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Original Article

Design and efficacy of a novel low-cost ventilator: A feasibility study on artificial lungs

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ABSTRACT

Objectives: The emergent need for ventilators amidst the COVID-19 pandemic has catalyzed the production of innovative ventilator designs in hopes to optimize supply, manufacturing, ease of use, and cost in disaster situations. We created a novel and low-cost ventilator called QuantumAir, which uses "choked flow" to perform volume assist-control ventilation.

Material and Methods: To evaluate the efficacy and safety of QuantumAir, we tested the ventilator across eight test cases on a lung simulator, with each test case trial lasting for at least 24 breath cycles. Delivered tidal volumes, peak inspiratory pressures, and plateau pressures were measured, and linear regression models were used to assess for non-inferiority of the QuantumAir ventilator as compared to that of a Food and Drug Administration (FDA)-cleared ventilator.

Results: For each of the test cases, the standard deviation for the tidal volumes delivered during the 24 measured breaths on the QuantumAir ranged from 0.11 to 0.80 mL. The QuantumAir was found to be non-inferior to the FDA-cleared ventilator for both delivered tidal volumes and plateau pressures across all test cases and non-inferior for peak inspiratory pressures in six of the eight test cases.

Conclusion: Although future in vivo studies are still needed, our data shows promise to offer a more affordable solution to mechanical ventilation in resource-limited situations, as was experienced during the peak of the COVID-19 pandemic.

Keywords: COVID-19, Critical care, Biotechnology, Pulmonary medicine, Health-care economics and organizations, Health-care rationing

INTRODUCTION

Mechanical ventilation has become a staple of modern medical care, with the global market for mechanical ventilators growing at an annual rate of 12.5%.[1] Their high cost and complexity, however, limit their adoption in many locations around the world.[2] A full-featured device, similar to what is found in standard intensive care units, may cost more than $40,000 and requires a highly trained clinician to operate it.[3] While Nigeria has approximately one ventilator per every 1,266,440 people,[4] the United States has one ventilator per every 5,076 people, or 250 times more ventilators per capita than Nigeria.[5] Further, low-resource settings have a variety of challenges including limited oxygen delivery equipment, unreliable electricity, and few biomedical engineering technicians.[6]

The COVID-19 pandemic has further highlighted the need for adequate access to respiratory care and mechanical ventilation. Studies estimate that 3.2% of infected patients require support

from a mechanical ventilator.[7] With over 200 million people having been infected with COVID-19 to date, over 6.4 million people have likely needed mechanical ventilation due to the COVID-19 pandemic.[8]

We developed a low-cost ventilator that can provide consistent, reliable, and high-quality ventilatory support to combat global healthcare disparities. To test our hypothesis that this ventilator would be able to deliver consistent and reliable lung volumes and pressures, we then tested this ventilator on a high-fidelity breathing simulator and compared it to a ventilator currently cleared by the Food and Drug Administration (FDA).

MATERIAL AND METHODS

This study adhered to the Standards for Quality Improvement Reporting Excellence Guidelines.[9]

Ventilator development

A prototype ventilator was constructed using a fundamental principle of fluid mechanics known as "choked flow" to create a set of constant flow paths to provide volume assist-control ventilation to patients. "Choked flow" is a known method of controlling mass flow used in rocket engines and spacecraft.

Downstream conditions do not impact the flow rate for a system that is choked. Therefore, any changes to the patient's pathophysiology, including changes in lung compliance or airway resistance, will not impact the delivered tidal volume. The only factors that impact the flow rate are the upstream pressure and the diameter of an orifice plate.

The QuantumAir device includes multiple orifice plates to allow for multiple different flow rates. While a single orifice diameter can only achieve a single flow rate, two orifice diameters allow for up to three possible combinations of achieved flow rates.

With the implementation of a quantized number of flow paths, the operation of the QuantumAir device is different from a traditional ventilator. Most ventilators allow for independent control over the target tidal volume, respiratory rate, and flow rate.[10] The QuantumAir, however, links these variables. Users can adjust the target tidal volume and respiratory rate, and internal software will calculate the optimal flow rate or orifice combinations, to achieve that while maintaining an inspiratory-to-expiratory ratio (I : E ratio) as close to 1:2 as possible.

