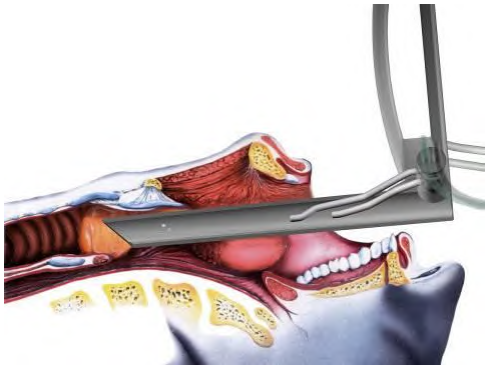
CARL REINER GmbH
Medical technology for diagnosis and therapy
Manufacture of surgical instruments

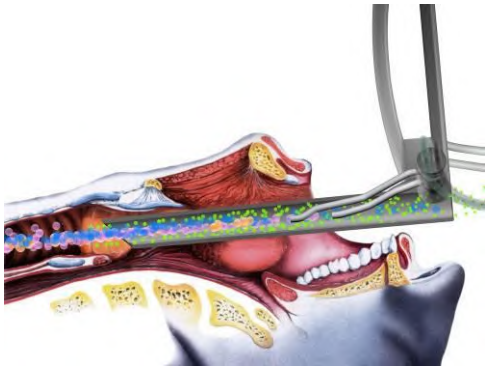
Mariannengasse 17, 1090 Vienna, AUSTRIA T +43 (0) 1 402 62 51-0 F +43 (0)1 402 62 51-19 office@carlreiner.at www.carlreiner.at

TwinStream™

Multi Mode Respirator for SHFJV®

BRIEF USER MANUAL





1. OPERATIONAL START-UP

1.1 Regular Start

Commissioning may only be carried out by trained personnel (nursing training or higher qualification) who have been instructed by an authorized body!
Connections and O-rings should be checked before using the apparatus, the accessories and the tubing sets. Damaged components can cause air leaks and should not be used in the interest of the patient's safety. Before connecting the apparatus to the patient, the devices being used to monitor the patient's condition, such as a pulse oxymeter, ECG monitor, etc. should be checked for correct function in accordance with the corresponding instructions for use!

