

## Implementation of Improvements to Increase Quality in the Production of Medical Equipment: A case study in a Small Business

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### Abstract

The global context, due to the pandemic and attention to the production of medical equipment, requires companies to have an optimized production capacity. Thus, this research demonstrates a case study of a small manufacturer, focusing on the production of a power module capable of delivering an electrical stimulation intensity superior to that of all other equipment available in the world market. During the process, quality tools were used (5W2H - *What-Who-Where-When-Why-How-How Much*, PDCA - *Plan-Do-Check-Act*, Flowchart, Organization Chart, and Ishikawa), aligned with modeling and simulation via Petri Net, to identify and solve bottlenecks. With the use of these methodologies, it was possible to find and prioritize the root cause of one of the problems that influences the quality of the product and later model and simulate the process and propose a more profitable and effective solution. This study enabled the implementation of a new production model that allowed for cost reduction and minimized material losses. Specifically, it was possible to verify the optimization of the production of the external protection structure (cabinet), with a saving of 88% in the value of this equipment component.

**Keywords:** Petri Nets; Medical equipment; Quality tools; Process Management

## **1. Introduction**

The use of appropriate medical equipment is essential for healthcare professionals to make an accurate diagnosis and provide targeted treatment, thus allowing for more effective procedures. In Brazil, the National Health Surveillance Agency (ANVISA) is responsible for regulating the medical device market, and products must be registered with the agency before commercialization (ANVISA, 2020). Medical equipment refers to equipment used in the healthcare field for medical purposes, either directly or indirectly. They fall under the category of health products and are largely composed of active medical products (ANVISA, 2020). According to the 2020/2021 economic data survey conducted by the Brazilian Association of Medical, Dental, Hospital and Laboratory Equipment and Supplies Industry (ABIMO), about 86.8% of medical equipment companies were micro-businesses, with up to 19 employees (ABIMO, 2022). The pandemic caused by the spread of COVID-19, considering the Brazilian scenario, led to the death of approximately 680 thousand citizens and affected about 34 million people by September 2022 (CORONAVÍRUS-BRASIL, 2022). According to Sahada et al. (2020), in the diagnosis and treatment of COVID-19, medical equipment and devices play a necessary role and can define the success of the fight against the virus in proportion to the availability of these devices. Parallel to this scenario and focusing on a perspective of industrial productivity, techniques for optimizing production processes have reinforced the need for efficiency in organizations (Kiran, 2019).

There are tools that support the strategic management of organizations, such as quality tools, which are methodologies for improving the quality of projects, products, systems, and processes. The quality tools work by retaining information for analysis, sizing, and deployment and aim to reduce costs, provide continuous improvement, and develop process and/or production optimization. There are numerous quality tools, however, it is necessary to verify which one best fits the process of the company or the problem to be addressed (Venâncio et al., 2020). In addition to strategic tools for organizational purposes, the current industry has modeling and simulation techniques, which are used as an evaluation capacity for scenarios to minimize uncertainties (Lisboa et al., 2019). An important modeling and simulation tool is Petri nets, which according to Murata (1989), is a graphical and mathematical model that can be applied to various types of systems.

This study focused on a company that operates in the process of automating evoked muscle activation, capable of enhancing the beneficial effects of rehabilitation in immobilized patients with reduced mobility and spinal cord injuries. Its production focuses on a power module capable of delivering an electrostimulation intensity superior to all other competitor equipment available on the market. Thus, the present article aims to present a case study for increasing the quality of production of medical equipment from the aforementioned company, with the support of quality tools, modeling, and simulation based on Petri nets. To this end, specific objectives were outlined, such as analyzing current production processes using quality tools,

proposing an initial study using Petri net modeling and simulation to evaluate possibilities and scenarios, and proposing optimizations weighted by PDCA (*Plan-Do-Check-Act*) and 5W2H (*What-Who-Where-When-Why-How-How Much*) to compose a plan based on assumptions of resources and execution responsibilities. This work is justified by the existing expenses in the area, not only in terms of consumption but also during the production process of biomedical equipment, the quality of the equipment, and production planning, including methods and processes.

## 2. Materials and Methods

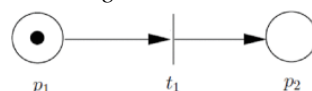
### 2.1 Theoretical References

The theoretical references in this article focused on the definitions of biomedical equipment, production management, quality tools and Petri Nets.

