CHARACTERISTICS OF RAPIDLY MANUFACTURED VENTILATORS: A SCOPING REVIEW

by

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ABSTRACT

The mechanical ventilator shortage caused by the Sars-CoV-2 (Covid-19) respiratory virus revealed healthcare systems worldwide were not equipped to handle mass-casualty events. Rapidly manufactured ventilators (RMVs) are low-cost machines made from readily available materials capable of performing the basic requirements of mechanical ventilation and posed a potential solution when intensive care unit ventilators were occupied. In the current literature, a plethora of RMVs exist in a variety of designs and capabilities; however, a lack of universal standards regarding their design and testing procedures restrict their safe introduction into the clinical setting. Standards for medical devices, like the International Organization for Standardization (ISO), help ensure safe, reliable and effective performance while also reducing the risk for recalls or adverse events. This scoping review collected and synthesized all available evidence on RMVs for critically ill patients. In April 2022, a systematic search was completed in numerous databases, resulting in the inclusion of 52 articles (53 RMVs). Four categories (operating, performance, other general features, and engineering components) created based on the information from six RMV guidance documents described the characteristics of the RMV designs and are presented in textual and graphical form. There was a large amount of variability in the characteristics of the RMVs, with some including several design elements and quality testing, while others including very few. Based on the synthesis of the 53 RMVs and six previously published RMV guidance documents, 11 suggestions regarding RMV design, performance and testing are provided. These suggestions may serve as a useful tool for

development of universal standards such as those published by the ISO or for teams wishing to design their own RMV.

Key Words: Mechanical ventilators; rapidly manufactured ventilators; artificial respiration; disaster planning; COVID-19; Pandemic; open-source; Resource-Limited Settings

AUTHORS DECLARATION

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I hereby certify that I am the sole author of this thesis. No part of this thesis has been published or submitted for publication. Standard referencing practices were used to acknowledge ideas and collect information from other authors. Lastly, I hereby certify that I am the sole source of the creative works and/or inventive knowledge described in this thesis.

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LIST OF ABBREVIATIONS

AARC	American Association for Respiratory Care
ABBU	Automated breathing bag unit
ARDS	Acute respiratory distress syndrome
ASV	Adaptive support ventilation
bpm	Breaths per minute
CMS	Content management system
CMV	Continuous mandatory ventilation
CNC	Computer numerical control
CPAP	Continuous positive airway pressure
E-P	Electro-pneumatic
ETT	Endotracheal tube
FDA	Food and Drug Administration
FDM	Fuse deposition modelling
FiO_2	Fractional concentration of inspired oxygen
GUI	Graphical user-interface
HEPA	High efficiency particular air
HME	Heat and moisture exchange
HMI	Human-machine interface
ICU	Intensive care unit
IEC	International Electrotechnical Commission
ISO	International Standardization Organization
I:E	Inspiratory to expiratory ratio
LCD	Liquid crystal display
LED	Light-emitting diode
MHRA	Medicines and Healthcare Regulatory Agency
MR	Manual resuscitator
OL-CMV	Open loop – continuous mandatory ventilation
PCB	Printed circuit board

PCV	Pressure control ventilation
PC-A/C	Pressure control – assist/control
PC-A/C-PRVC	Pressure control – assist/control – pressure regulated volume control
PC-CMV	Pressure control – continuous mandatory ventilation
PC-IMV	Pressure control – intermittent mandatory ventilation
PC-PSV	Pressure control – pressure support ventilation
PEEP	Positive end expiratory pressure
PIP	Positive inspiratory pressure
PRVC	Pressure regulated volume control
PSI	Pound per square inch
PSV	Pressure support ventilation
RMV	Rapidly manufactured ventilator
RMVS	Rapidly manufactured ventilator system
RR	Respiratory rate
SARS-CoV-2 (or COVID-19)	Severe Acute Respiratory Syndrome Coronavirus 2
SIMV	Synchronized intermittent mandatory ventilation
SIMV-VC	Synchronized intermittent mandatory ventilation – volume control
SLS	Selective laser sintering
TV	Tidal volume
USD	United states dollar
V	Voltage
V_E	Minute ventilation
VCV	Volume control ventilation
VC-IMV	Volume control – intermittent mandatory ventilation
VILI	Ventilator induced lung injury

CHAPTER 1: INTRODUCTION

The influenza and Middle Eastern Respiratory Syndrome (MERS) outbreak in the early 2000s revealed that intensive care unit (ICU) mechanical ventilators were not available in high enough quantities to meet the large volume of patients requiring this life-supporting treatment (El Haddi et al., 2020). Since the 2000's, little changed to prepare for future mass-casualty events. The SARS-CoV-2 (Covid-19) outbreak was declared a global pandemic in March 2020, yet again another shortage of mechanical ventilators was a major contributing factor to the rise of mortality rates and the cause of difficult triaging decisions by healthcare professionals (HCPs) (King et al., 2020). In developed countries the ventilator shortage quickly became a real and pressing issue; but in low- and middle-income countries (LMICs), who are under-resourced even during usual times, this issue was disastrous (Krishnamoorthy et al., 2014). For example, there were less than 2000 ventilators distributed among 41 African countries, compared to the United States who have more than 120,000 (Wells et al., 2020). In some LMICs (e.g., Kenya, Cameroon, Nigeria), a single ventilator did not even exist (Krishnamoorthy et al., 2014). To find a solution to the ventilator shortage, supply distributors upscaled manufacturing of ventilators but were unable to meet demand in such a small timeframe (Pearce et al., 2020). This is because the healthcare system relies on specialized, patented, mass-manufactured ventilators from a small number of suppliers which costed upwards of $50,000 USD (estimated cost in 2023) and take months to produce (Dondrop et al., 2020). In addition, more staff and training would be required to operate and manage these machines, which is often not feasible, especially during events like a global pandemic. This supply model is flawed when there is a rapid surge in demand for

a low-quantity specialty product (Pearce et al., 2020). Additionally, the thousands of stockpiled ventilators in developed countries were not utilized because preventative maintenance on the devices was not completed over the years they were stored, rendering them inoperable (Stracqualursi, 2020).

Rapidly manufactured ventilators (RMVs) were presented as a possible solution during the Covid-19 pandemic. RMVs were easy to manufacture, low-cost, simple to construct and operate in a similar manner to their ICU counterparts (Pearce et al., 2020). Experts from various academic disciplines (e.g., medicine, engineering) quickly collaborated to create ventilators through “open source” networks; designs shared publicly with a freely available license allowing others to replicate the design or suggest improvements (Pearce, 2020). RMVs can be mass-manufactured in a fraction of the time compared to ICU ventilators due to the use of “off-the-shelf” parts (e.g., parts found in local hardware stores) or readily available materials (Pearce, 2020). Three-dimensional (3D) printing (also known as additive manufacturing (AM)) is a technology used internationally (Shahrubudin & Ramlan, 2019) and played a key role in the development of RMVs. In the months following the ventilator crisis, a plethora of designs were published online and in the peer-reviewed literature. However, RMV designs have highly variable features, settings, and other characteristics likely because of a lack of standardized guidelines and testing procedures. This also makes it difficult to determine which designs are best suited for the clinical setting.

Mechanical ventilator manufactures are held to a much higher standard than manufactures of most other products due to the serious consequences if administered improperly (McAllister & Jeswiet, 2003). For example, the alveoli in the lungs are

subject to stress and strain from the delivery of high pressures (i.e., barotrauma) or high volumes (i.e., volutrauma) which can result in ventilator induced lung injury (VILI) (Vieillard-Baron & Dreyfuss, 2017). To mitigate serious adverse events, ICU ventilators must follow the ISO 80601-2-12:2020(en) *Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators* set of standards published by the International Standardization Organization (ISO). These technical specifications and precise guidelines ensure reliability, effectiveness and safety of the medical device before it can enter the market and be used in the clinical setting.

As of April 2023, no international standards for RMVs exist but several "recommended" guidelines and specifications have been published (Branson et al. 2020; CIEHF, 2021; Einav et al., 2014; Government of Canada, 2021; Hakimi et al., 2022; MHRA, 2020; Pearce, 2022; WHO, 2020). Specific "minimally acceptable" RMV characteristics identified in these guidelines include operating features, performance features, engineering features and other general features. However, like the RMV designs, variation exists between the recommended guidelines as well. For example, there is variation in the ranges of ventilation parameters, required modes of ventilation, alarm triggers and other general components such as back up battery, end-user training program and more. Developing international standards for RMVs before the next pandemic or future mass-casualty events may help address potential ventilator shortages. However, work to do this should begin promptly as it can take upwards to three years from first proposal to final publication for standards to be developed on medical devices within the ISO (*International Organization for Standardization*, n.d.).

In this scoping review, the basics of mechanical ventilation and how it interacts with the human body to support a patient until their disease state improves enough to no longer require support will be discussed. The characteristics of RMVs will be analyzed using four broad categories: operating features, performance features, engineering components and other general features. The minimum clinical features, settings and testing procedures will be described in detail and inform suggestions on universal standards for effective and safe RMV designs. This research is not meant to provide the definitive RMV standards recommendations, but is the first steps toward universal standards for RMVs to ensure safe and effective operation.

CHAPTER 2: BACKGROUND AND CONTEXT

2.1 Lung Physiology

The lungs are a major organ within the respiratory system responsible for supplying oxygen (O_2) rich air to the body and removing left-over carbon dioxide (CO_2). Oxygen rich air enters through the nose or mouth, travels down the trachea to the right and left bronchus which further divide into bronchioles, and alveoli or alveolar sac. The alveoli (together with the circulatory system) are responsible for gas exchange (respiration) where O_2 and CO_2 diffuse from higher concentrations to lower concentrations. Before gas exchange can occur, the ventilation process must take place. Ventilation is the mechanical movement of air in and out of the lungs and is triggered by the brain. The brain monitors the body and constantly receives signals to achieve homeostasis (i.e., balance between all body systems). The brain is capable of detecting the amount of O_2 and CO_2 in the blood and can change the rate of ventilation by transmitting signals to the respiratory muscles to contract or relax. (Sheel & Romer, 2011). When the body is active (e.g., during exercise) the rate of ventilation and tidal volume increases to keep up with increased energy expenditure, whereas during sedentary activity the rate of ventilation and tidal volume decreases (Dominelli & Sheel, 2012). Ventilation begins with signals from the brain telling the respiratory muscles (e.g., intercostal muscles) and diaphragm to contract allowing for air to enter the mouth or nose. Once air enters the body it travels past the pharynx (back of throat), larynx (voice box) and down the trachea (windpipe). The airway passage splits into two called the primary bronchi leading to the right and left lungs. The primary bronchi are further divided up into the secondary bronchi, tertiary bronchi, bronchioles, alveolar duct and

the alveoli. The alveoli (air sacs) are where gas exchange takes place. Normally, ventilation is automatic (i.e., involuntary), and dependent on the degree of resistance to air flow through the respiratory tract (i.e., resistance) and the lungs ability to stretch and expand (i.e., compliance) (Walter et al., 2018).

Certain conditions, such as acute respiratory distress syndrome (ARDS) cause an excess build-up of fluid in the alveoli (Force et al., 2012). This can cause impairments in the frequency and volume of ventilation (due to reduced lung compliance) and prevent adequate gas exchange (Russotto et al., 2018). This leads to shortness of breath, and dangerously low O_2 (hypoxia) and high CO_2 (hypercarbia) levels. According to a global literature survey analyzing the incidence of ARDS and outcomes in hospitalized patients with Covid-19, 33% - 75% of Covid-19 patients develop ARDS and 16% - 63% receive invasive mechanical ventilation treatment (Tzotzos et al., 2020).

2.2 Mechanical Ventilation

Mechanical ventilation is a type of life-supporting therapy used regularly in the clinical setting by partially or completely taking over a patients breathing by providing a positive pressure breath to facilitate the movement of gases (O_2 and CO_2) in and out of the lungs (Pham et al., 2017; Hess & Kacmarek, 2019). The air/oxygen mixture can be delivered non-invasively via a mask or invasively via an endotracheal tube placed in patient's trachea depending on patient circumstances (Pham et al., 2017). It is used when patients cannot maintain their airway (e.g., decreased level of consciousness), or have inadequate gas exchange (low O_2/high CO_2) or ventilation issues (e.g., pneumonia, spinal cord injury, general anesthesia) (Esteban et al., 2008).

2.2.1 Ventilation Modes

Modern mechanical ICU ventilators offer numerous modes of ventilation. Three characteristics define the mode: *trigger* is the signal that tells the ventilator when to initiate the breath, *target/limit* is the maximum level provided by the ventilator for a given breath (pressure, volume or flow limited), and *cycle* is the signal that tells the ventilator to transition from inhalation to exhalation (pressure, volume, flow, or time) (Pham et al., 2017). Ventilation modes can be *controlled or mandatory,* with the ventilator determining when to trigger and cycle the breath (based on a set respiratory rate (RR)) (Hakimi et al., 2022). Modes can be *spontaneous or supported,* with the patient effort determining the trigger and cycle of the breath (Hakimi et al., 2022). Modes can also be a combination of the two, with the patient being provided a set number of controlled breaths and any "extra" spontaneous breaths they may need. Controlled ventilator modes are typically used for critically ill patients who are not able to initiate any breaths (Hakimi et al., 2022). As their acute illness resolves (or with decreases levels of sedation), they are usually able to transition to combination modes, and eventually a fully spontaneous mode before being liberated from the ventilator (Pham et al., 2017).

Mechanical ventilators have several different target/limit options, the most common being pressure or volume focused. In pressure-limited modes, the peak inspiratory pressure (PIP) is the target/limit set. In these modes, the ventilator pressure remains constant, while the patient's tidal volume (TV) may vary depending on the lung's resistance and compliance (Pham et al., 2017). Examples are Pressure Controlled Ventilation (PCV, a mandatory mode), and Pressure Support Ventilation (PSV, a spontaneous mode). In volume-limited modes, the TV is the target/limit set. The

ventilator delivered volume remains constant, while the patient's airway pressure may vary (e.g., Volume Controlled Ventilation VCV, mandatory).

The names of the modes may vary depending on target/limit and/or cycle and manufacturers. Assist Control (A/C) or Continuous Mandatory Ventilation (CMV) provide set volume-limited or pressure-limit breaths whether it's by the machine or if the patient makes a spontaneous effort (all breaths delivered are the same) (Hakimi et al., 2022). Normally, A/C or CMV are volume-limited unless indicated otherwise e.g., Pressure Control A/C (PC-A/C) or Pressure Control CMV (PC-CMV) are pressure-limited (Hakimi et al., 2022). Intermittent Mechanical Ventilation (IMV) or Synchronized IMV (SIMV) also provide set breaths, however the mandatory breaths are usually set differently than the spontaneous ones. Mandatory breaths are usually PCV or VCV, and the spontaneous breaths limited by pressure, volume, flow (the last being most common such as is PSV) (Hess & Kacmarek, 2019). IMV and SIMV usually facilitate synchronization and comfort with the patient and helps facilitate the weaning and liberation process (Hess & Kacmarek, 2019). Finally, Pressure Regulated Volume Control (PRVC) is a unique dual mode involving both pressure volume targets/limits working together in a breath-by-breath algorithm (Hess & Kacmarek, 2019). There are many more modes of varied combinations that are not discussed as it is beyond the scope of this thesis.

2.2.2 Ventilation Settings

Mechanical ventilators have a wide variety of settings to meet the patient's treatment goals. Ventilator settings include tidal volume (TV) (millilitres), respiratory rate (RR) (breaths per minute (bpm)), inspiratory to expiratory (I:E) ratio, positive-end expiratory pressure (PEEP) (centimetres of water (cm H_2O), peak inspiratory pressure

(PIP) (cm H_2O), flowrate (litres per minute (LPM)), and fractional concentration of inspired O_2 (FiO_2). Tidal volume is the amount of air delivered to the lungs during a normal breath. RR is the number of breaths delivered to the patient per minute. I:E ratio is the ratio of time spent in the inspiratory and expiratory phase. PEEP is the positive pressure applied by the ventilator that remains in the lungs at the end of the expiratory phase to prevent alveolar collapse and improve oxygenation. In conditions such as ARDS the lungs may require higher levels of PEEP. PIP is the highest pressure applied to the lungs during the inhalation phase. Flowrate usually refers to maximum flow delivered by the ventilator. FiO_2 is the fractional concentration of oxygen in the gas mixture that is delivered to the patient. All of the above-mentioned ventilator settings will vary depending on the severity of the underlying respiratory or ventilatory conditions and/or patient age (Pham et al., 2017).

2.3 Standards for Mechanical Ventilators

Over time mechanical ventilators have evolved and have also become increasingly complex. For any medical device, strict standards outlining machine requirements and testing procedures must be followed before introduction into the clinical setting. Although RMVs may not be used in the clinical setting but rather in a home, transportation or emergency area setting, standards are still required to ensure the machines are safe and reliable. The International Organization for Standardization (ISO) is a worldwide federation responsible for developing international standards on a variety of products before they can be used. Specific health and safety standards help reduce workplace accidents while quality management standards help ensure products work efficiently and reduce product failures (International Organization for

Standardization, 2018). ISO standards are developed and completed over a two-year period and are initiated by industry or stakeholders (not the ISO themselves) (International Organization for Standardization, 2018). Experts in the discipline come to an agreement on the best standards and approaches to ensure consumers have confidence that the products are safe, reliable and of good quality (International Organization for Standardization, 2018). There are several ISO standards for different types of ventilation including intensive-care ventilators, anaesthesia ventilation, emergency and transport ventilation and home-care ventilation, including sleep-apnoea breathing-therapy equipment (ISO, 2020). For example, intensive care unit (ICU) mechanical ventilators must meet the *ISO 80601-2-12:2020(en) Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*. Currently there are no ISO standards for RMVs.

2.3.1 RMV "Standards"

Standards and recommendations both contain certain characteristics that are necessary for their application however, recommendations are not mandatory whereas standards are. Although no ISO equivalent standards exist for RMVs, recommendations exist to help guide clinical and/or engineering teams manufacture and test their RMVs (Branson et al. 2020; CIEHF, 2021; Einav et al., 2014; Hakimi et al., 2022; MHRA, 2020; Pearce, 2022). These six RMV "standard" documents described various operating features, performance features, engineering features (i.e., hardware and software), safety features, other features, and recommended documentation. These guidance documents do not represent standards for RMVs, however, these were as close to standards as could be at the time. Due to the variability in recommendations, the RMV

designs themselves are diverse in character and do not meet some (or any) of the RMV recommendations. The multifactorial issue of many RMVs of varying design (e.g., Table 6), multiple overlapping yet conflicting recommendation guidelines (e.g., Table 1 – 4) and no common universal standard, highlights the requirement to determine what should be included for the RMV design to be safe and effective for use on humans. Described below are six guidance documents which presented recommendations for optimal RMV design performance, with details provided in Tables 1 to 4.

The **American Association for Respiratory Care (AARC)** (Branson et al., 2020) is a not-for-profit professional association consisting of respiratory therapists, and allied health practitioners caring for patients with lung disorders and other conditions. Their guidance document published in May 2020, included frequently asked questions and concerns regarding SARS-CoV-2. Major questions answered in this guidance document include “What are the major findings in patients with SARS CoV-2 viral pneumonia requiring mechanical ventilation?”, “Can the Strategic National Stockpile ventilators manage patients with COVID-19?”, “Can bilevel ventilators be used for invasive ventilation?”, “Can I ventilate more than one patient with a single ventilator?” and “What about using artificial resuscitators or minimal function mechanical ventilators?”. Within the detailed document, the AARC recommended mandatory operating features for ventilators such as TV, PEEP, breathing frequency, FiO_2, breathe type and more. These mandatory specifications used the CHEST Consensus statement (Einav et al., 2014) as a guide when determining what RMV would be best suitable for the clinical setting.

CHEST is an American based peer-reviewed medical journal that publishes papers on chest diseases and other related issues such as breathing, airway diseases and emergency medicines (Einav et al., 2014). In 2014, CHEST published a Consensus Statement regarding approaches to care for the critically ill within the context of pandemics and disasters. The article discussed surge capacity logistics and careful planning for disasters situations to prevent hospitals from becoming overwhelmed due to depletion of resources. This included describing stockpiling of equipment (including positive pressure ventilators) and ancillary supplies for a potential surge. This document also included mandatory and optional recommendations on operating, performance, safety, and maintenance features for stockpiled mechanical ventilators. Mandatory and optional features were offered in the document.

A government agency based out of the United Kingdom called the **Medicine and Healthcare products Regulatory Agency (MHRA)** published a document in April 2020 discussing specifications for Rapidly Manufactured Ventilator Systems (RMVS) (MHRA, 2020). This agency is found within the Department of Health and Social Care and is responsible for ensuring medical devices operate and are safe for human use. Within the document, specifications regarding ventilation, gas and electricity, infection control, monitoring and alarms, biological safety, software safety and testing of RMVs are presented with “must have” and “could have” features for their development and design.

The **Chartered Institute of Ergonomics & Human Factors (CIEHF)** based out of the United Kingdom is a professional society for ergonomists, human factors specialists, and others involved in user-centered design (CIEHF, 2020). The goal of this society is to examine the interactions between technology (i.e., RMVs) and humans to

achieve optimal human safety and performance. A guidance document by CIEHF published in 2020 called *Human Factors in the Design and Operation of Ventilators for Covid-19* discussed seven important topics that designers and manufactures of ventilators requiring rapid design and production should address. The seven topics include: graphical user-interface (GUI), users of ventilators, environment of use, task, the risks, instructions for use and training.

A book published in 2022 called ***Mechanical Ventilation Amid the COVID-19 Pandemic*** by editors Hakimi and colleagues included various chapters by numerous authors and served as a guide for physicians and engineers (Hakimi et al., 2022). Chapters of the book include: Part 1 – *Lung Physiology and Ventilator Basics*, Part 2 – *SARS CoV-2 Transmission and Innovative Protective Barriers*, Part 3 – *Bridge Ventilator Design and Components* (a bridge ventilator is a term that has been used interchangeably with RMV*)*, Part 4 – *Regulatory Factors and Device Testing* and Part 5 – *Pandemic Innovations*. All chapters described mechanical ventilation during Covid-19, however, the main chapter of interest was Part 3, which provided recommendations on hardware, software, mechanical and electrical components for RMV design and construction, especially with minimum cost.

Lastly, a peer reviewed article published in April 2020 by **Pearce** called *A review of open source ventilators for COVID-19 and future pandemics* was also included because of the useful information regarding documentation for RMVs (Pearce, 2020). This included article files, instructions, diagrams and other documentation (i.e., bill of materials and list of tools required) recommended for all RMV designs. Although this article was not a guidance document, it was included as part of our RMV “standards”

because the information presented was not included in the other recommendation guidelines described below.

Table 1: Operating Features based on Guideline Recommendations (Branson et al. 2020; CIEHF, 2021; Einav et al., 2014; Hakimi et al., 2022; MHRA, 2020)

Operating Features	***Description***	**CHEST Mandatory Features (American)**	**AARC Mandatory Features (American) (March 2020)**	**MHRA Mandatory Features (UK)**	**Mechanical Ventilation Amid the COVID-19 pandemic**	**Human Factors in the Design and Operation of Ventilators for COVID-19 (HF)**
US FDA approved for pediatric use	*Is the device required to be approved for pediatric use?*	Pediatric and infant approved	Pediatric and adult approved			
Power Source (overlap with Eng. Section)	*Ventilator will use hospital electricity from a wall outlet but if for whatever reason electricity is no longer available (power outage) how is the ventilator powered?*	AC with battery backup		Must have back up battery backup of at least 20 minutes in case of mains electricity failure		
Modes of ventilation	*What are the necessary modes of ventilation for emergency ventilators?*	CPAP volume control (assist/control and SIMV)	Volume and pressure control. CMV (assist-control) is recommended due to often heavy sedation requirements.	Must have CMV. The CMV mode must be either (1) (ideally) Pressure Regulated Volume Control, or (2) pressure-controlled ventilation (PCV), or (3) minimally a volume-controlled ventilation (VCV)		

Operating Features	***Description***	**CHEST Mandatory Features (American)**	**AARC Mandatory Features (American) (March 2020)**	**MHRA Mandatory Features (UK)**	**Mechanical Ventilation Amid the COVID-19 pandemic**	**Human Factors in the Design and Operation of Ventilators for COVID-19 (HF)**
Control of settings	*What ventilation parameters are controlled during treatment?*	Respiratory rate, PEEP, Vt, Flow or I:E ratio, FiO2 (on 50-55 psi source O2)			5 essential knows would control for the following parameters: tidal volume, respiratory rate, Inspiratory time, overpressure, assist mode threshold	
Range of Flow	*The ratio of maximum to minimum flow the transmitter can measure*	Minimum of 10L/min, Upper limit 80L/min				
PEEP	*Pressure maintained in the breathing system during expiration*	Internal PEEP, PEEP compensation	0 - 20 cm H2O (Optimum PEEP is often in the range of 8 - 12 cm H2O)	5 - 20 cm H2O, adjustable in 5 cmH2O increments. PEEP must be maintained during expiration. Default setting: 35 cm H2O.	5-20 cm H2O	
Oxygen Titration	**N/A**	Room air to FiO2 1.0 on 50-55psi oxygen source				
Operate without 50-55 psi oxygen source	*Is the machine capable of operating with high flow (50 PSI) gas sources?*	Able to operate on oxygen concentrator or low-flow oxygen source				

Operating Features	***Description***	**CHEST Mandatory Features (American)**	**AARC Mandatory Features (American) (March 2020)**	**MHRA Mandatory Features (UK)**	**Mechanical Ventilation Amid the COVID-19 pandemic**	**Human Factors in the Design and Operation of Ventilators for COVID-19 (HF)**
Measurements/ Monitoring	*What does the ventilator monitor? What measurements does it record?*	Measure and display inspiratory Vt, Peak inspiratory pressure	Measured exhaled Vt	Must show Vt, frequency, PEEP, FiO2, ventilation mode. Must show the actual current airway pressure. If pressure support mode is provided there must be real time confirmation of each patient breath and an alarm if below acceptable range.		
TV	*The volume of gas flowing into the lungs during one inspiratory cycle*		250 - 750 mL (or 4- 8 mL/kg of predicted body weight)	(1) Must have at least one setting of 400ml +/- 10 ml. (2) Should have 350ml and 450 ml options. (3) Could have a range 250 – 600 ml in steps of 50ml. (4) Could have a range up to 800 ml. Default Setting: 400 ml	200 to 800 mL (to meet the ventilatory needs of most adults)	

Operating Features	***Description***	**CHEST Mandatory Features (American)**	**AARC Mandatory Features (American) (March 2020)**	**MHRA Mandatory Features (UK)**	**Mechanical Ventilation Amid the COVID-19 pandemic**	**Human Factors in the Design and Operation of Ventilators for COVID-19 (HF)**
RR	*Number of breaths per minute*		6 - 35 breaths/min	Default setting: 20 breaths/min Must provide a range 10 - 30 breaths per minute in increments of 2 (only in mandatory mode) that can be set by the user	10 - 30 BPM	
FiO2	*Fractional concentration of inspired O2*		0.21 - 0.95	User must be able to control inspired oxygen proportion (FiO2). Must provide 50% - 60% and 90 - 100% options. (Default setting: 90 - 100% oxygen)		
Inspiratory Flow	*Chest: Trigger mode, trigger sensitivity, alternative ventilation modes, flow waveform*		Low < 10 L/min, High > 80 L min	Plateau pressure should be adjusted to achieve volume and must be limited to 35 cmH2O by default. Peak pressure should be no more than 2 cm H2O greater than plateau pressure. The user must be able		

Operating Features	***Description***	**CHEST Mandatory Features (American)**	**AARC Mandatory Features (American) (March 2020)**	**MHRA Mandatory Features (UK)**	**Mechanical Ventilation Amid the COVID-19 pandemic**	**Human Factors in the Design and Operation of Ventilators for COVID-19 (HF)**
				to set inspiratory airway pressure limit in the range at least 15 - 40 cmH2O in at least increments of 5 cmH2O (if pressure control ventilation is used)		
I:E Ratio	*The proportion of each breathing cycle that is spent breathing in compared to breathing out*			Must provide 1:2 as default setting.		
Oxygen Sensor	*Does the machine have an oxygen sensor?*	*Optional: Oxygen sensor*				
Alarms (Safety)	*What type of alarms does the ventilator have? When do the alarms go off (what for)? How loud are they? Are the visible?*	Audible and visible. Sounds for patient disconnect, apnea, high pressure, low source gas pressure	Sounds for patient disconnect, apnea, high pressure, low source gas pressure	Gas or electricity supply failure. Machine switched off while in mandatory mode. Inspiratory airway pressure exceeded. Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm). Tidal volume not	High priority alarms (indicated by flashing LED light and/or audio alarm): overpressure, under pressure (less than 3 cm H2O), loss of power. Low priority alarms: tidal volume out of spec.	**User interface:** alarms included for critical situations where a user response is required. Alarms must be audible in a noisy critical care environment. Note that different alarms/tones may mean different things to user.

Operating Features	***Description***	**CHEST Mandatory Features (American)**	**AARC Mandatory Features (American) (March 2020)**	**MHRA Mandatory Features (UK)**	**Mechanical Ventilation Amid the COVID-19 pandemic**	**Human Factors in the Design and Operation of Ventilators for COVID-19 (HF)**
				achieved. The disconnect alarm will sound within 3 seconds of disconnection.		

Table 2: Performance Features based on Guideline Recommendations (Einav et al., 2014; MHRA, 2020)

Performance Features	*Description*	CHEST Mandatory Features	MHRA Mandatory Features
Ease to set up/set ventilation settings/troubleshoot/user-friendly	*What is the process to get the ventilator up and running? (Is it easy or complicated?). How user-friendly is the machine? Is the machine easy to use in the hospital setting where health care providers may be fully equipped in PPE?*	Ability to read screen: at a distance, in sunlight, in low ambient light	User must be able to instantly see the settings selected and be able to easily operate all controls while dressed in protective gear (which includes - eye goggles, face shield, plastic apron, surgical gown, two layers of gloves, gloves are donned in layers and sticky taped onto sleeves of gown in between layers.

Performance Features	*Description*	CHEST Mandatory Features	MHRA Mandatory Features
Ventilator Testing & Sustained Use	*Testing the initial design/prototype mechanical ventilator. How was the machine tested (simulator, animal, human)? How long was the machine tested for (duration - hours, days)? Were different stages of disease tested using different parameter outcomes?* *How does the machine function over long periods of time? Has the machine been tested for long durations?*	**Documented evidence of sustained performance for**: 2,000 h Assist-volume control 16-L minute ventilation 35 breaths/min 15 mL/cm H 2 O compliance 20 cm H 2 O/L/s resistance **Documented evidence of sustained performance for (may be a separate machine for both 2,000-h evaluations):** 2,000 h Assist-volume control 8-L minute ventilation 60 breaths/min Compliance 3 mL/cm H 2 O Resistance 200 cm H 2 O/L/s **Reference contacts for three or more clinical institutions where equipment used 2 week continuously**	Usability testing at both prototype and final production stages will be required. When undergoing testing the "tester" must be wearing complex protective clothing: eye googles, face shield, plastic apron, surgical gown and two layers of gloves. Other tests such a pressure relief tests, closed suctioning tests and sound level tests.

Performance Features	*Description*	CHEST Mandatory Features	MHRA Mandatory Features
Graphical User-Interface (GUI) Testing	*What testing protocols must the end-user complete in the setting of use prior to hooking up to a patient. (Initial set up of parameters, trouble shooting, disconnect, changing parameters, answering alarms).*		Compliance with the essential safety standards must be demonstrated for patient safety. Usability testing at both prototype and final production stages will be required.

Performance Features	*Description*	CHEST Mandatory Features	MHRA Mandatory Features
Oxygen Consumption	*How much oxygen is consumed during operation?*	**Time to empty 680-L E tank:** Assist-volume control 16-L minute ventilation 35 breaths/min 15 mL/cm H 2 O compliance 20 cm H 2 O/L/s resistance 10 cm H 2 O PEEP F IO 2 1.0 and 0.5 1:2 I:E ratio >38 min F IO 2 5 1.0 >104 min F IO 2 5 0.5 **Time to empty 680-L E tank:** Assist-volume control 6-L minute ventilation 12 breaths/min 30 mL/cm H 2 O compliance Resistance 20 cm H 2 O/L/s resistance 5 cm H 2 O PEEP F IO 2 1.0 and 0.5 1:2 I:E ratio >100 min F IO 2 5 1.0 >280 min F IO 2 5 0.5	Average oxygen consumption must be no more than 6 lpm. This may be allowed to increase as greater certainty is gained over oxygen supply.

Table 3: Other Features based on Guideline Recommendations (Branson et al. 2020; CIEHF, 2021; Einav et al., 2014; MHRA, 2020)

Other Features	*Description*	**CHEST Mandatory Features *("Stockpiling Features")***	**AARC Mandatory Features**	**MHRA Mandatory Features**	**Chartered Institute of Ergonomics & Human Factors (CIEHF)**
General Durability	*Ability to withstand damage.*	Fluid spill resistance Mechanical shock (similar to 4-ft drop, military standard) Mechanical vibration EMC and electrical safety testing **Storage temperature and humidity:** 2 20°C to 60°C, 0 to 95% RH **Operating temperature and humidity**: 5°C to 40°C, 0 to 95% RH		Must be capable of continuous operation (100% duty cycle) for 14 days. The expected durability must be specified. Device should be robust as possible (it may be dropped from bed height to floor).	

Other Features	*Description*	**CHEST Mandatory Features *("Stockpiling Features")***	**AARC Mandatory Features**	**MHRA Mandatory Features**	**Chartered Institute of Ergonomics & Human Factors (CIEHF)**
Recalls	*Does the vendor include recalls on the ventilator?*	Vendor must disclose all recalls on ventilator and equipment in the past 3 years			
Vendor and Support Contract	*Do the manufacturers provided support if issues arise with the machine? Warranty?*	Company will continue to produce ventilator model for at least 5 years and continue to support model 10 years after order is completed. Able to produce all ventilators within 18 months from order; if unable to meet this criterion, estimated ramp-up/surge period and time frame for delivery must be stated. 24 h, 7 d/week direct phone access to senior-level technician			

Other Features	*Description*	**CHEST Mandatory Features *("Stockpiling Features")***	**AARC Mandatory Features**	**MHRA Mandatory Features**	**Chartered Institute of Ergonomics & Human Factors (CIEHF)**
		Vendor responsible for maintaining call coverage Warranty Provide any storage life data, if available			
Maintenance	*Do the manufacturers provided maintenance for the machine?*	1 year for battery and all equipment interval maintenance; also include battery replacement if needed			

Other Features	*Description*	**CHEST Mandatory Features *("Stockpiling Features")***	**AARC Mandatory Features**	**MHRA Mandatory Features**	**Chartered Institute of Ergonomics & Human Factors (CIEHF)**
Purchasing costs	*Total to build, what is included?*	$13,000 (2014 USD) Cost must include kitted ventilator, end-user training program, maintenance, and all necessary equipment (ancillary supplies) to ventilate one patient on both 50-55 psi and low-flow oxygen			

Other Features	*Description*	CHEST Mandatory Features ***("Stockpiling Features")***	AARC Mandatory Features	MHRA Mandatory Features	Chartered Institute of Ergonomics & Human Factors (CIEHF)
End-user Training Program	*Does a training program exist when the machine is set up and ready to be used by a professional? All manufacturers of ventilators highly recommend a pre-operational check prior to the use of the ventilator on a patient. This precheck is designed to check the integrity of the ventilator circuit, confirm the functioning of the components, the humidifier system, tubing and assess primary caretakers' level*	Laminated instruction materials attached	Must not be excessively cumbersome so that it would impede hospital operations or prevent easy movement within hospitals circumstances.	Must be reliable. Must be capable of continuous operation for 14 days. Must be intuitive to use for qualified medical personnel, but these may not be specialists in ventilator use. Must not require more than 30 minutes training for a doctor with some experience of ventilator use. Must include instructions for use. Must include labelling of all critical functions and controls using standard terms, pictograms and colours that will be readily recognised by healthcare staff. Must have transparent design, supply chain, manufacture, quality assurance and testing processes that are of sufficient quality to enable MHRA officials to deem	Must be as short and straight to the point as possible (may not have much time in critical periods). Training is minimized through good user design. Training might include routine tasks, such as basic interaction with the device (e.g. setting up parameters and starting ventilation), critical task steps (e.g. changing ventilation modes), responding to alarms or patient deterioration, and managing device issues or problems (e.g. power failure). Additional scenarios might include maintenance activities.

Other Features	*Description*	**CHEST Mandatory Features *("Stockpiling Features")***	**AARC Mandatory Features**	**MHRA Mandatory Features**	**Chartered Institute of Ergonomics & Human Factors (CIEHF)**
	of competency to navigate the controls.			appropriate for usage in exceptional circumstances.	

Other Features	*Description*	CHEST Mandatory Features ***("Stockpiling Features")***	AARC Mandatory Features	MHRA Mandatory Features	Chartered Institute of Ergonomics & Human Factors (CIEHF)
Additional approvals/clearances	*Does the machine require any additional approvals in order for hospital use?*			When the current emergency has passed, these devices will NOT be usable for routine care unless they have been CE marked through the Medical Devices Regulations. The device must display a prominent indelible label to this effect.	

Other Features	*Description*	CHEST Mandatory Features ***("Stockpiling Features")***	AARC Mandatory Features	MHRA Mandatory Features	Chartered Institute of Ergonomics & Human Factors (CIEHF)
Labelling	*Are any labels required to be a part of the machine?*			A clearly visible permanent label must be attached with the words “Follow Instructions for Use”. A clearly visible permanent label with the words “Restricted device for use during COVID-19 pandemic, only to be used for emergency ventilation - any adverse incidents must be reported to MHRA." The size and font of the text on the labels should be appropriate to the size of the device. Breathing system inlets and outlets must be clearly marked with direction arrows. A clearly visible permanent label with the words “Manual Back Up Ventilation Must Be Available” in a minimum of 50-point text. Must include clear marks or labels to indicate the	

Other Features	*Description*	**CHEST Mandatory Features *("Stockpiling Features")***	**AARC Mandatory Features**	**MHRA Mandatory Features**	**Chartered Institute of Ergonomics & Human Factors (CIEHF)**
				default settings of 90-100% oxygen, 400mls tidal volume and / or inspiratory plateau pressure 35 cmH2O, 15 cmH2O PEEP, rate 20 breaths min-1.	

Other Features	*Description*	CHEST Mandatory Features ***("Stockpiling Features")***	AARC Mandatory Features	MHRA Mandatory Features	Chartered Institute of Ergonomics & Human Factors (CIEHF)
Infection Control	*What protocols are in pace to prevent infection?*		Maintain strict infectious disease precautions	**1.** All parts coming into contact with the patient's breath must be either disposable or designed to be reusable **2.** All working components of the device must be contained within an impermeable casing. **3.** All external surfaces must be cleanable in the likely event that they get respiratory secretions or blood splatter on them. Cleaning would be by healthcare workers manually wiping using an approved surface wipe with disinfectant or cloths and approved surface cleaning liquid. **4.** There will be a separately sourced HMEF-bacterial-viral filter between the machine and patient which may impact on resistance within the system, which may need	

Other Features	*Description*	CHEST Mandatory Features ***("Stockpiling Features")***	AARC Mandatory Features	MHRA Mandatory Features	Chartered Institute of Ergonomics & Human Factors (CIEHF)
				to be accounted for with some designs. The pressure being delivered to the patient is the specified pressure. If the filter has a resistance of, say 2 cmH2O at 30 lpm, the ventilator needs to output 37 cmH2O to achieve a set 35 cmH2O at the patient. This will need further detailed consideration. Viral filtering filters may have much higher resistance that may be clinically relevant.	

Other Features	*Description*	**CHEST Mandatory Features *("Stockpiling Features")***	**AARC Mandatory Features**	**MHRA Mandatory Features**	**Chartered Institute of Ergonomics & Human Factors (CIEHF)**
Ventilator Kit/Environment of Use	*What is the description of the ventilator (e.g., dimensions, weight)? Is there consideration for how the ventilator may be used in a clinical setting?*	Rigid case Weight of kit with ventilator and all ancillary equipment needed to ventilate one patient must not exceed 30 lb Wheels provided on case			If the ventilator is intended to be moved it needs to be lightweight and on a base that allows easy repositioning to avoid musculoskeletal health issues for staff. Screens and displays should be adjustable for height. Retractable cables are ideal. Buttons far enough away so two aren't activated by accident. Consider limitations of new operational environments. Ensure appropriate connectors and power supplies are in place. Avoid obstacles in areas where ventilators need to be moved.

Table 4: Engineering (Hardware, Software and Documentation) Components based on Guideline Recommendations (Branson et al. 2020; CIEHF, 2021; Einav et al., 2014; Hakimi et al., 2022; MHRA, 2020; Pearce, 2022)

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
Manufacturing Process (risk from contaminants) ***(Biological Safety)***	*Was the process of building/manufacturing the RMV described?*			**A)** Mould release agents used within extrusion or injection moulding techniques may be required in setting up the machine, they should not be needed once a process is in full scale production **B)** Approximately, the first 20 or so items in an injection moulding production run should be discarded to minimise risk from contamination with mould release agents **C)** Extrusion and moulding techniques are comparatively simple and well controlled; therefore, ventilators will not			

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
				be required to be manufactured within cleanroom specifications **D)** Manufacture in a reasonably clean room and protection of components and products from contamination should suffice **E)** If A-D is followed, chemical or particulate testing of the air coming out of the breathing circuit should not be necessary			

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
Hazard Mitigation *(Biological Safety)*	*Was anything mentioned within the design process to help minimize hazards?*			**A)** Particulate matter: solid particles suspended in a gas-Particulate matter emissions are not of significant concern if the manufacturing process is adequately controlled as per the above criteria **B)** Volatile organic compound (VOC): organic compound whose boiling point is in the range of 500C to 2600C-Risk of exposure to VOCs can be minimised through the appropriate choice of materials as set out in section 1 **C)** Leachable substances (incondensate): chemical removed from the medical			

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
				device by the action of water, other liquids or other gases related to the use of the medical device- insure a HME filter is used between the ventilator and breathing system.			

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
Materials (Materials of raw construction (i.e., Biological safety)) and Parts	*What are all of the mentioned materials and parts of RMV?*	Positive Pressure Ventilation Equipment: airways, manual resuscitator with face mask, T-piece resuscitators Ancillary Respiratory Equipment (Airway Care): Closed-circuit suction catheter, Endotracheal tube, Tube guide, Endotracheal tube securing device, Single-use suction catheter, Yankauer suction catheter, Suction trap and hoses (regulator to trap and trap to suction device), Vacuum source and suction regulator, Fingertop for suction Circuits: Circuit for use with HME, Circuit for use with	Humidifiers: While heated humification has advantages, the use of a heat and moisture exchanging filter (HMEF) can provide sufficient humidification while also protecting staff and the environment. These can be standard or HEPA filters.	Must be made from materials and parts readily available in the UK supply chain (anticipating increasing global restrictions of freight movement). The chosen material must be reasonably pure and simple in nature (minimise the use of additives where possible). For components requiring flexibility avoid the use of materials requiring plasticizers. Polyvinyl chloride (PVC) must be avoided in the patient gas pathway. A) The chosen material must be reasonably pure and simple in nature (minimise the use of additives where possible)	Ancillary Respiratory Equipment (Airway Care): Range of endotracheal tube (ETT) sizes, ETCO2 monitoring, tube ties Humidifiers: Heat and moisture exchanger (HME) filter		

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
		hated humidifier with wire, Expiratory limb filter in ventilator circuit, HEPA style filter Humidifiers: HME (with or without filter), Heated humidifier (no heated wire circuit), water traps, Heated humidifier (with heated wire circuit), Chamber, Sterile water Medical Gas: Compressed air, Compressed oxygen, 50-55 psi line with quick connection from source to ventilator, Liquid oxygen, Oxygen reservoir for low-flow oxygen use by mechanical ventilator (if applicable), Oxygen regulators		B) For components requiring flexibility avoid the use of materials requiring plasticizers. Good candidates are those materials that belong to the polyolefin family, examples include polyethylene and polypropylene C) For structural components materials such as polycarbonate or Acrylonitrile butadiene styrene (ABS) should be used without additives, although reinforcement with glass fibre would be acceptable D) Polyvinyl chloride (PVC) must be avoided in the patient gas pathway E) PVC should be avoided elsewhere			

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
		Monitoring Devices: Pulse oximeter, Pulse oximetry probe, capnograph, capnograph tubing, capnograph fluid trap Oxygen Delivery: Oxygen, air regulators, flow meters, Nasal prongs, Face masks, Face mask with reservoir, Intubation equipment					

Software (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
Software Development Process/Plan	*Was a software development plan mentioned? How the software implemented? What does it do? What programming language does it run on?*			The software development must be planned. Where possible software for a RMVS should be developed in a facility that has experience of developing software using the standards - "BS EN 62304:2006+A1:2015 Medical device software — Software life-cycle processes and BS EN ISO 14971:2012 Medical Devices – Application of risk management to medical devices". Since the software is likely to be developed to an accelerated life cycle it is essential that the following principles are adhered to: **1.** The software is developed under	Mentions 4 main components to consider throughout the software design process 1. Users 2. Environment 3. Tasks 4. Risks		

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
				strict process control using a quality management system, ideally BS EN ISO 13485 or BS EN ISO 9001. **2.** A process is followed to determine the risks arising from the operation of the software and to mitigate those risks. This is most easily done by the application of BS EN ISO 14971. **3.** A software development process is followed to achieve a low probability of failure of the software in use. This is most easily done by the appropriate application of BS EN 62304 based on the risk management process in 2 above.			

