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To Dräger Customers and  
Health Care Professionals  
in the United States of America



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Please visit the Dräger COVID-19 website

[https://www.draeger.com/en-us\\_us/Home/novel-coronavirus-outbreak](https://www.draeger.com/en-us_us/Home/novel-coronavirus-outbreak)  
for updates and other useful information

April 24<sup>th</sup> 2020

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

Rev. 5

Dear Customers and Health Care Professionals,

The World Health Organization (WHO) declared COVID-19 a pandemic on March 11<sup>th</sup>, 2020 with currently over 2,600,000 confirmed cases of the coronavirus illness reported in over 180 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 anesthesia devices for long-term ventilation as an alternative ventilator for ICU patients when existing devices are fully utilized and there is no other ventilator option.

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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 anesthesia devices for long-term ventilation.

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,



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## Index

<b>Legal and regulatory perspective .....</b>	<b>5</b>
<b>Known limitations of Dräger anesthesia devices regarding use in long-term ventilation .....</b>	<b>6</b>
<b>1 General instructions .....</b>	<b>6</b>
<b>2 Prerequisites &amp; preparation .....</b>	<b>6</b>
2.1 Training of medical personnel .....	6
2.2 Location requirements .....	7
2.3 Manual resuscitator .....	7
2.4 Oxygen backup cylinder .....	8
2.5 Evacuation of gases (Scavenging) .....	8
2.6 Disconnection of vaporizers & N <sub>2</sub> O .....	8
2.7 Infection prevention .....	9
2.8 Filters & humidification .....	9
2.9 Breathing bag .....	11
2.10 Water Trap - Waterlock 2 .....	11
2.11 CO <sub>2</sub> absorber .....	11
2.12 System configuration / default settings .....	12
<b>3 Regular checks .....</b>	<b>13</b>
3.1 System Test .....	13
3.2 System restart & refreshing internal memory .....	14
3.3 Check for overall status and accessories .....	14
<b>4 Therapy .....</b>	<b>15</b>
4.1 Fresh gas flow .....	15
4.1.1 General recommendation – high fresh gas flow .....	15
4.1.2 Additional fresh gas flow .....	15
4.1.3 Reduced fresh gas flow .....	15
4.2 Handling leakages .....	17
4.3 Modes of operation .....	17
4.3.1 Ventilation mode - Man / Spon .....	17
4.3.2 Discouraged use – external Fresh Gas Outlet, Pause, and Monitoring mode .....	18
4.4 Alarm volume 100% .....	18

4.5	Patient-specific limits for all alarms .....	18
4.6	Alarm notifications .....	19
4.7	Gas measurement .....	19
4.7.1	FiO <sub>2</sub> .....	19
4.8	Endotracheal suctioning in a closed system.....	19
4.9	Nebulization of drugs and aerosol therapy .....	20
4.10	In case of failure .....	20
<b>5</b>	<b>Consumption of fresh gas and soda lime .....</b>	<b>20</b>
<b>6</b>	<b>Oxygen concentrator “O<sub>2</sub> 93” .....</b>	<b>21</b>
<b>7</b>	<b>Direct injection of volatile agents at Y-piece (not recommended) .....</b>	<b>21</b>
<b>8</b>	<b>Ventilating multiple patients with one device (not recommended).....</b>	<b>21</b>
<b>9</b>	<b>Attachments .....</b>	<b>22</b>
9.1	Attachment 1: Comments on particular modes of operation .....	23
9.2	Attachment 2: Overview of Ventilation Modes.....	24
9.3	Attachment 3: Dräger Fabius Family with Installed Fresh Gas Outlet (FGO).....	26
9.4	Attachment 4 – Active Gas Scavenging (AGS) alternatives .....	27
9.5	Attachment 5: Increasing fresh gas flow by opening the emergency O <sub>2</sub> flow control .....	27
9.6	Attachment 6: Fresh gas settings .....	28
9.7	Attachment 7: Decision support in case of supply shortages .....	29

## **Legal and regulatory perspective**

The intended use of each Dräger anesthesia 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 recognizes 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 anesthesia device has to be weighed against the risk of the off-label usage of a Dräger anesthesia 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.

**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.**

## Known limitations of Dräger anesthesia 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 anesthesia 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 anesthesia 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.

### 1 General instructions

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

Refer to the following website [https://www.draeger.com/en-us\\_us/Home/novel-coronavirus-outbreak](https://www.draeger.com/en-us_us/Home/novel-coronavirus-outbreak) for an additional check list that you may provide at every workplace. Please be aware, that this customer letter is more detailed and prevails over the additional check list.

### 2 Prerequisites & preparation

#### 2.1 Training of medical personnel

- Anesthesia 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.**

- 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 anesthesia device,** the user requires **device knowledge and clinical experience** with anesthesia 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>)

## 2.2 Location requirements

- Anesthesia devices should be used only in **rooms with adequate ventilation.**
- The user interface of Dräger anesthesia devices cannot be protected against non-authorized users. Therefore, the **operating organization 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).

## 2.3 Manual resuscitator

- 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 anesthesia devices, it is particularly important that **in case of irregularities** or unexpected system behavior impairing patient therapy, the patient has to be disconnected from the anesthesia 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.

