



Research Article | Artículo de Investigación

Improving the sustainability of emergency ventilators for Covid-19 : A case study on OxyGEN-IP | Mejorando la sostenibilidad de los respiradores de emergencia para el Covid-19: un caso de estudio sobre OxyGEN-IP

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Abstract

Sustainable medical device design in the context of a health emergency is an unexplored area of research. The urgency to save lives implies that eco-design strategies may not be considered. However, some of these strategies could lead to cost and manufacturing time reduction, implying that more units could be produced, and more patients reached. This paper aims to provide feasible eco-design strategies that could be shared with the stakeholders involved in the product design and manufacturing of emergency ventilators for Covid-19. The objective is to help tackle the Covid-19 crisis in a more sustainable way, and increase the access to healthcare of people requiring assisted ventilation during the health emergency.

Adopting a Whole Systems Design perspective (Blizzard & Klotz, 2012), this research has applied the Holistic Design Framework (Aranda-Jan et al., 2016) and the Eco-design Strategy Wheel (Brezet & Hemel, 1997) to elaborate preliminary strategies aligned with the emergency design objectives. Different design for sustainability tools, approaches and principles have been used to discuss, analyse and provide a final set of recommended strategies. These can be grouped in four categories: design for assembly, extension of product lifetime, usage of materials, and lean manufacturing. Despite further efforts are needed to overcome implementation challenges identified during the definition of strategies, it is expected that the above recommendations can be put in practice in a short-term to bring benefits in terms of better environmental impact, lower costs and total manufacturing time.

Key Words: Ecodesign; Sustainability; sustainable design; covid-19; ventilator; medical device

Resumen

El diseño de dispositivos médicos sostenibles durante una emergencia sanitaria es un área inexplorada de investigación. La urgencia para salvar el mayor número de vidas suele significar que no se utiliza ninguna estrategia de ecodiseño durante el desarrollo de estos productos. Sin embargo, algunas de estas estrategias podrían conducir al ahorro de costes y tiempos de fabricación, con lo que sería posible producir más unidades y llegar a más pacientes. Este trabajo persigue aportar estrategias de ecodiseño factibles que puedan ser compartidas con aquellos involucrados en el diseño y fabricación de respiradores de emergencia para dar apoyo durante la pandemia. El objetivo es ayudar a abordar la crisis del Covid-19 de forma más sostenible, y aumentar el acceso a la atención sanitaria a aquellas personas que necesitan respiración asistida.

Desde una perspectiva de Diseño de Sistemas Completos (Blizzard and Klotz, 2012), se han aplicado herramientas de diseño holístico de dispositivos médicos y de eco-diseño estratégico para elaborar estrategias preliminares coherentes con los objetivos del diseño durante emergencias sanitarias. Después, se han utilizado otros principios y herramientas de diseño para analizarlas y ofrecer una recomendación definitiva de estrategias. Éstas se pueden agrupar en cuatro categorías: diseño para el ensamblaje, extensión de la vida del producto, uso de materiales, y fabricación lean. A pesar de algunos retos para la implementación de estas estrategias, se espera que puedan ser puestas en práctica a corto plazo para conseguir beneficios en materia de impacto ambiental, reducción de costes y tiempo total de fabricación.

Palabras clave: Ecodiseño, sostenibilidad, diseño sostenible, covid-19, respirador, dispositivo médico.

Introduction

Due to the Covid-19 pandemic, ventilators needed for treating patients with severe respiratory problems are in critical short supply in high-income countries, leading to ethically defying triage measures and a steep increase in mortality because of the lack of equipment (Cohen et al., 2020; Pearce, 2020).

Regarding manufacturers' low capacity to supply enough ventilators to cope with the pandemic, different teams around the world have worked to provide an open-source solution that can be locally manufactured and ready-to-use in a conventional high-income country hospital (Peñarredonda, 2020). This urgency to provide quick solutions to tackle the health emergency and save lives implies that Design for Environmental Sustainability (DfES) strategies may not be considered as one of the priorities for the development of these new products. This

way, high-obsolescence ventilators like VITAL by NASA (intended to last up to four months) are being delivered (Greicius, 2020). Furthermore, some ventilators may need to be discarded prematurely to ensure that medical regulations are met, or need to be discarded if only one part stops working because they cannot be easily repaired (Protofy, 2020b).

While there is no data available yet on the environmental impact of these new ventilators, exploring the challenge of how DfES could be feasibly applied in the design of Covid-19 emergency ventilators is interesting because of two key reasons.

First, DfES strategies may bring other benefits apart from a better environmental impact, such as optimizing the usage of scarce resources that are harder to get under lockdown restrictions to suppliers (Sherman, 2020), and lowering costs and total manufacturing time, implying that more units could be afforded and made,

therefore reaching more patients. More and cheaper devices available means fewer people left behind, especially senior citizens and patients in under-privileged healthcare facilities (Cohen et al., 2020; Protofy, 2020b).

Secondly, since UN Sustainable Development Goals (SDGs) give the same priority to “climate action”, “responsible consumption and production”, and “good health for all” (United Nations, 2019), trying to reach one of the goals should not go in detriment of others. Learnings from studying this challenge could provide new insights on the trade-offs that are needed to achieve these three SDGs simultaneously. In this sense, medical devices are made to improve people’s health, therefore it seems logic for them to avoid as much pollution as possible, which damages public health and the environment (Fischer & Riechers, 2019; Proust et al., 2012). And, after all, “good design must conserve resources and minimise pollution throughout the life-cycle of the product”, as stated by Rams (1976).

Therefore, this paper aims to provide feasible DfES strategies that could be shared with the stakeholders involved in the product design and manufacturing of one of these ventilators, with the objective to help tackle Covid-19 in a more sustainable way. These strategies will be provided after addressing two research questions: (1) What is the context (frame of reference and enabling networks) affecting the design and manufacturing of the selected ventilator?; (2) Which DfES strategies could be feasibly implemented to improve the environmental performance of the selected ventilator?

This research has been conducted between the 27th of March and 10th of April 2020, during a time of high uncertainty because of Covid-19 and within an environment of imperative

need for ventilators. To be able to respond to the previous research questions, it is needed to choose an emergency ventilator for Covid-19 as a case study. Due to the uncertainty during the time this research was carried out, a local Spanish ventilator has been chosen for the analysis, so that the information was easier to access, and the results easier to share.

In Spain, six main emergency ventilator designs have come up (as of 10th April 2020): Andalucía Respira, Reespirator, Leitac-1, The Open Ventilator, Acute-19, and OxyGEN by Protofy. The last, the only open-source one, is being downloaded by many volunteers throughout the country to manufacture parts, including big manufacturers like SEAT or Bosch (McCloughlin, 2020; Pérez, 2020; Vall-Llosada & Marco, 2020) and universities with manufacturing capacity. There are two versions of the design: OxyGEN-M, designed for makers; and OxyGEN-IP (Figure 1), designed for industrial production and requiring engineering skills and machinery. Only OxyGEN-IP counts with official legal support and is under testing (IDNEO Technologies, 2020; Protofy, 2020b; Spanish Agency for Drug and Medical Device & Spanish Healthcare Ministry, 2020).

