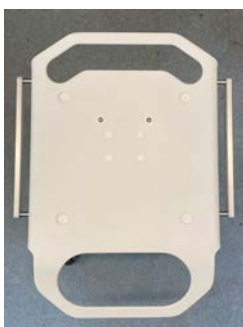


Fig.3 Trolley platform



Fig.4 TwinStream™ EVO S-HFJV with trolley



Fig.5 TwinStream™ EVO HFJV with trolley

Caution:

Using screws for mounting the device which are too long can damage the housing and the unit!

3.3 Mounting the mains cable and the CGS tubes on the rear side of the Jet Ventilator

The prefabricated connection tubes for oxygen and compressed air, including the external filters/water traps (depends on country specific requirements), must be screwed to the specific gas inlets in the apparatus by an authorised customer service. The power cable should be plugged in and it should be ensured that the plug snaps in place. The connection cable for the data transfer will be provided according to specifications by the authorised customer service.



Fig.6 TwinStream™ EVO rear view

3.4 Battery Cell Installation (INR18650-35E)

When receiving a new device, the battery cells from the battery pack will be shipped in a not installed way – therefore the battery cells have to be installed first.

1. Open battery compartment
2. Disconnect the plug from the battery pack
3. Pull out the empty battery pack
4. Put in the new cells (pay attention to polarity)
5. Push the battery pack back in
6. Connect the plug to the battery pack again
7. Close battery compartment



Fig.7



Fig.8



Fig.9

⚠ Caution:

- Make sure the device is switched off!
- When installing or replacing battery cells, pay attention to the polarity of the cells! If they are put in upside down (wrong polarity), damage can be caused!
- Replacement may only be performed by trained maintenance personnel authorised by the manufacturer.

3.5 Self-securing power cable

Before performing any technical work on the device, the power cord must be unplugged!

To connect the cable, plug it in as usual. To disconnect the cable, pull the red little trigger and the cable at the same time out the socket.

⚠ Caution:

The power cord used for this device is self-securing! Be aware that this type of power cord must be used!



Fig.10

3.6 Installation Notice

- Textiles should not be stored near the CGS connections and gas outlets of the unit.
- In order to avoid accumulation of lint or textiles with oxygen, the area around the back of the unit must be kept free so that escaping gas can mix easily with the room air. Between the ventilator and the load no textiles may be stored!
- The device may not be operated covered!
- Nothing must obstruct the device!
- The gas outlets of the safety valves on the back of the unit must not be blocked!
- The device must not be placed against a wall in such a way that the gas outlets are blocked!
- The device must be set up at the place of use in such a way that the on-off switch is easily accessible at all times.

**Warning:**

It is prohibited to place or store liquid containers on top of the housing. Liquid ingress can damage the equipment permanently.

3.7 Initial Use

Once the apparatus has been installed it can be taken into service. The authorised customer service responsible for the delivery will run the first self-test on site. Thereafter, the loudness of the alarm will be adjusted to the ambient acoustic conditions. Furthermore, the installation report must be completed. The ventilator should only be accepted by the client if the outcome is positive.

4. Intended Use

The TwinStream™ EVO Jet Ventilator is intended for normal/high frequency jet ventilation of patients in medical facilities during diagnostic and surgical interventions in the entire airway with or without laser. It is also intended for use during imaging procedures and/or radiation therapy in order to reduce respiratory motion including organ movement, caused by mechanical ventilation and/or spontaneous breathing. It can be used on patients with a body weight of 3 to 200 kg.

4.1 Intended Environmental Conditions

Only use the device in "Environment of professional health care facilities".

5. Intended User

The intended operators are exclusively medical specialists such as anesthesiologists, surgeons, ENT physicians, pulmonologists/internists and nursing staff who have been trained in the use of the TwinStream™ EVO and its accessories. Based on his/her professional training, the user must have knowledge of proper handling and should have been properly instructed by an authorised person (the person responsible for the device).

5.1 Training

As part of the development of the TwinStream™ EVO system, a stepped training scheme is developed. More information about training program, please contact the Sales Representative or email to office@carlreiner.at.

6. Intended Patient

The patient population ranges from neonates up to obese adults. The normal/high frequency jet ventilation can be set for patients from 3 up to 200 kg.

7. Device Overview

7.1 Physical Characteristics

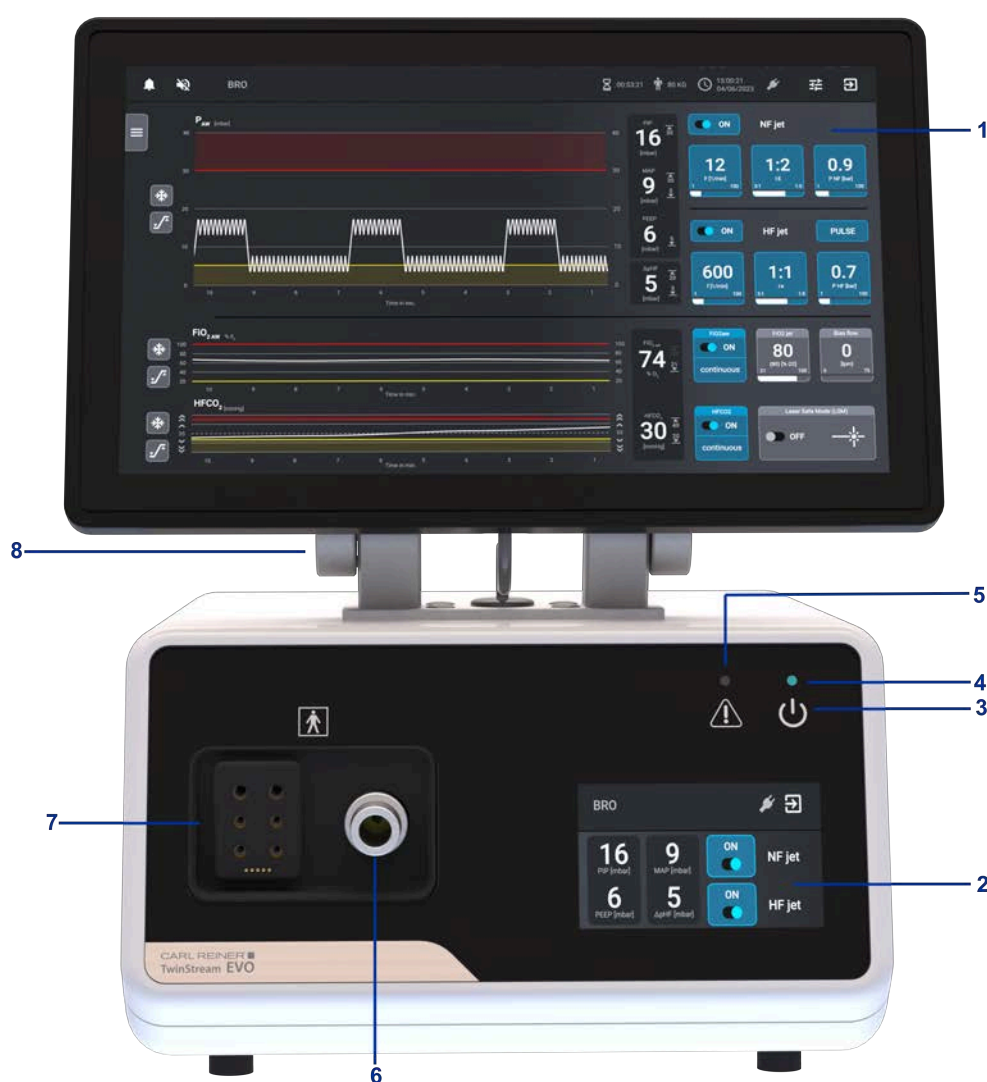


Fig.11 TwinStream™ EVO Front View

1. 15,6" Touchscreen
2. 5" Touchscreen
3. Power switch
4. Power status
5. Alarm light
6. Outlet O₂ bias flow
7. Connector patient tubing set
8. Tilting mechanism

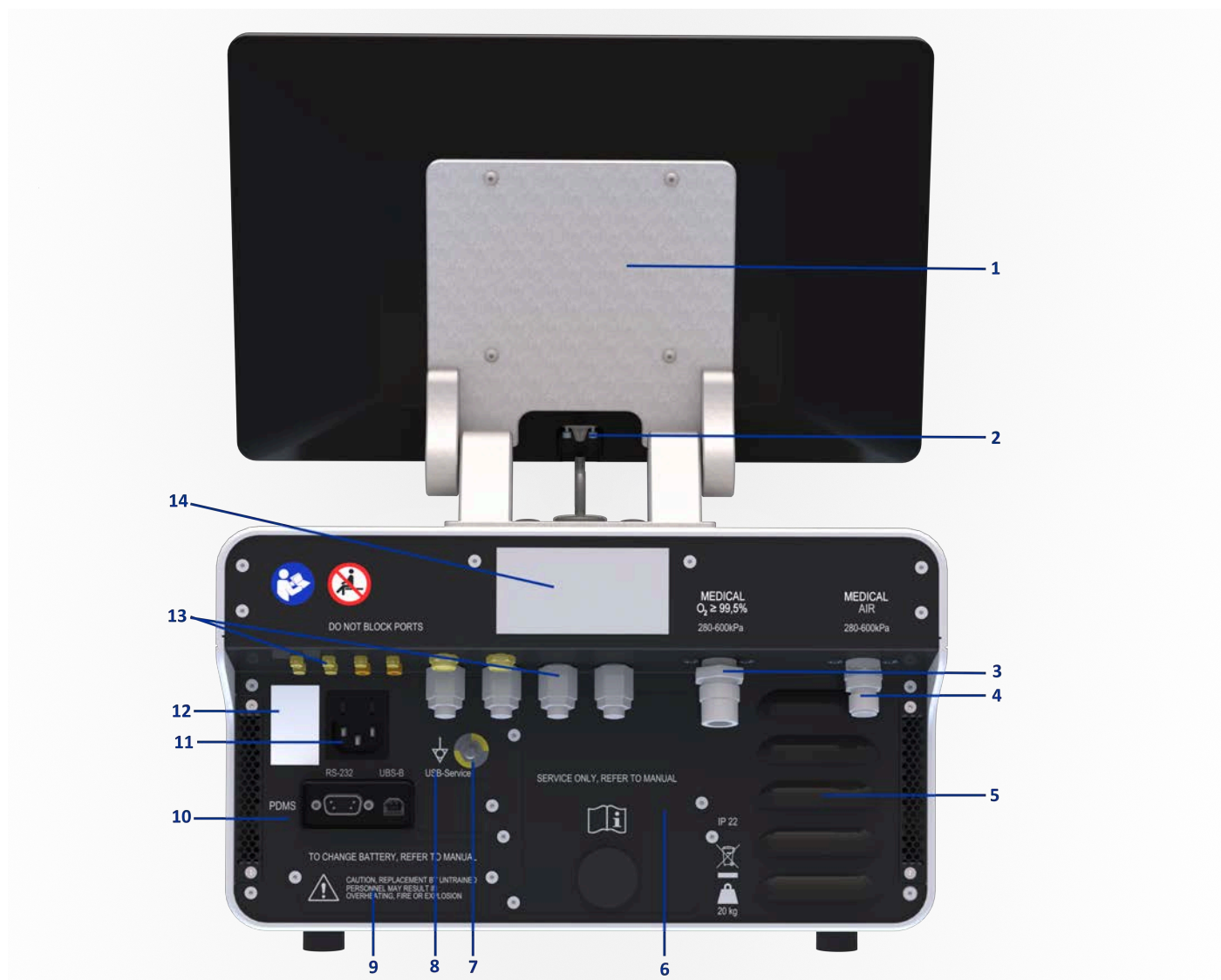


Fig.12 TwinStream™ EVO Rear View

1. VESA-Mount
2. Display connector (open only with tools)
3. Gas inlet for O₂
4. Gas inlet for Compressed Air
5. Reference outlet for ambient air
6. Cover for service compartment of display connector, RJ-45 and oxygen cell (open only with tools and authorised personnel)
7. Potential equalization connection protective conductor-equipotential bonding cable
8. USB service
9. Battery box
10. PDMS interfaces: RS232+USB B
11. IEC power socket with build in strain relief and integrated safety fuse
12. Label of the voltage plate
13. Gas outlet for sensors & mixing chamber
14. Label of the type plate

7.2 TwinStream™ EVO Standard Configuration and Options

The TwinStream™ EVO ventilator is available in two different variants. The HFJV variant is provided on the market with the basic functions, while the S-HFJV variant includes additional functions and an additional large touch display as standard.

Hardware Configuration

Hardware Options	TwinStream™ EVO HFJV	TwinStream™ EVO S-HFJV
Basic Module	✓	✓
Basic Jet Module	✓	✓
Second Jet Module	X	✓
FiO ₂ jet Module	✓	✓
Blender Module	✓	✓
Bias flow Module	X	✓
Bias flow Connection	X	✓
FiO ₂ AW Module	O (15" panel needed)	O
etCO ₂ Module	O (15" panel needed)	O
Panel (15,6" Touchscreen)	O	✓
Airway Pressure Measurement (P _{AW})	O (15" panel needed)	✓
Power Supply	✓	✓

Standard: ✓ Optional: O Not Applicable: X

Ventilation Modes Configuration

Ventilation Mode	TwinStream™ EVO HFJV	TwinStream™ EVO S-HFJV
LAR	X	✓
BRO	X	✓
ETT/LMA	X	✓
Expert	X	✓
4 LUM	X	✓
3 LUM	X	✓
2 LUM (GAS & PAW)	X	✓
1 LUM	✓	✓

Standard: ✓ Not Applicable: X

8. Indication

TwinStream™ EVO is indicated for ventilation of patients during interventional, diagnostic and surgical procedures.

- bronchological procedures
- laryngotracheal procedures

Due to the wide spectrum of application devices, such as Laryngoscopes, Tracheoscopes, Bronchoscopes, Jet Catheters and Adapters up to a semi-closed circuit, the following medical conditions are covered:

- ENT / ORL
- Pneumology
- Thoracic surgery
- Respiratory motion and organ movement

9. Contraindication

- Severe restrictive and obstructive pulmonary disease
- Massive laryngeal or tracheal haemorrhage at the surgical site
- Expected heavy bleeding risk in nasopharyngeal space
- Extreme obesity (body weight > 200 kg)
- Aspirating (reflux) and non-fasting patients
- Expected drainage impediments in narrow tracheal stenoses or tumors, especially if the remaining expiratory airway cross-section is less than 50%
- Increased risk of infection, airborne depended diseases e.g. HIV, hepatitis C, HPV, CJK, BSE, TSE
- Pulmonary edema and pulmonary fibrosis
- Rigid thorax
- General contraindications that apply to any anaesthesia
- Respiratory Anesthesia with volatile anesthetics

10. Complications and Undesirable Side Effects

- Barotrauma
- Hypothermia: Jet Ventilation may cause cooling and dehydration effects for 60-minute exposures. Therefore, during scheduled surgery longer than 60 minutes, a gas conditioning unit (humidifier) should be used.
- Risk of aspiration:
 - As with all other forms of Jet ventilation, there is no absolute aspiration protection with S-HFJV.
 - Ventilation via the Jet instruments or via Jet Catheters is usually performed during elective procedures on fasting patients.
 - Only the use of the S-HFJV generates a positive end expiratory pressure.
 - Therefore, the risk of aspiration can be considered low only with S-HFJV.
- Dehydration of mucosa
- Laser risk :
 - Fire and explosion hazard with increased O₂ concentrations of the inspiratory gas mixture.
 - Formation of laser smog during laser exposure of tissue or other carbon donors due to thermal effects.
 - Formation of harmful polymer fume due to pyrolysis. (always evacuate reaction products, otherwise risk of non-cardiac pulmonary oedema).
 - Potential risk of infection for operating staff due to backflow of laser smog because of the open ventilation system.
 - Visual impairment and inhalation trauma due to laser induced smoke and dusts.
- Bradycardia: the insertion of a laryngoscope may lead to bradycardia (one may need to administer atropine) as well as to an increase in blood pressure.
- Stridor/laryngeal spasms: in the extubating phase the patient may experience stridor/laryngeal spasms.

11. Risk Factor

- Limited lung function (decreased lung compliance and/or obstructive pulmonary disease)
- Pronounced or extreme obesity
- High grade stenosis
- Restrictive and obstructive pulmonary disease
- Expected heavy bleeding risk

- Pulmonary edema and pulmonary fibrosis
- Rigid thorax
- Combination of several risk factors

12. Function

12.1 Principles of jet ventilation

12.1.1 What is jet ventilation?

Jet ventilation:

The term jet ventilation refers to a targeted administration of many small gas volumes at high pressure and high velocity through a nozzle. Upon exiting the nozzle, there is a pressure drop and acceleration of the gas particles with the typical flow noises. The achieved tidal volumes are smaller than the natural dead space.

Characteristics:

- Small tidal volumes of 1-3 ml per kg body weight.
- Adjustable high frequency between 60 and 2000 pulses per minute whereby applies:
 - Higher jet frequency → improved oxygenation
 - Lower jet frequency → improved CO₂ elimination
- Combination of different gas flow mechanisms.
- Provides a gas mixture of medical air and medical oxygen

Open Breathing Circuite:

Since ventilation is carried out exclusively without a cuff and in an open system (without inspiratory or expiratory valve), it is not possible to measure tidal volume or minute volume.

Breathing gas conditioning:

Heating and humidification of the gas flow is recommended. Hygienic aspects must be taken into account. It is optimal if the gas flow is heated in the jet ventilator, but the humidity is only supplied in the hose system. This prevents germination of water-bearing elements in the jet ventilator and eliminates the need for time-consuming preparation of the jet ventilator.



Notice:

Although this method allows sufficient oxygenation, hypercapnia can develop very quickly. Due to injector effects, the initially very small tidal volumes undergo augmentation so that, at frequencies between 15 and 20 per minute, they are comparable to conventional breaths.

12.1.2 Superimposed High-Frequency Jet Ventilation (S-HFJV)

Normal Frequency:

The Normal-Frequency Jet Ventilation (NFJV frequency adjustable from 1-120 pulses/min) is responsible for the PIP and enables CO₂ elimination.

High Frequency:

The High-Frequency Jet Ventilation (HFJV frequency adjustable from 50 - 2000 pulses/min) is responsible for the PEEP and sufficient oxygenation.

S-HFJV:

Superimposed High-Frequency Jet Ventilation [S-HFJV] is defined as the simultaneous administration of a high-frequency jet gas and a normal-frequency jet gas into the patient's trachea.

Functionally, the combination of the two jets streams of different frequencies creates two variable pressure levels. The upper (= inspiratory) pressure level (PIP=Pin_{sp}) is generated by the jet pressure of the normal-frequency gas flow, the lower (= expiratory) pressure level (= PEEP) is generated by the jet pressure of the high-frequency gas flow.

Ventilation Patterns:

Since both normal-frequency and high-frequency jet ventilation can be activated and deactivated independently (by means of one ON/OFF button per ventilation unit), a total of three different ventilation modes are possible with this unit.

1. S-HFJV combines both NFJV and HFJV. This standard ventilation mode is the combination of the two, which is Superimposed High-Frequency Jet Ventilation with and without PULSE.

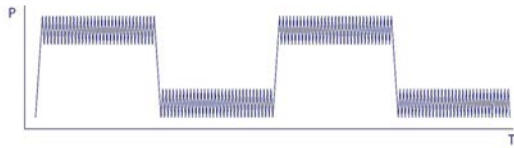


Fig.13 Ventilation with PULSE

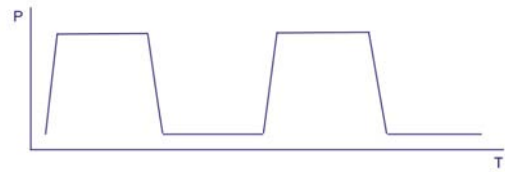


Fig.14 Ventilation without PULSE

1. HFJV generates pulsatile PEEP/CPAP. HFJV with deactivated PULSE generates continuous PEEP/CPAP.



Fig.15 Ventilation with PULSE



Fig.16 Ventilation without PULSE

2. NFJV generates a pressure plateau during the inspiration phase, similar to a conventional PCV.



Fig.17

12.1.3 Influences on Gas Exchange

- The inspiratory oxygen concentration can be regulated between 21 and 100% and has a significant influence on oxygenation.
- The emission pressure HF influences the oxygenation via the resulting PEEP.
- The emission pressure NF influences the CO₂ elimination (PIP over PEEP).
- The frequency NF influences the CO₂ elimination (change from PIP to PEEP).
- The I:E ratio of the NF influences the CO₂ elimination (long E phase).

12.2 Pressure Measurement

The mean airway pressure measurement shall be referenced to the trachea.

12.2.1 Airway pressure measurement (P_{AW}) during S-HFJV

Depending on the ventilation mode, airway pressure P_{AW} is measured continuously and monitored by the alarm unit. Due to the open system, the resulting airway pressure is dependent on the accessories used. This measurement is used during the S-HFJV in the entire frequency range. The pressure curve is displayed on the screen with real time raw data.

Terms of Pressure Measurement Values:

- **PIP:** The fluctuations in the high frequency are removed from the continuous pressure measurement. This results in the pressure from low frequency ventilation plus the average pressure of high frequency ventilation. The displayed value then corresponds to the maximum value during the inspiration phase.
- **MP_{AW} :** The displayed value corresponds to the mathematical mean value of a period (I + E phase of the NF) of the continuous pressure measurement. The sampling rate is 5ms.
- **PEEP:** The fluctuations in the high frequency are removed from the continuous pressure measurement. This results in the average pressure of high frequency ventilation. The displayed value then corresponds to the minimal value during the expiration phase.
- **Δp_{HF} :** After each period of the HF (i:e phase), the difference between the maximum and minimum of the previous phase is determined. This value is averaged over the last 3 periods.

⚠ Caution:

- During the use of ETT/LMA mode the Mean Airway Pressure Measurement (MP_{AW}) is not available!
- During the use of 1 LUM, 2 LUM PAW and 2 LUM GAS mode Δp_{HF} is not available.

12.2.2 Pause Pressure Measurement PP during HFJV

The Pause Pressure is the pressure measured in the jet line between two jet pulses. The Pause Pressure is measured 10 milliseconds before the next inspiration phase. The Pause Pressure is related to the actual airway pressure but is not a substitute for continuous measurement of airway pressure which is always to be preferred. Pause Pressure is only able to deliver information about the End-Expiratory Pressure! This measurement is used during HFJV in the safe frequency window of 50-200/minute.

12.3 Respiratory Gas Analysis

This respiratory gas analysis is informative in nature for the OR applications and is equipped with alarm functions. The sensors for gas analysis are calibrated and tested during the start-up self-test. If there is a disturbance the user is informed by an error message. However, the apparatus can be used when these disturbed functions are specifically deactivated (FiO₂ AW and/or etCO₂ inactive). A blood gas analysis should then be performed at intervals of 5 - 10 minutes.

Within the operating range mentioned in chapter 20.1 the accuracy mentioned in chapter 23.6 is not effected.

⚠ Caution:

Humidity in the gas sample higher than 95% relative or condensate can negatively effect the accuracy of the FiO₂ AW and etCO₂ measurement.

12.3.1 FiO₂ AW measurement

The measurement of the FiO₂ AW is useful for assessing the risk of the use of lasers in the airway. For maximum safety do not use lasers in oxygen concentrations above 40% and check that the Laser Safe Mode lights up green.

Comparison with the FiO₂ jet helps in assessing the amount of entrainment during supraglottic Jet Ventilation.

Also, it helps to interpret the etCO₂ via the difference of FiO₂ AW to FiO₂ jet.

FiO₂ AW displays the highest measured value within the last inspiration of the NF.

⚠ Caution:

- Leaks in the measurement line negatively effect the accuracy of the measurement.
- Manipulation with surgical instruments or similar inside the instrument during measurement can effect the accuracy of the measurement.

12.3.2 etCO₂ and cCO₂ measurement

The etCO₂ value provides information about the efficiency of ventilation. Based on this information, hypocapnia as well as hypercapnia can be remedied by changes in the ventilation parameters. A closely-monitored measurement is recommended approximately every 5 minutes. The etCO₂ measurement is an on demand measurement that can be started manually (manoeuvre mode).

etCO₂ displays the highest measured value within the last 3 NF cycles (Breaths).

cCO₂ measures the highest measured value within the last 5 NF cycles (Breaths). This is corrected with the initial value of the etCO₂ baseline measurement and displayed. Values are measured continuously (continuous mode).

⚠ Caution:

- Leaks in the measurement line negatively effect the accuracy of the measurement.
- Manipulation with surgical instruments or similar inside the instrument during measurement can effect the accuracy of the measurement.

12.4 Bias Flow Module

The O₂ bias flow is a continuous gas flow emitted by the ventilator and is responsible for the replenishing of oxygen and removing carbon dioxide from the patient circuit. Bias flow has always 100% FiO₂. O₂ bias flow can be used in any mode with external display in TwinStream™ EVO S-HFJV variant.

Moreover, the bias flow is often used to prepare patients for the anaesthesia or to introduce the anaesthesia with a ventilation bag before intubation.

In ear-nose-throat (ENT) and bronchoscopy departments the bias flow is also sometimes used to mixture the jet streams in the instrument with warmed and moisture to prevent the airways and lung from drying.

12.5 Laser Safe Mode

12.5.1 Intended Purpose

The Laser Safe Mode has a special behavior to avoid the risk of burns, explosion or explosive fires in the airway during laser application in the surgery, which could result in severe damage to the patient. Therefore, the FiO₂ jet value must be reduced to maximum 40% before the application of laser energy. Furthermore, only anaesthetic procedures are to be selected which do not require inhalation anaesthesia. TIVA anaesthesia cannot produce alveolar-damaging pyrolysis

products. The TIVA and TwinStream™ EVO combination meets these requirements and has been implemented in the TwinStream™ EVO as Laser Safe Mode.

Warning:

The operating instructions of the laser must be followed. The prescribed Personal Protective Equipment (PPE) and smoke evacuation must be used to prevent the risk of infection to the operating theater team. The smoke evacuation prevents the backflow of the laser smog even with the open ventilation system.

12.5.2 FiO₂ jet Value

For LSM FiO₂ jet is configured between 21% and 40%. If LSM is activated, FiO₂ jet is reduced to this range and returns to the previous value after deactivation. User can reduce the maximum FiO₂ jet lower than 40% either in system menu or when LSM is activated. After selecting the ventilation mode or with active ventilation, the configured FiO₂ jet is set automatically by the device after the start of the Laser Safe Mode.

