D2.1 - Manufacturing Settings – Intermediate Results

WP2 - Build Measure Learn - Minimum Viable Demonstrators

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Project details and Deliverable information

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Quality check review

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Robert Lovas	Minor formatting

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List of abbreviations and definitions

Abbreviation	Definition
B-M-L	Build-Measure-Learn cycle
CE	European Commission in French
CPAP	Continuous Positive Airway Pressure
EC	European Commission
FEM	Finite Element Model
FFP1	Face mask that filters at least 80% of airborne particles
FFP2	Face mask that filters at least 94% of airborne particles
FFP3	Face mask that Filters at least 99% of airborne particles
GPU	Graphical Processing Unit
H2020	Horizon 2020
HPC	High Performance Computing
MS	Manufacturing Setting
MS1-2-3	Silicone Masks
MS4	Electrostatic Disinfectant Spray Systems
MS5	Ramping up Production of Respiratory Devices
MS6	Machine for Reconfigurable Mask Production
MS7	Resilient Automation for Manufacturing
MVP	Minimum Viable Product
OEM	Original Equipment Manufacturer
PBS	Physically Based Simulation
PPE	Personal Protecting Equipment
ROM	Reduced Order Modelling
SCALP	Small Component Assembly Loop

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Executive summary

The CO-VERSATILE project aims at increasing the adaptation capacity, resilience and flexibility of the European manufacturing sector, focusing on vital medical supplies and equipment, to support Europe in improving its response and preparedness to deal with pandemics. CO-VERSATILE aims to demonstrate how existing technologies and results of previous European projects can be customised, adapted and reused in order to deliver flexible 48-hour industrial response capability at scale. The delivery of such response capacity is demonstrated on seven Manufacturing Settings implemented within the project. These Manufacturing Settings target to produce a wide range of vital medical supplies, including face masks, respiratory devices and disinfectant spray systems.

CO-VERSATILE implements its Manufacturing Settings based on a highly agile approach. The implementation is performed in six iterative cycles, each including build, measure and learn phases (Build-Measure-Learn = B-M-L). As we are currently at month 12 of the project duration, this deliverable presents the technical activities and results of the first year of the project.

Each Manufacturing Setting is introduced first, presenting the setting focus, objectives, and methodology. Then, the main technical activities performed so far in the project are detailed, highlighting the targets, the methodology and the tools utilized to execute them. The main results and their impact on the manufacturing setting development are discussed, in order to provide a clear picture of the status of the project evolution towards the final objectives in each of the settings. This is achieved also through a visualization of the main results and lessons learned at the end of each B-M-L cycle, which provide an overview of the progress of the activities in each setting. In parallel, the work plan and objectives for the next B-M-L cycles are proposed and discussed.

1. Introduction

The CO-VERSATILE project aims at increasing the adaptation capacity, resilience and flexibility of the European manufacturing sector, focusing on vital medical supplies and equipment, to support Europe in improving its response and preparedness to deal with pandemics. CO-VERSATILE builds upon past and current industry-driven research and innovation initiatives to deliver demonstrators of a flexible 48-hour industrial response capability at scale, to cope with sudden spikes in demand of strategic products, and for requalification or release of seven Manufacturing Settings.

Towards this objective, WP2 represents the core of the technical development performed in the CO-VERSATILE project, aiming at repurposing, adapting and setting up the technologies and services that will enable manufacturing settings reach their adaptation, ramping up or repurposing goals. The aforementioned objective is being achieved through the iterative cycles of activities, divided in three steps that are defined as follows:

- *Build phase*: Through an iterative process of interaction between the Manufacturing Settings owners and technology providers, the technical activities and developments will be performed for each Manufacturing Setting. Main expected activities in this phase are:
    - Automation and System integration
    - Manufacturing simulation models and Digital Twins
    - Supply network simulation and risk management
- *Measure phase*: In this stage, the outcomes of the technical developments will be measured and tracked, to validate the achieved results.
- *Learn phase*: The main outcomes emerging from the information collected during the measure phase will be processed and transformed into lessons learned. These will generate a task plan for the next Build phase.

Each Build cycle lasts for 2 months and is followed by a Measure and a Learn cycle of 0.5 months each. It is envisaged that at least 6 of such cycles will be completed during the lifetime of the CO-VERSATILE project. The actual implementation and technical work within a Build cycle depends on the nature of the experiment and may also change from one cycle to another. Within each B-M-L iteration, the technology providers work with the Manufacturing Setting owners to adapt, integrate, evaluate and improve the technologies that will allow to reach the repurposing goals.

The present report provides an overview of the first 12 months of technical activities of the CO-VERSATILE project in the framework of WP2, corresponding to 4 B-M-L cycles. For each Manufacturing Setting, the main activities performed since the beginning of the project are presented and analysed, describing the evolution of each scenario towards the achievement of its own repurposing goals. Each Manufacturing Setting follows the same structure, as follows:

1. Presentation of the partners involved
2. Manufacturing setting overview
3. Detailed description of all main activities performed in the first year of the project
4. Brief presentation of the key outcomes from each of the first four B-M-L cycles
5. Brief presentation of the main objectives for the next year of the project

It is worth noting that, when describing the main technical activities performed, a brief update on the developments concerning training is provided. While training activities are related with WP3, their advancement is strongly connected with the status of the technical activities performed in WP2 and, therefore, it has been decided to integrate such update in this report as well.

2. Manufacturing Settings 1-2-3 – Silicone Masks

2.1. CO-VERSATILE partners involved in MS1-2-3

Participating partners and their role:

Experiment owners:

ORP Stampi, Manufacturing Partner: Mould Maker
contact persons: Anthony Dossy (anthonyd@orpstampi.it)

ML Engraving, Manufacturing Partner: Laser Engraving of Mould Surface
contact persons: Ersilio Lodetti (ersilio@ersiliolodetti.com)

SKM Aeronautics, Manufacturing Partner: Rubber Parts Manufacturing
contact persons: Yuval Erez (yuval@skm.co.il)
Haim Chikurel (chikurel@netvision.net.il)

Service and technology providers:

ITA, Mould Flow Simulations
contact persons: Manuel Laspalas (mlaspalas@itainnova.es)

IDS, LUH, surface definition and prototype surface testing
contact persons: Matthias Wangenheim (wangenheim@ids.uni-hannover.de)

IGD, product simulation
contact persons: Tim Grasser (Tim.Grasser@igd.fraunhofer.de)

IML, supply chain simulation
contact persons: Saskia Sardesai (saskia.wagner-sardesai@iml.fraunhofer.de)

Business coaching:

SUPSI, business coaching, certification, training
contact persons: Marzio Sorlini (marzio.sorlini@supsi.ch)
Riccardo Canavesi (riccardo.canavesi@supsi.ch)

HSSMI, virtual environment for training of manufacturing and customers with digital content
contact persons: Katarina Deme (katarina.deme@hssmi.org)

IE, risk management
contact persons: Elena Revilla (Elena.Revilla@ie.edu)

2.2. Overview of the Manufacturing Setting

In the beginning of the pandemic, the unprecedented demand for face masks became one of the major challenges to be faced by European manufacturers. To protect European citizens, patients and front-line practitioners and to rapidly address their needs, CO-VERSATILE consortium partners joined forces to prepare Europe for managing pandemics by elevating the adaptability and resilience of the manufacturing sector.

MS1-2-3, lead by end users ML, SKM and ORP, aims at further developing a repurposing model to allow the production of multiple types of medical components, which they intend to demonstrate with silicone masks including a disposable N95 filter which can be fitted in the mask. The objective is to innovate and deploy high-performance, silicone bio-compatible multi-use face masks, with a novel design and new texture finishes that will ensure a more comfortable fit and improved air circulation.

MS1-2-3 are composed of three manufacturing steps to be able to manufacture silicone masks, designed by SKM, in mass production:

- mould manufacturing (**ORP**),
- mould laser texturing (**ML**) and
- mask production with textured mould (**SKM**).

Building upon past and current innovation initiatives, the group of partners for MS1-2-3 focuses on achieving the following results:

- Offer manufacturing companies a replicable method for fast re-purposing of their production lines for manufacturing vital personal protective equipment in high volumes and on short notice.
- Make the design of the mask simple to produce by other manufacturers.
- Make the masks comfortable to wear by using lightweight material and special velvet skin textures.
- Make masks re-usable and affordable by inserting special filter.
- Support manufacturing and logistics firms with a simulation service to ramp up their supply chains and optimise material flow processes – a service that can be particularly beneficial to SMEs looking at rebalancing their short-term sourcing decisions.
- Develop a manual of operation in 3D-PDF format to be supplied alongside the moulding machine to support employees of future adopters of the machine.

The manufacturing solution for the 'Silicone masks' production line will additionally include guidelines, recommendations and tools to support companies in reconfiguring their supply chains to cover a sudden surge in demand and assess the supply chain risks caused by the pandemic.

2.3. Activities performed during the first year of the project

In the following sections, the main activities performed in the first 12 months of the project concerning MS1-2-3 are presented, detailing all technical developments and main achieved results. The basis for the activities to be performed in the second half of the CO-VERSATILE project are also introduced.

2.3.1. Mask design optimization

Based on a market study of existing reusable face masks, SKM, ORP, MLE derived a list of main requirements and design goals for the Co-Versatile MS1-2-3 mask, which are presented below:

- *Transparency*: It is needed to transmit facial expressions and lip movement through the mask, to improve communication and, in particular, for the hearing impaired.

- *Structural wearing comfort*: The mask shall enable comfortable wearing for several hours, sealing well the user mouth and nose but without being too tight.
- *Haptic wearing comfort*: Areas in direct contact with skin shall be textured comfortably.
- *Sealing exhalation air*: This aspect is very important to avoid fogging for wearer of glasses.
- *Filter grade selectable*: The mask shall enable the use of exchangeable filters of different classes, such as N95, FFP2 and paper or cloth filters.
- *Reusable*: Mask material shall be washable (e.g. in dish washer) and filter material shall be washable or disposable/biodegradable.
- *Biocompatible*: This aspect is important since the mask will be in direct skin contact for multiple hours, i.e. it must fulfil respective HSE criteria.

According to common product engineering and design rules, the mask design was developed iteratively in several design readiness stages. Below, the main steps of this process are summarized:

1. First mask design, presenting a simpler geometry and printed in plastics material. Laces and filter are attached manually to the mask.

Figure 1: First prototype of face mask

2. Mask design optimization, as visible in Figure 2 (in pink the old design and in green the optimized one). In this second iteration the mask volume has been reduced, the laces have been included in the mould design and therefore are directly fixed to the mask body, (one piece design means less manufacturing steps) and the filter position has been lowered towards chin.

Figure 2: Mask design optimization

3. Mask size finalization: the mask now presents 2 different strap lengths, to improve comfort for different users, the straps position on the mask have been modified and their diameter has been adjusted for an optimum retaining of force.

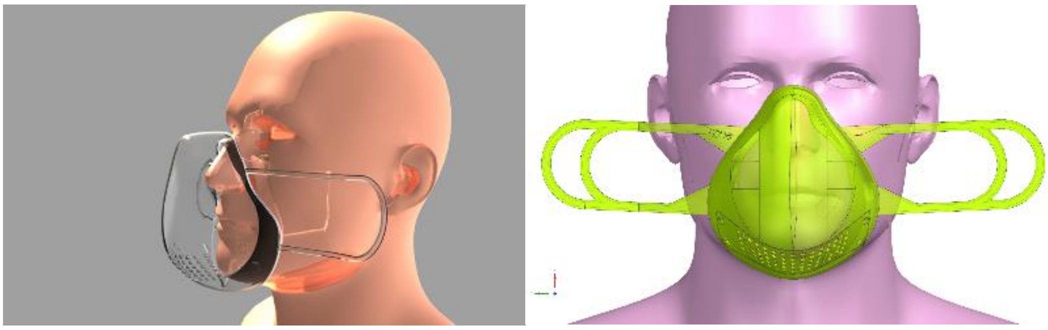


Figure 3: Mask design finalization

In the second half of the project a second, smaller mask design version will be derived.
In parallel with the optimization of the mask design, the definition and selection of the mask material have been investigated. Rubber quality was selected to medical grade solid silicone rubber (HCR, supplier Mesgo, IT), because all rubber vulcanization presses and tools can work with these compounds, which is important for later upscaling the mask production to other manufacturing sites. The level of compound hardness (expected 50 ShA) will be defined after the execution of a mask prototype vulcanisation that will be achieved in later BML cycles, to balance form stability, comfort and tear resistance.
Two types of filters have been assessed, both fulfilling the FFP2 criteria: filter cloth (supplier Albini, IT) and paper filters (supplier AL Filters, IL). While filter cloths are washable, their handling during manufacturing (unravelling after cutting) is difficult and will require extra sewing steps. In addition, the cloth is not form stable when connecting to the mask. On the other side, paper filters are disposable (and biodegradable) and present the advantage of an easy handling during manufacturing and its stability on the mask. Suppliers for compostable grade have currently been contacted.
Lastly, concerning the wearing comfort of the mask, a specific surface textures to increase the mask comfort have been defined. They will be applied on mould inserts in later BML cycle.

IGD simulated the mask and the mould to optimize their design using the RISTRA simulation software. UoW collected the contact details and the technical parameters of this simulation software that are presented in Table 1.

Table 1: RISTRA simulation software details

simulation types	
product simulation	x
manufacturing simulation	
supply chain simulation	
manufacturing setting supported	
MS1-2-3	x
MS4	
MS5	
MS6	
MS7	
simulation software	
open source	
commercial	RISTRA
user interface	
command line	
GUI	
other	x
operating system	
Linux	x
Windows	x
other	
computing platform	
desktop	x
cloud	
HPC	
other	
processors	
multi core	x
GPUs	x
other	
memory requirements [GB]	
	0.2 + model size
data requirements [GB]	
input data	depends on model size
temporary data	depends on model size
output data	depends on model size
scalability	
horizontal	x
vertical	x
security	
authentication	
authorization	
encryption/decryption	
others	

IGD and UoW investigated how to cloudify RISTRA to provide this simulation software on demand basis for ORB and SKM. First, UoW will containerize RISTRA. Next, UoW will deploy and run RISTRA on cloud resources using MiCADO. CLESGO and UoW started a discussion how to offer RISTRA through the Digital Technopole.

2.3.1.1. Simulation of the mask

In the design process of the mask, a simulation software which simulates the behaviour of the mask under external forces is helpful to find the optimal design. Furthermore, it is of interest to evaluate the behaviour of the mask when interacting with a face. As the mask is a thin-walled structure, a shell simulation is most suitable to perform the static deformation simulation. Shell simulation is based on a two-dimensional mesh given by quadrilateral or triangular elements. In general, this mesh needs to be generated from a CAD model, e.g. by extraction of the mid-surface and performing a meshing step of this surface.

Especially when dealing with high-resolution meshes yielding large degrees of freedom for the simulation, simulation times can be very long. This can be reduced by parallelizing the simulation algorithm. As time is a crucial factor in the Co-Versatile setting, an efficient GPU-accelerated shell simulation will be developed by Fraunhofer IGD.

In the first half of the project, the simulation framework RISTRA (developed by IGD) was extended by a prototypical implementation of shell simulation capabilities. The software is now able to perform linear structural deformation simulation of manifold triangular meshes, given a load case and boundary conditions.

In the following, the developed building blocks are specified. The simulation is conducted using the finite element method (FEM). FEM is based on subdividing the simulation space into elements. For each element, integration points are used to define the structural properties of interest on each element. MITC3 elements have been chosen, which is a modelling approach for linear shell simulation with triangular meshes, which resulted more suitable to be integrated into our framework.

Based on the discretization, a local stiffness matrix that models the deformation behaviour of the structure can be defined for each element, to be then assembled in a global stiffness matrix. To compute the global solution of the deformation simulation, a linear equation system is solved using the global stiffness matrix. To speed up the computation of the element stiffnesses, which can be very time consuming, these computations have been conducted in parallel on the GPU.

A further crucial part of this implementation is IGD linear solver. The resulting linear system is solved using algorithms from RISTRA framework, which were adapted to suit the problem of shell simulation. The resulting systems from FEM are in general given by large sparse matrices. To solve these types of systems efficiently, we use an iterative solver based on the preconditioned conjugate gradient method which exploits parallelizability of specific operations. The algorithms have been implemented in C++ and CUDA. After solving the simulation, the results have been exported as VTK files and can be viewed using, for example, the open-source third party software Paraview.

The obtained simulation algorithm was validated by comparing its results for a simple shell model to the results obtained in Ansys for the same structure (see Figure 4).

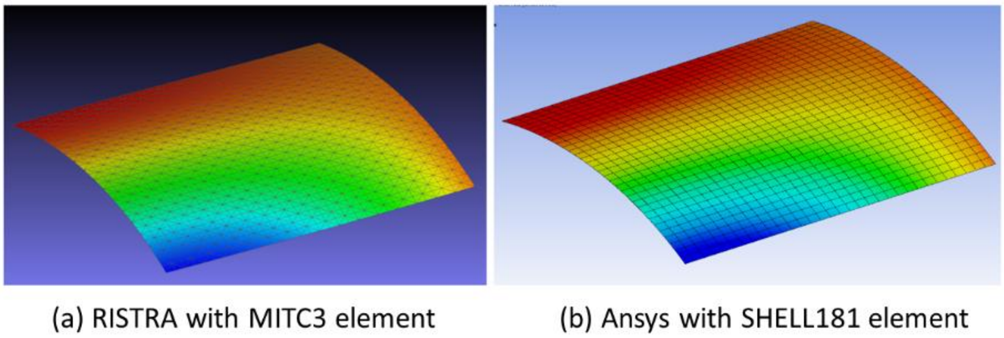


Figure 4: Visualization of displacement values computed using RISTRA and Ansys.

IGD shell simulation algorithm has then been used to perform a structural simulation of the silicon mask, modelled as a triangular mesh with linear material properties. Furthermore, due to the restrictions of the developed algorithms, it is assumed that the mask undergoes small deformations.

A triangle mesh of the mask, which was generated by meshing one side of the CAD geometry, was received from ITAINNOVA. This mesh was modified to suit the following predefined constraints: i) the straps were removed as the model focuses on small deformations; ii) the quality of the mesh was increased, avoiding small angles to improve the numerical behaviour. To perform an exemplary static deformation simulation, an example load case and boundary conditions were defined: forces were applied to model the straps and fixed boundary conditions were set at the nose and chin to simulate the behaviour of the mask on the face. The results of such a simulation are shown in Figure 5.Figure 5: Results of a deformation simulation performed in RISTRA. The original shape is indicated by the transparent black mesh. The deformed shape is coloured visualizing the displacements.

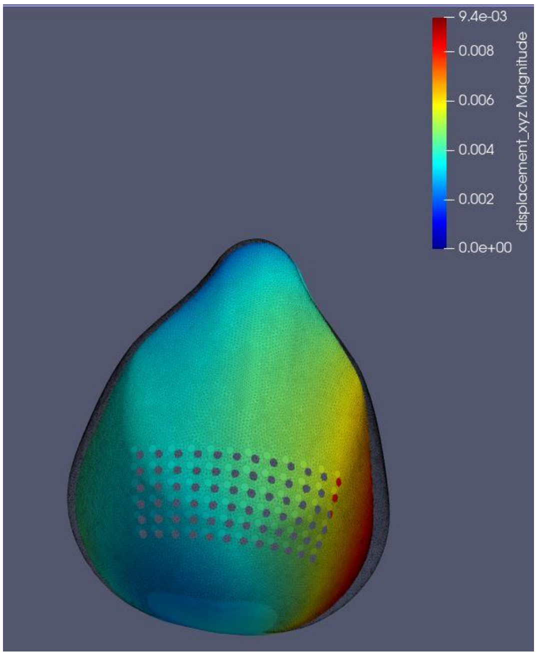


Figure 5: Results of a deformation simulation performed in RISTRA. The original shape is indicated by the transparent black mesh. The deformed shape is coloured visualizing the displacements.

Contact simulation is a further aspect of IGD technical improvement. The static deformation simulation capabilities in RISTRA have been extended by a prototypical implementation of a contact simulation algorithm. The implementation includes a quadratic program solver for large sparse matrices. Currently, the contact simulation capabilities are only for tetrahedral meshes.

IGD plan for the next period is to further develop its shell simulation to incorporate contact handling based on the experience obtained in this first year in the areas of shell simulation and contact simulation. For this, it is necessary to adapt the contact algorithms to be able to handle shell elements first, and then to explore GPU-parallelizability of IGD contact simulation algorithms.

2.3.2. Manufacturing simulation

The activities related to the mask manufacturing simulations, performed by ITAINNOVA, started with a general planning for the project, aiming at supporting the manufacturing process setup by means of CAELIA moulding simulation, ending up in a tailored App that would make accessible the knowledge on material/mould/processing for the mask generated by injection moulding simulations.

ITAINNOVA is responsible for the manufacturing simulations and the development of a CAELIA web application, to support a quick mould and process set-up. The following blocks compose the core of the simulation:

- physically based simulation model of the moulding (PBS)
- design of Experiments (DOE) to explore suitable ranges of moulding conditions,
- reduced order modelling (ROM) to extract relevant KPI results and
- Digital Twin (DT) to encapsulate all the ROMs in an applications that allows quick try-outs.

The manufacturing simulation will create a Digital Twin based representation of mask manufacturing, being able to transfer production know-how to other manufacturing sites in Europe.

Towards the achievement of such result, in the initial stage of the project, the model requirements were specified. Figure 6 shows the two most relevant sets of material properties required to run a moulding simulation. On the left, the viscosity dependency on time at different temperatures is shown, where it can be appreciated the viscosity jump associated to the vulcanization progress. On the right graph, the vulcanization kinetics is shown, which is a thermally activated process.

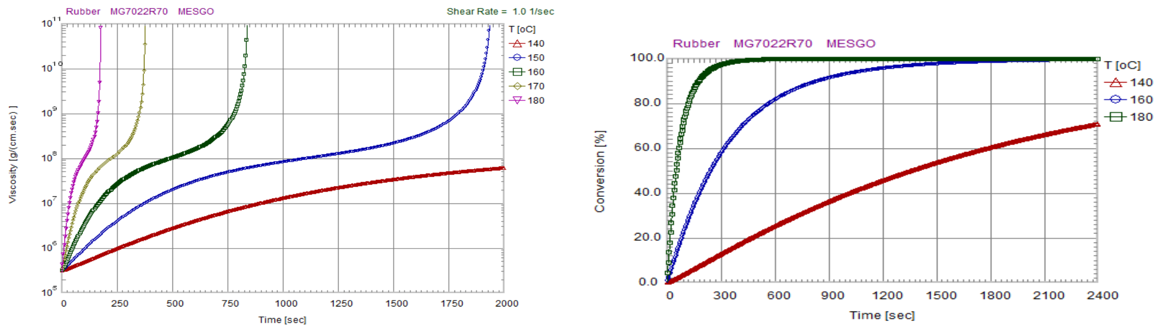


Figure 6: Viscosity evolution at different T (left) and vulcanization conversion kinetics

The rest of required material input parameters are the pvT model (or pvTC), thermal conductivity and specific heat.
The initially selected silicon rubber grade candidates were MG6538T30P, MG3360T40P, MG7915T50P and MG5725T60P, that cover a range of final transparent silicone material hardness. The available data consisted of the technical data sheets that includes the general characteristics of the cured silicone (hardness, density, tensile modulus and strength, tear strength and brittleness point) and a rheometry curve at a single temperature.
Characterization tests were then performed to complete the set of available data. Specifically, for the vulcanization kinetics, Differential Scanning Calorimetry (DSC) data at different temperatures or heating rates are required. For the reactive viscosity model, on the other side, multiple viscosity measurements are required:

- for the cure independent part of the model, viscosity measurements on a rotational rheometer at different shear rates and temperatures (at least 3 different temperatures) are required,
- for the cure dependent part of the model, measurements at maintained temperature (at least 3 different temperatures) are needed.

Following the initial preliminary analysis of the model requirements, the moulding simulation model of the preliminary mask design is built. Figure 7 shows the CAD model of the initial mask design used as a basis.

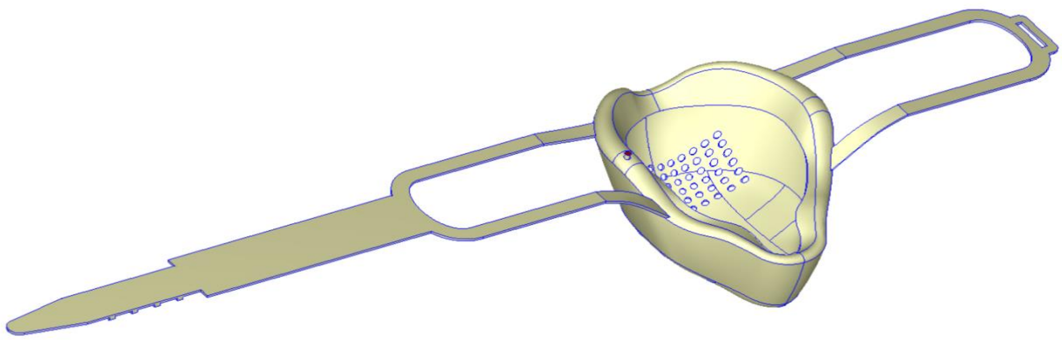


Figure 7: Initial mask design CAD model

Some details of the two meshing approaches considered are shown in Figure 8, where, in the case of the 3D mesh, a section cut has been performed to show the number of elements through the thickness.

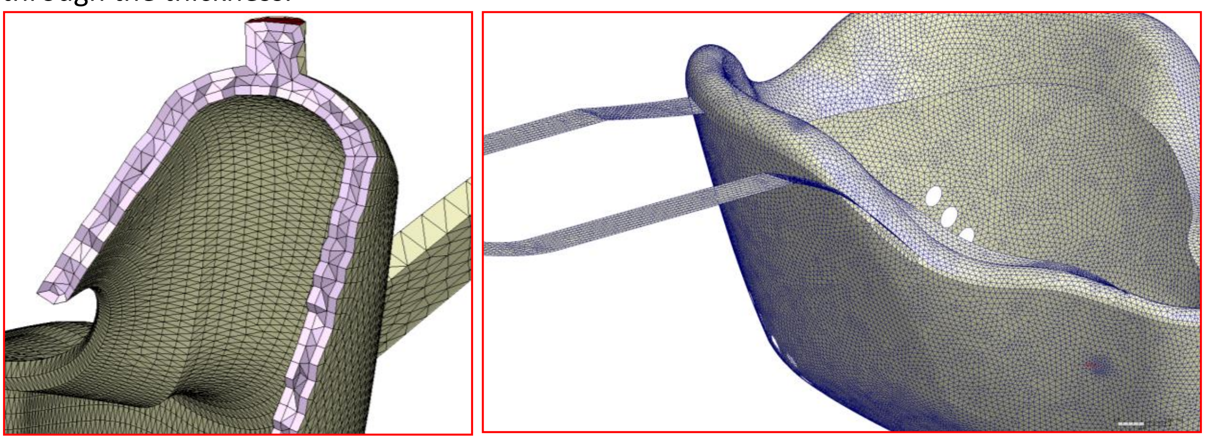


Figure 8: 3D meshing -3 layers (left) 2.5D meshing (right)

Some first relevant results are shown in Figure 9. On the left picture, the filling pattern distribution of the mask during the moulding process is shown and, on the right picture, the pressure evolution during moulding is presented.

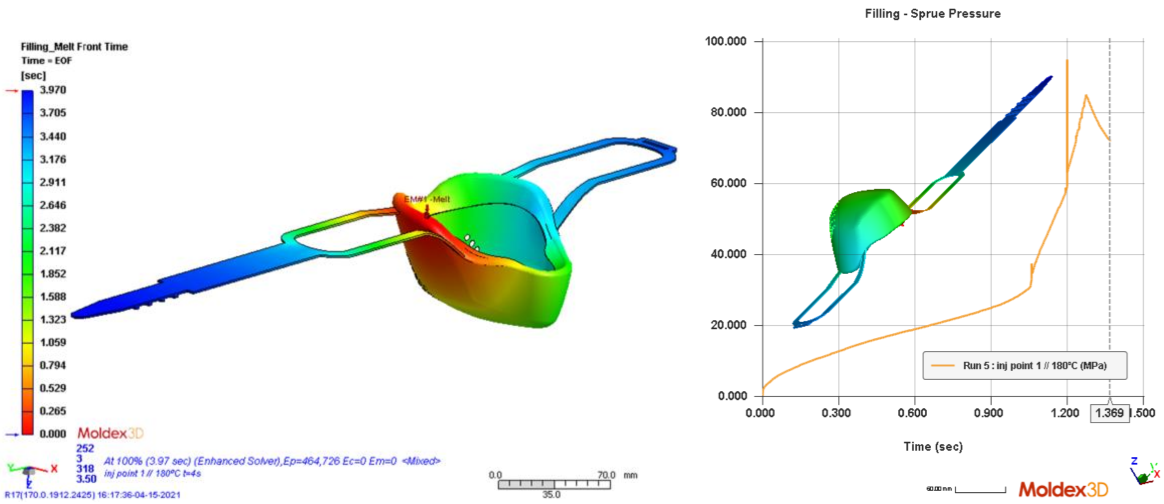


Figure 9: Filling pattern (left) and Injection pressure (right)

The measuring cycle consisted of comparing the computation performance of the different approaches. This allowed to exploit the simulation model through an extensive DOE in later activities.

Table 2: Measuring cycles

Model	Nº elements	Computation time	Vulcanization included
3D solid – 3 layers	464k	1:10 h	Yes
3D solid – 7 layers	838k	2:40 h	Yes
2.5D shell – 12 layers	77k	0:10 h	No

Also using a 2.5D model, different mask thicknesses were compared to quantify the impact on the injection pressure, as shown in Figure 10.

