White Paper

Ventilator Modifications for Supplying Multiple Patients



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We dedicate our small contribution towards COVID-19 response in honour of all the frontline health and medical staff who are fighting a difficult battle, putting themselves at risk for our well-being. We are very grateful.

Executive Summary

The spread of COVID-19 is expected to rapidly increase the demand for critical care facilities in general and invasive mechanical ventilation in particular. For developing countries which have limited critical care infrastructure, many are at risk of death simply from lack of ventilation capacity. This paper extends previous work on reliably splitting a ventilator between four patients as a means to meet the anticipated spike in demand for ventilators. Our unique contribution is in providing a set of detailed instructions for splitting any type of ventilator adhering to ISO 5356 standard between four patients including descriptive schematics, bill of materials, and approximate price list.

Our manual also contains a dedicated section on the potential negative side to splitting a ventilator between patients. We urge clinicians and healthcare workers to pay due attention to these concerns and come to their own informed conclusions on whether to proceed with this technique.

Our motivations for compiling this manual are (i) help physicians make an informed decision on whether split ventilator support is viable in the context of COVID-19 by collecting as much information into one document and (ii) in the event clinicians decide to support multiple patients on a single ventilator, provide a clear step-by-step guide on how to do so. We believe all available options for meeting the surge demand for critical care must be explored and hope that this document helps evaluate the use of split ventilator supply scientifically.

Keywords:

COVID-19, critical care, ventilation, invasive ventilation, split ventilation

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Ventilator Modifications to Support Multiple Patients

1. Overview

There are 99 public hospitals in Sri Lanka equipped with a total of 500 ICU beds¹; not all of these beds have access to mechanical ventilators (Pinto, et al. 2019).² Further, ICU units across the country operate at full capacity nearly all the time. A Capital Alliance survey placed the ventilator per 100,000 population to be 1.9.

As COVID-19 sweeps across the world, Sri Lanka - like every other country - must prepare for the worst-case scenario. COVID-19 causes severe respiratory arrests and failures. A cohort study (Zhou, et al. 2020) performed in Wuhan, China on 191 patients hospitalised for COVID-19 – which is an acute respiratory distress syndrome caused by the novel Corona virus SARS-CoV-2 – showed that about 17 percent developed severe lung distress and required invasive mechanical ventilation, often for several days on end.³

Thus, increasing the invasive ventilation capacity across public hospitals in Sri Lanka is a major and immediate challenge to effectively combat the anticipated demand surge for critical care.

This paper discusses splitting one ventilator supply between four patients – primarily based on extensive documentation on the subject by the reputed medical blog on emergency care EmCrit.org⁴ – to rapidly scale up existing mechanical ventilation capacity in our hospitals if our medical professionals deem it safe and prudent to do so.

While this manual was drafted by engineers, information presented in this paper was verified for accuracy by Sri Lankan and UK-based physicians.

¹ Reliable data on the total available mechanical ventilators is currently absent from public domain. Ventilators are available with anaesthetic beds as well. We estimate the total available ventilators to be under thousand.

² Pinto, V. Amarasena, R. et al. (2019) 'Critical Care in Sri Lanka'. SLMA. Available HTTP: <u>https://criticalcare.lk/wp-content/uploads/2019/04/SLMA-publication-edited-for-word-count-1.pdf</u>

³ Zhou, F. Yu, T. et al. (2020) 'Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study'. Lancet. Available HTTP: <u>https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30566-3/fulltext</u>

⁴ EMCrit Project. Online Medical Education on Emergency Department (ED) Critical Care, Trauma, and Resuscitation. Available HTTP: <u>https://emcrit.org/about/</u>

2. Split ventilator

A Wiley study published in 2006 describes a method to reliably split a single ventilator among four patients (Neyman and Irwin 2006).⁵ While this study supplied artificial lungs, a later study (Paladino, et al. 2008) successfully applied the method on four sheep, each weighing 70 kilograms.⁶

As the COVID-19 crisis unfolds, these studies have received renewed interest from clinicians battling a sudden and unprecedented surge in demand for mechanical ventilation and recently, the US Food and Drug Agency approved a Y connector that facilitates splitting a ventilator for supplying four patients.⁷

We note at the outset that this is, both medically and technically, non-optimal and is a last resort in an emergency. However, split ventilation offers the following concrete benefits as opposed to DIY or from-scratch ventilator designs that are being presently circulated:

- New designs necessarily come with major reliability issues.
- Materials used in new ventilators may not always be medical grade
- It may be impossible to ramp up production of novel designs within a short time given how rapidly COVID-19 virus is spreading. This is particularly true for Sri Lanka where sourcing component parts locally in the context of global supply chain breakdown and newly introduced import restrictions is largely infeasible.
- Splitting between patients is significantly cost effective and therefore scales better.