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
				4. Less emphasis need be placed on the requirements of BS EN ISO 62304 software post-production monitoring and maintenance processes.			
Graphical User-Interface/Software	*Description of the user interface? How easy is it to set up? What does the display include?*				Try to align new design with existing designs. Alarms should be included for critical situations where a user response is required. Alarms should be audible in a noisy critical care environment. Note that different alarms/tones may mean different		

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
					things to user. Ventilators need to be usable by novices (technicians and maintenance staff) as well as experienced users. User interface might include warnings or alarms for critical steps or in situations that are unsafe. Need to assume that the ventilators will be used by both clinicians who have used ventilators before as		

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
					well as clinicians who might not have much experience with ventilators. Medical technicians will also be required to inspect and maintain devices. Experienced users will come with a set of expectations about how to interact with the ventilator. A radically new design could potentially lead to confusion. It might be useful to aim to make the		

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
					interface similar to existing devices. Expected those operating the ventilator will be in several PPE. User interface: alarms should be included for critical situations where a user response is required. Alarms should be audible in a noisy critical care environment. Note that different alarms/tones may mean different things to user.		

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
Software Components	*Other important software components?*			**1.** Must be reliable. RMVS must be capable of continuous operation (100% duty cycle) for 14 days (should be capable for more than 14 days). The expected durability must be specified. **2.** Software must be intuitive to use for qualified medical personnel, but these may not be specialists in ventilator use (Must not require more than 30 minutes training for a doctor with some experience of ventilator use. Must include instructions that are built into the labelling of the ventilator. Must include clear labelling of all critical function and controls using	Formative usability testing will allow the user to perform tests on the software to ensure they are familiar with the program, know what to do when issues arise and can set up parameters, settings, etc., for patients.	1. Analog input acquisition 2. Hardware and timer Interrupts 3. PWM timer and encoder Interrupts 4. Motor control task 5. Alarm class 6. Display class 7. Flash storage 8. Watchdog timer	

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
				standard terms, pictograms and colours that will be readily recognised by UK healthcare staff.) The system requirements specifications must be translated into software requirements specifications.			
Hardware & Software Documentation (Engineering)	**Description**	**CHEST Mandatory Features (American)**	**AARC Mandatory Features (American) (March 2020)**	**MHRA Mandatory Features (UK)**	**Chartered Institute of Ergonomics & Human Factors (CIEHF)**	**Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)**	**Pearce**

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
Fully annotated circuit diagrams, wiring diagrams, design source/production files	*Instructions to build, any diagrams, bill of materials or other relevant documentation pertaining to the overall design of the ventilator. Documentation outlining/displaying printed circuit board (PCB) layouts. Documentation discussing design source and production including such components like CAD drawings (3D files, fully annotated 2D drawings, 3-D mesh files), STL files.*					Doxygen Documentation	Design source files; Production files; Printed Circuit Board (PCB) layouts & other electronic design files. Bill of materials, List of tools required. Instructions for Assembly, Calibration and Operation. Wiring Diagrams.

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
A software risk management plan & report (Risk Control Measures (RCM))	*Are risk control measures mentioned with the RMV? Risk RCM are actions that are taken in response to a risk factor that has the potential to cause accidents or harm in the workplace*			The risks arising from the operation of the software must be determined and the risk control measures (RCMs) for these risks must be translated into software requirements. Special attention must be paid to any software of unknown provenance or commercial off the shelf software incorporated into the device. The implementation and effectiveness of the RCMs must be verified and validated. software design to enable the risks arising from the use of the software to be determined.			

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
Software verification & validation plans and reports	*Does the reference include software verification and validation plans/reports for the RMV ensuring that the system meets specifications and requirements so that it fulfills its intended purpose?*			The implementation and effectiveness of the RCMs must be verified and validated. The verification and validation of the software must be planned and reported on. The outputs of the software must be reviewed against the software requirements prior to the release of the software for clinical use.			

Hardware (Engineering)	Description	CHEST Mandatory Features (American)	AARC Mandatory Features (American) (March 2020)	MHRA Mandatory Features (UK)	Chartered Institute of Ergonomics & Human Factors (CIEHF)	Mechanical Ventilation Amid the COVID-19 pandemic (MCAtCP)	Pearce
A software release note	*A software release note refers to the technical documentation produced and distributed alongside the launch of a new software product or a product update (e.g., recent changes, feature enhancements, or bug fixes). Does the reference mention this with the RMV?*			The outputs of the software must be reviewed against the software requirements prior to the release of the software for clinical use.			

2.4 Purpose and Rationale

The RMVs analyzed for this scoping review present with high variability in characteristics similar to the recommendations from the six guidance documents presented in section 2.3. The lack of universal standards for RMVs presents as a gap in the literature and may explain the high variability in RMV designs and recommendations from the guidance documents. While the six guidance documents presented by categories (operating features, performance feature, engineering features and other features) in section 2.3 share many commonalities in recommended characteristics for RMVs they also present unique features and settings that were not reoccurring throughout all six documents. The high variability in the six guidance documents, RMVs and the lack of universal standards present as major gaps in the literature that this review aims to minimize.

The purpose of this scoping review was to collect and synthesize all available evidence on Rapidly Manufactured Ventilators (RMVs) to treat critically ill patients during mass-casualty events or in jurisdictions with resource limitations. Specific objectives were to:

1. Describe the characteristics of the RMVs including operating and performance features, other features outside routine use, and engineering features.
2. Provide suggestions on recommended standards for effective and safe RMV designs to inform future or ongoing events where resources are limited.

The three research questions guiding the objectives of this study originally included in the protocol (Mikkelsen et al., 2022) (DOI: https://doi.org/10.17605/OSF.IO/RNU6V) were:

1. What are the minimum clinical features, settings, and testing procedures of RMVs to treat critically ill adults and pediatric patients during mass-casualty events or in jurisdictions with accessibility limitations e.g., developing nations?
2. What is the recommended engineering (technical), safety and human factor components for RMVs?
3. What are the recommended standards for effective and safe RMV designs to inform future or ongoing events where resources are limited?

The first two were amalgamated because there was overlap between the different characteristics of the RMVs, especially considering the six guidance documents (described in Section 2.3.1). Dividing into operating, performance, and other features (that included testing and human factors), and engineering features also provided better organization of the information. In addition, these characteristics helped inform the third objective (now second). The two research questions guiding the objectives of this scoping review after changes from the protocol were made include:

1. What are the minimum operating, performance, engineering and other features of RMVs to treat critically ill adults and pediatric patients during mass-casualty events or in jurisdictions with accessibility limitations e.g., developing nations?
2. What are the recommended standards for effective and safe RMV designs to inform future or ongoing events where resources are limited?

It is anticipated that this research will serve as a useful tool for HCPs and engineering teams when creating their own RMVs; and will help inform organizations such as the ISO on the creation of RMV international standards. This research will help determine what RMV design requirements might be needed to obtain regulatory approval,

receive ethics approval to conduct human trials, and ultimately reach commercial production, and be used for patients in future mass-casualty events or in LMICs (Garmendia et al., 2020).

CHAPTER 3: STUDY DESIGN AND METHODOLOGICAL APPROACH

3.1 Methodological Approach

The methodological approach for this thesis is a scoping review. A scoping review involves transparent and rigorous methods to identify and analyze all relevant information pertaining to the outcome of interest. The purpose of a scoping review is to map the breadth and depth of literature on a broad topic and present an overview of research findings on a larger and diverse body of literature. Scoping reviews often include studies of various designs and methodologies. Scoping reviews may or may not include critical appraisal of the individual studies (Arksey & O'Malley, 2005; Levac et al. 2010).

Many RMVs exist in the literature with varying settings, features and designs, However, due to their emerging popularity prompted by the Covid-19 pandemic, investigations on them have yet to be reviewed comprehensively. Therefore, to examine the extent, range, and nature of the large and diverse body of literature a scoping review was chosen as the best method to analyze and synthesize the knowledge.

This study used the Joanna Briggs Institute (JBI) methodology for scoping reviews (Peters et al., 2020) which is based on a multi-step, analytical framework by Arksey and O'Malley (2005) and further updated by Levac et al. (2010). The steps used for this investigation include (1) identifying the research question (protocol development), (2) search strategy (3) selection of relevant studies, (4) data extraction, and (5) collating, summarizing and reporting the articles. The sixth optional step of formally consulting stakeholders and translating the data does was not conducted. Since this area of research is so new, it was unlikely expert consultation would provide relevant information to answer the research questions considering very little research has been conducted on this topic.

3.2 Development of the Protocol

A detailed plan of the scoping review in the form of a protocol was developed and pre-defined the objectives, study aims and purposes, eligibility criteria and reporting process. The protocol aligned with the JBI Manual for Evidence Synthesis PCC Framework (Peters et al., 2020) and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) (Tricco et al., 2018). The research questions defined in the protocol aligned with the JBI (2020) PCC Framework and JBI System for the Unified Management, Assessment and Review of Information (SUMARI) (Peters et al., 2020), Table 1. This protocol is registered on the Open Science Framework (Mikkelsen et al., 2022) (DOI: https://doi.org/10.17605/OSF.IO/RNU6V).

3.2.1 Deviations from the Protocol

Changes from the original protocol were made: exclusion of non-invasive ventilators and hypothetical RMV designs. This was to help focus the scoping review to better meet the study objectives. For study Objective 1, the data was summarized into categories (operating features, performance features, engineering features, and other features). These categories deviated slightly from the original DEF in the protocol to improve organization. Specifically, safety was combined with operating features and documentation was added to engineering features for better organization.

3.3 Identifying of Relevant Literature (Eligibility Criteria)

To identify relevant literature on the topic, inclusion and exclusion criteria were created using the PCC Framework (Peters et al., 2017). The inclusion and exclusion (with reasons) are presented in Table 5.

Table 5. Inclusion/Exclusion Criteria based on PCC Framework

PCC Framework	Inclusion	Exclusion	Reason for Exclusion
Population /Participants	Critically ill adults or pediatric patients who require mechanical ventilation treatment	Non-human studies	Only interested in how RMVs interact with humans
Concept	**Objective 1** Describe the characteristics of the RMVs including operating and performance features, other features outside routine use, and engineering features. **Objective 2** Provide suggestions on recommended standards for effective and safe RMV designs to inform future or ongoing events where resources are limited.	Non-invasive ventilation (NIV) (i.e., continuous positive airway pressure (CPAP). Hypothetical RMV designs (computer simulations).	Invasive ventilation (IV) is more commonly used in the treatment of acute and severe conditions (e.g.. ARDS). These conditions would likely be present in the context of this scoping review. Focused only on the RMVs that were actually built and operated.
Context	RMVs designed for 1) mass-casualty events, 2) emergency situations in which medical supplies (e.g., mechanical ventilators) may become depleted (and alternative solutions are required), and 3) in low-resource jurisdictions where accessibility to ICU mechanical ventilators may not be available	Studies in languages other than English or French.	Resources to translate were not available.

3.4 Types of Sources

All studies, regardless of design or date, that met the inclusion criteria were included in the scoping review. This included descriptive studies (qualitative and

quantitative), experimental studies and/or a combination of the two. The descriptive portion included various characteristics of the RMV including the parts/materials required to build the machine and the process to do so. The “experimental” portion of the studies presented the process and findings of how the RMVs were tested.

3.5 Search Strategy

The purpose of the search strategy was to identify all published literature that pertained to the eligibility criteria. A comprehensive search strategy was developed with a health sciences librarian (MT) in collaboration with the research team. The search strategy was developed by including a list of keyword combination and phrases related to RMVs and mass-casualty events. The comprehensive search strategy is included in Appendix A. The MEDLINE search strategy was peer-reviewed by another health sciences librarian and translated to other databases to locate all relevant citations on the broad topic. An electronic search was completed in the following databases: Ovid MEDLINE (1946 to April 2022), Ovid EMBASE (1947 to April 2022), Cochrane (1947 to April 2022), Cochrane Database of Systematic Reviews (2005 to April 2022), Cochrane Central Register of Controlled Trials (March 2022 to April 2022), CINAHL (1937 to April 2022), Elsevier (Compendex and Scopus) (1972 to April 2022), IEEE Xplore (2000 to April 2022), and ACM Digital Library (1951 to April 2022). A search of the grey literature was completed in Google Scholar to identify any relevant unpublished literature including government documents, practice guidelines, clinical aids educational materials and reports.

3.6 Selection of Relevant Studies

All citations identified in the electronic search of the databases and grey literature were uploaded into EndNote™ 20 software (Clarivate™). Duplicated studies were

removed in EndNote then transferred to EPPI Reviewer (EPPI Centre, London, UK). In the EPPI-Reviewer software, title and abstract screening against eligibility criteria was completed by two independent reviewers (KM, MZ). Prior to this, the two reviewers completed a pilot screen of the title and abstracts on a random 5% sample of included studies with the goal of at least 90% agreement. To ensure the two reviewers were screening in a similar manner throughout the title and abstract screening, every 500 articles a comparative analysis test was run to ensure decisions were still at 90% agreement or greater. All full text of included papers at the end of title and abstract screening were retrieved and uploaded to EPPI-Reviewer software. Full-text screening against eligibility criteria of potentially relevant studies was completed by the same two independent reviewers. Any studies excluded during full-text screening were recorded and reported with reasons. Any disagreements were resolved with further discussion between the two reviewers. A 3rd reviewer (MLN) was consulted to resolve any discrepancies. Search results for the scoping review from initial database "identification" stage to "include" in final synthesis stage were reported and presented in the PRIMSA-ScR flow diagram (Tricco et al., 2018).

3.7 Data Extraction

Data from the papers included in the scoping review were extracted using a data extraction form (DEF). The DEF was created from the six guidance documents described in Section 2.3.1. These recommendations were used because they were the closest to "standards" that existed in the literature at the time of conducting this review. Other key features of each article extracted included author, year of publication, geographical origin of article, study design, key outcomes, concept/intervention, and limitations (see Appendix

B for DEF). Two reviewers independently (KM, MZ) extracted data from all studies included in the scoping review then met to compare and agree on extractions.

3.8 Collating, Summarizing, Analysing and Reporting the Studies

For study Objective 1, the data was summarized into categories (operating features, performance features, engineering features, and other features). For RMV settings and ranges, numerical analyses in tabular and graphical form were completed in Microsoft (MS) Excel, including descriptive statistics such as the mean, standard deviation (SD), medians, counts and percentages. A descriptive narrative summary discussed the remaining RMVs characteristics including patterns (i.e., commonalties), differences and important outcomes (e.g., different mechanisms used to compress the AMBU bag). All the information from the dual data extraction of included studies was exported from EPPI-Reviewer and organized in MS Excel.

For Objective 2, the tabular summaries of the six RMV guidance documents (Section 2.3.1) were used to create MS Excel documents (Appendix 4) displaying the 53 RMVs on the y-axis (first column) and the various recommendations on the x-axis (first row). This document acted like a checklist; “Y” indicating yes, the RMV met that recommend, “N” did not, or “P” for partially meeting the recommendation. The purpose of this checklist Excel document was to determine which RMV met the most guidance recommendations to help inform our conclusions and suggestions. The top two RMVs which met the most recommendations were identified within each guidance document. A top 11 suggestion list was created from the information within the six guidance documents based on most common recommendations and which ones were deemed most important for the development of future designs and standards.

3.9 Ethical Considerations

This scoping review collected all secondary data already published in the public domain. No primary data collection was conducted; therefore, this study was exempt from Research Ethics Board's review (Panel of Research Ethics, 2023).

CHAPTER 4: RESULTS

4.1 Search Results and Study Characteristics

The search of the five electronic databases and grey literature (Google Scholar, n=2) returned 3803 articles (Figure 1). After deduplication and removal of non-English and non-French articles, 2669 were screened by title and abstract and 2526 were excluded. Full text screening against eligibility criteria was completed on 143 articles and 81 articles were excluded. Sixty-three articles were included in qualitative and quantitative synthesis but 11 were excluded during this stage for various reasons (Figure 1) resulting in a total of 52 full-text articles included for final analysis. Throughout Chapter 4 and Chapter 5 of this scoping review the total number of RMVs were presented rather than the total number full-text articles. Fifty-three RMVs were analyzed because one author discussed the same RMV in two separate articles and one article discussed two different RMVs.

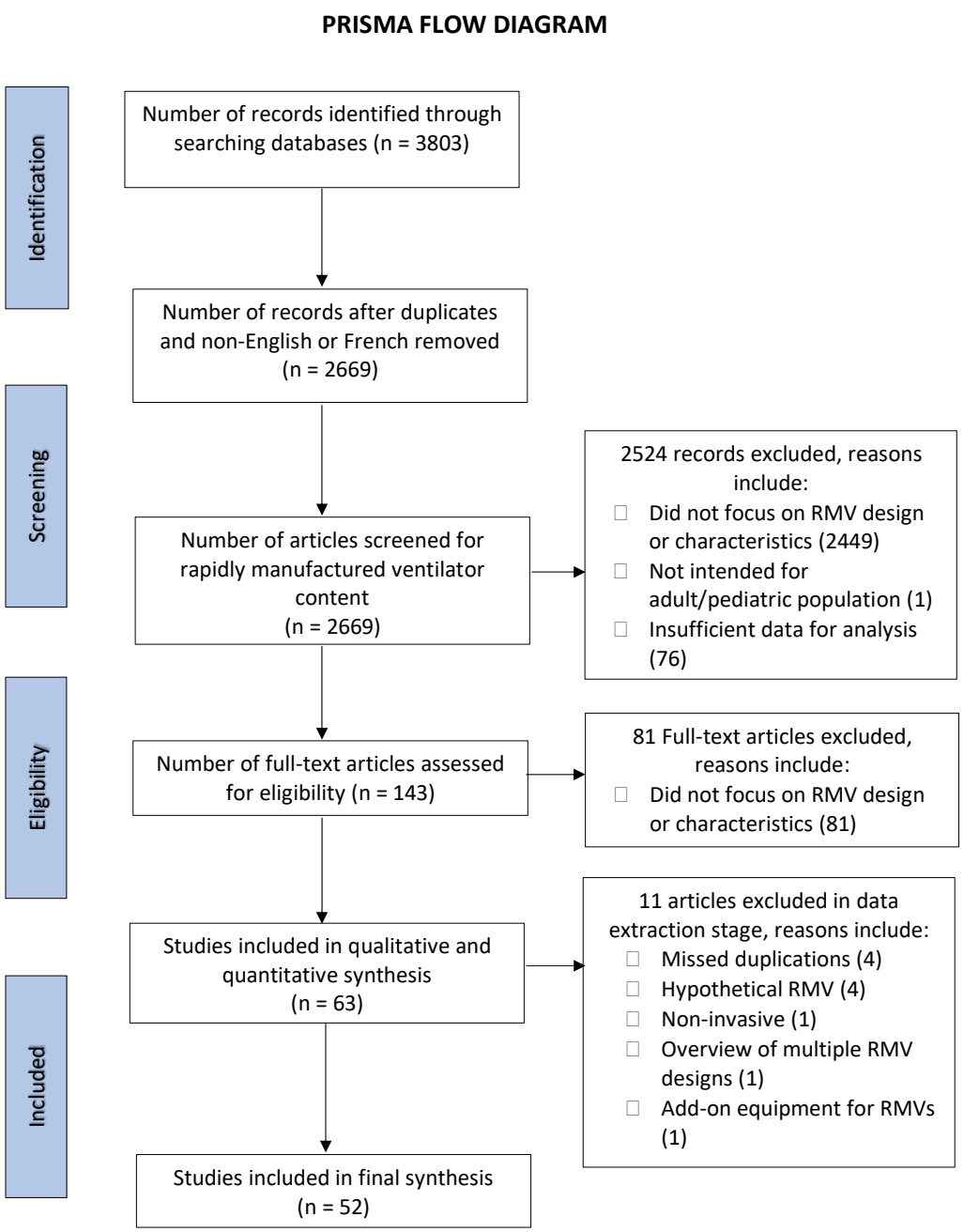


Figure 1. PRISMA-ScR Flow Diagram showing process of reported articles.

The structure of the articles included in this review first described their RMV design from initial development to final prototype then conducted testing to evaluate the machine's efficacy and performance. Most articles included a combination of the following study designs: descriptive, experimental and bench. The detailed description of the RMVs

from the construction process of raw materials and tools to the final prototype were classified as descriptive study design. A description of the experiments (i.e., experimental study design) conducted for the performance of RMVs and the subsequent results were also described. The articles included in this review also align with a bench study design. A bench study includes a critical evaluation of a new device to ensure high quality, proper performance and overall correctness of the design (Omair, 2015). The results from bench-based studies are used to implement and develop new ways to treat patients (Omair, 2015) which was the purpose of designing and developing RMVs. The study by Chiang et al., 2021 was the only article that tested their RMV on humans and therefore their study aligned more strongly with clinical and observational study designs.

The majority articles (89%) were published during or after the Sars-CoV-2 (Covid-19) global pandemic (2020). Figure 2 shows publication year. The articles were published in 18 countries with the majority, 22 (42%) in the United States of America (USA) (Figure 3).

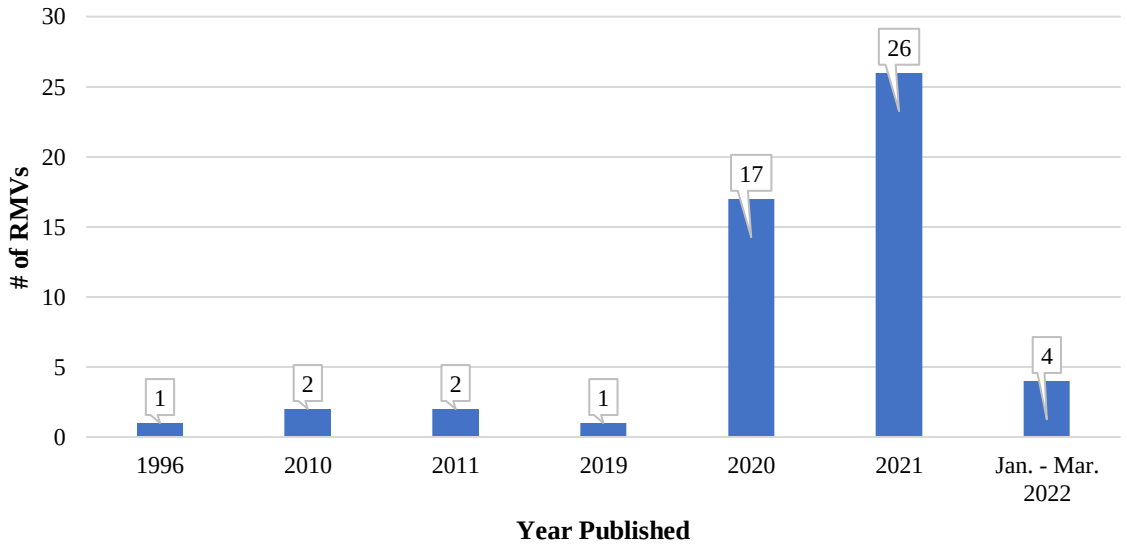


Figure 2. Year RMV articles were published.

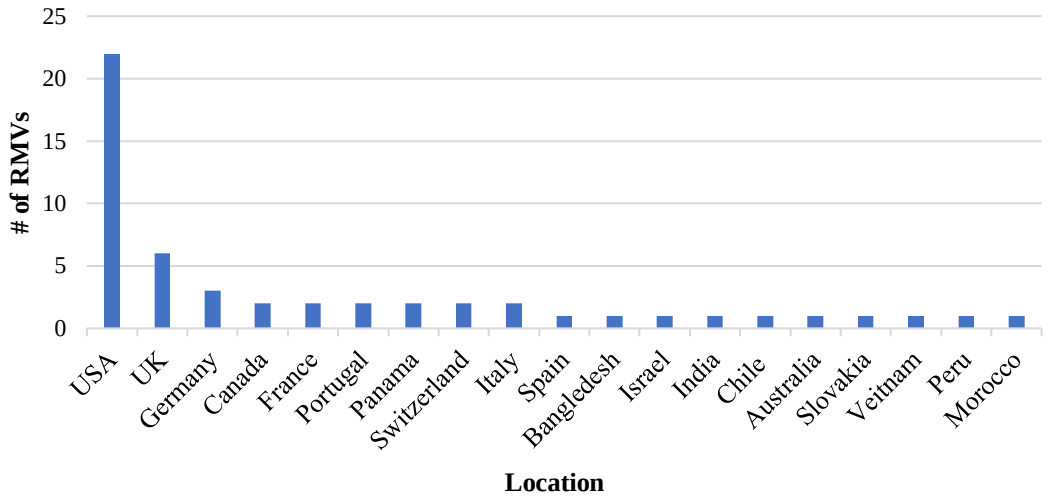


Figure 3. Geography of where RMV were designed and published.

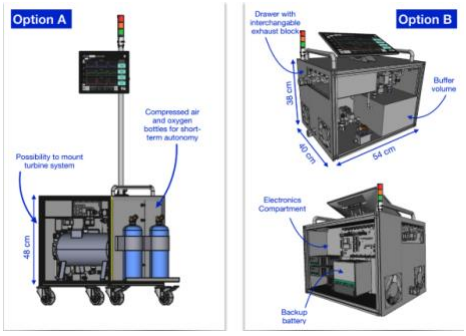
There were four main ventilator designs: electro-pneumatic (E-P), automatic compression of manual resuscitator (MR), automatic compression of MR with electro-pneumatic component (E-P & MR) and “other”. The E-P designs mimicked intensive care unit (ICU) ventilators using compressed gas (typically 50 PSI) as its driving mechanism to ventilate. The MR design incorporated a manual resuscitator (sometimes referred to as a bag-valve mask or self-inflating bag), with a motor and arm used to automatically compress the bag to ventilate.

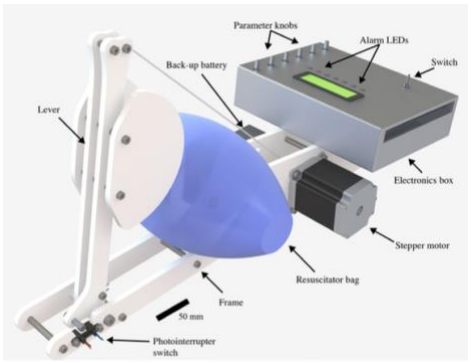
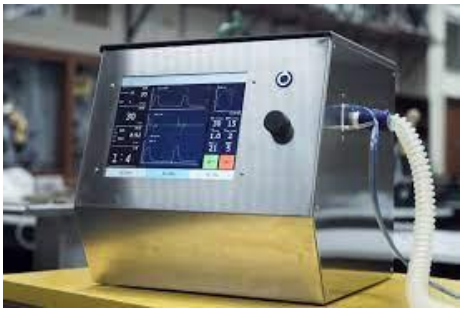
4.2 Characteristics of Included RMVs

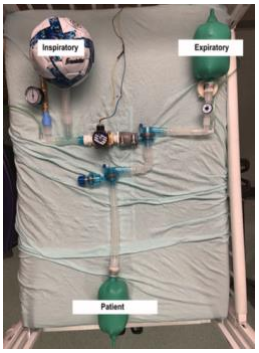
Out of the 53 RMVs identified, 16 (30%) were E-P, 21 (40%) automatic compression of MR, four (7%) had components of both automatic compression of MR and E-P and 12 (23%) were categorized as “other” not following either design (Table 6). A few examples of the “other” designs included cable driven origami-inspired bellow (Aihaitijiang et al., 2021), centrifugal impeller connected to an electric motor (Darwood et al., 2019), motor driven compression of a cylinder-shaped column (El Majid et al., 2020), piston driven pneumatic design (Szlosarek et al., 2021) and water-based columns with electronic

interface (Pereira et al., 2020). Four categories were created to describe the characteristics of the RMVs – 4.2.1 operating features, 4.2.2 performance features, 4.2.3 engineering features and 4.2.4 other features.

Table 6: Ventilator Design with corresponding example picture.

Ventilator Design	Picture Examples*
Electro-Pneumatic (EP)	 Abba et al. 2021  Buyaert et al. 2020
Automatic Compression of MR	 Gruslova et al. 2021

	 Vasan et al. 2020
Dual – EP and MR	 Beale et al. 2022  Chang et al. 2021

“Other”	 Pereira et al. 2020  Zuckerberg et al. 2020
*If provided by authors	

4.2.1 Operating Features

This section describes operating features of the RMVs including overall functions and controls. The operating features discussed below include: 4.2.1.a oxygen/gas source, 4.2.1.b power supply, 4.2.1.c user-input controls/monitoring, 4.2.1.d ventilator modes, 4.2.1.e alarms, 4.2.1.f ventilation parameters that included flowrate (L/min), TV (mL), PEEP (cm H2O), FiO_2, RR (bpm), I:E, and PIP (cm H_2O). Details are provided in Table 7.

4.2.1.a Oxygen/Gas Source

Of the 53 RMVs, 46 (87%) used an oxygen/gas source for operation. Fifteen (33%) E-P designs had compressed gas (air and oxygen) sources, and one article (2%) did not report any information about an oxygen/gas source. All 15 E-P RMV designs required standard medical air and oxygen (i.e., 50 PSI). Three (19%) E-P RMVs used lower gas pressure options like compressors, concentrators, turbines or mobile tanks to operate but authors recommended to use 50 PSI. Of the 21 automatic compression of MR, 20 (43%) had an oxygen/gas source. Twelve (26%) required a compressed gas source (i.e., to provide high or low flow), three (6%) required only an O_2 source (due to the MR's natural ability to take in room air during passive inflation), two (4%) did not require compressed gas, two (4%) used low flow O_2 but was not required and one (2%) had compatibility with "standard oxygenation" without providing a definition. Of the four RMVs with both E-P and MR components three had an oxygen/gas source of compressed O_2 (high flow or low flow). For "other" RMVs outside the MR and E-P design, gas source varied or were not reported.

4.2.1.b Power Supply

A power supply was included in 40 (75%) of the 53 RMVs. A voltage (V) of 24 or lower was sufficient power for 20 (50%) RMVs to operate, five (13%) required 100V or higher, and six (15%) were powered by gas (i.e., pneumatically powered). Three (8%) RMVs had power convertors and adaptors. A power failure back-up battery was included in 13 (33%) RMVs and were either lead or lithium ion. The back-up battery lifespan ranged from 20/30 minutes (Cole et al., 2020; Vasan et al.,2020) to 2 hours (Abba et al., 2021)

4.2.1.c User-Input Controls and Monitoring

The six main ventilator parameters reported across all RMV designs were RR, PEEP, TV, FiO2, PIP and I:E ratio. In E-P RMVs, controlling and monitoring PEEP (88%) was most common followed by RR (81%), FiO2 (81%), TV (56%), I:E ratio (56%) and PIP (38%). In MR RMVs, controlling and monitoring RR (95%) was most common followed by TV (76%), I:E ratio (71%), PEEP (43%), PIP (33%), FiO_2 (10%). See Table 7 for all other ventilator parameters.

Table 7. RMV User-Input Controls and Monitoring.

Ventilator Parameter	RMV Design				TOTAL
	E-P (n = 16)	Automatic Compression of MR (n = 21)	E-P + MR (n = 4)	Other (n = 12)	n = 53
RR	13 (81%)	20 (95%)	4 (100%)	6 (50%)	43 (81%)
PEEP	14 (88%)	9 (43%)	3 (75%)	4 (33%)	30 (57%)
TV	6 (56%)	16 (76%)	4 (100%)	3 (8%)	29 (55%)
FiO2	13 (81%)	2 (10%)	3 (75%)	1 (8%)	19 (36%)
PIP	6 (38%)	7 (33%)	1 (50%)	2 (17%)	16 (30%)
I:E	9 (56%)	15 (71%)	2 (100%)	4 (33%)	30 (57%)
Inspiratory Time	3 (19%)	2 (10%)	0	1 (8%)	6 (11%)
Inspiratory Flowrate	(25%)	0	0	1 (8%)	5 (9%)
Inspiratory Pause	0	1 (5%)	0	0	1 (2%)
Inspiratory Trigger	0	0	0	1 (8%)	1 (2%)
Expiratory Time	1 (6%)	0	0	0	1 (2%)
Peak Pressure	0	0	0	1 (8%)	1 (2%)
Plateau Pressure	0	1 (5%)	0	0	1 (2%)
Airway Pressure	0	1 (5%)	0	0	1 (2%)

Fixed Settings	0	0	0	1 (8%)	1 (2%)
Unclear	1 (6%)	1 (5%)	0	0	2 (4%)
Not Reported	1 (6%)	0	0	3 (25%)	4 (8%)

4.2.1.d Ventilator Modes

Ventilation modes were present in 43 (81%) of the 53 RMVs, and categorized as (1) pressure, (2) volume, (3) dual, or (4) other. Eighteen (42%) RMVs had the ability to perform more than one ventilation mode while 25 (58%) had a single ventilation mode. The most common ventilation mode regardless of RMV design was volume control ventilation (VCV) at n = 32 (60%), followed by pressure control ventilation (PCV) at n = 20 (38%). PCV was more prevalent in E-P RMVs (50%) compared to MR RMVs (24%), while VCV was more prevalent with MR RMVs (76%) compared to E-P RMVs (69%). Details are provided in Table 8.

Table 8. RMV Ventilator Modes.

Ventilator Mode		**RMV Design**				TOTAL
		E-P (n = 16)	**Automatic Compression of MR (n = 21)**	**E-P & MR (n = 4)**	**Other (n = 12)**	**n = 53**
Pressure Modes	**PSV**	3 (19%)	1 (5%)	2 (50%)	0	6 (11%)
	PCV	8 (50%) [1]	5 (24%)	1 (25%)	6 (50%) [6]	20 (38%)
	PC-PSV	1 (6%)	0	0	0	1 (2%)
	PC-IMV	0	0	0	1 (8%)	1 (2%)
Volume Modes	**VCV**	11 (69%) [2]	16 (76%) [5]	3 (75%)	2 (17%)	32 (60%)
	ASV	0	0	1 (25%)	0	1 (2%)
	SIMV-VC	2 (13%) [3]	0	0	0	2 (4%)
	SIMV	0	0	0	1 (8%)	1 (2%)
Dual Mode	**PRVC**	4 (25%) [4]	0	0	1 (8%)	5 (9%)

Other	**CPAP**	2 (13%)	0	0	0	2 (4%)
	Not Reported	1 (6%)	6 (29%)	1 (25%)	3 (25%)	10 (19%)

[1]Includes PC-A/C, [2]Includes CMV, [3]Includes VC-IMV, [4]Includes PC-A/C-PRVC, [5]Includes CMV, OL-CMV, [6]Includes PC-CMV. **Abbreviations:** Electro-Pneumatic (EP); Manual Resuscitator (MR); Pressure support ventilation (PSV); Pressure control ventilation (PCV); Pressure control – Pressure support ventilation (PC-PSV); Pressure control – Intermittent mandatory ventilation (PC-IMV); Volume control ventilation (VCV); Adaptive support ventilation (ASV); Synchronized intermittent mandatory ventilation – Volume control (SIMV-VC); Synchronized intermittent mandatory ventilation (SIMV); Pressure regulated volume control (PRVC); Continuous positive airway pressure (CPAP).

4.2.1.e Alarms

Of the 53 RMVs, two (4%) did not include alarms into their design and 13 (25%) provided no details about alarms. For the 36 (70%) RMVs that did include alarms into their design, 30 (83%) had audible alarms, 15 (42%) visual alarms and 15 (42%) both audible and visual alarms. Six (17%) RMVs included an alarm system in their design but provided no details about type.

4.2.1.f Ventilation Parameters

Tidal Volume (TV) (mL)

Tidal volume range was available in 25 (47%) of the 53 RMVs (Figure 4), with a mean value of 514mL. The lowest deliverable TV was 0mL, however, the most common minimum deliverable TV was 200mL (8 (32%) RMVs). The highest deliverable TV was 2000mL, however, the most common maximum deliverable TV was 800mL (8 (32%) RMVs). TV in two RMVs was only achievable in increments: Buyaert et al. (2020) in increments of 50mL and Cole et al. (2020) in increments of 45mL. Beale et al. (2022) reported a TV of “up to 600mL” (assumed 0 mL to 600 mL for data analysis).

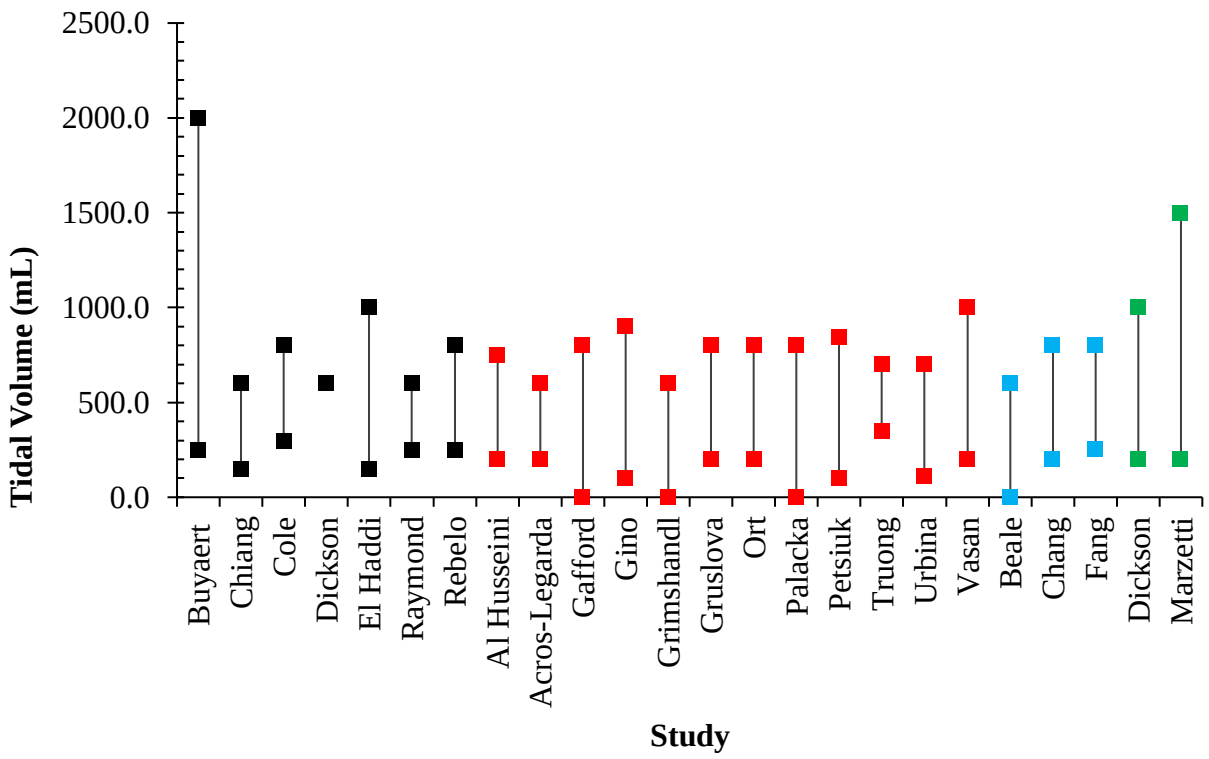


Figure 4. Minimum and maximum TV (mL) ranges by design. Black is E-P. Red is automatic compression of MR. Blue is E-P and MR. Green is "other". One RMV was excluded because TV was reported as "30 – 100% of bag squeeze" (35). **Abbreviations:** Electro-pneumatic (E-P); Manual resuscitator (MR).

Positive-End Expiratory Pressure (PEEP) (cm H_2O)

A PEEP range was available in 17 (32%) of the 53 RMVs (Figure 5) with a mean value of 13 cm H_2O. The lowest deliverable PEEP was 0 cm H_2O and the most common 0 cm H_2O and 5 cm H_2O (8 (47%) RMVs each). The highest deliverable PEEP was 60 cm H_2O, however, the most common maximum deliverable PEEP was 20 cm H_2O reported in 11 (65%) RMVs. The RMV by Buyaert et al. (2020) reported a PEEP range of 5 to 20 cm H_2O only achievable in increments of 5 cm H_2O and the RMV by Dickson et al. 2011 reported a fixed PEEP value of 0 cm H_2O instead of a range.

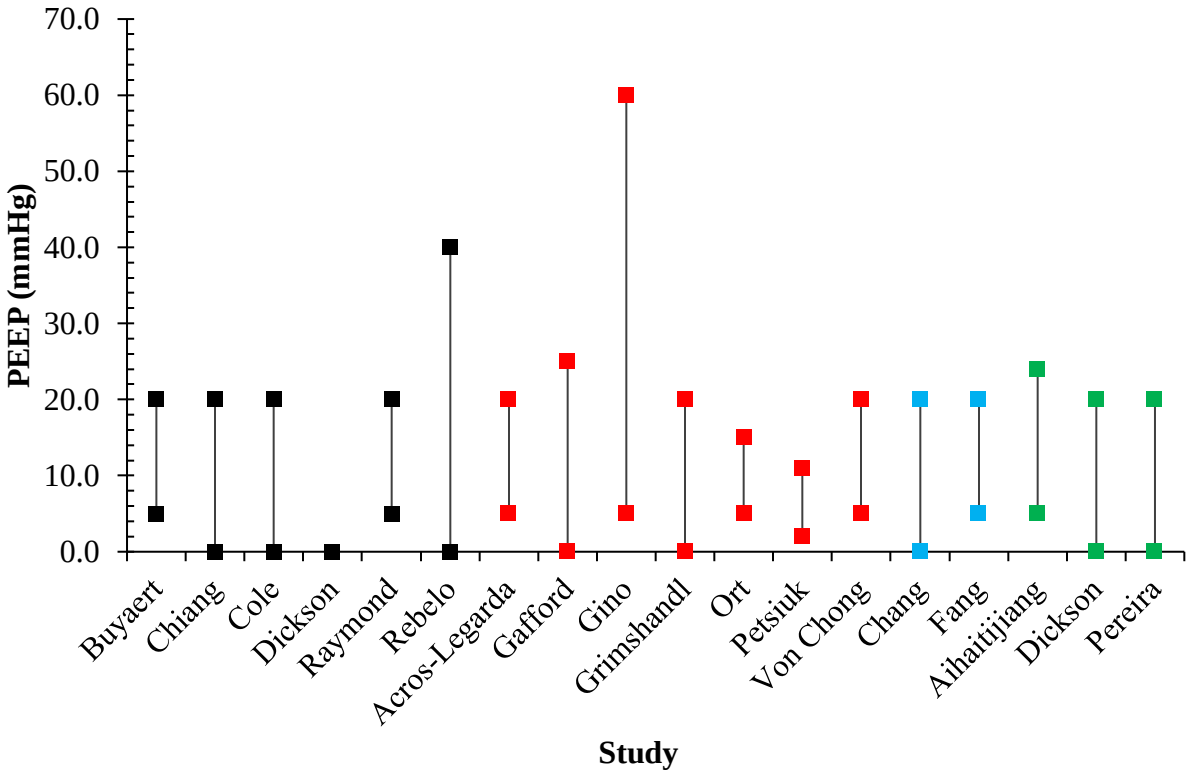


Figure 5. Minimum and maximum positive end-expiratory pressure (PEEP) (cm H_2O) by design. Black is E-P. Red is automatic compression of MR. Blue is E-P and MR. Green is "other". **Abbreviations:** Electro-pneumatic (E-P); Manual resuscitator (MR).

Fractional Concentration of Oxygen (FiO_2)

Fractional concentration of inspired O_2 was available in 16 (30%) of the 53 RMVs (Figure 6). Twelve (75%) had a minimum value of 0.21, and 12 (81%) could deliver 1.0. The mean was 0.61. All 16 RMVs were able to provide a FiO_2 of 0.50 – 0.80, with one achievable only in increments of 0.10 (Buyaert et al., 2020).

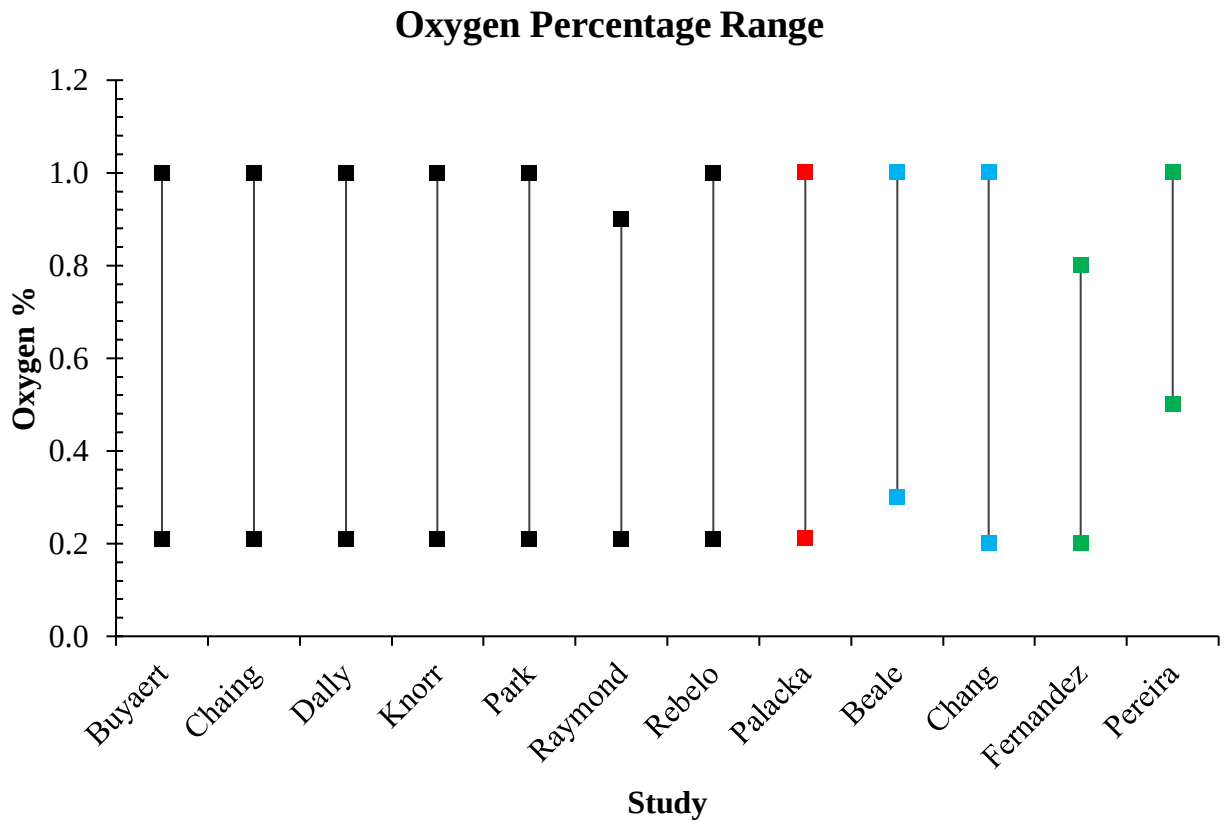


Figure 6. Minimum and maximum oxygen percentage by design. Black is E-P. Red is automatic compression of MR. Blue is E-P and MR. Green is "other". Four RMVs were excluded because definitive FiO_2 ranges were not provided. King et al. (2020) reported 0.50 or 1.0; Gino et al. (2020) 0.21 or 1.0; Cole et al. (2020) 0.21, 0.50-0.60 and 0.90-1.0; Aihaitijiang et al. (2021) "adjustable O_2". **Abbreviations:** Electro-pneumatic (E-P); Manual resuscitator (MR).

