RAD:OS
respiratory aid device

A Respiratory Aid Device for local build and use

Ventilator Project Rationale

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The primary object of this project was to produce a 'field ventilator' that would serve to increase the availability of 'temporary' ventilators and which would allow increased survival of patients. To fulfil this objective the developers sought to use commonly available and perhaps salvaged components in order to overcome potential difficulties with supply. The intention of the developers was to provide a low cost electro mechanical ventilator that could be simply fabricated and required no electronic or software controls. To simplify the development of a bellows for pumping air/oxygen it was decided to apply a Bag Valve Mask (AMBU bag) as the core air delivery component. Based upon medical and operational requirements the team drew up a draft specification.

1.0 Proposed Specification

1.1 Universally available materials

The selection of a manufacturing material that is easily available throughout the world and locally used in fabrication workshops. Possible alternatives included sheet timber, sheet metal and sheet plastic. Consideration was given to both plywood and MDF and although MDF has more dimensional consistency it was considered that plywood is more universally available.

1.2 Easily replicated, simplest manufacturing methods

Consideration must be given here to the quantity of units required to be made locally. The authors considered that quantity required might vary from five to five hundred. Joinery manufacture appeared in the first instance to offer the most flexible possibilities for varied scale production.

1.3 Electrical rather than software/electronic control

The choice of electrical control was made to simplify the technical expertise required to assemble the unit, also to reduce the service requirement for a technical expert to maintain the units in operation in clinics with a wide geographical spread. Electrical parts were considered simpler and faster to find and to repair faults on site.

1.4 Readily available motive and power components that are easily replaceable

These available parts included the possibility of utilizing scavenged parts from commonly available household or office/industrial products as well as parts that could be easily obtained from an electrical supplier or a radio repair shop.

Functional Principles

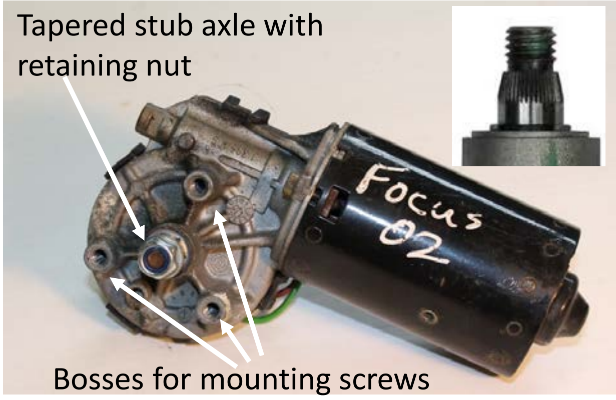
1) Able to operate continuously for a week
2) Once set up by a health care professional, the unit can be monitored by a competent person
3) Tidal Volume adjustment from 300ml to 800ml
4) Breaths per minute (BPM) adjustment from 12 to 20 BPM
5) Inhale/Exhale (IE) ratio from 1 to 3
6) A facility for pressure control (PEEP)
7) A facility for oxygen introduction

2.0 Housing Construction

To allow for the simplest possible manufacture of the mechanics and housing it was decided to design the structure to be made from standard 19mm board materials, typically plywood but also from natural timber boards. These parts could be made and assembled in low volumes very simply by woodworkers or in greater quantities by CNC routing equipment in joinery workshops.

3.0 Motor Selection

Very early in the project a 12v geared wiper motor was identified as the primary motive component and visits were made to car dismantlers to select a unit that had the required output. It was established that Bosch made a unit that was common to many makes of family vehicles and that this particular wiper motor format had also been cloned by several other motor makers. The early units we obtained were from Fords and were 55 W. These units are also available in 40 W. A number of units were obtained from both car dismantlers and new stock from motor factors.



