RESPIRA-GUATEMALA:

Concrete solutions to the COVID19 pandemic in developing countries

RESPIRA GUATEMALA

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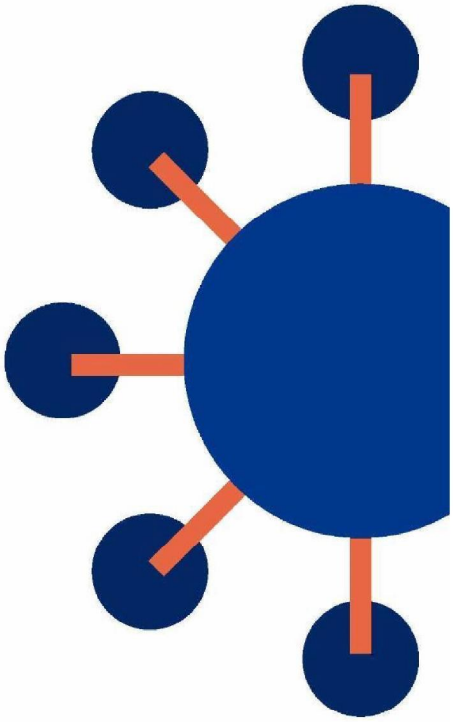


An initiative of
Quantum Energy & Engineering
in collaboration with
Studio Dosis

TU Delft
Delft University of Technology

Project Inspiration

Process & Energy

QUANTUM

DOSIS

TALLERES HERNANDEZ TH

Executive Summary

The COVID-19 pandemic has exacerbated some of the fundamental limitations that the current development model in Latin America and the Caribbean already had: poverty, inequality, weak healthcare systems, amongst others. This calls for integrated, sustainable, and locally-driven solutions based on science.

Guatemala is being affected particularly hard, since the country has the smallest number of hospital beds per capita in the region, and only 56 mechanical ventilators dedicated to COVID-19 patients. In response to these issues, we launched Respira-Guatemala, in collaboration with Project Inspiration from TUDelft, in The Netherlands. Together, we developed a mechanically invasive ventilator that meets the necessary clinical criteria and costs roughly one-tenth of its commercial counterpart.

Moreover, Respira-Guatemala established production and an assembly line of mechanical parts of the ventilator in Guatemala successfully producing two working machines, which will be used in the Roosevelt Hospital, starting the third week of August. A logistics line, including diplomatic partners, was also established to speed up the import time of electronic components.

Our solution consists of two phases. In the first phase, we aim to produce 96 mechanical ventilators by the end of the year, and 160 more in the first five months of next year, to supply the hospitals of Guatemala and other neighboring countries with resources needed to face the COVID-19 pandemic. At the same time, our team of researchers will be improving the current model to be more flexible for various emergencies (other than COVID-19). Since the need for ventilators will not stop with the pandemic, our second phase's goal is to produce 320 improved ventilators to ensure that the region can be better prepared for challenges it may face in the future. Our estimated cost for the first phase is approximately EUR 1.2 million and EUR 2.5 million for the second phase (given we expect the price to increase for the more advanced model).

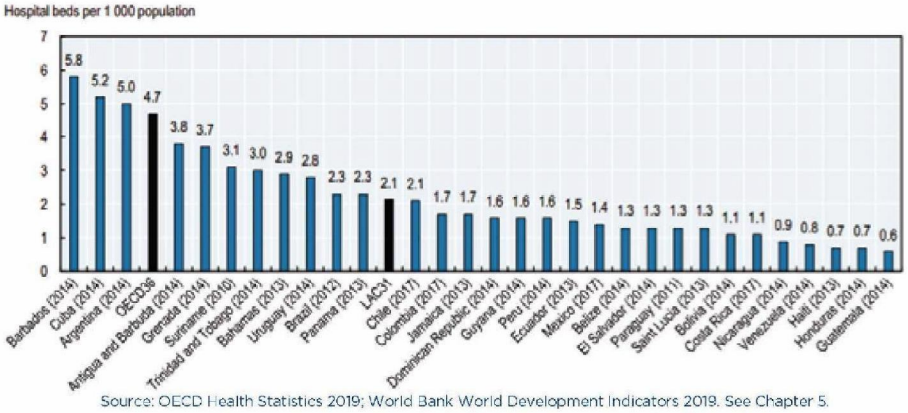
Locally produced Mechanically Invasive Ventilators for critically-ill COVID-19 patients

1.1 The problem

According to the Minister of Health of Guatemala, as of April 4th, there were 56 mechanically invasive ventilators available for COVID-19 patients in the entire country. This quantity would need to cater for the country's population of 17.5 million people. As of August 11th, Guatemala has a total of 57,966 confirmed COVID-19 cases. Recent studies have shown that around 2% of the total cases will require mechanical ventilation (Auld et al., 2020). Studies have suggested that Guatemala required over 700 mechanical ventilators as of the end of July (IHME, 2020). The data above makes it clear that there is a significant shortage of mechanical ventilators in Guatemala.

