



# Implementation of Continuous Flow for Manufacturing Process at BD Humacao

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 Prof. Carlos Gonzalez | IE 4995 - 39 Capstone Design Course Extension | SP-22



## DEFINE

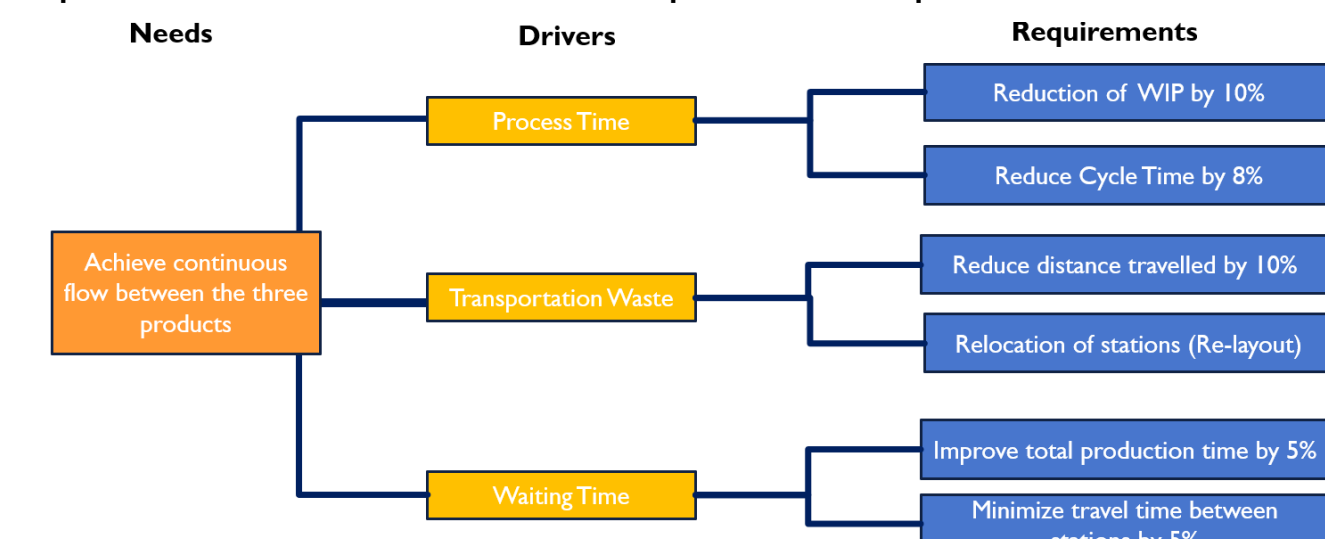
BD Humacao has been operating for about 37 years, where almost 700 BD associates engage in manufacturing and exporting activities at the facility. BD company was founded in 1897 and has more than a century of experience and global reach. For this reason, BD leads in patient and healthcare worker safety and the technologies that aid in medical research and clinical laboratories. BD Humacao manufactures products for two divisions: Peripheral Intervention and Suroevr.



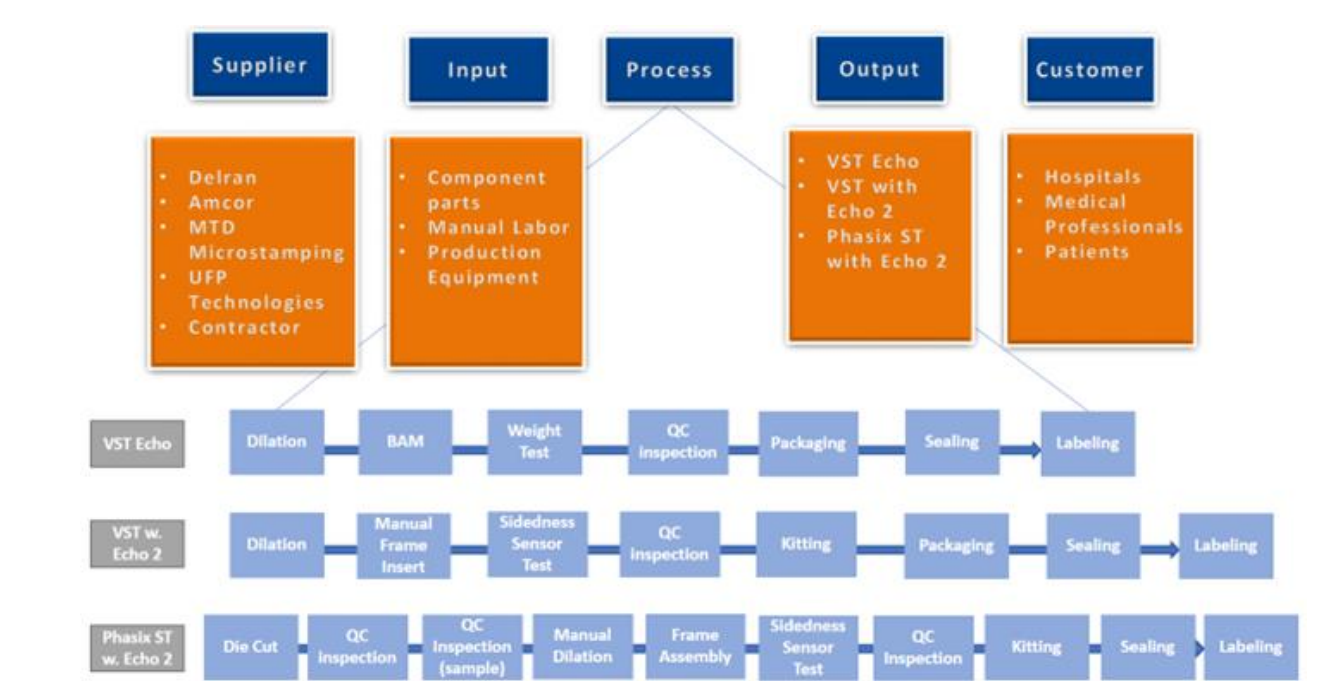
The products above which are manufactured at BD Humacao site were part of the project. **VST Echo** is a product that uses a balloon that inflates and causes the deployment of the mesh during laparoscopic ventral hernia repair, the balloon deflates quickly and is completely removed from the body. **VST with Echo 2** is a deployment and positioning device that comes attached to Ventrailight™ ST Mesh. It facilitates mesh positioning and centering over the hernia defect, for a consistent, reproducible technique. **Phasix ST with Echo 2** is a bioresorbable mesh with a positioning system designed to streamline laparoscopic and robotic hernia repairs.