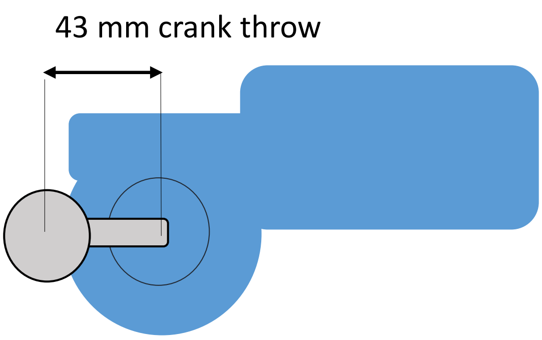


Fig: 2) Typical Bosch Wiper Motor – Note mounting screw bosses and crank/spigot arrangement

It was decided for simplicity to utilise the existing crank arm on the wiper motor where possible. These are mostly but not always set on centres of 43mm from motor centre to spigot. A type 6300 roller bearing at 35mm dia. was inserted to replace the spigot and provide a smooth actuating contact to roll on the actuating arm.
Note: many cars manufactured from 2018 utilise a different wiper system which was not applicable to this project.

4.0 Power Supply Selection

An examination of different electrical products found in a typical home was conducted to identify an appropriate Power Supply Unit (PSU). It quickly became apparent that the PSU in an ordinary Personal Computer could be readily adapted for this purpose.
A PC's power supply has several 12 V sources means multiple electrical demands can be fed. It was easily capable of both powering the wiper motor and an optional back up battery unit. PC's from several manufacturers were dismantled and their PSU's examined for compatibility with the project.
All the examined PSU's were found to be readily adaptable. The common availability of scrap PC's made this source for a PSU an easy choice. The wiring colour/cable plans for the output voltages of various makes of PC PSU's are shown in Figure 6 below, but are also available on the internet allowing for the easy identification of the correct outputs.

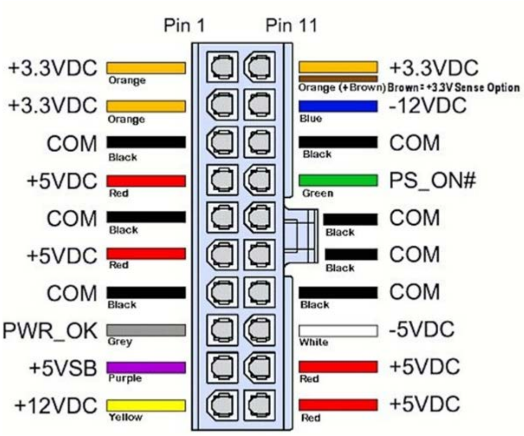


Fig: 6) Output voltages of a typical personal computer power supply

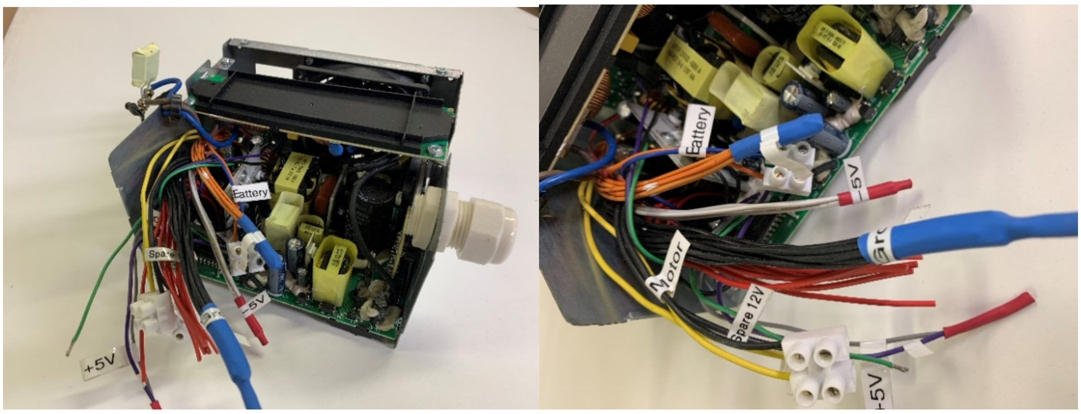


Fig: 3) Picture showing sample opened PC power supply with labelled cables

5.0 Bag Value Mask (BVM)

A bag valve mask (BVM), is often known by the generic term an Ambu bag. It is a manually operated self-inflating resuscitator that is commonly used to provide positive pressure ventilation to casualties who are not able to breathe adequately in an ambulance or for short term ventilation of patients in a hospital setting.
The bag is squeezed by the paramedic or nurse to initiate inspiration and self inflates with air as the bag recovers its shape during the expiration phase, additional oxygen (O2) may also be added. The inclusion of oxygen is not necessary for the bag to function and commonly room air is utilised.

