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Challenging the engineering design process for the development of facial masks in the constraint of the COVID-19 pandemic

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Abstract

The most effective ways to mitigate the diffusion of the COVID-19 pandemic are social distancing and the use of face masks as barrier to avoid droplets and to filtrate exhalations coming from infected subjects. Currently used face masks are products developed to be used by workers, both in health care and other contexts, where their use is limited in time and the disposal scenario is properly managed. Their use in a pandemic situation can be thus considered a remedial action due to the emergency. New masks or mask families are needed based on the desirable requirements retrieved by the analysis of the current worldwide situation and covering the gap observed in the market. The present paper aims to describe the complete product development process of a new facial mask (or mask family) for a daily use on a pandemic situation. It challenges the time constraint of the COVID-19 pandemic by adopting a four-step approach and concurrent development of the first phases (definition of requirements and functional derivation). The engineering design process allows to derive two different solutions able to fulfil all the requirements (demands and wishes) of final users, by assuring high ergonomic performance, as well as environmental, economic, and social sustainability.

Keywords: Engineering design, product development process; facial mask, pandemic, COVID-19

1. Introduction

The COVID-19 pandemic caused by the new SARS-CoV-2 virus has infected several millions of people all around the world, greatly affecting how humans interact, work, and go about their daily life. On the beginning of 2020, the pandemic was declared a global health emergency by the World Health Organization (WHO), and it will stay until an effective medical treatment or a vaccine will be developed and distributed on large scale [1]. It is well known that the main route of virus transmission and infection among individuals is caused by "respiratory fluid droplets" capable of transmitting the virus unknowingly whilst breathing or speaking [2][3]. These droplets can spread the viruses through different methods such as airborne (infection due to the inhalation of droplets in the air - small droplets < 5-10μm) and direct contact (result of the droplets landing on an individual or a surface and then being transmitted to an area where infection can occur - large droplets > 20μm) [4][5][6].

Both WHO guidelines for the prevention of infection of COVID-19 and recent research works recommending the use of facial masks as the most effective way to protect people from contagion [1][7][8]. Masks essentially work as physical barriers to avoid droplets and to filtrate exhalations coming from infected subjects [9]. The effectiveness of a face mask is determined by two significant factors, the filtration efficiency and facepiece leakage [10]. Filtration efficiency measures how well the mask filters particles in a specific size range (including viruses), while facepiece leakage measures how well the mask prevents the leakage around the facepiece. Medical masks must comply with the requirements of European Standard (EN 14683:2019; EN 149:2001) that classify filtering masks (filtering face pieces – FFP) based on their filtration efficiency.

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FFPs are further divided into FFP1, FFP2 and FFP3, with an efficiency of 80%, 94% and 99%, respectively (EN 149:2001).

Face masks are generally fabricated using different layers of nonwoven fibers made of thermoplastic polymers [11], or functionalized materials [12][13]. Within the emergence of the COVID-19 pandemic, the significant increment in the demand of face masks caused a global shortage in the availability of such equipment. However, other relevant issues have been observed. Face masks has been developed for workers, both in health care and other contexts, where their use is limited in time and the disposal scenario is properly managed. Requirements used to develop facial masks in working environment are different than requirements observed during the pandemic and the use of such equipment for daily activities is only an adaptation (remedial action due to the emergency), highlighting ergonomic requirements. Moreover, the use of the equipment available in the market arises different sustainability issues: (i) economic (supply and manufacturing of the facial mask), (ii) social (covering the face of a person prevents the possibility to show his/her personality), and (iii) environmental (a huge amount of plastic waste not properly managed).

For the above-mentioned reasons, a new product (facial mask for daily use) or a set of products is needed based on the requirements coming from the market. The new product should be designed and developed considering the desirable requirements (demands and wishes) retrieved by the analysis of the current worldwide situation and covering the gap observed in the available products used in this context. Moreover, the development process required some modifications to cope with the high market demand and the time constraints caused by the COVID-19 pandemic.

