

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To whom it may concern



Our reference

COVID-19 – PM Anaesthesiology

Phone

+49 451 882-2665

Fax

+49 451 882-72665

E-mail

Moritz.Rahlf-Luong@draeger.com

Please visit the Dräger COVID-19 website
https://www.draeger.com/en_corp/Corporate/Coronavirus-COVID-19
for updates and other useful information

April 3rd, 2020

COVID-19: Usage of Dräger anaesthesia devices for long-term ventilation

Rev. 3

New contents and updates to the second version of this letter on March 20th, 2020 are highlighted. If you have missed any updates from a previous version, please read the complete document.

Dear Customers and Health Care Professionals,

The World Health Organization (WHO) declared COVID-19 a pandemic on March 11th, 2020 with currently over 1,000,000 confirmed cases of the coronavirus illness reported in over 160 countries worldwide. The pandemic has created a high demand for mechanical ventilation that may exceed the number of available ICU ventilators in hospitals treating patients with the disease. In the last few days, many customers and health care professionals have approached us to obtain information about possibly using Dräger anaesthesia devices for long-term ventilation as an alternative ventilator for ICU patients when existing devices are fully utilised and there is no other ventilator option.

Under these special circumstances, we believe it is our responsibility to provide some insights both (i) on the legal and regulatory perspective as well as (ii) on some known limitations of Dräger anaesthesia devices for long-term ventilation.

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
VAT no. DE135082211

Bank details:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift-Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

Chairman of the Supervisory Board
for Drägerwerk AG & Co. KGaA
and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

I. Legal and Regulatory Perspective

WARNING: The following information on the legal and regulatory perspective is limited to the laws in force in the European Union (EU) as of the date of this letter and provides only general guidance. Please contact your legal counsel for guidance on your particular case.

The intended use of each Dräger anaesthesia device is described in the relevant instructions for use. Although the wording of the intended use may vary among the devices, the content is very similar: The devices are specified for use during surgical or diagnostic interventions under the constant supervision of the user(s).

Any use of the device outside of the intended use specified in the instructions for use (e.g. long-term ventilation) constitutes off-label use.

If a device is used off-label, the user recognises that it is not the intended use of the device and does so at their own responsibility and at his own (liability) risk. However, in a situation in which a patient requires long-term mechanical ventilation but cannot be ventilated due to a lack of intensive care ventilators, the benefit of being able to ventilate such a patient with a Dräger anaesthesia device has to be weighed against the risk of the off-label usage of a Dräger anaesthesia device. This risk benefit assessment and the resulting decision have to be made by the responsible health care professional, based on the circumstances of the particular case.

II. Known Limitations of Dräger Anaesthesia Devices regarding Use in Long-Term Ventilation

WARNING: The following information is based on our currently available knowledge as of the date of this letter. It only applies to Dräger anaesthesia devices still being marketed. It is most likely not complete or exhaustive. If you detect important points that are missing, please let us know.

WARNING: Dräger as the manufacturer cannot and is not allowed to market or promote or sign-off such off-label use of Dräger anaesthesia devices. The following information is therefore provided only to give the responsible health care professional a better basis for decision-making. If a device is used off-label, the user does so under their own responsibility and at their own (liability) risk.

The following proposals support the targets that the off-label-use is as secure as possible, and that as many anaesthesia devices as possible will maintain their ventilation capacities, even under long-term ventilation.

Please note: Not all of the following mentioned or shown products, functions or services are available in every country.

- Anaesthesia devices have a different working principle and different user interface (e.g. different operating modes) than intensive care ventilators. Therefore, **medical personnel using the device must be well trained and familiar with the unique performance characteristics of the devices.**
- Anaesthesia devices should be used only in **rooms with adequate ventilation.**
- Before connecting a patient, the user must be able to check the proper device status, ensure that all accessories (e.g. ventilation hoses, bacteria filter, gas sampling line, manual breathing bag, water traps) are properly connected and that the device is able to generate gas flow and pressure at the patient connector. With the exception of Australia and New Zealand, the connectors for the manual breathing bag and ventilation hoses have the same diameter. Therefore, the risk of incorrectly connected patient hoses is given. A false connection (e.g. bag hose connected to inspiratory port) would make the ventilation of the patient impossible. As a result, **particularly when connecting a patient to an anaesthesia device,** the user requires **device knowledge and clinical experience** with anaesthesia devices. Directly before connecting the patient, the user has to check if the device is able to deliver pressure to the

patient connector and that by unblocking the patient connector the pressure can be released and gas can flow out (see e.g. website of European Patient Safety Foundation: <https://www.eupsf.org/safety-alert-wrong-tube-connections>)

- To prepare the software (clean internal memory components) of a Dräger anaesthesia system for long-term ventilation, we recommend that you restart (switch the device off and on again at the user interface) the device before preparing it for a new patient.
 - o Perseus & Atlan family: A restart is required after 28 days, but only after switching to standby. Starting operation again will only be possible in that situation, after a restart and system test of the device.
 - o Zeus IE: After 7 days a technical alarm (blue) message will appear and after 14 days a cautionary (yellow) alarm to remind the user to restart the device. If the alarm appears, perform the restart before performing the next system test.
 - o Primus family: A restart is necessary to access the system test.
 - o Fabius family: The restart procedure is part of the Fabius system test and occurs by pressing “Run System Test”. No separate restart required.
- The instructions for use state a manual **resuscitator must always be available at the device** which enables back-up ventilation of the patient in case of problems or malfunctions with the device. Particularly for users with limited knowledge of anaesthesia devices, it is particularly important that **in case of irregularities** or unexpected system behaviour impairing patient therapy, the patient has to be disconnected from the anaesthesia device and ventilated with an operator powered **resuscitator**. **Due to the situation of the patient, it is recommended that you have a manual resuscitator available that allows the application of a PEEP.**
- The user has to understand **the Man/Spon mode (Manual or Spontaneous Ventilation)**, which is a unique ventilation mode that is not available in most intensive care ventilators. This mode can be life-saving in case of a failure of automatic ventilation and in absence of a resuscitator. The influence of the **APL valve has to be understood as well**. Users with no

anaesthesia background may expect that it also limits airway pressure during mechanical ventilation. **The APL valve has no influence on mechanical ventilation.** It is only active in Man/Spon mode. In the event of a ventilator failure, Man/Spon becomes active automatically and the fresh gas flow will make the airway pressure rising up to the APL setting. Therefore, **in mechanical ventilation, the APL valve always has to be set to a value suitable for the patient.** When setting the APL valve to the desired PEEP level (or alternatively SPONT, which equals zero), you prevent excessive airway pressures from being applied to the patient in the event of a ventilator failure. For the system test, the APL valve must be set to a relatively high value. Therefore, the user also has to actively reduce this value for mechanical ventilation.