- Biomedical Equipment: “*Medical equipment [...] comprises all equipment for use in health with medical, dental, laboratory or physiotherapy purposes, used directly or indirectly for diagnosis, therapy, rehabilitation or monitoring of human beings, and also for those for the purpose of beautification and aesthetics*” (ANVISA, 2020).
- Strategic Production Management: The strategic production management is one of the greatest demands in an industry, therefore, well-founded techniques must underpin the continuous production process (Kiran, 2019).
- Quality Tools: aim to optimize and organize the management of information and process. In this study, the following tools were addressed: Flowchart; Organogram, PDCA, Ishikawa Diagram, 5 Whys, 5W2H and GUT Matrix (*Gravity-Urgency-Tendency*) (Vargas et al., 2023).

Regarding the modeling and simulation process, the Petri net was used, which according to Murata (1989) is one of the modeling and simulation techniques that comprises graphic and mathematical modeling, and it can be applied to different types of systems. In a Petri net  $P$  is a finite set of places of dimension  $n$ ,  $T$  is a finite set of  $m$ -dimensional transitions, Pre:  $P \times T \rightarrow IN$  is the input application (preceding places or previous incidence), Post:  $P \times T \rightarrow IN$  is the output application (next places or later incidence);  $x$  = markup vector. In figure 1, it is possible to graphically see an example of a Petri net with two places  $P = \{p_1, p_2\}$ , a transition  $T = \{t_1\}$ , and two connection arcs (input and output applications) Pre=  $\{p_1 t_1\}$  and Post=  $\{t_1 p_2\}$ , with demarcation  $x = [1 \ 0]$ , which explains the number of chips present in each place  $P$ .

Figure 1: Petri Net



Source: (Lisboa et al., 2019)

An analysis of the literature was performed to evaluate the processes that could contribute to the challenge presented in Table 1.

Table 1: Related Works

References	Description	Comparison
<b>Venâncio, et al (2020)</b>	This study presents the optimization of the production line of a company in the meat sector, seeking to standardize production and reduce costs.	It used the same production processes and the same techniques but in the meat production sector.
<b>Santos, et al (2021)</b>	This article consists of identifying and evaluating processes and inputs promoting improvements in equipment maintenance, in order to make the process more effective, economical and safer for patients.	It used the same improvement processes, in the same sector, but on different equipment.

Source: (Auhors, 2023)

## 2.2 Methods

The present study aims to identify opportunities for improvement within the manufacturing process of medical equipment, from the entry of the equipment order to the moment the finished product is obtained. Quality tools were used to diagnose the problem, identify its cause, and subsequently explain the solution proposal for identified bottlenecks. At this stage of the research, the following quality tools were used: **organization chart** (after a visit to the company, a visual representation of the organizational structure was created); **flowchart** (it was used to map the production process of the company, from the moment the sale is consolidated, until the delivery of the finished product); **Ishikawa Diagram** (from the problems mapped with the flowchart, the implementation of the Ishikawa Diagram was fundamental in the search for the possible causes of these failures, and to identify the bottlenecks); and **5 Whys and GUT Matrix** (the survey of the causes, made in the Ishikawa Diagram, was used to unfold in depth the whys, seeking to identify the root cause of the problems to be prioritized in the GUT matrix).

To complement the study, a simulation was performed using via Petri Net to strengthen the analysis of bottlenecks within the process. Finally, the 5W2H tool is executed and supported by the PDCA cycle. The tool was used to build an Action Plan for prioritized causes in a more agile way. The 5W2H questions were used to generate insights. Such responses guided the conduction of the PDCA cycle in each of its analyses.

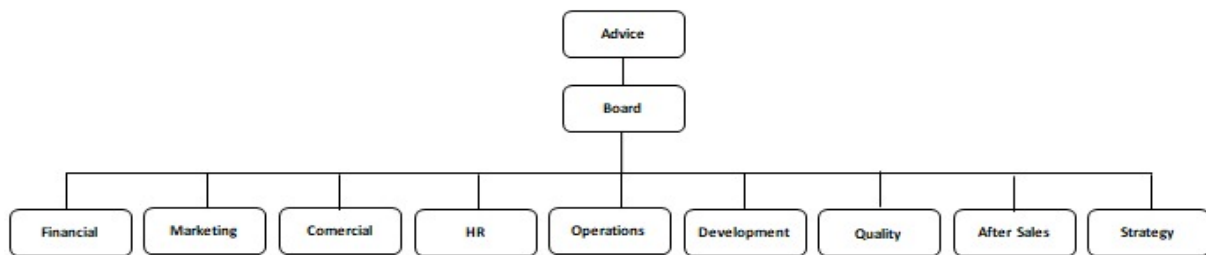
## 3. Results

### 3.1 Analysis via Quality Tools

The first element produced during the research was the organizational chart, as depicted in Figure 2, and responsibilities were generated. The Board is responsible for monitoring and directing the business affairs to ensure sustainability and to make strategic decisions. The Management team is responsible for managing the processes of the company, planning and

guiding the allocation of resources, and implementing new strategic initiatives. The Finance department manages the financial resources of the company. Marketing is responsible for understanding the market vision and satisfying customer needs through products and services targeted at a specific audience.

