

- 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.

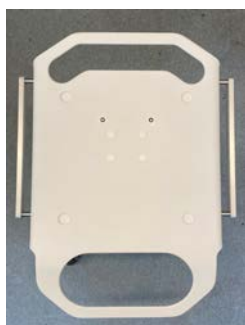


Fig.3 Trolley platform



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!

## **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](mailto: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

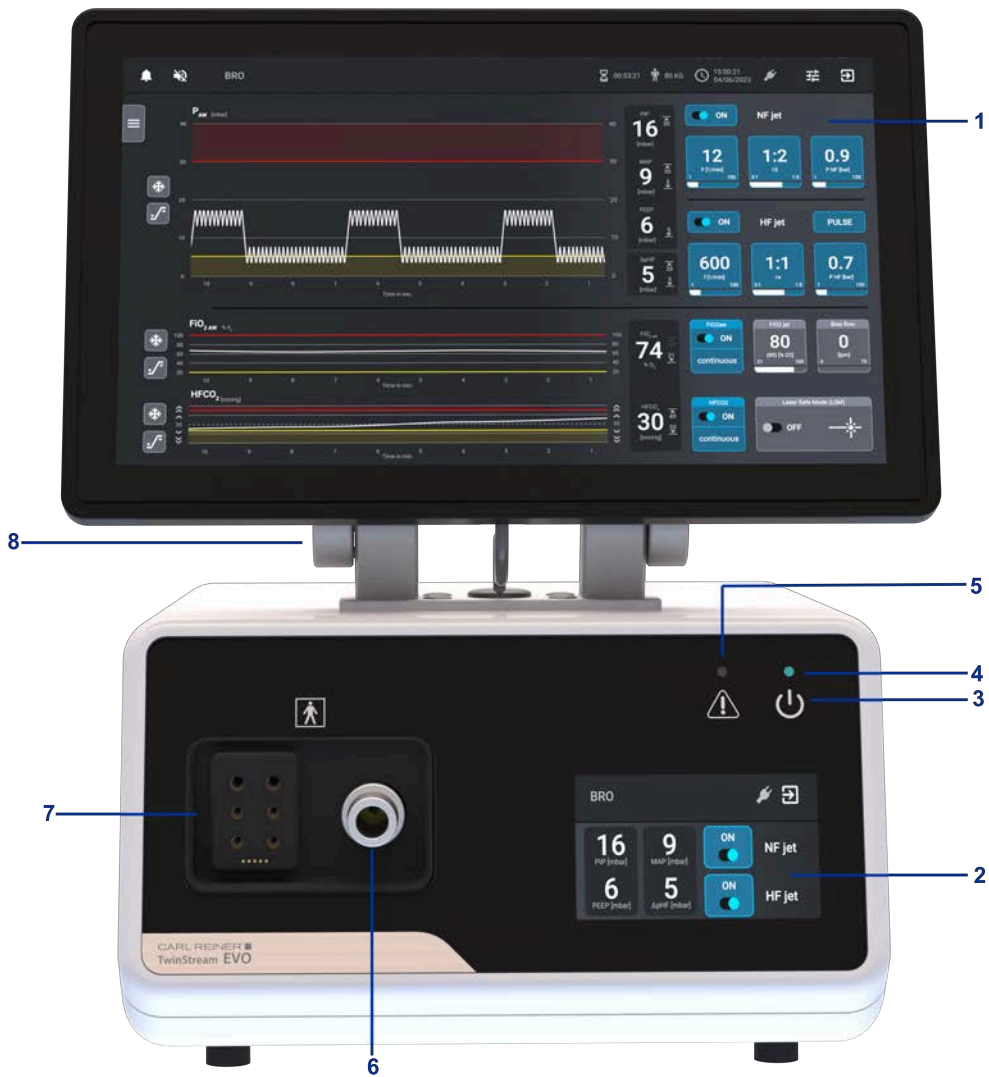


Fig.11 TwinStream™ EVO Front View

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

- 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 CO<sub>2</sub> 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 CO<sub>2</sub> 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=P<sub>insp</sub>) 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.

