



# Article Advanced Manufacturing Design of an Emergency Mechanical Ventilator via 3D Printing—Effective Crisis Response

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Abstract: Nowadays, there is a market need that is pushing manufacturers to support more sustainable product designs regardless of any crisis. Two important lessons that society inferred from the COVID-19 pandemic are that the industry needs an improved collaboration efficiency that can handle such emergencies and improve its resource conservation to avoid having shortages. Additive manufacturing technologies use 3D object scanners to direct hardware to deposit material, layer upon layer, in precise geometric shapes, and are positioned to provide a disruptive transformation in how products are designed and manufactured. They can provide for the planet in fighting against crisis from a materials and applications perspective. In this context, the optimization and production of emergency ventilators in health systems were investigated with plans for 3D printing received from the University of Illinois Urbana-Champaign. An evaluation of the printability of CAD files and a partial redesign to limit dimensional variability, acceptable surface finish, and a more efficient printing process were performed. Six parts of the design were redesigned to make printing easier, faster, and less expensive. In the case of the O<sub>2</sub> inlet attachment, the necessary supports were difficult to remove due to the part's geometry, leading to redesign. The modulator top and bottom part, the patient tee, the manometer body, and the pop-off valve cap were also redesigned in order to avoid dimensional variability and possible rough surfaces. Metallic and thermoplastic composite ventilators were produced and then tested in real operating conditions, such as in a hospital setting with a realistic oxygen supply. The preliminary findings are promising compared to the initial design, both in terms of construction quality and performance such as exhalation rate adjustment and emergency valve operation. Also, a combination of manufacturing technologies was evaluated. The modifications allowed optimal casting (injection molding) of the parts and therefore faster production, instead of printing each part, when high output is required.

**Keywords:** design optimization; sustainable industrial manufacturing; COVID-19 pandemic; additive manufacturing; emergency ventilator demand; experimental assessment

# 1. Introduction

Supply chain crises can be prevented with sustainable product design and development [1,2]. The four key areas of sustainable manufacturing are sustainable supply chain, materials, design and production, management/organization, and policy-making that achieve the industry's sustainability support of the circular economy [3]. However, the COVID-19 pandemic showed that the industry needs improved collaboration efficiency to cope with emergencies like this, as well as to improve resource efficiency and avoid shortages [4,5].

A pandemic crisis such as the coronavirus disease (COVID-19), a severe acute respiratory infection caused by a novel coronavirus (SARS-CoV-2), began to spread from



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**Copyright:** © 2023 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). Wuhan (China) to the rest of the world in December 2019 [6]. The COVID-19 pandemic overwhelmed the medical infrastructure at global, national, and regional level in most countries, causing high mortality rates [7]. For instance, the FDA issued emergency use authorization (EUA) for ventilators as they became insufficient [8]. COVID-19 patients can develop acute respiratory distress syndrome (ARDS), causing severe difficulty in breathing because of fluid leakage into the lungs [9].

The World Health Organization (WHO)'s guidelines suggested that patients with known or suspected COVID-19 should be treated at an early stage with less invasive treatments, including continuous positive airway pressure (CPAP) or noninvasive ventilation (NIV) (also known as an emergency ventilator) [10]. Early intubation of a patient with ARDS could result in the intubation and mechanical ventilation of patients who would have otherwise improved on CPAP or NIV [11]. In a pandemic crisis and resource-limited conditions, hospitals are overwhelmed, as cases rise at an 'alarming rate', and unnecessary intubation and ventilation of one patient can cause life-saving treatment for another patient.

Emergency mechanical ventilation can be used in the treatment of these patients by supplying oxygen. The key component of critical care to avoid mortality due to ARDS and hypoxemia is an appropriate oxygen supply [12]. Scientific groups and organizations investigated the manufacturing of emergency ventilators in case of high demand such as a pandemic crisis [13,14]. Many different strategies of positive pressure ventilation are available; these are triggered volume-cycled and pressure-cycled ventilations, delivered at a range of rates, volumes, and pressures. Ventilatory strategies have been devised for different disease processes to protect pulmonary parenchyma while maintaining adequate gas exchange, and they may be responsible for the increased rates of survival for pathologies such as ARDS [15].

