



Miniature Transport Respirator Performance Evaluation for Ventilatory Support

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Abstract. In the face of the coronavirus pandemic (COVID-19), in hospital and emergency units, there is low availability of mechanical respirator for patients in need of this support, greatly improving the survival rate. In these situations, there is a need for simpler equipment, easy access, low cost, and fast manufacturing. In this study, a 3D prototype transport respirator was developed using as a model the Takaoka 600 Mini Respirator, national technology from the 1950s. The influence of adjustable parameters of the respirator was evaluated to understand it is functioning: maximum and minimum lung pressure; respirator intake pressure; respiratory rate; inspiratory and expiratory time according to the sensitivity of the mini respirator; and pressure and flow of O₂ line intake. The increase in sensitivity led to an increase in maximum and minimum pulmonary pressure, decreased inspiratory and expiratory time, with margins of 1/1, 1/2, 1/3 inspiratory/expiratory time ratio (I/E ratio). The intake flow of O₂ varied proportionally with the pressure of air intake into the respirator, with its increase leading to an increase in respiratory rate, without major influences on lung pressure and the I/E ratio. The O₂ line intake pressure without major influences on lung pressure, showing and I/E ratio >1 in values below 3.5 kPa x 100. In conclusion, it was possible to obtain a pulmonary ventilator-dependent only on positive O₂ flow, compact and effective for patient transport, and in cases of emergencies with control of maximum pressure and respiratory rate offered to the patient. Among the parameters evaluated for this respirator, an line pressure of O₂ from 3.5 kPa x 100, sensitivity between 3 and 5, a flow of 5 to 15 L/min is recommended.

Keywords. *Transport respirator, Ventilatory support, Takaoka 600, COVID-19.*

Introduction. Mechanical ventilatory support is of great importance in the survival of patients admitted to emergency hospital and intensive care units (ICUs). In face of today's outbreak of the disease caused by the new coronavirus (COVID-19) in hospital and emergency units (1,2), there is low availability of mechanical respirators for patients in need of this support (3). In numbers, confirmed by WHO, COVID-19 generated 7,805,148 cases, with 431,192 deaths in 216 countries (WHO, data from 14 July 2020, 21:00 GMT-3) (4), not counting a large number of underreported cases and uncertainties (5). It is estimated that approximately 5% of patients with COVID-19 end up requiring ventilatory support (3).

Currently, the respirators available in ICUs are developed with large management protocols and work in different modalities, either for non-invasive or invasive type ventilation (1). However, in emergencies, there is a need for simpler equipment, of easy access, with low cost and fast manufacturing.

Based on this theme, a mechanical transport respirator was developed. The development was based on the Takaoka 600 Mini Respirator, a national pneumatic respirator developed in the 1950s by Dr. Kentaro Takaoka, an anesthesiologist (6). The differential of this equipment is in its dimensions (fitting in the palm of one hand), it does not depend on electrical energy, only on a line of oxygen (6,7), which is very important in emergencies.

The cycling of this respirator occurs by pressure (controlled pressure, PC) with CMV ventilation mode (controlled mandatory ventilation), i.e., breathing is generated and controlled by the respirator (control of respiratory rate, inspiratory time, I/E ratio, maximum inspiratory pressure) (7,8).

Due to the large scale and decentralized production of this respirator, the Dante Pazzanese Institute of Cardiology opted to work with 3D prototyping in its development. To yield, once the functionality of the prototype was proven, the designs to be printed in 3D resin or polymeric filament printers.

Materials and methods. 3D Printing. The Takaoka 600 mini respirator was reverse engineered, prototyping the parts in a 3D printer (CONNEX 350, Objet, Israel) with resins (FullCure720, Objet, Germany) as the main material and (FullCure705, Object, Germany) as the support material.

The mini respirator (**Figure 1**) requires only the oxygen line provided to the patient for its operation. In general, cycling is ensured by a magnetic valve driven by the internal pressure of the oxygen gas. The valve acts under two positions determining the inspiratory phase (air entering the lungs) and the expiratory phase (air leaving the lungs).



Figure 1. Reverse Engineering of the prototyped Takaoka 600 Mini-Respirator per 3D Printer.

The sensitivity of the device is adjusted by the button at the top of the device, acting on the setting of the maximum inspiratory pressure.

Operational Evaluation. A test bench (**Figure 2**) was mounted with pressure sensors, a manometer, and a standard O₂ line flow meter and expiratory phase regulator (FE Regulator). The collected data was recorded using an application developed in LabView® (National Instruments, Austin, USA) (**Figure 3**).