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 FiO<sub>2</sub> jet Value

For LSM FiO<sub>2</sub> jet is configured between 21% and 40%. If LSM is activated, FiO<sub>2</sub> jet is reduced to this range and returns to the previous value after deactivation. User can reduce the maximum FiO<sub>2</sub> jet lower than 40% either in system menu or when LSM is activated. After selecting the ventilation mode or with active ventilation, the configured FiO<sub>2</sub> jet is set automatically by the device after the start of the Laser Safe Mode.








To reach this set FiO<sub>2</sub> 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 FiO<sub>2</sub> 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.

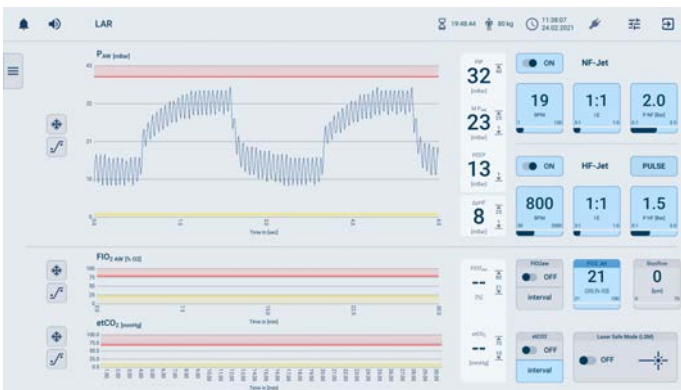


Fig.18 LAR mode PULSE active



Fig.19 LAR mode PULSE inactive

### 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.

## 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

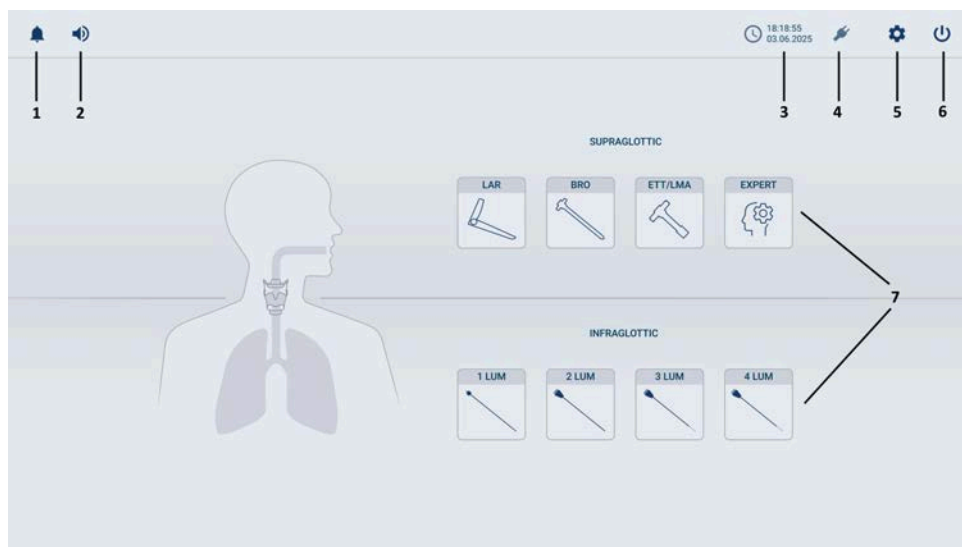


Fig.32 Main menu-external panel

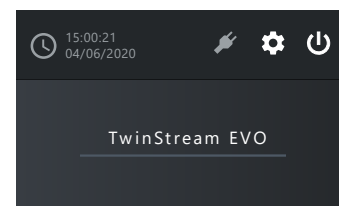



Fig.33 Main menu-internal display


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

### 15.1.6.2 O<sub>2</sub> bias flow Setting

1. Press "O<sub>2</sub> 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.

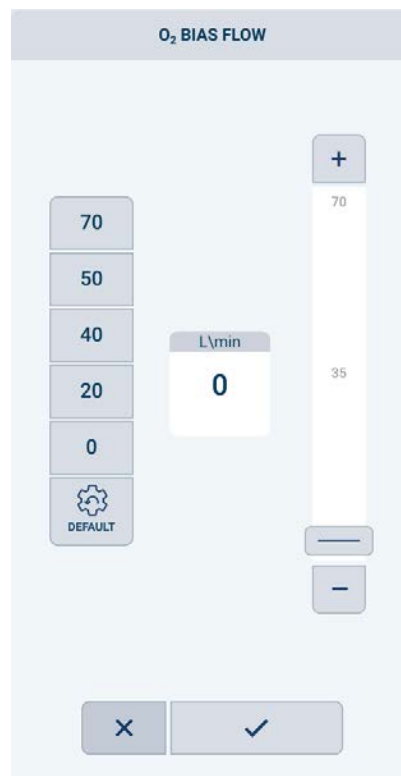


Fig.59 O<sub>2</sub> bias flow setting window

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



Fig.60



Fig.61 O<sub>2</sub> bias flow active = Blue



Fig.62 O<sub>2</sub> bias flow inactive = Gray

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

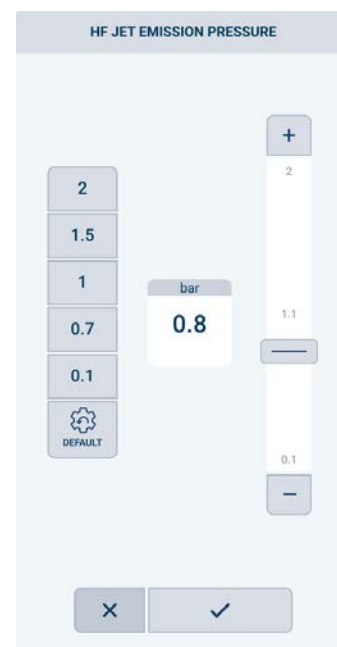


Fig.70 HF jet pressure setting window

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 FiO<sub>2</sub> AW is displayed to show the actual oxygen concentration in the airway (optional).