Respiratory Rate (RR) (breaths per minute (bpm))

A respiratory rate range was available in 26 (49%) of the 53 RMVs (Figure 7) with a mean RR of 20 bpm. The lowest deliverable RR was 0 bpm with the most common being 10 bpm (11 (42%) RMVs). The highest deliverable RR was 60 bpm, with the most common being 30 bpm (13 (50%) RMVs. Two of the 26 RMVs were only able to provide changes in RR in increments of 2 bpm (Buyaert et al., 2020; Meiry et al., 2022). The RMV in the Dhanani paper had a RR "up to 25 bpm" (assumed 0 bpm to 25 bpm for data analysis), the RMV in the Dickson paper had a fixed RR of 10 bpm rather than a range.

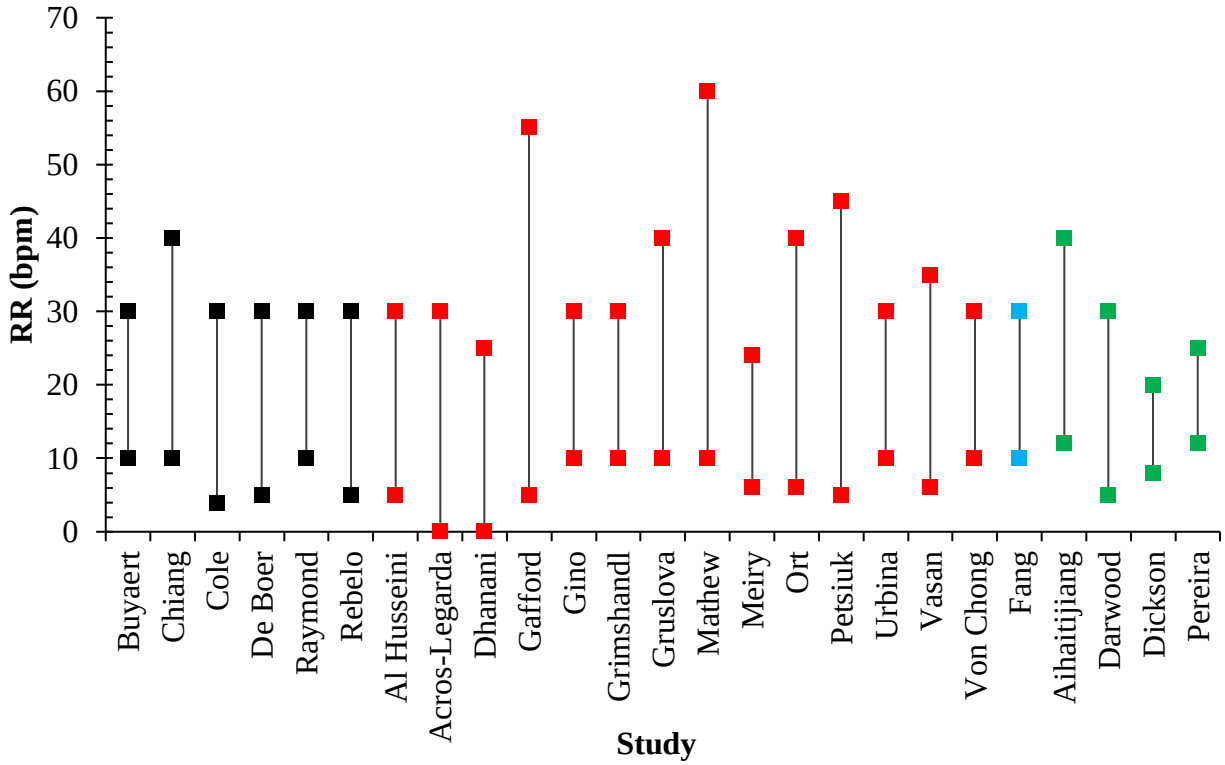


Figure 7. Minimum and maximum RR (bpm) by design. Black is E-P. Red is automatic compression of MR and MR. Blue is E-P and MR. Green is "other". **Abbreviations:** Electro-pneumatic (E-P); Manual resuscitator (MR); Breaths per minute (BPM).

Inspiratory to Expiratory Ratio (I:E ratio)

Of the 53 RMVs included for analysis, 18 (34%) had an I:E ratio feature (Figure 8). For 15 RMVs a I:E ratio of 1:2 was the most common (13 [17%]) with a range that varied between 1:1 to >1:5. The remaining 3 (17%) RMVs reported an I:E ratio of "21%-100%", "0.5s-1.5s" or "inspiratory time 1-3.0s".

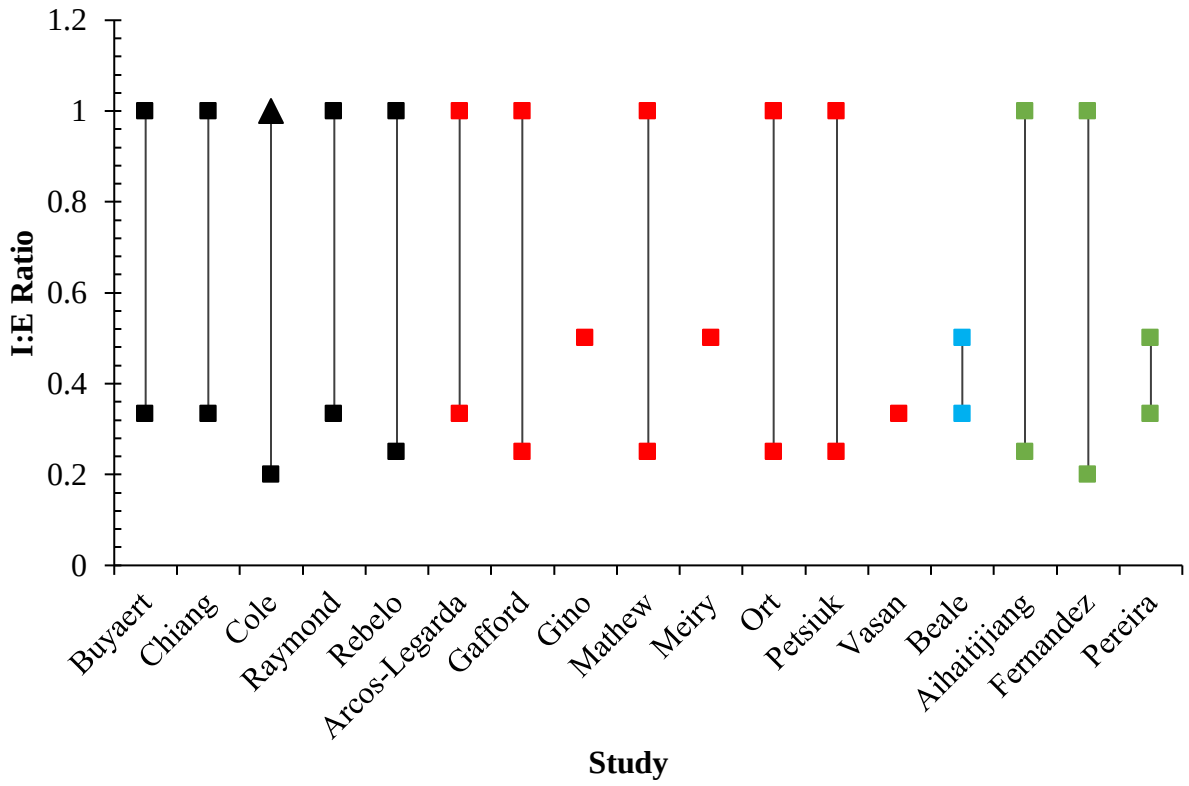


Figure 8. Minimum and maximum inspiratory to expiratory (I:E) ratio by design. Black is E-P. Red is automatic compression of MR. Blue is E-P and MR. Green is "other". Gino et al. (2020), Meiry et al. (2022), and Vasan et al. (2020) reported fixed I:E ratios of 1:2 as indicated by the single red points. Cole et al. (2020) reported a maximum I:E ratio of >1:5 which is indicated with a up black arrow**. Abbreviations:** Electro-pneumatic (E-P); Manual resuscitator (MR).

Positive Inspiratory Pressure (PIP) (cm H_2O)

A PIP range was available in 12 (23%) of the 53 RMVs (Figure 9) with a mean value of 26 cm H_2O. The lowest deliverable and the most common PIP was 0 cm H_2O (5 (42%) RMVs)). The highest deliverable PIP was 70 cm H_2O and the most common was 40 cm H_2O (5 (42%) RMVs)). All 12 (100%) RMVs were capable of delivering a PIP of 30 cm H_2O to 35 cm H_2O.

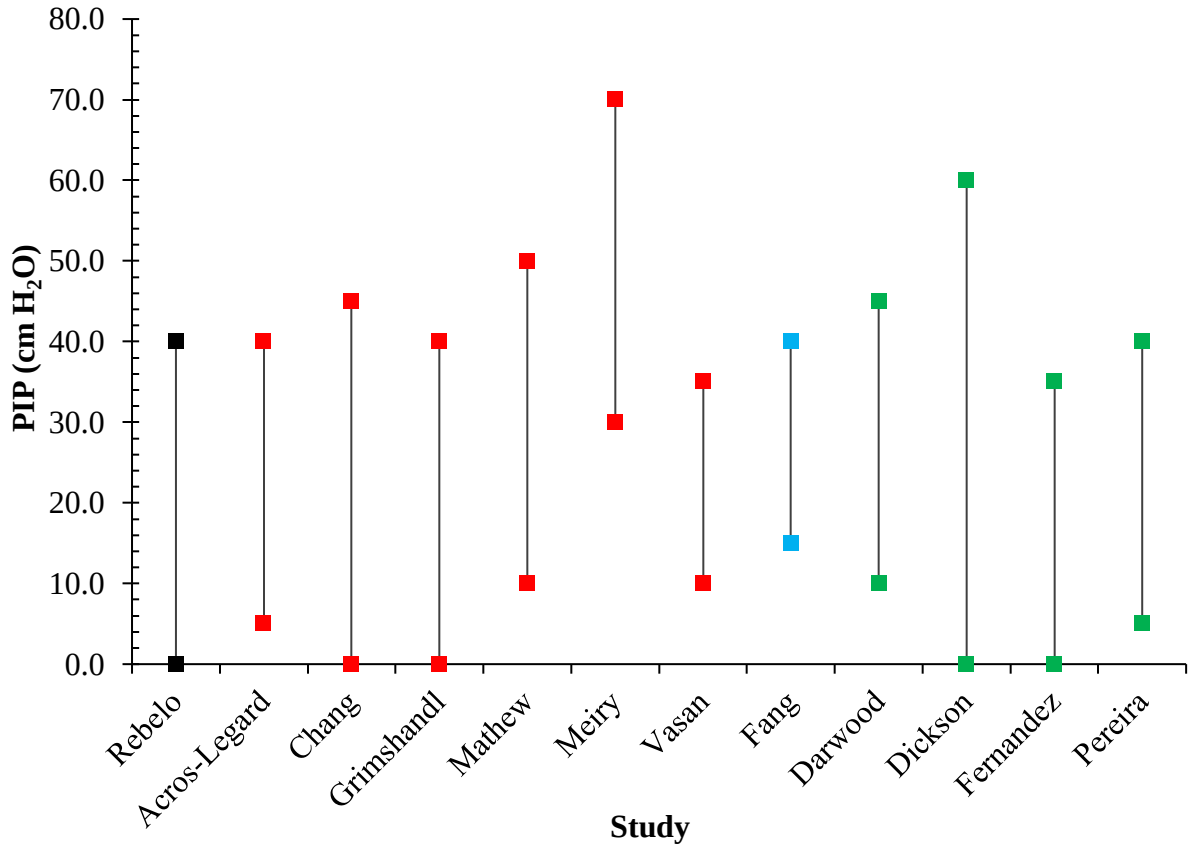


Figure 9. Minimum and maximum PIP (mm Hg) by design. Black is E-P. Red is automatic compression of MR and MR. Blue is E-P and MR. Green is "other". **Abbreviations:** Electro-pneumatic (E-P); Manual resuscitator (MR).

Flowrate (liters per minute (L/min))

A flowrate range was available in 10 (19%) of the 53 RMVs (Figure 10) with a mean value of 40 lpm. The lowest deliverable and most common flowrate was 0 lpm (6 (60%) RMVs). The highest deliverable flowrate was 140 lpm, however, the RMV in the Beale (2022) paper had a flowrate of >49.5 lpm (assumed 0 lpm – 49.5 lpm for data analysis). The most common maximum deliverable flowrate was 120 lpm (2 (20%) RMVs). All 10 RMVs that reported a flowrate range capable of delivering 9 lpm to 30 lpm, except the RMV in the Dickson (2011) paper with a fixed flowrate value of 16 lpm.

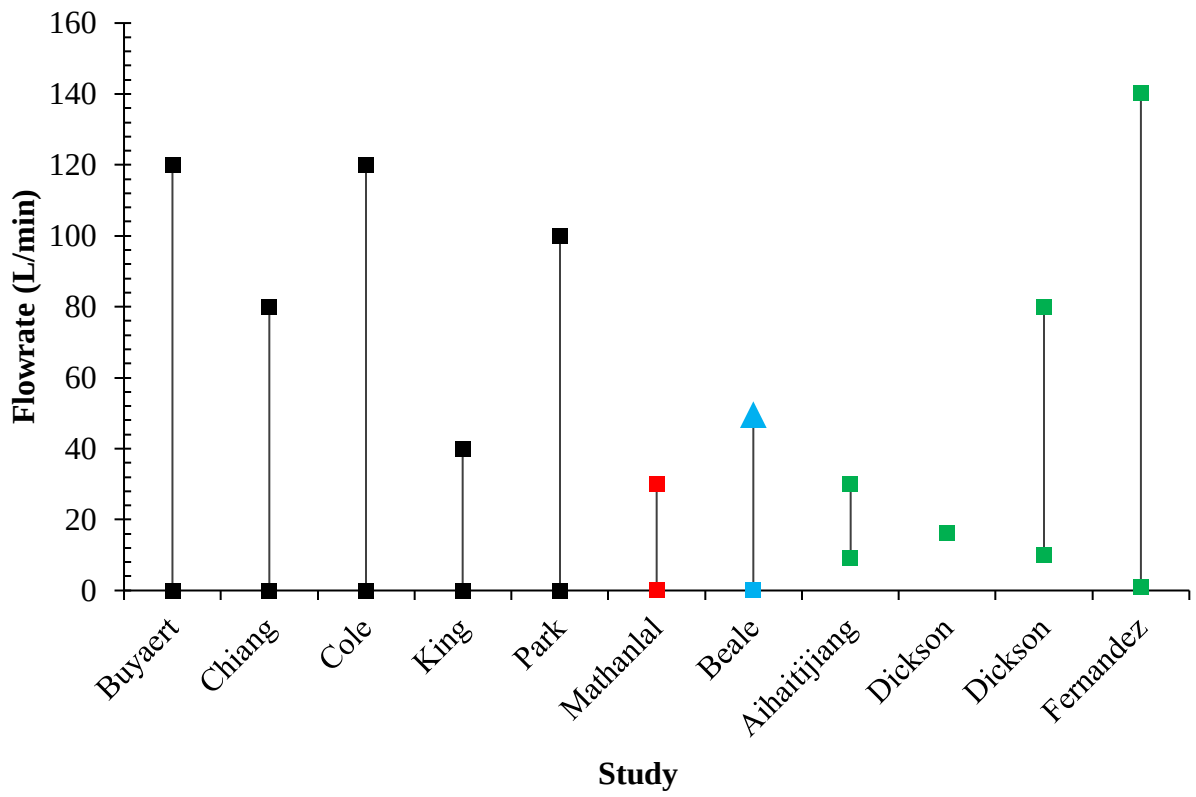


Figure 10. Minimum and maximum flowrate (L/min) by design. Black is E-P. Red is automatic compression of MR. Blue is E-P and MR. Green is "other". Beale reported a maximum flow rate of >49.5 lpm and is indicated by the up blue arrow. Dickson reported a fixed flowrate of 16 lpm as indicated by the single green point. **Abbreviations:** Electro-pneumatic (EP); Manual resuscitator (MR).

4.2.2 Performance Features

This section describes features relating to how the RMVs performed. The performance features discussed here include: 4.2.2a ventilator testing and sustained use, 4.2.2b end-user training/testing, 4.2.2c process to set-up/assemble (user-friendliness) and 4.2.2d oxygen consumption.

4.2.2a Ventilator Testing and Sustained Use

Two (4%) RMVs did not have information about device testing and three (6%) intentionally did not test their device due to insufficient resources, or testing was not an objective of the project. The remaining 46 (87%) of the 53 RMVs tested performance in

various ways. The most common testing method was a lung simulator or mannequin (n = 37, 80%). Animal testing was completed in 16 (35%) RMVs, 13 with pigs, one with rabbits, one with sheep, and one did not provide details. Human testing was only completed in one (2%) RMV with five participants. Of the 46 RMVs that performed testing, 12 (26%) used more than one method: 11 (24%) with a lung simulator and animals, and 1 (2%) with animals and humans. Two (4%) RMVs tested their device but either provided no details about the methods or mentioned “minimal testing” without providing a definition. Of 27 (59%) RMVs, 20 (43%) tested for 1 day or less, two (4%) for >1 day to 2 weeks, and six (13%) for > 2 weeks.

4.2.2b End-User Training/Testing

Of the 53 RMVs two (4%) had end-user training/testing to aid navigation and setting of appropriate parameters for mild to severe respiratory conditions. The training and/or testing was created to ensure full understating of how to operate the machine before ventilating a patient. The E-P RMV by Abba et al. (2021) had a program integrated in the graphical user interface (GUI), guiding end-users through various procedures including start-up, setting operating parameters, alarm thresholds and completing hardware and software tests. They also included a self-test procedure to complete after start-up. The end-user was required to complete all of the self-tests on the GUI (e.g., setting appropriate parameters and alarm thresholds) before being able to operate the ventilator. The MR RMV by Gruslova et al. (2021) tested their GUI by providing instructions via a training manual and instructional video about the machine (the intended audience being respiratory students). This was followed by a post training assessment

quiz evaluating how well they could efficiently perform circuit and basic operation set-up on the GUI (Gruslova et al., 2021).

4.2.2c Process to Set-up/Assemble (User-Friendliness)

Processes to set-up/assemble the RMV was included in 15 (28%) of the 53 RMVs. Eight (53%) provided step-by-step instructions for product assembly, operation and GUI navigation (Chang et al., 2021; Chiang et al., 2021; DeBoer et al., 2021; Gruslova et al., 2021; Kindomba et al., 2021; King et al., 2020; Petsiuk et al., 2020; Urbina et al., 2021). Knorr et al. (2020) mentioned their RMV design was intended for operators with little to no experience with mechanical ventilation. For two RMVs, respiratory students (Gruslova et al., 2021) or those with basic knowledge of engineering (DeBoer et al., 2021) would have "no problem" assembling or operating the device. Other RMVs were simply described as "easy to set-up and use" (Dally et al., 2021; Buyaert et al., 2020; Beale et al., 2022), "user-friendly" (Mathew et al., 2021) and "minimal training required for operation" (Christou et al., 2020). Two RMVs reported assembly time as 30 minutes (Dally et al., 2021) or 8 hours (Fernandez et al., 2020).

4.2.2d Oxygen Consumption

Of the 53 RMVs two (4%) reported oxygen consumption for their device. In the E-P and MR RMV by Williams et al. (2010) the mean (SD) oxygen consumption was reported for various lung scenarios. When lung compliance was 70 mL/cm H_2O, I:E ratio set at 1:1 and tidal volume at 500 mL, oxygen consumption was 0.857 (0.228) L/min. Conversely, when lung compliance was 40 mL/cm H_2O, I:E 1:2 and tidal volume 700 mL, oxygen consumption was greatest at 1.246 (0.228) L/min. These results showed that oxygen consumption was dependent on lung compliance. When lung compliance was reduced,

oxygen consumption is greater due to increased mechanical work of ventilation and vice versa. Williams et al. (2010) did mention regardless of lung volumes and compliances, their RMV only required very low oxygen consumption if powered by an oxygen cylinder thus having long endurance. The RMV in the Beale et al. (2022) paper mentioned at nominal settings (TV = 400 mL, RR = 20 bpm, FiO_2 = 0.50) their oxygen consumption was 4L/min, well below the upper bound of 6L/min recommended by MHRA in the RMVS specification (MHRA, 2020). This oxygen consumption was 2-3 times lower than a standard ICU ventilator (Beale et al., 2022).

4.2.3 Other Features Outside Routine Use

This section discusses other features of the RMVs that did not fall within operating or performance features. This includes 4.2.3a general durability, 4.2.3b recalls/vendor & support contract/maintenance, 4.2.3c cost, 4.2.3d additional approvals/clearances, 4.2.3e labelling, 4.2.3f infection control and 4.2.3g ventilator kit description/environment of use.

4.2.3.a General Durability

Of the 53 RMVs, 12 (23%) were tested for their ability to withstand continued functioning over time (i.e., durability). The durability testing for six E-P RMVs included durations of 48 hours (Knorr et al., 2020), 72 hours (Dhanani et al., 2020), 84 hours (King et al., 2020), 14 days (Gafford et al., 2021), 15 days (Madekurozwa et al., 2021) and 3 months (Abba et al. 2021). Two MR RMVs tested the durability of the BVM, conducting tests for >7 days (Gruslova et al., 2021) or 30 and 45 days (1.3 million compressions) (Urbina et al., 2021). The MR RMV described in the Gruslova (2021) paper tested the durability of the Cadone electric motor by compressing the BVM continuously for >30 days but did not provide an exact duration (Gruslova, 2021). One of the “other” RMV designs

(Aihaitijiang, 2021) that utilized a bellows, tested its compression and decompression durability for 24 hours.

There were some RMVs that completed multiple durability testing. The Q-Vent MR RMV was dropped and checked afterwards for proper functioning, utilized in an ambulance-type setting, continuously run for 14 days, and tested for strong and sturdy connections (Palacka et al., 2020). The CRISIS E-P RMV was autoclaved and drop tested (specific details not provided) (El Haddi et al., 2022). Lastly, the RMV in the Pereira paper was run for 35 full days at a rate of 120 bpm (which was described as equivalent to 140 days of normal operation at 30 bpm).

4.2.3.b Recalls/ Vendor & Support Contract/ Maintenance

None of the RMVs had a process for product recalls, nor discussed vendor and support contracts for providing support or maintenance if technical issues with the machine should arise.

4.2.3.c Cost

The RMV cost was provided for 35 (66%) of the 53 RMVs. All costs were converted to United States Dollar (USD) using rates according to the year of publication, then corrected for inflation to 2023 ("*Inflation calculator: Find US Dollar's value from 1913-2023",* 2023). The lowest reported cost to build an RMV was $22 (Aihaitijiang et al., 2021) and the highest cost was $2,653 (Dickson et al., 2011). The mean RMV price across all designs was $720. The E-P designs had the highest mean (SD) cost at $871 (533) and the automatic compression of MR designs the lowest at $601 (567). The combination E-P and MR designs had a mean (SD) cost of $871 (533) and the "other" RMV designs $728.

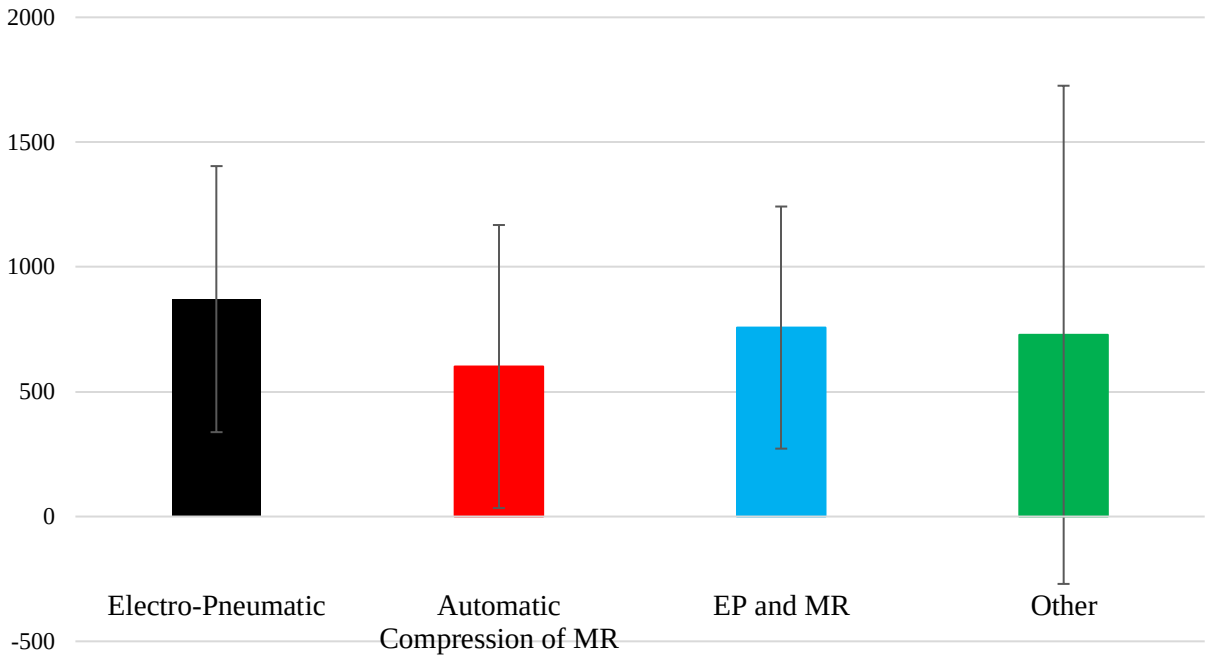


Figure 11. Average cost (2023 $USD) of RMV based on design.

4.2.3.d Additional Approvals/Clearances

In order to get approval for medical devices to be used on animals, humans or in the clinical setting certain requirements must be met. These requirements are made by regulatory agencies whose main responsibility is to ensure safety and efficacy of products. One major regulatory agency is the United States Food and Drug Administration (FDA). Other regulatory agencies listed here are specific to the countries in which the RMVs were built. More information regarding regulatory agencies is in Chapter 2: Background and Context.

Four (8%) RMVs obtained approval from reputable agencies. The Mechanical Ventilator Milano RMV by Abba et al. (2021) was certified by the a) Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA) for Emergency Use Authorization in May 2020 and b) Health Canada Medical Device Directorate Authorization for Importation or Sale, under Interim Order for Use in Relation to Covid-19

in September 2020. The RMV by Chiang et al. (2021) was fully validated under the Consejo Multidisciplinario de Facilitacion de Gestion Crisis Covid-19 (CMFCC) special validation protocol indicating its use was only valid as an emergency ventilator during the Covid-19 pandemic. The E-P RMV by Raymond et al. (2022) and SAVe I RMV by Dickson et al. (2011) received FDA approval. De Pasquier et al. (2021) reported successfully fulfilling the MHRA list of requirements (MHRA 2020) for RMVs, however, approval to conduct clinical trials and approval from FDA are still required. The dual E-P and MR RMV by Beale et al. (2022) passed electromagnetic compatibility and electrical safety tests but did not mention if the testing met the requirements of a regulatory agency. The dual E-P and MR RMV by Chang et al. (2021) was the only RMV (at the date of submission) to have units deployed to ICUs in Peru after receiving approval from a Peruvian regulatory authority called DIGEMID. All remaining 44 RMVs did not mention any specific approvals or clearances received for their device.

4.2.3.e Labelling

Three (6%) of 53 RMVs had labelling. The Rapidly Manufactured Ventilator System (RMVS001) specification document issued by MHRA (2020) described mandatory labels that must be clearly visible on the machine. These included “follow instructions for use”, “device restricted for use during Covid-19 pandemic, emergency ventilation use only” and “manual back-up ventilation must be available” labels. The E-P RMV by Chiang and colleagues (2021) described “passing” labelling and indication testing but did not mention details of what labels or indications were included in the design. The E-P RMV by King and colleagues (2020) stated *“We refer to the device of this study as an emergency ventilator or EV, because of its intended use in an emergency and because we*

demonstrate ventilation of an animal using the device." (pg. 2) but did not mention if a label was included to reiterate this. The MR RMV by Palacka et al. (2020) included labels on their device for HCPs as recommended by the MHRA RMVS specification document (MHRA, 2020).

4.2.3.f Infection Control

Infection control processes were described in 28 (53%) of the 53 RMVs. This included incorporating various filters in the breathing circuit to avoid contamination to the patient and/or HCPs: bacterial (6, 21%), high efficiency particulate air (HEPA) (7, 28%), and heat and moisture exchanger (HME) (6, 21%). Two (7%) RMVs had “easy access” for maintenance and disinfection. Six (21%) RMVs came with instructions to replace or disinfect/sterilize all items that come into contact with or near patients, before each use. These items were already widely used in clinical practice (e.g., patient breathing circuit) meant to make replacement easy.

4.2.3.g Ventilator Kit Description/Environment of Use

Of the 53 RMVs, n = 20 (38%) had design descriptions for increased convenience in the environment in which it will be used. Weight (kg) (SD) was described for n = 13 (65%) RMVs and averaged 10.7 kg (14.9). Length (cm), width (cm) and height (cm) (SD) were described for 11 (55%) RMVs. The average length was 35 cm (13.8), width 31 cm (10.4) and height 55 cm (48.2). Six (30%) RMVs were described as lightweight for easy portability (Aihiaitijiang et al. 2021; Al Husseini et al. 2010; Haque et al. 2021; Mathew et al. 2021; Meiry et al. 2022; Palacka et al. 2020), two (10%) included a handle to facilitate transportation or could be hung by bedside (Al Husseini et al. 2010; Mathew et al. 2021) and two (10%) had wheels to facilitate movability (Buyaert et al. 2020; Rebelo et al. 2021).

The RMV by Buyaert et al. (2020) purposely included extra space within compartments for easy exchange of parts.

4.2.4 Engineering

Within this section the RMV engineering characteristics will be discussed in detail. This section is divided into 3 subsections: 4.2.4.a hardware, 4.2.4.b software/interface and 4.2.4.c hardware and software documents.

4.2.4.a Hardware

This subsection describes the physical characteristics of the RMVs including: oxygen sensor, pressure sensor, materials (including additive manufacturing), parts, motor and control system. An *oxygen sensor* is a device used to measure the proportion of oxygen delivered to the patient (Ramamoorthy et al., 2003). A *pressure sensor* measures the gas pressure within the system and is used to set and monitor ventilator parameters, and vital for safety e.g., avoiding high pressures that could cause pulmonary barotrauma (Almassri, et al., 2015). *Materials* are substances used to construct an object including those used in additive manufacturing (i.e., a process of building objects layer by layer) (Bourell et al., 2017). *Parts* are various smaller components that when combined, help construct the end product. A *motor* is a machine that when powered, produces a motion or action (Scarpino, 2015). A *control system* manages the behaviour of a device using control loops to achieve desired outcomes (Nise, 2020). Details are provided in Table 9 and Table 10.

Oxygen Sensor

An oxygen sensor was included in 12 (23%) of the 53 RMV designs, and in 26 (49%) it was unclear (did not report if one was included).

Pressure Sensor

A pressure sensor was included in 36 (69%) of the 53 RMVs, 5 (10%) did not include one, and in 10 (19%) it was unclear. One (2%) RMV did not explicitly have a *pressure sensor*, instead described having a flow transducer (De Pasquier et al., 2021) which is used interchangeably with pressure sensor to achieve the same outcome of measuring pressure within the RMV system.

Materials

Materials were described in 33 (62%) of the 53 RMVs and divided into design to better understand what materials were used for each build including the type of materials used for additive manufacturing. To form custom shapes for some RMV designs, two techniques were used: computer numerical control (CNC) laser cutting used for five (15%) RMVs and water jetting for one (3%). CNC laser cutting uses high-powered laser beams to carve the material into the desired shape (Khatak, 2022). Water jetting can be used exclusively with high-pressured water or can be mixed with an abrasive substance to cut or erode the surface of the material into the desired shape (Natarajan et al., 2020). See Table 9 for list of materials.

Materials - E-P and Automatic Compression of MR RMV Designs

Ten (63%) of the 16 E-P RMVs used materials such as stainless steel, brass, aluminum, polyvinyl chloride (PVC), silicone 30 (SIL-30), polyamide, copper, fluroelastomers (FKM) and poly-tetrafluroethylene (PTFE). One RMV used a “safe plastic” but did not provide any further details (Dally et al., 2021).

Sixteen (76%) of the 21 automatic compression of MR RMV designs used poly(methyl methacrylate) (i.e., acrylic), acrylonitrile butadiene styrene (ABS), polyglass, stainless steel, polypropylene, steel and polyactic acid filament.

Stainless steel was used for only one (25%) of the four dual E-P and MR designs. The remaining three designs did not mention any materials.

Materials - Other RMV Designs

Materials used in six (50%) of the 12 “other” RMV designs included silicon, rubber, plastic, wood, acrylic, polyvinyl chloride (PVC), thermoplastic polyurethane (TPU), polyethylene terephthalate (PET) and polyactic acid (PLA). Specific materials for one RMV (Szlosarek et al., 2021) were not detailed, however, the article reported manufacturing could be completed using plastics or metals such as polyethylene (PE), polypropylene (PP), PET, polyvinylchloride (PVC), polycarbonate (PC), poly-tetrafluoroethylene (PTFE), polyoxymethylene (POM) and stainless steel.

Additive Manufacturing (AM)

Thirteen (25%) of the 53 RMVs used AM for the entire design or in combination with traditional build techniques. Two major AM methods used were: fuse deposition modelling for 3 RMVs (FDM, a filament is injected through a nozzle and deposited onto the bed to create the desired object (Surange & Gharat, 2016); and selective laser sintering for one RMV (SLS, melting a spread powdered material using a high-powered laser beam to create successive layers (King & Tansey, 2003).

Table 9. List of materials used to build RMVs.

Materials	RMV Design				TOTAL
	E-P (n = 16)	Automatic Compression of MR (n = 21)	E-P + Automatic compression of MR (n = 4)	Other (n = 12)	n = 53
Stainless Steel	3 (19%)	1 (5%)	1 (25%)	1 (8%)	6 (11%)
Brass[1]	4 (25%)	0	0	0	4 (8%)
PVC	1 (6%)	0	0	1 (8%)	2 (4%)
Plastic[2]	1 (6%)	0	0	3 (25%)	4 (8%)
Aluminum	1 (6%)	2 (10%)	0	0	3 (6%)
Polyamide	1 (6%)	1 (5%)	0	0	5 (9%)
Copper	1 (6%)	0	0	0	1 (2%)
Acrylic[3]	0	2 (10%)	0	1 (8%)	3 (6%)
Polyglass	0	1 (5%)	0	0	1 (2%)
Steel	0	2 (10%)	0	0	2 (4%)
Polypropylene	0	1 (5%)	0	0	1 (2%)
Polyactic Acid (PLA)	0	5 (24%)	0	1 (8%)	6 (11%)
ABS	0	3 (14%)	0	0	3 (6%)
Plywood	0	1 (5%)	0	0	1 (2%)
Sheet metal	0	2 (10%)	0	0	2 (4%)
Birch hardwood	0	1 (5%)	0	0	1 (2%)
Polycarbonate	0	1 (5%)	0	0	1 (2%)
Polyoxymethylene (acetal)	0	1 (5%)	0	0	1 (2%)
Fold plastic	0	0	0	1 (8%)	1 (2%)
Polyethylene terephthalate (PET)	0	0	0	1 (8%)	1 (2%)
Nitrile exam glove material	0	0	0	1 (8%)	1 (2%)
Silicon Sheet	0	0	0	1 (8%)	1 (2%)
Rubber	0	0	0	1 (8%)	1 (2%)
Wood	0	0	0	1 (8%)	1 (2%)
Not Reported	6 (38%)	6 (29%)	3 (75%)	6 (50%)	20 (38%)

[1] Includes Brass/FKM, Brass/PTFE; [2] Includes plastics such as polyethylene (PE), polypropylene (PP), polyethylene tere-phthalate (PET), polyvinylchloride (PVC), polycarbonate (PC), poly-tetrafluoroethylene (PTFE) or polyoxymethylene (POM); [3]Includes acrylic – poly(methyl methacrylate)

Parts

All RMVs used parts for their design, however, details were only provided for 46 (87%) of the 53 RMVs. In Table 10 a list of the major parts used to construct the RMVs is provided. Table 10 does not present all parts of each design, only the major ones, however, **Appendix C** shows all parts reported for each of the 53 designs.

Parts - E-P Design

Fourteen (88%) of the 16 E-P RMVs had parts described. Two RMVs (14%) were made entirely from off-the-shelf parts, two (14%) a combination of off-the-shelf parts and 3D printed parts, and for 10 (71%) it was not clear if the parts were off-the-shelf or 3D printed.

For the pneumatic components of these designs, parts were reported in 7 (50%) RMVs and comprised of a breathing circuit such as the hose, hose fittings, hose tee, solenoid valve and flow control.

Electric components included valves and sensors. Valves for regulating flow and pressure were used in 8 (50%) E-P designs. These included emergency (positive and negative pressure relief), PEEP, inspiratory and expiratory, proportional, “on-off” solenoid, pressure regulating, flow regulating, one-way, 3-way, exhale actuation, exhale diaphragm, main control, piezo-electric and pinch.

Sensors (differential, gauge and compound) help convert physical properties within the system to a readable display for the end-user and are important for safety

performance of the machine (West et al., 2013). Sensors for this design included pressure sensors, bidirectional pressure/flow sensors, temperature sensors and oxygen sensors.

Other important parts used to build the RMVs included pressure regulators, inhale and exhale regulators, bacterial filters, humidifiers, transformers, 2L or 10L reservoir/buffer containers, safety fuses and breakers, liquid crystal display (LCD) display, O2 adapter, patient-T, modulator, and microcontroller.

Parts - Automatic Compression of MR Design

Details of parts were provided for 21 (91%) of the 23 MR RMVs. Standard existing parts were used for this design including resuscitator bag or self-inflating bag, endotracheal tube (ETT), O_2 connection and tubing, reservoir bag, O_2 reservoir socket and exhalation port. Valves related to the bag included air-inlet one-way, expiratory, PEEP, pressure release and pop-off. Other valves used for this design included a 3-way solenoid, patient, safety inlet, check, Y-valve, failsafe, duck-bill, one-way, double-way, pressure limiting, relief and electromagnetic control. Sensors used in the MR RMVs included feedback pressure and flow. Adaptors used in this design include a relief adaptor, PEEP adaptor and mass air flow (MAF) sensor adaptor.

A motor, motor controller/motor driver, microcontroller and microchip were used in all these designs to automate the manual compression process in the MR RMVs. The mechanisms and/or corresponding parts for this automated compression included pivoting cam arm, strap, crank-slider mechanism, scotch yoke mechanism and drawers' gliders, lever controlled by a linear actuator, pinion gear, angled grippers and novel torque conversion mechanism via a simple pulley and lanyard system.

The filters reported in this design were similar to the E-P design including HEPA filter, DrägerSafe™ Star filter, HME filter, filter composed of FFP3 micro texture and UV sterilizing light emitting diode (LED).

Other parts used in this design include an “on/off” switch, handle, latch, LCD display, flow meter, parameter knobs, pressure sensing lines for the MR and patient, photo interrupter switch and spirometer. A box chamber or chassis to house the MR including the necessary bolts, nuts, screws, washers and spacers was used to hold and support the structure during operation in 5 (24%) RMVs.

Parts - Dual E-P and Automatic Compression of MR

Parts for both the dual MR and E-P design was those common to both designs. Standard MR bag parts included an MR bag, ETTs, corrugated inspiration circuit tubing, PEEP valve, spirometry kit, pressure release valve and HME filter. In order to operate the E-P components, compressed gas sources were required. Other parts included printed circuit board (PCB), motor, motor driver, CTS-frequency controls (a device which regulates the frequency of an alternating current (AC)), general purpose digital isolator, position card connector microSD, isolated module DC convertor and a WiFi transceiver module.

Parts - “Other” RMV Design

In nine (75%) of the 12 “other” designs, similar parts were used. Valves such as electro-valves, airflow needle, PIP safety, inspiration, overpressure, spontaneous inhalation, solenoid, one-way, PEEP and pressure relief were used in these designs. Sensors for oxygen, pressure (manometer/pressure gauge) and flow were also used.

Some structural parts reported include support box, bendable wire and cables and connectors. The electronic parts reported for this design include data acquisition and control system, timing circuit for electro-valves and alarms, electronics boards and modules, electric air pump, computer and pressurized air interface. Some RMVs used a standard patient breathing circuit including the hose and tubing, filters for laminar flow and air, a motor, buzzer, battery pack and pressure regulator.

Parts unique to the “other” RMV category included origami-inspired air-tight bellows, spool, water columns, turbine, fishing wire, soccer ball, centrifugal fans, plastic air tank, piston and wooden or plastic circles (fixed or mobile discs).

Table 10. List of parts used to make RMVs.

Parts	RMV Design				TOTAL
	E-P (n = 16)	Automatic Compression of MR (n = 21)	E-P + MR (n = 4)	Other (n = 12)	n = 53
Filters[1]	3 (19%)	6 (29%)	2 (50%)	3 (25%)	14 (26%)
Motor	1 (6%)	21 (100%)	1 (25%)	6 (50%)	29 (55%)
Control System	11 (69%)	16 (76%)	3 (75%)	7 (58%)	37 (70%)
Oxygen Sensor	8 (50%)	0	2 (50%)	2 (17%)	12 (23%)
Pressure Sensor[2]	12 (75%)	18 (86%)	2 (50%)	7 (58%)	39 (74%)
***Other* Sensors[3]**	6 (38%)	4 (19%)	0	1 (8%)	11 (21%)
PEEP Valve	3 (19%)	8 (38%)	2 (50%)	2 (17%)	15 (28%)
Solenoid Valve	6 (38%)	1 (5%)	1 (25%)	1 (8%)	9 (17%)
Relief Valves	3 (19%)	2 (10%)	0	2 (17%)	7 (13%)
***Other* Valves [4]**	7 (44%)	7 (33%)	1 (25%)	4 (33%)	19 (36%)
Back-Up Battery	4 (25%)	6 (29%)	0	1 (8%)	11 (21%)
Humidifiers	1 (6%)	2 (10%)	0	0	3 (6%)
Airway Tubing	6 (38%)	5 (24%)	2 (50%)	2 (17%)	15 (28%)
Screen Display/GUI	6 (38%)	5 (24%)	2 (50%)	2 (17%)	12 (23%)

Resuscitator Bag	0	21 (100%)	4 (100%)	0	25 (47%)
Compressed Gas	16 (100%)	17 (81%)	4 (100%)	5 (42%)	42 (79%)
Nuts/bolts/ washers/screws	0	4 (19%)	0	0	4 (8%)
Frame/Chassis /Housing	0	5 (24%)	1 (25%)	2 (17%)	8 (15%)
Not Reported	2 (13%)	2 (10%)	0	3 (25%)	7 (13%)

[1]Filters include bacterial/viral, HME, HEPA; [2] Includes pressure sensors such as differential, gauge, compound, inspiratory pressure, airway pressure, feedback pressure; [3]Includes other sensors such as temperature, flow, spirometer-based expiratory volume; [4]Includes other valves such as inspiratory, expiratory, proportional, pressure regulating, flow regulating one-way, 3-way, exhale actuation, exhale diaphragm, main control, piezo-electric, pinch, pressure limiting, non-return

Motor

Of the 53 RMVs, 29 (55%) included a motor in their design, 21 (72%) being the automatic compression of MR design. The most common motor used was a stepper motor, 10 (34%) of the 29 RMVs. Direct Current (DC) geared motors were the second most common motor used in eight of the 29 (28%) RMVs. Three (10%) used a motor for their design but no details of brand or type was provided. The remaining eight (28%) motors included solarbiotics motor driver, windshield wiper motor, cardone electric motor, motor driver VHN3SP30, impeller electric motor, AndyMark- 2235a Snow Blower Motor, servomotor, and 7040 DC 12V centrifugal turbo turbine (which is not a motor but served in a similar function).

Control System

Thirty-seven (70%) of the 53 RMVs had a control system (the remaining 16 (30%) had no details provided). A control system is a broad term and used interchangeably with

microcontroller, microprocessor, microcomputer, microchip or programmable logic controller (Golnaraghi & Kuo, 2017). The Arduino microcontroller was the most common across all designs: 26 (70%) RMVs had an Uno, Due, Nano or Mega 2560 type. The Teensy microcontroller was used in two (5%) RMVs. Eight (22%) RMVs used more than one control system, with 5 (14%) using the microprocessor Raspberry Pi. Two (5%) RMVs included a microchip (ATMEGA48PB-AUR) as an additional control system and one (3%) a programmable logic controller (Barth STG600). Five (14%) RMVs had a microcontroller within their design but no provide were details, and four (11%) were described as “other”.

