DAMECA AX500

INSTRUCTIONS FOR USE

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Contents

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1 Introduction

The Dameca AX500 anaesthesia machine is intended to provide inhalational anaesthesia and ventilation support to neonatal, paediatric and adult patients. The device is intended to provide volume or pressure controlled ventilation as well as supportive modes of ventilation.

The intended patient population ranges from neonates to adults, weighing from 2 -150 kg.

The machine is used together with the patient's respiratory system, connected to the patient via an endotracheal tube, a laryngeal mask or a face mask which allows for gas delivery and subsequent oxygenation and ventilation for the patient.

The machine is primarily to be used in an operation room and the machine will generally be used 1-10 times (start and end case) per day, depending on the length of the case. It is expected that the machine has a life time of 10 years.

The machine must only be used by healthcare professionals who are familiar with the machine as well as trained and certified to provide anaesthesia and manage patients who are receiving ventilator support. Other users of the machine are biomedical engineers who may be servicing the machine.

Training in the use of the Dameca AX500 anaesthesia machine is required for safe and effective use. Training is offered by Dameca clinical specialists and comprises these topics: primary operating functions, safety, operating principles, alarm handling, data collection, cleaning and maintenance.

The machine is not MRI compatible.

Who should use the Instructions for Use

The Instructions for Use is intended for clinical personnel who prepare the machine for daily use, operate the machine during surgical procedures and clean the machine after use, typically:

- Nurse anaesthetists
- Anaesthesiologists or anaesthetists
- Anaesthesia technicians

The guide uses the generic term "user" to refer to all the different types of clinical operators, and addresses the user directly with "you".

About the Instructions for Use structure

Chapters 1 through 3 are introductory information intended primarily for users who are new to the machine.

Chapters 4 through 10 are step by step instructions in setup, preparation for daily use, operating the machine, alarm handling, cleaning and modifying default settings.

Chapters 11 and the remainder of the guide are reference sections intended for lookup and search for information.

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2 About safety

Always ensure that the machine is working properly before use.

- For information about setting the machine up for first use, see “Set up the machine for first use” on page 29
- For details about preparing the machine for the first patient as well as preparations between each patient, see “Prepare for the first patient of the day - Full test” on page 34

WARNING
A warning indicates a potential risk for the patient or user that they may be in danger of injury.

CAUTION
A caution indicates a risk of damage to either the machine or other equipment.

NOTE
A note indicates circumstances to be considered while using the machine.

2.1 Warnings

- No add-ons, removals, or changes should be made to this machine unless authorised by Dameca.
- Disregarding the information on safety is considered abnormal use.

Power

- The machine must only be connected to properly grounded hospital grade electrical outlets. The machine must not be connected to an extension cord that is shared with other equipment.
- The machine should only be used with the power cord supplied by Dameca.

Maintenance and service

- Do not remove service hatches or covers. There are no parts or components inside the machine that can be repaired by the user. Always have a qualified technician to perform maintenance and repairs.
- Prior to servicing, cleaning, or disinfection, unplug the power cord from the electrical outlet. Allow the machine to dry completely before reconnecting the power cord to the electrical outlet.
- Do not use silicon-based lubricant and non-combustible oils and grease with this machine; only PTFE-based, oxygen-compatible lubricants can be used.
- The user must not access the batteries as they are placed inside the machine and require tools to open.

Breathing system, filters, hoses and masks

- External breathing systems used with this machine must comply with EN ISO8835-2, IEC 60601-2-13, ISO 80601 -2-13, ISO 80601-2-13+A1, or a similar standard.
- Bacteria filters used with this machine must comply with ISO 23328-1 and ISO 23328-2 or a similar standard.
- Anti-static or electrically conducting breathing hoses and masks can cause burns if used with high-frequency diathermy equipment and are therefore not recommended for use with this machine.
- The O_2 concentration in the breathing system can differ significantly from the O_2 concentration in the fresh gas.
- Special conditions like malignant hyperthermia in susceptible patients require special precautions, please refer to our separate guidelines.

Heat and moisture

- Heat and moisture exchangers used with this machine must comply with EN ISO9360-1 and EN ISO9360-2 or a similar standard.
- Humidifiers used with this machine must conform to EN ISO8185 or a similar standard.

Patient suction

- External suction or vacuum controls used with this machine must comply with EN ISO10079-1, EN ISO10079-2 and EN ISO10079-3 or similar standards.

auxiliary O_2 flow metre

- The auxiliary O_2 flow metre bypasses the maximum pressure limit (MPL) valve. This means that pressure from the flow metre may exceed the pressure from the fresh gas outlet, potentially causing high pressure in the patient lungs.

Absorbers

- If using a reusable CO_2 absorber, note the following concerning replacement of the soda lime absorber: Absorber soda lime is caustic and can produce burns in the respiratory airway if inhaled. Use breathing protection equipment to prevent inhalation of soda lime dust.
- When using soda lime in absorbers, always follow the manufacturer’s instructions.

Vaporizers, anaesthetic agents and gases

- Do not use flammable anaesthetic gases, such as ether or cyclopropanae, with this machine. Use only anaesthetic agents that comply with the recommendations from the manufacturer of the anaesthesia vaporizer.
- Anaesthesia vaporizers connected to this machine must comply with ISO 8835-4, IEC 60601-2-13, ISO 80601-2-13 or a similar standard, and must be used according the instructions for use for the vaporizers.
- Medical gases or anaesthetic agents used with this machine must comply with the US Pharmacopoeia, European Pharmacopoeia or local recognised requirements for medical gases.
- The machine is compatible with medical gases of O_2, Air and N_2O and anaesthetic agents of halothane, enflurane, isoflurane, sevoflurane and desflurane.
- All cylinders used with this machine must comply with ISO407 or ISO5145 or similar standards. The central gas supply used with this machine must comply with EN ISO9170-2 and ISO7396-2 or a similar standard.
- Use only the anaesthetic agent for which the vaporizer is calibrated. Use of the wrong anaesthetic agent in the vaporizer may be fatal to the patient.

- Use of anaesthetic agents in the machine may result in the presence of residual agents (ppm) within the machine (vaporizer manifold, back-bar, etc.). These residuals can be minimised by setting a high fresh gas flow for an extended period of time.
- After use, close the fresh gas flow before leaving the machine. This is to avoid unintentional fresh gas consumption.
- The use of 100% O_2 can cause retinal fibroplasia in neonatal patients.

Monitors

- The machine should always be used with a separate monitor for O_2, anaesthetic agent, and CO_2 concentrations when not configured with the optional integrated multigas module. This monitor must comply with ISO21647, ISO80601-2-55 or a similar standard. A separate monitor must be connected to the patient breathing circuit per the instructions for use for the monitor.
- Use only monitor arms approved for this machine. See the manufacture´s Instruction for Use for correct use and installation.
  Observe the maximum loads on the various components such as: the top shelf, the table plate, drawers and accessories.
- If volume monitoring* is not installed, the machine should be used with a separate monitor for expired volume. This monitor must comply with the requirements in ISO60601-2-13, ISO80601-2-13 or similar standard.
- An external gas monitor connected to the breathing system could cause leakage, even if the monitor is in standby mode.
- If a monitor arm/arms are mounted on the machine the brakes must be activated.

External equipment

- Any person adding an external medical device is responsible for updating the pre-use checklist.
- If more than one external device is connected to the auxiliary electrical outlets*, a high leakage current from one device, for example a defective ground conductor, will affect the leakage current from the other equipment.
- External equipment not powered from the auxiliary outlets on the Dameca AX500 machine should be connected to the equipotential point at the rear of the machine. See “The rear of the machine” on page 20.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Medical Equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Environment

- This machine must not be used in an environment that exceeds the EMC levels stated in the IEC 60601-1-2 standard.

Preparing the machine

- Ensure that all cables and hoses are intact and in good condition before connecting the machine to a patient.
- The Anaesthesia Gas Scavenging System (AGSS) must always be activated when the machine is in use.
- Do not connect cylinders to the machine unless they are clean, undamaged and intact. Using unclean or damaged cylinders can cause leakage, which may raise the risk of burns or fire.
- Before use, check all hose connections and ensure that the machine is working correctly. Pay special attention to the breathing system and O-rings to ensure that there are no loose connections or leaks in the breathing

system.

- Precautions should be taken to prevent cross infections between patients. For details about maintenance and cleaning, see “Cleaning and maintenance” on page 57.
- Components for single-use should not be re-used, as this could introduce a patient risk due to possible cross contamination. Single-use components cannot be sterilized as the component materials are not compatible with cleaning methods.
- If the machine does not perform as described, it should not be used until the malfunction has been corrected by a qualified technician.
- Spilled fluids can cause electrical shock.
- To ensure that alarm sounds can be heard by the clinical personnel operating the machine, make sure that the speakers are not obstructed.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Using the machine

- Do not use the machine for clinical procedures until qualified personnel has ensured that the entire system is operating correctly.
- If all gas supply fails, delivery of fresh gas flow to the patient and automatic ventilation of the patient will also fail. In addition, the optional auxiliary gas outlet on this machine will also fail.
- Do not begin any test procedure with a patient connected to the machine. Test procedures are designed to ensure safe and correct machine performance. Test procedures should not be bypassed unless the patient’s condition requires immediate use of the machine.
- Once the patient is under anaesthesia or connected to the machine, the patient should be monitored by qualified personnel. Machine malfunction may require immediate action.
- When operating the machine, an alternative O_2 gas supply must always be available.
- When using the machine, alternative patient ventilation equipment, like a manual resuscitator or self-inflating bag appropriate for the patient’s age and size, must always be available.
- Do not use the machine in insufficiently ventilated areas. Use the Anaesthesia Gas Scavenging System (AGSS) to prevent elevated levels of anaesthetic gases in the operating room. Make sure that the ball in the flow marker is visible.
- Observe when closing the drawers that nothing gets caught or damaged, including the user’s fingers.
- When using low fresh gas flow in long duration procedures, periodic checks for excessive moisture in the breathing system and hoses are recommended. Generation of moisture is a natural consequence of a re-breathing ventilation system and does not represent a malfunction.
- When 100% O_2 from the auxiliary O_2 flow metre gets in contact with certain types of facial creams it can ignite.

2.2 Cautions

Power

- Before connecting the machine to the power supply, verify that the voltage and frequency comply with the main label on the rear of the machine.
- Do not attempt to connect any power cords to the auxiliary outlets other than those designed for the specific socket type.
- The machine can be disconnected from the mains supply by disconnecting the power plug from the wall socket

or by turning the power switch on the back of the machine to the OFF position.

- Make sure to position the machine so that the power from either the power cord connection on the back of the machine or the wall can be easily disconnected.
- No additional power socket or extension cord should be connected to the system.
- The auxiliary electrical outlets have fuses and circuit breakers which may cause the power to be switched off without warning if excessive current is drawn by external devices.
- The internal batteries only power internal systems, not the auxiliary electrical outlets and the down-light.

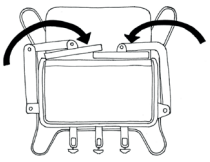
Maintenance and service

- This machine should be tested before use and serviced at least once a year by a technician trained and qualified by Dameca.
- Vaporizers should be serviced at an authorised service center in accordance with the manufacturer's directions.

Spare parts and accessories

- Use only hoses and accessories referenced in this guide or recommended by Dameca for use with the Dameca AX500; other hoses and accessories may cause malfunction if they do not have the same dimensions or are not made of the same materials.
- Use only original Dameca O-rings; other O-rings may cause problems if they do not have the same dimensions or are not made of the same materials.
- The reserve cylinder valves must be closed when the machine is using the central gas supply.
  The pressure provided by the reserve cylinders may be higher than the central gas supply pressure; thus, the cylinders could be depleted.
- To ensure correct gas measurement, the water trap for the optional integrated multigas module should be changed in accordance with its stated lifetime.
- When the machine is not in use, disconnect it from the power supply and central gas supply to prevent pollution.
- The machine is tested to be used with a range of monitor arms. If the monitor arm is mounted on the machine the brake on the arm must be activated. As the arm is balanced with a 10-15 kg monitor the user must firmly hold the handle of the arm when releasing the brake.
- Patient hoses used with this machine must comply with the EN 12342 standard, and the respiration bags must comply with the EN 1820 standard.
- All attached equipment and consumables used in the gas delivery system must be biocompatible and suitable for the intended use.

Transportation mode



- When moving the machine, make sure that peripherals on the sides of the machine, for example a monitor arm with a monitor, are placed as far towards the front center of the machine as possible. This gives a better balance and eases transportation as the total width is reduced.
- When the machine has been moved a Full test must be conducted before the machine is used on a patient.

External equipment

- External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations and systems shall comply with the safety requirements stated in the collateral standard IEC 60601-1-1 or the general standard IEC 60601-1, edition 3, clause 16. Any equipment

not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient.

- Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.
- The anaesthesia device should not be used next to other devices, unless those devices are compatible with IEC 60601-1-2. In the event the anaesthesia machine is used next to other electrical devices, it is recommended that the user verify that the performance is not affected.

2.3 Symbols

For screen symbols, see “Screen layout” on page 21.


Type B (EN 60601-1) protection against electrical shock


Consult instructions for use


Adjustment of fresh gas flow and patient suction: Turn counterclockwise to increase flow. Turn clockwise to decrease flow


ON/OFF switch for down-light


Protective earth (ground)


Equipotential point


ON/OFF


Patient flow sensor


Manufacturer


USB stick


Suction


Electrical and electronic equipment must not be discarded as normal waste

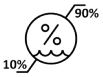

Connection for manual respiration bag


Inspiratory (inspiratory cone)

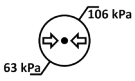

Expiratory (expiratory cone)


Class

CE mark

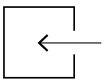


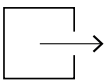
Humidity limitation



Barometric pressure limitation


Irritant


Inlet


Outlet


Keep away from sunlight


Keep dry


Warning

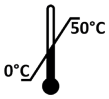

Caution

Part number of the machine 10621-00


General symbol for recovery/recyclable


Follow Instructions for Use


Interference may occur in the vicinity of equipment marked with this symbol



Temperature limitation


This way up


Fragile, handle with care

Stacking limit by number

Stacking limit by mass

2.4 Manufacturer's liability

Dameca is only liable for equipment safety, reliability, and performance, provided that:

- Assembly, operation, add-ons, adjustments, modifications, repairs, and periodic maintenance are performed by persons authorised by Dameca.
- The medical gas supply in the relevant rooms comply with medical gas requirements.
- The machine is used in compliance with these instructions for use.

2.5 Safety features

Gas supply

The ventilator, patient suction, and active Anaesthesia Gas Scavenging System suction are powered by the primary drive gas, Air or O_2. In the event that the primary drive gas fails, a drive gas valve will automatically switch to the secondary drive gas, O_2 or Air.

The machine has system alarms to alert to low inlet pressure of O_2, Air and N_2O.

Check valves prevent reverse gas flow, gas flow out of the machine.

Vaporizer back-bar

The interlock system on the back-bar ensures that only one of the two vaporizers that can be mounted can be opened.

Ventilator

In the event that the patient airway pressure is too high, the ventilator automatically switches to expiration phase to prevent exposing the patient to excessive airway pressure. This happens when the *Airway pressure high* alarm is triggered.

Minoxyguard

The minoxyguard ratio control ensures a minimum of 25% O_2 in the O_2-N_2O mix. If the O_2 flow is <150 mL/min N_2O

supply is automatically closed.

N_2O can only be used together with O_2.

Maximum Pressure Limiting valve (MPL)

The ventilator manifold has a built-in pressure relief valve that limits the maximum pressure to max. 125 hPa (cmH_2O).

Negative Pressure Limiting Valve (NPL) in VCV and SIMV modes

The IBS base has a built-in NPL valve which opens if spontanaeous breathing of the patient generates a negative pressure of -11 +/- 5 hPa (cmH_20). Negative airway pressure is only possible if the patient takes a large spontanaeous breath around the same time as a mandatory breath.

Adjustable pressure limiting valve (APL)

The IBS body has an integrated APL valve that opens according to the set pressure range from SP to 75 hPa (cmH_2O).

Battery backup

In the event of power failure during a procedure, the built-in battery will ensure that the machine runs uninterrupted for at least 90 minutes.

The battery is automatically charged when the machine is connected to mains power.

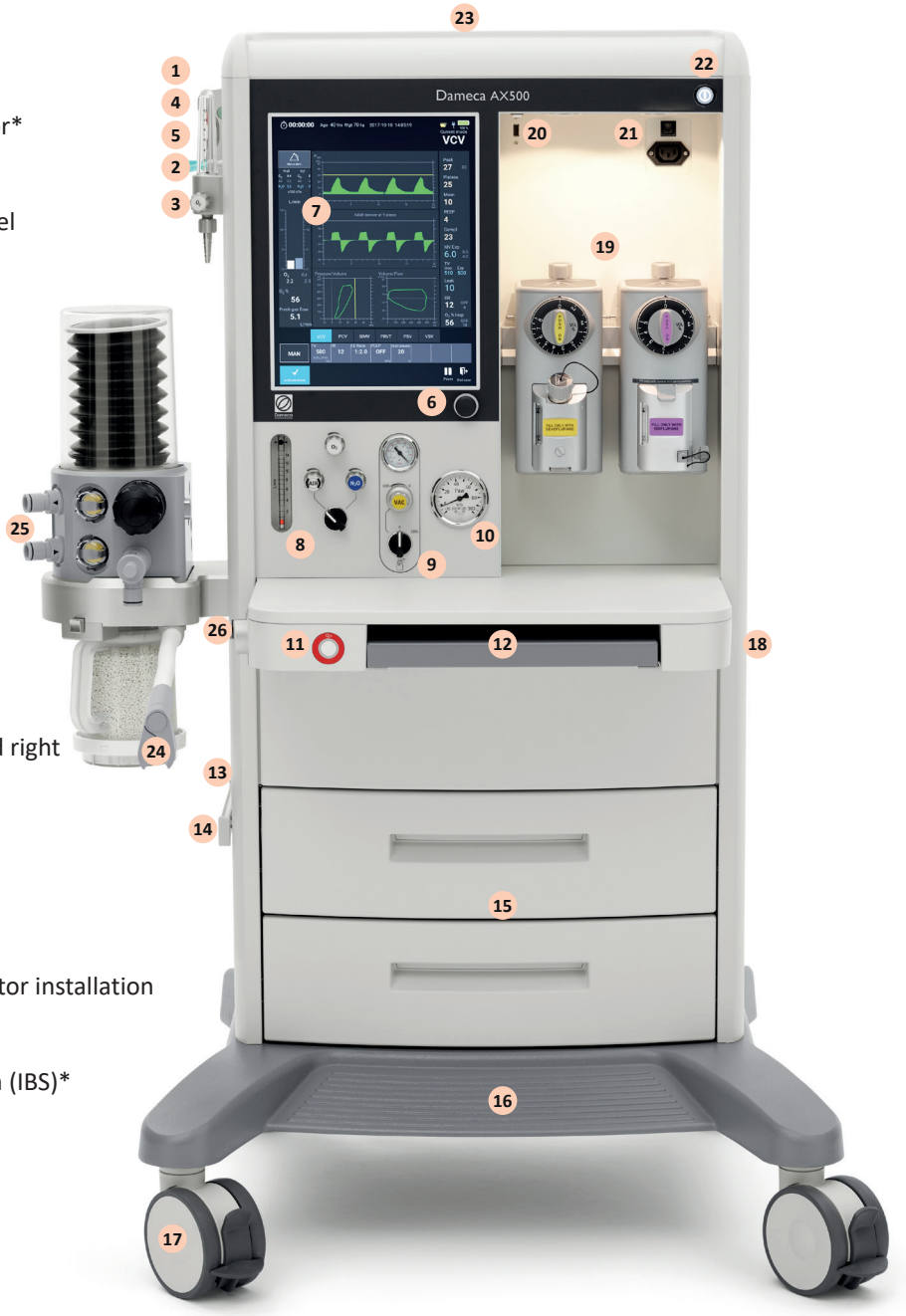
When the machine is running on battery, the machine's down-light is turned off to preserve battery power. The external power outlets, one on the front and three on the rear of the machine, are not powered when the machine is running on battery. Note, this also mean that if a desfluranae vaporizer is used, this is not powered when the machine is running on battery power.

3 Overview of the machine

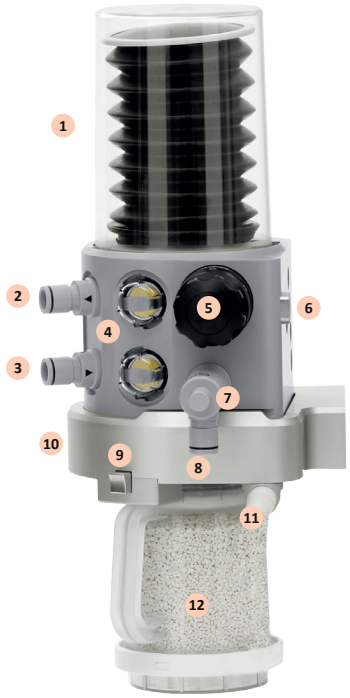
The following pages give an overview of the anaesthesia machine front and back and describe the layout and use of the screen.

3.1 The front of the machine

1. Anaesthetic Gas Scavenging system (AGSS) with flow marker
2. Flow sensor connection
3. Auxiliary O_2connection *
4. Water trap*
5. Integrated O_2 fuel-cell sensor*
6. Control dial
7. Touch screen / user interfacel
8. Fresh gas settings
9. Suction system*
10. Airway pressure gauge
11. O2 flush
12. Integrated pull-out plate
13. Suction port*
14. Side rail
15. Drawers with soft close
16. Foot rest
17. Wheels with brakes
18. Integrated side rails left and right
19. Back-bar for two vaporizers
20. USB port
21. Power outlet for vaporizer*
22. ON/OFF
23. Top shelf prepared for monitor installation
24. Bag arm*
25. Integrated Breathing System (IBS)*
26. Auxiliary fresh gas outlet



Integrated breathing system (IBS)



1. Bellows in chamber; bellows ascend during expiration.
2. Inspiratory cone (arrow pointing TOWARDS the patient) where patient hoses are connected.
3. Expiratory cone (arrow pointing AWAY from the patient) where patient hoses are connected.
4. Inspiratory and expiratory check valves.
5. Adjustable Pressure Limiting (APL) valve for use during manual ventilation and spontaneous breathing.
6. Release button for APL valve.
7. Test adapter for the Y-piece connecting the patient hoses; the test adapter is used during machine test.
8. Connection for respiration bag used in manual ventilation.
9. Absorber release button.
10. IBS base. Release handle on the back.
11. Bag arm.
12. i-SORB CO_2 absorber that removes CO_2 from the patient airway gases.

Anaesthetic Gas Scavenging System (AGSS)

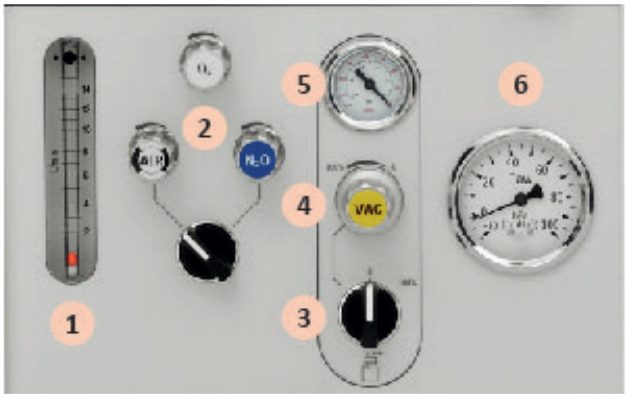
Anaesthetic Gas Scavenging System with a flow marker that indicates whether the AGSS system is on or off and whether the flow is in the correct range.

If a passive AGSS driven by vacuum is used, the ON/OFF switch is not available.

Water trap and multigas module fuel-cell*

Water trap with connection for the sample gas line. The water trap has a built-in overflow protection.
For multigas module with paramagnetic sensor, the fuel-cell is installed under the lid below the water trap.

Fresh gas settings, suction system and airway pressure gauge



1. Flow metre showing the total fresh gas flow, consisting of either O_2 and Air, or O_2 and N_2O.
2. Mechanical knobs to control O_2 and carrier gas and a selector switch to choose the carrier gas.
3. Mechanical knob to control the patient suction state: off, adjustable or maximum. The suction connection is placed on the left hand side of the machine, beneath the IBS.
4. Flow control knob to adjust suction when suction is in adjustable state.
5. Negative pressure gauge indicating the suction vacuum.

* option

6. Patient airway pressure (PAW) gauge, supplementary to the measurements on the screen.

O_2 FLUSH AND INTEGRATED PULL-OUT PLATE

1. The O_2 flush button provides a rapid supply of oxygen.
2. Table top with an integrated pull-out plate

AUXILIARY FRESH GAS OUTLET*

Auxiliary fresh gas outlet for connecting an external patient breathing circuit to the Dameca AX500.

Note! that the ventilator cannot be used when the auxiliary fresh gas outlet is activated.

BACK-BAR FOR VAPORIZERS, ELECTRICAL OUTLET AND USB PORT

1. Back-bar for up to two vaporizers. A security mechanism ensures that only one vaporizer can be used at any time.
2. Electrical outlet for a desflurane vaporizer. Note that the electrical outlet only has power if the machine is operated on mains power.
3. USB port to be used for printable reports in PDF format.

DRAWERS WITH SOFT CLOSE

Soft close feature ensures that nothing gets caught or damaged, including the operator's fingers when closing the drawers.

PENDANT PREPARE*

Preparation of the machine for mounting on a pendant, incl. removal of the foot piece.

3.2 The rear of the machine

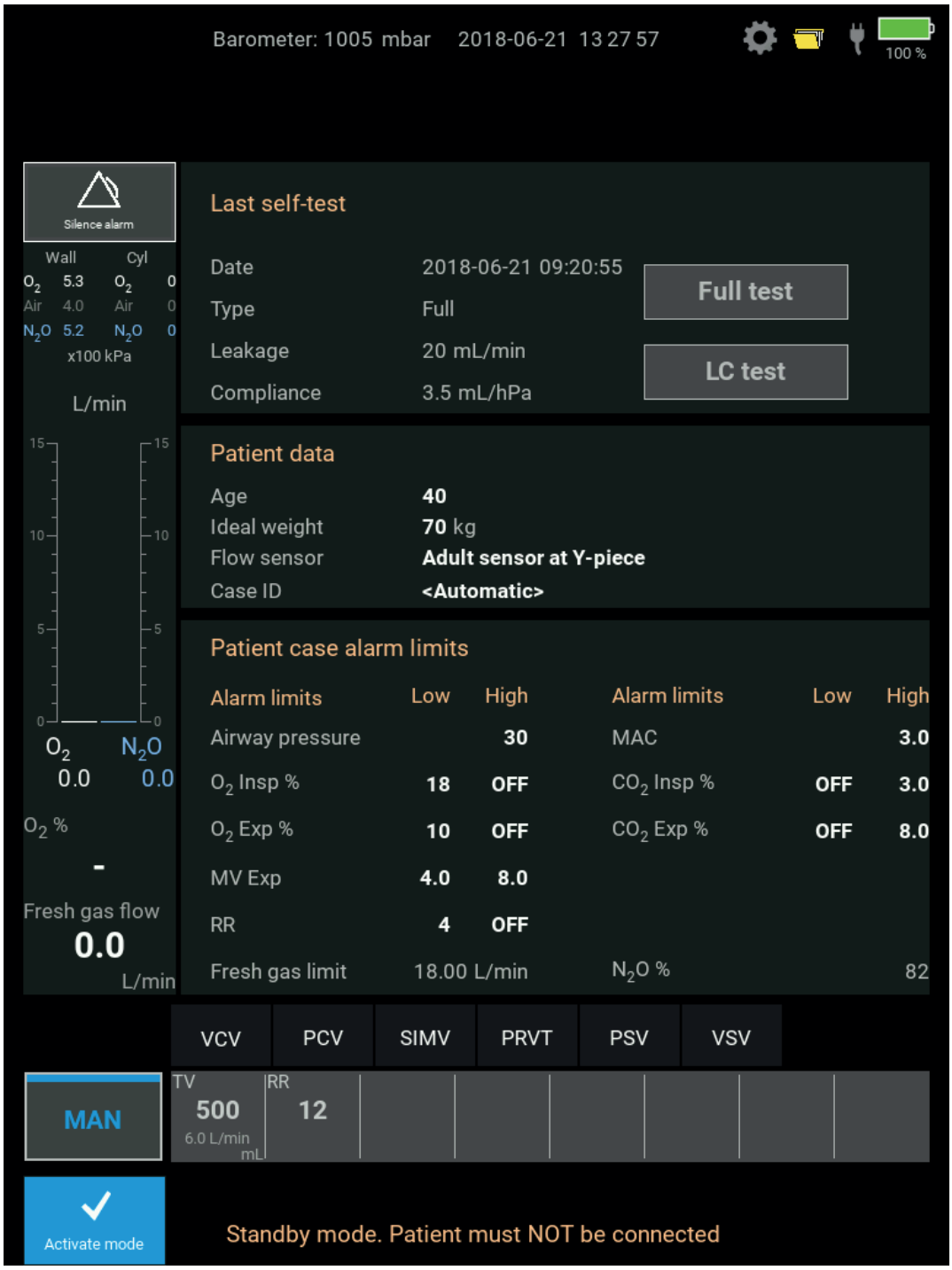
1. O_2, Air, N_2O inlets
2. AGSS outlet
3. Auxiliary O_2 outlet
4. Fan
5. D-Com port
6. Switch for auxiliary power outlets*
7. Auxiliary power outlets* and circuit breakers
8. Mains inlet switch
9. Equipotential grounding point
10. Yokes for reserve gas cylinders*
11. Auxiliary AGSS connection
12. VAC inlet*
13. Sample gas return
14. Connection for O_2 fuel-cell sensor
15. Hose support bracket
16. Patient suction ejector outlet*
17. Cylinder support bar*
18. IBS release handle

3.3 Screen layout

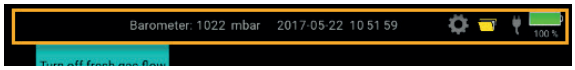
3.3.1 Preparation screen

The preparation screen displays when you turn on the machine, after you have run a self-test, and when you end a case

The screen is divided into sections for information and different types of preparation, as described in the following:



Top area

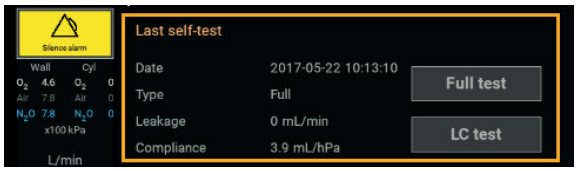


The top area of the screen shows the barometric pressure level, current date and time, power connection status, and battery charge level. It also provides access to change default settings, and to logged data for previous patient cases. For details about data and reporting, see “View data from previous patient cases” on page 53

Alarm area

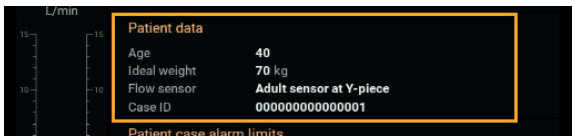
The top area of the screen can show patient alarms and technical alarms, for example, that the airway pressure is high. For details about changing default settings for alarms, see “Change default settings” on page 65.