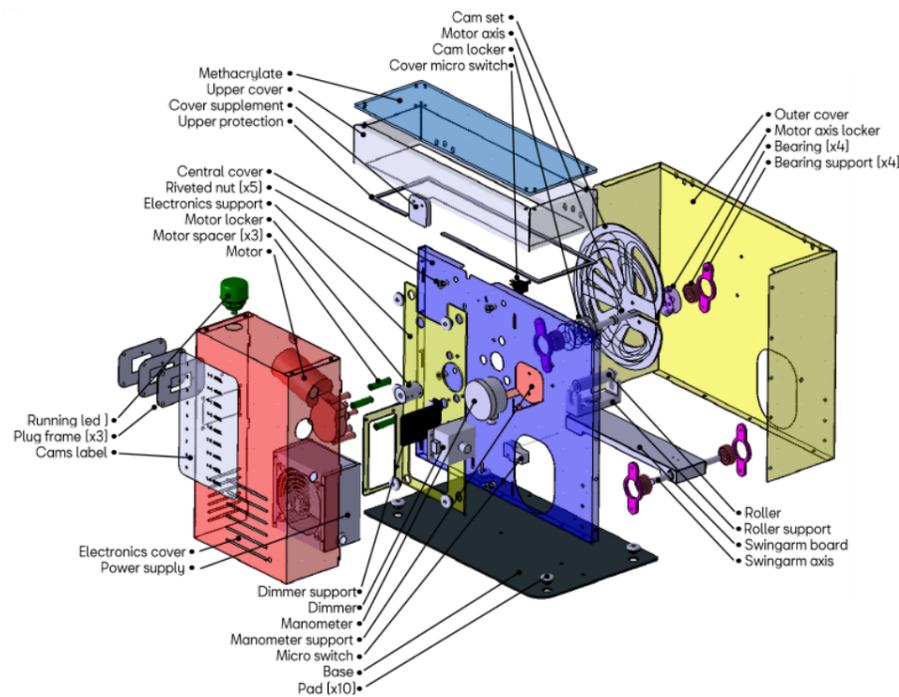


Figure 1. OxyGEN-IP most relevant elements (Protofy, 2020e).

Protofy has enabled an online platform where the different multidisciplinary stakeholders (hospitals and patients (users); researchers testing the device; manufacturers (volunteer companies and universities); supply chains (volunteers); volunteer interconnected developers; and governmental institutions providing the relevant permissions) can share information (Protofy, 2020a) with the aim of saving the highest amount of lives as possible, in the shortest period of time. This focus is based on concurrent engineering, defined as “multi-discipline teams carrying out parallel processing activities to continuously consider all constraints” (Duffy, 1998). Due to all the above reasons, OxyGEN-IP has been selected as the case study.

OxyGEN-IP provides a mechanism to automatize an AMBU (manual ventilator/resuscitator), easily found in hospitals and ambulances. The frequency of air intakes, which depend on the patient, is adjusted by basic electronics and the five levers available to customize the volume of air required. This emergency solution is meant for mass production in sheet metal and industrial scale, encouraging to use parts from other products, like small appliances (Protofy, 2020a). The product has 177 parts in total (Protofy, 2020c), categorized in Table 1. The most relevant elements are shown in Figure 2.

Table 1. Parts of OxyGEN-IP (Protofy, 2020, 2020d, 2020c, 2020e).

Type	Sheet metal	Mechanised / 3D printed	Electronics	Assembly and other	TOTAL
Number	8 (1mm), 3 (3mm)	10	34	122	177

The product description would be incomplete without providing information that helps understand how this product is meant to be used: the context of use. “Context of use” can be defined as “all factors that influence the experience of a product use” (Visser et al., 2005), or the characterisation of “product-user interactions as a pre-cursor to developing a design solution” (Aranda-Jan et

al., 2016). A context mapping generative tool defined by Stappers (2003) has been used to summarise the information provided by Protofy about the context of use of OxyGEN-IP (Figure 2).

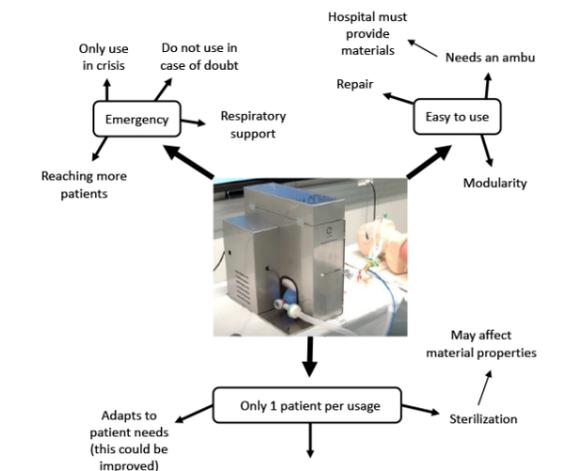


Figure 2. Oxygen-IP use context (figure by author). Information from OxyGEN-IP user guide (Protofy, 2020b).

Methodology

This case study has been examined from a Whole Systems Design (WSD) perspective. This framework created by Blizzard and Klotz (2012) shows how sustainable designs can be created by analysing the interrelations between the different systems involved with the design, problems and solutions, and is meant to be useful to address harsh challenges.

As seen in Figure 3, the WSD framework proposes three design pillars. The first pillar is focused on the design process: establishing a common vision to define goals and incentives, practice mutual learning within the multidisciplinary team, and transparently share information with everyone (Blizzard & Klotz, 2012). From the literature available, it is assumed that Protofy is already aligned with these recommendations, therefore this pillar will not be further explored.

The second pillar presents two design principles that can be especially relevant to answer the research questions. The first principle is to apply systems thinking, which

helps study and understand the context of the product to determine contextual elements that may enable or constrain the DfES strategies. The second principle is to maintain the focus on the fundamental desired outcome, which in this case would mean that the DfES strategies should help improve the access to healthcare of Covid-19 patients requiring respiratory support (Blizzard & Klotz, 2012).

aims to be useful to tackle the current health emergency, the time that is saved in learning new methods implies that the research results can be shared earlier.

Following the previous discussion, two phases of research emerge (Figure 4). First, selecting and applying a design framework to acknowledge the relations between the different contextual factors affecting the product development process of OxyGEN-IP (e.g.: material supply, workforce and machines available, legal requirements, etc.) during the Covid-19 exceptional circumstances, and find the enablers and barriers to implement DfES strategies.

The outcome of this stage will answer the first research question. Second, selecting and using an eco-design framework to identify DfES improvement opportunities throughout the entire life-cycle of OxyGEN-IP, and define design strategies that can be feasibly implemented to enhance OxyGEN-IP's sustainability. The outcome of this stage will answer the second research question.

