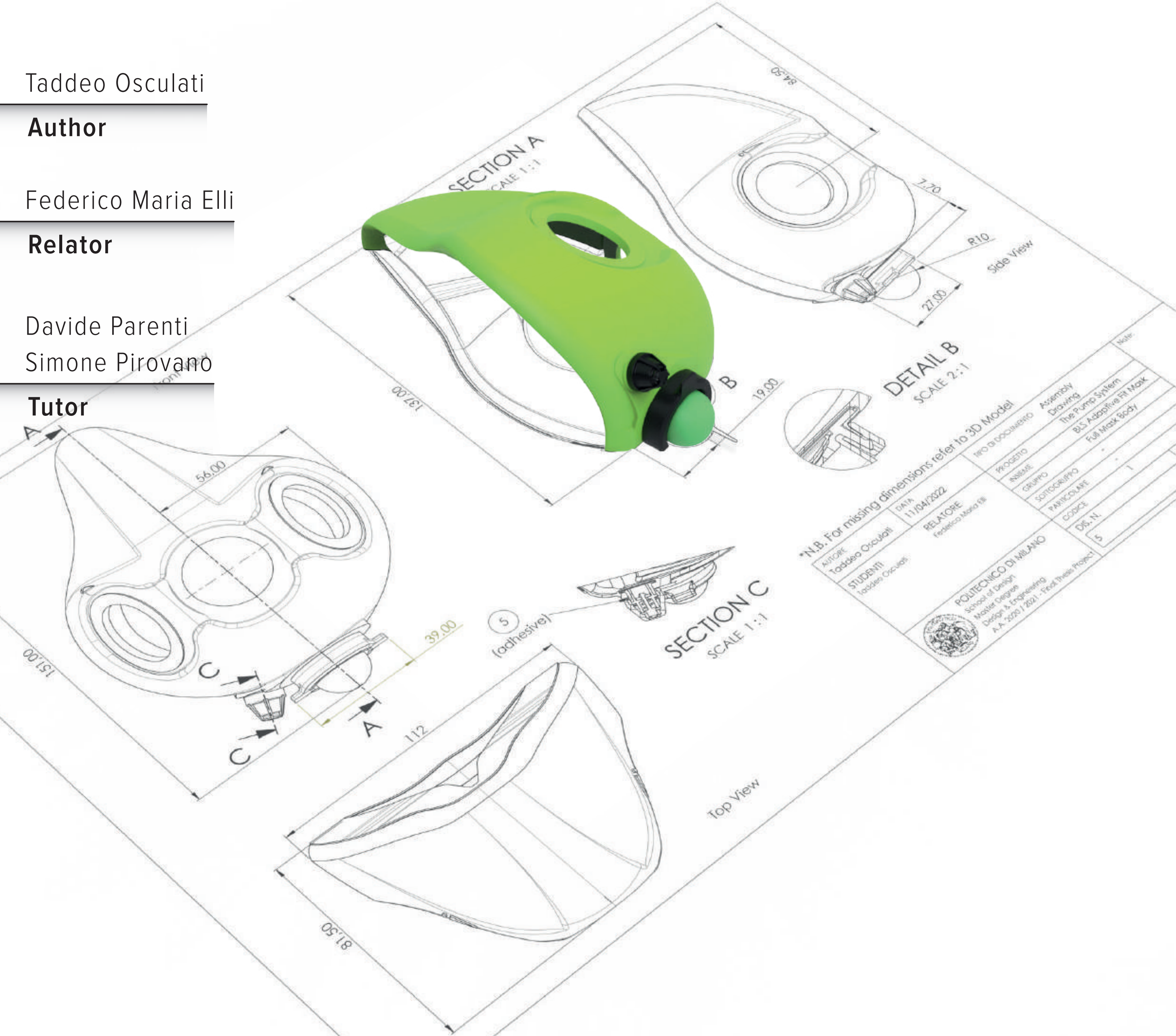
RESPIRATORY PROTECTION PRODUCTS

POLITECNICO MILANO 1863

Politecnico di Milano

Design Engineering master degree course



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The Pump System

respiratory mask adaptive-fit

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Acknowledgments

The development and work around my thesis project involved the last 3 years of my life and overlapped with several other signifying milestones of my journey.
During the last years my personal and professional path went through many changes and many many events happened to me.
A continuos and steady activity of improvement carried on with dedication to my academic life and to the project addressed (and the things i care) couldn't have been possible without the influence and the presence of some very important important actors in my life. This words of sincere thanks goes to all who have believed in me and left a trace during my path.
First of all my family, all of it, who supports my passions since day one, sustaining and helping my activities.
To my girl, for the constant support and love, for making me take a breathe while running together this crazy life.
To my friends all over the world and my colleagues in PoliMi, my other-family, the continuos source of inspiration and confrontation during this years of common-fatigue.
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To all the other companies and actors that helped the realization and conceptualization of the PUMP System:
Thank you for making it possible!

ENGINEERING

the PUMP project

The PUMP system is the result of a 3 year long working activity which involved efforts on research, analysis, development and has recently entered the final enegineering and product grounding phase.
The project takes root back to 2019 where it was initially formulated during a 3day workshop in collaboration with PoliMi and the company BLS. On the occasion a very first definition of the concept was given and the base was setted for further product development.
Since the beginning of this journey i believed in the strength of the concept and worked hard to bring the innovation alive, in an individual manner initially and now with the support of BLS. After 3 years of iterations and verifications i'm today really proud to present to the world the concept of the Adaptive Fit, introduced by the PUMP System invention.

0.0 Abstract

introduction to the project

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What is the purpose of the negative pressure seal check?

"The Negative Pressure Test (or Fit Check) checks the presence and functioning of the respirator exhalation valve as well as potential leakage due to improper cartridge seal or respirator/face fit. This test is performed to help the wearer assess respirator function and to find gross leaks between the face and the face piece"

Intro

Respiratory protective face-masks are widely employed in industrial fields to protect worker during working activity.
The face-piece provides protection against repeated exposure to contaminants by sealing respiratory tracts from surrounding working enviroment and filtering the air by forcing it through filter units; the mask is usally worn for hours during the course of the activity. To meet the demand of different size-shaders, mask manufacturer are providing different size ranges to cover user requests.
Face traits and facial characterization can be affected by many aspects such as ethnicity, gender, age and different physiognomies, thus affecting negatively the selection of a mask and the search of a "custom fit" by the users.
Under this circumstances, critical aspects related to mask use and practices emerged during in-field research: first of all the inability of the system to adapt to severe facial differences and the discomfort caused by wearing the mask for multiple hours during working activitles.
The project aims to equip current face-masks design with an adaptive fit: the concept consists in an inflatable harness element capable of compensating facial differencies between users by providing a custom, comfortable and safe seal every time of use.

[A]

picture showing myself, during some prototyping activities

[B]

picture showing prototypes developed for testing

The concept has been developed, tested and evaluated according to project key-drivers and resulted in an improved user-experience. The PUMP system provides an unique solution among multiple (and different) users, thus by improving workers safety and comfort during activity.

personal motivations

During the course of study in Design and my personal activities i often had the chance to use and interact with PPE (or DPI), putting myself in the user perspective.
Protective face-pieces (especially negative pressure half-face masks) are often very intricate and painful to be worn, affecting negatively the activity performed by the user; also regulation on visage results cumbersome when operating with this garment, and a safe and tight-seal is often not guaranteed, exposing the worker to harm and danger. I always found these elements very frustrating and limiting the use of respiratory protective equipment, representing real annoyances, in some cases
If the PPE is not worn correctly it can really represent an hazard and expose to harmful contaminants, often without any real awarness or perception by the user.
For these, and for many other reasons i wanted to design and improve the concept of face-mask: i really feel that design and engineering applied to this product category can improve several functional aspects and directly impact final user behaviour by offering many benefits and, most of all, a safer working experience.
These were the grounding motivations that started my research and guided me into the conceptualization and development of the Adaptive Fit concept (PUMP system).

0.1 Health masks

mask over ages

0.1 Health mask invention

born, growth and evolution of the concept of “health mask”

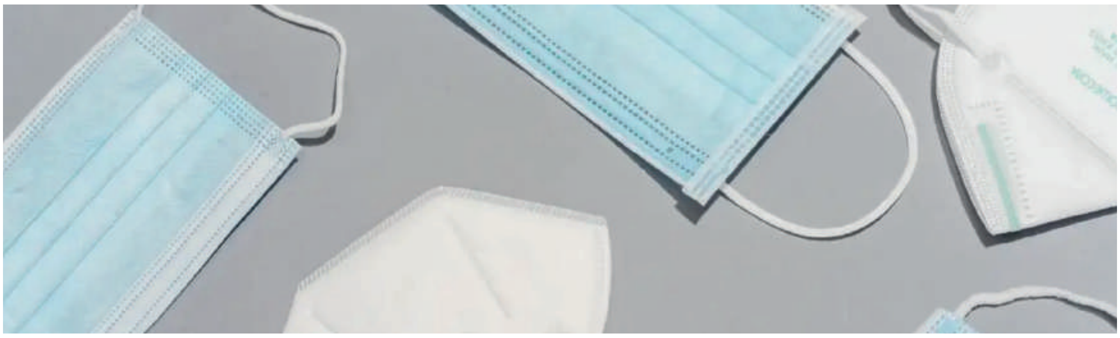
with the term health mask we refer to:

those masks that over the centuries have been developed for medical or protective purposes, even in sport and work

protecting people, saving lives and slowing the spread had always beeen core functions of the health mask.
In this chapter i’m going to trace the history and origin of this term, focusing on effective examples and case studies that setted the way to our modern concept of “face mask” .

core function of the face mask has always been to protect the owner from some kind of risk, regardless of the nature or entity of the hazard. Therefore in this chapter i’m going to trace back the history and origin of this term; this leads us to the concept of “mask” we have in mind nowadays.

[A] disposable mask models



disposable mask visualization [B]

apotropaic mask

american native face mask [C]

american native face mask [D]

It is wrong to think that masks have a function only in biomedicine, specially for modern typical Western medicine. Masks are a very ancient and common tradition for most of our cultures and ancestors.
Masks are also a fundamental element of ethno-medicine, traditional medical cultures present in other territorial areas such as Africa and Asia, where they perform an *apotropaic* function. They are worn by shamans and sorcerers during rites to heal people or to prevent a pathological condition from intervening and often reproduce a pathological condition against which protection is sought.
Furthermore, it should be considered that especially in Africa, but also in the East, the disease is not something related to the individual but is due to the alteration of a social/all-around balance.
Therefore, therapy is aiming to restore order in a social environment, more than in the sick subject, at restoring order in a social environment that, having been altered, has led to the realization of the disease. [A]
The rituals of the shamans of wearing the mask, dancing and singing have to help in this sense.

mamuthones - italian sardinian traditional mask [E]

representative-theatrical mask

Probably one of the first testified uses of proper masks in mankind's history is for theatral and representative purposes.

The use of the mask was initially zoomorphic, and can be traced back to prehistoric times.
On the walls of the deux frères cave, in the French Pyrenees, a painting depicts a hunter disguised as a goat while hunting.
The tradition of dressing up in animal skins and masks and imitating their movements is present in all human cultures.

In the Greek theater, which used them systematically from the beginning, the masks had the double function of characterizing the character and making him visible even from a great distance (given the size of Greek theaters).
The masks had fixed characters which were used to confidently attribute the class of belonging, the state of mind, the age and the personality of the character who was staged.

In Europe the use of the mask was very successful with the Italian *commedia dell'arte* of the sixteenth century, which elaborated the characteristic masks of the characters starting from previous masks and from animals. [B]

During this period theatre masks were mainly attributed to the function of resembling someone and to communicate its main traits, related to the scenario and theaters carachter.

[F] theatrical character mask

plague mask

plague face mask visualization [G]

representation of plague doctor suit [H]

The story begins during the Renaissance and the idea was made that the contagious diseases of the time - including the black plague - had been scaturated from the so-called "miasmas". With the term “miasma” we refer to the bad, pungent and unhealthy air that according to the beliefs of the time was the cause of most infections. Thus, tissues and towels impregnated with essences began to be used, which had the requisite of removing deadly miasmas.
These solution were employed as coverage for face and respiratory tracts to preserve them from the bad smell. [A]

This lead us to the more elaborate "plague masks", equipped with a long beak into which the doctors inserted a series of fragrant essences and straw.
The doctors who remained and decided to assist and treat ill patients, in addition to the characteristic mask, used to wear a long oilcloth overcoat, gloves, glasses, a wide-headed hat, and a stick that allowed them to visit the sick from a distance without directly interacting with their hands.
This clothing, known as the plague doctor's dress, was inspired by the armor of soldiers and has been the way doctors tried to defend themselves against contagion.
It was an ineffective defense but it also gave the idea of “protection” against something/someone ill, and it can be therefore considered the *first of the health masks, which will be developed a few centuries late.*
It will be necessary to wait until the nineteenth century before stumbling upon the first true medical mask, namely the surgical one

surgical mask

In the second half of the century the concept of miasmas was finally overcome, also thanks to the studies of Robert Koch who discovered (in 1882) the causative agent of tuberculosis, demonstrating that germs are the cause of infectious diseases. Thus *we begin to think of possible remedies designed to selectively kill the pathogen that causes the infection*.
Drugs that work as a sort of "magic bullets" as Paul Ehrlich, Nobel Prize in Medicine in 1908 and founder of the chemotherapies, called them of infectious diseases.
In parallel, surgery begins to be more effective: anesthetics and chemicals are used to sterilize the operating field, even if in a preliminary and rough way. However, the risk of infection remains high and is often the cause of patient death.
Sanitizing the surgical field has been a minor topic of interest until Carl Flügge thoughts were published - Flügge demonstrates that normal conversation is enough to spread droplets containing bacteria from the nose and mouth into the air - it is understood that the cause of sepsis can also be the surgeon, who simply breathing or speaking is in able to contaminate the wound [A] .

In 1897 the Austrian surgeon Johann von Mikulicz Radecki hypothesized to use a protection - a simple gauze - on the mouth and nose to prevent droplets from falling into the operating field.
In the same year, the French surgeon Paul Berger operated for the first time with a gauze mask on his face. *"It was the starting point for using increasingly elaborate gauze"* [C]

[I] Prof. Berger (surgeon) portrait

Fig. 29. — How the gauze-cotton mask should be worn. (Chapter VII.)

[L] first face-mask concepts

anti-contagion mask

first face-mask concepts [T]

portrait picture of doctor Wu Lien-teh [M]

However, the surgical mask, as is now well known, is useful for protecting others from contagion, if the wearer is infected, but not very useful for protecting the wearer in the case of a healthy person. In this case, to limit contact with the virus or bacterium as much as possible, it is more suitable to use another type of mask, the filtering one, such as the now famous FFP2 or FFP3. [A]

The first examples of this device are due to Wu Lien-teh, a Chinese doctor who collaborated in keeping under control a plague epidemic that spread in Manchuria between 1910 and 1911, with a very high mortality. [C]
Wu Lien-teh realized that the surgical masks indicated as an anti-contagion means had a decidedly low efficacy. So he developed a more elaborate version, composed of various layers of overlapping gauze and cotton, with a shell shape that allowed it to adhere perfectly to the face to cover the nose and mouth. *"Although the filter masks as we know them today were developed in the 1960s, the idea was born at that time"*

therapeutic mask

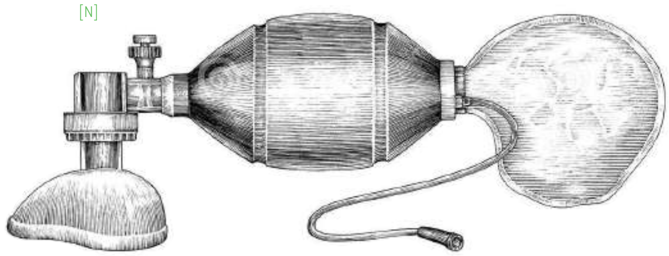
Beyond the protective function against pathogens, the mask can also have a therapeutic function in the medical field. Such as those mask used for anesthesia or respiratory purposes.
For example anesthesia mask at the beginning of the twentieth century were made only with a crossed iron wire, on which a gauze was placed where ether or chloroform was then drawn.
However, *therapeutic masks were born in the 1960s with a precise history,* strongly related to the widespread of therapeutic comunities and the definition and adoption of the therapeutic method [A].

These include the ambu-equipped mask with a self-expanding bag used to support respiratory activity and as a maneuver in resuscitation.

The C-pap (continuous positive airway pressure) mask, which allows continuous positive pressure mechanical ventilation, used to manage various respiratory problems that did not require intubation (for which both masks and specially developed helmets were used later in the years).

Many other models were introduced during the years of growth in the medical research field. Each mask responding to a specific patient-need and used to accomplish a given therapy. [D]

[N]



first face therapeutic mask model

[O]

first particle-filtration mask models

protective mask

The so-called “anti-gas mask”.
This corresponds to another widely used category of masks: the protective ones.
This kind of mask, such as the anti-gas, was heavily developed during the First World War when chemical weapons were used for war purposes.
The mask was initially intended to protect soldiers on field from harmful gases or particles wich were spreaded between the trenches.

The technology developed during this period of struggle enhanced further discoveries and searches around the topic of hazardous gas and powders in different fields of application, creating awareness from which a whole series of professional devices were born, used by those who work with gas and powders nowadays.
From this current, modern industrial PPE (personal protection equipment) were introduced to every-day use in some very specific scenarios in order to protect operator’s health and life. [D]

anti-gas mask model for war purposes [P]

anti-gas masks supplied to military forces [Q]

industrial mask

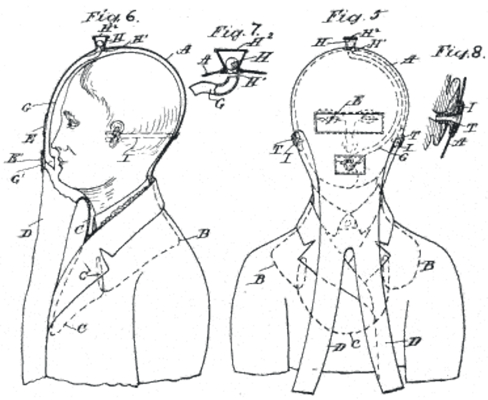
As we already mentioned, the development of masks and technologies for the protection of operators in the workplace, draws its origins from the innovation pushed during the world wars.
It is precisely during these years that man finds himself facing dangers related to the respiratory tract for the first time, in particular for the use of chemical weapons and consequent exposure to harmful gases and dust.

One of the first inventions in this regard was the "Safety and smoke protection hood" invented by Garrett Morgan in 1912 and patented in 1914. It was a very simple device to be worn. Consisting of a cotton hood with two tubes hanging down to the floor, allowing the wearer to breathe clean air. Wet sponges were inserted at the end of the tubes to better filter the air.
It was patented and awarded a gold medal two years later by the International Association of Fire Chiefs. [A]

On July 1910, the United States Department of the Interior established the United States Bureau of Mines (USBM). USBM worked to address the high mortality rate of miners and in 1919, started the first respirator certification program in the United States.
This led to the creation of the first American company dedicated to the mass production of individual protection equipment for operators, which still exists today under the name MSA (The Safety Company).
Over the years, technological evolution has led personal protective equipment to become increasingly sophisticated systems and competition between brands has raised a lot due to the numerous emerging players entering in this sector. [E]

[R]

[R] first patented particle filtrating mask concept



sport mask

[S] different mask models for practicing sports activity

Beyond the protective function against pathogens or contaminants masks, more in general face coverings, had been used for ages to shield the human body.
With the increase of sport practices and disciplines and with the widespread of sport activities and lifestyles, the need for protecting equipment started to increase.

During the years many different masks and helmets have been fine-tuned in order to meet the requirments given by the practiced activity to guarantee effective protection.
This is the case of football or fencing practitioners, where the “mask” is made of a metal-wire net to avoid direct contact with eyes and other exposed face areas.
Same happens in case of water sports, where a soft and rubber harness ensures tight seal all around the mask once it’s worn underwater by the user.

In many other sports (ski, cycling, baseball..) masks are employed for safety reasons and are nowdays fully integrated into the official and correct practice for sports. [A]

0.2 Overview - milestones of personal protection
the evolution of mask concept over ages

European Black Plague
1347 - 1353

Modern Medicine diffusion
XIX century

Manchurian pneumonic plague
1910 - 1911

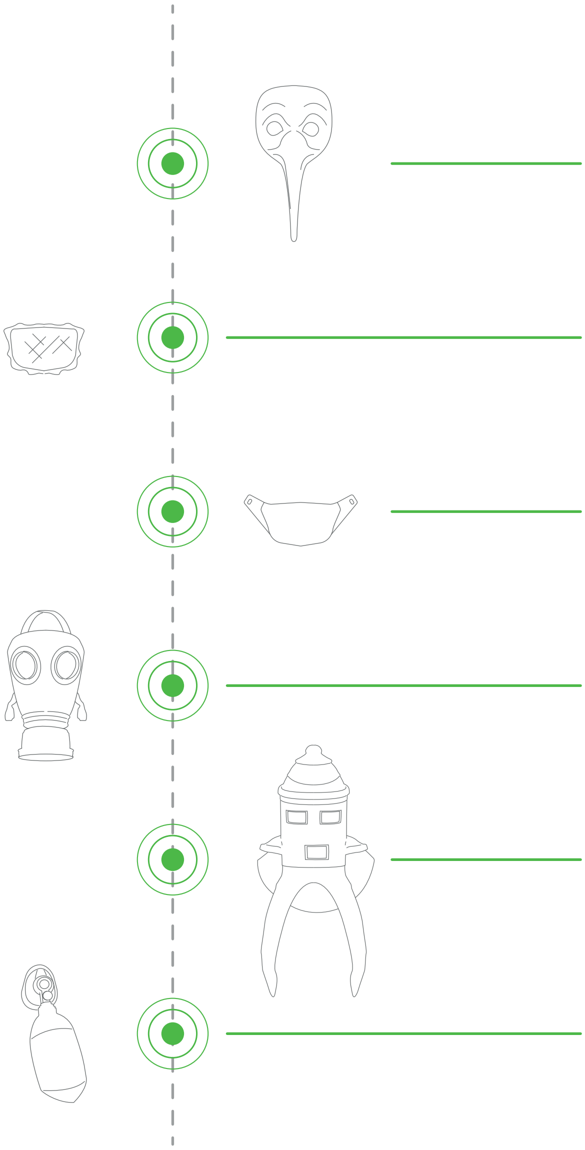
World War I
1914 - 1918

Accidents at work
1920s

Medical therapies diffusion
1960s

Overview

documented evolution of face-mask concept



plague mask was invented during this period to prevent doctors from direct contact with contaminated patients

first anti-contagion mask concept was born around mid-'800. It was a simple cotton and gauze layer to cover respiratory tracts

a more structured proposal was formulated from a Chinese doctor while studying plague in Manchuria. Gauze and cotton were brought togheter in the shape we recognise nowdays

first anti-gas mask was developed to help soldiers to survive the new chemical weapons used during World War I

first personal-protective industrial mask started to appear after WWI to protect workers on hazards and accidents at work. It was initially employed by firemans and miners.

many medical devices started to appear after '60s where the mask was used to deliver custom medical therapy. This thanks to the increasing interest for the research on therpies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1.0 the use of PPE

personal protection equipment

1.0 The use of PPE
definition of the term in it's meanings

with the term PPE mask we refer to:

personal protective equipment

commonly referred to as the equipment worn to minimize exposure to hazards that cause serious workplace injuries and illnesses. These injuries and illnesses may result from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards.

In italian the term DPI is used to define the same garment category, by the mean of:

dispositivi di protezione individuale

Protective equipment may be worn for job-related occupational safety and health purposes, as well as for sports and other recreational activities. [A]
The purpose of personal protective equipment is to reduce employee exposure to hazards when engineering controls and administrative controls are not feasible or effective to reduce these risks to acceptable levels.
PPE is needed when there are hazards present. PPE has the serious limitation that it does not eliminate the hazard at the source and may result in employees being exposed to the hazard if the equipment fails. [B]

[A] different kinds of PPE presentation

short history about safety


picture of welding worker [B]

As already mentioned, the development of masks and technologies for the protection of operators in the workplace, draws its origins from the innovation pushed during the world wars.
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Over the years, technological evolution has led personal protective equipment to become increasingly sophisticated systems and competition between brands has raised a lot due to the numerous emerging players entering in this sector and making “personal sfatey” a hot topic

picture of worker in shed [C]

safety in the industry

It is right at the turn of the second World War that themes such as protection of individual safety of the worker and long-term work-related accidents became popular and began to be investigated under different aspects.
With the end of the conflict much attention was put on the safeguarding of working conditions and the question gained popularity in different fields, also thanks to public opinion.
From this moment on the protection and safeguarding of workers became a very hot topic in many industrial fields and sectors; even nowdays the topic is treated with much regard.

Rules, manuals and documentation was created around the topic. Coded practices and procedures are nowdays available and shared among different industrial realities in order to allign behaviours and countermeasures in specific fields to protect workers safety. [D]

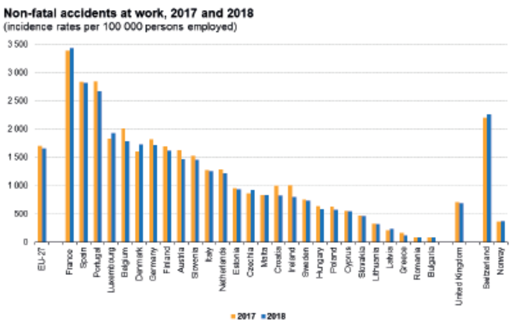
Personal Protective Equipment were introduced in many sectors to partially mitigate users risk exposure where danger cannot be completely removed. For certain applications, adopting a PPE when working, contributed enormously to decrease user risk exposure and to reduce fatal accidents on work. The topic growed and gained importance during years and is now a very recognized and well-known topic, with its own literature and case studies. In the following pages definitions and examples of applications will be given. [E]

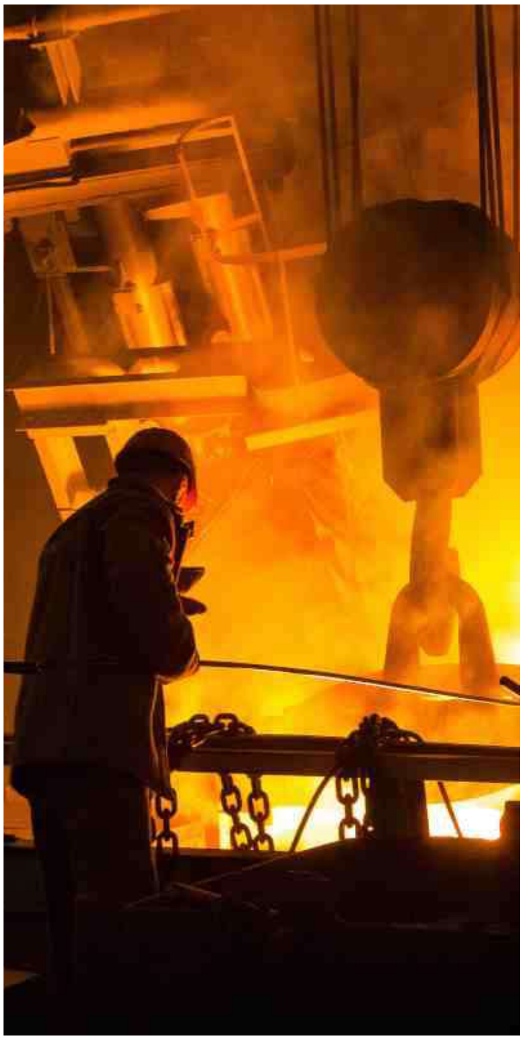
1.1 Occupational hazards

hazard categorization and ways of protection on work

Practices of occupational safety and health can use *hazard controls and interventions* to mitigate workplace hazards, which pose a threat to the safety and quality of life of workers. The hierarchy of hazard controls provides a policy framework which ranks the types of hazard controls in terms of absolute risk reduction.

At the top of the hierarchy are *elimination* and *substitution*, which remove the hazard entirely or replace the hazard with a safer alternative.
If elimination or substitution measures cannot be applied, *engineering controls* and *administrative controls* (which seek to design safer mechanisms and coach safer human behavior) are implemented.
Personal protective equipment *ranks last* on the hierarchy of controls, as the workers are regularly exposed to the hazard, with a barrier of protection.
The hierarchy of controls is important in acknowledging that, while personal protective equipment has tremendous utility, it is not the desired mechanism of control in terms of worker safety. Eliminating the cause of hazard at the source is always the best (and safer) choice if viable. [F]





[D] picture of worker in a blast furnace

[G] source: https://ec.europa.eu/eurostat

types of hazard

[E]

picture of medical operator wearing full face mask

Personal protective equipment can be categorized by the area of the body protected, by the types of hazard, and by the type of garment or accessory. A single item – for example, boots – may provide multiple forms of protection: a steel toe cap and steel insoles for protection of the feet from crushing or puncture injuries, impervious rubber and lining for protection from water and chemicals, high reflectivity and heat resistance for protection from radiant heat, and high electrical resistivity for protection from electric shock. The protective attributes of each piece of equipment must be compared with the hazards expected to be found in the workplace. More breathable types of personal protective equipment may not lead to more contamination but do result in greater user satisfaction.

the role of design

Any item of PPE imposes a barrier between the wearer/user and the working environment. This can create additional strains on the wearer, impair their ability to carry out their work and create significant levels of discomfort. Any of these can discourage wearers from using PPE correctly, therefore placing them at risk of injury, ill-health or, under extreme circumstances, death. Good ergonomic design can help to minimise these barriers and can therefore help to ensure safe and healthy working conditions through the correct use of PPE.

1.2 PPE categories and garments
hazards and employed garment

respirators

respirators serve to protect the user from breathing contaminants in the air, thus preserving the health of their respiratory tract. There are two main types of respirators. *One* type of respirator functions by filtering out chemicals, gases or airborne particles, from the air breathed by the user. The filtration may be either passive or active (powered). A *second* type of respirator protects users by providing clean, respirable air from another source. This type includes airline respirators and self-contained breathing apparatus (SCBA). In work environments, respirators are relied upon when adequate ventilation is not available or other engineering control systems are not feasible or inadequate

- gas mask
- particulate respirator
- PAPR
- SCBA

skin protection

Skin hazards, which lead to occupational skin disease, can be classified into four groups. Chemical agents (through direct contact with contaminated surfaces, deposition of aerosols, immersion or splashes), Physical agents (such as extreme temperatures and ultraviolet), Mechanical trauma occurs (in the form of friction, pressure, abrasions, lacerations and contusions), Biological agents (such as parasites, microorganisms, plants and animals) In this category we find any article of clothing or protection worn with the purpose of protecting the skin.
Lab coats , face shields and gloves are examples of this category of garment

- coats & suits
- hood
- gloves
  - cut-resistant
  - rubber (antistatic)
  - chainsaw
  - heat-resistant

eye protection

- welding / general hood
- face shields
- full-facepiece respirators
- goggles

chemicals, impact, dust, welding — goggles

Eye injuries can happen through a variety of means. Most eye injuries occur when solid particles such as metal slivers, wood chips, sand or cement chips get into the eye. Smaller particles in smokes and larger particles such as broken glass also account for particulate matter-causing eye injuries.
While the required eye protection varies by occupation, the safety provided can be generalized. Safety glasses provide protection from external debris, and should provide side protection via a wrap-around design or side shields.

hearing protection

- ear plugs
- ear muffs / ear flaps
- integrated helmet
- special hoods

Industrial noise is often overlooked as an occupational hazard, as it is not visible to the eye. Occupational hearing loss accounted for 14% of all occupational illnesses, with about 23,000 cases significant enough to cause permanent hearing impairment.
PPE for hearing protection consists of earplugs and earmuffs. Workers who are regularly exposed to noise levels above the NIOSH recommendation (85dB>8hr) should be provided with hearing protection by the employers. A personal attenuation rating can be objectively measured through a hearing protection fit-testing system. The effectiveness of hearing protection varies with the training offered on their use.

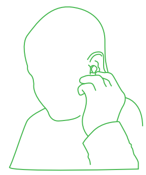
protective clothing and ensambles

This form of PPE is all-encompassing and refers to the various suits and uniforms worn to protect the user from harm. Lab coats worn by scientists and ballistic vests worn by law enforcement officials, which are worn on a regular basis, would fall into this category. Entire sets of PPE, worn together in a combined suit, are also in this category.

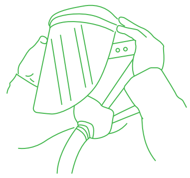
- gas mask
- particulate respirator
- PAPR
- SCBA

picture of worker exposed to burns and sparks while machining a component [F]

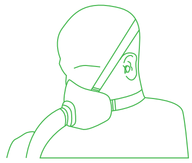
On workplace
welder case study



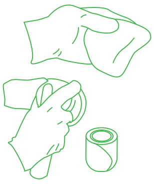
hearing protection



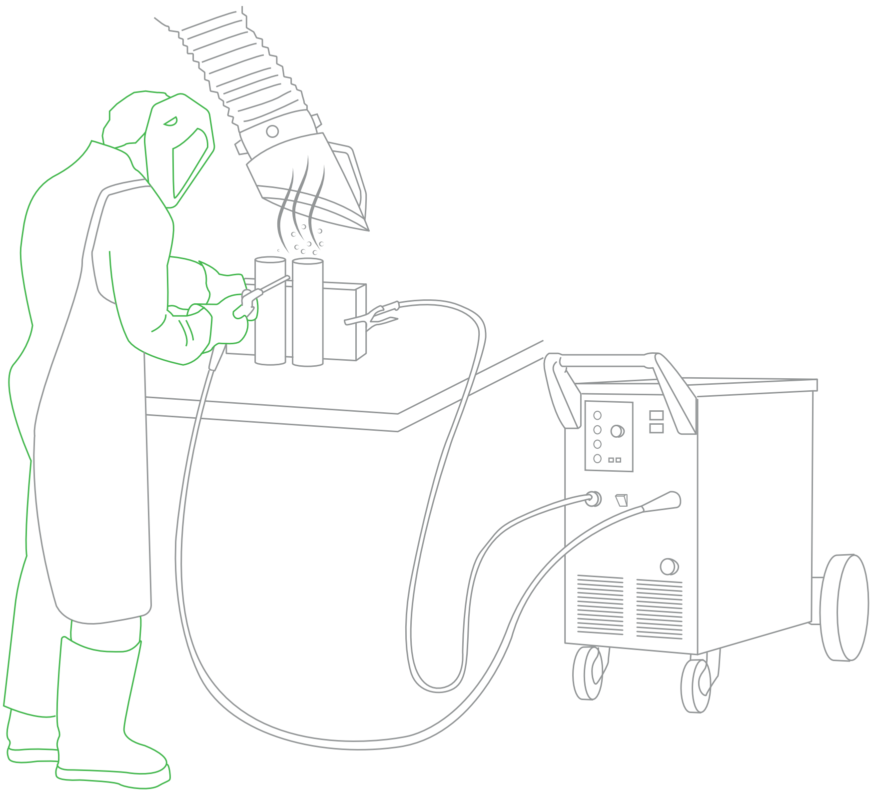
eyes/face protection



respirator fitting



gloves and protective gears



welder case study working ambient

1.3 Laws and regulations

hazard categorization and ways of protection on work

Personal protective equipment regulation at work seeks to ensure that where risks cannot be controlled by other means PPE should be correctly identified and put into use.
Depending on where the worker is employeed, the use of PPE on the workplace can be regulated by different laws, this can differ by nation and region.

In Europe, UK or US employees will not be charged with or contribute to the provision and maintenance of PPE. If there is a need for PPE items they must be provided free of charge by the employer.
Same definitions may not apply for all the categories of PPE (such as respirators) where special requirements are detailed in other regulations or may change from country to country.
Here presented an overview on main laws and regulations applied in different countries:

[G]


Certificate of Compliance
With EU Directive
Personal Protective Equipment(EU 2016/425)

Certificate No :TXB202004025Y08
Holder : Hunan Kangduoya Medical Equipment Co., Ltd.
Address :No.102, workshop no.5, zhigu phase I, no.188, east renmin road, quantang street, economic and technological development zone, changsha
Product :protective mask KN95
Model(s) :KN95
Standards :EN 149:2001+A1:2009 FFP2 NR D

As Shown in the
Test Report Number : TXB202004025Y08
Based upon the voluntary assessment of product sample and technical Construction File,the apparatus is deemed to meet the requirements of the above standards and EC directives.

Of the products are in compliance with the specification of the sample submitted for assessment and detailed in the technical file.

ex. of compliance certificate

(UK) HSWA 1974

As known as Safety and Work Act 1974.
It sets out the general duties which: employers have towards employees and members of the public/ employees have to themselves and to each other/ certain self-employed have towards themselves and others [I]

(UK) COSHH 2002

Control of Substances Hazardous to Health.
Is the law that requires employers to control substances that are hazardous to health and includes nanomaterials to prevent and reduce workers exposure to hazardous substances [I]

OSHA 1910.132 (US)

Occupational Safety and Health Standards.
Point 1910.132 regulates the use of PPE, setting guidelines to worker categories involved, kind of equipment required, general rules maintenance and pollutant/hazard considerations. Different and more in depth regulations are provided for each specific industrial sector [L]

OSH Law on Work Safety (CN)

The legislative structure of OSH in China is based on the Constitution, and consists of laws, administrative regulations, local regulations, departmental rules, local rules and OSH standards. The major OSH laws are Law on Work Safety, Prevention and Control of Occupational Diseases (1994) [M]

JISHA 2008 (JP)

Code of rules and practices addressed to monitor and prevent workers health during working activity. JISHA bureau stands and depicts different programs and regulations for different industrial sectors in Japan [N]

Code on Wages (IND)

in 2020 the Indian Parliament combined 25 labour laws into three codes: the Social Security Code, the Code on Industrial Relations and the Code on Occupational Safety, Health and Working Conditions [O]

Lorem ipsum

(EU) 2016/425 of 9th March 2016

Is the number of legislation regulating the use and production of Personal Protection Equipment in Europe.
The PPE regulation covers the design, manufacture and marketing of personal protective equipment. It defines legal obligations to ensure that PPE on the EU internal market provides the highest level of protection against risks. The CE marking affixed to PPE provides evidence of compliance of the product with the applicable EU legislation.

As legislation based on the 'new approach' alligned to the new legislative framework policy, manufacturers or their authorised representative in the EU must comply with the essential health and safety requirements of the PPE regulation, directly or by using harmonised European standards. The latter confer presumption of conformity to legal requirements. [P]

The PPE regulation guidelines (1st edition - April 2018) aim to facilitate a common understanding and implementation of the PPE regulation. In fact, the First Edition contains the new risk categories of PPE. [Q]

The risk categories from which personal protective equipment are intended to protect users, following the new guidelines, are three.

[H] category I DPI examples

[I] category II DPI examples

[L] category III DPI examples

category I

includes only the following minimum risks:

superficial mechanical injuries (a)
contact with mildly aggressive cleaning products or prolonged contact with water (b)
contact with hot surfaces that do not exceed 50 °C (c)
eye injuries due to exposure to sunlight (other than injuries due to observation of the sun) (d)
atmospheric conditions of a non-extreme nature (e)

category II

only the risks that can cause very serious consequences such as death or irreversible damage to health with regard to the following:

substances and mixtures dangerous to health (a)
oxygen-deficient atmospheres (b)
harmful biological agents (c)
ionizing radiation (d)
high-temp environments having effects comparable to those of an air temperature of at least 100 °C (e)
low temp environments having effects comparable to those of an air temperature of - 50 °C or lower (f)
falls from a height (g)
electric shock and live work (h)
i) drowning (i)
cuts from portable chain saws (j)
high pressure jets (k)
bullet or knife wounds (l)
harmful noise (m)

category III

includes risks other than those listed in categories I and III and usually refers to mixed or combined type of hazard.

1.4 Approvals and certifications
internal and external PPE production regulations

Chapter *III-IV-V* and *VI* of *reg. EU 2016/425* are those defining and regulating PPE conformity, certifications and procedures shared between European members; in this regard PPE risk category is crucial and strictly related to the PPE conformity assessment procedures (the *EU declaration of conformity* certifies compliance with the essential health and safety requirements).
In particular, the conformity assessment procedures to be followed, for each of the risk categories, can be found in the aforementioned chapters and described as follows:

A) category I: internal production control

B) category II: EU-type examination followed by conformity to type based on internal production control

C) category III: EU-type examination and one of the following:

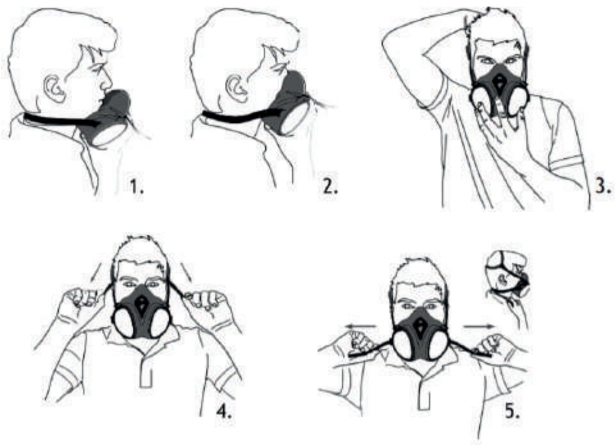
(i) conformity to type based on internal production control plus officially controlled product tests carried out at random intervals

(ii) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.

By way of derogation, for PPE produced as single units to be adapted to a single (specific) user and classified according to category III special procedures and certifications, defined in the EU conformity declaration may be followed (Chapter V-VI, letter B). [R]

[M] picture of mask collected after manufacture

technical documetation



I report here some indications on the technical documentation to be provided for personal protective equipment, as pointed out in final Chapters of the EU guidelines.

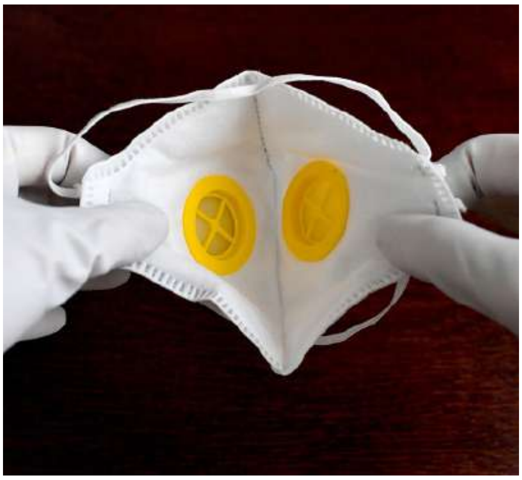
In fact, the technical documentation must specify the means used by the manufacturer to ensure compliance of the personal protective equipment with the applicable essential health and safety requirements referred to in Article 5 of the EU Regulation. [R]

I'll conclude by pointing out that the technical documentation must include at least the following elements:

- a) full description of the PPE and its intended use
- b) an assessment of the risks from which the PPE is intended to protect
- c) list of the essential health and safety requirements applicable to the PPE
- d) design and manufacturing drawings and schemes of the PPE and its components and circuits
- e) the descriptions and explanations necessary for understanding the drawings and schemes
- f) the results of the design calculations, inspections and examinations carried out to verify the compliance of the PPE with the applicable essential health and safety requirements
- g) reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and to establish the relevant class of protection
- h) a description of the means used by the manufacturer during the production of the PPE to ensure compliance of the manufactured PPE with the design specifications
- i) a copy of the manufacturer's instructions and information

1.5 Italian case
regulations and certificiations in our territory

As we highlighted till here the choice of the correct PPE should be driven through technical characteristics and conformity assessment.
In this regard PPE must possess a series of special requirements that allow the employer to make a correct choice.
In this chapter i'm going to deepen the certification procedures, the characteristics for suitability for use and the functional requirements of the products and materials produced and certified in Italy.
The issues of choice, adequacy, management and supervision of personal protective equipment are cross-cutting issues of great importance for the prevention of health and safety problems in the workplace.
On these topics various reports were held at the *73rd National Congress SIMLII* (Italian Society of Occupational Medicine and Industrial Hygiene) entitled *"Occupational Medicine as an improvement element for the protection and safety of the Worker and of the Company's activities"* (Rome, December 2010).
The reports were published in the first supplement of the *Italian Journal of Occupational Medicine and Ergonomics* and collected together in the section dedicated to *"Personal protective equipment: selection and management criteria"*.
In particular i'm going to focus on the report *"Technical characteristics and conformity assessment of PPE"* edited by (Galimberti, Cer.Co.sas) which emphasizes PPE to meet current legislation and, more importantly, for the purposes of their effective protective efficacy at the time of their use, *"they must possess a series of particular requirements such as to allow the final user (Employer) to make a correct choice".* [S]



[N] picture showing mask inner inspection

In fact, the Personal Protective Equipment, as defined in *Art. 74* of the *Legislative Decree 81/2008*, must "necessarily possess specific characteristics necessary to demonstrate their suitability for the use for which they will be intended". And suitability "must be determined through a complex and careful evaluation process of the devices identified during the risk assessment phase. This process has the purpose of highlighting the characteristics deemed necessary for the maximum achievable protection of the worker and comparing them with those that the market makes available ".

manufacturer and employer duties

It is then indicated that the suitability for the protection of the user from the risks for which the PPE was designed is closely linked to the technical characteristics that it must necessarily possess to be considered as such. Characteristics that *the manufacturer*, in the design phase, must identify and assign to the device on the basis of the rules established by *Legislative Decree 475/92* (transposition of the *European Directive 89/686 / EEC* known as the directive relating to 'CE marking').
And it is through these characteristics that the manufacturer is able to "demonstrate possession of the now famous 'essential health and safety requirements' referred to in the CE certification procedures".

However, if these essential requirements are the exclusive prerogative of the manufacturer, Art. 76 of Legislative Decree 81/2008 also attributes to the employer, "for the purposes of determining suitability, the task of verifying other aspects that are not always easy to satisfy". [T]

In particular, according to paragraph 2 of article 76, PPE must:

- be adequate for the risks to be prevented, without entailing a greater risk per se;

- be adapted to the conditions existing in the workplace;

- take into account the ergonomic or health needs of the worker;

- can be adapted to the user according to his needs.

While paragraph 3 is dedicated to the verification of the compatibility between the different PPE in the event that they must be used at the same time.

Ultimately, in addition to establishing that the characteristics and requirements of the PPE that are being evaluated fully meet the specific legislative requirements and that the requirements indicated in Art. 76 of Legislative Decree 81/2008, *"you will have to worry about verifying other requirements"* which the speaker summarizes in *functional requirements*, requirements of the *artifacts* and requirements of the *materials*.

functional requirements

The characteristics of the device must be such as to:

- be able to neutralize the specific risk, i.e. the PPE must be designed in such a way as to be able to cancel or at least reduce as much as possible the probability of injury for the protected part;

- not to limit the operational functions (it must be designed in such a way that, while maintaining the protective characteristics unaltered, the working capacities are limited as little as possible);

- be well tolerated and accepted by the worker and constructed in such a way that in no case can it be a source of discomfort;

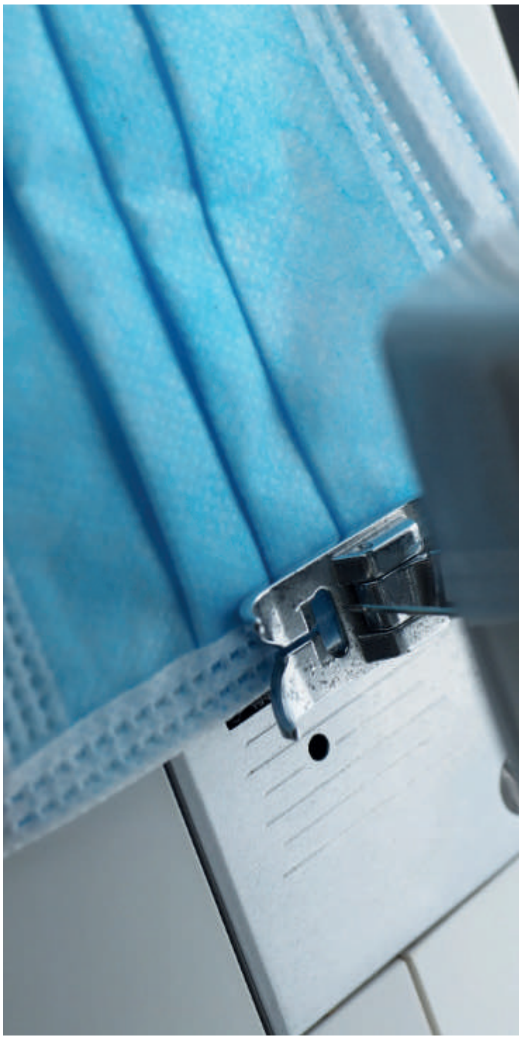
- be resistant and long-lasting;

- be economical (as far as possible)

[O]

picture showing how to wear mask on ears

[M]



picture showing mask sewing process

artifact requirements

In addition to the functional requirements, the PPE must meet the following requirements:

- specific suitability for the use for which they are intended by evaluating the effective protective capacity against the risks to be prevented (effectiveness criteria);

- adaptability to the person, good endurance and comfort, in order to allow its use without excessive discomfort in relation to the methods and time of use (ergonomic criteria);

- adequate solidity and resistance to specific agents, mechanical stresses, corrosive agents..

- simplicity of packaging and, more generally, ease of being able to carry out the required cleaning operations, maintenance and any disinfection or remediation (hygienic and functional criteria);

- absence of elements or parts that may constitute a danger to the operator;

- ease of use (eg ease of wearing and quickness in removing it in case of need);

- if necessary, appropriate colors for correct identification or to highlight, for example, the presence on the device of dangerous substances;

- aesthetically pleasing shape and appropriate colors also for reasons of good visibility (for example clothing for emergency team operators or for workers working at night) or to obtain the maximum contrast with respect to harmful substances from which one must protect oneself (criteria of best acceptability and functionality).

material requirements

The report emphasizes that the materials chosen for the construction of the PPE play a decisive role in the efficiency of the device itself.
And if the maintenance of the protection characteristics can be negatively influenced by the particular environmental conditions in which the device is called to operate, it is precisely in relation to the type of risk related to the environmental conditions in which it operates, that it is necessary to proceed with the choice of suitable material.
Without forgetting that the materials that come into direct contact with the epidermis must have compatibility with it and must be mechanically resistant to all maintenance and sterilization operations, if necessary. [T]

conclusions

The final part of the report - to which I direct anyone interested for a more exhaustive reading - reminds us that as an aid to manufacturers and to facilitate CE type certification procedures, the *D.E. 89/686 / EEC* (or *Decree 475/92*) provides for the possibility of having technical standards to identify and meet the essential health and safety requirements required by the same directive.
After an excursus on the genesis of European technical standards, also in relation to the definition and use of harmonized standards, the report ends with a description of the certification procedures according to the category to which the PPE belongs: first, second or third.


BLS

2.0 Face mask

protect your breathe

2.0 Face Mask
the ultimate DPI - definition and categories

As we have already seen many different types of mask can be found on the market, each developed for a specific use or task.
Requirements, apllications and behaviour can be really different from mask to mask, hardly influenced by the workplace where the worker operates and contaminants that must be faced.

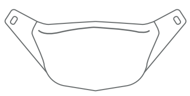
For the scope of my thesis i analyzed in depth 5 main categories of safety mask diffused and used as PPE in the B2B industry, with particular focus on the concept of *"full face negative-pressure mask"*, topic of my thesis.

In this chapter general introduction and discussion on industrial protective mask categories and equipment will be covered, looking at the following topics:

- fit test and how to choose a mask
- filter units and typologies
- mask categories
- working principle
- types and specifications
- use and maintenance
- working practice

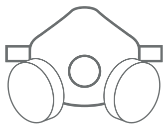
[A] picture showing welder worker during activity

categories



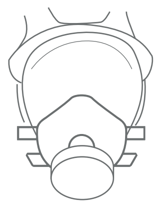
half-face fabric mask

usually simplier and cheaper masks, made to be disposed after use in some cases. These masks are entirely made of filtering material (all over surface)



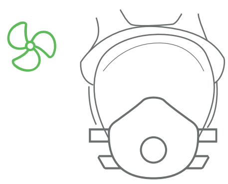
negative pressure mask

a rubbery mask body holds in place filtering units where air is forced to flow. Filters can be substituted over time and the mask can be restored by washing after use



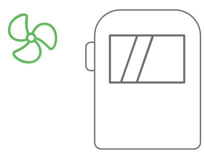
full-face mask

similar to the half-face mask this category shares its freedom to change filters. The main advantage is in the combined safety offered by the integration of the visor



PAPR mask

(Powered Air Purified System) is a system where positive pressure is maintened in the mask to help ventilation and breathing during use



PAPR hood

the same system can be used for protection hoods. In this case pressure are less consistent and no tight seal is achieved for the DPI

2.1 Fit Test procedure
qualitative test

Fit Test is globally recognised as the selection procedure for professional and operative respiratory masks. The test has to be performed by every employee/operator wich falls into the obligation of wearing a respiratory face-mask when working. The test is borned by the employer and aims to spot the right category and size of PPE for each individual, as a result every operator is paired with a given (and correct) PPE that is going to be provided every day for the whole duration of the job.
Fit testing the PPE is a mandatory procedure in Italy for all those practices they foresee to require respiratory masks.
For half-face mask a qualitative test is sufficient to individuate the right candidate. In case of full-face masks and PAPRs a quantitative test is performed. [A]

[B] nebulizier filled with tetsing solution

why a qualitative test

Over the years an increasing attention to health in the workplaces has developed. The wrong use and the lacking selection of respiratory protection products are still widespread problems. The qualitative fit test is a simple and effective method to evaluate if a protection product fits the user's face and if its use is correct.

wich device have to be tested

The qualitative fit test is suitable for the evaluation of disposable cup shaped filtering face-pieces that belong to FFP1, FFP2 and FFP3 classes and of negative pressure half masks.
This test is not suitable for the evaluation of full-face masks or positive pressure products.

regulatory framework

Qualitative fit test have to be executed following the references of Health and Safe Executive (HSE) and Occupational Safety & Health Administration (OSHA) who released specific procedures for the execution of the Test (respectively norm HSE OC 282/28 and norm 1910.134 App A).

kit's content

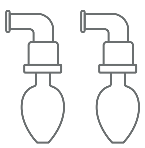
Qualitative fit test have to be executed following the references of Health and Safe Executive (HSE) and Occupational Safety & Health Administration (OSHA) who released specific procedures for the execution of the Test (respectively norm HSE OC 282/28 and norm 1910.134 App A).

general description

The test includes two phases:

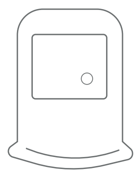
PHASE 1: taste threshold screening

PHASE 2: fit test


2 Nebulizers

1 Sensivity Solution
(for taste threshold screening)

1 Fit Test solution
(for qualitative fit test)


Hood with visor

The solutions of the kit produces sodium saccharin USP aerosol, completely harmless for the user's health.
There are two different types:

• Solution A_ low-concentration solution:
To use during test in order to verify that the user is able to perceive the substance.

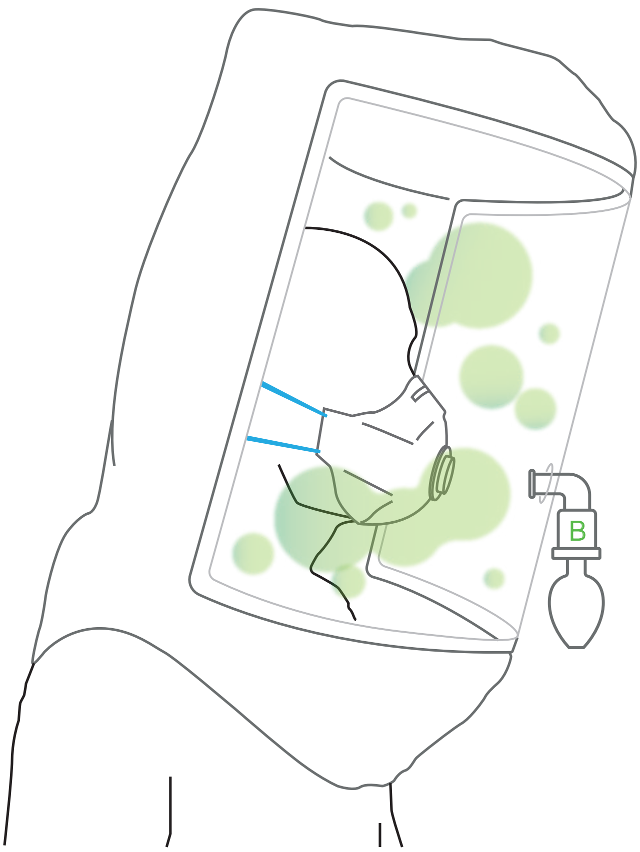
• Solution B_ high-concentration solution:
To use during the fit test in order to verify that the protection device works correctly.

Phase 1
threshold screening

The aim of the taste threshold screening is to determine if the person exposed to the fit test is able to detect the taste of saccharin. In the case in which the tester is not able to perceive the substance, the obtained results cannot be considered reliable.

1. The user wears the hood with visor. Thanks to the hood, which delimits a specific volume of air around the user's head, the air aerosol concentration can be controlled.
2. The laboratory technician inserts the nebulizer in the appropriate hole on the visor and he begins to vaporize the A-type aerosol inside the hood realizing 10 nozzles.
3. The user has to breathe through his slightly open mouth with extended tongue and has to communicate to the technician whether he perceives the taste of saccharin or not. If the user perceives the taste of saccharin within 10 nozzles, the taste threshold screening can be considered concluded and 10 will be the Threshold limit value of the user.
4. In the case in which the user hadn't perceived it, the technician will have to do other 10 nozzles. If the user perceives the sweet taste of saccharin between 21 and 30 nozzles the taste threshold screening can be considered concluded and 30 will be the specific threshold limit value of that user.
5. The user wears the hood with visor. Thanks to the hood, which delimits a specific volume of air around the user's head, the air aerosol concentration can be controlled.
6. If the user does not perceive the nebulised substance after 30 nozzles he will be considered a non-suitable subject for this type of test.

Phase 2
fit test



The fit test has to be carried out only if the user wears the protection device correctly (following the manufacturer instructions). During the test, the user will be asked to carry out some exercises that simulate common movements during the use of the respiratory protection device.

1. The user puts on his head the hood with visor after wearing the protection device which is to be tested.
2. The technician who carries out the test inserts the nebulizer in the appropriate hole on the visor and he begins to vaporize the B-type aerosol inside the hood, making the same number of nozzles as the threshold limit value obtained with the taste threshold screening . After the first series of nozzles, every 30 seconds, he will carry out half nozzles than the threshold limit value established.
3. The user begins with the execution of the seven expected exercises, of the duration of 1 minute each:
    1. Breathe normally
    2. Breathe deeply
    3. Turn the head on the right and on the left
    4. Flex the head up and down
    5. Speak aloud
    6. Flex the chest ahead
    7. Breathe normally

5\. If the user doesn't perceive the nebulized substance, the test can be considered concluded with a positive outcome. This means that the device guarantees the correct respiratory protection.

4\. If during any of these exercises the user perceives the B solution in spite of the protection device the test has to be considered concluded with a negative outcome. This means that the device hasn't been worn correctly or it doesn't fit the dimensions or the shape of the user's face.

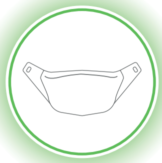
2.3 Fit Test procedure
quantitative test

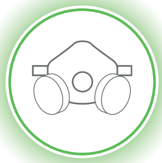
As previously stated Fit Test is globally recognised as the selection procedure for professional and operative respiratory masks.
Fit testing the PPE is a mandatory procedure in Italy for all those practices they foresee to require respiratory masks.
A quantitative test is the best way to ensure the protective respiratory mask is fitting the user. Quantitative Fit Test are carried out by operators with professional equipment and aim to "quantificate" the grade of fitting by determining a Fit Factor.
The quantitative Fit Test can be applied to all categories of respiratory face-pieces, each requiring a different grade of Fit Factor.
Once the correct PPE is established for each worker, it is going to be provided during the task execution. [A]

[C] fit-test operation during performance

why a quantitative test

Over the years an increasing attention to health in the workplaces has developed. The wrong use and the lacking selection of respiratory protection products are still widespread problems. The quantitative fit test is used to evaluate if a protection product fits the user's face and if its use is correct.





wich device have to be tested

The quantitative fit test is suitable for the evaluation of disposable cup shaped filtering face pieces that belong to FFP1, FFP2 and FFP3 classes, of half masks and full face masks even related to positive pressure devices.

regulatory framework

Quantitative fit test has been made following the references of Health and Safe Executive (HSE) and Occupational Safety & Health Administration (OSHA) who have released specific procedures for the execution of the Test (respectively norm HSE OC 282/28 and norm 1910.134 App A).

general description

The test is carried out with PortaCount Pro+ 8038 of TSI, an equipment that works using the microscopic solid particles, normally scattered in the environment. The equipment measures the particulate concentration in the test-environment and it compares it with the concentration contained inside the device worn by the use.

kit's content

- 1 Adaptor* (specific for the half masks and full face masks different types of connection)
- 2 Dust filters (P3)

Phase 2
environmental analysis

Every time the device is turned on for a new testing session, it carries out an environmental analysis in order to verify that the quantity of the solid particles that are in the environment is sufficient. The environmental concentration is measured to have a reference sample in order to compare the values that will be measured inside the protection device during the fit test. In fact, the equipment is provided with two analysis inlets: the first one that draws directly from the environment and the second one that analyses the air inside the protection device worn by the user. The connector in the kit is necessary exactly to insert the flexible tube in the mask, avoiding that losses around the insertion point (see image).

Depending on the type of product that has been worn, the minimum fit value has to be the following:

TYPE of PRODUCT	MINIMUM FACTOR
FFP1	100
FFP2	100
FFP3	100
Half mask	100
Full face mask	2000

[E]

1. The fit test has to be carried out only if the user wears the protection device correctly (following the manufacturer instructions). During the test the user will be asked to carry out some exercises that simulate common movements during the use of the respiratory protection device.

