

**UNIVERSIDAD SAN FRANCISCO DE QUITO USFQ**

**Colegio de Ciencias e Ingeniería “El Politécnico”.**

**Thermoforming chamber simulation for prosthetic applications**

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**Ingeniería Mecánica**

Trabajo de fin de carrera presentado como requisito  
para la obtención del título de  
Ingeniero Mecánico

Quito, 08 de mayo de 2020

# **UNIVERSIDAD SAN FRANCISCO DE QUITO USFQ**

**Colegio de Ciencias e Ingeniería “El Politécnico”.**

## **HOJA DE CALIFICACIÓN DE TRABAJO DE FIN DE CARRERA**

**Thermoforming chamber simulation for prosthetic applications**

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Quito, 08 de mayo de 2020

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## RESUMEN

En esta publicación, se presenta el diseño, plan de manufactura previsto y simulación de un sistema de termoformado. Se han diseñado cada uno de los componentes necesarios para crear un sistema de fabricación de prótesis animales basándose en el uso de polímeros y se ha comprobado mediante cálculos y simulaciones tanto en estado estable como transiente para demostrar su eficacia. El proyecto consiste en dos partes, la modificación de un horno reciclado para formar la cámara térmica y en el diseño de un sistema de vaciado para el moldeo del polímero. De acuerdo con los resultados obtenidos, el horno adaptado calentaría de manera uniforme al polímero hasta una temperatura de 170 °C en aproximadamente 8 minutos, volviéndolo maleable. En cuanto a toda la estructura, sobreestimando a los moldes se obtuvo un factor de seguridad global de 2.26 a fatiga, lo cual garantiza una larga vida al proyecto y por último, la diferencia de presión de 0.95 atm entre el tanque y la atmósfera reafirma que el sistema de bomba invertida funciona exitosamente como sistema de succión. Además, se simuló el análisis de esfuerzos del tanque de vaciado. Se considera que el siguiente enfoque que se le podría dar al proyecto es un mejoramiento en su relación precio/eficiencia al rediseñar un sistema de vaciado que sea con materiales reciclados o incluso diseñar un sistema de varias entradas para el vaciado.

Palabras clave: Termoformado, prótesis, polímero, simulación, vaciado

## ABSTRACT

In this publication is shown the design process, manufacturing plan and the simulation of a thermoforming chamber. Each necessary component has been designed in order to build a thermoforming system capable of make prosthesis based on the usage of polymers. This project has been double-checked by doing calculus and simulations either considering steady-state and transient-state for comparing and proving its efficiency. The project consists in two modulus or main components. The first modulus consists in the modification of a recycled bread-baking oven to convert it into a furnace and the second modulus is the design of the vacuum system for the polymer molding. According to the results, the furnace will heat uniformly the polymer at 170 °C in 8 minutes approximately, making this material malleable. In the structural analysis, by using an overload, compared to the average load of a mold, a safety factor of 2.26 at fatigue has been obtained. This guarantee a long-lasting lifetime of the project. Finally, the difference of pressure of 0.95 atm between the atmosphere and the tank proves that the inverted pump system works perfectly as a suction system. Additionally, it has been simulated the stress analysis of the tank. It is considered that the following steps for the project might be the improvement of the price/efficiency ratio by redesigning the vacuum system based on recycled materials or modifying this design to build a system of various inputs.

Key words: Thermoforming, prosthesis, polymers, simulation, vacuum



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## INTRODUCTION

### **Executive summary**

A thermoforming chamber is a machine built for turning a solid sheet of polymer into a malleable sheet in order to build close-fitting prosthesis. Nowadays, the animals have more possibilities of suffering an accident which makes them lose any of their extremities. Although, the pet's life is more valuable now; there are not many places capable to build prosthesis and some of them are made in foundations like "Fundación Hermano Miguel" that make prosthesis for humans. The lack of thermoforming chambers in Ecuador is the main motivation for designing one that would make prosthesis for animals so the foundations could make more prosthesis for humans. This project consists in the designing and calculations of the thermoforming chamber and each of its component that fulfill each requirement of the client, including the simulations that prove its functionality. The document contains the designs analysis, the calculus for the prototype and the simulation of each component to prove that each one accomplishes its function.

### **Problem statement and Project specification**

This project consists in the construction of a thermoforming chamber for polymers applied to prosthesis production for animals that suffered partial amputation of an extremity. The customer "Mechanimals" produce animal prosthesis to improve their quality of life. The production of prosthesis requires engineering criteria to achieve the precise geometry that fits animal's part. 3D modeling has been employed presenting difficulties because of the irregular shape of body part and the printing time required. Therefore, polymer thermoforming alternative will be design and employ to obtain prosthesis with proper geometry and satisfy customer's requirements.

**Requirements.**

The client needs a thermoforming chamber to produce their own prosthesis and reduce its cost of production. A limited budget would be considered for the project as well as the customer's requirements. Listed below are the requirements and the could-be's of the customer for the project.

***Must.***

- The heating system must have a temperature controller
- The vacuum system must be stable and controllable
- The vacuum structure must be firmly fixed to a base
- The system must provide operator's safety
- It must have a uniform temperature distribution over the area of the polymer sheet heating system.

***Could-be.***

- Use the least amount of budget
- Compact as possible
- Easy to handle

**Preliminary information.**

Vacuum thermoforming consists of a technique where a sheet of heated thermoplastic is deformed using negative pressure (vacuum pressure) between the sheet and a solid mold. This process is common along industry to produce large numbers of pieces at relatively low costs and with the needed precision. In the words of Oliveira (February, 2018), the quality of the final product manufactured by this method usually could only be determined by the results, as there are some factors that may cause failures or defects. The appropriate control of this factors

assures not only the quality but also the efficiency of the system, which is the reason for many manufacturing companies to automate these processes and replicate the same results with the minimum number of errors, always searching for improvements using analytical, numerical and computational methods to predict the results avoiding trial and error physical tests.

According to Jamil (June, 2018), there are several key factors that determine the success of the process. The temperature control is one of the most important as the polymer sheet heating process depends on the material and its future application. The clamping of the sheet for handling is determining too, as it prevents the formation of material drops and critical deformations that could lead to a poor wall thickness. The handling also plays a role in forming, as it needs to bring the capacity to manipulate the piece with total comfort. After the forming process, controlled cooling could help to avoid imperfections, being fans and water sprays the most used cooling mechanisms.

At first instance, the paper from Nwoye (January, 2009) was analyzed. In this work, the author explains the process and needs of a basic thermoforming machine to operate efficiently, so it was used to settle some bases and obtain technical data for developing this design. Information that was considered important from this guide was the material selection and parameter criteria to apply on its construction. Going into the initial design steps a 0.5 HP single phase vacuum pump, a middle-vacuum pressure generation () and heat source of 1.8 kW were the parameters that most suited the needs of the project, and were the first numerical values to be considered to start iterations.

The automatization of the process analyzed by Foor et. Al. was considered for the project as there are several methods to automate a system like the one which is on development. As the most critical parameter to consider is the temperature control, it was determined that it must be driven by a PID control or a precise analog temperature setting system. Additionally, the

literature offers more data on design parameters for the heating system and on methods for effective clamping between the vacuum and the mold.

Thermoforming system and the bonding of an adhesive polymeric film to a substrate during its process is analyzed by Pata (1991). This study describes the properties of polymers to support its application in prosthetics. The procedures of thermoforming wherein the sheet is heated and then drawn by vacuum into bonding contact with the substrate are discussed and it concludes that the handling and movement of the semi melted polymer sheet could introduce errors to the final result. So, it seemed imperative to develop a simple method to improve results with lower economic investment.

With the requirements being set and after the initial data was analyzed under basic engineering criteria, it was determined that the most critical aspects on the design of a thermoforming process are the temperature control for the polymer sheet heating system and the efficiency in operation of the vacuum molding. It's also important to mention that the system must be ergonomic and suitable for continuous operation cycles, assure safety for the operator and adjust to the energy efficiency standards.

## **Design concepts and selections**

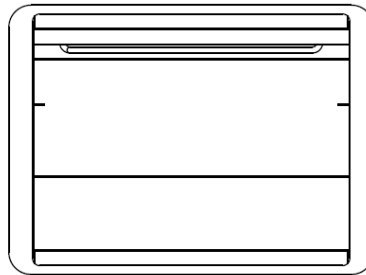
### **Alternative solutions.**

The design concept for the project was divided in three major steps: the design process for the heating system, for the vacuum system, and for the heat source. For the heating system design, the options considered were, to modify a bread oven taking advantage its utility to employ it on the project, or design and build a completely new heating system structure from scratch.

The first alternative consists in modifying a bread oven with the addition of an electric resistance on the top sheet inside the structure that would heat the interior space uniformly, as

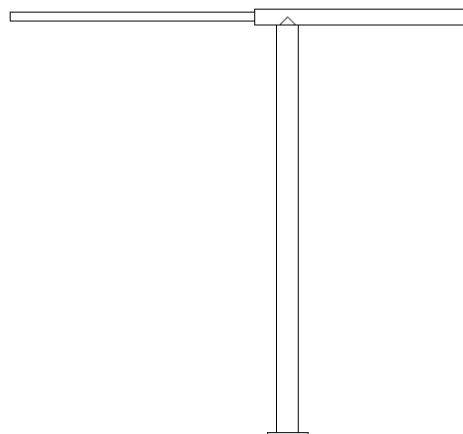


a uniform temperature distribution along the polymer sheet is required for thermoforming process. The second alternative consists of the design of a new oven structure, adapted to the requirements of the customer. Each of these alternatives needed an evaluation by a selection method in which the criteria are qualified by the performance of the alternative in relation with the other. The result would define the viable alternative according to selected criteria and the variables set for them.



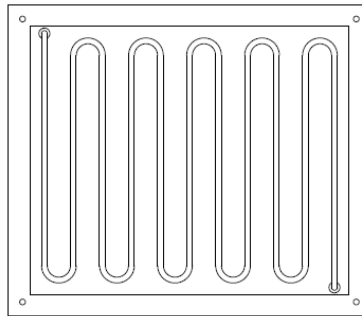
*Figure 1. Furnace design selected alternative*

For the vacuum system design with two alternatives were also considered. The first one consisted in employing a vacuum cleaner as the vacuum generation system. The second alternative considered using a compressor or a pump instead, as this tool bring the option of having ranges from mild to strong vacuum pressure as a result. Like for the oven design selection, the same method has to be applied for these two alternatives corresponding to the vacuum system in which the mold will be set to form the polymer sheet.



*Figure 2. Vacuum system design selected alternative*

In the case of the heat source that will increase the oven temperature to the required values, there are two alternatives of electric heating devices to be considered. The first one is an electrical resistance in the interior sheet surface of the top of the oven. The distribution of the wire over the area must deliver uniform heat as required. This option also implies that there must be a heat distribution interface between the resistance and the polymer sheet to avoid burning the plastic material. The second alternative is a distribution of heat radiation tubes located at the interior top of the oven with the same purpose of uniform heat distribution. Both alternatives for heat source must be evaluated under the same method as previous design selections, to avoid ambiguities on the selection procedures.



*Figure 3. Electrical wire resistance, heat source selected alternative.*

## Project Management

### Schedule

*Table 1. Initial schedule for the project*

<b>Activity</b>	<b>Estimated date</b>
First milestone: Transient heat transfer distribution in the furnace	April 6th
Second milestone: Fluid dynamics simulation on the vacuum system	April 13th
Third milestone: Static failure stress analysis in the structural components	April 18th
Static pressure analysis in the tank	April 27th

The schedule of *table 1* was proposed based on the syllabus of the course. Each component will be checked, and It may be varied if necessary.

### Project Budget.

*Table 2. Project budget planning*

Item	Quantity	Description	Price
Steel pipe 2[in]	3[m]	Pipe for main vertical support	\$8,00
Steel pipe 1/2[in]	3[m]	Pipe for horizontal support	\$6,00
M10x40 bolt	4	To fix structure to the ground	\$1,81
1/2[in] L steel profile	6[m]	For oven support structure	\$11,00
Sheet iron	2x2[m <sup>2</sup> ]	For oven and support structure	\$8,00
Oven door	1	Oven sealing	\$40,00
Water pump 1,5HP	1	Vacuum system	\$115,00
Manometer	1	Vacuum pressure measurement	\$15,00
3500W resistor	1	Oven heating system	\$95,00
Water tank	1	Inverse vacuum system	\$26,00
1/2[in] fitting	2	Vacuum system accessories	\$4,00
1/2[in] butterfly valve	1	Vacuum system accessory	\$3,95
Pipe sealant	1	Vacuum system sealing	\$6,74
Electric cable	4[m]	Electrical power supply	\$2,40
Connection cable	3[m]	Electrical sealed connections	\$7,23
Power control system	1	Temperature control	\$22,00
M8x30 bolt	4	Pump fixing to tank lid	\$1,67
		<b>Total</b>	<b>\$373,80</b>

The costs listed on *Table 2.* are estimations according to common prices in the market, so they may vary depending on the provider. As the vacuum system is not critical and the selected pump supplies more power than the minimum required, it has been considered to buy a used pump, that must be working on optimal conditions, to adjust the budget for risk management. The oven is not listed as it was already in hand, but the door spare is needed so it was added to project expenses.

### Engineering Standards

There are technical standards to be considered during the design process of a thermoforming machine with vacuum pressure molding system. The research of the standards was classified by subject and the ones considered relevant for the project are listed below.

- ISO/IEC 13273-1:2015. Energy efficiency
- ISO 8549-1:1989. Prosthesis terminology
- ASTM F732 – 17 Standard Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses
- ISO 17853:2011. Wear of implant materials — Polymer and metal wear particles — Isolation and characterization
- ASME B19.1-1995. Compressors
- ISO 13404:2005. Electrical resistances
- ASME EA-1G-2010 (R2015). Energy efficiency

#### **Engineering Criteria.**

To achieve the goals that were defined by client needs, is essential to settle each requirement into a measurable engineering criterion. Thus, all the technical requirements were briefly analyzed to set up the initial conditions to focus on the project development and set the path to an efficient design process.

#### ***Must.***

- The heating system must be capable to reach a maximum temperature of 300 degrees Celsius.
- The heating system must have a control that stabilizes the system at the desired temperature.
- The vacuum system must have a manometer to measure the vacuum pressure generated using a precision valve.

- Adjustable connection to the mold with a clamping tolerance of 3[mm] between the male and female connector.
- It must satisfy technical standards for safety factors.

***Could-be.***

- Capable of being disassembled to a minimum of 3 main pieces or subsystems.
- Fit the heating system in a space of one cubic meter.
- Make the system weighs no more than 100 kg.

