The Journey of the CSIR L.I.F.E. CPAP Ventilator

Peter A. Bosscha[1*], *and Willis de Ronde*[1]

[1]Centre for Robotics and Future Production, CSIR Manufacturing Cluster, Pretoria, South Africa

Abstract. The development, manufacturing and deployment of a South African engineered Continuous Positive Airway Pressure Ventilator is described. The CSIR L.I.F.E. (Lung Inspiratory Flow Enabler) Ventilator was developed during the COVID Pandemic in response to the need for a ventilator solution to assist patients suffering from respiratory distress. A supply chain was created resulting in a near fully locally sourced product of which 18,000 units were manufactured and distributed to hospitals throughout South Africa.

1 Introduction

In January 2020, the World Health Organisation (WHO) declared the COVID-19 outbreak a global health emergency [1], and this escalated in March to the declaration of COVID-19 being a global pandemic [2]. The seriousness of the situation resulted in governments world-wide severely restricting not only the movement of people, but also that of medical supplies [3] necessitating the creation of local solutions for the required medical interventions.

Especially with the first variants of the virus the lungs of patients were affected such that they suffered from shortness of breath, low blood oxygen and eventually respiratory distress. Detailed studies [4] have since confirmed that the use of non-invasive ventilation for patients that display mild to moderate Covid-19 symptoms can lead to improved patient recovery

The South African National Ventilator Program (NVP) [5] was created to select and support a suitable locally manufactured Continuous Positive Airway Pressure (CPAP) Ventilator [6] which would be low-cost and simple to use in South African Hospital settings. South Africa traditionally imports over 90% of its total medical supplies [7], and therefore during the Covid-19 crisis the need for locally manufactured non-invasive ventilators was identified by the NVP call.

A team from the Centre for Robotics and Future Production (CRFP) which is part of the Council for Scientific and Industrial Research (CSIR) had already commenced with their own ventilator developments. The CRFP's final design was, after several national elimination rounds, eventually selected by the NVP technical team as one of the ventilator solutions that would be produced and distributed.

* Corresponding author: pbosscha@csir.co.za

The South African Health Products Regulatory Authority (SAHPRA) instituted a special Pandemic ruling [8] which allowed for a rapid certification process of medical devices for use during the Pandemic. Nevertheless, this process still demanded extensive documentation to be in place supporting the design and detailing performance of the solution. With some minor clarification and rework of documentation, the CSIR L.I.F.E. (Lung Inspiratory Flow Enabler) CPAP Ventilator was approved by SAHPRA under emergency regulations, opening the door for a manufacturing and distribution cycle to commence.

We describe in this paper the engineering efforts in creating the ventilator solution, whilst in parallel a large multi-disciplinary team drawn from various groups inside and outside of the CSIR was involved with product documentation, medical approvals, production planning, execution, and distribution. In addition, the overall project included the creation of training videos, online assistance in the form of an automated WhatsApp-bot and web presence, and even the establishment of a staffed call-centre for support.

2 Methodology and Results

The Methodology and Results section describes the engineering processes followed to achieve the eventual CSIR L.I.F.E. CPAP solution. This includes the requirements process, project management and system engineering, development process, testing, and eventual production.

2.1 Requirements

In the early days of the pandemic, many engineers started designing and publishing ventilator solutions, such as the ever popular 'automated bag valve' concept [9], and many other schemes that seem usable to the layperson or even engineer, but which have many practical issues when used in a hospital setting.

Similarly, the CSIR team had to go through a steep learning curve to understand what the actual needs and issues were. Several anaesthesiologists were able to assist, from both a practical need and usage but also to comment on the criticality and tolerances of some of the specifications.

It was clear that any design had to follow a clear set of requirements such that the solution would be usable and appropriate for the needs of the medical personnel.
The main requirements for a CPAP Ventilator came from the NVP specification [10] as well as the UK Medicines & Healthcare products [11] specifications. From the list of requirements, the following key needs can be highlighted, where the solution must:

- use and be compatible with existing Oxygen supplies in Hospitals
- be able to supply an adjustable mixture of Oxygen and Ambient Air
- be able to maintain an adjustable Positive End-Expiratory Pressure (PEEP)
- supply patient flow levels appropriate for high flow oxygen therapy
- be a complete offering, not only a ventilator but also a full patient circuit consisting of coupling hoses, mask, and filters.

The demands for flow vs. oxygen levels were not stated in the original NVP call, but in discussions with several experts this settled on a need for high gas flow therapy and

performance similar to venturi-based CPAP devices such as the Philips Respironics Whisperflow [12].

Figure 1 shows some of the advertised performance of the Whisperflow, but this specification is unclear in places as it does not mention behaviour of the device when invariably a less than ideal Oxygen pressure is available in the Hospital setting, and the graphs give data at different operational settings which are not necessarily linked to each other.
In addition, there have been cautions made in literature: Glower et al. [13] made assessments of actual performance of such a device, where less than optimal results were found.
The advantage of being able to refer to the Whisperflow was in the product documentation and resulting medical certification application of the L.I.F.E. CPAP, where reference could be made to a predicated device, as the operating principles are similar.