## 2.4 Oxygen backup cylinder

- In case of shortages or loss of central gas supply, Dräger anesthesia devices will continue with mechanical ventilation. Shortages will lead to alarms of the anesthesia, please refer to the instructions for use and check under the chapter “Fault - Cause - Remedy”. To ensure the desired FiO<sub>2</sub> level, an **O<sub>2</sub> 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 anesthesia device will continue ventilation with ambient air (21% FiO<sub>2</sub> and no volatile agents can be applied), because of the electrically driven ventilators.

## 2.5 Evacuation of gases (Scavenging)

- **To avoid oxygen accumulation in the direct environment of the device, a proper scavenging is recommended although no anesthetic agent is used**. For more information see Attachment 4 – Active Gas Scavenging (AGS) alternatives

## 2.6 Disconnection of vaporizers & N<sub>2</sub>O

- In order to prevent the use of anesthetic agents in a situation that might harm the patient or the patient’s environment, it is recommended that you **disconnect all vaporizers** from the anesthesia device and store them in the operation room. This is particularly important because even **very small concentrations of volatile agents may trigger malignant hyperthermia** (e.g. of the clinician or the patient).
- The fresh gas flow must only contain a mix of oxygen and medical air. The use of nitrous-oxide (N<sub>2</sub>O) during long-term ventilation must be prevented as users with no anesthesia experience are possibly not familiar with the fact that a decrease of the oxygen concentration in the fresh gas flow would increase the N<sub>2</sub>O concentration in the inspiratory gas. Therefore, it has to be ensured that **no N<sub>2</sub>O hose and no N<sub>2</sub>O cylinder are connected to the anesthesia device**. Furthermore, in Dräger anesthesia devices with an electronic gas mixer (Perseus A500 with electronic gas mixer) usage without N<sub>2</sub>O has to be configured in the system configuration.



## 2.7 Infection prevention

- **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. More information regarding infection prevention in the context of COVID-19 is provided in the Dräger 2019-nCoV infection prevention customer letters for anesthesia and intensive care and their supplements, please refer to the following website: [https://www.draeger.com/en-us\\_us/Home/novel-coronavirus-outbreak](https://www.draeger.com/en-us_us/Home/novel-coronavirus-outbreak)

## 2.8 Filters & humidification

- **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.

- Two different solutions for the use of mechanical filters are recommended:
  - o **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)
  - o **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 anesthesia device
    - Please consider the following information regarding active humidification in combination with anesthesia devices.

If possible from a clinical perspective, use HME / mechanical breathing system filters at the Y-piece (solution 1) with Dräger anesthesia devices.

- The use of **active humidification** is not approved with Dräger anesthesia 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 anesthesia device. Breathing circuits require **a water trap in the expiratory limb. Dual heated breathing circuits must not be used** with Dräger anesthesia 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 anesthesia device. As mentioned before, only mechanical 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.** For the reprocessing of the anesthesia device after each patient follow the recommendations for anesthesia devices potentially contaminated with SARS CoV-2.

## 2.9 Breathing bag

- The breathing bag of Dräger anesthesia 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 liter breathing bag) is recommended** to avoid having the breathing bag limit the spontaneous breath of the patient.

## 2.10 Water Trap - Waterlock 2

- The water trap (Waterlock2) at the gas measurement module of Dräger anesthesia 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 anesthesia 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.

## 2.11 CO<sub>2</sub> absorber

- One significant difference between intensive care ventilators and anesthesia devices is that anesthesia ventilators are based on a rebreathing system and adjustable fresh gas flows. This requires the use of a CO<sub>2</sub> absorber to prevent high CO<sub>2</sub> levels in the circuit. It is important to examine the CO<sub>2</sub> absorber and change it before it is exhausted. An exhausted absorber can be

detected by an increasing inspiratory CO<sub>2</sub> measurement or a change in color (purple) of the Dräger CO<sub>2</sub> absorber (see instructions for use of anesthesia device and CO<sub>2</sub>-absorber for more information). **Generally the absorber will absorb CO<sub>2</sub> and thus change color from the bottom to the top. Due to the fact that high fresh gas flows dry out the CO<sub>2</sub> absorber there might be a color 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 because no volatile agents must be used. An exchange of the absorber is not required in this case.** The **activation of an inspiratory CO<sub>2</sub> high alarm limit** helps to directly inform the user about an exhausted absorber.

- The anesthesia device should never be operated without a CO<sub>2</sub> absorber, except when changing a used absorber. The **permanent use of a CO<sub>2</sub> absorber** ensures that the patient does not inhale inspiratory CO<sub>2</sub> 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 A500 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.

## 2.12 System configuration / default settings

- Default settings can be configured at Dräger anesthesia devices. The default settings become automatically active when starting a new patient case, when performing a device restart or when using a dedicated device function (e.g. in Apollo via the soft key “restore default settings”). Particularly the following default settings should be adapted for the use in long-term ventilation: alarm volume, alarm limits, ventilation settings (particularly P<sub>max</sub> in volume controlled ventilation modes), fresh gas flow and fresh gas oxygen concentration, all alarms shall remain active in MAN/SPON (i.e. the suppression of alarms in MAN/SPON is configured with “no”; this setting can only be configured in Perseus and Apollo), deactivate N<sub>2</sub>O (all devices with electronic

gas mixer), units (e.g. for etCO<sub>2</sub>), activation of alarm entries in the device logbook, and set entry interval to ≤ 2 minutes (Perseus and Apollo).

