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## LETTER

### Life Plus Mini Capsule S<sup>®</sup>, Novel Intubating Box – A Pilot Study

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#### Abstract:

To protect clinicians without access to recommended personal protective equipment during aerosol-generating procedures such as endotracheal intubation, various products have been introduced to clinical practice. The authors would like to present a pilot study with a novel intubating box, the LIFE PLUS MINI CAPSULE S<sup>®</sup>, which has improved systems to prevent the egress of particles from the box as well as a built-in HEPA (High Efficiency Particulate Air) aspiration filter.

Nineteen anesthesiologists simulated endotracheal intubation on a mannequin in test conditions with and without using the LIFE PLUS MINI CAPSULE S<sup>®</sup>. All anesthesiologists successfully intubated the mannequin at first attempt, and there were no failed intubations. The median (range) intubation time was 9.1 (2.0–25.0) seconds longer when the LIFE PLUS MINI CAPSULE S<sup>®</sup> was used, and there were no breaches of personal protective equipment. The leakage of airborne particles was analyzed using a Qualitative and a Quantitative Fit Test.

Although our pilot study shows promising results, further research is required to validate our results *in vivo* and in a larger sample size which will provide us with a better insight into the efficacy and applicability of this safety tool in emergency and elective clinical conditions.

**Keywords:** Intubating box, Aerosol-generating procedures, HEPA filter, Mannequin, Endotracheal intubation, Elective clinical conditions.

#### Article History

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## 1. INTRODUCTION

Personal Protective Equipment (PPE) shortages present a tremendous challenge to healthcare systems around the world due to the COVID-19 pandemic. To protect clinicians without access to recommended PPEs during Aerosol-generating Procedures (AGP), such as endotracheal intubation, various products have been introduced into clinical practice. The first “Aerosol Box” was introduced by Dr. Hsien Yung Lai in late March 2020 [1], and since then, other companies and organizations have followed suit with their own versions, generally known as “intubation boxes” [2, 3].

Unfortunately, this simple solution to a difficult problem does not provide as much protection as many had hoped for. A recent paper published by Turer and colleagues [4] suggested that the use of an intubation box alone may not be sufficient to contain airborne virus particles, although a previous study simulating laryngoscopy on a mannequin, which was designed to expel fluorescent dye, showed that this type of barrier greatly reduced the exposure of Health Care Professionals (HCPs) [5].

The authors would like to present a pilot study with a new intubation box called the Life PLUS MINI CAPSULE S<sup>®</sup>,

manufactured by Strata Manufacturing PJSC (UAE), with improved systems to prevent the egress of particles from the box as well as a built-in HEPA (High Efficiency Particulate Air) aspiration filter.

LIFE PLUS MINI CAPSULE S<sup>®</sup> is a flat-packed system which, when assembled, forms a box consisting of four fixed Perspex<sup>®</sup> panels making the roof, head end, and sides of the box. The foot end of the box is made from a long clear, flexible drape that sits over the patient’s chest and prevents egress of aerosolized particles caudad. The head and sides of the box also include self-closing iris ports which are constructed of flexible triangular plastic segments in an overlaid pattern so as to prevent the egress of aerosolized particles through them (Fig. 1).

Previous concerns regarding concentrating infectious material within intubating box were reduced by adding a negative pressure pump with a HEPA filter, which filters and reduces the amount of airborne virus particles inside the box. The HEPA filter is effective at filtering out 99.97% of airborne particulates at 0.3 microns. The COVID-19 virus is approximately 0.125 micrometres in diameter [6]. However, it often travels in biological aerosols generated by coughing and sneezing, which range in size from 0.5-3 micrometres. Hence, such particles are sufficiently large to be filtered through a HEPA filter.

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**Fig. (1).** LIFE PLUS MINI CAPSULE S<sup>®</sup>

The novel intubating box, with the flexible drape fully extended, has a volume of approximately 99.47L. The pump generates a negative pressure with a flow rate of 170L/min, so all of the air inside the intubation box will be replaced in approximately 36 seconds.

## 2. MATERIALS AND METHODS

The LIFE PLUS MINI CAPSULE S<sup>®</sup> was analyzed for leakage of airborne particles, using a Qualitative Fit Test (QLFT) and a Quantitative Fit Test (QNFT) and was also assessed for ease of use during simulated intubation.

The QLFT was performed with the bitter-tasting Bitrex<sup>®</sup> test agent, which was aerosolized by squeezing an aerosolizing device rapidly thirty times inside the box. If the taste of Bitrex<sup>®</sup> was detected outside the box, the leak test was positive and the device failed. The QNFT was performed with the PortaCount<sup>®</sup> Pro Respirator Fit Tester 8030. This device generates aerosol particles within a respirator, and then measures the concentration of these particles outside and inside of the respirator, with the ratio of these concentrations giving a numerical value called a “fit factor”. A fit factor of at least 100 is required for half-mask respirators to pass this QNFT.