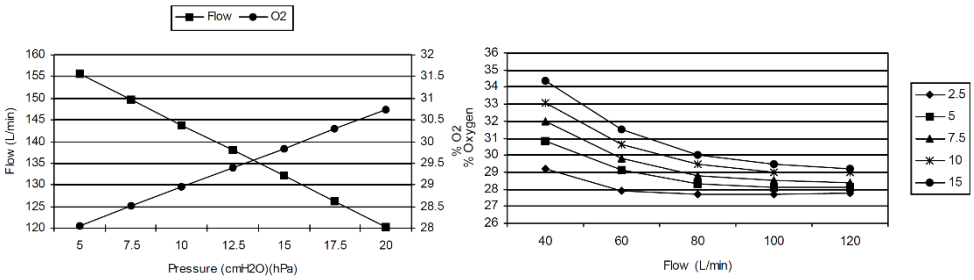


Fig. 1. Whisperflow performance; Flow vs. PEEP and min. achievable O_2 at different PEEP settings

During evaluation of the ventilator, critical factors were especially the performances of the CPAP's minimum oxygen delivery and its maximum flow delivery at different PEEP settings.

2.2 Project Management and System Engineering

The NVP call for proposals came out on the 3rd of April 2020 with a closing date of the 6th of April 2020, and from there on the timelines were extremely tight, requiring a daily project management process. An initial project plan was drafted to note the overall milestones, but during the running of the project many of the details were captured and managed using a Kanban [14] system.

The total timeline for the project from the NVP call for proposals until production can be seen in Figure 2.

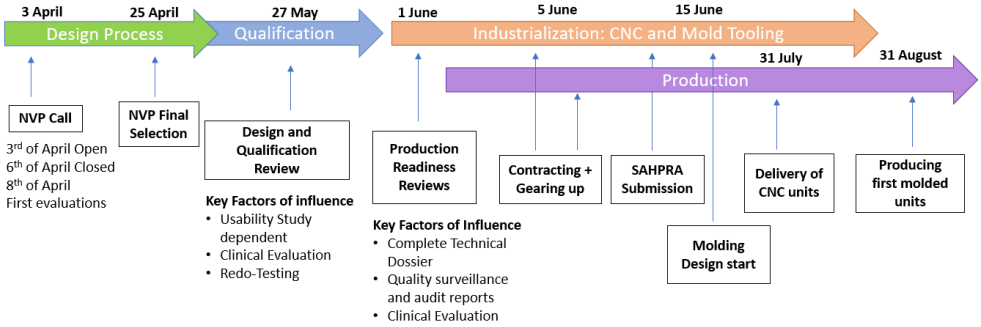


Fig. 2. Project Timeline from call for proposals until production roll-out

A typical V-Model Systems Engineering [15] process was followed. Figure 3 shows the version as used by CRFP, where a highly detailed requirements specification was compiled with inputs from several requirements specifications. The requirement specification was matched by an equally detailed verification specification which included specifications of test bench configurations, such that any design could be verified against all requirements. Sub-assemblies of the ventilator had their own requirements and acceptance test documentation. All requirements documentation, design documentation, Computer Aided Design (CAD) files and medical documentation pack were managed and coordinated through the Product Lifecycle Management (PLM) tool known as Siemens Teamcentre [16], which allowed centralised version-controlled project information.

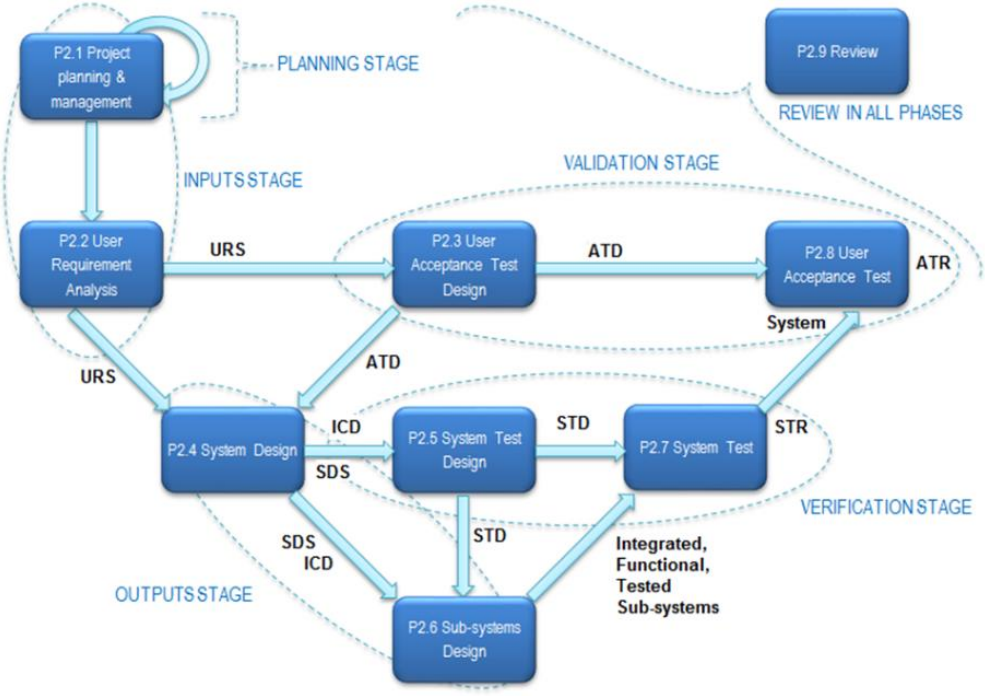


Fig. 3. CRFP System Engineering V-Model

2.3 Development Stages

Several stages of development are described in this section, starting with design through to the eventual final moulded design.