2. The expected exercises are seven, of the duration of 1 minute each:

    1. Breathe normally
    2. Breathe deeply
    3. Turn the head on the right and on the left
    4. Flex the head up and down
    5. Speak aloud
    6. Flex the chest ahead
    7. Breathe normally

3. For each of the seven exercises the equipment shows a fit value (calculated comparing the environmental concentration and the concentration inside the mask) which describes how much a device fits together with the user's face, isolating him from the external environment. If it turns out that the given value is lower than the limit specified by the regulatory references, the test has to be considered concluded with a negative outcome. This means that the device has not been worn correctly or it does not fit the user's face.

2.3 Filter units
at the core of personal protection

As we already mentioned, the development of masks and technologies for the protection of operators in the workplace, draws its origins from the innovation pushed during the world wars.
It is precisely during these years that man finds himself facing dangers related to the respiratory tract for the first time, in particular for the use of chemical weapons and consequent exposure to harmful gases and dust.

One of the first inventions in this regard was the "Safety and smoke protection hood" invented by Garrett Morgan in 1912 and patented in 1914. It was a very simple device to be worn. Consisting of a cotton hood with two tubes hanging

How to determine wich protection grade?

each substance has its own *TLV threshold limit value* (limit value) which indicates the concentration below which it is believed that workers can be repeatedly exposed, day after day, to a substance without suffering negative effects. [B]

anti-dust prefilter
weight 20g

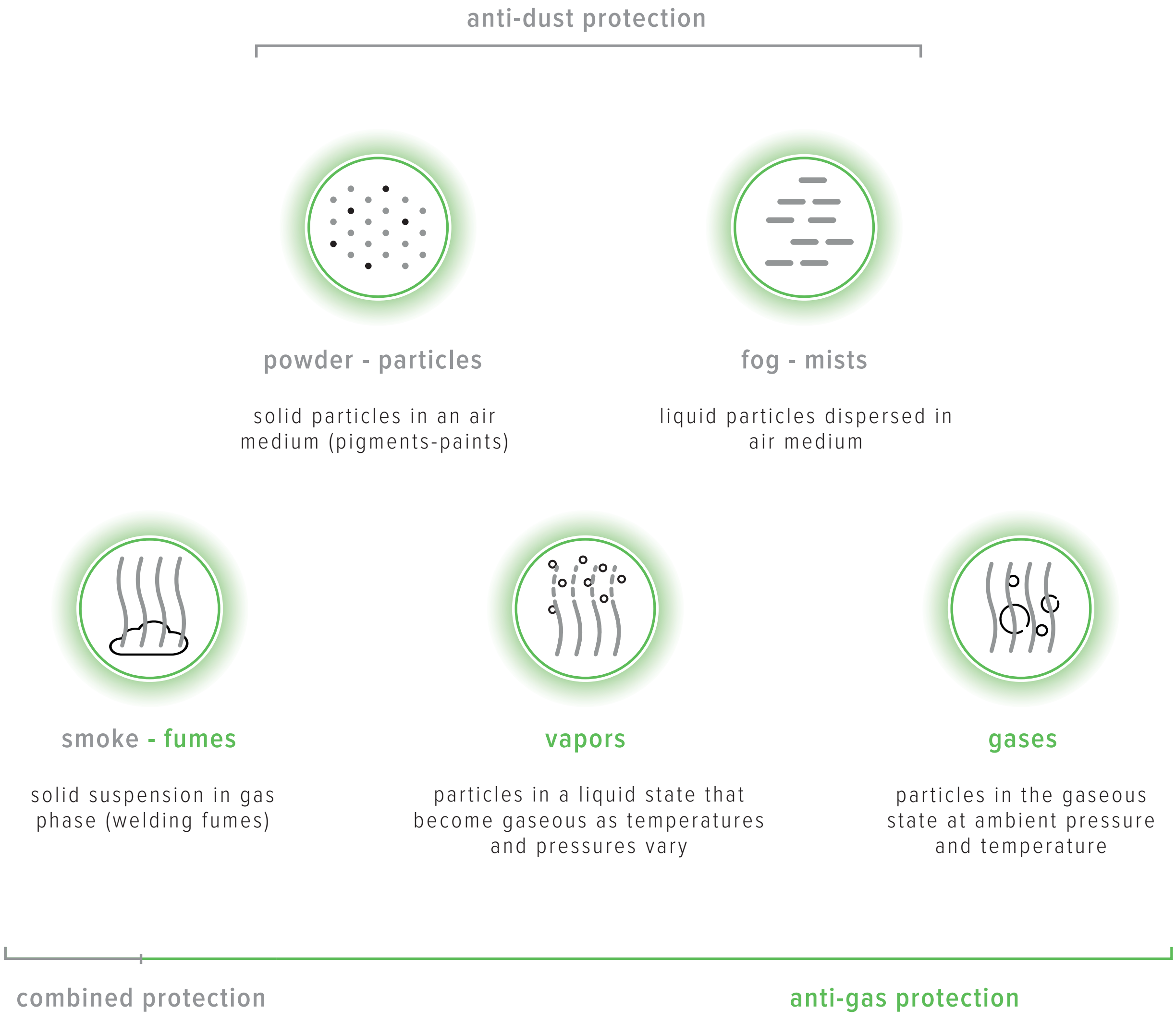
anti-dust filter
weight 100g

anti-gas filter
weight 150g

combined filter
weight 200g

[F]

contaminants categories



How to determine wich protection grade?

As we have seen, contaminants in workplace can be different and cause various hazards. [B]

Each substance has its own *TLV threshold limit value* (admitted range) which indicates the concentration below which it is believed that workers can be repeatedly exposed, day after day, to a substance without suffering negative effects. The TLV specific to each substance is published annually by the American Association of Industrial Hygienists (*ACGIH*).
Concentration (or diffusion) of the contaminant is crucial to determine how dangerous it can be for the worker to operate in its own workplace; the necessary data is the *weighted average concentration of the pollutant present in the environment*.
To know the exact data it is necessary to carry out environmental measurements (specific certification agencies are in charge of this task). The concentration of the dangerous substance is expressed in mg/m^3 or ppm.
The *protection factor* can be expressed as follows:

$$\frac{\text{concentration of the pollutant}}{\text{TLV (substance specific threshold value)}} = \text{protection factor required}$$

[F]

anti-dust prefilter

anti-dust filter

anti-gas filter

combined filter

protection factor

4	12	50	4	12	48	50	4	12	48	5	16	1000	2000	5	16	1000
FFP1	FFP2	FFP3	half P1	half P2	half P3	half gas	half gas-P1	half gas-P2	half gas-P3	full P1	full P2	full P3	full gas	full gas-P1	full gas-P2	full gas-P3

protection factor should be equal or minor to:

types of filter

◉	A	organic gases and vapors with boiling points > 65 ° C
◉	AX	organic gases and vapors with boiling points ≤ 65 ° C
◉	B	inorganic gases and vapors (CO excluded)
◉	E	acid gases and vapors (ex. sulfur dioxide, hydrochloric acid)
◉	K	ammonia and organic derivatives
◉	P3	powders, dusts, mists and fumes
◉	SX	specific cdustom-declared filters (by manufacturer)
◉	NO-P3	nitrogen fumes
◉	Hg-P3	fumes of mercury

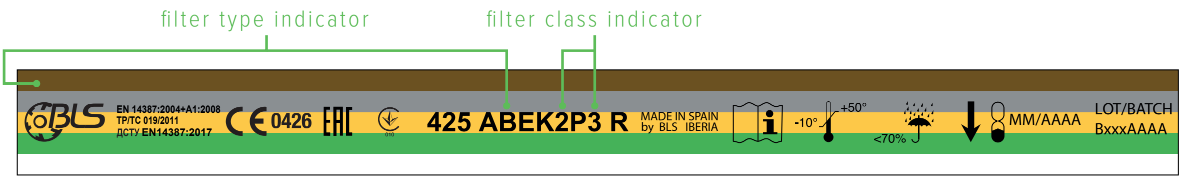
filter class

anti-dust filters efficiency:

CL P1	>80%	low
CL P2	>94%	medium
CL P3	>99.95%	high

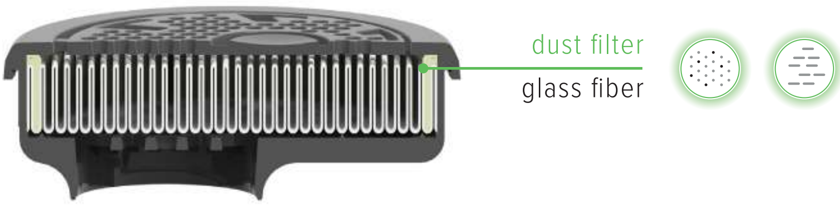
anti-gas filter duration:

1 CL	≤1000 ppm	low
2 CL	≤5000 ppm	medium
3 CL	≤10.000 ppm	high

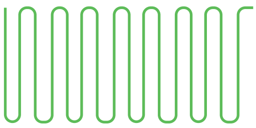


ex. label shown on filters

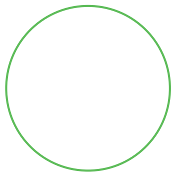
Filter units



- glass fibers filtering capacity increases with use (clogging improves mechanical filtration)
- pleated fiberglass filters contain a larger surface area of filter material and therefore have a longer life

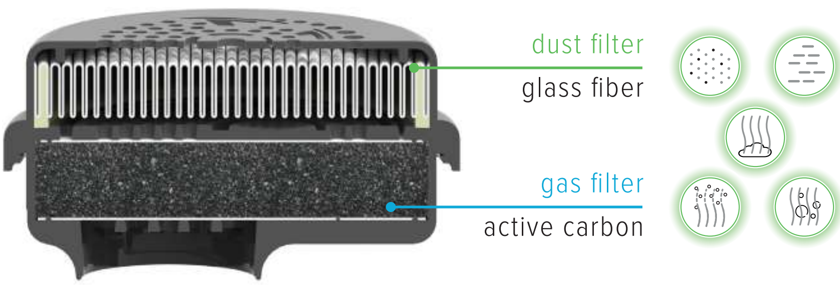


pleated glass-fiber section development



filtering surface of a pleated glass-fiber filter

filtering surface of a non-woven filter (same dia.)




filter outlet cover
pleated glass-fiber
coupling method can be:
RD 40 thread (standard)
bayonet mount (proprietor)
vortex or others (proprietor)
filter mid-cover
strapping clips
active carbon
non-woven fabric

2.4 Face filtering piece (textile)
particle protection

The following category has spread all over the world and gained definetly much popularity in last years of Pandemic due to Covid-19, mainly because it well suited the function of offering protection from the virus (having sizes comparable to many common contaminants) while beeing employed in idustrial fields for particulate and particles protection (P1/P2/P3).
In this chapter i'm going to analyze and deepen differences and functions of several face-masks models on market. [C]

[G] user wearing particle filtrating face-piece

main functions

The working principle of a textile face-pieces is very simple: the surface is entirely made of filtering material (usually non-woven fabric or cotton) and, when positioned as coverage for respiratory tracts, it performs active filtration by shielding the air we breathe and blocking particles at the surface by absorbing and retaining the contaminants.
Elastic band are suited to keep the mask in place and to ensure a correct adhesion to visage and the ability of the mask to deform (so as for the metal bridge) enables user to last adjustments.

materials

ELASTICS	Welded thermoplastic elastomer (TPE)
NOSE CLIP	Reinforced Polypropylene (PP) with heat treated metal
VALVE	Polypropylene (PP); rubber
GASKET	Foamed polymer coupled with polyester textile (PES)
FILTERING MATERIAL	Polypropylene (PP - non-woven fabric)
PROTECTIVE LAYER	Polyethylene (PE)
CARBON LAYER	Polyester (PES)

[H] face filtering pieces mask features

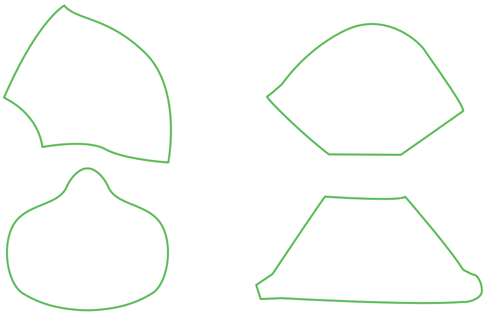
disposable or reusable

Many PPE face-pieces or face-masks are usually suited for a single task/activity/operating time and are meant to be disposed after use. This function is strictly related by work-place requirements and by the presence of very specific contaminants; this reason often influences a choice of simplier manufacturing processes or cheaper materials in case of disposable goods. The state of the mask has to be coded on the facepieces and can be checked by the perator (R/NR reusable or not)

[I] mask codes marking

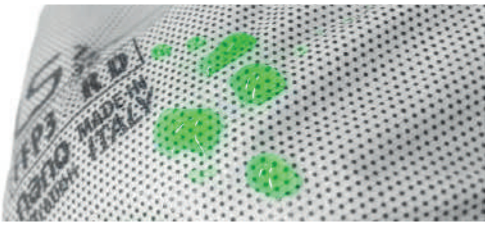
shape

Users faces and shapes can be very different and the PPE always has to ensure the maximum grade of safety possible, for this reason mask facepieces are provided in different sizes by manufacturers and have to be fit-tested by the user before wearing the PPE on work-place.
During years, to meet comfort requirements and anatomical differences new shapes of mask were created, strating by flkat development such as foldable, flat, KN95 and others pre-formed such as cup-shaped. This offers a lot of freedom to choose the best PPE for the user



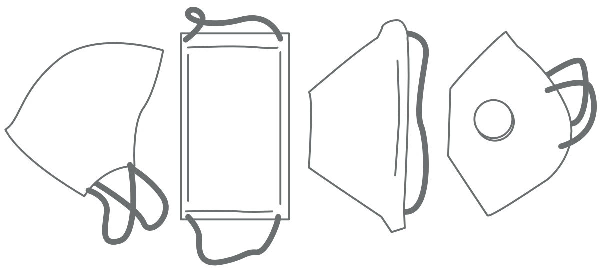
other functions

Sometimes an exhale (non-return) valve is employed to minimize breathing resistance of the user and CO2 buildup inside the facepiece. Additional layers such as active carbon (for odour removal and partial gas shielding) or external protective layers (anti-drop or anti-scartch) cabn be added to empower the filtering action or for specific applications



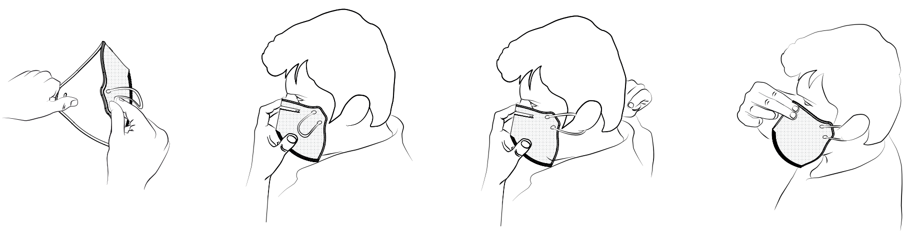
[L] anti-drop effect on net

elastic band



As already mentioned key function of elastic band is to retain the mask pushed and tensioned on user face, avoiding the creation of gap and holes all around. For their function bands are often seen as painful or annoying, especially for users with long hairs, beard or accessories. Facepieces are provided with 2 alternatives: auricular or nuchals. Nuchal bands are generally known to be much tensiuoned and safe during use and for this reason preferred in industrial fields. [C]

nuchal bands wearing procedure



auricular bands wearing procedure

2.5 Half-face negative pressure Mask
the ultimate DPI - definition and categories

Half face dust masks and respirators are manufactured with different styles of head harnesses whatever your preference, and have been designed to be worn with other head PPE with providing a great and flexible field of vision.
Key function of the half-face mask is to protect respiratory tracts by providing a tightproof seal around users face. Thanks to an isolating (non-permeable) material forcing air to enter from specified gates where filters are located.
The air flow exchange from inner mask chamber and external enviroment is regulated by a series of one-way valves, located at each filter access and used as exhale valve in the opposite direction to prevent CO_2 build-up; for this reason negative pressure is generated in inner mask volume during inhalation/exhalation.
Filter units can be integrated or externally added in a half face-mask, thus depending on the working activity, purpose or personal comfort. [D]

The importance of wearing the PPE correctly is even more crucial in case of a half-face mask, since it can deeply influence safety and health of the worker, especially over time. For this reason half-face mask design progressed a lot during years and has gone through many innovations. Basic functions were implemented in current masks to improve user comfort and safety can be here summarized:

retention straps: an elastic adjustable band allows the user to regulate tension through zips and ensures a tight and comfortable fit by compressing the elasto-deformable body

[M] half-face mask with integrated filter units

flexible body: generally made of TPE or Silicone (depending on the use/user needs) has the active fuction of deforming by adapting to users visage. The dome presents an inner lip and has the very important function of compensating gaps among faces and ensuring thight seal among the surrounding perimeter. The dome is deformed by the compression induced by straps

head crown: is used to compensate and equally distribute the front weight, mainly caused by filter units. The weight stregth is distributed on the arc-crown, suited at the same time to retain and regulate straps tension thanks to a clamping mechanism

stripping clips: quick-release clips allow an easy wearing procedure and the so called ”drop-off”, enabling the user to take breathe by keeping the mask unit safe around the neck


head crown
elastic straps
filter unit
exhale valve
elastic body
inhale valve
frame - filter mount
stripping clip
[N]

Components
part and function scheme

mask body

an elasto-flexible component. The main body is used to create a sealing chamber around users respiratory tracts. The body is deformed thanks to the tension provided by the laces and can be used as housing for attaching other components to the mask (mounting frame/front shield)

filter unit

filtering units are retaining contaminants by filtering the entering air when user inhales. Filters are attached to inlet valve and contain filtering materials such as glass fiber or active carbon

front shield

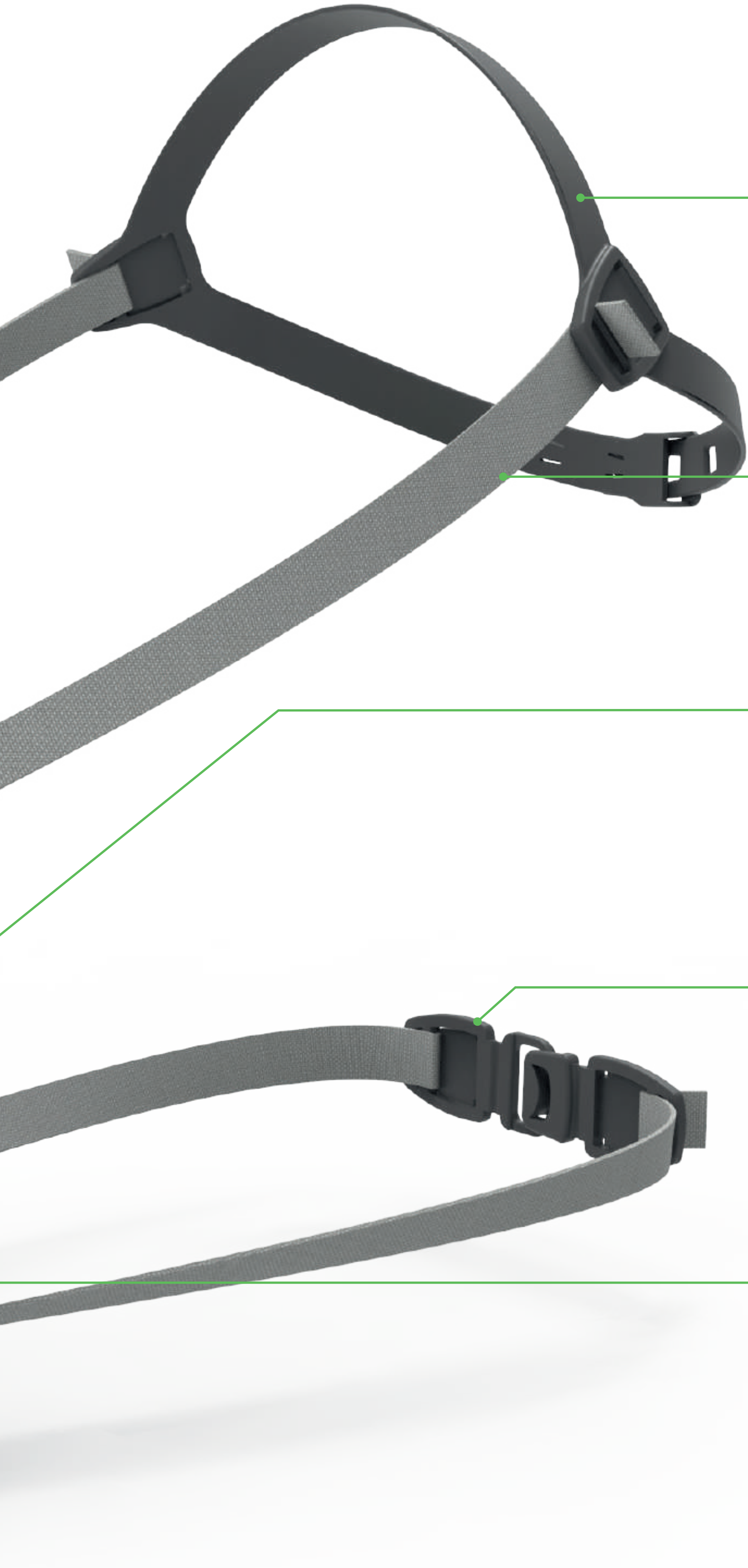
is a rigid plastic part attached to to the mounting frame. It acts as coverage for the exhale valve and as tensioner for the passersby tensioning laces

exhale valve

a one-way valve actived during the exhale operation by the user. This valve enables air to flow out and prevents CO_2 buildup in mask body

inhale valve

a one-way valve actived by the user when breathing and inhaling. This valve forces the air to flow through filter units and filtering material



crown tensioner

a semi rigid plastic crown is used to retain tensioning laces over users head. The crown is very important since it helps to distribute and balance weight and tension over the mask. Usually 2 to 3 anchor points crown are used to keep the half-mask stable in place during use. Crown size can be adjusted to meet users anatomy.

tensioning harness

an elastic lace is used as bridge from mask body to crown; this allows the user to adjust masks tension/compression against face and to adapt the facepiece to different sizes. Tension is regulated thanks to a through buckle

mounting frame

a rigid frame is used as housing for inlet/outlet valves and for attaching filters and front shield as well. The mounting frame acts as support for assembling components around the main body and is positioned inside mask-body. Mounting frame might differ or be missing depending on the mask design and manufacturing brand

strapping clips

clips are made to wear and remove half-face masks in ease from users neck during long-term usage. This allows also “drop-off” operation, where the user can take a quick breathe without the need of removing the entire equipment. Strapping clips act as a snap-clip and a through buckle at same time, permitting easy lock and regulation by the user

filter (bayonet) mount

parts are attached togheter thanks to different mounting mechanisms; this coupling mechanisms can be propertary or shared between different brands/models (as for the bayonet here shown). A coupling mechanism also provides tight sealing between mask, filters and workspace

3.2 Use and maintenance
part and function scheme

As we highlighted till here the choice of the correct PPE should be driven through technical characteristics and conformity assessment, as well as an analysis of working enviroment and ambiental conditions.
In this regard PPE must possess a series of special requirements that allow the user/operator to make a correct choice when selecting the equipment.
In this chapter i'm going to deepen the selection procedures and criterias behind the use of a safety mask at work, the characteristics for suitability during use and the functional requirements of the products as the materials employed to manufacture half-face negative pressure mask. In the following pages side-aspects about use/maintenantece of the specific mask typology will be covered and deepened. [D]

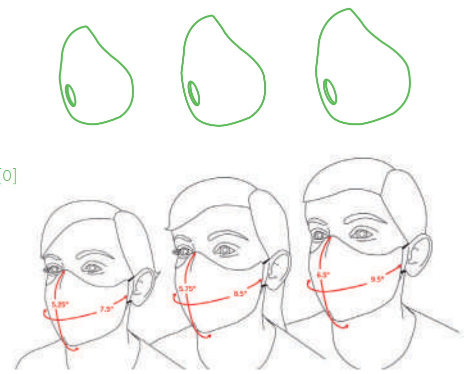
reusability - maintenance

Negative pressure half-face masks are usually considered reusable goods and can therefore be restored after a working-cycle.
Filter units are considered consumable goods in teh system and are disposed when saturation is reached and substituted with new ones, the rest of the system can be disassembled to be deeply washed and cleaned in order to be re-used.
As we can see from the picture (right page) the product can be subdivided in different groups (sub-assemblies) for easy access and maintenance of main components.
Materials and surfaces are treated in a way dust and dirt are less inclined to accumulate and can be easily removed by washing with water or solvents. [E]

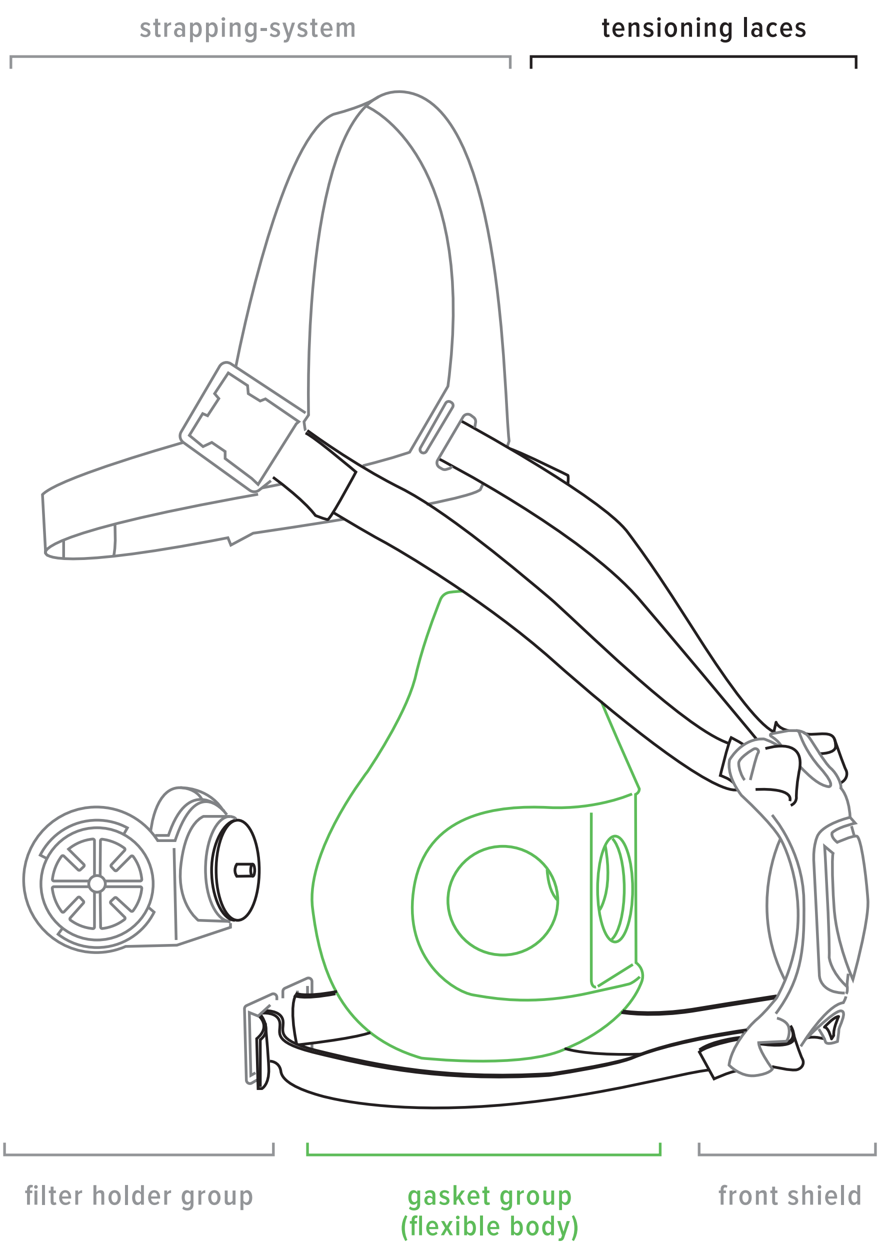
size

Users faces and shapes can be very different and the PPE always has to ensure the maximum grade of safety possible, for this reason mask facepieces are provided in different sizes by manufacturers and have to be fit-tested by the user before wearing the PPE on work-place.
During years, to meet comfort requirements and anatomical differences new shapes were created, usually provided into 3 macro-ranges to fullfill market and user needs (S-L-M). These difference can be mainly applied to elastic body (key component, responsible of deformation and face fitting) while leaving the rest of the system
Each mask manufacturer provides it's own shape and dimension shader to meet user needs and to ensure facial fitting. In general, key dimensions driving different sizes can be related to Bizygomatic Breadth (face width) and Menton-Nasion Length (face legth).
In the case of BLS oronasal bodies are provided in two difference sizes (S and M-L).

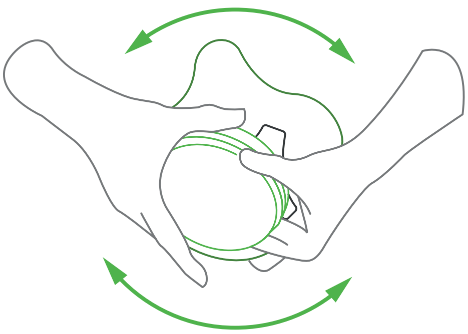
[O]



S L M

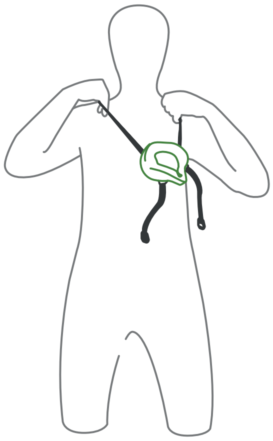

strapping-system
tensioning laces
filter holder group
gasket group
(flexible body)
front shield

wearing and use procedure



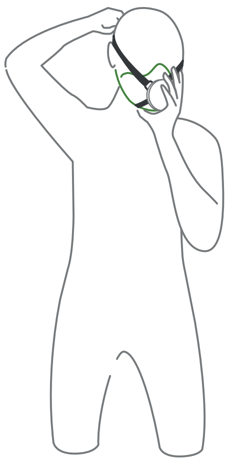
1 connect filter unit

standard connections allow
half and full-face masks to be
adapted at different filter units



2 wear harness on neck

first step to wear a mask is
to ensure retaining clips
behind the neck (shoulders)



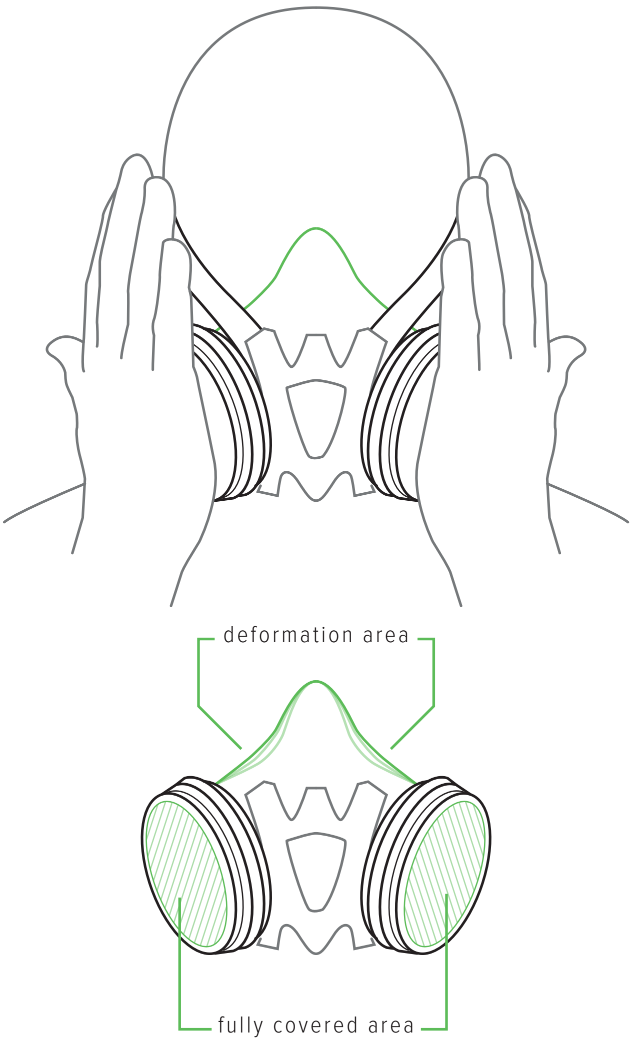
3 wear harness on crown

after the harness is in place,
at the neck, the operator
can stretch the crwon

4 fit-check

after setting the mask on visage
a fit-check is performed by the
operator to verify correct wearing

fit check procedure



④ what is a fit check?

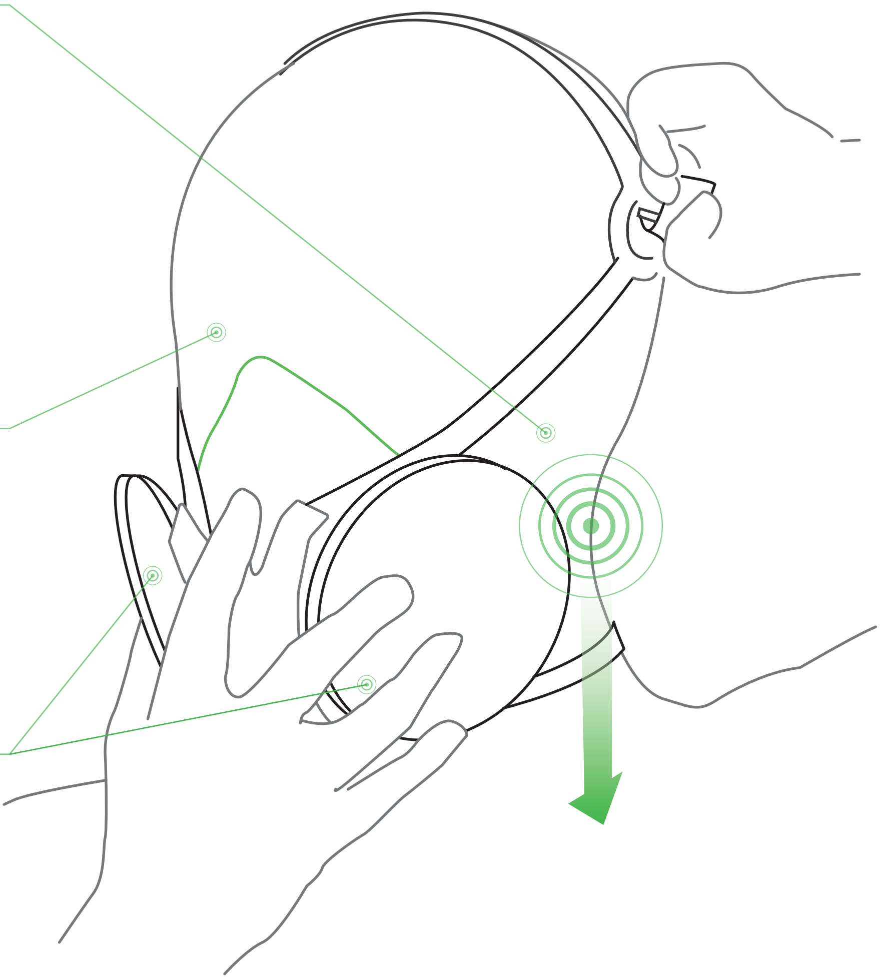
A Fit Check is a procedure deployed to verify the quality of seal between a person's face and a respirator or mask. It is required for many jobs in a wide variety of industries, as previously mentioned. It is mandatory to perform a Fit test before choosing the PPE and a Fit Check is reccomended every time of use.
The Fit Check is performed after the equipment is worn and setted by operator and and can be subdivided in 5 easy steps:

1. Wear the mask correctly
2. Adjust mask on face and tension harness
3. Entirely cover filter surface with the hand
4. Breathe deeply
5. Observe mask/feel behaviour

✓ If the mask compresses and pushes against the face it means the seal is tight and the mask is worn correctly. The air holded when breathing is responsible of deforming the elastic body by creating negative pressure in the inner dome. Deformation of the mask is an indicator of negative pressure achievement (good seal)

✗ If the mask is leaking no negative pressure is obtained in the inner chamber and, when breathing, the air is forced to flow through the gaps/holes created around the gasket.
A non-uniform seal (bad seal) can compromise worker safety and has to be tested again after re-adjusting the PPE on the user.

wearing and use procedure



center of gravity

balancing weight in a correct and uniform way is very important when dealing with humans face and head.
The total weight of worn garments should never exceed 1kg for operators facepieces; and the weight should be also managed symmetrically. A good harness and tensioning system can help in the task of distributing weight

field of view

a crucial aspect while wearing half-face negative pressure mask with mounted filters is the limited field of view.
Blind spots are common when operating with big filter units and can hardly influence operators activity

filter units

Filters can vary a lot depending on the practice.
Filters can be provided in different sizes and weights, single or coupled. This affects a lot the field of view and the weight distribution.
Paired filters are usually better to balance weight.

filtration

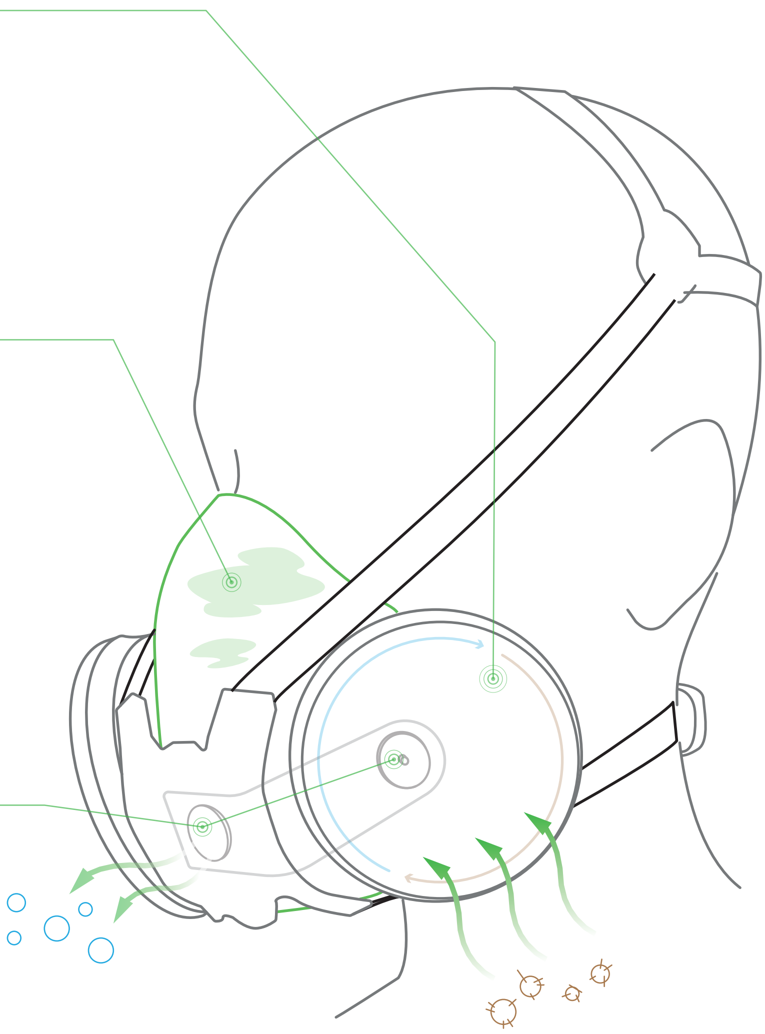
filter is absorbing and retaining the contaminants when the air is forced through the interchange surface, providing “clean” air to the worker

CO2 buildup

key factor when wearing a mask during work operations is the buildup of inner CO_2. CO_2 is produced every time we exhale and tends to accumulate for the poor air recirculation. Saturation of CO_2 can be harmful for respiration (especially over time). An efficient exhale valve can solve or mitigate the problem

one-way valves

one-way membrane valve regulateS the flow during inhalation/exhalation. Air is forced to enter from filters and can only escape from front shield thanks to valves orientation and air circuiting

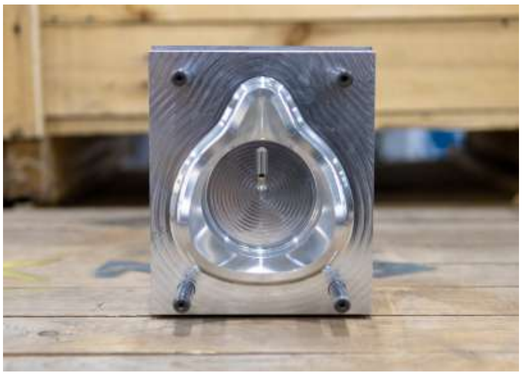


2.6 Manufacturing
focus on half-face rubber mask manufacturing method

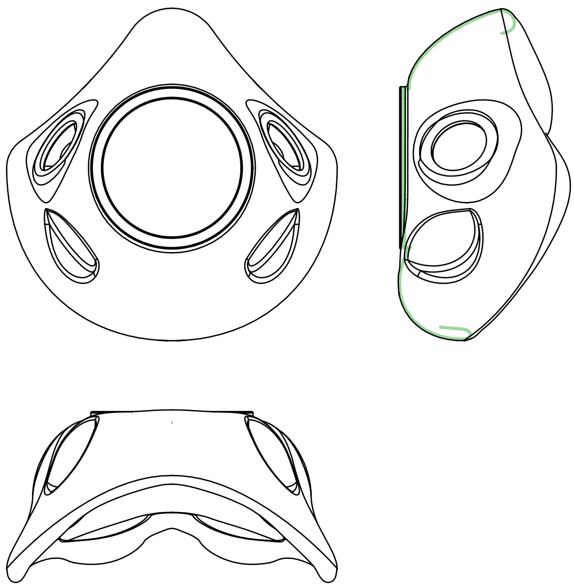
Respiratory protection negative pressure face-masks are very diffused in the B2B market and notorious for the iconic shape. Manufacturer do their best to differentiate themselves from competitors and to impose a winning design on market; even if most of these mask might look different they always share some common features such as:

- filtering materials
- manufacturing materials
- rigid frame, flexible body and tensioning laces
- disassemblable and reusable

One of the most interesting and complex component under the design perspective is the flexible/elastic mask body obtained from rubbery/soft materials. As seen in previous chapters, the elastic dome is at the core of mask working-principle, responsible of the tight sealing of the mask against face. This unit represents an unique component in the assembly of the mask and is directly linked to the ability of fitting the user, while providing safety and comfort at the same time. For this reason the elastic body element is at the center of the engineering process and is the one unit requiring a very high design effort and need-for-investments to be manufactured.
The flexible mask body is at the center of the useful design investigation of the project and will be at the center of the design and development phase. For this reason i decided to deepen productive and manufacturing aspects related to the realization of the mask.
The mask unit is at the center of any protective mask model general behaviour and might slightly change from manufacturer to manufacturer. In every design complexity of the mask (and so of the mold) has to be carefully managed in order to assure a repeatable and stable manufacturing processfor the component. [F]



[P] example of a mask mold for injection



geometry example of an injection molded mask


1 mold elements opening


1 mold closing


2 cavity injection


3 body ejection


4 finished part removal

mask body injection molding

As mentioned, the productive method applied to rubber face-masks is common to most face-piece manufacturers, with slight differencies between models.
The selected manufacturing process consists in Injection Molding, a very particular kind of injection that needs to meet specific rules and relies on the flexible properties of the employed materials.
In the following page the basic steps to be accomplished in order to manufacture a mask body will be explained:

1 The mold is composed by 3 main elements: two closing female valves and a punching male, able to lift. When molds come together parts are joined and a defined empty mold cavity is created inside the mold.

2 Liquid material is injected in the cavity through an injection channel. The material is forced to flow under pressure in order to reach tiny spots and small features of the cavity.

3 The mold is mantained closed, under pressure, in vaacum condition untill the material completely hardens and is then opened again. The punching dome is able to lift and to free the body from the cavity.

4 The body remains attached to the punching element thanks to surface adhesion and mold undercuts and needs to be removed by hand by an operator. The undercut is overcome and released by taking advantage of material properties.

To overcome the very pronounced undercut of such molds material properties play a crucial role: a highly elastic and tear resistant material is therefore a requirement of the process. For this reason categories such as silicon rubbers and thermoplastic elastomers (TPE) are usually employed for face-piece manufacturing. Elastic materials are also responsible of the deformation behaviour of the dome: hardness ranges around 50-60 shoreA used to be employed

2.7 Respiratory Full-face Mask

the ultimate DPI - definition and categories

Full face-mask represent the highest grade of protection and security provided to workers when operating in industrial fields; it provides protection to faces respiratory tracts, eyes and skin all in once.
The full-face mask working principle is very similar to the one of the half-face negative pressure mask: an airtight seal is provided by the elastic-deformable body to isolate the user from external enviroment; when inhaling air is forced through filters and reaches the user.
The main difference between the previous-seen model consists in the presence of a visor made of transparent plastic (usually PC) and an allround deformable harness. Filter units are attached at the inlets and can be substituted when needed, in the same way same as the half-face negative mask. [G]

visor

represents a key component into the full-face-mask assembly. It has the main function of offering protection to eyes and isolating the face while permitting a good field of view and reduced interference with users gestures.
Visors can be treated or coated to improve anti-scratch, anti-fog and anti paint peel-of solutions

inner mask

A smaller inner mask retains CO_2 buildup, water droplets and vapours to prevent visor from internal fogging and keep the worker “fresh” and comfortable during usage

4-6 point harness

4 to 6 point clip retention harness is suited for full-face mask kits. The full-face itself respresents a bulky and quite invasive PPE, for this reason balancing the overall weight and retaining the mask plays an important role for user safety and comfort.
At least 4 point of regulation are used to tension the laces and fit the mask to workers face; an elastic back acts on users neck by compressing against crown and front visage.

[Q] 4 point rubber harness


all-round seal
visor
inner mask
filter mount
stripping clip
4-6 point harness
[R]
[R]

2.8 PAPR Mask and Hood

the ultimate DPI - definition and categories

PAPR (Powered Air Purified Respirator) is a positive pressure respiratory system employed where enviromental working condition impose the user to be supplied with a high flow of air during operations.
The mask (generally a common full-face or half-face mask) is equipped with a flexible hose connected on filters access overture, other eventual openings are then closed.
The other end of the hose is ensured at the shroud of the blowing unit; the blower acts as a vacuum and drives air into the system, the air is forced through the filter unit and gets purified before entering the system and reaching the user. The blowing unit is responsible of supplying the desired amount of air (flow) by increasing or decreasing RPM of the motor, the value can be setted by the operator. PAPR are generally dispensed with safety detection system embedded. [H]

tight fit

For some application (ex. military, fireman, mining..) a tight seal is needed to ensure protection by the contaminant, in this case half and full-face mask are suited by worker and regulated/tensioned to perform an adherent fit on visage. For this kind of application a high flow is usually employed (around 160 l/min).

flowmeter (rotameter)

A mechanical safety check is required to be on-board for PAPRs in case of electrical damage or malfunction. For this reason most PAPRs present a rotameter installed at the beginning of the hose to warn the worker in case of misbehaviours by the machine

[S] full-face mask equipped with PAPR system

loose fit

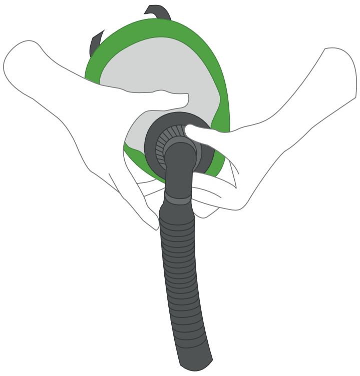
For other applications (ex. pharmaceutical, medical, chemical..) a loose fit can be suited by operators and is generally obtained through a hood or a helmet. The protective element presents a surrounding skirt protecting the operator till chin or shoulders. The contaminant is avoided by the positive pressure generated in the internal systemn keeping it in the external envviroment (even without a tight sealing gasket). For this kind of application flowrates of approximately 90 l/min are suited.

securing belt

To carry the weight of the blower + filter unit and to interphere as less as possible with worker gestures PAPRs are provided with differnet solutions to be worn by the user (belt, backpack, baldric..)

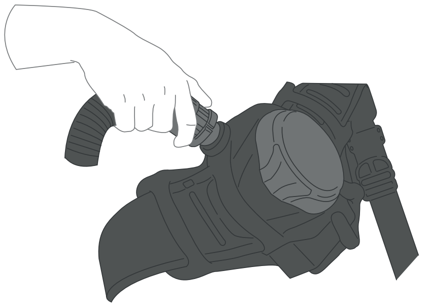

[T]
blower unit + filter
flowmeter - rotameter
(loose fit) hood
(loose fit) helmet - visor
flowing tube (hose)
wearing belt
battery pack + charger
[T]
standard connections allow half and full-face masks to be adapted at the hose
the hose is than connected to the blower on the other end with another mechanism

wearing and use procedure



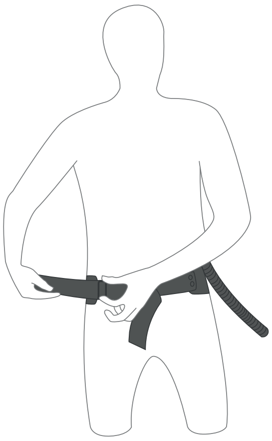
① hose lock

standard connections allow half and full-face masks to be adapted at the hose



② hose lock on blower

the hose is than connected to the blower on the other end with another mechanism



⑤ size adjust

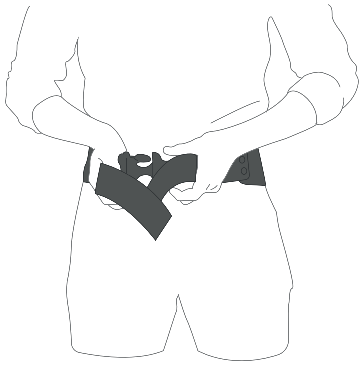
the belt is regulated to meet user needs and to fit comfortable during use

⑥ mask wearing

the mask is initially worn by attachng first 2 points behind the neck (shoulders)

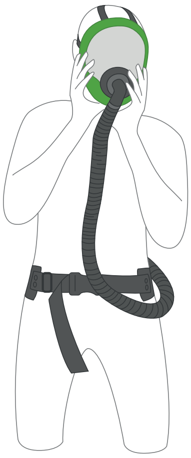
③ inserting filter

the filter is inserted in the housing and covered to mantain it in place



④ harness closure

operator ensures the blower system on the body by pressing the clip



⑦ adjust/ fit-check

fit check is performed by operator to verify correct sealing of mask body/gasket

⑧ control interaction

PAPR is activated by hand through control panel (usually located on the unit itself)

3.0 user & context

worker and working enviroment

3.0 User and context
worker and workplace general overview - methodology

In this chapter the user will be at the center of the design investigation, in the attempt of tracing it's main traits and discovering the modes of use and behaviours taking place in a depicted scenario.
The subject of this exploration will be the the user wearing half-face negative pressure mask in his daily activity, and so a very particular kind of worker.

The user analysis phase has undergone almost 3 years of research adopting several methods and aims to acquire information of meaning for the definition and development of the project.
The project was grounded and carried out based on the observation of user needs and depositions. Studies in the field had started in May 2019 using the following strategies:

- desk research
- etnographical analysis
- questionnaires
- personal interviews
- in-situ monitoring
- focus groups

All of the reported methods were fielded at different stages of the deign process, starting from the initial conceptual insights, into the more defined refinment of the project, untill the very final testing phase.

[A] post-it used during brain-storm activity

worker duties

workers at work in a construction site [B]

The term worker can so be defined:

"A person who works, especially one who does a particular kind of work"

Oxford Dictionary

The worker can therefore be associated with a certain amount of tasks or duties, such as: [A]

- Perform and report on, daily safety and maintenance checks.
- Works with and assists the crew in digging ditches and trenches, hoisting material, tools, equipment, and any related work with a backhoe, excavator, or front-end loader
- Assist in restoring worksite at completion of daily work
- Place, remove or maintain underground utilities as directed. This includes but is not limited to: carrying pipe, bags of material, and other heavy items, jack hammering, shoveling, tamping, and installing pipe, duct, or cable
- Operates equipment of various sizes and weights in the loading, hauling, and unloading of various equipment, materials, and supplies

risk exposure

	Risk		How to solve it
Action	Risks for height exposure		adopting safe measures and dotation
	Risks from noise		protect auditive system
	Airborne fibers and materials	protect respiratory system	protect from lacerations, abrasions, bruns,
	Asbestos		protect respiratory system and from contact
	Moving objects		human contact, psycological support

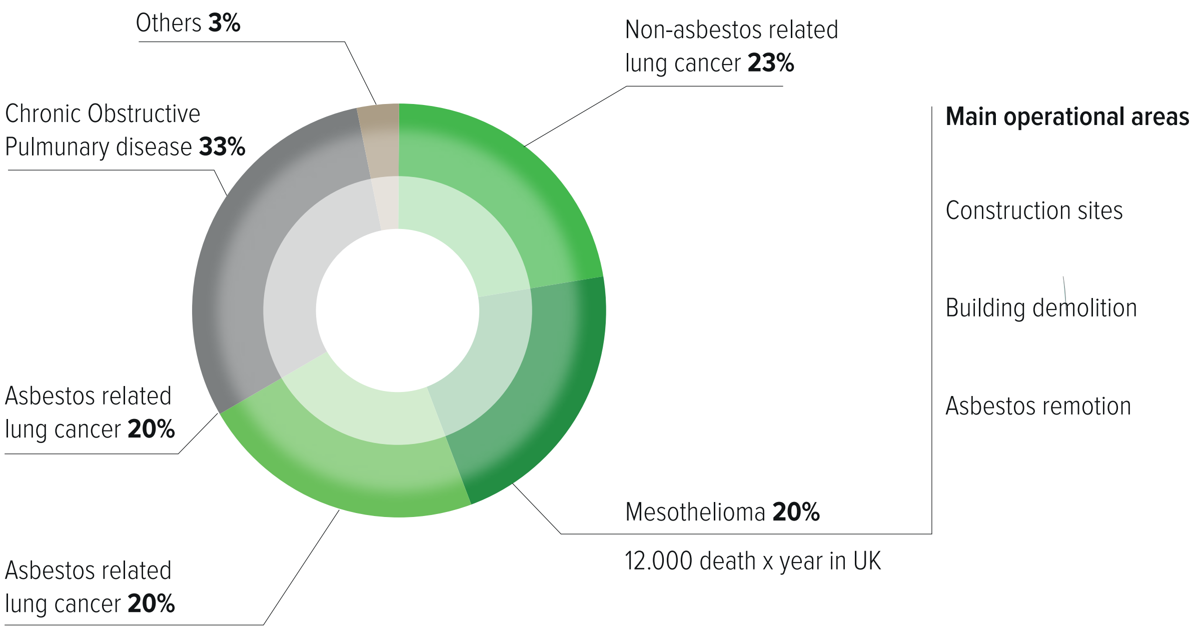
worker operational outfit (PPE)

	VIS Clothes	Boots	Helmet	Safety Gloves	Dust mask	Safety Goggles	Respirator	Ear Plugs
								
Hazards	Fire and heat Injuries and damages Aggressive liquides Scratches Harmful dusts Chemicals	Fire Injuries and damages Aggressive liquides Abrading or lacerating Prevent holes Chemicals	Falling objects Injuries and damages Abrading or lacerating	Fire Heat injuries Abrading or lacerating	Dust Particulate Powders Abrasives	Particulate Dust Liquids Radiation (some cases)	Smoke Gas Asbestos Paintings	Noise Dust (some cases)
Protect	Body	Legs	Head / face	Hands	Respiratory system	Eyes	Respiratory system	Auditive
Detect	-	-	-	-	-	-	-	-

[B] source: https://www.hse.gov.uk/toolbox/ppe.htm

worker's respiratory diseases

Respiratory-related long term diseases are related to a frequent and repeated exposure to contaminants on workplace. The cause can be often found in workers behaviour or lacking of system control. Long-term diseases are usually related to a misuse of the Personal Protective Equipment or an underestimation of the risk exposure by the user, precarious or non-unfirom working-condition can also be at the origin.

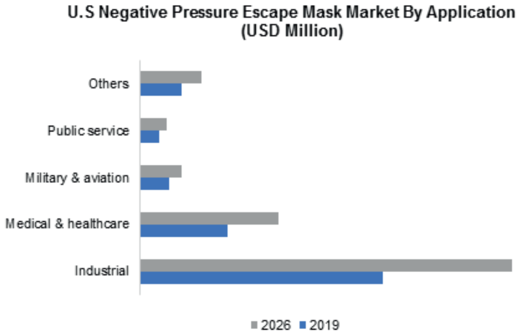


Workers long-term incidence on respiratory (UK 2018)

[B] source: https://www.hse.gov.uk/statistics/causdis/index.htm

3.1 Industrial fields
target

The term *worker* includes a wide variety of people or “workers” as said but for the scope of my project i wanted to precisely focus on those relevant to me, the ones wearing full-face negative pressure mask to get they respiratory traits protected on daily working activity. For this reason first step i went to was to identify wich industrial categories of workers i was referring to.
From the desk research and thanks to the spreading of a first questionnaire around community of workers and mask customers i focused on 2 main worker categories, ending up to be the ones adopting the most half-negative pressure maks and encountering many diseases during use:



[C] industrial sprayer

[D] agricultural operator

[D] source: https://www.gminsights.com

workers user questionnaire

For the scope of my investigation 3 different questionnaire forms were created and spreaded at different stages of the project to collect hints and impressions by target users. The first questionnaire was directed to general industrial workers and had the scope of getting a general idea about the activity and market individuating a more defined sub-class of target user: industrial painters and agricultural operatore.
Both these categories of workers seemed to correspond to researched attributes and represent key users of half-face negative pressure safety systems.
Other 2 questionnaire forms were created, one each working activity, in the intent of familiarizing with the practice and deepending the

Form links:

Industrial worker empolyees questionnaire
(July 2019)

https://docs.google.com/forms/d/e/1FAIpQLSfAsDIybr75mmdbEFUILyQjw2NK-LeIjBz-CfEbY4k0flHTSA/viewform

Industrial sprayer and varnisher questionnaire
(February 2020)

https://docs.google.com/forms/d/e/1FAIpQLSdcmQc9W2ictLylqC5kSY9UbD7s-WoC9mmaZIlekkFOUR6GdA/viewform?usp=sf_link

Agricultural operator questionnaire
(July 2020)

https://docs.google.com/forms/d/e/1FAIpQLSf_HhpaPyledbUA7gBhLwYhIm7srDQawcsIwv9YJ_lKajdfEw/viewform?vc=0&c=0&w=1

[E]


Grinding workers
User questionnaire
F
Age
La tua risposta
Gender
Male
Female
Prefer not to say
How long are your facial hair?
1 2 3
No facial hair

3.2 User analysis
industrial painter - varnisher

From the exit of the questionnairs and the results collected i ended up choosing to deepen the figure of the industrial painter; i decided to go for this user case study because i could get larger and more meaningfull results from this category. This kind of activity is frequent to be found around my local area and this was another encouragment to move me into the analysis of the industrial painter:

his job consists of applying the surface painting treatment to different kind of objects. In the manufacturing industry he is part of the production line. The majority of varnishers work in industries that produce cars, motorbikes, boats or furniture, or in enterprises active in the wood, plastic, glass or building sector. [E]

[C]

Working area	Typical hazards	Type of filters	Normative
Painting	VOCs / dust	A/AX/P3	EN149

Works on:

Examine the surface that he has to paint
Prepare the surface to paint
Apply the preparatory treatment on the surface
Prepare and mix paint and the other subastances to be applied
Paint the surface
Check the quality
Carry out the maintenance of the instruments

Skills:

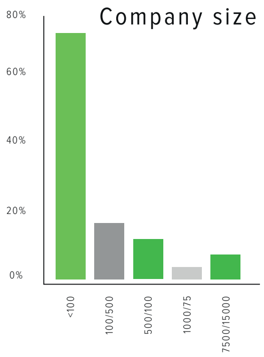
Mechanical knowledge about instruments and machines to use
“Scientific” knowledges, in order to know materials’ features and how they react to treatments
Know paints and the chemical substances used
Know the different surface treatments, and in particular painting methods
Good manual skills

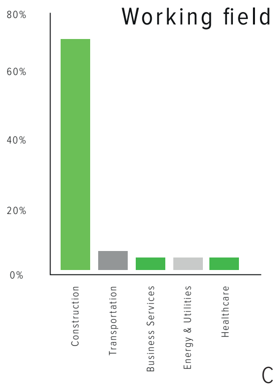
Experienced worker average salary (USA)
25 $ / h
52700 $ / year

Beginner worker average salary (USA)
19 $ / h
40400$ / year

[F] source: https://www.salary.com/tools/salary-calculator/entry-painter/italy-tx

painting activity





The atomization of paint increases the surface area of the liquid. Although this method is favored for painting large areas in a fairly short amount of time and, in some cases, using less product than with brush or roller applications, two primary hazards exist: worker exposure to toxic substances and fires or explosions. Indeed workers performing spray paint operations are at a higher risk than with brush or roller applications. [G]

Can lead to:

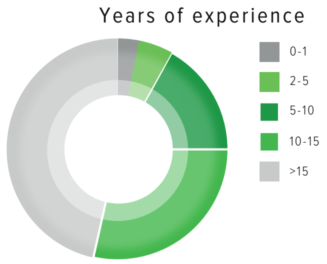
Toxic/Hazardous Substances
Exposure occurs when the paint becomes airborne, and this is especially true in a confined space

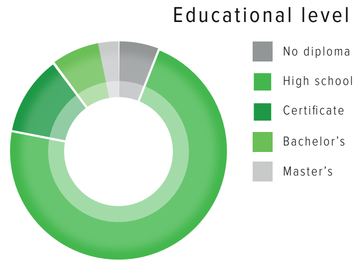
Fires/Explosions
Organic solvent-based paint contains flammable and explosive solvents with flash points usually below 27°C.