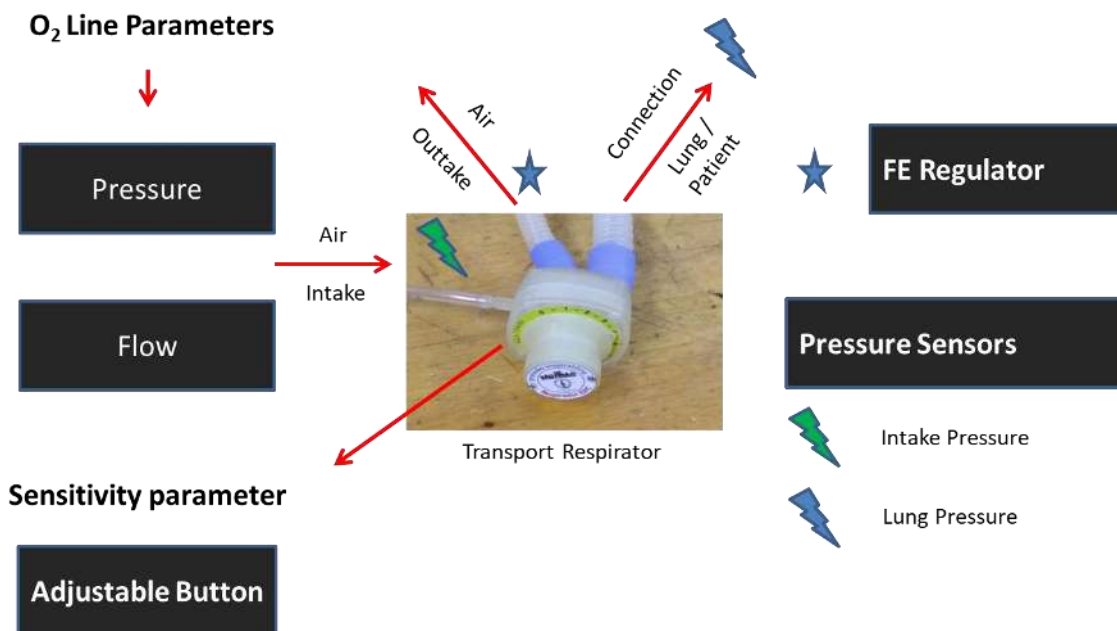


Figure 2. Test Bench Elements for the Performance Evaluation of the Mini-Respirator

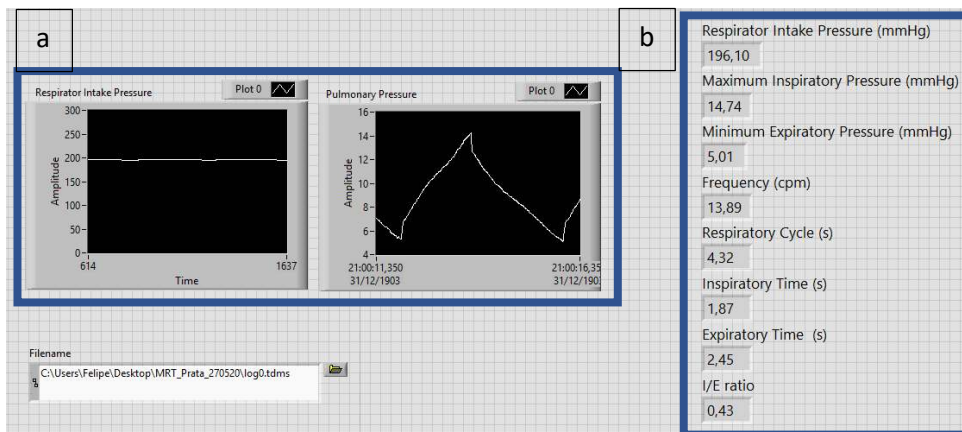


Figure 3. Image of the Mini-Respirator Functional Signal Capture System

The data presented by the developed application demonstrate, the amplitude of the respirator intake pressure and pulmonary pressure for a respiratory cycle (period) for the corresponding time (**Figure 3a**), along with data on the respirator intake pressure, maximum inspiratory pressure, minimum expiratory pressure, frequency and respiratory cycle, inspiratory time and expiratory time, and the I/E ratio (inspiratory time / expiratory time) (**Figure 3b**).