Volume-cycled mode: Inhalation continues until a predetermined tidal volume (TV) is reached, followed by passive exhalation. At rest, tidal volume is a physiological concept that refers to the quantity of air transported between inspiration and expiration. Adults breathe about 7 milliliters (mL) per kilogram (kg) of ideal body weight on average [16]. Gas is supplied with a steady inspiratory flow pattern in this mode, resulting in peak pressures added to the airways that are greater than the pressure needed for lung expansion (plateau pressure), resulting in elevated airway pressures and the risk of barotrauma. Peak pressure rises as a result of these pathophysiological conditions. Despite this, a ventilatory mode like this is a common first option because it guarantees continuous minute ventilation despite potentially irregular pulmonary compliance, which is a test of the lung's capacity to extend and expand.

Pressure-cycled mode: As a predetermined peak inspiratory pressure (PIP) is applied, the pressure differential between the ventilator and the lungs causes inflation before the peak pressure is reached, at which point passive exhalation occurs. The amount delivered with each breath is determined by pulmonary and thoracic compliance. A decelerating inspiratory flow pattern, in which inspiratory flow tapers off as the lung inflates, is a potential benefit of pressure-cycled modes [17]. As a consequence, the gas delivery in the lungs is normally more uniform. Nonetheless, pressure-cycled ventilation has grown in importance in the intensive care environment for the treatment of patients with ARDS, whose lungs are more likely to have a wide variety of alveolar dysfunction and are more susceptible to the symptoms of volutrauma and barotrauma [18]. Dynamic variations in pulmonary dynamics can result in differing tidal volumes, which is a significant drawback. Newer ventilators, on the other hand, provide volume-assured pressure-cycled ventilation, under which peak pressures are increased as required to provide a predetermined minimum tidal volume.

Pressure-cycled pneumatic ventilators, such as the Illinois RapidVent [19,20], are particularly appealing for this emergency because they run without the use of electronic components since they are operated by pressurized gas and driven by a mechanical modulator. Successful manufacture of these ventilators must be accompanied by low production costs and high output rates.

Additive manufacturing, also known as 3D printing, is an advanced manufacturing process that produces objects by adding the required materials, which removes the necessity of subtracting materials by means of milling, machining, etc., to obtain desired shapes [21,22]. AM is a quickly developing area of technology that has developed into a whole new method of designing and building objects, opening up previously unimagined possibilities and it is regarded as one of the cornerstones of the upcoming technological revolution, alongside the Internet of Things and big data analytics (Industry 4.0) [23]. In response to the COVID-19 pandemic, AM has emerged as an alternative and fast distribution of medical devices and a new model has emerged in that design, distributed manufacturing, rapid deployment, materials, and repairs can be used for future risk mitigation in emergency situations [24,25]. Several manufacturing companies and universities such as Italian company Isinnova; Airwolf3D, a 3D printing company in the USA; Italian 3D printing company Weerg; and Prisma Health collaborated with Clemson University and University of South Carolina; Materialize; and a Belgium-based 3D printing company, University of Illinois Urbana-Champaign; designed and produced ventilator parts with AM during the pandemic [26].

There is limited work focusing on the science and engineering of emergency ventilators, and there is a need for new research into emergency ventilator performance, design, and testing. In this work, the optimization and production of metallic and thermoplastic composite respirators with AM and their testing in real operating conditions was investigated, having originally received plans for 3D printing from the University of Illinois Urbana–Champaign, which produced disposable mechanical ventilators. The CAD files were analyzed in order to evaluate their printability, resulting in a partial redesign in order to limit dimensional variability, produce an acceptable surface finish, and make the printing process generally easier, faster, and less expensive. In addition, the combination of manufacturing technologies was evaluated in order to achieve high output production.

#### 2. Materials and Methods

# Initial Design

The initial design was the Illinois RapidVent technology that was provided by the University of Illinois Urbana–Champaign [19,20] (Figure 1a). The internal mechanism of the ventilator under study induces mechanical ventilation cycles with the options of PIP and breath per minute control. The PIP/PEEP is intrinsic to the unit; nevertheless, it can be altered by use of external components. The ventilator is composed of three basic sections (Figure 1b), namely:



**Figure 1.** (a) Schematic of the oxygen flow; (b) exploded view of the ventilator assembly (modified from [15,16]).

Patient tee: As the name implies, this section includes the patient connection via a tapered inside diameter, the inlet of pressurized oxygen with an  $FiO_2$  attachment (percentage of oxygen in the air mixture that is delivered to the patient) so as to provide 100 or 50% of oxygen. The patient tee also incorporates two safety features: a pop-off valve to

prevent over-pressurization and a one-way valve so as to provide additional flow rate upon a probable spontaneous inhalation.

Manometer: this section, at the middle of the ventilator, measures the pressure of the breathing cycles.