Figure 2: Company organization chart



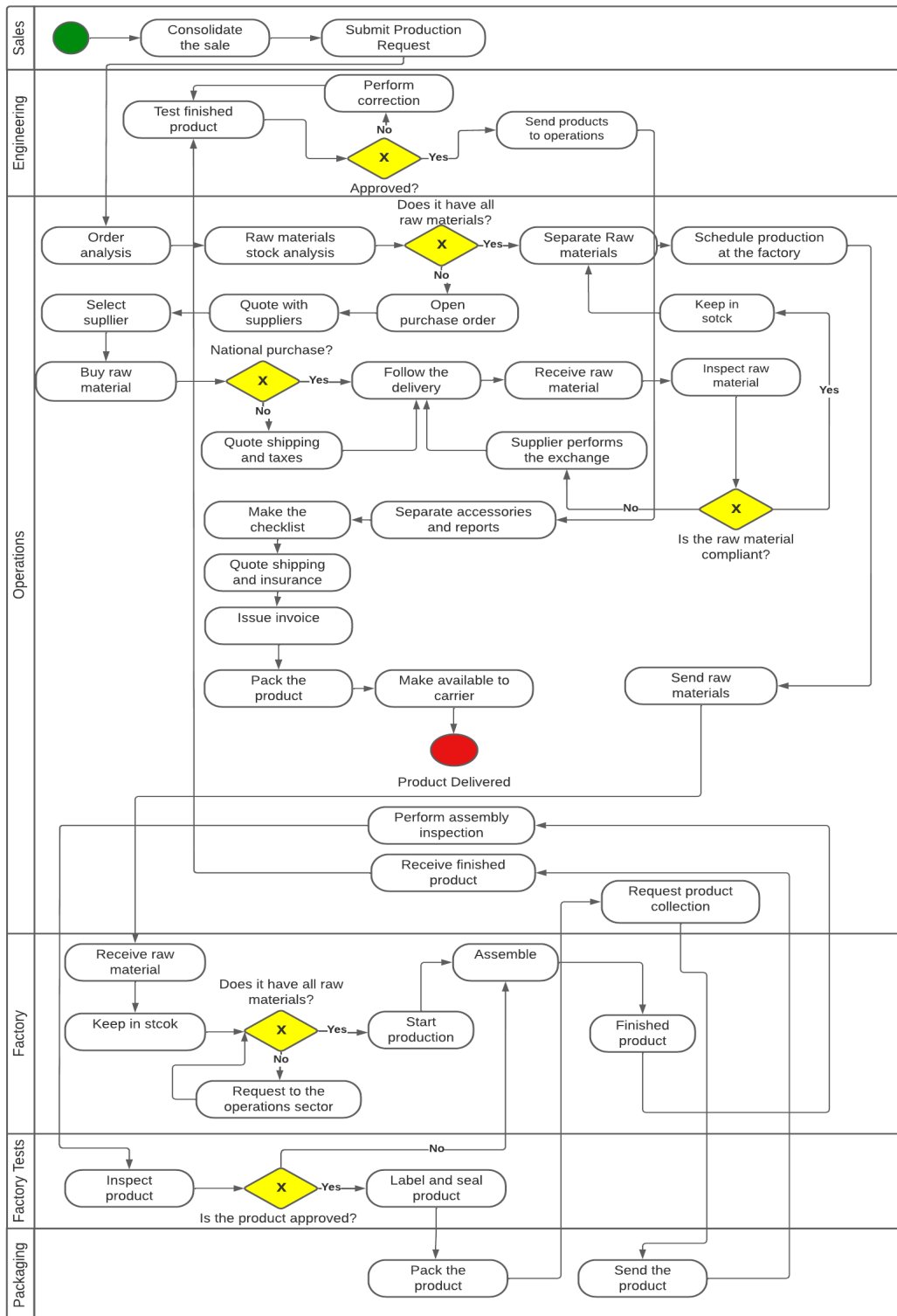
Source: (Auhtors, 2023)

At this stage, a mapping of the departments in the company is elaborated. The Sales team engages in B2B (*Bussines-to-Business*) consultative selling, handles campaigns, fairs, and marketing conferences as necessary. They work with management to organize and manage the sales funnel within the CRM (*Customer Relationship Management*) system and triage leads for referral to management or regional distributors for commercial follow-up. The Human Resources department is responsible for ensuring that new employees are hired in accordance with the job requirements and behavioral profile, in line with company policies. They assist employees in developing their careers and provide necessary training for professional growth. They design employee performance evaluation methods, conduct organizational climate surveys, and manage the termination process. The Operations department is responsible for national and international purchases, receiving materials and equipment for maintenance, ensuring inspection of incoming and outgoing materials, designing production plans, issuing production orders in the factory, and managing the entire process. They also contract and manage equipment logistics and accessories, contact and follow up with suppliers, manage parts and finished product inventory, issue invoices, arrange equipment insurance with the finance department, and ensure the traceability of equipment and components.

