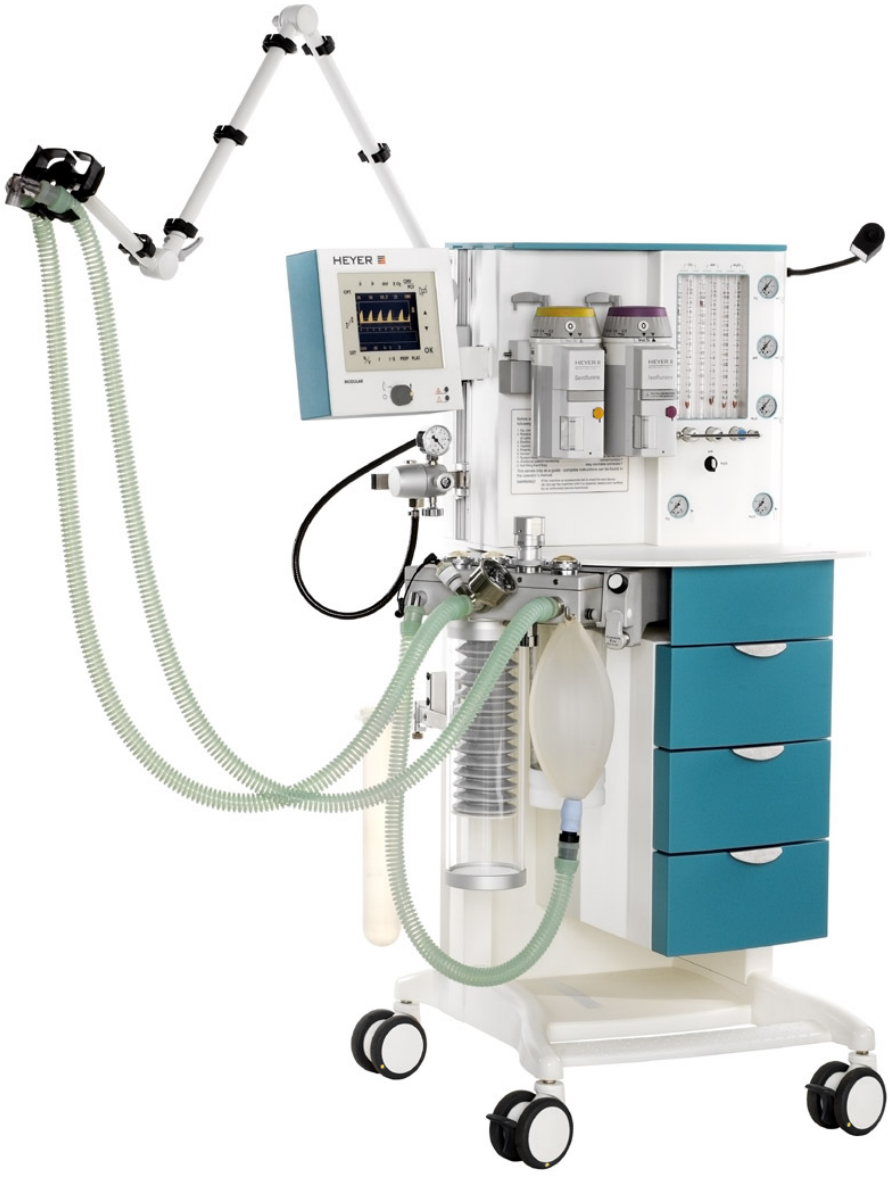
Modular

Anesthesia System

Operator's Manual

Rev. 1.1 – 07/07



HEYER MEDICAL AG

MODERN SOLUTIONS FOR ANESTHETICS AND INHALATION

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1 Details of the Manufacturer

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2 Description and Utilization of the Apparatus

2.1 General

2.1.1 Introduction

The HEYER Modular anesthesia system represents a flexible anesthesia workplace for implementing and monitoring inhalation anesthesia in the half-closed system and the nearly closed system for low-flow techniques with minimum gas and anesthetic agent utilization.
During the development of the system special emphasis was placed on the ergonomic design and consequently the safe and easily learnable operation. Furthermore the excellent air-tightness of the system ensures the economical daily high and low pressure utilization.

The standard model contains the following system components:

A. Electronic ventilator:

The processor-controlled ventilator allows constant-volume ventilation for all patient groups with a body weight of 3 kg upwards. Due to the system compliance compensation, even small tidal volumes can be precisely administered. The ventilation type CMV as the standard and PCV as the optional ventilation type as well as considerable variation options of the artificial ventilation cycle facilitate secure ventilation for complicated lung conditions. A comprehensive test and alarm management ensures the required safety for patients and prevents out-of-control operating conditions. The clear design of the user interface and the display allow the secure operation and a quick detection of the selected ventilation parameters.

B. Patient module

The circular patient absorber system is highly integrated and compacted in an aluminum block. This block is tempered to prevent the formation of condensation. It also contains a monitored emergency air valve, a fresh gas reservoir in form of a hand-held anesthesia bag and an expiratory flow sensor. All sensors are continuously monitored during operation. The sensors are automatically calibrated during the start-up of the apparatus.

C. Integrated fresh gas dosing system including vaporizer unit:

The flowmeter tube block contains all mandatory safety equipment as well as a pneumatic regulation system to maintain a minimum oxygen concentration of 25% in the fresh gas flow (ratio system).

2.1.2 Intended purpose

The Heyer Modular anesthesia system is suitable to make available anesthetic gases and to perform automatic or spontaneous/manual ventilation with a circular system in a semi-closed system. This procedure can be used on adults as well as children. The use of an open system to anesthetize small children and newborns is possible.
The Modular anesthetic system is intended for use in operating rooms in clinics and mobile doctor's practices. It is not suitable for use in the vicinity of MRI scanners. Possible anesthetic procedures that are supported by automatic or manual artificial ventilation are:

- Full anesthetic with volatile anesthetic agents
- Full anesthetic with balanced anesthesia
- Full anesthetic with intravenously applied anesthetic agents
- Partial anesthetic

2.1.3 Product improvements

HEYER Medical AG reserves the right to make changes and/or to revise devices and/or operating instructions without prior notice. These instructions deal with all the characteristics of the anesthetic system HEYER Modular according to the state of information at the time of going to print. Instructions and devices created or manufactured at a later date may already include improvements or changes not featured in earlier models.

2.1.4 Responsibility of the operating personnel

The proper functioning of the anesthetic system HEYER Modular is only warranted if the apparatus is used and maintained n accordance with the directions provided by the manufacturer. Not observing these instructions will void any warranty claims with regard to HEYER Medical AG.

<u>ATTENTION:</u> Before using the apparatus, please read the operating instructions, as well as the section "General precautionary measures" and observe in particular all directions in these instructions that are titled ATTENTION or WARNING. These instructions merely describe the operation of the device. A qualified professional can find instructions regarding maintenance and repair in the SERVICE INSTRUCTIONS HEYER MODULAR.

The device may only be operated by qualified, trained professional personnel. Prerequisite for this is the unlimited observance of these operating instructions and/or additional accompanying documents and manufacturer's indications, as well as the adherence to the general precautionary measures listed in the following, and the briefing by authorized medical product consultants.

Additional gas monitoring is prescribed to operate the device.
The following conditions must be met at a minimum (DIN EN 740):

At least the following are to be monitored:
- concentration of the anesthetic gas
- concentration of carbon dioxide

For these additional monitoring parameters, it must be possible to set upper and lower alarm limits. When reaching one of these upper or lower alarm limits, a visual or acoustic alarm needs to be activated.

The measuring adapter to be inserted into the circle system or patient's tube system must be equipped with ISO cones (DIN EN 740).
This is to be applied at the inspiration tube connection or ideally the Y-piece. Measurement close to the tube is recommended, however, since this makes the collection of inspiratory and expiratory gas values possible. Monitors that work using the sidestream procedure should definitely be preferred in order to complement the additionally required gas monitoring.

In case a device should not work as described in these instructions, the device in question may not be used until the fault is eliminated. The operating personnel carry the responsibility for damages and injuries whose causes can be traced back to the improper operation and/or repair/maintenance of the device by unauthorized persons.

2.1.5 Liability of the manufacturer

The HEYER Medical AG is only liable for the safety, reliability and functionality of the device if:

- the device was operated corresponding to the directions provided by the manufacturer.
- additions, new settings, changes or repairs were carried out by professionals qualified by the manufacturer.
- the device and was only operated in buildings with facilities for protective grounding in compliance with the regulations of the IEC.

2.2 General precautionary measures

2.2.1 Warning directions

Avoiding potentially dangerous situations in which an injury to the patient and/or the operating personnel cannot be excluded.

Carry out the tests listed on the checklist daily and in case of any fault that occurs do not use the system until the fault has been eliminated.

Always connect the output of the ventilation pressure valve for gas overflow with the anesthetic gas ongoing flow installation, usually installed in operating rooms.

The patient should also be observed closely by qualified professional personnel. In certain situations, life-threatening circumstances may occur that don't necessarily trigger an alarm.

Always set the alarm limits so that the alarm is triggered before a hazardous situation occurs. Incorrectly set alarm limits may result in operating personnel not being aware of drastic changes in the patient's condition.

In order to prevent an electric shock, the apparatus (protection class I) may only be connected to a correctly grounded mains connection (socket outlet with grounding contact).

Danger of explosion! The device may not be operated in the immediate vicinity of flammable anesthetics of other flammable substances. The use of flammable anesthetics (e.g. ether, cyclopropane) is not permitted.

Since this device is not permitted for use with flammable anesthetics (e.g. ether, cyclopropane), the use of antistatic breathing hoses and facemasks is not required (DIN EN 740).

Electric shock and fire hazard! Always switch off the apparatus and disconnect it from the mains before cleaning.

Fire hazard! The fuses (e.g. the additional sockets) may only be replaced by fuses of the same type and with the same fuse value.

Electric shock hazard! The device may only be opened by qualified or authorized professional personnel.

In case of a failure of the protective conductor the connection of the apparatus via the additional socket may lead to a discharge current exceeding the permissible values.

Ambient interference caused by electromagnetic radiation exceeding the specifications of EN 60601-1-2 can influence machine functions.

2.2.2 Precautionary measures

Avoid situations in which the device may malfunction or be damaged.

This device may only be operated by trained professional medical personnel.

Before putting the device into service, the operating personnel must be familiar with the directions and information in these instructions and must have been briefed by a medical product consultant.

If the apparatus does not function as described, it must be examined and possibly repaired by qualified service personnel before being used again.

Treat the device with care in order to avoid damages and faults in its functionality.

Always make sure that the device is supplied with gas in a way that conforms to the technical specifications.
Before operating the device, it must be properly calibrated and the corresponding device tests need to be carried out, as described in these instructions.

Should the device display any functional faults during the calibration and tests prior to operation, it may not be operated until the faults have been eliminated by a qualified professional.

After any maintenance tasks, a function test and the compliance and system tests need to be carried out before the device is put into clinical use.

Only bacteriological filters with a low flow resistance must be connected to the patient module and/or patient connection.

3 Functional Description

3.1 Anesthesia ventilator

Ventilators are described according to the principle of controlling the change over from inspiration to expiration. The HEYER Modular apparatus offers the following characteristics I the controlled ventilation mode or so-called CMV mode (**C**ontrolled **M**andatory **V**entilation).

- time-controlled:
The timely sequence of inspiration and expiration has been specified by the ventilation frequency settings. The ration of the inspiration to the expiration time of the individual ventilation cycle is determined by the adjustable I/E ratio.

- pressure-limited:
The tidal volume during a controlled ventilation is supplied during the entire period if the inspiratory flow and can be set as a ventilation parameter. The inspiration is, however, terminated before the tidal volume has been administered once the measured airway pressure reaches the set peak pressure alarm limit.

- constant-volume:
The inspiratory flow to the patient required for a ventilation with the set parameters frequency f, tidal volume V_t and ventilation time ratio I/E, is automatically calculated by the ventilator. This inspiratory flow is generated via the drive gas for the patient module. In standard anesthesia ventilators deviations in the tidal volumes actually administered to the patient could occur due to the respective fresh gas setting and system compliance of the ventilation system. The ventilator of the HEYER Modular apparatus supplies a constant volume, as on the one hand the patient module is uncoupled from the fresh gas system. On the other hand the system compliance of the patient module is automatically taken into consideration by the ventilator when generating the breathing volume.

3.1.1 Fresh gas decoupling

During fresh gas decoupling in CMV mode, the fresh gas flow is directed into the manual ventilation bag. The manual ventilation bag thus serves as a fresh gas reservoir. This principle offers the following advantages for machine-controlled ventilation:

1. The tidal volume is completely independent from the set fresh gas flow. This ventilation is therefore referred to as constant volume ventilation.

2. The fresh gas flow can be maintained at a very low level, e.g. below 500 ml/min, depending on the patient. The manual ventilation bag serves as a fresh gas reservoir for the fresh gas administered during inspiration. The entire fresh gas volume is available during the next inspiration, i.e. not only the fresh gas stored in the reservoir but also the fresh gas supplied during expiration.

3.1.2 Constant volume provided by machine-controlled ventilation

During controlled CMV ventilation, the set tidal volume is administered irrespective of the pulmonary circumstances. In principle the ventilator drive represents a constant flow generator. The inspiratory flow of the ventilation gas is automatically adapted to the respective settings of the tidal volume V_t, the ventilation frequency rate f and the ventilation time ratio I/E.

3.1.3 Compliance compensation

The administered tidal volume is corrected to the target value set by the user with the aid of the compliance compensation. The system compliance of each ventilation system i.e. the compliance of patient hoses and the patient module itself always leads to losses in the administered tidal volume. In the case of the HEYER Modular, a control loop can correct this volume loss as an automatic compensation function. For this purpose several ventilation cycles are required. The drive gas flow is then increased to just above the normal values, i.e. values to achieve the set ventilation volume. The correct tidal volume is, however, administered to the patient, while the slightly higher volume is absorbed by the system compliance due to the effective compliance compensation.