### Problem Statement

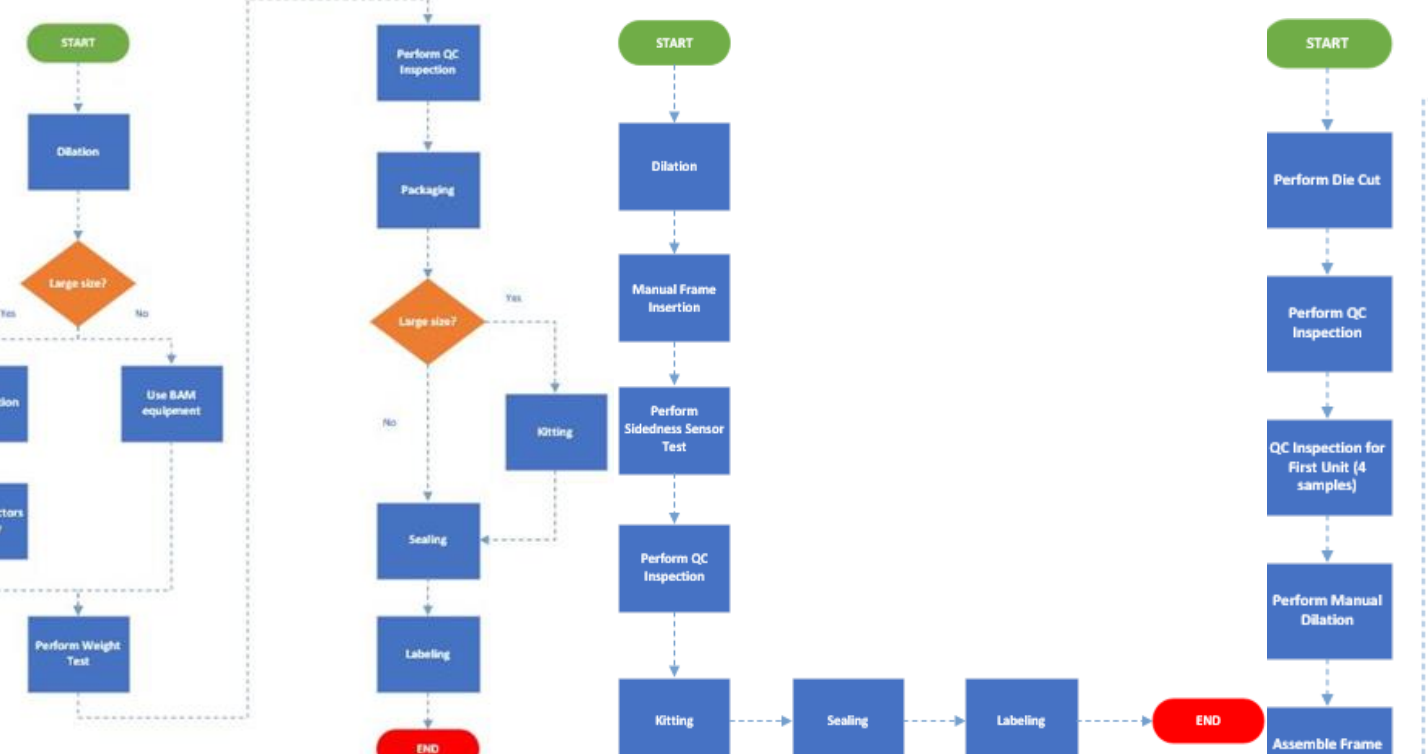
The current process manufactures the units by batches. This means that the production of the units in each process steps is not continuous. Factors that will be evaluated that may be contributors to the manufacturing processes being performed in batches instead of continuous flow include unnecessary movement, excess transportation, more points of inventory than required and idle time between process steps.