Modulator: Probably the most important component of the assembly, as it cycles the pressure and flow between the inspiratory and exhalation times. The rate and pressure dials adjust the total respiratory rate and PIP, respectively. The whole process is based on a diaphragm inside the modulator, whose preparation is crucial. Specific mechanical performance should be met so as to guarantee reliability of the end product.

#### 3. Results

#### 3.1. Design Optimization

In order for a CAD manifold to be printable, it has to fulfill some specifications. These specifications are related to the size of the parts to be printed as well as the ability of the material to sustain its own weight when there are features such as overhangs, bridges, holes, and hollow sections. In FDM (fused deposition modeling), the layers are printed in a way that they slightly protrude and that way the object can expand beyond its previous layer width on the XY plane. However, when the overhangs are more than 45°, supports are needed in order to provide stability to the part during the printing process.

The received RapidVent CAD device was analyzed in order to evaluate its printability. It was decided that six parts of the design that needed supports in order to be printed should be redesigned. In the case of the  $O_2$  inlet attachment, the necessary supports would be very difficult to be removed due to the part's geometry, leading to redesign. On the other hand, the modulator top and bottom part, the patient tee, the manometer body and the pop-off valve cap were also redesigned in order to avoid dimensional variability, possible rough surfaces that could be provoked by support removal and to make the printing process easier, faster, and less costly. Furthermore, these modifications produce more suitable parts for molding, in the case where increase in production is demanded.

The most important part that needed redesign was the inlet attachment. The initial part geometry does not provide access for support removal post printing. The inlet dimensions are critical to air flow regulation and a small change in the geometry caused by the supports would affect its functionality dramatically. Specifically, the small orifice is responsible for the flow rate when the inlet is set to 50 psi. The channels' diameters provoke an ejector effect that defines the flow rate of the air drawn in, from the outside, through the entrainment slot.

An attempt was made to print the geometry in various orientations, but none of them allowed use without supports (Figure 2). In order to bypass this problem, the Ejector-FiO<sub>2</sub> part was cut into two pieces and extra threads were added in the two new parts so that they could be jointed again (Figure 3).

The dimensions of the orifice as well of the channels were kept at the initial values in order to assure the functionality of the device. As seen in Figure 3, an internal thread was designed at the one part and an external thread was added to the connector body so that a watertight connection could be achieved.



Figure 2. The supports needed (in green color) in two possible printing orientations.



**Figure 3.** (a) Initial CAD of the ejector being compact with the connectors body; (b,c) the redesigned parts with the new threads; (d,e) cross section of the new parts.

It was decided that the bottom modulator had to be redesigned as well. In order to minimize supports, avoid printing defects and maximize surface quality, material was added in the bottom modulator with a conical shape and the thread where the rate dial adjusts was also prolonged so that it could offer steadiness while printing. The material was added only externally, and the channel's dimensions were thus not affected. The original and new designs are shown in Figure 4a,b.



Figure 4. (a) Initial CAD of the bottom modulator; (b) final CAD of the bottom modulator.

The top modulator was also redesigned because the initial design would need supports, possibly rendering the part nonwatertight. The tube that connects to the manometer body was removed from the design so that the manometer body can attach directly to the modulator top as seen in Figure 5.



Figure 5. (a) Initial CAD of the top modulator; (b) final CAD of the top modulator.

Similarly, the manometer connector was designed with a curve, so that the printing could occur without any supports, as seen in Figure 6.



Figure 6. (a) Initial CAD of the manometer body; (b) final CAD of the manometer body.

The patient tee section, where the O<sub>2</sub> attachment, the pop-off valve cap, the one-way valve flapper and the patient connection are attached, has been redesigned, as seen in Figure 7. Once more, the ability to be printed using the fewest supports necessary was the criterion for the reshaping. In order for the one-way valve flapper to face the same way as the  $O_2$  attachment, it was specifically turned 90 degrees. In this manner, the printing process is made simpler, quicker, less expensive, and requires fewer supports. Additionally, the extruded threads were divided into separate pieces, and the main body was provided with a negative thread pattern. In this manner, the system's operation is unaffected, and the pieces do not need to be printed with supports.



(a)

Figure 7. (a) Initial CAD of the patient tee; (b) final CAD of the patient tee.

Last but not least, the pop-off valve cap was gently modified to remove minor features without compromising its operation (Figure 8).



Figure 8. (a) Initial CAD of the pop-off valve cap; (b) final CAD of the pop-off valve cap.

The pieces were printed after the final CAD was created to verify the operation of the revised sections. The MarkForged Mark 2 and MarkForged Metal-X 3D printers were employed. The materials utilized were 17-4 PH Stainless Steel and Markforged Onyx (fused nylon and chopped carbon fibers).