Last Self-test



The values in this section are not editable but show details for the most recently performed self test of the machine. This information becomes part of the logged data for the patient case. For details about testing the machine as preparation for a procedure, see “Prepare the machine for use” on page 33.

Patient data

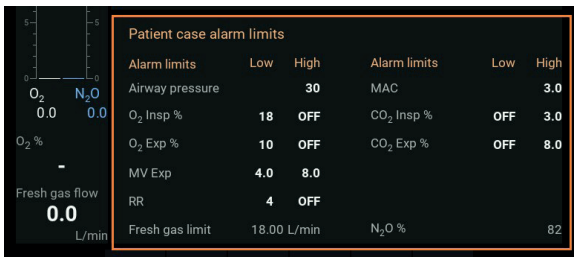


The values in this section relate to the next patient the machine will be used on.

Age and ideal weight are used to calculate ventilation settings. We recommend entering this information; the machine will use default values if no data is provided. For details about patient data, see “Prepare a patient case” on page 42.

Flow sensor indicates the type and placement of the patient flow sensor used. You should always provide this information. For details about flow sensor types and placement, see “Flow sensor” on page 29.

Patient case alarm limits



The values in this section relate to alarm limits for values measured by the machine during a procedure. The alarm limits are proposed settings based on the patient data entered (age and ideal weight). For details about setting alarm limits, see “Prepare a patient case” on page 42.

Ventilation modes

This section has a tab for each of the up to six automatic ventilation modes with the settings relevant for a mode displayed when the mode is selected. Use this section to prepare settings for a ventilation mode, or to start ventilation. For details about preparing a ventilation mode, see “Ventilation modes” on page 69. For details about settings during operation, see “Define ventilation settings” on page 44.

Message area

The message area (next to the Activate mode button) can show information about the self-test status.

Screen symbols


Stop watch


Patient case


Power cable

Pause

Resume

Activate mode


Confirm button


Repeat button


Settings


Open file

Battery status

End case


More alarms


Silence alarms


Cancel button

3.3.2 Active screen

The active screen has a clear separation of settings and measurements with settings to the left and measurements and corresponding alarm limits to the right.

The middle area of the screen is reserved for waveforms and loops.

Ventilation modes and settings are located in the lower area of the screen while the top area is dedicated to alarms.

The following sections describe each of the screen areas.

Settings left: Gas supply pressures and fresh gas flow

Gas supply pressures and fresh gas flow settings are displayed in the left side of the screen.

Gas supply pressures are shown both for wall connections and for cylinders, provided the cylinders are open.

The fresh gas flow is set using the mechanical knobs below the screen but the actual flow is displayed digitally by numeric values and with a visual indication in form of a column on a scale.

In addition to displaying the flow for each gas applied, the total fresh gas flow as well as the calculated oxygen concentration are also displayed.

NOTE

The O_2% shown below the flow columns is a calculated value for O_2% in the fresh gas flow, and may differ from the O_2% in the breathing circuit which can be measured by the integrated multigas module option or by an O_2 fuel-cell sensor at the inspiratory cone of the breathing circuit.

Measurements right: pressure, volume, gas

Measurements of pressure, volume and gas are positioned in the right side of the screen.

The measurements are readings to be monitored at intervals but they do not require any engagement.

Pressure related measurements are placed at the top followed by volume related measurements and then gas related measurements at the bottom. The gas measurement is the inspired oxygen percentage.

For measurements that have alarm limits defined, these alarm limits appear immediately to the right of each measurement, in smaller font size. The alarm limits can be adjusted directly on the screen.

Middle area: Waveforms and loops

The middle area of the screen is used to display a maximum of two waveforms and two loops.

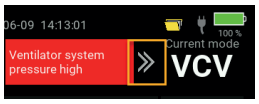
TOP AREA: ALARM MESSAGES

Alarm messages are displayed below the area with the stop watch, patient data and the current date and time.

Alarms are categorized by importance into high, medium and low priority alarms. Alarms can be system-related, for example loss of gas supply, or patient-related alarms, for example airway pressure high.

The alarm area can display three active alarms at the same time with the highest prioritized alarm in position number 1: an alarm is not ranked based on when it occurred but on importance.

An alarm can be temporarily silenced by selecting *Silence Alarm* below the alarm area.



If more than three alarms should occur, you can scroll through them by pressing the arrow to the right. The arrow appears only if there are currently more than three alarms.

Pressing one of the alarms opens a list of all alarms.

BOTTOM AREA: VENTILATION MODES AND SETTINGS

Ventilation modes and parametres are placed at the bottom of the screen.

The currently active mode is highlighted in blue in the ventilation mode tab and shown in the *Current mode* field at the top right of the screen.

When a ventilation mode tab is selected all associated settings are shown and can be changed, without affecting the active mode.

To change ventilation mode press the *Activate mode* field.

3.4 Ventilator settings inherited between modes

The machine can have up to six ventilation modes (VCV, PCV, SIMV, PRVT, PSV and VSV); for each mode settings like respiration rate and tidal volume or inspiratory pressure can be seen and changed before the mode is activated.

Initial ventilation settings are calculated based on the patient data that the user has entered: age and ideal body weight. Settings are automatically adjusted according to the Radford nomogram. If you do not enter patient data, the configured default settings are used. You can always modify ventilation parametre settings before activating a ventilation mode.

When switching from one mode to another the settings proposed for the new ventilation mode correspond to the settings of the active ventilation mode: settings are inherited between modes.

When a ventilation mode has been used for a period of time longer than one minute, the proposed settings for other ventilation modes will be based on the active mode. This means that the proposed settings will either be

directly inherited (for settings that apply to both the active and the new ventilation mode) or calculated (if a setting in the new ventilation mode does not exist in the active mode). The inheritance principle ensures that the proposed settings are clinically relevant and tolerable for the patient as they correspond to ventilation already being applied to the patient.

Again, you always have the option of changing the proposed settings prior to activating a new ventilation mode.

For details about how the inherited settings are calculated, see “Inherited settings” on page 91.

3.5 General operating principles

Confirmation required to change a setting

To change a setting, select the field by pressing it on the touch screen, change and confirm that you want to change. Any change needs to be confirmed; otherwise it will remain unchanged.

Ventilation settings for a new mode can be set without affecting the current mode

During a procedure you can select a different ventilation mode from the one currently used, and define settings for the new mode without affecting the current mode.

This enables you to prepare for a switch of ventilation modes.

The ventilation mode is not changed until you select *Activate mode*. For details about alarm handling, see “Ventilator settings” on page 69.

Using the control dial

Operation of the machine is highly dependent on the touch screen: settings are defined and confirmed through screen interaction as is change of ventilation mode.

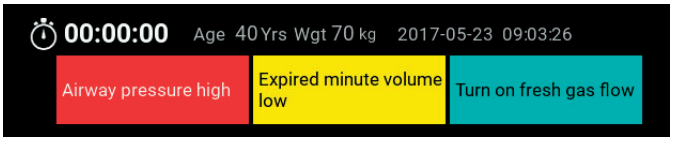
Note, that the control dial can be used to set values also. This is especially useful for values that have large ranges and if you want to change the value from one end of the scale to the other.

Alarms have text and sound

The anaesthesia machine has an alarm system for measured parametres as well as for machine functions; all alarms have text as well as sound.

Alarms can be silenced for 120 seconds by pressing the *Silence Alarm* field on the screen. When an alarm is silenced, the icon for silenced alarm appears on the *Silence Alarm* field along with the remaining time for the silencing. A few alarms related to machine performance cannot be silenced, though.

There are three different alarm priorities:



- High: red back ground, text in white, and the alarm has sound.
- Medium: yellow back ground, text in black, and the alarm has sound.
- Low: cyan back ground, text in black, and the alarm has a double beep tone.

Several alarms can exist at the same time. When you remove the alarm condition, for example by changing a setting, the alarm disappears.

For details about alarm handling, see “Handle alarms” on page 49.

3.6 Gas monitoring

Integrated multigas module

When equipped with an integrated multigas module, the machine analyses a sample flow from the Y-piece to measure inspired and expired concentrations of O_2, N_2O, $CO_2$and AA (anesthetic agent).

The sample flow is directed through a water trap and into the measurement chamber of the multigas module, where the absorption of up to 8 different wavelengths of infrared light is measured. The multigas module automatically detects and identifies the AA. The multigas module identifies any secondary AA in use and measures the actual concentration, too.

Once the multigas module analyses the sample flow, it is directed back into the breathing system's expiratory limb through an internal bacterial filter. The gas composition in the breathing system may be slightly impacted by the small amount of room air used during automatic zeroing of the multigas module. Automatic zeroing occurs approximately once every hour after the multigas module has reached operating temperature.

Two integrated multigas modules are available:

- Platinum, where Oxygen is measured by an integrated paramagnetic sensor
- Argentum, where Oxygen is measured by an exchangeable galvanic sensor (OXIMA™)

External fuel-cell sensor

If a multigas module is not installed, the inspired O_2 can be measured using an optional fuel-cell sensor placed onto the inspiratory port in the breathing system.

4 Set up the machine for first use

Below steps describe how to set up the anaesthesia machine for the first time or in case the machine has been moved from its usual location. These steps are not required for subsequent use of the machine.

WARNING
When using the ventilator, alternative patient ventilation equipment, like a manual resuscitator or self-inflating bag appropriate for the patient's age, must always be available.

Power

Plug the machine into the power outlet of the hospital installation and set the mains inlet switch on the rear to ON position. The mains inlet switch has a built-in circuit breaker and must therefore be pressed fully to stay in the ON position.

The machine must be connected to a properly grounded electrical outlet and must not be connected to an extension cord that is shared with other equipment.

Gas supply

Connect the machine to gas supply.

Anaesthesia gas scavenging system

1. Connect the anaesthesia gas scavenging system (AGSS/WAGD).
2. Verify that this is working by turning it on, either by using the AGSS ON/OFF switch on the top left side of the machine or by connecting to the hospital AGSS system. Make sure that the ball in the flow marker is visible. For details on possible leakages in the AGSS system, see "Anaesthesia gas scavenging system - AGSS" on page 108.

Patient hoses and flow sensor

Connect inspiratory and expiratory patient hoses to the cones marked with arrows on the breathing system, including the flow sensor and a bacterial filter at the Y-piece.

WARNING
Use only standard filters and hoses.

Flow sensor

Connect the flow sensor and a bacterial filter at the Y-piece.

Depending on what you want to measure, the flow sensor can be placed at the expiratory cone or at the Y-piece.

Flow sensor at the expiratory cone

Placing and configuring the flow sensor at the expiratory cone enables you to see expired tidal volume and minute volume.

Note! if the flow sensor is placed at the expiratory cone, PSV and VSV ventilation modes will not be available.

Flow sensor at the Y-piece

Placing the flow sensor at the Y-piece enables you to see inspired and expired tidal volume, pressure-volume and time-volume loop as well as time-flow waveform on the screen.

Note that to ensure correct measurements you must place a bacterial filter between the patient and the flow sensor.

Flow sensors

Different flow sensors are available for children and for adults.

- A paediatric flow sensor is used for patients with a tidal volume up to 300 mL (Insp./Exp. flow 2–35 L/min).
- An adult flow sensor is used for patients with a tidal volume between 200 and 1500 mL (Insp./Exp. flow 10–120 L/min).

NOTE
A bacterial filter must always be placed between the patient and the flow sensor.

Water trap

If the machine is equipped with a multigas module, the water trap must be mounted before use.

1. Make sure that the water trap is not filled with water. If the water trap is full of water, it must be emptied. The water contained in the water trap should be handled as hospital waste.
2. Attach it to the left side of the machine.
3. Attach a sample tube between the water trap and the Y-piece, for example, using a bacteria filter.

The sample tube hose should be 2–3 m long and have an interior diameter of at least 1.5 mm for adult patients and infants or 0.9 mm for neonatal patients, if a neonatal water trap is used.

Integrated O2 fuel-cell sensor

If the machine is equipped with a multigas module using an integrated O_2 fuel cell-sensor, the sensor must be installed before use.

1. Remove the exterior lid from the O_2 fuel-cell sensor holder.
2. Loosen the interior lid. This is fixed by a strap to the holder.
3. Insert the O_2 fuel-cell sensor and close the interior lid
4. Mount the exterior lid again

NOTE
If an integrated multigas module is installed, the module will not work for the first two minutes after powering up.

O_2 fuel-cell sensor

If the machine is not equipped with a multigas module, use an external O_2 fuel-cell sensor at the inspiratory cone.

1. Make sure that the T-piece connector is placed on the inspiratory cone of the integrated breathing system (IBS), connecting the cone and the patient hose.
2. Connect the O_2 fuel-cell sensor cord to the top of the sensor and the O_2 sensor connection on the rear of the machine.
3. Place the O_2 fuel-cell sensor in the T-piece connector. The O_2 fuel-cell sensor must always face upward.

NOTE
Use the Teledyne R-17MED Medical Oxygen Sensor for oxygen concentration measurement.

To preserve the life time we recommend that the O_2 fuel-cell sensor is removed from the T-piece connector and that the Y-piese is open to ambient air when the machine is not in use.

In the event that the fuel cell sensor has been contaminated it must be discarded, as it can not be disinfected.

RESPIRATION BAG

1. Connect the manual respiration bag to the bag connection on the IBS.
2. Set the APL valve to SP.

WARNING
Use only a standard respiration bag, sized appropriately for the patient. The bag must have a volume of 0.5 to 3 L for the self-test to function correctly.

ABSORBER

Mount the i-SORB absorber at the bottom of the IBS and lift up until the lock clicks into position.

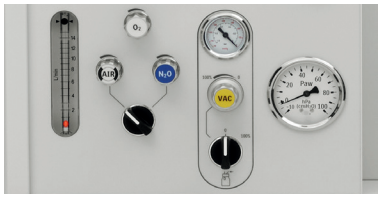


AUXILIARY FRESH GAS*

Ensure that the auxiliary fresh gas outlet is switched off.

SUCTION*

Verify that the suction is properly connected by turning on, and adjusting using the switch in the mid section of the front panel. To read the suction, block the suction tube.



VAPORIZER

Place and lock the vaporizer on the back-bar.

The machine has now been assembled and connected to the necessary hospital supplies and outlets.

NOTE
Use only anaesthetic agents for which the vaporizer is calibrated according to the Instructions for Use for the vaporizer.

NOTE
Before using the machine you must run the required tests to verify that the machine is working properly; see “Prepare the machine for use” on page 33 for instruction in preparing the machine at startup and between each patient.

NOTE
The machine has a large range of settings which have been set initially when the machine was produced. For information about these settings and how to change them, see “Change default settings” on page 65.

Connect patient monitor

To be able to display data from the machine on a patient monitor, connect a compatable patient monitor to the communication port on the rear of the machine, see “The rear of the machine” on page 20.

If the monitor comes with a multi gas module, attach a sample line between the Y-piece of the patient system and the gas module inlet. On the patient system end, the sample line can either be connected via the dedicated sample line port of the flow sensor (if this is mounted at the Y-piece) or alternatively to a sample line port of the bacterial filter placed at the Y-piece. This will ensure that the gas module can analyse the the inspired and expired gases and display the measured values on the monitor.

After analysis in the multigas module, exhausted gases can be handled as follows:

- The sample gas can be returned to the breathing system by connecting a sample line between the gas module sample gas outlet and the expiratory cone on the breathing system via a T-piece adapter or an additional bacterial filter with a sample port connector. In this case there will be no airway gas loss as the sample gas is re-used in the patient system. Scavenging will follow the normal process built into the machine.
- The sample gas can be returned to the scavenging system by connecting a sample line between the gas module sample gas outlet and the sample gas return connector at the back of the machine. The sample gas will be lost from the patient system and will not be re-used but it will not cause a hazard by polluting room air.

Use the appropriate option according to local hospital guidelines or government regulation.

5 Prepare the machine for use

This chapter describes the recommended procedures for preparing the machine for use with patients once the machine has been set up as described in the previous section.

The most comprehensive preparation procedure is the one to follow when turning on the machine for use on the first patient of the day. This procedure consists of a semi-automated, full test and a number of manual tests for the mechanical functions.

In between each patient a shorter procedure can be used. This procedure consists of changing or cleaning parts that have been in direct contact with the patient followed by a semi-automated Compliance and leakage test with fewer steps.

If the machine has been moved, for example to another operating room, or if gas supplies have been disconnected, we recommend that you perform a Full test.

No patient must be connected when turning on the machine nor during any of the automated and semi-automated tests.

WARNING
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

5.1 Prepare for the first patient of the day - Full test

FULL TEST

When you turn on the machine it will automatically check the alarms, prepare for the Full test and prompt you to perform the test. The test comprises a function test of the system, valves, gas mixer, compliance and leakage of the breathing system, including hoses.

NOTE
In case of an emergency you can bypass the test at any time by pressing the Cancel button. For details about emergency use, see "Emergency startup of the machine" on page 40.

The Full test runs automatically but does require some interaction: you must read the instructions on the screen, follow the instructions and press the Confirm button to confirm each step.

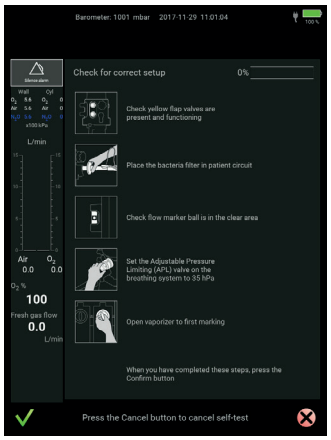
Depending on your familiarity with the process, the test takes approximately 3 minutes.

The Full test will lead you through a number of screens with detailed instructions for what you need to do. When possible, for example when you are asked to adjust a flow, you can verify your actions on the screen. As part of the test, the audible alarms are also verified.

A percentage at the top of each screen indicates how much of the test has currently been completed.

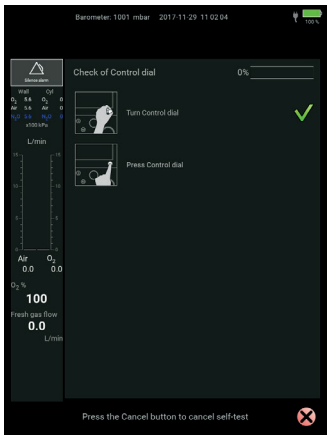
If you accidently cancel the self-test, you will be asked to confirm if you want to cancel the test. If you press No you will return to the test.

1. **Check for correct setup.** First sequence in the Full test prompts you to go through five steps to check for correct setup and continue by pressing the Confirm button.

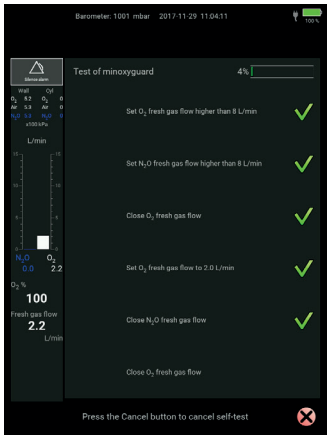


If the machine is equipped with an external gas monitor and no sample from this monitor is returned to the breathing system, the tube for sample flow must not be connected to the breathing system during the test. Otherwise, the leakage will be too high.

2. **Check of Control dial.** Second sequence will prompt you to turn and press the Control dial.

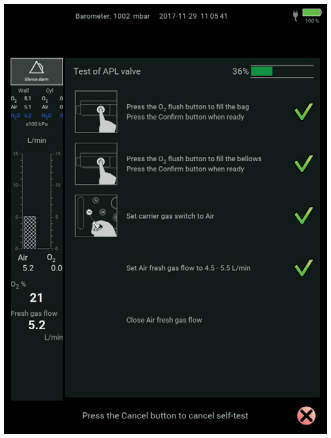


3. **Test of minoxygard**. During this test you will be asked to set and close the fresh gas flow accordingly. If the flow is not achieved a message will appear on the screen. Follow the instructions and repeat the test by pressing the Resume button.

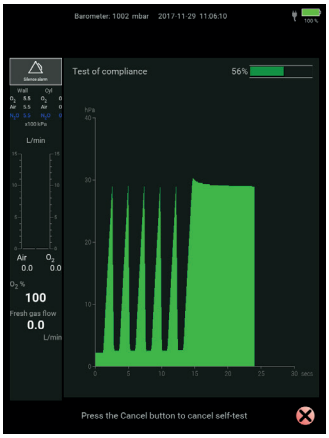


4. **Test of APL valve.** This sequence tests the APL valves. You will be asked to inflate the bag and bellows during the test. When inflating the bag, check Paw gauge to ensure the required pressure is reached.

   If the APL valve is set too low or the pressure in the bag has not reached approximately 35 hPa (cmH_2O), a message will appear on the screen. Follow the instructions and repeat the test.

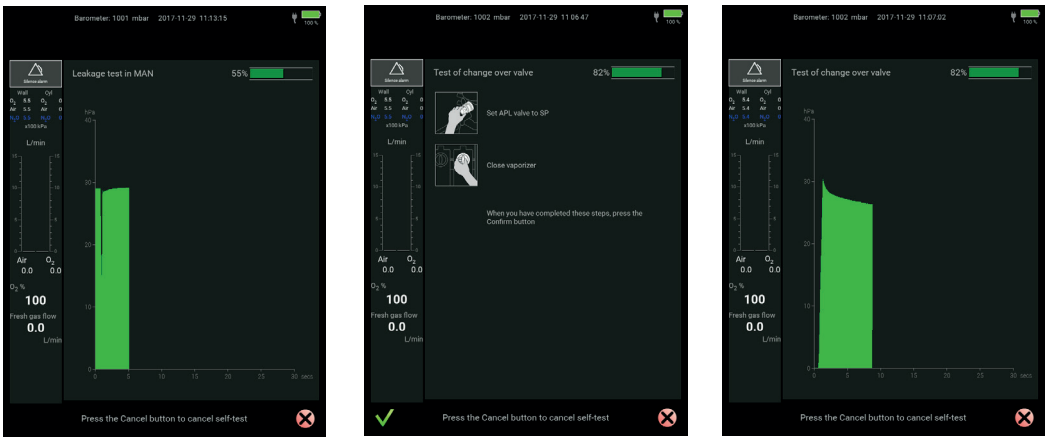


5. **Test of compliance**. The fifth sequence tests the compliance and leakage in the ventilator and patient breathing system. Once the pressure is achieved, a leakage check is performed based on the pressure drop over time. The leakage acceptance criteria is max 100 mL/min. If the leakage is between 100 mL/min and 1000 mL/min, the

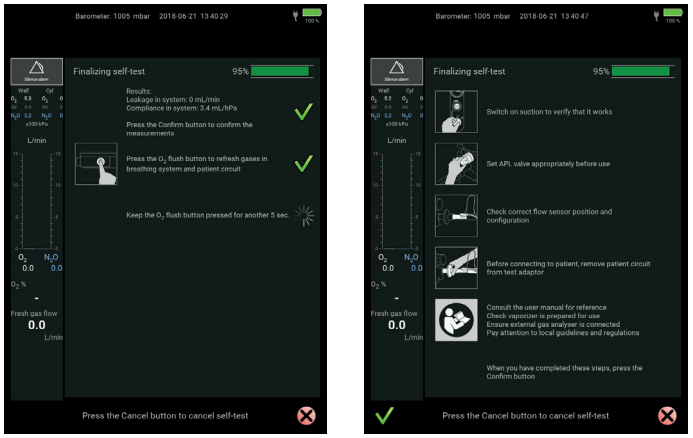


   user is prompted to accept or reject. If the leakage is greater than 1000 mL/min the test will fail. Follow the instruction on the screen and repeat the test.

6. **Leakage test in MAN.** This sequence performs a leakage test of the ventilation bag and patient circuit in MAN mode. Following the test, a leakage test of the system will be performed. Follow the directions on the screen.



7. **Finalizing self-test.** The next sequences will show the result of the leakage test, prompt you to refresh gases in the breathing system and patient circuit, check the alarm sound, and prepare the machine for the first patient.



When the Full test has completed successfully, the machine returns to the Preparation screen.

To complete the daily testing you should now manually verify that central components are in proper working order.

NOTE

If the machine has been running on battery power and the battery has become depleted, you will be prompted to set the date and time during startup.

COMPONENTS TESTING

The manual tests focus on verifying that core components work as expected including:

- O_2 sensor accuracy.
- Flow sensor measurements.
- Alarm on high airway pressure.
- Reserve gas cylinders sufficiently filled and in working order.
- Suction components are correctly assembled and work.
- Vaporizer is correctly attached and adequately filled.
- Auxiliary O_2 flow metre works.
- Switches for absorber, and breathing system work.

NOTE
A test lung is required for several of the tests.

Multigas module test

If the machine is equipped with a multigas module, the following test must be performed:

1. Activate MAN mode. The Y-piece must be open to ambient air.
2. Open the Air fresh gas flow to 10 L/min and wait until the displayed O_2% reading stabilises. Check that the reading shows 19–23% O_2. Close the Air fresh gas flow.
3. Open the O_2 fresh gas flow to 10 L/min and wait until the displayed O_2% reading stabilises. Check that the reading shows 97–103% O_2. Close the O_2 fresh gas flow.

O_2 fuel-cell sensor test

If the machine is not equipped with an integrated multigas module and has an external O_2 fuel-cell sensor, (see "O_2 fuel-cell sensor" on page 30) the following test must be performed:

1. Set status to MAN. The Y-piece must be open to ambient air.
2. Set the Air fresh gas flow to 10 L/min and wait until the displayed O_2% Insp reading stabilizes. Check that the reading shows 20–22% O_2. If not, recalibrate the O_2 fuel-cell sensor as described in "Calibrating the O_2 fuel-cell sensor" on page 63.
3. Set the O_2 fresh gas flow to 10 L/min and wait until the displayed O_2% Insp reading stabilizes. Check that the reading shows 98–102% O_2. If not, recalibrate the O_2 fuel-cell sensor.

External gas module test

1. Ensure the gas sample line is connected to the external gas module (see "Connect patient monitor" on page 32).
2. Verify the functionality of the external gas module according to the manufacturer's Instruction for Use that came with the gas module.

Ventilation on test lung

1. Attach a test lung to the Y-piece and start the ventilator in VCV mode.
2. After 5 breaths check that no alarms have occured.
3. If a flow sensor is installed; Read the measured tidal volumes and check they correspond with the set tidal volume, taking into account the accuracy of the measurement.
4. Check that the inspiratory and expiratory valves in the breathing system move during inspiration and expiration.
5. Set the *Airway pressure high* alarm limit to a value 5 hPa lower than the measured Peak pressure.
6. Check the alarm starts and the Peak pressure is limited to the alarm setting.
7. Set the alarm limit to the same value as before and check the alarm stops (after one breathing cycle).
8. Disconnect the mains power supply to the machine and check the *Mains power failure* alarm starts.
9. Check the machine continues to to ventilate, and that no other alarms occur.
10. Reconnect mains power supply and check the alarm stops.

O_2 alarm and N_2O cut off test

With N_2O connected

- Set the carrier gas to N_2O.
- Set the fresh gas flow to 1 L/min O_2 and 1 L/min N_2O.
- Disconnect the O_2 gas supply from the machine and wait until the O_2 flow bar graph on the screen drops to zero.
- Check that the alarm for *O_2 supply pressure is low* is triggered and that the N_2O flow bar graph on the screen drops to zero with the O_2 flow dropping to zero.
- Reconnect the O_2 supply to the machine and check that flows reappear and that the alarm stops.

Without N_2O connected

- Set the fresh gas flow to 1 L/min O_2.
- Disconnect the O_2 gas supply from the machine and wait until the O_2 flow bar graph on the screen drops to zero.
- Check that the alarm for *O_2 supply pressure is low* is triggered.
- Reconnect the O_2 supply to the machine and check that flow reappears and that the alarm stops.

Reserve gas cylinders test

If the machine is set up with reserve O_2, Air or N_2O cylinders, the following test must be performed:

1. Open the reserve gas cylinders.
2. Read the pressure in the reserve cylinders on the gauges on the front of the machine (the pressure in the cylinders must never go below 20 bar).
3. Close the reserve cylinders and reconnect the central gas supply to the machine.