In the Critical to Quality tree above, is presented the need of the project, which is to be able to achieve continuous flow between the three products. Then, we observe the drivers which are divided in: Process Time, Transportation Waste and Waiting Time. Lastly, we have the requirements that are the performance specifications that must be met by its corresponding drivers to satisfy the client to achieve continuous flow.



In the above SIPOC chart: the different Raw Material Suppliers; Inputs which are the Component Parts, Manual Labor and Production Equipment; Processes Flow Charts for the three products; Outputs which are the three Products; and Customers such as Hospitals, Medical Professionals and Patients are presented.



Flow Charts were created to visually display the sequence of activities in each of the product's processes. During the process, these products go through various manual operations and inspection points, and end with packaging and labeling.

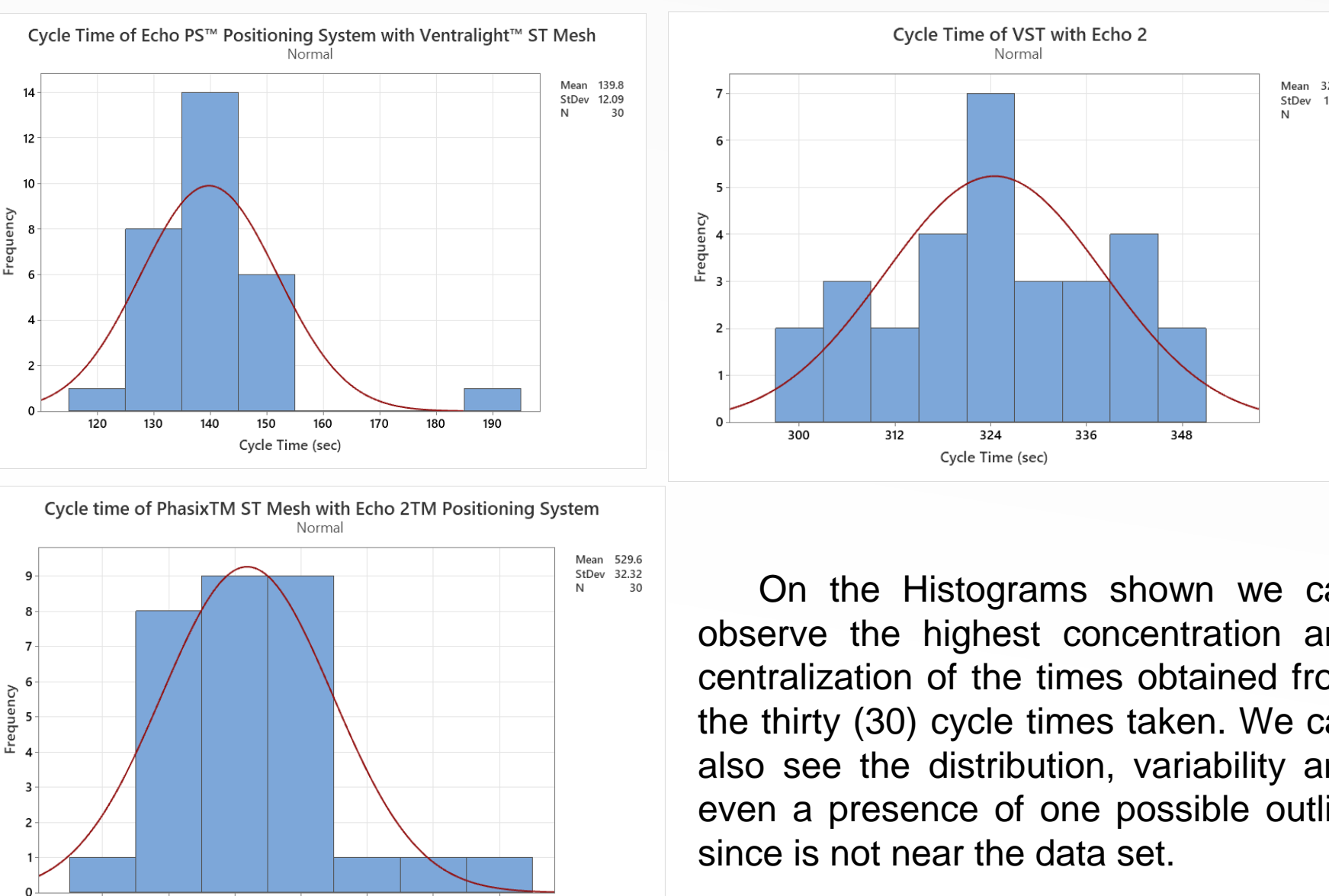
## MEASURE

Variable	Total Count	Mean	StDev	Variance	CofVar	Minimum	Median
Echo PS™ Positioning System with Ventrailight™ ST Mesh	30	139.77	12.09	146.25	8.65	122.57	137.95
VST with Echo 2	30	324.47	13.71	188.07	4.23	297.45	324.32
Phasix™ ST Mesh with Echo 2™ Positioning System	30	529.65	32.32	1044.65	6.10	472.30	523.34