The FE regulator (**Figure 4**) is represented by a resistance at the end of the air outlet from the lungs at expiration. In the evaluation test, this resistance was modeled as the adjustment of the height of the water column (cmH₂O) inside a bottle. Due to infection problems related to the COVID-19 pandemic, a HEPA (High-Efficiency Particulate Air) filter was added to the air outlet of this regulator for particle retention.



Figure 4. Expiratory Phase Regulator (FE Regulator).

The TAKAOKA 600 mini respirator has a maximum inspiratory pressure of 70 to 80 cmH₂O, with frequency control performed by the O₂ intake flow (between 0 and 15 l/min). The influence of the adjustable parameters of the respirator was evaluated to understand its operation: sensitivity, flow, and O₂ line intake pressure (control parameter used when the flow meter is not available (7)).

Maximum and minimum pulmonary pressure, respiratory inlet pressure, respiratory rate, inspiratory and expiratory times were evaluated according to the sensitivity of the mini respirator, pressure, and O₂ line intake flow.

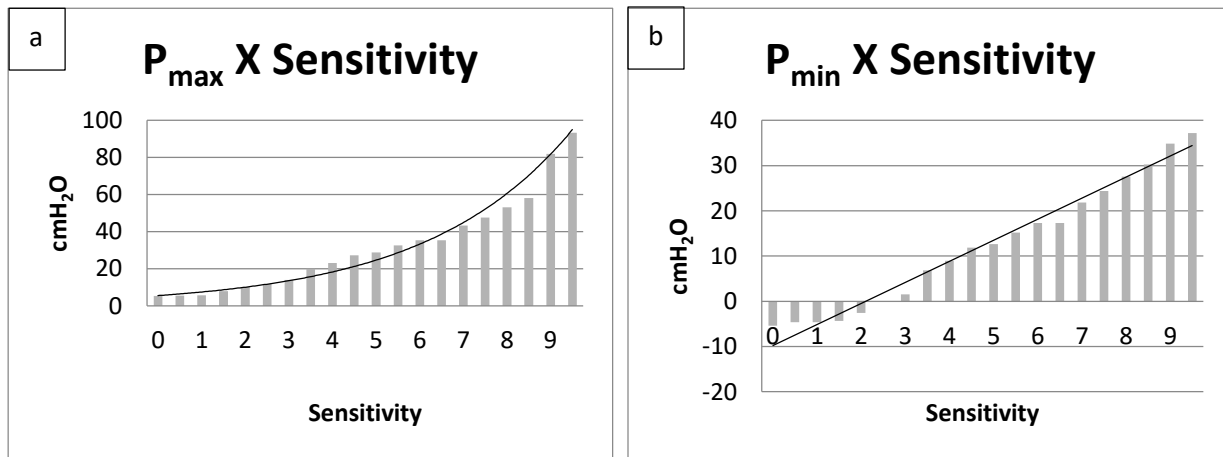
The lung model used in the test was an expandable pouch-shaped reservoir representing the lung of a 1L adult individual (190#6006832, Siemens, Germany) (9).

To evaluate the influence of sensitivity adjustment on the behavior of the respirator, a pressure of 5 kPa x 100 was maintained on the O₂ intake and a flow of 12 L/min, maintaining the EF regulator at 2 cmH₂O, varying the sensitivity from 0 to 10.

To evaluate the influence of the O₂ intake flow on the behavior of the respirator the O₂ intake was maintained at a pressure of 5 kPa x 100, sensitivity at 3.5, FE regulator at 2 cmH₂O, varying the flow from 5 to 15 L/min.

To evaluate the influence of the O₂ inlet pressure, the flow rate of 12 L/min, sensitivity at 3.5, with an FE regulator at 2 cm H₂O, varying the inlet pressure from 3 to 7 kPa x 100, was maintained at the O₂ intake.

Results. Influence of Respirator Sensitivity. There was no cycling of the respirator not valued 10 of the sensitivity scale, so this situation was removed from the analyses below. Maximum and minimum lung pressure increased with increased sensitivity (**Figure 5a,b**). For sensitivity values lower than 3, the minimum pressure was negative (**Figure 5b**). Sensitivity affects both inspiratory time (T_{insp}) and expiratory time (T_{exp}), inversely proportional in the sensitivity adjustment range between 0 and 8.5, with an atypical value of the curve at a sensitivity of 1.5, increasing again in sensitivity of 9 and 9.5 (**Figure 5c,d**). The inspiratory time/expiratory time (R I/E) ratio was inverted in the sensitivity from 0 to 1.5, 8 (small difference, T_{insp} = 0.54 and T_{exp} = 0.57), 9 and 9.5 (**Figure 5e**).