The present paper aims to describe the complete product development process of a new facial mask (or mask family) for a daily use on a pandemic situation. The process is grounded on consolidated techniques in the field of engineering design and it is based on four main phases: (i) definition of requirement list, (ii) functional analysis, (iii) module derivation, and (iv) technological implementation. The novel contribution of this research lies in three main streams. Firstly, it can be considered the first attempt done for the development of dedicated personal protection equipment against pandemic (facial mask for daily use). Secondly, the developed solutions can tackle main issues related to the use of available solutions (i.e., environmental, social, and economic issues). Finally, the product development methodology required a concurrent approach to provide a reactive response to the world crises caused by the COVID-19 pandemic.

The paper is structured as follows: after this introduction (section 1), the materials and methods section report all the phases of the product development process (section 2). Results section describes a set of alternative products derived by implementing different design solutions for each module (section 3). Discussion section argues about outcomes of the presented work to develop new solutions (section 4), while conclusions summarize main results and limitations (section 5).

2. Materials and methods

The paper aims at identifying new requirements, not originally considered, to develop an *ad-hoc* personal protection equipment against virus infection during a pandemic. A new product was then developed based on these requirements. The product development workflow, consisting of four phases, is reported in Fig. 1, which illustrates the overall process followed, including the design tool used in each phase, and the temporal sequence of the activities.

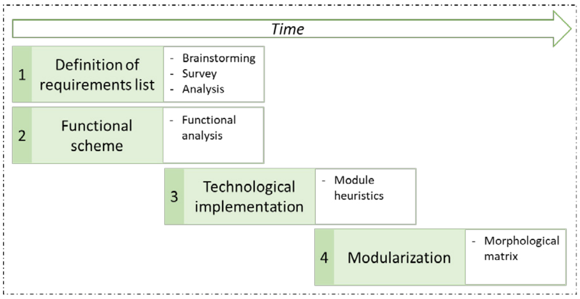

Fig. 1. Product development process workflow for a facial mask

The first phase of the design development process was the definition of requirements. The purpose of this phase is to collect information about the requirements that must be fulfilled by the product (facial mask), and about the existing constraints (regulations and standards). This phase consisted in a set of actions and analyses that allow members of this research team to define the requirements' list. Existing products' analysis was done to identify main issues of commercial equipment. At the same time, brainstorming sessions, with research team members and external persons, were performed as well to identify a new set of requirements based on specific areas. The main areas covered by requirements are the following: (i) safety - SA, (ii) ergonomic - ER, and (iii) sustainability – SU (environmental, economic, and social). The requirement list was organized according to the following criteria: (i) ID (label), (ii) type (demand - D or wish - W), (iii) area, and (iv) requirement. It is worth to noting that the record about the source of demands and wishes is also very important for subsequent step where main functions and auxiliary functions were defined as well as to track changes over time (i.e., standards upgrade). For the sake of brevity, an extract of the requirements' list developed for the facial mask is reported in Table 1. Among the items of the entire list, few hotspots are reported here as interesting examples. The first two refers to the ergonomic area: (i) the need to be fixed on the face (demand) and (ii) the need to be comfortable (demand). Indeed, daily use of facial mask showed how surgical masks or other type of masks (i.e., FFP2 or FFP3) may move from the original position during talking, causing irritations of the face skin due to the friction of the plastic material (e.g., polypropylene and polyethylene). Other three interesting requirements reported here as example and referring to the sustainability area are the following: (i) might be durable (demand), (ii) might provide filtering status information (wish), and (iii) need to allow to see the face (demand). The first two requirements refer to the environmental pillar of sustainability and originate from the fact that available mask can be used only for a limited time (max 4 hours for the surgical mask and max 8 hours for the FFP2 and FFP3 masks) [14] [15]. Thus, the possibility to monitor the status of the filtering efficiency can prevent the discard of masks with residual life, increasing the product lifetime. On the other hand, the requirement related to the social pillar of sustainability recalls the possibility to show the face when wearing the mask itself. This requirement is of great importance for gender aspects (e.g., show personality, physical aspect and emotions) and allows to facilitate comprehension during normal talking (for hiring-impaired) and for safety reasons in special environments (e.g., airports).