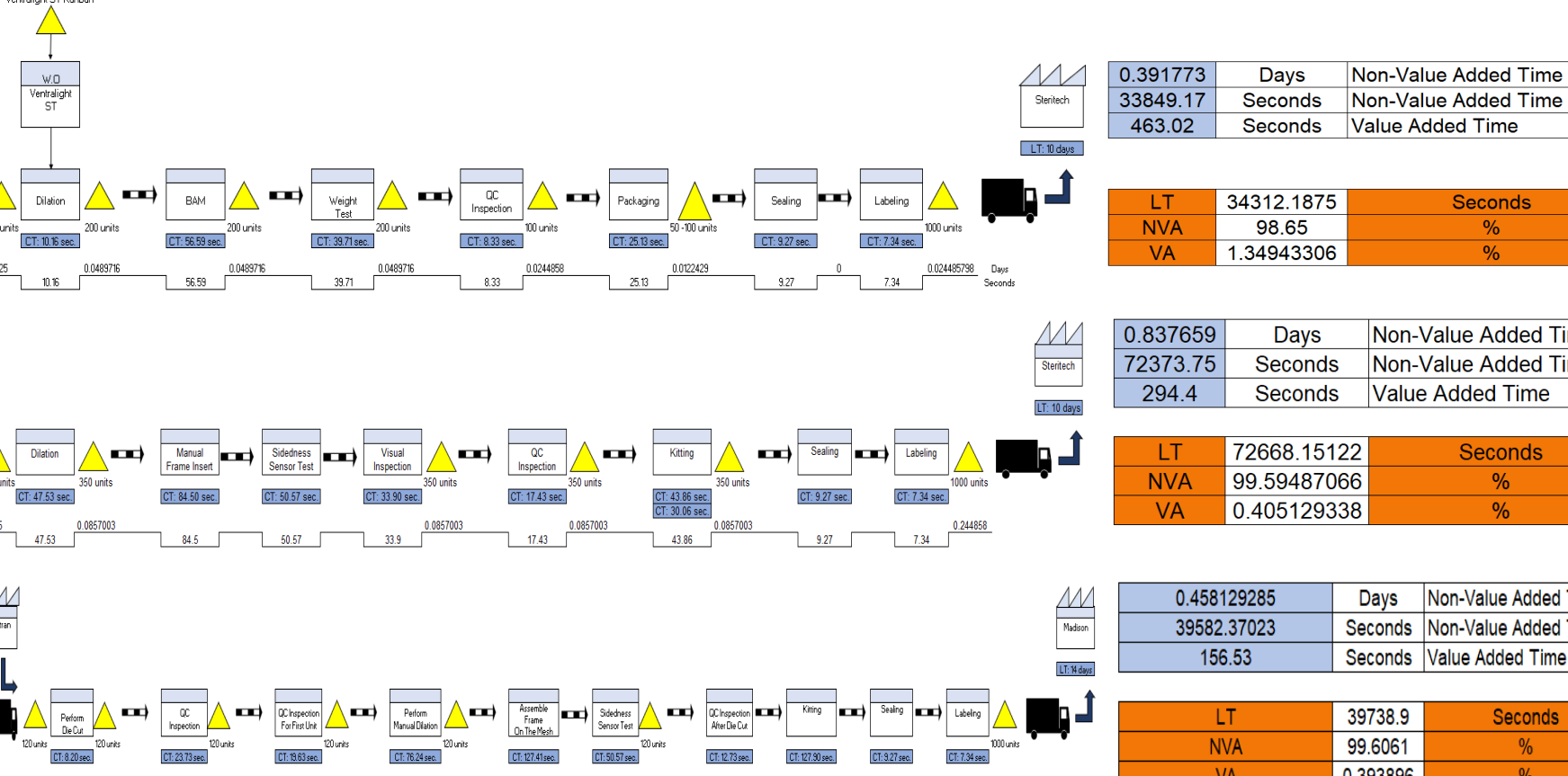
Variable	Maximum	Range
Echo PS™ Positioning System with Ventrailight™ ST Mesh	188.95	66.38
VST with Echo 2	349.98	52.53
Phasix™ ST Mesh with Echo 2™ Positioning System	632.49	160.19

In the descriptive statistics shown above are the samples of the thirty (30) cycle times that were taken from the three (3) products which are: Echo PS™ Positioning System with Ventrailight™ ST Mesh, VST with Echo 2 and Phasix™ ST Mesh with Echo 2™ Positioning System.