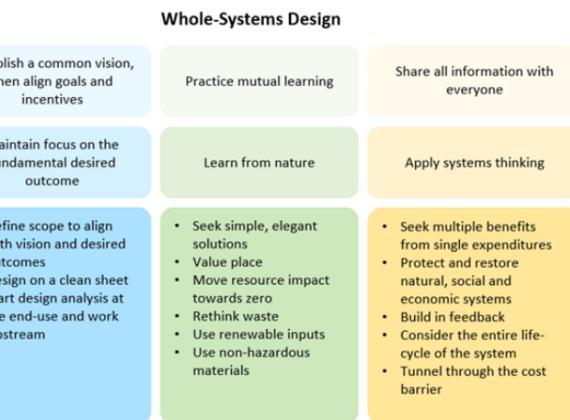


Figure 3. Whole-Systems Design framework, adapted from Blizzard & Klotz (2012).

Finally, the third pillar presents a set of eco-design methods. While all of these can add value when tackling the second research question, it has been decided to select one of these methods as a main guidance for decision-making when addressing research question 2, as applying all methods with specific frameworks might be too time consuming and the results should be obtained as fast as possible.

The selected method is "considering the entire life-cycle of the system" (Blizzard & Klotz, 2012), because: (i) It is a comprehensive method that encompasses or deeply affects others, such as: rethinking waste; seeking simple solutions; using renewable inputs; moving resource impact towards zero; using non-hazardous materials; protecting and restoring the natural, social and economic systems; or seeking multiple benefits from single expenditures; (ii) It is aligned with the definition of good design by Dieter Rams presented at the introduction section; (iii) The author is familiarised with this design method. Given that this work

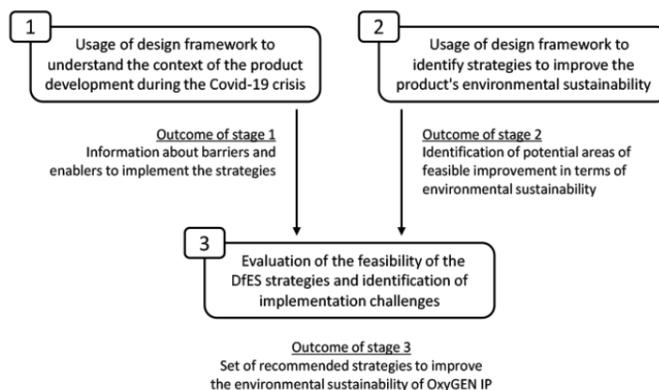


Figure 4. Stages of research (by author).

The framework selected for the first stage of the research is the Holistic Contextual Framework (HCF) for medical device design developed by (Aranda-Jan et al., 2016) (Figure 5). The HCF is focused on Limited-Resource Settings (LRS), and provides a good summary of the holistic contextual categories that should be explored for effective medical device design. Whereas the situation in Spain is different from a LRS, the imposed lockdown restrictions

and disruption of supply chains are severely limiting any product development and access to some resources. Therefore, if and only if applied within the system boundary of the Covid-19 emergency restrictions, this framework can be a good approach not to dismiss any relevant factor that can affect the OxyGEN-IP design during the health emergency.

Then, the design framework selected for the second stage of research is based on the Eco-design Strategy Wheel (ESW) framework by Brezet & Hemel (1997) (Figure 6). This visual tool helps find areas of environmental improvement in order to select eco-design strategies (Olieman, 2011b). The ESW is recommended to present and select product design strategies when a product idea is available, in the early stages of the development and early problem analysis (Olieman, 2011b). That is why it is considered to be adequate in this case.

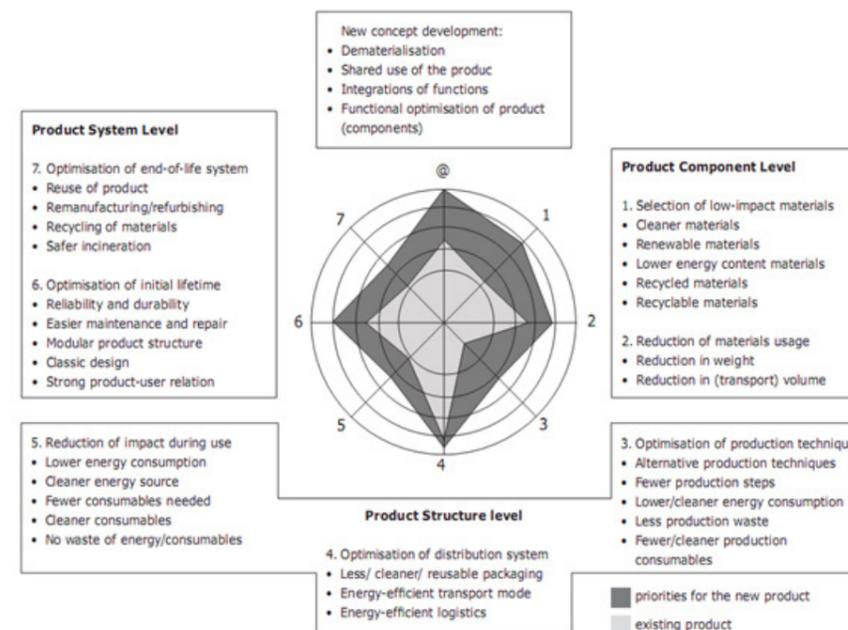


Figure 6. The Eco-design strategy wheel (Brezet & Hemel,

Normally, the starting point is the result of a MET matrix and a Eco-design checklist (Olieman, 2011b). The MET matrix is used to

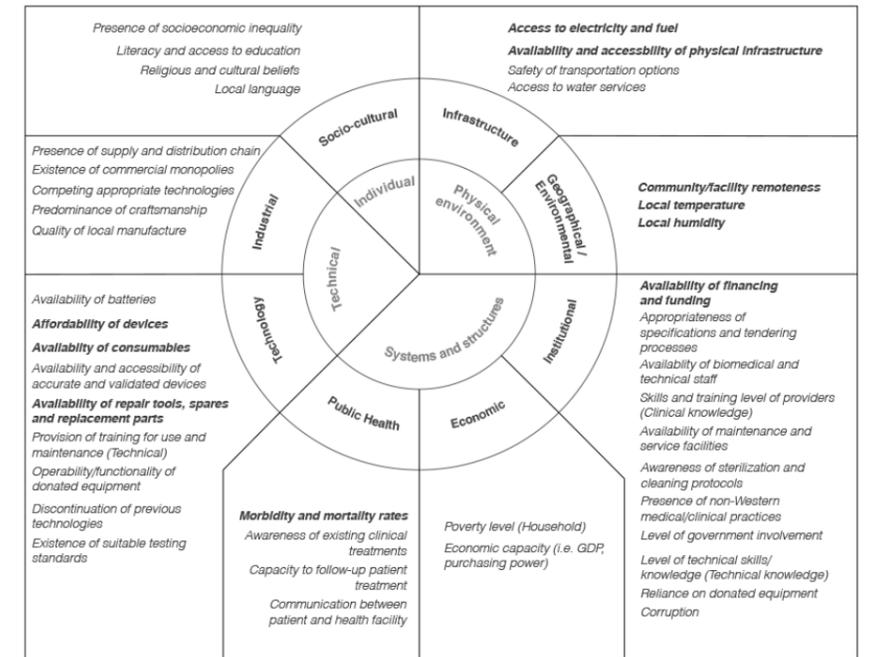


Figure 5. HCF Contextual factors (Aranda-Jan et al., 2016)

