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INTEGRATION AND REPLACEMENT OF INTERNAL PARTS OF AN EMERGENCY MECHANICAL VENTILATOR

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Abstract. *The COVID-19 pandemic has created worldwide intense development of low cost solutions to provide mechanical ventilator devices. Despite the diverse alternatives, the equipment is complex and relays on sensors and valves to adjust and maintain the proper pressure, oxygen saturation and other parameters critical to help and also to avoid damage to the lungs. In this context, an initiative from Jet Propulsion Laboratory (JPL-NASA, USA) provided a low cost ventilator design that avoided components that are commonly used in the production of traditional ventilators. Despite the lower cost, there were also restrictions found in the supply chain on some of the components of the ventilator. This work presents the design alternative to reduce the dependency on importing flow sensors and integration to other components inside the VITAL Mechanical Ventilator developed by JPL team. The design change kept the principles of the original Design but it improved integration of the components, local manufacturing, reduction of components, improved internal space and made maintenance easier.*

Keywords: *mechanical ventilator, covid-19, flow sensor*

1. INTRODUCTION

The pandemic generated by Corona Virus Disease 2019 (COVID-19) demanded extra health equipment around the world to save lives. Common symptoms of SARS-CoV-2 infection include respiratory symptoms and the patients diagnosed who show moderate to severe signs should initiate treatment with oxygen therapy (Motta et al, 2021). One of the most important equipment to support life of critical ill patients were the mechanical ventilators (Iyengar et al 2020). Nevertheless, the shortage from consumables to high-end equipment was high, especially during 2020.

Pulmonary Mechanical ventilators are medical equipment that provide supply of air and supplemental O2 to the lungs of a patient. They are used to control the flow and amount of gases that enters and leaves the patient`s lung. Usually, the patient is sedated and cannot breathe on their own. The equipment provide the pressure to ensure gas flow but it must not exceed pressure limit that could damage the lungs of each patient. It also has to maintain a pressure level during the expiration to avoid lungs to collapse, that is called PEEP (Positive End Expiratory Pressure). There are many other parameters to ensure gas exchange and optimal O2 absorption by the patient, such as pressure, volume, fraction of inspired oxygen (FiO2), respiratory frequency and expiratory pressure.

With the strangled supply chain of components used in the manufacturing of mechanical ventilators, diverse initiatives around the globe pursued low cost and easy to manufacture solutions to provide pulmonary mechanical ventilation. One of these initiatives was the VITAL Mechanical Ventilator developed by NASA (National Aeronautics and Space Administration) from USA (Strickland, 2020). VITAL is an acronym of Ventilator Intervention Technology Accessible Locally. The engineering team at the NASA-JPL (Jet Propulsion Laboratory, California Technology Institute) developed two versions of mechanical ventilators trying to use components that are not used by the supply chain of other commercial mechanical ventilators. One version was based on air and O2 compressed supply lines (pneumatic) and the other version was based on blower for air intake and compressed O2 supply line (compressor). The ventilators, besides some restrictions for use, had all functions necessary to be used in an emergency scenario compared to a traditional ventilator and is composed of fewer parts, many of which are currently available to potential manufacturers through existing supply chains. In Figure 1 is presented a photograph from the project publicity by NASA-JPL-Caltech.

Figure 1. Public publicity from the Vital Mechanical Ventilator by NASA-JPL-Caltech.

After finishing the design and preliminary tests, NASA-JPL invited worldwide companies and institutions to manufacture the VITAL ventilator to make the access to the equipment easy. Important to notice that the VITAL use was intended only for the COVID-19 pandemic situation. NASA-JPL allowed licensees to explore commercially the developed apparatus without any financial return to NASA-JPL.

Among the 28 licensees, in Brazil, SENAI CIMATEC and RUSSER do Brasil were selected. Both institution joined forces in a strategic partnership to adjust the design, manufacture parts, assembly and distribute the VIDA, name of the local version of the original VITAL design (Good et al, 2020). NASA-JPL made available to the licensees around the world all the mechanical, pneumatic, electronic and software designs to allow the manufacturing of the ventilators. Nevertheless the original design intended to use an alternative supply chain, looking at the local Brazilian market, there were accessibility and availability issues for some components necessary to build the ventilator. The development team in Brazil worked to replace some components and to improve the design to the local reality. Table 1 presents some of the adaptations made by the team to localize the VITAL design (original design) to VIDA ventilator (local design).