## MATERIALS AND METHODS

### Material and component selection

The selection method for each step is shown below in *Table 3*.

*Table 3. Design selection method*

%	Criteria	Oven design				Vacuum system				Heat source			
		A		B		A		B		A		B	
15	Budget: consist in spending less on its manufacturing	4	0.6	3	0.5	3	0.45	3	0.5	3	0.45	3	0.5
15	Ergonomics: consist in designing machines that are adaptable to the operator.	4	0.6	4	0.6	2	0.3	3	0.6	4	0.6	3	0.6
20	Simplicity: consist in the difficulty of obtaining the parts and its construction	4	0.8	3	0.6	4	0.8	3	0.6	4	0.8	3	0.6

20	Safety: defines the level of hazardous for the operator.	4	0.8	4	0.8	2	0.4	3	0.8	5	1	2	0.4
10	Maintenance: the ease for gathering parts and repairing it at low cost.	4	0.4	3	0.3	3	0.3	3	0.3	4	0.4	3	0.3
15	Product diversity: The range of products capable to produce in this machine	5	0.75	5	0.8	2	0.3	3	0.8	5	0.75	3	0.8
5	Energy consumption: it focuses on the energetic efficiency.	4	0.2	5	0.3	4	0.2	3	0.15	4	0.2	1	0.05
100	Total		4.15		3.8		2.75		3.75		4.2		3.25

### Design for Simulation

A computer engineering software will be implemented with the geometry parameters settled in the CAD model of the thermoforming system to obtain relevant information. The simulations that are needed to analyze the design results are a heat transfer analysis for the heating system, an structural analysis for the mold vacuum support, and a CFD simulation of the vacuum system with an stress analysis of the water tank. The results are going to be shown in the same order as mentioned before because this is the order of importance and impact that has each component on this project. After analyzing each component and its conditions, the simulations were made, and it was a success. Each component attains all the expectations of the client and demonstrate that this prototype is fully functional.

**Objectives.**

- Demonstrate that the calculus made before to design the prototypes are right by comparing the results.
- Test every system and evaluate the design chosen so they fulfill all the expectations of the client by using professional software like ANSYS or CFD.
- Determine the safety factor and the limits of the prototypes to prevent overloading.

**Simulation.*****Heat Transfer.***

The present report is an analysis of the heat transfer simulation proposed for first project's milestone. The furnace component of the system has been simulated for its real operation conditions with the implementation of a multiphysics software, ANSYS. The importance of this process is to determine potential critical conditions when furnace is under operation with the parameters settled by the authors criteria and verify its efficient functionality. A description of the process is provided, and the results are presented and discussed.

First, the CAD model of the furnace previously designed in INVENTOR based on a bread oven design with some necessary modifications to be implemented in the thermoforming process has been exported to ANSYS compatible format. Next, a transient thermal project has been established with the furnace model as the geometry in study. The process of meshing is applied to the model and its success proves the geometry converges for finite element analysis. The mesh of the model is presented below in *Figure 4*.

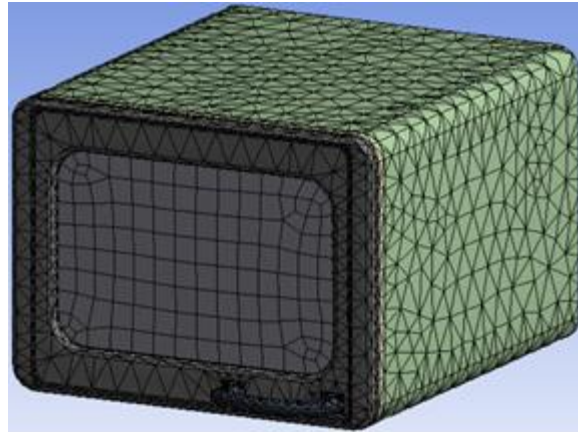


Figure 4. Mesh of the modified oven model

The setup process (*figure 5*) for the transient thermal problem in the furnace consist in creating and defining all the heat transfer modes presented on the real operation conditions. For this case, it has been settled two convection forms, one is in the interior space of the furnace with air at  $280\text{ }^{\circ}\text{C}$  and a convection coefficient of  $h = 6.5\text{ W/m}^2\text{ }^{\circ}\text{C}$  and the other convection in the external space with ambient air conditions. A heat flow of  $\dot{Q} = 1500\text{ W}$  corresponding to the electrical resistor and a perfect isolation to the superior surface of the ceramic plate where the electrical resistor is adapted.

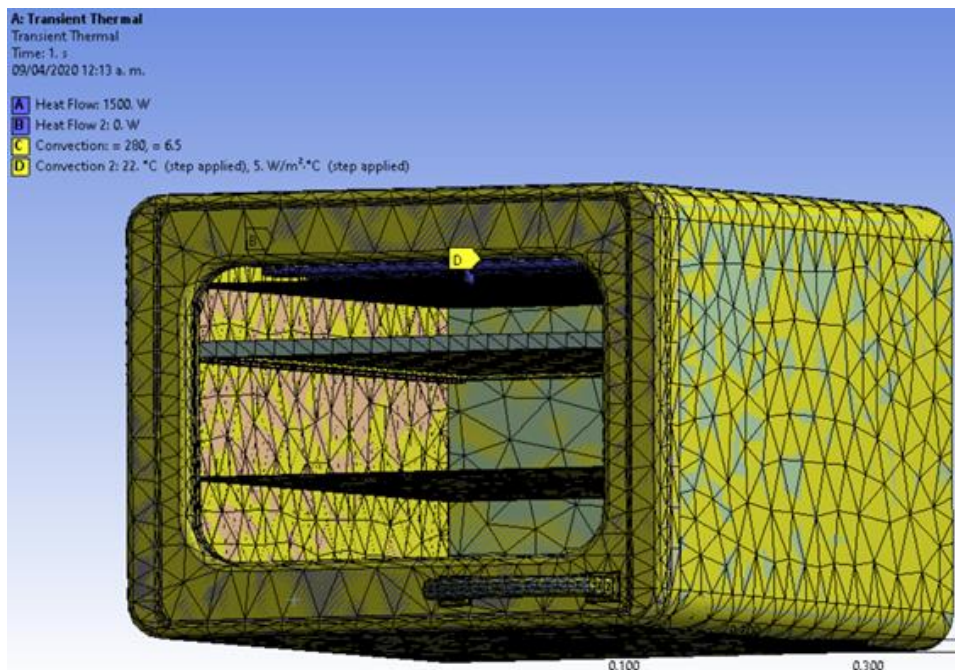


Figure 5. Boundary and initial conditions for simulating the furnace



The simulation was run for 500 steps, each step represents 1 s, so the results will show 8 minutes approximately of the furnace component operation.

A thermocouple is going to be located at the back and middle of the oven cavity and at a height of 2 [cm] above the tray so we can get the most reliable data for controlling the temperature. This thermocouple is going to be directly connected to the controller. The thermocouple could be a type K. The controller that is planned to use in this project is a PID Voltage regulator of 1/8 DIN. The location of the electrical resistance is at the center of the ceiling and in front of it is going to be an Aluminum plate that distribute heat uniformly around the cavity.

### ***Structural stress analysis.***

Failure analysis is based on failure theories, for this case the von Mises theory has been considered since structural steel is a ductile material. Additionally, a maximum principal stress and a total deformation analysis has been applied to the structure plots.

First, the CAD models of the structures, previously designed on INVENTOR based on the design criteria calculations and ergonomic dimensions for thermoforming process application, have been exported to an ANSYS compatible format. Some of the ergonomic solutions were to take out the front bar of the oven support in order to prevent mobility accidents, risk for the operators and building a base of the vacuum pipe structure which is smaller than the suction tube. Next, a static structural project has been established for each structural component model settled as the geometry in study. The meshing process, shown in *Figure 6*, has been applied to the models and their success prove the geometries converge for finite element analysis.

The setup for the simulations is detailed as following

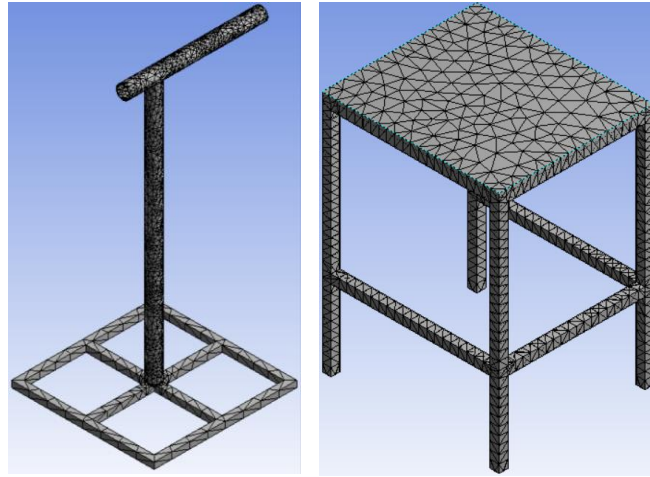


Figure 6. Mesh of the oven support and the pedestal

For the oven support structure.

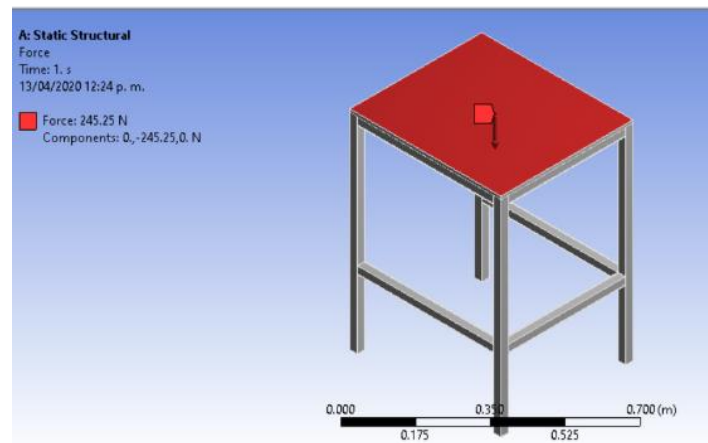


Figure 7. Initial conditions of the oven support

In figure 7, the force  $F$  is the resultant force of a distributed load that corresponds to the weight of the oven applied in the centroid of the external surface of the panel in which the oven is supported. The selected material for this structure is structural steel (AISI-1018, ASTM A36).

For the pedestal structure.

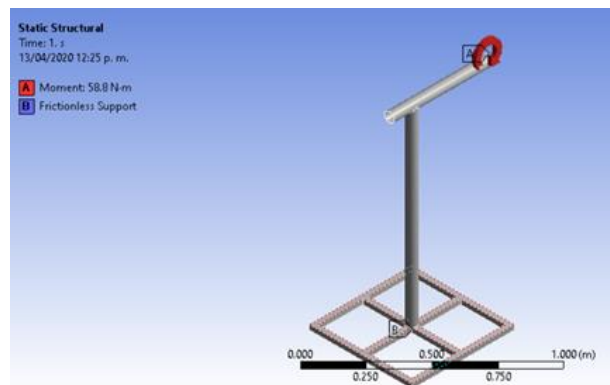


Figure 8. Initial conditions for the pedestal

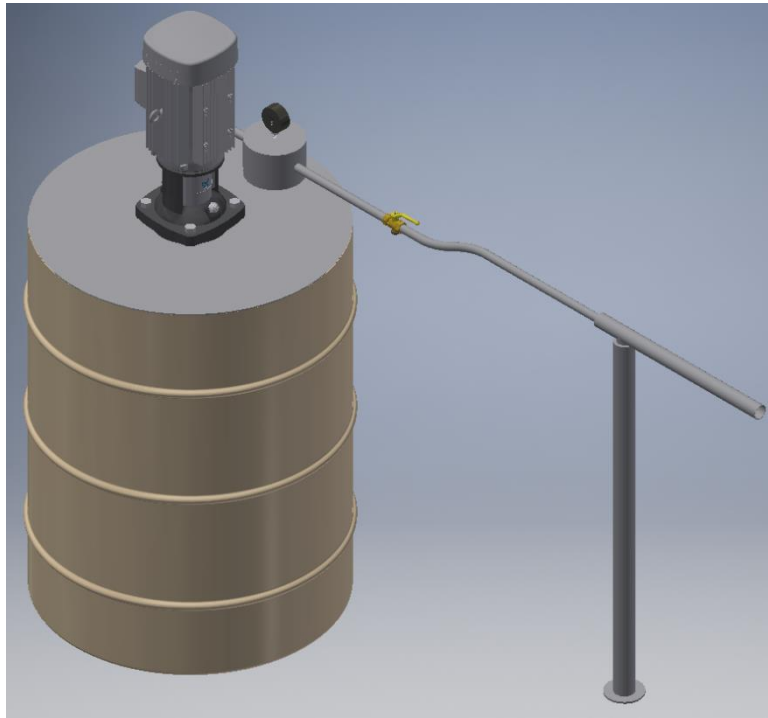
In Figure 8, the bending moment A is a resultant of the punctual force corresponding to the mold weight with an approximate distance to its centroidal point. The frictionless support is established for the lower surface in contact with the floor. The selected material for this structure is structural steel (AISI-1018, ASTM A36).

### ***Vacuum system.***

The study consists of a Computational Fluid Dynamics simulation that evaluates the working performance of the vacuum system. For this system, an inverse water pump generates the negative pressure, and is important to obtain results of the pressure at the pipe end where the mold will be set. Two of these three pipes must be longer than half the tank's height and the other one must be shorter. The longer pipes are going to be connected to the inlet of the pump and to the suction tube. It is important to consider this because if a shorter pipe is used at any case, the values of the pressure may vary. Half of the tank must be filled with water, because if the inlet tube is shorter it will not carry water to the pump, or by the other way it will take a mixture of water and air that will damage the pump. On the other hand, if the suction tube is shorter the pressure will remain constant on the suction system so it will not generate a pressure differential.

This tank must have a gauge in order to control the pressure inside the tank and to have an instrument to measure and determine the amount of differential pressure that is going to be need for the vacuum depending on each mold used. The differential pressure is proportional to molds volume; this means that the bigger the mold is, the greater differential pressure is needed. Also, it is important to have a valve in the system, so it is manually controllable the suction system and the amount of air took out.