- The adaption of default settings can only be done in standby and is protected by a password. For adapting the settings, please contact the responsible person in your organization and check the instructions for use. If further help is required, please contact your local Dräger representative.
- **WARNING:** If the device configuration is not adapted for the use in long-term ventilation, the active settings (especially the above mentioned settings) have to be checked and adapted particularly carefully whenever a new patient case is started.

### 3 Regular checks

#### 3.1 System Test

- 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 anesthesia device cannot be calibrated during operation. Measured values may change their color 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 O<sub>2</sub>-sensor of the Fabius family. Please be aware that the anesthesia devices may raise technical alarms regarding required calibrations of flow measurement and the Fabius FiO<sub>2</sub> measurement; nevertheless these values can be used in the case of long-term ventilation. **If in doubt, perform a system test.**
- Each time the anesthesia device is prepared for long-term ventilation of a new patient, perform a complete system test (not only a leakage test).

- To perform the system test, the patient must be disconnected from the anesthesia 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 Apollo- and 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 performing 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 a (semi-) automatic part, for which both have to be performed.**

### 3.2 System restart & refreshing internal memory

- To prepare the software (clean internal memory components) of a Dräger anesthesia 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 A500: 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 Apollo: 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.

### 3.3 Check for overall status and accessories

- Since Dräger anesthesia 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 CO<sub>2</sub>-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.

- If a shortage (e.g. of accessories) exists or is unavoidable, refer to Attachment 7: Decision support in case of supply shortages.

## 4 Therapy

### 4.1 Fresh gas flow

#### 4.1.1 General recommendation – high fresh gas flow

- **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: Fresh gas settings if you have questions in regards to fresh gas settings and refer to chapter 5 for gas consumption.

#### 4.1.2 Additional fresh gas flow

- When using Perseus A500 with electronic gas mixer the **fresh gas flow can be additionally increased by opening the emergency O<sub>2</sub> flow control**. Please refer to Attachment 4 – Active Gas Scavenging (AGS) alternatives Attachment 5: Increasing fresh gas flow by opening the emergency O<sub>2</sub> flow control.. 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).

#### 4.1.3 Reduced fresh gas flow

- **If reduced fresh gas flows are used** (e.g. due to shortage of supplied gases 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, see chapter 5

- condensation may block filters in the patient circuit (especially a filter at the inspiratory port)

Therefore, we recommend that you:

- **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 CO<sub>2</sub> (e.g. having high fever) significantly raise the fresh gas flow (e.g. to >50% of the minute volume).
- Use **hose systems with water traps** in the inspiratory and expiratory limb; the longer the hoses, the better
- **Do not use a filter at the inspiratory port** of the breathing system
- 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 (Apollo, Fabius family)
- **Set an alarm limit for FiO<sub>2</sub> low with adequate buffer** because the difference between the set fresh gas flow and the FiO<sub>2</sub> will increase and the system will react far slower to modifications of the O<sub>2</sub> setting
- **Set an alarm limit for inspiratory CO<sub>2</sub> high to an appropriate value**
- If required, update the default settings, refer to chapter 2.12
- 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 CO<sub>2</sub> absorber (exchange at least when 2/3 has changed its color to purple to reduce condensation in the breathing system; consumption of CO<sub>2</sub> 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.**



## 4.2 Handling leakages

- In general, **leakages are not compensated** by Dräger anesthesia 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. Appropriate alarms like "Fresh gas low or leakage" will appear. The immediate reaction of the operator is required (reduce leakage, increase FG flow; add up 70 L/min O<sub>2</sub> by pressing the O<sub>2</sub>-flush to refill the system with pure oxygen immediately). 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.

## 4.3 Modes of operation

- Modes, measurement values, settings, maneuvers etc. that are possibly used with ICU ventilators might not be available in the anesthesia devices.

### 4.3.1 Ventilation mode - Man / Spon

- 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 anesthesia 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 rise 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.

#### **4.3.2 Discouraged use – external Fresh Gas Outlet, Pause, and Monitoring mode**

- 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 3: Dräger Fabius Family with Installed Fresh Gas Outlet9.2. Furthermore, **several modes may behave differently than in intensive care ventilators.** Details are listed in the Attachment 1: Comments on particular modes of operation.

#### **4.4 Alarm volume 100%**

- The alarm and safety systems of Dräger anesthesia devices are designed for the user to always be within 4 meters (~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 recognized in time.

#### **4.5 Patient-specific limits for all alarms**

- 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 CO<sub>2</sub> (lower and upper limit) are particularly important for generating alarms when hypo- or hyperventilation occurs. Additionally, the alarm limit for FiO<sub>2</sub> (lower limit) has to be adjusted because FiO<sub>2</sub> cannot be set directly.

- In contrast to most ICU ventilators some Dräger anesthesia 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.

#### 4.6 Alarm notifications

- Please be aware that in Dräger anesthesia 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 anesthesia device** to see if any alarms have been generated in the absence of the user.

#### 4.7 Gas measurement

- **The gas measurement of the anesthesia device**, if included in the device, **always has to be connected**. Unlike many ICU ventilators, the gas measurement of anesthesia devices is a side-stream monitoring. Therefore, the gas measurement values and waveforms have a delay of several seconds.

