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HEMODIALYSIS SUPPORT EQUIPMENT DEVELOPMENT PROCESS

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Abstract: Scales are essential weighing equipment for various products and processes, including medicine and hemodialysis procedures. In this case, weighing patients is essential for correctly prescribing the procedure, as well as analyzing its effectiveness in terms of removing liquid. This work aims to use the Product Development Process Reference Model (PDP) by Rozenfeld et al. (2006) to develop and apply a prototype of patient weighing equipment, aiming to optimize the hemodialysis process. For this, a prototype was created in CAD (Computer Aided Design), as well as simulation in CAE (Computer Aided Engineering) before manufacturing a physical prototype. This was implemented at ``*Clínica Nefrocor*``, where its operation was analyzed in a meeting with stakeholders. Its use proved to be satisfactory, justifying the manufacture of more units.
Keywords: Product Design; Balance; Weighing; Hemodialysis; Prototype.

INTRODUCTION

Chronic Kidney Disease (CKD) is the progressive and irreversible loss of kidney functions, so that the kidneys are unable to maintain the body's metabolic and water-electrolyte homeostasis (OLIVEIRA et. al., 2015; ROMÃO JUNIOR et. al., 2004). CKD is a global public health problem, thanks to its high incidence and prevalence rates. It is estimated that the prevalence of CKD is 7-10% of adults over 30 years old, and 23-36% in individuals over 64 years old, being that approximately 4 million people around the world require dialysis (VERONESE et. al., 2019).

This is mainly due to the increase in chronic non-communicable diseases, mainly Systemic Arterial Hypertension (SAH) and Diabetes Mellitus (DM), in addition to other factors such as aging, obesity, smoking and sedentary lifestyle (OLIVEIRA et. al., 2015; VERONESE et. al., 2019).

The management of patients with end-stage renal disease is done through hemodialysis, peritoneal dialysis or kidney transplantation. In conventional hemodialysis, the patient is connected to equipment that acts in a similar way to the kidneys, filtering the blood by removing metabolites and liquids, three times a week, for four hours. (OLIVEIRA, et. al., 2015; VERONESE et. al., 2019)

For hemodialysis treatment to be effective, it is extremely important to carry out strict control of body fluids, before and after a hemodialysis session. To carry out this control, an assessment of the patient must be carried out to determine their dry weight (post-dialysis) and their wet weight (pre-dialysis). From there, the nephrologist will prescribe the dialysis session with a fluid loss appropriate to the patient's needs (DAUGIRDAS et. al., 2017). Currently, the way used to analyze the effectiveness of dialysis in terms of fluid removal is by weighing the patient before and at the end of the session on conventional scales.

Patients with chronic renal failure who require hemodialysis often have mobility restrictions due to underlying diseases, as well as the natural evolution of the disease. The most common causes of CKD are hypertension and DM, with an incidence of 35% and 30%, respectively. These illnesses have complications, in addition to CKD, including loss of vision, stroke and limb amputations (VERONESE et. al., 2019). Therefore, it is common for patients to require assistance from nursing technicians to move to the scales, and they often use wheelchairs, including during weighing. Weighing errors also occur when this is done by the patient themselves, which leads to inappropriate treatment prescription.

An alternative is then proposed to evaluate the effectiveness of fluid removal in the dialysis session, in which the patient is weighed during

treatment, allowing the doctor to adjust the prescription. The use of this method minimizes interdialysis and post-dialysis complications, such as cramps, hypotension, cardiac overload and congestion, resulting from inadequate fluid removal (SANCHO et. al., 2013).

To solve the problem, the study proposes to apply the Product Development Process (PDP) methodology to develop a prototype of equipment to be used at Clínica Nefrocor, a nephrology clinic specialized in hemodialysis, located in the city of Cachoeirinha, RS, which serves patients from the Unified Health System and the state's main private health plans. As a specific objective, the work proposes to evaluate the perception of those involved regarding the use of the final prototype developed, visualizing whether it brings a reduction in weighing reading errors, an increase in the ease of the weighing process and an increase in the quality and effectiveness of the dialysis treatment.

To develop the equipment, the Product Development Process Reference Model (PDP) by Rozenfeld et al. (2006). This is made up of three macro phases: Pre-project, Development and Post-project. The CAD (Computer Aided Design) tool was used to design the prototype. This tool is considered one of the most important tools used in the PDP in the current scenario (AZEMI et. al., 2018). After validating the prototype in CAD, a functional prototype was manufactured to evaluate the technique in situ.

The problem to be solved is not a problem exclusive to the Nefrocor Clinic; it is a problem reported in several dialysis centers around the world. Therefore, if the project is carried out successfully, it aims to be patented and the possibility of starting production for the sale of units to Nefrocor and other health establishments that are interested in purchasing the equipment developed is studied.

The work is temporally limited to a period of six months, between January and June 2022. During this period, the theoretical part, the development of the prototype, the testing of the prototype and the evaluation of its use were carried out.

LITERATURE REVIEW

This section covers knowledge and aspects about weighing equipment, existing solutions for weighing objects and patients, the history and evolution of weighing equipment, as well as how it is used and calibrated. Scales and weighing equipment have been used by industry, commerce and medicine for centuries, and are of fundamental importance for various processes, products and procedures. They not only guarantee precision, but also enable the existence of different processes and products.