To reach this set FiO₂ jet will take a few minutes - this is important in order to wash out a possibly very high oxygen concentration from the respiratory tract and thus also to reduce the oxygen saturation of the affected tissue. The actual oxygen concentration is shown on the screen FiO₂ AW (optional).

12.6 Rechargeable Batteries

In the event of loss of power or a mains voltage failure, TwinStream™ EVO automatically switches to the internal battery without interrupting the ventilation. An alarm sound occurs to signal the switch-over "Switch to battery mode"(see "Alarm List-Device Alarm").

Batteries are charged whenever the ventilator is connected to the primary power supply.

Following information is shown in battery mode depending on the battery state:

-  Switch to internal power supply battery, battery full (>80%), lasts at least 15 minutes
-  Battery less than 80%
-  Low battery, 10 minutes remaining
-  Low battery, 5 minutes remaining
-  Battery empty, device will be switched off in the next minutes
-  Battery loading
-  No battery connected or battery defective

The operating time of the battery depends on the settings and the condition of the battery (age and battery charge). A fully charged battery can supply for at least 15 minutes.

All monitoring functions remain in operation until the battery is completely discharged and all electronic components are switched off.

When the battery is completely discharged, TwinStream™ EVO switches off. All individual settings, including the alarm limits that deviate from the standard settings get lost.

12.7 PULSE

PULSE is used for deactivation or activation of the pulsatile part of the ventilation pattern. TwinStream™ EVO S-HFJV variant can be equipped with PULSE option, except for 1LUM CAT and 2 LUM CAT modes. The example screens from each mode with or without PULSE option can be found in the [chapter 14.1.2 "System Overview-Operating Screen"](#).

The following two screenshots display the graphs in LAR mode when PULSE function is active and inactive.



Fig.18 LAR mode PULSE active



Fig.19 LAR mode PULSE inactive

12.8 Ventilation Modes

TwinStream™ EVO offers different ventilation modes such as LAR, BRO and ETT/LMA based on an algorithm which provides the default ventilation parameters depending on the patient weight. For ventilation with Jet Catheters the device offers 1-4 LUM modes depending on the used catheter.

12.8.1 Definition

- **LAR:** Ventilation mode for application with a Jet Laryngoscope.
- **BRO:** Ventilation mode for rigid bronchoscopy with a Jet Bronchoscope or Jet Coupling with a standard bronchoscope.
- **ETT/LMA:** Ventilation mode with Jet Converter.
- **4 LUM, 3 LUM, 2 LUM PAW, 2 LUM GAS, 1 LUM:** Ventilation modes with a Jet Catheter for the respective mode.
- **Expert mode:** Ventilation mode for application with a Jet Endoscope for different new operation techniques. The sidebar can show all available and measured parameters.

12.8.2 Ventilation Mode Standard Configuration and Default Settings

Ventilation Mode Standard Configuration and Options

TwinStream™ EVO S-HFJV										
Ventilation Mode	LSM	O ₂ bias flow	NF	HF	PP	P _{AW}	FiO ₂ AW	etCO ₂	PULSE	BW Required
LAR 	✓	✓	✓	✓	X	✓	✓	✓	✓	✓
BRO 	✓	✓	✓	✓	X	✓	✓	✓	✓	✓
ETT/LMA 	✓	✓	✓	✓	X	✓	✓	✓	✓	✓
4 LUM 	✓	✓	✓	✓	X	✓	✓	✓	✓	X
3 LUM 	✓	✓	✓	✓	X	✓	X	X	✓	X
2 LUM PAW 	✓	✓	X	✓	✓	✓	X	X	X	X
2 LUM GAS 	✓	✓	X	✓	✓	X	✓	✓	X	X
1 LUM 	✓	✓	X	✓	✓	X	X	X	X	X
Expert 	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Applicable: ✓ Not Applicable: X

TwinStream™ EVO HFJV										
Ventilation Mode	LSM	O ₂ bias flow	NF	HF	PP	P _{AW}	FiO ₂ AW	etCO ₂	PULSE	BW Required
1 LUM 	✓	X	X	✓	✓	X	X	X	X	X

Applicable: ✓ Not Applicable: X

After selection of the ventilation mode and the accessories needed for its use, and after entering the current weight of the patient (LAR, BRO and ETT/LMA mode), the particular default ventilation settings are generated. Depending on the mode, the emission pressures are calculated and frequencies, I:E ratios, FiO₂ jet, and the upper and lower pressure limits are set.

Ventilation Mode Default Settings

Ventilation Mode	Weight Group	FiO ₂ jet	O ₂ bias flow (L/min)	NF Pressure (bar)	NF Frequency (BPM)	NF Ratio I:E	HF Pressure (bar)	HF Frequency (BPM)	HF Ratio i:e
1 LUM	NA	80%	0	NA	NA	NA	1	120	1:2
2 LUM (GAS / PAW)	NA	80%	0	NA	NA	NA	1	120	1:2
3 LUM	NA	80%	0	1	12	1:1	1	600	1:2
4 LUM	NA	80%	0	1	12	1:1	1	600	1:2
LAR	0-200 kg	80%	0	0,6 - 2,0 WD*	12 - 20 WD*	1:1 - 1:1.5 WD*	0,5 - 1,3 WD*	600	1:1 - 1:1.5 WD*
BRO	0-200 kg	80%	0	0,3 - 1,5 WD*	12 - 20 WD*	1:1 - 1:2 WD*	0,2 - 0,8 WD*	600 - 800 WD*	1:1 - 1:1.5 WD*
ETT/LMA	0-200 kg	80%	0	0,3 - 1,5 WD*	12 - 20 WD*	1:1 - 1:2 WD*	0,2 - 0,8 WD*	600 - 800 WD*	1:1 - 1:1.5 WD*

*WD = value depends on selected weight

The values suggested at the default setting are based on experience and minimize the risk of complications due to the ventilation technique. After start of ventilation, the parameters must be adjusted to the requirements. For further settings, please refer to the chapter "Operation". There can be several presets, depending on the area of application. Only authorized personnel can change the presets.

13. Clinical Application

The TwinStream™ EVO is very versatile and can be used in a variety of situations according to the clinical need.

Application in Operation

Technique	Applicator	Mode	Patient Group	
			Adult/Pediatric	Babies ab 3 kg
Supraglottic S-HFJV	Jet Laryngoscope	LAR	✓	✓
	Jet Tracheoscope	LAR	✓	✓
	Jet Bronchoscope	BRO	✓	✓
	Jet Converter	ETT/LMA	✓	✓
Infraglottic S-HFJV	4 Lumen Catheter	4 LUM	✓	X
	3 Lumen Catheter	3 LUM	✓	X
Infraglottic HFJV	2 Lumen Catheter	2 LUM	✓	X
	1 Lumen Catheter	1 LUM	✓	X
	Ravussin needle	1 LUM	✓	X
	Rigid Bronchoscope	1 LUM	✓	✓

Applicable: ✓ Not Applicable: X

Note:

The following illustrations are schematic illustrations and always apply as appropriate to the respective application with and without humidification. A conventional ventilator must be ready for use during TwinStream™ EVO ventilation in order to be able to ventilate the patient at any time in an emergency.

13.1 Supraglottic S-HFJV with the original CARL REINER® Jet Laryngoscope or Jet Coupling

Ventilation Mode LAR

The ventilation mode LAR and accessories allow S-HFJV to be used with gas analysis and airway pressure measurement, with or without additional respiratory gas conditioning (optional).

LAR/S-HFJV with P_{AW} and gas analysis

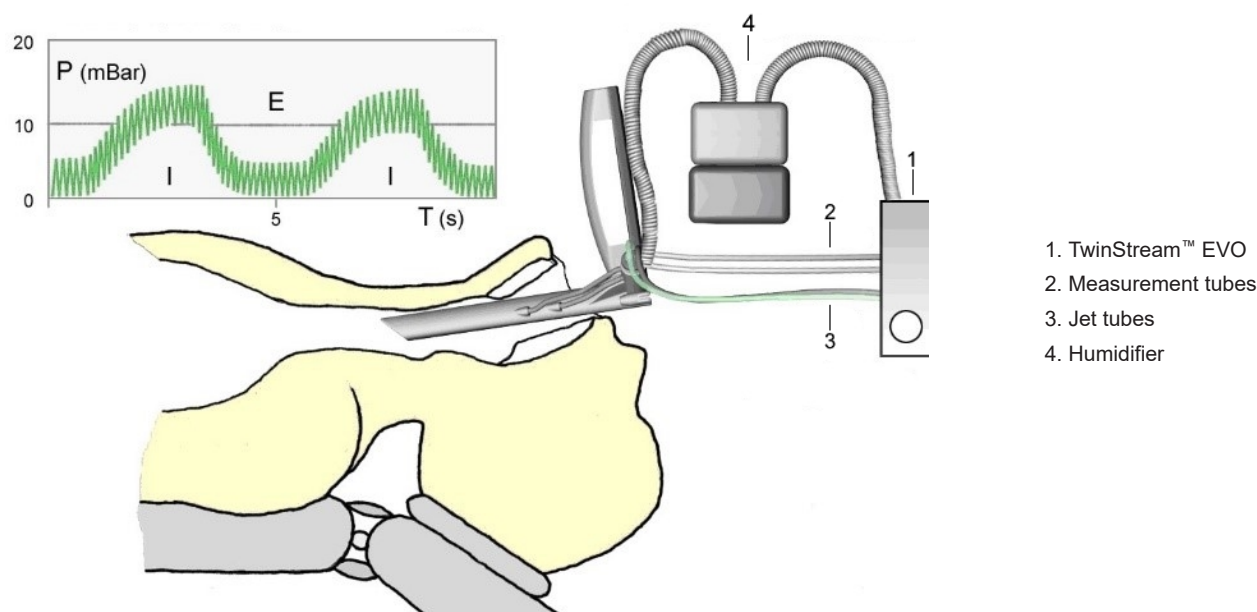


Fig.20 Dr. Aloy's technique

Application (Dr. ALOY's technique):

Ventilation mode for microlaryngeal interventions during supraglottic ventilation with the Jet Laryngoscope.

S-HFJV is applied via Jet Laryngoscopes in various sizes, and is suitable for nearly every patient from neonates to obese adults.

In laser surgery this procedure has become the method of choice because no inflammable materials are present at the operation site. This method is the only one to allow the larynx to be visualised naturally since there is no displacement of tissue due to the tube or Jet Catheter.

This ventilation technology offers very high security, since all relevant parameters are measured.

This mode provides the Laser Safe Mode.

Application Field in Surgery:

- . Laryngotracheal diagnostic procedures
- . Microsurgical interventions in central processes
- . Laser surgery
- . Vocal cord augmentation
- . Processes at the lateral commissure
- . Tumours and stenosis in the region of the glottis or in the subglottic space
- . Removal of foreign objects
- . Vocal cord polyp
- . Chronic laryngitis
- . Synechiae
- . Laryngomalacia
- . Glottis dilating lateral fixations
- . Subglottic hemangiomas
- . Reinke's oedema
- . Cysts
- . Bilateral vocal cord paresis
- . Sub-/supraglottic laryngeal stenosis
- . Posterior/anterior glottic stenosis
- . Tracheal stenosis
- . Papillomatosis
- . Amyloidosis
- . Granulation
- . Inspections
- . Chordectomy (vocal fold excision)
- . Leukoplakia

13.2 Supraglottic S-HFJV for stenting with the original Jet Laryngoscope

Ventilation Mode LAR

The ventilation mode LAR and accessories allow S-HFJV with gas analysis and of airway pressure measurement with or without additional respiratory gas conditioning. Furthermore, the stent forceps with the Y-stent is shown.

LAR / S-HFJV with P_{AW} and gas analysis

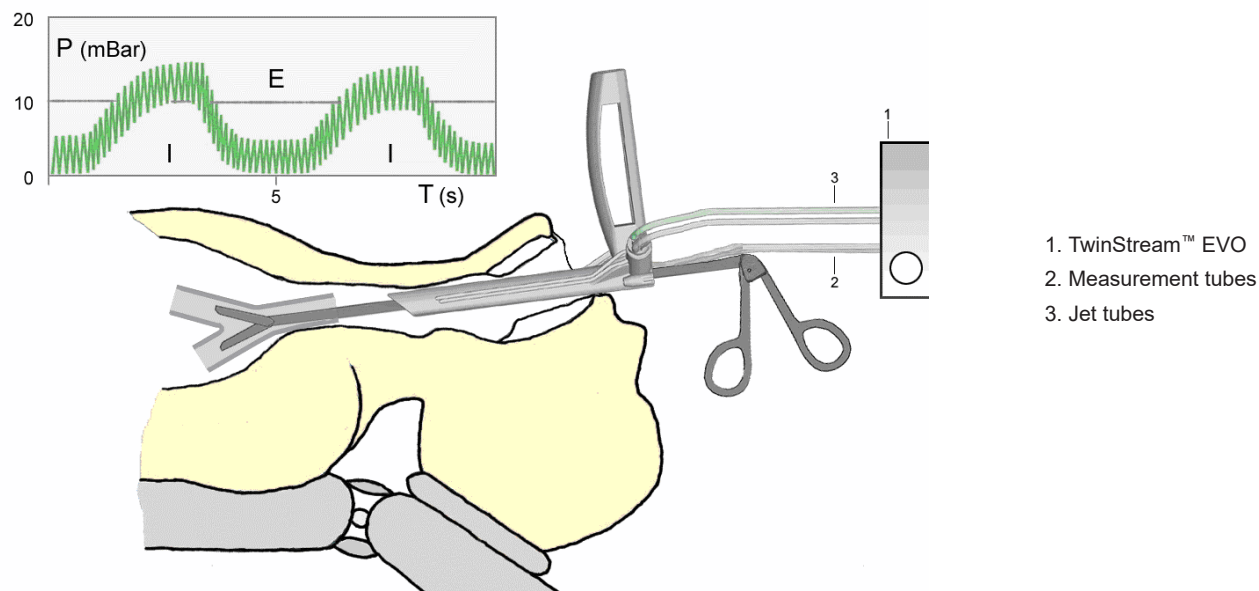


Fig.21 Dr. Aloy's technique

Application (Dr. ALOY's technique):

Ventilation mode for stenting (endoluminal splinting for tracheal and bronchial stenosis) during supraglottic ventilation: The method according to Dr. Aloy allows the application of Y-stents under continuous ventilation.

With stenting forceps, the stents are inserted through the Jet Laryngoscope (a small-bore laryngoscope with round design, which must be checked before use to see if the stent fits through the laryngoscope).

13.3 Supraglottic S-HFJV with Jet Bronchoscope or Jet Coupling

Ventilation Mode BRO

The ventilation mode BRO and accessories allow S-HFJV with gas analysis and airway pressure measurement with or without additional respiratory gas conditioning.

BRO / S-HFJV with P_{AW} and gas analysis

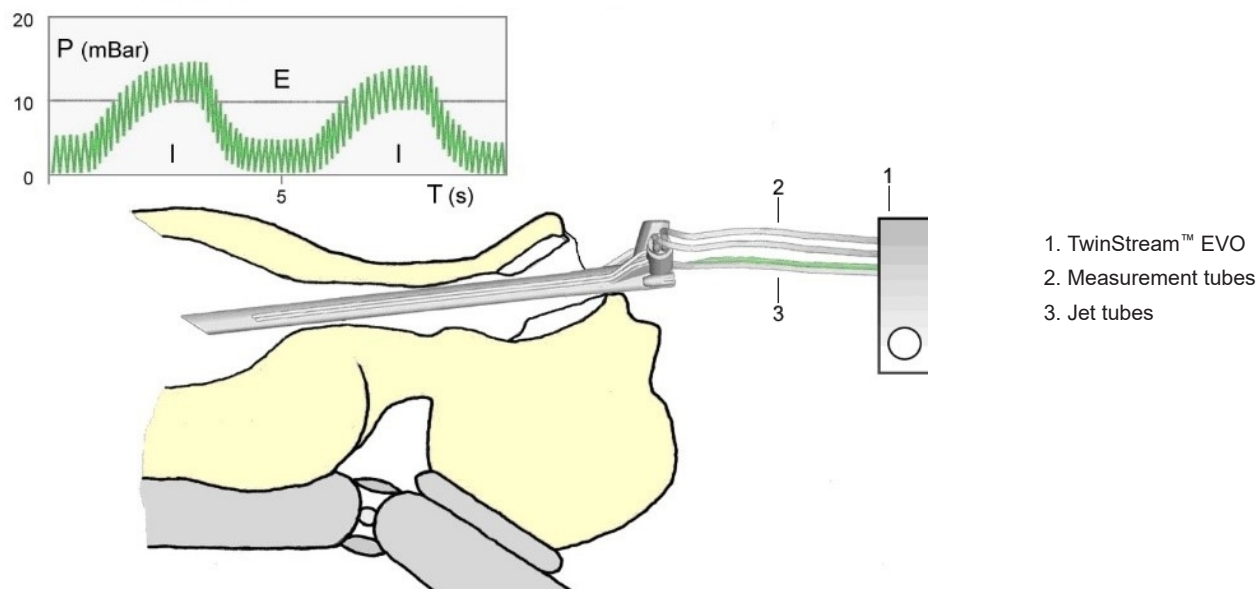


Fig.22 Dr. Aloy's technique

Application :

Ventilation mode for rigid bronchoscopy combined with a flexible endoscope (interventional bronchoscopy) (Sanders technique).

Combined rigid bronchoscopy extends the diagnostic options and allows mechanical re-canalization under optimized visibility. S-HFJV allows interventions to be performed in severely ill patients with reduced lung function because there is virtually no ventilatory limitation when the TwinStream™ EVO ventilator is used.

Application Field in Surgery:

- . Bronchological diagnostic procedures, including excisional biopsy
- . Extraction of foreign objects from the lower respiratory tract
- . Mechanical removal of granulation tissue
- . Placement (or removal) of stents
- . Endobronchial resection of tumours or tumour obstructions
- . Removal of loosened and aspirated tissue fragments
- . Removal of large blood clots
- . Primary and secondary bronchial toilet
- . Debridement after laser procedures
- . Debridement after photodynamic therapy
- . Laser surgery
- . APC-Coagulation

13.4 S-HFJV with Jet Converter for surgical procedures

Ventilation Mode ETT/LMA

ETT/LMA / S-HFJV with Jet-Converter for surgical interventions

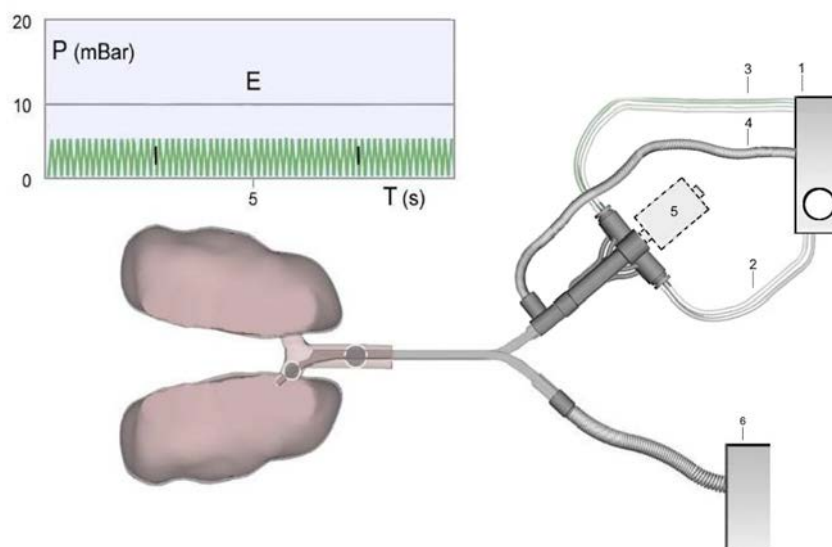


Fig.23 Jet Converter connected to heating and Filter
ETT/LMA / S-HFJV with Jet-Converter for cardiology etc.

1. TwinStream™ EVO
2. Measurement tubes
3. Jet tubes
4. Humidifier
5. Filter
6. Anaesthesia machine

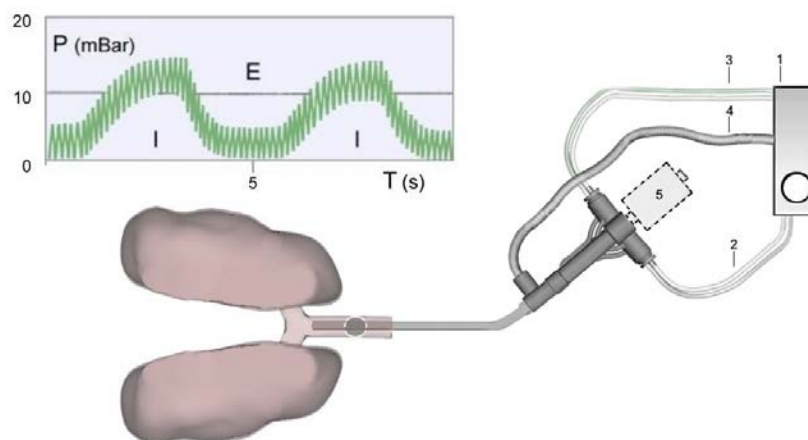


Fig.24

Application:

Mode for Independent Lung Ventilation, Normal-Frequency, High-Frequency or S-HFJV (E.g. for lung resection) using the Jet Converter for lung surgery with a double lumen tube.

Description of the application cardiology etc. where we want to deactivate the lung movement to create the best possible conditions for the procedure. To immobilise the lung while undergoing several treatments e.g. RF ablation, 3D-navigational bronchoscopy, liver ablation etc.

In terms of ventilation technique this mode offers a high degree of safety because all relevant parameters are measured. Also, the Laser Safe Mode can be used.

13.5 S-HFJV with Jet Catheter for surgical procedures

Ventilation Mode 4 LUM

The ventilation mode 4 LUM and accessories allow S-HFJV with gas analysis and measurement of airway pressure with or without additional respiratory gas conditioning.

4 LUM Catheter / S-HFJV with P_{AW} and gas analysis

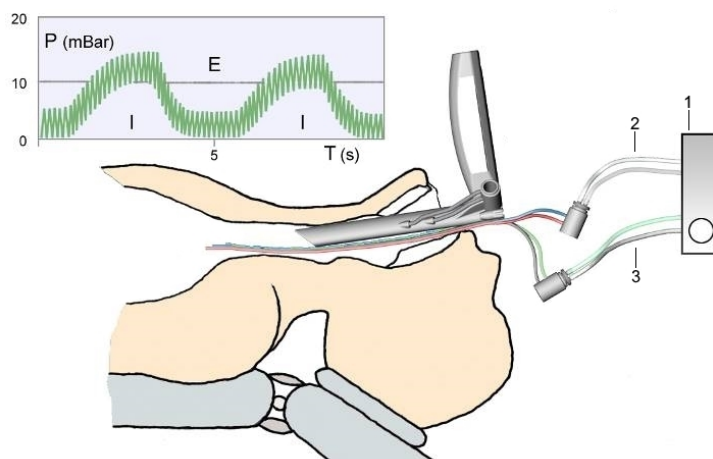


Fig.25 shows the situation during MLS under poor anatomical conditions, 4 -lumen Catheter/S-HFJV with P_{AW} and gas analysis

4 LUM Catheter / S-HFJV with P_{AW} and gas analysis

1. TwinStream™ EVO
2. Measurement tubes
3. Jet tubes

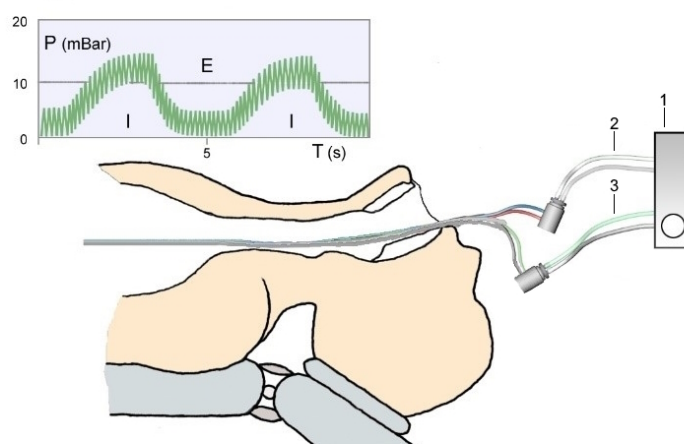


Fig.26 shows the situation during lung surgery

Application:

Ventilation mode for microlaryngeal surgery under infraglottic jet ventilation with a Jet Catheter and a standard laryngoscope.

This ventilation mode is used for microlaryngeal surgery only in cases of complex anatomical conditions. Laser surgery should not be performed with this mode because the 4-lumen catheter is made of non-laser-safe material! Details please refer to the IFU of Jet Catheter.

Ventilation mode for selective unilateral isolated Jet Ventilation, Normal-Frequency or High-Frequency or S-HFJV (in cases of lung resection) under infraglottic ventilation with a Jet Catheter without an endoscope, for chest surgery with a special Jet Catheter.

Because of the optional length of the catheter single-lung ventilation is possible during chest surgery. Due to the diameter of the Jet Catheter this method can only be used in adults.

Provides very high safety in terms of ventilation technique because all relevant parameters can be measured via the catheter lumen.

Ventilation Mode 3 LUM

The mode of ventilation 3 LUM and accessories allow S-HFJV with airway pressure measurement with or without additional respiratory gas conditioning.

