Antony, 05/01/2023

For the attention of the Medical Device Vigilance Officer
For the attention of the Biomedical Manager
-

Subject: Important information regarding the safety of Monnal T60 ventilators (Ref R2218602)

Dear client,

As part of its monitoring of customer feedback (incidents or near misses), Air Liquide Medical Systems has assessed three situations concerning the settings of ventilation parameters for the Monnal T60 range that could pose a risk, despite the existing software safety features.

To enable users to use all of the ventilation modes or specific functions without risk of misuse, Air Liquide Medical Systems voluntarily provides safety information for all products in the Monnal T60 range.

This corrective action involves updating all devices in the Monnal T60 range placed on the market, by deploying the software versions listed below, as well as providing a new associated user manual (UM):

- Monnal T60 range: software version V2.8.x
- Monnal T60 Advanced range: software version V1.2.x

It is important to give proper consideration to the implications of this notice and we would ask you to share this information with all users of this device.

The relevant health authorities have been informed of this express safety notice.

We apologize for the inconvenience. Please rest assured that we are introducing all appropriate means to deploy this action under the best possible conditions.

If you have any further questions, please do not hesitate to contact our hotline or your usual contact person.

Air Liquide Medical Systems
PARC DE HAUTE TECHNOLOGIE
6 RUE GEORGES BESSE - 92182 ANTONY CEDEX – France
A LIMITED COMPANY WITH CAPITAL OF €4,240,800 LISTED IN THE NANTERRE TRADE AND COMPANIES REGISTER UNDER No. B 348 921 735 – SIRET No. 348 921 735 00026

www.device.airliquidehealthcare.com

Description of the Problem

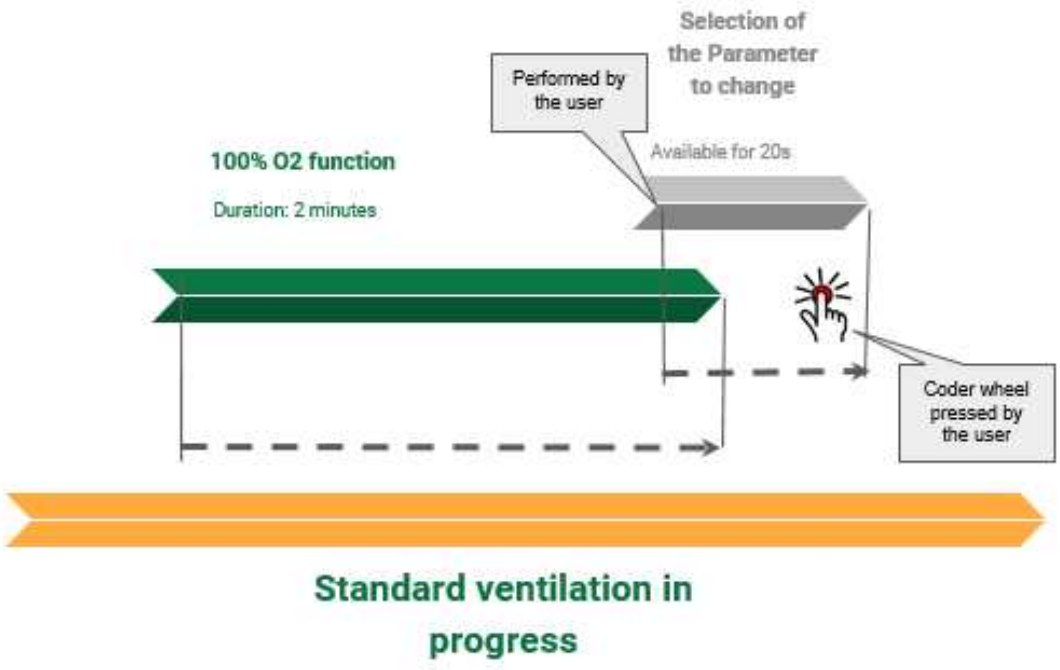
Situation 1: Possibility of having an Fio2 setpoint applied that is different to the setpoint displayed after using the 100% O2 function.

During a ventilation sequence, the user can start the "100% O2" function if necessary.

This function lasts for two minutes but can be interrupted by pressing the 100% O2 key.

After the 100% O2 function has been used, the FIO2 setpoint originally entered is reapplied.

Description of the problem: If the user wants to change the FIO2 setpoint a few seconds before the end of the two-minute period of the 100% O2 function, and this setpoint was confirmed just after the end of the 100% O2 function (see graph below), this can cause a conflict between the setpoint applied and its display.



Situation 2: Inheritance of setpoints

For each ventilation mode, the parameters displayed when the mode is launched can be:

- The original parameters, known as the "factory" configuration
- The parameters specifically configured by the user, called the "user" configuration

Description of the problem: Starting in a standard ventilation mode, if the user switches to an emergency ventilation mode (CPV, Emergency VAC or Pre-Oxygenation) and then returns to the initial standard ventilation mode, the ventilation parameters displayed are the "factory" configuration parameters, even if a "user" configuration has been set on the device.

Situation 3: Oxygen therapy

The use of an Oxygen Therapy session causes a specific window to open on the screen.