2.3.1 Design

The total ventilator solution needs to provide a gas mixture to the patient, where the oxygen to air ratio can be adjusted, at different flow settings and different Positive End-Expiratory Pressure (PEEP) settings. All these settings will be adjusted by medical personnel as the therapy on a patient requires. The additional oxygen in the gas mixture assists with achieving required blood oxygen levels and the PEEP assists in keeping the lungs inflated, assisting in better gas absorption.
An anti-asphyxiation valve is included in the circuit, which is intended to allow the patient to breathe should the oxygen supply fail. Also included is an overpressure relief valve if for any reason a pressure greater than 25cmH_2O is applied to the patient circuit.

As stated in the requirements, the solution will be used in a hospital setting, most probably in a COVID ward, where oxygen is available from the hospital supplies. The use of this ventilator is aimed at assisting patients such that they do not further deteriorate and need to be placed in high-care or Intensive Care Unit (ICU).

The CPAP Ventilator, also known as an air blender, works on the venturi principle, as shown in figure 4, where oxygen flow is used to entrain ambient air, and the gases are then mixed. The configuration of mixing chamber, venturi needles and specially shaped inlet valves and the outlet shape combine into a design that ensures the design meets the required performance in terms of total gas flow and fraction of inspired oxygen (FiO_2).

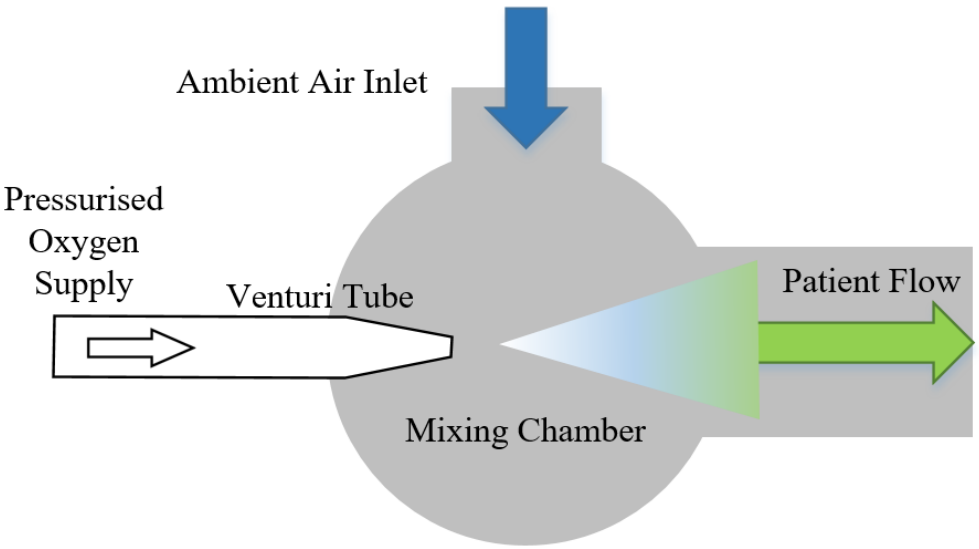


Fig. 4. Venturi System – Air Blender

The design and production of the CSIR L.I.F.E. CPAP Ventilator body followed several stages of development, from a variety of prototypes through pre-production models, a limited run machined production version and eventually an injection moulded production version.

Because of the urgency of the situation, rapid iterative cycles were followed where fluid dynamics simulations and experimental testing of physical models was combined.

The initial design was loosely based on the looks of the British UCL/F1 Ventilator [17] design which in turn was based on older designs, but from the start used own design for the internal functions. Designing the solution ourselves gave benefits both in functionality as well as in manufacturability, as the UCL/F1 design required a high part count and a complex assembly process.

From the requirements listed in the sources, the inspired oxygen (FiO_2) proportion should be adjustable between 30% and 100%, with PEEP levels adjustable between 5cmH_2O and 25cmH_2O. The flow requirements were not clearly defined, but in discussions with medical experts were agreed to be at the very least 30 l/min at all FiO_2 and PEEP settings.

To achieve these performance goals, use was made of Computational Fluid Dynamics (CFD) to guide the design. Calculations were initially performed by CSIR experts from the Aeronautics Systems group using the STAR-CCM+ package. The highly detailed CFD process required many person-hours to achieve the intended results, where CAD needed to be imported and then translated into a model with which the software could work. During later design stages of the project, simulation was done using the SolidWorks CFD plugin known as FlowEFD. The outcomes of the SolidWorks simulation, whilst not being as detailed, gave results that matched the STAR-CCM+ calculations whilst allowing for very rapid iterations of the design. Figure 5 shows the graphical representations of the STAR-CCM+ and FlowEFD outcomes.

