SEMMELWEIS UNIVERSITY

FACULTY OF MEDICINE

Department of Anesthesiology and Intensive Therapy

Head of Department: *Prof. Dr. János Gál*

Interim state of clinical testing of the "LUCA" ventilator

The "LUCA" (ver. 3.1) is a rapidly manufactured ICU ventilator developed in 2020 in Hungary during the COVID-19 pandemic to provide an alternative option for the increased demand for mechanical ventilators. The ventilator is a regulated flow system equipment and has a pressure controlled (PC) and a pressure supported (PSV) mode both equipped with a patient trigger function. To ensure staff safety, a high capacity viral/bacterial filter is included at the exhalation port. The design includes a manual PEEP valve, and the ventilator software is upgradeable. The device is not yet supplied with a CE marking.

According to the EU and Hungarian regulations, the use of a medical device without CE marking is restricted. In special cases rapidly manufactured ventilators without CE markings are allowed to be used in a clinical emergency setting. The "LUCA" ventilator does have certifications like oxygen compatibility and electrical conformance, necessary for appropriate clinical testing. The "LUCA" went through a 14-day durability test with success.

The clinical testing protocol for the device was approved by the Hungarian Medical Research Council and the clinical study was authorized by the National Institute of Pharmacy and Nutrition (OGYÉI) that is appointed by the 28/2005. (II. 25.) Government Decree as a licensing authority for pharmaceutical and public administrational matters under the reference: OGYÉI/25837-7/2020.

The clinical study has 4 stages; with each consecutive stage requiring a passed previous stage.

Stage one investigates the operation of the ventilator according to the study protocol based on the RMVS guideline in 72 different settings.

Stage two investigates the alarm and safety features of the ventilator.

Stage three focuses on usability; after a 5-minute short user guidance on the device, 16 different parameter settings and tasks are performed by 10 clinicians. The usability of the device is verified by System Usability Scale.

At stage four, the device is used to ventilate real life patients in the ICU for a period of one hour and the clinical parameters of ventilation are compared to those achieved by a standard ICU ventilator (vital parameters, arterial blood gas values, frequency of ventilator alarms, the need for medical intervention, the need for ventilator setting change, visual score for dyspnoea etc.)

Address: 1082 Budapest, Üllői út. 78/a.
Postal address: 1085 Budapest, Üllői út. 26.; 1428 Budapest, Pf. 2.
E-mail: titkarsag.aitk@med.semmelweis-univ.hu

Tel.: (+36-1) 459-1234, (+36-1) 459-1500/12345
Fax: (+36-1) 459-1234, (+36-1) 459-1500/12345
Web: http://semmelweis.hu/aneszteziologia

"LUCA" has passed the first 3 stages with exceptional results, 100% both in stage one and two and scored more than 90 in the usability test (out of 100).

According to the requirements of the authorization institution, the first 5 real-patient interim results must be assessed to gain approval for further clinical investigations.

During the stage four tests, the "LUCA" was well tolerated, patients reported no difference in the comfort of ventilation and equivalent ABG and clinical parameters were achieved as with standard ventilators. There were no safety issues or adverse events.

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Lorx András MD Ph.D.

Principal Investigator
Associate professor
Dept., Anesthesiology and Intensive Therapy
Semmelweis University

Cím: 1085 Budapest, Üllői út. 26.
Postacím: 1085 Budapest, Üllői út. 26.; 1428 Budapest, Pf. 2.
E-mail: minta.nev@semmelweis-univ.hu

Tel.: (06-1) 459-1234, (06-1) 459-1500/12345
Fax: (06-1) 459-1234, (06-1) 459-1500/12345
Web: http://semmelweis.hu/alhonlapcim