POLITECNICO DI TORINO

DEPARTMENT OF MECHANICAL AND AEROSPACE ENGINEERING

Master of Science program in Mechanical Engineering

Master Thesis

Development of an automated system for the production of "Devices for Gradual Dermal Maturation" (DMDGs) for the treatment of burn or surgical scars in children: milling and casting of medical materials in 3D

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Abstract

The Medical Center of Pediatric Reeducation *ROMANS FERRARI* requires an automated system to perform chalk engraving and silicone deposit processes inside their laboratories. The system is developed as to provide the suitable quality level in order to substitute part of the artisanal work that is currently performed. This robotic element will become the junction between the workshop and the additive manufacturing laboratory that are present at the Medical Center.
This document is composed by different parts: a detailed analysis of the required functions (statement of work), research of valid industrial options, choice and validation of the most suitable ones, some tests of the available technologies and the mechanical design of a link between the elements of the final system. The designed system is composed by a 6-axis robotic arm equipped with a 3D vision scanner, a micro end mill and a valve for the silicone.
The final aim is to allow another student to further develop this project in the next semester by testing different configurations of the system that is foreseen in this report and validate it.

Acknowledgements

I wish to thank all of those who took part in the realization of this project and contributed to the double presentation and redaction of this thesis work, in France and in Italy.
Primarily, I want to thank the two professors that allowed me to present this project. M. Saïd Mabchour from *INSA Lyon*'s mechanical engineering department has been an always present guide thorughout the project development, from the acceptance to its presentation in France. Mr. Alessandro Salmi from *Politecnico di Torino* has welcomed this project with enthusiasm and allowed to present it today in its original version, compliant to the french standards.
I want to thank my tutors from *INSA Lyon*: M. Arnaud Lelevé for teaching me the basics of robotic movement with kindness and M. Maxime Belfort for the patience with which he guided me through the french practices.

This project has required a lot of work on the *ROMANS FERRARI* site in Miribel and many hours of exchange with all the staff members involved in the scar healing process. I want to thank the director M. Joël Lehrmenaut, my tutor M. Jean-François Veauville and the chief of the reeducation team M.me Aurélie Lacroix. Most of all, my gratitude goes to the technicians who welcomed me in their laboratory, in particular Alix, Denis and Virginie, as well as Dr. Sara Arias and Dr. Lorraine Charvolin who allowed me to fully understand how to match the medical requirements and the technical properties of the system.

The synergy with many industrial partners has been fundamental to produce this output in quick times and with realistic perspectives. I want to personally thank the director M. Maxime Robin and M. Quentin Delagrange from *INNODURA TB* for their time, availability and helpfulness. Along with them my thanks go to M. Eric Sanloup and M. Mickaël Marcillat from *Stäubli France*, M. Remi Bittel from *Precise France* and M. Franck Bonneton from *Nordson EFD*.

Clarissa

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Chapter 1

Introduction

1.1 The *ROMANS FERRARI* Medical Center

The *ROMANS FERRARI Medical Center for Pediatric Rehabilitation* in Miribel (FR) is a medical structure of the French public healthcare system. It is a fully pediatric structure specialized in the cure of non critical patients belonging to these main categories:

- brain-damaged, all children affected by traumatic injuries or neurological accidents under rehabilitative treatment;
- poly-traumatised, children recovering and healing from big traumatic events such as car accidents;
- great burns, children with recent to very old scars from chemical, heat or cold burns as well as surgical scars.

This last category of patients is the one involved in this research project. Over the last forty years, the *ROMANS FERRARI* Medical Center has seen hundreds of patients from zero to twenty years of age require cures for severe burns. A secondary structure uses the same curing practices for adults in ambulatory treatment[13].

The typical therapeutic path is the following. After the acute phase of the accident recovery, children from other hospitals located in France are hospitalized in one of the one hundred of places available at the *ROMANS FERRARI* Medical Center. During hospitalization they start functional and psychological rehabilitation if needed. At the same time the team of doctors specialized in scars treatment (Dr. Renaud Tavernier, Dr. Sara Arias, Dr. Lorraine Charvolin) foresee the re-education treatment jointly the re-education team. The latter is directed by Mme Aurélie Delacroix and composed by a great number of physiotherapists, occupational therapists, kinesiotherapists, speech therapists, ortho-prosthetists and seamstresses. The chosen therapy is carried out daily during the hospitalization with various treatments: in the field of scar healing a relevant role is played by water treatment. For example, the hospitalized children have access to filiform showers that stimulate that soothe itching and pain. All the hospitalized children have access to schooling in order to keep up and rejoin their classmates at the end of the stay.

Figure 1.1: *Ortho-prosthetist adjusting a patient's devices at the ROMANS FERRARI Medical Center[27].*

Once the hospitalization isn't necessary anymore, the children can switch to periodic visits and continue with the kinesiotherapy and orthoses or compressive garments wearing. For the many children coming from outside the french borders, all of these treatments are equally available and covered by international health insurances if possible. The families of treated children can be accommodated in the surroundings of the Medical Center too.

The core topic of this project is the cure of scar tissue. The practice that will be presented is an exclusive of the *ROMANS FERRARI* Medical Center, despite not being patented. Many young patients reach the Medical Center from all over Europe to have their scar tissue treated despite this practice is not promoted. Most of those who reach the Medical Center from abroad come to know about it only thanks to some experts that know personally someone who works there.

The development of this engineering project had a role in pushing for the patenting of this method, as well as carrying on further medical studies so as to make this technology available in more places around the world. The first step in this direction has been taken with the validation of the standard procedures that are performed at the workshop, that are here reported at the Section 1.3. With the same objective, some last generation ultrasound machines have been recently purchased by the association that administers the Medical Center to evaluate the thickness of the scar tissue along the healing journey.

Now the goal would be to possibly expand this practice and make it available for distant patients too. By digitalizing the process it might be soon possible to send a 3D scan and the DMDGs disposition to the technicians in Miribel and receive the orthesis once it is produced.

1.2 The cure of scar tissue

The healing process has both aesthetic and functional objectives. It can last from six months up to two years during which the treatment is articulated into active re-education and passive systems. The scar tissue is extremely sensible and tends to retract over time. In the worse cases, this causes deformation and loss of functionality of some body parts. In other cases, during the acute phase, a skin graft is needed and the sutures or the graft itself can relax and create creases over time.

More than 25 years ago a former doctor of the Center came up with the use of textured silicone on the most severe scars, custom made for the shape of the zone and the orientation of the damaged skin. Since then the practice has been developed to the point that there are seven technicians working day by day on the handcrafting of these devices for more than one hundred children divided between the hospitalized ones and those who travel to Miribel periodically.

The care of burns, and scars in general, requires compression on the skin. The risk is that the scar might not only retract and cause deformities, but also have: either by becoming hypertrophic or by receding and causing deformities of body parts. For this reason, compression garments are often accompanied by rigid or semi-rigid orthoses. In addition, the care of burns always makes it necessary to prevent and reduce the thickening of the skin so that it retains its elasticity in anticipation of their growth. Over the last 25 years *ROMANS FERRARI* MC has developed a more effective treatment technique that is still being tested. It consists of layers of silicone with *Gradual Dermal Maturation Devices* (which we will call "DMDGs" in the rest of this report) that take the form of small drawings made with the same silicone. This layer of silicone will be positioned between the scar and the compressive element (be it garments, orthoses, masks) with the reliefs in contact with the skin. As scars are naturally anisotropic and have a variable thickness, the effect of these patterns is to increase the pressure on specific points of the scar and/or to stimulate the regeneration of the skin in a preferential direction as well as to maintain its elasticity.

Figure 1.2: *DMDGs stamps and sheets in silicone and ERKOFLEX.*

1.3 Current production processes

At the *ROMANS FERRARI* Medical Center seven technicians work day by day on the manufacture of DMDGs in a completely craft way. Each DMDG is a precisely positioned pressure element that can have one among five standard shapes: flower, bean, double bean, butterfly and ball. For each element the characteristic dimensions are:

- total width and height, ranging between 4 and 25 mm and depending on the depth of the scar tissue and the foreseen amount of skin retraction;
- orientation, depending on the surface geometry and the orientation of the maximum tension directions of the scar;
- depth, ranging between 1 and 4 mm and depending on the treated body part and the medical history (thick scars, healed skin and soft body parts require deeper DMDGs);

- line thickness, chosen accordingly to the overall size of the pressure element.

Depending on the type of material used, the additional parameter of hardness can be adjusted. Closely to the depth, the hardness of the DMDGs sheet depends on the level of sensitivity and the position of the scar. In the majority of the cases of burn or surgical scars, hypertrophy or keloides, outside of the *ROMANS FERRARI* Medical Center the treatment involves adhesive plain sheets of silicone or silicone gels[1] . To provide the same level of comfort to the most recent wounds and stimulate the collagen while ensuring the ideal water and air transpiration, the technicians of the *ROMANS FERRARI* Medical Center produce sheets of DMDGs with a minimum level of hardness of 4 ShA. According to the medical progresses, the DMDGs inserted in the compressive devices are replaced with new ones. This happens every two to four months and is a process of constant adjustment of the above mentioned parameters and gradual increase of the efficiency of the treatment during the healing process.

The hardest silicone reaches 25 ShA, while the maximum hardness available is 40 ShA and is achieved with *ERKOFLEX*. As can be seen in Figure 1.2, *ERKOFLEX* is a thermo-formable polymer available in multiple thicknesses. It is conveniently used with the thermoforming machine that produces the rigid masks for face burns. Silicone DMDGs are created by casting silicone onto parts (called "positives") with grooves, which are the negatives of the DMDGs. These parts are either plaster copies of body parts with hand-engraved grooves, or copies of body parts obtained by scanning and 3D printing with grooves obtained by digital processing. They can also be in the form of plaster or polymer plates designed for the production of DMDGs in excavations. This last solution is rather reserved for scars that concern parts of the body with simple shapes (thighs, etc.) or scars so small that the curvature is not excessive.

The engraving process is currently carried out by hand with a pneumatic micro-mill and drills with diameters of 1,0 mm, 1,5 mm, 2,0 mm, 2,5 mm. The depth of each DMDG is determined by the expertise of each operator: it varies between approximately 1,0 and 2,5 mm, but it is not measured during manual work. However, in additive manufacturing, it is well determined. When using RTV (*Room Temperature Vulcanization*) silicone, the casting is done with a two-component cartridge gun. The silicone that is mainly used has a hardness of 12 ShA. It is of two types: simple liquid silicone and thyxotropic silicone; the latter is enriched - directly in the cartridge by the supplier or with a syringe by the technicians - to increase its viscosity during casting and to adapt it to casting on inclined surfaces, but this change does not create any changes during hand casting.

In this section a crucial step of the work is reported. The development of this project was the first chance for the team of the Medical Center to merge their knowledge and delineate a common ground between their personal habits and create a standard protocol for each of the processes.

In the following pictures each step is summarized and characterized by a colour: the blue steps will be conserved, instead the light blue ones will be affected by the project and change accordingly.

1.3.1 Plaster positive copy of the body part for silicone DMDGs

This method is currently the most used. It involves the production of a 3D plaster copy of the body part to be treated, which ensures the best accuracy and allows treating small parts and complex surfaces (e.g. ears, fingers and palms, etc.). Given the frequency of this process, time becomes a relevant performance parameter for the technicians: air drying of the copies can take between 24 and 72 hours depending on the dimension of the cast. For this reason, this process is the most affected by the project and is addressed to most of the time.

The Figure 1.3 allows to better understand the objects that are most frequently mentioned. The mask in the front has been thermo-formed on a plaster positive equipped with the DMDGs sheets. It can be seen how the DMDGs dispositives in silicone appear inside the mask.

Figure 1.3: *Compressive mask equipped with DMDGs[4].*

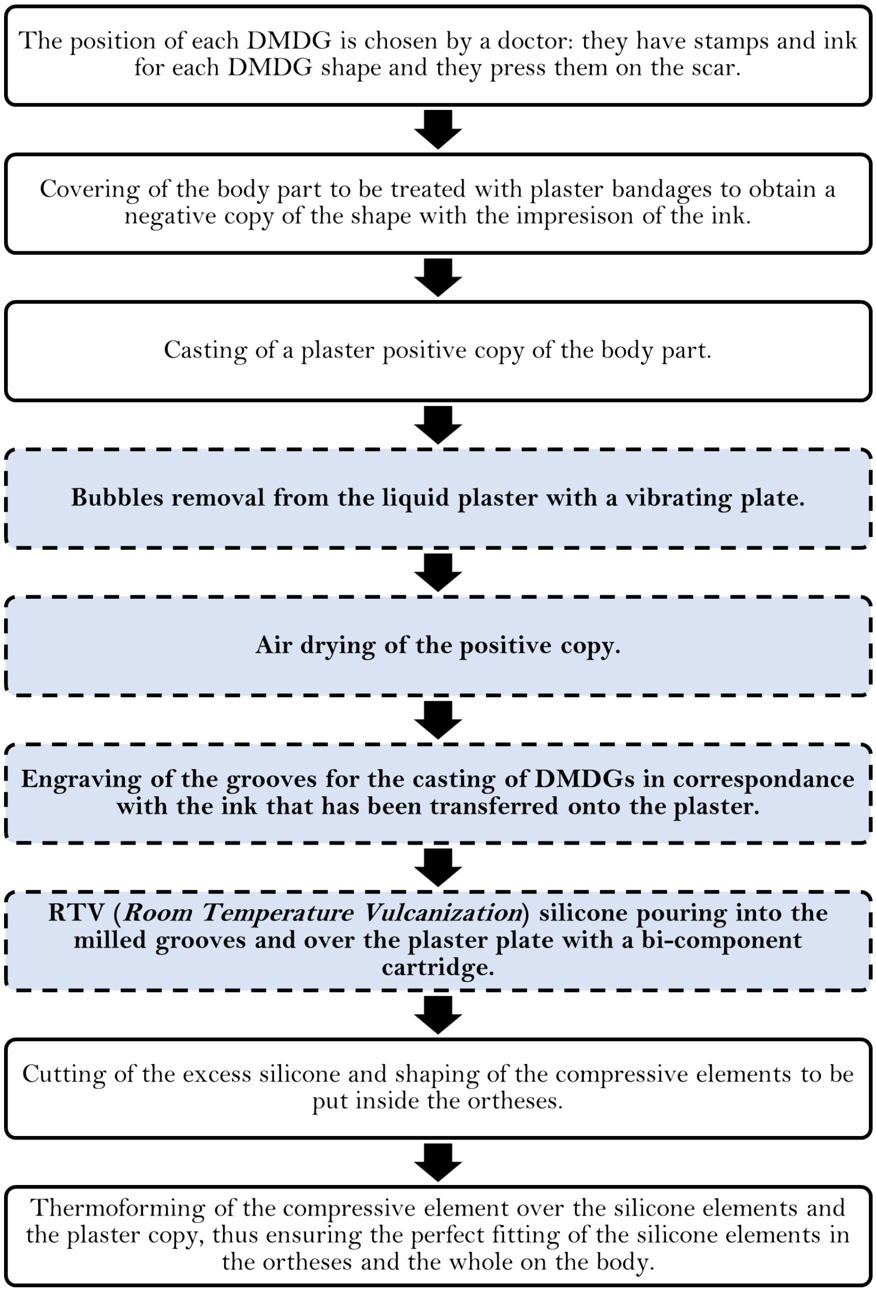

Figure 1.4: *DMDGs production process with plaster positive copy.*

1.3.2 Plaster positive copy of the body part for *ERKOFLEX* DMDGs

Differently from the above mentioned method, in this case the material used for the DMDGs is *ERKOFLEX*, a thermo-formable polymer used on the toughest and least sensitive scars. The main difference with respect to silicone pouring is the need for some draining channels that prevent air bubbles from being trapped between the plaster and the *ERKOFLEX* during thermoforming. This requires the technicians to manually sculpt some links between all the DMDGs to make air flow towards the border of the area.

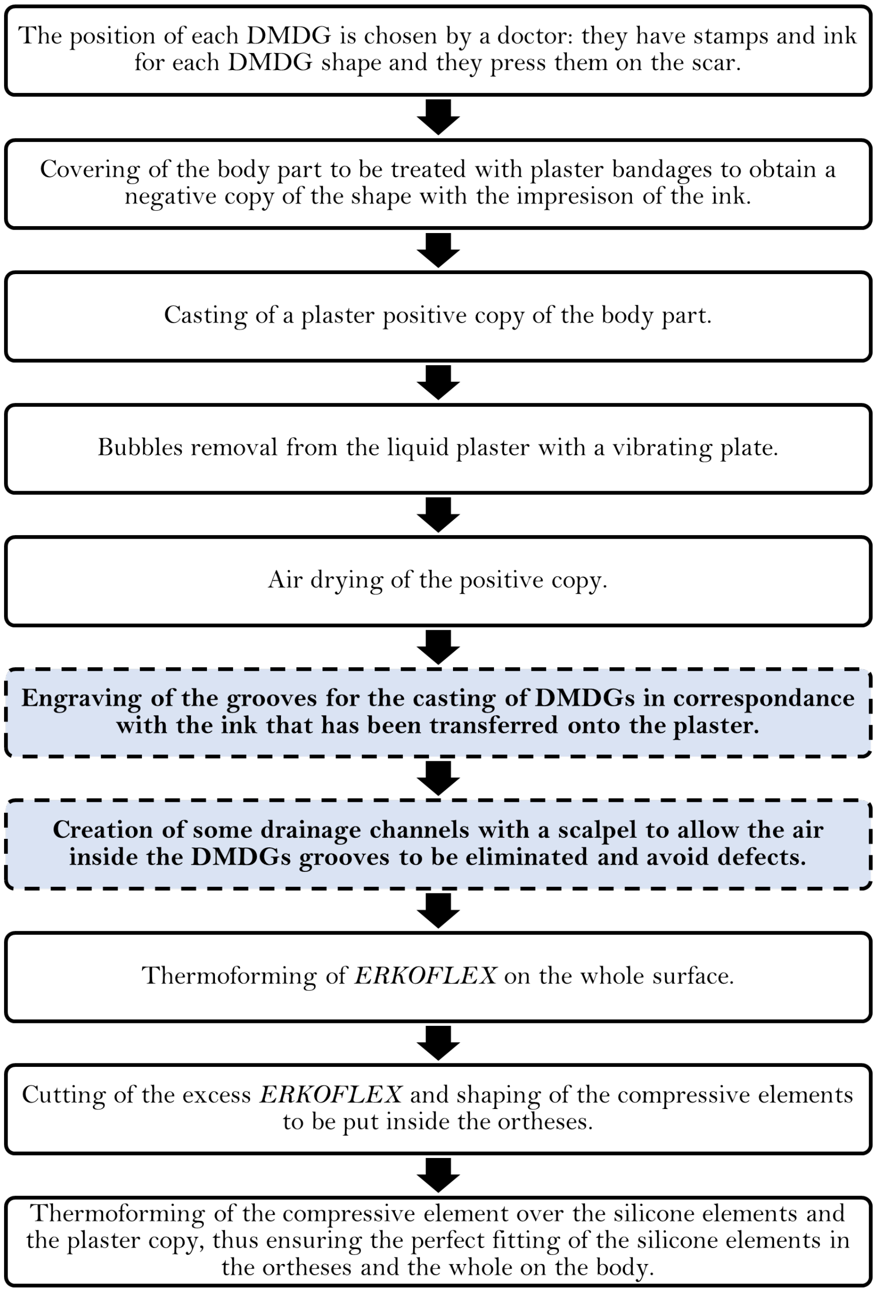

Figure 1.5: *DMDGs production process with ERKOFLEX.*

1.3.3 Plaster boards for planar and flexible DMDG sheets

This second method is mainly used for big areas (such as on thighs, backs) and for smooth body parts. The DMDG sheets produces in this way can be either applied inside the rigid orthoses and braces, either sewn inside the compressive garments. For this reason, in the last case a sheet of textile material is incorporated the silicone sheet.

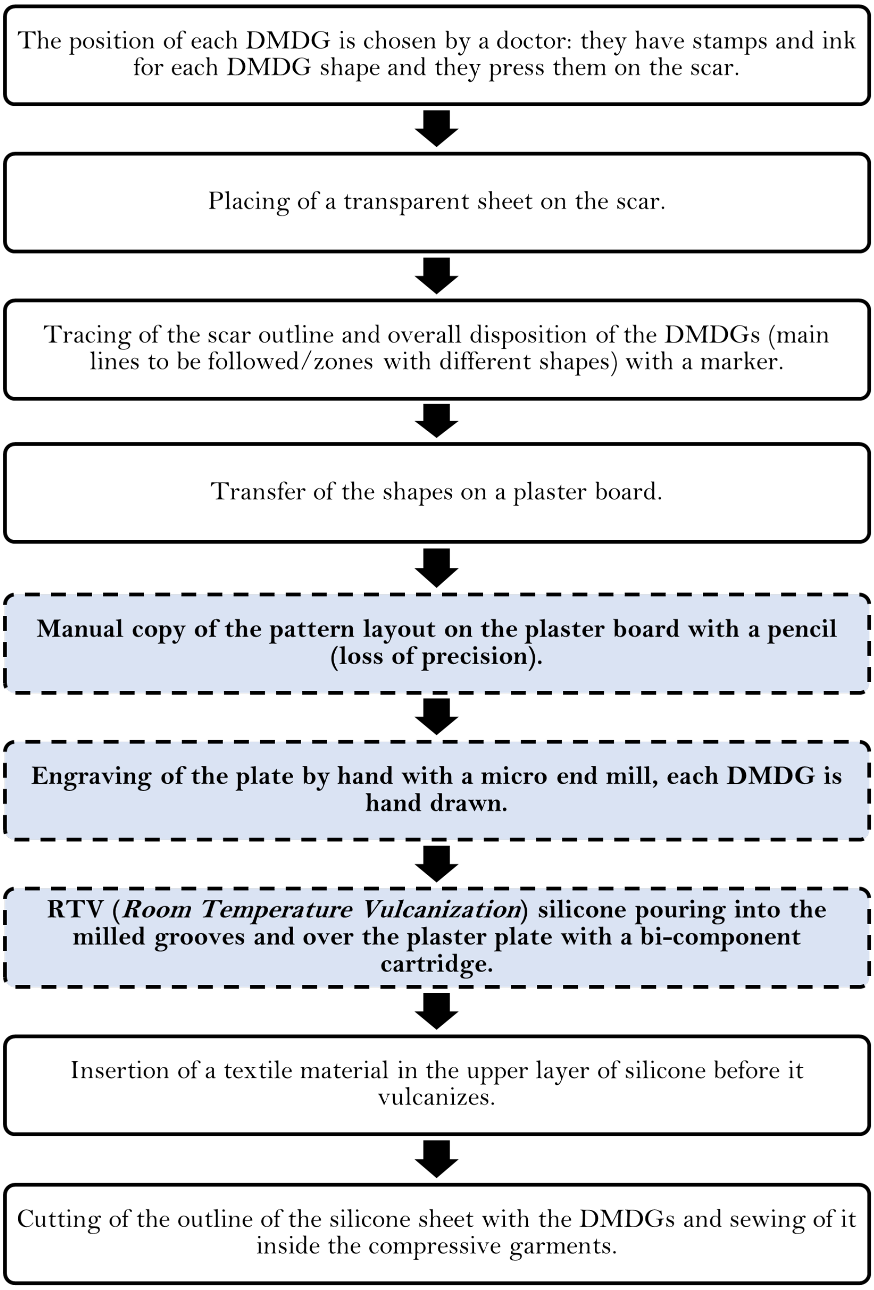

Figure 1.6: *DMDGs production process with plaster planes.*

1.3.4 3D printed positive copy of the body part

This is the most recent method, which involves the AMI (see the following Section 1.4). In this case the production of the copy of the body part is realized digitally and by additive manufacturing. The DMDGs production instead is still carried out by hand with silicone, as can be seen in the Figure 1.8.

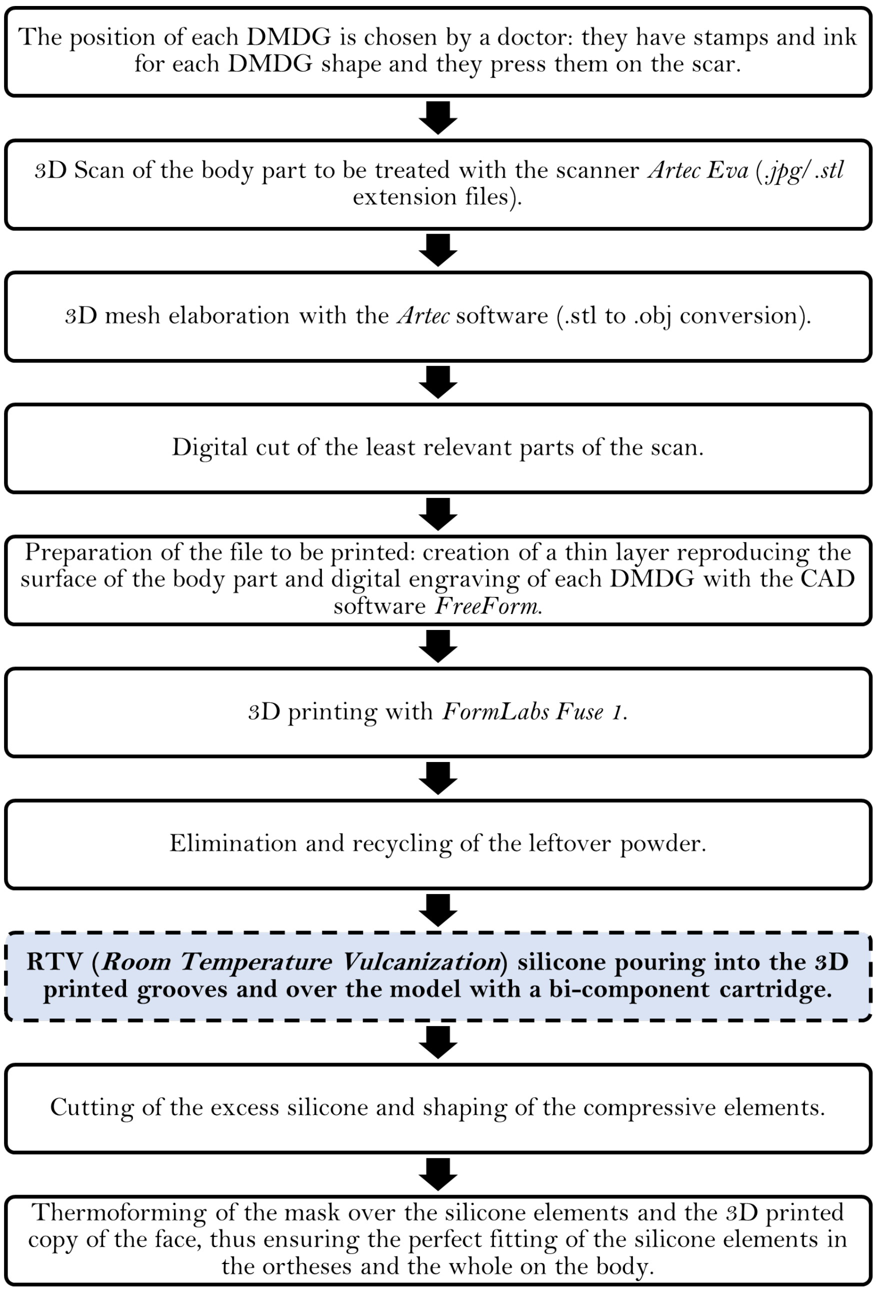

Figure 1.7: *DMDGs production process with plaster planes.*

Figure 1.8: *Three steps of DMDGs and compressive mask production on a 3D printed positive.[31]*

1.4 AMI: Atelier for the production of masks with 3D printing

The *ROMANS FERRARI* Medical Center is managed by a no-profit organization, hence it seldom receives donations. This project itself has been conceived after the reception of some donated resources. In an analogue way, two years ago the ortho-prosthetics laboratory has seen an improvement and the implementation of new technologies. Up to that point in time it has always been fully manual work, but some technicians started showing interest in the additive manufacturing and automation field and started to attend seminars and exhibitions on these topics. They stimulated a debate among the other technicians and a discussion with the board for the research of suitable technologies for the production processes of the laboratory.

