08 April 2020

April 08, 2020

Topic: COVID-19 Information regarding the off-label use of Medisorb™ CO2 Absorbent products and airway management products for anesthesia devices for ICU patient ventilation

Dear Customer,

The COVID-19 pandemic has placed a great demand on the need for Intensive Care Unit (ICU) ventilators for care of critically ill patients who have respiratory failure or insufficiency. Health care professionals have asked about the best means by which to address ventilator shortages with anesthesia devices and products as a temporary solution for critical care settings. In response, we want to convey information in this letter about such off-label use of Medisorb™ CO2 Absorbent products and other Vyaire airway management products.

IMPORTANT: This document contains off-label information.

- Use of an anesthesia machine and supplies as an ICU patient ventilator is off-label.
- Information in this document is provided **only** with regard to the COVID-19 pandemic, and not for routine care for patients with respiratory failure or insufficiency.
- Use of any anesthesia devices and Vyaire supplies as safe and effective replacement for ICU ventilators has **not** been approved or cleared by any medical device regulatory authority.
- **On March 24, 2020, the FDA published guidance on the emergency use authorization for anesthesia gas machines modified for use as ventilators.**
- For countries other than the United States, please consult with the relevant regulatory authority regarding exemptions or relaxations for off-label anesthesia devices and supplies use during the COVID-19 pandemic.
- Use of anesthesia devices and Vyaire supplies as substitutes for ICU ventilators has **not** been verified or validated.
- Off-label use of anesthesia devices and Vyaire supplies is the **sole** responsibility of the device owner and is undertaken with the understanding that the owner assumes all liability for this use.

In sending you this letter, Vyaire is not seeking to promote, endorse or advise the use of any anesthesia equipment or supplies as ICU ventilators for critical care of patients with respiratory failure or insufficiency. However, we recognize the unusual and acute circumstances created by the COVID-19 pandemic and the needs of health care professionals to consider modifications to standard clinical practices in an effort to address the needs of critically ill patients.

IMPORTANT: The information presented here is based on the current understanding of the potential risks and device functionality of the Vyaire Medisorb™ CO2 Absorbent products and other anesthesia and airway management products referred to below. This information is **not** comprehensive for all uses. As care for patients diagnosed with COVID-19 evolves, Vyaire will update information on our web site, so please bookmark it for easy access: **US: https://www.vyaire.com/Covid-19; International: https://intl.vyaire.com/Covid-19**

[1] FDA. Emergency use authorization for ventilators. March 24, 2020. Accessed at https://www.fda.gov/media/136423/download?utm_campaign=2020-03-

Anesthesia devices and supplies significantly differ from ICU ventilators even though they both used to ventilate patients. We want you to understand these differences to minimize risks to your patients.

Both ICU ventilators and anesthesia machines are designed to work as a part of a breathing system or circuit to deliver oxygen and ventilate a patient.

> **Anesthesia machine:** Uses a closed breathing circuit, also called a circle system, in which the exhaled air from the patient is filtered to remove carbon dioxide before re-inhalation by the patient. (In normal care, anesthesia machines also deliver inhalation anesthetic gases to patients to provide anesthesia.) During use, an anesthesia provider - either a physician or certified registered nurse anesthetist - continuously monitors the patient to ensure that the products absorbing carbon dioxide do not become saturated, which could potentially lead to the patient rebreathing carbon dioxide that could result in patient death.
>
> **ICU ventilator:** Uses forms of an open breathing circuit that brings oxygen to the patient for inhalation as well as removes carbon dioxide from the system, so no recirculation occurs and products to remove carbon dioxide are not needed.

The use of anesthesia machines requires constant attention during operation by qualified professional healthcare personnel.

Anesthesia machines may also require a variety of additional airway management products. These consumables can include:

- HEPA filter and bacterial/viral filters
- Water traps
- Anesthesia breathing circuits
- Carbon dioxide absorbent

IMPORTANT SAFETY INFORMATION

WARNING: Anesthesia machines and Vyaire supplies are equipment that support and sustain life. If this equipment is not used properly in accordance with instructions and continuously monitored by trained health care professionals, a risk of serious injury or death can occur.