The mechanical balance two plates were the first measuring instrument created by man, and has been used for approximately four thousand years. This uses the comparison between the mass of a known object to determine the mass of another object. It is based on the principles of a lever and the balance of moments of inertia, in which an oscillating rod moves in front of a graduated scale. To weigh an object on a two-pan scale, the object to be weighed must be placed on one of the pans, and weights of known mass must be placed on the other pan, until balance is reached between the two sides of the scale (AFONSO, 2004).

The evolution of mass measuring equipment meant that two-pan scales were manufactured from lighter and more resistant materials, so that they could be more easily transported. The use of different metals also allowed new manufacturing methods to be used, allowing different lever arm support configurations, so that the scales could have increased sensitivity, bringing more reliable results (JENSEN, 1965).

Around 1870, German Florenz Sartorius developed equipment that revolutionized the world of scales; the first use of a scale enclosed in a glass box, mounted on the scale structure itself. This feature, as well as the use of aluminum for its construction and small lever arms, brought precision gains not seen since the creation of the first two-pan balance. This model introduced by the German became the reference model, and was widely adopted in the market. It was the main model used, until it was replaced in the 20th century (AFONSO, 2004).

From the 20th century onwards, the "knight" model became widely used as it was a scale that did not require the use of weights that were too small. Even so, the scales that used this system were able to detect mass variations of up to 0.0001 grams. These scales employed a 3-point support system, thus reducing weighing errors due to vibrations in the environment (AFONSO, 2004; JENSEN, 1965).

The next evolution in the scales market was the development of single pan, or electromechanical, scales. These were widely adopted despite their higher manufacturing cost than purely mechanical scales. Instead of a plate with weights, it uses suspended counterweights. When an object is positioned on the plate to be weighed, the Counterweights are removed from their axis so that the counterweight has the same mass as the object to be weighed. This mechanism is operated by a button, so that this is the user's only interaction with the scale (AFONSO, 2004).

Since 1946, electronic scales have mostly been used, which already have very competitive manufacturing costs, and have a much lower probability of mechanical failures than purely mechanical scales, in addition to being less sensitive to mechanical vibrations during measurement. Its operating principle is based on a coil and a magnet. When placing an object on the measuring plate, the magnet is moved through the coil causing a change in its electromagnetic field, generating an electric current interpreted by a microprocessor. This will show the value on the selected scale, referring to the current that was generated.

Due to their ease of use and great precision, electronic scales are the most used in manufacturing lines, medical offices and hospitals (AFONSO, 2004). A summary of the evolution of the scales can be seen in Figure 1.

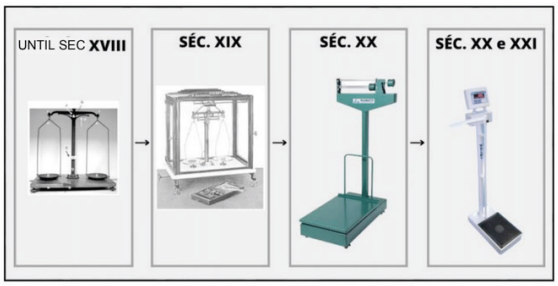


Figure 1: Timeline with representative scales for each group of equipment described.

These electronic scales use few components for operation, unlike old mechanical scales, thus reducing mechanical wear and the likelihood of failures. Scales currently consist, in general, of a platform on which the object to be weighed is placed; a load cell; and an electronic data acquisition and display system. Use is extremely simple, with only on/off and reset buttons, making use more accessible for any user (AFONSO, 2004).

The components of current scales can be purchased ready-made, so they only need to be installed and calibrated. Some of these components are presented in Figure 2.

There is a lot of space in the market for innovation using these pre-ready component modules, thus eliminating the need to manufacture them from scratch. This reduces the cost of manufacturing and product development, improving the attractiveness of the final value.

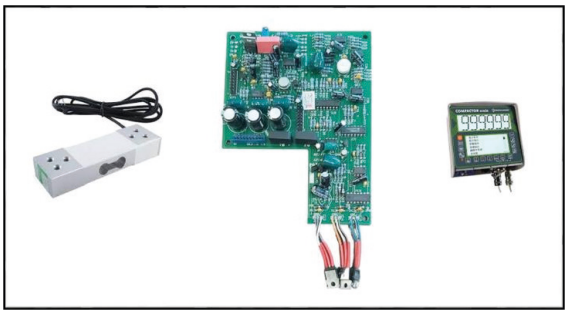


Figure 2: Load cell, embedded data acquisition system and LCD display

Like any measuring equipment, scales are also subject to losing their calibration as they are used. Therefore, for them to present the best performance, they must go through the calibration process periodically. This process takes place through the use of standard weights to check equipment reading errors. Thus, INMETRO (National Institute of Metrology, Quality and Technology) regulates not only the manufacturing, but also the use, maintenance and calibration of scales, currently through Ordinance 236/1994.

Figure 3: Example of standard weights used to calibrate scales.

Each piece of equipment has a classification, which will influence the maximum error allowed when reading a standard weight, illustrated in Figure 3, and is divided into 7 distinct classes: E1, E2, F1, F2, M1, M2 and M3, each with their maximum permissible errors as shown in Table 1. Class E1 is the one with the highest accuracy in the averages, and M3 is the one with the least accurate values (CAMPOS, 2013). It is important to know how to use the correct standard weight classes when calibrating equipment, because if an incorrect class is selected, it may become impossible to detect the error, or to classify whether the measurement error found is due to the scale. or the standard weight used (CAMPOS, 2013).