# 3.2. Manufacturing Process

The best designs were used to produce metal and plastic ventilators. The capabilities of the 3<sup>\mathbf{Y}</sup> ltd firm, which exhibits significant activity in the additive manufacturing industry, were utilized for this aim. Figure 9a,b depict the reinforced nylon and steel ventilators that were created using specialist 3D printers. Figure 10a,b show the completed goods.





Figure 9. (a) MarkForged Composite Nylon printer; (b) Metal-X printer.





Internal components are necessary for the final assembly to work properly. These are two sets of silicone diaphragms and springs. The pop off valve uses one set to enable decompression in the event of over-pressurization, while the modulator uses the other set to determine the fundamental parameters for the desired respiration cycle. In order to find the ideal stiffness, K, a number of springs were made (Figure 11a). Additionally, silicone diaphragms were cast, and their hardness was tested (Figure 11b).



Figure 11. (a) A produced series of springs; (b) casted silicone diaphragms.

The finished assemblies (Figure 12) were subsequently tested under actual operational circumstances, such as in a hospital setting with a realistic oxygen supply. Initial outcomes



are viewed favorably in terms of both building quality and performance (exhalation rate adjustment, emergency valve operation, etc.).

**Figure 12.** Final assembly including: 1. a test lung; 2. HEPA and moisture filters; 3. the ventilator; 4. a flow meter; 5. the oxygen supply.

#### 3.3. Mass Production

Two different 3D printers were used in the manufacturing process, namely, Mark 2 and Metal X.

Mark 2 uses the continuous fiber reinforcement (CFR) printing process. It is a carbon fiber composite 3D printer enabling the production of strong parts easily and repeatably. It has a 2nd generation fiber reinforcement system, enabling the printing of continuous fibers into parts that can be as strong as aluminum. The Z-layer resolution it supports is 100–200 µm. Metal X uses the metal-fused filament fabrication (FFF) printing process. The printing technology is ADAM (atomic diffusion additive manufacturing), in which the printed material results from metal powder, which is embedded in a special filament together with polymeric linker. After the printing is completed, the material is heated to remove the plastic and allow sintering, leading to a high strength material and a density of 97% corresponding to metal pieces made with traditional techniques. More specifically, ADAM technology is an end-to-end process in which metal powder is embedded in a filament with a polymeric binder providing convenience and safety during the handling. The material is printed in successive layers, then placed in the washing machine where most of the polymer binder is removed using Opteon sion and finally is placed in the furnace where the sintering takes place, during which the material and the powder is fixed to a high density metal piece. A variety of metallic materials can be printed, such as 17-4PH stainless steel, copper, and Inconel for a plethora of industrial applications. The printer can provide a Z-layer resolution of 50–125 µm (post-sinter).

Due to local availability of substitute equipment and realistic estimates of building schedules and prices, the demand for such devices has been constrained.

Due to budgetary and time restraints, as well as the accessibility of suitable alternatives in the area, the demand for such tools has decreased. On the other hand, simpler components, such as cables, have often been used in practice, allowing for the reuse or recycling of current supplies and machinery. Similar to RapidVent, low demand has limited practical usage despite efficient manufacturing of the specification with adjustments for local connection sizes, filters, and instruments. This is despite scaling up production capabilities, present stockpiles, material reuse, and COVID entry volumes. There are many ways that 3D printing may be applied as a technology to receive better outcomes. As an illustration, consider the rapid and mass production of mechanical ventilators in response to rising demand (due to the criticality of the situation). Designing a prototype, optimizing it, and then using 3D printers to build a metal mold are the solutions to this challenge. Compared to the conventional method, the mold is produced fast and is used to produce injection-molded goods. As can be seen in Table 1, casting is a very effective production method that cannot be compared to 3D printing. Estimated costs are listed for each component.

**Table 1.** Comparing 3D printing to injection molding.

	<b>3D Printing</b>		Injection Molding	
Material	Cost/Part	<b>Production Time/Part</b>	Cost/Part	<b>Production Time/Part</b>
NYLON	EUR 200	1 working week	EUR 20	2 h
Steel	EUR 700	2 working weeks	EUR 100	4 h

#### 4. Discussion

Additive manufacturing (AM) can play a key role in a crisis such as the COVID-19 pandemic due to unprecedented demand. The geometric freedom provided by additive manufacturing and the ability to provide more personalized patient care in a cost-effective manner is extremely attractive [27]. In this context, in this work, the optimization and production of emergency ventilators via 3D printing were investigated.

