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Stockholm, Sweden

To whom it may concern

Maquet Critical Care AB
Röntgenvägen 2
S-17154 Solna
Sweden

CUSTOMER NOTIFICATION LETTER
COVID-19 Pandemic
Ventilating ICU patients using Flow-i, Flow-c and Flow-e anesthesia machines

Dear all,

In view of the situation with the coronavirus, Novel Coronavirus (2019-nCoV), and the possibility to repurpose Flow-i, Flow-c and Flow-e anesthesia machines for use in the ICU as a ventilator only, Getinge would like to draw your attention to important information in the following three sections:

1. General information and warnings
2. Preparations for use
3. Key system differences (between Flow anesthesia machines and ICU-ventilators)
    - Rebreathing
    - Manual and automatic ventilation (MAN/AUTO) and APL
    - O_2 flush
    - Sampling line and water trap
    - AGSS (Anesthesia Gas Scavenging System)
    - Emergency ventilation
    - Alarms and monitoring
    - Leakage
    - System checkout

1. General information and warnings

As outlined in the user manuals the Flow family systems are intended for use:

- in administrating anesthesia while controlling the entire ventilation of patients with no ability to breathe, as well as in supporting patients with a limited ability to breathe.
- by healthcare professionals, trained in the administration of anesthesia
- on neonate to adult patient populations.
- hospital environments, except MRI environments.

When not in operation, the systems are designed for in-hospital transport.

The following information is being provided as a guidance. Using the anesthesia device outside of the intended use as specified in the user manual and as noted above (e.g. long-term ventilation) is considered off-label use. If the user (health care provider) decides to use the anesthesia device off-label, he/she is responsible to make this determination and so at his/her own (liability) risk. The risk benefit assessment has to be made by the responsible health care provider based on the circumstances. Please also be aware that this information is only intended for the duration of the COVID-19 emergency.

Maquet Critical Care AB is providing the following information for a better understanding of how the anesthesia device functions so that the health care provider can make the decisions on how to proceed when using a Flow-i, Flow-c and Flow-e anesthesia system for use in the ICU as a ventilator only.

Please be specifically aware of the following:

- *The devices are specified for use during surgical or diagnostic interventions under constant supervision of a trained user. It is, therefore, important that the personnel using the anesthesia device is familiar and well-trained on the user interface, the controls and the alarms of the machine, or, that someone who is supervises the user. This has to be determined by the health care provider based on the situation on the site.*

- *Certain patients are susceptible to malignant hyperthermia and it is, therefore, important to prepare the anesthesia device prior to treating such patients. Make sure to follow the instructions in the Cleaning and Maintenance Manual (for US - MCV00011319_REVA).*

- *The User Manual states that a resuscitator must always be available at the anesthesia device to mitigate if any malfunctioning of the device should occur that disturbs the oxygen intake of the patient.*

- *The anesthesia device is designed with alarms that are constantly supervised by the user and safety measures that are dependent on user presence. The healthcare provider must be aware of this and take appropriate actions so that it is always possible to react on alarms and perform safety measures.*

- *Please be aware that nebulization of drugs is not approved with this anesthesia device. Using aerosol therapy might affect the device negatively causing malfunction.*

- *The anesthesia device is not validated or intended for use with active humidification. Should this nevertheless be used, the HME filter at the y-piece cannot be connected to the system, as the humidification created will be filtered by the HME filter and will not reach the patient. This will most likely also result in excessive condensate in the anesthesia device. If active humidification is used, the system shall run with high fresh gas flows and be equipped with filters on both the inspiratory and expiratory limbs. Close monitoring of the ventilatory and patient parameters is mandatory. Dual heated breathing circuits should not be used.*

- *If inhalation anesthetic agents are used as sedation, the user must be aware that the surplus of the agents could be transported out into the environment. It is, therefore, important to connect an Anesthesia Gas Scavenging System (AGSS) to the system.*

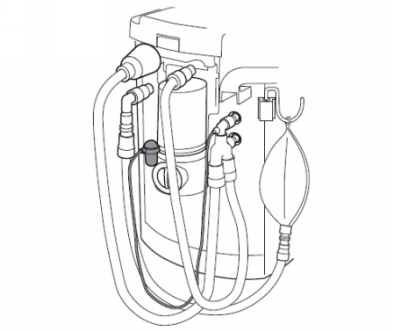
- *Reprocessing of applicable parts of the anesthesia device shall be performed according to the information in the Cleaning and Maintenance Manual, i.e. between each patient after treating a known carrier of pulmonary contagious agents.*

- *Please ensure that the system has the latest available software installed.*

2. Preparations for use

For more detailed information, see section 3 in this letter.