Preparation of the apparatus

1. Connect CGS hoses
(Connection type may vary according to country)

Fig. 1

2. Connect power plug (CPS) and equipotential bonding

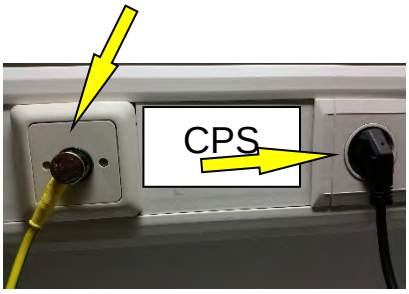


Fig. 2

3. Switch on (rear)

Fig. 3

4. Read and press "OK" button

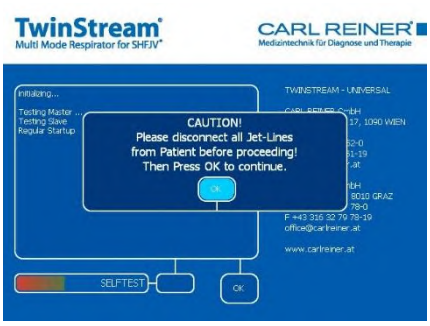


Fig. 4

5. Press "OK" button

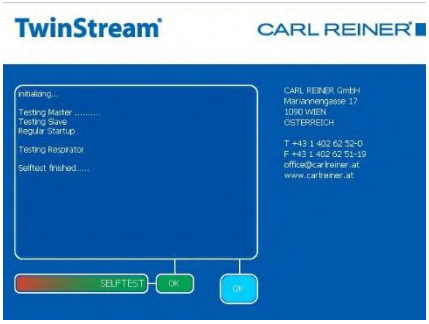


Fig. 5

6. Main Menu

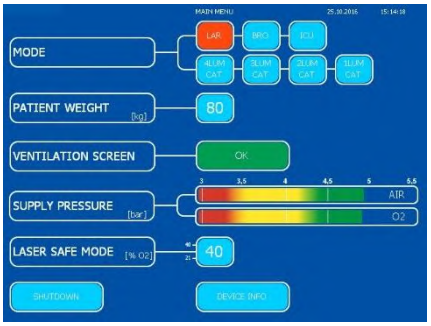


Fig. 6

Note:
For safety reasons the patient should not be connected to the device during the self-test!
Go to the ventilation screen, see chapter 1.3 MAIN MENU.

If a faulty gas supply pressure was detected during the self-test (for example, because of a faulty connection), the following error message is displayed:

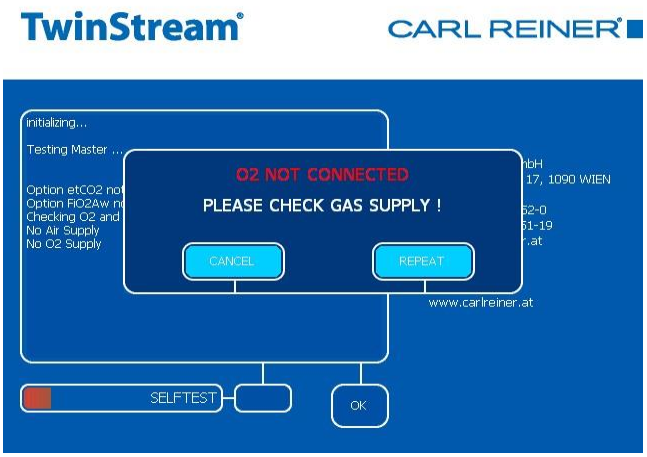


Fig. 7

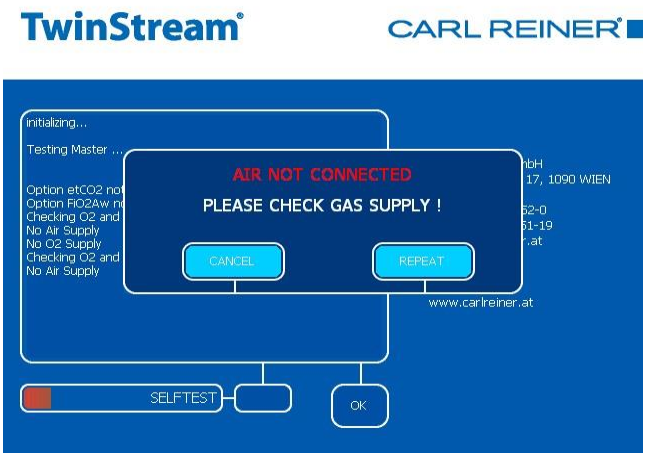


Fig. 8

After the error has been corrected, pressing the "REPEAT" button to continue the self test.

1.2 Emergency-Start - This option is available on all TwinStream™ models

Connections and O-rings should be checked before using the apparatus, the accessories and the tube systems. Damaged components can cause air leaks and should not be used in the interest of the patient's safety. Before connecting the apparatus to the patient, the devices being used to monitor the patient's condition, such as a pulse oxymeter, ECG monitor, etc. should be checked for correct function in accordance with the corresponding instructions for use!

