GE Healthcare
Life Care Solutions
Datex-Ohmeda, Inc.

23 March 2020

Topic: COVID-19 - Requests for information regarding the off-label use of GE Healthcare anesthesia devices for ICU ventilation

Dear valued customer,

The pandemic situation related to COVID-19 is leading to significant concern around the world regarding the availability of ICU ventilators to meet potential needs. We have generated this letter in response to numerous requests for information regarding whether existing anesthesia devices could temporarily be used to supplement ventilator capacity.

IMPORTANT: This document contains off-label information. This information is only being provided for consideration during the COVID-19 pandemic. Regulatory authorities (e.g. U.S. FDA, Health Canada, TGA, EU Competent Authorities) have not cleared or approved these anesthesia devices as safe and effective for use as ICU ventilators. The use of these devices as ICU ventilators has not been verified or validated.

However, recent U.S. FDA guidance[1] published 22 March 2020, states that during this COVID-19 health emergency, the U.S. FDA does not intend to object to the use of anesthesia gas machines for patients needing mechanical ventilation.

As U.S. FDA stated, "wherever possible, health care facilities should use cleared [or approved] conventional/standard full-featured ventilators when necessary to support patients with respiratory failure." The use of an anesthesia machine is considered off-label use (not formally cleared or approved by any regulators) and GE Healthcare does not in any way promote or recommend the use of anesthesia devices as ICU ventilators in any normal circumstances. However, we understand the extreme circumstances driving this request and the need to weigh the relative risks and benefits to support patients in these unprecedented times. While an anesthesia device has a ventilator within it, the overall device is not the same as an ICU ventilator, and it is critical to understand the differences in order to minimize risks to patients. The information presented below is intended to describe the key differences between these anesthesia devices and ICU ventilators, and present important information related to the device functionality and patient safety.

IMPORTANT: The information presented is based on the current understanding of the potential risks and device functionality of the GE Healthcare Anesthesia devices mentioned below. This may not be comprehensive and may not cover all use scenarios and risks. As the COVID-19 situation and understanding evolves, we will do our best to continue to provide the most accurate information.

- **We recommend regularly checking the GE Healthcare website (https://www.gehealthcare.com/covid19) for updates to this letter and additional information.**

IMPORTANT: Use of the device in an off-label manner is the sole responsibility of the device owner and is done at his/her own (liability) risk.

For the European Union and other countries, consult with your relevant Competent Authority or regulator regarding derogations for off-label device use/compassionate use during the COVID-19 pandemic.

1) US FDA - Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency Guidance for Industry and Food and Drug Administration Staff, March 2020

Refer to **Appendix 1** for the cleared indications for use/intended use for the GE Healthcare anesthesia devices.

IMPORTANT SAFETY INFORMATION

WARNING: GE Healthcare anesthesia machines are life supporting/life sustaining devices. There is a risk of serious injury or death if the devices are not used by properly trained clinicians, continuously monitored, and used in accordance with the instructions for use.

Intended Use

- The cleared indications for use/intended use information is listed in Appendix 1. There are risks related to any use of those devices other than that for which they are indicated. Clinicians considering such use during the pandemic must weigh the risks and benefits and ensure proper training and safe handling of the devices.
- The risks of an anesthesia device used for ICU ventilation may be significantly greater for pediatric or neonatal patients. Such use is strongly discouraged.

Attended Devices

- Anesthesia devices are designed and intended to be fully attended/monitored devices, which requires a clinician to be in proximity of the device at all times. This is different from the potential use case in ICU ventilation. It is critical to ensure the proper use and continuous monitoring of the anesthesia device function and ventilation is maintained.

Training/Knowledge of the System

- Anesthesia devices are complex systems which rely on user knowledge and training for safe operation. The devices are intended to be used by clinicians who are trained in the administration of general anesthesia. There are unique characteristics that differentiate anesthesia devices from standard ICU ventilators. New or different personnel intended to handle the devices must be appropriately trained on the anesthesia device and complete instructions for use.
- All users should be familiar with the anesthesia system user interface, controls, functions, configurations, alarms, and theory of operation before using these devices.
- Ensure the device instructions for use are available for training and for reference during use.