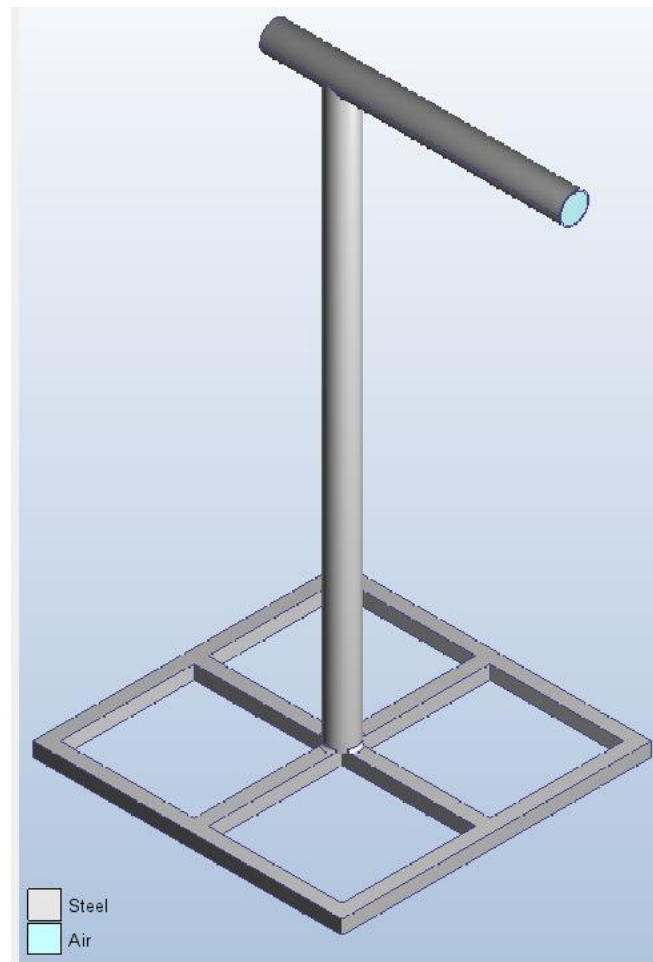
The purpose of this simulation is to analyze these components on their real operation conditions considering all factors. Therefore, the CAD model shown in *Figure 9* has been settled in AUTODESK CFD as the geometry for a fluid analysis.



*Figure 9. CAD design of the vacuum system using a hydraulic pump*

Due to geometry complexity and simulation simplifications, the tank has been suppressed from the model with the pump system. The pedestal structure with the piping were kept since they are the relevant components in the thermoforming process.

For the setup of the simulation, the material for the structure and piping has been defined and the volume in the interior of the pipe has been filled with fluid as shown in the *Figure 10*.



*Figure 10. Material assignation for the fluid simulation*

The next step consists in applying the conditions to the fluid that would cause the water pump operation, since it has been suppressed in the model. For this, we have defined a pressure boundary condition in the surface in contact with the pipe outcoming from the water pump with value of 0.607 psi pressure gage, a value obtained by previous calculation. Additionally, a pressure boundary condition in the surface in contact with the atmospheric air has been set with value of 0 Pa pressure gage.

Finally, an automatic size meshing was applied, and the simulation solution set up was established for 400 steps. The CAD used for the simulation is shown in the following figure because it is more approximate to the real system. The simulation made for this milestone is a transitory state fluid simulation.

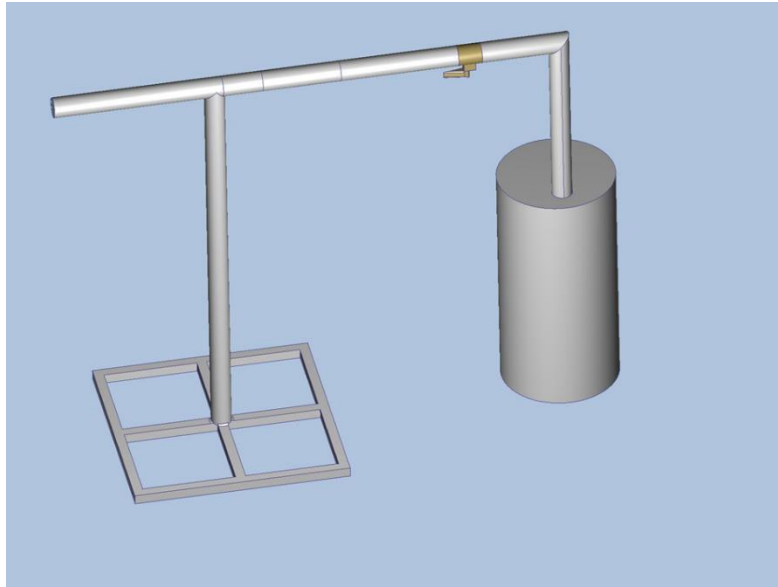


Figure 11. Minimalist vacuum system redesign for simulation

### ***Tank stress analysis.***

The tank stress analysis consists in the simulation of the tank based on the difference between the inner pressure and the outer pressure, which is the atmospheric pressure. This simulation is to check out the stress on the tank and determine if there is going to be any failure or if the tank will collapse because of a big compression in the tank. The differential pressure used as a parameter is a 0.95 atm. Thus, the pressure at the outside surface is 1 atm and the inside surface pressure is 0.05 atm. The material defined for the water tank is Polyethylene. The design is based on a commercial water tank of 55 gallons.

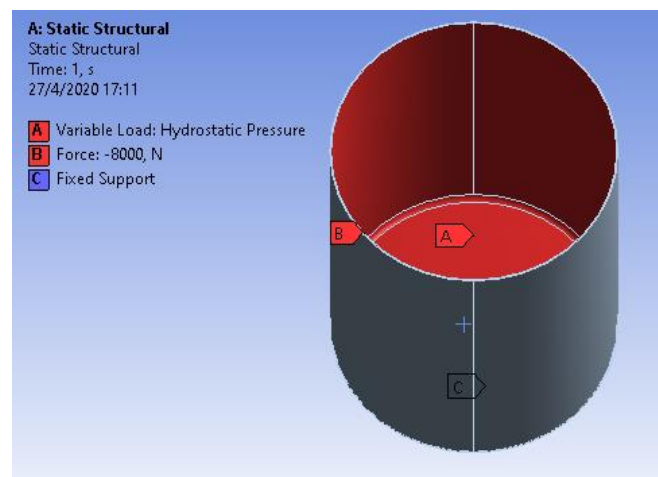


Figure 12. Initial conditions of the vacuum tank for stress analysis

The *Figure 12* shows the CAD model for the tank and the setup simulation applied. A hydrostatic pressure in the bottom of the tank is settled to recreate the tank filled with water. A force of  $-8000$  [N] is applied to the top edge of the tank. This force is a resultant from the weight of the lid with the pump adapted. The fixed support represents the tank is leaning on the floor.

## RESULTS AND DISCUSSIONS

### Design report

The dimensions of each component were based on ergonomics and its ease of construction. The comfort while using these machines is essential. For the furnace, the dimensions were given by the recycled oven which are  $36 \times 50 \times 50$  cm<sup>3</sup>. The distance between the resistance and the tray is 0.17 m. For the vacuum system, the pedestal must have a height of 1 m and the pipes used are of 1 ½ in of diameter. The input tube, which is going to connect the mold to the vacuum system is going to be of 0.4 m length.

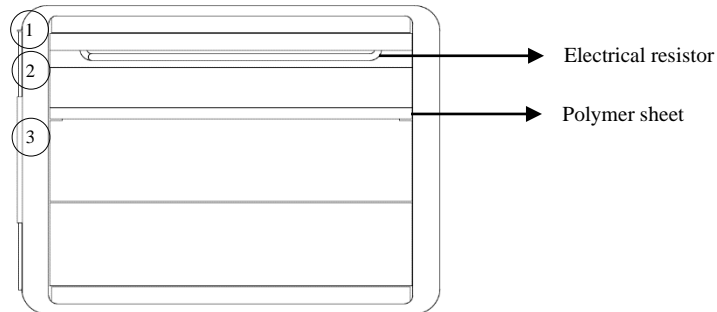
### Engineering analysis

#### Calculations.

To build a fully functional project it is necessary to do some calculus and simulations. The four main calculus are: thermal distribution, the electrical power component analysis, the vacuum analysis, and the stress analysis.

### *First Calculus.*

For the heat transfer calculations, it is used the main heat transfer equation taking into consideration that it is a linear unidimensional heat transfer problem applied to the furnace as



*Figure 13. Furnace diagram for heat transfer calculus*

shown in the *Figure 13*.

Thereby, the calculus was made with the following equation:

$$\frac{\partial q}{\partial x} = \rho c_p \frac{dT}{dt}$$

By considering steady state the temperature variation during the time would be zero so the heat transferred is constant and the conduction through the oven varies with each material the heat passes through the equation used depends on different resistances. Its important to consider that the contribution of radiation from the heat source is negligible for the calculus as the oven design is intended to work by heating the PE sheet by convection.

$$\begin{aligned} \frac{\partial}{\partial x} \left( k_{total} \frac{dT}{dx} \right) &= 0 \\ k_{total} \frac{dT}{dx} &= q \end{aligned}$$

Where there is convection and it is considered the area, so the main equation is:

$$\frac{1}{R_{total} * A} * \Delta T = Q$$

Finally, it is gathered the final equation where the total resistance is the sum of the air convection, the PE conduction and the air convection that is in contact with the tray.



$$\frac{1}{\left(\frac{1}{h_{air} * A_1} + \frac{L}{k_{PE} * A_2} + \frac{1}{h_{air} * A_3}\right)} * \Delta T = Q$$

Assuming that the variation of Temperature is 30 degrees Celsius, where the highest temperature is 230 °C, and the dimensions of the PE sheet are 33 x 54 x 3 cm , it was obtained the amount of power needed to make malleable the plastic on steady state.

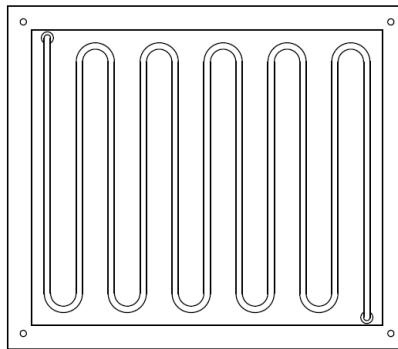
$$Q = 29.58 \text{ W in steady state}$$

And the temperature of the tray would be:

$$T_{tray} = 164^{\circ}\text{C}$$

### *Second Calculus.*

The next calculus is about the energy supply and electrical resistance. It was necessary to use two main equations applied for the electrical resistor shown in the next figure (*Figure 14*).



*Figure 14. Diagram of the resistance distribution.*

These equations are:

$$\begin{cases} P = V * I \\ R = \rho * \frac{L}{A} \end{cases}$$

It is known that the current and the resistance are proportional, and the heat value calculated before is in Watts, the unit of Power so we use this value to find out which length is suitable for the project.

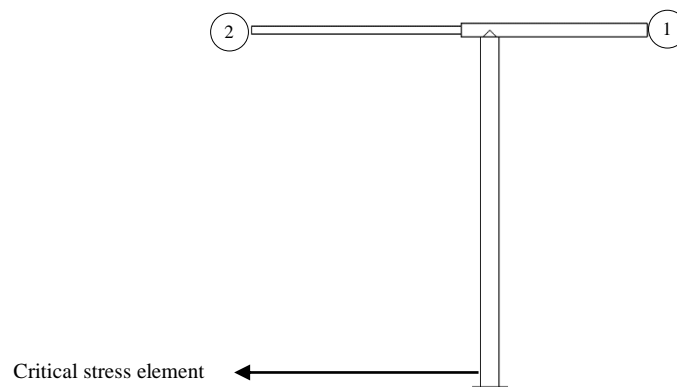
$$\begin{cases} P = \frac{V^2}{R} \\ R = \rho * \frac{L}{A} \end{cases}$$

By knowing the material used to make the thermal resistance and its most common dimensions this calculus can be made to find out how much resistance is needed, and which length is suitable for this furnace. The material used in the resistance construction is Nichrome and it has established diameters. The data for this second calculus were the Power of 400W, which would be the maximum limit taken from a furnace, the Nichrome resistivity of  $10e-6$  and a diameter of the resistance of 1,5 mm.

$$\begin{cases} R = 30,25 \Omega \\ L = 5,34 m \end{cases}$$

### *Third Calculus*

The third calculus is based on the mold support, also known as pillar, or holding shown in the next figure (*Figure 15*).



*Figure 15. Diagram of the pedestal for stress analysis*

For this it is important to calculate the combined stress analysis. In the case of this support there will be one acting force and the objective is to determine the maximum force capable to resist. The safety factor used is 1.35 and the formulas are:

$$\sigma_{compression} = \frac{F}{A}$$

$$\sigma_{flexion} = \frac{M * c}{J}$$

Also, it is known that the total stress in the critical point it is the sum of the traction made by flexion and the compression. Thus:

$$\sigma_{total} = \sigma_{compression} + \sigma_{flexion}$$

And this formula is replaced in the formula of the safety factor, and the formula is the following knowing that the tubes are circular, and it is used the yield stress.

$$F * \left( \frac{1}{A} + \frac{l * \frac{d}{2}}{\frac{\pi d^3}{32}} \right) = \frac{\sigma_{yield}}{f.s.}$$

With this force, the following step is to calculate the mass and the volume capable to resist by the support with the following formulas.

$$\left\{ \begin{array}{l} F = m * g \\ \delta = \frac{m}{V} \end{array} \right.$$

With these formulas the maximum volume is calculated, and it was found out that with the cast density the maximum volume will never be reached by a mold of a prothesis. The data used for the calculus and design were the following: The supporting tube is a AISI 1018 1 m length tube and diameter of 1 ½ in while the suction tube is from the same material and diameter but the length is 0.7 m. The results for this calculus where:

$$F = 3,06 \text{ kgf}$$

Knowing that the material used for the mold production is yeast, the calculation of the volume could be made, and it is obtained that:

$$V = 0.6 \text{ m}^3$$

#### ***Fourth Calculus***

For the vacuum calculus, the principles used were the Bernoulli equation and the pascal definition of pressure to determine the pressure pump needed. First it is necessary to determine the suction force with the pascal formula as shown on the following equation:

$$F = F_1 + F_2 + F_3 + F_4$$

$$F = A_{face\ 1}\Delta P + A_{face\ 2}\Delta P + A_{face\ 3}\Delta P + A_{face\ 4}\Delta P$$

Where the forces 2 and 4 are the radial forces made to the system walls, so they are not taken into consideration for the suction calculus, and they are null because of the radial distribution.

$$F = \pi * r_0^2 * (P_{atm} - P_1) + \pi * (r_2^2 - r_1^2) * (P_{atm} - P_2)$$

For a better understanding look at the calculus diagram on the index. There is specified that the  $r_0$  is the radius of the mold tube, the  $r_1$  is the radius of the support tube and  $r_2$  is the radius of the vacuum connection tube. Also, it is known that  $P_{atm}$  is the atmospheric pressure,  $P_1$  is the pressure inside the mold tube and  $P_2$  is the pressure inside the support tube before it gets connected to the vacuum pump. The next formula used is the Bernoulli equation in the following way:

$$\frac{P_{atm}}{\rho g} + \frac{v_0^2}{2g} + h_0 + \Delta h_{pump} = \frac{P_2}{\rho g} + \frac{v_2^2}{2g} + h_2 + \Delta h_{lost}$$

Knowing that the point 0 and the point 2 are at the same height and gathering some data from the pump fabricants like the air velocity and the head pump, the pressure  $P_2$  is obtained. Also, it is demonstrated that the variation between  $P_1$  and  $P_0$  is almost 0 so the suction force only depends on  $P_2$ . The formula that gives the suction force is the following. It is important to say that the pressure lost is neglectable because the length is too short and the pressure lost by accessories is nearly zero.

$$F = \pi * (r_2^2 - r_1^2) * \left(-\rho \frac{v_0^2}{2} + \rho \frac{v_2^2}{2} - \rho g \Delta h_{pump}\right)$$

Which makes sense because the suction force is negative and by doing a sign brief analysis of the equation the result is negative in mostly every case. According to this calculus the power of the vacuum pump is determined and its head pump so the project would be fully functional. In this calculus the numerical values would be  $r_2 = \frac{1}{4}$  in, which is the radius of the pipe,  $r_1 = \frac{3}{4}$  in, which is the radius of the tube and  $\Delta h_{pump}$  is the average head pump of a pump of 1/3 HP and 4,5 CFMs. Therefore, the suction force is

$$F = -88,15bf$$

For more information review the calculus in the appendix section at the end of this document.