The Development team contributes to mobile product and service development as well as hardware and firmware development, and monitors the entire application lifecycle. They handle the internal equipment maintenance problem resolution. The Quality department ensures that all equipment is calibrated and in good working conditions. They must ensure that risk management is assessed, mitigation requirements are met, and all non-conforming product registration processes within the organization are solved and monitored. The Strategy department of the company aims to direct LEADS and define sales strategies and processes according to an analysis of reports and metrics to ensure alignment with the goals. A flowchart of the general operating process is shown in Figure 3. The process begins with the sales team,

who has the initial contact with customers, providing assistance, and defining the objective of the transaction, whether it is a purchase, rental, or try-buy.

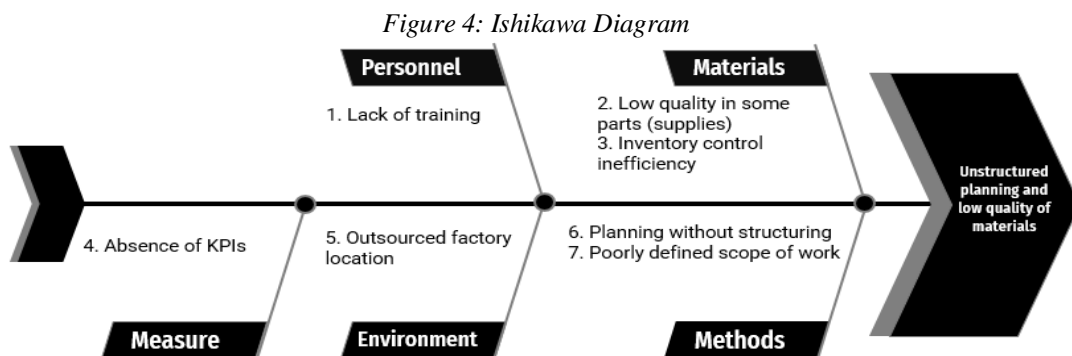
Figure 3: Company General Action Flowchart



Source: (Auhtors, 2023)

After completing this process, the sales team forwards a request to the Operations department to start the production development process, which begins with the identification of the order analysis. In sequence, an analysis is performed on the raw material inventory to determine whether the company has all the components necessary for production. If so, the items are separated, scheduled in the factory, and directed to the same location. If not, the missing items must be identified, a purchase order generated, quotes obtained from the respective suppliers, and raw materials purchased. In the case of domestic purchases, the process is more straightforward: purchase directly from the partner company, receive materials, inspect them, and direct them to the inventory. In the case of international purchases, the company must bear the costs of international freight, taxes, and cargo insurance. If the received material is not in a good condition, the items must be replaced. After directing the materials to the factory, it directs these products to its internal inventory and analyzes the existence of all the components. If something is missing, the operations sector is notified to treat this case. Following the assembly procedure, the trained technician starts producing the equipment. At the end of this step, the assembly of the product is inspected. It is then directed to the testing industry, where usability is tested and generates a functional report along with the auto-calibration checking document, and later packaged in such a way that it does not suffer damage during its transportation to the warehouse of the company.

The operations sector contacts the carrier to collect the product at the factory and direct it to the warehouse. Upon receipt, it is sent to the engineering team to perform the latest tests. If the equipment is not approved in these tests, the sector acts to solve the problem, if approved, the product is directed to the operations sector to transfer it to the customer, separating its accessories and reports, performing the checklist, counting the freight and insurance, and issuing the invoice. After performing these tasks, the product is packaged and made available to the carrier for delivery. The next step consists of the Ishikawa diagram, shown in Figure 4.



Source: (Auhtors, 2023)

Based on the Ishikawa diagram, possible causes of failures were diagnosed. Unruly planted planning and poor quality of materials were identified as key elements. Starting with labor, the

need to enable employees to perform their functions was analyzed to ensure excellence and operational safety. The next factor observed was that the faults found in some parts that make up the equipment are related to the poor quality of materials that are used by external suppliers. Problems were identified in the stock of parts, which generated inefficiency in control of the inventory, having a negative influence on production planning and control.