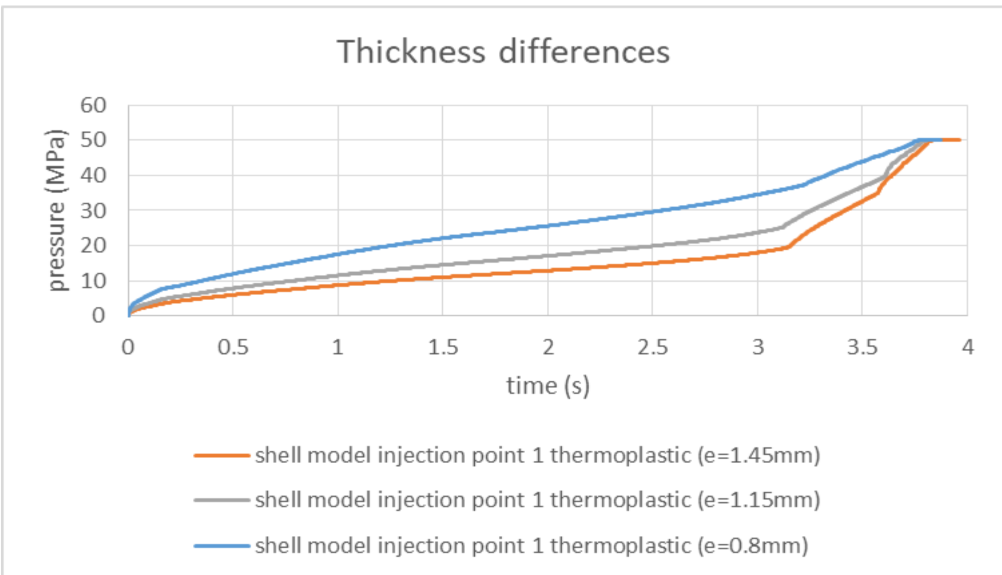


Figure 10: 3D Effect on mask thickness on required injection pressure (at constant injection time)

The 2.5D simulation model proved to be much more computationally efficient than the 3D model for this component. However, an important limitation of the 2.5D approach is that the used simulation software release could not allow the simulation of the vulcanization process, nor the simulation of the effect of the vulcanization on the viscosity. Therefore, the interest of this 2.5D model is limited to the analysis of the filling behaviour, assuming little vulcanization progress during it. The simplified approach is, nonetheless, still useful to make quick simulation trials, aiming at quantifying the effect of the thickness and the location of the injection point/s in the filling pattern and to determine required injection pressure. For the full analysis of the process including vulcanization, the full 3D approach needs to be used. The capabilities of the new coming simulation software release will be re-checked to confirm if the identified limitation still holds.

Following the initial analysis on the mask material, SKM has selected the silicone grade for injecting the masks: MG7915T50P with 50 ShA hardness transparent silicone rubber with platinum base curing system. The material compounder (MESGO) was required to provide all the material information available, basically, a technical datasheet, a material security data sheet, and a MDR rheological data. In parallel, a set of python scripts have been developed that are able to take data from material characterization tests and adjusting curing kinetics and rheology models, as shown in Figure 11.

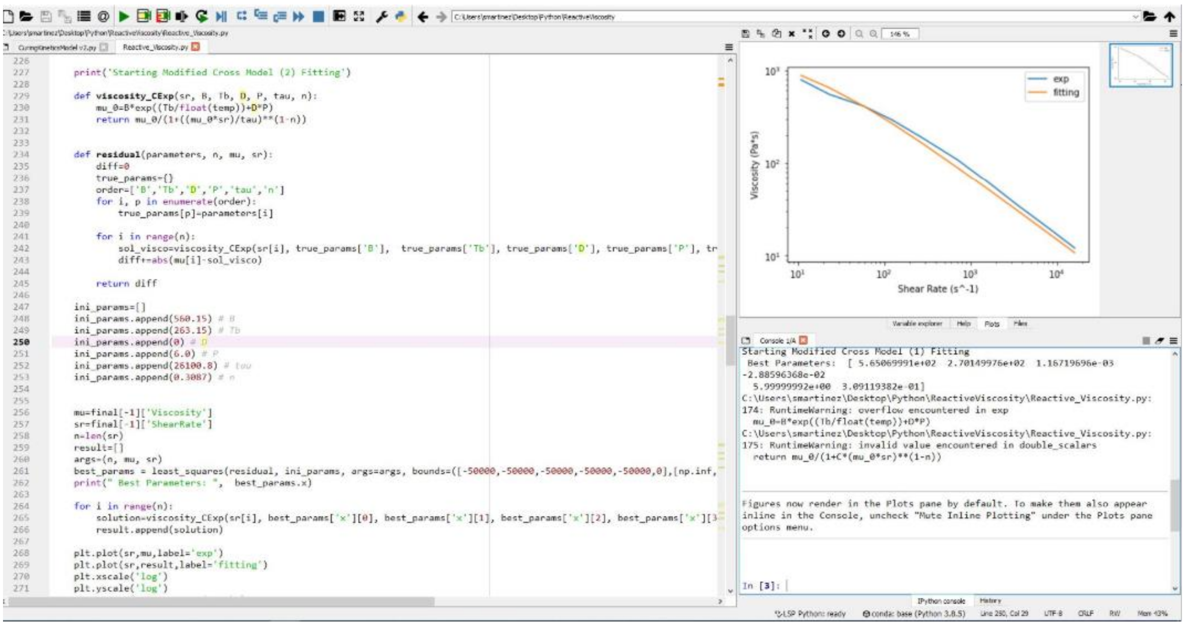


Figure 11: Python script for material model fittings

This analysis has allowed to determine that the information received from MESGO was not sufficient to adjust the material models required for the injection simulation. MESGO stated that they do not have the capabilities to perform the required tests to collect the missing data, so a characterization campaign was planned for the next months. SKM arranged with MESGO compounding an initial batch of material and ITAINNOVA organised a delivery to receive 5kg of material for the characterisation campaign for the two main models required to be fitted, the rheology and the curing kinetics. The silicone curing kinetics was determined by means dynamic differential scanning calorimetry (DSC) tests at different heating rates (2 ºC/min, 5 ºC/min, 10 ºC/min and 20 ºC/min) following the recommendations of the standard ISO 11357-1 and ISO 11357-5. The obtained heat flux curves are shown in Figure 12.

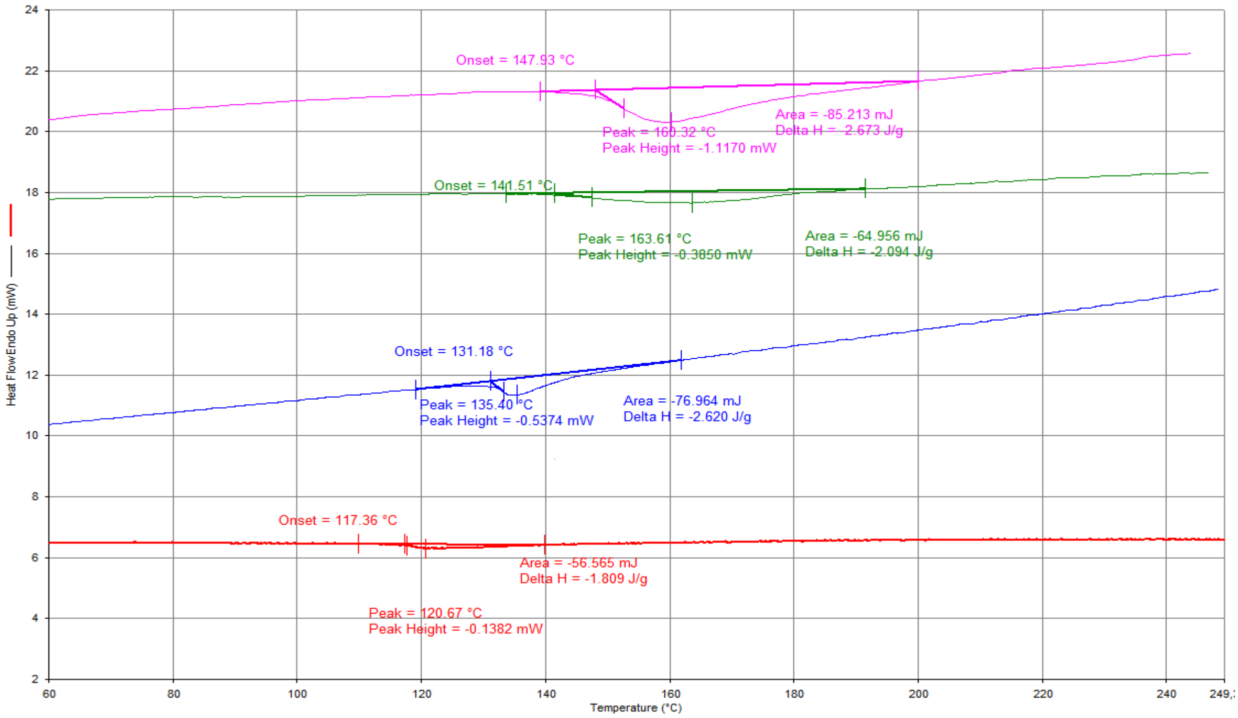


Figure 12: Heat flux curves obtained in a Perkin Elmer DSC6

The silicone viscosity was determined in a parallel plates rheometer by means of oscillatory strain control tests at different heating rates (2 ºC/min, 5 ºC/min, 10 ºC/min) and two shear rates following the recommendations of the standard ASTM D4440. The results are shown in Figure 13.

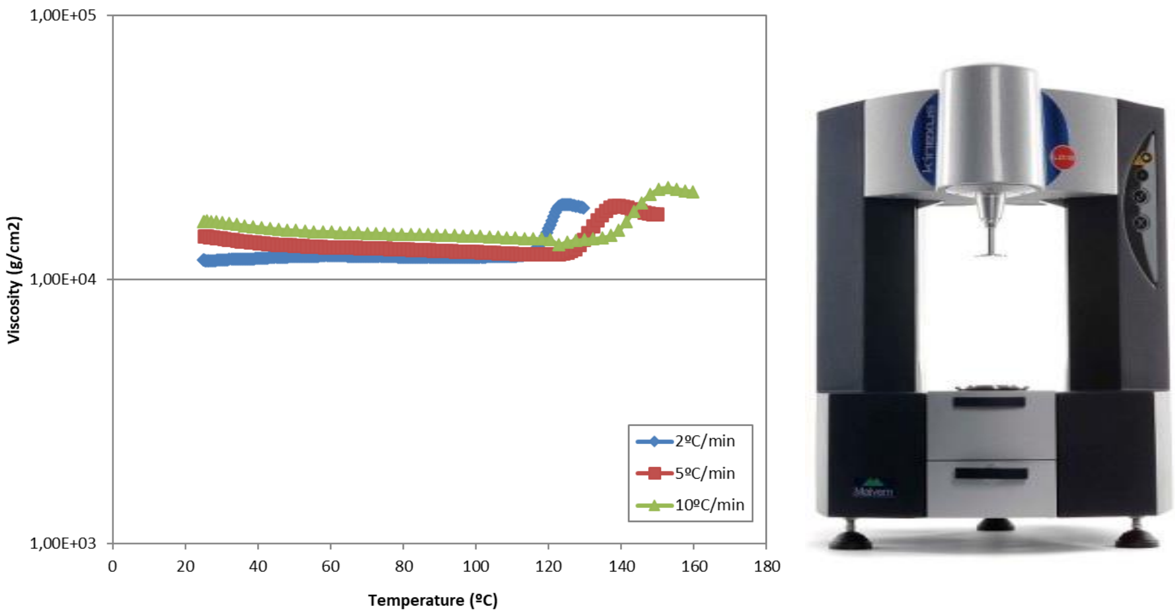


Figure 13: Viscosity curves obtained at different heating rates in a Malvern Kinexus rheometer

Furthermore, the effect of shear rate at three temperatures (40, 60 and 80ºC) was determined following the same standard. The obtained test data were then treated through the model adjustment subroutines developed in previous project activities (Figure 14).

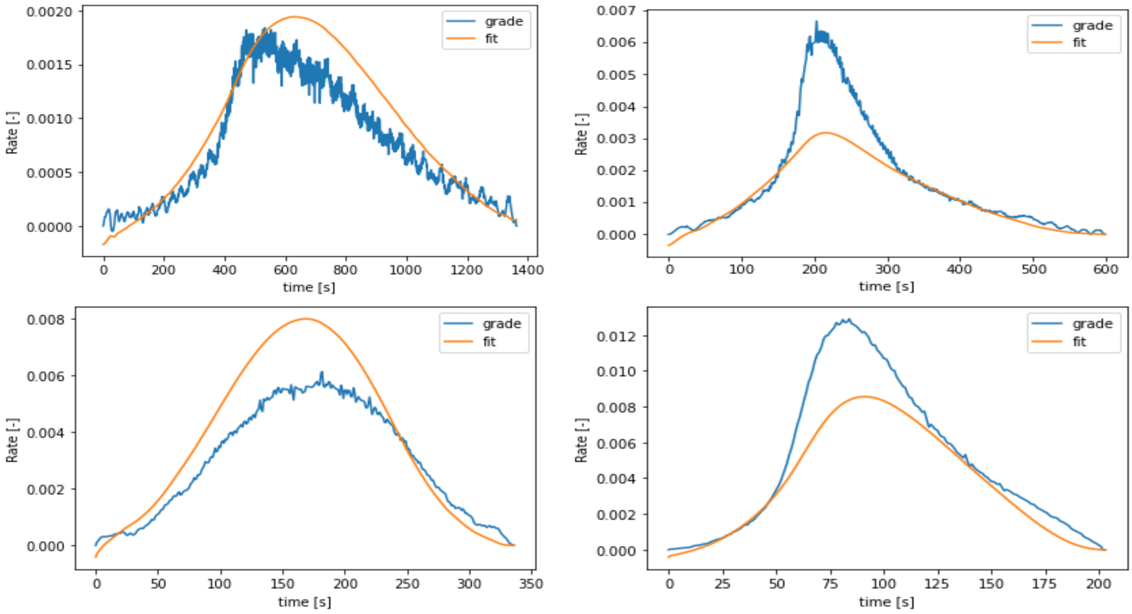


Figure 14: Fitting results of the curing kinetics model at 2, 5, 10 and 20 ºC/min

From the obtained data it was observed that the fitting quality was not as good as initially expected. For that reason, some complementary tests have been planned and a set of crosscheck tests have been contracted, as a technical assistance, to the representative of the simulation program to be used in the simulations.

In parallel with the technical activities described above, UoW and ITAINNOVA have carried out initial conversations for the definition of the cloudification strategy of the CAELIA application in the final BLM cycles of the CO-VERSATILE project.

As detailed above, ITAINNOVA offers different simulation services for the mould manufacturing that can be categorized in three phases of simulation of the mould manufacturing:

- Phase 1: simulation software with licence, for example Moldex3Dm, runs the simulation locally and produces the simulation results,
- Phase 2: ITAINNOVA simulation software generates some ROMs (Reduced Order Simulation) from the simulation results using command line/script
- Phase 3: ITAINNOVA Python based software runs ROMs through GUI to complete the simulation

ITAINNOVA also offers three types of Graphical User Interfaces to be used for this simulation:

- option 1: Jupiter notebook + Voila (ITAINNOVA solution)
- option 2: C++ application (ITAINNOVA solution)
- option 3: web-based GUI implemented in DIGITbrain (developed by partners who do not participate in CO-VERSATILE)

UoW collected the contact details and the technical parameters of ITAINNOVA simulation software. These are depicted in Table 3.

Table 3: ITAINNOVA simulation software details

simulation providers	
name	e-mail
Manuel Laspalas	mlaspalas@itainnova.es
simulation types	
product simulation	
manufacturing simulation	x
supply chain simulation	
manufacturing setting supported	
MS1-2-3	x
MS4	
MS5	
MS6	
MS7	
simulation software	
open source	ITAINNOVA software
commercial	
user interface	
command line	
GUI	x
other	
operating system	
Linux	x
Windows	x
other	
computing platform	
desktop	x
cloud	x
HPC	
other	x
processors	
multi core	x
GPUs	
other	
memory requirements [GB]	
	2
data requirements [GB]	
input data	50Mb
temporary data	
output data	
scalability	
horizontal	x
vertical	
security	
authentication	x
authorization	
encryption/decryption	
others	

ITAINNOVA and UoW investigated how to cloudify phase 2 and phase 3 of the simulation to support mould manufacturing. CLESGO and UoW started a discussion how to provide phase 2 and phase 3 of the simulation through the Digital Technopole.

2.3.3. Mould design optimization

In parallel with the masks manufacturing simulations and based on the iterative obtained results, the mould design for the masks realization was also carried out. The mould has been designed as a transfer injection moulding tool with one insert per cavity, as shown in Figure 15. The main advantage of inserts is in the texturing phase, since only inserts have to be transported to the engraver and not the whole mould. Another advantage of the proposed solution is in the ease of demoulding the product when moving the insert as well during opening of the mould.

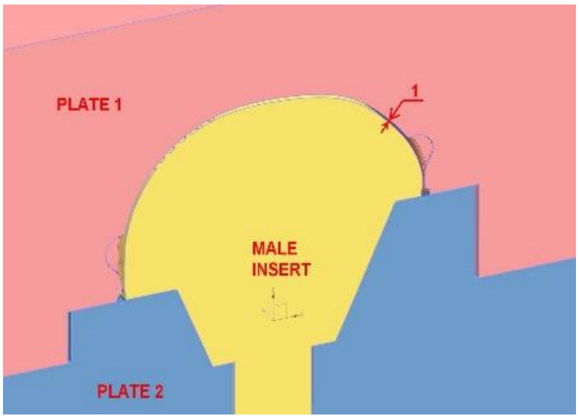


Figure 15: Male insert detail in the injection mould

Ideally, two cavities can be fit into one mould tool with the current mask design to double production capacity per press. An initial layout for this solution is presented in Figure 16.

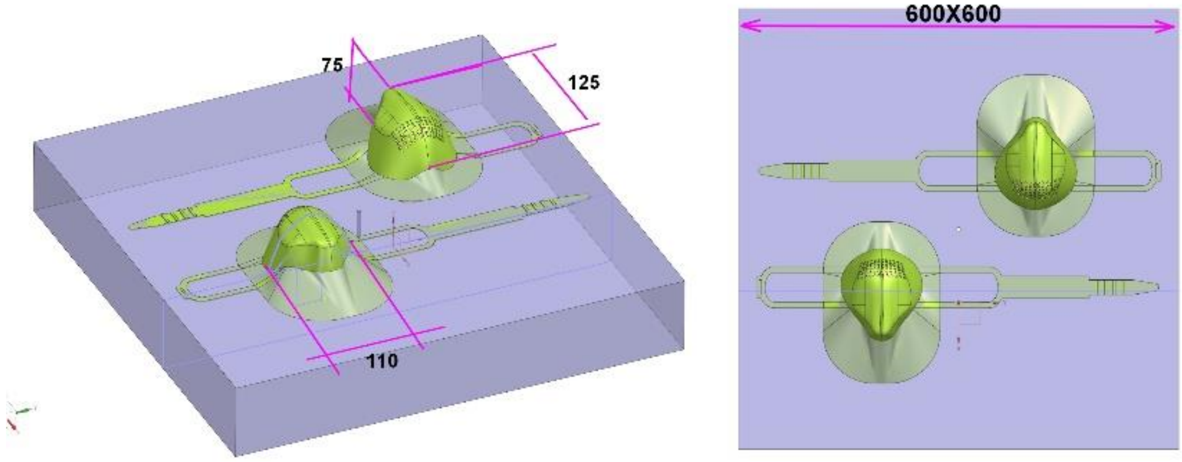


Figure 16: Two mask cavities can fit in a single mould, to double production capacity

The results coming from the manufacturing simulations have allowed to support the selection of the optimal position and orientation of the masks in the mould, as well as the number and position of injection inlets/gatings. An important aspect that is driving the final selection of the mould configuration is the size of the presses that are foreseen to be used in the manufacturing of the masks in case of a new pandemic. As the most common presses have a 500x500 mm² area moulds, the final mould layout and arrangement of the masks inlets has been selected in order to be compliant with this type of press. In this way, the production of these masks can easily be transferred to other manufacturing facilities with minimum required setup. The final mould layout is shown in Figure 17.

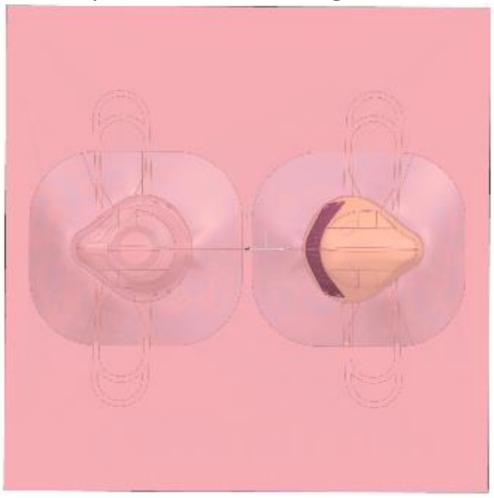


Figure 17: Final mould layout with two mask cavities

2.3.4. 3D prototyping of masks and casting in 3d printed molds

In case of an unforeseeable emergency such as a pandemic, fast actions to mitigate the negative impact are fundamental and, therefore, it may be necessary, for manufacturing companies, to rapidly take action through the development of new products or through the rapid repurposing of their manufacturing lines. Therefore, the assessment of rapid prototyping of functional products based on 3D printing was performed in Co-versatile.

In the framework of this assessment, a functional rubber prototype (hardness ShA 50) was printed with an SLA printer (Formlabs 3L), using the second iteration of the mask design, in scale 1:1. This prototype is visible in Figure 18.

Figure 18: SLA 3D printed mask

Printing time of this first prototype was approximately 18 hours with all functions (fitting, transparency, closing of laces) testable a few times. The sealing lip design around the face in this version provided some undercut regions. These undercuts lead to some difficulties in removing the support structures required for the 3D printing, and the same issue would be present when moulding the mask, as the same undercuts would lead to demoulding problems. In a series of 3D printing tests, different surface texture qualities were replicated by the printer, to assess their quality. The same part was printed 6 times under variation of the printing angle (0° to 80°). It was observed that, in dependence of the orientation of the texture in the printing space, its quality varies:

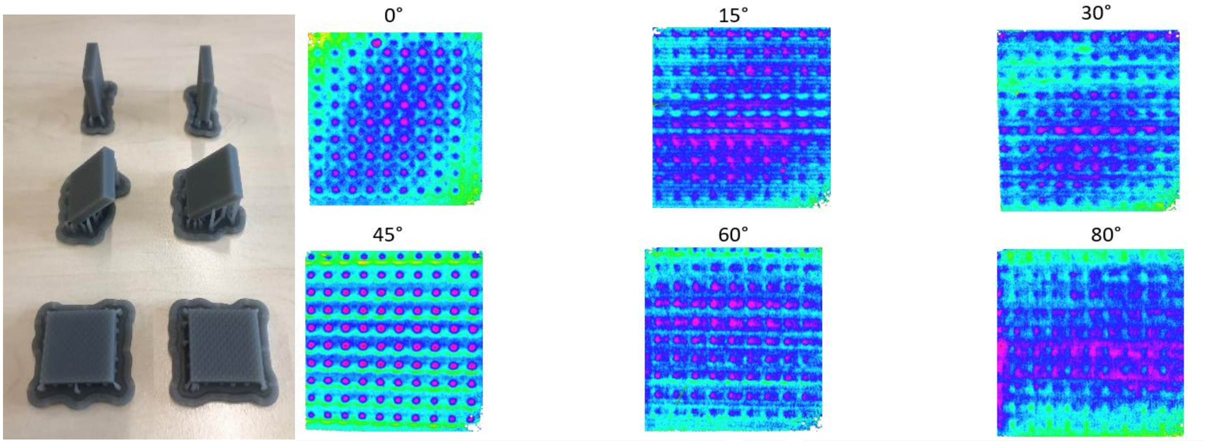


Figure 19: 3D printing quality dependency from surface orientation

The optimum resolution of 25 µm was achieved in a 45° inclination. This resolution enables the printer to replicate all texture features applied to the mould by laser engraving. Thus, the possibility to assess haptic wearing comfort of textured surfaces with the help of 3D printed prototypes was demonstrated, resulting in a highly valuable tool towards the optimization of the mask design in terms of material selection and texture.
As a following activity, 3D printed resin moulds were manufactured to rapidly enable testing of casted or injected products. The mould, depicted below in Figure 20, was filled with liquid silicone to form a star-shaped structure with varying thickness, ranging from 50 µm to 1.6 mm (Figure 21).

Figure 20: 3D printed resin moulds to test mask wall thickness

All beams were moulded in excellent quality, meaning that structures of wall thickness of less than 1 mm can be moulded (and demoulded) from 3D printed prototype moulds without damaging them.

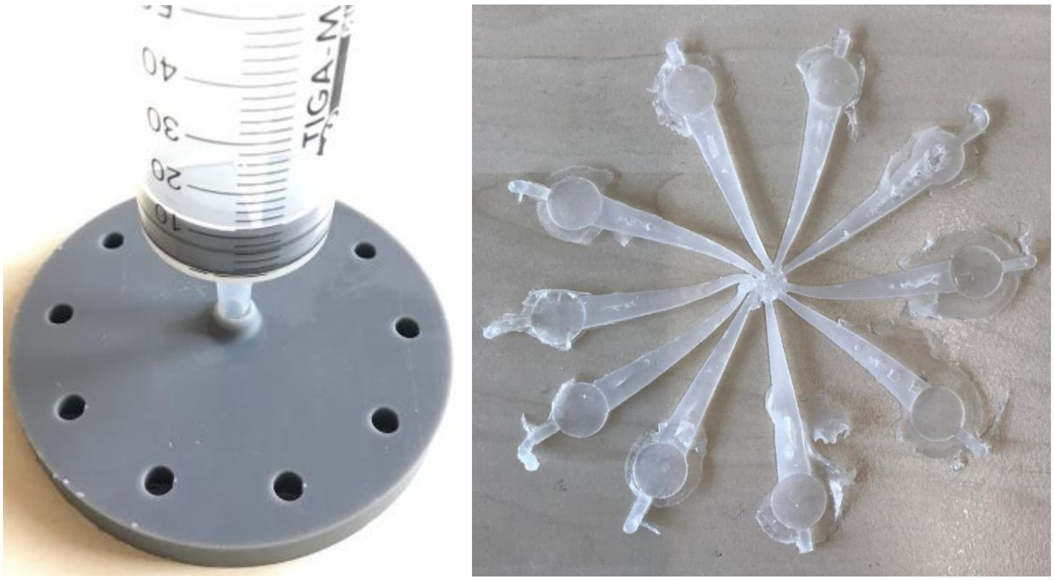


Figure 21: Silicone structure to test the properties of mask wall thickness during demoulding

2.3.5. Business coaching

Inside Manufacturing Setting 1-2-3, partners are designing a business case aiming to be adaptable and valuable for possible other disruptive crises and be financially suitable for the manufacturer partners.

The shared vision among MS partners is to provide a "bunch" of services to establish an autonomous mask manufacturing supply chain in relevant European countries, going from selling the mould design, including manufacturing instructions and technical specification for masks, moulds and materials, to provide consultancy in terms of setting up the production line and the supply chain at the customer locations.

The D3.6 reported a detailed analysis of such a business case, including the market and competitors' analysis. The next 12 months of the project will further investigate the business analysis, focusing on the financial aspects and replicability.

2.3.6. Supply chain modeling

A supply chain simulation for MS1-2-3 provides a service for SMEs to mirror regional production facilities to other regional areas while ensuring a smooth and effective operation of the supply chain. The purpose of this service is to generate a rapid design of a regional supply chain in case of increased demand of a specific product that is required in a pandemic situation. The service finds ideal settings for regional supply chains under pandemic risks, evaluates the logistics costs, and identifies bottlenecks in the regional supply chain.

The supply chain setting can be amended by specifying the location of the production unit, the supplier locations, and lead time of supply.

In order to achieve this service, FhG IML created conceptual model that identifies the basic features of the supply chain and the data requirement (Figure 22). The conceptual model has been created and validated along with the partners of MS1-2-3.

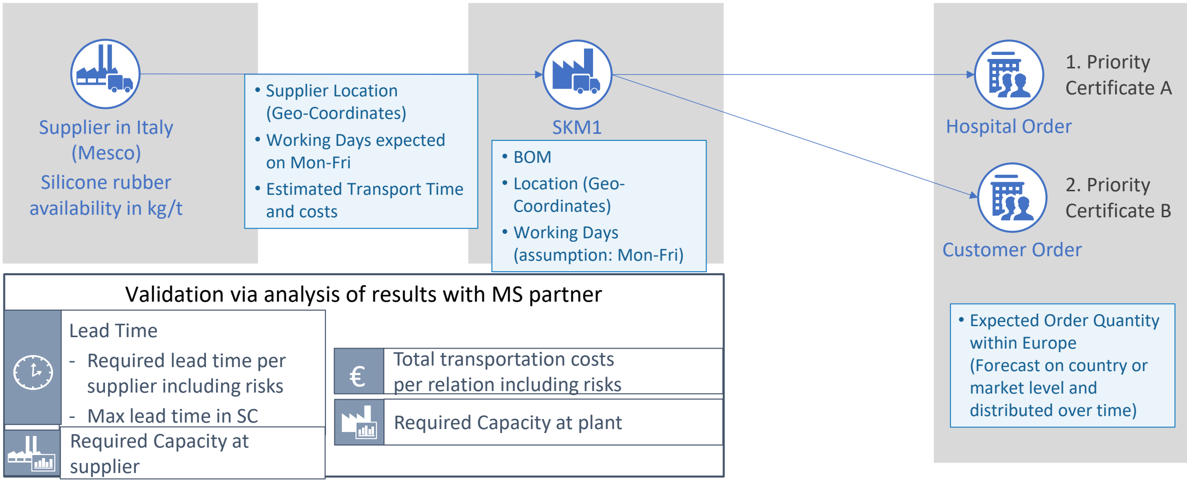


Figure 22: Masks production supply chain conceptual model

The specific supply chain settings from MS1-2-3 have been integrated into the conceptual model and transferred to the supply chain simulation tool OTD-NET. Upon the transfer of the specific data, the supply chain structure visible in Figure 23 was obtained as result. The supplier structure has two suppliers while different product quality grades have to be considered, hence, for each quality grade a specific supplier has been introduced.