The QuantumAir ventilator provides a single mode of mandatory ventilation, volume assist-control ventilation.

In vitro study design

A test matrix was adapted from the International Organization for Standardization (ISO) to test the performance of the QuantumAir mechanical ventilator.[11] The ISO test matrix had to be adapted slightly due to the operating principle of the QuantumAir device, as the inspiratory time is not independently controllable by the operator. The ventilator settings of delivered tidal volume, ventilator frequency, and PEEP were varied along with physiologic parameters of the artificial lung including lung compliance and airway resistance to create a set of eight test cases [Supplementary Table S1].

Each test case was run for at least 24 breath cycles on an ASL 5000 Breathing Simulator artificial lung in the Simulation Center at the David Geffen School of Medicine at UCLA [Supplementary Figure S1]. Delivered tidal volumes, peak inspiratory pressures, and plateau pressures were analyzed across different test cases and aggregates of multiple test cases. Airway pressure was measured through a pressure sensor along the breathing simulator airway, and alveolar pressure was taken from a pressure sensor inside the breathing simulator lung chamber. Data were collected using internal sensors on the ASL 5000 Breathing Simulator at a rate of 512 Hertz.

We also compared the performance of the QuantumAir ventilator to the Maquet SERVO-i ventilator, which is currently cleared by the FDA and used in clinical practice. Data were collected using the Maquet SERVO-i ventilator for a set of eight similar test cases [Supplementary Table S2].

Data analysis

Summary statistics were performed to obtain the mean and standard deviations for each of the eight test cases on both ventilators. To assess for non-inferiority, linear regression models were used to estimate the 95% confidence interval of the relative difference and the 95% confidence interval of the absolute difference between the QuantumAir and Maquet SERVO-i for each test case. Global differences across all test cases were assessed using the same models using Huber-White standard errors for clustering by test case.[12] A 5% relative difference was used as our non-inferiority threshold. In instances where the upper bound of the 95% confidence interval of the difference was <5%, non-inferiority was declared. This one-sided evaluation of non-inferiority from a 95% confidence interval utilized an alpha level of 0.025.

RESULTS

Waveforms plotting pressure versus time, flow versus time, and volume versus time for a representative set of breathing cycles for test case 1 are shown in [Figure 1] for the QuantumAir ventilator.

The delivered tidal volumes for test cases 1 through 8 for both the QuantumAir and Maquet SERVO-i ventilators are shown in [Table 1]. For each of these test cases, the standard deviation for the tidal volumes delivered during the 24

measured breaths for the QuantumAir ranged from 0.11 to 0.80 mL. This was similar to the standard deviation for the tidal volumes delivered by the Maquet SERVO-i ventilator, which ranged from 0.11 to 1.41 mL.

The measured plateau and peak inspiratory pressures for test cases 1 through 8 for both the QuantumAir and Maquet SERVO-i ventilators are shown in [Tables 2 and 3], respectively. The standard deviation for plateau pressures across the 24 breath cycles with the QuantumAir ventilator ranged from 0.04 to 0.15 cm of water (cm H_2O), which was comparable to the Maquet SERVO-i ventilator, which had a standard deviation ranging from 0.01 to 0.16 cm H_2O. The standard deviation for peak inspiratory pressures for the QuantumAir ventilator ranged from a minimum of 0.04 cm H_2O to a maximum of 0.15 cm H_2O; this was similar to the Maquet SERVO-i ventilator, which had a maximum standard deviation for peak inspiratory pressure of 0.14 cm H_2O.

Non-inferiority plots across all test cases comparing the QuantumAir to the Maquet SERVO-i ventilator are shown in [Figure 2]; non-inferiority plots across individual test cases are shown in [Supplementary Figure S2]. The QuantumAir was found to be non-inferior for both delivered tidal volumes and plateau pressures across all test cases. Compared to the Maquet SERVO-i ventilator, there was an absolute difference in delivered tidal volumes ranging from 0.4 to 6.8 mL and a relative difference ranging from 0.09% to 2.35% [Supplementary Table S3]. For plateau pressures, the absolute difference between the QuantumAir and the Maquet SERVO-i ventilator ranged from 0.0 to 1.3 cm H_2O, with a relative difference ranging from 0.00%