Maximum errors allowed (+- in mg)							
Nominal value)	E_1	E_2	F_1	F_2	M_1	M_2	M_3
50 kg	25	75	250	750	2.500	7.500	25.000
20 kg	10	30	100	300	1.000	3.000	10.000
10 kg	5	15	50	150	500	1.500	5.000
5 kg	2,5	7,5	25	75	250	750	2.500
2 kg	1	3	10	30	100	300	1.000
1 kg	0,5	1,5	5	15	50	150	500
500 g	0,25	0,75	2,5	7,5	25	75	250
200 g	0,1	0,3	1	3	10	30	100
100 g	0,05	0,15	0,5	1,5	5	15	50
50 g	0,03	0,1	0,3	1	3	10	30
20 g	0,025	0,08	0,25	0,8	2,5	8	25
10 g	0,02	0,06	0,2	0,6	2	6	20
5 g	0,015	0,05	0,15	0,5	1,5	5	15
2 g	0,012	0,04	0,12	0,4	1,2	4	12
1 g	0,01	0,03	0,1	0,3	1	3	10
500 mg	0,008	0,025	0,08	0,25	0,8	2,5	
200 mg	0,006	0,02	0,06	0,2	0,6	2	
100 mg	0,005	0,015	0,05	0,15	0,5	1,5	
50 mg	0,004	0,012	0,04	0,12	0,4		
20 mg	0,003	0,01	0,03	0,1	0,3		
10 mg	0,002	0,008	0,025	0,08	0,25		
5 mg	0,002	0,006	0,02	0,06	0,2		
2 mg	0,002	0,006	0,02	0,06	0,2		
1 mg	0,002	0,006	0,02	0,06	0,2		

Table 1: Representative table of maximum errors allowed by equipment class

Source: https://blog.labstore.com.br/peso-padrao/

MATERIALS AND METHOD

This study aims to apply the methodology developed and described by Rozenfeld et al. (2006) to manufacture a prototype of weighing equipment for hemodialysis patients. All stages of the project development will be described, as well as the milestones that must be reached at the end of each stage, in order to release development for the next stage. Figure 4 shows the four main steps of the method used, as well as its main characteristics. The steps are addressed and explained individually.

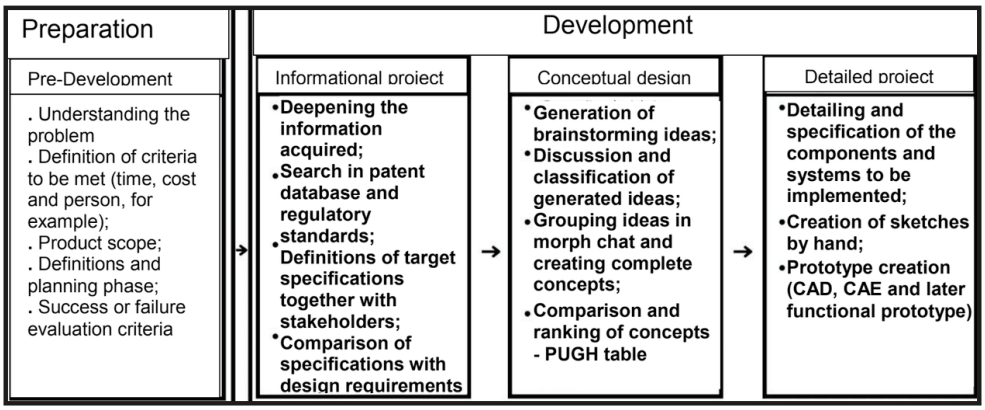


Figure 4: Descriptive table of the development stages.

PRE-DEVELOPMENT - PREPARATION

The first stage of product development involves understanding the problem to be solved, in order to define product criteria that must be met in order to develop a suitable prototype. For this initial phase of product planning to be carried out successfully, the scope of the product and the needs for its development (time, cost and personnel) must be defined and detailed. Based on this information, the attractiveness of the project is decided, to determine whether it will be developed or not. This stage of the process does not generate direct capital gains for the customer; it is a phase of definitions and planning only (ROZENFELD et.al. 2006).

The pre-development of a project is based on defining its scope and the scope of the product, the activities carried out and the development schedule, the criteria for evaluating the success or failure of the product, as well as its quality. The project draft is defined as the documentation that combines the premises and elements necessary in the project for it to be successful, and for it to be actually used (ROZENFELD et. al., 2006).

DEVELOPMENT - GENERATION

The second macro phase of product development following the methodology developed by Rozenfeld et al. (2006) is development, covering: Informational Design, Conceptual Design, Detailed Design, Preparation for Production and Product Launch. The phases applicable to the development of the project in this article will be described below.

For a phase to be defined as completed, a previously determined Gate (objective) must be reached. These objectives may be deliverables that must be evaluated, in order to validate the step taken and prepare the development team for the next step.

The general objective of this macro phase of the PDP is to generate specifications that must be met by the prototype and, consequently, by the product. These specifications range from customer requirements (aesthetics, dimensions, operation), to technical standards that must be met and whether there are similar products on the market (ROZENFELD et.al. 2006).