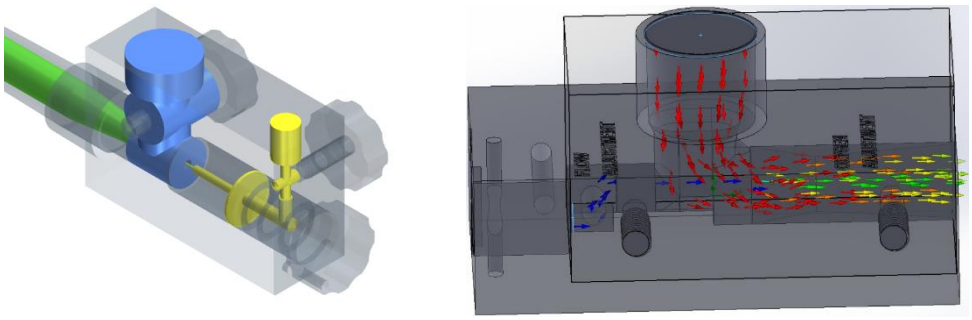


Fig. 5. CFD Models; STAR-CCM+ left, FlowEFD right

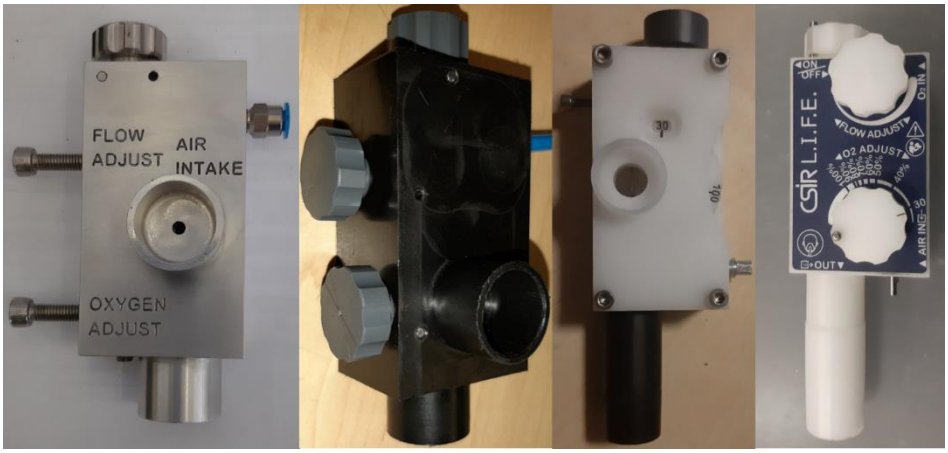
2.3.2 Prototyping

Especially during the first weeks of the COVID-19 lock-down when only a few suppliers were active, any materials were difficult to come by. Therefore, the very first complete prototype version of the L.I.F.E. CPAP was machined in aluminium as that material was at hand. Where needed, several plastic inserts were used in this design to achieve the intended functionality. The aluminium model was used as an initial trial prototype to test the overall concept and its performance, but at the same time this material is not suitable in medical settings due to oxygenation of the material. The first prototype with an aluminium body is show in Fig 6a. Therefore, the next iterations of the design were machined using the medically approved material known as Acetal [18], a model using this material is shown in

Fig 6b. Initially this material was only available in black colouring from suppliers, but later models were manufactured in white to make contamination more easily visible.

The prototype physical models were created using a combination of in-house CNC machining and creation of some of the parts using a Flashforge Guider 2 series 3D printer [19] in Polylactic Acid plastic (PLA) material. Using this prototyping methodology allowed for a very quick and flexible work style, with near daily iterations and ideas being tested.

As iterations progressed, different approaches to valve operations and positioning were attempted. In one version, shown in figure 6c, a different concept FiO_2 valve operation was attempted. All these experiments and concepts narrowed down to a stable design, with final iterations of the prototypes given more attention towards manufacturability of the design. From the beginning of the developments until a production ready CNC model a total of 13 revisions were created, the final pre-production prototype is shown in figure 6d.



(a) (b) (c) (d)

Fig. 6. Several iterations of CPAP Concepts

2.3.3 Production Versions

Because of timing constraints and volume requirements, the initially chosen manufacturing methodology consisted of the production of sub-assemblies using CNC machining which were created at three separate suppliers' workshops. In this manner the first batch of 1000 CPAP units were manufactured using CNC production methods.

It was clear though that for reasons of cost and delivery deadlines the required high volume of ventilators could not be produced using CNC manufacturing as a methodology, and it was decided to iterate the design further to an injection moulded solution. The decision to do so was made easier when a mould maker and plastic converter partner was located who was willing to put in significant effort as well as being able to speed up the process by having available existing toolsets. Traditionally, a mould design in South Africa takes many months to achieve, but in this case a turn-around time of 6 weeks was achieved for the very first samples; initial design started in mid-June 2020 and samples were received on the 1st of

August 2020. The original approval from SAHPRA was based on the CNC model, but type approval was also obtained for the moulded version.

The change from a CNC based model to moulding design is not a trivial exercise as many parameters change. Instead of a solid block of material that is machined, an injection moulded design follows a specific shape requiring minimum wall thickness to avoid sagging, and the shapes of valve designs and other ports are changed to a tapered shape to allow for release out of moulds. Figure 7 shows the final CNC and moulded solutions side by side. To the casual eye the units look identical, and indeed the functionality and placement of controls is identical. However, some differences can be seen in actual construction; a slightly wider moulded body, the use of dowel pins in the knobs of the CNC version, the metal vs. plastic 'hook' for suspending the unit from a drip stand and the inverted On/Off operation. The On/Off operations was changed in the moulded version based on comments made during review sessions with the NVP technical committee.

