EMERGENCY BIPAP VENTILATOR FOR BREATHING ASSISTANCE

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Abstract

The paper proposes the concept of a simplified ventilation device that meets the requirements for the South African Health Products Regulatory Authority (SAHPRA) approval and may be manufactured in large numbers at moderate cost to meet the requirements of the current or future pneumonic type pandemics. The paper further describes the development of such a device and presents descriptions of the final prototype.

The philosophy behind the design was to take an engineering view of the problem of safe ventilation, which also meets World Health Organisation (WHO) guideline 'Technical specifications for invasive and non-invasive ventilators for COVID-19' (2020), whilst using the human biological responses to control the aspiration boundaries, thereby avoiding the very complex processes which simulate the breathing mechanism.

The methodology employed was a conceptual design phase followed by an engineering design phase, prototyping, testing, and further developments. The concept was based on guidelines from WHO, 2020: Technical specifications for invasive and non-invasive ventilators for COVID-19: Interim guidance: paragraphs 2.1.2 and 2.2.2.(2020) and measured against the UK standard of the Medicines and Healthcare Products Regulatory Agency (MHPRA) 'Rapidly manufactured ventilator system' (2020). Each component of the conceptual design was developed in this way and a final prototype was assembled for independent evaluation and eventual SAHPRA evaluation.

The finished prototype meets WHO guidelines for a Bi-level Positive Airway Pressure (BiPAP) system and also meets the guideline requirements for portability. The prototype also meets the initial intent regarding simplicity, functionality and cost. The further developments to mass production will reduce the part count and assembly processes, with some components to be reconfigured as disposable items, not for sterilisation or re-use. The project has shown that specialised equipment may be viewed pragmatically according to the requirement — to treat all breathing difficulties with a full specification ventilator is not possible or necessary; to assist the majority of ostensibly minor cases with a Bi-PAP system is both practical and more affordable. The intent is not to compete with the high technology commercially sourced equipment, or even the rapidly prototyped re-purposed industrial efforts worldwide, but rather to initiate some progress in the Republic of South Africa to quickly produce an abundance of these machines, to cope with the possible deficit of medical ventilators expected in future.

The solution lies in a simple but failsafe device that provides assisted breathing with the option of oxygen enrichment. It is intended to be locally manufactured with the minimum of skills and is easily maintained and sterilised.

Keywords: COVID-19; Bipap Ventilator; Pneumonia; Pandemic

1. INTRODUCTION

A ventilator device is presented which was conceived by the author during the Novel Coronavirus Pandemic (COVID-19) Level 5 lockdown of 2020, and developed to full prototype as part of a ventilator challenge hosted by the Manufacturing, Engineering, and Related Services Sector Education and Training Authority (merSETA) to develop medical device manufacturing skills in RSA.

Figures released by WHO on their website during February and March 2020, World Health Organisation COVID-19 Statistics (2020), at the initial stages of this project, indicate that the number of COVID-19 infected persons requiring hospitalisation at that time was 15% of all infected, a subset of 5% to 6% experienced lung dysfunction of such a severity that high care attention was required, which in most cases includes mechanical respiration assistance. Sadly, a percentage of these serious patients succumbed to the pneumonic effects of the infection. This subset of fatalities was dependent on many factors, stated within the limits of 0.9% and 3.4%. Considering that the majority of the

hospitalised cases recover with assistance, it was estimated by the author that, should assisted breathing facilities not be available due to excessive requirement, the proportion of patient mortality would edge closer to the 5% of cases identified, a significant percentage of the populace. During the second and larger wave of infections of the pandemic during early 2021, the above fatality rate indeed exceeded 6% of confirmed cases in some provinces. Fortunately, this figure was offset by several rapidly adopted treatment methodologies and practises, such as early high flow Oxygen treatment, the essential addition of a Post Exhalation Excess Pressure (PEEP) device in assisted respiration, and the placement of the patient in the prone position. The third wave of this pandemic and a modified variant of the original virus now accounts for unprecedented numbers of infections and fatalities.

An article published in The Daily Maverick by The Scientists Collective, titled 'All you should know about where we are with Covid-19 vaccines' (2020) on 21 December 2020, poses the case for population immunity being possible once 60% to 70% of the populace has gained immunity either through vaccination or having survived an infection, Gray *et al.* (2020). Further insights from this August collection of authors state that population immunity is most unlikely due to the high infectiousness of the virus and its ability to mutate readily. Their article published on 15 August 2021 provides some insight into the most likely future scenarios where sufficient population immunity exists to cause the virus to become another seasonal influenza-like consideration. For now, the Delta variant provides present statistics of infectiousness and mortality. Considering a worst-case eventual infection tally of 70% of the populace, (natural infections offset by the numbers of vaccinated persons, generously assuming equal numbers of both types), which approximates the figure required for sustained low numbers of new infections, RSA stands to see around 21 million natural infections. Using the median 5% fatality statistic implies a million potential fatalities over the previous and future 'waves' of infection. The possibility of re-infections is excluded from the above scenario, as well as more serious later mutations of the virus, and serves to amplify the magnitude of the problem.

In the face of this and possible future waves or new pandemics, a simplified human ventilation device that could be used outside the hospital environment could save many lives in the RSA. Such a device would need to be functionally effective, should be re-usable for many patients, requires several power supply options, should have a long life and should be mass-produced using readily available materials. This device is intended as a medical equipment capital item, intended for long-term use with a capital depreciation life of five years, although further development may result in disposable valve components as an alternative to the conventional system of maintenance comprising stripping, servicing and sterilisation.

A device as envisaged above has been developed to the prototype stage and is reaching readiness for evaluation. The stages and development phases are presented in the article. The article is a summary of many previous and frequently updated notes, resulting from a concept for a machine that was originally conceived by the author during the lockdown period of April 2020 and the subsequent months.

2. METHOD

The journey from the initial idea to the final product requires a methodology that follows the following sequence.