2.1. Considerations

- 1. Patients who are connected to a ventilator should have similar severity of lung damage.
- 2. To prevent one patient from either over ventilating or under ventilating the other patients, all patients are continuously and mandatorily ventilated. This means that all patients are passive with respect to the ventilator and do not trigger its breath cycles. This may be achieved mechanically by (i) when such a facility is present in a ventilator, by activating the 'Continuous Mandatory Ventilation' mode; or, (ii) when such a facility is unavailable, setting the trigger threshold of the ventilator to the highest to prevent 'lock outs'.

If the above does not work in ventilators where CMV is not present, as the provisional clinical guidelines for treating COVID-19 patients published by the Ministry of Health, Sri Lanka

⁵ Neyman, G. and Irwin, C.B. (2006) 'A Single Ventilator for Multiple Simulated Patients to Meet Disaster Surge'. Wiley. Available HTTP: <u>https://onlinelibrary.wiley.com/doi/epdf/10.1197/j.aem.2006.05.009</u>

⁶ Paladino, L. Silverberg, M. et al. (2008) 'Increasing ventilator surge capacity in disasters: Ventilation of four adulthuman-sized sheep on a single ventilator with a modified circuit'. Elsevier. Available HTTP: <u>https://www.sciencedirect.com/science/article/pii/S0300957207005825#bib23</u>

⁷ PrismaHealth. (2020). 'How VESper works'. Available HTTP: <u>https://www.prismahealth.org/vesper/</u>

recommends, all patients' respiratory function has to be sedated, or as a last resort patients being supported may be paralysed (Ministry of Health, Sri Lanka, 2020).⁸

- 3. Between volume cycled ventilation and pressure cycled ventilation for supplying multiple patients with a single ventilator, the latter is preferred for the following reasons:
 - a. Preventing harmful interactions between patients: for example, under volume cycled control, if one patient's endotracheal tube gets twisted or blocked, others will receive excessive oxygen whereas if the same scenario arises under pressure cycled control, only that patient will receive less oxygen while others' supplies remain the same.
 - b. While volume cycled control does not provide control over the tidal volume a single patient receives or the airway pressure, pressure cycle control enables maintaining constant airway pressure across all patients.
 - c. Under pressure cycled ventilation, it is not mandatory that lung sizes of those patients sharing a ventilator match.

2.2. Limitations

The following limitations apply to splitting one ventilator between multiple patients:

- 1. We cannot control the tidal volume supplied to an individual patient.
- 2. The maximum number of patients that can be supported by a ventilator depends, primarily, on the maximum tidal volume that the ventilator is able to supply. A ventilator capable of delivering 2 litres can support up to four COVID-19 patients.
- 3. Efficacy of supply will be reduced due to the dead space introduced by additional connectors and extensions.
- 4. There is a possibility of cross contamination of germs and diseases between patients. However, we mitigate this problem with the use of antimicrobial filters in the expiratory circuit.

2.3. Continuous patient monitoring

Under pressure cycled control in one-to-one supply, while the tidal volume supplied to the patient is continuously monitored by a flow sensor, a CO_2 sensor measures the concentration of CO_2 of end tidal inspiration and expiration. However, in split supply, unless we have access to four patient monitoring devices and four CO_2 sensors, we will not be able to continuously monitor all four patients' CO_2

⁸ Ministry of Health. (2020) 'the Provisional Clinical Practice Guidelines on COVID-19 Suspected and Confirmed Patients'. Available HTTP: <u>http://www.epid.gov.lk/web/images/pdf/Circulars/Corona_virus/covid-</u> <u>19%20cpg%20_%20version%204.pdf</u>

concentrations at all times.⁹ As such, split ventilator support does not explicitly provide for monitoring this critical detail on which much clinical decisions depend.

