



March 23, 2020

## **Mindray A-Series Anesthesia Delivery System Consideration for use as a Ventilator**

Dear Valued Customer:

In response to the COVID-19 pandemic, the US Food and Drug Administration (FDA) has provided guidance<sup>1</sup> that allows for the use of anesthesia delivery systems for continuous ventilation. This is due to the increased demand for mechanical ventilation that is estimated to exceed the available ventilators in Intensive Care Units (ICUs) in the US.

While Mindray does not promote anesthesia delivery systems for continuous ventilation, this information is provided in direct response to the current public health crisis. It is advised that the user becomes completely familiar with the information provided and considers all risks and benefits prior to using the anesthesia system for continuous ventilation.

When considering the use of an anesthesia delivery system for continuous ventilation, the following functional differences should first be noted:

- 1) The indications for use are different (please reference the appropriate product Operator's Manual at <https://www.mindraynorthamerica.com/technical-documents/>). Specifically, an anesthesia system is used, primarily, in Operating Rooms (ORs) where the case may last for a relatively short period or for several hours, under worst-case conditions. A continuous stand-alone ventilator is used, primarily, in the ICU and may operate continuously for several days.
- 2) Anesthesia systems are used, primarily, for mandatory ventilation on sedated and muscle-relaxed patients. Continuous stand-alone ventilators are used for spontaneous breathing support.
- 3) Manual mode on the anesthesia system is used for manually ventilating a patient or letting a patient breathe spontaneously, and is only available on the anesthesia systems (when the APL valve is set to "SP", the PEEP will be zero (0) and the patient can respire spontaneously). If the user switches the Auto/Manual switch to "Manual", the mechanical ventilation will cease and manual mode is activated. To exit the standby mode and start a new mechanical case, the Auto/Manual switch needs to be set to manual first, then switched to Auto again to start the case. The APL valve is used to set the maximum pressure that can be delivered to the patient in manual mode (please note that the APL valve has no effect on mechanical ventilation). It will automatically open to release the excessive gas when the pressure in the airway (PAW) exceeds the preset pressure limit in the APL valve to ensure that the PAW is within safe range.
- 4) Anesthesia systems use a semi-closed circulated breathing circuit (rebreathing system) so

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<sup>1</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus>

that CO<sub>2</sub> absorbent is utilized to prevent high CO<sub>2</sub> levels in the circuit. Continuous ventilators use an open breathing circuit and no CO<sub>2</sub> absorbent is needed.

- 5) Anesthesia systems rely on adjustable fresh gas flows to adjust the O<sub>2</sub> concentration, and the oxygen concentration of the inhaled gas (FiO<sub>2</sub>) may differ from the preset oxygen concentration in the fresh gas. For continuous stand-alone ventilators, the oxygen concentration is controlled by adjusting the O<sub>2</sub> and Air flow meter directly so that the preset oxygen concentration is the actual FiO<sub>2</sub>.
- 6) Anesthesia systems cannot support non-invasive ventilation, a common function of continuous ventilators. Anesthesia systems are limited in this manner because if a large leak were to occur, the bellows would collapse. An anesthesia system cannot continuously compensate for the large volume gas loss that may occur during non-invasive ventilation.
- 7) Anesthesia systems do not support some particular functions for critical care such as inspiration hold, expiration hold, ATRC, NIF and low-flow PV-Loop, which are common features in continuous ventilators.