Anesthetic Agent

- Anesthesia systems may contain residual amounts of anesthetic agents in the breathing system. Be sure to flush out any residual agent prior to use as an ICU ventilator to prevent the risk of medication interactions. There is a risk of malignant hyperthermia if the patient is susceptible to inhaled anesthetic agents. Even small amount of agent may trigger this risk.

- It is highly recommended to remove/disconnect the vaporizers and any other unnecessary connections, such as N2O, before using the device.

Circle Breathing Circuit, CO2, and Humidity/Moisture

- Circle breathing systems, such as those used in anesthesia devices, use unidirectional valves which may prevent the release of pressure from the patient connection; for example, if the expiratory breathing tube is occluded. Users must be familiar with the theory of operation of circle breathing systems, including CO2 absorption function, including how and when to change CO2 absorbent canisters, and flow and pressure delivery functions prior to using the device.
- Use of circle systems for long-term ventilation may result in a buildup of excess moisture and condensation in the breathing system and device. Excess moisture can degrade the performance of the ventilator sensors and reduce ability to keep the system clean. Periodically monitor the device for indications of moisture build-up in the breathing tubes.
- If moisture or condensation occur, increasing the fresh gas flow may provide adequate gas flow to reduce excess buildup. It is recommended that the Fresh Gas Flow setting be set to at least 50% or more of the patient's minute volume to ensure adequate oxygenation and to reduce CO2 rebreathing. Higher FGF closer to the minute volume will reduce rebreathing but may lead to drier inhaled gases. Drain water as necessary if condensation in the breathing system occurs.
- Water condensation in the breathing circuit tubing may be lessened by using a Heat and Moisture Exchange Filter (HMEF) at the airway connection. Monitor and replace patient circuit filters as necessary. When using a GE Healthcare respiratory gas module, make sure to connect the sampling line to the sampling port on the device side of the HMEF, or to another sampling port (elbow connectors, T-pieces) proximal to the anesthesia device with respect to the HMEF, to protect the gas module from excess moisture and from contamination.
- It is NOT recommended to use active humidification with these anesthesia systems. Consider use of an HMEF for patients ventilated with anesthesia systems. If active humidification is required, consider transferring the patient to an ICU ventilator.
- Anesthesia devices are equipped with CO2 absorbers, which have a limited useful life. Failure to change the CO2 absorber when depleted, as described in the instructions for use, will result in an increase in inspired CO2. Always use proximal / end-tidal CO2 and O2 monitoring.
- For devices which are compatible with the GE Healthcare respiratory gas module, the FiCO2 High alarm is disabled by factory default on many anesthesia systems. It is recommended to ensure this limit is set to an appropriate value to prevent CO2 rebreathing for an ICU patient.

Length of Use and Checkout

- Anesthesia devices are not intended for long term ventilation use and are designed to be rebooted/restarted every day to ensure proper calibration, accuracy, and performance. If an anesthesia device is used to provide mechanical ventilation in emergency/pandemic scenarios,

it is recommended that patients requiring long term therapy are transferred to an ICU ventilator more suited for long term ventilation.

- GE Healthcare anesthesia devices are intended to be power cycled (turned on/off) and tested/checked out fully at least once a day. Complete circuit checks should be performed before each patient use and periodically for monitoring. Use of the device without appropriate periodic calibration per the instructions for use may result in the degradation of device delivery and monitoring performance, including pressure, flow and volumes, and spontaneous breath triggering. It is highly recommended that the checkout procedure is performed on these devices daily. To do this checkout during ventilation, you would need to disconnect the patient and manually ventilate. If this is not possible, devices must be power cycled and checked out between patients.
- The Aisys, Avance, Aespire and Aestiva family of anesthesia devices will shut down (stop ventilation) if they run for 49 days consecutively without a reboot. Do not use anesthesia devices for extended time periods without rebooting.
- If a device has been used for more than 24 hours since the last checkout was completed, circuit compensation information will be cleared the next time the "Therapy" state is exited. This may affect the accuracy of delivered volumes. Checkout may need to be completed during the ventilation period for a single patient if the Therapy state is exited after 24 hours since the last checkout.

