

Technical Documentation

Fabius MRI Anesthesia System



WARNING!

Each servicing and/or testing of the device requires full understanding of this Technical Documentation. Carefully read this Technical Documentation and any applicable Instructions for Use prior to any use of the device.

**Revision 1.0
5330.660
9036337**

General

1	Symbols and Definitions	6
2	Notes	6
1	Cautions and Warnings	8
1.1	Patient safety	8
1.2	Warnings	8

Function Description

1	Abbreviations	12
2	General	12
3	Basics of magnetic resonance tomography	12
4	Safety instructions	12
5	General Information about the Fabius MRI	14
6	Battery backup	17
7	Fabius MRI Piping Diagram	18
8	Function description of the gas box	18
9	SORC (Sensitive Oxygen Ratio Controller)	19
10	Cosy 2.6 breathing system	21
10.1	Ventilation mode	25
10.2	Manual ventilation	26
10.3	Spontaneous breathing	27
10.4	Volume/pressure control ventilation mode	29
10.5	Cosy 2.6 absorber	31

Inhaltsverzeichnis

11	Lung ventilator	31
11.1	Pressure limiting valve	34
11.2	Auxiliary-air valve	34
12	Pneumatic assembly	35
12.1	PEEP/Pmax valve control	35
12.2	APL bypass valve control	36
13	Control PCB	36
14	Function Description: Control PCB	37
15	Control panel assembly	38
16	FiO2 measurement	40
17	Respiratory flow measurement	41
18	Gas flow rate measurement	42
19	Anesthetic vaporizer(s)	43

Maintenance Procedures

1	Diagnostics	46
----------	--------------------	-----------

Annex

Parts catalog

Test List

General

1 Symbols and Definitions

WARNING

A **WARNING** statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

A **CAUTION** statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the equipment or other property.

NOTE

A **NOTE** provides additional information intended to avoid inconvenience during operation or servicing of the equipment.

Definitions:

Inspection	= examination of actual condition
Maintenance	= measures to maintain specified condition
Repair	= measures to restore specified condition
Servicing	= inspection, maintenance, and repair

2 Notes

This Technical Documentation conforms to the IEC 60601-1 standard.

Read each step in every procedure thoroughly before beginning any test. Always use the proper tools and specified test equipment. If you deviate from the instructions and/or recommendations in this Technical Documentation, the equipment may operate improperly or unsafely, or the equipment could be damaged.

Dräger recommends that only Dräger supplied repair parts be used for maintenance. Otherwise the correct functioning of the device may be compromised.

The maintenance procedures described in this Technical Documentation may be performed by properly trained service personnel only. These maintenance procedures do not replace inspections and servicing by the manufacturer.

This Technical Documentation is for the purpose of information only. Product descriptions found in this Technical Documentation are in no way a substitute for reading and studying the Instructions for Use.

NOTE

Unless otherwise stated, reference is made to laws, regulations or standards (as amended) applicable in the Federal Republic of Germany for equipment used or serviced in Germany. Users or technicians in all other countries must verify compliance with local laws or applicable international standards.

NOTE

If the test values are not met, please contact your local service organization.

1 Cautions and Warnings

1.1 Patient safety

The design of the medical device, the accompanying literature, and the labeling on the medical device take into consideration that the purchase and use of the medical device are restricted to trained professionals, and that certain inherent characteristics of the medical device are known to the trained operator.

1.2 Warnings

The following WARNINGS and CAUTIONS apply to general operation of the device. WARNINGS and CAUTIONS specific to subsystems or particular features appear with those topics in later sections of the manual.

WARNING

Any person involved with the setup, operation, or maintenance of the Fabius MRI anesthesia system must be thoroughly familiar with the instruction manual.

CAUTION

Only the accessories indicated on the list of accessories 8607185 en (1st edition or higher) have been tested and approved to be used with the medical device. Accordingly it is strongly recommended that only these accessories be used in conjunction with the specific medical device. Otherwise the correct functioning of the medical device may be compromised.

WARNING

This MR conditional anesthesia machine has been tested with magnets with field strengths of 1.5 tesla and 3 tesla by a fringe field strength of 40 mtesla. Use of the machine with higher strengths could result in ventilator and device malfunction. Additionally, unmanageable attractive forces could lead to serious injury.

CAUTION

No third-party components shall be attached to the anesthesia machine, ventilator, or breathing system (except for certain approved components), otherwise the correct functioning of the medical device may be compromised. For more information, contact DrägerService or your local authorized service organization.

CAUTION

Only the combinations approved by Dräger Medical, with monitoring may be used. Otherwise the correct functioning of the device may be compromised.

WARNING

Always lock the caster brakes after the Fabius MRI has been positioned in the MRI scanner room. Magnetic attractive forces between the magnet and the anesthesia machine may cause unintentional movement of the anesthesia machine if the casters are unlocked.

WARNING

Do not place any object on this machine unless it is specifically labeled to be used in an MR scanning room and on a Fabius MRI anesthesia system. Objects placed on this machine that are not designed for use with this anesthesia system may be strongly attracted to the magnet and may cause serious injury or death when the machine is used in an MR scanning room.

WARNING

Do not bring any ferromagnetic tools or equipment into the scanning room. Ferromagnetic objects (made of steel, iron, or stainless steel) are strongly attracted to the magnet and can become harmful projectiles.

WARNING

Be careful in handling the power cord and main power plug. These parts still contain minor magnetic components. The power cord can be attracted to MRI system.

WARNING

The Fabius MRI and its patient connections must be carefully positioned so that the patient cannot be disconnected when being removed from the MRT system.

CAUTION

Do not use any type of Desflurane vaporizer in the MR environment. In an MR environment functionality of the Desflurane vaporizer will be compromised.

CAUTION

Only Vapor 2000 vaporizers can be used on the Fabius MRI in MRT scanner rooms.

Function Description

- 1 Abbreviations**

MRI →Magnetic Resonance Imaging

MRT →Magnetic Resonance Tomography

Tesla (T) →Magnetic flux density/induction

HF →High Frequency
- 2 General**

Fabius MRI is a variant of the Fabius GS/Tiro which operates in a MRI environment.
- 3 Basics of magnetic resonance tomography**

Magnetic resonance (MR) or nuclear magnetic resonance imaging is a diagnostic technique which produces high-resolution pictures (images) of the human body without the use of dangerous X-rays.

Signals are generated and received using a strong magnet and a radio-frequency antenna. The resulting images are evaluated and displayed by a computer.
- 4 Safety instructions**

As the MR scanner generates very strong magnetic fields, special safety precautions must be taken.

Strong, high-frequency magnetic fields can heat metal. There is a risk of burns caused by metal objects on the person or implants.

Ferromagnetic (metal) objects can also be accelerated with great force and could cause injury.

The data content of cards featuring magnetic strips (such as credit cards) may be wiped.

Before entering the MR scanner room remove all metal objects from your person. This includes:

 - Coins
 - Key
 - Watches
 - Items of jewelry
 - Tools
 - Cards with magnetic strips

Persons with implants should consult a specialist doctor before entering the room.

Metal implants inside the body may cause pain and injuries when they are introduced into the magnetic field. Therefore, patients with certain implants are contraindicated from MR imaging. Prior to MR examination, the MR physician or technologist will ask the patients about the following risk factors:

- cardiac pacemakers
- metal plates, nails, or metal implants
- artery clamps
- artificial cardiac valves
- intrauterine contraceptive devices
- body jewelry
- cosmetic decorations or tattoos (the dyes used may contain metal flakes or slivers)
- shrapnel
- pregnancy (should be reported)

According to current knowledge, damaging effects are unlikely at the magnetic field strength used (up to 3.0 tesla).

5 General Information about the Fabius MRI

- The Fabius MRI comprises the following assemblies:
- Display and control panel
 - Flowmeter assembly
 - Gas box: Gas inlet assembly and related items
 - Breathing system
 - Pneumatic assembly
 - Lung ventilator
 - Anesthetic vaporizer(s)
 - Trolley
 - Cover with additional alarm

Monitoring, electrical connections and gas connections as shown in Fig. 1, Fig. 2, Fig. 3, Fig. 4 and Fig. 5.

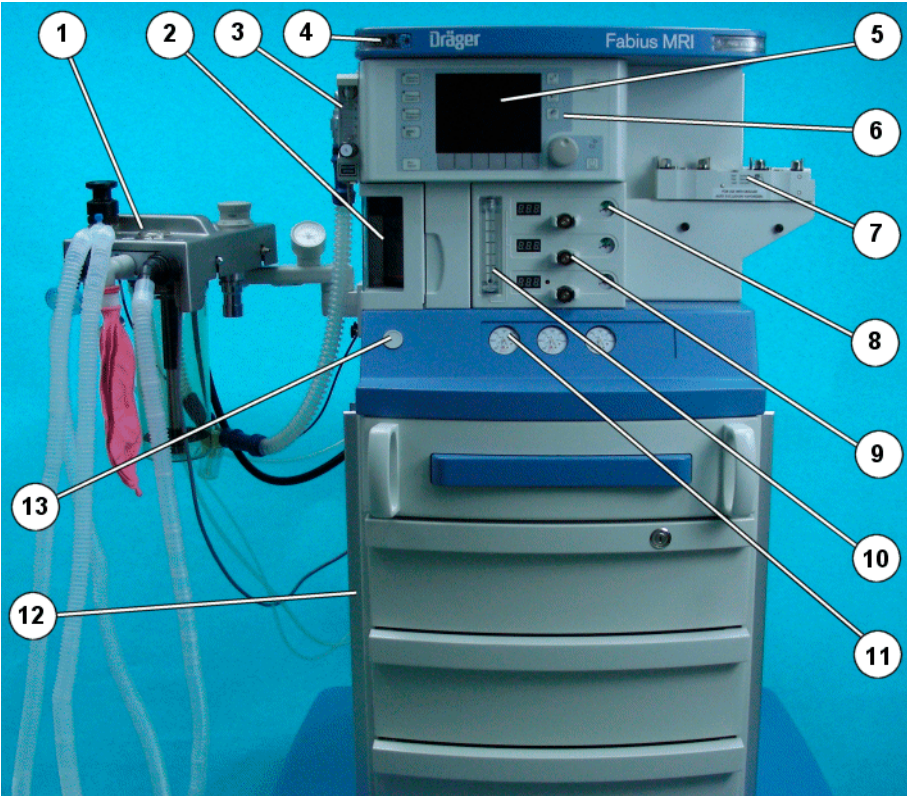


Fig. 1 Front view of Fabius MRI anesthesia system, for legend see Table 1

Table 1 Legend to Fig. 1

No.	Name
1	Breathing system Cosy 2.6
2	Lung ventilator
3	Oxygen flowmeter (auxiliary)
4	Additional alarm lights
5	Display

No.	Name
6	Control panel
7	Anesthetic vaporizer mount
8	Pipeline supply manometers
9	Flow control valves
10	Total fresh gas flowmeter
11	Cylinder Manometer
12	Trolley
13	O ₂ flush key

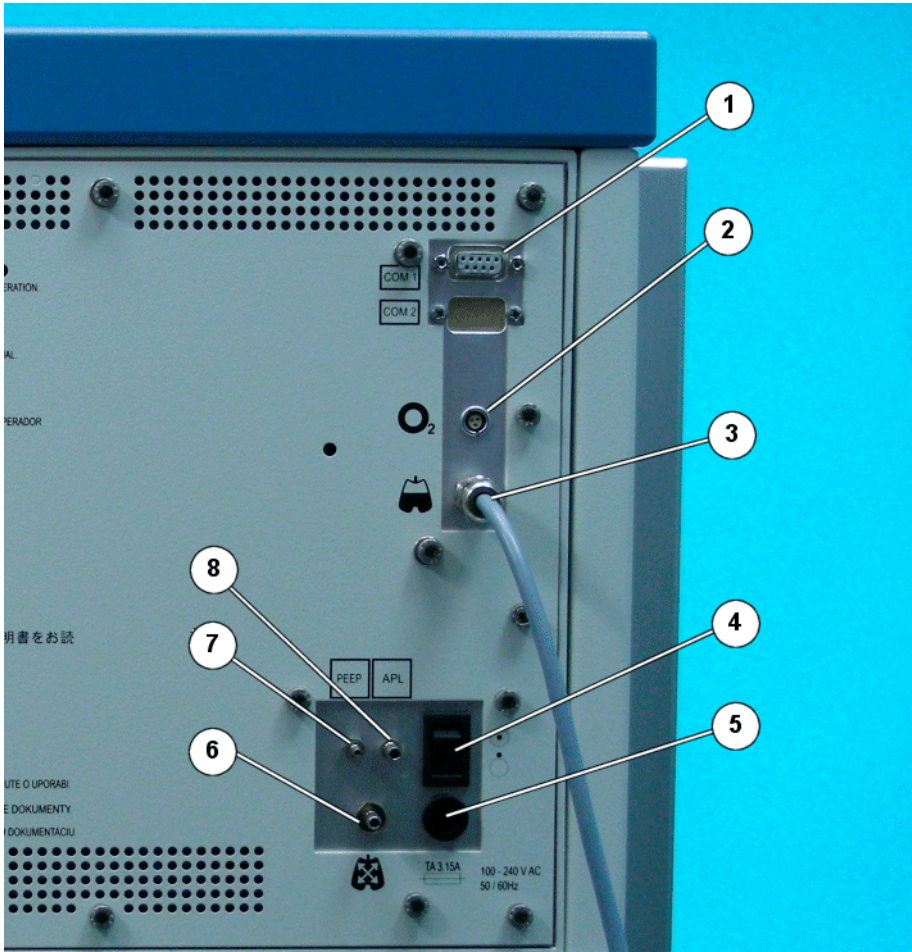


Fig. 2 Rear view with interface plate; legend, see Table 2

Table 2 Legend to Fig. 2

No.	Name
1	Serial communication ports
2	O2 sensor connection
3	Spirolog sensor cable
4	ON/OFF switch

No.	Name
5	Battery fuse
6	Airway pressure connection
7	Tube connection for PEEP valve
8	Tube connection for APL bypass valve

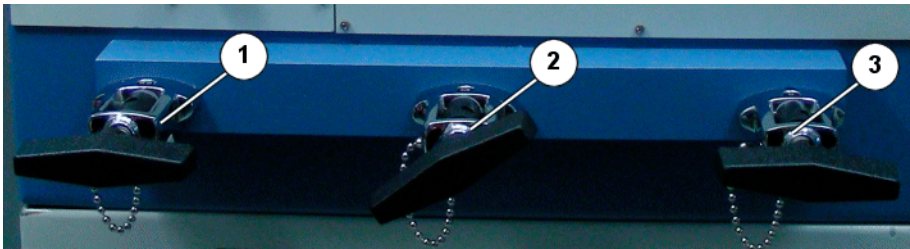


Fig. 3 Rear view showing gas pipeline and PIN index cylinder connections, for legend see [Table 3](#)

Table 3 Legend to [Fig. 3](#)

No.	Name
1	N2O PIN index cylinder connection
2	O2 or AIR PIN index cylinder connection
3	O2 PIN index cylinder connection

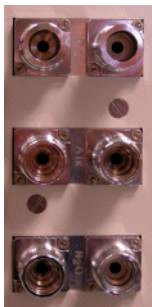


Fig. 4 Central tube connections and high-pressure connections



Fig. 5 Multiple socket strip

6 Battery backup

Fabius MRI battery power is provided by two rechargeable series-connected 12 V batteries. These batteries remain on charge as long as the machine is plugged into an active AC outlet. Should power supply fail while the machine is in operation, the batteries will allow the machine to continue operating for a minimum of 45 minutes, provided that the batteries are fully charged.

The batteries are accessible by opening the ventilator compartment. The 3.15A battery fuse is located at the back of the control box.