INFORMATIONAL PROJECT

Based on the information collected in the previous planning stage, a set of specifications will be developed so that the product can be developed successfully. These specifications are used throughout the development of the project to generate solutions, to develop ideas and serve as a parameter for evaluating the success of the prototype. It is important to fully understand the problem you want to solve, so it will be necessary to deepen all the information that was previously collected. If the information that was collected is incorrect or deviates from the problem to be solved, a project may be developed that does not solve the initial problem (ROZENFELD et.al. 2006)

A search and analysis of the technologies to be used for development in patent banks and regulatory standards was also carried out. This stage is particularly important, as it is here that manufacturing methods that can be used are discovered, and whether similar products already exist on the market, so as not to violate any patent.

The product requirements were defined together with the stakeholders (parties interested in the project), these being the 5 front-line employees of the aforementioned hemodialysis clinic interested in the solution, being nursing technicians, nurses and doctors. The target specifications were developed by the author himself based on his interpretation of the requirements. The product's target specifications must be compared with the project requirements, to ensure that they will solve the problem that was proposed for resolution. If they agree, the next stage of development can begin (ROZENFELD et. al., 2006).

CONCEPTUAL DESIGN

The next phase of product development is generating ideas through brainstorming (idea generation technique). This serves to develop new ideas on how to solve the problem, without judging them as feasible or not, as the intention of this stage is to develop as many ideas as possible. After brainstorming is completed, the ideas generated must be discussed, classified and grouped (ROZENFELD et. al., 2006).

Following the process, a morphological matrix, Morph Chart, must be created, using the ideas generated, and grouping them into categories depending on their specific attributes or functions. The Morphological Matrix offers a structured way to approach generating complete concepts for a well-defined problem. It does this visually and exploring different combinations with ideas obtained through brainstorming, in order to obtain the best functionality (ROZENFELD et. al., 2006).

To determine which configuration will be taken forward in development, Pugh Screening and Scoring must be carried out. This methodology serves to compare the solution concepts that were developed with the system that is currently used. To achieve this, a system of weights is assigned to each of the project's requests, in order to create a ranking of the solutions. The solution with the highest score will be chosen to be developed and detailed, so that it will be tested in prototype form (ROZENFELD et.al., 2006).

When scoring and ranking the concepts, only one of them is taken forward, so that it will be prototyped and its use will be analyzed and evaluated. In this study, brainstorming and the organization of Morphology ended up being developed by the author together with a technician graduated in automation. The attribution of Pugh's values was by the author's own choice.

DETAILED PROJECT

In the detailed design phase of product development, the components, systems and subsystems that must be implemented have already been determined, with only details remaining on the ways to make the specifications viable and tangible. At the end of the detailed design phase, the deliverable that will allow moving to the next stage is, therefore, the functional prototype, which must have been approved by the team (ROZENFELD et.al., 2006).

The hand-drawn sketch is a resource frequently used in product development to start the development of the prototype, and create the first visual representation of what the product will look like. The sketch serves as the basis for developing the prototype in CAD. Due to the extensive use of tools such as CAD, the prototype development stage becomes more direct, as it allows for greater dynamism in design changes. This occurs due to the fluidity and ease of generating changes to a CAD prototype, so that the project can be adapted to production realities as the project progresses, as well as adapting the project to new requirements that may arise. Furthermore, the use of simulation in CAE (Computer Aided Engineering) adds another stage in the development, but allows failures in production and use of the product to be reduced, since its mechanical behavior is extensively analyzed (AZEMI et. al., 2018). This CAD and CAE project was developed by the author himself, using the raw material selected for the project, serving as a validation stage. Finally, the author carried out an assessment of the perceived gain obtained with the adoption of the system, in order to determine the positive and negative aspects of the project.

METHOD

The methodology developed by Rozenfeld et. al (2006) to develop a system for weighing hemodialysis patients for the Nefrocor Clinic. The methodology, described in sections 3.1 and 3.2, was followed in its entirety. For the development of the project, a handmade sketch was developed, a prototype made in CAD, as well as a physical prototype, which was applied to the aforementioned company.

RESULTS

PRE-DEVELOPMENT RESULT

In conversation with doctors from Clínica Nefrocor, a recurring problem in dialysis clinics was noted, which consists of the patient needing to get up at the end of the hemodialysis session, go and weigh themselves and talk to the nurse to be released. This procedure is widely adopted, but it entails risks for the patient and weighing errors, meaning that the best metrics for evaluating the effectiveness of dialysis are not obtained when dealing with fluid loss; in addition to causing queues for weighing and delays in releasing patients.

Therefore, it is a problem that affects the efficiency of the procedure, as in the hemodialysis procedure each patient has an HD machine to use, and there can be up to 36 patients dialyzing simultaneously in the same room.

It was also found that dialysis can be considered a fixed procedure, as there is currently no direct methodological way to assess whether the procedure is having the desired effect before its completion, therefore allowing few personalized adaptations and adjustments based on the patients' response to the configured conditions. in the equipment over the approximately four hours during which hemodialysis is being performed. In this sense, real-time monitoring of the effectiveness indicator is unfeasible.

It was then discussed that the scope of the project would be to solve both problems with a single solution. Thus, the opening draft of the project was organized, indicating the scope of problem resolution and other definitions. The draft is shown in Figure 5.

DEVELOPMENT RESULTS

RESULTS OF THE INFORMATIONAL PROJECT

In interviews with stakeholders, it was possible to identify the most common problems when using the system currently used. In this conversation, some criteria were defined that must be met so that the product can serve patients in the best possible way, and to facilitate the work of nurses and nursing technicians, who are responsible for monitoring dialysis and assisting the patient.