3.1.4 Bag-in-Bottle System

The so-called Bag-In-Bottle system is part of the patient section or circuit system. The gas-conducting sections are divided from the ventilator into a primary (ventilator) and a secondary circuit (patient). The gas volume provided by the drive is not directly administered to the patient but instead compresses a bellows inside a pressure dome. As a result the ventilation gas contained in the bellows is administered to the patient. The larger the drive volume flowing into the pressure dome, the greater the tidal volume will be. Once the drive gas flow has finished the pressure compensation between the primary and secondary circuit is also ended. A distinctive plateau in the ventilation pressure curve is formed if the system does not switch over to the expiration directly after the end of the inspiratory gas flow. For this purpose the drive volume contained ion the pressure dome us maintained at a steady level for some time. The bellows are suitable for adults and children. An exchange of the bellows for different patient groups is not necessary.

3.2 Fresh gas dosing

The adjustment of the amounts of gas delivered to the patient is handled at the measuring tube block. It contains flow measurement tubes, also described as rotameters. These measuring tubes consist of a vertically aligned glass tube with a floating element inside. Since the glass tube widens toward the top, a certain flow of gas will lift the floating element to a corresponding height. Adjusting the gas flow is handled by valve spindles inside the respective measuring tubes.

The choice between a setting of gas types O_2/AIR and/or O_2/N_2O is made via a change-over switch, which opens the respective gas line to the measuring tube block.
The fresh gas cannot be set with a mixture of AIR and N_2O as in this case a decrease of the oxygen content to below 21% could not be avoided.
Reducing the oxygen content to less than 21% is theoretically also possible when dosing the O_2 and N_2O gases. Such unfavorable settings are prevented by a pneumatic safety system. This mechanism, also described as the “Ratio system”, ensures a steadily present minimum content of 25% O_2 along with the N_2O in the gas mix dosage. When raising the flow of N_2O, the required flow of O_2 is also raised automatically. The fresh gas thus adjusted will be fed to the vaporizer automatically and mixed with the anesthetic there.

3.3 Vaporizer mounting device and vaporizer

The appliance contains a Selectatec® compatible vaporizer mounting device (standard configuration) for two vaporizers. The vaporizer has a chamber, which contains the anesthetic in liquid form in its lower part. A wick made of metal mesh enriches the upper part of the chamber with saturated vapors of the anesthetic. The concentration of the saturated vapor at room temperature is much higher than is clinically justifiable. A suitable mixing ratio of the gas with anesthetic with a flow of gas passing by this chamber can lead to the desired concentration. This is handled by the adjusting wheel. This adjusts the ratio of the streams of carrier gas via a bypass channel and through the vaporizer chamber in such a way that the desired concentration is attained at the vaporizer outlet. In the zero position of the vaporizer this bypass channel remains open, while the vaporizer chamber is completely closed off to the flow of gas.
The anesthetic vapor concentration in the vaporizer chamber may be saturated, but the absolute content of anesthetic is still dependent on temperature. This is why there is a temperature compensation valve in the bypass channel, which in the case of vapor pressure changes caused by temperature fluctuations changes the set dilution ratio in such a way that a temperature-independent concentration output of the anesthetic is warranted.

For additional indications see:
Operating instructions of the anesthetic vaporizer used.

3.4 Patient module

3.4.1 Circuit absorber system

A circuit absorber system is a ventilation system with a CO_2 absorber. This system allows anesthetics to be carried out at extremely low fresh gas settings. The ventilation gas contains various parts of re-breathing gas i.e. expiratory gas freed from CO_2 parts. This is achieved with a circuit ventilation system facilitating a re-breathing of the expiratory CO_2-containing gas. A circuit system with high re-breathing contents causes a reduction of the consumption of anesthetic gases. This type of system also offers an improved breathing gas conditioning.
The patient module is designed as a circuit absorber system in the form of a compact aluminum block. The hose connections normally required between the ventilator and the circuit system are thus no longer needed.

3.4.2 CO_2 absorber

The absorber serves to absorb the breathing lime. It aims to remove the CO_2 from the expiration air. The absorption process is a chemical reaction in which carbon dioxide is bound and most of the reaction water evaporates and the lime is removed. This is why used breathing lime is dry and hard. The lime must be hermetically sealed for storage in a cool and dry place so as not to become malabsorbant.

3.4.3 Reservoir and manual ventilation bag

The reservoir consisting of a manual ventilation bag serves as an inspiratory interim storage facility for the fresh gas. The reservoir pressure during machine and spontaneous ventilation is limited to 1-2 bar by the excess / ventilation pressure valve, also known as the overflow valve. This valve serves additionally for setting the desired ventilation pressure for manual ventilation.

3.4.4 Volume measurement

Volume measurement takes place by means of measuring the flow in the expiration branch using a flow sensor, which works according to the hot-wire anemometer principle. The ventilator processors integrate this measured value with the displayed tidal and ventilation minute volumes. The tidal volume shown in the display is a purely measured value. The tidal volume displayed during machine-controlled ventilation is measured by an internal flow sensor and is not dependent on the expiratory volume measurement.

3.4.5 Oxygen measurement

Oxygen measurement is metered by a measuring cell installed on the inspiration valve. This single-cathode measuring cell, also referred to as a fuel cell, offers a longer service life compare to other oxygen cells and is less sensitive to existing anesthetic gases.

3.4.6 Patient module heating

The heating prevents the formation of condensation in the patient module and on the valve caps of the inspiration and expiration valve. The heating positively contributes to a ventilation gas conditioning. The heating mat also functions as a sealing mat and is installed between the top and bottom sections of the patient module. An electronic control integrated in the ventilator keeps the temperature of the patient module constant at approx. 36°C. An over-temperature protection protects the apparatus against overheating.

3.5 Touch screen display

The “Touch screen” display acts as the user interface for the HEYER Modular. With the exception of the ventilation mode dial, all data input is done via light finger pressure on the touch screen. Therefore it is no problem to operate the system with moist or dirty hands. To change a value, for instance, you press the corresponding symbol of the value you wish to change. The illumination of the selected symbol will then be intensified as confirmation. You can then increase or decrease the value using the arrow symbols. To confirm the data change, press the OK button.

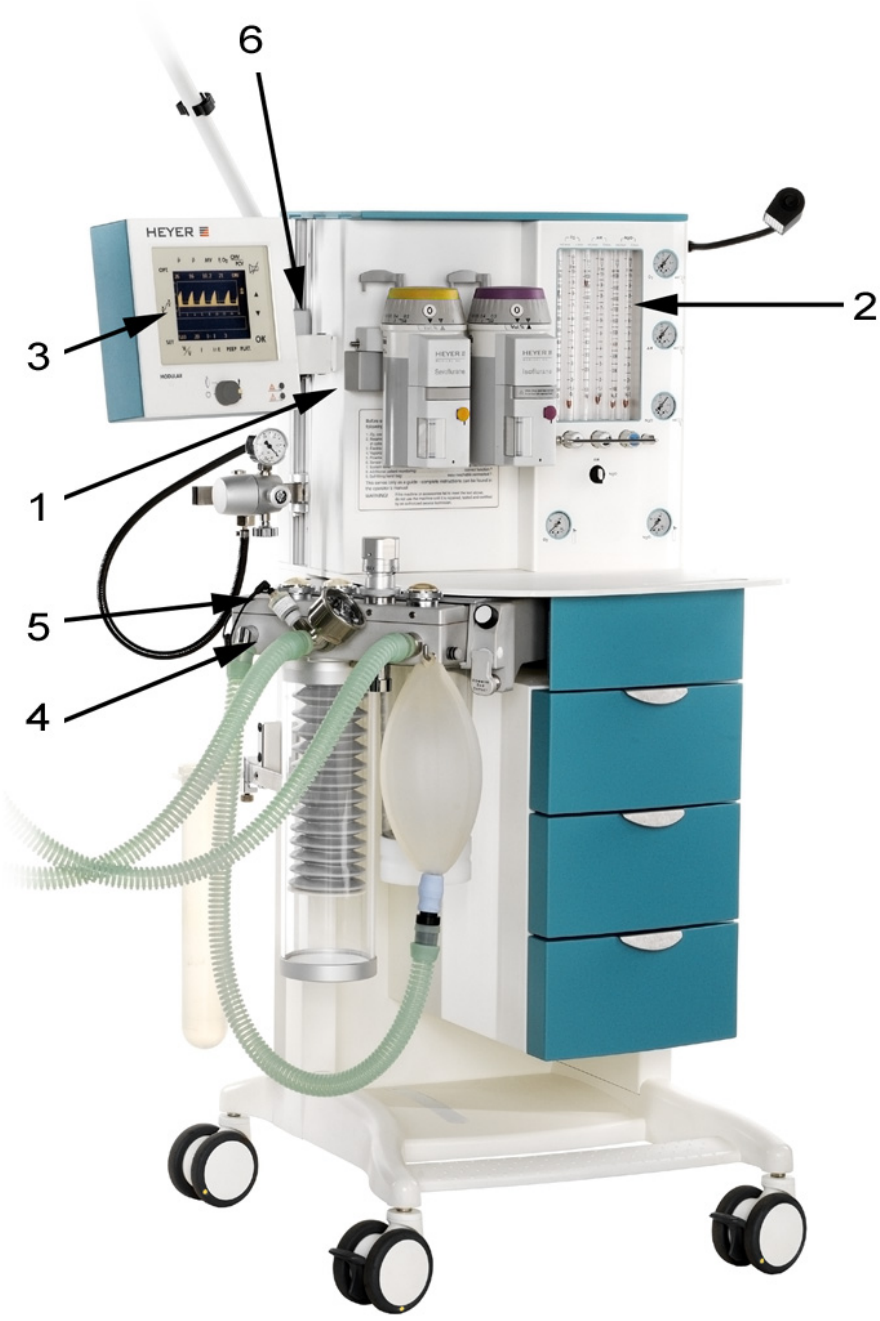
3.5.1 Symbol description

Fig. 1 Touch Screen Display

$\hat{P}$	Peak airway pressure in mbar
$\bar{P}$	Mean airway pressure in mbar
MV	Minute volume in liters
FiO_2	Inspiratory oxygen concentration
CMV / PCV	CMV or PCV ventilation mode
	Mute switch for acoustic alarm signals
	Cursor for increase or decrease of set values
OK	Confirmation of entered values
PLAT.	Plateau pressure in % of the inspiration time
PEEP	Positive Expiratory End Pressure
I:E	Inspiratory to expiratory ratio
f	Ventilation frequency
V_t / $\dot{V}$	Tidal volume in mL in CMV mode; Drive gas in l/min in PCV mode
SET	Display change-over from measures values to SET values
	Alarm limits setting mode
OPT.	Options

4 Operating Elements / Device Connections

4.1 Views of apparatus



1 Vaporizer mount
Selectatec® compatible vaporizer mount for two vaporizers
(As an option, a single mount for Dräger vaporizers is available.)

2 Flowmeter block
5-fold flowmeter block with integrated ratio system, O_2 bypass and N_20/AIR change-over switch.

3 Ventilator unit
Microprocessor-controlled ventilation unit with EL display

4 Patient module
Absorber circuit system with integrated "Bag-in-Bottle" system, active and passive valves as well as APL ventilation pressure valve

5 Oxygen sensor with connecting cable

6 Mount for holding arm

Fig. 2 Front view

4.1.2 Rear view / right-hand side view

1 Mains cable
Power supply cable for the connection of the apparatus to a socket with grounding contact.

2 Hook for cable winding

3 Additional sockets
Other apparatus with a maximum power consumption of 3.5 A each can be connected to 2 additional sockets.

4 fuses (resetable)
Over current triggering device 5A, 2 each for the ventilator, one for the backup battery for power supply in the event of a mains failure.

5 Reserve bottles – connections

6 Type plate with serial number

7 Fan for housing ventilation

8 Mains connection for the central gas supply
With 3 manometers for pressure monitoring

9 Mains switch
The apparatus is switched on/off via this switch and the supply of mains voltage is created. This switch stays in ON position during operation.

