

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 6 months.

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

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A FRENCH PUBLIC LIMITED COMPANY WITH CAPITAL OF €4,240,800 - NANTERRE TRADE AND COMPANIES REGISTER: B 348 921 735 -

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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.

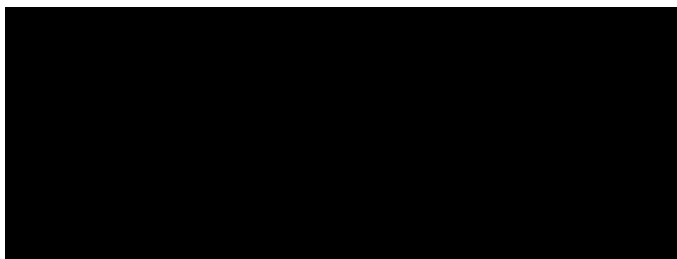
Air Liquide Medical Systems Technical Support

- 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,



Air Liquide Medical Systems

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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: <i>Required</i>	
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Tel: (33) 01 40 96 66 00
Fax: +(33) 01 40 96 67 00

To the attention of the Medical Vigilance Coordinator

Antony, 10 March 2019

**Purpose: Important Safety Information concerning Monnal T60 ventilators
(Ref. R1904280)**

Dear customer,

Air Liquide Medical Systems are voluntarily issuing safety information with the introduction of preventive measures for Monnal T60 appliances, a list of which is given in an appendix to this document.

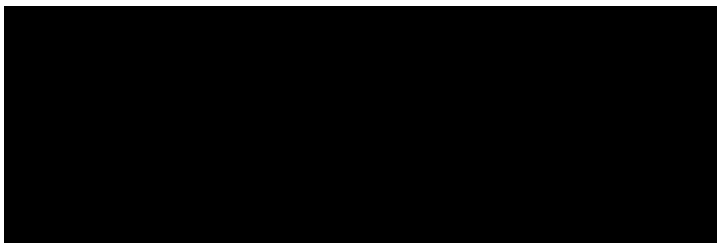
In the next few days, the establishments who are customers concerned by this measure will receive the necessary information for deploying the operating method described below.

It is important to be aware of the implications of this communication and we would ask you please to share this information as described with all users of the appliance.

The health authorities concerned have been given this voluntary safety information.

We wish to apologize for the inconvenience and to assure you that we are putting into place every necessary measure to deal with this situation as quickly as possible.

For any other questions, do not hesitate to contact our hotline or your usual contact.



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Description of the problem

The Monnal T60 is a ventilator designed for patient admission to Hospital, and in particular for Pre/Intra and Extra hospital transport.

When using the Monnal T60 for Pre/Intra and Extra hospital transport, the use of an interchangeable battery combined with an internal battery in the appliance is recommended.

It is in this, and only this, context of hospital use that 3 incidents have been reported to us.

No deaths or serious degradation of the patient's health has been reported to us for any of these incidents.

After running on the interchangeable battery, the 3 appliances correctly switched to running on the internal battery, informing the user of the change in power source.

At the end of internal battery autonomy, the appliance unexpectedly failed to raise the Batteries nearly discharged" and "Batteries inoperative" alarms.

Information on the potential risk

The cases reported and subject to investigation by Air Liquide Medical Systems confirm that:

- Depending on the conditions/frequency of use, the internal battery may have lost significant capacity after 2 years from installation.
- This significant loss of capacity does not systematically allow the algorithm to raise end of autonomy alarms ("Batteries nearly discharged" and "Batteries inoperative").

The failure to raise the "Batteries nearly discharged" and "Batteries inoperative" alarms before switching off the appliance prevents users from anticipating provision of a new power source at the end of internal battery autonomy.

In this situation, when the appliance is switched off, there is an audible "safety buzzer" signal to warn the user.

Preventive measures

ALMS has requested the following preventive measure for the devices listed in the section "Pool concerned".

It consists in checking that the internal battery end of autonomy alarms ("Battery autonomy low" and "empty batteries") are raised as expected.

Please note that a communication describing the complete operating method will be sent to customers who have the appliances listed below.

If the alarms are not raised as expected, Air Liquide Medical Systems:

- Requests that the appliance be isolated.
- Will make available the internal battery for the appliance concerned.

Products concerned

Monnal T60 Ref. KA010000

Monnal T60 JP Ref. KA013700

Serial number:

- Between MT60-02061 (inclusive) and MT60-03775 (inclusive)
- Together with machines with the following serial numbers:
MT60-01593 / MT60-01607 / MT60-01643 / MT60-01718 /
MT60-01790 / MT60-01822 / MT60-01836 / MT60-01840 /
MT60-01841 / MT60-01886 / MT60-01968 / MT60-01980 /
MT60-01981 / MT60-01982 / MT60-01984 / MT60-01987 /
MT60-01988 / MT60-02039.

Acknowledgement Customers who have one or more of the appliances concerned by this measure have received the document and description of the operating method.

A form associated with this operating method should be returned to us at the address given with the result of the test carried out.

Until a correction can be made, Air Liquide Medical Systems requests that the test described in the operating method be carried out.

Air Liquide Medical Systems is planning to issue definitive corrective actions by the end of May 2019.