Dear HME/DME,

As the CEO of Movair, who is the exclusive USA dealer for the Löwenstein LUISA ventilator with high flow, I want to share with you the facts concerning the regulatory status of the LUISA per the US government, Emergency Preparedness Act and the FDA. I also want to clear up any misunderstandings concerning the LUISA and its FDA EUA authorization and pending 510K clearance.

The LUISA is an FDA EUA authorized ventilator that is specifically named in the Emergency Preparedness Act, not unlike vaccinations which also fall under this Act, and are exempt from general product liability. This a benefit of the EUA and Emergency Preparedness Act system. See attached for detailed information and links to the appropriate government documents.

The LUISA ventilator is also pending its FDA 510(k) clearance (#K221316) which we anticipate issuing in 2023. At that point, the LUISA will be like any other FDA 510(k) cleared medical device and all LUISA's in the field should only require a firmware and label/documentation updates. Upon its 510(k) clearance, the LUISA will be also indicated for use for pediatrics, as well as adults, and include full telemedicine portal cloud-based data utilizing modem.

I hope the attached answers any questions you may have concerning this topic and clears up any misunderstandings in the marketplace.

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Frequently Asked Questions Regarding the Regulatory Status of the LUISA® Home Ventilator

MOVAIR, INC. is providing this position paper to provide greater transparency and clarification, and address potential market disinformation, concerning the U.S. regulatory status of the LUISA home ventilator product. Contact your Movair representative, or call us at (512) 326-3244, if you have any questions, or would like more information, or become aware of any statements being made which are inconsistent with the facts.

QUESTION: Is there any increased liability for distributing or using the EUA-approved LUISA vs. other ventilators cleared under 510(k)?

ANSWER: NO. In fact, there is broad immunity from liability for EUA-authorized products, such as ventilators and vaccines.

The Public Readiness and Emergency Preparedness Act (PREP Act)[1] authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue declarations providing immunity from liability for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency **to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures**. A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.[2]

Effective February 4, 2020, the HHS Secretary issued just such a declaration under the PREP Act to provide liability immunity for activities related to medical countermeasures against COVID-19.[3]

Most importantly, the Prep Act expressly stipulates that any medical device that is authorized for emergency use under the Federal Food, Drug, and Cosmetic Act **is** a "covered countermeasure" that is entitled to this immunity protection.[4]

QUESTION: Who is entitled to this immunity from liability under the Prep Act?

ANSWER: The "Covered Persons" who are afforded liability immunity under the 2020 Declaration (as amended) include manufacturers, distributors, program planners, qualified persons, and their officials, agents, and employees. "Qualified persons" specifically include licensed professionals and other individuals authorized to prescribe, administer, or dispense covered countermeasures under state law.[5] A March 2021 amendment to the Declaration makes crystal clear that the immunity protection specifically extends to any "person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an **Emergency Use Authorization** in accordance with Section 564 of the FD&C Act."[6]

QUESTION: What kind of liability protection is afforded by the Prep Act?

ANSWER: The Prep Act provides immunity to all covered persons from suit and liability with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.[7] The sole exception to this immunity is for death or serious physical injury proximately caused by willful misconduct[8] that is proven by clear and convincing evidence.[9] "Willful misconduct" means an act or omission that is taken intentionally to achieve a wrongful purpose, knowingly without legal or factual justification, and in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.[10]

QUESTION: Are Ventilators and home Ventilators included as "covered countermeasures" under the Prep Act?

ANSWER: Yes, Ventilators and home Ventilators are "covered countermeasures" under the Prep Act[5]. In response to the HHS Secretary's 2020 Declaration, the Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUAs) for ventilators and ventilator accessories. The "LUISA Life Support Ventilator LM150TD" are among those identified by the FDA as Authorized Ventilators.[11]

QUESTION: What is the intended use for the LUISA under EUA?

ANSWER: The intended use of the LUISA under the EUA issued by the FDA is:

> *The LUISA provides continuous or intermittent ventilatory support for adult patients who require mechanical ventilation. The LUISA device is intended to be used in home, institution/hospital and portable applications for both invasive and non-invasive ventilation.*
> *Caution: The LUISA device is not intended for use as an emergency transport ventilator. Caution: In the US, Federal law restricts this device to sale by or on the order of a physician.*

The LUISA user manual also includes required language about EUA products and each device also comes with the required Fact Sheets for both patients and healthcare providers regarding EUA devices.

QUESTION: What happens when the EUA is withdrawn by FDA?

ANSWER: According to draft FDA Guidance issued in December 2021, the FDA does not intend to object to continued distribution of EUA devices so long as the manufacturer has submitted a marketing submission (such as a 510(k)) to the FDA which has been accepted by FDA prior to the EUA termination date, and no final decision on that submission has been reached. In addition, FDA does not intend to request withdrawal of EUA devices which are already being used on patients.[12]

A 510(k) submission for the LUISA ventilator has been accepted by the FDA and is pending for 510(k) clearance. The assigned 510(k) number is K221316. The planned indications for use under the 510k include both adult and pediatric populations, as well as invasive or non-invasive ventilation. Once 510(k) cleared,

Movair believes the most likely scenario to bring EUA devices into compliance with the 510(k) will involve performing a field firmware update and provide updated labeling for EUA devices.

QUESTION: Is billing for a homecare product any different under EUA?

ANSWER: No, the LUISA is approved by PDAC for codes E0465 and E0466.[13]

QUESTION: Is the LUISA widely used? How many devices are currently in use in the USA?

ANSWER: As of August 31, 2022, nearly 10,000 LUISA ventilators have been distributed in the USA. The LUISA ventilator has been CE-Marked and distributed in Europe since November 2020. The LUISA ventilator is manufactured in Hamburg, Germany under current Good Manufacturing Practices (cGMP's), including FDA QSR and ISO 13485.

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[1] Pub.L. 109–148, codified at 42 U.S.C. § 247d-6d.
[2] https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx.
[3] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 15198, available at https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures.
[4] 42 U.S.C. § 247d-6d(i)(1)(C). See also, PREP Act Q&As, https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx.
[5] The PREP Act and COVID-19, Part 1: Statutory Authority to Limit Liability for Medical Countermeasures. Congressional Research Service, April 13, 2022. Available at https://crsreports.congress.gov/product/pdf/LSB/LSB10443.
[6] Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, eff. March 11, 2021, available at https://www.phe.gov/Preparedness/legal/prepact/Pages/PREP-Act-Guidance.aspx.
[7] 42 U.S.C. § 247d-6d(a)(1).
[8] 42 U.S.C. § 247d-6d(d)(1).
[9] 42 U.S.C. § 247d-6d(c)(3).
[10] 42 U.S.C. § 247d-6d(c)(1)(A).
[11] https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas.
[12] Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, available at https://www.fda.gov/media/155039/download.
[13] Correct Coding and Coverage of Ventilators - Revised July 2020, available at https://www.dmepdac.com/palmetto/PDACv2.nsf/DIDC/N9L9D6LL9U~Articles%20and%20Publications~Advisory%20Articles.