If the clinical decision is made to utilize an anesthesia system for continuous ventilation it is strongly recommended the system should be operated, and the patient monitored, by a clinician experienced in anesthesia delivery. However, if the lack of staffing prohibits such, a facility may consider utilizing critical care staff and providing training on the use of anesthesia systems. Please consider the following:

- 1) Before connecting the patient to an anesthesia system, please check the overall status of the machine and make sure that all accessories (such as gas hoses, breathing tubes, filter, gas sampling line and water traps) are properly connected and the machine can generate gas flow and pressure.
- 2) Patients should be continually monitored in the event of a system leak or other event. In the case of a large leak causing the bellows to collapse, fresh gas should be increased to ensure continued ventilation. To ensure proper ventilation, the bellow needs to reach the top of the bellow housing at the end of expiration phase. If this requirement cannot be met, increase the fresh gas flow until it reaches the top of the bellows housing. Backup ventilation devices, such as a resuscitator, must always be available near the device in case of emergencies in which patients need to be temporarily disconnected from the anesthesia system.
- 3) For patients who have spontaneous breathing, muscle relaxants may be considered to assist with relaxing the respiratory muscle and reducing the human-machine asynchrony.
- 4) Replace CO<sub>2</sub> absorbent every 6 to 8 hours, or earlier, as indicated. Monitor CO<sub>2</sub> concentration at all times. Failure to replace expired CO<sub>2</sub> absorbent could result in the generation of toxic compounds and acidosis.
- 5) It is not recommended to use an anesthesia system for non-invasive ventilation.
- 6) Mixed air and oxygen, rather than pure oxygen, should be used as the ventilation gas.
- 7) Placing a HMEF (Heat and Moisture Exchange Filter) at the patient end of the breathing

circuit is recommended to keep the inspiratory gas filtered and humidified. Additional information on the placement of these filters, and use of Mindray anesthesia system with confirmed or highly-suspected COVID-19 patients, can be found on the COVID-19 page of the Mindray North America website<sup>2</sup>.

- 8) Increasing the fresh gas flow to a setting at least as high as the minute volume being delivered to the patient, will impact the following:
  - Reduce the amount of moisture in the breathing circuit and at the inspiration port filter (significant moisture accumulation will degrade ventilation performance)
  - Reduce the need to frequently change the CO<sub>2</sub> absorbent
- 9) Nebulization of drugs or aerosol therapy cannot be used with an anesthesia system.
- 10) The anesthesia system is a closed loop system and, as such, the delivered FiO<sub>2</sub> value will be lower than the set FiO<sub>2</sub> value. This is a result of O<sub>2</sub> being utilized by the patient.
- 11) To eliminate the possibility of delivering anesthetic agent, disconnect all vaporizers and do not connect any N<sub>2</sub>O source (either a pipeline or cylinder) to the anesthesia system.

Additionally, the FDA has requested that Mindray provide guidance on the following specific points:

1) **What is the suggested self-check frequency when using the anesthesia system long-term:**

It is recommended to conduct the machine self-test every 24 hours to ensure readiness for operation. If it is not feasible due to personnel shortages, it is recommended to perform the self-test at least every 72 hours to reduce the risk of device malfunctions. When performing the self-test, the patient must be disconnected from the anesthesia system and therefore, an alternate ventilation device, such as a resuscitator, will be needed for the patient during this time.

In addition, during extended periods of use, the following items should be addressed:

- Check for excessive moisture/water in the water trap of the gas module.
- The water trap at the gas measurement module should be emptied or exchanged before it becomes full.
- The water trap on the bottom of the breathing system (below the absorber canister) can be removed and emptied.
- Drain water from the bottom of the absorber canister. Turn the condensate drain valve clockwise to open the drain and collect any water that may have gathered. Turn the drain valve counter-clockwise to close the drain.
- Check for standing water in breathing hoses. Remove the hoses and drain the water, when needed.
- Check the CO<sub>2</sub> absorbent level every 6-8 hours, looking especially for any color change or increase in FiCO<sub>2</sub> measurement.
- Confirm ventilation delivery is as expected. If the flow measurement becomes inaccurate, the Flow Sensor Calibration needs to be performed immediately (please refer to the Flow Sensor Calibration section in the Operator's Manual for more details).

