Dräger

Instructions for Use

Fabius MRI

WARNING
To properly use this medical device, read and comply with these Instructions for Use.

Anesthesia Workstation Software 3.n

Working with These Instructions for Use

Header Line

The header line on each page contains the title of the chapter.

Page Body

The page body in these Instructions for Use combines text and illustrations. The information is presented as sequential steps of action, giving the user hands-on experience in learning how to use the Fabius MRI workstation.

Left-Hand Column - the Text

The text in the left-hand column provides explanations and step-by-step instructions on the practical use of the machine.

- Bullet points indicate separate actions.

1 Where several actions are described, numbers are used to refer to relevant details in the illustrations. On each page the numbering restart with “1”.

– Dashes indicate the listing of data, options or objects.

Right-Hand Column - the Illustrations

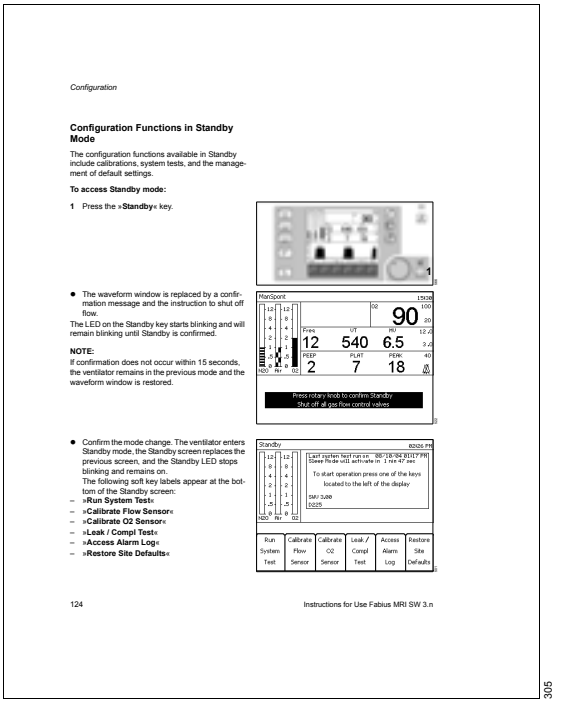
The illustrations provide visual reference for the text and for locating the various parts of the equipment. Elements mentioned in the text are highlighted. Renderings of screen displays guide the user and provide a way to reconfirm actions performed.

Typing Conventions in this Manual

– User controls, such as hard keys and soft keys, and screen pages are printed in bold within quotation marks, e.g., »**PEEP**« or »**Volume Settings**«

– Screen messages are printed in bold within quotation marks, e.g., »**Flow Calibration in progress**«

– Alarm messages are printed in bold within quotation marks, including the exclamation marks that indicate their alarm urgency level, e.g., »**APNEA PRESSURE!!!**«



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All other products or brand names are trademarks of their respective owners.

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.

Abbreviations and Symbols

Please refer to “Abbreviations” on page 34 and “Symbol Definition” on page 35 for explanations.

Notice

This document is provided for customer information only, and will not be updated or exchanged without customer request.

Depending on the configuration of the individual medical device, the images in the Instructions for Use may differ.

Definition of target groups

For this medical device users, service personnel, and experts are defined as target groups.

These traget groups have been instructed in the use of the medical device and have the necessary knowledge to use, install, reprocess, maintain or repair the medical device.

Dräger emphasizes that the medical device must be used, installed, reprocessed, maintained or repaired exclusively by defined target groups.

Users

Users are persons who may use the medical device in accordance with its intended use.

Service personnel

Service personnel are persons who are responsible for the maintenance of the medical device towards the operating organization.

Service personnel are persons who may instal, reprocess, or maintain the medical device.

Experts

Experts are persons who may carry out repair or complex maintenance work on the medical device.

Magnetic Resonance (MR) Definitions

Term	Meaning
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
MRT	Magnetic Resonance Tomography
MR Safe	An item that poses no known hazards in all MR environments.
MR Environment	This term is used to describe the general environment present in the vicinity of an MRT scanner. In particular, this refers to the area within the 5-gauss line around the scanner. Characteristics of the environment include the following: 1) the static magnetic field (the range of 0.2 to 3 tesla is most common, but it can exceed 4.0 tesla*) and associated spatial gradients; 2) rapidly changing magnetic fields (imaging gradients ~kHz); and 3) radio frequency (RF) magnetic field pulses (on the order of tens to hundreds of MHz, i.e., in the FM radio band). The "MR Environment" includes anywhere in the MR procedure room, including the center of the bore of the MRT scanner. *1 tesla = 10000 gauss
Five-Gauss Line	This line specifies the perimeter around an MRT scanner within which the static magnetic fields are higher than five gauss. Five gauss and below are considered "safe" levels of static magnetic field exposure for the general public. (5 gauss = 0.50 mtesla)
Image Artifact	This is a general term that refers to an inappropriate image signal at a specified spatial location. It is generally characterized as increased signal intensity in an area which is known to contain no signal producing material or decreased signal intensity (voids) where signal should be produced.
MR Conditional	An item that has been demonstrated to pose no known hazards in a specified MR enviroment with specified conditions of use. Field conditions that define the specified MR enviroment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields and specific absorption rate (SAR).

Contents

For Your Safety and that of Your Patients

Strictly follow these Instructions for Use

WARNING

Strictly follow these Instructions for Use. Any use of the medical device requires full understanding and strict observation of all portions of these instructions. The medical device is only to be used for the purpose specified under “Intended Use” on page 16 and in conjunction with appropriate patient monitoring (see page 9). Strictly observe all WARNING and CAUTION statements throughout this Instruction for Use and all statements on medical device labels.

Maintenance

WARNING

The medical device must be inspected and serviced regularly by trained service personnel.
Repair of the medical device may also only be carried out by trained service personnel. Dräger recommends that a service contract be obtained with DrägerService and that all repairs also be carried out by them. Dräger recommends that only authentic Dräger repair parts be used for maintenance. Otherwise the correct functioning of the medical device may be compromised.
See chapter "Maintenance".

Accessories

WARNING

Only the accessories indicated on the list of accessories 9052103 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.

Not for use in areas of explosion hazard

WARNING

This medical device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely to occur.

Safe connection with other electrical equipment

WARNING

Electrical connections to equipment which is not listed in these Instructions for Use should only be made following consultation with the respective manufacturers.

Safe networking of computers

When networking with electrical devices, the operator is responsible for ensuring that the resulting system meets the requirements set forth by the following standards:

– EN 60601-1 (IEC 60601-1)
  Medical electrical equipment
  Part 1: General requirements for safety
– EN 60601-1-1 (IEC 60601-1-1)
  Medical electrical equipment
  Part 1-1: General requirements for safety
  Collateral standard: Safety requirements for medical electrical systems
– EN 60601-1-2 (IEC 60601-1-2)
  Medical electrical equipment
  Part 1-2: General requirements for safety
  Collateral standard: Electromagnetic compatibility; Requirements and tests
– EN 60601-1-4 (IEC 60601-1-4)
  Medical electrical equipment
  Part 1-4: General requirements for safety
  Collateral standard: Programmable electrical medical systems

Follow associated Assembly Instructions and Instructions for Use.

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. Instructions, warnings, and caution statements are limited, therefore, largely to the specifics of the Dräger design.
This publication excludes references to various hazards which are obvious to a medical professional and operator of this medical device, to the consequences of medical device misuse, and to potentially adverse effects in patients with abnormal conditions. Medical device modification or misuse can be dangerous.

Patient monitoring

The operators of the medical device must recognize their responsibility for choosing appropriate safety monitoring that supplies adequate information on medical device performance and patient condition.
Patient safety may be achieved through a wide variety of different means ranging from electronic surveillance of medical device performance and patient condition to simple, direct observation of clinical signs.
The responsibility for the selection of the best level of patient monitoring lies solely with the medical device operator.

General WARNINGS and CAUTIONS

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 these Instructions for Use or in the device-specific Instructions for Use.

Note on EMC/ESD risk for the device function

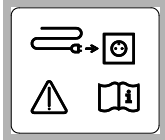
General information on electromagnetic compatibility (EMC) pursuant to international EMC standard IEC 60601-1-2
Electromedical devices are subject to special precautionary measures concerning electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the EMC information included, see page 207.
Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING

Connector pins with an ESD warning sign should not be touched and no connections should be made between these connectors without implementing ESD protective measures. Such precautionary procedures may include antistatic clothing and shoes, the touch of a ground stud before and during connecting the pins or the use of electrically isolating and antistatic gloves. All staff involved in the above shall receive instruction in these ESD precautionary procedures.

WARNING

Risk of electric shock.



Connecting devices to the Medical Power Outlet Strip can cause an increase in leakage current beyond permissible values if the protective conductor of a device fails. Check the leakage current when connecting devices to the Medical Power Outlet Strip. If connecting a device (or devices) increases the leakage current to a value which exceeds the permissible value, do not use the auxiliary outlets of the Fabius MRI: use a separate wall socket.

The system must meet the requirements for medical equipment in accordance with IEC/EN 60601-1-1 and IEC/EN 60601-1-2 and the particular standards of the connected devices.

Accessories in sterile packaging

Do not use accessories in sterile packaging if the packaging has been opened, damaged or if there are other signs that the accessories are not sterile. Reprocessing and resterilization of single-use accessories is not permitted.

CAUTION

Risk of patient injury
An incorrect diagnosis or misinterpretation of measured values, or other parameters, may endanger the patient.
Do not base therapy decision on individual measured values or monitoring parameters.

Software

The device's software has been developed and tested carefully in accordance with Dräger's high quality standards. It is therefore highly improbable that software errors can become a hazard to the patient.

Additionally, independent protective functions are extensively implemented in the software, as well as in electronics and mechanics, for all safety-related functions of the device.

Through this, the probability that an error in the software or other functions can be detected before it affects the patient's safety is very high. Regular automated or manual tests ensure the effectiveness of all protective measures.

WARNING

Do not use conductive breathing hoses or face masks.

They may cause burns during HF surgery.

WARNING

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

WARNING

Do not use conductive breathing hoses or face masks.

They may cause burns during HF surgery.

WARNING

This MR conditional anesthesia workstation has been tested with magnets with field strengths of 1.5 tesla and 3 tesla by a fringe field strength of 40 mtesla (400 gauss). Use of the machine with higher strengths could result in ventilator and device malfunction. Additionally, unmanageable attractive forces could lead to serious injury.

WARNING

This anesthesia workstation will not respond automatically to certain changes in patient condition, operator error, or failure of components. The anesthesia workstation has to be operated under the constant supervision and control of a qualified operator in order to provide immediate corrective action.

WARNING

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.

WARNING

Each institution and user has a duty to independently assess, based on its, his, or her unique circumstances, what components to include in an anesthesia system. However, Dräger, in the interest of patient safety, strongly recommends the use of an oxygen analyzer, pressure monitor, volume monitor, and end-tidal CO_2 monitor in the breathing circuit at all times.

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

Risk of fire

Drugs or other substances based on inflammable solvents, such as alcohol, must not be introduced into the patient system.

Adequate ventilation must be ensured if highly flammable substances are used for disinfection.

WARNING

Explosive anesthetics, such as ether or cyclopropane, must not be used due to the risk of fire.

WARNING

Do not use conductive breathing hoses or face masks.

They may cause burns during HF surgery.

WARNING

Do not apply unregulated suction to the patient circuit when using this device.

WARNING

Always keep a breathing bag at hand. If ventilation of the patient is compromised, the patient must be immediately ventilated with a separate emergency ventilator.

WARNING

Remove any equipment mounted to the machine before transport. The writing table should also be free of all objects and pushed back in the locked position.

If these precautions are not followed, the device may tip over and pose a risk to safety.

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

All the procedures described in this manual require that any use of ferromagnetic tools is done only while the Fabius MRI is out of the scanner 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

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

WARNING

A pre-use checkout procedure must be performed immediately before each use of the Fabius MRI. A recommended procedure is provided in this Instruction for Use, see “Appendix 1 - Daily and Pre-use Checkout Form” on page 225.

WARNING

To avoid electrical shock hazard:

Due to the risk of electrical shock, do not remove any component cover.

Refer any servicing to DrägerService.

Use only hospital-grade grounded electrical outlets and power cord.

This device is to be used only in rooms with line power installations complying with national safety standards for hospital patient rooms (e.g., IEC 60601-1 "Safety of Medical Electrical Equipment").

Make sure the external equipment is hospital-grade grounded (regarding national regulations) before connecting the equipment.

Disconnect the power supply from the electrical outlet before cleaning or servicing. Let it dry completely before reconnecting it to the electrical outlet.

Always ensure that the clamp for the power cord at the power supply end is tight, thus preventing an accidental disconnect from the unit.

Do not connect additional external equipment other than equipment specified by Dräger.

WARNING

When moving the anesthesia machine, remove all monitors and equipment from the top shelf and hinged arms, remove the absorber system, vaporizers, and reserve gas cylinders, push in the writing tray, and use only the machine handles to push or pull the unit (see “Accessory Mounting” on page 32).

The anesthesia machine should only be moved by people who are physically capable of handling its weight. Dräger Medical recommends that two people move the anesthesia machine to aid in maneuverability.

Exercise special care so that the machine does not tip when moving up or down inclines, around corners, and across thresholds (for example, in door frames and elevators). Do not attempt to pull the machine over any hoses, cords, or other obstacles on the floor.

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.

WARNING

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING

Use only non-rebreathing systems having a reservoir bag in compliance with ISO 5362 and/or a pressure relief valve to ensure correct pressure at the patient connection port. If disregarded, this could lead to personal injury.

CAUTION

Risk of pinching fingers or breathing hoses and objects falling down

If the writing table is not engaged correctly, objects can fall down and fingers or breathing hoses can be pinched.

CAUTION

Do not use the following non-rebreathing systems: Magill, Kuhn or Bain. They are not MR safe or MR conditional.

Otherwise the diagnostic quality of the MRT images will be affected.

CAUTION

Use MR safe or MR conditional non-rebreathing systems. Otherwise the diagnostic quality of the MRT images will be affected.

CAUTION

Provide sufficient length of hoses for movement.

CAUTION

Communications with external equipment may be temporarily affected by electromagnetic interference due to the use of electrosurgical equipment.

CAUTION

Watch hoses connected to the patient while moving the Fabius MRI.

CAUTION

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

CAUTION

Risk of injury and image artifacts

The Fabius MRI is designed for use in MR environment only as a system. The user should not assume that individual components of the system can be safely used in MR environment.

CAUTION

Risk of injury

Do not service this device while it is in the MR environment.

CAUTION

Risk of physical injury

To avoid physical injury, pay special attention to edges, moving parts and corners when working with

– drawers,
– the ventilator module,
– the writing tray,
– swivel arms for mounted devices,
– gas cylinders,
– vaporizer units,
– CLIC absorbers and CLIC adapters,

as well as other accessories.

NOTE

Software must be installed by qualified personnel. We recommend to contact DrägerService for software installation.

NOTE

If the correct functionality of the protective earthing conductor or its connection to the device is doubtful, the device must be operated using the internal power supply (battery).

Intended Use

Intended Use

Fabius MRI is an inhalation anesthesia machine for use in MRI environments in operating, induction and recovery rooms. It can only be used in MRI scanner rooms with magnets 1.5 tesla and 3 tesla at a fringe field strength of 40 mtesla (400 gauss) or less.

It may be used with O_2, N_2O, and AIR supplied by a medical gas pipeline system or by externally mounted gas cylinders.

Fabius MRI is equipped with a compact breathing system, providing fresh gas decoupling, PEEP, and pressure limitation.

The following ventilation options are available:

– Volume Controlled Ventilation
– Pressure Controlled Ventilation
– Pressure Support (Optional)
– SIMV/PS (Optional)
– Manual Ventilation
– Spontaneous Breathing

Fabius MRI is equipped with an electrically driven and electronically controlled ventilator and monitors for airway pressure (P), volume (V), and inspiratory oxygen concentration (FiO_2).
As per IEC 60601-2-13 (Anesthetic Workstations and their Modules-Particular Requirements), additional monitoring of the concentrations of CO_2 and anesthetic agent is required when the machine is in use.

NOTE

O_2 Monitoring Disabled" is a local authorized service organization-configurable option. See "O_2 Monitoring Disabled" on page 132 for more information. In this case, external FiO_2 monitoring must be available.

IEC 60601-2-13 :2003 requires that a manual ventilation bag must be available for emergency use.
Fresh gas enrichment is provided by the Dräger Vapor anesthetic vaporizer.

Indications for Use

The Fabius MRI is indicated as a continuous flow anesthesia system useable in an MRI environment. The Fabius MRI may be used for manually assisted or automatic ventilation, delivery of gases and anesthetic vapor, and monitoring of oxygen concentration, breathing pressure and respiratory volume.

MEDIBUS Protocol

MEDIBUS is a software protocol for use in transferring data between the Fabius MRI and an external medical or non-medical device (e.g., hemodynamic monitors, data management systems, or a Windows-based computer) via the RS-232 interface (see 9038530, 3rd edition or higher).

WARNING

Data transferred via MEDIBUS interfaces are for information only and are not intended as a basis for diagnosis or therapy decisions.

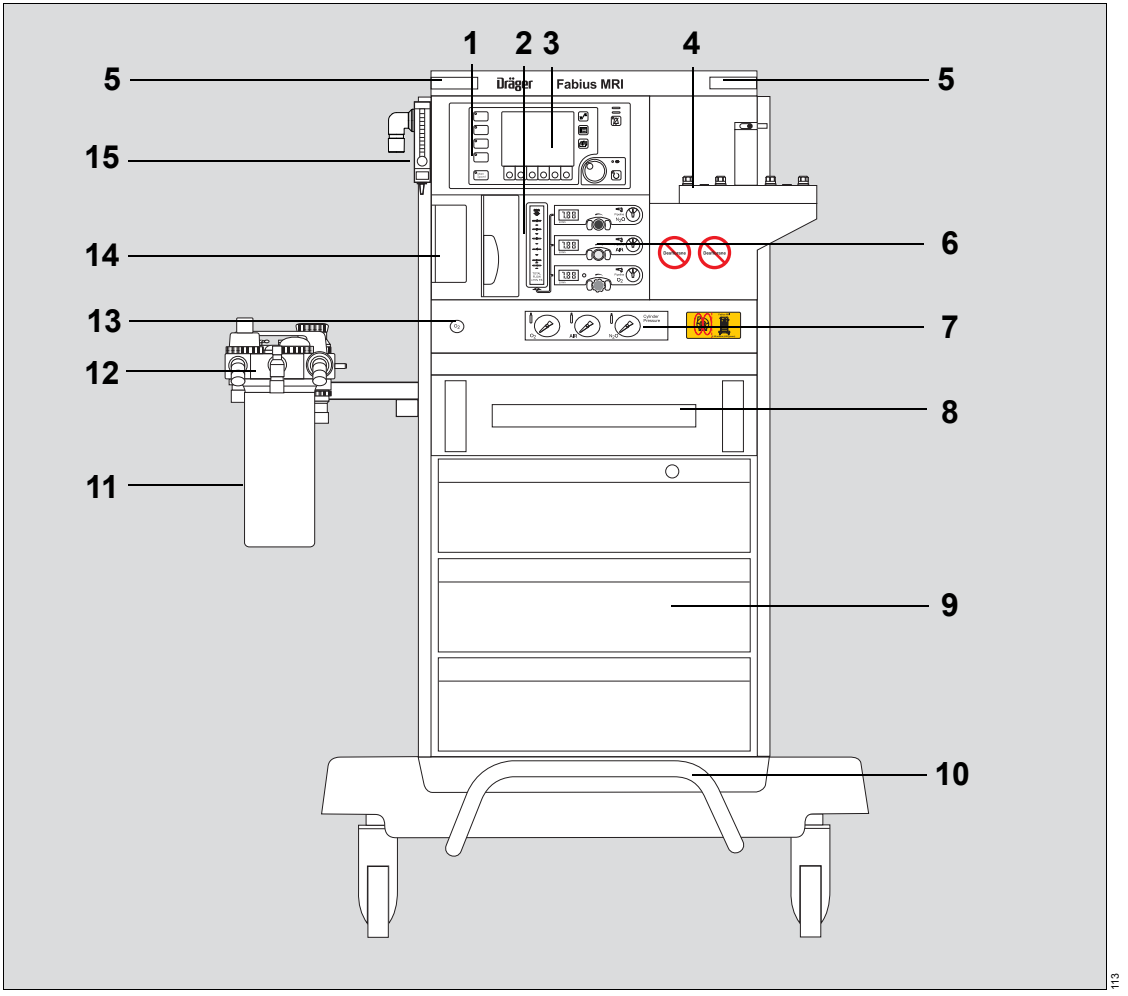
WARNING

In order to protect patients and users from electrical hazards, is it imperative that all systems consisting of electrical medical devices and other electrical devices, such as but not limited to PCs, printers, etc., be mounted exclusively by trained personnel.

The system must meet the requirements about medical electrical equipment in accordance to IEC/EN 60601-1-1 and IEC/EN 60601-1-2.

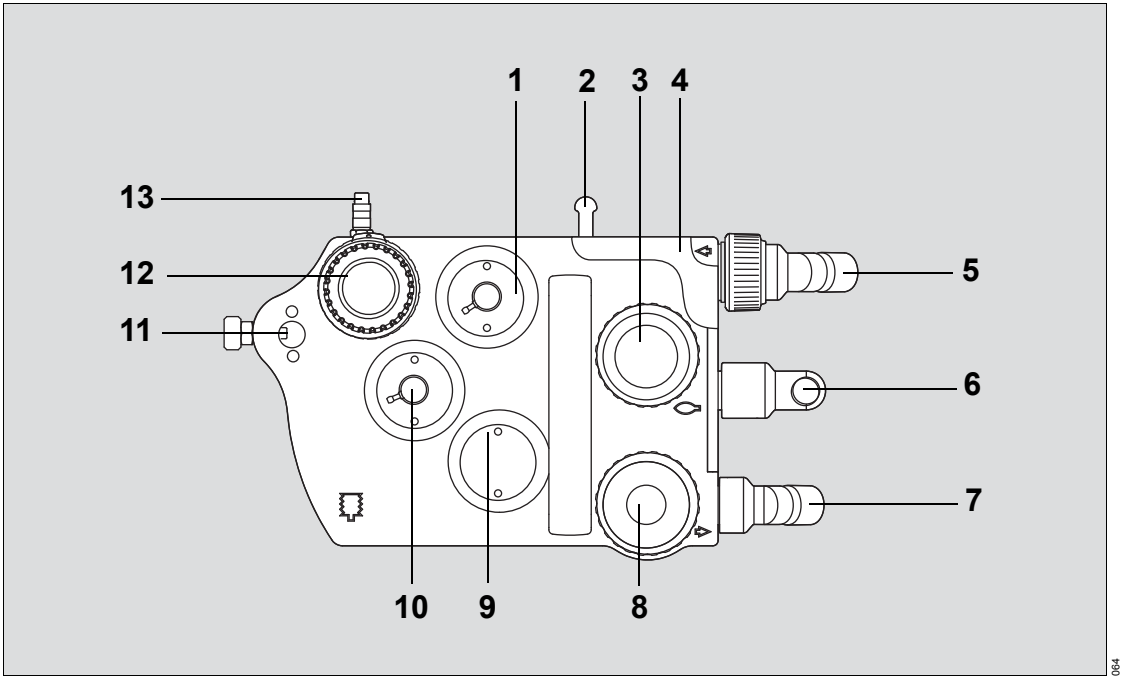
System Overview

Front View



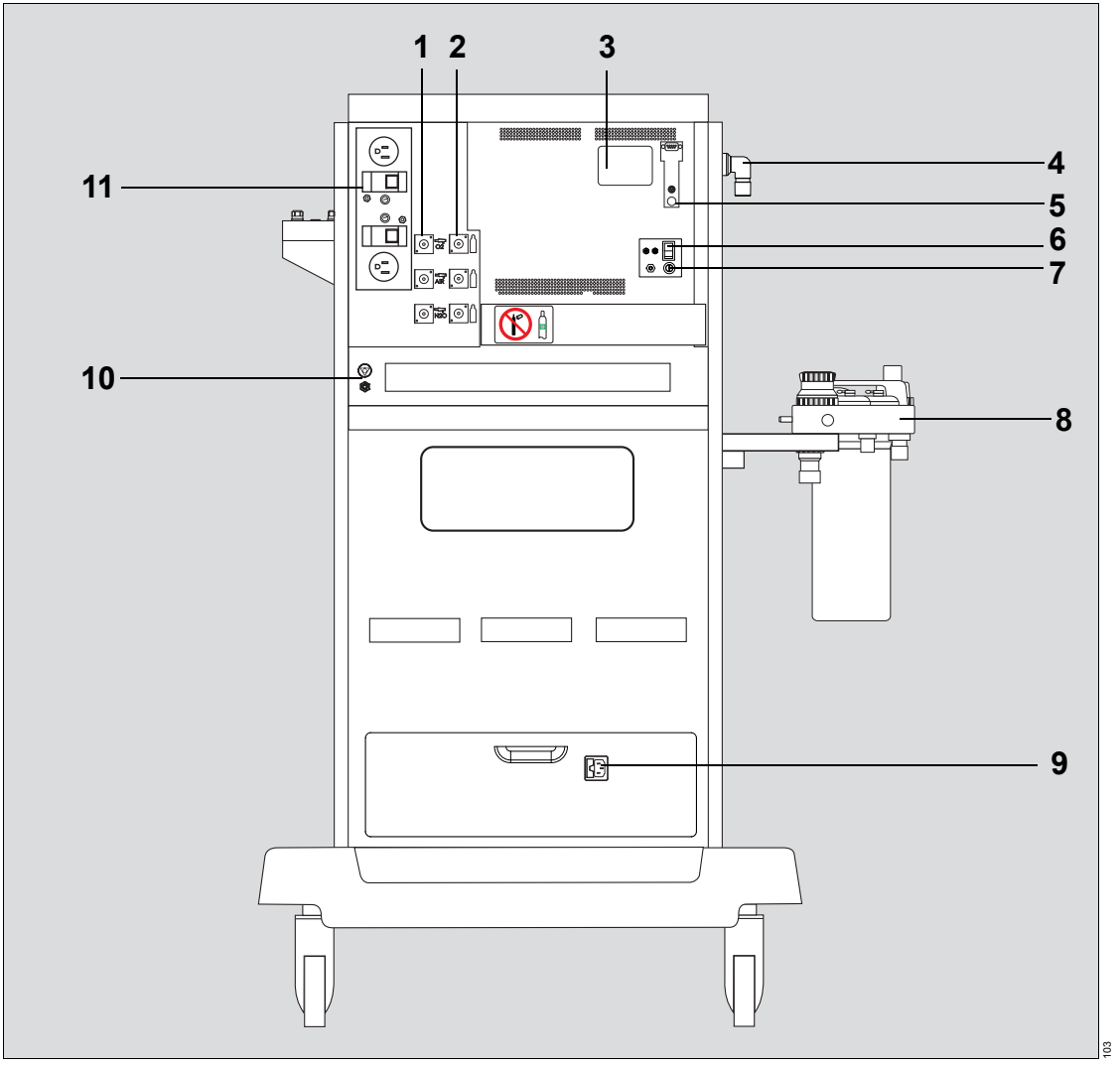
1 Ventilator control panel (settings for ventilation parameters and airway monitoring)
2 Total fresh gas flowmeter
3 Display screen
4 Interlock or Auto Exclusion Vapor mount
5 Additional alarm indicators
6 Fresh gas controls
7 Gauges (Pin-Index cylinders)
8 Writing table
9 Storage drawers
10 Central brake
11 Absorber
12 Compact Breathing System (COSY)
13 Oxygen flush button
14 Ventilator
15 Auxiliary oxygen flowmeter

Compact Breathing System (Top View)



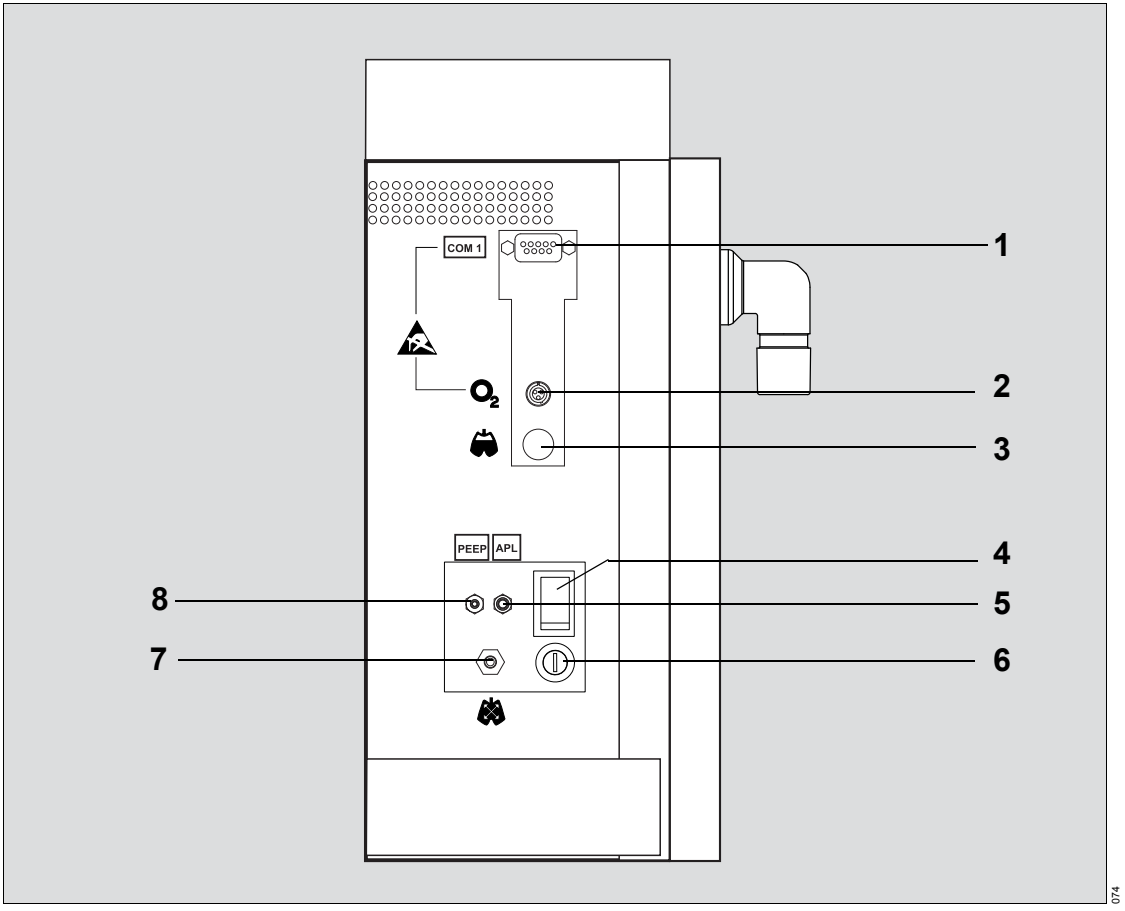
1 PEEP/PMAX valve connection port
2 Bag holder
3 Expiratory valve
4 Flow-sensor guard (flow-sensor protection)
5 Expiratory port
6 Connector for breathing bag
7 Inspiratory port
8 Inspiratory valve
9 Fresh gas decoupling valve
10 APL bypass valve connection port
11 Breathing system mount with locking bolt
12 Selecting knob for »**MAN**« and »**SPONT**« on pressure limiting (APL) valve
13 Sample gas return port

Rear View (Threaded Connectors)



1 Connector for medical gas pipeline supply (central supply)
2 Connector for cylinders (threaded connectors)
3 Type plate
4 Ventilator hose connection
5 Interface panel
6 ON/OFF switch
7 Fuse
8 Compact Breathing System (COSY)
9 Power cable connection
10 Potential equalization pin
11 Auxiliary power outlets

Interface Panel



1 COM 1 (for Service or fiber optic cable (8608376) only)
2 Oxygen Sensor
3 Volume Sensor
4 ON/OFF switch
5 APL
6 Fuse
7 Breathing Pressure
8 PEEP

Vaporizers (Optional)

The Dräger Vapor anesthetic agent vaporizers are used to enrich the fresh gas with a precisely metered quantity of vapor from the liquid anesthetic agent being used, i.e., Isoflurane, Halothane, Enflurane, or Sevoflurane.

WARNING

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 by used on the Fabius MRI in MRT scanner rooms.

For complete information, consult the appropriate Instruction for Use provided with the vaporizer.

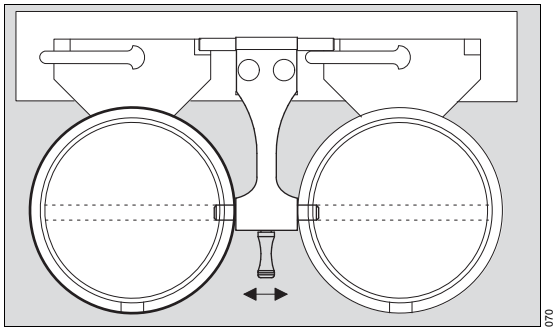
Vaporizer Exclusion Systems

The exclusion systems available for the Fabius MRI are described below.

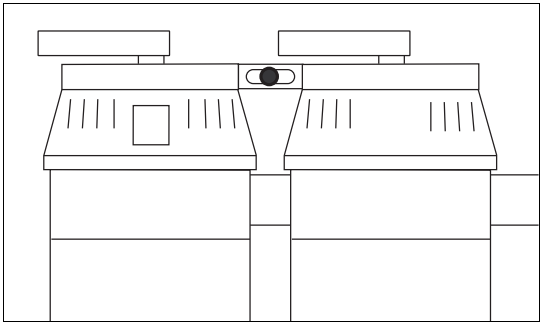
Dräger Vapor Interlock 2 System (Optional)

The Dräger Interlock 2 system is used to ensure that only one of two vaporizers can be used at a time. It has a selector lever used to select which vaporizer is enabled.

Moving the selector lever away from the desired vaporizer allows that vaporizer to be used and the other to be locked out of use.



Note that the selector lever is shown in the center position. This ensures that both vaporizers are in the locked position. Also, this is the recommended position for the selector lever when moving the Fabius MRI.



Dräger Auto Exclusion 2-Vaporizer Mount (Optional)

This system has an automatic interlock system that ensures only one vaporizer can be used at a time. When one of the two vaporizers is selected for use (opened), the interlock mechanism within that vaporizer's mounting system is activated automatically, preventing the other vaporizer from being used.

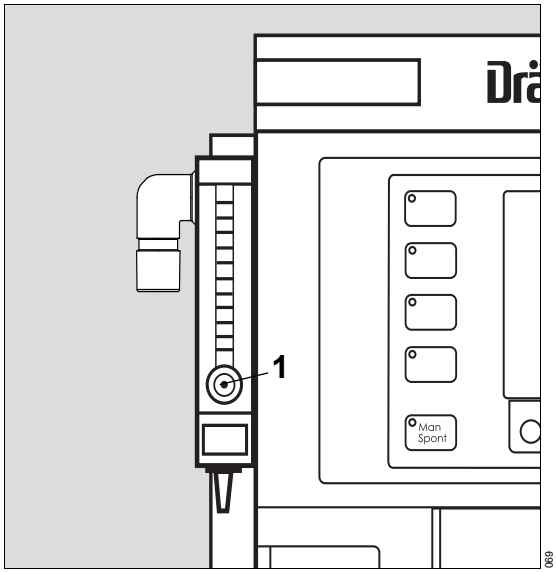
NOTE

Only Dräger vaporizers labeled as "AUTO EXCLUSION" vaporizers are compatible with the Dräger Auto Exclusion 2-Vaporizer Mount.

Auxiliary Oxygen Flowmeter

The auxiliary oxygen flowmeter delivers a metered flow of pure oxygen, used, for example in the delivery of oxygen through a nasal cannula. Auxiliary oxygen can be used in any ventilation mode, in Standby, or even if the machine is switched off.

The auxiliary oxygen flowmeter may be used to provide supplemental inspired oxygen to a patient under spinal, epidural, or other regional anesthesia. It may also be used to enrich the inspired gas mixture provided by a manually powered selfinflating resusciator bag*.



- Test the auxiliary oxygen flowmeter. Adjust the flow knob (**1**) and make sure the float moves freely over the full range of the flowmeter.

WARNING
Risk of patient injury
Do not connect the patient directly to the auxiliary oxygen outlet.
High pressure will be applied and the patient endangered.

WARNING
Risk of fire
Cauterizing close to a source of oxygen can lead to fire.

When finishing oxygen therapy, make sure the flow meter is completely closed:

- Turn the flow knob (**1**) clockwise until it can no longer be turned.

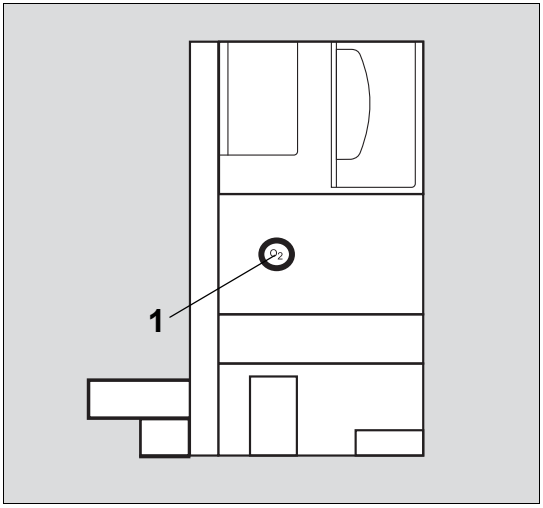
Only then the oxygen flow is completely off.

WARNING
Risk of fire
Before cauterizing, close the flow meter, remove the mask and wait a few moments to ensure that any oxygen accumulation has dissipated.

* ASTM F1850-22(2005) §76

O_2 Flush Button

A manually operated O_2 flush button (**1**) is located on the front of the machine. When actuated, the valve delivers an unmetered flow of at least 35 L/min to the breathing system and breathing bag while bypassing the ventilator. The Fabius MRI does not need to be switched on in order to use the O_2 flush.



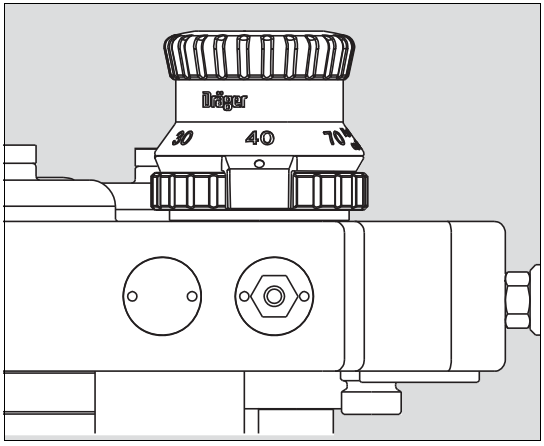
APL Valve

WARNING
Risk of patient injury
Route all lines/cables away from the APL valve to prevent interference with the APL valve adjustment knob. Lines/cables caught underneath the APL valve adjustment knob could interfere with proper functioning of this valve.

The APL valve has two functions. It limits the maximum pressure during manual ventilation. It also exhausts excess gas into the scavenger system during manual and spontaneous ventilation.
The APL valve is connected to the patient airway through the ventilator. It functions only when the ventilator is in ManSpont mode or ventilator override condition.

The APL valve has a labeled knob for selecting between spontaneous and manual modes of ventilation and for indicating approximate pressure settings.

– When the APL valve knob is rotated fully counterclockwise, pressure is released for spontaneous ventilation. Spontaneous ventilation automatically eliminates resistance to patient exhalation.
– In manual mode, the APL valve knob can be rotated to change the pressure threshold at which gas will flow through the valve and into the scavenging system. Clockwise rotation of the APL valve knob increases the pressure threshold, and counterclockwise rotation of the APL valve knob decreases the pressure threshold. Lifting the top of the APL valve knob will temporarily relieve pressure.



NOTE

The APL valve is automatically excluded from the breathing circuit whenever an automatic ventilator mode is selected.

NOTE

Even in automatic ventilation, the APL valve must be adjusted to a pressure that is safe for the patient!

Writing Table

The writing table is a telescopic tray that has two positions.

1 To use the writing table, pull it out completely until it engages.

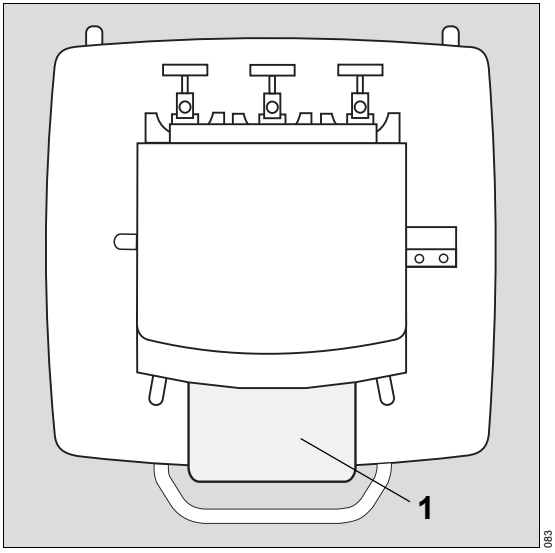
- To place the writing table in its park position, push it in completely until it engages.

WARNING

Ensure that any loose parts that are not marked as MR safe or MR conditional are removed from the writing table at MRT room.

CAUTION

For use, pull out the writing table until it engages.
For parking position, push the table back until it engages.



Communication Port

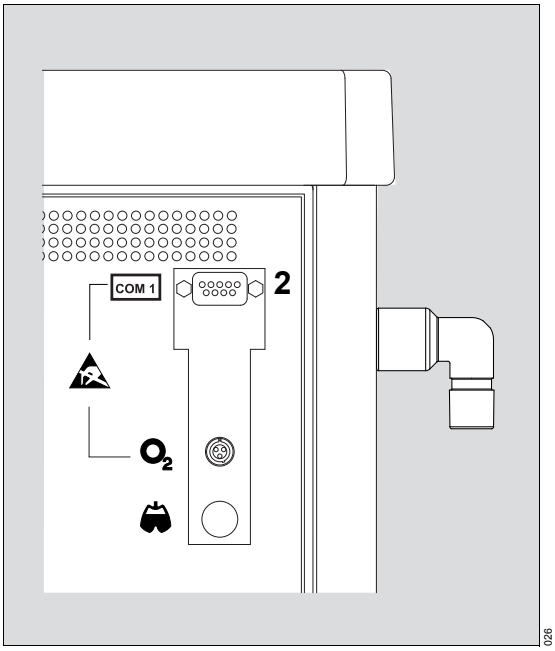
2 The Fabius MRI has one port on the back. It is labeled as COM 1.
The use of COM1 for MEDIBUS communication with an external device in the MRI environment has to be certified by Dräger.

WARNING

A test for leakage current must be performed by qualified engineering personnel before use if the Fabius MRI is interfaced with other equipment.

WARNING

Only the combinations approved by Dräger, with monitoring and the correspondingly defined assembly parts, may be used. Otherwise the correct functioning of the device maybe compromised.

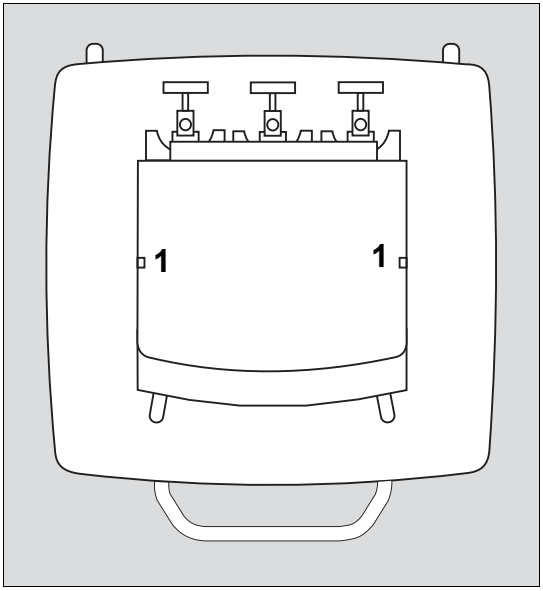


Teslameter

To ensure that the Fabius MRI works safely and without interference in the proximity of an MRT system, and that the MRT's imaging is not influenced out of margin, there is defined distance that the Fabius MRI machine must maintain from the MRT system. For exposition in a homogenous magnetic field, there is a limit of 40 mtesla (400 gauss) to be kept for the Fabius MRI.
The Fabius MRI is a floor-based workstation that can be moved around the room as required by the patient's respiration/anesthesia during the MRT treatment. If the fringe field strenght is exceeded, an acoustic signal is annunciated and continues to annunciate until the Fabius MRI is repositioned to the required limit of 40 mtesla (400 gauss). The array for detecting the magnetic field is a positioning aid towards the MRT magnet.

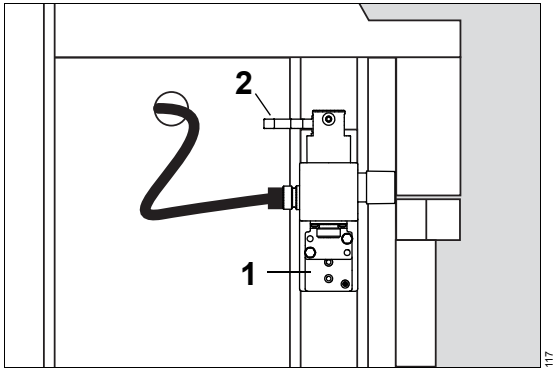
Location of the Sensors

There are two sensors (one on each side) located in the lower part of basic unit (**1)**.
Checking the sensors in self-test mode, e.g., after switching on the machine, is not necessary. Both Tesla sensors are constantly active when the Fabius MRI main power switch is turned on, including in Standby mode and operation on battery power.



External fresh-gas outlet with an additional switch*

The changeover switch permits simple switching of the fresh-gas from the Compact Breathing System (COSY) to the non-rebreathing system, e.g. Waters. The fresh-gas hose does not need to be changed.
The external fresh-gas outlet with switch is attached to the lateral rail system using a separate holder (**1**).



NOTE
The external fresh-gas outlet with switch can be mounted to the vertical rails either on the left side or on the right side of the trolley. It might be necessary to change the position of the rail adapter.

The lever (**2**) on the top of the switch is used to change the direction of the flow.

- Set the lever on the switch to **»**  **« or** to **»COSY«.**

WARNING
Danger to the patient caused by too high pressures
To ensure the correct inspiratory pressure at the inspiratory port, use only non-rebreathing systems with a reservoir bag conforming to ISO 5362 and/or a pressure relief valve.

WARNING
Do not use the following non-rebreathing systems in the MRI suite: Magill, Kuhn or Bain. They are not MR safe or MR conditional. Otherwise the diagnostic quality of the MRT images will be affected.

* optional

WARNING

Risk of insufficient gas supply to the patient

Non-rebreathing systems are suitable and intended only for manual ventilation or spontaneous breathing and may only be connected to the external fresh-gas outlet.

WARNING

Risk of misinterpreting the measurements

The measurements and alarms are displayed on the breathing monitor. They do not correspond to the measurements for the patient connected to the external fresh-gas outlet.