Table 1. List of major modifications from original design to adapted design.

Item	***Original Design***	***Local Design***
Cover/Panels	Aluminum	Steel
Internal Valves	US standard	Brazilian standard
Inlet Pressure regulators	US standard	Brazilian standard
Hospital hose connections	US standard	Brazilian standard
O2 sensor	Optical sensor	Galvanic fuel cell
Air mixture flow sensor (“Venturi tube”)	Sensor and Injection molded plastic part / Additive manufactured option	Sensor and Aluminum milled with integration with other components.
UPS Uninterruptible Power Supply	Non-present	Custom Nobreak

Once the local team started to work in the project, air mixture flow sensor became the biggest challenge. The sensor used for the project was based on ready-made kit available in the US market that had the accuracy required for the application. Nevertheless, the deliverable of the called “Venturi tube” had a long lead time. The critical component of the Venturi tube was the plastic “venturi” shape part. The differential pressure MEMS sensor to be connected to the plastic part was easy to find from different suppliers around the world. The original project considered that an alternative was to 3D print the “Venturi tube”, but after analysis, it became clear that additive manufacturing with the quality and quantity required to this internal component of the pneumatic ventilator was not the best option. A typical assembly of MEMS differential pressure sensor in venture tubes for medical air mixture use is presented in Figure 2. The differential pressure sensor is a robust technology that can be implemented in different geometries. Consequently, this kind of assembly requires a calibration to use on different geometries of Venturi tube.

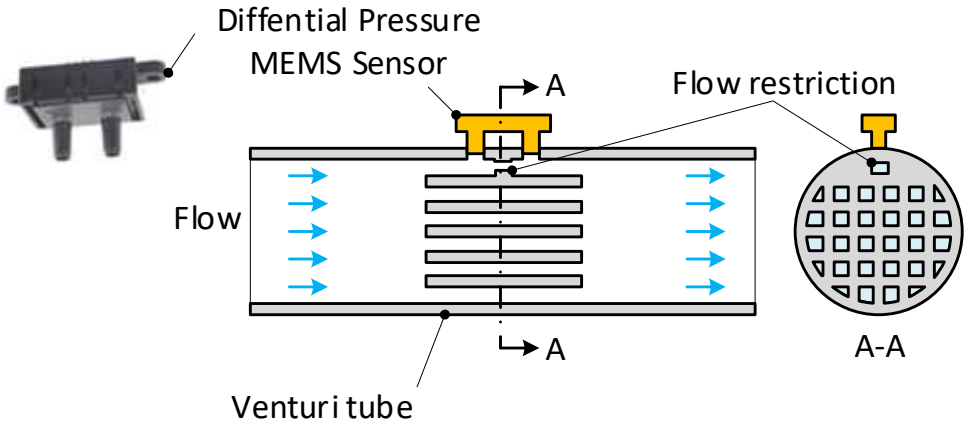

Figure 2. Typical differential pressure sensor assembly.

In this paper, we discuss the design changes to the Venturi tube and integration with other components aiming to reduce the number of components, to avoid a lack to supply chain and to increase the internal space to improve heat exchange. Some of the information presented is limited due to non-disclosure agreements.

2. METHODOLOGY

As soon the engineering team had access to the list of parts and components of the pneumatic mechanical ventilator they started to search for the suppliers to quote and to obtain the estimated deliverable dates. It became clear that large quantities requests were required to the negotiation with the suppliers and that timing was crucial. All the different licenses from NASA-JLP were consulting and requesting the same parts at the same time with the urgent need of delivering ventilators to fight the pandemic death toll.