Preparation of the apparatus

1. Connect CGS hoses
(Connection type may vary according to country)

Fig. 9

2. Connect power plug (CPS) and equipotential bonding

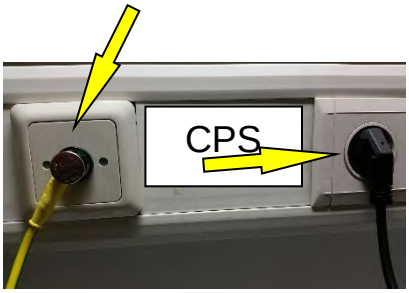


Fig. 10

3. Switch on (rear)

Fig. 11

4. Read and press Emergency button

Fig. 12

5. Press "YES" button

Fig. 13

6. Main Menu

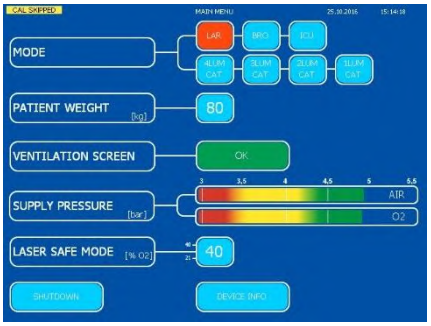


Fig. 14

Warning:
For safety reasons the patient should not be connected to the device during the self-test!

Attention:
The emergency mode is available for clinical emergencies and must not be abused.
The device must be started in the normal way for proper operation!

1.3 MAIN MENU

Mode selection - select the desired ventilation mode for the planned operation (select the necessary jet instruments with the surgeon and keep them ready) refer to chapter 14, of the User Manual, for description of the various modes of ventilation.

Check that the mode you require has been installed on the TwinStream™ you are using. If the mode is not available, please call Customer Support at CARL REINER® or your supplier. Select the required mode, checking also that the necessary accessories (Jet Endoscopes, Jet Converter, ***p-BLV***™ Module, Jet Catheters, etc.) are available and sterile as appropriate. If appropriate for the selected mode, enter the patient's gross, unadjusted weight. Press the numerical value (default setting is 80 Kg) and adjust it in the range 1-200 Kg and confirm by pressing the numerical value again within 5 seconds!

The emission pressures suggested for the initial settings of the LAR and BRO ventilation modes are set according to the patient's weight. For the other ventilation modes, the values from mode tables are suggested for the initial setting. After the start of ventilation, the ventilation parameters must be adapted to the requirements.

Check that the air and oxygen supply pressures are in the green range on the display.
Press "OK" to go to the Ventilation Screen.

After the TwinStream™ has been put into operation, the alarm functions must be checked.
The fully automatic self-test checks the sensors, pneumatics and electronics at the start. The function of the loudspeaker is not checked, this is to be verified by the user. At the start of the device an alarm tone sounds - this proves that the loudspeaker is functional.

1.4 Manual testing of the alarm and hose system

Subsequent Tests # 1 (Bend Test Tubing System) and 2 (Bend Test to trigger overpressure alarm) must be performed before each patient application (and after each change of tubing system).
Performing Tests 3 through 5 is **recommended** once a week.
The test described under 6 is only recommended during maintenance.

1.4.1 Bending test EasyConnect™ tube system with the EasyConnector

The patient tubing should be bent and released approximately 90 degrees immediately after opening and connecting the TwinStream™ (see illustrations Fig. 15 and Fig. 16).
A tube that endures this procedure can be used on the patient and then sent for treatment.

Fig. 15

Fig. 16

This test improves patient safety, should Jet tubing show signs of cracking at the sign of bending or even break, it is not suitable for use on a patient. Defective tubing sets have to be send to the customer support of the manufacturer.

The manufacturer will replace the defective tubes and the tubing system is measured against specification to ensure patient safety. All steps are documented.

1.4.2 Test of the upper pressure alarm / kink test

To trigger the alarm, bend or kink the red (pressure measurement) tubing to prevent measurement flow. The alarm should sound within one second and cease when the tubing is deblocked and the Reset button is pressed (not necessary in ICU mode). If the alarm stops, the device is ready for use. If this is not the case, please contact customer service.

1.4.3 Test of the lower pressure alarm

Switch on both NF and HF Jets. While the TwinStream™ is running, disconnect the monitoring tubing (red/yellow) from the TwinStream™. The alarm should sound within one cycle and cease when the tubing is reconnected. If the alarm stops, the device is ready for use. If this is not the case, please contact customer service.