## Safety through design

### Risk analysis and management plan.

Risk based engineering is an effective method to obtain optimum results, operation and maintenance planning (Fujiyama, 2011). Machine manufacturing process must be analyzed for risks. The importance on identifying the possible risks that implies the process consist of preventing them and propose a mitigation risk plan. Each identified risk has been evaluated according to its probability and the impact it could represent to the project, determining the critical cases and the needed management. For the critical risks, a solution must be applied to reduce the probability of occurrence. The requirement is that every possible risk could be manageable if it comes to happen, to assure safety and economical values.

The range of evaluation considered is presented below:



The method of probability score has been applied, where the number and color are a representation of the respective probability of the risk.

Table 4. Risk matrix (Hoffman, 2014)

Probability score	1	2	3	4	5
Descriptor	Highly unlikely	Unlikely	Possible	Likely	Almost certain
Chance of occurrence, %	<5	Between 5 and 20	Between 20 and 50	Between 50 and 80	Between 80 and 100

Table 5. List of risks, its probability of happening and the impact that might cause

Description	Probability	Impact on the project
Electrocution	2	3
Burns	1	2
Flexion failure	1	4
Irregular Heat Distribution	3	3

Muscular injuries	1	4
Not sealed vacuum sys.	3	4
Unfollowing the schedule	3	5
Wrong budget planning	2	3
Overheating (Polymer burning)	2	2
Low energetic efficiency	2	1
Overprice (compared to the market)	1	1

Table 6. Table of risks analysis, its classification by importance and solutions

Code	Description	Type	Priority = Probability + Impact	Person in charge	Solution	Status	Observations
001	Unfollowing the schedule	Planification	15	Christian	Reschedule the Gantt diagram with a more detailed process, being the goal to finish one week before deadline.	Solved	In case of a delay on construction, there are seven days more to finish it on time.
002	Not a sealed vacuum system	Operational	12	Martin	Design an upgrade for the system, that could be easily mounted.	Solving	In the manual will be a brief explanation of how to fasten the components to seal the system.
003	Irregular Heat Distribution	Technical	9	Christian	Cover all the area with thermal resistance and implement a heat transfer plate to distribute	Unsolved yet	Have not done all the calculus and simulations in order to check the heat distribution.

					heat uniformly		
004	Electrocution	Technical	6	Christian	Hire experienced electricians to build up the circuit and controller.	Solved	Extra cost
005	Wrong budget planning	Economic	6	Carlos	Talk with the client about the possibility of needing extra budget.	Solved	The client confirmed the possibility of extra funding
006	Overheating (Polymer burning)	Ambiental	4	Martin	Design a safety system for automatic shutdown (Controller)	Solving	Planned to have a timer for shutting down after 30 min
007	Muscular injuries	Operational	4	Carlos	Give advice of heavy weight handling on the manual	Unsolved yet	The design is meant to be used for short distances handling.
008	Flexion failure	Technical	4	Martin	Design pipes and holder according to the policies and statements.	Solved	The pipes and clamps must tolerate the mold loads with a safety factor.
009	Burns	Operational	2	Carlos	Detail the usage and operation steps on the manual.	Solved	-----
010	Low energetic efficiency	Legal	2	Martin	-----	Unsolved yet	An energy efficiency analysis will be performed to adjust to commercial values.

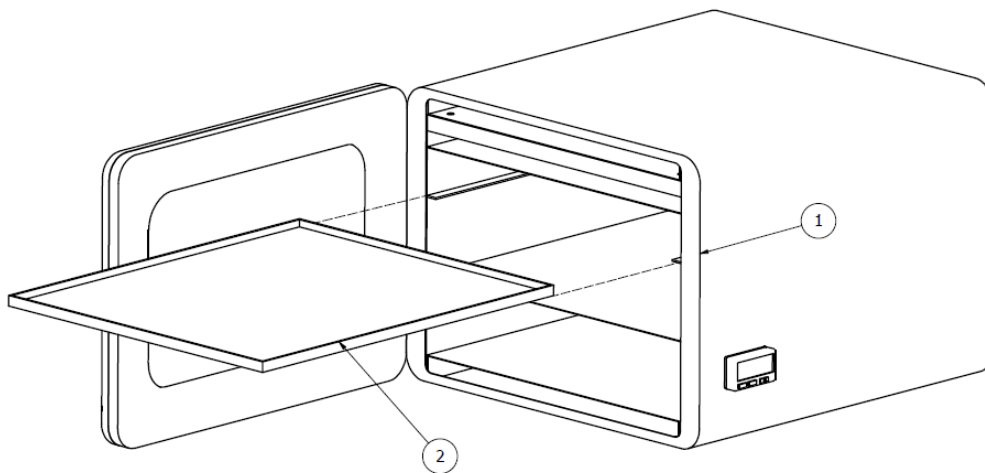
011	Overprice (compared to the market)	Commercial	1	Carlos	Search for the best components and machinery prices to build it with the lowest cost.	Solving	-----
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### **Maintenance and operating manual**

The present maintenance and operation manual provide the thermoforming chamber user's required information. A list of parts of the system is detailed and the operation procedure is described step by step. Additionally, a suggested maintenance procedure is described to extend the system lifetime and an emergency plan procedure in case of need.

#### **List of parts.**

##### ***Oven.***





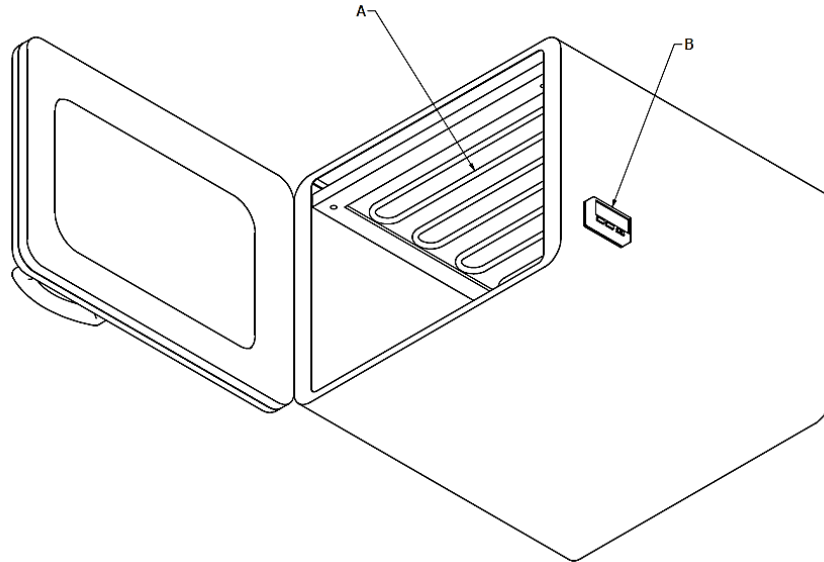
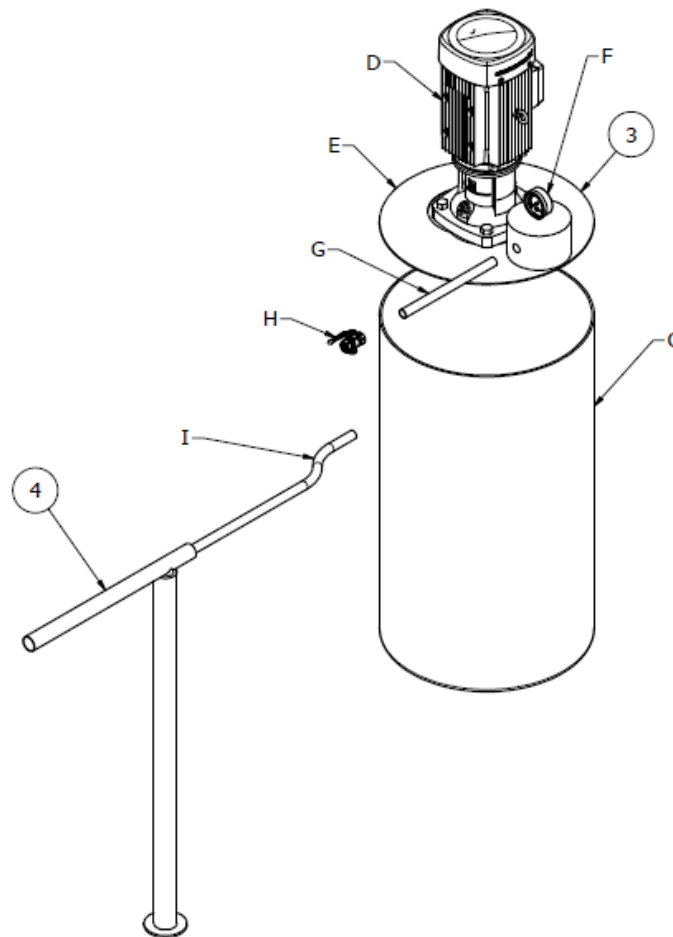


Figure 16. Diagram of the furnace with the list of parts

1. *Main oven structure (does not require any extra assembly).*
- A.** Electric resistor
- B.** PID control
2. *Tray (Polyethylene sheet holder).*
  - Must be inserted in the oven rails as shown by the stripped line in *Figure 16*

***Vacuum system.***



*Figure 17 Diagram of the vacuum system with the list of parts*

***3. Inverse water pump vacuum system.***

- C.** Water tank: Must be filled between half and three quarters of its capacity.
- D.** Water pump: A 1/3HP pump working on reversed conditions to generate negative pressure (vacuum).
- E.** Tank lid: Once the tank is filled, clamp the lid. Verify its holding still (may be hard to handle as it carries the water pump).
- F.** Manometer: Measures the air pressure in the internal pipe, equivalent to the vacuum pressure at the end of pipe (4).
- G.** Connection pipe: It must be adjusted to the vacuum system, as suggested in *Figure*

**H.** Suction valve: A ball valve (for better results it is suggested to use a butterfly valve) that regulates the air flow across the pipe. Must be adjusted to the end of the connection pipe (G) and sealed with the pipe sealant of your preference.

4. *Mold holder/vacuum pipe.*

**I.** Hose: Flexible hose with threaded mobile ends. Must be connected to the vacuum pipe (2) and to the suction valve (H) and sealed with the pipe sealant of your preference.

**Operation procedure.**

The operating procedure consists in 5 main processes. These processes are turning on the oven, setting the temperature and wait for the sheet to heat up, setting the mold, form the sheet over the mold and cutting the excess of material. Each of the steps are going to be detailed below. It is important to highlight that this manual does not explain the process to make a mold. If there is any doubt about this process a web search could help to find more information.

- a) *Turning on the system:* In this step, it is important to double check if the two components are connected to a 220V source. It is recommended to test the 220V source before connecting the pump and the oven. Then, verify that the vacuum system and the oven have a separation of 2 meters approximately between each other. After all the verifications done, turn on the oven and the inverse water pump.
- b) *Controlling temperature:* Take out the tray from the oven and with the digital control set up the temperature need for the specific material. It is recommended to use 200°C for Polyethylene. Once the temperature is set up, it is necessary to wait between 8 to 10 minutes to put in the tray. Meanwhile, cut the sheet of PE to desired dimensions and put it on the tray. After the oven reaches the set temperature (look at the controller

display), put the tray inside the oven and wait from 8 to 12 minutes depending on the material properties.

- c) *Holding the mold:* The mold must have a holding pipe with diameter of 1 inch and minimum 10 inches of length that fits the vacuum system. First, cover the mold with a nylon sock (if it is possible cover it twice). Once it is completely covered, put the mold in the pedestal and adjust it with the screw. It is important to check that the mold is tight adjusted.
- d) *Vacuum-form the mold:* For this step, the plastic must be malleable thus the heat inside the furnace. If you are not sure if the plastic is malleable, see over the window and you will notice that the polyethylene changed its appearance and it is more translucent. After that, take out the polyethylene sheet by taking it from both sides and cover the mold with it. It is indispensable to use leather gloves to prevent skin burns. The plastic must cover all the mold surface and it must be sealed by pressing both sides. Then, open the vacuum system by turning the valve on the pedestal and let it sit for around 2 minutes.
- e) *Cutting the excess of material:* After all the air around the mold was sucked, you will notice that there are some parts where there is excess of plastic. All the excess from the knot and give a better form to the mold.

### **Maintenance procedures.**

The maintenance procedures are going to be divided in two sections, depending on the system function. The maintenance includes regular cleaning of each system to prevent corrosion. It is also important to take care of the electronic systems of each component by having the oven and the vacuum system in a place with no direct sunlight and low humidity.