- Check that the manual resuscitator is readily available and is working correctly.
- Remove the vaporizers by lifting up the front and gently pulling outwards.
- If the system is equipped with N_2O gas module and/or with the alarm options Mute Apnea Alarms and/or HLM/CPB (heart lung machine mode/cardio pulmonary bypass) these should be turned off in the Service & Settings menu. The alarm modes above will silence and, for HLM/CPB, disable crucial alarms and are not to be used in the ICU. Please contact a certified Getinge trained service engineer to assist.

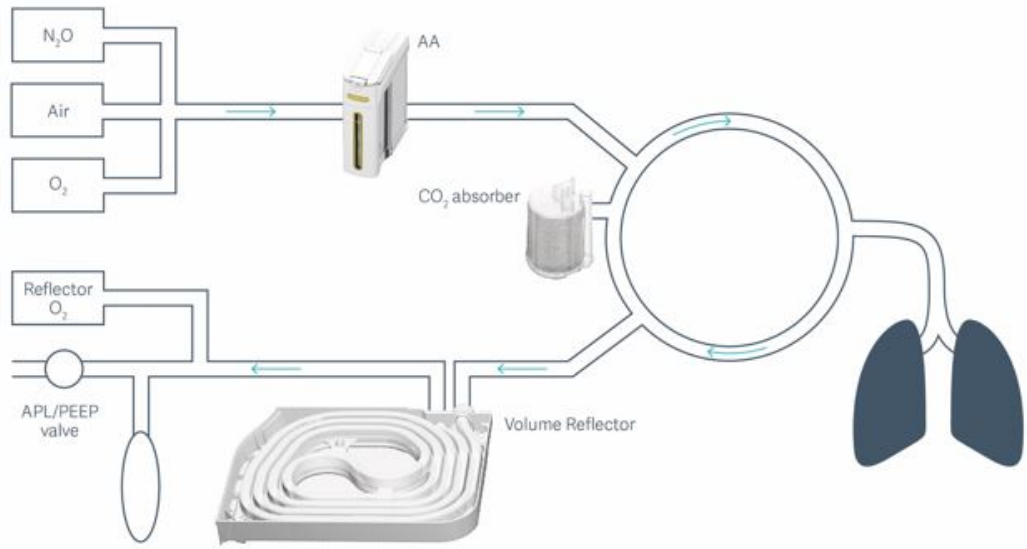


- Connect breathing circuit according to user manual.
- Use a high quality antiviral HMEF (heat and moisture exchange filter) placed between the breathing circuit and the patient's airway, this will protect the machine from contamination. The gas sampling line should be connected to the HMEF on the machine side of the filter to ensure sampled gas is not contaminated as it enters the water trap.
- Make sure to use an expiratory bacterial/viral filter, to minimize cross-contamination. Make sure to follow the filter manufacturer's recommendations for exchange interval of the filters.
- Perform a system checkout (SCO) according to instructions on screen. The test will take 6-8 minutes. Back-up gas cylinders are included in the check-out procedure should they be connected.
- Set alarm sound level to 100% and modify alarm limits accordingly

3. Key system differences

Rebreathing

The most significant difference between intensive care ventilators anesthesia devices is that anesthesia ventilators are based on a rebreathing system and adjustable fresh gas flows. This



means that depending on the set fresh gas flow, expired gases will be rebreathed.

If non-rebreathing is desired, we recommend the user to set the fresh gas flow higher than the patients expired minute volume. If the user to set the fresh gas flow to 20 l/min, the system is designed to automatically adjust the fresh gas flow to just above the patient's minute volume and thus guarantee a non-rebreathing system.