analyse the material cycle, energy use and toxic emissions during the obtainment and consumption of raw material, manufacturing, distribution, usage and end of life (Olieman, 2010). However, such analysis cannot be included in this research due to the lack of data available, recognising this is a limitation to elaborate any sustainability improvement strategy. Consequently, the MET is not

going to be used. On the other hand, the Eco-design checklist provides a set of questions related to each stage of the eco-design wheel, and helps highlight environmental bottlenecks in the various stages of the product's life-cycle (Olieman, 2011a). It has been used to characterise the current state and identify suitable areas suitable action. Additional questions have been added where considered relevant to identify further drivers or barriers.

The ESW is going to be applied according to the following procedure, based on (Olieman,

2011b) recommendations: (1) Defining OxyGEN-IP (the product definition provided in the introduction will be completed with the contextual information obtained thanks to the HCF); (2) Scoring OxyGEN-IP on each dimension of the ESW, using information from the EcoDesign Checklist; (3) Elaborating DfES strategies for each dimension in which improvement is feasible and needed (worst scores will be more carefully examined).

Finally, the feasibility of the DfES strategies for product improvement will be evaluated taking into consideration all the contextual information gathered thanks to the HCF. The outcome of this analysis will consist on a set of recommended strategies.

Results

The information about the holistic context of OxyGEN-IP, obtained as a result of applying the HCF within the system boundary of Covid-19 restrictions, is summarised in Table 2.

Table 2. HCF of OxyGEN-IP within the boundary of only relevant Covid-19 restrictions, based on Aranda-Jan, Jagtap and Moultrie (2016).

Systems and infrastructures	
Public Health	Covid-19 pandemic in Spain: Top 2 most affected countries in Europe (in terms of total confirmed cases and death toll), as of 10 th April 2020 (WHO, 2020). Overwhelmed healthcare system and workers in some regions. Some patients are not being treated due to mechanical ventilators shortage (Guerrero, 2020).
Economic	Citizens are in lockdown conditions until end of April, as of 10 th April 2020. Regional and national governments are making efforts to get more funding to purchase materials. Experts estimate an increase of 30% of public debt because of the pandemic outbreak, meaning that debt would reach approximately 130% over GDP (Faes, 2020). All non-essential workers have been asked to quarantine at home. Many people are becoming unemployed, or are temporary unemployed and subsidized.
Institutional	Governmental management has three levels: local, regional and national. There have been issues when transferring competencies from regions to the national Ministry of Health, but coordination among regions is being more fluid. Other ministries are adopting measures that should be taken by the Ministry of Health. (Garcia de Blas, 2020) Healthcare staff is overwhelmed and requesting help. There is plenty of well-trained professionals with knowledge to both develop and use the product.
Physical-environment context	
Infrastructure	High-income country infrastructure.
Geographical-environmental	Medical devices need to be discarded under special requirements.
Individual context	
Socio-cultural	High solidarity. Many volunteers have shown interest in collaborating with the project, such as SEAT, national universities, local maker communities connected by social media, and individuals.
Technical context	
Technology	Affordability of devices, consumables, accessible devices, repair tools and replacement parts available and international standards in place. Existence of suitable testing standards. Medical devices must be certified by the Spanish Agency of Drugs and Medical Devices.
Industrial	High quality manufacturing capacity, constrained supply chains, commercial monopolies. Many companies are currently under Covid-19 legal paralysation.

The holistic contextual analysis, together with the information gathered thanks to the Eco-design checklist, has helped answer all questions in the ESW. Relative punctuations have been given to the current environmental performance in each dimension of the wheel, to visually detect improvement opportunities (Figure 7). A lower punctuation means an estimated major need of improvement. Dimension 4 has been left out of this assessment due to the lack of sufficient information to provide any assessment.

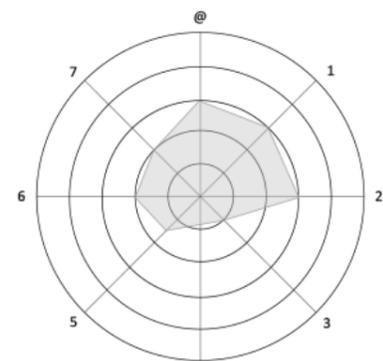


Figure 7. Assessment of the current state of OxyGEN-IP (by author), based on the Eco-design strategy wheel by Brezet and Van Hemel (1997).

After this exercise, it has been concluded that potentially feasible strategies for improving the environmental sustainability of OxyGEN-IP may be related to the following dimensions of the ESW: (a) Optimising function (dimension 0): Avoiding redundant parts, regarding that the actual design requires 177 components, and improve compatibility with hospital required devices. (b) Choosing materials with low environmental impact (dimension 1), and decreasing the amount of material used (dimension 2). Improvements in this area can be challenging because of the deceleration of the industrial network and suppliers. The usage of functional electronic components of non-operative devices that are available should be considered.; (c) Optimising production

techniques to save time and increase efficiency (dimension 3). Manufacturing processes available cannot be changed, but assembly. Lean manufacturing techniques can also be explored. (d) Evaluating if cleaner consumables can be used (dimension 5), with special regards to AMBU disposable bags; (e) Lengthen duration of product life (dimension 6), with special regards to maintenance and sterilization. (f) Optimisation of the end-of-life (dimension 7). In Spain, the disposal of medical devices must follow a strict regulation, so the challenge could be to safely encourage the re-use of the whole product (or only certain parts) and its dismantling.

Next, information from the HCF and Eco-Design checklist, together with some other different tools, approaches and principles has been used to analyse, discuss and recommend final improvement strategies for each or various dimensions (as some of the strategies mentioned are interrelated). After the discussion, a summary of implementation challenges is provided.

The ESW framework advises that only short-term eco-design strategies are included in the list of requirements for redesign (Olieman, 2011b). In this case, given the emergency situation, all actions to be made should be implemented in the short-term. This does not mean that long-term actions that may come up are dismissed; they are just unprioritized.

Reducing the number of parts

The main problem of OxyGEN-IP is its high number of components: 177. This leads to long assembly and disassembly times, that could be used to manufacture more units. Additionally, discarding so many parts is not unlikely: The developers emphasize that this emergency device should be replaced in doubt of a correct functioning, which would translate into an avoidable waste of valuable materials.

