For the attention of

Chairman Medical Board

Head Office

Medical Device Vigilance Coordinator

Antony, 29th July 2019

Reference: R1913764

Subject: Important information regarding the safety of ventilators from the MONNAL range

Products affected:

MONNAL T50	**Monnal T50 (KC027500, KC072219, KC07220) // Monnal T50 DE (KC037600) // Monnal T50 JP (KC039100)**
MONNAL T40	**Monnal T40 (KC027600) // Monnal T40 DE (KC037500)**
MONNAL T60	**Monnal T60 (KA010000, KA017114, KA017115) // Monnal T60 JP (KA013700)**
MONNAL T75	**Monnal T75 (KB022600,KB040001) // Monnal T75 JP (KB032100) // Monnal T75 CO2(KB033600, KB040003)**

Dear customer,

Air Liquide Medical Systems are voluntarily issuing a safety notice for ventilators from the MONNAL range specifying:

- The conditions for deploying bacteriological filters, as well as a reminder of good practice. (Appendix 1)
- Amended recommendations for cleaning autoclavable MONNAL EVA Expiratory Valve membranes. (Appendix 2)

It is important to give proper consideration to the implications of this notice and we would ask you to share this information with all users of devices within your organization.

The relevant health authorities have been informed of this voluntary safety notice.

We apologize for any inconvenience and, should you have any further questions, please contact our hotline or your usual contact.

Mickaël JOUVE
Head of Patient Safety and Reliability
Medical Device Vigilance Coordinator

Air Liquide Medical Systems
PARC DE HAUTE TECHNOLOGIE
6 RUE GEORGES BESSE - 92182 ANTONY CEDEX– France
A LIMITED COMPANY WITH CAPITAL OF €4,240,800.00 LISTED IN THE NANTERRE TRADE REGISTER WITH THE NUMBER B 348 921 735 – SIRET No. 348 921 735 00026

www.device.airliquidehealthcare.com

Information APPENDIX 1
- Bacteriological Filter Position -

This document serves as an addendum to the applicable user manual for the products in question.

It should be retained and made available to user services.

Background

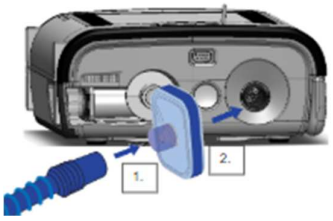
Within the framework of using a ventilator from the Monnal range and more particularly in emergency situations, we have received reports of cases of internal contamination at the device's inspiratory outlet.

This contamination of the device occurred in cases where the bacteriological filter was not present on the inspiratory branch.

Air Liquide Medical Systems wishes to better clarify the installation conditions for different protective filters to protect the integrity of the device, in order to prevent any risk of cross-contamination for patients.

New recommendations

It is necessary to use a hydrophobic bacteriological filter on the ventilator's inspiratory outlet as shown in the following example for connection with the MONNAL T60.



If a HME (heat and moisture exchanger) filter is used, it must be positioned at the Y-piece.

Air Liquide Medical Systems recommends use of the hydrophobic bacteriological filter, **item reference KV103300**

Reminder of good practices

The bacteriological filter must be replaced at the frequency recommended by its manufacturer. Please refer to the user instructions supplied with the filter.

Clogging of the bacteriological filter, as well as the use of a humidification system, may lead to an increase in inspiratory and expiratory resistance. Filters should be checked frequently to detect an increase in resistance or an obstruction.

In order to prevent the ingress of dust between 2 uses, it is essential to leave a bacteriological filter on the device's inspiratory outlet.

Air Liquide Medical Systems
PARC DE HAUTE TECHNOLOGIE
6 RUE GEORGES BESSE - 92182 ANTONY CEDEX– France
A LIMITED COMPANY WITH CAPITAL OF €4,240,800.00 LISTED IN THE NANTERRE TRADE REGISTER WITH THE NUMBER B 348 921 735 –
SIRET No. 348 921 735 00026

Information APPENDIX 2

- Monnal EVA Valve Disinfection Recommendations -

This document serves as an addendum to the applicable user manual for the products in question.

It should be retained and made available to user services.

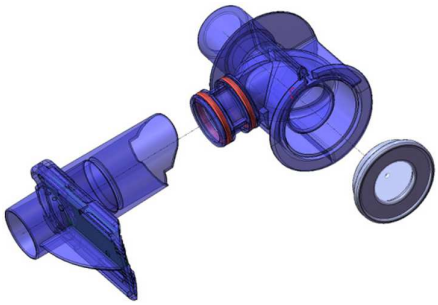
Description of the problem

There are two types of MONNAL EVA expiratory valves, one in a single use version (transparent valve), one in an autoclavable and reusable version (blue valve).

NB.: The autoclavable version of the expiratory valve is the only one covered by this safety notice.

The expiratory valve has 3 component parts:

- A valve body (with its 2 red seals)
- An expiratory flow sensor
- A silicone membrane



We have detected premature hardening of the silicone membrane, depending on the product used, during the immersion disinfection phase.

The rigidity of this membrane may have a negative impact on the quality of ventilation when the PEEP (Positive End-Expiratory Pressure) is set at 0 cmH20 or is virtually zero. It may cause a leak at the expiratory valve, which does not allow the patient to be correctly ventilated.

New recommendations

The silicone membrane on the autoclave version of MONNAL EVA expiratory valves **becomes a single use spare.**

This membrane must be withdrawn from the sterilization and cleaning process for the expiratory valve.

A new membrane (sold with the item reference KY665300) **must be fitted to the expiratory valve assembly after each of the latter's sterilization and cleaning cycles.**

Air Liquide Medical Systems
PARC DE HAUTE TECHNOLOGIE
6 RUE GEORGES BESSE - 92182 ANTONY CEDEX– France
A LIMITED COMPANY WITH CAPITAL OF €4,240,800.00 LISTED IN THE NANTERRE TRADE REGISTER WITH THE NUMBER B 348 921 735 –
SIRET No. 348 921 735 00026

CLIENT RESPONSE FORM

Safety notice dated 29th July 2019 – R1913764

Please complete and return this form immediately

by fax: **01 40 96 67 21**

or by email: fr-2019-hygiene-monnal-range@airliquide.com

Name and address of the establishment:	
Contact name:	
Title:	
Email and phone number:	

We acknowledge receipt of this safety notice R1913764

We confirm that we understand its content and have circulated this information to the relevant people/departments.

Signature and date: ***Mandatory field***	