March 25th, 2020

Mindray WATO and A-Series Anesthesia System
Consideration for use as a Ventilator

Dear Valued Customer:

In response to the COVID-19 pandemic, several Healthcare organizations provided a guidance that allows for the use of anesthesia 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 (ICU).

IMPORTANT: This document contains off-label information. Regulatory authorities (e.g. U.S. FDA, Health Canada, TGA, EU Competent Authorities) have not cleared or approved these anesthesia systems as safe and effective for use as ICU ventilators. Please consult with local Competent Authorities for detailed requirements or limitations about off-label use of anesthesia systems as ICU ventilators.

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

When considering the use of an anesthesia system for continuous ventilation the follow functional difference should first be noted:

1）The indications for use are different (please reference the appropriate product Operator's Manuals). 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. An ICU 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. ICU stand-alone ventilators are used for the same purpose and spontaneous breathing support.

3）Manual mode on the anesthesia system is used for manually ventilating a patient

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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 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. 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 that CO2 absorbent is utilized to prevent high CO2 levels in the circuit. ICU ventilators use an open breathing circuit and no CO2 absorbent is needed.

5）Anesthesia systems rely on adjustable fresh gas flows to adjust the O2 concentration, and the oxygen concentration of the inhaled gas (FiO2) may differ from the preset oxygen concentration in the fresh gas. For ICU stand-alone ventilators, the oxygen concentration is controlled by adjusting the O2 and Air flow meter directly so that the preset oxygen concentration is the actual FiO2.

6）Anesthesia systems cannot support non-invasive ventilation, a common function of ICU ventilators. 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 ICU ventilators. 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, APRV and AMV. For a description of each mode, please, refer to Attachment 1

<u>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 systems.</u> However, if the lack of staffing prohibits this, a facility may consider utilizing critical care staff and provide training on the use of anesthesia systems. Please consider the following:

1) To eliminate the possibility of delivering anesthetic agent, disconnect all vaporizers and do not connect any N2O source (either a pipeline or cylinder) to the anesthesia system before use.

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2) A mix of air and oxygen, rather than pure oxygen, should be used as the ventilation gas. But oxygen generators cannot be used as a primary oxygen supply as this will likely cause the system to generate low pressure and flow alarms.

3) 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.

4) During extended periods of use, 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 or by implementing guidelines for reducing the risk of contamination during de-connecting of the ventilation device, 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.

5) During extended periods of use, the following items should also be addressed:
   - Check the CO2 absorbent level every 6-8 hours, looking especially for any color change or increase in FiCO2 measurement (The parameter of FiCO2 needs to be monitored at all times). Failure to replace expired CO2 absorbent could result in the generation of toxic compounds and acidosis.
   - 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.
   - Confirm ventilation delivery is as expected. If the flow measurement becomes inaccurate, the Flow Sensor Calibration should be performed immediately (please refer to the Flow Sensor Calibration section in the Operator's Manual for more details).

6) 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. Or a HME at the patient end of breathing circuit and filters placed on

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both the inspiratory and expiratory ports. Please note that circuits and filters (including HMEF and HME) should be replaced for every patient. Filters should be replaced 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. Additional information on the placement of these filters, can be found on the site: https://www.apsf.org/faq-on-anesthesia-machine-use-protection-and-decontamination-during-the-covid-19-pandemic/#filter

7) Patients should be continually monitored in the event of a system leak or other event. Leakages peculiar to anesthesia system include the potential for leaks from the CO2 absorber, breathing tubes and sampling lines. In the case of a large leak causing abnormal ventilation, fresh gas should be increased to assure continued ventilation. 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.

8) It's strongly recommended to increase 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 CO2 absorbent

9) Muscle relaxants may be considered to assist with relaxing the respiratory muscle and reducing the human-machine asynchrony. Please refer to the publication of the WHO on this topic: https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected

10) Set the alarm volume to maximum (100%) to facilitate immediate recognition and response. Please note that alarm notifications will stop when the state causing the alarm is resolved. To view alarm history, check "History" then "Event Log".

11) It is not recommended to use an anesthesia system for non-invasive ventilation.

12) Active humidification cannot be used on an anesthesia system as this will cause incorrect flow rate measurement. A HMEF or HME may be utilized.

13) Nebulization of drugs or aerosol therapy cannot be used with an anesthesia system.

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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 your local Technical Support.

Sincerely,

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Attachment 1

Mindray WATO and A-Series anesthesia systems have up to the following ventilation modes: VCV, SIMV-VC, PCV, PCV-VG, SIMV-PC, SIMV-VG, CPAP/PS,APRVor AMV:

- **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 Vt within the gas delivery time. To ensure a certain amount of Vt, 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 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 trigger window. Spontaneous breathing outside trigger window can acquire pressure support when pressure support is activated. In VCV and SIMV-VC modes, when inspiration pressure reaches Plimit, the inspiration pressure is held.

- **Pressure control ventilation (PCV) mode** is a fully-mechanical ventilation mode. In the PCV mode, each time mechanical ventilation starts, PAW rises rapidly to the preset Pinsp. 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. Pressure control level will vary according to the tidal volume setting, resistance and compliance of the patient's lungs

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- **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

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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 trigger window. Spontaneous breathing outside trigger window can acquire pressure support. when pressure support is activated.

- **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 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 trigger window can acquire pressure support when pressure support is activated.

- **Continuous Positive Airway Pressure (CPAP) mode** (when ΔP 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.

- **Pressure Support (PS) mode** (when ΔP 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 air way pressure in conjunction with an inverse I:E ratio to assist in maintaining lung inflation may provide benefits to difficult to oxygenate patients.

- **Adaptive Minute Ventilation Mode (AMV**) is a pressure controlled optimum target ventilation mode that allows easy switchover between controlled and spontaneous ventilation without extra adjustment and is based on the usage of the Otis equation for optimizing the WOB of the patient.

- **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

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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.

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