2.1. Conceptualisation

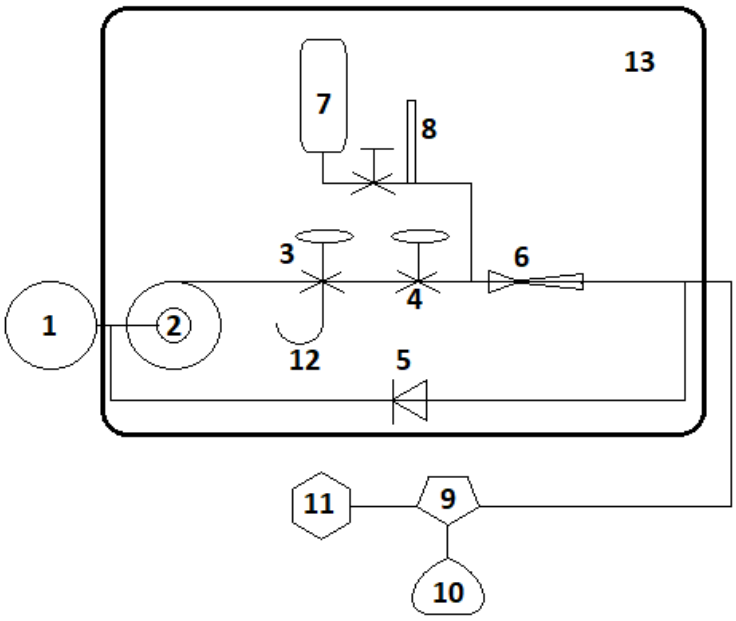
An idea is extended into a description and the description is further expanded to include numerical, dimensional and other tangible descriptors to form the performance criteria.

This description is then ratified by comparison to known requirements or standards and constraints by legislation to form a conceptual design. To create a useful concept, the ventilator requirements were based on the World Health Organisation guideline as well as the UK specification by the Medical and Healthcare products Regulatory Agency for a Rapidly Manufactured Ventilator System.

2.2. Engineering design phase

The concept above is further expanded into engineering terms, which will eventually dictate materials, dimensions and performance.

The basis of the design is the process. Air is to be sourced, cleaned, pressurised, and the resulting flow is to be controlled and delivered to a patient. The flow is to be applied only as required and so must be triggered by the patient's impulse to inhale. Further to this process, the tidal flow of respiration must be reversed in such a way that the device must sense the patient's impulse to exhale and comply by allowing a path for the spent gases to be released at a lower level of pressure. Figure 1 illustrates this basic process layout.



KEY

1. Inlet filter
2. Blower
3. Pressure Limiting Valve (PLV)
4. Flow Limiting Valve (FLV)
5. Anti-suffocation bypass
6. Venturi
7. Oxygen supply
8. Blender
9. Shuttle Aspiration Valve (SAV)
10. PEEP valve
11. Mask
12. Wastegate
13. Enclosure

Figure 1: BiPAP Process flow diagram

2.3. Development Phase

In this phase, the components and assemblies are prototyped and tested. Deviations from the required performance are investigated and solutions found, resulting in changes to the shape, fit or materials and the test regimen applied. This cycle is repetitive until the performance criteria are met.

Sub-assemblies are created from components and the sub-assemblies are then arranged and connected to form process trains. The process trains are tested for conformance to the performance criteria. The process trains are linked and built into the portable closure.

2.4. Confirmation Phase

The various systems and components are disclosed for evaluation of their novelty. Where a novelty claim may exist, applications for the relevant patent or design registrations are already submitted.

It is intended to submit the prototype for SAHPRA evaluation. The result of this submission will serve as a guide to any remedial work that may be required before acceptance by SAHPRA for approval.

2.5. Production Phase

This final phase extends beyond the current scope of the project. The device is disclosed to the Industrial and Manufacturing Engineering disciplines to continue the work of configuring the design for mass production.

3. CONCEPTUALISATION

To enable effective design and reduce development time, the many requirements of the device must be researched and stated.

3.1. Air supply

After many articles and statements by medical professionals and technicians alike, it is clear that pressurisation by a positive displacement type air supply is not simple to control and is potentially dangerous. See for example the article by technician Teschler, 'more dangerous than the virus? Converting manual resuscitators to ventilators' (2020), who questions whether the practice of automating manual resuscitators may pose a greater risk than Covid-19 due to the lack of precise control of pressure and flow. Even healthy lungs are fragile organs that can easily be damaged by a relatively small pressure, the lung tissue of an infected patient is even more fragile so that the pressure control function should be precise and fail-safe, with the functionality to vent to atmosphere any pressure over 2.55 kPa (gauge) or the recommended Peak Inhalation Pressure (PIP). This value should therefore also be adjustable for younger or more fragile persons. WHO guidelines recommend an 800 Pascal minimum and 2500 Pascal maximum applied pressure for Peak Inhalation pressure (PIP).

Any device used to assist medical practises and procedures should naturally cause no harm to the individual, despite the chronic nature of the malady.

The outcome of these considerations led to the decision to use a curved vane blower or turbine type blower for air supply which avoids the risk of serious over pressurisation, in unison with a valve set that is sensitive enough to vent excess pressure rapidly.

To expedite the development progress on the system generally, a commercially sourced blower was imported to provide the airflow for the testing of the circuit, whilst development of the blower continued in parallel. This blower was tested to establish a baseline performance for compact blowers for this application.

3.2. Pressure control

Due to pressure losses along the air supply route, the blower output pressure must necessarily exceed the prescribed PIP, which varies from one patient to the next. The PIP is the prescribed maximum pressure delivered in the mask, which cannot be exceeded for safety reasons. The pressure from the blower is a function of the blower's speed and flow. For an intermittent flow, the blower speed will increase when the flow rate is reduced, such as during the exhalation period. For this reason, pressure regulation is required immediately after the blower. As the output is limited only to the maximum pressure, the type of regulation required is a Pressure Limiting Valve (PLV), a device that allows unrestricted flow but discharges air through a wastegate once the set pressure is exceeded. This is achieved by using a plug valve that opens to the atmosphere, connected to a diaphragm that senses the static pressure in the airflow. The wastegate is capable of delivering the entire blower flow capacity to the atmosphere but throttled to the required value through a spring tensioner behind the diaphragm.

3.3. Flow control

Similar to the PLV above, a Flow Limiting Valve (FLV) was required to limit the flow in the system in proportion to the maximum pressure delivered. The valve construction uses an adjustable spring-tensioned diaphragm to position an aerofoil in the path of the airflow, effectively reducing the flow area as static pressure increases. Once the backpressure has reduced, the flow area increases again.