- The user interface of Dräger anaesthesia devices cannot be protected against non-authorized users. Therefore, the **operating organisation must ensure that non-authorized users cannot approach the device** to avoid settings being changed, or therapy being stopped (no alarm is generated when the device is switched to standby).
- The alarm and safety systems of Dräger anaesthesia devices are designed for the user to always be within 4 metres (~13 feet) of the device. This allows the user to quickly recognize and respond in the event of an alarm or malfunction. Thus, the alarm volume always has to be set to a sufficiently loud level, particularly in noisy environments. The alarm distribution via serial interface is not designed in a redundant (fail-safe) way. Therefore, remote supervision (e.g. via a central station) is not sufficient. In situations where a user is not within direct proximity of the device, it has to be ensured that the **alarm volume is set to maximum (100%)** to increase the probability that potentially life-threatening situations are recognised in time.
- To enable the device to generate the necessary alarms, **set patient-specific limits for all alarms** and limits may have to be changed over time to adapt to changing clinical situations. Alarm limits for the minute volume (lower and upper limit) and the expiratory CO₂ (lower and upper limit) are particularly important for generating alarms when hypo- or hyperventilation occurs. **Additionally, the alarm limit for FiO₂ (lower limit) has to be adjusted because FiO₂ cannot be set directly.**
- In contrast to most ICU ventilators some Dräger anaesthesia devices also have an adjustable Paw low alarm limit. This alarm limit has to be set either to “automatic” / “AUTO” (if available) or

between PEEP and inspiratory pressure / plateau pressure to detect unintentionally applied continuous airway pressures as well as intrinsic PEEP situations.

- Please be aware that in Dräger anaesthesia devices, alarm notifications are automatically removed when the alarm situation that caused the alarm is no longer valid. In general, the alarm design of ICU ventilators is completely different in this respect. Therefore, it is recommended that the user **checks periodically the alarm history / alarm log of the anaesthesia device** to see if any alarms have been generated in the absence of the user.

- The **devices are designed to be tested every 24 hours** to ensure readiness for operation. If the device test is not done, the readiness of operation is not tested, and particularly the flow measurement may become inaccurate. **In general never rely on a single measured value for clinical decisions.** Unlike many ICU ventilators, the flow measurement of the anaesthesia device cannot be calibrated during operation. **Measured values may change their colour to indicate an inaccurate status.** The accuracy of gas measurement should not be affected because the gas measurement modules perform a zeroing during operation independently of the system test, **except the mainstream O₂-sensor of the Fabius family.** Please be aware that **the anaesthesia devices may raise technical alarms regarding required calibrations of flow measurement and the Fabius FiO₂ measurement; nevertheless these values can be used in the case of long-term ventilation. If in doubt, perform a system test.**

- To perform the system test, the patient must be disconnected from the anaesthesia device. During this time, sufficient ventilation of the patient (e.g. via the resuscitator) has to be ensured. Because the system test takes up to 8 minutes (depending on the device type), the assistance of an experienced user is required for this step. **Before starting the system test for any device of the Atlan-, Primus-, Fabius families, it is important to inspect the piston membrane for condensation and remove any condensation.** If, for clinical reasons, it is not feasible to perform a system test every 24 hours, we recommend to perform the test **at least every 72 hours** to reduce the likelihood of device malfunctions. **The system test always consists of a manual part (checklist) and an automatic part, for which both have to be performed.**

- **Each time the anaesthesia device is prepared for long-term ventilation of a new patient, perform a complete system test (not only a leakage test).**

- Since Dräger anaesthesia devices are not designed for long-term ventilation, the **overall status of the device and its accessories has to be checked regularly** (at least every 12 hours, ideally more frequently). In particular, the following situations have to be prevented: exhausted CO₂-absorber, full gas measurement water trap, increased water accumulation in breathing hoses, and excessive condensation at filters and HMEs (heat and moisture exchangers) that may lead to increased resistance.
- One significant difference between intensive care ventilators and anaesthesia devices is that anaesthesia ventilators are based on a rebreathing system and adjustable fresh gas flows. This requires the use of a CO₂ absorber to prevent high CO₂ levels in the circuit. It is important to examine the CO₂ absorber and change it before it is exhausted. An exhausted absorber can be detected by an increasing inspiratory CO₂ measurement or a change in colour (purple) of the Dräger CO₂ absorber (see instructions for use of anaesthesia device and CO₂-absorber for more information). **Generally the absorber will absorb CO₂ and thus change colour from the bottom to the top. Due to the fact that high fresh gas flows dry out the CO₂ absorber there might be a colour change from the top to the bottom of the absorber. This does not impact the absorption capability of the soda lime and does not pose any risk to the patient unless volatile agents are used. An exchange of the absorber is not required in this case.** In the case of dosing volatile agents, it is important to avoid dry soda lime; please refer to **Attachment 1**. The **activation of an inspiratory CO₂ high alarm limit** helps to directly inform the user about an exhausted absorber.
- The anaesthesia device should never be operated without a CO₂ absorber, except when changing a used absorber. The **permanent use of a CO₂ absorber** ensures that the patient does not inhale inspiratory CO₂ even in the case of error – such as problems with the fresh gas supply and/or delivery. By using high fresh gas flows of at least 150% of the minute volume of the patient, there will only be limited rebreathing and therefore the absorber will last a longer time. **Nevertheless, the absorber should be changed every 7 days, regardless of whether the absorption capacity has been spent.**