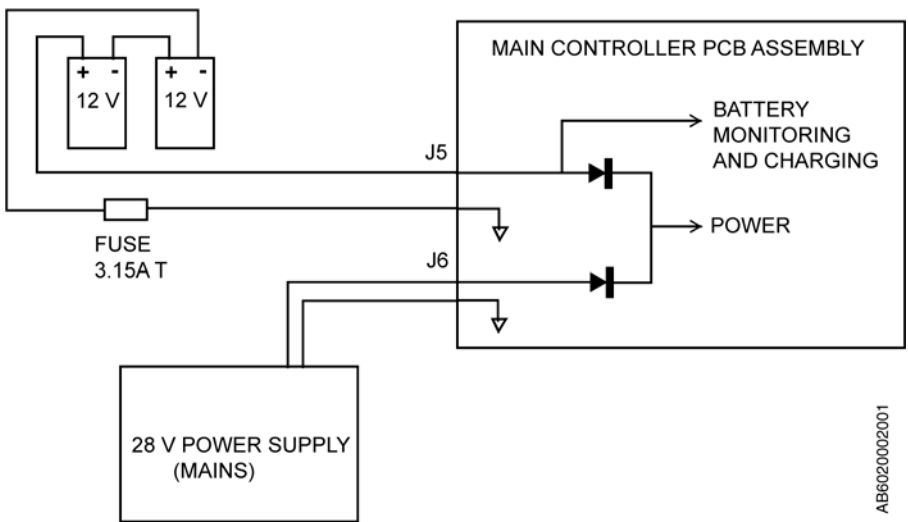


Fig. 6 Battery backup arrangement

7

Fabius MRI Piping Diagram

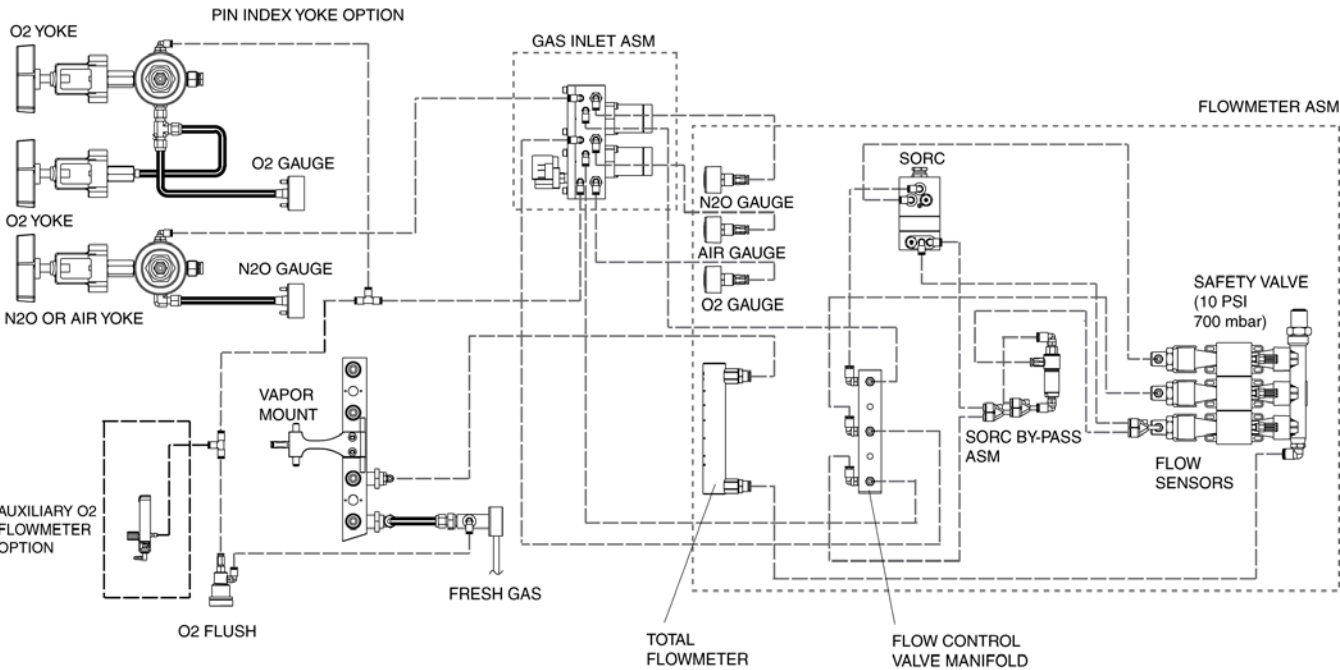


Fig. 7 Fabius MRI piping diagram, variant US 2-Gas

8

Function description of the gas box

The supply gases flow through the filters and non-return valves in the gas inlet assembly. Pipeline supply pressures are indicated on pipeline pressure gauges located on the flowmeter assembly. Cylinder pressure gauges are located on the trolley assembly. The pressures of O2 and N2O delivered to the flowmeter assembly are set by regulators on the gas inlet assembly.

If the O2 supply fails or its pressure decreases below a certain limit, the O2 low alarm switch generates an alarm.

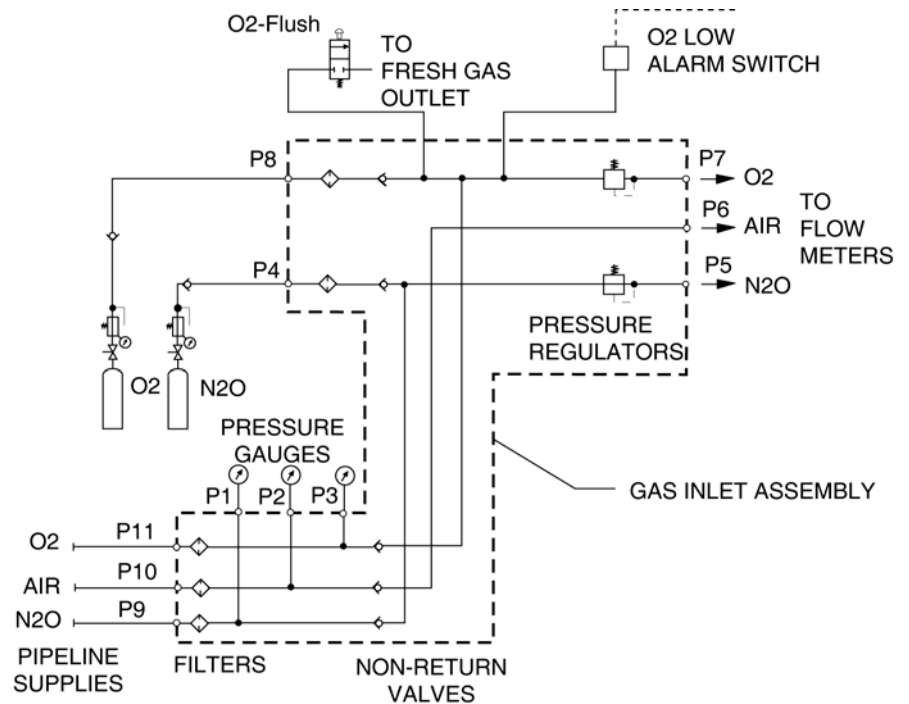


Fig. 8 Gas Box Function Diagram, part 1

If the O2 flush button is pressed, oxygen is delivered to the fresh-gas outlet. The fresh-gas ejector prevents the fresh gas from flowing back into the anesthetic vaporizer. This avoids an increase in anesthetic gas concentration.

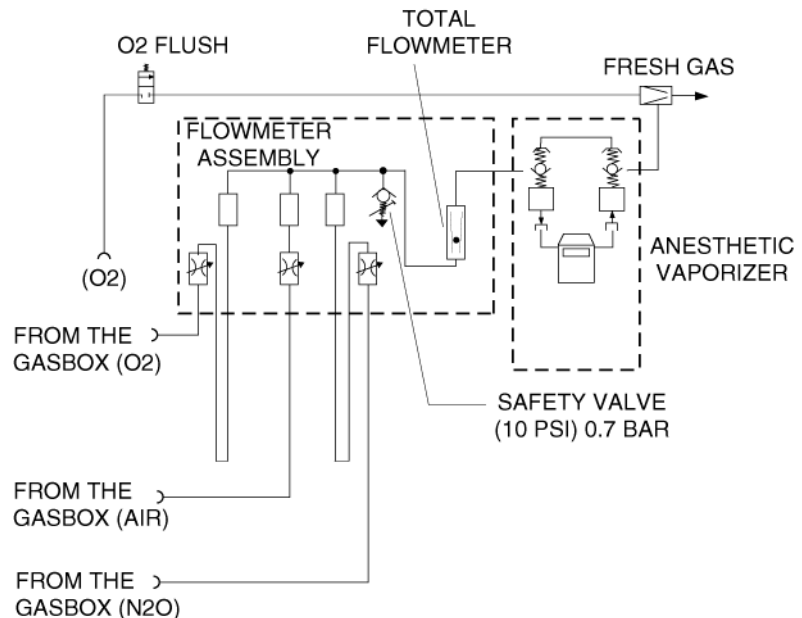


Fig. 9 Gas Box Function Diagram, part 2

9

SORC (Sensitive Oxygen Ratio Controller)

The SORC is a control element that functions like an N2O shut-off device and ensures a vital O2 concentration in the fresh gas. In the event of an O2 shortage, the SORC limits the N2O flow such that the O2 concentration in the fresh gas does not decrease below 21 vol.%.

If the O₂ flow control valve is closed or if the O₂ flow is lower than or equal to 200 mL/min, the SORC interrupts the N₂O flow.

N₂O can be added as of an O₂ flow of approx. 300 mL/min. In this case, the SORC also prevents O₂ concentrations below 21 vol. %.

The SORC bypass allows the oxygen to bypass the resistor in the SORC when O₂ flows above 10 L/min are needed.

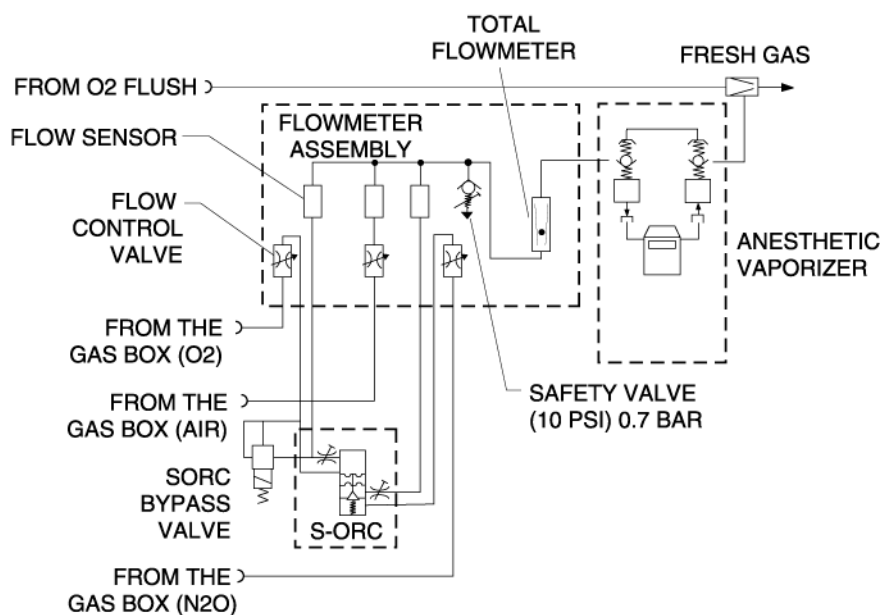


Fig. 10 SORC function diagram, part 1

The O₂ and N₂O flows are adjusted with the flow control valves.

Resistors located at the outlets of the SORC generate back-pressures. These back-pressures exert a force on the control diaphragms of the SORC. The O₂ back-pressure opens the SORC. The N₂O back-pressure closes the SORC. The pressure ratio at the control diaphragm affects the N₂O flow.

The resistors and the spring force are dimensioned such that a minimum concentration of 21 vol. % of O₂ is always ensured. The maximum O₂ flow is approx. 12 L/min.

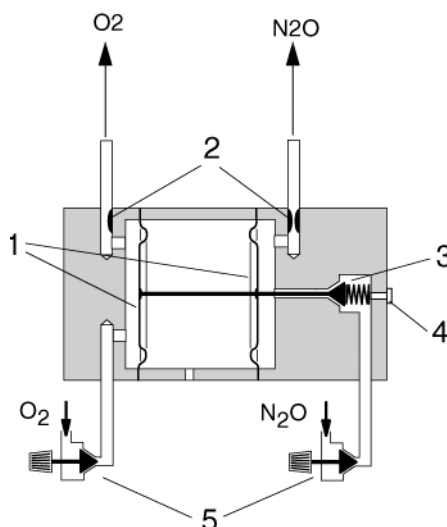


Fig. 11 SORC function diagram, part 2, for legend see [Table 4](#)

Table 4 Legend to [Fig. 11](#)

No.	Name
1	Control diaphragms
2	Resistors
3	N2O non-return valve
4	Operating-point adjusting screw
5	Flow control valves

10 Cosy 2.6 breathing system

The Cosy 2.6 breathing system allows three modes of patient ventilation:

- Manual ventilation and spontaneous breathing
- Volume controlled ventilation
- Pressure controlled ventilation

On APL valves with control knob, switching from “IPPV/SPONT” to “MAN” is carried out by turning the knob.

In the “MAN” position, the breathing system is closed to atmosphere. This position is used for manual ventilation of the patient. The APL valve opening pressure can be adjusted from 5 to 70 cmH₂O (mbar).

In the “SPONT” switch position the APL valve is open to atmosphere. This position is used for spontaneous breathing.

Using the control box and the PEEP/P_{max} valve, the pressure limit (P_{max}) can also be adjusted during volume control from 15 cmH₂O (mbar) to 70 cmH₂O (mbar) via the membrane keypad.

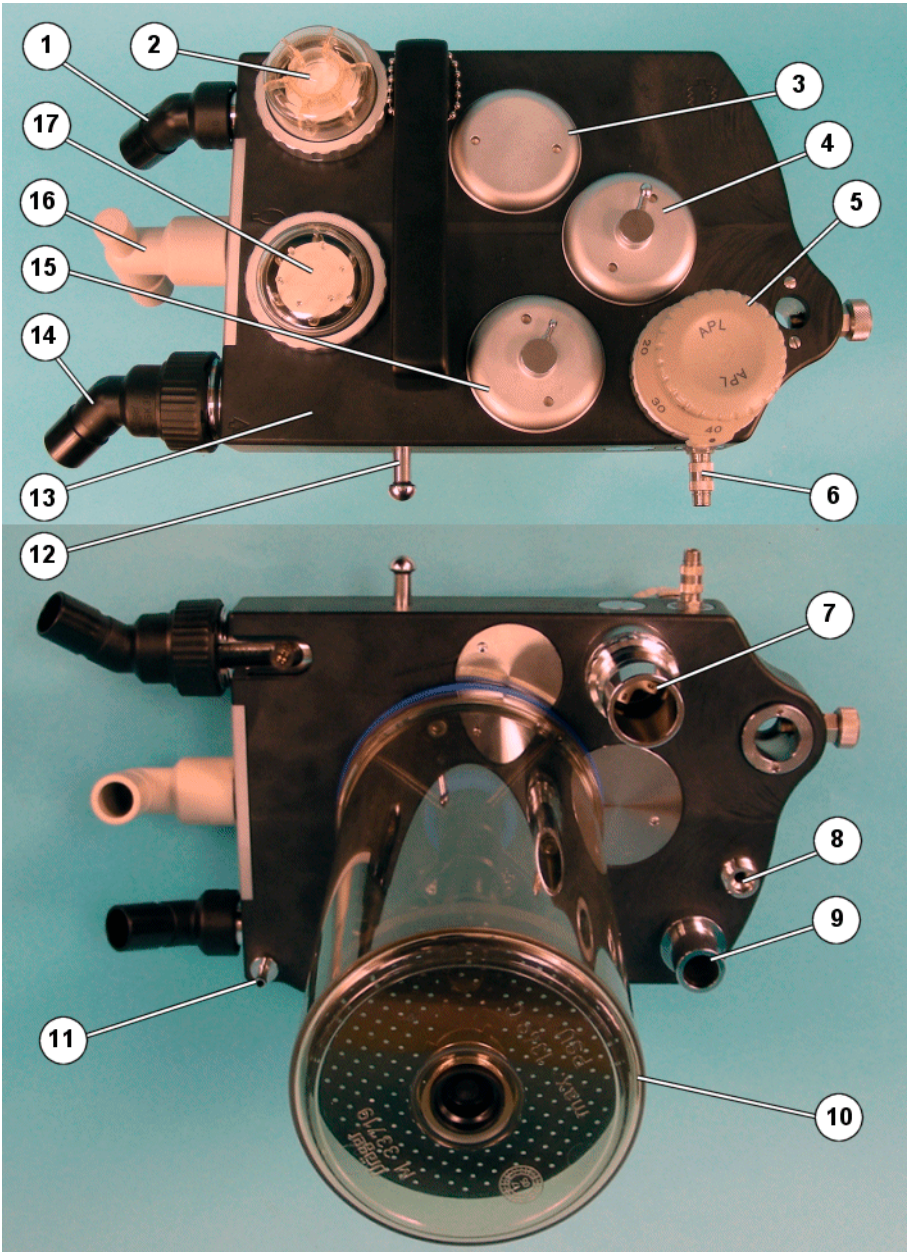


Fig. 12 Cosy 2.6 breathing system, for legend see [Table 5](#)