Fig: 4) Ambu Bag (Reference)

6.0 Results

The initial concept was for a pivoted rocker arm driven by the crank on the wiper motor and utilising a cylindrical extruded plastic actuator. The actuator was made from 67mm diameter extruded pipe. Very simply the prototype was pumping air. There was no motor speed or tidal volume control and the motor was driven by an off the shelf vehicle battery charger.

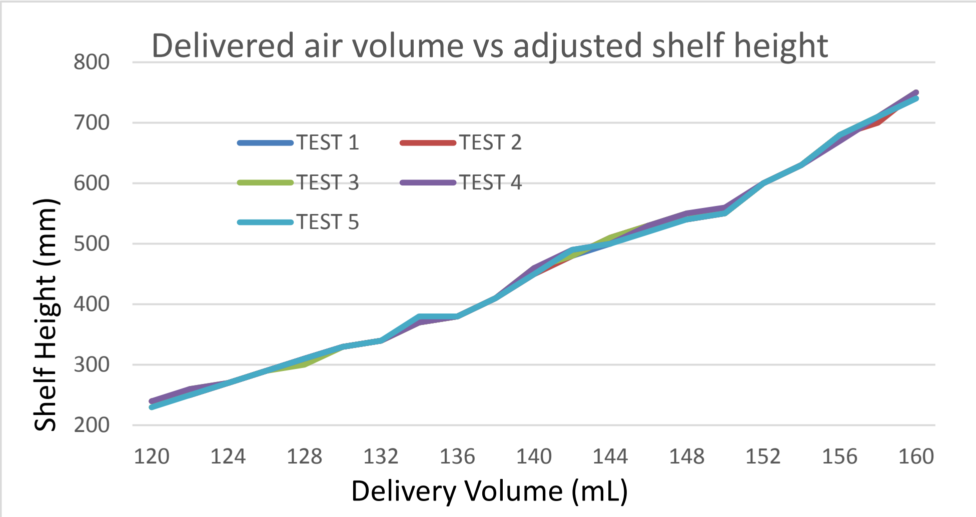
Fig: 7) Actuator arm on basic prototype

6.1 Tidal Volume testing

Methods for varying the air volume were examined and the most promising method was to maintain the motion of the actuator/rocker arm as constant but to vary the height of the AMBU bag under the actuator to increase or to reduce the tidal volume.

A sliding horizontal shelf upon which the bag was accurately located was devised to vary the bag height and this was locked at the desired height by two M6 bolts and butterfly nuts. A spiro-trac measurement system and software were obtained to examine the consistency of volume output for each stroke of the actuator. The results showed a surprisingly accurate correlation per cycle of the actuated AMBU bag. The test volumes were measured at the end of a standard 22mm tube normally applied in ventilation.

Table: 1) **Volumes per Shelf height**



However the range of tidal volume required only occurred within a vertical distance of approximately 40mm making precise adjustment difficult. A modification was implemented by which the vertical adjustment was achieved by a threaded bar and this vertical movement was linked to a pointer mechanism with an arc length of 150mm. Thus a much improved scale for the adjustment of tidal volume was made possible. ***(see fig 8)***

The scale was further improved with the addition of extra scales which allow for changes in volume due to alterations in peep pressure.