Instruments
Noise
Vibration

Long term health effect
Allergic contact dermatitis
Respiratory diseases: asthma, lung cancer
Cardiovascular diseases
Painter's syndrome: brain damage, damage to the reproductive system and kidney or liver damage, caused by prolonged inhalation of paints and solvents

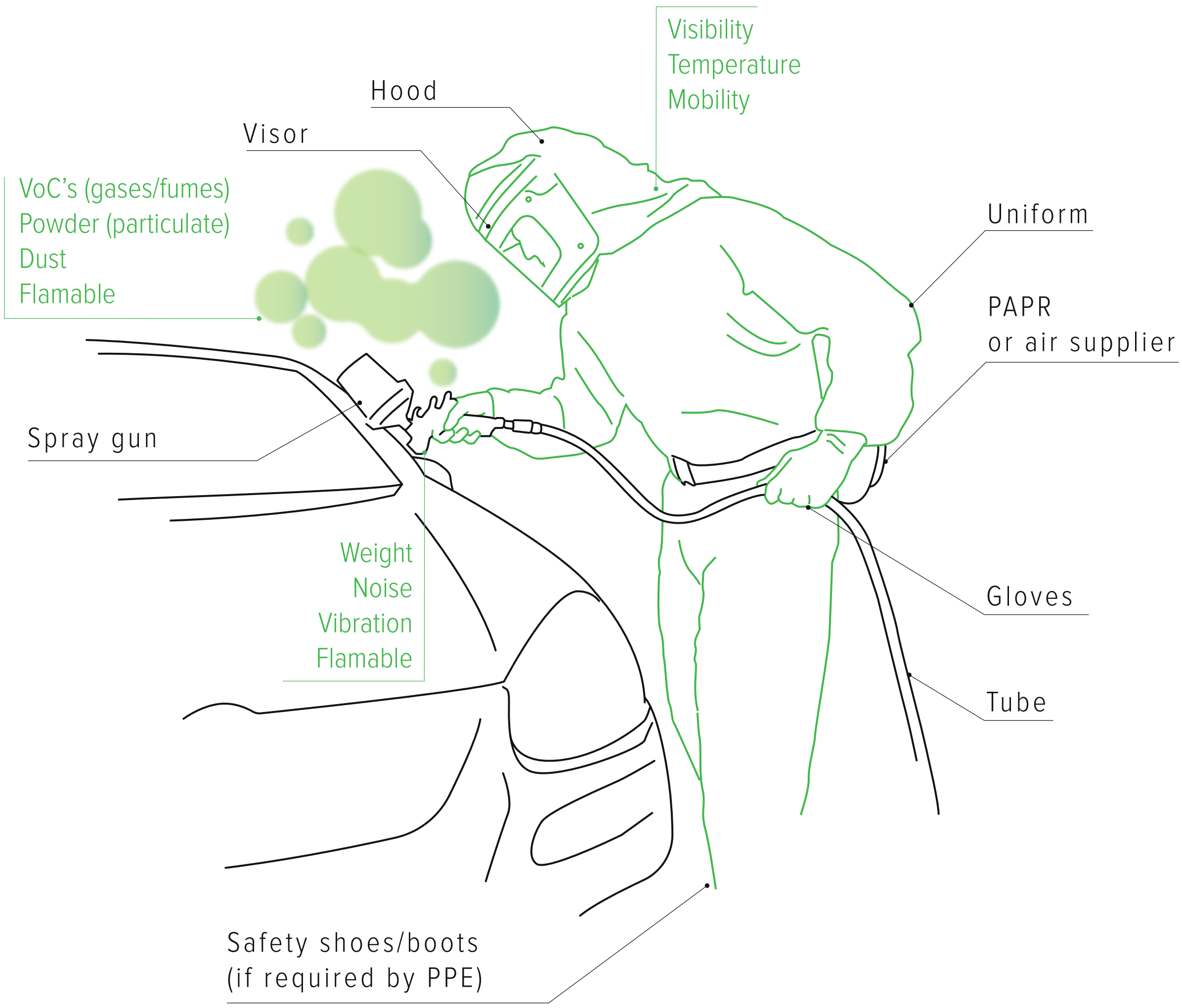
Short term health effects
Irritation contact dermatitis
Irritation to the nose, throat and lungs
Burns to the skin and eyes
Headaches, dizziness, nausea and fatigue
Coughing, painful breathing
Pneumonia, bronchitis
Reynaud's Syndrome (due to vibration from the equipment)



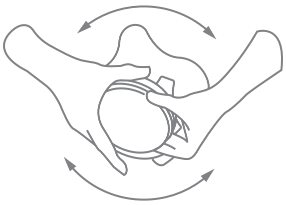


[F] source: https://www.salary.com/tools/salary-calculator/painter-senior/italy-tx

types of paint

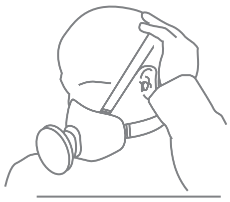


relevant safety - protective aspects



filter mount

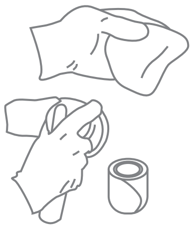
hearing protection



respirator fitting

paint preparation

eyes/face protection



tools/part preparing

Combustible vapors
Closed space
VoC's
Particulate
Dust
Eye and skin irritation

types of paint

The purpose of wearing a respiratory protective mask (combined with protective goggles as well) is to preserve the operator from harmful contaminants disperded by lacquers and paints during working activity. [H]
A general definition of most diffused paint categories is here provided:

Organic solvent-based paint

Pigment + bonding agent, dispersed in an organic solvent.
The main hazard related to this kind of paint are emissions from the evaporating solvents, consisting of VOCs (Volatile organic compounds, highly toxic), and reacting in sunlight to form smog.

Water-based paint

Synthetic resins and pigments + coalescing agents + surfactants + water. They have lower VOC emission thansolvent-based paint, and they are not flammable.

Powder paint

Thermoplastic / thermoset polymer + pigments + additives. They contains no solvents and release little or no amount of VOC. Curing time is significantly faster with powder coating than with liquid coating.
It's applied to metal surfaces, glass or MDF objects through electrostatic spray deposition using a spray gun.

[F]

High-pressure spray

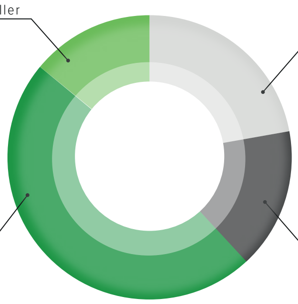
[F]

HVLP system

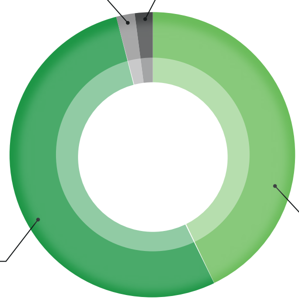
[F]

Airless spray

What kind of spraying system do you use mostly?



What kind of paint do you use mostly?



	Uniform	Hearing protection	Hood	Gloves	Respirator
					
Hazards	Irritation, burns	Noise, irritation, burns	Irritation, burns	Irritation, burns	Carcinogenic and toxic substances
Protect	Entire body	Hearing	Head	Hands	Respiratory system

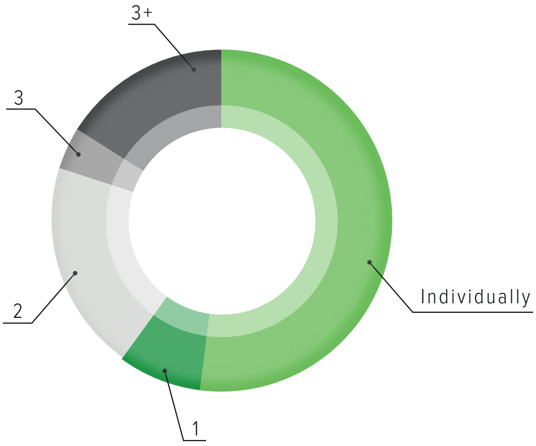
[I] source: questionnaires

3.3 Working ambient
enviroment and workspace

To analyze workspace and working condition for industrial painters i started by interpreting results of questionnaires spreaded within varnisher communities. The results were very useful to depict industrial situation for the sector by providing a general idea about companies size, workspace structure, daily routine, tasks and key aspects related to the practice.

Workspace represents a key factor into user habits, espcially because is where the exposure to contaminants and dangers takes place and is also where the worker spends most of his day (up to 8 to 12 hours).
Under this circumstances analyzing the ambient and the surrounding enviroment has represented a crucial factor for the development of this project. [L]

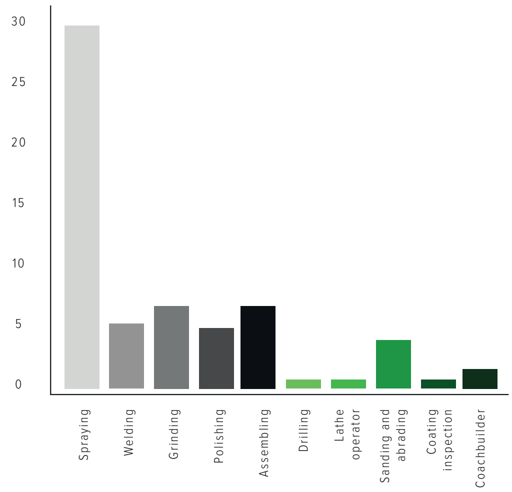
How many workers are there with you in your workstation?



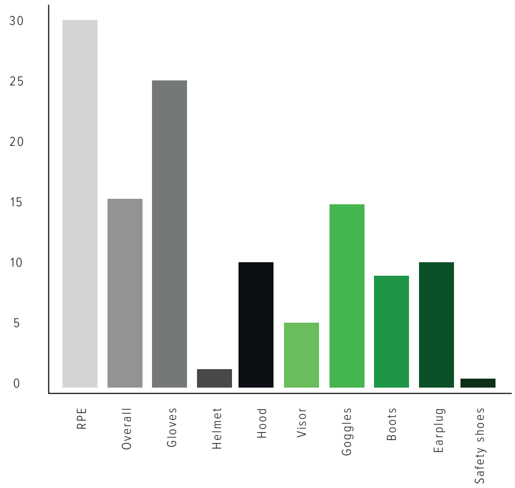
[G] painters working in team in a painting room

[I] source: questionnaires

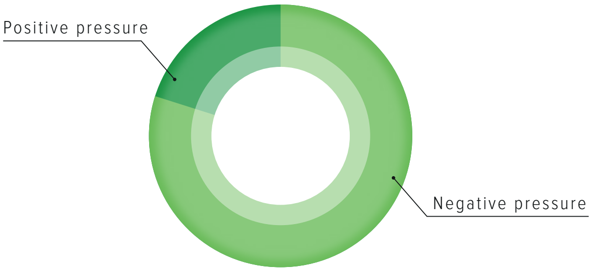
Which tasks do you perform?



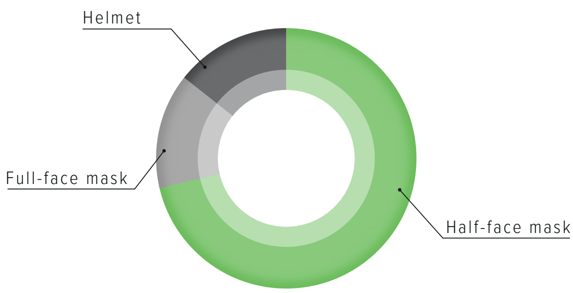
What kind of equipment do you usually use?



Which kind of respiratory protection do you use?



If you use a positive pressure respiratory protection, what kind of mask do you use?



[I] source: questionnaires

painter workflow

phase 1 - preparing the surface

activities included:

- grinding surfaces
- polishing
- cleaning surfaces
- removing dust/defects
- applying masks/stencils
- using pre-treatment paints

[H]

painters preparatory activity frames

phase 2 - preparing the paint/tool

activities included:

- wearing all protections
- assembling
- managing small parts
- moving paint containers
- mixing paint components
- filtering paint
- filling tools

[H]

paint mixture preparation frames

phase 3 - painting and finishing

activities included:

- painting
- cleaning tools
- removing masks/stencils
- preparing tools for next use
- washing garment after use

[H]

painters at work frames

[M] https://www.youtube.com/watch?v=EZmFzstDQIs

key aspects related to practice

work station

painter workin in cabin [H]

difficult access areas for the worker while painting, potentially using other tools (stairs, etc..).
Often the activity requires the accomplishment of different tasks (noit strictly related with painting) and requires transition between more than a single work-space

painting object

painter reaching object areas [H]

difficult access to parts for the user into the painting object itself. It is often required to reach hidden spots or interdicted areas, making the task even much difficult and tiresome (operator bending, leaning, etc..)

noise & obstacles

painters working in wider spaces [H]

needs for a more comfortable area to operate: noise, vibrations and many workers in the same workspace make it a confusional enviroment. Concentration is hard to be kept for many hours and tools in the space interphere with movement and gestures (the tube itself e.g.)

[N] https://www.youtube.com/watch?v=uAjr4bLquRM

Working ambient
different case studies

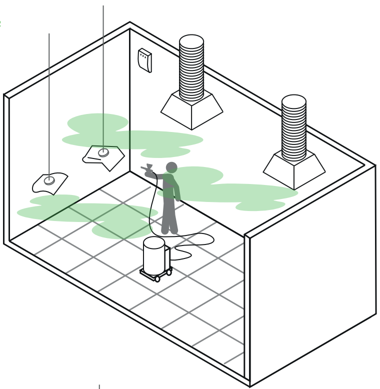
To analyze workspace and working condition for industrial painters i started by interpreting results of questionnaires spreaded within varnisher communities. The results were very useful to depict industrial situation for the sector by providing a general idea about companies size, workspace structure, daily routine, tasks and key aspects related to the practice.
I was able to individuate and define 3 main working scenarios where painting activity takes place and is at the center of workflow.
Working-ambient may vary depending on compines size, operating field and operational workflow of a the given activity.
In general the working ambient for industrial painters can be seen as a very noisey and disturbing working ambient, spraying gun vibrates a lot and is loud, powder spreading in the room is limiting view field, the worker is usually involved in multiple tasks with different tools, often in cooperation with other workers moving and handling in same places. [L]

In the following pages i summarized what can be seen as the key aspects of the 3 different working scenarios related to industrial painters. I tried to underline and highlight key-features and blind-sposts energed to be influent in the daily routine of industrial sprayer workers.
The insights were taken by questionnaires and in-site observation and interview.
Before the undergoing Covid-19 i had the chance to visit two different painting activities, around the area of Varese, in the neighbouhood of my own town. These testimony were very useful to better define the user aspect and inspiring for the grounding of my thesis.

- Decover srl https://www.decoversrl.it/
- Rigo http://www.rigosrl.com/home.html

[I] painter reaching a difficult area

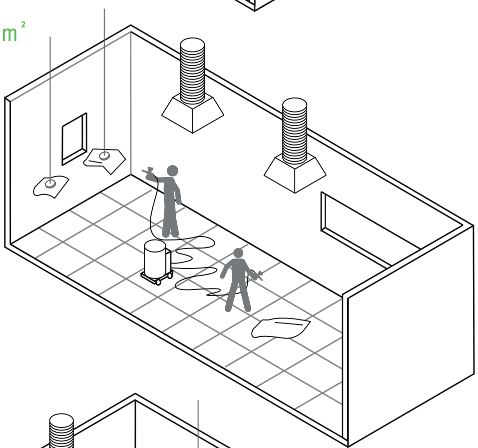
15 - 45 m²



spray booth

the smallest workspace to operate for a varnisher. It consists in a single blind room with air-recirculatory system and alarm embedded.
It is meant for indivdual job or for a maximum of 2 people (depending on the amount of space).
Spaces are very tight, gestures are compromised and visibility is reduced (by fog accumulation). Usually dotated of control and emergency systems to monitor room status and worker condition. An emergency button is present for calling assistance in case of need by the operator.

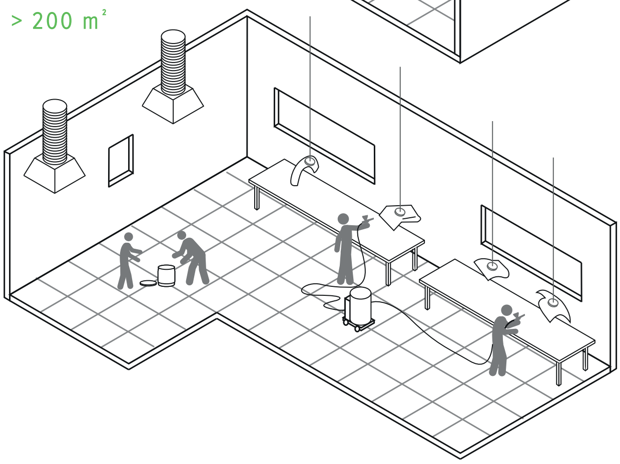
60 - 200 m²



varnishing cabinet

small to medium wokspaces usally well ventilated and without sophisticated integrated safety systems. From 1 to 4 workers are usually operating at the same time in this enviroment practicing activities individually or joined. This configuration is usually adopted for samll-to-medium companies and muktiple tasks of different kinds can be unwined at the same time.

> 200 m²

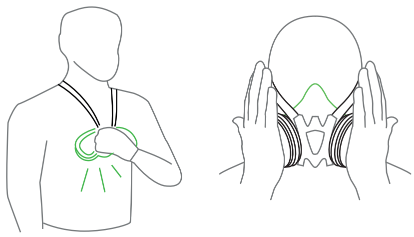


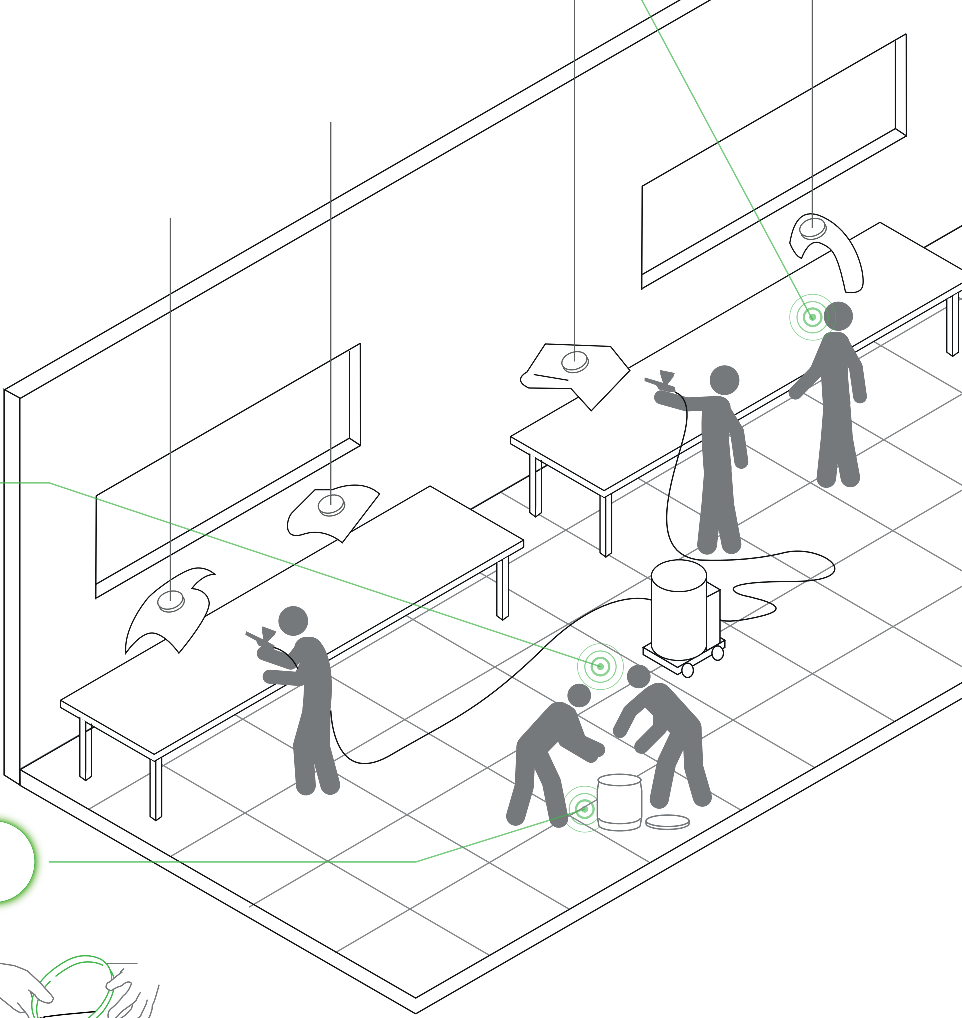
painting shed

open rooms or sheds that can receive more workers. Usually this kind of spaces are subdiveded into working areas where different tasks are perfromed by stationary or moving operators. Spaces are wide and open, often well ventilated and illuminated. The working ambient can be crowded and co-operation between workers is common to take place over the daily working cycle.

mask drop-off

mask drop-off is an operation that can be performed by user during working activity. The action is intended for the purpose of refreshing and providing a breathing rest for the user when taking a break from regular activity. Often the drop-off is performed when the user is still under exposure of contaminants and fit-check is rarely performed when wearing the mask again





noise and vibration

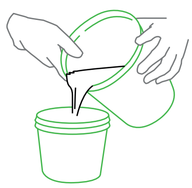
a lot of disturbance is brought in the working ambient by simply using the working tools. Industrial spraying systems can cause a lot of vibrations and noise when in-use (making it hard to manipulate). Fogging is caused by pigment diffusion

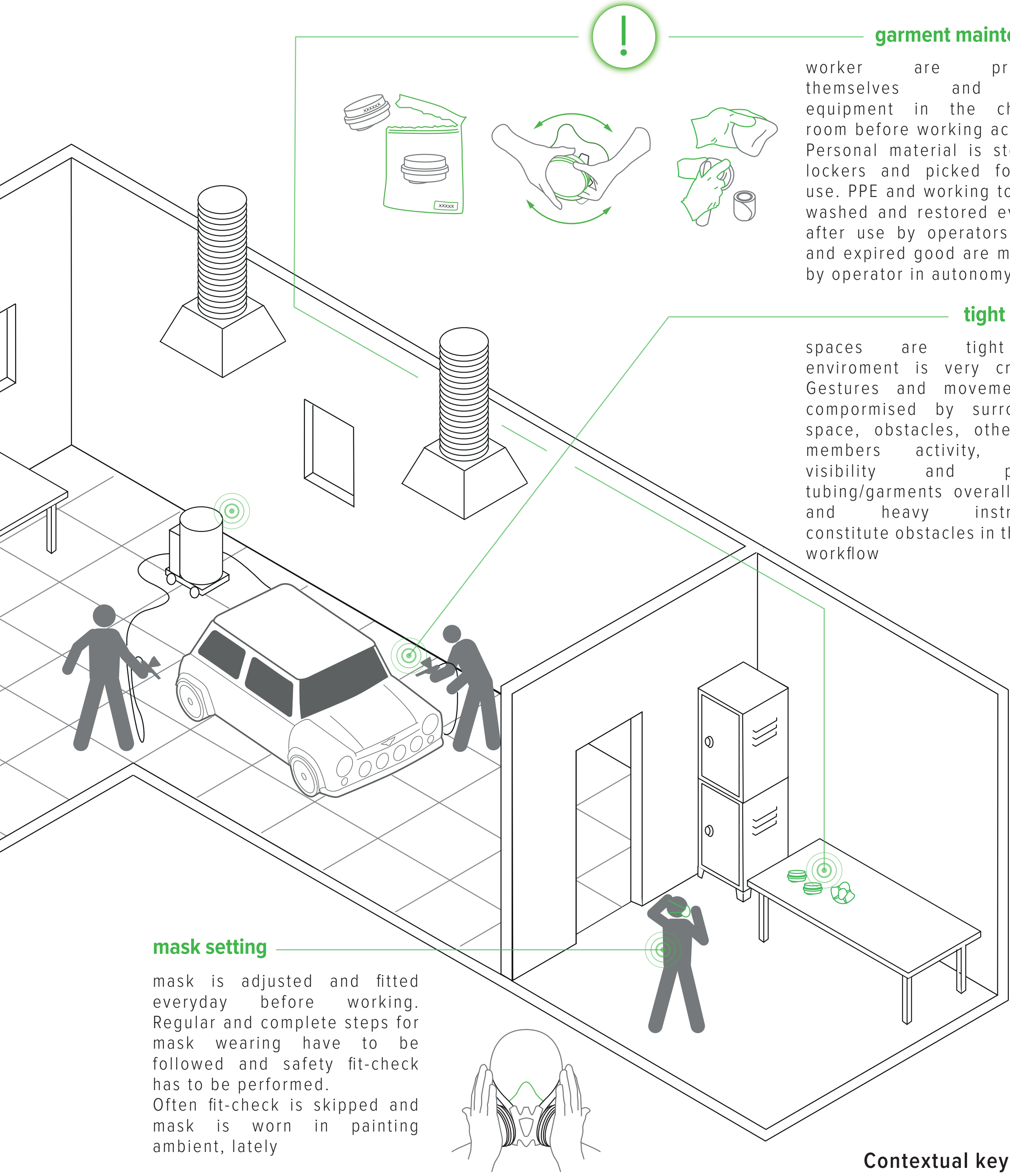
co-operation

in some enviroments workers may have to cooperate and actively collaborate during daily routine. Wearing a mask can hardly compromise efficiency in communications and view field, limiting those operations

tools setting

when preparing paint and setting tools many volatile compounds and harmful contaminants are spreading in the work-ambient. Often these operations are performed by user without wearing the correct PPE and underestimating risk exposure





garment maintenance

worker are preparing themselves and their equipment in the changing room before working activities. Personal material is stored in lockers and picked for daily use. PPE and working tools are washed and restored everyday after use by operators, filters and expired good are managed by operator in autonomy

tight spaces

spaces are tight and enviroment is very crowded. Gestures and movement are compormised by surrounding space, obstacles, other team members activity, limited visibility and painting tubing/garments overall. Bulky and heavy instruments constitute obstacles in the daily workflow

mask setting

mask is adjusted and fitted everyday before working. Regular and complete steps for mask wearing have to be followed and safety fit-check has to be performed.
Often fit-check is skipped and mask is worn in painting ambient, lately

Contextual key points

3.4 User Testimony
grounding impressions

As previously said, the genesis of the project was hardly influenced by user testimonials.
I had the chance to get in touch and interview many workers working in the painting/varnishing field and collect they're feelings about the use of negative pressure respiratory masks.

I was astonished by the number of feedbacks i received, but what surprised me most has been the very bad feeling complained by most in regard of the worn PPE.
Most of the face-piece were declared to be unsuitably or highly discomfrotable, often subject to regulation or drop-offs to take breathe. The very bad impressions collected and the detailed description of the feeling induced by the mask on user's face helped me a lot to define e conceptualize the current project. The following comments were marked down by users impression on the use of negative half-face masks:

" I rarely have my mask on "
Mauro C.

" It hurts! "
Matteo F.

" I don't feel it comfrotable on my face"
Mattia B.

" It ruins my hairs "
Alice M.

" It rips my hairs "
Frncesca P.

" It doesn't fits me! "
Elia G.

" I barely pass the fit-test threshold "
Cinzia M.

[L]

pictures of workers wearing respiratory maks

misuse

A first bunch of user impressions were collected and resumed in those features identified as exposing the user to danger. This kind of behaviours are mainly scaturated by a misuse or underestimatione of the role of PPE during the working activity.

comfort

A second list of key points is listed and accumunated by the procured discomfort to the user.
Almost every user analyzed and interviewed declared frustrations against mask wearing procedure and lack of fitting and face adaptivity,

risk underestimation

worker (experienced worker especially) tend to underestimate the risk exposure and often do not wear PPE. This happens mostly during mid-operations (polishing, sanding, paint mixing)

misuse

often PPE are not correctly worn, often dyuring quick and “spot” work operations. Laces are not correctly tensioned and fit-test is not performed at every new wearing

safety concerns

even in those worker following the rule and wearing the mask by caring of each step depicted in the procedures there are some concerns about complete adaptivity on the mask to the face. Leackage and gaps are suspected by those worker wearing a mask with beard or facial hairs

size shades

many user are complaining too small or too big masks for their visage. This is the case of many women trying to fit a bigger mask and ending at the boarder with the required fit-factor.
Masks are usually provided in S-L-M sizes

high tension

after hours of work users are suffering mask compression against face. Laces has to be tensioned in the right amount to guarantee a safe seal over visage; the tension is mantained during the wole duration of the job, thus creating a lot of pain and discomfort to the user

wearing inconvenience

even in those worker following the rule and wearing the mask by caring of each step depicted in the procedures there are some frustration related to the complicated and bulk gestures required to correctly wear the PPE. Many users declared to struggle when wearing the mask.


BLS

4.0 The journey of the Pump

project birth and inspirations

4.0 The journey behind the PUMP project
milestones of the process

The conceptualization of the PUMP project dates back to 2019, where it was generated during a 3 day workshop taking place in PoliMi and involving companies and group of students. The workshop was held by BLS, partner company of the workshop and key manufacturer of respiratory protective products. In this occasion i had the chance to get in touch for the first time with the company and to present the fresh-born concepts in fornt of an audience. In this occasion a very primordial idea of the PUMP was already traced and collected many approvals between spectators.
I started an autonomus collaboration with BLS in the intent of improving and further investigating the concept. After almost a year of work i had the chance to join BLS team to internally work and dedicate myself to the project. The following steps can be seen as the milestones followed for the development of this project:

[A] picture shooted during BLS x PoliMi workshop

Bachelor workshop PoliMi x BLS

During the 3rd year of Industrial Product bachelor degree at Politecnico di Milano i joined a curricular workshop in partnership with BLS. I worked with other 2 colleagues into the development of a highly innovative mask concept; in the concept (Reptil), between many features presented, the first theorization of the PUMP concept and the adaptive fitting. The workshop ended with an elevator pitch in front of an audience where every group had the occasion to present the fresh-born concepts, gaining much attention in this occassion.

Autonomus implementation

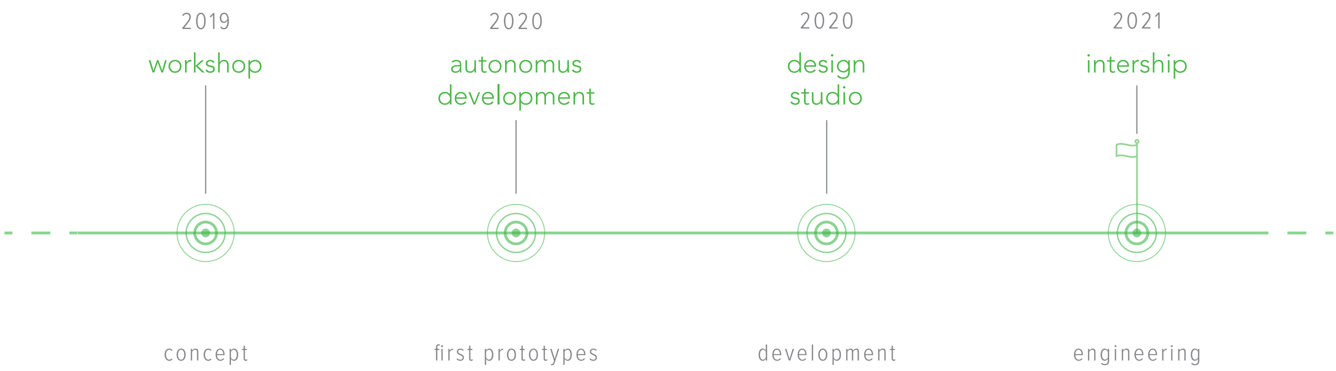
After a few months I got contacted by the company (BLS), interested into the development of several aspects of the project. We decided to carry on an autonomus investigation and development of the project. I decided to focus on the specificity of the adaptive fit and to dig deeper in the question.
I began the first studies in the field, initial research on materials was made and preliminary prototypes were carried out.

1st year Design Engineering Design Studio

Coincidence wanted me and BLS to meet together again. During the 1st year of Master Degree at PoliMi in Design Engineering i had the chanche to work again with BLS, as partners of our 2nd semester Design Studio. In this occasion the topic was around PAPRs (positive pressure systems) but it gave me the opportunity to further investigate respiratory protection field and to bring on other interviews and questionnaire about the researched topic.

BLS Intership

At the point of completing my course of study me, together with the company, decided to start an intership in order to work and implement the concept of the PUMP and the adaptive fit.
I joined BLS team one year ago, working in the Technical Department and the stage was prorogated to 1 year to get enough time to bring on the project. In this time, between many other things, i had the chance to dedicate myself at the project, by realizing and testing many prototypes and reaching a very mature phase of the development.



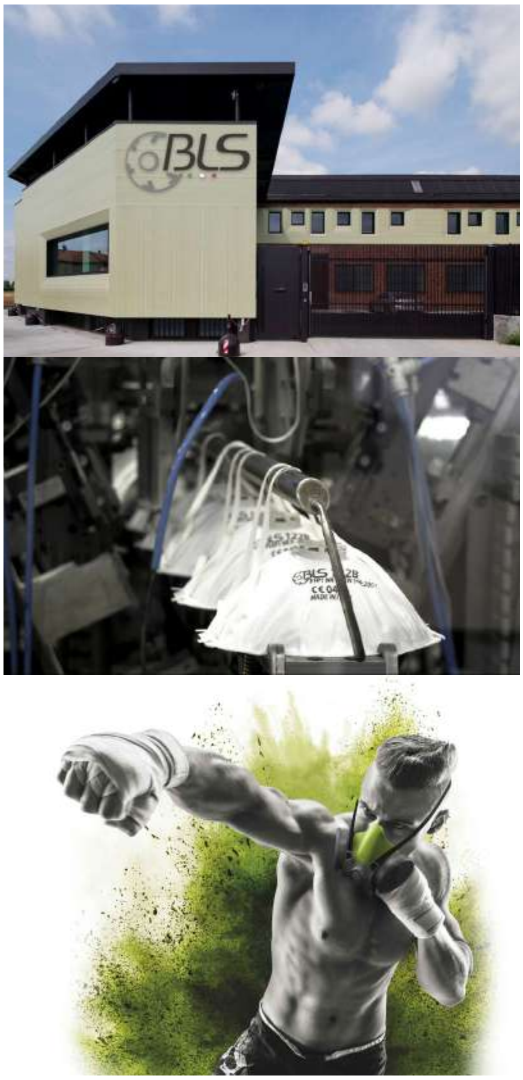
4.1 The company

deepening of company profile

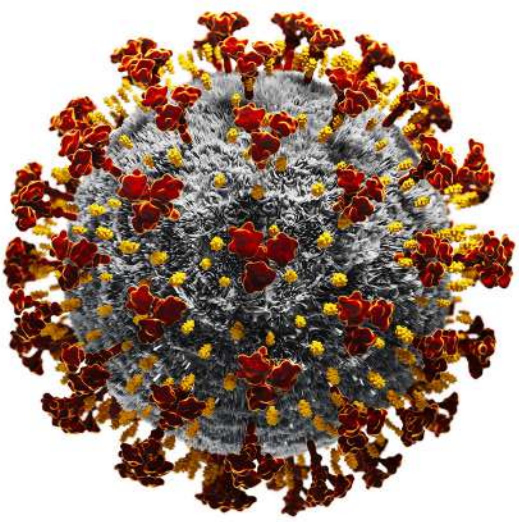
BLS is positioned in the market as a company operating in the field of respiratory health, specifically it has been deployed for over 70 years alongside workers and operators to ensure the protection of the respiratory tract and maximum performance.

BLS operates mainly in the B2B market, specializes in providing support and IPR for various activities in very disparate sectors. It also provides a wide range of respiratory protection products: from disposable filtering face masks, to reusable ones, to half masks with integrated and non-integrated filters, up to the design and production of full-face masks, filters and accessories to support the system. A vast catalog and meticulous attention to the product place BLS among the leaders in the sector, comparing itself with companies of the caliber of 3M, Moldex, Draeger.
Innovation, research, development and design are fundamental drivers for BLS that make it a dynamic reality in step with the times; in constant research and investment for the launch of new products, conceived and developed with the support of the Politecnico and numerous other players.

And it is precisely between these two realities that my journey at BLS begins: from a three-year workshop as a student, to my entry into the company's Technical Office.
My role within the company was at the Technical Office, specifically I was involved in product design, research and development. On the right a schematic of the company organization chart and the various departments I had to deal with during the activity.



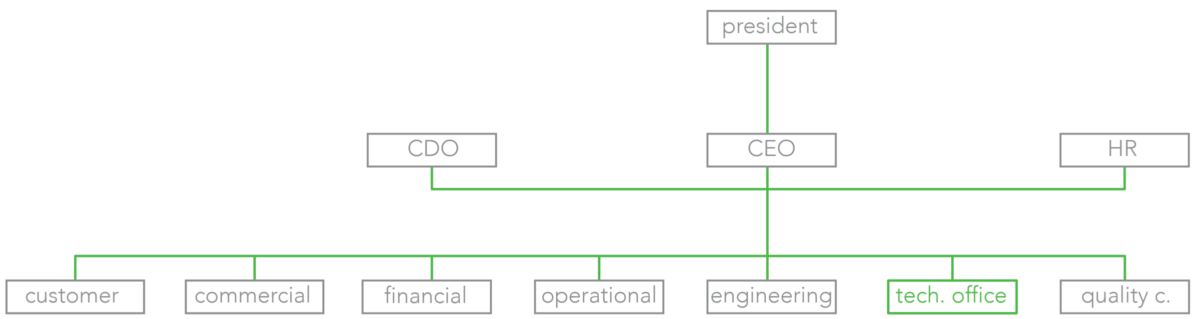
[B] BLS headquarter and brand identity



[C] covid-19 virus representation

Current situation

The period undergone between 2020-2021 will be remembered by many as the sars-Covid19 pandemic.
In a period of national and international health emergency such as the one that has just passed and is underway, a reality like BLS is led to play a role at the forefront. For this reason the production cycles and lines used for the production of filter masks FFP2 and FFP3 have had an increase like never before in history, going through intensive cycles and requiring efforts above expectations. The pandemic has favored and encouraged the development of technologies and innovation in the world of respiratory protection.
It is therefore an honor as well as a pride to have been able to contribute in this phase.



BLS hierarchical internal organization

4.2 Inspiration
project drivers

When approaching the design and definition phase of the PUMP project i went out scouting for similar or motivational references.
I could define 3 macro-categories or drivers wich were of much inspiration during the design process and fundamental for the development of several technical and engineering aspects of the final solution. A similar working principle found in other solutions on market (applied to other categories of products) prooved the viability of the project.

All the solution reported have in common the use of pressurized air to obtain a certain kind of deformation. The desired effect is reached by stiffening or relaxing the designed body by forcing an air flow and air pressure. The precise action can be calibrated by the geometry of the body/cavity and in the examples analyzed the operations are carried out by the products in a very efficient way.

Inspiration came from 3 different case studies, reported by following:

- Anesthesia cushion mask

- Reebok Pump sneakers

- Soft robot applications

In the next pages each category will be explained by highlighting pints in common with the PUMP project.

[D]

sealing bags used in the packaging industry

ANESTHESIA CUSHION MASK

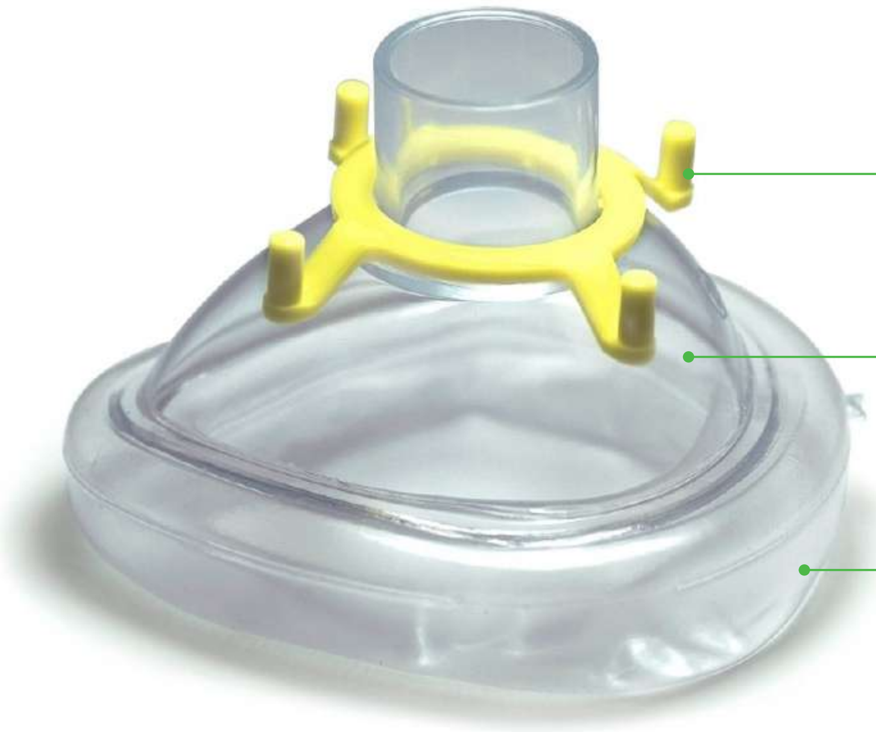
REEBOK PUMP

SOFT-ROBOT

Anesthesia cushion mask

Anesthesia face masks are rubber or silicone masks that cover both the mouth and nose of the patient. Face masks are used to deliver O_2, N_2O-O_2, and/or other inhalation anesthetics before/during/after anesthetic procedures. Because of the variations in the size and shape of faces, several different sizes of face masks should always be available.

Typically, face masks are made from a clear plastic or rubber that allows the patient's mouth and nose to be seen so that foreign material (e.g., vomitus, blood) and condensation may be observed. [A]



hook ring

color coding hook ring
for easy size identification

HDPE

transparent rigid crown

soft clear crown design for
better patient observation

PVC
PC

air cushion + valve

leak-proof, soft and comfortable seal cushion in facial contoured design; clear material for patient observation; valve cushion allows for adjustment of cushion air

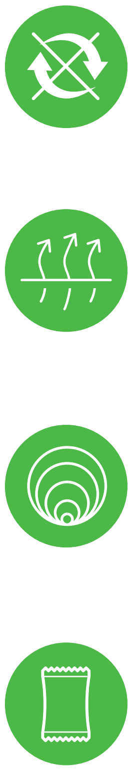
PVC
SILICONE
RUBBER

[E] anesthesia mask compponents and materials

Analysis - inspirational

Many different connectors of various materials and shapes attach the face mask to the anesthesia circuit, continuing to connect to the machine. The mask can be inflated and gently compressed against patience face to limit leackeage during administration. [B]

The case study of the anasthesia mask is much relevant to my project and also shares some aspects in common. First, both concepts are meant for half-face respiratory masks, accomunating them by product category; on the second hand they both share a pneaumatic sealing system in the oronasal area. [C]



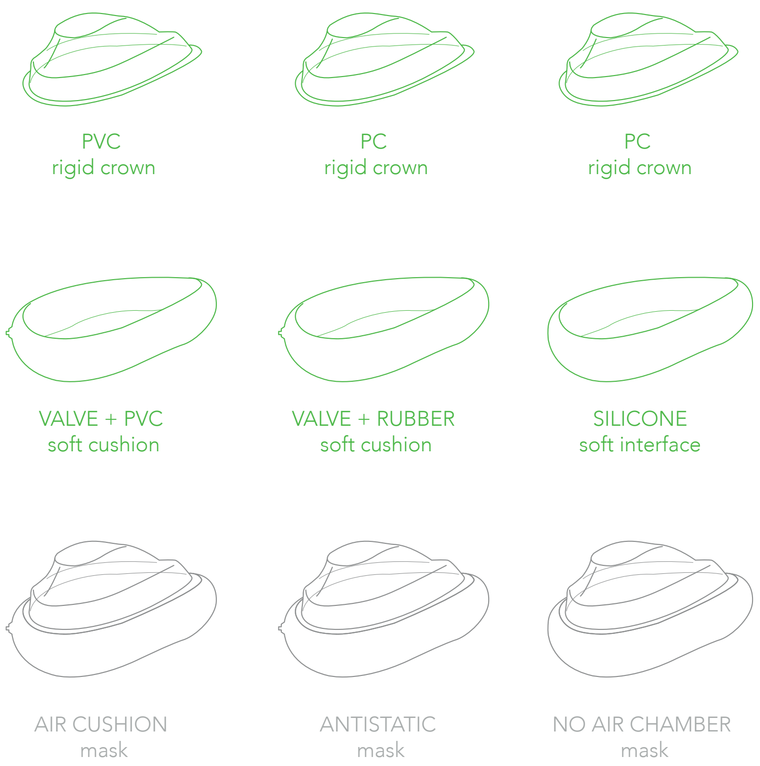
disposable
single patient use to prevent cross contamination

surgical use
aircushion mask is designed for anesthesia, respiratory or resuscitation

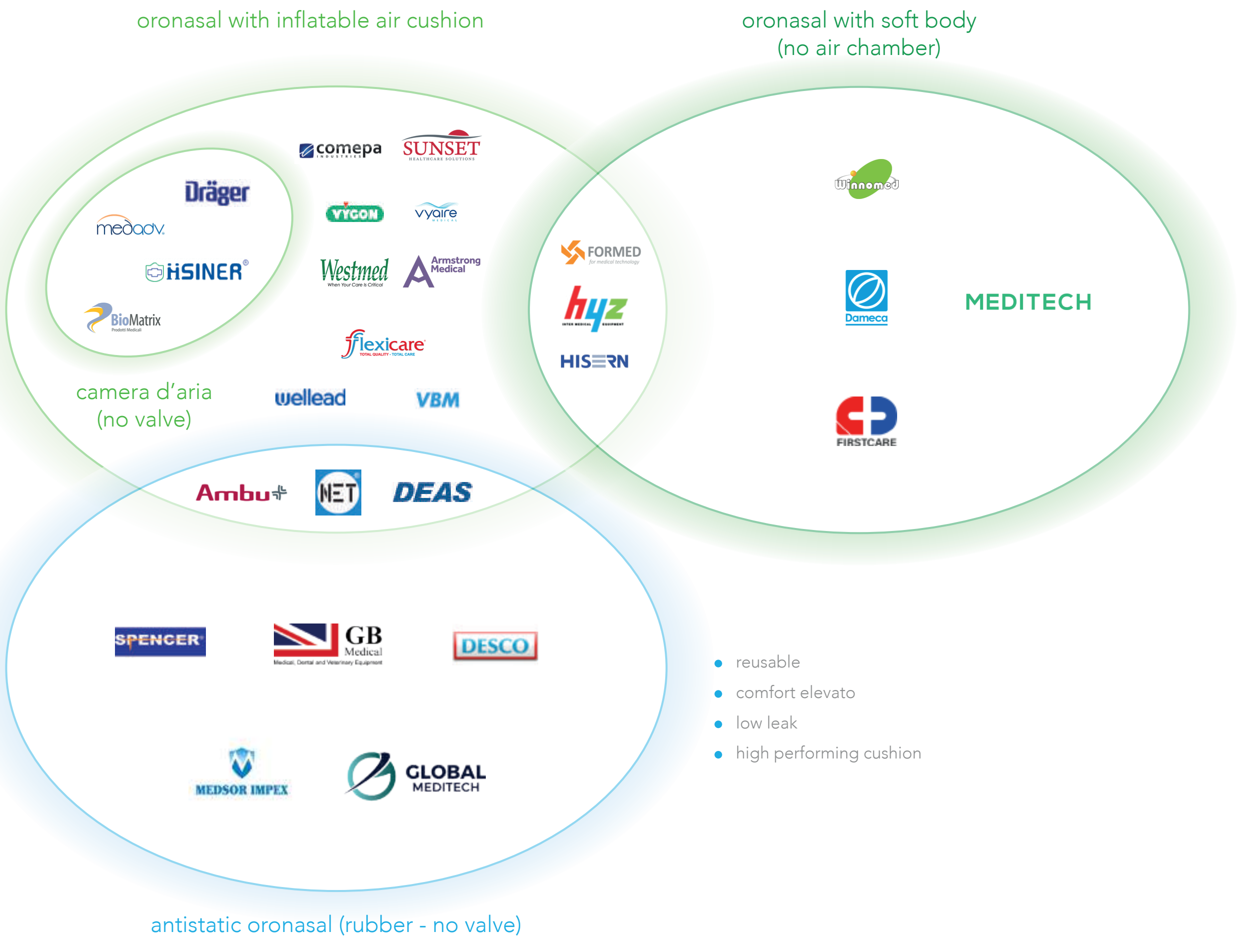
different sizes
Different Sizes available depending on user
Size # 0, 1, 2, 3, 4, 5, 6

air cushion
soft light weight air cushion offers patient great comfort

anesthesia mask main features



anesthesia mask combination on market



- reusable
- comfort elevato
- low leak
- high performing cushion

anesthesia mask differences, brands and presence on market

[F] anesthesia mask during use

Reebok Pump sneakers

The Reebok Advanced Concepts (RAC) team, created in the late 1980s, was dedicated to giving life to the most innovative ideas on behalf of the famous brand and soon became a point of reference in the sneakers universe. There have been many creations and inventions of the group, such as the split sole, the DMX technology and the 3D Ultralite midsole, but among all the Pumps they still remain an icon that makes people talk about themselves.

In 1989, on the model of the high-top sneakers of the late 80s and early 90s, Reebok launched the PUMP shoes, which soon became the brand's calling card in the world of basketball. Created from an idea by the leader of the RAC group, Paul Litchfield, the PUMPs represented no small challenge, as ideas for similar projects were already circulating at the time. As reported in the Reebok archive, the PUMP technology is equipped with integrated air chambers that inflate or deflate to allow the parts of the shoe that wrap around the ankle to adapt to the foot, providing stability and support. The design of the pneumatic cages has been carefully studied in order to allow only a limited amount of air to reach the most flexible parts of the foot and support movement. [D]

reebok pump sneaker [G]

[H] pump system detail visualization

working principle

The architecture of Reebok Pump Sneakers has much in common with The Adaptive Fit PUMP developed for this project.
Studying Reeboks case study helped me a lot during the engineering phase and with the interpretation of key components to be used in a flexible/pneumatic safety systems. [E]

Reeboks PUMP concept was conceived under the marco-category of Sports, in the specific the concept was intended to procure higher performance to professional athlete categories. Same as for the sneaker the project aims to provide a high-performance fit, being safe and comfortable at the same time. [F]

pump system elements [I]

Soft robots

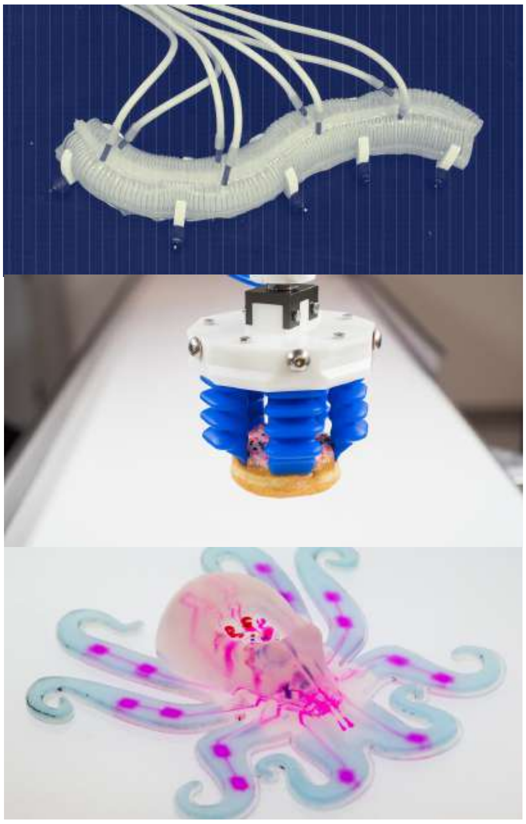
The goal of soft robotics is the design and construction of robots with physically flexible-bodies and mechanics. Sometimes softness is limited to part of the machine. For example, rigid-bodied robotic arms can employ soft end effectors to gently grab and manipulate delicate or irregularly shaped objects. However, the field of soft robotics generally leans toward machines that are predominately or entirely soft. Robots with entirely soft bodies have tremendous potential. For one their flexibility allows them to squeeze into places rigid bodies cannot, which could prove useful in disaster relief scenarios. Soft robots are also safer for human interaction and for internal deployment inside a human body.

Nature is often a source of inspiration for soft robot design given that animals themselves are mostly composed of soft components and they appear to exploit their softness for efficient movement in complex environments almost everywhere on Earth. Thus, soft robots are often designed to look like familiar creatures, especially entirely soft organisms like octopuses. However, it is extremely difficult to manually design and control soft robots given their low mechanical impedance. The very thing that makes soft robots beneficial (their flexibility and compliance) makes them difficult to control. The mathematics developed over the past centuries for designing rigid bodies generally fail to extend to soft robots. Thus, soft robots are commonly designed in part with the help of automated design tools, such as evolutionary algorithms, which enable a soft robot's shape, material properties, and controller to all be simultaneously and automatically designed and optimized together for a given task. [G]

[L] soft robot working principle

Compliant mechanism

Compliants are structures substituting traditional and mechanical elements by performing the same task using intrinsic geometry and material properties

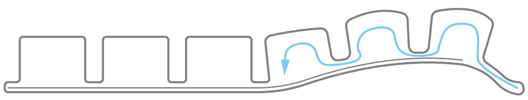


examples of soft-robot actuators [M]

A soft robot can definetly be considered a compliant mechanism. By accurately designing its geometry it is possible to control the behaviour of the body and to program deformation. In this way geometry and patterns can reproduce a gesture or motion when filled by air or reached by a fluid flow. [H]
A very similar working principle has been applied and researched for the development of the PUMP project; for this reason the study of soft-robots category was very precious and useful to my research.
It is very hard to predict and correctly design soft robots and flexible bodies in general. Body deformation and subjection to air flow can be hard to predict and require many testing to be defined and detailed. Some of the reasons related to this limitation can be seen as:

- flexible bodies
- soft materials
- required pressure
- deformation range
- manufacturability
- repeatibility of the process
- reliability of the desired action

soft robot relaxed body



soft robot deformed under air pressure

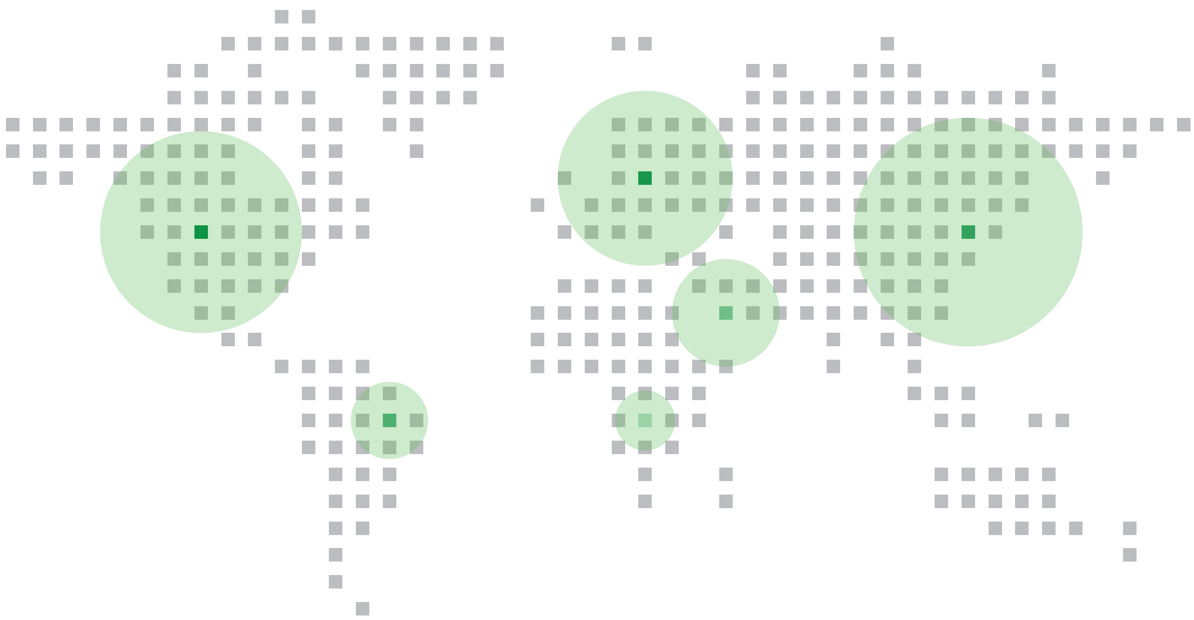

BLS
5000 SERIES
CALIBRATED BY:

5.0 Core of the project

differences among people

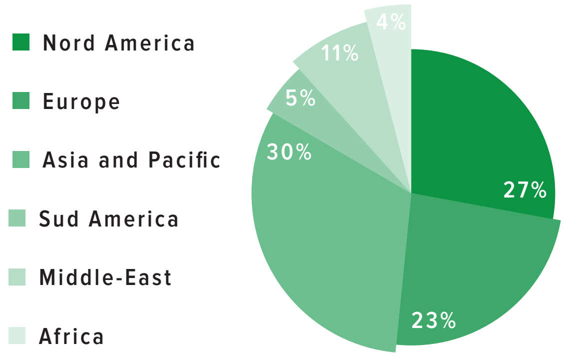
5.0 Core of the project

Focus on disposable global market dirstibution



Introduction to the analysis

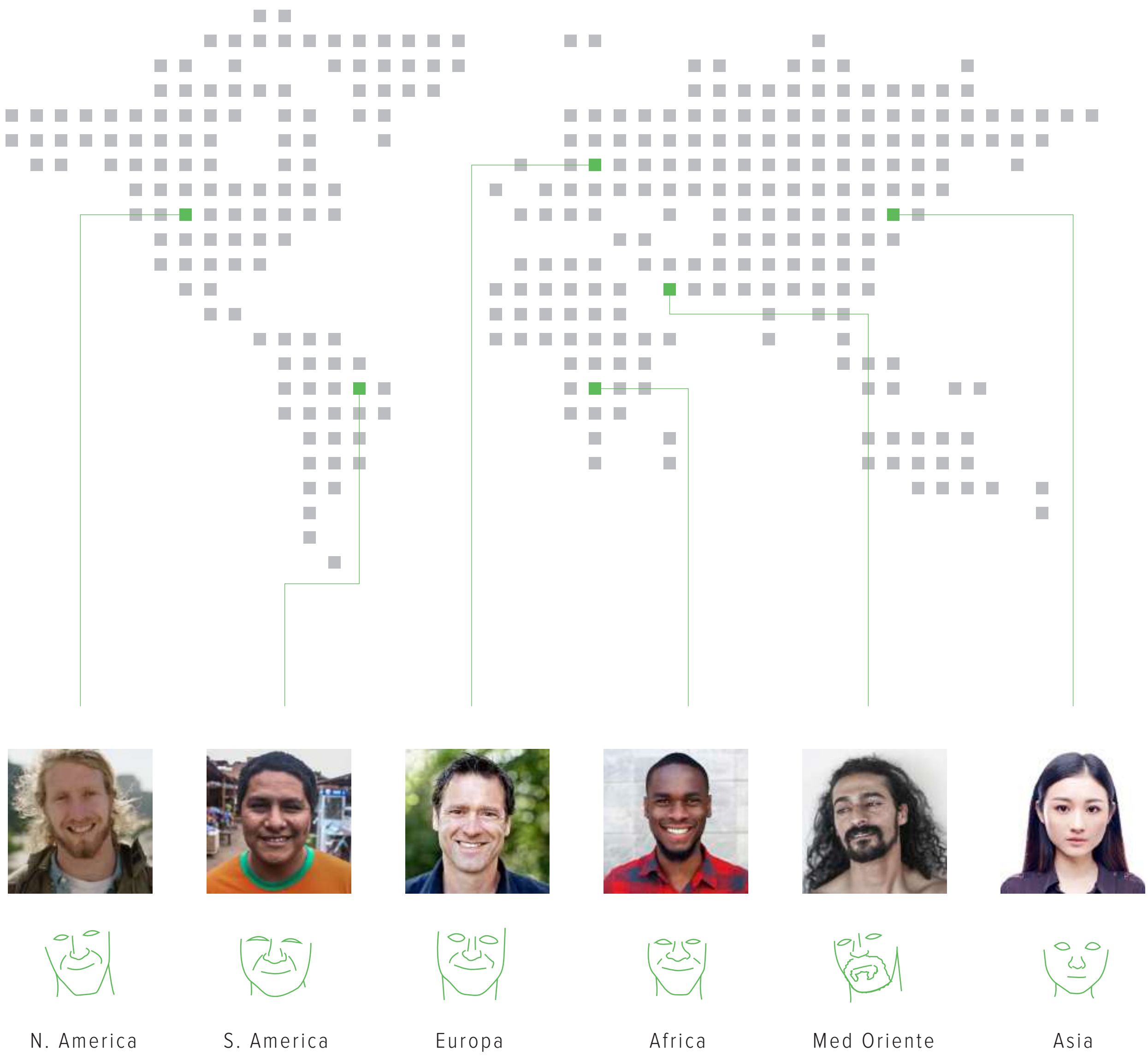
In this chapter, the figure of the user has been analyzed in greater detail. Particular attention has been paid to the physiognomic and anthropometric question. Considerations and explorations will be reported below regarding the different characteristics that, in each individual, contribute to defining the facial fitting. The purpose of the following study is to get acquainted with the indexes and key measures of the human face for the correct sizing and conception of the "Universal Fitting" system; it also serves to analyze the elements that contribute to defining the comfort of the mask on the face.