The limitations imposed by the suppliers were causing difficulties to the localization progress of the product. Therefore, a methodological process to evaluate each schematic/component and not lose too much time on trying to optimize the project and trying to avoid risks from the supplier chain. This proposal is summarized by the flow analysis presented in Figure 3. The aim of this working flow is to evaluate each part and to take one of the four possible actions:

1. Search for exclusion or reduction: Leads the designer to remove parts or try to reduce amount of these parts required in the product. Also, alternatives to fasten parts should be evaluated;

2. Search for substitution or integration: The designer should rethink the part to evaluate the possibility for integration of different parts or to substitute for easy access in the supply chain;

3. Search for supplier commitment: If the only alternative was a specific part from a specific supplier, procurement should be made on a manner to reduce the associated risks: high costs and delays;

4. Search for supplier diversification: More suppliers should be found to reduce the risks. Nevertheless, design should be flexible to allow differences between components provided from different manufacturers/suppliers.

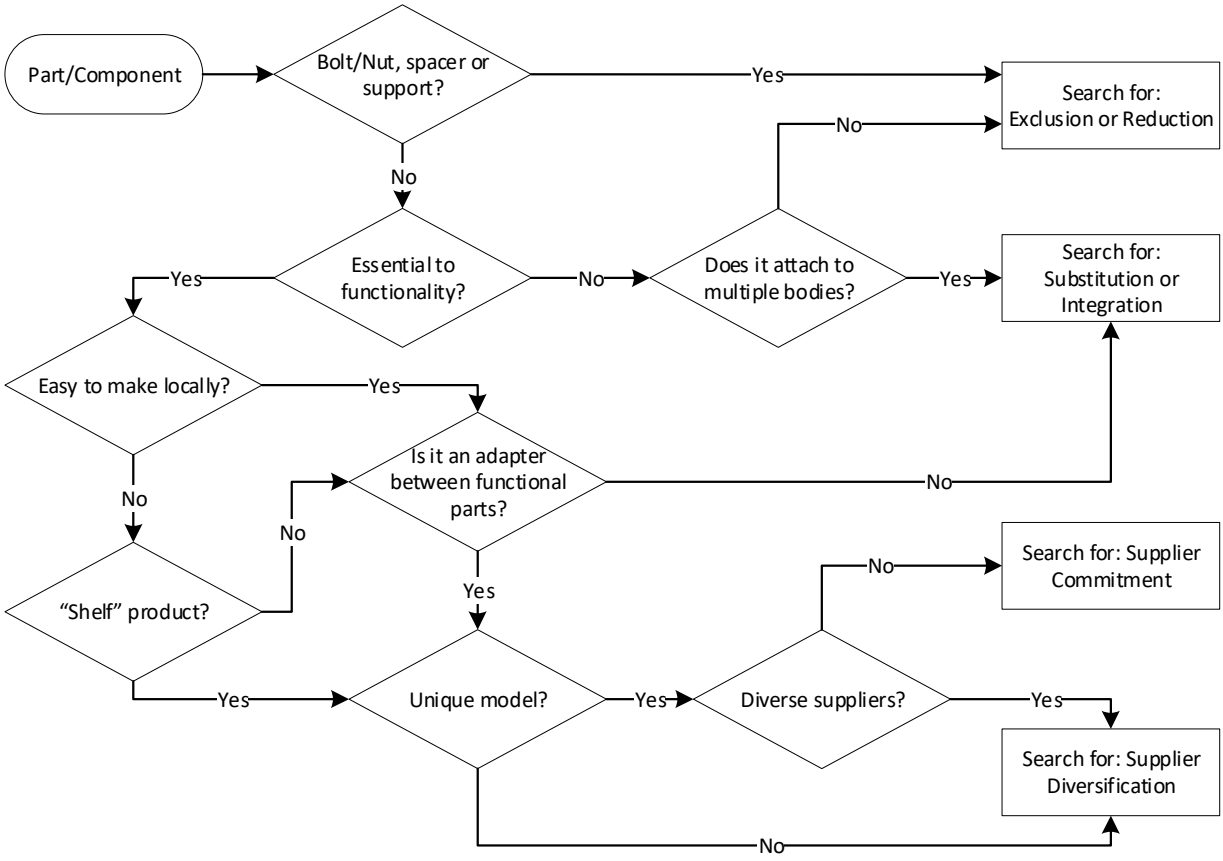

Figure 3. Flow analysis for design directives for components evaluation.

Analysis of each component lead to propositions to replace parts/components all over the original design. Nevertheless, some premises drove the engineering team: maintain same functionalities; not change too much of the design; use appropriate materials for medical use and use reliable materials and components.