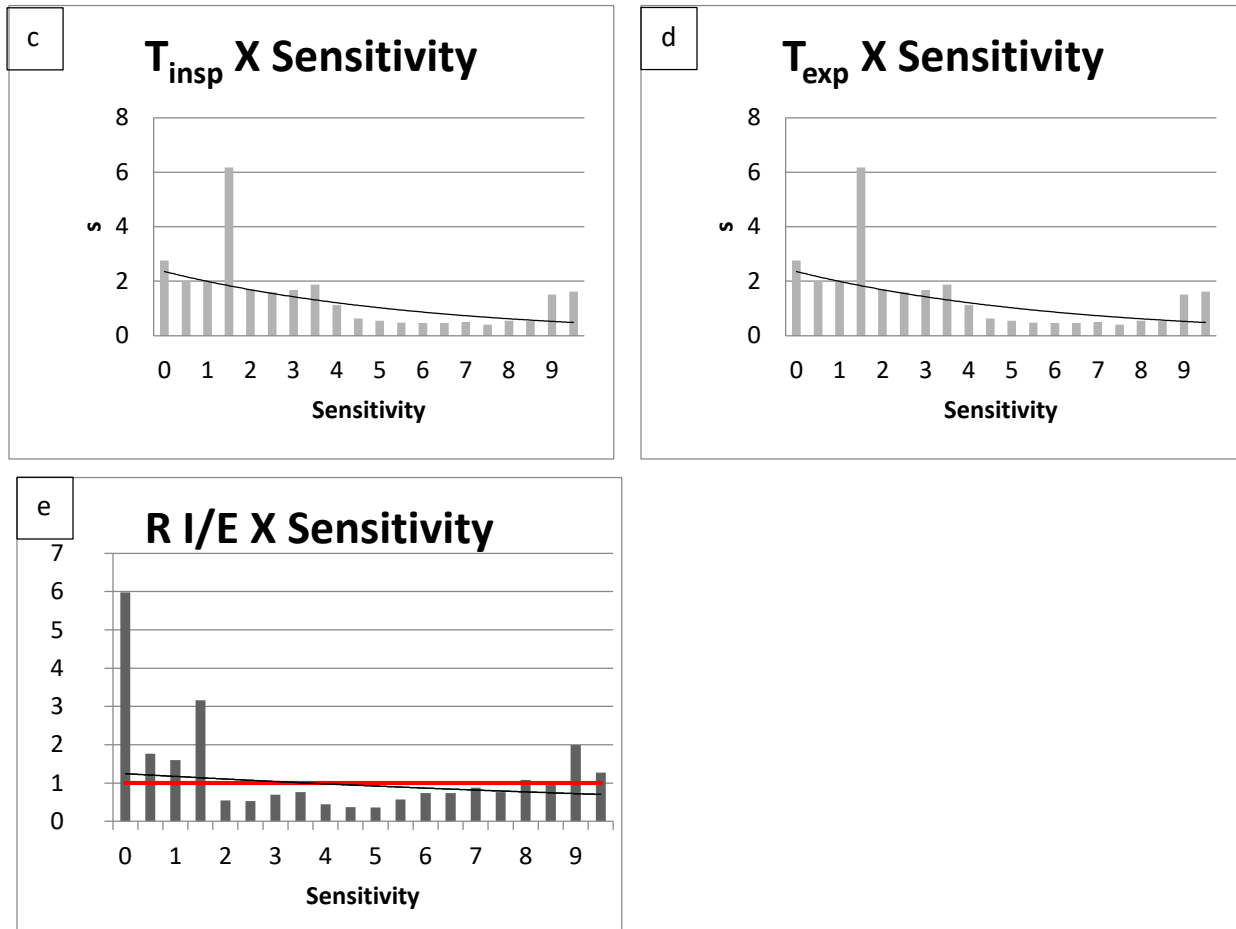


Figure 5. Influence of Respiratory Sensitivity on Maximum (P_{max}) and Minimum (P_{min}) Lung Pressures, Inspiratory (T_{insp}) and Expiratory (T_{exp}) Times, and T_{insp}/T_{exp} Ratio (R I/E)

Influence of the O₂ intake flow. The O₂ inlet flow has a low influence on maximum and minimum pressure generated in the lung. For the flow ranging from 5 to 15 L/min, the maximum pressure varied from 19.43 to 19.69 cmH₂O and minimum pressure from 5.57 to 7.41 cmH₂O (Figure 6a,b). With the increase in flow, there is a proportional decrease in T_{insp} and T_{exp} (Figure 6c,d), leading to an increased respiratory rate (Supplementary Figure 1). The flow does not interfere in the R I/E because all values are below 1 (Figure 6e). According to Figure 6f, the flow is proportional to the intake pressure of O₂ on the respirator ($P_{respirator\ intake}$).