The majority of components are used for the assembly of parts (122), therefore it is clear

that this process leads to a sustainability bottleneck. This issue should be tackled with a “design for assembly” strategy, consisting on reducing the part count of a product and making the assembly process easier and faster (for both manual and automatic handling) (Kent, 2016) to save cost, time, resources and waste (Blizzard & Klotz, 2012).

Questioning the function and design of components, using tools such as function hierarchy, can be useful to address this simplification process (Morgan, 2020). For example, the cover of the mechanism box is comprised by 14 parts (see Figure 8), and it has the functionality of protecting the mechanism while closed and facilitating access to change levers or broken components if opened (thanks to its hinge). An hermetic closure is not required. After a function hierarchy analysis, it turns out that those 14 parts could be simplified to one sliding part, equally functional and easier to manufacture. It is recommended that the design team practices this exercise with other product components so analyse if further simplification could be possible.

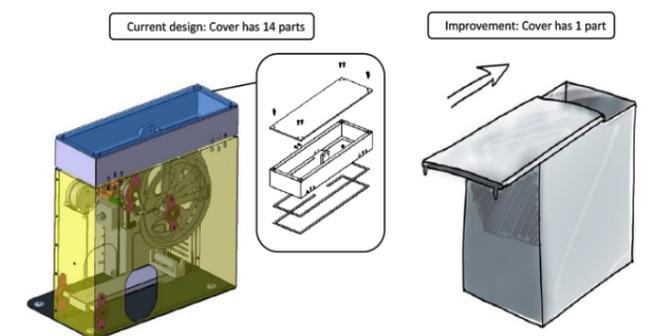


Figure 8. Original sketch of part reduction proposal (by author), based on (Protofy, 2020d, 2020c, 2020e).

The lever system functionality should also be examined, as other researchers have found simpler ways to press the AMBU bag (Peñarredonda, 2020), which translate into fewer parts and avoiding extracting the lever – any lever extracted from the inside must be sterilised, making hospitals lose time and resources in sterilization.

Finally, the most outstanding consumable required by OxyGEN-IP is the AMBU bag, which is plastic made and must be discarded after a patient has been treated (AMBU Australia, 2020). Evaluating the functionality of the AMBU, with the ultimate aim to develop a safely reusable device, might open a longer-term parallel research line that might be out of the system boundaries of this research.

3.2 Design for compatibility and adaptability
One should keep in mind that OxyGEN-IP is an emergency product that might not be further needed in Spanish hospitals after the coronavirus crisis. Therefore, there are several options surrounding its end of life: 1) medical device disposal, generating pollution in case it is considered unsafe to be recycled (as the product is under testing, this is still an unknown (IDNEO Technologies, 2020)); 2) donate to medical facilities in need (this could be another high-income or low-income country needing low-cost mechanical ventilation devices), if the device is still working, to continuing saving lives.

As stated by the material management hierarchy, reducing is preferred than re-using or recycling (Blizzard & Klotz, 2012; Linton & Jayaraman, 2005), so this second option seems to be more sustainable. But there is an obstacle: OxyGEN-IP is only compatible with two different kinds of manual resuscitator AMBU, and must be connected to both the oxygen circuit in the hospital and a reliable source of electricity under European regulation, limiting its usage to healthcare facilities with that availability.

Two circular product design strategies can be useful to lengthen and optimise the product life: "Design for compatibility", a circular product design strategy consisting on standardising products as much as possible so that they fit a wider range of other product parts (Bocken et al., 2016); and "design for adaptability", seeking modifications that allow further usage (Morgan, 2020).

This way, OxyGEN-IP should be modified in a way so that it can be used with more types of manual resuscitators, regarding the different equipment available per hospital

(Peñarredonda, 2020), and connected to an oxygen bottle in case treatment is needed in a healthcare facility without an oxygen installation. This change may be enabled by the modularity of the design, which allows to modify the electronic and electric components, in case it is necessary to adjust the electric compatibility to a different context.

Material strategies

Main body parts are meant to be manufactured in stainless steel, nylon, methacrylate, steel or silicon (Protofy, 2020b), by metalwork skills, laser cutting and machining. Volunteering organisations have also offered their additive manufacturing machines, despite these processes and materials are not included in the OxyGEN-IP manual neither testing.

Material selection would not be a challenge under normal conditions, but it is when supply chains are paralysed, leading companies to use any material they have in stock or can get with relative ease. Then, context constraints make it difficult to freely access low-impact materials. That is why volunteers within a region or project should share an inventory of the resources they could make available in a shared cloud-based platform to help re-allocate, adapt or re-use local resources (also electronics), as advised by sustainable design principles by Blizzard and Klotz (2012) mentioned at the start of section 2. It is recommended to use, when possible, clean, low energy, recycled or recyclable materials (Olieman, 2011a) that are certified for healthcare usage; and then, apply design strategies to reduce the material weight, aiming to maximise the number of parts that could be manufactured from the limited resources available.

Another restriction is given by the function: the chosen material must bear with disinfecting methods like chemicals or UV; not to add the long list of strict requirements for ordinary medical devices (Peñarredonda, 2020) and their disposal.

3D printing can be interesting to reduce the weight of materials used and manufacture complex shapes (Plocher & Panesar, 2019). However, in this case, 3D print is recommended for disposable items instead of re-usable parts (such as mechanisms), as the porosity of the plastic may retain the virus, and thermal sterilisation may compromise the structural stability of the material (Maróti et al., 2020).

Research has shown some positive results regarding H2O2 sterilization (Oth et al., 2019), which may cause slight mass or dimensional changes and deformations, depending on the material (not significant in PLA or PCL, for instance), but not affect the usage if and only if they are anticipated by designers (Sosnowski & Morrison, 2017). However, some authors are still reticent to recommend this technology for ventilator manufacturing given the safety concerns (Aydin et al., 2021; S. Singh et al., 2020; S. N. Singh et al., 2021).

Optimising production

Whereas production is already very constrained, as volunteering companies cannot change their resources, it can be optimised by simplifying assembly (as explained in 2.2.1) and adopting a lean manufacturing approach. Lean manufacturing aims to continuously eliminate waste from the manufacturing process, understanding waste as anything undesired such as idle times or pollution. One of the lean tools is related to the overlap of production phases when possible to reduce time to market (Orji & Liu, 2020).

Henao, Sarache and Gómez (2019) show how sustainable and resilient organizations use lean techniques extensively, particularly in addition to supply chain or technology integration and agility. The fact that the OxyGEN-IP design process follows a concurrent engineering approach for its development is another enabler.

Many volunteer teams have hitherto worked independently, manufacturing

all parts they could sequentially. In other Covid-19 emergency product development, lack of coordination translated into overproduction of devices (Temple, 2020). This is why volunteering groups willing to manufacture the OxyGEN-IP ventilator should coordinate with other local groups to overlap manufacturing phases depending on each's capacity. It is expected that the sum of coordinated efforts translates into emergency ventilators delivered faster, because the parts required to manufacture a unit would be obtained earlier. Also, this approach is expected to prevent unnecessary waste due to overproduction.