- **The measurements (O2, pressure, volume) and alarms displayed on the breathing monitor correspond to the measurements on the Compact Breathing System (COSY).**
- **Switch to the Standby mode when using the external fresh-gas outlet.**

WARNING

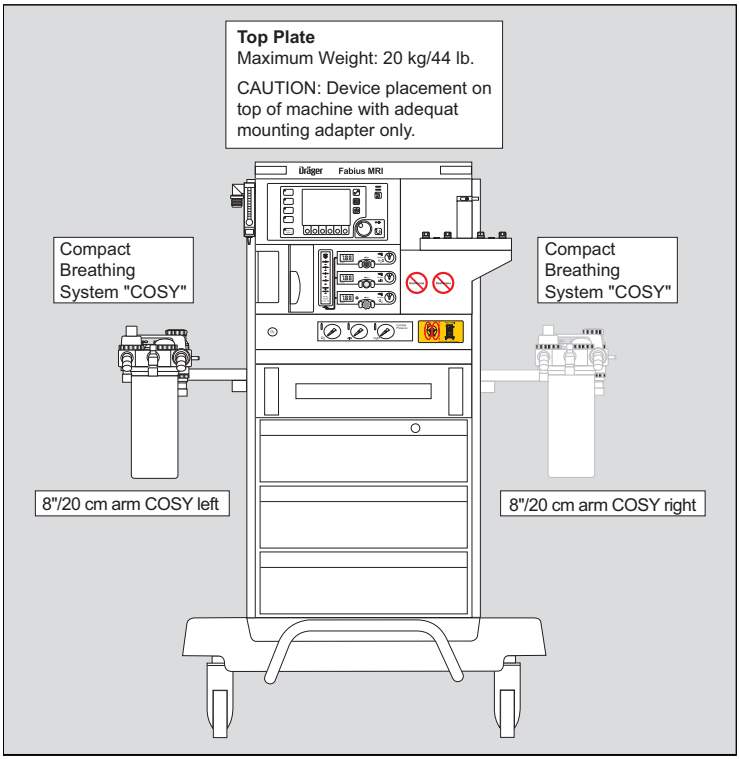
Danger to the patient

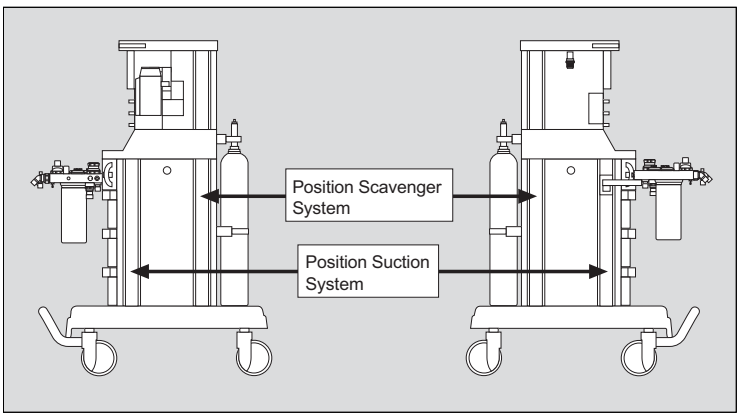
There is no monitoring of pressure, volume or O_2 for the external fresh-gas outlet.

An external monitoring unit must be used to perform the required monitoring of O_2, CO_2, anesthetic gas, volume and pressure.

Accessory Mounting

The following figure shows the permitted mounting locations for accessories available for the Fabius MRI.





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Maximum Weight Loads

Component	Maximum weight
Top of machine (with adequate mounting adapter only)	20 kg/44 lb
Drawers (each)	4 kg/8.8 lb
Writing table	25 kg/55 lb
Syringe/Infusion pump (Note: mounted to Dräger-supplied IV pole)	9 kg/20 lb

WARNING

Do not place any object on this machine, writing table, or in the drawers 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 the MR scanning room.

Abbreviations

Abbreviation	Meaning
AGS	Anesthetic Gas Receiving System
AGSS	Anesthetic Gas Scavenging System
AIR/Air	Compressed air for medical use
APL	Adjustable Pressure Limitation
bpm	Breaths per minute
CAL	Calibration
cmH_2O	Centimeters of water
CO_2	CO_2 concentration
COM	communications port (serial interface)
COSY	Compact Breathing System
ΔP_{PS}	Pressure difference for pressure support in pressure support mode
Des.	Desflurane
Des Comp	Desflurane Compensation
EMC	Electromagnetic Compatibility
Exp	Expiratory
f	Breathing frequency
FiO_2	Inspiratory O_2 concentration
FLOW	Expiratory flow
Freq	Frequency
Freq Min	Mandatory minimum frequency in pressure support mode
hPa	Hectopascal
in./insp.	Inspiratory
Insp Flow	Inspiratory flow
L/min	Liters per minute
Man MAN	Manual ventilation
mbar	Millibar
MEAN	Mean pressure
MR	Magnetic resonance

Abbreviation	Meaning
MRI	Magnetic resonance imaging
MRT	Magnetic resonance tomography
MV	Minute volume
N_2O	Nitrous oxide
O_2	Oxygen
P_{AW}	Airway pressure
PEAK	Peak pressue
PEEP	Positive end-expiratory pressure
P_{INSP}	Pressure limitation in Pressure Control mode
PLAT	Plateau pressure
P_{MAX}	Pressure limitation in Volume Control mode
PS	Pressure support
psi	Pounds per square inch
SIMV	Synchronized Intermittent Mandatory Ventilation
S–ORC	Sensitive Oxygen Ratio Controller
spont SPONT	Spontaneous breathing
STP	Standard conditions for temperature and pressure
T_I:T_E	Ratio of inspiratory to expiratory time
T_{IP}:T_I	Ratio of inspiratory pause time to inspiratory time
T_{INSP}	SIMV Inspiratory time
Trigger	Trigger Level
UPS	Uninterruptable power supply
VAC	Vacuum (e.g. for secretion suction)
VE	Expiratory minute volume
V_T	Tidal volume

Symbol Definition

The following symbols appear on the labels on the back of the Fabius MRI and are defined below:

Caution:
Refer to accompanying documents before operating equipment.

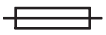
Caution:
Risk of electric shock, do not remove.

Degree of protection agains electric shock: Type BF

Registration mark for Canada and USA

Conformité Européenne
Directive 93/42/EEC
on Medical Products

Date of manufacture



Fuse

Catalogue number

Serial number

WEEE-labelling, EU Directive 2002/96/EC

The following symbols are used on other locations of the Fabius MRI to provice quick and easy recognition of product functions.

Oxygen Concentration Sensor Port

Breathing Pressure Sensor Port

Breathing Volume Sensor Port

Ventilator Port

Pipeline Gauge, Pipeline inlet

Breathing Bag

Flowmeter Level Indicator

Indicates Direction

Total Power Applied

connection for equipotential bonding

Partial Power Applied

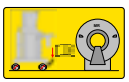
Cylinder Gauge, Remote Cylinder Inlet

Do Not Oil

ESD warning symbol:
Do not touch contacts of interface if not electrostatically discharged.

No known hazards in a specified MR environment with specified conditions of use.

Distance to MRT magnetic strength ≤40 mtesla (400 gauss)



Device central brake has to be locked at the desired position beside the MRI immediately!

Use only MR labeled cylinders

Do not use any type of Desflurane vaporizer in MR environment


external non-rebreathing system


Consult Instructions for Use

Use-by date


Observe leakage current


Transportation label,see page 119


CO_2 absorbent bypass


Vaporizer plug-in system

O_2-Flush

The following symbols are used on the Fabius MRI monitoring user interface.


Upper and Lower Alarm Limits


Return to Home Screen


Suppress Alarm Tone for Two Minutes


Suppress Alarm Tone for Two Minutes*


Standby Mode

Available Operating Capacity of UPS


Close Menu, Back to Previous Menu


Upper Alarm Limit


Lower Alarm Limit


Mains Applied/Mains Power


Alarm Off

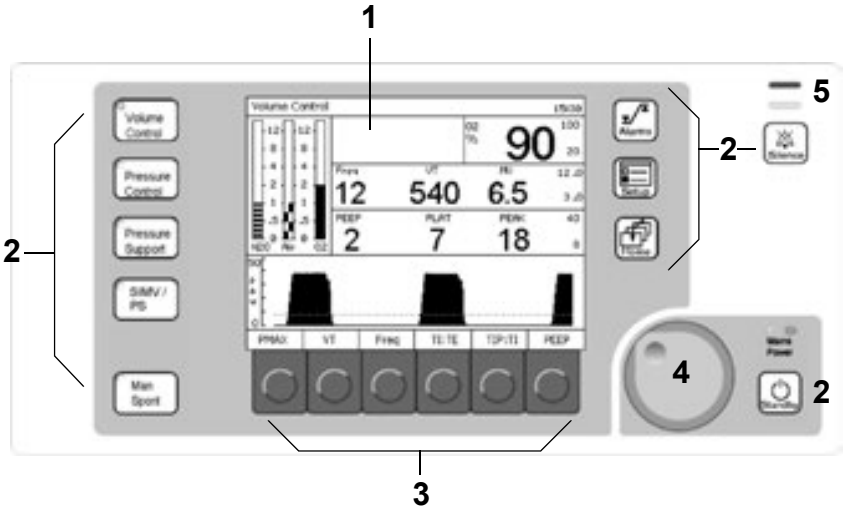

Alarm Off*


Setup Screen

* as of SW 3.20

Operation Concept

Control Panel



The control panel on the Fabius MRI is characterized by a small number of elements, clear layout, and ease of operation.
Its main elements are:

1 A screen displaying all monitoring and ventilation information in numeric and graphic form

2 Fixed-function (“hard”) keys beside the screen for quick access to major functions

3 Keys with variable functions (referred to as “soft keys” in this manual)

4 Rotary dial knob for selecting and confirming screen settings.

5 LED indicators

All controls and LEDs are described in detail beginning on page 40.

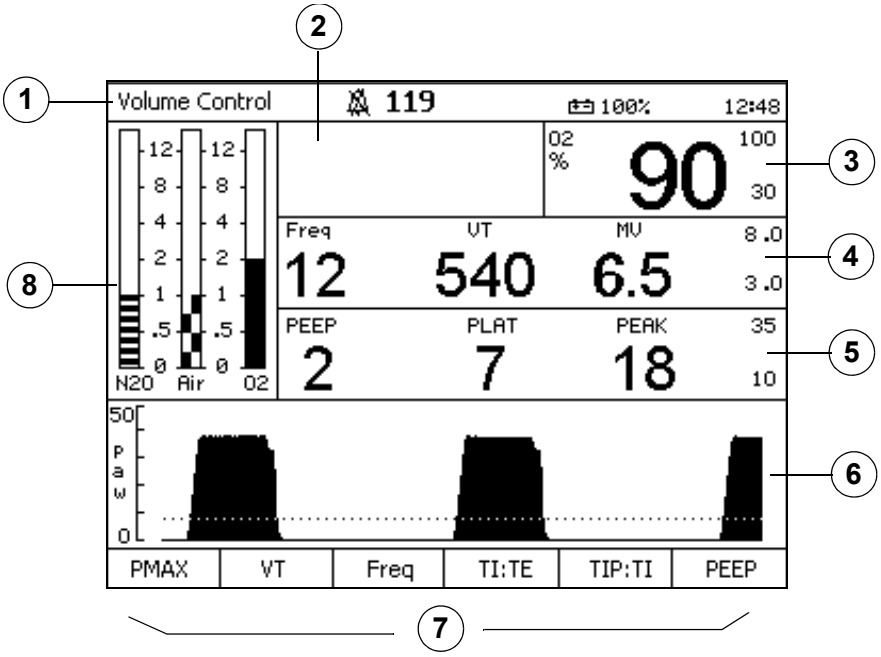
NOTE

On U.S. machines, the following fixed function keys are labeled with text in addition to the graphical symbols: »**Alarms**«, »**Setup**«, »**Home**«, »**Silence**«, and »**Standby**«. Non-U.S. machines have graphical symbols only.

NOTE

Screens depicted in this manual show the U.S. screens in order to avoid unnecessary duplication of illustrations.

The Screen Display



500

The screen shows status, ventilation, and monitoring data at a glance. The various screen pages use largely the same layout to enable the user to find information quickly.

1 Status bar displays the following status information (from left to right):
- Current ventilation mode
- Time remaining in the alarm silence period
- Status of reserve battery power
- Current time

2 Alarm window which displays up to four of the highest priority alarms.

3 Oxygen monitoring window which displays the inspiratory oxygen concentration in percent (%) along with high and low alarm limits

4 Respiratory volume monitoring window which displays the patient's respiratory rate in breaths per minute (Freq), tidal volume (V_T), minute volume (MV), and the minute volume high and low alarm limits

5 Breathing pressure monitoring window which displays the patient's positive end expiratory pressure (PEEP), mean or plateau airway pressure (MEAN or PLAT), and peak airway pressure (PEAK) in cmH_2O (hPa) with high and low alarm limits.

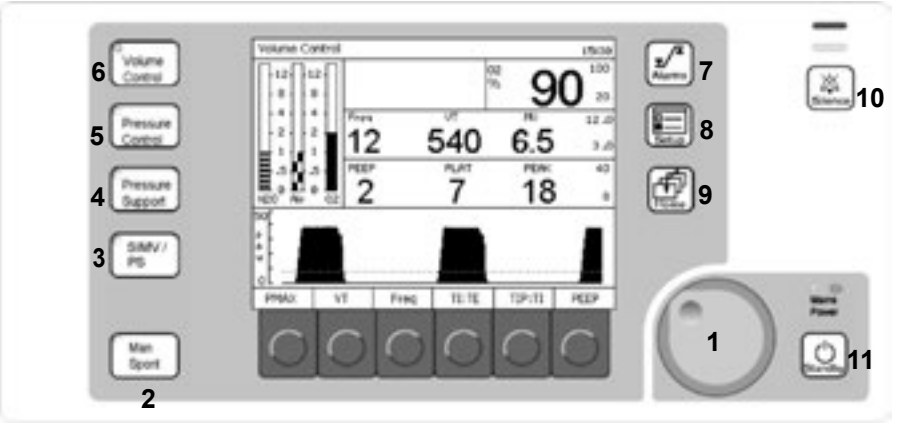
6 Breathing pressure trace window which displays a trace (waveform) of the patient's breathing pressure

7 Soft key labels

8 Flow Meter Monitor Window which displays a graphical display of flow rates for O_2, AIR, and N_2O in L/min

NOTE

On some Fabius MRI units, the positions of the O_2 and N_2O virtual flow tubes are reversed.



566

Rotary Knob

1 The rotary knob is the main control used to select and confirm all monitoring and system settings.

– **Turn** the rotary knob to change or select a value or parameter (clockwise rotation increases a value; counterclockwise rotation decreases a value). This function is indicated in the examples and instructions in this manual by “select.”

– **Press** the rotary knob to set a value or confirm a selection. If the selection is not confirmed, the value or parameter will not change. This function is indicated in the examples and instructions in this manual by “confirm.”

Fixed Function Keys

The fixed function keys positioned on both sides of the screen provide access to major machine and monitoring functions. Most fixed function keys must be confirmed by pressing the rotary knob.

2 The »**ManSpont**« key selects the Manual/Spontaneous ventilation mode.

3 The »**SIMV/PS**« key is used to select the SIMV/PS ventilation mode (optional).

4 The »**Pressure Support**« key is used to select the Pressure Support ventilation mode (optional).

5 The »**Pressure Control**« key is used to select the Pressure Control ventilation mode.

6 The »**Volume Control**« key is used to select the Volume Control ventilation mode.

7 The » « key (**Alarms)** displays the Alarm Limits window.

8 The » « key (**Setup)** provides two different functions, depending on mode:

– If pressed during Standby mode, it displays the Standby Setup screen which enables the user to define site defaults and configure system settings (see page 138).

– If pressed during a ventilation mode, it allows the user to view and change monitoring settings

9 The » « key (**Home)** displays the main screen from any other screen currently displayed

10 The » « key (**Silence)** silences all active alarm tones for two minutes.

11 The » « key (**Standby)** switches the machine to standby mode. Monitoring and alarms are turned off and the ventilator stops. Fresh gas monitoring continues.

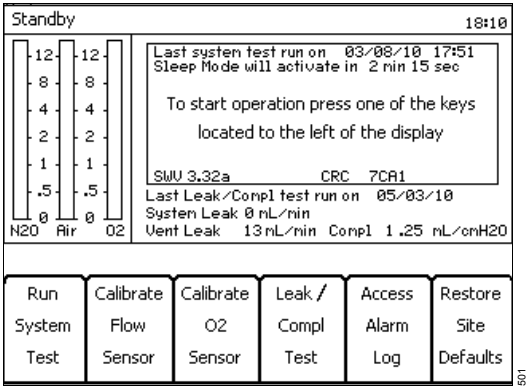
Soft Keys

The functions of the six soft keys located below the the screen are indicated by the labels shown above each key. The labels change depending on the current mode:

1 In Standby mode, the following soft key labels appear at the bottom of the Standby screen:

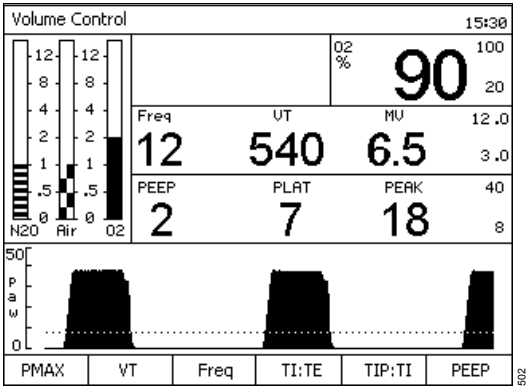
– »**Run System Test**«
– »**Calibrate Flow Sensor**«
– »**Calibrate O2 Sensor**«
– »**Leak / Compl Test**«
– »**Access Alarm Log**«
– »**Restore Site Defaults**«

See “Configuration Functions in Standby Mode” on page 138 for complete information.



1

2 In any ventilation mode, the soft keys labels show the ventilation parameters and functions that are available in that particular ventilation mode (Volume Control mode parameters are shown in the example illustration).



2

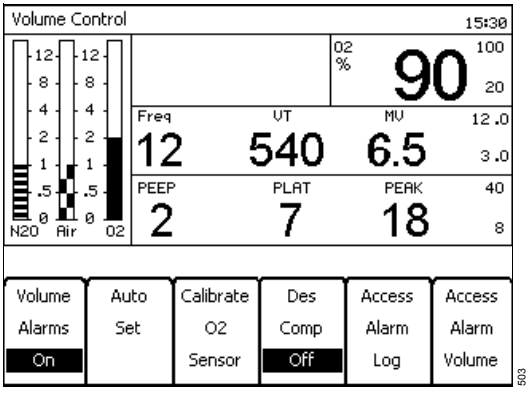
3 If the »[≡]« key (**Setup)** is pressed in any ventilation mode, the following soft keys appear at the bottom of the screen:

– »**Volume Alarms On/Off**«
– »**Auto Set**«
– »**Calibrate O2 Sensor**«
– »**Des Comp On/Off**«
– »**Access Alarm Log**«
– »**Access Alarm Volume**«

NOTE

The »**Volume Alarms On/Off**« soft key label does not appear in ManSpont mode because it is selectable on the ManSpont screen.

See “Configuration during Operation” on page 159 for complete information.



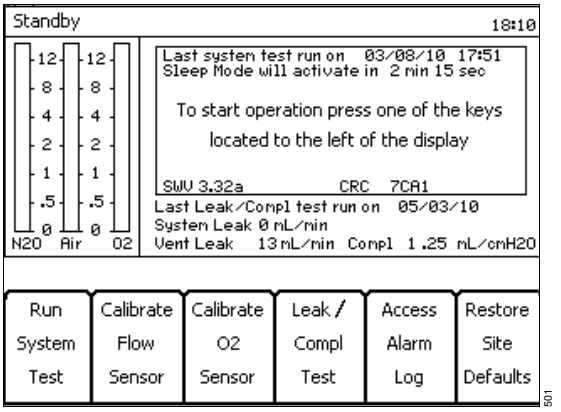
3

Selecting/Setting Monitoring Functions

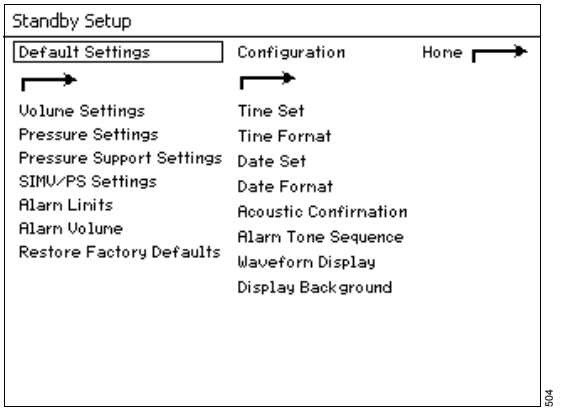
The following example describes changing alarm limits in the Standby Setup Screen.

Example:

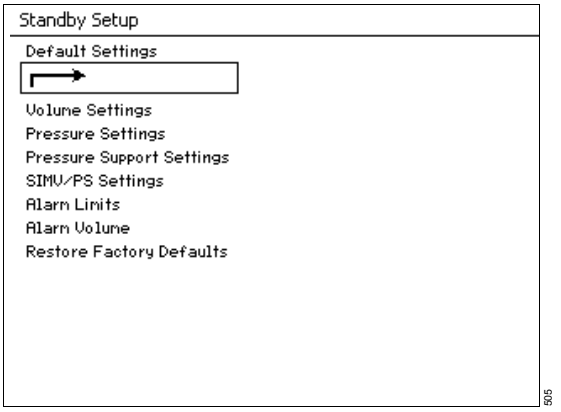
- Press the » ⏻ « key (**Standby)** and confirm to display the Standby screen.



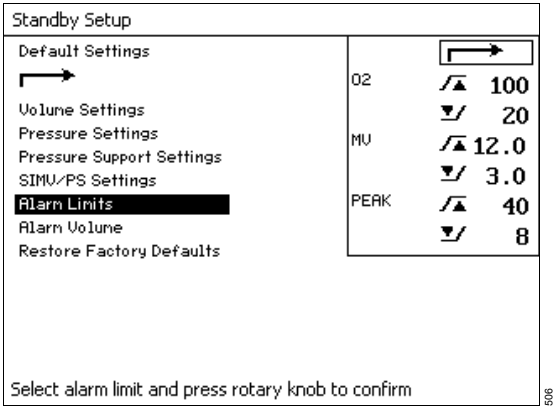
- Press the » ☰ « key (**Setup)** and enter the desired password to display the Standby Setup screen. (Selecting and confirming the return arrow on the right of the Setup screen will exit the Standby Setup screen and redisplay the Standby screen.)



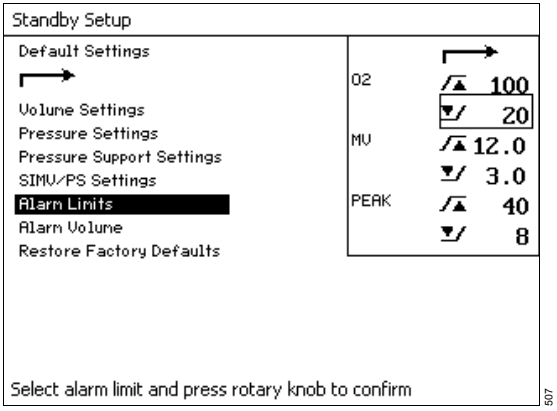
- The rotary knob enables you to select the »**Default Settings**« or »**Configuration**« label. Select and confirm the »**Default Settings**« label. The Default Settings column is selected. (Selecting and confirming the return arrow will exit the Default Settings column and redisplay the main Setup screen.)



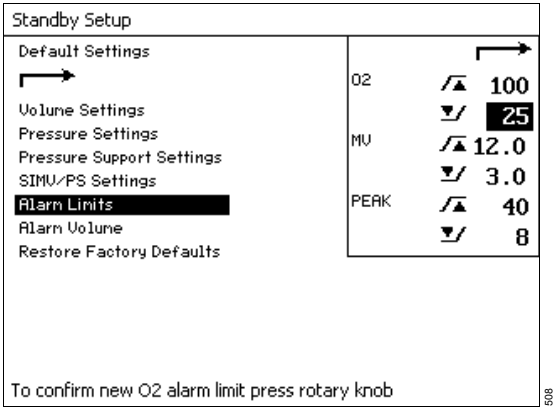
- Select and confirm the »**Alarm Limits**« label. The Default Alarm Limits window appears.



- Select the alarm limit value that needs to change.



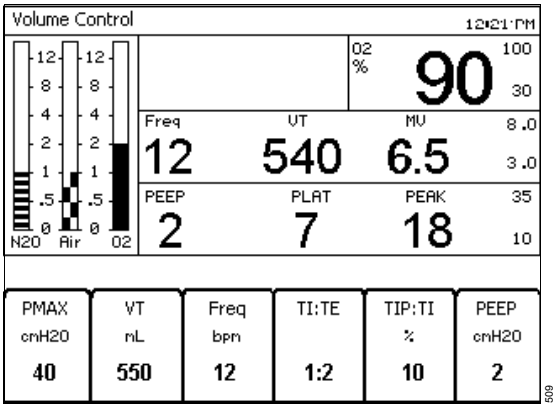
- Confirm the alarm limit value and select a new value. (For example in the illustration on the right, the alarm limit was changed from 20 to 25.)
- Confirm the new value for the alarm limit. The new alarm limit is saved and cursor moves to the return arrow.



Selecting/Setting Ventilation Parameters

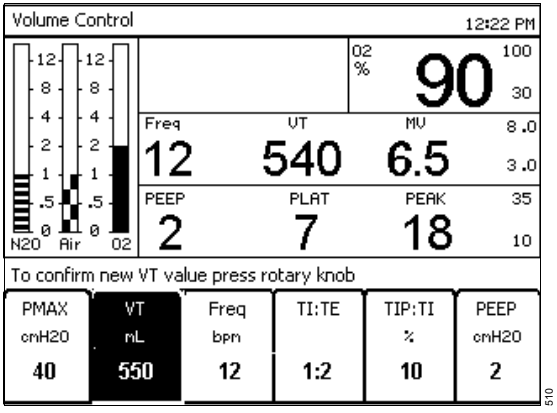
The following example describes changing the VT (tidal volume) parameter in Volume Control mode:

1 In Volume Control mode, press the »**Volume Control**« key. The Volume Control Ventilation Settings window replaces the Waveform window.



1

2 Press the »**VT**« soft key. The key becomes highlighted.



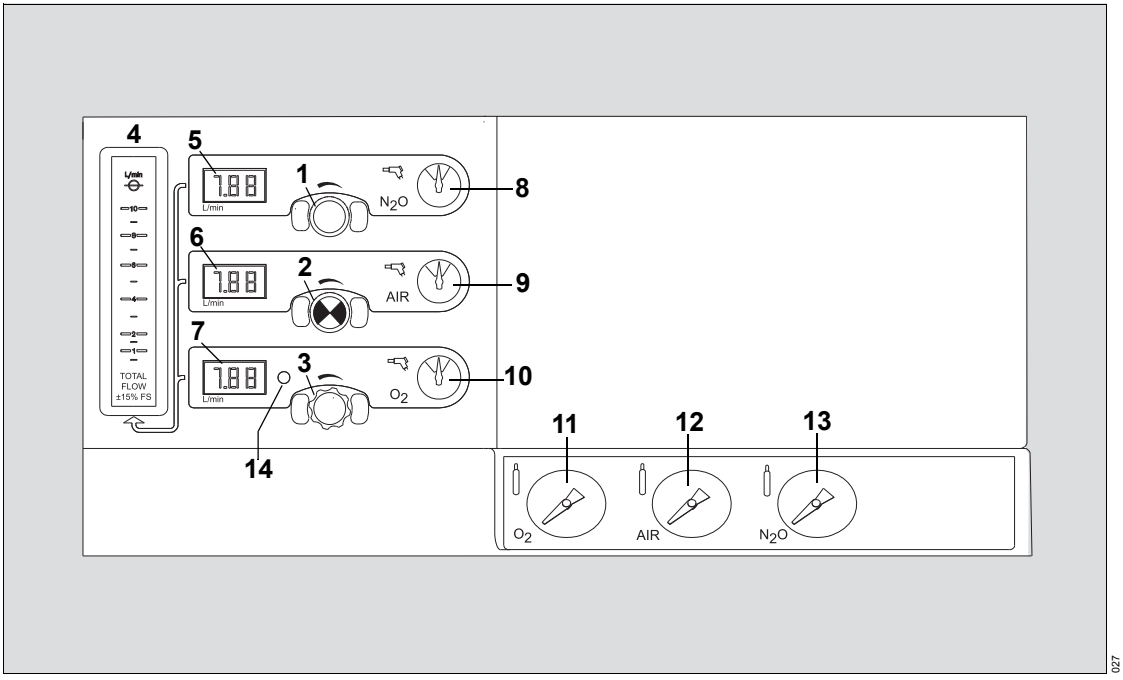
2

- Select a new value.
- Confirm the new value.

NOTE

There is a 15-second timeout period for making ventilation mode changes, with a 3-tone audible sequence after the first 10 seconds. If the new setting is not confirmed within the timeout period, the current ventilation setting remains in effect and the Ventilation Settings window returns to the Waveform window.

Fresh Gas Control



The Flow Meter and Pressure Gauge assembly is located on the front panel of the machine below the screen. There are three control knobs for the adjustment of N_2O, AIR, and O_2. The knobs are labeled and color-coded, see page 48. The O_2 control is also touch-coded with a fluted knob.

– To increase flow, turn the appropriate flow control knob counterclockwise.
– To decrease flow, turn the appropriate flow control knob clockwise.

1 N_2O flow control valve
2 AIR flow control valve
3 O_2 flow control valve
4 Total flow meter which displays the flow measurement of all applied gases combined
5 N_2O electronic fresh gas flow indicator
6 AIR electronic fresh gas flow indicator
7 O_2 electronic fresh gas flow indicator
8 N_2O central supply pressure gauge
9 AIR central supply pressure gauge
10 O_2 central supply pressure gauge
11 O_2 cylinder pressure gauge*
12 AIR cylinder pressure gauge*
13 N_2O cylinder pressure gauge*
14 O_2 Low Supply Pressure Alarm LED which flashes when the supply is below the factory set minimum pressure, nominally 20 psi (1.4 kPa x 100).

The displayed fresh gas flow ranges from 0 L/min to 12 L/min. In case of a greater fresh gas flow, the electronic fresh gas flow indicator (**5**, **6**, **7**) is blinking and in the flow meter monitor window appears the sign "**+**" above the graphical display of the flow rates.

NOTE

The electronic fresh gas flow meter is altitude-corrected.

* Only used with Pin-Index connectors (not present with threaded connectors).

Total Flow Meter

NOTE

The total flow meter is calibrated for a 50/50 mixture of N_2O and O_2. The accuracy of the flow meter may degrade with other gas mixtures. (See the Technical Data section for specifications.)

The total flow meter serves two purposes. The total flow meter provides a reference of the total fresh gas applied to the breathing circuit. (Flow rate measurements for each individual gas, N_2O, AIR and O_2, are provided by their respective electronic flow indicators.)
Should a fault develop in the electronic flow sensing, digital display, or power circuitry, the total flow meter is still functional. The measurement will indicate the total flow rate prior to the fault condition.
To adjust the fresh gas ratios while under the fault condition, shut off all flows (O_2 may be left on), and then restore each gas flow individually. For example, start with 2 L/min O_2. The total flow meter will read 2 L/min.
If 1 L/min of N_2O is needed, open the N_2O flow control knob until the total flow meter reads
3 L/min: 2 L/min O_2 plus 1 L/min N_2O.

Fresh Gas Flow Monitoring Resolution

The Fabius MRI can be configured by DrägerService or your local authorized service organization to display fresh gas flow rates either in a standard resolution mode or in a high resolution mode:

1 If **standard resolution** is configured, the electronic fresh gas flow indicators support 100 mL/min increments (format xx.x L/min), and the flow meters on the monitor screen indicate a range of 0 to 12 L/min.

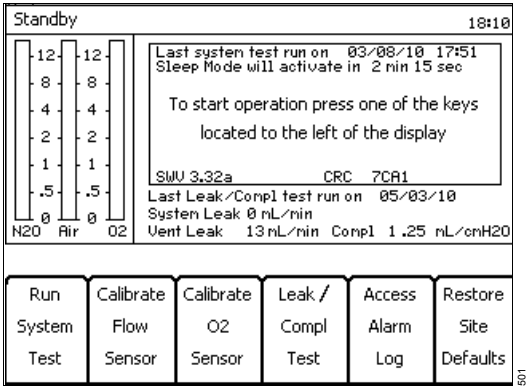
2 If **high resolution** is configured, the electronic fresh gas flow indicators support 10 mL/min increments (format x.xx L/min), and the flow meters on the monitor screen indicate a range of 0 to 10 L/min with an emphasis on resolution at the lower end of the scale.

High-resolution data is displayed when all individual gas flows are below 9.99 L/min.

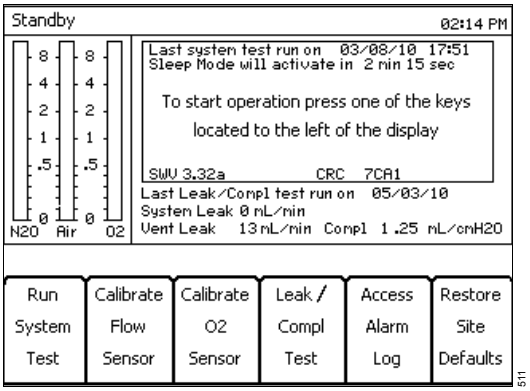
Switching to standard resolution occurs when the highest flow rate is greater than 9.99 L/min.

Switching to high resolution occurs when the highest flow rate drops below 9.00 L/min.

1



2



LED Indicators

A number of LED indicators are located on the front of the machine.

1 Mains Power LED is illuminated when the machine is connected to a Mains power source

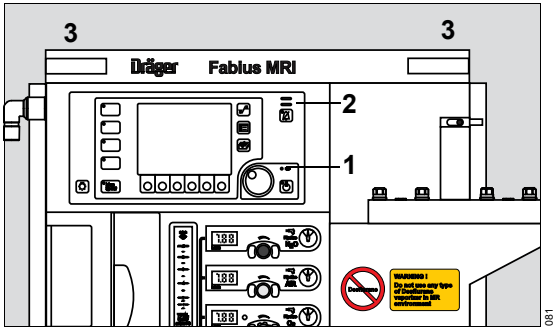
2 Alarm LEDs are illuminated to indicate the degree of urgency of currently active alarms:

– **Warning**: red blinking

– **Caution**: yellow blinking

– **Advisory**: yellow continuous

3 Two additional sets of alarm LEDs are located at the top of the monitor housing. These LEDs are illuminated during the same Warning and Caution alarm conditions as the front panel LEDs (**2**), but are visible from longer distances and various vantage points.



In addition, there are small LEDs on the Standby key and all the ventilation mode keys to indicate the currently active mode.

Gas System Color Coding

Each connection, valve, gauge, and flow meter on the Fabius MRI is color-coded for the appropriate gas, as shown the table below:

Gas	USA	ISO
AIR	Yellow	Black/White Checkered
N_2O	Blue	Blue
O_2	Green	White

Screen Color Concept

The Fabius MRI displays screen elements such as soft keys, alarms, virtual flow tubes, and screen backgrounds in different colors for improved visibility.

Assembly

WARNING

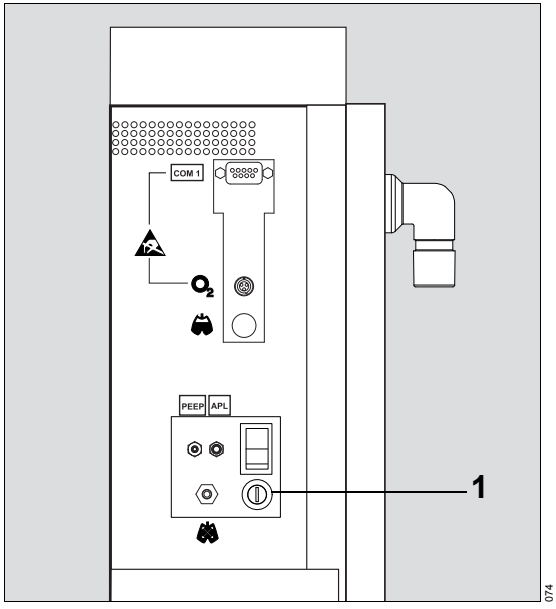
For operation in magnetic fields the combination of vaporizers, anesthesia workstation, and MRI scanner must be tested by experts (trained and factory authorized technical service representatives for anesthetic machines and MRI scanners) prior to the first use to ensure proper vaporizer and interface function in the specific magnetic fields. Otherwise uncontrolled concentrations, leakage, and/or malfunction of the interlock system may occur. The testing has to take into consideration all positions of the anesthesia workstation, including the vaporizer, in which it will operate in the MRI environment during daily use. Additionally, it is necessary to check if the imaging of the MRI scanner is adversely affected by the vaporizer and the anesthesia workstation.

Activating the Battery

The Fabius MRI anesthesia machine is shipped with the battery fuse disconnected in order to prevent discharge during shipment and storage prior to installation.

- Remove the battery fuse from the top drawer of the machine.
- Remove the battery fuse from its packaging.

1 Insert the battery fuse into the battery fuse holder. Turn the fuse holder 1/4-turn clockwise until it is snug.



Fitting the CO_2 Absorber on the Compact Breathing System

- Fill the absorber with fresh CO_2 absorbent. Dräger recommends the use of Drägersorb 800 Plus or Drägersorb FREE. For detailed information on filling and installing the reusable absorber, see page 197.

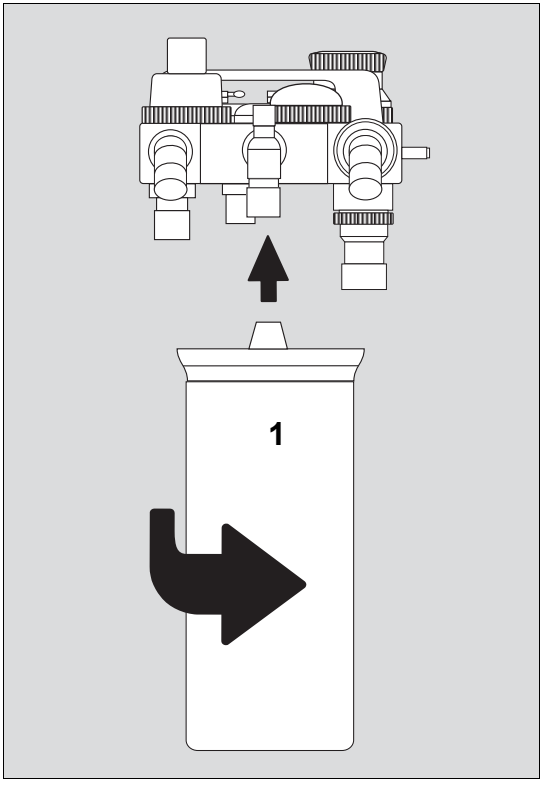
CAUTION

Risk of unintended perioperative awareness
Make sure that during ventilation the absorber canister is tightly connected to the COSY.

NOTE

Ensure that no CO_2 absorbent dust/particles have been deposited between the gaskets and sealing surfaces. Such dust and particles can cause leaks in the system.

1 Fit the absorber canister into position below the breathing system and turn it counterclockwise as far as possible.



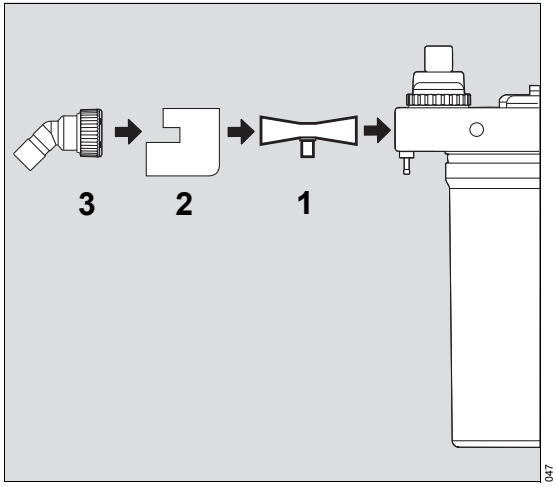
Inserting the Flow Sensor

- Unscrew and remove the expiration port and the flow-sensor guard (flow sensor protection).

1 Insert the flow sensor.

2 Reinstall the flow-sensor guard.

3 Reinstall the expiration port .



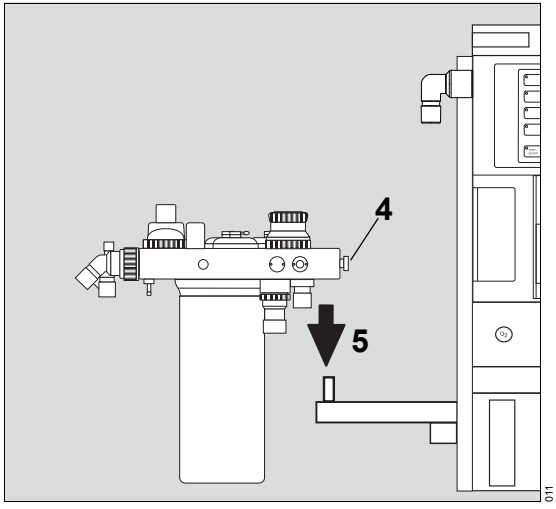
Connecting the Compact Breathing System

4 Pull out locking bolt to its full extension and hold.

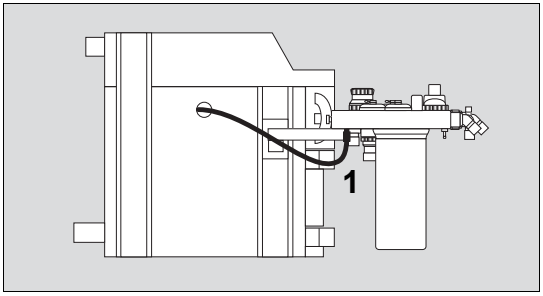
5 Fit the compact breathing system onto the compact breathing system mount.

- Release the locking bolt and rotate the compact breathing system until the locking bolt locks into position.

For information on filling and installing the reusable absorber, see page 197.

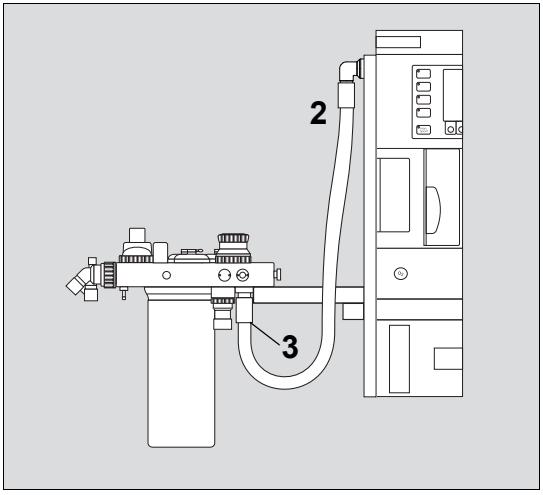


1 Connect the fresh gas hose from the Fabius MRI to the compact breathing system.



2 Connect the ventilation hose to the ventilator and

3 attach it to the conical connector ventilator port on the compact breathing system.



If the Fabius MRI is equipped with a threaded connector, the sealing rings on the threaded connector must be undamaged and clean.

Only hand-tighten the threaded connector. Do not use tools.

Installing the Drägersorb CLIC Adapter*

The disposable absorber:
– CLIC Absorber 800+,or
– CLIC Absorber Free, or
– Infinity ID CLIC Absorber 800+, or
– Infinity ID CLIC Absorber Free

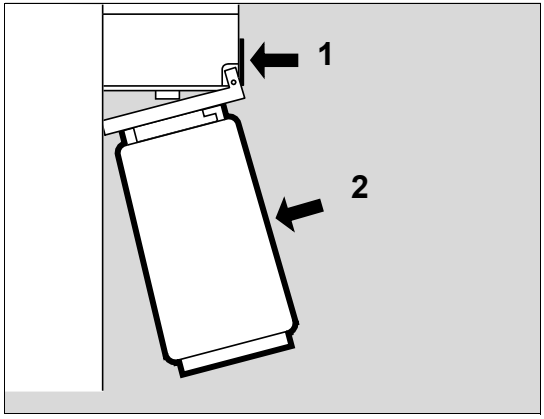
can be used on the Fabius MRI by using the Drägersorb CLIC adapter.
For information on installing the Drägersorb CLIC adapter, consult its Instructions for Use.

WARNING

The disposable absorber must be clicked into place before switching on the Fabius MRI, so that the absorber is included in the leak and compliance test for the machine.
Otherwise breathing circuit leaks could be undetected.

To click the absorber into place:
1 Press the button; the mounting swings open.
- Before fitting, shake the disposable absorber, e.g. by turning it upside down several times in order to loosen up the soda lime.
- Remove seal from new disposable absorber.
- Slide the new disposable absorber onto the mounting and

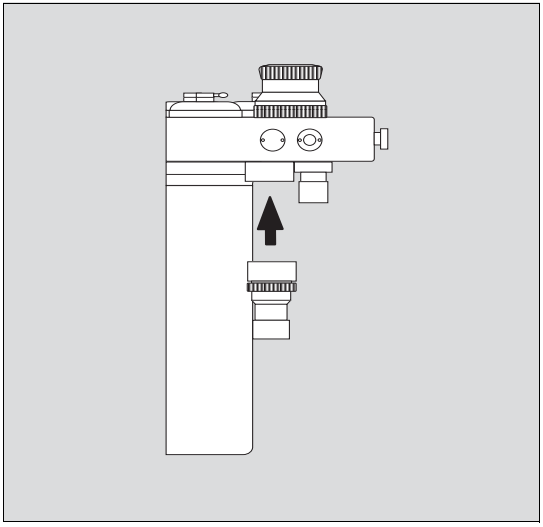
2 Push the disposable absorber in the direction of the machine until it engages.



* optional

Connecting the Waste Gas Outlet Port

- Screw the waste gas port into the compact breathing system from underneath.



048

Installing the Breathing Bag Extension and Bag*

WARNING

Do not install the Dräger flexible bag arm (P/N 8606462.) This arm contains magnetic parts and is not MR safe or MR conditional. This arm would be attracted to the MRT system which would create a risk of injury.

WARNING

Risk of use of toxic or incompatible materials

Breathing bags used on the Fabius MRI must comply with current National standards.

CAUTION

Risk of unintended perioperative awarness

Make sure that during ventilation the bag is tightly connected to the bag arm.

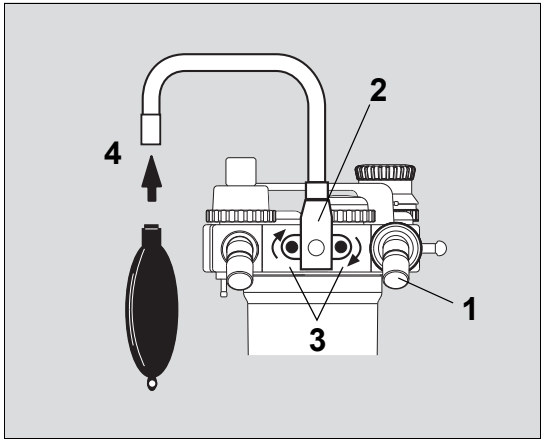
1 Remove the expiratory hose terminal from the breathing system.

2 Slide the breathing bag extension assembly onto the breathing bag port on the side of the breathing system.

- Align the bracket on the assembly with the holes on the breathing system.