The time taken to reach the target FiO<sub>2</sub> AW will depend on the patient's lung volume, compliance, resistance and on the ventilation settings.

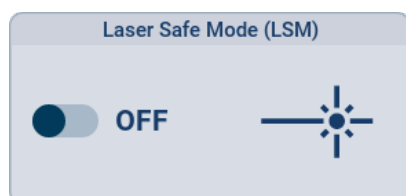


Fig.74 LSM off

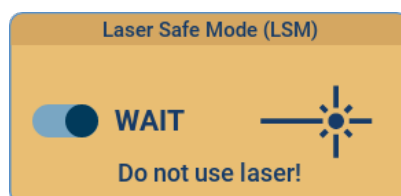


Fig.75 LSM not ready

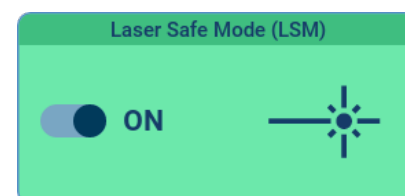


Fig.76 LSM on

## 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 H<sub>2</sub>O 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 FiO<sub>2</sub> AW high

#### LSM Active

If the FiO<sub>2</sub> 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 FiO<sub>2</sub> 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 FiO<sub>2</sub> 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 FiO<sub>2</sub> AW is too high. An info message "FiO<sub>2</sub> 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.



Priority/ID	Alarm Message Basic	Alarm Message Main Screen	Possible Cause	Solution
M/134	FiCO <sub>2</sub> too high	FiCO <sub>2</sub> too high		
M/135	cCO <sub>2</sub> too low	cCO <sub>2</sub> too low		
M/136	FiO <sub>2</sub> AW too low	FiO <sub>2</sub> AW too low	<ul style="list-style-type: none"> <li>. High admixture of room air</li> <li>. Gas analysis tube leakage</li> <li>. Alignment of instrument / catheter</li> <li>. Internal unit error</li> </ul>	<ul style="list-style-type: none"> <li>. Check the connector of tubing set / instrument connection</li> <li>. Check the connector of tubing set / device connection</li> <li>. Increase FiO<sub>2</sub> jetuntil FiO<sub>2</sub> AW is reached</li> <li>. Use additional O<sub>2</sub> admixture via bias flow</li> <li>. Readjust alarm limit</li> <li>. Call technical service</li> </ul>