***Vacuum system.***

- If planned to be used, check that the level of water is above the middle of the tank and that the tank lid is tightly sealed.
- Change the water of the tank every two months. This is very important, even if the vacuum system was not used over this time.
- Every six months check the inner section of the pipes. If there are some stains on them, you should clean all the surfaces. Otherwise, if there is corrosion on the walls, the pipes would not have a long lifespan.
- For cleaning the pipes, a steel brush and baking soda could be used. First, use the baking soda and water by mixing it in a proportion of 1:2, respectively. Wipe the area with the mix and the brush until the stains go out. If this method does not work, use any commercial deoxidant mixed with water in a proportion of 2:1. If none of this techniques work, prevent the increase of corrosion by using anticorrosive protectors.
- Dismount all the piping system when cleaning.
- When mounting the pipes, it is important to use thread seal tape in the joints, as during the assembly.
- Check the hydraulic pump every year and clean the rotational disk for preventing it to get stuck.

***Oven and structure.***

- Disconnect the oven if it is not in use.
- Always clean the inside of the oven before and after using it
- After its usage, clean the tray and scrap every residual of polyethylene that may remain on the surface.

- Every 6 months clean the stains from the structure and from the oven. The stains could cause the oven to corrode because of heat and temperature fluctuation. It is essential to disconnect the oven before cleaning.
- After cleaning with soap and water it is important to dry the surface.
- Every year check the surface of the resistance. It is important to check if there is any corrosion or salty residuals. Clean the resistance.
- Change the stoppers every 10 year or when they got damaged.

### **Emergency procedures.**

The thermoforming chamber was designed considering operator's risks exposure on its operational process. Some preventive solutions have been applied to assure operator's safety; however, any risk is possible to occur. For these cases, an emergency procedure plan has been developed. This plan is based on possible emergencies during the thermoforming chamber operation. Main emergencies considered are:

#### *a) Furnace burning*

The temperature inside the furnace may cause the burning of material that is not polyethylene. In case the operator accidentally drops any flammable material inside the furnace, it will cause its burning. A fire extinguisher must be close to the thermoforming chamber to solve this emergency. The recommendation is to avoid flammable material manipulation while the thermoforming process is running.

#### *b) Skin burns*

The manipulation of hot surfaces require protection as gloves and an apron to prevent skin burns. In case the operator suffers any skin burn, he must wash the burn with cold water for at least 3 minutes and then cover it with gauze. The recommendation is to use the protection required for the thermoforming process. A poster in the wall on the room

where the thermoforming process is running would help to avoid this emergency. Additionally, the operator must locate a sink close.

*c) Air leakage*

The air leakage is considered an emergency even though it would not expose the operator to a possible harmful condition, but it would cause a defective final product since the suction force would be decreased. To solve this emergency, the operator must stop the thermoforming process running to repair the leakage or contact the responsible technician.

*d) Short circuit*

The electrical connections may cause a short circuit. In case it occurs, the operator must disconnect all the electrical connections from current. A fire extinguisher must be close to the thermoforming chamber to solve this emergency. The recommendation is to verify the connections are well adapted.

*e) Injuries*

The operator may suffer injuries during the thermoforming process. The main injuries considered may occur while manipulating sharp tools and handling of weighted molds. To solve this emergency, the employer must purchase a health insurance to the operator. To prevent these injuries, the recommendation is to train the operator with safety rules in the procedure.

## **Results, discussion, and conclusions**

### **Heat transfer simulation results.**

The desired results here are the temperature of the tray and the time it takes to reach 200 °C, the average temperature of malleability in PE.

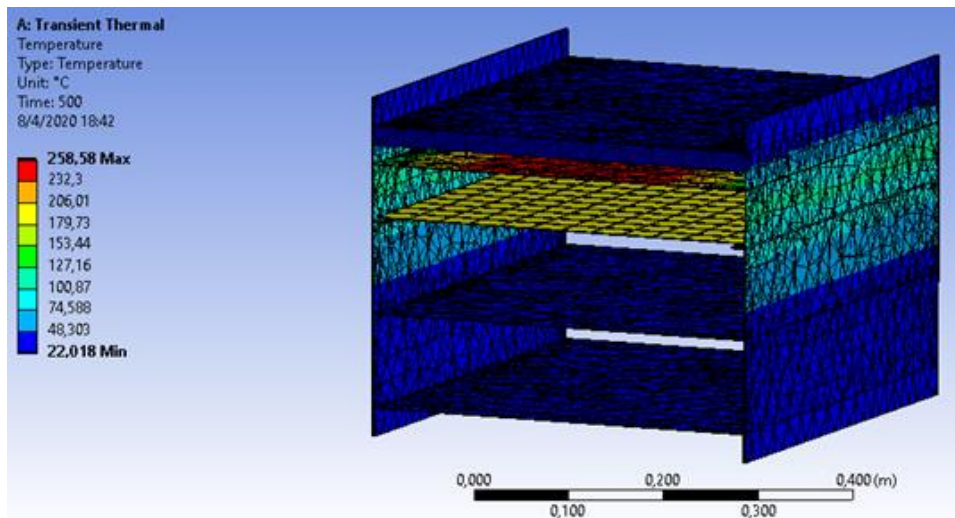


Figure 18. Internal structure contour plot

Figure 18 shows a uniform temperature distribution along the sheet where the polymer will be set to heat (orange zone), reaching temperatures between 215°C and 225°C which was the design consideration for the oven. Also, as it can be seen, there is no considerable heat losses to the external walls of the oven. The red zones where the temperatures reach nearly 260°C are from the sheet metal that serves as a heat distributor to avoid the polymer to burn or exceed the needed temperature to soften and be molded. In this contour plot the resistance was omitted to reduce the shown temperature ranges bringing the opportunity visually to analyze the variations and distributions.

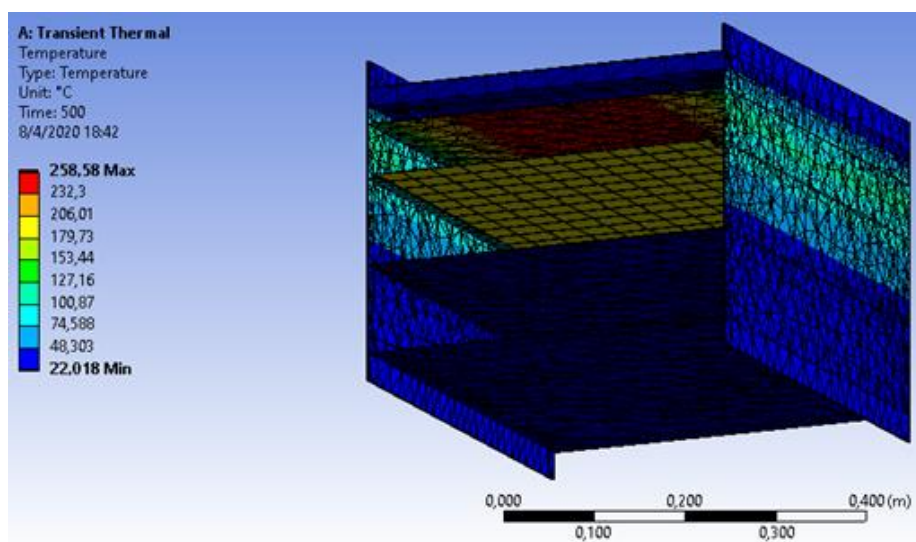


Figure 19. Internal structure contour plot (additional view).



## Structural stress analysis results.

The results for each static structural simulation are presented and discussed below:

### *Furnace support.*

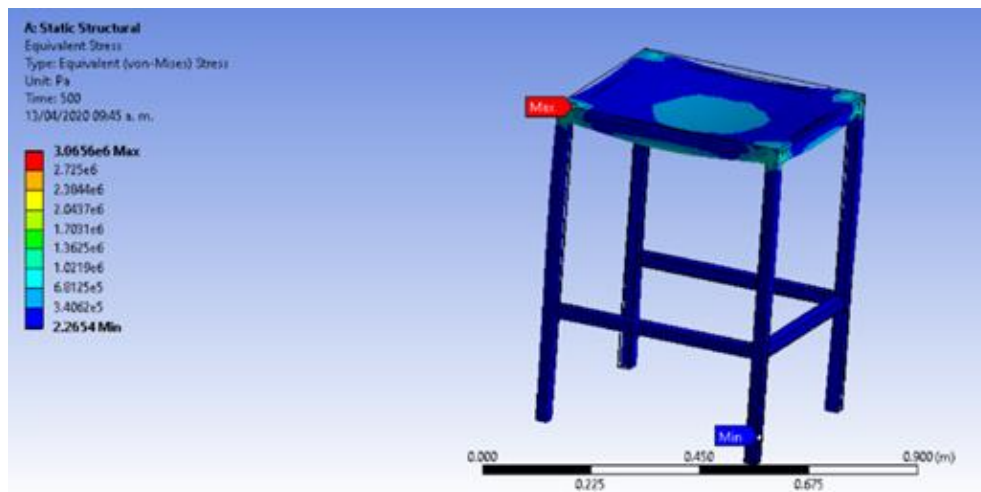


Figure 20. von-Mises stress simulation results for the furnace support

For the support structure made of structural steel (AISI-1018, ASTM A36), a load of 250[N] was applied taking into consideration that the mass of the oven is 25[kg]. As it can be seen on *Figure 20*, the equivalent Von-Misses stress does not reach critical levels nor has critical points where the structure could fail. This affirmation could be set considering that the load that is supporting is relatively small compared to the maximum load that it could handle in other conditions of heavy loads. Additionally, is possible to say that is not necessary to consider fatigue conditions as the variation on the mass of the oven system will only be in the range of grams when the polymer sheet is being heated.

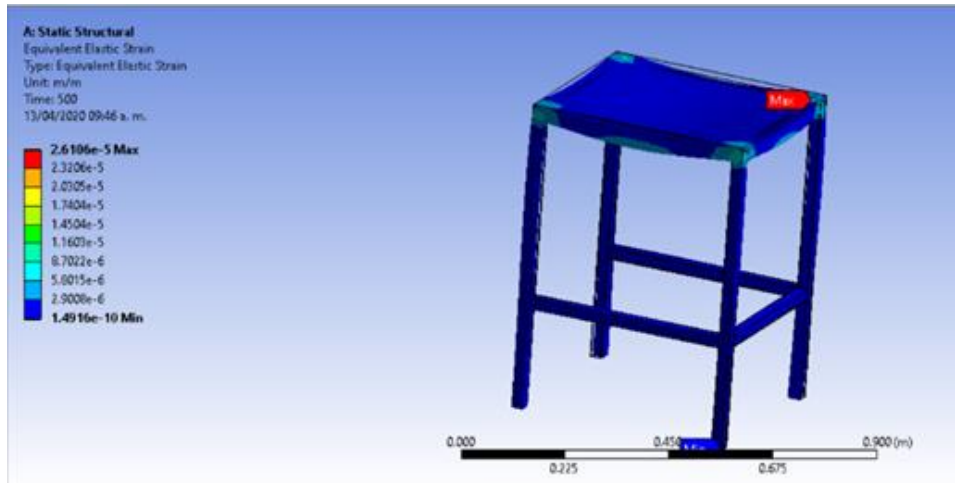


Figure 21. Strain simulation results for the furnace support

In *Figure 21*, it is possible to see that the maximum deformations happen only on the top part of the structure, specifically on the corners of the sheet iron that is going to be welded to the L profiles rectangular structure. As it was said before, these values are not critical due to the load that the material of the structure will handle, so the security factor has a value of 15 along the complete structure (*Figure 22*).

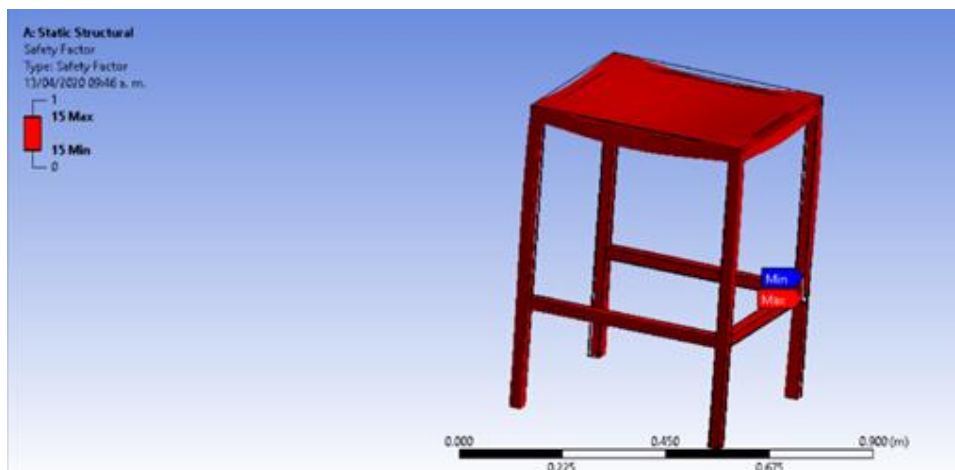


Figure 22. Safety Factor Simulation of the furnace support

### ***Pedestal.***

In the case of the pipe structure for the vacuum system, which is also made of structural steel (AISI-1018, ASTM A36), the load was set on the top pipe at the right end. The load considered for this analysis was 3000[N] due to the maximum mass of the molds that it will be supporting, which is 30[kg]. Taking into consideration that the structure will be loaded and unloaded

constantly, the fatigue analysis is imperative to determine the reliability of the system along time.

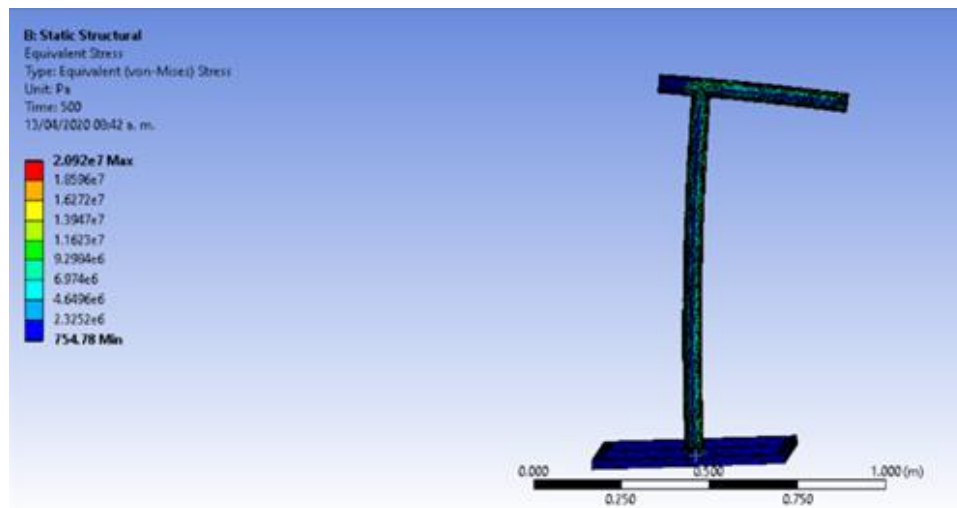


Figure 23. Analysis of Equivalent Stress with Von Mises for the pedestal

In Figure 23, the results show that the stresses over the structure do not reach critical values for the maximum load. Also is important to discuss that for this simulation, the negative load generated by the air pressure on the pipe was omitted as it was considered neglectable for the structural analysis.

