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To the attention of the Medical Devices Vigilance Coordinator
-

Antony, the July 9th of 2018

Object: Return to compliance concerning the **ventilators Monnal T60.**

Reference: R1810999

Dear customer,

In order to respect our compliance to the standard EN 13718-1, relative to the requirements for medical devices used in air ambulances and revendicated for the Monnal 60, Air Liquide Medical Systems issues voluntarily a return to compliance action.

This action concerns 362 devices manufactured from October 31st of 2017 to March 22nd of 2018.

This mail is addressed to you as you are owning xx of the concerned devices.

It is mandatory to well take into consideration the impactation of this communication, and we hereby ask you to share the information hereafter to the whole users population of this device.

The concerned Health Authorities have been informed of this voluntarily return to compliance action.

Issue description	Air Liquide Medical Systems has identified a manufacturing non-conformity concerning a limited and identified quantity of Monnal T60. This concerns the microprocessor board, on which has been identified the absence of glue dots on some components. This glue absence challenges the Monnal T60 compliance regarding the requirements of the standard EN 13718-1 (Requirements for medical devices used in air ambulances).
Information about the non-conformity	Monnal T60 is intended to be used by hospital medical staff (doctors, nurses,etc.) and is used: ● for pre-admission transportation* ● for transportation within an hospital ● for transportation between hospitals* ● for intra-hospital emergencies ● in post-operative recovery rooms ● in intensive care units. *Land transportation and **air ambulances** The device having been homologated for an **air ambulances use** with a microprocessor board equipped with glue dots on some components, the absence of these glue dots doesn't allow Air Liquide Medical Systems to ensure the compliance to the standard EN 13718-1 for the concerned devices. **<u>Important:</u> The devices remain conform for the other use contexts intended.**
Concerned devices	Ventilators **Monnal T60** Ref. KA010000 **Monnal T60 JP** Ref. KA013700 The traceability records allow us to accurately identify the list of concerned devices.

Information about the potential risk	No field issue in relation with this non-conformity has been recorded as per today, hence, Air Liquide Medical Systems considers the potential associated risk as acceptable, even if it could be decreased again. By the way, we propose the following actions here-after.
Conservative actions	Use of Monnal T60 can be carried if users are duly informed of the potential risk detailed in this field safety notice, until application of the corrective action described here-after. As a reminder, our user manual mentions in the main safety conditions that: *"It is nevertheless recommended, in cases of complete patient dependence, that you provide an additional, fully autonomous system which can be used to check the effectiveness of the ventilation, as well as a back-up device, such as a suitable manual insufflator."*
Corrective actions	The corrective action consists in the recovery of the revendicated standard EN 13718-1 compliance, for the listed devices. In order to, it is necessary to proceed to glue dots implementation on the concerned components of the microprocessor board. Air Liquide Medical Systems will directly contact each user, owner of one or more of the devices concerned by this return to compliance action.

We do apologize for the inconvenience caused by this corrective action.
Should you have any question, do not hesitate to contact our hotline or your usual contact.

Please accept, Madam, Sir, the assurance of our highest consideration.

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

CUSTOMER ANSWER FORM

Important Field Safety Notice dated July 9th 2018 – R1810999

MONNAL T60 Ventilator

Product designations: Monnal T60 & Monnal T60 JP
Product references: KA010000 - KA013700
List of the xx concerned products:

Fill and send back as soon as possible this form

by fax : **+33 1 40 96 67 00**

or by email : **almedicalsystems.vigilance@airliquide.com**

Customer Name and Address:	-
Contact name:	
Position:	
Email and phone number:	

We acknowledge receipt of the Field Safety Notice R1810999 and hereby confirm:

1. **having understood its content**
2. **having forwarded this information to the concerned users.**

Name:	Signature :	Date :