## 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)		<ul style="list-style-type: none"> <li>Switch to alternative ventilation immediately!</li> <li>Call technical service!</li> </ul>
H/2	Internal error (ECU fault)	Internal error (ECU fault)		<ul style="list-style-type: none"> <li>Switch to alternative ventilation immediately!</li> <li>Call technical service!</li> </ul>
H/5	FiO <sub>2</sub> jet too high! LSM active	FiO <sub>2</sub> jet too high! (LSM active)	<ul style="list-style-type: none"> <li>Gas supply AIR too low / failed.</li> <li>O<sub>2</sub> sensor defective</li> <li>Mixer error</li> </ul>	<ul style="list-style-type: none"> <li>Interrupt laser operation.</li> <li>Deactivate LSM - Ventilation will be continued.</li> </ul>
H/7	AIR supply pressure too low	AIR supply pressure too low	Gas supply AIR too low / failed.	<ul style="list-style-type: none"> <li>Interrupt laser operation</li> <li>Deactivate LSM - Ventilation will be continued with 100% O<sub>2</sub>.</li> </ul>
H/9	Tubing set not connected or blocked	Tubing set not connected or blocked	<ul style="list-style-type: none"> <li>P<sub>AW</sub> tube blocked</li> <li>Pressure measuring channel in the instrument blocked</li> <li>Tubing set not connected</li> </ul>	<ul style="list-style-type: none"> <li>Check tubing set</li> <li>Check pressure measuring channel in instrument</li> <li>Connect tubing set</li> </ul>
H/13	Device temperature critical!	Device temperature critical!	<ul style="list-style-type: none"> <li>Housing fan defective</li> <li>Heat accumulation / device covered</li> </ul>	<ul style="list-style-type: none"> <li>Check appliance fan and fan slots</li> <li>Call technical service!</li> </ul>
H/14	FiO <sub>2</sub> jet under 18%	FiO <sub>2</sub> jet under 18%	<ul style="list-style-type: none"> <li>Wrong gas supply</li> <li>O<sub>2</sub> sensor defective</li> <li>Mixture of foreign gas</li> </ul>	<ul style="list-style-type: none"> <li>Check gas connection</li> <li>Switch to alternative ventilation with other gas source</li> </ul>
H/16	PP measurement fault	PP measurement fault	PP sensor failed	<ul style="list-style-type: none"> <li>Ensure open airway</li> <li>Switch to alternative ventilation!</li> </ul>
H/19	Battery Error	Battery Error	<ul style="list-style-type: none"> <li>Battery defective</li> <li>Battery not connected</li> </ul>	<ul style="list-style-type: none"> <li>Call technical service!</li> </ul> <p><b>Note:</b> Battery operation not possible in case of power supply failure!</p>
H/20	P <sub>AW</sub> measurement defective	P <sub>AW</sub> 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	<ul style="list-style-type: none"> <li>Interrupt laser operation</li> <li>Deactivate LSM - Ventilation will be continued</li> <li>Restore gas supply AIR</li> </ul>
H/22	O <sub>2</sub> supply too low	O <sub>2</sub> supply too low	Gas supply O <sub>2</sub> too low / failed.	<ul style="list-style-type: none"> <li>Restore gas supply O<sub>2</sub></li> <li>Increase O<sub>2</sub> supply pressure</li> <li>Ventilation will be continued with AIR.</li> </ul>
H/23	AIR supply too low	AIR supply too low	Gas supply AIR too low / failed.	<ul style="list-style-type: none"> <li>Restore AIR gas supply</li> <li>Increase AIR supply pressure</li> <li>Ventilation is continued with O<sub>2</sub>.</li> </ul>
H/24	O <sub>2</sub> supply too high	O <sub>2</sub> gas pressure supply too high	Gas supply O <sub>2</sub> > 6 bar!	Reduce O <sub>2</sub> 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	<ul style="list-style-type: none"> <li>NF line blocked in tubing set</li> <li>NF line blocked in the instrument / catheter</li> </ul>	<ul style="list-style-type: none"> <li>Check NF line in tubing set</li> <li>Check NF line in instrument / catheter check</li> </ul>