Patient suction test

If the machine is equipped with patient suction, the following test must be performed:

1. Check that the suction components are correctly assembled and connected to the suction inlet on the left side of the anaesthesia machine.
2. Block the suction line. Turn the suction switch to the left “adjustable” position and check the suction level, from weak to strong, by turning the knob.
3. Turn the suction switch to the right “100%” and check that the suction vacuum is at least -0.60 bar.

Vaporizer test

If the machine is equipped with a vaporizer, the following test must be performed:

1. Check that the vaporizer or vaporizers are correctly attached to the machine.
2. For each vaporizer, check that the vaporizer knob can freely turn throughout the full regulation range and can be locked in the “0” position.
   If the machine has more than one vaporizer, check that when one is open the other is blocked and vice versa.
3 Check that the vaporizers are adequately filled.

Auxiliary O_2 test

If the machine is equipped with an auxiliary O_2 flow metre, the following test must be performed:

1. Open the flow metre regulator (counterclockwise).
2. Check that the flow rate can reach 12 L/min.
3. Close the flow metre regulator (clockwise) and check that the flow rate reduces to zero.

Internal switches test

1. Remove the CO_2 absorber, and check whether the following message appears after about 30 sec: *Absorber disconnected*.
   Remount the CO_2 absorber, and check that the message disappears.
2. Remove the patient system (unlock handle), and check that the following message appears: *Patient system disconnected*.
   Remount the patient system (lock the handle), and check that the message disappears.
3. If an auxiliary fresh gas outlet is installed, set it to ON and check that the following message appears on the screen: *Fresh gas delivered at auxiliary outlet*. Block the outlet with a finger and push the O_2 flush for two seconds to test the Maximum Pressure Limiting (MPL) valve's pop-of function.
   Set the switch to OFF and check that the message disappears.

When the above tests have been completed, you can proceed to set up the machine for the first patient of the day, see "Prepare a patient case" on page 42.

5.2 Prepare between each patient - LC test

Always follow departmental instructions with respect to cleaning and changing parts that have been in direct patient contact.

When parts have been cleaned or changed according to procedure, you should run the leakage and compliance test.

The leakage and compliance test is used to measure leakage and compliance when parts of the breathing system, for example hoses and respiration bag, have been changed.

LC test

The leakage and compliance test is a shortened version of the Full test see "Prepare for the first patient of the day - Full test" on page 34 for details on each sequence.

To start the leakage and compliance test press the LC test button on the Preparation screen.

The test runs automatically but does require some interaction and requires that you press the Confirm button when you have completed what each screen instructs you to do.

The following shows the LC test sequences:

1. Check for correct setup
2. Test of APL valve
3. Test of compliance
4. Leakage in MAN mode
5. Finalizing self-test

When the test has completed successfully, the machine returns to the preparation screen.

After the leakage and compliance test, the machine is ready for use with the next patient, see "Prepare a patient case" on page 42.

5.3 Using an external non-rebreathing system

You can choose not to use the machine's breathing system but instead use an external non-rebreathing system with the machine, for example a Mapleson system or a Bain system.

Assemble the non-rebreathing system following the manufacturer's Instructions for Use and connect the system to the auxiliary fresh gas outlet port on the machine. Turn the auxiliary fresh gas switch to ON.

The fresh gas flow, including anaesthetic agent, is now delivered through the auxiliary fresh gas outlet.

Airway gas monitoring can be displayed on the machine if the gas sample line is connected to the gas module or if an external O_2 fuel-cell sensor is connected to the inspiratory cone of the breathing system.

Minute volume (MV) and tidal volume (TV) monitoring are possible if the patient flow sensor is placed at the Y-piece of the non-rebreathing system.

The airway pressure monitoring of Dameca AX500 will not work with an external breathing circuit.

The excess fresh gas can be removed via the anaesthesia gas scavenging system (AGSS) in the machine: connect a gas scavenging hose to the non-rebreathing system and to the AGSS inlet port on the back of the machine. Remember to turn on the AGSS system.

Automatic ventilation is not possible while the auxiliary fresh gas outlet is activated.

NOTE
As there may be a risk associated with the use of a very high fresh gas delivered directly to the patient, we recommend only using a non- rebreathing systems with a reservoir bag and an adjustable pressure limiting valve.

Do not use the auxiliary fresh gas outlet to drive external ventilators or jet ventilation.

5.4 Emergency startup of the machine

NOTE
The procedure below should only be used in an emergency situation.

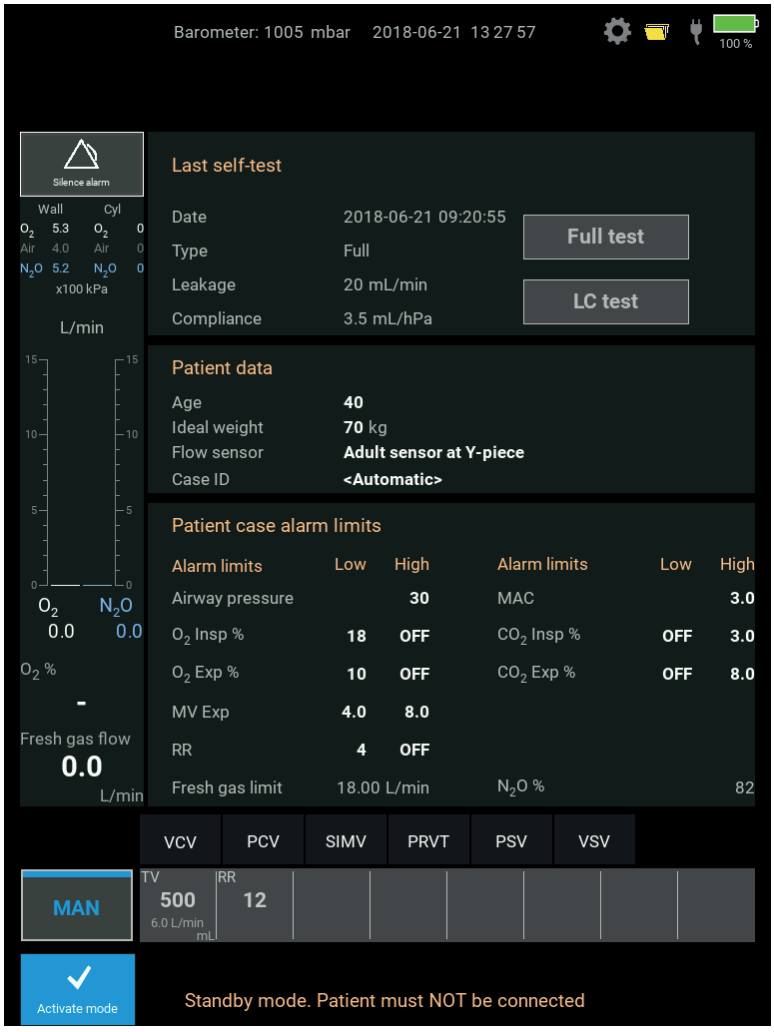
For normal use of the machine, always follow the preparation procedures described in the two previous sections. In case of an emergency, you can follow the minimal preparation procedure described in this section.

1. Verify that the machine is connected to gas supplies.
2. Ensure that the breathing system has been assembled and is connected, including all tubes, flow sensor, bacterial filter and O_2 fuel-cell sensor if the machine is not equipped with an integrated multigas module.
3. Activate O_2 and set the desired flow.
4. Adjust the fresh gas flow and read the total flow on the flow metre next to the flow regulators.
5. The machine is now ready for manual ventilation.
6. Turn on the machine by pressing the ON/OFF button.
7. When the machine is ready to run the self-test, press the Cancel button to cancel the self-test.
8. A text informing you that *Self-test has been bypassed* is displayed on the screen. Default patient data is used (age, weight, patient ID).
9. The machine is now ready for use.

6 Operate the machine

This chapter describes how to use the anaesthesia machine in a typical surgical procedure workflow like the following:

1. Patient data is entered, alarm limits and ventilation settings are defined, and the machine is put in manual mode.
2. The patient is frequently pre-oxygenated with an O_2% between 80-100 in a high fresh gas flow. The Adjustable Pressure Limiting (APL) valve is typically set to SP.
3. The patient is intubated and typically ventilated manually for a number of respirations before automatic ventilation is started with the preset values; fresh gas flow, oxygen level and ventilation parametres are adjusted and mode changed during the case if necessary.
4. Patient measurements are available on the screen, alarm text and sounds alert to any exceeded alarm limits.
5. The clinical user monitors measurements on the screen and responds to alarms that alert to exceeded limits.
6. Patient breathing is supported or the patient is ventilated manually to support the waking up phase.
7. The patient is extubated and on spontaneous respiration often supported with nasal O_2 supply.
8. Patient data is saved and the machine is reset for the next patient.



6.1 Prepare a patient case

When the full test or the leakage and compliance test has completed as described in the previous chapter, the machine returns to the Preparation screen where you type patient data, define type of flow sensor and where it is placed, and specify alarm limits.

6.1.1 Patient data

Patient data consists of the patent's age, ideal weight, flow sensor setting, and patient case ID

Patient's age and ideal weight

The machine uses the patient's age and ideal weight to calculate settings, for example respiration rate and tidal volume.

During a procedure, the age and ideal weight can only be changed while the machine is in *MAN* mode. To change settings press the value on the screen, select the new value and press the Confirm button.

We recommend that you always enter the patient's age and weight.

Flow sensor

Depending on what you want to measure, the flow sensor can be placed at the Y-piece or on the expiratory cone, for details see "Set up the machine for first use" on page 29. If you are physically moving the flow sensor from where it is normally placed, you need to select the new position by pressing *Flow sensor* in the *Patient data* field.

You also need to make sure that the flow sensor type selected, adult or paediatric, matches the actual flow sensor used and the patient undergoing procedure.

During a procedure, the flow sensor configuration can only be changed while the machine is in *MAN* mode. To change the configuration, press the flow sensor configuration displayed above the time-flow waveform, select the value and press the Confirm button to confirm the change.

Case ID

The *Case ID* is any numeric value of up to 15 digits. The value is used as part of the file name when data is logged and saved during the procedure. You can choose to type a numeric value, for example the patient file number, or have the machine automatically assign one. An automatically generated patient ID is based on the date (8 digits) and the time (6 digits).

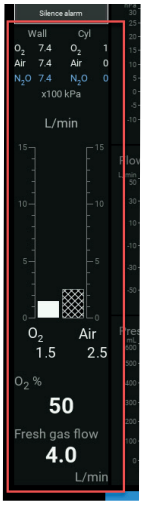
6.1.2 Patient case alarm limits

The alarm limits have default values. Review the values for the initial ventilation mode and adjust if necessary; you can change alarm limits at any time during a procedure as well.

Airway pressure high	The limit for patient airway pressure.
Insp O_2% low	The low limit for the inspired O_2 percentage.
Insp O_2% high	The high limit for the inspired O_2 percentage.
MV Exp low	The low limit for expired minute volume.
MV Exp high	The high limit for expired minute volume.
RR low	The low limit for measured respiration rate.
RR high	The high limit for measured respiration rate.
Fresh gas limit	The maximum limit of fresh gas for the specific ventilator settings. The value changes according to entered patient data. For details about alarm limits and ventilation settings, see “Ventilator settings” on page 69.

6.2 Adjust fresh gas flow

The fresh gas columns on the display show the flows as controlled by the mechanical knobs. The O_2% field shows the calculated O_2 concentration, based on the measured fresh gas flows.



NOTE
The O_2 concentration of the fresh gas is a calculated value.

The flow is controlled by the mechanical control knobs beneath the display.

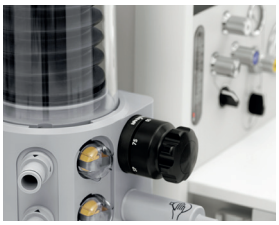
Control O_2 with the knob at the top.

Use the selector switch to select either Air or N_2O and then use the appropriate knob to control the gas.

To increase the flow, turn the control knob counter-clockwise.

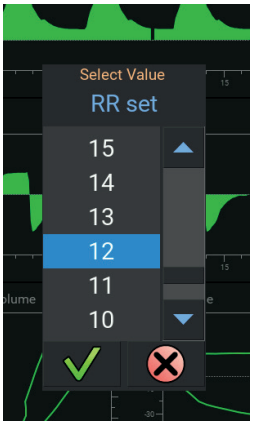
To decrease the flow, turn the control knob clockwise.

Adjustable Pressure Limiting (APL) valve



The APL valve is only active in *MAN* mode. Normally it is set between 5 and 20 hPa (cmH_2O). Press the respiration bag to ventilate manually.

6.3 Define ventilation settings



Ventilation settings can be defined from the Preparation screen and from the Active screen.

1. Select the ventilation mode you want to define settings for. On the Active screen the current mode is always indicated at the top right of the screen.
2. Select the setting you want to change and in the dialog box that opens, change the setting and then press the Confirm button. The setting can also be changed using the control dial and confirm the setting pressing the Control dial.

Only settings relevant for the selected ventilation mode are displayed; each setting has its own allowed range and the machine automatically ensures that you cannot define a setting outside this range.

For details about ventilator settings, see “Ventilator settings” on page 69.

NOTE
You are able to prepare the next ventilation mode and then activate it; you cannot prepare a sequence of modes.

6.4 Switch ventilation mode

Switch to a ventilation mode by selecting the mode and then selecting the *Activate mode* field at the bottom left of the screen.

On the Active screen the current mode is always indicated at the top right of the screen.

While using one ventilation mode, you can prepare settings for the ventilation mode you plan to use next by selecting the mode at the bottom of the screen and defining settings.

Ventilation mode will not change until you select *Activate mode*.

6.5 Adjust anaesthetic agent

The anaesthetic agent concentration can be adjusted on the vaporizer.

If an integrated multigas module is installed, the measured expired and inspired gas concentrations of the anaesthetic agent, O_2, N_2O, and CO_2 in the breathing system are shown in the display.

If an O_2 fuel-cell sensor is connected to the inspiratory cone, only the measured inspired O_2 is displayed on the screen.

WARNING
When using anaesthetic agents, the gas concentration should always be monitored on a separate gas monitor if the machine is not equipped with an integrated multigas module .

6.6 Use the stop watch

Use the stop watch to track time during a procedure.

1. Press the stop watch field to start the time. The colour of the HH:MM:SS changes from white to green to indicate that the watch has started counting.
2. Press the stop watch field to stop the watch again. The colour changes to white.
3. Press the stop watch field twice to reset the stop watch. The stop watch cannot be reset unless it has been stopped.

6.7 O_2 flush

The O_2 flush button located left on the table top provides a rapid supply of oxygen.

CAUTION
You should use caution when activating the O_2 flush with an intubated patient connected, as it may cause a significant increase of the airway pressure.

6.8 Use suction

1. Turn the suction switch left to make vacuum adjustable from minimum to maximum.
2. Use the VAC control knob to adjust vacuum. The current flow displays on the flow above the flow control knob.

If you need suction urgently, turn the suction switch right to 100%. In this state the vacuum is at maximum and the control knob cannot be used.

6.9 Stop automatic ventilation

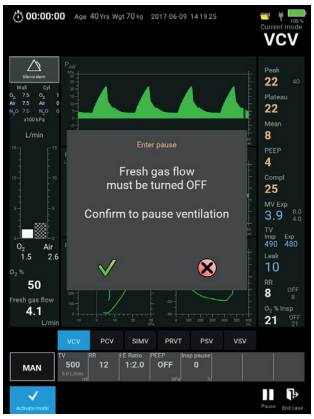
Either go to *MAN* ventilation, *Pause* or *End case*.

6.10 MAN ventilation

1. Press the *MAN* field and then press the *Activate mode* field to confirm that you want to ventilate manually.
2. Adjust the APL valve; normally it is set to between 5 and 20 hPa (cmH_2O). When the APL valve exceed 20 hPa (cmH2O) the user will feel the built-in “click” function as the setting increases.
3. Press the respiration bag to ventilate manually.

WARNING
If the APL valve is set above 35 hPa (cmH_2O) special attention must be paid in order to prevent high airway pressure. The *Airway Pressure High* alarm is not active during manual ventilation.

6.11 Pause ventilation



Use the pause function to temporarily stop the ventilation of the patient.

1. Select the *Pause* field at the bottom right of the screen.
2. In the dialog box that opens, press the Confirm button to confirm that you want to pause ventilation.

When *Pause* is activated the following happens:

- Any automatic ventilation is stopped.
- A message is displayed asking you to *Turn off the fresh gas flow*.
- All alarms related to lack of ventilation *RR low* and *Apnea more than 60 sec* are disabled.
- The text *Current mode* above the current ventilation mode field is replaced with *Paused mode* and the paused ventilation mode flashes.

To stop the *Pause* mode and resume ventilation, press the *Resume* button at the bottom of the screen. You will be asked to turn on the fresh gas flow again. Press the Confirm button to leave *Pause* mode. The ventilation will automatically start with the same settings as prior to activating the *Pause* mode.

6.12 Using waveforms and loops

Provided the flow sensor is placed at the Y-piece, you have two waveforms and two loops available; if the flow sensor is placed on the expiratory cone, only the airway pressure waveform is available.

The waveforms and loops are windows showing the last 10, 20, 30 or 60 seconds, depending on the selected time scale.

Use the graphics as a help to optimize ventilation and maximize patient comfort.

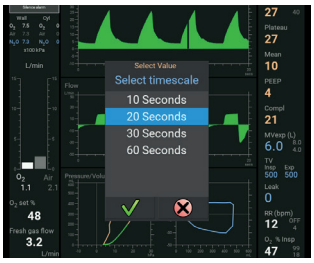
Waveforms

The (P_{AW}) airway pressure waveform shows pressure on the patient's airway against time; time is the X-axis.

The *Flow* waveform shows the patient's inspired flow (upward) and expired flow (downward) against time; time is the X-axis.

The CO_2 waveform shows the inspired and expired CO_2 concentrations.

To change the time scale

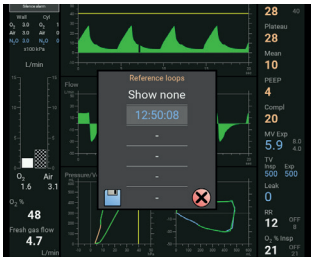


- Press the waveform area and in the dialog box, select a different interval and then confirm.

Loops

The loops have pressure and volume on the X-axis and volume and flow on the Y-axis.

To save a loop



- Press the loop area and in the dialog box, press the save-icon.

You can save up to five loops; the machine saves in time sequence and automatically overwrites the oldest of the saved loops.

To see a previous loop overlayed

- Press the loop area and in the dialog box, select one of the saved loops and press the Cancel button to confirm.

The saved loop is now shown on the screen in a different colour from the current one, which is always green. The purpose of placing two pressure-volume loops on top of each other is to compare the patient's current state with the previous state.

- To remove a loop overlay, press the loop area, press *Show none* and press the Cancel button to confirm.

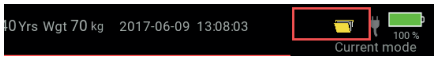
6.13 View patient case data

Typically you will read data to be recorded in the anaesthesia journal directly on the screen but if the situation does not allow making notes in the journal immediately, patient case data is available from start to end.

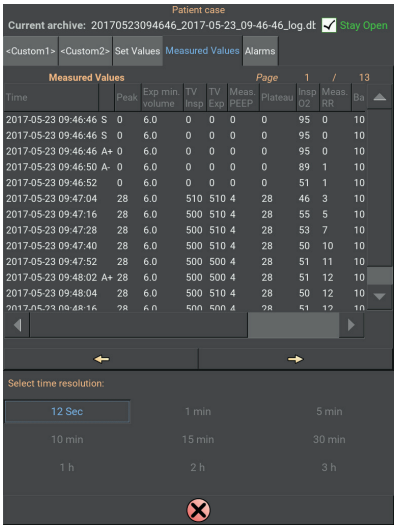
Patient case data comprises:

- Set values.
- Measured values.
- Alarms.

1. To view patient case data, press the Patient case icon at the top right of the screen or press the alarm area.



2. View e.g. the measured values by pressing the *Measured Values* tab.



Use the *Select time resolution* buttons to change the intervals with which values are displayed; the highest resolution is 12 seconds and the lowest is 3 hours.

The trend data window automatically closes when an alarm comes in or after 20 seconds. If you do not want the window to close automatically after 20 seconds, mark the *Stay Open* at the top right of the screen; the trend data window will still close if an alarm comes in.

For details on reporting on logged data, see "View or print logged data" on page 53.

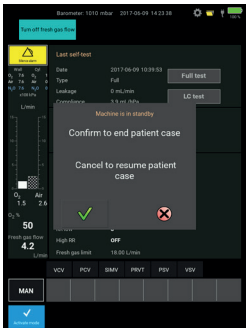
6.14 End a patient case

To end a patient case, select *End case* at the bottom right on the screen. In the dialog box that opens you are asked if you want to end the patient case.

Cancel to resume patient case

Press the Cancel button and the machine will return to Active screen and resume settings and ventilation mode.

Confirm to end the patient case



If you press the Confirm button, the machine suspends ventilation and enters stand-by mode.

A new dialog box opens and prompts you to confirm to end patient case or cancel to resume the patient case.

NOTE
The machine can be left in this mode in the event that the patient condition deteriorates and ventilation should be restarted.

End patient case

Pressing the Confirm button, will end the patient case. The patient file with all alarms and values that have been set and measured during the procedure are saved to the database. The machine returns to the Preparation screen and default settings, ready for the next patient.

Cancel patient case

Pressing the Cancel button, the machine returns to Active screen in *MAN* mode with unchanged settings and alarm limits.

NOTE
When you no longer use the machine ventilating a patient, remember to close the fresh gas flows to avoid excess use of gases.

6.15 Emergency ventilation during a patient case

Should the unlikely event occur that the machine fails and the screen does not respond, manual ventilation is always available; you can use an emergency shutdown feature to force the machine into emergency mode and you can continue any ongoing procedure with manual ventilation.

Emergency shutdown

NOTE
This is not a normal use scenario but a safety feature.

1. Press and hold the ON/OFF button on the front for 7-8 seconds. While holding the button pressed in, the machine will shut down and a high priority alarm sound may start and stop again. For a description of alarm sounds, see “Handle alarms” on page 49.
2. Adjust the fresh gas flow to the appropriate setting for manual ventilation, including the vaporizer if you are using an anaestetic agent.
3. Adjust the APL valve to the appropriate setting.
4. Ventilate the patient manually using the ventilation bag.
5. Monitor the airway pressure at the airway pressure gauge at the machine front.
6. By pressing the ON/OFF button, the machine will startup directly in the Active screen, in *MAN* mode with the same patient data and settings as before.

7 Handle alarms

An alarm message indicates that a measured value related to the patient or related to the system is above or below a defined limit.

Examples of patient-related alarms are: *Expired minute volume high and Resp rate low*; examples of system-related alarms are: *Mains power failure and System pressure failure*.

Alarm messages display at the top of the screen, below the area with the stop watch, patient data, and current date.

An alarm will remain on the screen for as long as the alarm condition is present and the information relevant.

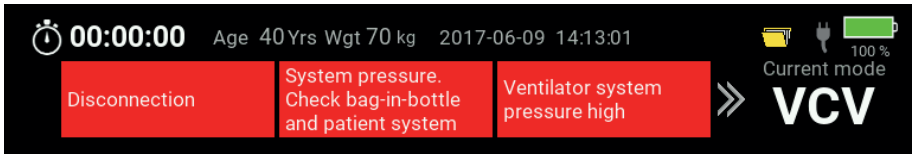
Alarms are categorized by importance into high, medium and low priority alarms with different background colour and audio for each priority.

	dBA	Background colour	Audio pattern
High priority	70,3	Red background with white text.	B_B_B___B_B ... B_B_B___B_B which repeats. B is beep _ is pause between beeps within a beep train ... is pause between beep trains
Medium priority	68,1	Yellow background with black text.	B_B_B which repeats. B is beep _ is pause between beeps within a beep train
Low priority	61,1	Cyan background with black text.	B_B which does not repeat.

See alarms

The alarm area can display three active alarms at the same time with the highest prioritized alarm in position number 1: an alarm is not ranked based on when it occurred but on priority.

If more than three alarms occur, you can scroll through them by pressing an arrow that displays to the right. The arrow appears only if there are more than three concurrent alarms. To see a list of all alarms, press one of the alarms.



Silence alarm

To silence an alarm for 120 seconds, press *Silence alarm* below the alarm area.

When an alarm is silenced, the icon for silenced alarm appears with the remaining time for the silencing.

Alarms that are critical for patient safety cannot be silenced, for example system alarms related to the ventilator.

If multiple alarms exist when you press *Silence alarm*, all active alarms will be silenced for 120 seconds. If a new high priority alarm occurs, the alarm sound will automatically turn on.

To cancel the silenced alarms timer and re-activate the alarms, press *Silence alarm* again.

Remove alarm

An alarm message is removed by remedying the cause of the alarm.

The proper corrective action depends on the cause of the alarm. Checking patient status is typically the first corrective action; secondary actions might include raising or lowering alarm limits on the screen, checking ventilation settings and verifying that the fresh gas flow is suitable.

For a list of alarms along with the cause for each alarm and suggested corrective action, see “Alarms: cause and action” on page 95.

Change alarm limit

For measurements that have adjustable alarm limits defined, these alarm limits appear immediately to the right of each measurement, in smaller font size.

The alarm limits can be adjusted directly on the screen by pressing the alarm limit.

Alarm limits should always be set according to the patient’s needs and not to extreme values.

Alarm log

Along with values that are set and measured during a patient case, alarms for the past 50 patient cases are saved in log files. Log files remain intact in the event of unplanned power outage or machine restart.

For details about logging intervals, logging conditions and reports, see “View or print logged data” on page 53.

8 Fail-safe features

This chapter gives an overview of the built-in safety features which have been designed to prevent or mitigate an unexpected system failure.

Emergency startup	In case of an emergency situation, you can always ventilate manually with a fresh gas flow and delivery of an anaesthetic agent. See “Emergency startup of the machine” on page 40.
Emergency shutdown	In the unlikely event that the machine fails and the screen does not respond, manual ventilation is always still available; you can use an emergency shutdown feature to force the machine into manual ventilation and you can continue any ongoing procedure with manual ventilation. See “Emergency ventilation during a patient case” on page 48
Primary drive gas	In the event that the primary drive gas fails, a drive gas valve will automatically switch to the secondary drive gas, *Air* or O_2. See “Safety features” on page 15
Airway pressure	In the event that the patient airway pressure is too high, the ventilator automatically switches to expiration phase to prevent exposing the patient to excessive airway pressure. This happens when the *Airway pressure high* alarm is triggered.
Use of Control dial	In case of a screen failure, the Control dial can be used to change ventilation modes or values and to activate manual ventilation.
Running on battery	In the event of power failure during a procedure, the built-in battery will ensure that the machine runs uninterrupted for at least 90 minutes. There is no difference in performance when the machine is battery powered.
Change over valve	When automatic ventilation is activated, the ventilator applies pressure to the change-over valve, thereby activating the A-valve in the IBS. This bypasses manual ventilation of the patient during automatic ventilation. In the event that a serious system error occur, the pressure to the change-over valve will be removed, thereby forcing the system into manual ventilation.

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9 View or print logged data

This chapter describes how to view the logged data, how to generate a printable report based on this data and how to create custom reports.

During a procedure the following data is logged and saved in a patient case file:

- Self-test data
- Set values
- Measured values
- Patient and system alarms

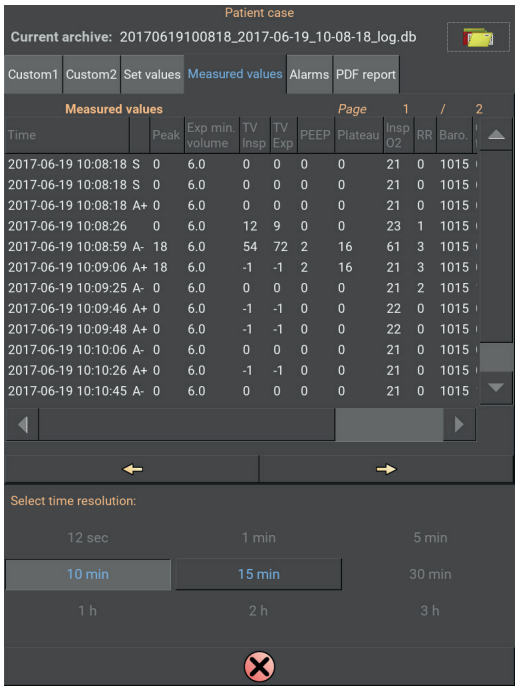
All data is logged with intervals of 12 seconds. In addition, events are logged when they occur: when a value is set, when an alarm occurs, and when an alarm disappears.

Up to 50 patient cases are saved; the oldest file is automatically overwritten.

9.1 View data from previous patient cases

1. On the preparation screen, press the Patient case icon. 
2. Press the Open file icon at the top right, select the relevant patient case and press *Open*.

   File name consists of patient ID; the patient ID is either one that you typed when you started the case or one that the machine has generated, plus date and time.



3. On the Patient case page, select the relevant tab to view the data you want.

   The two tabs to the left are custom reports that have been created to extract and present the data the department or hospital needs. For details, see “Define a custom report” on page 55.

   The three tabs *Set values*, *Measured values* and *Alarms* are built-in standard reports that you can view on the screen while PDF report is where you choose which report to save to a PDF file.

   The area below the tabs displays data for each of the selected values above.

   The column following the *Time* column in each of the reports can be blank or have the values *S*, *A+* or *A-*.

S	Indicates a value which has been set manually during the procedure.
A+	Indicates that an alarm started.
A-	Indicates that an alarm ended.
<empty>	Indicates that this is a measured value, sampled every 12 seconds.