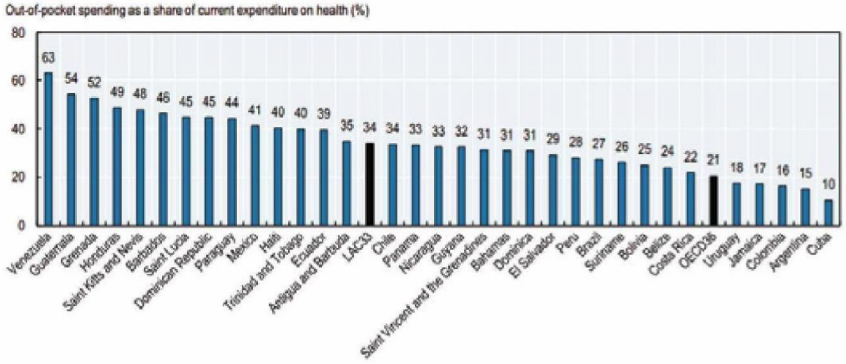
Currently, Guatemala is the country with the least amount of hospital beds at 0.6 per 1000 people (Haiti and Honduras are at 0.7) (The World Bank, 2020b), and the second largest "Out of pocket spending"

Figure 3: Number of hospital beds in LAC countries and OECD average, latest year available



Source: OECD Health Statistics 2019; World Bank World Development Indicators 2019. See Chapter 5.

Figure 2: Out of pocket expenses. Obtained from The World Bank (2020a)

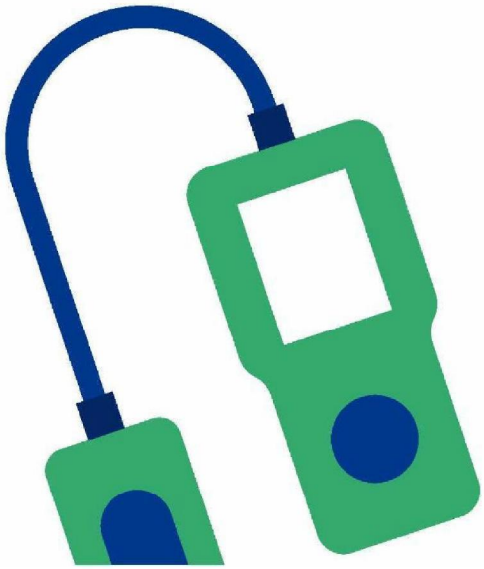


1.2 Our response: Respira-Guatemala, a combined effort to tackle the COVID-19 crisis

In April, Acknowledging the emergency that the COVID-19 was going to impose in Guatemala, and seeing the impact that the pandemic had had in more developed nations with better health care systems, Quantum Energy & Engineering and the local Design Studio DOSIS partnered up to create the Respira-Guatemala initiative, with the goal of relieving the strain on the health-care system and provide the critically needed, life saving mechanically invasive ventilators which we had seen were needed and in shortage. We partnered up with Project Inspiration, led by the biomedical engineering Professor Gerwin Smit fromTUDelft, who developed a ventilator model that meets all the necessary medical criteria (See section 1.4).

The model is based on the East Radcliff Ventilator. This popular design was successfully used throughout Europe for over two decades, and was capable of fully ventilating critical patients for over two years without stoping. This model was imporoved upon with state-of-the-art technology from TUDelft.. After establishing the partnership with TUDelft, we quickly contacted different actors in our network, including the four largest universities, 5.1.2e 5.1.2e among others (See the partner network in Figure 1.3). Furthermore, we created different communication channels e.g., www.respira-Guatemala.com, with the intention of providing accurate and essential information on COVID-19 prevention, good practices and our ventilator development work to the general public.

We then moved towards establishing our production line in Guatemala. For this, our long time technology development partner, the workshop Talleres Hernández, which we knew had experience working for the pharmaceutical, food, medical, chemical, among other industries. They agreed to support the initiative to help the hospitals by producing all the molds and mechanical pieces of the ventilator. To get the process started, TUDeflt's Project Inspiration team, in collaboration with the Process & Energy department donated a full mechanical system, as well as their technical advice for the specifics of the materials needed to produce them. As of today, with the help of Talleres Hernández we produced two full mechanical systems, and proceeded to perform a stress test that lasted over three weeks without any errors. Thanks to the big head start time, they were able to prepare their workshop to have enough capacity to produce up to eight full mechanical systems in a week (see the letter in the Appendix).




RESPIRA GUATEMALA
QUANTUM energy & engineering
DOSIS
TU Delft
Project Inspiration
Process & Energy
Production, import and logistics
Research + Development
Hospital Roosevelt
1st Hospital to use the ventilator
Dutch Consulate in Guatemala
Network and diplomacy
DACO HEAVY LIFT
Logistics and imports to Guatemmala
CMI
Anonization
TALLERES HERNANDEZ TH mecánica industrial
Mechanical Parts
ARA
Manufacture Advisor
IEGSA Instalaciones Electromecánicas de Guatemala, S. A.
Assembly Space
GLOBAL INITIATIVE NETWORK OF EXPERTS
Administrative Advisor
INTERRARAY
Electronic Parts
Diplomacy
GOBIERNO de GUATEMALA
MINISTERIO DE SALUD PÚBLICA Y ASISTENCIA SOCIAL
FOOD SECURITY
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People, finance, land
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Kwoledge