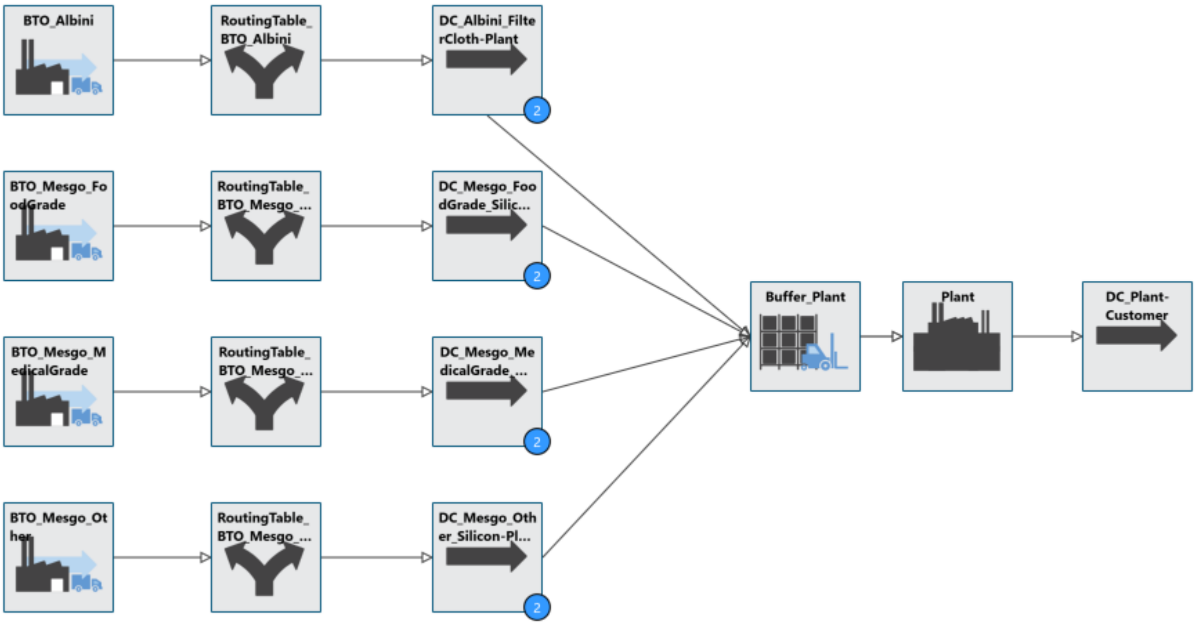
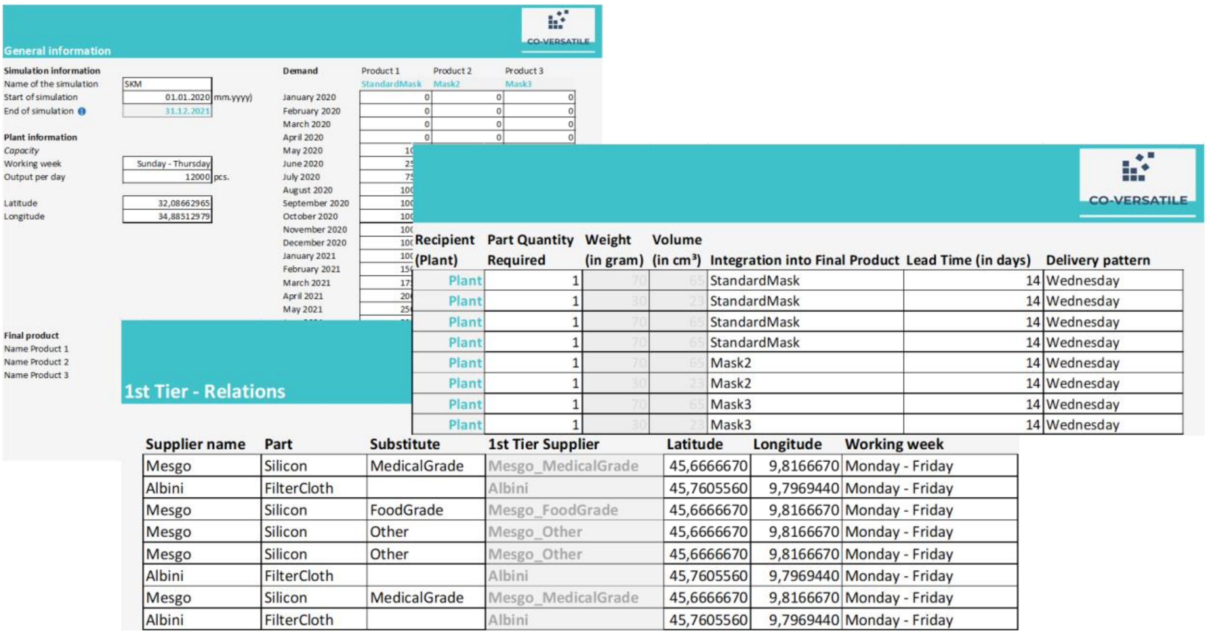


Figure 23: Supply chain structure

The simulation model includes the capacity at each supplier including working times, their geolocations (cities), the bill of material for the products, and the required supplier-plant relation. Those specific data sets are flexibly amendable via an excel interface for the user of the service. Parts of the excel are shown below.



Recipient (Plant)	Part Quantity Required	Weight (in gram)	Volume (in cm³)	Integration into Final Product	Lead Time (in days)	Delivery pattern
Plant	1	70	65	StandardMask	14	Wednesday
Plant	1	30	23	StandardMask	14	Wednesday
Plant	1	70	65	StandardMask	14	Wednesday
Plant	1	70	65	StandardMask	14	Wednesday
Plant	1	70	65	Mask2	14	Wednesday
Plant	1	30	23	Mask2	14	Wednesday
Plant	1	70	65	Mask3	14	Wednesday
Plant	1	30	23	Mask3	14	Wednesday

1st Tier - Relations

Supplier name	Part	Substitute	1st Tier Supplier	Latitude	Longitude	Working week
Mesgo	Silicon	MedicalGrade	Mesgo_MedicalGrade	45,6666670	9,8166670	Monday - Friday
Albini	FilterCloth		Albini	45,7605560	9,7969440	Monday - Friday
Mesgo	Silicon	FoodGrade	Mesgo_FoodGrade	45,6666670	9,8166670	Monday - Friday
Mesgo	Silicon	Other	Mesgo_Other	45,6666670	9,8166670	Monday - Friday
Mesgo	Silicon	Other	Mesgo_Other	45,6666670	9,8166670	Monday - Friday
Albini	FilterCloth		Albini	45,7605560	9,7969440	Monday - Friday
Mesgo	Silicon	MedicalGrade	Mesgo_MedicalGrade	45,6666670	9,8166670	Monday - Friday
Albini	FilterCloth		Albini	45,7605560	9,7969440	Monday - Friday

Figure 24: Supply chain data sets in the excel interface

The excel interface is part of the envisaged simulation modelling architecture as represented in Figure 25.

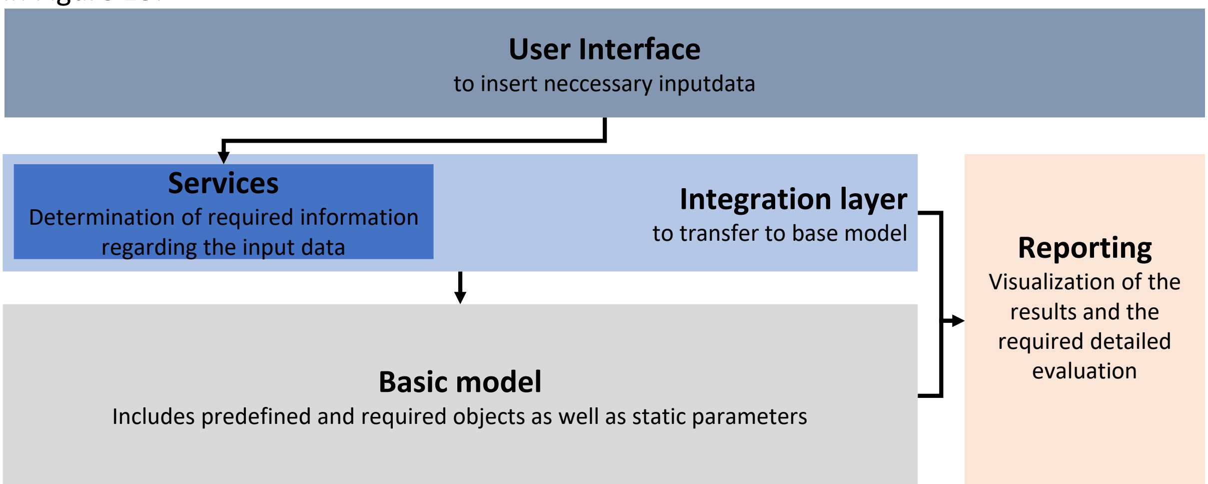


Figure 25: Simulation model architecture

Next steps will include two major components. On the one hand, it is required to define and implement the set-up of the architecture for the supply chain simulation application. On the other hand, the simulation output needs to be adjusted to the requirements. It comprises specific requests to the simulation data base and its transfer into the reporting component. The reporting component will contain a visualization of the results and a dashboard functionality. The overall setting needs then be validated by the MS1-2-3.

2.3.7. Supply chain risks evaluation

As with any supply chain, the silicone mask designed by MS1-2-3 is exposed to adverse occurrences that could be translated into negative impacts. IE has prepared an extensive and comprehensive report to better understand those risks, their likelihood of occurrence and, the identification of mitigating actions and resilience capabilities to prepare the supply chain for a quick and cost-efficient recovery. The analysis is based on the review of the existing documentation of the project, external sources of information (e.g. web, companies' reports, managerial and academic literature) and on in-depth interviews with key supply chain representative of MS1-2-3 involved in the mask design and manufacturing, as well as first-tier suppliers of the business case (silicone and filter).

The document is conceived as a "living" document that will be modified as the design and manufacturing processes evolve from prototype to final product. It is structured in two main parts. First, it presents the CO-VERSATILE mask solution: product design, process design and the manufacturing process and supply chain. Second, the industrial business case is summarized as well as the identified risks. The different risks in the business case are quantified and categorized by their risk level. Each of the involved companies are assigned a compounding risk level based on their role. Finally, risk control and mitigation strategies are offered for each of the identified risks.

The main findings of the risk evaluation are presented in tables 1 and 2. Table 1 summarizes the risks presented in the Industrial Business Case along with their likelihood of occurrence and some risk mitigating actions. Considering the risks identified in the business case and the project role of each company, Table 2 presents the compounding risks corresponding to each mask manufacturing supply chain partner. Two different criteria to obtain a global risk associated to each company are provided. The first one (Criteria A) is a combined risk and it is obtained using the formula of $RL_A = 1 - \prod_i (1 - P_i)$, where P_i is the probability associated to each risk from Figure 5. In the second criteria (Criteria B), the risk level corresponds to the highest risk associated to each company of Figure 5.

Table 4: Assessment of the risks identified in the business case

Risk Ref.	Risk Identified	Likelihood	Impact	Risk Level(1)	Risk Control and Mitigation Strategy
BC.1.1	Mask manufacturing process (complexity and flexibility)	Very low 0.10	Low 0.10	Low 0.01	1. Small workshop sessions with the involved workforce performed in advance 2. Advance study of the demand of each mask size to adapt production accordingly 3. Manufacture using half of the mould to meet the demand
BC.1.2	Mask manufacturing – mask transportation	Very low 0.10	Very Low 0.05	Low 0.01	1. Continuous monitoring of drivers' availability and infrastructure conditions 2. Identification of alternative options if a disruption occurs
BC.2.1	Silicone supplier – capacity of the raw silicone and additives supplier	Very low 0.10	Very low 0.05	Low 0.01	Advance planning and pre-arrangement with the silicone compound supplier (MESGO)
BC.2.2	Silicone supplier – transportation of the silicone compound with hot weather	Very low 0.10	Very low 0.05	Low 0.01	Securing transportation capacity in advance is desirable, especially if transportation occurs during the summer months and refrigerated trucks are needed
BC.2.3	Filter supplier – non-woven certification	Low 0.30	Moderate 0.20	Moderate 0.06	1. Immediate start cooperation with A.L. GROUP to certified filters according to the requirements of a FFP2 certified mask 2. Alternatively, find a filter supplier with already FFP2 certified filters
BC.2.4	Filter supplier - meltblown dependency	Very low 0.10	Moderate 0.20	Moderate 0.02	1. Understanding of A.L. GROUP supply chain related to the meltblown layer 2. Assure that the meltblown material used by A.L. GROUP is FFP2 certified
BC.2.5	Transportation of filters and silicone compound – port and border disruption in Israel	Very low 0.10	Low 0.10	Low 0.01	1. Continuous monitoring of the port and border situation 2. Identification of alternative transportation mode if a disruption occurs

Risk Ref.	Risk Identified	Likelihood	Impact	Risk Level[(1)]	Risk Control and Mitigation Strategy
BC.2.6	Alternative: Filter supplier - cloth certification	Very high 0.90	High 0.40	Critical 0.36	1. Identification of an alternative supplier with the certification of the final product requirements 2. Advance planning and pre-arrangement with the filter provider
BC.2.7	Alternative: Filter supplier – cloth cutting and preparation	Medium 0.50	Low 0.10	Moderate 0.05	1. Automatize the cutting of the cloth filter 2. Ask ALBINI to supply already pre-cut filters

(1) Refer to risk matrix detailed in *Annex section*

Table 5: Assessment of the global risk corresponding to each partner of the business case supply chain

Company	Role	Risk Level Criteria A – Compound risks	Risk Level Criteria B – Highest risk	Main impact	Main mitigation actions
SKM Aeronautics Ltd.	Mask manufacturing	Low 0.01	Low 0.01	Existing threat of not meeting the demand corresponding to both masks sizes	Forecasting regarding the two different sizes of masks
MESGO compounding solutions A HEXPOL COMPANY	Silicone compounder supplier	Low 0.01	Low 0.01	Small delay in the business case if the required amount of silicone cannot be provided	Advance planning with MESGO to secure the amount of silicone needed
A.L.GROUP	Non-woven filter supplier	Moderate 0.07	Moderate 0.06	The fact that the provided filters are N99 certified but not FFP2 will delay the desirable FFP2 certification of the silicone mask to use for the business case	Look for an alternative FFP2 filter provider
Albini GROUP	Alternative: cloth filter supplier	Critical 0.39	Critical 0.36	Working with a cloth filter will effectively jeopardize any type of certification	Look for an alternative FFP2 filter provider

In the next stage of the research, and based on the work performed up to date, the risks associated with a future pandemic stage will be evaluated in detailed.

2.3.8. Training

The training package that has been developed for MS 1-2-3 aims at developing a manual for maintenance and operation in 3D-PDF format. This manual will be supplied as a useful tool to support new employees in the correct use of the moulding machine targeted in MS1-2-3. ORP, MLE and SKM have been collaborating with HSSMI towards the development of a 3D-PDF template that includes information on both the mask and the moulding process, as shown in Figure 26 and Figure 27.

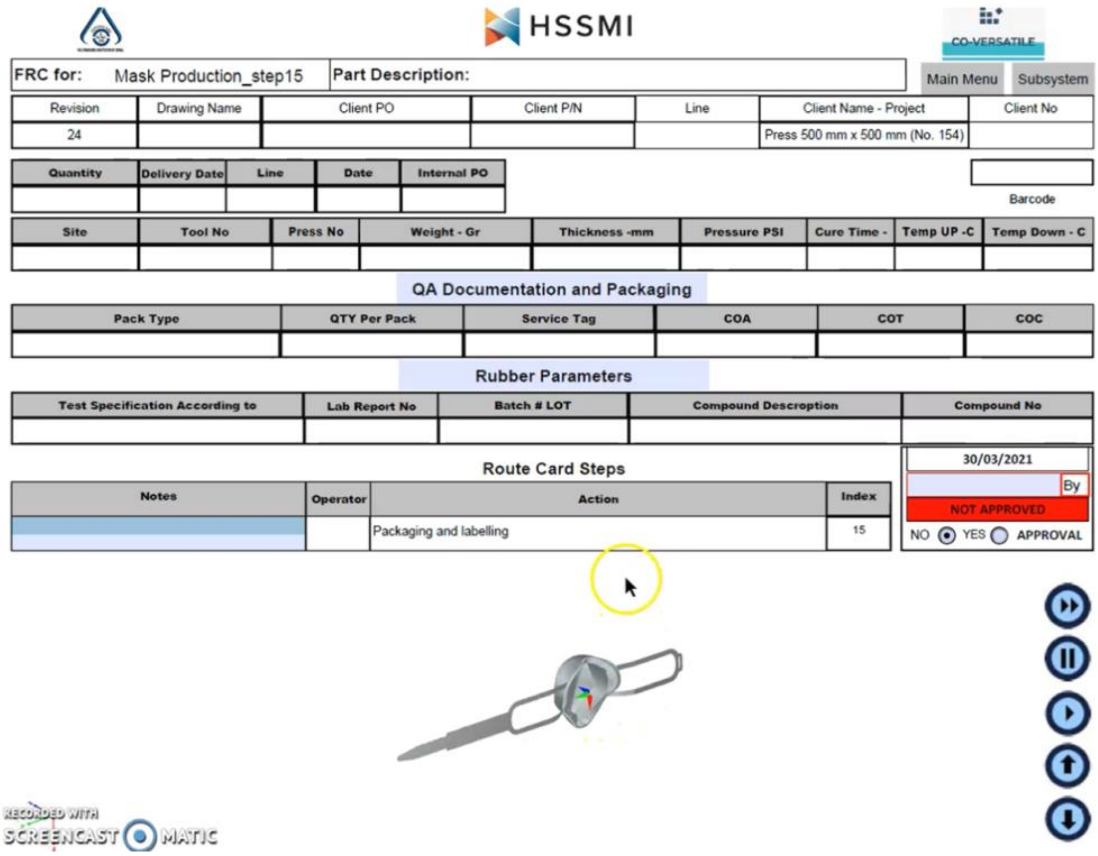


Figure 26: First MS1-2-3 template draft of the 3D-PDF

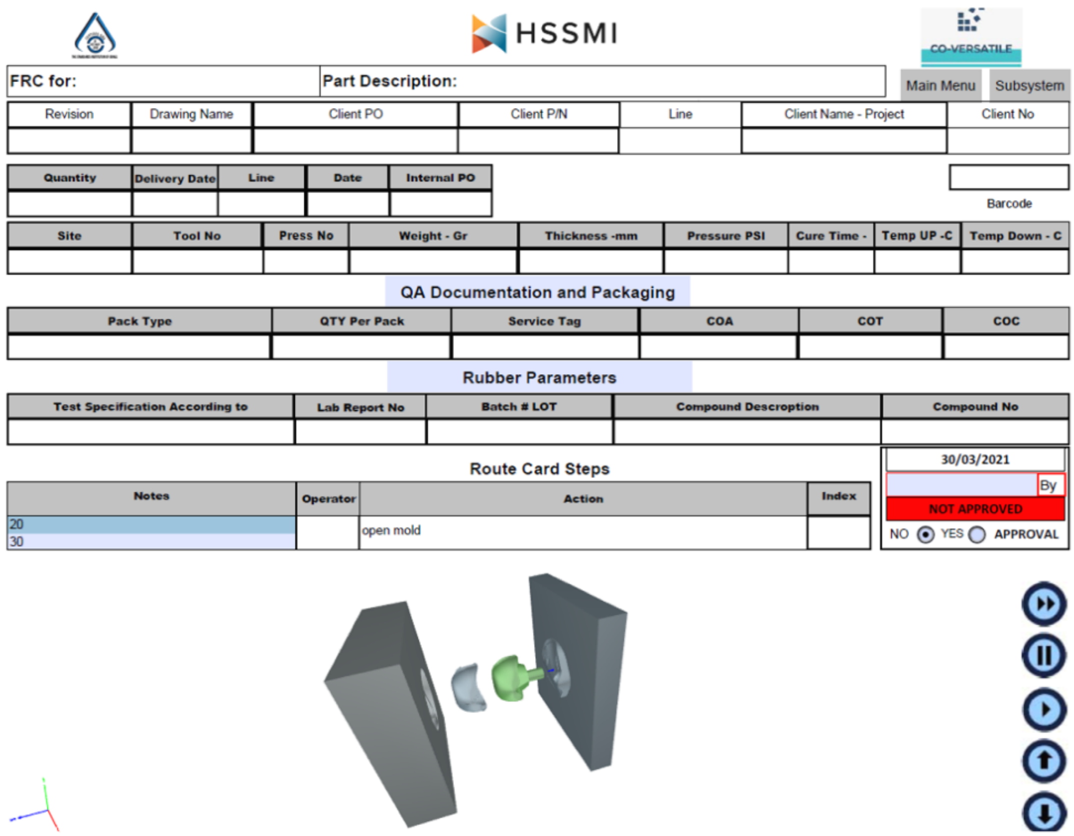


Figure 27: MS 1-2-3 3D-PDF template showing the mask mould

Step-by-step instructions for the mask moulding are being integrated in the template, to better support the operators with clear instructions towards the correct execution of the complete moulding process. In the second half of the project, the training material will be finalized and tested on-field with real workers.

2.3.9. Key Outcomes of the 1st—4th Build, Measure and Learn Cycles

1st B-M-L cycle

Prototype/product:

- Process simulation model requirements established
- First version of the mask designed and 3D printed
- Butterfly mould (1,2, and 4 cavities) designed
- First texture of the negative mask surface proposed

Supply chain:

- First version of supply chain model for MS3 mask ready

Training, certification and standardization:

- Identification of certification needs: either PPE or respiratory device

2nd B-M-L cycle

Prototype/product:

- Initial process simulation trials with preliminary mask design
- Proper injection process modelling approach established.
- 3D prototyping with surface texture
- 3D prototyping of moulds

Supply chain:

- Simulations + first risk assessment

Training, certification and standardization:

- Discussion about PPE vs surgical/medical mask
- Build-up of 1st training 3D-pdf
- Fixing of Certification, business modeling, IPR strategy

Communication/dissemination

- Identification of topics for communication and dissemination

3rd B-M-L cycle

Prototype/product:

- Macros for material model adjustments for process simulation prepared
- Finalized mask size, lace design, texture positioning
- Filter cloth tests: die-cutting and breathing
- Direct 3D printing of textured rubber and plastic (thermoset) prototypes
- 3D printing of textured resin molds and casting of textured silicon products
- Molding simulation material and rheology models defined

Supply chain:

- Risk analysis report available
- Supply chain model available

Training, certification and standardization:

- Draft business model available

4th B-M-L cycle

Prototype/product:

- Material characterization tests of the selected silicone rubber for process simulation
- Mask design has been defined and accepted
- Made progress with mould design details
- New design pictures of the mask were presented

Supply chain:

- Analysis of risk probabilities to include them in the supply chain simulation analysis report

Training, certification and standardization:

- Creation of the business model canvas

2.3.10. Plans for the 5th – 8th Build, Measure and Learn Cycles

Product:

- Finalize the mould design: plate arrangement, definition of mold parting lines, insert design, injection points for mask body
- Start manufacturing of the mask

Process:

- Update the injection process simulation model with the final geometry of the mask and mould design.
- Define moulding parameters and ranges of interest.
- Perform DOE of simulations and analyse the results.
- Create reduced order models (ROMs).
- Adapt a user interface (UI) for the created ROMs.

Upscaling:

- Upload the UI and created ROMs in the cloud as a service.
- Further investigation of all aspects of the business model canvas
- Detailed evaluation of the risks associated with a future pandemic
- Define and implement the set-up of the architecture for the supply chain simulation application
- Adjust the simulation output to the specific MS1-2-3 requirements

3. Manufacturing Setting 4 – Electrostatic Disinfectant Spray Systems

3.1. CO-VERSATILE partners involved in MS4

Participating partners and their role:

Experiment owners:

TECNOSTATIC, Manufacturing Partner: specification and design of the spraying system

contact persons: Cristóbal Rodríguez (info@TECNOSTATIC.es)

Service and technology providers:

IML, supply chain simulation for raw material requirements,

contact persons: Saskia Sardesia (Saskia.Wagner-Sardesai@iml.fraunhofer.de)

STAM, automatic quality control

contact persons: Marco Barbagelata (m.barbagelata@stamtech.com)

ITA, research in the development of the spray system and the battery pack, involvement in first design cycle

contact persons: José Manuel Bielsa Gimeno (jmbielsa@itainnova.es)
Fernando Arteche (farteche@itainnova.es)
Mario Miana (mmiana@itainnova.es)

Business coaching:

HSSMI, virtual environment for training of manufacturing and customers with digital content

contact persons: Katarina Deme (katarina.deme@hssmi.org)

SUPSI

contact persons: Marzio Sorlini (marzio.sorlini@supsi.ch)
Riccardo Canavesi (riccardo.canavesi@supsi.ch)

3.2. Overview of the Manufacturing Setting

In the midst of the COVID-19 pandemic, time quickly became one of the key life-saving factors. Patients depended on prompt diagnosis and often instantaneous interventions and therapy. Emergency units, ambulances and other hospital facilities required immediate disinfection to be prepared for new patients to receive the right care safely and at the right time.

The speed of the virus spread immediately moved safety and infection prevention measures to the top of the agenda. As a result, most European countries experienced spikes in demand for professional disinfection and cleaning products. Infection prevention became mandatory not only in hospitals but also in care homes, on public transport, in schools, gyms and at many other public places.

MS4 is lead by TECNOSTATIC, an SME providing non-contact disinfection solutions against different types of microorganisms (viruses, bacteria, fungi, etc.). Its products include both surface and aerial disinfection systems based on advanced electrostatic spraying technologies. MS4 focuses on technologies and product design processes for developing and scaling up non-contact disinfection spray systems based on already existing electrostatic spraying innovation from TECNOSTATIC. This unique electrostatic spraying technology

reduces the disinfection time from a few hours to just a few minutes. Electrostatic disinfection is environmentally friendly and requires only 35% of chemical disinfection products in comparison to traditional spraying systems.
MS4 partners are working together to build a solution for a local European production that can rapidly address surges in demand at times of crises. The following results are expected to be achieved:

- Develop and scale up the production of disinfectant spray systems using the components of the regional and European supplier networks;
- Set up supply chain network design in Europe to ramp up production with a specific focus on the evaluation of lead times required by suppliers;
- Incorporate sourcing of alternative components and parts in Europe;
- Further improve the design of the spray system and the battery pack by means of computational simulation.
- Support the end user of the spraying device with a virtual how-to-guide, with considerations to health and safety in the handling of chemicals.

3.3. Activities performed during the first year of the project

In the following sections, the main activities performed in the first 12 months of the project concerning MS4 are presented, detailing all technical developments and main achieved results. The basis for the activities to be performed in the second half of the CO-VERSATILE project are also introduced.

3.3.1. Numerical CFD simulations of spray system

For the analysis and optimization of the spray nozzle design and to define the pump capacity, ITAINNOVA has used CFD simulation as main computational design tool. Ansys-Fluent software, a commercial Computer-Aided-Engineering (CAE) tool, has been used in the firsts part of the project. The use of expensive commercial computational simulation software, though, requires a lot of computing resources to develop models and run simulation methodologies for the CFD analysis. For this reason, in the future phases of the project, ITAINNOVA will convert these solutions into more accessible engineering tools, using more widely used environments such as MS-Excel / Python / etc. This will be achieved in the context of the CO-VERSATILE Digital Technopole and DIH environments.
In particular, the DIH platforms may help ITAINNOVA in scaling up their simulation services to a wider business sector, outside the CO-VERSATILE industrial partners. The work performed on the spray system, to optimize the product and improve and adapt the manufacturing process, will allow to develop generic simulation and design tools that will be made available in the Digital Technopole. DIHs will support in disseminating the obtained results, so that manufacturing SMEs and Midcaps throughout Europe can use and take advantage of these tools in their own processes. In particular, the CFD models and methodologies/workflows (through ROMs or apps) developed for the optimisation of spray systems could be used by SMEs and companies manufacturing other types of spray systems, such as lubricant nebulisation systems.
In the first months of the project, ITAINNOVA achieved the setup of a preliminary physical bi-phasic model (air-water) for computational CFD simulation of the spray nozzle, with reasonable computational cost levels and avoiding numerical convergence problems. As planned, these preliminary simulations were done using commercial CFD software (Ansys-Fluent) and ITAINNOVA 's own computing hardware. According to the first CFD simulation

results, preliminary critical areas in the nozzle design were identified (Figure 28). In addition, the main KPI parameters of the spray nozzle to be measured experimentally in laboratory tests (air pressures, mass flow rates and temperatures) were successfully identified.