Fig. 7. CSIR L.I.F.E. CPAP, CNC (left) vs. Moulded (right) model

Daily interaction between mould maker and design team resulted in a rapid development of the mould design. To test this design before committing to cutting the tool steel, a high-resolution Formlabs - Form2 - 3D resin printer [20] was used to rapidly create parts as they would be produced from a mould, and these parts could then be tested to verify whether they would perform as required when integrated into the total design, a sample of this process can be seen in figure 8. Typical creation time for a total ventilator parts print job was in the order of 17 hours, but this was still very much worth the time spent to verify correct functionality of the final product.

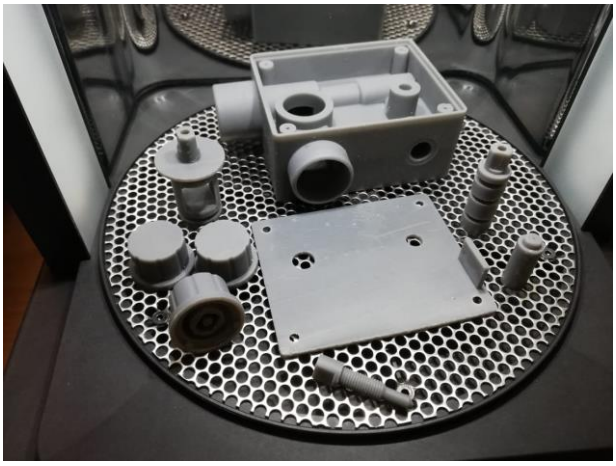


Fig. 8. Printed parts produced by the resin printer

Further improvements were made by making the venturi part of the mould. Whereas in the CNC model the venturi needles were bought out hollow needles which were fitted to a plastic block during manufacturing, this production step was eliminated through the injection moulded design which changed this to a moulded insert, easing manufacturability even further. A total of nine CAD iterations resulted before finalisation of the tooling design.

2.3.4 Final Moulded Design

During production, various materials were used for the final moulded model as shown in Figure 9.

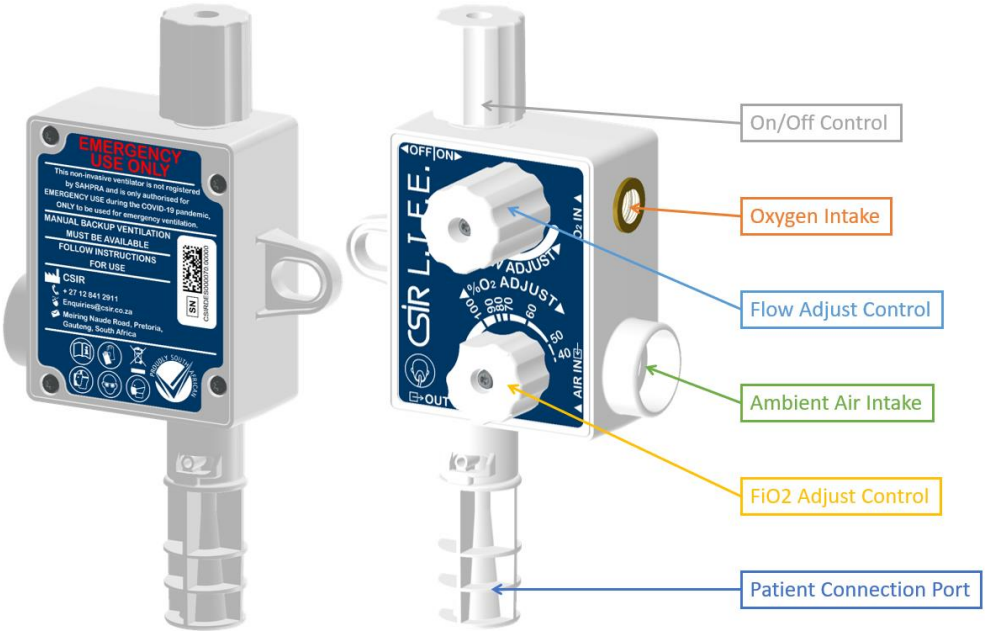


Fig. 9. CSIR L.I.F.E. Air Blender back and front

The top and bottom lid parts of the moulded design were made from a polycarbonate material [21], whilst the internal parts in contact with oxygen flow were produced out of medically approved acrylic material.

2.4 Testing

Verification of the performance of the system was done in different settings, both in the CSIR laboratory as well as externally by an independent testing laboratory. During initial development, tests were done against simple pressure and flow sensors as well as against a test dummy as shown in figure 10.