3 Tighten the two thumb screws to secure.

4 Attach the breathing bag to the end of the breathing bag extension.



* optional

Connecting Pipeline Supply of N_2O, AIR and O_2

WARNING

Carefully check hoses each time you connect a machine to a wall outlet to ensure that both ends of the hose are indexed for the same gas. Pipeline delivery hoses used between wall outlets and anesthesia machines have caused accidents when, during assembly, an oxygen fitting was placed on one end of the hose and a nitrous oxide fitting on the other end.

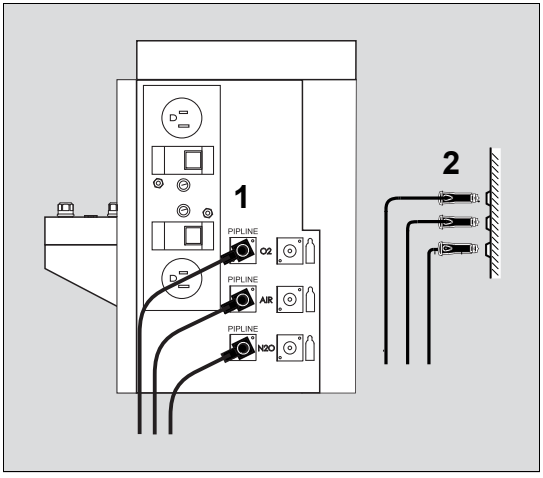
1 Connect the gas fitting on each pipeline supply hose to the corresponding fitting on the rear of the machine.
2 Connect the other end of each pipeline supply hose to the appropriate functioning wall outlet.

CAUTION

To ensure that gas supplies are at adequate pressure, pipeline pressure gauges must indicate steady pressures of between 41 and 87 psi (2.8 and 6 kPa x 100).

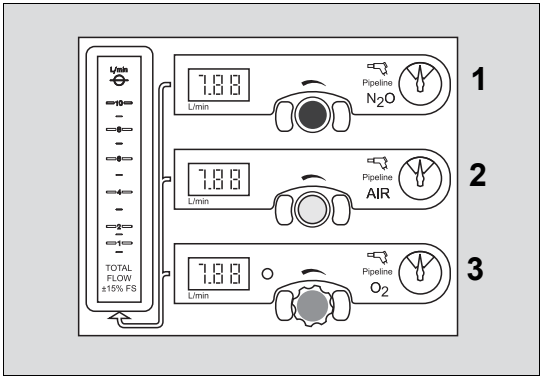
NOTE

The loss of the pipeline supply could cause the loss of combined devices.



Pipeline Pressure Gauges

Pipeline pressure gauges for N_2O (**1**), AIR (**2**), and O_2 (**3**) are standard. These gauges are located directly to the right of their corresponding flow control valves. A typical pressure gauge and flowmeter assembly is shown in the figure.



Connecting the Reserve Gas Cylinders for N_2O, AIR and O_2 (for Pin-Index Mounting)

WARNING

Use only non-magnetic (e.g., aluminum) cylinders with the Fabius MRI. Steel cylinders will cause serious injury or death if brought into an MR scanning room.

WARNING

When attaching a cylinder, ensure that only one washer is installed between the cylinder and the yoke gas inlet. The use of multiple washers will inhibit the pin-index safety system. Be sure to verify the presence of the index pins each time a cylinder is installed. Never attempt to override the pin-index safety system.

WARNING

Do not oil or grease the O_2 cylinder valves and O_2 pressure regulator. There is a risk of explosion.

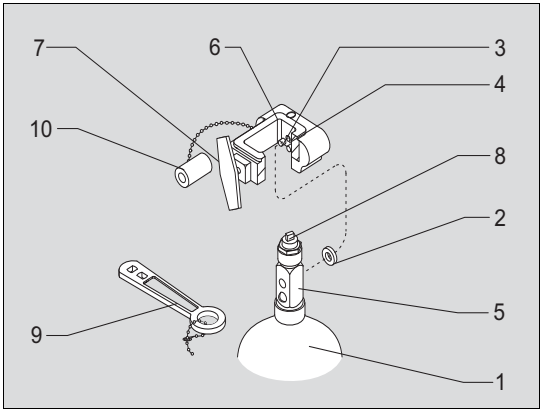
CAUTION

Even if the gas supply is connected to a medical gas pipeline, the cylinders should remain on the device in reserve.

NOTE

If cylinder valves are leaky or difficult to open or close, they must be repaired in accordance with the manufacturer’s specifications.

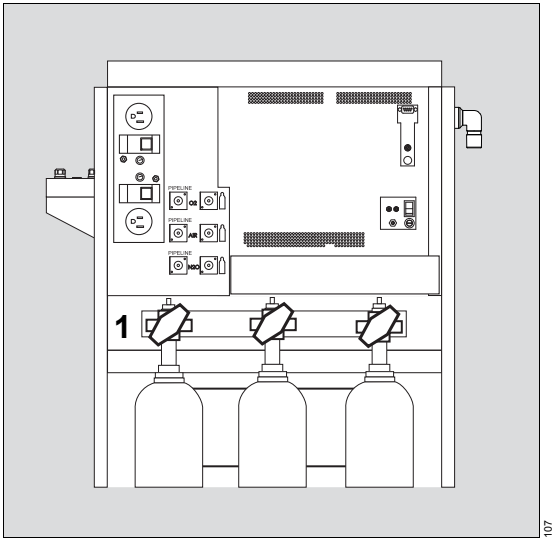
- Connect a gas cylinder (**1**) to its yoke as specified below:
- Remove the old washer (**2**) and install a new washer on the seat of the yoke gas inlet connection.
- Verify that the two index pins (**3**) below the gas inlet (**4**) are present.
- Insert the head (**5**) of the gas cylinder into the yoke from below. Ensure that the gas outlet and indexing holes on the cylinder head align with the gas inlet and index pins of the yoke assembly (**6**).
- Engage the indexing holes with the index pins.
- Turn the yoke handle (**7**) clockwise against the cylinder head, so that the point of the yoke handle bolt is aligned with the indent on the back of the cylinder head. Verify that the washer is in place, the index pins are engaged, and the cylinder hangs vertically.
- Tighten the yoke firmly.
- When required, the cylinder valve (**8**) is opened using the cylinder wrench (**9**) that is provided.
- When a cylinder is removed, place the yoke plug (**10**) in the yoke assembly and tighten.



1 Open the cylinder valves.

- To ensure that the cylinder pressures are adequate, check that the cylinder gauges indicate pressures recommended in the table below.
- Close the cylinder valves.

Cylinders attached to the hanger yokes must contain gas at the recommended pressures shown in the table below. (Indicated pressures are for E-size cylinders at 70 °F/21 °C.) Cylinders measuring less than the minimum recommended pressure (PSI - MIN) should be replaced with new, full cylinders.



Gas	PSI/kPa x 100 - FULL (typical full load)	PSI/kPa x 100 - MIN
AIR	1900/131	1000/69
N_2O	745/51	600/42
O_2	1900/131	1000/69

Dimensions of Usable Cylinders

E-size Pin-Index Cylinder	
4.7 L	Height 25.5 in (654 mm) Diameter 4.3 in (111 mm)
D-size Pin-Index Cylinder (without valve)	
4.0 L	Height 25.5 in (654 mm) Diameter 4.3 in (111 mm)
2.8 L	Height 16.5 in (419 mm) Diameter 4.3 in (111 mm)

Connecting the Reserve Gas Cylinders for N_2O, AIR and O_2 (for Cylinders with Threaded Connectors)

WARNING

Use only non-magnetic (e.g., aluminum) cylinders with the Fabius MRI. Steel cylinders will cause serious injury or death if brought into an MRI scanning room.

WARNING

Risk of explosion

Do not oil or grease the O_2 cylinder valves and O_2 pressure regulator.

CAUTION

Use only non-magnetic, MR compatible-marked pressure regulators for cylinders with threaded connectors.

CAUTION

Even if the gas supply is connected to a medical gas pipeline, the cylinders should remain on the device in reserve.

NOTE

If cylinder valves are leaky or difficult to open or close, they must be repaired in accordance with the manufacturer's specifications.

NOTE

The cylinder valves must only be opened or closed manually. Never use tools

NOTE

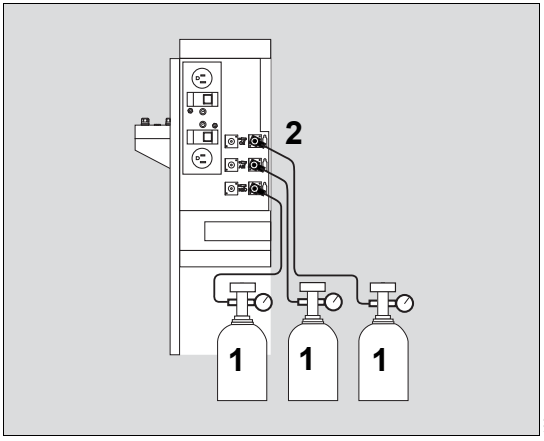
Backup gas cylinders should remain closed when not in use. Risk of unintentional emptying of cylinders

1 Place the full cylinders in the cylinder holders and secure them in position.

- Screw the pressure regulators onto the cylinder valves.

2 Screw the compressed gas hoses to the pressure regulators and to the connections of the gas inlet block.

- Open the cylinder valves.



Connecting the AGSS Anesthetic Gas Scavenging System*

Every Anesthetic Gas Scavenging System (AGSS) used on the Fabius MRI must follow ISO standard 8835-3.
The scavenging system is used with vacuum waste-gas disposal systems.
The AGS is not applied as an independent system. It is used as one of the three components of the AGSS.

WARNING

Risk of patient injury

If the side openings of the receiving system are blocked, negative pressure may result in the breathing system and the patient's lungs. Always make sure the side openings of the receiving system are not blocked.

NOTE

The scavenger hoses must not be pinched, kinked, or blocked in any manner.

NOTE

Remove the socket from the scavenger hose before connecting.

* optional

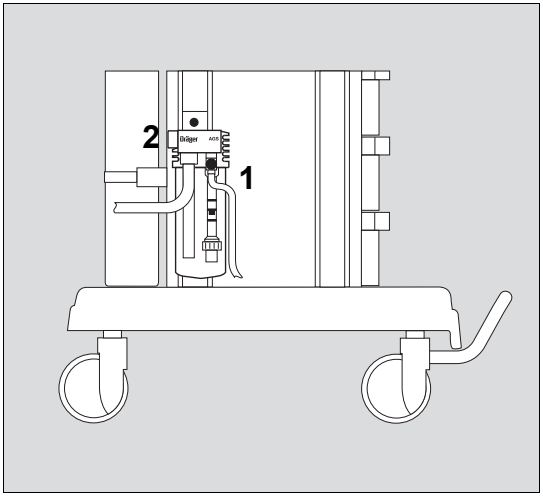
- Hook receiving system (AGS) with the slots over the appropriate pins of the basic device and allow it to slide down into place.

1 Connect the scavenging hose to the relevant socket of the receiving system.

- Connect the connector of the scavenging hose to the terminal unit of the disposal system.

2 Close the connection that is not used with a screw cap.

- Push the transfer hose on the designated socket.
- Connect the other end of the transfer hose to the waste-gas port located on the underside of the breathing system.



NOTE

Activate hospital vacuum system before using scavenger system.

NOTE

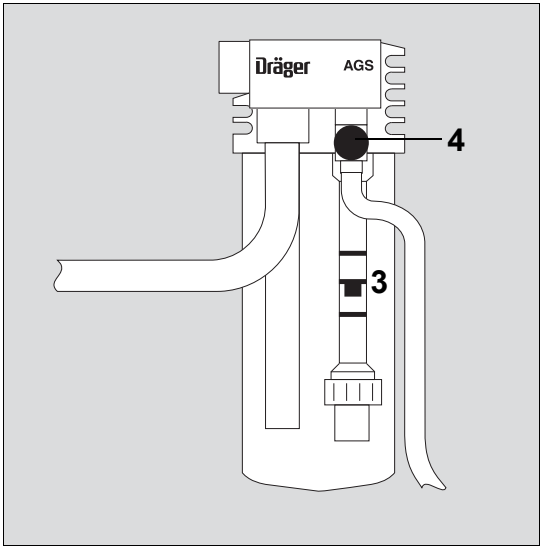
During use, the float indicator in the flow indicator (**3**) should stay between the upper and lower marks. If necessary, regulate flow using the optional flow adjustment valve (**4**).

WARNING

Danger to the patient

Do not cover the side openings of the receiving system. Otherwise there may be a shortage of fresh-gas in the breathing system.

For detailed information on the AGS, refer to the specific Instructions for Use provided with the anesthetic gas receiving system AGS (9038579).



Connecting the Suction System*

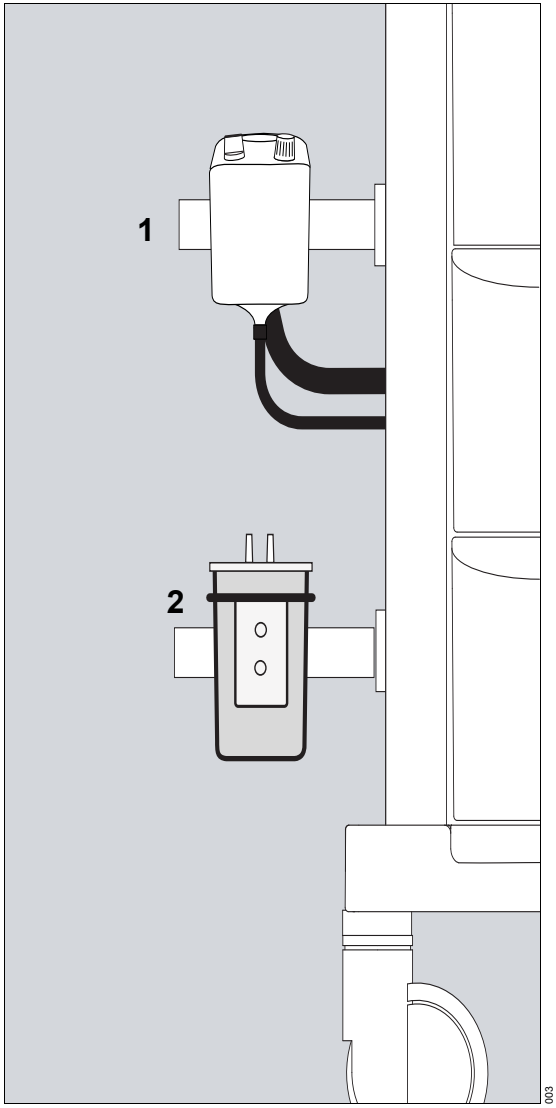
The optional suction system for the Fabius MRI consists of a suction regulator and a suction bottle system. The suction regulator is attached to a holder, which is fastened on the side channel on the anesthesia device. The suction bottle desired by the customer is attached to a separate swivel rail on the side channel.

- Attach the carrier arm of the suction system on the side channel on the side of the anesthesia device.

1 Mount the suction regulator onto the bracket.

2 Install the bottle assembly in the slide mount on the bracket.

- Prepare the suction system according to the Instructions for Use provided with the suction system.



Depending on the suction system used:

If air or O_2 is used as the driving gas:

- Secure the air connection hose of the suction system to the air outlet on the gas supply block (optional) or directly to the pipeline gas supply.

For vacuum-driven suction:

- Connect the vacuum hose of the suction system directly to the pipeline gas supply.

Check that the suction system is ready for operation according to the Instructions for Use provided with the suction system.

WARNING

Risk of equipment damage

The suction system should be used only in ManSpont mode or with the Y-piece disconnected.

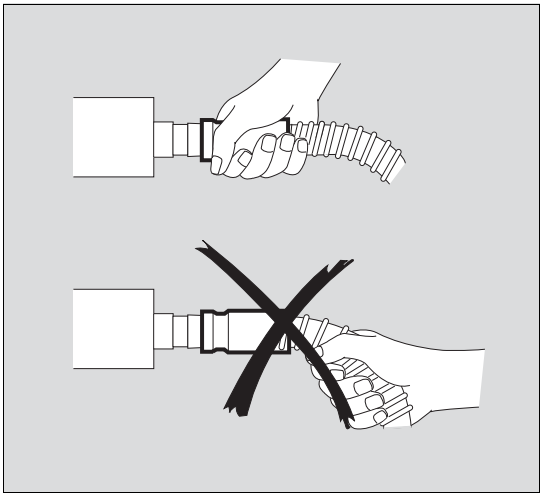
* optional

Connecting the Breathing Hoses and Breathing Bag

NOTE

Take care not to damage the breathing hoses.

When connecting and disconnecting, always hold the breathing hoses by the end sleeve, not by the spiral reinforcement. Otherwise, the spiral reinforcement may be torn loose.
Breathing hoses with a damaged spiral reinforcement can kink or become occluded.
Before each use, check the breathing hoses for damage.



WARNING

Risk of use of toxic or incompatible materials Breathing hoses used on the Fabius MRI must comply with current National standards.

WARNING

Do not use antistatic or conductive breathing hoses or masks. There is a risk of burns in the MRI environment or when using high frequency electrosurgical equipment.

WARNING

Do not use silicone breathing hoses. They are visible in MRI images and can be interpreted as an artifact.

Fabius MRI has no components containing latex.

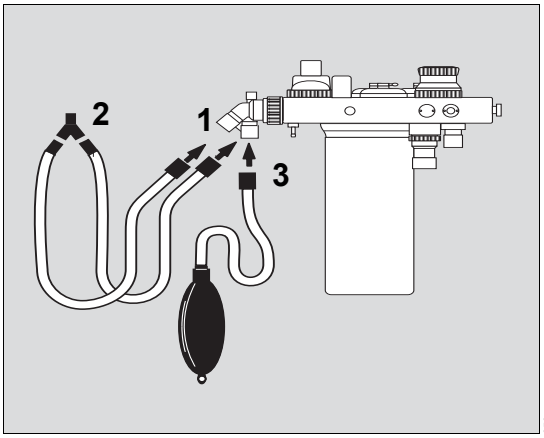
For latex-free use:

- Use latex-free breathing bag and breathing hoses!

1 Push patient breathing hoses onto both the inspiratory and expiratory connectors or onto optional microbial filters.

2 Connect both patient breathing hoses to the Y-piece.

3 Connect the breathing bag to the bag fitting on the breathing system.



WARNING

Risk of strangulation

Use caution when connecting the patient.

Instructions for Use of Bacterial Filters, Endotracheal Tubes, Y-pieces, Breathing Hoses, Soda Lime and other Breathing System Accessories

WARNING

When using accessories in breathing systems or configurations that deviate from standard hose systems, the inspiratory and expiratory breathing resistances may exceed normal requirements (e.g., extended hoses with lengths of 3 m (10 feet) used with MRI systems).
The user should exercise particular care and monitoring when using such configurations.

CAUTION

The reusable microbes filter 654 ST isoclic (part number 6733895) must be connected directly at the cosy side of the breathing tubes to avoid risk of image artifacts.

With increased breathing resistance, more effort is required on the part of the patient during spontaneous breathing. With volume-controlled ventilation, increased breathing resistance during inspiration has a negligible effect on the administered volume. The peak pressure is however increased during constant plateau pressure. Therefore, during the expiration phase, the time constant (RC) increases. When expiratory times are too short, this may result in the lungs not fully emptying, leading to dynamic lung air trapping. With pressure-controlled ventilation, increased airway resistances may result in reduced inspiratory or expiratory volumes.

Before performing the self-test on the device used, the accessory to be used for the application must first be connected. Expander hoses must be pulled out to the appropriate length in order for compliance to be accurately determined and, in the case of volume-controlled ventilation, for the correct tidal volume to be administered.
When using coaxial hoses, leaks between the inner and outer hoses cannot be detected during the self-test/leak test.

Resistance summation of the breathing system and connected accessories

In the chapter Technical Data, the inspiratory and expiratory breathing resistance of the breathing system is given without considering the breathing hoses. This allows for the determination of the resistance at the patient using different hose sets and/or filters.
To calculate the Resistance (R) use the following formula:

$$R_{Expiration} = R_{Breathingsystem\_exsp} + R_{ExpHose} + R_{ExpFilter}$$

$$R_{Inspiration} = R_{Breathingsystem\_insp} + R_{InspHose} + R_{BagHose} + R_{InspFilter}$$

Ensure that only accessory resistance data is used for system resistance calculation using the peak flow applicable for the accessory and patient category, e.g. for adults resistance data at 60 L/min, for children at 30 L/min, and for neonates at 5 L/min.

If a filter is used on the Y-piece, the resistance for the inspiratory and expiratory direction must be considered.

The standard for anesthesia breathing systems (ISO 8835-2:2007) allows an overall resulting pressure loss at 60 L/min of max. 6.0 cmH_2O (6.0 hPa) both inspiratory and expiratory.

- Refer to the Instructions for Use of the respective accessory.

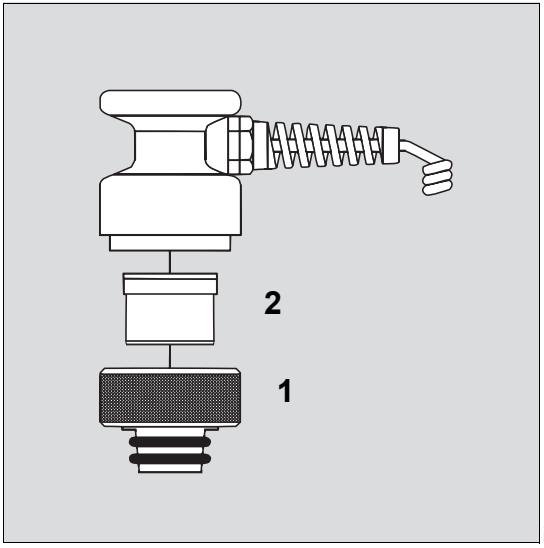
Inserting a new O_2 Sensor Capsule

1 Unscrew the cap from the sensor housing.

- Remove the new sensor capsule from its packaging.

2 Insert the capsule in the housing, with the ring-shaped conductors against the contacts in the housing.

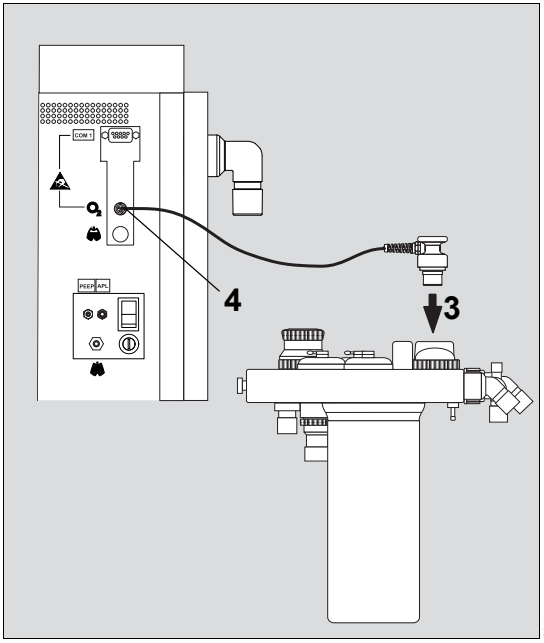
- Screw the cap on firmly by hand.



Connecting the O_2 Sensor

3 Push the O_2 sensor into the port opening of the inspiratory port dome, and

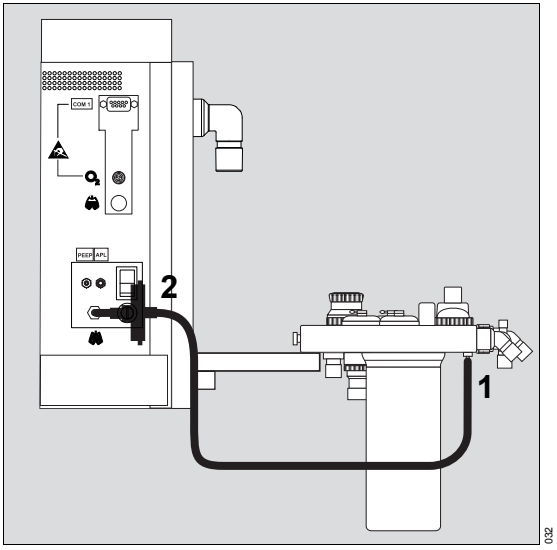
4 plug the connector into the fitting labeled O_2 on the connector panel on the back of the machine.



Connecting the Pressure Sensor

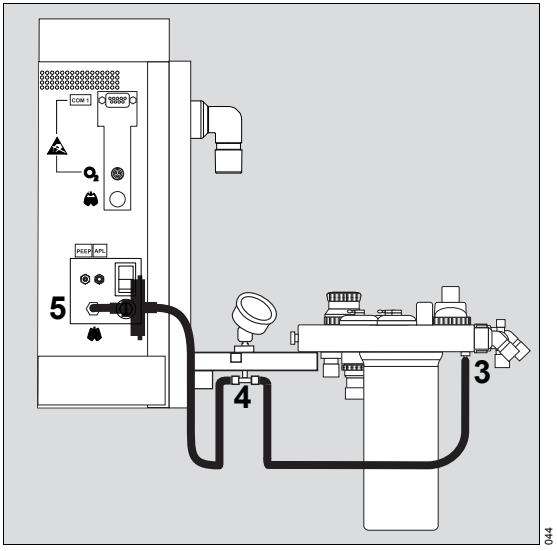
1 Press the pressure measuring line onto the hose barb on the underside of the breathing system until it engages.
Do not squeeze the pressure measuring line when pressing it onto the hose barb.

2 Connect the pressure measuring line to the bacterial filter, and plug it firmly onto the port labeled on the connector panel on the back of the machine.



Connecting the Breathing Pressure Gauge*

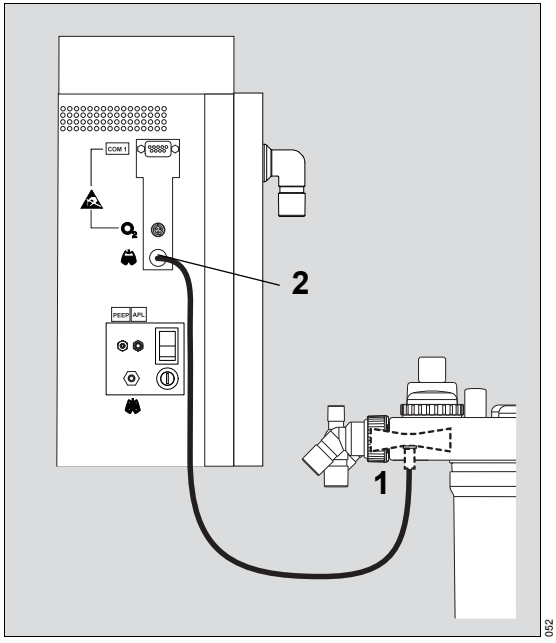
- Push the pressure measuring line onto the hose barb (**3**), the breathing pressure gauge port (**4**) to the pressure gauge connector, and then to the bacterial filter and onto the port labeled on the connector panel on the back of the machine (**5**).



* optional

Connecting the Flow Sensor

1 Connect the volume line cable onto the connector on the underside of the breathing system.
2 Connect the volume line cable to the port labeled on the connector panel on the back of the machine.

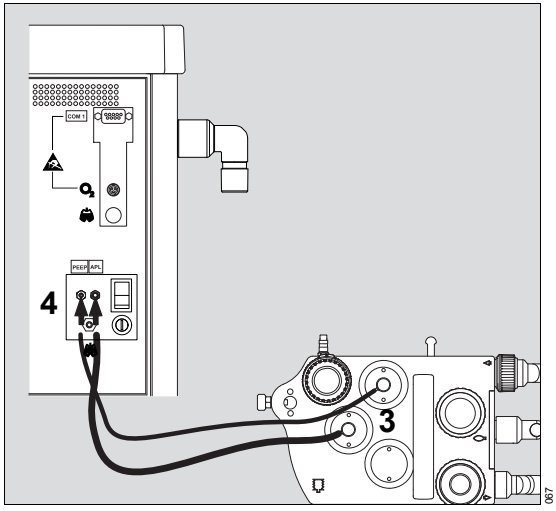


Connecting the APL Bypass and PEEP/PMAX Hoses

3 Plug the control hose to the connection port on the PEEP/PMAX valve and to the connection port marked PEEP on the connection panel.
4 Plug the control hose to the connection port on the APL Bypass valve and to the connection port marked APL on the connection panel.

NOTE

The APL bypass hose is larger than the PEEP/PMAX hose.



Preparing the Ventilator

Use only disinfected/sterilized components.

1 Open the ventilator door with the attached ventilator unit.

2 Unlatch the three clasps.

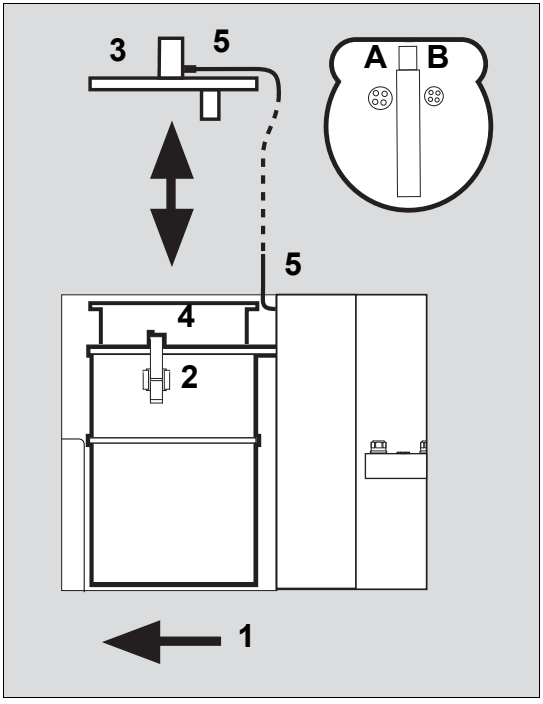
3 Remove the cover.

4 Insert the diaphragm.

- Fit the cover and lock the three clasps.

5 Connect pressure sensor line of the ventilator chamber to the respective connector.

1 Close the the ventilator door with the attached ventilator unit.



Ventilator Safety Features

– High pressure safety relief valve (**A**).
– Negative pressure safety relief valve (**B**).
– Ventilator chamber pressure sensor.

Installing Vaporizers

Install vaporizers as directed in the appropriate Instructions for Use supplied with the vaporizers available for use with the Fabius MRI.
The anesthetic vaporizer used with the anesthesia workstation shall comply with ISO 8835-4.
The anesthesia workstation must be used with anesthetic gas monitoring complying with ISO 21647, if an anesthetic vaporizer is used.

WARNING

Risk of injury

Vaporizers can be moved by magnetic attraction. Use only anesthetic delivery systems and accessories designed for use in magnetic fields.

WARNING

For operation in magnetic fields the combination of vaporizers, anesthesia workstation, and MRI scanner must be tested by experts (trained and factory authorized technical service representatives for anesthetic machines and MRI scanners) prior the first use to ensure proper vaporizer and interface function in the specific magnetic fields. Otherwise uncontrolled concentrations, leakage, and/or malfunction of the interlock system may occur. The testing has to take into consideration all positions of the anesthesia workstation, including the vaporizer, in which it will operate in the MRI environment during daily use. Additionally, it is necessary to check if the imaging of the MRI scanner is adversely affected by the vaporizer and the anesthesia workstation.

WARNING

Risk of spillage or mix-up

Use only suitable adapters for filling and emptying the vaporizer.

WARNING

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

WARNING

For operation in magnetic fields, it is not permitted to connect the vaporizer via hose connectors or tapered connectors with the anesthesia workstation.

WARNING

Risk of injury

Do not use ferromagnetic keyed filler or drain adapters or tools when the filling or draining procedure is carried out in magnetic fields. Ferromagnetic adapters or tools can be moved by magnetic attraction.

WARNING

Risk of injury

Vaporizers have to be mounted and removed outside of the MR room.

Do not exchange any vaporizer in the MR room.

Vaporizers can be moved by magnetic attraction.

WARNING

Risk of injury

Do not use filling adapters without a label "MRI". Adapters can be moved by magnetic attraction.

CAUTION

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

CAUTION

Risk of injury

Dräger metal keyed filler adapters and Dräger fill adapters are labeled with "MRI" are not ferromagnetic.

Connecting Auxiliary Equipment

- Prepare additional equipment as specified in the specific Instructions for Use.

WARNING

Risk of tip-over and personal injury

If monitors and other equipment are placed on top of the Fabius MRI, the risk of tipping over the unit is increased, especially when rolling over thresholds etc.

Remove all monitors and other equipment from the top of the Fabius MRI before moving the unit.

- Connect the equipment to the one of the auxiliary outlets on the back of the Fabius MRI

CAUTION

Risk of adversely affecting imaging of MRT.

Inside the MR room wired RS232 cables may not be used under any circumstances.

Use only the fiber optic cable set released by Dräger (part no. 8608376).

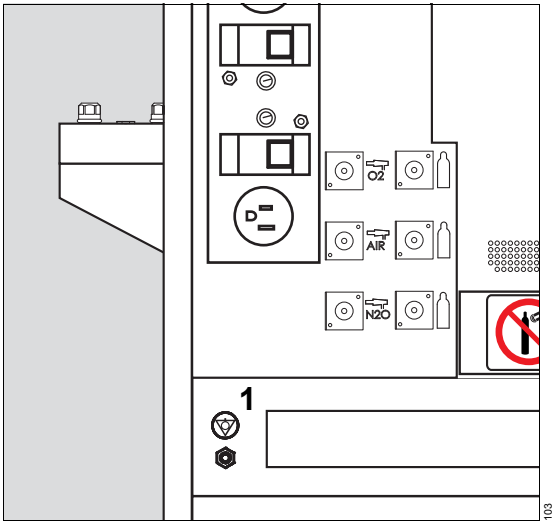
Equipotential Bonding

e.g. intra-cranial or intra-cardiac operations

- Use cable e.g. 83 01 349.

1 Connect the terminal on the back to an equipotential bonding point in the operating room.

- Connect one end of the earth cable to one of the connecting pins ⏚ located on the back of the Fabius MRI
- Connect the other end of the earth cable to the specified equipotential bonding point, e.g., on the operating table or ceiling lamp.
- Connect equipotential bonding to the auxiliary equipment



Auxiliary power outlets

In cases of a blown safety fuse for the auxiliary outlets:

– Remedy the fault
– Have the safety fuse replaced by an electrician

WARNING

The auxiliary outlets are not powered by the uninterruptible power supply (UPS) in the event of a power failure

WARNING

Risk of electric shock

Connecting equipment to the auxiliary power outlets may cause the patient leakage current to rise above the permitted values if a protective earth conductor should fail. The risk of electric shock cannot be excluded in such cases.

WARNING

Do not connect life-supporting devices to the auxiliary power outlets of the anesthesia workstation. The auxiliary power outlets are not powered by the uninterruptible power supply (UPS) in the event of a power failure.

WARNING

Risk of increased leakage current

Do not connect HF surgical devices to the auxiliary power outlets.

WARNING

Risk of increased leakage current

Additional power adapter outlets must not be connected to the auxiliary power outlets.

Positioning the Fabius MRI at MRT System

WARNING

The Fabius MRI anesthesia machine has been tested with magnets with field strengths of 1.5 tesla and 3 tesla by a fringe field strenth of 40 mtesla (400 gauss). Use of the machine at higher strengths could result in ventilator and device malfunction. Additionally, unmanageable attractive forces could lead to serious injury.

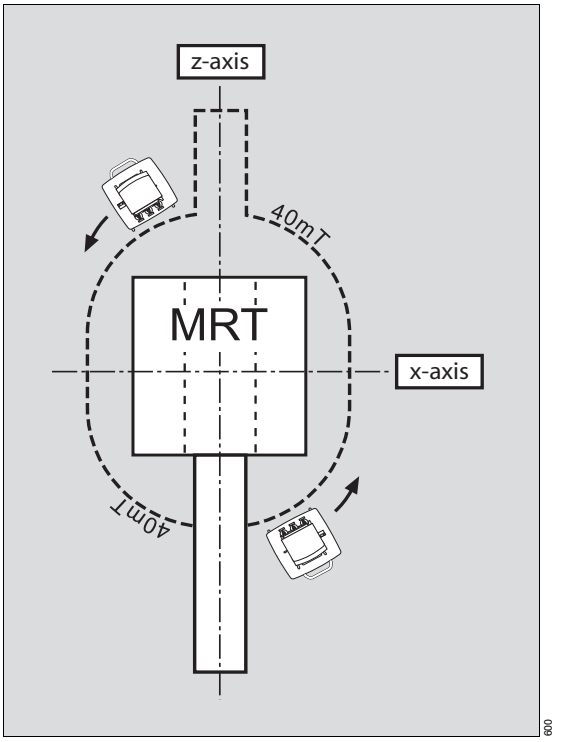
Preparation

Before first use of the Fabius MRI in the MRT room, perform steps as follows:

- Define the 40 mtesla (400 gauss) field strength distribution in Z and X direction by using an external Tesla meter.
- Locate the desired position for Fabius MRI (e.g., left or right side of MRT system).
- Using an anti-magnetic tape measure, mark the position for the trolley on the floor with yellow/black adhesive tape and enter it in the equipment installation drawing.

NOTE

Fill in the “Record of Transfer and Installation” provided in the Appendix 3 of this manual.

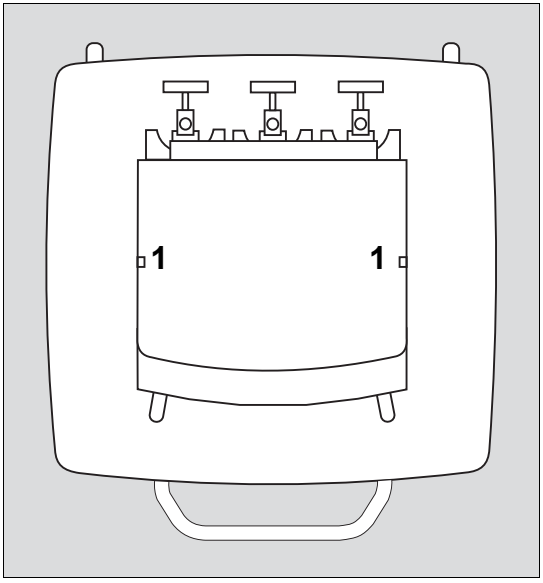


Positioning

WARNING

After positioning, lock the castors on the trolley by central brake at all times in the MRI room. Magnetic attractive forces between the magnet and the anesthesia machine may cause unintentional movement of the anesthesia machine if the casters are unlocked.

- Place the Fabius MRI at the desired position (right or left side). Teslameter sensorics, located at the middle of both sides, will generate an acoustic alarm when the 40 mtesla (400 gauss) fringe field strength is exceeded. The Fabius MRI must be moved away from the MRI system until the acoustic alarm is silenced.
- Indicate the positon of the device on the floor using hazard warning tape (black/yellow).



NOTE

The two teslameter sensorics (**1** in illustration) detect and alarm independently.

CAUTION

Make sure that the display and the additional alarm lights at the edges of the top plate of the Fabius MRI are always visible.

Following the setup and positioning of the Fabius MRI, perform the imaging test protocol provided in Appendix 2 of this manual.

CAUTION

Perform the imaging test protocol every time after:

– Fabius MRI is set up for the first time
– additional parts or any device is mounted on the Fabius MRI for the first time
– maintenance is performed

This ensures that the Fabius MRI does not interfere with the MRT system.

See the test protocol provided in Appendix 2 of this manual.

Connecting AC Power

Fabius MRI can be operated at mains voltages from 100 V to 240 V.

1 Push power plug into supply mains socket.

2 Switch on the machine by using the ON/OFF switch on the rear of the machine.

WARNING

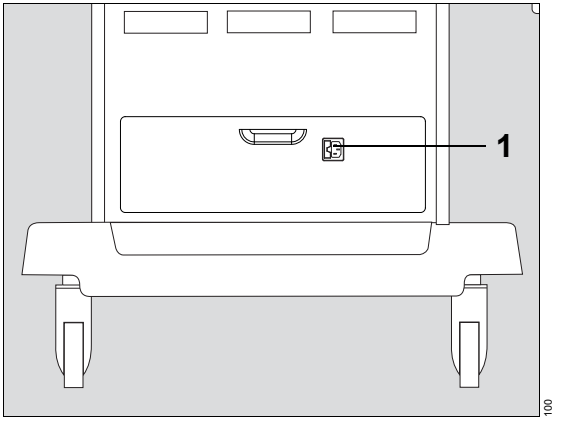
Only connect device to approved “hospital grade”outlets having the appropriate grounding reliablity.

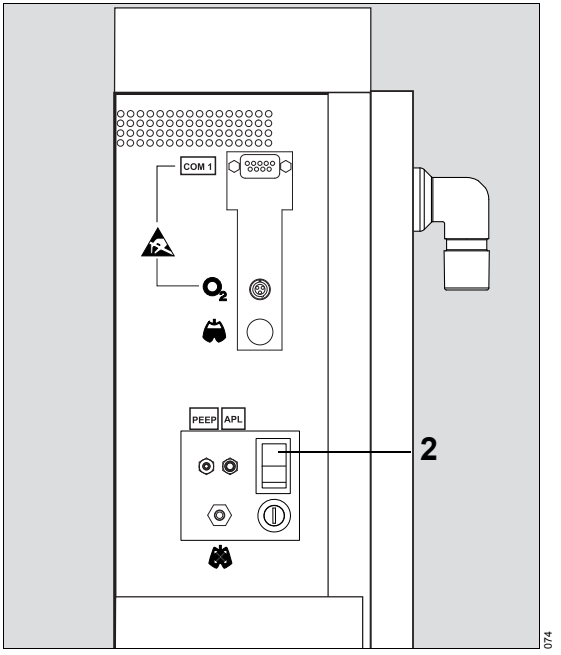
WARNING

Do not connect life-supporting devices to the auxiliary power outlet(s) of the anesthesia machine; if the mains/hospital power supply fails, devices connected to the auxiliary power outlet(s) will not be supplied by the anesthesia machine’s battery backup and will discontinue operation.

WARNING

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





Checklist

Use the following checklist during the assembly procedure to make sure all required components are installed.

- ❒ Secure swivel arm for breathing system (left or right side)
- ❒ Install the compact breathing system “COSY”
  - – mount COSY to swivel arm
  - – connect fresh gas hose
  - – connect ventilator hose or moisture reduction kit (optional)
  - – connect muffler to waste gas port of COSY
- ❒ Fill and install the absorber or install the optional Drägersorb CLIC Adapter
- ❒ Install the breathing bag extension arm to breathing system (optional)
- ❒ Install the flow sensor
- ❒ Connect the flow sensor cable
- ❒ Install the O_2 capsule in O_2 sensor housing
- ❒ Install and connect the O_2 sensor
- ❒ Connect the bypass and PEEP/P_{MAX} hoses
- ❒ Connect the pressure sensor hose
- ❒ Connect pipeline supply of N_2O, AIR and O_2
- ❒ Connect reserve gas cylinders for N_2O, AIR and O_2
- ❒ Install and connect the scavenger system (optional)
  - – mount the holster to the channel profile
  - – install the AGS scavenger or the passive scavenger
  - – connect hoses
- ❒ Install and connect the suction system (optional)
  - – mount the bracket for the suction bottle assembly to the channel profile
  - – install suction bottle system
  - – install regulator bracket to channel profile
  - – install and connect suction regulator (ejector or vacuum)
- ❒ Install the vaporizers
- ❒ Connect the breathing hoses
- ❒ Install sample gas return hose (optional)
- ❒ Connect AC power
  - – connect auxiliary devices
  - – connect Fabius MRI to mains power
- ❒ Check teslameter

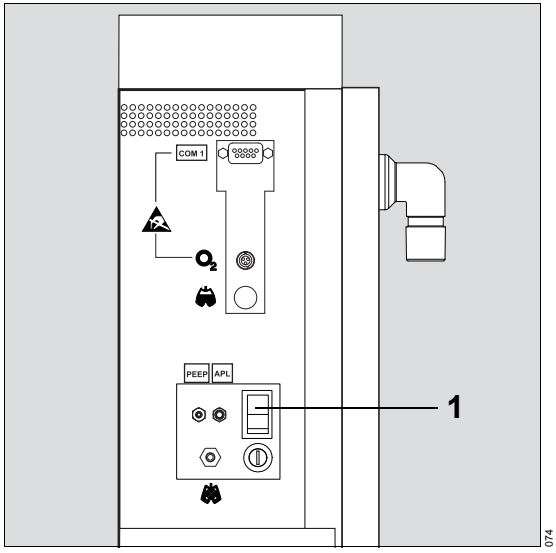
Daily and Pre-use Checkout

At the completion of the assembly of the Fabius MRI, perform the Daily and Pre-use Check-out procedure provided in the Appendix 1 of this manual to ensure that the machine is ready for operation.

Getting Started

Powering-Up the Machine

1 Turn the ON/OFF switch to the ON position. When the ON/OFF switch is turned to the ON position, the Fabius MRI performs extensive self-tests on its internal hardware. As these diagnostics are performed, each test and its result appear on the screen. The result, Pass or Fail, indicates the status of the tested component.



We recommend the user to remain close to the device within a range of up to four meters (13 feet), to ascertain the verification by the acoustic tones of the speakers.

During this self-test, two test tones are emitted to show speakers functionality.

CAUTION

The user must verify the acoustic tone are emitted as the device can only verify the presence of the speakers.
If no or only one tone is sounded, the device is conditionally functional.
The complete loss of ventilation and monitoring functionality might not be noticed.
Contact DrägerService.

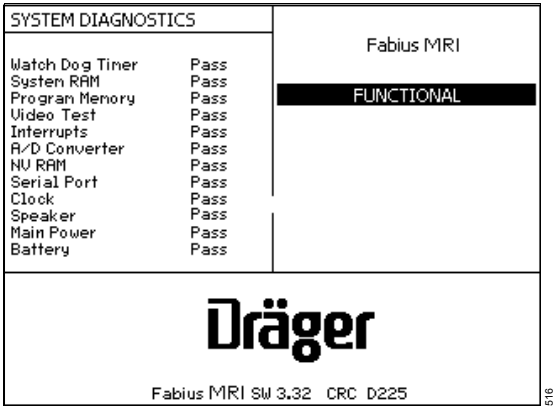
At the end of the self-diagnostics, one of three possible conclusions to the self-tests is posted on the screen:

FUNCTIONAL

Every component of the monitoring system is in satisfactory operational order. After a brief delay, the Standby screen appears.

CONDITIONALLY FUNCTIONAL

A noncritical fault was detected. The Fabius MRI may be used, but call DrägerService or your local authorized service organization.
Press the rotary knob to continue operation.



NON-FUNCTIONAL
A serious fault was detected and operation of the monitor and ventilator is inhibited. Do not use the machine. Immediately call DrägerService or your local authorized service organization to correct the problem.

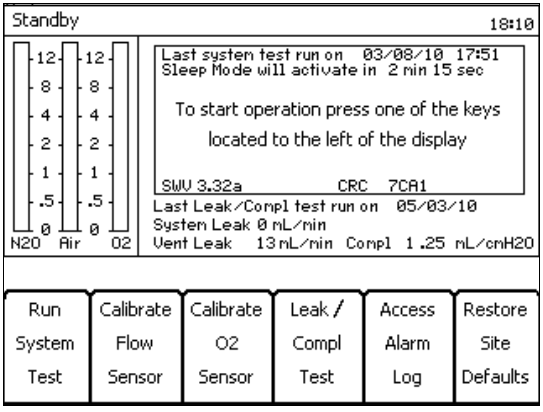
WARNING
The power-on self-test should be carried out once a day.
Switch Fabius MRI off and on or start the self-test by pressing the soft key »Run System Test«.