Intended Use of Medisorb™ CO2 Absorbent Products (per Attachment A – Table 1 & below)

- Medisorb™ CO2 absorbent products are intended to be used with anesthesia systems to remove carbon dioxide from exhaled gases when providing anesthesia in hospitals or surgery centers under constant attention of qualified professional healthcare personnel.
- The Medisorb™ CO2 Absorbent products should be used **only** with air, oxygen, nitrous oxide, halothane, enflurane, isoflurane, desflurane and sevoflurane.
- Risks are related to any use of Medisorb™ CO2 Absorbent products other than that for which they are indicated. Clinicians considering such use during the COVID-19 pandemic must weigh the risks and benefits and ensure proper training and safe handling of the products.
- Medisorb™ CO2 Absorbent products have been specified for use with and validated for optimal performance with GE Healthcare anesthesia systems. Make sure the correct product is used with the specific system as follows:

Vyaire Catalogue Number	Description	Color Change
For use with GE Healthcare anesthesia systems Aespire™, Avance™, Aisys™ and ADU™		
M1173310	Medisorb™ multi-absorber original	white to violet
M1173311	Medisorb™ multi-absorber EF, lower alkaline, lower pH	white to violet
For use with Carestation™ 600 series		
2079796-001	Medisorb™ EX, original	white to violet
2079797-001	Medisorb™ EF EX, lower alkaline, lower pH	white to violet
Loose fill		
8570043	Medisorb™ twin pack, original, loose fill	white to violet
For use with Aestiva™		
427000100	Medisorb™ pre-packed cartridge, original	white to violet
Accessories for reusable Multi canisters for use with Aespire, Avance, Aisys and ADU		
1407-3201-000	Medisorb™ multi-absorber dust filter 40	N/A

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Intended Use of Vyaire Anesthesia Circuits – (Per Attachment A – Table 2)

- A Vyaire anesthesia circuit is intended for conduction of respiratory gases between the anesthesia machine and the patient. It is a single use, disposable product. It should not be used if physical deterioration, brittleness or discoloration occurs.
- **An anesthesia circuit is not recommended to be used for long-term, mechanical ventilation** as this use would be considered off-label. Only if there is a shortage of anesthesia circuits should the long-term use of anesthesia circuits be considered.
- If an anesthesia circuit is to be used for long-term mechanical ventilation on an anesthesia machine:
    - Ensure all connections remain tight and do not loosen during mechanical ventilation.
    - All circuits should be tested for obstructions, occlusions, or leaks in accordance with the ventilator manufacturer's specifications.
    - If any port openings are not used, ensure the attached cover/port caps are secure to prevent leakage.
    - Ventilator monitoring and warning systems should be operational and used as recommended by the ventilator manufacturer.
    - Condensation accumulation within the circuit should be continually monitored during use and evacuated routinely to reduce the hazard of accidental aspiration by the patient.
- Vyaire does **NOT** recommend the heating of anesthesia circuits.
- Vyaire does **NOT** recommend multiple patients on single anesthesia machines, as this would be considered off-label use. If there is a shortage of ventilators and multiple patients, using multiple circuits, are placed on single anesthesia machines, risk of excessive leak, inadequate tidal volumes, increased condensation and cross-contamination may occur.

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Intended Use of AirLife™ HEPA/HMEF products with Bacterial/Viral Filter (Per Attachment A – Table 3)

- Our AirLife™ HEPA/HMEF products are intended to be used to provide filtration to reduce possible cross contamination between patients and equipment.
- HEPA/HMEF products are for use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired.
- These devices are for single-patient use. Vyaire does **NOT** recommend using a HEPA/HMEF products on more than one patient as such would be off-label and may cause risk of cross-contamination, affect the measurement accuracy and/or system performance, or cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization and/or reuse.
- If multiple HEPA/HMEF products are used within the same circuit at the same time because of a shortage of anesthesia circuit, there may be an increased resistance to air flow that may result in patient harm. Monitor the patient for adequate tidal volumes and peak airway pressures.
- The HEPA/HMEF products can also be used for gas sampling. HEPA/HMEF products are indicated for use by qualified medical personnel only. If a sampling tube is not connected, make sure that the sampling port cap on the filter is properly attached.
- Replace the filter at least every 24 hours or earlier if increased resistance is noted secondary to excessive condensation, obstruction or other indications of malfunction present. Use of a filter for > 24 hours is not recommended and would be considered off-label use. If there is a shortage of filters and they used for > 24 hours, the anesthesia machine may become contaminated and need to be flushed and sterilized.
- The HEPA/ HMEF device has dead space, which should be taken into consideration when calculating tidal volume and patient ventilation requirements.

