

To the attention of the Medical
Device Vigilance correspondent

Antony, the 2021/04/27

Reference: FRC20-0517

Object: Important Safety Information about the Wall Charging Station KA010300 used with Monnal T60 ventilators.

Dear customer,

Air Liquide Medical Systems voluntarily deploys a safety information related to the use of the Monnal T60 ventilator on its wall charging station.

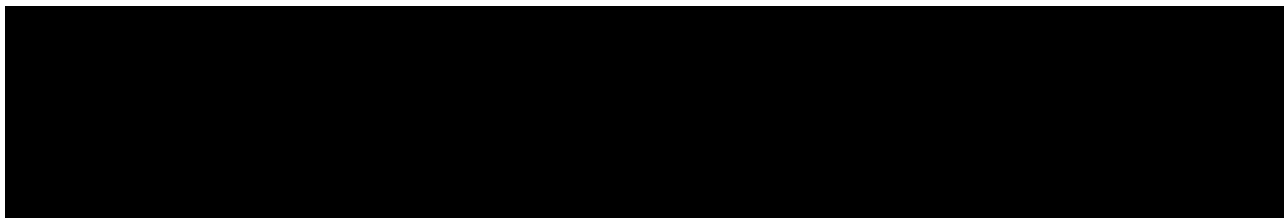
Indeed, we wish, through this information, specify the empowerment solutions to be considered while the Monnal T60 is locked to the wall charging station KA010300.

The customers owners of the wall charging station KA010300 received this safety information.

It is important to well take into consideration the implications of this communication, and we ask you to forward this information described hereafter within your organization.

The Healthcare authorities concerned have been informed of this volunteer safety information.

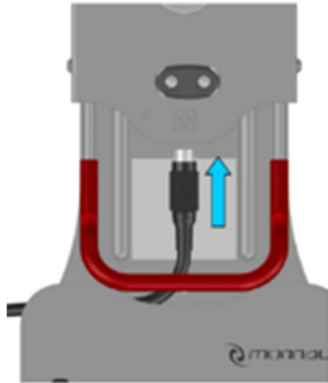
Thank you for considering this information and for any complementary question, do not hesitate to contact our hotline or your usual contact.



Available empowerment solutions

When our ventilator MONNAL T60 is used in a ground intervention vehicle, it can be hold on our wall charging station KA010300 in order to:

- Beneficiate of a plug and play locking system of the ventilator during the transport
- Empower the ventilator through the charging station.



The wall charging station user manual (YL068200) currently refers (graphically) to the installation of the external power supply, providing a 24VDC current to empower the Monnal through the wall charging station. However, it seems necessary to us to specify the empowerment solutions available for the customers.



The main accessory which can be used to empower the ventilator through the wall charging station is the external power supply YR115700 provided with the Monnal T60 (inlet: 100 - 240VAC 50-60 Hz // outlet: 24VDC)

Air Liquide Medical Systems has been informed of an isolated incident on a wall charging station, which electrical configuration was as following:

- The involved Monnal T60 was empowered through the wall charging station
- The wall charging station was itself empowered thanks to the cigarette lighter adapter.
- The electric current supplied by the ground ambulance was a 12VDC voltage.

Empowering the Monnal T60 by a 12 VDC through the wall charging station can lead to a high current consumption through the contact charging points on the backside of the Monnal T60, which can lead to an excessive overheating in their neighborhood (the plastic housing around the contact points having been altered).





In situations where the user wish use the YR123700 cigarette lighter adapter to empower the Monnal T60 through the wall charging station, he has to first check the electric network provided by the ground ambulance is a 24VDC.



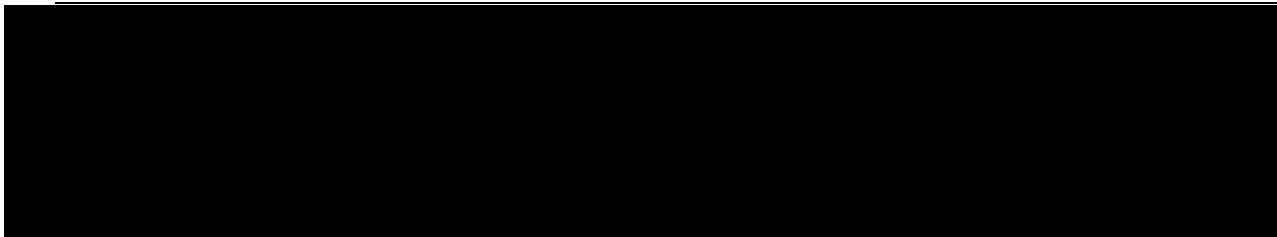
In case the electric network provided by the ground vehicle is a 12VDC, the Monnal T60 cannot be empowered through the wall charging station. The user has to connect the cigarette lighter adapter directly on the Monnal T60 left side (see appendix 1). *In this case, the wall charging station should be used only for its mechanical function (not for the powering of the Monnal T60).*