1.4.4 Oxygen supply alarm (CGS-Pressure Test)

To check the alarm, disconnect the oxygen hose from the central supply.
The alarm for failure of the O_2 supply appears. Close the gas opening of the connector with one finger for approx. 3s. When removing the finger, no gas may escape. The alarm simulation is terminated by connecting the oxygen line. If the alarm goes out, the device is ready for use. If this is not the case, please contact customer service.

1.4.5 Air supply alarm (CGS-Pressure Test)

To check the alarm, disconnect the air hose from the central air supply.
The alarm for failure of the air supply appears. Close the gas opening of the connector with one finger for approx. 3s. When removing the finger, no gas may escape. The alarm simulation is terminated by connecting the air line. If the alarm goes out, the device is ready for use. If this is not the case, please contact customer service.

1.4.6 Alarm sound for Power failure

To trigger the alarm, switch it off using the main switch on the back of the device. An alarm tone sounds, the display turns black (dark) and does not respond to operating commands.

2. AT THE START OF AN OPERATING SESSION

Preparing the patient

When the TwinStream™ is used with Jet Endoscopes in the operating room, the patient must be anaesthetised with non-volatile agents (TIVA) induced by the Anaesthesiologist and ventilated with a mask or LMA as appropriate. The artificial respiration in this phase takes place with a conventional anaesthetic machine via respiratory mask.

Before ventilation is started

The appropriate accessories and ventilation mode for the indication / operation at hand have to be chosen. It is essential that for a given purpose the correct accessories are chosen and subsequently the TwinStream™ is set to the proper mode (see chapter 14, of the User Manual)! A wrong combination of those two factors can affect the ventilation performance and therefore harm the patient.

After choosing the setup, the patient weight is input, this is independent of previous settings. Pressing the OK button, you are now on the ventilation screen where you see the initial settings.

The tubing set, consisting of…

- Jet Tubing Set TwinStream™, white/green, e.g. REF CTNS-220-1S0
- Monitoring Tubing Set TwinStream™, yellow/red, e.g. REF CTNS-220-200

…has already been attached and connected to the TwinStream™.

Alternatively, the single-tube system CTFS-220-SU1 can be used.

To ensure the proper operation of the alarm system (see chapter 1.4, Manual testing of the alarm and hose system), the red patient tube hast to be bend 90° sharply to block the gas flow. Blocking of the tube has to result in an alarm situation, where an acoustic alarm can be heard and a warning highlighted in red can be seen on the screen. If this is the case the Ventilator is operational. Releasing of the tube should resolve the alarm situation.

Insertion of the Jet Endoscope of the Jet Catheter

Supraglottic laryngoscopy with the original Jet Laryngoscope

The patient's head is stretched back and the anatomically most compatible Jet Laryngoscope is inserted by the operating surgeon as with any straight laryngoscope, using a dental guard. In order to avoid injury to nerves or jaw and head joints, the position of the head and the upper body should be considered. A view to the glottis is established and the Jet-Laryngoscope adjusted and fixed in its position supported by the chest support arm.

Infraglottic laryngoscopy with a Jet Catheter and a standard laryngoscope

The TwinStream™ may be used with an inserted Jet Catheter and a standard endoscope when a suitable catheter mode has been selected from the Main Menu.

Warning:
When a laser operation is to be performed please select a laser-resistant Jet Catheter.

Bronchoscopy with the original Jet Bronchoscope

The TwinStream™ may be used with a rigid original Jet Bronchoscope inserted into the trachea by the surgeon.

Bronchoscopy with the original Jet Coupling and the standard bronchoscope

The TwinStream™ may be used with a standard rigid Jet Bronchoscope with a tested Jet Coupling and optionally a measuring cannula inserted into the trachea by the surgeon.

Warning:
Use only the correctly specified and certified Jet Coupling for the chosen bronchoscope in order to ensure that it is of the correct length and provides the correct flow for the instrument. Correct and safe function can only be assured if the correct Jet Coupling is matched to the bronchoscope!