Control System - E-P Design

Of the eleven E-P RMVs, six (55%) control systems were Arduino and two included more than one (ESP32 Microchip, Raspberry Pi). Two (18%) used Teensy control system and one included a second control system (Programmable logic controller Barth STG600). A control system was mentioned in three E-P RMVs but no details were provided of brand or type.

Control System - Automatic Compression of MR Design

Seventeen MR RMVs included a control system with the majority being Arduino (14, 82%). Raspberry Pi was included in 3 (18%) MR RMVs and two were paired with Arduino as a second controller.

Control System - Dual E-P and MR Design

Two (100%) Arduino microcontrollers were reported for the two dual E-P and MR design.

Control System - “Other” Design

The seven “other” RMV designs control systems were mostly Arduino (6, 86%) and one was paired with a second control system, Raspberry Pi. A microchip PIC24FJ64GB004 was the control system for Marzetti et al. (2021).

4.2.4.b Software and Interface

This subsection discusses characteristics of the RMVs software and interface, specifically the architecture/components, programming language and development process.

Architecture/Components

Software architecture/components were discussed in 17 (32%) of the 53 RMVs and not reported or unclear in 36 (68%). Software architecture was generally divided into 3 main components: GUI, control system and supervisor. DeBoer et al. (2021) reported the software was further separated into an eight-step process discussing the opening/closing of specific valves during operation and measuring pressure. Other RMVs did not provide as much detail. Software modules reported by Dally (2021) included alarms, real-time control (RTC) (interrupted every 2 milliseconds), flow, sensor, sensor drivers, peripheral drivers. Software self-checks were present in the architecture. Closed-loop negative feedback, open-loop negative feedback and proportional integral derivative (feedforward) were reported as control algorithms for the RMVs. The RMV by Von Chong et al. (2022) reported their human-machine interface (HMI) mimicked a traditional mechanical ventilator for ease-of-use and minimal training. One unique feature presented by Gruslova et al. (2021) in the automated MR RMV design was the ability of the MR to sense patient inspiratory effort below a software-calculated pressure threshold and trigger a breath. The RMV by Christou et al., (2020) reported the use of tablets/phones for its software

resource. Park et al's (2022) RMV mentioned all components were consolidated and manipulated by the content management system (CMS). Grimshandl et al's (2020) RMV used state machine architecture to control ventilation cycles and provide displays on the user interface. With respect to interfaces, the MR RMV by Meiry et al. (2022) had a detailed description and included potentiometers (knobs) to control specific ventilation parameters, buttons for on/off, testing/calibration and alarms, a small LCD screen to display the GUI and LED indicators to display the RMV's state and visual cues for alarms.

Programming Language

Eleven (21%) of the 53 RMVs used and described a programming language with the most common being "C" (or an extension of "C" such as C++ or C#) in 5 (50%) of the RMVs. Python was used in four (40%) RMVs, Java in one (10%) RMV and "Arduino programming language" (Dhanani et al., 2020) in one (10%) RMV.

Programming language was included in four E-P RMVs ("C++" "C#", "C" and "python"), three MR RMVs ("Arduino programming language", "C++" and "python"), and four "other" RMVs ("python" x2, "Java" and "C#").

Development Plan/Process

It was important that the software development for RMVs was planned to achieve a low probability of failure and have the ability to reliably ventilate. The development plan/process were made up of the software and interface, including the programming language and architecture/components. Abba et al. (2021) were the only authors for their E-P RMV providing details on a development plan and process. This "V-model" was designed by the authors and complied with organizations such as the IEC and ISO (see

Figure 12). The V-model was a process where each development task on one side of the V corresponded to a testing task on the right, Figure 12 (Abba et al., 2021).

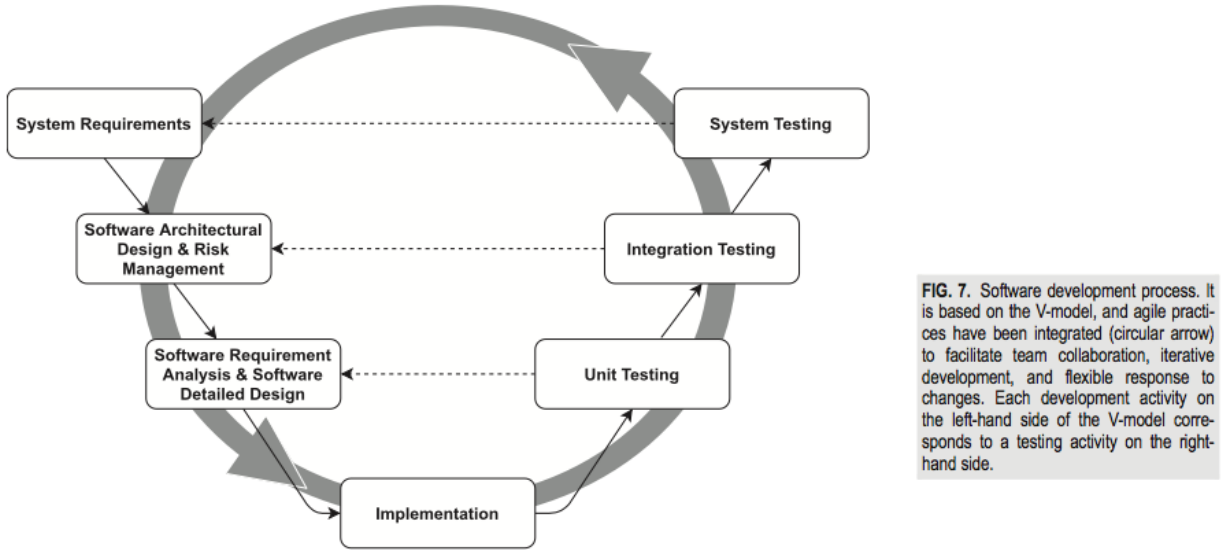


Figure 12. Abba et al. (2021) V-model software developmental process.

4.2.4.c Hardware and Software Documents

In the hardware and software documents the following were included: (1) fully annotated circuit diagrams, wiring diagrams and design source/production files, (2) hardware/software design documents, (3) software verification/validation plans and reports, (4) software risk management plan and report, (5) software release note, (6) firmware and software (including code), (7) bill of materials, (8) instructions to build and (9) regulatory standards used.

Of the 53 RMVs, 37 (70%) included fully annotated circuit and wiring diagrams and design source/production files, 16 (30%) included hardware/software designs documents, four (8%) included software verification/validation plans and reports and 12 (23%) reported firm and software including the code. None of the RMVs included a software risk

management plan and report or a software release note. A bill of materials breaking down the cost to build the machine was included in 9 (17%) of the 53 RMVs with 35 (66%) not providing any descriptions. Instructions to build and operate the machine were included in eight (15%) of the 53 RMVs. Seven (13%) RMVs reported the document was not included and 38 (72%) did not report any details.

4.3 RMV and Standard Guidelines

Regulatory standards were referenced in 19 (36%) of the 53 RMVs and six of the 19 referenced more than one. Ten (53%) referenced the Medicines & Healthcare Products Regulatory Agency (MHRA) outlining specifications for rapidly manufactured ventilator systems (RMVS), eight (42%) referenced the International Organization for Standardization (ISO), three (16%) referenced the Food and Drug Administration (FDA), two (11%) referenced the American Association for Respiratory Care (AARC) and one (5%) referenced the International Electrotechnical Commission. The E-P RMV by Chaing et al. (2021) was fully validated under Chilean special regulations by CMFCC regarding emergency mechanical ventilators for the Covid-19 pandemic. The MR RMV by Al Husseini et al. (2010) referenced the American Society for Testing Materials (ASTM F920-93) standard requirements. All 12 RMVs that did not have an E-P or MR design (“other” design) did not reference any regulatory standards. Details of each RMV and recommended standards can be found in Appendix D.

For the AARC guide (Branson et al., 2020), the most common item met was *measurements/monitoring* with 30 (57%) meeting the criteria, 23 (43%) not, and 0 (0%) partially. The second most common item was *including TV* with 15 (28%) meeting the criteria, 29 (55%) not, and 9 (17%) partially. An example of a RMV that met a partial

recommendation was an RMV providing a TV of 150 – 600 mL, compared to the recommended 250-750 ml. The ventilators that met the most recommendations (5 (50%) out of the 10 AARC items) were the VEMERS (Chiang et al., 2021), ALIVE Vent (Park et al., 2021), ATENA (Rebelo et al., 2021) and Masi (Chang et al., 2021).

For the MHRA guide (MHRA, 2020), the most common item met was *modes of ventilation* with 41 (77%) meeting the criteria, 11 (21%) not, and 1 (2%) partially (e.g., providing the ventilation mode PC-IMV but CMV mode was recommended). The second most common item met was *including TV* with 21 (40%) meeting the criteria, 29 (55%) not, and 3 (6%) partially (e.g., RMV providing a TV of 350 – 7000 mL, but 250-600 ml was recommended). The ventilator that met the most recommendations (9 (29%) out of the 31 MHRA items) was the HEV (Buyaert et al., 2020).

For the MCAtCP guide (Hakimi et al., 2022), the most common item met was *including RR* with 20 (38%) meeting the criteria, 28 (53%) not, and 5 (9%) partially (e.g., providing a RR of 0 – 25 bpm, but 10 – 30 bpm was recommended). The second most common item met was *control of settings* with 16 (30%) meeting the criteria, 7 (13%) not, and 30 (57%) partially (e.g., controlling the settings of RR, PEEP, FiO2, PIP, and FiO2 but TV, RR, I:E and overpressure was recommended). The ventilators that met the most recommendations (4 (57%) out of the 7 MCAtCP items) were the HEV (Buyaert et al., 2020) and Portsmouth Ventilator (Cole et al., 2020).

For the CHEST guide (Einav et al., 2014), the most common item met *was operation without 50-55 PSI* with 28 (53%) meeting the criteria, 17 (32%) not, and 8 (15%) partially (e.g., stated “compressed air and oxygen required” but did not specify if the requirement was low or high flow). The second most common item met was *oxygen*

titration with 11 (21%) meeting the criteria, 39 (74%) not, and 3 (6%) partially (e.g., providing an FiO_2 of 0.21-0.95 with 50-55 PSI gas, but an FiO_2 of 1.00 was recommended). The ventilators that met the most recommendations (5 (20%) out of the 25 CHEST items) were the HEV (Buyaert et al., 2020), VEMERS UC (Chiang et al., 2021) and ALIVE Vent (Park et al., 2021).

For the CIEHF guide (CIEHF, 2020), the most common item that was met was alarms with 31 (58%) meeting the criteria, 16 (30%) not, and 6 (11%) partially (e.g., mentioning alarms but providing no details, when the recommendation was defining critical situations that trigger audible alarms). The second most common item that was met was *humidifiers* with 7 (13%) meeting the criteria, 46 (87%) not, and 0 (0%) partially. The ventilator that met the most recommendations (3 (43%) out of the 7 CIEHF items) was the Mechanical Ventilator Milano (Abba et al., 2021).

For the article *A Review of Open-Source Ventilators for COVID-19 and Future Pandemics* guide (Pearce, 2020) the most common item met was *files and diagrams* with 37 (70%) meeting the criteria, 16 (30%) not, and 0 (0%) partially. The second most common item met was *"other" documentation* with 10 (19%) meeting the criteria, 43 (81%) not, and 0 (0%) partially. The ventilators that met the most recommendations (3 (100%) out of the 3 Pearce items) were the VEMERS UC (Chiang et al., 2021), ProtoVent (Kindomba et al., 2021), RepRapable (Petsiuk et al., 2020), Masi (Chang et al., 2021) and the ventilator by Deboer et al. (2021).

CHAPTER 5: DISCUSSION AND RECOMMENDATIONS

5.1 Summary

The purpose of this scoping review was to investigate the clinical and engineering characteristics of rapidly manufactured ventilators (RMVs) and to provide suggestions for essential design features of this medical device. Recommendation guidelines for mandatory features for RMVs from several sources were also analyzed. Building off of the descriptive narrative summary and numerical analysis of the RMVs presented in Chapter 4, Objectives One and Two are further discussed in detail, including implications of the findings. The strengths and limitations of this study are also discussed, as well as identified gaps in the literature and recommendations for future research.

Fifty-two studies of varying design and methodologies were included in this scoping review, however, 53 RMVs were analyzed because two articles discussed the same RMV, and one articled described two different RMV designs. Most of the studies originated in the United States and were published during or after the Sar-CoV-2 (Covid-19) global pandemic in 2020. Four common RMV designs were identified – electro-pneumatic (EP), automatic compression of MR, a combination of automatic compression of MR with E-P system, and “other”. The broad RMV characteristics included operating and performance features, other features outside routine use, and engineering features.

The *operating features* included the oxygen/gas source, power supply, mode, user-input controls/monitoring, ventilator modes, alarms and seven ventilation parameters: TV, PEEP, FiO2, RR, I:E ratio, PIP and flowrate. All RMVs not capable of independently taking in room air (e.g., some of the MR designs) required low flow or high flow compressed medical air and/or oxygen. Low flow compressed air sources included

compressors, concentrators, turbines, etc. High pressure gas sources were the standard medical gas sources used in hospitals operating at 50 PSI. An external electrical power supply was required for all RMVs except for those powered by compressed gas. The top three control and monitor ventilator parameters across all designs included RR, PEEP and I:E ratio. The top three ventilator modes offered across all RMV designs included VCV, PCV and PSV. Audible alarms were included in all the RMV designs that reported alarms while almost half included both audible and visual. TV ranged from 0 mL to 2000 mL, PEEP 0 cm H_20 to 60 cm H_20, FiO2 0.21 to 1.00, RR 0 bpm to 60 bpm, I:E ratio 1:1 to >1:5, PIP 0 cm H_2O to 70 cm H_2O and flowrate 0 L/min to 140 L/min.

The *performance features* included ventilator testing and sustained use, end-user training/testing, process to set-up/assemble (user-friendliness), and oxygen consumption. Of the RMVs that tested their device a lung simulator or mannequin was the most common followed by animal testing. Human testing was completed in one RMV with five participants. Tested duration lasted from as little as 1 day or less to >2 weeks. Of the RMVs that reported end-user-training/testing, a program or set of tests was included, such as setting up operating features, alarm thresholds, and completing hardware and software tests to ensure the end-user was knowledgeable, confident and ready to operate the machine. Training manuals or step-by-step guides were provided with some of the RMVs while others simply stated how easy or user-friendly the machine was to set-up and use. Oxygen consumption ranged from 1.2L/min to 4L/min which was well below the upper bound of 6L/min recommended by the MHRA (MHRA, 2020).

The *other features* outside of routine use included general durability, recalls/vendor & support contract/maintenance, cost, additional approvals/clearances, labelling, infection

control and ventilator kit description/ environment of use. Various durability tests were conducted to test the RMVs ability to withstand continued functioning overtime. Overall durability testing duration of the RMV ranged from 48 hours to 3 months. Durability testing of the bag used in the automatic compression of a MR RMV design ranged from 7 days to 45 days. Durability testing of electric motors was conducted for an average 30 days. Other testing included autoclave and drop testing, utilizing the RMV in an ambulance setting, and checking the sturdiness of connections. No recalls, maintenance or vendor and support contracts were included with the RMVs. The cost of RMVs (2023) ranged from $22USD to $2,653USD and the mean across all designs was $720USD. Three RMVs received FDA approval, one was fully validated under the CMFCC special validation protocol, one after received approval from a Peruvian regulatory authority called DIGEMID and one passed electromagnetic compatibility and electrical safety tests. Labels such as “follow instructions for use”, “device restricted for use during Covid-19 pandemic, emergency ventilation use only” and “manual back-up ventilation must be available” were included on the devices to help inform HCPs. For infection control, HEPA, HME and bacterial filters were incorporated into the RMV designs to avoid contamination to the patient and/or HCPs. Instructions to replace or disinfect/sterilize items that comes into contact with the patient were also provided as part of infection control. The average RMV weight was 10.7 kg while the average length was 35 cm, width 31 cm and height 55 cm.

The *engineering features* were divided into three subsections: hardware, software/interface and hardware and software documents. Within the hardware section physical components such as an oxygen sensor, pressure sensor, materials, parts, motor and control system were discussed. A pressure sensor was the most common sensor

incorporated into the RMV designs, oxygen sensor was second and all other sensors such as temperature, flow, spirometer-based expiratory volume were third. The top three materials used across all designs include stainless steel, polyactic acid (PLA) and polyamide. Other common parts included compressed gas, control system and a motor. Another important part of RMVs were the valves with the top three being PEEP valves, solenoid valves and relief valves. The most common motor reported was a stepper motor followed by a DC geared motor. The Arduino microcontroller was the most common control system with specific types including Uno, Due, Nano and Mega 2560. The specific software/interface characteristics included the architecture/components, programming language and development process. Software architecture was generally divided up into three main components: GUI, controller and supervisor. The most common programming language was “C” or an extension of “C” such as C++ or C#, followed by Python. A software development plan/process was only reported in one article which was unique as the authors designed it themselves. Within the hardware and software documents section fully annotated circuit and wiring diagrams was the most common document provided, while a software release note and risk management plan and report were not included in any. Regulatory standards reported included those from the following: MHRA, ISO, FDA, IEC, AARC, CMFCC and ASTM (Medicines and Healthcare Regulatory Agency, 2020: International Organization for Standardization, n.d.: U.S. Food and Drug Administration, 2019; International Electrotechnical Commission, n.d.; Branson et al. 2020; ASTM International, n.d.; Sochimi & Sach, 2020).

5.2 Objective 1: Characteristics of the RMVs

The RMVs identified in this scoping review possessed a variety of operating and performance features and engineering components. The number and type usually depended on the design of the RMV, which included three major types, and another category (i.e., “other category”) that included completely unique designs. The four RMV designs are discussed here in detail presenting advantages and disadvantages of each including a discussion on how and to what extent the RMVs were tested.

5.2.1. Electro-Pneumatic

Sixteen (30%) RMVs were of the electro-pneumatic (E-P). These were similar to mechanical ventilators found in intensive care units (ICUs), which are a combination of electrical and pneumatic (e.g., compressed gas) components (Rajendran & Nanda, 2009). These designs usually included a control system, sensors (e.g., pressure, oxygen, and other), valves (e.g., PEEP, solenoid, relief and other), a back-up battery, airway tubing, screen display/GUI and compressed gas. Two important parts that were lacking (or not reported) from the E-P designs were humidifiers and filters which are essential for safe and sterile delivery of mechanical ventilation treatment. Without filters there is increased risk of pathogens not only infecting patients but HCPs as well, which is extremely important during respiratory virus outbreaks such as Covid-19. The top material used for E-P RMVs included stainless steel mainly as an enclosure to house the electrical and pneumatic components. Stainless steel is a durable and strong material that is highly resistant to impact or damage, which is suitable for a medical device that is transported or relocated several times (Baddoo, 2008). Stainless steel is also an affordable material which helps keep RMVs at a low cost and may be accessible for LMICs (Baddoo, 2008).

Brass was the second most common material used for the construction of E-P RMVs. Brass is more malleable than most other materials, is more resistant to corrosion than materials such as steel, has high tensile strength and is ideal for intricate and low-friction parts (Schultheiss et al., 2017). Other materials used for E-P designs include PVC, various types of plastic, aluminum, polyamide and copper. PVC, various types of plastic and aluminum are lightweight materials which would help reduce overall weight of the RMV. Polyamide, aluminum and various types of plastic are durable but PVC is not (Titow, 2012; Mondolfo, 2013; Manas et al., 2008; Zhang et al., 2020). PVC is low-cost while aluminum is relatively expensive (Titow, 2012; Mondolfo, 2013). Various types of plastic are corrosion-resistant and can be molded in different shapes. PVC is easy to install and has good electrical insulation properties and aluminum is also corrosion-resistant and has good electrical conductivity (Mondolfo, 2013; Manas et al., 2008; Zhang et al., 2020).

The control and feedback loops included in E-P RMVs allowed for numerous respiratory parameters and ventilation modes to be set. The E-P design was the only RMV type able to provide pressure, volume, and dual modes of ventilation, including more options for mandatory with spontaneous modes. This made the E-P design advantageous because they may be able to support a wider range of respiratory conditions and facilitate ventilator weaning. The E-P RMVs were also able to control and monitor for more ventilatory parameters, providing statuses on the GUI. Additionally, if ventilation parameters fell out of range, the GUI was equipped with an alarm system. This may provide HCPs greater ability to wean, and/or to respond to patient situations when values get out of range (including dangerous ones). Although all the RMV designs had alarms,

the E-P RMVs were advantageous, compared to others, because of the GUI. The GUI embedded in the E-P designs was similar to those found on ICU ventilators which displays monitored parameters and waveforms such as tidal volume, airway pressure, and air flow. In addition, the GUI provided a way to visualize the steps and progress for start-up procedures such as setting operating parameters and alarm thresholds, and performance tests for the hardware and software components. These technological abilities make this design superior as the RMV could operate more independently and may be better at alerting the HCP if there is an issue with the patient. A disadvantage to the GUI was the cost, which contributed significantly to the higher cost for E-P RMV manufacturing.

All of the E-P designs were dependent on compressed gas sources for operation usually at 50 PSI. This can be a disadvantage if compressed gas sources are not available or are occupied in the clinical setting. This is especially true in the context of a pandemic or mass-casualty event where supply chains may be disrupted or in LMIC where these sources may not be available (LaBelle & Santacreu, 2022; Hopman et al., 2020). In addition, most of these designs required electricity. Some of the E-P designs were fully powered by 50 PSI gas sources and did not require an electrical hook-up; therefore, when compressed gas is available the E-P design may be advantageous if electricity is not available.

A programming language was required for the E-P designs for the software, hardware and GUI to communicate and function. The most common programming languages were “C” (including its extensions) and Python. Each programming language possesses unique features, advantages and disadvantages, and computing requirements (e.g., memory) (Pierce, 2002). For example, Python is easier to learn, write and read

because it requires fewer “keywords” and has more English language syntax, while C’s syntax is more complex (Pedamkar, 2023). However, execution of the C code is faster because it can be converted directly into the “machine language”, whereas Python requires an extra “step” via an interpreter before being converted; processing speed for C is faster and requires less computing power compared to Python (Pedamkar, 2023). In addition, more advanced programming (regardless of type) requires more enhanced hardware to match.

The parts used in E-P designs used either 3-D printing or “off-the-shelf” components such as those found in hardware stores in developed regions like North America. Two types of 3-D printing included fuse deposition modelling (FDM) and Selective Laser Sintering (SLS), with FDM being more cost-effective but not as accurate as SLS (Choudhari & Patil, 2016). The E-P designs that used “off-the-shelf” components may be advantageous because parts found at retail stores are usually produced according to quality standards. The disadvantages are these components may be disrupted by supply chain issues or have higher costs over time. For example, in 2022 there was a shortage of tracheostomy tubes which impacted the care delivered to pediatric patients (Center for Devices and Radiological Health, 2022).

5.2.2. Automatic Compression of Manual Resuscitator

The *Automatic Compression of Manual Resuscitator* (MR) was an RMV design (21, 40%) that utilized a resuscitator bag, replacing manual operation with an electronically controlled mechanical actuator that repeatedly compressed the bag to provide ventilation. These designs usually included an enclosure or frame to house the resuscitator bag, a motor, filters (e.g., HME, HEPA and bacterial/viral), control system, sensors (e.g.,

pressure and other), valves (e.g., PEEP, solenoid, relief, and other), back-up battery, airway tubing and miscellaneous equipment to hold the structure together (e.g., nuts, bolts, washers, screws). Compressed gas was also widely used to facilitate more efficient ventilation, however, due to the resuscitators bag natural ability to self-inflate and take in room air, compressed air was not always necessary. Parts that were not common with this RMV design, possibly due to lack of reporting, included an oxygen sensor, solenoid valve, and humidifier.

Various mechanisms were used to automatically compress the resuscitator bag with the top three being: a sliding mechanism using a moveable plate or piston to compress the bag against a fixed plate, angle grippers which both move inwards to compress the bag and an actuator and rotating arm. The majority of the mechanisms used to compress the resuscitator bag utilized a motor that performed a rotational motion as this allowed for steady and consistent compressions of the bag that gradually forced air out.

Materials that were common with this design included polyactic acid (PLA) which in comparison to ABS (another common material used for construction of RMVs) is easier to print, cost-effective and has a higher stiffness (Rodriquez-Panes et al., 2018). Although PLA is stronger than ABS, PLA does not handle high temperatures (i.e., is not heat-resistant) or respond well to significant stress (Rodriquez-Panes et al., 2018). ABS has superior mechanical properties (it is tough and resistant) to PLA as well as the material is light, more durable, and can deflect heat better (Rodriquez-Panes et al., 2018). However, higher temperatures are required for effective printing with ABS (Rodriquez-Panes et al., 2018). Other materials included aluminum, polyamide, acrylic, polyglass, steel,

polypropylene, plywood, sheet metal, birch hardwood, polycarbonate, polyoxymethylene (acetal). Three-dimensional printing was also used for the construction of MR RMV designs and possess the same advantages and disadvantages presented above with the E-P design.

Unlike the E-P design, the automatic compression of MR design lacked a built-in LCD screen/display (GUI). Instead this design required a hook-up to an external screen such as a computer, tablet, smartphone or standard monitor. This reduced manufacturing costs with an average of $601 USD compared to $871 USD for the E-P RMVs. While the exclusion of an LCD screen may be cost effective, this could be a limitation if an external screen is not accessible. Similar to the E-P design, the MR design also utilized FDA approved airway tubing and typical connections from machine to patient.

The design simplicity, ease of use, low-cost, and rapid scalability were all useful features of this RMV design. One major advantage of the MR approach to ventilation was some of the designs were not dependent on compressed gas for operation. In addition, the resuscitator bags were already widely used in clinical practice. One disadvantage of these MR designs was the number of available ventilator modes, mainly volume-type (n = 11, 52%) as controlling peak pressure was more challenging. Of the RMVs that were able to do this, (n = 5, 24%) an in-line pressure sensor was included to continually monitor pressure within the system and provide information to the control system through feedback loops. In addition, these “bag squeezer” RMVs required many moving parts for the automatic compression, that may increase the likelihood of wear and tear over time. Several articles included in this review not only tested the overall performance of their RMV but also tested the durability of the motor and resuscitator bag by completing

millions of compressions. Resuscitator bags are typically used for short-term ventilation in between procedures, while being transported from one location to another or, in case automatic mechanical ventilation fails (Hussy et al., 2004). It is likely that during a pandemic or mass casualty event, the duration of mechanical ventilation would be long, potentially requiring millions of compression cycles over time. Although two MR RMVs successfully tested the durability of the resuscitator bags for >7 days (Gruslova et al., 2021) and for > 1 million compressions (Urbina et al., 2021), it is unknown if repeated use would provide the same results. Gruslova et al. (2021) also successfully tested their Cadone electric motor continuously for >30 days. The durability tests completed with the MR designs was superior to that of the E-P designs due to the ability to perform tests on focused components within the machine such as the bag and motor.

The MR design did not possess a GUI, which may be a limitation for detection of ventilation parameters that become out of range. Due to this, increased supervision and monitoring may be required from HCPs which may be challenging in a mass-casualty event or LMIC.

The MR RMV designs were able to monitor and control tidal volume. To produce the volume, the MR bag required compression using a cam mechanism, mechanical arms and linkages with servo motors. While this design approach using robotic mechanisms appeared to be less costly and easy to implement, the inability to accurately control inspiratory pressure was a major limitation. Controlling and monitoring for pressure would allow for more ventilator mode options to be offered which may be more effective in patients with respiratory pathologies where compliance and resistance are abnormal such as in Covid-19.

5.2.3. Dual Electro-Pneumatic and Automatic Compression of Manual Resuscitator

The dual E-P and automatic compression of manual resuscitator designs shares many commonalities with the previous two designs (Section 5.2.1 and 5.2.2). What sets this design apart was the requirement for compressed gas, electricity and the inclusion of a GUI. However, this design was costlier than the MR design due to its additional features, and inclusion of more electronic components. With the inclusion of electronic components, the complexity and feedback within this design provides superior ventilation to those lacking electronic components and is likely the safest for patients. This design provided a combination of pressure and volume modes and used similar materials and parts to the two designs discussed above.

5.2.4. "Other"

The RMV designs that did not fall into the prior three categories possessed unique characteristics and the overall intent appeared to be more *concept* based rather than for actual use. Of all four RMV designs presented in this review, this design lacked referencing any of the six "standard" guideline documents (Branson et al. 2020; CIEHF, 2021; Einav et al., 2014; Hakimi et al., 2022; MHRA, 2020; Pearce, 2022). Thus, minimal information was available on these RMVs because the data of interest were not reported.

Some of the unique designs categorized as "other" included: bellows, centrifugal impellers, cylinder-shaped columns, and water-based columns. The unique materials used for this design included plastic, PET, PLA, PVC, nitrile exam glove material, silicon sheet, wood and soccer balls. Since the overall end-goal of ventilating and providing oxygen to the patient was the same across all designs, the parts used here were similar to

those of the previous three designs. This included filters, motors, control system, sensors, valves, airway tubing and compressed gas.

The testing completed for the RMVs within this category was lacking (compared to the other three designs). The majority of the testing for this category did not surpass 1 hour. The RMV by Aihaitijiang et al. (2021) only tested their device with a balloon. The SAVeI RMV by Dickson et al. (2020) did receive FDA approval but did not conduct testing beyond 1 hour in animal (12 pigs) subjects

5.2.5. Testing the Performance of RMVs

All medical devices are required to undergo extensive testing to assess their performance and to measure overall quality and risks (Van Norman, 2016). Since RMVs are a new therapeutic device prompted mainly by the Covid-19 pandemic, little is known about their interaction with humans because most of the included studies did not conduct human trials. This scoping review brought up some potential concerns regarding the use of these low-cost, rapidly manufactured machines because of the lack of testing and overall guidance for the design process. Testing the performance of the RMVs generally occurred in steps. First, the majority were tested using a lung simulator. A lung simulator is a device used in respiratory care that mimics the complex functioning of healthy and diseased state human lungs for mechanical ventilation testing (Pasteka, 2019). Using a lung simulator is an easy and convenient way to test the performance of RMVs as simulators can mimic lungs of different ages, and different levels of compliance and resistance (Heili-Frades et al., 2007). Additionally, ethical approval by a research ethics board is generally not required in contrast to animal or human trials. Testing results from a lung simulator may provide preliminary information on the basic functions of the RMVs.

However, overall performance and how the device will interact with humans requires human trials to ensure patient safety in the clinical setting (International Organization for Standardization, 2020). Disadvantages to testing RMVs with a lung simulator is they are not capable of producing sudden or multiple pulmonary changes that may occur in critical care scenarios (Marchese et al., 2009), and the more state-of-the-art machines can cost up to tens of thousands of dollars (Robert et al., 2015). In our included studies, some authors conducted animal trials after successful trials with a lung simulator. While animal testing addresses some of the limitations of a lung simulator, this research can be costly and require approval by an Animal Care Committee (Lang, 2009; Canada N. R. C, 2022). If possible, Efinal performance and functionality should again be done on humans. Only one study by Chiang et al. (2021) conducted a human trial for eight hours with five participants. Human testing of any medical device is a basic requirement (International Organization for Standardization, 2020), however the time, resources and ethical requirements to conduct human clinical trials may be a limiting factor given the high demand for RMVs at the time of production (Sathian et al., 2020). Some studies did not conduct durability testing due to time constraints while some only did for a few hours or a couple months. In clinical practice, patients may require mechanical ventilation treatment for a couple of hours, a couple of weeks or even months depending on the severity of their condition. Lastly, it is important to consider how the machines operate in different settings in which they may be used and how HCPs interact with them (i.e., human factors/ergonomics) (Vincent et al., 2014). Most studies did not operate their RMV in different environments (e.g., clinical settings, climate, transportation) to determine if performance was consistent. Many also did not conduct tests on how the end-user (i.e.,

the HCPs) might interact with the machine. Modern mechanical ventilators used in the ICU follow a strict set of standards by the ISO which is updated as the machines become more advanced overtime (International Organization for Standardization, 2016). At the time of writing this review, there were no standards or testing procedures for RMVs. This created a lot of variability in how the devices were manufactured and tested making it hard to determine which RMV would be best for clinical practice. Having standard RMV recommendations for manufacturing and clinical could help address this issue.

5.3 Implications of Objective 1 and the Impact on Objective 2

The original intent of this scoping review was to describe what was known about RMVs with respect to their design, components, and performance (Section 5.1). This information will serve as a useful tool for HCPs and engineering teams if the need arises to create their own RMVs. As the scoping review progressed, we determined a second implication worth noting. It became clear that established standards like those published by the ISO did not exist for RMVs. In addition, very few (n = 3, 6%) received local approval, such as the USA Food and Drug Administration or Health Canada, for clinical use. Standards on medical devices are necessary to ensure high quality and consistency of performance to protect the safety and well-being of humans when receiving treatment (International Organization for Standardization, 2020). Instead, several professional organizations published recommendations and guidance documents for RMVs which like the designs, had a lot of variability (Section 2.3.1). Since ISO standards take nearly three years to develop and be approved (ISO, n.d.), steps towards developing standards for RMV safe and effective use should begin immediately. This scoping review provides the initial information for this standardization process, by describing the extent each RMV

design met the *recommended* requirements (and have the potential to reach the clinical setting once further testing is completed). Based on this information, we provide suggestions on the priority items required for all RMV designs (Section 5.4 below).

5.4 Objective 2: Suggested Standards for RMV Designs

This section will provide 11 suggestions that should be considered during the manufacturing process of RMVs: ventilator settings, monitoring capabilities, alarms, back-up power, other safety mechanisms, end-user testing for operation, ventilator testing, GUI, materials and parts, infection control and other. These are based on the findings of this review, and the six guidance recommendations discussed in Section 2.3 (Branson et al. 2020; CIEHF, 2021; Einav et al., 2014; Hakimi et al., 2022; MHRA, 2020; Pearce, 2022). The 11 suggestions provided below were deemed the most important because the 53 RMVs included in this scoping review met most of the criteria within these six guidance documents. They are ordered according to the number (most to least) of criteria met (Appendix D). These 11 suggestions provide novel information for future developers because they include evidence from the diverse six documents, *and* the individual features of the 53 RMVs. Referring to these 11 suggestions in addition to consulting previously published guidance document(s) will likely result in a safe and higher quality RMV.

5.4.1 Ventilator Settings

The ventilator settings should include at minimum the mode of ventilation and the following ventilatory parameters: RR, PIP, TV, FiO2 and I:E. It is suggested ventilation parameters are adjustable and able to provide a wide range to accommodate patients of various ages and sizes, and/or with varying respiratory disease conditions. A RR of 20-35

bpm has been typically provided to Covid-19 patients with an I:E ratio of 1:1 to 1:2 (Price et al., 2020) but some underlying complex pathologies may require RRs upwards to 50 bpm and I:E ratios of 1:4 (Sembroski et al., 2020). Tidal volume is typically set based on the patient's weight (6-8 mL/kg ideal body weight) (Malhotra, 2007) which can guide manufacturers when considering which populations they serve. It is suggested RMVs be able to provide PEEP as this mechanism allows for a positive pressure to remain in the lungs during the entire ventilation process allowing for improved oxygenation at the alveolar level (Branson et al., 2008; Rubinson et al., 2006). Since patients can have a wide range of oxygenation needs, and it is unknown the condition of the patient prior to use, it is suggested RMVs provide a similar FiO_2 as those in the ICU (i.e., 0.21 to 1.00). It is suggested RMVs have the option to provide both volume and pressure ventilation modes and both mandatory and spontaneous breathing. Providing more mode options may allow the RMV to support a wider range of treatment options for various lung diseases and facilitate with the weaning process.

5.4.2 Monitoring Capabilities

The ideal monitoring capabilities of RMVs should function during mechanical ventilation treatment. One of the most important is airway pressure. If the pressure is too high there is risk for barotrauma, or if too low could cause hypoxemia or respiratory acidosis (Vieillard-Baron & Dreyfuss, 2017). It is suggested that for each breath PEEP and PIP are displayed to allow HCPs to monitor and make treatment changes, or when pressures go out of range. It would be ideal to display this on an integrated GUI like those in the E-P designs. If a GUI is not an option, an external hook-up to a computer or tablet is suggested. To help monitor pressure within the system, it is suggested all RMV designs

include an in-line pressure sensor. When a patient is being ventilated, resistance and compliance of their lungs will change during the course of treatment. Therefore, it is suggested the RMV is capable of detecting various ventilatory parameter changes such as TV, RR, PEEP, PIP and can be displayed for the user.

5.4.3 Alarms

Alarms to alert HCPs of parameters out of range or other critical patient situations are essential in the development of RMVs. Specifically, alarms should be triggered when pressure or volume are too high, to prevent barotrauma or volutrauma. Alarms should also be triggered when pressure or volume are too low to avoid under-ventilation due to changes in patient circumstances. Other alarm critical situations suggested are power (gas or electricity) failure, circuit disconnection or blockage, airway system leaks and abrupt changes in compliance or resistance. All alarms regardless of purpose should be both audible and visual. It is also suggested the audible alarms have adjustable volume and visual adjustable brightness to consider the clinical environment e.g., noise, time of day. It is also suggested that the intensity of alarms is paired with how critical the situation is. For example, gas or electricity failure and high airway pressure are high priority critical alarms that should use both visual and loud audible alarms. For RMVs that operates solely on battery, it is suggested that an alarm be present when there is a minimal amount (at least 20%) of battery power remaining. This type of alarm could be considered “low priority” i.e., a flashing LED light, which does not require immediate attention but informs the HCP that attention may be required soon. The inclusion of effective and responsive alarms in RMV systems may facilitate a more efficient clinical environment by alerting HCPs of patient ventilation changes, decreasing the need for constant mechanical

ventilation monitoring. This could help them with shared focus on other vital tasks, which is crucial given the shortage of HCPs combined with the increased number of patients in the context of a mass-casualty or low resource situation.

5.4.4 Back-Up Power

The majority of RMVs presented in this review were dependent on external electricity or compressed gas at 50-55 PSI for operation. To avoid the negative consequences associated with a potential power outage, it is suggested RMVs include a back-up power source that is capable of temporarily continuing mechanical ventilation until alternative power becomes available. It is suggested that the back-up power source minimally impacts the weight or size the RMV. This is an important safety mechanism because in a setting where several RMVs may be used, it is unlikely there will be enough HCPs to provide manual ventilation.

5.4.5 Other Safety Mechanisms

A suggested important safety mechanism, specifically with RMV designs that utilize a motor, is to incorporate a temperature sensor to monitor thermal issues such as the motor overheating. For example, in the automatic compression of MR RMVs the repeated compression motion of the motor may overheat.

5.4.6 End-User Testing for Operation

Prior to using the RMV, it is suggested a knowledge and skills testing procedure exists. This should include a self-test to ensure the end-user knows how to set-up ventilation for various conditions, how to trouble-shoot the machine if issues arise, and how to monitor and attend to alarms during the treatment. It is suggested the testing procedures include the most fundamental information to facilitate the end-user’s capacity

and time to learn its operation. This is especially important as the requirement for the device may be immediate. An instructional video or guide may help HCPs who are not familiar with the device better navigate the machine and feel more confident using it. It is suggested the RMV has a program that allows the HCP to practice setting up ventilation treatment for a simulated patient by changing or altering ventilation settings during treatment and responding to various alarms. In addition, it is suggested a hardcopy of instructions for use are included to help users quickly learn how to set up, operate and monitor the device, or to be used as a reference/refresher after initial training.

5.4.7 Ventilator Testing

Like any medical device, testing the function and safety of RMVs is essential (International Organization for Standardization, 2020). It is suggested all RMVs are operated to the point where it does not function efficiently. Determining the lifespan of the device may be important considering it is unknown the length of time a patient may require the treatment. It is also suggested that when testing RMVs that various patient scenarios are considered, including mild to severe conditions (where compliance and resistance may reach extremes ranges).

For the automatic compression of MR RMV design, since it incorporates many different parts, it is suggested that testing include durability of the individual parts, especially the mechanism of compression (e.g., how many compressions before wear and tear begins). It would also be ideal to test various MR bags to determine which brand and type is best for the patient population and offers the greatest longevity. The motor of the MR design should also be tested to determine its durability including wear and tear over time, and potential issues with overheating.

5.4.8 Graphical User-Interface (GUI)

The GUI is important for displaying important ventilation parameters, especially to monitor changes in the patient's condition. This was first described in Sections 5.4.1 and 5.4.2 but will be expanded here. It is suggested that the GUI be incorporated as part of the RMV, removing the need for additional monitoring equipment. This integration would be similar to mechanical ventilators used in the ICU, which HCPs would be more familiar with and potentially reduce the amount of training required.

For a GUI to operate efficiently, a computer programming language must be used to develop the software. When choosing a programming language for RMV development considerations should be made for the RMV design, the knowledge and skills of the programmer, computing power (including memory), and hardware capabilities.

5.4.9 Materials and Parts

When choosing RMV materials and parts, it is important to balance the cost while optimizing performance. Consideration should also include the local availability of supplies. This is especially important in jurisdictions that are resource limited (e.g., LMICs). For example, off-the-shelf components may be available and less costly in LMICs where RMVs could be used for usual care (not just catastrophic events). Since supply chain distribution may decrease (Pujawan & Bah, 2022) it is suggested that materials and parts are commonly available (not specialized), be interchangeable or have multiple options, and available in multiple wholesale or retail locations.

The choice of which additive manufacturing technique to use will depend on the availability and accuracy of the technology, and materials used (Gibson et al., 2021). For example, for automatic compression of MR designs materials used for the motor should

be heat tolerant. Materials such as PLA and ABS are not 100% heat tolerant and should be avoided in construction of or near the motor for this specific design. PLA however is suggested for 3D printing because it is cost-effective and has easy printing capabilities (Li et al., 2020).

For the automated compression of MR RMV design, easy replacement of the bag is suggested. For the majority of the MR RMVs the lifespan of resuscitator bags was unknown, therefore, it is important to prepare in case of failure from repeated compressions and to increase its lifespan.

5.4.10 Infection Control

Infection control is paramount for any healthcare setting. This is especially true for aerosol generating procedures such as mechanical ventilation (Ari et al., 2021) and within the context of respiratory mass-casualty events like the Covid-19 pandemic. It is suggested a detailed cleaning and disinfection guide is provided with all RMVs and is created collaboratively by HCPs (e.g., respiratory therapists), the designers (e.g., engineers), and the manufacturers. The guide should also consider local infection control policies and procedures, and if one does not exist, using one by established organizations like the World Health Organization (WHO, 2014).

5.4.11 Other

Within this category, other important suggestions are presented. When developing and manufacturing any type of RMV, it is suggested that all appropriate experts are included. This is important because the construction of an RMV involves input from various disciplines to ensure the machine operates efficiently, minimizing the possibility for adverse events and harm to the patient receiving treatment. At minimum, this should

include HCPs with mechanical ventilation experience (e.g., respiratory therapists), and engineers to design and analyze the RMV build. It is also suggested that experts in computer programming and those with manufacturing experience be considered throughout the design process and during RMV's lifespan (Sodhi et al., 2023).

Since RMVs are used as back-up options, it is suggested these devices are clearly labelled to help HCPs distinguish them from established ICU mechanical ventilators, and to stress they be used as a last option.

Human factors should be considered when designing and manufacturing the RMV in the context of the ICU (Nacul, 2020). For example, ICU settings are typically small but require adequate space for the patient (and caregivers), staff, and equipment. (Hakem Alomani et al., 2022). Therefore, it is suggested the RMV is made compact and as lightweight as possible while not compromising functionality. For E-P designs, compressed gas sources can significantly increase the overall weight of the machine which can pose as a challenge to HCPs if they are required to move or transport the device. In these circumstances, the addition of wheels for easier transportability is suggested.

Once RMVs has been approved for and put into clinical practice, it is suggested manufactures provide recalls, vendor & support contracts and/or provide yearly preventative maintenance on the machine if they are being stockpiled. During the Covid-19 pandemic, thousands of ventilators in North America were stockpiled and became unusable due to lack of maintenance for the duration of the storage period (which were sometimes years) (Sodhi et al., 2023). Inconsistent policies and poor management of ventilator stockpiles and other supplies results in unusable products when required (Sodhi

et al., 2023). To ensure all products, especially mechanical ventilators are in good condition, proper management of stockpiles should include inventory rotations, audits, and consistent inspection (Sodhi et al., 2023). This approach will help ensure products in stockpile are ready for use at any time including in emergency situations.

5.4.12 Rationale

The 11 suggestions provided in this section may be more useful than following just one guidance document because the diversity between the documents was high in terms of what was recommended for the RMVs. It is possible that by following one guidance document an important recommendation may be missed but by using the 11 recommendations presented here which were chosen from a compilation of the six guidance documents that possibility is reduced.

5.5 Strengths and Limitations

This scoping review presented many strengths. Firstly, a well-recognized methodological framework for conducting scoping reviews was used. This review was led by a step-by-step process developed by Arksey and O'Malley (2005), further enhanced by Levac and colleagues (2010) and following JBI best practice guidelines (the aim to be as transparent and replicable as possible). The second strength of this review was the use of a health sciences librarian for development of the comprehensive literature search strategy which was then translated and run in five electronic databases for retrieval of articles to ensure a broad search of the literature. Thirdly, for title/abstract screening, full-text screening and data extraction a secondary reviewer was involved. Dual screening and data extraction reduced the potential for bias during selection of relevant articles (Stoll et al., 2019).

A few limitations are present in this review. The first limitation of this review is a lack of quality assessment conducted on the articles. This step is required for systematic reviews but optional for scoping reviews (Arksey and O'Malley, 2005). Quality assessment of the included articles was out of scope for this review because of the wide variety (heterogeneity) of study designs. In addition, the intentions of the review were not to directly impact or change clinical practice but rather provide broad information to help inform future standards/recommendations for RMVs.