   These events are logged in addition to the data logging every 12 seconds.

4. Select the *Select time resolution* tab to define the time resolution you want for the presentation of the data . The filter choice you make will be saved as a preference until you choose a different resolution.

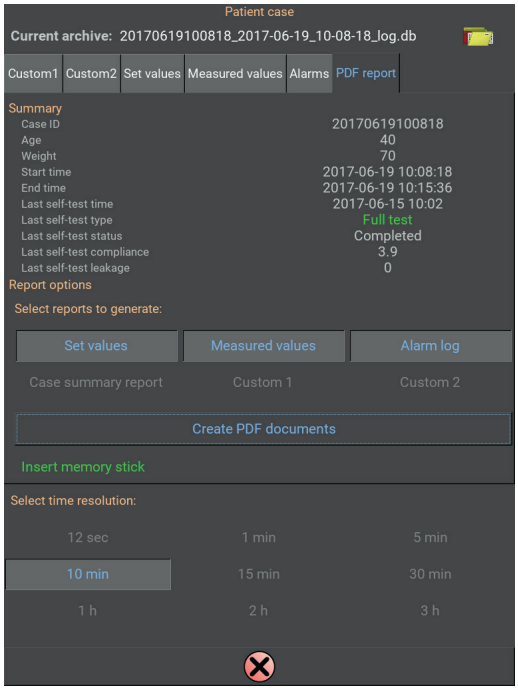
9.2 Create a printable report on a patient case

PDF reports on a specific patient case can be stored on a USB memory stick. A PDF report can only be created if a USB memory stick is in the USB port.

WARNING
Do not use the USB port with a patient connected to the machine

Create a report

1. Place the USB memory stick in the USB port on the front of the machine.
1. On the Preparation screen, press the Patient case icon.
2. Press the Open file icon, select the relevant patient case and press *Open*.
3. On the Patient case page, press the *PDF report* tab.
4. Select one or more types of data for the PDF report in the *Select reports to generate* area. One file is generated for each type of data.
5. Press *Create PDF documents* to create the report.
6. When the report has been created and saved on the USB memory stick, a message will appear *Data and reports transfered. Remove memory stick*.



View and print a report

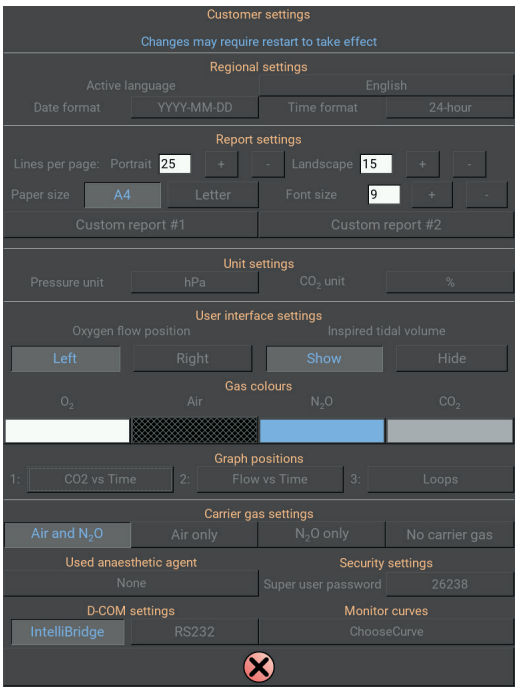
1. To view or print the reports, place the memory stick in the USB port on a computer that has access to a printer.
2. Open and print each file.
3. When you print the file you can choose to print in portrait or landscape format, using the number of print lines defined for the report.

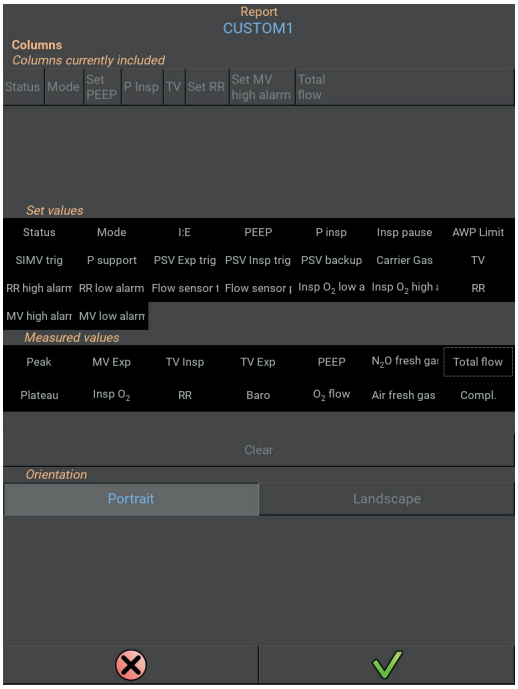
9.3 Define a custom report

Content for the two custom reports is defined from settings and requires that you are a super user.

1. On the Preparation screen, press the Settings icon at the top right.
2. Press the Login icon and enter the Super User code to login.
3. On the *Settings and Tools* page, press *Settings* and then *Customer settings*.
4. In the *Report settings* area, press *Custom Report #1* or *Custom Report #2* depending on which report you want to edit or create.
5. On the *Report* page, select the values from the *Set values* and *Measured values* fields you want to include in the report. Columns are added to the *Columns currently included* field in the order they are selected. If you want to delete values from the field, press the *Clear* button.
6. Select orientation from the *Orientation* field.
7. Press Confirm to save the report. To return to the Preparation screen, press Cancel on the following pages.

When the report has been saved, it is available on the Patient case page and can be used on any of the logged data.





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10 Cleaning and maintenance

This chapter describes cleaning procedures for the anaesthesia machine, procedures for replacing consumables, as well as calibrating the O_2 fuel-cell sensor.

Preventive maintenance must be performed on the machine at least once a year by an authorized technician. Daily maintenance carried out by the user is limited to function control and cleaning.

For all parts, in particular parts which may come into direct contact with the patient, carefully follow the manufacturer's cleaning instructions.

For disposal of any component, follow local hospital guidelines or government regulation.

10.1 Cleaning the surface

This cleaning procedure should be followed between patients.

1. Wipe the machine's outer surface with a cloth moistened with a mild detergent or isopropyl alcohol. Avoid abrasive or caustic cleaners as they can damage the machine. Avoid organic liquids, such as acetone, turpentine and thinners.
2. Dry the machine with a clean, dry cloth.
3. Replace filters and tubings that have been in direct contact with the patient.

10.2 Cleaning the integrated breathing system (IBS)

Cleaning procedures and intervals should follow local hospital guidelines or government regulation.

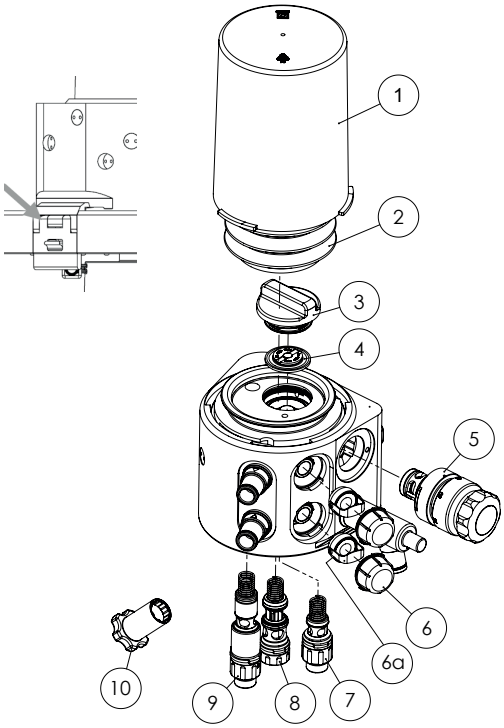
The breathing system consists of 13 individual components which can all be washed in a washing machine, autoclaved, and tolerate chemical disinfectants.

10.2.1 Disassemble the breathing system

To prepare for washing or chemically disinfecting the breathing system, disassemble the system as follows:

1. Release the IBS body from the IBS base by pressing the red button on the handle upwards.
2. Remove the IBS body and place it on a stable surface.
3. Remove the chamber (1) and bellows (2).
4. Remove the cap (3) and spill valve membrane (4).
5. Remove the APL valve (5) by pressing the release button on the right side of the base while simultaneously pulling the valve outward.
6. Remove the valve domes (6) and then the Insp/Exp yellow valves (6a) by pulling their bracket.
7. Remove the absorber valves: the inspiratory check valve (7) is labeled C and the expiratory check valve (9) is labeled B.
8. Remove the changeover valve (8) marked A, by using the special tool that was supplied with the machine(10).

The breathing system can now be washed or disinfected.



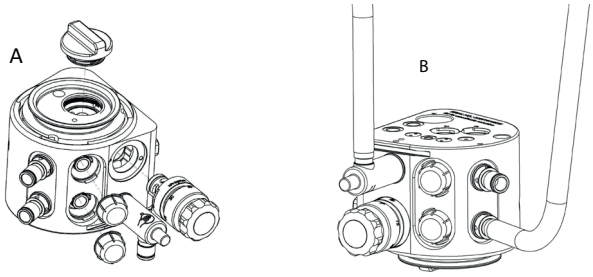
10.2.2 Wash the breathing system in a washing machine

Only use a washing machine constructed to clean instruments and anaesthesia equipment. The washing cycle and detergent must be appropriate for cleaning plastic and rubber goods. The cleaning procedure must conclude with a clean water rinse, heat disinfection, and drying. The bellows must be hung or otherwise kept open.

NOTE
The detergent should have a pH final dissolution of 7 to 10.

FLUSH THE CHANNELS IN THE BREATHING SYSTEM BODY

1. Put the cap, valve domes and APL valve onto the IBS body. See figure A.
2. Place the IBS body upside down and attach the washing hoses to the inspiratory cone and the respiration bag cone. See figure B.



3. Put all the components to be washed into the washing machine.

After washing, remove the caps, valve domes and the APL valve before drying.

10.2.3 Chemically disinfect the breathing system

For all chemical disinfectants, carefully follow the manufacturer's instructions. The disinfectant must be suitable for the component being disinfected.

- Immerse the components in a 3.4% gluteraldehyde solution for 20 minutes.

Following disinfection, all components must be thoroughly rinsed in sterile water and dried.

10.2.4 Autoclaving the breathing system

After washing, all components can be autoclaved at up to 134 °C for a maximum of seven minutes. This may only be done a limited number of times (approximately 100 times).

After autoclaving, all the components must be placed at room temperature for approximately eight hours before assembling.

10.2.5 After cleaning procedure

After washing and autoclaving or chemically disinfecting the breathing system components:

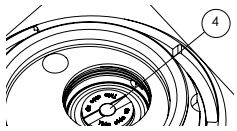
- Inspect the bellows, spill valves and check valves, and replace as required.
- Check that all components are thoroughly dry and undamaged.
- Apply a thin film of special lubricant to the O-rings.

10.2.6 Assemble the breathing system

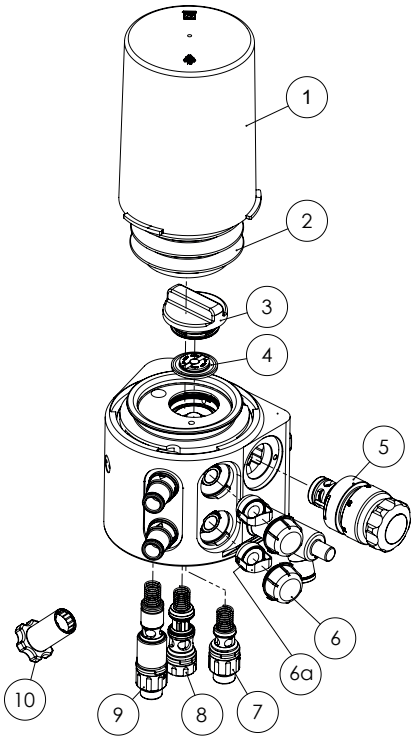
1. Mount the inspiratory and expiratory valves (6a) with the groove in the valve body fitting over the pin in the breathing system body.

   Ensure that the valves are fully inserted by pushing on the valve bracket. Do not touch the valve flaps with your fingers. Inspect the valve flaps for visible damage. If a valve flap is damaged, the whole valve must be replaced.

2. Mount the valve domes (6).
3. Mount the changeover valve (8) marked A, by using the special tool (10).
4. Mount the absorber valves (7) and (9) (marked B and C).
5. Mount the APL valve (5). Push the valve in until the lock clicks.
6. Fit the spill valve membrane (4) into the housing with the metal disc upward (4) and securely place the cap (3) on top.
7. When mounting the cap, slowly turn it counterclockwise until reaching the start of the thread, and then turn it clockwise to engage. Do not over tighten.



8. Mount the bellows (2).
9. Mount the chamber (1).



10.3 Cleaning hoses, Y-piece and respiration bag

Cleaning procedures and intervals should follow local hospital guidelines or government regulation.

Clean, disinfect, and dry hoses, Y-piece, and manual respiration bag in accordance with normal hospital procedures.

10.4 Cleaning and refilling the reusable CO_2 absorber

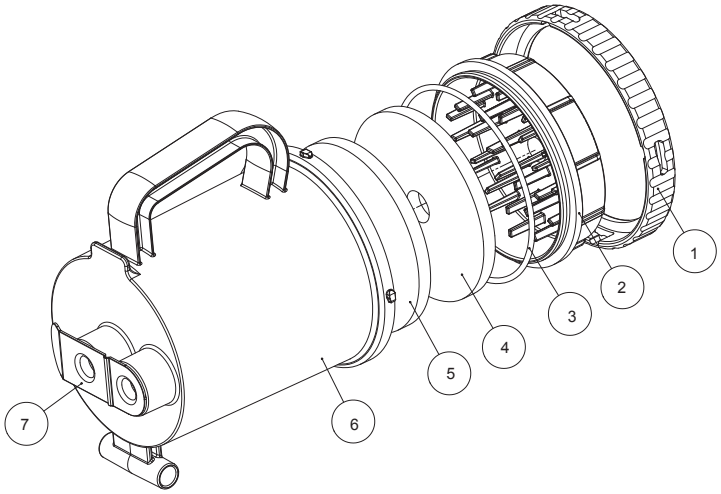
If the machine has a reusable absorber, this item needs to be emptied, cleaned and refilled when the soda lime colour indicates exhaustion, or if the inspired CO_2 level exceeds a defined limit. See the manufacturer's Instructions for Use.

10.4.1 Emptying and cleaning the absorber

For safety reasons the person handling the filling and emptying of the absorber should wear suitable eye, face and hand protection.

1. Unscrew the locking ring (1) and separate the absorber lid (2) and the filter (4). Discard the filter.
2. Discard the absorbent according to departmental safety procedures.
3. Discard the second filter (5).

4. Remove the O-ring (3) from the absorber lid.
5. Clean and disinfect the absorber following the procedures described for the breathing system in chapters “Wash the breathing system in a washing machine” on page 58”Wash the breathing system in a washing machine” on page 58 and in “Chemically disinfect the breathing system” on page 58.



NOTE
The reusable absorber can not be autoclaved.

10.4.2 Refilling the CO_2 absorber

The reusable absorber should be filled with absorbent from a Soda Lime Carbon Dioxide Absorbent manufacturer, the following absorbents can be used: Sofnolime, Medisorb, Prosorb, Soda lime, LimePak, Agasorb, Sefasorb, CarboLime, Chemosorb, Vitalime, and VentiSorb.

The i-SORB reusable absorber has been tested with Sofnolime® Carbon Dioxide Absorbent.

Before filling and using an absorber for the first time, it should be cleaned as described in the previous section.

For safety reasons, the person handling the refilling of the absorber should wear suitable eye, face and hand protection. Always follow the Instructions for Use provided by the manufacturer of the absorbent.

Check that the absorber is undamaged and intact before use.

Open the container by unscrewing the locking ring (1) on the bottom of the container.

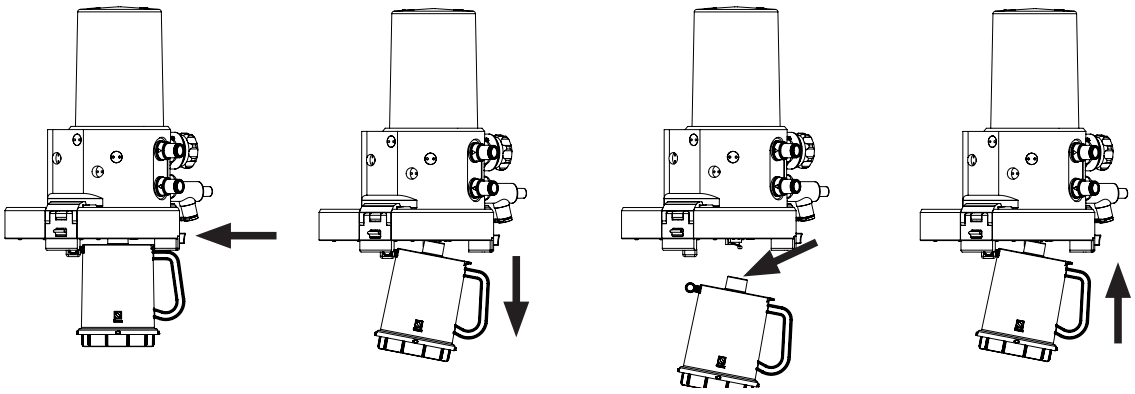
1. Remove the absorber lid (2), and filters (4, 5).
2. Place one of the filters (4 or 5) in the top of the absorber chamber.
3. Gently pour in about one third of the absorbent granules to the absorber chamber. Tap the sides to settle the granules and repeat for the next third, then again for the final third until the chamber is full and there is room for the second absorber filter.
4. Place the second absorber filter (4 or 5) on top of the granules. Remove any residual granules or dust from the sealing area.
5. Place the absorber lid (2) and tighten it with the locking ring (1).
6. If it is a new absorber - remove the absorber seal (7) before mounting.
7. Clean the surfaces of the absorber to ensure residual granules or dust are removed.

The i-SORB reusable absorber is now ready to be mounted on the breathing system. The absorber should always be tested before use.

10.5 Replacing consumables

10.5.1 Replacing the disposable CO_2 absorber

When the soda lime colour indicates that no more CO_2 can be absorbed, or when the inspired CO_2% measurement indicates this, the disposable absorber must be replaced.



1. Press the button above the handle to release the absorber.
   The two absorber valves close to prevent loss of gas while replacing the absorber.
2. Remove the used absorber by using the handle, and lift the absorber of, the bracket.
3. Remove the protection seal from the new absorber and place it in the bracket.
4. Lift the absorber handle until the lock clicks.

The new absorber is now connected to the breathing system.

Discarding the used disposable CO_2 absorber

Remove the red protection seal from the new disposable absorber and place it on the used disposable absorber before discarding. The disposable CO_2 absorber can be discarded as other hospital waste.

10.6 Consumables

10.6.1 i-SORB absorbers

i-SORB disposable absorber (box of 8 pcs.)
i-SORB reuseable absorber (box of 1 pc.)
Filter for reusable absorber (box of 40 pcs., 2 filters required per refil)
Oxygen compatible grease (solid)

10.6.2 Other consumables

For all consumables carefully follow the manufacturer's Instructions for Use.

Below table lists the consumables available for the machine and constitute the list of applied parts.

External patient flow sensor
Adult Patient Spirometry Set for Dameca anaesthesia machines, 2 m (20 pcs.)
Adult Patient Spirometry Set for Dameca anaesthesia machines, 3 m (20 pcs.)
Adult Patient Spirometry Set for Dameca anaesthesia machines, 6 m (20 pcs.)
Paed. Patient Spirometry Set for Dameca anaesthesia machines, 2 m (20 pcs.)
Paed. Patient Spirometry Set for Dameca anaesthesia machines, 6 m (20 pcs.)
Adult flow sensor for Dameca anaesthesia machines (25 pcs.)
Paediatric flow sensor for Dameca anaesthesia machines (25 pcs.)
Spirometry tube, 2 m (5 pcs.)
Spirometry tube, 3 m (5 pcs.)
Spirometry tube, 6 m (5 pcs.)
D-LITE Adult flow sensor, disposable (1 pc.)
PaedI-LITE flow sensor, disposable (1 pc.)
Consumables for multigas module (optional)
Artema gas sample line, 2 m (100 pcs.)
Artema Neo gas sample line, 2.5 m (25 pcs.)
DL II water trap, Adult (10 pcs.) for gas module (lifetime: 1 month)
DL II water trap, Neonatal (10 pcs.) for gas module (lifetime: 1 month)
OXIMA™ galvanic oxygen sensor
External O_2 fuel-cell sensor (optional)
O_2 fuel-cell sensor
Cable for O_2 fuel-cell sensor
T-piece for O_2 fuel-cell sensor
Breathing hoses
Respiration Bag, Silicone, 2300 mL
Respiration Bag, Silicone, 3000 mL
Anaesthetic System for Paediatric
19 mm Respiration Tubing, Silicone, 22 mm/22 mm cuffs, 60 cm long
19 mm Respiration Tubing, Silicone, 22 mm/22 mm cuffs, 180 cm long
Y-connector, straight , 15 mmI.D./22 mmO.D.
Connector, straight, with 22 mm O.D. on both sides
Bacteria filters
Single use (box of 50 pcs.)

Below table lists the resistance value (hPa) for the Dameca consumables:

Resistance	2.5 L/min	15 L/min	30 L/min
Bacterial filter	0 (hPa)	0.5 (hPa)	1 (hPa)
Y-piece, adult	0 (hPa)	0 (hPa)	0 (hPa)
Y-piece, paediatric	0 (hPa)	0 (hPa)	0.5 (hPa)
Patient hose, adult	0 (hPa)	0 (hPa)	0 (hPa)
Patient hose, paediatric	0 (hPa)	0.5 (hPa)	2.5 (hPa)
Hose for respiration bag	0 (hPa)	0 (hPa)	0 (hPa)
Connector for respiration bag	0 (hPa)	0 (hPa)	0 (hPa)
Flow sensor, adult, reusable	0 (hPa)	0 (hPa)	0.5 (hPa)
Flow sensor, paediatric, reusable	0 (hPa)	1.5 (hPa)	6 (hPa)
Flow sensor, adult, disposable	0 (hPa)	0 (hPa)	0.5 (hPa)
Flow sensor, paediatric, disposable	0 (hPa)	1.5 (hPa)	6 (hPa)
T-piece connection for O_2 fuel-cell sensor	0 (hPa)	0 (hPa)	0 (hPa)

10.7 Calibrating the external O_2 fuel-cell sensor

The O_2 fuel-cell sensor requires occasional calibration to ensure the accuracy is within specifications.

NOTE
Before starting the calibration, make sure that the O_2 fuel-cell sensor has been placed correctly as described in “Set up the machine for first use” on page 29.

To preserve the O_2 fuel-cell sensor’s lifetime, we recommend that the fuel-cell sensor is removed from the T-piece connector when the machine is not in use.

1. On the Preparation screen, press the Settings icon.
2. Press O_2 Calibration and follow the instructions on the screen.

NOTE
O_2 calibration is only available if the machine is not equipped with an integrated multigas module.

10.8 Internal OXIMA™ O_2 fuel-cell sensor

10.8.1 Calibration of the internal O_2 fuel-cell sensor

If the machine is equipped with a multigas module using an integrated OXIMA™ O_2 fuel-cell sensor, the sensor is automatically calibrated by the internal multigas module.

10.8.2 Replacement of the internal O_2 fuel-cell sensor

When the internal fuel-cell sensor is worn out it must be replaced.

1. Remove the exterior lid from the O_2 fuel-cell sensor holder.
2. Loosen the interior lid. This is fixed by a strap to the holder.
3. Remove the used fuel-cell sensor.

4. Insert the new O_2 fuel-cell sensor and close the interior lid.
5. Mount the exterior lid again.
6. On the preparation screen, press the setting icon.
7. Press O_2 calibration.

11 Change settings

When the machine is delivered and installed all settings have default values; these values can be changed to match hospital practices and environment.

This chapter describes how users with the appropriate access rights can change settings for the anaesthesia machine.

To change machine settings, press the Settings icon at the top right of the Preparation screen.

Changing settings requires that you are a super user.

You can change two types of settings:

Default settings — Default settings include settings related to the Preparation screen, like alarm limits and patient data.

These settings are automatically applied when you turn on the machine and when you end a patient case using *End case*.

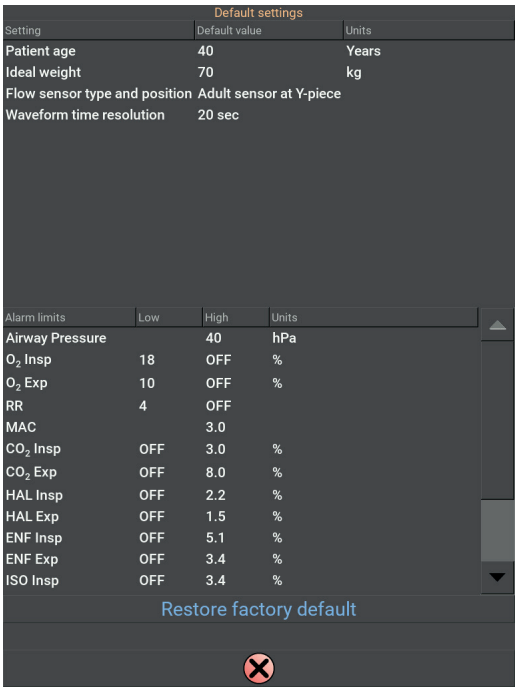
Customer settings — Customer settings include *Regional settings*, *Unit settings*, *User interface* settings and *Colours, Carrier gas setting, gas measurement settings and Security settings*.

Several of these settings depend on the hospital environment; you will typically define the settings once and never or rarely change them again.

The following sections describe these two types of settings.

11.1 Change default settings

1. On the Preparation screen, press the Settings icon, press the login icon and enter the super user password.
2. Press *Settings* and then *Default settings*.
3. Select the setting that you want to change and in the dialog box that opens, make the change and press the Confim button to confirm the change.
4. To leave *Default settings*, press the Cancel button.
5. To activate the new settings, a Full test is required.



NOTE
If you are unsure about any settings you have changed, you can always bring back the settings to factory settings by pressing the *Restore factory default* button at the bottom of the screen.

Alarm limits

The first five values are the default values for the alarm limits. When you change one of the values here, the new value will appear as default on the Preparation screen.

Patient data

The next two values are the default values for patient age and ideal weight.

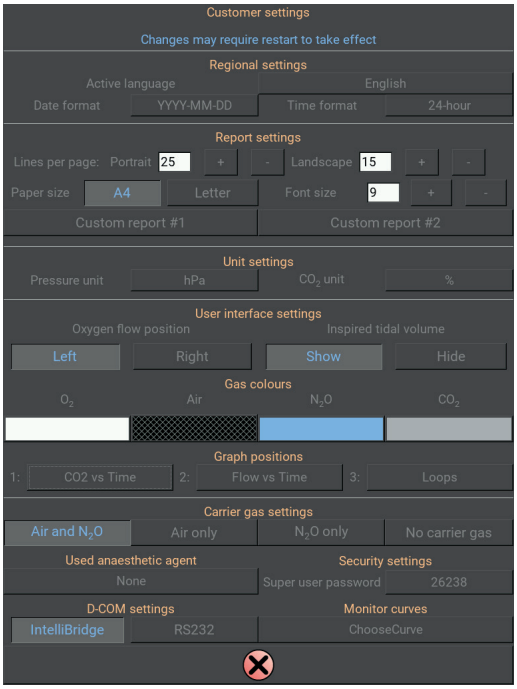
Flow sensor

In this section you indicate where the flow sensor is positioned and whether it is an adult or paediatric sensor. For details about placing the flow sensor and impact on functionality, see “Flow sensor” on page 29.

Waveforms

The default time resolution (x-axis) for waveforms.

11.2 Change customer settings



1. On the Preparation screen, press the Settings icon and press the login icon and type the super user password.
2. Press *Settings* and then *Customer settings*.
3. To leave *Customer settings*, press the Cancel button.

NOTE
To activate any settings that have been changed the machine must be turned OFF and ON again.

The *Customer settings* page is divided into a number of sections, each focusing on a different area:

Regional settings

The machine was ordered with specific settings such as language, time and date, but these can be changed. Press the appropriate fields and press the Confirm or Cancel buttons to confirm og cancel.

Active language	The user interface language and language used in logged data.
Date format	The user interface date format and date format used in logged data.
Time format	The user interface time format and time format used in logged data.

Report settings

Lines per page - portrait
The number of print lines when PDF reports are generated and printed in portrait.

Lines per page - Landscape
The number of print lines when PDF reports are generated and printed in landscapes.

Font size	The font size used when PDF reports are generated and printed. Press “+” or “-” immediately after the values to increase or decrease the value.
Paper size	The paper size of the PDF reports. You should make sure that the number of lines per page does not exceed what fits on the paper size you choose.
Customer reports	Define a customized report. See “Define a custom report” on page 55 for more details.

Unit settings

Pressure Unit — The measure unit used for airway pressure measurements.

User interface settings

Oxygen flow position — Place the O_2 flow column to the right or to the left of the carrier gas (Air or N_2O) flow column.