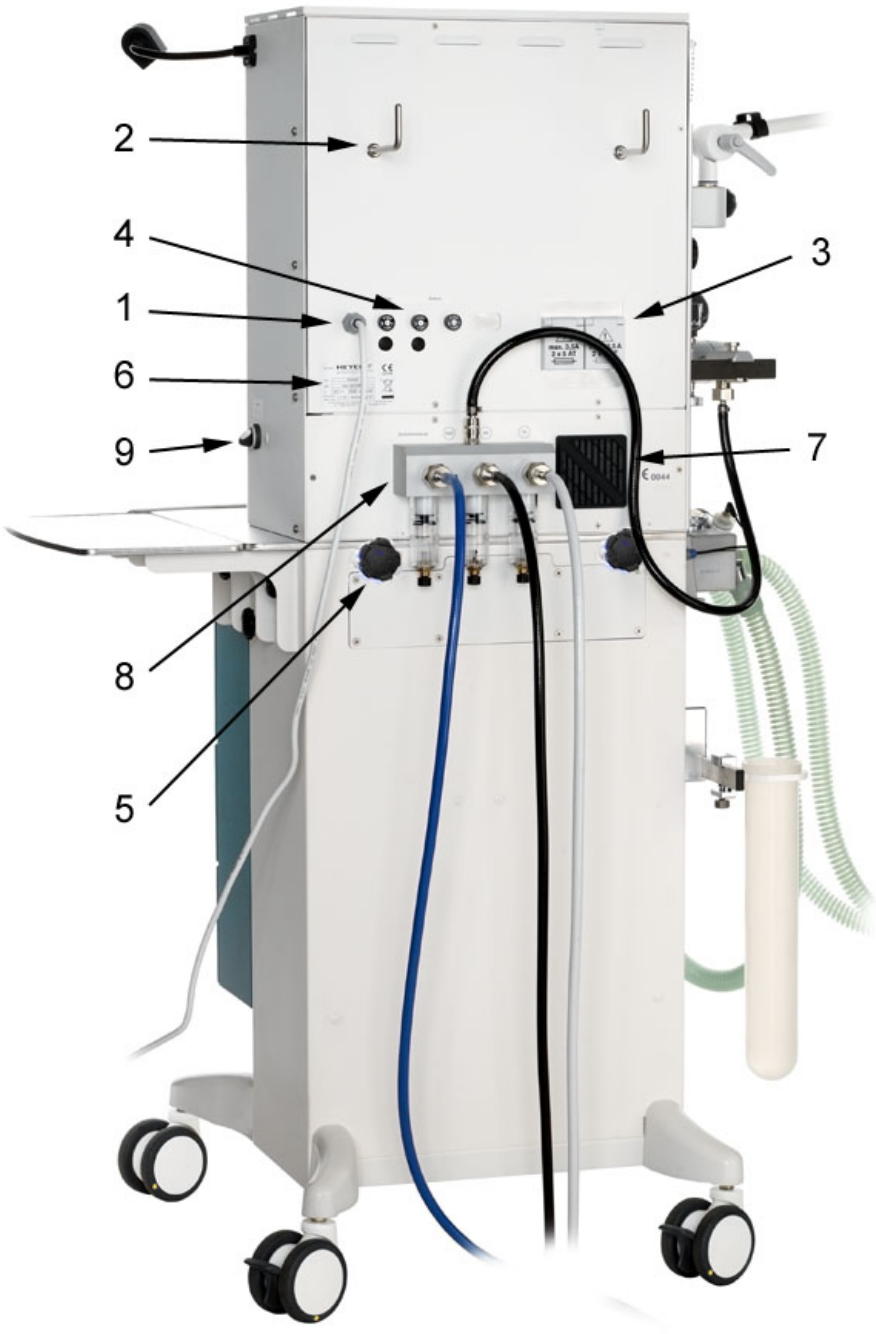


Fig. 3 Rear view

4.2 Ventilation unit

Fig. 4 Ventilator display and ventilation mode selector switch

The ventilator has a color LCD display (an EL display is optionally available. This high-contrast display allows a clear overview of the measured values and ventilator settings. A clear side read-off is possible.

4.2.1 "Ventilation Mode"- selector switch

The rotary switch for the selection of the ventilation mode has four positions:

Standby:
Position for the commissioning and implementation of compliance and system tests

Manual/Spont:
This position switches the ventilator to manual ventilation or spontaneous ventilation mode.

CMV child:
This position switches the ventilator to CMV mode for machine-controlled ventilation of children.

CMV adult:
This position switches the ventilator to CMV mode for machine-controlled ventilation of adults.

4.3 Flowmeter tube block with fresh gas dosing

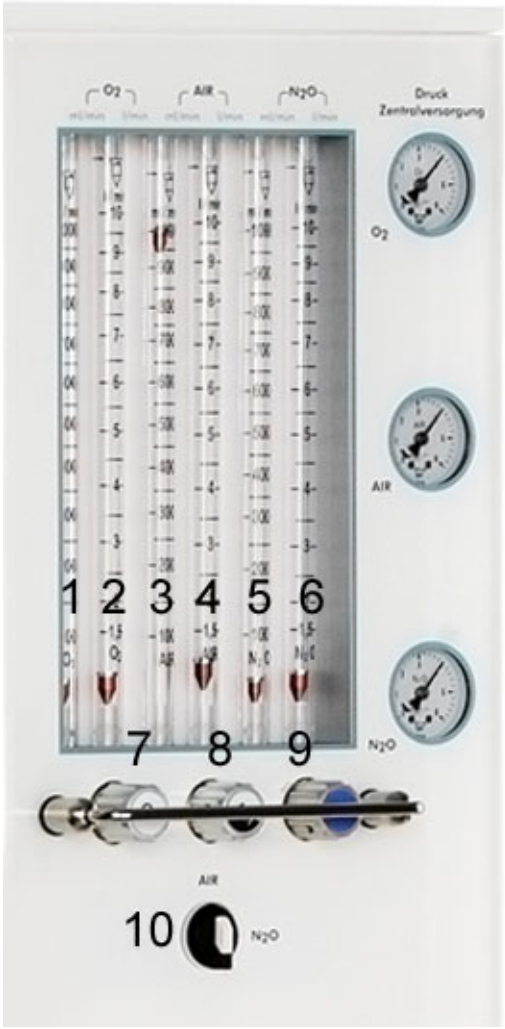


Fig. 5 Flowmeter tube block with fresh gas dosing

1 **Flowmeter tube O_2**
with low measuring range, for settings from 0 to 1000 ml/min

2 **Flowmeter tube O_2**
with high measuring range, for settings from 1.5 to 10 l

3 **Flowmeter tube AIR with low measuring range, for settings from 0 to 1000 ml/min**

4 **Flowmeter tube AIR**
with high measuring range, for settings from 1.5 to 10 l/min

5 **Flowmeter tube $N_2O$with low measuring range, for settings from 0 to 1000 ml/min**

6 **Flowmeter tube N_2O**
with high measuring range, for settings from 1.5 to 10 l/min

7 **Valve spindle for O_2 gas dosing**

8 **Valve spindle for AIR gas dosing**

9 **Valve spindle for N_2O gas dosing**

10 **N_2O/AIR change-over switch**
This switch allows the pre-selection of the gases N_2O or AIR, which can subsequently be dosed with the respective valve spindles. The previously set volume flow is retained after switching back to the same gas type.

4.4 Vaporizer mount

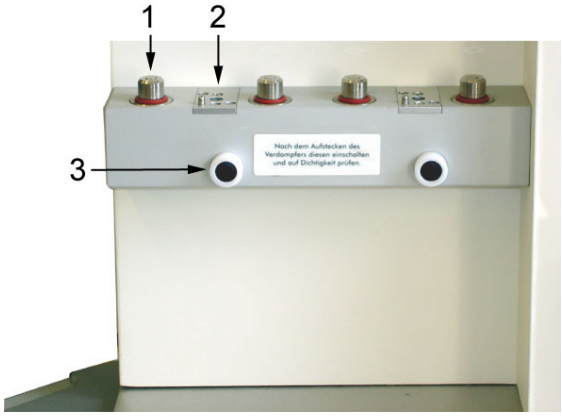


Fig. 6 Vaporizer mount

1 **Valve cartridge of vaporizer mount**

2 **Locking device**

3 **Stop buffer (support) for vaporizer**

4.5 Patient module (circle system)

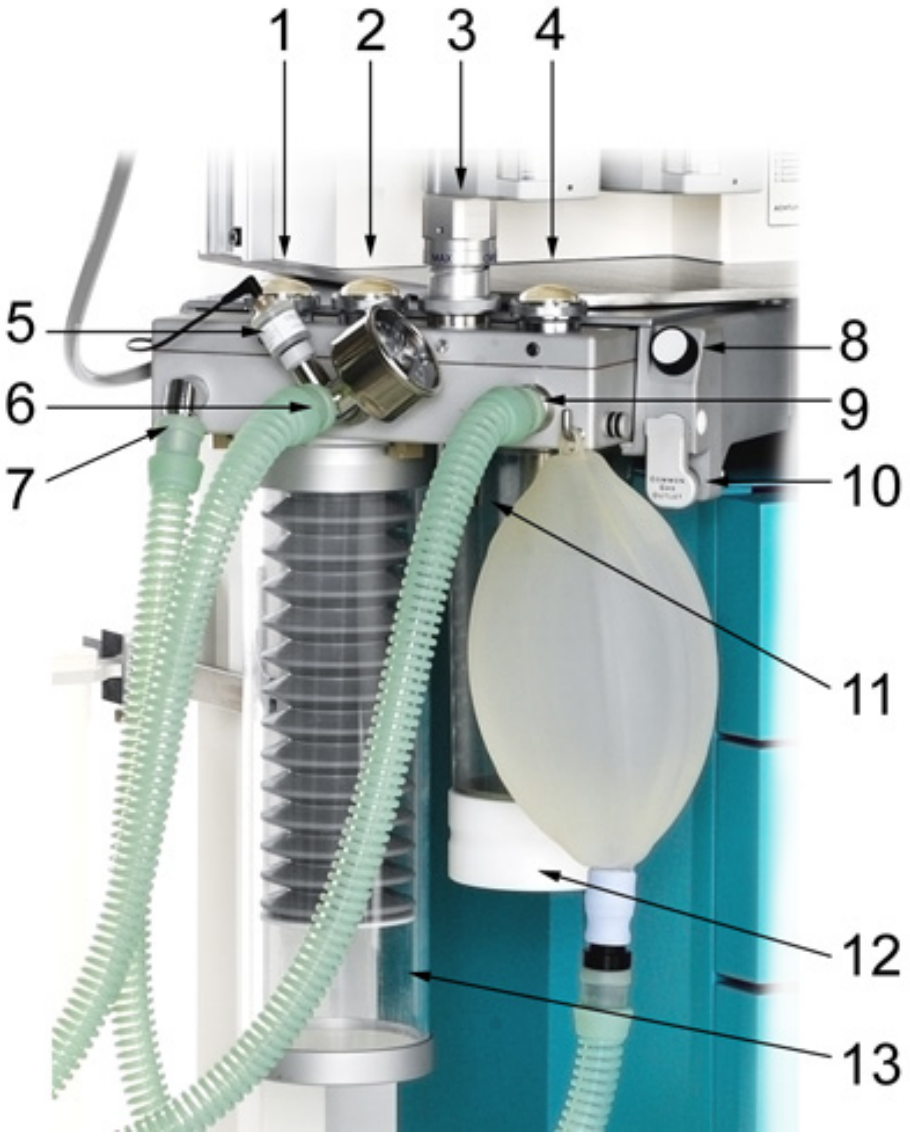


Fig. 7 Patient module (circle system)

1 **Emergency air valve**

2 **Inspiration valve**

3 **Ventilation pressure valve**
Including rotary regulator for setting the pressure control during manual ventilation or for setting it as an overflow valve for CMV or spontaneous ventilation.

4 **Expiration valve**

5 **Oxygen measuring cell**

6 **Connection for inspiration hose**

7 **Hose connection for reservoir/ manual ventilation bag**

8 **Outlet of the ventilation pressure valve**
Here the anesthetic gas suction unit is connected.

9 **Connection for expiration hose**

10 **Fresh gas outlet**

11 **O_2 bypass**
The O_2 bypass supplies a high flow of O_2 (approx. 50 l/min) directly to the fresh gas outlet or to the patient module. When releasing the O_2 bypass button, this returns to its original position and the O_2 bypass is interrupted automatically.

12 **CO_2 absorber**

13 **Bellows with pressure dome**

4.6 IR adapter

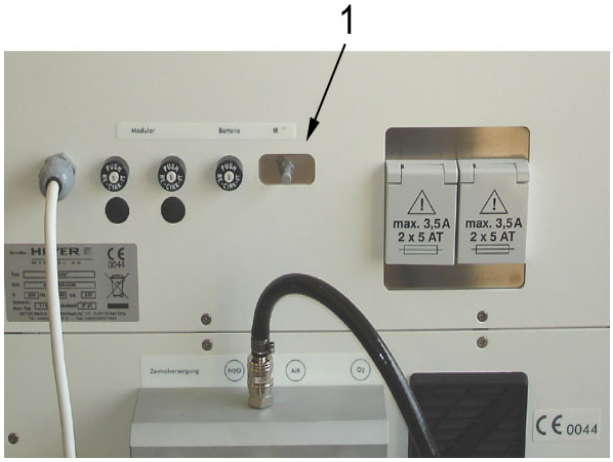


Fig. 8 IR adapter

1 **IR adapter**
The optical infrared interface allows the connection of computers or monitoring systems.

4.7 Compressed air injector for bronchial suction (optional)

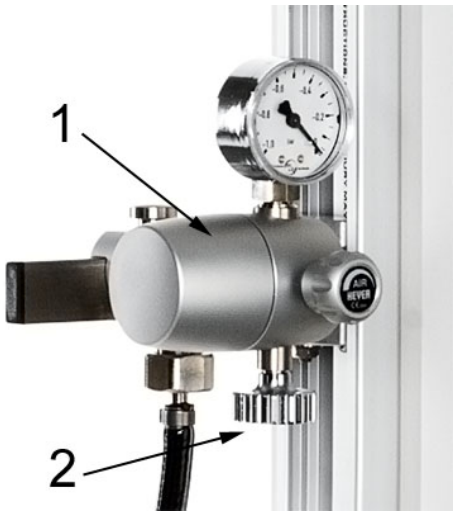


Fig. 9 Suction

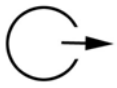
1 **Compressed air injector (drive for suction unit)**
Compressed air injector with vacuum display and vacuum regulating button.

2 **Connection for vacuum hose**
Connection for hose to suction glass connection “vacuum”

4.8 Symbols on the apparatus

Caution! Please observe the following documentation

On / Off (connection to power supply)



IR adapter

5 Alarm Messages and Safety Devices

The HEYER Modular anesthesia system shows alarm messages on the EL display during operation. The alarm message is displayed until the fault condition that triggered the alarm is resolved.
High-priority alarms are display against a light background. Low-priority alarms are display against a dark background.
The alarm indication on the display is not affected by pressing the mute button for the acoustic alarm. A bell will appear on the right-hand side of the screen to indicate the acoustic alarm suppression.

In the following information all alarms able to occur during the various operating statuses are explained.