Table 5 Legend to [Fig. 12](#)

No.	Name
1	Inspiratory connection
2	Inspiratory valve and O2 sensor connection
3	Fresh-gas decoupling valve
4	APL bypass valve
5	MAN/SPONT APL valve
6	Sample gas connection
7	Anesthetic gas scavenging port

No.	Name
8	Fresh-gas port
9	Lung ventilator port
10	Absorber
11	Pressure sensor connection
12	Breathing bag hook
13	Flow sensor (Spirolog) (not shown)
14	Expiratory connection
15	PEEP/Pmax valve
16	Breathing bag terminal and standby holder for Y-piece
17	Expiratory valve

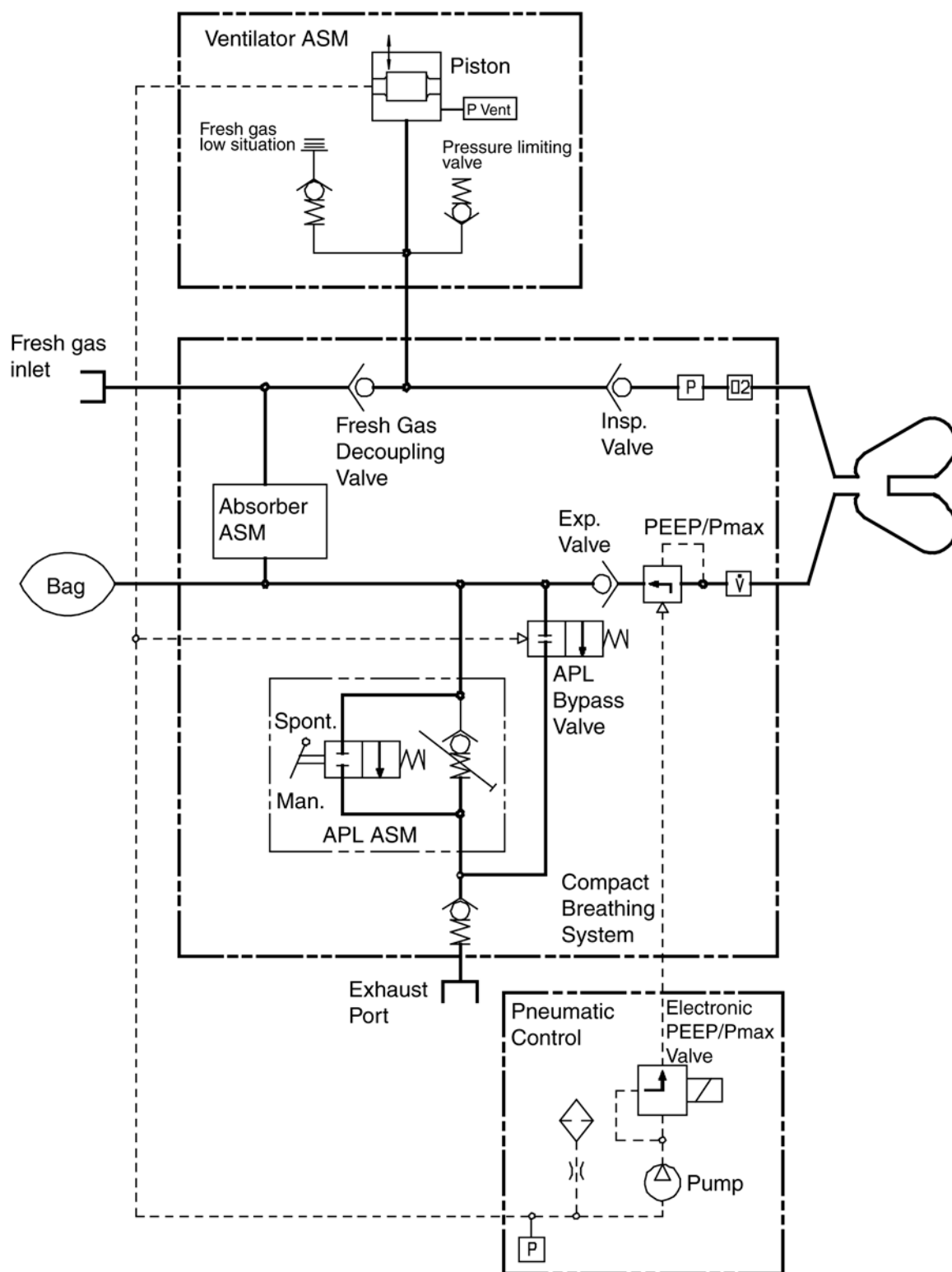


Fig. 13 Function diagram of Fabius MRI - Cosy 2.6 breathing system

10.1 Ventilation mode

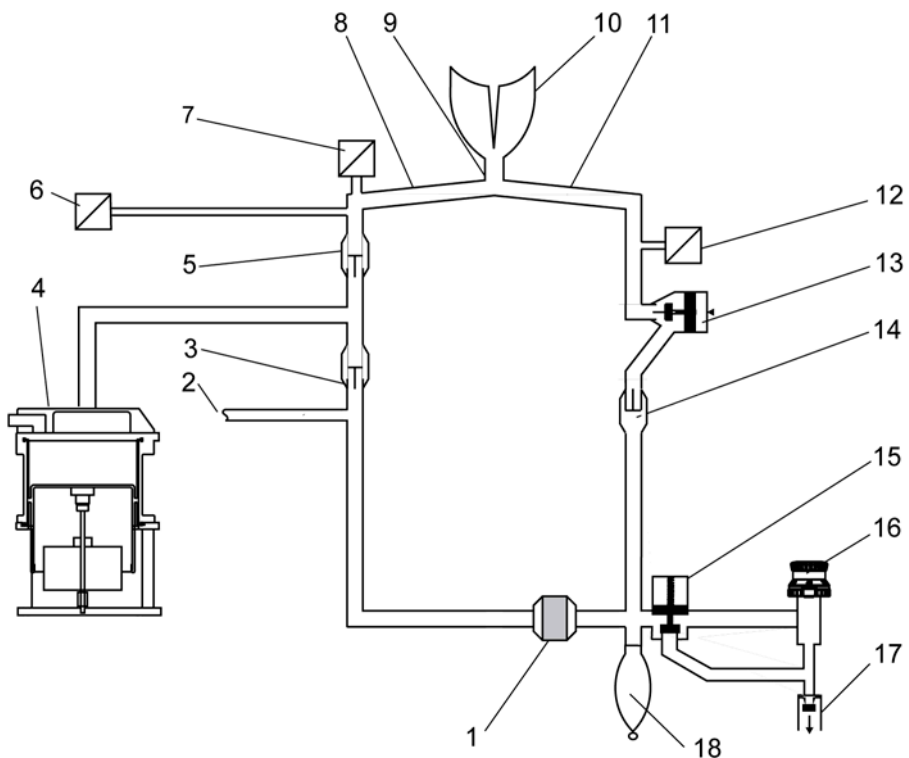


Fig. 14 Functional diagram of the ventilation mode, for legend see [Table 6](#)

Table 6 Legend to [Fig. 14](#), [Fig. 15](#), [Fig. 16](#), [Fig. 17](#), [Fig. 18](#), [Fig. 19](#), [Fig. 20](#)

No.	Name
1	Absorber
2	Fresh gas inlet
3	Fresh-gas decoupling
4	Lung ventilator
5	Inspiratory valve
6	Pressure sensor
7	Oxygen sensor
8	Inspiratory tube
9	Y-piece
10	Lung
11	Expiratory tube
12	Flow sensor
13	PEEP/Pmax valve
14	Expiratory valve
15	APL bypass valve

No.	Name
16	APL valve
17	Non-return valve
18	Manual breathing bag

10.2 Manual ventilation

Manual ventilation: General

During manual ventilation, the APL valve is set to the “MAN” position. The safety valve of the patient system is activated.

The item numbers mentioned in the following paragraphs refer to [Fig. 15](#).

Manual ventilation: Inspiration

During inspiration, expiratory valve **14** remains closed. When the operator compresses the manual breathing bag **18** the gas mixture (expiratory gas and fresh gas **2**) flows through the absorber **1**, the fresh-gas decoupling valve **3**, the inspiratory valve **5**, the O2 sensor **7**, the inspiratory hose **8**, and the Y-piece **9** into the patient’s lung **10**. The pressure sensor **6** measures the air-way pressure. The ventilation pressure is limited by the APL valve **16**. Any excess amount of the gas mixture flows through the APL valve and the non-return valve **17** to the anesthetic gas scavenging system.

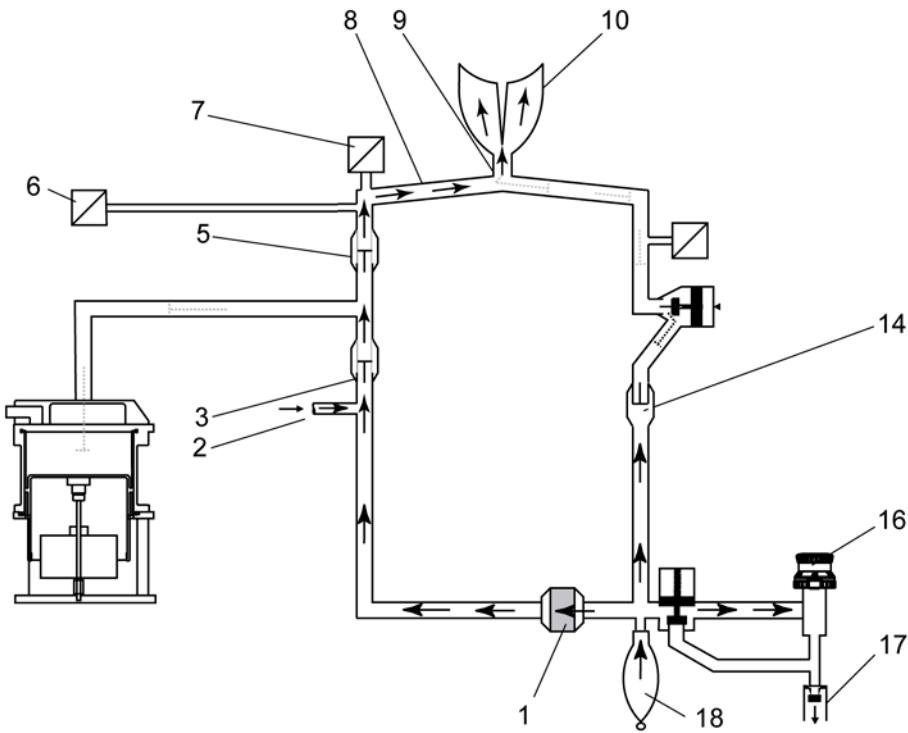


Fig. 15 Manual ventilation (inspiration) - Cosy 2.6 breathing system; for legend see [Table 6](#)

Manual ventilation: Expiration

During expiration, the inspiratory valve remains closed thus preventing the expiratory gas from flowing back into the inspiratory branch.

The item numbers mentioned in the following paragraphs refer to [Fig. 16](#).

After releasing the breathing bag **18**, the expiratory gas from the lung **10** flows through the expiratory tube **11**, the flow sensor **12**, the PEEP/Pmax valve **13**, the expiratory valve **14**, into the manual ventilation bag and through the absorber **18**. At the same time, new fresh gas **2** flows into the manual ventilation bag.

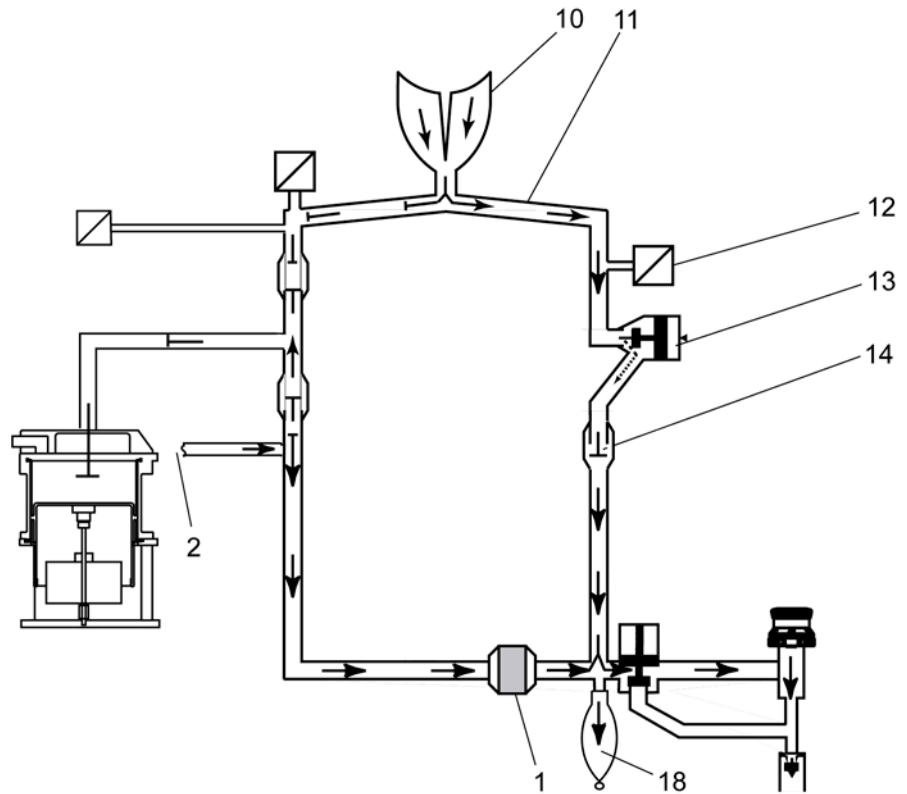


Fig. 16 Manual ventilation (expiration) - Cosy 2.6 breathing system; for legend see [Table 6](#)

10.3 Spontaneous breathing

Spontaneous breathing:
General

A prerequisite for spontaneous breathing is that the patient is supplied with a sufficient amount of fresh gas. The APL valve selector must be set to the "SPONT" position. No pressure builds up in the compact breathing system.

Spontaneous breathing:
Inspiration

During inspiration, the expiratory valve remains closed thus preventing rebreathing of expiratory gas containing CO₂.

The item numbers mentioned in the following paragraphs refer to [Fig. 17](#).

The patient inhales the gas mixture (expiratory gas and fresh gas **2**) from the manual ventilation bag **18**. The gas mixture flows through the fresh-gas decoupling valve **3**, the inspiratory valve **5**, the O₂ sensor **7**, the inspiratory hose **8**, and through the Y-piece **9** into the lung **10**. The pressure sensor **6** measures the airway pressure.