To assess the safety and practicality of our intubation box, we enlisted nineteen (consultant) anesthesiologists to test it by intubating a mannequin (SimMan<sup>®</sup> 3G) in test conditions in our simulation center. A video-laryngoscope (GlideScope<sup>®</sup> – blade 3) and a tracheal tube (internal diameter of 7.5 mm) were used for all intubations, and all anesthesiologists wore PPEs consisting of a surgical mask, a surgical gown and gloves. The anesthesiologists were all experienced at video-laryngoscopy and were oriented to the simulation environment, the mannequin, and the LIFE PLUS MINI CAPSULE S<sup>®</sup> by the same doctor. They were allowed to perform one practice intubation,

one intubation without and one with the LIFE PLUS MINI CAPSULE S<sup>®</sup>.

We determined success at first-attempt intubation, reported laryngoscopy grade (using the modified Cormack and Lehane Score (MCLS)), intubation time, and any breaches to PPEs. Intubation time was defined as the time from removing the facemask until delivery of the first breath [7]. Failed intubation was defined as failure to achieve successful tracheal intubation in a maximum of three attempts without the time limit.

## 3. RESULTS

The fit factor for the LIFE PLUS MINI CAPSULE S<sup>®</sup> during the QNFT was 195 and the taste of Bitrex<sup>®</sup> test agent was not detected during the QLFT. Hence, the test was negative and the LIFE PLUS MINI CAPSULE S<sup>®</sup> passed the test.

The nineteen consultant anesthesiologists reported a median (range) of 14.5 (4.0-30.0) years of experience and a median (range) of 8.6 (2.5-17) years in performing video-laryngoscopy. All anesthesiologists successfully intubated the mannequin at first attempt, and there were no failed intubations with or without using the LIFE PLUS MINI CAPSULE S<sup>®</sup>. The MCLS grade of laryngoscopy was reported as “1” by all anesthetists. The sample size (19 participants) was not large enough to indicate statistically significant differences in the intubation time with or without the use of the LIFE PLUS MINI CAPSULE S<sup>®</sup> but can provide us with some clinical orientation. The median (range) intubation time was 9.1 (2.0-25.0) seconds longer when the LIFE PLUS MINI CAPSULE S<sup>®</sup> was used, but all participants intubated in less than 60 seconds with or without the LIFE PLUS MINI CAPSULE S<sup>®</sup>. There were no breaches of PPEs. Results are presented in Table 1.

**Table 1. Study outcome for a mannequin (SimMan® 3G) intubation with and without LIFE PLUS MINI CAPSULE S®**

-	Mannequin (SimMan® 3G) without LIFE PLUS MINI CAPSULE S®	Mannequin (SimMan® 3G) with LIFE PLUS MINI CAPSULE S®
First-pass success	19 (100%)	19 (100%)
MCLS grade	1 - by all anesthetists	1 - by all anesthetists
Time to intubation median (range)/s	22.2 (15.9-35) seconds	31.3 (21-49.2) seconds
PPEs Breaches	0	0

#### 4. DISCUSSION

Aerosol-generating procedures, such as intubation, present a significant risk to HCPs during a viral pandemic, and the LIFE PLUS MINI CAPSULE S® represents the next generation of intubation boxes which potentially can increase the safety during AGPs.

Results obtained in our pilot study are promising and in contrast to a study recently published by Begley and colleagues [7], where they found that the use of the aerosol boxes significantly slowed intubation time when used by experienced airway specialists, also affecting first-pass success rate. Study participants in our pilot study also had the opportunity to provide subjective feedback regarding the LIFE PLUS MINI CAPSULE S®, most commonly this related to the limited space for manipulation as well as the fear that in case of difficult and/or urgent intubation, optimal conditions will not be achieved.

HEPA filter is the heart of biological safety cabinets that have also limited life span and are most effective when they are clean, unclogged, and air is able to pass freely through them. The HEPA filter duration is determined by the atmosphere and contaminant in which it is being used. In order to be able to monitor the life-span of the device, it is desirable to have an alarm system like an airflow level indicator, which would guide us when the filter needs to be replaced. The HEPA filter in the LIFE PLUS MINI CAPSULE S® is for one-time use or a 6-8 hours work use. This product is not equipped with an airflow level indicator or similar alarm system. Disposal of the filters must be in strict accordance with local, state and/or federal regulations.

The negative pressure pump that was added to the box creates a stream of air, entraining aerosolized particles generated during AGPs through the HEPA filtration system, filtering out these airborne particles, and exhausting clean, decontaminated air. Although we do not have reference fit factor values for intubation boxes, the results achieved during QNFT suggest that the box is safe, protecting clinicians from external cross-contamination during the intubation maneuver.

The present pilot study has some limitations. This is a single-center study having a small sample size and a limited number of anesthesiologists available at our institution. The Bitrex® and PortaCount® fit testers were used off-label to test something for which they were not designed and in which the volume of the test area was much larger. However, our study presents a novel method for measuring the efficiency of aerosol particle removal in such devices, which is practical and widely available.

#### CONCLUSION

Much as we strive for innovation, efficacy and safety should always be the priority when considering a novel medical device for clinical use. Although our pilot study shows promising results, further research is required to validate our results *in vivo* and in a larger sample size which will provide us with a better insight into the efficacy and applicability in everyday clinical conditions.

#### ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

#### HUMAN AND ANIMAL RIGHTS

Not applicable.

#### CONSENT FOR PUBLICATION

Not applicable.

#### AVAILABILITY OF DATA AND MATERIALS

Not applicable.

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#### CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

#### ACKNOWLEDGEMENTS

Declared none.

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