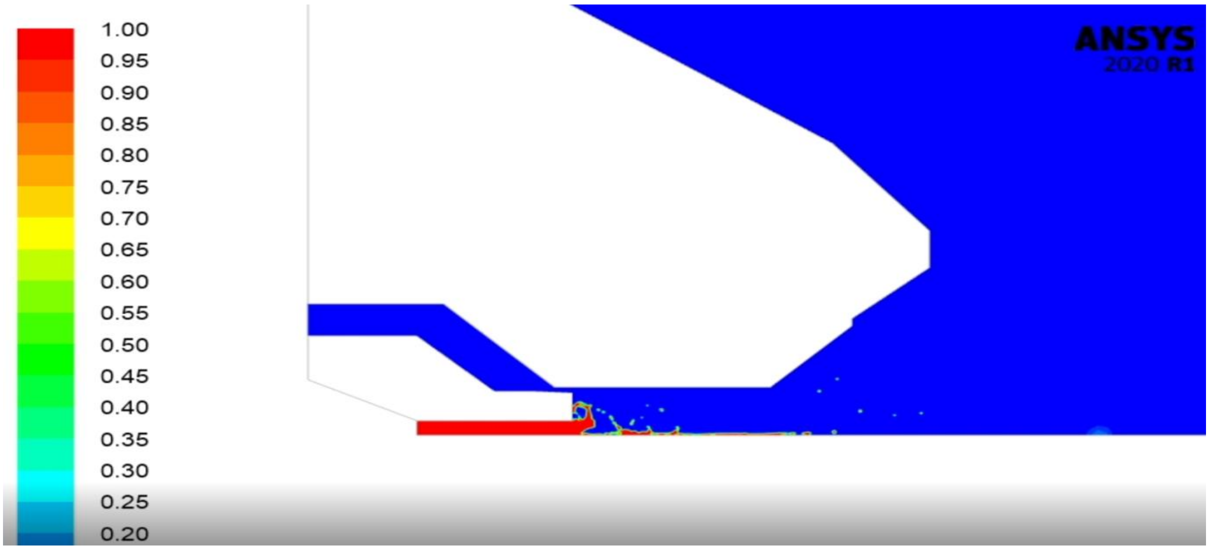


Figure 28: Preliminary fluid-air mixture CFD results results in MS4 spray nozzle

The conclusions drawn after these first simulation activities were the following:

- Improvement was needed on computational CFD model for better accuracy and computational efficiency, according to experimental measurements done on spray nozzle and used as input in CFD simulations.
- Improvement was required on spray gun design to optimize efficiency (cross-section and air flow requirements), according to critical areas detected in CFD simulation

In the following activities, ITAINNOVA achieved the improvement of the CFD simulation model of the spray nozzle, including both geometries of MVP from 1st B-M-L cycle and of the improved one designed by TECNOSTATIC for the 2nd B-M-L cycle with the conclusions drawn from the preliminary CFD analysis.
In the improved simulation procedure, the flow transport equations are solved iteratively. The results provide a comprehensive description of the distribution of water and air inside of the spray gun, the fluid velocities, and the pressure along the simulated regions. However, computational efficiency was lower than expected.

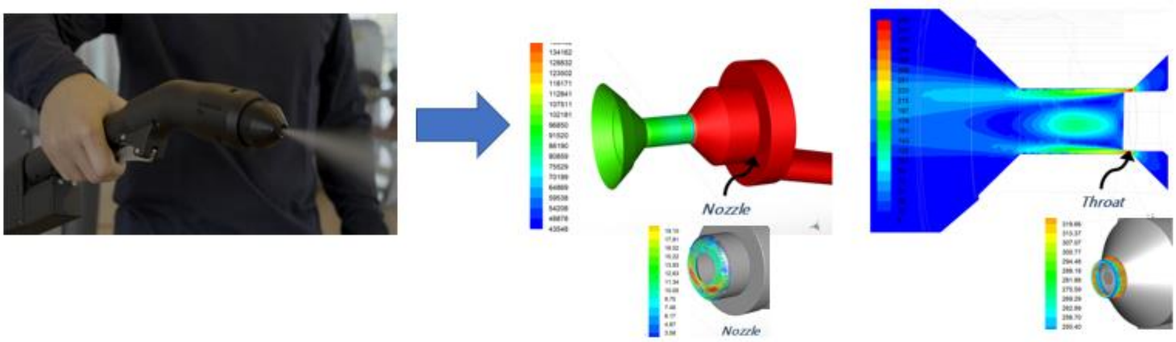


Figure 29: CFD results in MS4 spray nozzle, 2D to 3D modelling

It was then identified that the improvement of the computational efficiency of the CFD model needed some additional technical tasks:

- Bibliographical review of the SOA in spray nozzle analysis.
- Development of improved CFD flow simulation model, based on a mixed VOF (*Volume Of Fluid*)-to-DPM (*Discrete Particle Method*) modelling scheme.

After the SOA review, the flow variables and the non-dimensional numbers that characterize the flow behaviour inside the nozzle were identified in Table 6:

Table 6: Flow variables that characterize the flow behaviour inside the nozzle

Parameter	Definition	Value
U_w	Water velocity	2.6461 m/s
U_a	Air velocity	320 m/s
ρ_w	Water density	998 kg/m^3
ρ_a	Air density	2.8839 kg/m^3
μ_w	Water viscosity	0.0010016 Pa·s
σ_w	Water surface tension	0.0728 N/m
T_{spray}	Spray temperature	20 ºC
$\dot{m}_w$	Mass flow rate of water	0.002072 kg/s
$\dot{m}_a$	Mass flow rate of air	0.001817734 kg/s
A_{Throat}	Cross – section area of the throat	1.9697·10^{-6} m^2
D_w	Diameter of the water tube	0.001 m
$m = \frac{\dot{m}_w}{\dot{m}_a}$	Water / Air flux ratio	1.14
$M = \frac{\rho_a U_a^2}{\rho_w U_w^2}$	Momentum flux ratio	42.3
$VR = \frac{U_a}{U_w}$	Velocity ratio	120.9
$Re_w = \frac{\rho_w U_w D_w}{\mu_w}$	Water Reynolds number	2646
$We = \frac{\rho_a D_w (U_a - U_w)^2}{\sigma_w}$	Weber number	3990
$Oh = \frac{\mu_w}{\sqrt{\rho_w \sigma_w}}$	Ohnesorge number	0.00371

Following the information extracted from references [1], [2] and [3], the tendencies followed by each dimensional number were also predicted and are discussed below.

Effects of the increment of the air flow rate

The increment of the air mass flow rate increases both the Weber number and the momentum flux ratio. On the contrary, the Sauter Mean Diameter (SMD) of the droplets is decreased, so it yields finer atomization, resulting in larger number of particles. The evolution of the SMD along the center line shows that SMD is augmented up to a certain distance, because smaller particles are easily dispersed from the jet center, see figure 4 in [1]. To sum up, the increment of the air mass flow rate has two opposite effects: improvement of the atomization but deterioration of the rate of spread of droplets.

For this reason, a compromise solution must be found between the improvement of atomization and the right mixture of liquid and gas phases in the zones near the nozzle. In zones far away from the nozzle, the differences with respect to the rate of spread of droplets are reduced because sprays with larger air flow rate are wider due to the expansion of the gas phase. A final comment must be done. The current spray system analysed in CO-VERSATILE project is characterized by flow variables that are twice the ones reported in [1], increasing the complexity of the simulation. Then, it is mandatory to study from numerical simulations if the increment of the air flow rate still improves the atomization while the deterioration of the rate of spread of droplets is affordable.

Effects of the increment of the water flow rate

The increment of the water has a negligible influence in the *We* number, but it significantly reduces the momentum flux ratio. These effects are then translated in a worse atomization. But an increment of both variables (*We* and *M*) improves atomization. The increment of the water flow rate slows down the droplets at the center line, so the jet breakdown distance is augmented.

The increment of the water velocity implies a reduction of the relative velocity between air and water. The decrement of the relative velocities means worse atomization. According to Fig 5 in [2], the increment of the liquid velocity increases the SMD. However, when liquid velocities tend to 0, atomization is worse too. Therefore, intermediate velocities minimize SMD. Moreover, as water/air flux ratio is augmented, SMD is more sensible to the increments of the water velocities.

The rate of spread of droplets is affected too by the liquid flow rate, since larger droplets are obtained and the dispersion of them from the centerline is more difficult. In faraway zones from the nozzle, large droplets affect negatively to the mixture due to their worse rates of spread and dispersion.

Effects of the decrement of the diameter of the tube of water

The atomization device analyzed in the Co-Versatile project has a diameter of 1 mm. In [2], the diameter of the tube is reduced from 2.3 mm to 1.1. mm. Consequently, atomization is improved by 25 %, but the rate of spread is reduced by 20 %. A compromise solution must be found between these opposite tendencies. Fig 3 in [2] shows that there is an optimum diameter that minimizes SMD for several water/air flux ratios.

Large tube diameters are adverse for atomization. For example, particle diameters are proportional to the diameter of the liquid jet [3].

Effects of the relative position between the liquid and air tubes

The water tube is ahead of the air tube in the atomization device studied in the CO-VERSATILE project. In [2], the water tube is located at 0, 2 and 3 times its diameter behind of the air tube. For all cases, atomization is reduced, being larger as the tube is put back and as the velocity ratio is increased. Besides, the rate of spread of the spray is improved by 40 % when the liquid tube is moved behind.

Effects of the shape of the nozzle

Convergent nozzles improve both the atomization and the rate of spread compared to concentric tubes. In [2], a convergent nozzle of 28º is studied with velocity ratios of 24 m/s and 41 m/s. Further increments of the velocity ratio do not improve the atomization and even, the rate of spread next to the nozzle is worse.

Atomization regimes

Ref [3] points out that atomization is preferred when the liquid jet velocity is between 1.5 and 4 m/s and the regime is in the fiber type zone. Fig 2 in [3] defines the different zone types in terms of the Re_w and We numbers. Form the values of the current design (Re_w = 2646 and We = 3990), it can be concluded that the analyzed device operates inside of the fiber type zone.

Regarding the development of the numerical simulations to study the flow pattern in the current design, the use of a novel numerical tool has been proposed based on a mixed VOF-to-DPM model. This model converts detached liquid lumps to discrete particles that captures the liquid and air interactions when the liquid phase has a diameter larger than a reference value. The mesh has then been adapted to capture the liquid – gas interfaces, but when the liquid lump is under the reference diameter, the liquid is converted into a discrete particle, allowing larger mesh sizes. The new mixed modelling showed the following list of pros and cons:

- Advantages:
  - It captures all physical interactions between liquid and gas phases for lump diameters larger than the reference value.
  - A large scientific knowledge is available for the simulation of discrete particles in similar flow patterns.
- Disadvantages:
  - Large effort to build proper orthogonal 3D mesh
  - Large computational resources to capture time and length scales of liquid – air interfaces larger than the reference diameter.

For the current design, a poly-hex core mesh composed of 1.217 millions of cells has been built as shown in Figure 30.

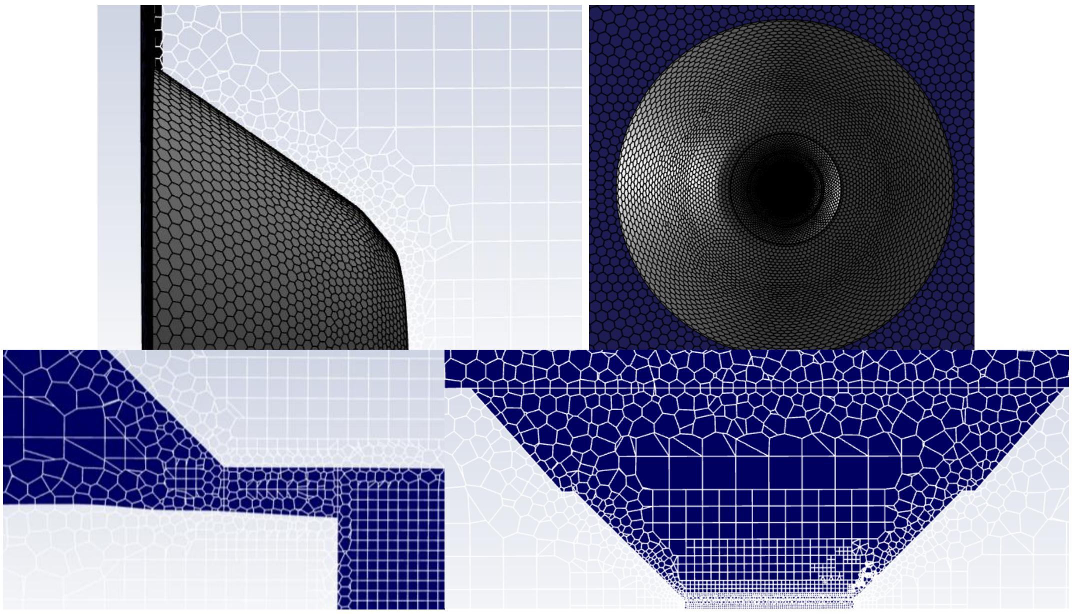


Figure 30: Views of the polyhex core mesh for the analyzed nozzle.

The simulation of 0.0023 seconds took more than 20 days running on 16 CPUs of a computer server. Figure 31 shows the results obtained at this time by means of the contours of velocity magnitude, pressure, and volume fraction of liquid.

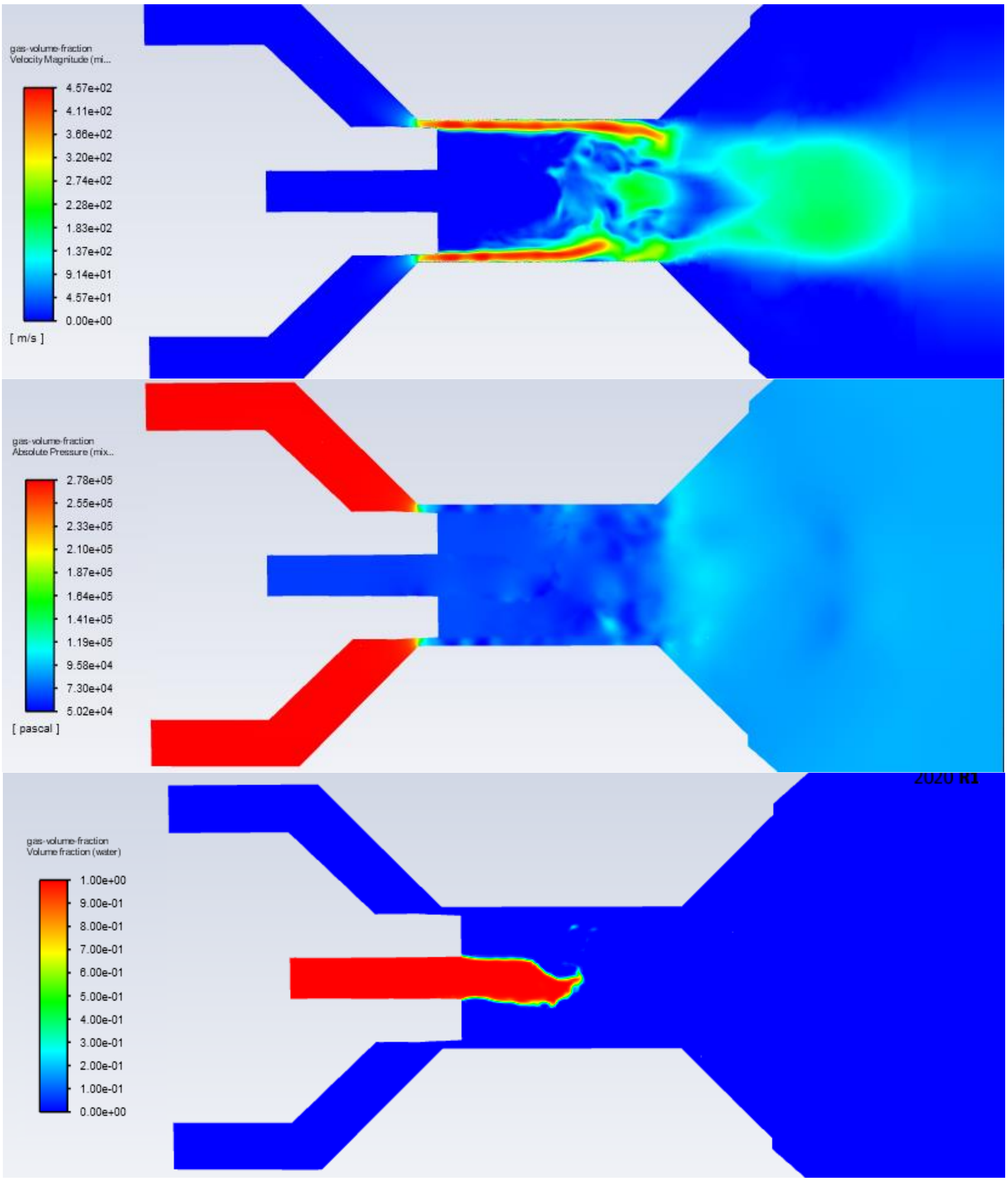


Figure 31: Contours of velocity magnitude (top), pressure (centre) and volume fraction of liquid (bottom) at 0.0023 s.

The mesh was automatically adapted to capture accurately the liquid/gas interface. At this moment, the numerical model which converts the detached liquid lumps into discrete particles is enabled. However, convergence problems have arisen, and no significant advancements were achieved. These type of numerical issues are common when using recent developed models. Mesh adaptation and motion of droplets are quite mature models, but the coupling from detached liquid lumps into discrete particles is a recent feature which is not yet fine-tuned. The documentation from the technical support of the software is scarce so it is difficult to know the influence of critical variables in such numerical problems.

In addition, the computational time required to get a statistically converged solution resulted to be larger than 1 month for each design.
It is worth remembering that the objective of the project is to develop numerical tools to predict the atomization under different operating conditions, considering some ranges for critical dimensions of the nozzle. This predictive tool is based on ROMs, which require results from many simulations. Therefore, the large computational time of every VOF-to-DPM simulation makes it unaffordable to fulfil the necessary DOE and a new simulation strategy will be proposed in the second part of the project.

3.3.2. Design and building of high voltage power supply card prototype

In the case of the design of the battery pack, simulations have been used for supporting the prototype design using the commercial software Cadence. Regarding the design of the power pack, ITAINNOVA has worked on the integrated power pack design, development and prototyping. The development of the final spray system is based on three important challenges: high energy/power densities, integrated topology and intelligent regulation of the energy. During the course of the project, these challenges are analyzed in detail by simulations models in order to fulfill all technical specs. Four main tasks are tackled in the project:

- *CFD models development:* It aims at improving the spray system and adapt its manufacturing process.
- *Development of quasy-dynamics energy model of the final system*: It aims at evaluating the electrical energy / power demanded by the actual unit and to evaluate the energy/power density of the unit to select the proper battery and power system characteristics (topology and technology).
- *Battery pack design and development:* The battery pack is designed and developed based on energy model simulation. The selection of the number cells and power/ operation voltage will be based on the technical report.
- *Prototype development*: It is based on previous simulations. It will integrate several power converters that operate at different voltages and power levels in a single unit. The prototype design will be based on simulations performed with Cadence Tools. Later, a prototype of this unit will be manufactured in order to perform some test.

In addition, ITAINNOVA also has designed and built the hardware of the first prototype of the high voltage (HV) electronic card of the electrostatic spray system. The design phase of the HV electronic card has been first carried out by means of computational simulation of the energy model of the autonomous electrostatic spray system.

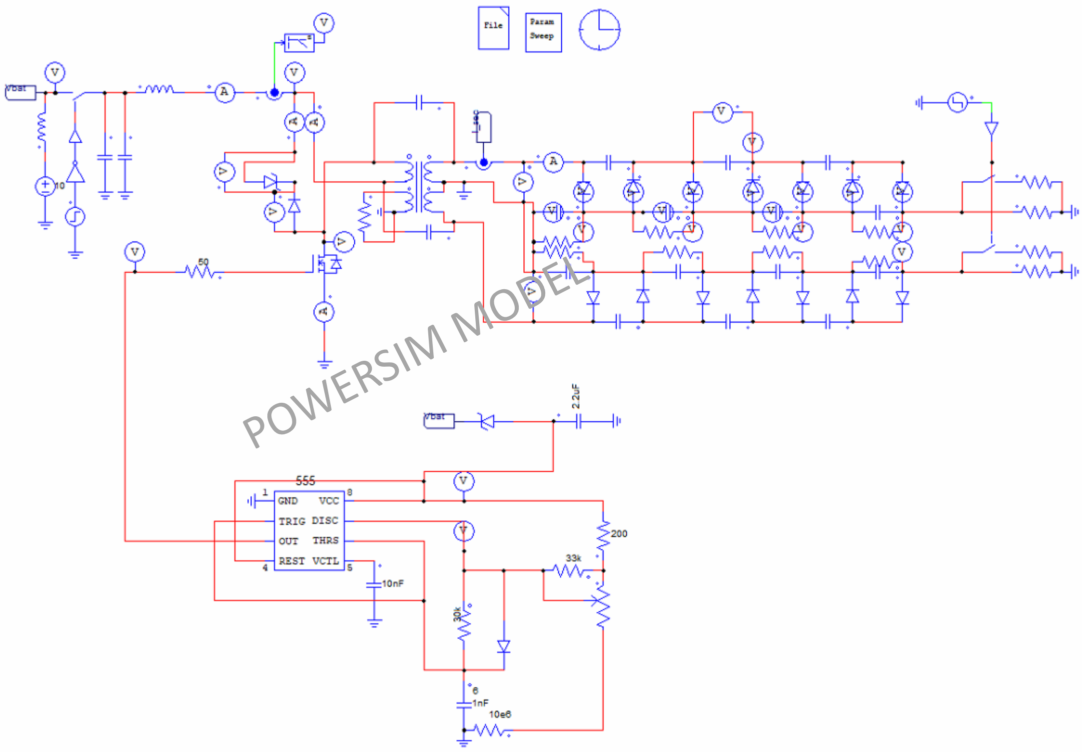


Figure 32: HV power supply simulation design phase

With the energy model, it has been possible to design and simulate the HV card for an adjustable output (amplitude and polarity). The aim of this design requirement of the HV card prototype is to be able to ease the design and optimisation of the rest of the spray system components by providing different combinations of amplitude and polarity of output voltage.

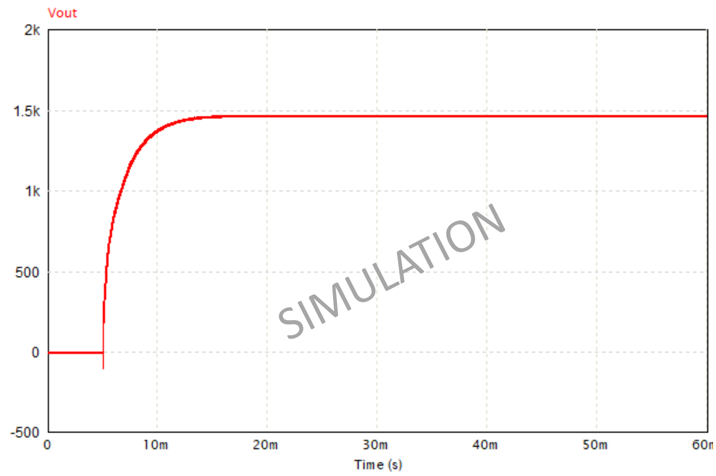


Figure 33: HV card output results in energy model simulation

After the design phase of the HV card, a hardware prototype has been also built (Figure 34) with the help of CAE tools, starting from the layout designed with the energy model.

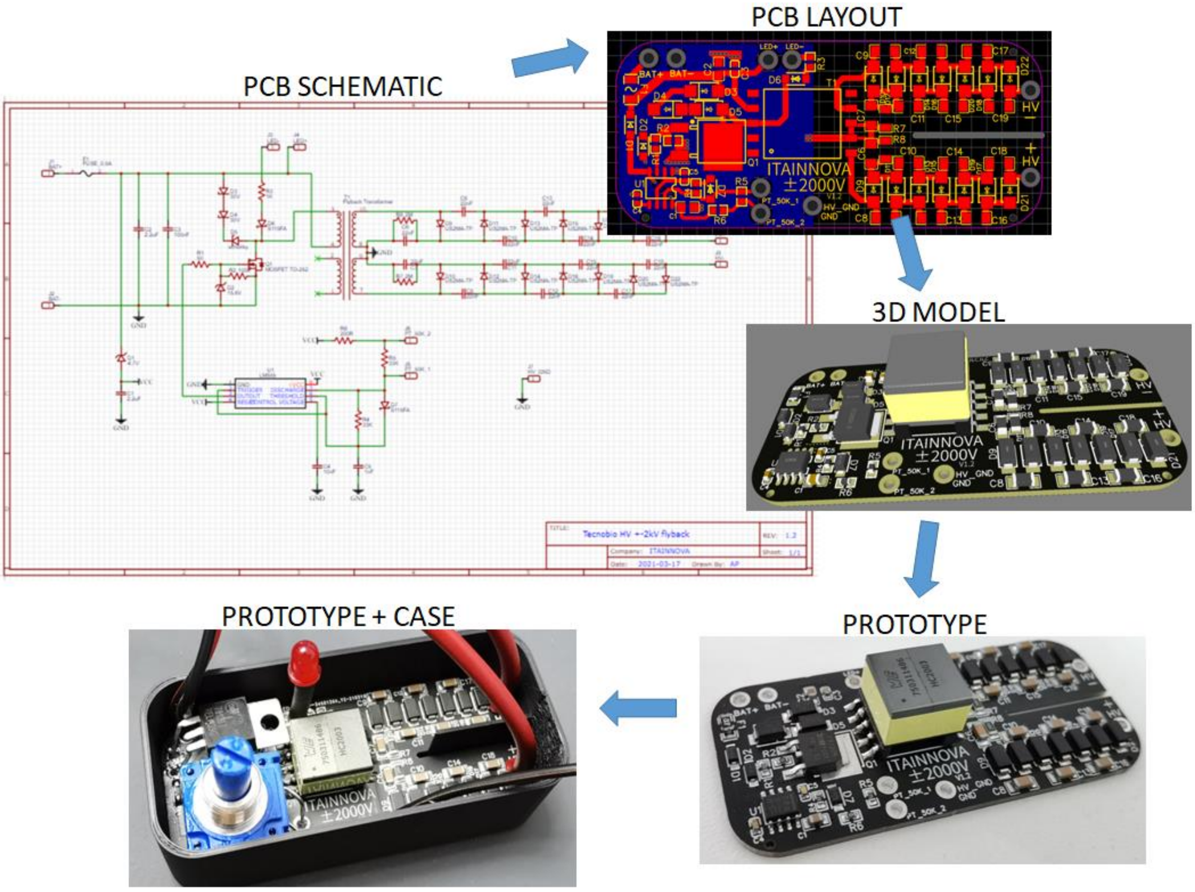


Figure 34: HV card prototype design and hardware building

The hardware prototype of HV card has also been measured experimentally to validate its design by obtaining correlation of the output voltage between simulation values with energy model and the experimentally measured ones, as shown in Figure 35.

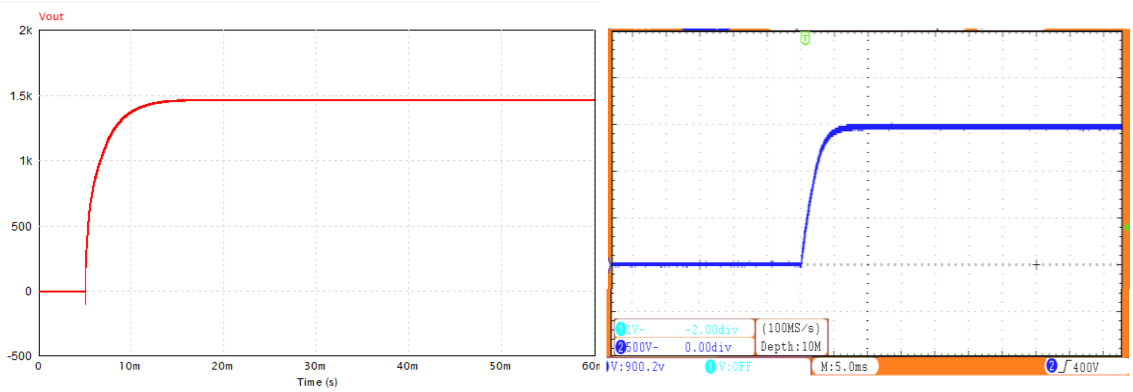


Figure 35: HV prototype card validation: simulation (left) vs measurement (right) of output voltage

Conclusions drawn at the end of the experimental-numerical analysis of the spray system have shown that a downsizing of the design is possible, from “portable” to “autonomous”, especially in terms of spray nozzle design and compressor size downscaling, keeping the rest of the flow parameters (coverage) similar in both cases. It was also possible to show a promising reduction in production costs and times and the possibility to upscales on manufacturing volumes.

3.3.3. Design and build of backpack prototype

In parallel with the simulation activities described above, the backpack prototype has been designed and realized. This activity has been performed in an iterative process of improvement, receiving inputs from the CFD simulations and providing valuable experimental outputs to improve those simulations. Following this process, two backpack prototypes have been designed and built so far and a third one is currently being investigated.
The first part of the activity was focused on the identification and selection of the backpack components, performed by TECNOSTATIC, both from European and International manufacturers. In particular, the focus was on the investigation of suppliers for the batteries and compressors. TECNOSTATIC performed a testing campaign on different batteries to achieve better performance, increase their lifetime and minimise the size of the compressor, i.e. to find an optimal solution to reduce the spray flow.
Following this preliminary research and testing of components, a first prototype of the autonomous spray backpack has been designed and produced (Figure 36).