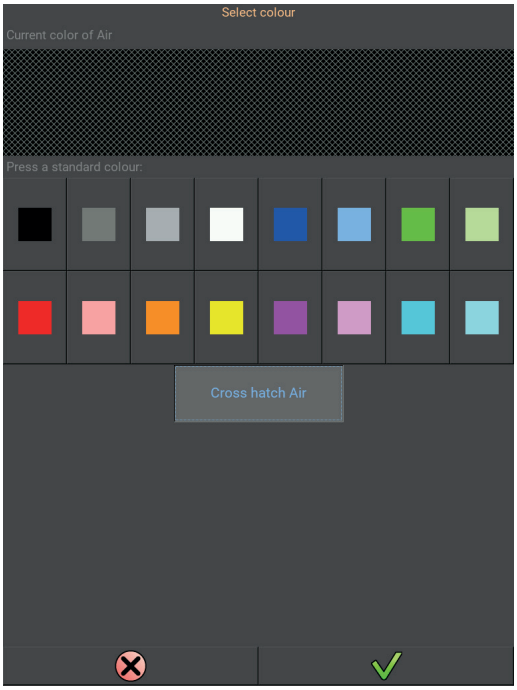
Inspired tidal volume — Show or hide inspired tidal volume during VCV, SIMV or PRVT mode; expired tidal volume is always displayed.

Gas colours

Change colour — The machine was ordered for a specific country and the gas colour was set according to the country standard. To change the gas colour press the appropriate gas field. In the window that opens you can change the standard colour.

Modify a colour — Press on the colour component to change and type in the value using the key pad. Press the Confirm button to confirm and return to *Customer settings*.

Cross-hatched Air — Press the field to cross-hatch the Air fresh gas flow column.



CAUTION
Changing the gas colours may impose a risk. The colours should follow local standards

Carrier gas settings

The selected carrier gas configuration.

Gas measurement settings

Indicate whether the machine is equipped with:

- an integrated multigas module with paramagnetic O_2 sensor (Platinum)
- an integrated multigas module with galvanic O_2 sensor (Argentum)
- an external O_2 fuel-cell sensor is available in the patient circuit
- no gas measurements

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12 VENTILATION MODES

To ensure the ventilation delivered to the patient is both effective and as gentle as possible, different ventilation modes are available with settings for each mode.

The clinician selects the optimum ventilation mode and adjusts settings to deliver the ventilation best suited to the patient needs.

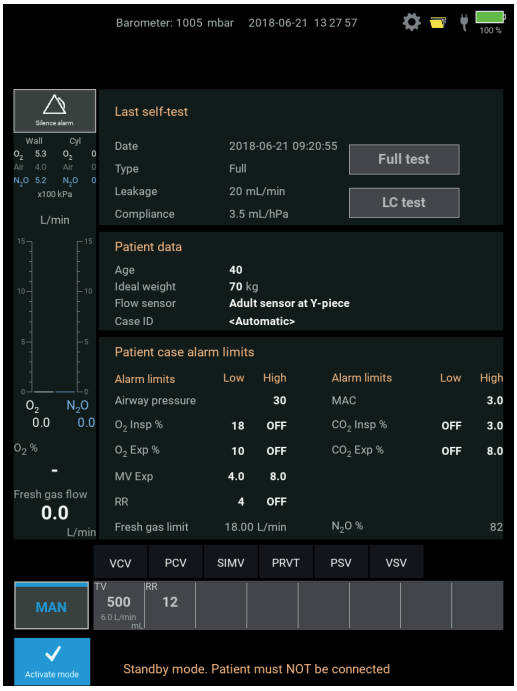
This chapter gives an overview of the ventilation modes supported with Dameca AX500.

VENTILATON MODES	
VCV	Volume Controlled Ventilation
PCV	Pressure Controlled Ventilation
PRVT*	Pressure Regulated Volume Target
PSV*	Pressure Support Ventilation
VSV*	Volume Support Ventilation
SIMV	Synchronized Intermittent Mandatory Ventilation

In addition to the controlled and support modes, manual ventilation (*MAN*) is always possible.

12.1 Ventilator settings

To adjust the ventilator to deliver the required ventilation to the patient, several parameters can be set and many parameters are used in multiple ventilation modes.



The parameters are:

TV	Tidal Volume, setting the volume delivered to the patient at each breath. Activate in VCV, SIMV, PRVT and VSV mode. Range: 20 to 1500 mL
RR	Respiration Rate, the number of breaths in a minute, 60 seconds. Range: 4 to 80 resp./min
MV	Minute Volume, is not set but depends on the TV and the RR and is calculated as follows: MV = TV * RR. Range: 0.2 to 60 L/min
I:E ratio	I:E ratio, the timing ratio between inspiratory time and expiratory time. Range: 3:1 to 1:9.9
PEEP	Positive End Expiratory Pressure. The airway pressure applied during the expiratory phase. Range: OFF, 4 to 20 hPa
P Insp	Inspiratory Pressure. The pressure above PEEP used to inflate the airways and lungs during the inspiratory phase in PCV mode. Range: 4 to 67 hPa
P Support	Support Pressure. The pressure above PEEP used to support the patient's spontaneous breaths as the patient triggers the ventilator in PSV mode. Range: 4 to 50 hPa
Insp trig	Inspiratory Trigger. The level of effort delivered by the patient to initiate a breath in PSV and VSV mode. The ventilator senses the efforts via the inspiratory flow and the clinician sets a level at which the patient will activate the ventilator to deliver inspiration. Range: 1 to 10 L/min
Exp trig	Expiratory Trigger. Trigger used in PSV and VSV mode to stop the inspiratory support from the ventilator. The trigger is based on the inspiratory flow measurement. The breath stops as the trigger flow level is reached, by a comparison of inspiratory Peak flow in the breath. Range: 10 to 80%
Backup	Ventilation backup safety timer. A timer making sure the patient will get ventilation even in case the patient condition during PSV or VSV mode changes to no breathing state; the ventilator automatically switches from PSV to PCV or from VSV to VCV. The timer counts after each inspiration or expiration time, in case the time to next expiration or inspiration is longer than the setting of the backup then the ventilator will force to controlled mode to ensure patient ventilation. Range: 10 to 40 sec
SIMV Trig	Pressure level for trigger. Triggering is based on a pressure drop initiated by the patient initiating a breath. The trigger level is set by clinician, as the patient's breathing efforts make the pressure drop to the trigger level the ventilator will deliver inspiratory flow in SIMV mode. Range: -0.5 to -10 hPa
Insp pause	Inspiratory pause. When in VCV or SIMV the clinician has the option to activate and set the length of the inspiratory pause. The pause length is measured in % of the inspiratory time. Range: 0 to 70%

A note on PEEP

PEEP cannot be set higher than the setting for the high-pressure alarm.

If PEEP is set to OFF the PEEP in the breathing system will be approximately 3 hPa (cmH_2O), depending on the fresh gas flow, because of the bag-in-bottle.

WARNING
The machine may develop an increased PEEP over the set PEEP value if operated outside the typical combinations of set tidal volume TV, respiration rate RR, I:E ratio and fresh gas flow FGF. The additional PEEP will be low if you stay within the following limits:

TV <= 1000 mL, FGF <= 10 L/min, I:E <= 1:2, and an RR <= 15 per minute, or

TV <= 500 mL, FGF <= 5 L/min, I:E <= 1:2, and an RR <= 40 per minute, or

TV <= 200 mL, FGF <= 5 L/min, I:E <= 1:2, and an RR <= 60 per minute

A PEEP high alarm will be issued to make you aware of this situation, when the measured PEEP is 3 hPa (cmH_2O) or more above the set PEEP, i.e. at 6 hPa (cmH_2O) if the PEEP is set to OFF.

Ventilator alarms

The alarm settings are intended to help ensure patient safety and should be set at the beginning of every case and updated during the case to reflect the patient needs.

When set appropriately alarms notify the clinician when a value is moving outside the set range; this could point to a potential misconfiguration of the machine delivery as compared to the patient needs.

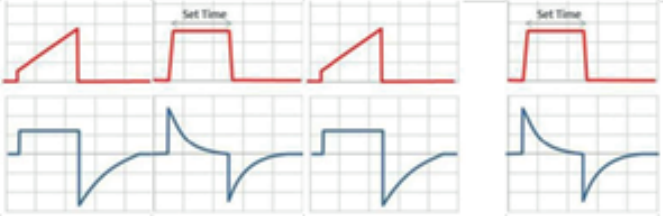
MV low	Minute volume low Range: 0.0–79.9 L/min and OFF Resolution: 0.1 L/min Standard setting: 67% of set MV (TVxRR)
RR low	Respiration rate low Range: 4–80 resp/min and OFF Resolution: 1 resp/min Standard setting: 4 resp/min
MV high	Minute volume high Range: 0.1–80.0 l/min and OFF Resolution: 0.1 L/min Standard setting: 133% of set MV (TVxRR)
RR high	Respiration rate high Range: 4–80 resp/min and OFF Resolution: 1 resp/min Standard setting: OFF

In addition to alarm settings, fresh gas flow and O_2 concentration also require attention from the clinician.

An alarm is related to fresh gas flow:

Fresh gas flow too high	Active in VCV and SIMV. Indicates the fresh gas flow is too high in relation to the set TV, the set RR and the I:E ratio in combination; in this case the fresh gas flow will deliver a tidal volume to the patient which is higher than the set tidal volume. As the ventilator is not in control of the delivered volume in this case, the alarm is issued. It is recommended to check the level of fresh gas flow in comparison to the set TV as well as the ventilation settings to optimize and make sure the fresh gas flow is lower than the required inspiratory flow. The alarm would normally be raised when ventilating paediatric patients where the fresh gas delivery in the inspiratory phase can create a considerable volume. The fresh gas limit is indicated on the Preparation screen, based on the ventilator settings.

Ventilation mode versus ventilator settings

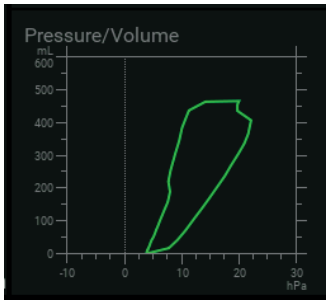
Mode	VCV	PCV	SIMV	PRVT	PSV	VSV
Waveform						
Ventilator parameters	TV (MV) RR I:E PEEP Pause	P Insp RR I:E PEEP	TV (MV) RR (Insp time) I:E PEEP Pause SIMV trigger	TV (MV) RR I:E PEEP	P Support PEEP P Insp (Backup) Insp trig Exp trig Backup	TV (MV) PEEP Insp trig Exp trig Backup

Loops

With data available for the different parameters and with the patient flow sensor placed at the Y-piece, the anaesthesia machine is able to display ventilator loops.

The loops constitute a different way to present the patient condition and rapidly show even small changes in the patient status.

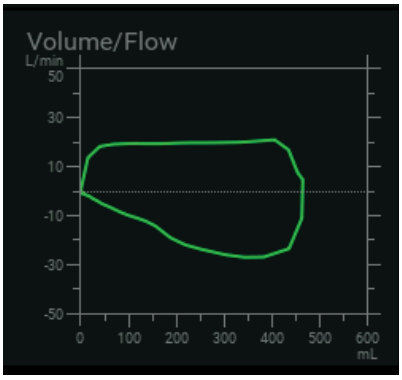
The P-V loop, consists of the delivered pressure in relation to the delivered volume. To the trained eye, the loop will show patient compliance and even small changes in the ventilator dynamics of the patient.



The P-V loop visualizes:

- Lung overdistension
- Airway obstruction
- Bronchodilator response
- Respiratory mechanics
- Work of breathing (WOB)
- Flow starvation
- Leaks
- Triggering effort

Another loop, the V-F loop, consists of the delivered flow in relation to the delivered volume.



The F-V loop visualizes:

- Air trapping
- Airway obstruction
- Airway resistance
- Bronchodilator response
- Inspiratory/expiratory flow
- Flow starvation
- Leaks
- Water or secretion accumulation
- Asynchronous

Performance

The ventilator is designed to provide an inspiratory flow in the range:

- Continuous flow: 2–80 L/min
- Max Peak flow: 120 L/min

No matter which mode is used, the set tidal volume (TV), respiratory rate (RR), I:E ratio and inspiratory pause (Insp pause) are controlled to ensure that the inspiratory flow remains in the range 2–80 L/min.

Inspiratory flow = Tidal volume x respiration rate x ((I+E)/I) x (100/(100-Insp pause))

The breathing system (IBS) has an expiratory and inspiratory resistance of:

Pressure/Flow charateristics when tested according to ISO8835-2:

Resistance	60 L/min
Expiratory	4.3 hPa
Inspiratory	3.4 hPa

Pressure/Flow charateristics when tested according to ISO80601-2-13:

Resistance	30 L/min	15 L/min	2.5 L/min
Expiratory	5.1 hPa	2.9 hPa	2.0 hPa
Inspiratory	1.8 hPa	0.7 hPa	0.9 hPa

NOTE
30 L/min is tested with 22 mm adult patient hoses where 15 L/min and 2.5 L/min are tested with 15 mm paediatric patient hoses.

Compliance = 4 mL/hPa with adult hoses 22 mm (0.866 inches) diameter. and approximately 122 cm (48.0 inches) length, this equals 120 mL at 30 hPa (cmH_2O).

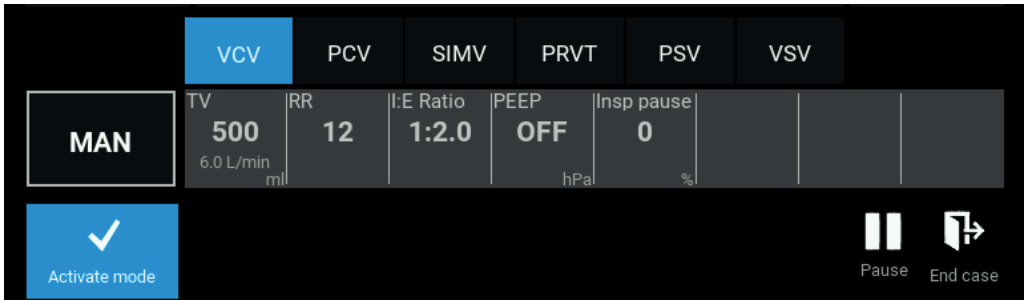
12.2 Volume Controlled Ventilation: VCV

VCV is a ventilation mode delivering a certain and controlled volume for each breath to the patient airway. Based on the settings of tidal volume, respiration rate, I:E ratio and Pause, a constant flow is delivered in the filling phase of the inspiratory time.

A limiting parameter for the delivered tidal volume could be the setting *Airway pressure high*. This is limiting the pressure added to the patient's lungs by stopping the ongoing inspiration if the set pressure limit is reached. In the expiration phase, PEEP can be controlled in order to give better gas exchange. PEEP can be used to prevent alveolar collapse.

Keys at the display and parameter setting

Below is a snapshot of the display when preparing for use of VCV mode.



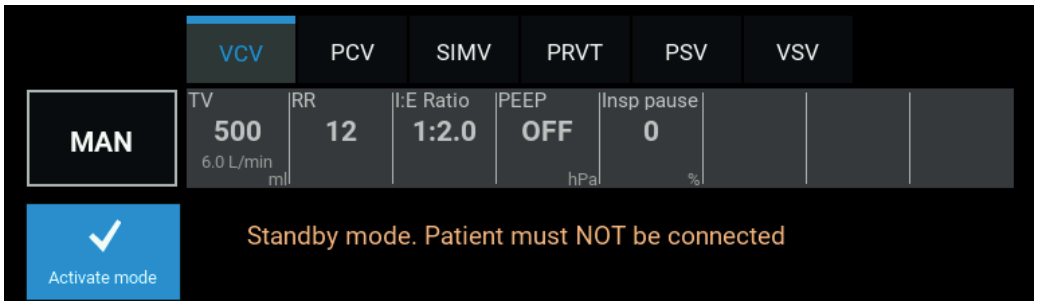
The VCV parameters are:

TV	set tidal volume (20-1500 mL)
RR	set respiration rate (4–80 L/min)
I:E ratio	set relation, inspiration versus expiration time (3:1 to 1:9.9)
PEEP	set Positive End-Expiratory Pressure (OFF, 4-20 hPa)
Insp pause	set pause at the end of the inspiration (0-70%)

How to activate VCV mode

To start using the VCV mode activate the VCV tab, set individual parameter settings and press *Activate mode*.

The profile of the VCV mode



As delivering a constant inspiratory flow in the inspiratory phase the inspiratory flow is given by:

Inspiratory flow = Tidal volume x respiration rate x ((I+E)/I) x (100/(100-Insp pause)).

In VCV mode the ventilator automatically compensates for for fresh gas flow, system compliance and leakage.

Respiration rate is the number of controlled respirations per minute.

NOTE
Some combinations of TV, RR, I:E and Insp pause cannot be set on the ventilator because the continuous inspiratory flow from the ventilator must be between 2 and 80 L/min.

Example of minimum inspiratory flow

Set: TV = 20 mL, I:E = 1:2, Insp pause = 70.

These settings give a minimum respiratory rate of 10.

Example of max inspiratory flow

Set: RR = 20, I:E = 1:2, Insp pause = 0.

These settings give a max tidal volume of 1330 mL.

Fresh gas flow compensation:	Compensates the inspiratory flow from the ventilator by subtracting the flow delivered from the constantly supplied fresh gas
System compliance compensation:	Compensates the inspiratory flow from the ventilator by adding the flow to fill the volume created by the system compliance and pressure in the patient system.
Leakage compensation:	The system has leakage compensation. When delivering volume controlled breaths, the system is able to compensate up to ± 10% of the set TV as leakage compensation. The function compensates the system for leakages in the sense of delivering the set volume to the patient, when the system is not leaking this is the same as the expiratory volume measured at the flow sensor. To calculate the leak for the leakage compensation, the system needs to be in a stable condition. After one minute without changes in settings, the system reads the measured expiratory tidal volume, and then compares the set tidal volume to the measured tidal value. If there is a difference, the ventilator will make a compensation for leakage (cfl=compensated for leakage) by the calculated difference volume, which is an expression for the leak: ΔV_{cfl} = Set TV – measured TV The delivered tidal volume compensated for leakage, TV_{cfl}, is then: TV_{cfl} = Set TV + ΔV_{cfl} Every minute the ventilator will compare the set tidal volume to the measured tidal volume in order to compensate for leakage.

Insp pause:

VCV mode has an option for inserting an inspiratory pause at the end of the inspiratory phase. The pause will improve the gas exchange as the pause will give more time for the airway gases to distribute in the lungs. At the same time the introduction of the inspiratory pause will increase the peak pressure applied to the lungs. As the inspiratory pause is part of the inspiratory phase and the volume delivered is constant, the difference is the inspiratory flow and a higher flow will result in a higher peak pressure.

Things to bear in mind

As the ventilator is delivering the set volume to the patient, it is recommended that the clinician observes the effect of the ventilation and sets the alarm limit for the peak pressure in relation to the patient physiology and condition.

In case the fresh gas flow is in the range where the flow in the inspiratory phase builds up a volume equal to or larger than the set tidal volume, an alarm is issued: *Fresh gas flow high. Check fresh gas and ventilation settings*. Check flow and ventilation settings to optimize and make sure the fresh gas flow is lower than the inspiratory flow.

NOTE

If the patient is connected to the anaesthesia machine in a volume controlled ventilation mode and attempts a large spontaneous breath around the same time as a mandatory breath, it is possible for the patient to create a high negative airway pressure. If the negative airway pressure is below -11 hPa (cmH_20), the NPL valve of the anaesthesia machine will open, but due to the resistance of the flow and the time taken to reach the patient, the airway pressure may decrease a bit further. The negative pressure, however, is not sustained. If the patient is breathing spontaneously, and if the machine is installed with support ventilation modes, VSV or PSV should be considered.

Typical alarms

Airway pressure high:

In VCV the volume delivery to the patient is set, delivering the tidal volume depends on the patient compliance to the ventilation. If the patient compliance is low, the peak pressure could go high during inspiration and even alarm.

In this case, look into the settings and change settings and/or ventilation mode as appropriate.

Fresh gas flow high. Check fresh gas and ventilation settings:

Indicates that the fresh gas flow is too high in relation to the set tidal volume. In this case the flow from the fresh gas flow will deliver the volume filling the lungs and maybe even more volume.

As the ventilator is not in control of the delivered volume, in this case the alarm is issued. It is recommended to check the level of fresh gas flow in comparison to the set TV as well as the ventilation settings to optimize and ensure the fresh gas flow is lower than the required inspiratory flow.

The alarm would normally be raised when ventilating paediatric patients, where the fresh gas delivery in the inspiratory phase creates a considerable volume.

12.3 Pressure Controlled Ventilation: PCV

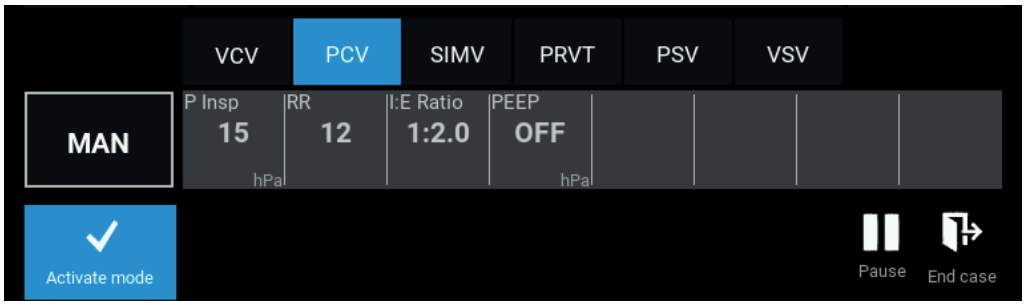
PCV is a ventilation mode applying a certain and controlled pressure above PEEP to the patient airway during each inspiration, based on setting for inspiratory pressure, PInsp. The pressure is applied constantly in the inspiratory phase. In the expiratory phase, PEEP can be controlled to increase the handling of the lungs, by giving more optimal settings for the gas exchange, thereby using PEEP to prevent alveolar collapse.

By applying a constant pressure at the airway, a decelerating flow profile is created where the larger and easily filled volumes of the upper airways are filled quickly using a high flow. At the same time, the alveoli will be filled over the full inspiratory time of the breath, and in this way make the airway gases available for respiration, gas exchange.

A limiting parameter for the delivered tidal volume could be the compliance of the patient, which determines the volume added to the patient lungs, i.e. if the patient is unrelaxed and contracted, the compliance is low and thus the volume delivered by the pressure applied to the airway will be low in the typical clinical setting. If the patient is relaxed, athletic and easy to ventilate, the compliance is high and thus the volumes delivered could be high.

Keys at the display and parameter setting

Below is a snapshot of the display when preparing for use of PCV mode.

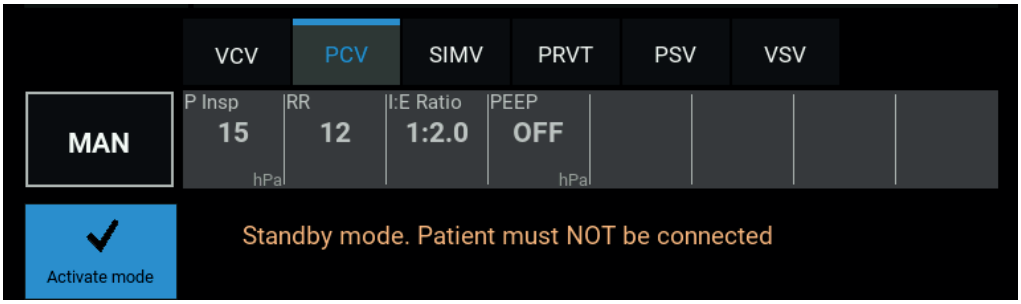


The PCV parameters are:

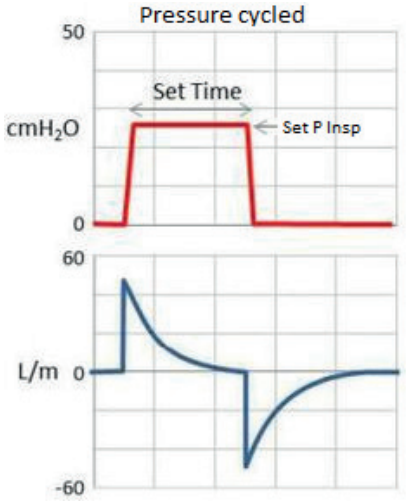
P Insp	set inspiratory pressure above PEEP (4-67 hPa)
RR	set respiration rate (4–80 L/min)
I:E ratio	set relation, inspiration versus expiration time (3:1 to 1:9.9)
PEEP	set Positive End-Expiratory Pressure (OFF, 4-20 hPa)

How to activate PCV mode

To start using the PCV mode, activate the *PCV* tab, set individual parameter settings and press *Activate mode*.



The profile of the PCV mode



Things to bear in mind

When using pressure controlled ventilation, the delivered volume is determined by the applied inspiratory pressure in combination to the compliance of the patient. In this way the delivered volume would have variations related to variations of compliance in the patient. It is important to observe that the delivered volume satisfies the patient needs and is neither too low nor too high.

Ventilation of small children is challenging; in situations where very low volumes are needed, consider the option to use the settings of the inspiratory pressure above PEEP as low as 4 hPa. In this way, depending on the physiology and compliance of the patient, you are able to deliver volumes as low as 3-4 mL in controlled ventilation.

Typical alarms

MV high/ MV low: In PCV the volume delivered depends on the patient compliance. The volume may run low or high compared to the alarm setting. Please bear in mind the alarm setting is typically based on the TV and RR setting but in PCV mode, the ventilator is not in control of the volumes delivered.

In this case, look into the settings and change settings and/or ventilation mode as appropriate.

System Pressure. Check bag-in-bottle and patient system:

Could indicate that the bellows does not have sufficient volume to deliver the required tidal volume to the patient without being pressed to the bottom of the chamber.

May occur due to a leak in the patient system.

In this case please look into the fresh gas flow settings as well as the ventilator settings and change settings and/or ventilation mode as appropriate.

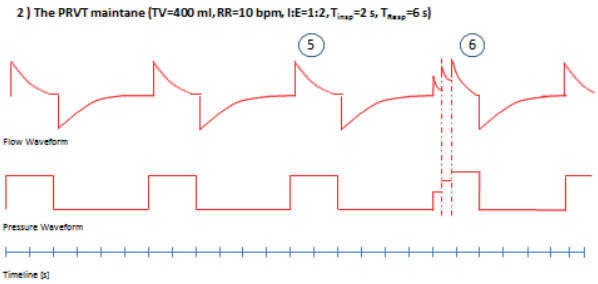
12.4 Pressure Regulated Volume Target: PRVT

PRVT is a pressure controlled ventilation mode that applies a calculated and controlled pressure above PEEP to the patient airway in each inspiration. The applied pressure above PEEP is based on the setting for tidal volume compared to the measured expiratory tidal volume.

In the expiratory phase, PEEP can be controlled to increase the handling of the lungs, giving more optimal settings for the gas exchange, and thereby using PEEP to prevent alveolar collapse.

When initializing, the system will measure the compliance by applying a series of three volume controlled breaths with an inspiratory pause of 20%, to deliver a reliable measurement of the plateau pressure. The measured plateau pressure is used for the compliance calculation:

Compliance = expiratory tidal volume / (plateau pressure – PEEP)



Initial calculation of inspiratory pressure above PEEP:

When the initial pressure controlled breaths are delivered and the compliance is calculated, the number is used to set the inspiratory pressure for the next breaths:

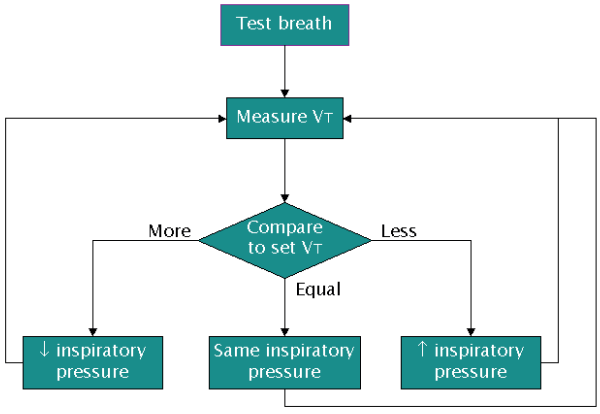
$$\text{Insp Pressure}_{\text{calculated}} = 0.9 \text{ (Set TV / Compliance)}$$

The regulated inspiratory pressure above PEEP:

When delivering pressure controlled breath the regulation starts.

By comparing the set target tidal volume to the measured expiratory tidal volume:

$$\Delta V = \text{Set TV} - \text{measured TV}$$

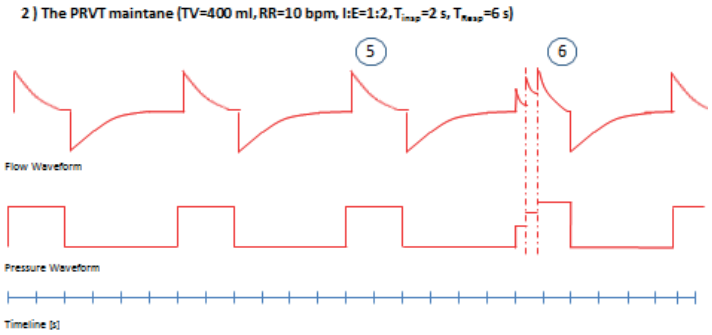


If there is a difference between the set tidal volume and measured tidal volume, the machine can calculate the needed inspiratory pressure to deliver the target tidal volume. This is possible as the system is calculating the Compliance.

$$\Delta P = \Delta V / \text{Compliance}$$

The new inspiratory pressure to be delivered, Insp. Pressure$_{next}$, for reaching the Target Volume:

$$\text{Insp Pressure}_{next} = \text{Insp Pressure}_{current} + \Delta P$$



The pressure is applied as a constant pressure in the inspiratory phase of the breath. In the expiration phase, PEEP can be controlled to increase the handling of the lungs, by giving more optimal settings for the gas exchange.

Applying the constant pressure at the airway will create a decelerating flow profile, where the larger and easy to fill volumes of the upper airways are filled quickly using a high flow. The lower parts of the airway, the alveoli, would as complying to the applied pressure be filled over the full inspiratory time of the breath, giving a decelerating flow profile.