Ventilation Modes/Alarms/Settings

- Anesthesia devices and ventilators frequently use similar names / nomenclature to refer to ventilation modes, settings, and procedures which may be slightly different. Ensure device users are familiar with the performance requirements and limitations of the system.
- Anesthesia systems are designed for use in an attended environment. Device audio alert levels (volume) may not be adequate for the ICU use environment. Ensure the device audio level is adequate for the ICU or provide alternative methods of continual status monitoring. The anesthesia machines do not have the ability to generate alerts via the hospital nurse call alarm systems.
- It is vital to ensure alarm limits are configured appropriately to provide warning of patient or device issues during mechanical ventilation. It is recommended that all alarms are enabled at all times.
- Anesthesia devices do not provide automatic leak compensation found in many ventilators, and while higher fresh gas flow may compensate small leaks, they are not designed to be used with large leaks in the breathing circuit, such as non-invasive ventilation. If non-invasive (masked) ventilation must be used, use a spontaneous, pressure-target mode such as CPAP + PSV. Increasing fresh gas flows may provide additional compensation, if the leaks from the mask are small. The device may alarm if leaks exceed the configured alarm limits. Bellows provide a visual indication of leaks: if the bellows does not reach the top of the housing at the end of expiratory cycle, check for leaks. Ventilation delivery accuracy cannot be guaranteed with large leaks and the patient may not have sufficient oxygenation or CO2 clearance. Always ensure alternative methods of ventilation and monitoring are available.

- Anesthesia devices may be optionally equipped with non-ventilation modes such as Monitoring Only mode, and Cardiac Bypass. These modes are designed for little to no ventilatory support or monitoring and should not be used for ventilation purposes.
- Anesthesia devices may have different performance specifications from ventilators, such as inspiratory flow capability, pressure limitations and other ventilation performance needs. Anesthesia devices may have increased inspiratory and expiratory resistance compared to traditional ICU ventilators. Ensure patients are suitable for ventilation based on the specifications of the anesthesia devices before beginning therapy.
- Anesthesia devices (other than those with "PSV Pro" mode) are not equipped with "Backup Mode" functionality, which is provided with many ventilators. Devices will not provide baseline mechanical ventilator support unless initiated and configured, and will not switch to mechanical modes in the event of an apneic event. Always ensure the ventilation mode is adequate to ventilate the patient. Always provide continuous monitoring of patients.
- The CPAP + PSV mode may be configured with a minimum rate setting.
- The PSV Pro mode is an optional vent mode on some anesthesia systems, and this mode does utilize backup ventilation functions. Ensure the user is familiar with configuration of the mode and backup ventilation settings prior to using these advanced modes.
- Pmax - Anesthesia devices and ICU ventilators are both equipped with automatic response to high pressure scenarios, by cycling to exhalation (ending an inspiratory period early) if a Pmax alarm limit violation occurs. Anesthesia devices are not equipped with the ability to open the patient circuit to atmosphere under sustained pressure or occlusion scenarios, unless the working pressure exceeds 110 cmH2O. The devices will cut off inspiratory flow if prolonged pressure scenarios occur, but do not have the ability to immediately relieve pressure in case of an obstruction.
- There should always be an alternative oxygen source such as an oxygen cylinder and a self-inflating bag available and tested. If there is any problem with the ventilation, the first action is to connect the self-inflating bag directly to the patient airway, without any filters or adapters, to ensure ventilation and oxygenation of the patient.

Gas Monitoring (O2 and CO2)

- Always use proximal / end-tidal CO2 and O2 monitoring. Ensure the actual delivered O2 levels are appropriate for the patient. Remember, when fresh gas flows are lower than minute volume, the O2 concentration in the fresh gas will be diluted, so the set O2 level will be different from what the patient actually receives.
- Elevated FiCO2 values are an indication that the CO2 absorber canister requires replacement / refill. The CO2 absorber is used to remove excess CO2 from the circle system; failure to change the absorber may result in rebreathing, excess CO2, or insufficient oxygenation. Consult the device instructions for use on how to exchange the CO2 canister during a case.