Since the craft work presents many drawbacks in terms of intensity and complexity, the chosen solutions are oriented not only towards the technological improvement, but mostly towards the safety and comfort of both technicians and patients. The chosen technological solutions address two relevant issues.

In first place, the *ROMANS FERRARI* Medical Center board wants to ensure the best working experience to the technicians. This means that it's a priority to limit the manual work and automate as much as possible the most uncomfortable production phase, that is the hand milling.
Hand milling is constantly performed in the laboratory in a small room that can accommodate up to two technicians at a time. It is equipped with a suction system for the plaster dust, a grinding wheel for the masks and the hand mills.
The main issues of hand milling are the presence of plaster and polymeric dust and

the production of vibrations and noise. Despite the availability personal protective equipment such as hearing protectors and filtering masks, this type of work can become extremely uncomfortable when large pieces are produced. It should be considered that some of the largest pieces can be a thorax or a thigh of a twenty year old young man, and the machining of such pieces can last even more than one hour. Being this activity the most troublesome for the technicians, the goal is to take away at least a part of the positives to be machined by hand.

The second issue to be addressed is the discomfort of the patients when it comes to face burns. The archive of the great burned section of the *ROMANS FERRARI* Medical Center shows how this body part is quite common at all ages.
The archive and the data collected in the years show how some body parts are mostly cured in children of a certain age and in specific parts of the year. An example is the burn of hand palms in toddlers during the winter: when children learn how to walk and keep their hands high in front of them they often touch or grab pots with boiling water or fireplaces and similar objects. The face burns instead can have a great variety of causes and can be of different types, from chemical to heat or cold. This variety of causes and the criticality of the position make the cure of these scars extremely frequent at the Medical Center. Children and young adults come from all over Europe to have these scars treated. Some of them just left the hospital, so the skin is extremely sensible and hurting.
The sensitivity of the skin and the treatment of all ages, including newborns, makes the use of plaster bandages uncomfortable. The obtained mold is extremely accurate, but the experience of covering a child's face in plaster bandages can be complicated and painful. For this reason the second goal of this technological improvement is to introduce a touch-free system for the production of DMDGs and compressive masks, while keeping the same accuracy level and shorten the production time.

To satisfy these two needs, the chosen solutions are a 3D scanner and a 3D printer for polymers. The two, along with the needed software supports, constitute the new *AMI*, Atelier for the production of masks with 3D printing.
The digital vision system is a 3D scanner by *Artec 3D*. The model *Artec Eva* is a movable, lightweight scanner that is conceived for reverse engineering, mechanical and health applications as shown in Figure 1.9.

This 3D scanner's use is very intuitive: it allows to construct a 3D image little by little until the full coverage of the surface. It must simply be displaced around the subject while it keeps a steady position. In this case, it is sufficient for the patient to sit on a stool in a well illuminated place with clear surroundings and wait for around one minute until the captured image is complete. This scansion time is kept to the minimum to avoid imperfections due to small involuntary movements of the patient.
The technical specifications of the *Artec Eva* are here reported in the Table 1.1.

Figure 1.9: *Scanner Artec 3D Eva*[2] .

3D accuracy	0,1	mm
3D resolution	0,2	mm
Object size	> 100	mm
3D reconstruction rate	16	fps
Target-free tracking	*Hybrid geometry and colour based*	$\setminus$
Weight of scanner	0,9	kg

Table 1.1: *Technical details of the Artec Eva*[32].

It must be noticed that some categories of patients are not eligible for this procedure due to the need to be as still as possible for around one minute. Steadiness of the part to be scanned is extremely important to ensure the most accurate reproduction of the volumes. The *Artec Eva* 3D scanner works with a flashing white light, so the youngest patients under three years of age who can't understand the situation tend to follow the light and move their heads. Similarly, patients that suffer from neurological problems are sometimes incapable of keeping a steady position for a sufficient amount of time. As for the other patients, the procedure is extremely quick and easy.

Each scansion produces two main files: a point cloud file (*.stl* extension) and a colour texture file (*.jpg* extension) that is a 2D development of the scanned surface. The first allows to have a digital positive copy of the body part, and when superposed with the second it reproduces the whole DMDGs disposition that is visible on the stamped skin. In Figure 1.10 the two dimensional development of a scansion. It allows to appreciate the manner in which the doctors apply the tampons: some are superposed, their positions are not a strong constraint: this is mostly useful to outline different zones with different shapes or orientation of the DMDGs.

Figure 1.10: *Sample of a colour texture file from a scansion with Artec 3D Eva*[4] .

The choice of this solution for the creation of positives reaches the goal of a higher patient's comfort. In fact, the whole scanning operation takes about fifteen minutes for setup and elaboration, and an average of only 30 seconds for the whole touchless scan itself.
The main phases of the process are the following:

- set up of the workspace with a clear and uniform background, a stool and a mobile pc station cable linked to the 3D scanner;
- reception of the patient and explanation of the procedure;
- scan of the body part to be treated, making sure that all the relevant details are well depicted in the 3D file;
- dismiss of the patient and cleaning of the ink from the skin;
- digital cut of the point cloud file (*.stl* extension) thanks to the *Artec* software.

To produce the positives out of the 3D scans, a polymeric powder 3D printer is chosen. This type of technology allows to produce in the time span of few hours a positive that is lightweight yet suitable for silicone molding. To reach the goal of limiting the technician's milling job, the digital elaboration software that produces the *.stl* file for the 3D printer is equipped with a library of the DMDGs shapes that allows to produce the positive with the necessary grooves ready for silicone molding.

The chosen 3D printer is the *Formlabs Fuse 1* that works with PA12 nylon and is equipped with an external powder collection and regeneration system called *Formlabs Fuse Sift*. The productive process is called *Selective Laser Sintering* [33] and is divided in two main phases: creation of a thin layer of powder on the whole surface of the printing chamber and laser polymerization and solidification in the area the given by the *.stl* file. At the end of the print, the solid positive is surrounded by the excess powder that can partially be regenerated thanks to the *Formlabs Fuse Sift* unit. The main technical characteristics of the *Formlabs Fuse 1* are summarized in the Table 1.2.

Build volume	$165 \times 165 \times 300$	mm
Layer thickness	110	m
Build speed	10	mm/h
Material Refresh Rate	30% to 50%	$\setminus$
Start-up time	60	min
Weight of scanner	0,9	kg

Table 1.2: *Technical details of the Formlabs Fuse 1* [33].

Figure 1.11: *3D printer Formlabs Fuse 1 and powder recovering system Formlabs Fuse Sift*[3].

At the *ROMANS FERRARI* Medical Center a small room is dedicated to the 3D printing. It contains the two *Formlabs* hardware components and a pc work station. The software that communicates with the 3D printer is *Formlabs PreForm Desktop*, which is the one feeding the *.stl*.

The digital engraving of the DMDGs instead is carried out on a different software that allows the manipulation of the point cloud: *GEOMAGIC FreeForm*. This software is touch-based and allows surfaces creation and manipulation. The scanning integration *GEOMAGIC Freeform* allows to capture the body part with the 3D scanner *Artec Eva* and import it directly into the software interface. The software comprehends a movable haptic tool used for 3D sculpting, surfacing and design of molds. Its purpose is to recreate the concept of clay modelling by giving to the user the feeling of the 3D object in space.

The *PHANTOM Omni* haptic tool is a 6-degrees of freedom pen-like 3D modelling device. At the *ROMANS FERRARI* Medical Center its pointer can be substituted with one of the standard shapes of the DMDGs and used to physically impress it on the point cloud coming from the 3D scansion. Each shape can be loaded as the point of the pen and appears fixed in the pen's frame of reference. In this way, the user can rotate it and position it.

Figure 1.12: *PHANTOM Omni haptic device for surfaces modelling[35].*

The *PHANTOM Omni* is the interface between the 3D model and the user: they can see the coloured scan on the screen and replicate the DMDGs pattern with the different shapes in the library. Some adjustable parameters govern the dimension and depth of the impressed profile. The FreeForm systems use a virtual clay metaphor for the digital editing, while the user's feeling is the force feedback of the *PHANTOM* device. In the Table 1.3 the main technical characteristics are summarized.

Workspace dimensions	$160 \times 120 \times 70$	mm
Maximum extractable force	3,3	N
Inertia at tip	45	g
Nominal position resolution	0,055	mm

Table 1.3: *Technical details of the PHANTOM Omni[36].*

1.5 Approach to the project

Since this project has been carried out in France at the *Institut International des Sciences Appliquées* in Lyon (*INSA Lyon*), the approach to the project reflected entirely the french policy. In particular, the reader will find in the next chapter a deep analysis of the customer's needs and requirements as well as a time plan of the work, a state of art section and a functional analysis. This last element is the most relevant for it constitutes the founding of all the steps that are further taken and all the work that the students who will conclude the project will do. This section is the equivalent of the *Cahier des charges*, a document that has to be written and signed by all the parties involved in a project.

The project sheet received from the *ROMANS FERRARI* Medical Center already contained some ideas on the type of system that they required, but at the same time left space for imagination and innovation. This stimulated a debate around all the possible solutions applicable, involving experts, professors and technicians. In particular, considering the choice of commercial solutions, this work of research has been performed with various figures. *INSA Lyon* is in fact an Engineering School oriented to the working experiences with many contacts with the majority of the enterprises in the surroundings of Lyon and many of the most known french companies (e.g. *Airbus*, *Cartier*, etc.). In this context, the research of solutions passes through personal contacts and business relationships with the engineering school. For this project my academic advisor Mr. Saïd Mabchour has allowed me to personally contact the companies and the people that could have been involved in the project. This practice allows the enterprises to possibly conclude a contract with the customer who ordered the project. For this reason no deep market research is present in this thesis, and all the involved enterprises and experts have been personally reached.

On the economic side, a relevant feature of the *ROMANS FERRARI* Medical Center is the non-profit management. Since it is managed by an association, it's eligible for multiple calls for funding in France and all over the European Union. For this reason the cost of the global system here presented can't comply with the set budget (see Table 2.2, SF5 row). It can instead be portioned: the project has been conceived as modular, so as to build up the global system one step at a time according to the money flows. These general aspects (see Table 2.2) and the milling function (see Table 2.3) are the main ones that will need to be put in place at one time.

This project regards a very uncommon practice which isn't codified in any way. This makes the state of the art analysis quite complex and not as helpful as in other cases, because of the lack of literature regarding the use of DMDGs or similar products. The craftwork and common practices are confined into the Medical Center's laboratory and no document is available to collect the processes standards. For this reason a relevant part of the work has consisted in meeting all the staff members involved in the DMDGs production and application, from the medical to the technical staff, from the sewers to the patients. The basis of the project development has been developed in months of regular attendance to all the phases of the DMDGs use. The approach has been of constant communication with all the staff members and attentive listening to the needs and requirements of each part, be it technical, medical or managerial. This makes this project extremely accurate in responding to the needs and constitutes a basis for future analysis of the technical processes carried out inside the *ROMANS FERRARI* Medical Center.

The first step of this project was to codify the different production processes for the DMDGs. As practices were not harmonized, there were small but relevant differences in the way each operator did them. The aim was to codify a standard process to be automatized, and it resulted in the first ever common practice statement for the Medical Center's technicians. During a brainstorming session with all the operators and representatives of the care team, we were able to identify four different processes represented schematically on the following pages. In order to make the information readable, all examples are related to sewing (with plaster board) or to the production of thermo-forming masks The other types of orthoses can be mostly assimilated to these two types.

1.6 Criticality analysis of the current process

During debates with the technical and medical staff it clearly appeared that the current handcraft process is rather imprecise. Yet, the produced DMDGs are effective. There is a gap between the medical indications and the technical realization, such as the effective depth of the grooves, which is never checked in any way and fully depends on the technician's ability. While this is true for handcrafted DMDGs, the ones produced with 3D printed positives have a higher level of accuracy. An issue is the lack of technologies that allow to distinguish between the effectiveness of the two and evaluate the differences in treatment quality.

When treating a new patient, a doctor and a technician meet and work out the healing solution together, since many cases might be complicated by the presence of other orthoses or physical complications. Afterwards, the milling is done by drawing each DMDG by hand. The location tolerances are therefore extremely wide. On the other hand, by pouring the silicone by hand it becomes impossible to achieve a uniform layer, because of the viscosity level and the amount of silicone poured with the cartridges. This causes drips, bubbles and an extra thickness on the most vertical sides. Furthermore, the use of hand pouring significantly increases the loss of silicone and productivity.

As far as the total working time is concerned, it should be considered that the scars treated take a quantity of DMDGs that varies between one and some hundreds, so between the minimum and maximum working time there is a great variability. The work is distributed over several hours and even days to allow plaster and silicone drying. Afterwards, some more days are required for the fitting adjustments of the orthosis. This means that the time between the doctor's prescription and the effective placement of the final orthosis is between four and seven days.
In addition to this, no work programming is done and no division of mansions either. This means that each technician works on their own with their own patients that are followed during all the process by the same person. Not only the work is not programmed, but it is also subject to technical delays due to errors and technical problems. One among them might be the time lost in the silicone pouring depending on its viscosity: thyxtropic silicone avoids dripping and lowers the number of pours to achieve the required thickness of the silicone layer, but it's very rarely used.

Chapter 2

Functional analysis

This analysis is intertwined with the observations made in the previous chapter, since it has been developed during two months of attendance to all the processes carried out at the *ROMANS FERRARI* Medical Center regarding the treatment of scars. The analysis that follows is compliant with the french practice of writing a "*Cahier des Charges*". This document is the key link between the request paper of the customer and the final realization of the system. In particular it must contain a deep analysis of the environment and specific requirements for the system as well as a brief state of the art analysis, see Section 2.5.

This functional analysis is split into the four main functions of the system, that are studied separately. They are respectively: the general aspects, the details regarding the two functions of milling and silicone casting and the installation aspects. Despite the first and the last are not production functions, they are needed to put the system in operation and answer to all the environment and practical requirements that, if absent, would make it impossible to perform the milling and molding functions.
For what concerns the 3D vision, it is mostly included into the milling section. It is never explicitly mentioned because it is not currently used in the analysed processes. As it can be seen in the following sections, the functional analysis normally relies on the current process, since it is the benchmark and starting point for the designed system. Moreover, in this specific case the goal is to reproduce the current production process rather than improve the quality or change the paradigm.

Each of the main functions is linked in a chart to all the elements that interact with it. This interactors diagram is meant to explain the relationship between all the involved elements and to link them to the functions and sub-functions analysed. In fact, each interactor must be associated to at least one function or sub-function. This indicates the functions where its contribution is most relevant. The interactors are people, environments or entities that concur in choosing the criteria that allow to evaluate each function.

The main part of the functional analysis is the table that follows the interactors chart. Each of the main functions of the system is divided into smaller sentences, reported in the first two columns along with the hierarchy degree:

- F $\Longrightarrow$ it is the principal function;
- SF $\Longrightarrow$ it is the sub-function.

For each of these, there must be some measurable criteria that are chosen by the customer in accordance to the academic team. These criteria appear in the third column, followed by their range of acceptability in the fourth. This explains the need for measurability: the system performances and properties must be clearly stated and the outcome of the real system must be measurable and comparable to the acceptability range. This range can be defined as the intersection between the customer's requirements and the legislation (e.g. noise level in a closed environment, admissible weight per floor square meter). An additional element that allows to create a hierarchy between all the criteria is a degree of flexibility:

Flexibility	**Expression**
F0	The range is not editable, strong constraint
F1	Editable only after discussion with the customer
F2	Editable provided that the customer is informed
F3	Editable without the need to inform the client, no constraint

Table 2.1: *Flexibility degrees fot the functional analysis' criteria.*

The union of the interactors charts and the functional analysis tables of each of the functions allows to summarize a long cooperation work with the personnel of the *ROMANS FERRARI* Medical Center.

This functional analysis' development has been carried out with continuous check-ups with the director, the technicians team, the re-education chief and the medical staff. It has been officially presented to the board of the Medical Center and is signed by the Medical Center director, the Medical Center project reference and the academic tutor. It has been used to present the project objectives to the industrial partners too. This document becomes an unquestionable benchmark for the choice of suitable solutions and states all that can be accepted as a suitable solution.

2.1 General aspects

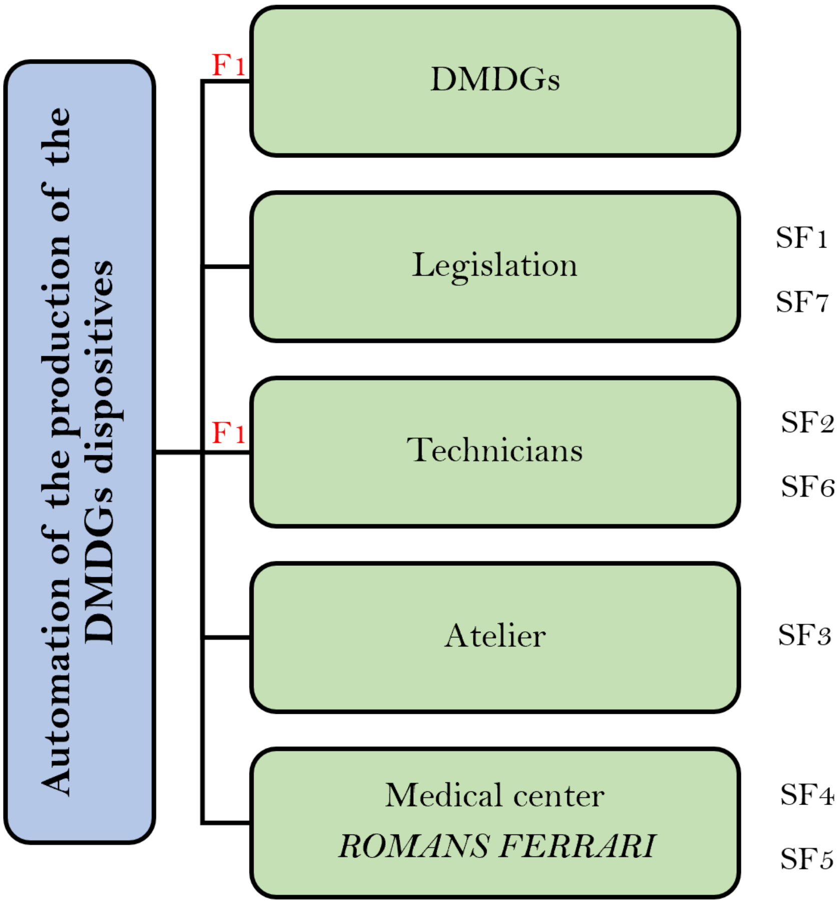

Figure 2.1: *Interactors diagram for the general aspects.*

This first interactors diagram (Figure 2.1) sets the environment in which the designed system will be integrated. The main function is a synthesis of the requirement in the project statement: the production of DMDGs inside the *ROMANS FERRARI* Medical Center's laboratory. It links the DMDGs and the technicians as main interactors involved in the physical productive process.
As can be seen in the Table 2.2, the sub-functions set all the environmental conditions, be them on the managerial side (*ROMANS FERRARI* Medical Center), on the labour law side or on the logistical side. These aspects set the expected boundaries for the existence of the system inside the Medical Center. This is a critical point: the spaces are limited and the amount of different people, machines and processes carried out in the laboratory make it complicated to fit the system in it, especially considering the safety of the many children that visit the atelier daily.

Function	Expression	Criterion	Level	Flexibility
FP1	Semi-automatisation of the two manual processes	Tool change	Minimal time	F2
			Optional intervention of a technician	F2
		Boot time	$2 \div 3\ h$	F2
		Autonomous operation in presence of staff	Minimal intervention in operation	F2
SF1	Be used in the *ROMANS FERRARI* MC atelier	Environmental temperature	$15 - 30\ °C$	F1
		Environmental humidity	Variable	F1
		Noise level	$80\ dB$	F1
		Power supply	$230\ V$ or $380\ V$	F0
			Possibility of moving the electrical socket	F2
		Presence dust	Presence of polymeric dust due to the masks sanding	F3
			Presence of plaster dust due to the milling	F2
		Safety	Directive 2006/42/CE	F0
SF2	Allow for inspection during operation and technicians intervention	Allow supervision during operation	Presence of windows/absence of casing	F1
		Qualification of staff	Minimal level	F1
		Practical training	2 days max	F2
		Downtime during one whole production	$< 50\%$ of the total	F3
		Number of interventions during one production	~ 10	F2
SF3	Being compact and movable	Mass	$200\ kg$	F3
		Height	$180\ cm$	F1
		Footprint	$2\ m^2$	F1
		Safety border	$4\ m^2$ depending on the chosen solution	F2
SF4	Expected service life	Service time	$30000\ h$ according to the robotic arm supplier	F3
		Maintenance	Regular preventive maintenance, contract with supplier	F3
		Software support	Annual software maintenance, contract with supplier	F3
		Robotic arm support	On demand, performed by the supplier	F3
SF5	Expected total cost	Assembly cost	40000 € pre-tax	F2
SF6	Pre-study phase	Number of involved software	3 max	F3
		Cost of software and silicone casting tools	20000 € to be defined	F1
SF7	Use standard and replaceable components	Hardware equipment	Chosen from standard	F1

Table 2.2: *Functional analysis of the general aspects.*

This part of the functional analysis is a synthesis of the project: it summarizes everything that concerns the production process in the main function F1. All the sub-functions are an expression of the general requirements of the *ROMANS FERRARI* Medical Center as an institution.

It should be noticed that the *ROMANS FERRARI* Medical Center is run by an association, as previously mentioned. This means that all profits are reinvested in the center and that the monetary resources come in large part from the benefactors and international funding. For this reason the SF5 has a rather high level of flexibility.

To stimulate the funding of this project and ensure some flexibility in terms of budget, this designed system has been presented to all the representatives of the associations and entities that fund the *ROMANS FERRARI* Medical Center at the Partners' Night. In this occasion all the current and future projects that are developed in the context of the *ROMANS FERRARI* Medical Center were presented to the members of the association. In such events the partners of the Medical Center meet the single benefactors and representatives with the aim of providing information about the projects that are foreseen or that have already been implemented. This stimulates the benefactors to fund or push for funding a specific project. The presentation of this automation process met great interest and was highly appreciated, leading to thinking that the set budget might increase. Some members decided to commit to the realization of this project and share it with other people. To motivate the fundraising, the *ROMANS FERRARI* Medical Center board asked for a provisional plan of the expected expenses.

2.2 Milling function

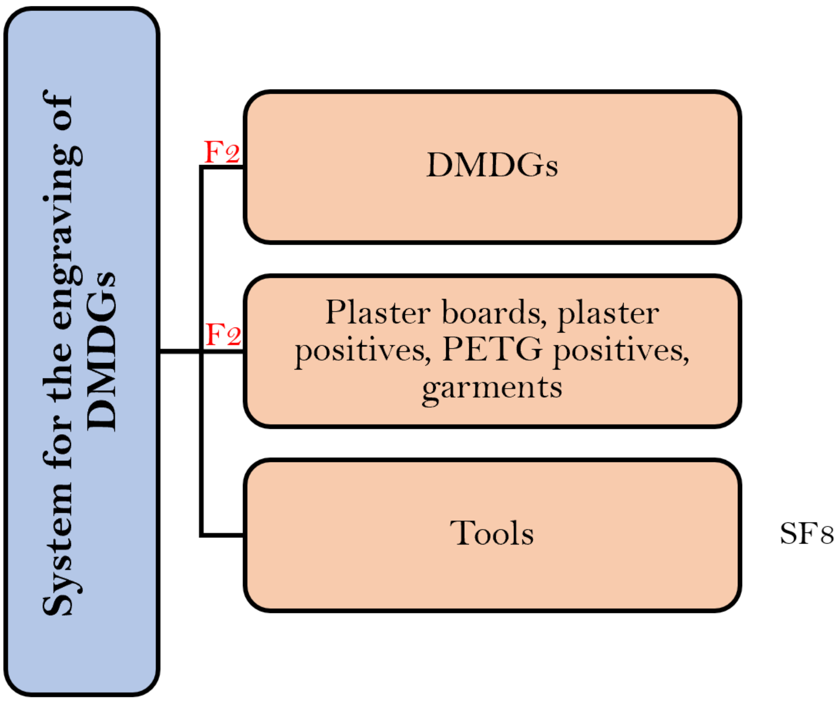

Figure 2.2: *Interactors diagram for the milling function.*

The most critical interactor of this function is the DMDGs (Figure 2.2). In this section their production is decomposed in multiple parameters that have been largely discussed with the *ROMANS FERRARI* Medical Center's board and all the re-education and medical teams. This function has the peculiarity of being extremely complex while interacting with a limited amount of entities.