In practice, this measure is required only at the start of the inhalation period, when little backpressure exists and the blower set pressure is available in the air supply tube. Once the aspiration valve port opens into the mask volume, the trapped air in the supply tube is allowed to expand into the mask without additional supplementary air being supplied by the blower and which supplies sufficient pressure to initiate a strong flow into the mask without shock. At this stage of the cycle, the flow control valve will almost be fully shut due to the excess upstream pressure and may only allow flow once the backpressure is reduced. This valve will open proportionally with the receding backpressure but it will also limit the maximum flow rate.

3.4. Air metering

The design basis for the maximum flow rate was taken from the WHO guideline where 0.8 lps flow corresponds to 800 Pa and 1.2 lps corresponds to 2500 Pa, and any flow or pressure between these limits falls on the proportional line matching these limits. Yet the system is flexible and any prescribed pressure and flow combination can be dialled in through the adjustment of the diaphragm-spring load.

3.5. Aspiration control

To reduce dead space to a minimum the aspiration control valve must ideally be placed at the mask. This adds the essential requirements of small construction and low mass, to be as non-invasive as possible to the patient's comfort. Estimations of mass and length limitations were made at 150g and 75mm length beyond the mask. The shape was also considered to allow the stressed patient an unhindered field of view of their surroundings.

3.6. Post Exhalation Excess Pressure (PEEP) provision

It is common practise with ventilated patients to prevent full exhalation. The practice for many years has been to incorporate some measure of PEEP control as laid out in the journal article by Acosta, Santisbon and Varon (2007: 251). Inflamed and damaged lung tissue suffers further attrition if the lungs are not kept slightly distended at the end of exhalation. The method used is to employ a Post Exhalation Excess Pressure (PEEP) valve which allows the free flow of any gas above a set pressure limit, around 100 to 1000 Pa but prevents full exhalation. The prescribed pressure will always be determined by the health professional based on their evaluation as described in the journal paper by Britos, Smoot and Liu (2011). The patient may induce a negative pressure at the inhalation impulse but the lungs will still contain enough distention to prevent interference.

For this system, the PEEP valve may be positioned at the end of a short exhalation tube or routed back to within the machine casing for sterile handling and condensate management.

3.7. Suffocation protection

If the prime mover has stopped for whatever reason, the patient would attempt to breathe against a closed system until help arrives. Seriously ill patients may not be conscious during this event or may be weakened to the point where they are unable to remove the face mask.

3.8. Inlet air purity

The person receiving ventilation is likely occupying a space in which the air is contaminated by the COVID-19 virus or perhaps many other pathogens. In their weakened state, the burden of re-infection or constant infection may well be unmanageable for the patient. For this reason, the mechanical ventilator is required to filter out any vapour droplets or contaminated dust from the inlet air. As prescribed by the College of Intensive Care Medicine training materials (2021), air entering the device must pass through a bio-filter with due consideration that the patient will need to ingest this air, hence scrubbing agents which produce vapours and fumes must be avoided.

3.9. Discharge air sanitation

When the patient being treated is not contagious, such as a pneumonia sufferer, the outlet tube may be short and there may be no need for a PEEP valve.

Assuming that the patient being treated is contagious, the respiratory vapours may be highly contagious and should be scrubbed before being discharged into the treatment space. That air filtration (heat, moisture, particulates) is essential equipment, is illustrated by the essential reading portion of intensive care training examinations as provided by the College of Intensive Care Medicine (CICM, 2021). As the air travels in one direction only, it will not be re-ingested by the patient, so the outlet may contain an antiseptic scrubbing agent.

3.10. Power supply

The device is intended to be portable for use in a variety of scenarios which extend from in-patient clinic environments, through travel by ambulance or private transport, and into the domestic environment. The power supply must necessarily be flexible enough to run on domestic mains, automotive DC, or for the prescribed period on battery storage alone.

4. ENGINEERING DESIGN CONSIDERATIONS

4.1. Air supply

Initial logic indicated that a low-speed large radius blower would provide the pressure and flow requirements whilst keeping speed to a minimum with the associated benefits of lower noise and vibration. A single-stage 250mm diameter unit was built and tested, followed by a 200mm dual-stage unit, all using brushed DC motors and regulating the speed below 10 000 RPM. Flow and pressure outputs were adequate but power consumption was excessive due to the large internal recirculation flow, caused by the necessary clearances between fixed and rotating parts.

A compact blower of 40mm diameter and using an enclosed runner was designed with inlet and outlet vane angles of 60 and 15 degrees and purely radial vane curvatures. Several variations on this concept were printed and assembled. The final variant of this blower was tested using a 40W brushless DC motor and running at speeds up to 22 000 RPM. For reasons of expedience, an imported blower unit was purchased and used in the development of the device. The in-house blower development is at an advanced stage and shows the promise of meeting or exceeding the performance of the imported unit.
The in-house design lends itself to the mass production of injection moulded components in ABS material.

4.2. Pressure control

A PLV as described above was designed and developed. The valve was tested and found to limit the pressure in the system to the desired value at any blower speed when the valve outlet is fully blocked off.

4.3. Flow control

Using interchangeable components with the PLV, a valve of similar construction was designed and developed to limit the maximum flow at maximum pressure conditions.

4.4. Air metering

The venturi was manufactured and tested against a known flow meter and used a digital manometer for comparison. The design was intended as non-choking and subsonic, using the gas flow theory from Balachandran (2012). The Co-efficient of Discharge (Cd) of the venturi was found by experimentation to average 0.933 across the flow range 0.8lps to 1.2lps.

The flow calculation was simplified to assume incompressible flow, due to the small pressure and temperature variations experienced. A volumetric error at Normal Temperature and Pressure (NTP) indicates an under-reading error of only 0.6% of the indicated flow against the actual polytropic flow. Compensating for lower density at higher altitude inland locations, e.g. 85 kPa(abs) barometric pressure in the highveld regions, an error of 0.8% is expected.

The venturi test results are displayed in Table 1.

4.5. Pressure and flow measurement

For measurement of flow and pressure, two electronic sensors are employed with a venturi meter, installed beyond the FLV. The venturi was designed to a 19° inlet angle and 4° outlet, from an upstream tube diameter of 10 mm and a throat size of 8 mm. The meter has two tapping points, the first being in the upstream tube (HP) and the second in the venturi throat (LP), both providing local

static pressure. A third sensor is provided to allow constant recalibration relative to barometric pressure, for instances where the barometric pressure may vary e.g. travelling from Johannesburg to Durban where the atmospheric pressure varies around 15kPa.