Design for product durability

Despite medical device disposal is regulated, hence cannot be included into this research scope, principles to lengthen the product durability can be reviewed. In this case, durability is mainly related to product maintenance, sterilization resistance and wear (Pearce, 2020; Protofy, 2020b).

An improvement in this line could be to modify the lever system used to adjust insufflation volume and frequency, since the current one leads to maintenance problems: Two parts (the spring and the roller) are likely to suffer from wear under the current distribution, needing to be replaced several times during the product life (Protofy, 2020b). A re-distribution of components or surface treatment could avoid such problem.

When it comes to replacing failing components, research by Linton and Jayaraman (2005) shows that repair is an economically attractive option for electronic products life extension, as the case of OxyGEN-IP. This makes sense: Protofy recommends to reuse the motor and electronics, and encourages the repair of the product by providing a modular design.

Repair is linked to the circular product strategy "design for ease of maintenance and repair". This strategy, used by mobile manufacturer Fairphone to allow users fix their own phones, is based on an effortless

inspection of potential failures and replacement of broken parts (Fairphone, 2020). Both can be enhanced by another circular product strategy called “design for dis-assembly and re-assembly” (related to the design for assembly strategy described in section 2.2.1), making it easier and faster to separate components when it comes to repair or discard the product, as well as to re-assembly the whole (Bocken et al., 2016)

Discussion

The main challenge to implement the proposed design strategies is the uncertainty reigning during the Covid-19 public health crisis. The novelty of the virus means that new findings and data are generated every day, and that policymakers might unexpectedly allow or ban some products depending on the circumstances, as it happened to the 3D printed face shields that were rejected in Madrid three days after their approval because they were uncertified (Peinado, 2020). OxyGEN-IP is also subjected to a high uncertainty, regarding that it is still under some technical testing.

The concurrent engineering approach taken by open-source concurrent engineering projects like OxyGEN-IP and other people aiming to help tackle the Covid-19 pandemic has been criticised, claiming that an overwhelming production and disperse teamwork can lead to inefficient results that are not helpful to save lives (Temple, 2020), just generating waste. Moreover, some patent-owner medical device monopolies have started legal action against some open-source groups, as it has happened in Italy (Pearce, 2020). Such issues could have been avoided if groups had carried out an holistic analysis of the context (as in this work) to identify such potential risks and try to find solutions, reaffirming the importance of the broad context analysis in section 2.1.

Some improvement strategies, such as reducing the number of parts or product durability, are more manageable to implement, as they solely depend on the development team and such work can

be done from home. However, Covid-19 lockdown constraints are a serious threat to implement a more sustainable material strategy, as it is not easy to acquire low-impact materials compliant with medical device regulation in a context of a paralysed economy, increasing debts and companies going into bankruptcy (Faes, 2020). These constraints also may impede the interchange of components, or shut down productive centres, complicating the lean optimised production network. It should also be considered that in case that suppliers, manufacturers or distributors do not get legal permission to take action, the whole project might be paused until further notice.

The design for compatibility strategy aims to create an universal product within a high market competence (this means, compatible with a multitude of varieties of the same device), so this might not be feasible in the short-term. For example, there are more than sixteen companies manufacturing their own AMBU models (Grand View Research, 2019). Therefore, it might be more fruitful to start by focusing efforts on a constrained target context.

Finally, there is another concern related the durability of the product. Research by Pearce (2020) shows that, if not kept in a sterile environment, devices could become biologically contaminated, needing a washing or chemical bath. Healthcare workers in Spain are reporting that the sterilization of plastic emergency products reduces drastically their use life (Bañuelos, 2020), hence something similar could happen to OxyGEN-IP.

The research methodology is also subjected to some limitations. Until 10th April 2020, day when this research was completed, searches in Science Direct and Scopus with the keywords “sustainable OR sustainability” AND “design” AND (Covid-19 OR coronavirus OR Covid OR Ventilator) provided 0 relevant results for the objectives of this research. This means that, while this research was being conducted, there was no literature on this specific topic and that, consequently, it

was a novel research. Such novelty means that getting insights to inform decision-makers was harder, as there was no reference on what might go wrong or well. Also, there is not much detailed information available on the design of other emergency ventilators, so comparisons with other designs, beneficial to bring different insights and ideas, will be superficial. Moreover, the Covid-19 situation became critical in Spain only two weeks before the completion of this work, it is changing quickly, and new discoveries are made in a daily basis, some of them contradicting. For example, many open-source ventilators which were praised in March are being criticized now for being unsafe (McManus, 2020). This means that maybe, some of the strategies proposed as a result of this research may not be considered as feasible in a future.

Inevitably, the selection of frameworks and interpretation of results will be subjective to the author’s criteria, perspective and experience as design engineer. The fact that this work had to be conducted individually, even with the ultimate goal of sharing the results, may contradict the WSD principle of mutual learning. To mitigate this, it would be interesting to ask a group of designers (both internal and external to the OxyGEN-IP design) for feedback, to reduce the subjectivity, and verify or discard some of the assumptions made (such as the assumption made on Protofy effectively promoting mutual learning and internal communication).

Conclusions

This novel research has involved finding trade-offs between delivering environmental sustainability and amplifying the access to healthcare. Adopting a Whole Systems Design perspective (Blizzard & Klotz, 2012), this research has applied the Holistic Design Framework for medical device design (Aranda-Jan et al., 2016), the Eco-design Strategy Wheel (Brezet & Hemel, 1997) and some other tools and principles to recommend design and manufacturing strategies that help improve the environmental sustainability of the

emergency mechanical ventilator OxyGEN-IP developed by Protofy, with the aim to help tackle the Covid-19 public health problem in a more sustainable way.

The recommended design and manufacturing strategies can be grouped in four categories: design for assembly, lifetime of the product, usage of materials, and lean manufacturing approach.

A design for assembly approach is recommended to drastically reduce the high number of assembly parts (122 in total), which may also lead to cost and time reduction.

Then, it is recommended to extend the lifetime of the product by: (a) modifying design so it is compatible with more types of AMBUs or oxygen bottles, therefore increasing its accessibility; (b) improve the modular design with design for disassembly techniques, so that the electronics and electric components can be easily accessed and then effectively repaired and modified; (c) redistribute the components of the lever system, or apply superficial treatments, to reduce the wear suffered by these components.

With regards to material usage, it is recommended to set up a cloud-based platform where groups of near volunteers can share information about the resources they can offer, and this way help re-allocate, adapt or re-use local resources. Additionally, it is recommended to select materials that can bear with disinfecting methods (chemical or UV), and only 3D print if it is ensured that those parts can be safely disinfected without losing their functionality.

Finally, it has been recommended to adopt a lean manufacturing perspective to reduce the overall production time and unneeded waste due to over-production. This could be achieved by coordinating and planning the interrelated tasks of local volunteers.