Function	Expression	Criterion	Level	Flexibility
F2.1	Comply with the recommendations of the care team creating the grooves for the silicone molding	Position accuracy	$\pm 1\ mm$	F2
		Orientation	$360° \pm 15°$	F2
		Shape	Flower, beans, simple bean, papillon	F1
		Depth	$1{,}00$; $1{,}50$; $2{,}00$; $2{,}50\ mm \pm 0{,}15\ mm$	F2
		Drill diameter	$1{,}00$; $1{,}50$; $2{,}00$; $2{,}50\ mm$, if possible $1{,}25$ and $1{,}75\ mm$	F2
		Time	$1\ h$ on average for the milling	F2
F2.2	Engraving the grooves for the DMDGs that will be seen inside the compressive garments or put inside the ortheses	Work area	$350 \times 500\ mm$	F2
		Maximal volume	$220 \times 220 \times 400\ mm$	F3
		Plaster boards thickness	Between $20\ mm$ and $30\ mm$	F2
		Material	Plaster	F2
		3D printing chamber dimensions	$165 \times 165 \times 300\ mm$	F1
SF8	Replicate the exact geometry of the body shape	Convex surfaces	90% of the total	F3
		Concave surfaces	10% of the total	F3

Table 2.3: *Functional analysis of the milling function.*

As shown in detail in the Table 2.3, in this part of the functional analysis the milling function of the system is well articulated in two main functions. It must be noticed that this is the first function that will be implemented in the modular conception of the system, meaning that the first step of the implementation will involve the milling function.
All the positional tolerance criteria are collected in the F2.1 and summarize the requests of the healthcare team and the standards that are currently expected to be maintained. The F2.2 is expressed by criteria that have a high degree of flexibility. This is to be imputed to the fact that they represent the current standard practices but are easily modifiable and adapted in most of the cases. For example, the maximal volume machinable is the dimension of a twenty year old boy's thigh, which is an exceptional work that rarely happens.
The SF8 was defined after long discussions and observations in the laboratory. The only definition possible relies on the technicians' experience of many years and the observation of the positives produced over a sample time span. The first ideal requirement of the customer was to machine about 80% of the parts: it requires a

solution that is rather versatile in terms of the maximum size of the parts but also in terms of critical shapes. The convex surfaces are the wide majority, but some of them might not be suitable for the robotic system. For this reason, even without strong constraints, it's still important to take into account the size of the tool terminals and the existence of narrow spaces. It should always be remembered that children's body parts are generally small and that the scars tend to retract and can cause deformations of the anatomical shapes.

2.3 Silicone casting function

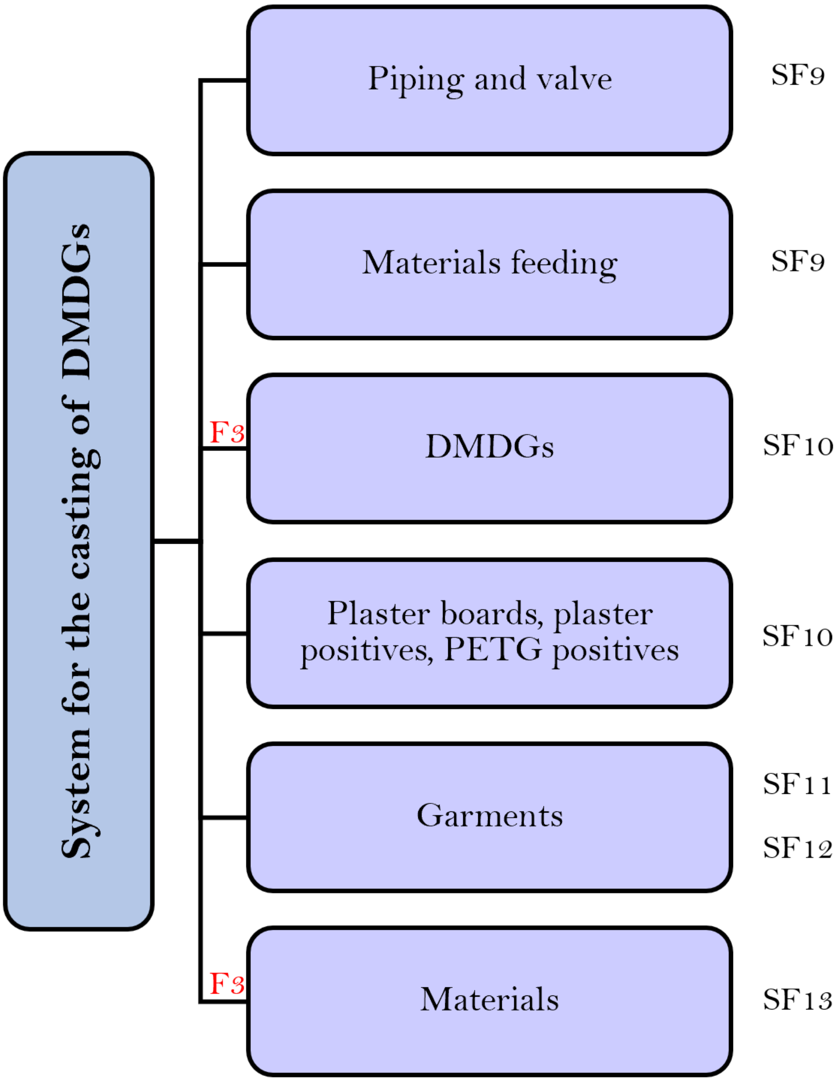

Figure 2.3: *Interactors diagram for the silicone casting function.*

This interactors diagram (Figure 2.3) is the most complex since the casting function not only requires tooling but also the integration with medical materials and a feeding system. The produced silicone devices must then be suitable for all sorts of compressive elements, hence the sewing workshop has a role too in this section.

Function	Expression	Criterion	Level	Flexibility
FP3	Production of silicone DMDGs	Waiting time to evacuate bubbles	10 min maximum	F1
		Uniform thickness of DMDG support	1 mm on average	F2
		Type of medical silicone used	Silicone two-component cartridges $\sim 80\%$ of the time	F1
			Hand mixed potted silicone	F3
SF9	Mix of the two-component silicone	Mixing accuracy	$50\% - 50\%$ on average in a cartridge	F2
		Use of potted silicone instead of cartridges	Usage of hand mixed potted silicone	F3
SF10	Produce DMDGs on all three kind of supports: plaster positive, plaster board, additive manufactured positive	Working area	350×500 mm	F2
		Maximal volume	$220 \times 220 \times 400$ mm	F2
		Application to most of the cases	At least 60% of the parts are suitable	F3
SF11	Usage of the chosen materials	Final silicone hardness	12 ShA in $\sim 80\%$ of the parts	F2
			$4 \div 40$ ShA otherwise	F3
		Avoid silicone drying in the circuit	As indicated by the supplier ($15/30$ min)	F2
			Depending on the presence of fast-setting additives	F2
SF12	Allow an easy set up of the materials	Possibility to use different materials	Quick change of cartridges (accessible)	F2
		Housing for cartridge in use	Easily accessible	F0
		Easy connection with a mixer (if needed)	Quick and easy with minimal tools	F0
SF13	Produce DMDGs sheets suitable for sewing	Thickness of the DMDGs support	1,50 $mm \pm 0{,}25$ mm	F2
		Insertion of a textile weft	After bubbles evacuation	F2
		Presence of attachment points	Optional	F3

Table 2.4: *Functional analysis of the silicone casting function.*

As detailed in the Table 2.4, for the deposition function, the criteria again depend on the technology in use in the *ROMANS FERRARI* Medical Center workshop as well as in the centre's external workshop that treats adult patients.

In this second workshop, which is not concerned by the project, the use of silicone in pots is preferred. The presence of a technician from that laboratory stimulated the discussion over the use of potted silicon, which is then the chosen solution for the final system. Both alternatives are covered by this analysis, since the cartridges remain the most expensive but functional option for quick craft work and the potted silicone is in any case already proven to be functional and no new suppliers need to be contacted.

2.4 Installation and implementation

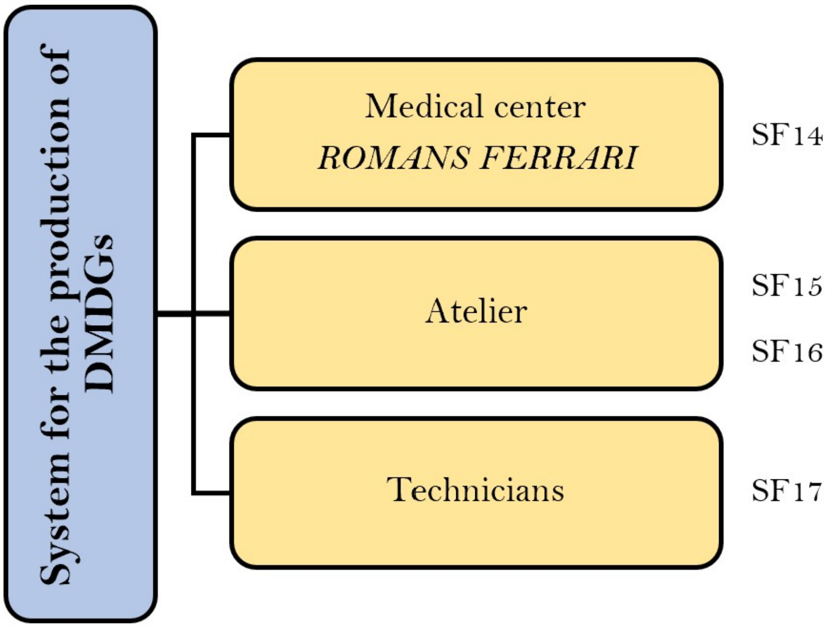

Figure 2.4: *Interactors diagram for the installation and implementation aspects.*

As shown in the interactors diagram (Figure 2.4) and detailed in Table 2.5, this last function links the designed system to all the environmental constraints for the critical part of the set-up of the system. The *Cahier des Charges* is a document that ensures to the customer that the required project will respect some standards and will fit into the chosen environment, and part of this last aspect is surely the implementation.

For what concerns the Atelier, in the context of this function it plays two roles: it's both considered as a work environment and as a building. In the first case it is involved in the issue of ensuring that the installation and the prosecution of ordinary work can coexist. Despite the installation time should be in the order of two days, it is almost impossible to foresee a total closure of the laboratory for more than half a day. At least half of it must be available for the many small adjustments that orthoses need daily. All the patients can at any moment reach the laboratory to have some adjustments done, be it sanding a mask's side or relieving the pressure on a overtargeted zone by heating the mask and slightly modifying its shape.

On the other side, the atelier is also the physical place that will host the system and so it has some specific structural requirements as well as some critical points. A relevant benefit of working in a medical environment is that most of the spaces respect the legislation standards for the movement of handicapped people. This means that all passages have a minimum width of 90 cm and all rooms have accessible ramps.

Function	Expression	Criterion	Level	Flexibility
SF14	Delivery of the system	Final reception time	By the 2023	F2
		Transportation cost	Included in the purchase (supplier)	F1
		Installation cost	Included in the purchase (supplier)	F1
SF15	Installation in the atelier	Passage through existing doors	900 mm	F1
		Critical passages	Angle 90° (respecting the normative PMR*)	F1
		Total installation time for the hardware	2 days max	F3
		Downtime in half of the workshop during installation	$1 \div 2$ days	F3
SF16	Assembly	Use of specific installation tools and machines by experts on site	Always possible	F3
		Maximal height	180 cm	F1
		Footprint	2 m^2	F1
		Total mass	200 kg	F3
SF17	Formation technicians	Formation time	2 days max	F2
		Formation cost	Included in the purchase	F2
		Cost of software licences	To be defined	F2

**PMR* $\longrightarrow$ Personnes à Mobilité Réduite.

Table 2.5: *Functional analysis of the installation and implementation aspects.*

This part concludes the functional analysis with indications that are more logistical and related to the necessary training of the equipment operators. One of the requirements of the *ROMANS FERRARI* MC is the availability of technical support from the suppliers, which is why we have sought standard solutions within the framework of the project, in order to maintain the guarantee of intervention by the producers to ensure maintenance and possible repairs.

2.5 State of the art

This section is a part of the functional analysis that changes multiple times during the process of definition of all the functions required and specific needs of the customer. This state of the art has a specific function: it justifies to the customer the choices made and their field, by showing the most similar technologies or situations existing on the market. The proposed state of the art analysis revolves around some key-words that are relevant for this project:

- additive manufacturing;

- three dimensional custom components;
- silicone casting;
- milling.

2.5.1 Digital dentistry

Milling is actually performed at the *ROMANS FERRARI* Medical Center in a fully manual way. It's an activity that can be carried out in several ways: either manually, either with CNC machines or more complex automated systems.

The most common CNC systems aren't suitable for this project, since they rely on the knowledge of precise geometrical references and surfaces. While this would be applicable to plaster boards with standard tool paths for each DMDG shape and location coordinates, the work on plaster positives that change every time requires a completely different solution.

Diving into the consolidated technologies that exist nowadays, the best match with the exigences of this project is dental prosthetics. The main similarities with this project are the following:

- each piece is custom made and has a unique shape;
- the milling surface is determined by a 3D scan that is digitally elaborated;
- the piece is produces by milling or 3D printing.

This field is in constant evolution, stepping forward to digital elaboration. Some companies are specializing entirely on this field. Among them, 3 shape offers a range of intra-oral scanners and software solutions for the elaboration of 3D files[18]. Besides offering hardware solutions and training, 3 shape also collects studies that prove the efficiency of this method. From the clinical point of view, the accuracy of image capturing via 3D vision is comparable to the one of conventional impressing[19]. What really makes a difference is the comfort of the imaging procedure.

The time intensive part of custom orthoses realization is the production process. The two main options available are, in analogy with this project too, additive manufacturing and CNC machining. For what concerns CNC machining, specific CAD/CAM software allow to switch from the *.stl* (standard tassellation language) to a CAM file, and more generally they are all-in-one digital dentistry suites. This solution in particular, when integrated with additive manufacturing technologies, allows to have extremely short turnarounds. For what concerns milling, most of the times it is performed by a three-axes mill with an additional two-axes located on a moving plate. One example is the *Orotig Whitec 5.3 Milling machine* (Figure 2.5). Its wet milling chamber allows for X-Y-Z-axes displacements in the volume 320 mm $\times$ 260 mm $\times$ 260 mm, whereas the A and B axes can be oriented in the respective angle ranges $[0°; 180°]$ and $[-30°; 30°]$ [20].

Figure 2.5: *Orotig Whitec 5.3 Milling machine milling chamber detail[20].*

The alternative production system is additive manufacturing. In the dentistry field, materials are the main concern. The most used material is zirconia ceramic, thanks to its durability, mechanical and aesthetic properties[21]. Its logistic drawback is the need of a furnace to allow sinterization after the 3D print. Other technical options are vat-polymerization, metallic and polymeric powder selective sintering. All of these technologies can't currently handle the most convenient ceramic materials[22].

One among the various commercial alternatives available comes from *Formlabs*. They have a range of dentistry high-resolution stereolithography (SLA) and low force stereolithography (LFS) 3D printers. They offer training for the use of the software *Mesh-mixer*[17] as well as a range of suitable materials. The *Freeform Form* range is composed by three printers that answer to different requirements. In terms of dimensions, the biggest printing chamber available belongs to the *Formlabs Form 3BL*, which has a printable volume of 335 mm × 200 mm × 300 mm.

2.5.2 Silicone casting

Medical silicone is widely used in orthopedics and podiatry. One existing and more and more widespread technology is 3D printing. An example is the *Lynxter S600D* 3D printer, a multi purpose device used in many different fields. It has a cylindrical printing chamber with a 390 mm diameter and 600 mm of height[24].

This *Lyntex S600D* (Figure 2.6) is a compact 3D printer that allows the creation of custom components in reasonable times. It is used in the medical field and more specifically in orthopedics for the production of polymeric lightweight casts. This type of technology doesn't require a positive to print on, and in general it is not expected for the printed part to be else but stand-alone.

Figure 2.6: *Lynxter S600D 3D printer[24].*

Lynxter proposes some solutions of tool heads that can allocate a whole cartridge. The most interesting two are:

- *LIQ21* $\Longrightarrow$ two component liquid tool-head (Figure 2.7). It performs 3D printing with volumetric pumps that dose the silicone components and a static mixer at the nozzle. This might allow to keep on buying the same type of silicone that is currently used and avoid pre-mixing in pot. In details, the materials used are in the following range[29]:
  - silicone RTV2 25 ShA;
  - silicone RTV2 40 ShA;
- *LIQ11* $\Longrightarrow$ single component liquid tool-head (Figure 2.8). So, it allows to allocate a bi-component cartridge. In details, the materials used are in the following range[29]:
  - silicone RTV1 34 ShA;
  - silicone RTV1 57 ShA.

At the mean time, the major drawbacks of these solutions are the weight and the dimension of the tool heads. In the specific context of this project, the weight applied to the robotic arm needs to be kept at minimum considering the presence of the 3D scanner always mounted on-arm. Moreover, the pieces to be machined are of various shapes and often present narrow spaces: this makes the dimension of the silicone valve a critical parameter to be minimized in order to machine the majority of the parts.

Figure 2.7: *Lynxter LIQ21 tool-head[29].*

Figure 2.8: *Lynxter LIQ11 tool-head[29].*

This technology allows for extreme precision but at the same time presents a cost and an impractical dimension, since the AMI has a very limited space (see Section 1.4). When considering the production of DMDGs by additive manufacturing without the support of the positive, it will be necessary to take into consideration the training of the equipment operators. This type of process often requires the production of adequate supports for the cantilever parts of the piece. Moreover, it must be considered that this device must be integrated into the AMI and therefore must first be effective for the production of masks. As explained in Section 1.2, the compressive elements are efficiently produced by thermo-forming a mask on the positive equipped with its DMDGs, so a positive must be in any case produced.

It is possible to extend the typical 3D printing concept (horizontal layer-by-layer) to additive manufacturing on generic surfaces. This methodology uses common 6-degrees of freedom industrial robots to follow non-planar manufacturing paths. Thanks to the angular displacement, they can produce layers with custom shapes. This system is currently being studied and implemented at the *Cornell University Medical Centre*[37].

The interesting part of this system is the possibility to print a chosen volume on a curved support. This system is not necessarily suitable for random supports, but it surely constitutes an interesting possibility in the field of additive manufacturing. A computer simulation is here represented in the Figure 2.9: this is the building of a custom heart membrane.

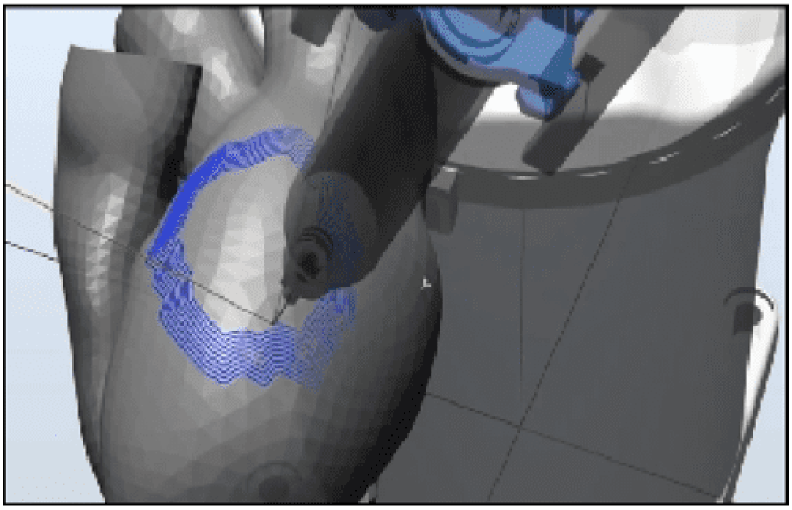

Figure 2.9: *Simulation of additive manufacturing processes on curved surfaces at the Cornell University Medical Center*[37].

Chapter 3

Choice of commercial solutions

3.1 Considered options

As mentioned at the Section 1.5, this project starts as a blank page. Many possible solutions have been considered thanks to the exchange with the *ROMANS FERRARI* Medical Center board, chief of reeducation team and all the re-education staff. In addition, the main industrial partner of this project *INNODURA TB* and all the suppliers contributed to suggest possible solutions that they have seen in real cases.

Hand milling, as the state of the art suggests, has been in many cases superseded by numerical control or additive manufacturing systems. At the *ROMANS FERRARI* Medical Center the engraving of the shapes of the DMDGs on the copies of body parts is in some cases already performed digitally, see Section 1.4. The *Formlab Fuse 1 3D printer* allows to produce the 3D copies of a body part with the digital 3D engravings for each DMDG thanks to the software *FreeForm*.
For what concerns the physical milling function, from the beginning of this project the main idea has always been a micro-end mill mounted on a robotic system. There are two main options: cartesian robots and robotic arms.

In the first case the silicone casting would be extremely easy since it would auto level on a planar surface and automatically fill all the grooves in an even way. For milling too it becomes quite simple, since it would just be sufficient to determine the cartesian coordinates and angular orientation of each DMDG and set the depth indication for each of them. This would take some time for the user to selects variable depths, but with standard tool paths it should be quite quick. The main drawback of such a system would be the 2D development. Despite the existence of 2D developments of each scansion performed with the *Artec Eva* (see Figure 1.10), there are some issues with this hypothetical solution.

Considering that the DMDGs are often placed on very sensible skin and the main parameter is the thickness of the silicone, it is clear that a two dimensional development of a three dimensional surface would produce some overlapping flaps and loss of precision when it comes to match the patient's body part. In addition to this, as anticipated in Section 1.3.3, positives are always necessary for the thermo-forming of masks with DMDGs already in position. This might lead to deformed masks and great loss of accuracy and imprecisions superposition. The main issues of this solution are here reported:

- double engraving, once on the positive, once on the plate;
- inaccuracies when developing the surface, even with the elasticity of silicone it's impossible to replicate a 3D surface As DMDGs have to be put on the positive before thermo-forming, the matching becomes complicated. In addition, there is a need to perhaps make beads by hand to join flaps;
- shapes too complicated to be developed (e. g. ears, fingers, body parts of small children) without loss of accuracy and with single DMDGs cut in the 2D development.

These observations made it clear that the system should be able to work on the two dimensional plaster boards, but most importantly on positives. It becomes clear that the most suitable solution is a multi-axial robotic arm. To ensure the possibility of machining most of the parts without changing the set-up, a possible future perspective is to install the part on a turntable with a position controller. This would allow the part to rotate from 0° to 180° in order to avoid any possible limit of the robotic arm's range of movement and machine every side in the most convenient configuration. Implementing this would require some software development in order to transmit the change of angular position in the robot's fixed frame of reference, so as to avoid coordinates setting. It must always be remembered how the user-friendliness of the system is one of its most important characteristics. A critical part of such a solution is the algorithm: it must be possible to cut the work into two parts without causing imperfections in the machining or casting of any DMDG positioned between the two machined sides.

The most complicated phase to be automatized is silicone casting. It is in fact the last of the modules that will be implemented. Considering that many 3D casting systems exist, such as deposition of sealing cords on automotive wind-shields, the solution foreseen from the beginning is 3D casting with a valve. The main issue is that the current process of hand casting on positives requires many attentions and multiple passages performed by the technicians. Examples are adding material where it flows down, using a spatula to distribute it better, waiting for a partial drying before pouring a second layer and so on. Creating an automated system that replicates all these attentive tasks is rather complicated. For this reason the focus must move from replicating exactly the current process with the currently used materials.

The goal is to create a three dimensional casting system that uses the same tool path as the milling system to cast the silicone in a way that prevents it from flowing down. This might as well improve the quality of the DMDGs produced by creating a uniform sheet of silicone on top of them. The final hardware solution is reported below in Section 3.4 and has been suggested by an expert from *Precise France*. Mr. Remi Bittel suggested a valve with an extremely low and precise volumetric flow rate that ensures precise results at any viscosity. This solution required the use of potted silicone.

One critical point is the type of interface with the technician and especially the complexity of starting the job. As already mentioned in Section 2.1, the user-friendliness of the solution is fundamental.
Thinking about the existence of standard DMDG shapes, the first idea was to produce tool-paths for each one (to be replicated by the micro-spindle or the silicone valve) and to create a system of geometrical location of each DMDG based on that. For example, the *FreeForm* software allows the creation of DMDG grooves from standard shapes: it may be possible to create tool paths based on these known shapes. One possibility WAs to scan each part, design it digitally by creating DMDGs and receive in output the associated tool path. This type of processing works well with a limited number of DMDGs, because for each one you have to give dimensions, position and depth. In addition, during the machining process it is necessary to give reference marks for the work-piece. The solution chosen was to do something similar, but with a scanner and an algorithm for automatic tool-path creation without standardized shapes.

To complete the automation of the system a possible future development is the installation of a tool rack and the possibility for the robot to make autonomous changes. This will pave the way for automated and autonomous work also in the absence of personnel.

3.2 Robotic arm *Stäubli TX2-60L*

The choice of a *Stäubli* robotic arm is motivated by an existing partnership with *INSA Lyon*. The choice of a 6-axes robotic arm instead of a simpler solution has been previously explained. This particular choice is oriented towards the highest versatility for future development and functions improvement.

A discussion with Mr. Mickaël Marcillat from *Stäubli France* steered the choice towards the *Stäubli TX2* range. This is a range of robotic arms that are applied in medical industry and surgery too. The available models are here reported in Figure 3.1.

Figure 3.1: *Stäubli TX2 robotic arms range*[12].

The functional analysis underlined the importance of a reduced dimension of the whole system and at the same time of its versatility. These two characteristics may in some cases be in conflict, since machining a wide range of positives means to have large motion field, hence longer axes. Inside the *ROMANS FERRARI* Medical Center's laboratory the space management is an ongoing issue: many different processes are carried out at the same time in differently equipped stations, while many patients with their relatives occupy the fitting slots. Taking this into account, the choice is made by focusing on the central models of the range: *TX2-60*, *TX2-60L*, *TX2-90*, *TX2-90L*. The Table 3.1 below compares the most relevant characteristics of the four models.