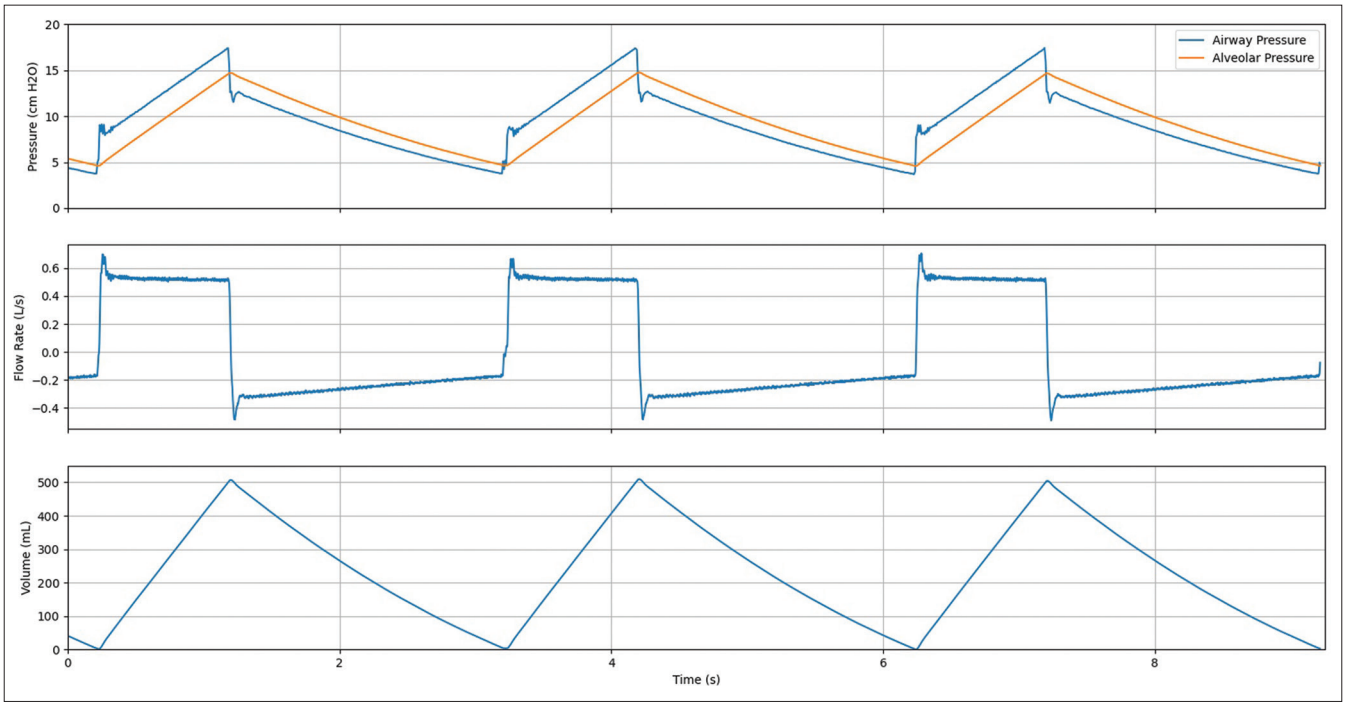

Figure 1: Waveforms of pressure, flow rate, and delivered volume over time for test case 1 on the QuantumAir ventilator.

Table 1: Set and delivered tidal volumes for QuantumAir (QA) and Maquet SERVO-i (Maquet) across individual test cases.

Test No.	Set tidal volume in mL	Mean delivered tidal volume in mL (SD) – QA	Mean delivered tidal volume in mL (SD) – Maquet	Absolute difference between delivered tidal volumes (95% CI)
1	500	505.75±0.80	498.93±0.11	6.8 (6.5, 7.2)
2	500	477.82±0.39	477.37±0.24	0.4 (0.3, 0.6)
3	500	467.30±0.56	462.95±0.26	4.4 (4.1, 4.6)
4	500	445.74±0.34	440.77±1.41	4.9 (4.4, 5.4)
5	300	272.66±0.43	271.25±0.49	1.4 (1.2, 1.6)
6	300	251.94±0.11	246.16±0.22	5.8 (5.7, 5.9)
7	300	224.86±0.28	222.82±0.15	2.1 (1.9, 2.2)
8	300	226.87±0.26	224.62±0.37	2.3 (2.1, 2.4)

Table 2: Plateau pressures for QuantumAir (QA) and Maquet SERVO-i (Maquet) across individual test cases.