Use Environment/Transport/Drive Gas

- The anesthesia devices are not intended or designed to function while moving and are not for use during transport within a facility or between facilities.
- The anesthesia devices should not be used for agent delivery outside of an Operating Room (OR) environment and without users trained on the proper setup of the system.
- If the device is moved to use environments outside of its normal location in the OR, the device must be re-installed/configured by professionals trained in the proper setup of facility connections such as scavenging and gas inputs.
- The anesthesia devices are not intended or designed to function without adequate scavenger extract flow. Without adequate scavenger extract flow, unintended Positive-End Expiratory Pressure (PEEP) may occur. The anesthesia gas scavenging system (AGSS) must be opened to atmosphere by removing the hose connected to the AGSS and removing the visual indicator bag (if equipped).
- To conserve supplies of O2, the drive gas may be changed from O2 to medical air in accordance with the service instructions (Technical Reference Manuals). This must be performed by trained and authorized service personnel and they must complete the appropriate testing outlined in the Technical Reference Manual.

Reprocessing and Cross-contamination

- Facilities should follow local procedures and guidelines and the device instructions for use regarding device reprocessing. You may also refer to the GE Healthcare Anesthesia and Respiratory Cleaning Guidance Letter for COVID-19. It is strongly recommended that viral/bacterial filters be used to protect the patient connection ports (inspiratory and expiratory).
- If an HMEF is used at the patient Y-piece, additional filtration is not required at the inspiratory port. If an HME is used at the patient Y-piece, ensure filtering is present at the inspiratory port. Use an expiratory viral/bacterial filter at all times. Follow filter guidelines on replacement timelines/frequency.
- Devices equipped with airway module sample gas configured to the breathing system should disable Sample Gas Return, including disconnecting the tube connecting the gas monitor to the device. Contact GE Healthcare Service representatives for support.
- If the device uses the "Circuit O2 Cell" for oxygen monitoring (e.g. Aestiva and Aespire families), ensure precautions are taken to replace or protect the O2 cell from contamination. The O2 cell cannot be reprocessed.

Case Setup

- Anesthesia devices are designed and intended to be used by trained clinicians who have detailed knowledge of the equipment. The devices are also designed to be attended/monitored at all times. The device instructions for use should be consulted for configuration, setup,

navigation and utilization, and troubleshooting. It is recommended that users with extensive experience with the device perform any necessary configurations and installations, and execute the system checks.

- The devices are intended to be power-cycled and to complete checkout daily. If the device cannot be cycled and checked daily, it must be power cycled and checked between patients. Always complete checkout with the circuit used for the patient to be ventilated, including any filters or circuit accessories. This is important to ensure the circuit compliance and other parameters that impact ventilation delivery are accurate.
- If checkout is not completed every 24 hours, the device may indicate a "Please Do Checkout" general message. If this message is displayed, the device will clear the internally stored circuit compensation data upon ending a case. Do not select End Case until Therapy is completed for the current patient.
- Anesthesia devices equipped with the "ACGO" circuit option have similar looking patient connection ports. The ACGO configuration is intended for single limb flow and not for mechanical ventilation. Ensure the patient circuit is connected to the circle system ports; consult the device operating instructions for proper circuit setup. Always confirm adequacy of ventilation before leaving any device and always maintain monitoring.

Start a case

- When starting a case, always ensure gases are flowing. Always ensure the ventilation mode and settings are appropriate for the patient prior to beginning mechanical ventilation. Mechanical ventilation begins as soon as the "Bag to Vent" switch is placed in "Vent" mode, after a case is started.
- Anesthesia devices are designed for use in an attended environment. It is vital to ensure alarm limits are configured appropriately to provide warning of patient or device issues during mechanical ventilation. It is recommended that all alarms are enabled at all times.
- Always use a respiratory gas monitor for CO2 and O2. If the respiratory gas monitor is not directly connected to the anesthesia device, external monitoring solutions are required.