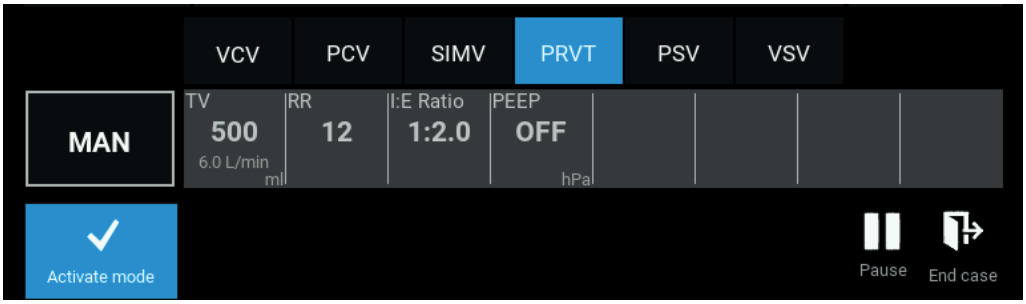
In this way PRVT is using the most gentle ventilation mode, PCV while combining pressure controlled ventilation with the volume guarantee by the option to change the inspiratory pressure to target delivering the set tidal volume to the patient.

A limiting parameter for the patient ventilation could be the alarm settings. The high airway pressure alarm will limit the increasing pressure, if the required inspiratory pressure is closer than 5 hPa to the set airway pressure high alarm limit. In case a higher pressure is needed, the alarm *TV limited. Required P Insp too close to alarm limit* is issued, indicating that the limit for increasing the inspiratory pressure is reached. In this case please look into the alarm settings as well as evaluate the ventilator settings for optimal patient ventilation.

In case the patient compliance is high, the delivered volume may be higher than the set target volume, even if the ventilator is delivering the lowest possible inspiratory pressure of 4 hPa above PEEP. If the inspiratory pressure cannot be lowered, the alarm *Required P Insp too low, below 4 hPa* is issued, indicating that the ventilator cannot lower the delivered inspiratory pressure. In this rare case you could either change settings or ventilation mode for a more optimal patient ventilation.

Keys at the display and parameter setting

Below is a snapshot of the display when preparing for use of PRVT mode.

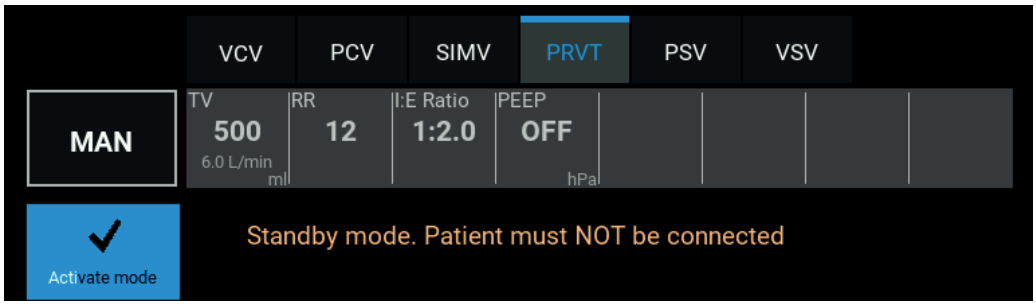


The PRVT parameters are:

TV	set tidal volume (20-1500 mL)
RR	set respiration rate (4–80 L/min)
I:E ratio	set relation of Inspiration versus expiration time (3:1-1:9.9)
PEEP	set Positive End-Expiratory Pressure (OFF, 4-20 hPa)

How to activate PRVT mode

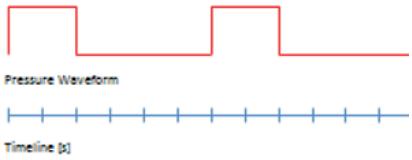
To start using the PRVT mode activate the PRVT tab, set individual parameters settings and press Activate mode.



The profile of the PRVT mode

The first three breaths are volume controlled breaths with an inspiratory pause of 20% to measure compliance.

These are followed by the pressure controlled breaths, delivered with a calculated inspiratory pressure, based on the compliance measurement.



Breath number six and the following breaths are still pressure controlled breaths, and are regulated at the inspiratory pressure from the comparison of the set tidal volume versus the measured expiratory tidal volume.

Things to bear in mind

When using pressure controlled ventilation, the delivered volume is determined by the applied inspiratory pressure in combination with the compliance of the patient; in this way the delivered volume would have variations related to the variations of compliance in the patient. In PRVT mode the ventilator will calculate the necessary inspiratory pressure to obtain the set volume and in case needed, the inspiratory flow will be changed. The change could happen at every second breath.

Restrictions

Maximum changes in inspiratory pressure delivered by the ventilator is 3 hPa from currently delivered inspiratory pressure to next used inspiratory pressure, and changes cannot happen at two consecutive breaths– in this way the system ensures that the volume delivered is not based on an artifact.

In case the volume needed requires a pressure more than 3 hPa from the currently delivered inspiratory pressure, it is important to observe that the delivered volume satisfies the needs of the patient and is neither too low nor too high. The system will make a change of the maximum 3 hPa, then make new comparison to the new condition, set a new inspiratory pressure, as needed.

Typical alarms

TV limited. Required P Insp too close to alarm limit:

Regulation of the inspiratory volume is needed to deliver the set tidal volume and at the same time the safety of the patient is based on the set high airway pressure alarm limit.

This alarm indicates that the required pressure to deliver the set tidal volume is not possible to deliver due to the setting of the *Airway pressure high* alarm limit. The delivered pressure can only be increased to 5 hPa below the set *Airway pressure high* alarm limit.

12.5 Pressure Supported Ventilation: PSV

PSV is a ventilation mode that enables the patient to guide the ventilator to deliver the needed inspiratory pressure. The system will detect the patient activity and the patient's wish for an inspiration by the measurement of the flow in the flow sensor at the Y-piece.

In PSV mode, the inspiration in each breath is patient initiated, based on setting for inspiratory trigger flow. When the patient inspiratory flow is triggering the ventilator, the ventilator applies the support pressure above PEEP, P Support, to the airways.

The applied pressure is constant in the inspiratory phase of the breath, the inspiratory flow is controlled by the patient and the patient physiology. As the inspiratory flow drops to a set threshold level the inspiration will stop and the ventilator will change to the expiratory phase.

In the expiratory phase, PEEP can be controlled to increase the handling of the lungs, by giving more optimal settings for the gas exchange, and thereby using PEEP to prevent alveolar collapse.

By applying a constant pressure at the airway, a decelerating flow profile is created.

The larger and easily filled volumes of the upper airways are filled quickly using a high flow.

The lower airway would be filled over the full inspiratory time of the breath, in this way make the airway gases available for gas exchange in the alveoli.

When setting up the PSV mode, the clinician sets:

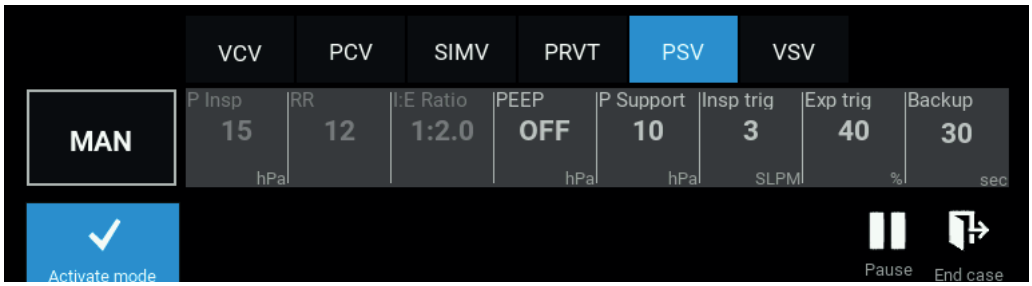
- the support pressure, "P Support", to be applied to the airway at inspiration.
- the "Insp trig" which is the flow measured at the Y-piece where the ventilator starts the inspiration.
- the "Exp trig" which is the flow measured at the Y-piece where the ventilator stops the inspiration and goes to expiration.

In this way the patient is in full control of the ventilator breath delivery as long as there are efforts for spontaneous breathing.

In case the patient is unable to trigger the ventilator, a built-in timer is counting the time elapsed, and at the set Backup time the corresponding backup mode (PCV) is activated. The controlled mode will ventilate the patient, and an alarm sound and alarm text is issued.

Keys at the display and parameter setting

Below is a snapshot of the display when preparing for use of PSV mode.

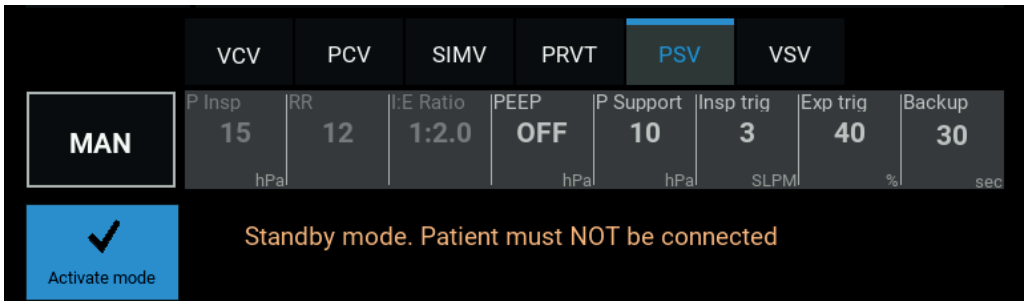


PSV parameters

P Insp	backup inspiratory pressure (4-67 hPa)
RR	backup respiration rate (4–80 L/min)
I:E Ratio	backup relation of inspiration versus expiration time (3:1 to 1:9.9)
PEEP	set Positive End-Expiratory Pressure (OFF, 4-20 hPa)
P Support	set support pressure above PEEP (4 - 50 hPa)
Insp trig	set inspiratory trigger flow (1-10 L/min)
Exp. trig	set expiratory trigger flow (10-80%)
Backup	backup time until change to controlled mode (10-40 s)

How to activate PSV mode

To start using the PSV mode activate the PSV tab, set individual parameter settings and press Activate mode.



Things to bear in mind

In case the patient is unable to trigger the ventilator, a built-in timer is counting the time elapsed, and as soon as the set Backup time, from 10 to 40 seconds, is passed, the corresponding backup mode is taking over, i.e. PCV. The controlled mode will ventilate the patient using the settings for the PCV mode, and alarm sound and alarm text *PSV backup ventilation. PCV activated* is issued.

When using pressure supported ventilation, the delivered volume is determined by the applied support pressure in combination with the patients spontaneous breathing efforts. In this way the delivered volume would have variations related to the variations of compliance in the patient as well as to the breathing efforts of the patient.

It is important to observe that if the delivered volume satisfies the needs of the patient and is neither too low nor too high. In case of dis-synchrony of the settings and the patient requirements, it could affect the efficiency of patient ventilation negatively.

In normal use of PSV, the “Exp trig” is the parameter determining the end of the inspiration. Nevertheless, there are three different ways to stop the delivery of the inspiratory pressure:

1. Inspiratory flow lowered to the setting of the “Exp trig”
2. Inspiratory time exceeds 2.5 seconds when using the adult flow sensor, or exceeds 1.5 seconds when using the paediatric flow sensor
3. The measured airway pressure is higher than the high airway pressure alarm settings.

Typical alarms

PSV backup ventilation. PCV activated:

In PSV the ventilator delivers breaths based on the patient’s breathing efforts, measured as inspiratory flow.

In case the patient stops breathing, the ventilator will switch to controlled mode, PCV, after the set Backup time to ensure that patient ventilation and the gas exchange is not compromised.

12.6 Volume Supported Ventilation: VSV

VSV is a ventilation mode enabling the patient to guide the ventilator to deliver the inspiratory volume. The system will detect the patient activity and the patient’s wish for an inspiration by the measurement of the flow in the flow sensor at the Y-piece.

In this mode, the inspiration in each breath is patient initiated, based on settings for inspiratory trigger flow.

When the patient inspiratory flow is triggering the ventilator, the ventilator applies the calculated inspiratory pressure above PEEP to the airways.

The applied pressure is constant in the inspiratory phase of the breath. The inspiratory flow is controlled by the patient and the patient physiology, as the inspiratory flow drops to a set threshold level, the inspiration will stop and the ventilator will change to the expiratory phase. In the expiratory phase, PEEP can be controlled to increase the handling of the lungs, by giving more optimal settings for the gas exchange, thereby using PEEP to prevent alveolar collapse.

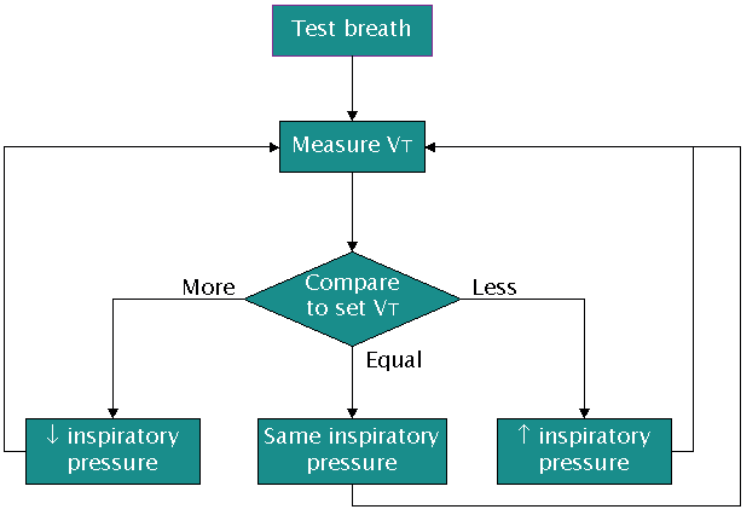
When setting up VSV mode, the clinician sets:

- the tidal volume, “TV”, to be applied to the airway at inspiration.
- the “Insp trig” to which the ventilator should initiate the inspiratory pressure.
- the “Exp trig” setting, the flow at which the inspiration stops and the ventilator opens for expiration.

In this way the patient is in full control of the ventilator breath delivery as long as there are efforts for spontaneous breathing. In case the patient is unable to trigger the ventilator, a built-in timer counts the time elapsed, and at the set Backup time, the corresponding backup mode is activated. The backup mode is VCV, the controlled mode which will ventilate the patient, and alarm sound and alarm text is issued.

The inspiratory pressure in VSV is calculated on the basis of the comparison of the set support tidal volume to the delivered and measured expiratory tidal volume.

By comparing the set supported tidal volume to the measured expiratory tidal volume:



ΔV = Set TV – measured TV

If there is a difference between the set tidal volume and measured tidal volume, the machine can calculate the needed inspiratory pressure to deliver the target tidal volume. This is possible as the system is calculating the Compliance.

$\Delta P = \Delta V * \text{Compliance}$

The new inspiratory support pressure to be delivered, for reaching the Target Volume:

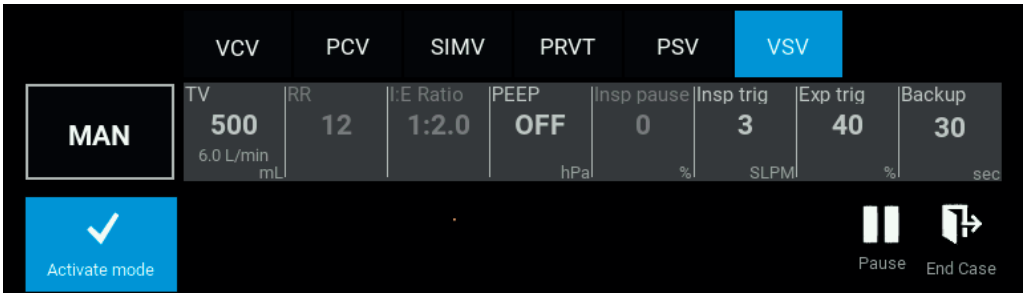
$\text{Sup. Pressure}_{next} = \text{Sup. Pressure}_{current} + \Delta P$

By applying a constant pressure at the airway, a decelerating flow profile is created, where the larger and easily filled volumes of the upper airways are filled quickly using a high flow. At the same time the lower parts of the airway, focusing the alveoli, as complying with the applied pressure. The alveoli would be filled over the full inspiratory time of the breath, and in this way make the airway gases available for gas exchange.

Keys at the display and parameter setting

Below is a snapshot of the display when preparing for use of VSV mode.

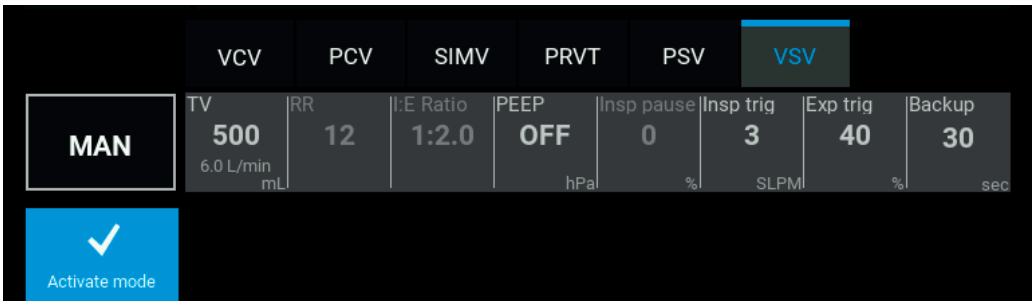
The VSV parameters are:



TV	set tidal volume (20-1500 mL)
RR	backup respiration rate (4–80 L/min)
I:E Ratio	backup relation of inspiration versus expiration time
Insp trig	set inspiratory trigger flow, (1-10 l/min)
Exp trig	set expiratory trigger flow (10-80%)
PEEP	set Positive End-Expiratory Pressure (OFF, 4-20 hPa)
Backup	Backup time until change to controlled mode (10-40 s)

How to activate VSV mode

To start using the VSV mode activate the VSV tab, set individual parameter settings and press Activate mode.



Things to bear in mind

In case the patient is unable to trigger the ventilator, a built-in timer counts the time elapsed, and as soon as the set Backup time, from 10 to 40 seconds, is passed the corresponding backup mode is taking over, i.e. VCV. VCV mode will ventilate the patient using the settings for the VCV mode, an alarm sound and alarm text *VSV backup ventilation. VCV activated* is issued.

When using volume supported ventilation, the delivered volume is determined by the applied calculated support pressure in combination with the ventilatory drive of the patient. In this way the delivered volume will have variations following the variations of compliance in the patient and the variations in the patient breathing efforts.

It is important to observe that the delivered tidal volume and minute volume satisfy the needs of the patient, and are neither too low nor too high. In case of dis-synchrony of the settings and the patient requirements, it could affect the efficiency of the ventilation lung tissue negatively.

Typical alarms

VSV backup ventilation. VCV activated

In VSV mode, the ventilator delivers breaths based on the breathing efforts from the patient, measured as inspiratory flow.

In case the patient stops breathing, the ventilator will switch to controlled mode, VCV, after the set Backup time to ensure that patient ventilation and the gas exchange is not compromised.

TV limited. Required P Support too close to alarm limit

This alarm indicates the support pressure required to deliver the set tidal volume is too close to the *Airway pressure high* alarm limit. The delivered support pressure can only be increased to 5 hPa below the set *Airway pressure high* alarm limit.

12.7 Synchronized Intermittent Mandatory Ventilation: SIMV

SIMV is a ventilation mode delivering a certain and controlled minimal volume for the patient airway, based on settings for tidal volume and respiration rate, at the same time allowing the patient to spontaneously breathe and to trigger the ventilator to deliver supported ventilation.

In SIMV mode there are three different breath types:

A mandatory breath: A VCV breath delivered by the ventilator, synchronized to start at the end of the previously unused trigger window. In case a breath was triggered in the trigger window, mandatory breath is suppressed. Refer to graphics below.

A triggered breath: The patient can trigger the ventilator in the trigger window. If the patient triggers the ventilator, it will deliver a VCV based breath, synchronized to the spontaneous breathing efforts to avoid breath stacking. If a triggered breath is missing, the ventilator will deliver a mandatory breath after the end of the trigger window. Refer to graphics below.

A spontaneous breath: The patient is able to breathe freely. In case the spontaneous breath is initiated in the trigger window and has strength to trigger the ventilator it will result in a triggered breath. Refer to graphics below.

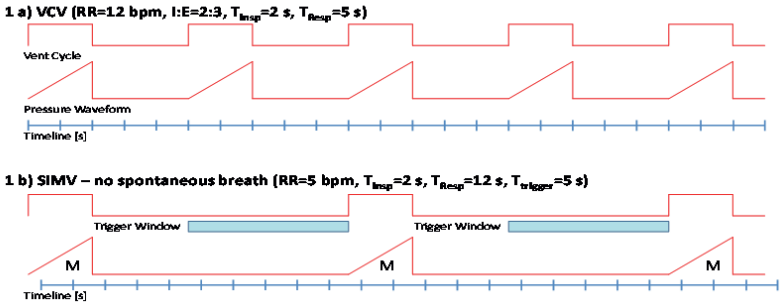
Triggering the ventilator happens as the patient initiates a breath and inhales, the inhalation will lower the pressure in the patient system. The pressure trigger is activated if the pressure drop is sufficient compared to the trigger setting.

Prerequisites for using SIMV:

SIMV mode will take over the RR and I:E ratio from the previously used ventilation mode, in below example VCV.

In SIMV mode, the inspiratory time from the previously used mode is kept, and the previously used mode will set the trigger windows used in SIMV.

When the RR is lowered the inspiratory time is kept and in this way I:E ratio is changed automatically. The trigger window is now induced at the end of the breath and will have the length of a full breath from the previously used mode. Refer to graphics below.



The trigger window is automatically calculated from the previous ventilation mode (one full breath = inspiration + expiration) using the available information:

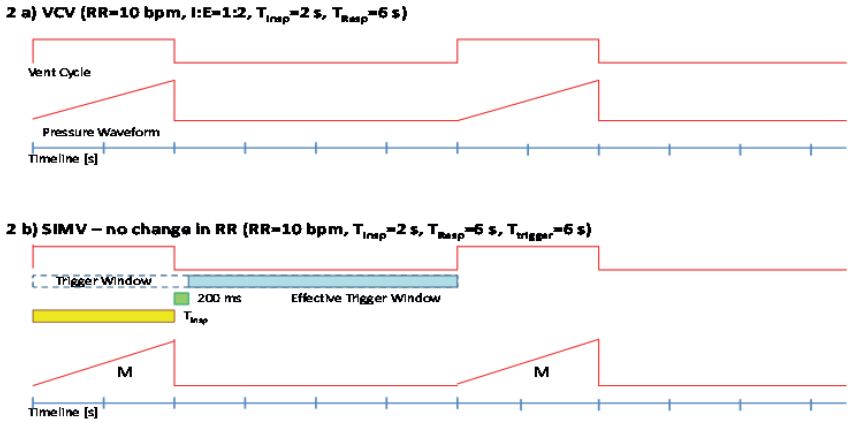
- The default settings for the RR and I:E.
- The setting of the patient data defined in the Preparation screen.
- The clinician made settings before start of the ventilator.

Example:

As timing is a major factor in SIMV, mode below example shows SIMV used without lowering the RR, giving time for spontaneous breathing.

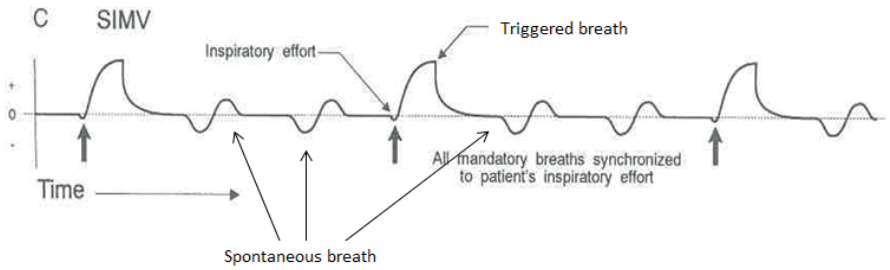
In the below example, the trigger window (with the length of one breath) is combined with continuous use of the respiration rate from the previous mode. As the SIMV prevents stacked breath the trigger window induced at the end of the breath, is reduced to the lenght of the expiratory phase in SIMV mode, minus 200 msec (see graphics below).

The result is that the patient is able to trigger the ventilator for a triggered breath nearly all of the expiratory time (in below graphics in blue)



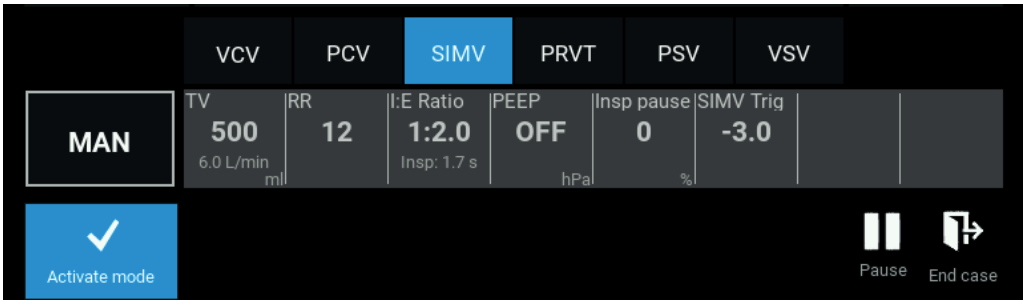
As long as the patient is triggering the ventilator in the trigger window, the patient is control. In case the patient is unable to trigger the ventilator, the mandatory breaths from the ventilator will secure that the patient gets sufficient ventilation due to the mandatory breath delivery. Should the patient again be able to trigger the ventilator, the patient can take control of the breathing.

In the example below the breaths initiated by the patient are seen as pressure drops. When a breath initiated by the patient occurs within the trigger window, the ventilator initiates a syncronized breath, delivering the the set tidal volume.



Keys at the display and parameter setting

Below is a snapshot of the display when preparing for use of SIMV mode.

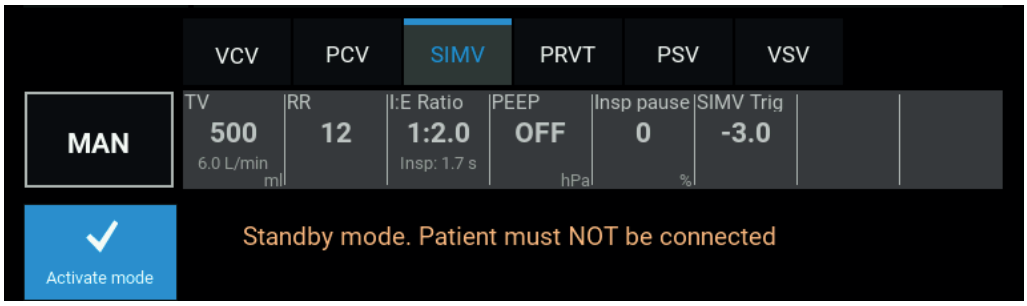


The SIMV parameters are:

TV	set tidal volume (20-1500 mL)
RR	set respiration rate (4-80 L/min)
I:E	set relation of Inspiration versus expiration time and inspiratory time (3:1-1:9.9)
PEEP	set Positive End-Expiratory Pressure (OFF, 4-20 hPa)
Insp pause	set pause in the end of the inspiration (0-70%)
SIMV trig	the trigger level for the pressure trigger (0.5-10 hPa)

How to activate SIMV mode

To start using the SIMV mode activate the SIMV tab, set individual parameter settings and press Activate mode



NOTE
Some combinations of TV, RR, I:E and Insp pause cannot be set on the ventilator because the continuous inspiratory flow from the ventilator must be between 2 and 80 L/min.

Example of minimum inspiratory flow

Set: TV = 20 mL, I:E = 1:2, Insp pause = 70.

These settings give a minimum respiratory rate of 10.

Example of max inspiratory flow

Set: RR = 20, I:E = 1:2, Insp pause = 0.

These settings give a max tidal volume of 1330 mL.

During the delivery of the mandatory and the triggered breaths, the ventilator is using the same compensations as VCV mode:

Fresh gas flow compensation:	Compensates the inspiratory flow from the ventilator by the flow delivered from the constantly supplied fresh gas.
System compliance compensation:	Compensates the inspiratory flow from the ventilator by adding the flow to fill the volume created by the system compliance and pressure in the patient system
Leakage compensation:	When delivering volume controlled breaths, the system is able to compensate up to ± 10% of the set TV as leakage compensation. The function compensates the system for leakages in the sense of delivering the set volume to the patient, when the system is not leaking this is the same as the expiratory volume measured at the flow sensor. To calculate the leak for the leakage compensation, the system needs to be in a stable condition. After one minute without changes in settings, the system reads the measured expiratory tidal volume, and then compares the set tidal volume to the measured tidal volume. If there is a difference, the ventilator will make a compensation for leakage (cfl=compensated for leakage) by the calculated difference volume, which is an expression for the leak: ΔV_{cfl} = Set TV – measured TV The delivered tidal volume compensated for leakage, TV_{cfl}, is then: TV_{cfl} = Set TV + ΔV_{cfl} Every minute the ventilator will compare set tidal volume to the measured tidal volume in order to compensate for leakage.

Things to bear in mind

In case the patient does not trigger the ventilator within the trigger window, a mandatory breath is delivered after the trigger window has ended.

As the ventilator is delivering the set volume to the patient, it is recommended that the clinician observes the effect of the ventilation and sets the alarm limit for the peak pressure in relation to the patient physiology and condition.

In case the fresh gas flow is in the range where the flow in the inspiratory phase builds up a volume in the size or larger than the set tidal volume, an alarm is issued: *Fresh gas flow too high*. Check fresh gas flow settings and ventilation settings to optimize and ensure the fresh gas flow is lower than the inspiratory flow.

