

COVID-19 and Recommendations for Handling of Mindray Anesthesia Workstations

April 1, 2020

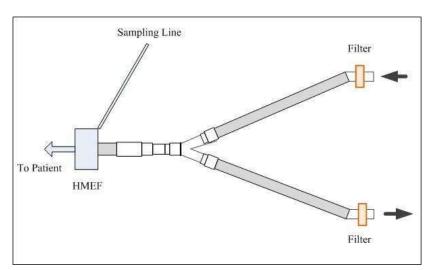
To Our Customers and Partners,

The novel coronavirus (COVID-19) has spread to more than 100 countries all over the world. It can spread from person to person through respiratory droplets produced when an infected person coughs or sneezes. It's a new strain that has not been previously identified in humans and it poses a great threat to the healthcare and economy around the world.¹

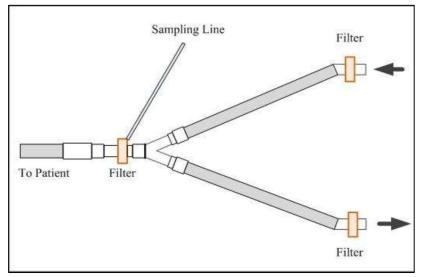
To help Mindray customers reduce the risk of contamination during operation, the following recommendations are targeted to Mindray Anesthesia Workstations used on patients infected or highly suspected to be infected with the novel coronavirus (COVID-19). Additional information can be found on the following organizational websites:

- https://www.who.int/health-topics/coronavirus
- https://www.cdc.gov/coronavirus/2019-ncov/index.html
- https://www.apsf.org/novel-coronavirus-covid-19-resource-center/
- 1 Recommendations for operation of Mindray Anesthesia Workstations with confirmed or highly suspected COVID-19 patients:
- 1.1 The operation for COVID-19 patients should be performed in negative pressure Operating Rooms. However, if an emergency surgery needs to be performed immediately, but only a positive pressure Operating Room is available, the exhaust air flow should be increased in the Operating Room to keep the negative pressure of the clean Operating Room to be no less than 5Pa.
- 1.2 To reduce the possibility of infection in the breathing circuit, an HMEF (HME with filter) needs to be placed at the patient's end (Figure 1). However, if an HMEF is not available in the Operating Room (OR), one disposable breathing system filter ² can to be placed between the tracheal tube and Y-piece of the breathing circuit (hoses) instead of an HMEF (Figure 2). In addition, it's strongly recommended to use two (2) additional breathing system filters at the inspiratory and expiratory ports of the breathing system (between the breathing hose and inspiratory/expiratory port of the device) (Figure 1 & Figure 2). Please note that the gas sample line of the gas measurement unit must be connected on the device side of the breathing system filter in order to avoid contamination of the gas measurement unit or the anesthesia device.³











Note: The (disposable) filters and HMEF above should be replaced every 3 to 4 hours, but replaced immediately if there are airway secretions or blood contamination during the operation, to avoid the failure of filtration function or increased ventilation resistance.

1.3 All of the components and/or accessories that are in contact with the patient's breathing gas are recommended to be disposable such as breathing circuit (hoses), filters, HMEF and disposable gas measurement accessories (sampling line), etc. If the recommendations in Part 1.2 are met, then the gas module water trap can be replaced every 30 days as recommended in the Operators Manual. If the recommendations in Part 1.2 are not met, then the gas module water trap should be replaced between patients.

Disposable monitoring accessories, such as ECG leads, SPO2 sensors, NIBP cuffs, and temperature probes, should be used and disposed of after each patient.



Note: The filter of the gas module water trap is $0.45 \,\mu$ m.

1.4 If the Mindray A7 anesthesia machine is used on patients without the Y-piece (for example cases that use the ACGO or Auxilary Air/O2 outlet and MAC cases) the output from the gas module needs to be connected directly to the AGSS rather than the breathing system to avoid contamination of the breathing system.

2 Recommendations for operation after usage of Mindray Anesthesia Workstations with confirmed or highly suspected COVID-19 patients:

- 2.1 The Mindray anesthesia machine, including reusable accessories, should be cleaned and disinfected thoroughly with a suitable disinfectant ⁴ every morning before the first surgery, after each surgery, and every day after all surgeries. After the cleaning and disinfection process the components need to be allowed to dry thoroughly before next use. Note: Please follow the Operator's Manual (Section 7.10) or Instructions for Use (IFU) for proper autoclaving, disinfecting and cleaning methods.
- 2.2 If the recommendations in Part 1.1 to 1.4 can be met, please refer to Section "7.10 Cleaning and Disinfection" in the Operator's Manual or Instructions for Use (IFU) for details about disinfection and autoclaving methods. For the recommended types of cleaners and disinfectants that offer virucidal efficacy, please consult with local competent authorities. Note: Please refer to the Cleaning and Disinfection section of the Operator's Manual (Section 7.10 in the IFU) for the allowable cleaning and disinfecting agents list as well as the autoclaving process for the anesthesia machine and breathing system.

Note: If the disposable filters or HMEF are used, the PAW gauge and O2 can be wiped down per procedures in the operator's manual.

- 2.3 If the recommendations in 1.1 to 1.3 cannot be met (e.g. emergency surgery), after the cleaning and disinfecting procedures in 2.2, it is also recommended to wrap the anesthesia device and reusable components completely with a plastic cover and store them safely for a specified time (e.g. 21 or 28 days) at room temperature or higher, and then follow the cleaning and disinfecting procedures in the operator's manual before next use. If the operation is conducted in a positive pressure Operating Room, both of the filters at the air inlet and outlet of the Operating Room should be replaced after the operation. The exhaust outlet, air inlet and air outlet should be wiped down and disinfected.
- 2.4 All the disposable accessories should be removed after each case. To ensure the safe disposal of contaminated devices, please refer to the hospital guideline or local regulations.

If you have any further questions, please do not hesitate to contact your local sales or service



representative.

References:

1. Coronavirus disease (COVID-19) outbreak. URL: https://www.who.int/health-topics/coronavirus

2. What type of breathing circuit filter is likely to prevent passage of the SARS COV-2 virus from the patient to the anesthesia machine? URL: <u>https://www.apsf.org/faq-on-anesthesia-machine-use-protection-and-decontamination-during-the-covid-19-pandemic/</u>

3. Guidelines for perioperative infection control of patients with novel coronavirus pneumonia, perioperative infection control Society of Chinese Society of Cardiothoracic and Vascular Anesthesia. URL: http://subject.med.wanfangdata.com.cn/UpLoad/Files/202003/d0b40b70bc124da198c3e8058212162d.pdf

4. Mindray Document: H-046-009638-00 (2.0) A-Series Cleaning and Disinfection Quick Reference Card