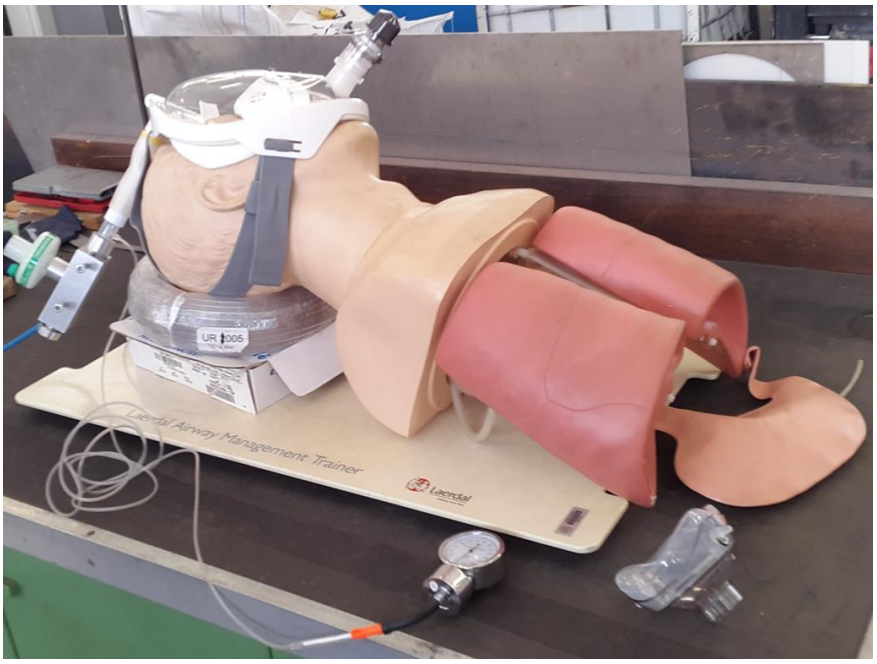


Fig.10. Ventilator and mask testing against test dummy

This method is fine for very static tests, but a more detailed test apparatus was required and use was made of a borrowed ventilator analyser system known as the IMT Analytics Citrex H4 [22], whilst another instrument known as Certifier Flow Analyzer Plus [23] was procured. The Citrex H4 was used initially whilst waiting for delivery of the long lead-time procured system.

Numerous test data was captured at many different settings of flow, input pressure and patient PEEP values. The graphs shown in figure 11 show one such set of data, where FiO_2 is measured as a function of Flow Rate at different PEEP settings. The result indicates acceptable performance of the FiO_2 dial against the original requirements at the typically used flow rates, which enabled operation of the ventilator in a general ward without a separate in-circuit oxygen sensor.

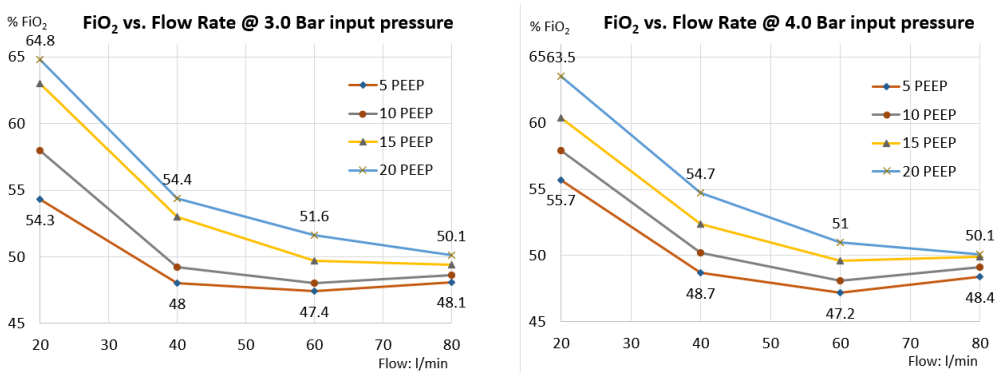


Fig.11. Ventilator FiO_2 performance under varying input conditions at 50% setting

2.5 Localisation Efforts

In parallel to the ventilator body design and development efforts, a local supply chain had to be developed for many of the additional components required. As stated in the requirements, the solution had to be a complete offering which could be used in a hospital setting without any additional equipment requirements, which meant that aside from the described ventilator body, solutions needed to be found for the patient mask, filters, hoses, couplers, valves, and many other small components. The overall delivered system can be seen in Figure 12.