This process was followed for all components, but the objective in this paper is to detail the changes and improvements in the end flow circuit of the pneumatic ventilator. It is relevant to not confuse with the end patient circuit that is disposable. The end flow circuit is responsible to measure the air/O2 mixture before entering the patient end circuit. It checks the flow speed pressure, oxygen content. It also has safety features to release high pressure, filter particles and adjust the pressure/flow if not in the correct specification. A schematic flow/control diagram is presented in Figure 4 from the original design. The "Elbow" in the figure represents an integrative part made from aluminum AISI 6061 T4 or T6. Some elements, such as adapters, supports and fasteners are omitted in order to make it simpler to understand the diagram.

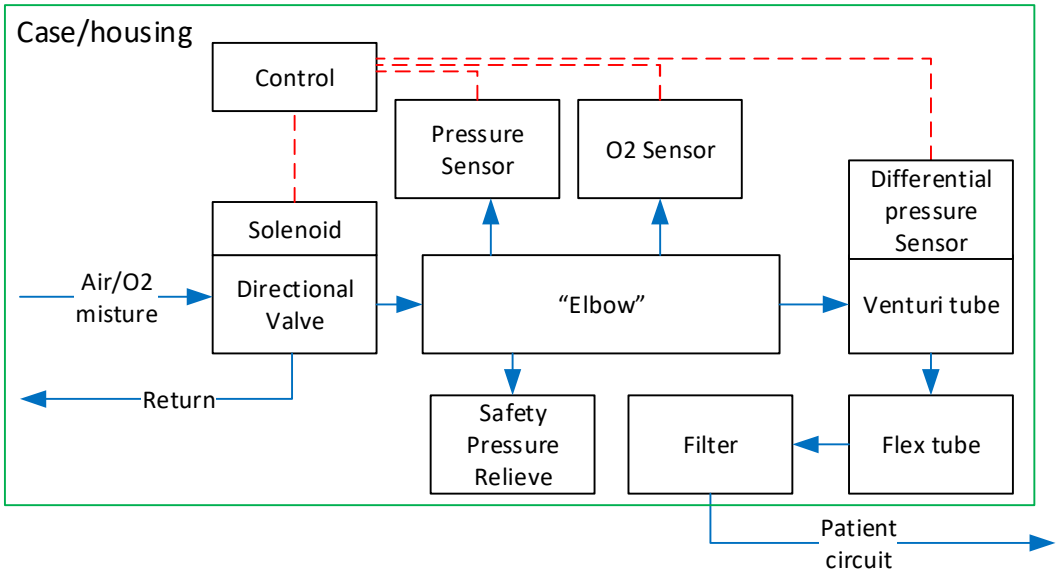

Figure 4. End flow circuit original subassembly of the VITAL project.

3. RESULTS AND DISCUSSION

For the end flow circuit assembly, a new organization of the elements was proposed and applied to de VIDA product. These changes can be seen in Figure 5. The major change was the integration of the "elbow" from the original design. In the original design this part was already an integration part. The new design, the part was integrated also with the flow sensor. The plastic Venturi tube that was a restriction to be supplied of difficult to be made locally, was integrated to the "elbow". The physics of Venturi tube was preserved but all parts were made from milled aluminum blanks and sheets. The significant change was to remove the filter to the external side of the case as this filter is changed frequently. The original design intention was to keep the filter inside the cabinet to force the equipment to regular maintenance. However, it would require large dissemble of the case. In addition, it would not necessarily create a condition to force predictive maintenance, especially on desolated places. Therefore, the local design team changed to outside of the case. Also, a flexible medical grade tube used inside the case to connect the Venturi to the filter was removed. This flextube usually is applied in the external patient end circuit and is disposable. Consequently, due to the high demand it was also difficult to find in the market. The filter was could be connected to the new structure with the Venturi, with or without an adapter depending on the filter model.