Figure 36: First backpack prototype

With the first prototype available, a set of functionality and performance test have been run. In parallel, the study of the new and improved backpack design was kicked-off. TECNOSTATIC started working on a new nozzle to avoid dropping or at least minimize drops, while continuing the research and testing of fast charging batteries and compressors. It resulted that all high-quality compressors are manufactured outside EU, while some suppliers of fast charging battery were identified in Spain.
Towards the realization of the second backpack prototype, the design of the components' layout was performed, together with the analysis of different types of nozzle existing in bibliography, studying sensitive parameters affecting venturi effect. The HV power supply card was also added to the backpack design, in order to check its performance.
From the first prototype, the following modifications have been performed:

Pistol

The size of the gun has been reduced and the valve for the manual trigger of the gun has been replaced with an electro valve, as shown in Figure 37 and Figure 38.

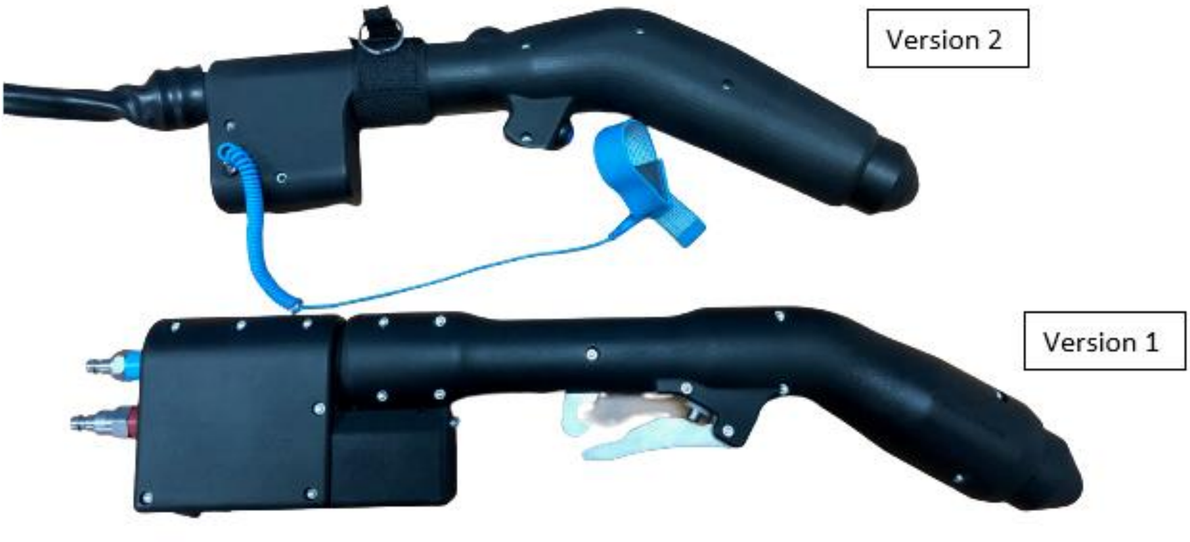


Figure 37: Comparison between first and second version of spray gun

Figure 38: The spray gun is actuated with an electrovalve in the second prototype

In addition, the 9V batteries that powered the gun have been eliminated and power is now supplied to the gun directly from the machine's battery. In this way space is saved and two components, the charger of the 9V batteries and the batteries themselves will not be necessary. Figure 39 shows the old design from the first prototype.

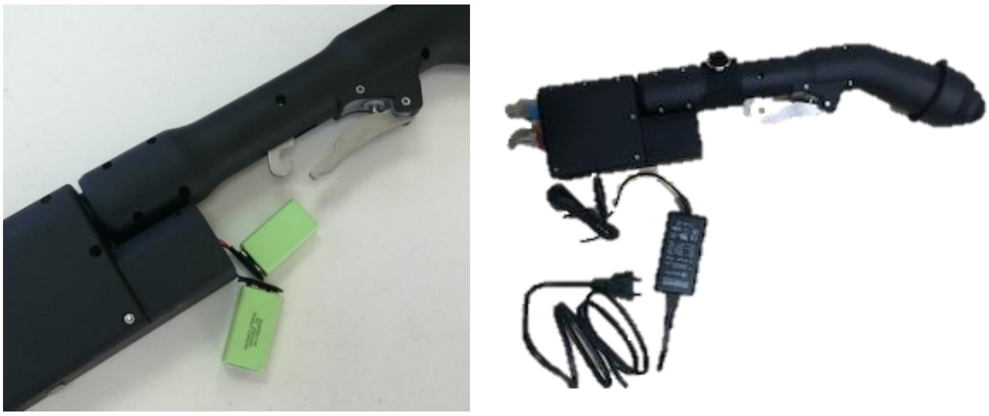


Figure 39: Gun power supply in first prototype

Furthermore, the air and liquid gun connectors have been eliminated. In the second version these air and liquid ducts are connected directly to the machine. Figure 40 shows the two connectors in the first prototype, while Figure 41 shows the connectors in the new prototype.

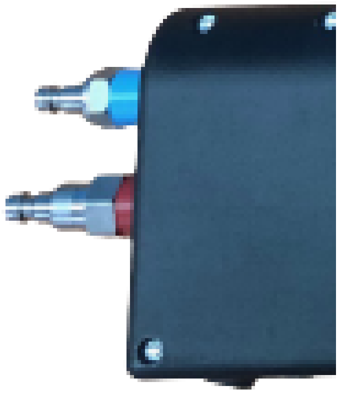


Figure 40: Gun liquid and air connectors in first spray gun prototype

Figure 41: Liquid, air and energy connectors in the second prototype

A new nozzle thread (Figure 42) has also been developed, which has been able to spray correctly minimizing dropping. Moreover, the electrostatic connection has improved.

Figure 42: Nozzle thread views for the first and second prototype

Compressor

The compressor type has been changed, improving air flow and decreasing its size. In Figure 43 it is possible to visualize the old and new compressor models.

Figure 43: Compressor for the second (top) and first (bottom) backpack prototype

Backpack battery
The size of the battery has been modified, with a noticeable improvement in autonomy and space reduction. In Figure 44 is well visible the reduced size of the new battery.

Figure 44: Backpack battery old (top) and new (bottom) design

Overall, the following improvements have been achieved:
1. Lower weight
2. Smaller volume size
3. Better spraying
4. More autonomy
5. Fewer components

TECNOSTATIC is currently testing the 2nd backpack prototype considering fluid coverage (different surfaces, adherence in 360º…) in different operational modes, including different HV power supply card polarities. This activity will constitute the basis for the design and realization of the third prototype.

3.3.4. Experimental laboratory tests on spray system

For the successful fitting of the physical CFD models of the spray system, ITAINNOVA carried out the development of an experimental methodology for the measurement of the MVP nozzle fluid and fluid-air performance. This included the setup of a test bench and the corresponding sensors selection and placement to measure experimentally the KPIs identified during previous tasks.

Figure 45: Setup of test bench and sensorization for experimental KPI measurements in MS4 MVP spray nozzle

Pressure, mass flow rate and temperature were measured experimentally at critical sections of both suitcase and bag devices, to determine the flow regime and to provide realistic values for the boundary conditions of numerical CFD simulations of the spray nozzle.

Following these preliminary activities, ITAINNOVA performed the experimental measurement of the fluid and fluid-air performance on the new nozzle section developed by TECNOSTATIC. This has led to preliminary conclusions of the spray nozzle performance, comparing initial MVP system (1st prototype) and autonomous backpack system (2nd prototype) in terms of flow measurements (pressure, temperature, and volume flow rate), and to learn which are the main parameters to be considered in the compressor optimisation to be done in future project activities. An overview of the results of these experimental measurements is provided in Figure 46.

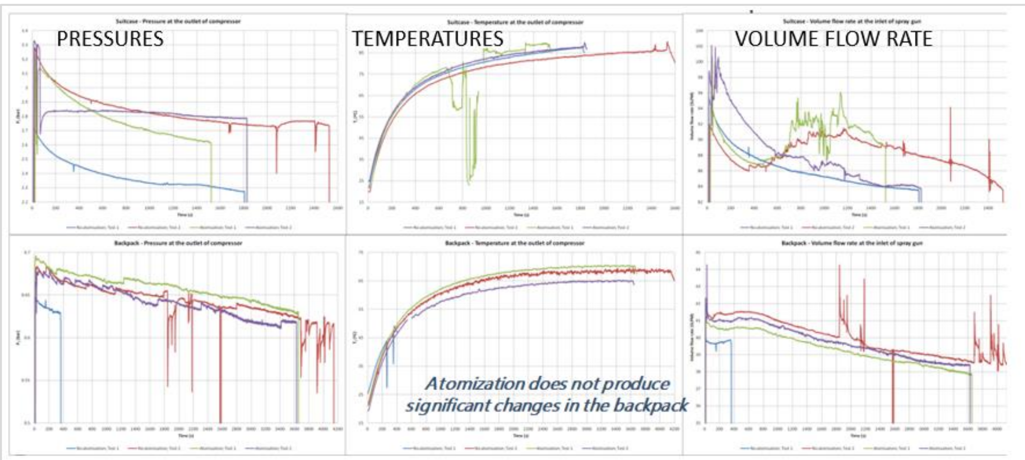


Figure 46: 1st (up) and 2nd (down) spray system prototypes experimental measurements done at ITAINNOVA facilities

Experimental laboratory tests on spray system for comparison of flow measurements (pressure, temperature, and volume flow rate) with and without water atomization for both suitcase (MVP) and backpack have been performed.

3.3.5. Realization of 3D-PDF manual for training

The main goal of MS 4 in terms of training is to create instructions on how to operate the disinfectant spraying equipment to support the end user of the spraying device with a virtual how-to guide, with considerations to health and safety in the handling of chemicals. TECNOSTATIC provided to HSSMI two already available instruction manual for the backpack safe use, which have constituted the basis for the first version of the 3D-PDF manual.

This manual shows the operational and maintenance instructions step-by-step and the interactive 3D model of the disinfectant backpack. Figure 47 provides an overview of the current version of the 3D-PDF manual.

Figure 47: The first MS4 3D-PDF draft

3.3.6. Business coaching

In the first 12 months of the project, SUPSI has investigated and analysed the current TECNOSTATIC business model, focusing on the new needs and business opportunities that the improvement product can bring. An analysis of the market and competitors was necessary to be ready in the next 12 months of the project to deep analyse the financial aspects, including the pricing for good competitiveness and replicability.

3.3.7. Key Outcomes of the 1st—4th Build, Measure and Learn Cycles

1st B-M-L cycle

Prototype/product:

- Preliminary definition of KPI parameters of spray gun to be measured experimentally in laboratory tests
- Preliminary selection of components for manufacturing the autonomous electrostatic spray system
- Preliminary setup of physical bi-phasic model (air-liquid) for computational CFD simulation of the spray gun
- Started the selection of new EC components to improve the battery charging time and working time
- Testing of the first backpack started
- Identification of the improvement needed on computational CFD model for better accuracy and computational efficiency
- Identification of the improvement required on spray gun design to optimize efficiency (cross-section and air flow requirements)

2nd B-M-L cycle

Prototype/product:

- Backpack tested in several working modes
- Achievement of constant spray flow of 40ml/minute at different levels of battery charge (full charge / half charge / minimum charge)
- discharge the product load in a measuring glass with a voltmeter placed on the batteries to control its discharge.
- Measurement of the range of the gun jet in the different states of the battery (full charge/half charge/minimum charge)
- Demonstration that batteries made in Europe perform better than batteries made outside Europe

3rd B-M-L cycle

Prototype/product:

- New simulation methodology of spray system (CFD mixed VOF+DPM methods) developed (further developments are planned)
- Design of HV electronic power supply card done. Prototype built and integrated into backpack.
- Analysis of the performance of the 2nd backpack prototype with the new compressor, HV power supply card (negative polarities) and new batteries.
- Performance tests carried out at both ITAINNOVA (air-liquid fluid system monitoring) and TECNOSTATIC (scope and coverage of sprayed liquid) facilities
- Second prototype completed, with the best battery option established and the HV electronic power supply card integrated
- Experimental laboratory test performed on spray system for comparison of flow measurements (pressures, temperatures)
- Experimental laboratory tests performed on backpack for comparison of sprayed fluid coverage and scope

4th B-M-L cycle

Prototype/product:

- Selection of HV power supply card parameter configuration for optimized scope and coverage of sprayed fluid
- Finishing CFD simulation methodology of spray system following the mixed VOF+DPM methodology
- First version of energy model of the backpack defined
- Search for new simulation methodology that allows the conversion into ROM, as the current computational time is too long (20 days)

Supply chain:

- Investigated prospective collaboration with EIR Manufacturing to identify EU component providers

3.3.8. Plans for the 5th – 8th Build, Measure and Learn Cycles

Product:

- Improvement to the current backpack design and realization of the final version

Process:

- Improve the simulation model of the spray system and optimize computational cost.
- Develop the energy model of the backpack.
- Perform DOE of simulations and analyse the results.
- Create reduced order models (ROMs) with offline results (no simulation with commercial software will be cloudified).
- Adapt a user interface (UI) for the created ROMs.

Upscaling:

- Upload the UI and created ROMs in the cloud as a service.

4. Manufacturing Setting 5 – Ramping up Production of Respiratory Devices

4.1. CO-VERSATILE partners involved in MS5

Participating partners and their role:

Experiment owners:

DEMCON, manufacturer of respiratory devices

contact persons: Jan Leideman (jan.leideman@demcon.com)
Clint Scholten (clint.scholten@demcon.com)
Becem Bourbita (becem.bourbita@demcon.com)

Service and technology providers: (indicative list)

IML, supply chain simulation

contact persons: Saskia Sardesai (saskia.wagner-sardesai@iml.fraunhofer.de)

SZTAKI, manufacturing simulation

contact persons: Jozsef Vancza (vancza@sztaki.hu)

UoW, supporting running simulation on cloud and edge resources

contact persons: Gabor Terstyanszky (terstyg@gmail.com)

Business coaching:

HSSMI, work force training

contact persons: Katarina Deme (katarina.deme@hssmi.org)

4.2. Overview of the Manufacturing Setting

During the COVID-19 pandemic, spikes in demand for hospital respiratory equipment - much needed for COVID patients - required a rapid ramp-up of production capacities. To prevent the deaths of thousands, medical device manufacturers producing medical ventilators boosted their production output. However, with a sharp ten-fold increase in demand compared to the standard quantities that hospitals require, the manufacturers could not meet the continuously growing demand. Here are the main reasons why:

- Medical ventilators are typically produced in relatively small volumes and require a considerable amount of skilled workforce for assembly and testing.
- The production of medical ventilators is based on Build-to-Order approach.
- Some of the critical components, such as electronics and plastic parts are supplied globally.

MS5, led by DEMCON, address the issues that prevent companies to increase the production in Europe at short notice. DEMCON has been offering CE-marked smart ventilator modules and blower modules for OEM (Original Equipment Manufacturer) customers, who integrate them into their respiratory systems. Before the arrival of COVID-19, one certified production line with a low throughput had been operated for several years in Enschede, The Netherlands. Since the beginning of the crisis in Europe, the capacity of the existing production line has increased and the realization of several new production lines has been addressed, in order to achieve up to ten times of the original production capacity. Before COVID-19, DEMCON has never offered a complete ready-to-use respiratory device to the end users. A dedicated device

called “DEMCAIR” has now been developed and can be distributed with CE exemption status during the on-going crisis to the care providers in the Netherlands.
MS5 is therefore focusing on ramping up the production of ventilators based on the DemcAir production line. The project scope includes the following:

- Analyse and research ventilator supply chain to address the challenges of availability of its parts and components focusing on boosting resilience;
- Build automation tools to assist assembly and testing of the ventilators to reduce the production time while increasing production output with fewer staff;
- Produce a training manual in 3D-PDF format for operators to aid scaling up and down the production according to the market demand for medical ventilators.

4.3. Activities performed during the first year of the project

In the following sections, the main activities performed in the first 12 months of the project concerning MS5 are presented, detailing all technical developments and main achieved results. The basis for the activities to be performed in the second half of the CO-VERSATILE project are also introduced.

4.3.1. DemcAir CE certification

The first activity for MS5 have been the finalization of the design and production process for the respiratory device called “DemcAir”. Technical modifications have been implemented to improve the system and the improved prototype has been manufactured and tested. The DemcAir production system has also been completed and the respiratory device has been successfully produced. A relevant objective of this activity has been the achievement of a general CE certification, which is an important prerequisite for direct distribution to all European and many non-European countries at short notice without legal hurdles. Additional tests have been performed on the respiratory device to check how different types of material affects its behaviour and performance.
Following the testing campaign, the DemcAir ventilator has then received the CE certification, through intensive cooperation with the certification body Dekra who, among other things, supported DEMCON in the preparation of the technical documentation and risk management plan. The CE certification, which follows exactly six months after the start of the DemcAir development process, represents an important step for DEMCON towards the commercialization of its product.

4.3.2. Conception of the supply chain model

During the first COVID-wave DEMCON noticed that it could not obtain all the needed materials needed to ramp up production with the ‘old’ DEMCair systems, containing more hard-to-obtain components. The supply of much needed materials turned out to be, in fact, a bottleneck.
To prevent this in a future pandemic, first of all, the product design was changed to facilitate fast ramp through e.g. easily available components. Subsequently, once the bill of materials was complete, supply chain management needed improvement. DEMCON, therefore, started a collaboration with consortium partner IML Fraunhofer, with the aim to assess the suppliers, from the first tier up to the third tier, capable of supplying the necessary components in order to address the current inventory management challenges. A focus should lie on obtaining second level sources for critical components, re-shoring of component production and investment in production capacity of certain component suppliers. In order to test the

possibilities, DEMCON and Fraunhofer IML started setting up a supply chain simulation. During the last few months, both parties defined the purpose of the simulation and discussed the expected outcome of the simulation and how it would help MS5 to deal with supply chain bottlenecks. The boundaries of the conceptual model have been defined, to form the basic structure of the supply chain simulation model. Figure 48 shows the structure of the conceptual model along with the respective data requirement.

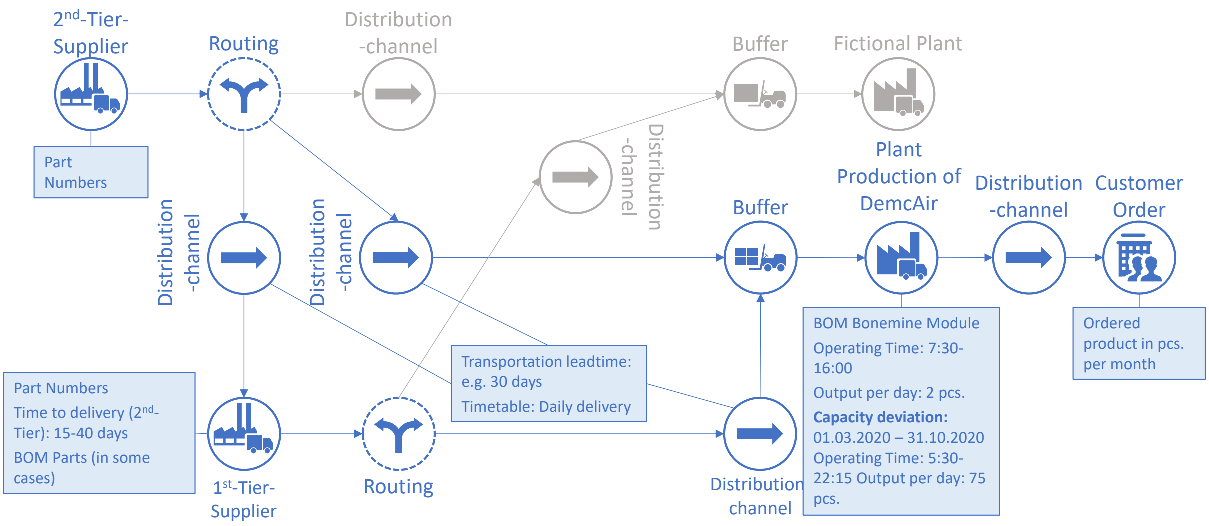


Figure 48: DEMCON supply chain conceptual model

4.3.3. Update of the supply chain model

Several iterations on the conceptual model came from discussion rounds with Fraunhofer IML. DEMCON was requested to share input for the creation of a conceptual model and the first model of the supply chain simulation for MS5.

The discussions clarified the respective lead times on first and second tier level. In particular, some problems were identified in the process of getting data from first-tier suppliers because of data privacy and security issues. Through multiple iterations and discussions with both first-tier and second-tier suppliers, in order to define how to share their data, the supply chain model design could be moved forward, including also a visualization considering daily and weekly supplies. A following analysis was focused on the DemcAir supply chain bottlenecks, in order to enable the re-design of the supply chain to better handle key issues such as increasing and fluctuating demand. One of the key problems identified was that DEMCON communicates directly with all suppliers, even 2nd tier suppliers, and has to order components 120 days in advance. In addition, data on transport times are usually not available and cannot be made available without extensive work. It has been decided, therefore, that the information about transport times will be applied and considered as an approximation in the supply chain simulation.

For the production capacity, a special feature has been introduced to calculate the available capacity slots from the suppliers based on the parts commitment from the suppliers. Figure 49 shows the different supplier entities and the supply chain structure.

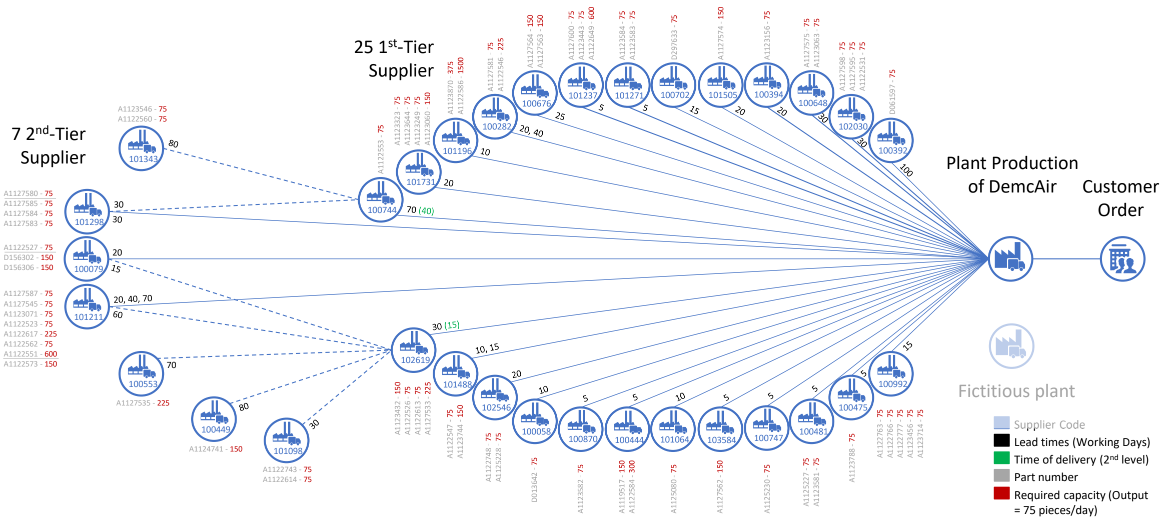


Figure 49: Supply chain structure with focus on supplier entities

Fraunhofer IML made use of the commonly available excel to transfer the data into the simulation software and, hence, to allow for quick amendments and recalculations. This approach enables an SME to apply the tool without additional help, modifying the model parameters and settings to better match the SME specific supply chain characteristics.
The excel template is structured into four different input sheets, concerning: i) general information, ii) information about the supply chain relations and transportation time, iii) information on parts ordered for the specific product under consideration and iv) similar parts ordered for other parts produced at Demcon Plant.

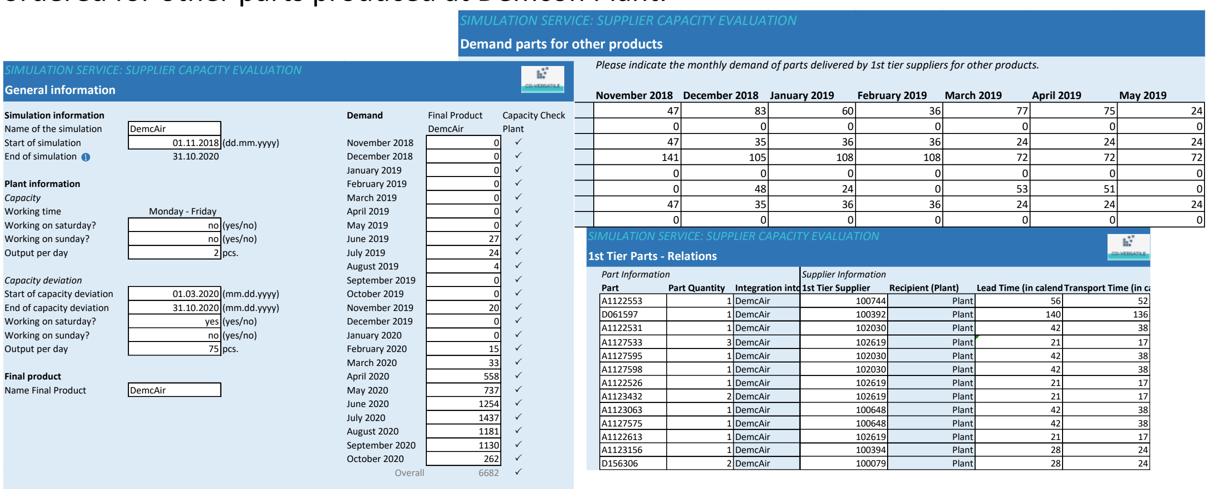


Figure 50: Supply chain simulation software overview

DEMCON is currently discussing with the IML team how to provide the supply chain simulation service for users. Two options have currently been identified and are being discussed:

- uploading the simulation software to the Digital Technopole so that user can download it.
- developing and/or integrating the user interface for the simulation software and providing it as a cloudified service.

In the second half of the project, it is expected to make use of the developed simulation model of the supply chain to perform a more detailed risk evaluation, to support DEMCON in the anticipation and reaction of different possible future scenarios.

4.3.4. Realization of the simulation software

IML developed the OTD-NET simulation software to model supply chain. UoW collected the contact details and the technical parameters of this software that are presented in Table 7.

Table 7: IML OTD-NET simulation software details

simulation providers	
name	e-mail
Wagner-Sardesai, Saskia	saskia.wagner-sardesai@iml.fraunhofer.de
Görtz, Michael Dominik	michael.dominik.goertz@iml.fraunhofer.de
simulation types	
product simulation	
manufacturing simulation	
supply chain simulation	x
manufacturing setting supported	
MS1-2-3	x
MS4	planned
MS5	x
MS6	
MS7	
simulation software	
open source	OTD-NET
commercial	
user interface	
command line	
GUI	x
other	
operating system	
Linux	x
Windows	
other	
computing platform	
desktop	
cloud	x
HPC	
other	
processors	
multi core	x
GPUs	
other	
memory requirements [GB]	
Per model	16
data requirements [GB]	
input data	1
temporary data	0
output data	0.1
scalability	
horizontal	x
vertical	x
security	
authentication	SSO / OAuth2
authorization	x
encryption/decryption	SSL / TLS
others	

IML and UoW investigated how to cloudify OTD-NET to support on-demand business model. They agreed that the simulation should contain the following steps:

- downloading the excel based UI to the user's desktop
- generating the excel file adding input parameters using the excel based UI on the desktop and
- uploading .xls file with the inputs to the Digital Technopol and executing the simulation
- uploading the .xls file with the simulation results to a temporary storage and kept for 30 days
- forwarding the link to the storage to the user who can download the simulation result from the storage

IML containerized the OTD-NET simulation software. UoW deployed and executed a sample supply chain simulation in the Cloud using these containers.

4.3.5. Set up instruction and training manual

A faster ramp up can be achieved by offering e-manuals capable of instructing the machine operator more efficiently. This will be made possible from the collaboration between DEMCON and HSSMI. A full comprehensive instruction manual in a classical form has been shared, with the goal to adopt it in a 3D-PDF format, to improve insights and understanding of the process in a more efficient way, in particular for new employees. With this, the gain should be an improvement of the ramp up with newly recruited personnel. Currently, the 3DPDF draft, containing the relevant information fields, steps and the animated CAD, has been created and shared with DEMCON, as described in D3.3 and shown in Figure 51.

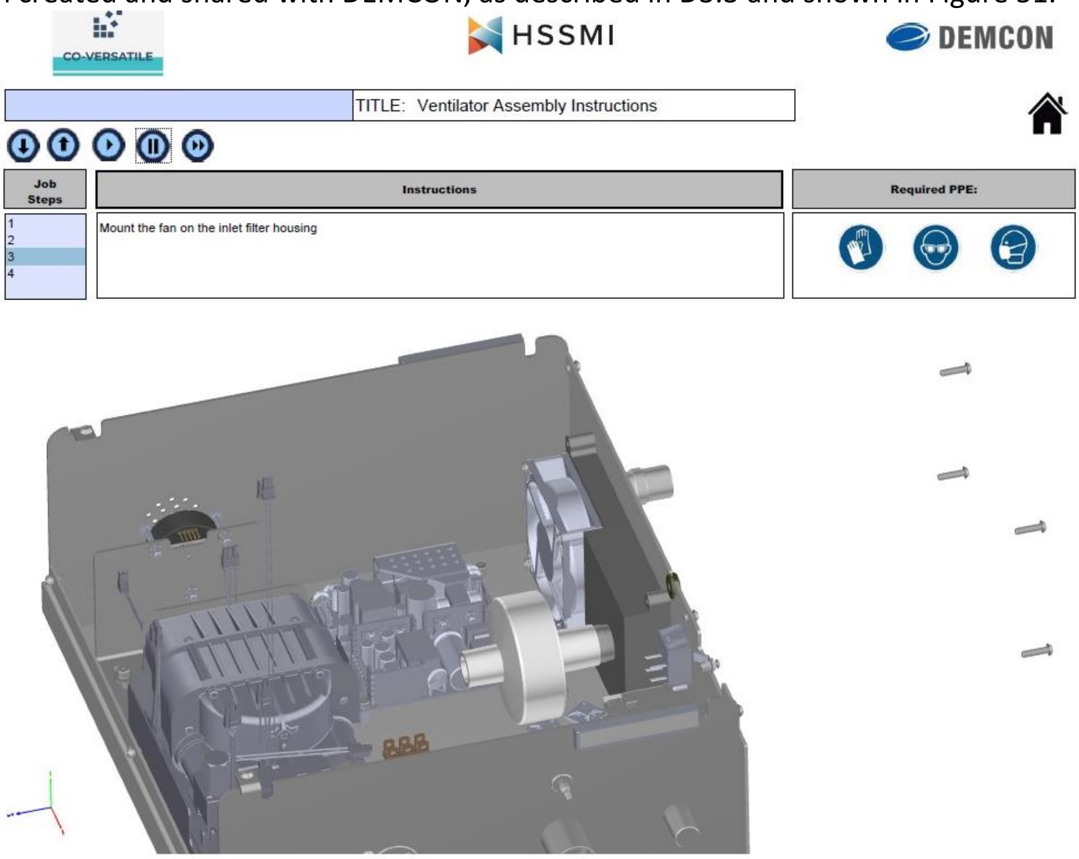


Figure 51: Draft of MS5 3D-PDF

In the next phase of the project, the above draft will be further refined and tested. In addition, the next activities will see the initial testing of the training material on DEMCON employees, to validate the defined approach and identify any possible need for improvement. Additional solutions will be evaluated in parallel, such as AR/VR technologies, to further simplify the learning process for new employees.