The omission of guidelines and standards recommended by the WHO and Health Canada which were not identified until after the scoping review process was completed presents as another limitation. WHO and Health Canada are both reputable sources recognized at the international level or higher which possess information that may have been valuable to the findings of this research (WHO, 2020; Government of Canada, 2021). By not including these sources, important information regarding recommended guidelines and standards for RMVs may have been missed. However, although these documents were not included in the review their criteria specifically the ventilation modes, monitored and controlled parameters, displayed parameters, alarms and accessories were similar to the AARC, MHRA, MVAtCP and CHEST guidance documents included in this scoping review (Branson et al., 2020; MHRA, 2020; Hakimi et al., 2020, Einav et al., 2014).

In Arksey and O'Malley's (2005) six-step methodology, the sixth step involves a consultation exercise with stakeholders. This step helps with the accuracy and validity of the inferences made from the included articles. This step was not completed in this review, and information from various stakeholders may have helped support our

recommendations for RMV standards. In this scoping review two respiratory therapists (MZ, MLN), two knowledge synthesis experts (GB, MZ) and one engineer with expertise in advanced manufacturing (SAH) were “stakeholders”. Adding other individuals with expertise in ISO standards, mechanical ventilator manufacturing and testing, computer programming, and/or simulation may have provided additional validity and help support our recommendations for RMV standards.

Another limitation is that only English and French studies were included for analysis in this scoping review. This is a limitation because potential publications in languages native to LMICs may not have been included.

The final limitation of this review was the lack of extensively searching grey literature, especially given the “open source” nature of this topic. A grey literature search was conducted through Google Scholar, however, government reports, graduate dissertations, conference proceedings and other unpublished literature was not searched. As a result, articles containing relevant information may have been missed.

5.6 Gaps in Literature and Future Considerations

Numerous gaps in the literature were identified in this scoping review, providing opportunities for future research. First, it is important to consider the disruption of supply chains that is likely to occur during mass-casualty events and how to avoid shortages of crucial materials or parts used for the construction of RMVs. Designers of RMVs should offer options to substitute in other materials and parts that do not compromise the performance of the device. This includes consideration of all different types of supply chains required for RMV materials and parts. There should also be consideration of

regular maintenance and storage space if these RMVs were stockpiled for future use (Sodhi et al., 2023).

Second, prior to the Covid-19 pandemic very little was known about RMVs, as very few were developed. RMVs prior to Covid-19 were intended for catastrophic needs in the context of natural disasters, terrorist events or wars and were developed because experts predicted healthcare systems were not equipped with enough full-function ICU ventilators (Dickson et al., 2021). Covid-19 caused an unexpected surge in need, with mechanical ventilator demand outnumbering supply in both developed and LMICs (Pearce, 2020). RMVs were developed by clinicians and engineers to help with demand, but also as part of design challenges or competitions. For example, the RMV developed by DeBoer et al. (2021) was as part of a “challenge” which entailed designing and building a ventilator within 10 days. Unfortunately, there was a lack of standards for their design and performance, with guidance documents quickly being created in response (Branson et al. 2020; CIEHF, 2021; Einav et al., 2014; Hakimi et al., 2022; MHRA, 2020; Pearce, 2022). This scoping review provides general suggestions for future RMV design and construction, but future research should include detailed reports that could be incorporated within ISO standards. This may help facilitate more rigorous study designs. For example, a study (published after the search for this scoping review) by Jonkman et al. (2021) was a randomized control trial comparing their RMV with an established ICU mechanical ventilator on pigs. They found that their ventilator was capable of delivering stable ventilation with comparable arterial oxygenation, CO_2, and pH levels statistically similar to standard ICU ventilators (Jonkman et al., 2021). More rigorous study designs and results may eventually help RMVs reach the clinical setting more efficiently.

Finally, another knowledge gap not addressed in this scoping review was the human resources components. The expertise of qualified HCPs (e.g., respiratory therapists, physicians, nurses) is required to run these machines, and facilitate the medical management of the patient. If these machines were introduced into the clinical setting, additional personnel would be required, including the appropriate training. During Covid-19 the responsibilities of HCPs were stretched thin (Lia et al., 2020; de Oliveira, 2020; Pourteimour et al., 2021) and even after the pandemic was declared “no longer a public health emergency of international concern” (WHO, 2023) there exists a short supply in all health care sectors (Harp, 2023). Future research should investigate alternate models of critical care including innovative funding, and how to optimize health care professional’s scopes of practice.

Building off the information presented in this review, there are many future considerations. Firstly, this scoping review requires an updated search (after April 19th 2022) and a more comprehensive search of the grey literature. By performing a more comprehensive grey literature search, additional unpublished articles on RMVs may be found, especially given the open source nature of the technology. For example, the WHO and Health Canada guideline and standard documents may have been identified (Governement of Canada 2021; WHO, 2020). In addition, the document by the FDA discussing issued Emergency Use Authorization’s (EUA) for RMVs to help increase availability of medical devices to treat patients with Covid-19 may have been identified with a more comprehensive search of the grey literature. Numerous RMVs were FDA approved under the EUA, some of which were included in this review but also some that were likely missed due to the lack of extensively searching the grey literature. Three

RMVs (Mechanical Ventilator Milano (MVM), O2U Ventilator, SAVe II Series Ventilator) were EUA FDA approved and were identified in this scoping review. The SAVe I ventilator by Dickson et al. (2011) which was recognized in this review as FDA approved is a first-generation ventilator part of the SAVe II Series ventilator which at the time of publication (2011) was not FDA approved yet. The SAVe II Series ventilator is FDA approved under the EUA. One of these EUA FDA approved RMVs were however approved after the literature search was completed which explains why it was not identified in the literature search. The other RMVs that were EUA FDA approved before the literature search was completed were likely not published anywhere as the authors intent was not to publish the construction and characteristics of their RMV but rather help relieve the shortage of ICU ventilators as quickly as possible. However, it is unknown how many of these RMVs were actually put into practice, therefore, future research is needed to analyzed the remaining EUA FDA approved RMVs that were not included in this scoping review.

Another future consideration is developing future RMV standards that cater to differing resources (supply and demand) and cost. The resources available in developed countries greatly differ compared to developing countries, and some LMICs may not be able to afford the more sophisticated RMV features such as the GUI. In addition, the availability and expertise of administrative approval agencies such as the FDA, WHO and Health Canada may not exist in smaller jurisdictions or have standards for RMVs that are not applicable or attainable. Developing different standards for RMVs catered specifically to each region is best approached with consultation with stakeholder groups such as developers and users of ventilators in LMIC and developed.

In addition to development of RMV standards based on resources and cost, determining which RMV would be best suited for specific setting is a future consideration. For example, RMVs requiring compressed gas sources at 50 PSI may be best suited for hospital settings, whereas RMVs that can operate on lower gas pressure or do not require compressed gas may be best suited in settings requiring quick mobility or transport. In developing countries where resources are not as accessible, the use of off the shelf, low-cost parts and materials may be best suited, while in developed countries more complex RMVs (i.e., E-P RMVs) that require 3-D printing may be accessible.

The development of standards for RMVs like any medical product requires a thorough process before approval is granted. A stepped approach to RMV standards is another possible future consideration. For example, step 1 “required” RMV features are those that perform the basic functions of mechanical ventilation, while step 2 “recommended” features may be any additional features that offer benefits but are not required for function. Including consulting stakeholder groups such as ISO representative and manufactures would help guide this future consideration.

CHAPTER 6: CONCLUSIONS

The Covid-19 pandemic brought healthcare systems worldwide to the brink of collapse due to the shortage of HCPs and essential medical equipment such as mechanical ventilators. During the early stages of the Covid-19 pandemic, the concept of open-source RMVs was very appealing, however, their transition to the clinical setting presents many challenges. Suggestions for minimal functional capabilities have been offered by experts but there currently is no consensus and standards against which to evaluate the RMVs. It is important to note that RMVs are not intended to replace clinically approved ventilators but instead are meant to be used as a back-up solution when ICU ventilators are not available. The main requirements of RMVs should be affordability, accessibility and functionality; designs should use inexpensive components and have simple manufacturing methods. Establishing a safe and effective back-up solution may help HCPs avoid difficult triaging decisions including the discontinuation of care for patients whose outcome is unfavourable in an effort to make ventilators available for those with a more favourable prognosis.

Although efforts have been made to encourage urgent authorization of newly developed RMVs, the currently available testing protocols are not internationally accepted, standardized and none address testing in clinical settings. The results from this review may do little to directly impact or change clinical practice but provides broad information to inform standards/recommendations of RMVs and help guide future design teams. Although the creation of RMVs was prompted by the Covid-19 pandemic, their application is valuable beyond respiratory viruses and can be used in other mass-casualty events

including natural disasters, wars, and particularly in LMICs who are not equipped with enough resources even during normal circumstances.

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GLOSSARY

Acute Respiratory Distress Syndrome (ARDS)	A serious lung conditions resulting in fluid build-up inside the alveoli of the lungs causing low blood oxygen
Additive Manufacturing (AD)	The constructions of three-dimensional objects from a CAD model (also called 3D- Printing)
Control system	System responsible for regulating, managing and directing the actions of a device to achieve desired outcomes. Used interchangeably with microcontroller, microprocessor, microcomputer, microchip or programmable logic controller
Electro-Pneumatic (E-P)	System that utilizes electricity and compressed gases to operate
Fuse deposition modelling (FDM)	Additive manufacturing technique completed in successive layers by a filament injecting through a nozzle and deposited onto a bed to create the desired object
Manual Resuscitator (MR)	Hand held breathing bag used to manually deliver positive pressure ventilation to individual who cannot breathe adequately themselves
“Off-the-shelf”	Products commercially ready-made and available to general public at local stores
Rapidly manufactured ventilator (RMV)	A machine that provides mechanical ventilation, however, is manufactured in a fraction of time it takes to manufacture ICU ventilators. These ventilators are generally less sophisticated than ICU ventilators but the out (i.e., to provide positive pressure ventilation) is the same.
Standards	A document which provides a set of agreed-rules, guidelines or characteristics for activities or their results
Selective laser sintering (SLS)	Additive manufacturing technique where powered material is spread over a table and using a high-powered laser beam to trace the profile and melt the power into the desired shape

APPENDICES

APPENDIX A: SEARCH STRATEGY

Innovative ventilators in mass casualty, pandemic, and low-resource contexts.

Database(s): **Ovid MEDLINE(R) ALL** 1946 to April 04, 2022

#	Searches	Results	Annotations
1	Diffusion of innovation/	18266	
2	exp Printing, Three-Dimensional/	9440	
3	((improvise* or rapid* or "low-cost" or accessible or imagin*) adj3 (creation or design$1 or produced or production or manufactur* or assembl* or prototyp* or strateg* or solution*)).tw,kf.	32720	
4	("instant-build" or "just-in-time" or "make-do" or jerry- rigg* or "make-shift" or makeshift or macgyver* or innovative or innovation* or novel or creative or ingenuity or ingenious or imaginative or "cutting edge" or unconventional or "non-conventional" or "stop-gap").tw,kf.	1664061	
5	("3D printing" or "3D-printed" or "3-D printing" or "3-D printed" or "three-dimensional printed" or "three-dimensional printing").tw,kf.	17453	
6	(inexpensive or "fraction of the cost" or affordable or opensource or open-source or open-licen?e*).tw,kf.	91717	
7	or/1-6	1800274	
8	exp Ventilators, Mechanical/	9850	
9	*Respiration, Artificial/ or Non invasive ventilation/ or exp Positive-pressure respiration/	55295	
10	(ventilator or ventilators or respirator or respirators or bagger* or "bag-breathing unit" or "breathing device*" or "respiratory-support device").mp.	44719	
11	or/8-10	87601	

12	(VESper or ResUHUrge or "Q-vent" or Oxvent or Corovent or "COVENT-tester" or "ATMO-Vent" or "bridge ventilator*").mp.	66	
13	7 and 11	2795	
14	12 or 13	2855	Innovation/Low-cost + Ventilators
15	*Mass Casualty Incidents/	1855	
16	exp *Disasters/	52583	
17	Disaster Medicine/	905	
18	("mass casualt*" or (mass adj3 incident*) or "mass trauma" or disaster*).ti,ab,kw.	33642	
19	(disaster adj (preparedness or relief)).ti,ab,kf.	2576	
20	(Mobile Health Units/ and (hospital or hospitals or medical unit* or containment unit* or ward or wards or "health care facilit*" or "medical treatment facilit*").ti,ab.) or ((temporary or deploy* or portable or mobile*) adj (hospital or hospitals or medical unit* or containment unit* or ward or wards or "health care facilit*" or "medical treatment facilit*")).mp. or ("Mobile Army Surgical Hospital*" or "field hospital*").mp.	1797	
21	or/15-20	71796	Mass casualty/Emerg Medicine/Temporary hospitals
22	*epidemics/ or *pandemics/	41894	
23	(epidemic* or pandemic* or h1n1 or sars or sars-cov* or covid or covid19 or "corona virus" or coronavirus* or outbreak* or "highly communicable" or respiratory disease spread or "infectious diseases").ti,ab,kf.	536829	
24	22 or 23	538376	Epidemics/Pandemics
25	14 and 24	644	
26	Developing Country/	79007	
27	(Africa or Asia or Caribbean or West Indies or South America or Latin America or Central America).hw,ti,ab,cp.	300884	

28	(Afghanistan or Albania or Algeria or Angola or Antigua or Barbuda or Argentina or Armenia or Armenian or Aruba or Azerbaijan or Bahrain or Bangladesh or Barbados or Benin or Byelarus or Byelorussian or Belarus or Belorussian or Belorussia or Belize or Bhutan or Bolivia or Bosnia or Herzegovina or Hercegovina or Botswana or Brasil or Brazil or Bulgaria or Burkina Faso or Burkina Fasso or Upper Volta or Burundi or Urundi or Cambodia or Khmer Republic or Kampuchea or Cameroon or Cameroons or Cameron or Camerons or Cape Verde or Central African Republic or Chad or Chile or China or Colombia or Comoros or Comoro Islands or Comores or Mayotte or Congo or Zaire or Costa Rica or Cote d'Ivoire or Ivory Coast or	4094931	

	Croatia or Cuba or Cyprus or Czechoslovakia or Czech Republic or Slovakia or Slovak Republic or Djibouti or French Somaliland or Dominica or Dominican Republic or East Timor or East Timur or Timor Leste or Ecuador or Egypt or United Arab Republic or El Salvador or Eritrea or Estonia or Ethiopia or Fiji or Gabon or Gabonese Republic or Gambia or Gaza or Georgia Republic or Georgian Republic or Ghana or Gold Coast or Greece or Grenada or Guatemala or Guinea or Guam or Guiana or Guyana or Haiti or Honduras or Hungary or India or Maldives or Indonesia or Iran or Iraq or Isle of Man or Jamaica or Jordan or Kazakhstan or Kazakh or Kenya or Kiribati or Korea or Kosovo or Kyrgyzstan or Kirghizia or Kyrgyz Republic or Kirghiz or Kirgizstan or Lao PDR or Laos or Latvia or Lebanon or Lesotho or Basutoland or Liberia or Libya or Lithuania or Macedonia or Madagascar or Malagasy Republic or Malaysia or Malaya or Malay or Sabah or Sarawak or Malawi or Nyasaland or Mali or Malta or Marshall Islands or Mauritania or Mauritius or Agalega Islands or Mexico or Micronesia or Middle East or Moldova or Moldovia or Moldovian or Mongolia or Montenegro or Morocco or Ifni or Mozambique or Myanmar or Myanma or Burma or Namibia or Nepal or Netherlands Antilles or New Caledonia or Nicaragua or Niger or Nigeria or Northern Mariana Islands or Oman or Muscat or Pakistan or Palau or Palestine or Panama or Paraguay or Peru or Philippines or Philipines or Phillipines or Phillippines or Poland or Portugal or Puerto Rico or Romania or Rumania or Roumania or Russia or Russian or Rwanda or Ruanda or Saint Kitts or St Kitts or Nevis or Saint Lucia or St Lucia or Saint Vincent or St Vincent or Grenadines or Samoa or Samoan Islands or Navigator Island or Navigator Islands or Sao Tome or Saudi Arabia or Senegal or Serbia or Montenegro or Seychelles or Sierra Leone or Slovenia or Sri Lanka or Ceylon or Solomon Islands or Somalia or South Africa or Sudan or Suriname or Surinam or Swaziland or Eswatini or Syria or Tajikistan or		

	Tadzhikistan or Tadjikistan or Tadzhik or Tanzania or Thailand or Togo or Togolese Republic or Tonga or		

	Trinidad or Tobago or Tunisia or Turkey or Turkmenistan or Turkmen or Uganda or Ukraine or Uruguay or USSR or Soviet Union or Union of Soviet Socialist Republics or Uzbekistan or Uzbek or Vanuatu or New Hebrides or Venezuela or Vietnam or Viet Nam or West Bank or Yemen or Yugoslavia or Zambia or Zimbabwe or Rhodesia).hw,ti,ab,cp.		
29	((developing or less* developed or under developed or underdeveloped or middle income or low* income or underserved or under served or deprived or poor* or "resource-limited") adj (countr* or nation? or population? or world)).ti,ab.	120775	
30	((developing or less* developed or under developed or underdeveloped or middle income or low* income or "least-developed" or "under-resourced") adj (economy or economies)).ti,ab.	770	
31	(low* adj (gdp or gnp or gross domestic or gross national or resource*)).ti,ab.	9325	
32	(low adj3 middle adj3 countr*).ti,ab.	24225	
33	(lmic or lmics or third world or lami countr*).ti,ab.	10543	
34	transitional countr*.ti,ab.	174	
35	("resource-poor" or "low-resource" or (resource adj2 limited)).mp.	26267	
36	or/26-35	4280770	
37	21 or 24 or 36	4708197	Mass Casualty/Emergency Medicine OR Epidemic/Pandemic OR LMIC/low-resource
38	14 and 37	849	Innovative/rapidly manufactured Ventilators AND (Mass Casualty/Emerg med OR Pandemics OR LMIC/low-resource)
39	remove duplicates from 38	846	

APPENDIX B: DATA EXTRACTION FORM (DEF)

REFERENCE DATA EXTRACTION FORM			
Full reference selected			Completion rate
Reference data and dataset			
Section	**Variable**	**Unit**	**Information ("YES")**
1	**REFERENCE**		
1.1	**DATA ENTRY**		
1.1.1	Publication ID	(#)	
1.1.2	Reviewer	(txt)	
1.1.3	Date	(dd/mm/yy)	
1.2	**PUBLICATION**		
1.2.1	Title	(txt)	

1.2.2	Authors	(txt)	
1.2.3	Affiliation	(txt)	
1.2.4	Country	(txt)	
1.2.5	City of Origin	(txt)	
1.2.6	Year of Publication	(txt)	
1.2.7	EndNote Nb	(txt)	
1.2.8	Dataset ID	(txt)	
1.3	**DESCRIPTOR**		
1.3.1	Ventilator Name	(txt)	
1.3.2	Aims of study	(txt)	
1.3.3	Methodology/design	(txt)	
1.3.4	Concept/intervention	(txt)	
1.3.5	Key outcome 1	(txt)	

1.3.6	Key outcome 2	(txt)		
1.3.7	Key outcome 3	(txt)		
2	**VENTILATOR DESCRIPTION/ CHARACTERISTICS *(CLINICAL PERSPECTIVE)***			
2.1	**OPERATING FEATURES**			
2.1.1	FDA approved for pediatric use	YES	NO/DNM	
2.1.2	Power source	YES	NO/DNM	
2.1.3	Modes of ventilation	YES	NO/DNM	
2.1.4	Control of settings	YES	NO/DNM	
2.1.5	Range of flow	YES	NO/DNM	
2.1.6	PEEP (Range)	YES	NO/DNM	
2.1.7	Oxygen Titration	YES	NO/DNM	
2.1.8	Operate without 50 – 55 psi oxygen source	YES	NO/DNM	
2.1.9	Measurements/ Monitoring	YES	NO/DNM	

2.1.10	Tidal Volume (V_t)	YES	NO/DNM	
2.1.11	Breathing frequency	YES	NO/DNM	
2.1.12	FiO2	YES	NO/DNM	
2.1.13	Inspiratory flow	YES	NO/DNM	
2.1.14	Respiratory rate	YES	NO/DNM	
2.1.15	I:E Ratio	YES	NO/DNM	
2.1.16	Oxygen Sensor	YES	NO/DNM	
2.2	**PERFORMANCE FEATURES**			
2.2.1	Process to set-up (User-friendly?)	YES	NO/DNM	
2.2.2	Sustained Use	YES	NO/DNM	
2.2.3	Testing user-interface	YES	NO/DNM	
2.2.4	Sustained Use	YES	NO/DNM	
2.2.5	Oxygen Consumption	YES	NO/DNM	

2.3	**SAFETY FEATURES**			
2.3.1	Alarm (Triggers?) **High-priority vs. Low Priority*	YES	NO/DNM	
2.3.2	Alarm Characteristics (Visible/Audible)	YES	NO/DNM	
2.3.3	User-interface alarms	YES	NO/DNM	
2.4	**OTHER FEATURES**			
2.4.1	General Durability	YES	NO/DNM	
2.4.2	Recalls	YES	NO/DNM	
2.4.3	Vendor and Support Contract	YES	NO/DNM	
2.4.4	Maintenance	YES	NO/DNM	
2.4.5	Purchasing Costs	YES	NO/DNM	
2.4.6	Material and Parts	YES	NO/DNM	
2.4.7	Additional approvals/clearances	YES	NO/DNM	

2.4.8	Labelling		YES	NO/DNM		
2.4.9	Infection Control		YES	NO/DNM		
2.5	**HUMAN FACTOR CONSIDERATIONS**					
2.5.1	User interface design/software		YES	NO/DNM		
2.5.2	User interface training program		YES	NO/DNM		
2.5.3	Ventilator kit description (Weight, Wheels (movability), etc.)		YES	NO/DNM		
2.6	**TESTING**					
2.6.1	Ventilator	No Testing	Lung Simulator	Animal (What animal?) _____	Humans	Duration?
2.6.2	Sustained Use	No testing		___ Weeks ____ Days ____ Hours		
2.6.3	User-interface	YES	NO/DNM			
3	**VENTILATOR ENGINEERING/COMPUTER CHARACTERISTICS *(ENGINEERING PERSPECTIVE)***					
3.1	**HARDWARE**					
3.1.1	Gas and electricity		YES	NO/DNM		

3.1.2	Optical reflectors	YES	NO/DNM	
3.1.3	Pulse with modulation (PWM) board	YES	NO/DNM	
3.1.4	Pressure transducers	YES	NO/DNM	
3.1.5	User input controls	YES	NO/DNM	
3.1.6	Monitoring	YES	NO/DNM	
3.1.7	Alarms	YES	NO/DNM	
3.1.8	Biological safety	YES	NO/DNM	
3.1.9	Other respiratory equipment	YES	NO/DNM	
3.1.10	Reliability and safety	YES	NO/DNM	
3.2	**SOFTWARE**			
3.2.1	Software safety	YES	NO/DNM	
3.2.2	Software development process/plan	YES	NO/DNM	
3.2.3	Software verification and validation plans/reports	YES	NO/DNM	

3.2.4	System and software requirement specifications	YES	NO/DNM	
3.2.5	Appropriate software architecture	YES	NO/DNM	
3.2.6	Software risk management plan and report	YES	NO/DNM	
3.2.7	Software release note	YES	NO/DNM	
3.2.8	Software components	YES	NO/DNM	
3.3	**DOCUMENTATION**			
3.3.1	Installation and user guide	YES	NO/DNM	
3.3.2	Design source and production files	YES	NO/DNM	
3.3.3	Fully annotated circuit diagrams	YES	NO/DNM	
3.3.4	Wiring diagrams	YES	NO/DNM	
3.3.5	Functional block diagram	YES	NO/DNM	
3.3.6	Firm and Software (including code)	YES	NO/DNM	
3.3.7	Bill of materials (BOM)	YES	NO/DNM	

3.3.8	Test methods and test results	YES	NO/DNM	
3.3.9	Regulatory standards used	YES	NO/DNM	

APPENDIX C: RMV CHARACTERISTICS RESULTS EXCEL TABLE

1. Operating Features
2. Performance Features
3. Other General Features
4. Engineering Components
    a. Hardware
    b. Software / User-Interface
    c. Documentation

APPENDIX C: OPERATING FEATURES

Electro-Pneumatic Designs													
Author (Vent. Name)	**Oxygen/ Gas Source**	**Power Supply**	**Mode**	**User-input controls/ monitoring**	**Flow Rate**	**Tidal Volume (mL)**	**PEEP (cm H20)**	**FiO2 (%)**	**RR (BPM)**	**I:E Ratio**	**PIP (cm H2O)**	**FDA Approval**	**Alarms**
Abba (Mechanical Ventilator Milano (MVM))	Requires compressed oxygen and medical (50 PSI) air to operate	Provided via external unit. Equipped with battery (2hr autonomy)	PCV, PSV	RR, PEEP, FiO2, PIP, inspiratory time	NR	NR	NR	NR	NR	NR	NR	Yes	Audible "Integrated alarm system"
Buytaert (HEV)	Standard hospital air and oxygen supplies (50 PSI).	Set according to the MHRA standards	PC-AC PC-A/C-PRVC PC-PSV CPAP	RR, PEEP, TV, I:E ratio, FiO2	Up to 120 L/min	250 – 2000 (Inc. 50)	5 – 20 (Inc. 5)	21 – 100 (Inc. 10%)	10 – 30 (Inc. 2)	1:1 – 1:3	NR	No	Visual (LED) and audible Gas or electricity

	Also works with lower pressure options like compressor, concentrator or turbine.												supply failure, machine switched off, airway pressure exceeded, tidal volume not achieved, hypoventilation, high leakage
Chiang (VEMERS UC)	Requires compressed air and oxygen	24V, 9V and 5V	VCV	RR, PEEP, TV, FiO2, I:E, PIP, Inspiratory Flowrate	Up to 80 LPM	150 - 600	0 - 20	21 - 100	10 - 40	1:1 – 1:3	NR	NR	Audible Maximum value exceeded for PIP, PEEP, flow rate, TV, FiO2, RR and I:E
Cole (Portsmouth Ventilator)	Requires compressed air and oxygen supply	US standard 120V 3 pin plug. Lithium polymer battery for 30 mins of back-up	VCV	TV, RR, inspiratory time, PEEP, FiO2	Up to 120 L/min	300 – 800 (Inc. 45)	0 - 20	21%, 50-60%, 90-100%	4 - 30	1:1 to > 1:5	NR	No	Audible and visual (LED) Gas, electricity or circuit supply failure, high or low pressure,
Dally (OP-Vent)	Requires compressed air	NR Has a	VCV, PCV, PRVC	TV, RR, I:E,	NR	NR	NR	21 – 100	NR	NR	NR	No	Audible Disconnec

	and oxygen supply	back-up battery		PEEP FiO2									tion, High pressure, High and low minute volume, Apnea, Low input voltage, Low input air pressure, Low input O2 pressure
DeBoer (NR)	Compressed air and oxygen (O2) using standard hospital (50 PSI) pipeline supply or mobile tanks	12V	VCV, CMV	RR, PEEP, TV and FiO2	NR	NR	NR	NR	5 - 30	NR	NR	No	Audible Blockage or parameters out of range
El Haddi (CRISIS)	Requires compressed air and oxygen supply	No power. Operates off compressed gas.	CMV	Inspiratory flow rate, PIP, I:E ratio, PEEP, TV	NR	150 - 1000	NR	NR	NR	NR	NR	No	NR
F (DIGIT)	Requires compressed air and	NR	VCV, PCV	Unclear	NR	NR	NR	NR	NR	NR	NR	No	Visual and Audible Max. pressure

	oxygen supply												
King (RapidVent)	Requires 50 PSI oxygen source	Gas powered from 50 PSI source	NR	PIP, PEEP, FiO2, inspiratory flowrate, RR, Expiratory time	0 – 40 L/min	NR	NR	50 or 100	NR	NR	NR	NR	Audible Ventilator stops working, breathing pattern changes, PEEP, PIP or RR falls out of normal ranges and high- and low-pressure readings are too close together.
Knorr (CLEVent EV)	Requires 50 PSI oxygen source	A standard 120 V AC to 12 V DC converter w/ 2 amps of current was used to power the electronic circuit	VCV, VC-IMV	RR, PEEP, I:E ratio, FiO2 and PIP	NR	NR	NR	21 - 100	NR	NR	NR	No	Audible High and low airway pressure, circuit disconnection
Madekurozwa (NR)	Compressed gas supplies	Medical PC that typically	PRVC, PCV	TV, RR, PEEP, I:E ratio	NR	NR	NR	NR	NR	NR	NR	No	NR

	or portable O2 concentrator	uses ~40–50W at 24 VDC		and FiO2									
Park (ALIVE Vent)	Uses 50 PSI pressurized air/oxygen. Electric generators and lightly compressed air/oxygen cylinders can still provide sufficient voltage and pressure gradients for basic operation because the operational power and pressure requirements for our device	Powered by pressured air/oxygen source	PCV, VCV	RR, PEEP, TV, I:E ratio, FiO2, PIP	0 – 100 LPM	NR	NR	21 - 100	NR	NR	NR	No	NR

	are low. Contains internal gas blending features to independently titrate the Fio2 of inhaled gas.												
Raymond (O2U Ventilator)	Uses pressurized medical gases (50 PSI) to operate	Powered by pressurized gases	CPAP, SIMV-VC	Inspiratory time, RR, PEEP and FiO2	NR	250 - 600	5 - 20	21 - 95	10 - 30	1:1 – 1:3	NR	Yes	Audible High and low pressure, low tidal volume.
Rebelo (ATENA)	Uses pressurized medical gases (50 PSI) to operate	100–240 Vac (50–60Hz) 30 W Back-up battery - Lead-acid Nominal voltage - 12 V 7 Ah capacity	PCV, VCV, PSV, PRVC	I:E ratio, RR, FiO2, TV, PEEP and Flow	NR	250 - 800	0 - 40	21 - 100	5 - 30	1:1 – 1:4	0 - 40	No	Audible, Visual and Specific alarm text on display.
Von Chong (NR)	50 PSI	NR	VCV	NR	NR	NR	NR	NR	NR	NR	NR	No	Mentions alarms but no details.

Wittenberg (CoVent)	NR	NR	PCV, PSV	PEEP, RR, I:E ratio, FiO2	NR	NR	NR	NR	NR	NR	NR	No	NR
Automatic Compression of MR													
Author	**Oxygen/ Gas Source**	**Power Supply**	**Mode**	**User-input controls/ monitoring**	**Flow Rate**	**Tidal Volume (mL)**	**PEEP (cm H20)**	**FiO2 (%)**	**RR (BPM)**	**I:E Ratio**	**PIP (cm H2O)**	**FDA Approval**	**Alarms**
Al Husseini (NR)	Requires O2 source	AC/DC convertor can be used to power ventilator directly from wall outlet 14.8 VDC battery	VCV	RR, I:E, TV	NR	200 - 750	NR	NR	5 - 30	NR	NR	NR	High pressure
Arcos-Legarda (NR)	NR	NR	PCV, VCV	RR, PEEP, TV, I:E, PIP	NR	200 - 600	5 - 20	NR	0 - 30	1:1 – 1:3	5 - 40	No	Audible Over pressure, over volume
Christou (GlasVent)	Requires compressed air and oxygen supply	7 to 12V supply for Arduino microcontroller Can be powered	CMV, PCV, VCV	TV, RR, PIP, PEEP, airway pressure, plateau	NR	NR	NR	NR	NR	NR	NR	NR	NR

		with 3 Li-Ion battery cells for back-up.		pressure									
Dhanani (NR)	Does not require compressed air source. Requires O2.	12V 5A	NR	RR, TV, I:E ratio	NR	NR	NR	NR	Up to 25	NR	NR	No	None
Du (ETH Breathe**)	Does not require compressed air source	NR	VCV	RR, PEEP, TV, I:E ratio	NR	NR	NR	NR	NR	NR	NR	No	Electricity, system or supply failure, Vt not delivered, Max. pressure exceeded, Min. pressure not reached (disconnection)
Gafford (VOV - Vanderbilt Open-source Ventilator)	Directly compatible with many standard oxygenation	12-Vdc, 5-A, ISO 60601-compliant	VCV	RR, TV, I:E ratio	NR	0 - 800	0 – 25	NR	5 - 55	1:1 – 1:4	NR	NR	Audible and Visual Min and max pressure
Gino (AIR – Automated Inflating	Requires O2	15 Watt	VCV	RR, TV, PEEP, FiO2	NR	100 – 900	5 - 60	21 or 100	10 - 30	1:2	NR	No	NR

Resuscitator)													
Grimshandl (HDvent Emergency Ventilator System)	The bag takes in room air or optionally oxygen-enriched room air via a reservoir.	Built in 24V	PCV, VCV, OL-CMV	Unclear	NR	0 - 600	0 – 20	NR	10 - 30	NR	0 - 40	No	Visual and Audible Thresholds for minute volume and inspiratory pressure
Gruslova (ABBU: Automated Bag Breathing Unit)	Can use low flow oxygen from widely available sources (e.g., concentrators, hospital wall-source, tanks, and liquid oxygen reservoirs).	Standard electrical power. No back-up battery.	NR	TV, RR, PEEP, I:E ratio	NR	200 - 800	NR	NR	10 - 40	0.5 - 1.5 s	NR	NR	Visual and audible Circuit blockage, air-leaks, low pressure (e.g., disconnection), motor, and electric failure
Kindomba (ProtoVent)	Connects to low flow O2 source	DC Motor Power Supply	NR	RR	NR	NR	NR	NR	NR	NR	NR	No	NR
Mathanlal (ATMO-Vent)	Compressed medical-grade air	220V AC → PC Power Supply 12 V DC	NR	RR, VT, Insp. Pause, I:E ratio and PIP	Up to 30 LPM	NR	NR	NR	NR	NR	NR	NR	Visual and Audible RR, PIP and TV

	and oxygen	Convertor is required for Raspberry Pi (operates on 5V DC)											thresholds exceeded
Mathew (Artificial Breathing Capability Device (ABCD))	Does not require 50 PSI Connects to low flow	NR	NR	PIP, RR, inspiratory time and I:E ratio	NR	NR	NR	NR	10 - 60	1:1 – 1:4	10 - 50	NR	Visual and Audible physiological values out of range. Endotracheal tube blockage, endotracheal tube displacement, leakage in the ventilation circuit and displacement of SIB
Meiry (Ambo Vent)	Can be connected to hospitals clean air supply (50 PSI).	110-220V 12V back-up battery	PCV, PSV	RR, I:E ratio and PIP	NR	30 to 100% of bag squeeze	NR	NR	6 - 24 (inc. 2)	1:2	Sensing threshold 30 – 70 (Inc. 10)	No	Visual and audible alarms. Power supply failure. Operates on battery or reaches

													2hr of battery remaining. Internal backup battery voltage drops. Device turned off during active ventilation. Pressure rises above the PIP threshold. Sudden, unexpected pressure drops. Deviation from the rate-setting that is in effect.
Ort (MIT EV)	Does not require 50 PSI. Low flow oxygen.	5A at 12V or 60W	VCV	RR, VT, I:E ratio	NR	200 - 800	5 - 15	NR	6 - 40	1:1 – 1:4	NR	No	Visual and audible Exceeded PIP pressure, Low Pressure, High Resistive Pressure,

													Over Current Fault, Tidal volume not delivered, Tidal pressure not detected
Palacka (Q-Vent)	Works with both 50 PSI and low flow	12 W, 6VDC, 2A Independent power backup source.	VCV	RT, TV, I:E ratio, PEEP, FiO2	NR	0 - 800	NR	21 - 100	NR	NR	NR	NR	Audible Device power failure, pressure limit exceeded, O2 supply failure, breath below acceptable, hyper-, hypocapnia, PEEP failure, IA pressure failure, VT not achieved, battery power failure
Petsiuk (RepRapable)	Works with low flow	12V	CMV (IRV)	RR, TV, I:E ratio	NR	100 - 846	2 - 11	NR	5 - 45	1:1 – 1:4	NR	No	Audible and visual (LED) low and

													high pressure, wire disconnect
Terzi (eSpiro)	Does not require pressurized oxygen source	"Medical device power supply" Lead back-up battery	VCV	RR, PEEP, TV, I:E ratio	NR	NR	NR	NR	NR	NR	NR	No	Audible High and low airway pressure
Truong (NR)	Connected to low flow O2	NR	VCV	RR, TV, I:E ratio and PIP	NR	350 - 700	NR	NR	NR	NR	NR	No	"Might generate a warning if…" Pressure exceeds the PIP or PEEP limit range,
Urbina (Automated manual resuscitator- based emergency ventilator-alternative (AMREV))	Low flow O2	low-voltage 12V 2A DC	VCV	RR, PEEP, TV, I:E ratio	NR	110 - 700	NR	NR	10 - 30	NR	NR	No	NR
Vasan (MAD Vent)	Low flow O2	Medical grade 12 VDC wall	PCV	RR, PIP and	NR	200 - 1000	NR	NR	6 - 35	Inspiratory	Target IP	No	Audible and visual

		adapter Rechargeable lead back-up battery capable of powering the system for at least 20 mins		inspiratory time						time 1 - 3.0s	10 - 35		low and high pressure, low and high volume, mechanical failure, overheating, pressure sensor disconnection or failure, wall power disconnection or low battery.
Von Chong (NR)	BVM design uses low flow O2.	NR	VCV	RR, TV, % of lever compression on bag (10-100%) which controls TV, PEEP	NR	NR	5 - 20	NR	10 - 30	NR	NR	No	Mentions alarms but no details.
Automated Compression of AMBU Bag with Electro-Pneumatic System													
Author	**Oxygen/ Gas Source**	**Power Supply**	**Mode**	**User-input controls/ monitoring**	**Flow Rate**	**Tidal Volume (mL)**	**PEEP (cm H20)**	**FiO2 (%)**	**RR (BPM)**	**I:E Ratio**	**PIP (cm H2O)**	**FDA Approval**	**Alarms**

Beale (Ox-Vent)	Requires compressed oxygen.	NR	VCV, PSV, ASV	PEEP, TV, FiO2, RR, I:E	>825 mL/s *Convert * 49.5 L/min	Up to 600	NR	30 - 100	NR	1:2, 1:3	NR	NR	Audible Maximum inspiratory pressure threshold is met
Chang (Masi)	NR	Grounded AC electrical outlet with a protection fuse of 3A. The power is handled by an AC/DC Mean Well DRC-100 uninterruptible power supply (UPS) with a nominal power of 96 W and a self-voltage input of 90VAC to 264VAC.	PCV, VCV, PSV	TV, PIP, RR, PEEP, I:E ratio, FiO2	NR	200 - 800	0 - 20	21 - 100	NR	NR	0 - 45	No. Did receive approval of DIGEMID (Peruvian regulatory authority).	"Programmed alarms that surpass MHRA recommended setups" **MHRA does not mention if alarms must be audible or visual. It is assumed that only audible alarms were included.* High or low pressure or volume. Alarms must be set for RR, difference from

													PEEP and FiO2 difference.
Fang (AmbuBox)	Requires compressed air and oxygen supply	Power supply adapter	NR	TV, RR, PEEP, FiO2	NR	250 - 800	5 - 20	NR	10 - 30	NR	15 - 40	No	High and low pressure
Williams (NR)	Low flow O2	Gas-powered	VCV	RR and TV	NR	NR	NR	NR	NR	NR	NR	No	NR
"Other"													
Author	**Oxygen/ Gas Source**	**Power Supply**	**Mode**	**User-input controls/ monitoring**	**Flow Rate**	**Tidal Volume (mL)**	**PEEP (cm H20)**	**FiO2 (%)**	**RR (BPM)**	**I:E Ratio**	**PIP (cm H2O)**	**FDA Approval**	**Alarms**
Aihaitijiang (Ori-Vent)	NR	120V or lower (ideally 6V)	NR	NR	150-500 cm3/s *convert* 9-30L/min	NR	5 - 24	“adjustable O2”	12 - 40	1:1 – 1:4	NR	NR	NR
Darwood (NR)	Supplemental oxygen at low pressure can be added	4 lithium ion cells	PCV	RR, I:E Ratio, peak pressure	NR	NR	NR	NR	5 - 30	NR	10 - 45	No	Mentions alarms, not much details. Hardware failure, circuit leak and changes in resistance and

													compliance.
Dickson (SAVe I)	Does not require compressed air source	Alternating current battery	VCV	Do not control any parameters. Everything is fixed.	16	600	0	NR	10	NR	Up to 38	Yes	Audible and Visual Disconnect, High peak pressure
Dickson (SAVe II)	Does not require compressed air source	Alternating current battery	VCV	VT, RR PEEP	10 – 80 L/min	200 - 1000	0 – 20	NR	8 - 20	NR	Up to 60	No	Audible and Visual Disconnect, High peak pressure
El Majid (NR)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	No	NR
Fernandez (ResUHUrge)	Requires O2 tank	Two low-cost medical-standard 5 VDC and 12 VDC	PCV (BiPAP)	Inspiratory flowrate, I:E ratio, inspiratory trigger	1 - 140 L/min	NR	NR	21 - 80	NR	20 – 100%	Up to 35	No	Audible Minimum and maximum pressure, minimum inspired volume, maximum inspired volume, maximum breathing frequency, apnea
Haque (NR)	NR	24 V Panasoni	PCV, SIMV, PRVC	NR	NR	NR	NR	NR	NR	NR	NR	NR	Visual and audible

		c NCR18650B batteries had been used as backup power for portable operation. A 3S2P battery configuration is used, ultimately getting 6800mAh and 85.68 Wh at 12.6V. This system is expected to run for 5.6 hours at a stretch.											Disconnection and low PIP
Marzetti (NR)	Not specific. "Air or gas is directed by garden hoses"	Hand-held power tool battery delivering 18 V DC	NR	RR	NR	200 - 1500	NR	NR	NR	NR	NR	No	NR
Pereira (NR)	Requires air and O2 from	NR	PC-CMV	RR, PEEP, I:E ratio,	NR	NR	0 - 20	50 - 100	12 - 25	1:2 – 1:3	5 - 40	No	Audible Few

	hopsital like supply (50 PSI)			FiO2, PIP									alarms - apneaand power loss
Szlosarek (NR)	Doesn't mention requirement of 50 PSI, just says compressed gas from portable air compressors or pressurize tanks	Powered by pressurized gases	PCV	PEEP	NR	NR	NR	NR	NR	NR	NR	No	NR
White (FALCON - Fast-Assembly COVID-Nineteen)	NR	5V/12V power supply	PCV	RR, PEEP , PIP	NR	NR	NR	NR	NR	NR	NR	No	No
Zuckerberg (ALFA)	Compressed medical gas	NR	IMV-PC	RR, inspiratory time and I:E ratio	NR	NR	NR	NR	NR	NR	NR	No	NR

APPENDIX C: PERFORMANCE FEATURES

Electro-Pneumatic Designs				
Author (Vent. Name)	**Ventilator Testing & Sustained Use**	**User-Interface Testing**	**Oxygen Consumption**	**Process to set-up/User-friendly**
Abba (Mechanical Ventilator Milano (MVM))	LS 3 months	After start-up the supervisor waits for the operator to start the self-test procedure.	NR	NR
Buytaert (HEV)	LS Time NR	NR	NR	"Easy to use" The Native UI is automatically displayed on power up of the device. At start-up, a mode selection screen allows for selection of one of the modes. Associated with each mode are the set parameters to be chosen for that mode. The parameter settings can be revisited at any time during operation. Each setting change requires a confirmation from the user.
Chiang (VEMERS UC)	A (pig) & H(#5) 8 hours - Human Prototype ran for 700 hours	NR	NR	After testing many possibilities, authors found the easiest and quickest procedure for configuring VEMERS UC (Steps listed in article). The VEMERS UC development team made an online presentation to this committee and presented written documentation and videos explaining the principle of operation of VEMERS UC and the user interface. UI is touchscreen rather than a keyboard, knobs are protected from being moved or stuck accidently, test is big enough to see from a distance, all knobs increase or decrease in the same direction to allow for more intuitive operation.

Cole (Portsmouth Ventilator)	LS and A (pig) 2 hours - Animal	NR	NR	NR
Dally (OP-Vent)	LS Time NR	NR	NR	Easily Assembled: With a pre-assembled printed-circuit board, and a chassis with pre-drilled holes, an OP-Vent can be assembled in about 30 minutes using only wrenches and screwdrivers.
DeBoer (NR)	Minimal Testing Time NR	NR	NR	The ventilator is easy to operate with minimal training for a variety of situations. An easy-to-follow assembly instruction manual was prepared so anyone with a basic knowledge of engineering could assemble the product.
El Haddi (CRISIS)	LS Time NR	NR	NR	NR
F (DIGIT)	NR	NR	NR	NR
King (RapidVent)	Prototype testing, LS and A (pigs) 84 hours - Device ran 24 hours - A	NR	NR	NR
Knorr (CLEVent EV)	LS 48 hours	NR	NR	Design intended for operators with little or n experience with mechanical ventilation
Madekurozwa (NR)	LS 15 days	NR	NR	NR
Park (ALIVE Vent)	LS and A (sheep) 60 mins (A) Tested with varying resistance and compliance ranges.	NR	NR	NR

Raymond (O2U Ventilator)	LS and A (pig) Time NR	NR	NR	NR
Rebelo (ATENA)	LS and A (pig) 24 hours (LS), Time NR (A) Tested with various physiological conditions	NR	NR	NR
Von Chong (NR)	LS and A (NR) 5 minutes Stable functionality, alarms, changeable set up thresholds, and compliance with safety operations.	NR	NR	NR
Wittenberg (CoVent)	NR	NR	NR	NR
Automated Compression of AMBU Bag				
Author (Vent. Name)	**Ventilator Testing (&Sustained Use)**	**User-Interface Testing**	**Oxygen Consumption**	**Process to set-up/User-friendly**
Al Husseini (NR)	LS <4 hours	NR	NR	NR
Arcos-Legarda (NR)	LS Time NR	NR	NR	NR
Christou (GlasVent)	Mannequin Time NR	NR	NR	Requires minimal training for operation.