	TX2 - 60	**TX2 - 60L**	**TX2 - 90**	**TX2 - 90L**	
CS9 Controller weight	38				kg
Controller dimensions	$270 \times 445 \times 365$				mm
Robotic arm weight	52	53	114	117	kg
Total weight	90	91	152	155	kg
Robotic arm reach	670	920	1000	1200	mm
Forearm type	$short$	$long$	$short$	$long$	$\diagdown$
Maximal cartesian speed	8,4	11,1	10,9	11,1	$\frac{m}{s}$
Load capacity	4,5	3,7	14,0	12,0	kg
Price range	$35000 \div 45000$		$50000 \div 60000$		€
Repeat accuracy	0,020	0,030		0,035	mm

Table 3.1: *Comparison between the most relevant options of the range TX2.*

As the price range of the *TX2-90* and *TX2-90L* models is around €50000/€60000 and their dimensions ensure that they can work on any positive, but require a lot of space in the workshop, they were rejected. The final choice was the *TX2-60L*: its price range is the same as the *TX2-60* model, around the expected €40000, but there is the advantage of more favourable arm dimensions and still smaller footprint. So, in the Figure 3.2, the nominal dimensions of the *Stäubli TX2-60* and *TX2-60L* are shown.

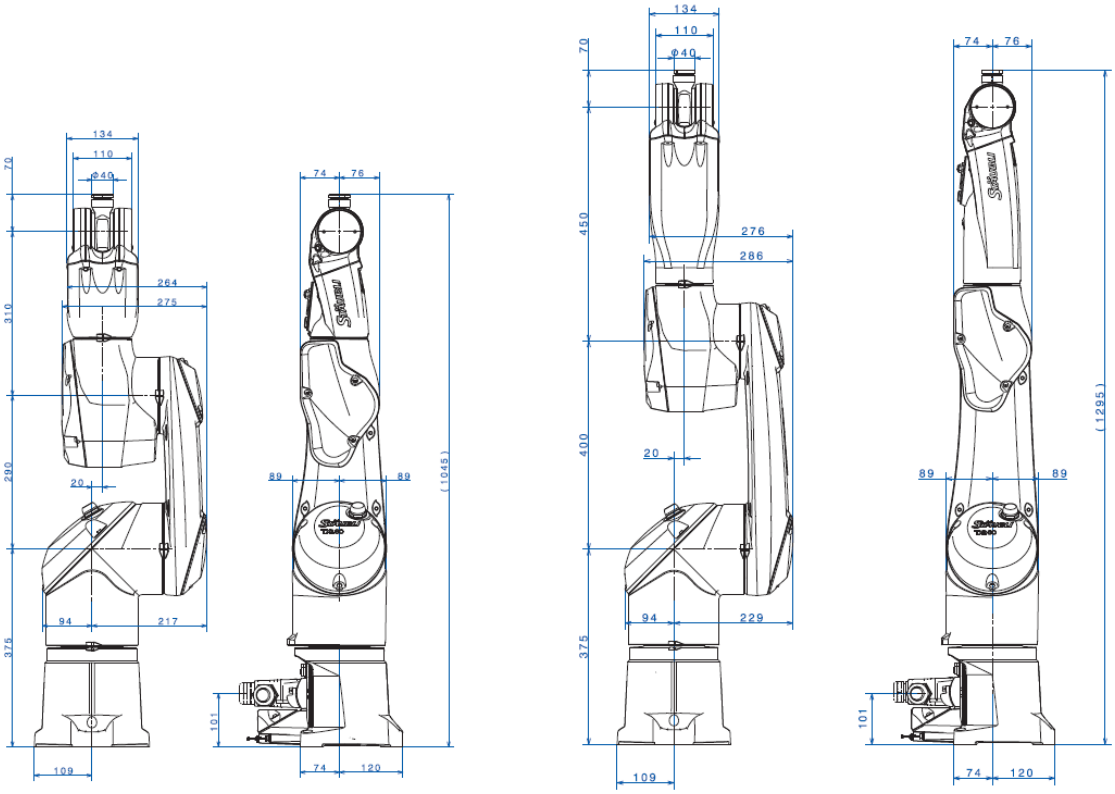

Figure 3.2: *Stäubli TX2-60 and TX2-60L nominal dimensions*[13].

With *INNODURA TB*, the constant presence of a 3D scanner next to the robot terminal was envisaged, and therefore a rather cumbersome interface with the tool. The choice of the model with the long forearm therefore goes in the direction of compensating for the size of the attached tooling and avoiding as much as possible the displacement of the object to be worked. A larger forearm size allows the terminal with the tool to be moved also to the sides not adjacent to the base of the robot (in the absence of a turntable) or to the upper part of higher work-pieces.

A critical point when choosing between the *TX2-60* and *TX2-60L* models is also the load capacity. In anticipation of always having the scanner and its holder attached to the arm and in addition the milling or casting tool with its holder, the decrease in load for the 60L model can be a problem. The given maximum speed of the centre of mass of the load is 11,1 m/s for the *TX2-60L* model, meaning that it can safely move 2,7 kg at the speed of 11,1 m/s. This speed is not needed in the context of this project, considering that the only displacement needed is between one DMDG and the other. At the same time, the load is quite close to the theoretical static loading of the tool head. For this reason, the supplier *Stäubli France* has been reached to discuss some

adjustments.
It is possible to have a customized arm that is certified with different characteristics: *Stäubli* can be able to reconfigure the robotic arm properties according to the needs of the *ROMANS FERRARI* Medical Center and reduce the maximum speed available while increasing the admissible load. The expected outcome is an increase in the load of around 1,5 kg.

3.3 Micro-end mill *Sycotec 4015 DC*

The machining process carried out at the *ROMANS FERRARI* Medical Center by the technicians is currently carried out with manual micro-end mills. Since it is only performed on chalk, it is characterized by low torque and higher speeds that ranged around 40000 rpm. Each DMDG should be customized not only in its total dimension but also in the width of the trait: this means that different drills will be needed. The drills used are of standard diameter: 1,0 mm, 1,5 mm, 2,0 mm and 2,5 mm. A rack to collect the different tools is foreseen as a future development of the system, while in first place it will be a fully manned task to change them. The main requirements are budget and size, especially in terms of the load applicable to the robot. Thanks to the previous commercial relationship between *INSA Lyon*, it has been possible to reach Mr. Remi Bittel from *Precise France*, supplier of *Sycotec* devices. The final choice is the *4015 DC ref 1.001.2437* model with cooled clamping support *4825* (see Figure 5.3) and the associated drive *4624*, all by *Sycotec*. In the Table 3.2 below the most relevant technical details are summarized[11].

Outside diameter	25,4	mm
Minimal speed	5,000	rpm
Maximal speed	80,000	rpm
Maximal cutting torque	400	Nm
Minimal tool diameter	0,5	mm
Maximal tool diameter	4,0	mm

Table 3.2: *Technical details of the Sycotec 4015 DC micro-end mill[11].*

This spindle is cooled by compressed air and by the fins of the support. In Chapter 5, the connection between the spindle support and the scanner support is studied.

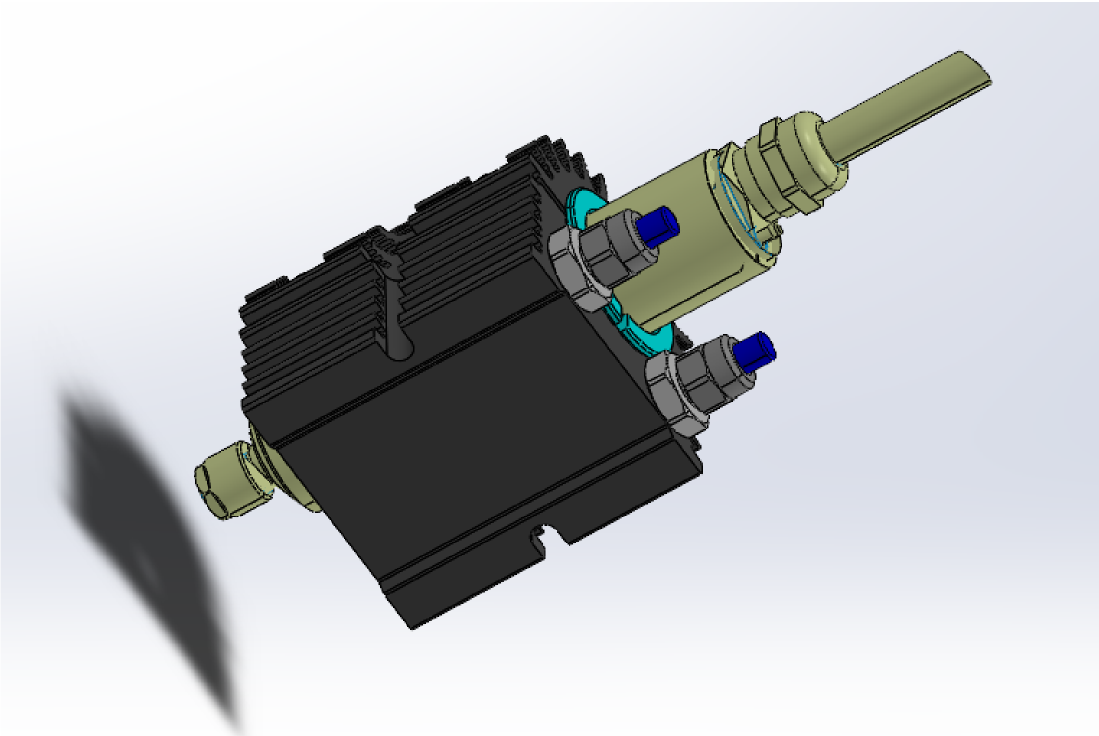

Figure 3.3: *CAD model of Sycotec 4015 DC micro-end mill with support*[10].

3.4 Needle valve *NORDSON XQR41V*

As suggested by M. Maxime Robin, Director of *INNODURA TB*, the silicone casting system has been studied with an expert from *Precise France*. The proposed solutions belong to different *NORDSON EFD* ranges. In particular, there could have been different interesting options for different possible applications in the context of this project:

- high flow piston valve *725 HF* $\Longrightarrow$ it's used to fill small containers and for the dosage of liquids. A possible scenario imagined was the use of a cartesian robot and produce all the DMDGs sheets by developing them in two dimensions. In that case this valve would have been suitable for the casting on plaster boards;
- progressive cavity pump *797PCP* $\Longrightarrow$ it's a pump that reproduces the shape and functioning of the bi component cartridges. As in Section 2.5.2, the main issue is the dimension of the tool head that would make it hard to reach the narrowest spaces.

NORDSON is the world leader in fluid deposition systems for grease, silicone and medical materials, and its *EFD* division is dedicated to micro-quantities. Thanks to a long exchange with Mr. Franck Bonneton, we considered to pre-mix the silicone. In fact they have only one option with a double screw pump system which works as two valves in parallel. This system is the most cumbersome and less versatile, so it remains as the last choice. On the other hand there are extremely light and versatile systems in terms of single component valves. After considering non-contact solutions (jet dispensing, very fast but larger), the most suitable solution for our project turned out to be the needle valve model *XQR41V* with its *Back-pack Valve Controller*.

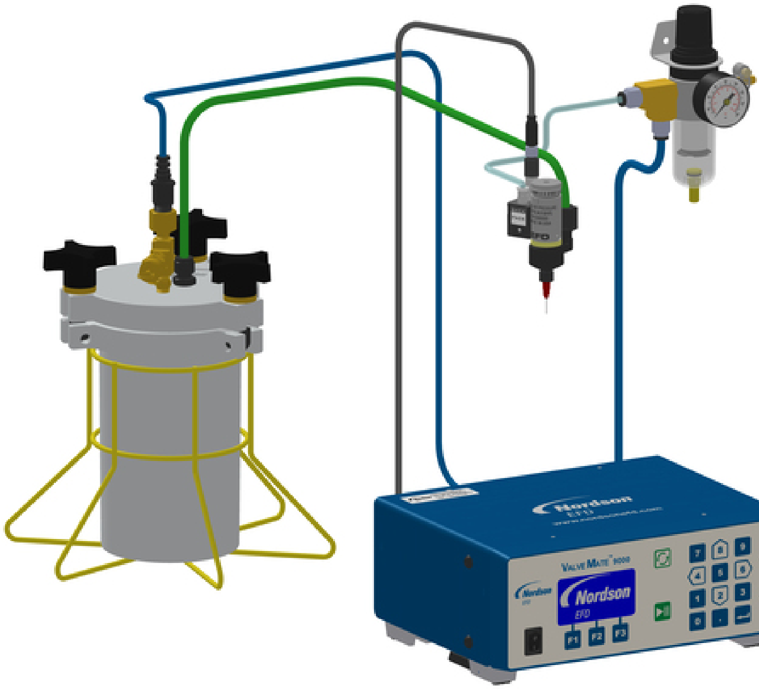

Figure 3.4: *NORDSON XQR41V full controlling and feeding system*[6].

As seen in the Figure 3.4, the valve must be connected at a time to the feeding pipe and the controller. The feeding system requires to put silicone in a pot, hence the use of bi-component cartridges should be abandoned in the context of this project. As seen in the Section 2.5 the tool heads that can allocate bi-component cartridges are extremely big, while one constraint for the choice of the silicone molding solution is the possibility to reach also narrow spaces.

The chosen valve, namely a needle valve, is the extremely compact terminal of the system and is represented in Figure 3.5.

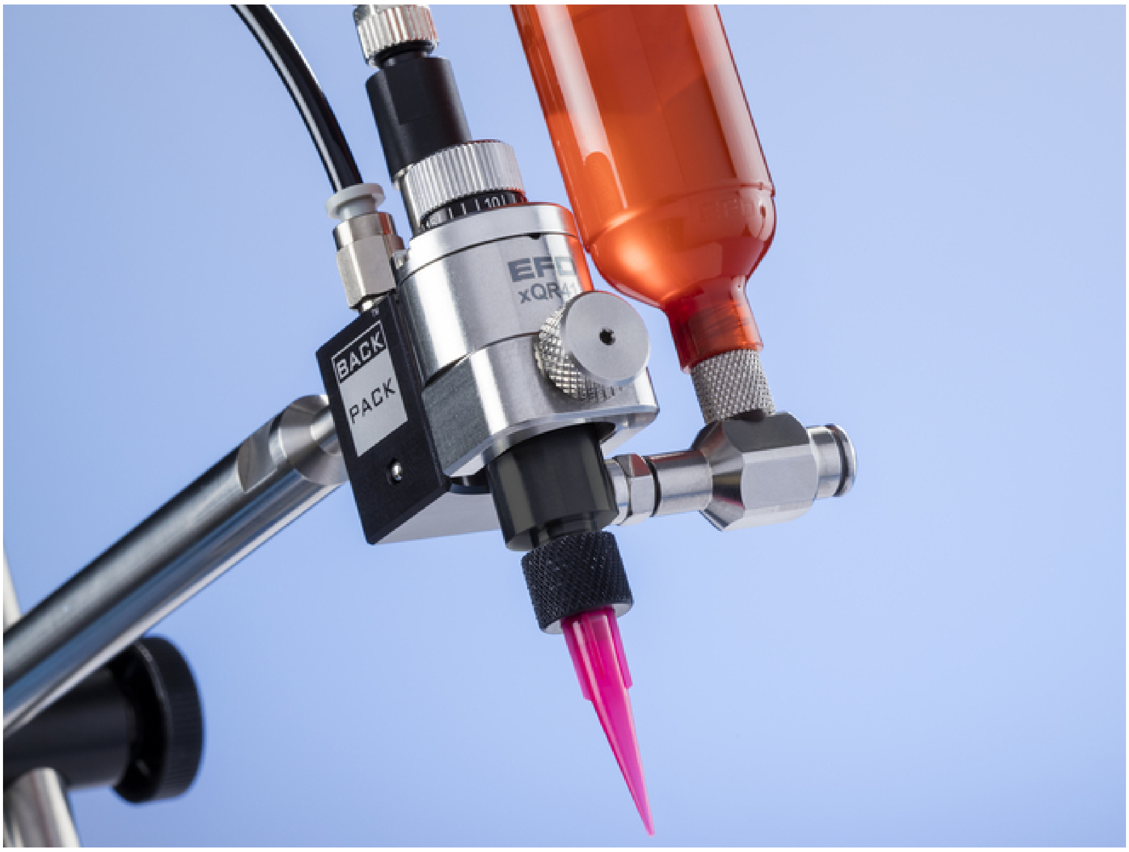

Figure 3.5: *NORDSON XQR41V needle valve*[6].

This component is designed to ensure a precise and consistent fluid control, it allows to limit almost completely the casting inertia and therefore to work also on vertical surfaces without defects. It has a modular design and 60% lower form factor with respect to analogue solutions. This valve perfectly meets the needs of the *ROMANS FERRARI* Medical Center: the compact dimensions allow it to be used also in narrow spaces such as contracted palms, back of ears and fingers.

The choice of this valve is extremely favourable from the point of view of the load on the robotic arm too. In fact, its mounting block is compact and lightweight. It can be equipped with various types of feeding systems while keeping the quick insert and release simple and reliable. The quick release requires to untighten the rounded grip that can be seen in Figure 3.5 and only leave the *backpack* support on-arm, allowing to clean in brief times the valve's channels. Below, in the Table 3.3, are the basic technical characteristics[9].

Valve dimensions	64	mm
Required pressure	$4{,}8 \div 6{,}2$	bar
Valve weight	115	g
Weight with mounting block and control system	195	g
Output	> 400	$\frac{cycles}{minute}$

Table 3.3: *Technical details of the NORDSON XQR41V silicone valve[9].*

In addition, the "*QR*" abbreviation stands for "*Quick Release*": a release system without the need for tools that allows the valve to be separated from the tool head in a few seconds when work is interrupted. Since the system will be located in an environment where work planning is not performed and the productive process is often subject to sudden changes or interruptions, it is interesting to allow the technicians to switch between the activity of milling and silicone deposit in the easiest possible way. Moreover, this system will be used by personnel with limited time and training, and the user friendliness is a key characteristic to ensure that the system will be used regularly and by the majority of the staff.

This valve has two main interesting characteristics: the lightweight and compact design and the quick release. As previously mentioned, the robotic arm will always be equipped with a 3D scanner, thus limiting the available loading capacity. At the same time it is known that the valve will be use with almost no additional load, since it doesn't have to perform machining or anything in direct contact with the positives. In any case, it should be noticed that the more the system works in the good range of loading, the better the precision and the energy consumption will be.

3.5 Robotic Vision

The main industrial partner *INNODURA TB* allowed to design and test robotic vision systems on their *Stäubli TX2-90* robotic arm. *INNODURA TB*'s systems use artificial intelligence, 3D scanners and algorithms to make robotic systems more efficient and autonomous. Their participation in this project starts from the analogies with their system *INNOPICK*. By equipping the robotic arm with an *Ensenso N35-606-16-BL* 3D scanner and a custom algorithm, the robot performs fully autonomously the picking of different components,. The algorithm compares the scan (knot of points, *.stl* file) with the CAD model of the parts and deduces the position of those that are more accessible. By giving a confidence level to each comparison, the algorithm chooses the parts to be moved and the relative position of the gripper among the library of possible positions.

By positioning the scanner between the robot interface and the tool, this system avoids the need for any localization, as what is scanned is already located in the robot's frame of reference. This eliminates an annoying step in the typical machining process and simplifies the work. This system then compares the scanned surface and the CAD model of the component to be picked. With a colour texture scanner it is also possible to make comparisons between an image (*.jpg* extension) or library of shapes such as the DMDG "*stamps*" and the scanned textured surface.

A six-axis robot can be programmed with geometric data and work with common CNC systems if the pieces to machine have a well defined geometry. Since in this project no component is equal to any other, the geometry can only be imported via a 3D vision system. To perform the comparison and recognize the shapes to machine, it must be able to produce information on the colours. This motivates the choice of this specific 3D scanner, the *Zivid Two*.

3.5.1 3D scanner

The *Zivid Two* 3D scanner is a lightweight 3D scanner. It is designed for 3D machine vision systems and performance and productivity boosts. It is used in bin picking, assembly and robot guidance operations.
The standard support provided by *Zivid* is compatible with the *Stäubli* arm end, according to ISO 9409-1-50-4-M6. In the Table 3.4 below, the main technical characteristics are reported[7].

Working distance	from 500 to 1400	mm
Optimum focal length	700	bar
Shutter speed	max $1/600$	s
Minimum acquisition time	60	ms

Table 3.4: *Technical details of the Zivid Two 3D scanner[7].*

The stand is available in two versions that put the scanner in two positions: the first parallel to the sixth axis of the arm, the second with a 15° angle. I chose the latter, as the micro-spindle and valve will be positioned perpendicular to the sixth axis.

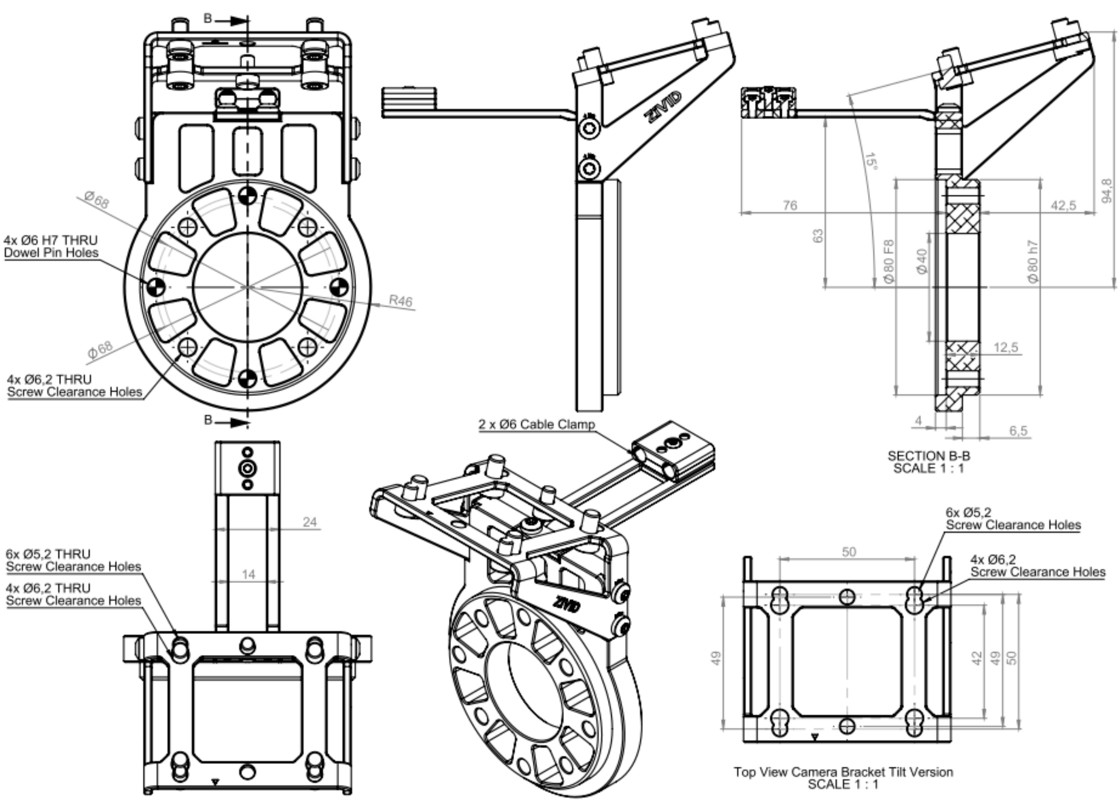

Figure 3.6: *Zivid Two on-arm mount option with 15° angle[7].*

This choice has been made to facilitate the cables arrangement and the process of changing of the tool and, most importantly, to ensure the usage of all the scanner's field of view. Considering that the scanner will be always mounted on-arm, it is mostly important to keep it clear of plaster dust and possible damages in the tool changing operations.

In terms of algorithm and numerical control, this choice does not add any particular complication, since it is simply required to set the scanning positions with a negative angle of 15° of the forearm. This lightweight 3D scanner has a wide field of view with a vertical angle of 36°, see picture below. This means that the angular mount at 15° ensures that most of the 18° semi-angle of view is free of interference with the tools and wiring system.

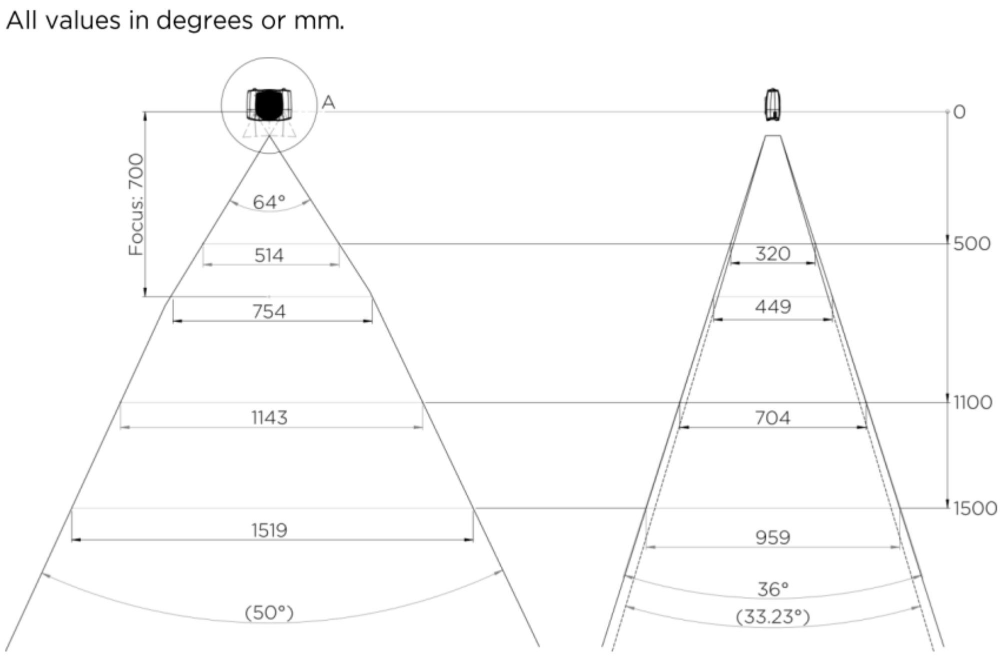

Figure 3.7: *Zivid Two field of view*[7].