5.1 Alarm messages and corrective measures

Alarm message	Cause	Corrective Measures
Compliance test carried out	The initial compliance test was carried out successfully.	The system is ready for operation.
Test passed Leak rate is more than 300 ml/min. Please check breathing circuit. Press OK to continue	The initial compliance test was carried out successfully. Leak rate is between 300-600 ml/min .	The ventilator can be safely operated with an adequate fresh gas flow. If necessary repeat the compliance test in the OPTIONS menu after having tightened the cap nuts and correcting the hose connections.
Test passed Leak rate is more than 600 ml/min. Please check breathing circuit. Press OK to continue	The leak rate of the circuit and the patient hoses is greater than 600 ml/min at 40 Pa x 100.	The ventilator can be safely operated with an adequate fresh gas flow. If necessary repeat the compliance test in the OPTIONS menu after having tightened the cap nuts and correcting the hose connections.
ATTENTION! Use Manual ventilation mode only.	The compliance test was not carried out or not passed. Machine-controlled ventilation is not possible until the compliance test has been passed.	Carry out the compliance test in the Standby/OPTIONS menu. If this is not successful, please call a service technician.
System Resistance too high.	The resistance of the ventilation hoses or the bacteriological filter is too high.	Renew the bacteriological filter and/or the ventilation hoses. Carry out the compliance test in the Standby/OPTIONS menu. If this is not successful, please call a service technician.
Compliance out of range.	The compliance of the connected ventilation hoses is outside the permissible range of 3.0 to 9.9 ml/mbar.	Remove the bacteriological filter and/or the ventilation hoses. Carry out the compliance test in the Standby/OPTIONS menu. If this is not successful, please call a service technician.
Leak test Complete Leak rate is higher than 500 ml/min. Verify that APL is set to MAX position CO_2 absorber, vaporizers locked.	The leak rate of the entire circuit higher than 500 ml/min at 40 Pa x 100.	The ventilator can be safely operated with an adequate fresh gas flow. If necessary repeat the compliance test in the OPTIONS menu after having tightened the cap nuts and correcting the hose connections to the vaporizer and absorber.
Leak test Complete Leak rate is higher than 1,000 ml/min. Verify that APL Valve is set to MAX position CO_2 absorber, vaporizers locked.	The leak rate of the entire circuit higher than 1,000 ml/min at 40 Pa x 100.	The ventilator can be safely operated with an adequate fresh gas flow. If necessary repeat the compliance test in the OPTIONS menu after having tightened the cap nuts and correcting the hose connections to the vaporizer and absorber.

Alarm message	Cause	Corrective Measures
O_2 Sensor Calibration Successful	O_2 Calibration is OK.	System is ready for the FiO_2 measurement.
O_2 cell invalid. Press OK to start	The O_2 call either has a concentration of <21% O_2, is not connected or faulty.	Expose O_2 sensor with connected cable connection to room air with 21% O_2 or replace.
O_2 concentration too high. Expose Sensor to room air. Press OK to start	The O_2 call either has a concentration of <21% O_2, or is faulty.	Expose O_2 sensor to room air with 21% O_2 or replace.
A P N E A	The system is not measuring an expiratory volume of the patient.	Check the ventilation of the patient and the hose connections. The initial Apnea alarm tone can be selected between 15, 30 and 45 sec. A continuous tone sounds after 2 min Apnea.
Breathing Circuit Disconnection	No relevant pressure increase measured during ventilation.	Connect ventilation hoses.
Peak pressure greater than alarm limit	The peak pressure is higher than the set alarm limit P_{max} .	Check the tidal volume setting, check that P_{max} is reached, the ventilator changes over to expiration and check the P_{max} setting.
Peak pressure below alarm limit	The peak pressure is lower than the set alarm limit P_{max} .	Check the tidal volume and/or plateau setting. Check the hose connections.
FiO_2 lower than O_2 min	The measured FiO_2 value is lower than the set alarm limit FiO_2 min.	Verify that the O_2 supply is adequate and check the O_2 alarm setting.
FiO_2 greater than FiO2 alarm limit	The measured FiO_2 value is higher than the set alarm limit FiO_2 max.	Check the fresh gas composition and the O_2 alarm setting.
Tidal volume lower than V_t min	The measured V_t value is lower than the set alarm limit V_t min.	Check the tidal volume setting and the Vt alarm setting.
Check Vent Dial position.	The vent dial has been in a position that is not allowed for longer than 3 sec.	Turn the vent dial to a permissible position. Select a ventilation mode and re-start ventilation.
Minute volume below alarm limit	The measured minute volume value is lower than the set alarm limit AMV min.	Check the ventilation parameters and the AMV min alarm setting.
PEEP greater than P_{min}	The measured PEEP value is higher than the set alarm limit P_{min}.	Check the correct APL valve and the P_{min} alarm setting.

Alarm message	Cause	Corrective Measures
PEEP greater than PEEP setting	The measured PEEP value is higher than the set PEEP value.	Check the correct APL valve setting.
Unable to attain target pressure. Adjust flow or I:E ratio	The inspiration time is too short and/or the drive gas flow is too low.	Check the settings of I:E, frequency and drive gas flow.
Set APL Valve to CMP/SP position	Reminder for the user that the APL valve must always be in CMV/SP position for machine-controlled ventilation. This message appears when the measured PEEP value is higher than the set PEEP value.	Set the APL valve to CMV/SP position if this is not already the case.
Ambient air intake; Check Fresh Gas setting	The room air valve in the patient module is opening.	Check whether the fresh gas flow is adequate and the patient is spontaneously breathing.
Too high pressure or no expiration.	A continuous ventilation pressure without a significant change of the pressure value is measured.	Set the APL valve to CMV/SP position.
Invalid CMV parameters	The set parameters require a drive gas flow that cannot be achieved by the ventilator. The AMV must not exceed 20 l/min and the inspiratory flow must not be higher than 75 l/min.	Check whether the set values are correct.
PCV Setting not valid.	The combination of the set ventilation parameters cannot be realized by the ventilator.	Change the PCV settings.
Expiratory time too short.	The expiration time is not sufficient to completely fill the bellows.	Check the settings of I:E and ventilation frequency.
Resume Ventilation	Ventilation can be resumed after having stopped due to lack a drive gas.	Select a ventilation mode. Resume ventilation.
System pressurized	The system is measuring too high a pressure in the circuit.	Relieve the pressure in the system and close the fresh gas supply.
System vented	The system cannot build up any pressure during the compliance test or fresh gas test.	Check whether the O_2 cell and ventilation hoses are correctly connected. If necessary set the APL valve to maximum position.
Drive Gas missing; after standby then CMV	The compressed air supply that drives the ventilator has failed.	Check the compressed air supply.

Alarm message	Cause	Corrective Measures
Caution! Ventilator has stopped. Check position of mode selector switch	The selector switch has been in an impermissible position for more than 12 sec.	Turn the selector switch to a permissible position. Select a ventilation mode and resume ventilation.
AC Power lost, using Battery	Mains voltage failure. Machine running on batteries.	Check the mains connector. Call a service technician if required.
AC Power lost, using Battery 30 min. (to 10 min) remaining	About 20 min battery supply remaining.	Check the mains connector.
AC Power lost, using Battery 5 min remaining	About 5 min battery supply remaining.	Machine-controlled ventilation will end in approx. 5 minutes. The display will remain until the battery is fully discharged. The patient can be manually ventilated as long as compressed air is available.
AC Power lost, using Battery. Battery running low. Use Manual Ventilation	The voltage supplied by the battery is too low for machine-controlled ventilation. The display will go out within a few minutes.	Check the mains connector. Call a service technician if required.
EEPROM – Error during writing.	Data for parameters or alarm limit settings were not correctly stored.	Repeat function. Call a service technician if required.
Data exchange faulty.	The data exchange between the ventilation modules has failed.	Repeat function. Restart the machine. Call a service technician if required.
Pressure sensor faulty.	The system has detected a fault on one or both pressure sensors.	Repeat function. Restart the machine. Call a service technician if required.
Breathing system is unlocked.	The breathing system is not correctly adapted.	Carefully push the patient module into the docking station and lock it.
Hotwire measurement invalid	The hotwire did not pass the test. It may be damaged.	Repeat function. Restart the machine. Call a service technician if necessary.

Alarm message	Cause	Corrective Measures
System vented or drive gas missing	The system was not able to build up pressure.	Check the drive gas supply and verify that the system is closed.
Fault in CPU system	The automatic test has detected a fault in the processor system.	Call a service technician.
CPU monitor failure	The processor monitoring system has detected a fault.	Call a service technician.
Expiration valve blocked	The airway pressure is not being reduced during the expiration phase.	Inspect the APL valve and check the control membranes on the back of the patient module.
Fault on solenoid valve(s)	One or more solenoid valve(s) has/have failed.	Repeat the compliance test in standby mode. If the problem still exists, please call a service technician.
Check the bellows valve.	The system has detected a pressure increase. The control membranes could leak and control gas could penetrate the system.	Check the control membranes.
Fault in proportional valve	The proportional valve that regulates the tidal volumes is not working properly.	Carry out the compliance test in the Standby/OPTIONS menu. If this is not successful, please call a service technician.
Pressure Reading out of tolerance.	The system has detected a fault on one or both pressure sensors.	Carry out the compliance test in the Standby/OPTIONS menu. If this is not successful, please call a service technician.
Flow/Volume Readings not available Replace Flow Sensor –Call Service	The external flow sensor that measures the expiration volume is faulty.	Carry out the compliance test in the Standby/OPTIONS menu. If this is not successful, please call a service technician.
Flow Error: Use Manual Ventilation Call Service	The internal flow sensor and/or the measurement of the generated drive gas is not working properly.	Carry out the compliance test in the Standby/OPTIONS menu. If this is not successful, please call a service technician.
Temp Sensor readings not available Call Service	The temperature sensor in the patient module is defective.	Carry out the compliance test in the Standby/OPTIONS menu. If this is not successful, please call a service technician.
Temp Sensor out of tolerance	The control system for the patient module heating or the heating mat is defective.	Inform the service department.

Alarm message	Cause	Corrective Measures
Fan Error Check Fan Call Service	The fan for the ventilation of the housing and the cooling of installed modules is defective.	Inform the service department.
EEPROM data not saved!	The start-up test for the internal circuits has detected an error. EEPROMS are defective.	Call a service technician.
System error, call a service technician.	The ventilator has a technical defect, machine-controlled ventilation is not possible.	Call a service technician.

5.1.1 Alarm messages during the compliance test

During and after the system test, alarm messages are displayed in the lower part of the system test window:

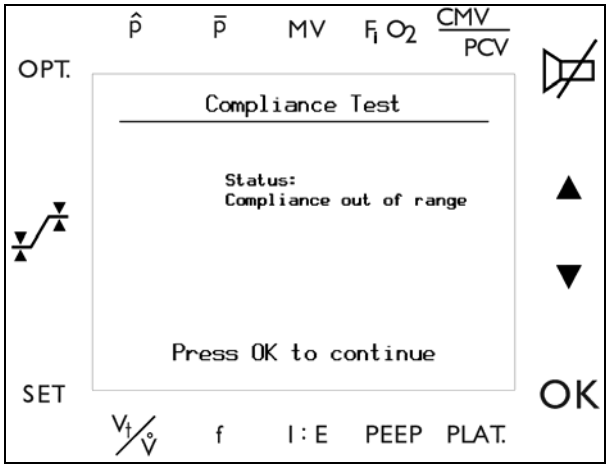


Fig. 10 Example of an alarm message during the compliance test

If the system is error-locked due to a sensor fault, only use the apparatus in an emergency for manual ventilation and inform the technical service department in the case of repeated failure of the compliance test.

Alarm messages during the compliance test (continuation)

#	Alarm message	Meaning/Cause	Alarm type
S1	System Resistance too high.	The resistance of the patient hoses or the bacteriological filters is too high.	System alarm
S2	Leak rate too high.	The leak rate of the patient module including the patient hoses is greater than 100 ml/min.	System alarm
S3	Compliance incorrect	The compliance of the connected patient hoses is outside the range able to be compensated by the ventilator of 3.0 to 9.9 ml/mbar.	System alarm
S4	Error while saving.	Saving of data for parameter and/or alarm limit setting was faulty.	System alarm
S5	Check the bellows valves.	The system has detected a pressure increase. The bellows valves are leaking.	System alarm
S6	Pressure sensors faulty.	The system has detected a fault on one or both of the double pressure sensors.	System alarm
S7	Flow Error: Use Manual Ventilation Call Service	Test of internal flow sensor indicates a defect or an internal mis-adjustment of the ventilator.	System alarm
S8	Flow/Volume Readings not available Replace Flow Sensor –Call Service	The external flow sensor has not measured the required flow during the test, calibration was not successful. Sensor may be faulty.	System alarm
S9	Proportional valve def.	The proportional valve of the ventilator is defective.	System alarm
S10	Flow control system def.	The flow control system of the ventilator for the breathing volume is defective.	System alarm
S11	No data exchange	The data exchange between the modules of the ventilator for the control and the display representation is faulty.	System alarm
S12	Fault on solenoid valve(s)	One or several of the solenoid valves for the control of the bellows valves in the patient module is/are defective.	System alarm

5.1.2 Alarm messages during the system test

During and after the system test, alarm messages are displayed in the lower part of the system test window:

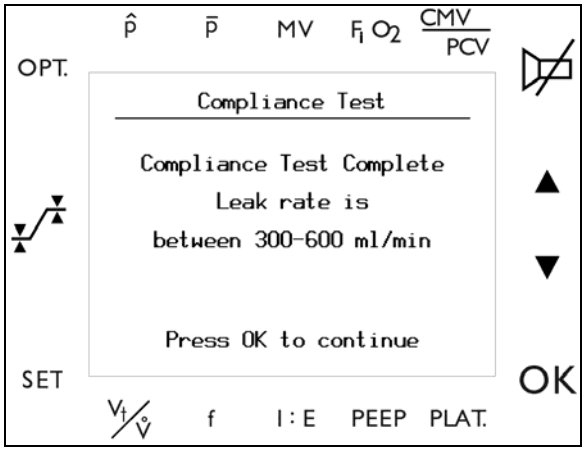


Fig. 11 Example of an alarm message during the compliance test

If the total leakage of the system exceeds 300 ml/min at 40 mbar, this message is displayed in the bottom part of the system test window, for example.