3 LUM Catheter / S-HFJV with P_{AW}

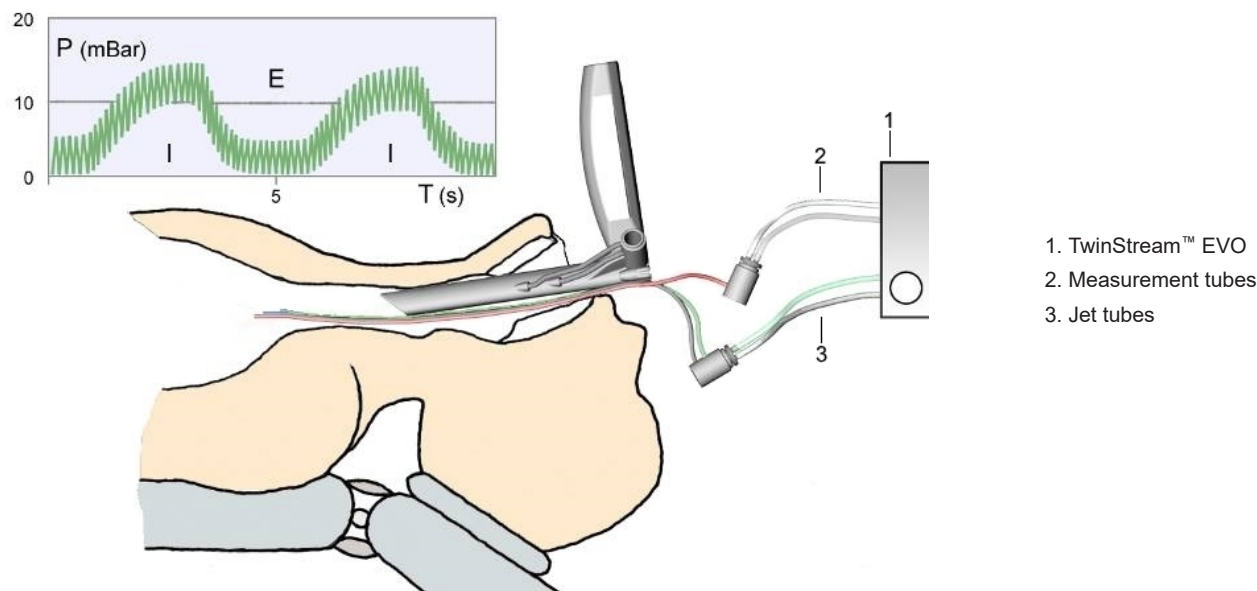


Fig.27 shows the situation in MLS under poor anatomical conditions

Application:

Ventilation mode for microlaryngeal interventions under infraglottic jet ventilation with Jet Catheter and standard laryngoscope.

This ventilation mode will be used for microlaryngeal surgery in difficult anatomical conditions. Laser surgery must not be carried out with this mode because the 3-lumen Catheter is made of non-laser-safe material! Details please refer to the IFU of Jet Catheter.

Ventilation is very safe as the P_{AW} is measured and displayed.

13.6 HFJV with Jet Catheter for surgical procedures

Ventilation Mode 2 LUM GAS

The ventilation mode 2 LUM GAS and accessories offer High-Frequency Jet Ventilation, respiratory gas analysis and pause pressure measurement.

2 LUM GAS/ HFJV with PP and gas analysis

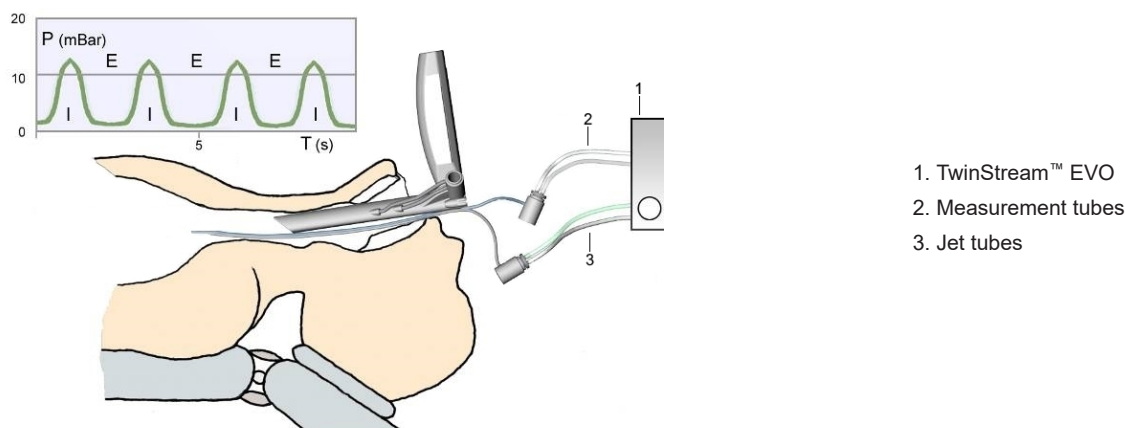


Fig.28 shows the situation during MLS under poor anatomical conditions

Application:

Microlaryngeal interventions under infraglottic jet ventilation with a Jet Catheter and selective unilateral isolated High-Frequency Jet Ventilation (for lung resection) under infraglottic ventilation, with a Jet Catheter for lung surgery.

This ventilation mode will only be used for microlaryngeal surgery in difficult anatomical conditions. Laser resistance is only guaranteed to a limited extent. The Jet Catheter material is not flammable but damage is possible. Details please refer to the IFU of Jet Catheter.

This method is applicable for adults and children, whereby the ratio of the trachea DM to the Jet Catheter DM must be observed.

Ventilation must be adjusted by means of gas analysis and pause pressure measurement - whereby the PP corresponds to the PEEP. At higher frequencies, either the blood gas control must be closely meshed or a tcCO_2 measurement must be used. In both cases, ventilation must be adapted to the user's experience and requirements.

From a ventilation point of view, this ventilation mode offers indirect safety since ventilation stops if the pause pressure is exceeded.

Ventilation Mode 2 LUM PAW

The ventilation mode 2 LUM PAW and accessories offer High-Frequency Jet Ventilation with airway pressure measurement.

2 LUM PAW/ HFJV with PP and airway pressure measurement

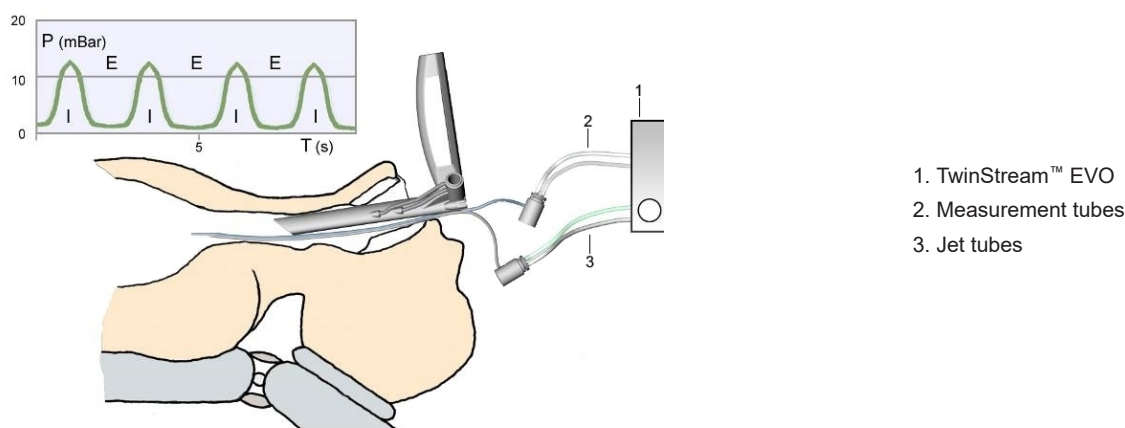


Fig.29 shows the situation during MLS under poor anatomical conditions

Ventilation Mode 1 LUM

The ventilation mode 1 LUM and the accessories allow High-Frequency Jet Ventilation and pause pressure measurement with or without additional respiratory gas conditioning.

1 LUM Catheter / HFJV with PP

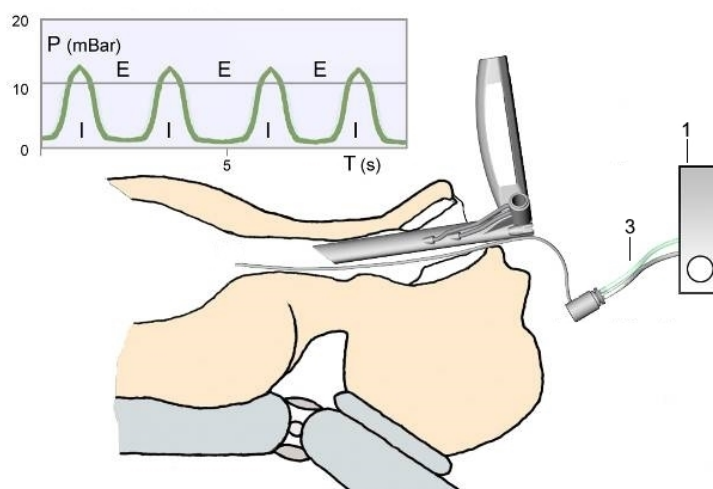


Fig.30 shows the situation during MLS under poor anatomical conditions
RAVUSSIN / HFJV with PP

- 1. TwinStream™ EVO
- 3. Jet tubes

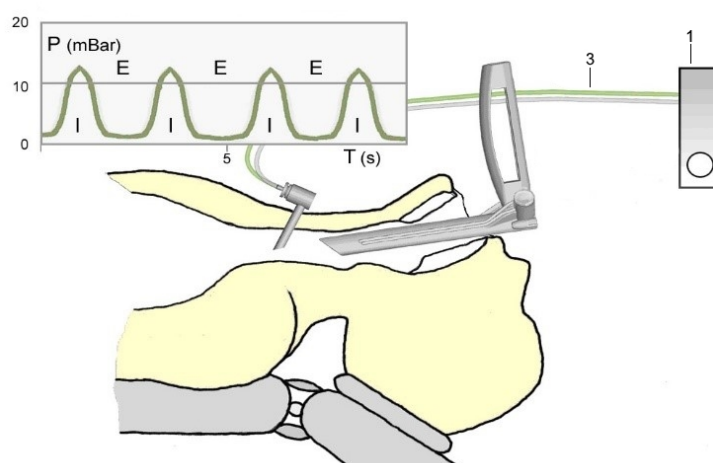


Fig.31 Percutaneous transtracheal Jet Ventilation using the
Ravussin technique Ravussin/HFJV with pause pressure tubing set

Application:

Microlaryngeal interventions under infraglottic jet ventilation and selective unilateral isolated High-Frequency Jet Ventilation (for lung resection) under infraglottic ventilation with a Jet Catheter for lung surgery or percutaneous transtracheal Jet Ventilation using the Ravussin technique.

Laser resistance is only guaranteed to a limited extent with the laser protective Jet Catheter types. Details please refer to the IFU of Jet Catheter. This Jet Catheter material is not flammable but damage is possible.

This method is applicable for adults and children, whereby the ratio of the trachea DM to the Jet Catheter DM must be observed.

Ventilation must be adjusted by means of pause pressure measurement - whereby the PP corresponds to the PEEP. At higher frequencies, either the blood gas control must be closely meshed or a tcCO_2 measurement must be used. In both cases, ventilation must be adapted to the user's experience and requirements.

From a ventilation point of view, this ventilation mode offers indirect safety since ventilation stops if the pause pressure is exceeded.

 Note:

In percutaneous transtracheal Jet Ventilation with "ravussin" technique, a ravussin cannula is placed (see operating instructions for ravussin cannula) and connected to the Jet tubes .

Application field in Surgery:

Injuries in the cervical spine, surgery of the vocal cords and emergency treatment, if intubation is impossible (for instance, in cases of massive injury to the skull).

13.7 Minimum Requirements for MLS in the Operating Theatre

- anaesthesia respirator for ventilation during initial and final phases and emergencies
- CGS outlets for 2 respirators
- CGS pressure: minimum 2.8 bar, maximum 6 bar
- ECG monitor
- pulse oximeter
- infusion syringe pump for TIVA
- stethoscope
- blood pressure monitoring device
- ETT of correct size
- for additional safety a blood gas analyser should be available close by
- Laser surgery: Laser as well as effective smoke extraction unit!

14. System Overview

14.1 TwinStream™ EVO S-HFJV

TwinStream™ EVO S-HFJV has two displays:

- External panel (15,6" touchscreen) which displays safety relevant information and implements the most important interaction functions. External display has dark and light modes which can be set in the configuration.
- Internal display (5" touchscreen) in housing which consists of a simple User Interface and can be used as fallback solution in case of a panel failure. Internal display has only dark mode.

14.1.1 Main Menu

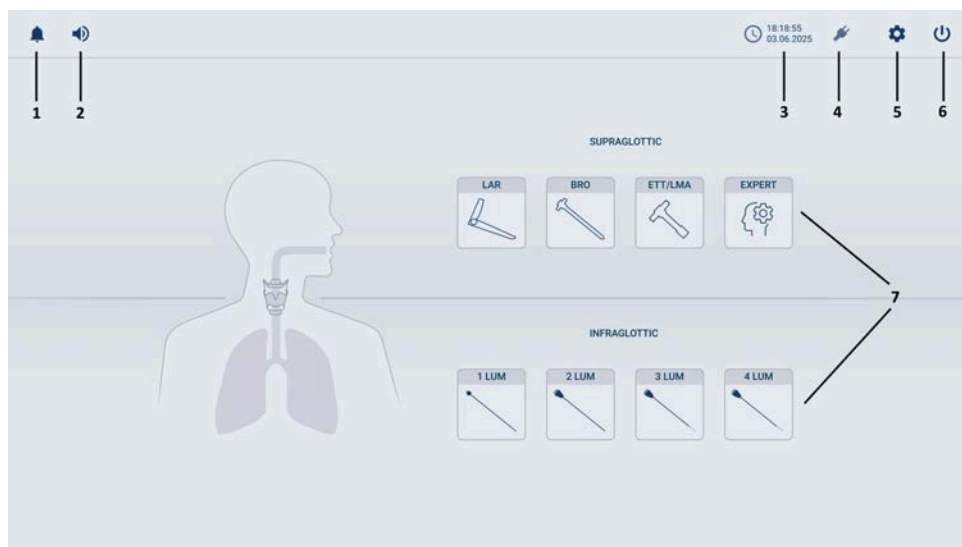


Fig.32 Main menu-external panel

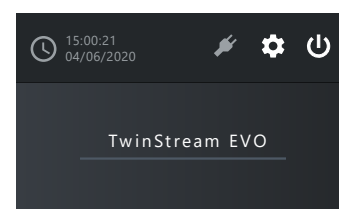


Fig.33 Main menu-internal display

1. Alarm indicator
2. "Mute" button to mute the acoustic alarm signal for 1 minute
3. Current time and date
4. Device power state (on power, on battery, battery status)



Main power supply



Switch to internal power supply battery, battery full (>80%), lasts at least 15 minutes



Battery less than 80%



Low battery, 10 minutes remaining.



Low battery, 5 minutes remaining



Battery empty, device will be switched off in the next minutes



Battery loading



No battery connected or battery defective

5. Configuration menu access
6. Power switch
7. Ventilation modes

14.1.2 Operating Screen

LAR, BRO, ETT/LMA, 4 LUM mode

Except the name of the ventilation mode, external and internal displays from LAR, BRO, ETT/LMA and Expert modes show same safety relevant information and implements the most important interaction functions.

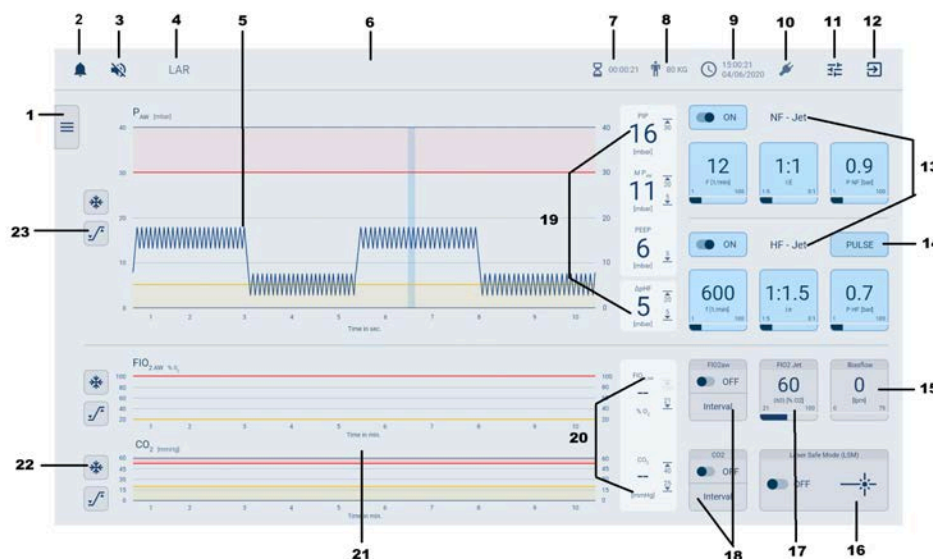


Fig.34 LAR mode-external display

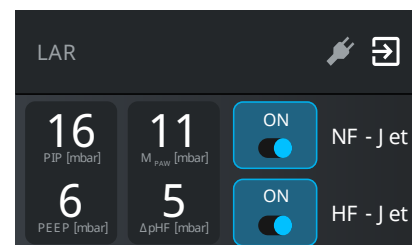


Fig.35 LAR mode-internal display

1. Sidebar
2. Alarm indicator
3. "Mute" button to mute the acoustic alarm signal for 1 minute
4. Current ventilation mode
5. Airway pressure /pause pressure graph (pause pressure graph only available in 1 or 2 LUM mode)
6. Alarm message bar
7. Ventilation time since starting the ventilation mode
8. Patient weight
9. Current time and date
10. Device power state (on power, on battery, battery status), details refer to No. 4 from main screen
11. Quick setting (volume and display brightness)
12. "Exit Button", exit ventilation mode and switch back to the main menu
13. NF & HF ventilation units
14. PULSE: Activates/deactivates the pulsation from the high frequency jet stream
15. O₂ bias flow button
16. Laser Safe Mode (on/off)
17. FiO₂ jet function
18. Gas analysis function
19. Airway pressure monitoring values:
 - . Peak pressure (PIP)
 - . Medium/Average airway pressure (MP_{AW})
 - . Positive end-expiratory pressure (PEEP)
 - . ΔpHF
20. Gas analysis measurement values (FiO₂ AW & etCO₂)
21. Gas analysis graph
22. Freeze button, to stop the continuous display of P_{AW}/PP or etCO₂/FiO₂ AW graph.
23. Alarm limits settings

Expert Mode

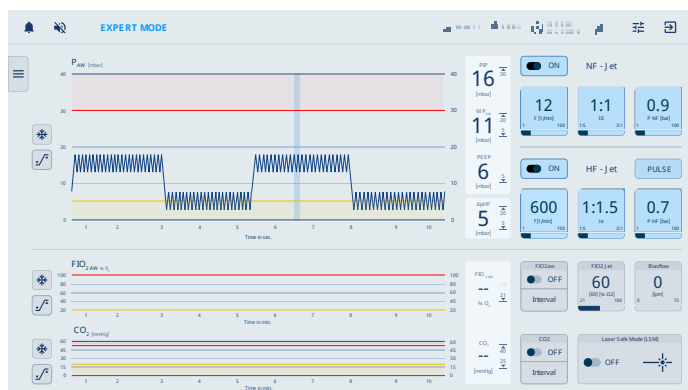


Fig.36 Expert mode-external display



Fig.37 Expert mode with sidebar settings-external display

3 LUM mode



Fig.38 3 LUM mode-external display

**Note:**

The internal displays from Expert and 3 LUM modes are the same like LAR, BRO, ETT/LMA, 4 LUM modes.

2 LUM GAS mode

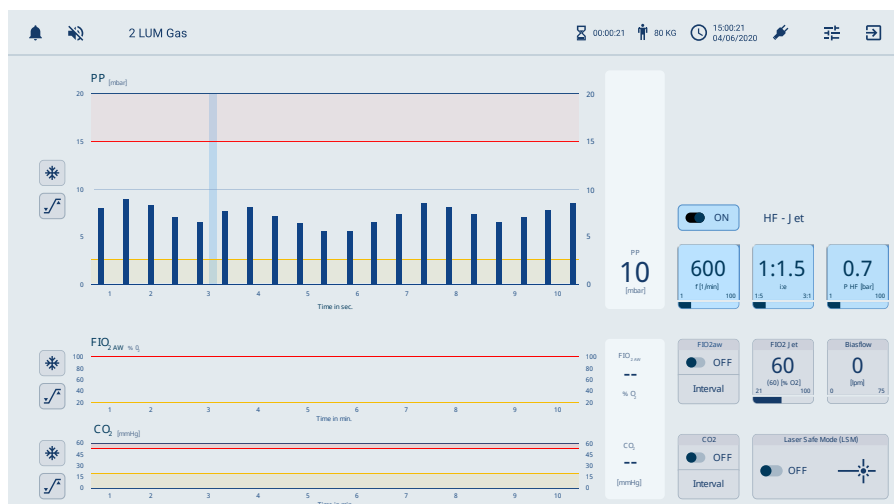


Fig.39 2 LUM GAS mode-external display

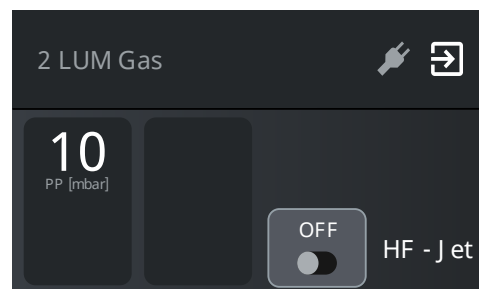


Fig.40 2 LUM GAS mode-internal display

2 LUM PAW mode



Fig.41 2 LUM PAW mode-external display

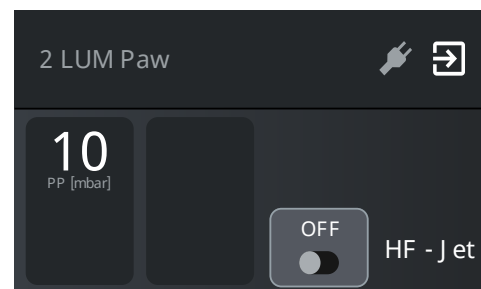


Fig.42 2 LUM PAW mode-internal display

1 LUM mode

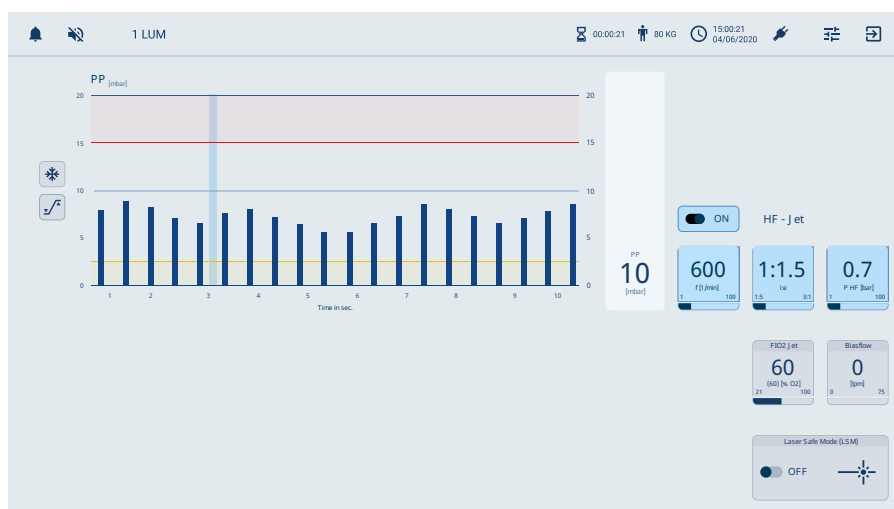


Fig.43 1 LUM mode-external display

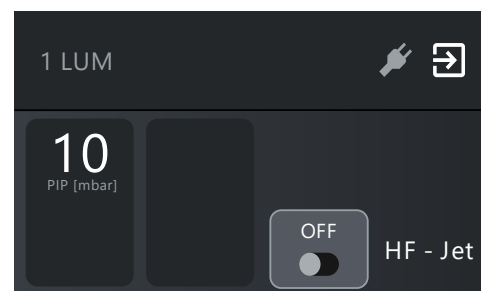


Fig.44 1 LUM mode-internal display

14.2 TwinStream™ EVO HFJV

TwinStream™ EVO HFJV has one internal display (5" touchscreen) which displays all safety relevant information and implements the most important interaction functions. It has only dark mode.

14.2.1 Main Menu

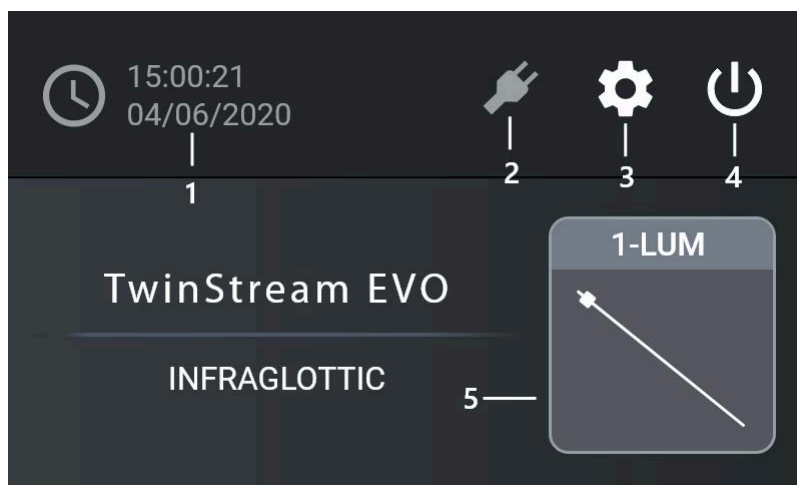


Fig.45 TwinStream™ EVO HFJV main menu

1. Current time and date
2. Device power state (on power, on battery, battery status), details refer to No. 4 of TwinStream™ EVO S-HFJV "Main Menu".
3. Configuration menu button
4. Power switch
5. Ventilation mode

14.2.2 Operating Screen



Fig.46 TwinStream™ EVO HFJV operating screen

1. "Mute" button to mute the acoustic alarm signal for 1 minute
2. Current ventilation mode
3. Device power state (on power, on battery, battery status), details refer to No. 4 from TwinStream™ EVO S-HFJV main screen
4. "Exit Button", switch back to the main menu from the current ventilation mode
5. HF ventilation unit (on/off)
6. Alarm limits settings
7. Pause pressure monitoring value
8. FiO₂ jet button
9. Laser Safe Mode (on/off)
10. Parameter settings

15. Operation

Disclosure / Description of the workspace:

- To use the TwinStream™ EVO properly, the operator must stand facing, and within reach of, the display screen.
- The display can be read anywhere within a distance of 3 m and an angle of 160°. (Normal vision assumed).