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<sup>2</sup> <https://www.mindraynorthamerica.com/covid-19-response/>

- 2) **Provide a guide for the use of active humidification:**  
Active humidification cannot be used on an anesthesia system as this will cause incorrect flow rate measurement. A HMEF or HME may be utilized.
- 3) **Describe the sterility/reprocessing including how often circuits, HMEF (type of filter and placement of filter), and water traps need to be changed out:**
- Filters should be placed on both the inspiratory and expiratory ports.
  - Circuits and filters (including HMEF and HME) should be replaced for every patient
  - Filters should be changed during patient use based on the recommendations of the HMEF/HME manufacturer.
  - The water trap on the gas module should be replaced once every 30 days.
- 4) **Describe all modes of ventilation, and provide a description of the APL valve and manual ventilation mode:**
- Mindray anesthesia systems offer the following ventilation modes (based on model and configuration): Manual, VCV, SIMV-VC, PCV, PCV-VG, SIMV-PC, SIMV-VG, CPAP/PS or APRV. For a description of each mode, please, refer to Attachment 1.
  - The purpose of the APL valve is to set the maximum pressure that can be delivered to the patient in Manual mode. The APL valve has no effect on mechanical ventilation and will automatically open to release excessive gas when the pressure in the airway (PAW) exceeds the preset APL pressure limit. When the APL valve is set to "SP", the delivered PEEP will be zero (0), allowing the patient to respire spontaneously.
- 5) **Describe alarm function including the suppression of alarms since non-anesthesia personnel may manage the anesthesia system during the pandemic:**  
Set the alarm volume to maximum (100%) to facilitate immediate recognition and response. Alarm volume can be adjusted by pressing the "Alarms" button and then selecting the "Audio" tab. Please note that alarm notifications will stop when the state causing the alarm is resolved. To view alarm history, check "History" then "Event Log".
- 6) **What is the recommended Fresh Gas Flow (for non-rebreathing and also for rebreathing since Oxygen supply may diminish)?**  
Increasing the fresh gas flow to a setting at least as high as the minute volume being delivered to the patient, will impact the following:
- Reduce the amount of moisture in the breathing circuit and at the inspiration port filter (significant moisture accumulation will degrade ventilation performance).
  - Reduce the need to frequently change the CO<sub>2</sub> absorbent.
- 7) **Indicate whether vaporizers and nitrous oxide can be removed for safe use:**  
To eliminate the possibility of delivering anesthetic agent, disconnect all vaporizers and do not connect any N<sub>2</sub>O source (either a pipeline or cylinder) to the anesthesia system.
- 8) **Describe leakages that are peculiar to anesthesia delivery systems:**  
Leakages peculiar to anesthesia system include the potential for leaks from the CO<sub>2</sub> absorber, breathing tubes and sampling lines.
- 9) **Provide a general statement on performance of the anesthesia system as a long-term ventilator. If you have information from other countries on how your machines have been used for this purpose, please include this information for clinicians:**  
Mindray is not aware of our anesthesia systems being used as a continuous ventilator in any global market.

10) **Describe any modifications needed if oxygen generators are used as primary oxygen supply:**

Oxygen generators cannot be used as a primary oxygen supply as this will likely cause the system to generate low pressure and flow alarms.

Mindray is committed to ensuring that our customers and their patients remain safe, especially in challenging times such as these. We are prepared to direct our technical and clinical resources to address your immediate needs. Our in-house technical support team remains available 24/7 to ensure all telephone and email inquiries are addressed in a timely and effective manner. If assistance is needed, please contact Technical Support directly at (800) 288-2121, option 2.