#	Alarm message	Meaning/Cause	Alarm type
T1	O_2 cell is faulty.	The O_2 cell has been correctly calibrated. Please check O_2 cell and repeat test.	System alarm
T2	System Resistance too high.	The resistance of the patient hoses or the bacteriological filters is too high.	System alarm
T3	Leak rate greater than 300 ml/min.	The leakage test for the fresh gas system has detected a leakage greater than 300 ml/min.	System alarm
T4	Compliance incorrect	The compliance of the connected patient hoses is outside the range able to be compensated by the ventilator.	System alarm
T5	Error while saving.	Saving of the data was faulty.	System alarm
T6	Check the bellows valves.	The system has detected a pressure increase. The bellows valves indicate a leak, please check.	System alarm
T7	No data exchange	The data exchange between the modules of the ventilator for the control and the display representation is faulty.	System alarm

5.1.3 Alarm messages in normal mode

During and after normal operation, alarm messages are displayed in the lower part of the ventilation mode window:

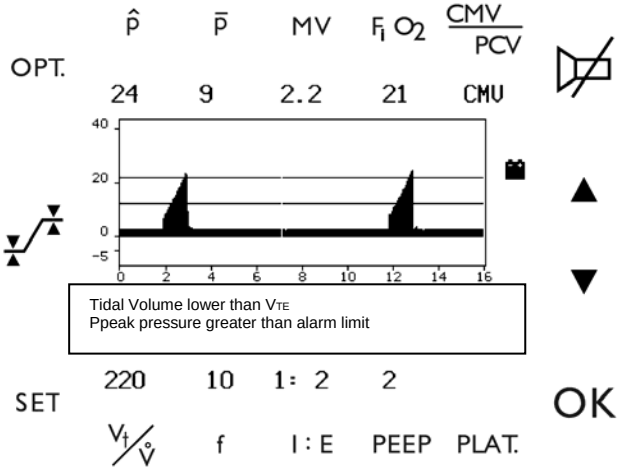


Fig. 12 Example of an alarm message during normal mode

After each activation of CMV mode, for example, the following alarm message appears as a reminder to check the setting of the ventilation pressure valve (APL) in the lower part of the ventilator display.

Alarm messages in normal mode (continuation)

#	Alarm message	Meaning/Cause	Alarm type
B1	Fault in CPU system	The self-testing routine of the CPU system has detected a fault in the CPU control system.	System alarm
B2	CPU monitor failure	The monitoring function for the CPU has failed.	System alarm
B3	Expiration valve blocked	The ventilation pressure is not falling during expiration.	System alarm
B4	Flow Error: Use Manual Ventilation Call Service	The internal flow sensor for the measurement of the generated breathing volume is not working properly.	System alarm
B5	Fault in proportional valve	The proportional valve for the generation of the breathing volume is not working properly.	System alarm
B6	Fault on solenoid valve(s)	One or several of the solenoid valves for the control of the bellows valves in the patient module is/are defective.	System alarm
B7	Pressure sensors faulty.	The system has detected a fault on one or both of the double pressure sensors.	System alarm
B8	Drive gas failure	The compressed air supply that generates the drive gas for the ventilator has failed.	System alarm
B9	Ext. flow sensor faulty.	The external flow sensor for expiratory volume measurement in the patient module is defective.	System alarm
B12	A P N E A	No breathing or ventilation activity has been detected via the expiratory volume measurement.	Alarm for patient monitoring
B13	Breathing Circuit Disconnection	No adequate pressure increase measured during ventilation.	Alarm for patient monitoring
B14	PEEP greater than P_{min}	The measured PEEP value is higher than the set pressure limit P_{min}.	Alarm for patient monitoring

#	Alarm message	Meaning/Cause	Alarm type
B15	FiO_2 lower than FiO_2 min	The measured FiO_2 value is lower than the set minimum oxygen concentration limit FiO_2 min.	Alarm for patient monitoring
B16	Tidal volume lower than V_t min	The measured tidal volume V_t value is lower than the set limit for V_t min.	Alarm for patient monitoring
B17	Peak pressure greater than alarm limit	The peak pressure P_{peak} is higher than the set pressure limit P_{max} .	Alarm for patient monitoring
B18	Peak pressure below alarm limit	The peak pressure P_{peak} is lower than the set pressure limit P_{min} .	Alarm for patient monitoring
B19	Minute volume below alarm limit	The breathing minute volume AMV is lower than the set limit AMV min.	Alarm for patient monitoring
B20	FiO_2 greater than FiO_2 alarm limit	The measured FiO_2 value is higher than the set minimum oxygen concentration limit FiO_2 max.	Alarm for patient monitoring
B21	PEEP exceeded	The measured PEEP value is higher than the pre-set value.	Alarm for patient monitoring
B22	Temperature sensor defective	The temperature sensor in the patient module is defective.	System alarm
B23	Fault on patient module heating	The control system for the patient module heating or the heating mat is defective.	System alarm
B24	Fan failure	The fan for the ventilation of the housing and the cooling of installed modules is defective.	System alarm
B25	AC Power lost, using Battery	The mains voltage supply has failed, the apparatus is running on power supply form the installed battery.	System alarm
B26	Too high pressure or no expiration	A continuous ventilation pressure without a significant change of the pressure value is measured.	System alarm
B27	Power supply failure	The power supply from the battery is no longer given and will fail shortly.	System alarm
B28	Ambient air intake; Check Fresh Gas setting	The emergency valve in the patient module is opening, please check the fresh gas setting and increase the fresh gas flow if necessary.	System alarm

#	Alarm message	Meaning/Cause	Alarm type
B30	Set APL Valve to CMP/SP position	Reminder that the ventilation pressure valve (APL) must also be switched to CMV/SP position after activating CMV mode.	System alarm
B31	f min not reached	The measured breathing frequency f falls below the set limit for f min.	Alarm for patient monitoring
B32	f max exceeded	The measured breathing frequency f exceeds the set limit for f max.	Alarm for patient monitoring
B33	Invalid CMV parameters	The set parameters for ventilation in CMV mode give an inspiratory flow that can no longer be achieved by the machine. A minute volume of > 20 L/min, and/or an inspiratory flow of > 80 L/min are considered as the limit values here.	System alarm
B57	P_{peak} lower than selected plateau	The peak pressure P_{peak} achieved in PC mode does not reach the set plateau pressure. Check the PCV parameters and increase the set inspiratory flow if necessary.	Patient alarm
B58	PCV set values not possible	The inspiratory flow set in PCV mode cannot be generated in combination with the parameters for frequency and I/E ratio. Please check the parameter settings.	Patient alarm
B59	Expiratory time too short.	The remaining expiratory time in PCV mode to too short with the set parameters. Check the parameter settings for frequency and I/E ratio.	Patient alarm

5.1.4 Alarm message “Technical fault”

#	Alarm message	Meaning/Cause	Alarm type
H01	Technical fault	The ventilator indicates a serious technical fault and stops machine-controlled ventilation in CMV mode.	System alarm

This alarm is not displayed in the other used alarm windows of the various displays. This fault is displayed in a window of its own due to its exceptionally high priority level.

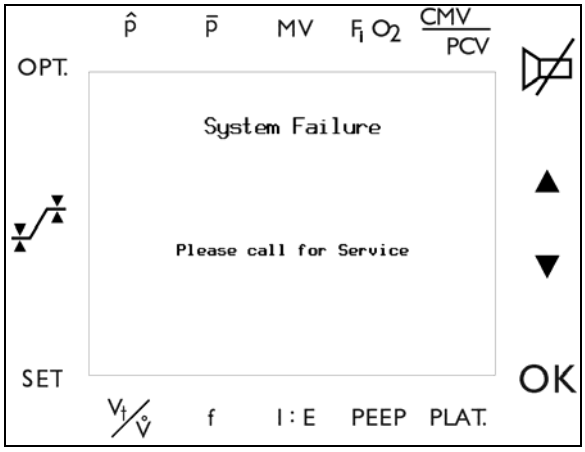


Fig. 13 Alarm message “Technical fault”

5.2 Test of alarm functions

APNEA: Please switch the selector switch for ventilation mode to Manual/Spontaneous position and wait for 30 seconds without carrying out any ventilation action. After this time the alarm message “APNEA“ must appear on the screen.

$P>P_{max}$: Please switch the selector switch for ventilation mode to CMV position. Connect the apparatus to a test lung and sect the ventilation parameters and alarm settings such that the airway pressure will reach the upper alarm limits. Make sure that the inspiration phase is no active and check the alarm message ”P greater than P_{max}“ on the screen after 3 ventilation cycles.

$FiO_2>O_{2\ min}$: Expose the O_2 measuring cell to the ambient air and select a O_2-min value higher than 25%. After 3 ventilation cycles the alarm message “$FiO_2>O_{2\ min}$“ must appear on the screen.

6 Start-up and Functional Test

6.1 Preparing for operation

1. Install the apparatus in such a way that the operating panel at the font of the apparatus is within easy reach and the flow measuring tubes can be easily read.
2. When the apparatus has been installed in the correct position, engage the brakes on the front rollers to prevent accidental movement.
3. Connect the gas connection lines to the gas connections near the rear of the unit. Check that the pressure of the gas supply complies with the specifications of the apparatus. Connect the gas supply by plugging the connectors into the gas supply sockets. Ensure that the connectors are not in the park position.
4. Plug the mains cable into a grounded socket. Switch on the power supply using the mains switch at the rear side of the apparatus.
5. Wait until the ventilator display requests the compliance test. If the patient module should not yet be connected to the apparatus, remove the transportation cover if necessary and push the patient module into the mount. After pushing in the patient module as far as it will go, lock it in by turning the lever on the underside of the swivel mechanism.
6. Next equip the patient module with the ”Bag-In-Bottle” system, consisting of the bellows and the patient dome. Attach the CO_2 absorber. Connect the set of hoses for the anesthesia gas scavenging to the outlet of the overflow/ventilation pressure valve. Create the connection to the anesthetic gas suction unit.
7. Connect the manual ventilation bag to the corresponding hose on the patient module. Connect the patient hose set to the inspiratory and expiratory connections.

6.2 Pre-operative tests

The tests and examinations described below must be carried out before each system start. They are also listed on the check list on the apparatus.

1. Install and lock the vaporizers to be used on the device.
2. Start the compliance test on the apparatus. Follow the instructions on the ventilator display.
3. Carry out the leak test and the O_2 calibration. Instructions on these procedures also appear on the ventilator display.
4. Ensure that a suitable independent device for manual ventilation (e.g. ambulatory bag) is available at or near the apparatus.
5. If required, start the additional monitoring for CO_2 and anesthesia gases and if available for the ECG and check their function according to the respective operating instructions. The gas return line from monitors operating according to the sidestream procedure should be connected to the connection at the rear side labeled measuring gas return.

6.2.1 Compliance test

When the automatic self-test of the system has been completed, the following display appears for the performance of the compliance test.

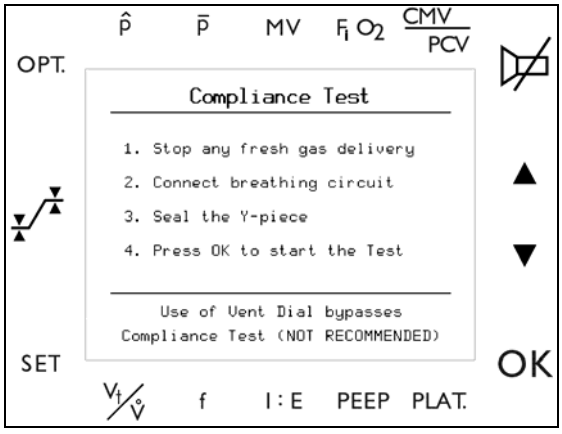


Fig. 14 Display before the compliance test

Follow the instructions on the ventilator display and activate by pressing the OK button on the touch screen display.

The system now checks and calibrates all sensors such as e.g. the expiratory flow sensor and the pressure sensors. Also the internal sensors of the ventilator drive and the active components such as pneumatics control valves are checked during the compliance test.

The patient module, patient connection hoses, the Y-piece etc. are also tested for leaks. Furthermore the system compliance to which in particular also the patient hoses contribute is detected during the compliance test.

During the compliance test a display message confirms that the test is running and a bar indicates its progress.

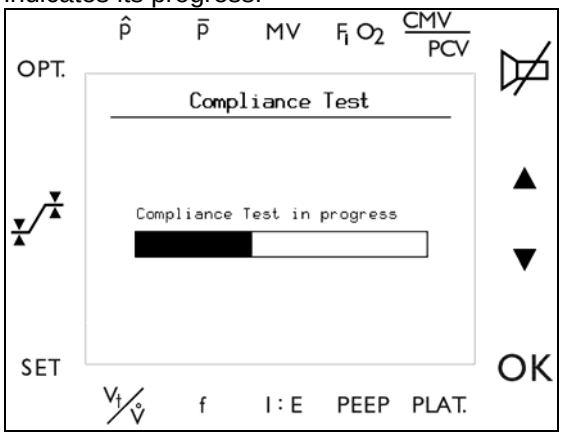


Fig. 15 Display during the compliance test

After the successful compliance test, information on the result is displayed with the message “Compliance Test Passed” including details on the determined system compliance and leakage of the patient module.

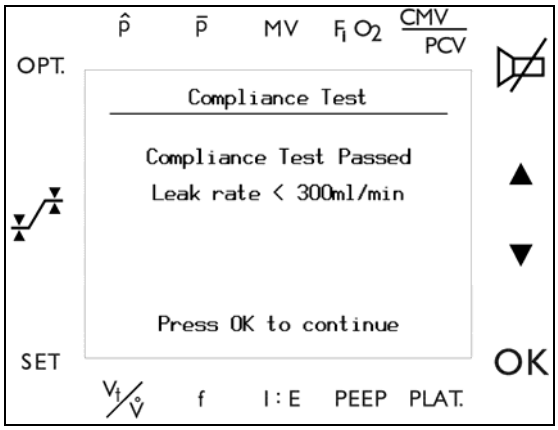


Fig. 16 Display after the compliance test

If the patient tubes were exchanged against others with different hose compliance, the test should be repeated.

6.2.2 O_2 Sensor calibration

The following display appears upon the start of the O_2 sensor calibration.