Despite further efforts are needed to overcome implementation challenges identified during the definition of strategies, it is expected that the above recommendations can be put in practice in

a short-term to bring benefits in terms of better environmental impact, lower costs and total manufacturing time.

The immediate next steps would be to share these results with the Protofy team or other volunteers manufacturing OxyGEN-IP to assess the feasibility of the strategies in the real setting and materialise them into changes in the product design. This would allow to measure and validate the environmental impact of the proposed changes. Further work lines could focus on improving the sustainability of other products designed to tackle the Covid-19 emergency.

It would be worth to further explore the problem from the social sustainability perspective. This dimension of sustainability has been left out of the scope of this research but might bring new benefits that, otherwise, would remain unexplored. One tool that could be used for such analysis is Corsini and Moultrie's Design for Social Sustainability Framework (Corsini & Moultrie, 2019). It would also be interesting to analyse this case study with other environmental sustainability tools, and then compare results.

Finally, this research has highlighted the inexistence of frameworks or guides to help design and manufacture sustainable emergency medical devices. It would be particularly interesting to explore how learnings from this case study could be applied to design sustainable medical devices for low-resource settings, where limited access to healthcare is a constant challenge not only in times of Covid-19. This future research could bring benefits to humanitarian design, and help achieve the sustainable development goal "healthcare for all" while working towards "responsible consumption and production" and "climate action".

References

AMBU Australia. (2020). Ambu—Devices that save lives & improve patient care. <https://www.ambu.com/>

Aranda-Jan, C. B., Jagtap, S., & Moultrie, J. (2016). Towards A Framework for Holistic Contextual Design for Low-Resource Settings. *10(3)*, 21.

Aydin, A., Demirtas, Z., Ok, M., Erkus, H., Cebi, G., Uysal, E., Gunduz, O., & Ustundag, C. B. (2021). 3D printing in the battle against COVID-19. *Emergent Materials*, *4(1)*, 363–386. <https://doi.org/10.1007/s42247-021-00164-y>

Bañuelos, J. (2020, March 30). Ayuso se ve obligada a suspender el uso de protecciones impresas en 3D por no tener el visto bueno de Sanidad. *Cadena SER*. https://cadenaser.com/emisora/2020/03/30/radio_madrid/1585522735_465105.html

Blizzard, J., & Klotz, L. (2012). A framework for sustainable whole systems design. *Design Studies*, *33*, 456–479. <https://doi.org/10.1016/j.destud.2012.03.001>

Bocken, N. M. P., de Pauw, I., Bakker, C., & van der Grinten, B. (2016). Product design and business model strategies for a circular economy. *Journal of Industrial and Production Engineering*, *33(5)*, 308–320. <https://doi.org/10.1080/21681015.2016.1172124>

Brezet, H., & Hemel, C. van. (1997). Ecodesign: A Promising Approach to Sustainable Production and Consumption. United Nations Environment Programme, Industry and Environment, Cleaner Production.

Cohen, I. G., Crespo, A. M., & White, D. B. (2020). Potential Legal Liability for Withdrawing or Withholding Ventilators During COVID-19: Assessing the Risks and Identifying Needed Reforms. *JAMA*, *323(19)*, 1901. <https://doi.org/10.1001/jama.2020.5442>

Corsini, L., & Moultrie, J. (2019). Design for Social Sustainability: Using Digital Fabrication in the Humanitarian and Development Sector. *Sustainability*, *11(13)*, 3562. <https://doi.org/10.3390/su11133562>

Duffy, A. H. B. (Ed.). (1998). *The Design Productivity Debate*. Springer-Verlag. <https://doi.org/10.1007/978-1-4471-1538-0>

Faes, I. (2020, April 4). La crisis del coronavirus disparará la deuda hasta el 130% y aboca a España a un rescate. *El Economista*. <https://www.eleconomista.es/economia/noticias/10462410/04/20/La-crisis-del-coronavirus-disparara-la-deuda-hasta-el-130-y-aboca-a-Espana-a-un-rescate.html>

Fairphone. (2020). Fairphone | The phone that cares for people and planet. <https://www.fairphone.com/en/>

Fischer, J., & Riechers, M. (2019). A leverage points perspective on sustainability. *People and Nature*, *1(1)*, 115–120. <https://doi.org/10.1002/pan3.13>

García de Blas, E. (2020, April 5). La crisis tensiona el Estado autonómico. *El País*. <https://elpais.com/espana/2020-04-05/la-crisis-tensiona-el-estado-autonomico.html>

Grand View Research. (2019). *Manual Resuscitators Market Size | Industry Analysis Report, 2019-2025 (Industry Analysis Report GVR-1-68038-012-5; p. 100)*.

Greicius, T. (2020, April 23). NASA Develops COVID-19 Prototype Ventilator in 37 Days [NASA Jet Propulsion Laboratory]. NASA. <http://www.nasa.gov/feature/jpl/nasa-develops-covid-19-prototype-ventilator-in-37-days>

Guerrero, A. (2020, April 1). Coronavirus: 'Hemos dejado de intubar a enfermos por su edad porque no hay respiradores para todos'. RTVE.es. <https://www.rtve.es/noticias/20200401/hemos-dejado-intubar-enfermos-su-edad-porque-no-hay-respiradores-para-todos/2011083.shtml>

Henao, R., Sarache, W., & Gómez, I. (2019). Lean manufacturing and sustainable performance: Trends and future challenges. *Journal of Cleaner Production*, *208*, 99–116. <https://doi.org/10.1016/j.jclepro.2018.10.116>

IDNEO Technologies. (2020). *Compliance Laboratory—EMC Test Report accredited by ENAC according to EN ISO/IEC 17025 (No. BE2020063)*.

Kent, R. (2016). Chapter 8—Design quality management. In R. Kent (Ed.), *Quality Management in Plastics Processing* (pp. 227–262). Elsevier. <https://doi.org/10.1016/B978-0-08-102082-1.50008-3>

Linton, J. D., & Jayaraman, V. (2005). A framework for identifying differences and similarities in the managerial competencies associated with different modes of product life extension. *International Journal of Production Research*, *43(9)*, 1807–1829. <https://doi.org/10.1080/13528160512331326440>

Maróti, P., Kocsis, B., Ferencz, A., Nyitrai, M., & Lórinçzy, D. (2020). Differential thermal analysis of the antibacterial effect of PLA-based materials planned for 3D printing. *Journal of Thermal Analysis and Calorimetry*, *139(1)*, 367–374. <https://doi.org/10.1007/s10973-019-08377-4>

McLoughlin, M. (2020, March 23). Respiradores (y más) hechos en casa: Las impresoras 3D se movilizan en España. *El Confidencial*. https://www.elconfidencial.com/tecnologia/2020-03-23/impresion-3d-respiradores-mascarillas-biseras_2509855/

McManus, B. (2020, April 4). A Guide To Designing Low-Cost Ventilators for COVID-19. <https://www.youtube.com/watch?v=7vLPefHYWpY>

Morgan, D. (2020, January 23). ESD 560 Lecture 2: Sustainable Design Strategies.

