



Synopsis on the use of the Frequencer® for Treatment of COVID-19

COVID-19 leads to acute respiratory distress syndrome (ARDS) in many patients

Although data is still being collected, the clinical spectrum of COVID-19 is wide, encompassing asymptomatic infection, mild upper respiratory tract illness, and severe viral pneumonia with respiratory failure. In a considerable number of cases, COVID-19 requires hospitalization, eventually leading to acute respiratory distress syndrome (ARDS) and death. Large amounts of sticky mucus and hyaline membranes in the deep-seated airways have been found upon autopsy in some patients. **A non-invasive device that is compatible with ventilation that effectively clears airway secretions would be extremely valuable.** Additionally, a treatment modality that rapidly and effectively clears the airways of mucus and fluid and recruits smaller airways in the early stages of infection could alter the course and outcome of disease.

Dymedso's Frequencer® uses acoustics to promote airway clearance

Dymedso's Frequencer® is a novel device that promotes bronchial drainage by using acoustic waves at an optimized frequency that easily travels through the chest, causing the lungs to vibrate and the viscosity of mucus to decrease. It can be positioned selectively on different areas of the chest (front or back), particularly the low lung areas, with no discomfort or pain, and can be used in intubated patients. **The Frequencer® is effective and consistent at clearing pulmonary secretions in a variety of airway clearance diseases,** and prior to COVID-19 more than 600 devices were deployed across the world.

The Frequencer® for COVID-19 treatment

Based on available data, **Dymedso strongly believes that the Frequencer® could help a significant number of COVID-19 patients potentially alleviating the need for mechanical ventilation and ultimately reducing mortality.** Several devices are currently in the hands of clinicians for treatment of COVID-19.

At the **Asklepios Klinik** Barmbek, Hamburg, Dr. Lars Fischer utilized the Frequencer® in combination with FLO cough assist to treat COVID-19 patients during the first wave. Although difficult to make direct correlations to outcome due to patients being treated with multiple therapies, the Frequencer® was safely and successfully incorporated into the COVID-19 clinical setting and appeared useful as a tool for the treatment of COVID-19.

The Frequencer® was placed at the **Jaber Hospital, Corona Centre, Kuwait** in June, 2020 and is

routinely used in the ICU to improve airway clearance. In June 2020, Dr. Samar Haitham provided written case studies on 4 patients. All patients were on ventilation and were treated with the Frequencer® for 1 week, 20 minutes daily, followed by closed catheter suctioning. Improvement was observed after application of the device (i.e., breathing function showed improvement) in 2 of the 4 patients. Treatment was halted due to inability to conduct closed suction due to a bleeding tracheostomy (this was not caused by the Frequencer®) in 1 patient, while one patient showed no significant improvement due to a host of other complications. The physician concluded that the Frequencer® *“should be used for most of the patients with COVID-19, especially those having high thick mucus. It provides easy and consistent effective therapy, also it was very safe to use for patients on ventilators or having tubes.”*

Dymedso has solidified a collaboration with the **Ministère de la Santé et des Services sociaux (MSSS), Quebec**, to address the critical need for treatment of COVID-19 patients during the second wave. An observational study is underway on COVID-19 patients whereby 25 devices are being or will be deployed in the upcoming weeks at **11 University Hospitals and 1 Long-Term Care Facility** (Centre Hospitalier Univ. Sainte-Justine, CUSM Glen, CUSM Hôpital Général de Montréal, CHUM Hôpital de Verdun, Hôpital Sacré-Cœur, Hôpital St-Jérôme, Hôpital Charles-Le Moyne, Hôpital Honoré-Mercier, Hôpital Pierre Boucher, Hôpital de Gaspé, Hôpital de Chicoutimi, CHSLD Monseigneur Ross). The Frequencer® will be employed in this non-comparative multicenter clinical-economic study as an addition to standard care with the goal of demonstrating clinical relevance and economic efficiency. Several outcomes will be assessed including the frequency of use of the device; exposure time of the professionals to contagious patients during treatment, length of hospital stays, ICU admissions, need for ventilation, quality of life and patient satisfaction. Additionally, clinical efficacy will be measured where possible by documenting the evolution of O2 saturation, evolution of the respiratory rate and other parameters such as subjective dyspnea, patient and caregiver satisfaction.

Finally, a multicenter prospective crossover noninferiority randomized controlled trial is underway at **CHU Sainte-Justine, Dept of Pediatrics, Montreal** and the **Montreal General Hospital** to compare the effectiveness of the Frequencer® vs. Chest Physiotherapy (CPT) for mobilizing secretions in mechanically ventilated children and adults with respiratory distress linked to COVID-19 infection. The trial design was recently published by Kawaguchi and colleagues in the medical journal *Trials* (2020, 21:610, see <https://doi.org/10.1186/s13063-020-04533-6>). Rationale for the study include expected improvement in the respiratory status of patients with COVID-19 due to the ability for increased treatments vs. CPT, reduction of the impact of COVID-19 on the health system, decreased exposure of physiotherapists to COVID-19 and improved working conditions in ICUs.