



Air Liquide Medical Systems
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To the attention of the Materiovigilance
Correspondent

Antony, the 28th of January 2015

Object : Field Safety Notification concerning Monnal T50 ventilators (Ref. 201500780)

Dear Madam, Dear Sir,

Air Liquide Medical Systems deploys a safety action. We thank you to send this information to whom it may concern.

This document contains important information for the continued safe use of your equipment. Please review the following information with all members of your staff who need to be aware of the contents of this communication.

Concerned products	Ventilators Monnal T50 Ref. KC027500
	Monnal T50 DE Ref. KC037600
	Monnal T50 JP Ref. KC039100

Serial numbers: all equipments are concerned.

Information about the potential risk and the safety improvement

Air Liquide Medical Systems has become aware of some cases of cessation of the ventilator function, which have occurred caused by unexpected high electromagnetic disturbances. Our investigation of the reported incidents clearly showed that the Monnal T50 is resistant to the required EMC limits.

To improve the safety of the patient in such situations, Air Liquide Medical Systems has developed a new software feature. When unexpected high electromagnetic disturbances occur that forces the device to involuntary stop ventilation, this new feature enables the Monnal T50 to restart automatically ventilation function in a few seconds, without the interaction of the caregiver.

The implementation of this new software will improve the intrinsic safety of the Monnal T50 ventilator.

Actions to be taken

To ensure the highest level of safety for the patients, we request to implement the new software, in all Monnal T50, primarily for patients who are ventilo-dependent. Therefore, we ask you to perform the software update for ventilo-dependent patients within 6 months at the latest and, for all other patients, during the next annual maintenance procedure, that is within 12 months at the latest.

The Authorities have been informed about this voluntary safety measure.

The operation consists in installing the new software version according to the procedure described in Technical Notes NT608 and NT609 (for Monnal T50) / NT610 (for Monnal T50DE) / NT611 (for Monnal T50JP).

The software can be downloaded on alms-services.com following the procedure describes on the Technical Notes.

In case you need help to update the devices, please contact our Hotline :

+33 179 51 7001

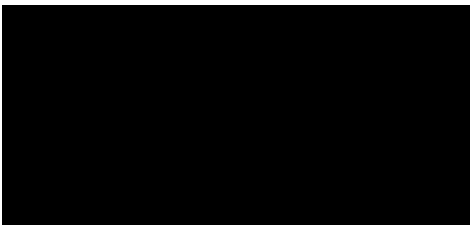
almedicalsystems.services@airliquide.com

Follow-up

We ask you to confirm to us the software update for each of your devices by registering their serial numbers and by sending back to us the traceability document which is enclosed to the Technical Note describing the procedure.

Air Liquide Medical Systems apologizes for any inconveniences caused by this safety measure. Be assured that we implement all appropriate means to resolve this situation with you as soon as possible. For further questions, please feel free to contact our hotline or your usual contact.

Please accept, Madam, Sir, the expression of our sincere greetings.



Quality & Regulatory Affairs Director