##### 4.7.1 FiO<sub>2</sub>

- The rebreathing of exhaled patient gases is a significant difference from ICU ventilators. The oxygen concentration of the inhaled gas (measured as “FiO<sub>2</sub>”) 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 FiO<sub>2</sub> values and the FiO<sub>2</sub> low-alarm limit**. The difference between the fresh gas oxygen concentration and FiO<sub>2</sub> 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: Fresh gas settings.

#### 4.8 Endotracheal suctioning in a closed system

- **Negative pressures by suctioning** can harm the lung of the patient and impair the function of the anesthesia 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 anesthesia device for endotracheal suctioning** (consider the loss of PEEP). Alternatively, by disconnecting the manual breathing bag you can ensure that the bag won't collapse due to the suctioning. By this measure, the potential of negative pressures in the system is reduced. Pay special attention to the fact that after the suctioning the manual breathing bag has to be reconnected by the user.

#### 4.9 Nebulization of drugs and aerosol therapy

- **Nebulization of drugs and aerosol therapy** are not approved with anesthesia devices. If aerosol or other drugs are given to the airways, malfunctions can occur. Without a mechanical filter between the connection port of the nebulizer and the anesthesia device, malfunctions are very likely to occur (e.g. incorrect measurement of the gas analyzer, erroneous measurement of expiratory flows, tidal and minute volumes). If no mechanical filter is used on the Y-piece, disconnect the sampling gas line during nebulization and aerosol therapy.

#### 4.10 In case of failure

- **If a main component of the anesthesia device**, such as the mixer, ventilator or screen **shows a failure, immediately switch to an alternative means of ventilation.**

### 5 Consumption of fresh gas and soda lime

- Dräger anesthesia devices work with an electronically driven ventilator (piston ventilator in Apollo and Fabius- family devices; blower ventilator in 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-O<sub>2</sub>-concentration 50%, this will lead to a consumption of approx. 5.7 L/min AIR and 3.3 L/min O<sub>2</sub>. Please note that when using active scavenging (AGS) the consumption of centrally supplied gases will be higher.

- For a rough estimation of the consumption of fresh gas please refer to the calculation sheet provided on the following website: [https://www.draeger.com/en-us\\_us/Home/novel-coronavirus-outbreak](https://www.draeger.com/en-us_us/Home/novel-coronavirus-outbreak)

## 6 Oxygen concentrator “O<sub>2</sub> 93”

- The use of **concentrated oxygen (“O<sub>2</sub> 93”)** is not approved with Dräger anesthesia devices. In case of shortages of pure oxygen, “O<sub>2</sub> 93” can be used with most Dräger anesthesia 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 FiO<sub>2</sub> 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 anesthesia workstation standards may not be fully achieved, e.g. patient flow measurement, fresh gas flow, and fresh gas concentration.

## 7 Direct injection of volatile agents at Y-piece (not recommended)

- **Systems for direct injection of volatile agents at the Y-piece** (e.g. Anaconda, MIRUS) are not approved with Dräger anesthesia devices.

## 8 Ventilating multiple patients with one device (not recommended)

- 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” on the following website: [https://www.draeger.com/en-us\\_us/Home/novel-coronavirus-outbreak](https://www.draeger.com/en-us_us/Home/novel-coronavirus-outbreak)

## 9 Attachments

9.1	Attachment 1: Comments on particular modes of operation .....	23
9.2	Attachment 2: Overview of Ventilation Modes .....	24
9.3	Attachment 3: Dräger Fabius Family with Installed Fresh Gas Outlet (FGO) .....	26
9.4	Attachment 4 – Active Gas Scavenging (AGS) alternatives .....	27
9.5	Attachment 5: Increasing fresh gas flow by opening the emergency O2 flow control .....	27
9.6	Attachment 6: Fresh gas settings .....	28
9.7	Attachment 7: Decision support in case of supply shortages .....	29

## 9.1 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 anesthesia 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 anesthesia 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 anesthesia 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 anesthesia 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).
- **Inspiratory Flow and Slope:** In Pressure Control and Pressure Support on Fabius family devices, users can adjust the insp. flow to impact the speed at which the pressure curve rises. On Perseus and Apollo, the “slope” setting is used to define the time for the pressure rise in Pressure Control, Pressure Support, VC-AutoFlow and APRV (only available in Perseus). Therefore, to achieve a ventilation pressure quicker, the user can set a high inspiratory flow (Fabius) or a short Slope (Apollo, Perseus).
- **Non-Invasive Ventilation (NIV):** Dräger anesthesia 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 anesthesia devices do not offer Nasal High Flow Therapy.

## 9.2 Attachment 2: Overview of Ventilation Modes


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

### Apollo Family:

Mode name ICU ventilator	Mode key name Apollo	Mode name on screen Apollo
VC-CMV	Vol. mode	Volume
VC-SIMV	(Activate Trigger parameter)	Volume Sync
VC-SIMV/PS	(Activate $\Delta$ 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 $\Delta$ Pps parameter)	Volume AF Sync PressSupp
PC-CMV	Press. mode	Pressure
PC-SIMV	(Activate Trigger parameter)	Pressure Sync
PC-SIMV/PS	(Activate $\Delta$ 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

\*(Apnea Ventilation available with setting FreqMIN)