Olieman, A. (2010, December 11). MET matrix. The Industrial Design Engineering Wiki - Technical University Delft. http://wikid.io.tudelft.nl/WikID/index.php/MET_matrix

Olieman, A. (2011a, May 2). EcoDesign checklist. The Industrial Design Engineering Wiki - Technical University Delft. http://wikid.io.tudelft.nl/WikID/index.php/EcoDesign_checklist

Olieman, A. (2011b, May 2). EcoDesign strategy wheel. The Industrial Design Engineering Wiki - Technical University Delft. http://wikid.io.tudelft.nl/WikID/index.php/EcoDesign_strategy_wheel

Orji, I. J., & Liu, S. (2020). A dynamic perspective on the key drivers of innovation-led lean approaches to achieve sustainability in manufacturing supply chain. *International Journal of Production Economics*, 219, 480–496. <https://doi.org/10.1016/j.ijpe.2018.12.002>

Oth, O., Dauchot, C., Orellana, M., & Glineur, R. (2019). How to Sterilize 3D Printed Objects for Surgical Use? An Evaluation of the Volumetric Deformation of 3D-Printed Genioplasty Guide in PLA and PETG after Sterilization by Low-Temperature Hydrogen Peroxide Gas Plasma. *The Open Dentistry Journal*, 13(1). <https://doi.org/10.2174/1874210601913010410>

Pearce, J. (2020). A review of open source ventilators for COVID-19 and future pandemics. <https://doi.org/10.12688/f1000research.22942.1>

Peinado, F. (2020, March 29). Madrid dice no a la solidaridad de los impresores 3D. *El País*. <https://elpais.com/espana/madrid/2020-03-29/madrid-dice-no-a-la-solidaridad-de-los-impresores-3d.html>

Peñarredonda, J. L. (2020, April 1). Covid-19: The race to build coronavirus ventilators. *BBC*. <https://www.bbc.com/future/article/20200401-covid-19-the-race-to-build-coronavirus-ventilators>

Pérez, E. (2020, April 5). Respiradores artificiales fabricados en España: Por qué su certificación es tan lenta cuando tantas vidas dependen de ellos. *Xataka*. <https://www.xataka.com/medicina-y-salud/respiradores-artificiales-fabricados-espana-que-su-certificacion-lenta-cuando-tantas-vidas-dependen-ellos>

Plocher, J., & Panesar, A. (2019). Review on design and structural optimisation in additive manufacturing: Towards next-generation lightweight structures. *Materials & Design*, 183, 108164. <https://doi.org/10.1016/j.matdes.2019.108164>

Protofy. (2020). Github shared folder of OxyGEN IP. GitHub Protofy Team / OxyGEN. <https://github.com/ProtofyTeam/OxyGEN>

Protofy. (2020a). OxyGEN project: About. New Website. <https://www.oxygen.protofy.xyz/about>

Protofy. (2020b). OxyGEN V14 Instrucciones de USO (Borrador) (OxyGENIP_V1, legal and tech docs). OxyGEN #HOPE; <https://701f4afe-64ef-424a-8bec-754f5dc1ea0a.filesusr.com/>

Protofy. (2020c). OxyGEN-IP V1.0 Exploded (OxyGENIP_V1). <https://701f4afe-64ef-424a-8bec-754f5dc1ea0a.filesusr.com/>

Protofy. (2020d). Proceso ensamblaje equipo ayuda respiración OxyGEN-IP (OxyGENIP_V1, legal and tech docs). <https://701f4afe-64ef-424a-8bec-754f5dc1ea0a.filesusr.com/>

Protofy. (2020e). Ventilator explo & views (OxyGENIP_V1). <https://701f4afe-64ef-424a-8bec-754f5dc1ea0a.filesusr.com/>

Proust, K., Newell, B., Brown, H., Capon, A., Browne, C., Burton, A., Dixon, J., Mu, L., & Zarafu, M. (2012). Human Health and Climate Change: Leverage Points for Adaptation in Urban Environments. *International Journal of Environmental Research and Public Health*, 9(6), 2134–2158. <https://doi.org/10.3390/ijerph9062134>

Rams, D. (1976). *Design by Vitsoe*.

Sherman, E. (2020, February 21). 94% of the Fortune 1000 are seeing coronavirus supply chain disruptions: Report. *Fortune*. <https://fortune.com/2020/02/21/fortune-1000-coronavirus-china-supply-chain-impact/>

Singh, S. N., Venkatesh, V. S. S., & Deoghare, A. B. (2021). A review on the role of 3D printing in the fight against COVID-19: Safety and challenges. *Rapid Prototyping Journal*, 27(2), 407–420. <https://doi.org/10.1108/RPJ-08-2020-0198>

Singh, S., Prakash, C., & Ramakrishna, S. (2020). Three-dimensional printing in the fight against novel virus COVID-19: Technology helping society during an infectious disease pandemic. *Technology in Society*, 62, 101305. <https://doi.org/10.1016/j.techsoc.2020.101305>

Sosnowski, E. P., & Morrison, J. (2017, May 23). Sterilization of medical 3D printed plastics: Is H2O2 vapour suitable? The 40th Conference of The Canadian Medical and Biological Engineering, Winnipeg. <https://pdfs.semanticscholar.org/11a1/>

Spanish Agency for Drug and Medical Device & Spanish Healthcare Ministry. (2020). Autorización de investigaciones clínicas para ‘Estudio RES-COVID: BALÓN RESUCITADOR AUTOMATIZADO MECANIZADO COMO ALTERNATIVA A LA COMPRESIÓN MANUAL PARA LA VMI DE PACIENTES EN SITUACIÓN DE ALARMA: PROTOCOLO DE USO COMPASIVO’.

Stappers, P. J. (2003). Generative tools for context mapping: Tuning the tools. 6. Temple, J. (2020, April 1). Gracias, impresión 3D, pero no todo vale para combatir el coronavirus. *MIT Technology Review*. <https://www.technologyreview.es/s/12065/gracias-impresion-3d-pero-no-todo-vale-para-combatir-el-coronavirus>

United Nations. (2019). Sustainable Development Goals Report 2019. <https://unstats.un.org/sdgs/report/2019/The-Sustainable-Development-Goals-Report-2019.pdf>

Vall-Llosada, C., & Marco, B. (2020). SEAT arranca la producción de respiradores de emergencia en su fábrica de Martorell.

Visser, F. S., Stappers, P. J., van der Lugt, R., & Sanders, E. B.-N. (2005). Contextmapping: Experiences from practice. *CoDesign*, 1(2), 119–149. <https://doi.org/10.1080/15710880500135987>

WHO. (2020). Coronavirus disease 2019 (COVID-19) Situation Report 81 (No. 81). World Health Organisation. <https://reliefweb.int/sites/reliefweb.int/files/resources/20200410-sitrep-81-covid-19.pdf>

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