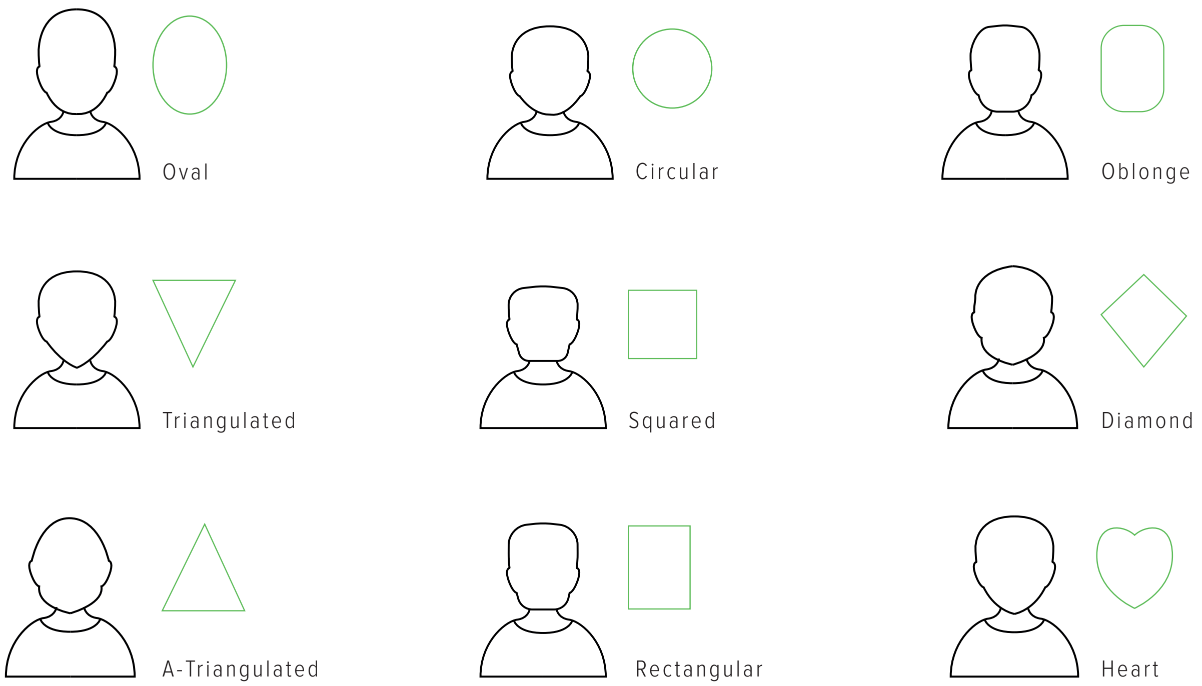
[A] source: https://www.veraciousstatisticsresearch.com/research-study/disposable-face-masks-market/

5.1 Relevant differences

Mapping of anthropomorphic differences in faces in different regions of the globe



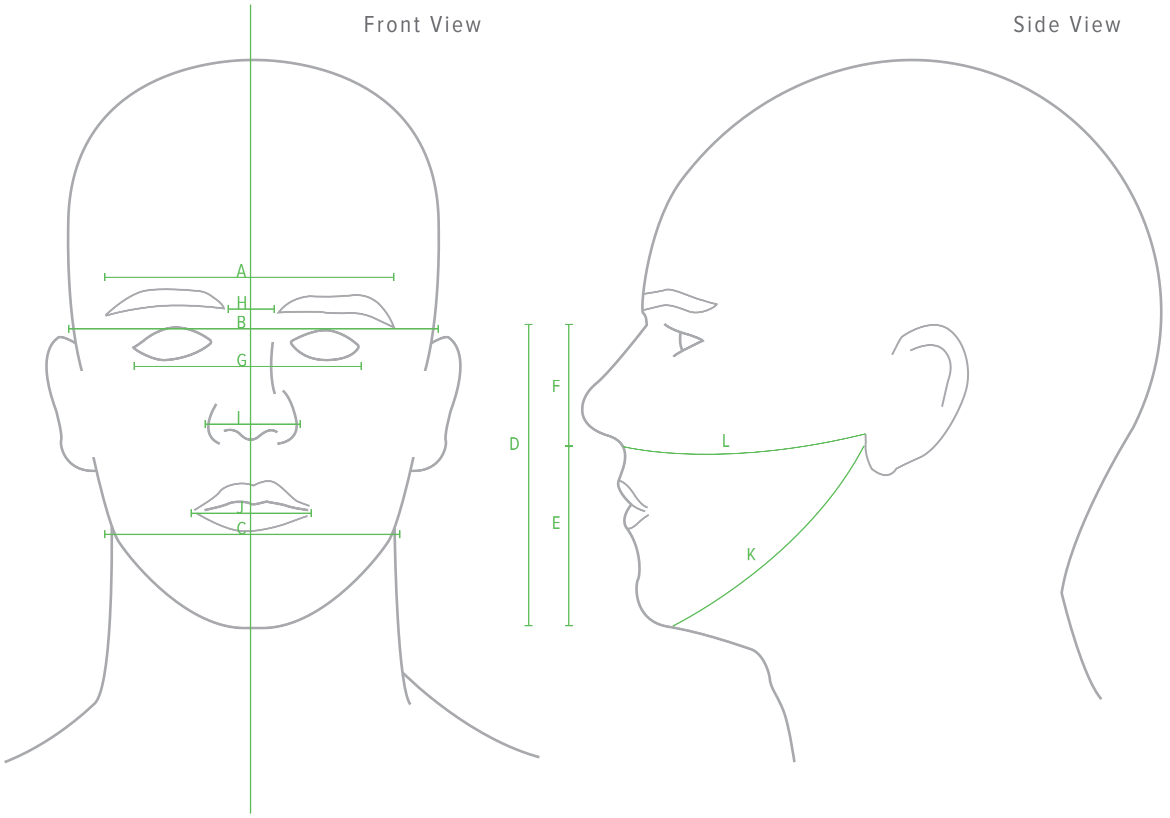
Mapping of facial shapes and forms



Parameters that affect the fit/comfort of the mask:

- physiognomy
- ethnicity
- age
- gender
- beard/moustaches
- hair-style
- ears
- neck
- ear rings
- glasses
- other accessories

Physiognomic and anthropometric analysis 4.2
Parametric investigation of the human face



Ⓐ Biectoorbitale Breadth (ECTO)
Ⓑ Bizygomatic Breadth (ZYGO) f-width
Ⓒ Bigonial Breadth (BGON)
Ⓓ Menton-Nasion Length (MN-N) f-length
Ⓔ Menton-SubNasale Length (MN-S)
Ⓕ Subnasal-Nasion Length (SU-N)
Ⓖ Biocular Breadth (BIOC)
Ⓗ Nasal Root Breadth (NRBR)
Ⓘ Nose Width (NOSW)
Ⓙ Lip Width (LIPW)
Ⓚ Bitragion-Menton Arc (BTMA)
Ⓛ Bitragion-Subnasale Arc (BTMS)

[B] source: https://www.jstage.jst.go.jp/article/indhealth1963/41/1/41_1_8/_pdf

5.3 Mapping the differences

Critical dimension for correct fitting

The 12 measurements (shown in the figure) are reported according to the studies, such as the dimensions directly related to the fitting performance of the mask (quarter and half mask respirators). In particular, 5 of these measurements (reported in the tables) are transversal to most of the world population, representing an important common donor to achieve a "universal fitting." Through the correct interpretation of these parameters lies one of the keys to calibrating the Ultimate Fitting solution. [C]

[A]

picture showing a family with different face traits

Male Dimensions	Korean: This study (n=70)	Korean: Han[1] (n=408)	Korean: Korea[12)A] (n=272)	American: Gross & Horstman[10] (n=61)	American: Oestenstad & Perkins[8] (n=38)	American: USAF[18] (n=2420)	American: Brazile et al.[9)B] (n=32)	American: Liau et al.[4] (n=190)	Australian: Hughes & Lomaev[20] (n=389)
Face width	147.6 ± 5.0	145.1 ± 5.9*	–	140.6 ± 6.4*	139.0 ± 8.0*	142.3 ± 5.2*	134.0 ± 8.0*	136.6 ± 7.5*	140.4 ± 5.8*
Face length	120.6 ± 5.9	120.2 ± 6.2	120.1 ± 6.1	122.1 ± 7.1	126.0 ± 7.0*	120.3 ± 6.1	118.0 ± 6.0	113.7 ± 7.3*	115.5 ± 7.1*
Lip width	49.3 ± 3.8	50.4 ± 4.2	51.1 ± 6.2	53.3 ± 4.5*	51.0 ± 4.0	52.3 ± 4.5*	51.0 ± 5.6	56.2 ± 5.5*	48.8 ± 3.7
Nose width	36.7 ± 2.7	–	38.3 ± 2.9*	35.3 ± 3.5	36.0 ± 3.0	35.4 ± 2.9*	29.0 ± 4.0*	–	–
Nasal root breadth	11.4 ± 1.0	–	–	12.3 ± 1.6*	16.0 ± 2.0*	–	15.0 ± 2.0*	16.4 ± 2.0*	–

Female Dimensions	Korean: This study (n=40)	Korean: Han[1] (n=101)	Korean: Korea[12)A] (n=250)	American: Gross & Horstman[10] (n=60)	American: Oestenstad & Perkins[8] (n=30)	American: USAF[19] (n=1905)	American: Brazile et al.[9)B] (n=34)
Face width	136.6 ± 4.9	134.1 ± 5.9	–	130.1 ± 5.7*	129.0 ± 6.0*	129.0 ± 5.8*	129.0 ± 6.0*
Face length	109.6 ± 4.2	109.5 ± 5.2	110.9 ± 5.3	110.9 ± 6.5	118.0 ± 5.0*	106.3 ± 6.1*	109.0 ± 7.0
Lip width	44.1 ± 3.2	44.5 ± 3.7	48.8 ± 4.6*	51.6 ± 3.9*	48.0 ± 3.0*	43.8 ± 4.2	49.0 ± 3.0*
Nose width	33.2 ± 1.9	–	34.6 ± 2.8*	31.3 ± 2.9*	33.0 ± 4.0	31.9 ± 3.3	27.0 ± 3.0*
Nasal root breadth	11.4 ± 0.8	–	–	10.8 ± 1.4	16.0 ± 0.2*	–	16.0 ± 0.2*

Continent
Region
N. of samples
Measurements

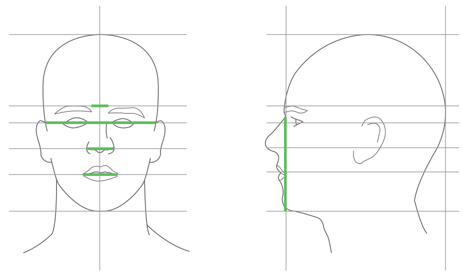
The tables in the figure show physiognomic differences for the main face measurements between East and West.

A *Data obtained by the National Anthropometric Surveys Korea, Korea Research Institute of Standards and Science (2000)*
B *Brazile et al .: considered only fair-skinned subjects*
Unit of measurement: mm

[B] source: https://www.jstage.jst.go.jp/article/indhealth1963/41/1/41_1_8/_pdf

Physiognomic and anthropometric analysis

On the basis of the parameters highlighted, it is possible to define the entire spectrum of sizes necessary to guarantee "total" coverage of the universal fitting technology. In particular, it seems that for Caucasians the differences in the main measures of the face are greater than in oriental individuals.



	Korean		American		Universal	
	Male	Female	Male	Female	Male	Female
Face width	148 - 144	140 - 129	147 - 128	135 - 123	148 - 128	140 - 123
Face length	121 - 119	114 - 104	131 - 112	122 - 100	131 - 112	122 - 100
Lip width	57 - 46	49 - 41	61 - 47	55 - 40	61 - 46	55 - 40
Nose Width	40 - 34	37 - 31	39 - 25	37 - 26	40 - 25	37 - 26
Nasal root breadth	12 - 10	12 - 10	18 - 11	16 - 9	18 - 10	16 - 9

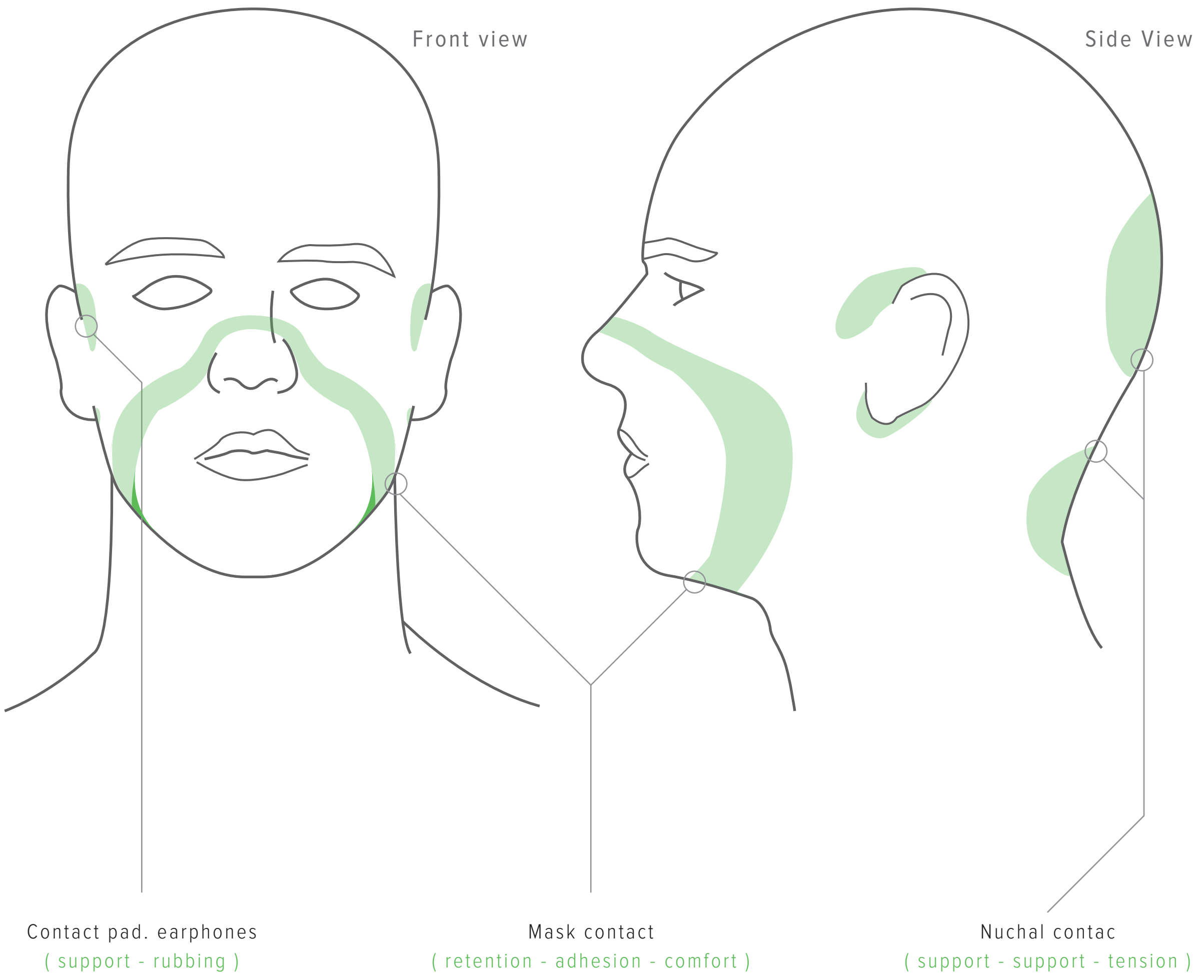
Safety rules and Fitting Factor

As a last step, a look at the rules that define the safety factor and the comfort factor in the semi-face mask category. The Fitting Factor is given by the measurements of the individual's face and by the breathing test while wearing the mask.

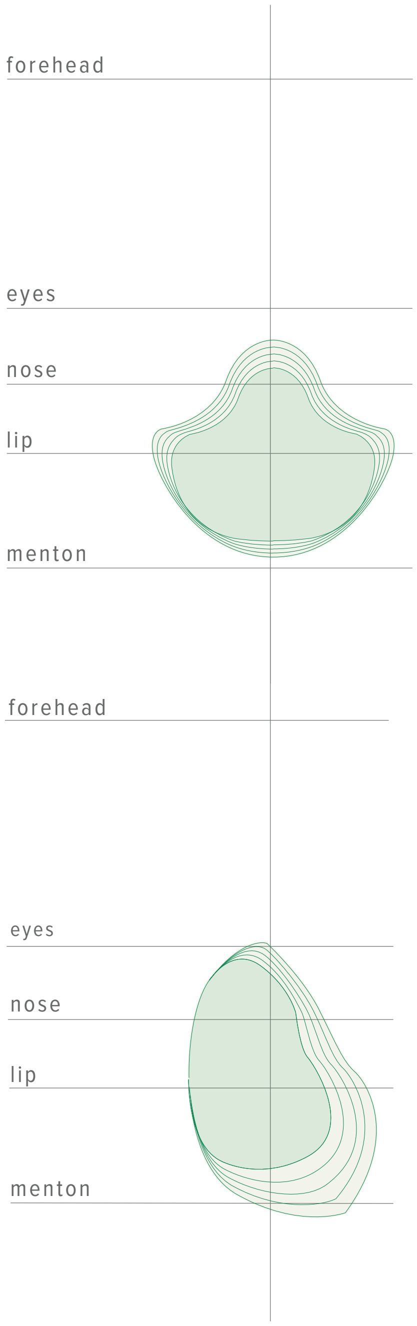
- **ANSI:** the fitting test is considered satisfactory when the individual reaches a Fitting Factor of at least 100
- **OSHA:** if the fitting value is greater than or equal to 100, the test is considered positive for FFP1
- **ANSI Z88.2 face masks:** for negative pressure half face masks the Fitting Factor must be at least 10 times the APF of the protection K
- **ANSI respirator:** the APF (Assigned Protection Factor) for semi-face masks is of the standard value of 10, resulting in an FF > 100

Display of mask-face contact points

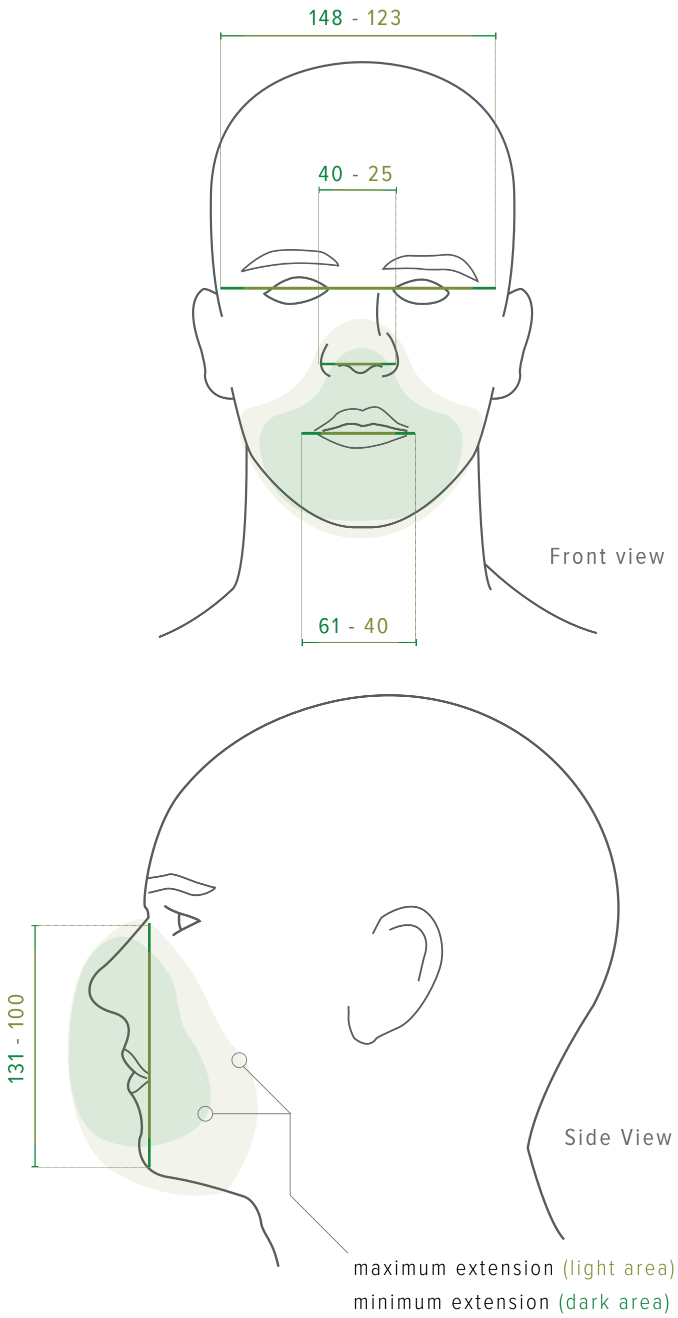
Having identified the adaptive spectrum, the attempt was to map the deformations to which the mask body must respond to satisfy the range of sizes selected.



body mask mapping (action required)



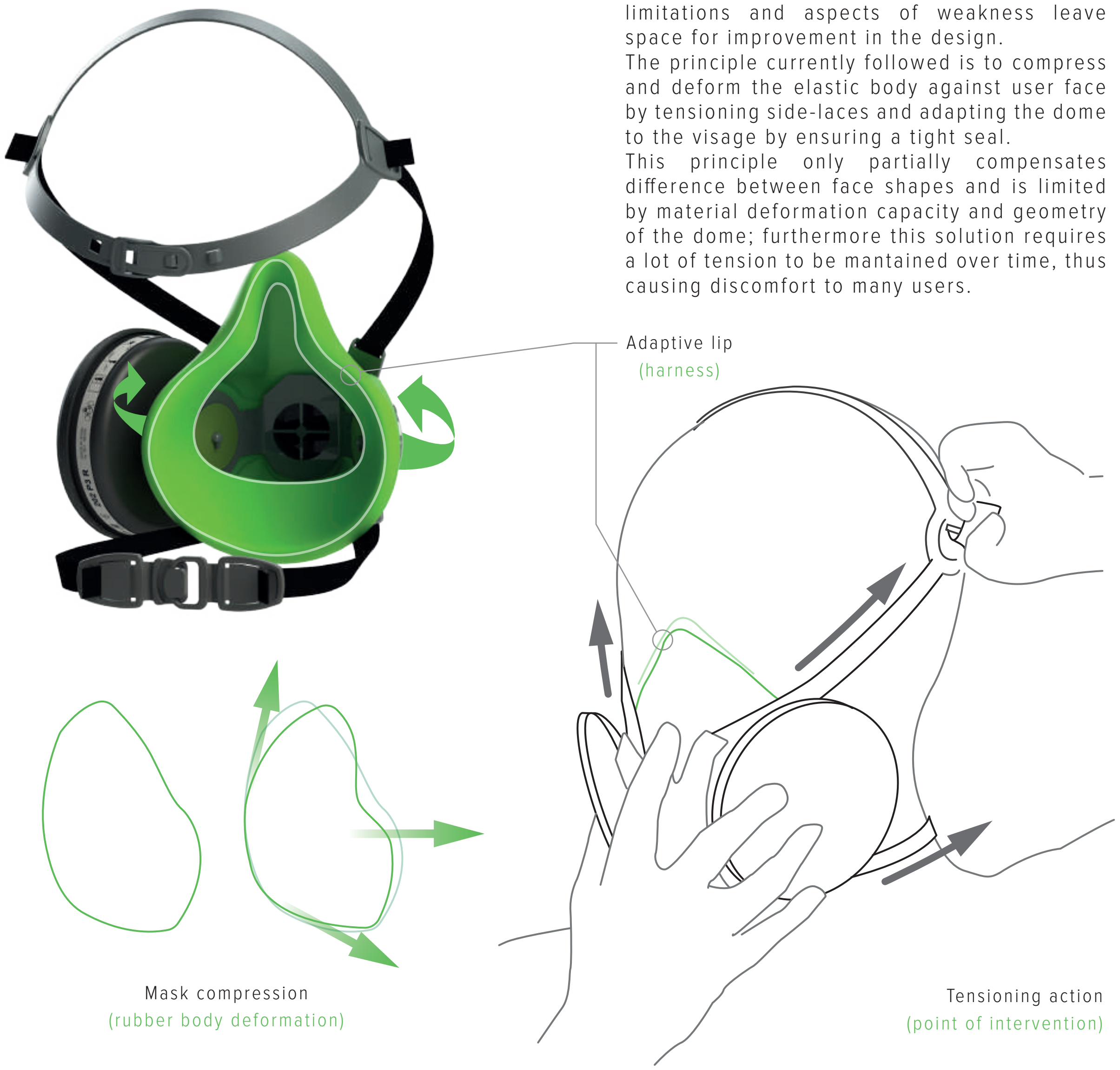
key parameters measurement (coverage range)



5.4 Spotting the problem

Negative pressure half-face mask sealing principle

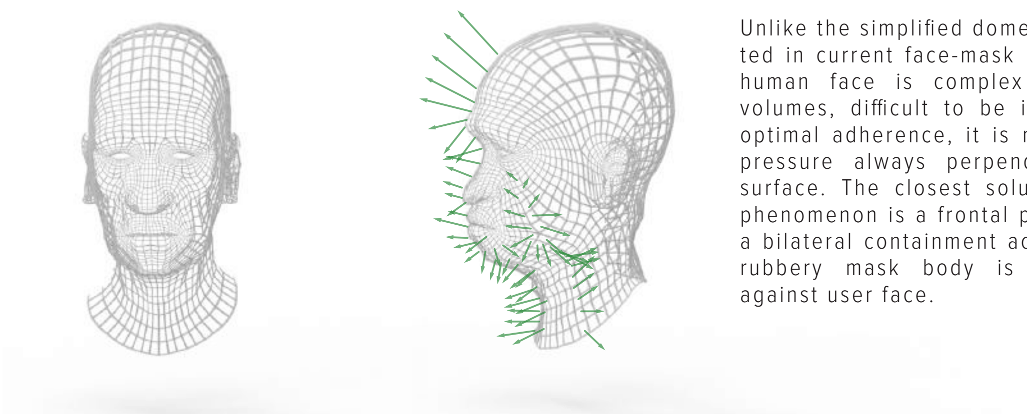
By analyzing face-mask fitting solutions in the actual market it appears clear that some limitations and aspects of weakness leave space for improvement in the design.
The principle currently followed is to compress and deform the elastic body against user face by tensioning side-laces and adapting the dome to the visage by ensuring a tight seal.
This principle only partially compensates difference between face shapes and is limited by material deformation capacity and geometry of the dome; furthermore this solution requires a lot of tension to be mantained over time, thus causing discomfort to many users.



Mask compression
(rubber body deformation)

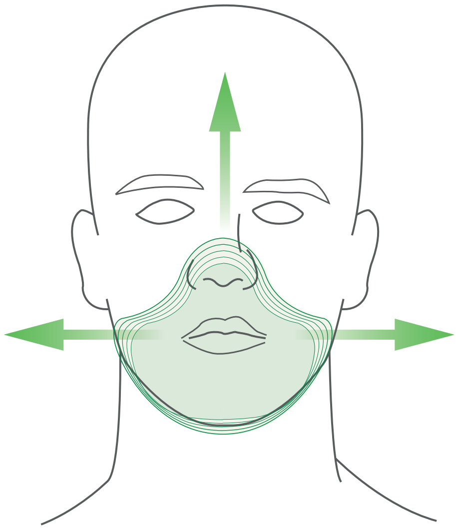
Tensioning action
(point of intervention)

Combined action

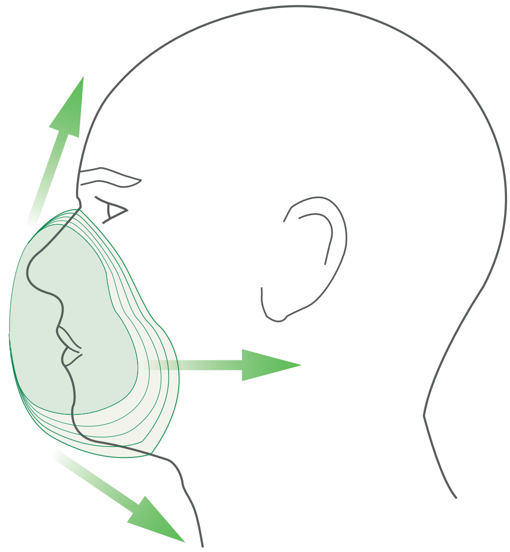


Vectors normal to face mesh
(visualization)

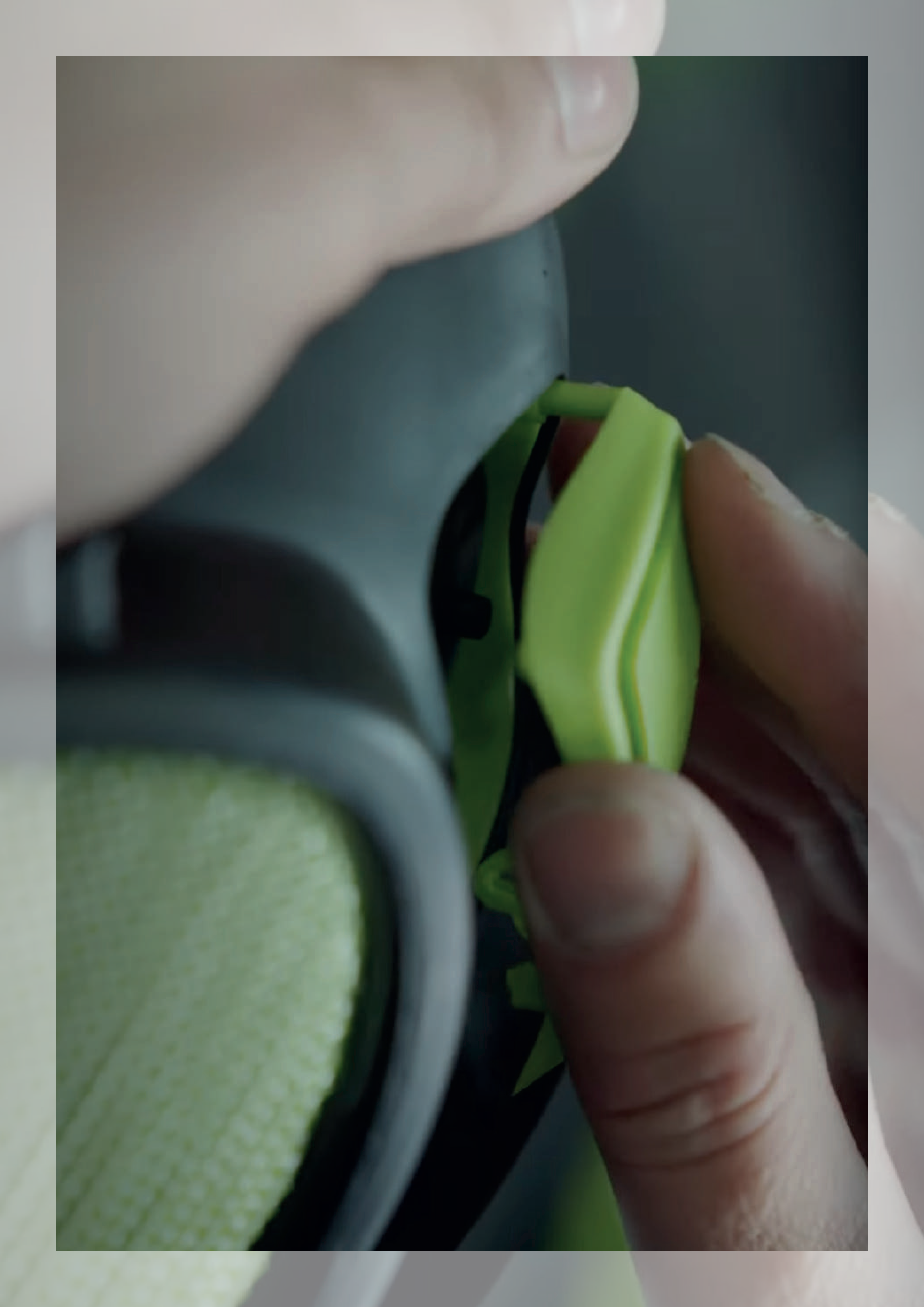
Unlike the simplified dome/calotte shape adopted in current face-mask bodies, the shape of human face is complex and with different volumes, difficult to be interpreted. To exert optimal adherence, it is necessary to apply a pressure always perpendicular to the face surface. The closest solution to this type of phenomenon is a frontal pressure combined to a bilateral containment action. In this way the rubbery mask body is correctly deformed against user face.



Frontal action
(expansion-expansion)



Side action
(extension-compression)



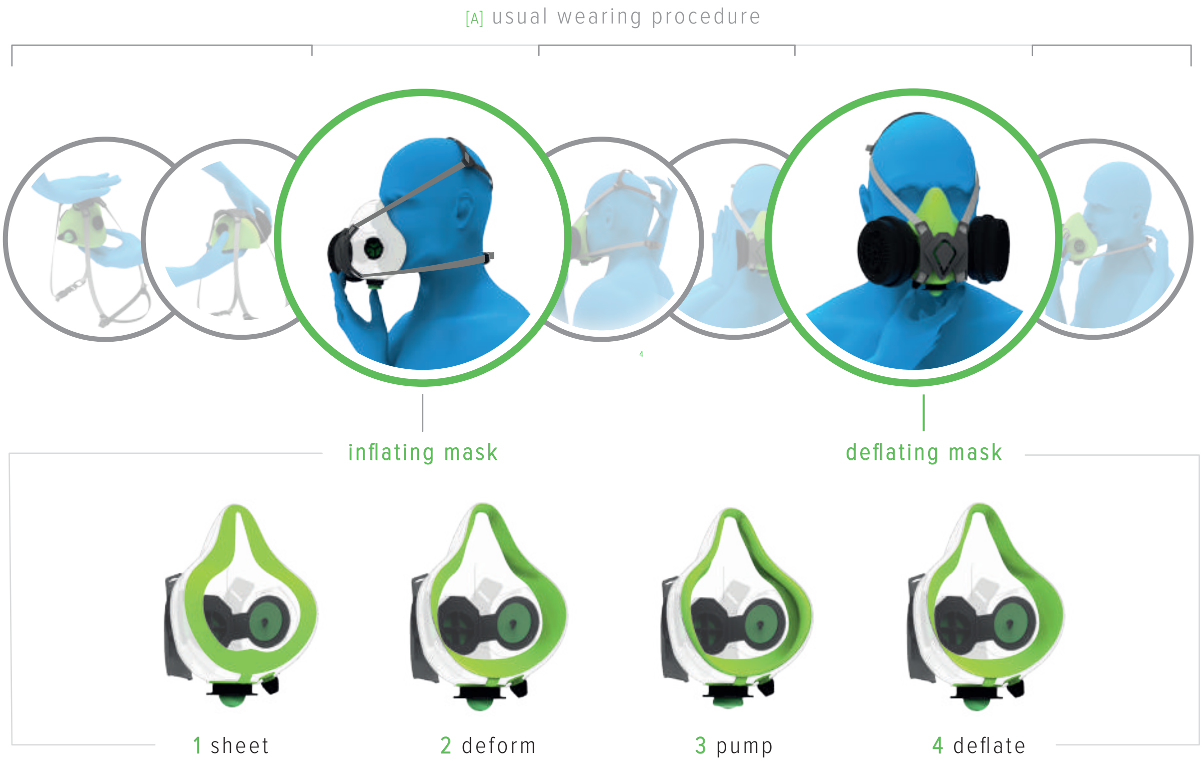
7.0 Product interaction

user journey and workflow

7.0 Product interaction
user journey

Here introduced the user experience and interactive work-flow to be performed when wearing and operating with the “Pump system”. In the following pages every step will be deepened and covered to describe the intended (correct) procedure when using the product. The complete operation is subdivided in 8 main steps and will be the topic of this chapter. The overall work-flow stays almost the same without undergoing significant variation if compared with usual hal-face negative pressure masks.

In the below picture a simplified overview of the complete procedure is given; the two green highlighted steps are those were innovation is taking place and represent a point of break with the past. This areas stand for something new, it is where inflation and deflation operations take place and represent the addition to something new to users routine. Areas in grey are those shared with current masks wearing procedure. The concept introduces a disruptive innovation with the intent of altering minimally user habits during the daily-working routine.



[B] visualization of inflating operation (pump)

[B] visualization of inflating operation (pump)

[C] visualization of deflating operation

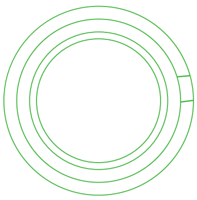
1 Mask assembly

composing the structure

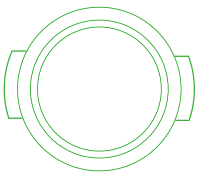
[D]

Structure

The first step to be performed during the wearing procedure is assembling the mask.
This steps is performed on every reusable half-face negative pressure mask before use and remains unaltered in the case of the Pump system.
In BLS face-mask architecture the rubber body is compressed between mounting frame and front-shield thanks to a bayonet mount between the components. The frame acts as structure to form the mask body, couples the shield and houses inhale valves; the front shield preserves the exhale valve and belt loops.



RD 40
threaded mount

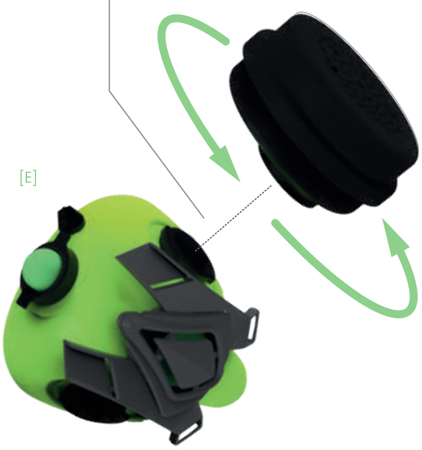


B-LOCK
bayonet mount

Mount filter
air push-in mechanism

2

[E]

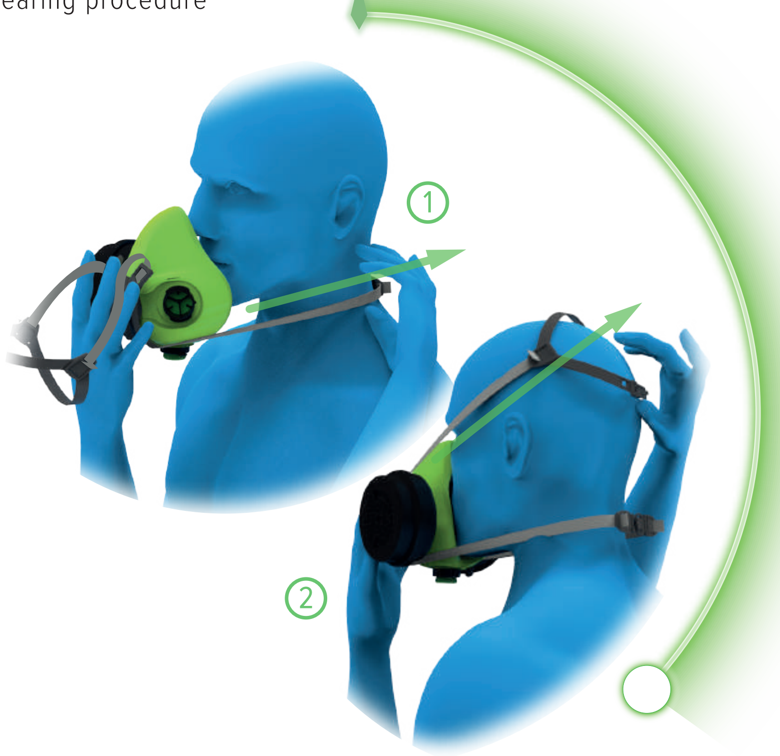


Coupling

After the mask is correctly set and before wearing it on the visage by the user, filters are coupled and mounted to the structure.
Protective face mask are available with a single centered filter or with twin side filters, such as in this configuration. Filters are provided with different categories of protection, dimensions and (most relevant) different coupling mechanism; a bayonet mount is used to join and tighten filters to the frame. After filters are mounted the mask is ready to be worn.

3

Wear mask and adjust laces
wearing procedure



Less demanding tightening

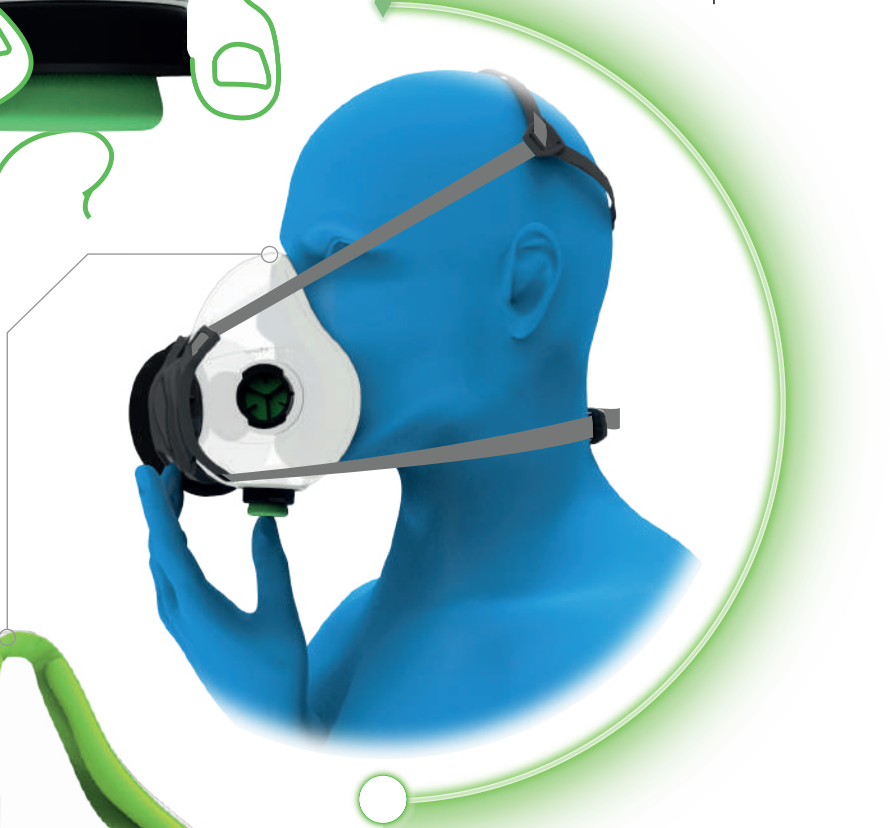
As for normal masks, the face-piece has to be worn by the user to cover respiratory tracts and subsequentially adjusted on laces to tight and meet the right fit.
While this phase is crucial and usually requires a lot of tensioning force on the belts to be correctly accomplished on common face-pieces, the scenario is different for the Pump system: the inflatable lip is made of a very thin soft silicone layer, this allows the surface to easily adapt to user visage without requiring excessive tension. In this way it is enough for the user to gently step-in the mask with the visage, making the lip adapt to it and regulating the laces to mantain the position on face.

a pinch-notch helps to manipulate and hold the pump dome during operation

Pump

adaptive fit inflation

4

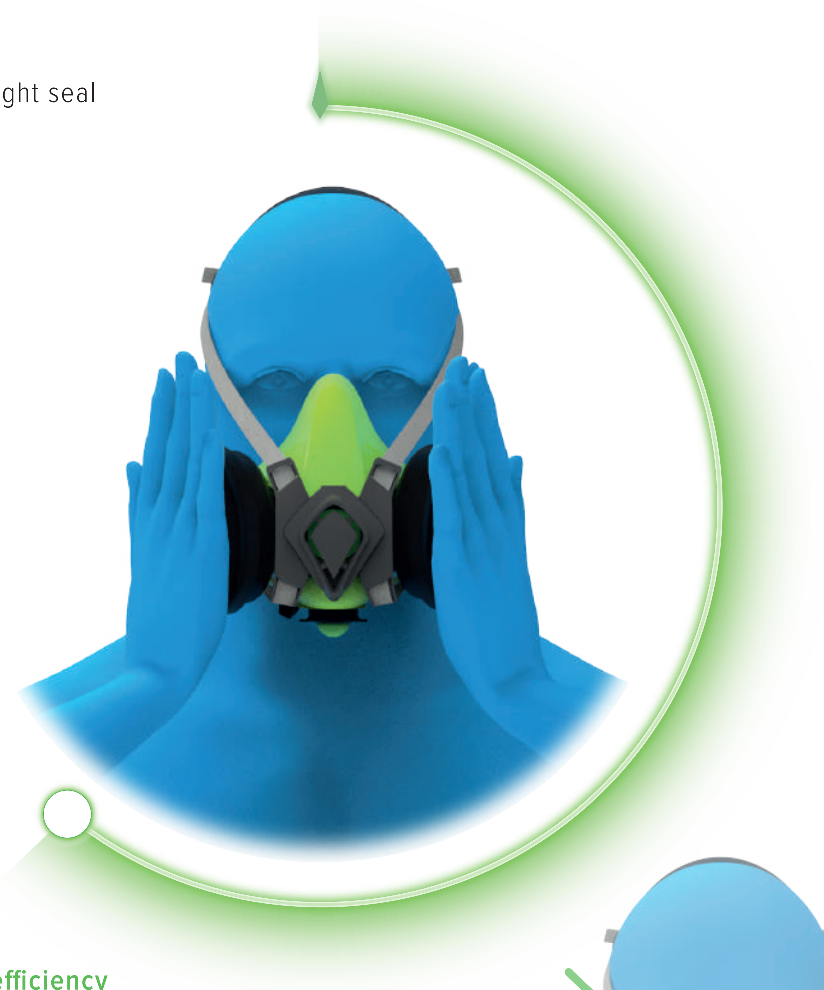


[G]

Push-in to adapt

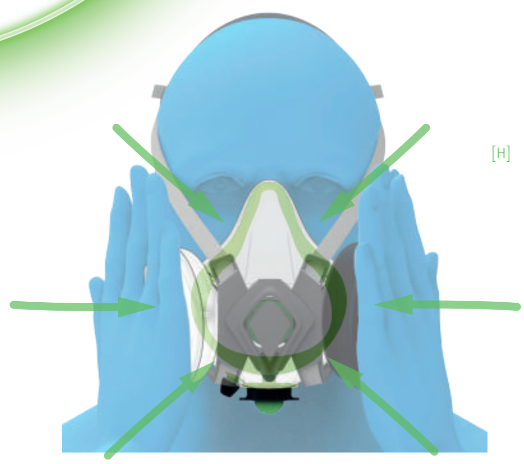
Core of the wearing process and user experience is the pumping procedure!
The pumping phase allows the user to regulate the pressure inside the lip chamber and to inflate the cushion untill it is fitted safely and comfortably on the visage. The inflatable lip allows compensation of different face sizes and shapes. The user can increase the pressure of the chamber by pushing multiple times on the elastic pump dome, thus by directing air into the circuit. The Pump system allows custom regulation by providing a personalized experience every time of use.

5 **Fit-check**
ensuring tight seal



Testing protective efficiency

The fit-check is a mandatory operation for industrial workers and has to be accomplished every time after wearing the mask and before starting with the working activity. The same procedure has to take place after adjusting the Pump pressure on visage: in order to verify the presence of a tight seal and to ensure the correct fit negative pressure is induced in the mask body. If the seal is tight the rubber body is going to deform and deflect because of the inner pressure. In case of a loose fit pressure in the chamber can be increased to fill leacking gaps and to compensate even more marked differencies.

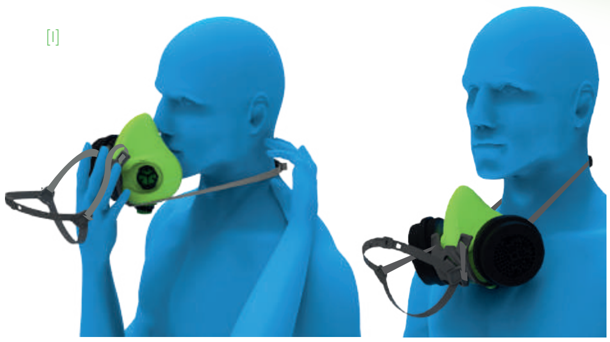


[H]

Working activity during use 6

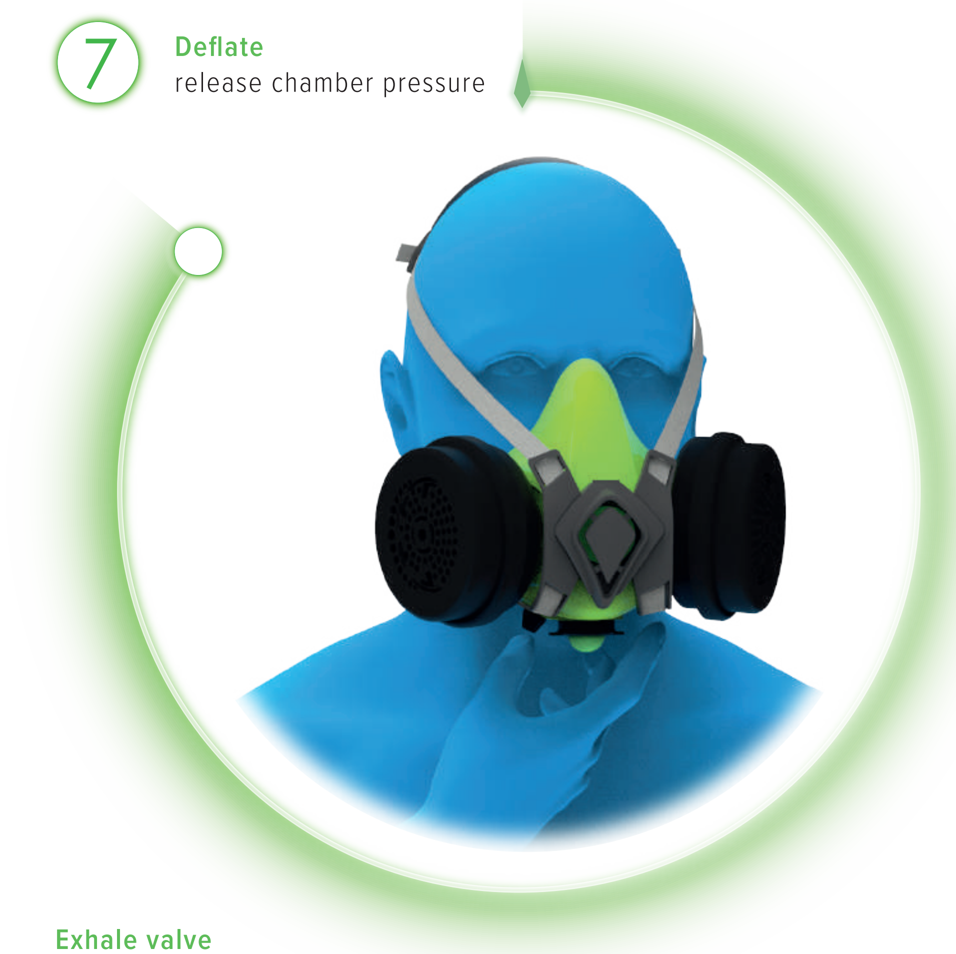
At work

[I]



During the execution of the working activity and when operating while wearing the mask the user can benefit of several advantages brought by the “Pump system” such as comfortable fit, less tensioned laces and less pain while working, resulting in higher concentration and comfort. In case of pressure loss (after hours of activity this might happen) the desired pressure can be easily restored by simply pushing the dome again. The same is happening in case of a mask drop-off by the user: every time the mask in unworn the chamber has to be deflated and inflated at every new use, this allows the worker to experience a custom and adaptive fit for every activity.

7 **Deflate**
release chamber pressure



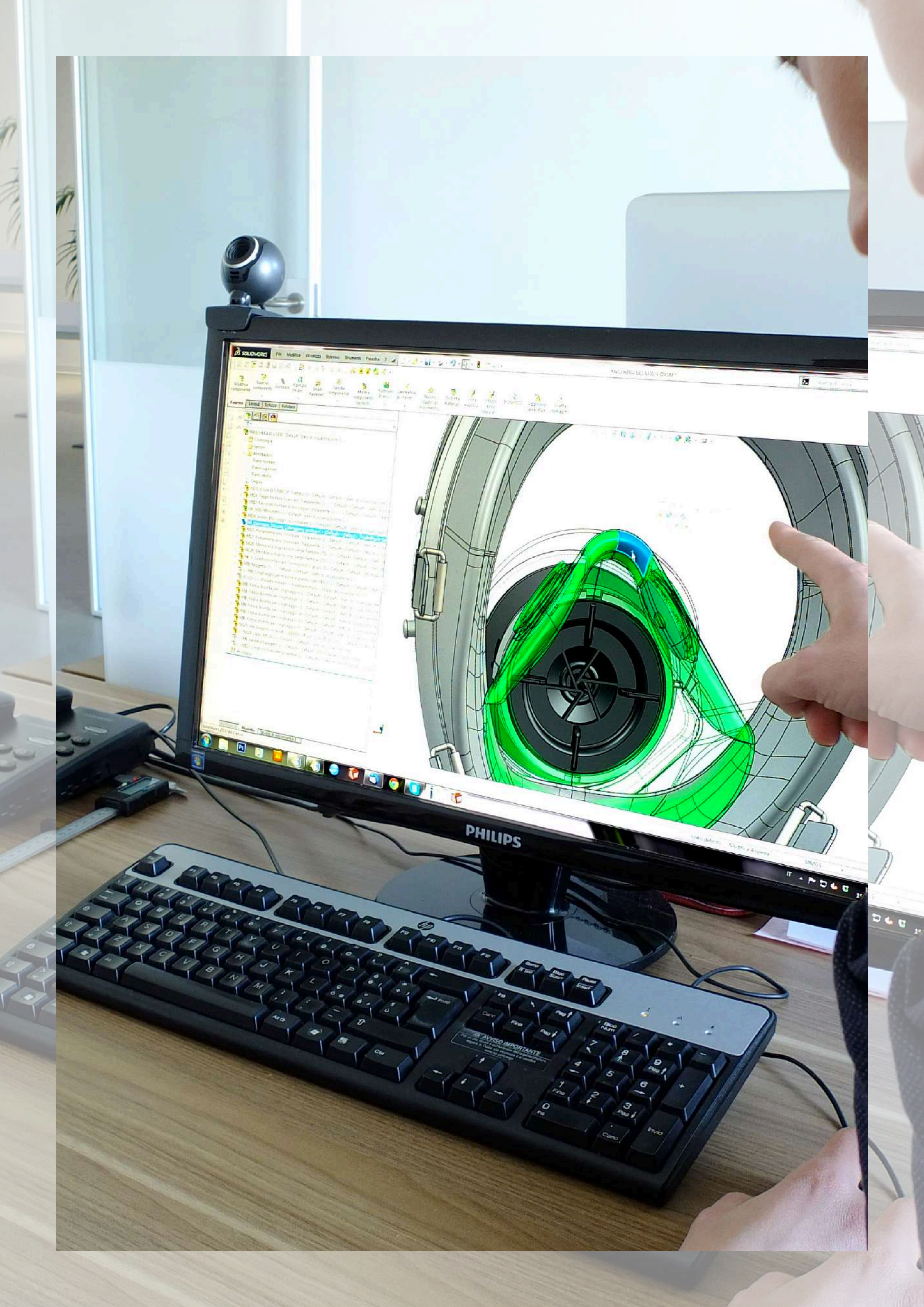
Exhale valve

After performing the working activity the exhalation valve can be activated to release internal residual pressure.
By pushing the soft dome with the finger air is free to escape and the inflated body can be relaxed.
The soft dome is evident and very easily manageable even in shaked conditions and when wearing gloves.
The deflating operation is lightning fast and immediately escapes the inner air within seconds. The finger is mantained pushed during the entire operation and air flow is interrupted as soon as the finger is removed. The chamber relaxation can be perceived by the user all around the face.

Unwearing

[M] mask disassembling

After the activity is over and the pressure chamber deflated, the mask can be finally removed by the user.
The steps to follow are, in order: first remove head retention and bring it to front, then unlock the clipping frame on the neck.
After this operation are perfomed the mask can be disassembled, restored and put away until next use.
Particular care has to be put by the user when handling the mask after use: the inflatable lip represents a fragile component and can be considered a weak component because sensitive to holes and openings


PHILIPS

8.0 Detail design

definition of functional aspects

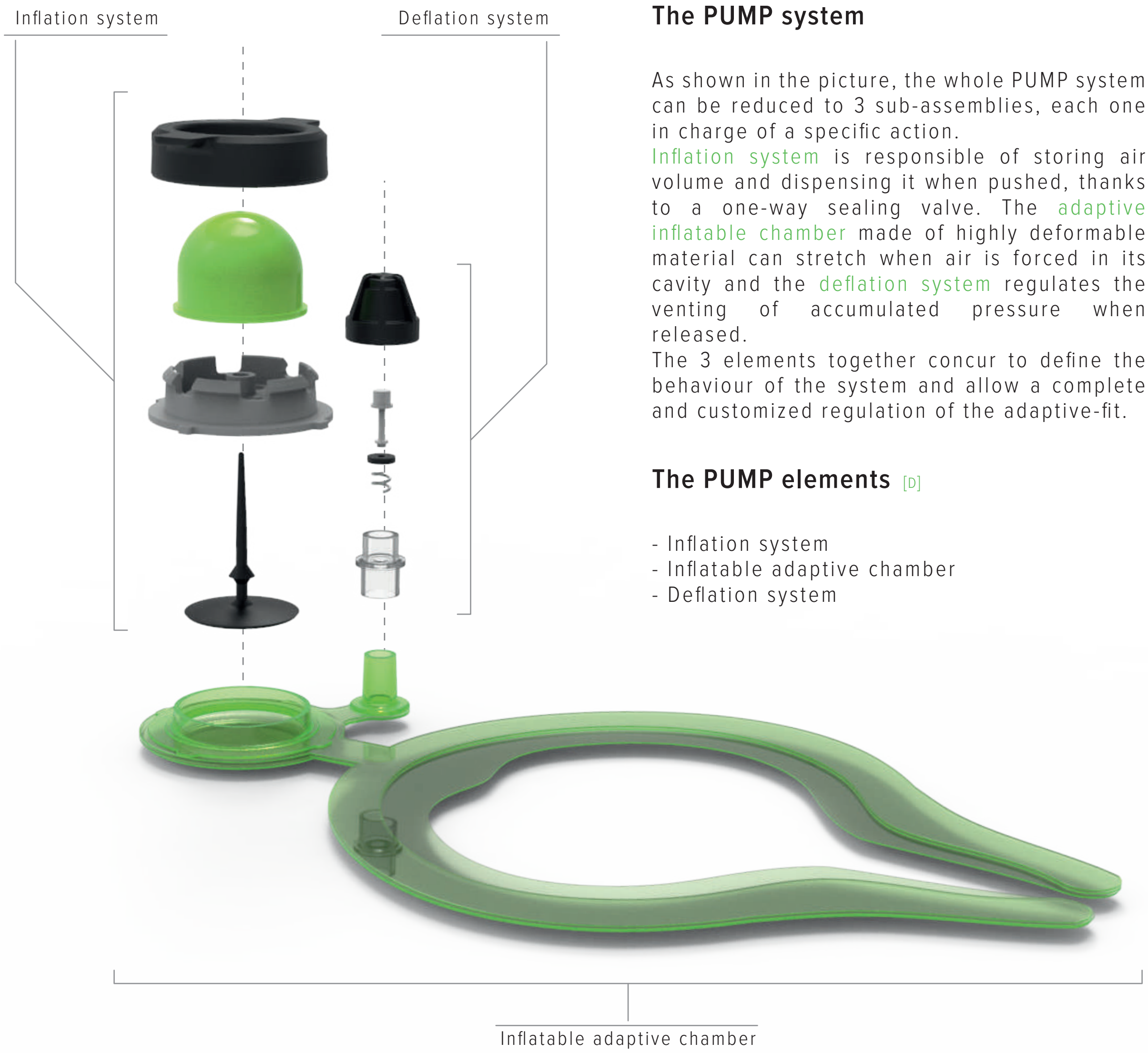
8.0 Detail design - functional aspects
design and definition of detailed elements

In this phase of the project i focused on technical and specific considerations around the design of key elemets defining the concept of the PUMP and its working principle.
As previously shown, the main innovative aspects introduced and theorized in the adaptive-fit concept are referred to the inflating chamber system to be finally equipped on any negative pressure half-face mask.
The elements are designed to provide an all-in-one solution integrated with face-mask body. In the following pages the critical aspects and key features in the selection of the technical solution employed are highligted.

The main effort behind the conceptualization and realization of the PUMP system has been put into the refinment of the components here shown. The selection and choice of the functional/key elements of the system has undergone many comparisons and validation phases. I ended up by selecting already diffused and in-use components (BUY) for some of the project aspects, while I designed custom elements for the intended specific behaviour/action required by the system.
In this way i could obtain the working principle researched by compromising with efficiency, customization and cost of the investment.

[A]

[B] elements visualization



The PUMP system

As shown in the picture, the whole PUMP system can be reduced to 3 sub-assemblies, each one in charge of a specific action.
Inflation system is responsible of storing air volume and dispensing it when pushed, thanks to a one-way sealing valve. The adaptive inflatable chamber made of highly deformable material can stretch when air is forced in its cavity and the deflation system regulates the venting of accumulated pressure when released.
The 3 elements together concur to define the behaviour of the system and allow a complete and customized regulation of the adaptive-fit.

The PUMP elements [D]

- Inflation system
- Inflatable adaptive chamber
- Deflation system

8.1 Inflation system
air push-in mechanism

One-way inflating system

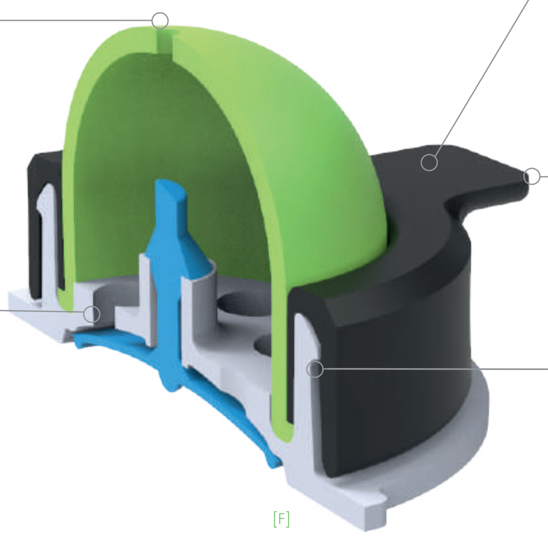
This part of the system deserves a crucial role into the PUMP working mechanism and has been at the center of the design exploration during the whole development of the project.
The system consists in a single unit performing a double action: from one side it act as an air storing chamber, thanks to the volume of the elastic dome it is able to accumulate air in its inner cavity. On the other side, when pushed on the chamber the body is compressed and the air is forced into the chamber and sealed thanks to a one-way umbrella valve. After releasing the pressure exert by the finger the elastic dome is able to relax and can return to its initial shape, thus restoring the initial amount of air in its cavity. The system behaves like a very small pump, directing the air into the inflatable chamber. In this way, with a simple action, the dispenced amount of pressure can be regulated by the user.