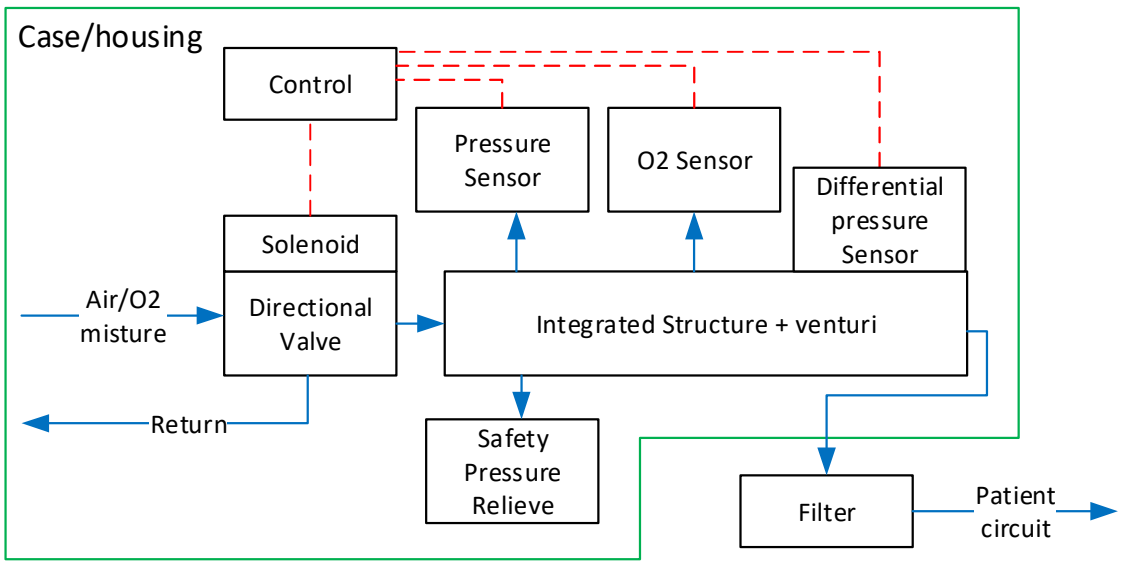

Figure 5. End flow circuit assembly after the design changes.

The new Venturi tube, integrated to the support of the sensors required a calibration. It was performed to correct the deviations from the original design. Figure 6 show the calibration curve to adapt the new design.

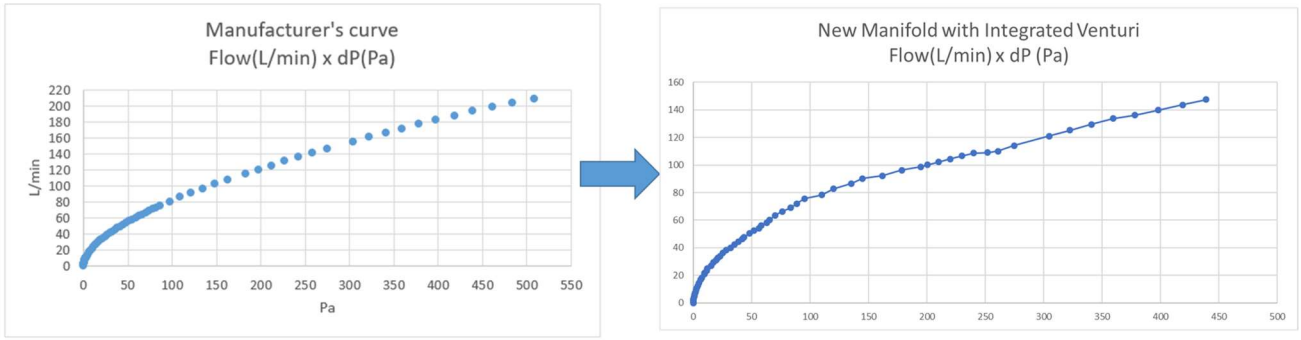

Figure 6. Differential pressures sensor calibration: left, original response curve; right, adjusted curve.

The new local design is present in Figure 7. The original elbow aluminum structure was already milled from aluminum blank. Tree extra aluminum milled parts were made following the same principles from the Venturi plastic tube. They were assembled with screws but to avoid any oxygen leakage inside the case, an especial glue was used. The glue was also approved for the application/ventilator use.