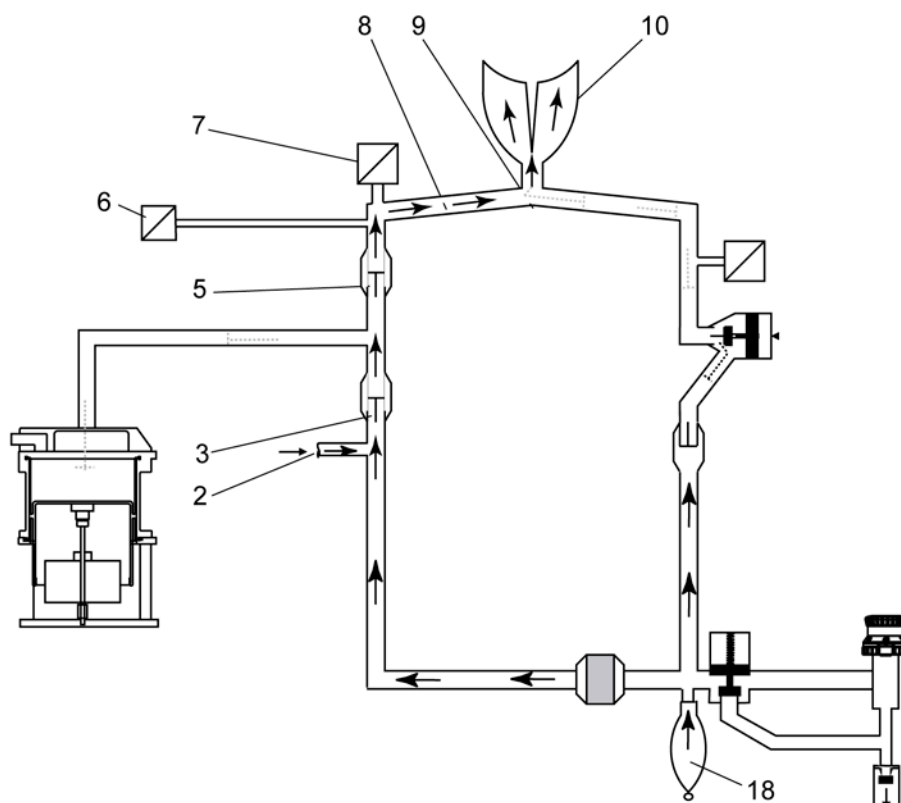


Fig. 17 Spontaneous (inspiration) - Cosy 2.6 breathing system; for legend see [Table 6](#)

Spontaneous breathing:
Expiration

During expiration, the inspiratory valve remains closed thus preventing the expiratory gas from flowing back into the inspiratory branch.

The item numbers mentioned in the following paragraphs refer to [Fig. 18](#).

The APL valve **16** is open, irrespective of its pressure setting.

The expiratory gas flows from the lung **10** through the expiratory tube **11**, the flow sensor **12**, the PEEP control valve **13**, the expiratory valve **14**, the manual ventilation bag **18** and through the absorber **1**. At the same time, new fresh gas **2** flows into the manual ventilation bag.

When the manual ventilation bag is full, any excess gas mixture flows through the non-return valve **17** into the anesthetic gas scavenging system.

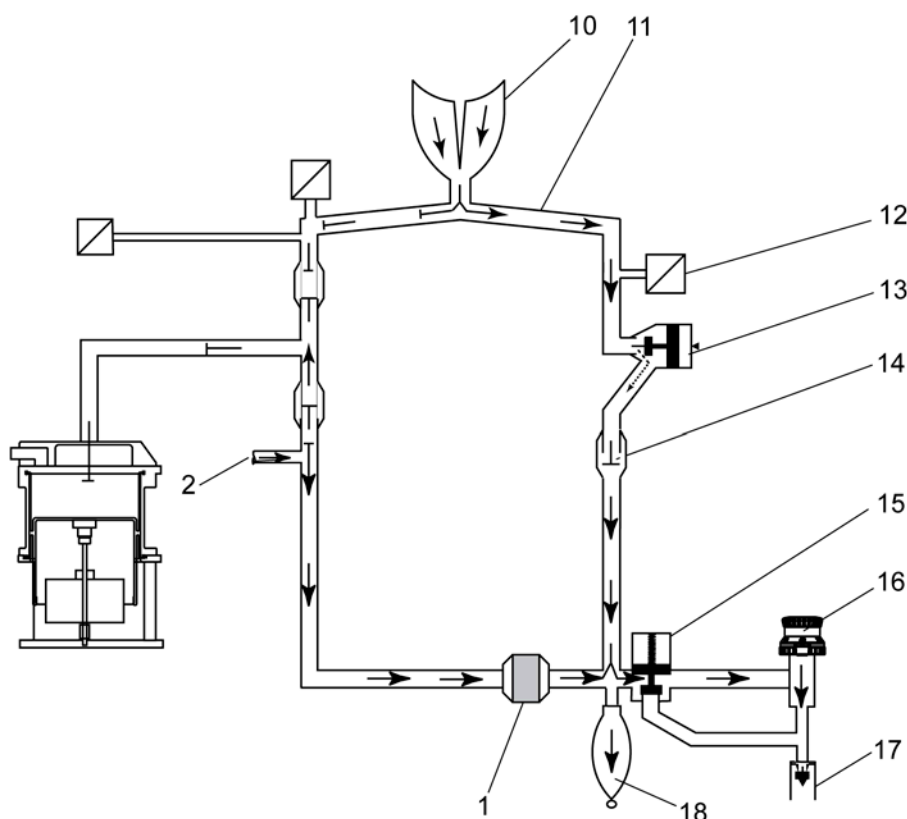


Fig. 18 Spontaneous (expiration) - Cosy 2.6 breathing system; for legend see [Table 6](#)

10.4 Volume/pressure control ventilation mode

Volume control ventilation mode: General

A prerequisite for volume control ventilation is that the patient is supplied with a sufficient amount of fresh gas.

The APL bypass valve opens in volume control mode, allowing excess gas to be vented to the scavenging system regardless of the MAN-SPONT valve setting.

The safety valve of the patient system makes sure that no pressures greater than 75 cmH₂O build up in the system.

During ventilation, the pressure limit (P_{max}) can be adjusted on the control box.

Volume/pressure control ventilation mode: Inspiration

During inspiration, the PEEP/P_{max} valve remains closed. The control pressure present at the PEEP/P_{max} valve varies with the set pressure limit (P_{max}).

The item numbers mentioned in the following paragraphs refer to [Fig. 19](#).

The pressure generated by the piston 4 of the lung ventilator closes the fresh-gas decoupling valve 3. The gas mixture (expiratory gas and fresh gas 2) flows through the inspiratory valve 5, the O₂ sensor 7, the inspiratory tube 8, and the Y-piece 9 into the lung 10. The pressure sensor 6 measures the air-

way pressure. The ventilation pressure cannot exceed the pressure limit (Pmax) set on the control box because the PEEP/Pmax valve **13** opens. The fresh gas then fills the manual ventilation bag **18**.

Any excess fresh-gas flows through the open APL bypass valve **15**, and the non-return valve **17** into the anesthetic gas scavenging system.

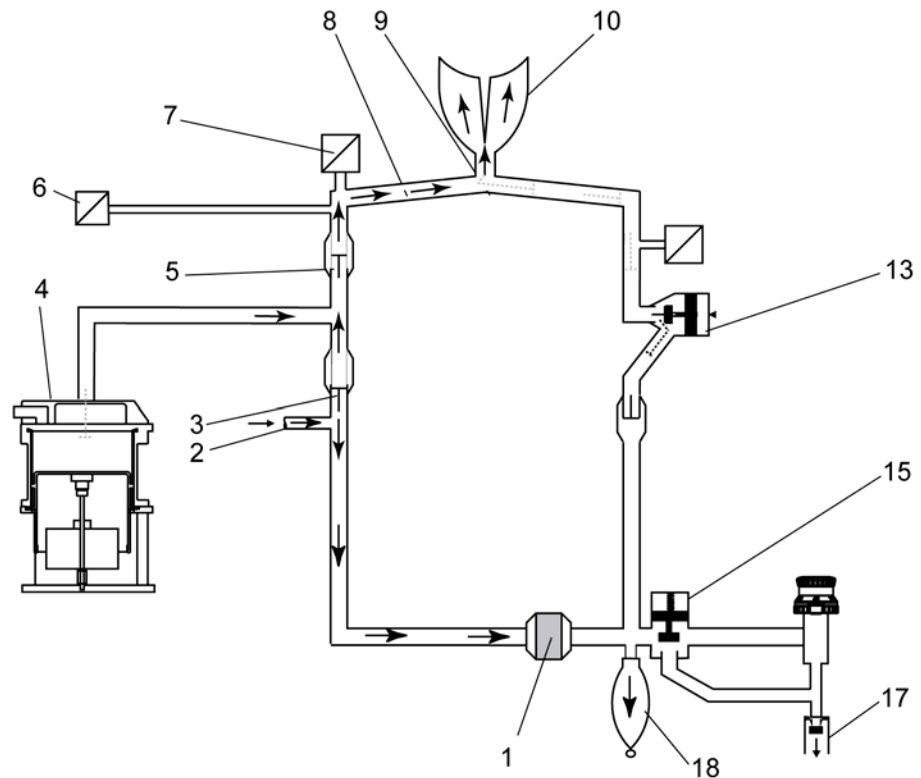


Fig. 19 Volume control ventilation (inspiration) - Cosy 2.6 breathing system; for legend see [Table 6](#)

Volume/pressure control ventilation mode: Expiration

During expiration, the inspiratory valve remains closed thus preventing rebreathing into the inspiratory branch.

The item numbers mentioned in the following paragraphs refer to [Fig. 20](#).

The expiratory gas from the lung **10** flows through the expiratory tube **11**, the flow sensor **12**, the PEEP/Pmax valve **13**, the expiratory valve **14**, and the absorber **18** back into the manual ventilation bag **18** mixing with fresh gas **2** also flowing into the manual ventilation bag.

The lung ventilator's piston **4** moves back drawing the gas mixture needed for the next inspiration into the piston space.

Any excess fresh-gas flows through the open APL bypass valve **15**, and the non-return valve **17** into the anesthetic gas scavenging system.

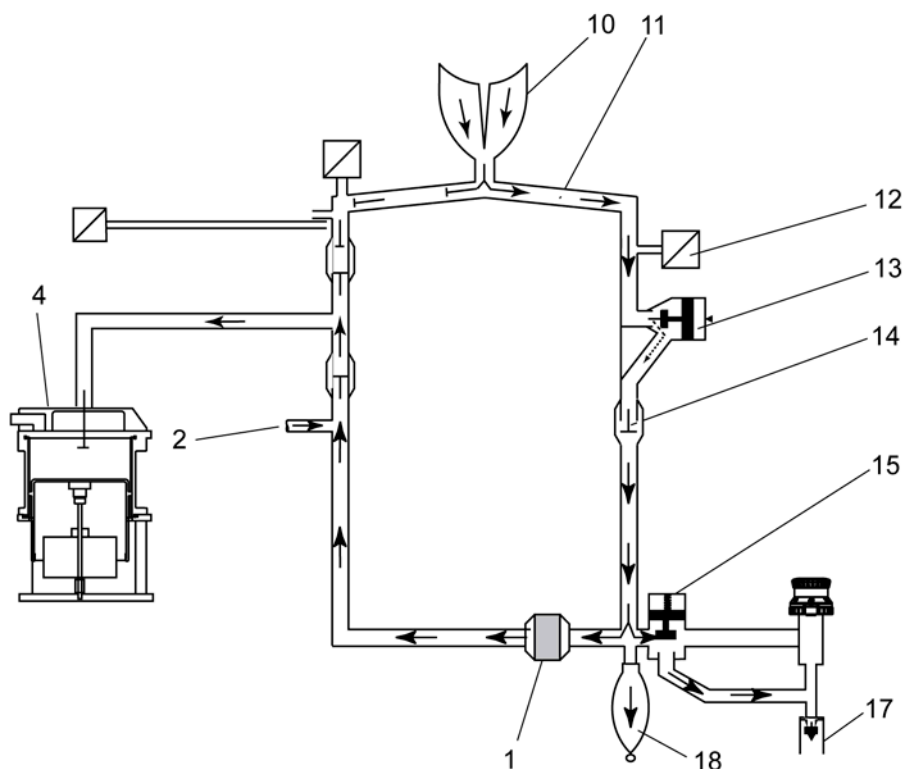


Fig. 20 Volume control ventilation (expiration) - Cosy 2.6 breathing system; for legend see [Table 6](#)

10.5 Cosy 2.6 absorber

The absorber canister is filled with fresh soda lime. The CO₂ is scrubbed from the expiratory gas by the soda lime.

CAUTION

Expired soda lime changes its color. The soda lime must be replaced when two thirds of the soda lime in the absorber canister is discolored.

11 Lung ventilator

The ventilator is located in a swing-out compartment at the left side of the Fabius Tiro M. A hose terminal is provided on the left side of the compartment for connection to the breathing system. Fresh gas is delivered to the patient by a piston that is driven by a motor and ball-screw arrangement. A sight window on the compartment allows the operator to verify movement of the piston.

Two diaphragms (upper and lower) comprise a bag-type rolling seal that surrounds the piston. Vacuum from the pneumatic assembly (described in a later paragraph) is provided between the outside of the seal and the cylinder, to ensure proper operation of the seal during piston movement.

During inspiration, the lung ventilator delivers fresh gas at a given volume, pressure and frequency. These parameters are set at the control panel. Refer to the Operator's Manual for details on ventilator settings, displays and controls. During expiration, the bag-type rolling seal fills with expired gas from the patient and with fresh gas stored in the breathing bag.

The lung ventilator motor is powered from the Control PCB. A position sensor on the ventilator signals the Control PCB when the piston reaches its lower limit. An incremental encoder on the motor shaft determines the number of revolutions and provides piston travel information to the Control PCB.

Lung ventilator pressure is monitored by a transducer on the Control PCB. When the auxiliary-air valve on the patient system opens, a fresh-gas low alarm is generated, provided that it has been enabled in the service mode.

The pressure sensor is the same type as the one used for measuring airway pressure. A tube connects the pressure sensor's positive pressure port to a connector located on the top cover of the ventilator. The purpose of this sensor is to allow the software to sense when a condition exists that would cause the ventilator's auxiliary air valve to open. The threshold that is used by the software for this condition is -8 mbar. In normal use the primary cause for this condition is an insufficient amount of reserve gas in the manual breathing bag. The operator is alerted when this condition exists, with a medium priority "Fresh gas low" alarm. This alarm can be disabled in service mode.

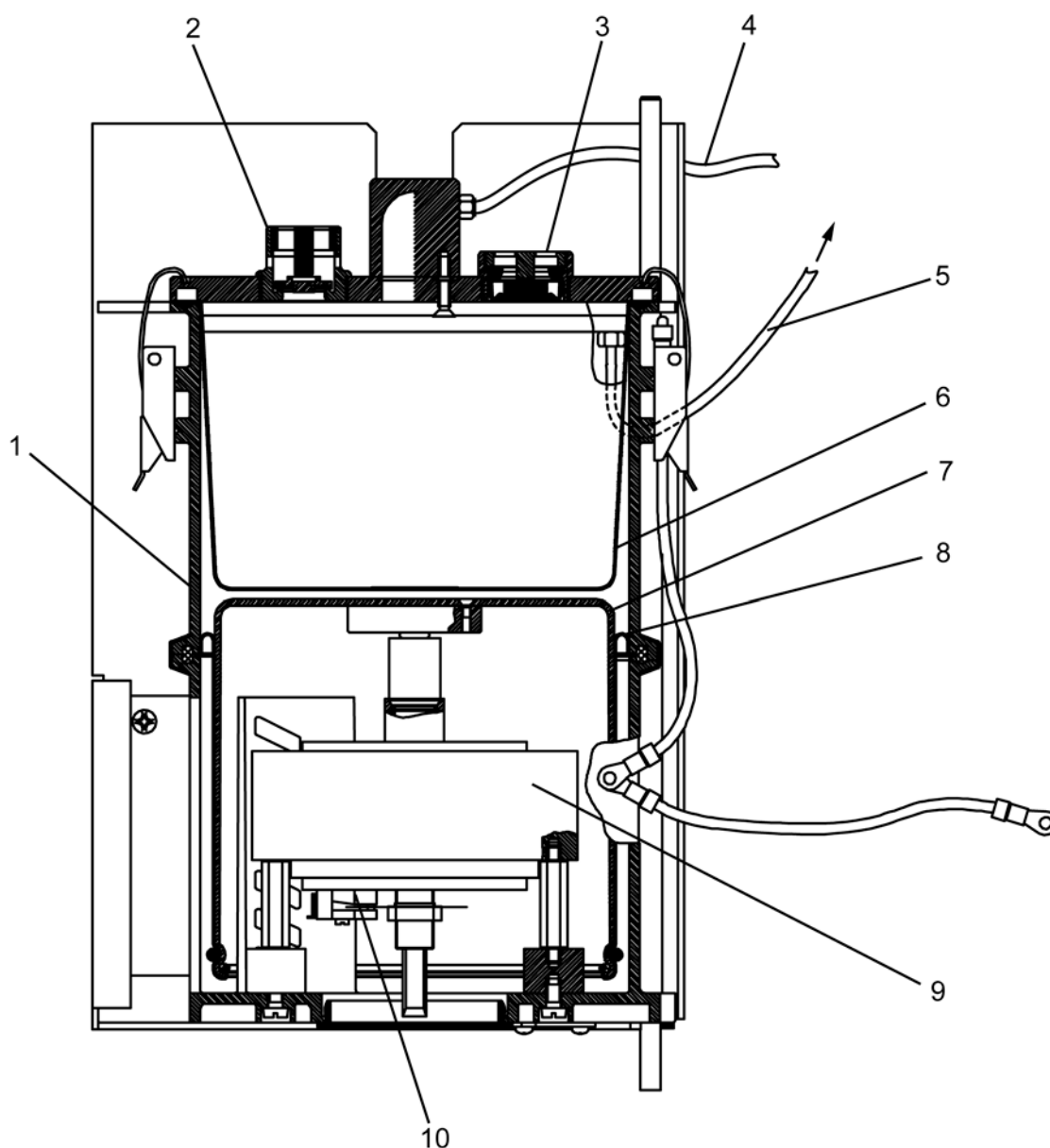


Fig. 21 Ventilator (piston shown in 'down' position), for legend see [Table 7](#)

Table 7 **Legend to Fig. 21**

No.	Name
1	Top section of housing
2	Pressure limiting valve
3	Auxiliary-air valve
4	Pressure sensor line to the Control PCB
5	Vacuum line to the pneumatic assembly
6	Patient seal
7	Piston

No.	Name
8	Lower diaphragm
9	Motor/ballscrew assembly
10	Incremental encoder

The top of the ventilator assembly (patient system) contains two valves:

11.1 Pressure limiting valve

If the pressure limit control fails, the ventilator's safety valve limits the gas pressure. This valve opens at approximately 75 cmH2O (mbar).