Power-Up Standby Screen

Following a successful power-up, the Standby screen appears and provides instructions on starting the operation of the Fabius MRI.

Checking Readiness for Operation

Check the readiness of the Fabius MRI by testing all required components as specified in the daily and pre-use checkout provided in the appendix of this manual. If all checks are satisfactorily completed, begin operation as specified in “Operation” on page 85.



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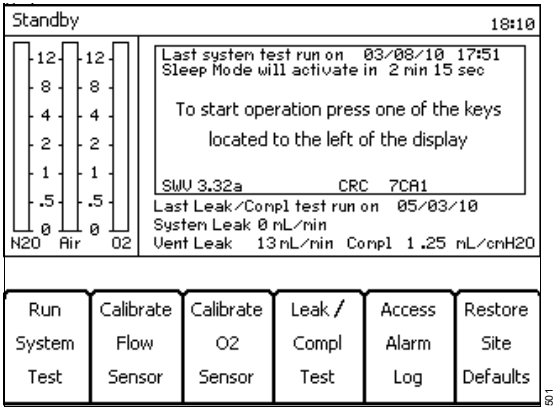
Operation

Power-Up Standby Screen

Following a successful power-up, the Standby screen appears and provides instructions on starting the operation of the Fabius MRI.



Setting Fresh Gas Flow

Set the fresh gas flow to the desired concentration using the flow control knobs on the front of the machine.

S-ORC (Sensitive Oxygen Ratio Controller)

S-ORC is a control element which guarantees a minimum O_2 concentration in the fresh gas flow. As from a flow rate of approx. 300 mL/min, the N_2O concentration in the fresh gas can be freely set between 0 and 75 %.

During O_2 shortage S-ORC limits the N_2O concentration in the fresh gas, so that the O_2 concentration does not drop below 23 vol.%.

S-ORC prevents N_2O flow if the N_2O metering valve is open and O_2 metering valve closed or if the O_2 flow is less than 0.2 L/min.

During N_2O failure O_2 may still be administered. No alarm sounds. The float in the N_2O measuring tube drops to zero.

After each O_2 supply failure the O_2 shortage alarm must be reactivated.

CAUTION

Risk of inaccurate measuring values

After the O_2 supply has been restored, a supply pressure of at least 2.7 kPa x 100 must be applied for at least 20 seconds before another O_2 shortage signal can be emitted.

During this period, do not activate any devices that consume O_2 (e.g. O_2 flush, O_2 fresh gas flow or secretion aspiration).

However, S-ORC is not an oxygen-specific monitoring device and therefore cannot provide any protection against the effects of accidental use of the wrong gas.

Therefore **always** monitor the O_2 concentration.

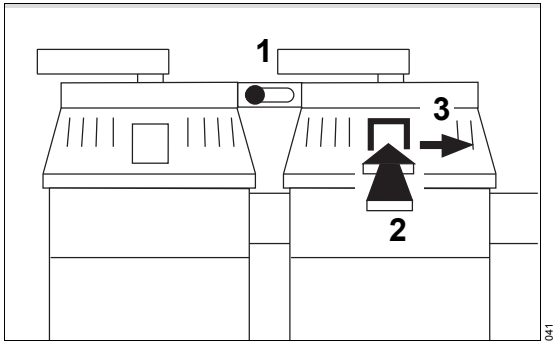
WARNING

Damage to materials and health risks

Never switch off fresh-gas flow before the vaporizer is switched off. A vaporizer must never be left switched on without a fresh-gas flow, because high-concentration anesthetic vapor may leak into machine lines and ambient air, causing damage to materials and health risks.

Setting Vaporizer Concentration

Refer to the appropriate Instructions for Use for the vaporizer being used. Vapor 2000 is shown and described below.



For the Dräger Interlock 2 system:

- Ensure that the vaporizer is properly seated.

1 Lock the unused vaporizer by moving the selector lever completely towards it. For example, to lock the left vaporizer, move the lever to the left.

2 With the handwheel set to »**T**« position on the unlocked vaporizer, press the button and engage the handwheel at »**0**«. Wait five seconds for the pressure to balance.

3 Press the button and turn the handwheel counterclockwise to set the required anesthetic gas concentration.

- Regularly check the filling level on the sight glass. When reaching the minimum mark, fill the vaporizer with anesthetic agent.

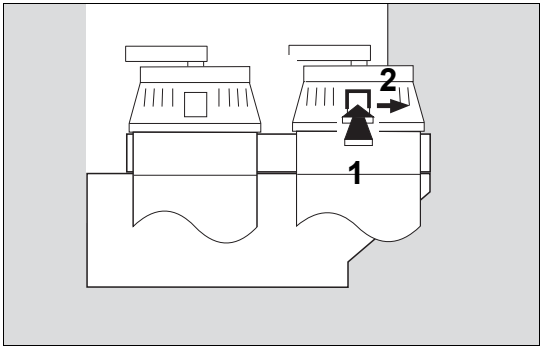
For the Dräger Auto Exclusion system:

- Close any open vaporizers.
- Ensure that the vaporizer is properly seated.

1 With the handwheel set to »**T**« position, press the button and engage the handwheel at »**0**«. Wait five seconds for the pressure to balance.

2 Press the button and turn the handwheel counterclockwise to set the required anesthetic gas concentration.

- Regularly check the filling level on the sight glass. When reaching the minimum mark, fill the vaporizer with anesthetic agent.



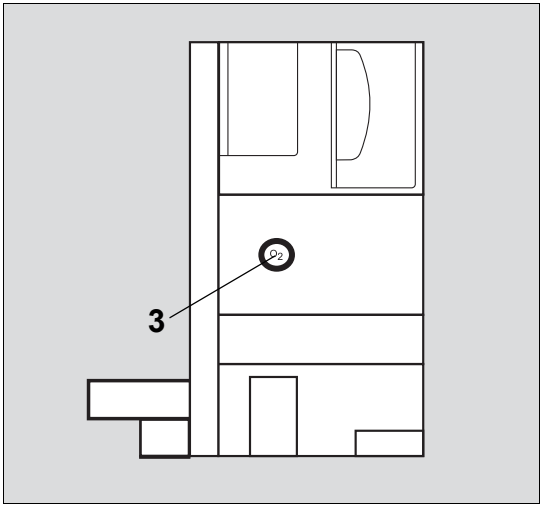
O_2 Flush

A manually operated O_2 flush valve is located on the front of the machine. When actuated, the valve delivers an unmetered flow of at least 35 L/min to the breathing system and breathing bag while bypassing the ventilator. The Fabius MRI does not need to be switched on in order to use the O_2 flush.

3 Press the O_2 flush button. Additional O_2 flows into the compact breathing system as long as the button is pushed in. The flow control elements and the anesthetic agent vaporizer are bypassed.

NOTE

In ManSpont mode, pressure may rise rapidly up to the setting of the APL valve.



Low Flow Anesthesia

With low flow anesthesia (means flow ≤1.0 L/min) the condensation of patients humidity from the expired breath is natural. Condensation occurs in the hoses. To avoid water accumulating in the hoses, a water trap is integrated in the ventilator hose. In long term low flow anesthesia the additional use of watertraps in the expiratory hose is recommended. Empty water traps if their water level exceeds the maximum water level limit.

Nitrogen Wash-Out (If Required)

During anesthesia induction, air containing about 77 % nitrogen (N_2) remains in the compact breathing system (and in the patient's lungs). If the unit will be used for a low-flow anesthesia case, press the O_2 Flush to remove this N_2.

Replacing CO_2 Absorbent

The CO_2 absorbent in the compact breathing system should be replaced when two-thirds of the CO_2 absorbent has changed color. Dräger recommends the use of Drägersorb 800 Plus or Drägersorb FREE. The color change indicates that the CO_2 absorbent can no longer absorb CO_2 (Drägersorb 800 Plus and Drägersorb FREE change from white to violet).

WARNING

Do not flush dry gas continuously for unnecessarily long periods through the soda lime in the anesthesia system!

Otherwise the soda lime will dehydrate. If the moisture level falls below a minimum level, undesirable reactions generally occur, regardless of the type of soda lime and the inhalation anesthetic used:

- **reduced CO_2 absorption,**
- **increased heat generation in the absorber and therefore increased breathing gas temperature,**
- **CO formation,**
- **absorption and/or breakdown of the inhalationanesthetic.**

The above mentioned reactions may endangerthe patient, e.g.:

- **CO poisoning**
- **insufficient depth of anesthesia**
- **burns of the airway.**

CAUTION

Soda lime irritates the skin and there is a risk of serious damage to eyes.

If soda lime has leaked:

- Powdered soda lime must not be inhaled or swallowed.
- Put on protective gloves and goggles, or a face mask.
- In case of coming in contact with eyes, rinse immediately with large amounts of water and consult a physician immediately, otherwise it may lead to eye damage.
- Powdered soda lime on the skin must be washed off immediately, because it may irritate the skin.

NOTE

Please refer to the specific Instructions for Use for "Drägersorb 800 Plus or Drägersorb FREE".

- Remove the absorber canister by turning it clockwise.
- Empty the expired CO_2 absorbent from the absorber into an appropriate refuse container.
- Fill the absorber with fresh CO_2 absorbent.

NOTE

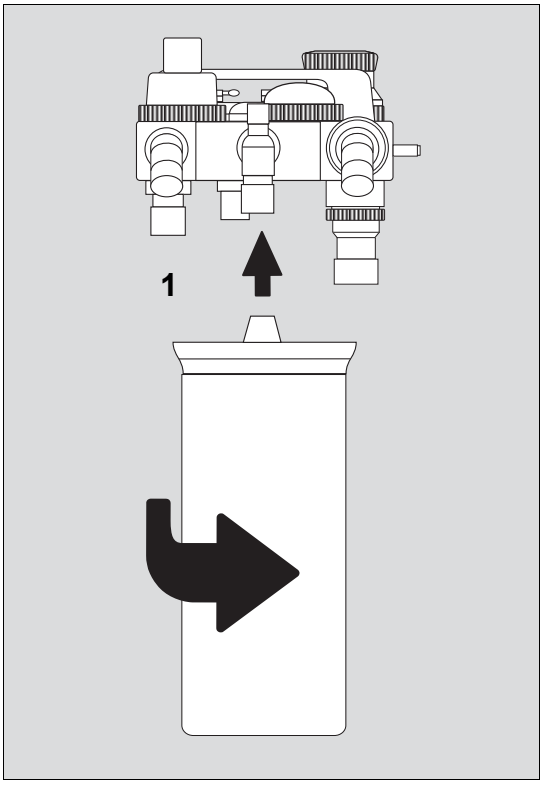
Ensure that no CO_2 absorbent dust/particles have been deposited between the gaskets and sealing surfaces. Such dust and particles can cause leaks in the system.

1 Fit the absorber canister into position below the breathing system and turn it counterclockwise as far as possible.

CAUTION

Risk of unintended perioperative awarness

Make sure that during ventilation the absorber canister is tightly connected to the COSY.



CLIC Adapter (Optional)

The disposable CLIC adapter absorber can also be used on the Fabius MRI. For information on installing the CLIC adapter, consult its Instructions for Use.

Points to note when using the CLIC adapter with neonates and infants

The compliance of the breathing system is reduced when the disposable absorber is removed. As a result, the ventilator delivers a higher tidal volume to the patient during IPPV/SIMV and the airway pressure increases accordingly. The effect on the tidal volume and airway pressure is negligible in adults with a lung compliance of approx. 50 mL/cmH_2O. In neonates and infants with a lung compliance of approx. 5 mL/cmH_2O or less, the tidal volume and airway pressure can increase considerably and harm the patient if the disposable absorber is removed during IPPV/SIMV.

Before removing the disposable absorber:

- Set **PMAX** to the plateau pressure.

As soon as the absorber has been replaced:

- Set **PMAX** to the original value again.

Ventilation

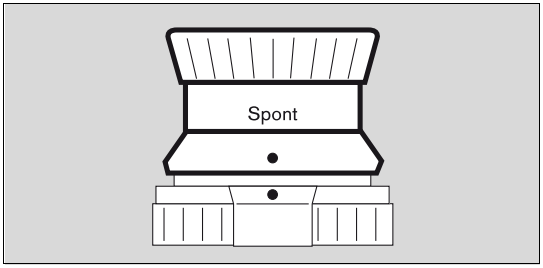
WARNING
Risk of strangulation
Use caution when connecting the patient.

Manual/Spontaneous Ventilation Mode

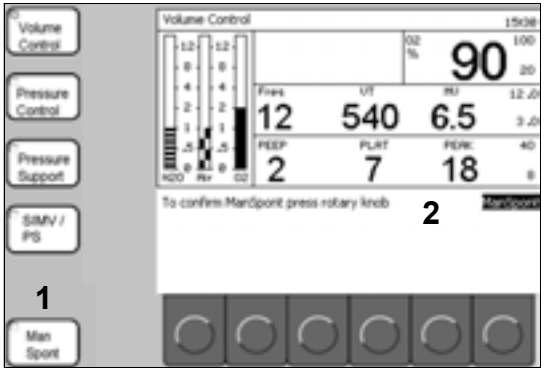
ManSpont (Manual/Spontaneous) is a non-automatic mode of ventilation. However, the ventilation monitor and alarms are still operational. In ManSpont mode, the ventilator piston is moved partially upward to reduce system compliance. Manual ventilation (with APL valve pressure limit) can be delivered with the APL valve in the MAN position. Spontaneous ventilation (APL valve wide-open) can occur with the APL valve in the »**Spont**« position.
The following examples and illustrations describe starting Man/Spont ventilation from the present ventilation mode »**Volume Control**«:

For Spontaneous Breathing:

- Rotate the APL valve knob fully counterclockwise until the index mark on the knob lines up with the index mark on the bottom of the valve.The valve is now open for spontaneous patient breathing.
- Set the appropriate fresh gas flow.

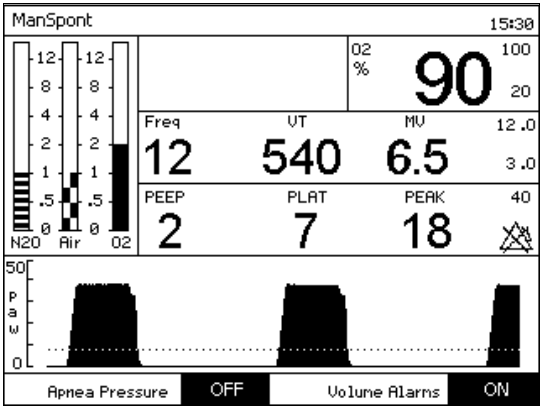


1 Press the »ManSpont« key. The LED associated with this key starts blinking. It remains blinking until the selected mode of operation is confirmed.
2 The Waveform window is replaced by the ManSpont window and a message that provides instructions to confirm the mode change.



- Confirm the mode change. The ManSpont screen is activated. After the mode change is confirmed, the »**ManSpont**« key LED switches from blinking to constantly on and the waveform is restored.

The ManSpont screen allows the user to adjust two parameters: Apnea Pressure alarm ON/OFF (see page 136) and Volume alarms ON/OFF (see page 134). Pressing the »**ON/OFF**« soft key toggles the corresponding alarm between ON and OFF.

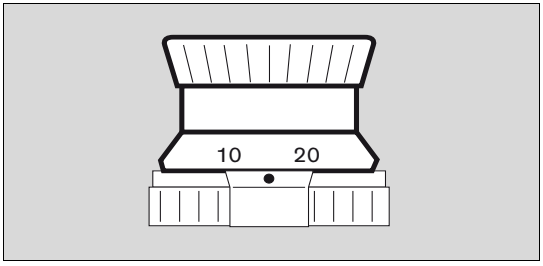


For Manual Ventilation:

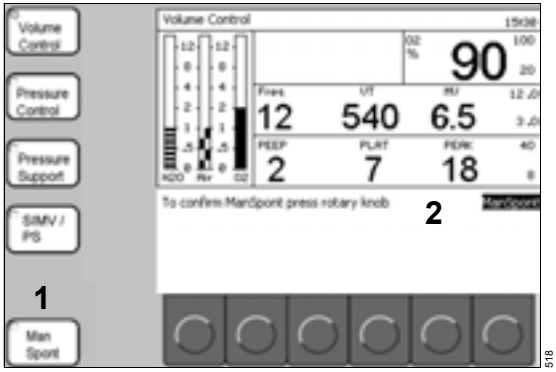
NOTE

In ManSpont mode, the apnea volume timer countdown for caution alarms changes from 15 seconds to 30 seconds, and for warning alarms from 30 seconds to 60 seconds.

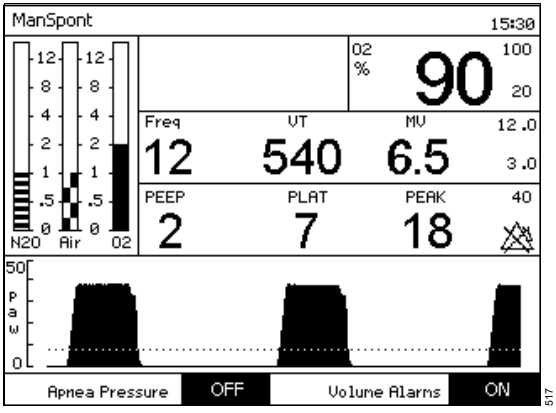
- Rotate the APL valve adjustment knob to the desired pressure. Clockwise rotation increases the pressure, and counterclockwise rotation decreases the pressure.



1 Press the »**ManSpont**« key. The LED associated with this key starts blinking. It remains blinking until the selected mode of operation is confirmed.
2 The Waveform window is replaced by the ManSpont window and a message that provides instructions to confirm the mode change.



- Confirm the mode change. The ManSpont screen is activated. After the mode change is confirmed, the »**ManSpont**« key LED switches from blinking to constantly on and the waveform is restored.

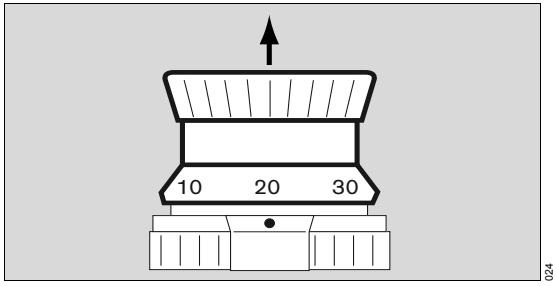


The ManSpont screen allows the user to adjust two parameters: Apnea Pressure alarm ON/OFF and Volume alarms ON/OFF. Pressing the »**ON/OFF**« soft key toggles the corresponding alarm between ON and OFF.

- Press the O_2 flush button, as required, to reinflate the bag.
- Set the appropriate fresh gas flow.
- Start manual ventilation. The pressure will be limited to the value set on the APL valve.
- Start manual ventilation by hand via the breathing bag.

To temporarily relieve pressure:

- Pull up on the APL valve knob.



Volume Control Ventilation

Ventilator Compliance Compensation

Ventilator compliance compensation is continuously applied during Volume Control so that the tidal volume delivered to the patient corresponds to the V_T setting. Ventilator compliance is determined during the leak and compliance test performed from the Standby mode (see “Leak/Compliance Test” on page 142). To have compliance compensation work accurately, it is important that the patient hoses used during the leak/compliance test match the type of hoses used during the procedure.

NOTE

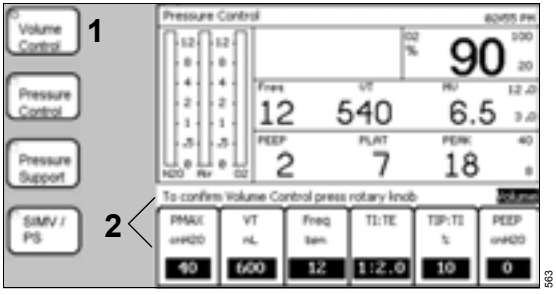
When the ventilator settings for Volume Control cause the ventilator to operate at its limits of performance, it is not possible for the Fabius MRI to apply compliance compensation. If the ventilator's performance limit is reached, it is not possible to increment the V_T setting via the Volume Control Settings window.

Starting Volume Control Ventilation

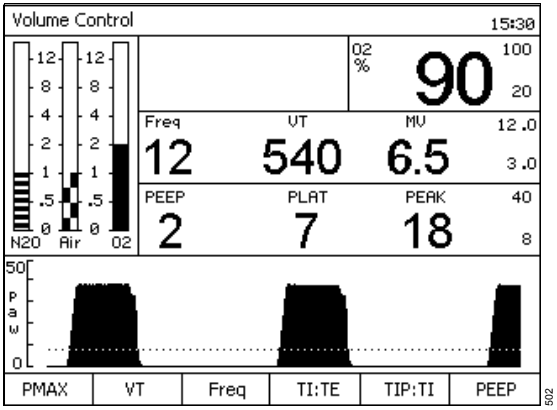
The following examples and illustrations describe starting Volume Control ventilation from the present ventilation mode “Pressure Control”:

1 Press the »**Volume Control**« key. The LED associated with this key starts blinking. It remains blinking until the selected mode of operation is confirmed.

2 The Waveform window is replaced by the ventilator settings window and a message that provides instructions to confirm the mode change.



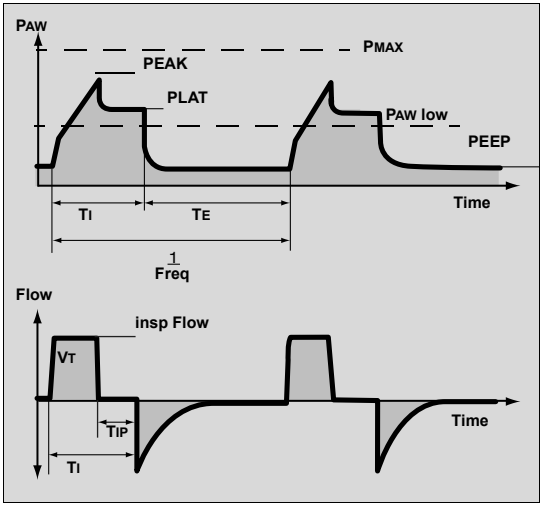
- If the ventilator settings are correct, confirm the mode change.
- If the ventilator settings are not correct, for each parameter that needs to change, press the corresponding soft key, select the correct value, and confirm the change. When the parameter changes are completed, confirm the ventilation mode change.
- After the mode change is confirmed, the »**Volume Control**« key LED switches from blinking to constantly on, the ventilator switches to the Volume Control mode, and the waveform is restored.



The parameters that can be set for Volume Control mode are shown the adjacent table, along with their adjustment ranges and factory default values.

Ventilation Parameter (Volume Control Mode)	**Adjustment Range**	**Factory Default Value**
Pressure Limitation P_{MAX} [cmH_2O] ([hPa])	15 to 70 min. PEEP+10	40
Tidal Volume V_T [mL]	20 to 1400	600
Frequency Freq [bpm] ([1/min])	4 to 60	12
Insp time: Exp time T_I:T_E	4:1 to 1:4	1:2
Insp pause time: Insp time T_{IP}:T_I [%]	0 to 50	10
PEEP [cmH_2O] ([hPa])	0 to 20	0

Based on a defined frequency (**Freq**) and a defined ratio of inspiratory time to expiratory time (**Ti:TE**), a tidal volume (**VT**) is applied at a constant inspiration flow (**Insp Flow**).
The inspiration flow (**Insp Flow**) results from the tidal volume (**VT**) and the ratio of inspiratory pause time to inspiratory time (**TIP:TI**).
When **TIP:TI** is set to 0, the tidal volume (**VT**) is applied at the lowest inspiration flow (**Insp Flow**) which is possible at the corresponding frequency (**Freq**). In addition, a positive end-expiratory pressure (**PEEP**) can be set.
To avoid too high pressures, the alarm limit **PMAX** can be set according to the physiological state of the patient.

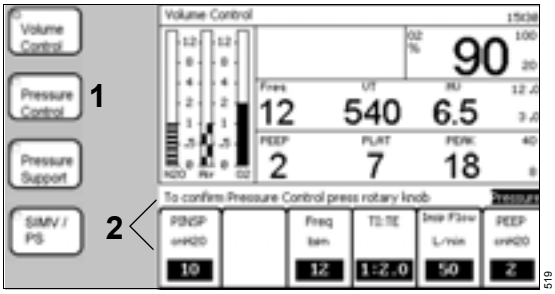


The lower pressure limit **PAW low** is used for pressure monitoring to detect apneas (disconnection) and continuous pressure. An alarm is generated when the pressure curve does not cross the pressure threshold either from above or below.

Pressure Control Ventilation

Starting Pressure Control Ventilation

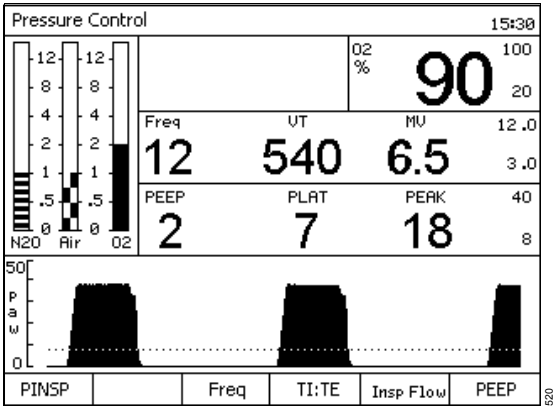
The following examples and illustrations describe starting Pressure Control ventilation from the present ventilation mode “Volume Control”:



1 Press the »**Pressure Control**« key. The LED associated with this key starts blinking. It remains blinking until the selected mode of operation is confirmed.

2 The Waveform window is replaced by the ventilator settings window and a message that provides instructions to confirm the mode change.

- If the ventilator settings are correct, confirm the mode change.
- If the ventilator settings are not correct, for each parameter that needs to change, press the corresponding soft key, select the correct value, and confirm the change. When the parameter changes are completed, confirm the ventilation mode change.
- After the mode change is confirmed, the »**Pressure Control**« key LED switches from blinking to constantly on, the ventilator switches to the Pressure Control mode, and the waveform is restored.



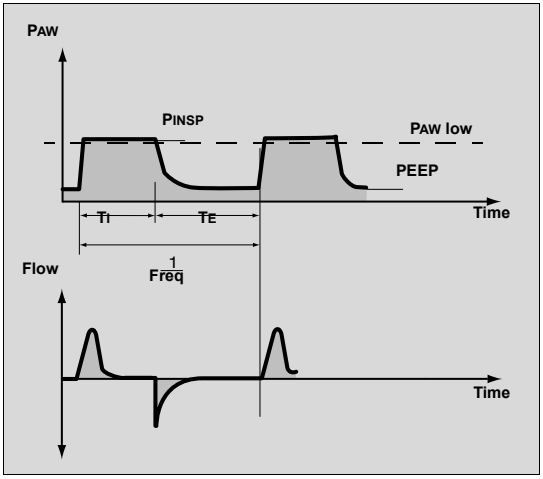
The parameters that can be set for Pressure Control mode are shown in the adjacent table, along with their adjustment ranges and factory default values.

Due to compliance and resistance combinations, the adjusted Freq Min might not applied accurately in the Pressure Control Mode.

Ventilation Parameter (Pressure Control mode)	**Adjustment Range**	**Factory Default Value**
Inspiratory Pressure PINSP [cmH2O] ([hPa])	5 to 65 min. PEEP+5	15
Frequency Freq [bpm] ([1/min])	4 to 60	12
Insp time: Exp time TI:TE	4:1 to 1:4	1:2
Inspiratory Flow Insp Flow [L/min]	10 to 75	30
PEEP [cmH2O] ([hPa])	0 to 20	0

Based on a defined frequency (**Freq**) and a defined ratio of inspiratory time to expiratory time (**Ti:TE**), a volume is applied. This volume depends on the set inspiratory pressure (**PINSP**) and the patient compliance. The **Insp Flow** key is used to set the slope of the pressure waveform. In addition, a positive end-expiratory pressure (**PEEP**) can be set.

The lower pressure limit **PAW low** is used for pressure monitoring to detect apneas (disconnection) and continuous pressure. An alarm is generated when the pressure curve does not cross the pressure threshold either from above or below.



Pressure Support Ventilation

Pressure Support ventilation is intended to reduce the work of breathing and is indicated for use only in patients who are breathing spontaneously. Patients who are not making spontaneous breathing efforts are not candidates for Pressure Support ventilation.

Pressure Support ventilation is triggered by the patient's spontaneous effort to breathe. Most anesthetic agents will cause patients to have reduced ventilatory responses to carbon dioxide and to hypoxemia. Therefore, patient triggered modes of ventilation may not produce adequate ventilation. Additionally, the use of neuromuscular blocking agents will interfere with patient triggering.

Apnea Ventilation is a feature within Pressure Support ventilation. To enable Apnea Ventilation, adjust the **Freq Min** setting to a value other than **OFF**. If the detected patient spontaneous breathing rate falls below the set value, the ventilator automatically delivers a Pressure Support breath.

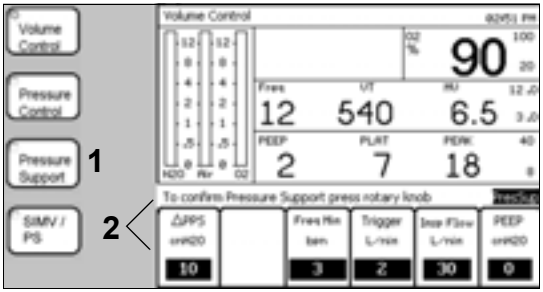
Apnea ventilation is intended to provide some degree of gas exchange if the patient’s respiratory rate falls below the desired minimum setting. It is not intended as a primary mode of ventilation.

When delivering Apnea Ventilation, the Fabius MRI uses the Pressure Support settings for Δ**Pps**, **Freq Min**, **Insp Flow**, and **PEEP**.

If two consecutive Apnea Ventilation breaths occur, the Caution message »**APNEA VENTILATION!!**« appears in the Alarm window. The alarm is cleared when a spontaneous breath is detected.

Starting Pressure Support Ventilation

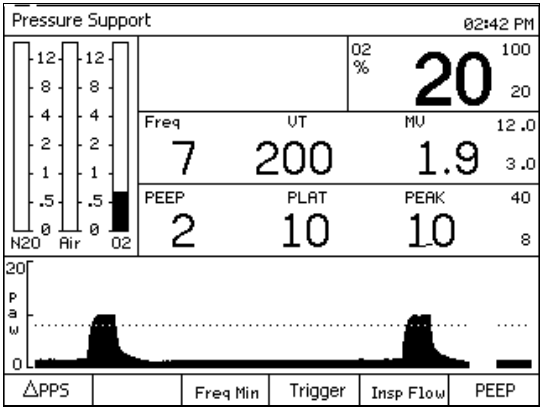
The following examples and illustrations describe starting Pressure Support ventilation from the present ventilation mode “Volume Control”:



1 Press the »**Pressure Support**« key. The LED associated with this key starts blinking. It remains blinking until the selected mode of operation is confirmed.

2 The Waveform window is replaced by the ventilator settings window and a message that provides instructions to confirm the mode change.

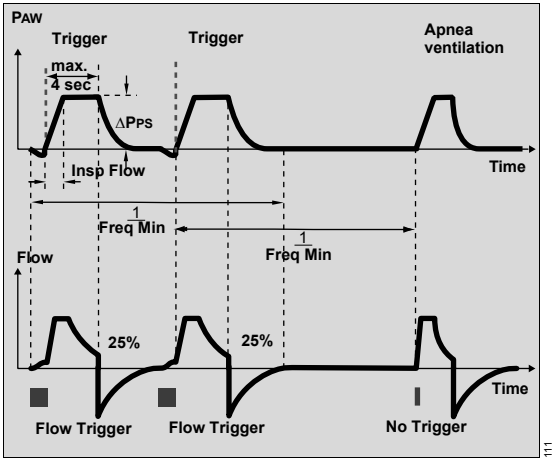
- If the ventilator settings are correct, confirm the mode change.
- If the ventilator settings are not correct, for each parameter that needs to change, press the corresponding soft key, select the correct value, and confirm the change. When the parameter changes are completed, confirm the ventilation mode change.
- After the mode change is confirmed, the »**Pressure Support**« key LED switches from blinking to constantly on, the ventilator switches to the Pressure Support mode, and the waveform is restored.



The parameters that can be set for Pressure Support mode are shown the adjacent table, along with their adjustment ranges and factory default values.

Ventilation Parameter (Pressure Support mode)	**Adjustment Range**	**Factory Default Value**
Support pressure ΔP_{PS} [cmH_2O] ([hPa])	3 to 20, OFF	10
Min frequency for apnea vent. Freq Min [bpm] ([1/min])	3 to 20, OFF	3
Trigger Sensitivity Trigger [L/min]	2 to 15	2
Inspiratory Flow Insp Flow [L/min]	10 to 85	30
PEEP [cmH_2O] ([hPa])	0 to 20	0

Pressure Support (**PS**) can be used to support the spontaneous breathing of the patient.
If the inspiration flow (**Insp Flow**) during inspiratory effort is greater than the set trigger flow (**TRIGGER**), the device supports the patient according to the Pressure Support setting (Δ**PPS**).
The set inspiratory flow (**Insp Flow**) defines how fast the Δ**PPS** pressure is reached. The end of inspiration is automatically triggered when reaching 25% of maximum inspiratory flow (**Insp Flow**) or after a maximum of 4 s. The value **Freq Min** (e.g.,3 bpm (1/min)) is used to set a safety period (safety period = 1/**Freq Min**, e.g., 20 s). If no inspiratory effort is detected and the safety period has expired, the device applies a pressure-controlled breath with **PINSP** = Δ**PPS**.



The lower pressure limit **PAW low** is used for pressure monitoring to detect apneas (disconnection) and continuous pressure. An alarm is generated when the pressure curve does not cross the pressure threshold either from above or below.

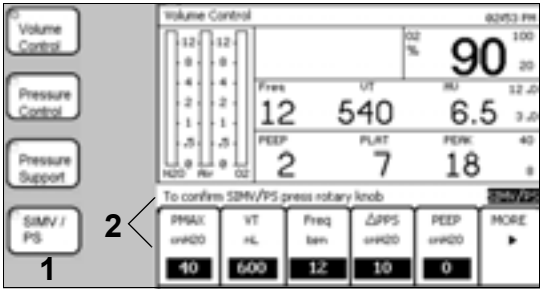
SIMV/PS Ventilation

Synchronized Intermittent Mandatory Ventilation (SIMV) mode is a mixture of mechanical ventilation and spontaneous breathing. In SIMV mode, the patient can breathe spontaneously. SIMV will attempt to synchronize the mandatory ventilation strokes with spontaneous efforts.
The mandatory ventilation strokes are the same as those for volume ventilation. They are defined by the parameters **VT**, **Freq**, **TINSP**, **TIP : TI**, and **PEEP**.

Pressure support can be added during SIMV mode to augment the patient's spontaneous breathing efforts. Adjusting the ΔP_{PS} level to a value other than **OFF** will enable Pressure Support during SIMV mode. (Refer to "Pressure Support Ventilation" on page 102 for additional information on Pressure Support ventilation.)

Starting SIMV/PS Ventilation

The following examples and illustrations describe starting SIMV/PS ventilation from the present ventilation mode Volume Control:



1 Press the »**SIMV/PS**« key. The LED associated with this key starts blinking. It remains blinking until the selected mode of operation is confirmed.

2 The Waveform window is replaced by the ventilator settings window and a message that provides instructions to confirm the mode change.

- If the ventilator settings are correct, confirm the mode change.
- If the ventilator settings are not correct, for each parameter that needs to change, press the corresponding soft key, select the correct value, and confirm the change. When the parameter changes are completed, confirm the ventilation mode change.

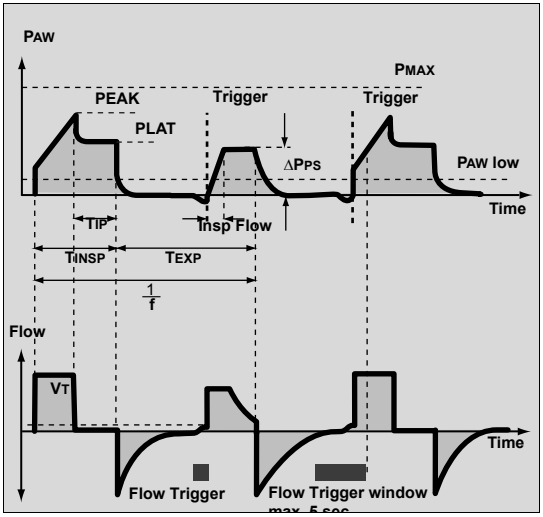
The parameters that can be set for SIMV/PS mode are shown the adjacent table, along with their adjustment ranges and factory default values.

- To access the **Trigger**, **Insp Flow**,**TINSP**, and **TIP:TI** parameters, press the »**MORE**« key on the SIMV/PS screen.

- After the mode change is confirmed, the »**SIMV/PS**« key LED switches from blinking to constantly on, the ventilator switches to the SIMV/PS mode, and the waveform is restored.

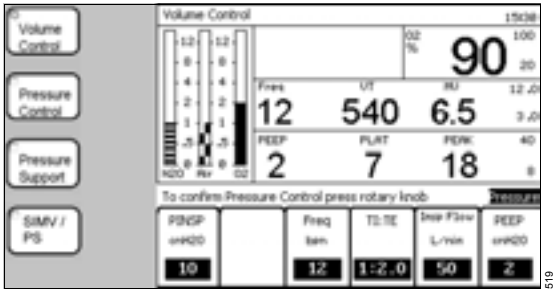
Ventilation Parameter (SIMV/PS Mode)	**Adjustment Range**	**Factory Default Value**
Pressure Limitation P_{MAX} [cmH_2O] ([hPa])	15 to 70 min. PEEP+10 and >ΔP_{PS}+PEEP	40
Tidal Volume V_T [mL]	20 to 1100	600
Frequency Freq [bpm] ([1/min])	4 to 60	12
Support pressure ΔP_{PS} [cmH_2O] ([hPa])	3 to 20, OFF	10
PEEP [cmH_2O] ([hPa])	0 to 20	0
Trigger Sensitivity Trigger [L/min]	2 to 15	2
Inspiratory Flow Insp Flow [L/min]	10 to 85	30
SIMV insp. time T_{INSP} [seconds]	0.3 to 4.0	1.7
Insp pause time: Insp time T_{IP}:T_I [%]	0 to 50	10

The ventilation mode **SIMV** (synchronized intermittent mandatory ventilation) applies volume-controlled breaths at a constant inspiratory flow with defined settings for **VT**, **TINSP**, **TIP:TI** and **PMAX**. Ventilation is applied in synchronization with inspiratory effort of the patient. The frequency **Freq** defines the time between the individual volume-controlled breaths. The synchronization of the breaths is done with a **TRIGGER** which is activated a certain amount of time before a new breath is applied: 5 s for frequencies (**Freq**) below 12 bpm (1/min). At higher frequencies, synchronization is done directly after the preceding expiration. In between these mandatory breaths the patient can breathe spontanously. Mandatory breaths are synchronized with the spontaneous breaths of the patient. These spontaneous breaths can be supported with Pressure Support.



The lower pressure limit **PAW low** is used for pressure monitoring to detect apneas (disconnection) and continuous pressure. An alarm is generated when the pressure curve does not cross the pressure threshold either from above or below.

When Changing Between Ventilation Modes



Selected ventilator settings for the new mode of operation are automatically derived from the settings and performance of the last confirmed automatic ventilation mode. Settings affected in the new mode will be highlighted as shown in the figure.

The settings for **Freq, TI : TE,** and **PEEP** are taken directly from the settings used in the former mode as applicable.

When changing from Volume Control to Pressure Control, **PINSP** is set to the Plateau pressure developed in Volume Control.

When changing from Volume Control or Pressure Support to Pressure Control, the suggested value for **Insp Flow** is either the last used value or the site default value.

When changing from Pressure Control to Volume Control, **VT** is set by dividing the last minute volume by the respiratory rate.

When changing from Pressure Control to Volume Control, the suggested value for **TIP : TI** is either the last used value or the site default value.

When changing from Pressure Control to Volume Control, **PMAX** is set 10 cmH_2O (hPa) higher than the plateau pressure developed during Pressure Control.

When changing from Volume Control or Pressure Control to Pressure Support, the suggested value for **Insp Flow** is either the last used value or the site default value.

When changing from Volume Control or Pressure Control to Pressure Support, the suggested value for **ΔPPS** is either the last used value or the site default value.

When changing from Volume Control or Pressure Control to Pressure Support, the suggested value for **Trigger** is either the last used value or the site default value.
When switching between Volume Control mode and SIMV/PS mode, the **PMAX** and **PEEP** settings shall automatically be transferred from the previous mode to the new mode.

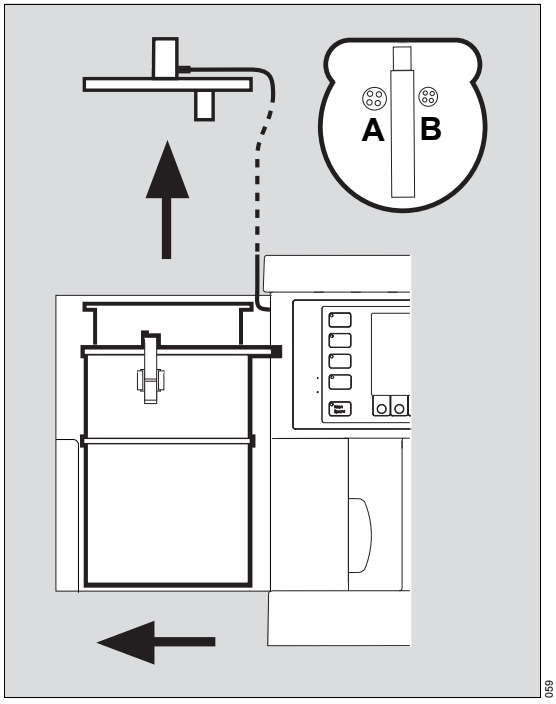
When switching from Pressure Support mode to SIMV/PS mode, the **ΔPPS**, **Insp Flow**, **Trigger**, and **PEEP** settings shall automatically be transferred from the previous mode to the new mode.

When switching from SIMV/PS mode with Pressure Support enabled to Pressure Support mode, the **ΔPPS** and **Insp Flow** settings shall automatically be transferred from SIMV/PS to Pressure Support.

When switching from SIMV/PS mode to Pressure Support mode, the **Trigger** and **PEEP** settings shall automatically be transferred from SIMV/PS to Pressure Support.

Ventilator Safety Features

– High pressure safety relief valve (**A**)
– Negative pressure safety relief valve (**B**)
– Ventilator chamber pressure sensor



Behavior during Lack of Fresh Gas

Background

Due to a very low fresh gas flow or an excessive leakage in the breathing system, a lack of fresh gas can occur. This can be recognized by observing the gradual emptying of breathing bag.

NOTE

The user should then take action to resolve this, for example by increasing the fresh gas flow.

Fabius MRI behavior in case of no action taken by the user

– breathing bag gradually empties completely
– after two more strokes the alarm »**FRESH GAS LOW**« and additional alarms occur
– the ventilator absorbs its reserve volume since it is not supplied with sufficient fresh gas.

As long as a lack of fresh gas exists, the safety valve (**B**) for ambient air is opened during expiration.

CAUTION

If remedial actions are omitted, ambient air will be taken in which will dilute the fresh gas.
The concentration of (e.g.) oxygen or other anesthetic gases will decrease.

Advantages: Even in extreme cases emergency ventilation with limited V_T is possible. A "sudden" shutdown of the ventilator does not occur.

Changing Patients

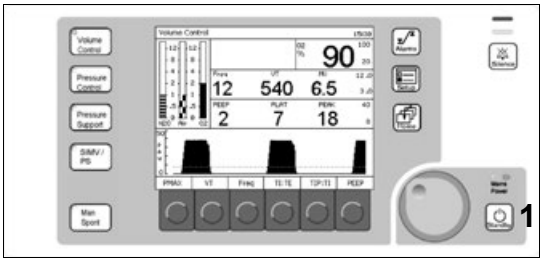
WARNING
Risk of inappropriate alarm settings
As it is possible that Fabius MRI devices within in a care area have different site default alarm limit configurations, check whether the pre-set alarm limits are appropriate to the new patient. Also check that the alarm system has not been rendered useless by setting the alarm limits to extreme values.See “Default Settings in Standby Setup” on page 147.

Follow the steps below for successive cases.

1 Press and confirm the »**Standby**« key.

Monitoring and alarms are turned off and the ventilator stops. Fresh gas monitoring continues and the current settings are retained.

To activate default settings instead of using the current settings, press the »**Restore Site Defaults**« key on the Standby screen.



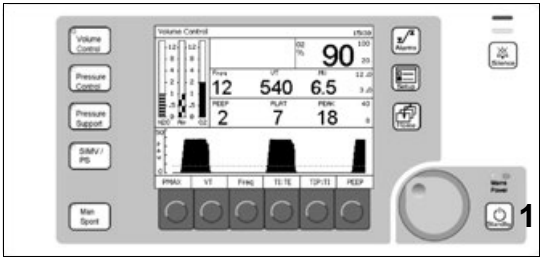
- Check all components identified as Pre-use Checkout items in the Daily and Pre-use Checkout form on page 225.
- If needed, perform the leak/compliance test as as described on page 142. The leak/compliance test should be performed each time the absorbent or breathing hoses have been changed, or when a vaporizer has been changed or filled.

WARNING
Risk of patient hazard
Do not perform the leak/compliance test with a patient attached to the workstation.

- Set the ventilation mode as described in “Ventilation” on page 94, and proceed with the case.

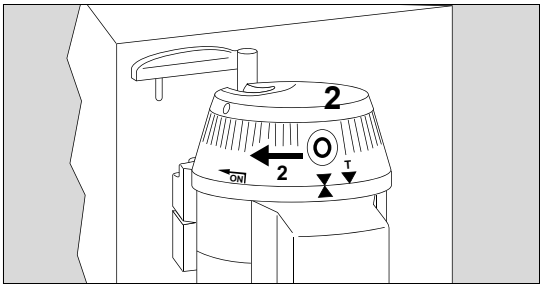
Ending Operation

1 Press and confirm the »⏻« key (**Standby)**. Monitoring and alarms are turned off and the ventilator stops.



2 Turn vaporizers off by turning the handwheel to »**0**« until the button engages.

- Turn off fresh gas flow on the Fabius MRI. Sleep mode will activate 2.5 minutes after fresh gas is turned off.
- Close the cylinder valves.



End of Vaporizer Use

If the Vapor is not going to be used for up to six months, it may remain filled;
If the Vapor is not going to be used for more than 6 months, see "Shut-Down" in separate Instructions for Use provided with the vaporizer.
If the Vapor remains on the machine:

- For intervals of more than one week, anesthetic agent loss from the vaporizer chamber can be minimized by using the »**T**« setting.
- The locking lever on the plug-in adapter should remain in the left (locked) position.
- Keep Vapor within the permissible temperature range (see separate Instructions for Use provided with the vaporizer
- Observe expiration date of anesthetic agent.

If the Vapor does not remain on the machine:

- see "Disconnecting the Vapor" and "Transport of Filled Vapors" in separate Instructions for Use provided with the vaporizer.

WARNING

Damage of materials and health risks

Never switch off fresh gas flow before the vaporizer is switched off. A vaporizer must never be left switched on without a fresh gas flow, because high-concentration anesthetic vapor may leak into machine lines and ambient air.

When Fabius MRI is not in use

If Fabius MRI is not used for an extended period:

- Unplug the medical gas hoses from the wall supply points of the central gas supply.
- Close the cylinder valves on the reserve gas cylinders.