 CO_2 sensors are expensive (Rs. 432,000) as are patient monitoring devices. Therefore, we recommend one of the following two methods to proxy measure tidal volume:

- As indicated in Figure 4, attach a CO₂ sensor adapter to each patient's breathing circuit and rotate one CO₂ sensor among the four patients to take readings at a fixed time interval deemed appropriate by a clinician.
- (ii) In the event of shortage of CO₂ sensors adapters, rotate a single CO₂ sensor and adapter pair between the patients. This can be done by disconnecting the patient whose tidal volume needs to be monitored from the grid briefly at the point where the HME filter and the endotracheal tube meet and fixing the CO₂ sensor-adapter pair in between the two components. For the brief moment that the patient is disconnected from the grid, clinicians must use a bag valve mask (BVM), also known as Ambu bags after its primary manufacturing brand, to supply the patient. However, this method risks aerosolizing the virus and is not recommended.

Further, an emergency alternative for patient monitoring is the use of contactless health monitors that typically fit underneath the mattress. A typical contactless health monitor is able to measure both heart and respiratory rates with > 98 percent accuracy.¹⁰ Remote monitoring capabilities of these devices enable safer monitoring, guarding the health professionals from potential exposure. These contactless health monitors also come with alarming systems which may be used to replicate the performance of alarm systems typically employed in ventilators.

Similarly, oxygen saturation is measured by fingertip oximeters that are plugged into the patient monitoring device for display. Again, in the absence of four patient monitoring devices, continuously monitoring oxygen saturation for all patients would be impossible. In this instance, we may use fingertip pulse oximeters that have their own displays as a suitable replacement.¹¹

2.4. Antimicrobial and antiviral filtering to prevent cross contamination

Since we will apply a positive bias pressure from the ventilator to the lung at all times, the inspiratory circuit should largely remain uncontaminated. However, as a precaution, we recommend the use of

⁹ Some ventilators come with in-built CO₂ sensor ports. Others require additional patient monitoring devices.

¹⁰ See: Dozee, an Indian product that states 98.4% measuring accuracy. The product costs Rs. 20,000. Available HTTP: <u>https://www.amazon.in/Dozee-Contactless-Health-Monitoring-System/dp/B07PZSHTZ9</u>

¹¹ <u>https://www.walgreens.com/store/c/walgreens-fingertip-pulse-oximeter/ID=prod6089451-product</u>

antiviral and antimicrobial filters for each patient's inspiratory and expiratory circuits.¹² See Section 3.2 for greater detail. If using disposable filters replace them every six hours. If using reusable filters sterilize according to the standards followed in the hospital.

2.5. Issues arising from increased dead space

EmCrit.org's extended discussion (see Footnote 12) on splitting a ventilator states that increased mechanical dead space created by the additional circuitry in a split setup would result in reduced carbon dioxide removal from the lungs, resulting in a condition called hypercapnia in patients. However, mechanical dead space refers to those portions in the circuit that are shared by both the inspiration and expiration lines (i.e. the section from the Y connector terminal to the end of the endotracheal tube). As such the dead space volume for a patient connected to a split supply grid and a patient connected to a single ventilator is, in fact, roughly the same: tubing away from the shared areas does not increase dead space.

2.6. Standard settings to be applied to the ventilator

As discussed above, we will apply continuous mandatory ventilation (CMV) to all patients using pressure cycle control.

Patients must be grouped by severity of lung damage by physicians. Josh Frakas, a US clinical associate professor and intensivist recommends (Frakas, J. 2020) the following settings for five different patient groups by severity of lung damage.¹³

- 1. Ventilator 1: Mild injury settings (FiO2 50%, PEEP 10 cm, peak pressure 20 cm)
- 2. Ventilator 2: Moderate injury settings (FiO2 60%, PEEP 14 cm, peak pressure 26 cm)
- 3. Ventilator 3: High injury setting (FiO2 80%, PEEP 18 cm, peak pressure 30 cm)
- 4. Ventilator 4: Refractory hypoxemia settings (FiO2 100%, PEEP 22 cm, peak pressure 35 cm).
- Ventilator 5: Salvage settings (FiO2 100%, PEEP 22 cm, peak pressure 35 cm, inverse ratio ventilation with inspiratory time >> expiratory time).