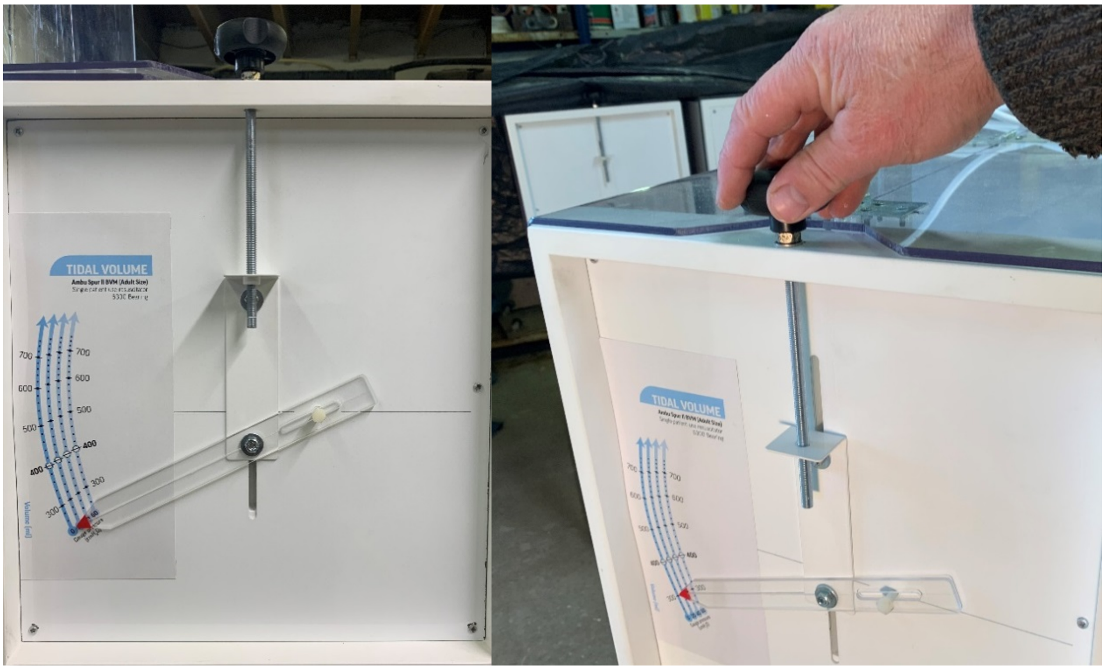


Fig: 8) Tidal volume handwheel/pointer adjustment range for different Peep pressures

6.2 Respiration Rate (BPM)

The breaths per minute (BPM) for the ventilator was required to be adjusted within the range of 12 to 20 BPM. This was achieved by the design of a motor control circuit comprising of several resistors, a transistor and a potentiometer. Such a unit was also immediately available from RS components and to speed up the development this off the shelf unit was utilised. Adjustment of BPM was undertaken by using the stopwatch facility on a smartphone to count the motor RPM per 30 seconds and reducing or increasing the motor speed accordingly. This is a reliable method for setting the BPM but requires some fine adjustment when the resistance incurred by attachment to the patient is considered. This has the effect of slowing down the motor, particularly at lower BPM rates.

Table: 2) **Seconds/BPM rate**

<u>**Respiratory Rate (BPM)**</u> The normal respiration rate for an adult at rest is 12 to 20 breaths per minute(BPM)		
1 Breath = 1 Revolution	1 Breath per Minute (BPM) = 1 Revolution per Minute (RPM)	
12BPM	12RPM	1 Revolution in 5 seconds
15BPM	15RPM	1 Revolution in 4 seconds
20BPM	20RPM	1 Revolution in 3 seconds

The initial specification was extended to include the addition of two extra features, a counter unit and display to exhibit real time BPM and allow for real time speed adjustment.

6.3 IE ratio

The inhale and exhale (IE) ratio are a critically important part of an intensivist's prescription. The ratio will vary depending upon the age, elasticity and medical condition of the patients lungs.

The intensivists who contributed to this project indicated that a range of IE Ratios from 1 to 3 were desirable. This feature was achieved mechanically by articulating the actuator arm directly above the centre of the motor/gearbox. Bench testing of models of the bearings interaction with various forms of actuator arm led to a balanced solution that married a simple linking of tidal volume to arm incline for the desired IE Ratio. (see fig.9)

The calibration of the IE adjustment scale was facilitated by utilising video technology which allowed for accuracy levels down to milliseconds during measurement.