- Only use Dräger absorber due to **minimal dust emission**. If using Perseus and Zeus IE with a reusable absorber please always use a fresh dust filter when exchanging the soda lime. Using soda limes of lesser quality may cause device failures.
- Zeus IE: Using the Fresh Gas Mode reduces the consumption of the soda lime.
- The rebreathing of exhaled patient gases is a significant difference from ICU ventilators. The oxygen concentration of the inhaled gas (measured as “FiO₂”) may differ from the set oxygen concentration in the fresh gas as the result of mixing fresh gas with rebreathed gas of the patient. Therefore, **pay special attention to FiO₂ values and the FiO₂ low-alarm limit**. The difference between the fresh gas oxygen concentration and FiO₂ can be reduced to a minimum by increasing the fresh gas flow to at least 150% of the minute volume. For further help regarding fresh gas settings please refer to Attachment 6.
- **The gas measurement of the anaesthesia device**, if included in the device, **always has to be connected**. Unlike many ICU ventilators, the gas measurement of anaesthesia devices is a side-stream monitoring. Therefore, the gas measurement values and waveforms have a delay of several seconds.
- Dräger anaesthesia devices work with an electronically driven ventilator (piston ventilator in Atlan-, Primus-, Fabius- family devices; blower ventilator in Zeus IE, Perseus). Thus these devices do not consume any driving gas, and the consumption of gases supplied by the central gas supply or from cylinders equals the fresh gas flow settings. For Example, if your fresh gas setting is FG-Flow 9 L/min and FG-O₂-concentration 50%, this will lead to a consumption of approx. 5.7 L/min AIR and 3.3 L/min O₂. Please note that when using active scavenging (AGS), an AGS ejector (up to 70 L/min), or ejector-driven suction unit (only temporarily, when using), the consumption of centrally supplied gases will be higher.
- The breathing bag of Dräger anaesthesia devices acts as a reservoir during mechanical ventilation. The exhaled breathing gas is captured in the breathing bag. Therefore, the breathing bag moves during mechanical ventilation. **The capacity of the breathing bag should always be sufficient**. A high fresh gas flow increases the robustness of the ventilation. When the fresh gas flow is too low, the manual breathing bag (reservoir for the patient gas) may collapse in a

leakage situation, which would impair the ventilation. In particular, patients breathing spontaneously might require very high tidal volumes, which they inhale from the manual breathing bag. **Using a very large breathing bag (e.g. Dräger 3 litre breathing bag) is recommended** to avoid having the breathing bag limit the spontaneous breath of the patient.

- In general, **leakages are not compensated** by Dräger anaesthesia devices. This has to be considered by the user, especially during all volume controlled ventilation modes. Otherwise, insufficient ventilation situations may occur. If leakages can't be avoided, the Pressure Control mode has an advantage in that it delivers the set inspiratory pressure independently of any leakage as long as the capacity of the breathing bag is sufficient. Depending on the device type, the PEEP level might not be maintained. In fresh gas deficit situations (leakage plus patient uptake are higher than fresh gas flow), ventilation will be affected and the immediate reaction of the operator is required (reduce leakage, increase FG flow). As an alternative, disconnect the manual breathing bag to entrain ambient air. This prevents a low fresh gas situation and increases the availability of ventilation. In this case, the resulting inspiratory oxygen concentration will be between the set fresh gas oxygen concentration and the 21% of the ambient air. If the fresh gas flow is high, less ambient air is entrained and the inspiratory oxygen concentration increases.
- In order to prevent the use of anaesthetic agents in a situation that might harm the patient or the patient's environment, it is recommended that you **disconnect all vaporisers/agent dosing modules** from the anaesthesia device and store them in the operation theatre. This is particularly important because even **very small concentrations of volatile agents may trigger malignant hyperthermia** (e.g. of the clinician or the patient). If use of anaesthetic agents is intended, please see the additional information about sedation with volatile agents in Attachment 1.
- The fresh gas flow must only contain a mix of oxygen and medical air. The use of nitrous-oxide (N₂O) during long-term ventilation must be prevented as users with no anaesthesia experience are possibly not familiar with the fact that a decrease of the oxygen concentration in the fresh gas flow would increase the N₂O concentration in the inspiratory gas. Therefore, it has to be ensured that **no N₂O hose and no N₂O cylinder are connected to the anaesthesia device.**

Furthermore, in Dräger anaesthesia devices with an electronic gas mixer (Zeus IE, Perseus A500, Atlan A350/A350XL, Primus/Primus IE) usage without N₂O has to be configured in the system configuration.

- **To avoid having the rebreathing of the patient create excessive additional humidity in the system, a fresh gas flow of at least 150% of the minute volume** of the patient is required. If the device has a heated breathing system, we recommend that the heating remains active for long-term therapy. Please refer to Attachment 6 if you have questions in regards to fresh gas settings.
- When using Primus, Primus IE, Perseus, Atlan A350/A350XL and Zeus Family, the **fresh gas flow can be additionally increased by opening the emergency O₂ flow control**. Please refer to Attachment 5. This gas is added to the already set fresh gas flow of the mixer. An alarm will occur. The priority can be reduced by resetting the alarm (only possible with some devices). If a vaporiser is installed and opened, the gas passes through the vaporiser. The usage of vaporisers with additional emergency O₂ flows added is not recommended.
- **If lower fresh gas flows are used** (e.g. due to shortage of supplied gases, need for volatile sedation, or need for increased humidity of the patient gas) more rebreathing will take place in the system, and
 - o condensation may compromise the system functionality (up to malfunction of ventilation)
 - o the consumption of soda lime will increase
 - o condensation may block filters in the patient circuit (especially a filter at the inspiratory port)

Therefore, we recommend that you:

- o **Do not to use a fresh gas flow less than 20%** of the minute volume of the patient or **less than 1 L/min**. Dealing with patients producing increased amounts of CO₂ (e.g. having high fever) significantly raise the fresh gas flow (e.g. to >50% of the minute volume).
- o Use **hose systems with water traps** in the inspiratory and expiratory limb; the longer the hoses, the better
- o **Do not use a filter at the inspiratory port** of the breathing system
- o Always use a mechanical filter, if available with HME at the Y-piece. Be aware that the filters may get clogged and have to be exchanged earlier; therefore, **set close alarm limits for minute volume low and Paw high**

- Perform a **system test every 24 hours** if possible and **empty the piston membrane** before performing the system test (Atlan-, Primus-, Fabius- families)
- **Set an alarm limit for FiO₂ low with adequate buffer** because the difference between the set fresh gas flow and the FiO₂ will increase and the system will react far slower to modifications of the O₂ (and vaporiser) settings
- **Set an alarm limit for inspiratory CO₂ high to an appropriate value**
- Check the following parts for humidity more regularly (at least every 4 hours)
 - water traps in patient hoses (drain, if condensation is detected)
 - water trap at the gas bench - Waterlock2 (drain, if more than 50% is filled with condensate)
 - filter (exchange if increased condensation is detected)
 - remaining capacity of CO₂ absorber (exchange at least when 2/3 has changed its colour to purple to reduce condensation in the breathing system; consumption of CO₂ absorber will increase significantly when lowering the fresh gas flow)
- The device has to be operated by a constant supervision of an operator with extensive knowledge of a rebreathing system

The measures above are very important for keeping the installed base of ventilators in your institution functional for the patients that need long-term ventilation.