Then, we can have **2 empowerment configurations possible and allowed** when the wall charging station assumes the empowerment of the ventilator, resumed in the figure hereafter:

Accessory used			
Inlet specification	100-240VAC 50-60Hz	24VDC	12VDC
Outlet specification	24VDC	24VDC	12VDC
Configuration	Allowed	Allowed	Not allowed

Conservatory actions

We hereby ask you to first diffuse this safety information to any concerned user and biomedical department within your organization, then to leave at their disposal the appendix 1 hereafter during the update period of the wall charging station user manual.



Corrective actions

Air Liquide Medical Systems will update the use instructions of the Monnal T60 wall charging station.

This modification aims to specify the different empowerment solutions allowed for a Monnal T60 while empowered by the wall charging station, and to highlight the corresponding warnings.

When this modification will be issued, all customers impacted by the use of the wall charging station will receive the updated user manual.

Acknowledgement of receipt

All concerned customers have received this safety information.

We ask you to return us the following form in the shortest delays to the mail address:

- almedicalsystems.vigilance@airliquide.com
 - Or by fax +33 140 966 621
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CUSTOMER ANSWER FORM

Safety notice issues 2021 04 27 – FRC 20-0517

WALL CHARGING STATION - KA010300 for MONNAL T60

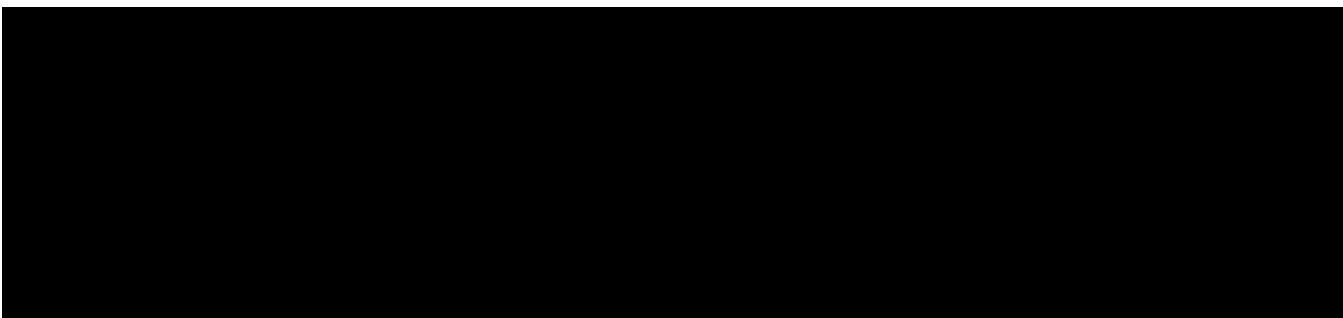
Please complete and return this form as soon as possible
by fax: **+33 140 966 621**
or by email: almedicalsistemas.vigilance@airliquide.com

Institution name and address:	
Contact person:	
Position:	
Email and telephone number:	

Before returning to Air Liquide Medical Systems, please tick the following boxes:

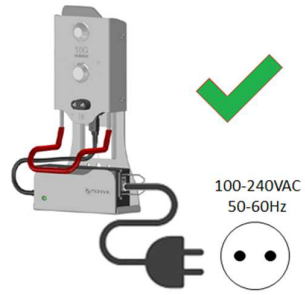
- We acknowledge receipt and confirm having understood the content of this safety notice FRC 20-0517**
- We confirm having relayed this information to the necessary parties within our organization.**

Signature and Date:	
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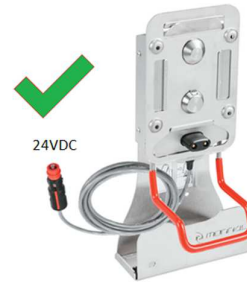


APPENDIX 1 - Configurations Allowed with the wall charging station

The ground vehicle provides an electric supply in alternative current (100- 240V 50-60Hz)



The ground vehicle provides an electric supply in continuous current at 24VDC



The ground vehicle provides an electric supply in continuous current at 12VDC



If the ground vehicle provides 12VDC current, the use of the cigarette lighter adapter is allowed if connected on the Monnal T60 left side as illustrated below.

