

Air Liquide Medical Systems
Parc de Haute Technologie
6, RUE GEORGES BESSE
92182 ANTONY CEDEX- France
Tél : (33) 01 40 96 66 00
Fax: (33) 01 40 96 67 00
www.airliquidemedicalsystems.com

To the attention of our customers, owners users
of the ventilator Monnal T50

Antony, 21st July 2017

Reference: R1705295/R1708030

Object **Field Service Corrective Action of Monnal T50 ventilators
in reference to the Field Safety Notice R1705295 from April 20th, 2017**

Dear customer,

Air Liquide Medical Systems in order to improve the safety of Monnal T50 in reference to the Field Safety Notice R1705295 from April 20th, 2017, now would like to inform you about the following Field Service Corrective Action.

This corrective action includes:

- Installation of the new software version V 2.3.x on all MONNAL T50, including
 - Improvement of the battery charging management,
 - Improvement of the battery depletion alarm system and
 - Improvement of the battery autonomy management
 - Recognition of degradation issues of the internal battery
- Replacement of the power supply board on all MONNAL T50 with serial number lower than MT50-04540, including
 - Replacement of the internal battery
 - Replacement of the mains power cord and
 - Management of battery ageing
- A new instruction for use for MONNAL T50 including the battery / alarm management changes

Considering the different clinical conditions of patients ventilated with Monnal T50 Air Liquide Medical Systems requests you to perform the above service actions within the following time frame:

- Within 12 months on all Monnal T50 in use with ventilator dependent patients

- Within 20 months on all other Monnal T50 in use.

Air Liquide Medical Systems is notifying customers of this issue via this information.

Air Liquide Medical Systems will start the shipment of the parts to be replaced in all MONNAL T50 with serial number lower than MT50-04540 and will provide the new software version V2.3.x end of July.

Your Air Liquide Medical Systems Services contact partner or your local partner will contact you in due time to organize the hard and software upgrade of the Monnal T50 concerned.

Should you have any questions or need further information regarding this information, please do not hesitate to contact us at:

- From France: 0820 146 359 (Indigo number – 0,12 € TTC/min)
- From Abroad: +33.179.51.7001

Until the above service action has been completed **we advise you to maintain the safety measures communicated in the Field Safety Notice of April 2017, especially with Monnal T50 being used with ventilator dependent patients.**

- *Ensure that a backup ventilator or at least manual breathing bag is available in the close vicinity of the patient.*
- *To increase the recognition of the auditory alarm signal the Monnal T50 should be equipped with an external alarm box.*
- *The external alarm box should stay connected and switched on all the time the Monnal T50 is in use*
- *The batteries of the external alarm box should be checked on regular basis ensure the function of the additional auditory alarm signal.*

This notice has been reported to the appropriate regulatory agencies.

We appreciate your support in reacting to this Field Service Corrective Action and sincerely regret any inconvenience that this action may cause to you.

Sincerely,

Mickaël JOUVE



Directeur Sécurité Patient Et Fiabilité - Correspondant Local Matériovigilance
Patient Safety & Reliability Manager - Vigilance correspondent