The high-pressure signal is split to provide a system gauge pressure signal and the HP signal for electronic comparison of the LP signal to provide a differential pressure value. Both of these values are displayed using Light Emitting Diode (LED) modules for Pressure and Flow indication.

4.6. Aspiration control - mask mounted Shuttle Aspiration Valve (SAV)

The SAV unit contains a shuttle that resides in one of two positions and which covers and uncovers the inlet and outlet ports. In either position, the common port is always open, which communicates with the internal space of the mask. A small diaphragm is connected to the shuttle and is exposed to the internal pressure of the mask. The diaphragm causes the shuttle to be drawn forward to open the inlet port, where it is held in place by a variable tension ball detente. Once the PIP value is reached, the ball détente releases and the shuttle snaps to the opposite position, closing the inlet port and revealing the outlet port.

4.7. PEEP valve

Two variations of the PEEP valve were designed, prototyped and tested, despite the availability of relatively inexpensive disposable plastic models.

The first design uses a diaphragm stretched across a nozzle, through which the exhalation flow passes. A cup rests lightly on the diaphragm and is adjustable so that the diaphragm tension may be varied. The valve meets the pressure retention requirement of 0 to 100 Pa backpressure but is physically large and complex.

A second variant uses a silicone washer and screw tensioner to allow large flows above the set backpressure but also regulates well between 0 and 100 Pa backpressures. This design is simple and compact and can be further simplified to be set at 100 Pa and sealed. A disposable unit of this configuration is possible for mass production.

Table 1: Venturi Cd testing

Differential Pressure	Throat Diameter	Throat Area	Inlet Diameter	Inlet Area	Ratio	Throat Velocity	Flow	Reynolds Number	Anemometer Reading	Flow Co-efficient
dP (Pascal)	d (m)	A_t x10^{-3} (m^2)	D (m)	A_px10^{-6}(m^2)	A_t / A_p	V (m/s)	Qt (LPS)	Re	Qa (LPS)	Cd
100	0.008	5.0265	0.01	78.54	0.64	16.8	0.844	8659	0.782	0.926
110	0.008	5.0265	0.01	78.54	0.64	17.62	0.886	9081	0.821	0.927
120	0.008	5.0265	0.01	78.54	0.64	18.403	0.925	9485	0.859	0.928
130	0.008	5.0265	0.01	78.54	0.64	19.155	0.963	9873	0.895	0.930
140	0.008	5.0265	0.01	78.54	0.64	19.878	0.999	10245	0.930	0.931
150	0.008	5.0265	0.01	78.54	0.64	20.575	1.034	10605	0.964	0.932
160	0.008	5.0265	0.01	78.54	0.64	21.25	1.068	10953	0.996	0.933
170	0.008	5.0265	0.01	78.54	0.64	21.904	1.101	11290	1.028	0.934
180	0.008	5.0265	0.01	78.54	0.64	22.539	1.133	11617	1.059	0.935
190	0.008	5.0265	0.01	78.54	0.64	23.157	1.164	11935	1.089	0.936
200	0.008	5.0265	0.01	78.54	0.64	23.759	1.194	12245	1.119	0.937
210	0.008	5.0265	0.01	78.54	0.64	24.345	1.224	12548	1.147	0.938
220	0.008	5.0265	0.01	78.54	0.64	24.918	1.253	12843	1.175	0.939
230	0.008	5.0265	0.01	78.54	0.64	25.478	1.281	13132	1.203	0.939

4.8. Anti-suffocation device

The safety mitigation for this scenario is a lightly loaded check valve to the atmosphere, which opens if the pressure in the air supply tube reduces below atmospheric pressure. In this case, the patient's inhalation impulse will draw the SAV shuttle into the inhalation position and air will flow through the anti-suffocation valve and into the mask. On exhalation, the patient's exhalation impulse will snap the shuttle to the exhalation position and air will be discharged through the SAV exhalation port to the PEEP valve, thereby retaining PEEP integrity without powered flow.

The porting size has been designed to cater for such an emergency although it is a short-term measure only and the patient's oxygen saturation alarm is intended to summon assistance in this event. For the prevention of accidental contamination, the valve is located within the closure and sources air from the blower inlet area, after the inlet filter. It can be seen that the function of the SAV is working as intended, fresh air and spent air are moving in one direction only, albeit without a pressurised air supply.

4.9. Inlet air filtration

A commercially available solution was found in the INEX® range of mask and ventilator filtration products. The selected material MSDS can be found on the INEX website at https://www.inexmask.co.za/wp-content/uploads/2020/09/Inex-MSDS-document.pdf.

4.10. Condensate management and Biohazard measures

The method envisaged for this is the provision of a disposable plastic bag that attaches to the outlet of the PEEP valve and causes the exhausted gas to swirl through the bag before exiting. The bag is initially wetted with a concentrated disinfectant which provides a gauntlet of sterilising vapour for the contaminated gases to pass through. The exhaled gases contain moisture vapour which will condense in the system and flow to the bag. The bag is periodically replaced and disposed of as for catheter practises.

4.11. Power supplies and power flexibility

With reference to WHO guidelines and UK guidelines, the pressure delivery of this class of device ranges between 800Pa and 2500Pa.

The WHO guideline recommends a flow rate of up to 1.2 litres per second or 72 litres per minute. A supply of air that meets WHO guideline is proposed, with the capacity to exceed the recommended flowrate by 50% should the need arise.

An important design factor is the scavenging ratio between total internal volume and swept volume. Excessive dead space reduces the swept volume efficiency of the patient's lung capacity by recycling some of the exhaled gas. For this reason, a dual hose is essential for this application to achieve a mask-mounted aspiration system with a minimum amount of air recycling.

4.12. Power and energy considerations

The basic power requirement stems from the air volume requirement of 72 litres per minute of air at 2.5 kPa gauge pressure, sourced from the air at barometric pressure. Assuming constant temperature i.e. negligible temperature change due to the small pressure differential, the delivery volume is considered equal to the free air volume. This is very small, as demonstrated below by the energy requirement estimate at sea level to supply the maximum flow (1.2 lps) and pressure (2500Pa) -

$E = (P_1V_1 - P_2V_2)$, $V_1 = V_2$

$E = [(101.3 - 103.8) \times 0.0012] \times 10^{-3}$

E = -3 J/s

Actual energy requirements will naturally exceed this value due to motor and blower inefficiencies and inlet and outlet airflow system friction, yet the absorbed energy of the blower would still not exceed 10 J/s. The airflow value is also roughly doubled due to the wastegate flow during the exhalation phase, hence the power absorbed estimate of 20W.