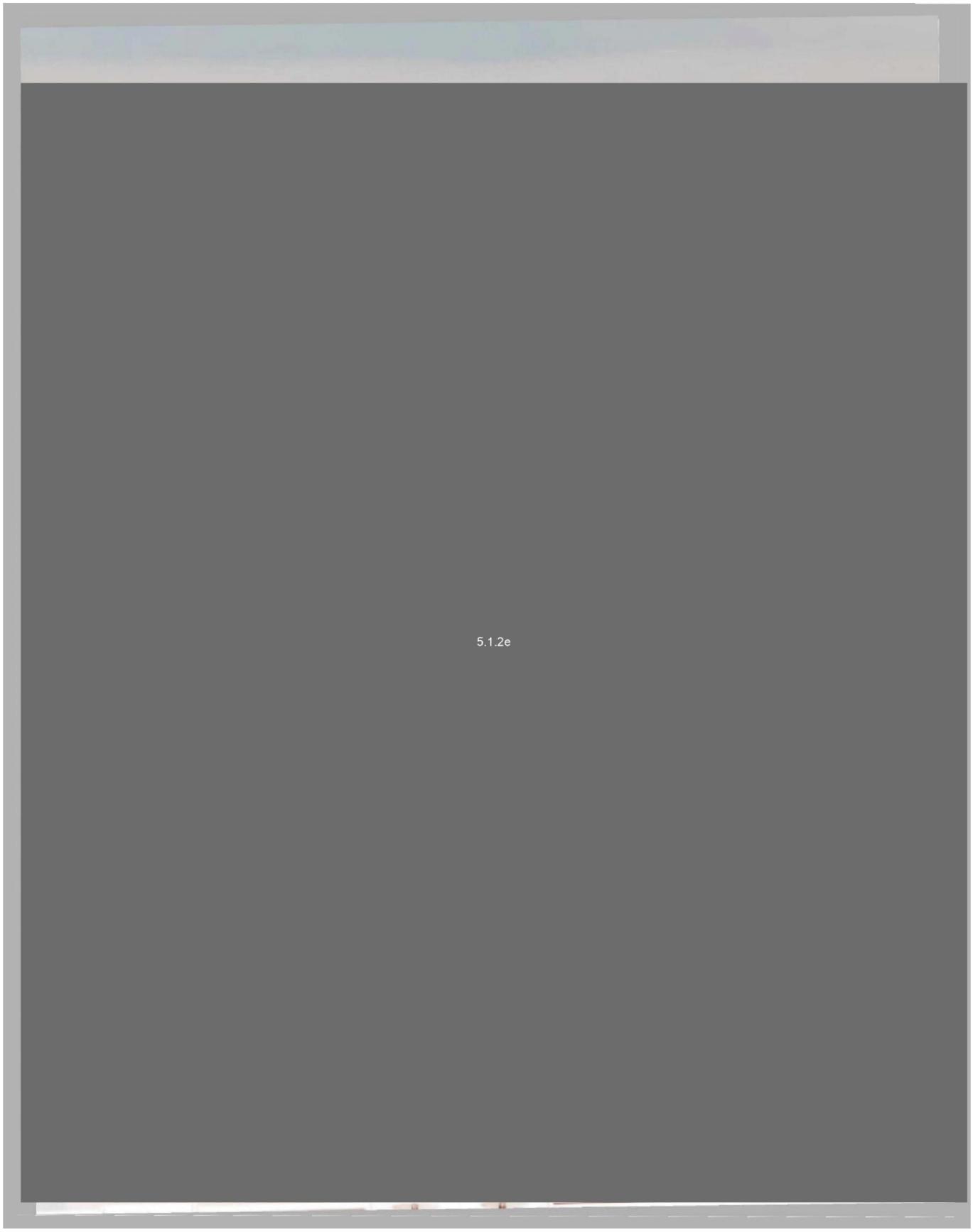
Some key parts of the ventilator had to be done in other specialized companies, for instance, the aluminum chambers need to be anodized to protect them from a high oxygen concentration. In Guatemala, it seems like this process is rarely done. Nevertheless, we reached out to Procesos en Aluminio -CMI- S.A., to our knowledge, the only company in Guatemala that can perform this process. They have been keen towards the project and succesfully completed the anodization process for the first two machines, and stated their willingness to support the scale up.

The auxiliary monitoring system can not be produced in Guatemala at the moment, nor any other country in Central America, as far as we know. This requires specialized equipment for multi-layer electronic board design, testing and production. However, our team members in The Netherlands together with Project Inspiration have established a sound network of suppliers for all the electronics, which come from different Switzerland, Germany, the U.K. and several parts of The Netherlands.

Currently, the electronic board is being developed by Interarray a Dutch company specilized in this processes. Their help was key in improving the efficacy and reliability of the circuit boards used in the ventilator. Furthermore, they have the infrastructure to easily scale up and an existing inventory of the materials that we need for the ventilator. For the first two ventilators, Global Initiative from TUDelft provided the resources to purchase them, as well as their technical advice with our administrative structure. Once our team in the Netherlands collected all the pieces, the company recommended by the Dutch Consulate in Guatemala, Daco Heavy Lift supports us with the logistics and customs processes.

Finally, once all the mechanical and electronic pieces made it to Guatemala, the company IEGSA supports us to with space to ensemble, test and clean the machines. As technical advisors, we have direct daily contact with the Project Inspiration Team and we also have the support from ARA, a sister company of Interray, who offers advisory in the manufacturing process.