System key properties

- low cracking pressure
- high resistance to backward pressure
- tight seal (precise coupling and housing)
- sufficient air capacity in the dome

closed valve - high backward pressure
(deflation)

opened valve - low cracking pressure
(inflation)



[F]

vent

a small hole on the top of the dome allows the passage of air. When the dome is pushed the user covers the hole and forces the air one-way

housing

base housing must provide a tight seal by coupling with the the umbrella valve. A series of openenings allows the air to flow in the desired direction

clipping cover

a cover clips the system togheter and locks the dome by sandwiching with the housing base

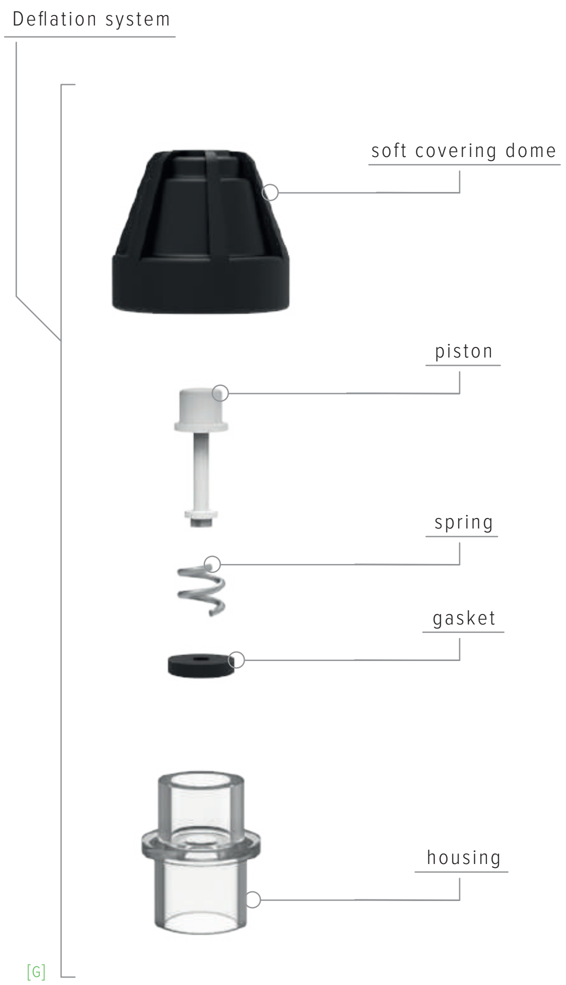
pinch hold

an easy grippable pin helps the user to push against the dome when wearing the mask

press-fit

a safe press-fit gripping all around the circumference ensures the coupling between components

8.2 Deflation system
air escaping mechanism

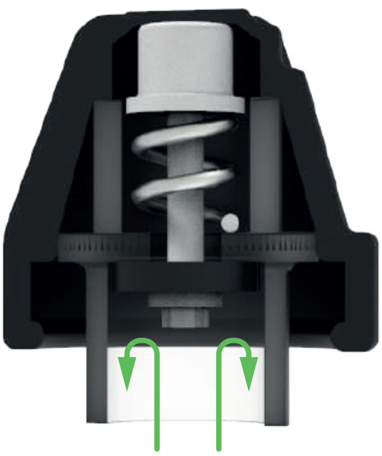


Deflating system

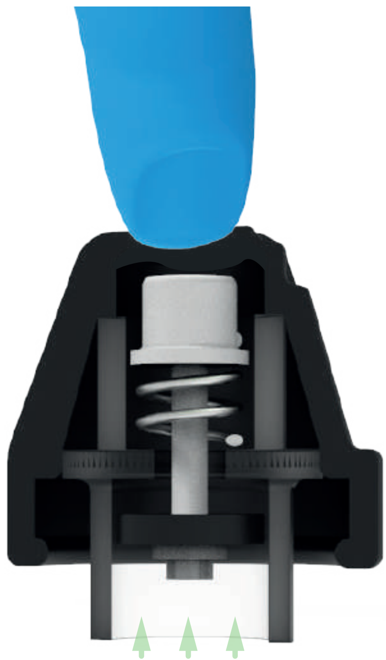
To release the accumulated pressure in the chamber an exhale system is required.
Another very important aspect of the project has been the research, development and comparison of exhale valve solutions.
After documenting myself in the field, i decided to go for an already manufactured exhaling system (BUY component). The exhale valve is mantained in a closed state by a spring acting in compression and pushing a tiny gasket against the inner channel. When the spring is relaxed by the action of the user, the gasket is moved apart from the channel and air can escape. To facilitate the action to the user (often wearing gloves) and to cover inner mechanism from possible damage i designed a custom soft cover to be installed on top of the ready-to-go valve

System key properties

- safe (no leackage - high backward pressure)
- quick to be released/activated
- quick deflation
- non invasive
- simple to be installed (manufacture)
- simple to interact (user)
- BUY component (if possible)



valve in tension
(closed valve)



valve relaxed
(open valve)

stem
a rigid piston is kept in tension by the action of a coil spring. It acts as a pin to be pushed by the user. When pushing the stem the spring is compressed and air is free to leak

o-ring
an o-ring gasket provides sealing by covering air vent. The gasket is supportive to the rigid body of the stem

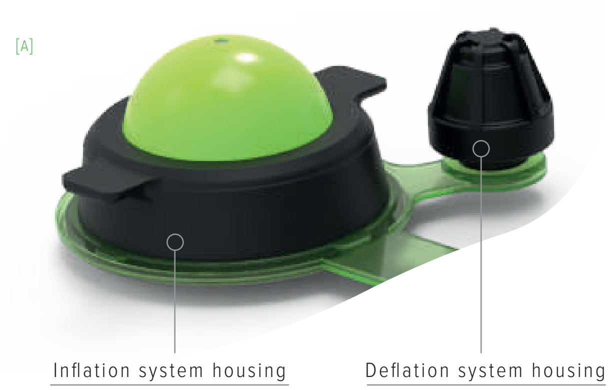
soft cover
a rubber cover is added to the system to enable easy manipulation even with gloves on

coil spring
a steel spring can be relaxed to let the air escape. When active the spring pushes up the piston

housing
a PVC housing contains the main working mechanism elements and allows to be glued and manipulated

8.3 Inflatable chamber
sealed air cushion

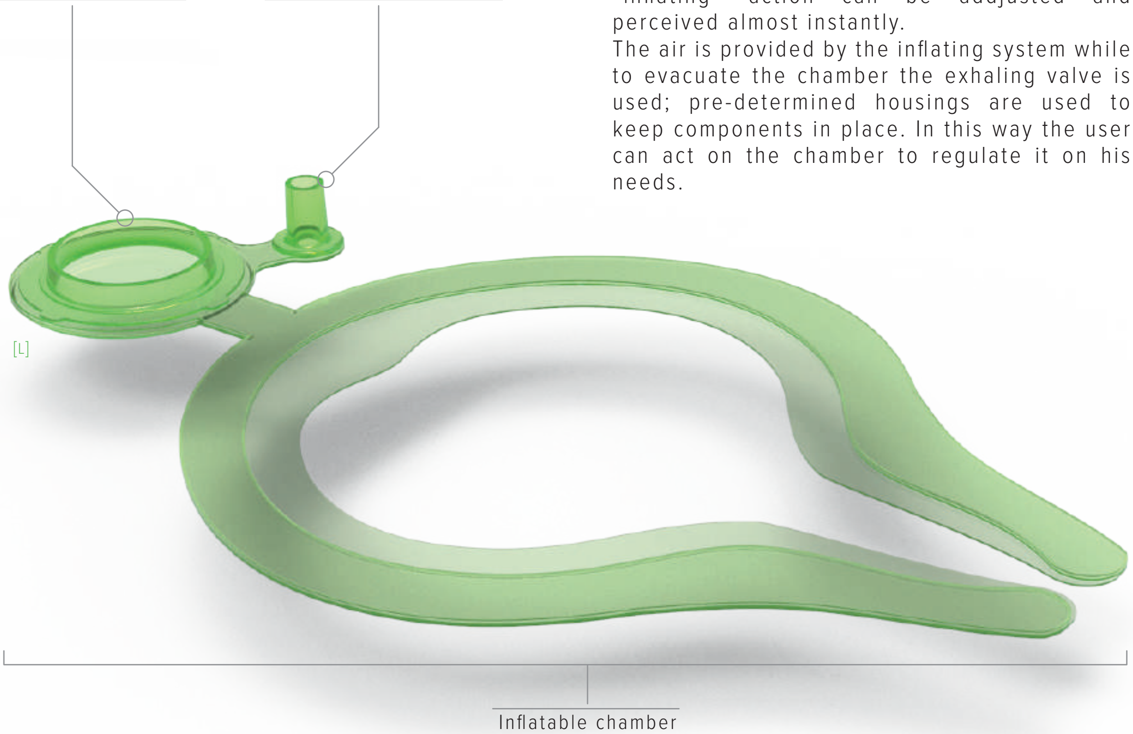
[A]



Inflatable cushion-chamber

The inflatable and deformable body is at the core of the adaptive-fit concept. The circuiting shape is the result of many iteration and tests, and is proved to be efficient in compensating different face ergonomies when inflated.
The body is made of two ultra-thin (0.30 mm) silicon layers joined togheter to create a tight chamber. Beeing the chamber so tight and the material highly deformable due to its thickness, geometry and hardness (shoreA 15) it is very susceptible to pressure introduction and the "inflating" action can be addjusted and perceived almost instantly.
The air is provided by the inflating system while to evacuate the chamber the exhaling valve is used; pre-determined housings are used to keep components in place. In this way the user can act on the chamber to regulate it on his needs.

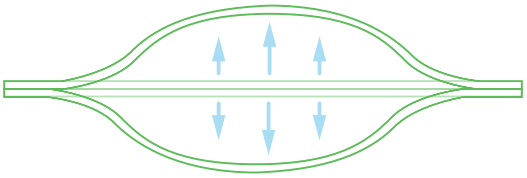
[L]



System key properties:

- material (hardness)
- geometry
- wall thickness
- max. pressure
- air tight and sealed
- material compatibility and manufacturability

relaxed chamber - section view

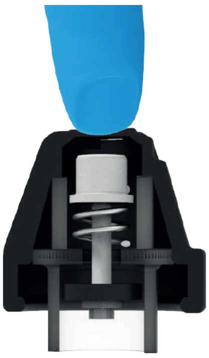


inflated chamber - section view

air circulating path

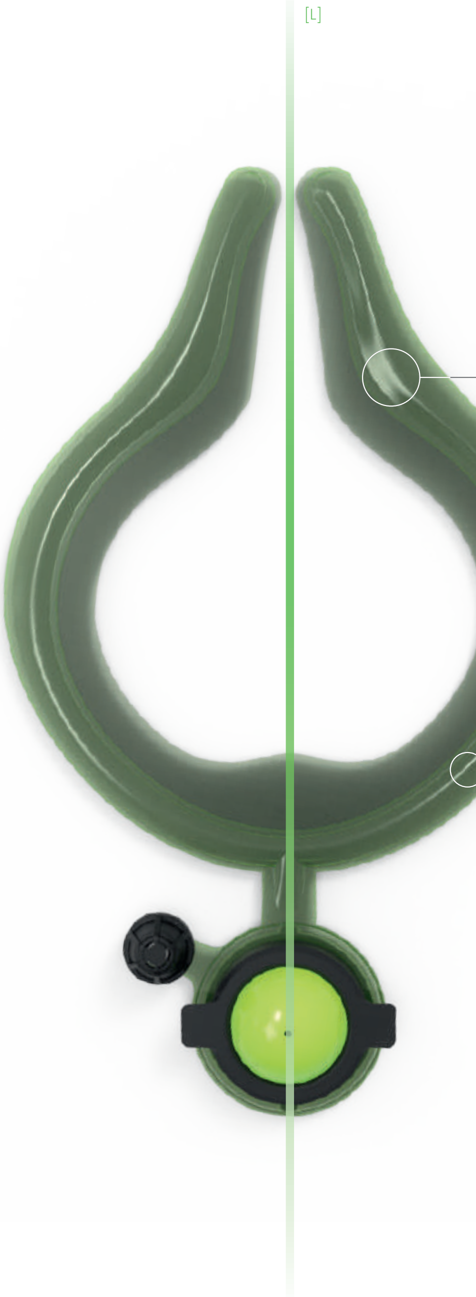
8.4 Functional details

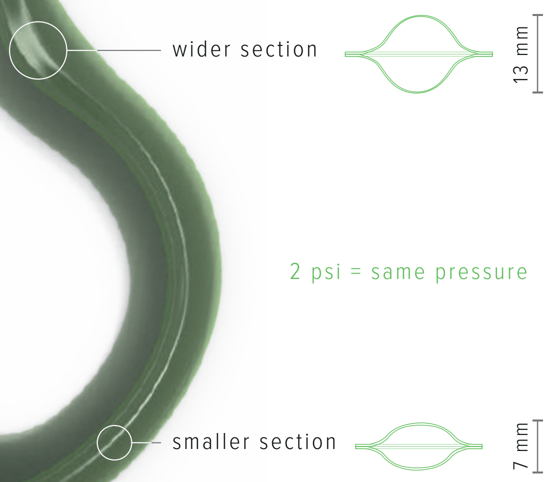
system behaviour during use



- single push
- 1-2 seconds
- pressure release

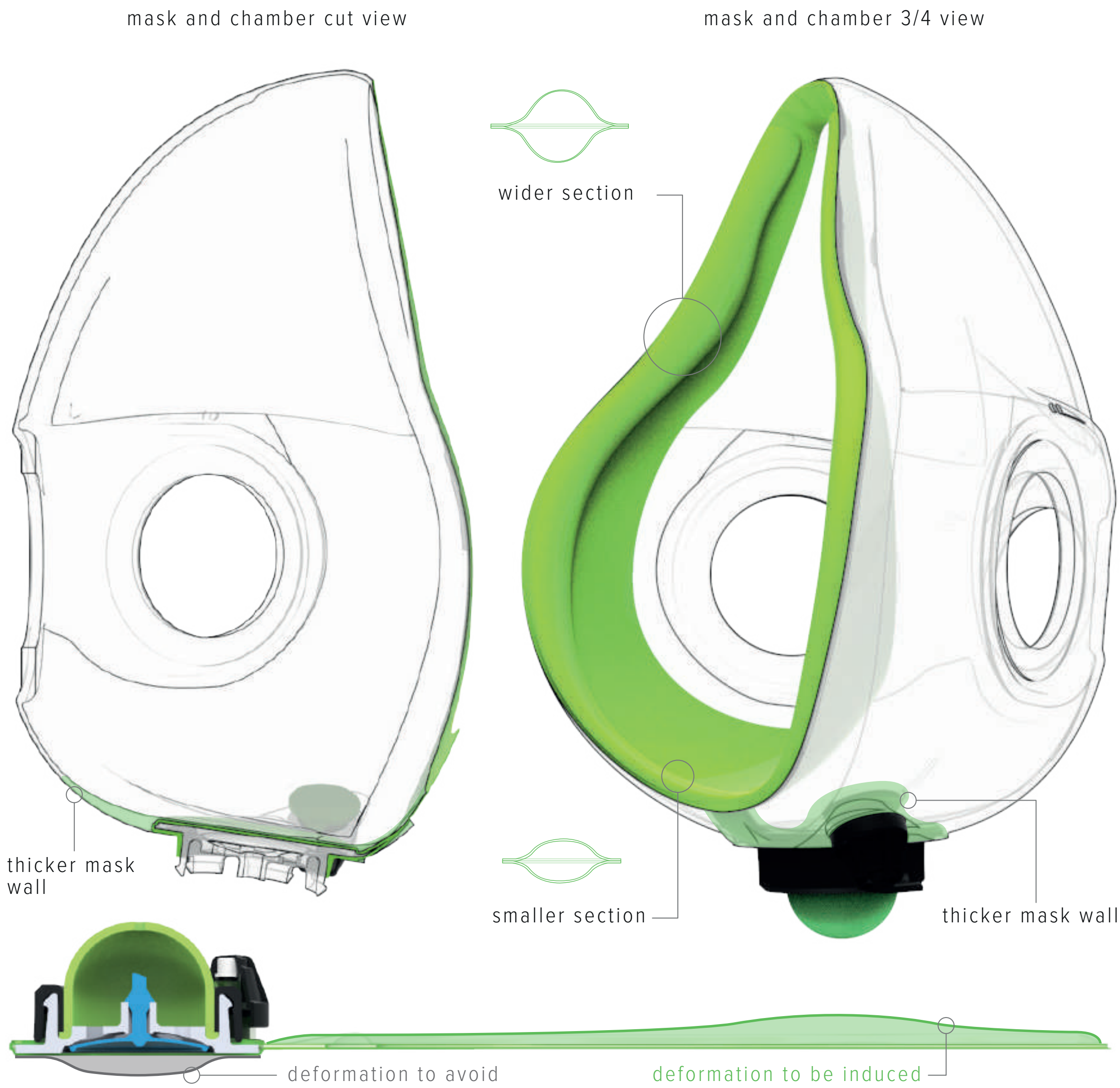
- 5 to 6 pushes
- 10 to 30 seconds
- max inner pressure





Inflation behaviour

Thanks to a variable path-size of the harness chamber the action of air can be modulated differently in the selected areas. To stem unwanted deformations when inflated in mask the chamber is surrounded by extra material, thus thickering the body and directing active deformation to the lip sealing area



[M] flat chamber representation


BLS 122B

9.0 Manufacturing and assembly

productive aspects

9.0 Production and assembly

manufacturing steps

In the following pages I'll give an overlook on the different phases and processes required in order to manufacture the complete Pump system, and how to integrate it in the production of any half-face mask.
The proudctive sequence has been entirely conceived and designed.
Custom-made and non-standard solutions were put in place to obtain the very specific product requirements and to define a straight-forward manufacturing strategy.
The process wanted to be automated (as much as possible) and reduce possible defects during production, especially during the creation of the inflatable chamber. The manufacturing phase can be divided into 2 macro-steps:

1 mask body

- 1.2 pump dome
- 1.3 press-fit cover
- 1.4 soft cover
- 1.1 overmolded mask body
  - 1.1.1 inflatable chamber
    - 1.1.1.11 silicone chamber
      - 1.1.1.11.1 layer A
      - 1.1.1.11.2 layer B
    - 1.1.1.12 check valve
    - 1.1.1.13 infl. housing
    - 1.1.1.14 exhale valve

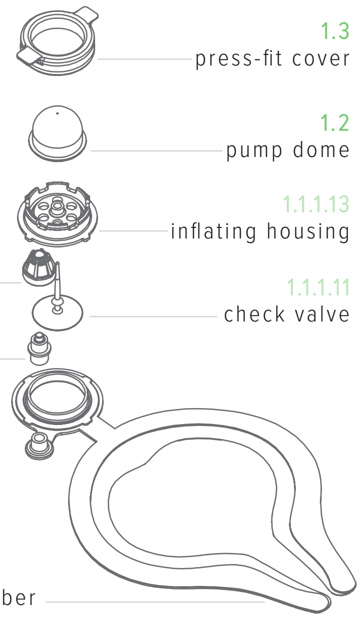
injection molding extraction asset [A]

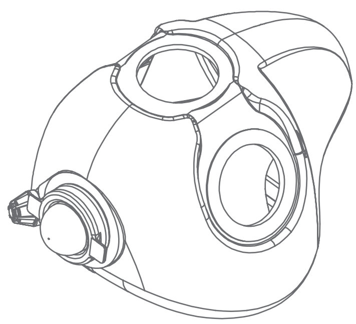
manufacturing of the inflatable chamber

The first part of the following pages is entirely dedicated to the manufacturing procedure in order to produce and assemble the “Inflatable Chamber” unit. The unit (composed by its “exhale” and “inhale” sub-systems) can be seen as the grounding element for the creation and performance of the “Pump” inflatable mask body.
The unit is designed to be processed indipendetly by the rest of the body and is the result of a dedicated production line. In this way the unit can be seen as a product for itself and is handled and integrated with the mask in a second moment. In the picture below an exploded view of the “inflatable chamber assembly” is provided for clarity.

integration with face-mask

In the second part of this chapter the focus will be put on the integration of the “inflatable chamber” with the half-face mask body.
A separate operation is required to manufacture the mask and to integrate the inflatable unit in-process. The mask manufacturing technique differs short from what is actually the practice on market (injection moulding); the peculiar aspect is the addition of the inflatable unit prior to mold clamping and closure. This allows the chamber to be incorporated into the body and to be merged together thanks to an overmolding process.
In the chapter general description and overview of the process and procedural steps to manufacture the mask will be given.

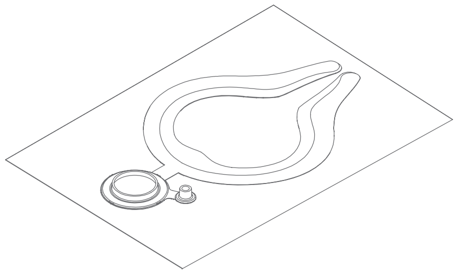




9.1 Inflatable chamber
manufacturing process

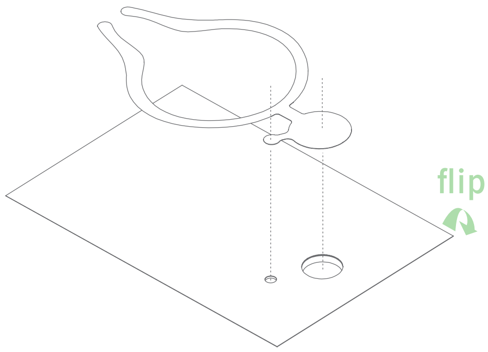
1
cast

The first halve of the geometry is obtained through a silicone die cast or injection moulding.
Tight tolerances are required for this part since it carries housing for the inflation-deflation systems and has to interface with its rigid components. A 0.2mm thickness is achieved on the rest of the sheet



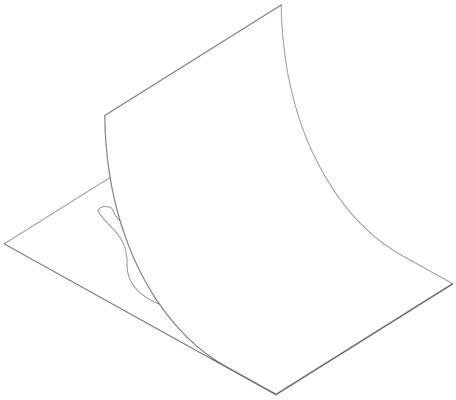
2
mask

The casted sheet is flipped in the direction and processed from the other side. A very thin TPU sheet is juxtaposed on the silicone layer and used to mask the desired area to be inflated. Thanks to its high creep resistance and low thickness the TPU mantains its position during the whole process



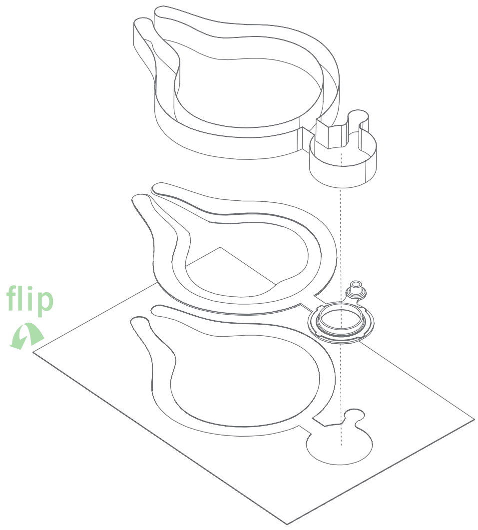
3
cover

After covering the silicone sheet with a mask, another thin silicon layer can be deposited over the entire surface.
The TPU acts as barrier between the previous layer and the fresh casted silicone. Liquid silicone is deposed and stretched equally on the entire surface



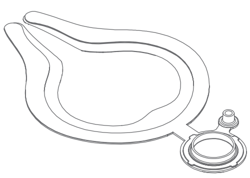
A roll of 0.2mm thick silicone is unwinded on the fresh silicone, bonding together the two layers.
The process can be accellerated by inducing pressure and heat in the enviroment, enabling the silicone to cure faster. The conditions are mantained untill silicone completely cures and bonds.

4
bond



The bonded layers are finally punched by a die and cut in the desired shape.
The final inflatable chamber is obtained and the rest of the sheet is left as scrap. It appears clear how allignment between different work-stations or working phases has to be managed carefully

5
punch



The final inflatable chamber entirely made of silicone is obtained. Inflation tests are perfomed at this stage in order to ensure lack of defects in the system. When the chamber is considered "reliable" it can move to next phase.

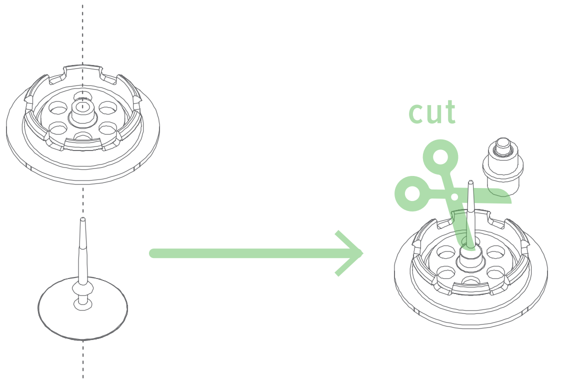
6
test

9.2 Inflatation and deflation system

manufacturing process

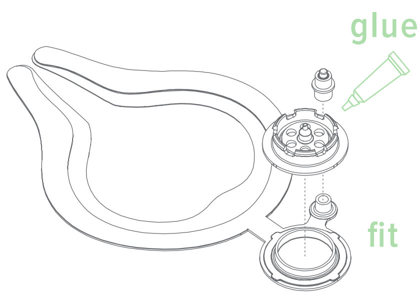
1
valve

The inflation system is assembled before being inserted in the silicone chamber. The valve is forced in the housing and shortened by the tail, once inserted. The valve is cut to reduce the overall dimension and to limit the interference when pushing the dome during inflation



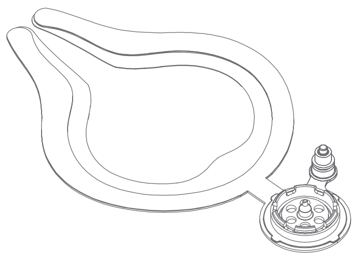
2
housing

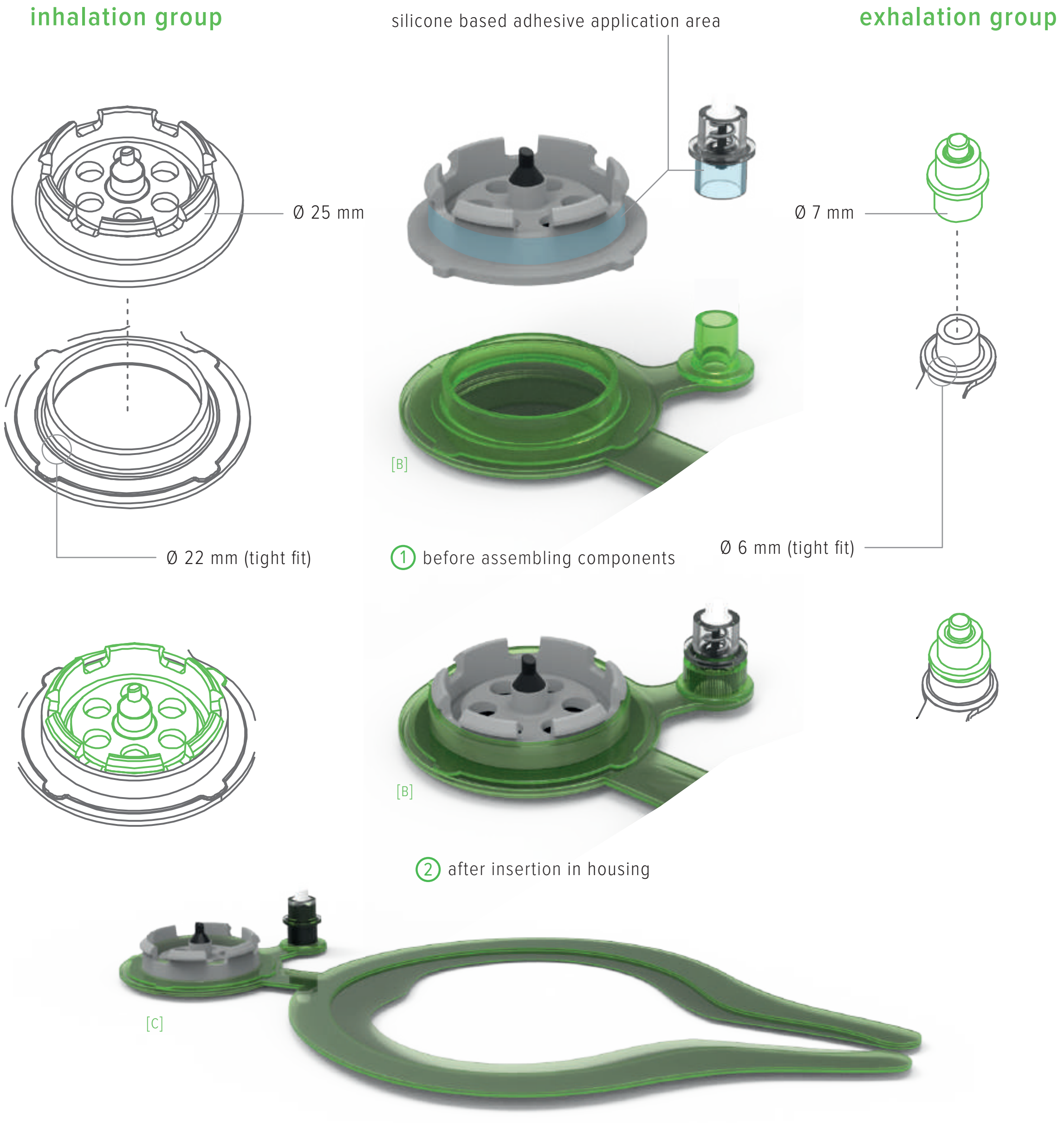
The inflation [CUSTOM] and deflation [BUY] systems are inserted into the silicone inflatable chamber. The housings in the main body provide a safe and unique way to insert elements. Interference diameter are slightly smaller than nominal dimensions and need to be deformed during insertion. A silicon glue is used during insertion to enforce the coupling



3
system

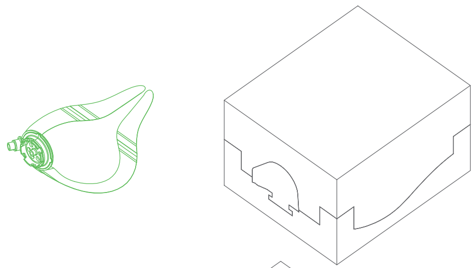
After the glue hardens the entire system can be tested one more time by using inflation and deflation elements in order to evaluate the overall efficiency. The chamber at this phase must prove the functioning of the one-way valve and of the releasing stem system.





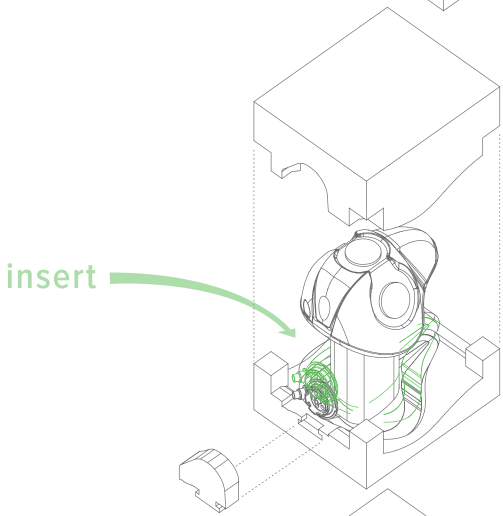
fully assembled chamber before mould insertion

9.3 Half-face mask inflatable chamber integration
manufacturing process



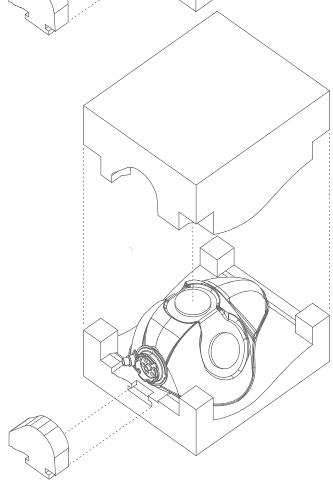
1
integrate

After the inflatable chamber + the basic elements of the pumping system are produced and sealing of the chamber in ensured; the chamber can be finally integrated with the face-piece. The system will be inserted in the mould prior to material injection



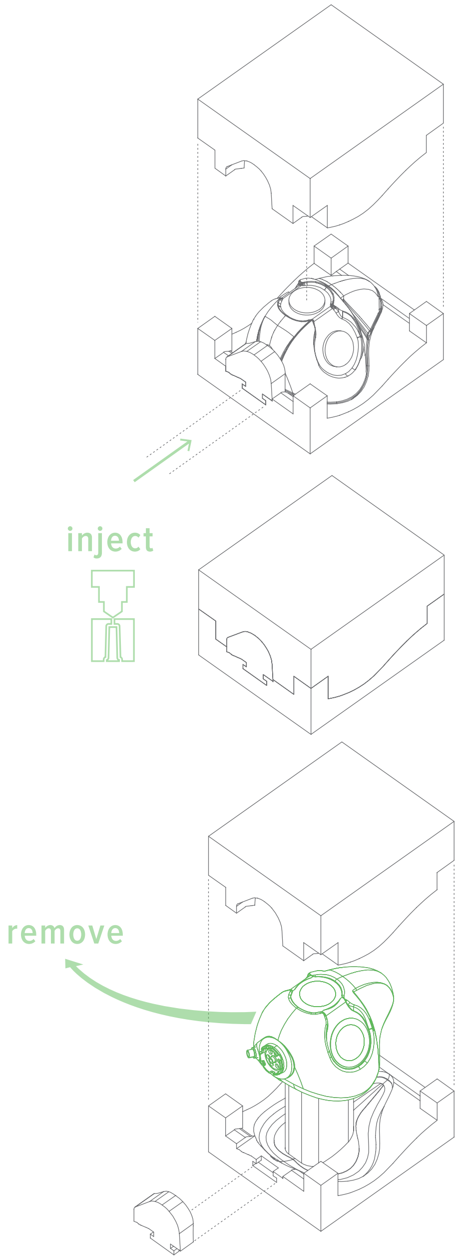
2
insert

The mould is opened and the main body (punching dome) is lifted with respect of the grounded basement. This allows the pump system to be inserted by placing it flat on the base and adjusting its positioning. Mould impressions are moving actuated by carriages



3
position

When the chamber layer is inserted the dome is closing and returns to its initial position. The chamber is pinched between the two molds while leaving out only the inflation/deflation interaction area. This area is momentarily fitted on the male-dome to mantain its position during next phases



4 position

The lateral sliding mould is responsible of compressing the interaction unit of the pump against the mould and acts as housing for the inflating and deflating elements, defining the position to be mantained by the system during the injection phase

5 injection

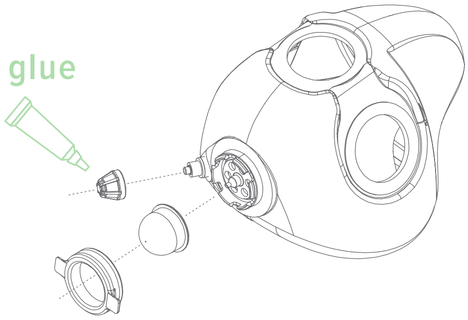
The mould is closed and every unit is returning to its initial position. Silicone can now be injected under pressure in a flowable fluid state, allowing the material to reach every small feature inside the cavity. The process is performed under heat and pressure, inducing the silicone to cure faster

6 removal

Finally the mould is re-opened and the punching dome is lifted once again to facilitate mask removal. The resulting body is wrapped around the male-dome and needs to be stretched in order to be removed from the mould undercut. The operation is performed by hand by an operator

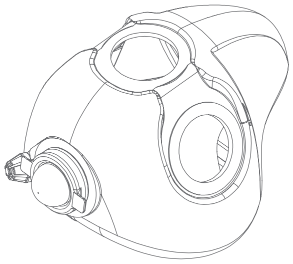
7
assembly

After the mask is removed from the mould-die final elements can be added to the pump system.
The silicone pump dome is positioned in the housing and compression-locked thanks to a press-fit mechanism coverage.
A soft dome is glued and inserted on top of the exhale valve



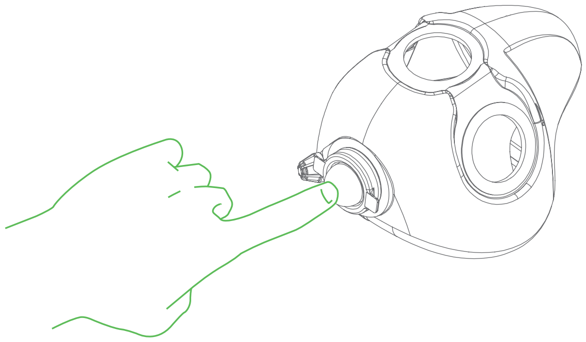
8
mask

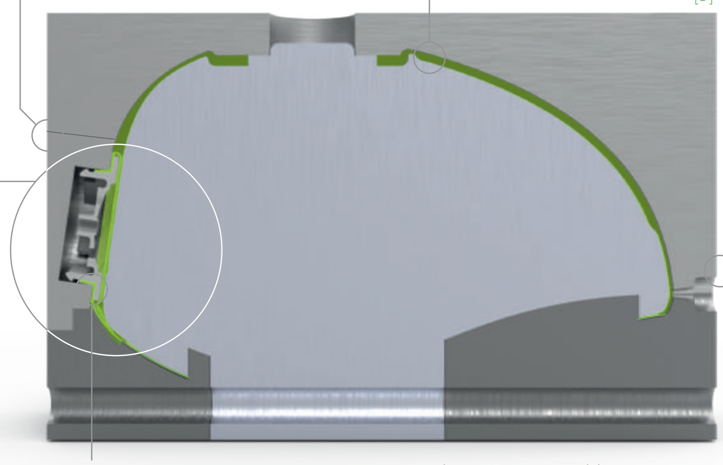
At this point the face-mask can be considered ready to use and completely integrates the inflatable cushion system.
The inflatable chamber is developed around the entire oronasal lip and can be regulated by interaction elements (inflate, adjust and deflate)



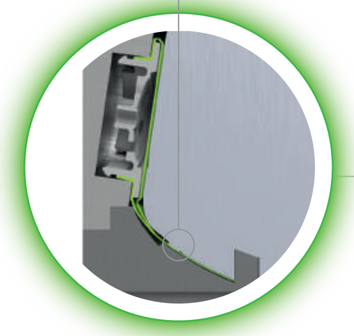
9
final test

A last check is performed on the whole system to ensure efficiency and reliability of the assembly and it's components.
Air leackage, flow intensity, cushion deformation and general presence of defects is what is investigated during this phase to ensure safety of the product

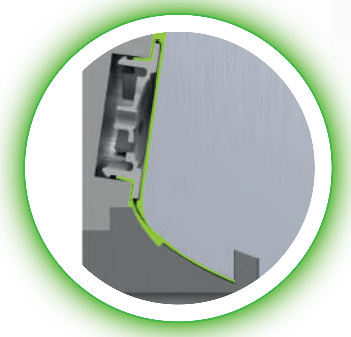




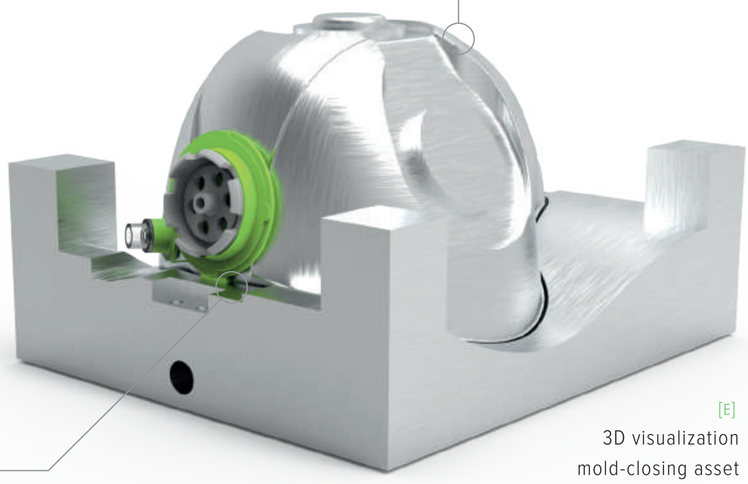
rapid prototyping mold section view



① chamber in-mold insertion



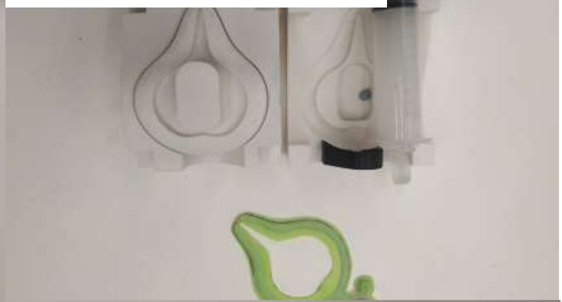
② mask body overmolding

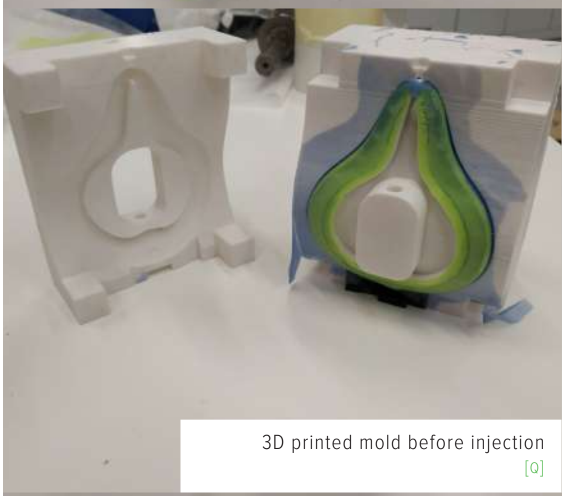


3D visualization
mold-closing asset

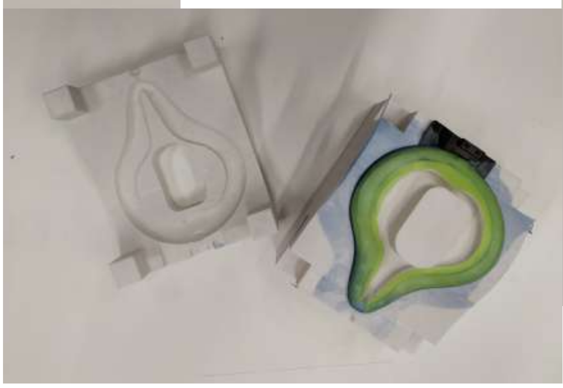
after punching the chamber between the two molds the inhalation and exhalation group is fixed on the male punch prior to insert actuation thanks to a small retaining fetaure. The body is so held in place

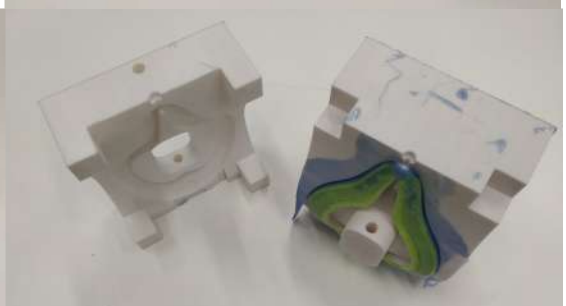
3D printed mold asset chamber insertion
[P]





3D printed mold before injection
[Q]





[R]
3D printed mold asset mold opening

[s] overmolded mask extraction

9.4 Final elements

components realization and process selection

In this phase a short overview on manufacturing processes of each component of the PUMP System is given. The short deepening aims to provide a description of the intended manufacturing processes and to point out general design rules followed during parts design. The chapter also tries to relate process to material and to spot criterias behind process selction. The overall processes can be brought back to 3 main manufacturing methods:

- vacuum casting
- compression molding
- injection molding (overmolding only for mask body)

[F]

DIY injection moulded parts

[G]

vacuum casting

refers to the production under vacuum of plastic or rubber components from moulds. Parts produced using the vacuum casting process are dimensionally accurate, precise replicas of the master pattern. This technology is suited to obtain the thin layers of the inflatable chamber and get a reliable and precise result even in case of smaller features or housings. [A]

design considerations

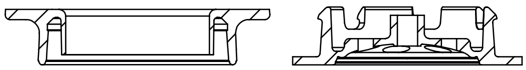
- draft angles
- avoid undercuts
- uniform thickness
- rounded corners

compression moulding

is a process of molding in which a given quantity of feeding material (charge) is placed into an open and pre-heated mold cavity. The mold is then closed with a top plug and compressed with large hydraulic presses in order to have the material contact all areas of the mold. The charge directly cures in the heated mold and the process can be done in minutes. The process is particulary suitable for thermoset polymers and rubbers, enabling the material to cure faster under compression and heat conditions. [B]

design considerations

- draft angles
- avoid undercuts
- limit holes
- uniform thickness
- rounded corners
- multiple cavities pattern

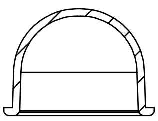


injection molding

probably the most diffused manufacturing process for large scale plastic processing. Injection molding is a method to obtain molded products by injecting plastic materials molten by heat into a mold, and then to cool and solidify them for final part extraction and remotion.
In the case of the mask rubber body a complex mold is used for part injection and the process can be defined as “overmolding”: an element is inserted in the mould prior to the injection phase. When the material is allowed to flow and solidify the two parts come toghether thanks to chemical bondage bewtween the elements. [C]

design considerations

- draft angles
- avoid undercuts
- limit holes
- uniform thickness
- rounded corners
- multiple cavities pattern
- housing design



9.5 Material selection

material choice and selection

A short overview on the materials selected for final manufacturing of the system is here given, as well as a brief explanation on material properties and key features that influenced the material selection.
Material choice also took into account process compliance, trying to individuate candidate materials suitable for the intended manufacturing method.
The materials in question are here presented:

- Thermoplastic Elastomers (TPE) [D]

Thermoplastic Elastomers, are a class of copolymers (usually a plastic and a rubber polymer blends) with both thermoplastic and elastomeric properties. While most elastomers are thermoset, TPEs are relatively easy to use in manufacturing (for ex. injection molding). The main difference between thermosetting and thermoplastic elastomers is the type of crosslinking of their structures. In fact, crosslinking is a fundamental structural factor that contributes to conferring the high elastic properties. Thermoplasts also offer the big advantage of being reprocessable and restorable by means of heat, thus allowing the material to be welded or heat-deformed.

- Polyamide - Nylon (PA) [E] [F]

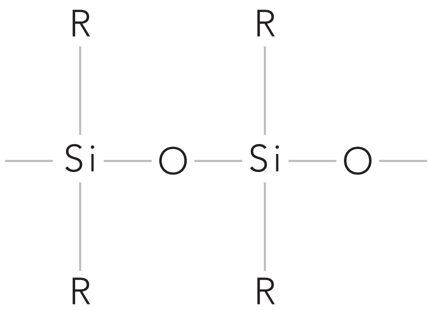
Exhibiting high temperature and electrical resistances, polyamides (nylon) are considered as high performance plastics and are widely used in mechanical applications and for components subjected to wear. Nylon is a polymer with repeating units linked by amide bonds. Polyamides occur both naturally and artificially along with the main applications and benefits of some common polyamides: PA11, PA12, PA6, PA66 and PPA (polyphthalamides).
Polyamides represent an ideal choice in high-end engineering applications and for these reason they were selected for the components of the snap-fit sub-assembly.

[H]

[I]

TPE pellets *(upper pic.)* and TPE products *(lower pic.)*

[L] PA compound pellets



[M] silicone rubber general formula

[N] bi-component silicone used for prototyping

[O] silicone finished products examples

Liquid Silicone Rubber

The silicones differ from most industrial polymers in that the chains of linked atoms that make up the backbones of their molecules do not contain carbon, the characteristic element of organic compounds. This lack of carbon in the polymer backbones makes polysiloxanes into unusual “inorganic” polymers—though in most members of the class two organic groups, usually vinyl (CH_2), methyl (CH_3), or phenyl (C_6H_5), are attached to each silicon atom. A general formula for silicones is (R_2SiO) *[picture on the left]*, where R can be any one of a variety of organic groups. [G]

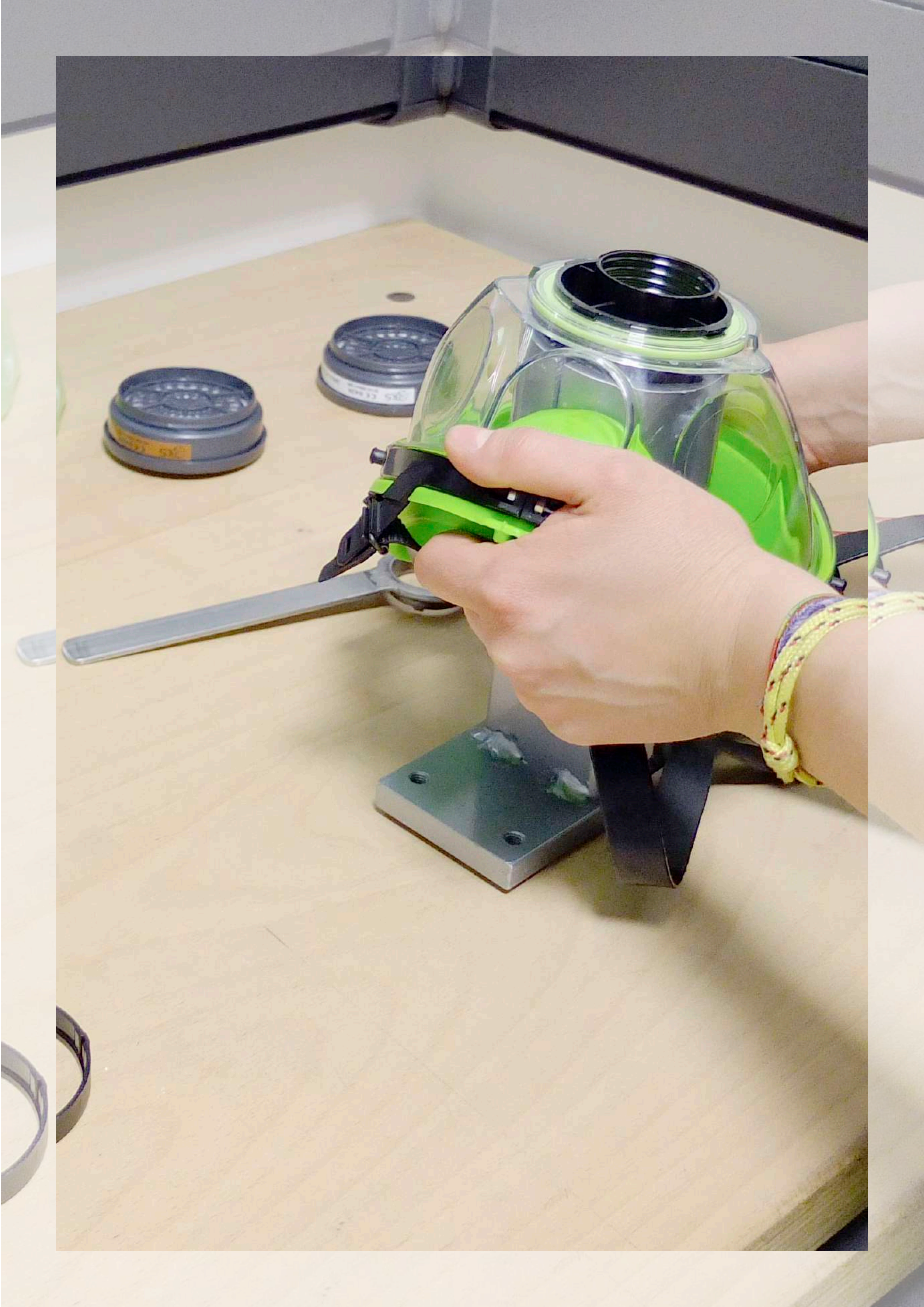
For the scope of the project, among the main silicone rubbers, i considered the so-called **liquid silicone rubbers** (LSR) which are particularly suitable, due to their low viscosity, to be injected into a mold and are generally made up of two components (base + catalyst) to be instantly mixed before or in-process; under this definition Platinum Silicones are found.

Platinum silicone is a premium quality silicone. Contains platinum catalysts which accelerate the vulcanization process with a yield close to 100% (platinum catalysis). [H]

Compared to other types of silicone available on the market, platinum silicone is by far the purest and capable of guaranteeing full compliance with the various certifications of suitability for bio-contact. It does not contain toxic components, has the lowest content of volatile substances and is commonly used in the delicate medical sector. [I]

general properties

- hardness ranges from shore 30A to 80A (30A suited for the project)
- impact resistance up to 40-60%
- elongation at break from 100% to 400%
- up to 200°C resistance (300 °C also common)
- resistance to bacteria and fungi

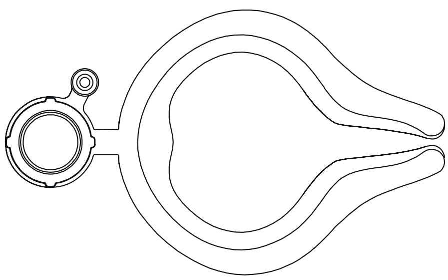


10.0 Iteration and prototypes

approaching the design problem

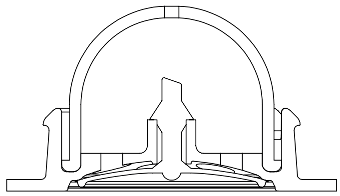
10.0 Iteration
design iterative procedure

After theorizing the concept of the "Pump system" and defining its working principle and the main elements of the system several aspects have been deepened in order to get it from the paper to a working concept.
When approaching the issue of an "inflatable daptive chamber" many blind sposts appeared during the iterative path; first of all the issue emerged while dealing with inflated (soft bodies) deformed under the flow of a fluid. It is very hard to predict the behaviour of such systems and the design path required many more prototypes and tested samples than other projects or in the case of usual products/rigid bodies.
The second challenging aspect when designing (or more in general prototyping) soft bodies actuated by air is air leackage. It is very hard to create a perfectly tigh-sealed pressurized air chamber, especially if it has to be DIY-made or it can hardly affect system evaluation during tests (no interest in evealuating chambers not retaining air or leacking during tests).
For this and other reasons, the design and test phase of the project has been very challenging and has undergone many iterations and evloutions during the process.
Under this circumstances, the system has been focused in the development and implementation of those spotted as key elements of the system, here reported with the relative aspects considered:



AIR CHAMBER

chamber evaluation and construction:
- supporting documentation
- operating principle
- technology selection
- material / mat categories selection.
- welding tests
- permeability and air leakage tests
- fit and comfort test on mask
- validation of geometry, elasticity and inflation

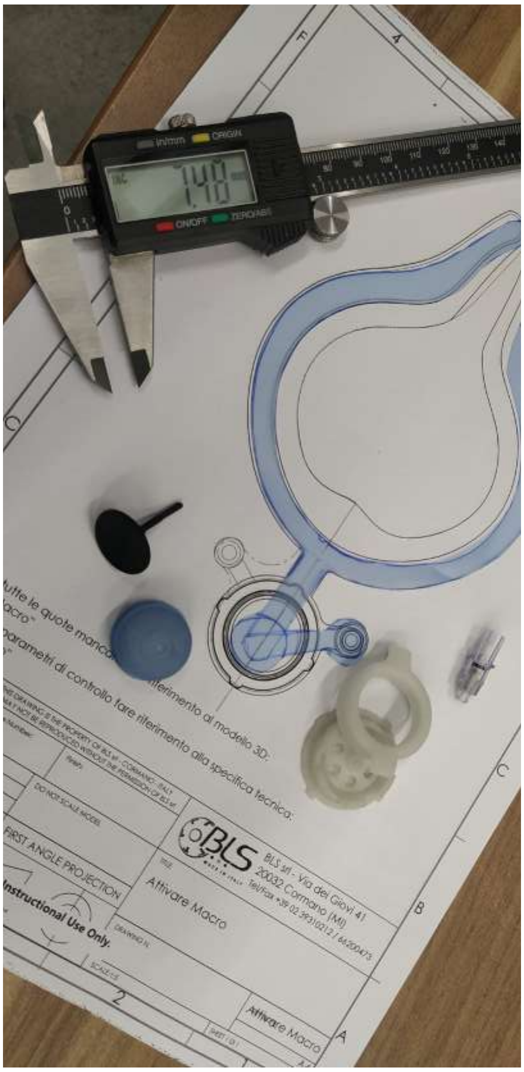


PUMPING SYSTEM

valve evaluation and selection:
- supporting documentation
- operating principle
- valve planarity (two-dimensional)
- dimensions - pressure / flow evaluation
- inflation resistance test (balloon)
- permeability test (balloon)

Air Chamber 10.1

design iterative procedure



elements of the system during prototyping [A]

The first (and most releveant) element of the "Pump system" design is the inflatable chamber. The design of the cushion has undergone many phases and is at the center of the project development; it is strictly linked with the other halve of the assembly (pumping system) and has been tested in different sets of combinations during the various phases of the process.
The crucial function to be performed by the chamber is: "the ability to deform and stiffen under the application of a pressurized air-flow, thus by adapting and matching user face".
To obtain the desired behaviour many tests had been taken out and the following parameters appeared to be the ones influencing the most efficiency of the component:

- shape and geometry of the chamber
- material category and softness
- material thickness

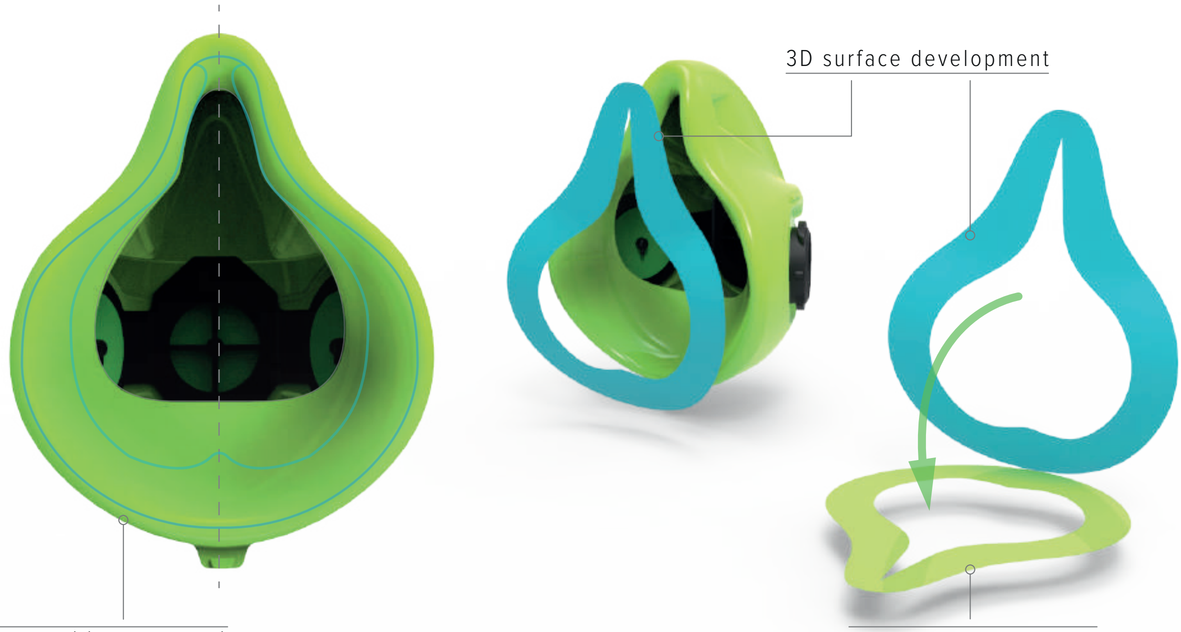
The research has moved into the identifaction and evaluation of the correct candidate under this 3 parameters. Many material categories and geometries were evaluated in combination of chamber thickness and other elements of the system. In the following pages a short overview is given on main choices and tests carried out during the selection and design of this component.

Shape and geometry

The first crucial aspect to be considered in the design of the functional “Pump system” is the geometry (and so the shape) of the inflatable chamber. Similar to the “soft robot” category the shape of the inflatable body is responsible of the intended “deformation sequence”; by correctly designing the cushion contour we can direct the body to deform under a predicted path. To obtain the correct behaviour from the system, multiple tests were performed, changing profile and trying different solutions changing chamber position in the mask.
To approach the problem i started from existing BLS hal-face mask by considering the flat development of the lip-harness. I started reasoning and sketching from the following configuration:

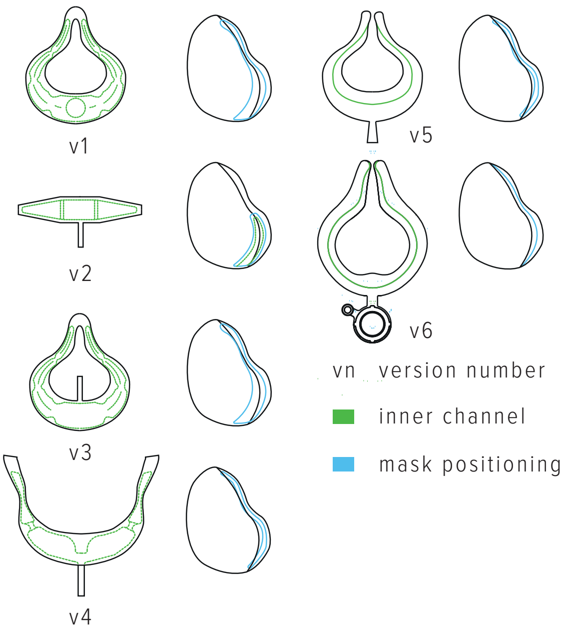
[B] mask harness lip flat development

[C]



Working principle

inflatable chamber shape iteration [D]



As aforementioned, many tests were performed in order to define and individuate the most effective sealing and adaptive chamber. After several datas collected I ended up moving away from the “classical” conception of oronasal harnessing lip and i redefined the term and its function on the mask working-principle. I will here present main differences between the existing principle and the one developed during my project.