NOTE

Leave the Fabius MRI plugged into mains power in order to charge the battery.

Using the external fresh-gas outlet with an additional switch*

WARNING

Risk of adversely affecting the diagnostic quality of the MRT images

Do not use the following non-rebreathing systems in the MRI suite: Magill, Kuhn or Bain. They are not MR safe or MR conditional.

WARNING

Danger to the patient caused by too high pressures

To ensure the correct inspiratory pressure at the inspiratory port, use only non-rebreathing systems with a reservoir bag conforming to ISO 5362 and/or a pressure relief valve.

WARNING

Risk of insufficient gas supply to the patient

Non-rebreathing systems are suitable and intended only for manual ventilation or spontaneous breathing and may only be connected to the external fresh-gas outlet.

WARNING

Risk of misinterpreting the measurements

The measurements and alarms are displayed on the breathing monitor. They do not correspond to the measurements for the patient connected to the external fresh-gas outlet.

- **The measurements (O_2, pressure, volume) and alarms displayed on the breathing monitor correspond to the measurements on the Compact Breathing System (COSY).**

Switch to the Standby mode when using the external fresh-gas outlet.

WARNING

Danger to the patient

There is no monitoring of pressure, volume or O_2 for the external fresh-gas outlet.

An external monitoring unit must be used to perform the required monitoring of O_2, CO_2, anesthetic gas, volume and pressure.

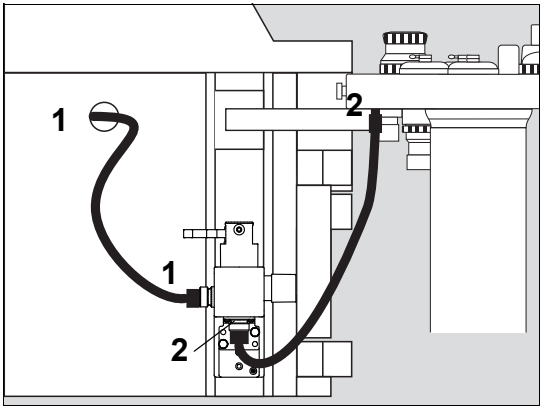
* optional

Preparation

Connecting the external fresh-gas outlet, (e.g., on the left side)

1 Connect the fresh-gas hose from the Fabius MRI to the external fresh-gas outlet.

2 Connect the separate short fresh-gas hose to the COSY fresh-gas port and to the lower vertical port of the external fresh-gas outlet.

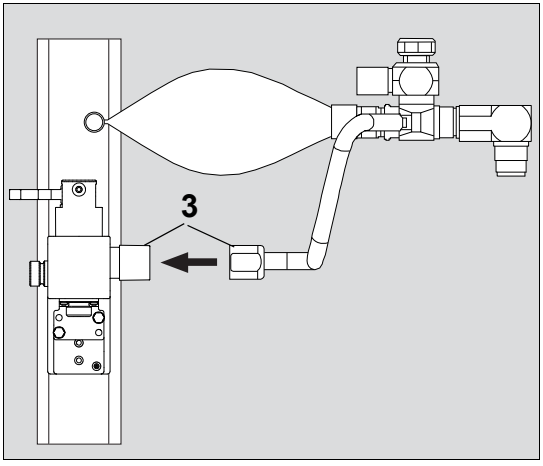


NOTE

Make sure that the external fresh-gas outlet with switch is completely assembled.

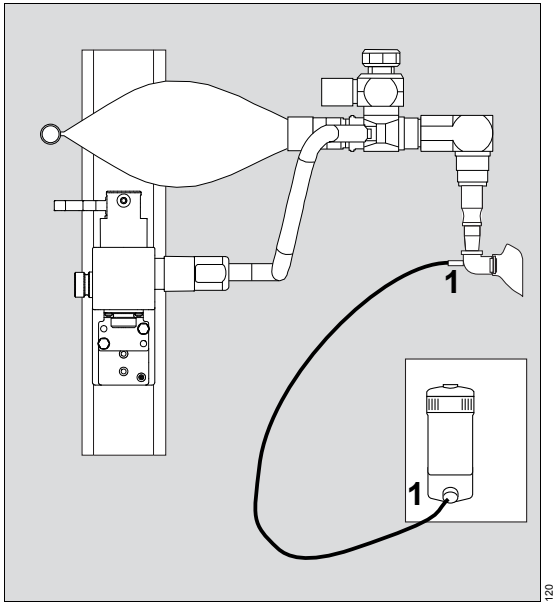
Connecting the non-rebreathing system, (e.g., “Waters”)

3 Connect the fresh-gas connector of the non-rebreathing system “Waters” to the cone port of the external fresh-gas outlet.



Connecting the sample line to the gas monitoring

1 Screw the sample line to the connections on the breathing mask or the breathing system filter and to the water trap on the gas monitor.

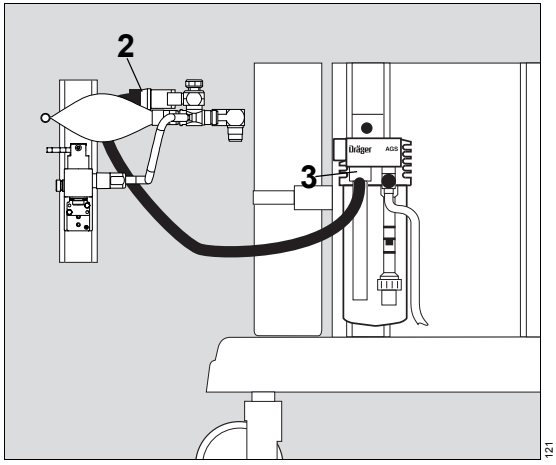


Connecting the Anesthetic Gas Receiving System (AGS)

2 If required, connect the anesthetic gas scavenging hose to the AGS adapter of the non-rebreathing system.

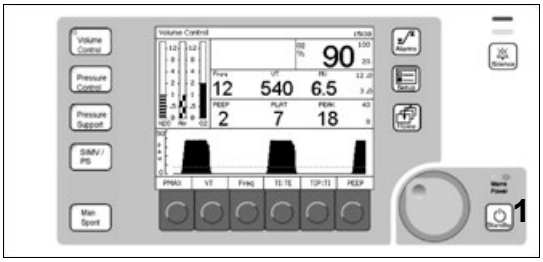
3 Connect the other end the anesthetic gas scavenging hose to the second port of the anesthetic gas receiving system (AGS).

- Follow the Instructions for Use included with the non-rebreathing system and the anesthetic gas receiving system (AGS).



Operation

1 Switch Fabius MRI to standby mode when using the external fresh gas outlet.

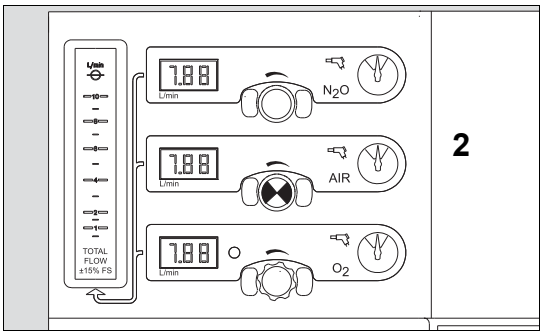


2 Set the fresh-gas flow.

NOTE

The fresh-gas supply must be equal to at least twice the minute volume in order to prevent rebreathing.

- Operate the non-rebreathing system according to the corresponding Instructions for Use.



Operation with non-rebreathing system

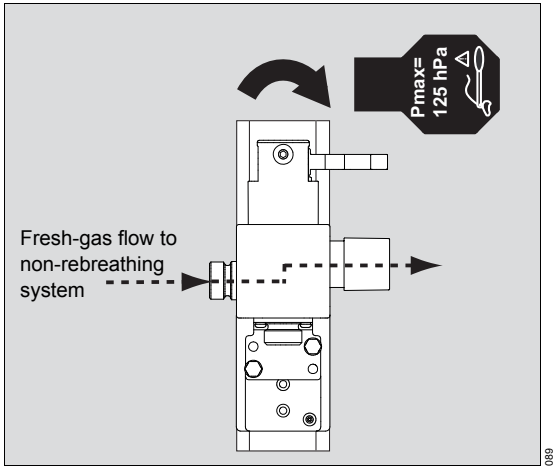
Fresh-gas flow to the non-rebreathing system:

- Set the lever on the switch to »  «.
  The lever points in the direction of the non-rebreathing system and shows the symbol for the non-rebreathing system.
- Set the fresh-gas flow.

NOTE

The fresh-gas supply must be equal to at least twice the minute volume in order to prevent rebreathing.

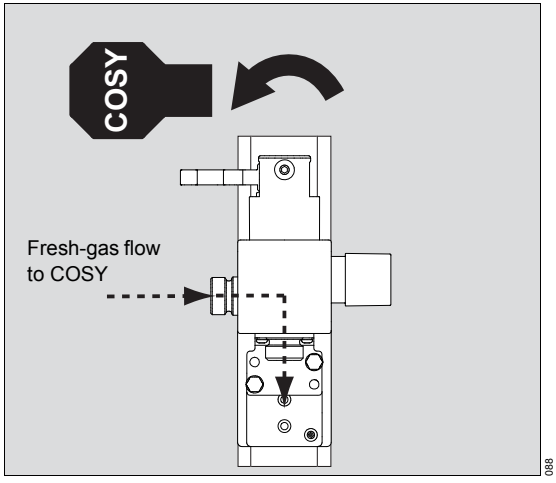
- Operate the non-rebreathing system according to the corresponding Instructions for Use.



Operation with COSY

Fresh-gas flow to the COSY:

- Set the lever on the switch to »**COSY**«.
  The lever points in the direction of the external fresh-gas outlet and shows »**COSY**«.



End of operation

- Close all the fresh-gas control valves on Fabius MRI.
- Make sure that the lever on the switch is set to »COSY«.
- Disconnect the non-rebreathing system from the external fresh-gas outlet.
- Connect the sample line to the Y-piece on the breathing circuit connected to the Compact Breathing System (COSY).

Preparing for Storage or Transport

WARNING

When moving the anesthesia workstation, remove all monitors and equipment from the top shelf and hinged arms, remove the absorber system, vaporizers, and reserve gas cylinders, push in the writing tray.

The anesthesia workstation should only be moved by people who are physically capable of handling its weight. Dräger recommends that two people move the anesthesia workstation to aid in maneuverability.

Exercise special care so that the machine does not tip when moving up or down inclines, around corners, and across thresholds (for example, in door frames and elevators). Do not attempt to pull the machine over any hoses, cords, or other obstacles on the floor.

WARNING

All the procedures described in this manual require that any use of ferromagnetic tools can only be done while the Fabius MRI is out of the scanner room.

WARNING

Do not bring any ferromagnetic tools or equipment into the scanning room.

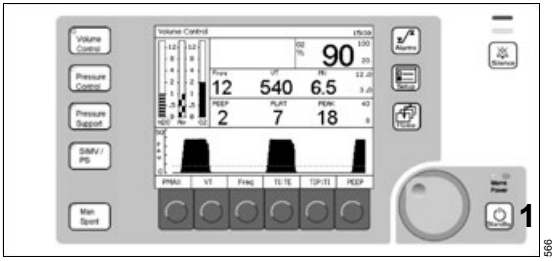
Ferromagnetic objects (made of steel, iron, or stainless steel) are strongly attracted to the magnet and can become harmful projectiles.

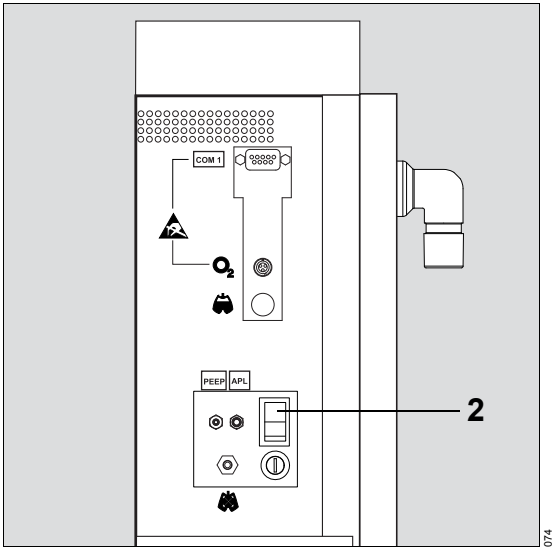
1 Press and confirm the »⏻« key (**Standby)**.
Monitoring and alarms are turned off and the ventilator stops.

- Turn vaporizers off by turning the handwheel to »**0**« until the button engages.
- Turn off fresh gas flow.
- Close the cylinder valves.
- Remove the O_2 sensor from the inspiratory valve and leave it exposed to air. This precaution prolongs the service life of the sensor.

2 Switch off system power using the switch on the back of the machine, and disconnect the power plug.

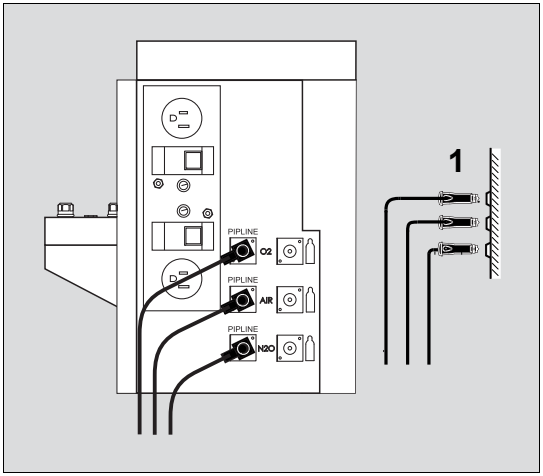
- Disconnect the scavenger hoses.





1 Remove the pipeline supply hoses from the central supply.

- Press the O_2 flush to depressurize the entire system.



Moving the Machine

The Fabius MRI has a central caster brake bracket on the front of the machine. To unlock the castors, release the brake by lifting the bracket (e.g., with the tip of your foot).

CAUTION

Do not attempt to move the anesthesia machine while the casters are locked.

CAUTION

Watch hoses connected to the patient while moving the Fabius MRI.

CAUTION

Do not push or pull the Fabius MRI using the absorber system, vaporizers, ventilator, or monitor.

CAUTION

The Fabius MRI should be moved by people who can handle its weight (approximately 425 lb (192.8 kg)). Take extra care to avoid tipping when moving on ramps, around corners, and over raised thresholds such as door frames and elevators.

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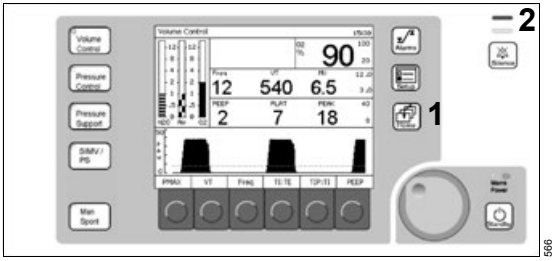
Monitoring

Main Screen

1 To display the main screen at any time, press the »⌂« key (**Home)**.

The Fabius MRI main screen displays current alarms, oxygen monitoring, breathing pressure monitoring, and respiratory volume monitoring information.



Alarms

Fabius MRI alarms are organized into three categories based on urgency:

– **Warning**: highest priority alarm, requiring immediate response
– **Caution**: medium priority alarm, requiring prompt action
– **Advisory**: low priority alarm/message that must be noted and action taken if necessary

Alarm Indication

The priority of Alarms is indicated to the user in three ways:

– a message appears in the alarm window
– an LED indicator (**2**) lights up
– an acoustic tone or sequence of tones is annunciated

The table to the right summarizes the specific way each type of alarm is indicated.

The alarm messages are only displayed on colored backround if the option “Color display” is enabled.

Alarm	Indication
Warning	– warning message appears in red in alarm window, followed by three exclamation marks (!!!) – red LED alarm indicator (**2**) blinks – alarm tone sequence (of five-beeps repeated two times) sounds every 10 seconds
Caution	– caution message appears in yellow in alarm window, followed by two exclamation marks (!!) – yellow LED alarm indicator (**2**) blinks – alarm tone sequence (of three-beeps) sounds every 30 seconds
Advisory	– advisory message appears in alarm window, followed by an exclamation mark (!) – yellow LED alarm indicator (**2**) lights continuously with internal priority ≥6: – a 2 tone sounds with internal priority <6: – no tone sounds

Sorting of displayed alarms

The alarms are sorted according to these categories. In the categories, the alarms are sorted and displayed according to the internal priority system. Priority 31 means the highest and priority 1 the lowest priority. The priority numbers are shown in the table "Fault-Cause-Remedy" on page 170.

A maximum of four alarms can be displayed in a list at the same time. High-priority alarms are displayed before low-priority alarms. Low-priority alarms are sometimes only displayed after the cause for a high-priority alarm has been remedied.

Example of audible alarm notification in the event of several alarms.

If an alarm with the category Warning is currently active and a new alarm with the category Warning is generated, the alarm sequence starts again by issuing an alarm with the same priority.

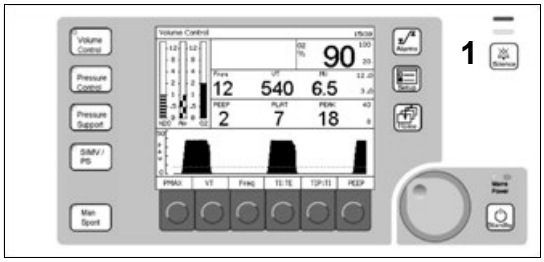
If alarm with the category Caution is also generated, no new audible alarm is issued. The Warning alarm notification is not interrupted because it has a higher priority.

If an alarm with the category Caution is currently active and a new alarm with the category Caution is generated, the alarm sequence starts again by issuing an alarm with the same priority.

If an alarm with the category Caution is active and an alarm with the category Warning is generated, the alarm sequence is started for the warning because the warning is assigned the highest priority.

Silencing Alarms

1 Press the »🔕« key (**Silence)** to silence all active audible alarms for two minutes. The yellow LED lights up.
The symbol »🔕« appears in the status bar with an indication of the silence time remaining.



To enable the alarm tone:

1 Press the »🔕« key (**Silence)**, the yellow LED turns off.

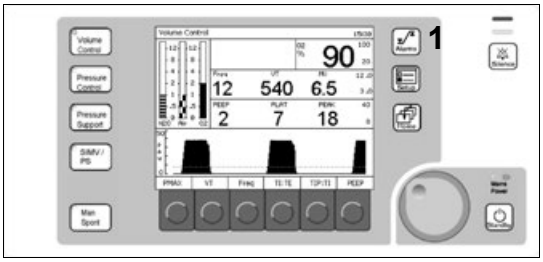
Disabling Volume Alarms

Visual and audible volume alarms can be turned on or off during operation using the »📋« key (**Setup)**.
See “Volume Alarms On/Off” on page 160.

Setting Alarm Limits

- To set the default alarm limits that take effect at machine power-up, see page 147.

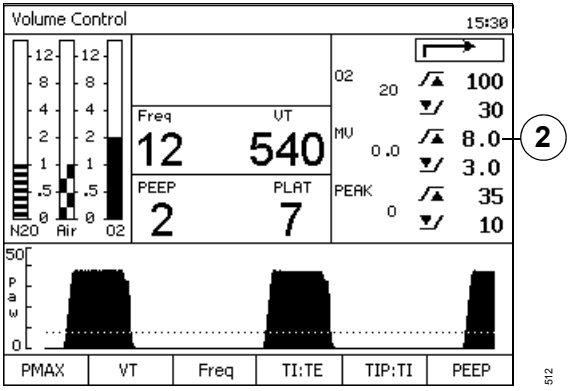
1 To set alarm limits for the current procedure, press the »[🔔]« key (**Alarms)**.



2 The alarm limits window is displayed on the screen.

The lower pressure limit PAW low is used for pressure monitoring to detect apneas (disconnection) and continuous pressure (on the screen represented as a dotted line). An alarm is generated when the pressure curve does not cross the pressure threshold either from above or below.

- Select the alarm limit value that needs to change.
- Confirm the alarm limit value and select a new value.
- Confirm the new value for the alarm limit. The new alarm limit is saved and the cursor moves to the return arrow.



The adjustment range and factory default values for all alarms on the Fabius MRI are shown in the following table.

Alarm Parameter		Adjustment Range	Factory Default Value
O_2 %	▲ ▼	19 to 100 18 to 99	100 20
MV L/min	▲ ▼	0.1 to 20.0 0.0 to 19.9	12.0 3.0
Pressure cmH_2O (hPa)	▲ ▼	10 to 70 5 to 30	40 8

Oxygen Monitoring

Inspiratory oxygen concentration is measured with a dual galvanic cell sensor, which is attached to the inspiratory valve dome. The sensor contains two independent electrochemical cells, or sensor halves. When the sensor is exposed to oxygen, an electrochemical reaction occurs within each cell. The oxygen monitor measures the current produced in each cell, computes an average for the two cells, and translates the average into an oxygen concentration measurement.

CAUTION

Risk of inaccurate measuring values

Never remove an oxygen sensor from its housing, except to replace it. If a sensor is removed from its housing, you must do the following before continuing normal operations:

– Reinstall the sensor in the housing.

– Calibrate the sensor.

NOTE

When the machine is not in use, remove the oxygen sensor assembly from the inspiratory valve dome, and insert the valve dome plug into the dome.

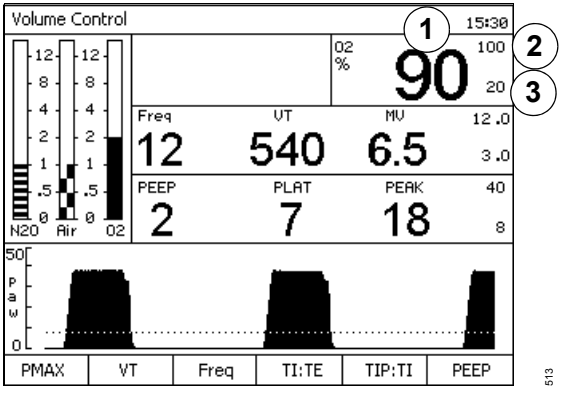
Oxygen Monitoring Window

The oxygen monitoring window shows the following information:

1 numerical value for inspiratory oxygen concentration in percent (%) within the range of 10 % to 100 %

2 high oxygen concentration alarm limit

3 low oxygen concentration alarm limit



Setting Oxygen Monitoring Alarm Limits

Follow the procedure "Setting Alarm Limits" on page 127 to change the high or low alarm limit.

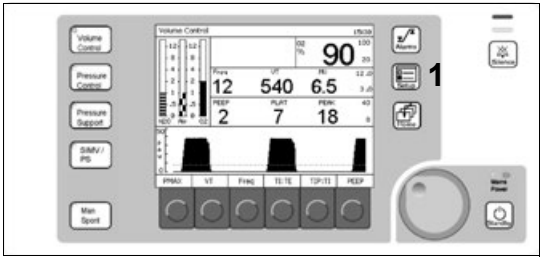
Calibrating the Oxygen Sensor

To calibrate the oxygen sensor correctly, make sure it is exposed only to room air during the entire calibration period. The oxygen sensor should be calibrated as part of the daily preoperative setup of the anesthesia equipment.

The oxygen sensor can be calibrated during Standby as described in “Calibrate O_2 Sensor” on page 161.

To avoid leakage, remove the oxygen sensor assembly from the inspiratory valve dome, and insert the valve dome plug into the dome.

To calibrate the oxygen during operation, follow the procedure below:



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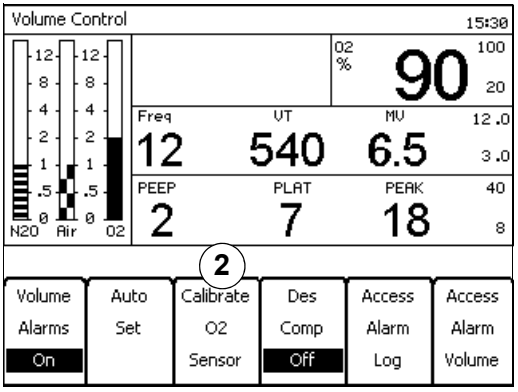
1 Press the »⊟« key (**Setup)** on the front panel. The Setup window appears at the bottom of the screen.

2 Press the »**Calibrate O_2 Sensor**« soft key.



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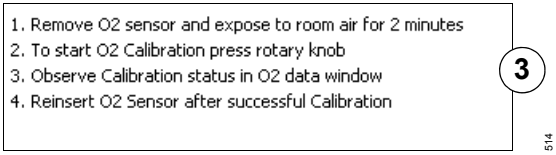
3 The calibration instruction window replaces the Setup window. Follow the directions provided.



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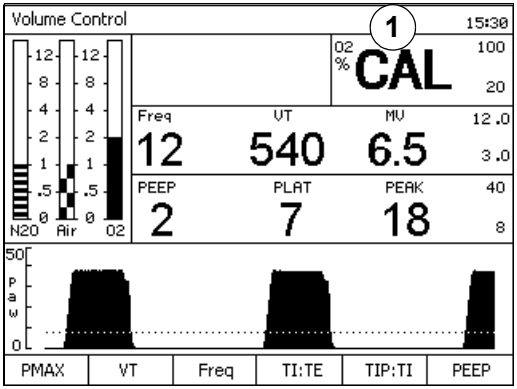
1 During the calibration period, the word »**CAL**« replaces the O_2 value in the oxygen monitoring window. Upon successful completion of the calibration, the O_2 measurement value will be restored.

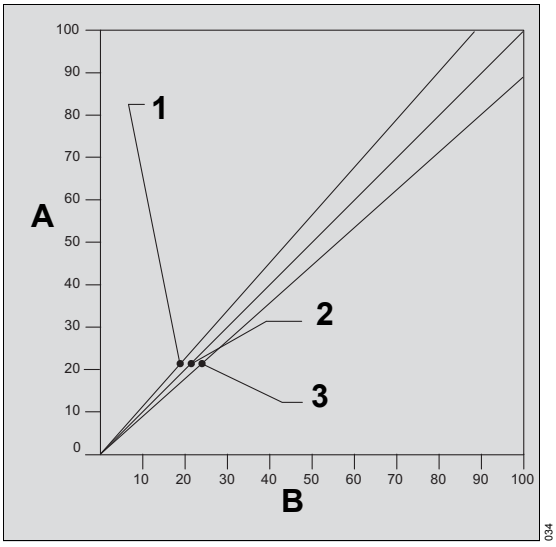


If, at the end of the calibration period, the »**O2 SENSOR FAIL!**« Advisory message appears in the Alarm window, the calibration was not successful.
An unsuccessful calibration can be caused by several conditions as described in the following table.

Cause	**Remedy**
Sensor was exposed to an excessively lean or excessively rich oxygen calibration mixture.	Make sure that the sensor is exposed to room air for the entire calibration period.
Sensor was exposed to a constantly changing calibration mixture.	Make sure that the sensor is exposed to room air for the entire calibration period.
Sensor did not receive the proper waiting period.	If the sensor capsule was removed from the sensor assembly, a waiting period equal to the time that the capsule spent outside the sensor assembly is necessary prior to calibration. New sensors require a 15-minute waiting period.
Sensor is exhausted.	If the oxygen sensor has decayed beyond its useful service life (see the “Specifications” section of the manual), replace the exhausted sensor with a new sensor and allow the proper waiting period.
Sensor is disconnected.	When the sensor is disconnected or if there is no cell in the housing, the display area is blank, and the message »**O2 SENSOR FAIL!**« appears in the Alarm window. If this happens, ensure that the sensor is correctly assembled and recalibrate the oxygen sensor.

Consequences of Incorrect O_2 Calibration

If the oxygen sensor is improperly calibrated, it can cause inaccurate measurements. When a calibration gas mixture is excessively rich or lean in oxygen, the Fabius MRI will not complete an attempted calibration; however, if the calibration gas is rich or lean but is within certain limits, the Fabius MRI will complete the calibration. As a result, when displaying sensor measurements, the Fabius MRI displays an oxygen percentage either higher or lower than the actual oxygen percentage. Therefore, make sure that the sensor is exposed only to room air during the entire calibration period.
The figure illustrates the relationship between the calibration mixture and the accuracy of oxygen measurement.



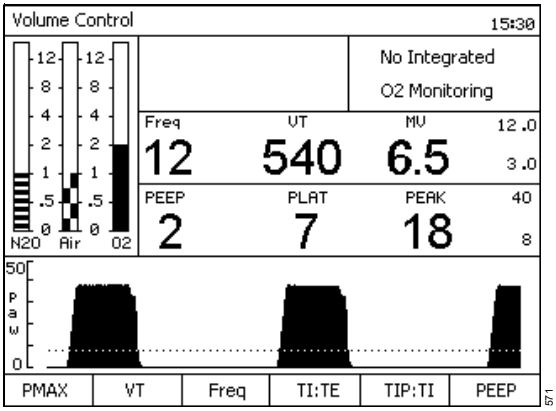
A Displayed O_2 Percentage
B Actual O_2 Percentage

1 At calibration, sensor exposed to <21 % O_2. Thus, displayed % O_2 will be higher than actual O_2.
2 Correct calibration of room air (21 % O_2) for entire calibration period.
Displayed % O_2 = actual % O_2.
3 At calibration, sensor exposed to >21 % O_2. Thus, displayed % O_2 will be lower than actual % O_2.

O_2 Monitoring Disabled

The following oxygen monitoring functions are disabled if the Fabius MRI is configured by DrägerService to run using the O_2 Monitoring Disabled option.

- “Oxygen Monitoring Window” on page 128
- “Setting Oxygen Monitoring Alarm Limits” on page 128
- “Calibrating the Oxygen Sensor” on page 129
- Fabius MRI-generated inspiratory O_2 and O_2 sensor alarms.



NOTE

If internal FiO_2 monitoring is deactivated, external FiO_2 monitoring must be available (according to ISO 21647).

NOTE

The message »**No Integrated O_2 Monitoring**« is displayed in the oxygen monitor window when O_2 monitoring is disabled.

Respiratory Volume Monitoring

Respiratory volume is measured using thermal anemometry. The flow sensor output is converted into meaningful readings for minute volume, tidal volume, and respiratory rate displays.

CAUTION

The functioning of the respiratory volume monitor may be adversely affected by the operation of electrosurgical equipment or short wave or microwave diathermy equipment in the vicinity.

NOTE

Sudden, irregular expiratory flow may cause erratic tidal volume and respiratory rate displays. To avoid such erroneous measurements, defer reading the display until a full minute has elapsed after the irregular flow has stopped.

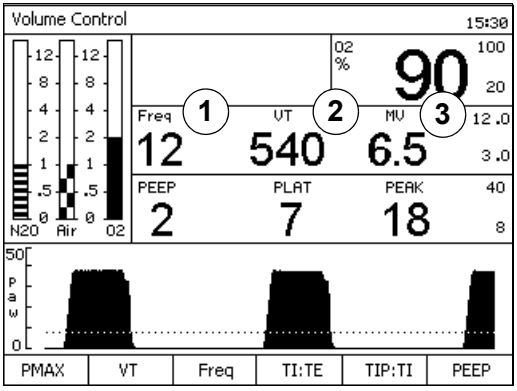
Respiratory Volume Monitoring Window

The respiratory volume monitoring window shows the following information:

1 Frequency (Freq) shows the number of breaths during the previous minute of respiration in units of Breaths Per Minute (bpm) (1/min).
Readings appear after two breaths.
The display range is from 2 bpm (1/min) to 99 bpm (1/min).

2 Tidal Volume Measurement (V_T) displays the expired volume for each breath in units of milliliters (mL).
The display range is from 0 mL to 1400 mL.

3 Minute Volume Measurement (MV) continuously displays the volume of exhaled gas accumulated during the previous minute of respiration in units of liters/minute (L/min).
The display range is from 0.0 L/min to 99.9 L/min.



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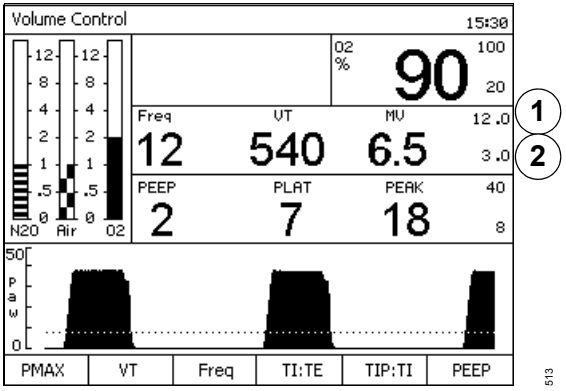
1 Minute Volume Alarm High Limit indicates the volume above which an alarm condition occurs (L/min).

2 Minute Volume Alarm Low Limit indicates the volume below which an alarm condition occurs (L/min).



Volume Monitoring Alarms

While the ventilator is on and the volume alarms are enabled, apnea alarms are generated if the respiratory volume monitor does not sense a valid breath for a specified period (see »**APNEA FLOW**« on page 170).
While the ventilator is off and the system is in ManSpont mode, these alarms are generated at 30 seconds (Caution) and 60 seconds (Warning).
The Fabius MRI's volume alarms are automatically enabled when the ventilator is switched from Standby to a ventilation mode.

Setting Minute Volume Alarm Limits

Follow the procedure "Setting Alarm Limits" on page 127 to change the high or low alarm limit.

Disabling Volume Alarms

Visual and audible volume alarms can be turned on or off during operation using the »⊟« key (**Setup)**. See “Volume Alarms On/Off” on page 160.

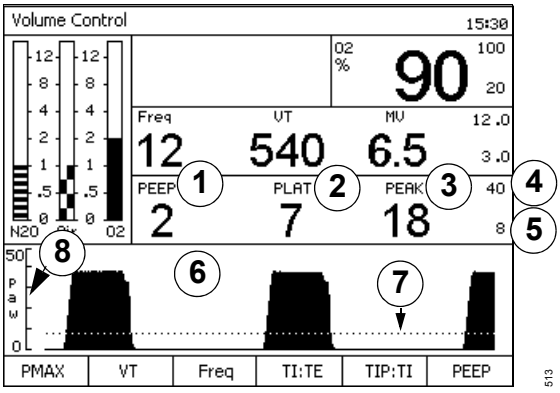
Breathing Pressure Monitoring

Breathing Pressure Monitoring Windows

The breathing pressure monitoring windows show the following breathing pressure information in numeric and graphic form:

NOTE

The Fabius MRI can be configured by DrägerService or your local authorized service organization to display mean pressure (MEAN) instead of plateau pressure (PLAT).



1 **PEEP** (Positive End Expiratory Pressure) shows the breathing pressure at the end of exhalation in cmH2O (hPa). The display range is from 0 to 30 cmH2O (0 to 30 hPa).

2 **PLAT** (Plateau) Breathing Pressure shows the breathing pressure at the end of inspiration in cmH2O (hPa). The display range is from 0 to 80 cmH2O (0 to 80 hPa)
or

2 **MEAN** Breathing Pressure shows the average of all the instantaneous pressure values recorded during each breath in cmH2O (hPa). The display range is from 0 to 50 cmH2O (0 to 50 hPa).

3 **PEAK** Breathing Pressure shows the highest instantaneous pressure value for each breath in cmH2O (hPa). The display range is from 0 to 80 cmH2O (0 to 80 hPa).

4 Pressure High Alarm Limit

5 Pressure Threshold Alarm Limit

6 Breathing Pressure Trace Window displays a breathing pressure trace (waveform).

7 Breathing Pressure Threshold Limit Line

8 Breathing Pressure Minimum and Maximum Trace Scale Limits Indicator. Pressure measurements are automatically scaled from 0 to 20, 0 to 50, or 0 to 100 cmH2O (0 to 20, 0 to 50, or 0 to 100 hPa).

Breathing Pressure Monitoring Alarms

While the ventilator is on, apnea pressure alarms are generated if the breathing pressure monitor does not sense a valid breath for a specified period of time (see »**APNEA PRESSURE**« on page 170). While the ventilator is off and the system is in ManSpont mode, these alarms are generated at 30 seconds (Caution) and 60 seconds (Warning).

Setting Pressure High and Threshold Alarm Limits

Follow the procedure "Setting Alarm Limits" on page 127 to change the breathing pressure high or threshold alarm limit.

NOTE

The pressure threshold alarm limit should be as close as possible to the sensed plateau pressure without exceeding it, approximately 4 cmH_2O (hPa) below the plateau pressure.

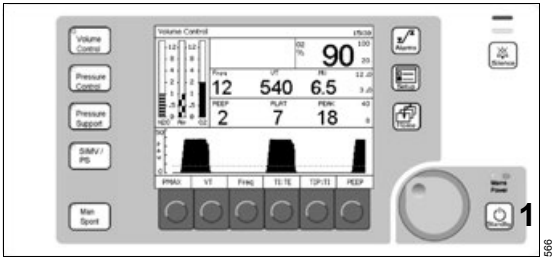
Configuration

Configuration Functions in Standby Mode

The configuration functions available in Standby include calibrations, system tests, and the management of default settings.

To access Standby mode:

1 Press the »⏻« key (**Standby)**.

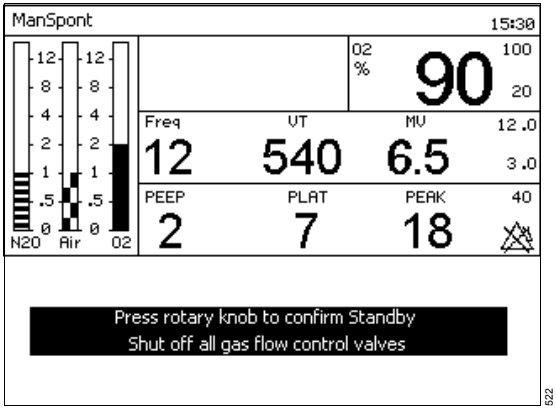


- The waveform window is replaced by a confirmation message and the instruction to shut off flow.

The LED on the Standby key starts blinking and will remain blinking until Standby is confirmed.

NOTE

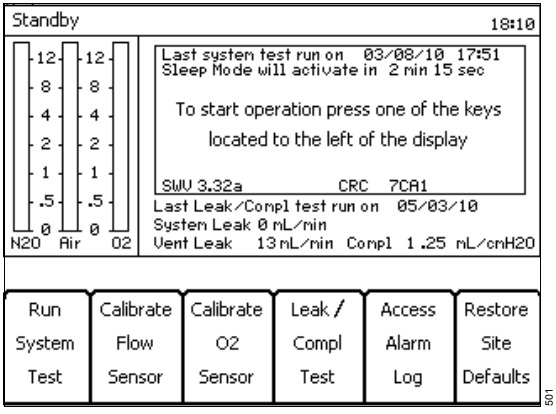
If confirmation does not occur within 15 seconds, the ventilator remains in the previous mode and the waveform window is restored.



- Confirm the mode change. The ventilator enters Standby mode, the Standby screen replaces the previous screen, and the Standby LED stops blinking and remains on.
  The following soft key labels appear at the bottom of the Standby screen:

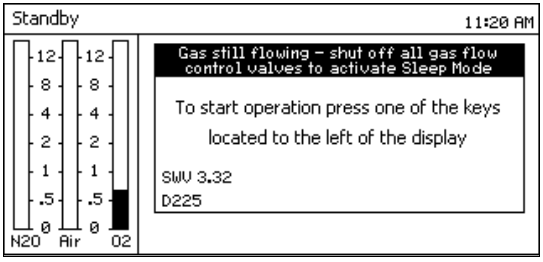
– »**Run System Test**«
– »**Calibrate Flow Sensor**«
– »**Calibrate O2 Sensor**«
– »**Leak / Compl Test**«
– »**Access Alarm Log**«
– »**Restore Site Defaults**«

- Turn off fresh gas flow.



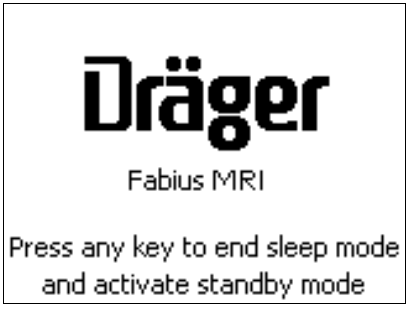
NOTE

If the flow control valves were not shut off before entering Standby mode, a »**Gas still flowing**« message appears on the Standby screen. The message will disappear once the flow is turned off.



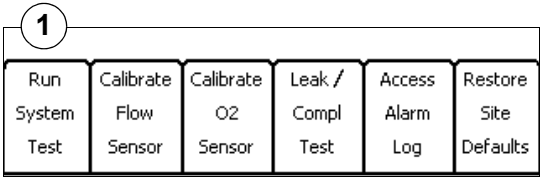
Sleep Mode

If 2.5 minutes elapse in Standby mode with no user input, Sleep mode is activated. The monitor screen is replaced by the screen saver. The screen saver displays a message that provides instructions on how to activate Standby mode.

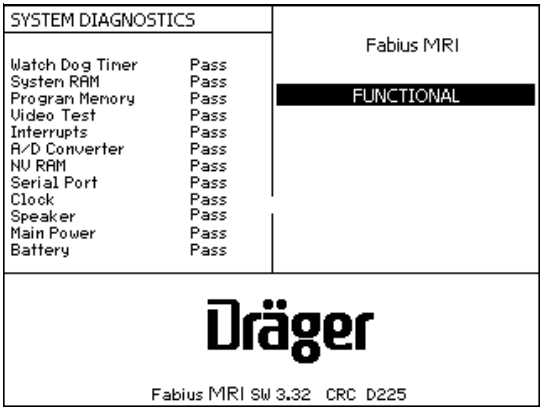


Run System Test

1 Press the »**Run System Test**« key. This test performs the power-up diagnostic tests (as described in “Power-Up Standby Screen” on page 86). Pressing this key restores the site defaults.



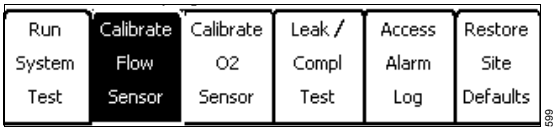
The test results are posted on the screen. Following successful completion, the system returns to the Standby screen.
This System Test checks the functionality of the electronics of the system.

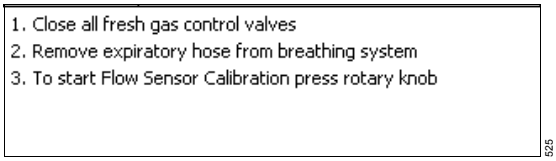


Calibrate Flow Sensor

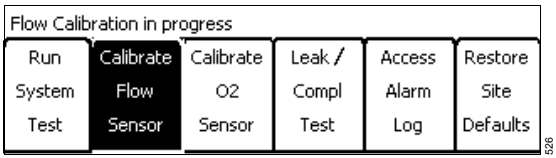
- Press the »**Calibrate Flow Sensor**« key on the Standby screen. The Standby soft key window is replaced by instructions for performing the calibration.
- Follow the instructions on the screen:

– Close all fresh gas control valves.
– Remove expiratory hose from breathing system.
– To start Flow Sensor Calibration press rotary knob.

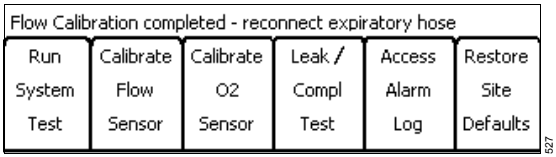




- When the calibration begins, the instructions are removed, and a »**Flow Calibration in progress**« message is displayed above the Standby soft keys.



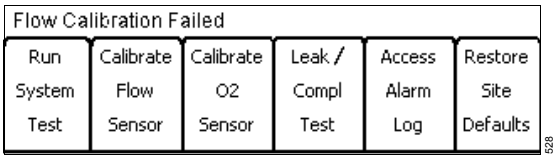
- When the calibration is completed, one of two messages is posted above the Standby soft keys: »**Flow Calibration completed - reconnect expiratory hose**« or »**Flow Calibration Failed**«.



Troubleshooting Flow Calibration Failure

If the flow sensor cannot be calibrated, retry the calibration.

If the flow sensor still cannot be calibrated, call DrägerService or your local authorized service organization.

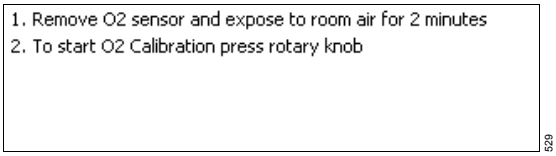


Calibrate O_2 Sensor

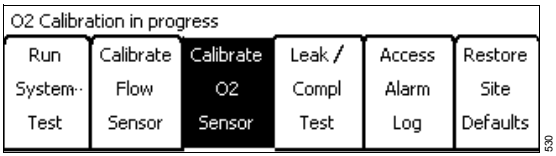
- Press the »**Calibrate O_2 Sensor**« key on the Standby screen. The Standby soft key window is replaced by instructions for performing the calibration.
- Follow the instructions on the screen:

– Remove O_2 sensor and expose to room air for 2 minutes.

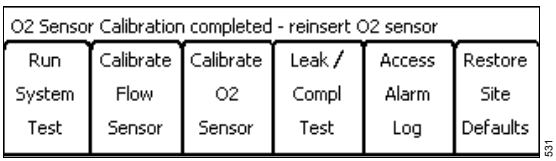
– To start O_2 Calibration press rotary knob.



- When the calibration begins, the instructions are removed, and a »**O_2 Calibration in progress**« message is displayed above the Standby soft keys.



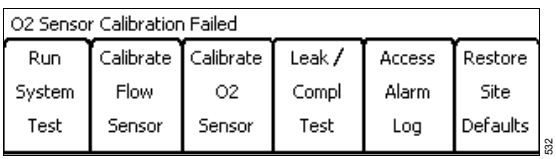
- When the calibration is completed, one of two messages is posted above the Standby soft keys: »**O_2 Sensor Calibration completed - reinsert O2 sensor**« or »**O_2 Sensor Calibration Failed**«.



Troubleshooting O_2 Sensor Calibration Failure

If the O_2 sensor cannot be calibrated, replace the O_2 capsule in the O_2 sensor housing (see page 197).

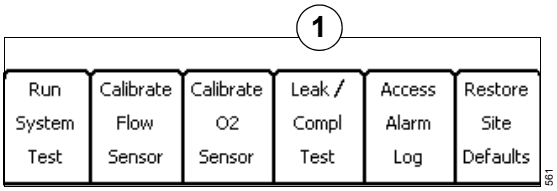
If the O_2 sensor still cannot be calibrated, call DrägerService or your local authorized service organization.



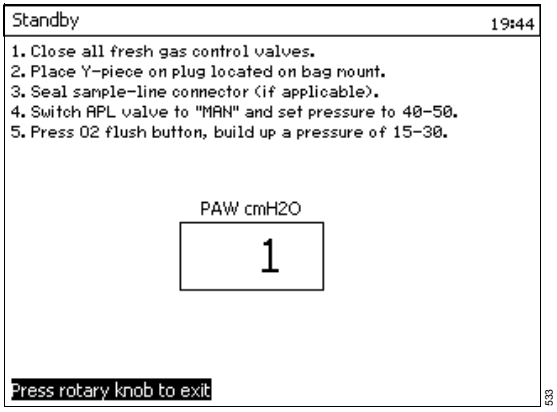
Leak/Compliance Test

The »**Leak/Compl Test**« key is used to initiate a system compliance test, a system leak test, and a ventilator leak test.