Connection:

1. Connect CGS hoses for medical oxygen and medical air. Gas supply specification please refer to Chapter 23.8
2. Connect power plug and equipotential bonding cable (If the device is operated via a multiple socket).

Warning:

To prevent increased patient leakage currents, the device and the patient must not be touched at the same time.

Caution:

- To ensure the ventilator maintains the accuracy of controlled and displayed variables as disclosed in chapter 23 the conditions of Chapter 20 must be observed.
- The device is not intended to be used with closed suction systems.

Notice:

- If the device is operated via a multiple socket, use the equipotential bonding cable! Equipotential bonding prevents an electrically different potential between devices from leading to uncontrolled discharges.
- By connecting the equipotential bonding may a Medical Equipment system is build, requirements for medical equipment systems according to EN ISO 60601-1 must be observed

15.1 TwinStream™ EVO S-HFJV

15.1.1 Switching the ventilator on

Press the  Symbol on TwinStream™ EVO housing for 2 seconds, the light above the button will be illuminated in blue.

15.1.2 Selftest initiation

1. The ventilator executes a completely automatic selftest after it is switched on. The valves, the electronics, the sensors, the alarm system and the modules are tested. The test lasts about 1 minute.
2. If the selftest fails with errors, no ventilation is possible. An error or warning message is displayed. Detail information please refer to the [Chapter 17.11.3 "Alarm List-Selftest"](#).

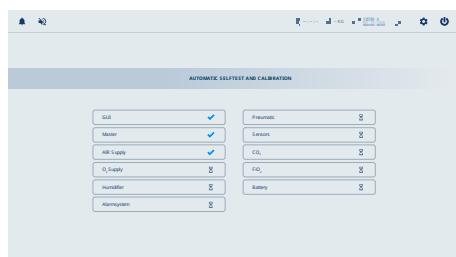


Fig.47 Selftest running

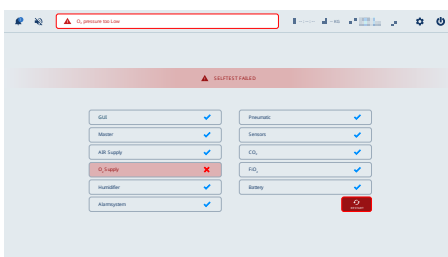


Fig.48 Selftest error

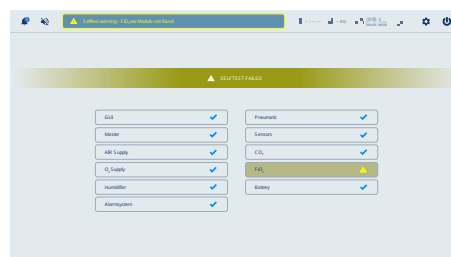


Fig.49 Selftest warning

Caution:

Tubing set and patient must be disconnected from the device during selftest!

15.1.3 Ventilation Mode Selection

1. After a successful selftest, the main menu will be shown on the display. Press one of the ventilation symbols to select a ventilation mode.
2. If one of the ventilation modes from LAR, BRO, ETT/LMA and EXPERT is selected, the current weight of the patient is required to be entered. Confirm with ✓ button, system switches into the selected ventilation mode.

Note:

"Patient Weight" dialogue closes after 10 seconds if there's not any operation.

Caution:

Always choose the correct ventilation mode and current patient weight to make sure alarm presettings are set adequate.

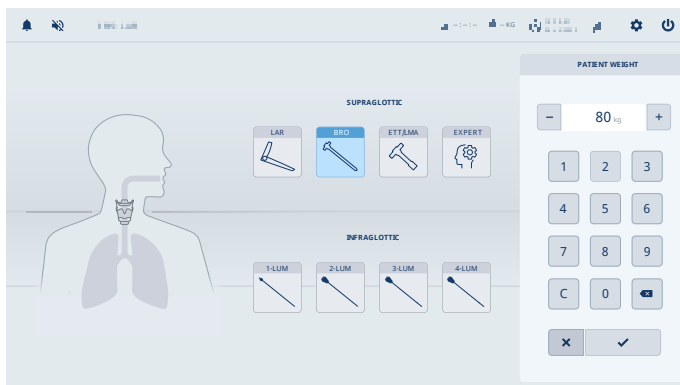


Fig.50 Selected ventilation mode BRO, current patient weight required

3. To select a ventilation mode from 4 LUM, 3 LUM, 2 LUM and 1 LUM, entering current patient weight is not required. System switches into the selected ventilation mode directly.

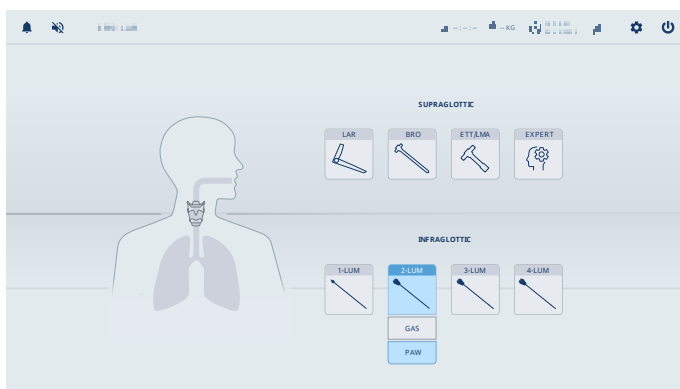


Fig.51 Selected ventilation mode 2 LUM PAW

Notice:

For easier operation, the unavailable operational elements in the selected ventilation mode are dimmed. The user can instantly see, which elements can be used for the specific ventilation modes.

15.1.4 Quick Setting

During the ventilation, it is possible to set the brightness and audio volume with a quick setting button . Press + or - button to adjust the display brightness and device volume. Press X to exit the setting.

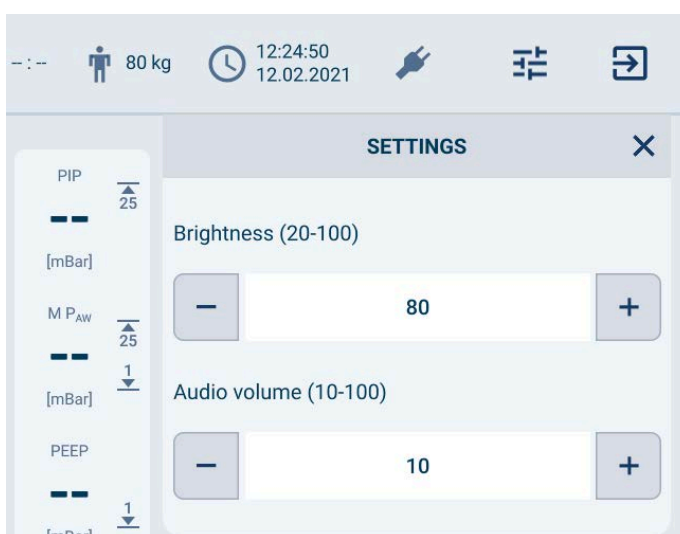


Fig.52 Quick setting window

15.1.5 Switch on/off Jet Unit

Press on/off button to switch NF/HF Jet on/off. The NF/HF button is in blue if it is switched on.



Fig.53 NF Jet on



Fig.54 HF Jet on

15.1.6 Parameter Settings

Note:

All setting windows close after 10 seconds if there's not any operation.

15.1.6.1 FiO₂ jet setting

Notice:

In LSM FiO₂ jet can only be set in the range 21% - 40%.

1. Press "FiO₂ jet" button to open the setting window

2. Slide on slider or press a quick selection button to change the value. Press ✓ to confirm the setting, or ✕ to exit the setting.

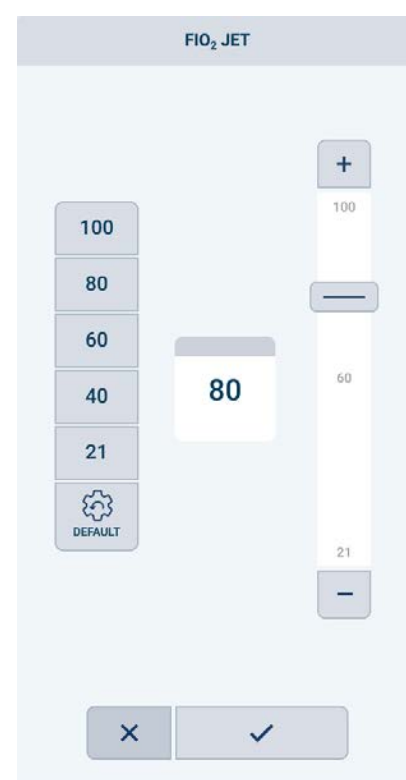


Fig.55 FiO₂ jet setting window

3. Press the "DEFAULT" button to load the preset value.



Fig.56

4. The FiO₂ jet button will turn in blue if the preset value is reached.



Fig.57 FiO₂ jet value not reached

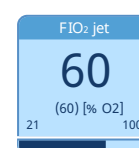


Fig.58 FiO₂ jet value reached

15.1.6.2 O₂ bias flow Setting

1. Press "O₂ bias flow" button to open the setting window.

2. Slide on slider or press a quick selection button to change the value.
Press ✓ to confirm the setting, or ✕ to exit the setting.

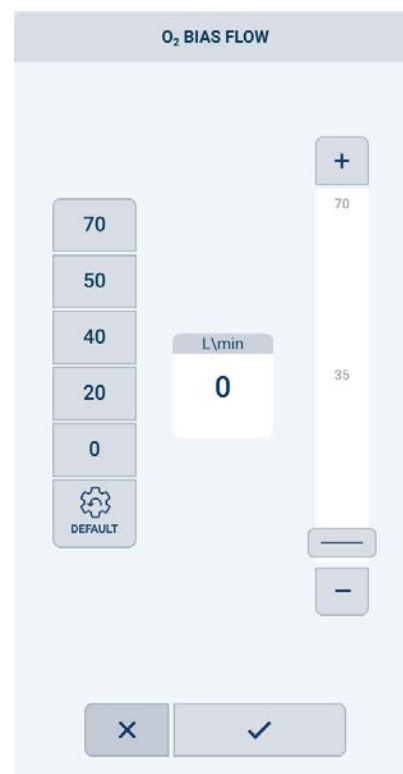


Fig.59 O₂ bias flow setting window

3. Press the "DEFAULT" button to load the preset value.



Fig.60



Fig.61 O₂ bias flow active = Blue

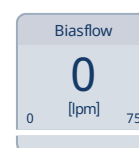


Fig.62 O₂ bias flow inactive = Gray

15.1.6.3 NF/HF jet Setting

Frequency setting

1. Press **frequency (BPM)** button "**F [1/min]**" to open the NF/HF frequency setting window.

2. Slide on slider or press a quick selection button to change the value. Press ✓ to confirm the setting, or ✕ to exit the setting.



Fig.63 NF jet frequency setting window



Fig.64 HF jet frequency setting window

3. Press the "DEFAULT" button to load the preset value.



Fig.65

Ratio setting

1. Press **ratio** button "**I:E**" or "**i:e**" to open the NF/HF insp. to expir. ratio setting window.

2. Slide on slider or press a quick selection button to change the value. Press ✓ to confirm the setting, or ✕ to exit the setting.

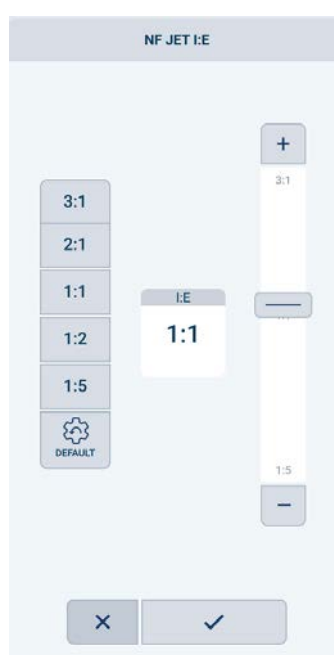


Fig.66 NF jet Ratio setting window

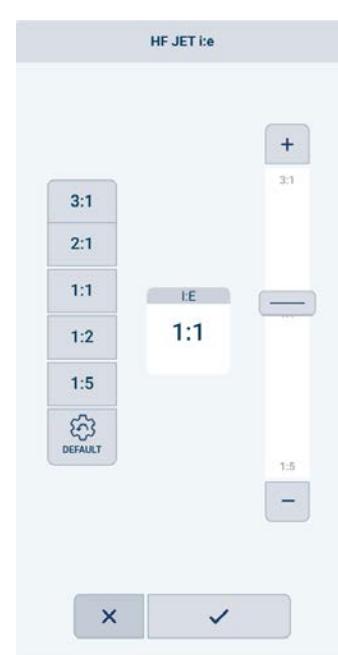


Fig.67 HF jet Ratio setting window

3. Press the "DEFAULT" button to load the preset value.



Fig.68

Pressure setting

1. Press *pressure* button "*P NF [bar]*" to open the NF/HF pressure setting window.

2. Slide on slider or press a quick selection button to change the value. Press ✓ to confirm the setting, or ✕ to exit the setting.



Fig.69 NF jet pressure setting window



Fig.70 HF jet pressure setting window

3. Press the "DEFAULT" button to load the preset value.



Fig.71

15.1.7 PULSE Option

TwinStream™ EVO can be equipped with the PULSE option. Press PULSE on the panel to activate or deactivate the pulsation.



Fig.72 PULSE active = Blue



Fig.73 PULSE inactive = Grey

15.1.8 Laser Safe Mode activate/deactivate

By pressing Laser Safe Mode "ON/OFF" button, LSM can be activated or deactivated.

As soon as the LSM is activated, the measured FiO₂ AW is displayed to show the actual oxygen concentration in the airway (optional).

The time taken to reach the target FiO₂ AW will depend on the patient's lung volume, compliance, resistance and on the ventilation settings.

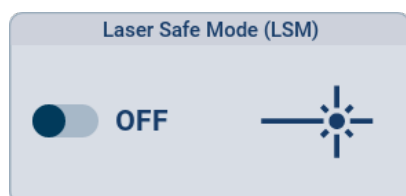


Fig.74 LSM off

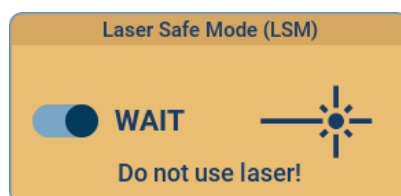


Fig.75 LSM not ready

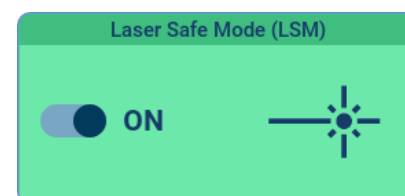


Fig.76 LSM on

15.1.9 Respiratory Gas Analysis

15.1.9.1 FiO₂ AW Measurement

There are two options available: FiO₂ AW interval and FiO₂ AW continuous.

- Starting Laser Safe Mode activates the FiO₂ AW measurement automatically.
- The FiO₂ AW measurement automatically stops after Laser Safe Mode is switched off.

FiO₂ AW Interval Measurement

1. Pressing "Interval" button to switch to FiO₂ AW interval measurement mode (Interval button in blue).
2. Pressing on/off button to start/stop the measurement.

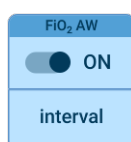


Fig.77 FiO₂ AW interval on

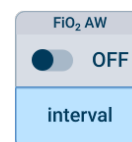


Fig.78 FiO₂ AW interval off

FiO₂ AW continuous measurement

1. Start/Stop FiO₂ AW measurement by pressing on/off button, to conduct a continuous measurement the button "Interval" switches to "continuous".
2. After the value appears on the screen the measurement can be manually switched off at any time.

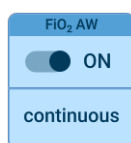


Fig.79 FiO₂ AW continuous on



Fig.80 FiO₂ AW continuous off

Notice:

- on/off button is to start/stop the measurement, the measurement mode (interval or continuous) is to be switched with the toggle "Interval" button.
- Measurement interval and time can be configured in the service mode.
- There is no warming up time needed for the FiO₂ AW measurement.

15.1.9.2 cCO₂ and etCO₂ measurement

etCO₂ manoeuvre measurement

Pressing "continuous" button switches to etCO₂ manoeuvre measurement mode (manoeuvre button in blue). Press on/off button to start/stop the measurement.

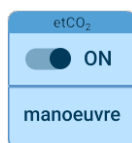


Fig.81 etCO₂ manoeuvre on



Fig.82 etCO₂ manoeuvre off

1. High-Frequency Jet Ventilation is deactivated during measurement (if HF jet activate and frequency above 120 BPM).
2. An information is displayed while the etCO₂ measurement is active
3. A sample is drawn by the pump and measured by the analyser.
4. After 3-5 breaths the highest measured value is displayed on the monitor, the measurement is switched off automatically.
5. The High-Frequency Jet Ventilation unit is reactivated (if it was running) at its previously set parameters.



Fig.83 etCO₂ manoeuvre measurement graph

Notice:

- For measurement of etCO₂ under S-HFJV, high-frequency ventilation (frequency above 120 BPM) is paused for 3 to 5 breaths in order to obtain end-tidal gas for evaluable results, there is no warming up time needed for the CO₂ measurement.
- etCO₂ gas from the airway can only be obtained up to a ventilation frequency of 120 BPM. At higher frequencies there is too much gas mixing to give an accurate value. For this reason, etCO₂ measurement is deactivated if HF jet activate and frequency above 120 BPM.
- There is no special precautions related to discharge of calibration gas or gas samples!

cCO₂ continuous measurement

Pressing "manoeuvre" button switches to cCO₂ measurement mode, pressing on/off button to start/stop cCO₂ measurement.

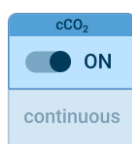


Fig.84 cCO₂ continuous on

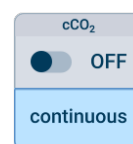


Fig.85 cCO₂ continuous off

1. An etCO₂ baseline measurement is done first, and High-Frequency Jet Ventilation is switched off (frequency above 120 BPM).
2. Afterwards High-Frequency Jet Ventilation is switched on automatically, cCO₂ is measured consistently, the highest value from every breath is displayed as a trend curve in the graph.



Fig.86 cCO₂ continuous measurement graph

15.1.10 Switching the ventilator off

1. Ending the ventilation by switching off NF/HF Jet Unit.
2. Exit  the ventilation mode.
3. Press the  symbol or the button  on the panel to shut down TwinStream™ EVO.
4. Press  button to confirm shut down, press  to exit the window.

 Note:

"Shut down" dialogue closes after 20 seconds if there' not any operation.



Fig.87

5. Disconnect hoses for oxygen and compressed air from the CGS.
6. Disconnect power plug and equipotential bonding cable.

 Notice:

- To disconnect the device at all-pole unplug the power cord!

 Warning:

- In case the  button on the housing is pressed longer than 30 seconds a hard shutdown is going to be performed. Only do this in case the device is not responding any more.

15.2 TwinStream™ EVO HFJV

15.2.1 Switching the ventilator on

The process to switch on the TwinStream™ EVO HFJV is the same like S-HFJV variant, detailed information please refer to the [chapter 15.1.1 "Operation-TwinStream™ EVO S-HFJV-Switching the ventilator on"](#).

15.2.2 Selftest initiation

A selftest is executed automatically like the variant S-HFJV. If the selftest fails with errors, no ventilation is possible. An error or warning message is displayed. Detail information please refer to the [Chapter 17.11.3 "Alarm List-Selftest"](#).

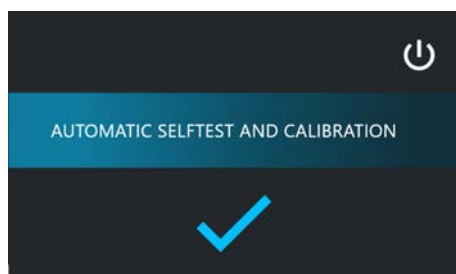


Fig.88 Selftest successful

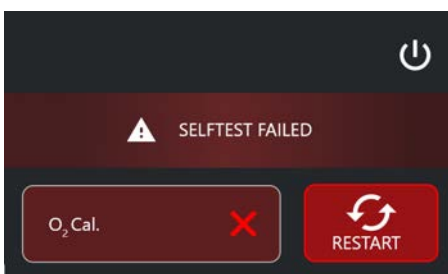


Fig.89 Selftest error

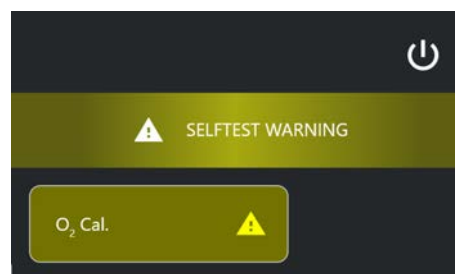


Fig.90 Selftest warning

Caution:

Tubing set and patient must be disconnected from the device during selftest!

15.2.3 Access the ventilation mode

If the self-test is complete without error or warning, press 1-Lumen button  to access the ventilation mode.

15.2.4 Switch on/off HF Jet Unit

Press on/off button to switch HF Jet on/off. The HF button is in blue if it is switched on.

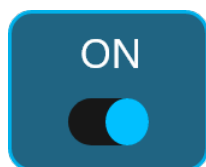


Fig.91 HF Jet on

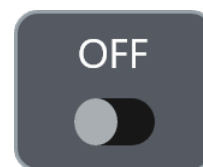


Fig.92 HF Jet off

15.2.5 Parameter Settings

Note:

All setting dialogues close after 10 seconds if there is not any operation.

15.2.5.1 FiO₂ jet Setting

Notice:

In LSM FiO₂ jet can only be set in the range 21% - 40%.

1. Press FiO₂ jet button to open the setting window.

2. Press + or - button to set the value, press ✓ to confirm the setting, or ✕ to exit the setting.

3. The FiO₂ jet button will turn in blue if the preset value is reached.



Fig.94 FiO₂ jet value not reached



Fig.93 FiO₂ jet setting window

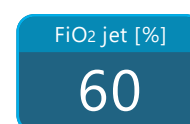


Fig.95 FiO₂ jet value reached

15.2.5.2 HF Jet Setting

Frequency Setting

1. Press *frequency (BPM)* button "*F [1/min]*" to open the HF pressure setting window.

2. Press + or - button to set the value, press ✓ to confirm the setting, or ✕ to exit the setting.

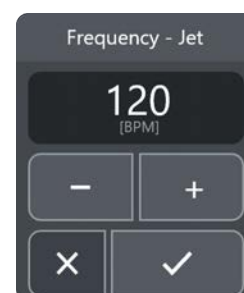


Fig.96 Frequency setting window

Ratio Setting

1. Press *ratio* button "*i:e*" to open the HF insp. to expir. ratio setting window.

2. Press + or - button to set the value, press ✓ to confirm the setting, or ✕ to exit the setting.

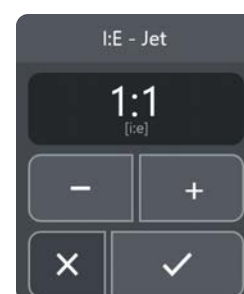


Fig.97 Ratio setting window

Pressure Setting

1. Press **pressure** button "**P HF [bar]**" to open the HF pressure setting window.

2. Press **+** or **-** button to set the value, press **✓** to confirm the setting, or **✕** to exit the setting.

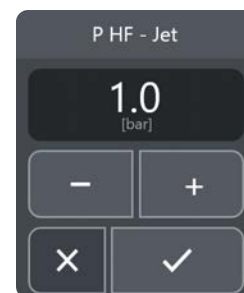


Fig.98 Pressure setting window

15.2.6 Laser Safe Mode Activate/Deactivate

Please refer to the description from TwinStream™ EVO S-HFJV.

15.2.7 Switching the ventilator off

1. Ending the ventilation by switch off HF Jet Unit.

2. Exit  the ventilation mode.

3. Press the  button to switch off TwinStream™ EVO HFJV.

4. Press **✓** button to confirm shut down, press **✕** to exit the window.

Note:

"Shut down" dialogue closes after 20 seconds if there is not any operation.

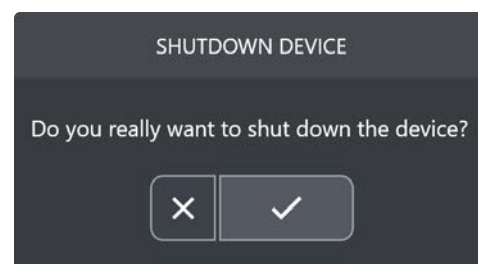


Fig.99

5. Disconnect hoses for oxygen and compressed air from the CGS.

6. Disconnect power plug and equipotential bonding cable.

Notice:

- To disconnect the device at all-pole unplug the powercord.

Warning:

- In case the  button on the housing is pressed longer than 30 seconds a hard shutdown is going to be performed. Only do this in case the device is not responding any more.

16. Configuration

16.1 TwinStream™ EVO S-HFJV

16.1.1 Access/Exit Configuration Mode

1. Press  button from the main menu to open the *configuration* window.
2. Select a button from "*Settings*", "*Options*", "*Selftest Logs*", "*Data Logs*" or "*Device*" to open a setting screen.
3. Select the appropriate settings as required. The selected buttons are in blue.
4. Close the configuration screen to finish the setting.