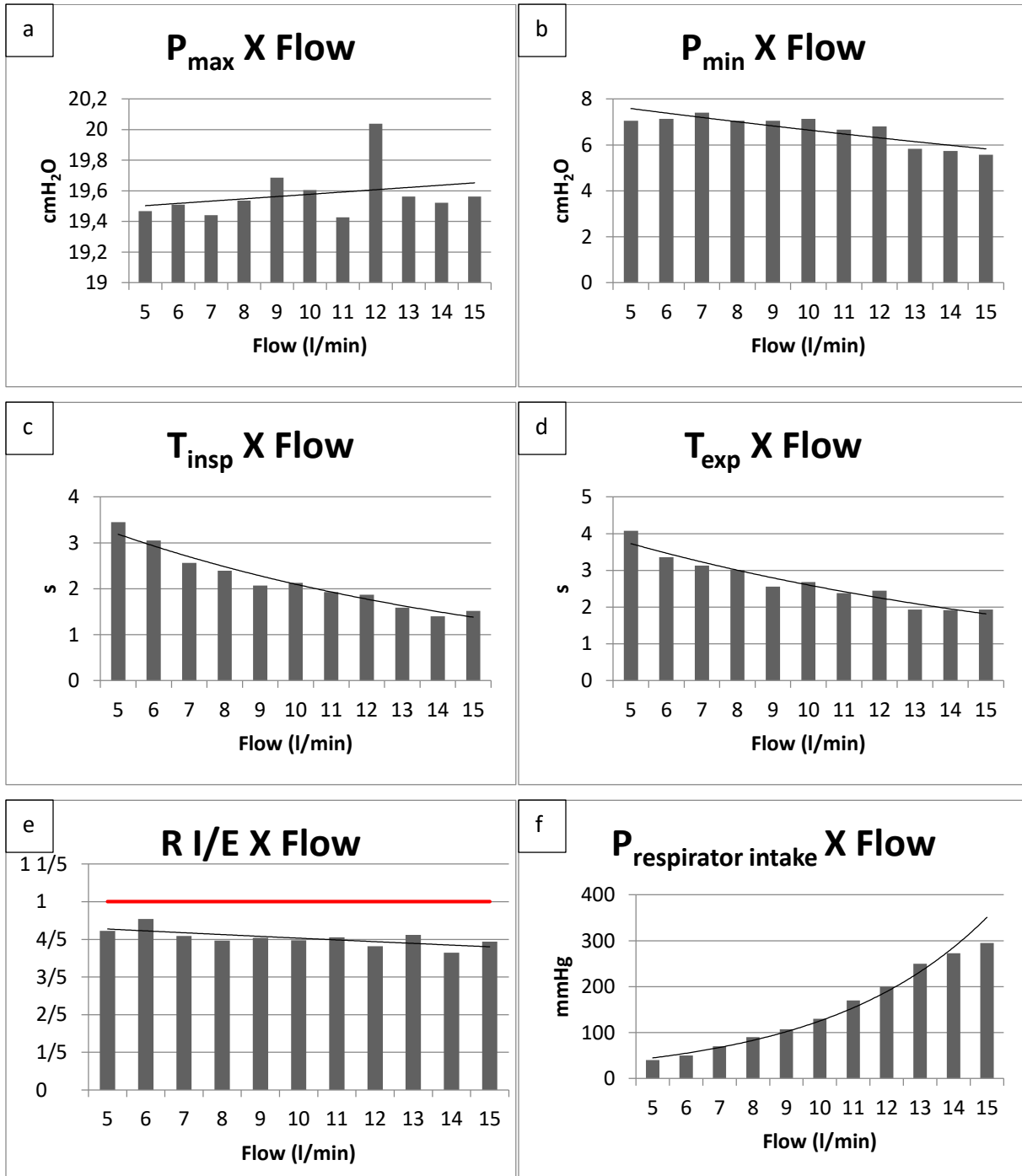
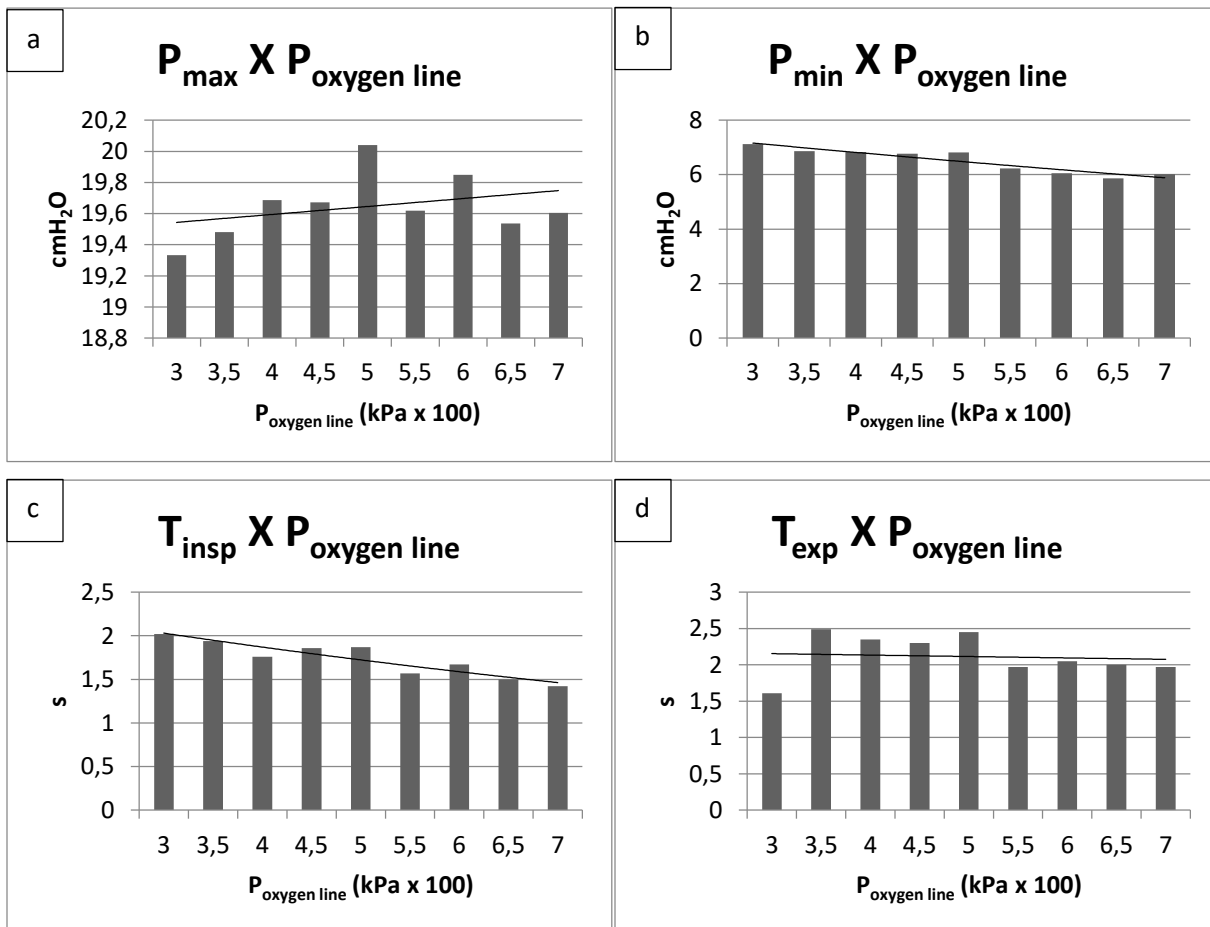