Dhanani (NR)	LS and A (pig) 12 hours	NR	NR	NR
Du (ETH Breathe**)	LS Time NR	NR	NR	Has a picture for set-up.
Gafford (VOV - Vanderbilt Open-source Ventilator)	LS and A (pig) 4 hours (A)	NR	NR	All manufacturing and assembly instructions were communicated to volunteers using the documents made available in the Supplementary File.
Gino (AIR – Automated Inflating Resuscitator)	No testing	No training program or test but mentions what should be emphasized during training scenarios.	NR	NR
Grimshandl (HDvent Emergency Ventilator System)	LS 3 days	NR	NR	NR
Gruslova (ABBU: Automated Bag Breathing Unit)	LS and A (pig) 32 days - Motor 7 days - AMBUBag 6-8 hours - Animal	A post training survey indicates that the user can quickly perform circuit and basic operation set-up.	NR	An ABBU training manual and instructional video were tested by respiratory therapy students at the University of Texas Health Sciences Center at San Antonio. A post training survey indicated that students could quickly perform circuit and basic operation set up.
Kindomba (ProtoVent)	No testing	NR	NR	NR
Mathanlal (ATMO-Vent)	Mannequin Time NR	NR	NR	NR
Mathew (Artifical Breathing Capability Device (ABCD))	LS (adult and paediatric) 60 days Types of tests: robustness, reliability, precision.	Software includes self-checks/self-regulatory checks.	NR	User- friendliness permitting input of parameters with a simple keypad, and visual display of set parameters. Online supplemental figure 2 shows the simple steps to input user settings of PIP, ventilation rate and I:E ratio.
Meiry (Ambo Vent)	LS and A (pig) 3 hours (A)	NR	NR	NR

	EMC, radiation emission, performance, capabilities, ease of use and weaknesses.			
Ort (MIT EV)	A (pig) Several hours Functional, operational, and alarms.	No test or training program but provides user manual	NR	NR
Palacka (Q-Vent)	LS 24 hours Tested with different ranges of PEEP and BPM settings. Additional tests completed with COVID-19 simulated conditions.	NR	NR	NR
Petsiuk (RepRapable)	LS Time NR Mechanical design was tested for consistency, accuracy and reliability.	NR	NR	NR
Terzi (eSpiro)	LS Time NR Texted with different levels of resistance and compliance.	NR	NR	NR
Truong (NR)	Minimal testing. Time NR	NR	NR	NR

	Tested different positions of how the grippers compress the bag.			
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	LS 7 days with several bag brands. A single bag was also tested at 30 and 45 days. Different disease states were account for.	NR	NR	User assembly and operation instructions provided
Vasan (MAD Vent)	LS 24 hours Tested under normal and extreme conditions.	NR	NR	NR
Von Chong (NR)	LS and A (NR) 5 minutes Stable functionality, alarms, changeable set up thresholds, and compliance with safety operations.	NR	NR	NR
Automated Compression of AMBU Bag with Electro-Pneumatic System				
Author (Vent. Name)	**Ventilator Testing (&Sustained Use)**	**User-Interface Testing**	**Oxygen Consumption**	**Process to set-up/User-friendly**
Beale (Ox-Vent)	A (pig) 23 days	NR	At nominal settings of VT = 400 mL, RR = 20/min and FIO2 = 50%,	"Qualitatively, the OxVent was easy to set-up and use."

			oxygen consumption is 4 L/min, well within the upper bound of 6 L/min set out in the RMVS specification. This oxygen consumption is lower than that of comparable transport or emergency devices; is 2, 3 times smaller than that of a standard ICU ventilator.	
Chang (Masi)	LS Time NR	NR	NR	Provides instructions on how to set-up the user interface. The UI displays mode of ventilation, ventilation settings (VT, RPM, TRIG, Ti, I:E) and external settings (PEEP, FiO2, O2 Flux). An alarm configuration screen is present to set alarms and a troubleshooting button.
Fang (AmbuBox)	LS 12 hours	NR	NR	NR
Williams (NR)	LS 5 hours Tested with various resistance and compliance levels	NR	Over the range of all tested compliances and I:E ratios, mean (SD) oxygen consumption was 0.913 (0.198) and 1.119 (0.267)	NR

			l.min)1 for tidal volumes of 500 and 700 ml respectively, reflecting the increased work required to generate the larger of the two tidal volumes.	
"Other" Ventilator Design				
Author (Vent. Name)	**Ventilator Testing (&Sustained Use)**	**User-Interface Testing**	**Oxygen Consumption**	**Process to set-up/User-friendly**
Aihaitijiang (Ori-Vent)	Balloon 24 hours	NR	NR	NR
Darwood (NR)	LS Time NR	Not so much a test. When ventilator first initialised and connected to a patient, a calibration protocol is automatically carried out.	NR	NR
Dickson (SAVe I)	A (pig) 1 hour	NR	NR	NR
Dickson (SAVe II)	A (pig) 1 hour	NR	NR	NR
El Majid (NR)	No testing	NR	NR	NR

Fernandez (ResUHUrge)	LS and A (pig) Time NR	NR	NR	Approx. manual assembly time of 8 hrs.
Haque (NR)	LS 10 mins	NR	NR	NR
Marzetti (NR)	LS Time NR	NR	NR	NR
Pereira (NR)	"Test lung" made from two sturdy plastic bags. 35 days of continuous operation Chemical, biological, bacteriological tests completed. Toxicity of materials evaluated by gas chromatography.	NR	NR	NR
Szlosarek (NR)	LS Time NR	NR	NR	NR
White (FALCON-Fast-Assembly COVID-Nineteen)	LS & A (Rabbits) LS 5 days & A 1hr 36 different test scenarios used	NR	NR	Step-by-step instructions provided
Zuckerberg (ALFA)	LS Time NR Large range of pulmonary diseases were mimicked during testing.	NR	NR	NR

APPENDIX C: OTHER GENERAL FEATURES

Electro-Pneumatic Designs										
Author (Vent. Name)	**General Durability**	**Recalls**	**Vendor & Support Contract**	**Maintenance**	**Cost (USD)** ***Corrected for 2022***	**End-User Training Program**	**Additional approvals/ clearances**	**Labelling**	**Infection Control**	**Ventilator Kit Description/Environment of Use**
Abba (Mechanical Ventilator Milano (MVM))	Several units tested continuously for 3 months	NR	NR	NR	1104	Yes	The MVM was certified by the Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA) for Emergency Use Authorization in May 2020, in response to concerns related to insufficient supply and availability of FDA-cleared ventilators for use in healthcare settings to treat patients during the COVID-19	NR	The breathing circuit and other items that get in contact with or are near the patient are replaced before each use. Includes a bacterial filter ensuring that the air exhausted from the ventilator is free from bacteria or virus particles.	NR

							pandemic, and received Health Canada Medical Device Directorate Authorization for Importation or Sale, under Interim Order for Use in Relation to COVID-19 in September 2020.			
Buytaert (HEV)	NR	NR	NR	NR	NR	NR	Requires approval/clearance	NR	All equipment that comes in contact with the patient needs to be either changed or disinfected and sterilised after every patient. There are multiple options to do this and currently autoclave cleaning is supported,	Additional space has been deliberately added, so that the working prototypes could be built as quickly as possible, and to ensure that there will be no problem to interchange components for others with similar properties if this is necessary for full medical compatibility. The resulting design iis a unit with approximate dimensions 500 × 500 × 1350 mm. The resulting cabinet is mounted

									i.e all the materials which will be reused need to withstand a temperature of 132◦C for up to 4 minutes. The entire exhaust block may be easily dismounted and swapped with a spare block, so that the ventilator can continue to be used for the next patient while the block undergoes steam or autoclave sterilisation.	on wheels, can easily be moved by one person, is very stable, and provides a convenient surface to mount the display at head height. The cabinet is closed with doors, so that easy access for cleaning is possible. The cabinet is subdivided internally into two separate compartments, front and back, housing the pneumatic and electronics components separately, which provides protection against explosion risk from potential oxygen leaks. The air tubes connect through a standard bulkhead thread connector on the outside. In this way it is easily replaceable to match hospital connection standards around the world. The prototypes have been built with

										a deliberately large amount of space to allow rapid development and exchange of parts. The final ergonomics of the HEV may look quite different depending on the requirements in the region of deployment and the accessories included. The HEV collaboration has provided two different mechanical designs to which the HEV design could be adapted to fulfill different needs. Option A is more compact and can be mounted on wheels or a trolley. Space is provided to support oxygen and compressed air bottles, as well as the turbine system, such that the entire system and accessories can be provided as one integrated unit, which can be desirable for certain geographical locations. Option B

										is a still more compact and light version, for which the total dimensions are comparable to existing commercial ventilators and the weight is targeted to be around 25 kg. The touch screen can be folded away for transport and the ventilator easily mounted on a trolley.
Chiang (VEMERS UC)	NR	NR	NR	NR	1797	NR	VEMERS UC was fully validated under the CMFCC special validation protocol. This is only valid for an emergency mechanical ventilator intended for the current pandemic circumstances. At this point in time, a full-fledged version is under development. The intention is to validate	Yes	Uses appropriate HEPA filters in both inhalation and exhalation ways. Has a disinfection test.	The unit is composed of the ventilator itself, a user interface computer, a UPS energy backup, and a stainless-steel support structure

							this new updated design according to ISO international standards ISO 80601-2-12 before beginning local and regional (Latin American) distribution.			
Cole (Portsmouth Ventilator)	NR	NR	NR	NR	289	NR	Requires approval/clearance	NR	NR	The ventilator hardware is built on a circuit board with dimensions of about 3 x 3 inches.
Dally (OP-Vent)	NR	NR	NR	NR	662	NR	Requires approval/clearance	NR	Filters present on the input and output of the unit to prevent unit from being contaminated by the patient	NR
DeBoer (NR)	NR	NR	NR	NR	723	NR	Requires approval/clearance	NR	NR	NR
El Haddi (CRISIS)	27 devices used for durability and autoclaving testing	NR	NR	NR	NR	NR	Requires approval/clearance	NR	Autoclave testing was performed by placing the device	NR

	(does not mention specifics). Drop testing performed from a height of 1.83m 3x per device.								in for a steam-based sterilizer for 30 min with a temperature of 121 ◦C and 15 p.s.i with a 5-min dry time. All performed properly	
F (DIGIT)	NR	NR	NR	NR	NR	NR	Requires approval/clearance	NR	NR	NR
King (RapidVent)	Durability of prototypes tested by running 10 devices for 84 hours	NR	NR	NR	116	NR	Requires approval/clearance	One of the only papers to classify their ventilator "We refer to the device of this study as an emergency ventilator or EV, because of its intended use in an emergency and	NR	NR

								because we demonstrate ventilation of an animal using the device."		
Knorr (CLEVent EV)	Run for 48 hr demonstrating reliable function for >58,000 cycles without interruption	NR	NR	NR	578	NR	Requires approval/clearance	NR	Mentions "can incorporate" (assuming current design does not already include). Humidification can be supplied using standard heated or passive systems as needed, and the expiratory outlet to the single limb circuit can incorporate an N100 filter to prevent	The device weighed 4 kg and measured 8 cm × 30 cm × 40 cm as tested, allowing for use on a bedside table or movable stand.

									aerosolization of viral particles.	
Madekurozwa (NR)	Demonstrated long-term durability over 15 days	NR	NR	NR	NR	NR	Requires approval/clearance	NR	NR	NR
Park (ALIVE Vent)	NR	NR	NR	NR	1546	NR	Requires approval/clearance	NR	High-efficiency particulate air (HEPA) filtering system, preventing the exhaust of airborne viruses.	NR
Raymond (O2U Ventilator)	NR	NR	NR	NR	1022	NR	Received FDA Approval	NR	HME	NR
Rebelo (ATENA)	NR	NR	NR	NR	NR	NR	Requires approval/clearance Specifically - Additional tests for extended parameter limits, pressure support, and pre-clinical studies demonstrated that it can	NR	NR	Length 23.6 in Width 19.68 in Height 66.3 in Weight 53.4 kg Has wheels for better movability but cannot be moved during operation

							perform as required. Further clinical trials must be performed to ultimately and unequivocally validate ATENA in clinical practice.			
Von Chong (NR)	NR	NR	NR	NR	NR	NR	Requires approval/clearance	NR	NR	NR
Wittenberg (CoVent)	NR	NR	NR	NR	NR	NR	Requires approval/clearance	NR	NR	NR
Automated Compression of AMBU Bag										
Author (Vent. Name)	**General Durability**	**Recalls**	**Vendor & Support Contract**	**Maintenance**	**Cost (USD)** ***Corrected for 2022***	**End-User Training Program**	**Additional approvals/ clearances**	**Labelling**	**Infection Control**	**Ventilator Kit Description/Environment of Use**
Al Husseini (NR)	NR	NR	NR	NR	583	NR	Never tested on animals or humans - requires approvals and clearances	NR	NR	It is portable, weighing 9 lbs (4.1 kg) and measuring 11.25 x 6.7 x 8 inches (285 x 170 x 200 mm) , and has a handle and easy

										to use latches. The prototype can display settings and status on a computer screen.
Arcos-Legarda (NR)	NR	NR	NR	NR	469	NR	Requires approval/clearance	NR	NR	The total number of mechanical parts is 22, the overall dimension is 25 X 25 X 25 cm, and the total weight is 3.5 kg.
Christou (GlasVent)	NR	NR	NR	NR	282	NR	Requires approval/clearance	NR	NR	NR
Dhanani (NR)	Tested for 3 days (72 hrs) continously	NR	NR	NR	231	NR	Requires approval/clearance	NR	NR	NR
Du (ETH Breathe**)	NR	NR	NR	NR	1104	NR	The device also successfully fulfills a list of requirements defined that is based on the Medicines and Healthcare products Regulatory Agency (MHRA) guidelines for Rapidly Manufactured Ventilator Systems in the COVID-19	NR	Exhalations from the patient are filtered by a HEPA filter	Size 30 x 25 x 35 cm

							crisis [18], the Code Life Ventilator Challenge [19], and the ISO80601-2-12 standard.			
Gafford (VOV - Vanderbilt Open-source Ventilator)	Continuous operation for >14 days Durability experiments on a mechanical test lung, pursuant to testing standards set forth in ISO 80601-2–80:2018(E), "Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Insufficiency"	NR	NR	NR	NR	NR	Requires approval/clearance The only components that come into contact with the patient's air-way are clinically approved	NR	The only components that come into contact with the patient's air-way are clinically approved and disposable or otherwise subject to rigorous reprocessing protocols.	NR

Gino (AIR – Automated Inflating Resuscitator)	NR	NR	NR	NR	84	NR	Requires approval/clearance	NR	Follows MHRA guidelines: 1. All parts coming into contact with the patient's breath are disposable or designed to be reusable. 2. All working components are contained within an impermeable casing. Healthcare workers are able to manually wipe clean all external surfaces. 3. The AIR can connect to a viral hygroscopic filter.	NR
Grimshandl (HDvent Emergenc	NR	NR	NR	NR	578	NR	"Our system has not yet been tested in	NR	A HEPA filter between	NR

y Ventilator System)							a clinical setting and will not be submitted for approval as a medical device"		the valve and the patient ensures that the in- and exhaled air is free of virus material and particulate contaminants.	
Gruslova (ABBU: Automated Bag Breathing Unit)	Tested durability of bags for >7 days. Tested Cadone electric motors for continuous use for > 30 days.	NR	NR	NR	2208	Yes	Requires approval/clearance	NR	NR	NR
Kindomba (ProtoVent)	NR	NR	NR	NR	221	NR	Requires approval/clearance	NR	NR	NR
Mathanlal (ATMO-Vent)	NR	NR	NR	NR	NR	NR	Requires approval/clearance	NR	NR	NR
Mathew (Artifical Breathing Capability Device (ABCD))	NR	NR	NR	NR	883	NR	Requires approval/clearance	NR	NR	Lighter weight than current mechanical ventilators, sturdy, easy to handle and safe to transport. Physical characteristics

										making it feasible to place at the patient's bedside, without interference with clinical observations or procedures. The device is just 15 inches by 12 inches, with an overall height of 20 inches
Meiry (Ambo Vent)	NR	NR	NR	NR	685	NR	Requires approval/clearance	NR	Design includes an HME filter	It is compact and lightweight, 40 cm long, 30 cm wide, 30cm high, and weighs 5 kg (without its backup battery). It can be easily positioned next to the patient's beds. Compact and lightweight. Can be positioned with flexibility around the patient's bed, up to 1.5 meters away without fear of increasing the dead space.
Ort (MIT EV)	NR	NR	NR	NR	NR	Yes	Requires approval/clearance	NR	NR	NR
Palacka (Q-Vent)	Performed durability tests (check	NR	NR	NR	NR	NR	Requires approval/clearance	Yes	Exhaled air from the PEEP comes out	The high durability of the aluminium blocks along with their low density

	article for details on type of tests).								to the integrated filter with a chosen filter pad of FF1-FFP3 to remove any airborne pathogens during exhalation. The filter includes a germicidal chamber with UV LEDs and a heater element. Table 5 in article - Validation test results of the infection control	ensures that the device's overall weight is kept under 5 kilograms. Lightweight, with backup battery supply, a portable system with robust design
Petsiuk (RepRapable)	NR	NR	NR	NR	197	NR	Requires approval/clearance	NR	NR	NR
Terzi (eSpiro)	NR	NR	NR	NR	NR	NR	Requires approval/clearance	NR	NR	The overall system is hosted in two stacked and attached plastic boxes for a total size of 48 × 40 × 60 cm, weighing 27 kg.

Truong (NR)	NR	NR	NR	NR	NR	NR	Requires approval/clearance	NR	HEPA filter included	NR
Urbina (Automated manual resuscitator- based emergency ventilator-alternative (AMREV))	A single Rusch BVM was tested a 30 and 45 days to evaluate the consistent after approx. 1.3 million compressions	NR	NR	NR	NR	NR	Requires approval/clearance	NR	NR	The AMREV is adaptable to multiple clinical environments with a housing design and attachment configuration that supports mounting of the device to a bedside IV pole.
Vasan (MAD Vent)	NR	NR	NR	NR	289	NR	Requires approval/clearance	NR	Designed to provide easy access for maintenance and disinfection. Includes filter.	NR
Von Chong (NR)	NR	NR	NR	NR	NR	NR	Requires approval/clearance	NR	NR	NR
Automated Compression of AMBU Bag with Electro-Pneumatic System										
Author (Vent. Name)	**General Durability**	**Recalls**	**Vendor & Support Contract**	**Maintenance**	**Cost (USD)** ***Corrected for 2022***	**End-User Training Program**	**Additional approvals/ clearances**	**Labelling**	**Infection Control**	**Ventilator Kit Description/Environment of Use**

Beale (Ox-Vent)	NR	NR	States Smith and Nephew joined the project to further develop and manufacture the device at scale	NR	1244	NR	The device passed electromagnetic compatibility and electrical safety tests performed in April 2020	NR	All patient-facing components are inexpensive single-use parts currently in widespread clinical use. This ensures biological safety, familiarity for users and, by replacing these parts between patients, helps minimise the risk of cross-contamination. Includes HMEF.	It is 480 mm high, 290 mm wide and 240 mm deep, weighs 7.25 kg, and can stand on the floor or be clipped to a bed or trolley. The body consists of a single sheet of laser-cut and folded steel, onto which the ventilator box assembly and control panel are bolted. The majority of electrical components are integrated directly onto the main circuit board at the time of manufacture of this component, which minimises the amount of assembly required further down the line.
Chang (Masi)	NR	NR	NR	NR	1104	NR	At the date of submission, 300 Masi units have been deployed to ICUs in our territory as the first locally designed and	NR	Before ventilating a new patient, the corrugated inspiration circuit tubes, ET and HMEF	NR

							produced ventilators under the approval of DIGEMID (Peruvian regulatory authority).		filters must be replaced by clinical standard. Mentions "easy-to-disinfect" design.	
Fang (AmbuBox)	NR	NR	NR	NR	347	NR	Requires approval/clearance	NR	The expired air from the patient is exhausted from a standard adjustable PEEP valve, while passing through a HEPA filter to capture aerosols from the patient, protecting health care workers.	NR
Williams (NR)	NR	NR	NR	NR	333	NR	Requires approval/clearance	NR	Mentions ventilators can be readily manufactured in bulk as disposable	NR

									single-use items to prevent cross-infection	
"Other"										
Author (Vent. Name)	**General Durability**	**Recalls**	**Vendor & Support Contract**	**Maintenance**	**Cost (USD)** ***Corrected for 2022***	**End-User Training Program**	**Additional approvals/ clearances**	**Labelling**	**Infection Control**	**Ventilator Kit Description/Environment of Use**
Aihaitijiang (Ori-Vent)	Ventilator bellows ran continuously for 24hrs.	NR	NR	NR	22	NR	Requires approval/clearance	NR	NR	Light weight
Darwood (NR)	NR	NR	NR	NR	228	NR	Requires approval/clearance	NR	NR	Functional device weighs approx. 450g and is able to fit comfortably into most equipment pockets.
Dickson (SAVe I)	NR	NR	NR	NR	2254	NR	FDA Approved	NR	NR	Weigh 1.4 kg
Dickson (SAVe II)	NR	NR	NR	NR	2653	NR	Requires approval/clearance	NR	NR	Weigh 1.4 kg
El Majid (NR)	NR	NR	NR	NR	NR	NR	Requires approval/clearance	NR	NR	NR
Fernandez (ResUHUrge)	NR	NR	NR	NR	620	NR	Requires approval/clearance	NR	The design incorporates a bacterial-viral filter	NR

									to avoid contamination of the device.	
Haque (NR)	NR	NR	NR	NR	314	NR	Requires approval/clearance	NR	Design includes a HEPA filter and a second filtration through the Heat and Moisture Exchanger (HME) filter before being inhaled by a patient.	Portability of the system was further increased through the implementation of the retractable mount that can be laid flat on the top body when not in use. The tablet used as the GUI and also can be carried out to a considerable distance if needed.
Marzetti (NR)	NR	NR	NR	NR	237	NR	They put a disclaimer - "This artificial ventilator is not intended to become a commercial product used in a modern hospital. It has not been certified as compliant to state of art medical regulations and will not be asked for. However, it	NR	NR	NR

							has been functionally tested successfully on an artificial lung. This test has been detailed in written report. However, Toulon University students and researchers cannot be liable of any damage, injury or death resulting from the use of this device."			
Pereira (NR)	Ventilator run for 35 full days (continuously)at rate of 120 bpm - corresponding to 140 days of normal operation at 30 bpm.	NR	NR	NR	NR	NR	Requires approval/clearance	NR	HMEF Filter included	NR
Szlosarek (NR)	NR	NR	NR	NR	110	NR	Requires approval/clearance	NR	It is possible to disassemble the ventilator and to sterilize all	The manufactured prototype has the dimensions 300 mm × 200 mm × 60 mm and a weight of 1.04 kg (including manometer).

									components	
White (FALCON-Fast-Assembly COVID-Nineteen)	NR	NR	NR	NR	NR	NR	Requires approval/clearance Specifically states - " prototype device was not constructed or tested under ISO standards for medical devices (ISO 13485:2016) and is not certified by the FDA's EUA or other regulatory agency for human use. "	NR	NR	NR
Zuckerberg (ALFA)	NR	NR	NR	NR	114	NR	Requires approval/clearance	NR	NR	NR

APPENDIX C: ENGINEERING COMPONENTS (HARDWARE)

Electro-Pneumatic Designs	HARDWARE						
Author (Vent. Name)	**Oxygen Sensor**	**Pressure Sensor**	**Materials**	**Parts**	**Motor**	**Control System**	**Ventilator Design (detailed)**
Abba (Mechanical Ventilator Milano (MVM))	Yes	Yes	Stainless steel enclosure	Doesn't provide list of parts. Relief valves, negative pressure relief, PEEP valve, check valve, bacterial filter, inspiratory valve, expiratory valve, gas blender, typical connections to the patient and to the oxygen and medical air lines, proportional solenoid valve,	NR	The board houses a micro-controller (Espressif-ESP32), a Raspberry Pi 4, and the supervisor. The ESP32 includes a dual-core 240 MHz micro-controller, 0.5 MB of RAM, Wi-Fi, and Bluetooth connectivity. It ESP32 is programmed using an Arduino core (Espressif).	Includes a gas blender with incoming air and O2, pressure valves, relief valves, negative pressure relief valves, vent, PEEP valve, check valve and a connection to the patient.
Buytaert (HEV)	Yes	NR	NR	• A proportional solenoid inhale valve with 8 mm internal diameter. • Two fast acting solenoid valves for inlet of air and	NR	Arduino (hardware control) ESP32 Microcontroller chip	The design is based around a central buffer which pneumatically decouples the ventilator circuit into two, almost independently functioning parts,

				oxygen into the buffer volume. • A solenoid valve for purging. It could be low volume, that in case of over-pressure only some air is released. • An exhale ON/OFF valve with large diameter internal orifice. • Five check valves. • Two pressure relief valves, one for the patient circuit and one for the buffer. • A 10 L buffer container. • Two pressure regulators, able to operate up to a maximum pressure of 10 bar, one for oxygen and one for air. • Eight pressure sensors. • A bidirectional differential pressure			relating to the filling of the buffer and the gas supply to the patient.

				sensor for the flow measurement. • Two temperature sensors. • PEEP valve • Breathing circuit • Filters • Humidifiers			
Chiang (VEMERS UC)	Yes	Yes	No special fabrication processes involved.	All off the shelf parts. Pneumatic electro valve, pressure regulating valve, flow regulating valve, gas tank, check valve, other pneumatic connectors, UPS Enersafe ESIT 1000, pressure sensor C-ROM model CNK 268, flow sensor, oxygen sensor, pressure sensor, MOsfet modules, Microcontroller ADC, other electronic components,	NR	Arduino Mega 2560	Electro-pneumatic circuit is composed of (1) Intake stage (two intakes for air and oxygen), (2) Blending stage (blending of air and oxygen to the desired FiO2%). Inspiratory Stage (gas mixture passes through the directional solenoid valve). Exhalatory stage controlled by 4 solenoid directional valves.

				Pastic cabinet, Medic table.			
Cole (Portsmouth Ventilator)	NR	Yes	NR	Medical air supply (50 PSI), Oxygen supply (50 PSI), charging solenoid, pressure chamber, inspiratory solenoid, expiratory solenoid, pressure transducer on PCB, inspiratory limb and expiratory limb.	NR	Mentions microcontroller costing under $2 USD but doesn't mention brand. The hardware and software controlling the ventilator were designed by our group specifically for this project.	The basic design involves three electrically controlled solenoid valves, a pressure chamber, the patient breathing circuit, a positive end-expiratory pressure valve, and an electronics control system. The ventilator uses a standard ventilator breathing circuit. It incorporates three solenoid valves (Charging, Inspiratory, and Expiratory represented by "C," "I," and "E," respectively, in the above diagram) controlled by a simple microcontroller-driven electronics circuit.
Dally (OP-Vent)	NR	Yes, 3.	All components that pass air or O2 to the patient are brass, stainless steel, or a safe plastic. Push-connect fittings with PVC	Exhale diaphragm valve, 3-way valve, exhale regulator, inhale regulator, PSV, flow meter,	Mentions motor but no brand or type	ATMega1284P	OP-Vent is an open-source ventilator based on closed-loop control of a proportional solenoid valve (PSV). The exhale circuit

			hose are used in the path that controls the exhale valve.	pressure relief, one-way valve.			consists of a pressure regulator, a three-way solenoid valve, and a diaphragm valve.
DeBoer (NR)	Yes	Yes	The mounting plate and enclosure material was aluminum, but other readily accessible materials can be used (e.g., plywood).	Pneumatic components ¼" NPTF to ¼" Hose, Pneumatic Fitting ¼" Pneumatic Hose Tee ¼" Pneumatic Hose 18.5 CFM 12V DC Pneumatic Solenoid Valve ¼" Flow Control Electrical components 16×2 LCD Display & Keypad Shield 6V -180 deg Servo Arduino Mega Relay Module ±7kPa Differential Pressure Sensor 200kPa Gauge Pressure Sensor ±100kPa Compound	NR	"Simple microcontroller programmed using open-sourced Arduino software" Arduino Mega	The mechanical ventilator was designed to be used with compressed air and oxygen (O2) using standard hospital pipeline supply or mobile tanks. The first step of the ventilator is to regulate the input gases into lower-pressure reservoirs (R1 and R2 of Figure 1) to 1-pound per square inch (PSI). The pressure regulation is conducted by selective solenoid activation of SV1 and SV3 until the required pressure was achieved. The final reservoir (R3) is then pressurized with the required fractional concentration of inspired oxygen (FiO2) mix by selective activation of SV2 and SV4 and verified by a single oxygen sensor (O1).

				Pressure Sensor			The FiO2 level is controlled by the flow metering valves (FMV1 and FMV2) located between R1, R2 and R3. The final FiO2 mixture is then presented to the patient by activating the solenoid SV5, in which the mixture is subjected to a water trap and the required filters used in ventilation. When the process of inhalation is complete, the ventilator applies the required backpressure for exhalation. The back pressure is generated by metering the flow of the exhalation conducted by FMV3.
El Haddi (CRISIS)	No	No	Uses 3Dprinted parts using selective laser sintering technique (SLS). (Average print time is 5 hours).	3D printed materials, a silicone membrane and a spring.	NR	NR	Resuscitator Device which does not depend on a bag-valve system and instead utilizes a modified pressure regulated ventilatory system. The resuscitator provides a continuous flow of blended oxygen until

							a peak inspiratory pressure is reached and the exhale rate is determined by the user.
F (DIGIT)	NR	NR	NR	NR	NR	NR	NR
King (RapidVent)	NR	Yes	The diaphragm material is Sil-30, which provides the softest available material on the Carbon machine. The total number of parts during the initial development phase was 283, which took 66 hours to print, divided over 43 builds. Additive manufacturing was used to develop this ventilator.	O2 Adapter, Patient-T, Modulator	NR	Shows microcontroller in figure but doesn't mention type	The RapidVent is powered by gas pressure from the oxygen source and uses a valve to cycle between inhalation and exhalation at specific pressures set by the operator. During inhalation, oxygen flows through the ventilator and into the patient's lungs, while the internal pressure increases until the maximum pressure at the end of inspiration. During exhalation, the oxygen supply continues to flow through the device and out through the exhalation port, which evacuates any CO2 from the device.
Knorr (CLEVent EV)	Yes	Yes	NR	Apart from the enclosure, the parts were easily found	NR	Arduino Nano 3 (ATmega328)	Ventilator design has a expiratory pneumatic circuit and an inspiratory

				and sourced from online retailers. Pneumatic valves were also easily sourced in this circumstance and could be found online or at local distributors.			pneumatic circuit. Inspiratory circuit includes a pressure relief valve. Expiratory circuit include a pressure regulator, PIP flow resistor, PEEP flow resistor and 3/2 solenoid valve.
Madekurozwa (NR)	Yes	Yes	Brass	Our proposed solution combines four on-off valves, a two-litre reservoir, an oxygen sensor and two pressure sensors. Replaced the proportional solenoid valve found n traditional ventilators with 2/2(two-port), or "on-off" solenoid valve The solenoid valves came from Emerson (262 series). The pressure sensors were from	NR	Programmable logic controller (Barth STG600) Teensy Microcontroller (PJRC)	NR

				Omegadyne (PXM319), and the oxygen sensor was from Teledyne (R-22MED). Pneumatic fittings (manifolds, connectors and bulkheads) were all standard off-the-shelf components using 1/8″-1/2″ BSP threads or 10mm push fittings, with the exception of the ventilator tubing connection ports, which were machined from brass.			
Park (ALIVE Vent)	Yes	Yes. Connected to the inspiratory solenoid for continuous monitoring of lung pressure.	No 3D printing involved.	Used commercially available parts. No 3D printing involved	NR	Mentions microcontroller but not the type - "The circuit board contains two N-channel MOSFETs connected to the microcontroller" GUI designed using PyQT5.	Our novel device operates using compressed oxygen and air to drive inspiration, while two solenoid valves ensure one-way flow and precise cycle timing. The ALIVE Vent is comprised of three subsystems: (1) the pressure regulating subsystem (PRS),

							(2) the inspiratory/expiratory subsystem (IES), and (3) the control and monitoring subsystem (CMS).
Raymond (O2U Ventilator)	NR	Yes.	NR	Contains 118 parts Inspiratory and expiratory valves Spirometer-based expiratory volume sensor Flow measuring sensors ET Tube HME Muffler Dual-limb Patient circuit Flow controller User Interface PEEP Valve Exhale actuation valve Exhale Diaphragm valve Inspiratory pressure sensor Emergency Valve Pressure limit pop-off valve Main control	NR	NR	The O2U ventilator relied on a known flow rate entering the system and control of the valve timings. The pressure-limited, time-cycled design included continuous monitoring of the pressures to detect any leaks or obstructions that could risk patient or device safety. The respiratory cycle of the ventilator includes, at the outset, closure of the inspiratory valve. With the onset of inspiration, the valve is opened and pressurized gas flow unimpeded to the patient until the inspiration time is complete. At the end of the inspiratory time, the inhalation valve is closed and the expiratory value is opened and

				valve Check ValveO2 Blender			passive recoil of the lung and patient chest wall permits the patient to exhale
Rebelo (ATENA)	Yes	Yes	Stain-less steel Sealed metal industrial boxes	Pressure Valves Flow Sensors Transformers Safety fuses and breakers Piezo-electric valves Pinch Valve	NR	NR	Air and oxygen enter the ventilator from a compressed source (likely hospital) where they both separately pass filters, pressure sensors, electro valves and flow sensors before mixing together. Once mixed, the air/oxygen mixture continues through the machine passing more pressure sensors, O2 sensors, under pressure and over pressure valves before entering the patient. The exhalation circuit consists of a flow sensor, exhalation pressure sensor and exhalation electro valve. The system has a control module connected to O2 electro valve, air electro valve, and exhalation electro valve to control data.

Von Chong (NR)	NR	Yes	Brass/FKM Brass/PTFE Polyamide Copper	Tubing (copper) Inspiratory valve Electro valves Proportional valve (Brass/FKM) Expiratory valve Solenoid valve (Brass/PTFE) Pressure sensor Flow sensor (multiple material) Pneumatic hose (Polyamide) Hose fittings (polyamide)	NR	Teensy 4.0	The IPPV device consists mainly of a pneumatic system and an electronic system. The pneumatic system involves the tubing and the electro-valves to be operated by the control circuit. In the IPPV MV, the algorithm was implemented as a closed loop On/Off controller
Wittenberg (CoVent)	NR	NR	NR	NR	NR	NR	NR
Automated Compression of AMBU Bag	**HARDWARE**						
Author (Vent. Name)	**Oxygen Sensor**	**Pressure Sensor**	**Materials**	**Parts**	**Motor**	**Hardware/Micro-Controller**	**Ventilator Design (detailed)**
Al Husseini (NR)	NR	Yes	Enclosed lid made of **acrylic**	Battery, CAM, on/off switch, microchip, motor controller, motor, AMBU Bag, latch,	Solarbiotics motor driver	Arduino Duemilanove	The ventilator delivers breaths by compressing a conventional bag-valve mask (BVM) with a pivoting cam arm, eliminating the

				handle, pressure sensors.			need for a human operator for the BVM. The cam concept utilizes a crescent-shaped cam to compress the BVM, which allows smooth, repeatable deformation to ensure constant air delivery. As it rotates, the cam makes a rolling contact along the surface of the bag and unlike the roller-chain, achieving low-noise of operation. By controlling the angle of the cam's shaft, the amount of air volume delivered can be accurately controlled.
Arcos-Legarda (NR)	NR	Yes	Housing structure is made of two plates made of acrylic - poly(methyl methacrylate). Polyglass, stainless steel, Polypropylene (general purpose), Steel	Lateral press 1, Spacer, Ambu bag, Pivot spacer, Pviot, Bearing, centering, bearing end, axis 1, traction, lateral press 2, strap, pin, ambu base, motor base, motor coupling, flat washer M6	DC geared motor	Arduino Mega 2560 Rev 3	The proposed design is a strap-based, bag-valve ventilator. In this design, the strap wraps around the bag and around a pivot roller. The pivot rotates around a fixed axle located below the bag. The fixed end of the strap is attached to a fixed pin on the

				x 12, Hex socket cylindrical M6 x 25, hex nut autolock M6, pin seger 12mm, Hex socket screw M4 x 8, DC gearmotor, Encoder			opposite side of the bag. The moving end of the strap is attached to a rotating wheel below the roller. The rotating wheel can be actuated by a stepper motor or a DC geared motor.
Christou (GlasVent)	NR	Yes	Majority of structure made from acrylic sheets. Moving parted were 3D printed with polylactic acid filament.	BVM, acrylic case, bolts and nuts, steel rods,	Stepper Motor The heart of the system is the stepper motor driver printed circuit board (PCB) module (DRV8825 Stepper Motor Driver Carrier, High Current, Pololu electronics).	Arduino Due	GlasVent is an automated version of manual resuscitator device, commonly known as big valve mask (BVM) or artificial manual breathing unit (AMBU) bag. The system utilizes a crank—slider mechanism to convert the rotation motion of the motor to reciprocal linear motion. The base of the motor is able to slide toward or away from the BVM to regulate the maximum compression of the bag and provides control over the tidal volume exerted by the system. The system has

							three operating schemes: a) mains or supply operated; b) battery operation, and c) manual operations via a small handle attached to the rotating disc of the system.
Dhanani (NR)	No	No	The machine was designed using CAD software (Autodesk Fusion 360). A prototype (version 1) was constructed with CNC cut plywood frame and polylactic acid (PLA) plastic gears. Motor material needs to be heat tolerant as the first ventilator design has issues with the heat the motor produced ((PLA) and ABS are not heat tolerant).	• The artificial manual breathing unit (AMBU. • A commercially available stepper motor (Nema 23 with 3Nm of holding torque) • motor driver (Toshiba TB6560) were powered by a 12 V 5A power supply. • A microcontroller (Arduino Mega 2560) provided the control software (written in Arduino programming language) • thin-film transistor (TFT)	Stepper Motor	Arduino Mega 2560	The ventilator mimics hand bagging by compression of the bag on one side using a mechanical arm which rotates about a fixed pivot point. The arm is driven by a computer-controlled motor and the machine has just two moving parts.

				liquid crystal display (LCD) display (Arduino Shield TFT) for the user interface.			
Du Pasquier (ETH Breathe**)	No	No, use flow transducers instead.	The paddles are 3D printed in ABS using FDM, however, the shapes are designed in 2.5D so that they could also be cut from plastic or hard foam. 23 out of 33 parts are standard (72%) and nine are custom. Of the nine custom parts, eight can be made by hand in a machine shop, using laser cutting or water jetting; the ninth can be made by hand in a machine shop. Of the nine custom parts, only the fingers, which transmit the compressing force, could be prone to breaking; they are made of	Microcontroller, motor driver, sensors (pressure and flow), interface	Motor Driver: IG420504-SY5513 (TRU Components Conrad Electronic SE, Hirschau, Germany) AKA DC geared motor	Arduino Mega 2560	The complete system can be broken down into four modules: mechanical system, breathing circuit, controls and electronics, and user interface. The compression mechanism and breathing circuit is composed of 4 main subsystems: the motor and holder, the gear system (composed of the gears and the paddles for compression of the bag), the bag holders and the assembly mounting structure. The mechanical compression system is composed of 3 gears: one driving gear that is connected to the motor and two driven gears mounted on parallel

			steel to avoid this problem.				shafts. Mechanical design is inspired from the MIT Emergency Ventilator Project (or AKA MIT E-vent). The breathing circuit has the following main requirements: (1) Dead-space in tubing is minimized to prevent re-inhaling CO2 (2) Exhalations from the patient are filtered by a HEPA filter (3) The PEEP is controlled with a standard mechanical PEEP valve (4) The flow and pressure sensor are easily integrated in the tubing (5) Only standardized and certified medical equipment are used.
Gafford (VOV - Vanderbilt Open-source Ventilator)	No	Yes	Plywood	Windshield wiper motor (low cost, availability and ease of sourcing), Arduino-based control electronics. Doesn't	Windshield wiper motor	Arduino-based control electronics	The purpose of the device is to mechanically compress an Ambu bag. The VOV described in this article provides ventilation by compressing an Ambu bag by a programmable

				mention must else around parts.			amount, implementing the VCV paradigm. The SYM allows for a sliding mechanism to compress the bag and deliver the desired/set amount of TV. The SYM is a reciprocating motion mechanism that converts rotary motion into linear motion.
Gino (AIR – Automated Inflating Resuscitator)	NR	Yes, 2.	Each AIR component was purchased, fabricated from commonly available commercial material, or printed using a 3D printer. This bag is made of a malleable material.	Exhalation port, patient valve, oxygen inlet, self-inflated bag, pressure control system, oxygen reservoir, oxygen reservoir socket, patient connection port, patient connector, pressure valves	Mentions motor but no type	NR	Self-inflating BVM with four parts: exhalation port, patient valve, self-inflated bag and oxygen inlet.
Grimshandl (HDvent Emergency Ventilator System)	NR	Yes, 2.	Sheet metal enclosure	Ambu-bag, mechanical arms, safety valve, Y-valve PEEP, spirometer tube,	NEMA 34 Stepper Motor	Arduino Mega2560 controller. Raspberry Pi	Air Management: We work with the Dr¨ager Oxylog 2000 Ventstar® breathing circuit and theAmbuSPUR II system. The bag

				HEPAfilter, HDvent device, monitoring unit.			takes in room air or oxygen-enriched room air. It is followed by a 40 mbar over-pressure safety valve and 2 metres of flexible hose. Near the patient a membrane Y-Valve separates in- from exhaled air. The open end of the Y-Valve is piloted with a mechanical valve from the Ambu-bag system to set the positive end-expiratory pressure (PEEP). The flow rate of in- and exhaled air is monitored with a spirometry tube. The pressure is picked up near the patient mouth piece using two thin (2mm ID) hoses connected to the HDvent. Mechanical Design: The compression system consists of two mechanical arms and is driven by a NEMA 34 stepper motor rated at 4Nmholding torque. One arm is fixed and the other

							one rotates on a ball bearing. The device is completed with a sheet metal enclosure which provides electrical grounding and protection from pinch hazards.
Gruslova (ABBU: Automated Bag Breathing Unit)	No	Yes, 2.	NR	ET Tube, Drager SafeStar Filter, Patient airway pressure sensing line, PEEP valve, 6ft, 22mm ID corrugated circuit tubing, BAG pressure sensing line, Ambu-bag, bag PEEP valve.	Cardone electric motors	NR	Caster Wheel and Lever arm compress an AMBUBag enclosed in a case with knobs on front to control various ventilation parameters.
Kindomba (ProtoVent)	NR	NR	The ProtoVent consists of 3D printed components and store-bought hardware. Several essential components were 3D printed to help support the base and improve functionality. First, a soft pad is used at the tip of the actuator to softly hit the bag.	Reservior bag, self-inflating bag, face mask, power supply unit, base and support, bag support, soft pad, DC motor, curved lock, controller, side adjustable lock.	DC gear motor	NR	The ProtoVent combines design elements from existing DC motor actuator systems into an easily printed, assembled, and installed device. The ProtoVent consists of four main parts: reciprocating motion system, bag valve mask, base components, and auxiliary components.

			Second, two side adjustable locks were placed on the sides of the frame. The base frame used to support the DC motor system was made of .5 x 2 x 4 birch hardwood. The bag support was made of a 3D printed part with PLA plastic.				The reciprocating motion system consists of a small 12V 5A linear actuator with a DC gear motor, a controller, and a power supply unit. The BVM with the self-inflating bag for the ProtoVent is a Ventlab V-Care Small Adult Resuscitator VN 5000 series. The volume of the bag is 1500 mL, and its tidal volume is 1500 mL.
Mathanlal (ATMO-Vent)	NR	1 Pressure sensor located in proximal tube close to patient	NR	Arduino Mega 2560, Solenoid safety valve, Differential Pressure Sensor, Flow Meter, Raspberry Pi, Monitor, Linear Actuator, Flow meter, check valve, Reservoir bag, BVM, Duck-bill Valve 1, MAF Sensor Adaptor, Duck-bill Valve 2, Pressure	Motor driver VHN3SP30	2 Arduinos (Mega 2560) Raspberry Pi (Raspbian operating system is used)	BVM using a linear actuator. Has 6 sections to its design: Air-Oxygen Mixture Optimization, Actuating Mechanism, Measurements, Power Supply and Conditioning, Computing and Interface, PC-Cabinet

				sensor and relief adaptor			
Mathew (Artificial Breathing Capability Device (ABCD))	NR	2 pressure sensors (1) in adapter to read PIP delivered to patient; (2) close to outlet of SIB to read PIP released from SIB	NR	NR	Stepper-motor driven ball screw and ball nut drives a single moving metal plate	NR	A stepper- motor driven ball screw and ball nut assembly drives a single moving metal plate to intermittently compress a SIB.
Meiry (Ambo Vent)	NR	Pressure sensor: Sensirion SDP600 Series	1) Polycarbonate skeleton carved with CNC laser cutting. 2) 3D printed parts. 3) Polyamide polymers with short fiberglass 4) Polylactic acid 5) Aluminum	Oxygen reservoir bag, oxygen tubing connector from regulator, connection to patient, HME filter, pressure sensor pipe connection, PEEP adapter, PEEP valve, BVM, standard BVM 3-way valve, ventilator tubing & pressure sensor pipe, safety inlet valve.	AndyMark-2235a Snow Blower Motor	Arduino Nano	Automated BVM mechanism. The device includes a frame and mechanical arm designed to periodically compress standard >1.1 L BVMs.
Ort (MIT EV)	No	Yes, connected	Aluminum frame, steel, tab-in-slot sheet metal parts	NR	Motor Selection: AndyMark	Arduino Mega	Automated resuscitator bag that uses a dual-hand

		to patient airway.			PG188 - gearmotor with integrated encoder. Motor Driver: BasicMicro Roboclaw Solo 30A		robotic gripper design to ensure the bag is compressed naturally on both sides as it would when squeezed by a human hand.
Palacka (Q-Vent)	NR	Yes, including pressure cough sensor	Polylactic acid (PLA) as a base and the antimicrobial dye Phloxine B which is secured to a Saponite matrix. Simple processing with the aid of a 3D printer (PLA and its composites), adequate durability of parts (aluminium chassis), as well as low electrical and thermal conductivity (ABS). The 3D-printing was carried out by the Rep-Rap 3D printer, Raiscube i3 (Marlin firmware 2.0.5.4,	Heater, humidifier, air inlet with attached particle filter replenishes oxygen source, lever, actuator, air outlet that pushes breathing mixture through failsafe valve, double-way valve, adjustable PEEP, filter composed of FFP3 micro texture and UV sterilizing LED and ceramic heated cartridge, microcontroller.	Rotary actuator based on a servomotor	Microchip S9GN48 V	In the Q-vent frame all movable and fixed parts, including the microcomputer are mounted. Mounted on top of the frame is a stand to clamp an Ambu breathing bag at the side of the discharge valve. The Ambu bag is compressed using a movable lever attached to a bicycle chain, spring and on the other side to the trimmer nylon line that ensures compression of the bag by winding on a pulley. Pulley is driven by a Servo.