In summary, the collective effort of Respira-Guatemala has been able to transfer critically required technology and has begun building the local capacity to face our own needs Our goal now remains to provide sufficient equipment for the local and regional hospitals, for which we need to scale up and consolidate the local capacity.


5.1.2e

1.3 Our plan

1.3.1 Phase 1:
Meet the current emergency needs of ventilators and improve the current model to meet the standards of "out-of-emergency conditions"

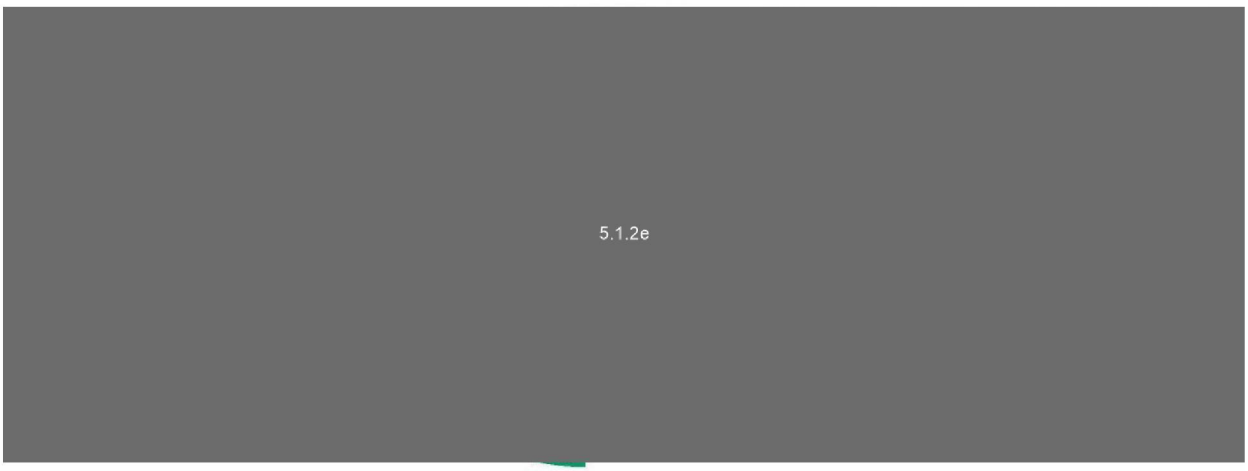
According to our conversation with the ICU director of Roosevelt Hospital, the hospital requires at least 50 ventilators more to satisfy their demand, as they have been at maximum capacity for months.

Hence, our goal is to meet the needs of this hospital and the other COVID-19 dedicated hospitals in the country. We aim to have a total of 96 ventilators in use by the end of the year. With our current suppliers and production line, we can produce an average of 8 ventilators per week, or 32 per month. With that, our goal until the end of the year is to have 96 new ventilators, fulfill the requirement of the Roosevelt Hospital, and have some units available to other hospitals in need. Furthermore, we plan to continue the production into the next year, to have a total of 256 ventilators produced by May of 2021.

Simultaneously, three features can be improved in the current model to meet all the requirements of a fully commercial device. These are:

- Variable inspiration-expiration ratio (I:E): Which currently is fixed at 1:2. The current value is sufficient to provide a mechanically invasive ventilator to a sedated patient, but in some cases, it might be desired to change this relation.
- Assisted ventilation: This requires measuring the voluntary pressure drop in the lungs of the patient.
- Touch-screen: In some cases, it is desired to have a more advanced monitoring system, for which more work on the electronics is required.

To achieve these, a continued partnership with TUDelft is required, to which they are readily open. In summary, the first phase's purpose is to help relieve the crisis in the short-term and establish the base for a new model that will allow us to help prepare for future needs.



1.3.2 Phase 2:
Capacity building and scale-up

Based on the statement by the World Bank, Latin America & the Caribbean countries need to spend more and better on health to be better able to face a major health emergency like COVID-19 effectively (The World Bank, 2020c), this phase is aimed at increasing the local capacity for production of the medical devices needed to meet the local needs in the future.

Table 1.1: Number of ventilator requirements in the last 6 years[1]

Year	Number of events	Cost
2020	760[2]	7,064,388.07 EUR
2019	1067	5,450,414.63 EUR
2018	1426	5,963,779.41 EUR
2017	944	4,651,614.84 EUR
2016	750	3,598,153.20 EUR
2015	590	2,286,896.85 EUR

During our conversations with different doctors in Guatemala, we learned that the country had a mechanical ventilator deficit before the COVID-19 crisis started, to the point where doctors frequently had to provide manual ventilation for their patients. After some further research into the topic, we found more evidence of this need through the great demand of such devices, as shown in Table 1.1. Moreover, this information is also accurate for many (if not all) other countries in Latin America.

Latin America produces only 4% of all the medical technologies used in the region. For the remaining 96% of the supplies, the countries are fully dependent on the international market. As a team, we believe that other countries should be able to benefit from a ventilator that costs less than a tenth of what they normally would.

For this reason, building on the research from phase 1, phase 2 is about continuing the production and distributing ventilators to other neighboring countries that would benefit from them. The pandemic will eventually be over, but we need to grow our inventory to better prepare for future challenges.