Following the diagram analysis, in the measurement stage, it was found that the company had no indicators to analyze the performance of the processes that could support planning and control. Regarding the environment, obstacles related to logistics was identified. The contracted factory is located more than 80 km from the headquarters, where the operations sector is responsible for the planning and control and storage of the inputs used in production.

Finally, regarding the methods, it has been detected that production planning is outdated and has several opportunities for improvement, which can bring effectiveness and contribute to more agile and quality production. Regarding the poorly defined scope of work, it is necessary for the company to redefine its processes and undergo restructuring to align them. The GUT matrix represented in Table 2 was used to prioritize the root causes. With the causes identified in the Ishikawa diagram, their deployment was performed using the method 5Whys to determine the root cause, as shown in Table 3. These results were identified, and an analysis was conducted based on modeling and simulation to understand the bottlenecks of production processes and a better foundation of their optimization strategies.

Table 2: GUT Matrix

GUT Matrix	G	U	T	Burden	Order
The part requires several manual process	5	4	5	100	1st
External factors (such as time) and qualities of the machinery impair the painting process	5	4	5	100	2nd
Inventory control software is not used	3	3	4	36	5th
Excess demand in the operating sector	4	4	3	48	4th
There is not contract with local factories	3	3	3	27	6th
No integrated system	3	2	3	18	7th
Undefined process	5	4	4	80	3rd

G - Gravity	U- Urgency	T- Tendency
1 There is no rush	1 Weightless	1 It will not get worse
2 It can wait	2 little serious	2 It will get worse in the long run
3 As early as possible	3 Grave	3 It will pay off in the medium term

Source: (Auhtors, 2023)



Table 3: 5 Whys

Cause	Why?	Why?	Why?	Why?	Why?	Why?	Root Cause	
Unstructured planning and low material quality	1	Low quality paint and parts	High rate of non-conforming parts	Cabinet structure not up to standard	Finish and cuts outside the specified standard	Complex processes that hinder assertiveness	The part requires several manual processes	The part requires several manual processes
				Cabinet painting is not up to standard	Coarse paint and coating not uniform	Failure during production	External factors, such as time, and the quality of the machinery impair the process	External factors, such as time, and the quality of the machinery impair the process
	2	Inefficient inventory control	Control quantities diverge from reality	It is not constantly updated	Manually done process	No software is used for inventory control	No software is used for inventory control	
	3	Absence of KPIs	Processes are not managed	No indicators	No data consolidation	Not prioritized by management	Excess request in the operations department	Excess request in the operations department
	4	Handling of inputs and finished products	Very high cost, time and distance	Factory located in another city	No contract with local factories			No contract with local factories
	5	Unstructured planning	Planning process is not managed	No consolidated data	No integrated system			No integrated system
6	Poorly defined scope of work and professional training	Centralized processes	Poorly delegated tasks	Lack of knowledge in the processes	Processes not defined		Processes not defined	

Source: (Auhtors, 2023)

### 3.2 Modeling and Simulation

In the first experiment, it was simulated the manufacture of the cabinet, an item that influences the quality of the finished product, and which was defined from the GUT matrix. The cabinet undergoes the process of plastic conformation and painting. Although, there are also other processes, they were not modeled or simulated. The values assumed for the transitions of the places of inspection of the conformation and painting during the Petri net simulations are presented in Table 4.

Table 4: Transition and Time Values

Place	Transition	Time ( $\mu$ )
Conformation Inspection	Validate Conformation	4
	Reject Conformation	3
Painting Inspection	Validate Conformation	7
	Reject Conformation	5

Source: (Auhtors, 2023)

Time values were defined from the historical data of parts inspections, according to Table 5 and 6, and were calculated as follows:

$$Time = 1 / x \quad (1)$$

where  $x$  is the average number of events of occurrence of non-compliant or compliant parts. The simulation tool does not assume decimal values, and given this restriction, the calculation was made by multiplying the time value by 10, in addition to the use of exponential distribution to validate the transition times, as recommended by Lisboa et al (2019), where such a distribution has an abstraction that can assist in processes with degree of uncertainties. Through the Petri network presented in Figure 5, the production of 100 cabinets that comprise the medical equipment (electro stimulator) was simulated. The process begins with the consolidation of cabinet production demand to start the product assembly.