16.1.2 Settings

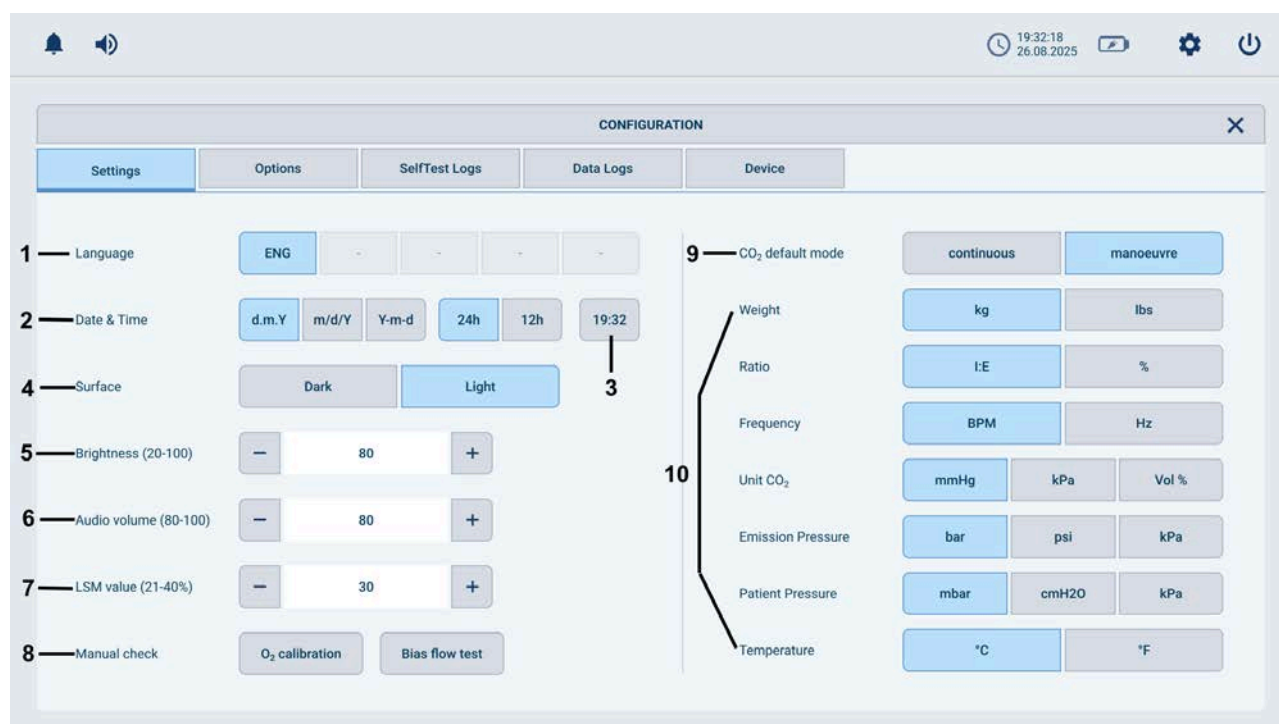


Fig.100 Configuration-Settings

1. Language selection: Touch Language button and select the desired language from the list.
2. Date & time format: select the desired date and time format from the list
 - dd:mm:yyyy | mm/dd/yyyy | yyyy-mm-dd
 - 24h / 12h

3. Device time setting: Press  button to open "*Change Time*" screen. Select current time with buttons + and -, Press ✓ to confirm the setting, press ✕ to exit the setting.

Notice:

Device date can only be set in the service mode.

4. Display appearance: Select *Light* or *Dark* mode.
5. Display brightness: Press + or - button to set the desired brightness. The brightness can not be set below 40% for safety reasons.
6. Audio volume: Press + or - button to set the desired volume. The volume can not be set below 80% for safety reasons.
7. LSM value: The O₂ concentration for LSM can be defined. Press + or - button to set the desired value in the range 21% - 40%.
8. Manual check: O₂ calibration and bias flow test (details of calibration and test steps listed below)
9. CO₂ manoeuvre/continuous measurement



Fig.101 Time setting

10. Unit setting: Different units can be selected for below values.

- . Weight: KG / lbs
- . Ratio insp. to expir: I:E / %
- . Frequency: BPM / Hz
- . Unit CO₂: (mmHg / kPa / Vol %)
- . Emission Pressure: (bar / psi / kPa)
- . Patient Pressure: (mbar / cmH₂O / kPa)
- . Temperature: (C° / F)

O₂ Calibration: Manual start the O₂ cell calibration

1. Press **O₂-Calibration** button to open the calibration window, it can be necessary after several hours of operation.

2. Press “Start” button to start O₂ Calibration.



Fig.102 O₂ calibration window

3. Calibration failed, call service!



Fig.103 O₂ calibration failed

4. Calibration successful, press **X** button to finish the calibration.

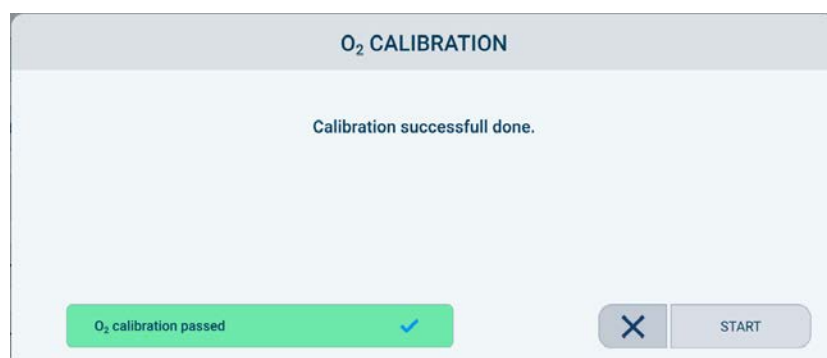
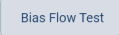


Fig.104 O₂ Calibration successful

Note:

While the calibration, the configuration screen cannot be exited and the calibration cannot be cancelled.

Bias flow test

1. Press  button to open the test window.

2. Press “Start” button to start bias flow test.

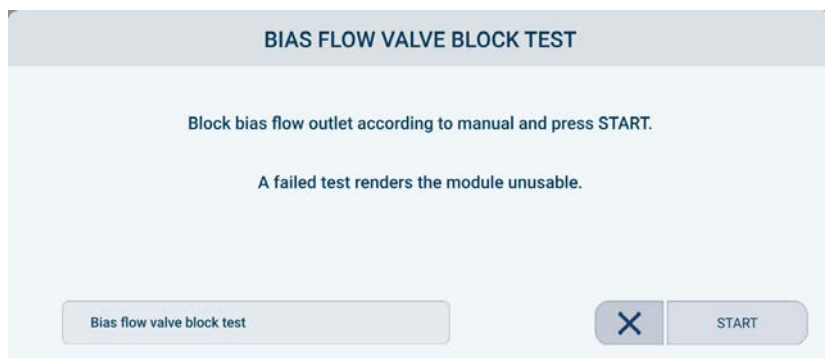


Fig.105 Bias flow test window

3. If test failed, option is disabled until a successful test is done.

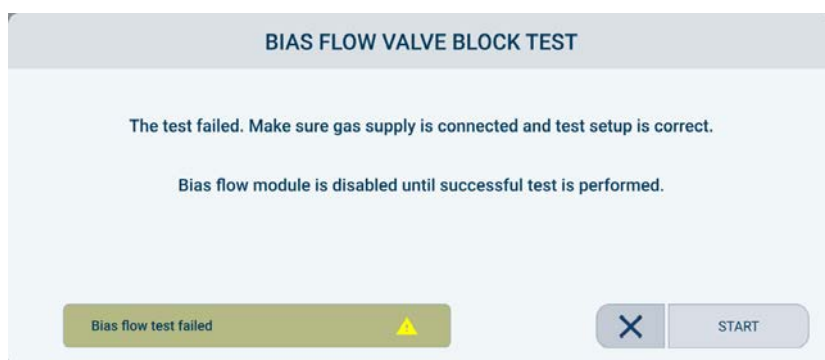


Fig.106 Bias flow test failed

4. Test successful, press  button to finish the test.

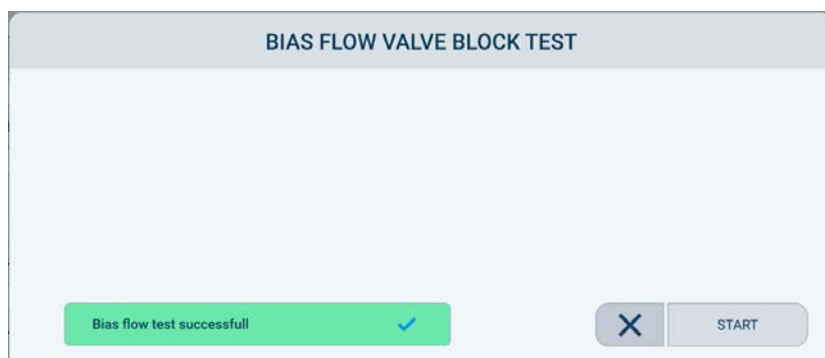


Fig.107 Bias flow test successful

16.1.3 Options

Press “Options” tab to open the option screen in the configuration window. This Screen shows the status of the available options (activated/deactivated/temporarily activated/ temporarily expired).



Fig.108 Configuration-Options

1. Modes: Available ventilation modes
2. PDMS option: Enable/disable PDMS interface
3. CO₂ & continuous CO₂: Enables continuous CO₂ and manoeuvre CO₂
4. Bias flow: Enable/disable bias flow function, activated by default
5. Pulse: Enable/disable PULSE function
6. Frequency 2000 (1200-2000): Enable high frequency up to 2000 BPM
7. FiO₂ AW/ FiO₂ AW interval: Enables continuous FiO₂ AW or FiO₂ AW interval measurement
8. Panel: External display activate/deactivate

Options can be enabled / disabled and temporarily unlocked. To change a status, a code must be entered to (temporarily) enable / disable an option. CARL REINER provides the algorithm.

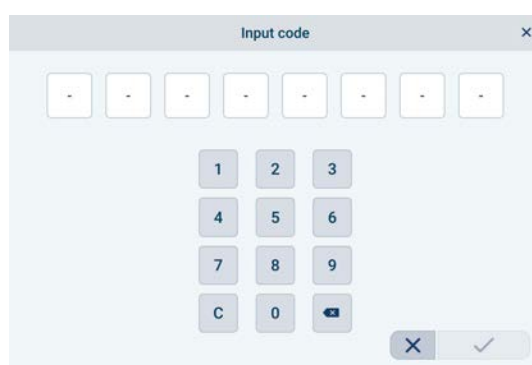


Fig.109 Option code input dialog

Notice:

If an option is not available because of missing hardware, it is displayed in grey.
 If an option is only available in a limited time, the button is still in blue but the expiry date will be displayed until the option is fully activated.
 If a ventilation mode is not available or deactivated, it is in grey on the main screen. Except for the Expert mode, which will not be shown on the main screen.

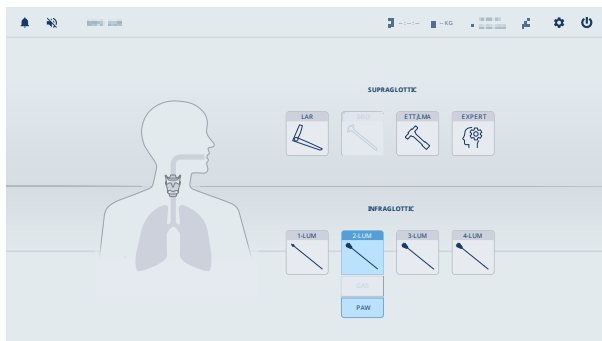


Fig.110 2 LUM GAS & BRO mode is deactivated

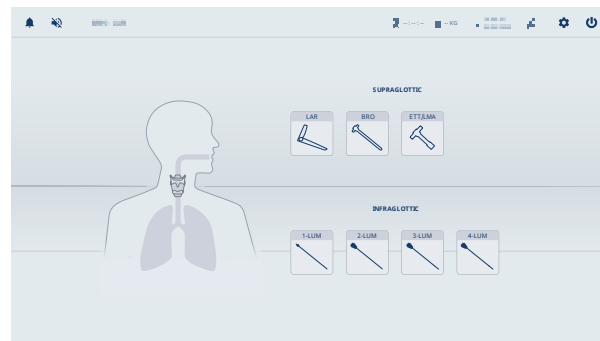


Fig.111 Expert mode is deactivated

16.1.4 Self-test Logs

In this tab a self-test history can be selected on the left column. The progress of the self-test is then displayed on the right column.

With the on/off button from "Failed self-tests only" the list shows only failed self-tests.

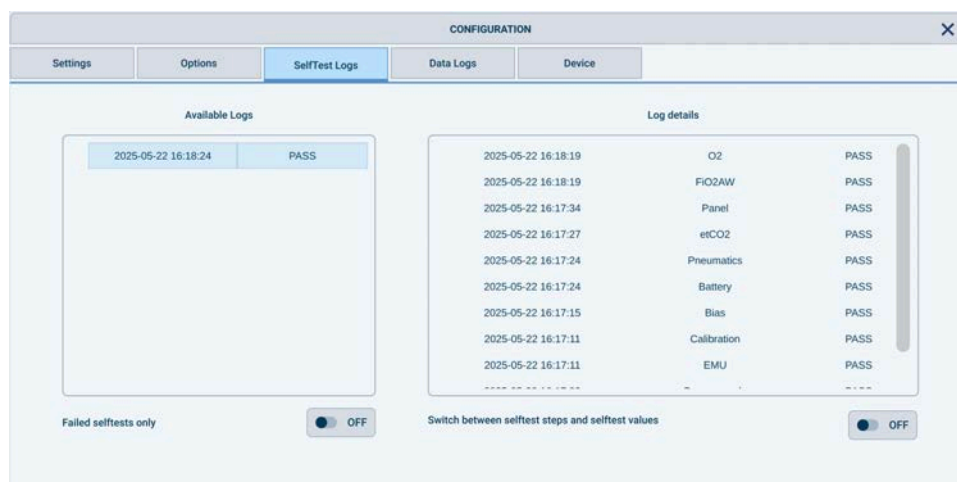


Fig.112 Self-test switch button off-self-test steps are shown

To see more details and self-test values the button "Switch between self-test steps and self-test values" can be switched on or off. In case the button is active detailed values e.g. Software versions, serial numbers and calibration values are shown.



Fig.113 Self-test switch button on-self-test values are shown

16.1.5 Data Logs

In the Data Logs section it is possible to load the user actions, ventilations entries and occurred alarms from the day.



Fig.114 Data Logs screen

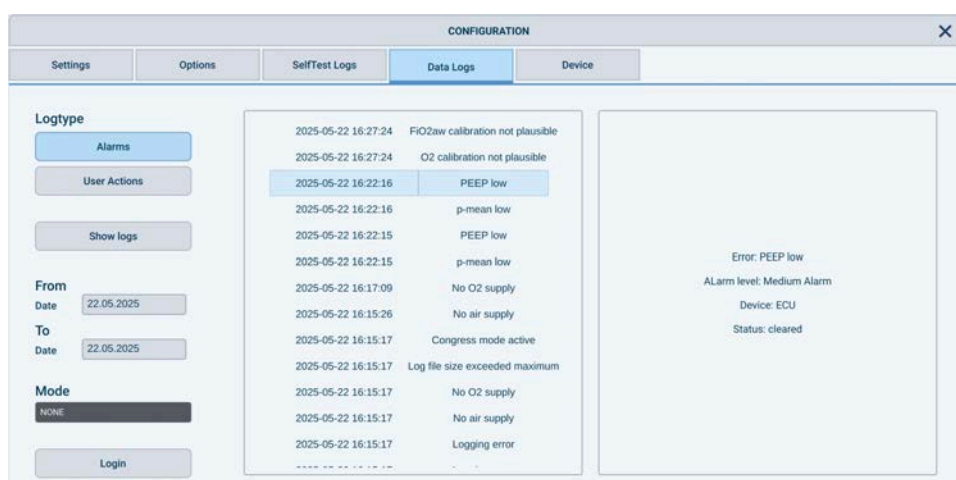


Fig.115 Data Logs screen with alarms information

16.1.6 Device

The Device tab shows detailed information of the device. Serial number, software version and available components can be read from the dialog.

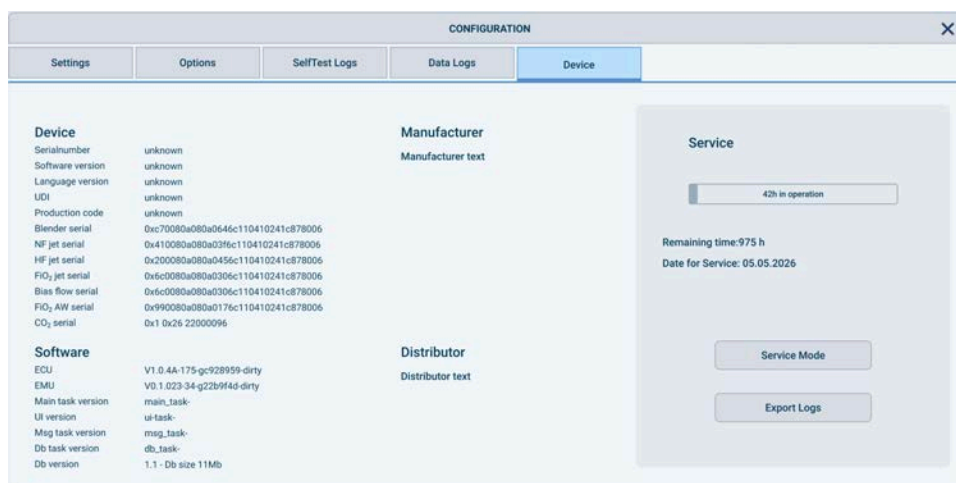


Fig.116 Configuration-Device screen

Two Buttons in Device Tab:

- Export Logs: Start Export Log-Files.
- Service Mode: Login in Service Mode, only operated by authorized personnel.

Information displayed in Device tab:

- Software information: All relevant software versions including firmware ECU and EMU
- Device information: UDI, Serial number, operating hours, ventilation hours
- Manufacture information
- Distributor information: Optional
- Component information: Including relevant serial numbers of the modules
- Service date/Service hours: Total operation time, ventilation time, time to next service

16.1.6.1 Export logs

To export the log files a USB stick must be connected to the device. After pressing "START" button the export procedure stores all relevant logs, settings and files into the USB media. Even if an error message appears on the screen, the log files are still on the device and will not be deleted.



Fig.117 Export start screen

Dialogue in case the export was successful.

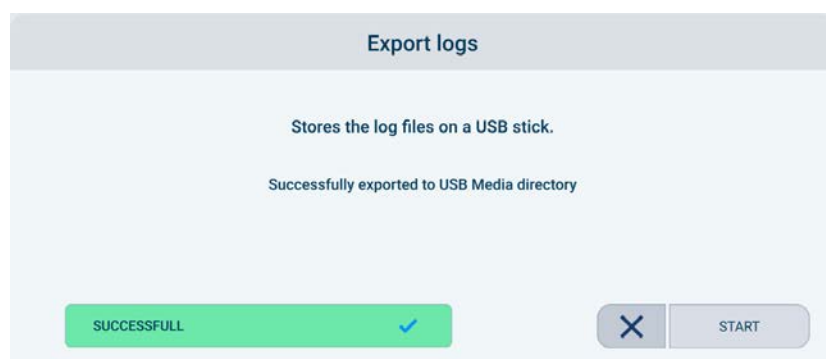


Fig.118 Export successful

Dialogue in case the export failed.

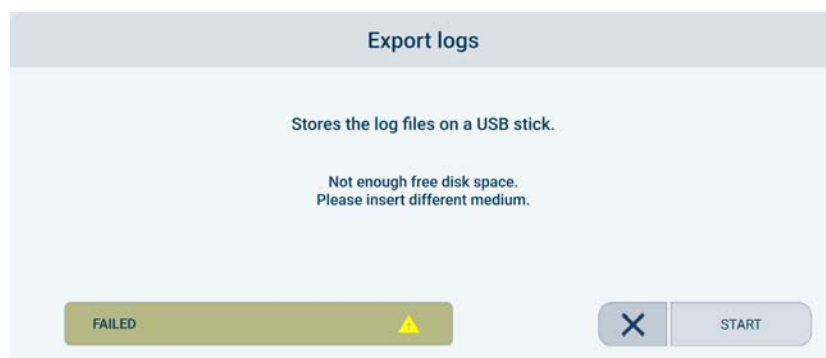


Fig.119 Export failed

16.2 TwinStream™ EVO HFJV

16.2.1 Access/Exit Configuration Menu

1. Press  button on the main menu to open the [settings](#) window.
2. Press  button to exit the setting.

16.2.2 General Settings



Fig.120 Settings-1/6

1. Language: Press < or > button to select the desired language.
2. Date and time format: Press the desired date and time format from the list
 - . d:m:y | m/d/y | y-m-d
 - . 24h/12h
3. Press  button to open "[Change Time](#)" screen to setting the current time. Select current time with buttons + and -. Press ✓ to confirm the setting, press ✕ to exit the setting.

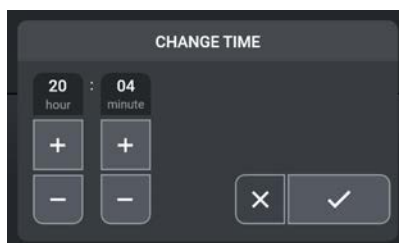


Fig.121 Time setting

Notice:

Device date can only be set in the service mode.

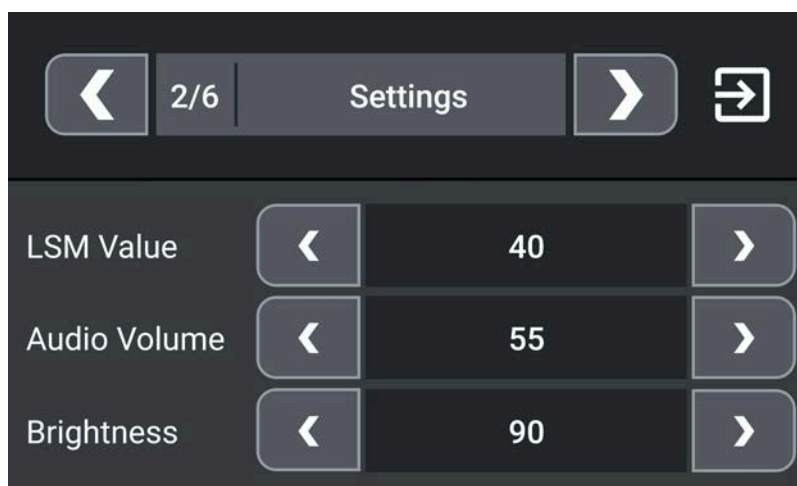


Fig.122 Settings-2/6

1. LSM value: The O₂ concentration for LSM can be defined. Press < or > button to set the desired value in the range 21% - 40%.
2. Audio volume: Press < or > button to set the desired volume. The volume can not be set below 80% for safety reasons.
3. Brightness: Press < or > button to set the desired brightness. The brightness can not be set below 40% for safety reasons.

 Note:

TwinStream™ EVO HFJV display has only dark mode.

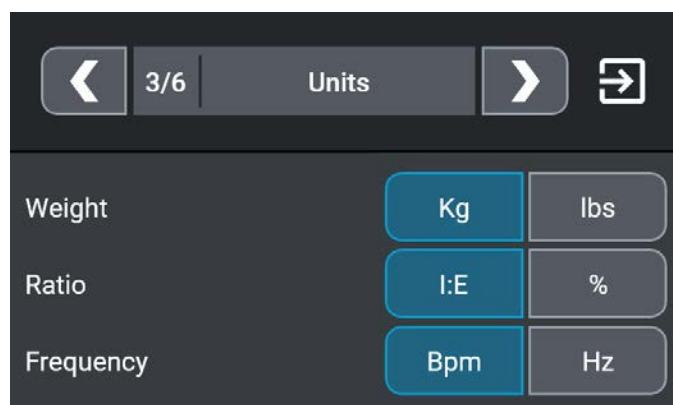


Fig.123 Settings-3/6 Units

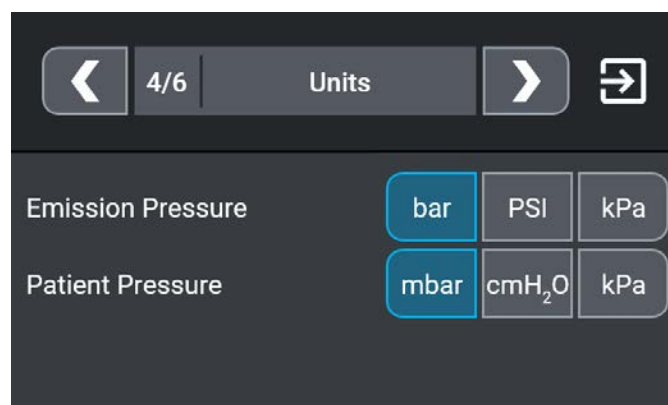


Fig.124 Settings-4/6 Units

Unit setting: Different units can be selected for below values.

- Weight: kg / lbs
- Ratio insp. to expir: I:E / %
- Frequency: BPM / Hz
- Emission pressure: (Bar / psi / kPa)
- Patient pressure: (mBar / cmH₂O / kPa)

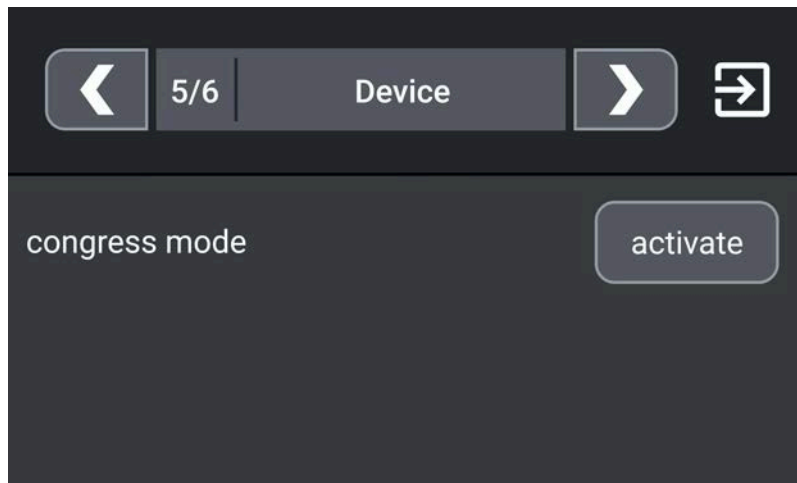


Fig.125 Settings-5/6

Congress mode is only to be used for congress purpose, it can only be set by the authorised personnel.

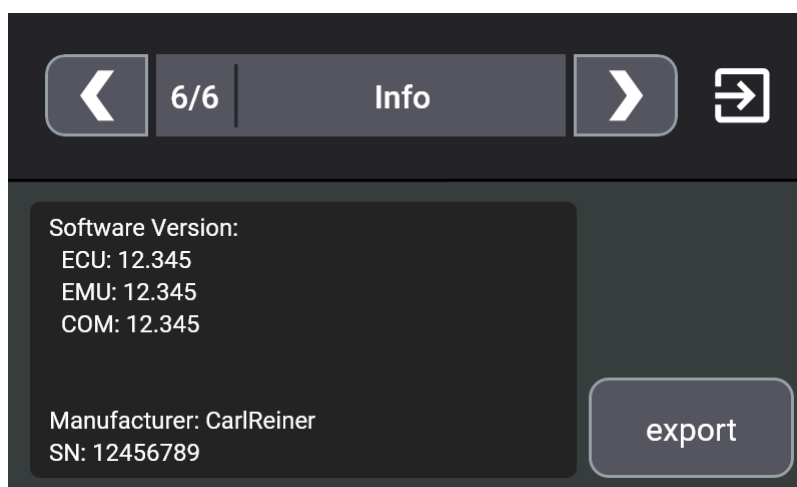


Fig.126 Settings-6/6

1. Device information: The system-information-screen shows detailed information of the device.
 - . Software version
 - . Manufacture information
 - . Serial number
2. Export button: Start export log-files, data will only be exported to USB stick, not deleted. In case the export failed a error code is shown. Refer list for more information.