3.5.2 Foreseen algorithm highlights

The first hint of a possible solution proposed by *INNODURA TB* is to retrieve the *.jpg* file from the *Zivid Two* output and recognize the shapes of the DMDGs on the plaster positive to create a tool-path.

The first idea that develops from the existence of a library of standard shapes in the software *Freeform* used at the *ROMANS FERRARI* Medical Center is to perform a comparison. The concept of a library instantaneously suggests to compare the detected shapes to the library and mark with a degree of confidence the recognition of each DMDG.

Image matching is an example of a similar concept: it is a technology that's currently largely used in the augmented reality field. It allows the recognition of a given object from any perspective[28]. This matches the need to recognize DMDGs deformed by the surface of the skin, but no imperfection is taken into account. In any case, after the recognition of a certain shape it is simply necessary to set up standard tool paths for each of the six DMDGs shapes and adapt it to the detected size. This type of algorithm would require an intense part of software development, but in first place it can be considered a valid option to be developed.
This first version of the foreseen algorithm is here represented in its main logical steps, see Figure 3.8.

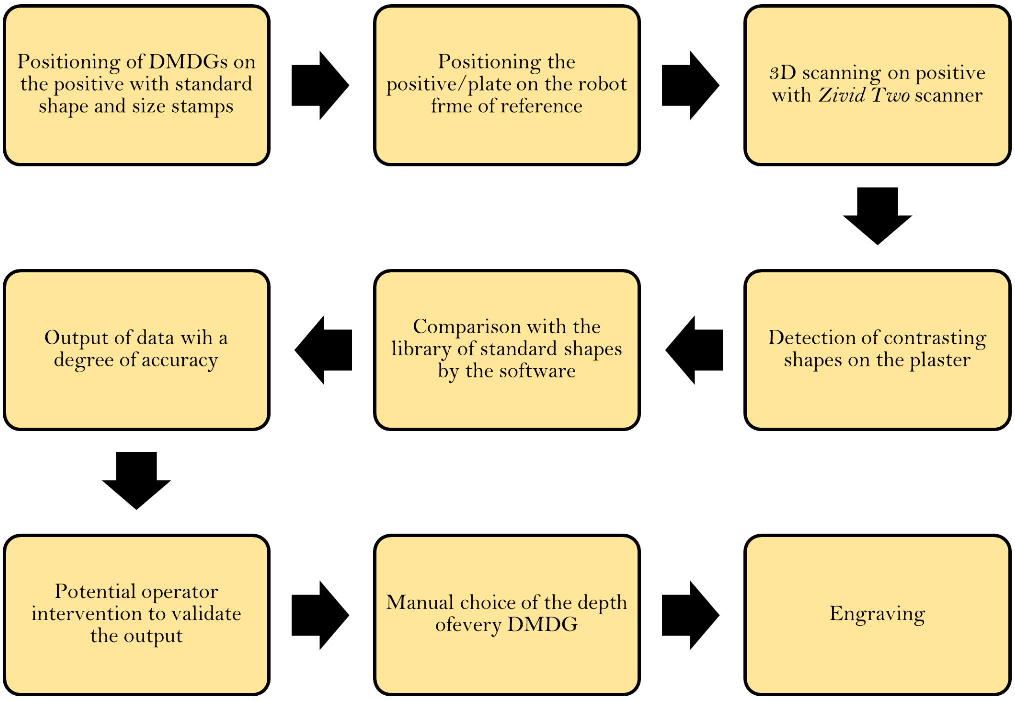

Figure 3.8: *Visual representation of the extraction of a tool path from a 3D coloured image by comparison - first option.*

With the further development of the project and the vision tests performed at *INNODURA TB*, different ideas are considered. In particular, the deep analysis of the subject that has been presented in the previous chapter highlights how the level of precision in this productive process is really variable. Most of the times, anyway, the precision reached in some of the produced DMDGs sheets is not even detectable nor distinguished from the least precise piece produced, since the outcome of the treatment is macroscopic and still extremely empiric. These observations lead to abandon the idea of reciprocating a perfect shape as given from a digital library, and simplify instead the vision algorithm. The objective is to have different tool paths for each machined component only depending on the detected DMDGs. The main part of this algorithm would firstly need to recognize the DMDGs impressed on the plaster positive with the tampons and ink thanks to the contrast of the colours, then to isolate the points corresponding to that contrast zone and create a new point cloud file with all of them, clear of all the rest of the scanned volumes. Lastly, it would create the mean line for each of the points portion (nominally each DMDG): this would be the tool path, that the robot can automatically perform with no former instructions needed.

This summarizes the algorithm that is finally chosen as the most suitable one for the purpose of this project. Its steps are briefly summarized in Figure 3.9.

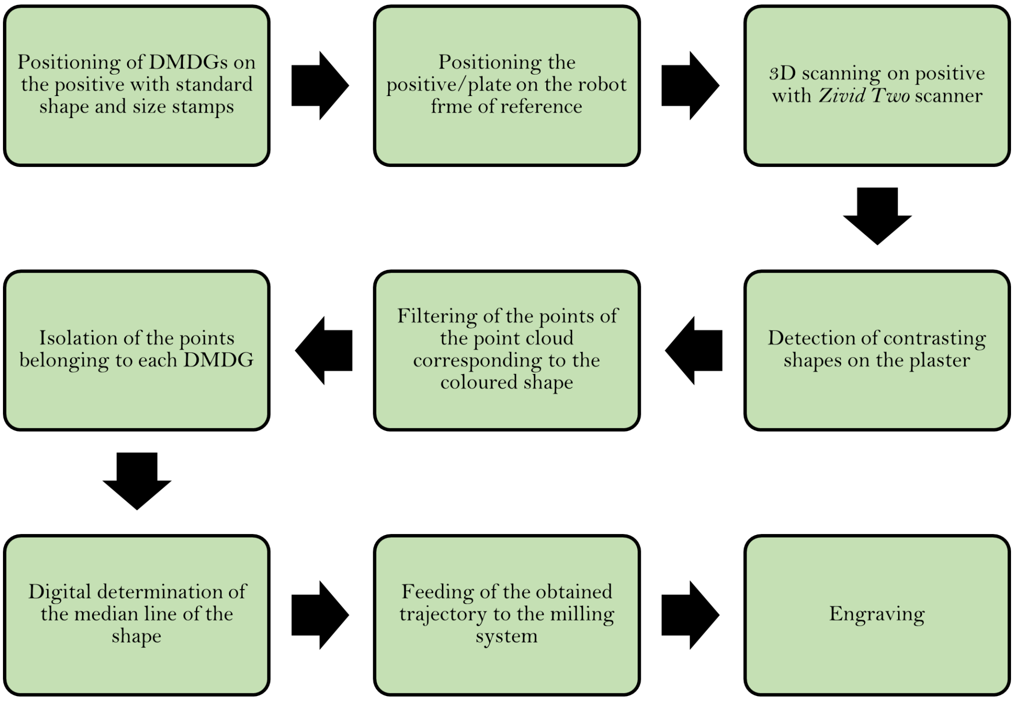

Figure 3.9: *Visual representation of the extraction of a tool path from a 3D coloured image by contrast detection - final option.*

The main point that allows to choose one algorithm with respect to the other is feasibility. The algorithm proposed in Figure 3.9 matches one of the fields of interest of the industrial partner *INNODURA TB*, this allows to deduce that it might be a quickly feasible option with their experience. A confirm of this is also the simple demo that M. Quentin Delagrange from *INNODURA TB* developed for a presentation.

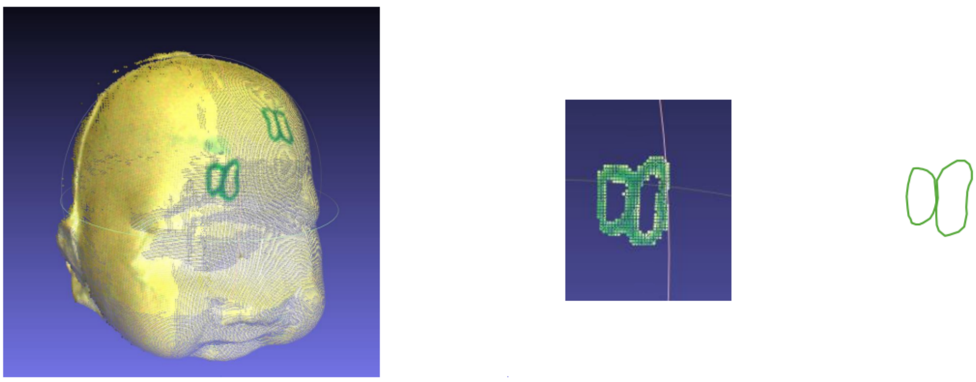

Figure 3.10: *Visual representation of the extraction of a tool path from a 3D coloured image*[8].

The main steps previously explained are visually explained in Figure 3.10.

Some issues that will have to be addressed during the development of the algorithm will be:

- degree of confidence in the isolation of the shapes in contrast;
- correction of illumination and exposition to avoid mistaking the shaded areas on the plaster due to contrast, since the shapes might have protrusions causing dark shadows;
- some DMDGs stamps might come in contact and the tool path created by the algorithm might unite them in a single trait, this might cause some imprecise profiles.

Chapter 4

3D vision tests at *INNODURA TB*

INNODURA TB is an enterprise located on the *INSA Lyon* campus. Its main field of work is 3D vision and 3D perception[5]. With their complementary knowledge in the fields of software development, mechatronics, AI and vibration analysis they are able to develop 3D perception systems tailored on every customer.

The chief and founder Mr. Maxime Robin dedicated his time and resources to the development of this project by opening the doors of *INNODURA TB* for some initial tests. *INNODURA TB* is currently working on the project *INNOPICK*. It involves the 3D scanner *IDS ENSENSO N35-606-16-BL*. Its main difference with respect to the *Zivid Two* is the absence of a color texture, which is replaced by a greyscale image. *INNOPICK* is a software suite that is currently being adapted for specific tasks, hence the engineers of *INNODURA TB* are working on a full scale picking system composed by robotic arm *Stäubli TX2-90* equipped with a 3D scanner *IDS ENSENSO N35-606-16-BL* on site.

This system is currently used in picking of randomly arranged components in a box, but it is also applied to bin picking and arrangement of random objects. The algorithm running it requires a preliminary import of the component's CAD model, then its operative sequence is divided into the preliminary setting and the operative steps that are repeated.

In the Figure 4.1 the preliminary operations are represented. This set of operations is required only once at the beginning of a new component's picking, then they can be stored for reuse. The third step is of particular interest, since it is an experimental value to be determined according to the size of the picking area and the component.

Its shape complexity and the lack of picking positions affect this parameter, as well as quantity of components and arrangement.

The fourth step is instead automatized: the on-arm 3D scanner allows to identify the picking area and set its coordinates in the robot's fixed frame of reference with a single scan, as well as it can identify the position of the delivery position. The only issue of an ordered arrangement is to choose the orientation of the parts and modify accordingly the possible picking positions.

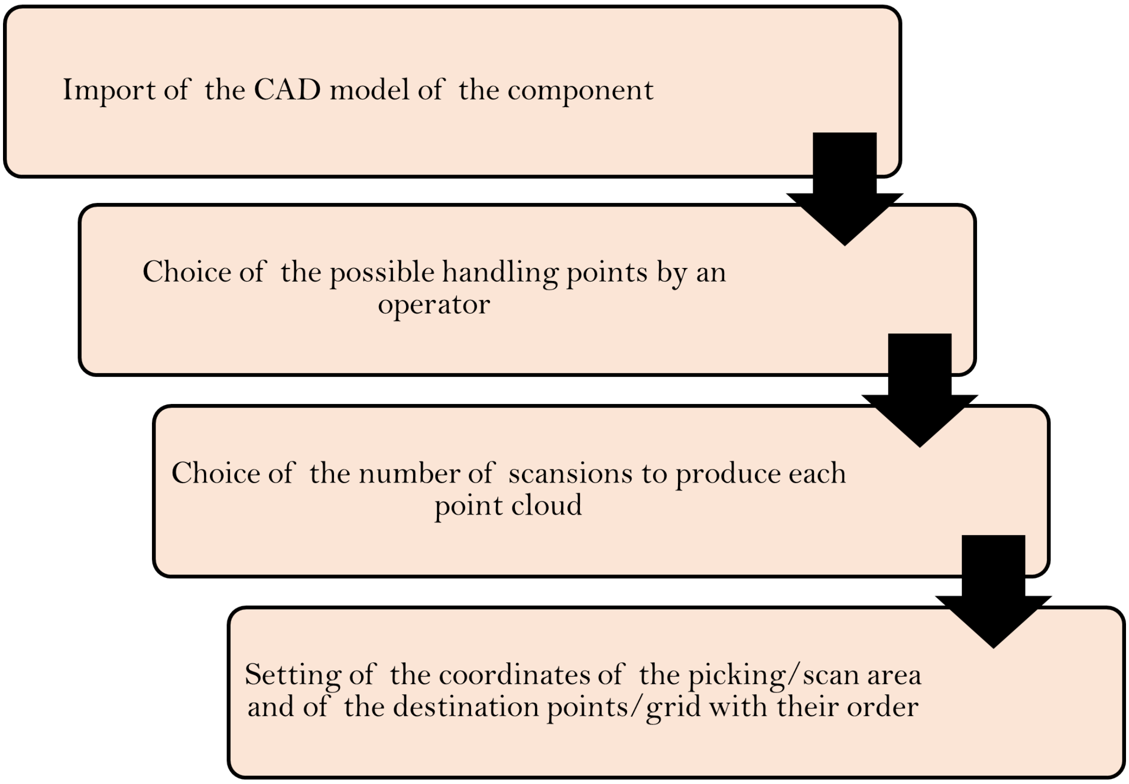

Figure 4.1: *Preliminary sequence of the import of the component's CAD model.*

With the start-up of the picking process, the cyclical steps repeated are represented in Figure 4.2. The multiple picking movements for each scan depend on the amount of detected components with the highest confidence and their arrangement. The algorithm chooses to only move component's that can be replaced without causing movements or changing the position of the others picked in the same session. Should the arrangement be too complex and the confidence level too low, the system requires an operator to confirm the movements.

This system has many common points with the process of scanning of the positives to engrave and produce the DMDGs. In fact it involves the 3D vision of elements that change all the time, and as mentioned before the project requires to work on positive copies of different body parts of different people, that are clearly single pieces. Moreover, this system involves the comparison and recognition of standard shapes, which in the studied case can be used to recognize the shapes of the DMDGs from the tampons pressed on the skin (see Section 3.5).

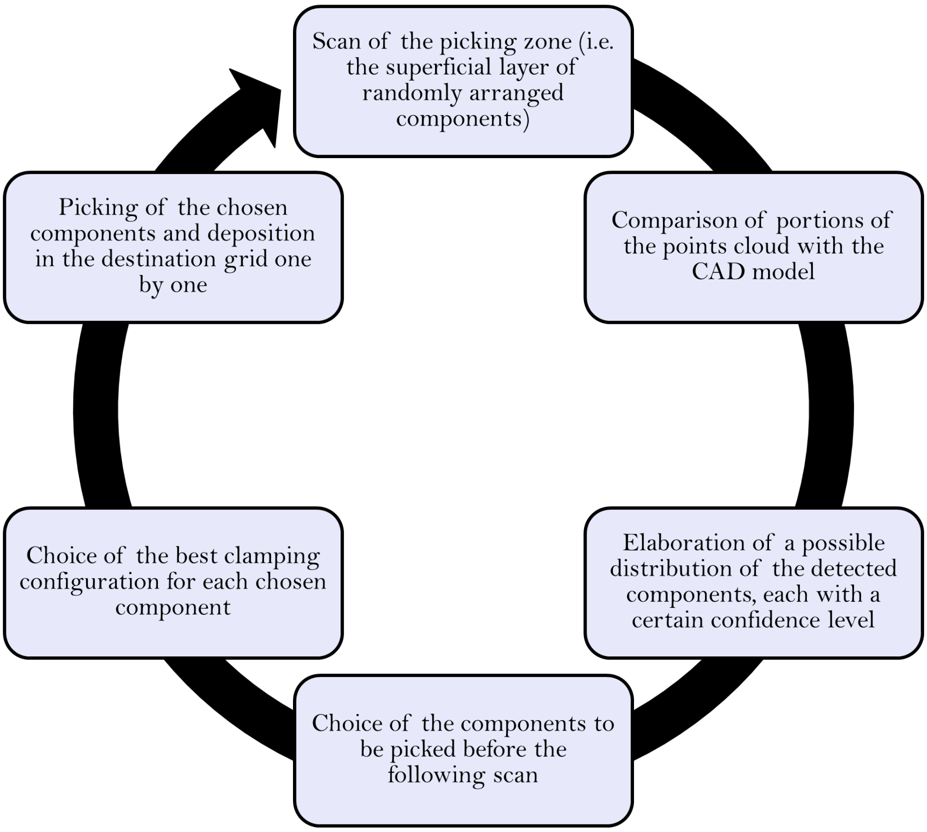

Figure 4.2: *Picking process sequence.*

4.1 Simulations with *IDS ENSENSO N35-606-16-BL*

The *IDS ENSENSO N35-606-16-BL* is a 3D scanner that produces point clouds and a greyscale texture. It is equipped with three cameras that work in stereo-vision, a technology inspired by human vision, using blue light. It has a clearing distance (CD) of 312 mm and a working distance (WD) of up to 464 mm. The sensor has a resolution of 1280 × 1024 Pixel (1.3 MP) and a focal length of 6 mm. The z-axis accuracy of the *IDS ENSENSO N35* at 400 mm WD is 0,192 mm[26]. This 3D scanner is currently used in all versions of *INNODURA TB*'s *INNOPICK* project, mounted on a *Stäubli TX2-90* arm. For this reason, despite this model will not be the one involved in the designed system, it has been used to perform some simple tests.

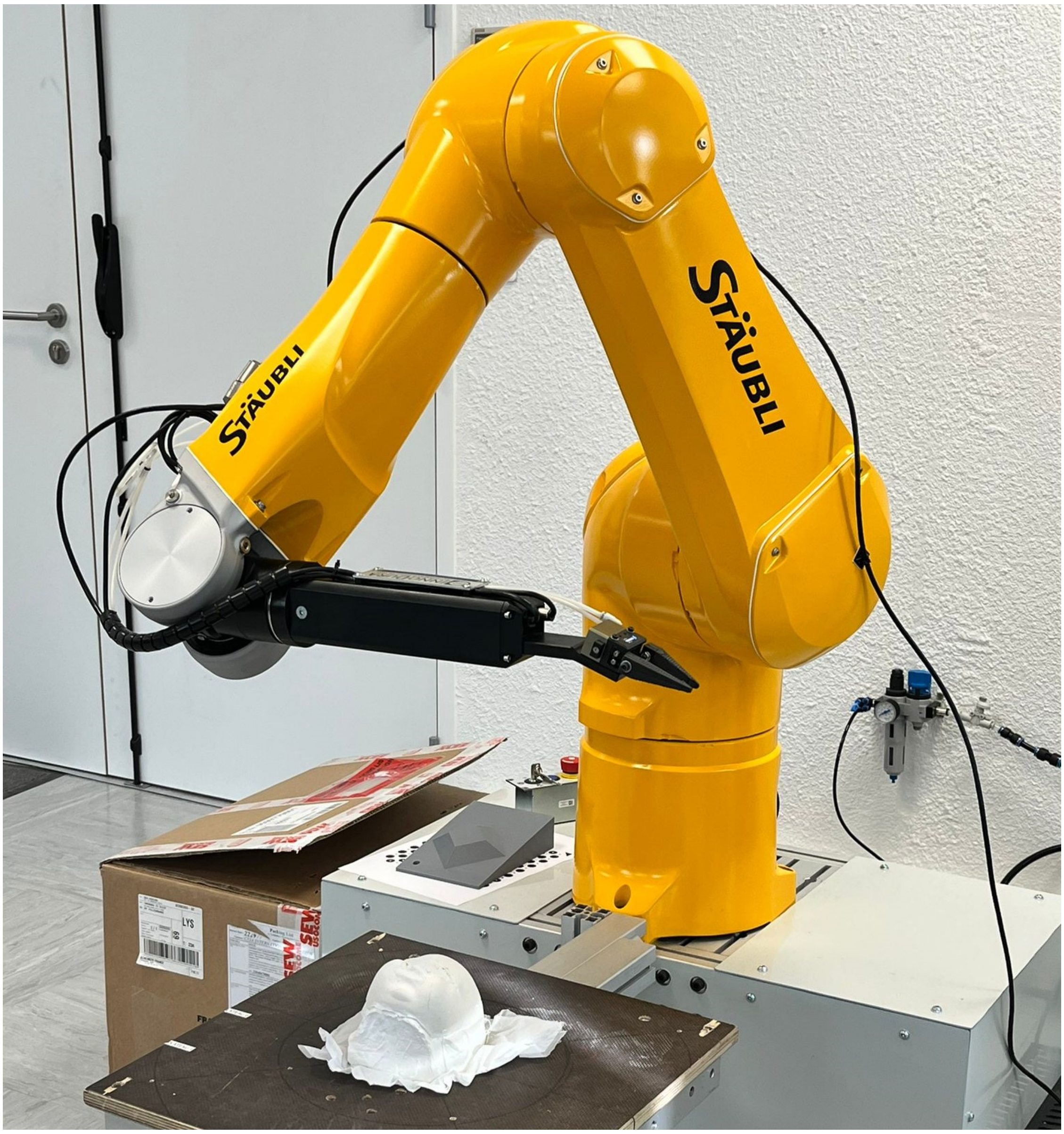

Figure 4.3: *INNOPICK picking system installed at INNODURA TB with IDS ENSENSO N35-606-16-BL[8].*

This experience has been a key point to foresee a potential algorithm and validate some hypotheses that had been made. The main differences with respect to the *Zivid Two* are the field of view, presence of a colour texture and focus distance. In this case, scansion time, precision of the data and user-friendliness of the suite have appeared to be perfectly aligned to the requirements of this project.

4.1.1 Greyscale scan

The simulations are made with a plaster positive that is a copy of a newborn's face[4]. This positive has some defects on the mouth and eyes part, since it was not molded. As can be clearly seen below in Figure 4.4, it presents a small hole which is a typical defect of bad air evacuation during plaster molding. The DMDGs marked on the forehead of the positive are made with a tampon (see Figure 1.2) and a felt tip pen. It should be noticed that their shape is not the same because the stamps are handcrafted too: they have been made by the technicians on a plaster board, hence the difference in the two shapes is representative of the variability of the current process.
This first set of images compares this positive and a 3D scan with the *IDS ENSENSO N35-606-16-BL* in greyscale texture. This test is the starting point to validate the idea of an algorithm capable of seeing the DMDGs tampons. Despite this 3D scanner doesn't have a color texture, this simulation proves how the contrast of the colored ink on the white plaster can be visible with some exposure adjustments. In Figure 4.5, it's possible to see that the positive was not exactly positioned below the scanning point, but the result is already very accurate: with a single scan all the details of the upper part are clearly visible.

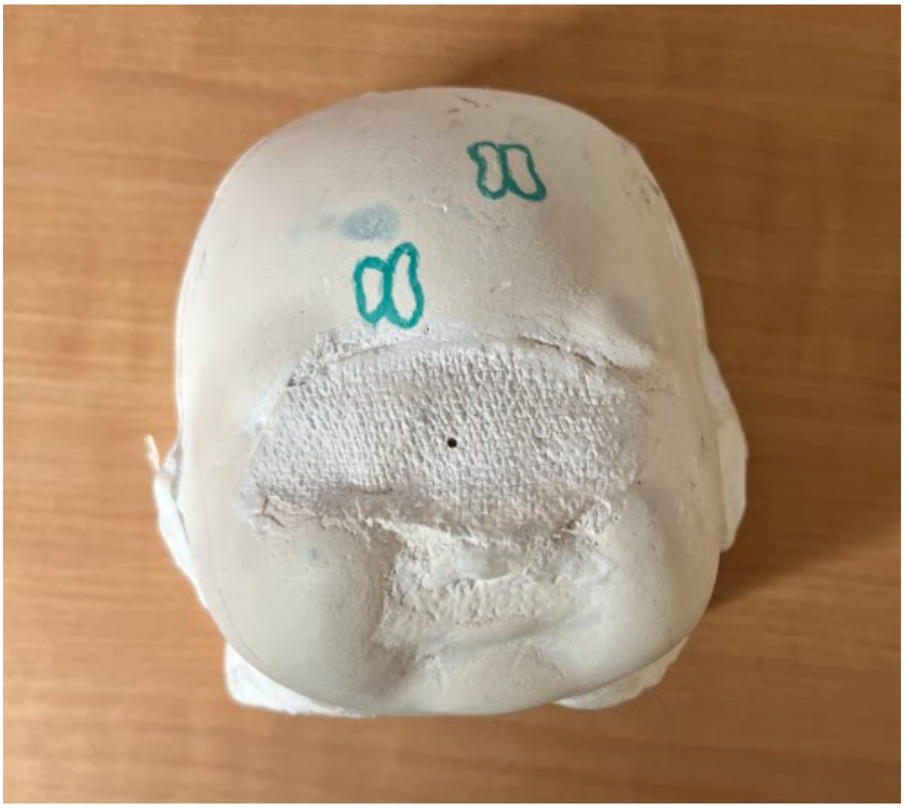

Figure 4.4: *Plaster positive of a newborn's face with stamped DMDGs[4].*

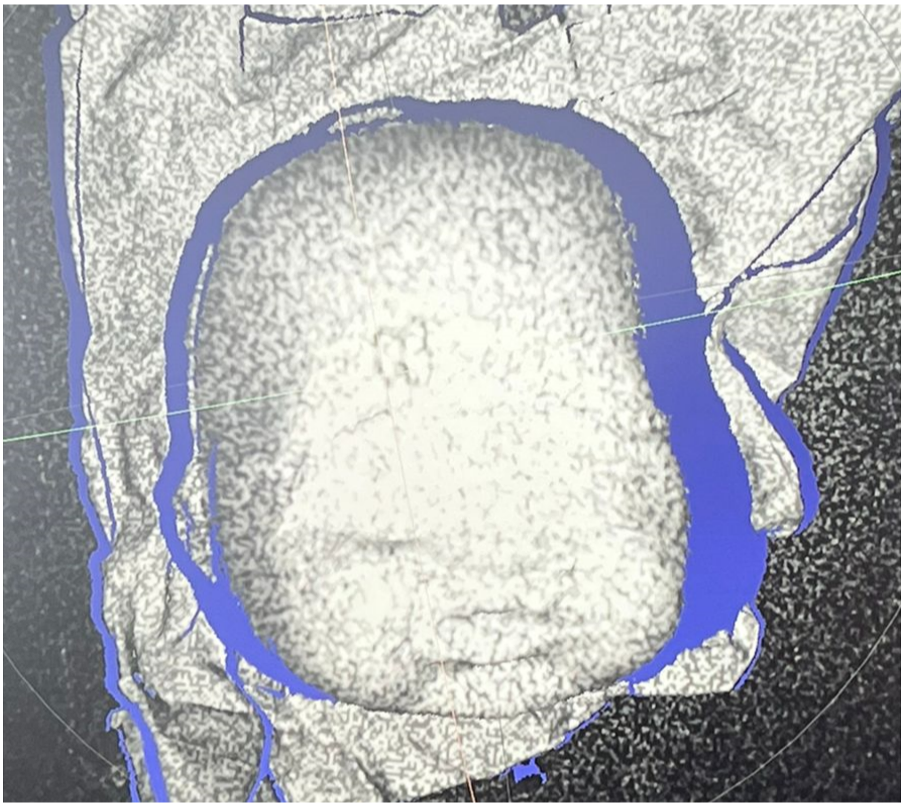

Figure 4.5: *IDS ENSENSO N35-606-16-BL single scan with greyscale texture[8].*

4.1.2 Multiple scans with *INNODURA TB*'s algorithm

To perform multiple scans and mesh the results on the same frame of reference, *INNODURA TB's INNOPICK* base algorithm has been used. As mentioned at the beginning of this chapter, this system relies on the vision or randomly arranged objects with a wide range of dimensions. While the picking task previously exposed can rely on a single scan image, some more complex or simply bigger systems may need the scanner to create a full 3D image on all sides. For this reason, *INNODURA TB* developed some scanning paths depending on the shape of the system. Be it a longitudinal arch around the object or any other trajectory, the user is allows to choose the number of scans to perform along it. The algorithm will autonomously divide the trajectory into equal parts and deduce the six degrees of freedom position of the 3D scanner. From this data, all the scans are meshed to result in a more detailed image.