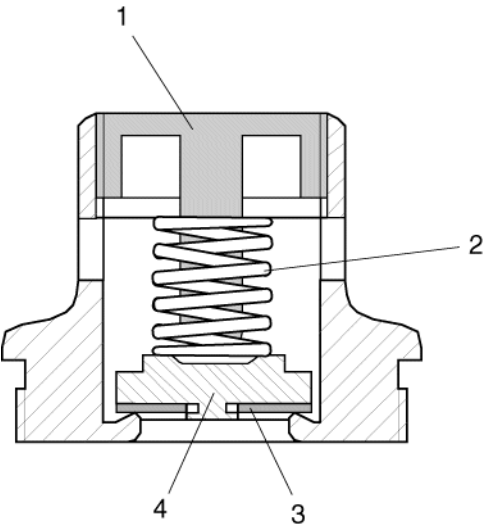


Fig. 22 Sectional view of the safety valve, for legend see Table 8

Table 8 Legend to Fig. 22

No.	Name
1	Screw
2	Spring
3	Washer
4	Valve disc

11.2 Auxiliary-air valve

The auxiliary air valve allows the patient to spontaneously breathe ambient air should the medical gas supply and/or Fabius MRI fail.

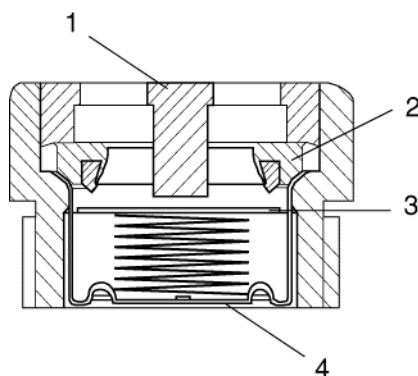


Fig. 23 Sectional view of the auxiliary air valve, for legend see [Table 9](#)

Table 9 Legend to [Fig. 23](#)

No.	Name
1	Threaded ring
2	Valve seat
3	Valve disc
4	Valve cross with spring

12 Pneumatic assembly

The pneumatic assembly provides pressure for the PEEP valve control, and also provides vacuum for the ventilator bag-type rolling seals and the APL bypass valve control.

The pump and the PEEP valve are shielded separately.

12.1 PEEP/Pmax valve control

When the Fabius MRI is operating in the automatic ventilation mode, the pump on the pneumatic assembly is running, and the electronic PEEP valve is actuated by the Control PCB. The current supplied to the coil of the electronic PEEP valve is proportional to the set PEEP value, and controls the position of the diaphragm within the electronic PEEP valve. This then determines the control pressure applied to the proportional PEEP valve in the breathing system, which maintains the desired amount of PEEP during patient expiration. The V1 reservoir smooths out pressure variations caused by the pump. See [Fig. 24](#).

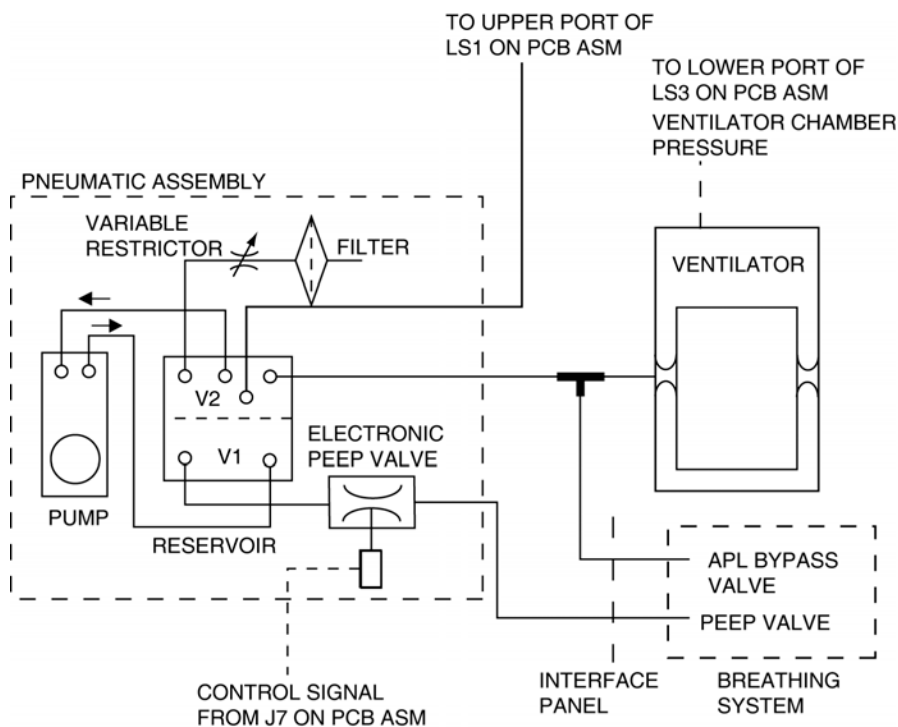


Fig. 24 Schematic of the pneumatic control

- 12.2

APL bypass valve control
- When the Fabius MRI is operating in the automatic ventilation mode, the pneumatic assembly provides a vacuum signal to hold open the APL bypass valve in the breathing system. The V2 reservoir and filter provide noise damping, and the variable restrictor is used to set the vacuum level in the range of -150 to -240 cmH₂O (mbar).

When the machine is operating in the manual ventilation mode, the pump on the pneumatic assembly (and the ventilator) is stopped, and the spring-loaded APL bypass valve in the breathing system closes, directing exhaled gas through the APL valve.
- 13

Control PCB
- The Control PCB is designed as an MRI shielded assembly.

The connections to the components are routed via P-filters, motor filters and shielded cables.

The shielded assembly is not opened for servicing!

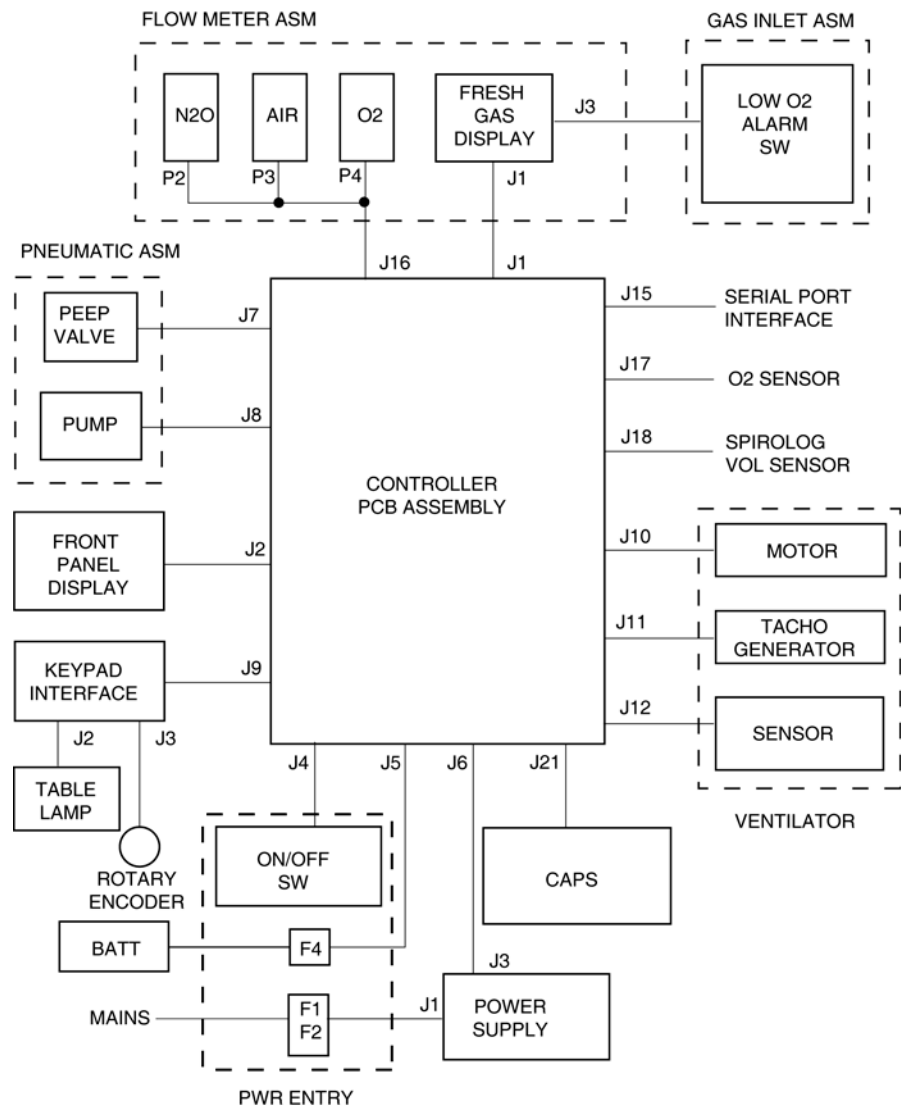


Fig. 25 Electrical Block Diagram

14 Function Description: Control PCB

The Control PCB contains the following functions:

- Motor control and monitoring
- Measurement of O2 and flow parameters
- Provision of one or two serial interfaces
- Evaluation of the O2 low signal
- Measurement and display of fresh-gas parameters
- PEEP valve control
- Pump control
- Front panel display control
- Evaluation of keypad and rotary encoder
- The required supply voltages are supplied by the power supply unit.

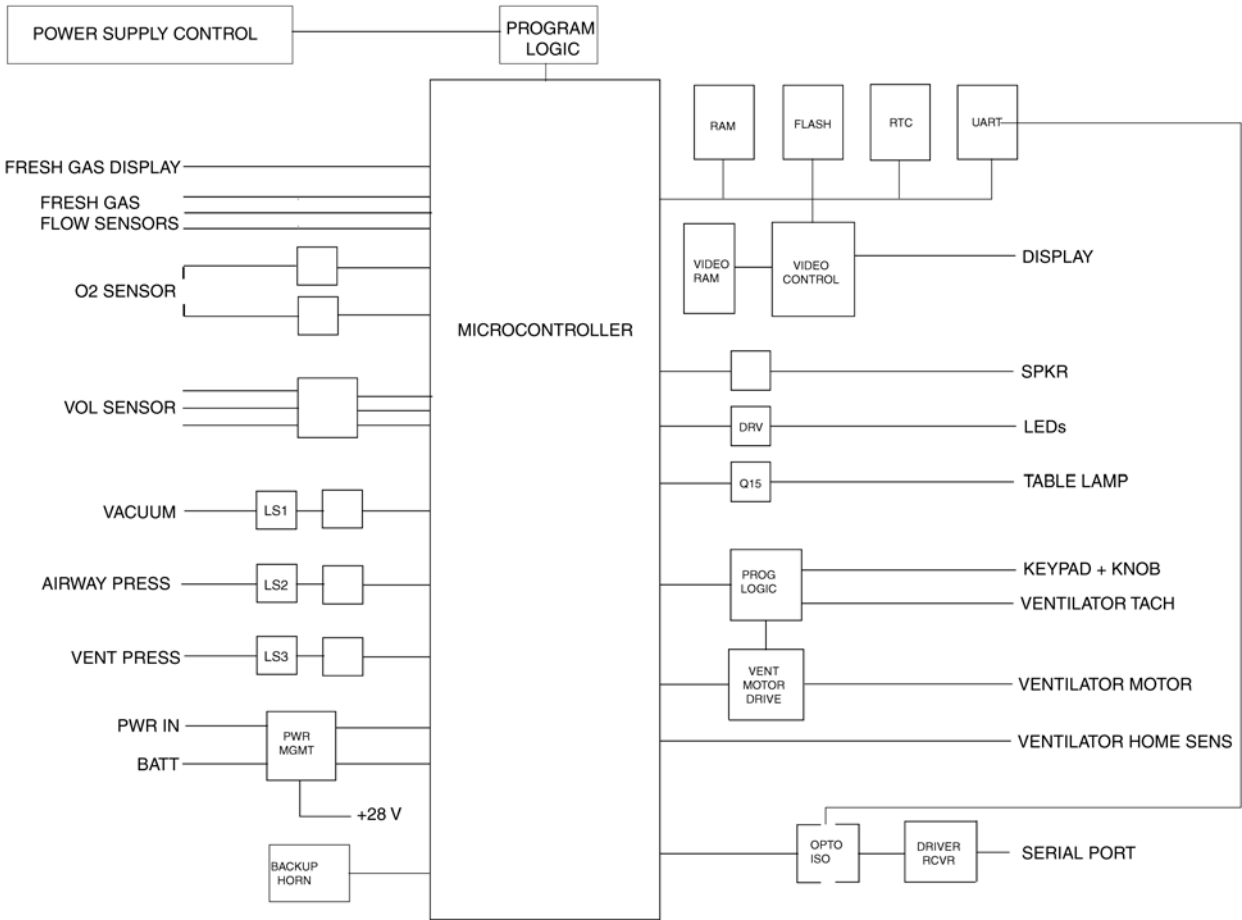


Fig. 26 Controller functional block diagram

15 **Control panel assembly**

The control panel comprises a 6.5" graphical display, a membrane keypad, a rotary encoder, the front frame and a loudspeaker.

The display has a shield. The connection from the Control PCB (Cu shield) to the display is routed via shielded round cables and D-Sub connectors.

Data and power for the display comes from the Control PCB via a 20-conductor ribbon cable. The keypad interface is connected to the Control PCB by a 30-conductor ribbon cable. A block diagram of the control panel assembly is shown in the following illustration.

The shielded display assembly is not opened for servicing.