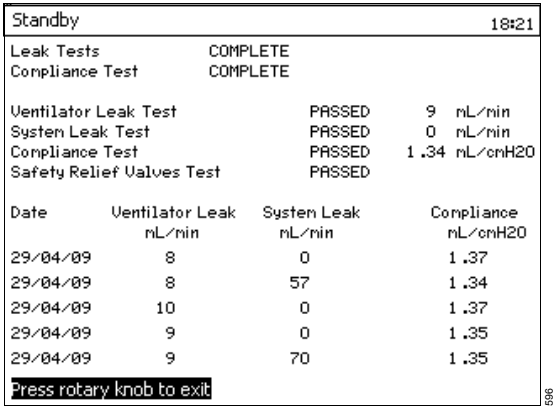
1 Press the »**Leak/Compl Test**« key on the Standby screen. The Standby soft key window is replaced by a ventilator preparation message and then instructions for performing the test.



- Follow the instructions on the screen:
- Close all fresh gas control valves.
- Place Y-piece on plug located on bag mount.
- Seal sample-line connector (if applicable).
- Switch APL valve to “MAN” and set pressure to 40 to 50.
- Press O2 flush button, build up a pressure of 15 to 30.



- Upon completion of the test, the results are posted on the screen.
- Press the rotary knob to return to the Standby screen.



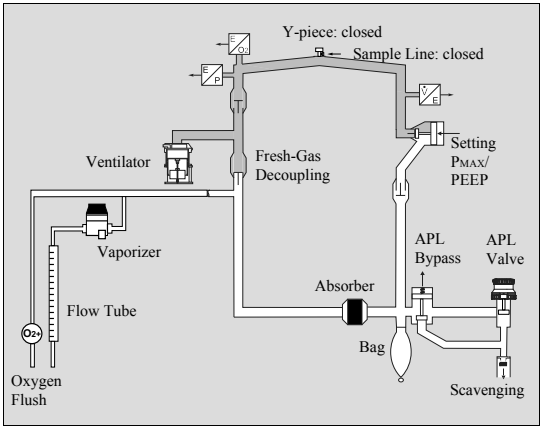
Compliance Test Results

The system compliance test determines the current compliance of the patient system with any filters, hoses, and Y-piece. The compliance value is used during volume controlled ventilation for applying a tidal volume matching accurately the set tidal volume. A system compliance value of up 6.5 mL/cmH_2O (6.5 mL/hPa) is posted as »**PASSED**« on the leak test result screen, and the compliance value is also displayed on the Standby screen.

Ventilator Leak Test Results

If a ventilator leak test is posted as »**PASSED**«, the value is displayed on the leak test result screen and the Standby screen.

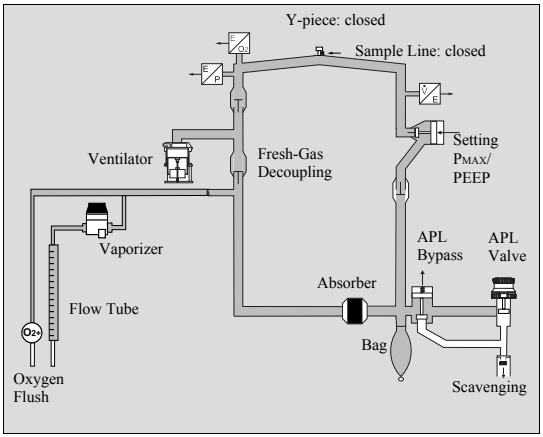
Measured ventilator leak [mL/min]	Displayed result [mL/min]
≤150	measured value and PASSED
151 to 250	measured value and FAILED
>250	>250 and FAILED



System Leak Test Results

System leak test results are posted on the leak test result screen.

Measured system leak [mL/min]	Displayed result [mL/min]
≤250	measured value and PASSED
251 to 350	measured value and FAILED
>350	>350 and FAILED



Safety Relief Valves Test

CAUTION
The high pressure safety relief valve (80 hPa (mbar)) is tested during the leak test. The test result is posted on the leak test result screen. In case the test has failed, the machine is conditionally functional. The valve may not be able to relieve an unexpected high pressure.

- Clean the valve or activate the valve manually, and repeat the leak test.

If the test fails again

- Contact DrägerService.

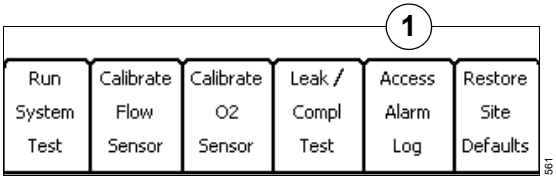
Possible Causes of Leaks

If the leak tests fail, check the following components of the breathing system, and repeat the leak test.

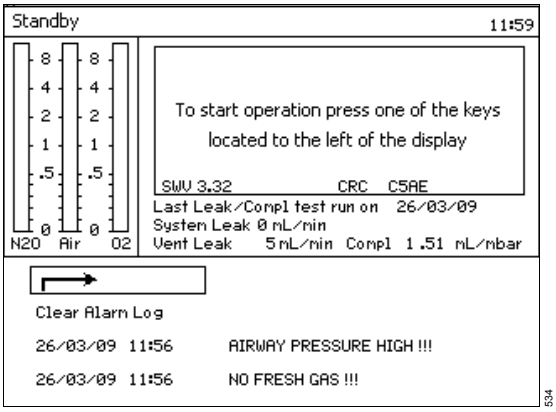
– damaged breathing hoses
– gas sample line fitting not plugged
– breathing bag/diaphragm defective
– vaporizer not connected correctly or filling device open
– absorber canister not firmly mounted in place
– flow sensor not installed properly
– breathing system not assembled and installed correctly
– microbial filters not connected securely
– breathing bag arm not tight or defective

Access Alarm Log

1 Press the »**Access Alarm Log**« key on the Standby screen. The Standby soft key window is replaced by the alarm log, which lists all alarms with their dates and times.



- To scroll through the alarm log, turn the rotary knob.
- To delete all alarms from the log, select and confirm the »**Clear Alarm Log**« label.
- To exit the alarm log and return to the Standby screen, select and confirm the return arrow.

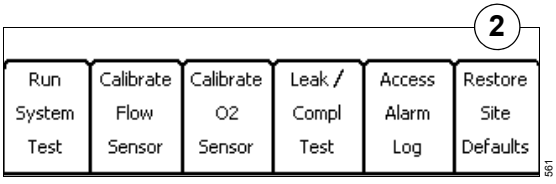


CAUTION

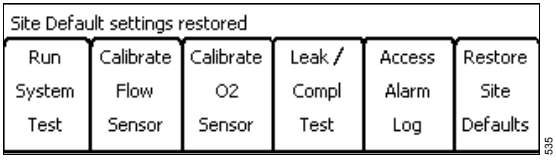
Alarm log data is deleted if Fabius MRI is switched off or a total loss of electrical power supply occurs.

Restore Site Defaults

2 Press the »**Restore Site Defaults**« key on the Standby screen. The predefined site defaults are restored, and a »**Site Default settings restored**« message is displayed above the Standby soft keys.



The site default settings are password protected. Changes of the settings can be made via the Standby Setup screen, see page 146.



WARNING

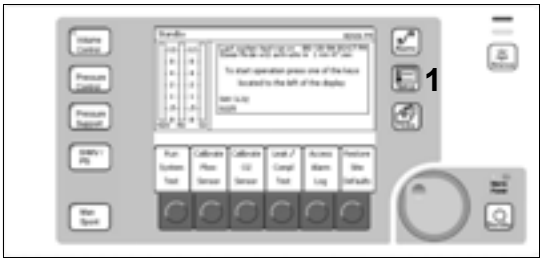
Risk of inappropriate ventilation settings

After site default settings have been restored check whether the ventilation and monitoring settings are appropriate to the patient.

Standby Setup Screen

Pressing the Setup key while in Standby provides access to various default and configuration settings. The settings made in this screen will be saved as Site Defaults.
In order for these settings to go into effect, press the »**Restore Site Defaults**« key on the Standby screen. The Site Defaults are also restored any time power is cycled or the system test is performed (see page 139).

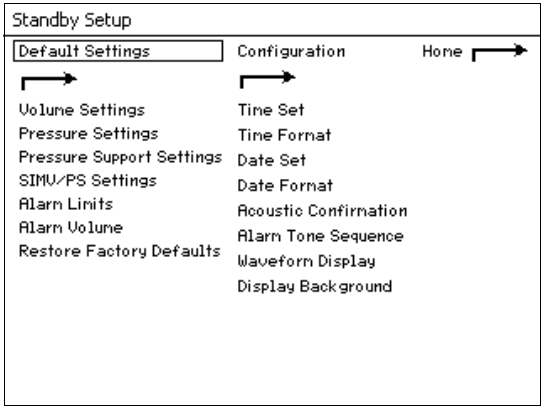
1 Press the »⊟« key (**Setup)** while in Standby mode.



The operator is requested to enter a four-digit password in order to prevent unauthorized changes to the basic functions. This password is allocated when commissioning the workstation. If desired, DrägerService can set an individual password or disable this functionality.

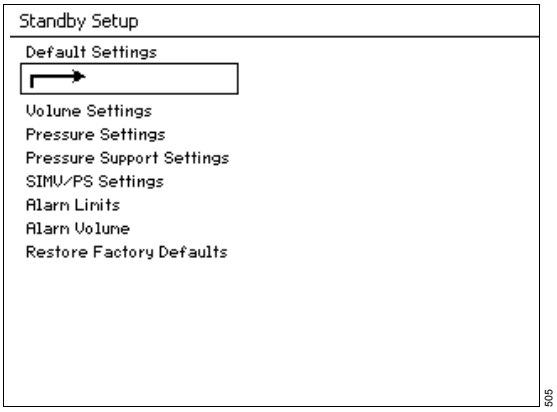
- Select and confirm the figures successively from the line displayed using the rotary knob.

- The Standby Setup screen replaces the Standby screen. The cursor allows the user to select »**Default Settings**« (see below) or »**Configuration**« (see page 153). (Selecting and confirming the return arrow on the right of the Setup screen will exit the Standby Setup screen and redisplay the Standby screen.)



Default Settings in Standby Setup

- Select and confirm the »**Default Settings**« label on the Standby Setup screen. (Selecting and confirming the return arrow will exit the Default Settings column and redisplay the main Setup screen.)

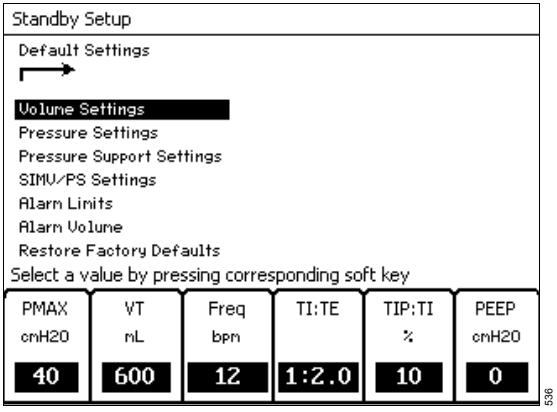


The following settings are available under Default Settings:

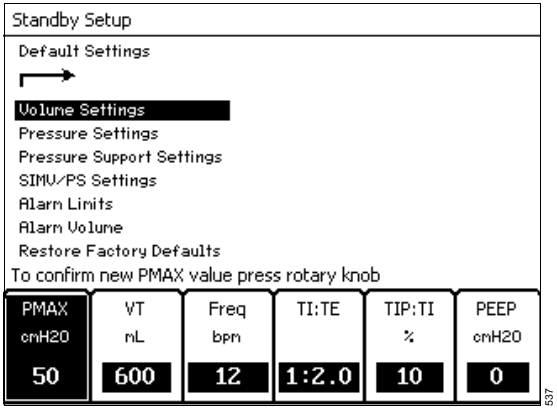
– »**Volume Settings**«
– »**Pressure Settings**«
– »**Pressure Support Settings**«
– »**SIMV/PS Settings**«
– »**Alarm Limits**«
– »**Alarm Volume**«
– »**Restore Factory Defaults**«

Volume Settings

- Select and confirm the »**Volume Settings**« label on the Standby Setup screen. The Default Volume Settings window appears at the bottom of the screen.

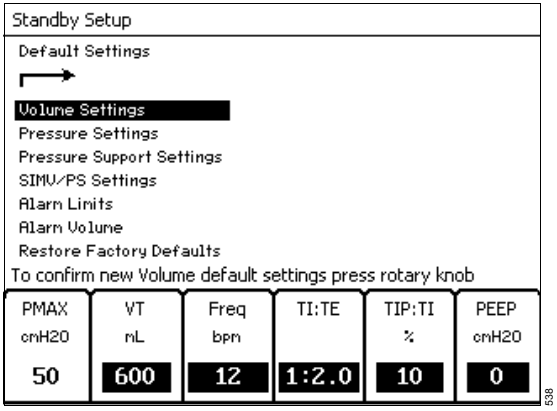


- Press the soft key for the parameter that needs to be changed (»**PMAX**« in the example illustration). The key becomes highlighted.
- Select a new **PMAX** value (in the example illustration, the value was changed from 40 to 50), and confirm as instructed by the message displayed above the soft keys.
- If necessary, repeat the process for the other Volume Settings parameters.



- When all Volume Settings parameters are set to desired values, confirm the default Volume Settings as instructed by the message displayed above the soft keys.

The Default Volume Settings window is then removed from the screen, and the cursor returns to the return arrow.



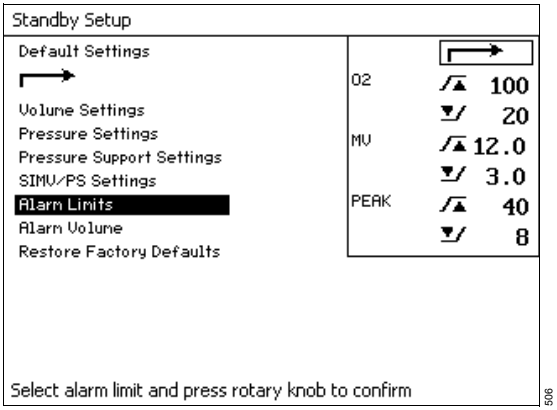
Pressure Settings, Pressure Support Settings, and SIMV/PS Settings

Use the procedure described in “Volume Settings” to change the parameters associated with these ventilator modes.

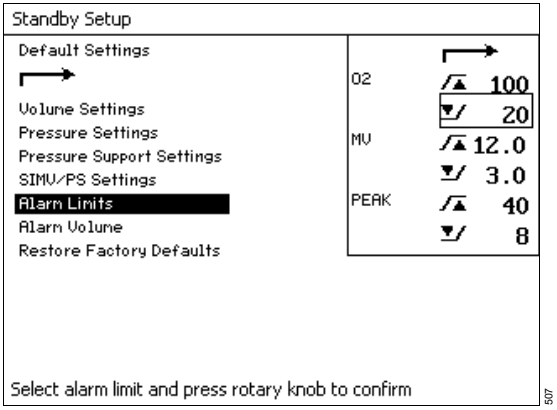
Alarm Limits

- Select and confirm the »**Alarm Limits**« label on the Standby Setup screen. The Default Alarm Limits window appears.

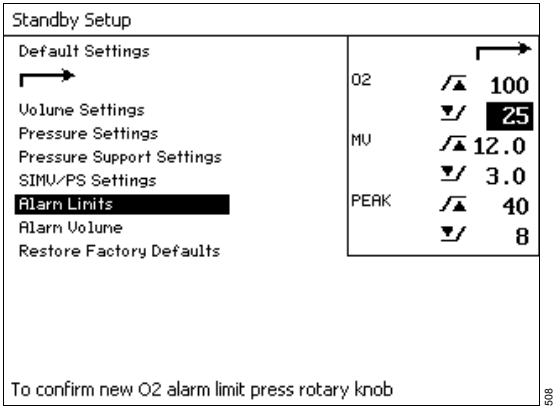
NOTE
Set the alarm limits to appropriate values.



- Select the alarm limit value that needs to change.



- Confirm the alarm limit value and select a new value. (In the example illustration, the O_2 alarm limit was changed from »**20**« to »**25**«.)
- Confirm the new value for the O_2 alarm limit. The new alarm limit is saved and cursor moves to the return arrow.
- If necessary, repeat the process for the other parameter alarm limits.

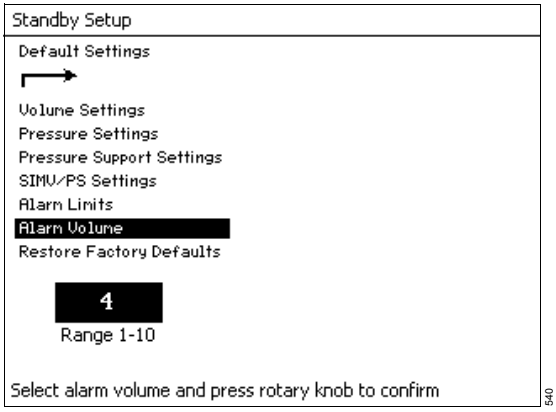


The adjustment range and factory default values for all alarms on the Fabius MRI are shown in the following table.

Alarm Parameter		Adjustment Range	Factory Default Value
O_2	⩘	19 to 100	100
%	⩗	18 to 99	20
MV	⩘	0.1 to 20.0	12.0
L/min	⩗	0.0 to 19.9	3.0
Pressure	⩘	10 to 70	40
cmH_2O (hPa)	⩗	5 to 30	8

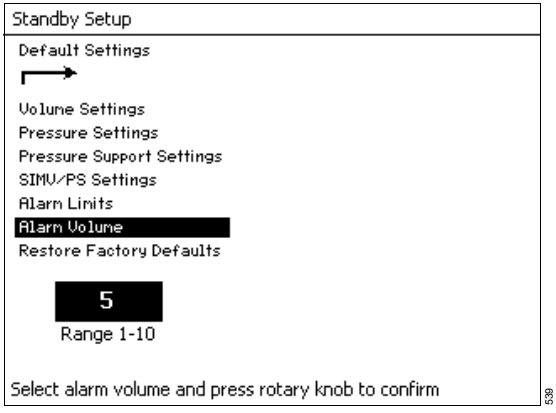
Alarm Volume

- Select and confirm the »**Alarm Volume**« label on the Standby Setup screen. The current alarm volume value appears on the screen.



- Select and confirm the new alarm volume value from 1 (minimum) to 10 (maximum) (range: >45 dB(A) to <85 dB(A)).

In the example illustration, the value was changed from »**4**« to »**5**«.
The Alarm Volume Setting window is then removed from the screen, and the cursor returns to the return arrow.

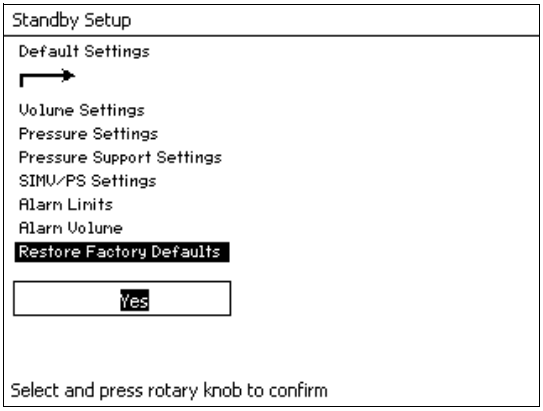


Current settings
The current settings cannot be saved as default settings.

To change the site defaults follow the instructions on pages “Restore Site Defaults” on page 145 to page 147.

Restore Factory Defaults

- Select and confirm the »**Restore Factory Defaults**« label on the Standby Setup screen. The Restore Factory Default setting window appears on the screen.
- Select and confirm »**Yes**« or »**No**«. When »**Yes**« is selected, the factory defaults are restored and replace the current default settings.



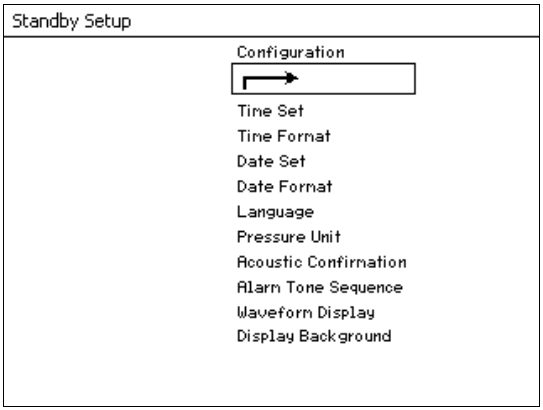
The factory defaults for the Fabius MRI are shown in the table below:

Parameter	Factory Default Settings
Volume Control	P_{MAX} = 40 V_T = 600 Freq = 12 T_I:T_E = 1:2.0 T_{IP}:T_I = 10 PEEP = 0
Pressure Control	P_{INSP} = 15 Freq = 12 T_I:T_E = 1:2.0 Insp Flow = 30 PEEP = 0
Pressure Support	ΔP_{PS} = 10 Freq Min = 3 Trigger = 2 Insp Flow = 30 PEEP = 0

Parameter	Factory Default Settings
SIMV/PS	P_{MAX} = 40 V_T = 600 Freq = 12 ΔP_{PS} = 10 PEEP = 0 Trigger = 2 Insp Flow = 30 T_{INSP} = 1.7 T_{IP}:T_I = 10
Alarm Default Settings for O_2	High = 100 Low = 20
Alarm Default Settings for MV	High = 12.0 Low = 3.0
Alarm Default Settings for Pressure	High = 40 Low = 8
Alarm Audio Volume	Volume level = 5

Configuration in Standby Setup

- Select and confirm the »**Configuration**« label on the Standby Setup screen. (Selecting and confirming the return arrow will exit the Configuration column and redisplay the main Setup screen.)

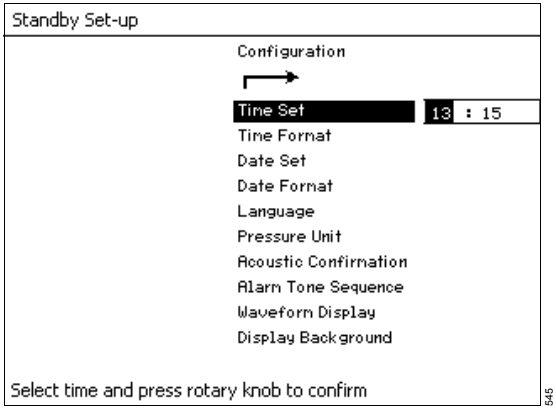


The following settings are available under Configuration:

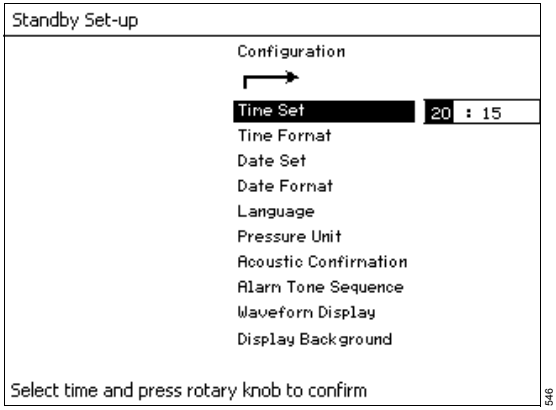
– »**Time Set**«
– »**Time Format**«
– »**Date Set**«
– »**Date Format**«
– »**Language**«
– »**Pressure Unit**«
– »**Acoustic Confirmation**«
– »**Alarm Tone Sequence**«
– »**Waveform Display**«
– »**Display Background**«

Time Set

- Select and confirm the »**Time Set**« label on the Standby Setup screen. The cursor appears over the hour field.

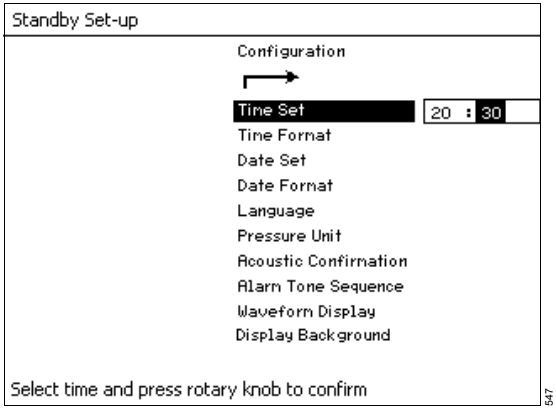


- Select and confirm a new hour time value (in the example illustration, the hour was changed from »**13**« to »**20**«). The cursor moves to the minutes field.



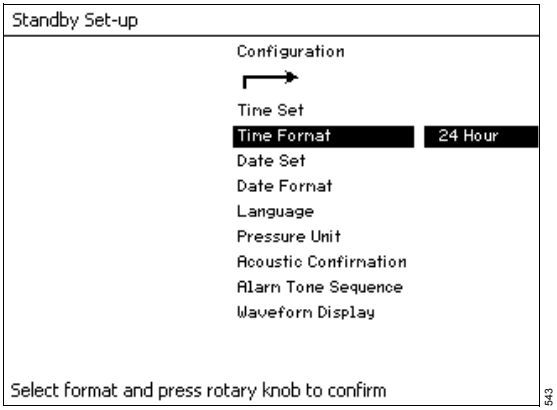
- Select and confirm a new minute time value (in the example illustration, the value was changed from »**15**« to »**30**«).

The new time values are saved, the Time Set window is removed from the screen, and the cursor returns to the Time Set label.



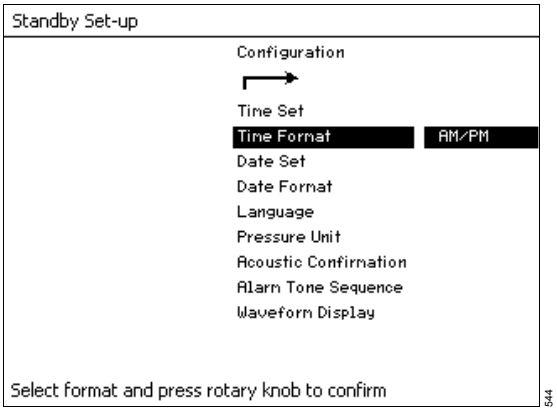
Time Format

- Select and confirm the »**Time Format**« label on the Standby Setup screen. The Time Format window appears next to the label.



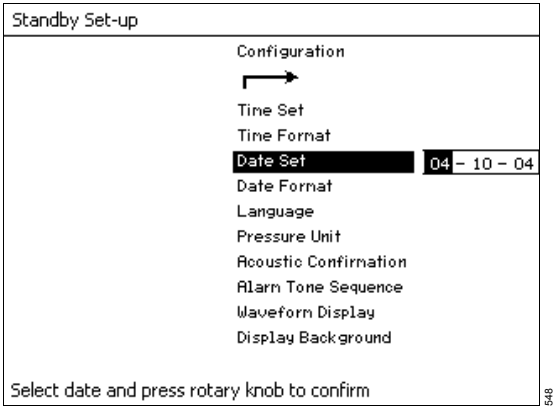
- Select and confirm the new time format value (in the example illustration, the value was changed from »**24 Hour**« to »**AM/PM**«).

The new time format value is saved, the Time Format window is removed from the screen, and the cursor returns to the »**Time Format**« label.



Date Set

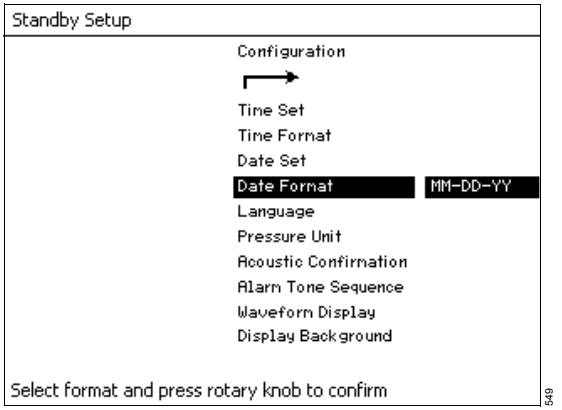
The values that can be selected are two-digit numerical values for day, month, and year.
Use the procedure described in “Time Set” on page 154 to change the date parameter.



Date Format

The values that can be selected for the date format are »**MM-DD-YY**« or »**DD-MM-YY**«.

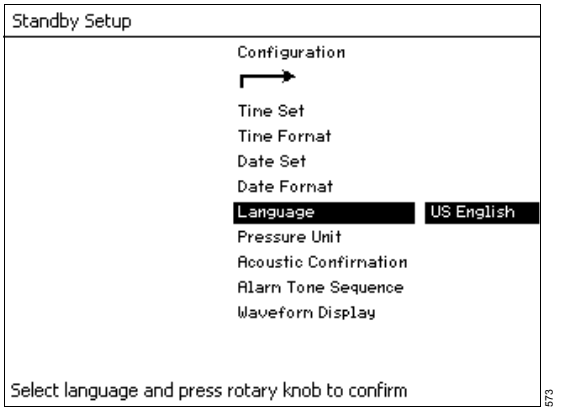
Use the procedure described in “Time Format” on page 155 to change the date format parameter.



Language

The user can select the language to be used for text display.

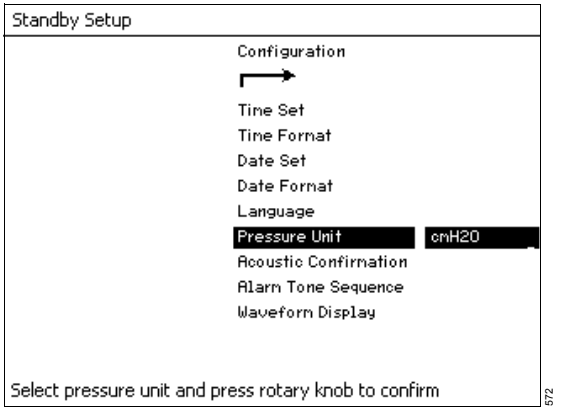
Use the procedure described in “Time Format” on page 155 to change the language parameter.



Pressure Unit

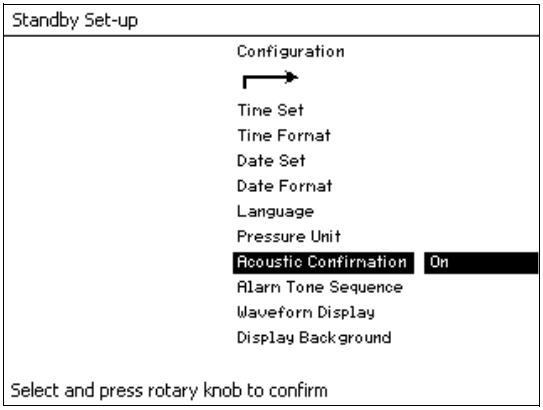
The values that can be selected are hPa (Hecto Pascal), cmH_2O (centimeters of water, and mbar (millibar).

Use the procedure described in “Time Format” on page 155 to change the pressure unit parameter.



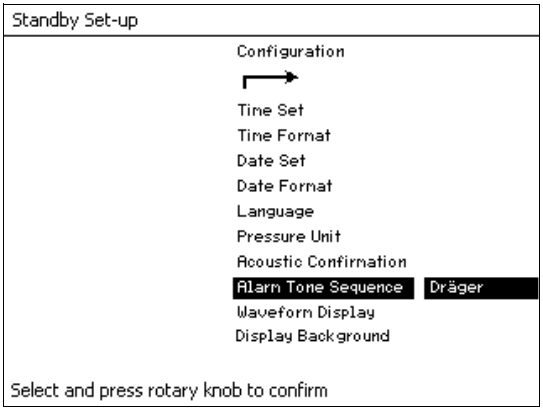
Acoustic Confirmation

The values that can be selected for the acoustic confirmation are »**On**« or »**Off**«.
If »**On**« is selected, an acoustic confirmation is annunciated every time that the rotary knob is pressed.
Use the procedure described in “Time Format” on page 155 to change the acoustic confirmation parameter.



Alarm Tone Sequence

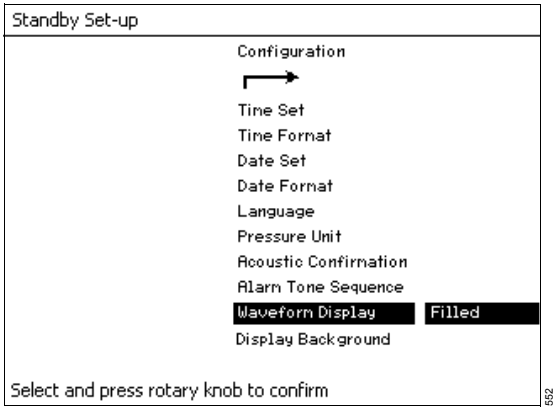
The values that can be selected for the alarm tone sequence are »**Standard**« or »**Dräger**«.
Use the procedure described in “Time Format” on page 155 to change the alarm tone sequence parameter.



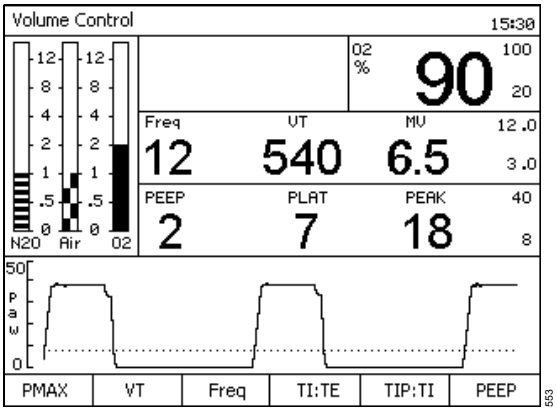
Waveform Display

The values that can be selected for the waveform display are »**Normal**« or »**Filled**«.

Use the procedure described in “Time Format” on page 155 to change the waveform display parameter.



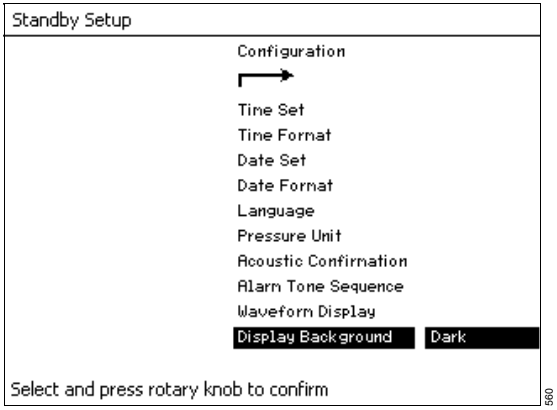
If »**Normal**« is selected, the waveform is not filled with a solid pattern, but appears as a line, as shown in the example illustration.



Display Background

The values that can be selected for the display background are »**Dark**« or »**Light**«.

Use the procedure described in “Time Format” on page 155 to change the display background parameter.



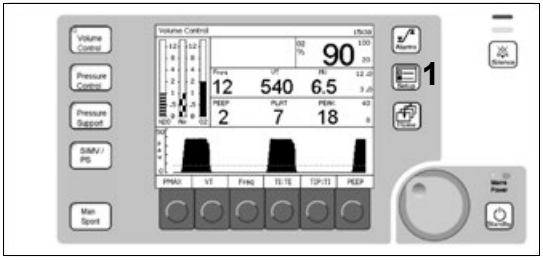
Configuration during Operation

The user can perform O_2 calibrations and view and change certain monitoring settings for the current operation while in Volume Control, Pressure Control, Pressure Support, SIMV/PS, and Man/Spont mode.

NOTE

To set default monitoring settings to be used at the power-up of each operation, see “Standby Setup Screen” on page 146.

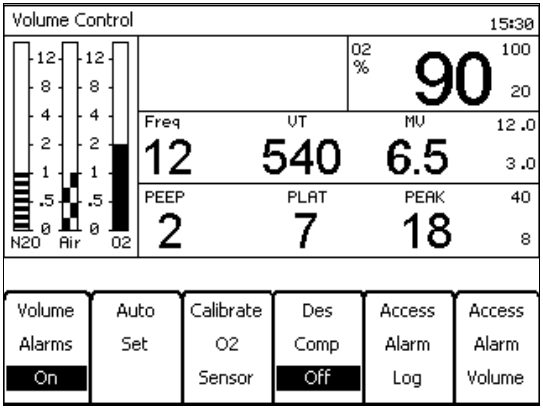
1 Press the »[Setup]« key (**Setup)** while in Volume Control, Pressure Control, Pressure Support, SIMV/PS, or Man/Spont mode.



- The Setup window replaces the waveform and soft keys for the current ventilator mode.

The following soft key labels appear in the Setup window:

– »**Volume Alarms On/Off**«
– »**Auto Set**«
– »**Calibrate O_2 Sensor**«
– »**Des Comp On/Off**«
– »**Access Alarm Log**«
– »**Access Alarm Volume**«



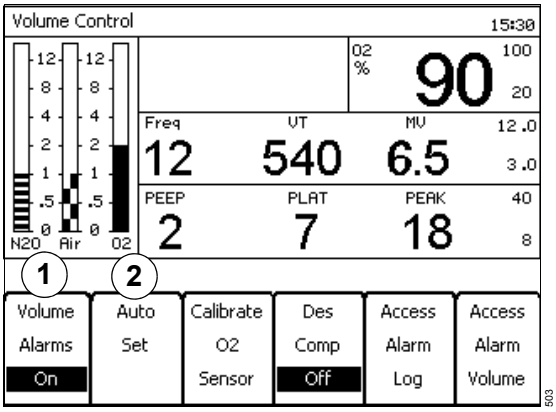
There is a 15-second timeout period for any of the Setup functions during operation. If no rotary knob activity occurs within 15 seconds, the Setup window is removed and the waveform window is redisplayed. The waveform window can be also be displayed by pressing the »[Home]« key (**Home)**.

Volume Alarms On/Off

1 Press the »**Volume Alarms On**« soft key in the Setup window. The key label changes from »**Volume Alarms On**« to »**Volume Alarms Off**«, and the volume alarms are disabled.

NOTE

The »**Volume Alarms On/Off**« soft key label does not appear in ManSpont mode because it is selectable on the ManSpont screen.



Auto Set

2 Press the »**Auto Set**« soft key in the Setup window. The breathing pressure threshold is set to 4 cmH_2O (hPa) below the current plateau pressure data value.

NOTE

The threshold setting may not be less than 5 cmH_2O (5 hPa) or greater than 30 cmH_2O (30 hPa).

NOTE

In the absence of a current plateau pressure data value, pressing the soft key will have no effect.

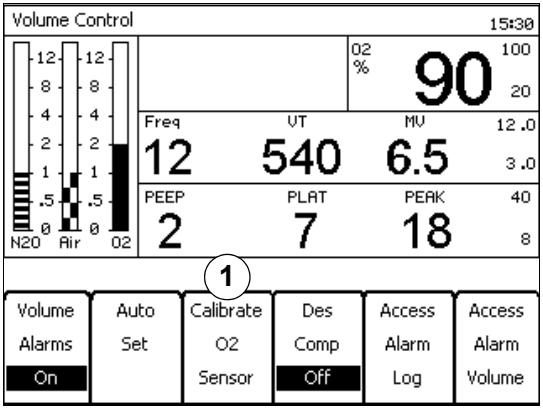
NOTE

In SIMV/PS mode, the breathing pressure threshold will be set relative to the mandatory ventilation stroke.

Calibrate O_2 Sensor

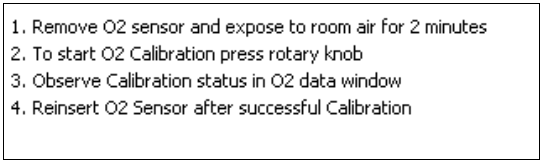
To calibrate the oxygen sensor correctly, make sure it is exposed only to room air during the entire calibration period.
To avoid leakage, remove the oxygen sensor assembly from the inspiratory valve dome, and insert the valve dome plug into the dome.

1 Press the »**Calibrate O_2 Sensor**« soft key in the Setup window.

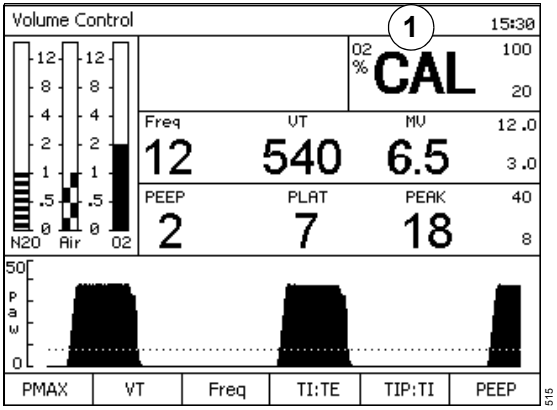


- The calibration instruction window replaces the Setup window. Follow the directions provided:

– Remove O_2 sensor and expose to room air for 2 minutes.
– To start O_2 calibration press rotary knob.
– Observe Calibration status in O_2 data window.
– Reinsert O_2 Sensor after successful calibration.



1 During the calibration period, the word “**CAL**” replaces the O_2 value in the oxygen monitoring window. Calibration time is approximately 15 seconds. Upon successful completion of the calibration, the O_2 measurement value will be restored.



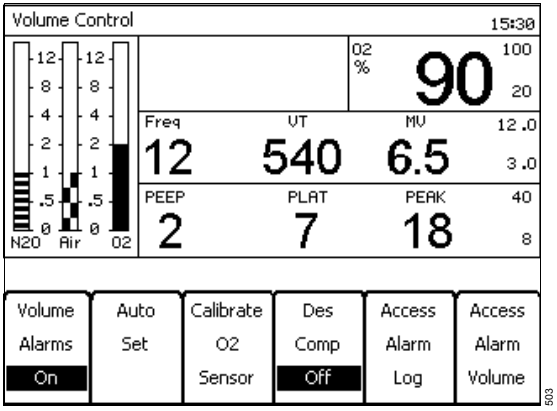
If the O_2 sensor cannot be calibrated, replace the O_2 capsule in the O_2 sensor housing (see page 197).
If the O_2 sensor still cannot be calibrated, call DrägerService or your local authorized service organization.

Des Comp On/Off

CAUTION
The Des Comp On/Off function is not relevant for MRI use.

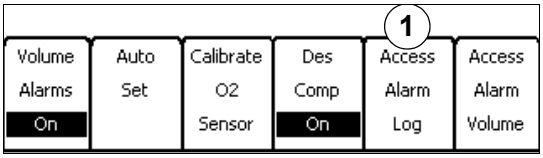
CAUTION
The Des Comp On/Off parameter remains in the Off position on the Fabius MRI.

WARNING
The Desflurane vaporizer is not useable in an MR environment. In an MR environment functionality of the Desflurane vaporizer will be compromised.

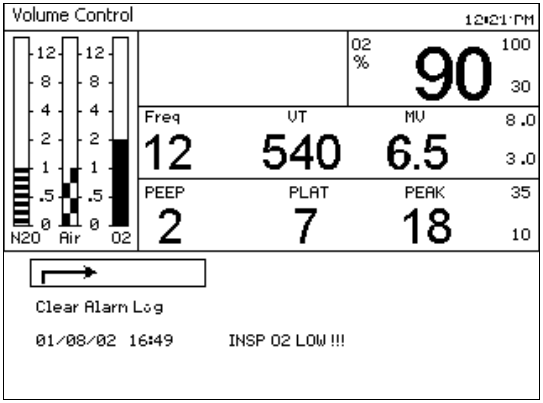


Access Alarm Log

1 Press the »**Access Alarm Log**« key in the Setup window. The Setup window is replaced by the alarm log, which lists all alarms with their dates and times.

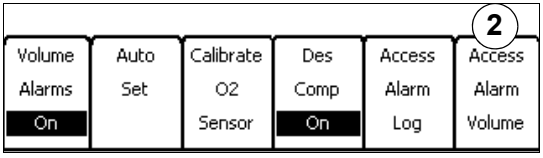


- To scroll through the alarm log, turn the rotary knob.
- To delete all alarms from the log, select and confirm the »**Clear Alarm Log**« label.
- To exit the alarm log and return to the Setup window, select and confirm the return arrow.



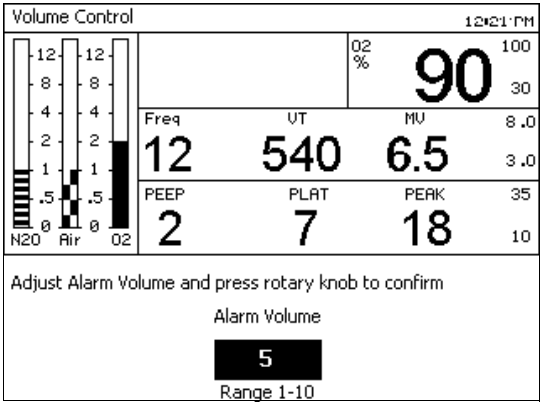
Access Alarm Volume

2 Press the »**Access Alarm Volume**« key in the Setup window.



- The Setup window is replaced by the Alarm Volume Setting window
- Select and confirm a new alarm volume value in the range of 1 (minimum) to 10 (maximum).

The value is saved and the Alarm Volume Setting window is replaced by the Setup window.



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Fault-Cause-Remedy

Power Failure Backup

When AC power is interrupted from the Fabius MRI, the internal battery backup will provide full operation of the ventilator and internal monitors for up to two hours after the power interruption. The battery depletion rate depends upon ventilator settings and the condition of the battery (age and level of charge), but under no circumstances should a fully charged battery provide less than 45 minutes of full functionality.

The transition to battery-powered operation will not interrupt any machine functions. At the transition, and as the battery is discharged, the following information will be displayed:

– The battery symbol ( ) appears in the status bar and the Mains Power LED turns off.
– The »**POWER FAIL!**« Advisory alarm message is displayed in the alarm window.
– When the battery is discharged to 20 % of its reserve power, the »**BATTERY LOW!**« Advisory alarm message is displayed in the alarm window.
– When the battery is discharged to 10 % of its reserve power, the »**BATTERY LOW!!**« Caution alarm message replaces the Advisory alarm message in the alarm window.
– When the battery is almost fully discharged, the ventilator will stop and the Ventilator Fail Warning alarm message (»**VENTILATOR FAIL!!!**«) is displayed in the alarm window.
– If manual ventilation is not provided, the Apnea Pressure Warning (»**APNEA PRESSURE!!!**«), Apnea Flow Warning (»**APNEA FLOW!!!**«), and Minute Volume Low Caution (»**MINUTE VOLUME LOW!!**«) alarm messages are displayed in the alarm window.
– The internal monitors continue to operate until the battery is completely discharged and all electronics are shut down.

WARNING

When the »BATTERY LOW!!« Caution alarm message is first displayed, the ventilator will continue to operate for up to an additional 10 minutes. Then, automatic ventilation is not available until AC power is restored.

CAUTION

Never allow the battery to completely discharge. If the battery is discharged completely, recharge immediately. Do not use the device until the battery is recharged completely as injury to the patient may occur if the battery is unavailable.

When the battery is completely discharged Fabius MRI switches off. As a consequence all individual settings, which are not saved in the default settings, will be lost.
All pneumatic functions of the Fabius MRI continue to be available (APL valve, breathing pressure gauge, cylinder and pipeline gauges, fresh gas and agent delivery, S-ORC, and total flowmeter). Manual or spontaneous ventilation can be maintained.

When the power supply is recovered and Fabius MRI restarted, all ventilation and alarm settings are reset to the saved default settings.

WARNING

Danger of patient injury by wrong device settings or patient settings.
Parameter for ventilation or monitoring may be set user-specific.
After restart of the device, check the settings and adapt them to your patient, if neccessary.

Ventilator Fail State

If the Fabius MRI does not recover from a »**VENTILATOR FAIL!!!**« condition:

- Switch to ManSpont mode by pressing the ManSpont key and confirming the mode change by pressing the rotary knob.
- Set the APL valve to MAN position.
- Adjust the APL pressure limit for the desired inspiratory plateau pressure.
- Press the O_2 flush button on the Fabius MRI as required to sufficiently inflate the breathing bag.
- Manually ventilate the patient by squeezing the breathing bag.