Table 1. Extract of the requirements' list

ID	Type	Area	Requirement
001	D	SA	Need to block virus and bacteria input
002	D	SA	Need to block virus and bacteria output
003	D	SA	Need to block pollution input
004	D	SA	Need to guarantee at least 95% of filtering efficiency
101	D	ER	Need to be fixed on the face
102	D	ER	Need to be comfortable for hours
103	D	ER	Need to avoid leakages (in and out)
104	D	ER	Need to allow to breath normally
104	W	ER	Need to allow to breath normally during sport activity
201	W	SU (Env.)	Might be made of sustainable materials
202	D	SU (Env.)	Might be reusable
203	D	SU (Env.)	Might be durable
204	W	SU (Env.)	Might provide filtering status information
205	W	SU (Env.)	Might be recyclable
206	D	SU (Soc.)	Need to allow to see the face
207	W	SU (Soc.)	Might be personalized
208	W	SU (Econ.)	Need to be cheap for daily use
209	D	SU (Econ.)	Need to be available for each person in very constrained time

The functional analysis was performed with the aim to retrieve the functional scheme. This phase was performed by applying the method proposed by Pahl & Beitz [16]. Functions were defined as well as mass, signal, and energy fluxes. The black box (Fig. 2) represents the main function (overall function) of the product, while the flows of material, energy and signal are transformed by the function itself passing through the black box [17]. In this specific case, the main function was defined as "*Filter Air from Viruses and Pollutants to protect a person*". Three input flows entering the black box were defined: (i) *Fresh contaminated air* describes the material that users need to breath, (ii) *Human force* reflects the force required by the user to apply the protection and, (iii) *Protection signal* represents the signal necessary to activate the protection. Two output flows going out from the black box were defined: (i) *Exhausted air* represents the air containing CO2 as a result of the breathing process, and (ii) *Heat* that is generated by the breathing process. The main function was then divided into sub-functions and a complex tree structure (function structure) was created. The overall result is depicted in Fig. 3.

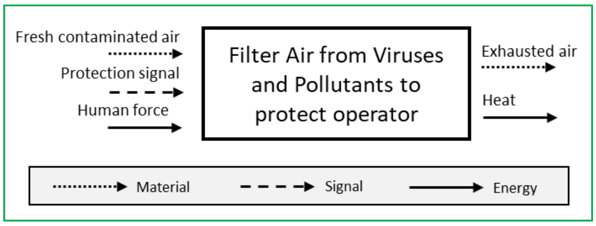

Fig. 2. Functional analyses (main level)

It is worth noting that most of these functions are primary functions such as "regulate air flow intake", "block viruses", "block pollution", etc., while others are auxiliary functions such as "personalize protection", "display filtering status", and so on. The generation of the functional analysis and the requirements' list are the most time-consuming phases. Indeed, the two phases were performed concurrently using the same brainstorming session to obtain both the requirements' list and the associated functions. This provides a substantial difference with the classical PDP process.

Once the functional analysis was obtained, it was possible to proceed with the generation of modules (modularization). The lowest hierarchical level of the function structure was used to identify modules by adopting the module heuristics method for product modularization [18]. This step consists of grouping functions by using three separate strategies (heuristics) to identify modules: (i) dominant flow - DF, (ii) branching flows BF, and (iii) conversion-transmission modules - CTM. It is worth noting that all retrieved modules were labelled from letter A to letter Q (15 modules). As reported in Table 2, the first heuristic (*dominant flow*) allows to obtain A, B, C, D, E, F, and G modules. By adopting the second (*branching flows*) and the third (*conversion-transmission modules*) heuristics, H, L and P modules, and Q module were obtained, respectively. Finally, I, M N and O modules were identified by using both heuristics. Finally, modules identified by different heuristics that collect the same functions were discarded, and only fifteen of them were selected as unique.

Last step of the workflow was the technological implementation. The tool used to support this phase was the morphological matrix (i.e. morphological chart) [21]. The morphological matrix aimed at generating an exhaustive set of solutions for a given problem (in this case each product module), organizing them into a matrix where rows identify modules and columns identify possible solutions (i.e., design options). The morphological matrix enabled to analyze all the engineering solutions that may occur during the development of the facial mask. It concerns the analysis and the permutations of any possible solution generated to fulfill each identified module [22]. Based on such approach the morphological chart was built and an extract for three main modules is reported in Fig. 4 (Module C, Module E and Module L).

To complete the matrix with design options for each module, research activities were focused on two sides: the overall product and each single module. Firstly, a research on patents was performed using a dedicated repository (i.e., Espacenet patent search). Secondly, the available solutions in the market was analyzed by consulting the websites of the facial mask and respirator manufacturers and sellers.