Overview of Ventilation Modes in Critical Care Ventilators and Terms Used in Different Dräger Anesthesia 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 <b>Sync. off</b> )	Volume Control-CMV
VC-CMV AutoFlow	Vol.Ctrl.AutoFlow (selection <b>Sync. off</b> )	Volume Control -CMV /AF
VC-SIMV AutoFlow	(selection <b>Sync. on</b> )	Volume Control -SIMV /AF
VC-SIMV/PS AutoFlow	(Activate <b>PS</b> parameter)	Volume Control -SIMV/AF/PS
PC-CMV	Pressure Control (selection <b>Sync. off</b> )	Pressure Control -CMV
PC-SIMV+	(selection <b>Sync. on</b> )	Pressure Control –SIMV+
PC-SIMV+/PS	(Activate <b>PS</b> parameter)	Pressure Control –SIMV+/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 (elec. mixer) – no ventilation and gas delivery Pause (mech. mixer) – no ventilation

\*(Apnea Ventilation available with setting RRapn)

## 9.3 Attachment 3: Dräger Fabius Family with Installed Fresh Gas Outlet (FGO)



**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>

## 9.4 Attachment 4 – Active Gas Scavenging (AGS) alternatives

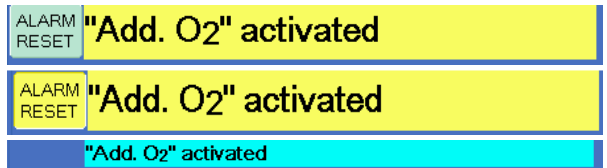
To avoid oxygen accumulation in the direct environment of the device, a proper scavenging is recommended although no anesthetic agent is used. If no AGS is available and the anesthesia device has the outlet of surplus gases behind doors, the doors must be left open to avoid oxygen accumulation.

## 9.5 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 is added to the already set fresh gas flow of the mixer. As only oxygen will be added, the FiO2 will increase.

An alarm will occur; the priority can be reduced by resetting the alarm.

### Perseus (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.

## 9.6 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 <sub>2</sub> -Concentration	FG-Flow O <sub>2</sub>	FG-Flow AIR	FG-Flow O <sub>2</sub>	FG-Flow AIR	FG-Flow O <sub>2</sub>	FG-Flow AIR	FG-Flow O <sub>2</sub>	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 O<sub>2</sub> 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 O<sub>2</sub> Concentration = 40%

Settings on devices with mechanic gas mixer:

O<sub>2</sub>-Flow = 2.4 L/min

AIR-Flow = 7.6 L/min

## **9.7 Attachment 7: Decision support in case of supply shortages**

This chapter gives decision support for the case of supply shortages during the use of anesthesia devices for long-term ventilation.

**IMPORTANT:** In general, the advice and recommendations in the customer letter “COVID-19: Usage of Dräger anesthesia devices for long-term ventilation” should be taken into account.

The following remarks should only be considered as an ultima ratio if a corresponding supply bottleneck exists or is unavoidable. Depending on the therapy goal and the available options, the alternatives given and the associated consequences must be weighed by the responsible user, possibly together with users who are very familiar with the anesthesia devices used. The sequence of the indicated measures does not necessarily represent a prioritization.

Clinic intern guidelines such as for example infection prevention or SOPs have to be followed.

## Index for Attachment 7

<b>1</b>	<b>Initial situation and consequences .....</b>	<b>31</b>
<b>2</b>	<b>Shortage in IV medication for sedation .....</b>	<b>31</b>
<b>3</b>	<b>Central gas supply shortage.....</b>	<b>31</b>
<b>4</b>	<b>Very high CO<sub>2</sub>-absorber consumption due to high minute volumes .....</b>	<b>32</b>
<b>5</b>	<b>Too much humidity in the breathing system .....</b>	<b>32</b>
<b>6</b>	<b>No fresh soda lime available.....</b>	<b>33</b>
6.1	Decision tree.....	34
<b>7</b>	<b>Only soda lime of lower quality (granular soda lime) is available .....</b>	<b>35</b>
<b>8</b>	<b>No fresh water trap for the gas measurement (Waterlock2) is available.....</b>	<b>35</b>
<b>9</b>	<b>No sample gas line is available .....</b>	<b>36</b>
<b>10</b>	<b>No breathing system filter is available .....</b>	<b>36</b>
10.1	Decision tree.....	37
<b>11</b>	<b>No disposable breathing circuit is available .....</b>	<b>38</b>
<b>12</b>	<b>Reduce the fresh gas flow .....</b>	<b>38</b>

## 1 Initial situation and consequences

Initial situation according to the customer letter “COVID-19: Usage of Dräger anesthesia devices for long-term ventilation”. That means:

- high fresh gas flow 1.5xMV
- no volatile anesthetic agent
- soda lime at the device
- active AGS
- manual breathing bag connected
- mechanical filters with HME connected

### Potential impact:

- ➔ High gas supply consumption according to the set fresh gas flow (150% of the minute volume)
- ➔ Compressed air consumption due to the active AGS additional to the fresh gas flow
- ➔ IV medication needed for sedation
- ➔ Low soda lime consumption
- ➔ Drying out of the soda lime, but no patient harm (e.g. compound formation), as no volatile anesthetic agent must be used
- ➔ No room air contamination
- ➔ Reduced humidity in the circle system

## 2 Shortage in IV medication for sedation

- Use alternative IV drugs for sedation
- Avoid usage of volatile anesthetic agents

## 3 Central gas supply shortage

- Reduce the fresh gas flow, see chapter 12
- If possible, connect gas cylinders to the device
- If one gas (O<sub>2</sub> or AIR) fails, fresh gas supply can continue with the remaining gas. However, it is not possible to adjust the fresh gas O<sub>2</sub> concentration any longer.