Test No.	Plateau pressure in cm H_2O (SD) – QA	Plateau pressure in cm H_2O (SD) – Maquet	Absolute difference between Plateau pressures (95% CI)
1	14.73±0.04	15.33±0.01	0.60 (0.58, 0.61)
2	19.41±0.12	20.04±0.07	0.63 (0.61, 0.65)
3	27.55±0.06	28.53±0.03	0.99 (0.96, 1.01)
4	32.63±0.04	32.54±0.16	0.09 (0.03, 0.15)
5	18.63±0.05	18.97±0.04	0.35 (0.32, 0.38)
6	23.46±0.15	22.72±0.01	0.74 (0.68, 0.80)
7	31.83±0.08	33.09±0.02	1.26 (1.23, 1.29)
8	28.30±0.06	28.30±0.07	0.00 (-0.05, 0.06)

Table 3: Peak inspiratory pressures for QuantumAir (QA) and Maquet SERVO-i (Maquet) across individual test cases.

Test No.	Peak inspiratory pressure in cm H_2O (SD) – QA	Peak inspiratory pressure in cm H_2O (SD) – Maquet	Absolute difference between peak inspiratory pressures (95% CI)
1	17.42±0.04	17.90±0.04	0.48 (0.45, 0.50)
2	25.26±0.13	29.69±0.07	4.43 (4.40, 4.46)
3	29.79±0.07	30.60±0.04	0.81 (0.78, 0.84)
4	41.56±0.07	41.15±0.14	0.40 (0.35, 0.46)
5	23.95±0.05	24.24±0.06	0.30 (0.26, 0.33)
6	33.63±0.15	35.95±0.03	2.33 (2.26, 2.39)
7	43.22±0.08	44.54±0.05	1.31 (1.27, 1.35)
8	39.80±0.09	39.83±0.11	0.04 (–0.04, 0.11)

to 3.91% [Supplementary Table S4]. For peak inspiratory pressures, the QuantumAir was non-inferior to the Maquet SERVO-i ventilator for test cases 1, 3, 4, 5, 7, and 8, with a relative difference of 0.08–2.96%. It was inferior to the Maquet SERVO-i ventilator, however, for test cases 2 and 6 with a relative difference of 14.92% and 6.45%, respectively. Peak inspiratory pressures were also inferior when the test cases were combined into a single group. The absolute difference between the ventilators for peak inspiratory pressures ranged from 0.04 to 4.43 cm H_2O I : E.

DISCUSSION

In this feasibility study on artificial lungs, we found that the performance of our novel and low-cost QuantumAir ventilator matches that of a currently FDA-cleared mechanical ventilator. Findings are based on eight test cases, which varied both ventilator settings and simulated respiratory mechanics over 24 breath cycles. This research is particularly important as the world battles the COVID-19 pandemic. The use of high-quality and low-cost mechanical ventilators has the potential to expand access to care for millions around the world.

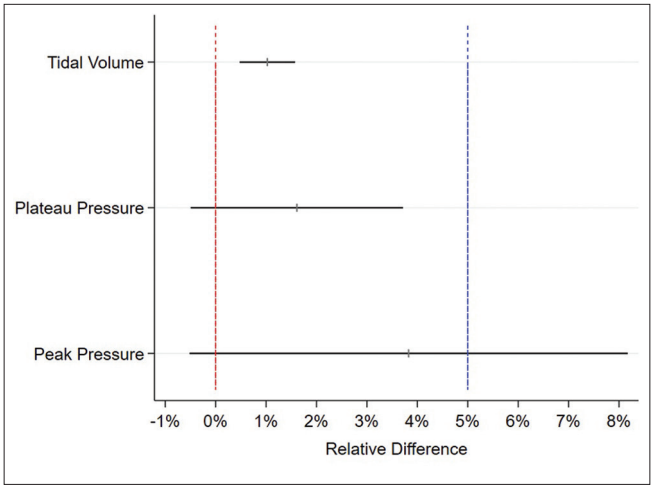

Figure 2: Relative difference between the QuantumAir and Maquet SERVO-i-ventilator across all test cases. Horizontal lines represent the 95% confidence interval for each value. Using a 5% non-inferiority threshold, confidence intervals that have an upper bound less than 5% (dashed blue line) indicate non-inferiority.