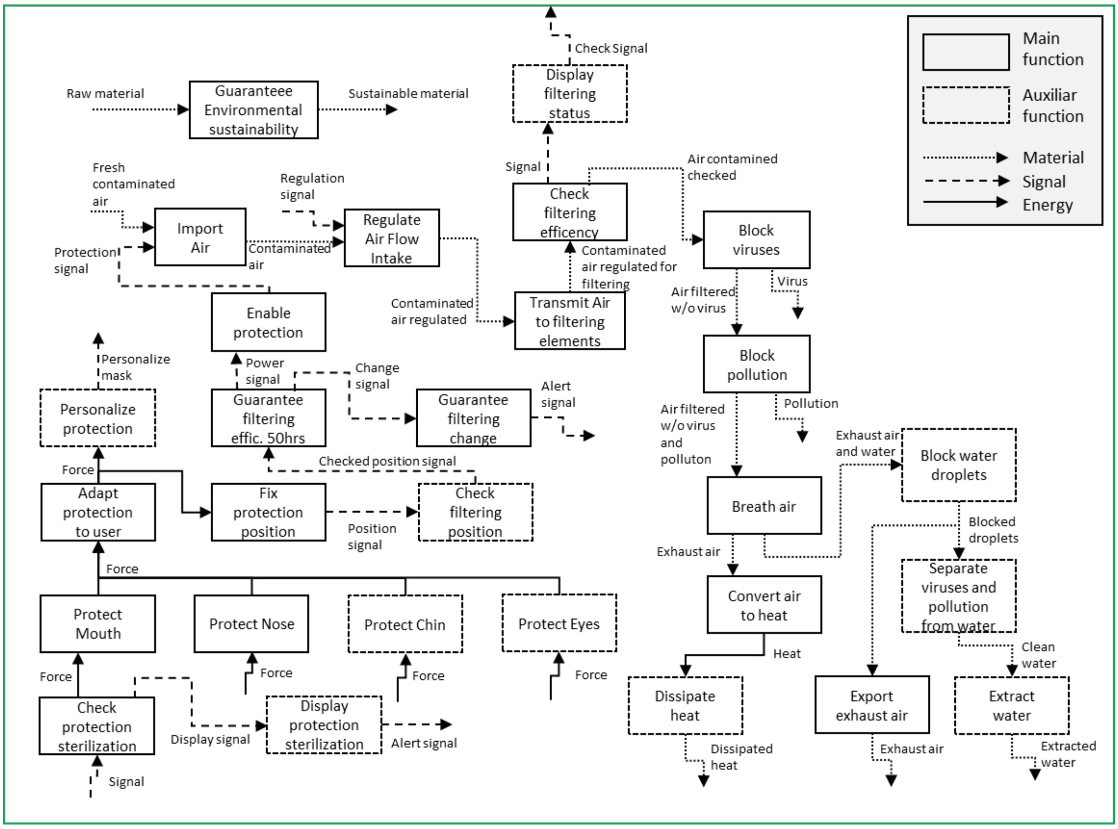

Fig. 3. Functional scheme

Table 2. Identified Modules

ID	Module	Type	DF	CTF	BF
A	Import & regulate air	Main	X		
B	Allow to safety breath	Main	X		
C	Protect & cover exposed body parts	Main	X		
D	Guarantee filter efficiency	Main	X		
E	Guarantee filter change	Main	X		
F	Personalize	Aux	X		
G	Display filtering status	Aux	X		
H	Display protection sterilization	Aux		X	
I	Extract water after virus separation	Aux		X	X
L	Monitor protection efficiency	Aux		X	
M	Convert air	Main		X	X
N	Dissipate exhaust air	Main		X	X
O	Block water droplets after breathing	Main		X	X
P	Ergonomic for fixation and adaptation	Main		X	
Q	Dissipate heat	Aux			X