If the fresh gas flow is set to less than expired minute volume, part of the expired gas will be returned to the inspiratory limb.

In a circular system, expiratory gas is purified in the CO_2 absorber before it is mixed with fresh gas and delivered to the patient. This requires the use of a CO_2 absorber to prevent high CO_2 levels in the circuit.

Please be aware that if high fresh gas flows are used, the CO_2 absorber will not be part of the breathing circuit and thus not be consumed.

When the gas passes through the soda lime, CO_2 is absorbed and water and heat are produced. A higher rebreathing fraction could thus humidify and warm inspiratory gases and may make active humidification redundant.

Anesthesia machine operators should change the absorber when the absorption material changes from white to pink/violet as the measured inspired CO_2 increases (indicating no more CO_2 can be absorbed). The activation of an inspiratory CO_2-high alarm limit helps to directly inform the user about undesired levels of inspiratory CO_2 ($FiCO_2$).

Another very important aspect of using rebreathing is that due to patient oxygen consumption and dilution effects within the circle system, **the inspired O_2-level might differ to that of the set O_2 concentration in the fresh gas delivered from the system. Make sure to continuously monitor inspired and expired values of O_2, (FiO_2, EtO_2) and CO_2 ($FiCO_2$ and $EtCO_2$).**

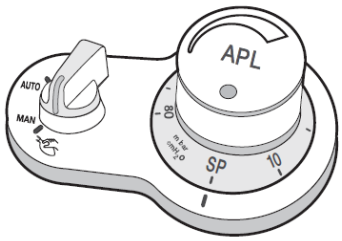
Should the FiO_2 decrease below 21% the Flow anesthesia system has a built in safety feature, O_2Guard, that will automatically set the O_2 setting to 60% and, if set lower, raise the fresh gas flow to 1 l/min. Please see the User Manual for further information.

Manual and automatic ventilation (MAN/AUTO) - APL

Manual ventilation is carried out using a traditional breathing bag connected to the patient cassette through a breathing bag tube. During manual ventilation the ventilator is passive which means that the patient is not ventilated unless the manual bag is pressed and the APL is set accordingly.

The MAN/AUTO ventilation switch is an electrical switch used to select manual or automatic ventilation. The APL (adjustable pressure limit) valve relieves the patient circuit of excess pressure at user defined values and ventilates the gas into the Anesthetic Gas Scavenging System (AGSS).

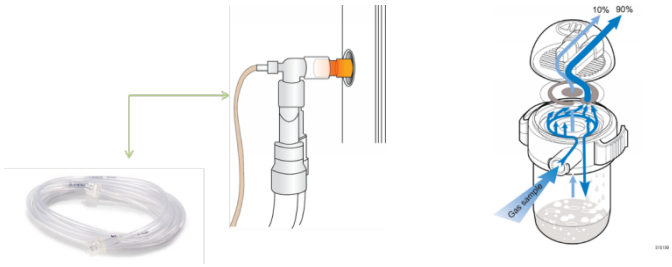
When the MAN/AUTO switch is set to “MAN” the manual ventilation valve opens and the manual ventilation bag is connected to the breathing system.



O_2 flush

Pressing the O_2 flush button manually supplies the system with an additional gas flow of approx. 50 l/min from the O_2 gas supply. The flow will continue as long as O_2 flush button is depressed. During the O_2 flush activation, the system will hold the set PEEP.

Sampling line and water trap



Always connect the sampling line to the HME-filter located on the endo-tracheal tube, this will minimize the risk of contaminating the anesthesia machine.

The Flow anesthesia machines are equipped with a side-stream multigas analyzer with an integrated O_2 sensor. The length and inner diameter of the sampling line determine how long time it will take before the gas data and curves information is displayed on the screen. **There will, in other words, be a delay in values and waveforms of several seconds compared to the ICU-ventilators.** Connection of several sampling lines in order to extend the line's reach will increase this time.

The water trap, sampling line and connectors are all part of a system optimized for the patient gas analyzer to protect it from condensed water, secretions, bacterial contamination and dust. The water trap comprises a filter housing (with hydrophobic anti-bacterial filter), and a water container for separated waste. The filter housing has one gas sampling inlet that is connected to the sampling tube.