Our ventilator was able to deliver highly consistent tidal volumes with negligible breath-to-breath variation, as evidenced by a standard deviation of <1 mL or <0.01% of the mean tidal volume value, for all delivered breaths on the QuantumAir ventilator over the 24 breath cycles. There was also minimal breath-to-breath variation for both plateau and peak inspiratory pressures, with a maximum standard deviation for both plateau and peak inspiratory pressures of 0.15 cm H_2O for all delivered breaths. The consistency of these delivered breaths by the QuantumAir ventilator mirrored that of the Maquet SERVO-i ventilator, which also had a tidal volume standard deviation of <1 mL along with a plateau and peak inspiratory pressure standard variation of ≤0.16 cm H_2O over all of the test case breath cycles.

For the non-inferiority comparisons, we found that the QuantumAir ventilator was non-inferior to the Maquet SERVO-i ventilator in terms of delivered tidal volumes across all test cases. The maximum difference in the volumes delivered between the two ventilators was <7 mL. Importantly, this included non-inferiority in specific test cases that modeled high lung compliance and airway resistance set points to simulate extreme physiologic conditions. The QuantumAir ventilator was also non-inferior in terms of plateau pressures across all test cases and non-inferior in terms of peak inspiratory pressures in six of the eight test cases.

The scenarios where the non-inferiority threshold was not met involved two test cases using a set respiratory rate of 12 breaths/min. In these cases, the QuantumAir produced significantly lower peak inspiratory pressures

than the Maquet SERVO-i ventilator. This is likely due to the differences in ventilator design and operation, as the Maquet SERVO-i ventilator used an I : E ratio of 1:4 for these cases, while the QuantumAir targeted a lower I : E ratio of 1:2. Because this lower I : E ratio led to a longer total inspiratory time, it resulted in lower peak inspiratory pressures with the QuantumAir ventilator as compared to the Maquet SERVO-i ventilator. While these findings are thus likely attributable to principles of operation and programmed ventilator settings, it could nonetheless have advantageous implications in clinical settings where clinicians wish to minimize high airway pressures.

In light of the COVID-19 pandemic's dramatic toll on health-care resources globally, there has been a large demand for low cost and rapidly available medical supplies. Of these resources, ventilators are in particularly high demand. Numerous ventilators have been developed, including the Portsmouth,[13] the E-Vent Project of MIT,[14] the VentilAid by Urbicum,[15] the Virgin Orbit Resuscitator,[16] and the Ventilator Intervention Technology accessible locally by the National Aeronautics and Space Administration.[17] Some of these have been granted Emergency Use Authorization of Medical Devices by the FDA.[18] Most emergency use ventilators focus on controlling gas flow through one of two mechanisms: through the collection of a known volume of gas which is then delivered to the patient (i.e., "Ambu bag design") or through a gas supply taken from a compression device and delivered at the time of a patient breath through a series of circuits and valves developed to interrupt gas flow.[19] Many of these devices are thus meant to function more as resuscitators rather than long-term ventilators, which often require careful patient monitoring and fine adjustments in ventilator settings to optimize patients from a respiratory standpoint. In contrast, the QuantumAir ventilator can be used for a more extended period of time and offers numerous flow rates to accommodate the patient. In health care, value is defined as the amount of care provided per unit cost. We believe that the QuantumAir ventilator provides substantial health-care value in that it can deliver a high-fidelity level of care at <10% the price of currently FDA-cleared mechanical ventilators.[20]

Limitations to this study include generalizability, given the limited number of cases tested and the simulation nature of the data. Although we modeled our test matrix after the recommended specification from the FDA for Emergency Use Authorization, the evaluated test matrix is not exhaustive of all possible combinations of patient and ventilator scenarios in clinical practice. In addition, the controlled environment of the Simulation Center limits generalizability to patients. Finally, as non-inferiority guidelines for tidal volume and pressure have not been previously defined in the literature, our non-inferiority cutoff of 5% was based on author consensus. While this led to a degree of subjectivity in the interpretation of our results, we developed these non-inferiority cutoffs *a priori* and after discussion with multiple intensivists to minimize bias.