Actual mask - passive fit

As deeply analyzed in chapter 3 (Face maks) the solution actually put in place to ensure tight sealing in negative pressure half-face masks is a simple elastic harnessing lip. The lip is preformed in a way it already tends to match face shape (usually 45° tilted to the interior) and becomes completely formed when the face is penetrating the flexible dome under the tensioning force induced by laces.

The Pump - adaptive fit

The difference compared to traditional system can be found mainly under two perspectives:
first, the lip is not “pre-formed” anymore but consists in a flat thin sheet, much shorter and less deeper than original lip. The sheet will be easily and completely deformed when wearing the mask without the need of special fits or forces.
Second, the formed sheet can be inflated with pressurized air in order to stiffen the structure and fill/compensate any eventual gap or hole.

Material

In order to orient myself in the selection of the correct material for the consitution of the chamber I started by a first step moved by general documentation and specific in-field research, followed by a series of sampling tests (manufacturing, compatibility, general behaviour, specific material conduct).
First inspiration and documentation has been adopted and researched starting from industrial best-practices and case studies; the emerged candidates were than referred to the specific requirements of the project and evaluated through a series of tests in order to define valuability and suitability of the material for the project.
Since earl design phases of the project the material and process selection has been carried out side by side in the attempt of merging the manufacturing and productive aspect with the functional requirements of the material. In this phase also availability and semi-finished product form/state were considered in order to define and design the subsequent process to be applied during manufacturing.

[E] ex. of chambers made of different materials

Material tested:

- Silicone
- TPU
- PVC
- EVA
- TPU coated Nylon

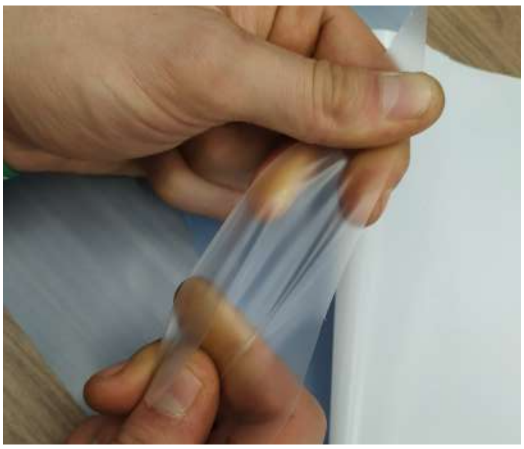
Technology tested:

- Casting
- Injection moulding
- 3D Printing
- HF welding
- Ultrasound welding
- Thermal welding
- Thermoforming

Material choice

After performing initial tests and evaluating material properties a first-macro selection was made. Two appeared to be the most promising categories of materials wich were deepened and further investigated.

self-made silicone sheets (0,6-0,2 mm thick) [F]



TPU sheets (0,5-0,1 mm thick) [G]

Silicone

These polymers consist of synthetic compounds inert in nature such as siloxanes, which are made up of atoms of silicon and oxygen with carbon and hydrogen. It is widely adopted in the industry for its unique properties such as heat resistance, passivity, biological compliance and (more influent for the scope of the project) softness and elongation. For the scope of the project multiple tests with different platinum-based-silicone (platinum catalyst to initiate the curing phase) were carried on. The following hardness were tested:

Shore A45 —— hard
Shore A30 —— medium
Shore A15 —— soft

(TPU) Thermoplastic-urethane

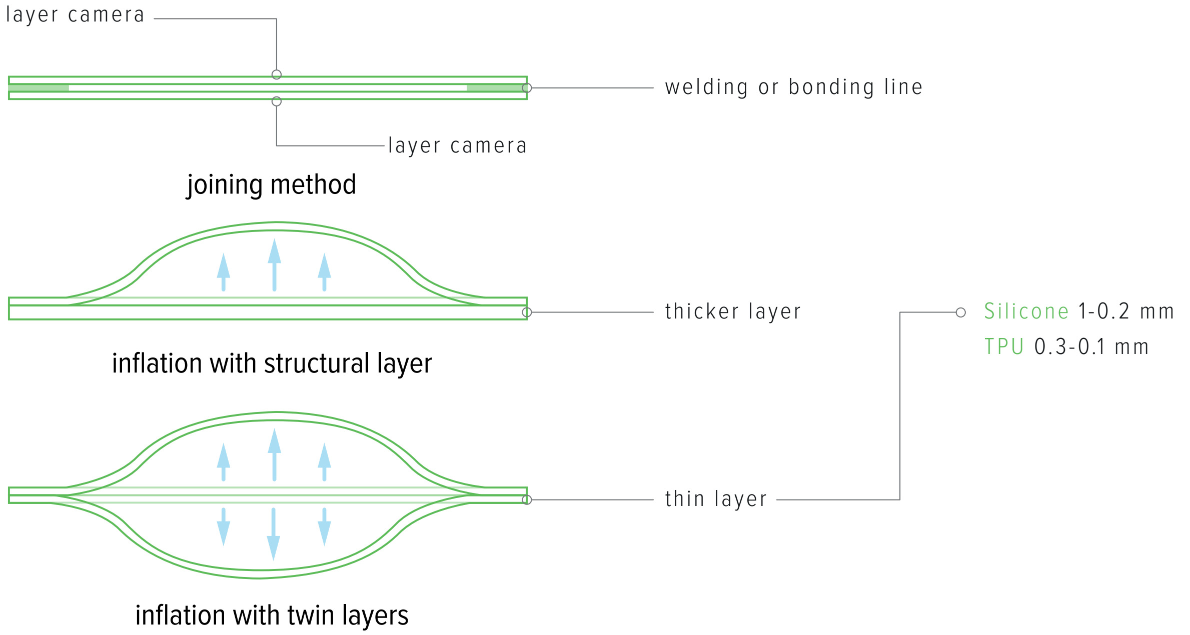
TPU or Thermoplastic Polyurethane is a category of plastic created when a polyaddition reaction occurs between diisocyanate and one or more diols. They are widely employed in the industry as a soft engineering plastic or as a replacement for hard rubber; represents a valid alternative to silicone, presenting similar properties. It has been selected for its softness and simplicity to be manufactured and processed. Two different TPU grade were processed and evaluated during tests:

TPU A60 100 micron —— hard
TPU A40 50 micron —— medium

Material thickness

The behaviour of the cushion and the capable elongation of the chamber during inflation is strictly related to the thickness and hardness of the material itself. For this reason different combination of materials and material thicknesses has been evaluated during the development phase. At the core of the testing and evaluation procedure there's the making of the chamber, obtained from welding/bonding together two layers of the same material (planar or/and non-planar) in order to define the inflatable area, as shown in the picture below. The specific behaviour/deformation of the chamber under the influence of air was calibrated by performing different tests in different configurations. An example is given in pictures below:

[H] picture showing silicone inflated circuit

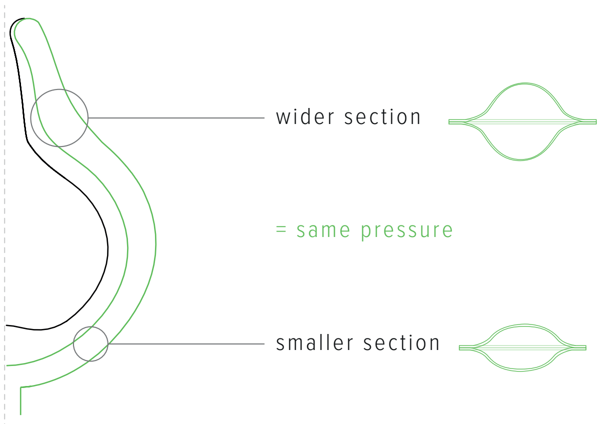


cushion behaviour

Another crucial aspect in order to guarantee and evaluate concept efficiency is the coverage provided by the mask when the inflatable chamber is worn and activated.
As previously spotted it is very hard to predict soft bodies behaviour under the influence of air; for this reason i identified 3 parameters that appeared to be strictly related to products efficiency and that helped me a lot in the design and testing of the system:

- bags shape and distribution
- area of interest on mask
- pressure induced

Many test were performed in order to identify and reduce defects in the design of the chamber and to make it "fittable" to most of visages. The efficiency of the system has been achieved by spotting and defining the correct areas where directing the pressure. The best performance has been observed with a continuos channel (almost constant width) increased where needed by raising the step of the chamber. Wall thickness was reduced (0.2mm) in order to provide the same deformation with less pressure demand.



[I]

ex. flat chamber

[L]

ex. inflation / deformation trigger

[M]

ex. final deformation

10.2 Pumping system
design iterative procedure

The other main assembly investigated during the creation and implementaion of the “Pump system” is the inflation/pumping system itself.
The system has to provide the main function of: “storing an air volume (capacity) to be released under a trigger and driven into the inflatable chamber, thus thanks to a one-way check valve and providing tight seal”. The system (because of deisgn choices) also wanted to be mantained analogical and as small (flat) as possible.
For this reason the current system was developed, consisting of 3 main components: the elastic dome, the one-way check valve and valve’s housing. In order to correctly design and select system components, functional tests were carried on and a list of key parameters affecting the success and efficiency of the employed solutions were traced. In this way i had the chance to compare and implement different aspects of the system and the procedure helped me a lot in the understanding the influence brought by every single component in the overall assembly.
The parameters reported in the below list are those affecting the most syhstems success.
It appeared clear how the valve and the design of its housing were playing a crucial role in the development of the concept.

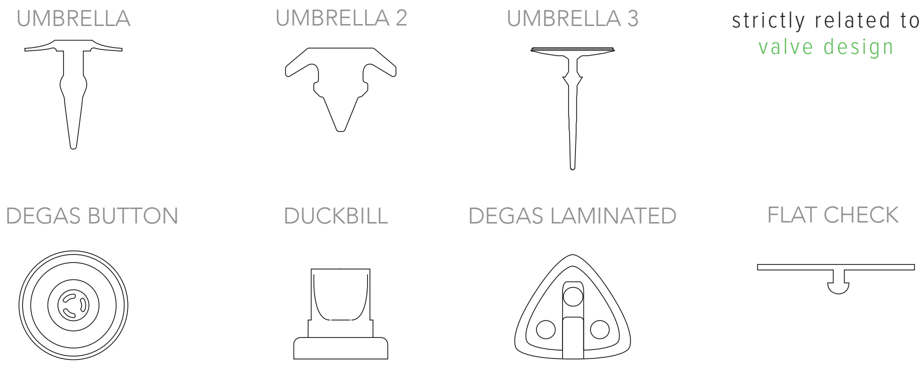
tests performed on different chambers


[N]

key parameters in the definition of the pump:

- system flatness
- quantity of air introduced by every push
- low cracking pressure
- high backward pressure resistance
- complete sealing
- joined/bonded/attached to chamber

strictly related to valve design



tested valves overview

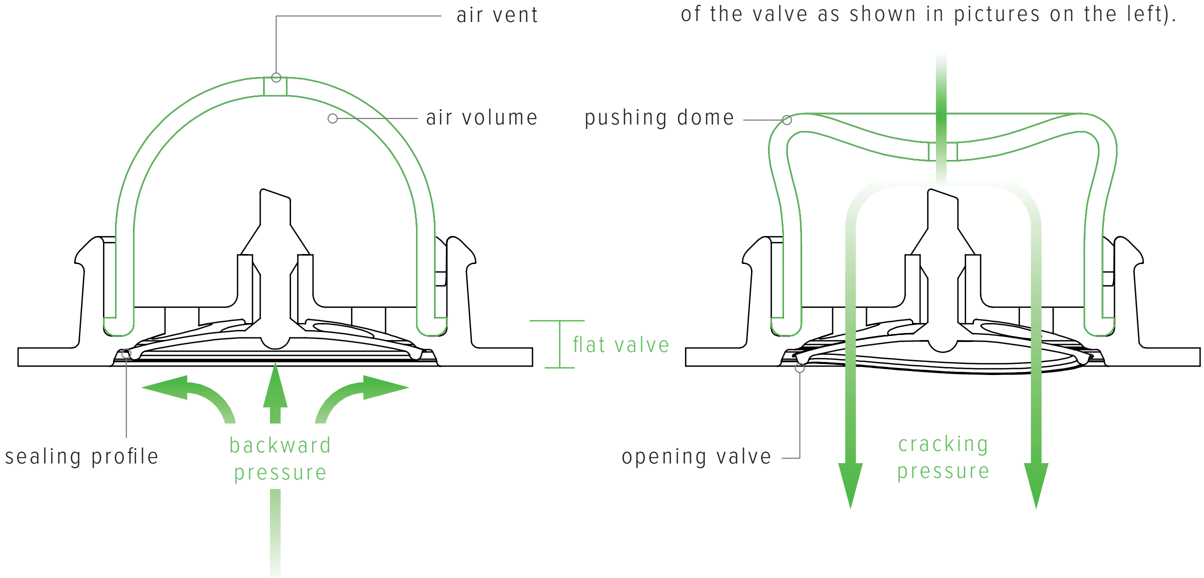
Working principle

Representing key elemets in the definition and realization of the working mechanism, the valve and its housing have been at the center of the entire Pump system development. For this reason they have been studied in depth and subjected to multiple tests (permeability, efficiency, filling capacity and air retaining properties).

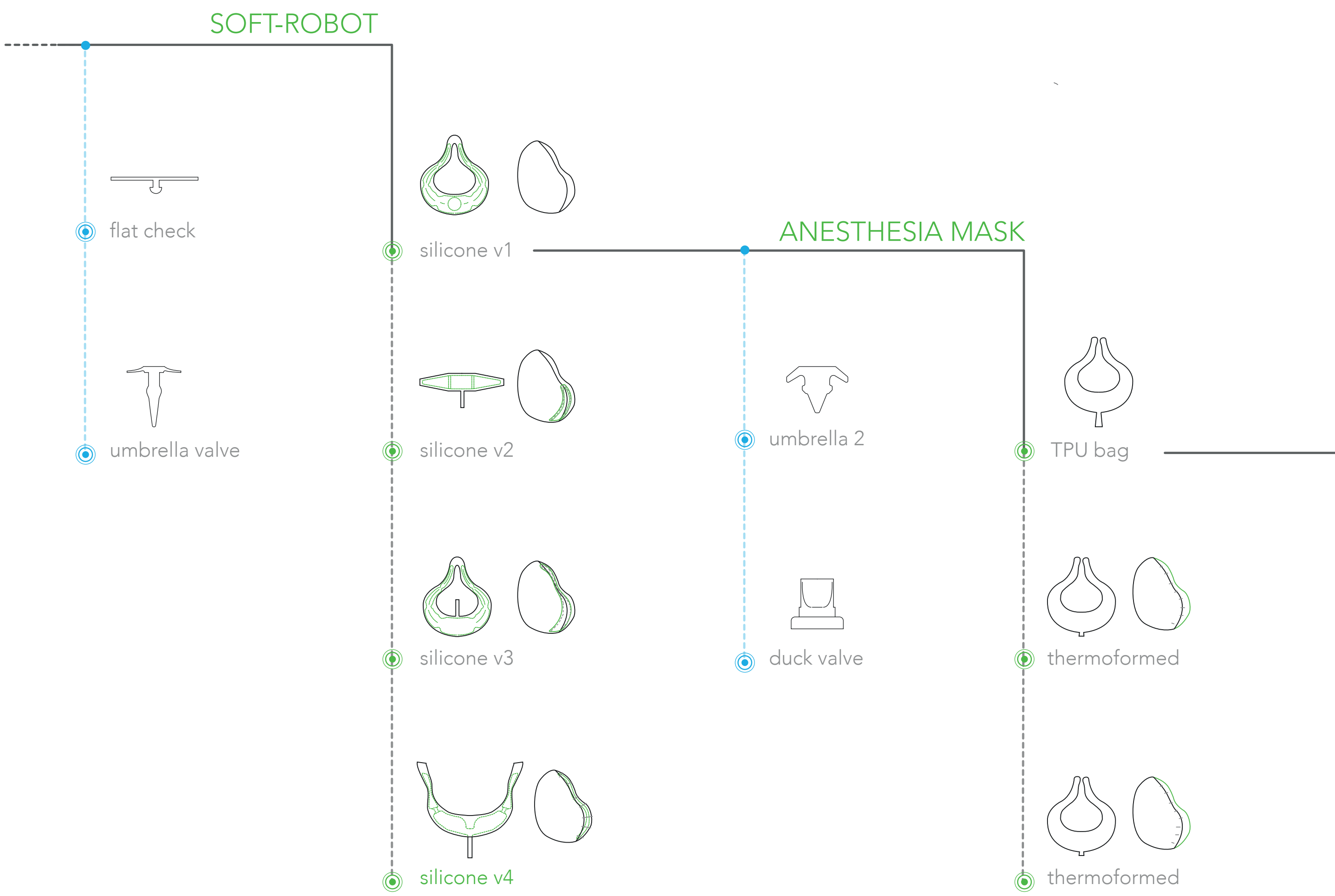
Air leak

One of the biggest challange to overcome when designing an inflatable system is taking care and managing air leakage during arrangement evaluation. For this reason the initial efforts were put in the definition and search of an efficient non-return valve, in combination with a good sealing housing, in order to guarantee filling of the chamber without deflation. For studying valve + housing behaviour several tests were arranged (for ex. air leackage in a pressurized enviroment or air retaining capacity of the valve as shown in pictures on the left).

sealing efficiency test [M]

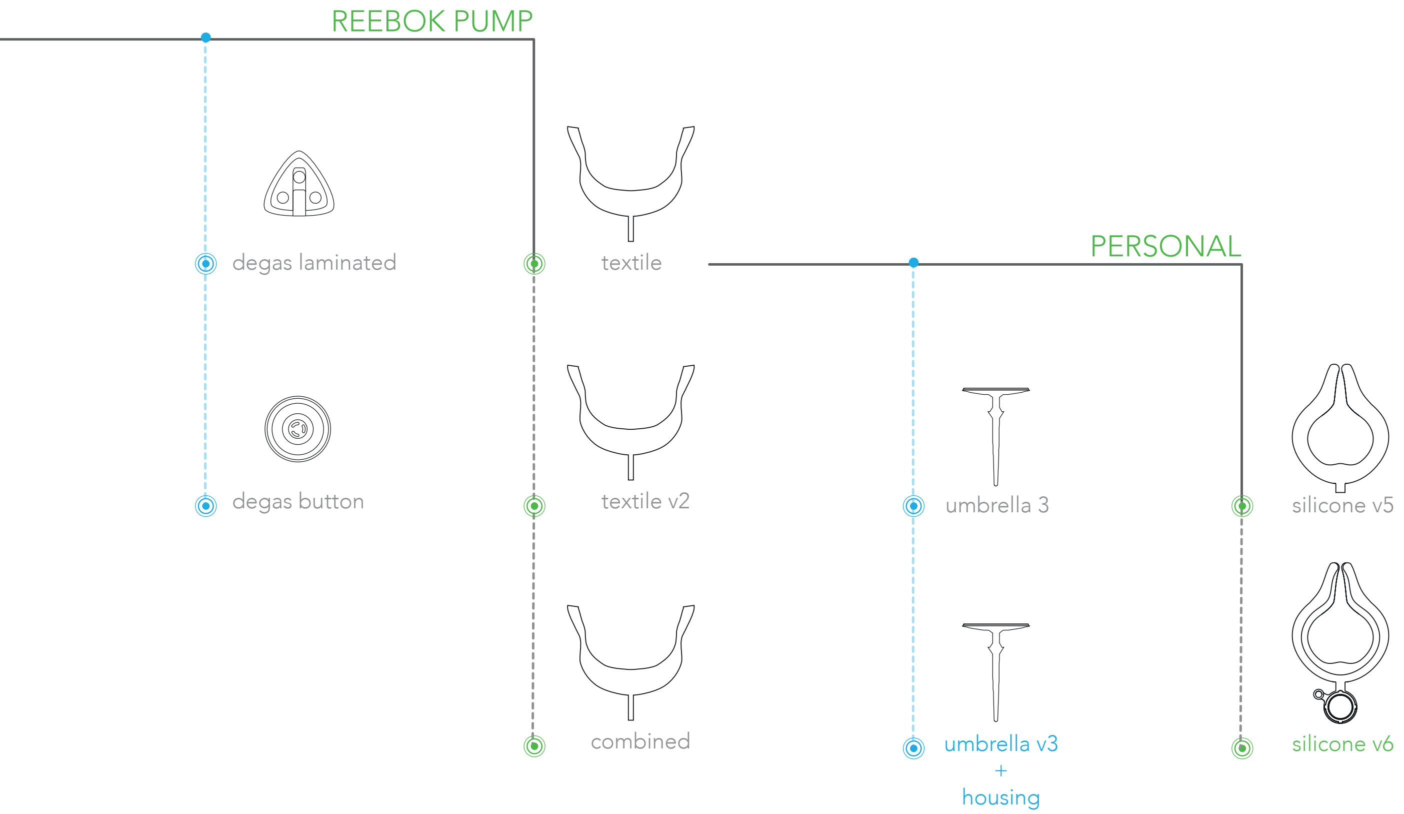


10.3 Pump project evolutive phases
manufacturing process



final asset

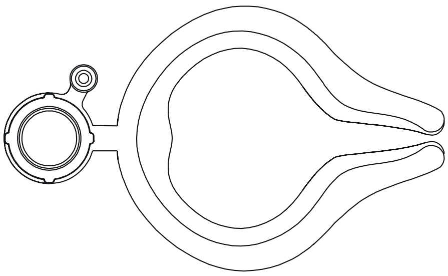
In this scheme the complete road to the Pump system definition.
The evolution of the concept can be here visualized among different project phases; in every phase the system has been set-up on mask and tested multiple times to evaluate efficiency and user perceptions.
The phases (and geometries) were developed and inspired by the 3 main working principle analyzed and studied during the research phase (green titles on the scheme); a last development path was individually theorized by the feedbacks/inputs received during sample evaluations. An incremental approach was applied to the Pump case study and every new design has been created based on hints and observation derived by previous version.
An overview is given on different combinations of materials, components and geometries tested during the design process.



10.4 Final considerations on components
key elements and design considerations

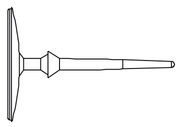
Here presented the final candidate components to be equipped on the first versions of the "Pump system". As previously seen an entire investigation was centered on these 2 aspects (pump and chamber) to identify best components for the cause. In the below picture the final components are reported, selected after a series of test and evaluations.

In order to proceed to a final and complete configuration of the product other aspects were brought into project perspectives, thus trying to converge and allign all efforts in the packaging of the ultimate solution, considering the design of every single element. In the following pages an overview of macro-themes approached during the iterative phase is given. For every iterative phase key parameters and researched performances are highlighted.



SILICONE v6

+



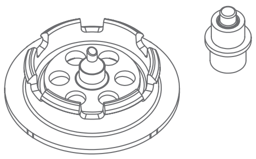
UMBRELLA VALVE v3

- highly elastic body
- thin wall thicknesses (contained material)
- "flat" manufacture
- small amount of air required
- profile/shape optimization
- channel optimization

bi-dimensional (flat) -
short and small (not deep) -
one-way effectiveness -
adjustable flow -
backpressure resistance -
weldable/jointable -
durable -

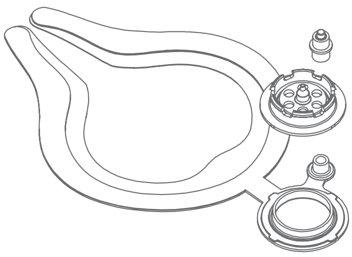
① INFLATING VALVE AND EXHALATION VALVE

- dimensioning
- functioning
- coupling and integration with the air chamber system
- high flow transmission
- no leakage



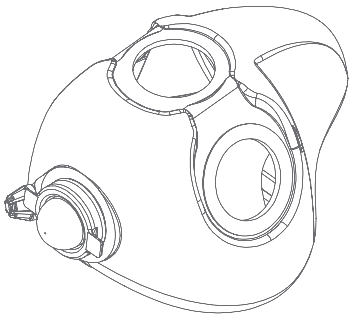
② INTEGRATING CHAMBER + VALVES

- bond silicone + other materials
- sealed chamber (tightproof)
- no leakage
- air volume sizing
- guided deformation check



③ INTEGRATION WITH FACE MASK

- pump to be accessible to user
- impermeabilità interno
- substitution & manutention aspects
- estetic and
- mask body engineering



10.5 Prototyping and testing
personal iteration

As widely mentioned during the thesis, one of the most demanding aspects of the project has been designing soft-elastic bodies to be deformed under the pressure induced by air.
For this reason the prototyping and testing activity represented a key tool in the development and grounding of the Pump system.
The prototyping activity has undergone many phases and supported the development of the project since early steps. This allowed to proceed faster in product evaluation, implementation and final selection of the components, especially in relation with milestones. Because of a wild experimentation (especially during first phases of the project) many scenarios were hypothesized and different productive techniques applied to material categories; this required a huge prototipying effort and many iterative steps. In this section of the thesis i'll provide a short description and a resume of reasoning behind the developed prototypes.

Personal motivations

During the years of study at PoliMi and outside activities i had the chance to mature knowledge and passion in the wide field of protyiping. During last years i started to actively collaborate with companies for means of product development and prototyping and what started as a hobby became my full-time occupation and main interest nowdays.
I always aim to include functional prototypes since very earl product development phases as a tool of incredible value allowing to use and evaluate rough concepts. For this project even more, i had to rely on functional prototypes as the only tool capable of evaluating and quantifying project advancement.

[N]

some of the material collected during prototyping

Prototyping

In the following pages a short overview is given on different productive techniques employed in the prototyping/ evaluating phase of the project. A particular focus is put on the relation between realized components, function to be performed, material category and the applied manufacturing method.

high-frequency welded parts [O]

thermal welded part [P]

ultrasonic welded samples [Q]

1 - Welding

Welding is a fabrication process whereby two or more parts are fused together by different means, thus obtaining a single, supportive part. Welding techniques are usually referred to metals and thermoplast, the latter was the application interesting to the scope of my project.I used welding techniques in the initial/evaluative phase of the project to investigate material categories and joining methods. The investigation was carried on to combine and evaluate sheets in the creation of an inflatable chamber and the ability to bond it with the other elements of the system. This were the welding techniques analysed:

thermal welding

with a heat source (usually a resistive metal path) and inducing compression thermoplast material are joined. This technique was applied in case of TPU sheets or TPU coated nylon, with the use of metal built circuiting die.

HF welding

High Frequence welding is a manufacturing process where two plastic parts are welded together using an electromagnetic field. It has been employed with TPU and PVC sheets to create and evaluate inflatable chamber solutions.

ultrasonic welding

is a solid-state welding process that produces a weld by local application of high-frequency vibratory energy while impressing pressure to the workpiece. This technology has been used to weld and mechanically bond components made of different materials; in particular it resulted very usefull to test material compatibility when attaching the rigid elements of the system to the inflatable chamber.

2 - Additive Manufacturing

3D printing or Additive Manufacturing, as technology in general, gained much popularity and diffusion during last years, especially for rapid prototyping purposes.
I am a lucky owner of a small 3D printing farm and 3D printing enthusiast. I also had the chance to put the hands on BLS industrial SLA printer during the course of my intership.
3D printing represented a key tool to increase productivity and to sustain the product among different aspects for the entire product development. Two were the main technologies employed in the AM field during the development: FDM printing and SLA printing

FDM Printing

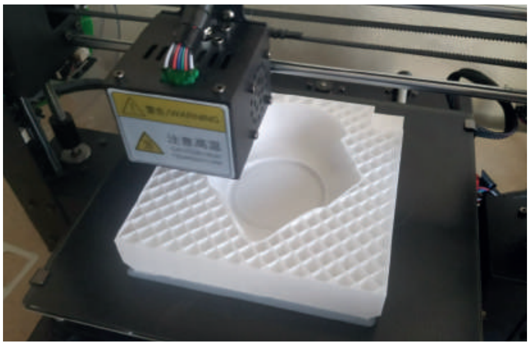
As known as Fused Deposition Molding, represents probably most diffused AM technology in the world. The processed material category are thermoplastic polymers, that can be molten and deposited to cool down and harden. With this technology many different polymers can be processed by the same machine and therefore it was mainly applied to functional prototyping and material sampling and evaluation. During the development of the project it was employed for the following reasons:

- **parts and components**

many parts and components were 3D printed during tests and system tuning. It was mainly employed for functional mechanical parts (ex. snap-fits, threads.. etc).

- **welding samples**

thermoplast can be easily reprocessed or thermally bonded; FDM technology was crucial in order to process different materials to create weldable samples (PLA, ABS, TPU, PP, PA..) and to test the compatibility between materials.

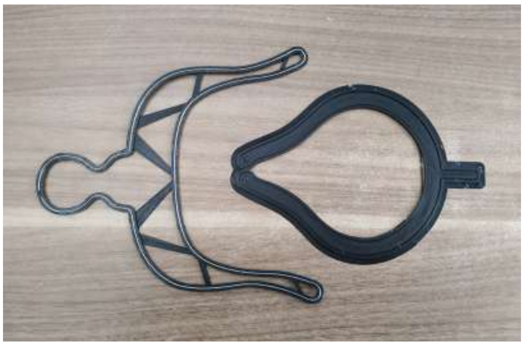


[R] mask mould during FDM printing

[S] FDM functional printed parts

[T] different materials FDM printed samples

FDM printed moulds and molded parts [U]



welding and casting FDM printed dies [V]

final elements of the assembly [W]

molds

FDM printing represnts a great tool in order to create cheap and fast moulds. Moulds obtained from 3D printing can be employed for cold/liquid casting or injecting resins and rubbers. It has been of incredible use during the whole development, allowing to create fast and custom molds when needed.

dies and testing equipment

similar to molds, 3D printing was used to create cutting mask or processing dies. In general FDM printing has been of great use during the whole process supporting the creation of tools and equipments specifically realized for parts testing.

SLA Printing

SLA technology is growing in popularity and diffusion during the last years. It allows to get very clean and accurate parts with a reliable and very high-speed workflow by selectively hardening photosensible resins (thermoset polymers). Another advantage offered by this technology is the creation of very "dense" parts characterized by a high compaction coefficient, that can be used for air tight application. For this reason resin printing was used for the following applications in the project:

final parts and components

SLA printing has been used in the creation of final components. After evaluating and defining elements by FDM sampling and testing, final parts were realized in resin. This allowed me to verify and check closer tolerances and avoid air leakage when evaluating tight seal or valve retention during last phases of the project.

tight-proof parts

potentials of the technology has been used on many components during the iterative and evaluative phase. SLA printing allows to obtain tight-proof parts that can be submitted to flow simulations and tests; this for functional components and evaluative tools/ adapters.

molds

for its high accuracy and tolerances SLA printing has been used for the creation of precise molds or in applications such as micro-molding or over-molding for certain specific components. Only some material categories can be casted/injected because the resin acts as inhibitor for most of the catalyst used during processes.

3 - Casting

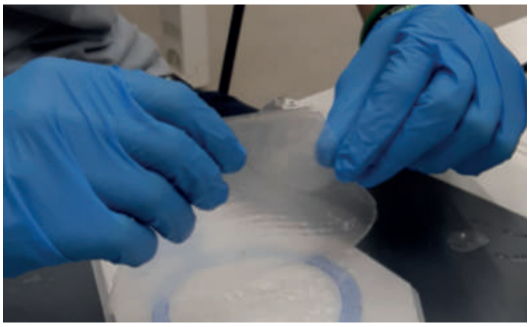
Casting is a manufacturing process in which a liquid material is usually poured into a mold, which contains a hollow cavity of the desired shape, and then allowed to solidify. The solidified part is also known as a casting, which is ejected or broken out of the mold to complete the process. For the means of the project casting was employed on bi-component thermoset polymers and resins (silicones and epoxies derivates mainly) for the creation of thin material slabs. Here an overview of the applications:

slab layers

open molds were used in order to create and define inflatable chamber walls. Liquid material is poured and left to settle in mold cavities untill completely hardened. In this way very thin material depositions are possible (up to 0.2mm)

[X] tight-proof testing elements realized in SLA

[Y] FDM functional printed parts



[Z] silicone casted layers and sandwich bonding

injection molded silicone parts [Aa]

elastic domes and soft gaskets [Bb]

silicone non-return (check) valves [Cc]

gaskets and soft housings

pouring liquid silicone into open or closed molds allows to obtain elastic gaskets. Gaskets were employed at different stages in order to seal and isolate the inflatable system circuit or to house rigid components.

4 - Injection molding

Injection molding is an industrial production process in which a thermoplastic material is melted and injected under high pressure inside a closed mold, which is opened after the solidification of the product. Same as for the casting process, for DIY inject-moulding thermoset resins are employed and can be injected directly into 3D printed mold cavities.
The process allows to process elastomers and resins deriving from cold-catalysis and to exploit all the common benefits of common-diffused injection molding. This process has been applied to manufacture the following elements during the product development:

elastic elements

silicone injection molding has been used in the fabrication of soft/elastic elements. Since the core of the project is an inflatable system, the use and application of this technology has been widely applied for different project means, in some cases directly applied to inflatable elastic chambers.

valves

to realize and test different types and sizes of valves, injection molding has been employed. Different hardness range of silicone (15/30/45 shoreA) were used and allowed to identify the most suitable candidate.

10.6 Testing
incremental product evaluation

mask bodies

to simulate final manufacturing process and product aspect many trials and tests were carried on elastic mask body and its manufacturing technique. The body is obtained from 3D printed split-molds.

pump dome and other elements

as previously mentioned injection moulding has been widely used for the production of elastic-rubber components during product development. In particular, in the pumping system the pump dome is entirely injected.

over-molding

to mechanically join two different parts or to cover/glaze materials in order to seal components over-molding can be suited. Over molding consists in an injection process that deposits material over a pre-inserted part; the fluid material can be bonded to the inserted part in a chemical or mechanical way. With this procedure i was able to obtain TPU pump domes isolated and covered with silicone rubbers.

5 - Gluing - Adhesives

Gluing is the operation used to stick on or together with an adhesive mixture. It is commonly used in industrial application to permanent bond different components in reversible or non-reversible ways. Many different adhesives are found on market, responding to specific requirements or material categories. For Pump project seeks gluing agents were used to seal and insulate components and as a medium between different (and mostly incompatible) materials. In particular epoxy and silicone glues were used.

A crucial aspect for product effectivness and final behaviour is how it responds to wearing and functional tests.
Beeing the “Pump system” an innovation driven by the core function of protecting the user while saving his life and consisting in an inflatable system (and so very susceptible to air leaks and loss of pressure) the system had to be fine tuned and tested during the whole development process in order to obtain a reliable and safe health care product.
Comparative charts and data matrix were collected and analysed after every test performed. The collected results were used to improve successive product speciments and to converge the efforts in final product asset development.
In this page i will shortly cover main tests and evaluations carried on during evoloutive phases.

[Dd]

me testing the system on mask during initial tries

production test

the main scope of this test is to gain confidence and verify eventual aspetcts of the manufacturing process and its capabilities. The verification is performed simulating the procedure and checking the parts after creation.
These tests can be employed to verify compatibility between materials or specific properties; functional requirements of a component can also be evaluated and represents a good way to spot defects and errors before mass production.

results of material welding tests [Ee]

comfort test

this kind of test is very subjective and may result diferent from user to user. The tool was used at different stages of the design process in order to evaluate and verify inflatable chamber sizing and comfort on visage.
Since one of the most relevant aspects of the Pump system is the ability to deform and adapt to different faces the intended action had to be observed and tested on many different users.
Comfort tests are only qualitative and helped me a lot to define operative limits and the shade to be covered by the Pump action.

different mask models evaluated for fit-test [Ff]

fit test

are used to quantify and trace the ability of the mask to fit the user, the expected result is a fit factor. This test is usually perfomed at the valley of the product development phase, when product is almost completely defined, in order to verify final geometry and overall behaviour.

results of mask fit-testing evaluations [Gg]


4000

11.0 Comparison and conclusion

to sum up at the end of the journey

11.0 Comparison and conclusions
product performance and final balance

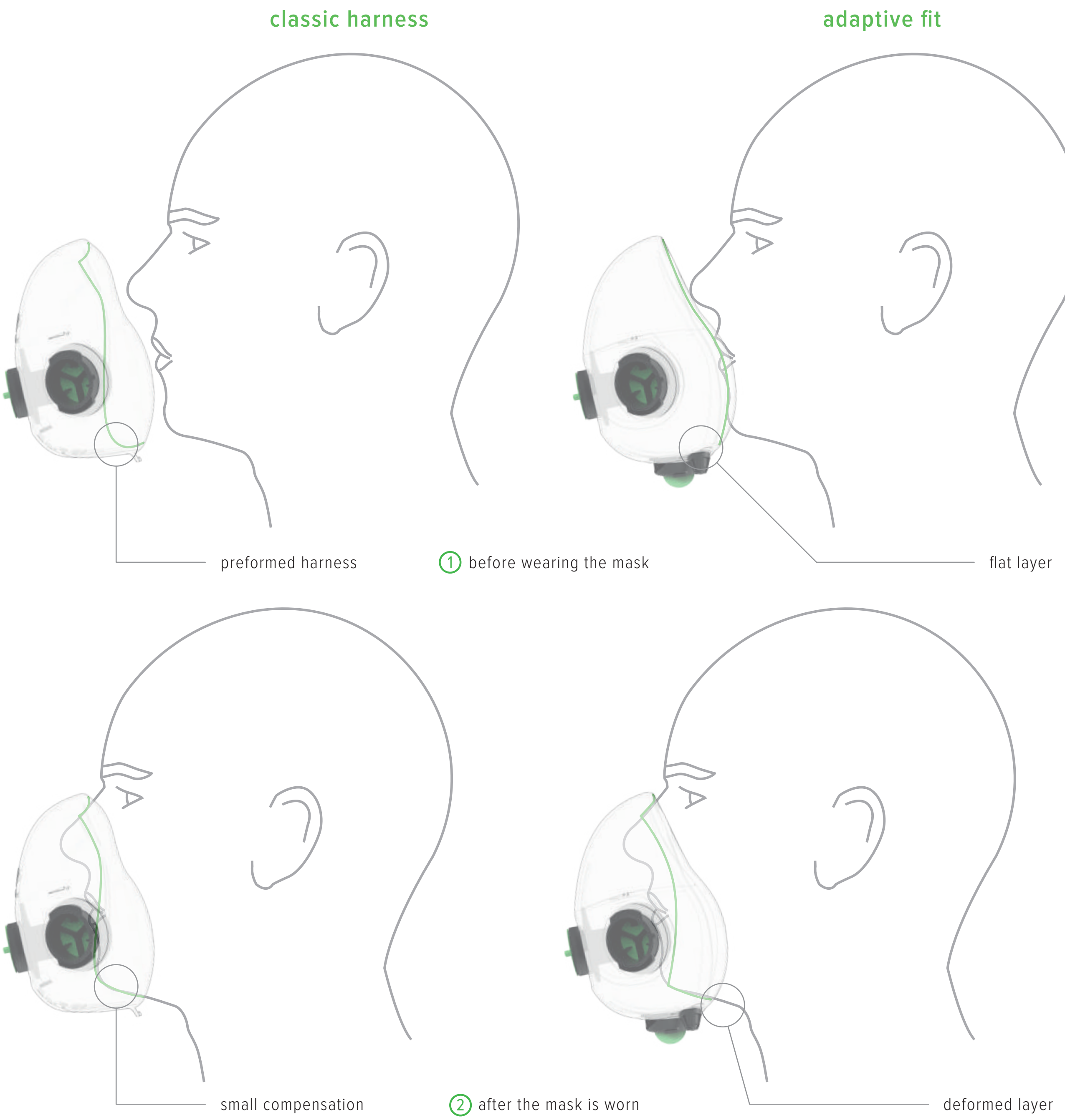
In this last chapter i try to spot and highlight products main features comparing the PUMP system working-principle and general behaviour to ordinary respiratory face masks on market.
The investigation aims to identify blind spots and threats in the current design as well as to define space for improvment of the PUMP concept.
The comparison has undergone qualitative and quantitative testing to check and evaluate different features of the face-piece. During this activity the focus has been put on the mask body component, analysing the harness lip element in particular.

harness working principle

Since the introduction of an inflatable adaptive harness has strongly influenced the way of wearing and sealing the mask, comparison was carried out considering these specific elements of the system.
On the right, the two masks can be seen in a side view; from this perspective the difference between the two profiles can be immediately recognized.
In the first case, with a standard mask, the harness curve is emphatizes and the profile tries to mimic anatomic shape of the face, it is usually folded inside the mask by 45° in the purpose of allowing normal (perpendicular) contact to visage; complete deformation and adhesion to face is obtained only when mask body is compressed against visage.
In the case of the Adaptive-Fit the profile curve of the mask body is very steep and straight, the harness is a highly-deformable thin and flat element, void of any pre-deformation. Because of it's elasticity the lip can be easily adapted to users visage while wearing the mask (passive action). The inflatable lip can then be inflated to the desired pressure, filling voids and compensating for an optimal and custom fit (active/adaptive action).

classic harness [A]

adaptive fit [B]


classic harness
adaptive fit
preformed harness
1 before wearing the mask
flat layer
small compensation
2 after the mask is worn
deformed layer

Classic harness

In the ordinary half-face negative pressure mask systems the harness of the sealing lip is a preformed element of the rubber body.

The pre-deformation is given by mask geometry/design and meant to match visage anatomy; final deformation on the lip is induced by the wearing action and regulation of tensioning laces. The fitting-principle can be considered as "passive" because it partially "anticipates" the acceptance of user face and can only partially compensate

Adaptive fit

The innovation introduced with the design of the PUMP system can be defined as an "Adaptive Fit". The improvement applies to mask bodies sealing lip and consists in a disruptive new concept: the harness is made of a flat and thin elastic layer, without any pre-deformation induced; the harness is first deformed by user face when worn and complete pheripheral adhesion is obtained thanks to the thin (highly deformable) layer. Final compensation is gained through harness pump and inflation, providing custom fit and comfort to the user

CLASSIC HARNESS

pros and cons:

- single unit ✓
- very durable and resistant ✓
- cheaper manufacturing ✓
- more sizes required ✗
- limited compensation ✗
- passive fit ✗
- high lace tension ✗
- discomfort ✗
- little costumization ✗

ADAPTIVE FIT

pros and cons:

- ✗ 2 units (chamber + mask)
- ✗ more sensistive to tear/punch
- ✗ more costly manufacturing
- ✓ less sizes required
- ✓ high compensation
- ✓ adaptive fit
- ✓ uniform tension
- ✓ comfortable
- ✓ quick operation
- ✓ high customization

In the last part of this chapter i decided to sum up all the positive and negative aspects related to the PUMP System design. I tried to look at the product with criticism and to write down pros and cons generated by products features. This activity is mainly oriented to empower and enhance further development of the product. A list of its capabilities and surrounding aspects of the concept are here deployed, all the analyzed themes were considered in relation to actual face-mask models on market:

the two systems in comparison [C]

- higher unit cost

Since the Adaptive-Fit mask concept is equipped with the inflatable PUMP System, overall complexity of the adaptive body is certainly greater than for other masks. The introduction of the inflatable chamber and inflating deflating elements results as a higher manufacturing cost

- breakable and fragile

The inflatable harness is made of two thin silicone sheets in the thickness of 0.2mm. With such a reduced thickness the chamber might represent a weak element for the assembly, exposed to possible damage

- stock reduction

With the Adaptive Fit most of the issues related to mask fitting are simply solved. This allows to reduce the offer of multiple sizes (S-M-L) by limiting the selection to a few sizes, compensated by the pneumatic action. This allows the company to save a lot of resources during manufacturing and logistic phases

- custom fit

One of the biggest advantage of the PUMP System is the ability to adapt and seal in a customized way for every user. The inflatable chamber is designed to adapt to visage and compensate for facial differencies; it can be regulated to

- comfortable and quick

Another big advantage offered by the PUMP System is the comfort and feeling provided by the inflated cushion. Thin silicone sheets deform under pressure and create a soft sealing circuit; the inner pressure can be regulated by inflation/deflation mechanism. For this reason laces job is somehow mediated and less tensioning force is required to operate with the mask, thus improving comfort.

11.1 Conclusions
final reflections

Not the end of the project

Even if the project might be perceived as mature or close to realization the path behind the PUMP has just begun, and continually improves.
A clarification is needed: the product configuration presented during the course of the thesis might differ from actual product development, since many improvments and further iterations were put in place. Improvments and changings in the design are minimal and aim to optimize and increase product performances, thus by meeting a simplier and straight forward manufacturing procedure.

Final considerations

The overall product behaviour and considerations around the system are the same and can be shared between previous and more recent designs of the system:
the main concept and idea of the adaptive-fit is effective and face fit compensation can be obtained through the deformation of an elastic-pneumatic harness.
There is space for improvment in the shape of the chamber but the generated design provides a good and safe seal for most of the users and presents a behaviour very similar to ordinary mask harness when hardened by pressure.

me showing and discussing the PUMP concept with my colleagues [D]

[D]

different phases of the project [E]

It has been proved to be very hard (almost impossible) to reduce user face-fitting to a unique and single size; overall differencies among people result in a very pronunced variation from upper to lower threshold.
Therefore the concept could eventually be applied to reduce number of sizes currently on market, still meeting bigger and smaller face requirments.
The other main advantage brought by the concept is to provide custom tightening and comfort in fit for every user, any time of use. For the following reasons potentials of the Adaptive-Fit introduced with te PUMP System are very high and represent a topic to be further deepended and fully discovered, even in other field of applications.
Searches and studies in the field will continue after graduation in order to walk the concept into production and marketing and to further investigate weak points and blind spots of the product.

technical considerations

The product development and definition couldn't have been possible without a continuos and steady iteration process.
The importance of prototyping and iterating while designing soft-deformable bodies has been crucial; this allowed to check and verify product behaviour and monitor evolution at different stages; on the other side, dealing with soft, deformable and air-tight systems has been a real challenge for prototyping purposes; it required many tries and efforts to land with a rewarding result. In the next future the goal is to individuate and develop more detailed and engineereed aspects related to the PUMP system (such as max. system pressure definition, safety factors and safety concerns) to gain complete control and awareness of the technology (currently under development) and to drive the concept to the market in an straight and manufacturbable way.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12.0 GENERAL NOTES AND THESIS RESEARCH

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General

12.2 TECHNICAL DRAWINGS

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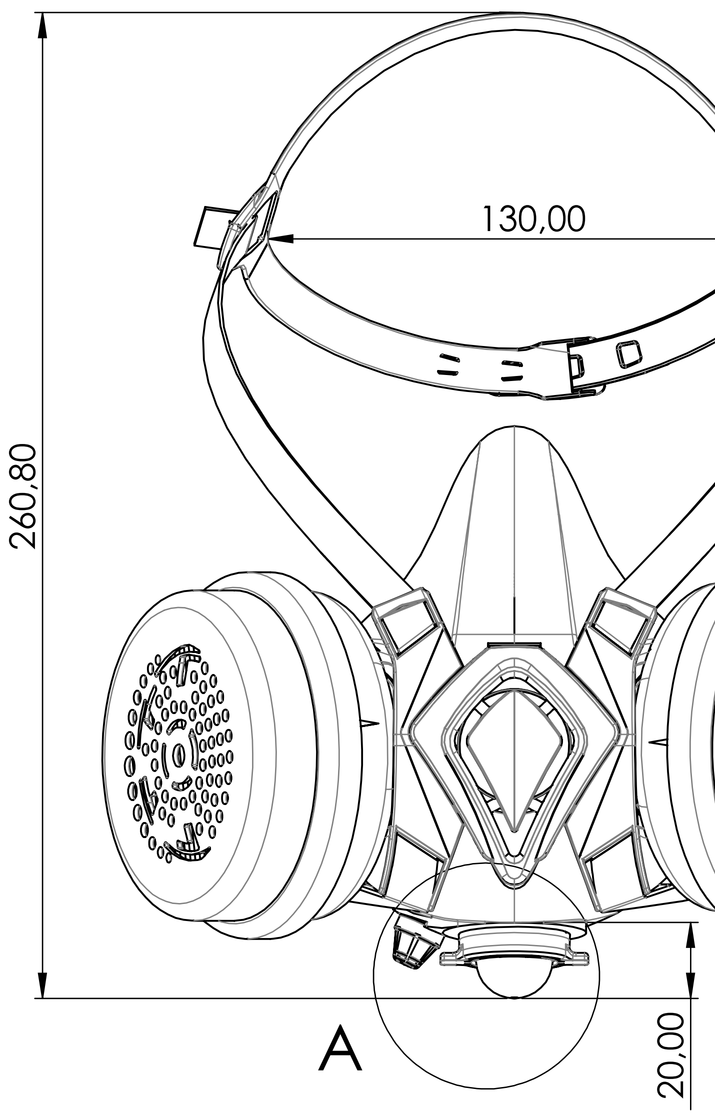
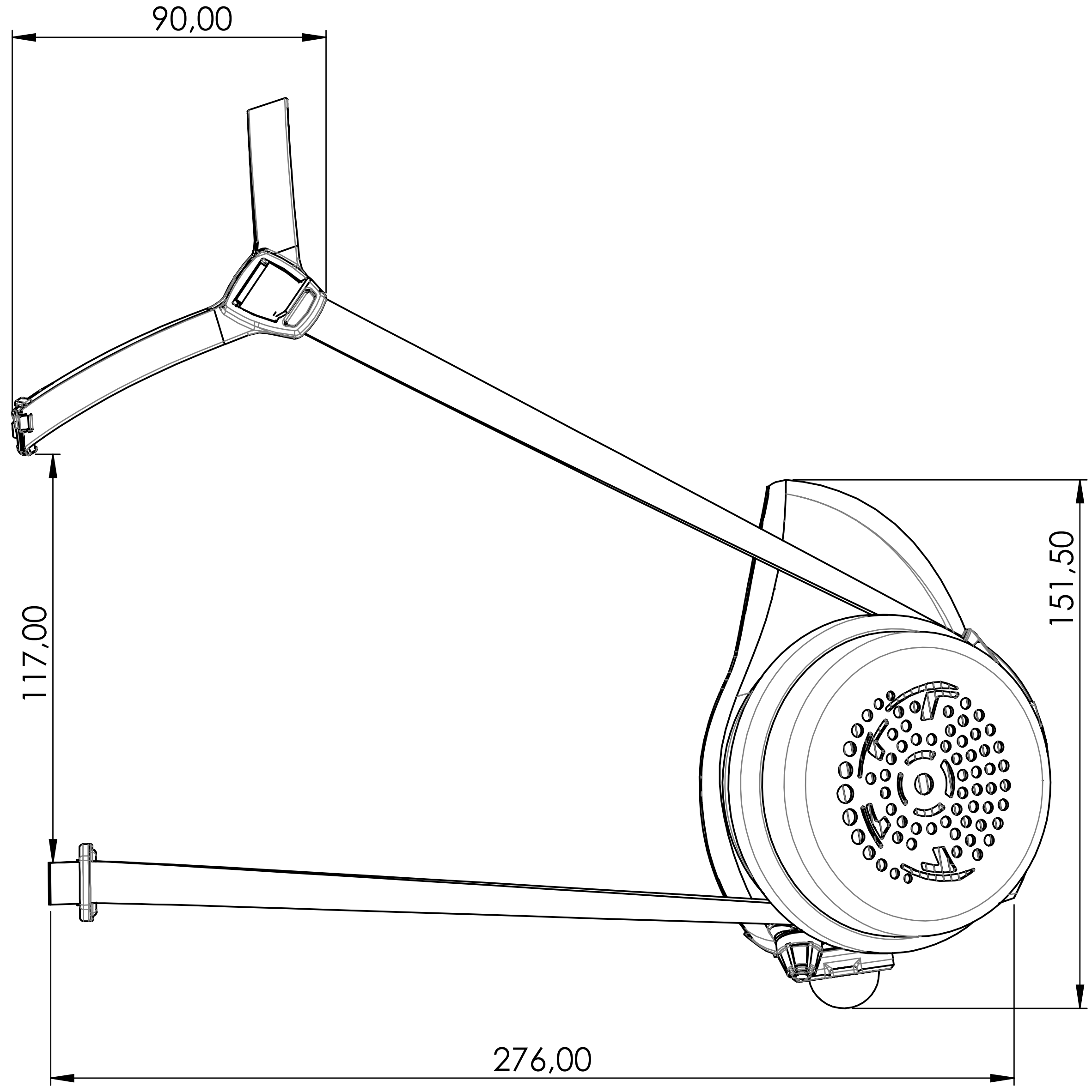
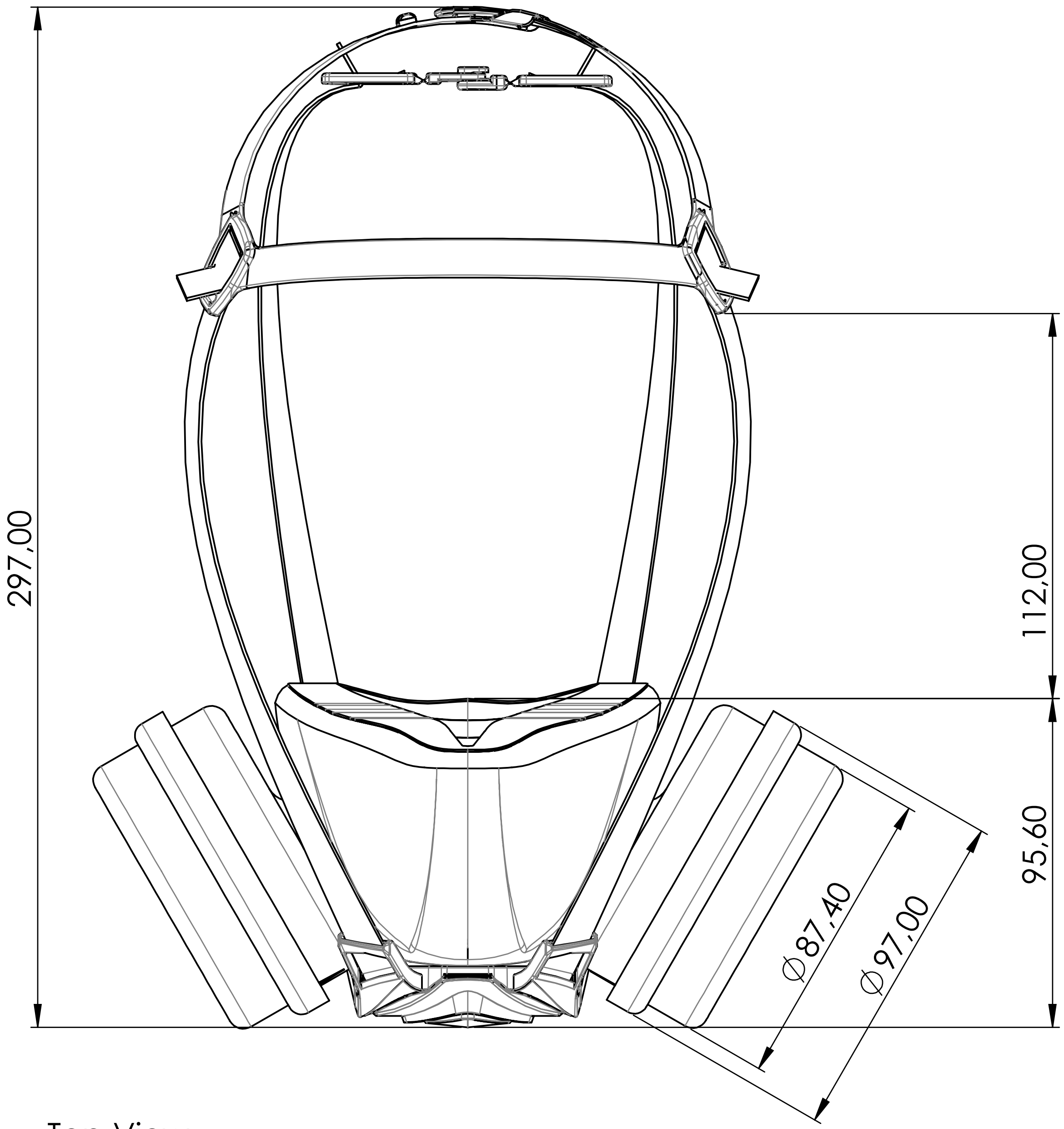
Front View

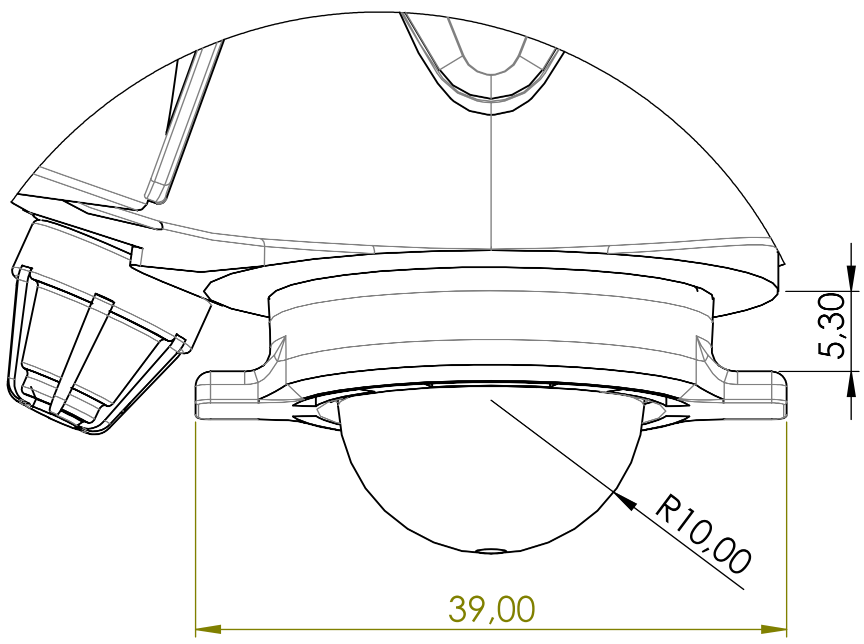


Side View





Top View



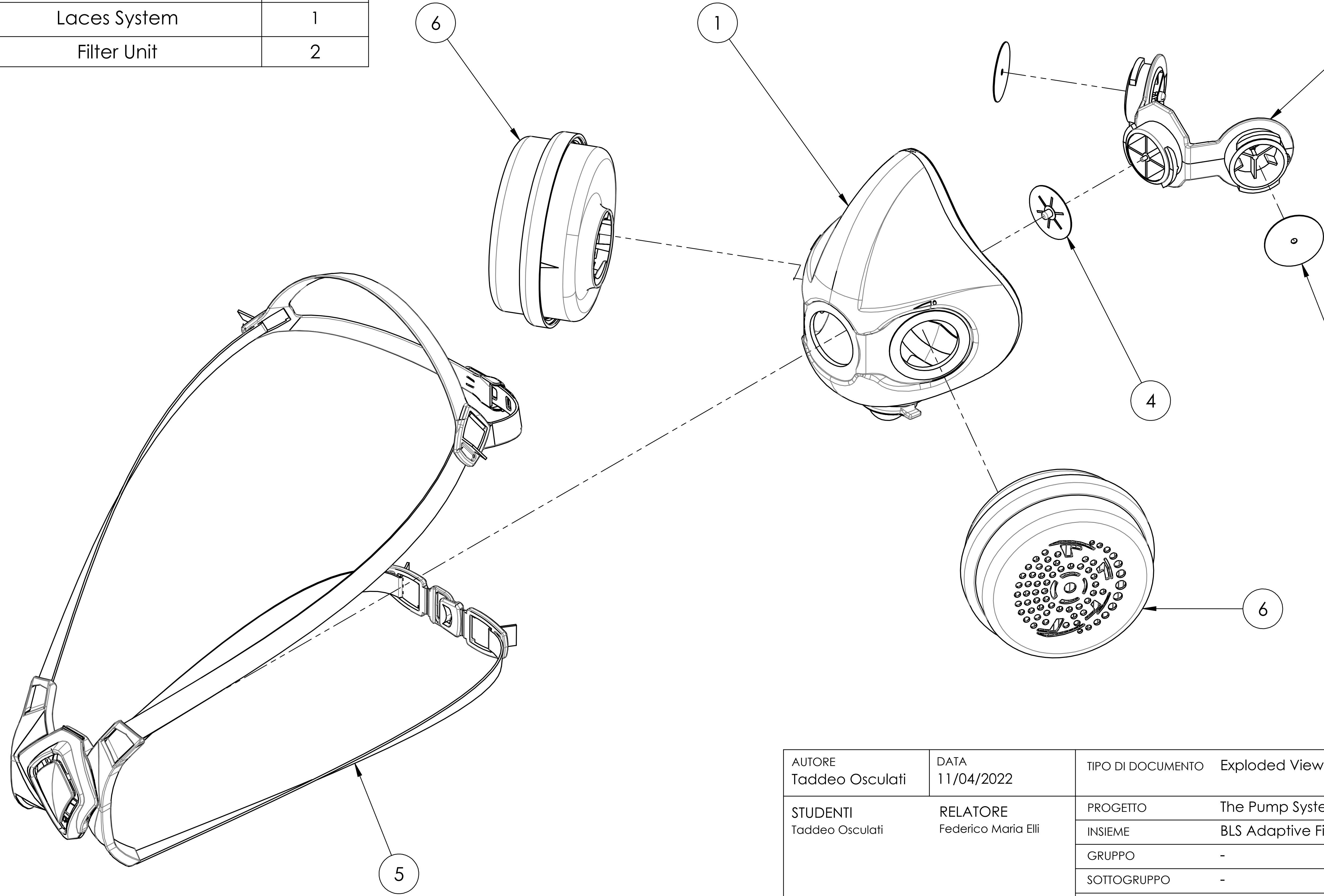
DETAIL A

SCALE 2 : 1

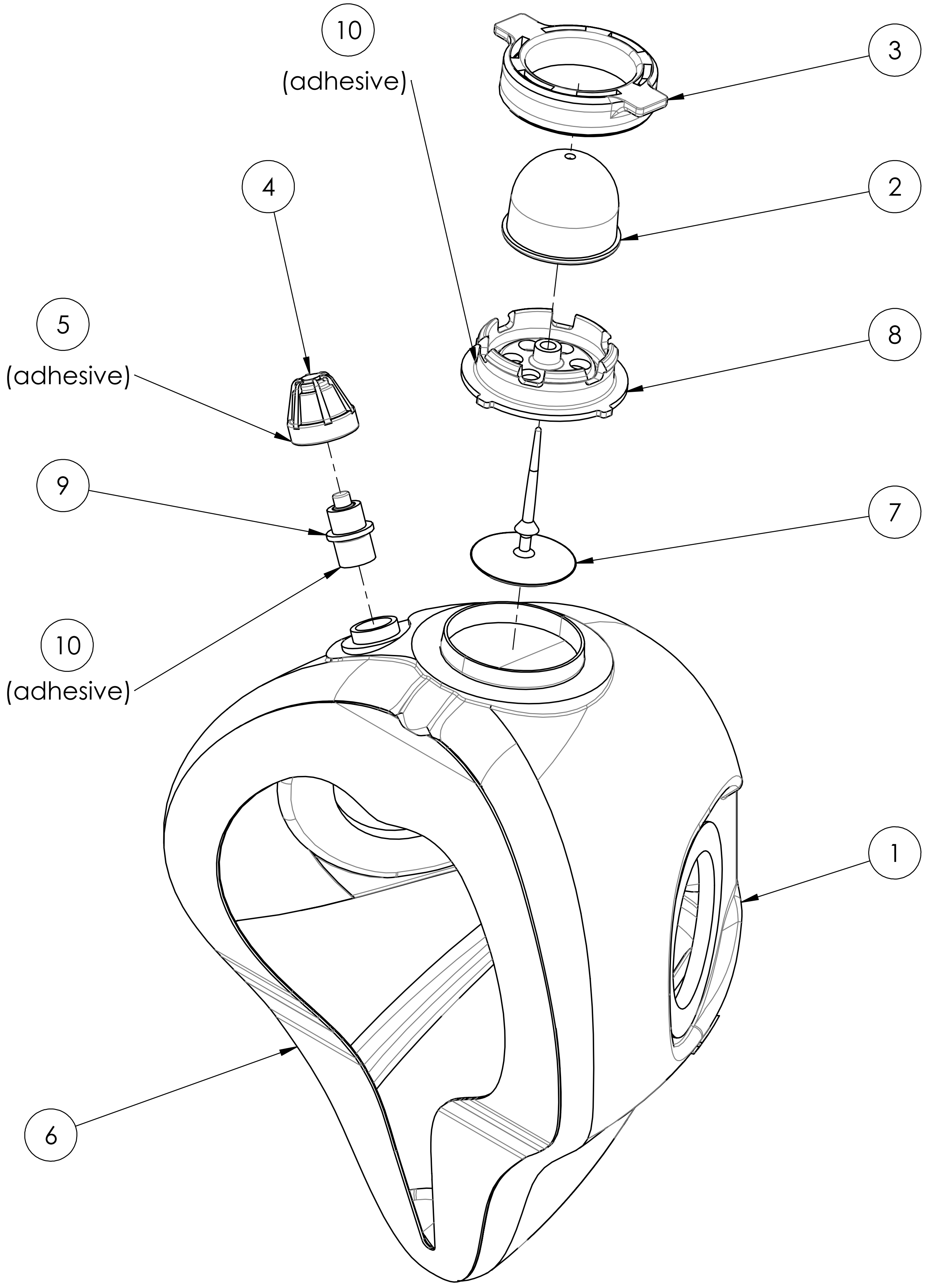
AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	General Assembly Drawing	Note:
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System	
		INSIEME	BLS Adaptive Fit Mask	
		GRUPPO	-	
		SOTTOGRUPPO	-	
		PARTICOLARE	-	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	0	
		DIS. N. 1	Scala 1:2 FOGLIO 0	