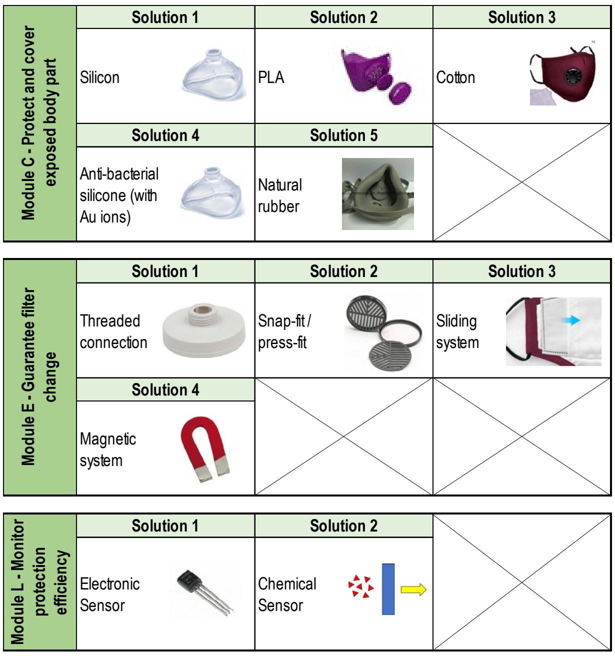

Fig. 4. Morphological matrix for Module C, Module E, and Module L.

3. Results

Combining all the solutions identified in the morphological matrix, it is possible to derive more than thousand different hypothetical face masks. Moreover, by collecting modules and solutions properly described in the morphological matrix, solution already available in the market are obtainable such as, surgical mask, FFP2 and FFP3 masks.

As described in the introduction, these solutions present well-known limitations, overcome through the development of few models of dedicated face masks which fulfill the requirements of a pandemic situation. The first proposed mask considers only "main" modules that have been derived by the definition of "demands" from the requirement list (Fig. 5).

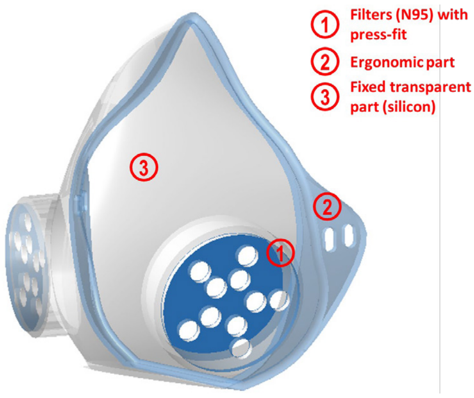

Fig. 5. Face Mask (first model)

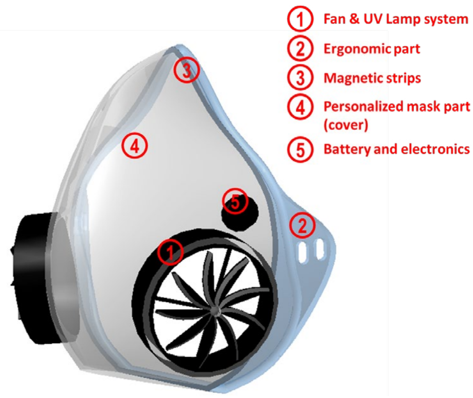

Fig. 6. Face Mask (second model)

Nine modules are considered as main modules: A, B, C, D, E, M, N, O, and P. By considering the design options listed above within the morphological matrix, the resulting face mask was made of the following solutions. For the module A – "*Import and Regulate Air*", natural depression (caused by breath inhale) was selected as design solution. This choice was made to avoid additional items on the mask that require the use of electronic devices and consequently an increment of cost and dimensions. For the module B – *"Allows to safety breath*", N95 filter was selected as primary filtering material. This choice was driven by the filter efficiency and the cost of this material. Size and shape were adapted to minimize the amount of material used due to environmental issues. For the module C – "*Protect and cover exposed body part*", silicon was selected as main material due to their property. Indeed, it is transparent, it can be easily cleaned and sanitized, and it can be manufactured with both traditional (i.e., injection molding) and innovative (i.e., additive manufacturing) processes. For the module D – "*Guarantee filter efficiency*", activation of N95 filter material surface with metallic oxides (i.e., CuO, ZnO or AgO) coating was selected. This kind of choice allows to increase the antimicrobial properties by a surface-deposition (nanoparticles) [13] [23]. For the module E – "*Guarantee filter change*", a press-fit solution was adopted as easy-to-use and economic solution to facilitate the filter changing. For the modules M – "*Convert air*" and N – "*Dissipate exhaust air*" natural pressure caused by breath exhalation was selected as design solution. For the module O – "*Block water droplets after breathing*", again N95 filter was selected as primary material. Finally, for the module P – "*Ergonomic for fixing and adaptation*" rounded curvature for face sealing and rubbers were selected as the most efficient solution to avoid air leakage and to guarantee the compliance when in contact with the face skin. For this module size and shape were developed by 3D CAD modelling according to anthropometric parameters.