Long Term Ventilation

A test lung has to be connected with the tube system in use. After the apparatus has been set to the same settings as those for conventional ventilation (essentially ventilation frequency, I:E, peak ventilation pressure and PEEP level), disconnect the test lung. Then, disconnect the ventilated patient from the standard respirator and connect him/her to the tubing system of TwinStream™. Please refer to chapter 14, of the User Manual, for detailed information.

Note:
Bias Flow - 20 LPM recommended

Start of Jet Ventilation

Connect the Tube Set to the Jet accessories and the Jet Ventilation Respirator. The EasyConnectors for the Jets cannot be confused with those for monitoring. The filter should be positioned close to the patient but can be positioned device-side if required by user-specific hygiene regulations!

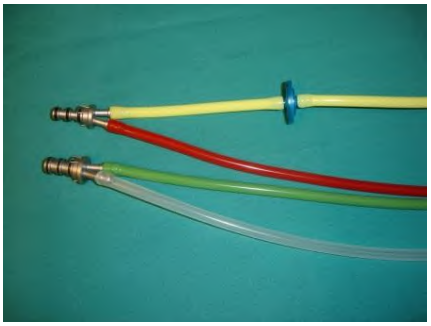


Fig. 17

Fig. 18

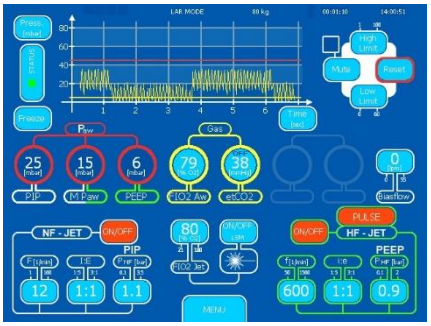


Fig. 19

Switch on the respirator by pressing the ON/OFF button of the HF and NF Jets on the touchscreen (as applicable according to the mode selected). The ventilation starts immediately with inspiration without delay. The PIP typically should be between +3 mbar and +15 mbar (depending on the Jet Endoscope and the patient's compliance). If necessary, the respiratory parameters should be adjusted individually by the anaesthesiologist (control respiratory pressure and emission pressures).
The larger the area of cross-section of the Jet Endoscope used, the lower the respiratory pressure. The more instruments in the Jet Endoscope (reduced cross-section), the higher the respiratory pressure.

Control of respiratory parameters and alarm limits

If the position of the Jet Endoscope is optimally set and Jet Ventilation sounds "normal" and uniform, the thorax rises and the respiratory pressure curve shows expected values, the alarm limits should be modified to the pressure curve as well as the patient. If pre-set values are used it needs to be checked if these values are applicable to situation and patient. Do not set alarm limits to inappropriate extreme values that will render the alarm system ineffective.

Attention:
Setting incorrect pressure limits will cause alarms to be triggered incorrectly!

When used in the ICU the usual parameters should be controlled.
Refer to chapter 16, of the User Manual.
After the start of ventilation with TwinStream™, when surgery is performed a BGA should be conducted every 5-10 minutes or $FIO_{2\ Aw}$ and $etCO_2$ measurement (optional) should be started.

Measures to be taken if the level of oxygen saturation drops

If the patient's oxygen saturation level drops the respiratory parameters must be adjusted. The first step is to increase the rate of the HF, then increase the emission pressures of both NF and HF to increase M P_{aw}. While checking the chest movement, the I:E ratio may also be changed to IRV. In addition, $FIO_{2\ Jet}$ can also be increased.

Influence of respiratory parameters on blood gas values

BGA parameter	$FIO_{2\ Jet}$	Emission pressure P_{NF}	Emission pressure P_{HF}	Frequency NF	Frequency HF	I:E ratio i.e portion
PaO_2 increase	↑	↑	↑	=	↑	↑
$PaCO_2$ reduction	=	↑	=	↑	↓	↓

Fig. 20 The selection of the individual parameters depends on the patient.