4.3.6. Key Outcomes of the 1st—4th Build, Measure and Learn Cycles

1st B-M-L cycle

Prototype/product:

- DemcAir respiratory device designed and tested
- DemcAir production system completed
- DemcAir respiratory device successfully produced

Supply chain:

- supply chain data collected and shared with Fraunhofer IML
- draft of conceptual supply chain model made in collaboration with Fraunhofer IML

Training, certification and standardization:

- DemcAir respiratory device certified

2nd B-M-L cycle

Prototype/product:

- Understanding of data input for supply chain model with Fraunhofer IML
- Model specifications have led to first definitions of system boundaries of the supply chain model

Supply chain:

- Construction of the first basic supply chain model of first and second tier suppliers, including leadtimes

Training, certification and standardization:

- n/a

3rd B-M-L cycle

Prototype/product:

- investigating how to get, manage store and secure suppliers' and company's data

Supply chain:

- Further developing the simulation model of the supply chain extending it with new parameters and new features
- More detail added to the supply chain model in order to strengthen/expand the supply chain model.

Training, certification and standardization:

- Working on the training manual with HSSMI and creating the first version of the manual
- Development of the training protocol for the DEMCON staff manufacturing DemcAir machine has been started

4th B-M-L cycle

Prototype/product:

- Further investigating how to get, manage store and secure suppliers' and company's data

Supply chain:

- Creation of results and an explanation on the usage of the simulation service

Training, certification and standardization:

- Development of the training protocol for the DEMCON staff manufacturing DemcAir machine continued

4.3.7. Plans for the 5th – 8th Build, Measure and Learn Cycles

Prototype/product:

- Determine and implement how to get, manage, store and secure suppliers' and company's data

Supply chain:

- Validation of the supply chain simulation
- Validation of the operator manual

Training, certification and standardization:

- Development, review and finalise the training protocol for the DEMCON staff manufacturing the DemcAir machine

5. Manufacturing Setting 6 – Machine for Reconfigurable Mask Production

5.1. CO-VERSATILE partners involved in MS6

Participating partners and their role:

Experiment owners:

DEMCON, manufacturer of face mask production machine

contact persons: Gido Akse (gido.akse@demcon.com)
Jan Leideman (jan.leideman@demcon.com)
Clint Scholten (clint.scholten@demcon.com)

Service and technology providers: (indicative list)

IML, supply chain simulation

contact persons: Saskia Sardesai (saskia.wagner-sardesai@iml.fraunhofer.de)

SZTAKI, manufacturing simulation

contact persons: Jozsef Vancza (vancza@sztaki.hu)

UoW, supporting the running simulation on cloud and edge resources

contact persons: Gabor Terstyanszky (terstyg@gmail.com)

Business coaching and training:

HSSMI, work force training

contact persons: Katarina Deme (katarina.deme@hssmi.org)

5.2. Overview of the Manufacturing Setting

COVID- pandemic caused disruptions in supply chains due to the unprecedented demand for personal protective equipment that required a rapid response and production at short notice. In most European countries, government-imposed orders to wear face masks very quickly became a proven and simple way to prevent the virus spread and protect citizens.

To provide a solution for the abovementioned issue, MS6, led again by DEMCON, is focusing on the development of a high-capacity solution based on DEMCON's modular face masks machine. DEMCON does not usually have its own portfolio of standard production machines. Instead, DEMCON is contracted either by the end user, i.e. an industrial manufacturing company, for the production of a single special machine that cannot be bought off-the-shelf, but is required for the company's own production, or to develop certain subsystems of a machine or a complete machine to be produced in mass by the customer company.

Upon arrival of COVID-19 in Europe early 2020, the required quantities of face masks had increased drastically as this type of Personal Protection Equipment (PPE) was strongly advised, or even made compulsory, in most countries and for many areas of public life. Motivated by the newly arisen demand, DEMCON started to develop and build a demonstrator for a fully-automated, high-throughput face mask production machine that can be adapted for different types of masks (FFP1, FFP2) and is suitable for use in Europe.

Following this initiative, MS6 partners have been working with DEMCON to build a solution for local European masks production. Key benefits of this production line include:

- Full automation of masks machine production processes - material infeed, nose clip and contour welding, print and strap application, folding, fold welding, contour cut and outfeed.
- Safety of the machine operation achieved with video surveillance of production steps and the product quality.
- Zero-defect production.

DEMCON will leverage its expertise and collaborate with consortium partners to:

- Set up a supply chain model to simulate several pandemic-like situations based on real-world experiences and run this model in the cloud as a cloudified service.
- Develop manufacturing models based on real-life examples, validate several optimisation scenarios and deploy the models.
- Develop a manual of operation and maintenance in 3D-PDF format to be supplied alongside the machine to support employees of future adopters of this equipment.

5.3.Activities performed during the first year of the project

In the following sections, the main activities performed in the first 12 months of the project concerning MS6 are presented, detailing all technical developments and main achieved results. The basis for the activities to be performed in the second half of the CO-VERSATILE project are also introduced. The activities for which DEMCON is responsible in MS6 have suffered some delays in the first part of the project, mainly due to problem in receiving the facemasks material, but MS6 activities have now sped up and are currently mostly aligned with WP2 timeline.

5.3.1. Facemask production machine

During the initial phase of the project, an automatic production machine for facemasks has been developed in a high pace, already offering faster ramp up. During this initial reporting period, the initial focus lied on the ramp up of overall production by enhancing the facemask machine itself. This resulted in a product capable of producing FFP1, FFP2 and FFP3 facemask fully autonomously. The system itself comprises of multiple innovative solutions to facilitate ramp-up. First of all, the material infeed allows for much faster uptake of the product. Subsequently, new print and strap applications were developed in order to fasten production, combined with a new design considering the fold welding, contour cutting and outfeed.
The result of our developments facilitating faster ramp up can be seen in Figure 52.

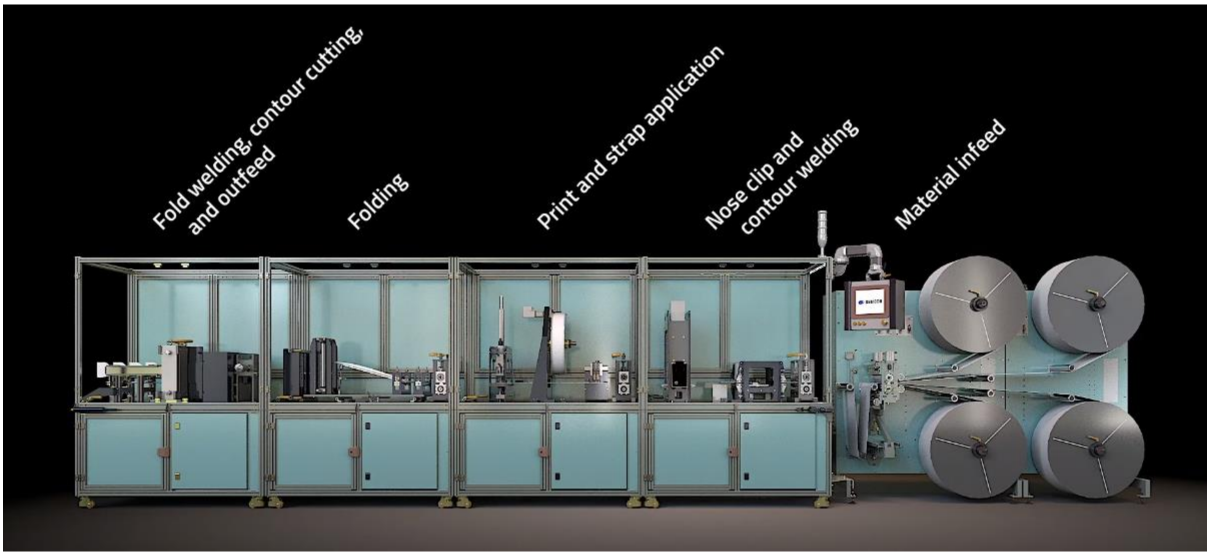


Figure 52: DEMCON machine for reconfigurable mask production

The machine has a modular design to facilitate the adaptation to custom products. It is constituted of five main modules, responsible for the following facemask manufacturing tasks:

- Material infeed
- Nose clip and contour welding
- Print and strap application
- Folding
- Fold welding, contour cutting and outfeed

Starting from the raw material, which is supplied on rolls with the correct width, it full automatically produces folded facemasks with elastic head straps. The machine can also be customized and adapted to specific requirements:

- other mask designs: FFP1, FFP2, FFP3 with different number of layers, different materials and different mask geometries
- integration in the existing production: interfacing with pre- and post-processing lines, e.g. for packaging

This has all been made available through the development of a new innovative controller system, consisting of actuators in each part of the machine module, realizing a flexible and modular system capable of functioning fully autonomously. High product quality is ensured by sensors in each machine module and machine vision-based final test. In addition, the overall design was realized with rather easily obtainable components.

5.3.2. Ramp up of facemask production

During the build and test runs of the facemask production machine, opportunities for improvements arose and have been encountered, leading to a better product and process, ultimately allowing for a faster ramp up of production. These included, amongst other:

- *Rubber band*: Initial choice was not the optimal one for the strapping purpose, after testing a change to another type was made.
- *Welding strength*: The strength of the welding was not sufficient for the use case. After testing and investigating, it was found that the use case created a peeling

effect of the weld, which is a load in the weakest direction. The welding orientation has been optimised to minimize this issue, obtaining satisfactory results.

- *Mask material*: Tests were performed to determine the best materials for the masks manufacturing. Apart from different types (non-woven fabric, meltblown, non-woven) a change of supplier was made as well. The machine was then modified accordingly, to facilitate the utilization of the new materials, with testing being planned.

In the future project months, further development and tests will be performed, in order to further upscale the production speed and the flexibility of the facemask machine. In addition, other relevant topics will be addressed to further improve the machine performances and the final facemasks quality.

5.3.3. Production and manufacturing simulation

First steps towards production and manufacturing simulation were taken with SZTAKI, to set up production and manufacturing simulations, in line with the areas that DEMCON wishes to focus upon. Based on the first data sets that have been shared, a first setup of the simulation has been defined and completed. A simulation test campaign is currently being performed and the results of these simulations will be reviewed and evaluated in the next months. The objective is to simulate all the five modules of the facemask production machine, to determine the optimal parameters for production to increase productivity and mask quality. A first overview of the output that can be provided by the simulation is visible in Figure 53. As visible in the figure, there are 5 cells producing in sequence, corresponding to the five modules presented in section 5.3.1.

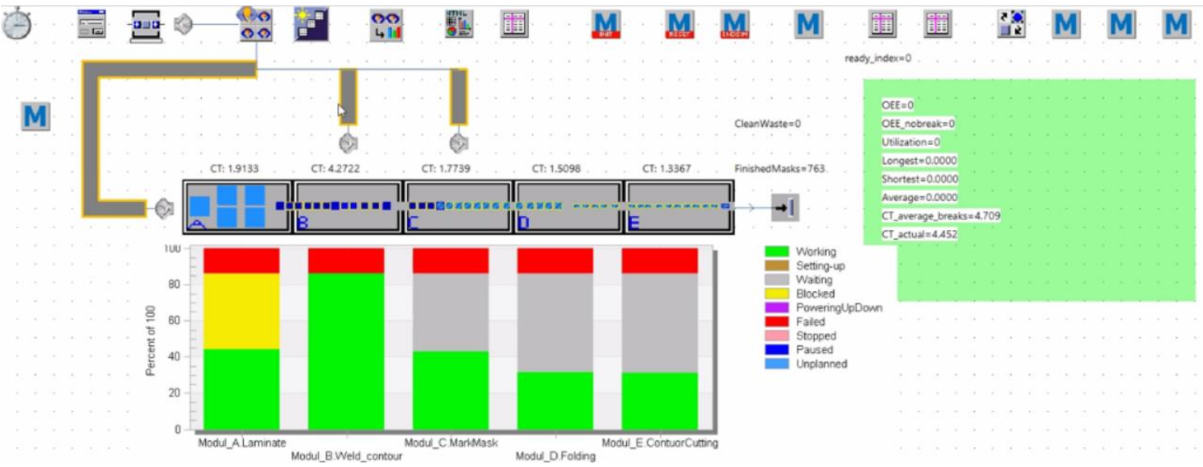


Figure 53: Initial overview of DEMCON manufacturing simulation

The workload per cell is visible, together with a visualization of the products running through the line. The main process output and KPIs are also visualized and, for each cell, the current status of production is provided in a simple diagram that is updated in real time. This is visible in Figure 54 and Figure 55.

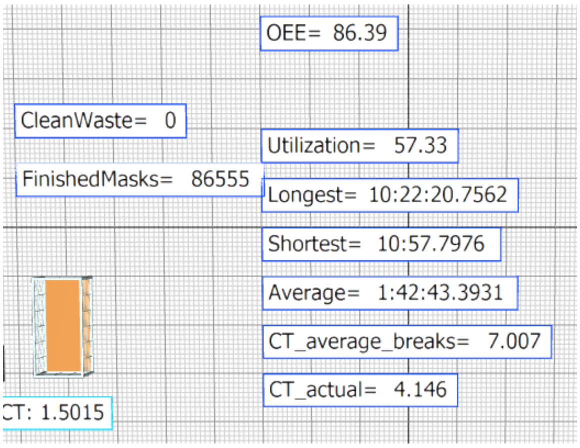


Figure 54: Facemasks production main production indicators in simulation model

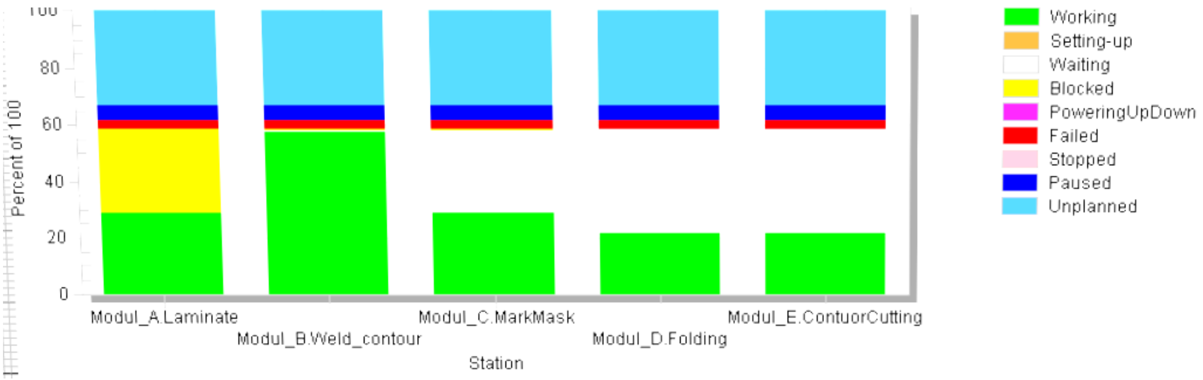


Figure 55: Production performances is highlighted for each module in the machine

In Figure 56, it is visible how the simulation software can provide also a 3D view of the flow in DEMCON shop floor, to have a better understanding of each module behaviour.

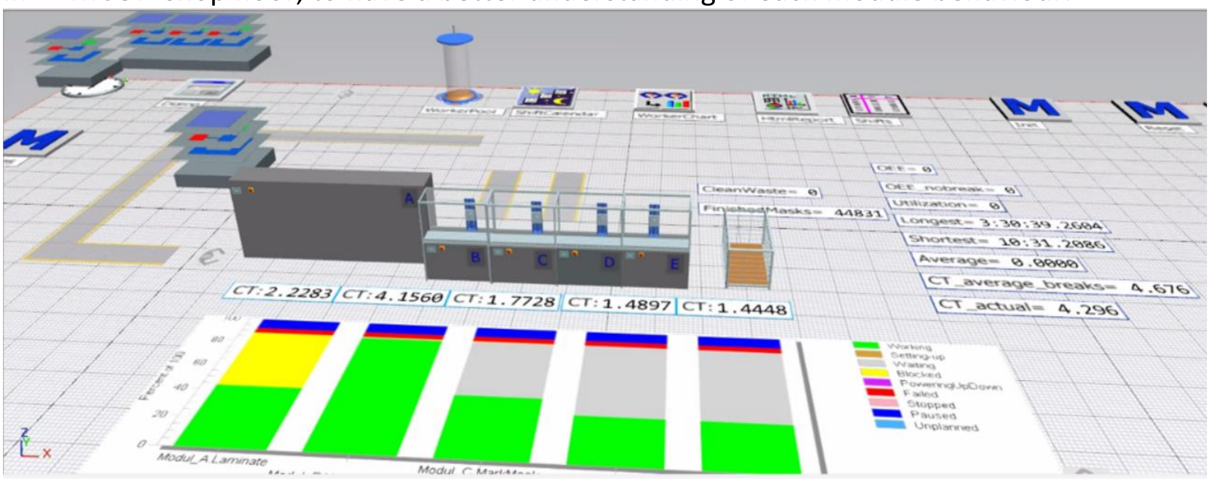


Figure 56: 3D view of DEMCON shopfloor in the simulation

5.3.4. Set up instruction and training manual

A faster ramp up can be achieved by offering E-manuals capable of instructing the work force in the assembly line more efficiently. This will be made possible in collaboration with our partner HSSMI. The training package for MS6 is expected to deliver a manual of operation and maintenance in 3D-PDF format to be supplied alongside the machine in order to support employees of future adopters of this equipment. The 3D-PDF template containing the relevant information fields has been created and presented to DEMCON and is shown in Figure 57. Currently the training manual is being set up, with a review session expected for the next phase.

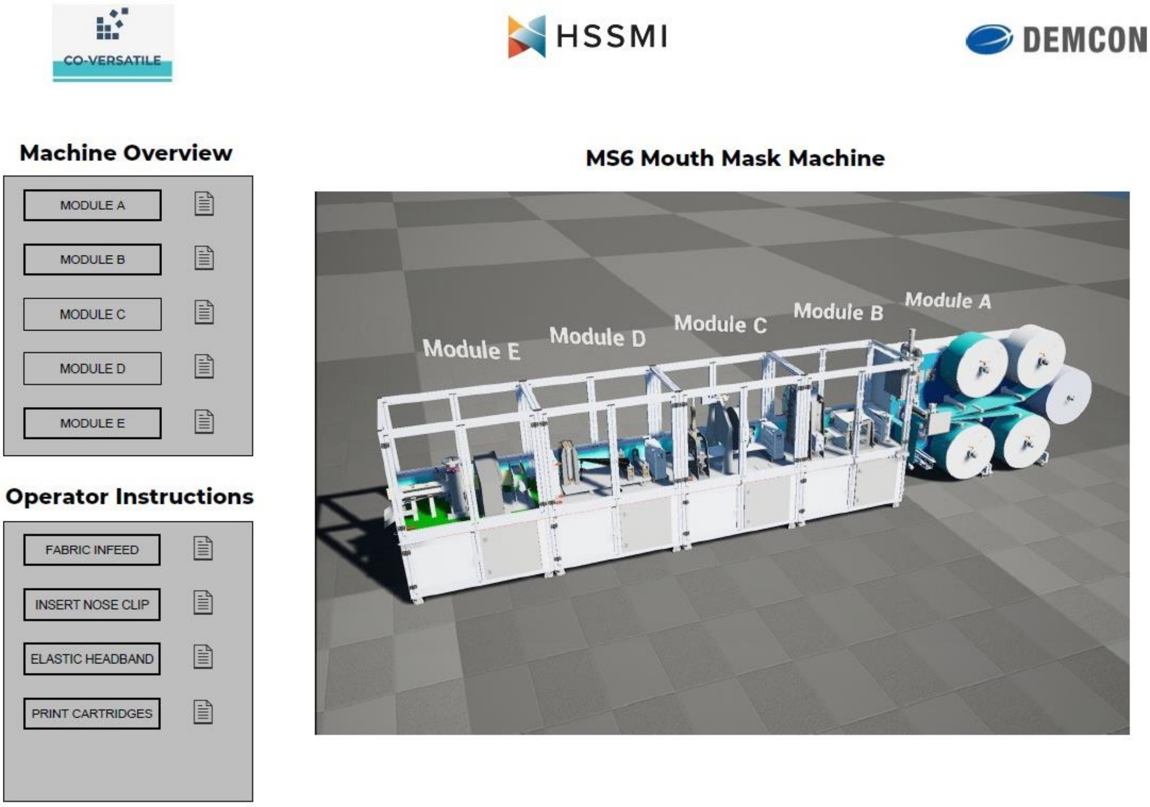


Figure 57: MS6 3D-PDF

The next activities will see the initial testing of the training material on DEMCON employees, to validate the defined approach and identify any possible need for improvement.

5.3.5. Certification activities

The progress with the certification activities includes the collection of required information and other pre-work activities required for the application for CE certification of the machine masks production. During the machine development stage, a set of production system testing have been performed towards machine certification, in order to gather as much data as possible about the system performances.

In the first half of the project, DEMCON has been defining the actions and inputs needed for the certification of the facemask production machine and the documentation for the facemask for certification is currently under finalization. SUPSI has been supporting the certification process providing a common base for the identified set of requirements with the other Manufacturing Settings of CO-VERSATILE. In the next months, the proper certification authority for certification of the facemask will be identified and the steps to achieve CE certification for the facemask production machine will be undertaken.

5.3.6. Key Outcomes of the 1st—4th Build, Measure and Learn Cycles

1st B-M-L cycle

Prototype/product:

- prototype of the face mask machine completed
- first production run of FFP2 type face masks completed

Training, certification and standardization:

- production system testing for machine certification

2nd B-M-L cycle

Prototype/product:

- First test runs and material combinations performed

Supply chain:

- Materials for test runs selected

Training, certification and standardization:

- Facemask machine certification started during BML2 for FFP2 mask types.
- Alignment to set up operator working instructions

3rd B-M-L cycle

Prototype/product:

- Certification activities (ongoing)
- Building manufacturing simulation started with SZTAKI
- Data for operation instructions reviewed by HSSMI

Supply chain:

- New materials selected for testing

Training, certification and standardization:

- kick off meeting taken place with HSSMI how to develop the work instruction for manufacturing staff

4th B-M-L cycle

Prototype/product:

- Simulate the manufacturing process with consortium partner SZTAKI to increase the overall flexibility, ultimately stimulating faster production and ramp up of facemask machines

Supply chain:

- Final material selection for future series production determined

Training, certification and standardization:

- Adopt faster ramp up by offering E-manuals capable of instructing constructors more efficiently. This will be made possible in collaboration with our partner HSSMI

5.3.7. Plans for the 5th – 8th Build, Measure and Learn Cycles

Product:

- Finalise certification

Process:

- Review and finalise production simulation
- Review and set up an operator training manual

- Finalization of the training manual and on-field tests to validate its efficacy

Upscaling:

- Awaiting sufficient material supply to test ramp up and increase production run.

6. Manufacturing Setting 7 – Resilient Automation for Manufacturing

6.1. CO-VERSATILE partners involved in MS7

Participating partners and their role:

Experiment owners:

MTC, developing innovative automation for manufacturing

contact persons: Anas Alhalabi (Anas.Alhalabi@the-mtc.org)
Jeremy Hadal

Service and technology providers:

STAM, support in automation of the assembly process

contact persons: Alberto Landini (a.landini@stamtech.com)
Andrea Pilloni (a.pilloni@stamtech.com)

Business coaching and training:

HSSMI, training

contact person: Katarina Deme (katarina.deme@hssmi.com)

ENG, business coaching and training

contact persons: Antonio Salis (Antonio.Salis@eng.it)

6.2. Overview of the Manufacturing Setting

The ability of manufacturers to implement robotics technologies and ramp up production during the COVID-19 crisis became crucial in a number of industries. For manufacturers of vital medical equipment that faced unforeseen spikes in demand, it turned out to be a deciding factor. Integrating advanced manufacturing technologies into production steps that traditionally depend on human skills, is not only enabling manufacturers to respond quickly to the pandemic, but it can also help them to gain a competitive advantage in post-COVID times and be better equipped to avoid future crises.

In the beginning of the COVID-19 crisis, one of the main challenges, caused by unprecedented demand for essential medical products, was the shortage of components. At the same time, the manufacturers' flexibility to adapt and develop agile production lines played an equally critical role.

Following Industry 5.0 principles, MS7, led by MTC, will be exploring and testing ways to integrate automation and smart human-machine collaboration aiming at demonstrating how automated manufacturing systems can be reconfigured quickly in times of special need, such as pandemics. MTC is a Research and Technology Organisation focused on the development and application of innovative manufacturing technologies, primarily active in the aerospace, defense, construction and food & drink industries. However, since the advent of COVID-19, there has been an increasing work carried out with the medical industry. The quick re-purposing, adaption and ramp-up of production lines to new and urgent production needs has stretched manufacturers and supply chains like never before. In many cases, this has meant reverting to traditional, manual methods as existing infrastructure has proven too rigid to adapt to demand. As such, the underlying motivation of MS7 is to show how automated and robotic manufacturing facilities can be configured to enable rapid repurposing in times of need.

In particular, the Small Component Assembly Loop (SCALP) demonstrator at MTC is a reconfigurable automation and robotics manufacturing cell. The system has been designed to demonstrate how automated manufacturing systems can be rapidly reconfigured. Whilst moderately successful in its current form, the system is complicated by its inherent flexibility, which increases the time required to reconfigure it. Through CO-VERSATILE, rapid reconfigurability of the system will be enabled through simulation and modelling, user friendly off-line cell re-programming and digitalisation of shared best practices.
The team of CO-VERSATILE partners is working collaboratively to achieve the following objectives:

- Research and demonstrate how automated manufacturing system can be reconfigured on short notice at times of crises, enabling rapid and flexible changeover between activities.
- Use parts of CPAP (Continuous Positive Airway Pressure) device assembly process to develop and transfer an exemplary robotic cell that would inspire other manufacturing firms. Shared best practices will incorporate hardware and software requirements, and the knowledge gained during robotic cell setup, upgrade and modelling – all available digitally.
- To ensure the availability of medical devices in high volumes when they are needed most, it is essential to achieve fast repurposing of the robotic cell setup to another compatible cell and with that increase the overall production.

MS7 partners are working together to find the right balance and the best combination of automated and manual production steps and to capture and share best practices to achieve replication of the solution by future partners and customers.

6.3. Activities performed during the first year of the project

In the following sections, the main activities performed in the first 12 months of the project concerning MS7 are presented, detailing all technical developments and main achieved results. The basis for the activities to be performed in the second half of the CO-VERSATILE project are also introduced.

6.3.1. Manufacturing process analysis towards automation

The first activity performed in the framework of MS7 has been the analysis of the CPAP manufacturing process, as it is performed when assembled manually. MTC has provided a CPAP assembly instruction document that present detailed step-by-step instructions to perform the complete assembly process of the CPAP. This document has then been used as a basis for the investigation of the main components of the assembly and the main tasks to be executed, in order to identify the most complex or repetitive tasks in the process. Figure 58 provided an overview of the complete workflow that the operator has to follow to assembly and test a CPAP.