[1] Data obtained from www.guatecompras.gob.gt. Here, the number 1067 means that the country leased ventilators 1067 times, with contracts that lasted as little as 1 day, up to a few months. Similarly, this applies for every other line.
[2] Up to August 11th

1.4 Technical Specifications of the Ventilator

The ventilator developed by Project Inspiration is designed based on the Rapidly Manufactured Ventilator System (RMVS) of the Medicines & Healthcare products Regulatory Agency.

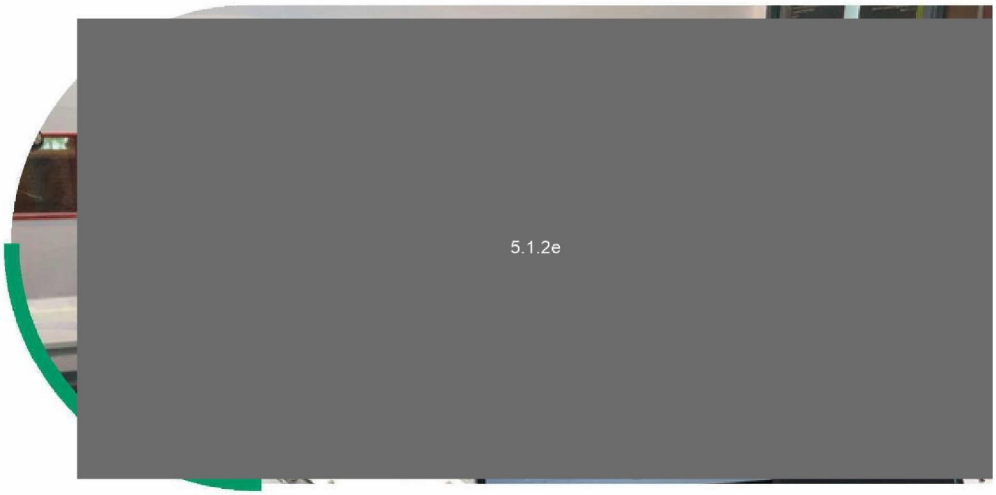


Figure 1.7: Project Inspiration Ventilator

The technical specifications are:

- Plateau Pressure regulated by moving/adding/removing weights: up to 30 cm H2O. In an exceptional case, up to 70 cm H20 is possible by adding more weight.
- Nearly constant pressure achieved by weighted bellow flow generation.
- PEEP pressure mechanically adjustable: 5 cm H2O to 25 cm H2O.
- Safety valve in inspiratory 70 mbar.
- Tidal Volume: results from lung compliance, pressure setting and breathing rate.
- Mechanical valve control, fixed I:E ratio: 1:2 (expiration longer than inspiration).
- Breaths per minute: adjustable between 10 and 40 breaths per minute.
- Only mandatory/forced ventilation possible.11
- Humidifier and heater optional second system: controlled to 35-37ÂřC inflow air and high (90%+ Rel Humidity).

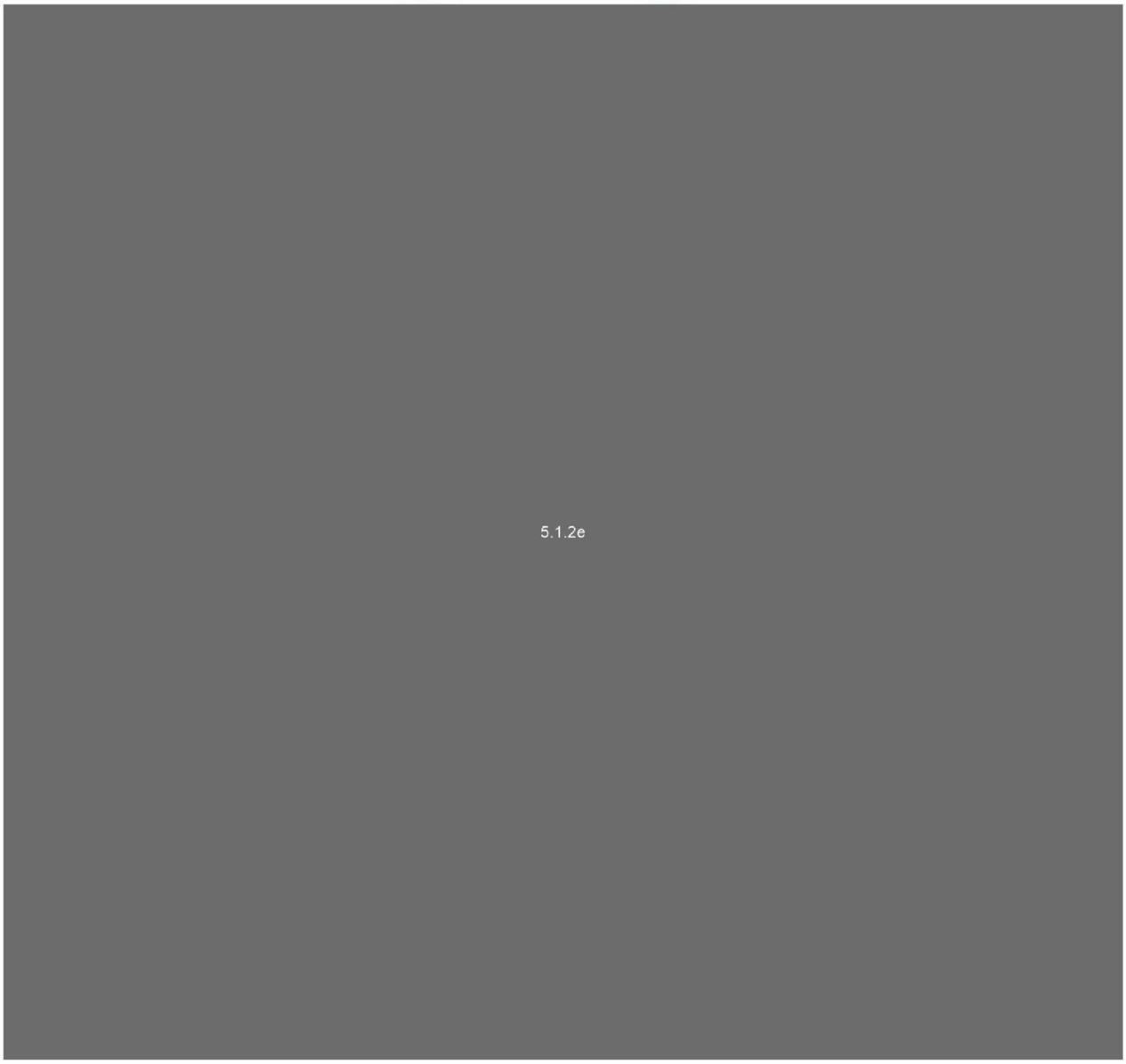
Alarms:

- Low battery.
- Plateau pressure (too high/low); adjustable limits.
- PEEP (too high/low); adjustable limits.
- Tidal volume (too high/low); adjustable limits.
- Minute volume; adjustable limits
- Oxygen fraction (Too high/low); adjustable limits.
- Sensor failure

Monitoring:

- Current achieved PEEP.
- Plateau Pressure.
- FiO2.
- VT and Breathing rate(BPM).
- Temperature of inspired air.
- Humidity of inspired air.
- Battery full/low.
- Real-time plots possible with connected laptop (USB).

1.5 The Quantum Energy & Engineering + Studio Dosis = Respira-Guatemala



1.5.2 Finances

		VENTILATORS MANUFACTURED		32	32	32	32	32	32			
		MONTH	0	1	2	3	4	5	6			
		EXPENSES		5.1.1c								
Costs	ASSEMBLY LINE	PLASTIC BOXES	€							€		
		RECEPTION CHAIRS	€							€		
		ASSEMBLY CHAIRS	€							€		
		RECEPTION TABLES	€							€		
		ASSEMBLY TABLES	€							€		
		STEEL CONTAINERS	€	5.1.1c						€		
		TOOL BOXES	€							€		
		TOOLS	€							€		
		PLASTIC TRAY	€							€		
		SHELVING	€							€		
	VENTILATORS	IMPORTED PARTS	€		€					€		
		LOCALLY PARTS			€					€		
	TAXES				€					€		
	WORKSHOP	Press bench			€					€		
		Bending machines			€					€		
		POLISHER			€					€		
		CUTTING DISKS			€					€		
		PEDESTAL DRILL			€					€		
		HAND DRILL			€					€		
		METAL TABLES			€					€		
		LATHE MACHINE			€					€		
		MILLING MACHINE			€					€		
		CNC HAAS VF2YT CNC Mill			€					€		
		WELDING MACHINE			€					€		
		INTEREST PER PURCHASE AT 18 MONTHS MACHINES			€					€		
Expenses	ASSEMBLY LINE	DOCTOR SUITS	€		€					€		
		MASKS	€		€					€		
		COPINGS	€		€					€		
		SHOE COVER	€		€					€	5.1.1c	
		ALCOHOL (L)	€		€					€		
		QUATERNARY AMMONIUM	€		€					€		
		ALCOHOL GEL	€	5.1.1c	€					€		
		TABLE COVER	€		€					€		
		PAPER ROLLS	€		€					€		
		PLASTIC TRAY	€		€					€		
		PACKING BOXES	€		€					€		
		PACKING BAGS	€		€					€		
		PACKING TAPE	€		€					€		
	COLLABORATORS	ASSEMBLERS			€					€		
		PRODUCTION MANAGER			€					€		
		WORKSHOP TECNICIANS			€					€		
		CONCIERGE			€					€		
		SECRETARY			€					€		
		ACCOUNTING			€					€		
		ADMINISTRATION			€					€		
	SERVICIOS	WORKSHOP RENTAL			€					€		
		ELECTROCITY			€					€		
		DELIVERYS			€					€		
		COMMUNICATION AND DESIGN			€					€		
		PROGRAMMER	€	5.1.1c						€		
		INTERNET AND WATER			€					€		
		Welding supplies			€					€		
		METAL SUPPLIES			€					€		
		OTHER SUPPLIES			€					€		
		POLISHING DISCS			€					€		
	R+D	ENGINEERS			€					€		
		MATERIALS			€					€		
		TESTS			€					€		
					€					€		