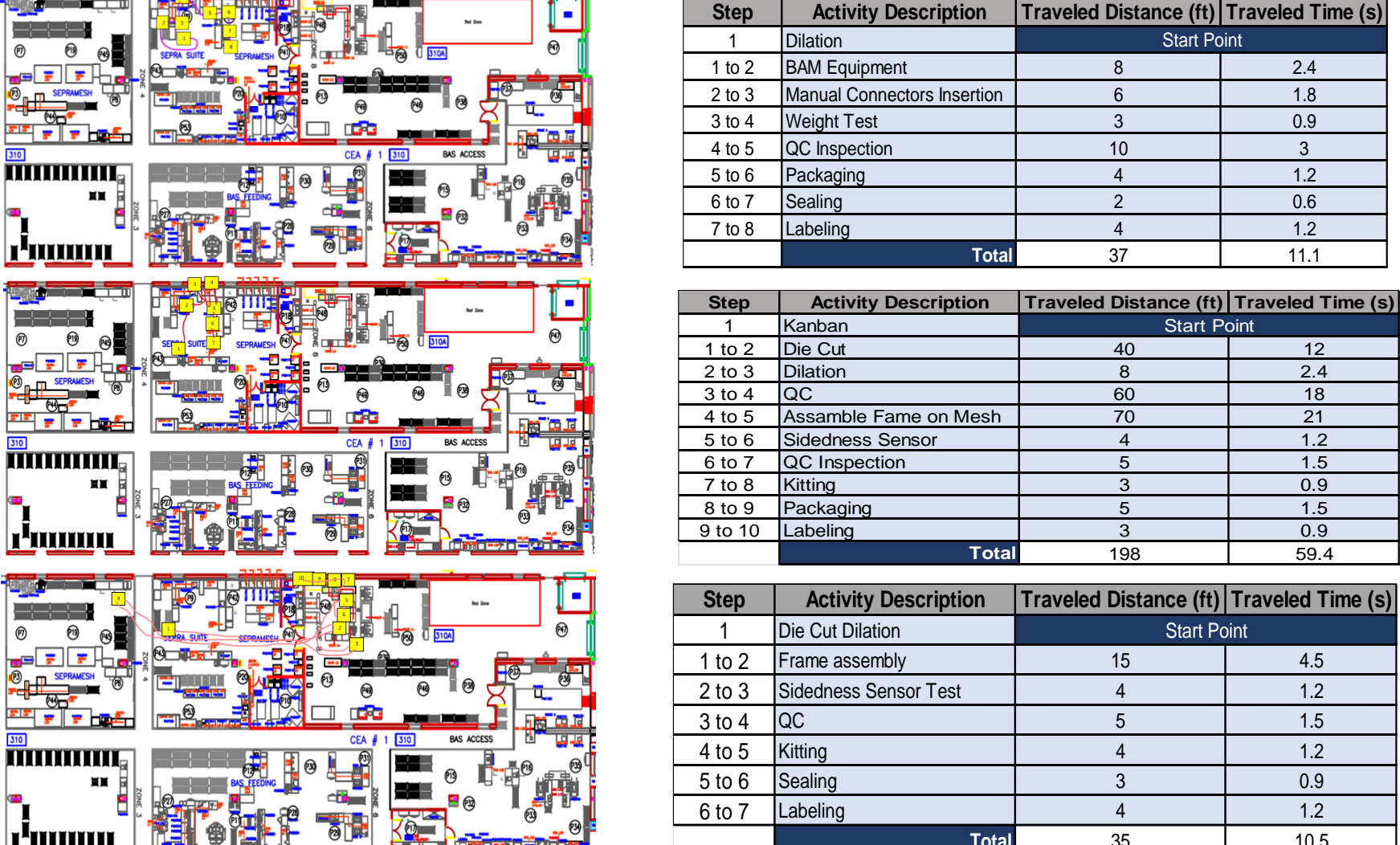


On the Histograms shown we can observe the highest concentration and centralization of the times obtained from the thirty (30) cycle times taken. We can also see the distribution, variability and even a presence of one possible outlier since is not near the data set.