Typically when using SIMV mode in the emergency phase, the respiration rate is lowered. This will normally call for a raised CO_2 level in the blood compared to the previous ventilation mode. The increased CO_2 level is desired to stimulate the breathing centre in the brain, giving the patient urge for breathing.

As the rate is lowered the expiratory time is increased to give more time for spontaneous breathing.

NOTE
If the patient is connected to the anaesthesia machine in VCV mode, and attempts a large spontaneous breath around the same time as a mandatory breath, it is possible for the patient to create a high negative airway pressure. If the negative airway pressure is below -11 hPa (cmH_20), the NPL valve of the anaesthesia machine will open, but due to the resistance of the flow and the time taken to reach the patient, the airway pressure may decrease further. The negative pressure however is not sustained. If the patient is breathing spontaneously, and if the machine is installed with support ventilation modes, VSV or PSV could be considered.

Typical alarms

Airway pressure high:	As in VCV mode, the volume delivery to the patient is set, delivering the tidal volume depends on the patient compliance to the ventilation. If the patient compliance is low, the peak pressure could go high during inspiration and even alarm. In this case look into the settings and possibly change settings and/or ventilation mode.
Fresh gas flow too high:	Indicates the fresh gas flow is too high in relation to the set tidal volume. The fresh gas flow limit is indicated on the Preparation screen, based on the set patient data. In this case the flow from the fresh gas flow will deliver the volume filling the lungs and maybe even more volume. As the ventilator is not in control of the delivered volume, the alarm is issued. It is recommended to check the level of fresh gas flow in comparison to the set tidal volume as well as the ventilation settings in order to optimize and ensure, the fresh gas flow is lower than the required inspiratory flow. The alarm would normally be raised when ventilating paediatric patients, where the fresh gas delivery in the inspiratory phase creates a considerable volume.

12.8 Inherited settings

When delivering ventilation to a patient, it is occasionally necessary to optimize and deliver better treatment. This could require changes in the ventilation mode and/or changes to settings for the mode in use. Change of ventilator settings requires experience and knowledge as changes may affect the efficiency of the patient ventilation and therefore affect the ongoing patient treatment.

The machine will propose settings when the clinician changes ventilation mode and the proposal is based on the ongoing delivery of ventilation. Ongoing delivery means that the ventilation has been active for more than a minute, without changing any settings.

Below are the tables and the calculations for the proposed values when changing ventilation mode, dependent on flow sensor availability and placement.

With flow sensor placed at the Y-piece:

TO → FROM ↓	VCV	PCV	SIMV	PRVT	PSV	VSV
VCV		P Insp = P Plateau – PEEP	Same settings	Same settings	P Insp = P Plateau – PEEP (Backup)	Same settings
					P Support = ½*P Plateau – PEEP	Calculated start pressure: P Support = ½*(P Plateau – PEEP)
PCV	TV= MV Exp/RR		TV = MV Exp/RR	TV = MV Exp/RR	Same P Insp (Backup)	TV= MV Exp/RR
					P Support = ½*P Insp	Calculated start pressure: P Support start= ½*P Insp
SIMV	Same settings	P Insp = P Plateau – PEEP		Same settings	P Insp = P Plateau – PEEP (Backup)	Same settings
					P Support = ½*(P Plateau – PEEP)	Calculated start pressure: P Support = ½*(P Plateau – PEEP)
PRVT	Same settings	P Insp = P Plateau – PEEP	Same settings		P Insp = P Plateau – PEEP (Backup)	Same settings
					P Support = ½*(P Plateau – PEEP)	Calculated start pressure: P Support start= ½*P Insp
PSV	Default settings	Same set P Insp	Default settings	Default settings		TV = MV Exp/RR measured
						Calculated start pressure: P Support start= ½*P Insp
VSV	Same settings	P Insp = P Plateau – PEEP (last used P Support)	Same settings	Same settings		

With flow sensor placed at the expiratory cone of the IBS:

TO → FROM ↓	VCV	PCV	SIMV	PRVT
VCV		P Insp = P Plateau – PEEP	Same settings	Same settings
PCV	Default value		TV = MV Exp/RR	TV = MV Exp/RR
SIMV	Same settings	P Insp = P Plateau – PEEP		Same settings
PRVT	Same settings	P Insp = P Plateau – PEEP	Same settings	

Without flow sensor:

TO → FROM ↓	VCV	PCV	SIMV
VCV		P Insp = P Plateau – PEEP	Same settings
PCV	Default value		Default value
SIMV	Same setting	P Insp = P Plateau – PEEP	

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13 Alarms: cause and action

Below table is an alphabetical list of all alarm texts with a description of the cause and a suggested action to remove the alarm.

Alarm text	Priority	Type	Cause	Corrective action
A				
Absorber disconnected	During automatic ventilation: Medium During manual ventilation or standby: Low	Technical	The CO_2 absorber has been disconnected from the breathing system for more than 30 sec.	Connect the CO_2 absorber to the breathing system and lock by lifting the handle until the lock clicks.
Air disabled - Air supply detected	Medium	Technical	Pressure sensor of Air supply detected that Air is connected to the machine.	Disconnect Air supply or configure the machine to use Air.
Air disabled - switch to N_2O	Low	Technical	The carrier gas selector switch is set to Air though the machine is not configured for use of Air.	Set carrier gas selector valve to N_2O.
Air supply pressure low	High	Technical	The Air inlet pressure is lower than 3.0 (x100 kPa) from wall supply or lower than 20.0 (x100 kPa) from gas cylinder.	Connect at secondary source if possible. Prepare for use without Air supply. Check fresh gas flow and settings are sufficient if Air supply is discontinued.
Airway pressure high	High	Clinical	Actuates during automatic ventilation when the measured pressure exceeds the high-pressure alarm limit.	Consider changing the high-pressure limit settings. Try to find the cause, such as: • Occluded tube or hoses. • Patient status. • Surgical pressure. Consider changing tidal volume and respiratory rate. Consider changing the ventilation mode.
Ambient CO_2 too high for gas module	Low	Technical	The measured CO_2 concentration in the ambient (room) air is too high for the multigas module to calibrate.	Improve the room ventilation where the machine is located.

Alarm text	Priority	Type	Cause	Corrective action
Apnea	Medium	Clinical	The ventilator has not detected a respiration, within the last 20 seconds.	Check the patient. Check airway management. Check ventilation status With multigas module: Check CO_2 waveform, gas sample tube & water trap
Apnea more than 60 secs	High	Clinical	The ventilator has not detected a respiration rate within the last 60 seconds.	Check the patient. Check airway management. Check ventilation status With multigas module: Check CO_2 waveform, gassample tube & water trap
B				
Battery low. Max 15 min left	High	Technical	Actuates if the charge in the built-in battery is too low to ensure proper performance for more than the next 15 minutes.	Check if the machine is correctly plugged into the mains power outlet. Check the mains power supply inlet switch on the rear of the machine. Consider contacting your service department.
D				
Data log is not generated	Low	Technical		
Disconnection	High	Clinical	The machine has not registered a pressure variation in the range 3 hPa, in the breathing system within the last 15 seconds.	Check that the breathing system, hoses and tubing are properly connected.
E				
Exp AA% high	Medium	Clinical	The measured AA% is above the set alarm limit.	Check the fresh gas flow settings and vaporizer settings. Check the sample hose and water trap, and replace, if necessary. Consider changing the vaporizer settings. Consider changing the alarm limits.
Exp AA% low	Low	Clinical	The measured AA% is below the set alarm limit.	Check the fresh gas flow settings and vaporizer settings. Check the sample hose and water trap, and replace, if necessary. Consider changing the vaporizer settings. Consider changing the alarm limits.

Alarm text	Priority	Type	Cause	Corrective action
Exp CO_2 high	Medium	Clinical	The measured CO_2% is above the set alarm limit.	Check the fresh gas flow settings and ventilator settings. If use of mask ventilation during MAN status is causing the CO_2 waveform to be unstable, consider using the "CO_2 alarms OFF" function. Check the absorber and the yellow valve flaps in the breathing system. Check the sample hose and water trap, and replace, if necessary. Consider changing the alarm limits.
Exp CO_2 low	Medium	Clinical	The measured CO_2% is below the set alarm limit.	Check the fresh gas flow settings and ventilator settings. If use of mask ventilation during MAN status is causing the CO_2 waveform to be unstable, consider using the "CO_2 alarms OFF" function. Check the absorber and the yellow valve flaps in the breathing system. Check the sample hose and water trap, and replace, if necessary. Consider changing the alarm limits.
Exp O_2% high	Medium	Clinical	The measured O_2% is above the set alarm limit.	Check the set fresh gas flow. Check the sample hose and water trap, and replace, if necessary. Consider changing the alarm limit.
Exp O_2% low	High	Clinical	The measured O_2% is below the set alarm limit.	Check the set fresh gas flow. Check the sample hose and water trap, and replace, if necessary. Consider changing the alarm limit.
F				
Fan stopped	Medium	Technical	One of the two fans at the back of the machine is not running.	Check whether the filters for the two fans are compacted with dust. For each fan , remove the filter from the front of the fan and check whether the fan is working. If the message persists, contact your service department.

Alarm text	Priority	Type	Cause	Corrective action
Fresh gas delivered at auxiliary outlet	Low	Technical	The auxiliary fresh gas flow switch has been set to ON. The message displays until the switch is set to OFF. Only manual ventilation at external patient system is possible when auxiliary fresh gas is ON.	Try to change to internal fresh gas flow by turning off the auxiliary fresh gas flow switch. If internal fresh gas flow cannot be used, contact your service department.
Fresh gas flow high. Check fresh gas and ventilation settings	Medium	Technical	The set fresh gas flow is too high with respect to the set ventilator parameters: tidal volume, RR, I:E ration and insp Pause from the ventilator.	Consider changing (reducing) the set fresh gas flow. Consider changing the set ventilator parameters.
G				
Gas module is in stand-by mode	Low	Technical	The preparation screen has been displayed for more than 5 minutes	The gas module automatically restarts when the “Activate mode” button is touched. Measurement of gas concentration resumes after approximately 20 seconds.
Gas module out of order	High	Technical	The multigas module is not responding and there are no gas concentration measurements taking place.	Turn the machine off and on. Call for technical assistance.
Gas module Red correctable	High	Technical	The measured gas concentrations cannot be used.	Replace the sample hose and water trap. If this does not resolve the problem, call for technical assistance.
I				
Insp AA% high	Medium	Clinical	The measured AA% is above the set alarm limit.	Check the fresh gas flow settings and vaporizer settings. Check the sample hose and water trap, and replace, if necessary. Consider changing the vaporizer settings. Consider changing the alarm limits.
Insp AA% low	Low	Clinical	The measured AA% is below the set alarm limit.	Check the fresh gas flow settings and vaporizer settings. Check the sample hose and water trap, and replace, if necessary. Consider changing the vaporizer settings. Consider changing the alarm limits.

Alarm text	Priority	Type	Cause	Corrective action
Insp CO_2 high	Medium	Clinical	The measured CO_2% is above the set alarm limit.	Check the fresh gas flow settings and ventilator settings. If use of mask ventilation during MAN status is causing the CO_2 waveform to be unstable, consider using the "CO_2 alarms OFF" function. Check the absorber and the yellow valve flaps in the breathing system. Check the sample hose and water trap, and replace, if necessary. Consider changing the alarm limits.
Insp CO_2 low	Medium	Clinical	The measured CO_2% is below the set alarm limit.	Check the fresh gas flow settings and ventilator settings. If use of mask ventilation during MAN status is causing the CO_2 waveform to be unstable, consider using the "CO_2 alarms OFF" function. Check the absorber and the yellow valve flaps in the breathing system. Check the sample hose and water trap, and replace, if necessary. Consider changing the alarm limits.
Insp N_2O% high	High	Clinical	The measured N_2O% exceeds 82.	Check the set fresh gas flow. Consider increasing the total fresh gas flow if ventilating with minimal flow Check the sample hose and water trap, and replace, if necessary.
Insp O_2% high	Medium	Clinical	The measured O_2% is above the set alarm limit.	Check the set fresh gas flow. Consider changing the alarm limit.
Insp O_2% low	High	Clinical	The measured O_2% is below the set alarm limit.	Check the set fresh gas flow. Consider changing the alarm limit.
Internal system error	High	Technical	A hardware error detected.	Contact your service department.
Invalid O_2 sensor offset on gas module	High	Technical	The gas module cannot calibrate to O_2 sensor	Restart the multigas module and perform a new calibration of the O_2 fuel-cell sensor.

Alarm text	Priority	Type	Cause	Corrective action
M				
MAC high	Medium	Clinical	The MAC value is higher than 3	Immediately reduce anesthetic agent concentration in the breathing circuit, by decreasing the setting on the vaporizer and increasing the fresh gas flow.
Machine closing down. Press ON/OFF button to cancel	During automatic or manual ventilation : High During standby: Low	Technical	The front-panel ON/OFF switch is pressed. The machine shuts down after 20 seconds. All settings, Trend data, and Alarms are reset (deleted).	To cancel shutdown, press the ON/OFF switch again within 20 seconds interval.
Mains power failure. External power outlets not supported	Low	Technical	The mains power supply to the machine is interrupted during use. NOTE: The battery supplies power for minimum 90 minutes	Note that if a desflurane vaporizer is being used, this is no longer powered. Check whether the machine is correctly plugged into the power supply. Check the mains power supply inlet switch on the rear of the machine. If the message persists, contact your service department.
Measurement exceeds specification for flow sensor	Low	Technical	Flow at patient flow sensor exceeded the specification for the sensor. Max. 35 L/min for Paediatric sensor, Max. 80 L/min for Adult sensor	Check the patient. Check airway management. If Paediatric flow sensor is used, change to Adult flow sensor. Consider changing ventilation settings.
Measured TV too high	Low	Technical	The flow sensor is set to Adult and the measured tidal volume exceeds 2000 mL (adult sensor) and 500 mL (paediatric sensor).	Check whether the correct flow sensor is being used. Check whether the spirometry hose (yellow) is constricted or occluded (consider moisture). Replace if necessary.
Measured TV too high. Change flow sensor to Adult	Low	Technical	The flow sensor is set to Paediatric and the measured expired tidal volume has been more than 350 mL for the last 60 seconds, or the tidal volume is set higher than 350 mL.	MAN mode, select adult sensor.

Alarm text	Priority	Type	Cause	Corrective action
Measured TV too low. Change flow sensor to Paediatric	Low	Technical	The flow sensor is set to Adult and the measured expired tidal volume has been less than 100 mL for the last 60 seconds, or the tidal volume is set lower than 100 mL.	MAN mode, select paediatric sensor.
MV Exp high	Medium	Clinical	The measured expired minute volume is higher than the high alarm limit.	Check the machine's flow sensor settings and whether the correct sensor is being used and is properly positioned. Check whether the minute volume alarm limits are correct with respect to the desired minute volume.
MV Exp low	Medium	Clinical	The measured expired minute volume is lower than the low alarm limit.	Check the machine's flow sensor settings and whether the correct sensor is being used and is properly positioned. Check whether the minute volume alarm limits are correct with respect to the desired minute volume.
N				
N_2O disabled - N_2O supply detected	Medium	Technical	Pressure sensor of N_2O supply detected N_2O is connected to the machine.	Disconnect N_2O supply or configure the machine for use of N_2O.
N_2O supply pressure low	High	Technical	The N_2O inlet pressure is lower than 3.0 (x100 kPa) from wall supply or lower than 20.0 (x100 kPa) from gas cylinder.	Connect at secondary source if possible. Prepare for use without N_2O supply. Check fresh gas flow and settings are sufficient if N_2O supply is discontinued.
N_2O disabled - switch to Air	Low	Technical	The carrier gas selector switch is set to use of N_2O though the machine is not configured for use of N_2O.	Set carrier gas selector valve to Air.
Negative airway pressure	High	Clinical	Airway pressure detected lower than -10 hPa for more than one second.	Check the patient status. Check the fresh gas settings. If using ventilator check the ventilator settings.

Alarm text	Priority	Type	Cause	Corrective action
No battery. Shutting down. Go to MAN ventilation	High	Technical	After about 15 seconds, the machine automatically shuts down.	Prepare for manual ventilation as the machine will switch off. Check whether the machine is correctly plugged into the power supply. Check the mains power supply inlet switch on the rear of the machine. Consider contacting your service department.
No water trap	High	Technical	The multigas module detects that the water trap is not (correctly) mounted.	Check whether the water trap is correctly mounted. Replace water trap, if necessary.
O				
O_2 sensor error. Check sensor	Low	Technical	The measurement returned from the O_2 sensor is out of range.	Check O_2 sensor and cable.
O_2 supply pressure low	High	Technical	The O_2 inlet pressure is lower than 3.0 (x100 kPa) from wall supply or lower than 20.0 (x100 kPa) from gas cylinder.	Connect at secondary source if possible. Prepare for use without O_2 supply, check fresh gas flow and Air fresh gas flow settings are sufficient if O_2 supply is discontinued.
Occlussion	High	Technical	The gas module cannot maintain a sample flow	Check that the sample tube between the Y-piece and the water trap is not blocked. Replace, if necessary. Check whether the water trap is full of water. Empty or replace the water trap if necessary.
P				
Patient system disconnected	Low	Technical	The integrated breathing system (IBS) has been disconnected.	Check whether the integrated breathing system is logged to the base as required. Check whether the handle is locked into the base. If the message persists, contact your service department.
PEEP high - more than 3 hPa above set value	High	Clinical	The pressure in the breathing system has been constantly higher than PEEP +3.0 hPa (cm-H_2O), during a period of 15 sec.	• Check for air trapping • Check patient status • Check tube conditions • Check for high fresh gas flow • Check for surgical pressure • Check correct function of expiratory valve. • Consider alternative ventilation equipment.

Alarm text	Priority	Type	Cause	Corrective action
PSV backup ventilation. PCV activated	Low	Clinical	The patient has not activated an inspiratory trigger before the "PSV backup" period expires. NOTE: The ventilator automatically switches to PCV mode.	Consider returning to PSV mode if the patient is breathing independently. Consider changing the settings within PSV mode. Consider changing the ventilation mode.
R				
Required P Support too high, above 50 hPa	Medium	Technical	The support pressure required to reach the set tidal volume in VSV mode is higher than 50 hPa (cmH_2O). NOTE: The alarm appears only in VSV mode.	Consider changing the alarm limit or look for the cause, such as: • Occluded tube or hoses • Patient status • Surgical pressure Alternatively you might: • Lower the tidal volume. • Consider changing the ventilation mode.
Required P Support too low, below 4 hPa	Medium	Technical	The support pressure required to reach the set tidal volume is less than 4 hPa (cmH_2O).	Consider increasing the tidal volume. Consider changing the ventilation mode.
RR high	Medium	Clinical	The ventilator has registered respiration and the measured respiration rate is higher than the set alarm limit.	Check the patient status. Check the ventilator settings. Consider changing the alarm limit settings.
RR low	Medium	Clinical	The ventilator has registered respiration and the measured respiration rate is lower than the set alarm limit.	Check the patient status. Check the ventilator settings. Consider changing the alarm limit settings. Consider changing the ventilation mode.
S				
Sample cell pressure in gas module out of range	High	Technical	The measured pressure in the gas module's measurement chamber is too high or too low. A low-pressure in the measurement chamber could be due to occlusion	Check that the sample tube between the Y-piece and the water trap is not blocked. Replace, if necessary. Check whether the water trap is full of water. Empty or replace the water trap if necessary.

Alarm text	Priority	Type	Cause	Corrective action
Sample flow rate error on gas module	High	Technical	The sample flow rate (measured by the multi-gas module) is too high or too low.	Check that the sample tube between the Y-piece and the water trap is not blocked. Replace, if necessary. Check whether the water trap is full of water. Empty or replace the water trap if necessary.
Secondary agent detected	Low	Clinical	The multigas module has detected a secondary anesthetic agent in the sample gas.	The message automatically disappears when a secondary agent is no longer identified. Detection of HAL as a secondary agent might be due to expiration of methane by the patient.
Self-test not available	Low	Technical	Due to internal tests, at the moment the self-test is not available.	Correct active alarm conditions. If the message persists, contact your service department.
Set P Insp not achieved	Medium	Technical	The Peak airway pressure does not reach the set inspiratory pressure + Set PEEP during a period of 20 seconds	Consider changing the ventilator settings or change ventilation mode for VCV.
Switching to primary drive gas	Low	Technical	As primary drive gas pressure is re-established, the machine is using the primary drive gas.	None
Switching to secondary drive gas	Low	Technical	As supply pressure of primary drive gas is lower than 3.0 (x100 kPa) from wall supply or lower than 20.0 (x100 kPa) from gas cylinder, the machine will automatically change for secondary drive gas if available. Requires that the machine is configured for both Air and O_2.	Re-establish supply of primary drive gas. If the message persists, contact your service department.
System pressure. Check bag-in-bottle and patient system	High	Technical	The difference between the ventilator pressure to the bag-in-bottle system and airway pressure in the breathing system exceeds 15 hPa (cmH_2O). The ventilator directly enters into expiration phase.	Try to find the cause, such as: • Occluded hose • Whether the inspiratory valve is opening correctly (visually inspect the valve). • Check whether the bellows is full. • Consider contacting your service department.

Alarm text	Priority	Type	Cause	Corrective action
T				
Turn off fresh gas flow	Low	Technical	Machine in Pause or Preparation mode. Fresh gas flow is not needed as patient should not be connected.	Close the fresh gas flow for all gases.
Turn on fresh gas flow	Low	Technical	Fresh gas flow not supplied to patient even though the machine is in use.	Turn on fresh gas flow to the patient needs.
TV limited. Required P Insp too close to alarm limit	Medium	Technical	The inspiratory pressure required to reach the set tidal volume is less than 5 hPa (cmH_2O) from the high airway-pressure alarm limit. NOTE: The alarm appears in PRVT mode only.	Consider changing the high-pressure limit settings or look for the cause, such as: • Occluded tube or hoses • Patient status • Surgical pressure Alternatively you might consider lowering the tidal volume or changing the ventilation mode, possibly to PCV or VCV.
TV limited. Required P Support too close to alarm limit	Medium	Technical	The support pressure required to reach the set tidal volume is less than 5 hPa (cmH_2O) from the high airway-pressure alarm limit. Note: The alarm appears in VSV mode only.	Consider changing the alarm limit or look for the cause, such as: • Occluded tube or hoses • Patient status • Surgical pressure Consider changing the ventilation mode, for example to PSV, PCV or VCV.
U				
User interface restarted unexpectedly	Medium	Technical	Internal processes made the machine restart the Graphical User Interface.	Check that settings and measurements are as expected. If the issue persists contact your service department.
V				
Ventilator failure. Use MAN ventilation	High	Technical	The ventilator registers an internal error. The ventilator automatically switches to MAN ventilation mode.	Turn the machine off, if error persists after turning on, contact your service department.
Ventilator stopped. Fresh gas delivered at auxiliary outlet	Medium	Technical	The auxiliary fresh gas flow switch has been set to ON. The message displays until the switch is set to OFF. Only manual ventilation is possible when auxiliary fresh gas is ON.	Try to change to internal fresh gas flow by turning off the auxiliary fresh gas outlet. If internal fresh gas flow cannot be used, contact your service department.

Alarm text	Priority	Type	Cause	Corrective action
Ventilator stopped. Patient system disconnected	Medium	Technical	The integrated breathing system (IBS) has been disconnected. Only manual ventilation is possible the IBS has been disconnected.	Check whether the IBS is locked to the base as required. Check whether the handle for the IBS lock is locked into the base. Try restarting the ventilator in the desired mode. If the message persists, contact your service department.
Ventilator system pressure high	High	Technical	Triggers when the ventilator pressure to the bag-in-bottle system is more than 10 hPa higher than the setting of high pressure alarm limit.	Alarm terminates when there is automatic respiration without the ventilator pressure to the bag-in-bottle system reaching the setting of high pressure alarm limit plus 10 hPa .
Ventilator communication error	High	Technical	Communication to ventilator unit is not running.	Contact your service department.
VSV backup ventilation. VCV activated	Low	Clinical	The ventilation is in VSV mode and the patient has not made a volume-supported breath before the VSV backup time has ended. Actuation of this alarm automatically switches the machine to VCV mode.	Consider whether the patient has sufficient spontaneous respiration to use VSV mode and whether the backup time is correctly set. Consider switching back to VSV mode.

14 Technical data

All measured values in the breathing circuit are based on BTPS conditions (body temperature and pressure, saturated). BTPS denotes volume of gas saturated with water vapor at 37°C (98.6°F) and at barometric pressure.

All other measured values, such as high pressure side of the anaesthetic workstation, are based on STPD conditions (standard temperature and pressure, dry). STPD means barometric pressure of 1013 hPa (cmH_2O) and temperature of 21°C (69.8°F).

NOTE
Unit of measurement: hPa = cmH_2O = mbar

In this section hPa is used only. If you use a different measurement, please note that the values are the same.

Consult the Dameca AX500 Service Guide for more detailed technical information.

14.1 General

General	
Height	1397 mm (55 inches)
Width	810 mm / 920 mm (31.88 inches / 36.22 inches) incl. IBS
Depth	750 mm (29.52 inches)
Weight	Approx. 150 kg (330.69 lb) in a standard configuration which includes IBS, absorber and integrated patient suction
Mechanical specifications	
Maximum load on table's side rail	20 kg
Maximum torque on table's side rail	20 Nm
Maximum load on table top	20 kg
Maximum load on pull-out plate	5 kg
Maximum load on top shelf	30 kg
Maximum load on drawer	5 kg
Electrical	
Class	I
Type	B
Power supply voltage	100V-127V, 220V-240V, 50/60 Hz
Power consumption *	130 VA + 20 VA (multigas module) + DES vaporizer. *Desflurane vaporizer power consumption depends on manufacturer and is not included in the power consumption specification.
Battery capacity	7.2 Ah
Battery backup time	Approx. 90 min
Battery type	2 pcs. Lead-Acid, 7.2 Ah

WARNING
Only Dameca certified engineers are allowed to change the battery. How to change battery is described in the Dameca AX500 Service Guide.

Battery charge time	Approx. 12 hours
Note: There is no difference in performance when the machine is battery powered. When the machine is battery powered the four external outlets, one on the front and three on the back, and the LED light are not powered.	
AUXILIARY ELECTRICAL OUTLETS AND VAPORIZER OUTLETS (OPTIONAL)	
Max current from each individual outlet	One power outlet at the rear of the machine supports 2A @220V-240V or 3A @100V-127V Two power outlets at rear on the machine support 1A @220V-240V or 2A @100V-127V
Max total current from 3 outlets on the rear of the machine	Max. combined current @100V-127V = 11A @220V-240V =5.5A
100V - 127V Circuit breaker rating	Vaporizer outlet: 2.5A
	Rear outlet - top: 3A
	Rear outlet - middle: 2A
	Rear outlet - bottom: 2A
	Common for all 4 outlet above: 10A
100V - 127V On-board fuse rating	Vaporizer outlet: T 8A H 250V
	Rear outlet - top: T 10A H 250V
	Rear outlet - middle: T 6.3A H 250
	Rear outlet - bottom: T 6.3A H 250
	Common for all 4 outlet above: T 16A H 250
220V - 240V Circuit breaker rating	Vaporizer outlet: 2.5A
	Rear outlet - top: 2A
	Rear outlet - middle: 1A
	Rear outlet - bottom: 1A
	Common for all 4 outlet above: 6A
220V - 240V On-board fuse rating	Vaporizer outlet: T 8A H 250
	Rear outlet - top: T 6.3A H 250
	Rear outlet - middle: T 3.5A H 250
	Rear outlet - bottom: T 3.5A H 250
	Common for all 4 outlets above: T 10A H 250
Frequency from each outlet	Equal to supply frequency
Voltage from each outlet - Approximately equal to supply voltage. There may be a small increase in the outlet voltage compared to the supply voltage, when the outlets are lightly loaded. Max voltage increase = 11V.	
POWER CORDS	
European North American Danish Swiss United Kingdom Indian Australian Chinese	

SERVICE LIFE	
10 years	
COMMUNICATION PORTS	
RS232	Data output according to protocol, for data collection. The RS232 serial port is isolated
SmartLog	Data output according to Philips IntelliBridge protocol, for data collection. The SmartLog port is isolated
USB	Used for printable reports. The USB port is not isolated
SCREEN	
15 inch touch	

14.2 Gases

Notes • All gases and anaesthetic agents must comply with the US Pharmacopoeia, European Pharmacopoeia or local recognized requirements for medical gases.	
CENTRAL GAS SUPPLY / WALL SUPPLY	
Inlet pressure	300-600 kPa, 44-87 psig for O_2, Air and N_2O Must comply with relevant national standards such as: ISO 9170, Terminal Units for Use in Medical Gas Pipeline Systems (Europe); CSA Z305.1, Non-flammable Medical Gas Piping Systems (Canada); or JIS T 7101, Medical Gas Pipeline Systems (Japan), or NFPA 99, Standard for Health Care Facilities (USA).
RESERVE GAS SUPPLY (OPTIONAL)	
Pin-index yokes	ø100, ø109 and ø120 cylinders (O_2, Air and N_2O)
GAS CYLINDER SUPPLY	
Gas cylinder	0-25000 kPa, 0-3626 psig for O_2 and Air 0-10000 kPa, 0-1450 psig for N_2O
AUXILIARY GAS OUTLET	
Flow for O_2 or Air (measured at inlet pressure)	15 L/min at 400 kPa, 58 psig (60 L/min at 1013 hPa) 14 L/min at 600 kPa, 87 psig (85 L/min at 1013 hPa) 13 L/min at 1200 kPa, 174 psig (155 L/min at 1013 hPa)
GAS ALARM	
Alarm start pressure	300 kPa, 44 psi for O_2, Air and N_2O
INTEGRATED AUXILIARY O_2 BALL FLOW METER	
Flow range	0–12 L/min
Accuracy	7.5% actual flow + 2.5% full scale
INTEGRATED PATIENT SUCTION	
Maximum vacuum	-70 kPa, -525 mmHg Gas driven: at minimum 400 kPa, 58 psig inlet pressure VAC driven: at minimum -80 kPa, from wall supply
Maximum suction flow	>25 L/min
Gas consumption (gas driven suction)	-25 kPa, -185 mmHg: Max. 15 L/min -50 kPa, -375 mmHg: Max. 22 L/min -70 kPa, -525 mmHg: Max. 27 L/min

ANAESTHESIA GAS SCAVENGING SYSTEM - AGSS	
Scavenging flow from the hospital installation (for a Dameca AX500 machine with passive AGSS)	28-40 L/min
AGSS/WAGD leakage test	This test checks for possible leakages in the AGSS/WAGD system, and must only be performed by qualified trained personal. Consult the Service Guide for more details. 1. Remove the IBS, and block the connection to the AGSS/WAGD and the ventilator valve block on the IBS base. 2. Block the AGSS/WAGD outlet on the gas connection manifold. 3. Remove the lower rear cover as described in “Accessing the machine” on page 125 in the Service Guide. 4. Disconnect the AGSS/WAGD reservoir tube from the right-side corner pole. 5. Connect a flow measuring reference instrument to the AGSS/WAGD reservoir tube and a pressure measuring reference instrument to the sample gas return port. 6. By using e.g. the auxiliary O_2 flowmeter supply flow until the pressure at the sample gas return is 30 hPa, and decrease the flow to maintain a pressure of 30 ± 2 hPa. 7. Check that the flow in the AGSS reservoir tube is < 100 mL/min. 8. After testing turn off the flow, remove the plugs, remount the IBS, remove the test equipment, and reconnect any hoses removed during the test.