Mode of action of high frequency

The higher the high frequency setting is, the less visible will be vibrations of the vocal cords in phonosurgery.
The lower the high frequency is set (below 500/min.), the more CO_2 will be expired. However, reducing the high frequency can be disturbing for the surgeon due to fluttering of tissues at the operation site.

Tip: Increase the high frequency from 500/min in steps of 50 until the operation site is subjectively free of disturbance.

Mode of action of the i:e ratio

The i:e ratio of high frequency also influences CO_2 elimination. Extreme inversion, in theory, may cause auto peep or air trapping. The smaller the area of cross-section of the laryngoscope or the less the available width, the longer the expiratory phase should be (1:1 - 1:3).

3. ENDING THE USE OF THE RESPIRATOR

Ending the surgical procedure

After surgery has been completed the anaesthetist starts to conclude the TIVA.

Supraglottic Jet Laryngoscopy with the Jet Endoscope

Jet Ventilation is ended prior to the return of protective reflexes and before the patient awakes (switch the NF and HF unit to the **OFF** position). After thorough removal of tracheal secretion, the Jet Endoscope is withdrawn.

Infraglottic Jet Laryngoscopy with Jet Catheter

Jet Ventilation is concluded prior to the return of protective reflexes and before the patient awakes (depending on the mode, switch the NF and HF unit to the **OFF** position). After thorough removal of tracheal secretion, the endoscope is withdrawn. Soon afterward the Jet Catheter is removed carefully, the tubes are withdrawn and the catheter disposed of.

Rigid bronchosopy

Jet Ventilation is concluded prior to the return of protective reflexes and before the patient awakes (switch the NF and HF unit to the **OFF** position). Remove the Jet Bronchoscope under thorough suction of tracheal secretion.

Optional for experienced users:
While carefully monitoring respiratory pressure, the patient can be ventilated for a short period with the high-frequency respirator component. If the patient coughs during this phase the pressure limit can be increased to maximum 40 mbar in order to avoid the alarm being set off. Following thorough removal of tracheal secretion, the high frequency ventilation is ended (switch the HF unit to the **OFF** position) and the Jet Bronchoscope withdrawn.

Jet Endoscopy with Jet Coupling

The procedure here is analogous to that with laryngoscopy or bronchoscopy. The Jet Coupling is detached from the tube system; after thorough suctioning it is removed together with the standard endoscope.

Wake-up phase

Immediately after removal of the Jet Endoscope, or the standard endoscope with Jet Coupling, end the anaesthesia using mask ventilation and a conventional anaesthesia apparatus, and bring the patient to the recovery room for post-operative monitoring. Conduct any post-operative treatment which is normal after such operations (e.g. aerosol therapy).

End of Long-term ventilation (ICU)

Turn off the apparatus on the monitor (switch the NF and the HF unit to the **OFF** position).
Detach the tube system from the main tube, conduct conventional follow-up treatment as is normal in an intensive care unit. Dispose of single use filter, tubing and heating chamber. Carefully detach the tube system from the ***p-BLV***™ Module / Jet Modifier or ***p-BLV***™ Converter. Proceed with the preparation of the Jet Modifier, Jet Converter and the re-usable Tubing Set as described in Chapter 22, of the User Manual.

Ending operational mode

After pressing MENU the following question appears:

ARE YOU SURE
YOU WANT TO
QUIT
VENTILATION *?*

Confirm by pressing YES and the main menu appears.

Attention:
In ICU mode only there is a possibility to switch to standby mode!