Figure 6. Influence of O₂ Intake Flow on Maximum (P_{max}) and Minimum (P_{min}) Lung Pressures, Inspiratory (T_{insp}) and Expiratory (T_{exp}) Times, T_{insp}/T_{exp} Ratio (R I/E) and Respiratory Intake Pressure ($P_{respirator\ intake}$).

Influence of the O₂ line intake pressure. The O₂ line intake pressure ($P_{\text{oxygen line}}$), as well as the flow (Figure 6 a,b) has little effect on the maximum and minimum pressure generated in the lung. For $P_{\text{oxygen line}}$ ranging from 3 to 7 kPa x 100, the maximum pressure varied from 20.04 to 19.33 cmH₂O and minimum pressure from 7.12 to 5.86 cmH₂O (Figure 7a,b). The T_{insp} decreased slightly with the increase in intake pressure (Figure 7c). At the 3 kPa x 100 inlet pressure, was lower than in other pressures, demonstrating an atypical value for the data. From 3.5 kPa x 100 there is a reduction of T_{exp} , stabilizing at pressures from 5.5 to 7 kPa x 100 (Figure 7d). The R I/E was inverted in the 3 kPa x 100 pressure, and in the others, the values were lower than 1 (Figure 7e). $P_{\text{oxygen line}}$ is proportional to the inlet pressure on the respirator ($P_{\text{respirator intake}}$) (Figure 7f).