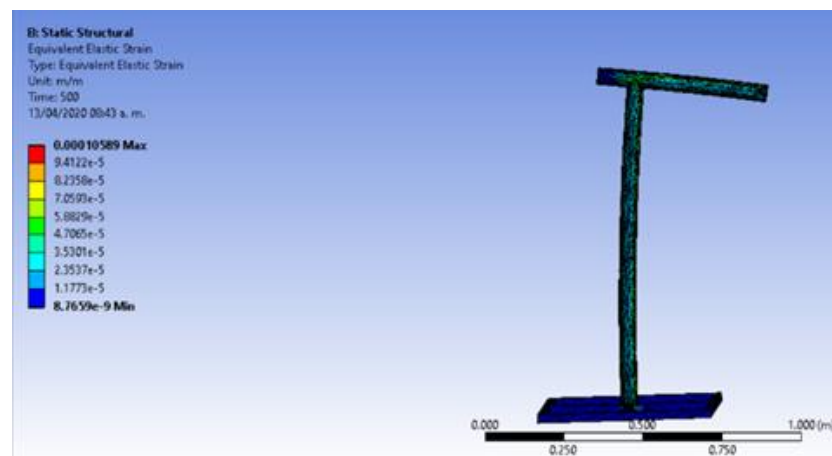


Figure 24. Strain simulation results for the pedestal

Figure 24 illustrates the material strain for the pipes and the results show that the maximum strain is in order of  $10E^{-5}$ , which tell us that the stresses are in the elastic zone of the stress-strain curve with no plastic deformation. In figure 17, the results for the safety factor show that

the minimum for this case is around 4 in some concentrators, making the design safe for working conditions.

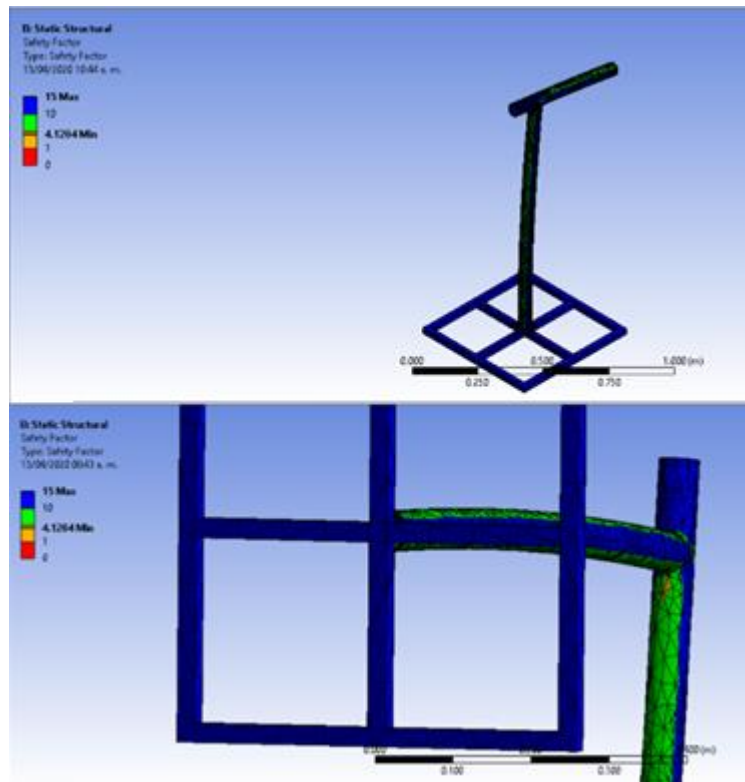


Figure 25. Safety Factor of the Pedestal and the critical element

In Figure 25, it is shown the results of calculating the safety factor of each element in the pedestal. The most elements on the pedestal are not critical because the moment applied is small; however, the minimum value which determine the safety factor of the pedestal is at the joint of the axis and the suction tube. This safety factor is 4.12, which means that the pedestal support for times the torque made by a mass of 30 kg at 0.2 m from the suction tube. Also, it is illustrated the critical element, where the failure is going to be if the pedestal is overloaded.

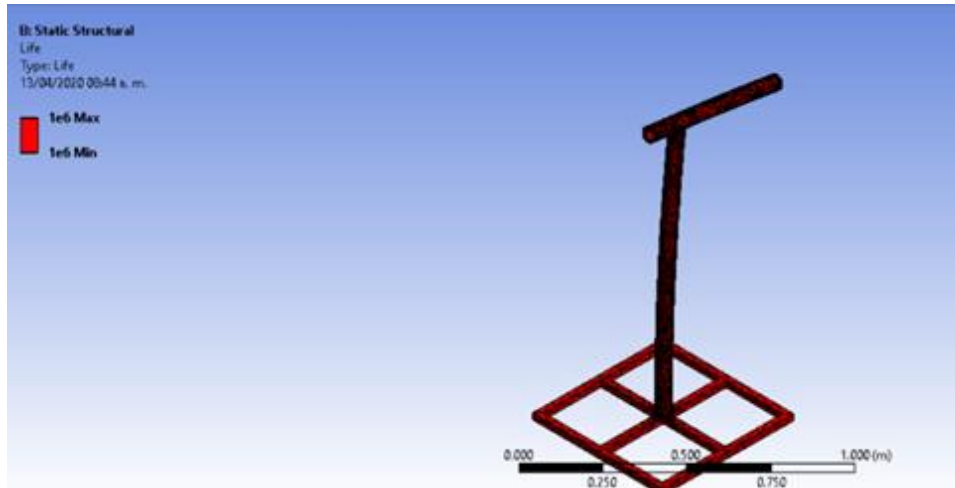


Figure 26. Life of the Pedestal before a fatigue failure

Finally, it is shown in the *Figure 26* that all the pedestal is going to last  $1 \cdot 10^6$  cycles before it could fail because of fatigue. This determines the limit of the pedestal and with this is possible to estimate when is recommended to change the pedestal for another or when to do a revision if there are any signs of failing before it happens. By seeing the graphic, it is considered that the best option is to change the pedestal rather than repairing it, repairing it is too risky because it can fail any other time another part of the pedestal.

***Fluid dynamics analysis in vacuum system results.***

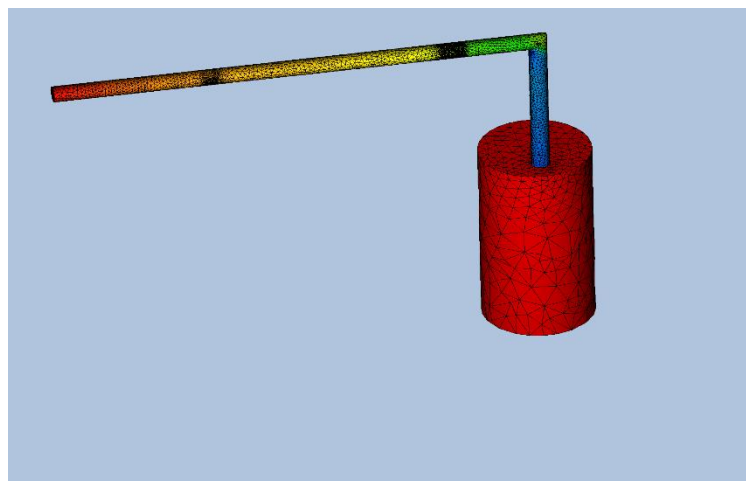


Figure 27. Pressure result design for the air inside the piping system

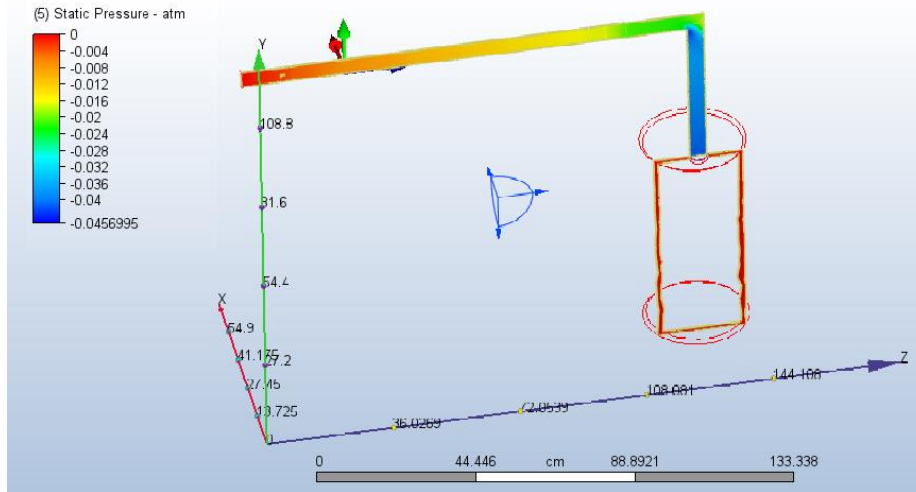


Figure 28. Air pressure simulation results shown in the plane YZ

As the contour plot illustrates, the lowest value for the pressure is located at the open end of the pipe where the mold will be located. The critical pressure reaches a value of 0 [atm] which is considered as a very strong vacuum. Assuming the losses that happen on real conditions and considering that the mold and polymer sheet do not seal completely the pipe hole, is possible to say that the vacuum pressure that will act over the mold is around the values of 0.4 and 0.2 [atm].

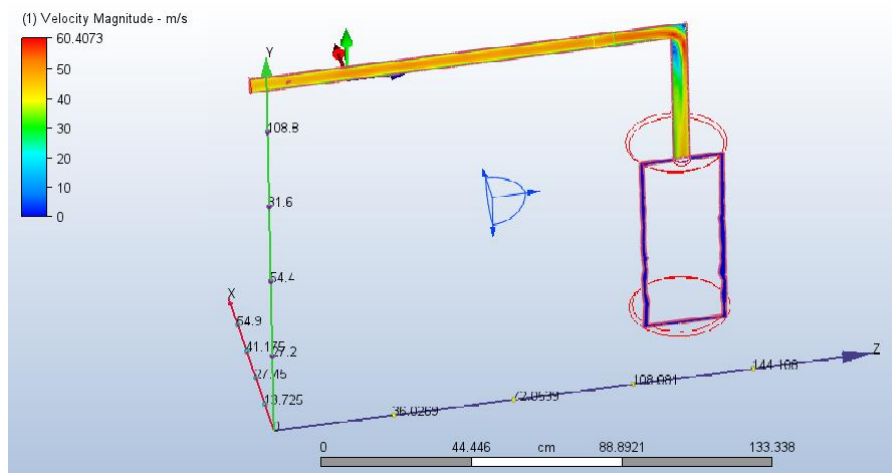


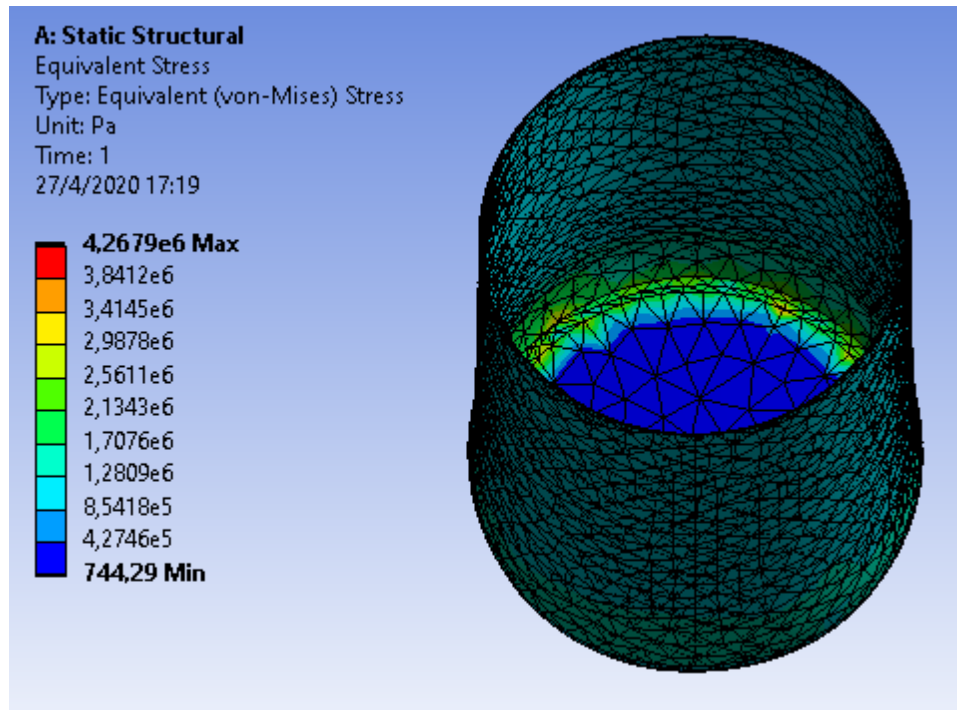
Figure 29. Velocity magnitude and fluid element movement trajectory

The velocity contour plot also shows that the air inside the pipe is moving from the outside to the interior of the tank as an effect of the negative pressure generated by the inverse water



### *Tank stress analysis*

The results for the static stress analysis are presented below. *Figure 31* shows the maximum stresses on the internal bottom surface, specifically on the border. This is caused because of the stress concentrator in the corner formed between the bottom and the wall.



*Figure 31. Tank stresses with lid, pump, and hydrostatic loads*

In *Figure 32*, the same stress analysis is presented in another view. The maximum stresses occur in the bottom of the tank.