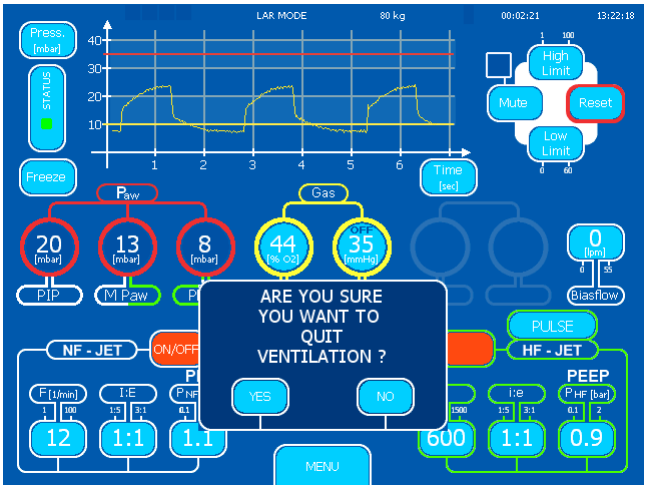


Fig. 21

Detach the tube system from the apparatus and prepare it for reprocessing. The used instruments should be cleaned as usual and also handed over for preparation and reprocessing - see Chapter 22, of the User Manual.

If the apparatus is to be used again, proceed as described in Chapter 1, Operational Start-Up, without turning off the apparatus. No self-test will be necessary.

Select the respiration mode, change the weight from SET to the current patient weight and confirm.
Press OK on the main menu screen. Thereafter see Chapter 2, At the start of an operating session.
If no further operation is planned, press SHUTDOWN.

SHUTDOWN

The respirator can only be shut down correctly from the main menu by selecting SHUTDOWN. To confirm: Press **YES** to prepare the apparatus for being turned off (Fig. 23). The system is rinsed with compressed air in order to rinse out oxygen from all sensors and connection tubes and thus prevent unnecessary strain and wear. The following message appears: “Please switch off the device on the backpanel” (Fig. 24).

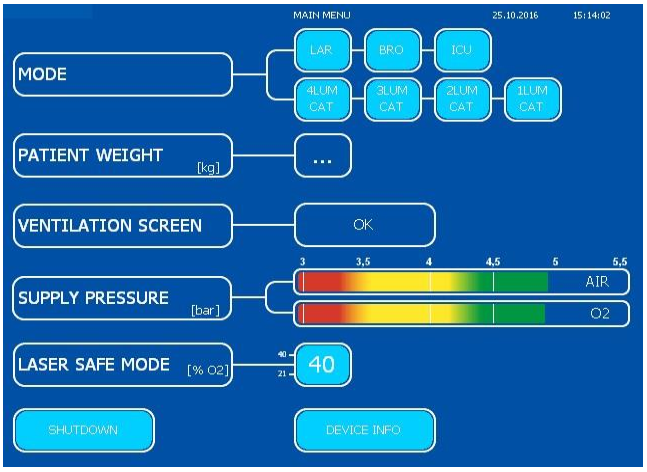


Fig. 22

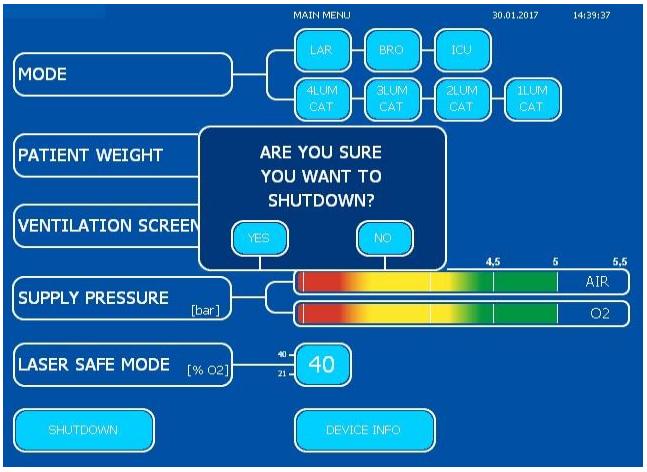


Fig. 23

Fig. 24

Fig. 25

Turn off the apparatus on the rear panel (an all-pole disconnection is only guaranteed by disconnecting the mains plug), disconnect hoses for oxygen and compressed air from the CGS and disconnect power plug from CPS.

Note:
Residual pressure may escape from the tube with a hissing sound (this is no cause for concern!).