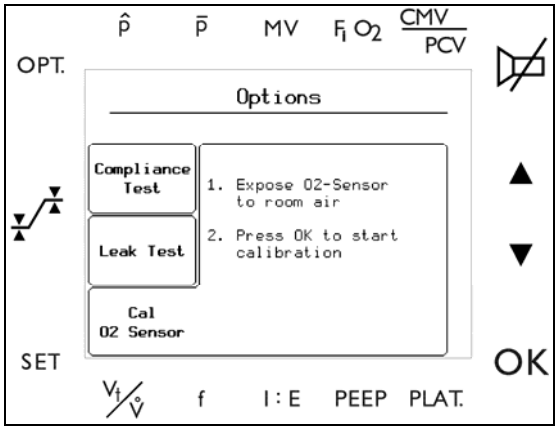


Fig. 17 Display 1 for O_2 sensor calibration

Pull the O_2 measuring cell out of the mount of the inspiration valve. Connect the cell to the calibration adapter next to the patient module. Then start cell calibration.

Attention:
The cell must be exposed to the ambient air long enough otherwise incorrect calibration may be the result.

During calibration of the O_2 sensor, a display appears providing information on the progress of the calibration process.

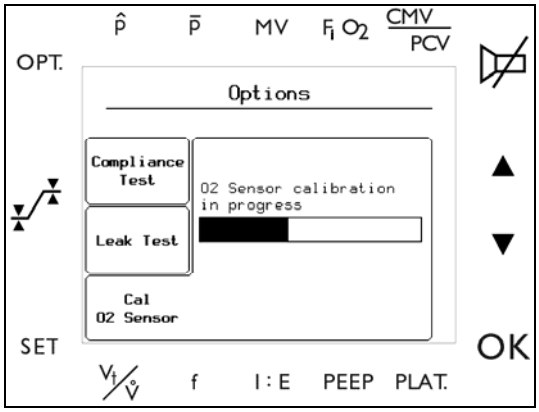


Fig. 18 Display 2 for O_2 sensor calibration

The result of the O_2 sensor calibration is then displayed as follows:

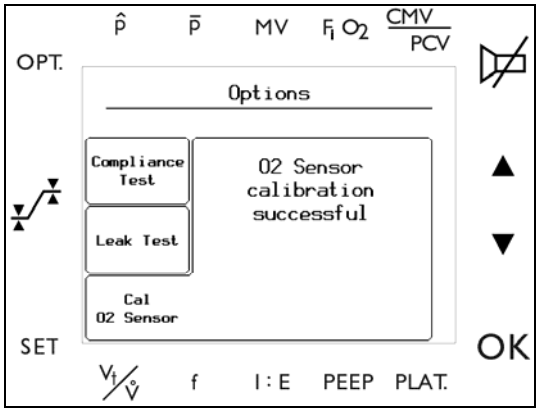


Fig. 19 Display 3 for O_2 sensor calibration

Remove the O_2 measuring cell from the calibration adapter and re-insert it in the inspiration valve mount. This completes the calibration of the O_2 sensor.

6.2.3 Leak test fresh gas system

To carry out a leak test for the entire fresh gas system, select the “Fresh gas test” button on the display.

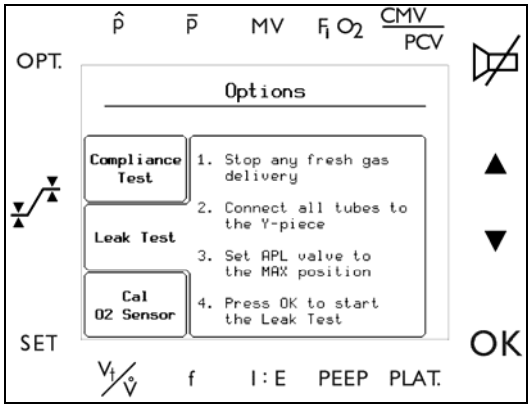


Fig. 20 Display before the leak test for the fresh gas system

Follow the instructions on the ventilator display. Connect the patient hoses and the hose of the manual ventilation device, i.e. of the reservoir/manual ventilation bag, to the Y-piece. Set the ventilation pressure valve (APL) to max position and start the fresh gas test by activating the Ok screen button.

Apart from the leak test for the fresh gas system on the patient module, patient connection hoses, Y-piece etc., the tightness of the measuring tube block, vaporizer mount, and/or activated vaporizer, absorber, manual ventilation hose and ventilation pressure valve is tested.

During the leak test on the fresh gas system, a display appears on the screen to confirm that this test is being carried out.

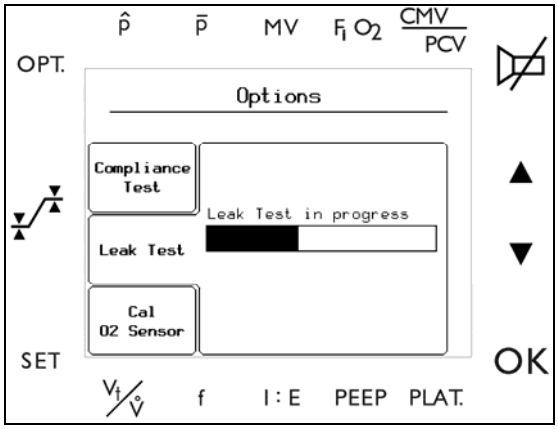


Fig. 21 Display during the leak test for the fresh gas system

The following message appears on the display after the successful leak test on the fresh gas system:

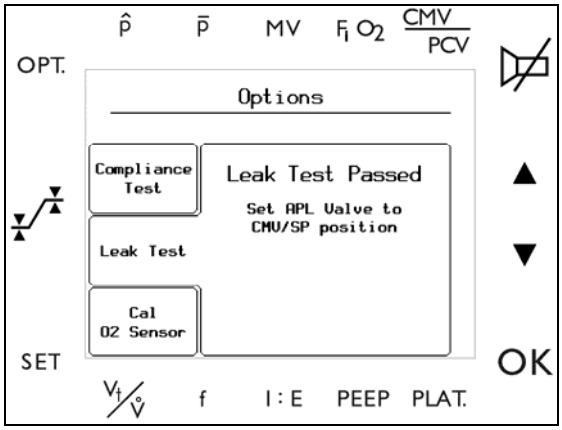


Fig. 22 Display after the leak test for the fresh gas system

Return the patient module hoses to their normal condition and re-connect the reservoir/manual ventilation bag to its hose. Return the ventilation pressure valve back to CMV/SP position. This completes the leak test on the fresh gas system.

Exit the window by pressing the “OK” screen button.

After carrying out the compliance and system test and after observing the test points on the check list, the ventilator is now ready for operation. The standby window for normal mode then appears. In the following section 7 "Operation in the Individual Functions" this display is described in section 7.1 "Standby Mode".

7 Operation in the Individual Functions

The preparation and operation of the system up to readiness for operation on standby mode is described in section “6 Start-up and Functional" and its sub-items. The following sections describe how to operate the system in the various ventilation modes, in standby mode and in the operating modes.

7.1 Standby mode

Standby mode is the waiting mode before and between the ventilation cycles. The system automatically goes to this mode after starting. The following display appears on the screen:

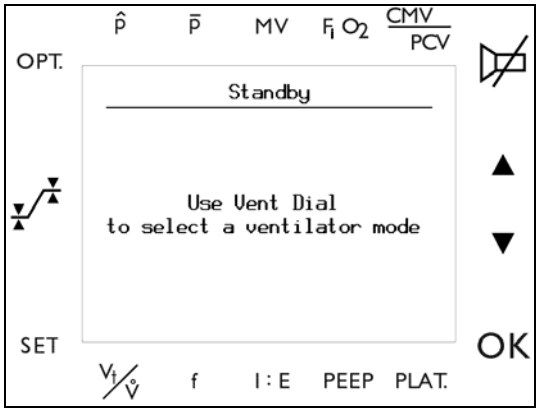


Fig. 23 Display in Standby mode

The ventilator display provides information on the status of the system tests.

7.1.1 The options window in standby mode

The “Options window“ can also be opened by pressing the symbol “OPT“ on the touch screen.

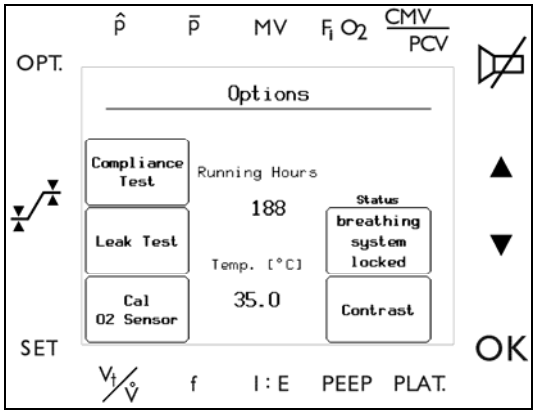


Fig. 24 Standby-Modus Options Window

The window informs about the overall operating hours and the measured temperature of the heated patient module. The volume of the alarm messages can be pre-selected here using the arrow keys.
You can close the window again by pressing the symbol “OPT“ on the touch screen.

7.2 “Manual/Spontaneous” ventilation mode

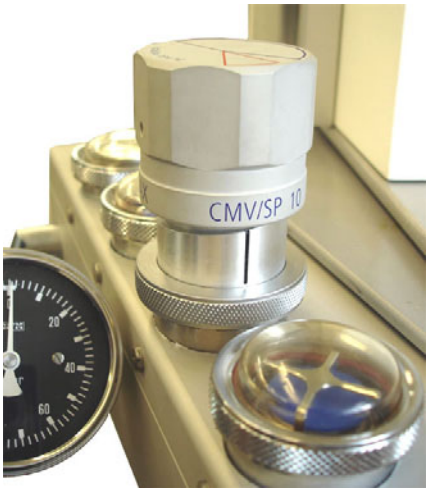


Fig. 25 Setting CMV/SP of the ventilation pressure valve for spontaneous ventilation

Return the ventilation pressure valve (APL) to CMV/SP position for spontaneous ventilation.

Fig. 26 Setting the ventilation pressure for manual ventilation e.g., to 20 mbar

For manual ventilation the ventilation pressure valve must be set to a corresponding value (e.g. 20 mbar) and the patient is to be ventilated using the manual ventilation bag (reservoir).

7.2.1 Setting alarm limits in "Manual/Spontaneous" mode

The setting of alarm limits takes place in "Manual/Spontaneous" ventilation mode by a single press on the "Limits" button on the operating panel.

The graphic presentation then opens up a window "Alarm settings" and indicates the alarm limits.

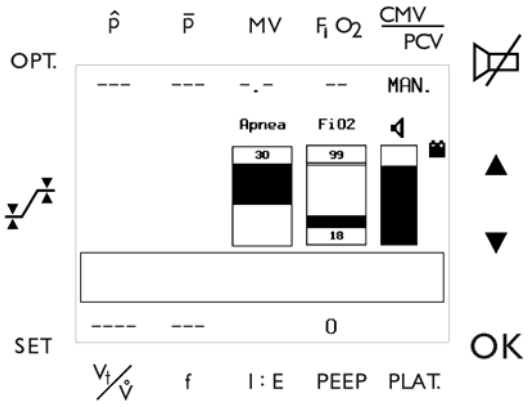


Fig. 27 Display of alarm limits in manual/spontaneous ventilation mode

The individual alarms have the following meanings:

Apnea Time delay in seconds between the occurrence of the Apnea and the issuance of the first alarm.

FiO_2 max Limit for max. FiO_2 value in %

FiO_2 min Limit for min. FiO_2 value in %

Vol. Volume of alarm tone

Display of adjustable alarm limits in manual/spontaneous ventilation mode				
Parameter	Basic setting for ON/OFF option	Basic setting	Increment	Adjustable values
O_2 high		100 [%]	5 [%]	30 – 100 [%]
O_2 low	ON (always)	18 [%]	2 [%]	18 – 90 [%]

7.3 CMV ventilation mode

For controlled ventilation, the HEYER Modular anesthesia system offers two ventilation modes; for adults and children, selectable via the selector switch on the operator panel. The difference between these modes lies in the variously adjustable ventilation parameters and alarm limits for these patient groups.

Select the ventilation mode depending on the ventilation requirements of the patient. Different bellows are not necessary for the ventilation of adults and children. The hose systems and filters used, however, should be adapted to the patient group.

7.3.1 CMV ventilation mode

Se the operator panel selection switch to "Child" for the machine-controlled ventilation of children and to "Adult" for the ventilation of adults.

Fig. 28 Start window for CMV ventilation mode

During CMV ventilation mode the display shows the measured pressure, volume, ventilation rate as well as the oxygen concentration values.

The measured values are displayed below the real-time graphic diagram.

When the button SET is pressed the set parameters are shown inversely. They disappear after approx. 5 seconds or by pressing the "SET " button again.
The measured values can be directly selected in order to change the setting parameters. The display changes over to the target value. This is displayed inversely and can be changed using the arrow keys. The OK button must be pressed to adopt the parameter changes. If no change is made within 5 seconds, the display will switch back to the measured value and the changed setting will not be adopted.

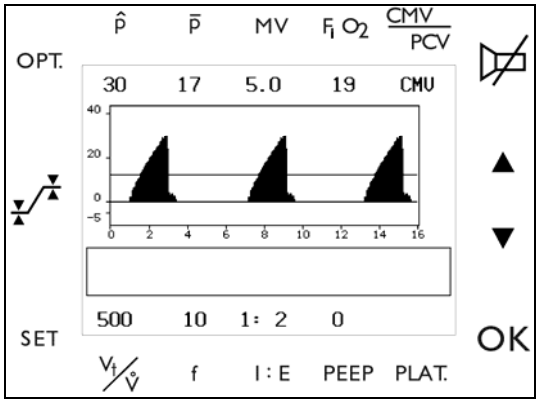


Fig. 29 Display CMV ventilation mode

The individual alarms have the following meanings:

$\hat{P}$	Airway pressure in mbar
$\overline{P}$	Average pressure in mbar
MV	Minute volume in l
FiO_2 %	Inspiratory O_2 concentration in
$V_t/\dot{V}$	Drive gas flow in l/min
f	Ventilation frequency in 1/min
I:E	Inspiratory to expiratory ratio
PEEP	Positive Expiratory End Pressure in mbar
Plat	Plateau pressure in mbar

7.3.2 Setting alarm limits in CMV mode

The window for alarm limits is opened by pressing the symbol "Alarm settings".