Sincerely,



Diane Arpino  
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## Attachment 1

Mindray A-Series Anesthesia Delivery Systems have some or up to all of the following ventilation modes: VCV, SIMV-VC, PCV, PCV-VG, SIMV-PC, SIMV-VG, CPAP/PS or APRV:

- **Volume Control Ventilation (VCV) mode** is a fully-mechanical ventilation mode. In the VCV mode, each time mechanical ventilation starts, gas is delivered to the patient at a constant flow, which reaches the preset  $V_t$  within the gas delivery time. To ensure a certain amount of  $V_t$ , the resulted airway pressure (PAW) changes based on patient pulmonary compliance and airway resistance.
- **SIMV-VC mode** means to deliver synchronized intermittent mandatory volume controlled ventilation to the patient. In the SIMV-VC mode, the ventilator waits for the patient's next inspiration based on the specified time interval. The sensitivity depends on Trigger. If Trigger is reached within the trigger waiting time (called synchronous trigger window), the ventilator delivers volume controlled ventilation synchronously with the preset tidal volume and inspiratory time. If the patient does not inspire within the trigger window, the ventilator delivers volume controlled ventilation to the patient at the end of the trigger window. Spontaneous breathing outside the trigger window can acquire pressure support. In VCV and SIMV-VC modes, when inspiration pressure reaches  $P_{limit}$ , the inspiration pressure is held.
- **Pressure control ventilation (PCV) mode** is a basic fully-mechanical ventilation mode. In the PCV mode, each time mechanical ventilation starts, PAW rises rapidly to the preset  $P_{insp}$ . Then gas flow slows down through the feedback system to keep PAW constant until expiration starts at the end of inspiration. The tidal volume delivered in the PCV mode changes based on patient pulmonary compliance and airway resistance.
- **Pressure regulated volume control ventilation (PCV-VG) mode** implements volume control by way of pressure control ventilation. In the PCV-VG mode, a relatively low pressure level is held as much as possible during the inspiratory phase and the gas volume delivered is guaranteed to be equal to the preset tidal volume. The pressure control level will vary according to the tidal volume setting, resistance and compliance of the patient's lungs
- **SIMV-PC mode** means to deliver synchronized intermittent mandatory pressure controlled ventilation to the patient. In the SIMV-PC mode, the ventilator waits for patient's next inspiration based on the specified time interval. The sensitivity depends on Trigger. If Trigger is reached within the trigger waiting time (called synchronous trigger window), the ventilator delivers pressure controlled ventilation synchronously with the preset inspiratory pressure and inspiratory time. If the patient does not inspire within the trigger window, the ventilator delivers pressure controlled ventilation to the patient at the end of the trigger window. Spontaneous breathing outside the trigger window can acquire pressure support.
- **SIMV-VG mode** delivers a synchronized intermittent mandatory pressure control volume

guaranteed ventilation to the patient. In the SIMV-VG mode, the ventilator waits for the patient's next inspiration based on the specified time interval. The sensitivity depends on Trigger. If Trigger is reached within the trigger waiting time (called synchronous trigger window), the ventilator delivers pressure control volume guaranteed ventilation synchronously with the preset tidal volume and inspiratory time. If the patient does not inspire within the trigger window, the ventilator delivers pressure control volume guaranteed ventilation to the patient at the end of trigger window. Spontaneous breathing outside the trigger window can acquire pressure support.

- **In Continuous Positive Airway Pressure (CPAP) mode** (when  $\Delta P$  is off, CPAP is displayed at the current ventilation mode area of the main screen), the airway pressure is held at the user-set positive pressure level throughout the ventilation cycle. The patient breathes spontaneously and determines his own breathing frequency, tidal volume, and breath time.
- **In Pressure Support (PS) mode** (when  $\Delta P$  is not off, PS is displayed at the current ventilation mode area of the main screen), the patient's effort is supported by the A7 at a preset level of inspiratory pressure. Inspiration is triggered and cycled by patient effort.
- **APRV** is airway pressure release ventilation. APRV applies a continuous positive airway pressure in conjunction with an inverse I:E ratio to assist in maintaining lung inflation and may provide benefits to difficult-to-oxygenate patients.
- **Manual ventilation mode** is the operating mode used for manually ventilating a patient or to let a patient breathe spontaneously. To use the manual mode, the user must first set the APL valve to the desired pressure value and then use the Auto/Manual ventilation switch on the breathing module to enter and exit Manual mode. Push the O2 flush button to inflate the bag if necessary.