For what concerns the simulations that follow, the proposed scanning configuration among the ones available at *INNODURA TB* on the demo of the *INNOPICK* system is the following. It is peculiarly divided into two parts as follows:

- single scan from the top, the scanner lenses are oriented downwards, perpendicularly towards the center of the robot frame of reference;
- multiple scans around the object, the scanner describes a circular trajectory around the first scan position and keeps the lenses directed towards the center of the robot frame of reference.

This particular configuration can be the most suitable for the *ROMANS FERRARI* Medical Center needs. It should be considered that most of the burns are located in a limited part of the body or on a certain side of a limb or body part. This means that most of the times the surface to be machine may be oriented facing upwards, with some details on the sides. For this reason, given the dimension of the field of view of the *Zivid Two* 3D scanner, such a trajectory might be the most useful. The operator can choose the vertical coordinate of the first scan and the radius of the circumference. This is mainly meant to keep a reasonable distance from the component. In fact, as Once the algorithm will be fully implemented, it will be in any case possible to add new trajectories and instructions to differentiate the scanning processes.

This set of 3D scans to be compared is composed by images obtained respectively with one, five, ten and twenty scans. Each scan sequence has been performed on the same positive and the same frame of reference with a mesh size of 0,5 mm.

Since the level of accuracy of the *Zivid Two* will ensure a top view of high quality with a single scan too, the comparison is presented between two different point of view: sagittal plane and perspective view. The former allows to see how the increasing number of scans progressively allows to define all the convex surfaces, while the tiniest concave parts (e.g. the back of the ear lobe) are only highlighted with 20 scans, as can be seen in Figure 4.12 and in Figure 4.13. At the same time, the higher the number of scans, the higher the possibility of spurious points. In fact, in the same Figure 4.12 and in Figure 4.13 it is clearly visible that in the surroundings of the positive there are some defects, mostly due to the huge amount of data acquired.

It can be noticed how between five and ten scans there only are minor changes in the sagittal view quality, see Figure 4.8 and Figure 4.10. In an analogue way, twenty scans don't add many data to the unknown zones, see Figure 4.12. It can be concluded that the most relevant quality gap is between one single scan and five scans. Looking at the perspective view, the gap in the quality of the surroundings of the center of the frame of reference catches the eye. Putting these observations in terms of practical use, it can be stated that a single scan as in Figure 4.7 would be suitable for small areas oriented upwards, such as the forehead of this positive sample. When it comes to more complex shapes and orientations, five scans as in Figure 4.9 will be more suitable. This is the best compromise between the poor data of a single scan and the huge amount of data of ten and twenty scans.

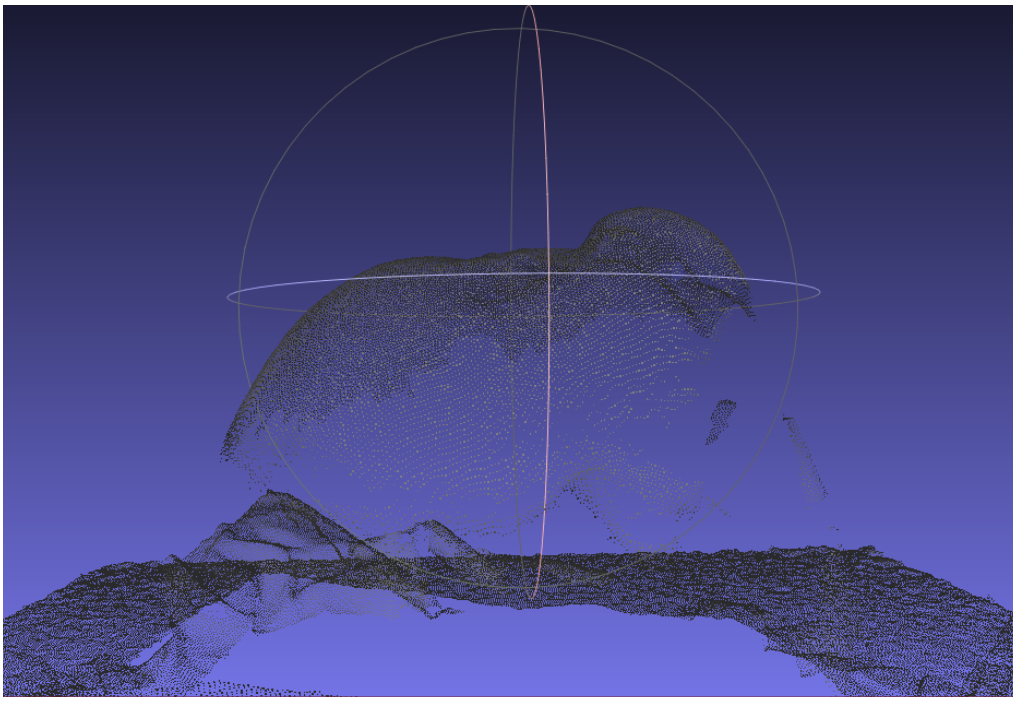

Figure 4.6: *IDS ENSENSO N35-606-16-BL point cloud with 1 scan[8]. - Sagittal view*

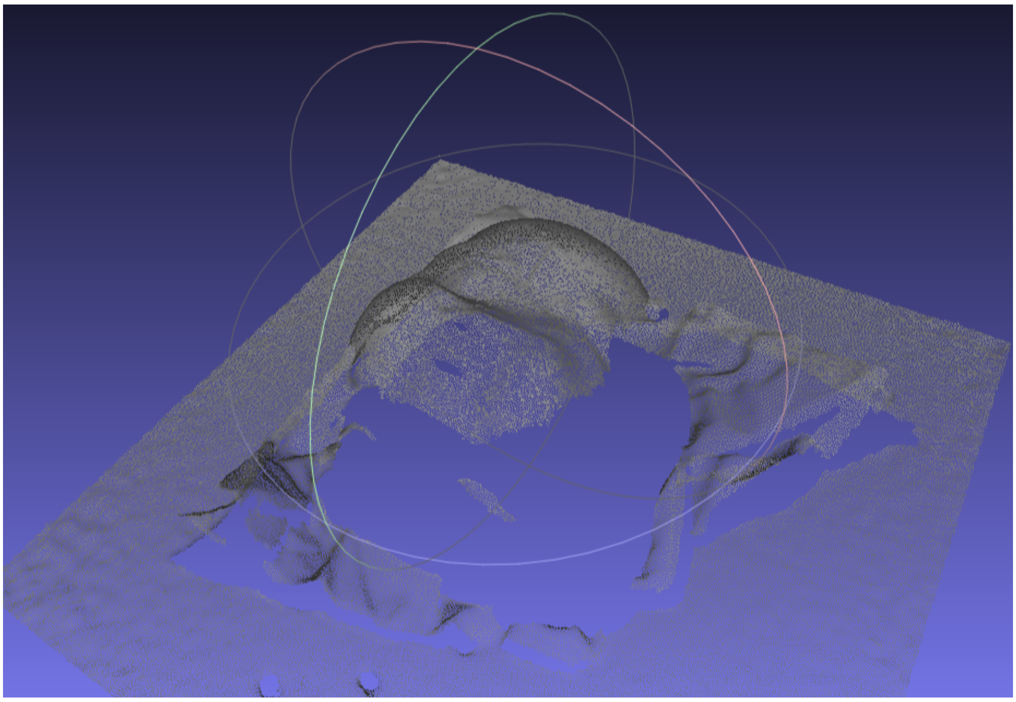

Figure 4.7: *IDS ENSENSO N35-606-16-BL point cloud with 1 scan[8]. - Perspective view*

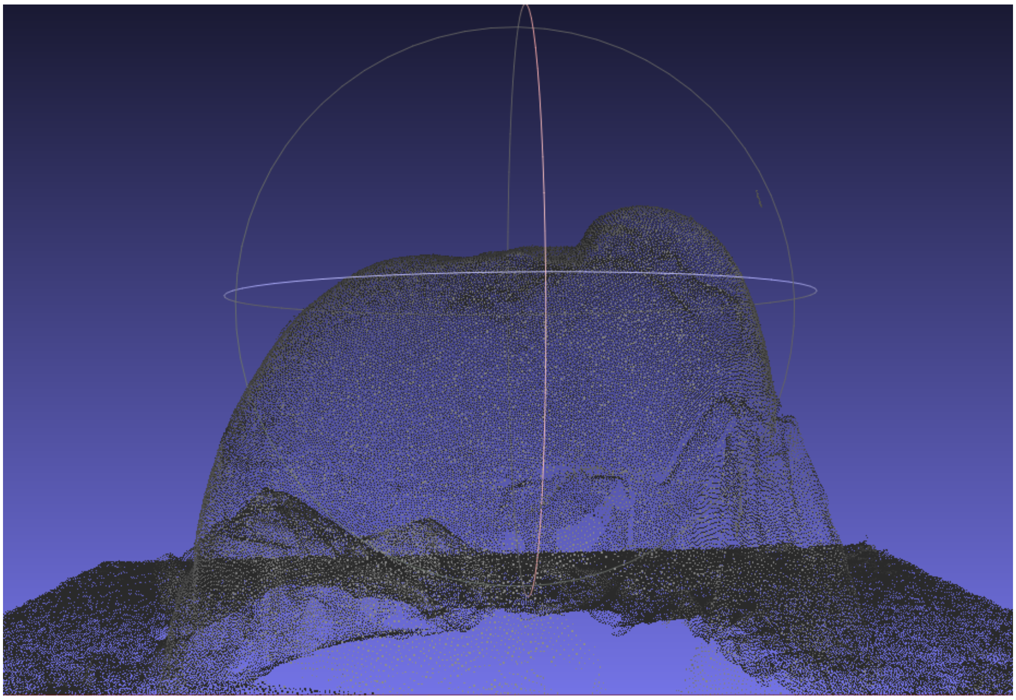

Figure 4.8: *IDS ENSENSO N35-606-16-BL point cloud with 5 scans[8]. - Sagittal view*

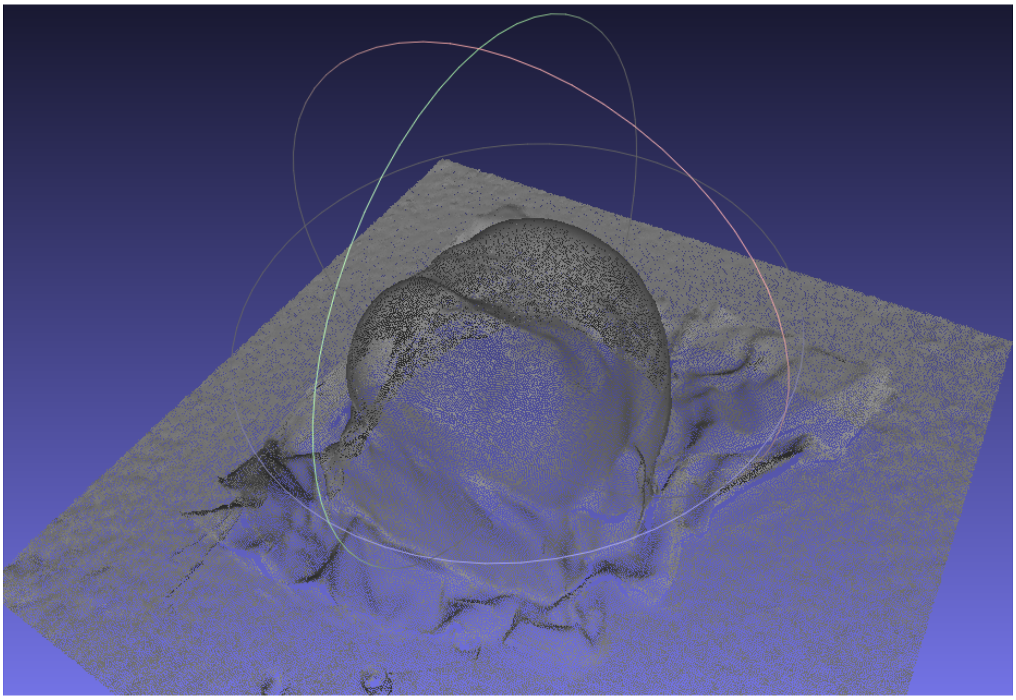

Figure 4.9: *IDS ENSENSO N35-606-16-BL point cloud with 5 scans[8]. - Perspective view*

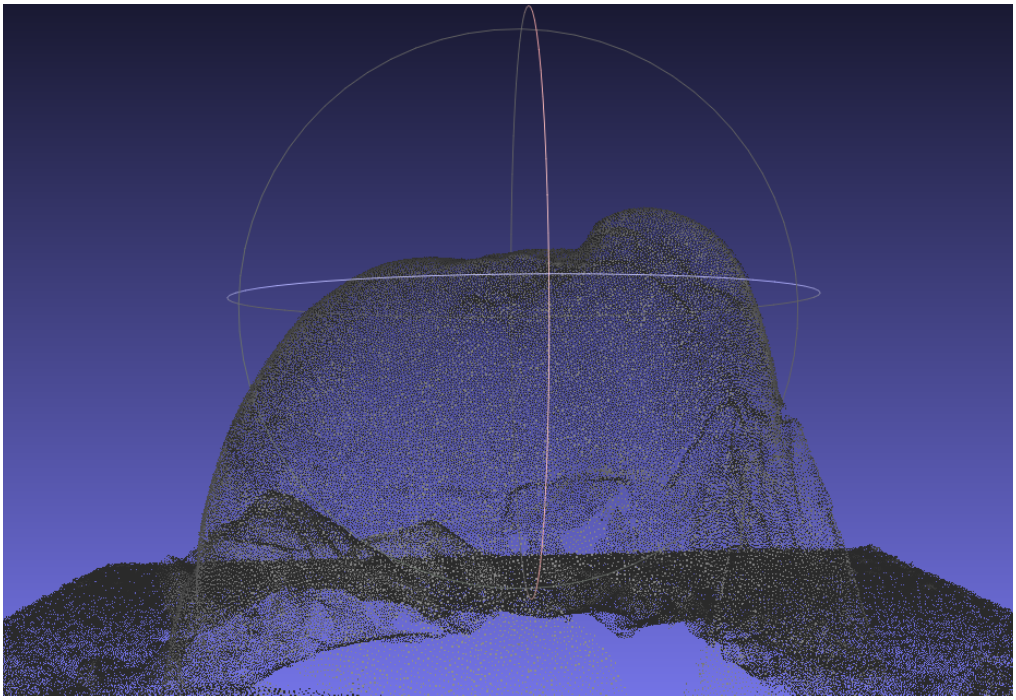

Figure 4.10: *IDS ENSENSO N35-606-16-BL point cloud with 10 scans[8]. - Sagittal view*

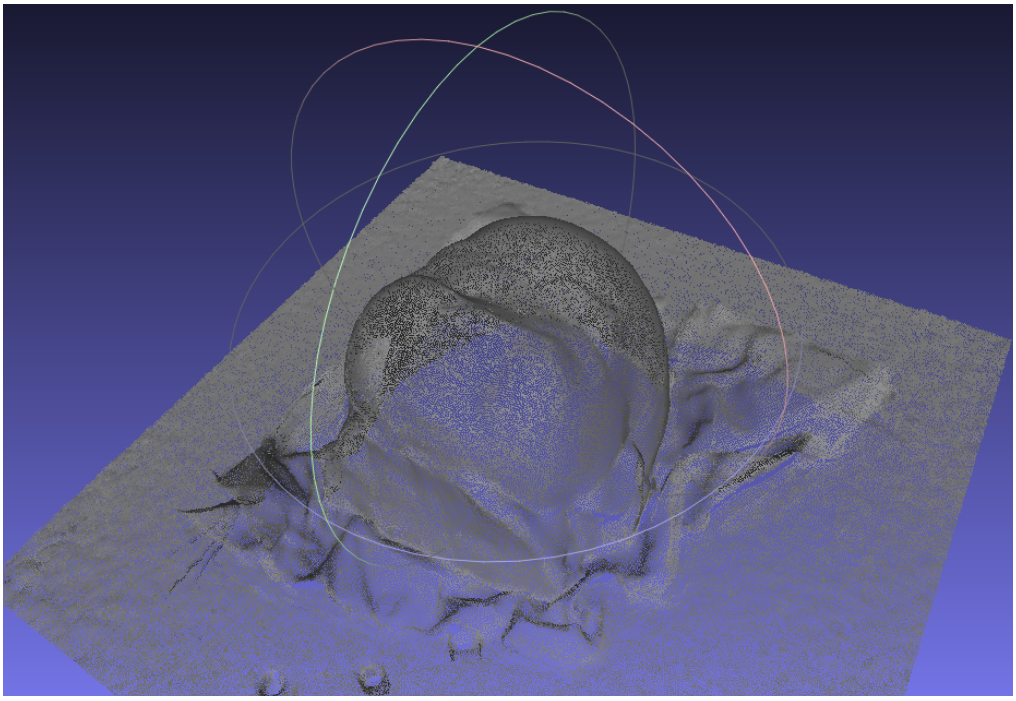

Figure 4.11: *IDS ENSENSO N35-606-16-BL point cloud with 10 scans[8]. - Perspective view*

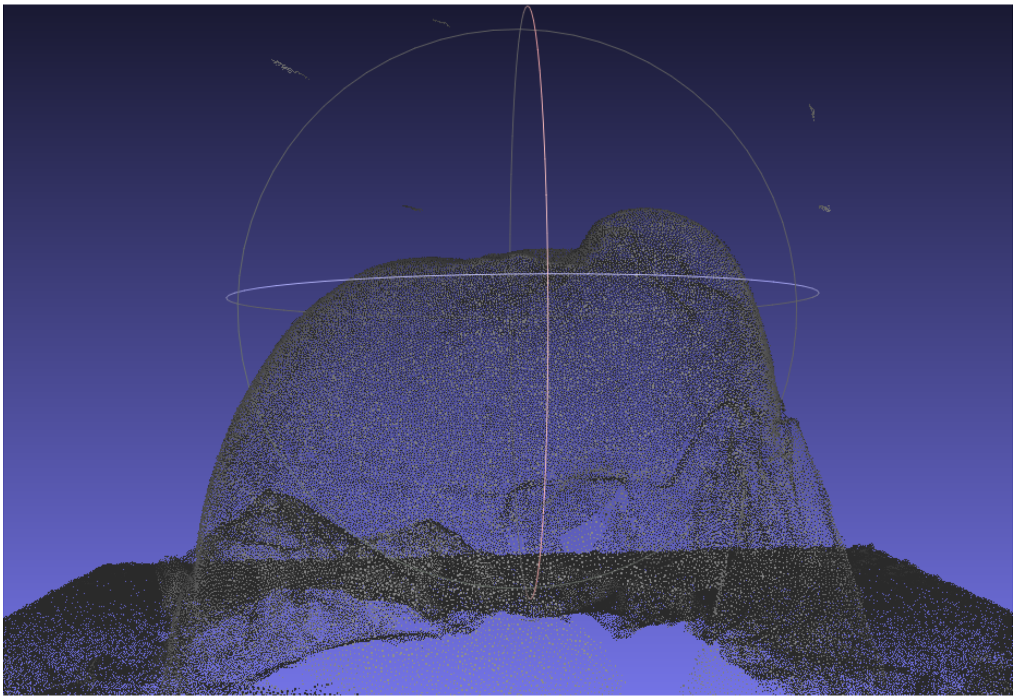

Figure 4.12: *IDS ENSENSO N35-606-16-BL point cloud with 20 scans[8]. - Sagittal view*

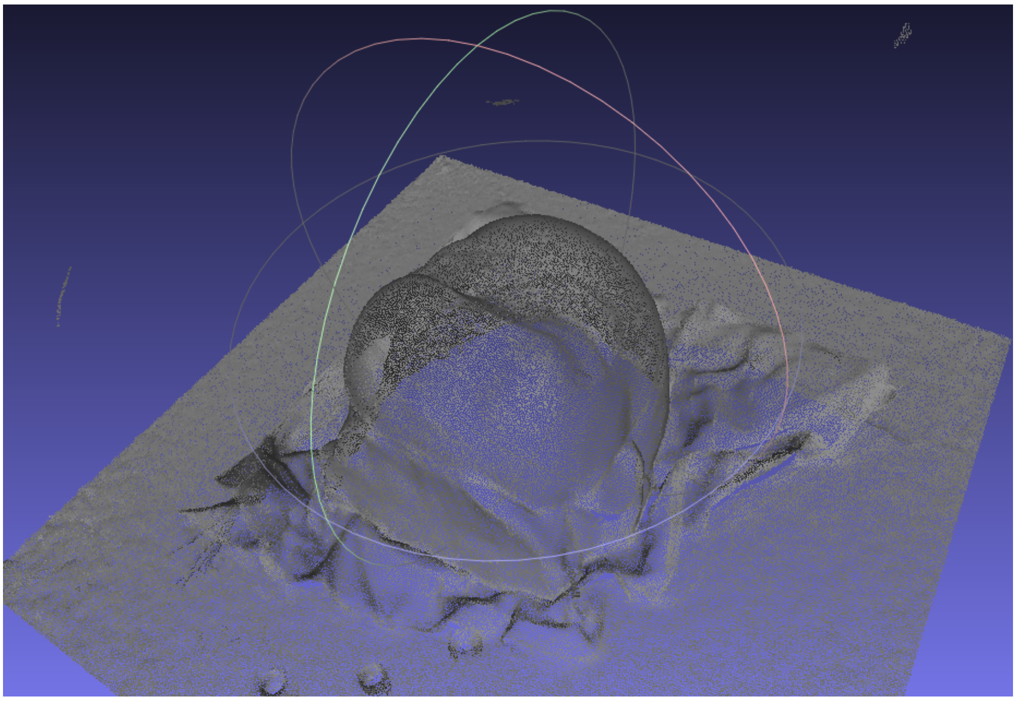

Figure 4.13: *IDS ENSENSO N35-606-16-BL point cloud with 20 scans[8]. - Perspective view*

4.1.3 Mesh size

This last series of scans with the *IDS ENSENSO N35-606-16-BL* is performed with a specific focus on the mesh size. The output of this whole project will need to be accompanied by the instructions and training of the technicians. The tests on the scanning system are a key point in the conception of the guidance on the process. The mesh size is a parameter that's easily modifiable from the software suite, however the goal is to choose a reasonable value to assign as a guideline. For this reason two different images obtained with different mesh sizes are compared, so as to be sure that a certain size can be in general acceptable and provide a suitable level of accuracy while keeping the file size limited.
The mesh emerging from the cloud points with vertices that coincide with the refinement points of the cloud[25]. The mesh size is defined here as the maximal distance between two adjacent points, without considering the shaded areas where no data is available. Depending on this parameter the file dimension changes: the smaller the mesh size, the bigger the amount of data stored in the file and the longer it takes to create the output. Concerning the time parameter, the difference is in the order of magnitude of tens of seconds, hence almost insignificant.

The *ROMANS FERRARI* Medical Center keeps an archive of all the positives used to create orthoses that are currently used by patients. Every two to three months, during the healing process, each patient changes its orthosis and DMDGs dispositives to adjust the compression levels and follow the scar's development. The last positive is kept in the laboratory up to this moment to keep a trace of the evolution of the clinical situation as well as the efficiency of the treatment. For this reason, a digital storage will be needed for the digitalized positives, hence the file size becomes a relevant parameter. The final goal of this simulation is to choose a mesh size with an adequate level of precision: high enough to allow a true representation of the body part, but still scaled to the modest level of accuracy of the rest of the cure process. It will always be possible to refine the mesh once the protocol requires higher precision.

All the following images are captured with ten scans each. From the top views Figure 4.14 and Figure 4.16 it can be observed how the mesh is well distributed in the main section to be machined, ideally always oriented upwards. The perspective views highlight the main volumes of the positive. While the sides have more shaded areas, the jaw and the cheeks appear very clearly defined in both Figure 4.15 and Figure 4.17. For the purpose of this project, the degree of refinement of 0,5 mm is sufficient to satisfy the needs of the technicians in terms of accuracy. The only concern is the quality of the *.stl* file fed the 3D printer: the shaded areas can be covered with interpolation surfaces causing some slight inaccuracies with respect to the face shape. This can be easily corrected by heating and adjusting the mask, as is currently done for the fitting adjustments of the masks.