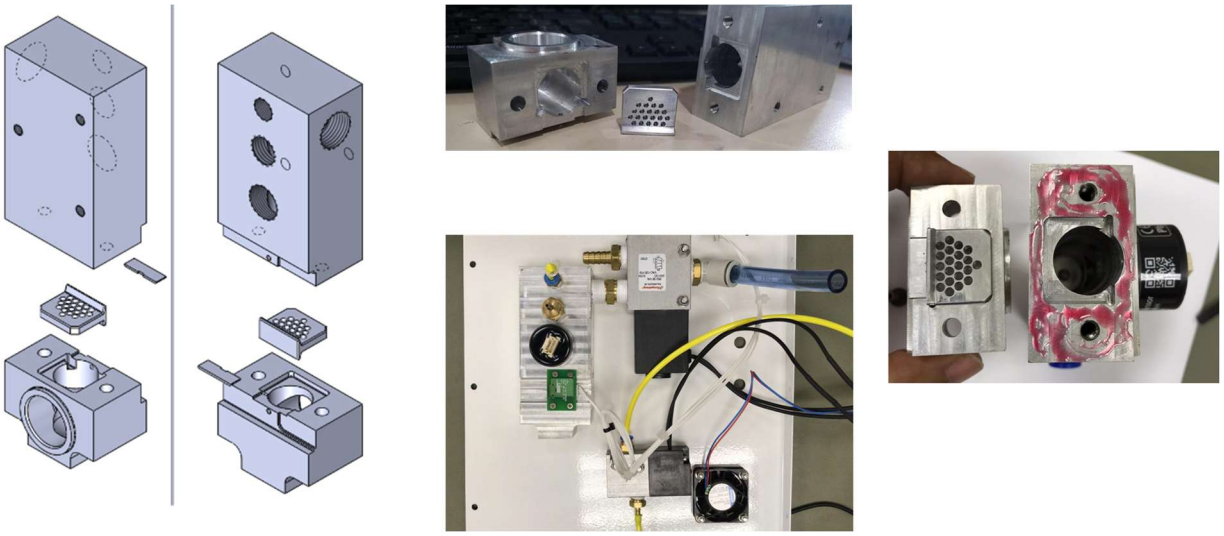

Figure 7. Details in the design and arrangement of the end flow circuit.

The impact on the redesign brought also other advantages. The internal space was increased, promoting heat exchange. It also allowed easier assembly, because more components were assembled in the same side panel and some brackets were suppressed. Of course, changes in the position of other components, like fans and hoses, were performed. These changes are presented in Figure 8 and Figure 9.

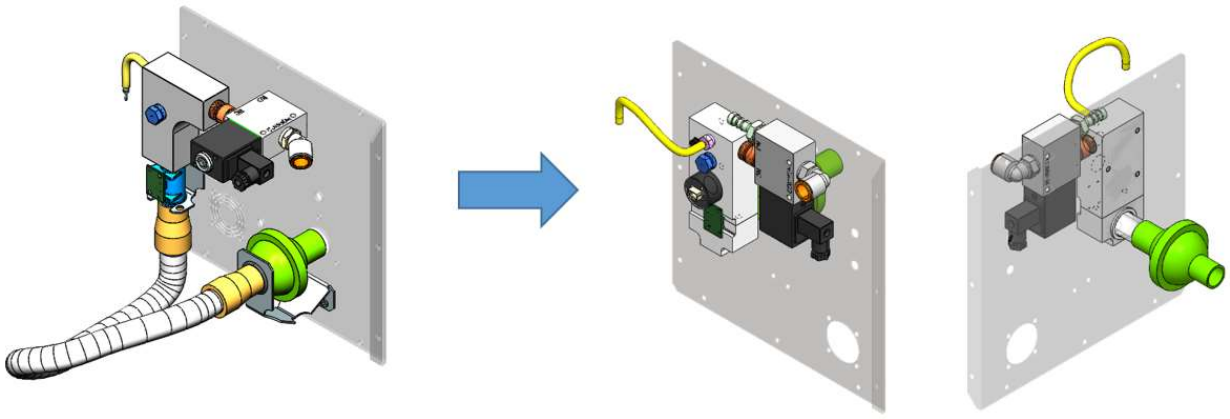

Figure 8. End flow circuit CAD design changes: Left: original design; Right: local design.

