

Customer Information

23.März 2020

Use of Löwenstein Medical Anaesthesia workstations LEON/LEONmri/LEONplus for long-Term Ventilation with COVID-19

Dear sir or Madam, valued Customers, and partners;

Due to the current situation, spread and severity of Corona virus and rapidly rising numbers of patients requiring artificial ventilation, we receive, beside the request for ventilators, also requests if our anaesthesia Workstations LEON/LEONmri/LEONplus can be used for long-term ventilation as well, in case there are not enough ICU Ventilators available.

Basically the following applies:

There is no regulatory scope for the use of LEON, LEONmri and LEONplus for long-term ventilation.

Both, the intended use of the devices, as well as the approval with related standards based on which the approval was made, allow no regulatory or legal scope for the use of LEON, LEONmri and LEONplus for long-term ventilation.

The use of the devices for long-term ventilation means an off-label use.

It is solely at the discretion and responsibility of the user/operator and his own risk-benefit analysis whether a LEON/LEONmri/LEONplus anaesthesia workstation is used for long-term ventilation in an emergency situation.

The user/operator bears the full risk of liability when using LEON/LEONmri/LEONplus for long-term ventilation.

For the reasons mentioned above, we cannot recommend the use of Löwenstein Medical's LEON, LEONmri and LEONplus anaesthesia workstations for long-term ventilation.

Nevertheless, we are aware that in an emergency situation and in the event that no alternative ventilation option is available, a Löwenstein Medical anaesthesia workstation LEON, LEONmri or LEONplus could be used for long-term ventilation after risk-benefit analysis by the user/operator

What you have to consider with an conscious off-label use, in any case:

- Basically, medical personnel must be trained on use of LEON/LEONmri/LEONplus and the DGAI recommendations for handling anaesthesia devices and related components should be considered.
- In contrast to intensive care ventilators, the operation of anaesthesia equipment is based on the assumption that the user is in close proximity to the device all the time to be able to immediately react to alarms or events. Adjust the alarm limits to the ventilation situation and set the alarm volume of the LEON/LEONmri/LEONplus to 100% to be able to hear alarm messages even when you are not in close proximity to the device.
- In order to ensure the trouble-free operation of LEON/LEONmri/LEONplus, we necessarily prescribe a restart of the certain device at least every 24 hours. Try to keep to this interval or, depending on the patient's condition, not to exceed it too much. Operating the device for a longer period of time without rebooting can affect the operational safety of the device.
- Perform a system test after each reboot, do not skip it! During the system test, a pressure and flow calibration is carried out and the compliance of the hose system is determined, a basic requirement for exact measurement and control of the system.
- We do not recommend using the device without absorber.
- We recommend a fresh gas flow of approx. 6l/min. and the control of humidity in the system. Due to the patient's rebreathing and the release of water during the chemical reaction in the absorber, there is enough moisture in the system to protect the patient from dehydration. If there is too much condensation in the ventilation hose, the fresh gas flow should be increased; However, if there is no condensation in the system, the flow should be slightly reduced.
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- Ensure that there are no volatile anaesthetics left in the system when the long-term ventilation is started and remove the anaesthetic vaporizer(s) from the device, for safety reasons.
- Make sure that the connected gas sample hose on the filter or Y-piece points upwards. A gas sample hose pointing downwards can suck-in condensed water, fill the water trap too quickly and eventually lead to a defective gas measuring bench.

In case there is any question left, if you need assistance/more information or if you have proposals related to the above, or any other topic, please do not hesitate to contact us.

Please get in touch with your responsible person in charge in back office or your regional sales manager, they will clarify all open issues.

Take care of yourself.

Yours sincerely,

Markus Stahlhofen
Produktmanager Anästhesie

Löwenstein Medical GmbH Co.KG