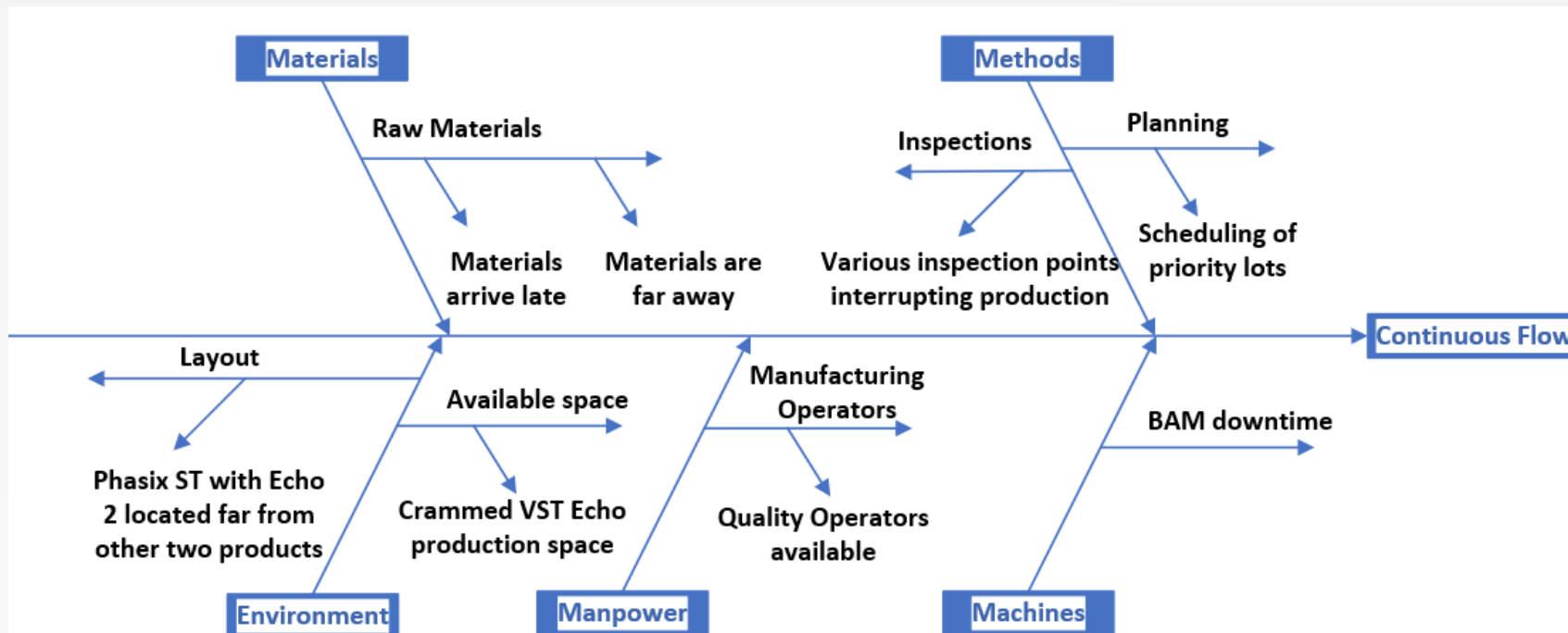
The three (3) Value Stream Map presented above display all critical steps process for each of the three (3) products and quantification of the time and volume taken at each stage to display all the important steps of the process necessary to deliver value. These Value Stream Maps shows the flow of both, materials, and information as they progress through each process. With this information it was able to calculate the total Value-Added Time (VA) as well of the total Non-Value-Added (NVA).



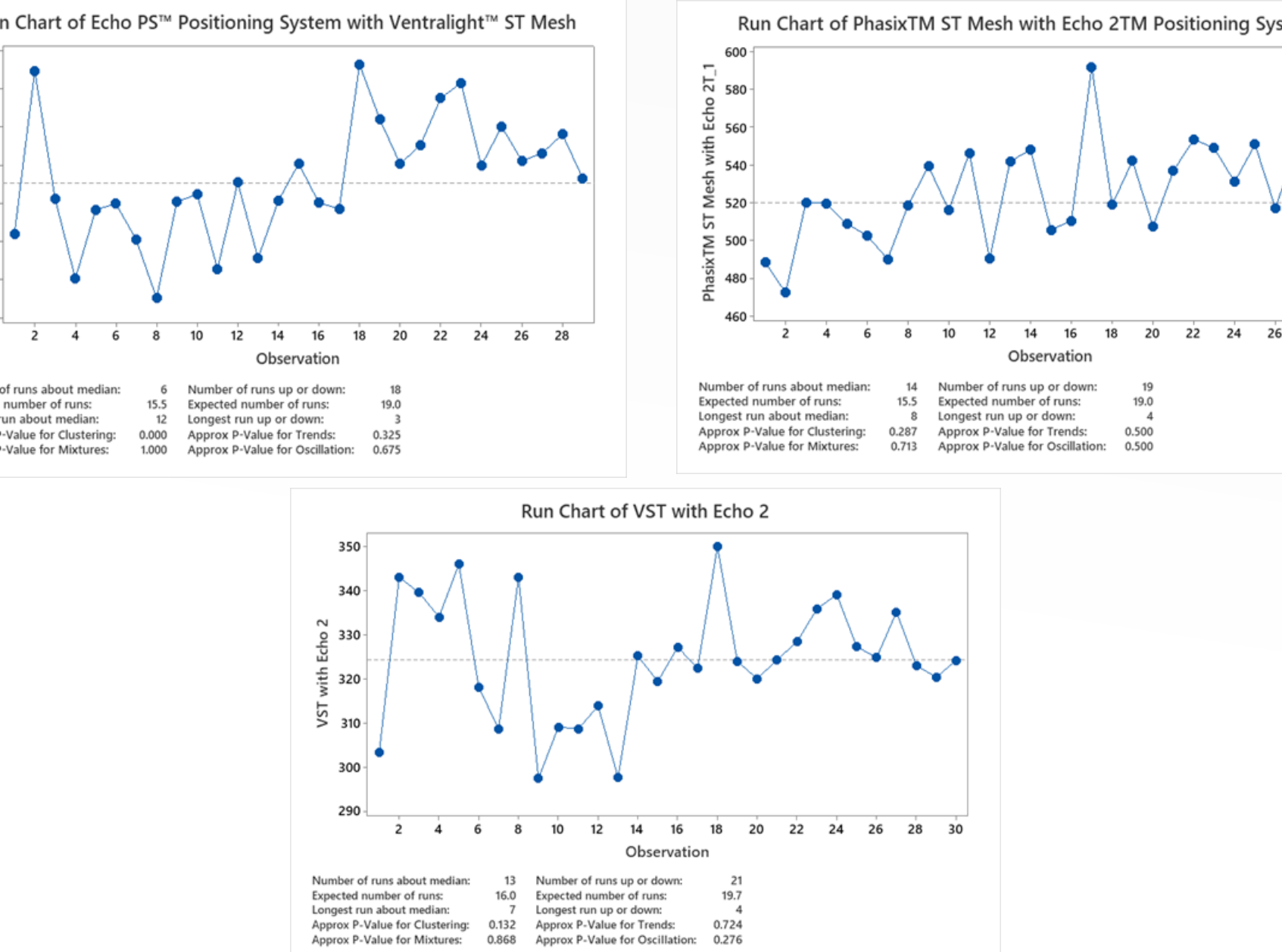
These Spaghetti Diagrams shows the current flow of the activities, travel distance, and process steps that are necessary for the manufacture of each product. The right tables captures the travel distance and travel time. The process steps that are required to produce the first product has a total travel distance of 37 feet and a total travel time of 11.10 seconds. For the second product, there is a total travel distance of 35 feet and a total travel time of 10.50 seconds. For the third product the total travel distance is 198 feet, and the total travel time is 59.40 seconds.