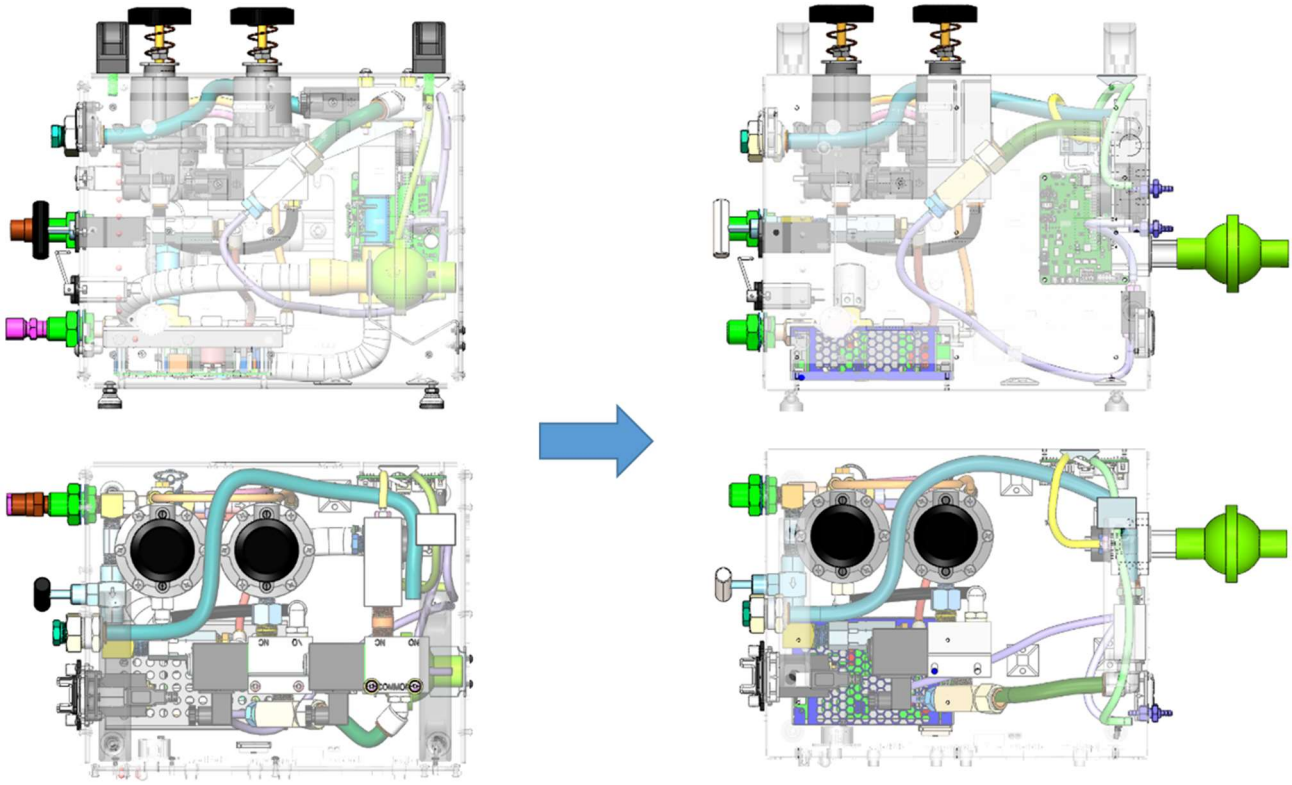

Figure 9. CAD view of the most impacted elements in the design: Left: original design; Right: local design.

The implemented changes reduced some risks in the supply chain for the manufacturing of VITAL pneumatic mechanical ventilator. The procedure followed by the design team helped to quickly evaluate parts and to put energy were it was crucial to deliver a full product to help patients with SARS-COV-2. The project was a success. The partnership between SENAI CIMATEC and RUSSSER do Brasil was the first in the world to produce and to commercialize the VITAL project. The Brazilian version, VIDA, passed some of the certifications tests before NASA-JPL team and helped VITAL licensee's community to move forward on bringing the solution to the market.

4. ACKNOWLEDGEMENTS

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