CONCLUSION

We found that our ventilator performs comparably to a standard FDA-cleared ventilator in producing consistent and reliable tidal volumes and pressures during multiple test cases using a high-fidelity breathing simulator. This *in vitro* study lays the groundwork for a future *in vivo* clinical study. We believe that the simplicity of our device's design makes it ideal for scenarios where constrained resources limit access to medical equipment.

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Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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SUPPLEMENT TABLES

Table S1: Test matrix showing QuantumAir device settings and simulated lung parameters.

Test No.	QuantumAir Device Settings					Test lung parameters	
	Volume (mL)	Ventilator frequency (breaths/min)	PEEP (cmH_2O)	I : E ratio	Inspiratory time(s)	Compliance (mL/cmH_2O)	Resistance ($cmH_2O/L/s$)
1	500	20	5	1:2.28	0.91	50	5
2	500	12	10	1:2.16	1.58	50	20
3	500	20	5	1:2.28	0.91	20	5
4	500	20	10	1:2.28	0.91	20	20
5	300	20	5	1:2.16	0.95	20	20
6	300	12	10	1:3.04	1.24	20	50
7	300	20	10	1:2.16	0.95	10	50
8	300	20	5	1:2.16	0.95	10	50

Table S2: Test matrix showing Maquet SERVO-i device settings and simulated lung parameters.

Test No.	Maquet SERVO-i device settings					Test lung parameters	
	Volume (mL)	Ventilator frequency (breaths/min)	PEEP (cmH_2O)	I : E Ratio	Inspiratory time(s)	Compliance (mL/cmH_2O)	Resistance ($cmH_2O/L/s$)
1	500	20	5	1:2	1.0	50	5
2	500	12	10	1:4	1.0	50	20
3	500	20	5	1:2	1.0	20	5
4	500	20	10	1:2	1.0	20	20
5	300	20	5	1:2	1.0	20	20
6	300	12	10	1:4	1.0	20	50
7	300	20	10	1:2	1.0	10	50
8	300	20	5	1:2	1.0	10	50

Table S3: Relative difference for delivered tidal volumes between the QuantumAir and Maquet SERVO-i ventilator across individual test cases.

Test No.	Mean delivered tidal volume in mL (SD) – QA	Mean delivered tidal volume in mL (SD) – Maquet	Relative difference between delivered tidal volumes (95% CI)
1	505.75	498.93	1.37% (1.30%, 1.44%)
2	477.82	477.37	0.09% (0.06%, 0.13%)
3	467.30	462.95	0.94% (0.89%, 0.99%)
4	445.74	440.77	1.13% (1.00%, 1.23%)
5	272.66	271.25	0.52% (0.44%, 0.59%)
6	251.94	246.16	2.35% (2.32%, 2.40%)
7	224.86	222.82	0.92% (0.85%, 0.99%)
8	226.87	224.62	1.00% (0.93%, 1.07%)

Table S4: Relative difference for plateau pressures between the QuantumAir and Maquet SERVO-i ventilator across individual test cases.

Test No.	Plateau pressure in cm H_2O (SD) – QA	Plateau pressure in cm H_2O (SD) – Maquet	Relative difference between plateau pressures (95% CI)
1	14.73	15.33	3.91% (3.78%, 3.98%)
2	19.41	20.04	3.14% (3.04%, 3.24%)
3	27.55	28.53	3.43% (3.36%, 3.54%)
4	32.63	32.54	0.28% (0.09%, 0.46%)
5	18.63	18.97	1.79% (1.69%, 2.00%)
6	23.46	22.72	3.26% (2.99%, 3.52%)
7	31.83	33.09	3.81% (3.72%, 3.90%)
8	28.30	28.30	0.00% (–0.18%, 0.21%)

Table S5: Relative difference for peak inspiratory pressures between the QuantumAir and Maquet SERVO-i ventilator across individual test cases.