Fig: 9) **Adjustment scale on actuator arm**

Table: 3) **Changes in IE ratios from bearing angular contact with articulated Arm**

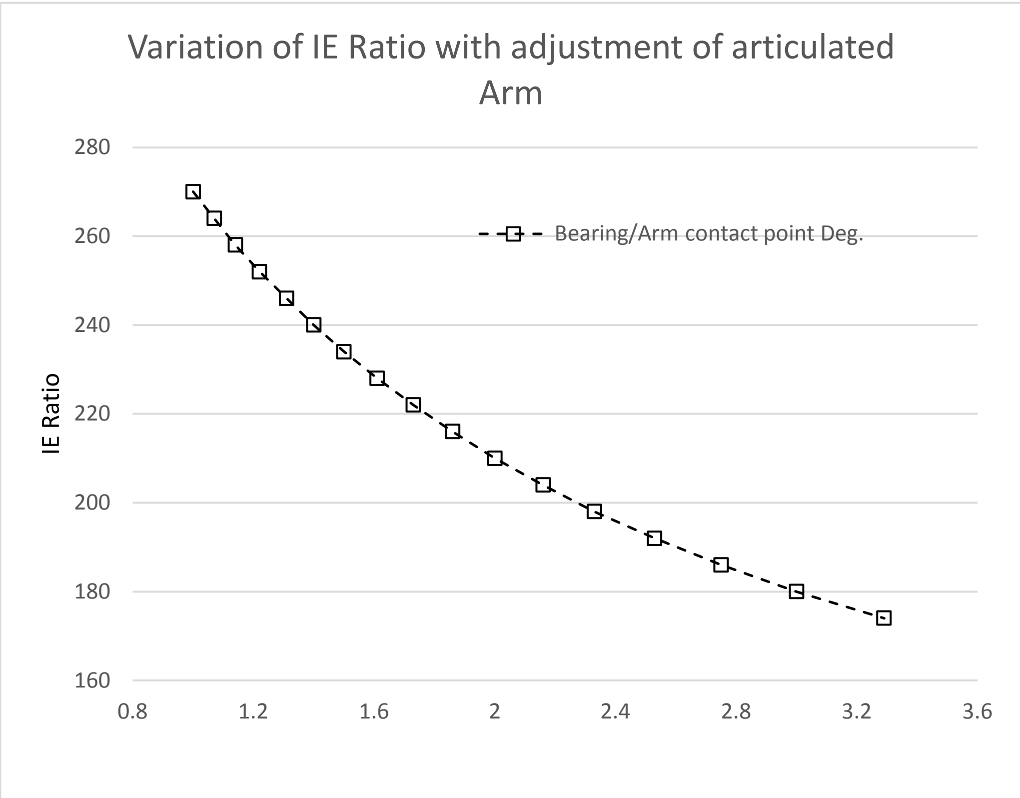
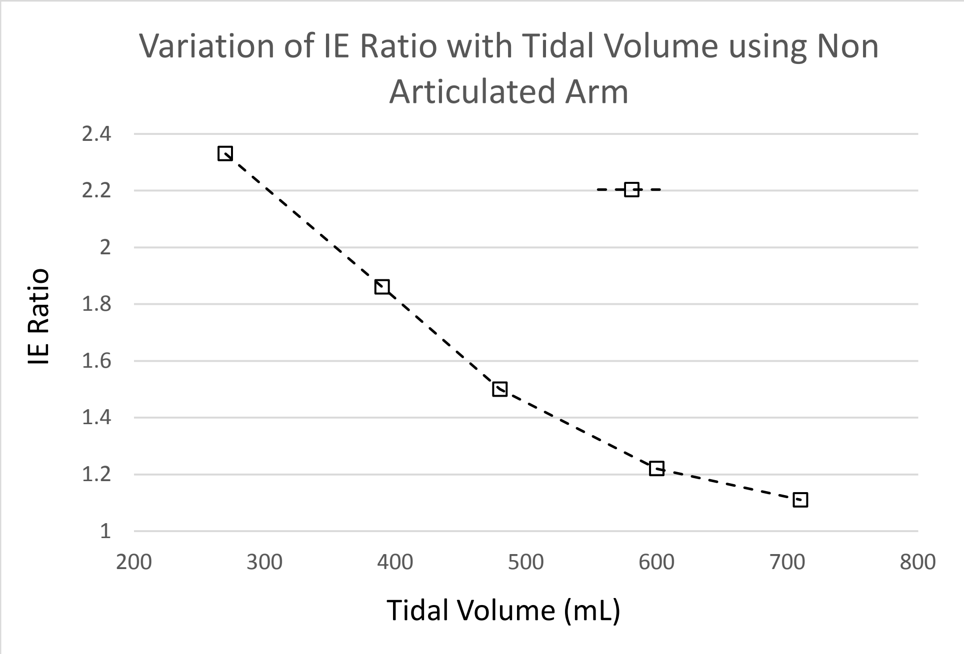