Using this information, it is possible to advance the project to the next stage, project development. Some requirements were brought forward, such as: determining a maximum cost for the prototype; the need to attach the prototype to the chairs already used today for dialysis; reduce patient weighing time; do not put the patient at risk with the equipment and support loads up to 180kg.

In Table 2, you can find the consolidated list of project requirements, with identifier, description, and target specification.

With this information, a search was carried out in the patent database to determine if there is any product that meets the project's requirements, and none was found. For this stage, research was carried out at the National Institute of Industrial Property, using the keywords: weighing patients, scales, hemodialysis. On 06/17/2022 the same research was carried out, and again no existing solutions were found. Thus, project development can be continued.

CONCEPTUAL PROJECT RESULTS

A brainstorming session was held to determine ideas for how the equipment would work, the components to be used and ways of using the equipment. After the end of brainstorming, the ideas generated were analyzed and evaluated to determine the feasibility of using them.

The ideas that showed the most promise was separated into groups, according to the system of which they are part.

Having the customer's requests for the product in hand, it is possible to start the process of generating ideas and classifying them. This process was carried out using the Morph Chart technique, or morphological matrix, which allowed the grouping of possible solutions according to the system of which they are part – they were organized into 6 systems – measurement, reading, fixing, energy, material and finishing. Below, in Table 3 you can find the table with the alternative ideas grouped together.

Starting from the grouped ideas, concepts of complete solutions were developed, using one idea from each grouping in the previous table.

Several different concepts were elaborated, but after feasibility analysis, 3 concepts were selected to be analyzed in greater depth. These 3 concepts are shown in Table 4. The elements that involve interactivity through connections are those that show the greatest variation between the concepts, since there are several connectivity options that can be used in the product, depending on the needs.

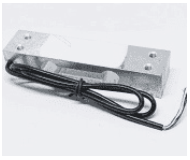
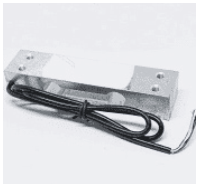
	Scouting	Reading	Fixation	Energy	Material	Finishing
1	1x Load Cell 	*Display*LCD 	Removable base	Battery 	Stainless steel	Galvanization 
2	4x Cells inCharge 	Connection with Computer 	Fixed base atarmchair	Electrical network 	Aluminum	Electrostatic painting 
3	Adapt measurement system from another scale	Connection perapplication 	Fixationin the existing hole and		Polymer	Hammered Painting 
4	Mechanical system 	Analytical Scale 			Carbon steel	No finishing

Table 3: Ideas grouped from Brainstorming

Company / Agency / Sector / Program: Nefrocor Clinic	
Project manager: Equipment Maintenance Technician	
Prepared by: Equipment Maintenance Technician	**Version:**1.0

Project Scope

Solution capable of weighing the patient throughout the dialysis session, so that liquid loss can be assessed in real time (gain in effectiveness), and so that, at the end of the session, the patient does not need to get up to weighs itself (efficiency gain).

Period							**Involved**
	J	F	M	A	M	J	
Pre-development	■	■					-Doctor –26 years of experience in the field
Informational Project			■				-Nurse –23 years of experience, works 10 shifts per week
Conceptual Project				■			-Nursing Technicians –work 6 shifts per week
Detailed project					■	■	

Acceptance Criteria	Restrictions
To advance at each stage, validations took place assessed on the support from the project supervisor progress Conference with stakeholders for stage passage approvals.	- Cost issues are notwith incorporated; - Possibility of connectivity

Figure 5: Draft project.

Identification	Description	Specification	Origin	Flexibility of Greeting
R1	Easy to use and move	One person does the movement	Management, Cleaning	Mandatory
R2	Low maintenance	Same maintenance as Others scales	Management, General Services	Optional
R3	Low cost	Below R$2,000.00	Management,	Mandatory
R4	Resistant to cleaning	Resist to hypochlorite	Cleaning, General Services	Optional
R5	Compatiblewith the seats used	HERVAL HT3705; Base measurements: 460mm x 540mm	Management	Mandatory
R6	Maintain the height of the armchair seat within of the norm	Between 550mm and 850mm	Management	Mandatory

Table 2: Project Requirements Table.

Requirement of project	Punctuation	Concept 1	Concept 2	Concept 3
R1: Ease of Use	2	0	0	2
R2: Low Maintenance	2	0	2	2
R3: Accuracy	1	1	1	1
R4: Manufacturing Cost	1	-1	-1	0
A5: Resistancethe cleaning	2	2	2	2
Total	8	2	0	7

Table 5: PUGH concept ranking table.

Concept 1	**Concept 2**	**Concept 3**
1 Load Cell 	4x Load Cells 	System adapted from another scale
Computer Connection 	Connection by application 	*Display*LCD 
Removable base	Fixed base on the armchair	Fixed base on the armchair
Electrical network 	Battery 	Electrical network 
Aluminum	Stainless steel	Carbon steel
No Finish	Hammered Painting	Electrostatic painting

Table 4: Details of the concepts generated

From the concepts, several configurations were found that could be solutions to the problem we are trying to solve. They were then taken to the next stage, which is PUGH SCREENING & SCORING.

To construct the PUGH Table, Table 5, the previously determined project requirements were used, in addition to a score assigned to each one. This score is determined according to the importance that each of the requirements has in the product, defined by the author himself based on what was interpreted together with the stakeholders.

