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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.

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

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.