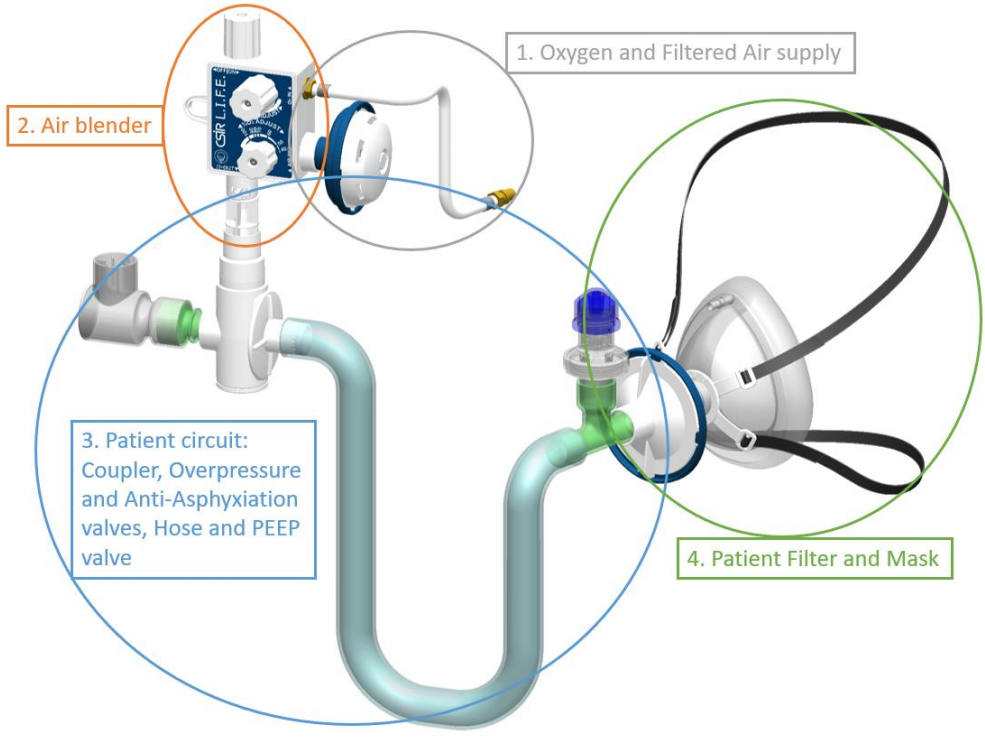


Fig. 12. Complete CSIR L.I.F.E. CPAP delivered system

During the process of building up the local supply chain, it became clear that South Africa relies to an exceptionally large degree on imported goods in that area. Solutions needed to be found for Oxygen Hose, Filtering, Couplers, and many other small components. Several local manufacturers stepped up who traditionally would not even supply medical components, and they were able and willing to create new or adapt existing solutions for the purpose.

When a patient is put on a ventilator, the patient filter (section 4 in Fig 12) in the circuit needs to be swapped out on a 24-hour basis, and each patient circuit needed to be supplied with sufficient filters for two patients to last at least 30 days. For the total volume of produced systems therefore, this adds up to more than 1 million required filters, something that was not available from the usual international sources.
In response to this need, the Central University of Technology (CUT) was able to design a filter solution for the ambient air entrainment circuit as well as the patient filtering. In this solution the filter holder could be opened and the filter material, which was available locally, could be replaced.

Another supplier, traditionally in the diving industry, was able to provide a coupler assembly which combined the fittings for overpressure valve, anti-asphyxiation valve (needed if oxygen supply fails) and coupling to the patient hose and ventilator device.

The hose that transports Oxygen to the ventilator falls under very strict guidelines defined in several International Standards Organisation (ISO) specifications. After some failed attempts, a supplier was found that was able to supply at the correct quality and requirements. This hose is traditionally imported from a single factory in the United State of America.

An adjustable PEEP valve was designed by a separate consortium, and this was fitted and made to work on the CSIR L.I.F.E. CPAP ventilator. This same consortium made a fixed PEEP valve set for 25cmH_2O which was used as an overpressure safety valve in the system.

Localisation of supplies was not always successful. Several efforts were made to obtain or create a mask solution, where diver masks and several Personal Protective Equipment (PPE) masks were tried out, but in the end no satisfactory solution could be found, as all these solutions are not designed to work with an overpressure inside the mask. A hooded solution was also attempted, but time ran out to make this production-ready. The ventilator mask was one of the very few items which had to be imported from several sources around the world.

2.6 Production ramp-up Processes

An ISO-13485 (Medical devices -- Quality management systems) accredited facility was found which was able to integrate the ventilator parts, as they were being manufactured in several places around South Africa, into a complete solution where each ventilator was tested on performance as part of the production process.

Production flow and testing procedures had to be developed in conjunction with the manufacturer for which an entire separate team was established. Test procedures with relevant equipment were established for the various manufacturing stages. Where not standardly available, specialised solutions were developed.
One example of a specialised solution was the creation of several flow/pressure/oxygen testers that were used on the production line to verify correct performance of the assembled systems. These purpose-built instruments were calibrated against the official ventilator tester,

which then gave sufficient accuracy on the production line to allow testing against the factory acceptance test documentation where a minimum performance requirement was described. The test devices consisted of a specialised bought out flow/pressure sensor assembly specifically intended for ventilator use, custom electronics and a 3D printed enclosure, and can be seen in Figure 13.

Fig. 13. Rapidly created production line Flow / Pressure / Oxygen Tester

As well planned as the production process was, there will always be unforeseen problems that occur. Traditionally this is resolved through ramping up production from small batches, through to larger quantities, but in this case due to the delivery pressures insufficient time was available to follow this pattern, and as a result problems that occurred on the production line had to be resolved as they occurred.

One example of these problems was the specialised screw parts which formed the innards of the valve assemblies in the designs which were custom CNC manufactured for the product during production. Initially specified as 316L stainless steel, due to material availability issues this was finally manufactured using 303 stainless steel and this resulted in an unfortunate oxidation process taking place. To achieve required medical grade parts, additional rework production steps had to be implemented, specifically ultrasonic cleaning and electro polishing.

3 CONCLUSION

The urgency of the situation created a willingness in many people, companies, government, and other entities to put in significant effort and get to a workable solution in much less time than traditionally would be the case.