- The use of **concentrated oxygen ("O₂ 93")** is not approved with Dräger anaesthesia devices. In case of shortages of pure oxygen, "O₂ 93" can be used with most of the Dräger devices. Ensure that the **fresh gas flow equals at least the minute volume** of the patient (to prevent argon accumulation). Make sure that the **alarm limit for FiO₂ low** is set to an appropriate value, considering enough buffer for reaction of the user, as an overload of an oxygen concentrator may result in lower oxygen concentration of the provided supply gas. Some accuracy values required by the anaesthesia workstation standards may not be fully achieved, e.g. patient flow measurement, fresh gas flow, fresh gas concentration. **Zeus IE should not be used with O₂ 93**. If unavoidable, the Zeus IE can be operated but the air dosage might automatically stop and oxygen ("O₂ 93") will be applied only. Corresponding alarms will occur.
- In case of shortages or loss of central gas supply, Dräger anaesthesia devices will continue with mechanical ventilation. Shortages will lead to alarms of the anaesthesia, please refer to the instructions for use and check under the chapter "Fault - Cause - Remedy". To ensure the desired FiO₂ level, an **O₂ backup cylinder is required**. For connection, check the instructions

for use. If both sources of oxygen (central gas supply and backup cylinders) are depleted, the hand bag (incl. the hose between the hand bag and the breathing system, or the flexible bag arm) has to be disconnected from the breathing system. The anaesthesia device will continue ventilation with ambient air (21% FiO₂ and no volatile agents can be applied anymore), because of the electrically driven ventilators.

- **To avoid oxygen accumulation in the direct environment of the device, a proper scavenging has to be ensured even if no anaesthetic agent is used.** For alternatives please see Attachment 4.

- **Regarding infection prevention, hospital guidelines have to be followed.** This includes the reprocessing of the device after usage on infectious patients (particularly the device surfaces) but also the adequate use of bacteria filters. **Only mechanical filters are suitable in long-term ventilation** because with electrostatic filters, the filtering performance is reduced when they become too humid. **The use of mechanical filters also ensures that the excess gas or gas that leaves the breathing system when the hand bag is detached will not be contaminated.** More information regarding infection prevention in the context of COVID-19 is provided in the Dräger 2019-nCoV infection prevention customer letters for anaesthesia and intensive care and their supplements.

- Two different solutions for the use of mechanical filters are recommended:

- Solution 1 – Passive humidification
 - Use of a combined element: Heat and Moisture Exchanger (HME) / mechanical breathing system filter (e.g. *Dräger TwinStar HEPA*)
 - Location: only at the patient connector (Y-piece)
- Solution 2 – Active humidification
 - In combination with active humidification, use two mechanical filters without HME (e.g. *Dräger SafeStar filter series*).
 - Location: at the inspiratory AND the expiratory ports of the anaesthesia device
 - Please consider the following information regarding active humidification in combination with anaesthesia devices.

- If possible from a clinical perspective, use HME / mechanical breathing system filters at the Y-piece (solution 1) with Dräger anaesthesia devices.
- The use of **active humidification** is not approved with Dräger anaesthesia devices. If, however, an active humidifier is used in this exceptional situation, rebreathed humid gas must not create excessive condensation in the breathing system of the anaesthesia device. Breathing circuits require **a water trap in the expiratory limb. Dual heated breathing circuits must not be used** with Dräger anaesthesia devices. Also, the use of filters or even HME/filters at the Y-piece must be avoided to prevent excessive breathing resistance due to clogged filters resp. HME/filters during active humidification. When using a filter at the expiratory port, the resistance can potentially exceed values demanded by the ISO 80601-2-13:2011 standard. Close monitoring of the respective ventilation, e.g. particularly narrow limits for the minute volume low alarm and vital parameters, are compulsory. Additionally, a filter must be used on the inspiratory port of the anaesthesia device. As mentioned before, only mechanic filters shall be used. **A high fresh gas flow of at least 150% of the minute volume helps avoid excessive condensation in the breathing system as well as at the filter at the inspiratory port.** Reprocessing of the anaesthesia device after each patient is essential and shall follow the recommendations for anaesthesia devices potentially contaminated with SARS CoV-2.
- The water trap (Waterlock2) at the gas measurement module of Dräger anaesthesia devices protects the gas measurement against humidity. **To ensure system functionality the water trap has to be emptied or exchanged before it becomes full.** Please refer to the IFU for how to drain the water trap. The required frequency of doing this depends on the humidity of the sample gas. For usage of the Dräger anaesthesia device with high fresh gas flows and a combined HME/ mechanical filter we expect that the filling level has to be checked every 12 hours. **If using the recommended filter on the Y-piece (combined Heat and Moisture Exchanger (HME) / mechanical breathing system filter (HMEF) or a mechanical breathing system filter) and the gas sampling line is connected on the device side of the filter, the water trap has to be exchanged at least every 4 weeks. If no mechanical filter or HMEF is used on the Y-piece or the gas sampling line is connected on the patient side of the filter, exchange the water trap at least every 7 days.**

- Modes that are not known by the user (e.g. Ext. Fresh Gas Outlet or Pause) should not be used. **When using Fabius devices with an installed Fresh Gas Outlet (FGO), ensure that the FGO is in the correct position and installed properly. See details in Attachment 2.** Furthermore, **several modes may behave differently than in intensive care ventilators.** Details are listed in the Attachment 1.
- **Negative pressures by suctioning** can harm the lung of the patient and impair the function of the anaesthesia device and thus may lead to **failures of the ventilation system.** Therefore, **reduce the power-setting of the suction system** accordingly if suctioning in a closed system / in-line suctioning or any other PEEP-saving suctioning procedures. **If in doubt, disconnect the anaesthesia device for endotracheal suctioning** (consider the loss of PEEP).
- **If a main component of the anaesthesia device,** such as the mixer, ventilator or screen **shows a failure, immediately switch to an alternative means of ventilation.**
- Modes, measurement values, settings, manoeuvres etc. that are possibly used with ICU ventilators might not be available in the anaesthesia devices.
- **Nebulisation of drugs and aerosol therapy** are not approved with anaesthesia devices. If aerosol or other drugs are given to the airways, malfunctions can occur. Without a mechanical filter between the connection port of the nebuliser and the anaesthesia device, malfunctions are very likely to occur (e.g. incorrect measurement of the gas analyser, erroneous measurement of expiratory flows, tidal and minute volumes). If no mechanic filter is used on the Y-piece, disconnect the sampling gas line during nebulisation and aerosol therapy.
- Ventilating **multiple patients with one device is not recommended.** Please refer to the Dräger customer letter “COVID-19: Usage of multiple patients on one ventilator”.