4.13. Chemical compatibility

Materials such as certain plastics may give off vapours and gases when heated. Other materials distort or dissolve in high humidity environments. Some disinfectants contain strong reducing agents or solvents which may adversely affect materials. For these reasons the materials used are limited to ASME 316 stainless steel, Aluminium 6010 and silicone rubber components. Plastic components for the prototype were made from laser-cut Plexiglas® and High Density Polyethylene, both of which may be replaced with medical-grade plastics for mass production.

4.14. Assembly and maintenance

Assembly is manual using basic hand tools. Wherever possible, components that are reduced to their simplest form can be sterilised as one piece.

Assembly is an exercise of around 5 minutes per valve, with practice. It is imperative to strip the unit completely for inspection and sterilisation between uses, taking all necessary precautions for any pathogens which exist in the internal spaces.

Particulates from a disintegrating membrane may clog a valve, or worse still, become ingested by the patient, yet conservative use may detect this type of fatigue during sterilisation for re-use. For safety reasons, there are spare components that are discarded at every sterilisation. Disposal of any parts which are replaced should be treated as bio-hazardous waste and incinerated.

4.15. Electrical power supply

The simplest power supply is an electrical 240V single-phase domestic connection, although for the off-grid environment and during transportation, domestic power may not be available. The chosen option is a 7 - 12 Volt DC drive which operates on a step-down transformer whilst charging a battery pack. When AC power is unavailable, the battery pack can maintain operation for 3 hours. The system also operates in a vehicle with a 12V power socket. The option of a stepdown transformer and 12V DC drive is cheaper and more efficient than the equivalent AC drive and 12 V/240V inverter option.

4.16. Materials

A primary consideration is the durability of the components operating dry or with water condensation. The stresses may be low due to the low pressure, but eventual fatigue may occur from light section materials. A three-week deployment may complete over 900 000 stress cycles.

Throughout the deliberations of the various component designs, the material critical questions below were met in the affirmative unless the question is irrelevant for that component e.g. for disposable parts the sterilisation questions are not relevant.

- Is the material commonly available?
- Does the material dissolve, swell or distort in water or moisture?
- Can the material absorb liquids that can harbour infectious agents?
- Can the material be sterilised in strong chemical solutions such as alcohols and bleach?
- Can the material withstand steam sterilisation?
- Will the material fatigue life meet 20 000 cycles?
- Does the material exude any harmful gases or vapours when stressed or heated?
- Does the material distort significantly when stressed?

The answers to all of these questions were available in the public domain.

4.17. Availability

The target unbroken deployment time between inspections would be three weeks, suggested by a study of COVID-19 ventilation durations by Hazard *et al.* (2020), where the average time of ventilation was an average of 9.85 days in an ICU stay of 28 days. During this time, the reliability of the machine must be absolute.

4.18. Ease of manufacture

The final configuration has benefitted from an exercise whereby each component and its interface with the system was reviewed in line with value engineering principles. Briefly, the following steps were followed:

- Assembly components were reviewed with a view to integrate parts.
- Machined parts were reviewed with the aim of replacement by castings or mouldings.
- Metal parts were reviewed to assess their suitability in plastic material.
- Component dimensions were reviewed to minimise excess materials and mass. This included the length of hoses and cables.
- Fastening methods were reviewed to eliminate permanent fastening by threaded fasteners, replacement by rivet, snap assembly, or adhesive bonding.
- Disassembly of certain components for repair or sterilisation was compared with disposable sealed equivalents.
- Materials were reviewed in light of their chemical compatibility and whether surface treatments could be avoided.

4.19. Temperature and Humidity control

The WHO guidelines specify heating and humidity correction within given parameters. The reason for these inclusions is to supply the patient with air as close to natural conditions as possible. The need for heating and humidification stems from the use of dry and sterile compressed hospital services air at 6 to 10 Bar, as used with many ventilator systems. This dry air is expanded to the relatively low pressure for ventilation service, creating a substantial refrigeration effect and greatly reducing the relative humidity so that the expanded air is very dry and cold.

The proposed system uses natural air from the ambient source which is at the prevailing humidity and temperature, apart from the minor heating produced by the motor cooling flow. This air can be ingested by the patient without discomfort and which then renders any temperature and humidity controls unnecessary. This position was postulated by Branson and Gentile (2010).

5. DEVELOPMENT PHASE

Having identified, designed and prototyped the various system components, these were assembled in their process positions and tested. The description below illustrates the final configuration.

The system was built into an aluminium casing which was compartmentalised and made practically airtight to enable light pressurisation, for the exclusion of dust and other contaminants. A wheeled exo-frame was designed and built to add portability and handling strength to the lockable enclosure. The selected casing is commercially available and has several useful features such as the draw and carry handles, a wheeled base, sturdy hinges and latches.

The battery, transformer and power components were mounted in a compartmentalised ‘engine room’ which is ventilated by the PLV wastegate during the exhalation phase. The blower is mounted in its compartment, which draws ambient air through a biofilter. Motor cooling is achieved by the passage of air through the blower, thereby minimising any requirement for additional heating of the air product.

Flow and pressure control are maintained by the series-connected Pressure Limiting Valve (PLV) and the Flow limiting Valve (FLV), which are mounted in a second compartment that also houses the pressure and flow indication sensors and the electrical main power switch. Pressure and flow adjusters and their indicators are accessed from the external control panel, as well as the master power switch.

The mask, hoses, and dry outlet filter casing as well as loose power cables are stored in the lid of the casing in specially adapted clips and holders. Machinery and Storage are separated by a hinged foil.

The blower is mounted on a vibration isolating structure and inside a closed compartment, which draws flow from the outside via a specially adapted housing that holds the biofilter element. The air is drawn into the blower inlet where it is in contact with the motor heat sink and which performs the dual function of raising air temperature whilst cooling the motor.

5.1. Development of the PLV and FLV

To reduce pressure from a potential 7.5kPa down to a minimum of 0.8 kPa, it was found that a diaphragm of 80mm provided the ideal range. The spring requirement is very specific and does not match standard spring production sizes, but a solution was found in the precise rolling of brass wire springs with ground ends, whose performance matches the calculated values closely. For standardisation and interchangeability, the two-port FLV was modelled on the three-port PLV and shares many components. The aerofoil 'bullet' was positioned in the throat at several positions and flow and pressure drop readings were taken to find the matching position for the given inlet pressure. The third port of the valve casing was blanked using a friction plug. Sectional illustrations of these valves are provided in Figure 2.