Alternate O2

- Alternate O2 is a mechanism to provide an alternative source of fresh gas flow to the patient, in the event of a gas mixer failure (only on applicable anesthesia devices). In some device malfunction conditions, ventilation may continue using Alternate O2 (100% O2) instead of the set Fresh Gas flow and concentration. Ensure the Alternate O2 flow setting is high enough to provide adequate oxygenation to the patient in the event of a gas mixer failure.
- There should always be an alternative oxygen source such as an oxygen cylinder and a self-inflating bag available and tested. If there is any problem with the ventilation, the first action is to connect the self-inflating bag directly to the patient airway, without any filters or adapters, to ensure ventilation and oxygenation of the patient.

Settings

- Anesthesia "Gas Settings" are used to configure the oxygen concentration to be delivered to the patient. In a circle system, delivered gas may be partially diluted if the fresh gas flow is set too low. It is recommended that the Gas Flow level is set to at least 50% or more of the patient minute volume.
- Anesthesia "ventilation settings" are used to determine the volume or pressure delivered to the patient, and the type of control mode used. Names of settings and modes may not directly match that of ICU ventilators. Ensure ventilation modes and settings are selected with an understanding of the anesthesia device theory of operation.

Bag to Vent (BTV)

- Anesthesia devices are not automatically configured to begin mechanical ventilation when a case is started. The devices are configured for both manual ventilation (often referred to as "Bag Mode") and mechanical ventilation. When the device is in "Bag Mode", that is when the "Bag to Vent" switch is in the Bag position, *the device is not providing any ventilation support to the patient.* There is gas flowing, however the clinician must manually provide ventilation using the equipped bag.
- When the device is in manual ventilation, maximum pressure is managed by the adjustable pressure limit (APL) knob. If ventilating the patient manually, ensure the APL pressure limit is appropriate for the patient. Too low of an APL setting may result in no flow actually delivered to the patient. Too high of an APL setting may result in barotrauma.
- Mechanical ventilation begins by moving the "Bag to Vent" switch to the Vent position. Ventilation will begin at the previously configured / default settings. Always ensure the ventilation settings are appropriate for the patient prior to starting mechanical ventilation. Automatic pressure protection using the Pmax setting is enabled while in mechanical ventilation.
- Consider placing the device in manual ventilation mode ("Bag Mode"), if a closed suction routine is required. Closed suction while in mechanical ventilation may temporarily cause system alarms. As discussed above, confirm the APL valve setting is appropriate for the patient to avoid barotrauma.

Nebulization

- Anesthesia devices are not equipped with compensations for external flows added, such as with pneumatic nebulizers. It is not recommended to use nebulized drugs added to the ventilation with these devices.

Troubleshooting

- Because anesthesia devices are designed as attended devices, most anesthesia devices do not continue ventilation therapy in the event of a critical device malfunction. Ensure the device troubleshooting information (located in the instructions for use) is available at all times. In the event of a system error, the device may transition to error states (and may not provide ventilation). Ensure constant monitoring of the device and patient status.

- The device bellows provides a visual indicator of ventilation status. If the bellows is not rising and falling, there is no ventilation being provided.
- Anesthesia devices equipped with an electronic gas mixture may provide 100% oxygen flow (Alternate O2, "Alt O2") in the event of a mixer failure. Ensure the Alt O2 flow setting is adequate to provide oxygenated gas to the patient prior to starting mechanical ventilation.

  Anesthesia devices can utilize manual ventilation mode, with either "Alt O2" or flow knobs, to manually deliver oxygenated flow to the patient in the event of an emergency.
- Please follow the normal practices for reporting of any adverse events to GE Healthcare and local regulatory authorities.

If you have any additional questions, please reach out to your local GE Healthcare representative.

Sincerely,

Matti E. Lehtonen
General Manager, Anesthesia and Respiratory Care

GE Healthcare