Export error codes

- 1 = No USB media found
- 2 = Low disc space
- 3 = Export path not found
- 4 / 6 / 7 = Database could not be exported
- 5 = No database information received
- 8 = Error creating export file
- 9 = Error while copying a settings file
- 10 = Error while copying log files
- 11 = Error while copying a system file
- 12 = Unknown error

17. Alarms, Alarm Settings and Alarm List

17.1 General Alarm Behaviour

The device can generate several alarms which are displayed to the user. It is an intelligent alarm system which displays the alarms according to priority. The importance of the alarm reflects the priority. The device always displays the pending alarm with the highest priority. Pending alarms with a lower priority are suppressed by the alarm system if the higher priority alarm is pending. Alarms automatically disappear if the alarm condition no longer exists or has been resolved. All alarm messages are shown in a status window and accompanied by an audible alarm. The alarm sound and colour of display are dictated by the highest priority of any active alarm(s). "Alarms" has higher priority than "self-test errors". If more than one alarms occur at the same time with the same priority, the alarm with the lowest ID is displayed to the user. The IDs can be found in the chapter "Alarm List".

17.2 Alarm Classification

The alarms are grouped into *"self-test errors"* and *"alarms"*.

Self-test errors can lead to following behaviour:

- Device Failure: The device cannot be used.
- Functional restricting error: The device can be used but specific functions are may not available

Functional restricting errors keep pending during use and are shown in the ventilation screen as low priority alarm.

Alarms are grouped into *"technical alarms"* and *"patient alarms"*.

Both "technical alarms" and "patient alarms" have different priorities as following:

- High Priority
- Medium Priority
- Low Priority

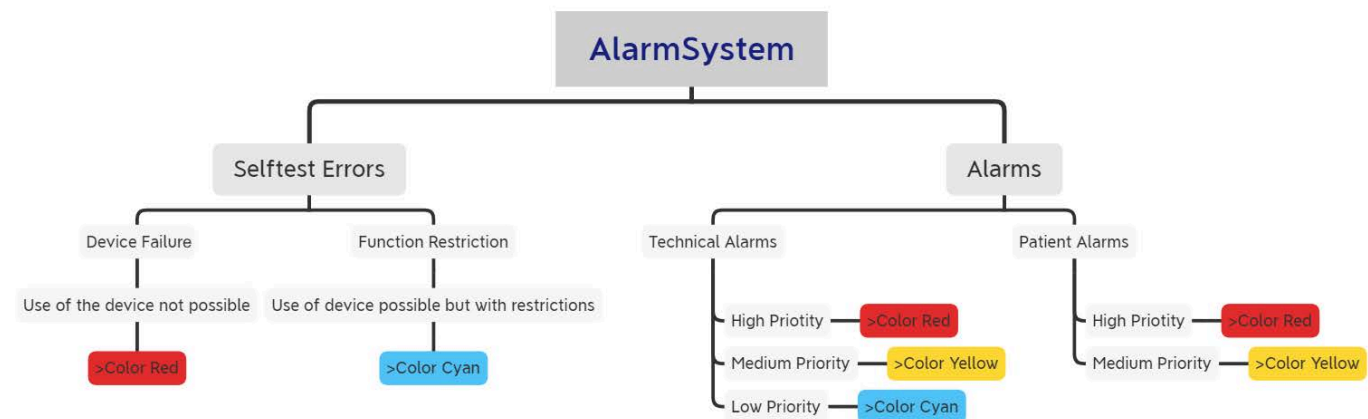


Fig.127

Alarm Priority	Color	Tone	Sound Pressure
High Priority	Red	Two groups of 5 signals which are separated by a ~2s pause. Within the group of 5 the pause between the 3rd and 4th sound is approximately 2 times longer than the pause between the other sounds (50 - 125ms) in the group.	Min. 71 dB Max. 81 dB
Medium Priority	Yellow	Three sounds, which are evenly separated by pauses between 10 ms	Min. 68 dB Max. 81 dB
Low Priority	Cyan	A single tone of approximately 1s at a 15s intervals.	Min. 68 dB Max. 72 dB

Warning:

- Sound pressure levels of the audible alarm signal, which are lower than the ambient levels, may prevent the operator from detecting alarm conditions!
- The use of medical equipment with similar sounding alarms may pose a risk. Operator should note and differentiate alarm priority settings of TwinStream™ EVO and other equipment, which can be located in the same Operation Room.

PEEP Low Alarm Behaviour

The peep low alarm condition is per default a medium alarm. If the condition persists for more than 60 seconds, the alarm is escalated to a high priority alarm.

17.3 Display of Alarm Limit

1. Upper and Lower Alarm

- The upper alarm limit of P_{AW} , PP, FiO_2 AW and $etCO_2$ is shown on the display as a horizontal red line
- The lower alarm limit of P_{AW} , PP, FiO_2 AW and $etCO_2$ is shown on the display as a horizontal yellow line



Fig.128

2. MP_{AW} and ΔpHF alarm limits are shown on the right of the graph



Fig.129



Fig.130

3. When the alarm limit is reached, an audible alarm occurs and an alarm dialogue box appears on the screen

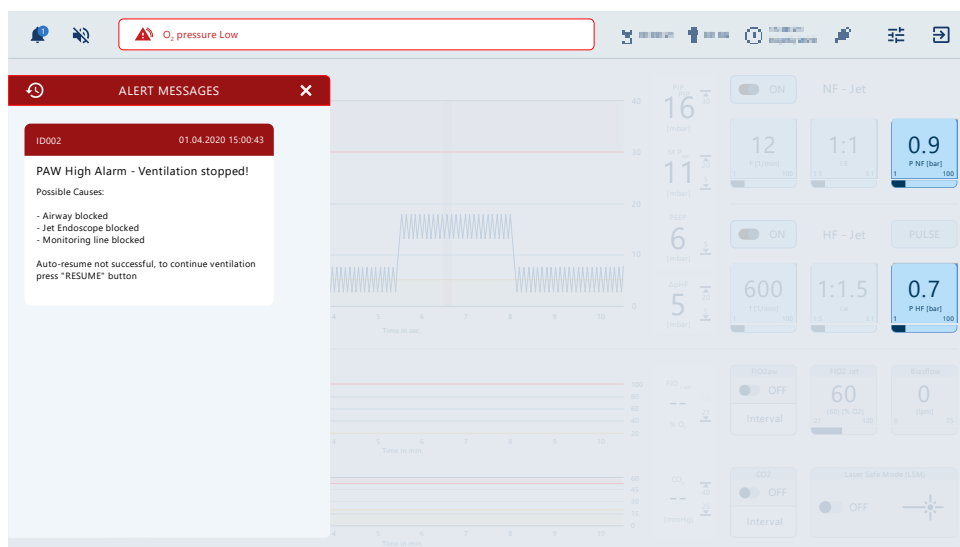


Fig.131 TwinStream™ EVO S-HFJV with alarm message



Fig.132 TwinStream™ EVO HFJV with alarm message

17.4 Pressure Measurement Alarm

17.4.1 Airway Pressure (P_{AW}) in LAR, BRO, ETT/LMA, 4 LUM, 3 LUM and 2 LUM PAW mode

The Airway pressure P_{AW} is measured and monitored continuously by the alarm unit. The alarm unit prevents the application of excessively high pressure to the patient (prevention of barotrauma). The low pressure alarm warns of insufficient pressure for ventilation or possible disconnection. The airway pressure alarm for upper and lower pressure limits can be set manually.

High Pressure Alarm

- The upper alarm limit is pre-set according to the patient's weight in the range 20 - 40 mBar.
- When the high-pressure alarm limit is reached (red line), ventilation stops to protect the patient from barotrauma, an audible alarm is sounded and an alarm dialogue box appears on the screen.
- In the event of an high pressure alarm, all valves are closed and the residual pressure is released from the chamber.

Low Pressure Alarm

The low priority alarm signal is triggered, when the numerical value PIP is lower than the value of the lower alarm limit e.g. Pressure drop or Disconnection, and will disappear when the PIP rises again above the set lower alarm limit or the lower alarm limit is adjusted.



Notice:

A setting of the upper alarm limit to a value higher than 40 mBar/cm H₂O is not recommended! A wrong or too high setting of the upper alarm limit can lead to a failure of the alarm system and consequently result in harm to or death of the patient! Changing the value limits, particularly increasing the upper alarm limit, requires good knowledge of the ventilation technique and is the sole responsibility of the user.

17.4.2 Pause pressure (PP) in 1 LUM and 2 LUM GAS & PAW mode

- Pause pressure (PP) is started by activating the Ventilator in one of these three modes.
- The default pressure alarm limit is 7 mBar and the alarm is triggered if it is over 7 mbar. But PP can be adjusted by the user according to clinical requirements.
- Setting of the upper Pause Pressure alarm limit to a value higher than 7 mBar is not recommended!

17.5 Respiratory Gas Analysis Alarm

17.5.1 FiO₂ AW high

LSM Active

If the FiO₂ AW value is too high during the laser safe mode, Valve will be closed. In addition, an alarm message appears. The user must confirm that FiO₂ AW is too high and the laser mode is terminated. If this is confirmed, the device will resume without LSM. If the message is still not confirmed but FiO₂ AW is back to the normal value, the message disappears and the device continuous in LSM.

LSM in progress

Laser will not be released as long as FiO₂ AW is too high. An info message "FiO₂ AW too high" appears.

17.6 Auto Reset Behaviour

The device has an automatic alarm reset function for high airway pressure alarms. If the airway pressure rises above the upper alarm limit, the ventilation is stopped. If the pressure drops below 30% of the high alarm limit within 20s, ventilation restarts after 1 second. If the high alarm is triggered three times, ventilation stops permanently. A restart button



appears. Ventilation must be started manually by the user. If ventilation continues for 5 seconds without a high-pressure alarm, the counter that counts to 3 is reset to 0.

During the pause pressure measurement (PP), only two attempts are made to switch ventilation back on. In the second attempt, ventilation is only resumed when the pressure has dropped to 2 mbar or lower.

17.7 Audio Off

Pressing the Mute button  suppresses the sound for 120 s without resetting the alarm.



Notice:

The visual alarms will still be displayed. Pressing the  button again restores audible alarms.

17.8 Freeze Button

Pressing **Freeze** button  allows closer inspection of the Airway Pressure or Gas Analysis graph. Press this button again to release freeze. Otherwise the graph will be frozen for 2 minutes.

With the Freeze Button a curve can be frozen. The curve remains unchanged and no new values are entered into the curve. If Freeze is deactivated, the curve is deleted and filled with the values already measured in the curve.

17.9 Operator Alarm Protocol

The device is equipped with an operator alarm protocol. The protocol logs the occurred alarms while ventilation.

To see the history of occurred alarm the operator alarm protocol (Alarm History) can be opened via the alarm window.

To access the “Alarm History” the button  must be pressed in the alarm window.

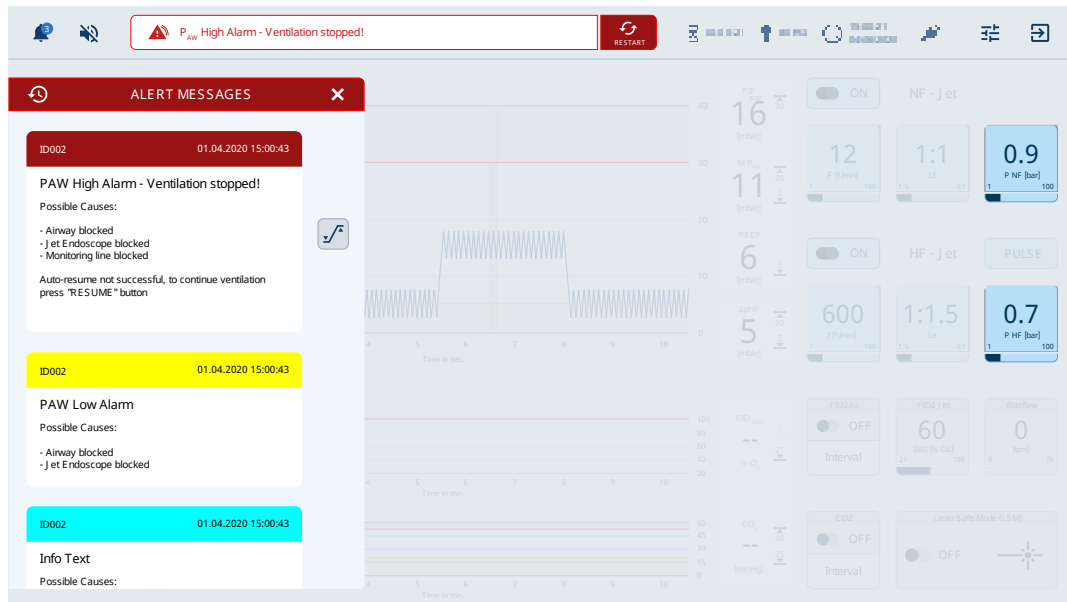


Fig.133 Alarm messages

The operator is able to see all occurred alarms, status and the occurred date time.

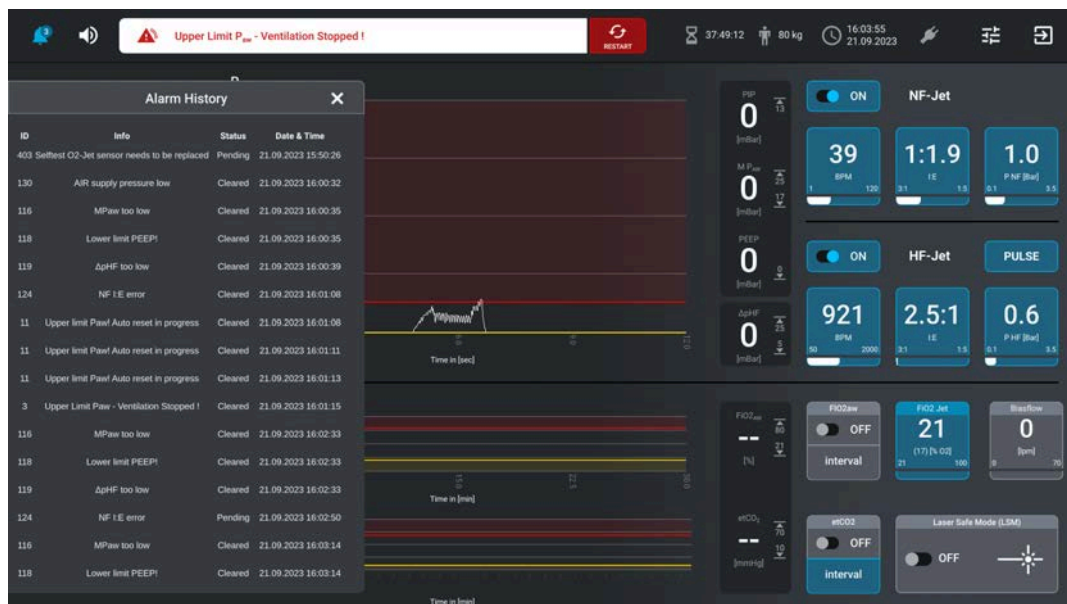


Fig.134 Alarm history

The operator alarm protocol is only available during ventilation screen. The alarm system cannot be switched off. After the device is powered off or has loss of power, the alarm log can be accessed in the configuration screen. Refer [chapter 16.1.5 Data Logs](#).

The protocol can handle up to 550 ventilation hours. If this limit is exceeded the oldest entries are deleted (FIFO principle).

17.10 Alarm Settings

17.10.1 Factory Settings of the Standard Pressure Limits

If the ventilation mode is selected in combination with the current body weight, the alarm limits are preset accordingly.

Alarm Limits per Ventilation Mode for Pressure Measurement

Ventilation Mode	Weight Group	Upper Limit P _{AW}	Upper Limit PP	Upper Limit MP _{AW}	Lower Limit MP _{AW}	Upper Limit Δ pHF	Lower Limit Δ pHF	Lower Limit PEEP
1 LUM	1-200 kg	NA	7	NA	NA	NA	NA	NA
2 LUM PAW	1-200 kg	25	7	15	2	15	2	5
2 LUM GAS	1-200 kg	NA	7	NA	NA	NA	NA	NA
3 LUM	1-200 kg	25	NA	15	2	15	2	5
4 LUM	1-200 kg	25	NA	15	2	15	2	5
LAR	0-20 kg	20	NA	15	2	15	2	5
	20-40 kg	20	NA	15	2	15	2	5
	41-90 kg	40	NA	20	2	20	2	5
	91-140 kg	40	NA	20	2	20	2	5
	141-200 kg	40	NA	20	2	20	2	5
BRO	0-20 kg	30	NA	15	2	15	2	5
	20-40 kg	30	NA	15	2	15	2	5
	41-90 kg	40	NA	20	2	20	2	5
	91-140 kg	40	NA	20	2	20	2	5
	141-200 kg	40	NA	20	2	20	2	5
ETT/LMA	0-20 kg	20	NA	15	2	15	2	5
	20-40 kg	20	NA	15	2	15	2	5
	41-90 kg	30	NA	20	2	20	2	5
	91-140 kg	35	NA	20	2	20	2	5
	141-200 kg	40	NA	20	2	20	2	5

Alarm Limits per Ventilation Mode for Gas Measurement

Ventilation Mode	Weight Group	Upper Limit etCO ₂ manoeuvre	Lower limit etCO ₂ manoeuvre	Upper Limit cCO ₂ Continuous	Lower Limit cCO ₂ Continuous	Upper Limit FiO ₂ AW	Lower Limit FiO ₂ AW
1 LUM	1-200 kg	NA	NA	NA	NA	NA	NA
2 LUM GAS	1-200 kg	45	25	45	20	43	40
3 LUM	1-200 kg	45	25	45	20	43	40
4 LUM	1-200 kg	45	25	45	20	43	40
LAR	0-20 kg	45	25	45	20	43	40
	20-40 kg	45	25	45	20	43	40
	41-90 kg	45	25	45	20	43	40
	91-140 kg	45	25	45	20	43	40
	141-200 kg	45	25	45	20	43	40
BRO	0-20 kg	48	28	48	20	43	40
	20-40 kg	48	28	48	20	43	40
	41-90 kg	48	28	48	20	43	40
	91-140 kg	48	28	48	20	43	40
	141-200 kg	48	28	48	20	43	40
ETT/LMA	0-20 kg	48	28	48	20	43	40
	20-40 kg	48	28	48	20	43	40
	41-90 kg	48	28	48	20	43	40
	91-140 kg	48	28	48	20	43	40
	141-200 kg	48	28	48	20	43	40

 Notice:

- It is important to pay attention that the ventilation mode corresponds to the chosen type of equipment and application! A faulty combination of mode and equipment or application can result in poor ventilation and a risk to the patient's health.
- The user must set the alarm limits according to the clinical requirements! The proper setting of the alarm limits is necessary for patient safety and the user may need to over-ride the default settings of pressure limit and display scales which are based on the patient's weight.
- Alarm settings cannot be saved and recalled. However, all changes to alarm settings made by the user are logged.
- When the device is switched off, alarm records are saved permanently given enough alarm memory is available. All alarms are permanently recorded in alarm history log, selftest log, or operation log. Memory size of log file is maximum 1 GB. Oldest entries will be dropped when the memory is full. The file is saved during every annual service or can be exported at any time.

 Caution:

When setting the upper and lower alarm limits, care must be taken to avoid extreme settings so as not to disable the alarm system.

17.10.2 Alarm Delays

To avoid false alarms, the delay times listed in the table below are permanently programmed until the alarm is triggered:

Alarm Message Main Screen	Alarm Message Basic	Delay of alarm condition [s]	Delay of alarm visualization [s]	Standard deviation of the sum of deviations
Internal error	Internal error	0	restart device: <6	1
Internal error	Internal error	0	restart ECU: <6 (for MMI and Panel)	1
Upper Limit PP - Ventilation Stopped !	PP High Alarm	HF period [1/bpm] ± 2	0	0.2
O ₂ jet too high! LSM active	O ₂ jet too high! LSM active	<30 / mean 7	0	0.3
FiO ₂ AW too high	FiO ₂ AW too high	<30 / mean 11	0	0.3
Tubing set not connected or blocked	Tubing set error - Blocked / Connected	15 $\pm$ 5	0	2
Upper limit PP! Auto reset in progress	Upper limit PP! Auto reset	HF period [1/ bpm] $\times 2 \pm 2$	0	0.2
O ₂ jet under 18%	O ₂ jet under 18%	<30 / mean 7	0	0.3
FiO ₂ AW under 18%	FiO ₂ AW under 18%	<30 / mean 11	0	0.3
PP measurement defective	PP measurement defective	HF period [1/bpm] ± 2	60 $\pm$ 1	1
Battery Error	Battery Error	2 $\pm$ 1	4 $\pm$ 1	0.5
P _{AW} measurement defective	P _{AW} measurement defective	1 $\pm$ 1	60 $\pm$ 1	0.5
NF-Jet line occlusion	NF line occlusion	<1	3 $\pm$ 1	0.5
HF-Jet line occlusion	HF line occlusion	<1	3 $\pm$ 1	0.5
Gas sample line blocked or flow too low	Gas sample line blocked or flow too low	<1	3 $\pm$ 1	0.5
EC2 plug not connected	EC2 plug not connected	1 $\pm$ 1s	30 $\pm$ 1	0.5
NF line disconnected	Jet line disconnect	HF period [1/ bpm] $\times 2 \pm 2$	30 $\pm$ 1	0.5
Jet lines or monitoring lines disconnected	Jet lines or monitoring lines disconnected	15 $\pm$ 2	0	0.3
Gas-Measurement not connected	Gas-Measurement not connected	0	30s (@continuous CO ₂ /FiO ₂ AW) FiO ₂ AW interval NF (@CO ₂ interval) NF-period [1/ bpm] $\times$ FiO ₂ cycles (@FiO ₂ interval) ± 5	2
Display not connected	Display not connected	3 $\pm$ 2	0	0.5

Alarm Message Main Screen	Alarm Message Basic	Delay of alarm condition [s]	Delay of alarm visualization [s]	Standard deviation of the sum of deviations
NF pressure to high	NF pressure to high	0	NF period [1/bpm] x4 ± 2	1
HF pressure to high	HF pressure to high	0	HF period [1/bpm] x10 ± 2	1
ΔpHF too high	ΔpHF too high	HF period [1/bpm] ± 2	0	1
MP _{AW} too high	MP _{AW} too high	NF period [1/bpm] ± 2	0	1
O ₂ jet too high	O ₂ jet too high	<30 / mean 7	O ₂ change / Jet start: 240 ± 5	1
NF Frequency Error	NF Frequency Error	0	NF period [1/bpm] x 4 ± 5	1
HF Frequency Error	HF Frequency Error	0	HF period [1/bpm] x 10 ± 5	1
NF I:E error	NF I:E error	0	NF period [1/bpm] x 4 ± 5	1
HF i:e error	HF i:e error	0	HF period [1/bpm] x 10 ± 5	1
Lower than limit etCO ₂ (intermittent measurement)	Lower than limit etCO ₂	NF period [1/bpm] x etCO ₂ cycles ± 5	0	1
FiO ₂ AW measurement not possible	FiO ₂ AW measurement not possible	<30 / mean 15	0	0.3
Upper limit value etCO ₂ reached (intermittent measurement)	etCO ₂ too high	NF period[1/bpm] x etCO ₂ cycles ± 5	0	1
Upper limit value CO ₂ reached (manoeuvre measurement)	CO ₂ too high	NF period [1/bpm] x etCO ₂ cycles ± 5	0	1
Upper limit Insp. CO ₂ reached (manoeuvre measurement)	FiCO ₂ too high	NF period [1/bpm] x etCO ₂ cycles ± 5	0	1
Lower limit value cCO ₂ (continuous measurement)	cCO ₂ too low	NF period [1/bpm] x etCO ₂ cycles ± 5	0	1
Lower limit FiO ₂ AW reached	FiO ₂ AW too low	<30 / mean 11	0	0.3
Bias flow not connected	Bias flow not connected	<1 ± 1	3 ± 1	0.5
Bias flow error	Bias flow error	<1 ± 1	3 ± 1	0.5

Line Disconnection Alarm Delay: 30 Seconds. e.g.

- Disconnection of the inspiratory breathing tube; or
- Disconnection at the patient connection port.

17.10.3 Airway Pressure Alarm Limits Setting-TwinStream™ EVO S-HFJV

Note:

All setting dialogues close after 10 seconds if there is not any operation.

17.10.3.1 Airway Pressure (P_{AW}) Limits in LAR, BRO, ETT/LMA, 4 LUM , 3 LUM, and 2 LUM PAW mode

- 1. Press button on the left of P_{AW} graph to open the P_{AW} Pressure setting window.
- 2. Press , or button to open upper/lower, MP_{AW} or ΔpHF limits setting window.
- 3. Slide or press the +/- buttons to change values in the default range, press to confirm the setting, or to exit the setting.



Fig.135 P_{AW} upper & lower limits setting

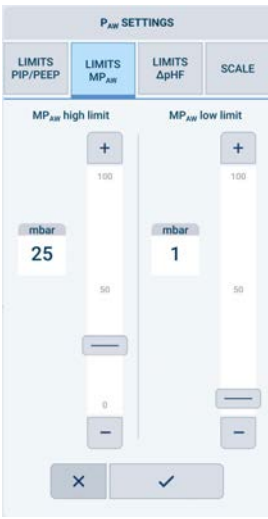


Fig.136 MP_{AW} limits setting



Fig.137 ΔpHF limits setting

- 4. The set upper and lower limits are shown as PIP and PEEP values.