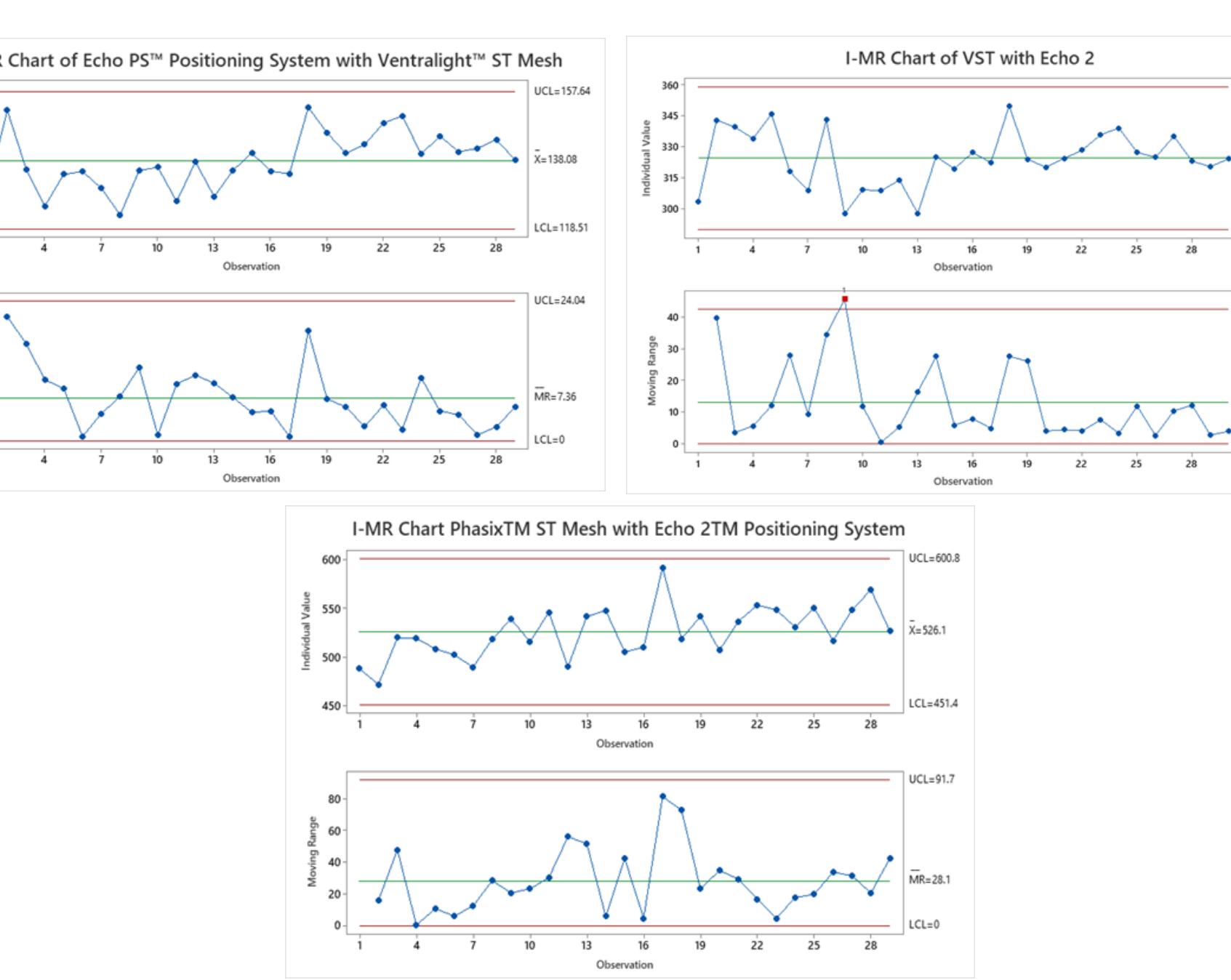
## ANALYZE



The Fishbone Diagram has five (5) categories in which the project team could identify different root causes to the main problem. The categories are as follows: Methods, Materials, Machines, Manpower, and Environment. All the categories evaluated and analyzed using the fishbone diagram contribute to the main problem "Continuous Flow". Knowing the root causes to problems allows the project team to focus on eliminating or reducing the factors that inhibit or interrupt the continuous flow between the products. Taking into consideration the observations obtained during the Measure phase of this project the causes that most inhibit the manufacturing process to produce the three (3) products evaluated are "Manpower", "Environment" and "Materials".