Based on this score, each of the concepts is evaluated as "+", "-" or "0", if it is higher, lower or equal to the reference concept, which in this case is the procedure used today for weighing patients. At the end, the score for each concept is added together, to define which of the concepts will be developed in the next stage.

Applying the PUGH concept analysis method, as seen in Table 5, it was possible to reach the conclusion that concept 3 is the most appropriate to the reality of the company in which the product will be used. Concept 1 was not selected because it required a computer for each system, making its use unfeasible. Concept 2, on the other hand, was not satisfactory because it was difficult to calibrate 4 load cells simultaneously, and it would be an expensive system to implement. It was also discarded due to the difficulty of implementing a system via application on a cell phone.

This way, the concept selected for development consists of a measuring system adapted from a commercial scale, with an LCD display for easy reading of results, fixed to the base of the seats, powered by a 12V and bivolt source (110V/220V), will be manufactured in steel 1020 carbon and will be painted. After this process of creating complete concepts, a conference meeting was held with stakeholders, in order to validate the concepts and ideas that were used. The customer's and user's vision during development is critical to creating a product that meets demands and is actually used. During this meeting, it was confirmed that the project developed up to this stage has the potential to solve the existing problem, and development was cleared to proceed to the next stage.

DETAILED PROJECT RESULT

According to the previous stage, it was defined that the concept to be taken forward to be developed and deepened consists of adapting a system of already existing measurement, which is powered by the clinic's electrical network, the prototype will be manufactured in 1020 carbon steel, will be fixed to the existing structure of the seats, in order to maintain their mobility, and will have an LCD screen for reading the measurement results. Due to the ease of manufacturing and maintenance, the prototype will consist of a flat base, which will be attached to the armchair structure, and the other components will be attached to the base.

To define the basic structure of the equipment, a hand-drawn sketch was created – See Figure 5.

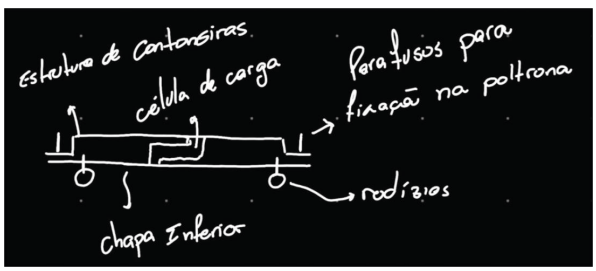


Figure 6: Hand-drawn sketch, representing the side view of the equipment structure.

After the basic definition of the structure, the CAD project began to study the feasibility of the prototype. Upon completion of the CAD project, a CAE study is carried out in order to validate the equipment's resistance.

Mechanical properties of steels under the following conditions:
Hot rolled: normalized and annealed

quality		Conditions	Austetizing temperature (°C)	Resists traction (MPa)	Yield limit (MPa)	Stretching (%)	Area reduction (%)	Toughnes (HB)	Impact (J)
AFP	AISI (1)								
1015	1015	Laminate Standardized Annealed	- 925 870	420 425 385	315 325 285	39,0 37,0 37,0	61 70 70	126 121 111	111 115 115
1020	1020	Laminate Standardized Annealed	- 870 870	450 440 395	330 345 295	36,0 35,8 36,5	59 68 66	143 131 111	87 118 123

Table 6: Mechanical properties of steels 1015 and 1020, under rolled, normalized and annealed conditions.

Source: FG Steel Catalog, available at: http

Gauge	Weight Theoretical kg/m	Gauge	Weight Theoretical kg/m	Gauge	Peso teórico kg/m	Bitola	Weight Theoretical kg/m
1/8 x 1/2"	0,55	3/16 x 1.3/4"	3,15	1/4 x 4"	9,81	3/8 x 6"	22,20
1/8 x 5/8"	0,71	3/16 x 2	3,63	5/16 x 2"	5,83	1/2 x 3"	13,90
1/8 x 3/4"	0,87	3/16 x 2.1/2"	4,52	5/16 x 2.1/2"	7,44	1/2 x 4"	19,05
1/8 x 7/8"	1,04	3/16 x 3"	5,52	5,16 x 3"	9,07	1/2 x 5"	24,10
1/8 x 1"	1,19	1/4 x 1"	2,29	5/16 x 3.1/2"	10,70	1/2 x 6"	29,20
1/8 x 1.1/4"	1,50	1/4 x 1.1/4"	2,86	5/16 x 4"	12,19	5/8 x 4"	23,42
1/8 x 1.1/2"	1,83	1/4 x 1.1/2"	3,48	3/8 x 2"	6,99	5/8 x 5"	29,80
1/8 x 1.3/4"	2,14	1/4 x 1.3/4"	4,12	3/8 x 2.1/2"	8,78	5/8 x 6"	36,00
1/8 x 2"	2,46	1/4 x 2"	4,75	3/8 x 3"	10,72	5/8 x 8"	48,78
3/16 x 1"	1,73	1/4 x 2.1/2"	6,10	3/8 x 3.1/2"	12,50	3/4 x 5"	35,10
3/16 x 1.1/4"	2,20	1/4 x 3"	7,30	3/8 x 4"	14,58	3/4 x 6"	42,70
3/16 x 1.1/2"	2,68	1/4 x 3.1/2"	8,63	3/8 x 5"	18,30	3/4 x 8"	57,80

Table 7: Catalog of dimensions of angles with equal edges.