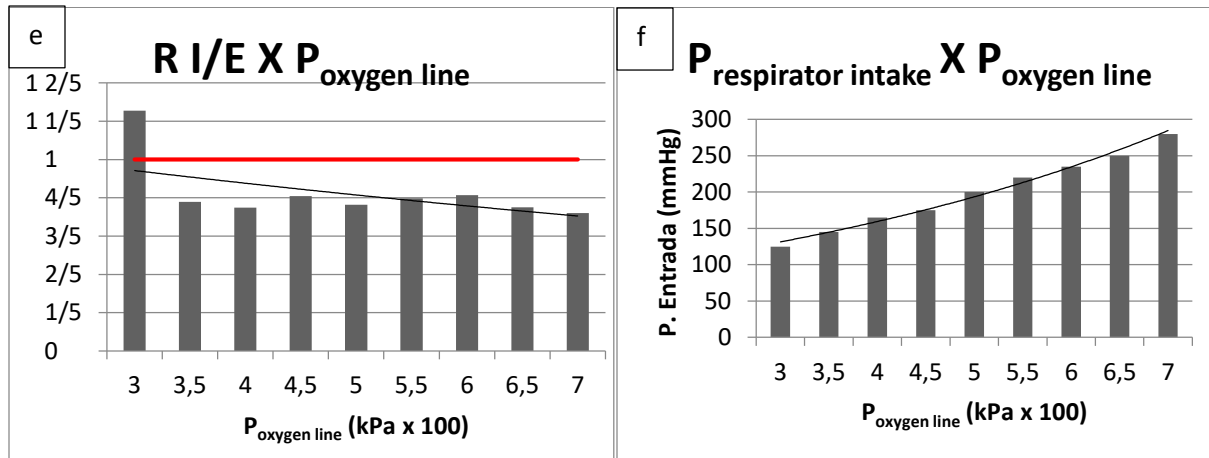


Figure 7. Influence of O₂ Line Intake Pressure (P_{oxygen line}) on Maximum (P_{max}) and Minimum (P_{min}) Lung Pressures, Inspiratory (T_{insp}) and Expiratory (T_{exp}) Times, T_{insp}/ T_{exp} Ratio (R I/E) and Respiratory Intake Pressure (P_{respirator intake}).

Discussion. The positive end-expiratory pressure (PEEP) (represented here by P_{min}) needs to be adjusted correctly for different pathologies. A minimum PEEP of 5 cmH₂O is generally recommended for an adult patient to avoid atelectasis. High PEEP values may be required in patients with COVID-19, values from 10 to 20 cmH₂O, for alveolar recruitment purposes (8).

Here the minimum pulmonary pressure values were only lower than 5 cmH₂O for sensitivities adjusted from 0 to 3, and up to 2.5 these values were negative (under the analyzed conditions) (Figure 5b). It is expected that PEEP can be altered by the FE (Expiratory Phase) regulator by the size of the water column. In the analyses, the water column remained constant at 2 cm. The influence of the FE regulator on the functional state of the respirator should be evaluated.

Respiratory rate is an important parameter in mechanical ventilation, being controlled by the flow (F) and by the intake pressure (P_{oxygen line}) O₂ supplied to the developed respirator (8). According to RDC no. 386, dated May 15, 2020 (10), respiratory rate values should be within the range of 8 to 40 cycles per minute (cpm). A frequency below 8 cpm was demonstrated in two conditions: with P_{oxygen line} of 5 kPa x 100, Flow of 12 L/min and sensitivity of 1.5, and the other with P_{oxygen line} of 5 kPa x 100, Flow of 5 L/min and sensitivity of 3.5, presenting frequency values of 7.39 and 7.96 cpm, respectively. A frequency above 40 cpm was observed in sensitivities of 5.5 to 8.5, maintaining the P_{oxygen line} of 5 kPa x 100 and Flow of 12 L/min (Supplementary Figure 1).