Table 5: Plastic conformation service

Lot	Rejected Parts	Approved Parts
5	4	1
5	2	3
5	4	1
10	5	5

Source: (Auhtors, 2023)

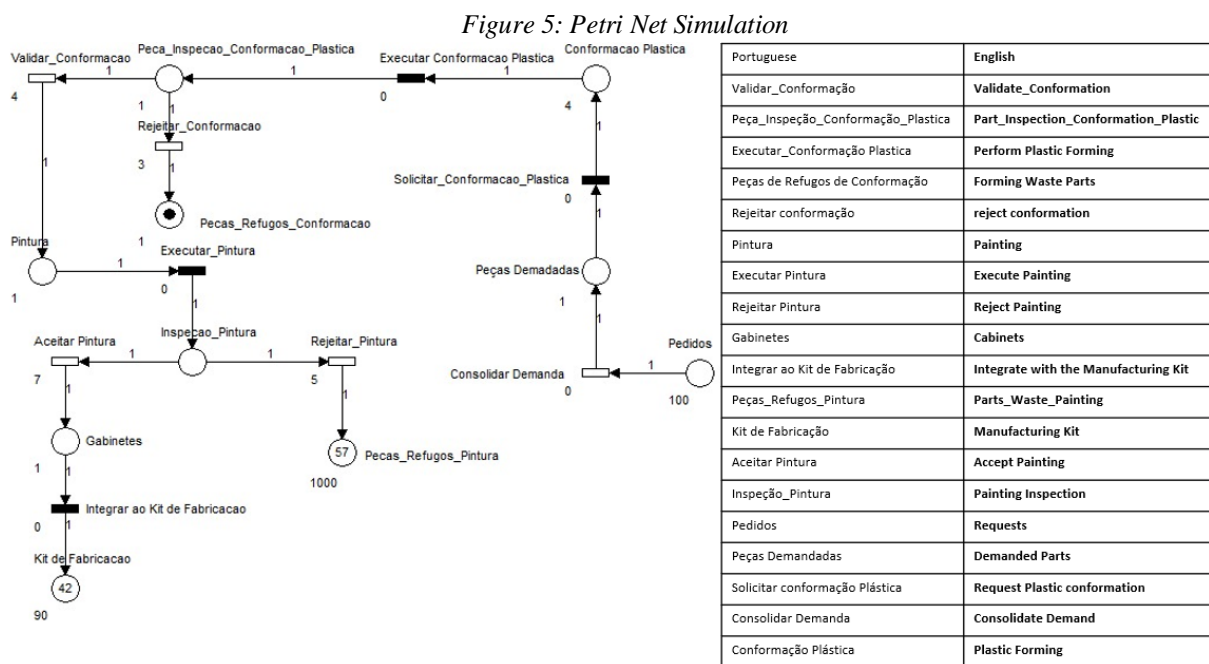
Table 6: Painting service

Lot	Rejected Parts	Approved Parts
1	1	0
3	0	3
5	4	1
4	2	2
2	0	2
4	4	0
4	2	2
1	1	0

Source: (Auhtors, 2023)

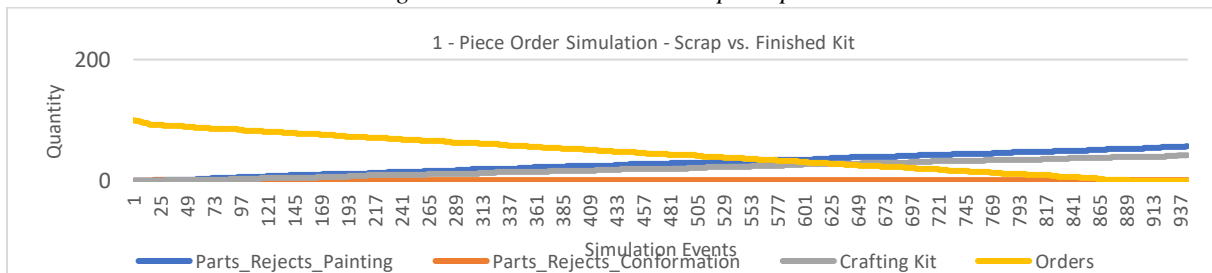
During production, a PSAI or HIPS (*High Impact Polystyrene*) plate with a thickness of 4mm was required to perform plastic conformation with ideal measurements according to the production files. The machine can eject four pieces at a time, so with each execution, the parts undergo a manufacturing inspection, where the material measurements that make up the cases are evaluated. If the part has no nonconformity, it is validated and directed to painting. Otherwise, the conformation is rejected, and the piece is directed to the refuse stock of the supplier, which is then used for rework or disposal. When the plastic conformation service is completed, the part is directed to painting, where the capacity is equal to demand. This is different from the service of plastic conformation, which is limited to four pieces at a time. At the end of the process, the inputs pass one by one by manual inspection, where they are defined as conforming or not conforming. In this experiment, the simulation will be performed until the production of a batch of 90 pieces is completed, and it may be likely to accept or reject

conformation as well as painting. The simulation was performed considering one part per order until the minimum required for operation, that is, four pieces. The chart in Figure 6 shows that the refuse of pieces in the process of plastic conformation remained stable and considerably low. In the painting process, the number of parts did not comply as the orders were completed, remaining above the number of kits ready. The second simulation (Figure 7) was made by attending to the same parameters as the first performed, but four pieces per request were taken into consideration.