Further photographic views of these valves are provided in Figure 3 and Figure 4.

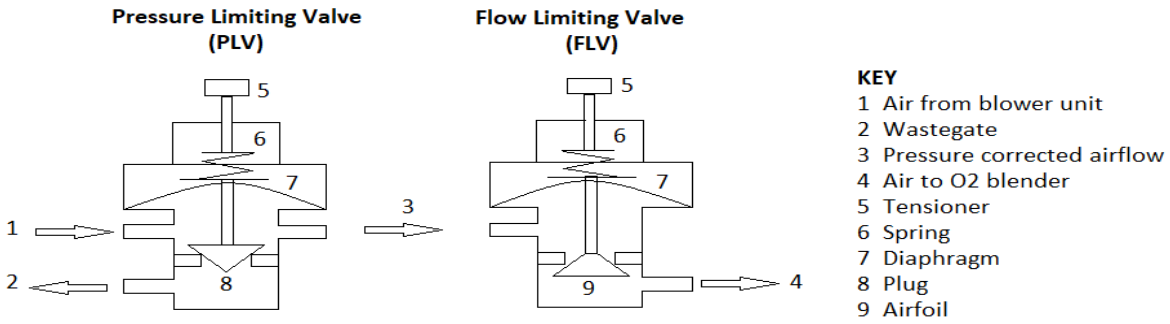


Figure 2: Schematic section of PLV/FLV tandem

Figure 3: Control fascia with valves fitted

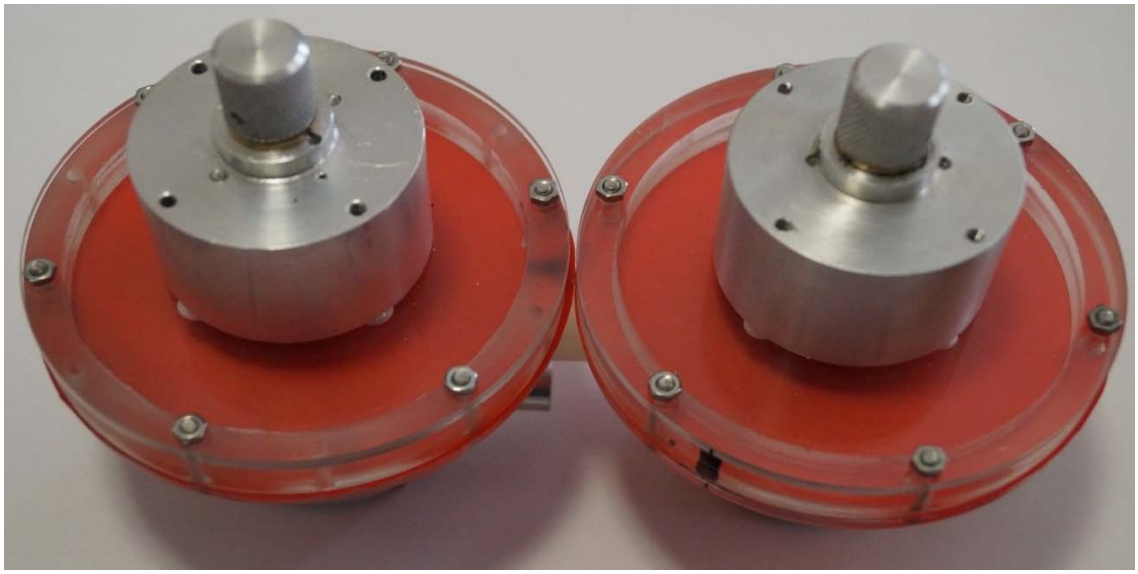
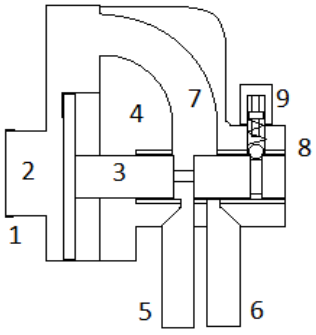


Figure 4: PLV and FLV valve prototypes

5.2. Development of the Shuttle Aspiration Valve (SAV)

This element ranks second in importance only to the blower. The concept of BiPAP relies on the patient's motor impulse to draw a breath, after which the air feed, flow, and pressure are supplied up to the set parameters, and exhalation is automatically triggered and controlled down to PEEP pressure. The system then maintains a state of rest until the patient initiates a subsequent breath. Unlike enforced ventilation, the BiPAP system is considered to be a semi-automatic process.

To meet this brief, a triggered valve unit was developed over several prototypes as shown in **Figure 5.**



KEY
1 Mask interface
2 Plunger
3 Shuttle
4 Valve body
5 Inhalation port
6 Exhalation port
7 Common port
8 Ball detente
9 Trigger adjuster

Figure 5: Sectional view of Shuttle Aspiration Valve (SAV)

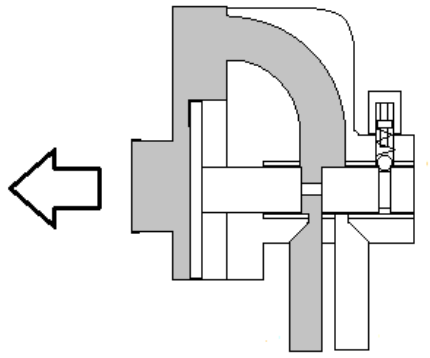
The valve employs a shifting shuttle element which reveals or covers ports to direct airflow. An impulse between 10 and 100mm WG of negative pressure is exerted on a plunger mounted in the valve unit and signals the patient's urge to draw a breath. The plunger displaces the shuttle and opens the air inlet port, simultaneously setting a ball détente, which is also self-centring and ensures good port alignment. As air flows to the mask with increasing pressure and decreasing flow, the patient's natural chest elasticity is tensioned and causes backpressure.

As the pressure approaches Peak Inhalation Pressure (PIP), the ball *détente* disengages due to the mask pressure applied on the plunger, and the shuttle is forcibly moved to uncover the exhalation port where it remains until mask pressure is once again reduced by an inhalation prompt. Whilst the exhalation port is open, the inhalation port is closed off. As the mask pressure reduces, the area ratio of the control surfaces ensures that the port remains open down to PEEP pressure. The system then remains at rest until the mask pressure is reduced below PEEP pressure and initiates a subsequent

breathing cycle. Illustrations of the SAV operation are provided in Figures 6 and 7, and a photo of the plunger assembly is presented in Figure 8.