Table: 4) **Changes in IE Ratios for tidal volume range – Non Articulated Arm**



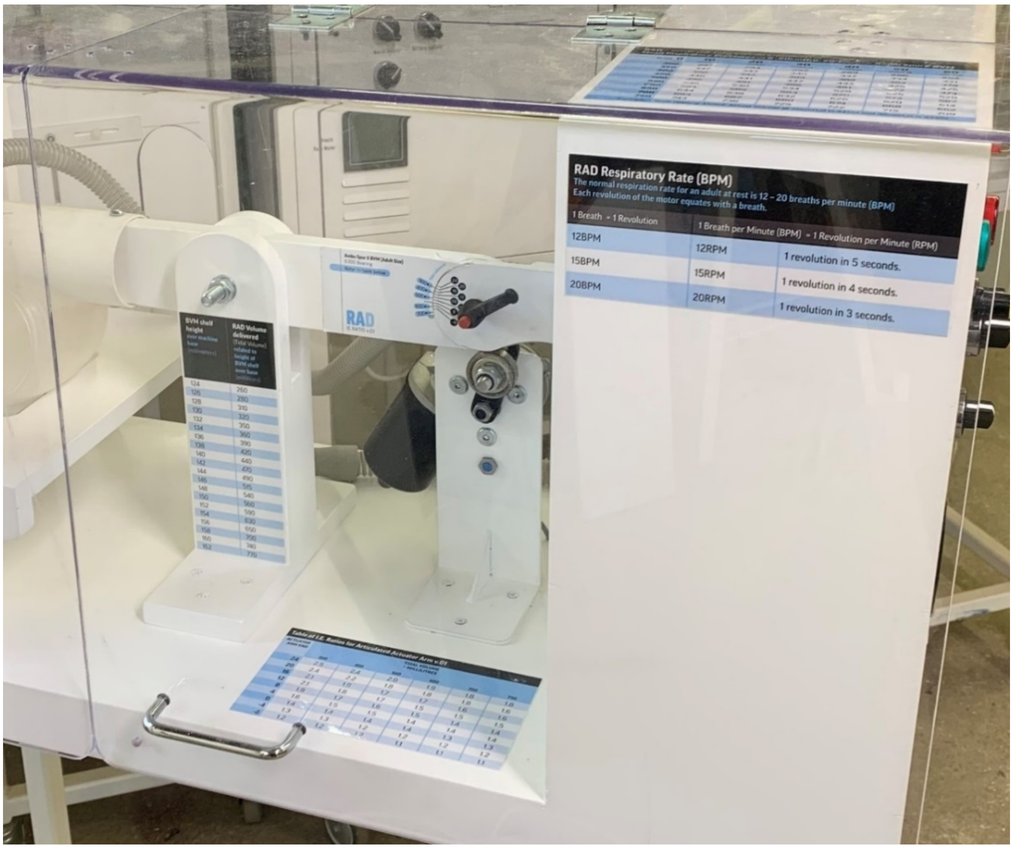


Fig: 10) **Applied adjustment tables**

Information tables were applied to the machine to show how to achieve desired tidal volume, IE ratio, BPM and the necessary volume compensations for variations in Peep pressure.