The sampling line is not reusable and must be replaced between patients or when the cleanliness of the tubing or connector is compromised.

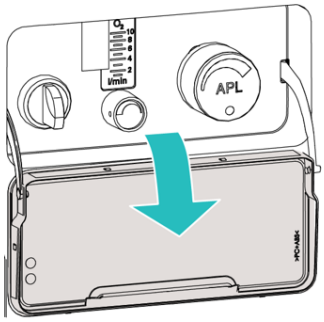
Check the water trap and sampling line regularly and discard/empty any water present in the water trap. Empty or discard the water trap after 17 hours of active use, or when half full. The content of the water trap should be handled as biological hazardous waste.

AGSS (Anesthesia Gas Scavenging System)

Caution: If inhalational anesthetic agents are used it is important to ensure that the machine is connected to a scavenging system as described in the manual.

When the AGSS is connected to the rear of the system, the flowmeter on the front indicates the rate of evacuation. The minimum level of evacuation flow is indicated by the floater being above the dashed area, corresponding to a flow of approx. 25 l/min. If the central scavenging system is inactive, the gases will be emitted into the room.

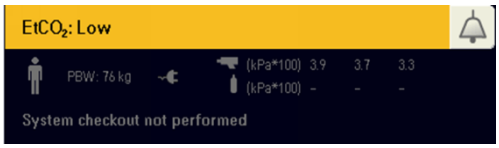
Emergency ventilation



Allows patient to be manually ventilated in case of system failure (i.e. mains power and battery) or other electronic failure and is accessible behind cover on front of machine. Replaces fresh gas flow (with 100% O_2) and electronic APL function.

During emergency ventilation the system cannot deliver anesthetic agents.

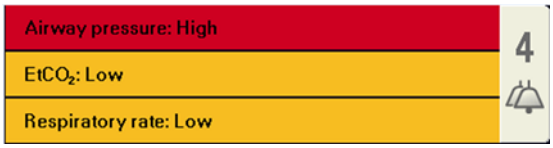
Alarms and monitoring



An anesthesia machine is designed for presence of a trained specialist by its side.
There are no lamps or remote monitoring, once an alarm is no longer valid it is not audible or visible anymore and the sound of the alarms in general are lower than an ICU-ventilator.

Taking this into consideration it is crucial that the clinician in charge has full control of the screen for the visual alarms and the sound turned up to 100%.

Alarm limits will need to be adapted for each patient.



The alarm area on the screen can display up to three alarms, listed in order of severity. Should there be more alarms that are ongoing a number will be visible to the right (in this case 4). Pressing the number shows up to 10 ongoing alarms. For previous alarms press “trends” on the same page.

Leakage

Should a leakage occur an alarm will be activated. In general the leakage will not be compensated. This is especially important during volume controlled ventilation modes. It´s important to find the source of leakage in order to rectify it as well as following of the patient´s vital signs and ventilation metrics.

System check-out

To ensure correct system functionality, optimal performance and patient safety, the Flow anesthesia system is designed to perform a system check-out every 24 h or before starting a new case. After 24 h the machine will continue to ventilate but with risk for minor device malfunctioning, such as drifting monitored values. It is however possible to continue ventilation for at least 12 days under extreme circumstances before conducting a new system check-out. At this time, the physician responsible needs to do a risk/benefit assessment if to interrupt ventilation and perform a system check-out. If it is decided to keep ventilating the patient, continue to monitor ventilatory measurements closely. Make sure to closely monitor and change water trap, HME and expiratory/inspiratory filters according to manufacturer’s recommended interval.

In order to perform a new system check-out the system needs to be in Standby and thus the patient needs to be disconnected from the ventilator and manually ventilated with a resuscitator. The test will take 6-8 minutes. Make sure to document the settings before going to Standby, as the machine will reset to startup configurations.

If you have any questions or remarks to this topic, please do not hesitate to contact your local Getinge representative.

Yours sincerely,

Miray Kärnekull, MD

Medical Director
Maquet Critical Care AB

Lena Evander

Product Management Anesthesia
Maquet Critical Care AB