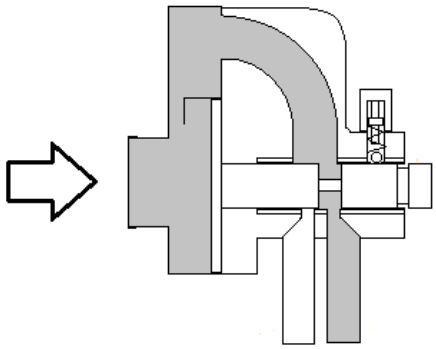
5.3. Avoiding pressure surges

System supply and demand require that a constant flow blower supply must provide for an intermittent demand-side flow as the average flow rate doubles during inhalation cycles and reduces to zero during the exhalation cycle. This characteristic would have negative effects on the constant flow supply side, as a conventional pressure regulating valve experiences full-stroke cycling, devastating normal pressure control logic through valve hysteresis and inertia and causing unnecessary wear. Intermittent flow testing proved that the PLV can cope and still maintain its function due to the gradual reduction of flow during the inhalation cycle, but would experience an undesirable control spike at the SAV inlet port opening. This spike is somewhat damped by the response of the FLV, thereby eliminating a pressure surge to the SAV and the patient. Another means of avoiding this shock was the shape of the inlet port, yet this was found to be impractical due to the required increase in stroke length and diameter of the shuttle, contrary to the aim of reducing the size and mass of the SAV.



Inhalation phase
Negative pressure in the mask from an inhalation impulse acts on the plunger, which in turn draws the shuttle into the range of the ball detente. This locks the shuttle in the forward position, exposing the inhalation port and blocking the exhalation port. Air flows into the mask at the pressure and flow set by the ventilator.

Figure 6: SAV inhalation phase



Exhalation phase
At the pre-determined Peak Inhalation Pressure (PIP), the force on the plunger exceeds the ball detente locking force and the shuttle snaps to the rearward position. This blocks the inhalation port and reveals the exhalation port. Exhalation flow is powered by the elasticity of the patient's chest and pressure is limited by the Post Exhalation Excess Pressure valve (PEEP) in the outlet tubing.

Figure 7: SAV exhalation phase

5.4. Meeting the WHO exhalation depression requirement

WHO guidelines call for a sudden pressure depression at the start of the exhalation stroke, causing the 'barb' shape in the pressure/time plot. The prototype achieves this by utilising a larger outlet tube beyond the aspiration valve port, which has the effect of delaying the increase in backpressure ahead of the PEEP valve and allowing the initial exhalation flow to be high and initiating some inertial flow.

Figure 8: SAV plunger and shuttle

5.5. Hose and connector options

The minimum flow area for short ports is 38mm^2, which equates to equivalent hole diameter of 7mm, but longer tracts such as ducting are necessarily larger to compensate for friction losses. The prototype functioned well using 10mm vinyl plastic tubing for test purposes, but the friction loss was too large for anti-suffocation flow without pressurised inlet air. Hoses up to 2m are necessarily large diameter, around 19mm internal diameter. This size matches commercial CPAP and BiPAP hoses with rubber friction connectors.

The valve connectors and other internal interfaces upstream of the anti-suffocation valve is an aluminium tube of outside dimension 12mm and bore 11mm and employing a rubber/metal friction connection. This allows a connection force exceeding the pressure force and which prevents accidental disconnection. This also allows for simple assembly and disassembly without additional connectors or components.

External connections are exposed to contact with surroundings and tampering, hence a firm friction connection is required. A ring-lock device is developed and proposed for these external connections to the ventilator, SAV, and any external scrubber employed, but is unnecessary as the 19mm rubber interface requires around 5kg force to dislodge and is considered adequate in commercial CPAP machines.

5.6. Exhauster filter

The exhauster filter is contemplated for fixed usage i.e. not for transportation. It comprises a chamber with a filtered exit to the atmosphere. A plastic vessel with a layer of plastic foam surrounding the exhalation tube in a bath of dilute disinfectant serves as an outlet scrubber. The foam wicks the disinfectant above the liquid level and exhausted air must follow a tortuous path through the saturated foam, entraining disinfectant vapour and effectively sterilising the flow. The exhaust sterilisation vapours cannot return to the patient so an aggressive concentration can be used. This filter is placed at a low elevation so that any accidental back-flow is impossible.

5.7. Mask unit

An initial survey of available re-usable and disposable ventilator masks produced none that could be converted to serve the device and house the SAV assembly. A proprietary mask was produced by establishing a chin-to-bridge common profile baseline and transferring this baseline onto a wooden blank. The internal shape of the mask was then sculpted into the wood to include the SAV interface platform and diaphragm mounting, leaving sufficient internal clearance for the passage of air and a sealing face resting on the upper surface of the chin, cheekbones, and bridge of the nose. The blank mould was then finished and smoothed. A 2mm hard vinyl blank was prepared and attached to the mould and the shape was formed by heating with hot air, creating a slump moulding as used with glass working. The finished mask was tested to fit and several changes were made to the shape

before the final shape was decided on. The mould final profile was copied as wireframe laminates and recorded as a 3D file. The first prototype masks were produced using the original wooden shape.

A far simpler option for rapid deployment was found in the imported resuscitation kits provided by local importers. The mask has an inflated cushion seal and a 22mm inlet aperture for the fitment of the resuscitation valve. The SAV unit was reconfigured to adapt this mask for ventilation duties. The elastic tensioning strap is marginally adequate and could be improved for ventilation duty. The complete assembly is shown in Figure 9.

Figure 9: SAV with mask fitted

5.8. Blower flow and pressure testing

The three prototype blowers as well as the imported commercial version were tested to determine their Pressure Flow curves and power consumption. The test apparatus comprised a fabricated flow tube with an outlet choke that connected to the blower outlet using a large-diameter surgical tube.

The flow tube housed a simple pitot tube and a separate static pressure tapping. The static pressure impulse was split with one tube connected to a water gauge U-tube manometer and the other connected to an electronic manometer (-) port. The total head measured from the pitot tube was connected to the manometer (+) port. At five different blower speeds at 20% intervals, static pressure, total head, and differential were measured, as well as supply voltage and current flow. The sequence was repeated at four different choke positions to simulate system backpressure. The temperature and barometric pressure were noted and the air density was calculated. The results were then entered onto a spreadsheet and plots were generated of static pressure against flow and power consumption against the flow. Flowrate was derived using the constant for the flow tube. Table 2 provides the results of the blower testing exercise.