- If the entire gas supply (central supply and cylinders) fails, the breathing bag (including the hose between the breathing bag and the breathing system or the flexible breathing bag arm) must be removed from the breathing system. The anesthesia device will continue mechanical ventilation with room air with 21 % FiO<sub>2</sub> (volatile anesthetic agent will not be delivered).

#### **4 Very high CO<sub>2</sub>-absorber consumption due to high minute volumes**

If possible: Ventilate patients with foreseeable high CO<sub>2</sub> production with an ICU ventilator. Anesthesia devices should rather be used for patients with expected normal or lower CO<sub>2</sub> production if problems with the availability of soda lime is expected.

- Increase the fresh gas flow to 150% of the minute volume (if necessary, open the emergency O<sub>2</sub> delivery and add the additional O<sub>2</sub> flow to the system), see Attachment 5: Increasing fresh gas flow by opening the emergency O<sub>2</sub> flow control
- If at least 100% of the minute volume is not possible as fresh gas flow (incl. emergency O<sub>2</sub> emergency delivery), remove the breathing bag (including the hose between the breathing bag and the breathing system or the flexible breathing bag arm)
- Do not use volatile anesthetic agents. Without volatile agents you avoid the formation of toxic substances (e.g. Compound A) when the CO<sub>2</sub>-absorber has dried out. Always use IV medication
- With Perseus A500 the FG flow of the electronic gas mixer might be limited at higher respiratory rates or lower tidal volumes

#### **5 Too much humidity in the breathing system**

If possible, ventilate patients with foreseeable high CO<sub>2</sub> production with an ICU ventilator. Anesthesia devices should rather be used for patients with expected lower CO<sub>2</sub> production.

- Increase the fresh gas flow to 150% of the minute volume (if necessary, open the emergency O<sub>2</sub> delivery and add the add. O<sub>2</sub> flow to the system), see Attachment 5: Increasing fresh gas flow by opening the emergency O<sub>2</sub> flow control
- Perform intermittent flushing phases from time to time by
  - Manually increasing the fresh gas flow or
  - Keep O<sub>2</sub> flush manually pressed for a longer period of time
- Use patient hose systems with water traps, empty water traps regularly (for systems without water trap, remove water from the hoses regularly)



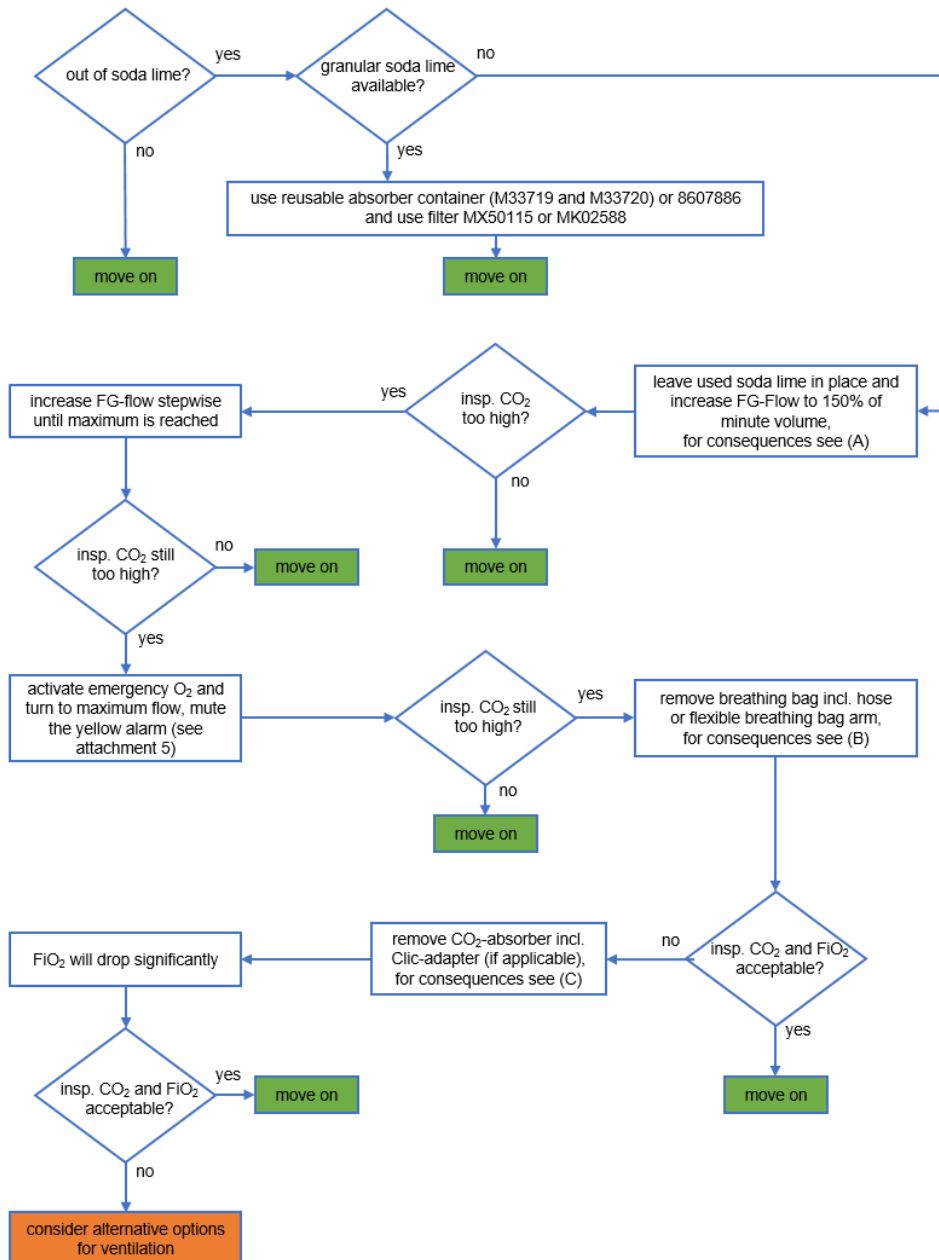
- Use a breathing hose system with water traps that is as long as possible
- For Clic-absorber, replace it earlier than usually (at least, if 2/3 of its content has turned purple)  
Use reusable CO<sub>2</sub>-absorber, fill only half of the specified content; in this case change the soda lime if it completely changed its color to purple or inspiratory CO<sub>2</sub> is detected; WARNING: Check the soda lime consumption regularly
- Remove breathing bag (including the hose between the breathing bag and the breathing system or the flexible breathing bag arm) from the breathing system; WARNING: Monitor the FiO<sub>2</sub> concentration closely, as the concentration may decrease due to dilution with ambient air; set the FiO<sub>2</sub> alarm limit accordingly