Description of the problem: If, at the end of the oxygen therapy session, the user switches off the device directly by pressing the ON/OFF side button (1) without closing the oxygen therapy window, a display conflict will appear at the next start-up:

- Either an oxygen therapy window will be visible without the associated setpoint parameters
- Or the setpoint parameters will be visible without the oxygen therapy window.

(1)

Information on the Potential Risk

Situation 1: Possibility of having an Fio2 setpoint applied that is different to the setpoint displayed after using the 100% O2 function.

The risk is that the applied Fio2 level is higher than the displayed setpoint, posing a risk of hyperoxia, or lower than the setpoint, posing a risk of hypoxia.

However, the risk is limited, as:

- Reproducing the fault is highly unlikely, as the window of time available to create this conflict is extremely short
- This requires the user to press the select/confirm button when there is nothing visible to prompt the button to be pressed.
- Monitoring of Fio2 delivered to the patient remains active and compliant.

Situation 2: Inheritance of setpoints

The risk of switching from one ventilation mode to another with unintended parameters is limited due to the fact that:

- the ventilation parameters to be applied are displayed
- a user confirmation step is necessary in order to change the ventilation mode.

However, the residual risk could be a delay in patient treatment when the mode is changed, as the user has to change one or more parameters before confirming the desired change of mode.

Situation 3: Oxygen therapy

The risk is being able to restart an oxygen therapy session without knowing what setpoints will apply.

However, this risk is limited, as if the device restarts with the oxygen window open, a user confirmation step is still necessary.

Corrective actions and implementation timeframe

Description of the correction made with respect to the three situations described above:

Situation 1: Possibility of having an Fio2 setpoint applied that is different to the setpoint displayed after using the 100% O2 function.
Air Liquide Medical has introduced a software correction that will prevent any "Awaiting confirmation" parameter from being maintained after the 100% O2 function two-minute period.

Situation 2: Inheritance of setpoints.
Air Liquide Medical has introduced a software correction that will make it possible to retrieve, between two standard ventilation modes, the parameters of the "user" configuration if it exists. If there is no "user" configuration, the "factory" configuration will be applied.

Situation 3: Oxygen therapy
Air Liquide Medical has introduced a software correction that will prevent the device from being switched off using the ON/OFF button (1) while the oxygen therapy window is still present on the screen.

Air Liquide Medical Systems requests installation of the latest available software version correcting the listed situations during the next maintenance of the device (preventive or corrective), and at the latest within one year.

Air Liquide Medical Systems requests that this safety information be immediately circulated within your facility to all users of the Monnal T60 and Monnal T60 Advanced ventilator.

The User Manual has been updated to more clearly specify the inheritance of setpoints when using the so-called emergency modes.

Procedure

Customers trained in maintenance will receive the implementation details through the usual information channel.

Customers not trained in maintenance will have their device updated during the next preventive or corrective maintenance, and within a maximum of one year by Air Liquide Medical Systems' technical teams.

Products affected

Monnal T60 range
References: KA010000 - KA013700 - KA017114 - KA017115

Monnal T60 Advanced range
References: KA017119 - KA017124 - KA017122 - KA017127 - KA017128 - KA017129 - KA017130.

Acknowledgment of receipt

All customers involved have received this safety information

Firstly, please return to us

- Form 1- acknowledgment of receipt below as soon as possible to the following address:
  - almedicalsystems.vigilance@airliquide.com
  - Or by Fax to (+33) 140 966 621

As soon as you update the software on one of your devices, please return to us

- Form 2 - Implementation as soon as possible to the following address:
  - almedicalsystems.vigilance@airliquide.com
  - Or by Fax to (+33) 140 966 621

FORM 1 - Distributor acknowledgment of receipt

Safety notice issued on 05/01/2023 R2218602

MONNAL T60 - References KA010000 - KA013700 - KA017114 - KA017115

MONNAL T60 Advanced - References KA017119 - KA017124 - KA017122 - KA017127 - KA017128 - KA017129 - KA017130.

Please complete and return this form immediately

by fax: **(+33)140 966 6 21**

or by email: almedicalsystems.vigilance@airliquide.com

Distributor name and address	
Contact name:	
Title:	
Email and phone number:	

☐ **We acknowledge receipt of this safety notice R2218602**

☐ **We confirm that we understand its content and have relayed the information to the necessary parties.**

☐ **We confirm that we have submitted this FSCA to our local health authority.**

It is important to return this document as soon as possible so that we can monitor the implementation of this corrective action

Signature and Date:	

FORM 2 - IMPLEMENTATION

Safety notice issued on 05/01/2023 R2218602

As soon as the software version is implemented on devices in your installed base, please complete and return this form immediately, confirming that the software version associated with this safety action has been deployed. by fax: **(+33)140 966 6 21** or by email: almedicalsystems.vigilance@airliquide.com	
Name and address of the facility:	
Contact name:	
Email:	

We certify that the FSCA R2218602 has been implemented on the devices listed below

Serial No.	Software version	Date

It is important to return this document to us regularly without waiting for the update of your entire installed base to be completed, and as soon as possible

This procedure will enable us to monitor the progress of this corrective action

Signature and Date:	