Intended Use of Vyaire Water Traps (Per Attachment A – Table 4)

- Vyaire water traps are recommended for the patient breathing circuit if using a low minute ventilation setting (fresh gas flow of less than 1 liter/minute) and when excessive condensed water accumulates in the limbs, the breathing tubes that connect the anesthetic device and patient.
- Use water traps in both expiratory and inspiratory limbs to remove water condensation.
- The use of water traps for ICU patients requiring long-term mechanical ventilation is considered off-label use.
- Excessive condensation can inhibit the function of the water trap. Excessive condensation is more likely during long-term mechanical ventilation.

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Attended Devices

- Medisorb™ CO2 Absorbent, anesthesia circuits, HEPA/HMEF products, and water traps are designed with the intention that their use occur in fully monitored care areas and under constant attention of qualified professional healthcare personnel.
- Users of Medisorb™ CO2 Absorbent, anesthesia circuits, HEPA/HMEF products, and water traps **must** ensure their proper use with continuous monitoring of the Medisorb™-containing device as well as of the amount of carbon dioxide in exhaled air (ETCO2) to ensure carbon dioxide is not retained.

Training/Knowledge of the System

- The safe use of Medisorb™ CO2 Absorbent products, anesthesia circuits, HEPA/HMEF products, and water traps relies on user knowledge and training.
- Medisorb™ CO2 Absorbent products, anesthesia circuits, HEPA/HMEF products, and water traps are intended to be used by clinicians who are trained to operate anesthesia machines as well as standard anesthesia monitors.
- Unique characteristics differentiate anesthesia machines, such as the use of Medisorb™ CO2 Absorbent products to prevent the rebreathing of carbon dioxide, from standard ICU ventilators.
- New or different personnel intending to use the devices in clinical care of patients in respiratory failure or insufficiency due to the COVID-19 pandemic **must** be appropriately trained on both on anesthesia machines and devices as well as its monitoring 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.
- Use of the anesthesia machine requires **constant attention** of qualified professional healthcare personnel.
- Ventilator monitoring and warning systems should be operational and used as recommended by the ventilator manufacturer.

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Circle Breathing Circuit, Medisorb™ CO2 Absorbent Products

- Users **must** be familiar with the theory of operation of circle breathing systems, particularly carbon dioxide absorption function, including how and when to change carbon dioxide absorbent canisters, and flow and pressure delivery functions prior to using the device.
- Circle breathing systems, such as those used in anesthesia devices, use one-way (unidirectional) valves that may prevent the release of pressure from the patient connection. For example, if the expiratory breathing tube is blocked or occluded, pressure will build up within the patient and carbon dioxide will not be absorbed by the Medisorb™ CO2 Absorbent products.
- Medisorb™ CO2 Absorbent products feature a color change as their active ingredient, soda lime, absorbs the carbon dioxide. This change is gradual as absorption capacity approaches exhaustion. The product label indicates the specific color change, which is from white to violet. However, the color change is only a rough indicator of carbon dioxide absorption exhaustion.
- Because the intensity of the Medisorb™ CO2 Absorbent products color change may vary from one procedure to another, **always** use proximal / end-tidal carbon dioxide monitoring to determine when to change the Medisorb™ CO2 Absorbent product. Please note that some portion of the soda lime may not change color at the bottom of the canister, which is normal.
- Discard Medisorb™ CO2 Absorbent products **as soon as** their labeled color change occurs. The color change of Medisorb™ CO2 Absorbent products is reversible, and the exhausted material will change back to its original color. Disposing saturated Medisorb™ CO2 Absorbent products immediately after use prevents their mistaken re-use.
- Only trained personnel should determine the remaining absorptive capacity of the Medisorb™ CO2 Absorbent products while patients are being mechanically ventilated.
- Excessive use of oxygen flush, which enables oxygen to pass from the source directly into the patient's breathing circuit, induces dehydration of Medisorb™ CO2 Absorbent products and inhibits their ability to absorb carbon dioxide. Also, higher than normal minute ventilation (the volume of air a patient inhales or exhales per minute) may significantly reduce the amount of time the Medisorb™ CO2 is effective.