Test No.	Peak inspiratory pressure in cm H_2O (SD) – QA	Peak inspiratory pressure in cm H_2O (SD) – Maquet	Relative difference between peak inspiratory pressures (95% CI)
1	17.42	17.90	2.68% (2.51%, 2.79%)
2	25.26	29.69	14.92% (14.82%, 15.02%)
3	29.79	30.60	2.65% (2.55%, 2.75%)
4	41.56	41.15	1.00% (0.85%, 1.12%)
5	23.95	24.24	1.20% (1.07%, 1.36%)
6	33.63	35.95	6.45% (6.29%, 6.65%)
7	43.22	44.54	2.96% (2.85%, 3.03%)
8	39.80	39.83	0.08% (–0.09%, 0.28%)

SUPPLEMENT FIGURES

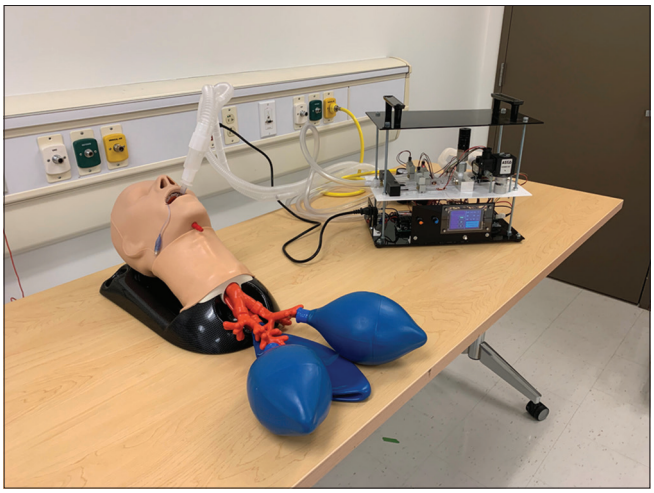

Figure S1: QuantumAir ventilator in the Simulation Center at the David Geffen School of Medicine at UCLA.

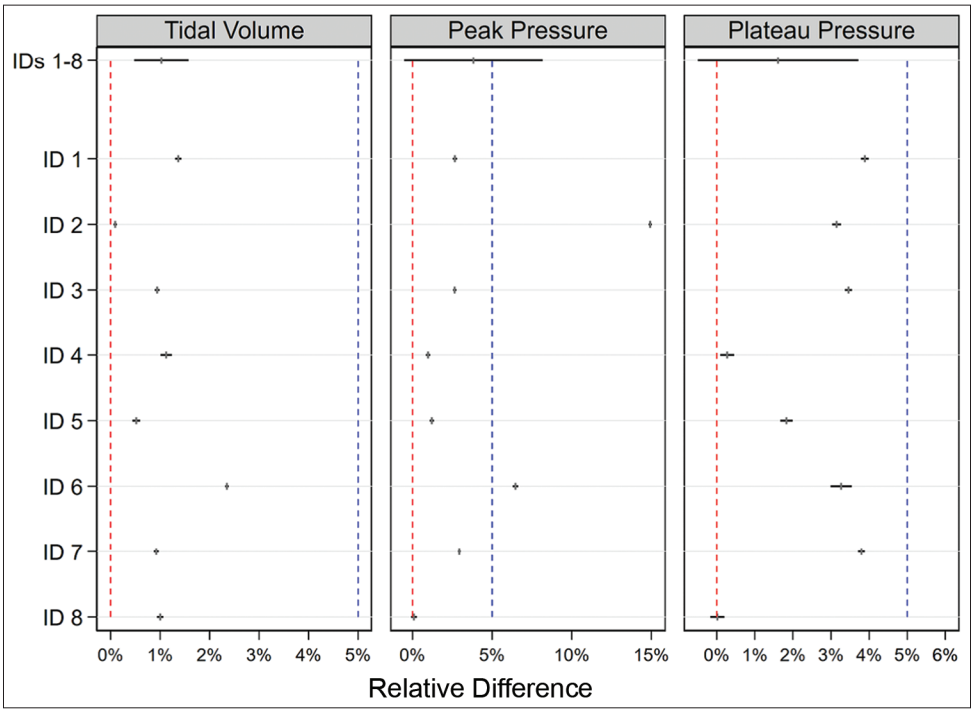

Figure S2: Relative difference between the Relative Maquet SERVO-i ventilator across individual test cases. Horizontal lines represent the 95% confidence interval for each value. Using a 5% non-inferiority threshold, confidence intervals that have an upper bound <5% (dashed blue line) indicate non-inferiority.