At the beginning of the pandemic, Ranney et al. [28] reported the life-threatening shortages and challenges of providing ventilators parts by the hospitals, as around 2–4% of the COVID-19 patients required ventilator supports [26]. Manufacturing sector failed to meet the unaccepted demand and thousands of people could not be treated properly [29]. For that reason, several AM research teams and organizations joined the fight against COVID-19 by producing components for medical equipment such as ventilators [26].

In the COVID-19 crisis, SEAT collaborated with the healthcare system and produced automated ventilators with adapted windscreen wiper motors [30]. Also, Ferrari, the car manufacturing company, designed and provided respirator valves [31]. In USA, Airwolf3D, a 3D printing company, printed emergency respiratory valves and other parts to support the high demand in the country [32]. Italian company Isinnova designed, using 3D printing, a prototype of a valve ventilator valve, named 'Charlotte' to connect respiratory tubing with the ventilator [33]. Other companies used the open-source Charlotte ventilator valve designed by Isinnova. In Italy, 3D printing company Weerg used Charlotte's design and distributed valves to the hospitals [34]. CRP technology, another Italian 3D printing company used the Charlotte ventilator valve and provided valves to healthcare system using their own filaments [35] and a creative solution in a case of emergency was provided by Roboze, a 3D printer manufacturer in Italy and the USA, that used a T-connector fitted with the Charlotte ventilator valve to connect one ventilator device for two patients [36].

Many 3D-printing companies have worked in collaboration with academia, research centers, and healthcare facilities [19]. A research group from the University of Texas Health Science Center used Neyman and Irvin's open-source ventilator prototype [37] and designed a ventilator splitter called VentSplitter (FDA-approved for emergency use) [38]. Illinois Grainger College of Engineering at the University of Illinois Urbana–Champaign designed a prototype of an emergency ventilator for COVID-19 patients, called Illinois RapidVent [19,20]. The University has made the design available as a free license and RapidVent ventilators were manufactured by Belkin, a cellphone accessories manufacturing company [39]. In this work, the partial redesign of Illinois RapidVent allowed the easier, faster, and less expensive printing process. The modifications allowed the optimal casting by injection molding of the parts and faster production.

While it is true that advances in 3D printing have increased the potential for high output, especially when using a large number of 3D printers running in parallel, it will be difficult for any 3D printing method to replace casting for mass-produced large-volume applications. Three-dimensional printing technology should be seen as complementary rather than as a competitor to injection molding. Industry uses injection molding to achieve very low unit costs for very large volumes of identical units. However, it usually takes a lot of repetition for weeks or months and high assets to properly design the mold. For mass production, there is simply no competition in cost or quantity against injection molding with tools designed to last for millions of cycles of use. Injection molding is ideal for mass production, while 3D-printing is suitable for producing objects with a complicated geometry. When these two technologies are combined, such multipart products can be cost-effectively manufactured, which would be too expensive if produced conventionally [40].

Therefore, additive manufacturing is a rapidly growing field of technology, which has evolved into a completely new way of designing and manufacturing objects, opening the way to new and unexplored possibilities. The medical industry is one of the fastest growing adopters of the technology. From medical devices to prosthetics and even biology, the applications of additive manufacturing for the medical industry are versatile and wide-ranging, driving this growth. The ability to provide more personalized patient care in a cost-effective manner is extremely attractive. Three-dimensional printing can be used to provide patient-specific solutions such as implants and dental appliances as well as customized prosthetic limbs. In crisis situations, such as the COVID-19 pandemic, the advantage offered by additive manufacturing technology concerns the rapid prototyping of a functional mechanical ventilator and then its production in large quantities through injection molding. In this way the surge in demand for such products can be met.

# 5. Conclusions

In today's market, manufacturers are confronted with a demand that is driving them to deliver more sustainable designs regardless of the crisis. A major lesson that society derived from the COVID-19 pandemic is the need for an industry focused on collaboration efficiency to deal with emergencies and conserve resources to be able to handle shortages in the future. In times of crisis, additive manufacturing can play a crucial role; a key advantage is its geometric freedom, which allows for more personalized patient care at a lower cost. This study focused on optimizing and producing emergency ventilators with 3D printing. A partial redesign of the Illinois RapidVent ventilator improved the construction quality and performance of produced metallic and thermoplastic composite ventilators. As a result of the modifications, the parts were cast by injection molding more efficiently and were produced faster. The key factor for sustainable, cost-effective manufacturing is the combination of injection molding and 3D printing for the production of multipart products. Future research directions could include additional tests on animals or humans. Regulatory approval is required before a medical product can be used in a clinical application.

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