WARNING

Risk of patient injury

If the ventilator fails, the anesthesia machine switches to the ventilation mode ManSpont. Set the APL valve to a correct pressure limiting value and ventilate the patient manually.

NOTE

In the ventilator fail situation, the ventilator piston assembly position may not be locked. As a result, airway pressure may initially push the piston back to its limit stop, increasing the volume of the breathing circuit. It may be necessary to press the O_2 flush button again to reinflate the breathing bag.

Overriding the Ventilator

In the unlikely event of a fault in which the ventilator does not recover, and the user cannot switch to manual ventilation mode through the use of the ManSpont key and rotary knob, manual ventilation is still possible.

- Locate the ON/OFF switch on the rear panel.
- Toggle the ON/OFF switch to “off” ( ) and then
- Toggle the ON/OFF switch back to “on” ( ). The ventilator now performs as in ManSpont mode.
- Set the APL valve to MAN position.

- Adjust the APL pressure limit for the desired inspiratory plateau pressure.
- Press the O_2 flush button on the Fabius MRI as required to sufficiently inflate the breathing bag.
- Manually ventilate the patient by squeezing the breathing bag.

NOTE

After toggling the main power switch, the Fabius MRI will perform its diagnostic tests. During the diagnostic tests, manual ventilation is possible. If the diagnostic tests result in **FUNCTIONAL**, the Fabius MRI will automatically switch to ManSpont mode if a fresh-gas flow is detected. Fabius MRI respiratory monitoring is available. If the diagnostic tests result in **NON-FUNCTIONAL**, manual ventilation is still possible but Fabius MRI respiratory monitoring is not available.

NOTE

In ventilator override situation, the ventilator piston position may not be locked, as in ManSpont mode. As a result, airway pressure may push the piston backwards to its limit stop, thus increasing the volume of the breathing circuit. It may be necessary to press the O_2 flush button again to reinflate the breathing bag.

- Contact DrägerService or your local authorized service organization before using the ventilator.

Fault-Cause-Remedy

The Fabius MRI divides alarm messages into three categories based on priority. Exclamation marks indicate the priority. The alarm messages are displayed on colored background if the option "Color display" is enabled:

!!!	Warning (red)	high priority
!!	Caution (yellow)	medium priority
!	Advisory (white)	low priority

Internal priority numbers, see page 125, for the ranking within an alarm category are written below in brackets, e.g. (23 / 31).

Priority	Alarm Message	Probable Cause	Remedy
!!! (31)	**AIRWAY PRESSURE HIGH**	Upper alarm limit for airway pressure has been exceeded, ventilation hose is kinked. Alarm limit has been set too low.	Check hose system on anesthesia machine. Check breathing circuit or alarm limit value.
!! / !!! (23/31)	**APNEA FLOW[1)]**	Breathing/ventilation stops. Leak or disconnect in breathing circuit.	Check ventilator. Check breathing circuit.
!! / !!! (23/31)	**APNEA PRESSURE[2)]**	Breathing/ventilation stops. Leak or disconnect in breathing circuit.	Check ventilator. Check breathing circuit.

1) APNEA FLOW alarm priorities are based on alarm duration and ventilation mode:
In Volume Control, Pressure Control, SIMV/PS with Freq ≥6, or Pressure Support with Apnea Ventilation OFF:
Caution = V_T <20 mL for >15 seconds
Warning = V_T < 20 mL for >30 seconds
In ManSpont, SIMV/PS with Freq <6, or Pressure Support with Apnea Ventilation ON:
Caution = V_T <20 mL for >30 seconds
Warning = V_T <20 mL for >60 seconds

2) APNEA PRESSURE alarm priorities are based on alarm duration and ventilation mode:
In Volume Control, Pressure Control, SIMV/PS with Freq ≥6, or Pressure Support with Apnea Ventilation OFF:
Caution = P_{AW} does not cross the pressure threshold for >15 seconds
Warning = P_{AW} does not cross the pressure threshold for >30 seconds
In ManSpont, SIMV/PS with Freq <6, or Pressure Support with Apnea Ventilation ON:
Caution = P_{AW} does not cross the pressure threshold for >30 seconds
Warning = P_{AW} does not cross the pressure threshold for >60 seconds

Priority	Alarm Message	Probable Cause	Remedy
!! **(20)**	**APNEA VENTILATION**	Breathing/ventilation stops. Leak or disconnect the breathing circuit. If two or more consecutive Apnea Ventilation breaths are auto triggered. Pressure Support settings are incorrect.	Check ventilator. Check breathing circuit. A spontaneous patient breath is detected by the Fabius MRI. Check Pressure Support settings.
! **(7)**	**BATTERY LOW**	AC failure and battery <20 %	Restore mains power.
!! **(17)**	**BATTERY LOW**	AC failure and battery <10 %	Restore mains power.
!!! **(26)**	**CHECK APL VALVE**	APL bypass valve fault.	Check ventilator diaphragm and close cover. Check APL bypass valve connection for disconnect or leak. Select Standby Mode and switch back to the previous ventilation mode. Check the APL valve setting.
! **(7)**	**CHECK BATTERY**	The reserve power is 0 % of a full charge.	Replace fuse. Call DrägerService or your local authorized service organization.
!!! **(31)**	**CONTINUOUS PRESSURE**	Breathing pressure above threshold for more than 15 seconds.	Check breathing circuit. If in ManSpont mode, check fresh gas flow. Check actual limit ▼/ for "Pressure threshold alarm limit".
!! **(15)**	**EXP PORT LEAKAGE**	Expiratory flow of more than 15 mL measured during inspiration in Volume Control, Pressure Control, or Pressure Support mode.	Check expiratory valve and valve disk. Check tubing of expiration control line. Check flow sensor. Follow the procedure to calibrate flow sensor. Call DrägerService or your local authorized service organization.
!! **(16)**	**EXP PRESSURE HIGH**	PEEP is more than 4 cmH_2O (hPa) above the PEEP setting in an automatic ventilation mode.	Check PEEP/P_{MAX}, etc. hoses for kinks.

Priority	Alarm Message	Probable Cause	Remedy
! **(4)**	**FLOW SENSOR CAL DUE**	More than 18 hours passed since last flow sensor calibration. Cable has been removed and reconnected.	Follow the procedure to calibrate flow sensor (see page 140).
! **(8)**	**FLOW SENSOR FAIL**	Sensor cable is disconnected. Flow sensor has not been properly calibrated. Sensor faulty.	Reconnect sensor cable to sensor at breathing system. Follow the procedure to calibrate sensor (see page 140). Replace sensor and calibrate. Call DrägerService or your local authorized service organization.
!! **(21)**	**FRESH GAS LOW**	Inadequate fresh-gas supply in all ventilation modes. Blocked/kinked hose. Leak or disconnect in breathing circuit.	Ensure adequate fresh-gas supply. Check hoses. Check breathing circuit.
!! **(13)**	**INSP O2 HIGH**	Inspiratory O_2 concentration exceeds the upper alarm limit.	Check flowmeter settings and O_2 high alarm limit.
!!! **(31)**	**INSP O2 LOW**	Inspiratory O_2 concentration is below lower alarm limit.	Check O_2 supply. Check flowmeter settings and O_2 low alarm limit.
!! **(11)**	**INSP PRES NOT REACH**	Plateau pressure is more than 3 cmH_2O (hPa) below the P_{INSP} setting and the expected Plat while ventilating in Pressure Control, Pressure Support, or SIMV/PS mode.	Check ventilator, patient circuit, and P_{INSP} settings.
!! **(14)**	**MINUTE VOLUME HIGH**	Minute volume has exceeded upper alarm limit. Flow sensor has not been calibrated. Sensor faulty.	Calibrate flow sensor. Replace if necessary.

Priority	Alarm Message	Probable Cause	Remedy
!! **(22)**	**MINUTE VOLUME LOW**	Minute volume has fallen below lower alarm limit. Blocked/kinked hose. Leak in breathing system. Reduced volume due to pressure limitation. Reduced lung compliance. Flow sensor not calibrated or faulty.	Check breathing circuit and alarm limit. Check breathing circuit. Check breathing system. Check PMAX setting on ventilator control panel. Check ventilator settings. Follow the procedure to calibrate flow sensor (see page 140), and replace if necessary.
!!! **(31)**	**NO FRESH GAS**	Inadequate fresh-gas supply. Fresh-gas control valve closed. Negative pressure safety relief valve opens automatically.	Ensure adequate fresh-gas supply. Open fresh-gas control valve.
! **(6)**	**O2 SENSOR CAL DUE**	More than 18 hours passed since last oxygen sensor calibration.	Follow the procedure to calibrate oxygen sensor (see page 141).
! **(8)**	**O2 SENSOR FAIL**	O_2 sensor has not been correctly calibrated. O_2 sensor replaced and/or not calibrated. O_2 sensor used up. O_2 sensor disconnected. Faulty sensor cable.	Follow the procedure to calibrate O_2 sensor (see page 141). Follow the procedure to calibrate O_2 sensor. Replace sensor capsule and calibrate. Connect O_2 sensor assembly. Replace O_2 sensor housing assembly.
!!! **(30)**	**O2 SUPPLY LOW**	O_2 supply line has less than minimum pressure permitted (approximately 20 psi) (approximately 1.4 kPa x 100).	Check O_2 supply and cylinder backup.
! **(9)**	**PEEP HIGH**	PEEP is higher than 4 cmH_2O (hPa) in ManSpont mode.	Check APL valve setting and/or fresh gas flow.
! **(7)**	**POWER FAIL**	Mains not connected. Facility power failure.	Connect mains.
! **(1)**	**PRES APNEA ALARM OFF**	Pressure alarms off in ManSpont.	
! **(9)**	**PRESSURE LIMITING** Volume Control mode	Measured pressure equals or exceeds PMAX ventilator setting.	Check ventilator and PMAX settings.

Priority	Alarm Message	Probable Cause	Remedy
!!! (25)	**PRESSURE NEGATIVE**	Measured P_{AW} is ≤-5 cmH_2O (hPa), or MEAN is ≤-2 cmH_2O (hPa).	Check breathing circuit and ventilator settings.
! (8)	**PRESSURE SENSOR FAIL**	Faulty sensor or pressure not calibrated.	Call DrägerService or your local authorized service organization.
! (2)	**PRES THRESHOLD LOW**	Ventilation parameters were changed without changing alarm settings (see page 149).	Push the Auto Set soft key and check ventilator settings.
! (1)	**RS232 COM1 FAIL**	External monitor cable disconnected from External Communication Port 1.	Check monitor interface cable.
! (1)	**SPEAKER FAIL**	Speaker failed.	Call DrägerService or your local authorized service organization.
!!! (28)	**VENTILATOR FAIL**	Ventilator not assembled correctly.	Check diaphragm and close cover. Check PEEP/P_{MAX} line for disconnect or leak. Select Standby Mode and switch back to the previous ventilation mode.
! (1)	**VOLUME ALARMS OFF**	Volume alarms disabled by operator.	

Cleaning

Safety information on reprocessing

CAUTION

To reduce the risk of infection to both hospital staff and patients, clean and disinfect medical devices after each use. Protective clothing, eye protection etc. must be worn.

- Comply with the hospital hygiene regulations!
- Reprocess the medical device after every patient.

The reprocessing recommendations do not exempt staff from the obligation to adhere to the hygiene requirements and directives on occupational health and safety relating to the reprocessing of medical devices.
To ensure the professional reprocessing of medical devices, the recommendations provided by the Robert Koch Institute in "Demands on Hygiene in Reconditioning Medical Products" should be followed.

Pre-cleaning

NOTE

To prevent heavy soiling of the breathing system, which is comparable to surgical instruments (proteins, blood, etc.), Dräger recommends the use of disposable filters on the medical device.
Otherwise, the described contamination requires a pre-cleaning in a ultrasonic bath. A positive cleaning effect, in the scope of the total pre-cleaning, has been shown in a test with the disinfection agent Gigasept AF (4 % solution).
Affected parts: compact breathing system, valve cover, expiration nozzle, absorber and APL valve.
Afterwards rinse all parts thoroughly under running water until no residue of the cleaning agents is detected (approx. 5 min).

Reprocessing methods

Machine cleaning and disinfection

Use a washer-disinfector in accordance with EN ISO 15883, preferably with a cart for anesthesia and ventilation accessories, for automatic cleaning and disinfection. Use mild alkaline or enzymatic (with neutral pH) cleaning agents. The user must strictly observe the manufacturer's instructions for use for the cleaning agent.

Placing parts in washer-disinfector

- Place parts in washer-disinfector. Observe Instructions for Use of washer-disinfector.
- Position parts so that all interior spaces are completely flushed (e.g. hoses) and water can drain off freely.

Cleaning program

- Select suitable program (preferably anesthesia program). Cleaning is carried out at 40 to 60 °C (104 to 140 °F) for at least 5 minutes.

Thermal disinfection

- Thermal disinfection is carried out at 80 to 95 °C (176 to 203 °F) and with corresponding contact time.
- Carry out final rinsing with deionized water.

After completion of cleaning and disinfection program

- Immediately remove parts from washer-disinfector.
- Inspect parts for visible soiling and damage. If necessary, repeat cycle or clean manually.
- Allow parts to dry thoroughly.

Cleaning agents

The material compatibility of reusable Dräger accessories has been tested with various mildly alkaline and enzymatic cleaning agents at 95 °C (203 °F) for 10 minutes.

The following cleaning agents showed good material compatibility at the time of the test:
– Neodisher FA, Neodisher Medizym manufactured by Dr. Weigert

The user must strictly observe the manufacturer's instructions for use for the cleaning agent.

Manual cleaning

If no washer-disinfector is available, clean parts manually under running water with commercially available cleaning agents. The user must strictly observe the manufacturer's instructions for use for the cleaning agent.

- Wash off soiling on surfaces under running water.
- Use cleaning agents in accordance with manufacturers specifications. Make sure that all surfaces to be cleaned can be efficiently reached (e.g. inside hoses). Use suitable brushes if necessary.
  Do not use any brushes for the flow sensor. Observe the relevant Instructions for Use.
- Rinse parts under running water until no cleaning agent residues are discernible.
- Check parts for visible soiling and damage. Repeat manual cleaning if necessary.

Manual disinfection

Manual disinfection should preferably be carried out with disinfectants based on aldehydes or quaternary ammonia compounds. The efficiency of the disinfectants used must be proven. Observe the applicable country-specific listings. The user must strictly observe the manufacturer's instructions for use for the cleaning agent.

Disinfectants

The material compatibility of Dräger accessories to be reprocessed has been tested with various disinfectants.
The test showed that the following disinfectants have a good material compatibility:
Surface disinfectant (for device surfaces)
– Incidin Extra N from Ecolab
– Incidur from Ecolab
Instrument disinfectant (for components or accessories):
– Korsolex extra manufactured by Bode Chemie
– Gigasept FF manufactured by Schülke & Mayr
The composition of the disinfectant is the responsibility of the manufacturer and can change over time.

Disinfecting surfaces

WARNING

Penetrating liquid may lead to failure of the medical device or damage to the medical device and endanger the patient! Only disinfect parts by wiping and make sure no liquids penetrate into the device.

- Following manual cleaning, carry out surface disinfection.
- Remove disinfectant residues.

Disinfecting components or accessories

- Disinfect parts by immersing.
- Sufficiently rinse parts under running water until no disinfectant residues can be recognized.
- Inspect parts for visible soiling and damage. Repeat manual disinfection if necessary.
- Shake out remaining water thoroughly. Allow parts to dry thoroughly.

Visual inspection

- Inspect all parts for damage and wear, e.g., cracking, embrittlement or pronounced hardening and residual soiling.

CAUTION

Even accessories designed to be reused (e.g. after reprocessing) have a limited service life. Due to a number of factors connected with handling and reprocessing (e.g.disinfectant residues can attack the material more intensely during auto-claving), increased wear can occur and the service life can be markedly shortened. These parts must be replaced if signs of wear become visible, such as cracks, deformation, discoloration, peeling, etc.

Sterilization

Use a vacuum steam sterilizer (in accordance with DIN EN 285), preferably with fractional vacuum, for sterilization.

CAUTION

Do not sterilize parts in ethylene oxide! Ethylene oxide may diffuse into the parts and cause damage to health.

CAUTION

The Spirolog Flow Sensor and the Infinity ID Flow Sensor must not be sterilized in hot steam. The flow sensors are not resistant to high temperatures and may be damaged.

- Hot steam sterilization can be carried out at 134 °C (273.2 °F). Observe Instructions for Use of medical device.

Reprocessing and disinfection

This section contains instructions for dismantling and cleaning the Fabius MRI anesthesia workplace.
During the reprocessing cycles, the vaporizers remain attached to the medical device.

CAUTION

When moving the writing tray, the holding arms and drawers, keep a distance from the edges to avoid crushing.

Device surfaces

CAUTION

Risk of damage to the medical device
The surfaces of Fabius MRI, the pressure gas hoses and cables must not be treated with alcohol containing agents.

Removing the Compact Breathing System

- Remove all breathing hoses.
- Disconnect the breathing bag extension and bag by loosening the two thumb screws.
- Remove the ventilation hose.
- Remove the fresh gas hose from the breathing system.
- Remove the scavenger hose.
- Remove the flow sensor cable.
- Remove the O_2 sensor cable.
- Remove the breathing pressure cable.
- Detach the APL-bypass and the PEEP/P_{MAX} lines from the breathing system and from the side of the machine.
- Remove the absorber (for complete instructions, see page 197).

- Remove the compact breathing system.

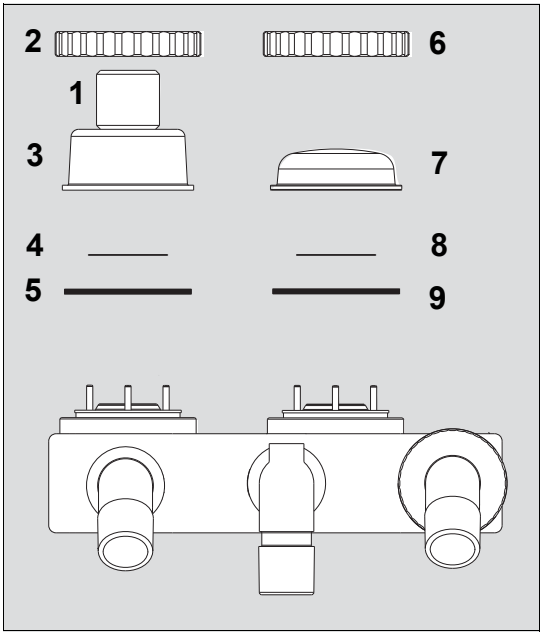
1 Remove plug for the inspiration dome.

Removing the Inspiratory Valve

2 Unscrew the retaining nut.
3 Remove the inspection cap.
4 Extract the valve disc.
5 Remove the gasket on top of the valve disc.

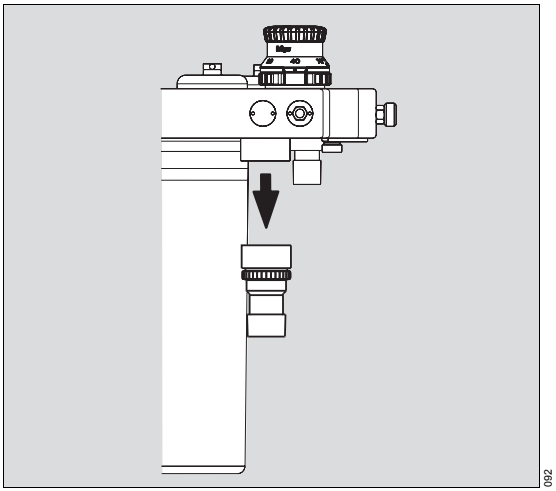
Removing the Expiratory Valve

6 Unscrew the retaining nut.
7 Remove the inspection cap.
8 Extract the valve disc.
9 Removet the gasket on top of the valve disc.



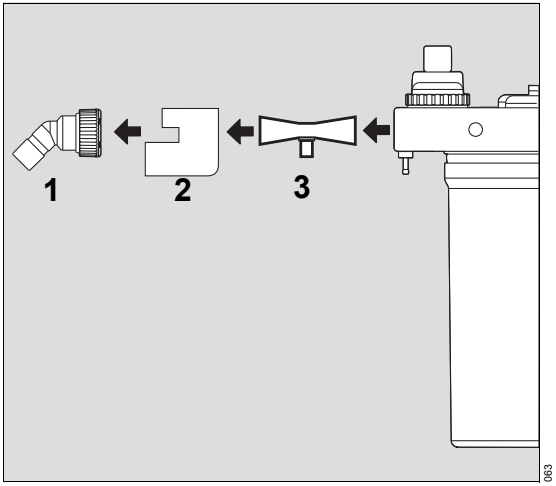
Removing the Waste Gas Port

- Unscrew the waste gas port



Removing the Flow Sensor

1 Loosen fitting on the expiration port.
2 Remove the flow-sensor guard.
3 Extract the flow sensor.



CAUTION

Risk of flow measurement failure

Disinfecting or cleaning the flow sensors by machine will damage them and cause the flow measurement to fail.

Disinfect and clean the flow sensors as described in the Instructions for Use of the Spirolog, Infinity ID flow sensor and SpiroLife flow sensors.

CAUTION

Risk of flow measurement failure

Sterilizing the Spirolog and Infinity ID flow sensors in high-temperature steam will damage them and cause the flow measurement to fail.

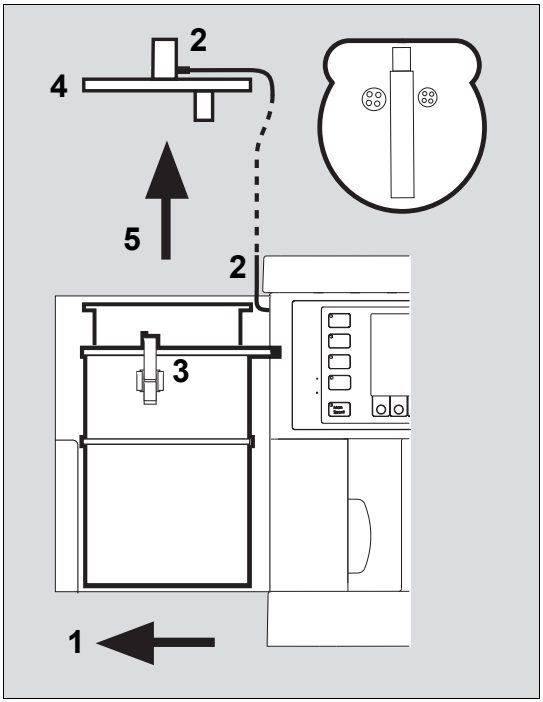
Disinfect and clean the flow sensor as described in the Instructions for Use of the Spirolog, Infinity ID flow sensor and SpiroLife flow sensors.

Removing the APL-Valve

- Unscrew the retaining nut.
- Remove the APL valve.
- Unscrew the waste gas outlet port.

Removing Parts of the Ventilator

1 Open the ventilator door.
2 Disconnect the pressure sensor line of the ventilator chamber from the respective connector.
3 Unlock the three clasps,
4 Remove the cover.
5 Remove the ventilator diaphragm.



Removing anesthetic gas scavenging system (AGSS)

- Remove the anesthetic gas receiving system (AGS) including scavenging hose and exhaust hose from the medical device.

Removing the Suction System

- Remove suction bottle assembly, including bottle and regulator.

WARNING

Risk of infection

Always wear protective gloves when emptying the suction bottle.

Observe the hospital hygiene regulations.

NOTE

Reprocessing/disinfection instructions for the reusable suction bottle and the suction regulator, refer to their respective Instructions for Use.

Reprocessing Breathing system

All parts of the respiratory system, ventilator diaphragm, Y-piece, respiratory hoses, respiratory bag, parts of the absorber, parts of the secretion suction unit and parts of the anesthetic gas scavenging system.

- Thermally disinfect in the cleaning/disinfection machine at 200 °F (93 °C) /10 minutes.

  Only use neutral or mild alcalic cleaning agents (e.g. Neodisher Medizym, Neodisher FA) and completely demineralized water!

  When using thermal disinfection, the addition of disinfectant chemicals is not necessary; risk of corrosion!

WARNING

After washing, a hot steam sterilization is required to completely dry the breathing system.

Insufficient drying of the control areas found in the valve plate can lead to impairment of device function or to failure of the medical device.

O_2 Sensor

CAUTION
Risk of equipment damage
The O_2 sensor must not be sterilized or disinfected!

Spirolog Infinity ID and SpiroLife flow sensors

Reprocess the flow sensor in accordance with the corresponding Instructions for Use.

CAUTION
The flow sensor must not be reprocessed in a washer-disinfector. Do not clean with compressed air, water jet, brush, etc. Otherwise, the thin wires in the flow sensor may be destroyed. The Spirolog and Infinity ID flow sensor must not be sterilized in hot steam. The flow sensor is not resistant to high temperatures and will be destroyed.

CAUTION
Only use clean disinfectant solutions to disinfect the flow sensor. Contaminants, e.g., lint, may lead to the destruction of the flow sensor.

WARNING
Risk of fire hazard
Allow the flow sensor to dry in air for at least 30 minutes after the use of disinfectants containing flammable substances. These substances give off vapors that could ignite during calibration.

CAUTION
The flow sensor can only be reused as long as automatic calibration is possible.

Sterilization

CAUTION
Risk of damage to the medical device
The Spirolog and Infinity ID flow sensors must not be sterilized.

Strictly follow the correct Instructions for Use.

Steam sterilization at 273 °F (134 °C)

CAUTION
Risk of damage to the medical device
SpiroLife flow sensors are not suitable for plasma or radiation sterilization.

Strictly follow the correct Instructions for Use. All components with the suitable reprocessing options are listed in the maintenance list for Fabius MRI components page 184. Follow the hygiene regulations of the hospital!

Care List for Fabius MRI Components

The following table lists Fabius MRI components with recommended processing methods. Processing refers to cleaning, disinfection, and/or sterilization, as appropriate for a given component. The table is intended as a guide. Follow the institution's policies regarding specific methods and agents for cleaning and sterilization.

CAUTION
Fabius MRI and its components must not be treated with formaldehyde vapors or ethylene oxide.

Applicable for non-infectious patients

CAUTION
For infectious patients, all parts that come into contact with breathing gas also have to be sterilized after disinfection and cleaning.

The list is only intended as a rough guideline. The instructions of the hospital´s hygiene officer shall prevail and must be observed!

Fabius MRI components which can be reprocessed	**Recommended reprocessing intervals**	**Manual pre-cleaning[1)]**	**Machine cleaning and thermal disinfection[2)]**	**Manual disinfection[3)]**		**Hot steam sterilization**
				Surface disinfection	**Immersion bath disinfection**	
Surfaces						
Device surfaces	Per patient	No	No	Yes[4)]	No	No
Power supply cable, pressure gas hoses	Per patient	No	No	Yes[4)]	No	No
Respiratory pressure meter	Daily	No	No	Yes	No	No
Components for carrying breathing gas						
Breathing system	Per patient	Yes	Yes[5)]	No	Yes	Yes
Inspiratory valve, Expiratory valve, APL valve	Per patient	Yes[6)]	Yes	No	Yes	Yes
Expiratory port	Per patient	Yes	Yes	No	Yes	Yes
Exhaust port valve	Per patient	Yes[6)]	Yes	No	Yes	Yes
Ventilator cover	Per patient	Yes[6)]	Yes	No	Yes	Yes
Ventilator diaphragm[7)]	Per patient	Yes	Yes	No	Yes	Yes
Ventilator hose	Per patient	No	Yes[5)]	No	Yes	Yes
Absorber and insert	Per patient	Yes	Yes	No	Yes	Yes
Infinity ID/Spirolog/ SpiroLife flow sensor	Note the Instructions for Use of the flow sensors					
Manual bag valve mask holder	Per patient	Yes	Yes	No	Yes	Yes

Fabius MRI components which can be reprocessed	**Recommended reprocessing intervals**	**Manual pre-cleaning[1)]**	**Machine cleaning and thermal disinfection[2)]**	**Manual disinfection[3)]**		**Hot steam sterilization**
				Surface disinfection	**Immersion bath disinfection**	
Other						
AGS scavenging system	Daily	Reprocessing according to appropriate Instructions for Use.				
Suction system and suction bottle assembly accessories	Daily	Reprocessing according to appropriate Instructions for Use.				

1) It is generally recommended to perform a pre-cleaning under running water for approx. 5 minutes.
For dried soiling an additional pre-cleaning step using an ultrasonic bath is recommended. The addition of a quaternary ammonium compound supports the cleaning performance effectively (e. g. Gigasept AF). Perform pre-cleaning in the ultrasonic bath for approx. 15 minutes. Afterwards rinse under clear running water for approx. 5 minutes (waste water must be free of visible cleaning residues).
2) Use mild alkaline or neutral cleaner
3) Use disinfectants based on aldehydes and quaternary ammonium compounds.
4) Do not use any agents containing alcohol.
5) After the machine cleaning and disinfection, a hot steam sterilization is required to dry the breathing system. Insufficient drying of the control areas found in the valve plate can lead to an adverse effect on the functions of the medical device or to its failure!
6) Valves, ventilator cover and AGS sleeve: Make sure that the cleaning and rinsing liquids can flow in the opening direction of the valve.
7) Remove any water which may have accumulated in the ventilator diaphragm. Large quantities of condensed water can negatively effect the operation of the device and lead to failure of the medical device!

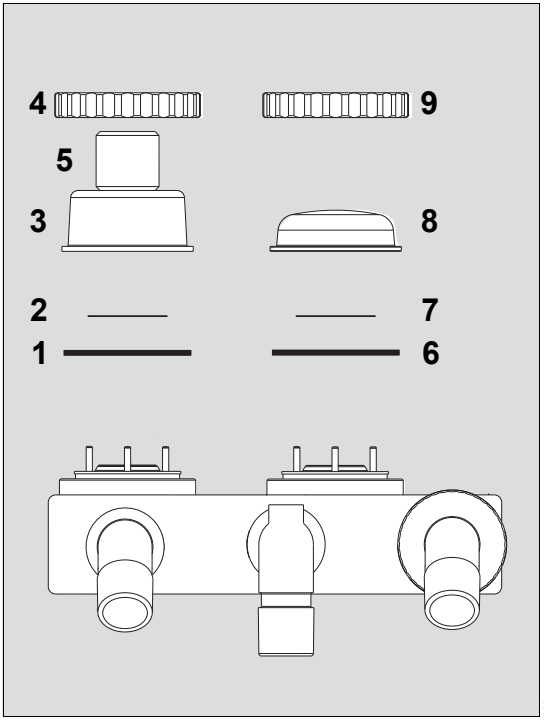
Reassembling the Breathing System

Attaching the Inspiratory Valve

1 Place the gasket on top of the valve disc.
2 Place the valve disc in the valve seat.
3 Fit the inspection cap (with port).
4 Tighten the retaining nut securely.
5 Insert the plug for the inspiration dome.

Attaching the Expiratory Valve

6 Place the gasket on top of the valve disc.
7 Place the valve disc in the valve seat.
8 Fit the inspection cap.
9 Tighten the retaining nut securely.

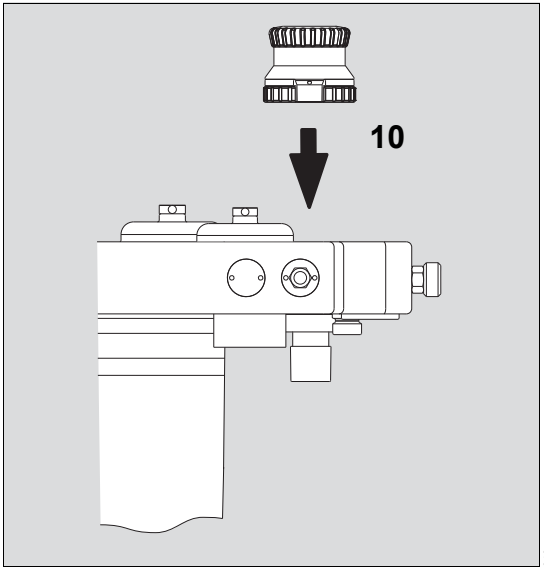


Attaching the APL Valve

WARNING

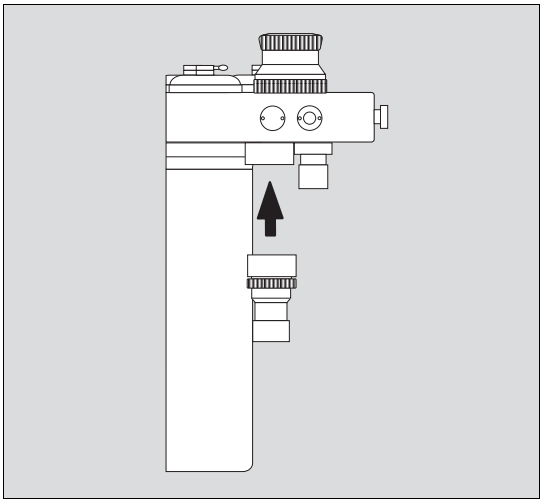
Route all lines/cables away from the APL valve to prevent interference with the APL valve adjustment knob. Lines/cables caught underneath the APL valve adjustment knob could interfere with proper functioning of this valve.

10 Position the APL valve in the valve seat, and tighten securely with the retaining nut.



Screw the waste gas port

- Screw in the waste gas port from below into the compact breathing system. Make sure there is a tight seal.



Installing Remaining Breathing System Components

- Follow instructions beginning on page 52 to reinstall the following breathing system components:

– flow sensor
– breathing system
– ventilation hose
– fresh gas hose
– breathing bag extension* and bag
– flow sensor and breathing pressure cables
– APL bypass and PEEP/P_{MAX} cables
– O_2 sensor cable
– breathing system hoses

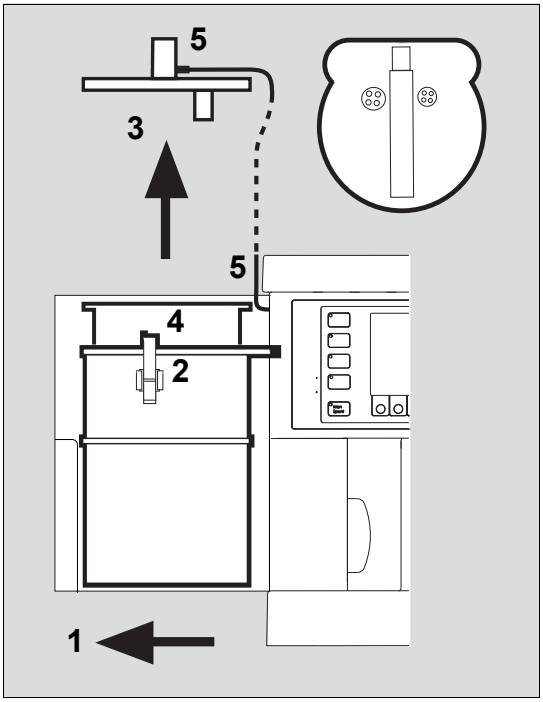
- Follow instructions on page 197 to reinstall the absorber system

* optional

Reinstalling the Ventilator

1 Open the ventilator door with the attached ventilator unit.
2 Unlatch the three clasps.
3 Remove the cover.
4 Insert the diaphragm.
- Fit the cover and lock the three clasps.

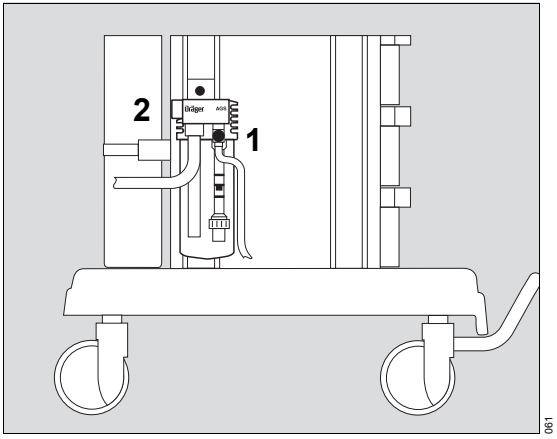
5 Connect the pressure sensor line of the ventilator chamber from the respective connector.
- Close the ventilator door with the attached ventilator unit.



Reinstalling the Scavenger System

Reconnecting the Anesthetic Gas Receiving System (AGS)

Every Anesthetic Gas Scavenging System (AGSS) used on the Fabius MRI must follow ISO standard 8835-3.
The scavenging system is used with vacuum waste-gas disposal systems.
The AGS is not applied as an independent system. It is used as one of the three components of the AGSS.



WARNING

Risk of patient injury

If the side openings of the receiving system are blocked, negative pressure may result in the breathing system and the patient's lungs.

Always make sure the side openings of the receiving system are not blocked.

NOTE

Remove the socket from the scavenger hose before connecting.

NOTE

The scavenger hoses must not be pinched, kinked, or blocked in any manner.

- Hook receiving system with the slots over the appropriate pins of the basic device and allow it to slide down into place.

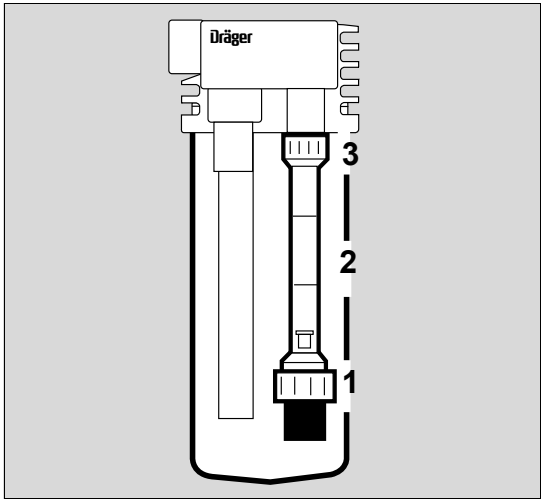
1 Connect the scavenging hose to the relevant socket of the receiving system.

- Connect the connector of the scavenging hose to the terminal unit of the disposal system.

2 Close the connection that is not used with a screw cap.

- Push the transfer hose on the designated socket.
- Connect the other end of the transfer hose to the waste-gas port located on the underside of the breathing system.

1 Install the particle filter and tighten the retaining nut.
2 Reinstall the flow tube with the scale facing the front of the machine.
3 Tighten the retaining nut.
- Reinstall the buffer volume container into the scavenger body.



WARNING

Danger to the patient

Do not cover the side openings of the receiving system. Otherwise there may be a shortage of fresh gas in the breathing system.

For detailed information on the AGS, refer to the specific Instructions for Use provided with the anesthetic gas receiving system AGS (9038579).

Reinstalling the Suction System

Reconnecting the Suction System

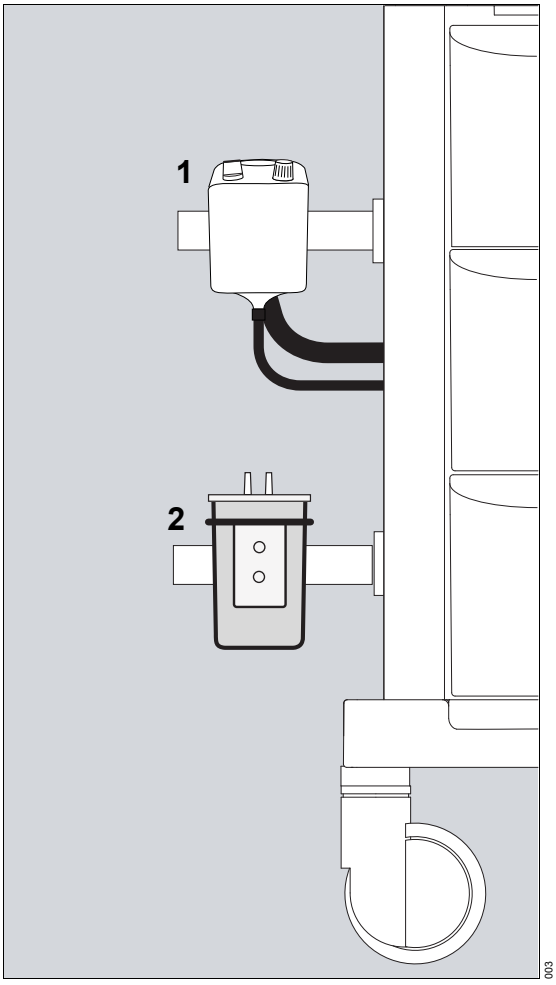
The optional aspiration system for the Fabius MRI consists of an suction regulator and a suction bottle. The suction regulator is attached to a holder, which is fastened on the side channel of the anesthesia device. The suction bottle desired by the customer is attached to a separate swivel rail on the side channel.

- Attach the carrier arm of the suction system on the side channel on the side of the anesthesia device.

1 Mount the suction regulator onto the bracket.

- Reprocess the suction bottle according to the instructions for use included with the bottle.

2 Attach the suction bottle on the swivel rail.



Depending on the aspiration system used:

With use of air or O_2 as driving gas:

- Connect the air connection hose of the suction system on the air exhaust of the gas supply block (optional) or directly on the gas supply line.

For vacuum aspiration:

- Connect the vacuum hose of the suction system directly on the gas supply line.

Make sure that the suction system is ready for operation according to the included Instructions for Use.

WARNING

The aspiration system must only be used in the »Man/Spont« mode or if the Y-piece is not connected.

Checking Readiness for Operation

At the completion of the reassembly of the Fabius MRI, perform the Daily and Preuse Check-out procedure provided in the Appendix of this manual to ensure that the machine is ready for operation.

Maintenance

Overview

This chapter describes all maintenance steps necessary to maintain the proper functioning of the device. These maintenance steps must be performed by professionals.

CAUTION

Clean and disinfect device or device parts before each maintenance step and also before returning for repair.

CAUTION

Risk of electric shock
Do not open the housing of the device. All service and repair work must be performed by professionals. Dräger recommends DrägerService to perform these tasks.

Definition of Maintenance Concepts

Concept	Definition
Maintenance	The combination of all technical and administrative measures taken during the life cycle of a medical device intended to retain or restore operating condition so that the medical device can perform its required functions.
Inspection	Measures intended to determine and assess the actual state of a medical device and to determine the cause of wear and deducing consequences necessary for future use.
Preventive maintenance	Measures intended to delay the depletion of the wear margin.
Repair	Measures intended to restore a medical device to operating condition, not including enhancement.

Inspection

Inspections must be carried out regularly according to the following specifications and in the specified intervals.

Check	Interval	Personnel responsible
Inspection and Safety Checks	every 12 months	professionals

Safety Checks

The safety checks are no substitute for the preventive maintenance measures (including preventive replacement of wear parts) indicated by the manufacturer.

CAUTION

The safety checks must be carried out in the specified intervals. Otherwise, the correct functioning of the medical device can be impaired.

1 Check accompanying documents:
– latest Instructions for Use are available
2 Verify that the device combination is in good condition:
– all labels are complete and legible
– there is no visible damage
– Fuses which are accessible from the outside are in compliance with the specified values
3 Check that the equipment of the medical device is complete according to the Instructions for Use.
4 Check the electrical safety according to IEC62353
5 Check safety features:
– Check correct functioning of the alarm generator.
– Check correct functioning of the alarm generation of lack of O_2.
– Check correct functioning of O_2 measurement.
– Check correct functioning of flow measurement.
– Check correct functioning of P_{AW}, PEEP, APL and P_{MAX} pressure measurement.
– Check correct functioning of power fail alarm and battery backup function.
– Check correct functioning of Vaporizer Interlock function.
– Check correct functioning of auxillary air supply and safety valves of ventilator.
– Check correct functioning of S-ORC.
– Check correct functioning of vaporizers according the IfU of vaporizers.

Preventive maintenance

CAUTION
This device must undergo inspection and preventive maintenance in the intervals specified by the manufacturer.

The following table shows the preventive maintenance intervals:

Component	Interval	Measure	Personnel responsible
Fabius MRI	Every 12 months	Inspection and service	Professionals
Breathing systems	Every 12 months	Inspection and service	Professionals
Vaporizers	Every 12 months	Inspection and service	Professionals
Sensors	Every 12 months	Inspection and service	Professionals
Service set major overhaul for high pressure cylinder connection[1]	After 6 years	Replace	Professionals
Service set major overhaul for high pressure cylinder connection label gas types[1]	After 6 years	Replace	Professionals

1 optional

NOTE
If desired, the customer may receive a list of those parts and their assembly instructions to be replaced in the event of repairs being necessary.

Routine Maintenance

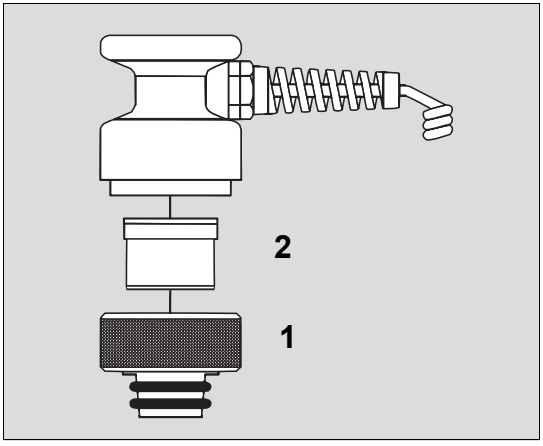
Routine maintenance must be performed regularly to ensure safe and effective operation. Regularly check the condition of the absorbent and the overall condition of the machine, power cord, hoses, and breathing bag.

CAUTION
Risk of electric shock
Do not remove cover. Refer servicing to a Dräger-Service representative.

Replacing the O_2 Sensor Capsule

1 Unscrew the cap from the sensor housing.
- Remove the new sensor capsule from its packaging.

2 Insert the capsule in the housing, with the ring-shaped conductors against the contacts in the housing.
- Screw the cap on firmly by hand.



Replacing CO_2 Absorbent

The CO_2 absorbent in the compact breathing system should be replaced when two-thirds of the CO_2 absorbent has changed color. Dräger recommends the use of Drägersorb 800 Plus or Drägersorb FREE. The color change indicates that the CO_2 absorbent can no longer absorb CO_2 (Drägersorb 800 Plus and Drägersorb FREE change from white to violet).

NOTE
Please refer to the specific Instructions for Use for "Drägersorb 800 Plus or Drägersorb FREE".

WARNING

Do not flush dry gas continuously for unnecessarily long periods through the soda lime in the anesthesia system!

Otherwise the soda lime will dehydrate. If the moisture level falls below a minimum level, undesirable reactions generally occur, regardless of the type of soda lime and the inhalation anesthetic used:

- **reduced CO2 absorption,**
- **increased heat generation in the absorber and therefore increased breathing gas temperature,**
- **CO formation,**
- **absorption and/or breakdown of the inhalation anesthetic.**

The above mentioned reactions may endanger the patient, e.g.:

- **CO poisoning**
- **insufficient depth of anesthesia**
- **burns of the airway.**

CAUTION

Soda lime irritates the skin and there is a risk of serious damage to eyes.