Mechanical ventilators are generally able to supply 2L of tidal volume. Recommended tidal volume for critically ill COVID-19 patients is $\sim 6 - 8$ ml per kilogram of predicted body weight¹⁴ (Meng, L. et al. 2020). This means that for an 80 kg of ideal weight individual we would need to supply a maximum tidal volume of 480 ml; thus, the capacity of standard mechanical ventilators is sufficient to support

¹² Even though the primary function of Heat and Moisture Exchanger (HME) filters is moisturizing and humidifying the air supply into the patient (similar to the function performed by nostrils), they now typically come with antiviral and antimicrobial filtering capability and are more commonly available than standalone antiviral, antimicrobial filters. Therefore, it is possible to use HME filters in place of antiviral and antimicrobial filters.

¹³ Frakas, J. (2020) 'Splitting ventilators to provide titrated support to a large group of patients'. PulmCrit. Available HTTP: <u>https://emcrit.org/pulmcrit/split-ventilators/</u>

 $^{^{14}}$ Ideal Body Weight is approximately calculated as $[22\ x$ (height in meters) $^2]$

up to four patients. Recommended maximum respiratory rate would vary by severity of disease with the worst affected requiring > 30 breaths per minute;¹⁵ generally, the recommended respiratory rate for COVID-19 patients tends to be 14 – 16 breaths per minute (Ministry of Health, Sri Lanka, 2020).¹⁶

2.7. Removing a patient from the split supply grid

In certain situations, a patient connected in the split supply may improve or deteriorate. In case of deterioration, the patient may have to be moved from a 'mild injury' category to 'high injury' category ventilator or a dedicated ventilator. When doing so, disconnect the patient to be moved at the end of the Y connector and seal the Y connector with the end-cap that comes with every breathing circuit. We do not have to be concerned about over ventilating other patients since the supply is pressure cycled, the flow will adjust itself.

2.8. Backflow

We expect minimal backflow – i.e. expired CO_2 flowing back into the mechanical dead space – under pressure cycled operation. This is so because the minimum pressure in patient lungs at any given time will always be greater than or equal to PEEP. PEEP in turn is greater than atmospheric pressure. As such expired CO_2 should flow out towards the expiratory port naturally. However, for added protection, we may deploy patient circuits that provide one way valves for inspiratory and expiratory lines.

¹⁶ See Footnote 8

¹⁵ Meng, L. Qiu, H. et al. (2020) 'Intubation and Ventilation amid the COVID-19 Outbreak: Wuhan's Experience'. Anesthesiology. Available HTTP: <u>https://anesthesiology.pubs.asahq.org/article.aspx?articleid=2763453</u>

3. Setting up a Ventilator to supply four patients

This section describes in detail how to set up a ventilator to support four patients. The following apply nearly uniformly to any ventilator that follows the ISO 5356 standard for anaesthetic devices.

3.1. Bill of materials

Table 1: BC	OM for splitting	an ISO 5356	standard	ventilator	between	four	patients
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	Item	Code to match with Figure 4	Quantity	Specification/Brand	Unit price (LKR)	Total cost (LKR)
1	T tubes ¹⁷	С	6		450	2,700
2	Extender tubes (Optional)	А	4		1000	4,000
3	Adult breathing circuit Vent Set ¹⁸	E	4	Evaqua 2	9,950	39,800
4	Disposable antiviral & antimicrobial filter	В	12			
5	Flow sensor ¹⁹	D	4		18,000	72,000
6	Disposable HME filter	G	4	Flexicare	550	2,200
7	Disposable catheter mount	F	4	Flexicare	900	2,280
8	Disposable endotracheal tube		4	Flexicare	465	1,860
9	etCO2 sensor adapter	Н	4		800	3,200
10	etCO ₂ sensor	1	1	(This will be available with the ventilator or the patient monitoring device)	(Cheap ones cost ~ Rs. 100,000)	100,000
11	ET tube	Ι	4			
12	Contactless health monitor		4	(Optional in the event physicians decide individual monitoring is absolutely necessary)	20,000	80,000
13	Oximeter (optional)		4	(fingertip pulse oximeter with display)	12,000	48,000

¹⁷ You can alternatively print the T tubes. See Section 3.2 for greater detail. We will make available the CAD drawings in a later version of this document.

