July 29, 2019

Attn: Medical Device Vigilance Representative

Reference: R1904280

Subject: Corrective measures for Monnal T60 ventilators in reference to safety notice FSN R1904280 dated March 10, 2019.

Dear Customer,

In March 2019, ALMS initiated protective actions regarding a limited number of Monnal T60 ventilators in specific geographic areas.

Continuing on from these initial protective actions, Air Liquide Medical Systems would like to inform you that the corrective action plan explained below impacting all these devices has been implemented to improve the safety of Monnal T60 ventilators.

- Version 2.7.1 of the software is now available. It will be deployed within a maximum of one year during the next curative or preventive maintenance period.

  Version 2.7.1 offers:

  - Improved charging/discharging cycles to preserve battery integrity.
  - Modified low internal battery warning criteria.
  - More accurate internal and replaceable battery charge level estimates.

- The internal battery replacement recommendations have changed. It should now be replaced every two years (instead of every three years). Since this battery is the main power source, this recommendation should be followed immediately.

Air Liquide Medical Systems
PARC DE HAUTE TECHNOLOGIE
6 RUE GEORGES BESSE - 92182 ANTONY CEDEX – France
A FRENCH PUBLIC LIMITED COMPANY WITH CAPITAL OF €4,240,800 – NANTERRE TRADE AND COMPANIES REGISTER: B 348 921 735 – SIRET 348 921 735 00026

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- The replaceable battery recommendations have also changed. It should now be replaced every two years (instead of every three years). This recommendation will apply to each new replaceable battery installed.

- The recommendations for using the Monnal T60 ventilator during transport within and outside hospitals (without an external power connection) have become stricter.
    - The internal battery is only a backup power supply. If the device cannot be connected to an external power source (primary source), a replaceable battery (secondary source) should be used.
    - Using the internal battery as the main power source can cause ventilation to stop unexpectedly.

Air Liquide Medical Systems is using this informational letter to notify its customers of this corrective action plan. Version 2.7.1 of the software will be distributed for installation through the normal channels.

Your Air Liquide Medical Systems France team can be contacted at the numbers provided below. Your local partner is also available to answer any questions about this notification.

Air Liquide Medical Systems Technical Support

- In France: 0820 146 359 (Hotline – €0.12 per min, including tax)
- From outside France: +33.179.51.7001

The appropriate authorities have been informed of this corrective information.

We thank you in advance for your support and apologize for any inconvenience caused by this corrective action plan.

Sincerely,

Mickaël Jouve
Patient Safety and Reliability Department
Medical Device Vigilance Representative

CUSTOMER RESPONSE FORM

Safety notice issued July 29, 2019☐–☐R1904280

Corrective Action Plan

Please complete and return this form as soon as possible by fax: **01 40 96 67 21** or by email: fralms-monnalt60-safety@airliquide.com

Institution name and address:	
Contact person:	
Title:	
Email and telephone number:	

We acknowledge receipt of safety notice number R1904280.

We confirm that we understand its content and have relayed the information to the necessary parties.

Signature and Date: ***Required***	

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