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Length of Use and Checkout

- **Failure to change the Medisorb™ CO2 Absorbent products when depleted will result in an increase of inspired carbon dioxide. Always use proximal / end-tidal carbon dioxide and oxygen monitoring.**
- Medisorb™ CO2 Absorbent products are not intended for long-term use.
- The use of Medisorb™ CO2 Absorbent products in anesthetics machines for the purpose of ventilating patients with respiratory failure or insufficiencies has not been studied, validated or verified. The duration of use for such critical care use will be influenced by a patient's health status, minute ventilation, moisture levels within the breathing circuit and whether the device is used continuously or intermittently. Changing Medisorb™ CO2 Absorbent products in critical care settings is therefore recommended **at 12 hours or less**.

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Gas Monitoring (O2 and CO2)

- **Always** use proximal / end-tidal carbon dioxide and oxygen monitoring.
- Ensure the actual delivered oxygen levels are appropriate for the patient.
- Remember, when fresh gas flows are lower than minute volume, the oxygen concentration in the fresh gas will be diluted, so the set oxygen level will be different from what the patient actually receives.
- Elevated Fractional Inspired Carbon Dioxide (FiCO2) values are an indication that the Medisorb™ CO2 Absorbent products canister requires replacement or refill. Failure to change the Medisorb™ CO2 Absorbent products may result in rebreathing, breathing excess carbon dioxide or insufficient oxygenation. Consult the anesthesia device instructions for use on how to exchange the Medisorb™ CO2 Absorbent products while the device in use with a patient.

Maintenance

- If an Medisorb™ CO2 Absorbent product is left mounted overnight, make sure that all gas flows are stopped. Otherwise the product may dry out and lose its activity.
- For safety, always replace a Medisorb™ CO2 Absorbent product when its state of desiccation is unknown.
- Medisorb™ CO2 Absorbent products must not be used with chloroform or trichloroethylene because they may react slightly to produce sodium formate/dichloroethylene, carbon monoxide and/or phosgene, which are harmful to the patient.
- Use a filter to minimize cross-contamination and the risk of foreign particles reaching the patient.

If you have any additional questions, please reach out to your local Vyaire representative, or visit our web sites; US: https://www.vyaire.com/Covid-19; International: https://intl.vyaire.com/Covid-19

As a world leader in respiratory care, we take our critical role in the response to this global health crisis seriously. At Vyaire, our goal is to meet the demand as best we can and ensure our customers have the products they need. We are truly proud to partner with you on the frontlines of the COVID-19 global health crisis. The work you are doing is improving outcomes for patients around the world.

Sincerely,

Michael Pedro
VP, Medical Director

Enclosure:
Attachment A – Vyaire Catalogue Information

Attachment A

Table 1 - Medisorb™ CO2 Absorbent Products

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For use with Aestiva™		
427000100	Medisorb™ pre-packed cartridge, original	white to violet
Accessories for reusable Multi canisters for use with Aespire, Avance, Aisys and ADU		
1407-3201-000	Medisorb™ multi-absorber dust filter 40	N/A

Table 2 - Vyaire Anesthesia Circuits

Vyaire Catalogue Number	Description
A4YX2XX4D	ANES CIRCUIT, ADULT, 120 IN EXP, 3L BAG
AFNX2XXZP	ANES CIRCUIT, ADULT, 72 IN LIMBO, 3L BAG
AIN52014	ANES CIRCUIT, ADULT, 72 IN LIMBO, 3L BAG
AFPX2XXZP	ANES CIRCUIT, ADULT, 108" LIMBO, 3L BAG
AFPX20XZP	ANES CIRCUIT, ADULT, 108" LIMBO, 3L BAG
A4UB20X4DXX*	ANES CIRCUIT, ADULT, 108 IN EXP, 3L BAG
A5U52X14	ANES CIRCUIT, ADULT, 108 IN EXP, 3L BAG

*not available for EU

Table 3 - AirLife™ HEPA/HMEF products with Bacterial/Viral Filter

Vyaire Catalogue Number	Description
M1004132	HMEF 750/S
557070100	HMEF 1000 with GSP
5708HEPA	AirLife HMEF HEPA with GSP
303HEPA	AirLife HEPA FILTER
5096HEPA	AirLife Bacterial/Viral
3007	HMEF HEPA
3009	HMEF with flex

Table 4 - Vyaire Water Traps

Vyaire Catalogue Number	Description
001860	Water trap, disposable W/2