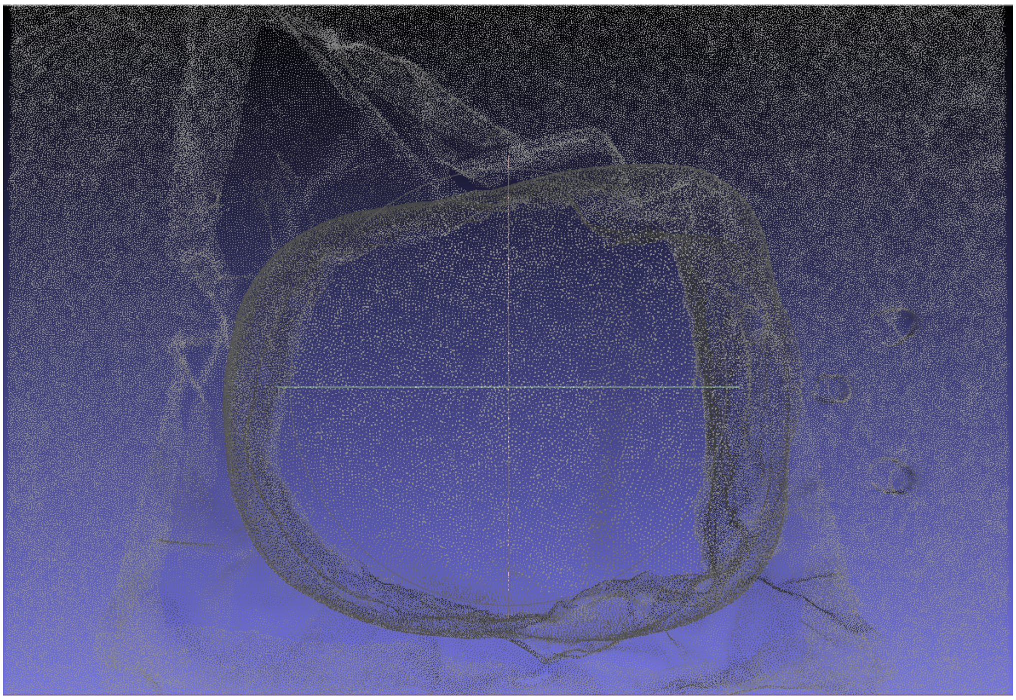

Figure 4.14: *IDS ENSENSO N35-606-16-BL top view of a scan with mesh size of 0,5 mm[8].*

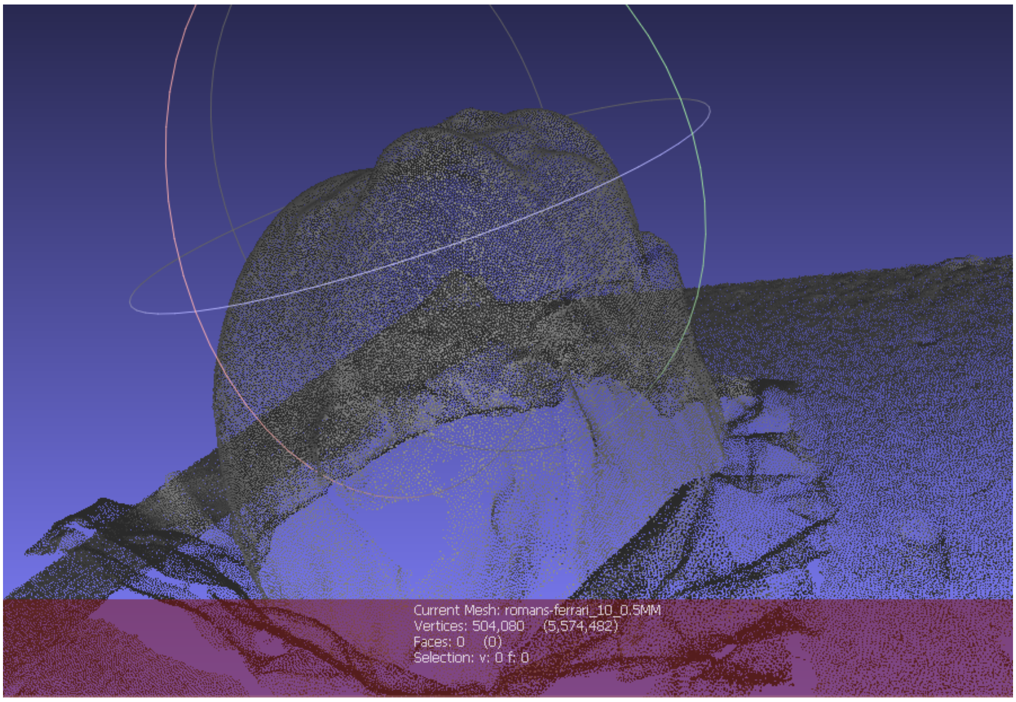

Figure 4.15: *IDS ENSENSO N35-606-16-BL perspective view of a scan with mesh size of 0,5 mm[8].*

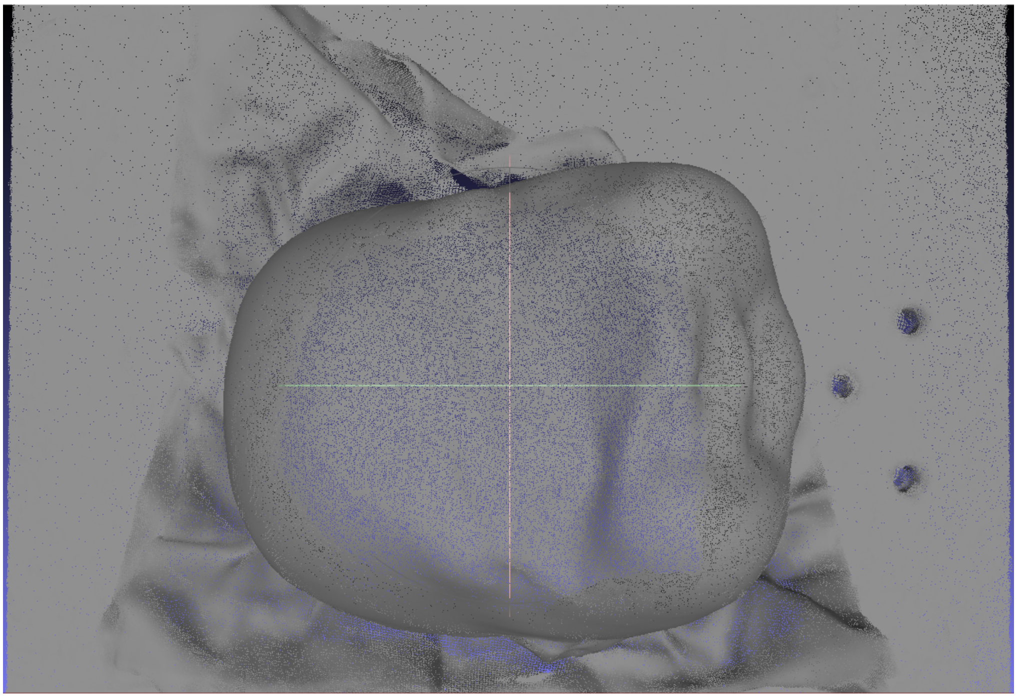

Figure 4.16: *IDS ENSENSO N35-606-16-BL top view of a scan with mesh size of 0,1 mm*[8].

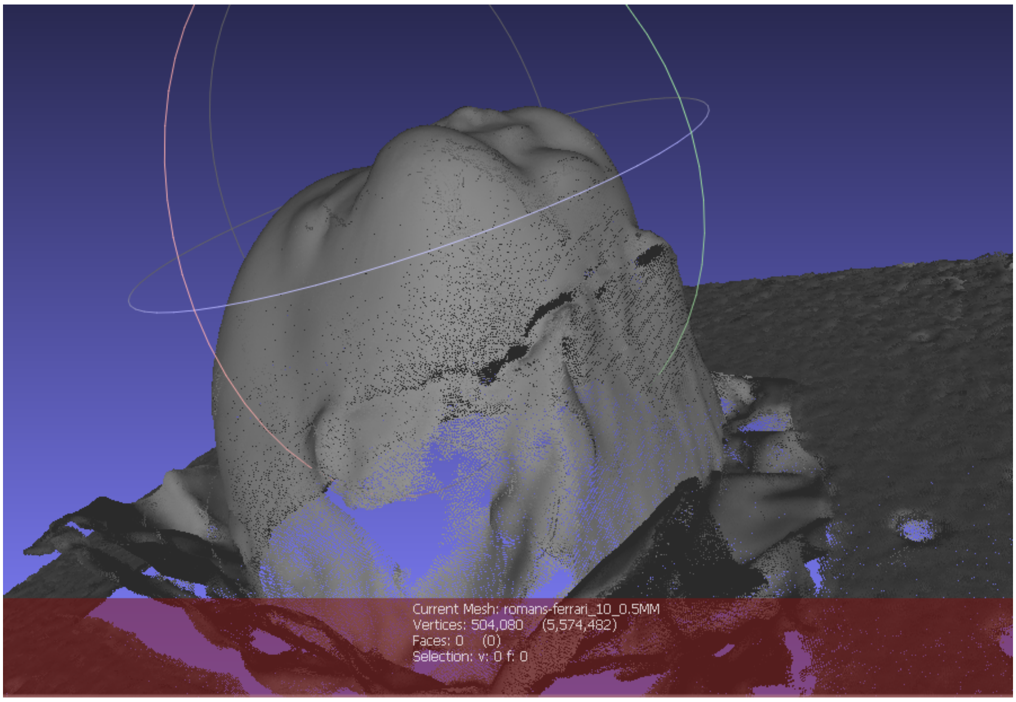

Figure 4.17: *IDS ENSENSO N35-606-16-BL perspective view of a scan with mesh size of 0,1 mm*[8].

4.2 Simulations with *Zivid Two*

It should be noticed how these tests have been performed at *INNODURA TB* during the last days of development of this project. The choice has been made while *INNODURA TB* decided to buy a *Zivid Two* for some further development of their projects. Thanks to their availability, as soon as the 3D scanner was delivered it has been possible to test its performances directly on site. The aim was to effectively provide the customer with some realistic content: the images that follow are of the exact same kind of those that will be produced by the system once it will be implemented. The content of this subsection must be ideally merged to what has been presented above in this chapter: the simulations with the *IDS ENSENSO N35-606-16-BL* have been made many weeks before the delivery of the *Zivid Two* and allow to picture the real machine motion of the robot and the technology that allows images merging, as well as some parameters setting. This 3D scanner is equipped with a dual camera for a structured point cloud view: 3D perception (x,y,z coordinates), *RGB* colour and *SNR* for each pixel. The data from this scanner is a *.stl* file and an associated *.jpg* image. As the scanner is not yet mounted on the robotic arm at *INNODURA TB*, the simulations are done with a single scan.

Figure 4.18: *Zivid Two 3D scanner installed at INNODURA TB*[8].

4.2.1 Single scan comparison with *IDS ENSENSO N35-606-16-BL*

This first test links the available system for the tests and the real choice of the 3D scanner. It puts into a realistic perspective the results presented at the Section 4.1: they show the available technology that might be adapted to this system, rather than the expected results. This reflects the steps of the project development too. At first the only available 3D vision technologies in the surroundings of *INSA Lyon* and the *ROMANS FERRARI* Medical Center were the following: the *Artec Eva* scanner and a *Faro* hand 3D scanner. Both of them work with an operator moving them, while the goal was to foresee a real integration with a robotic system. For this reason, *INNODURA TB*'s *INNOPICK* available demo was very effective. The *Zivid Two* 3D scanner was delivered to *INNODURA TB* only in the last weeks of this project, hence no installation on the demo has been possible in such a short time span.

The following images constitute the last part of the project, hence this simple section allows to imagine the union of the previously proposed technology and the image quality of the chosen 3D scanner.

The Figure 4.19 represents the sagittal view of a single *IDS ENSENSO N35-606-16-BL* scan performed with the system represented in Figure 4.3. The image has been captured from the downwards scanning position while the scanner was mounted on the robotic arm (see Figure 4.3). It can be noticed how the orientation of the positive makes the chin part more shadowed than the forehead. This defect is due to the simple positioning platform. In any case, it is not unrealistic to foresee the recurrent presence of this sort of defects. To comply with the user-friendliness imposed by the customer, the simple but correct positioning of the positives is a relevant aspect. There are no foreseen solutions for the working plate, which might be tilting or not. Considering the worst case scenario, it can be assumed that the plaster positives have sides to be scanned and machined that cannot be upward facing. One example would be a burn on the forehead that involves also one ear of the positive used in these tests. In this case, which is not unrealistic, the capacity of each single scan can make a slight change in the amount of data needed.

The Figure 4.20 instead has been captured in a single scan from the fixed position of the 3D scanner as in Figure 4.18. To make the two images comparable, the distance between the positive and the scanner has been kept in both cases as close as possible to the recommended focus distance in the two data-sheets. It should be noticed that in the second case the positioning of the positive has been slightly more accurate, in fact more details of th chin appear. The difference in terms of performance is visible in the ear and side of the positive: the *Zivid Two* has an excellent peripheral vision. The point cloud in Figure 4.20 has very little data on the surroundings of the scanning area, but is sensibly more developed on the sides.

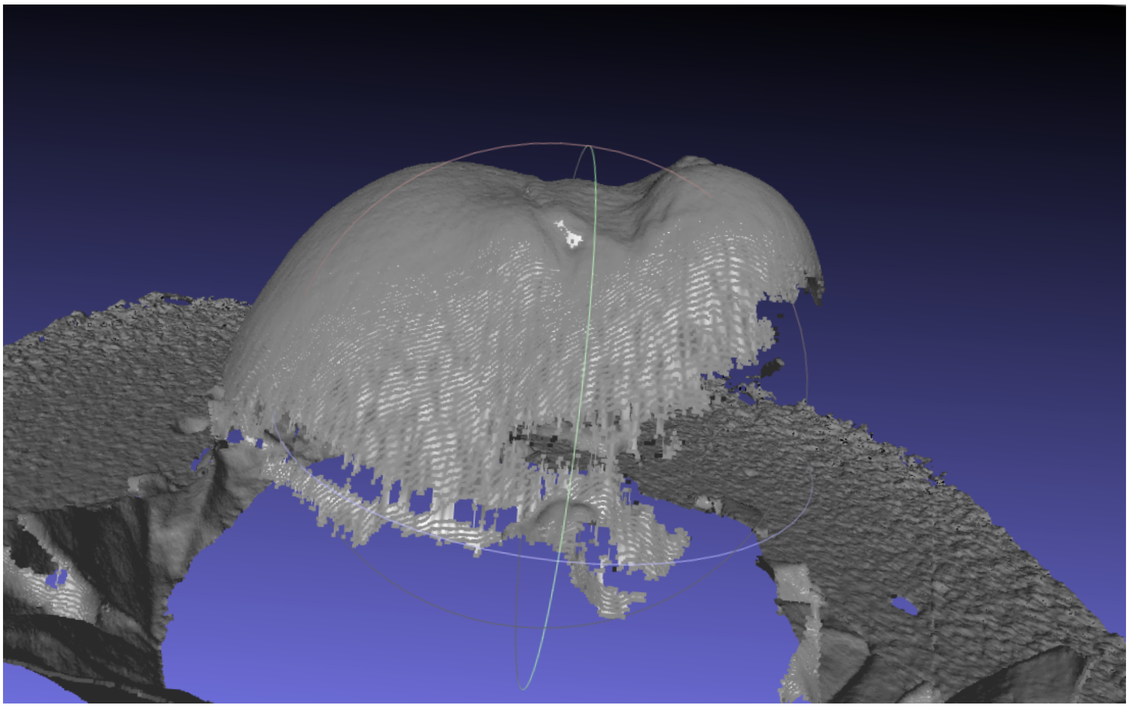

Figure 4.19: *ENSENSO N35-606-16-BL single scan[8].*

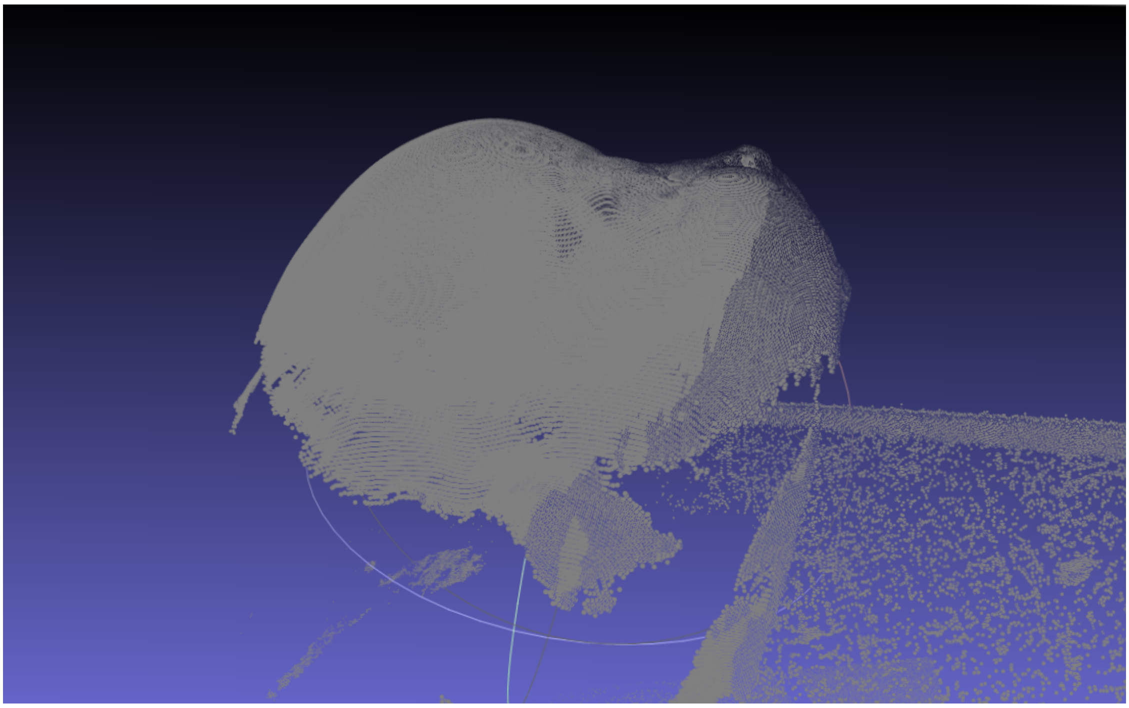

Figure 4.20: *Zivid Two single scan[8].*

4.2.2 Color texture

This very simple test allows to validate the choice of a color texture 3D scanner. As anticipated in the Section 3.5.2, the color texture will be a key point of the future algorithm. The capability of identifying the ink of the tampons on the plaster positives, as seen in the Section 4.1.1, might as well be performed with a greyscale image. What really makes a difference is the possibility to develop the colored scansion so as to identify the grooves made by additive manufacturing too.

The main goal of this test is to empirically verify whether the quality of a colored scan is suitable for the algorithm and production purposes or not. This generally means to simply verify that details on the 3D vision are rightly represented in the image, since this is not a given datum from the supplier. To appreciate the right superposition of the point cloud and the color texture, a reference is needed. In particular, the positive used for the test presents a small defect (see also Figure 4.5) due to a bubble left in the plaster. In the Figure 4.21, the hole is clearly visible on the lower right edge of the central area, which is partly shadowed. In the Figure 4.22, thanks to the *Meshlab* possibility to choose which layers to show, it appears perfectly superposed in the colored image. This empirical observation simply suggests that the accuracy of the superposition of the two textures is sufficient for the degree of precision required by the whole process and that there's no need for precautions in the scanning phase.

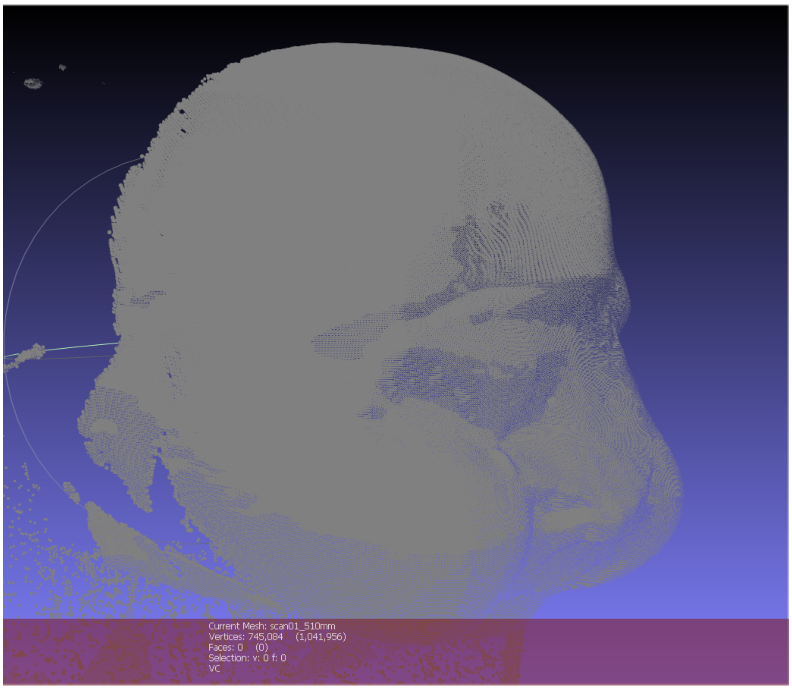

Figure 4.21: *Zivid Two scan without colour texture*[8].

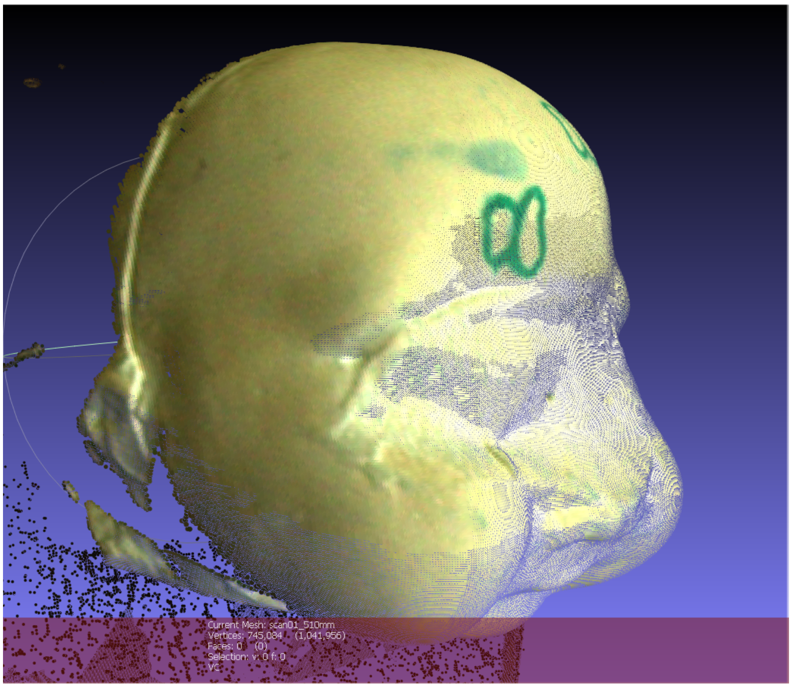

Figure 4.22: *Zivid Two scan with colour texture[8].*

4.2.3 Importance of focal length

The proposed solution involves a scanning process completely analogous to the one presented at the Section 4.1.2. The most user-friendly solution is the conception of standard scanning trajectories that change in the geometry but not in their dimensions. Although the geometrical parameters would be easily customizable from the software interface, at this stage the aim is still to find the most universal solutions possible with the minimal training and experience required.

This system will hence scan a great variety of pieces: they have unpredictable shapes and a wide range of dimensions. The direct consequence is that the focusing distance will very rarely be matched by the distance between the surface and the 3D scanner. For this reason, this last simulation is aimed at demonstrating that a scanning distance greater than the ideal one is still acceptable. This test validates the choice of standard scanning trajectories provided that the scanning distance is equal or greater than the ideal focusing distance.

In the Figure 4.23 the ideal focusing distance is set between the 3D scanner and the piece. The image is slightly overexposed but of high overall quality. In the Figure 4.24 instead, the previous distance is augmented almost by 40%. It can be seen how the output is still perfectly clear. The DMDGs are slightly less sharp than in the previous case, but it's still possible to detect and isolate them.

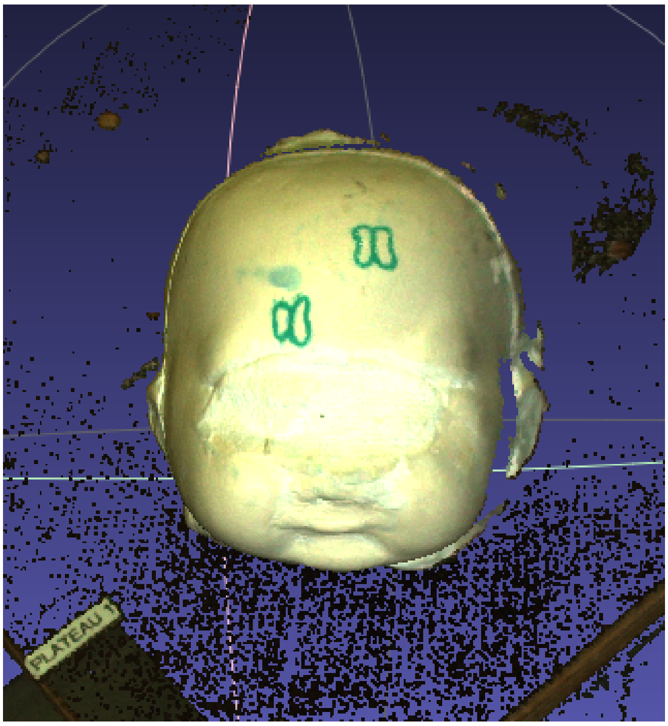

Figure 4.23: *Zivid Two scan at a distance of 510 mm[8].*

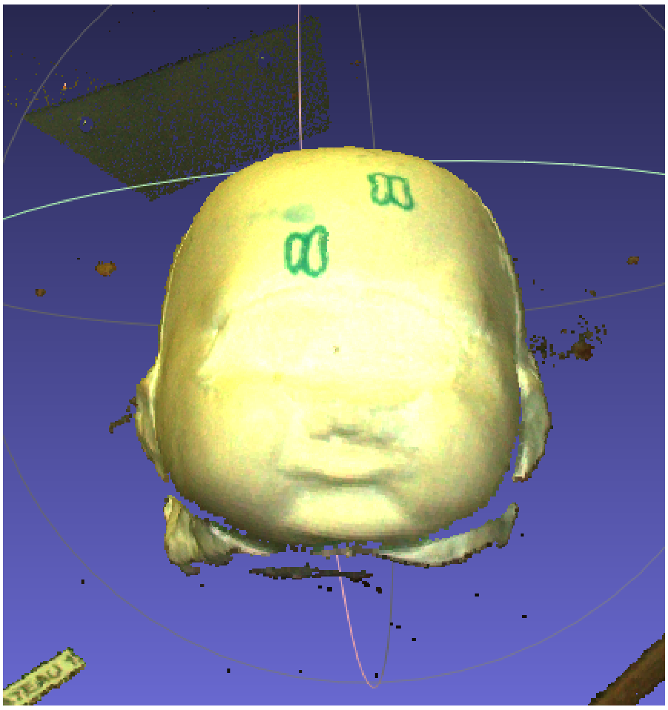

Figure 4.24: *Zivid Two scan at a distance of 730 mm[8].*

4.2.4 Tests outcome

These sets of simulations have been presented to the technicians and board of the *ROMANS FERRARI* Medical Center at the end of the project.