The second mask proposed within this work considers both "main" and "auxiliary" modules that have been derived by the definition of "demand" and "wish" requirements from the requirement list (Fig. 6). The mask presents three main advantages: (i) the presence of a UV system to filter the air avoiding the need of filter replacement, reducing the environmental impact related to the material waste, (ii) the use of a fan to facilitate the breathing process, and, finally, (iii) the possibility to personalize the mask (by using a magnetic strip to fix the customized part).

4. Discussion

The two identified solutions allow to consider new requirements to re-design an already and widely used product, such as the face mask. By the adoption of the morphological matrix it was possible to provide different mask designs, with different technological solutions and, indeed, costs. The proposed solutions allow to improve the whole life cycle of face mask.

The first solution (i.e., the one with exchangeable filters) enables the use of the same face mask for an extreme long period of time. Indeed, it is possible to change exhaust filters with new ones. The *personalized mask part* can be created using algorithms of face recognition to obtain anthropometric parameters and additive manufacturing techniques to reduce the production cost and increase the personalization. Moreover, a life cycle analysis, by means of both life cycle assessment (LCA) and life cycle cost analysis (LCCA), were performed to quantify the overall face masks impacts through the product lifecycle. Even if the cost of the fixed part of the mask is higher than a common one (i.e., surgical mask or FFP2 mask) the adoption of exchangeable filters allows to reduce the cost along the useful life of the product and to reach the breakeven point after nine months of use. This result was retrieved by a LCCA analysis. Concerning the environmental performances, reduction of environmental impacts is demonstrated by the LCA study, highlighting how the use of the proposed solutions in a time frame of a year allows to reduce of one order of magnitude most of the considered indicators (i.e., global warming potential – GWP and acidification).

The second mask (i.e., the one with UV system and fans) is a high-tech solution that implements innovative techniques to improve the users' experience. In fact, the fans allow a wider range of people to use the mask, such as people with breathing issues or people involved in sport activities (e.g., runners, etc.). However, the second solution requires the use electrical components that will necessarily increase the overall final cost, reduce the product sustainability (i.e., problems related to the batteries end-of-life) and may reduce the reliability of the mask due to the occurrence of technical issues (e.g., electronic obsolescence).

The proposed approach can be used to derive other face mask designs by identifying new requirements and/or implementing different solutions. However, it presents few criticalities due to the reduction of the PDP time. In fact, the definition of requirements' list performed concurrently with the functional derivation required more brainstorming sessions involving more experts, creating organizational problems. New aspects could be included to better fit the market requirements that were observed only after the use of the first mask model (i.e., nasal dryness). Moreover, some requirements may be missing since not enough time was given to the requirements' list definition and some functions might not be defined in a proper way. This may lead to inconsistent result. Thus, the reduction of the product development time, needed in a pandemic situation, should be carefully considered against the possible drawbacks it might lead.

5. Conclusions

The paper presents the overall engineering design process for the development of facial mask which fulfill specific requirements for a daily use on a pandemic situation. The standard design approach was used for the development of a design concept [16], and the generation of several design alternatives. Two different products were developed and modelled based on "demand" and "wish" requirements. The proposed solutions present important advantages in terms of sustainability. From the economic and environmental perspectives, these models allow to increase the life cycle performances, reducing the overall amount of plastic waste and the total cost of ownership. From the social perspective the two models allow to increase social inclusion (i.e., the possibility to communicate with deaf people) and safety in particular environment (i.e., airports). Additional requirements were fulfilled such as the safety/protection one by the use of high efficiency filtration methods and tools. In addition, ergonomic aspects were taken into account, providing comfortable solutions for everyday use.

About these latter aspects, more additional research works are necessary to include the possibility to develop highly personalized solutions based on the anthropometric parameters of any individual. This will be a future development, coupling facial parameter recognition (from 3D scan or image processing) and 3D printing of module components that are fitting with the face (dedicated customization of module P – "*Ergonomic for fixing and adaptation*").

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