If you have any questions or comments, please do not hesitate to contact your local Dräger representative. As mentioned, feedback is highly appreciated and enables us to share new information about this subject with medical caregivers worldwide.

With kind regards,



Ines Thams
Risk Manager



Ralf Heesch
System Engineer



Moritz Rahlf-Luong
Product Management Anaesthesiology

Attachments:

Attachment 1 – Comments on Particular Modes of Operation

Attachment 2 – Overview of Ventilation Modes in Critical Care Ventilators and Terms Used in Different Dräger Anaesthesia Devices

Attachment 3 – Dräger Fabius Family with Installed Fresh Gas Outlet

Attachment 4 – Active Gas Scavenging (AGS) alternatives

Attachment 5 – Increasing Fresh Gas Flow by Opening the Emergency O₂ Flow Control

Attachment 6 – Fresh Gas Settings

Attachment 1 - Comments on Particular Modes of Operation

- **Volume Control and VC-Autoflow:** In most ICU ventilators the upper airway pressure alarm limit “Paw-high” is not only used for generating the airway pressure high alarm but also for limiting the maximum pressure generated by the therapy device. In Dräger anaesthesia devices the alarm limit is only used for generating the alarm but does not limit the pressure. For the pressure limitation, the **Pmax** setting is used, which also has to be set specific to the patient and the clinical situation.
- **Pressure Support:** When the patient triggers breaths with a lower frequency than the set minimum frequency (RRmin), the anaesthesia device remains in the Pressure Support mode and non-triggered breaths are given in addition to the spontaneously triggered breaths to achieve the set minimum frequency. In addition, the alarm “Apnea Ventilation” is generated. In many of the Dräger anaesthesia devices, the alarm can be configured to low or medium priority. As in long-term ventilation, the user might not be permanently in front of the device, so the medium alarm priority is recommended. Dräger anaesthesia devices have no dedicated apnea-time and apnea back-up ventilation mode as it is available in most ICU ventilators. **As minute volume in this case will decrease the operator has to react and choose an appropriate ventilation mode or adapt ventilation settings (e.g. higher RRmin).**
- **Non-Invasive Ventilation (NIV):** Dräger anaesthesia devices do not offer a dedicated NIV-mode. Therefore, the user has to pay particular attention to leakages when doing mask ventilation.
- **Nasal High Flow Therapy:** Dräger anaesthesia devices do not offer Nasal High Flow Therapy.
- **Sedation with volatile agents:** If the long-term ventilation is combined with sedation of the patient with anaesthetic agents, the direct environment of the patient has to be protected against surplus anaesthetic agent. Typically in the operating theatre, active scavenging takes care that the surplus of fresh gas is evacuated. In environments of use without active scavenging, please read Attachment 4. Caution: Even very small concentrations of anaesthetic agent may trigger malignant hyperthermia. Please check your respective regulations, e.g. employment protection requirements. When using high fresh gas flow for long-term ventilation, the CO₂ absorber will become dry and compounds can be produced when volatile agents are used. To reduce anaesthetic agent polluting the OR environment and to prevent the CO₂ absorber from becoming dry, the fresh gas flow should be reduced. Please refer to page 10 of this document. The reduction of fresh gas flow requires deep knowledge of the rebreathing function and will lead over time to difficulties with water condensation in the system that may even cause system failures. Permanent supervision by an experienced anaesthesia user is mandatory.


Attachment 2 – Overview of Ventilation Modes in Critical Care Ventilators and Terms Used in Different Dräger Anaesthesia Devices

Possibly your device does not dispose of all described modes – sometimes they are not ordered in the device configuration.

Fabius Family:

Mode name ICU ventilator	Mode key name Fabius
VC-CMV	Volume Control
PC-CMV	Pressure Control
VC-SIMV/PS	SIMV/PS
SPN-CPAP/PS	Pressure Support*
Not available	Man / Spon

Primus Family:

Mode name ICU ventilator	Mode key name Primus	Mode name on screen Primus
VC-CMV	Vol. mode	Volume
VC-SIMV	(Activate Trigger parameter)	Volume Sync
VC-SIMV/PS	(Activate Δ Pps parameter)	Volume Sync PressSupp
VC-CMV AutoFlow	Vol. AF mode	Volume AF
VC-SIMV AutoFlow	(Activate Trigger parameter)	Volume AF Sync
VC-SIMV/PS AutoFlow	(Activate Δ Pps parameter)	Volume AF Sync PressSupp
PC-CMV	Press. mode	Pressure
PC-SIMV	(Activate Trigger parameter)	Pressure Sync
PC-SIMV/PS	(Activate Δ Pps parameter)	Pressure Sync PressSupp
SPN-CPAP/PS	Press. Supp.	Press. Support*
SPN-CPAP	Press. Supp.	Press. Support CPAP
Not available	Man / Spon	Man. Spont.
Not available	 Symbol (Semi-open circuit)	Ext. Outlet
Not available	Monitor. mode (Standby screen: Soft Key)	Monitoring

***(with RRmin setting)**

Overview of Ventilation Modes in Critical Care Ventilators and Terms Used in Different Dräger Anaesthesia Devices

Possibly your device does not dispose of all described modes – sometimes they are not ordered in the device configuration.

Atlan Family:

Mode name ICU ventilator	Mode key name Atlan	Mode name on screen Atlan
VC-CMV	VC (selection CMV)	VC-CMV
VC-SIMV	(selection SIMV)	VC-SIMV
VC-SIMV/PS	(Activate PS parameter)	VC-SIMV/PS
VC-CMV AutoFlow	VC-AF (selection CMV)	VC-CMV AF
VC-SIMV AutoFlow	(selection SIMV)	VC-SIMV AF
VC-SIMV/PS AutoFlow	(Activate PS parameter)	VC-SIMV/AF/PS
PC-CMV	PC (selection CMV)	PC-CMV
PC-SIMV	(selection SIMV)	PC-SIMV
PC-SIMV/PS	(Activate PS parameter)	PC-SIMV/PS
SPN-CPAP/PS	PSV	CPAP / PSV*
SPN-CPAP	PSV	CPAP / PSV
Not available	Man / Spon	Manual / Spontaneous
Not available	Ext.FGO	External fresh-gas outlet
Not available	Pause	Pause – no ventilation & gas delivery

***(with RRmin setting)**

Overview of Ventilation Modes in Critical Care Ventilators and Terms Used in Different Dräger Anaesthesia Devices

Possibly your device does not dispose of all described modes – sometimes they are not ordered in the device configuration.