Phase 1 **256 Ventilators** €

Phase 2 **320 Ventilators** €

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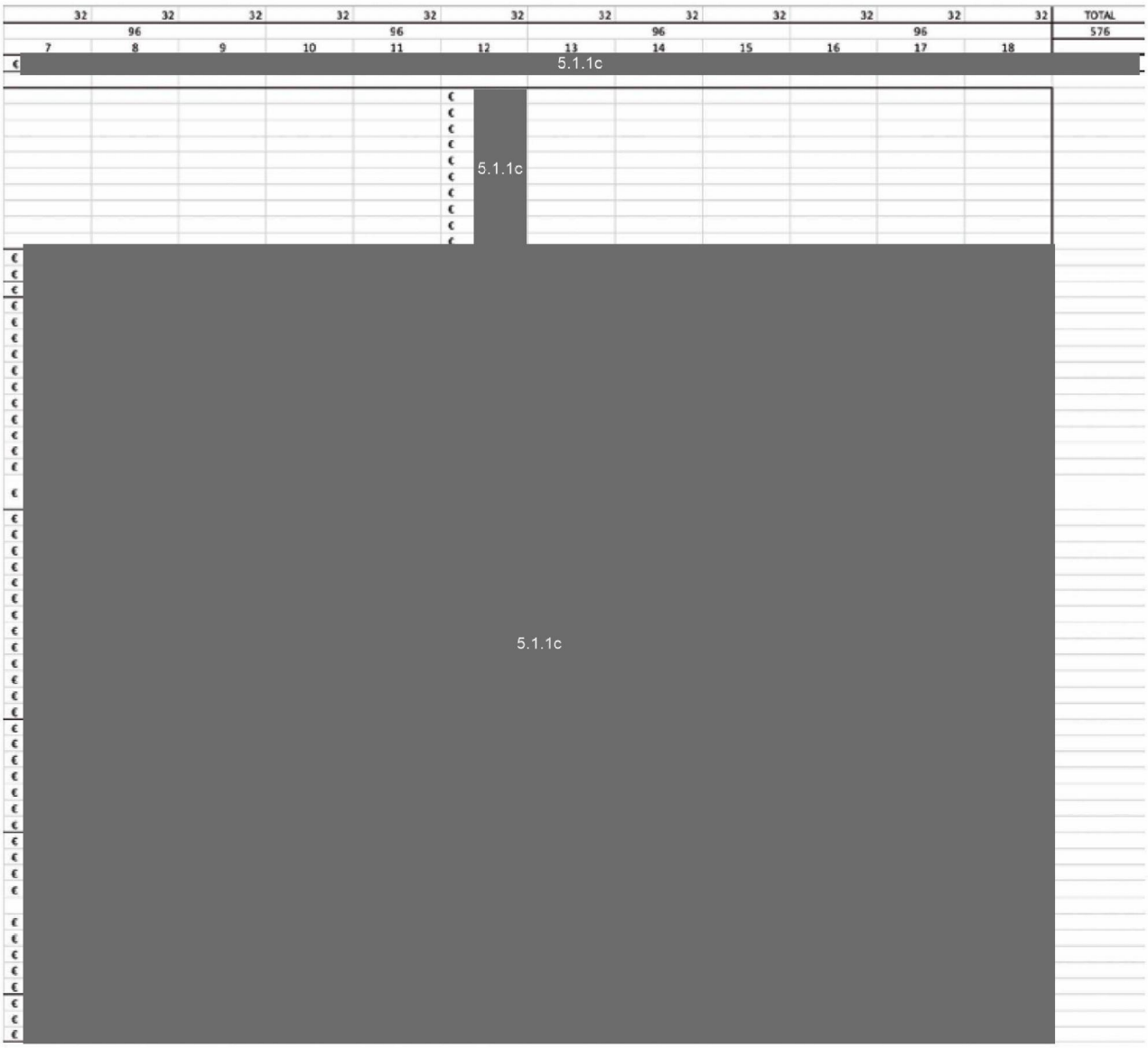
32 32 32 32 32 32 32 32 32 32 32 32 TOTAL
96 96 96 96 576
7 8 9 10 11 12 13 14 15 16 17 18
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The support we are seeking will cover the finances behind helping Guatemala breath again

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GOBIERNO de GUATEMALA
DR. ALEJANDRO GIAMMATTEI
MINISTERIO DE SALUD PÚBLICA Y ASISTENCIA SOCIAL
Hospital Roosevelt

Guatemala, 10 de Abril del 2020

Estimado 5.1.2e

Dándole continuidad a nuestra conversación de hoy, quiero solicitarte por este medio que comuniques al equipo de la Universidad Tecnológica de Delft que trabaja en el proyecto "Inspiración", que en el Hospital Roosevelt de Guatemala estamos interesados en el equipo de respiración mecánica asistida que han desarrollado, dado que en la situación actual no contamos con la capacidad necesaria para asistir la cantidad estimada de pacientes críticos de COVID19 que vendrán en las próximas semanas.

Estamos en la disposición de probar el equipo y evaluar si logra superar las pruebas clínicas de los parámetros críticos que necesitan controlarse durante una intervención en un paciente, para su posterior implementación.

De antemano agradecemos el esfuerzo.

Sin otro particular, se despide.