¹⁸ Do not dispose of the Y connector cap that comes with the breathing circuit as you may require it to remove a patient from the grid.

¹⁹ Flow sensors may be purchased for \$ 70 per unit. However, these need to be wired to a display via a microcontroller for obtaining reading. Additional circuity will cost under \$ 30. Next version of this document will have a section on wiring flow sensors to displays and related code.

Depending on the type or brand of the ventilator in your hospital, replace the items mentioned in this BOM with equivalent accessories. For further clarity match the alphabets within brackets with the same on the

Note that except for (1) and (2), other items are anyways essential to support a patient on a ventilator. Thus, the additional cost components associated with splitting a ventilator – i.e. providing for three more patients – are (1) and (2) which when tallied come under Rs. 10,000.

3.2. Manual: setup to split a single ventilator between four patients

Step 1: Group patients by severity of lung damage using the guidelines provided in Section 2.6. The following steps describe how to ventilate one such group containing four patients.

Step 2: Arrange the patients as shown in Figure 1. Such an arrangement ensures the recommended 1 meter separation for preventing cross infection while also optimally reducing the length of each patient's circuit. All dimensions are in millimetres. Total area occupied by this arrangement is 5620 mm (length) x 5305 mm (width).



Figure 1: Bed layout for split ventilator supply

Step 3: Create two T tube junctions (or equivalent Y tube junctions) using three T tubes per junction, as indicated in Figure 2.



Figure 2: Splitting inspiration or expiration circuit between four patients using a three T tube jubction

In the absence of T connectors that match the primary ventilator ports, one may consider 3D printing or injection moulding equivalent components.

However, it is important to ensure that the materials used are of medical grade. Suitable materials for our purposes here are (i) Polypropylene (PP) which is widely used in oxygen related applications in medicine including the construction of membranes for providing oxygen to blood and artificial vascular grafts and (ii) Polycarbonates (PC) which is widely used for constructing medical grade valves. Both materials are biocompatible and lend themselves to various 3D printing techniques such as Fused Deposition Modelling (FDM), Sterolithography (SLA), Selective Laser Sintering (SLS) (Pandey, K. et al. 2016).²⁰ These materials can be also used in injection moulding.

²⁰ Pandey, K. et al. (2016) 'Biocompatible Materials Used in Medical Practices – A Review'. International Journal of Pharmaceutical Sciences and Research. Available HTTP: <<u>http://ijpsr.com/?action=download_pdf&postid=25771</u>>

Step 4: Connect one T junction to the inspiratory port and the other to the expiratory port of the ventilator. In certain ventilators the ports may not connect to T tubes due to physical constraints. Under such conditions add the optional extender.



Figure 3: Schematic for splitting one ventilator between four patients; connections for Patient 1 and Patient 2 are shown

Step 5: Connect an HME filter to the Y connector at each patient's end. Link the endotracheal tube to the HME filter via an etCO₂ sensor adapter for each patient.



Figure 4: Complete breathing circuit for one patient under split supply

Note that in Figure 4, the connection is shown under the assumption that each patient connected to the grid has separate CO_2 sensor adapters (i.e. 4 sensor adapters + 1 sensor). If you are rotating a single sensor adapter pair between all four patients then it is perhaps worth plugging the pair between the catheter mount and the HME filter. This would help reduce contamination from expiration releasing directly into the atmosphere during disconnections for measurements. However, we do not recommend this.

Step 6: Apply the appropriate setting indicated in Section 2.6 according to the distress severity grouping.

Step 7: Carry out continuous monitoring as deemed appropriate by physicians.

Step 8: If you are using a single CO_2 sensor between multiple patients, normally leave the CO_2 sensor attached to a patient. At a predetermined time interval decided by clinicians, unplug the CO_2 sensor from the patient to whom it is normally attached to and plug on to the others in rotation. For each patient, leave adequate time for the sensor to calibrate and for the measurement to stabilize.

Step 9: In the event a patient needs to be removed from the grid and moved to another grid, disconnect the patient to be moved at the end of the Y connector and seal the Y connector with the end-cap that comes with every breathing circuit. Supply the patient with a bag valve mask (Ambu bag) during the interim between disconnection and connection to the new grid.