For the development teams, not only the CSIR but external entities as well, normal working hours turned into nights and weekends, as the NVP set very tight deadlines to meet the medical requirements. Rather than responding with resistance, these teams embraced the opportunity to be of assistance to the needs of the South African population.

The requirements for the CPAP ventilator set by the NVP specification were met in their entirety, this was verified in various laboratory settings and confirmed in several technical review meetings held between the NVP technical team and the CSIR development team.

From the start of the design to the production of the last unit a total period of 9 months elapsed, with first units produced and delivered in July of 2020. The fast time interval shows that a rapid response to resolve a crisis in South Africa is possible and that the required design tools, skills sets, and equipment are all available and can be coordinated to produce the desired resolution. In total 18,000 complete solutions were manufactured and distributed throughout South Africa, where the last units were manufactured in December 2020. The responses from doctors, ward sisters and other medical personnel have been overwhelmingly positive as the CPAP unit was easy to use and required little training.

Aside from the huge effort in resolving the technical aspects, another reason for the rapid success was the removal of the traditional obstacles such as procurement rules, which were addressed through an emergency procurement ruling and SAHPRA's implementation of a fast-track process under emergency pandemic rules which made the medical approval process much easier and rapid.

This paper has shown that with the use of modern design tools, structured design processes and manufacturing techniques it is possible to rapidly create a locally designed and produced ventilator solution which has saved many lives throughout South Africa. The decision to make the move from a CNC model to a moulded design was met with resistance but was eventually proven correct when the number of deliveries started ramping up.

References

1. Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV): https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)
2. WHO, Virtual press conference on COVID-19 – 11 March 2020 , https://www.who.int/docs/default-source/coronaviruse/transcripts/who-audio-emergencies-coronavirus-press-conference-full-and-final-11mar2020.pdf
3. WTO report finds growing number of export restrictions in response to COVID-19 crisis: https://www.wto.org/english/news_e/news20_e/rese_23apr20_e.htm
4. Zachary P. Sullivan, Luca Zazzeron, Lorenzo Berra, Dean R. Hess, Edward A. Bittner & Marvin G. Chang, Noninvasive respiratory support for COVID-19 patients: when, for whom, and how?, Journal of Intensive Care, **Volume 10**, Article number: 3 (2022)
5. National Ventilator Program Call: https://www.sarao.ac.za/media-releases/sarao-mandated-to-manage-the-production-of-respiratory-ventilators

6. Continuous positive airway pressure, https://en.wikipedia.org/wiki/Continuous_positive_airway_pressure
7. The Medical Devices Landscape in South Africa , https://www.samrc.ac.za/sites/default/files/files/2022-03-30/SAMRCMedicalDeviceLandscapeReport2022.pdf
8. MD010: Regulatory Requirements, Technical Specifications, Licence Conditions and Authorisation for Use of Unregistered Rapidly Developed Invasive and Non-Invasive Ventilators for Covid-19, https://www.sahpra.org.za/wp-content/uploads/2020/05/MD010_Guidance_Rapidly-developed-ventilators_26May2020_v1.pdf
9. A.Petsiuka, N.G.Tanikella, S.Dertinger, A.Pringle, S.Oberloier, J.M.Pearce, *Partially RepRapable automated open-source bag valve mask-based ventilator*, HardwareX, **Volume 8**, October 2021, Pages e00235
10. NVP Specification: SSA4003-0009-000, http://www.thedti.gov.za/news2020/CFP_NVP.pdf
11. Rapidly Manufactured CPAP System, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956346/Specification_for_RMCPAPS.pdf
12. Philips Respironics Whisperflow, https://www.usa.philips.com/healthcare/product/HC820860300/whisperflow-variable-generator-usa-whisperflow
13. G. W. Glover, S. J. Fletcher, *Assessing the performance of the Whisperflow® continuous positive airway pressure generator: a bench study*, in BJA: **Volume 102**, Issue 6, June 2009, Pages 875–881
14. Kanban (development), https://en.wikipedia.org/wiki/Kanban_(development)
15. V-Model Systems Engineering, https://en.wikipedia.org/wiki/V-Model
16. Siemens Teamcentre, https://www.plm.automation.siemens.com/global/en/products/teamcenter/
17. UCL / F1 Ventilator, https://www.ucl.ac.uk/healthcare-engineering/covid-19/ucl-ventura-breathing-aids-covid19-patients/accessing-ucl-ventura-cpap-nhs
18. Acetal Material Datasheet, https://ravagosp.com/DATASHEET/POM/KEPITAL/KEPITAL%20POM%20F20-03%20(BLACK).pdf
19. Flashforge Guider 2 series 3D printer, https://www.flashforge.com/product-detail/flashforge-guider-2s-3d-printer
20. Formlabs, Form2 3D Printer, https://formlabs.com/3d-printers/form-2/
21. Polycarbonate molding material, https://www.sabic.com/en/products/popup.html?q=PC1804R&grades=fc015952-bb19-e711-80fb-005056857ef3
22. IMT Analytics Citrex H4, https://www.imtanalytics.com/en/Analyser/CITREX_H4
23. Certifier Flow Analyzer Plus, https://tsi.com/products/certifier-flow-analyzers/certifier-flow-analyzer-plus/