Perseus A500:

Mode name ICU ventilator	Mode key name Perseus	Mode name on screen Perseus
VC-CMV	Volume Control (selection Sync. off)	Volume Control-CMV
VC-SIMV	(selection Sync. on)	Volume Control -SIMV
VC-SIMV/PS	(Activate PS parameter)	Volume Control -SIMV/PS
VC-CMV AutoFlow	Vol.Ctrl.AutoFlow (selection Sync. off)	Volume Control -CMV /AF
VC-SIMV AutoFlow	(selection Sync. on)	Volume Control -SIMV /AF
VC-SIMV/PS AutoFlow	(Activate PS parameter)	Volume Control -SIMV/AF/PS
PC-CMV	Pressure Control (selection Sync. off)	Pressure Control -CMV
PC-BIPAP	(selection Sync. on)	Pressure Control -BIPAP
PC-BIPAP/PS	(Activate PS parameter)	Pressure Control -BIPAP/PS
PC-APRV	Press. Ctrl. APRV	Pressure Control -APRV
SPN-CPAP/PS	Pressure Support	CPAP / Pressure Support*
SPN-CPAP	Pressure Support (setting $\Delta P_{supp} = \text{Off}$)	CPAP / Pressure Support
Not available	MAN/SPON	Manual / Spontaneous
Not available	Ext.FG Outlet	External fresh-gas outlet
Not available	Pause	Pause – no ventilation & gas delivery

*(with RRmin setting)

Overview of Ventilation Modes in Critical Care Ventilators and Terms Used in Different Dräger Anaesthesia Devices

Possibly your device does not dispose of all described modes – sometimes they are not ordered in the device configuration.

Zeus IE

Mode name ICU ventilator	Mode key name Zeus IE	Mode name on screen Zeus IE
VC-CMV	Volume Control (selection Sync. off)	Volume Control - CMV
VC-CMV AutoFlow	Vol.Ctrl.AutoFlow (selection Sync. off)	Volume Control - CMV - AF
VC-SIMV AutoFlow	(selection Sync. on)	Volume Control - SIMV - AF
VC-SIMV/PS AutoFlow	(Activate PS parameter)	Volume Control – SIMV – AF - PS
PC-CMV	Pressure Control (selection Sync. off)	Pressure Control - CMV
PC-BIPAP	(selection Sync. on)	Pressure Control - BIPAP
PC-BIPAP/PS	(Activate PS parameter)	Pressure Control – BIPAP - PS
SPN-CPAP/PS	Pressure Support	Pressure Support – CPAP*
SPN-CPAP	Pressure Support (setting $\Delta P_{supp} = \text{Off}$)	Pressure Support – CPAP
Not available	SVC	Smart Ventilation Control
Not available	MAN/SPON	MAN/SPON
Not available	External FG outlet	External fresh-gas outlet
Not available	Pause	Pause – no ventilation

*(with RRmin setting)

Attachment 3 – Dräger Fabius Family with Installed Fresh Gas Outlet



FGO variant A

FGO variant B

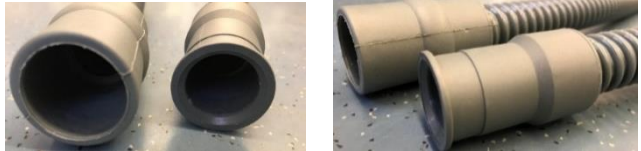


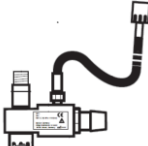
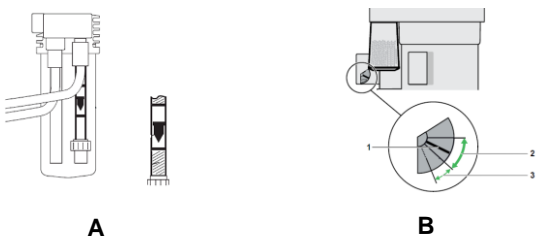

Different variants of the FGO exist. Please ensure that the switch of FGO variant A is at the COSY position, as shown in the picture. We also recommend that you secure the switch in the COSY position to prevent unintentional switching, by using tape for example. In Variant B, please ensure that the fresh gas connection from the FGO to the COSY breathing system is installed properly.

For further details, please refer to the IFU and watch: <https://www.youtube.com/watch?v=Sw5idUnpIZg>

Attachment 4 – Active Gas Scavenging (AGS) alternatives

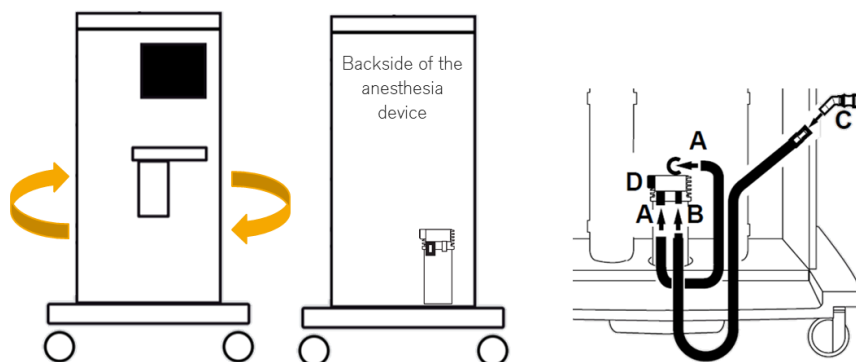
Please check your respective regulations, e.g. employment protection requirements.

Overview of the Components

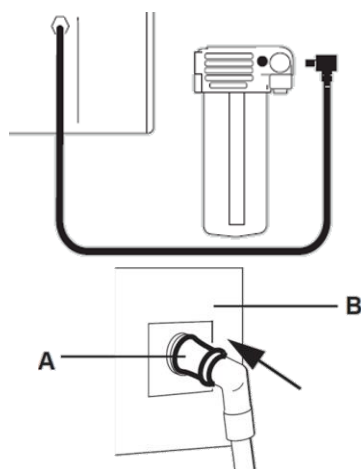
<p>AGS scavenging hose (smaller diameter)</p> <p>AGS transfer hose (bigger diameter)</p>	
<p>AGS receiving system for Fabius, Primus and Zeus</p>	
<p>AGS receiving system for Perseus and Atlan</p>	
<p>AGS ejector - M36175</p>	
<p>AGS flow indicator for Fabius, Primus and Zeus families (A) for Perseus and Atlan family (B)</p>	
<p>Metal AGS connector plug</p>	

Option 1: AGS connection for standard operation

A stylised Primus is used here for illustration. In case of any uncertainties, the instructions for use of the respective device should therefore be consulted.