Source: Riograndense Steel Catalog, available at: https://www.acosriograndense.com.br/cópia-tabela-barra- chata-1

The material selected for the prototype was 1020 carbon steel and has mechanical properties as shown in Table 6. This material was selected because it has mechanical properties compatible with the needs of the project, has good weldability and has an acquisition cost compatible with the budget.

After the lower plate was validated, the development process continued with the base design. This one uses angle brackets with identical flaps in the same material, 1020 carbon steel in dimensions 3/16" x 1.1/4". In Table 7 you can find the catalog of available dimensions of angles with equal edges.

After pre-selection of the materials to be used, the equipment must be designed in CAD and simulated in CAE, in order to validate the selection of materials.

CAD PROTOTYPE

To create the prototype in CAD, the AUTODESK INVENTOR 2022 software was used, using a student license obtained through PUCRS. When prototyping began, the weighing components and electronic components were measured, as well as the seats used at the Nefrocor Clinic. This step was carried out to ensure compatibility between all components. The CAD drawing is represented in Figure 7.

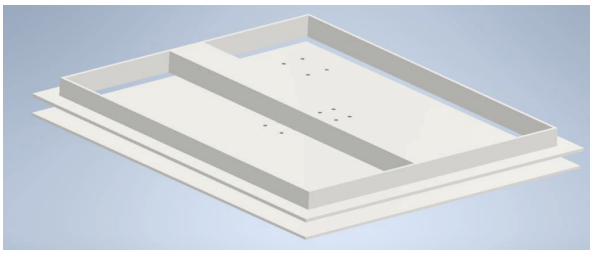


Figure 7: CAD prototype created using AUTODESK INVENTOR 2022 software.

Designs were carried out for each of the components that are part of the prototype, namely: lower plate, upper base manufactured with angles, load cell fixing beams and caster fixing system.

The 1020 steel lower metal plate that serves as the base and attachment point for the card cell and casters was designed and CAE analysis was carried out. As shown in Figure 8 below, it was possible to determine that the 3mm thick sheet would not be sufficient to support the 180 kg load determined in the project (160 kg from the patient + 20 kg from the chair and equipment).

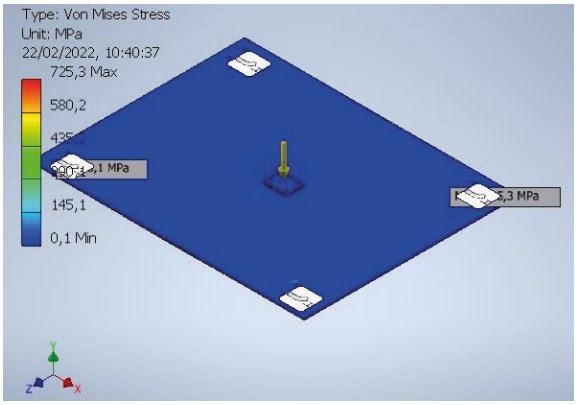


Figure 8: CAE simulation of the 3mm thick 1020 steel bottom plate, maximum stress of 725.3 MPa.

The simulation showed that the sheet would be subject to stresses in the order of 725 MPa, well above the material's yield stress. The points that showed tension accumulation occurred at the drilling points for fixing the load cell and casters. This way, the thickness of the sheet was increased to 4mm, and the positioning of the casters was changed, more towards the center of the sheet, in order to better distribute the load. The simulation was carried out again, and this time the results were satisfactory for the equipment to support the loads determined for the project. The results of the new simulation are in Figure 9.

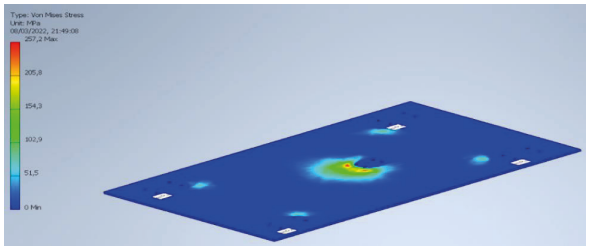


Figure 9: Simulation of the 1020 steel bottom plate with a thickness of 4mm.

After the lower plate was validated, the development process continued with the base design. This one uses angle brackets with identical flaps in the same material, 1020 carbon steel in dimensions 3/16" x 1.1/4". To join the rectangle-shaped angles, welds will be carried out along the entire length of the contact face between the pieces. To fix the load cell, eight-millimeter screws will be used, fixed to the lower plate and upper structure. Welding, carried out correctly, ensures that the welded parts behave in the same way as a single part. The same CAE simulation was used to predict the behavior of the component, demonstrating that the sizing was correct.

Figure 10 is the result of the simulation of the upper structure, and shows that the maximum stress in the component is in the order of 126.8 MPa, well below the yield stress of the material, as shown in Table 6. Therefore, the component is correctly sized, and will withstand the necessary stresses.

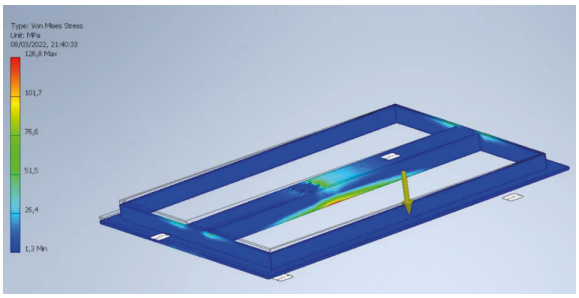


Figure 10: Simulation of the base made of 1020 carbon steel angles, with dimensions 3/16" x 1.1/4".