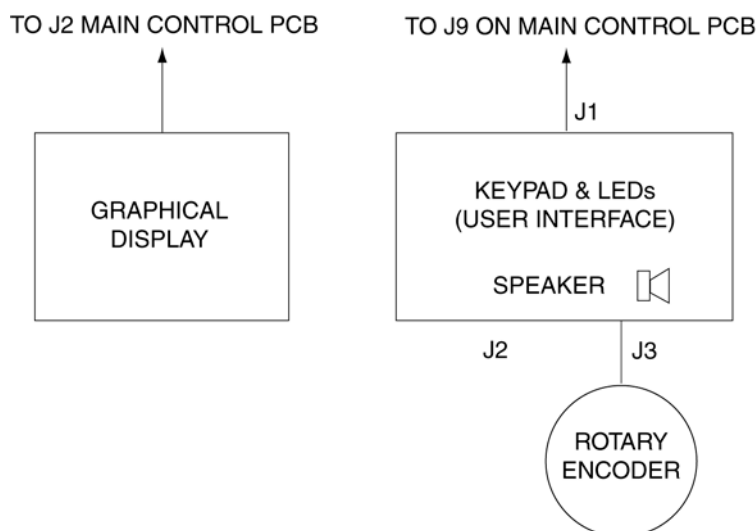


Fig. 27 Control panel block diagram

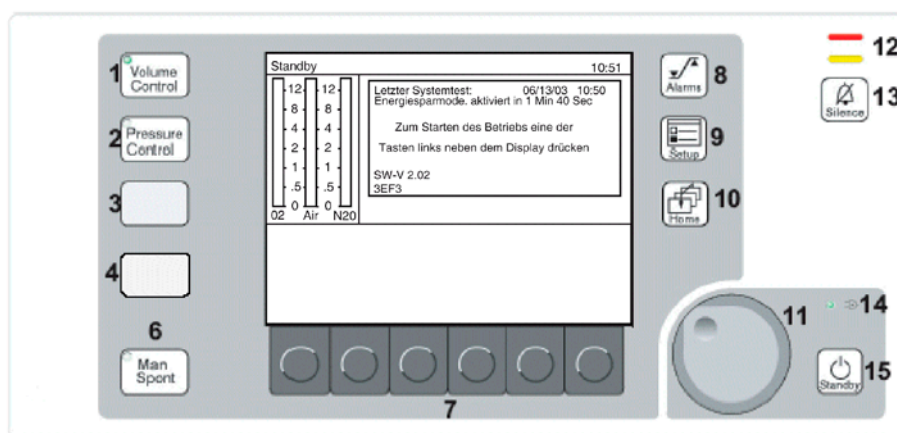


Fig. 28 Fabius MRI control panel ("Standby" screen shown), for legend see [Table 10](#)

Table 10 Legend to [Fig. 28](#)

Item	Function
1	Selects volume controlled ventilation mode Refer to Operator's Manual
2	Selects pressure controlled ventilation mode Refer to Operator's Manual
3	Pressure Support
4	SIMV
6	Places the ventilator in MAN/SPONT mode Refer to Operator's Manual
7	Programmable keys: activate the corresponding function that appears on screen above the key

Item	Function
8	For setting alarm limits Refer to Operator's Manual
9	Setup key: activates sub-screens for monitoring functions. Refer to Operator's Manual
10	Home key: returns display to main screen shown before standby
11	Rotary encoder: moves the cursor on the screen; confirms selection when pressed
12	Alarm status indicators: Flashing red: Warning; flashing yellow: Caution; solid yellow: Note
13	Alarm silence key: silences all active alarms for two minutes
14	Power ON indicator: lighted when machine is plugged into an active AC outlet
15	Switches the unit back to standby mode

16 FiO2 measurement

The O2 sensor measures the O2 concentration in the respiratory gas (FiO2).

The O2 sensor contains a capsule with alkaline electrolyte, a lead anode, two gold cathodes, and a Teflon membrane. The spatial separation of the two gold cathodes allows to carry out a voltage comparison.

The O2 sensor is an electrochemical cell that generates a voltage which varies with the O2 concentration.

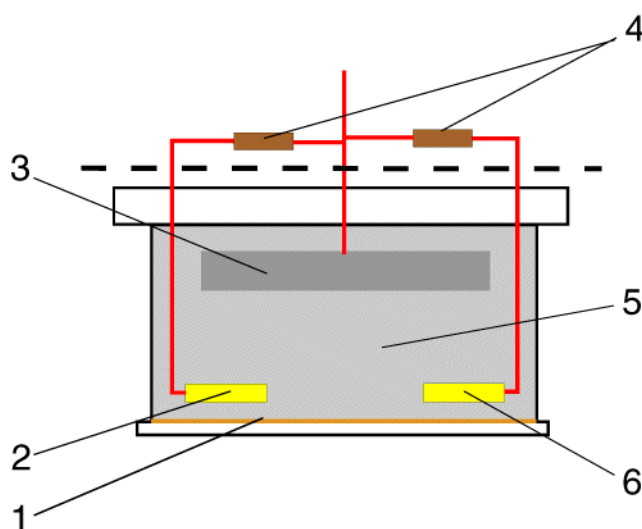


Fig. 29 O2 sensor, for legend see [Table 11](#)

Table 11 Legend to [Fig. 29](#)

No.	Name
1	Teflon membrane
2	Gold cathode A
3	Lead anode

No.	Name
4	Temperature compensation resistors
5	Alkaline electrolyte
6	Gold cathode B

The O₂ to be measured diffuses through the Teflon membrane, undergoes a chemical reaction at the gold cathodes (negative) and produces lead oxide and water at the lead anode (positive). During this chemical process, a voltage is generated that is proportional to the O₂ partial pressure.

The internal resistance of the cell is determined by the surface of the gold cathodes, the O₂ diffusion velocity, and the distance between the gold cathodes and the lead anode. This resistance is approximately 700 ohms.

The chemical process is temperature-sensitive. Therefore, thermistors are connected in parallel to the O₂ sensor. These resistors and the internal resistor of the O₂ sensor correct the measuring voltage. Since two cathodes are used in the O₂ sensor cell, two different voltages are generated. These voltages are compared with each other. If their difference exceeds a certain value, the machine prompts the operator to check the cell.

If the O₂ sensor fails, the control box will indicate an error on the graphics display.

17 Respiratory flow measurement

The flow sensor functions according to the constant temperature hot-wire anemometer principle. Respiratory gas flows past a thin platinum wire. This platinum wire (A) is located in a measuring tube and is electrically heated. The platinum wire is held at a constant temperature. Gas flow removes heat from the hot wire. The higher the gas flow rate, the greater the heat removal. The amount of electrical current needed to maintain a constant platinum wire temperature is thus proportional to the gas flow rate.

A second platinum wire (B) inside the measuring tube is used for temperature compensation.

Internal calibration tables for O₂/N₂O mixtures, Air and 100% O₂ are used to linearize the measured flow.

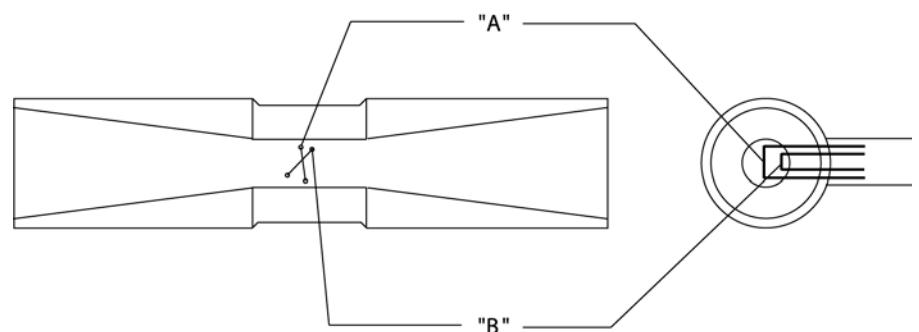


Fig. 30 Respiratory flow sensor, for legend see [Table 12](#)

Table 12 Legend to Fig. 30

No.	Name
"A"	Platinum wire "A"
"B"	Platinum wire "B"

18

Gas flow rate measurement

The gas flows past a heated wire, cooling it. The current necessary to keep the temperature of the wire constant is a measure of the flow.

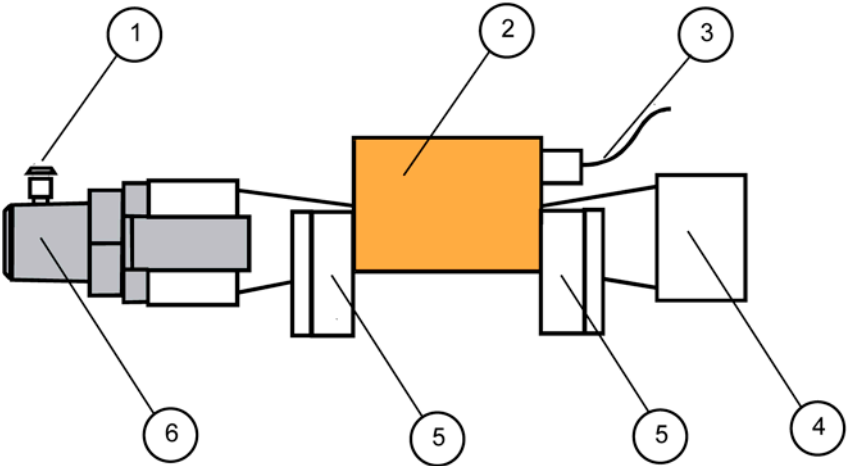


Fig. 31 Details of the flow sensor, for legend see Table 13

Table 13 Legend to Fig. 31

No.	Name
1	Tube connector
2	Electronic components
3	Electrical connection
4	Gas outlet port (to manifold)
5	Mounting pole
6	Gas inlet assembly

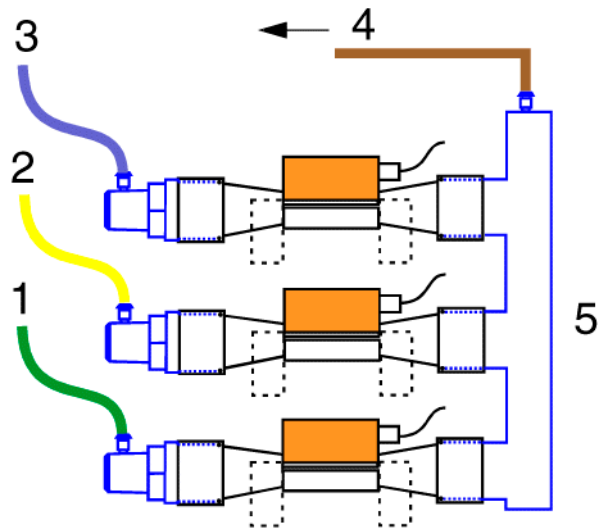


Fig. 32 Gas flow through sensors, for legend see [Table 14](#)

Table 14 Legend to Fig. 32

No.	Name
1	From the oxygen flow control valve
2	From the Air flow control valve
3	From the N2O flow control valve
4	Fresh-gas flow to the total fresh-gas flowmeter
5	Fresh-gas manifold

19 Anesthetic vaporizer(s)

Refer to separate technical documentation of the anesthetic vaporizer.

Maintenance Procedures

1 Diagnostics

NOTE

The screen illustrations contained in this section are for reference only and therefore may or may not reflect the software version currently installed.

The Fabius MRI diagnostic system monitors and records the status of its internal hardware when the machine is turned on. The status of each test is displayed on the power-up screen as shown in [Fig. 1](#). This screen is displayed for several seconds before proceeding to the Standby screen. The power-up screen also displays one of three messages at completion of the diagnostics:

FUNCTIONAL	This message indicates that the Fabius MRI has passed all power-up tests and is fully functional. The machine will proceed to the Standby screen (Fig. 2) after a short delay.
CONDITIONALLY FUNCTIONAL	This message indicates that a minor problem has been detected. The Fabius MRI may be used, but your local authorized service organization or Dräger-Service should be notified to correct the problem. Press the rotary control to proceed to the Standby screen.
NON-FUNCTIONAL	This message indicates that a serious problem has been detected, and the machine will not proceed to the monitor screen. Do not use the machine. Immediately notify your local authorized service organization or DrägerService to correct the problem.

The “Preventive Maintenance Due” message will appear on the screen if the current date exceeds the Periodic Manufacturer's Service (test procedure) due date stored in the machine.

SYSTEM DIAGNOSTICS		System Status
Watch Dog	Pass	Functional
System RAM	Pass	
Program Memory	Pass	
Video Test	Pass	
Interrupts	Pass	
A/D Converter	Pass	
NV RAM	Pass	
Serial Port	Pass	
Clock	Pass	
Speaker	Pass	
Main Power	Pass	
Battery	Pass	
<div>Dräger</div> <div>Fabius GS SW XXX CRC XXX</div>		

Fig. 1 Power-up diagnostics screen

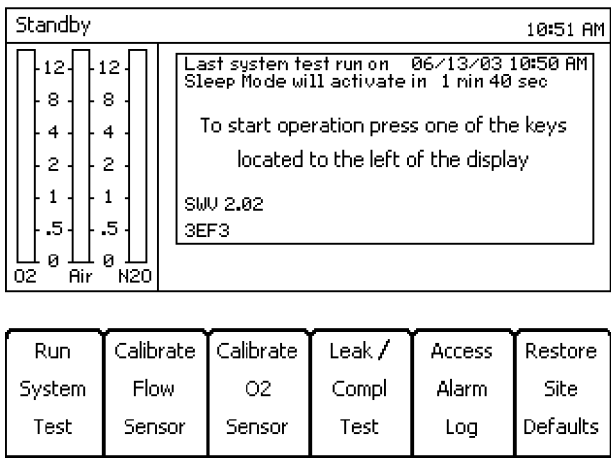


Fig. 2 Standby screen

NOTE
During display of the standby screen, a 2.5-minute count-down appears on the screen, after which the display changes to energy saving mode. Press any key on the panel to return to the Standby screen.

Annex

Parts catalog

Test List

Parts catalog

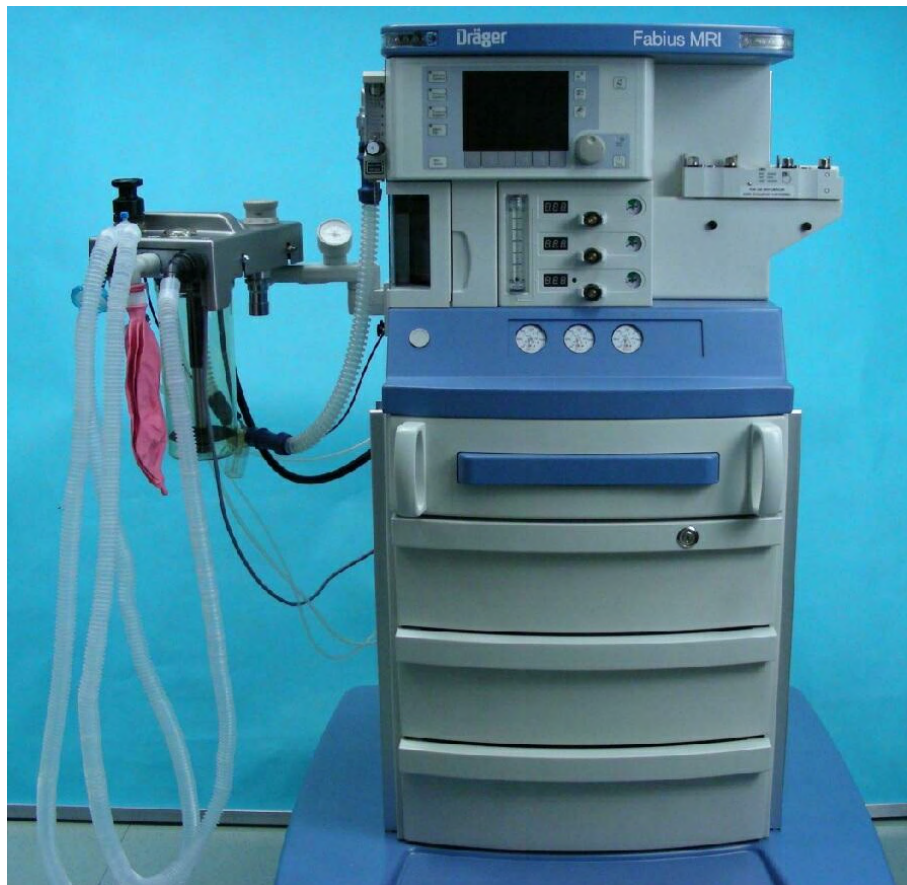
Fabius MRI

Revision: 00
2007-10-29
5330.660

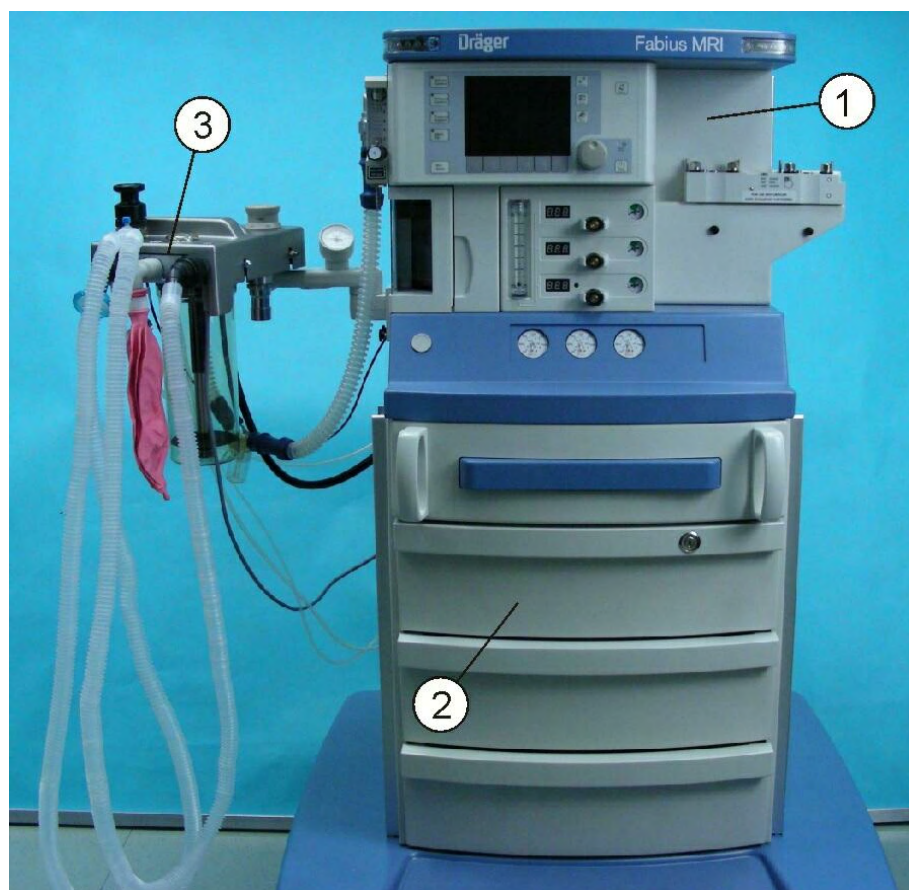


Item No.	Order No.	Description	Qty.	Qty.unit	Remark
		Products concerned	1.000	St	
		Basic unit	1.000	St	
		Manuals/Techn.Documentation	1.000	St	
		Modification kits/Options	1.000	St	
		Maintenance parts/Service kits	1.000	St	
		Accessories/Consumables	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