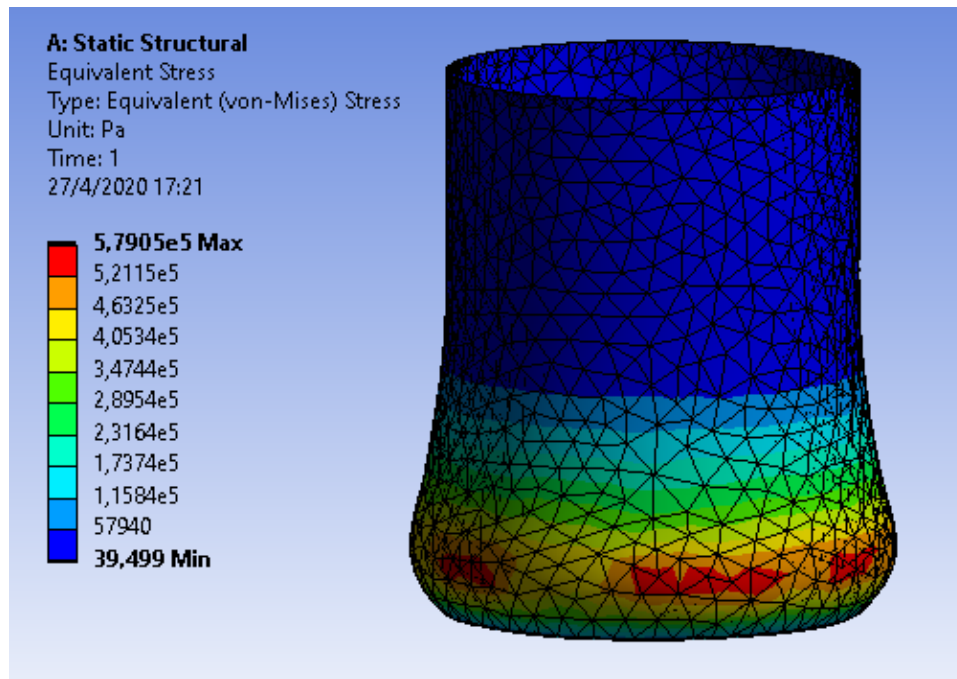


Figure 32. Tank stresses with hydrostatic load only

### Conclusions.

- The results obtained for heat transfer simulation demonstrate that the furnace is effective and functional as it was designed. The results show that the PE sheet is going to reach its malleable point in approximately 8 minutes, the variation of the temperature over the sheet is no more than 3°C and the external temperature is not too high.
- The results obtained in the structural analysis shows that the life cycle of the pedestal and the furnace support is a  $1 \times 10^6$  cycles; therefore, the structural supports can bear the prototype and by comparing both safety factors, the furnace support's safety factor is 15 and the pedestal 4.12, it was concluded that the global safety factor is 4.12. This result proof that the structural support bears all the loading that is meant to be used.
- The pressure differential of almost 0.95 [atm] is very efficient for making prothesis with thermoforming and this assures the functionality of the vacuum because a differential pressure of 0.7 atm or greater means a high-speed vacuum system.

- As shown on the results, this prototype of a thermoforming system is fully functional, it has a long-lasting life and it has no physical limits for the mold used to make a prosthesis. The prototype is not going to fail in a short duration of time, so it is an efficient and effective design

### **Future work**

This project is a first version prototype of a thermoforming system; therefore, there are a lot of features that could be improved. One of the main advices for future work is to focus on the vacuum system improvement. The usage of recycled materials and components could be a great improvement that lower its cost and redesigning a prototype that supports multiple vacuum inputs. Also, the new design could be improving in the clamping mode, giving the mold a rotation freedom without losing vacuum pressure. Once the vacuum system has been reviewed, the following step is to build the final prototype and evaluate its real efficiency to determine following improvements.

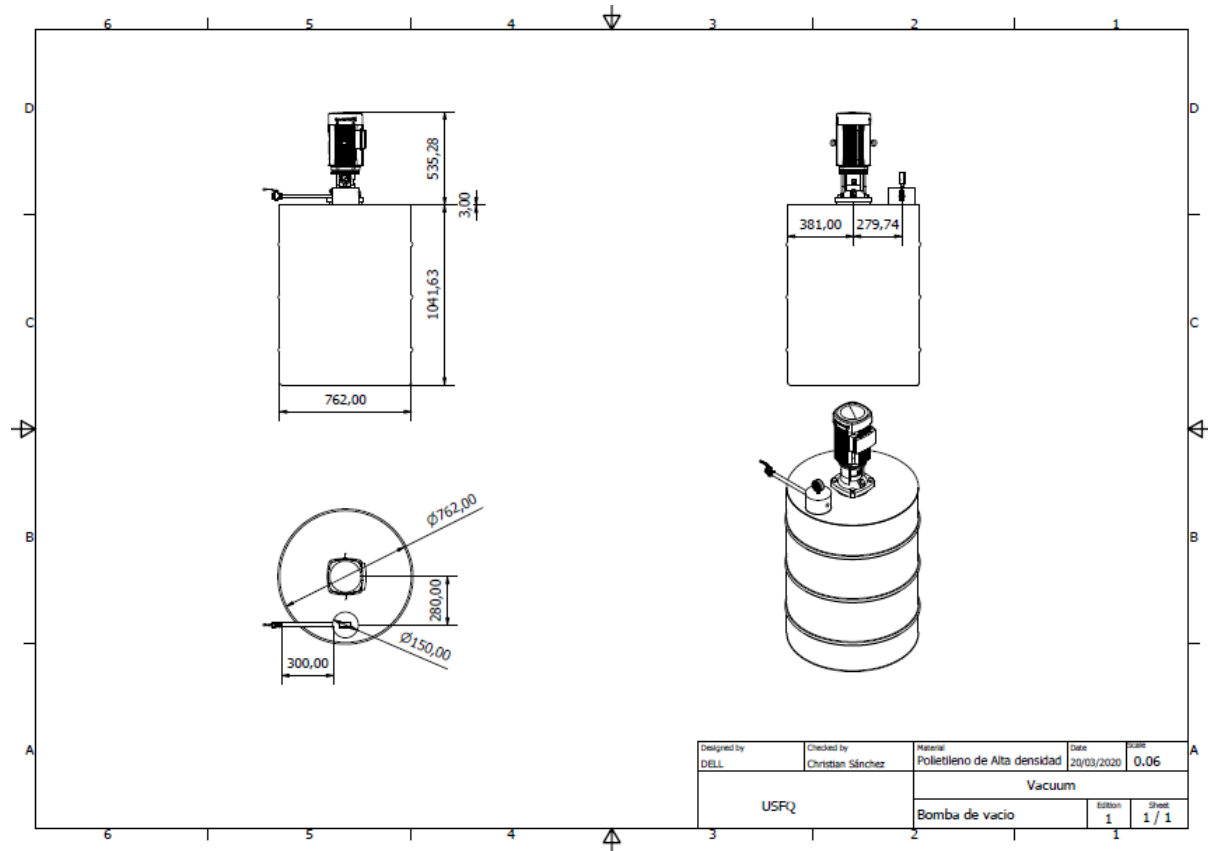
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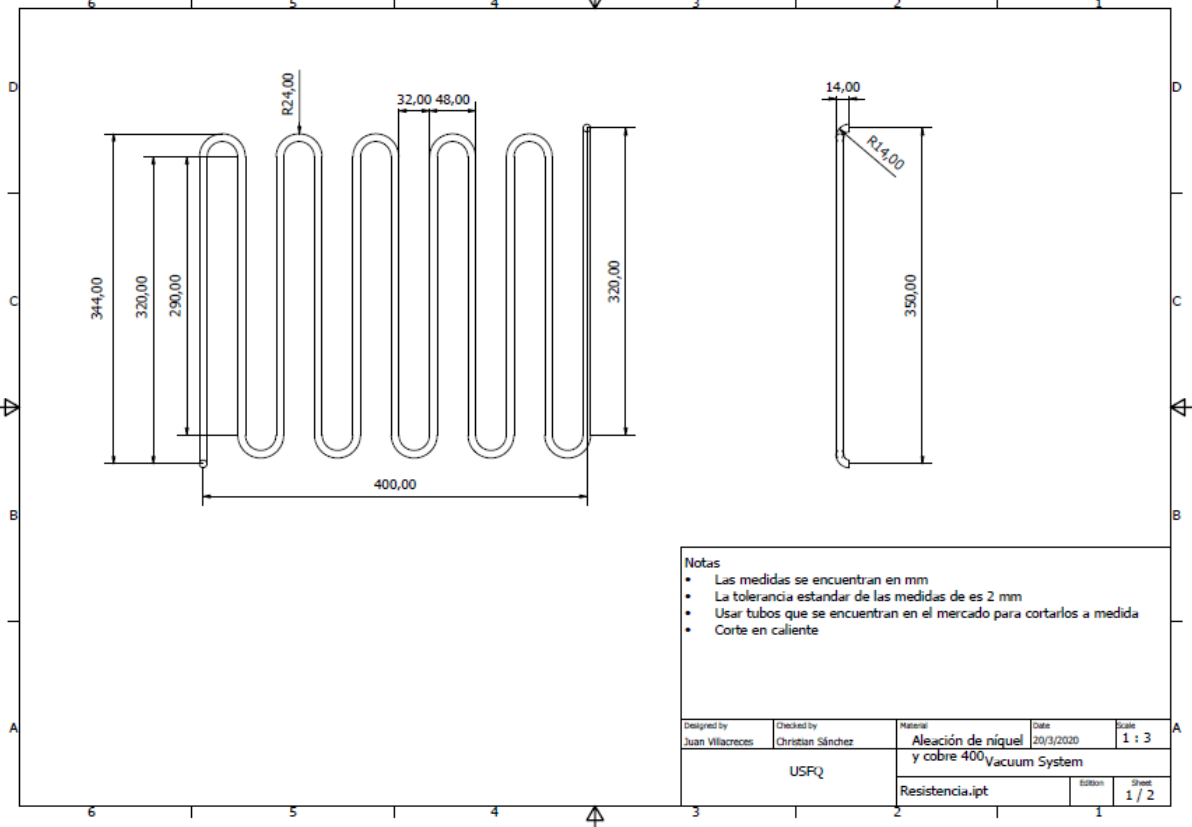
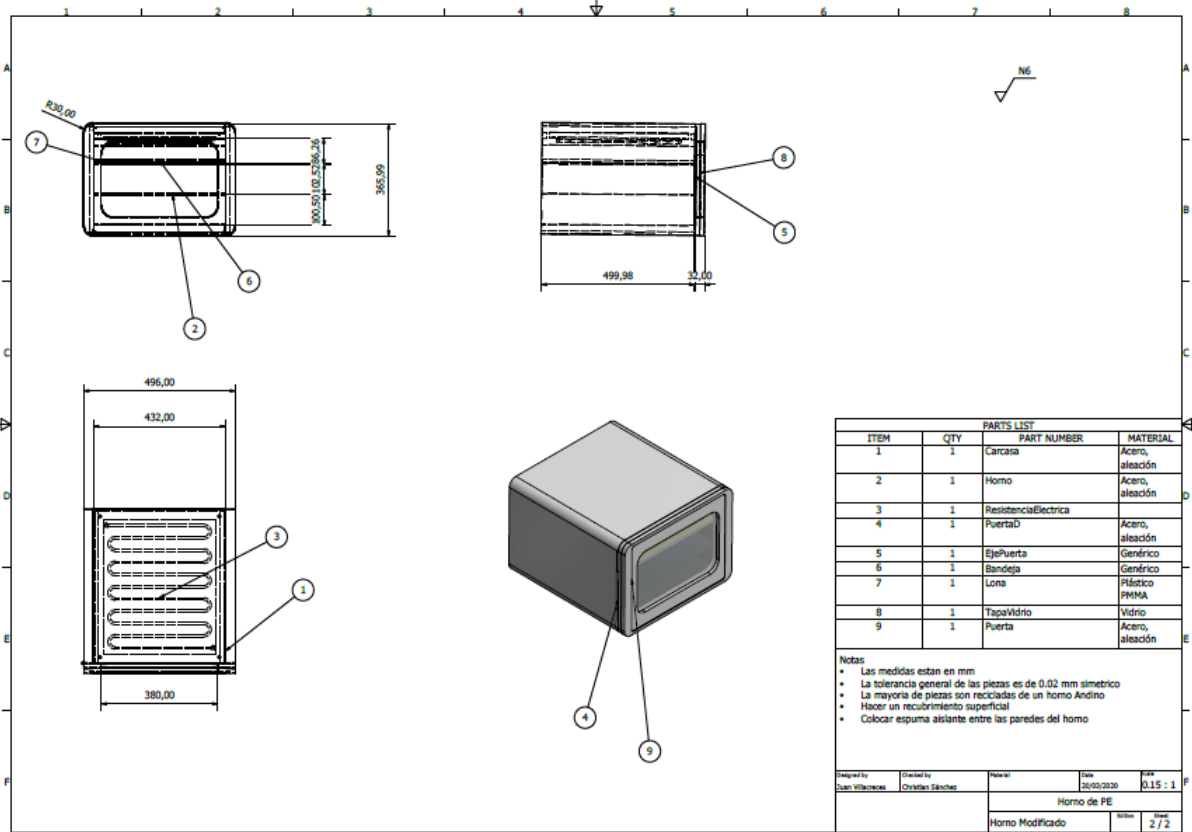
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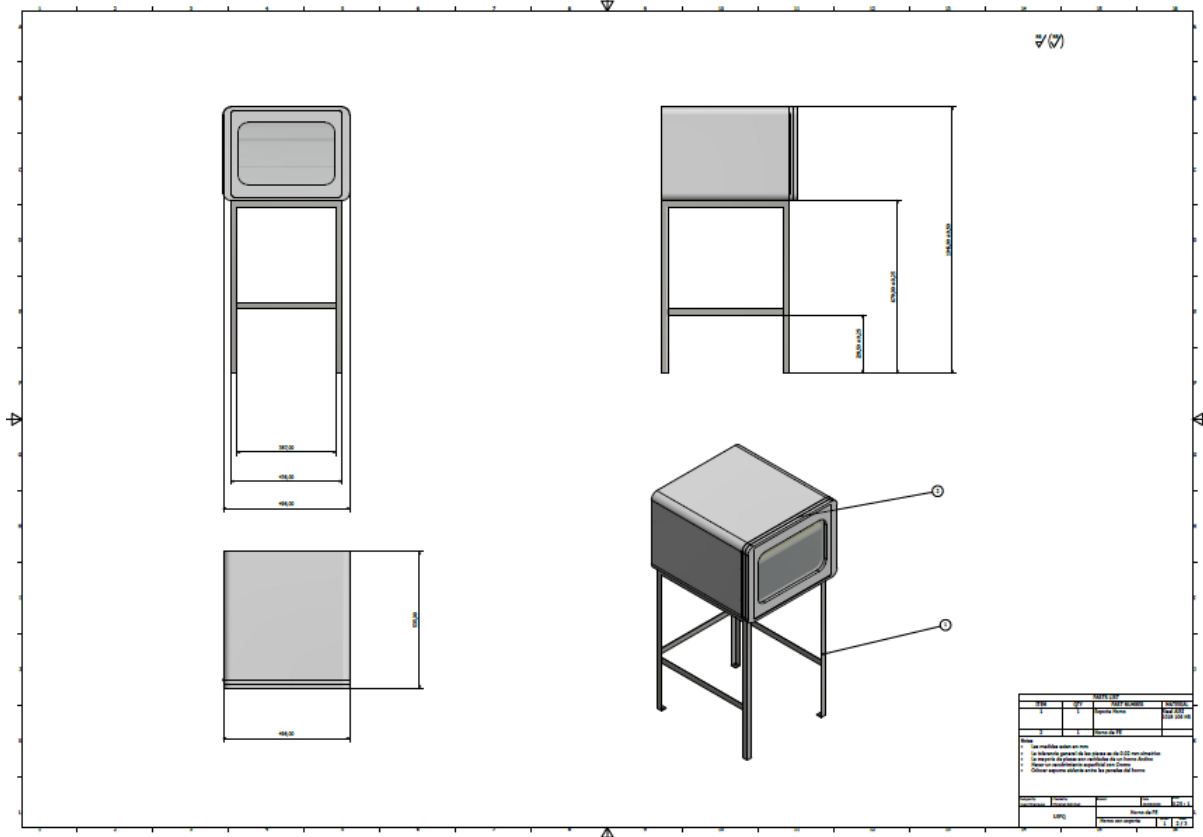
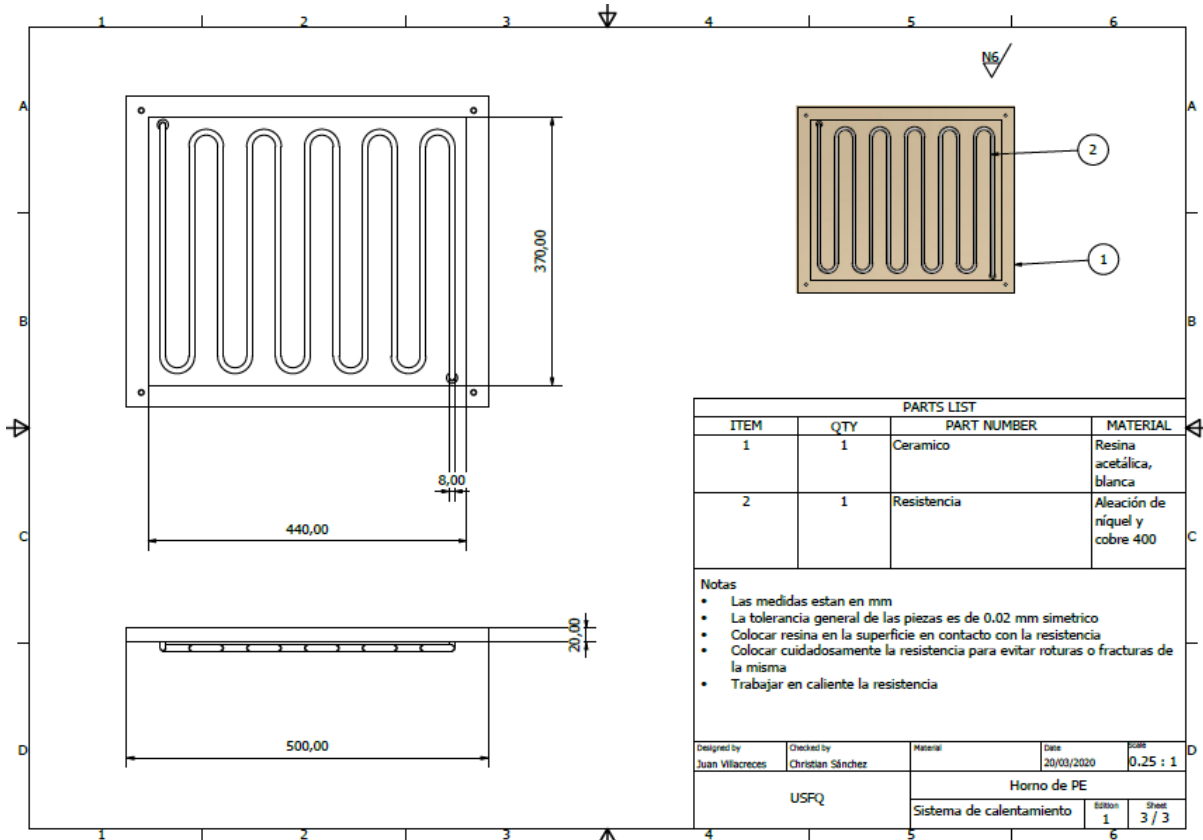
APPENDIXES