The display fixing system was designed using the same software, but was designed to be manufactured in MDF using Laser Cutting. This ensures ease and speed, allowing greater flexibility in manufacturing the prototype.

With the projects and simulations completed and properly validated, it is possible to continue with the product development process and move on to manufacturing a functional prototype. This will be applied and its functioning analyzed in practice.

FUNCTIONAL PROTOTYPE

As soon as the prototype was created in CAD and CAE software, successfully achieving the goals that were developed for it, the development of the functional prototype began.

For this, a Filizola brand scale, Personal model, with a capacity of 180kg was purchased, to be dismantled and its parts used to manufacture the prototype. The load cell, microcontroller and LCD display were used. These components were all measured and taken into consideration, when creating the prototype in CAD, in order to guarantee compatibility between the purchased parts and the designed parts.

The manufacturing process began by dismantling the acquired scale to measure and analyze its components. The unused parts were discarded, leaving only the necessary material. As decided during the detailed design stage, the material used for the prototype was 1020 carbon steel, both for the lower plate and the angle base. For the system's movement system, commercial casters with an individual load capacity of 50kg were selected, totaling 200kg of system load, and are from the Colson brand and model 6236.

When manufacturing the prototype, 45-degree cuts were made in the corners to form the base that will be fitted to the existing armchair. To do this, a band saw adjusted for angled cutting was used. Next, the bottom plate was drilled to secure the casters and load cell. Next, the angles forming the base were welded. For welding, the TIG method was used using direct current with a negative pole and a high frequency source to open the arc.

The LCD display fixing system was manufactured in the PUCRS laboratories using a laser cutting machine. The pieces were cut into 3 parts, so they were assembled using screws to ensure their union. The components were installed inside the fixing system, and this was installed on the base of the equipment. Weighing tests were then carried out to ensure the system was working as a whole. Figure 11 shows the equipment assembled and being tested for the first time.

After completing the prototyping, another meeting was held with stakeholders before implementing the equipment to ensure that it complied with the requirements. During the meeting, the project was approved, and the implementation of the prototype was released for use.

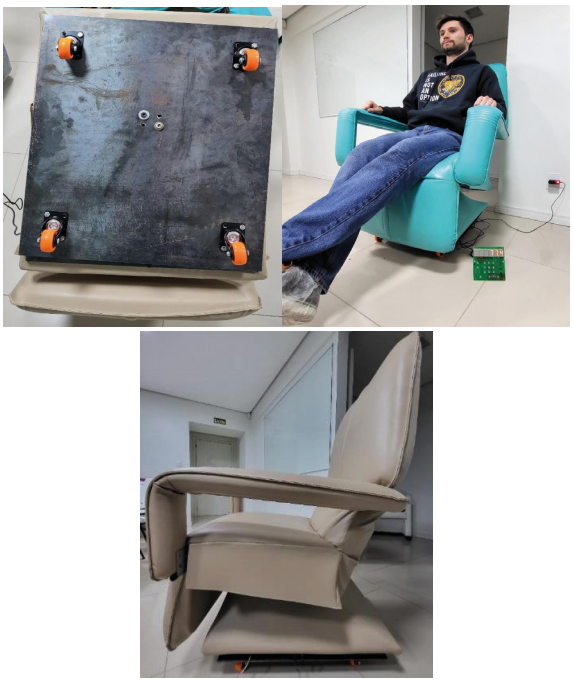


Figure 11: Bottom, side and front view of the equipment being installed and tested.

FUNCTIONAL ANALYSIS

After releasing stakeholders, the last stage of the project development process began, so that the prototype was implemented at Clínica Nefrocor. This operation was analyzed and evaluated by all project stakeholders.

A table was then created containing the strengths and weaknesses of the project and the prototype that were listed by the stakeholders. Weaknesses were listed in descending order of importance, so that the items that must be changed most urgently are at the top of the list.

Table 8 shows the characteristics of the prototype that must be maintained for the manufacture of future units. Also, problems and undesirable characteristics were exposed that must be reviewed to further improve the equipment. From this information collected, it was evident that the results obtained with the prototype were satisfactory to justify the manufacture of more units to be implemented in the Clinic.

Strong points	Weaknesses
Easy to use	Power supply exposed to liquids
Allows weighing of bedridden and low mobility patients	Heavy for moving between floors
Easy to move	Could have computer integration
Save time when weighing	Casters with brake
Improved quality of life for employees and patients	

Table 8: Results analysis table.

CONCLUSIONS

By using the project development method devised by Rozenfeld et al. (2006) the process of creating and manufacturing the proposed equipment proved to be quite objective, as it had a complete and comprehensive methodology to be followed. This allowed the prototype to be developed following all project requirements and within the stipulated deadline, so that its theoretical development was validated. Its conception and development covered the project objectives: increasing the ease of weighing patients and reducing the incidence of weighing errors.

Thus, it is possible to conclude that the project served to validate the proposed concept, so that the registration of intellectual property to enable the commercialization of a more refined version of the product is recommended, with a period of one year from July 1, 2022, the already manufactured prototype will continue to operate, and more units will be manufactured for use at the Nefrocor Clinic.

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