Priority/ID	Alarm Message Basic	Alarm Message Main Screen	Possible Cause	Solution
H/27	HF line occlusion	HF jet line occlusion	<ul style="list-style-type: none"> <li>HF line blocked in tubing set</li> <li>HF line blocked in the instrument / catheter</li> </ul>	<ul style="list-style-type: none"> <li>Check HF line in tubing set</li> <li>Check HF line in instrument / catheter</li> </ul>
H/29	Gas sample line blocked	Gas sample line blocked	<ul style="list-style-type: none"> <li>measurement line blocked in instrument / catheter</li> <li>Gas flow too low</li> <li>measurement line blocked in tubing set</li> </ul>	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	<ul style="list-style-type: none"> <li>NF-Jet tube leakage</li> <li>No tubing set connected / detected</li> </ul>	<ul style="list-style-type: none"> <li>Connect new tubing set</li> <li>Check the connectors of tubing set / instrument connection</li> <li>Check connectors of tubing set/device connection</li> </ul>
M/102	Jet lines or monitoring disconnected	Jet or monitoring lines disconnected	<ul style="list-style-type: none"> <li>Jet lines not connected</li> <li>Monitoring lines not connected</li> <li>No tubing set connected / detected</li> </ul>	<ul style="list-style-type: none"> <li>Connect new tubing set</li> <li>Check the connectors of tubing set / instrument connection</li> <li>Check connectors of tubing set/device connection</li> </ul>
M/103	Gas measurement not connected	Gas measurement not connected	<ul style="list-style-type: none"> <li>Gas analysis tube leakage</li> <li>No tubing set connected / detected</li> </ul>	<ul style="list-style-type: none"> <li>Connect new tubing set</li> <li>Check the connectors of tubing set / instrument connection</li> <li>Check connectors of tubing set/device connection</li> </ul>
M/104	Display not connected	Display not connected	<ul style="list-style-type: none"> <li>Cable not connected / defective</li> <li>Display defective</li> </ul>	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	<ul style="list-style-type: none"> <li>Water supply to the humidifier interrupted</li> <li>Humidifier defective</li> </ul>	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 <sub>2</sub> jet too high	FiO <sub>2</sub> jet too high	<ul style="list-style-type: none"> <li>Gas supply AIR too low / failed</li> <li>O<sub>2</sub> sensor defective</li> <li>Mixer error</li> </ul>	<ul style="list-style-type: none"> <li>Restore gas supply AIR</li> <li>Increase AIR supply pressure</li> </ul>
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 <sub>2</sub> jet too low	FiO <sub>2</sub> jet too low	<ul style="list-style-type: none"> <li>Gas supply O<sub>2</sub> too low</li> <li>O<sub>2</sub> sensor defective</li> <li>Mixer error</li> </ul>	Restore gas supply O <sub>2</sub> Increase O <sub>2</sub> 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 <sub>2</sub> measurement not possible	etCO <sub>2</sub> measurement not possible	<ul style="list-style-type: none"> <li>Implausible measured values</li> <li>Internal device error in the CO<sub>2</sub> module</li> </ul>	<ul style="list-style-type: none"> <li>Restart device and check connections</li> <li>Call technical service!</li> </ul>
M/128	FiO <sub>2</sub> AW measurement not possible	FiO <sub>2</sub> AW measurement not possible	FiO <sub>2</sub> Calibration error	<ul style="list-style-type: none"> <li>Restart device and check connections</li> <li>Call technical service!</li> </ul>
M/129	O <sub>2</sub> supply too low	O <sub>2</sub> supply pressure too low	CGS pressure O <sub>2</sub> too low	<ul style="list-style-type: none"> <li>Call technical service!</li> <li>Raise CGS pressure between 4 and 5 bar</li> </ul>