If soda lime has leaked:

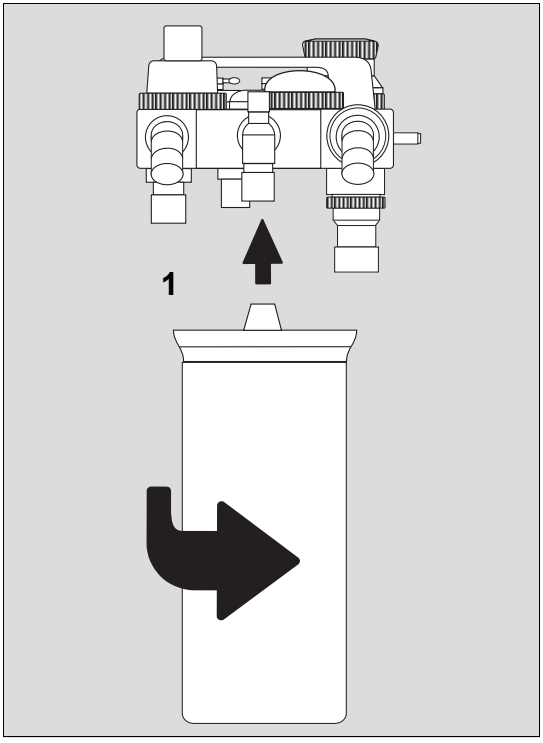
- Powdered soda lime must not be inhaled or swallowed.
- Put on protective gloves and goggles, or a face mask.
- In case of coming in contact with eyes, rinse immediately with large amounts of water and consult a physician immediately, otherwise it may lead to eye damage.
- Powdered soda lime on the skin must be washed off immediately, because it may irritate the skin.

- Remove the absorber canister by turning it clockwise.
- Empty the expired CO_2 absorbent from the absorber into an appropriate refuse container.
- Fill the absorber with fresh CO_2 absorbent.

NOTE

Ensure that no CO_2 absorbent dust/particles have been deposited between the gaskets and sealing surfaces. Such dust and particles can cause leaks in the system.

1 Fit the absorber canister into position below the breathing system and turn it counterclockwise as far as possible.



CLIC Adapter*

The disposable CLIC adapter absorber can also be used on the Fabius MRI. For information on installing the CLIC adapter, consult its Instructions for Use.

Checking Readiness for Operation

Perform the Daily and Preuse Checkout procedure provided in the Appendix of this manual to ensure that the machine is ready for operation.

* optional

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Disposal

Disposal of the Medical Device

When disposing of the medical device:

- Consult the relevant waste disposal company for appropriate disposal.
- Comply with the applicable laws and regulations.

For countries subject to the EU Directive 2002/96/EC

This device is subject to EU Directive 2002/96/EC (WEEE). In order to comply with its registration according to this directive, this device may not be disposed of at municipal collection points for waste electrical and electronic equipment. Dräger has authorized a company to collect and dispose of this device. To initiate collection or for further information, visit Dräger on the Internet at www.draeger.com. Use the Search function with the keyword "WEEE" to find the relevant information. If access to Dräger's website is not possible, contact the local Dräger Organization.

Disposal of Non-Rechargeable Batteries

WARNING
Risk of explosion
Do not throw batteries into fire.
Risk of chemical injury!
Do not force batteries open.

- Do not recharge batteries.

The medical device battery contains pollutant substances.
Observe the applicable laws and regulations for battery disposal.

Disposal of O_2 Sensors

NOTE
O_2 sensors are special waste. Dispose of the O_2 sensors according to local waste disposal regulations.

Expired O_2 sensors can be returned to:
Dräger Medical GmbH
Moislinger Allee 53 – 55
D-23542 Lübeck
Germany

Disposal of Bacterial Filter

Must be disposed of as infectious special waste. Can be incinerated at temperatures above 1472 °F (800 °C) with minimal environmental pollution.

Disposal of Flow Sensor

Dispose of spent sensor with infectious special waste. We recommend low-emission incineration at more than 1472 °F (800 °C).

Technical Data

MRI Use

Useable within magnets of 1.5 tesla and 3 tesla static magnetic field.
Distance to center of magnetic field: fringe field strength of 40 mtesla (400 gauss) or less

Ambient Conditions

During operation

Temperature	50 to 95 °F (10 to 35 °C)
Atmospheric pressure	700 to 1060 cmH_2O (hPa)
Relative humidity	20 to 80 % (no condensation)

During storage

Temperature	14 to 140 °F (–10 to 60 °C)
Atmospheric pressure	700 to 1060 cmH_2O (hPa)
Relative humidity	10 to 90 % (no condensation)

The service conditions for supplementary equipment must be noted. These may restrict the area of use for the system as a whole. Vaporizer units and the anesthetic agents used may restrict the area of use of the workstation in regards to its temperature range and maximum fresh-gas flow. The corresponding Instructions for Use of the supplementary equipment must be noted.

Machine Data

Gas supply from medical gas pipeline system

Pipeline System Pressure Range at Machine Connector

O_2, N_2O, AIR:	41 to 87 psi (2.8 to 6 kPa x 100) Note: Pipeline system supply pressure variation shall not exceed ±10 %
Gas supply connectors: Each inlet is fitted with a non-return valve	NIST or DISS (where required)
Pipeline Pressure Indicator Accuracy	±3 % of full scale from 40 to 120 psi (2.7 to 8.3 kPa x 100)

Gas supply from supplementary O_2 and N_2O cylinders (with threaded NIST connections)

Pressure at machine connector

O_2, N_2O	73 psi (5 kPa x 100)

Each inlet is fitted wih a non-return valve

Gas supply from supplementary O_2, AIR and N_2O cylinders (with pin-index connections)

Cylinder Connections	Pin-indexed hanger yokes (CGA V-1-1994)
Cylinder Gas Pressure (typical full loads at 70 ºF, 21 ºC)	O_2, AIR 1900 psi (131 kPa x 100) N_2O 745 psi (51.3 kPa x 100)
Cylinder Gauges	Conform to ASME B40.1 Grade B
Cylinder Gauge Range	O_2 0 to 3000 psi (206.8 kPa x 100) N_2O 0 to 3000 psi (206.8 kPa x 100) AIR 0 to 3000 psi (206.8 kPa x 100)

Compressed gas supply at workstation inlet

Dew point	>5 °C (41 °F) at ambient temperature
Oil content	<0.1 mg/m^3
Particles	dust-free air (filtered with pores <1 µm)

Internal Regulator Safety Relief Valve Pressure	70 psi (4.8 kPa x 100) opening pressure
Fresh-gas outlet for non-rebraething system (optional)	Male cone 22 ISO, Female cone 15 ISO, (with thread to secure)
Pressure limitation	Max. 80 hPa (cmH_2O) at 18 L/min
Fresh-gas flow	0 and 0.2 to 18 L per minute volume flow
Protection Class	I, in accordance with IEC 60601-1
Applied parts:	
Breathing system (nozzles, breathing hoses)	Type BF 
Ingress of Fluids	IPX0
Power supply, Rating Non-configurable	100 to 240 VAC, 50/60 Hz, 8.7 A including additional power outlets

Rechargeable batteries

Rating:	24 V; 3.5 Ah
Type:	sealed, gelled lead-acid
Recharging time:	≤16 hours on the mains or full operation time
Operation time with fully charged batteries:	45 minutes, minimum

Dimensions and Weight (Approximate)

Weight:	
Base unit with COSY and without supplementary	365.5 lb (165.8 kg)
Base unit with COSY and two vaporizers; without additional supplementary	403 lb (182.8 kg)
Dimensions W x H x D	
Base unit (caster) with central brake unlocked	approx. 30.7 x 55 x 35.5 in (78 x 140 x 90 cm)
Base unit (caster) with central brake locked	approx. 30.7 x 55 x 36.3 in (78 x 140 x 92 cm)
Dimensions W x H x D (with COSY, left or right side mounted)[1)]	approx. 39 x 55 x 35.5/36.3 in (99 x 140 x 90/92 cm)
Height writing tray	38.5 in (86 cm)
Height Teslameter sensoric	37.8 in (96 cm)

1) Width may vary with COSY arm position

Fuses

Mains fuses	For 100 to 240 V supply voltage: 2x T2.5 AL 250 V IEC 60127-2/V
Fuses located on circuit board	1x T1.6AL 250 V IEC 60127-2/III 1x T4AL 250 V IEC 60127-2/III 1x T2.5AL 250 V IEC 60127-2/III
Battery fuse	1x T3.15AH 250 V IEC 60127-2/V

Tesla Sensor

Range of the Tesla sensor	35 to 45 mtesla

Electromagnetic Compatibility (EMC)

General information

The EMC conformity of the Fabius MRI includes the use of following external cables, transducers and accessories:

Description	Order-No.
RS-232, optical interface, connected to COM1, 30 m	8608376
O_2 Sensor Cable (cable-shielded-28 AWG-4 cond)	8606051

Additionally, accessories may be used which do not affect EMC compliance, if no other reasons (see Accessories List) interdict the use of them. The non-observance may result in increased emissions or de-creased immunity of the equipment.

The Fabius MRI should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the Fabius MRI should be observed to verify normal operation in the configuration in which it will be used.

Other equipment which can be used adjacent to or stacked with this device are listed in the accessories list.

Electromagnetic emissions

The Fabius MRI is intended for use in the electromagnetic environment specified below. The user of the Fabius MRI should assure that is used in such an environment.

Emissions	**Compliance according to**	**Electromagnetic environment**
RF emissions (CISPR 11)	Group 1	The Fabius MRI uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class B	The Fabius MRI is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Class A	
Voltage fluctuations / flicker (IEC 61000-3-3)	Complies	

Information regarding electromagnetic emissions (IEC 60601-1-2: 2001, table 201)

Electromagnetic immunity

The Fabius MRI is intended for use in the electromagnetic environment specified below. The user of the Fabius MRI should assure that is used in such an environment.

Immunity against	**IEC 60601-1-2 test level**	**Compliance level (of this equipment)**	**Electromagnetic environment**
electrostatic discharge, ESD (IEC 61000-4-2)	contact discharge: ±6 kV air discharge: ±8 kV	±6 kV ±8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity shall be at least 30 %.
electrical fast transients / bursts (IEC 61000-4-4)	power supply lines: ±2 kV longer input / output lines: ±1 kV	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
surges on AC mains lines (IEC 61000-4-5)	common mode: ±2 kV differential mode: ±1 kV	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	3 A/m	3 A/m	In close vicinity to the Fabius MRI, no equipment with extraordinary power frequency magnetic fields (power transformers, etc.) should be operated.
voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	dip >95 %, 0.5 periods dip 60 %, 5 periods dip 30 %, 25 periods dip >95 %, 5 seconds	>95 %, 0.5 per. 60 %, 5 per. 30 %, 25 per. >95 %, 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If user requires continued operation during power mains interruptions, it is recommended to power the Fabius MRI from an uninterruptible supply or a battery.
radiated RF (IEC 61000-4-3)	80 MHz to 2.5 GHz: 10 V/m	10 V/m	Recommended separation distance from portable and mobile RF transmitters with transmission power P_{EIRP} to the Fabius MRI including its lines: $1.84\ m * \sqrt{P_{EIRP}}$ [1)]

Immunity against	**IEC 60601-1-2 test level**	**Compliance level (of this equipment)**	**Electromagnetic environment**
RF coupled into lines (IEC 61000-4-6)	150 kHz to 80 MHz: 10 V within ISM bands, 3 V outside ISM bands[2)]	10 V 3 V	Recommended separation distance from portable and mobile RF transmitters with transmission power P_{EIRP} to the Fabius MRI including its lines: 1.84 m * $\sqrt{P_{EIRP}}$[1)]

1) For P_{EIRP} the highest possible “equivalent isotropic radiated power” of the adjacent RF transmitter has to be inserted (value in Watt). Also in the vicinity of equipment marked with the symbol (((•))) interference may occur. Field strengths from fixed, portable or mobile RF transmitters at the location of the Fabius MRI should be less than 3 V/m in the frequency range from 150 kHz to 2.5 GHz and less than 1 V/m above 2.5 GHz.
2) ISM bands in this frequency range are: 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz, 40.66 MHz to 40.70 MHz.

Information regarding electromagnetic immunity
(IEC 60601-1-2: 2001, tables 202, 203, 204)

Recommended separation distances

Recommended separation distances between portable and mobile RF telecommunication devices and the Fabius MRI			
max. PEIRP (W)	**3 V/m distance[1] (m)**	**1 V/m distance[1] (m)**	**Note**
0.001	0.06	0.17	
0.003	0.10	0.30	
0.010	0.18	0.55	
0.030	0.32	0.95	e.g. WLAN 5250 / 5775 (Europe)
0.100	0.58	1.73	e.g. WLAN 2440 (Europe), Bluetooth
0.200	0.82	2.46	e.g. WLAN 5250 (not in Europe)
0.250	0.91	2.75	e.g. DECT devices
1.000	1.83	5.48	e.g. GSM 1800- / GSM 1900- / UMTS- mobiles, WLAN 5600 (not in Europe)
2.000	2.60	7.78	e.g. GSM 900 mobiles
3.000	3.16	9.49	

1) 3 V/m distance to transmitters with frequencies from 150 kHz to 2.5 GHz, otherwise 1 V/m distance.

Information regarding separation distances
(IEC 60601-1-2: 2001, tables 205 and 206)

Electrical Safety Conformance

Conforms to:
- UL 60601-1
- IEC 60601-1
- CAN/CSA C22.2 No. 601.1-M90

General Safety Standards for Anesthesia

- IEC 60601-2-13 plus US deviations
- ISO 8835-2
- EN 740

Freedom from latex

Fabius MRI is latex-free!
Latex-free breathing bags and breathing hoses must be used for latex-free use.

Ventilator

Conforms to:
- ISO 8835-5

Control Inputs Ranges

P_{MAX}	Pressure limiting	15 to 70 cmH_2O (1 cmH_2O resolution) (15 to 70 hPa (1 hPa resolution)) (setting must be at least 10 cmH_2O (10 hPa) above PEEP; and in SIMV/PS mode, the P_{MAX} setting must also be greater than ΔP_{PS}+PEEP)
V_T	Tidal volume	20 to 1400 mL (10 mL resolution)
V_T (SIMV/PS)	Tidal volume	20 to 1100 mL (10 mL resolution)
f	Breathing frequency	4 to 60 bpm (1/min) (1 bpm resolution) (4 to 60 1/min (1/min resolution))
T_I/T_E	Inspiration/expiration ratio	4 : 1 to 1 : 4
T_{IP}/T_I	Inspiration pause	0 % to 50 % (1 % resolution)
PEEP	End-expiratory pressure	0 to 20 cmH_2O (1 cmH_2O resolution) (0 to 20 hPa (1 hPa resolution))
P_{INSP}	Inspiratory pressure	5 to 65 cmH_2O (1 cmH_2O resolution) (5 to 65 hPa (1 hPa resolution)) (setting must be at least 5 cmH_2O (5 hPa) above PEEP)

Insp Flow	Inspiratory flow	10 to 75 L/min (1 L/min resolution) in Pressure Control mode 10 to 85 L/min (1 L/min resolution) in PS and SIMV/PS modes
ΔP_{PS} (Pressure Support)	Support Pressure	3 to 20 cmH_2O (1 cmH_2O resolution) (3 to 20 hPa (1 hPa resolution))
ΔP_{PS} (SIMV/PS)	Support Pressure	3 to 20 cmH_2O, OFF (1 cmH_2O resolution) (3 to 20 hPa, OFF (1 hPa resolution))
Freq Min	Apnea Ventilation minimum frequency	3 to 20 bpm (1 bpm resolution) and “OFF” (3 to 20 1/min (1/min resolution) and “OFF”)
Trigger	Trigger Level	2 to 15 L/min (1 L/min resolution)
T_{INSP}	SIMV Inspiratory Time	0.3 to 4.0 sec

Pressure Support Ventilation Mode

The Pressure Support Ventilation mode has been verified under the following range of simulated patient conditions:

Endotracheal Tube Size:	0.18 in to 0.32 in (4.5 mm to 8 mm)
Patient Lung Compliance:	10 mL/cmH_2O to 100 mL/cmH_2O (10 mL/hPa to 100 mL/hPa)
Unassisted Patient Tidal Volume:	50 mL to 1000 mL
Patient Breath Rate (bpm) (1/min):	10 to 35

Delivery Accuracy

P_{MAX}	Pressure limiting	±5 cmH_2O (±5 hPa) of setting
V_T	Tidal volume	±5 % of setting or 20 mL, whichever is greater discharged to atmosphere, no compliance compensation)
f	Breathing frequency	±1 bpm (1/min) of setting
T_I/T_E	Inspiration/expiration ratio	±5 % of setting
T_{IP}/T_I	Inspiration pause	±25 % of setting
PEEP	End-expiratory pressure	±2 cmH_2O (±2 hPa) or ±20 % of setting, whichever is greater

High Pressure Safety Relief Valve

75 ±5 cmH_2O (75 ±5 hPa)

Negative Pressure Safety Relief Valve (Ambient AIR Inlet Valve)

–7.5 to –9 cmH_2O (–7.5 to –9 hPa)

Minimal Limit Pressure

–8.5 cmH_2O (–8.5 hPa)

System Compliance Compensation Measurement

0.2 to 6.0 mL/cmH_2O (0.2 to 6.0 mL/hPa)	±0.2 mL/cmH_2O (±0.2 mL/hPa or ±10% of actual compliance, whichever is greater

Anesthesia Gas Supply Module

Fresh Gas Flow Indicators:	.
O_2, N_2O, AIR:	Range and accuracy: 0.0 to 12.0 L/min ±10 % of reading or 0.12 L/min into an ambient atmosphere of 14.7 psi (1.013 kPa x 100) at 20 °C (68 °F). Resolution: 0.1 L/min

Fresh Gas Flow Stability:

O_2 and N_2O: ±10 % of setting with pipeline pressures between 41 to 87 psi (2.8 to 6 kPa x 100
AIR: ±10 % of setting with pipeline pressures between 50 to 55 psi (3.4 to 3.8 kPa x 100)
Air flow rate will vary proportionally with supply pressures outside 50 to 55 psi (3.4 to 3.8 kPa x 100).

Total Fresh Gas Flowmeter:

Range and accuracy:	0 to 10 L/min ±10 % of full scale at STP, calibrated with 50 % O_2/ 50 % N_2O gas mixture 0 to 10 L/min ±15 % of full scale at STP for all other gas mixtures
Resolution:	0.5 L/min from 0.5 to 2 L/min 1.0 L/min from 2 to 10 L/min
O_2 flush (bypass):	at 87 psi (6 kPa x 100): max. 75 L/min at 41 psi (2.8 kPa x 100): min. 25 L/min
Common Gas Outlet Pressure Limit:	13 psi (0.9 kPa x 100), maximum

Auxiliary Oxygen Flowmeter

Connection	Staged connector for use with different hose diameters
Fresh-gas flow	0 to 10 L/min
Accuracy	±5 % of full scale
Resolution	0.5 L/min

Anesthetic Agent Vaporizer Interface

Dräger Vapor quick-change plug-in system for up to two anesthetic agent vaporizers.

The connections are automatically closed and sealed when the vaporizer is removed.

Vapor 2000 system only

Dräger Halothane Vapor 2000
Dräger Enflurane Vapor 2000
Dräger Isoflurane Vapor 2000
Dräger Sevoflurane Vapor 2000

See specific Instructions for Use manuals for technical data of anesthetic agent vaporizers.

Monitoring and Measurement Display		Range	Resolution	Accuracy	Condition
P_{AW}	Airway pressure (numeric)	–20 to 99 cmH_2O (hPa)	1 cmH_2O (hPa)	±4 %[1]	
	Airway pressure (wave)	0 to 99 cmH_2O (hPa)			
	Pressure gauge (mechanical)	–20 to 80 cmH_2O (hPa)	2 cmH_2O (hPa)	1.6 cmH_2O (hPa)	
V_E	Expiratory minute volume	0 to 99.9 L/min	0.1 L/min	±15 %[2]	with reference to 68 °F (20 °C), ambient pressure and saturated gas
	Expiratory tidal volume	0 to 1500 mL	1 mL	±15 %[2] or ±20 mL, whichever is greater	
f	Breathing frequency	2 to 99 bpm (1/min)	±1 bpm (1/min)	±1 bpm (1/min)	
FiO_2	O_2 measurement in the main gas flow	10 to 100 Vol.%	1 Vol.%	±(2.5 Vol.% + 2.5 % of the measured value) as per ISO 21647	with reference to ambient pressure during calibration

1) Max. ±4 % of the measured value or ±2 cmH_2O (±2 hPa), whichever is greater.
2) At standard test conditions per IEC 60601-2-13.

O_2 Cell Measurement Performance

Response time	Less than 16 seconds	measured values are not pressure compensated
Warm-up time	after 5 min	error ≤3 % of measured value
Drift Sensitivity		±1 % of measured value / 8h
Cross Sensitivity		≤1 vol.% O_2 at 70 vol.% N_2O and 5 vol.% CO_2
		with 4 vol.% Halothane
		or with 5 vol.% Enflurane
		or with 5 vol.% Isoflurane
		or with 10 vol.% Sevoflurane
effect of humidity / sensitivity	max. ±0.02 % of measured value / % relative humidity	
Service life of O_2 sensor cell	>12 months at 77 °F (25 °C), 50 % relative humidity, 50 % O_2 gas mixture (or >5000 hours at 100 Vol% O_2)	

Breathing System

Volume with reusable absorber

incl. filled absorber, excl. hoses	1.7 L + bag

Volume with Drägersorb CLIC adapter

incl. filled absorber, excl. hoses	1.7 L + bag
excl. absorber, excl. hoses	0.8 L + bag

Volume absorber

reusable absorber, filled	1.5 L
Clic absorber (Drägersorb CLIC Free)	1.2 L

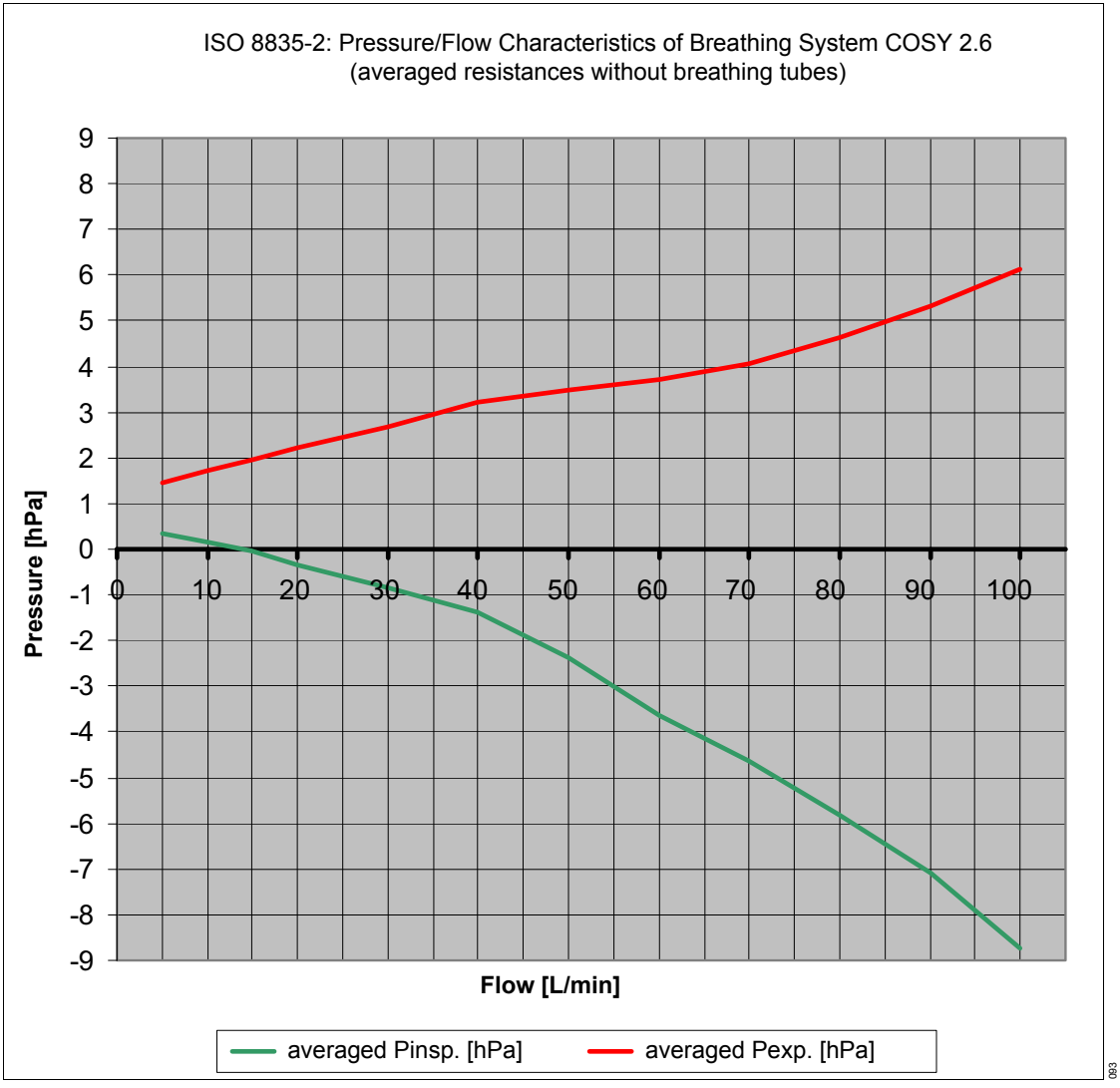
Compliance
(in automatic ventilation modes, e.g. Volume Control, excluding patient hoses)

with reusable absorber	0.35mL/cmH_2O (0.35 mL/hPa)
with Drägersorb CLIC adapter, including absorber	0.35mL/cmH_2O (0.35 mL/hPa)
with Drägersorb CLIC adapter, excluding absorber	0.35mL/cmH_2O (0.35 mL/hPa)

Resistance
(Reusable absorber or CLIC absorber with or without flexible bag arm, normal operation, filled with Drägersorb 800 +)

	Inspiratory	Expiratory
As per ISO 8835-2, dry, max. ±6 hPa (±6 cmH2O), with hose set for adults M30146	–4.4 cmH_2O (–4.7 hPa)	4.2 cmH_2O (4.4 hPa)
As per ISO 8835-2, dry, sole breathing system without patient hoses	–3.7 cmH_2O (–3.7 hPa)	3.7 cmH_2O (3.7 hPa)

Typical leak <50 mL/min


ISO 8835-2: Pressure/Flow Characteristics of Breathing System COSY 2.6
(averaged resistances without breathing tubes)
Pressure [hPa]
9
8
7
6
5
4
3
2
1
0
-1
-2
-3
-4
-5
-6
-7
-8
-9
0
10
20
30
40
50
60
70
80
90
100
Flow [L/min]
averaged Pinsp. [hPa]
averaged Pexp. [hPa]
093

Classification **II b**
Conforming to Directive 93/42/EEC Appendix IX

UMDNS Code **10-134**
Universal Medical Device Nomenclature System

Control Inputs Ranges

APL-Valve	MAN mode	5 to 70 cmH_2O (hPa)
	SPONT mode	1.5 cmH_2O (hPa)
accuracy from 5 to 15 L/min		±15 % of set value or ±3 cmH_2O (hPa) (greater applies)
pressure drop at 30 L/min		3.4 cmH_2O (hPa) (wet and dry)

Low Oxygen Supply Pressure Alarm

Alarm limit	Warning signal when the pressure drops below 20 ±4 psi (1.4 ±0.3 kPa x 100)
Alarm signal	High priority alarm (Warning)
LED indicator	The red LED indicator in the O_2 area of the gas flow control interface will flash until the O_2 supply is restored.

S-ORC (Sensitive Oxygen Ratio Controller)

S-ORC is a control element which guarantees a minimum O_2 concentration in the fresh gas flow. As from a flow rate of approx. 300 mL/min, the N_2O concentration in the fresh gas can be freely set between 0 and 75 %.

During O_2 shortage	S-ORC limits the N_2O concentration in the fresh gas, so that the O_2 concentration does not drop below 23 vol.%.
N_2O metering valve open and O_2 metering valve closed or O_2 flow less than 0.2 L/min	S-ORC prevents N_2O flow
During N_2O failure	O_2 may still be administered. No alarm.

Serial Interface

Type: RS - 232

Baud Rates: 1200, 2400, 4800, 9600, 19200, 38400

Parity: Odd, Even, None

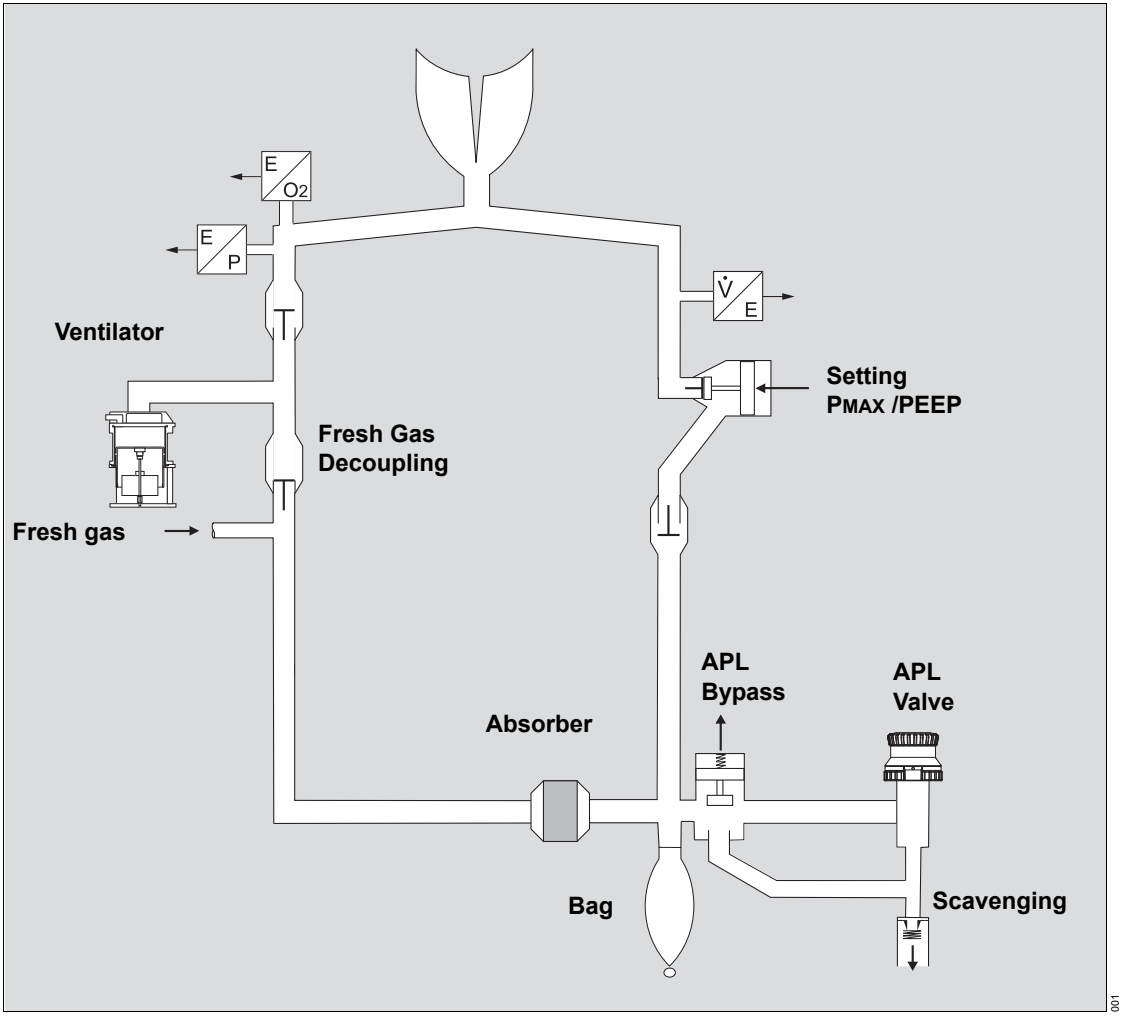
Data Bits: 7 or 8

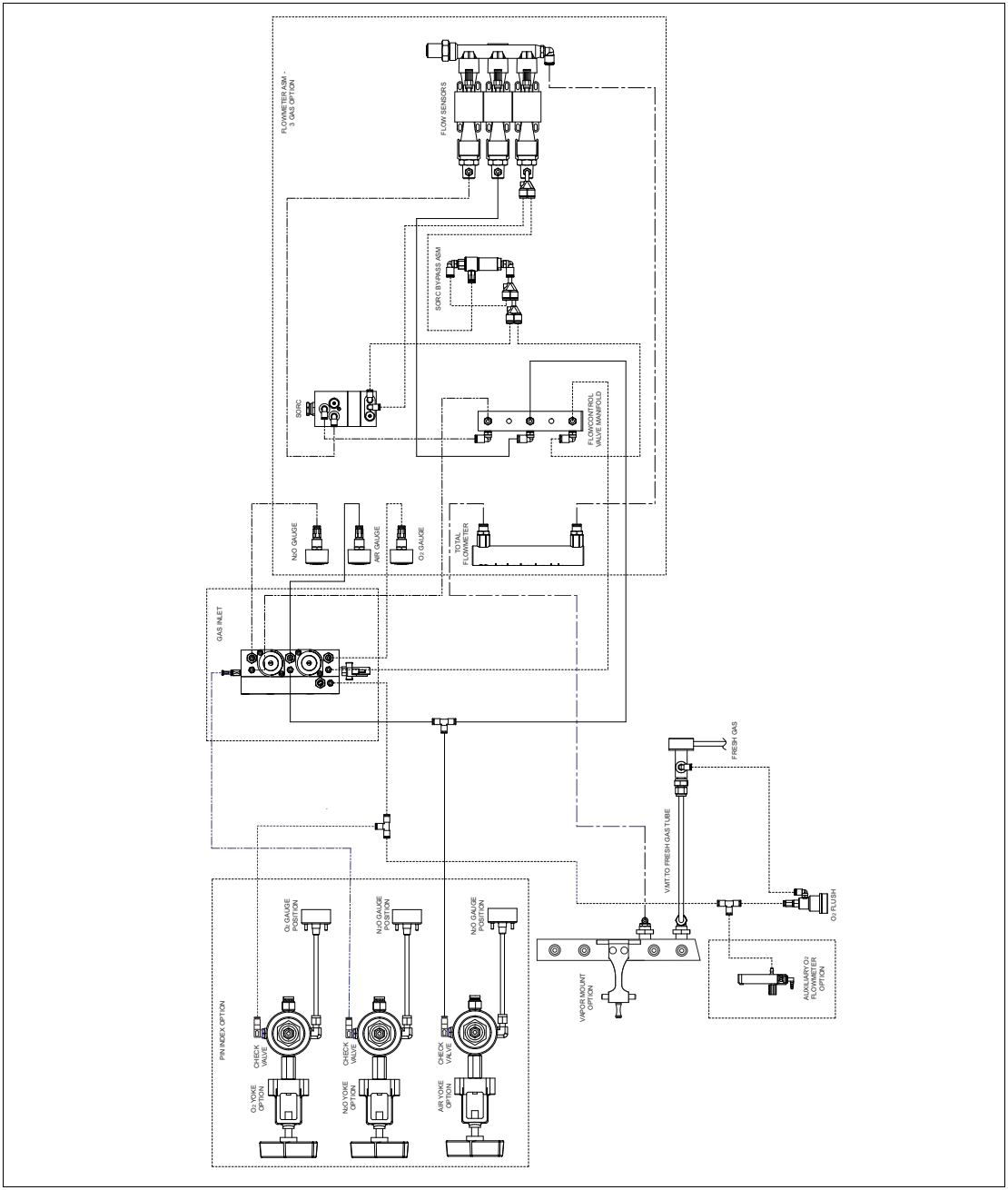
Stop Bits: 1 or 2

Protocol: MEDIBUS

Diagram

Gas flow diagram
Compact Breathing System




FLOWMETER ASM - 3 GAS OPTION
FLOW SENSORS
SORC BYPASS ASM
SORC
FLOW CONTROL VALVE MANIFOLD
N2O GAUGE
AIR GAUGE
O2 GAUGE
TOTAL FLOWMETER
GAS INLET
FRESH GAS
VAPORIZER MOUNT TUBE
O2 FLUSH
AUXILIARY O2 FLOWMETER OPTION
VAPOR MOUNT OPTION
PIN INDEX OPTION
O2 GAUGE POSITION
N2O GAUGE POSITION
NO GAUGE POSITION
CHECK VALVE
CHECK VALVE
CHECK VALVE
O2 YOKE OPTION
N2O YOKE OPTION
AIR YOKE OPTION
311

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Appendix 1 - Daily and Pre-use Checkout Form

Before operating the Fabius MRI, the following checkout verification form must be completed to ensure that the machine is ready for use. Do not insert any additional components into or modify the anesthesia workstation after the checkout procedure is started.

This is a recommended procedure. Follow your institution's policies for specific checkout procedures.

CAUTION

If any check cannot be carried out satisfactorily, the machine must not be used.
Call DrägerService or your local authorized service organization.

NOTE

Throughout this section, cmH_2O = mbar = hPa

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Please note that this Daily Pre-use check list takes into consideration all possible configurations of the Fabius MRI. The clinician need only use those areas that apply to their specific Fabius MRI configuration.

All checks must be carried out daily before equipment is used. The person who carries out the checks must be fully conversant with the Instructions for Use. Checks marked with a **P** must be carried out before each patient use. These pages should be removed and copied to establish a daily record of machines checks.
Mark each function when checks have been satisfactorily completed.

Fabius MRI Serial Number

Pre-conditions

- ❒ Inspection intervals for machine and accessories are current
- **P** ❒ Machine fully assembled and connected
- ❒ Monitors (O_2, P, V, CO_2, anesthetic agent) (when present) switched on and functioning, self test carried out satisfactorily
- ❒ System diagnostics for Fabius MRI carried out
- **P** ❒ Sampling line for gas monitoring (when present) connected to Luer Lock on the Y-piece, correct anesthetic agent selected

Checking Reserve Power

- **P** ❒ Verify that battery is fully charged. (If the battery does not show full a charge, the battery operation time is not guaranteed to be 45 minutes.)

Checking the Medical Gas Connections

- ❒ Visually inspect all gas supplies from the medical gas pipeline system and cylinders to make sure that they connect properly and fit securely
- ❒ Verify that all medical gas pipeline supplies are within acceptable pressure ranges.
- ❒ Open reserve gas cylinders (when present).
- ❒ O_2 pressure more than 1000 psi (70 kPa x 100)
- ❒ N_2O pressure greater than 600 psi (43 kPa x 100) if present
- ❒ AIR pressure greater than 1000 psi (70 kPa x 100) if present
- ❒ Close reserve gas cylinders.

O_2 Flush Function

- ❒ Press O_2 flush: A strong flow of gas should be emitted from the patient connection.
- ❒ Release O_2 flush button: flow of gas from patient connection stops.

Checking the Flow Control/Metering System

- ❒ Activate ManSpont mode.
- ❒ Fully open the O_2 metering valve. O_2 flow of at least 10 L/min present.
- ❒ Close air metering valve. Fully open the N_2O metering valve. N_2O flow of at least 10 L/min present.
- ❒ Verify that the float ball of the total fresh gas flowmeter moves up.
- ❒ Turn off the O_2 supply. Remove the O_2 connector and close the O_2 cylinder valve. The O_2 Low Supply Pressure Alarm LED is blinking. N_2O does not flow.
- ❒ Verify that the float ball of the total fresh gas flowmeter shows 0 L/min.

- ❒ Restore the O_2 supply: N_2O flow is present.
- ❒ Set O_2 metering valve to 1.5 L/min. N_2O flow = 3 L/min to 5 L/min
- ❒ Close the O_2 metering valve: No N_2O flow.

Checking the Flow Control/Metering System

- ❒ Open the AIR flow control valve. Air flow of at least 10 L/min present.
- ❒ Close all metering valves.

Sensor Calibration

- ❒ Remove O_2 sensor housing from inspiratory valve dome
- ❒ Calibrate O_2 sensor
- ❒ Calibrate flow sensor
- ❒ Replace O_2 sensor

Checking the Gas Type

- ❒ Set the O_2 metering valve to approx. 3 L/min.
- ❒ Verify an O_2 concentration indication of approx. 100 vol.%.
- ❒ Close O_2 metering valve.

Vapor 2000

P ❒ Fastening; Latched down firmly and set vertically

P ❒ Handwheel; In zero position and engaged

P ❒ Filling level between min. and max.

P ❒ Interlock; Locking function OK (when present)

P ❒ Key-indexed filling system; Sealing key or pin inserted and closed tight. (when present)
Filler opening locked shut.

P ❒ Quik Fil or Funnel filling system; Locking screw tight (when present)

Checking the Condition of CO_2 Absorbent

P ❒ Color change is no more than half the canister of CO_2 absorbent.

Testing the P_{AW} sensor

Switch to standby mode and press the function key for the leak test.

- ❒ Close all fresh gas valves.
- ❒ Fit the Y-piece to the fixture on the bag holder.
- ❒ Seal the sample line connection, if necessary.
- ❒ Remove the hose of the connection socket for the breathing pressure sensor on the rear.
- ❒ Check the pressure display on the leak test start screen: “0” to ±2 is OK. If the deviation is greater, contact DrägerService.
- ❒ Reconnect the hose of the connection socket for the breathing pressure sensor on the rear.

Leak Testing the Fresh Gas Circuit

Test once without the vaporizer and once with each Dräger Vapor with the handwheel set to zero.

- ❒ Go to Standby and press the Leak Test soft key.
Follow the instructions on the screen.

If the system leaks (i.e. pressure drops):

- Check that all plug-in, push-fit and screw connectors fit tightly.
- Replace any missing or damaged seals. If necessary, call DrägerService or your local authorized service organization.

Inspiratory and Expiratory Valves (Compact Breathing Systems)

- Press the ManSpont key and confirm.
- Set APL-valve to MAN position and adjust to 30 cmH_2O (hPa).
- Press O_2 flush.

P ❒ Breathing bag for manual ventilation fills

P ❒ Inspiratory and expiratory valve discs move freely when the breathing bag is squeezed and released.

Pressure-Limiting (APL) Valve (Compact Breathing System)

P ❒ Set APL valve to MAN and 30 cmH_2O (hPa).
Set fresh gas flow to 20 L/min.

P ❒ Press the ManSpont key and confirm.

P ❒ When the pressure waveform on the Breathing Pressure Trace window stabilizes (e.g., a flat line), flip the APL-valve to SPONT to release pressure.

P ❒ Peak pressure display on monitor reads 24 to 36 cmH_2O (hPa).

Checking Ventilator Operation

P ❒ Connect a breathing bag to the Y-piece to act as test lung.

P ❒ Press the Pressure Control key and confirm.

P ❒ Check that ventilation measurements are displayed.

P ❒ Check that the ventilator piston is cycling.

P ❒ Monitor the operation of the inspiratory and expiratory valve discs.

P ❒ Check that the breathing bag (test lung) on the Y-piece is ventilating.

P ❒ Press the Standby key and confirm.

Monitors

The alarm function can be tested by setting alarm limits to levels that are certain to trigger an alarm.

Check the alarm limit settings. The monitor alarm limits are automatically set to a default configuration when the ON/OFF switch is turned on. Check these settings and adjust them if necessary. Alarm limits can be adjusted at the beginning of or during a procedure. Also, make sure that any external monitors (if any) are connected properly.

Test the alarm functions for all monitors. Simulate alarm conditions and check for appropriate alarm signals.

❒ Test the O_2 monitor and alarm module.

❒ Test the volume monitor and alarm module.

❒ Test the pressure monitor and alarm module.

❒ Press the Standby key and confirm.

Additional Monitors (when present)

❒ Check the CO_2 monitor and alarm module.

❒ Check the anesthetic agent monitor and alarm module.

Anesthetic Gas Scavenging System

P ❒ Check the hose connections.

P ❒ Adjust the flow regulator to place the float between the "Minimum" and "Maximum" marks.

P ❒ Change to Man/Spont mode.
Press and hold the O_2 flush button and verify that airway pressure is <10 cmH_2O (hPa) with Y-piece occluded.
Wait until flow curve is refreshed.

P ❒ Close all flow control valves on the machine, with Y-piece occluded, and verify that airway pressure is ≥0.5 cmH_2O (hPa)

Manual Ventilation Bag for Emergency Ventilation

❒ Check that the bag is functioning correctly by pumping manually.

❒ When the bag is squeezed, air must audibly and tangibly flow out of the mask cone; when the bag is released, it must rapidly recover its original shape.

❒ Block off the mask connector (cone) with the ball of your thumb: you should only be able to squeeze the bag a little.

P ❒ **Before Connecting to Patient**

Verify that
- all vaporizers are off (the handwheels are set to zero),
- the APL Valve is set as desired,
- all flowmeters indicate 0,
- the patient suction is level adequate, and
- the breathing system is ready to use (the bag is in place and all hoses are connected properly

If any check can not be carried out satisfactorily, the machine must not be used.

Daily Checkout Signature

Name	
Date	

Pre-use Checkout Signature

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Pre-use Checkout Signature

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Appendix 2 - Imaging Test Protocol

The purpose of the imaging test protocol is to verify that the Fabius MRI does not interfere with the diagnostic quality of the MR images.

Imaging Test Protocol (ITP) Overview:

An ITP is required to complete the installation and approximately 30 minutes of magnet time is needed. The ITP consists of four scans, described as follows:

Type of scans: 3 scans: Gradient Echo (GE, FFE)

1 scan: customer choice

1 The first scan (a gradient echo scan with a small flipangle (e.g. ,10 degree)) should be performed with the anesthesia machine outside the MRI room and with a standard MRI phantom placed in the center of the head coil. This is a baseline scan to verify the room integrity (i.e., to prove the absence of image artifacts caused by non-optimal performance of the MR scanner itself or by interference with other external radio-frequency (RF) sources).

2 The next scan (using identical scan parameters as before), again with the head coil, is performed with the anesthesia machine in the MRI room in a position typical of where it is used clinically.

3 For the third scan, again with the machine in the MRI room in a position typical of where it is used clinically, remove the head coil from the MRI system and place the phantom in the center of the body coil. The scan has to be performed with the body coil (if necessary, sequence parameters may be adapted to body coil scanning).

4 The fourth scan shall be any type of clinical scan chosen by the MRI technician. The scan shall be performed using any type of imaging coil, with the anesthesia machine in the MRI room in a position typical of where it is used clinically. For example, a type of MRI scan known to be particularly sensitive to RF interferences may be selected. If the head coil is used in this sequence, scan #4 should be performed before scan #3 (the body coil scan) to avoid an extra change of RF coils and repositioning of the phantom. In case of MR imaging artifacts observed in scan #4, this scan should be repeated with the anesthesia machine being positioned outside the MRI room, for better direct comparison.

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Appendix 3 - Record of Transfer and Equipment Installation Drawing

Fabius MRI for nuclear magnetic resonance tomograph

Manufacturer: Dräger Medical GmbH

Manufacturer of MRI tomograph: _____

Equipment type: _____

Location: _____

Date of installation of anesthetic unit: _____

Signatures

Dräger representative: _____

Operator: _____

Fringe field definition for 40 mtesla (400 gauss)

Distance from the magnetic center: _____Z-axis in feet/in or cm

_____ X-axis in feet/in or cm

or

Distance from the MRT housing in the direction of Fabius MRI position: _____ Z-axis in feet/in or cm

_____ X-axis in feet/in or cm

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These Instructions for Use only apply to
Fabius MRI SW 3.n
with the Serial-Nr.:

If no Serial No. has been filled in by Dräger, these Instructions for Use are provided for general information only and are not intended for use with any specific machine or device. This document is provided for customer information only, and will not be updated or exchanged without customer request.

CE 0123
Directive 93/42/EEC
Concerning Medical Devices

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Dräger reserves the right to make modifications to equipment without prior notice.

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As of 2015-08:
Dräger Medical GmbH
changes to
Drägerwerk AG & Co. KGaA