- Connect the gray transfer hose (A) to the scavenging nozzles on the device and on the AGS.
- Connect the scavenging hose to the scavenging nozzle (B) of the AGS and to the scavenging connector (C).
- Make sure the second connection to the scavenging system is sealed by a screw plug (D).

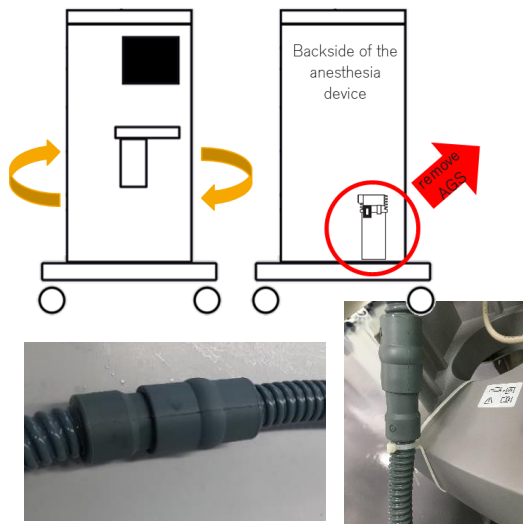


- If needed connect sample gas return of an external gas monitor.
- Connect the sample gas return line to the sample- gas outlet of the monitor.
- Plug the hose connector into the coupler on the receiving system until it clicks into place.
- Plug the connector of the scavenging hose (A) into the terminal unit of the disposal system (B), the readiness will be shown at the terminal of the disposal system

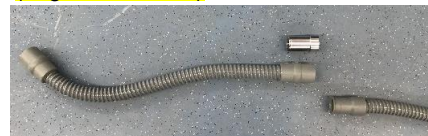
Option 2a for Primus/Fabius/Zeus families: Gas forwarding via hose (passive)

This option is only possible at devices of the Primus, Fabius, Zeus families and other Dräger devices with removable AGS system.

Use the devices only in well ventilated areas!



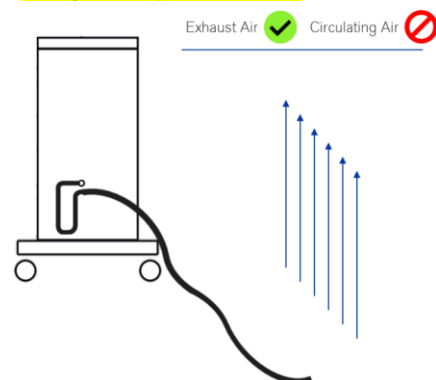
- Receiving system will be bypassed, **please remove the whole AGS system from the device**
- Disconnect the metal adapter of the transfer hose (might be difficult)



- The **scavenging hose will be connected directly to the transfer hose**
- You might need to humidify the end of the hoses to facilitate the connection
- Connect the transfer hose to the device
- Secure the scavenging hose at the device (e.g. with a cable tie) without reducing the diameter of the hose, if possible at the connection port of the scavenging hose

<p>Hose connection on Primus family devices</p>	
<p>Hose connection on Fabius family devices</p>	
<p>Hose connection on Zeus family devices</p>	

- **Remove metal AGS connector plug** from the end of the hose
- The **end of the hose must be placed at least 1 m away** from the anesthesia device and other electrical devices in such a way that it **cannot be closed / blocked**
- **Hose length max. 10 m**
- If you expect to use **volatile anesthetic agent ensure that the hose ends under an exhaust air extraction system** or be discharged to the outside air. **Warning:** Smallest amounts of volatile anesthetic agent might trigger **Malignant Hyperthermia.**



Option 2b for Perseus/Atlan family: Gas forwarding at the AGS (passive)

The AGS can neither be removed from devices of the Atlan family nor from Perseus devices. Due to this fact, make sure that the AGS scavenging hose is removed completely from the device. **WARNING:** The excess gas escapes into the environment directly at the AGS. Do not use volatile agents with this option.

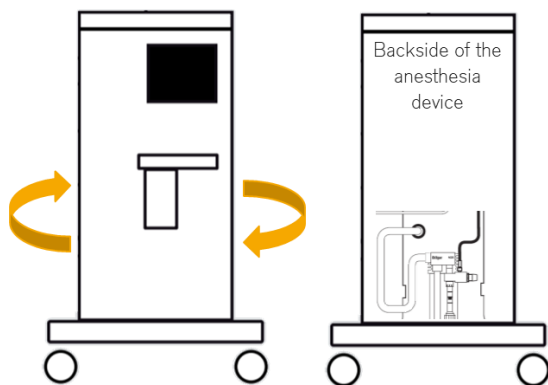


Perseus

Atlan

Option 3: AGS connection with Ejector

When using an active AGS, the ejector serves as a replacement for a permanently installed disposal system. Use at least this option for Perseus and Atlan devices, if volatile anaesthetic agents are in use. Use the devices only in well ventilated areas!



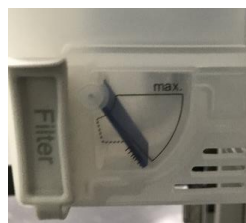
Connection of the ejector to the AGS receiving system:

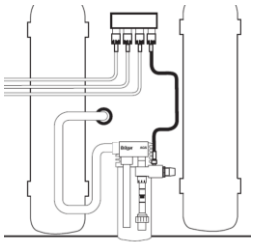
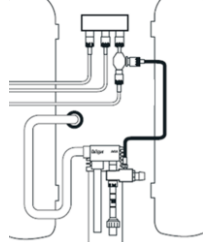
- Screw the ejector into the AGS
- If possible, supply the ejector **directly with AIR from the central gas supply** at the wall or the supply unit. Part numbers: ejector - M36175, supply the ejector via the device (AIR outlet or T-piece AIR - M36056).
- **Connect AGS scavenging hose to the ejector**
- Adjust the ejector so that the flow indicator is in **the lowest permitted range** to reduce the usage of driving gas. **Caution:** otherwise the ejector needs up to **70 L/min driving gas (AIR)**

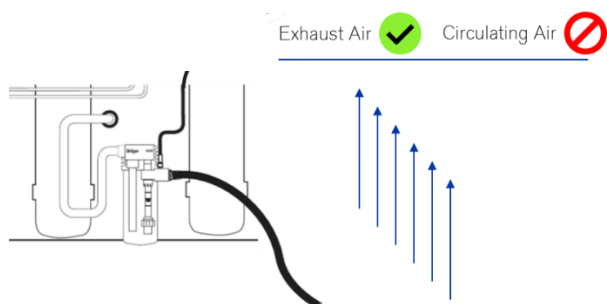
Flow indicator in the lowest permitted range at a Primus, Fabius or Zeus family device