			Arduino®) at the heated bed temperature of 60°C and layer thickness of 0.1 mm.				
Petsiuk (RepRapable)	NR	Yes. 2 located connected between the ventilator and patient via airway tube.	NR	1) bag mounting system, 2) self-inflating bag, 3) motor setup, 4) compression mechanism (pusher), 5) Positive End Expiratory Pressure (PEEP) valve, 6) feedback pressure sensors, 7) control system, 8) power supply with backup battery, 9) air mask, 11) airway pressure sensor.	NEMA-23 stepper motor	Arduino Uses an open-source real-time operating system (FreeRTOS) library for Arduino	Self-inflating BVM compression mechanism with controllable TV, RR, and I:E. The design is controlled by an Arduino microcontroller and uses stepper motors.
Terzi (eSpiro)	No	Yes	NR	Pivoting arms equipped with 3D printed jaws Stepper Motor Paraglider cord Pulley Bag Expiratory valve Electromagnetic control valve	Stepper motor	STM-32 controller connected to Raspberry Pi	Automatized BVM approach, providing closed loop control, monitoring and safety features. The mechanical compression of the bag is performed by two horizontally pivoting arms equipped with 3D

				One-way valves Pressure sensors			printed jaws to maximize the possible drawn volume and to reduce bag wear. Arms are driven by a 4.5 Nm gearless stepper motor, which pulls a paraglider cord winding through a freewheeling pulley on each arm, forming a snatch block reduction system. Positive end-expiratory pressure (PEEP) is generated by a tube dipping in water at the desired and controlled level. The up and down motion of the tube into the water column is controlled by the stepper motor.
Truong (NR)	No	Yes	"Low-cost, easy to find materials"	Humidifier HEPA filter Chamber for mixed air (oxygen and air) BVM Ventilator Flow sensor Sensor system PEEP valve One-way valve Relief valve Grippers DC Motor	DC Motor	NR	At the inspiration phase, two paddles squeeze the artificial manual breath unit (AMBU) bag which allows oxygen to move from the air mixer through the humidifier and the HEPA filter into the patient's lungs. Following this is the spontaneous exhaling of the

				Flexible tube Controller box Chassis			patient into the external environment due to the elasticity of the lungs and the operation of the one-way valve.
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	NR	NR	Created using additive manufacturing technology combined with traditional build techniques. 3D printed components were made of polycarbonate material fabricated on Stratasys 400 mc, 450 mc, and 900 mc Fortus series printers.	Motor Piston Rod Cam Housing BVM Motor control enclosure Piston Screw terminals Solder Commercial spade clips	high-torque geared motor	hardware-based pulse-width modulation (PWM) controller	The design uses an eccentric attachment of a rod and piston assembly to a cam plate driven by a simple low-voltage geared motor to compress the BVM. The rod attachment point on the cam controls the amount of compression of the manual resuscitator bag and therefore VT. Respiratory rate of the 30 rpm (without a load) geared motor is controlled by a hardware-based pulse-width modulation (PWM) controller.
Vasan (MAD Vent)	NR	Two pressure sensors were used to measure ambient and in-line pressure	polyoxymethylene (acetal)	Compressor Braided Nylon Lanyard PEEP Valve Electronics box Filter Lever Back-up Battery Photo	Stepper Motor with 1.89 N-m of holding torque and a maximum rotation speed of 180 rpm	Arduino	Automated Resuscitator bag compression with a novel torque conversion mechanism via a simple pulley and lanyard system.

				interrupter switch Frame Resuscitator Bag Stepper Motor Parameter knobs Alarms LED Switch			
Von Chong (NR)	NR	Yes	NR	PEEP and pressure release valves Tubing Bag Valve Silicon pressure sensor Flow sensor Stepper Motor Resuscitator bag	23HS45-420AS stepper motor	X20MM4456 The control algorithm was embedded in a 4PPC70.101G-20B programmable logic controller (PLC)	The device based on the bag-valve design (BVD) consists of a lever that, controlled by a mechanical actuator, squeezes the bag at user-defined distances to displace the required air volume. Includes a programmable logic controller and PWM motor bridge to drive the stepper motor which actuated on the lever to squeeze the bag. Also uses a open-loop control system. The ventilation process consisted mainly of three stages: inspiration (bag squeezing), hold (plateau) and exhalation (bag release).

Automated Compression of AMBU Bag with electro-pneumatic system	HARDWARE						
Author (Vent. Name)	**Oxygen Sensor**	**Pressure Sensor**	**Materials**	**Parts**	**Motor**	**Hardware/Micro-Controller**	**Ventilator Design (detailed)**
Beale (Ox-Vent)	Yes	NR	NR	Resuscitator bag, heat and moisture exchange (HME) filter, smoothbore hose, spirometry kit, pressure release valve and PEEP valve.	NR	32-bit ARM Cortex-M4 CPU on Arduino board	The Ox-Vent is a "bag in bottle" device. A single-use resuscitator bag is enclosed within a sealed chamber. Using an external compressed air supply, the chamber is pressurised, causing the bag to expel air into the patient airway via standard breathing tubing, inspiratory valve, and heat and moisture exchange filters. The device comprises two main assemblies: the electronics/control enclosure (white panel, top), and ventilator box ('bag in bottle', bottom). The system has inlets for electrical power, compressed air at 4 bar, and oxygen (the

							concentration of which is set via rotameter). Flow measurement is achieved via a spirometry kit placed close to the patient airway.
Chang (Masi)	Yes	Yes, 2 of them	Stainless steel	Endotracheal (ET) tubes and tracheotomy tubes, HMEF filter (Connecting the patient's ET tube and Masi), Corrugated inspiration circuit tube, Compressed oxygen tank or compressed oxygen network, PCB, Screen, Motor driver, Stepper motor, STM, CTS-Frequency controls, General purpose digital isolator x3, Position card connector microSD, Isolated module DC convertor, WiFi 802.11b/g/n	Stepper motor	Microcontroller = ATMEGA48PB-AUR Hardware in three major blocks: ventilation circuit, electrical circuit and mechanical system.	Masi hardware is distributed in three mayor blocks: The ventilation circuit, the electrical circuit and the mechanical system, all of them controlled simultaneously by the firmware.

				transceiver module.			
Fang (AmbuBox)	No	Yes	States Biocompatibility has been taken into consideration in the selection of materials and parts of AmbuBox to facilitate the future application of FDA EUA, in which the components of AmbuBox that connected directly to the patient's breath circuits are all in medical grades.	AMBUBag, extension tubing, HEPA filter, PEEP valve, pressure sensor, spirometer, acrylic AMBUBox chamber, 3-way solenoid valve, microcontroller unit, GUI	NR	Arduino Mega R3	The AmbuBox consists of three components: (1) a standard AmbuBag-type manual resuscitator with its accessories, (2) a laser-cut chamber with airtight and bidirectional sealing to the AmbuBag, and (3) a pneumatic control unit with solenoid valves and pressure- and flow-sensing feedback.
Williams (NR)	No	NR	NR	Non-return valve Ancillaries Self-inflating resuscitation bag with supplementary oxygen port, reservoir bag and pressure limiting valve.	NR	NR	Pneumatic mechanism that repeatedly compressed a single-use self-inflating bag.
"Other"	**HARDWARE**						
Author	**Oxygen Sensor**	**Pressure Sensor**	**Materials**	**Parts**	**Motor**	**Hardware/Micro-Controller**	**Ventilator Design (detailed)**

Aihaitijiang (Ori-Vent)	NR	NR	Flexible air-tight bellows made from either **fold plastic or NinjaFlex (a flexible TPU filament 3-D printed material).** We use a CO2 laser cutter to create perforation lines that create creases, but a simple plotting machine or manual folding are also possible. The material can be a thin film of **PET (polyethylene terephthalate)**, or any other low-cost and accessible plastic or even cardboard. To seal holes within the origami structure (1) nitrile exam glove material U(suited to most medical enviro. & puncture-resistance). Pieces of Nitrile	Origami inspired Air-tight bellows, single L-bend geared DC motor, holder, spool, cable.	L-Bend geared DC motor	Arduino Uno	The ventilator is based on this module crease pattern and consists of a flexible, air-tight bellows, either made from folded plastic or NinjaFlex, a flexible 3-D printed material. A single L-Bend geared DC Motor (224:1 gear ratio) mounted inside the structure drives a cable attached to the other end. When the motor wraps the cable around a spool, the bellows contracts and the system perform its intended function to push air as a ventilator (Cables are pulled with a clockwise rotation of the motor and are released with a counter clockwise rotation).

			exam glove were glued onto the structure using E6000 flexible, paintable glue. (2) Stretchlon200 vacuum bagging film (suited for stretching over complex shapes and has high elongation. Both these methods result in an air-tight and light-weight bellows.				
Darwood (NR)	No	No	NR	NR	Impeller electric motor (no brand or type)	Arduino Nano PCB with ATmega328 chip	A prototype ventilator was constructed with readily available electrical components including an electric motor connected to a centrifugal impeller to provide airflow. The ventilator consists of two separate hardware elements: a single-use 'disposable' patient connection element; and a re-usable powered 'motor unit'.
Dickson (SAVe I)	No	NR	NR	NR	NR	NR	The SAVe I is a limited-function ventilator with manufacturer-set VT and respiratory rate

							that is currently deployed with the U.S. Medical Corps and is available for purchase by medical and emergency medical services companies. The ventilator, as approved by the Food and Drug Administration for human use, has a set VT of 600 mL and respiratory rate of 10 breaths per minute.
Dickson (SAVe II)	No	NR	NR	NR	NR	NR	The SAVe II is a second-generation, limited-function ventilator based on the SAVe I with the added capability of adjustable VT and respiratory rate, entrainment of up to 15 L/min of O2, and the ability to deliver and control PEEP (i.e., internal PEEP) (Table 1). It has not received Food and Drug Administration approval at time of submission of this article.
El Majid (NR)	NR	No	NR	Plastic air tank, two wooden or plastic circles (fixed and	DC Motor	Arduino	Ventilator has two states - ON and OFF. In the ON state the motor is

				mobile discs), a bendable wire, two check valves, a DC motor, and a support box.			activated causing the upper circle to rotate in one direction. The movement of the motor causes the wire to bend. This pulls the bottom circle upwards, which pressurizes the air inside the tank. This pressurized air is consequently directed into pipes through the check valve. This state corresponds to the inspiration phase. In the OFF state (Fig. 3b), the motor is released. The bottom circle then moves downwards under the influence of its own weight and the release of the tension in the wire, which is restored to its initial position. Since the pressure in the lungs is higher than the pressure in the air tank, the device will draw air from the patient's lungs. Thus, the OFF state corresponds to the expiration phase.

							The cycling of ON and OFF states induces respiration.
Fernandez (ResUHUrge)	Yes	Yes	NR	Centrifugal fan, laminar flow filter, electro valve, Venturi, O2 sensor, pressure sensor, air filter, flow sensor, data acquisition and control system, computer, HMI, buzzer.	NR	The ATmega2560 microcontroller was used. The programming of this microcontroller was entirely developed in the Arduino IDE environment. Microcomputer - Raspberry Pi 4 Model B	ResUHUrge is a BiPAP (bi-level positive airway pressure)-type ventilator, with independent regulation of intrathoracic pressure, i.e., one level during inspiration, IPAP (inspired positive airway pressure), and another during expiration, EPAP (expired positive airway pressure). The ventilator works by generating a constant flow according to the maximum pressure selected (up to 35 cm H2O). This flow is regulated by a solenoid valve that diverts the flow towards the patient, regulating both the maximum inspiratory pressure (IPAP) and the pressure at the end of expiration (EPAP).

Haque (NR)	NR	Yes	Uses low-cost 3D printing technology (fuse deposition modelling). Other materials include silicon sheet, and rubber.	Turbine, Electronics boards and modules, electronics components, sensors, patient circuit and filter, cables and connectors, battery pack, hose and tubing	Not a motor but a turbine. 7040 DC 12V centrifugal turbo turbine	Arduino Mega	Turbine based ventilator and pressure release mechanism
Marzetti (NR)	NR	Yes	It can be built using only material plates such as wood or plastic, using a jigsaw or a laser cutter.	Fishing wire, aquarium tubing, hose and 3D printer stepper motors.	3D printed stepper motor	Microchip PIC24FJ64GB004 microcontroller	Mechanical structure is based on three bellows made from inner tire tube replacing the AMBU bag that is often used in artificial ventilators. Each bellow uses two limits sensors and is operated by a three-3D printer stepper motor using fishing wire. Supplied with a hand-held power tool battery delivering 18 V DC, electronic system control is based on a Microchip PIC24FJ64GB004 microcontroller. Actuators are Sanyo

							Denki 103H5208-5240 3D printer stepper motors driven by an Allegro A4988 motor driver.
Pereira (NR)	Yes	Yes	Water columns were manufactured from a standard acrylic pipe closed by POM machined plugs. Inner pipe is a standard PVC pipe.	Only locally sourced components were used. Pressure regulator, air flow needle valve, inspiration e-valve, PIP safety relief valve, PEEP pressurizer, %O2 sensor, HMEF Filter, timing circuit for electro valves & alarms, U-tube water manometer, water columns.	NR	NR	Design requires air and O2 from a hospital like supply. The design uses water columns to regulate pressure and a U-tube water manometer to measure PIP and PEEP. All valves are electronically commanded.
Szlosarek (NR)	NR	Yes	Possible to manufacture all components out of plastics or metals. Possible plastics are polyethylene (PE), polypropylene (PP), polyethylene tere-	Pressured air interface Patient interface Manometer Piston Outlet Overpressure valve Spontaneous inhalation valve	NR	NR	The O2U ventilator relied on a known flow rate entering the system and control of the valve timings. The pressure-limited, time-cycled design included continuous monitoring of the pressures to detect any leaks or

			phthalate (PET), polyvinylchloride (PVC), polycarbonate (PC), poly-tetrafluoroethylene (PTFE) or polyoxymethylene (POM). In case of metals it is suitable to use stainless steel like 1.4301 or 1.4401.				obstructions that could risk patient or device safety.
White (FALCON-Fast-Assembly COVID-Nineteen)	No	No digital pressure sensor, but include pressure manometer.	3D printed housing (STL printing files available upon request) using computer aided design software (Fusion 360) and 3D printed (TAZ Workhorse) using polylactic acid filament (2.85 mm PLA+).	Pressure gauge Power Supply 12V 8-amp electric Air Pump Timer relay (5V micro USB power adapter supplies the timer relay) PIP and PEEP PWMs	NR	NR	NR
Zuckerberg (ALFA)	No	Contains a pressure regulator	NR	Adjustable pressure relief valve Arduino microcontroller Flow-inflating Mapleson bag One-way valves Oxygen tubing Adjustable PEEP valve Size 3 soccer	Mentions motor but no type	Arduino Uno	The inspiratory limb consists of an elastic flow-inflating bag encased within a noncompliant sheath, which is pressurized using flow from a compressed gas source. The Arduino Uno microcontroller controls the programmable solenoid valve to

				ball Solenoid valve			open with a frequency and for a duration that is adjustable by the healthcare provider, resulting in a customizable respiratory rate, inspiratory time, and inspiratory-to-expiratory ratio. Upon opening of the valve, a large pressure gradient drives the delivery of the tidal volume to the patient. The expiratory limb consists of two one-way bidirectional splitter valves derived from a self-inflating bag system.

APPENDIX C: ENGINEERING COMPONENTS (SOFTWARE/INTERFACE)

Electro-Pneumatic Designs	**SOFTWARE / INTERFACE**		
Author (Vent. Name)	**Software (Architecture/components)**	**Programming Language**	**Software Development plan/ process**
Abba (Mechanical Ventilator Milano (MVM))	3 components: GUI, Controller and Supervisor. The GUI is written in Python3 using the	The controller and supervisor software implemented in C++	Software for mechanical ventilators must comply with the IEC 62304:2015, a global benchmark for the management

	PyQt5 library. It runs on Raseberry Pi (chosen for its wide availability and its computing power to power consumption ratio).		of the software development lifecycle. The standard was prepared jointly by the IEC (International Electrotechnical Commission) and the ISO technical committees. To comply, we have applied the V-model, which involves the development process shown in Fig. 7. The GUI and controller software were required to be in safety class A and the supervisor software in safety class C.
Buytaert (HEV)	The microcontroller software design consists of three distinct threads of processing: (1) A breathing loop responsible for operating the valves in a manner corresponding to the ventilator modes, (2) A user-interface (UI) loop for relaying the current status and readings to the Raspberry PI, and for accepting commands for setting modes and parameters, (3) A safety loop which is responsible for raising alarms when patient or system readings deviate from acceptable limits. Raseberry Pi software designed to display the readings from the microcontroller in a UI on the touchscreen. Raseberry Pi - Display webserver, Microcontroller comms server, Native display. Microcontroller (ESP32) - breathing loop, UI loop, safety loop. Communication between microcontroller	NR	The software development has been done in a robust and flexible manner, prioritising considerations of component failure from the start. Readability and simplicity of code has been favoured over complexity, for ease of bug tracing and testing. For the prototype, the guidelines of IEC 62304 have been used, and internal checking/assertions are included in the software. The communication protocols follow the High-Level Data Link Control recommendations from ISO/IEC 13239:2002. In particular, data transmission is done with acknowledgement, and checksums are performed to confirm the data integrity. While the software system in place for the prototype is not yet fully qualified to ISO standards, the structure has been set up in

	and Raseberry Pi is achieved through High-Level Data Link Control Porocol (HDLC) (ISO 13239:2002).		such a way as to show that this is possible.
Chiang (VEMERS UC)	NR	C#	NR
Cole (Portsmouth Ventilator)	NR	NR	Yes
Dally (OP-Vent)	Software modules: Alarms, RTC control, UI, Flow, Sensor Drivers, Peripheral Drivers. The control software is invoked by a real-time clock (RTC) interrupt every 1ms. 2 separate UI's are provided to set parameters.	The ventilator software is written in “C” and compiled using CrossPackAVR running under MacOS	Yes
DeBoer (NR)	The software was separated into an eight-step process, repeated continuously: closure of the exhalation port, pressure drop identification (representing the patients start of inhalation), the opening of the inhalation valve, set inspiratory tidal volume reached, closure of the inhalation valve, the opening of the exhalation valve, exhalation time complete, and ensuring exhalation complete by measuring the pressure. The controller also regulated the pressure in the R1 and R2 reservoirs, creates the FiO2 mixture in the R3 reservoir by reading the oxygen concentration from O1 and adjusting the FMV1 and FMV2, ensured adequate flow for inhalation, and created back pressure for exhalation throughout this process.	NR	Yes
El Haddi (CRISIS)	NR	NR	NR

F (DIGIT)	NR Software not applicable as it was in 1996	NR	NR
King (RapidVent)	NR	NR	NR
Knorr (CLEVent EV)	NR	NR	NR
Madekurozwa (NR)	NR	NR	NR
Park (ALIVE Vent)	Python software. The CMS consolidates and manipulates all of the components using a computer running our Python software application and a simple circuit board.	Python	NR
Raymond (O2U Ventilator)	NR	NR	NR
Rebelo (ATENA)	NR	NR	Software was designed in house.
Von Chong (NR)	Includes Human-Machine Interface mimicking a traditional mechanical ventilator for ease of use and reduced training	NR	Yes
Wittenberg (CoVent)	NR	NR	NR
Automated Compression of AMBU Bag	**SOFTWARE / INTERFACE**		
Author (Vent. Name)	**Software (Architecture/components)**	**Programming Language**	**Software Development plan/ process**

Al Husseini (NR)	NR	NR	NR
Arcos-Legarda (NR)	NR	NR	The software developed for this portable MV applies an active disturbance rejection control (ADRC) strategy
Christou (GlasVent)	NR Uses commercial tablets/ phones for its software resource. Just mentions the 3 modes it can perform.	NR	NR
Dhanani (NR)	NR	Written in Arduino programming language	NR
Du Pasquier (ETH Breathe**)	NR	The controller is implemented using MATLAB/SIMULINK/STATEFLOW R2020a	NR
Gafford (VOV - Vanderbilt Open-source Ventilator)	NR	NR	Yes
Gino (AIR – Automated Inflating Resuscitator)	NR	NR	NR
Grimshandl (HDvent Emergency Ventilator System)	The controller software is written in C++ using the standard Arduino library for all I/O operations. It uses a state machine architecture to control the ventilation cycle and to provide the user interface. One execution of the main program loop takes about 15 ms.	C++ using the standard Arduino library for all I/O operations.	NR
Gruslova (ABBU: Automated Bag Breathing Unit)	A unique feature is their inspiratory software****** ABBU senses the patient inspiratory effort below a software-calculated pressure threshold to trigger a breath.	NR	NR

Kindomba (ProtoVent)	No software	NR	NR
Mathanlal (ATMO-Vent)	NR	The processing unit of ATMO-Vent consists of two Arduinos and the Raspberry Pi computer. Raspbian operating system is used on the Raspberry Pi and it could be replaced with Realtime Operating Systems (RTOS) as the program itself has been designed in python to be flexible with a multitude of operating systems.	NR
Mathew (Artifical Breathing Capability Device (ABCD))	Software includes self-checks. Real time display of delivered ventilation parameters.	NR	NR
Meiry (Ambo Vent)	A small LCD and two LEDs are embedded to display indications of the system's state, the chosen ventilation parameters, and various alarms. The device interface has three potentiometers: knobs that control different variables (BVMs squeezing %, respiratory cycle per minute (RPM) and PIP range. It also has 3 buttoms for on/off, testing/calibration and control alarms.	NR	NR
Ort (MIT EV)	NR	NR	NR
Palacka (Q-Vent)	NR	NR	The company-developed control software of the MC (EMBASYS, Ltd) ensures the reading of data from the sensors, together with the control of the breath profile. The MC should be connected to the computer via a USB A port.
Petsiuk (RepRapable)	NR	NR	Uses an open-source real-time operating system (FreeRTOS) library for Arduino which allows

			for essential functions to software tasks such as scheduling, dispatching, inter-task communication and synchronization. Serial peripheral interface (SPI)
Terzi (eSpiro)	NR	NR	NR
Truong (NR)	NR	NR	NR
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	NR	NR	NR
Vasan (MAD Vent)	NR	NR	NR
Von Chong (NR)	The control scheme is that of an open loop control system. Includes Human-Machine Interface mimicking a traditional mechanical ventilator for ease of use and reduced training	NR	Yes
Automated Compression of AMBU Bag with electro-pneumatic system	**SOFTWARE / INTERFACE**		

Author (Vent. Name)	**Software (Architecture/components)**	**Programming Language**	**Software Development plan/ process**
Beale (Ox-Vent)	Closed-loop negative feedback proportional integral derivative (PID) algorithm running on an Arduino Nano 33 BLE development board.	NR	NR (Just mentioned software could be updated).
Chang (Masi)	Divide into 3 blocks: user interface, power/control and telemetry.	NR	NR
Fang (AmbuBox)	NR	NR	NR
Williams (NR)	NR	NR	NR
"Other"	**SOFTWARE / INTERFACE**		
Author (Vent. Name)	**Software (Architecture/components)**	**Programming Language**	**Software Development plan/ process**
Aihaitijiang (Ori-Vent)	NR	NR	NR
Darwood (NR)	Ventilator control algorithm overview. Calibration mode (a) allows mapping of patient airway and circuit conditions to optimise ventilator function. Successful calibration (1) allows algorithm to progress to normal ventilation mode (b). If a safety alert is detected, for example, leak, or a large change in resistance or compliance (2) the algorithm returns to calibration mode (a). If there are serial failed calibration attempts then a major alarm is sounded (c).	NR	NR

Dickson (SAVe I)	NR	NR	NR
Dickson (SAVe II)	NR	NR	NR
El Majid (NR)	NR	NR	NR
Fernandez (ResUHUrge)	NR	Python	NR
Haque (NR)	To facilitate all the asynchronous activities, the 'Thread Looper Handler Architecture' of android was put into use. Android Application– The efficient development of the app; sizing only 5 MB, made it possible to run using low resources, subsequently decreasing the price of the device used to operate. Amongst all the options, Java was chosen as the language to be used to develop because it is reliable, available libraries, easy debugging and adaptability to changes. Control algorithms (PID and feed-forward) have been embedded into the firmware for controlling the pressure and the flow rate. Firmware is solely responsible for conducting all the calculations, switching between different modes while maintaining all the safety procedures, and finally triggering necessary alarms if necessary.	Java	NR

Marzetti (NR)	User graphic interfaces for supervision and set-up are developed in C#, thus it can be run on a standard PC connected to the ventilator through a RS232 link. Sensors data is monitored in real time (intra-lung pressure and tidal volume).	C#	Embedded AI algorithm is based on characterizing interactions between the patient and the ventilator. This is done by extracting features from sensors signals, during breathing cycles, in order to later detect hardware failures or anomalies.
Pereira (NR)	NR	NR	NR
Szlosarek (NR)	NR	NR	NR
White (FALCON-Fast-Assembly COVID-Nineteen)	NR	Python	Yes
Zuckerberg (ALFA)	NR	NR	NR

APPENDIX C: ENGINEERING COMPONENTS (DOCUMENTATION)

Electro-Pneumatic Designs	HARDWARE & SOFTWARE DOCUMENTS						OTHER DOCUMENTS		
Author (Vent. Name)	**Fully annotated circuit diagrams, wiring diagrams and design source/production files**	**Design Documents**	**Verification/ Validation Plans and Reports**	**Risk Management Plan and Report**	**Release Note**	**Firm and Software (including code)**	**Regulatory Standards Used?**	**Bill of materials**	**Instructions to build and operate**
Abba (Mechanical Ventilator Milano (MVM))	Yes	Provides software development process (based on the V-model).	NR	NR	NR	NR	ISO, FDA, IEC	NR	NR
Buytaert (HEV)	Yes	NR	NR	NR	NR	NR	MHRA and ISO	NR	NR
Chiang (VEMERS UC)	Yes	NR	NR	NR	NR	NR	Fully validated under the CMFCC special validation protocol.	Yes	Yes
Cole (Portsmouth Ventilator)	Yes	Yes	NR	NR	NR	Yes	NR	NR	NR
Dally (OP-Vent)	Yes	Yes	Real-time operation of the control software was validated by toggling an I/O line	NR	NR	Yes	NR	No	No

			at the beginning and end of the RTC interrupt service routine to verify that the routine was completed in time.						
DeBoer (NR)	Yes	Yes	NR	No	NR	NR	NR	No	Yes
El Haddi (CRISIS)	No	NR	NR	NR	NR	NR	NR	No	No
F (DIGIT)	Yes	NR	NR	NR	NR	NR	NR	NR	NR
King (RapidVent)	NR	NR	NR	NR	NR	NR	NR	Yes	Yes
Knorr (CLEVent EV)	Yes	NR	NR	NR	NR	NR	MHRA, AARC	NR	NR
Madekurozwa (NR)	NR	NR	NR	NR	NR	NR	NR	NR	NR
Park (ALIVE Vent)	Yes	Yes	NR	NR	NR	Yes	AARC	NR	NR
Raymond (O2U Ventilator)	Yes	NR	NR	NR	NR	NR	FDA EUA requirements	NR	NR
Rebelo (ATENA)	NR	NR	NR	NR	NR	NR	MHRA	NR	NR

Von Chong (NR)	NR	NR	NR	NR	NR	NR	NR	NR	NR
Wittenberg (CoVent)	NR	NR	NR	NR	NR	NR	MHRA	NR	NR
Automated Compression of AMBU Bag	**HARDWARE & SOFTWARE DESIGN DOCUMENTS**						**OTHER**		
Author (Vent. Name)	**Fully annotated circuit diagrams, wiring diagrams and design source/production files**	**Design Documents**	**Verification/ Validation Plans and Reports**	**Risk Management Plan and Report**	**Release Note**	**Firm and Software (including code)**	**Regulatory Standards Used?**	**Bill of materials**	**Instructions to build and operate**
Al Husseini (NR)	Yes	NR	NR	NR	NR	NR	ASTM F920-93 standard requirements	NR	NR
Arcos-Legarda (NR)	Yes	NR	NR	NR	NR	NR	NR	Yes	NR
Christou (GlasVent)	Yes	NR	NR	NR	NR	NR	NR	NR	NR
Dhanani (NR)	No	NR	NR	No	NR	NR	NR	No	No
Du Pasquier (ETH Breathe**)	Yes	Yes	Yes	NR	NR	Yes	MRHA, ISO	Yes	No
Gafford (VOV - Vanderbilt Open-source Ventilator)	Yes	Yes	Yes	NR	NR	Yes	ISO	No	NR

Gino (AIR – Automated Inflating Resuscitator)	Yes	Yes	NR	NR	NR	NR	MHRA	NR	NR
Grimshandl (HDvent Emergency Ventilator System)	Yes	NR	NR	NR	NR	NR	NR	No	No
Gruslova (ABBU: Automated Bag Breathing Unit)	NR	NR	NR	NR	NR	NR	NR	NR	Yes
Kindomba (ProtoVent)	Yes	Yes	NR	NR	NR	NR	NR	Yes	Yes
Mathanlal (ATMO-Vent)	NR	Yes	NR	NR	NR	NR	UK-MHRA	No	NR
Mathew (Artifical Breathing Capability Device (ABCD))	NR	NR	NR	NR	NR	NR	NR	NR	NR
Meiry (Ambo Vent)	Yes	Yes	NR	NR	NR	Yes	UK-MHRA	NR	NR
Ort (MIT EV)	Yes	NR	NR	NR	NR	Yes	NR	NR	NR
Palacka (Q-Vent)	Yes	NR	NR	NR	NR	NR	NR	NR	NR
Petsiuk (RepRapable)	Yes	Yes	Yes	NR	NR	Yes	ISO, British Medicines &	Yes	Yes

							Healthcare Products Regulatory Agency		
Terzi (eSpiro)	Yes	NR	NR	NR	NR	NR	NR	NR	NR
Truong (NR)	Yes	NR	NR	NR	NR	NR	NR	NR	NR
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	Yes	NR	NR	NR	NR	NR	ISO	NR	Yes
Vasan (MAD Vent)	Yes	Yes	NR	NR	NR	Yes	ISO and US FDA	NR	NR
Von Chong (NR)	NR	NR	NR	NR	NR	NR	NR	NR	NR

Automated Compression of AMBU Bag with electro-pneumatic system	**HARDWARE & SOFTWARE DESIGN DOCUMENTS**						**OTHER DOCUMENTATION**		
Author (Vent. Name)	**Fully annotated circuit diagrams, wiring diagrams and design source/production files**	**Hardware/ Software Design Documents**	**Software Verification/ Validation Plans and Reports**	**Software Risk Management Plan and Report**	**Software Release Note**	**Firm and Software (including code)**	**Regulatory Standards Mentioned?**	**Bill of materials**	**Instructions to build and operate**

Beale (Ox-Vent)	Yes	NR	NR	NR	NR	NR	MRHA in RMVS specification of March 2020	NR	NR
Chang (Masi)	Yes	Yes	NR	NR	NR	Yes	ISO *All the components of the circuit ventilation systems are medical grade and comply with regulations and permits for use in hospitals.*	Yes	Yes
Fang (AmbuBox)	Yes	Yes	NR	NR	NR	NR	NR	NR	NR
Williams (NR)	NR	NR	NR	NR	NR	NR	NR	NR	NR
"Other"	**HARDWARE & SOFTWARE DESIGN DOCUMENTS**						**OTHER**		
Author	**Fully annotated circuit diagrams, wiring diagrams and design source/production files**	**Design Documents**	**Verification/ Validation Plans and Reports**	**Risk Management Plan and Report**	**Release Note**	**Firm and Software (including code)**	**Regulatory Standards Mentioned?**	**Bill of materials**	**Instructions to build and operate**
Aihaitijiang (Ori-Vent)	NR	NR	NR	NR	NR	NR	NR	NR	NR

Darwood (NR)	Yes	Yes	NR	No	NR	NR	NR	No	No
Dickson (SAVe I)	No	NR	NR	NR	NR	NR	NR	NR	NR
Dickson (SAVe II)	No	NR	NR	NR	NR	NR	NR	NR	NR
El Majid (NR)	No	NR	NR	NR	NR	NR	NR	NR	NR
Fernandez (ResUHUrge)	Yes	NR	NR	NR	NR	No	No	Yes	No
Haque (NR)	Yes	NR	NR	NR	NR	Yes	NR	Yes	NR
Marzetti (NR)	Yes	NR	NR	NR	NR	NR	NR	NR	NR
Pereira (NR)	Yes	NR	NR	NR	NR	NR	NR	NR	NR
Szlosarek (NR)	Yes	NR	NR	NR	NR	NR	NR	NR	NR
White (FALCON-Fast-Assembly COVID-Nineteen)	Yes	NR	NR	NR	NR	NR	NR	No	NR
Zuckerberg (ALFA)	Yes	NR	NR	NR	NR	Yes	NR	NR	NR

APPENDIX D: RMV Standards Checklist

Appendix D: RMV Standards Checklist Excel Document

1. AARC
2. MHRA
3. Pearce
4. MVAtCP
5. CHEST
6. CIEHF

APPENDIX D: STANDARDS CHECKLIST – AARC → Branson, R. D. *et al.*, "SARS-CoV-2 guidance document,"Amer. Assoc. Respiratory Care, Tech. Rep., May 2020. [Online]. Available: https://www.aarc.org/wp-content/uploads/2020/03/guidance-document- SARS-COVID19.pdf

Standard Document	**AARC**									
Component Recommended	US FDA Approved for Pediatric Use	Modes of Ventilation	PEEP	Measurements / Monitoring	TV	RR	FiO2	Inspiratory Flow	Alarms	Infection Control (Humidifiers)
Details on recommendation	Pediatric and adult approved	Volume and pressure control	0 - 20 cm H2O (Optimum PEEP is often in the range of 8 - 12 cm H2O)	Measured exhaled TV	250 - 750 mL (or 4- 8 mL/kg of predicted body weight)	6 - 35 breaths/min	0.21 - 0.95	Low < 10 L/min, High > 80 L min	Sounds for patient disconnect, apnea, high pressure, low source gas pressure	Maintain strict infectious disease precautions. HMEF, standard filters or HEPA filters.
Abba (Mechanical Ventilator Milano (MVM))	P	P	N	N	N	N	N	N	P	P
Buytaert (HEV)	N	P	P	Y	Y	P	Y	Y	P	N

Chiang (VEMERS UC)	N	P	Y	Y	P	P	Y	Y	P	Y
Cole (Portsmouth Ventilator)	N	P	Y	Y	P	P	P	Y	P	N
Dally (OP-Vent)	N	Y	N	Y	N	N	Y	N	P	P
DeBoer (NR)	N	P	N	Y	N	P	N	N	P	N
El Haddi (CRISIS)	N	P	N	Y	Y	N	N	N	N	N
F (DIGIT)	N	Y	N	N	N	N	N	N	P	N
King (RapidVent)	N	N	N	N	N	N	P	P	P	N
Knorr (CLEVent EV)	N	P	N	N	N	N	Y	N	P	P
Madekurozwa (NR)	N	P	N	Y	N	N	N	N	N	N
Park (ALIVE Vent)	N	Y	N	Y	N	N	Y	Y	N	Y
Raymond (O2U Ventilator)	P	P	P	N	P	P	P	N	P	P
Rebelo (ATENA)	N	Y	Y	Y	Y	P	Y	N	P	N
Von Chong (NR)	N	P	N	N	N	N	N	N	P	N

Wittenberg (CoVent)	N	P	N	N	N	N	N	N	N	N
Al Husseini (NR)	N	P	N	Y	Y	P	N	N	P	N
Arcos-Legarda (NR)	N	Y	P	Y	P	P	N	N	P	N
Christou (GlasVent)	N	Y	N	Y	N	N	N	N	N	N
Dhanani (NR)	N	N	N	Y	N	P	N	N	N	N
Du (ETH Breathe**)	N	P	N	Y	N	N	N	N	P	Y
Gafford (VOV - Vanderbilt Open-source Ventilator)	N	P	Y	Y	Y	Y	N	N	P	N
Gino (AIR – Automated Inflating Resuscitator)	N	P	P	Y	Y	P	P	N	N	P
Grimshandl (HDvent Emergency Ventilator System)	N	Y	Y	N	P	P	N	N	P	Y
Gruslova (ABBU: Automated Bag Breathing Unit)	N	N	N	Y	Y	P	N	N	P	N
Kindomba (ProtoVent)	N	N	N	N	N	N	N	N	N	N

Mathanlal (ATMO-Vent)	N	N	N	Y	N	N	N	P	P	N
Mathew (Artifical Breathing Capability Device (ABCD))	N	N	N	N	N	P	N	N	P	N
Meiry (Ambo Vent)	N	P	N	N	P	P	N	N	P	P
Ort (MIT EV)	N	P	P	Y	Y	Y	N	N	P	N
Palacka (Q-Vent)	N	P	N	Y	Y	N	Y	N	P	P
Petsiuk (RepRapable)	N	P	P	Y	Y	Y	N	N	P	N
Terzi (eSpiro)	N	P	N	Y	N	N	N	N	P	N
Truong (NR)	N	P	N	Y	P	N	N	N	P	Y
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	N	P	N	Y	P	P	N	N	N	N
Vasan (MAD Vent)	N	P	N	N	Y	Y	N	N	P	P

Von Chong (NR)	N	P	P	Y	N	P	N	N	P	N
Beale (Ox-Vent)	N	Y	N	Y	P	N	P	P	P	P
Chang (Masi)	P	Y	Y	Y	Y	N	Y	N	P	P
Fang (AmbuBox)	N	N	P	Y	Y	P	N	N	P	Y
Williams (NR)	N	P	N	Y	N	N	N	N	N	N
Aihaitijiang (Ori-Vent)	N	N	P	N	N	P	P	P	N	N
Darwood (NR)	N	P	N	N	N	P	N	N	P	N
Dickson (SAVe I)	P	P	N	N	N	P	N	P	P	N
Dickson (SAVe II)	N	P	Y	Y	Y	P	N	Y	P	N
El Majid (NR)	N	N	N	N	N	N	N	N	N	N
Fernandez (ResUHUrge)	N	P	N	N	N	N	P	Y	P	P
Haque (NR)	N	P	N	N	N	N	N	N	P	Y
Marzetti (NR)	N	N	N	N	Y	N	N	N	N	N

Pereira (NR)	N	P	Y	N	N	P	P	N	P	P
Szlosarek (NR)	N	P	N	N	N	N	N	N	N	N
White (FALCON-Fast-Assembly COVID-Nineteen)	N	P	N	N	N	N	N	N	N	N
Zuckerberg (ALFA)	N	P	N	N	N	N	N	N	N	N

APPENDIX D: STANDARDS CHECKLIST – MHRA (#1) → MHRA. (2020). *Rapidly Manufactured Ventilator System (RMVS)*. [Online]. Available: https://assets.publishing.service.gov.uk/government/

Standard Document	**MHRA**								
Component Recommended	Power Source	Modes of Ventilation	PEEP	Measurements/ Monitoring	TV	RR	FiO2	Inspiratory Flow	I:E Ratio
Details on recommendation	Battery backup of at least 20 minutes	Must have CMV. The CMV mode must be (1) (ideally) PRVC, or (2) PCV, or (3) VCV.	5 - 20 cm H2O. *(Default setting: 35 cm H2O.)*	Must show Vt, frequency, PEEP, FiO2, ventilation mode. Must show the actual current airway pressure. If pressure support mode is provided there must be real time confirmation of each patient breath and an alarm if below acceptable range.	(1) Must have at least one setting of 400ml +/- 10 ml. (2) Should have 350ml and 450 ml options. (3) Could have a range 250 – 600 ml in steps of 50ml. *(4) Could have a range up to 800 ml.**	Must provide a range 10 - 30 BPM. *(Default: 20 bpm)*	50% - 60% and 90 - 100% options. (*Default setting: 90 - 100% oxygen)*	Plateau pressure should be adjusted to achieve volume and must be limited to 35 cmH2O by default. Peak pressure should be no more than 2 cm H2O greater than plateau pressure. The user must be able to set inspiratory airway pressure limit in the range at least 15 - 40 cmH2O in at least increments of 5 cmH2O (if pressure control ventilation is used)	1:2

Abba (Mechanical Ventilator Milano (MVM))	Y	Y	N	P	N	N	N	N	N
Buytaert (HEV)	Y	Y	Y	P	Y*	Y	Y	N	Y
Chiang (VEMERS UC)	N	Y	Y	P	Y	Y	Y	N	Y
Cole (Portsmouth Ventilator)	Y	Y	Y	P	Y*	Y	Y	N	Y
Dally (OP-Vent)	P	Y	N	P	N	N	Y	N	N
DeBoer (NR)	N	Y	N	P	N	Y	N	N	N
El Haddi (CRISIS)	N	Y	N	P	Y*	N	N	N	N
F (DIGIT)	N	Y	N	N	N	N	N	N	N
King (RapidVent)	N	N	N	P	N	N	P	N	N
Knorr (CLEVent EV)	N	Y	N	P	N	N	Y	N	N
Madekurozwa (NR)	N	Y	N	P	N	N	N	N	N
Park (ALIVE Vent)	N	Y	N	P	N	N	Y	N	N
Raymond (O2U Ventilator)	N	N	Y	P	Y	Y	N	N	Y

Rebelo (ATENA)	P	Y	Y	P	Y*	Y	Y	Y	Y
Von Chong (NR)	N	Y	N	N	N	N	N	N	N
Wittenberg (CoVent)	N	Y	N	P	N	N	N	N	N
Al Husseini (NR)	P	Y	N	P	Y	Y	N	N	N
Arcos-Legarda (NR)	N	Y	Y	P	Y	Y	N	Y	Y
Christou (GlasVent)	P	Y	N	P	N	N	N	N	N
Dhanani (NR)	N	N	N	P	N	P	N	N	N
Du (ETH Breathe**)	N	Y	N	P	N	N	N	N	N
Gafford (VOV - Vanderbilt Open-source Ventilator)	N	Y	Y	P	Y*	Y	N	N	Y
Gino (AIR – Automated Inflating Resuscitator)	N	Y	Y	P	Y*	Y	P	N	Y
Grimshandl (HDvent Emergency Ventilator System)	N	Y	Y	N	Y	Y	N	Y	N
Gruslova (ABBU: Automated Bag Breathing Unit)	N	N	N	P	Y*	Y	N	N	Y

Kindomba (ProtoVent)	N	N	N	P	N	N	N	N	N
Mathanlal (ATMO-Vent)	N	N	N	P	N	N	N	N	N
Mathew (Artifical Breathing Capability Device (ABCD))	N	N	N	P	N	Y	N	Y	Y
Meiry (Ambo Vent)	P	Y	N	P	P	P	N	P	Y
Ort (MIT EV)	N	Y	P	P	Y*	Y	N	N	Y
Palacka (Q-Vent)	P	Y	N	P	Y*	N	Y	N	N
Petsiuk (RepRapable)	N	Y	P	P	Y*	Y	N	N	Y
Terzi (eSpiro)	P	Y	N	P	N	N	N	N	N
Truong (NR)	N	Y	N	P	P	N	N	N	N
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	N	Y	N	P	P	Y	N	N	N
Vasan (MAD Vent)	P	Y	N	P	Y*	Y	N	Y	Y

Von Chong (NR)	N	Y	Y	P	N	Y	N	N	N
Beale (Ox-Vent)	N	Y	N	P	Y	N	Y	N	Y
Chang (Masi)	N	Y	Y	P	Y*	N	Y	Y	N
Fang (AmbuBox)	N	N	Y	P	Y*	Y	N	Y	N
Williams (NR)	N	Y	N	P	N	N	N	N	N
Aihaitijiang (Ori-Vent)	N	N	Y	N	N	P	P	N	Y
Darwood (NR)	N	Y	N	P	N	Y	N	Y	N
Dickson (SAVe I)	Y	Y	N	P	N	N	N	P	N
Dickson (SAVe II)	Y	Y	Y	P	Y*	P	N	Y	N
El Majid (NR)	N	N	N	N	N	N	N	N	N
Fernandez (ResUHUrge)	N	Y	N	N	N	N	P	P	Y
Haque (NR)	Y	Y	N	N	N	N	N	N	N
Marzetti (NR)	N	N	N	P	Y	P	N	N	N

Pereira (NR)	N	Y	Y	P	N	P	Y	Y	Y
Szlosarek (NR)	N	Y	N	P	N	N	N	N	N
White (FALCON-Fast-Assembly COVID-Nineteen)	N	Y	N	P	N	N	N	N	N
Zuckerberg (ALFA)	N	P	N	P	N	N	N	N	N