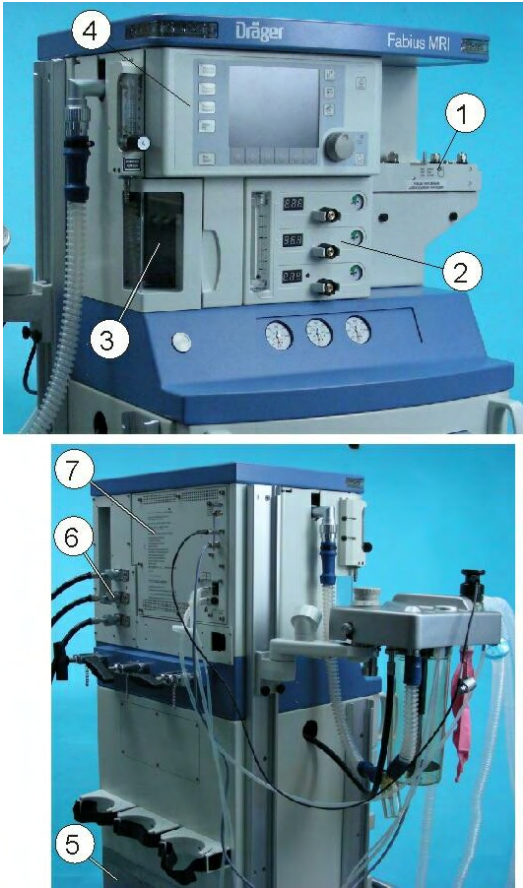


Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1	8607300	Fabius MRI	1.000	St	

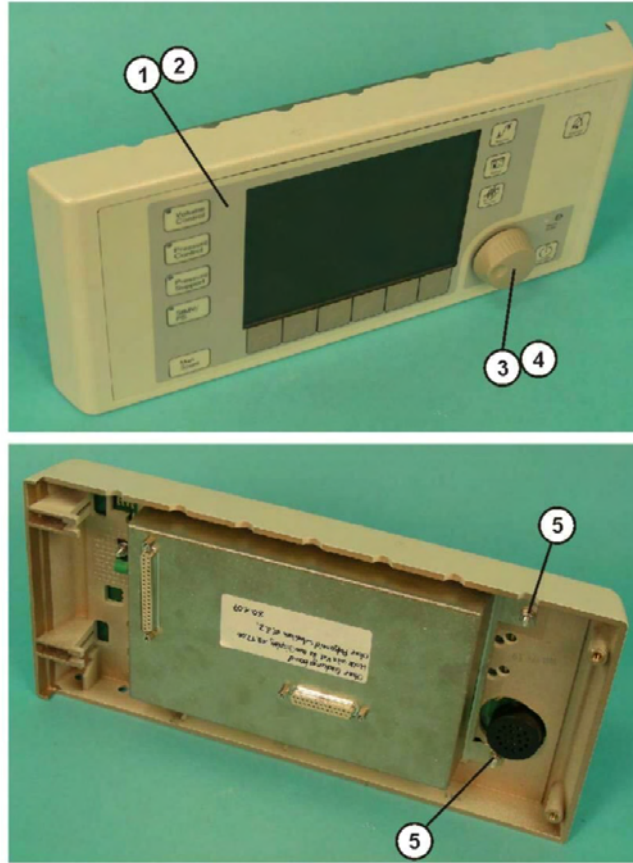


Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1		Basic device	1.000	St	
2		Trolley	1.000	St	
3		Breathing systems	1.000	St	

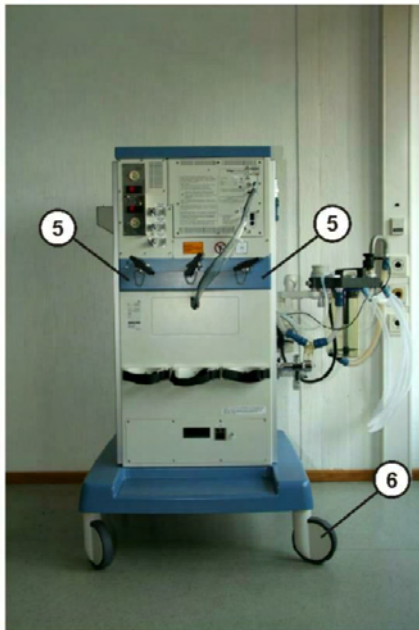
Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



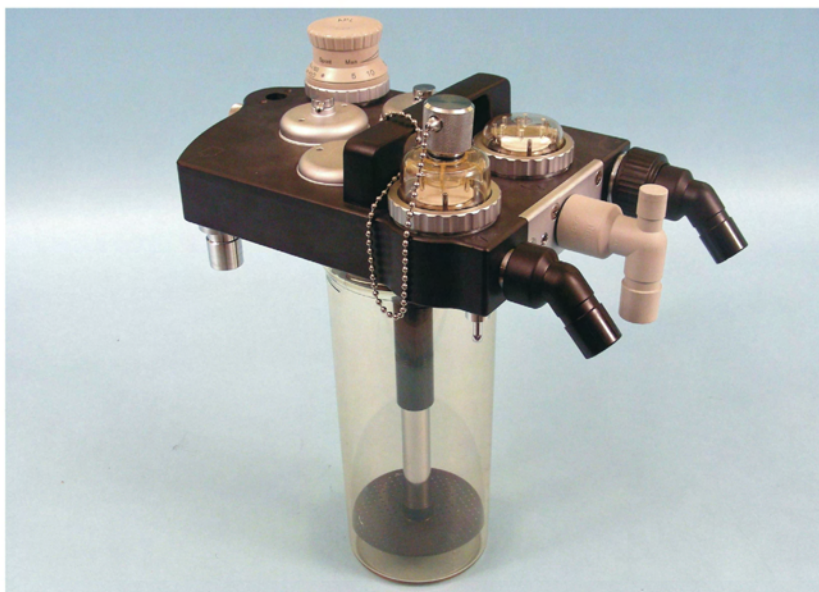
Item No.	Order No.	Description	Qty.	Qty.unit	Remark
1		Vaporizer holder	1.000	St	
4		User interface	1.000	St	



Item No.	Order No.	Description	Qty.	Qty.unit	Remark
3	M29655	CONTROL KNOB	1.000	St	



Item No.	Order No.	Description	Qty.	Qty.unit	Remark
6	MX08806	Castor	1.000	St	

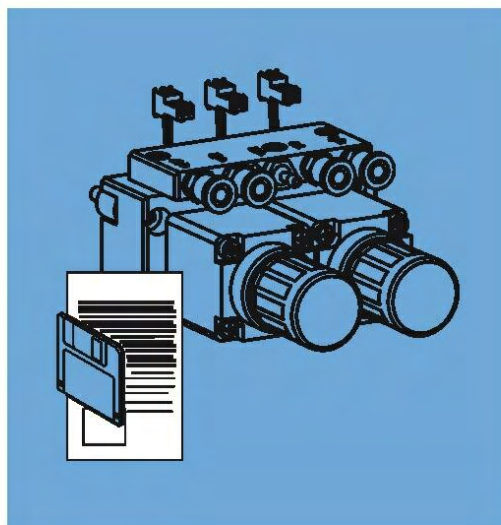


Item No.	Order No.	Description	Qty.	Qty.unit	Remark
		Breathing system COSY 2.6	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

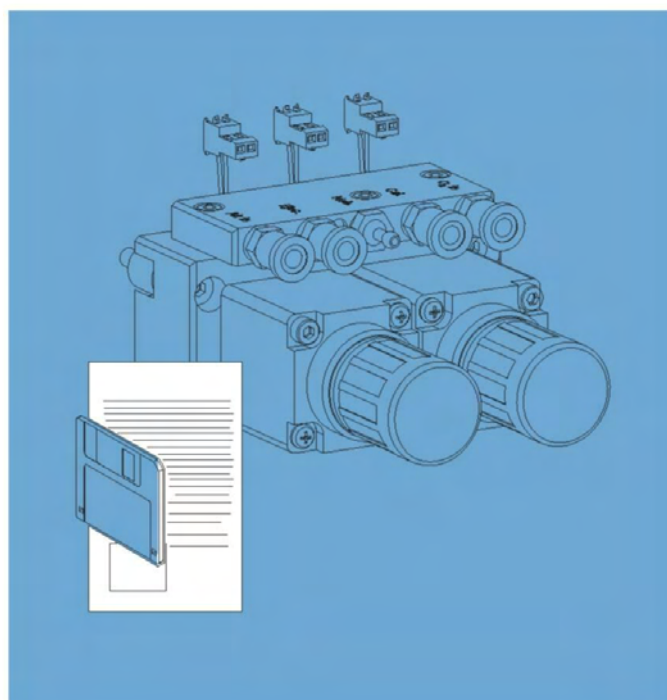


Item No.	Order No.	Description	Qty.	Qty.unit	Remark
	9039035	IFU Fabius MRI 3.n enUS	1.000	St	
	9039036	IFU Fabius MRI 3.n en	1.000	St	
	9039055	IfU Fabius MRI fr	1.000	St	
	9039056	IFU Fabius MRI de	1.000	St	
	9039058	IfU Fabius MRI es	1.000	St	
	9039059	IfU Fabius MRI it	1.000	St	
	9039060	IfU Fabius MRI ru	1.000	St	
	9039062	IfU Fabius MRI ptBras	1.000	St	
	9039065	IfU Fabius MRI nl	1.000	St	
	9039067	IfU Fabius MRI sv	1.000	St	



Item No.	Order No.	Description	Qty.	Qty.unit	Remark
		Software	1.000	St	
		hardware	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

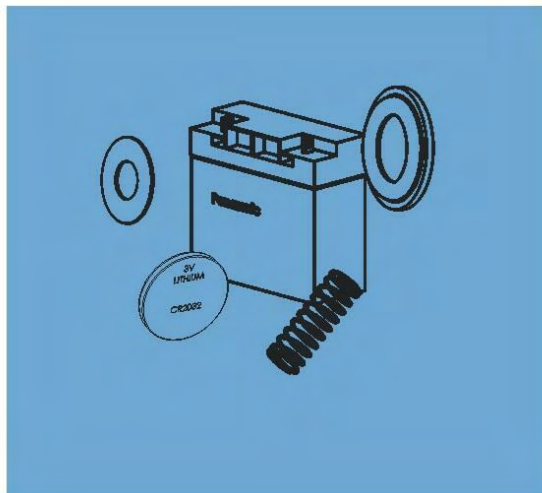


Item No.	Order No.	Description	Qty.	Qty.unit	Remark
		vac./eject. succ.system	1.000	St	
	8607593	adhesive tape 40mT/400 gauss	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

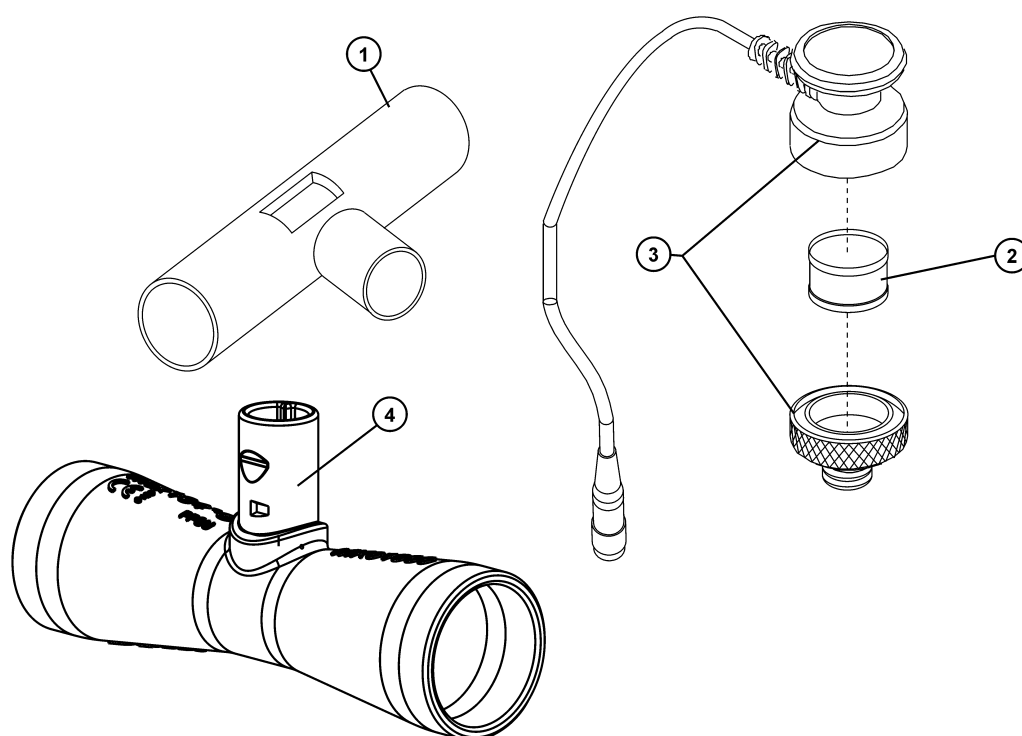
Parts catalog

Maintenance parts/Service kits



Item No.	Order No.	Description	Qty.	Qty.unit	Remark
	M23225	VALVE DISK	1.000	St	
	6850645	O2-Sensor (Capsule)	1.000	St	
	8403735	Set of 5 Spirolog sensors	1.000	St	
	8604874	Hose Asm-PEEP/Pmax-APL Byp RHS	1.000	St	
	1190520	HOSE 4X1,5-SI 50 SH A NF	1.000	m	
	8402868	BACTERIA FILTER	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



Item No.	Order No.	Description	Qty.	Qty.unit	Remark
	8301349	EARTHING CABLE, 3,2 M	1.000	St	
	8604310	hose-ventilator 110cm	1.000	St	
	1190520	HOSE 4X1,5-SI 50 SH A NF	1.000	m	
	U04314	O-RING SEAL	1.000	St	
	8607593	adhesive tape 40mT/400 gauss	1.000	St	
	2600651	DIAPHRAGM, PISTON	1.000	St	
	8402868	BACTERIA FILTER	1.000	St	
	1836722	SUPPLY MAIN 3,5M 3G1 CRSW	1.000	St	
	1841793	PWR Cord 10A,3m,gr,USA/J RoHS	1.000	St	
	8607055	Hose Asm PEEP-Pmax-APL Byp LH	1.000	St	
	4117266	POWER CORD ASM- 15FT FABIUS GS	1.000	St	
	6733895	SET MIC.FILTER 654ST-ISOCCLICK	1.000	St	
	8604831	O-RING 105 x 4	1.000	St	
	8301348	EARTHING CABLE, 0,8 M	1.000	St	
	8604287	Fan hose right	1.000	St	
	1851713	Cable Great Britian,3m,10A	1.000	St	
	1851705	Cable Australia,3m,10A,C13	1.000	St	
	1851721	Power cable DK, 3 m, 10 A	1.000	St	
	1859714	Power cable 10A,3m,black,China	1.000	St	
	8604874	Hose Asm-PEEP/Pmax-APL Byp RHS	1.000	St	
	M23225	VALVE DISK	1.000	St	
1	8403735	Set of 5 Spirolog sensors	1.000	St	
2	6850645	O2-Sensor (Capsule)	1.000	St	
3	8606055	O2 sensor housing, right	1.000	St	
4	MK01900	SpiroLife	1.000	St	

Copyright reserved.