## 6 No fresh soda lime available

If possible: Ventilate patients with a foreseeable high CO<sub>2</sub> production with an ICU ventilator. Anesthesia devices should rather be used for patients with an expected normal or lower CO<sub>2</sub> production.

- Set the alarm limit for inspiratory CO<sub>2</sub> (for fresh gas flows <150% of the minute volume, inspiratory CO<sub>2</sub> is hardly avoidable, therefore observe the measured value permanently)
- Do not use volatile anesthetic agents. Without volatile agents you avoid the formation of toxic substances (e.g. Compound A) when the CO<sub>2</sub>-absorber has dried out; always use IV medication

## 6.1 Decision tree



- (a) If a shortage of the fresh gas delivery occurs (fresh gas flow < 150% of minute volume) rebreathing will increase with a significant inspiratory CO<sub>2</sub> and reduced FiO<sub>2</sub> concentration.
- (b) FiO<sub>2</sub> will decrease due to entrainment of ambient air. No manual support of patient breathing via Man / Spon possible. No volatile agents must be used.
- (c) FiO<sub>2</sub> will drop immediately. FiO<sub>2</sub> may fluctuate. No manual support of patient breathing via Man / Spon possible. No volatile agents must be used. Take care that the connector for the absorber is not blocked (by e.g. a plastic bag).

Setup when CO<sub>2</sub>-absorber incl. Clic-adapter is removed:

Apollo Fam.



Fabius Fam.



Perseus



## 7 Only soda lime of lower quality (granular soda lime) is available

- Use a dust filter on the reusable absorber  
Part number: MX50115 (or as an alternative bacterial filter IBF MK02588)
- Exchange the filter with every change of the soda lime

## 8 No fresh water trap for the gas measurement (Waterlock2) is available

- Empty the water trap regularly, at the latest when it is half full
- In this case, continue using the water trap as long as possible
- Even if the water trap is blocked (swelling elements are soaked), leave it in place to protect the gas measuring bench. Due to the blocked water trap, there is no gas measurement available. Therefore, the fresh gas flow must be set to at least 150% of the MV. Volatile agents must not be used. Check alternative monitoring solutions (e.g. frequent blood gas analyses, narrow alarm limits for hemodynamic monitoring).

## 9 No sample gas line is available

- Use infusion line or CO<sub>2</sub> measurement line with LuerLock
- Gas measurement might be affected, especially when applying higher respiratory rates and lower tidal volumes
- Alarms like „sample line blocked“ or „sample line disconnected?“ might appear