7.0 . Discussion

The prescription for any particular patient depends upon age, physical size, general fitness, and clinical condition. Clinicians need to accurately prescribe tidal volume, breaths per minute and inhale/exhale ratio. This discussion considers the accuracy by which these factors may be measured and applied with the apparatus.

The results for tidal volume were remarkably consistent given the simple construction and control method of the apparatus. This may be observed in Table 1, where the variance over the group of tests was no more than 10ml. The contributing clinicians did not consider this 10 ml of variance as significant in an emergency apparatus.

The Spirotrac software in conjunction with the Pneumotrac device (which includes the flow transducer) is designed to comply with the American Thoracic Society and European Respiratory Society (ATS/ERS 2019) standard. This means that, once calibrated, the system is accurate for volume to within +/- 2.5%. In terms of the volume range being measured this will equates to +/- 7.5 ml at 300 mL and +/- 20 mL at 800 mL. The Spirotrac system made it possible to consider the potential variance in volume due to manufacturing inconsistencies between units. It is critical to maintain precise geometry for the motive components and accurate positioning of the bag relative to the actuating arm.

The authors acknowledge that the results obtained are relative to the Ambu Bag solely and that the use of BVM's from other manufacturers will require users to measure particular tidal volume scales for each BVM type.

It was realised that future builders of the machine in multiple locations would have need to measure the air volume output of their machine as they may not be using an identical BVM bag (AMBU) and may not have access to such a sophisticated measurement system for air volume. So alternative methods of air volume measurement were considered
(see Appendix A).

Seconds of rotation for breaths per minute may be observed in Table 2.
Employment of the crank means 1 cycle delivers 1 breath. The authors discussed various methods for timing the BVM actuation by observing speed of bearing/arm rotation. Simply timing the speed with a stopwatch from single rotations was quickly seen to have too much latitude for error.
A more accurate method was devised by recording the time taken for a quantity of rotations (i.e. 10) and dividing the time taken by the number of rotations to compute a more accurate result.
Achieving a useful range of Inhale/exhale ratios was challenging. The elastic condition of the patient lung impacts on the choice of IE ratio although in an emergency an imperfect IE selection is considered to be better than no respiratory intervention. Table 4 shows the IE ratios pertaining to the use of a straight actuating arm. Utilising this straight actuator the IE ratios are not adjustable. For instance, if a TV of 270ml is required, this is only available to be delivered at an IE of 2.33 etc. The straight arm does have the advantage of being simple to make.

Changing the actuator pivot point and the motor centre arrangements had no appreciable impact on IE but immediately this negatively affected the tidal volumes. The most promising direction to develop a solution appeared to be by alteration of the actuator profile where it was contacted by the motor crank bearing.

A test rig was set up with an actuator and crank arm on a board to track how modifications to the actuator profile would positively affect the IE ratio. Since the actuator rises to the horizontal at the peak of each cycle the it could only modified between the 90 degree bearing contact position and the end of the actuator. Placing a pivot on the actuator centrally above the 90 degree bearing position provided the best advantage to articulate the end of the actuator both up or downwards to alter IE ratio. Further articulated profile trials by the authors determined that a curved actuator profile matching the radius of the motor crank arm but offset from it provided the best balance of IE adjustment across the range of tidal volumes required.

The results achieved for the selected profile version may be observed in Table 3. The action of the bearing upon the arm was recorded by video and the IE ratio thus accurately determined. A scale and table were successfully devised for IE adjustment.