4. Criticism against split ventilator usage

While some emergency care doctors have openly promoted the use of split ventilators, others have warned against the practice. We summarise the key considerations against the use of split ventilators here to enable healthcare workers make a balanced and informed choice. We also tabulate what measures may be taken to mitigate some of the issues raised. Admittedly, such mitigation strategies may be insufficient and we encourage physicians to draw their own informed conclusions.

	Criticism	Mitigation
1	Volumes would go to the most compliant lung segments.	 Grouping patients by severity of lung disease helps reduce variance in compliance. Set a high enough inspiratory-time such that pressure equilibrates through all patients and end inspiratory flow drops to zero prior to the termination of breath.
2	Positive end-expiratory pressure would be impossible to manage.	- Grouping patients by severity allows for a fixed PEEP for a given ventilator.

Table 2: Issues arising from split ventilator usage and possible mitigation

3	Monitoring patients and measuring pulmonary mechanics would be challenging, if not impossible.	-	With all optional components mounted as shown in Figure 4 and alongside the deployment of contactless health monitors it is possible to monitor each patient to a significant degree.
4	Alarm monitoring and management would not be feasible	-	To a certain degree, this can be mitigated through the use of contactless health monitors for each patient. Such health monitors also provide alarming capability.
5	Individualized management for clinical improvement or deterioration would be impossible.	-	It is possible to shift patients between different grids. Further, one ventilator can be spared for individualised treatment in the event of unforeseen developments.
6	In the case of a cardiac arrest, ventilation to all patients would need to be stopped to allow the change to bag ventilation without aerosolizing the virus and exposing healthcare workers. This circumstance also would alter breath delivery dynamics to the other patients.	-	When removing patients from the grid, do so right at the end of the Y connector of that patient and immediately seal the end of the Y connector with the standard cap as discussed in Section 2.7. This means that the expiration of the patient actually passes through the HME filter before releasing to the atmosphere. The antiviral and antimicrobial filters on the inspiratory line do likewise for inspiratory line.
7	The added circuit volume defeats the operational self-test (the test fails). The clinician would be required to operate the ventilator without a successful test, adding to errors in the measurement.	-	We intend to reproduce this issue in a laboratory test. We will update our findings thereafter in the next version of this document.
8	Even if all patients connected to a single ventilator have the same clinical features at initiation, they could deteriorate and recover at different rates, and distribution of gas to each patient would be unequal and unmonitored. The sickest patient would get the smallest tidal volume and the improving patient would get the largest tidal volume.	-	Refer points (1), (4), and (5) of this table.
9	The greatest risks occur with sudden deterioration of a single patient (e.g., pneumothorax, kinked endotracheal tube), with	-	Under pressure cycled ventilation, the ventilator would control the inspiratory flow continuously to meet the pressure requirements. For example, in the event of a kinked ET preventing full supply to one

the balance of ventilation	patient, the total flow out of the inspiratory port
distributed to the other patients.	would reduce (Frakas, J. 2020).

Issues observed under the left 'Criticisms' column are taken verbatim from the joint statement issued by the Society of Critical Care Medicine (SCCM) and other related professional groups discouraging the use of split ventilators (SCCM 2020).²¹ For further reading on potential negatives to split ventilator usage please read (Iwashyna, J. 2020).²²

5. Additional information

5.1. T tubes available in the market

T Tubes	Unit price	Local supplier / buying link	
T Tube (22 mm MMF)	450	Techno Medics International (Pvt) Ltd, Sri Lanka	

²¹ The Society for Critical Care Medicine. (2020) 'Consensus Statement on Multiple Patients Per Ventilator'. Available HTTP: <<u>https://www.sccm.org/Disaster/Joint-Statement-on-Multiple-Patients-Per-Ventilato</u>>

²² Iwashyna, J. (2020) 'Should we put multiple patients on single ventilator?' Life in the Fast Lane. Available HTTP: <<u>https://litfl.com/should-we-put-multiple-covid-19-patients-on-a-single-ventilator/</u>>

6. Authors and acknowledgements

This manual was a joint effort by multiple people. Author names are in no particular order:

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