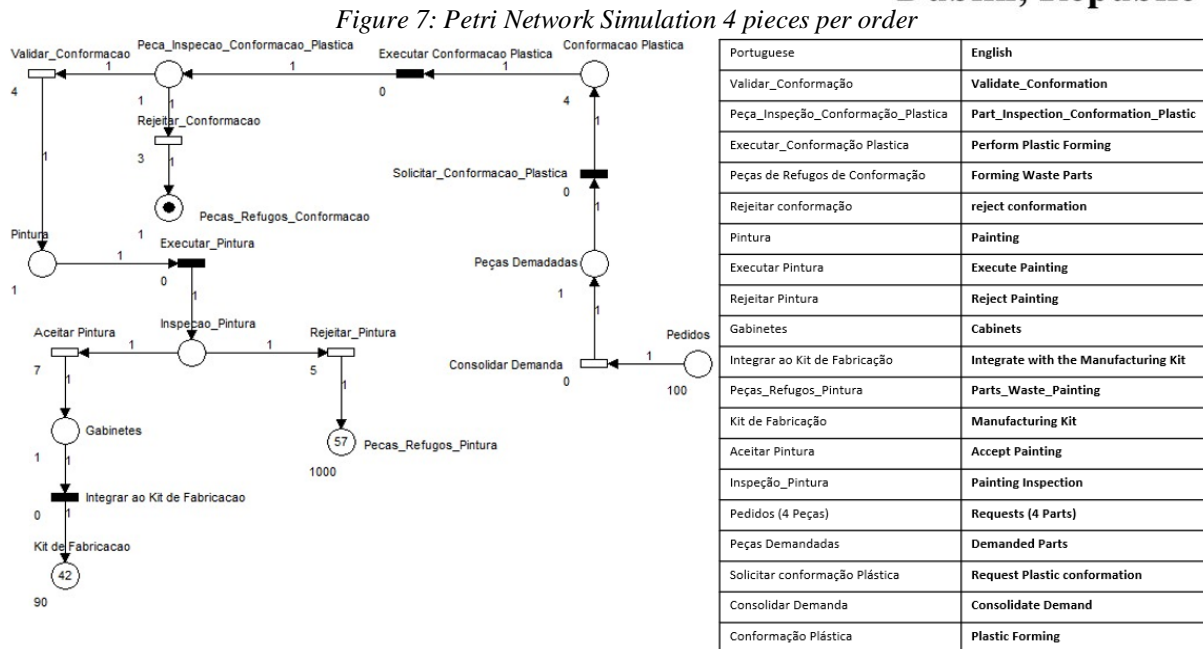
Source: (Auhtors, 2023)

Figure 6: Chart Simulation one piece per order

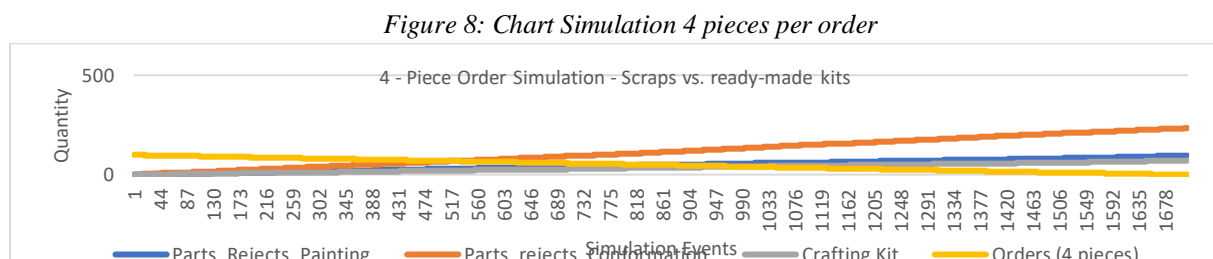


Source: (Auhtors, 2023)

In Figure 8, it is possible to observe a large number of parts that failed during the inspection processes, and it is found that as orders are produced, the number of refuses in the conformation process increases considerably in relation to the painting process and is higher than the number of kits ready.