Fig.138 P_{AW} upper & lower limits value



Fig.139 ΔpHF Limits value



Fig.140 MP_{AW} limits value

17.10.3.2 Pause Pressure (PP) Limit in 2 LUM GAS & PAW or 1 LUM mode

- 1. Press button on the left of PP graph to open the PP Pressure setting window.
- 2. Slide or press the +/- buttons to change value in the default range, press to confirm the setting, or to exit the setting.



Fig.141 Pause pressure setting window

17.10.4 Respiratory Gas Analysis Alarm Limits Setting-TwinStream™ EVO S-HFJV

Note:

All setting dialogues close after 10 seconds if there is not any operation.

17.10.4.1 FiO₂ AW Limits

1. Press  button on the left of FiO₂ graph to open the FiO₂ AW setting window.

2. Press "LIMITS" button to open limits setting window, slide or press +/- buttons to change high or low limit values in the default range, press  to confirm the setting, or  to exit the setting.



Fig.142 FiO₂ AW setting window

17.10.4.2 cCO₂, etCO₂ and FiCO₂ Limits

1. Press  button on the left of CO₂ graph to open setting window.

2. Press ,  or  button to open limits setting window.

3. Slide or press +/- buttons to change high or low limit values in the default range, press  to confirm the setting, or  to exit the setting.



Fig.143 cCO₂ setting



Fig.144 etCO₂ setting

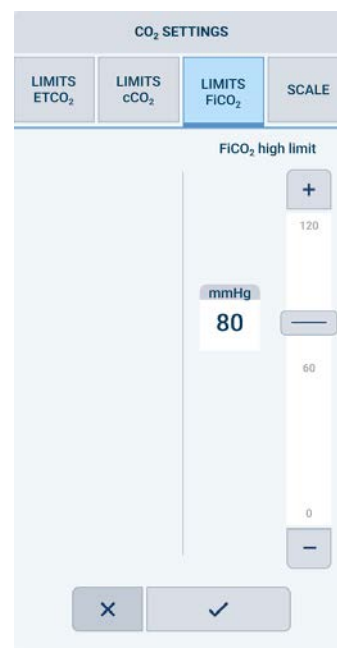


Fig.145 FiCO₂ setting

17.10.5 Pause Pressure (PP) Alarm Limits Setting-TwinStream™ EVO HFJV

 Note:

Setting dialogue closes after 10 seconds if there is not any operation.



1. Press button to open the PP Pressure setting window.

2. Press + or - button to set the value, press ✓ to confirm the setting, or ✕ to exit the setting.

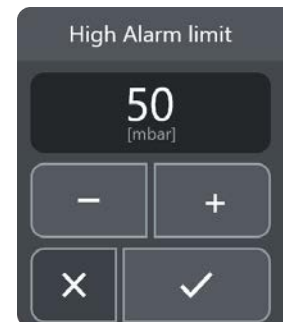


Fig.146 PP alarm setting window

17.11 Alarm List

Possible errors are listed below together with the displayed error messages and operational restrictions. The table also shows recommended solutions. In cases where the solution is "Call customer service" a quick resolution of the problem cannot be guaranteed, switch to an alternative ventilation system.

Priority: **H** = High **M** = Medium **L** = Low

17.11.1 Patient Alarm

Priority/ID	Alarm Message Basic	Alarm Message Main Screen	Possible Cause	Solution
H/3	P _{AW} High Alarm	Upper Limit P _{AW} – Ventilation Stopped!	Auto Alarm reset not successful! Possible causes: · Airway blocked · Jet Endoscope blocked · Monitoring line blocked	Press reset button to continue ventilation!
H/4	PP High Alarm	Upper Limit PP - Ventilation Stopped !	Auto Alarm reset not successful! Possible causes: · Airway blocked · Jet Endoscope blocked · Monitoring line blocked	Press reset button to continue ventilation!
H/6	FiO ₂ AW too high! LSM active	FiO ₂ AW too high (LSM active)	Possible causes: · Gas supply AIR too low/ failed · O₂ Sensor defective · Mixer error	· Interrupt laser operation · Deactivate LSM-Ventilation will be continued
H/11	P _{AW} too high!	Upper limit P _{AW} ! Auto reset in progress		
H/12	PP too high!	Upper limit PP! Auto reset in progress		
H/15	FiO ₂ AW under 18%	FiO ₂ AW under 18%	· Wrong gas supply · O₂ sensor defective · Admixture of foreign gas	· Check gas connection · Switch to alternative ventilation with other gas source
H/28	Bias flow over pressure	Bias flow over pressure	Bias flow control error	Call technical service
H/30	PEEP too low!	PEEP too low!	· Instrument / airway leakage · Alignment of Jet Endoscope	· Correct alignment of Jet Endoscope · Increase HF jet pressure until PEEP is reached
M/110	ΔpHF too high	ΔpHF too high	· Alignment of instrument / catheter · Change in compliance	· Check alignment of instrument/catheter · Compliance change (anaesthesia guidance)
M/111	MP _{AW} too high	MP _{AW} too high	· Alignment of instrument / catheter · Change in compliance	· Check alignment of instrument/catheter · Compliance change (anaesthesia guidance)
M/116	MP _{AW} too low	MP _{AW} too low	· Alignment of instrument / catheter · Change in compliance	· Check alignment of instrument/catheter · Compliance change
M/118	PEEP too low!	PEEP too low!	· Instrument / airway leakage · Alignment of jet endoscope	· Correct alignment of jet endoscope · Increase HF jet pressure until PEEP is reached
M/119	ΔpHF too low	ΔpHF too low	· Alignment of instrument / catheter · Change in compliance	· Check alignment of instrument/catheter · Compliance change (anaesthesia guidance)
M/126	etCO ₂ too low	etCO ₂ too low (manoeuvre mode)		
M/132	etCO ₂ too high	etCO ₂ too high		
M/133	cCO ₂ too high	cCO ₂ too high		

Priority/ID	Alarm Message Basic	Alarm Message Main Screen	Possible Cause	Solution
M/134	FiCO ₂ too high	FiCO ₂ too high		
M/135	cCO ₂ too low	cCO ₂ too low		
M/136	FiO ₂ AW too low	FiO ₂ AW too low	- High admixture of room air - Gas analysis tube leakage - Alignment of instrument / catheter - Internal unit error	- Check the connector of tubing set / instrument connection - Check the connector of tubing set / device connection - Increase FiO₂ jet until FiO₂ AW is reached - Use additional O₂ admixture via bias flow - Readjust alarm limit - Call technical service

17.11.2 Technical Alarm

Priority/ID	Alarm Message Basic	Alarm Message Main Screen	Possible Cause	Solution
H/1	Internal error (EMU fault)	Internal error (EMU fault)		- Switch to alternative ventilation immediately! - Call technical service!
H/2	Internal error (ECU fault)	Internal error (ECU fault)		- Switch to alternative ventilation immediately! - Call technical service!
H/5	FiO ₂ jet too high! LSM active	FiO ₂ jet too high! (LSM active)	- Gas supply AIR too low / failed. - O₂ sensor defective - Mixer error	- Interrupt laser operation. - Deactivate LSM - Ventilation will be continued.
H/7	AIR supply pressure too low	AIR supply pressure too low	Gas supply AIR too low / failed.	- Interrupt laser operation - Deactivate LSM - Ventilation will be continued with 100% O₂.
H/9	Tubing set not connected or blocked	Tubing set not connected or blocked	- P_{AW} tube blocked - Pressure measuring channel in the instrument blocked - Tubing set not connected	- Check tubing set - Check pressure measuring channel in instrument - Connect tubing set
H/13	Device temperature critical!	Device temperature critical!	- Housing fan defective - Heat accumulation / device covered	- Check appliance fan and fan slots - Call technical service!
H/14	FiO ₂ jet under 18%	FiO ₂ jet under 18%	- Wrong gas supply - O₂ sensor defective - Mixture of foreign gas	- Check gas connection - Switch to alternative ventilation with other gas source
H/16	PP measurement fault	PP measurement fault	PP sensor failed	- Ensure open airway - Switch to alternative ventilation!
H/19	Battery Error	Battery Error	- Battery defective - Battery not connected	Call technical service! Note: Battery operation not possible in case of power supply failure!
H/20	P _{AW} measurement defective	P _{AW} measurement defective	Internal device error	Switch to alternative ventilation
H/21	AIR supply pressure too low	AIR supply low during LSM	Gas supply AIR too low / failed	- Interrupt laser operation - Deactivate LSM - Ventilation will be continued - Restore gas supply AIR
H/22	O ₂ supply too low	O ₂ supply too low	Gas supply O ₂ too low / failed.	- Restore gas supply O₂ - Increase O₂ supply pressure - Ventilation will be continued with AIR.
H/23	AIR supply too low	AIR supply too low	Gas supply AIR too low / failed.	- Restore AIR gas supply - Increase AIR supply pressure - Ventilation is continued with O₂.
H/24	O ₂ supply too high	O ₂ gas pressure supply too high	Gas supply O ₂ > 6 bar!	Reduce O ₂ supply pressure less than 6 bar
H/25	AIR supply pressure too high	AIR gas pressure supply too high	Gas supply AIR > 6 bar!	Reduce AIR supply pressure less than 6 bar
H/26	NF line occlusion	NF jet line occlusion	- NF line blocked in tubing set - NF line blocked in the instrument / catheter	- Check NF line in tubing set - Check NF line in instrument / catheter check

Priority/ID	Alarm Message Basic	Alarm Message Main Screen	Possible Cause	Solution
H/27	HF line occlusion	HF jet line occlusion	- HF line blocked in tubing set - HF line blocked in the instrument / catheter	- Check HF line in tubing set - Check HF line in instrument / catheter
H/29	Gas sample line blocked	Gas sample line blocked	- measurement line blocked in instrument / catheter - Gas flow too low - measurement line blocked in tubing set	Check measuring lines, ensure patency
H/31	Battery mode < 5 min	Low battery, 5 min left		Connect device to power source
M/101	Jet line disconnect	Jet line disconnect	- NF-Jet tube leakage - No tubing set connected / detected	- Connect new tubing set - Check the connectors of tubing set / instrument connection - Check connectors of tubing set/device connection
M/102	Jet lines or monitoring disconnected	Jet or monitoring lines disconnected	- Jet lines not connected - Monitoring lines not connected - No tubing set connected / detected	- Connect new tubing set - Check the connectors of tubing set / instrument connection - Check connectors of tubing set/device connection
M/103	Gas measurement not connected	Gas measurement not connected	- Gas analysis tube leakage - No tubing set connected / detected	- Connect new tubing set - Check the connectors of tubing set / instrument connection - Check connectors of tubing set/device connection
M/104	Display not connected	Display not connected	- Cable not connected / defective - Display defective	Call technical service!
M/105	Battery mode < 10 min	Low battery, 10 minutes left		Connect to power source
M/106	Device temp. high!	Device temperature gets critical!		
M/107	Temp. of breathing too high	Temperature of breathing gas too high - humidifier will be switched off	- Water supply to the humidifier interrupted - Humidifier defective	Call technical service!
M/108	NF pressure too high	NF emission pressure too high!	NF control error	Call technical service!
M/109	HF pressure too high	HF emission pressure too high	HF control error	Call technical service!
M/112	FiO ₂ jet too high	FiO ₂ jet too high	- Gas supply AIR too low / failed - O₂ sensor defective - Mixer error	- Restore gas supply AIR - Increase AIR supply pressure
M/115	NF pressure too low	NF emission pressure too low	NF emission pressure setting too high CGS pressure setting too low	Check settings and connections
M/117	HF pressure too low	HF emission pressure too low	HF control error	Call technical service!
M/120	FiO ₂ jet too low	FiO ₂ jet too low	- Gas supply O₂ too low - O₂ sensor defective - Mixer error	Restore gas supply O ₂ Increase O ₂ supply pressure
M/122	NF frequency mismatch	NF frequency mismatch	NF control error	Call technical service!
M/123	HF frequency mismatch	HF frequency mismatch	HF control error	Call technical service!
M/124	NF I:E mismatch	NF I:E mismatch	NF control error	Call technical service!
M/125	HF i:e mismatch	HF i:e mismatch	HF control error	Call technical service!

Priority/ID	Alarm Message Basic	Alarm Message Main Screen	Possible Cause	Solution
M/127	etCO ₂ measurement not possible	etCO ₂ measurement not possible	- Implausible measured values - Internal device error in the CO₂ module	- Restart device and check connections - Call technical service!
M/128	FiO ₂ AW measurement not possible	FiO ₂ AW measurement not possible	FiO ₂ Calibration error	- Restart device and check connections - Call technical service!
M/129	O ₂ supply too low	O ₂ supply pressure too low	CGS pressure O ₂ too low	- Call technical service! - Raise CGS pressure between 4 and 5 bar
M/130	AIR supply too low	AIR supply pressure low	CGS pressure AIR too low	- Call technical service - Raise CGS pressure between 4 and 5 bar
M/137	Bias flow not connected	Bias flow not connected	Too low back pressure	- Check application part (nasal cannula, mask) - Call technical service!
M/138	Internal Error (Log)	Internal error (Log)	Internal device error	- Switch to alternative ventilation - Call technical service!
M/139	Bias flow error	Bias flow error	Too high back pressure	- Check application part (nasal cannula, mask) - Call technical service
L/200	Switch to battery mode	Power supply interrupted! Device is in battery mode	- Mains cable not plugged in - Voltage supply interrupted	- Reconnect mains cable / power supply - Call technical service!
L/201	Voltage supply fault	Voltage supply fault	Internal device error	Call technical service!
L/202	Fan fault	Fan fault	- Fan defective - Fan blocked	Call technical service!
L/203	O ₂ blender time out (AIR supply)	O ₂ blender time out	- O₂ sensor defective - Mixer error - Internal unit error	Call technical service!
L/207	LSM switched off	LSM off - Laser Safe Mode not available	Internal device error	- Interrupt laser operation - Call technical service
L/208	LSM Time out	LSM Time out- Laser Safe Mode not available	Internal device error	- Interrupt laser operation - Call technical service!
L/209	Error valve control	Valve overcurrent-Error in the valve control	Internal device error	- Switch to alternative ventilation - Call technical service!
L/210	Error in the safety ventilation	Error safety ventilation	Internal device error	- Switch to alternative ventilation - Call technical service!
L/211	Pump defect	Pump for gas analysis defective - measurement not possible	Pump defective	- Switch to alternative ventilation - Call technical service!
L/212	PDMS validation error	PDMS validation of result failed	- No Cable connected - Wrong settings	- Connect cable to PDMS - Check PDMS interface settings - Call technical service!
L/213	Perform bias flow test	Bias flow module not working - perform 'Bias flow test'	! Module is disabled until successful test ! - Wrong test setup - No gas supply connected	- Check test setup and connections - Check gas supply - Call technical service!
L/214	etCO ₂ measurement active	etCO ₂ measurement active	etCO ₂ measurement active. HF ventilation is disabled	- Finish etCO₂ measurement - Stop etCO₂ measurement

17.11.3 Selftest

17.11.3.1 Selftest Error

Priority/ID	Alarm Message Basic	Alarm Message Main Screen	Restart Button	Ventilation Possible
H/300	Selftest - Internal Error (External Flash ECU)	Selftest - Internal Error (External Flash ECU)	No	No
H/301	Selftest - Blender not found	Selftest - Blender not found	No	No
H/302	Selftest - Module HP not found	Selftest - Module HP not found	No	No
H/303	Selftest - Module FiO ₂ jet not found	Selftest - Module FiO ₂ jet not found	No	No
H/304	Selftest - Internal Error (EMU Voltage)	Selftest - Internal Error (EMU Voltage)	No	No
H/305	Selftest - Internal Error (External Flash EMU)	Selftest - Internal Error (External Flash EMU)	No	No
H/306	Selftest - Internal Error (Valve Disable Test)	Selftest - Internal Error (Valve Disable Test)	No	No
H/307	Selftest - Internal Error (EMU Test)	Selftest - Internal Error (EMU Test)	No	No
H/308	Selftest - Internal Error (OC signal test)	Selftest - Internal Error (OC signal test)	No	No
H/309	Selftest - Internal Error (Panel CPU Test)	Selftest - Internal Error (Panel CPU Test)	No	No
H/310	Selftest - Battery error	Selftest - Battery error	No	No
H/311	Selftest - Blender leak test failed	Selftest - Blender leak test failed	Yes	No
H/312	Selftest - Calibration pressure sensors failed	Selftest - Calibration pressure sensors failed	Yes	No
H/313	Selftest - Device Temperature too high	Selftest - Device Temperature too high	Yes	No
H/314	Selftest - Internal Error (VP1 Test)	Selftest - Internal Error (VP1 Test)	Yes	No
H/315	Selftest - Internal Error (VP2 Test)	Selftest - Internal Error (VP2 Test)	Yes	No
H/316	Selftest - Internal Error (VO1 Test)	Selftest - Internal Error (VO1 Test)	Yes	No
H/317	Selftest - Internal Error (VO2 Test)	Selftest - Internal Error (VO2 Test)	Yes	No
H/318	Self-test - Internal Error (HPC Leak Test)	Self-test - Internal Error (HPC Leak Test)	Yes	No
H/319	Selftest - Internal Error (VJHP Leak Test)	Selftest - Internal Error (VJHP Leak Test)	Yes	No
H/320	Selftest - Internal Error (VJHP Test)	Selftest - Internal Error (VJHP Test)	Yes	No
H/321	Selftest - Internal Error (VSHP Test)	Selftest - Internal Error (VSHP Test)	Yes	No
H/322	Selftest - Internal Error (VPPHP Test)	Selftest - Internal Error (VPPHP Test)	Yes	No
H/323	Selftest - Internal Error (VPO2 Test)	Selftest - Internal Error (VPO2 Test)	Yes	No
H/324	Selftest - O ₂ Calibration failed	Selftest - O ₂ Calibration failed	Yes	No
H/325	Selftest - Panel error No disc space	Selftest - No disc space	No	No

17.11.3.2 Selftest Warning

Priority/ID	Alarm Message Basic	Alarm Message Main Screen	Restart Button	Ventilation Possible
L/400	Remove tubing set	Remove attached tubing set	Yes	Yes
L/401	Check AIR supply	Check AIR supply and connections	Yes	Yes
L/402	Check O ₂ supply	Check O ₂ supply and connections	Yes	Yes
L/403	Selftest - Replace FiO ₂ jet Sensor	Selftest - FiO ₂ jet sensor needs to be replaced	No	Yes
L/404	Selftest - Replace FiO ₂ AW sensor	Selftest - FiO ₂ AW sensor needs to be replaced	No	Yes
L/405	Selftest - RTC Battery low	Selftest - RTC Battery low	No	Yes
L/406	Selftest - Service required	Selftest - Service required	No	Yes
L/407	Selftest - Service required	Selftest - Service required	No	Yes
L/408	Selftest - LP module not found	Selftest - LP module not found	No	No
L/409	Selftest - Bias flow module not found	Selftest - Bias flow module not found	Yes	Yes
L/410	Selftest - etCO ₂ module not found	Selftest - CO ₂ module not found	Yes	Yes
L/411	Selftest - FiO ₂ AW module not found	Selftest - FiO ₂ AW module not found	No	No
L/412	Selftest - Fan Test error	Selftest - Fan Test Failed	Yes	No
L/413	Selftest - Internal error (VHLP Test)	Selftest - Internal error (VHLP Test)	Yes	No
L/414	Selftest - Internal error (VHHP Test)	Selftest - Internal error (VHHP Test)	Yes	No
L/415	Self-test - Internal error (VBS Leak Test)	Self-test - Internal error (VBS Leak Test)	Yes	No
L/416	Selftest - Internal error (VSBS Leak Test)	Selftest - Internal error (VSBS Leak Test)	Yes	No
L/417	Selftest – Internal error (VBS/VSBS Test)	Selftest – Internal error (VBS/VSBS Test)	Yes	No
L/418	Selftest - Internal error (LPC Test)	Selftest - Internal error (LPC Test)	Yes	No
L/419	Selftest - Internal error (LPC Leak Test)	Selftest - Internal error (LPC Leak Test)	Yes	No
L/420	Selftest - Internal error (VJLP Leak Test)	Selftest - Internal error (VJLP Leak Test)	Yes	No
L/421	Selftest - Internal error (VJLP Test)	Selftest - Internal error (VJLP Test)	Yes	No
L/422	Selftest - Internal error (VSLP Test)	Selftest - Internal error (VSLP Test)	Yes	No
L/423	Selftest - Internal error (VPPLP Test)	Selftest - Internal error (VPPLP Test)	Yes	No
L/424	Selftest - Sample pump not found	Selftest - Sample pump not found	Yes	No
L/425	Selftest - FiO ₂ AW module could not be calibrated	Selftest - FiO ₂ AW module could not be calibrated	Yes	No
L/426	Selftest - etCO ₂ module not found	Selftest - CO ₂ module not found	Yes	No
L/430	Selftest - Panel error Log database full	Selftest - Log database full	No	Yes
L/431	Selftest - Panel error Disc space low	Selftest - Disc space low	No	Yes
L/432	Selftest -Option warning Options expiring soon	Selftest - Option(s) expire	No	Yes
L/433	Congress mode active	Congress mode active	No	Yes
L/434	Selftest - FiO ₂ jet cell warning lifetime expires	Selftest - Cell FiO ₂ jet lifetime expires	No	Yes

Priority/ID	Alarm Message Basic	Alarm Message Main Screen	Restart Button	Ventilation Possible
L/435	Selftest - FiO ₂ AW cell warning lifetime expires	Selftest - Cell FiO ₂ AW lifetime expires	No	Yes

18. Patient Data Management System-PDMS

18.1 Interfaces on the rear of the TwinStream™ EVO

On the back of the device there are several ports. Besides to the PDMS interfaces there are also service related USB interfaces.

The RS232 and USB-B interface is used for the PDMS option. When properly installed, the TwinStream™ EVO sends the data to the PDMS. Data transmission is only done in ventilation mode. It is not possible to execute commands or take control of the device via the connection.

The service related USB-A interfaces are secured by a cover which may only be opened by trained and authorized personnel. System updates, backups and exporting log files can be done via this interface.

18.2 Data Automatically Transferred to PDMS PC

For detailed information refer interface documentation.

- Parameter settings (e.g. NF pressure, HF pressure, NF Ratio, HF Ration, FiO₂ jet, Bias flow and many more)
- Measurement results (e.g. PIP, MPAW, PEEP, FiO₂ AW, etCO₂ and many more)
- Alarm status (High Alarm, Warning, Info)
- Alarm settings (Alarm limits for pressure parameters PEEP, PIP, ΔpHF, M PAW and gas measurement parameters FiO₂ AW, etCO₂)
- Meta information like software version, serial number, protocol version

Warning:

- If the device is connected to another none medical device via an electrical connection (USB-B, RS232), it must be galvanically isolated e.g. by network isolator.
- No other electrical device may be connected to the USB interface during operation.
- The interface may only be activated by authorised personnel!

Caution:

- The integration of the device into an IT network that includes other devices could lead to risks for patients, operators or third parties that were not previously known.
- The responsible organisation should identify, analyse and manage these risks.
- Changes to the IT network could lead to new risks and therefore could require additional analyses. Changes to the IT network can include following
 - Changes to the IT network configuration
 - Connecting additional elements to the IT network
 - Removing elements from the IT network
 - "Update" of devices that are connected to the IT network
 - "Upgrade" of devices that are connected to the IT network
- The use of none validated PDMS can lead to wrong or falsely displayed patient data. The use of this data can cause harm to the patient.
- An interruption of the data line or connection can lead to data loss.
- The PDMS interface is not intended to remotely send alarm signals to the user on a communicator. The interface is intended only for external recording of data.

Notice:

For installation and setup refer to service manual CJVDD120ENG and instruction PDMS CJVDD121ENG

19. Accessories

19.1 Tubing Sets

Reference Number	Name of Product	Brand Name
CJVNA112101	Jet-Ventilation tubing set, EvoConnect™ to EndoConnect™, single use, sterile, with air humidification	EvoConnect™ - EndoConnect™-SH
CJVNA112102	Jet-Ventilation tubing set, EvoConnect™ to EasyConnect™, single use, sterile, with air humidification	EvoConnect™ - EasyConnect™- SH
CJVNA112103	Jet-Ventilation tubing set, EvoConnect™ to LuerLock, 3-LUM / 4-LUM mode, single use, sterile, with air humidification	EvoConnect™ - LuerLock 3L/4L-SH
CJVNA112201	Jet-Ventilation tubing set, EvoConnect™ to LuerLock, 1-LUM mode, single use, sterile	EvoConnect™ - LuerLock 1L-S
CJVNA112202	Jet-Ventilation tubing set, EvoConnect™ to EasyConnect™, single use, sterile	EvoConnect™ - EasyConnect™-S
CJVNA112203	Jet-Ventilation tubing set, EvoConnect™ to LuerLock, 2-LUM mode, single use, sterile	EvoConnect™ - LuerLock 2L-S
CJVNA112204	Jet-Ventilation tubing set, EvoConnect™ to LuerLock, 3-LUM / 4-LUM mode, single use, sterile	EvoConnect™ - LuerLock 3L/4L-S
CJVNA112205	Jet-Ventilation tubing set, EvoConnect™ to EndoConnect™, single use, sterile	EvoConnect™ - EndoConnect™-S
CJVNA113201	Jet-Ventilation tubing set, EvoConnect™ to LuerLock, 1-LUM mode, single use	EvoConnect™ - LuerLock 1L
CJVNA113202	Jet-Ventilation tubing set, EvoConnect™ to EasyConnect™, single use	EvoConnect™ - EasyConnect™
CJVNA113203	Jet-Ventilation tubing set, EvoConnect™ to LuerLock, 2-LUM mode, single use	EvoConnect™ - LuerLock 2L
CJVNA113204	Jet-Ventilation tubing set, EvoConnect™ to LuerLock, 3-LUM / 4-LUM mode, single use	EvoConnect™ - LuerLock 3L/4L
CJVNA113205	Jet-Ventilation tubing set, EvoConnect™ to EndoConnect™, single use	EvoConnect™ - EndoConnect™

19.2 Rigid Instruments

Reference Number	Name of Product
CJVNB*****	Jet Bronchoscopes EVO
CJVNL*****	Jet Laryngoscopes EVO
CTNS-3**-***	Jet Laryngoscopes
CTNS-4**-***	Jet Bronchoscopes

19.3 ETT/LMA

Reference Number	Name of Product
CTNS-6**-***	Jet Converter

19.4 Catheters

Reference Number	Name of Product
CTFS-5**-***	Jet Catheter

19.5 Trolley

Reference Number	Name of Product
CJVNA115001	Trolley for TwinStream™ EVO
CJVNA115002	Basket for TwinStream™ EVO trolley
CJVNA115003	Drawer assembly for TwinStream™ EVO trolley

19.6 Oxygen Sensors

Reference Number	Name of Product
CSPNH111045	IT-Gambert MLF-16
CSPNH111046	Envitec OOMLF 103

19.7 Power Cords

Reference Number	Name of Product
CJVNA111005	Power cable 2m self securing
CJVNA111006	Power cable 3m self securing
CJVNA111007	Power cable 5m self securing

19.8 Equipotential Bonding Cable

Reference Number	Name of Product
CJVNA111008	Equipotential bonding cable 1,5m
CJVNA111009	Equipotential bonding cable 3m
CJVNA111010	Equipotential bonding cable 5m

19.9 PDMS Cable

Reference Number	Name of Product
CJVNA111001	USB-B cable 5m
CJVNA111002	RS 232 cable 5m

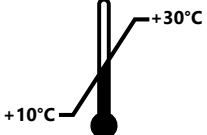
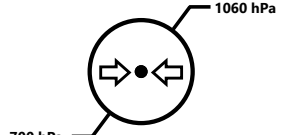
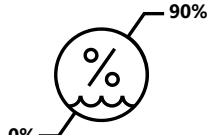
19.10 Central Gas Supply Tubing

Reference Number	Name of Product
CJVNA210010	NIST CGS-Tubing Set for TwinStream™ EVO for O ₂ and AIR, DIN/ISO, length 1,5 meters
CJVNA210011	NIST CGS-Tubing Set for TwinStream™ EVO for O ₂ and AIR, DIN/ISO, length 3,0 meters
CJVNA210012	NIST CGS-Tubing Set for TwinStream™ EVO for O ₂ and AIR, DIN/ISO, length 5,0 meters

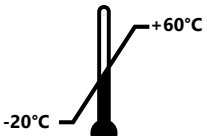
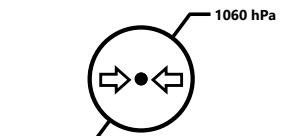
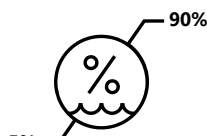
20. Storage and Transportation

Listed below are the conditions under which the TwinStream™ EVO ventilator maintains the accuracy of the controlled and displayed variables.