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Assembly

Description	Part No.
Accessories/Consumables	
adhesive tape 40mT/400 gauss	8607593
BACTERIA FILTER	8402868
Cable Australia,3m,10A,C13	1851705
Cable Great Britian,3m,10A	1851713
DIAPHRAGM, PISTON	2600651
EARTHING CABLE, 0,8 M	8301348
EARTHING CABLE, 3,2 M	8301349
Fan hose right	8604287
HOSE 4X1,5-SI 50 SH A NF	1190520
Hose Asm PEEP-Pmax-APL Byp LH	8607055
Hose Asm-PEEP/Pmax-APL Byp RHS	8604874
hose-ventilator 110cm	8604310
O2 sensor housing, right	8606055
O2-Sensor (Capsule)	6850645
O-RING 105 x 4	8604831
O-RING SEAL	U04314
Power cable 10A,3m,black,China	1859714
Power cable DK, 3 m, 10 A	1851721
POWER CORD ASM- 15FT FABIUS GS	4117266
PWR Cord 10A,3m,gr,USA/J RoHS	1841793
SET MIC.FILTER 654ST-ISOCCLICK	6733895
Set of 5 Spirolog sensors	8403735
SpiroLife	MK01900
SUPPLY MAIN 3,5M 3G1 CRSW	1836722
VALVE DISK	M23225
Breathing system COSY 2.6	
Cosy2.6	8605797
fine tuning valves	
CAP 1, SW AIR (D,A,CH)	M34307
CAP 1, SW O2 (D,A,CH)	M34305
CAP 1,BLACK-WHITE	M26205
CAP 1,BLUE	M24901
CAP 1,GREEN	M25147
CAP 1,SW N2O (D,A,CH)	M34306
CAP 1,YELLOW	M25797
CAP,WHITE	M25146
ISO rotary knob without cap	8604697
Rotary knob without cap	MK00360
hardware	
adhesive tape 40mT/400 gauss	8607593

Assembly

Description	Part No.
IFU SW 3.n	
IFU Fabius MRI 3.n en	9039036
IFU Fabius MRI 3.n enUS	9039035
IFU Fabius MRI de	9039056
IfU Fabius MRI es	9039058
IfU Fabius MRI fr	9039055
IfU Fabius MRI it	9039059
IfU Fabius MRI nl	9039065
IfU Fabius MRI ptBras	9039062
IfU Fabius MRI ru	9039060
IfU Fabius MRI sv	9039067
Maintenance parts/Service kits	
BACTERIA FILTER	8402868
HOSE 4X1,5-SI 50 SH A NF	1190520
Hose Asm-PEEP/Pmax-APL Byp RHS	8604874
O2-Sensor (Capsule)	6850645
Set of 5 Spirolog sensors	8403735
VALVE DISK	M23225
Products concerned	
Fabius MRI	8607300
Trolley	
Castor	MX08806
User interface	
CONTROL KNOB	M29655
vac./eject. succ.system	
Vacuum type aspir. Diss	MK03140
Vacuum type aspir. Diss Canada	MK03320
Vacuum type aspir. Nist	MK01422
Ventilator	
DIAPHRAGM,CUP	2600650
patient assembly	8604319

Test instructions (TL) Fabius MRI

This test list can be processed with standard commercially available test aids and tools, but does not replace the required inspections and maintenance work carried out by the manufacturer.



1	Device configuration	
1.1	Device configuration	6
1.1.1	Serial number / software (if not otherwise recorded)	6
2	Electrical safety	
2.1	Electrical safety according to VDE 0751	8
2.1.1	Basic unit	8
3	Function and condition test	
3.1	Basic unit	10
3.1.1	Labelling	10
3.1.2	Instructions for Use	10
3.1.3	Condition of basic unit	10
3.1.4	Condition of the breathing system	10
3.2	Basic unit self-test, calibration and leak test	11
3.2.1	Self-test/system diagnostics of the basic unit	11
3.2.2	Leak tightness of breathing system	11
3.3	Alarm volume, power failure alarm	12
3.3.1	Alarm volume	12
3.3.2	Power failure alarm, battery circuit	12
3.4	Testing the SORC	13
3.4.1	N2O shut-off	13
3.5	O2 flush	14
3.5.1	O2 flush valve	14
3.6	Low O2 alarm test	15
3.6.1	O2 low alarm	15
3.7	Pressure test	16
3.7.1	PEEP accuracy	16
3.8	Ventilation modes	17
3.8.1	Manual ventilation	17
3.8.2	Lung ventilator performance	17
3.8.3	Flow measurement	17
3.9	O2 measurement	18
3.9.1	O2 concentration 21%	18
3.9.2	O2 concentration 100%	18
3.10	Device handover	19

1 Device configuration

1.1 Device configuration

1.1.1 Serial number / software (if not otherwise recorded)

NOTE

The serial number is located on the rear of the unit.

Entry **Serial number of the unit**

[_____.txt]

NOTE

The serial number is located on the right-hand side of the breathing system.

Entry **Serial number of the breathing system (Cosy)**

[_____.txt]

2 Electrical safety

2.1 Electrical safety according to VDE 0751

NOTE

The Fabius conforms to the requirements of protection class I, type B.

2.1.1 Basic unit

- Action
- Check power fuses, plugs for non-heating apparatus, power supply cord including strain-relief device, convenience socket-outlets, and ground stud.

NOTE

When testing according to VDE 0751, test the system, not the individual devices.

Systems must be handled as devices.

A medical system is a combination of several devices of which at least one is a medical electrical device which is connected to other devices by functional connections or by a transportable multiple socket-outlet.

- Test
- The plugs for non-heating apparatus, power supply cord, and the ground studs are neither contaminated nor damaged.

Result

[] ok

Power fuses

- Test
- The power fuse-links match the specifications on the rating plate.

Result

[] ok

Protective earth conductor resistance

- Test
- The protective earth conductor resistance must not exceed **0.3** ohms (including power supply cord) in each case.

Result

Protective earth conductor resistance

[] Ohm

Equivalent unit leakage current

NOTE

Set up the Fabius so that it is insulated.

- Test
- The initial value must not exceed **1000** μA .

Result

Initial value

[] μA

- Test
- The recurrent measurement value must not exceed **1000** μA .

Result

Recurrent measurement

[] μA

3 Function and condition test

3.1 Basic unit

Prerequisites The device is fully assembled.

3.1.1 Labelling

Test Labels and markings are complete and legible.

Result Condition checked.

[_____]OK]

3.1.2 Instructions for Use

Test The Instructions for Use are available (according to user/owner).

Result Condition checked.

[_____]OK]

3.1.3 Condition of basic unit

Test The device is undamaged.

Result Condition checked.

[_____]OK]

3.1.4 Condition of the breathing system

Test The breathing system is undamaged.

Result Condition checked.

[_____]OK]

3.2 Basic unit self-test, calibration and leak test


Prerequisites The device is connected to the mains power supply.
The device is connected to the pipeline supply system or the cylinders are open, as applicable.

3.2.1 Self-test/system diagnostics of the basic unit

Action • Turn the device power switch to "ON".

Test

SYSTEM DIAGNOSTICS		System Status
Watch Dog	Pass	Functional
System RAM	Pass	
Program Memory	Pass	
Video Test	Pass	
Interrupts	Pass	
A/D Converter	Pass	
NV RAM	Pass	
Serial Port	Pass	
Clock	Pass	
Speaker	Pass	
Main Power	Pass	
Battery	Pass	



Fabius GS SW XXX CRC XXX

Fig. 1 System diagnostics screen

Check that the Fabius completes the self-test and that all tests indicate "pass".

Entry **Entering the software version**

[_____]txt]

Result **Self-test successfully completed.**

[_____]OK]

3.2.2 Leak tightness of breathing system

Action • Fully mount the breathing system's components.
• Call the "Standby" screen.
• Operate the "Leak/Compl.Test" button in the "Standby" screen.
• Follow the on-screen instructions.

Test Leak test successfully completed.

Result

[_____]OK]

3.3 Alarm volume, power failure alarm

Prerequisites The Fabius is switched on and in „Standby“ mode.

3.3.1 Alarm volume

- Action
- Press the setup key to open the "standby config" screen.
 - Confirm "default settings" using the rotary knob.
 - Enter code.
 - Operate „Return“ using the rotary knob.
 - Select "Alarm Volume" and confirm with the rotary knob.

Test Set the alarm volume to maximum using the rotary knob.

- Action
- Exit from Standby/configuration.
 - Switch to Volume Control mode.
 - Generate any alarm.

Test An audible and visual alarm is generated.

Result [_____]OK]

- Action
- Restore the original volume.
-

3.3.2 Power failure alarm, battery circuit

- Action
- Press the "Standby" key to access Standby mode.
 - Press the MAN/SPONT key on the control unit, and then confirm the displayed message using the rotary knob.

Test Disconnect the power plug to check that the "power failure" message and the icon appear within one minute of disconnecting the power plug.

Connect the power plug and check that the "power failure" message disappears.

Result [_____]OK]

3.4 Testing the SORC

Prerequisites The device is switched on and in „Standby“ mode.

3.4.1 N2O shut-off

- Action • Set the O2 and N2O flow control valves to 4 L/min.
 • Close the O2 flow control valve again.

Test The N2O flow stops when the O2 flowrate is less than 0.1 L/min.

Result

[_____]OK]

3.5 O2 flush

Introduction	These instructions describe the functional test of the O2 flush button.
Prerequisites	Device is fully assembled.

3.5.1 O2 flush valve

Action	<ul style="list-style-type: none">Press and release the O2 FLUSH button.
Test	The O2 flow stops immediately.
Result	<div>[] OK</div>

3.6 Low O2 alarm test

Introduction	These instructions describe the functional test of the low O2 alarm.
Prerequisites	The device is connected to the pipeline supply system or the cylinders are open, as applicable. Device is switched on.

3.6.1 O2 low alarm

Action	<ul style="list-style-type: none"> Set the O2 flow to 4 L/min. Disconnect the O2 pipeline supply connector or close the O2 cylinder supply, as applicable.
Test	After a short period, the "LOW O2 SUPPLY PRESSURE!!!" alarm message is displayed, an audible alarm sounds, and the red alarm LED comes on.
Result	[_____OK]
Action	<ul style="list-style-type: none"> Restore the pipeline supply or the cylinder supply, as applicable.

3.7 Pressure test

Prerequisites The device is switched on and is in "Volume Control" mode.
 The breathing system is fitted.

3.7.1 PEEP accuracy

Action • Set a PEEP pressure.
Test After a few breaths: The set PEEP pressure matches the displayed value.
Result

[_____OK]

3.8 Ventilation modes

Prerequisites	The device is switched on, has successfully completed the self-test, and is in "Standby" mode.
	The flow sensor is calibrated.
	The breathing system is fitted.

3.8.1 Manual ventilation

Action	<ul style="list-style-type: none"> • Connect a test lung to the Y-piece of the breathing system. • Select Man/Spont mode. • Set the O₂ fresh-gas flow to 3 L/min. • Set APL valve to MAN, 30 mbar.
Test	Manual ventilation can be applied by squeezing the manual breathing bag.
Result	[_____ OK]

3.8.2 Lung ventilator performance

Action	<ul style="list-style-type: none"> • Switch to Volume Control mode. • Press the flush button briefly to inflate the bag. • Confirm settings with the rotary knob.
Test	Volume Control ventilation mode is displayed.
	Ventilation starts.
Result	[_____ OK]

3.8.3 Flow measurement

Action	<ul style="list-style-type: none"> • Set V_t to 500 mL.
Test	The measured V _t matches the set V _t .
Result	[_____ OK]

3.9 O2 measurement

Prerequisites	<p>The MAN/SPONT ventilation mode has been selected.</p> <p>The O2 sensor has been calibrated.</p>
---------------	--

3.9.1 O2 concentration 21%

Action • Remove the O2 sensor from the inspiratory dome and expose it to ambient air. Wait until the pressure has stabilized.

Test The O₂ concentration is **21% ±2,5%**.

Result [_____%02]

3.9.2 O2 concentration 100%

Action • Set an O₂ flow of 3 L/min.

Test After a short period, the O2 concentration has reached **97** to **100**%.

Result [_____%O2]

3.10 Device handover

Entry Place fully functional device at the user's/owner's disposal.

[_____]OK]

Test Report (TL)

Institution: _____

Delivery date: _____

Serial no.: _____

Other: _____

OK	Para	Name	Result
	1	Device configuration	
	1.1.1	Serial number / software (if not otherwise recorded)	
<input type="checkbox"/>	1.1.1.1	Serial number of the unit	
<input type="checkbox"/>	1.1.1.2	Serial number of the breathing system (Cosy)	
	2	Electrical safety	
	2.1	Electrical safety according to VDE 0751	
<input type="checkbox"/>	2.1.1	Basic unit	
<input type="checkbox"/>	2.1.1.1	Power fuses	
<input type="checkbox"/>	2.1.1.2	Protective earth conductor resistance	Ohm
	2.1.2	Equivalent unit leakage current	
<input type="checkbox"/>	2.1.2.1	Initial value	µA
<input type="checkbox"/>	2.1.2.2	Recurrent measurement	µA
	3	Function and condition test	
	3.1	Basic unit	
<input type="checkbox"/>	3.1.1	Labelling	
<input type="checkbox"/>	3.1.2	Instructions for Use	
<input type="checkbox"/>	3.1.3	Condition of basic unit	
<input type="checkbox"/>	3.1.4	Condition of the breathing system	
	3.2	Basic unit self-test, calibration and leak test	
	3.2.1	Self-test/system diagnostics of the basic unit	
<input type="checkbox"/>	3.2.1.1	Entering the software version	

OK	Para	Name	Result
<input type="checkbox"/>	3.2.1.2	Self-test successfully completed.	
<input type="checkbox"/>	3.2.2	Leak tightness of breathing system	
	3.3	Alarm volume, power failure alarm	
<input type="checkbox"/>	3.3.1	Alarm volume	
<input type="checkbox"/>	3.3.2	Power failure alarm, battery circuit	
	3.4	Testing the SORC	
<input type="checkbox"/>	3.4.1	N2O shut-off	
	3.5	O2 flush	
<input type="checkbox"/>	3.5.1	O2 flush valve	
	3.6	Low O2 alarm test	
<input type="checkbox"/>	3.6.1	O2 low alarm	
	3.7	Pressure test	
<input type="checkbox"/>	3.7.1	PEEP accuracy	
	3.8	Ventilation modes	
<input type="checkbox"/>	3.8.1	Manual ventilation	
<input type="checkbox"/>	3.8.2	Lung ventilator performance	
<input type="checkbox"/>	3.8.3	Flow measurement	
	3.9	O2 measurement	
<input type="checkbox"/>	3.9.1	O2 concentration 21%	%O2
<input type="checkbox"/>	3.9.2	O2 concentration 100%	%O2
<input type="checkbox"/>	3.10	Device handover	

Report: _____

Test has been performed according to the test instructions (TL).

Name: _____

Date/signature: _____

This page has been intentionally left blank.

Manufacturer:

Dräger Medical AG & Co. KG
Moislinger Allee 53 – 55
23542 Lübeck
Germany

Phone: (+49) (0) 1805-3723437

Fax: (+49) (0) 451/882 - 3779

Web: <http://www.draeger.com>



Directive 93/42/EEC
concerning Medical Devices

Subject to change without notice.

Will not be replaced in the event of modifications.

© Copyright January 2008 by Dräger Medical AG & Co. KG, Lübeck, Germany.