The greyscale test (Section 4.1.1) and the colour texture test (Section 4.2.2) show how the idea of a system capable of identifying colour and coloured shapes in contrast is feasible. The best solution with this feature is surely the *Zivid Two*, as also observed in Section 4.2.1.

Thanks to M. Maxime Robin and M. Quentin Delagrange, engineer working on the *INNOPICK* project, the existing system of multiple scans on standard trajectories tested in Section 4.1.2 appears to be suitable for the needs of the *ROMANS FERRARI* Medical Center in terms of variety of treatable shapes.

For what concerns the variable dimensions of the positives, the focusing distance tests at Section 4.2.3 ensure that no adjustment should be needed to the geometrical parameters of the trajectories, no matter the positive's dimension. This test, along with the mesh size (see Section 4.1.3), allows the developer to set standard parameters that will make the system extremely user-friendly.

In conclusion, these tests allow to deduce some standard parameters as a base set for the system start-up and validate the choice of the *Zivid Two* 3D scanner.

Chapter 5

Mechanical interface design

Considering that the robotic system will not be used in an industrial environment, the user-friendliness is a key aspect to consider. The two main functions of the system are plaster milling and silicone casting. To do so, the 5-axes robotic arm needs a tool path. There are two possible ways to produce it:

- in case of 3D printed positives, the tool path can be extracted from the digital editing software. As mentioned in the Section 1.4, in the AMI the software is already equipped with a library of standard shapes of the DMDGs. Hence it can be possible to develop a standard tool path for each of them to be oriented according to the surface. With this sort of elaboration, 3D printed pieces would come with a tool path file to be fed to the robotic system;
- for plaster positives and plaster boards, the foreseen algorithm described in Section 3.5.2 involves the usage of the *Zivid Two* 3D scanner. This type of positives are the wide majority, hence the whole algorithm has been developed specifically to use the contrast of with plaster and the ink of tampons, creating a custom tool path for every component depending on the 3D coloured image. It must be noticed that this system could also be adapted to the previous case of 3D printed positives, so that instead of extracting a tool path from the *FreeForm* editing, the same concept of vision of the DMDGs shapes can be applied.

The relative relevance of the use of plaster positives with respect to the 3D printed ones and the possible future development of the system of vision to identify the DMDGs shapes in the 3D printed grooves are the main reasons for the choice of a fixed 3D scanner. While this is a drawback in terms of load of the robotic arm, it allows to skip the step of setting the coordinates of the positive in the fixed frame of reference of the robot. More precisely, being the scanner mounted on arm, the software suite is

capable of deducing the position of every point of the point cloud from the position of the five axes and the data extrapolated from the scanner. Since all dimensions are known, every scanned element is automatically fixed in the frame of reference. So, as in *INNODURA TB*'s *INNOPICK* system, the *Zivid two* scanner will always be mounted on-arm, leaving an attachment point for the valve or the micro-end mill.
The easy mount and dismount of these two tools is hence a relevant issue, considering also the absence of a production programming or work optimization. The main criteria for the design of this simple component are then:

- easy mount/dismount of the tool;
- sufficient heat exchange in the milling and scanning operations;
- 3D scanner's field of view clear of tools and wiring.

5.1 Attachment points

In this section the two attachment points that must be linked together are presented. Starting from the attachment point of the robotic arm, it should be noticed that the *Stäubli TX2-60L* is equipped with a flange *EN ISO 9409-1-31.5-4-M6*[15], represented in the Figure 5.1.

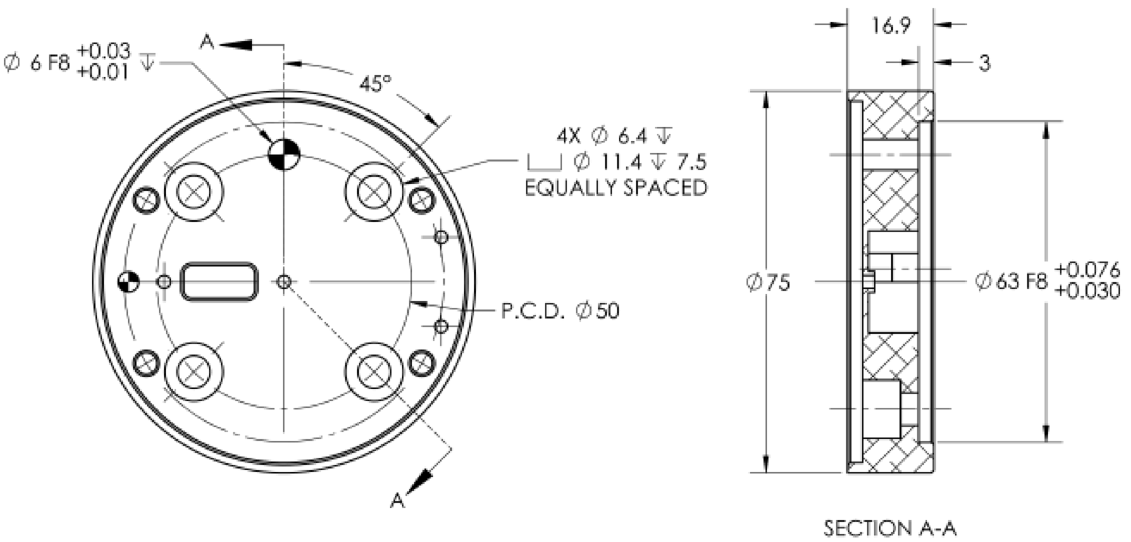

Figure 5.1: EN ISO 9409-1-31.5-4-M6 attach flange[16].

The *Zivid two* scanner holder matches this flange and replicates the same attachment point, again compliant with the norm EN ISO 9409-1-31.5-4-M6 (Figure 5.1). This type of attachment point is widely used by many robotic arms producers. The fact that the *Zivid Two* 3D scanner support replicates it and is attached with a thin flange that occupies a very narrow space indicates how it has been designed to be always mounted on arm. The design of the support seen in Figure 5.2 is optimized to keep the bending load as low as possible and be suitable for the vast majority of tools that are meant to match the EN ISO 9409-1-31.5-4-M6 support.

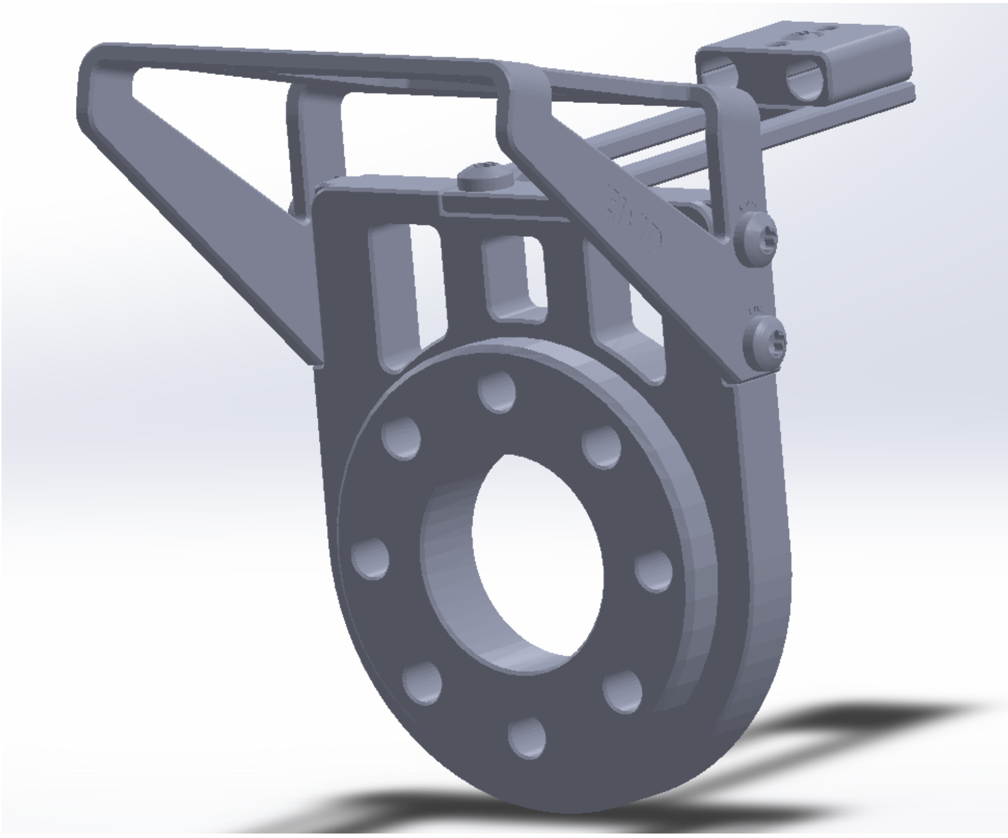

Figure 5.2: *Zivid Two scanner mount*[30].

The micro end mill instead is equipped with a finned tool holder. It has a very simple fixing system: its attachment point is composed by two planar rectangular surfaces located on the back side of the support and fixed with two M5 screws, see Figure 5.3.

Its shape is meant to facilitate the heat exchange in air. The micro-end mill in fact is an extremely compact tool that might heat up during the longest operation times. This might not only bring it to temperatures that aren't suitable for operation, but dissipation becomes extremely relevant when considering the application context. The tool should be changed very frequently between operational phases with a minimal waiting time.

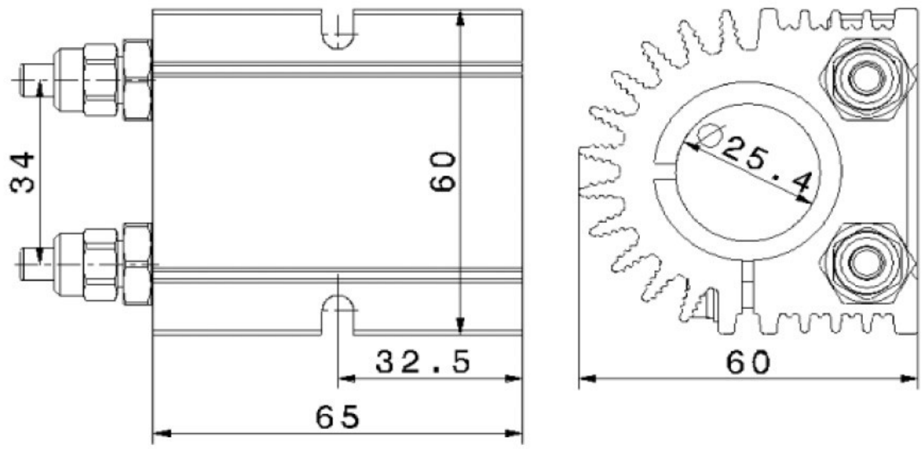

Figure 5.3: *Sycotec standard support for micro-end mills*[10].

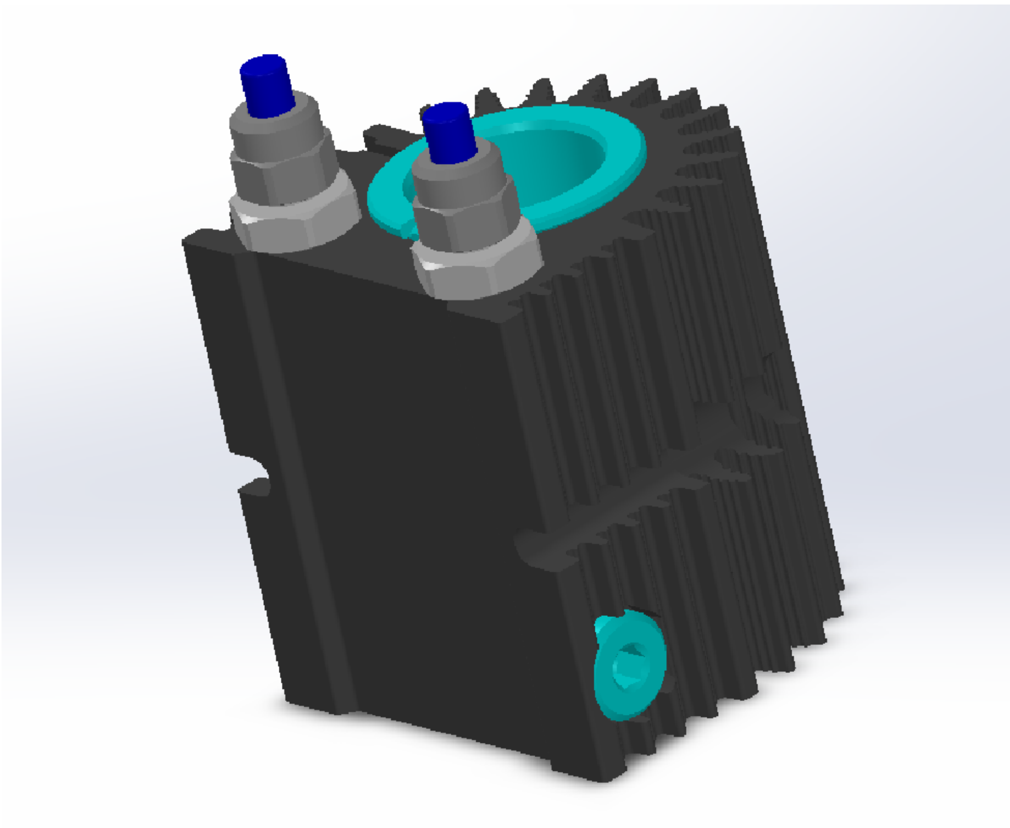

Figure 5.4: *Precise France 4015 DC micro end mill mount*[10].

5.2 Designed interface

A commercial solution put forward by M. Remi Bittel (Precise France) is a plate with two sets of holes: one set to accommodate the screw heads fixing the scanner mount to the robotic arm, one threaded set to tighten the mill support. The main drawbacks of this solution regard the milling operation, first of all the difficulty in the heat dissipation on the connection side of the mill support. In addition to this, despite the body of the micro end mill is small, it presents the drill on one side and the power supply attachment on the other side of it. This means that in any case the dimension of the body is augmented and could interfere with the field of vision of the scanner, be it with the mill or with the wiring. Moreover, since the system is conceived for the most continuous use possible, the proximity of the scanner lenses to the milling point might make cleaning necessary at the end of every procedure. For the purpose of this project, a slightly more complex interface has been designed, here reported in the Figure 5.5 and Figure 5.6.

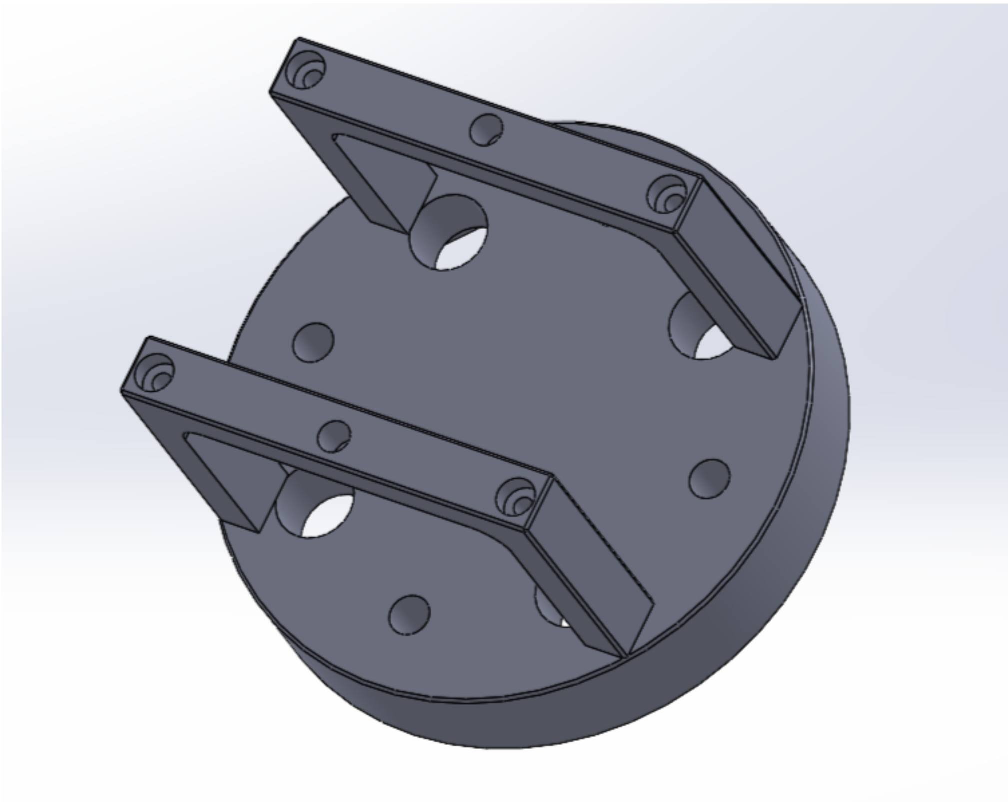

Figure 5.5: *Designed interface. - Precise France 4015 DC micro end mill side*

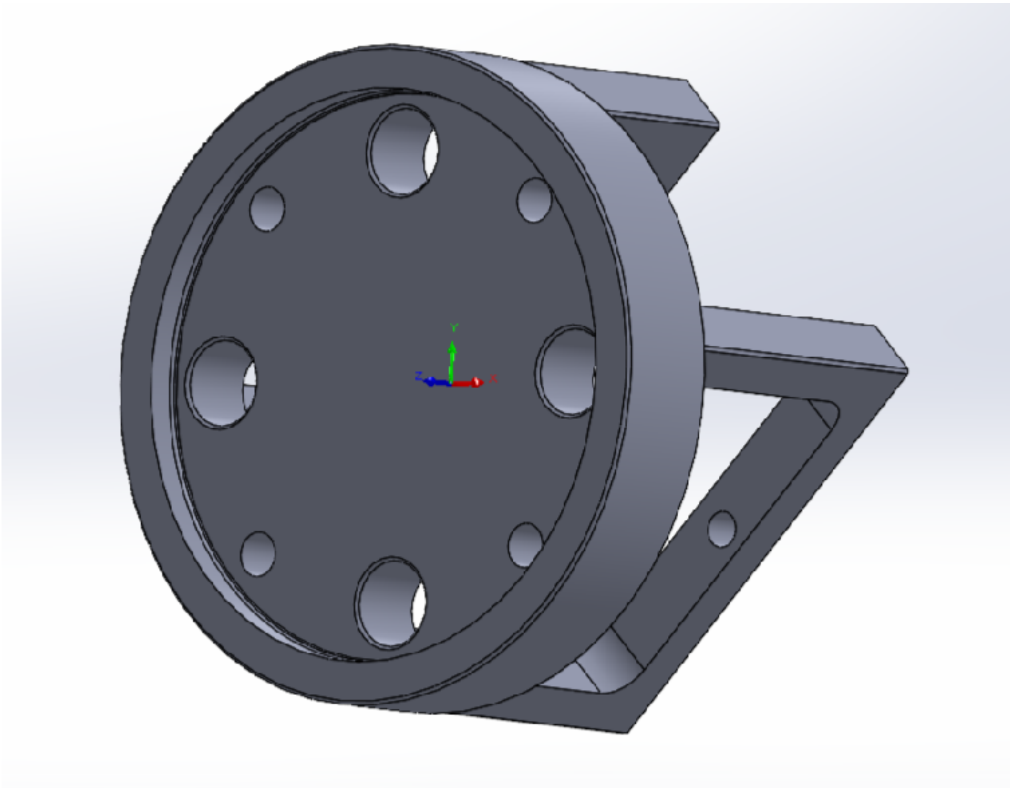

Figure 5.6: *Designed interface. - Zivid two 3D scanner side*

Since the designed system is tailored on the customer's needs, a single batch for a custom component is feasible. Thanks to the contacts of INSA Lyon's Mechanical Engineering department, it will be possible to produce this component in short times in an aluminium alloy. The result should be a lightweight assembly composed by a flange modelled on the EN ISO 9409-1-31.5-4-M6[15] norm and two bridge elements, that are easily replaceable in case of damage.
The arrangement of the three parts allows to place the micro mill with a 45° angle between its working axis and the axis of the 3D scanner. This allows to avoid interference of the wiring with the field of view. Moreover, the two bridge parts allow an easier dismount of the micro-end mill, keeping its attachment points divided from those of the plate and so the 3D scanner. In addition to this, the component allows for a better heat exchange. Both the 3D scanner and the micro-end mill are subject to heating when in operation. It should be noticed that the 3D Scanner shouldn't be operating for very long time spans, hence overheating is unlikely. On the opposite, the micro-end mill might be working for tens of minutes or more. It already has a support with cooling fins, which is rounded except for the side of the support. Since this side is the most critical, the spaced support in Figure 5.5 allows to increase the

heat exchange on the back too. The drawback of this design is the displacement of the mass center of the on-arm assembly, since the attachment point is shifted by 40 mm. This loads the arm end with a higher bending moment, but the design of the flange in Figure 5.6 and the lightweight design should keep it under an acceptable level while preserving the steadiness of the tool. This distance is in fact a mean value between the plate mentioned above and the *Zivid Two on-arm* extender. The extender can reach out for at maximum 65 mm.

Chapter 6

Conclusions and future perspectives

This chapter concludes a preliminary yet fundamental part of the realization of this project.

What's been presented to this point translates the customer's requirements into a set out system. The output of this work is a system layout: the main components needed for a demo are listed and the logical process is outlined.
To sum up, the main observations are the following:

- the process can't be fully automatized since it relies on human intervention. The designed system will require the technicians' contribution and will fit well into the laboratory's environment, allowing to cut the production times and ease the work.
- The set budget allows to only buy some components of the system, but further funding is being carried on. This matches the modular conception: the first step will be a milling demo with the 3D scanner, whose total cost will be of less than 100000€.
- The technical time needed for the delivery of the free loan robotic arm and the 3D scanner made it complicated to develop the project any further. This is left to the students who will take it in in the future.

The remaining part to do is the software and algorithm development and the set up of the system with the human-machine interface. While the set up process might be assigned to a student, it's possible that the development part will be entrusted to *INNODURA TB* with an agreed quotation with the *ROMANS FERRARI* Medical Center.

The project statement received by the *ROMANS FERRARI* Medical Center in February 2022 was very generic and required the student to use their imagination to create the most suitable system for all the constraints presented in the previous chapters. The expected outcome of the project was the following, in terms of deliverables:

- study of the current process;
- evaluation of the cobot-approach to the problem and knowledge of this tool;
- study of the equipment (etching, resin bead deposit, mixer) on this cobot;
- programming of the cobot using the files from the scan and image processing;
- estimated production times for the proposed solutions;
- estimated cleaning and maintenance requirements;
- file allowing the setting up of the equipped cobot;

The study of the current process is proposed in the first two chapters of this thesis work and has been delivered as the Cahier des Charges to the *ROMANS FERRARI* Medical Center board. It includes the first codification of the productive processes for DMDGs orthoses, which will be kept as a standard and validated document in the future.

The study of the cobot approach has been mostly a practical and personal experience at *INSA Lyon*'s robotic laboratory. Mr. Arnaud Lelevé provided all the teaching material and the full access to the controls of a *Stäubli TX2-40* robotic arm and its safety systems. Although this is not the proper definition of collaborative robotics, it allowed to understand that the most suitable and simple solution for this project is not collaborative, but fully automated as presented in the Chapter 3.

The study of the equipment is the main part of this work, which comprehends the choice of the commercial solutions in Chapter 3, the design of one of the custom components at Chapter 5 and the delivery of a list of possible future elements. They have been mentioned along this project and can be tool racks for a future tool change automatization or rotating working planes to allow machining bigger parts without displacing them in the robot's fixed frame of reference.

The remaining points are left to another student who will take in this project and hopefully carry it to an end, i. e. a demo. At the current time, commercial relationships with the enterprises mentioned in Chapter 3 are being set and the delivery of the components agreed. The robotic arm will be sent at *INSA Lyon* in free loan, foreseeing

the future purchase by the Medical Center.
On the digital side, the algorithm proposed at the Section 3.5.2 is quite complicated and relies on the knowledge acquired by *INNODURA TB* along the years. It's likely that a part of the budget will be devoted to buy from them the developed algorithm. In addition to this, they will develop a man-machine interface to maximize the user-friendliness that has been strongly pursued along all the project development.

For what concerns the economic side, the estimation of the total cost of what has been proposed in this project is between 200000 € and 300000 €, according to the experts from *INNODURA TB* and *Stäubli France*. Despite this is extremely greater than the set budget, during the project development multiple cut-price solutions have been foreseen. The first demo to be produced will be the robotic arm equipped with the 3D scanner and micro-end mill. It will have an algorithm capable of recognizing the DMDGs shapes firstly in a two dimensional board and the software associated will allow to choose the milling depth and launch the machining.

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