14.3 Fresh gas flow

SET PARAMETERS	
Flow resolution (all gases)	0.1 L/min
Flow range (O_2)	0 - 15 L/min (inlet pressure >400 kPa)
Flow range (Air, N_2O)	0 - 10 L/min (inlet pressure <400 kPa)
Accuracy (all gases)	4% of reading + 0.05 L/min
O_2 FLUSH VALVE	
Flow	30 ± 5 L/min
PRESSURE LIMITING	
Max pressure (MPL valve)	<125 hPa

14.4 Ventilator

DRIVE GAS (AIR OR O_2)	
Pressure	Min. 300 kPa, 43.5 psig at 80 L/min
Maximum consumption (Peak flow)	120 L/min
Mean consumption	Max. 80 L/min at 280 kPa, 40.6 psig

Pressure range	
Pressure limitation, opening pressure (P. lim max.)	< 125 hPa (mechanical, pressure limitation value)
Max. adjustable working pressure	Approx. 80 hPa
High-pressure alarm	10 to 80 hPa
Min. expiration pressure (P. lim min)	1 hPa
Cycling pressure	1-80 hPa
NPL valve opening pressure	11 hPa ±5 hPa
Note Negative pressure is only possible if the patient is exclusively breathing spontaneously.	
Set parameters	
Tidal volume	20 to 1500 mL
Delivered tidal volume accuracy (VCV and SIMV mode)	**Without patient sensor** < 400 mL: +/- 15 mL or +/- 12% of setting (whichever is greater) 400 – 1500 mL: +/- 50 mL or +/- 10% of setting (whichever is greater)
	With patient sensor Paediatric sensor: +/- 10 mL or +/- 10% of setting (whichever is greater) Adult sensor: +/- 50 mL or +/- 10% of setting (whichever is greater)
Respiration rate	4 to 80 resp./min
I:E ratio	3:1 to 1:9.9
PEEP	OFF, 4 to 20 hPa
Inspiratory pressure	4 to 67 hPa
Inspiratory pause	0 to 70%
Ventilation modes (controlled)	VCV, SIMV, PCV, PSV, PRVT, VSV
SIMV settings	
SIMV trigger point	-0.5 to -10.0 hPa
PSV/VSV settings	
Support pressure (PSV only)	4 to 50 hPa
Inspiratory trigger	1 to 10 L/min
Expiratory trigger	10 to 80%
PSV/VSV backup time	10 to 40 sec.
Airway pressure monitor	
Measured parameters	Peak, Plateau, Mean, PEEP, Compliance
Pressure range	-10 to 99 hPa
Accuracy	± 2 hPa
Volume monitor (optional)	
Measurement range, paediatric sensor	0 to 500 mL
Measurement range, adult sensor	0 to 2000 mL
Accuracy, paediatric sensor	<100 mL: ± 10 mL 100 to 300 mL: ± 10% of reading
Accuracy, adult sensor	200 to 500 mL: ± 50 mL 500 to 2000 mL: ± 10% of reading
High expired minute volume alarm	0.1 to 80.0 L and OFF
Low expired minute volume alarm	0.1 to 79.9 L and OFF

14.5 Integrated breathing system (IBS)

Dimensions	
Size (H x W x D)	335 x 200 x 275mm (13.18 inches x 7.87 inches x 10.82 inches) (incl. APL and bellows chamber)
Weight	4 kg (8.8lb) (complete system excl. i-SORB CO_2 absorber)
Total volume	1 L with a filled absorber canister. The volume from the patient hoses (typically 0.5 L) should be added. During manual ventilation, the volume from the respiration bag and the connecting hoses should be added. During automatic ventilation, the 1.5 L volume from the bellows should be added.
APL valve	
Setting	SP, 5 to 75 hPa
Accuracy	± 7 hPa at 4 L/min
i-SORB CO_2 absorber (reusable & disposable)	
Capacity	Approx. 880g (1.94 lb.) soda lime
Volume (empty)	1420 mL

14.6 Gas measurements

External O_2 fuel-cell sensor (optional)

O_2% fuel-cell sensor (optional)	
Measurement range	0 to 100% O_2 (v/v)
Accuracy	± 2% (v/v) at constant temperature, and pressure
High O_2% alarm	19 to 99% and OFF
Low O_2% alarm	18 to 100%
Sensor lifetime	More than 500,000 O_2% hours under normal conditions (equivalent to 33 months when placed in 25°C air)
Cross-gas interference	Less than 1.25% O_2 response to anaesthetic agents
Drift	Less than 1% O_2 over 24 hours
Rise time	Less than 10.5 sec for 90% of final value
System response time	Less than 17 sec.
High altitudes calibration	The O_2 fuel-cell sensor is not equipped with automatic barometric pressure compensation, therefore requires re-calibration when installed at high altitudes

Integrated multigas module (optional)

Correction	
Barometric pressure, samplegas pressure, temperature and full spectral interference correction	
Warm-up time	
Time needed to reach ISO accuracy specifications	45 sec. after powering up
Time needed to reach “full accuracy” specifications	2 min after powering up

ISO specifications	As “full accuracy” specs, but derated as follows: CO_2 Add ± 0.3% CO_2 AA: Add ± 8% of reading N_2O: Add ± (2% N_2O + 8% of actual reading)
Water trap	
Capacity	10 mL (Adult) / 6 mL (Neonatal)
Emptying interval (Half full, worst case)	Adult: 17 h @ 200 mL/min, 37°C, 100% RH Neonatal: 20 h @ 120 mL/min, 37°C, 100% RH
Sample flow	
Platinum multigas module	200 mL/min* with adult water trap installed (* +/-10%) 70 mL/min with neonatal water trap installed (* +/-10mL/min)
Argentum multigas module	120 mL/min (*+/-10%)
Measured parameters	
Insp. O_2%	0 to 100% Resolution: 1%
Exp. O_2%	0 to 100% Resolution: 1%
Insp. N_2O%	0 to 100% Resolution: 1%
Exp. N_2O%	0 to 100% Resolution: 1%
Insp. CO_2	0 to 100% Resolution: 0.1%
Exp. CO_2	0 to 100% Resolution: 0.1%
Insp. AA%	HAL, ENF, ISO: 0 to 7.5% SEV: 0 to 9% DES: 0 to 20% Resolution: 0.1%
Exp. AA%	HAL, ENF, ISO: 0 to 7.5% SEV: 0 to 9% DES: 0 to 20% Resolution: 0.1%
Resp. Rate	0 to 100 resp./min
Calculated parameters	
MAC	0 to 10. Resolution: 0.1
Resp. rate measurement accuracy	
Resp. Rate 0 to 60 resp./min	± 1 resp./min
Resp. Rate >60 resp./min	Not specified
Resp. Rate detection	CO_2 variation in measured CO_2
Gas measurement, typical response time 10–90% (Adult water trap and sample line)	
O_2	1000 msec.
N_2O	650 msec.
CO_2	450 msec.
AA	450 msec. (once the agent has been identified)
Gas measurement, typical response time 10–90% (Neonatal water trap and sample line)	
O_2	Platinum: 1750 msec. Argentum: 900 msec.
N_2O	1100 msec.
CO_2	500 msec.
AA	500 msec. (once the agent has been identified)
System response time	
Adult water trap and gas sample tube	max 3 m with inner diam. 1.5 mm: Max 6 sec.
Neonatal water trap and gas sample tube	max 3 m with inner diam. 0.9 mm: Max 8 sec.

PRIMARY ANESTHETIC AGENT IDENTIFICATION	
A primary anesthetic agent is identified by the multigas module if the concentrations are higher than:	
Halothane	0.25% HAL (0.50% at ISO spec.)
Enflurane	0.15% ENF (0.40% at ISO spec.)
Isoflurane	0.15% ISO (0.40% at ISO spec.)
Sevoflurane	0.15% SEV (0.40% at ISO spec.)
Desflurane	0.15% DES (0.40% at ISO spec.)
SECONDARY ANESTHETIC AGENT IDENTIFICATION	
A secondary anesthetic agent is identified by the multigas module if the concentrations are higher than:	
Halothane	0.30% HAL (0.50% at ISO spec.)
Enflurane	0.30% ENF (0.50% at ISO spec.)
Isoflurane	0.30% ISO (0.50% at ISO spec.)
Sevoflurane	0.30% SEV (0.50% at ISO spec.)
Desflurane	0.30% DES (0.50% at ISO spec.)
ALARM	
Insp. O_2% high	18 to 100% and OFF resolution: 1%
Insp. O_2% low	18 to 100% resolution: 1%
Exp. O_2% high	10 to 100% and OFF resolution: 1%
Exp. O_2% low	10 to 100% resolution: 1%
Insp. N_2O%	high Fixed at 82%
Insp. CO_2 high	0.1 to 3.0% and OFF resolution: 0.1%
Insp. CO_2 low	0.1 to 3.0% and OFF resolution: 0.1%
Exp. CO_2 high	0.0 to 15.0% and OFF resolution: 0.1%
Exp. CO_2 low	0.0 to 15.0% and OFF resolution: 0.1%
Insp. AA% high	0.0 to 30.0% resolution: 0.1%
Insp. AA% low	0.0 to 30.0% and OFF resolution: 0.1%
Exp. AA% high	0.0 to 30.0% resolution: 0.1%
Exp. AA% low	0.0 to 30.0% and OFF resolution: 0.1%
Resp. Rate high	4 to 80 resp./min and OFF resolution: 1 resp.
Resp. Rate low	4 to 80 resp./min and OFF resolution: 1 resp.

NOTE

The humidity content in the sampled gas is adapted to ambient humidity level in the Nafion section of the tubing that connects multigas module with the water trap receptacle. The multigas module then uses a fixed correction of 11 hPa (cmH_2O) to compensate for the influence of water vapor in the gas sample, when converting the gas readings to ATPD. Any other ambient H_2O partial pressure will dilute the gas sample to a different extent, causing a certain measurement error. Under typical operating conditions however, this effect is not noticeable. An increase in the ambient H_2O partial pressure to 30 hPa (cmH_2O) (i.e. 28°C, 80% RH or 33°C, and 60% RH) will cause a general error for all gases of only -2% REL.

Gas measurement accuracy ("full accuracy" specifications)

Resp. rate 1 to 60 resp./min

Gas	Concentration [%REL]	Tolerance [%ABS]	Interference [%ABS]	
CO_2	0–1 1–5 5–7 7–10 >10	± 0.1 ± 0.2 ± 0.3 ± 0.5 Not specified	N_2O O_2 All agents	0.1 0.1 0.1
N_2O	0–20 20–100	± 2 ± 3	CO_2 O_2 All agents	0.1 0.1 0.1
Platinum: O_2	0–25 25–80 80–100	± 1 ± 2 ± 3	CO_2 N_2O All agents	0.2 0.2 1.0
Argentum: O_2	0–40 40-60 60-80 80-100	± (1+1% of meas. value) ± (1+2% of meas. value) ± (1+3% of meas. value) ± (1+4% of meas. value)	CO_2 N_2O All agents	<0.3 <0.3 <0.3
HAL, ENF, ISO	0–1 1–5 >5	0.15 0.2 Not specified	CO_2 N_2O O_2 2^{nd} agent	0 0.1 0.1 0.1 (typical)
SEV	0–1 1–5 5–8 > 8	± 0.15 ± 0.2 ± 0.4 Not specified	CO_2 N_2O O_2 2^{nd} agent	0 0.1 0.1 0.1 (typical)
DES	0–1 1–5 5–10 10–15 15–18 >18	± 0.15 ± 0.2 ± 0.4 ± 0.6 ± 1 Not specified	CO_2 N_2O O_2 2^{nd} agent	0 0.1 0.1 0.1 (typical)
Note: Measurement drift is included in these specifications				

REGARDING CROSS-GAS INTERFERENCE

Contaminant	Interference [% ABS]				
	CO_2	N_2O	Agents	O_2 - Platinum	O_2 - Argentum
<100% Xenon	0.1	0	0	0.5	0.3
<50% He	0.1	0	0	0.5	0.3
Metered dose inhaler propellants	Unspecified	Unspecified	Unspecified	0.5	Unspecified
<1% Ethanol	0	0	0	0.5	0.3
Saturated Iso-propanol vapour	0.1	0	0	0.5	Unspecified
<1% Acetone	0.1	0.1	0	0.5	0.3
<1% Methane	0.1	0.1	0	0.5	0.3

NOTE

- Inaccuracy specifications are affected by the breath rate and I:E change. The end-tidal gas reading is within specification for breath rate below 15BPM and I:E ratio lower than 1:1 relative to the gas readings without breath; Add ±6%REL to inaccuracy for HAL and O_2 for breath rate higher than 15 BPM; Add ±6%REL to inaccuracy for all gases for breath rate higher than 30 BPM (inaccuracy for HAL and O_2 are unspecified in this case); inaccuracy is unspecified for breath rate higher than 60 BPM.
- The data sample rate is 25 Hz. Data presentation is 50 Hz, every second data point is interpolated.
- Inspiratory and end tidal CO_2 concentration readings are identified by AION™ multigas Module using the lowest and highest values respectively of the temporal CO_2-curve. Corresponding readings of N_2O and anesthetic agents (if applicable) are taken at the same point in time. Inspiratory and end-tidal O_2 concentration readings (if applicable) are identified by the O_2 mean value during the respiratory phase as identified by the temporal CO_2 curve. Once correctly identified, the highest and lowest O_2 concentration readings during each part of the phase will be presented as inspiratory and end-tidal O_2 respectively.

14.7 Environment

Storage and transportation temperature	-20°C to +50°C (optional O_2 fuel-cell sensor: 0°C to +50°C)
Ambient temperature during use	10°C to 40°C
Relative humidity	10 to 90% RH (non condensing)
Storage and transportation pressure	630 hPa to 1060 hPa (63 kPa to 106 kPa)
Ambient pressure during use	700 to 1060 mbar, equal to 3000 m to -100 m
The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals. The equipment is not intended for use in domestic areas.	

14.8 Standards

DAMECA AX500 COMPLIES WITH THE FOLLOWING STANDARDS
ISO 8835-2 : 2007
ISO 8835-3 : 2007
ISO 8835-5 : 2004
ISO 10079-3 : 2009
ISO 10524-1 : 2006
ISO 10993-1 : 2009
ISO 15001 : 2010
ISO 21647 : 2009
ISO 80601-2-55 : 2011
ISO 80601-2-13 : 2011
ISO 5356-1 : 2004
ISO 5359 : 2008
ISO 15223-1 : 2012
ISO 18082 : 2014
ISO 407 : 2004
IEC 60601-1 : 1988 + A1 : 1991 + A2 : 1995 + Corr : 1995 (2nd ed.)
IEC 60601-1 : 2005 + A1 : 2012 + C1 (3rd ed.)
IEC 60601-1-1 : 2000
IEC 60601-1-2 : 2007
IEC 60601-1-2 : 2014
IEC 60601-1-4 : 1996 + A1 : 1999
IEC 60601-1-6 : 2004
IEC 60601-1-6 : 2010 + A1 : 2013
IEC 62366-1 : 2015
IEC 60601-1-8 : 2006 + A1 : 2012
IEC 60601-2-13 : 2003 + A1 : 2006
IEC 62304 : 2006

IEC 60068-2-27 : 2008	
IEC 60068-2-64 : 2008	
EN55011 (reference IEC 60601-1-2) shall be Class A	
ASTM D 4169-09 : 2008	
EN 980 : 2008	
EN 1041 : 2008	
CGA C-9 : 2004	
CGA V-5 : 2008	
CLASSIFICATION ACCORDING TO EN 60601-1	
Class **I** equipment	Type of protection against electrical shock
Type **B** equipment	Degree of protection against electrical shock
Continuous operation	Mode of operation
CLASSIFICATION ACCORDING TO DIRECTIVE 93/42EEC CONCERNING MEDICAL EQUIPMENT	
The anaesthesia machine, model Dameca AX500, is classified as Class IIb.	

15 EMC DECLARATION

ELECTROMAGNETIC COMPATIBILITY (EMC)

SPECIFICATIONS

Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. You must operate your anaesthesia machine according to the EMC information provided in this guide. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

NOTE

The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class a). The Dameca AX500 is not intended for use in domestic areas.

ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration – electromagnetic emissions		
The anaesthesia machine is intended for use in the electromagnetic environment specified below. The customer or user of the anaesthesia machine should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
Radio Frequency (RF) emissions CISPR 11	Group 1	The anaesthesia machine 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.
RF emissions CISPR 11	Class A	The anaesthesia machine is suitable for use in all establishments other than domestic 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 emissions IEC 61000-3-3	Complies	

ELECTROMAGNETIC IMMUNITY

The essential performance of the Dameca AX500 is delivery of fresh gas flow to the patient and ventilation of the patient. Electromagnetic disturbances will not impact the delivery of fresh gas flow to the patient, but it may impact the ventilation of the patient. If that is the case, manual ventilation can be applied by using the manual respiration bag.

All essential performance of the machine was maintained during EMC testing.

<table>
<tr><th colspan="5">Guidance and manufacturer's declaration - electromagnetic immunity</th></tr>
<tr><td colspan="5">The anaesthesia machine is intended for use in the electromagnetic environment specified below. The customer or user of the anaesthesia machine should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601-1-2 Ed3 Test Level</th><th>IEC 60601-1-2 Ed4 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment - guidance</th></tr>
<tr><td>Electrostatic discharge (ESD)
IEC61000-4-2</td><td>Enclosure and input/output lines
±6 kV contact
±8 kV air</td><td>Enclosure and input/output lines
±15 kV air</td><td>Enclosure and input/output lines
±8 kV contact
±15 kV air</td><td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td></tr>
<tr><td>Radiated RF
IEC61000-4-3</td><td>10 V/m for
80 MHz-2.5 GHz</td><td>3 V/m for
80 MHz-2.7 GHz</td><td>10 V/m for
80 MHz-2.7 GHz</td><td></td></tr>
<tr><td>Electrical fast transient/
burst IEC61000-4-4</td><td colspan="2">±2 kV for power supply lines
±1 kV for input/output lines</td><td>±2 kV for power supply lines
± 1 kV for input/output lines</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Surge
IEC61000-4-5</td><td colspan="2">±1 kV line(s) to line(s)
±2 kV line(s) to earth</td><td>±1 kV line(s) to line(s)
±2 kV line(s) to earth</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Conducted disturbances induced RF fields
IEC61000-4-6</td><td>3 V for
0.15 MHz- 80 MHz
10 V for
0.15 MHz-80 MHz in ISM bands 80 % AM at 1 kHz</td><td>3 V for
0.15 MHz- 80 MHz
6 V for
0.15 MHz-80 MHz in ISM bands 80 % AM at 1 kHz</td><td>3 V for
0.15 MHz- 80 MHz
10 V for
0.15 MHz-80 MHz in ISM bands</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the anaesthesia machine, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[b], should be less than the compliance level in each frequency range.[c]
Interference may occur in the vicinity of equipment marked with this symbol:
  </td></tr>
<tr><td>Radiated RF
IEC61000-4-3</td><td>10 V/m for
80 MHz-2.5 GHz</td><td>3 V/m for
80 MHz-2.7 GHz</td><td>10 V/m for
80 MHz-2.7 GHz</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity				
The anaesthesia machine is intended for use in the electromagnetic environment specified below. The customer or user of the anaesthesia machine should assure that it is used in such an environment.				
Immunity Test	**IEC 60601-1-2 Ed3 Test Level**	**IEC 60601-1-2 Ed4 Test Level**	**Compliance Level**	**Electromagnetic Environment - guidance**
Voltage dips, short interruptions and voltage variations on power supply lines IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles	0% UT for 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	0% UT for 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	Main power quality should be that of a typical commercial or hospital environment. If the user of the anaesthesia machine requires continued operation during power mains interruptions. It is recommended that the anaesthesia machine be powered from an uninterruptible power supply or a battery.
	40% UT (60% dip in UT) for 5 cycles	0% UT for 1 cycle	40% UT (60% dip in UT) for 5 cycles 0% UT for 1 cycle	
	70% UT (30% dip in UT) for 25 cycles	-	70% UT (30% dip in UT) for 25 cycles	
	<5% UT (>95% dip in UT) for 5 sec	0% UT for 5 sec	<5% UT (>95% dip in UT) for 5 sec 0% UT for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	3 A/m	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Immunity to RF wireless communications equipment. Enclosure port immunity. IEC61000-4-3	-	27 V/m at 385 MHz, pulse modulation, 18 kHz	27 V/m	TETRA 400: 380-390 MHz band
	-	28 V/m at 450 MHz, FM ±5 kHz deviation 1 kHz sine	28 V/m	GSMRS 460; FRS 460: 430-470 MHz band
	-	9 V/m at 710 MHz, 745 MHz, 780 MHz Pulse modulation 217 Hz	9 V/m	LTE Band 13, 17 704-787 MHz band
	-	28 V/m at 810 MHz, 860 MHz, 930 MHz Pulse modulation 18 Hz	28 V/m	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5: 800-960 MHz band
	-	28 V/m at 1720 MHz, 1845 MHz, 1970 MHz Pulse modulation 217 Hz	28 V/m	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS: 1700-1990 MHz band
	-	28 V/m at 2450 MHz Pulse modulation 217 Hz	28 V/m	Bluetooth; WLAN 802.11 b/g/n; RFID 240; LTE Band 7: 2400-2570 MHz band
	-	9 V/M at 5240 MHz, 5500 MHz, 5785 MHz Pulse modulation 217 Hz	9 V/m	WLAN 802.11 a/n: 5100-5800 MHz band

NOTE

In this table, UT is the A.C. mains voltage prior to application of the test level.

RECOMMENDED SEPARATION DISTANCE

In the following table, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[a]

Portable and mobile RF communications equipment should be used no closer to any part of the anaesthesia machine, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[b], should be less than the compliance level in each frequency range.[c]

Interference may occur in the vicinity of equipment marked with this symbol: 

Immunity Test	IEC 60601-1-2 Ed3 Test Level	IEC 60601-1-2 Ed4 Test Level	Compliance Level	Recommended separation distance
Radiated RF EM fields IEC61000-4-3	10 V/m 80 MHz-2.5 GHz	3 V/m 80 MHz-2.7 GHz	10 V/m	$d = [\frac{12}{10}]\sqrt{P}$ 80 MHz-800 MHz $d = [\frac{23}{10}]\sqrt{P}$ 800 MHz-2.7 GHz
Immunity to RF wireless communications equipment. Enclosure port immunity. IEC 61000-4-3	-	27 V/m at 385 MHz	27 V/m	$d = [\frac{6}{27}]\sqrt{P}$ 380 MHz-390 MHz
	-	28 V/m at 450 MHz	28 V/m	$d = [\frac{6}{28}]\sqrt{P}$ 430 MHz-470 MHz
	-	9 V/m at 710 MHz, 745 MHz, 780 MHz	9 V/m	$d = [\frac{6}{9}]\sqrt{P}$ 704 MHz-787 MHz
	-	28 V/m at 810 MHz, 860 MHz, 930 MHz	28 V/m	$d = [\frac{6}{28}]\sqrt{P}$ 800 MHz-960 MHz
	-	28 V/m at 1720 MHz, 1845 MHz, 1970 MHz	28 V/m	$d = [\frac{6}{28}]\sqrt{P}$ 1700 MHz-1990 MHz
		28 V/m at 2450 MHz	28 V/m	$d = [\frac{6}{28}]\sqrt{P}$ 2400 MHz-2570 MHz
	-	9 V/M at 5240 MHz, 5500 MHz, 5785 MHz	9 V/m	$d = [\frac{6}{9}]\sqrt{P}$ 5100 MHz-5800 MHz
Conducted RF IEC61000-4-6	3 VRMS 150 kHz-80 MHz Outside ISM bands	3 VRMS 150 kHz-80 MHz Outside ISM bands	3 VRMS	$d = [\frac{3.5}{3}]\sqrt{P}$
	10 VRMS 150 kHz-80 MHz in ISM bands	6 VRMS 150 kHz-80 MHz in ISM bands	10 VRMS	$d = [\frac{12}{10}]\sqrt{P}$

NOTE

At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE

These guidelines may not apply in all situations. electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[b] Fields strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the machine is used exceeds the applicable RF compliance level above, the machine should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the machine.

[c] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

[d] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[e] See above.

Recommended separation distances from portable and mobile RF communication equipment

The anaesthesia machine is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the machine can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the machine as recommended below, according to the maximum output power of the communications equipment.

In the following table, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter – guidance			
	150 kHz to 80 MHz outside ISM bands $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \left[\frac{12}{10}\right]\sqrt{P}$	80 MHz to 800MHz $d = \left[\frac{12}{10}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{23}{10}\right]\sqrt{P}$
0.01 W	0.117 m	0.120 m	0.120 m	0.230 m
0.1 W	0.369 m	0.379 m	0.379 m	0.727 m
1 W	1.167 m	1.200 m	1.200 m	2.300 m
100 W	11.667 m	12.000 m	12.000 m	23.000 m

Service	Frequency band	Maximum power	Separation distance - guidance
TETRA 400	380 MHz – 390 MHz	1.8 W	0.3 m
GMRS 460; FRS 460	430 MHz – 470 MHz	2 W	0.3 m
LTE Band 13, 17	704 MHz – 787 MHz	0.2 W	0.3 m
GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	800 MHz – 960 MHz	2 W	0.3 m
GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	1700 MHz – 1990 MHz	2 W	0.3 m
Bluetooth; WLAN; RFID 2450; LTE Band 7	2400 MHz – 2570 MHz	2 W	0.3 m
WLAN 802.11 a/n	5100 MHz – 5800 MHz	0.2 W	0.3 m

NOTES

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTES

The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTES

An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges in the ism frequency bands: between 150 kHz and 80 MHz and between 80 MHz to 2.5 GHz. This is intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTES

These guidelines may not apply in all situations. electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

16 Abbreviations and terms

Abbreviation	Description
AA	Anaesthetic Agent
AGSS	Anaesthesia Gas Scavenging System, same as WAGD
Air	Medical compressed air
APL	Adjustable Pressure Limiting
BTPS	Body temperature and pressure, saturated.
Compliance or compl.	A measure of the stiffness of tubings. Two kinds of compliance: Compliance in the system during self-test and compliance during patient case.
DES	Desflurane
DUT	Device Under Test
ENF	Enflurane
Exp	Expiratory
FiO_2	Fraction of inspired oxygen
GUI	Graphical User Interface
HAL	Halothane
hPa	Hectopascal, unit of pressure
IBS	Integrated Breathing System
I:E or I:E ratio	Inspiratory-Expiratory; the ratio between the iinspiratory time and expiratory time
Insp	Inspiratory
ISO	Isoflurane
kPa	Kilopascal, unit of pressure
MAC	Minimum Alveolar Concentration
MPL	Maximum Pressure Limit
MV	Minute Volume
NPL	Negative Pressure Limit
Pa	Pascal (1 mbar = 100 Pa or 1 hPa), unit of pressure
Paw	Patient airway pressure
PCV	Pressure Controlled Ventilation
Peak	Peak Inspiratory Airway Pressure
PEEP	Positive End Expiratory Pressure
PM	Power Management
PSV	Pressure Supported Ventilation
psi	Pound force per square inch, unit of pressure
PRVT	Pressure Regulated Volume Target
RR	Respiration Rate
SEV	Sevoflurane
SIMV	Synchronized Intermittent Mandatory Ventilation
SLPM	Standard Liter per Minute
SP	Spontaneous breathing

Abbreviation	Description
STPD	Standard Temperature and Pressure (1013 mbar), Dry
TV	Tidal Volume
V(AC)	Voltage Alternating Current
VAC	Vacuum
VCV	Volume Controlled Ventilation
VSV	Volume Supported Ventilation
WAGD	Waste Anaesthesia Gas Disposal, same as AGSS

17 INDEX

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