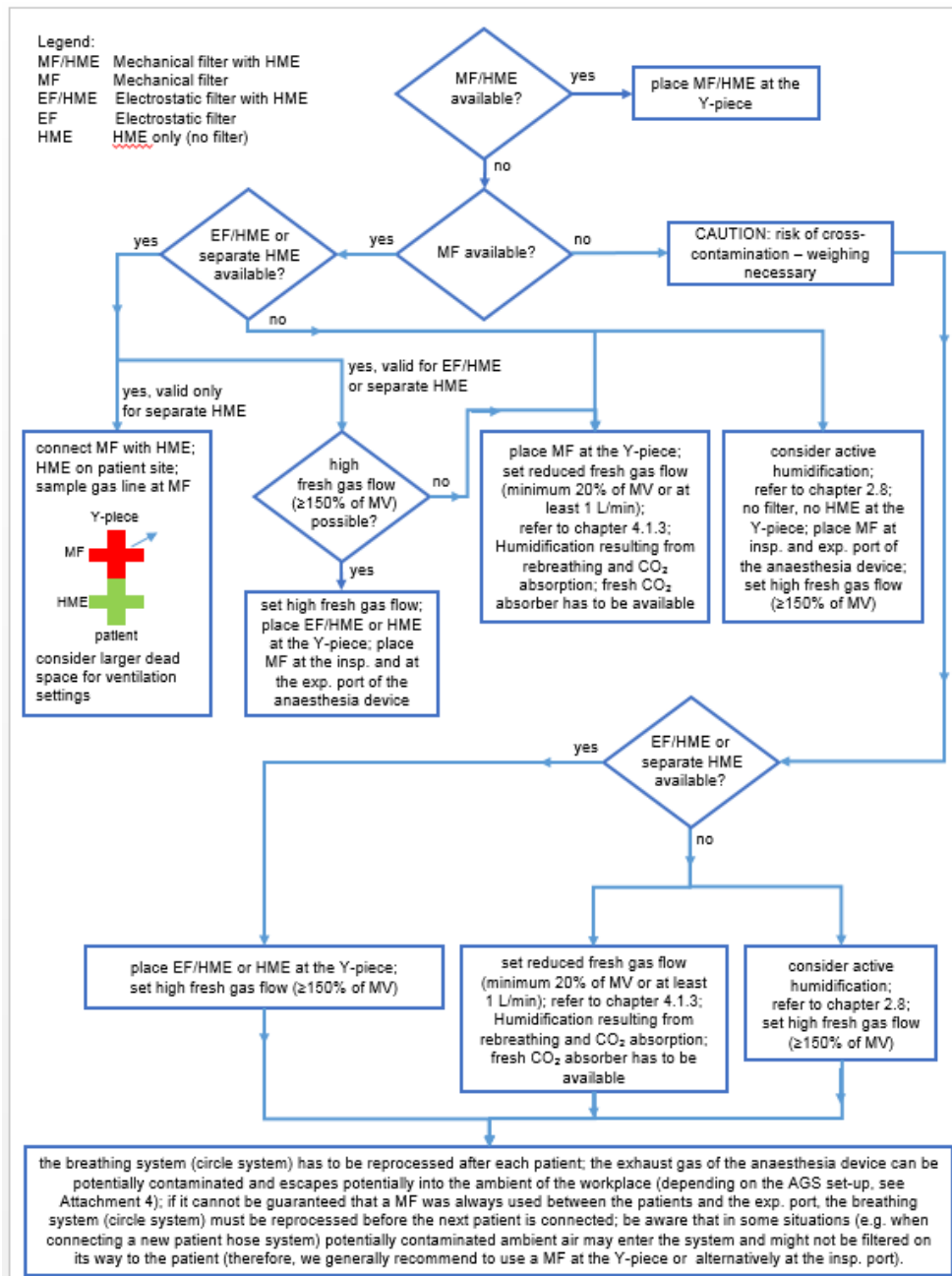
## 10 No breathing system filter is available

General information on the filter setup and necessary reprocessing measures are in the customer letter “SARS-CoV-2 and handling of Dräger Anesthesia Workstations“, [https://www.draeger.com/en-us\\_us/Home/novel-coronavirus-outbreak](https://www.draeger.com/en-us_us/Home/novel-coronavirus-outbreak)

Overview of Dräger filter / HME types and abbreviations for the decision tree:

- MF/HME Mechanical filter with HME = Dräger TwinStar HEPA
- MF Mechanical filter = Dräger SafeStar
- EF/HME Electrostatic filter with HME = Dräger TwinStar
- EF Electrostatic filter = Dräger CareStar
- HME HME only (no filter) = Dräger HumidStar

## 10.1 Decision tree



## 11 No disposable breathing circuit is available

Use reusable breathing hose systems, whenever possible with water traps.

## 12 Reduce the fresh gas flow

Fresh gas flow > 20% of the minute volume, at least 1 L/min. For patients with increased CO<sub>2</sub> production (e.g. high fever), the fresh gas flow should be set significantly higher (e.g. >50% of the minute volume).

- ➔ more humidity in the breathing system (circle system) and the piston ventilator
- ➔ higher consumption of soda lime due to more rebreathing, please refer to the following website [https://www.draeger.com/en\\_corp/Corporate/Coronavirus-COVID-19](https://www.draeger.com/en_corp/Corporate/Coronavirus-COVID-19) for a calculation tool.
- ➔ Deviation between set O<sub>2</sub> concentration in the fresh gas flow and measured FiO<sub>2</sub> increases
- ➔ The system reacts slower to changes of the fresh gas O<sub>2</sub> settings
- ➔ Check also chapter 4.1

### To be considered

- Adjust the filter set-up: no filter at the inspiration port, use mechanical filter (if possible with HME) at the Y-piece (TwinStar HEPA or SafeStar)
- Set narrow alarm limits for FiO<sub>2</sub>, MV low, Paw high and insp. CO<sub>2</sub> high
- Use the longest possible hoses with water traps in the inspiration and expiration limb
- Perform a system test of the anesthesia devices every 24 h. For devices of the Apollo and Fabius family, remove condensate out of the piston diaphragm before starting the system test. During the process of draining the patient must be ventilated differently.
- Check the accessories frequently, at least every 4 hours
- Check the water traps of the breathing hose system and drain them if they contain condensate
- Check the water trap of the gas measurement (Waterlock2) and drain it if it is half full with condensate
- Check the filter and change it if there is an increased amount of condensate present
- Change the CO<sub>2</sub> in time if 2/3 of its content has turned purple
- Permanent presence of an experienced user with detailed knowledge of rebreathing systems is necessary