5.9. Pressure and Flow regulation tests

Given the flow and pressure characteristics, the PLV was tested extensively during development to produce a pressure and flow range to match the WHO requirements. Development work was done to obtain an acceptable balance between spring tension range and control diaphragm area and elasticity, all the while maintaining a control range between 700 Pa and 2800 Pa to envelope the final output range. A final balance was found and further development was done to refine the valve plug for better linearity and to refine the spindle diameter and materials for lower friction and reduced

hysteresis. A lightened plug and brass wire spindle provided near-zero hysteresis and control within 5% of the set value.

The test instrumentation used was a digital manometer with the static pressure teed to a second manometer, with an electronic anemometer which was mounted at the end of a flow straightening tube. This apparatus was also used to verify the accuracy of the venturi.

The FLV unit was initially developed as a standalone flow regulator. Starting with a common set of housings with the PLV, a flow 'bullet' was manufactured and the resulting flow measured on the miniature flow tube developed for the purpose and utilising a simple pitot tube and static pressure connection, connected to a calibrated electronic manometer with sensitivity to 1mm WG. The PLV and FLV tandem were then tested for limiting pressures and maximum flows by using the early SAV prototype as a flow interrupter.

5.10. Aspiration valving

Having achieved reliable airflow and pressure control, an aspiration valve was designed and developed over several prototypes until the SAV concept was successfully function tested. Earlier versions of the SAV were intended to be mounted in the ventilator casing due to their weight and size. A wafer type of valve succeeded the earlier tensioned-diaphragm concept and was developed to the point where its mass and volume were reduced to be passably acceptable for in-mask mounting. More weight and size benefits were achieved with the adoption of a miniature shuttle and more research into the permissible minimum size of aspiration port areas.

Testing of the valve was done in several stages. Basic function testing using static pressure ensured that the PIP trigger setting range was comparable with the PLV range, and a system restriction was introduced to balance flow and pressure range at constant blower speed.

The system was assembled on the workbench and run at ten different pressure settings. In the absence of a patient, a plastic bag was prepared and weighted with a beanbag to simulate an adult lung set. In each case, the process was initiated with a pressure reduction in the feed tube to the simulated lung and monitoring the initiation pressure on a manometer. The system inflated the bag and triggered at PIP pressure with good repeatability across the range of pressure settings.

Encouraged by this, the author has tested the device at various pressure settings across the range and found the operation to be consistent.

Table 2: Blower test pressures and flows

Speed 1 36 67 RPM	**P_s (mmH20)**	**P_s (Pascal)**	**DP (Pascal)**	**v (m/s)**	**Q_t (LPS)**
	20	392	0	0	0
	21	412	3	2.914	0.1465
	21	412	7	4.451	0.2237
	16	314	22	7.891	0.3966
	5	98	67	13.77	0.6922
Speed 2 73 00 RPM	**P_s (mmH20)**	**P_s (Pascal)**	**DP (Pascal)**	**v (m/s)**	**Q_t (LPS)**
	75	1470	0	0	0
	72	1412	12	5.828	0.2929
	63	1236	30	9.214	0.4632
	50	981	96	16.483	0.8285
	16	314	343	31.156	1.5661
Speed 3 11000 RPM	**P_s (mmH20)**	**P_s (Pascal)**	**DP (Pascal)**	**v (m/s)**	**Q_t (LPS)**
	145	2844	0	0	0
	142	2785	20	7.523	0.3782
	128	2510	40	10.64	0.5348
	104	2039	170	21.934	1.1025
	36	706	767	46.59	2.3419
Speed 4 14600 RPM	**P_s (mmH20)**	**P_s (Pascal)**	**DP (Pascal)**	**v (m/s)**	**Q_t (LPS)**
	212	4158	13	6.065	0.3049
	205	4021	38	10.370	0.5213
	172	3373	109	17.563	0.8828
	148	2903	303	29.283	1.4719
	43	843	1074	55.131	2.7712
Speed 5 18300 RPM	**P_s (mmH20)**	**P_s (Pascal)**	**DP (Pascal)**	**v (m/s)**	**Q_t (LPS)**
	268	5256	30	9.214	0.4632
	257	5040	44	11.159	0.5609
	217	4256	125	18.808	0.9454
	156	3060	475	36.664	1.8429
	45	883	1384	62.584	3.1458
Speed 6 22000 RPM	**P_s (mmH20)**	**P_s (Pascal)**	**DP (Pascal)**	**v (m/s)**	**Q_t (LPS)**
	305	5980	20	7.523	0.3782
	275	5400	100	16.823	0.8456
	242	4750	200	23.791	1.1959
	175	3440	587	40.758	2.0487
	54	1056	1595	67.185	3.3771

6. DISCUSSION

The project was undertaken as part of the Ventilator Challenge sponsored by merSETA and accommodated at NMU, of which this work is designated as ViroVent Project 2.

The author and the team are assembling the final prototype for system and endurance testing. Some issues remain to be resolved in the final configuration. On completion, the final prototype will be presented for SAHPRA approval.

Further development will be the adaptation of the design for mass production using Value Engineering as a guide to the manufacturing processes for the various parts i.e. employment of CNC, injection moulding of sub-assemblies, and the refinement of fastening methods.

Other developments around this work will be the improvement of the local content to include a locally manufactured blower unit, as well as an evaluation of the possibility of employing a molecular filter to replace the bottled oxygen supply. The aspect of a buffering volume in the system to reduce energy consumption may be revisited should the need arise to extend the off-grid operating time without increasing the battery storage capacity.

7. CONCLUSIONS

With the SAHPRA registration only now in progress, the following provisional conclusions are drawn from the above:

- The device produces sufficient airflow to meet WHO guidelines, at the prescribed pressure range and within the variability limits of flow and actuation.
- The device is intrinsically safe, having safeguards against overpressure and suffocation.
- The device is portable but also meets the WHO definition for portability in terms of performance and operational stamina.
- The design brief has been met, having produced a working BiPAP ventilator with minimal complexity and low cost, which lends itself to mass production.

8. ACKNOWLEDGEMENTS

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