The I/E ratio (R I/E) in values of 1/2 and 1/3 are in general the most used, being R I/E > 1 unwanted in most procedures, associated with the development of dynamic hyperinflation (11). Values of R I/E > 1 were observed for sensitivities (Sens) adjusted between 0 and 1.5, 8 and 9 to 9.5 (P_{oxygen line} - 5 kPa x 100, Flow - of 12 L/min) and for admission pressure of 3 kPa x 100

(Flow of 12 L/min, Sens - 3.5) (Figure 5-e). The prototype generally demonstrated the operation with the R I/E at values close to 1 (**Figure 5e; 6e; 7e**), and in some cases with values at 1/2 ($P_{\text{oxygen line}} = 5 \text{ kPa} \times 100$, Flow -12 L/min, Sens - 2 and 2.5) (**Figure 5e**) and 1/3 ($P_{\text{oxygen line}} = 5 \text{ kPa} \times 100$, Flow -12 L/min, Sens - 4 to 5) (**Figure 5e**). Thus, it can work in I/E ratios different from the 1/1 ratio presented by the Takaoka 600 (7), mini respirator, which was the model for making this respirator under study.

Maximum pressure can be controlled by varying the sensitivity of the respirator. Values greater than 50 cmH₂O may lead to the development of traumas such as pneumothorax and pneumomediastinum (12). These increased values were observed for sensitivity setting greater than or equal to 8 ($P_{\text{oxygen line}} = 5 \text{ kPa} \times 100$, F -12 L/min) (**Figure 5a**). Reaching extremely high values in sensitivity of 9 and 9.5 ($P_{\text{oxygen line}} = 5 \text{ kPa}$, Flow of -12 L/min), 81.90, and 93.29 cmH₂O, respectively (**Figure 5a**). With the increase in the sensitivity of the respirator, there is an increase in both maximum and minimum pressure (**Figure 5a,b**).

Functional parameters are determined by the respirator inlet pressure, which is a variable dependent on the flow and O₂ intake pressure. For better evidence, two conditions are shown: the first $P_{\text{oxygen line}} = 5 \text{ kPa} \times 100$, F =11 L/min and Sens = 3.5; and the second at $P_{\text{oxygen line}} = 4.5 \text{ kPa} \times 100$, F -12 L/min and Sens - 3.5. Both conditions present values of pressures (**Figure 7a,b**), time (**Figure 7c,d**), and frequency similar (**Supplementary Figure 1**). The common factor is also that respiratory intake pressure values are practically equal (170 and 175 mmHg, respectively) (**Figure 7f**).

Inlet pressure of O₂ below 3.5 kPa x 100 led to an R I/E >1 (**Figure 7e**), thus being recommended the use of $P_{\text{oxygen line}}$ above 3.5 kPa. $P_{\text{oxygen line}}$ can be adjusted to increase the respiratory rate if the flowmeter is not available.

Conclusion. It was possible to obtain a pulmonary ventilator-dependent only on positive O₂ flow, simple and effective for patient transport, and in emergencies. With maximum pressure control and respiratory rate offered to the patient. Among the parameters evaluated for this respirator, an O₂ line intake pressure from 3.5 kPa x 100, sensitivity between 3 and 5, a flow rate of 5 to 15 L/min is recommended.

Future works: *In vivo* tests and clinical evaluation.

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Supplementary Data

Supplementary Figure 1. Respirator Respiratory Frequency (Freq) in the Pressure ($P_{\text{oxygen line}}$) and O2 Intake Flow (F) and Respirator Sensitivity (Sens) parameters.

$P_{\text{oxygen line}}$	F	Sens	Freq
<i>KPa X 100</i>	<i>L/min</i>	----	cpm
5	12	0	18.65
5	12	0.5	19.05
5	12	1	18.21
5	12	1.5	7.39
5	12	2	12.45
5	12	2.5	13.03
5	12	3	14.65
5	12	3.5	13.89
5	12	4	16.57
5	12	4.5	25.81
5	12	5	28.84
5	12	5.5	45.70
5	12	6	54.01
5	12	6.5	54.01
5	12	7	56,04
5	12	7.5	62.97
5	12	8	56.39
5	12	8.5	54.28
5	12	9	26.43
5	12	9.5	20.86
5	5	3.5	7.96
5	6	3.5	9.37
5	7	3.5	10.54
5	8	3.5	11.11
5	9	3.5	12.96
5	10	3.5	12.48
5	11	3.5	13.92
5	13	3.5	17.01
5	14	3.5	17.82
5	15	3.5	17.36



3	12	3.5	12.95
3,5	12	3.5	13.53
4	12	3.5	14.58
4,5	12	3.5	14.41
5,5	12	3.5	16.97
6	12	3.5	16.13
6,5	12	3.5	17.14
7	12	3.5	17.72