M/130	AIR supply too low	AIR supply pressure low	CGS pressure AIR too low	<ul style="list-style-type: none"> <li>Call technical service</li> <li>Raise CGS pressure between 4 and 5 bar</li> </ul>
M/137	Bias flow not connected	Bias flow not connected	Too low back pressure	<ul style="list-style-type: none"> <li>Check application part (nasal cannula, mask)</li> <li>Call technical service!</li> </ul>
M/138	Internal Error (Log)	Internal error (Log)	Internal device error	<ul style="list-style-type: none"> <li>Switch to alternative ventilation</li> <li>Call technical service!</li> </ul>
M/139	Bias flow error	Bias flow error	Too high back pressure	<ul style="list-style-type: none"> <li>Check application part (nasal cannula, mask)</li> <li>Call technical service</li> </ul>
L/200	Switch to battery mode	Power supply interrupted! Device is in battery mode	<ul style="list-style-type: none"> <li>Mains cable not plugged in</li> <li>Voltage supply interrupted</li> </ul>	<ul style="list-style-type: none"> <li>Reconnect mains cable / power supply</li> <li>Call technical service!</li> </ul>
L/201	Voltage supply fault	Voltage supply fault	Internal device error	Call technical service!
L/202	Fan fault	Fan fault	<ul style="list-style-type: none"> <li>Fan defective</li> <li>Fan blocked</li> </ul>	Call technical service!
L/203	O <sub>2</sub> blender time out (AIR supply)	O <sub>2</sub> blender time out	<ul style="list-style-type: none"> <li>O<sub>2</sub> sensor defective</li> <li>Mixer error</li> <li>Internal unit error</li> </ul>	Call technical service!
L/207	LSM switched off	LSM off - Laser Safe Mode not available	Internal device error	<ul style="list-style-type: none"> <li>Interrupt laser operation</li> <li>Call technical service</li> </ul>
L/208	LSM Time out	LSM Time out- Laser Safe Mode not available	Internal device error	<ul style="list-style-type: none"> <li>Interrupt laser operation</li> <li>Call technical service!</li> </ul>
L/209	Error valve control	Valve overcurrent-Error in the valve control	Internal device error	<ul style="list-style-type: none"> <li>Switch to alternative ventilation</li> <li>Call technical service!</li> </ul>
L/210	Error in the safety ventilation	Error safety ventilation	Internal device error	<ul style="list-style-type: none"> <li>Switch to alternative ventilation</li> <li>Call technical service!</li> </ul>
L/211	Pump defect	Pump for gas analysis defective - measurement not possible	Pump defective	<ul style="list-style-type: none"> <li>Switch to alternative ventilation</li> <li>Call technical service!</li> </ul>
L/212	PDMS validation error	PDMS validation of result failed	<ul style="list-style-type: none"> <li>No Cable connected</li> <li>Wrong settings</li> </ul>	<ul style="list-style-type: none"> <li>Connect cable to PDMS</li> <li>Check PDMS interface settings</li> <li>Call technical service!</li> </ul>
L/213	Perform bias flow test	Bias flow module not working - perform 'Bias flow test'	<p>! Module is disabled until successful test !</p> <ul style="list-style-type: none"> <li>Wrong test setup</li> <li>No gas supply connected</li> </ul>	<ul style="list-style-type: none"> <li>Check test setup and connections</li> <li>Check gas supply</li> <li>Call technical service!</li> </ul>
L/214	etCO <sub>2</sub> measurement active	etCO <sub>2</sub> measurement active	etCO <sub>2</sub> measurement active. HF ventilation is disabled	<ul style="list-style-type: none"> <li>Finish etCO<sub>2</sub> measurement</li> <li>Stop etCO<sub>2</sub> measurement</li> </ul>