20.1 In Operation

Temperature	Air Pressure	Relative Humidity (non-condensing)
+10°C to +30°C 	700 hPa to 1060 hPa 	0% to 90% 

20.2 For Transport and Storage

Temperature	Air Pressure	Relative Humidity (non-condensing)
-20°C to +60°C 	700 hPa to 1060 hPa 	5% to 90% 

Warning:

- Avoid direct sunlight!
- Water ingress during transport or storage can lead to functional impairment or even damage!
- Use only original packaging! Inadequate packaging may cause mechanical damage during transport.
- Do not turn over the device! Incorrect handling may cause damage of the device during transport.
- In the event of the packaging being damaged, unintentionally opened or exposed to environmental conditions out of this specification, please contact Carl Reiner before use. The authorised person will test device conditions.

Caution:

If the temperature, air pressure and humidity are too high or too low, the service life of the used materials may be shortened.

21. Cleaning and Disinfecting the Ventilator

21.1 General Information

The device surface must be disinfected after each use by manual wipe disinfection with alcoholic surface disinfectant (possibly ready-to-use disinfectant wipe).



Notice:

During normal use or first failure no parts of the device gas path way can be contaminated.

21.2 Disinfectant

The disinfectability of the device surfaces is validated with the following disinfectant: mikrozid® AF wipes (active ingredients in 100 g solution: 25 g Ethanol (94%), 35 g Propan-1-ol).

Disinfectants that must not be used, are products containing:

- acetone
- benzol (e.g. benzaldehyde, benzyl alcohol, toluol)
- chlorinated compounds (e.g. chlorine, cyclohexanone, dichlorobenzene)
- strong acids and oxidizing agents the touchscreen can also be wiped with a soft cloth using the same disinfectant.

21.3 How to Disinfect the Ventilator

1. Before disinfection remove all visible dirt with a cloth soaked in disinfectant until visibly clean.
2. Perform surface disinfection. Carefully follow manufacturer's instructions for the disinfectant.
3. Remove any residual disinfectant after the disinfection time has elapsed.
4. Visually inspect the device for damage and residues of contamination.



Warning:

- Cleaning and disinfection work may only be carried out if the main plug is disconnected from the power supply!
- The device itself must not be immersed in liquid disinfectants or autoclaved!



Caution:

Do not introduce large quantities of disinfectant into the front panel outlets of the device, liquid ingress might damage the device.



Notice:

The above instructions have been validated by Carl Reiner as suitable for processing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

22. Safe Disposal

22.1 Packing

Dispose of the packaging material of the device and the accessories listed in the accessories list in accordance with the applicable legal regulations.

22.2 Used TwinStream™ EVO

The disposal of electrical and electronic equipment is subject to special guidelines. This appliance must be disposed of in accordance with national regulations. More information please visit WEEE Directive.

If disposal is not possible (for instance, no waste separation), the apparatus may be sent to CARL REINER® GmbH or the Business Partner for appropriate disposal.

22.3 Battery

The battery in the device contains harmful substances and must be disposed of in accordance with national laws and regulations. The battery must therefore be removed before the disposal of the device.

 Warning:

Risk of explosion and burns with improper handling of batteries.

- Do not throw batteries into a fire.
- Do not open batteries by force.

22.4 Sensor

The oxygen sensor is hazardous waste and should be disposed of in accordance with local waste disposal regulations.

23. Technical Data

23.1 Physical Specifications

Dimensions

	Weight	Height	Width	Depth
w/o external Display, w/o Trolley	15 kg	20.5 cm	34 cm	39.4 cm
w external Display, w/o Trolley	20 kg	48.4 cm	39.4 cm	39.4 cm
w/o external Display, w Trolley, w/o drawer or basket	30 kg	115 cm	55.3 cm	62 cm
w external Display, w Trolley, w/o drawer or basket	35 kg	143 cm	55.3 cm	62 cm

Display

	Size	Type	Resolution
External	15"6 Zoll	Touch screen	1920*1080 px
Internal	5 Zoll	Touch screen	800*400 px

23.2 Ventilation Parameters

Single jet (HFJV) - 1 LUM mode

Jet Unit	Frequency (f)	I:E Ratio (i:e)	Emission Pressure (PNF)
HF	50-200 1/min	1:1,5 - 1:5	0.1 -3.5 bar

Single jet (HFJV) - 2 LUM mode

Jet Unit	Frequency (f)	I:E Ratio (i:e)	Emission Pressure (PNF)
HF	50-130 1/min	1:2 - 1:5	0.1 -3.5 bar

Double jet (S-HFJV)

Jet Unit	Frequency (f)	I:E Ratio (i:e)	Emission Pressure	Max O ₂ bias flow output
HF	50-2000 1/min	3:1 - 1:5	0.1 -2.0 bar	70 l/min
NF	1-120 1/min	3:1 - 1:5	0.1 -3.5 bar 0.1 - 3.0 bar (ETT/LMA)	

23.3 Alarm Limit

High airway pressure: 0-100 mbar

Low PEEP: 0-100 mbar

High MP_{AW}: 0-100 mbar (+[3,0+(15%)] mbar/-[3,0+(50%)] mbar)Low MP_{AW}: 0-100 mbar (+[3,0+(15%)] mbar/-[3,0+(50%)] mbar)

High deltaHF: 0-100 mbar

Low deltaHF: 0-100 mbar

Pause pressure high: 0-100 mbar

High FiO₂ AW: 21-100%Low FiO₂ AW: 21-100%High CO₂ continuous: 0-120 mmhgLow CO₂ continuous: 0-120 mmhgHigh CO₂ intermittend: 0-120 mmhgLow CO₂ intermittend: 0-120 mmhgInspired CO₂: 0-120 mmhg

Notice:

- The upper alarm limit can be set to 100 mbar under normal conditions.
- In the first case of error, the following maximally limited pressures (PLIM max) can be achieved: 100 mbar.
- It is set through the software that no pressures above 100 mbar can be applied. If this alarm limit is exceeded, the software switches all valves off in the first fault and releases the pressure via the gas outlets on the back of the device.

23.4 Gas Mixer

FiO₂ jet setting range: 21-100%Rise time from 21% to 90% O₂: 16 sMixer accuracy: $\leq \pm 3\%$ absoluteO₂ sensor type: Galvanic cell

Supply pressure: 2.8 - 6 bar

23.5 Airway Pressure

There is no degradation in accuracy of monitored values with frequency. All accuracy specifications apply over the full frequency range.

PIP accuracy: $\pm(3 \text{ mbar abs} + (10\% \text{ of reading}))$
 PEEP accuracy: $\pm(3 \text{ mbar abs} + (10\% \text{ of reading}))$
 MP_{AW} accuracy: $\pm(3 \text{ mbar abs} + (10\% \text{ of reading}))$
 PP accuracy: $\pm(3 \text{ mbar abs} + (10\% \text{ of reading}))$
 ΔpHF accuracy: $\pm(3 \text{ mbar abs} + (10\% \text{ of reading}))$

Waveform displayed: Pressure vs. Time Waveform
 Pressure scale: 0-12 kPa
 Waveform time scale: 0.3-60 s

23.6 Gas Monitoring

Inspired O₂ Concentration

FiO ₂ jet range: 1-100%	FiO ₂ AW range: 1-100%
FiO ₂ jet sensor type: Galvanic cell	FiO ₂ AW sensor type: Galvanic cell
Rated respiration rate FiO ₂ jet: 3-2000 bpm	Rated respiration rate FiO ₂ AW: 3-2000 bpm
FiO ₂ jet response time: 18.85 s	FiO ₂ AW response time: 18.85 s
FiO ₂ jet accuracy: $\pm(1\% \text{ absolut} + (3\% \text{ relativ of the FiO}_2))$	FiO ₂ AW accuracy: $\pm(1\% \text{ absolut} + (3\% \text{ relativ of the FiO}_2))$

cCO₂ & etCO₂ Concentration

Operating principle: 0-16 vol. %	Sample flow: 450-460 ml/min
Operating pressure: 540-1200 hpa	Warm-up time: <5 s
Accuracy: $\pm 0.26\%$ in range 0-3.7 vol. %, $\pm 7\%$ in range >3.7 vol. %	Response time: <150 ms (detector)
Rated respiration rate etCO ₂ : 3-100 bpm	Calibration: Automatic barometric off set calibration
Rated respiration rate cCO ₂ : 3-2000 bpm	

23.7 Laser Safe Mode

Target FiO ₂ AW range: 21-40%	Activation/deactivation: Manually, ON/OFF
Operating principle: FiO ₂ jet reduction	Colour indication: Red $\geq 4\%$ of FiO ₂ jet reduction Green = $\pm 4\%$ of FiO ₂ jet reduction

23.8 Pneumatic Specifications

Gas Supply

Gas supply according to ISO 7396-1:	- Oxygen: medical oxygen $\geq 99.5\%$ - AIR: medical air
AIR / O ₂ inlet pressure: 280-600 kPa	AIR / O ₂ inlet type: G1/4 to DISS, NIST or AFNOR
Gas consumption: AIR: max 80 l/min O ₂ : max 125 l/min	

Patient Breathing Circuit

Circuit type: Open system	Max. insp. flow: up to 270 l/min
O ₂ bias flow: 0-70 l/min	O ₂ bias flow accuracy: $\pm(3 \text{ l/min} + (5\% \text{ of setting}))$

23.9 Mains Supply

Electrical Specifications

Voltage Input: ~110-240 V	Fuses: 2x1.6 AT H250 V
Power Input: 120 VA	Power cord: 5 m
Frequency: 50-60 Hz	

Internal Power Supply

Voltage: 24 V	Cells: 18650
Capacity: 18000 mAh	Cell Type: Lithium Ionen

23.10 PDMS Communication Ports

Serial interface: 1x RS232	USB: 1xUSB Typ B
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23.11 Maintenance Connection Ports

USB port: 3xUSB

23.12 Sound Pressure

Sound pressure level with average device setting at head height Patient:

LpA = 44,4 dB re 20 µPa

Sound pressure level with average device setting in height Device:

LpA = 47,2 dB re 20 µPa

Sound power level:

LWA = 55,2 dB re 1 pW

23.13 General Specifications

Medical device class: IIb

Electrical classification : Protection class I

Ingress Protection rating: IP22

- Protection against contact: Protected against contact with the finger.
- Protection against foreign bodies: Protected against medium-sized solid foreign bodies (diameter ≥ 12 mm).
- Protection against water: Protected against dripping water falling at an angle (up to 15°).

Classification of applied parts: Jet Endoscopes, Catheters and Tubing Sets are classified as Body Floating (BF)

Operation Mode: for use in continuous operation

23.14 Essential Performance Features

23.14.1 Essential Performance Features according to applied Standards

Applicable Standards regarding the determination of Essential Performance Features for the TwinStream™ EVO are the following:

- EN ISO 80601-2-87:2020
- EN ISO 80601-2-55:2018

Essential Performance Feature	Range	Unit	Accuracy	Source
EN ISO 80601-2-87				
Provision of ventilation at the patient connection port or at the distal Outlet of the jet system within the alarm limit set by the operator or generation of an alarm	-	-	-	EN ISO 80601-2-87 Table 201.101
The ventilator must be equipped with an alarm system that detects a technical alarm condition to indicate when conditions in the HFV breathing system reach the disconnected alarm limit connection is reached	-	-	-	EN ISO 80601-2-87 201.12.4.109
Alarm if oxygen concentration <18% occurs	-	-	-	EN ISO 80601-2-87 201.12.4.101-> EN ISO 80601-2-55 table 201.106
FiO ₂ measurement of the gas mixture within a defined accuracy	18-100	Vol.% O ₂	±(2,5%abs +(2,5% of reading))	EN ISO 80601-2-87 201.12.4.101
Alarm if VBS is disconnected	-	-	-	EN ISO 80601-2-87 201.12.4.107
Alarm if gas supply failure	-	-	-	EN ISO 80601-2-87 201.13.102
Alarm if internal electrical power source nears depletion	-	-	-	EN ISO 80601-2-87 201.11.8.101
Alarm if mean air way pressure too high or too low	-	-	-	EN ISO 80601-2-87 201.12.4.102
Alarm if an obstruction occurs	-	-	-	EN ISO 80601-2-87 201.12.4.106
Alarm if high oxygen occurs	-	-	-	EN ISO 80601-2-87 201.12.4.101
Alarm if high or low amplitude occurs	-	-	-	EN ISO 80601-2-87 201.12.4.103
EN ISO 80601-2-55				
Alarm if exhaled CO ₂ too high	-	-	-	EN ISO 80601-2-55 Table 201.106

Essential Performance Feature	Range	Unit	Accuracy	Source
Alarm if exhaled CO ₂ too low	-	-	-	EN ISO 80601-2-55 Table 201.106
etCO ₂ measurement within a defined accuracy	0-120	mmhg	±(0,43 % +(8 % of reading))	EN ISO 80601-2-55 Table 201.12.1.101

23.14.2 Essential Performance Features according to Risk Assessment

According to EN ISO60601-1:2014 Clause 4.3 the Essential Performance Features are determined as follows.

All clinical functions whose deterioration or failure can lead to an unacceptable risk.

Essential Performance Feature	Range	Unit	Accuracy	Source
Emission of a defined oxygen-air mixture	21-100	Vol% O ₂	±4% abs.	Risk Management and EN ISO 80601-2-87 Table 201.101
Emission of a defined emission pressure	0,1-3,5	bar	±(20 mbar abs. +(4% of reading))	Risk Management and EN ISO 80601-2-87 Table 201.101
Emission of a defined frequency	1-2000	bpm	±4% of reading	Risk Management and EN ISO 80601-2-87 Table 201.101
Emission of a defined I:E-Ratio	5:1-1:5	-	±0,1 abs.	Risk Management and EN ISO 80601-2-87 Table 201.101
High Airway Pressure Alarm	0-100	mbar		Risk Management

24. Service and Maintenance

24.1 General Information

The ventilator must be checked for technical safety (Safety Inspection, TSI) every 12 months, or after the periodic maintenance or any repair. Such persons must carry out all technical safety checks according to modern ethical professional practice and independently of external influences.

TwinStream™ EVO and all accessories (Jet Endoscopes, Jet Coupling, etc.) must be inspected and serviced either collectively or when any other expiry criterion is fulfilled (switch cycles, operating hours). After the self-test, a maintenance reminder appears in the form of a warning if the maintenance interval has expired. The time of the next maintenance and all relevant service information are displayed in the service menu.

Update work = updating of the software

Upgrade work = extension of the functions (e.g. installation of the etCO₂ or FiO₂ AW option)

Warning:

- Repair and maintenance must not be performed when the unit is used on the patient.
- The ventilator is delivered in an oxygen-compatible state after a comprehensive test run has been performed. No grease or oil should be used during repair or maintenance work in order to avoid malfunction of the apparatus, which may be as serious as explosions when the apparatus is used with oxygen.

Caution:

- All the service mentioned in this Manual (maintenance, repair, update/upgrade) must be carried out by the qualified personnel who is authorised by the manufacturer.
- To prevent malfunction of the ventilator, only original CARL REINER® spare parts may be used for any maintenance work.
- TwinStream™ EVO ventilator or Jet accessories (Jet Endoscope, Jet Coupling) which do not function or do not meet the manufacturer's specifications may not be used until all necessary repairs have been completed.
- Maintenance and repair work on the ventilator, parts of the ventilator or original accessories such as Tubing Set or Jet Endoscopes can only be conducted if these have been cleaned and disinfected prior to their being collected or sent in. We reserve the right to return contaminated instruments, tube systems or ventilator to the sender.

Note:

Checking safety and essential performance features according to TwinStream™ EVO Service Manual CJVDD120ENG.

24.2 Maintenance Interval

Warning:

Make sure that the maintenance interval is observed.

24.2.1 Maintenance interval after 12 Months

- Document the serial number of the device
- Document the service code
- Reading out the accumulated operating hours and ventilation hours
- Reading out the accumulated operating hours of the FiO₂ AW and etCO₂ module (optional)
- Reading out the unit IDs of installed modules in the pneumatics screen
- Reading out available software options
- Reading out customer information and languages
- Serial numbers of O₂ sensors (old and new) must be documented
- O₂ sensors must be replaced (see chapter 24.3)
- Performing an O₂ calibration
- Check the software status for updates
- TSI with a self-test afterwards
- Checking performance features and alarms

24.2.2 Maintenance interval after 24 Months

- Replacement of rechargeable battery (INR18650-35E)
- Replacement of 3 V = RTC - battery CR1225

24.3 Oxygen Sensor Replacement

TwinStream™ EVO is equipped with two independent oxygen sensors for accurate respiratory gas monitoring. An oxygen sensor is required to measure the delivered FiO_2 jet. The second sensor is needed to measure the oxygen concentration in the airway (FiO_2 AW). During the self-test the condition of the oxygen sensors is checked. If one or both O_2 sensors reach the end of their service life, a message will appear on the screen requesting replacement of the sensors. The oxygen sensors are located on the back of the unit in a compartment and can only be replaced with appropriate tools.

- Upper cell: FiO_2 AW - (oxygen measurement in the airway)
- Lower cell: FiO_2 jet - (oxygen measurement in the jet stream)

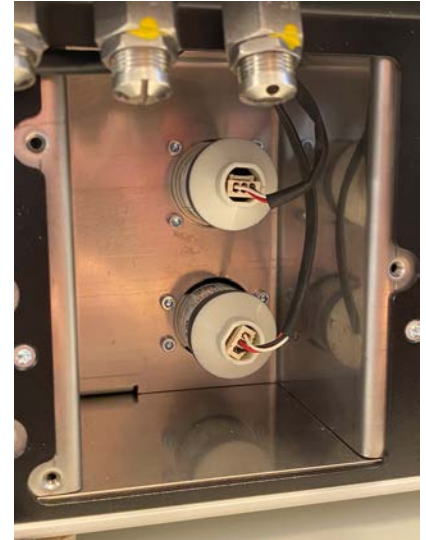


Fig.147

Replacement:

The cell replacement procedure is identical for both cells!

1. Open the service compartment
2. Remove the plug from the respective cell using a flat tool
3. Unscrew the cell
4. Screw in the new cell
5. Reconnect the plug
6. Close service compartment

⚠ Caution:

- Replacement may only be performed by trained maintenance personnel authorized by the manufacturer.
- Make sure the ventilator is switched off and disconnect with the power supply cable before replacement of Oxygen Sensor.

24.4 Rechargeable Battery Replacement (INR18650-35E)

There are two different methods of battery replacement:

- Battery cell exchange: only individual or all six cells of the battery are exchanged.
- Battery pack exchange: the entire battery slot is exchanged.

Warning:

To make sure the device works properly in case of an power outage, replace the battery cells every 24 months.

Caution:

- Replacement may only be performed by trained maintenance personnel authorized by the manufacturer.
- Make sure the ventilator is shut down before replacement of battery.

24.4.1 Battery Cell Replacement

1. Open battery compartment
2. Disconnect the plug from the battery pack
3. Pull out the battery pack
4. Replace individual cells (lever out using a flat plastic tool)
5. Push in new cells (pay attention to polarity)
6. Push the battery pack back in
7. Plug in the connector
8. Close the battery compartment



Fig.148



Fig.149



Fig.150

24.4.2 Battery Pack Replacement

1. Open battery compartment
2. Unplug the battery pack
3. Pull out the battery pack
4. Carefully insert the new battery pack
5. Plug in the connector
6. Close battery compartment



Fig.151

25. Declaration Concerning Electromagnetic Compatibility

25.1 General Information

The CARL REINER® TwinStream™ EVO device complies with the requirements of EN 60601-1-2: 2014 regarding electromagnetic emissions and immunity to interference. It should not be operated near motors or transformers, since electrical or magnetic interference fields can falsify measurements or impair the function. Neighbouring power lines are therefore also to be avoided.

When storing and installing electrically operated products, care must be taken that there is no negative effect on EMC of nearby products.

Existing environmental disturbances can lead to malfunctions without triggering alarms in the device. There must be a distance of 30cm to possible sources of interference.

Longer voltage interruptions do not lead to a long-term impairment of the measuring system still endanger the patient or user.

Warning:

- PORTABLE RF communications equipment (including radios) (including their accessories, such as antenna cables and external antennas) should not be used closer than 30 cm (or 12 inches) to those of the TwinStream™ EVO and its cables. Failure to do so may result in a reduction in the performance of the device
- Use of this product next to other equipment or stacked with other equipment should be avoided, as this could result in improper operation. If use is still necessary in the manner described above, this device and the other devices should be observed to make sure they are working properly.
- Leads of active electrosurgical equipment must be at least 30cm away from the TwinStream™ EVO. Using the TwinStream™ EVO immediately adjacent to the RF surgical leads should be avoided, as this could result in improper operation.
- Devices that may cause electromagnetic disturbances should not be operated in the vicinity of the ventilator (e.g., mobile phones etc.)
- Device should not be used in combination with an MRI or in MRI premises and not in a pressure chamber or hyperbaric therapy!

Caution:

- Use of accessories, cables, or transducers other than those specified herein with the TwinStream™ EVO may increase the emissions and reduce the immunity of the TwinStream™ EVO.
- The EMC characteristics of this equipment, permit its use in industrial and hospital environments (CISPR 11, Class A). When used in a residential environment (for which Class B is usually required by CISPR 11), this equipment may not provide adequate protection of radio services. The user may need to take corrective action such as relocation or reorientation of the equipment.

List of EMC relevant accessories

Power cord	only use original accessories
Equipotential bonding	only use original accessories
RJ45 PDMS cable	According to EN ISO 60601 max 3m, shielded
USB-A	The USB port is for service purposes only
USB-B	PDMS

25.2 Electromagnetic Immunity Special Requirements

The TwinStream™ EVO is intended for use in the electromagnetic environment specified below.

The operator or user of the TwinStream™ EVO should ensure that it is used in such an environment

Use of
Electrosurgical Devices

- Examination according to IEC 60601-2-2, Annex BB
- Wires of active electrosurgical units must be at least 30 cm away from the TwinStream™ EVO. Using the TwinStream™ EVO immediately adjacent to the RF surgical leads should be avoided, as this could result in improper operation

Emission & Immunity tests

Emission tests	Compliance
RF emissions CISPR 11 (Radiated Emission)	Class A, Group 1
Harmonic emissions IEC 61000-3-2,	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Passed
Immunity tests	Compliance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV; Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV; 100 kHz repetition frequency
Surge IEC 61000-4-5	$\pm 0,5$ kV, ± 1 kV, ± 2 kV
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° and 0 % UT; 250/300 cycle
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50
Conducted RF IEC 61000-4-6	3 V: 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC 61000-4-3	3 V/m: 80 MHz to 2.5 GHz
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3	28 V/m 450 MHz, 50% PM at 18 Hz 810 MHz, 50% PM at 18 Hz 870 MHz, 50% PM at 18 Hz 930 MHz, 50% PM at 18 Hz 1720 MHz, 50% PM at 217 Hz 1845 MHz, 50% PM at 217 Hz 1970 MHz, 50% PM at 217 Hz 2450 MHz, 50% PM at 217 Hz 27 V/m 385 MHz, 50% PM at 18 Hz 9 V/m 710 MHz, 50% PM at 217 Hz 745 MHz, 50% PM at 217 Hz 780 MHz, 50% PM at 217 Hz 5240 MHz, 50% PM at 217 Hz 5500 MHz, 50% PM at 217 Hz 5785 MHz, 50% PM at 217 Hz

26. Guarantee and Liability

CARL REINER[®] GmbH guarantees that the devices it supplies, including the accessories, are validated and without defect in terms of material and workmanship.

CARL REINER[®] GmbH assumes no liability for product performance and patient safety:

- if the devices aren't used and stored in accordance with the Instruction For Use (IFU)
- the warnings and precautions are not observed
- modifications of any kind are made to the product.
- the use of non-original spare parts
- misuse

In case of a serious incident that has occurred in relation to the device, the user and/or patient has to issue a report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

27. Legal Information



The declaration of conformity can be found in the delivery documents



e-IFU database

<https://qr.carlreiner.eu/CJVND001000>

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