The graphic presentation then opens up a window "Alarm settings" and indicates the respective alarm parameters in pairs above one another.

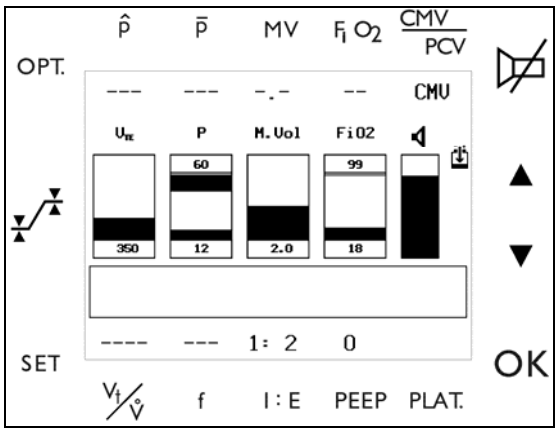


Fig. 30 Alarm settings in CMV ventilation mode

The individual alarms have the following meanings:

V_t min	Limit for minimum tidal volume
P max	Maximum pressure limit (highest pressure limit)
O_2 max	Limit for maximum FiO_2
AMV min	Limit for minimum minute volume
P min	Minimum pressure limit (Lowest pressure limit)
O_2 min	Limit for minimum FiO_2

If the measured values are within the area marked white, no alarm message will be generated. Through direct selection of the alarm messages in bold print, these can be changed.
After selection of an alarm limit value, this value is highlighted and can be changed using the arrow keys. To adopt the setting it must be confirmed by pressing OK. After confirmation the screen changes back to real-time graphic display.

7.4 PVC ventilation mode

The HEYER Modular anesthesia system offers the ventilation modes PCV Child and Adult for controlled ventilation.

With this **P**ressure **C**ontrolled **V**entilation (pressure-limited ventilation) a primarily pre-set maximum inspiratory pressure is maintained. The change to expiration is time-controlled as opposed to pressure-controlled ventilation.
Apart from the inspiration time and the pre-selected pressure limit, the tidal volume depends on the flow and the pulmonary resistance values. The advantage is the avoidance of high pressure peaks, so that it is mainly used in pediatrics but also increasingly to ventilate adults e.g. in cases of severe lung failure or ling leakage.

7.4.1 PCV ventilation mode

Se the operator panel selection switch to "Child" for the machine-controlled ventilation of children and to “Adult“ for the ventilation of adults.

In the display the required ventilation mode “PCV” can be selected by lightly pressing the CMV/PCV symbol.

Fig. 31 Start window for PCV ventilation mode

During PCV ventilation mode the display shows the measured pressure, volume, ventilation rate as well as the oxygen concentration values.

The measured values are displayed below the real-time graphic diagram.

When the button SET is pressed the set parameters are shown inversely. They disappear after approx. 5 seconds or by pressing the "SET " button again.
The measured values can be directly selected in order to change the setting parameters. The display changes over to the target value. This is displayed inversely and can be changed using the arrow keys. The OK button must be pressed to adopt the parameter changes. If no change is made within 5 seconds, the display will switch back to the measured value and the changed setting will not be adopted.

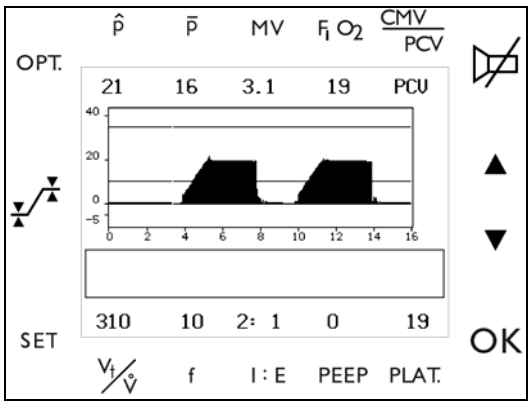


Fig. 32 Display PCV ventilation mode

The individual alarms have the following meanings:

$\hat{P}$	Airway pressure in mbar
$\overline{P}$	Average pressure in mbar
MV	Minute volume in l
FiO_2	Inspiratory O_2 concentration in %
$V_t/\dot{V}$	Drive gas flow in l/min
f	Ventilation frequency in 1/min
I:E	Inspiratory to expiratory ratio
PEEP	Positive Expiratory End Pressure in mbar
Plat	Plateau pressure in mbar

7.4.2 Setting alarm limits in PCV mode

The setting of alarm limits is made by pressing the symbol "Alarm settings" on the display.

The graphic presentation then opens up a window "Alarm settings" and indicates the respective alarm parameters in pairs above one another.

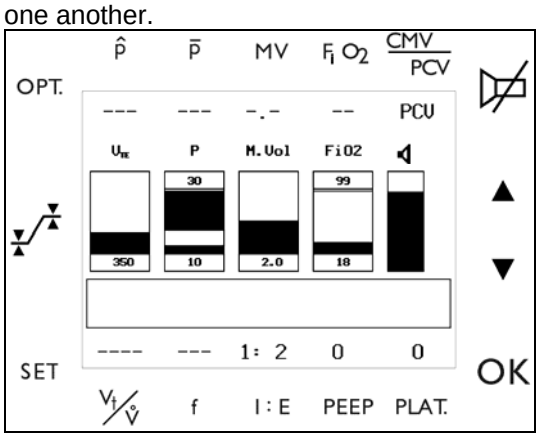


Fig. 33 Alarm settings in PCV ventilation mode

The individual alarms have the following meanings:

V_t min	Limit for minimum tidal volume
P max	Maximum pressure limit (highest pressure limit)
O_2 max	Limit for maximum FiO_2
AMV min	Limit for minimum minute volume
P min	Minimum pressure limit (Lowest pressure limit)
O_2 min	Limit for minimum FiO_2

If the measured values are within the area marked white, no alarm message will be generated. Through direct selection of the alarm messages in bold print, these can be changed.
After selection of an alarm limit value, this value is highlighted and can be changed using the arrow keys. To adopt the setting it must be confirmed by pressing OK. After confirmation the screen changes back to real-time graphic display.

8 Alarm Elimination

By pressing the alarm suppression key on the operating panel, all acoustic alarms are muted for a period of 2 minutes at the most.

Pressing this button a second time cancels thus mute command before the time expires.

The mute command is not active in case of the alarm message "Failure battery supply"!

9 Dismantling and Reassembling

9.1 The patient module

In order to dismantle the patient module, the CO_2 absorber and the Bag-in-Bottle system must be released. The patient module is carefully pulled out of the mount of the apparatus, after having previously turned the locking lever on the underside of the connecting block.

Note: The expiratory flow sensor can be changed and/or replaced without disassembling the top section of the patient module.

9.1.1 The CO_2 absorber

To release the CO_2 absorber from the patient module, the unit must be turned anti-clockwise and unscrewed together with the connecting pipe. Now the lime can be removed from the absorber.

Fill up with fresh lime up to approx. 4 cm below the edge of the absorber. Ensure that the mesh plate in the absorber is present and that there is no lime inside the connecting pipe.

Used lime changes its color. Replace the lime when about 2/3 of the absorber contents have changed color.

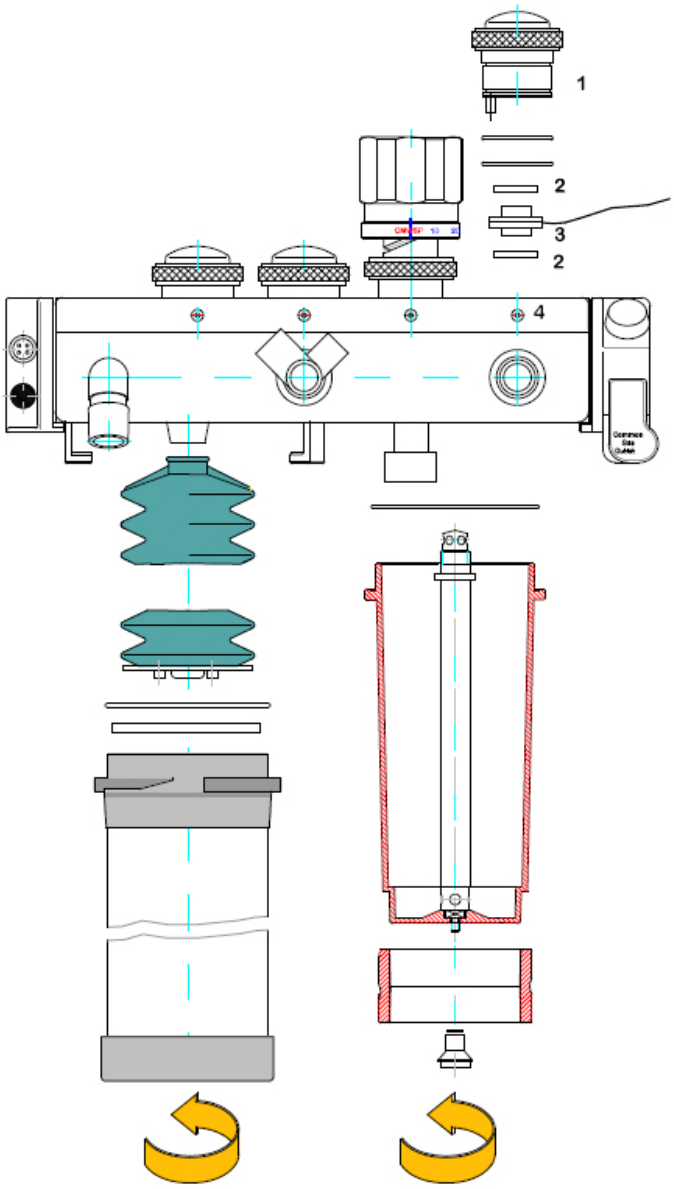
The discoloration of the lime disappears after a while if it is not used. If used again, the discoloration returns at a reduced level. Therefore, the decision to replace the lime should take place after a long period of use, e.g. at the end of each second workday.

Attention: After changing the lime, please carry out a leak test of the fresh gas system.

9.1.2 The Bag-in-Bottle system

The patient dome of the Bag-in-Bottle system is screwed out of the bayonet fitting clockwise. It can now be pulled out from below.

The bellows can be pulled off the connection cone.



9.1.3 Exchanging the expiratory flow sensor

To replace the flow sensor (3) the expiration valve body must be removed (1).

- For this purpose, remove the fixing screw (4) on the front and pull the valve body out of the cover.
- The flow sensor can now be carefully removed and replaced after releasing the plug-in connection.
- Slide the plug-in connection and supply line back into the recess in the bottom section.
- The flow sensor with sealing mats (2) is carefully placed into the recess with the larger connection facing down.
- The expiration valve is placed back into the cover and secured on the front side by means of the screw

Attention: After replacing the flow sensor, please carry out a leak test of the fresh gas system.

9.1.4 Dismantling the ventilation pressure valve

- To dismantle the ventilation pressure valve the cap nut must be unscrewed. The top section can now be removed.
- The membrane can now be removed from the bottom section and replaced if required.
- The membrane is re-inserted into the bottom section with the metal plate facing upwards.
- The top section of the ventilation pressure valve is re-attached and screwed down using the cap nut.

Attention: The spring in the top section of the ventilation pressure valve must not be loaded. After removing the top section from the bottom section, put the top section aside and avoid any exceptional loading of the spring.

9.1.5 Replacing the control membranes

- To replace the control membranes (2) on the rear side of the patient module, the connecting element (1) is screwed off first.
- The control membrane can be removed from the patient module using your fingers.
- Assembly takes place in reverse order.
- When reassembling, please make sure that the control membrane is installed in the patient module with the flat sealing side first.

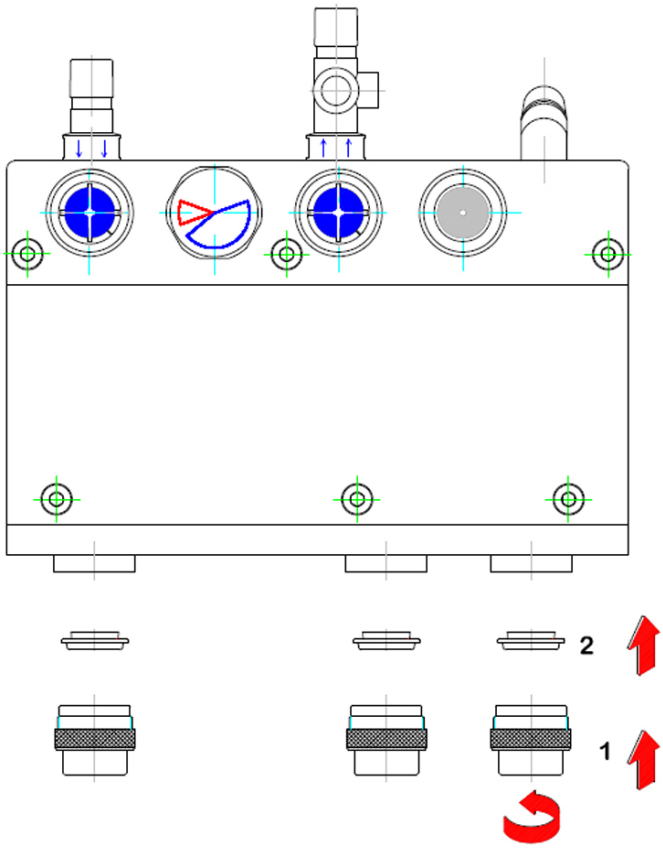


Fig. 35 Disassembly of the patient module, view from the top

9.2 The valves (expirations, inspiration and emergency air valve)

- To dismantle the vales, the coupling ring (1) must be unscrewed from the valve body (7, 8, 9). The valve cover (2) can now be removed.
- The O-ring (3) and the metal basket (5) in the expiration and/or inspiration valve can now be removed. The valve plate (6) can be removed. Assembly takes place in reverse order.
- The membrane of the emergency air valve (4) can be taken out of the valve body after removal of the coupling ring (1) and the valve cover (2). Assembly takes place in reverse order.