Flow indicator in the lowest permitted range at a Perseus and Atlan family device



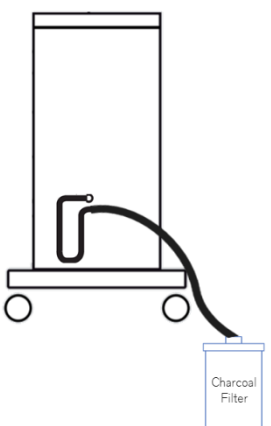

Connection of the ejector at the AIR outlet of the device	Connection of the ejector at the device via a T-piece (AIR)
	



- The **hose end must be placed at least 1 m** away from the anaesthesia device and **other electrical devices** in such a way that it **cannot be closed / blocked**
- If you expect to use **volatile anaesthetic agent** ensure that the hose ends under an **exhaust air extraction system** or be discharged to the outside air. **Warning: Smallest amounts of volatile anaesthetic agent might trigger Malignant Hyperthermia.**

Option 4 for Primus/Fabius/Zeus family: Connection of a charcoal filter

See variant 2a for Primus/Fabius/Zeus family: Gas forwarding via hose (passive) for the device specific set-up. Additionally a charcoal filter will be connected to the end of the scavenging hose in this option.

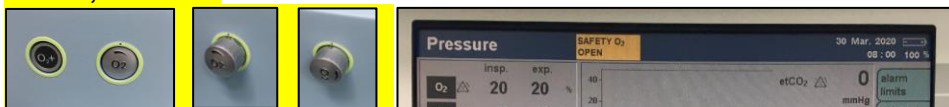
  <p>Anaesthetic Agent Filter 633 – 6724492</p>	<ul style="list-style-type: none"> • Filter outlet must be placed at least 1 m away from the anaesthesia device and other electrical devices. • The charcoal filter must be replaced before the charcoal is exhausted. To do so, follow the instructions for use of the filter used. Warning: Smallest amounts of volatile anaesthetic agent might trigger Malignant Hyperthermia. • Please follow the instructions for setting the Paw low alarm limit in this letter. If the PEEP measurement value increases unintentionally, a change of the anaesthetic filter should also be considered. (remove the filter and observe the PEEP behaviour for 3 breaths, if the measured value normalises, the filter should be changed)
---	--

Attachment 5 – Increasing Fresh Gas Flow by Opening the Emergency O2 Flow Control

Follow the description below to additionally increase the fresh gas flow by opening the emergency O2-flow-control. This additional gas passes through the vaporisers (if installed and opened; usage of vaporisers with additionally added emergency O2 flows is not recommended) and is added to the already set fresh gas flow of the mixer.

An alarm will occur; the priority can be reduced by resetting the alarm (only possible with some devices)

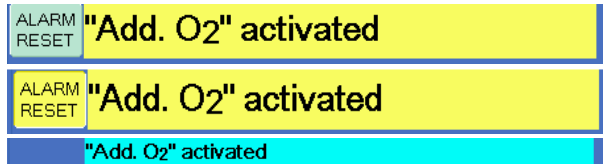
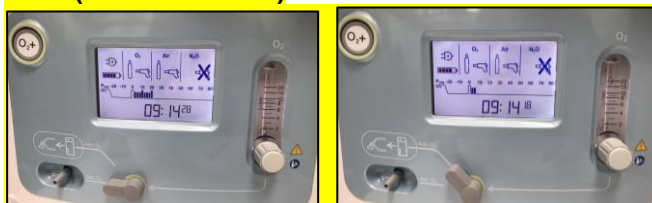
Primus, Primus IE



Press the emergency O2-flow-control and turn it to start the additional flow (up to 12 L/min)

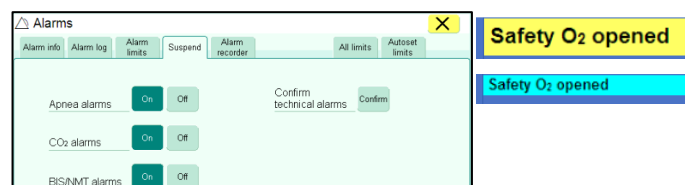
Perseus (electronic mixer)

Atlas (electronic mixer)



Switch the lever to “Add O2” and open the flowmeter to start additional flow (>20 L/min max), reset the alarm by pressing “ALARM RESET” and confirm by pressing the rotary knob.

Zeus Family



Press the emergency O2-flow-control (above breathing system) and turn it to start the additional flow (up to 12 L/min), reset the alarm by selecting “Alarms” – “Suspend” and “Conform technical alarms”.

Attachment 6 – Fresh Gas Settings

[L/min]	Total FG-Flow 2.5		Total FG-Flow 5		Total FG-Flow 10		Total FG-Flow 15	
Desired FG-O ₂ -Concentration	FG-Flow O ₂	FG-Flow AIR	FG-Flow O ₂	FG-Flow AIR	FG-Flow O ₂	FG-Flow AIR	FG-Flow O ₂	FG-Flow AIR
21%	0	2.5	0	5	0	10	0	15
25%	0.15	2.35	0.3	4.7	0.6	9.4	0.9	14.1
30%	0.3	2.2	0.6	4.4	1.2	8.8	1.8	13.2
35%	0.45	2.05	0.9	4.1	1.8	8.2	2.7	12.3
40%	0.6	1.9	1.2	3.8	2.4	7.6	3.6	11.4
50%	0.95	1.55	1.9	3.1	3.8	6.2	5.7	9.3
60%	1.25	1.25	2.5	2.5	5	5	7.5	7.5
80%	1.85	0.65	3.7	1.3	7.4	2.6	11.1	3.9
100%	2.5	0	5	0	10	0	15	0

Example:

Patient with ARDS, ideal bodyweight (IBW) 80 kg, protective tidal volume 6 ml/kgBW
 Fresh Gas O₂ Concentration 40%, Fresh Gas Flow 150% of Minute Volume

Expected Minute Volume = IBW x 6 ml/kg x Respiratory Rate
 Expected Minute Volume = 80 kg x 6 ml/kg x 14/min = 480 ml x 14 /min = 6,7 L/min

Fresh Gas Flow = Expected Minute Volume x 150%
 Fresh Gas Flow = 6,7 L/min x 1,5 = 10,1 L/min → rounded to 10 L/min

Settings on devices with electronic gas mixer:
 Fresh Gas Flow = 10 L/min
 Fresh Gas O₂ Concentration = 40%

Settings on devices with mechanic gas mixer:
 O₂-Flow = 2,4 L/min
 AIR-Flow = 7,6 L/min