*N.B. For missing dimensions refer to 3D Model

ITEM NO.	DESCRIPTION	QTY.
1	Inflatable Mask Body	1
2	Matte Support	1
3	Inhale Valve	1
4	Exhale Valve	2
5	Laces System	1
6	Filter Unit	2



AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Exploded View	Note:
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System	
		INSIEME	BLS Adaptive Fit Mask	
		GRUPPO	-	
		SOTTOGRUPPO	-	
		PARTICOLARE	-	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	0	
		DIS. N. 2	Scala 1:2 FOGLIO 0	

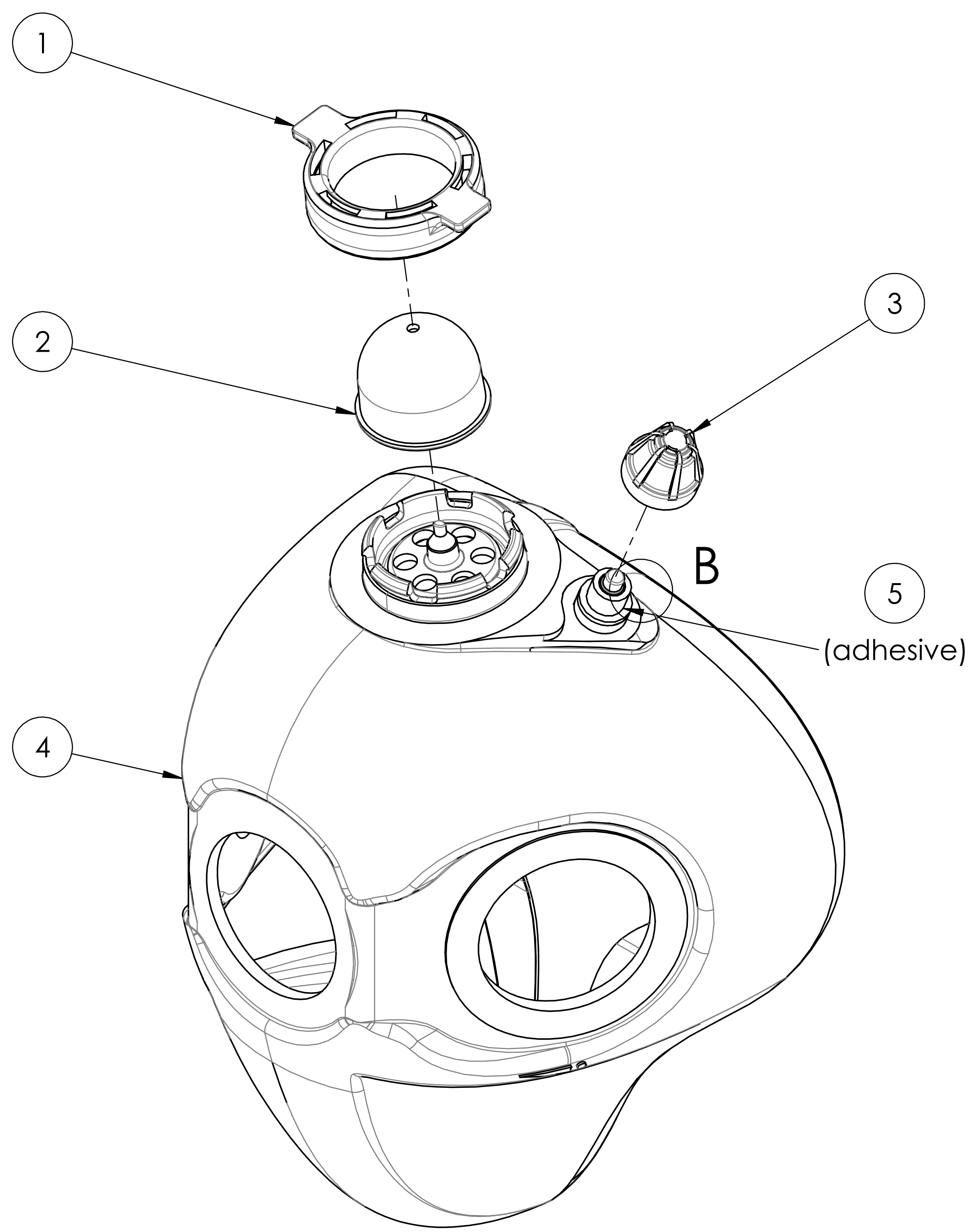


ITEM NO.	PART NUMBER	MATERIAL	MAN. PROCESS	QTY.
1	1	Silicone Rubber ShoreA 60	Over Moulding	1
2	1.2	Silicone Rubber ShoreA 50	Compression Molding	1
3	1.3	PA	Injection Moulding	1
4	1.4	TPE	Injection Moulding	1
5	1.5	Silicone Adhesive	BUY	AR
6	1.1.11	Silicone Rubber ShoreA 30	Vacuum Casting	1
7	1.1.12	Rubber	BUY	1
8	1.1.13	PA	Injection Moulding	1
9	1.1.14	-	BUY	1
10	1.1.15	Silicone Adhesive	BUY	AR

AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Exploded View
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System
		INSIEME	BLS Adaptive Fit Mask
		GRUPPO	Full Mask Body
		SOTTOGRUPPO	-
		PARTICOLARE	-
		CODICE	1
		DIS. N.	3
		Scala 1:1	FOGLIO 0

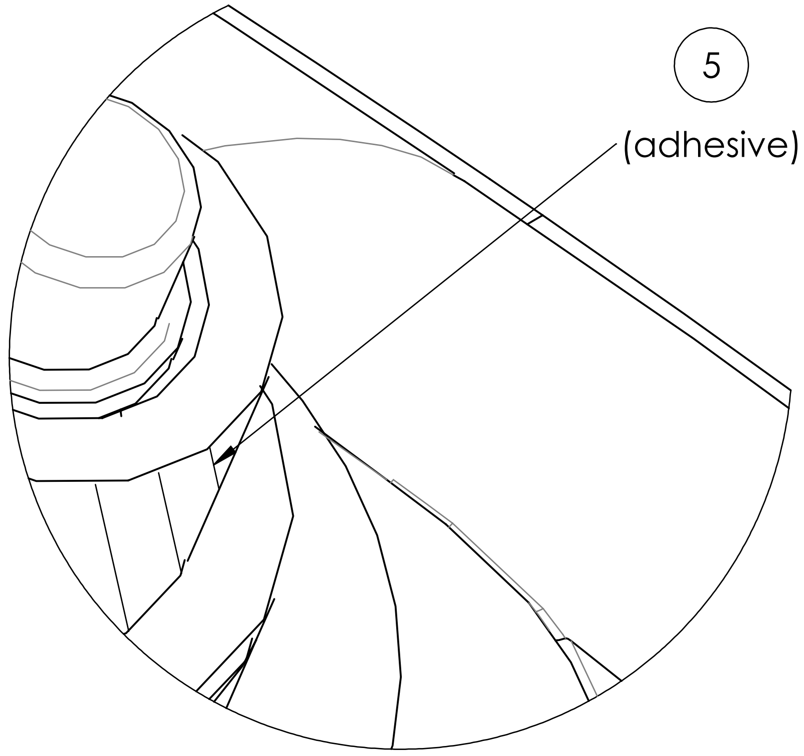
Note:

POLITECNICO DI MILANO
School of Design
Master Degree
Design & Engineering
A.A. 2020 / 2021 - Final Thesis Project



DETAIL B

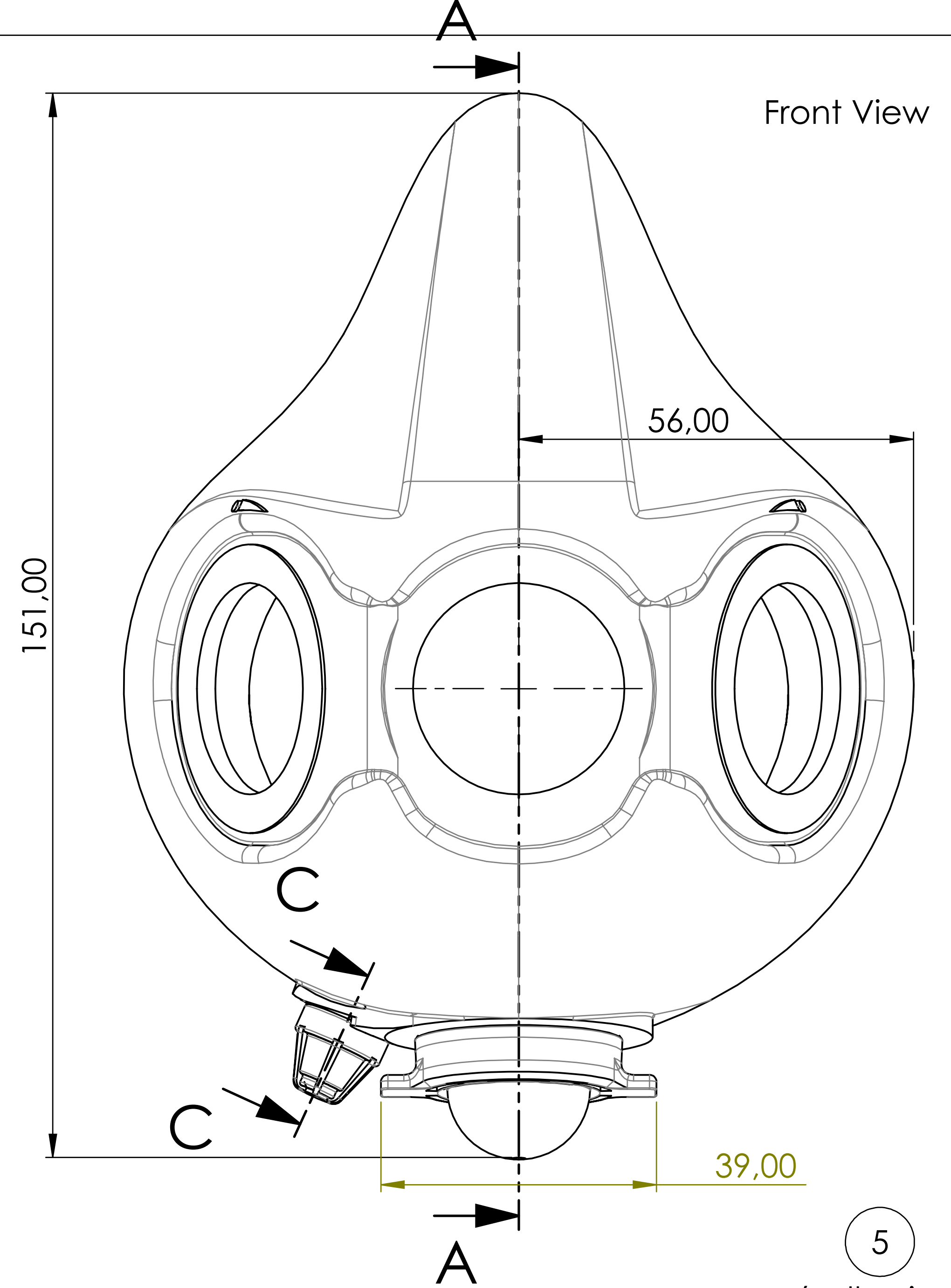
SCALE 10 : 1

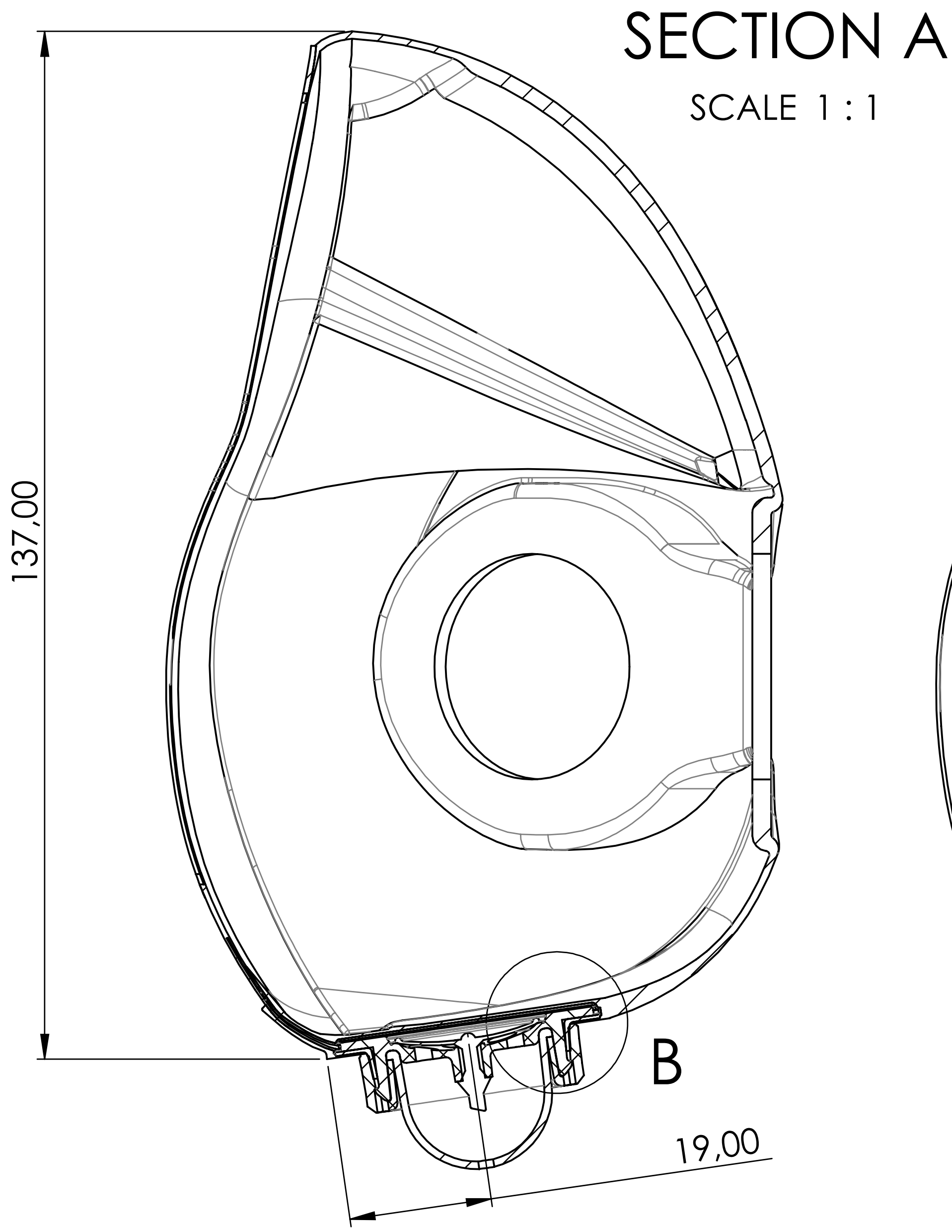


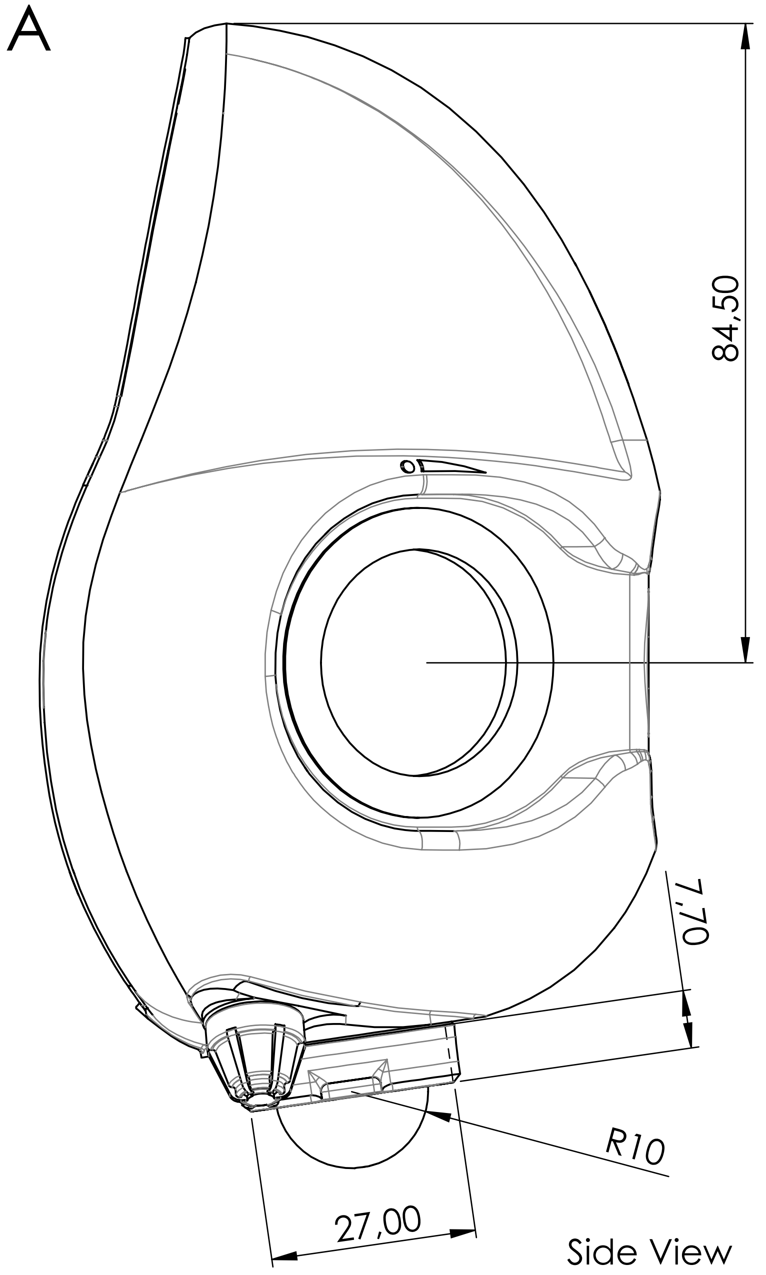
ITEM NO.	PART NUMBER	MATERIAL	MAN. PROCESS	QTY.
1	1.1	Silicone Rubber ShoreA 60	Over Moulding	1
2	1.2	Silicone Rubber ShoreA 50	Compression Molding	1
3	1.3	PA	Injection Moulding	1
4	1.4	TPE	Injection Moulding	1
5	1.5	Silicone Adhesive	BUY	AR

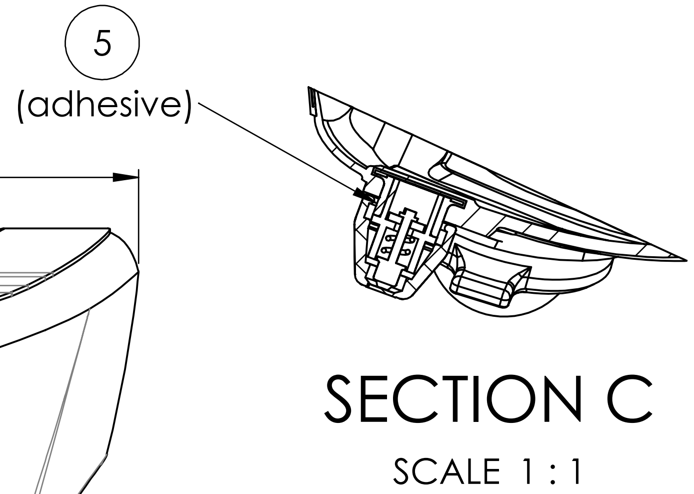
AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Exploded View
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System
		INSIEME	BLS Adaptive Fit Mask
		GRUPPO	Full Mask Body
		SOTTOGRUPPO	-
		PARTICOLARE	-
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1
		DIS. N. 4	Scala 1:1 FOGLIO 0

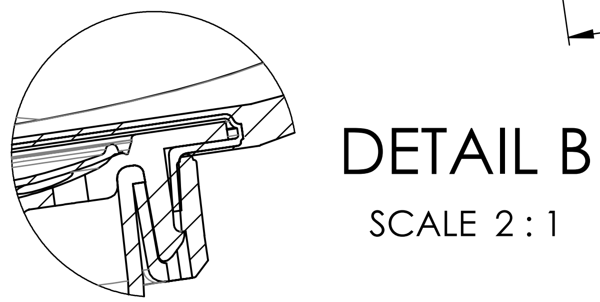
Note:

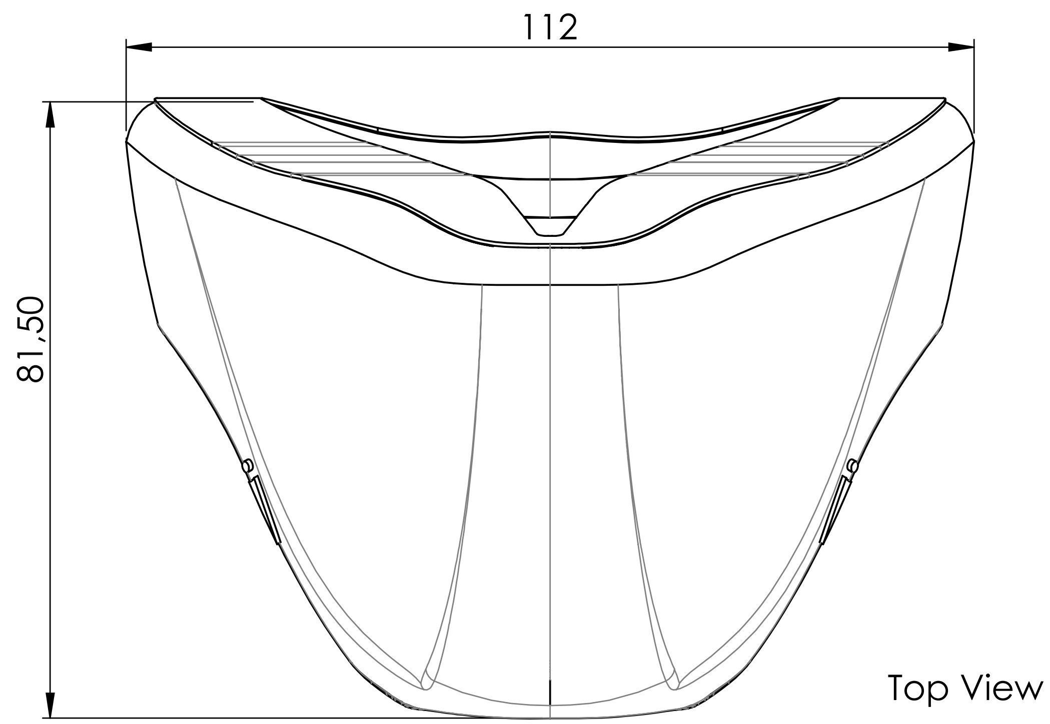








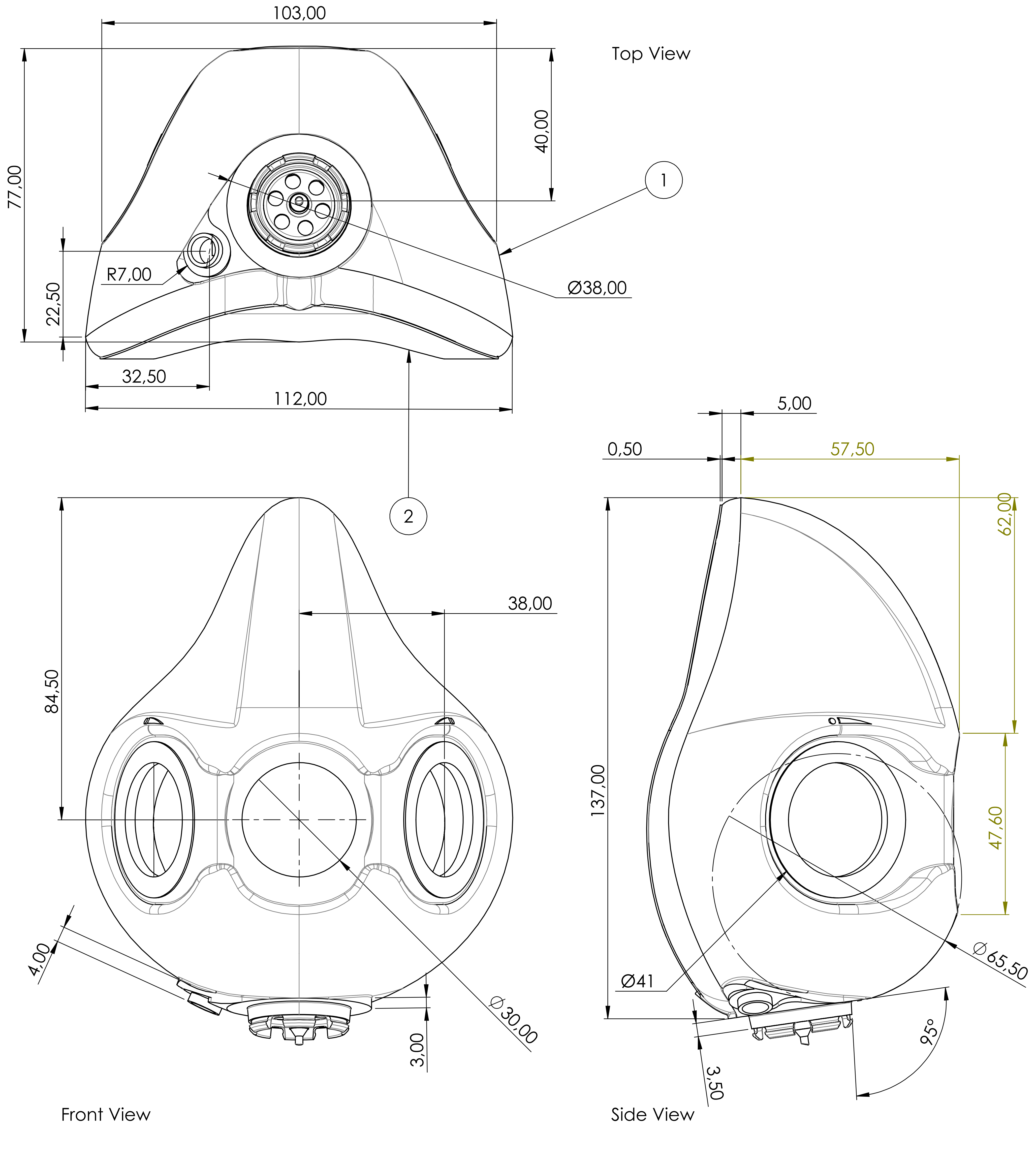




*N.B. For missing dimensions refer to 3D Model

AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Assembly Drawing
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System
		INSIEME	BLS Adaptive Fit Mask
		GRUPPO	Full Mask Body
		SOTTOGRUPPO	-
		PARTICOLARE	-
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1
		DIS. N. 5	Scala 1:1 FOGLIO 0

Note:

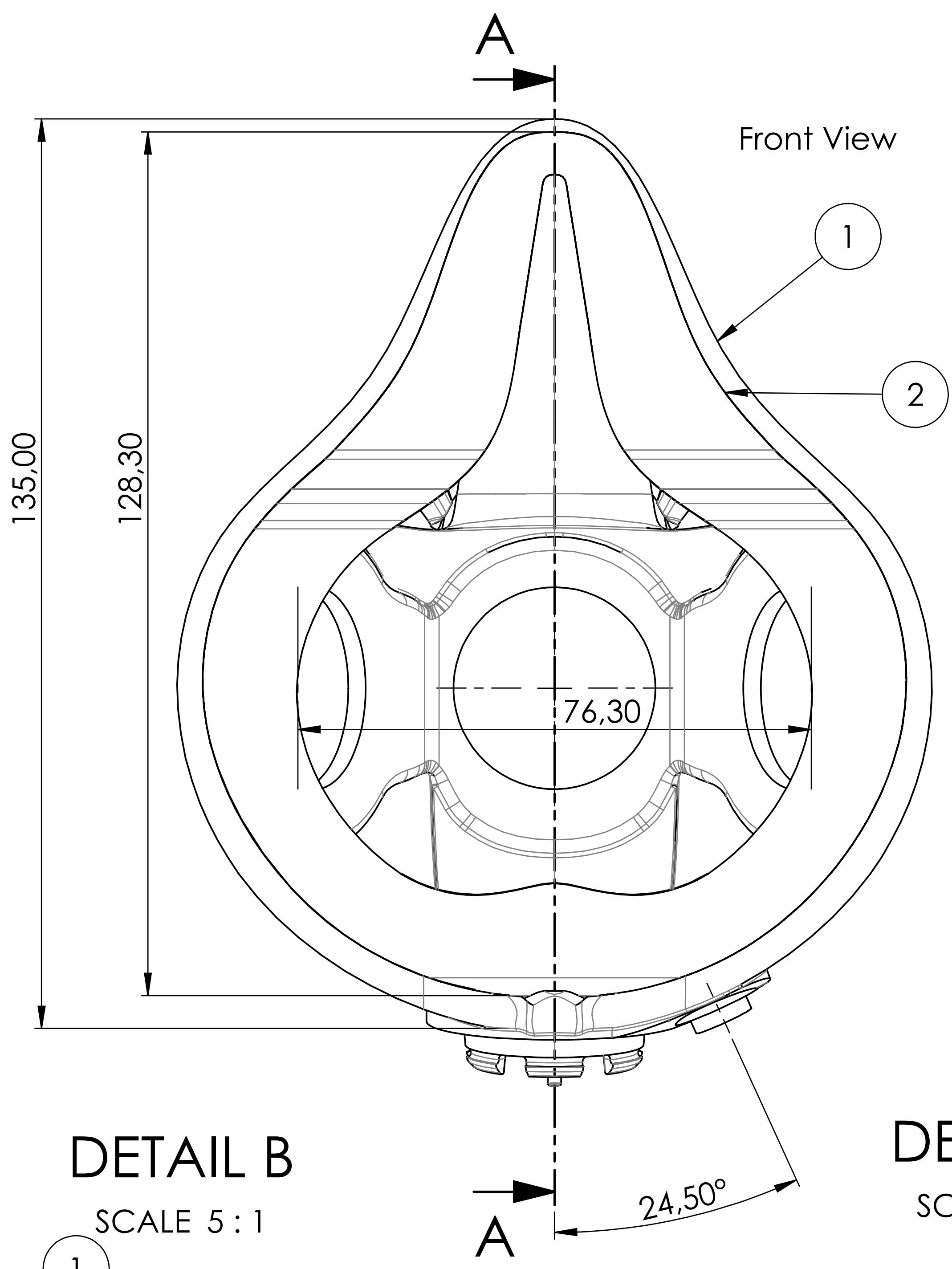


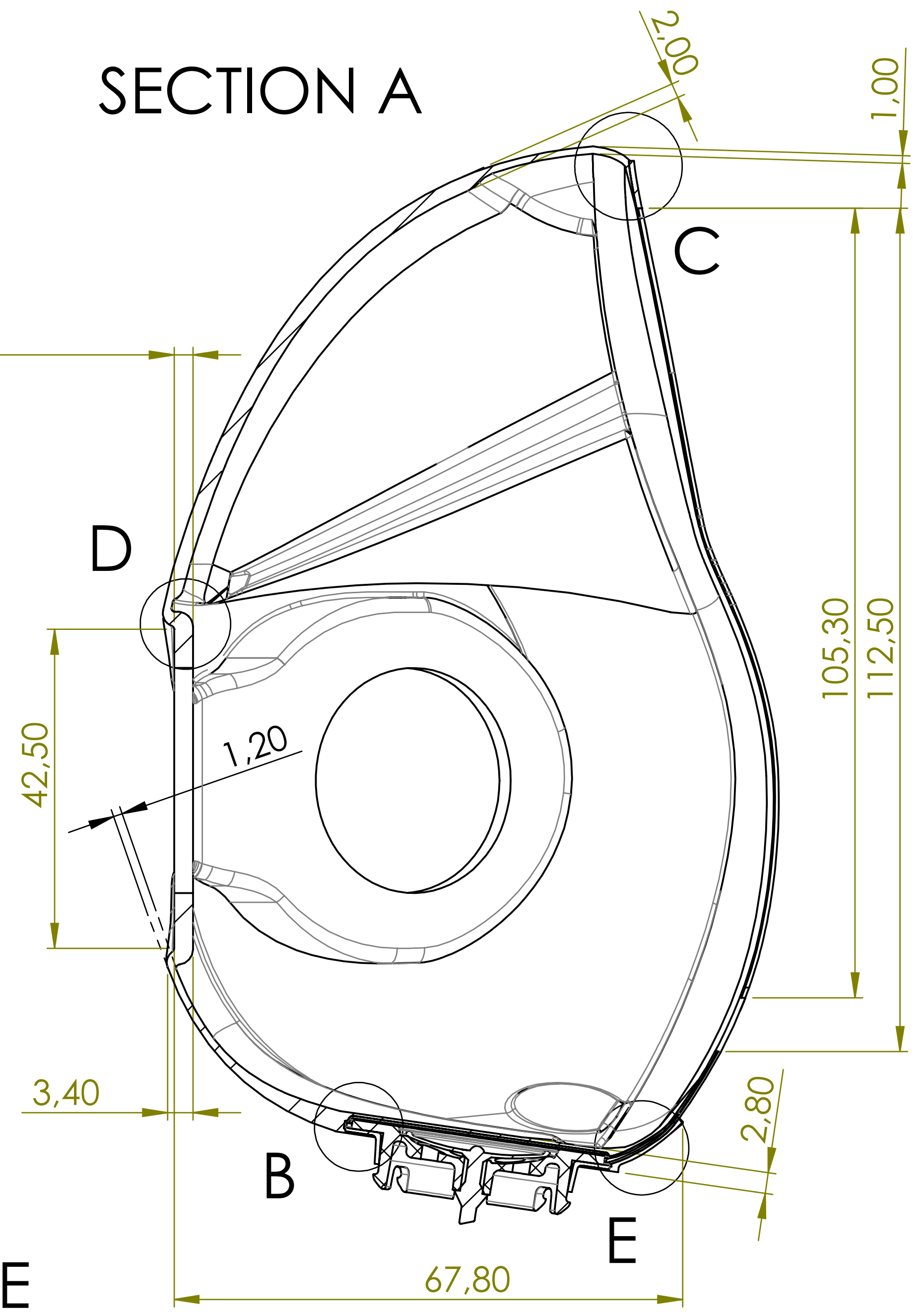
ITEM NO.	PART NUMBER	MATERIAL	MAN. PROCESS	QTY.
1	1.1	Silicone Rubber ShoreA 60	Over Moulding	1
2	1.1.1	Silicone Rubber ShoreA 30	Bonding	1

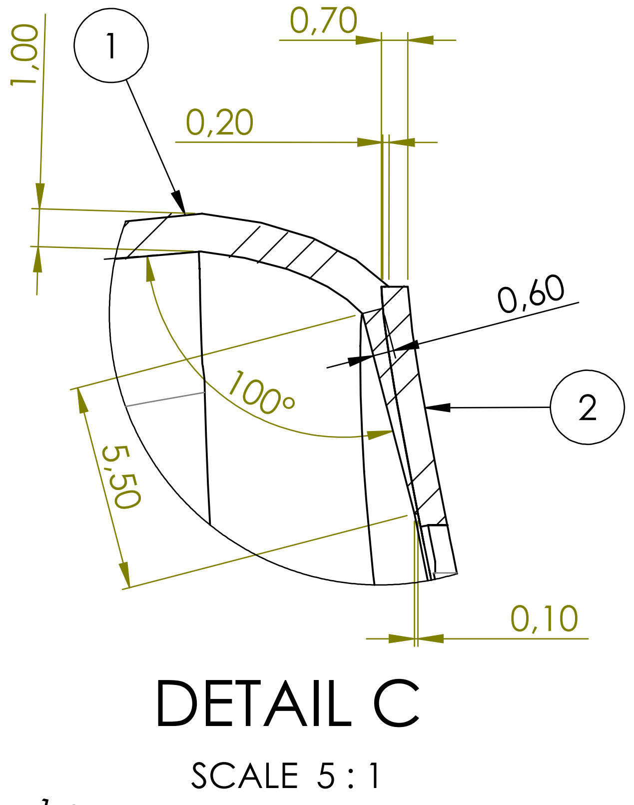
AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Assembly Drawing	Note:
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System	
		INSIEME	BLS Adaptive Fit Mask	
		GRUPPO	Mask Overmold Ass	
		SOTTOGRUPPO	-	
		PARTICOLARE	-	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1.1	
		DIS. N. 6	Scala 1:1 FOGLIO 0	

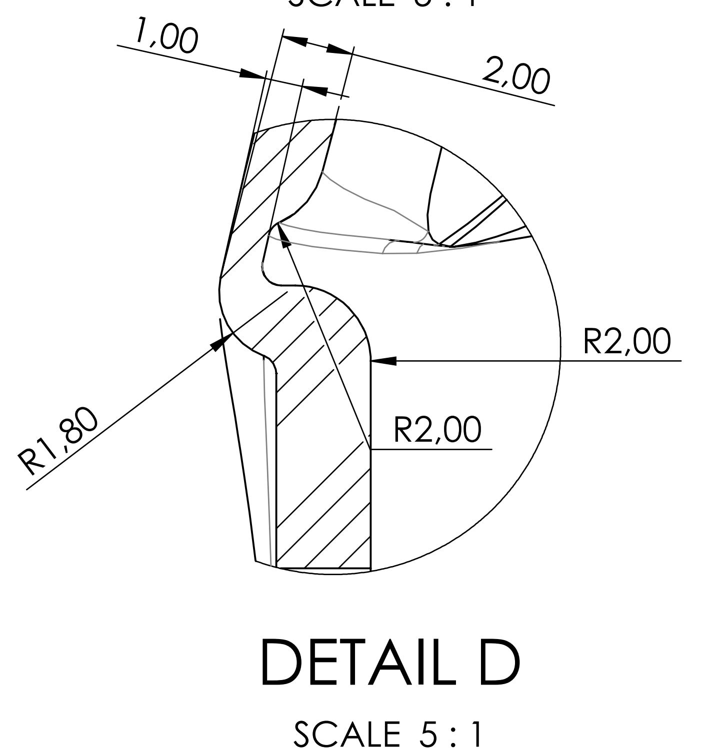
*N.B. For missing dimensions refer to 3D Model

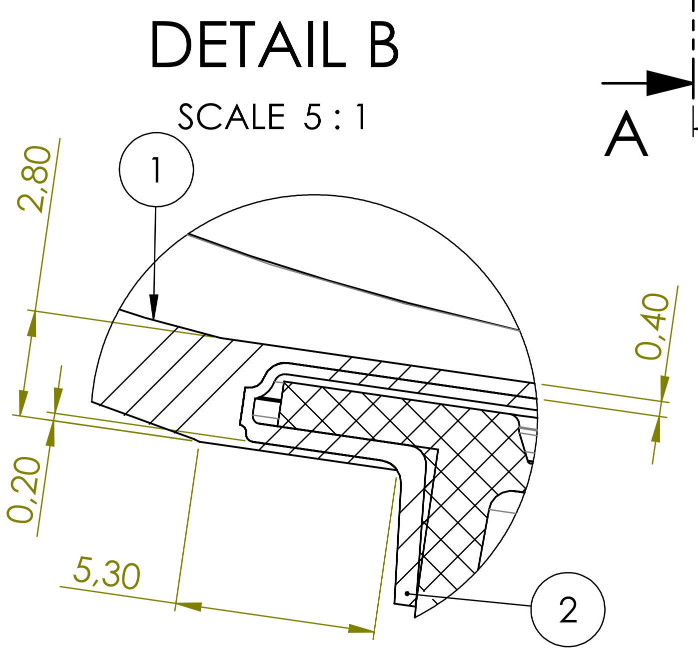
ITEM NO.	PART NUMBER	MATERIAL	MAN. PROCESS	QTY.
1	1.1	Silicone Rubber ShoreA 60	Over Moulding	1
2	1.1.1	Silicone Rubber ShoreA 30	Injection Moulding	1

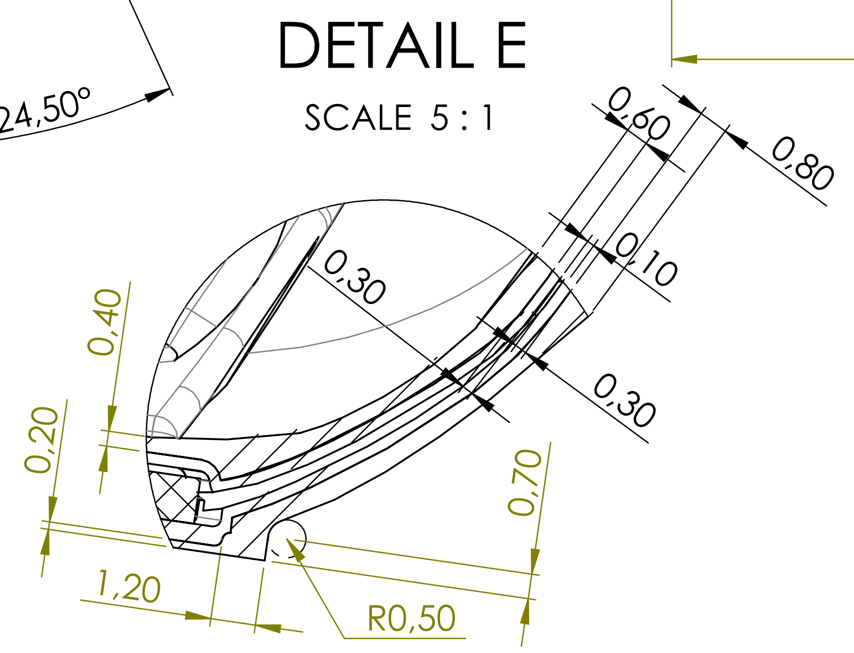












*N.B. For missing dimensions refer to 3D Model

AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Assembly Drawing	Note:
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System	
		INSIEME	BLS Adaptive Fit Mask	
		GRUPPO	Mask Overmold Ass	
		SOTTOGRUPPO	-	
		PARTICOLARE	-	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1.1	
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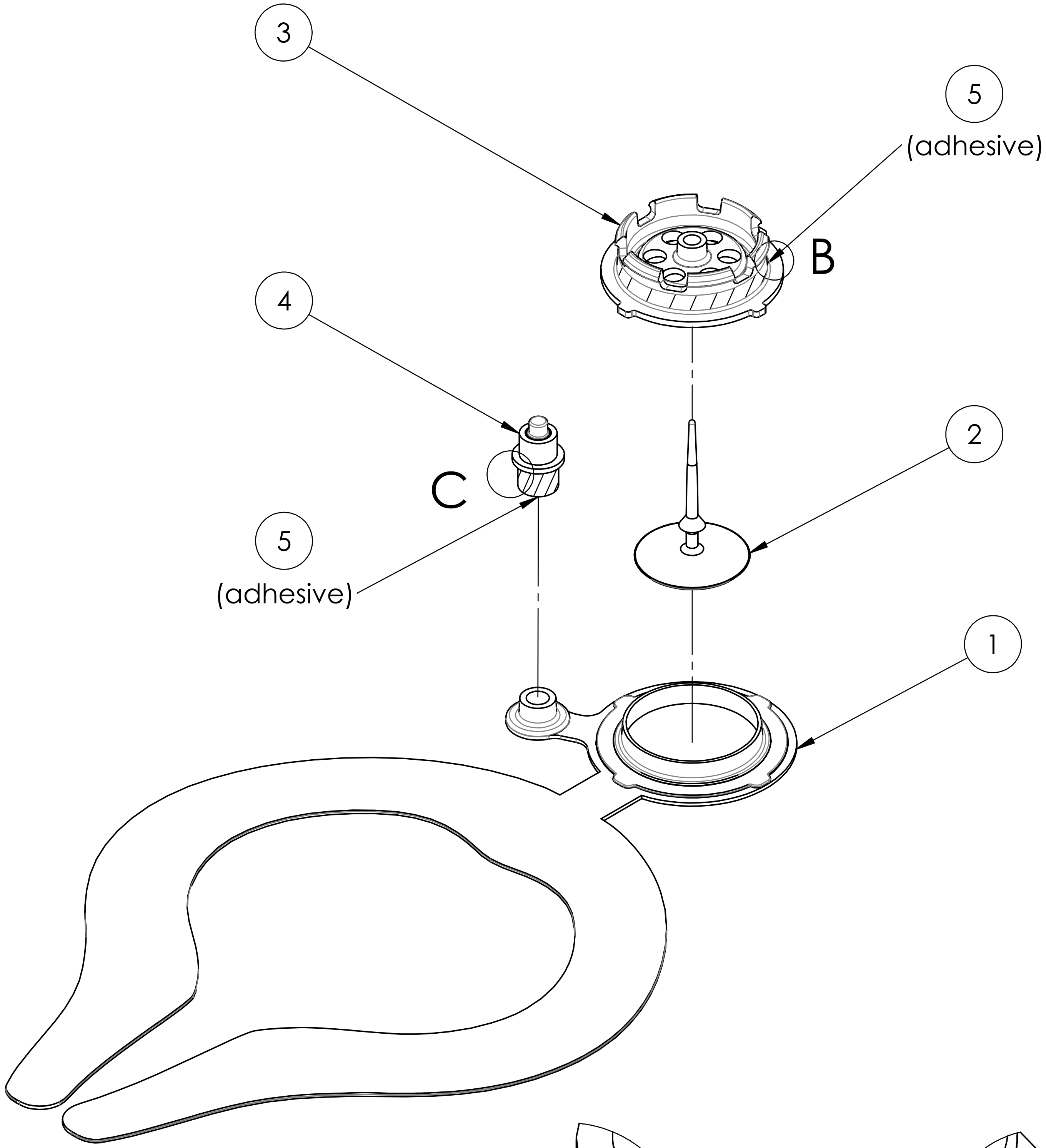
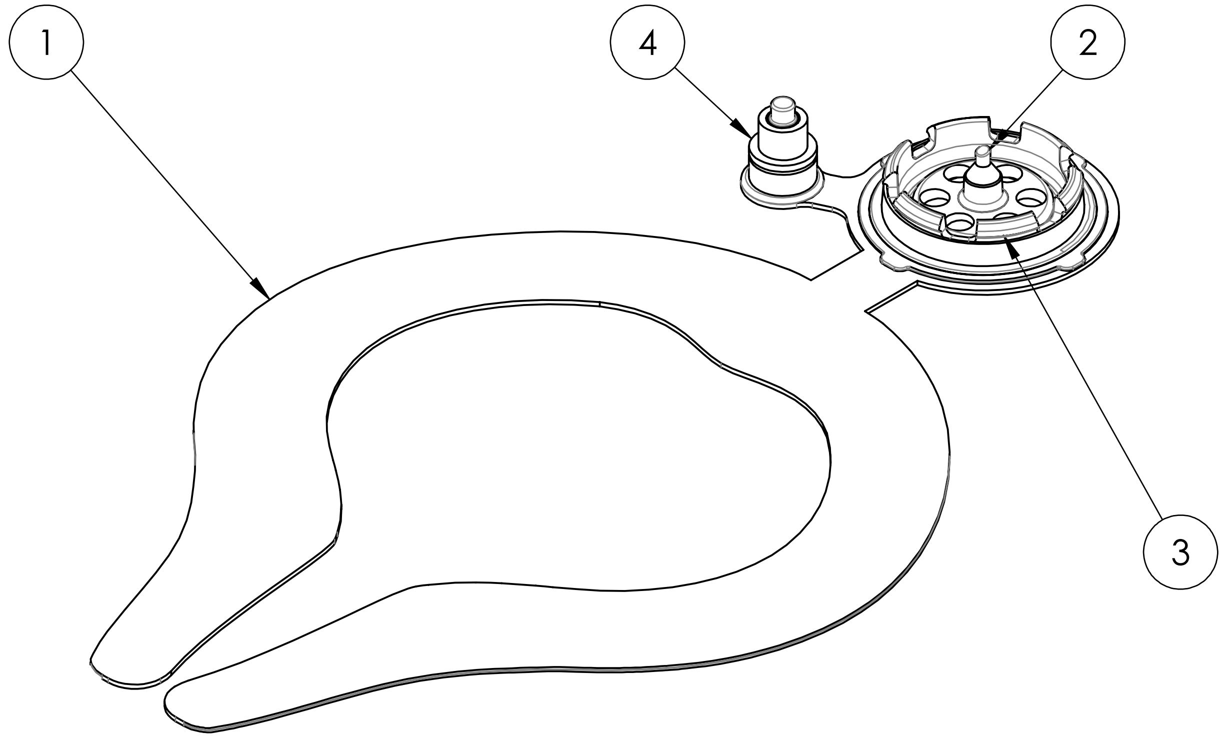
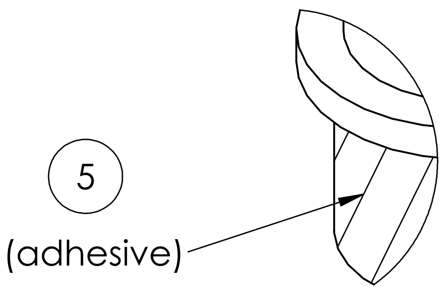
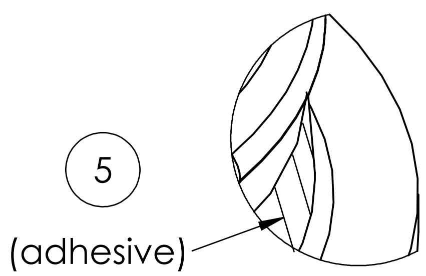




ITEM NO.	PART NUMBER	MATERIAL	MAN. PROCESS	QTY.
1	1.1.11	Silicone Rubber ShoreA 30	Sheet Bonding	1
2	1.1.12	Rubber	BUY	1
3	1.1.13	PA	Injection Moulding	1
4	1.1.14	-	BUY	1
5	1.1.15			AR



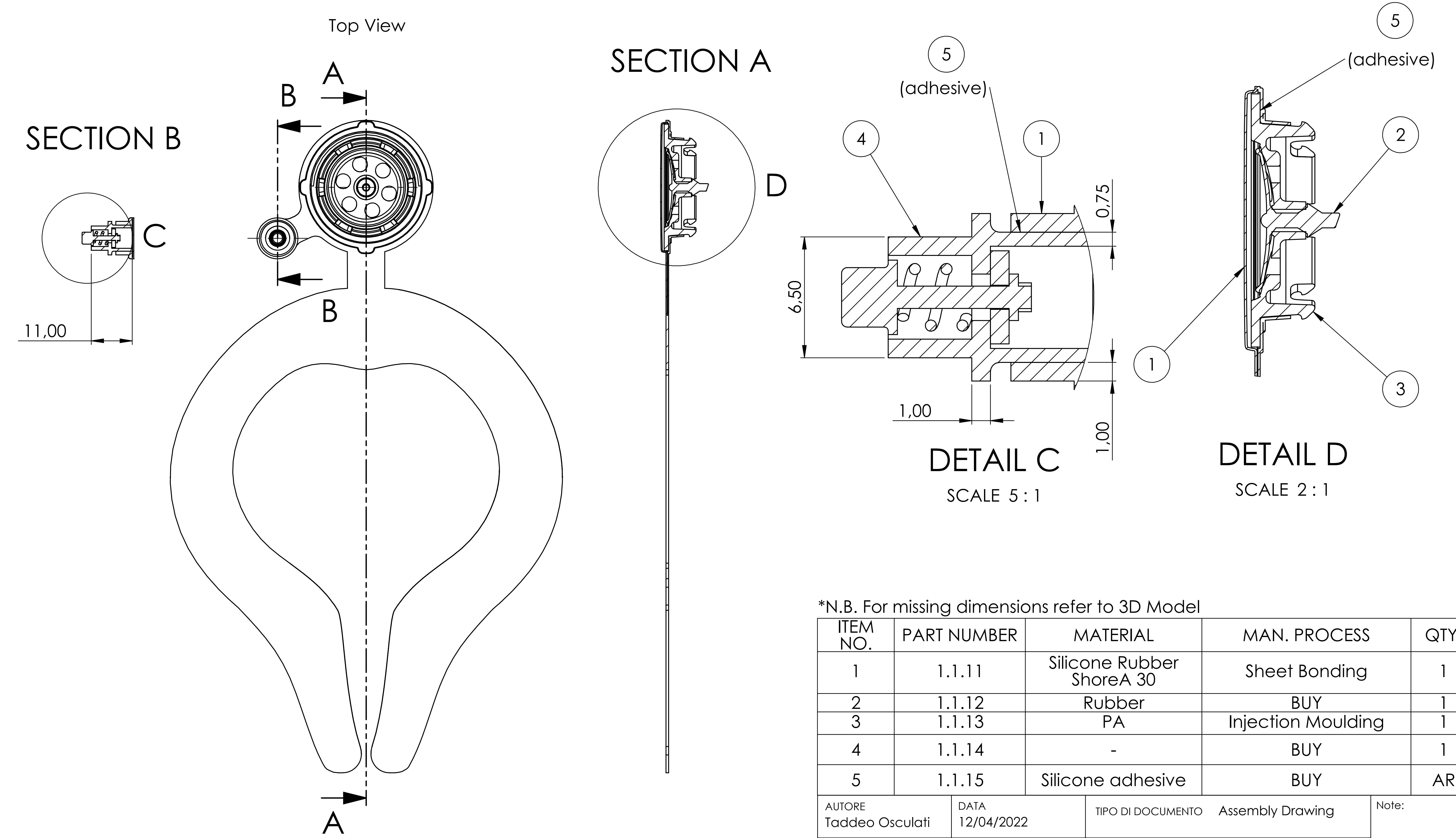
DETAIL C
SCALE 5 : 1

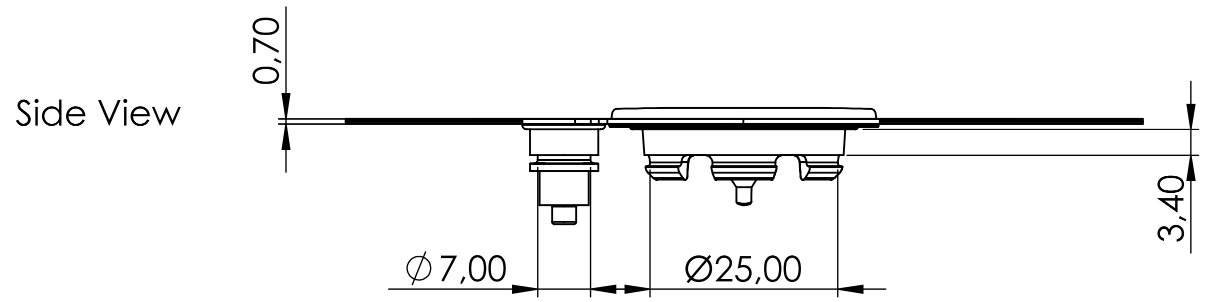


DETAIL D
SCALE 5 : 1

AUTORE: Taddeo Osculati	DATA: 11/04/2022	TIPO DI DOCUMENTO	Exploded View
STUDENTI: Taddeo Osculati	RELATORE: Federico Maria Elli	PROGETTO	The Pump System
		INSIEME	BLS Adaptive Fit Mask
		GRUPPO	Inflatable Chamber Ass
		SOTTOGRUPPO	-
		PARTICOLARE	-
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1.1.1
		DIS. N. 8	Scala 1:1 FOGLIO 0

Note:

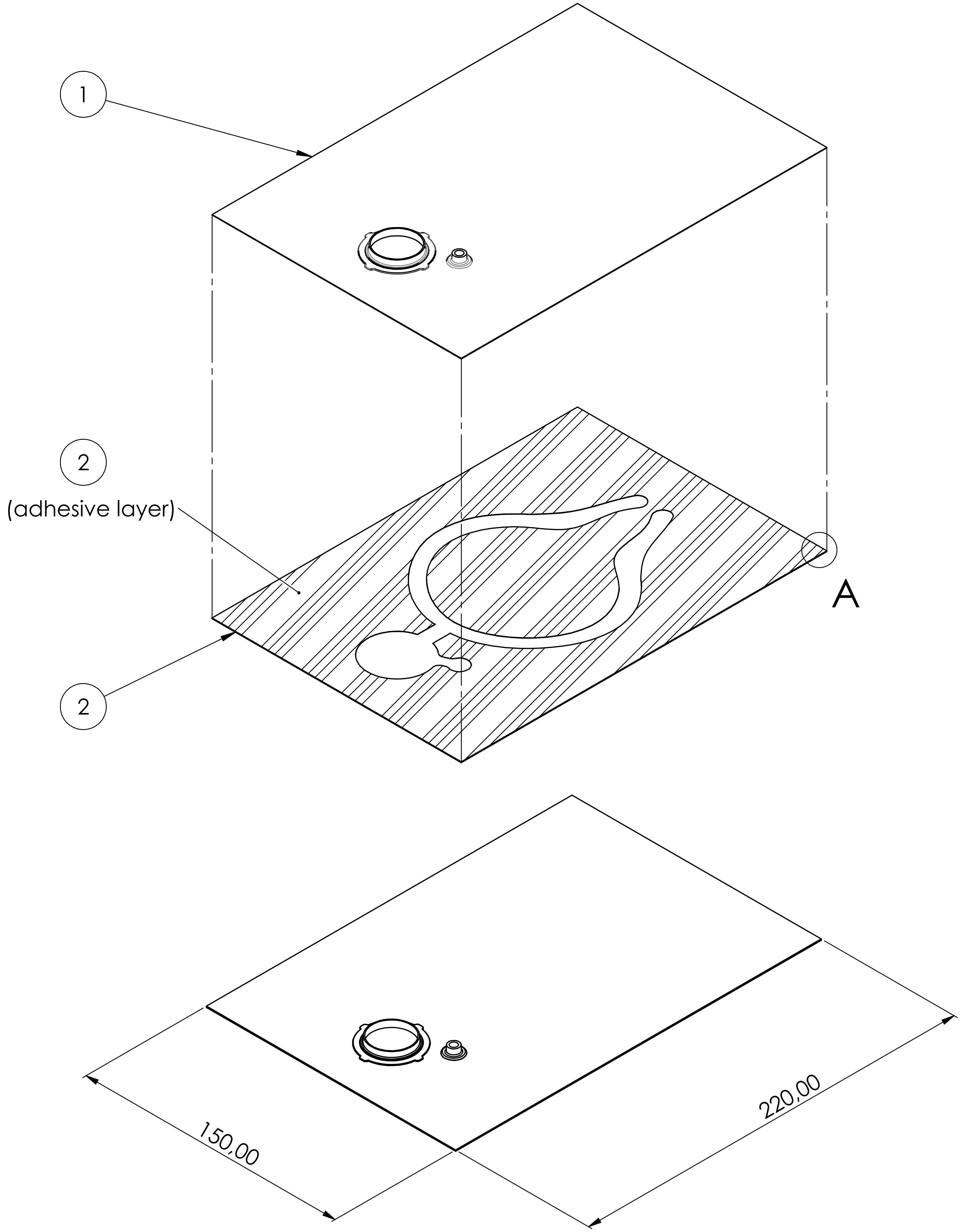


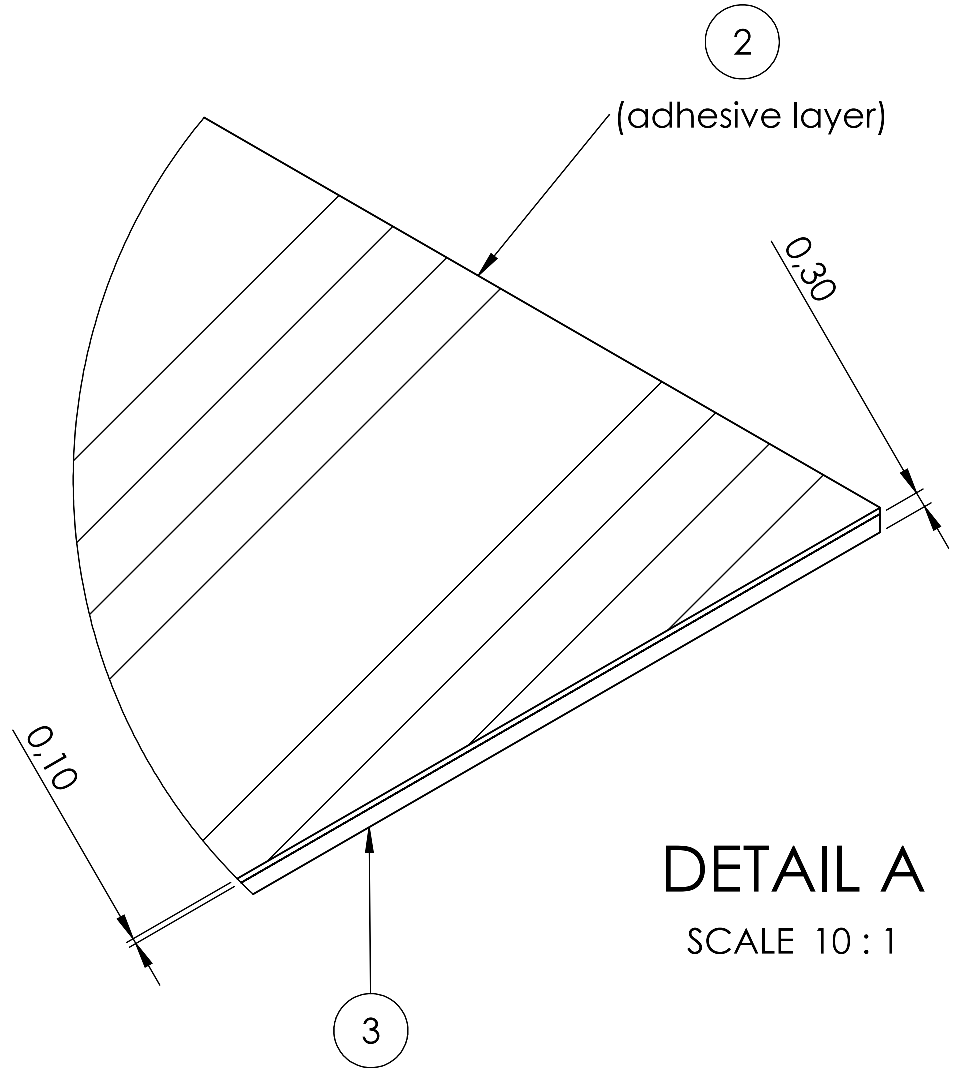


*N.B. For missing dimensions refer to 3D Model

ITEM NO.	PART NUMBER	MATERIAL	MAN. PROCESS	QTY.
1	1.1.11	Silicone Rubber ShoreA 30	Sheet Bonding	1
2	1.1.12	Rubber	BUY	1
3	1.1.13	PA	Injection Moulding	1
4	1.1.14	-	BUY	1
5	1.1.15	Silicone adhesive	BUY	AR

AUTORE: Taddeo Osculati	DATA: 12/04/2022	TIPO DI DOCUMENTO: Assembly Drawing	Note:
STUDENTI: Taddeo Osculati	RELATORE: Federico Maria Elli	PROGETTO: The Pump System	
		INSIEME: BLS Adaptive Fit Mask	
		GRUPPO: Mask Overmold Ass	
		SOTTOGRUPPO: Inflatable Chamber Ass	
		PARTICOLARE: -	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE: 1.1.1	
		DIS. N.: 9	Scala 1:1 FOGLIO 0





DETAIL A

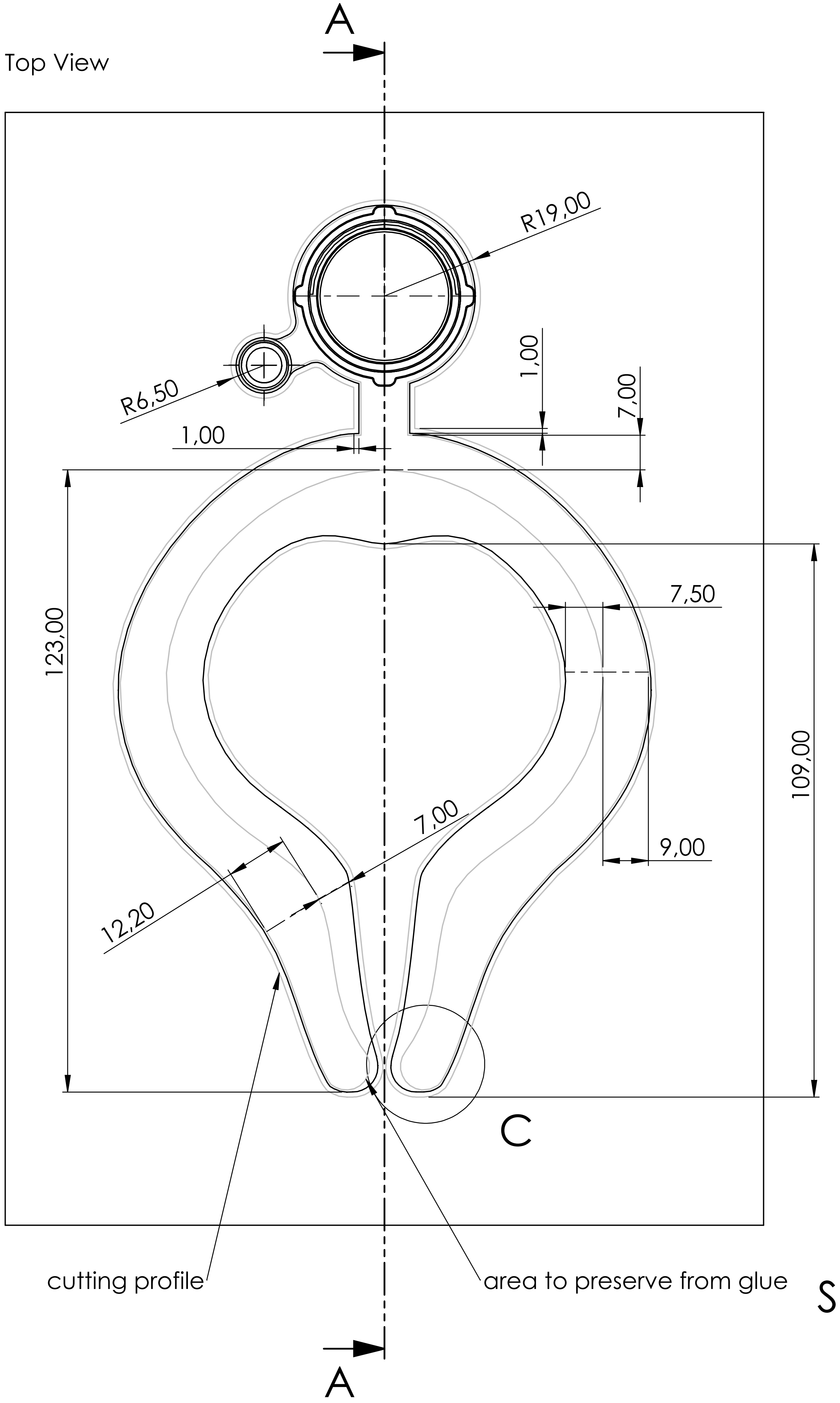
SCALE 10 : 1

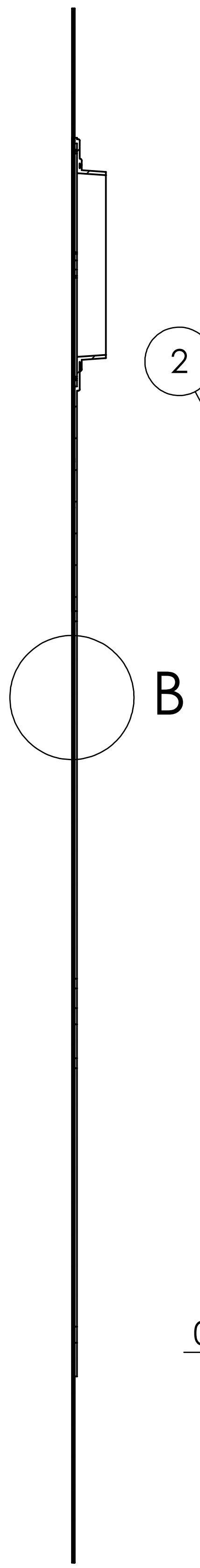
ITEM NO.	PART NUMBER	MATERIAL	MAN. PROCESS	QTY.
1	1.1.11.1	Silicone Rubber ShoreA 30	Vacuum Casting	1
2	1.1.11.2	Silicone Rubber ShoreA 30	BUY	1
3	1.1.11.3	Silicone Rubber ShoreA 30	BUY	AR

AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Production Drawing Sheet Bonding	Note:
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System	
		INSIEME	BLS Adaptive Fit Mask	
		GRUPPO	Silicone Chamber Ass	
		SOTTOGRUPPO	-	
		PARTICOLARE	-	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1.1.11	
		DIS. N. 10	Scala 1:2 FOGLIO 0	

ITEM NO.	PART NUMBER	MATERIAL	MAN. PROCESS	QTY.
1	1.1.11.1	Silicone Rubber ShoreA 30	Over Moulding	1
2	1.1.11.2	Silicone Rubber ShoreA 30	BUY	1
3	1.1.11.3	Silicone Rubber ShoreA 30	BUY	AR

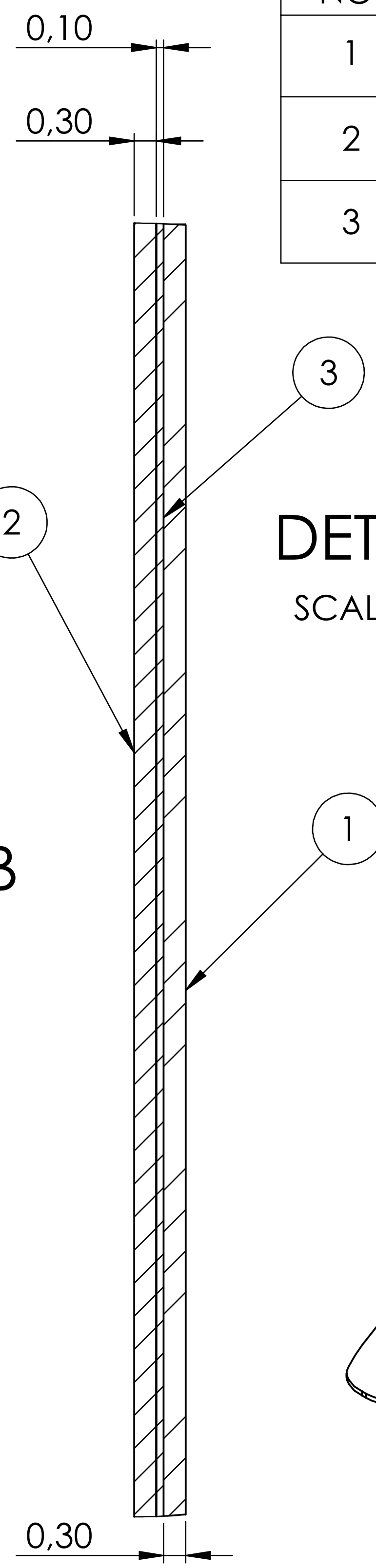
Top View





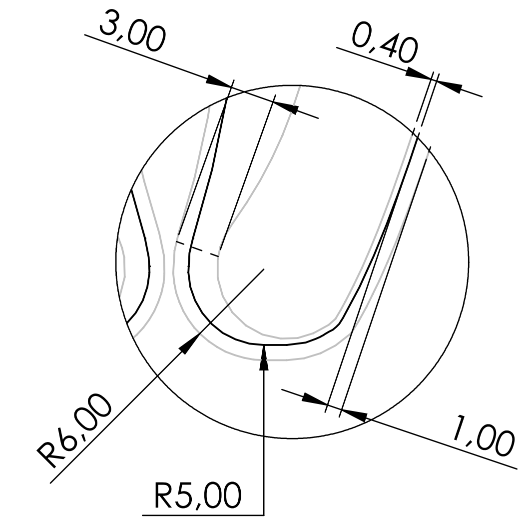
SECTION A

SCALE 1 : 1



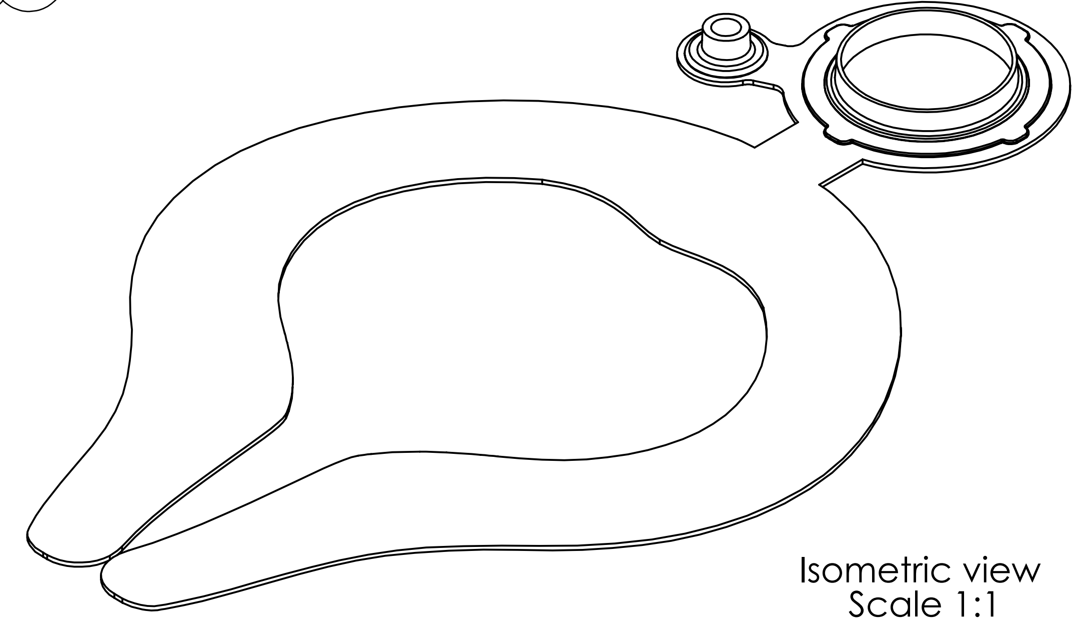
DETAIL B

SCALE 10 : 1



DETAIL C

SCALE 2 : 1

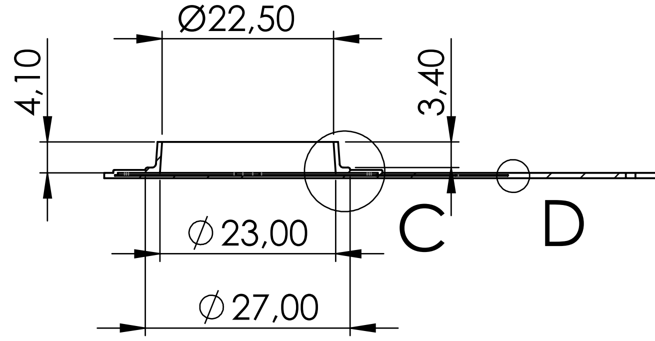


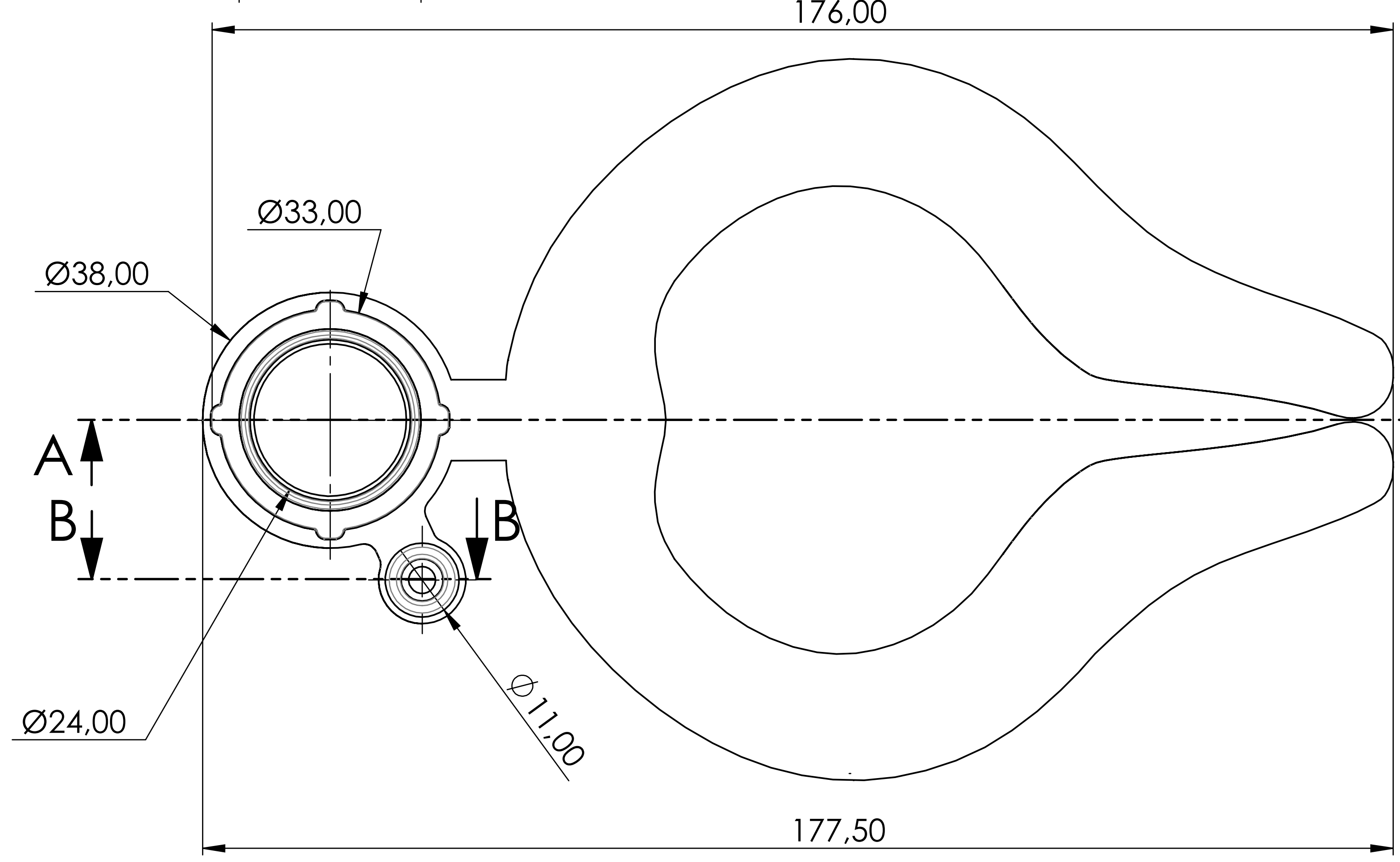
Isometric view
Scale 1:1

*N.B. For missing dimensions refer to 3D Model

AUTORE Taddeo Osculati	DATA 12/04/2022	TIPO DI DOCUMENTO	Production Drawing Bonding and Cutting	Note:
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System	
		INSIEME	BLS Adaptive Fit Mask	
		GRUPPO	Inflatable Chamber	
		SOTTOGRUPPO	-	
		PARTICOLARE	Silicone Chamber	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1.1.11	
		DIS. N. 11	Scala 1:1 FOGLIO 0	

SECTION A

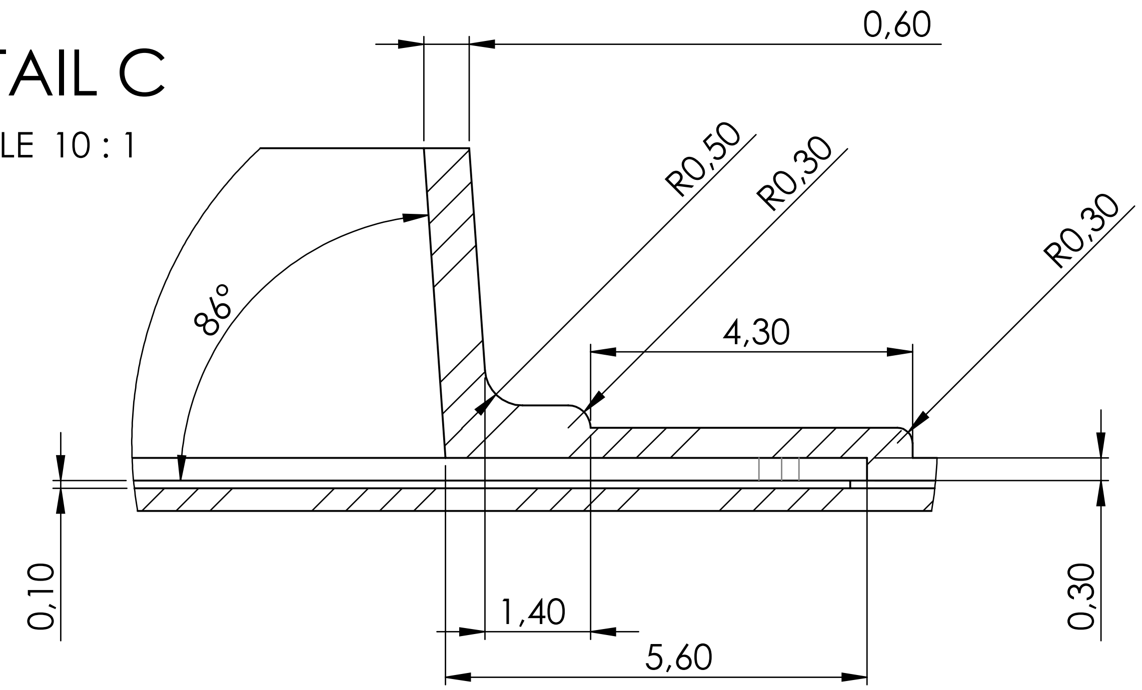




Top View

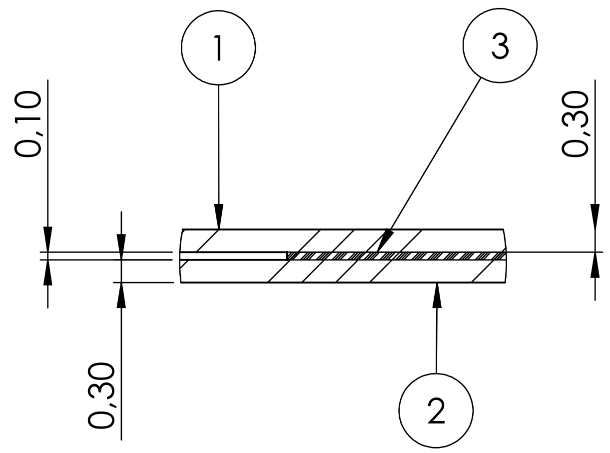
DETAIL C

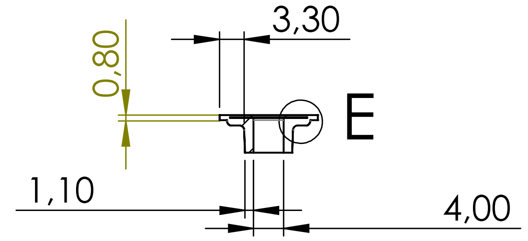
SCALE 10 : 1



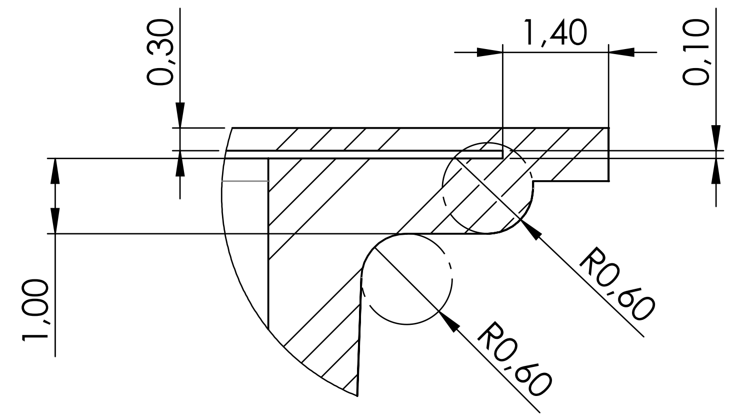
DETAIL D

SCALE 10 : 1





SECTION B



DETAIL E

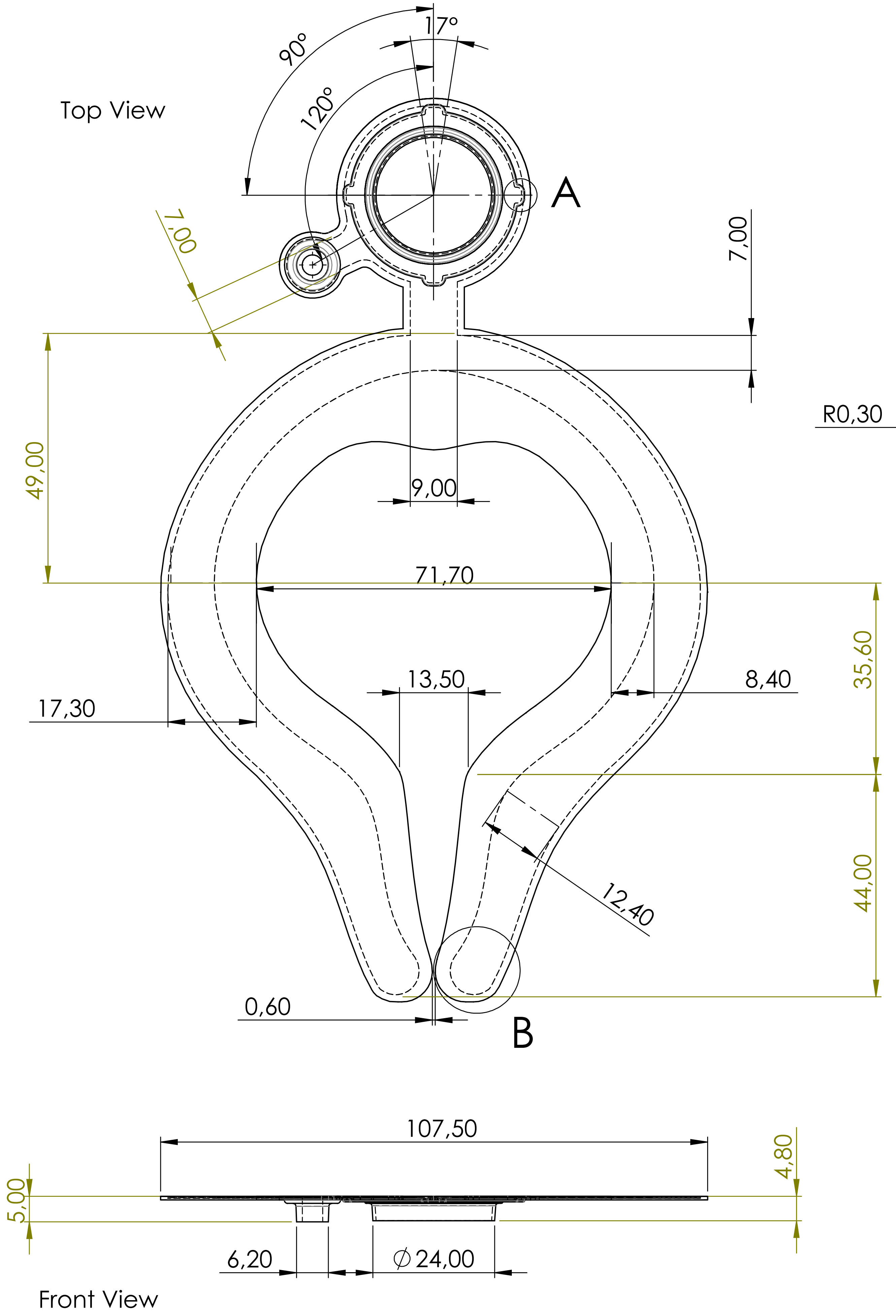
SCALE 10 : 1

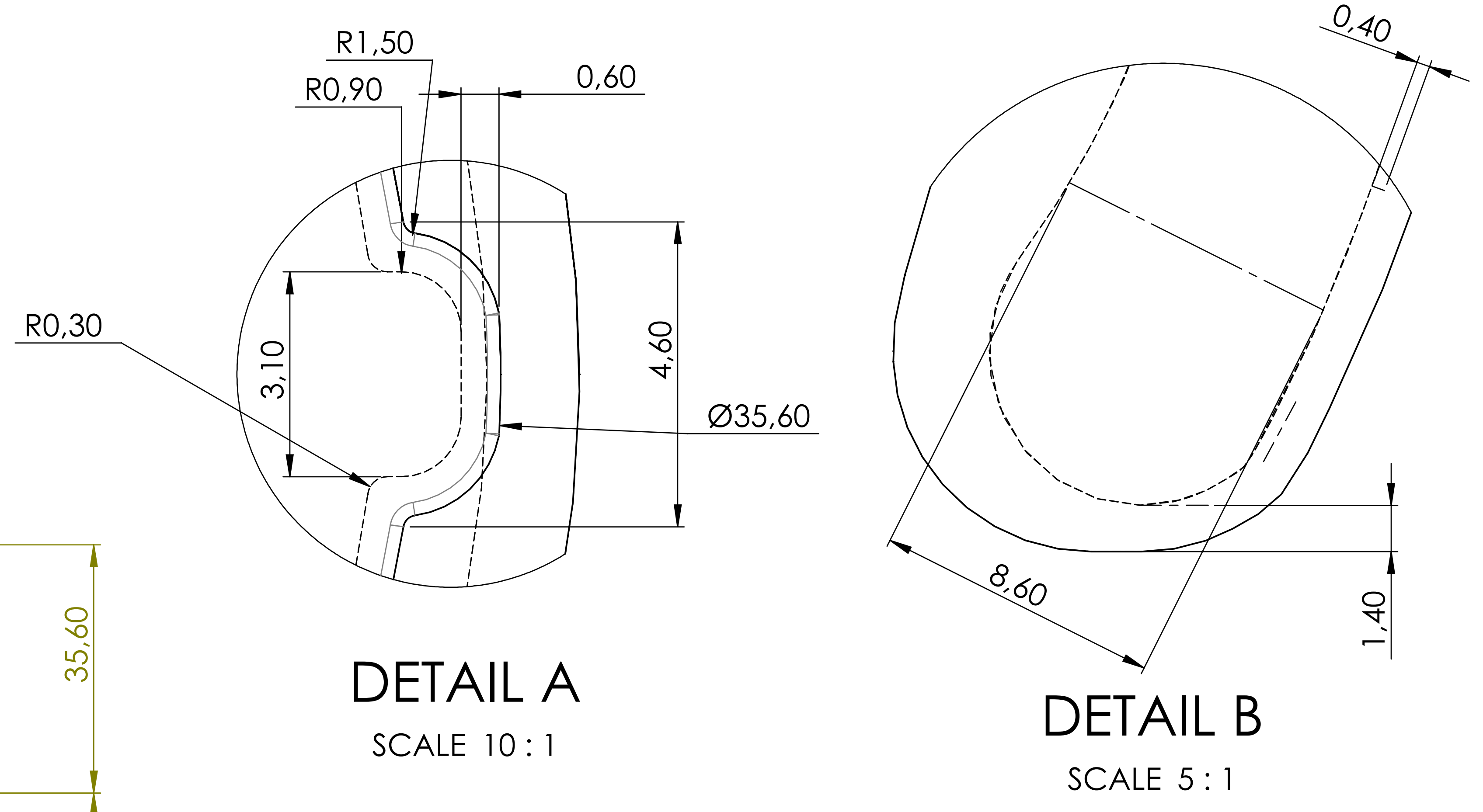
ITEM NO.	PART NUMBER	MATERIAL	MAN. PROCESS	QTY.
1	1.1.11.1	Silicone Rubber ShoreA 30	Vacuum Casting	1
2	1.1.11.2	Silicone Rubber ShoreA 30	BUY	1
3	1.1.11.3	Silicone Rubber ShoreA 30	BUY	AR

AUTORE	Taddeo Osculati
DATA	11/04/2022
STUDENTI	Taddeo Osculati
RELATORE	Federico Maria Elli
TIPO DI DOCUMENTO	Assembly Drawing
PROGETTO	The Pump System
INSIEME	BLS Adaptive Fit Mask
GRUPPO	Silicone Chamber Ass
SOTTOGRUPPO	-
PARTICOLARE	-
CODICE	1.1.11
DIS. N.	12
Scala 1:1	
FOGLIO	0
Note:	

POLITECNICO DI MILANO
School of Design
Master Degree
Design & Engineering
A.A. 2020 / 2021 - Final Thesis Project

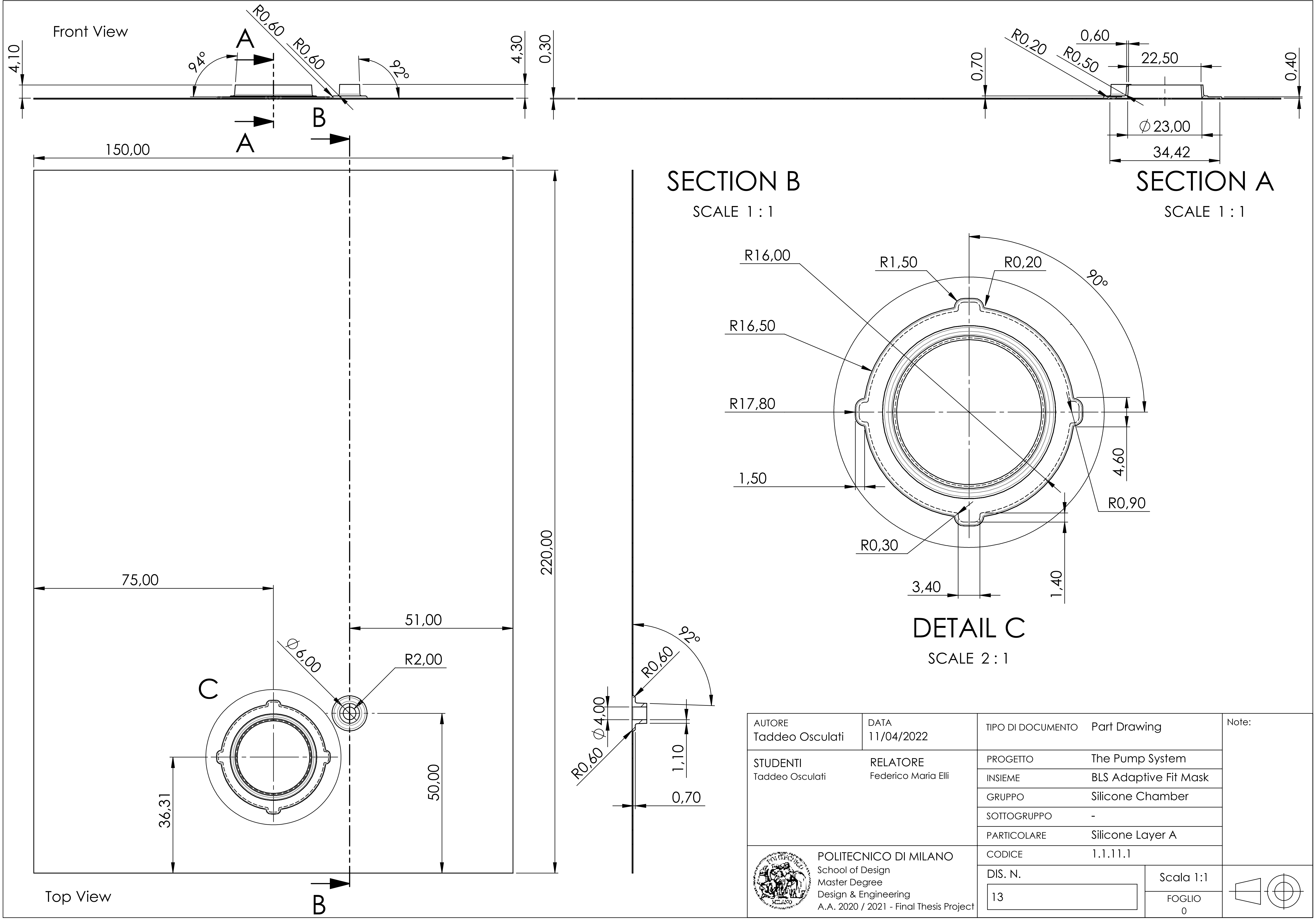
*N.B. For missing dimensions refer to 3D Model



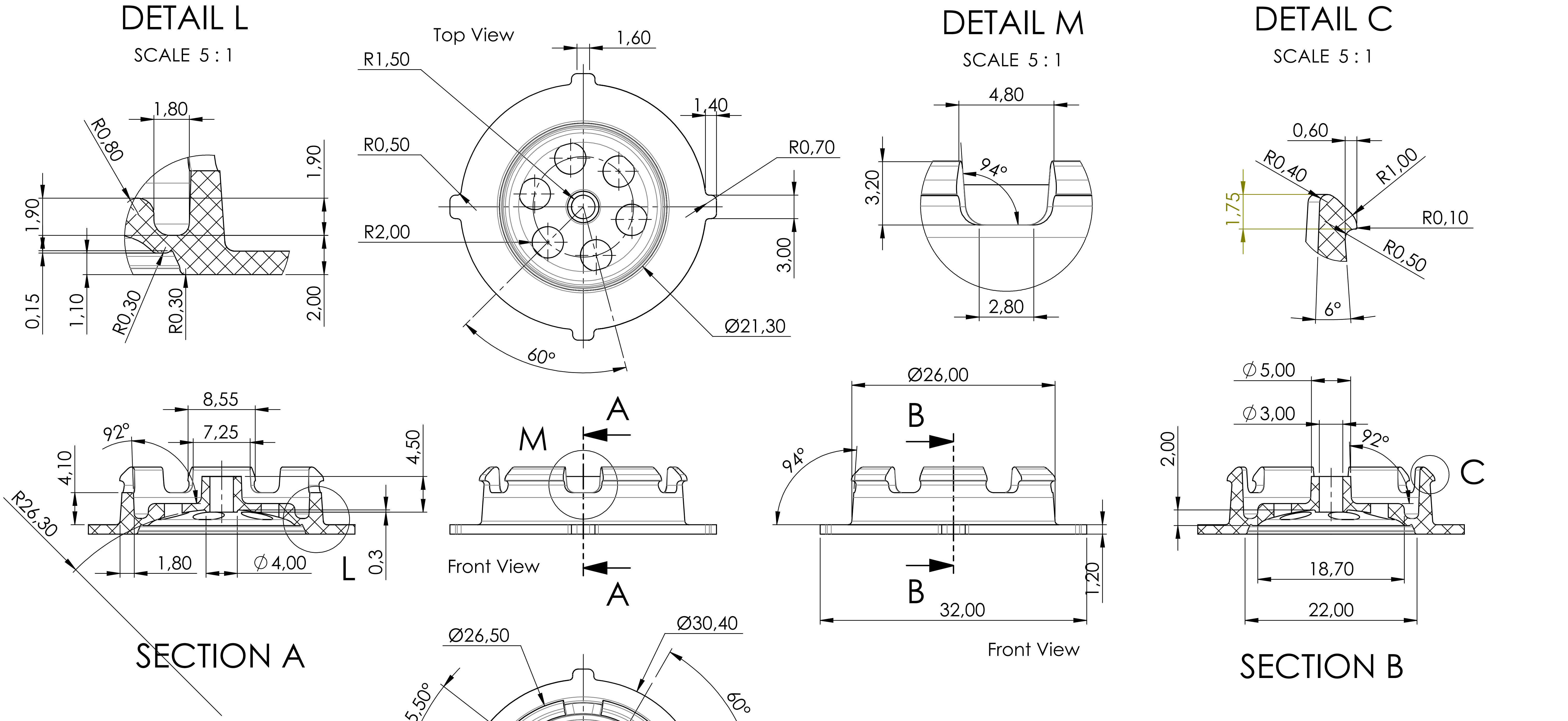


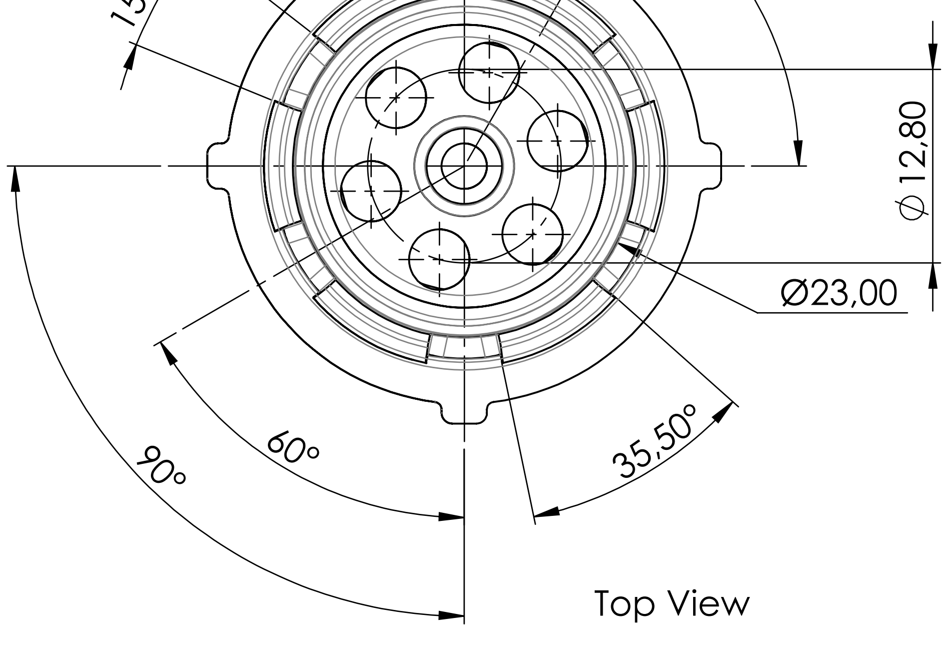
*N.B. For missing dimensions refer to 3D Model

AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Assembly Drawing	Note:
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System	
		INSIEME	BLS Adaptive Fit Mask	
		GRUPPO	Silicone Chamber Ass	
		SOTTOGRUPPO	-	
		PARTICOLARE	-	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1.1.11	
		DIS. N. 13	Scala 1:1 FOGLIO 0	



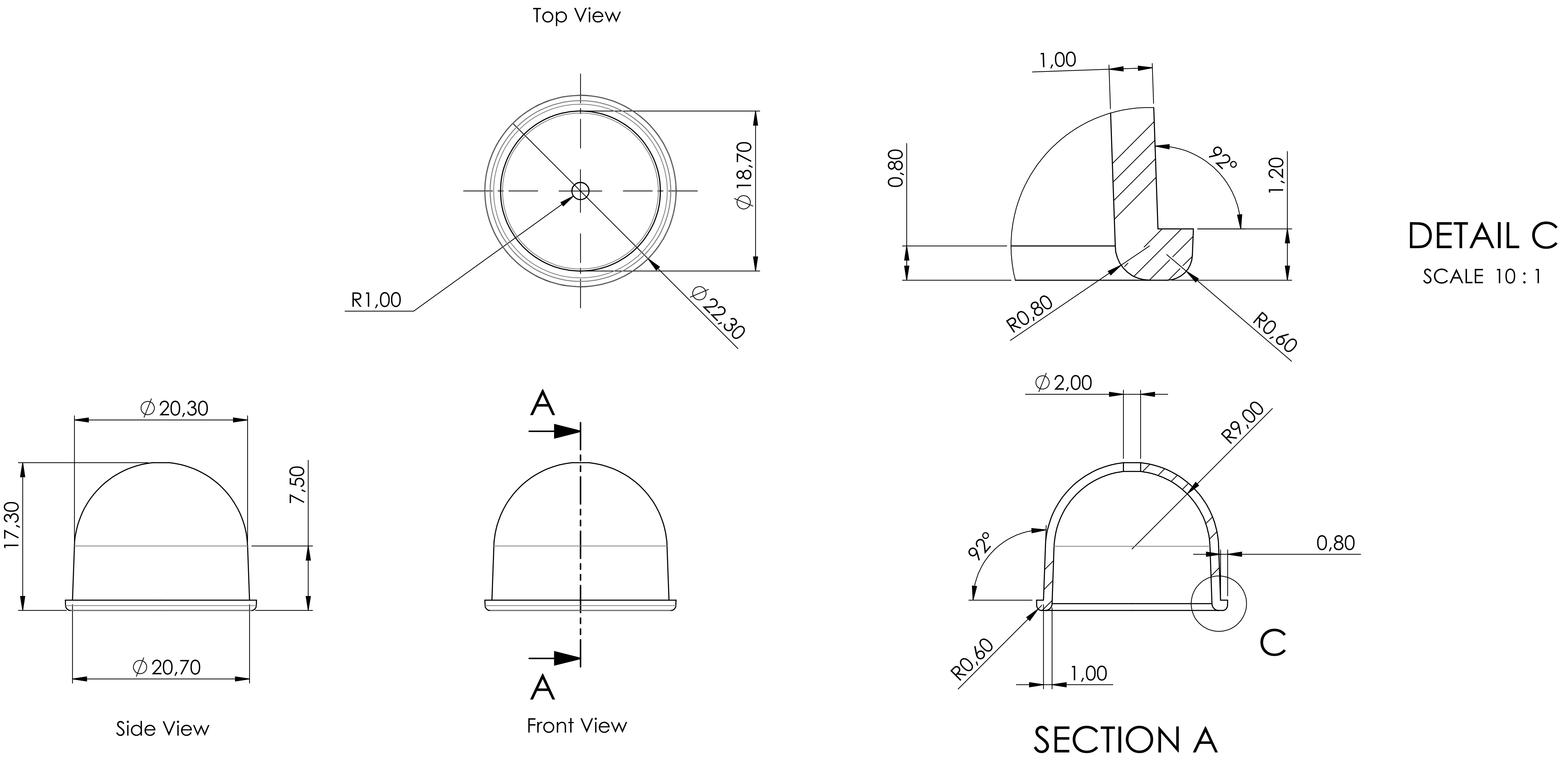
AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Part Drawing	Note:
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System	
		INSIEME	BLS Adaptive Fit Mask	
		GRUPPO	Silicone Chamber	
		SOTTOGRUPPO	-	
		PARTICOLARE	Silicone Layer A	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1.1.11.1	
		DIS. N. 13	Scala 1:1 FOGLIO 0	

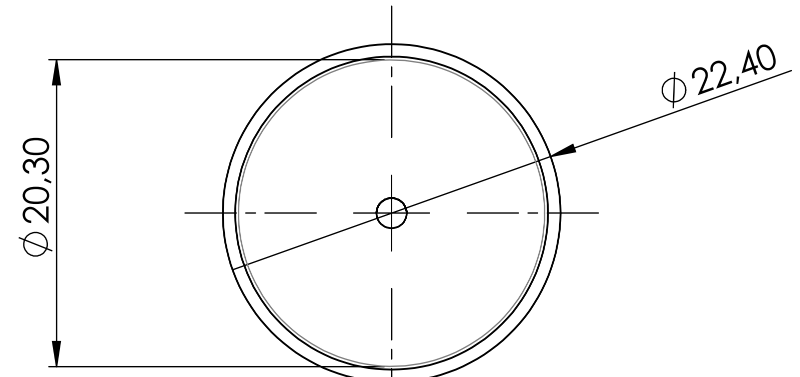




*N.B. For missing dimensions refer to 3D Model

AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Part Drawing	Note:
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System	
		INSIEME	BLS Adaptive Fit Mask	
		GRUPPO	Inflatable Chamber	
		SOTTOGRUPPO	-	
		PARTICOLARE	Valve Housing	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1.1.13	
		DIS. N. 14	Scala 5:1 FOGLIO 0	

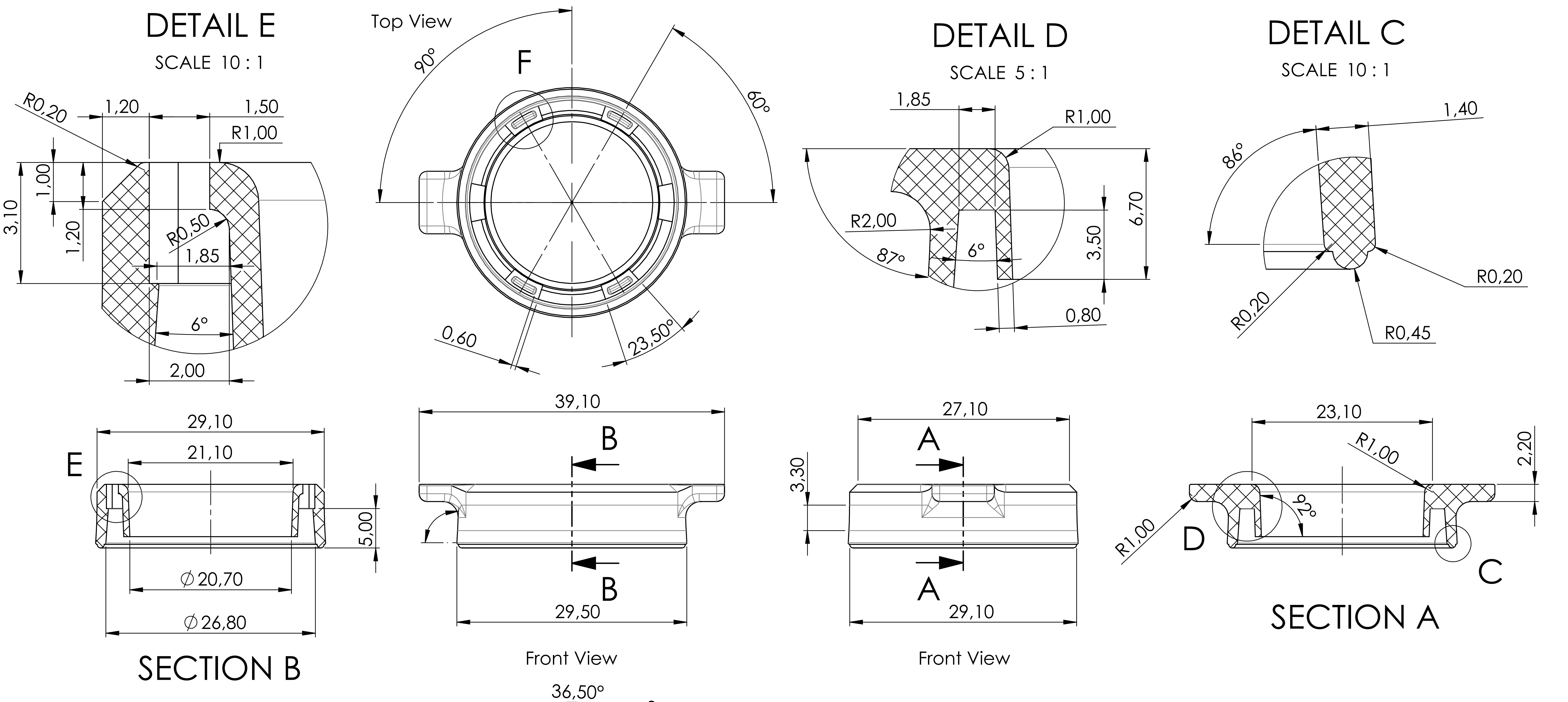


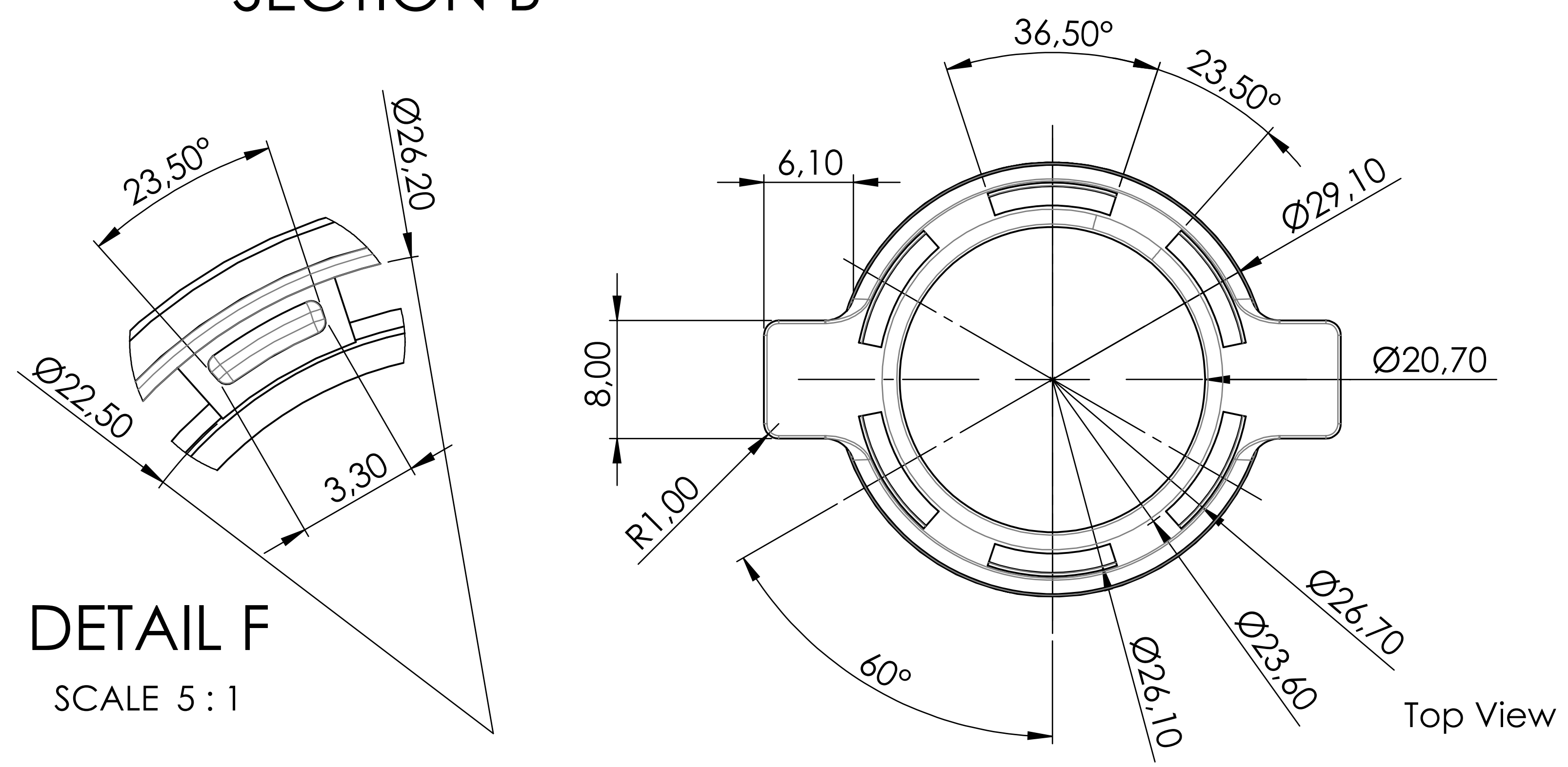


Top View

AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Part Drawing
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System
		INSIEME	BLS Adaptive Fit Mask
		GRUPPO	Mask Body
		SOTTOGRUPPO	-
		PARTICOLARE	Pump Dome
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1.1.12
		DIS. N. 15	Scala 5:1 FOGLIO 0

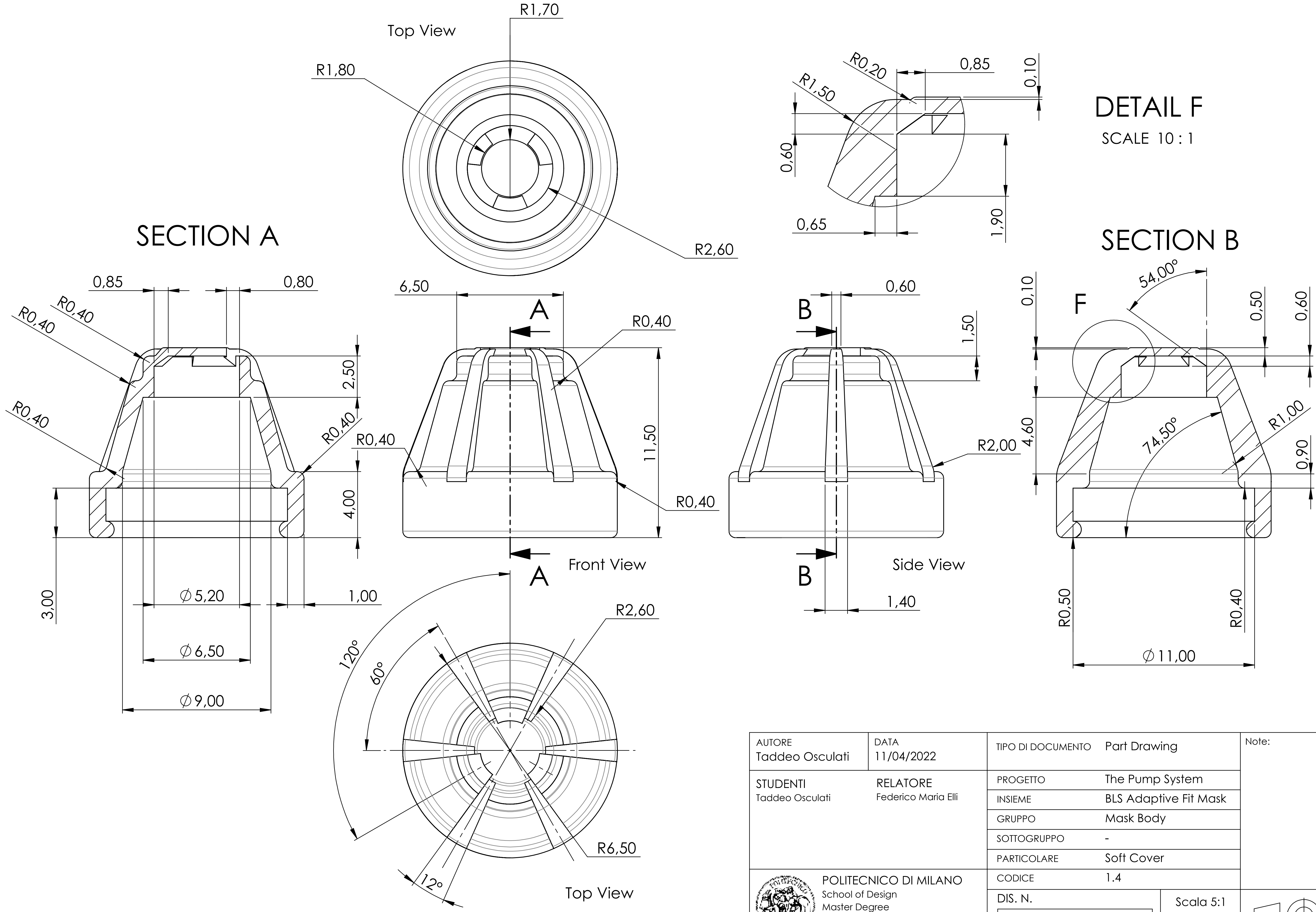
Note:





*N.B. For missing dimensions refer to 3D Model

AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Part Drawing	Note:
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System	
		INSIEME	BLS Adaptive Fit Mask	
		GRUPPO	Mask Body	
		SOTTOGRUPPO	-	
		PARTICOLARE	Press-fit Cover	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1.3	
		DIS. N. 16	Scala 5:1 FOGLIO 0	



AUTORE Taddeo Osculati	DATA 11/04/2022	TIPO DI DOCUMENTO	Part Drawing	Note:
STUDENTI Taddeo Osculati	RELATORE Federico Maria Elli	PROGETTO	The Pump System	
		INSIEME	BLS Adaptive Fit Mask	
		GRUPPO	Mask Body	
		SOTTOGRUPPO	-	
		PARTICOLARE	Soft Cover	
POLITECNICO DI MILANO School of Design Master Degree Design & Engineering A.A. 2020 / 2021 - Final Thesis Project		CODICE	1.4	
		DIS. N. 17	Scala 5:1 FOGLIO 0	