

To the attention of the medical
vigilance coordinator

Antony, the March 31 of 2020

ANSM reference: R2004739

Object: Temporary derogation relative to the use of MONNAL EVA expiratory assemblies for the Monnal range ventilators.

Products concerned: Monnal EVA valves and Expiratory Flow sensors, single use



Reference	Designation
KY694800	Monnal Eva Expiratory Valve, Single use (x5) (with membrane)
KY694900	Monnal Eva Expiratory Valve, Single use (x20) (with membrane)
KY664500	Expiratory Flow Sensor, Single use (x5)
KY664600	Expiratory Flow Sensor, Single use (x20)

Membranes for Monnal EVA valves, autoclavable version



Reference	Designation
KY665300	Membrane x5 (for autoclavable valve KY694500)

Dear customer,

Air Liquide Medical Systems (ALMS) voluntarily deploys, **in agreement with the ANSM (French National Agency for the Safety of Medicines and Health Products) and only during the period of treatment for COVID 19 patients**, the safety information concerning the use of Monnal EVA expiratory sets - Single Use version (UU) as well as for the Expiratory Valve membrane. (References above)

These specific measures linked to the current outbreak for the care of COVID-19 patients are based on the growing demand for supply of MONNAL EVA expiratory valves UU version and Membranes.

It is important to carefully consider the implications of this communication and we ask that you share this described information with all of the users of the devices within your organization.

Air Liquide Medical Systems

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The health authorities concerned have been informed of this voluntary safety information.

Rest assured of our full commitment during this particular period. Do not hesitate to contact your Air Liquide Medical Systems representative for any further information.



Context

As part of the treatment of COVID-19 patients, Air Liquide Medical Systems (ALMS) is facing a huge demand for Monnal EVA UU expiratory sets and also for the membranes (KY663500) used with the Monnal EVA expiratory valve autoclavable version.

ALMS, with the help of its industrial partners, has implemented a production ramp-up plan to quickly meet all needs. Unfortunately, this plan does not meet the immediate demand of the health professionals who are on the front line facing this pandemic.

The aim is to ensure continuity of the care pathway during this ramp up of production,

As consequence ALMS recommends by temporary derogation the implementation of 2 strategies to protect the integrity of the Monnal EVA expiratory systems

Strategy 1

Filters

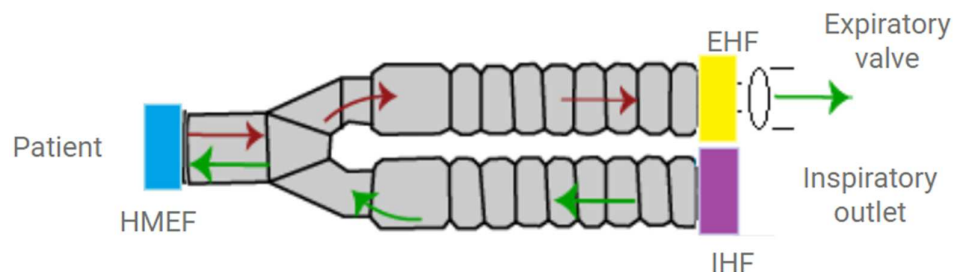
It is recommended to position 1 filter (FHE) **mechanical (pleated membrane)** OR **electrostatic** at the expiratory branch (see diagram below) and to replace it as per the recommendations of the manufacturer.

This filter aims to protect the expiratory assembly and makes it possible to simplify its cleaning under exemption during the care of COVID 19 patient (see Strategy 2).

EHF : Expiratory Hydrophobic Filter

IHF : Inspiratory Hydrophobic Filter

HMEF : Heat and Moisture Exchanger Filter



If the installation of the 3 filters as indicated in the diagram above has been applied when taking care of a COVID-19 patient, ALMS authorizes 5 intermediate-level disinfection cycles by immersion for:

- The Monnal EVA SU Expiratory set used.
- The membrane when fitted to the Monnal EVA exhalation valve autoclavable version

It is the responsibility of the user to take care not to exceed these 5 intermediate-level disinfection cycles.

Procedure : Single Use Monnal EVA expiratory assembly (translucid)

1. Disassembly of the 3 elements :
 - a) Flow sensor
 - b) Valve Body (rings haven't to be removed)
 - c) Membrane (disks haven't to be removed)



Strategy 2

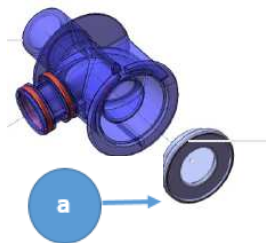
Disinfection of the expiratory assembly Monnal EVA Single Use

2. Clean the different components of the expiratory assembly in a detergent-disinfectant product for medical devices, taking care to avoid any mechanical action as:
 - Using a brush or a swab.
 - Using a water jet or an air jet on the hotwire of the flow sensor (risk of breaking this wire).
3. Process to rinsing, in a care standard water
4. Process to sinking this dismantled assembly in a disinfectant solution.

The products said "disinfectant" are products, which have to ensure a bactericidal, fungicidal and virucidal action. They are generally solution based with peracetic acid.

Both the flow sensor and the valve body are made of Polycarbonate, the membrane is made of Silicone
5. Carefully rinse the assembly with sterile water as per the process described in the used product user manual, taking care to protect the expiratory flow sensor (a) (no water stream on the flow sensor).
6. Process to a passive drying, depositing the components on an absorbing paper

Procedure: Membrane used in the autoclavable Monnal EVA Valve (blue)



Strategy 2

Disinfection of the membrane used in the autoclavable Expiratory Valves

The following procedure concerns **only the membrane** used in the autoclavable Expiratory valves.

The Autoclavable Monnal EVA expiratory valve (blue) must follow the standard protocol defined by the healthcare establishment for the treatment of autoclavable consumables.

1. The discs present within the membrane are not to be removed.
2. Clean the membrane in a detergent-disinfectant product for medical devices, taking care to avoid any mechanical action such as the use of a brush or a swab.
3. Process to rinsing, in a care standard water.
4. Process to sinking the membrane in a disinfectant solution.
The products said "disinfectant" are products, which have to ensure a bactericidal, fungicidal and virucidal action. They are generally solution based with peracetic acid.
The membrane is made of Silicone.
5. Carefully rinse the membrane with sterile water as per the process described in the used product user manual.
6. Process to a passive drying, depositing the membrane on an absorbing paper.

IMPORTANT:

The reassembly of the Monnal EVA Expiratory Sets must be carried out by the intended user.

It is mandatory to carry out an "autotest" after its installation on the ventilator of the Monnal range and is accompanied by the filters stipulated above as well as the patient circuit.

These self-tests make it possible to ensure the proper functioning of the medical device. Improper reassembly of the expiratory assembly can lead to degraded performance of the medical device (risk of leaks, poor pressurization, non-compliance with the volume, hypoventilation).