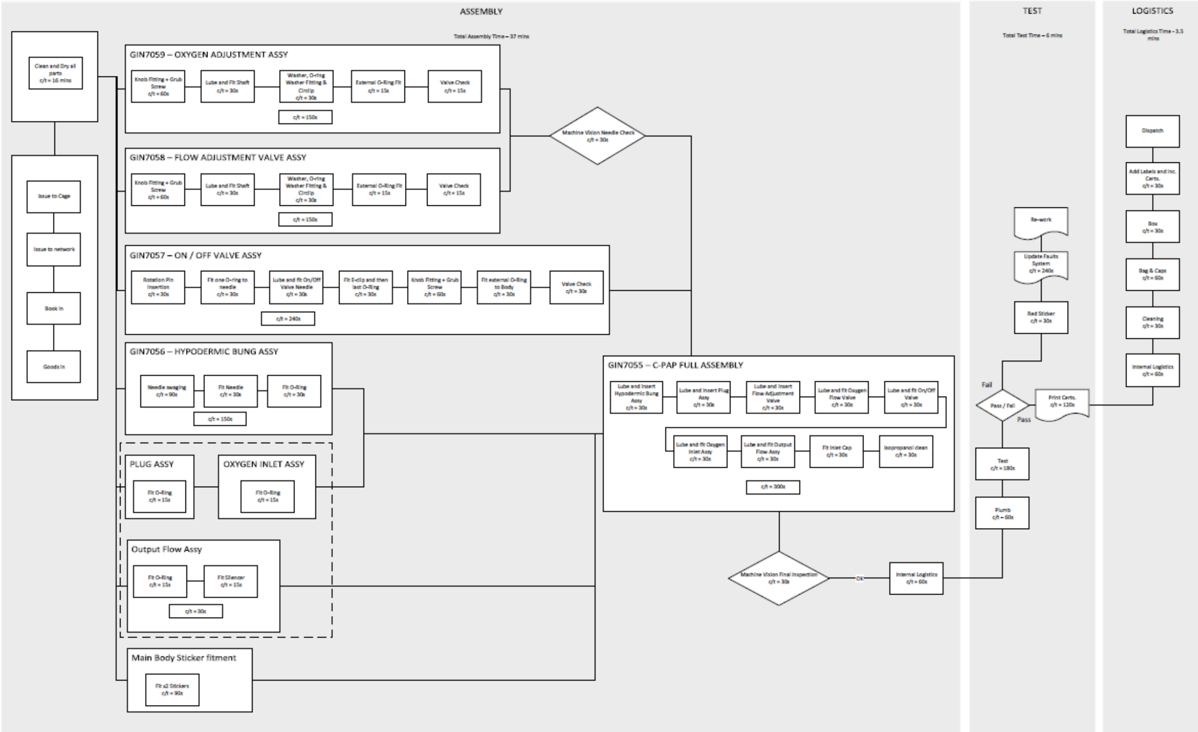


Figure 58: Workflow of the complete assembly and test process of the CPAP

The provided documentation then describes in detail each block of the workflow, with instructions that the operator has to follow and pictures of the components. An example is provided here for the CPAP Oxygen Inlet:

1. Apply grease to O-ring (BIC0068_01)
2. Using bullet (GIB2173_02) fit O-ring over the threads.

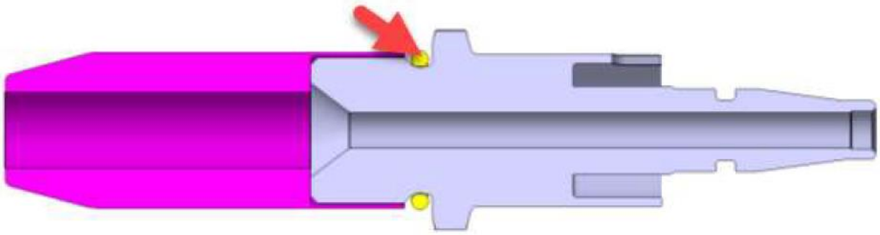


Figure 59: Instruction for the o-ring insertion on the oxygen inlet

3. Apply a small amount of grease to O-rings and thread

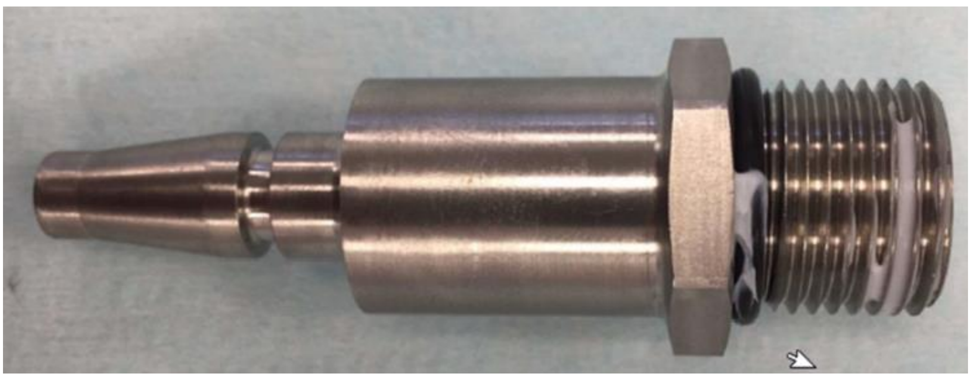


Figure 60: Instruction for the grease application on the oxygen inlet o-ring

In parallel with the product and process analysis, MTC robotics cell (SCALP cell) has also been analysed in detailed, inspecting all its components and capabilities. The SCALP robotic cell is visible in Figure 61.

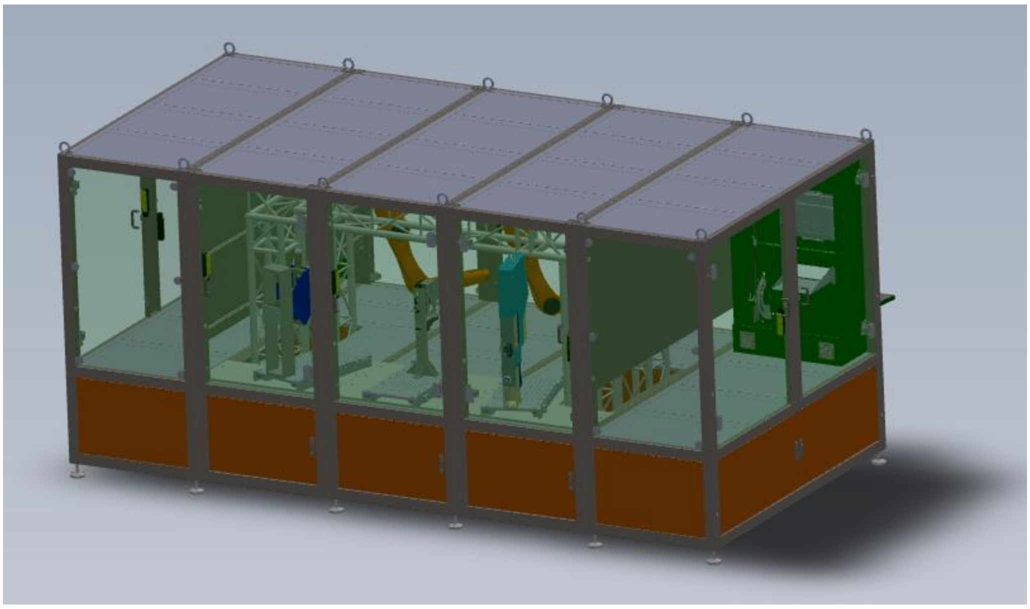


Figure 61: SCALP robotic cell

To allow the complete evaluation of the SCALP robotic cell, MTC has provided all required documentation on its HW components and system architecture, with an overview of the cell capabilities, the installed sensors and software and the expected improvements to be performed in the course of the project.
From the analysis of all provide details on the CPAP assembly process and the robotic system, STAM has defined a preliminary list of all the assembly actions that could be performed by the robotic cell, on the basis of the available HW and SW. For each action, it has been defined whether it can be performed by the robot, by an external sensor (e.g.: vision system) and the estimated time for the automated case. This is shown in Figure 62.

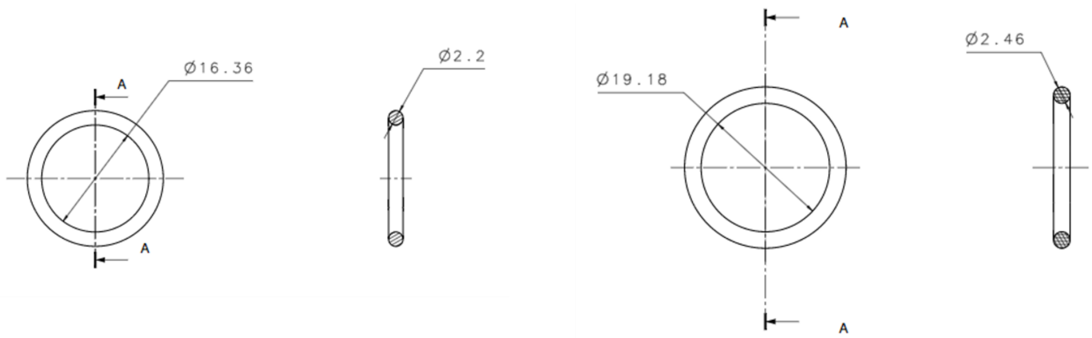
STAGE	Stage Title	General Code	General Acti	Specific Coc	Specific Action	Tool	Time Without Automation[s]	Time With
1	**Inlet, Outlet & Bung assembly**	**GIN1756_04**	**Oxygen Inlet**	**BIC0068_01**	**Apply grease to O-ring**	**Robot**	**10**	**5**
1	**Inlet, Outlet & Bung assembly**	**GIN1756_04**	**Oxygen Inlet**	GIB2173_02	Using bullet (GIB2173_02) fit O-ring over the threads.	Robot		
1	Inlet, Outlet & Bung assembly	GIN1756_04	Oxygen Inlet	No code	Apply a small amount of grease to O-rings	Robot	10	5
1	Inlet, Outlet & Bung assembly	GIN1741	Patient Outlet	BIC0064_01	Apply grease to O-ring	Robot	10	5
1	Inlet, Outlet & Bung assembly	GIN1741	Patient Outlet	No Code	Apply a small amount of grease to O-rings	Robot	10	5
1	Inlet, Outlet & Bung assembly	GIN1758_02	Bung	BIC0067_01	Apply grease to O-ring	Robot	10	5
1	Inlet, Outlet & Bung assembly	GIN1758_02	Bung	No code	Apply a small amount of grease to O-rings	Robot	10	5
2	Hypodermic tube swaging	GIN7056_01	Hypodermic Bu	No code step 7	Measure the flange with a micrometre	Vision System	15	5
3	Hypodermic tube fitting into bung & O ring	NO	NO	BIC0067_01	Apply grease to O-ring	Robot	10	5
3	Hypodermic tube fitting into bung & O ring	No	NO	No Code Step	Apply a small amount grease to O-ring	Robot	10	5

Figure 62: Preliminary definition of assembly tasks to be automated

From this analysis, it has emerged that the most repetitive task that could benefit from automation was the insertion of the o-rings on the CPAP inlets, which was then selected as the first task to be automated in the project.
With the selection of the task to be automated, a preliminary definition of the main robot step-by-step sequence was performed, identifying the needed components to correctly execute the task. This preliminary robot task definition acted as a basis for the planning of the technical development activities that have been performed in the following B-M-L cycles, which are detailed in the sections below.

6.3.2. Selection of robot gripper for O-Rings handling

As described in previous section, the insertion of O-rings in oxygen inlet and patient outlet parts of CPAP has been selected as a first task to be automated in MTC robotic cell. From the robotic point of view, this task corresponds to a pick & place operation that requires a tailored end-effector able to enlarge and positioning the O-ring in the dedicated groove.
CPAP oxygen inlet and outlet ducts present different geometries, which correspond to the O-ring sizes presented in Figure 63.



(1) Oxygen inlet (2) Patient outlet

Figure 63: (1) Oxygen inlet part, (2) Patient outlet part

In order to increase the flexibility of the reconverted production lines, the introduction of a specific gripper able to properly handle both the O-ring sizes, with the same configuration, was established as a fundamental requirement.
Since the O-ring placement represents a diffuse application in a wide range of industrial environment, a market analysis was performed to analyse which solutions are currently available, according to the specifications defined.
Two main relevant manufacturers have been identified, whose experience and competence in the development of high-performance robotic grippers are widely recognized: Zimmer Group and Schunk. The O-ring geometrical dimensions has led to three different gripper models, Schunk ORG 85, Zimmer GS65-B and Zimmer GS810-B, which are shown in Figure 64.

(1) (2) (3)

Figure 64: (a) Schunk ORG 85, (b) Zimmer GS65-B, (c) Zimmer GS810-B

All the models are pneumatically actuated and present similar working principles approaches. In fact, the action of picking and positioning the O-ring in the corresponding groove are based on specific mechanisms able to enlarge the O-ring and then to eject it. All these grippers are equipped with fingers tailored designed to handle O-rings, as is shown in Figure 65.

Figure 65: O-ring gripper's finger details

The Schunk gripper presents six fingers, all responsible for the enlargement of the O-ring, while three of them, complemented by a vertical translation inside the gripper body, are dedicated to the O-ring ejection (Figure 66). Thanks to the double-acting principle, the O-ring will be correctly placed in the dedicated groove.

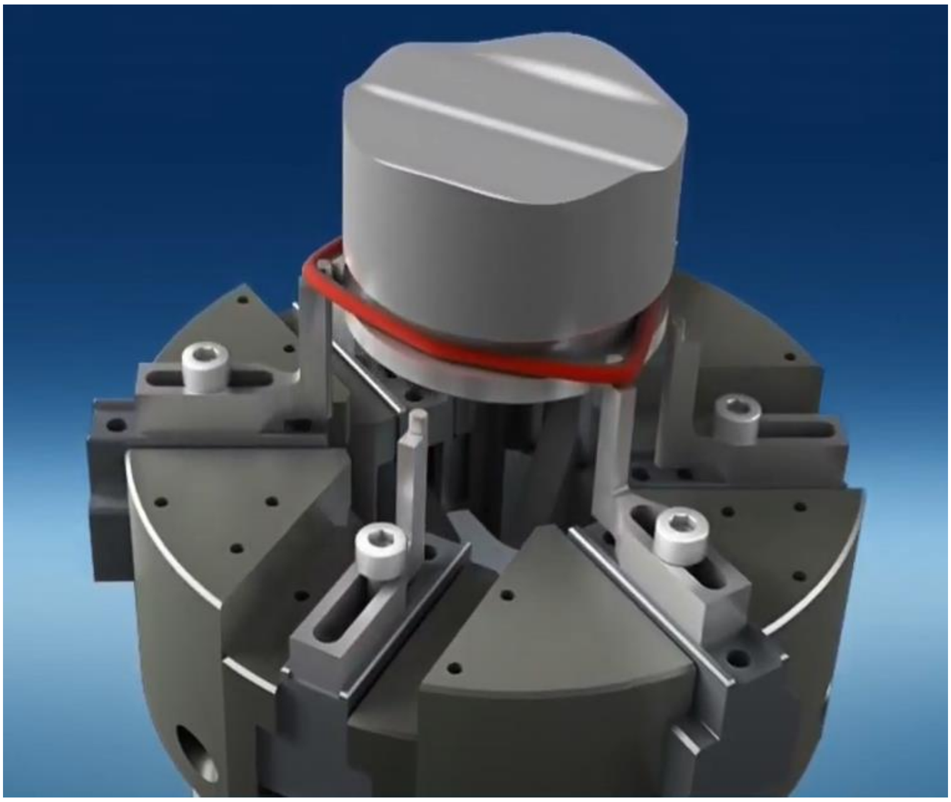


Figure 66: Actuation of the Schunk gripper

Zimmer's grippers exploit a similar conceptual idea, but the ejection action is performed through dedicated components, which vertical translation outside the gripper body ensure the expulsion of the O-ring, as is shown in Figure 67.

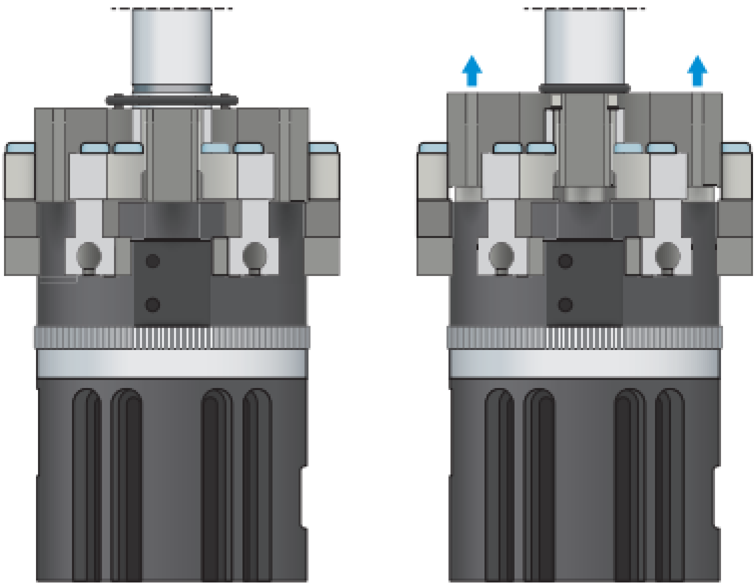


Figure 67: Actuation of Zimmer grippers

Although both mechanical principles presented above are theoretically suitable for the CO-VERSATILE purpose, it is important to consider the unconventional working conditions of the gripper in relation to the patient outlet part. In fact, the O-ring sizes considered suggest the adoption of the smaller models presented (the Schunk ORG 85 and the Zimmer GS65-B), but O-rings must be inserted at a heigh of about 40 mm, representing a challenging working condition for which the leverage effect may require higher force respect to what the gripper can exert. This unfavourable condition has led to the exclusion of the Schunk gripper, which presents the lowest force value in comparison with the Zimmer ones, able to exert at least 300 N (about twice the Schunk upper limit).

The accurate analysis of the Zimmer's gripper models have led to different aspects: from one side the GS65-B represents the most suitable model in relation to the O-ring sizes but with no guarantee of a properly operativity in relation to the force required, while the GS810-B, with higher dimensions and number of fingers (ten instead of six) requires the design of complex tailored components to handle the CPAP O-rings, thus overcoming the limitation of its excessive size. The most powerful gripper, in fact, can certainly exert enough force but the expanding jaws are designed to operate with bigger O-ring diameters. Since both the options would have required the manufacturing of additional parts to fulfil the requirements, it was decided to design a preliminary version of ejectors and adapters for the smaller Zimmer model, the GS65-B, in order to evaluate if it can properly perform the preestablished task, thus favouring the less time-consuming design activity.

The first activity was focused on the design of customized adapters for the expanding jaws able to increase the fingers height until the O-Ring groove. The design was performed taking into consideration the geometry of the Zimmer fingers, with the purpose of enabling the assembly of the standard components directly on the spacers. The adapter, presented in Figure 68, ensures the same degree of freedom of the Zimmer original design for the jaws assembly, making possible a proper position control on the base of the geometrical constraints identified on the inlet and outlet ducts.

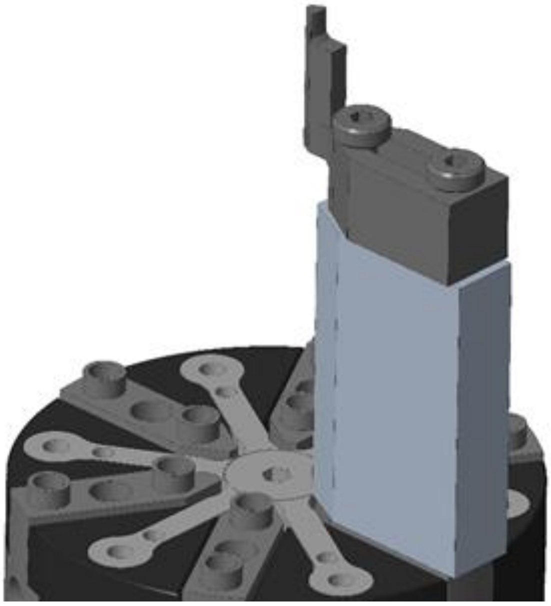


Figure 68: Expanding jaws adapter

The modification apported to the whole configuration of the expanding jaws was complemented by the introduction of a new set of ejectors. Since the original ones, provided by Zimmer, did not respond to the CPAP geometrical requirements, a totally new design was preferred. Ejectors are responsible for the O-ring expulsion, placing them in the dedicated groove. The design has taken into consideration the flexibility required to maintain the same configuration, in term of distance and calibration of the fingers position, both for the inlet and outlet components. Details of the new ejector design are presented in Figure 69.

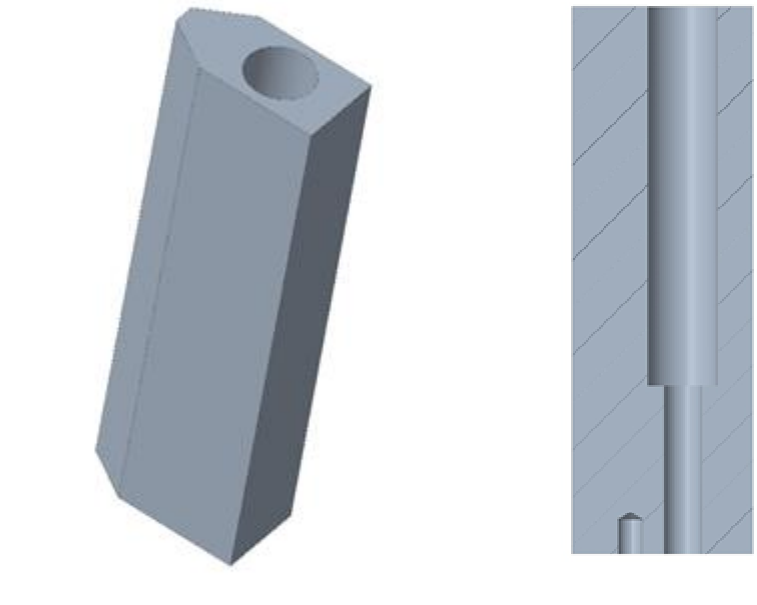


Figure 69: New ejector design

Figure 70 reports the result of the preliminary design of the ejectors and adapters for the expanding jaws mounted on the gripper GS65-B.

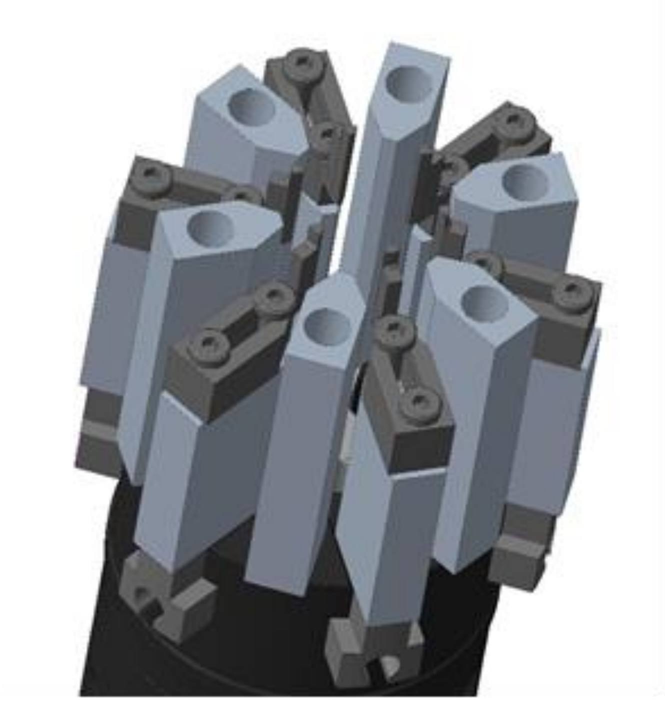


Figure 70: Ejector and expanding jaws assembly

Finalized the design phase, the ejectors and adapters have been manufactured and shipped to Zimmer Group for an experimental evaluation of the gripper behaviour in the unconventional working condition. The tests were executed for the CPAP inlet and outlet ducts, which geometric details was replicated through 3D printed components. Tests have led to positive results, highlighting the effective functioning the gripper, although the non-standard application, as is shown in Figure 71.
However, to perfectly match the geometries investigated, slight modifications were necessary; Zimmer has introduced some additional supports and reworked the ejectors tip to avoid any collision with the outlet part.

Figure 71: O-ring enlargement performed with the modified gripper

Figure 72 shows the achievement of the preestablished objectives through the minor modification apported by Zimmer to the current design. The O-ring is precisely inserted in the dedicated groove, validating the effectiveness of the solution developed.

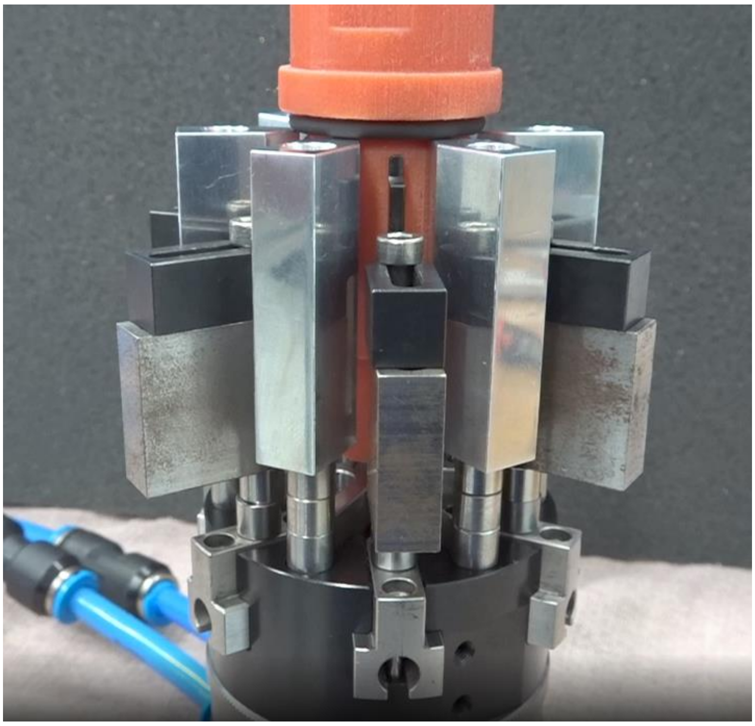


Figure 72: O-ring insertion in the groove

All the tests executed during the experimental campaign has shown that the Zimmer gripper GS65-B presents all the fundamental characteristics to fulfil the requirements identified. To improve the gripper behaviour, an optimization of the ejectors and expanding jaws design has been performed on the base of the reworks done by Zimmer, leading to an updated version able to correctly insert the O-ring both for the oxygen inlet and patient outlet parts.

6.3.3. Design and realization of the O-ring dispenser

The main objective of the O-ring dispenser is to feed O-rings to the robot so it can pick up one at a time automatically. There is also a stretch goal for the disperser which is to grease the O-ring before the robot grasps it.

To produce a design of the desired dispenser, the MTC Design and Build team has collaborated with relevant project members to understand and create a list of design requirements. Then the team sketched initial ideas on paper before progressing to a detailed design using CAD software, and then integrating suitable off-the-shelf sourced components online. Using MTC in-house 3D printing facilities, a prototype has been produced of this design, to provide the opportunity to identify minor flaws in the design, and incorporate improvements into the second iteration.

The full list of used parts to build the prototype can be found in the Appendix section. Please refer to Annex 2.

Figure 73 below shows the second iteration of the designed prototype of the O-ring dispenser.

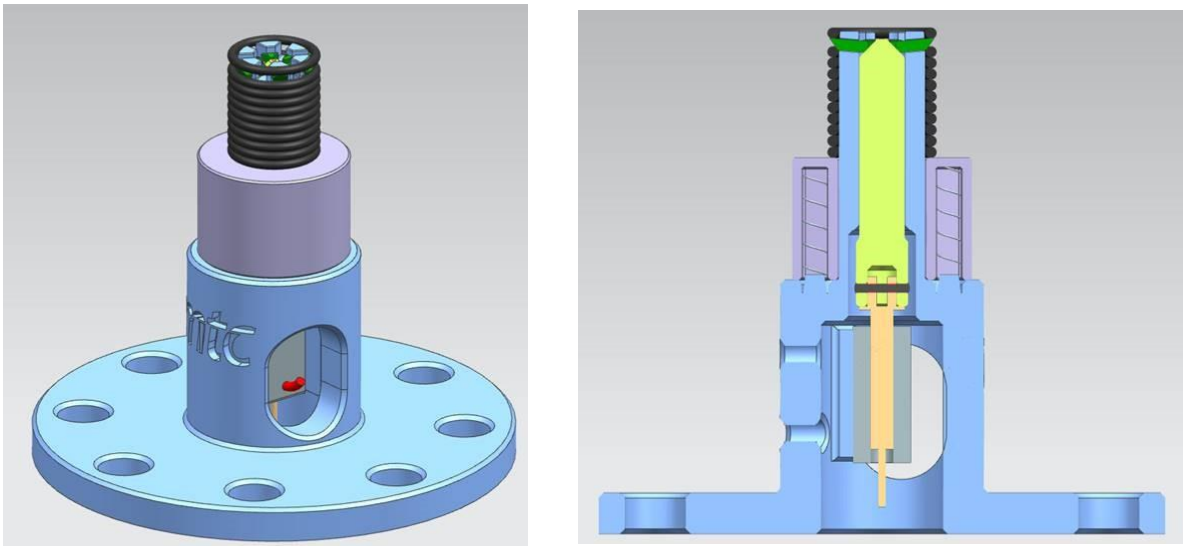


Figure 73: O-ring Dispenser Prototype (left) and O-ring Dispenser Sectional View (right)

At this stage of the project, the plan is to test the second iteration of the dispenser prototype once the purchased O-ring gripper arrives at the MTC site around late October 2021; to then record learnings for further development and optimisation.

In terms of defining a success criteria which the dispenser should achieve, a specified yield rate could be considered to measure successful O-rings dispensing for the robot to pick up. The ultimate aim is for 100% yield rate, though 90-95% is also deemed successful.

6.3.4. SCALP robotic cell upgrade

The cell upgrade activities comprise three main tasks:

1. Upgrade cell hardware.
2. Integrate new software packages.
3. Design new HMI screens for monitoring and controlling operations.

6.3.4.1. Upgrade Cell Hardware

The original control system for the SCALP cell was out of date and limited in terms of connectivity options. Consequently, the decision was made to replace the old control system with a new Siemens S7-1513F PLC accompanied with ET200SP distributed Inputs/Outputs modules to connect field sensors and actuators. The main reason we selected a Siemens PLC is because it supports various connectivity options and is naturally compatible with ProfiNet protocol - the existing cell communication backbone used to connect other components including two KUKA robots, a servo drive and 3 Murr distributed IO modules. Additionally, the chosen PLC supports safety functions and is compatible with the required safety system level. Moreover, the robots' safety signals are handled through ProfiSafe communications. Figure 74 and Figure 75 show the implemented control system.