## 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 <sub>2</sub> jet not found	Selftest - Module FiO <sub>2</sub> 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 <sub>2</sub> Calibration failed	Selftest - O <sub>2</sub> 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 <sub>2</sub> supply	Check O <sub>2</sub> supply and connections	Yes	Yes
L/403	Selftest - Replace FiO <sub>2</sub> jet Sensor	Selftest - FiO <sub>2</sub> jet sensor needs to be replaced	No	Yes
L/404	Selftest - Replace FiO <sub>2</sub> AW sensor	Selftest - FiO <sub>2</sub> 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 <sub>2</sub> module not found	Selftest - CO <sub>2</sub> module not found	Yes	Yes
L/411	Selftest - FiO <sub>2</sub> AW module not found	Selftest - FiO <sub>2</sub> 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 <sub>2</sub> AW module could not be calibrated	Selftest - FiO <sub>2</sub> AW module could not be calibrated	Yes	No
L/426	Selftest - etCO <sub>2</sub> module not found	Selftest - CO <sub>2</sub> 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 <sub>2</sub> jet cell warning lifetime expires	Selftest - Cell FiO <sub>2</sub> jet lifetime expires	No	Yes

Priority/ID	Alarm Message Basic	Alarm Message Main Screen	Restart Button	Ventilation Possible
L/435	Selftest - FiO <sub>2</sub> AW cell warning lifetime expires	Selftest - Cell FiO <sub>2</sub> 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, FiO<sub>2</sub> jet, Bias flow and many more)
- Measurement results (e.g. PIP, MPAW, PEEP, FiO<sub>2</sub> AW, etCO<sub>2</sub> 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 FiO<sub>2</sub> AW, etCO<sub>2</sub>)
- 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

## 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 <sub>2</sub> 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<sub>AW</sub>: 0-100 mbar (+[3,0+(15%)] mbar/-[3,0+(50%)] mbar)

Low MP<sub>AW</sub>: 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 FiO<sub>2</sub> AW: 21-100%

Low FiO<sub>2</sub> AW: 21-100%

High CO<sub>2</sub> continuous: 0-120 mmhg

Low CO<sub>2</sub> continuous: 0-120 mmhg

High CO<sub>2</sub> intermittend: 0-120 mmhg

Low CO<sub>2</sub> intermittend: 0-120 mmhg

Inspired CO<sub>2</sub>: 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

FiO<sub>2</sub> jet setting range: 21-100%

Rise time from 21% to 90% O<sub>2</sub>: 16 s

Mixer accuracy: ≤ ± 3% absolute

O<sub>2</sub> 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: $\pm(3 \text{ mbar abs} + (10\% \text{ of reading}))$	Waveform displayed: Pressure vs. Time Waveform
PEEP accuracy: $\pm(3 \text{ mbar abs} + (10\% \text{ of reading}))$	Pressure scale: 0-12 kPa
MP <sub>AW</sub> accuracy: $\pm(3 \text{ mbar abs} + (10\% \text{ of reading}))$	Waveform time scale: 0.3-60 s
PP accuracy: $\pm(3 \text{ mbar abs} + (10\% \text{ of reading}))$	
$\Delta$ pHF accuracy: $\pm(3 \text{ mbar abs} + (10\% \text{ of reading}))$	

### 23.6 Gas Monitoring

#### Inspired O<sub>2</sub> Concentration

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

#### cCO<sub>2</sub> & etCO<sub>2</sub> 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 <sub>2</sub> : 3-100 bpm	Calibration: Automatic barometric off set calibration
Rated respiration rate cCO <sub>2</sub> : 3-2000 bpm	

### 23.7 Laser Safe Mode

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

### 23.8 Pneumatic Specifications

#### Gas Supply

Gas supply according to ISO 7396-1:	<ul style="list-style-type: none"> <li>. Oxygen: medical oxygen <math>\geq 99.5\%</math></li> <li>. AIR: medical air</li> </ul>
AIR / O <sub>2</sub> inlet pressure: 280-600 kPa	AIR / O <sub>2</sub> inlet type: G1/4 to DISS, NIST or AFNOR
Gas consumption: AIR: max 80 l/min O <sub>2</sub> : max 125 l/min	

#### Patient Breathing Circuit

Circuit type: Open system	Max. insp. flow: up to 270 l/min
O <sub>2</sub> bias flow: 0-70 l/min	O <sub>2</sub> 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
----------------------------	------------------

### 23.11 Maintenance Connection Ports

USB port: 3xUSB