Atentamente,

5.1.2e
Hospital Roosevelt de Guatemala

Cc. Archivo

Guatemala, April 10th 2020

Estimado 5.1.2e

Continuing our conversation from today, I want to ask you by this means that you communicate to the team at Delft University of Technology working on the "Inspiration" project, that at the Roosevelt Hospital in Guatemala we are interested in the assisted mechanical ventilation equipment they have developed, given that in the current situation we do not have the necessary capacity to assist the estimated number of critical COVID19 patients who will come in the next weeks.

We are in the position to test the equipment and evaluate if it manages to pass the tests critical parameters that need to be monitored during an intervention in a patient, for its subsequent implementation.

We appreciate the effort in advance.

Without another particular, he says goodbye.

Sincerely,

5.1.2e

Roosevelt Hospital from Guatemala

cc. Archive

Toda Clase de Trabajos para la Industria Farmacéutica y Alimenticia,
Especialidad en Trabajos de Acero Inoxidable.

Guatemala, 17 de Agosto del 2020

A quien corresponda,

El motivo de la presente carta es para comunicar la disposición en apoyar la iniciativa de "Respira-Guatemala" en la construcción del sistema mecánico de los ventiladores invasivos urgentemente necesarios en los hospitales de Guatemala, dada la emergencia causada por el COVID-19 y la saturación de las unidades de cuidados intensivos.

En Talleres Hernández, tenemos más de 60 años de experiencia en la construcción de maquinaria para casi todo tipo de industria, incluyendo: farmacéutica, médica, química, alimenticia, azucarera, que ha sido utilizada en varios países del mundo.

En este momento tenemos la capacidad de construir entre 4 y 8 sistemas mecánicos, con intensión de expansión. Hemos construimos 2 sistemas basados en el diseño de TUDelft de manera exitosa, que han probado funcionar de manera correcta; además, en creamos máquinas auxiliares para agilizar la producción en serie, como inicialmente planificado con el equipo de "Respira-Guatemala".

Desde ya ponemos a la disposición nuestros servicios para apoyar al país y la región en esta crisis.

Se despide atentamente,

5.1.2e

TALLERES HERNANDEZ
mecánica industrial

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Talleres Hernández

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TALLERES HERNANDEZ

Toda Clase de Trabajos para la Industria Farmacéutica y Alimenticia,
Especialidad en Trabajos de Acero Inoxidable.

Guatemala, August 13, 2020

To whom it May concern,

The motive for this letter is to communicate the willingness to support the initiative of "Respira-Guatemala" in the construction of the mechanical systems of urgently needed invasive ventilators in the Guatemalan hospitals, given the emergency caused by COVID-19 and the saturation of intensive care units.

At Talleres Hernandez, we have more than 60 years of experience in the construction of machinery for almost every type of industry, including: pharmaceutical, medical, chemical, food, sugar, which has been used in various countries around the world.

At this moment we have the capacity to build between 4 and 8 mechanical systems, with the intention of expansion. Based on the TUDelft design, we have successfully built 2 systems that have proven to work correctly and we have tailored auxiliary machines to speed up serial production, as initially planned with the "Respira-Guatemala" team.

From now on we make our services available to support the country and the region in this crisis.

Sincerely,

5.1.2e

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TU Delft
Delft University of Technology

R&D by Delft University of Technology

Based on the feedback from the clinicians and their priorities, we will improve the ventilator system and add additional functionality. We expect that the following features can be added or improved:

Software and user interface

The current software provides basic processing of the sensors signals (airway pressure, air flow, breathing rate, airway temperature, oxygen level). Although the displayed values are within the required boundaries, it is desired to improve the data processing, to increase the accuracy and of the displayed values, to facilitate the reading for the medical personnel.

Furthermore, it is desirable to be able to display not only the pressure and flow values, but also graphically display the pressure and flow profiles. This can be realized by adding a touchscreen, or a display to the system, which requires redesign of the electronics system. Lastly, it would be desirable to add an external data output, which enables the recording of the measured data.

I:E ratio

The current ventilator has a fixed inspiration-expiration-ratio (I:E of 1:2), which is determined by a cam shaft. This means that the expiration is two times longer than the inspiration. Although this will suit most cases, in some cases it is desirable to have other I:E-ratios. Other ratios could potentially be added to the ventilator, by enabling the camshaft to rotate at a variable speed. This requires redesign of the electronics of the motor controller setup.

Breathing assist mode

The current ventilator model provides mandatory ventilation only. This means that ventilator imposes the breathing speed to the patient, which is sufficient for emergency situations like the COVID-19 crisis. The patient is not allowed to counteract the ventilator, and therefore needs to be sedated sufficiently. It would be desirable to add a breathing assist mode, in which the ventilator assists the patient, at the initiative of the patient, who breaths at a self-selected breathing speed. In this way, the patient needs to be less sedated. Adding a 'breathing assist mode', could be achieved by using pressure signals, to drive the motor controller. In this way, the camshaft can open and close the inspiration and expiration valves at the breathing initiative of the patient.

EMC testing

To ensure that the new developed electronics of the ventilator works well when they are exposed to electromagnetic interference, the machine needs to be subjected to EMC-tests. One EMC-test costs 10-15k. It is expected that 2-5 tests are necessary.

Technicians

The software programming requires one to two software engineers, working 12 months on the project. The modification of the electronics can be done by one electrical engineer.

5.1.2e

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