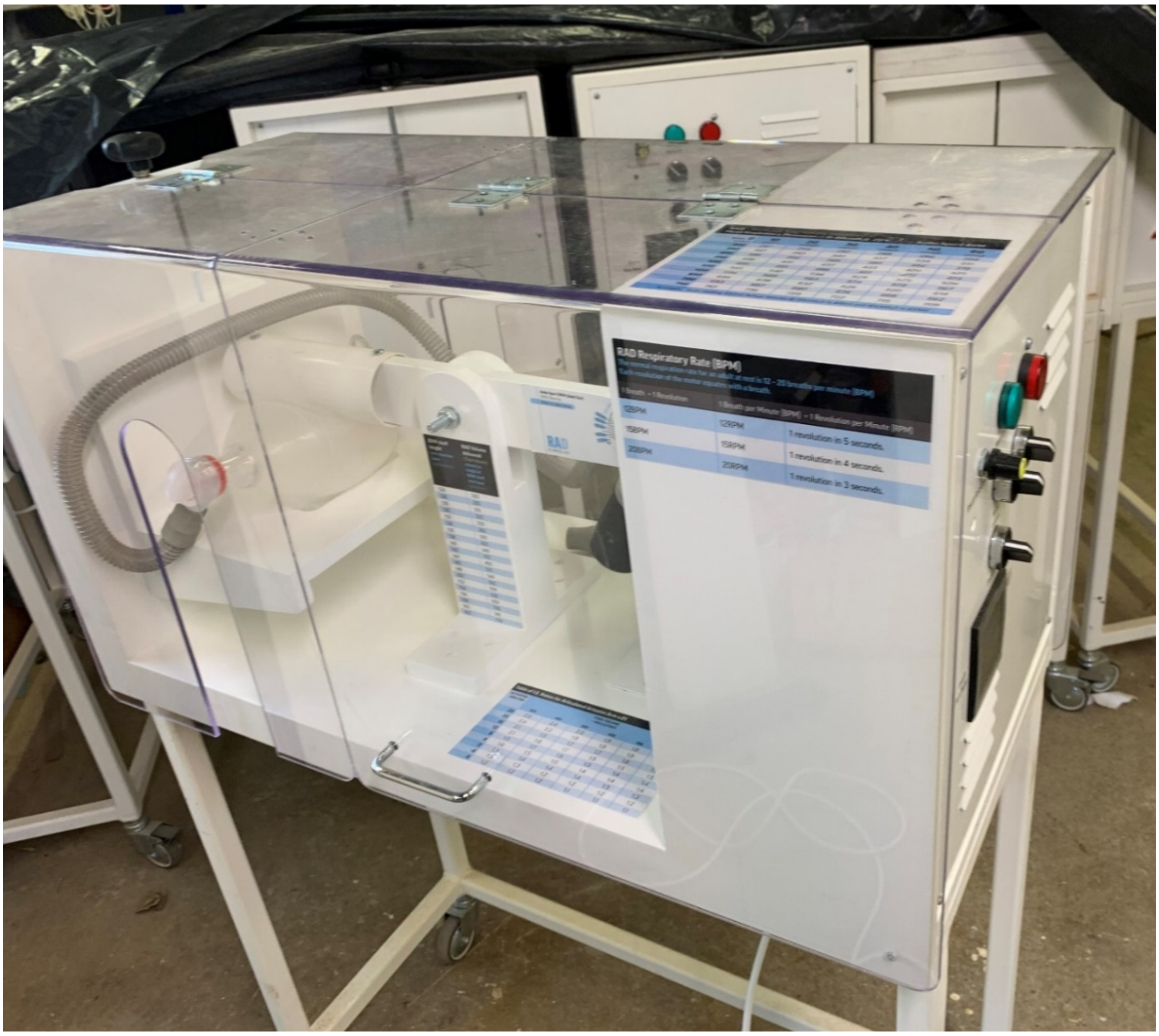


Fig: 11) **Completed Ventilato**

8. Conclusions

This study presents a model for the rapid development and manufacturing of control ventilators by individuals or companies with minimal resources. The ventilator is a solution for less well equipped/funded medical facilities as it is capable of being made in a very short time from locally sourced materials by skilled electrical and woodworking tradesmen. In its simplest iteration it merely requires a motor, a controller and a 12v battery.

The broader implications of this development highlight the ability of diverse groups of technical volunteers to rapidly mobilise cooperatively to develop and fabricate emergency equipment in response to a global pandemic.

The project was agreed from the beginning by the developers to become an open source project. The manufacturing and details will be made internet available by the Institute of Technology Sligo.