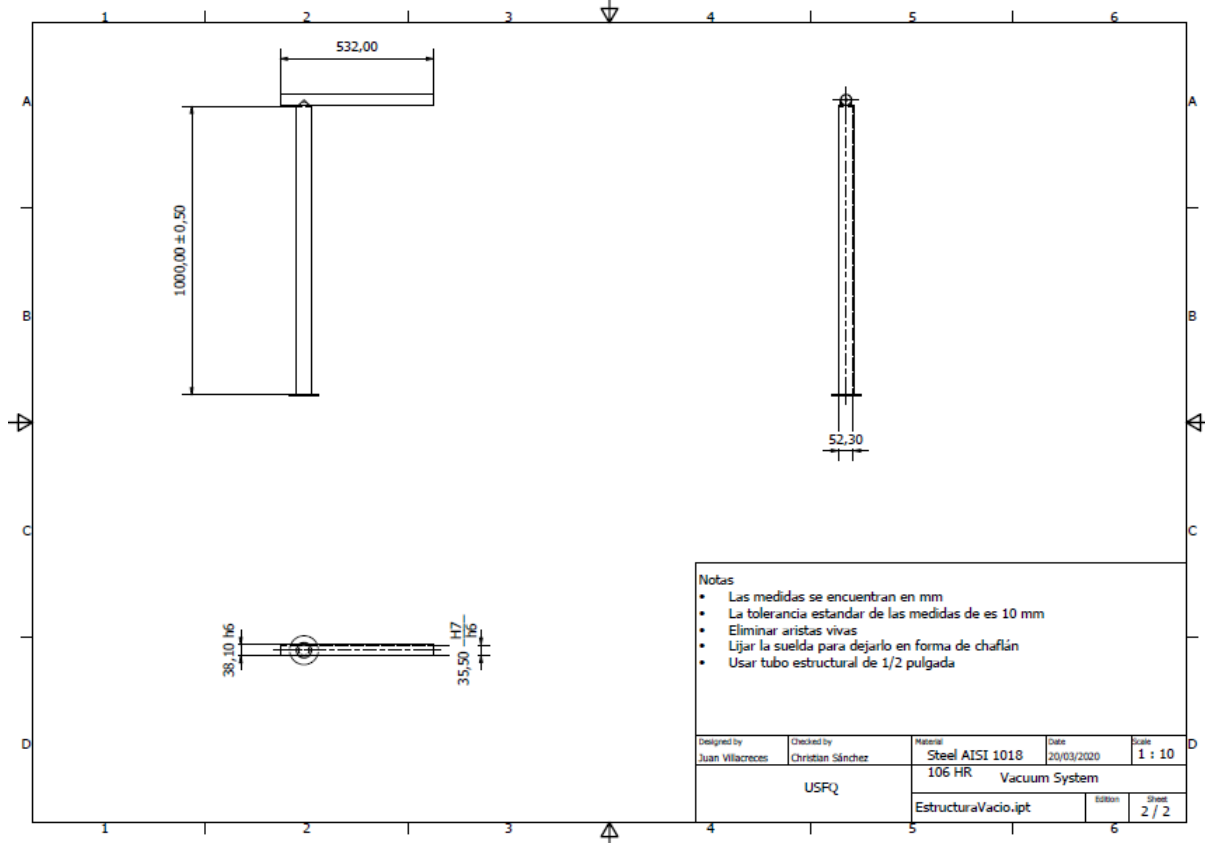
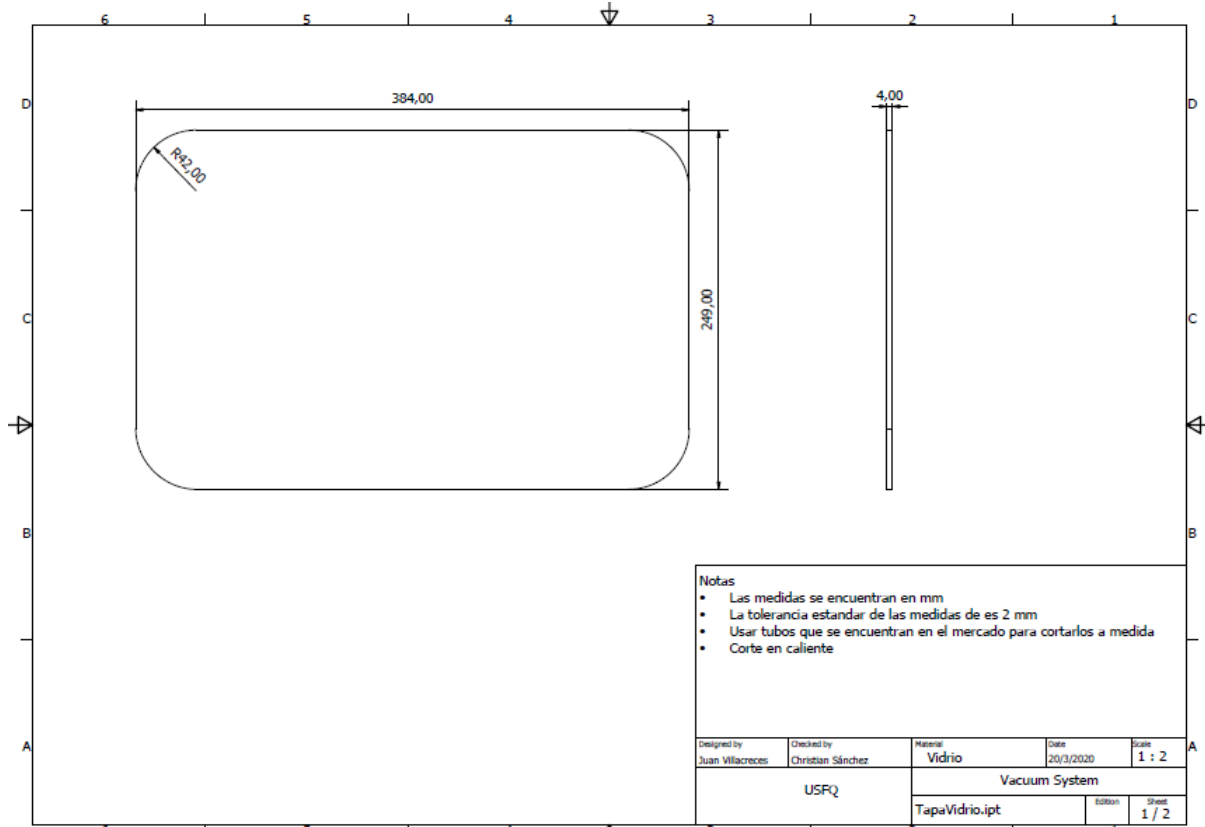
Appendix A – Engineering drawings and calculations

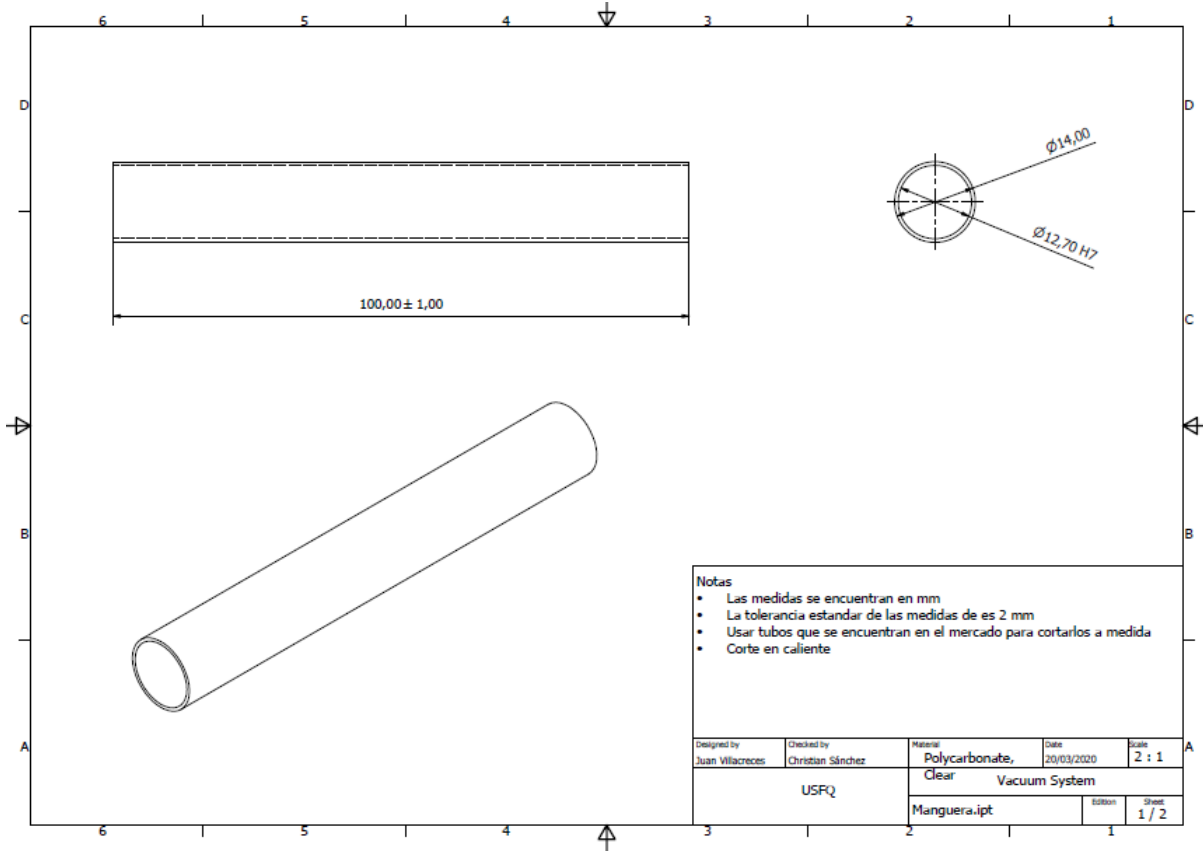
Engineering drawings.











- Notas**
- Las medidas se encuentran en mm
  - La tolerancia estandar de las medidas de es 2 mm
  - Usar tubos que se encuentran en el mercado para cortarlos a medida
  - Corte en caliente

Designed by Juan Vilacrez	Checked by Christian Sánchez	Material Polycarbonate, Clear	Date 20/03/2020	Scale 2 : 1
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