The O-rings (10) of the valve bodies must be replaced if necessary after dismantling of the valve bodies from the top section of the patient module.

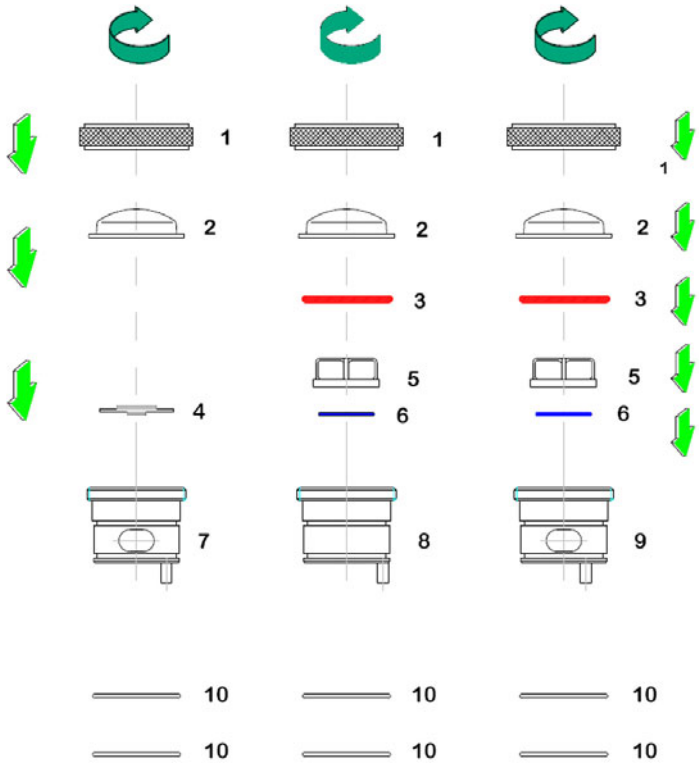


Fig. 36 Dismantling the valves

9.3 Installing the vaporizers

- To install the vaporizers on the apparatus, they must be carefully placed in a horizontal position on the vaporizer mount.
- Check that the vaporizer is correctly positioned and lock it.

Warning: Only vaporizers with an Interlock system may be used with this apparatus. The interlock system prevents both vaporizers from being activated at the same time.

Attention: After changing the vaporizers, please carry out a leak test on the fresh gas system.

Attention: To fill up and empty the vaporizer, remove it from the apparatus and set it on a suitable surface.

10 Cleaning

WARNING:
Electric shock and fire hazard! Always switch off the apparatus and disconnect it from the mains before cleaning.

10.1 Cleaning the housing

The apparatus housing can be cleaned with a cloth that has been previously moistened in a mild liquid cleaning agent. To avoid abrasion on the housing the cloth must be moistened before cleaning. If additional cleaning is necessary please use a conventional agent for surface disinfection.

ATTENTION:
Only use a little cleaning agent. Excess fluid can penetrate the interior of the apparatus and cause damage.

10.2 The patient module

The patient module can only be autoclaved up to max. 134°C. For this, remove the Bag-in-Bottle system and the absorber. The connecting element of the left control membrane (expiration valve membrane) and the membrane must be removed from the patient module. Also the connection element of the right control membrane (decoupling valve membrane) and the membrane.

ATTENTION:
The patient dome of the Bag-in-Bottle system cannot be autoclaved! It does not come into contact with ventilation gas. In case of soiling, the patient dome must be cleaned with water ands a liquid cleaning agent. Disinfection can take place using a conventional surface disinfectant, but please do not use alcohol.

The bellows can also be autoclaved at 134°C, as well as the CO_2 absorber. However, 121°C are preferred as regards the service life of the materials of the bellows and/or seals on the absorber.

For autoclaving the ventilation pressure valve (APLP) should be dismantled by unscrewing the top section.
Please autoclave the APL top section and the membrane a**s individual elements** with the patient module.

11 Service and Maintenance

11.1 General

In order to guarantee fault-free operation of the apparatus, the following maintenance work should be carried out at the specified intervals.

NOTE:
After completion of the maintenance work the pre-operative tests for the ventilation unit and the corresponding calibrations must be carried out. The appliance must not be used again for patients without these final tests/calibrations. Please compare the respective sections of these instructions.

11.2 Maintenance work

11.2.1 Maintenance work on the ventilator / patient module

Maintenance work as required:

- Cleaning, wipe disinfection of the basic apparatus and the operating panels
- Sterilization of the patient module
- Sterilization of the CO_2 absorber
- Sterilization of the bellows
- Replacement of the external flow sensor
- Replacement of the control membranes

ATTENTION:
The patient module and all components coming into contact with the ventilation gas must be sterilized at least once a day. If bacteria filters are continuously used, the sterilization interval for patient modules can be extended to once a week.

11.2.2 Maintenance work by a qualified technician

Testing of electrical safety acc. to IEC 601-1:

- Measurement of the ground conductor resistance
- Measurement of the leakage current of the apparatus
- Measurement of the insulation resistance

Visual check and functional test:

- Check for the presence of the check list and operating instructions.
- Check of the apparatus and accessories for external damage and completeness
- Check of all ground conductors
- Test of the apparatus acc. to the check list
- Test of all alarm functions and the pneumatic safety equipment

11.2.3 Maintenance work after 6 Month

- Replacement of the O-ring (art.-no. 323-0147) and the flat seal (art.-no.980-1170) of the absorber
- Replacement of the O-ring (art.-no. 323-0147) of the patient dome
- Replacement of the O-rings at the valve cartridges of the vaporizer holder (art.-no. -049-3110)
- Functional test of the ventilation pressure valve
- Performance of a compliance and system test
- Performance of a manual leak test
- Check of intake filters O_2, AIR and N_2O
- Check of reserve bottle pressure reducer, if present
- Test of pneumatic safety equipment: Laughing gas lock, O_2 shortage signal
- Concentration test ratio system
- Heating function test
- Check of holding arm joint settings

Attention:
After all maintenance work, carry out a pre-operative check before clinical use is considered.

11.2.4 Maintenance work after 12 Month

Maintenance work after 6 Month and in addition:

- Check of internal hose connections
- Replacement of the O-rings of the gas connectors at the connection block (art.-no. 49-3052)
- Replacement of the valve plates (art.-no. 610-3156)
- Replacement of the control membranes (3 x art.-no. 440-0021)
- Replacement of sealing sets for valve bodies (3 x art.-no. 323-0313)
- Replacement of the ventilation pressure valve membrane (art.-no. 323-0310)
- Replacement of the O-rings on the ventilation pressure valve (art.-no. 323-0272)
- Carrying out of the service software, calibration of the measuring modules for pressure, flow, internal flow
- Checking and if necessary setting of the internal HP and LP pressure reducers
- Check of solenoid valves MV1 to MV4

Attention:
After all maintenance work, carry out a pre-operative check before clinical use is considered.

11.3 Maintenance work on the vaporizer

The maintenance work can be found in the operating and service instructions for the anesthetic vaporizers used.

11.4 Other maintenance work

The service department will carry out other maintenance work on the gas preparation unit, fresh gas dosing system etc. For details and an exact description of the listed work, please refer to the service instructions for the HEYER Modular.

12 Technical data

General data:

Dimensions	
Height:	1350 mm
Width:	900 mm
Depth:	800 mm
Weight:	approx. 135 kg (without vaporizer)

Electrical connection data:

Mains supply:	230 V+/-10% / 50Hz
Power consumption, connected load:	15 A
of these, additional sockets:	10 A (maximum)
Power input:	210 VA
Battery supply:	approx. 30 minutes, battery capacity 6.5 Ah
Battery charging time:	max. 7 hours if the apparatus is running.
Additional sockets:	2 pc. (each protected with 2 x 5 AT fuse)
Electrical safety:	Apparatus protection class I, type of protection IP21 Apparatus type BF

Pneumatic connection data:

Centr. Gas supply (CGS)	O_2:	2.8 - 6 bar
	AIR:	2.8 - 6 bar
	N_2O:	2.8 - 6 bar

Ambient conditions:

Storage temperature:	-5 - 50°C
Working temperature:	+10 - 35°C

Humidity (relative humidity)**:**

Storage:	15 - 95 %, non-condensing
Work:	15 - 95 %, non-condensing

Fresh gas dosing: 6-fold measuring tube block

Standard measuring tubes:

O_2:	0.05 - 1 / 1.5 - 10 l/min
N_2O:	0.1 - 1 / 1.5 - 10 l/min
AIR:	0.1 - 1 / 1.5 - 10 l/min

Ratio system: integrated (at least 25 vol.% O_2 in fresh gas)

Mount for anesthetic vaporizer: "Selectatec"-compatible, dual holder

Patient module /circuit system:

Internal volume:	approx. 2.5l
Absorber volume:	approx. 1.4l
Absorber system:	Conventional filling
Patient module connection:	Mechanical, manual
Condensate block:	Heated patient module (36 +/- 2°C)
Preparation:	autoclavable at 134°C
System compliance:	automatically compensated
Fresh gas decoupling:	automatic during inspiration, thus enabling constant-volume ventilation

Mark of conformity: EC Type Test Certificate acc. to 93/42/EEC Annex III
Identification: 0 0044

Patient module materials:

Housing: :	Aluminum
Ventilation bag:	Silicone
Hoses:	Silicone
Valve plate:	Silicone
Valve plate holder:	Silicone
Bellows valves:	Silicone
Heating mat:	Silicone
Absorber container:	Polysulfon
Absorber inserts:	Chrome-plated metal

Ventilation unit:

Ventilator control:	time-controlled, pressure-limited, constant-volume
Ventilation types:	Manual ventilation, spontaneous ventilation, CM child, CM adult
Tidal volume:	20 - 1400 ml (+/- 5%), CMV child: 20 - 400 ml, CMV adult :300 - 1400 ml
Ventilation frequency:	4 - 60 l/min CMV child: 10 - 60 l/min CMV adult: 4 - 30 l/min
Ventilation minute volume:	max. 20 l/min
I:E ratio:	1:1; 1:1,5; 1:2, 1:3; inverses I:E ratio 2:1 and 3:1
Insp. pause:	max. 5 sec
Exp. pause:	max. 30 sec
Plateau (end insp.):	20 % or 30% of insp. time
PEEP:	0 - 20 +/- 2 mbar
Maximum insp. pressure:	80 mbar
Manual overpressure valve:	4 - 60 mbar
Compliance test:	automatic
Leak tests:	Circuit system, automatic after confirmation Fresh gas system, automatic after confirmation
Oxygen monitor:	Type: Fuel cell FiO_2 display 0- 100 Vol% O_2
Pressure monitor: Numerical pressure values for:	Real-time graphics PEEP, P_{mean}, P_{peak}
Flow monitor: Numerical values for:	Real-time graphics Tidal volume, breathing rate, minute volume

Tolerances for measured values:

Pressure:	+/- 5 % of the measured value
O_2:	
Volume:	Adults +/- 10 % of the measured value Child +/- 10 % of the measured value
Measuring tubes:	+/- 3 % of the scale value

13 Warranty

Warranty declaration by HEYER Medical AG

In addition to the legal warranty acc. to HBG §377, HEYER MEDICAL AG shall grant a warranty of 12 months for the purchase of a new apparatus from the HEYER product range. The warranty period begins with the date of invoice and is subject to the following conditions:

1. Within the warranty period we will eliminate free of charge any defects or damages on the device that are shown to be caused by a manufacturing or material error. The warranty does not include easily breakable parts, e.g. glass or consumable parts.

2. Warranty services can only claimed upon submission of a delivery note (bill of delivery or invoice); the type and method of damage remedy (repair or replacement) shall be at the discretion of HEYER MEDICAL AG. Warranty services do not result in an extension of the warranty period, nor do they entail a new warranty being granted. There is no independent warranty period for installed spare parts.

3. Excluded from the warranty are: Damages caused by improper use, operating errors, mechanical stress or non-observance of the operating instructions, as well as damages caused by force majeure or by extraordinary environmental conditions.

4. Warranty services may only be claimed if proof is submitted to confirm that all service and maintenance work has been carried out by authorized staff.

5. The warranty includes all faults that impair a faultless functioning of the device on the basis of technical defects of individual components. The warranty obligation can only be recognized by us if the device has been used properly and according to its intended use and no repair attempts have been undertaken by the client himself or by third parties. The warranty claim does not include faults caused by mechanical damages or if the device is being operated with accessories originating from third parties.

6. The warranty is also void if changes, alterations or repairs are made to the device by persons not authorized to do this.

7. The warranty claim only applies to customers of HEYER MEDICAL AG; it cannot be transferred to third parties.

8. The rejected device is to be shipped back to our plant postage free. In case of a request by our customer service department, the costs for shipping to the plant are to be initially generally borne by the customer. After successful repair, we will send the device back freight collect. If HEYER MEDICAL AG confirms the existence of a warranty claim, the customer will receive reimbursement for the costs of delivery and/or transport of the apparatus. Repair parts that do not fall under the warranty claim will be billed by us. The shipping of the device to us always counts as a complete assignment to eliminate all faults and/or replace missing parts, unless the customer expressly excludes partial services. Additional claims to transfer or reduce and replace damages of any kind in particular also of damages not incurred on the object of delivery itself are excluded.

Our service address:

HEYER Medical AG
Carl-Heyer-Straße 1-3
D-56130 Bad Ems
Tel.: (02603)791-3
Fax: (02603)70 424

Subject to technical changes!
Rev. No.: 1.1 dated 07.2007

Notes:

HEYER

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