APPENDIX D: STANDARDS CHECKLIST – MHRA (#2) → MHRA. (2020). *Rapidly Manufactured Ventilator System (RMVS)*. [Online]. Available: https://assets.publishing.service.gov.uk/government/

Standard Document	**MHRA**					
Component Recommended	Ease to Set-up/Set Ventilation Settings/User-friendly	Testing	User-Interface Testing	Oxygen Consumption	Alarms	General Durability
Details on recommendation	User must be able to instantly see the settings selected and be able to easily operate all controls while dressed in protective gear	Usability testing at both prototype and final production stages will be required. When undergoing testing the "tester" must be wearing complex protective clothing: eye googles, face shield, plastic apron, surgical gown and two layers of gloves. Other tests such a pressure relief tests, closed suctioning tests and sound level tests.	Compliance with the essential safety standards must be demonstrated for patient safety. Usability testing at both prototype and final production stages will be required.	Average oxygen consumption must be no more than 6 lpm.	Gas or electricity supply failure. Machine switched off while in mandatory mode. Inspiratory airway pressure exceeded. Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm). Tidal volume not achieved. The disconnect alarm will sound within 3 seconds of disconnection.	Must be capable of continuous operation (100% duty cycle) for 14 days. Device should be robust as possible (it may be dropped from bed height to floor).
Abba (Mechanical Ventilator Milano (MVM))	N	P	P	N	N	Y
Buytaert (HEV)	P	P	N	N	P	N
Chiang (VEMERS UC)	P	P	N	N	P	N

Cole (Portsmouth Ventilator)	N	P	N	N	P	N
Dally (OP-Vent)	N	P	N	N	P	N
DeBoer (NR)	N	P	N	N	P	N
El Haddi (CRISIS)	N	P	N	N	N	P
F (DIGIT)	N	N	N	N	P	N
King (RapidVent)	N	P	N	N	P	N
Knorr (CLEVent EV)	N	P	N	N	P	N
Madekurozwa (NR)	N	P	N	N	N	Y
Park (ALIVE Vent)	N	P	N	N	N	N
Raymond (O2U Ventilator)	N	P	N	N	P	N
Rebelo (ATENA)	N	P	N	N	P	N
Von Chong (NR)	N	P	N	N	P	N
Wittenberg (CoVent)	N	N	N	N	N	N

Al Husseini (NR)	N	P	N	N	P	N
Arcos-Legarda (NR)	N	P	N	N	P	N
Christou (GlasVent)	N	P	N	N	N	N
Dhanani (NR)	N	P	N	N	N	N
Du (ETH Breathe**)	N	P	N	N	P	N
Gafford (VOV - Vanderbilt Open-source Ventilator)	N	P	N	N	P	Y
Gino (AIR – Automated Inflating Resuscitator)	N	N	N	N	N	N
Grimshandl (HDvent Emergency Ventilator System)	N	P	N	N	P	N
Gruslova (ABBU: Automated Bag Breathing Unit)	P	P	P	N	P	P
Kindomba (ProtoVent)	N	N	N	N	N	N
Mathanlal (ATMO-Vent)	N	P	N	N	P	N
Mathew (Artifical Breathing Capability Device (ABCD))	P	P	P	N	P	N
Meiry (Ambo Vent)	N	P	N	N	P	N

Ort (MIT EV)	N	P	N	N	P	N
Palacka (Q-Vent)	N	P	N	N	P	**
Petsiuk (RepRapable)	N	P	N	N	P	N
Terzi (eSpiro)	N	P	N	N	P	N
Truong (NR)	N	P	N	N	P	N
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	N	P	N	N	N	P
Vasan (MAD Vent)	N	P	N	N	P	N
Von Chong (NR)	N	P	N	N	P	N
Beale (Ox-Vent)	P	P	N	Y	P	N
Chang (Masi)	N	P	N	N	Y	N
Fang (AmbuBox)	N	P	N	N	P	N
Williams (NR)	N	P	N	P	N	N

Aihaitijiang (Ori-Vent)	N	P	N	N	N	N
Darwood (NR)	N	P	N	N	P	N
Dickson (SAVe I)	N	P	N	N	P	N
Dickson (SAVe II)	N	P	N	N	P	N
El Majid (NR)	N	N	N	N	N	N
Fernandez (ResUHUrge)	N	P	N	N	P	N
Haque (NR)	N	P	N	N	P	N
Marzetti (NR)	N	P	N	N	N	N
Pereira (NR)	N	P	N	N	P	Y
Szlosarek (NR)	N	P	N	N	N	N
White (FALCON-Fast-Assembly COVID-Nineteen)	N	P	N	N	N	N
Zuckerberg (ALFA)	N	P	N	N	N	N

APPENDIX D: STANDARDS CHECKLIST – MHRA (#3) → MHRA. (2020). *Rapidly Manufactured Ventilator System (RMVS)*. [Online]. Available: https://assets.publishing.service.gov.uk/government/

Standard Document	**MHRA**					
Component Recommended	End-User Training Program (Software)	Additional approvals/ Clearances	Labelling	Infection Control	Ventilator Kit Description	Materials of Contstruction (raw materials)**
Details on recommendation	Must not require more than 30 minutes training for a doctor with some experience of ventilator use. Must include Instructions for use.	When the current emergency has passed, these devices will NOT be usable for routine care unless they have been CE marked through the Medical Devices Regulations. The device must display a prominent indelible label to this effect.	"Follow Instructions for Use". "Restricted device for use during COVID-19 pandemic, only to be used for emergency ventilation - any adverse incidents must be reported to MHRA." "Manual Back Up Ventilation Must Be Available" (minimum of 50 font) Must include clear marks or labels to indicate the default settings. Breathing system inlets and outlets must be clearly marked with direction arrows.	1. All parts coming into contact with the patient's breath must be either disposable or designed to be reusable 2. All working components of the device must be contained within an impermeable casing. 3. All external surfaces must be cleanable using an approved surface wipe with disinfectant or cloths and approved surface cleaning liquid. 4. HMEF-bacterial-viral filter	Must not be excessively cumbersome so that it would impede hospital operations or prevent easy movement within hospitals circumstances.	A) The chosen material must be reasonably pure and simple in nature (minimise the use of additives where possible) B) For components requiring flexibility avoid the use of materials requiring plasticizers. Good candidates are those materials that belong to the polyolefin family, examples include polyethylene and polypropylene C) For structural components materials such as polycarbonate or Acrylonitrile butadiene styrene (ABS) should be used without additives, although

						reinforcement with glass fibre would be acceptable D) Polyvinyl chloride (PVC) must be avoided in the patient gas pathway E) PVC should be avoided elsewhere
Abba (Mechanical Ventilator Milano (MVM))	P	N	N	Y	N	P
Buytaert (HEV)	N	N	N	P	Y	N
Chiang (VEMERS UC)	N	N	P	P	N	N
Cole (Portsmouth Ventilator)	N	N	N	N	N	N
Dally (OP-Vent)	N	N	N	P	N	N
DeBoer (NR)	N	N	N	N	N	P
El Haddi (CRISIS)	N	N	N	P	N	P
F (DIGIT)	N	N	N	N	N	N
King (RapidVent)	N	N	P	N	N	P

Knorr (CLEVent EV)	N	N	N	P	Y	N
Madekurozwa (NR)	N	N	N	N	N	P
Park (ALIVE Vent)	N	N	N	P	N	N
Raymond (O2U Ventilator)	N	N	N	P	N	N
Rebelo (ATENA)	N		N	N	Y	P
Von Chong (NR)	N	N	N	N	N	P
Wittenberg (CoVent)	N	N	N	N	N	N
Al Husseini (NR)	N	N	N	N	Y	P
Arcos-Legarda (NR)	N	N	N	N	Y	P
Christou (GlasVent)	N	N	N	N	N	P
Dhanani (NR)	N	N	N	N	N	P
Du (ETH Breathe**)	N	N	N	P	Y	P
Gafford (VOV - Vanderbilt Open-source Ventilator)	N	N	N	P	N	P

Gino (AIR – Automated Inflating Resuscitator)	N	N	N	Y	N	P
Grimshandl (HDvent Emergency Ventilator System)	N	N	N	P	N	P
Gruslova (ABBU: Automated Bag Breathing Unit)	P	N	N	N	N	N
Kindomba (ProtoVent)	N	N	N	N	N	P
Mathanlal (ATMO-Vent)	N	N	N	N	N	N
Mathew (Artifical Breathing Capability Device (ABCD))	N	N	N	N	Y	N
Meiry (Ambo Vent)	N	N	N	P	Y	P
Ort (MIT EV)	P	N	N	N	N	P
Palacka (Q-Vent)	N	N	P	P	Y	P
Petsiuk (RepRapable)	N	N	N	N	N	N
Terzi (eSpiro)	N	N	N	N	Y	N

Truong (NR)	N	N	N	P	N	P
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	N	N	N	N	Y	P
Vasan (MAD Vent)	N	N	N	P	N	P
Von Chong (NR)	N	N	N	N	N	N
Beale (Ox-Vent)	N	N	N	Y	Y	P
Chang (Masi)	N	N	N	P	N	P
Fang (AmbuBox)	N	N	N	P	N	N
Williams (NR)	N	N	N	N	N	N
Aihaitijiang (Ori-Vent)	N	N	N	N	P	P
Darwood (NR)	N	N	N	N	Y	N
Dickson (SAVe l)	N	N	N	N	P	N

Dickson (SAVe II)	N	N	N	N	P	N
El Majid (NR)	N	N	N	N	N	N
Fernandez (ResUHUrge)	N	N	N	P	N	N
Haque (NR)	N	N	N	P	Y	P
Marzetti (NR)	N	N	N	N	N	P
Pereira (NR)	N	N	N	P	N	P
Szlosarek (NR)	N	N	N	P	Y	P
White (FALCON- Fast-Assembly COVID-Nineteen)	N	N	N	N	N	P
Zuckerberg (ALFA)	N	N	N	N	N	N

APPENDIX D: STANDARDS CHECKLIST – MHRA (#4) → MHRA. (2020). *Rapidly Manufactured Ventilator System (RMVS)*. [Online]. Available: https://assets.publishing.service.gov.uk/government/

Standard Document	**MHRA**				
Component Recommended	Manufacturing Process (risk of contaminants) **	Hazard Mitigation**	Materials and Parts	Software Safety	Software Development Process/Plan
Details on recommendation	A) Mould release agents used within extrusion or injection moulding techniques may be required in setting up the machine, they should not be needed once a process is in full scale production B) Approximately, the first 20 or so items in an injection moulding production run should be discarded to minimise risk from contamination with mould release agents C) Extrusion and moulding techniques are comparatively simple and well controlled; therefore, ventilators will not be required to be manufactured within cleanroom specifications D) Manufacture in a reasonably clean room and protection of	A) Particulate matter: solid particles suspended in a gas- Particulate matter emissions are not of significant concern if the manufacturing process is adequately controlled as per the above criteria B) Volatile organic compound (VOC): organic compound whose boiling point is in the range of 500C to 2600C- Risk of exposure to VOCs can be minimised through the appropriate choice of materials as set out in section 1 C) Leachable substances (incondensate): chemical removed from the medical device by the action of water, other liquids or other gases related to the use of the medical	Must be made from materials and parts readily available in the UK supply chain (anticipating increasing global restrictions of freight movement). The chosen material must be reasonably pure and simple in nature (minimise the use of additives where possible). For components requiring flexibility avoid the use of materials requiring	1. Must be reliable. RMVS must be capable of continuous operation (100% duty cycle) for 14 days (should be capable for more than 14 days). The expected durability must be specified. 2. Software must be intuitive to use for qualified medical personnel, but these may not be specialists in ventilator use (Must not require more than 30 minutes training for a doctor with some experience of ventilator use. Must include instructions that are built into the labelling of the ventilator. Must include clear labelling of all critical function and controls using standard terms, pictograms and	The software development must be planned. Where possible software for a RMVS should be developed in a facility that has experience of developing software using the standards - "BS EN 62304:2006+A1:2015 Medical device software — Software life-cycle processes and BS EN ISO 14971:2012 Medical Devices – Application of risk management to medical devices". Since the software is likely to be developed to an accelerated life cycle it is essential that the following principles are adhered to: 1. The software is developed under strict process control using a quality management system, ideally BS EN ISO 13485 or BS EN ISO 9001. 2. A process is followed to determine the risks arising from the operation of the software and to mitigate those risks. This is most easily done by the application of BS EN ISO 14971. 3. A software development process is followed to achieve a low

	components and products from contamination should suffice E) If A-D is followed, chemical or particulate testing of the air coming out of the breathing circuit should not be necessary	device- insure a HME filter is used between the ventilator and breathing system.	plasticizers. Polyvinyl chloride (PVC) must be avoided in the patient gas pathway.	colours that will be readily recognised by UK healthcare staff.)	probability of failure of the software in use. This is most easily done by the appropriate application of BS EN 62304 based on the risk management process in 2 above. 4. Less emphasis need be placed on the requirements of BS EN ISO 62304 software post-production monitoring and maintenance processes.
Abba (Mechanical Ventilator Milano (MVM))	N	P	P	P	Y
Buytaert (HEV)	N	N	P	N	Y
Chiang (VEMERS UC)	N	P	P	P	N
Cole (Portsmouth Ventilator)	N	N	P	N	N
Dally (OP-Vent)	N	P	P	N	P
DeBoer (NR)	N	N	P	N	P
El Haddi (CRISIS)	N	N	P	N	N
F (DIGIT)	N	N	N	N	N
King (RapidVent)	N	N	P	N	N

Knorr (CLEVent EV)	N	P	P	N	N
Madekurozwa (NR)	N	N	P	P	N
Park (ALIVE Vent)	N	P	P	N	N
Raymond (O2U Ventilator)	N	P	P	N	N
Rebelo (ATENA)	N	N	P	N	N
Von Chong (NR)	N	N	P	N	N
Wittenberg (CoVent)	N	N	N	N	N
Al Husseini (NR)	N	N	P	N	N
Arcos-Legarda (NR)	N	N	P	N	P
Christou (GlasVent)	N	N	P	N	N
Dhanani (NR)	N	N	P	N	N
Du (ETH Breathe**)	N	P	P	N	N
Gafford (VOV - Vanderbilt Open-source Ventilator)	N	N	P	P	P

Gino (AIR – Automated Inflating Resuscitator)	N	P	P	N	N
Grimshandl (HDvent Emergency Ventilator System)	N	P	P	N	N
Gruslova (ABBU: Automated Bag Breathing Unit)	N	N	P	P	N
Kindomba (ProtoVent)	N	N	P	N	N
Mathanlal (ATMO-Vent)	N	N	P	N	N
Mathew (Artifical Breathing Capability Device (ABCD))	N	N	N	N	N
Meiry (Ambo Vent)	N	P	P	N	N
Ort (MIT EV)	N	N	N	N	N
Palacka (Q-Vent)	N	P	P	P	N
Petsiuk (RepRapable)	N	N	P	N	P
Terzi (eSpiro)	N	N	P	N	N

Truong (NR)	N	P	P	N	N
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	N	N	P	P	N
Vasan (MAD Vent)	N	P	P	N	N
Von Chong (NR)	N	N	P	N	N
Beale (Ox-Vent)	N	P	P	N	N
Chang (Masi)	N	P	P	N	N
Fang (AmbuBox)	N	P	P	N	N
Williams (NR)	N	N	P	N	N
Aihaitijiang (Ori-Vent)	N	N	P	N	N
Darwood (NR)	N	N	N	N	N
Dickson (SAVe l)	N	N	N	N	N

Dickson (SAVe II)	N	N	N	N	N
El Majid (NR)	N	N	P	N	N
Fernandez (ResUHUrge)	N	P	P	N	N
Haque (NR)	N	P	P	N	N
Marzetti (NR)	N	N	P	N	P
Pereira (NR)	N	P	P	P	N
Szlosarek (NR)	N	N	P	N	N
White (FALCON- Fast-Assembly COVID-Nineteen)	N	N	P	N	N
Zuckerberg (ALFA)	N	N	P	N	N

APPENDIX D: STANDARDS CHECKLIST – PEARCE (2020) → Pearce, J. M. (2020). A review of open source ventilators for COVID-19 and future pandemics. *F1000Research*, *9*.

Standard Document	PEARCE et al. 2020		
Component Recommended	Files & Diagrams	Instructions	Other Documentation
Details on recommendation	Design source files; Production files; Printed Circuit Board (PCB) layouts & other electronic design files. Wiring Diagrams.	Instructions for Assembly, Calibration and Operation	Bill of materials, List of tools required
Abba (Mechanical Ventilator Milano (MVM))	Y	N	N
Buytaert (HEV)	Y	N	N
Chiang (VEMERS UC)	Y	Y	Y
Cole (Portsmouth Ventilator)	Y	N	N
Dally (OP-Vent)	Y	N	N
DeBoer (NR)	Y	Y	Y
El Haddi (CRISIS)	N	N	N
F (DIGIT)	Y	N	N
King (RapidVent)	N	Y	Y

Knorr (CLEVent EV)	Y	N	N
Madekurozwa (NR)	N	N	N
Park (ALIVE Vent)	Y	N	N
Raymond (O2U Ventilator)	Y	N	N
Rebelo (ATENA)	N	N	N
Von Chong (NR)	N	N	N
Wittenberg (CoVent)	N	N	N
Al Husseini (NR)	Y	N	N
Arcos-Legarda (NR)	Y	N	Y
Christou (GlasVent)	Y	N	N
Dhanani (NR)	N	N	N
Du (ETH Breathe**)	Y	N	Y
Gafford (VOV - Vanderbilt Open-source Ventilator)	Y	N	N

Gino (AIR – Automated Inflating Resuscitator)	Y	N	N
Grimshandl (HDvent Emergency Ventilator System)	Y	Y	N
Gruslova (ABBU: Automated Bag Breathing Unit)	N	Y	N
Kindomba (ProtoVent)	Y	Y	Y
Mathanlal (ATMO-Vent)	N	N	N
Mathew (Artifical Breathing Capability Device (ABCD))	N	N	N
Meiry (Ambo Vent)	Y	N	N
Ort (MIT EV)	Y	N	N
Palacka (Q-Vent)	Y	N	N
Petsiuk (RepRapable)	Y	Y	Y
Terzi (eSpiro)	Y	N	N
Truong (NR)	Y	N	N
Urbina (Automated manual resuscitator- based emergency ventilator-alternative (AMREV))	Y	Y	N

Vasan (MAD Vent)	Y	N	N
Von Chong (NR)	N	N	N
Beale (Ox-Vent)	Y	N	N
Chang (Masi)	Y	Y	Y
Fang (AmbuBox)	Y	N	N
Williams (NR)	N	N	N
Aihaitijiang (Ori-Vent)	N	N	N
Darwood (NR)	Y	N	N
Dickson (SAVe I)	N	N	N
Dickson (SAVe II)	N	N	N
El Majid (NR)	N	N	N
Fernandez (ResUHUrge)	Y	N	Y
Haque (NR)	Y	N	Y

Marzetti (NR)	Y	N	N
Pereira (NR)	Y	N	N
Szlosarek (NR)	Y	N	N
White (FALCON- Fast-Assembly COVID-Nineteen)	Y	N	N
Zuckerberg (ALFA)	Y	N	N

APPENDIX D: STANDARDS CHECKLIST – MECHANICAL VENTILATION AMID THE COVID-19 PANDEMIC (MVATCP) → Hakimi, A. A., Milner, T. E., Rajan, G. R., & Wong, B. J. (2022). *Mechanical Ventilation Amid the COVID-19 Pandemic*. Springer International Publishing.

Standard Document	**Mechanical Ventilation Amid the Covid-19 Pandemic (MVAtCP)**						
Component Recommended	Control of Settings	PEEP	TV	RR	Alarms	Software Components	Documentation
Details on recommendation	TV, RR, I:E, Overpressure **Assist mode threshold*	5-20 cm H2O	200 to 800 mL	10 - 30 BPM	High priority alarms (indicated by flashing LED light and/or audio alarm): overpressure, under pressure (less than 3 cm H2O), loss of power. Low priority alarms: tidal volume out of spec.	1. Analog input acquisition 2. Hardware and timer Interrupts 3. PWM timer and encoder Interrupts 4. Motor control task 5. Alarm class 6. Display class 7. Flash storage 8. Watchdog timer	Doxygen Documentation
Abba (Mechanical Ventilator Milano (MVM))	P	N	N	N	P	P	N
Buytaert (HEV)	Y	Y	P	Y	Y	P	N
Chiang (VEMERS UC)	Y	Y	P	Y	P	P	N
Cole (Portsmouth Ventilator)	Y	Y	P	Y	Y	N	N
Dally (OP-Vent)	P	N	N	N	P	P	N
DeBoer (NR)	P	N	N	Y	P	P	N

El Haddi (CRISIS)	P	N	Y	N	N	N	N
F (DIGIT)	N	N	N	N	P	N	N
King (RapidVent)	P	N	N	N	P	N	N
Knorr (CLEVent EV)	P	N	N	N		N	N
Madekurozwa (NR)	Y	N	N	N	N	N	N
Park (ALIVE Vent)	Y	N	N	N	N	P	N
Raymond (O2U Ventilator)	P	Y	P	Y	P	N	N
Rebelo (ATENA)	Y	Y	P	Y	P	N	N
Von Chong (NR)	N	N	N	N	N	N	N
Wittenberg (CoVent)	P	N	N	N	N	N	N
Al Husseini (NR)	P	N	P	Y	P	N	N
Arcos-Legarda (NR)	Y	Y	P	Y	P	N	N
Christou (GlasVent)	P	N	N	N	N	N	N

Dhanani (NR)	P	N	N	P	N	N	N
Du (ETH Breathe**)	Y	N	N	N	Y	N	N
Gafford (VOV - Vanderbilt Open-source Ventilator)	P	Y	Y	Y	P	N	N
Gino (AIR – Automated Inflating Resuscitator)	P	Y	Y	Y	N	N	N
Grimshandl (HDvent Emergency Ventilator System)	N	Y	P	Y	P	P	N
Gruslova (ABBU: Automated Bag Breathing Unit)	Y	N	Y	Y	P	N	N
Kindomba (ProtoVent)	P	N	N	N	N	N	N
Mathanlal (ATMO-Vent)	Y	N	N	N	P	P	N
Mathew (Artifical Breathing Capability Device (ABCD))	P	N	N	Y	P	N	N
Meiry (Ambo Vent)	P	N	P	P	P	N	N
Ort (MIT EV)	P	P	Y	Y	Y	N	N
Palacka (Q-Vent)	Y	N	Y	N	P	N	N
Petsiuk (RepRapable)	P	P	Y	Y	P	N	N

Terzi (eSpiro)	Y	N	N	N	P	N	N
Truong (NR)	Y	N	P	N	P	N	N
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	Y	N	P	Y	N	N	N
Vasan (MAD Vent)	P	N	Y	Y	Y	N	N
Von Chong (NR)	P	Y	N	Y	N	P	N
Beale (Ox-Vent)	Y	N	P	N	P	N	N
Chang (Masi)	Y	Y	Y	N	P	N	N
Fang (AmbuBox)	P	Y	P	Y	P	N	N
Williams (NR)	P	N	Y	N	N	N	N
Aihaitijiang (Ori-Vent)	N	Y	Y	P	N	N	N
Darwood (NR)	P	N	Y	Y	P	N	N
Dickson (SAVe I)	N	N	P	N	P	N	N

Dickson (SAVe II)	P	Y	Y	P	P	N	N
El Majid (NR)	N	N	N	N	N	N	N
Fernandez (ResUHUrge)	P	N	N	N	P	N	N
Haque (NR)	N	N	N	N	P	P	N
Marzetti (NR)	P	N	Y		N	P	N
Pereira (NR)	P	Y	N	P	P	N	N
Szlosarek (NR)	P	N	N	N	N	N	N
White (FALCON-Fast-Assembly COVID-Nineteen)	P	N	N	N	N	N	N
Zuckerberg (ALFA)	P	N	N	N	N	N	N

Appendix D: Standards Checklist – CHEST (#1) → Einav S, Hick JL, Han ing D, et al. Surge capacity logistics: care of the critically ill and injured during pandemics and disasters: CHEST consensus statement. Chest. 2014;146(4 Suppl):e17S–43S.

Standard Document	**CHEST**							
Component Recommended	US FDA Approved for pediatric use	Power Source	Modes of Ventilation	Control of Settings	Range of Flow	PEEP	Oxygen Titration	Operate without 50-55 PSI
Details on recommendation	Pediatric and infant approved	AC with battery backup	CPAP volume control (assist/control and SIMV)	RR, PEEP, TV, Flow or I:E ratio, FiO2 *(on 50-55 psi source O2)**	Minimum of 10L/min, Upper limit 80L/min	Internal PEEP, PEEP compensation	Room air to FiO2 1.0 on 50-55psi oxygen source	Able to operate on oxygen concentrator or low-flow oxygen source
Abba (Mechanical Ventilator Milano (MVM))	P	P	N	P	N	P	N	N
Buytaert (HEV)	N	Y	P	Y	Y	P	Y	Y
Chiang (VEMERS UC)	N	N	P	Y	Y	P	Y	P
Cole (Portsmouth Ventilator)	N	P	P	Y	Y	P	Y	P
Dally (OP-Vent)	N	N	P	Y	N	P	Y	P
DeBoer (NR)	N	N	P	P	N	P	N	N
El Haddi (CRISIS)	N	N	P	P	N	P	N	P
F (DIGIT)	N	N	P	N	N	N	N	P

King (RapidVent)	N	N	N	P	P	P	Y	N
Knorr (CLEVent EV)	N	P	P	P	N	P	Y	N
Madekurozwa (NR)	N	N	N	Y	N	P	N	Y
Park (ALIVE Vent)	N	N	P	Y	Y	P	Y	Y
Raymond (O2U Ventilator)	P	N	P	P	N	P	P	N
Rebelo (ATENA)	N	Y	P	Y	N	P	Y	N
Von Chong (NR)	N	N	P	N	N	N	N	N
Wittenberg (CoVent)	N	N	N	P	N	P	N	N
Al Husseini (NR)	N	Y	P	P	N	N	N	Y
Arcos-Legarda (NR)	N	N	P	P	N	P	N	N
Christou (GlasVent)	N	P	P	P	N	P	N	Y
Dhanani (NR)	N	N	N	P	N	N	N	Y
Du (ETH Breathe**)	N	N	P	P	N	P	N	Y

Gafford (VOV - Vanderbilt Open-source Ventilator)	N	N	P	P	N	N	N	Y
Gino (AIR – Automated Inflating Resuscitator)	N	N	P	P	N	P	P	Y
Grimshandl (HDvent Emergency Ventilator System)	N	N	P	N	N	N	N	Y
Gruslova (ABBU: Automated Bag Breathing Unit)	N	N	N	P	N		N	Y
Kindomba (ProtoVent)	N	N	N	P	N	N	N	Y
Mathanlal (ATMO-Vent)	N	P	N	P	P	N	N	N
Mathew (Artifical Breathing Capability Device (ABCD))	N	N	N	P	N	N	N	Y
Meiry (Ambo Vent)	N	P	N	P	N	N	N	Y
Ort (MIT EV)	N	N	P	P	N	N	N	Y
Palacka (Q-Vent)	N	P	P	Y	N	P	Y	Y
Petsiuk (RepRapable)	N	N	N	P	N	N	N	Y
Terzi (eSpiro)	N	P	P	P	N	P	N	Y
Truong (NR)	N	N	P	P	N	N	N	Y

Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	N	N	P	P	N	P	N	Y
Vasan (MAD Vent)	N	P	N	P	N	N	N	Y
Von Chong (NR)	N	N	P	P	N	N	N	Y
Beale (Ox-Vent)	N	N	P	Y	P	P	Y	P
Chang (Masi)	P	P	P	Y	N	P	P	N
Fang (AmbuBox)	N	N	N	P	N	P	N	P
Williams (NR)	N	N	P	P	N	N	N	Y
Aihaitijiang (Ori-Vent)	N	N	N	N	P	N	N	N
Darwood (NR)	N	N	N	P	N	N	N	Y
Dickson (SAVe I)	P	Y	P	N	P	N	N	Y
Dickson (SAVe II)	N	Y	P	P	Y	P	N	Y
El Majid (NR)	N	N	N	N	N	N	N	N

Fernandez (ResUHUrge)	N	N	N	P	Y	N	N	Y
Haque (NR)	N	P	N	P	N	N	N	N
Marzetti (NR)	N	N	N	P	N	N	N	P
Pereira (NR)	N	N	N	P	N	P	Y	N
Szlosarek (NR)	N	N	N	P	N	P	N	Y
White (FALCON-Fast-Assembly COVID-Nineteen)	N	N	N	P	N	P	N	N
Zuckerberg (ALFA)	N	N	N	P	N	N	N	N

Appendix D: Standards Checklist – CHEST (#2) → Einav S, Hick JL, Han ing D, et al. Surge capacity logistics: care of the critically ill and injured during pandemics and disasters: CHEST consensus statement. Chest. 2014;146(4 Suppl):e17S–43S.

Standard Document	**CHEST**							
Component Recommended	Measurements/Monitoring	Ease to Set-up/Set Ventilation Settings/User-friendly	Sustained Use	Oxygen Consumption	Alarms	General Durability	Recalls/Vendor and Support Contract/ Maintenance	Cost
Details on recommendation	Measure and display inspiratory TV, Peak inspiratory pressure	Ability to read screen: at a distance, in sunlight, in low ambient light	*Refer to standards excel document	*Refer to standards excel document	Audible and visible. Sounds for patient disconnect, apnea, high pressure, low source gas pressure	"Fluid spill resistance Mechanical shock (4-ft drop) Mechanical vibration EMC and electrical safety testing Storage temperature and humidity: 2 20°C to 60°C, 0 to 95% RH Operating temperature and humidity: 5°C to 40°C, 0 to 95% RH"	Vendor must disclose all recalls on ventilator and equipment in the past 3 years. "Company will continue to produce ventilator model for at least 5 y and continue to support model 10 y after order is completed. Able to produce all ventilators within 18 mo from order; if unable to meet this criterion, estimated ramp-	$13,000 (2014 USD) Cost must include kitted ventilator, end-user training program, maintenance, and all necessary equipment (ancillary supplies) to ventilate one patient on both 50-55 psi and low-flow oxygen

							up/surge period and time frame for delivery must be stated. 24 h, 7 d/wk direct phone access to senior-level technician Vendor responsible for maintaining call coverage Warranty Provide any storage life data, if available" 1 y for battery and all equipment interval maintenance; also include battery replacement if needed	
Abba (Mechanical Ventilator Milano (MVM))	P	N	P	N	P	N	N	P
Buytaert (HEV)	P	N	N	N	P	N	N	P
Chiang (VEMERS UC)	Y	N	N	N	P	N	N	P

Cole (Portsmouth Ventilator)	P	N	N	N	P	N	N	P
Dally (OP-Vent)	P	N	N	N	P	N	N	P
DeBoer (NR)	P	N	N	N	P	N	N	P
El Haddi (CRISIS)	Y	N	N	N	N	P	N	P
F (DIGIT)	N	N	N	N	P	N	N	P
King (RapidVent)	P	N	N	N	P	N	N	P
Knorr (CLEVent EV)	P	N	N	N	P	N	N	P
Madekurozwa (NR)	P	N	N	N	N	N	N	P
Park (ALIVE Vent)	Y	N	N	N	N	N	N	P
Raymond (O2U Ventilator)	N	N	N	N	P	N	N	P
Rebelo (ATENA)	P	N	N	N	P	N	N	P
Von Chong (NR)	N	N	N	N	P	N	N	P
Wittenberg (CoVent)	N	N	N	N	N	N	N	P

Al Husseini (NR)	P	N	N	N	P	N	N	P
Arcos-Legarda (NR)	Y	N	N	N	P	N	N	P
Christou (GlasVent)	Y	N	N	N	N	N	N	P
Dhanani (NR)	P	N	N	N	N	N	N	P
Du (ETH Breathe**)	P	N	N	N	P	N	N	P
Gafford (VOV - Vanderbilt Open-source Ventilator)	P	N	N	N	P	P	N	P
Gino (AIR – Automated Inflating Resuscitator)	P	N	N	N	N	N	N	P
Grimshandl (HDvent Emergency Ventilator System)	N	N	N	N	P	N	N	P
Gruslova (ABBU: Automated Bag Breathing Unit)	P	N	N	N	P	N	N	P
Kindomba (ProtoVent)	N	N	N	N	N	N	N	P
Mathanlal (ATMO-Vent)	Y	N	N	N	P	N	N	P

Mathew (Artifical Breathing Capability Device (ABCD))	P	N	N	N	P	N	N	P
Meiry (Ambo Vent)	P	N	N	N	P	N	N	P
Ort (MIT EV)	P	N	N	N	P	N	N	P
Palacka (Q-Vent)	P	N	N	N	P	P	N	P
Petsiuk (RepRapable)	P	N	N	N	P	N	N	P
Terzi (eSpiro)	P	N	N	N	P	N	N	P
Truong (NR)	Y	N	N	N	P	N	N	P
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	P	N	N	N	N	N	N	P
Vasan (MAD Vent)	P	N	N	N	P	N	N	P
Von Chong (NR)	P	N	N	P	P	N	N	P

Beale (Ox-Vent)	P	N	N	N	P	N	N	P
Chang (Masi)	Y	N	N	N	P	N	N	P
Fang (AmbuBox)	P	N	N	P	P	N	N	P
Williams (NR)	P	N	N	N	N	N	N	P
Aihaitijiang (Ori-Vent)	N	N	N	N	N	N	N	P
Darwood (NR)	P	N	N	N	P	N	N	P
Dickson (SAVe I)	N	N	N	N	P	N	N	P
Dickson (SAVe II)	P	N	N	N	P	N	N	P
El Majid (NR)	N	N	N	N	N	N	N	P
Fernandez (ResUHUrge)	N	N	N	N	P	N	N	P
Haque (NR)	N	N	N	N	P	N	N	P
Marzetti (NR)	N	N	N	N	N	N	N	P
Pereira (NR)	P	N	P	N	P	N	N	P

Szlosarek (NR)	N	N	N	N	N	N	N	P
White (FALCON-Fast-Assembly COVID-Nineteen)	P	N	N	N	N	N	N	P
Zuckerberg (ALFA)	N	N	N	N	N	N	N	P

Appendix D: Standards Checklist – CHEST (#3) → Einav S, Hick JL, Han ing D, et al. Surge capacity logistics: care of the critically ill and injured during pandemics and disasters: CHEST consensus statement. Chest. 2014;146(4 Suppl):e17S–43S.

Standard Document	**CHEST**								
Component Recommended	End-User Training Program	Ventilator Kit Description	Positive Pressure Ventilation Equipment	Ancillary Respiratory Equipment	Circuits	Humidifiers	Medical Gas	Monitoring Devices	Oxygen Delivery
Details on recommendation	Laminated instruction materials attached	"Rigid case Weight of kit with ventilator and all ancillary equipment needed to ventilate one patient must not exceed 30 lb Wheels provided on case"	airways, manual resuscitator with face mask, T-piece resuscitators	Closed-circuit suction catheter, Endotracheal tube, Tube guide, Endotracheal tube securing device, Single-use suction catheter, Yankauer suction catheter, Suction trap and hoses (regulator to trap and trap to suction device), Vacuum source and suction regulator, Fingertop for suction	Circuit for use with HME, Circuit for use with heated humidifier with wire, Expiratory limb filter in ventilator circuit, HEPA style filter	HME (with or without filter), Heated humidifier (no heated wire circuit), water traps, Heated humidifier (with heated wire circuit), Chamber, Sterile water	Compressed air, Compressed oxygen, 50-55 psi line with quick connection from source to ventilator, Liquid oxygen, Oxygen reservoir for low-flow oxygen use by mechanical ventilator (if applicable), Oxygen regulators	Pulse oximeter, Pulse oximetry probe, capnograph, capnograph tubing, capnograph fluid trap	Oxygen, air regulators, flow meters, Nasal prongs, Face masks, Face mask with reservoir, Intubation equipment

Abba (Mechanical Ventilator Milano (MVM))	P	N	N	N	P	P	Y	N	N
Buytaert (HEV)	N	P	P	P	N	N	Y	N	P
Chiang (VEMERS UC)	Y	N	N	N	P	P	Y	N	N
Cole (Portsmouth Ventilator)	N	N	N	N	N	N	Y	N	N
Dally (OP-Vent)	N	N	N	N	P	P	Y	N	N
DeBoer (NR)	P	N	P	P	N	N	Y	N	P
El Haddi (CRISIS)	N	N	N	N	N	N	Y	N	N
F (DIGIT)	N	N	N	N	N	N	Y	N	N
King (RapidVent)	P	N	N	N	N	N	Y	N	N
Knorr (CLEVent EV)	N	P	N	N	P	P	Y	N	N
Madekurozwa (NR)	N	N	P	P	N	N	Y	N	P
Park (ALIVE Vent)	N	N	N	N	P	P	Y	N	N
Raymond (O2U Ventilator)	N	N	P	P	P	P	Y	N	P

Rebelo (ATENA)	N	Y	N	N	N	N	Y	N	N
Von Chong (NR)	N	N	P	P	N	N	Y	N	P
Wittenberg (CoVent)	N	N	N	N	N	N	Y	N	N
Al Husseini (NR)	N	P	N	N	N	N	P	N	N
Arcos-Legarda (NR)	N	P	N	N	N	N	N	N	N
Christou (GlasVent)	N	N	N	N	N	N	P	N	N
Dhanani (NR)	N	N	N	N	N	N	P	N	N
Du (ETH Breathe**)	N	N	N	N	P	P	P	N	N
Gafford (VOV - Vanderbilt Open-source Ventilator)	N	N	N	N	N	N	P	N	N
Gino (AIR – Automated Inflating Resuscitator)	N	N	N	N	P	P	P	N	N
Grimshandl (HDvent Emergency Ventilator System)	N	N	N	N	P	P	P	N	N
Gruslova (ABBU:	P	N	P	P	N	N	P	N	P

Automated Bag Breathing Unit)									
Kindomba (ProtoVent)	P	N	N	N	N	N	P	N	N
Mathanlal (ATMO-Vent)	N	N	N	N	N	N	Y	N	N
Mathew (Artifical Breathing Capability Device (ABCD))	N	P	N	N	N	N	P	N	N
Meiry (Ambo Vent)	N	P	P	P	P	P	Y	N	P
Ort (MIT EV)	N	N	N	N	N	N	P	N	N
Palacka (Q-Vent)	N	P	N	N	P	P	Y	N	N
Petsiuk (RepRapable)	P	N	N	N	N	N	P	N	N
Terzi (eSpiro)	N	N	N	N	N	N	P	N	N
Truong (NR)	N	N	N	N	P	P	N	N	N
Urbina (Automated manual resuscitator-based emergency ventilator-	P	P	N	N	N	N	N	N	N

alternative (AMREV))									
Vasan (MAD Vent)	N	N	N	N	P	P	N	N	N
Von Chong (NR)	N	N	P	P	N	N	N	N	P
Beale (Ox-Vent)	N	P	N	N	P	P	P	N	N
Chang (Masi)	P	N	P	P	P	P	N	N	P
Fang (AmbuBox)	N	N	P	P	P	P	P	N	P
Williams (NR)	N	N	P	P	N	N	N	N	P
Aihaitijiang (Ori-Vent)	N	P	N	N	N	N	N	N	N
Darwood (NR)	N	P	N	N	N	N	P	N	N
Dickson (SAVe I)	N	N	N	N	N	N	P	N	N
Dickson (SAVe II)	N	N	N	N	N	N	P	N	N
El Majid (NR)	N	N	N	N	N	N	N	N	N
Fernandez (ResUHUrge)	N	N	P	P	P	P	N	N	P

Haque (NR)	N	P	P	P	P	P	N	N	P
Marzetti (NR)	N	N	N	N	N	N	N	N	N
Pereira (NR)	N	N	N	N	P	P	Y	N	N
Szlosarek (NR)	N	P	N	N	N	N	P	N	N
White (FALCON- Fast-Assembly COVID-Nineteen)	N	N	N	N	N	N	N	N	N
Zuckerberg (ALFA)	N	N	P	P	N	N	P	N	P

Appendix D: Standards Checklist – Chartered Institute of Ergonomics and Human Factors (CIEHF) (#2) → Einav S, Hick JL, Han ing D, et al. Surge capacity logistics: care of the critically ill and injured during pandemics and disasters: CHEST consensus statement. Chest. 2014;146(4 Suppl):e17S–43S.

Standard Document	**CIEHF**							
Component Recommended	Alarms	User-Interface	End-User Training Program (Software)	Ventilator Kit / Environment of Use	Ancillary Respiratory Equipment	Humidifiers	Software Safety	Software Development Process/Plan
Details on recommendation	Alarms included for critical situations where a user response is required. Alarms must be audible in a noisy critical care environment. Note that different alarms/tones may mean different things to user.	Try to align new design with existing designs. Ventilators need to be usable by novices (technicians and maintenance staff) as well as experienced users.	Must be as short and straight to the point as possible (may not have much time in critical periods). Training is minimized through good user design. Training might include routine tasks, such as basic interaction with the device (e.g. setting up parameters and starting ventilation), critical task	Lightweight and on a base that allows easy repositioning to avoid musculoskeletal health issues for staff. Screens and displays should be adjustable for height. Retractable cables are ideal. Buttons far enough away so two aren't activated by accident. Consider limitations of new operational environments. Ensure appropriate connectors and power supplies are in place.	Range of endotracheal tube (ETT) sizes, ETCO2 monitoring, tube ties	Heat and moisture exchanger (HME) filter	Formative usability testing will allow the user to perform tests on the software to ensure they are familiar with the program, know what to do when issues arise and can set up parameters, settings, etc,. for patients.	Mentions 4 main components to consider throughout the software design process 1. Users 2. Environment 3. Tasks 4. Risks

			steps (e.g. changing ventilation modes), responding to alarms or patient deterioration, and managing device issues or problems (e.g. power failure).					
Abba (Mechanical Ventilator Milano (MVM))	Y	P	P	N	N	N	Y	Y
Buytaert (HEV)	Y	P	N	P	P	N	N	Y
Chiang (VEMERS UC)	Y	N	N	N	N	N	N	N
Cole (Portsmouth Ventilator)	Y	N	N	N	N	N	N	N
Dally (OP-Vent)	Y	N	N	N	N	N	N	P
DeBoer (NR)	Y	P	N	N	P	N	N	P
El Haddi (CRISIS)	N	P	N	N	N	N	N	N
F (DIGIT)	Y	N	N	N	N	N	N	N

King (RapidVent)	Y	N	N	N	N	N	N	N
Knorr (CLEVent EV)	Y	N	N	P	N	N	N	N
Madekurozwa (NR)	N	N	N	N	P	N	N	N
Park (ALIVE Vent)	N	N	N	N	N	N	N	N
Raymond (O2U Ventilator)	Y	N	N	N	P	Y	N	N
Rebelo (ATENA)	Y	N	N	Y	N	N	N	N
Von Chong (NR)	P	Y	N	N	P	N	N	N
Wittenberg (CoVent)	N	N	N	N	N	N	N	N
Al Husseini (NR)	P	N	N	P	N	N	N	N
Arcos-Legarda (NR)	Y	N	N	P	N	N	N	P
Christou (GlasVent)	N	N	N	N	N	N	N	N
Dhanani (NR)	N	N	N	N	N	N	N	N
Du (ETH Breathe**)	P	N	N	N	N	N	N	N

Gafford (VOV - Vanderbilt Open-source Ventilator)	Y	N	N	N	N	N	N	P
Gino (AIR – Automated Inflating Resuscitator)	N	N	N	N	N	N	N	N
Grimshandl (HDvent Emergency Ventilator System)	Y	P	N	N	N	N	N	N
Gruslova (ABBU: Automated Bag Breathing Unit)	Y	P	P	N	P	N	Y	N
Kindomba (ProtoVent)	N	N	N	N	N	N	N	N
Mathanlal (ATMO-Vent)	Y	N	N	N	N	N	N	N
Mathew (Artifical Breathing Capability Device (ABCD))	Y	N	P	P	N	N	N	N
Meiry (Ambo Vent)	Y	P	N	P	P	Y	N	N
Ort (MIT EV)	Y	N	N	N	N	N	N	N
Palacka (Q-Vent)	Y	N	N	P	N	N	N	N

Petsiuk (RepRapable)	Y	N	N	N	N	N	N	P
Terzi (eSpiro)	Y	N	N	N	N	N	N	N
Truong (NR)	Y	N	N	N	N	N	N	N
Urbina (Automated manual resuscitator-based emergency ventilator-alternative (AMREV))	N	N	N	P	N	N	N	N
Vasan (MAD Vent)	Y	N	N	N	N	N	N	N
Von Chong (NR)	P	Y	N	N	P	N	N	N
Beale (Ox-Vent)	Y	P	N	P	N	Y	N	N
Chang (Masi)	Y	P	N	N	P	Y	N	N
Fang (AmbuBox)	P	N	N	N	P	N	N	N
Williams (NR)	N	N	N	N	P	N	N	N
Aihaitijiang (Ori-Vent)	N	N	N	P	N	N	N	N

Darwood (NR)	P	P	N	P	N	N	N	N
Dickson (SAVe I)	Y	N	N	N	N	N	N	N
Dickson (SAVe II)	Y	N	N	N	N	N	N	N
El Majid (NR)	N	N	N	N	N	N	N	N
Fernandez (ResUHUrge)	Y	N	N	N	P	Y	N	N
Haque (NR)	Y	P	N	P	P	Y	N	N
Marzetti (NR)	N	P	N	N	N	N	N	P
Pereira (NR)	Y	N	N	N	N	Y	N	N
Szlosarek (NR)	N	N	N	P	N	N	N	N
White (FALCON- Fast-Assembly COVID-Nineteen)	N	N	N	N	N	N	N	N
Zuckerberg (ALFA)	N	N	N	N	P	N	N	N