Source: (Auhors, 2023)

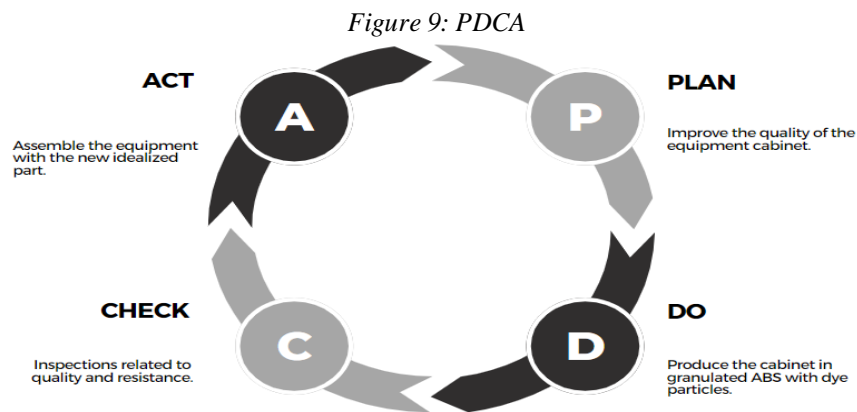


Source: (Auhors, 2023)

### 3.3 Implementation feasibility study

Purposing leveraging improvements and monitoring changes in the priority process, the PDCA cycle is shown in Figure 9. Given the data and information obtained by simulation and quality tools, it was suggested to change the material in which the part is produced. The modification of the production method, which is no longer by plastic conformation but becomes by plastic injection using granulated ABS (*Acrylonitrile Butadiene Styrene*) together with desired color dye particles. Therefore, the process of plastic conformation and painting is eliminated, reducing the number of pieces reworked and, consequently, the cost of production. As shown in table 7, the proposal to change materials in addition to maximizing the quality and stiffness of the part and reducing handicrafts, also results in minimization of costs and increased amounts produced in relation to time, making production more viable and profitable for the company. To execute the proposed improvements, 5W2H was used to assist and direct the action plan, as shown in Table 8.

Based on the evaluations made during the study of the company and the product, it was noticed that improvements need to be implemented so that the initial objectives are achieved, thereby minimizing the large number of nonconformities found in relation to quality. Thus, solutions were suggested for the processes of plastic conformation and painting of pieces. The value of the investment for the change of the cabinet to be completed is around sixty thousand Brazilian Reais (BRL).



Source: (Auhtors, 2023)

Table 7: Model Comparison

	Old cabinet	New Cabinet
Image		
Material	Polystyrene PSAl, thickness: 4 mm	Granulated ABS, thickness: 4 mm
Tonality	PTA 050 - White microtexture	PTA 050 - White microtexture
Production time	3 hours per piece	1 piece per minute
Painting method	Blasting	Dye fusion with ABS particles
Amount spent	RS 542,00	RS 65,00
Reduction	<b>RS 477,00</b>	

Source: (Auhtors, 2023)

Table 8: 5W2H

Causes Prioritized	5W2H						
	What?	Who?	When?	Why?	Where?	How?	How much?
The part requires several manual processes	Change in the part production process	Operations Sector	1st half of 2023	Due to several steps to produce the final structure	Provider	Printing a single part in Granulated ABS	~ BRL 65.00 / piece
External factors (such as climate) and qualities of the machinery impair the painting process				Due to the poor quality of the part in the end		Adding to the ABS Color Granules to obtain the desired color	

Source: (Auhtors, 2023)

The mechanical project of product construction and cabinet mold is included, and this investment will be paid with the production of approximately 140 pieces in the new model,

since in relation to the old cabinet the company will save about BRL 470.00 per piece. The total investment in the production of these pieces is equivalent to the cost reduction acquired by the material change. Analyzing the economic viability for the company, it is possible to verify that this investment is viable, as the equipment is an exclusive product that resulted from over ten years of investment in advanced technology.

#### **4. Conclusion**

In this study, it was analyzed the processes of the company, and identified points of improvement, and analyzed the quality of the manufactured product. A simulation for the data collection of the production process was conducted, where the number of non-compliant parts in the analyzed production lot was identified, which was greater than 50%. Parts that failed during inspection were redirected to production for non-conformities, generating rework, or discarded generating waste. In view of the data and analyses, it was suggested to exchange the manufacturing model of the parts using another material, the granulated ABS particles, along with the dye to reach the desired color. It was observed that this solution would be effective for the problem of plastic conformation and painting because the investment would be paid with the savings of the new cost of production.

Such analysis becomes pertinent since this research appears as a diversification and update of the studies by Venâncio et al. (2020) and Santos et al. (2021). Both evaluate the issue of optimizing the production process in their respective industrial sectors, however the results demonstrated here provide a practical demonstration for the medical equipment production sector, with the most robust evaluation than productive environment. This work contributes to future studies that need to conduct process analysis, problem identification, and propose solutions, and fosters the use of data, such as the results of Petri nets, which allows the use of various analysis methods to give credibility to the solutions.

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