

# Summary

The COVID-19 pandemic represented an unprecedented global health emergency, placing healthcare systems worldwide under significant strain. One of the most critical aspects of clinical management for patients with COVID-19 was the development of acute respiratory failure, a severe impairment of pulmonary function caused by the viral infection, which necessitated ventilatory support to ensure adequate oxygenation. According to guidelines from the World Health Organization (WHO) and leading scientific societies, Continuous Positive Airway Pressure (CPAP) therapy was identified as an effective strategy to improve oxygenation in patients with respiratory failure due to COVID-19, reducing the risk of invasive endotracheal intubation and the subsequent overload of intensive care units.

However, during the early stages of the pandemic, the rapid spread of the virus led to a severe shortage of ventilatory support devices, including ventilators and non-invasive ventilation systems such as CPAP therapy devices.

In response to both the shortage of respiratory support devices and the limited availability of therapeutic oxygen, several research groups developed alternative solutions, adapting existing equipment for the treatment of COVID-19 patients or designing new systems capable of providing non-invasive ventilation while optimizing oxygen consumption.

In this context, the Politecnico di Torino and clinicians from the Università del Piemonte Orientale in collaboration with the Piedmont-based company APR srl, patented a kit for non-invasive mechanical respiratory support. The invention aims to provide respiratory support, reduce the generation of potentially infectious aerosols, optimize oxygen consumption, and remain compatible with existing devices, while maintaining a relatively low cost.

The kit consists of a closed-circuit system designed to deliver a mixture of air and oxygen for CPAP therapy. It features separate inlets for pressurized air and oxygen, which converge at a mixing point before reaching the patient via a mask or other wearable non-invasive interface that covers the nose and mouth. The circuit enables reuse of exhaled air, which passes through a soda lime filter that removes carbon dioxide. Unidirectional airflow is maintained by a set of valves that regulate circulation in a controlled manner. These valves operate automatically in response to the patient's respiratory activity, without the need for electrical power. As a result, only the amount of oxygen required for metabolic respiration is consumed with each breath, minimizing waste and optimizing oxygen use. Despite its simplicity and lack of active components, the system is highly effective and particularly suitable for low-resource settings or environments with limited power availability.

Although the COVID-19 pandemic context accelerated the rapid development of innovative solutions, CPAP therapy and its benefits are not limited to the management of acute respiratory failure

from COVID-19. CPAP is, in fact, a well-established treatment for various respiratory conditions, such as obstructive sleep apnoea syndrome and acute respiratory distress syndrome. Moreover, it is also employed in the management of patients undergoing weaning from invasive mechanical ventilation, as well as in the postoperative setting to support respiratory function and prevent complication. Therefore, while the patent developed by the Politecnico di Torino and APR srl addresses an emergency need, the concept of a closed-circuit CPAP device that reduces oxygen consumption, viral contamination, noise, and improves patient comfort holds broad potential in general clinical practice.

Building upon this patent, the present research focuses on the design, development, and characterization of a medical device to deliver CPAP therapy via a closed circuit, aiming to meet clinical needs for efficiency, safety, and reduced resource consumption. Although initially conceived in response to emergency needs, this device could serve as an innovative and versatile solution for treating a variety of respiratory conditions, both acute and chronic, and could also support patients during the weaning process from intensive care, particularly in the postoperative phase.

Following a survey of project participants, the device was named AliseO<sub>2</sub>, combining 'Aliseo' (a steady wind, constant in direction and intensity) and 'O<sub>2</sub>' (oxygen), symbolizing the respiratory support system provided by CPAP therapy.

This work is guided by the structure and methodological requirements outlined in Regulation (EU) 2017/745 (MDR) for medical devices, particularly in the preparation of the technical documentation required for CE certification. Although obtaining certification is beyond the scope of this research, adopting this regulatory framework ensures a robust, transparent, and clinically relevant evaluation of the AliseO<sub>2</sub> prototype's performance and safety. This strategy not only enhances the scientific validity of the findings but also facilitates potential future translation into clinical practice.