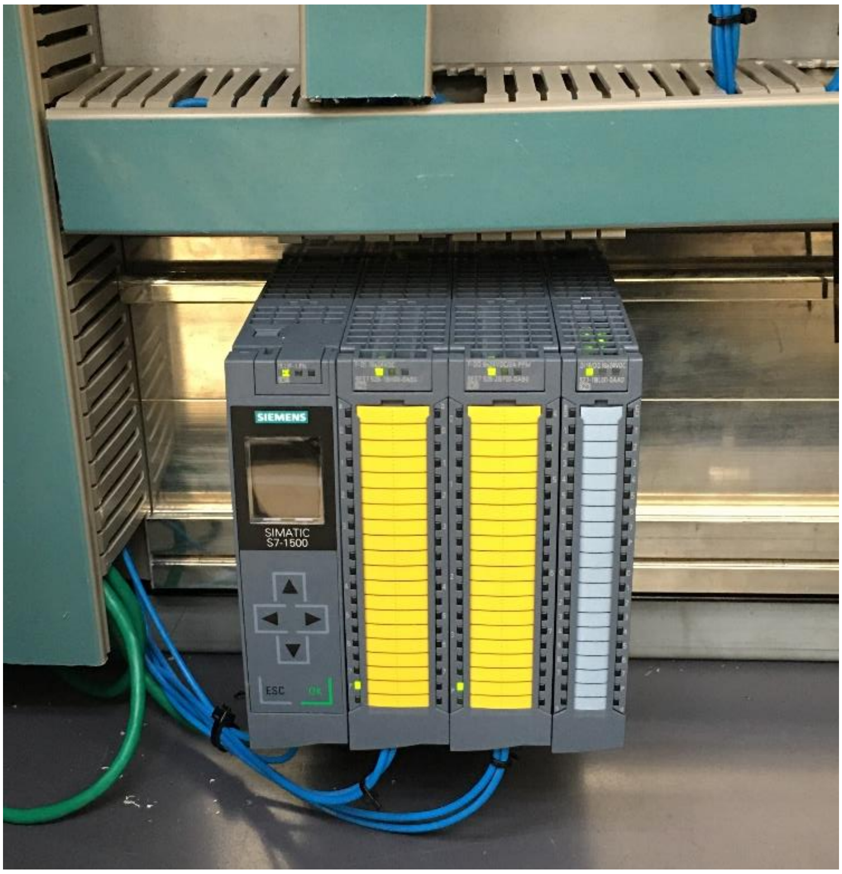


Figure 74: MTC robotic cell control system, S7 1513F PLC

Figure 75: MTC robotic cell control system, ET200SP Distributed IO Modules

6.3.4.2. Integrate new software packages

In order to add flexibility to the cell and enable a quick changeover between different operations, the operator should be able to edit or add new robot programs using a single User Interface. After searching for potential technologies that can enable this functionality, the Robot Integrator Library package –called KUKA.PLC mxAutomation developed by KUKA- was selected as it enables a high-level PLC to control up to 5 robots from a single HMI. In theory, through utilizing the provided function blocks the master PLC can control connected robots without the need to use the designated robot teach pendant. Eventually, there would be less reliance on a skilled robotics programmer every time a new product/operation (requiring new robot programs) is introduced.

So far, the following activities have been achieved:

- The Robot Integrator Library has been installed on both the new Siemens PLC and the robots' controllers.
- The connection to both robots has been initialised and the communication to the robot controllers has been established and tested.
- Using the new designed HMI screens, the two robots can now be jogged and taught for new points.

Next list of activities include:

- Develop additional HMI screens to enable further functionalities for the cell operator including creating a new path from the taught points.
- Testing and integrating created paths within a predefined sequence.
- Analyse the requirements to equip the cell with a vision capability to enable the robots to perform inspection process on the assembled parts to ensure quality.

6.3.4.3. Design new HMI for monitoring and controlling operations.

After upgrading the cell control system, it was required to design and implement new HMI screens from scratch to enable the user to monitor cell conditions and start desired operations. The chosen visualisation software is WinCC Advanced v16 from Siemens as it represents the natural method of communicating to a Siemens Controller. Figure 76 and Figure 77 show examples of the designed HMI screens.

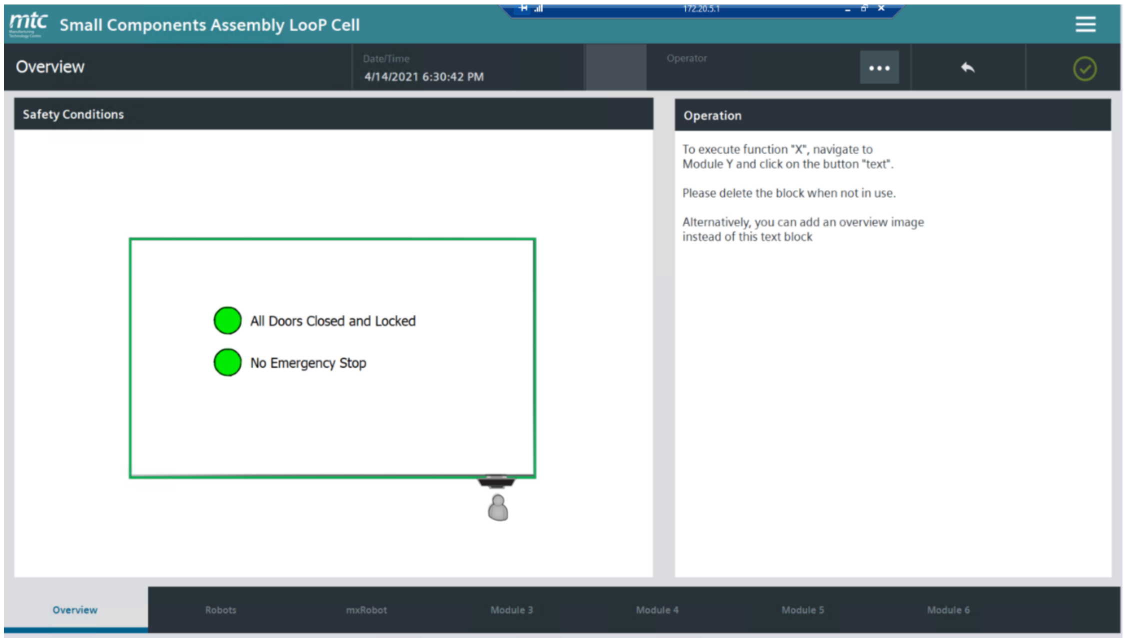


Figure 76: MTC HMI Overview Screen

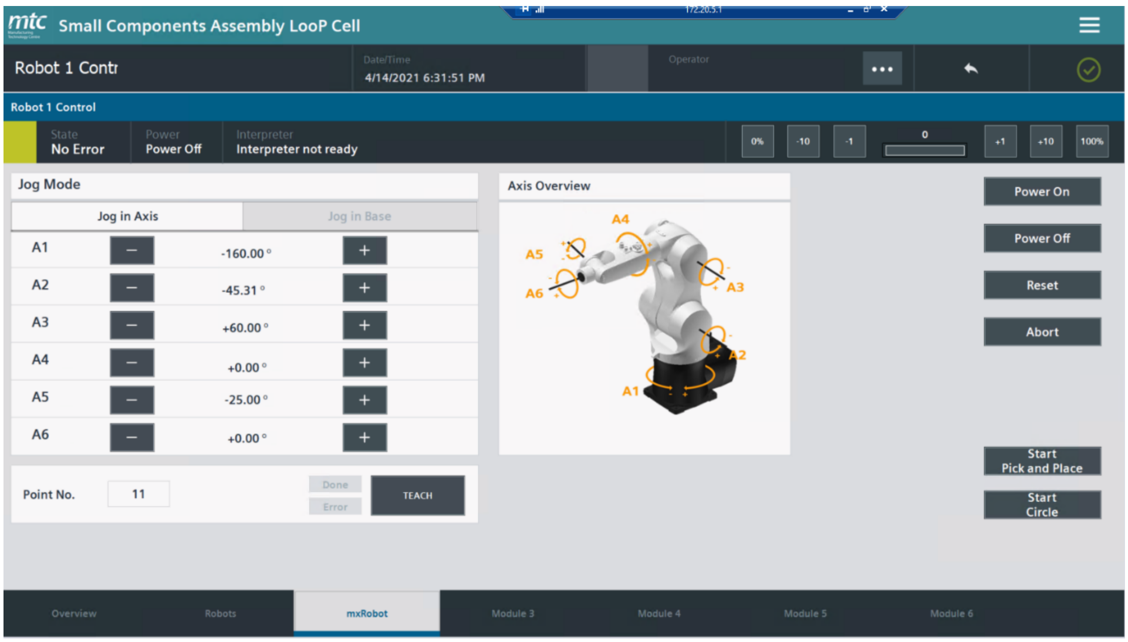


Figure 77: MTC HMI Robot Control Screen

The use of a simple and intuitive HMI will allow MTC workers with no expertise in robotics to easily change the robot task when needed. This approach will result beneficial both during standard manufacturing operations, to give the workers the possibility to easily select the needed robot task from the HMI, and when a repurposing of the cell is required to address a new manufacturing process, such as during a pandemic or any other emergency. In this case, the operator will have the possibility to set up a new specific robot task, defining and adjusting the robot trajectories directly from the HMI, as shown in Figure 78.

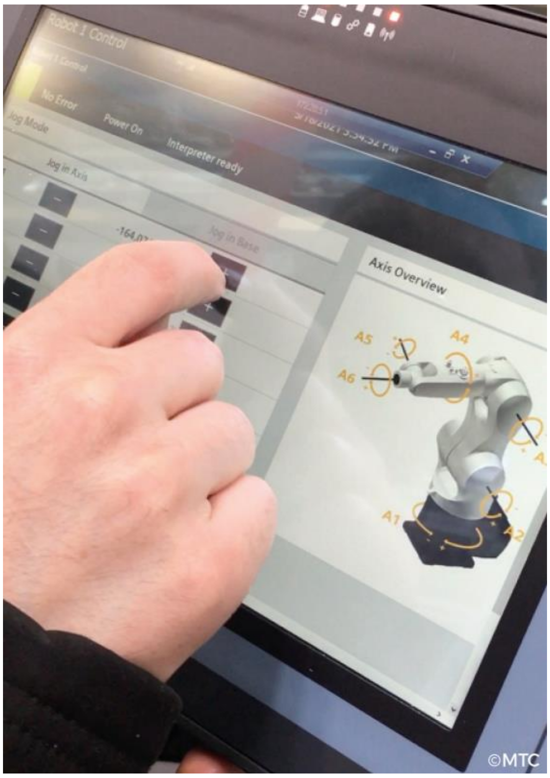


Figure 78: MTC operator using the HMI

6.3.5. Cell 3D model for process simulation

The SCALP simulation started with a model of the 'bare' SCALP cell, created in SolidWorks and imported into Visual Components. This consisted of the physical structure of the cell, including gantry supports holding the robot arms, and flexible mounting locations for tools and fixtures. Two KUKA robot arm models were imported into the model, complete with geometry, kinematics, and virtual controller. After this, models representing the tools and fixtures were imported into the model, and a reach analysis carried out: mounting the tool onto a robot arm, jogging it to find the limits where the tool could reach and positioning the fixtures accordingly. This then allowed an offline program to be created, teaching the virtual robot point positions and movements, and subsequently including virtual I/O to control the tooling.

Offline programming allows robot programs to be created and tested quickly and safely. Multiple different tooling and fixture configurations can be trialed without needing to physical reconfigure any hardware. A cell can be modelled and simulated before committing to any hardware selection or purchases. New programs can be made and tested while a robot is still in-use on a factory floor, or before the hardware is delivered. Programs can be run through multiple iterations, improving and optimising the sequence before it is transferred to a physical robot.

In terms of progress, MTC has been using Visual Components software to test different possible scenarios to fit an O-ring onto one of the CPAP device parts using SCALP KUKA robots. Visual Components 3D is a powerful and simple to use simulator that allows to recreate in 3D environment the robotics cell and easily define the robot tasks sequence in order to get an evaluation of the overall cycle time and any possible issues encounter by the robot during task execution (e.g.: collisions, bad posture). Figure 79 shows a screenshot of the cell model in Visual Components.

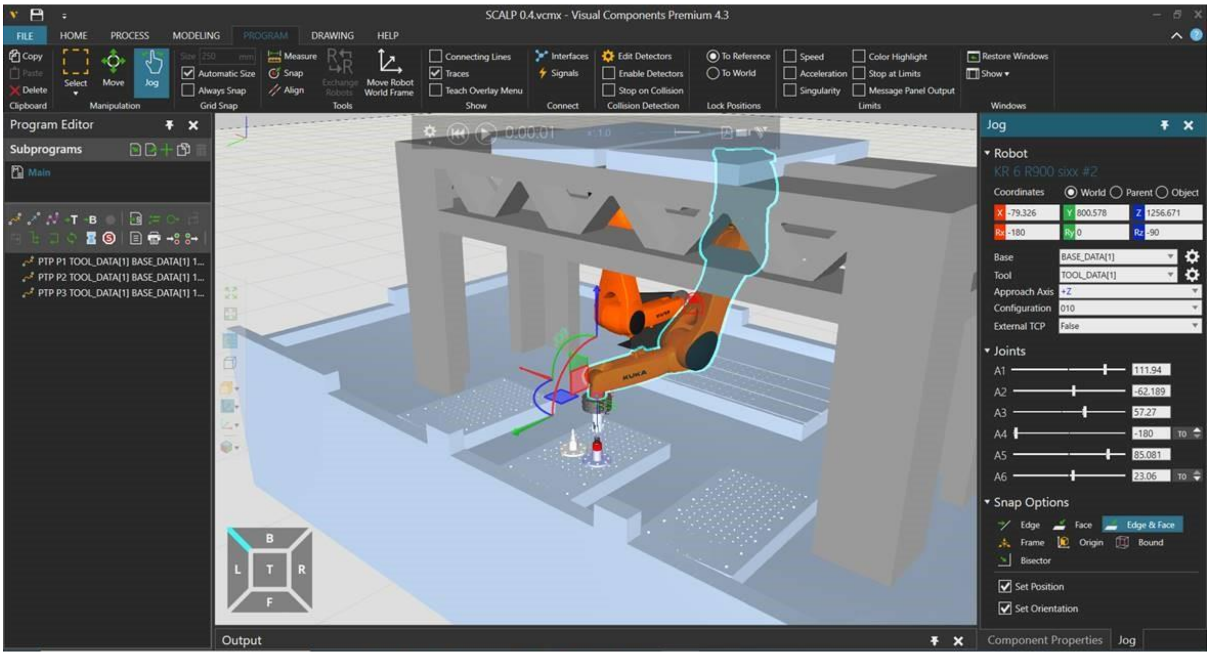


Figure 79: Cell Model in Visual Components Software

In parallel, STAM has also been working on the setup of a simulation environment for the SCALP robotic cell. In particular, STAM has been working with Gazebo simulator, an open-source 3D robotics simulator. Gazebo can use multiple high-performance physics engines, such as ODE, Bullet, etc (the default is ODE). It provides realistic rendering of environments including high-quality lighting, shadows, and textures and it can model sensors that "see" the simulated environment, such as laser range finders, cameras (including wide-angle), Kinect style sensors, etc. These features give the possibility to simulate multiple robots in the 3D environment and to test and validate even complex control algorithms in a dynamic and interactive way. The objective of simulations in Gazebo is to optimize the robot control in multiple configurations, in order to determine the best layout of the cell in terms of components positioning and the best robot motion to minimize the cycle time and avoid any risk of collisions. In Figure 80 a view of the SCALP robotic cell in 3D Gazebo environment.

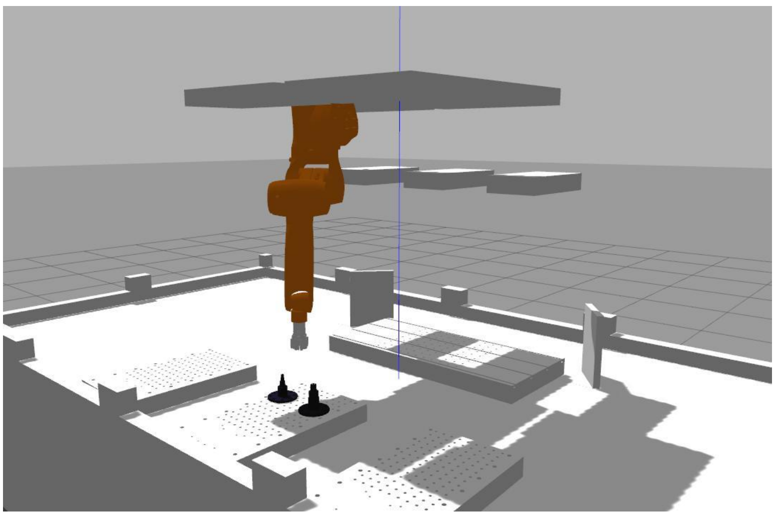


Figure 80: MTC robotic cell in Gazebo simulator environment

6.3.6. Preparation of infographics for training

MS7 deals with the realization of a reconfigurable robotic cell for the rapid repurposing of the manufacturing process and, as a direct consequence, with the definition and identification of best practices towards the achievement of such result. It becomes therefore relevant, for MS7, in terms of training, to share the knowledge that MTC is building up around the SCALP robotic cell setup, upgrade and modelling with other companies willing to implement the same approach or similar solutions. Towards this objective, MS7 partners have been collecting preliminary knowledge on the performed analysis towards cell upgrading, the setup of a new product, the collection of hardware and software requirements, the robotics cell modelling for simulation, and the use case implementation.
The objective is to collect and elaborate all this information into a clear and simple to read infographics that will act as a general support tool and guide for companies that want to undertake the same flexible robotics approach. An initial version of this infographics is visible in Figure 81.

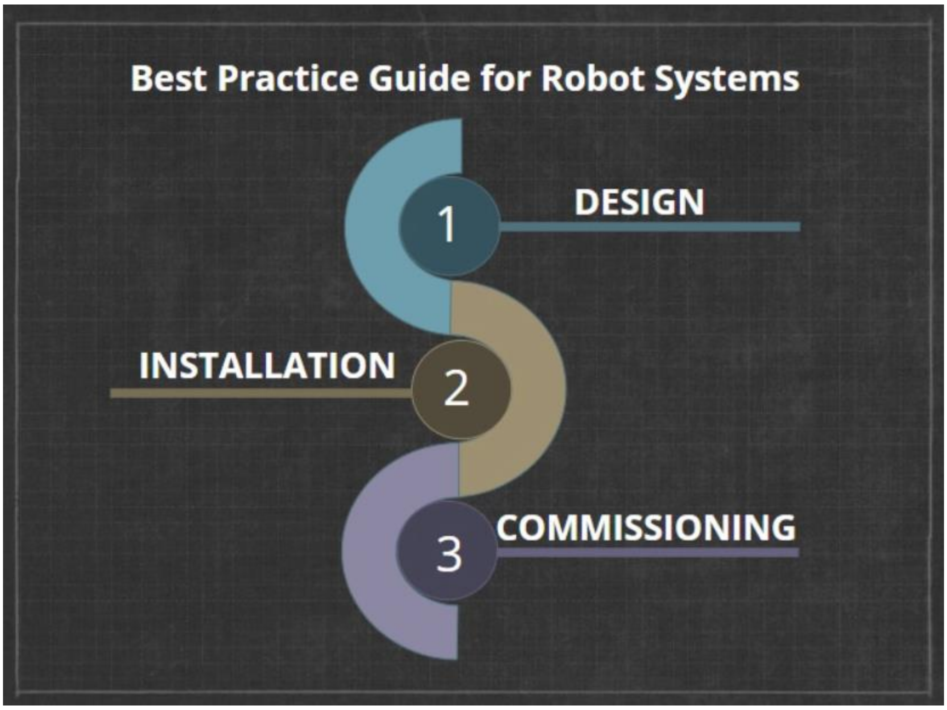


Figure 81: MS7 best practices infographics

As MS7 does not deal with a specific medical product, the collected information on lessons learned will be constantly updated during the course of the project, iteratively improving and upgrading the infographics with future developments and best practices.

6.3.7. Key Outcomes of the 1st—4th Build, Measure and Learn Cycles

1st B-M-L cycle

Prototype/product:

- Detailed system as-is architecture of SCALP cell and first version of documentation on as-is SCALP is produced.
- Analysis of the current process description to understand critical steps to be automated
- Selection of the first task to be automated, which is the o-ring assembly
- System to-be architecture defined

2nd B-M-L cycle

Prototype/product:

- SCALP robotic cell has been equipped with new Robot Integrator library package, which added new relevant functionalities.
- Robot-PLC communication issues have been solved.
- Started the integration of a dedicated HMI to the robotic cell to simplify its set-up.
- Market analysis of the potential O-ring gripper and first contact with suppliers.
- Identified the need to realize a custom design for the o-ring gripper fingers, since commercially available solutions cannot meet the required variability of the task (3 o-ring sizes to be positioned at different depths on CPAP components' shafts).

Training, certification and standardization:

- The collection of information and best practices for the training material has started.
- As there is no specific product to use to train operators, the aim is to produce a lesson.learnt on how to make a production line more flexible for reconfiguration.

3rd B-M-L cycle

Prototype/product:

- Finalization of the design of the custom gripper spacers/jaw adapters for the O-rings placing.
- New adapters manufactured at MTC and sent to Zimmer to perform a test campaign to validate the design towards the task execution.
- Improvement of the robotic cell HMI to give the possibility to the user to define new robot's paths
- Complete test of the robotic cell new functionalities.
- New CAD of the robotic cell created in Visual Components software to start simulation activities towards robot task optimization.
- Investigation currently performed to evaluate the best feeder for the O-ring. Options are automated system vs smaller fixed feeder for just a few O-rings that is manually positioned by the operator.

Training, certification and standardization:

- Steps forward in the definition of the training manual
- Collection of process analysis, best practices and lessons learned in the project so far for the creation of the training material

4th B-M-L cycle

Prototype/product:

- Design of the second iteration of the O-ring dispenser prototype finalized
- Zimmer test campaign of the o-ring with the custom spacer completed. The new design is working well, but some minor adjustments need to be performed.
- Further improvement of the robotic cell HMI.
- First robotic task simulations with Visual Components performed by MTC, to create off-line robot programs and verify different scenarios of the assembly process
- STAM replicated MTC robotic cell in Gazebo environment, to perform a parallel set of simulations and speed-up the definition of the optimal robotic tasks.

- Submitted the purchase order Zimmer Germany for delivering gripper
- Started discussions on adding vision capability to the cell system to handle inspection process, this will improve quality

Training, certification and standardization:

- Discussed and agreed on designing an infographic, to show the main topics to consider when selecting a robotic system.
- Collected coaching and training requirements and developed an infographic.

6.3.8. Plans for the 5th – 8th Build, Measure and Learn Cycles

Product:

- Further improvement of the robotic cell and HMI.
- Realization of the final dispenser prototype.
- Finalization of robot control to perform o-rings pick and place.
- Integration of the required vision system for process quality control.
- Define another use case (different to the CPAP assembly) to implement through the cell and analyse the steps required to perform the first test.

Process:

- Complete execution of the simulation campaign to study the robot motion inside the cell (workspace, singularities, constraints).
- Finalization of the optimal robot tasks towards CPAP components assembly. The objective is to minimize the robot cycle time.
- Test campaign in real environment to demonstrate the CPAP components assembly with MTC robotic cell.
- Perform primary tests and measure times needed to reconfigure the cell to handle the new use case.

Upscaling:

- Improvement and finalization of the infographic, including all future developments and lessons learned.
- Optimise and improve the process to meet the quick changeover objective (within 48 hours).

7. Conclusions

This report has presented all the main technical activities performed in the first year of the CO-VERSATILE project in the framework of WP2. For each Manufacturing Setting an overview of the main technical development has been provided, describing the status of the activities towards the achievement of its own specific repurposing goals.

To complete this information, a brief description of the lessons learned from each B-M-L cycle has been provided, detailing also the main objectives for the next cycles that will be executed in the second half of the project.

It emerges, from this report, that each Manufacturing Setting is working towards the achievement of its own original objectives and that important improvements to each manufacturing process and/or products have been performed in the first half of the project. With inherent differences occurring from on Manufacturing Setting to the other, both in terms of technical requirements and in terms of activities execution and timeline, some common activities have been performed throughout all or most of the Manufacturing Settings, such as the supply chain analysis, risk assessment, preparation of training support material or process simulation. This is a demonstration of how the CO-VERSATILE approach and the provided services can be reproposed to multiple industrial scenarios, reinforcing the expected value of the Digital Technopole.

Further important developments are expected in the second half of the project, to fully achieve each MS goals and objectives. The activities of the second half of the CO-VERSATILE project will be presented in D2.3/D2.4 that will be submitted at month 24.

8. References

1. Y Hardalupas, JH Whitelaw: *The Characteristics of Sprays Produced by Coaxial Airblast Atomisers.* AIAA 93-0698, 31st Aerospace Science Meeting & Exhibit, Jan 11-14, 1993, Reno

2. HF Liu, WF Li, X Gong, XK Cao, JL Xu, XL Chen: *Effect of liquid jet diameter on performance of coaxial two-fluid.* Chemical Engineering and Processing, 45, pp. 240 – 246, 2006.

3. JC Lasheras, E Villermaux, EJ Hopfinger: *Break-up and atomization of a round water jet by a high – speed annular air jet*, Journal of Fluid Mechanics, 357, pp. 351 – 379, 1998.

9. Annex 1

The matrix[1] level is calculated based on the intersection between the likelihood of occurrence and impact of the consequences. The likelihood of occurrence is categorized in very low, low, medium, high, and very high, while the impact is defined as very low, low, moderate, high, and very high. Four risks levels result accordingly: low, moderate, high, and critical.

Figure 82: Risk Matrix

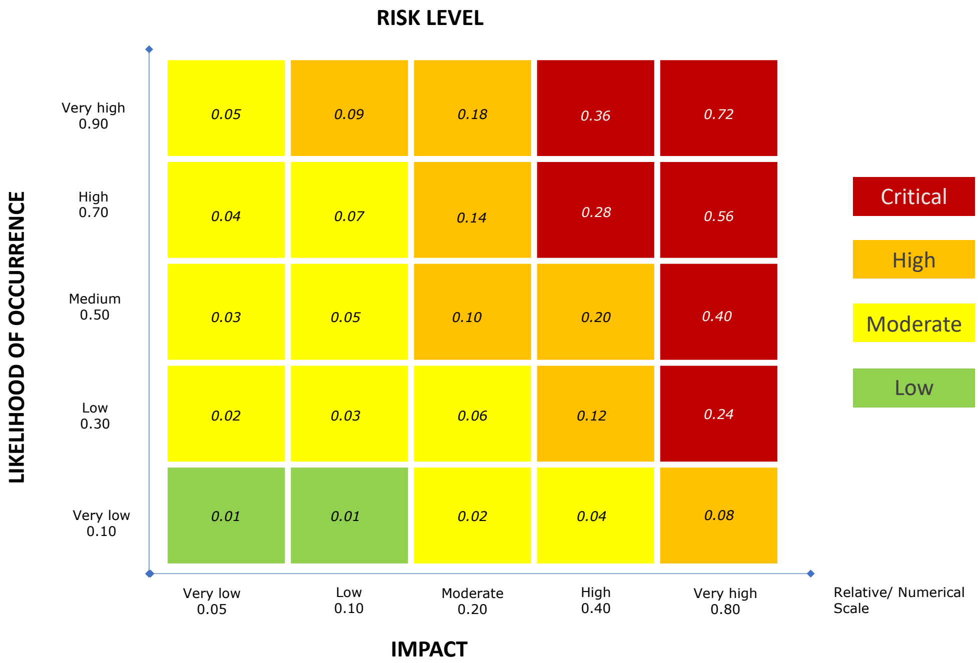


Table 8: Impacts definition

Mask manufacturing objective	Impact				
	Very low / 0.05	*Low / 0.10*	*Moderate / 0.20*	*High / 0.40*	*Very high / 0.80*
Cost	Insignificant cost increase	< 10% cost increase	10-20% cost increase	20-40% const increase	>40% cost increase
Time	Insignificant time increase	< 5% time increase	5-10% time increase	10-20% time increase	>20% time increase
Quality	Quality degradation and functionally impact barely noticeable	Minor impact on overall functionality and quality	Quality reduction requires EU, authorities and/or certifying organism approval	Quality reduction unacceptable to EU, authorities and/or certifying organism approval	Mask is effectively useless

[1] Adapted from: Project Management Institute, Inc. (2017). *A Guide to the Project Management Body of Knowledge (PMBOK® Guide)* – Sixth Edition. Newtown Square, Pennsylvania: Project Management Institute, Inc

10. Annex 2

The O-ring dispenser prototype built in MTC consists of the following parts which are illustrated in below figure:

1. PRT-001 Dispenser Body – 3D printed at MTC (MarkforgedMark2 – Onyx) – QTY 1
2. PRT-002 Retention Pins – 3D printed at MTC (MarkforgedMark2 – Onyx) – QTY 6
3. PRT-003 Pusher Pin – 3D printed at MTC (MarkforgedMark2 – Onyx) – QTY 1
4. PRT-004 O-ring Riser – 3D printed at MTC (MarkforgedMark2 – Onyx) – QTY 1
5. RS 821-318 - Stainless Steel Compression Spring, 53mm x 5.4mm, 0.09N/mm – QTY 10
6. RS 307-3332 - Mecalectro Linear Solenoid, 24 V dc, 0.1N, 30 x 12.7 x 10 mm – QTY 1