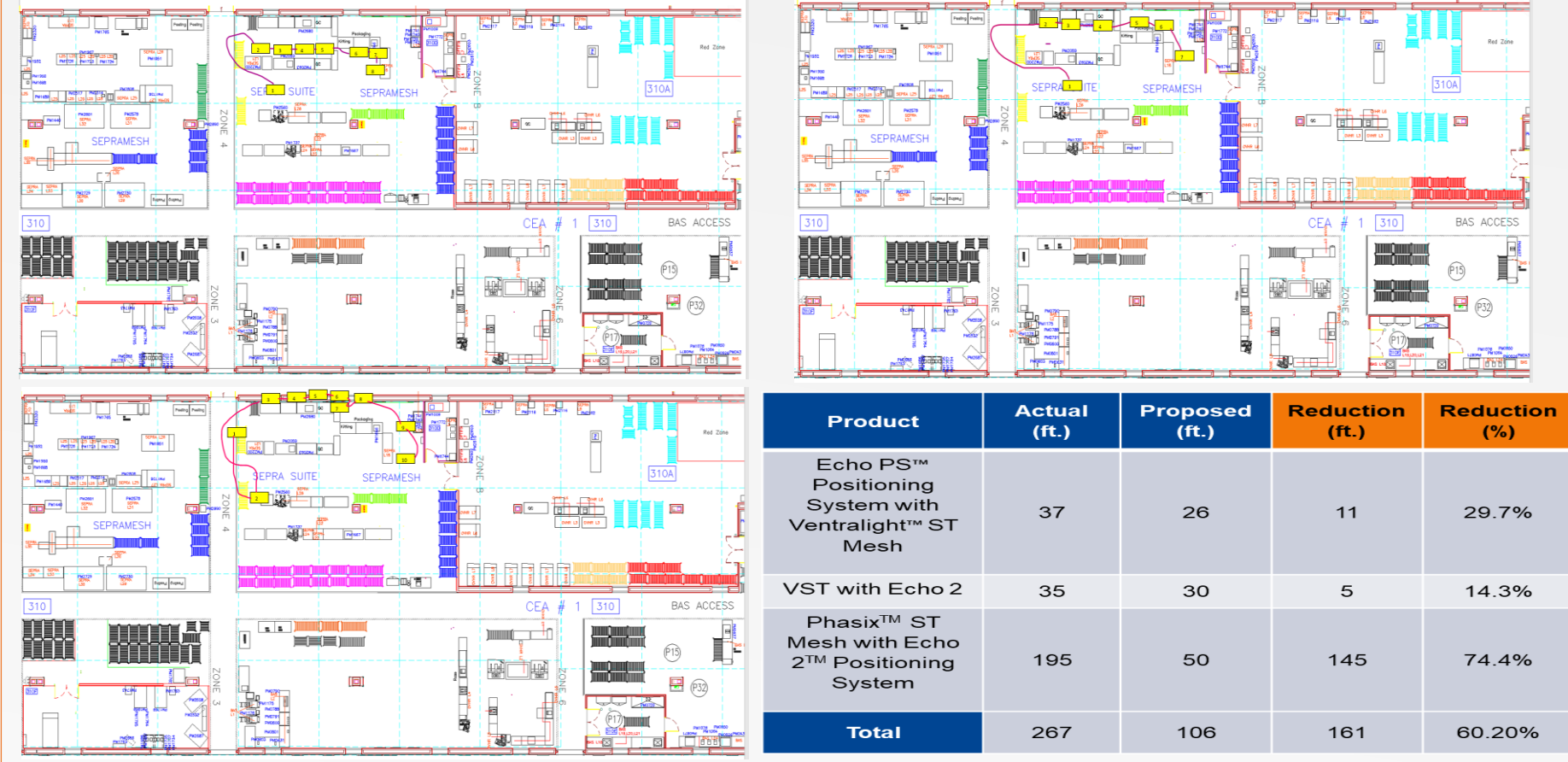


The run charts above were generated for each of the three (3) products using the thirty (30) cycle times collected per products. The run charts allows the different p-values to be observed and analyzed. All the run charts showed p-values greater than 0.05, which means that the variation present are due to common causes. The only exception was for the VST Echo run chart that presented a p-value for clustering of 0.000 and had more than six (6) consecutive points above and below the median, this chart shows variation due to special cause. The data used for the run charts showed behavior that the cycle times are under statistical control.

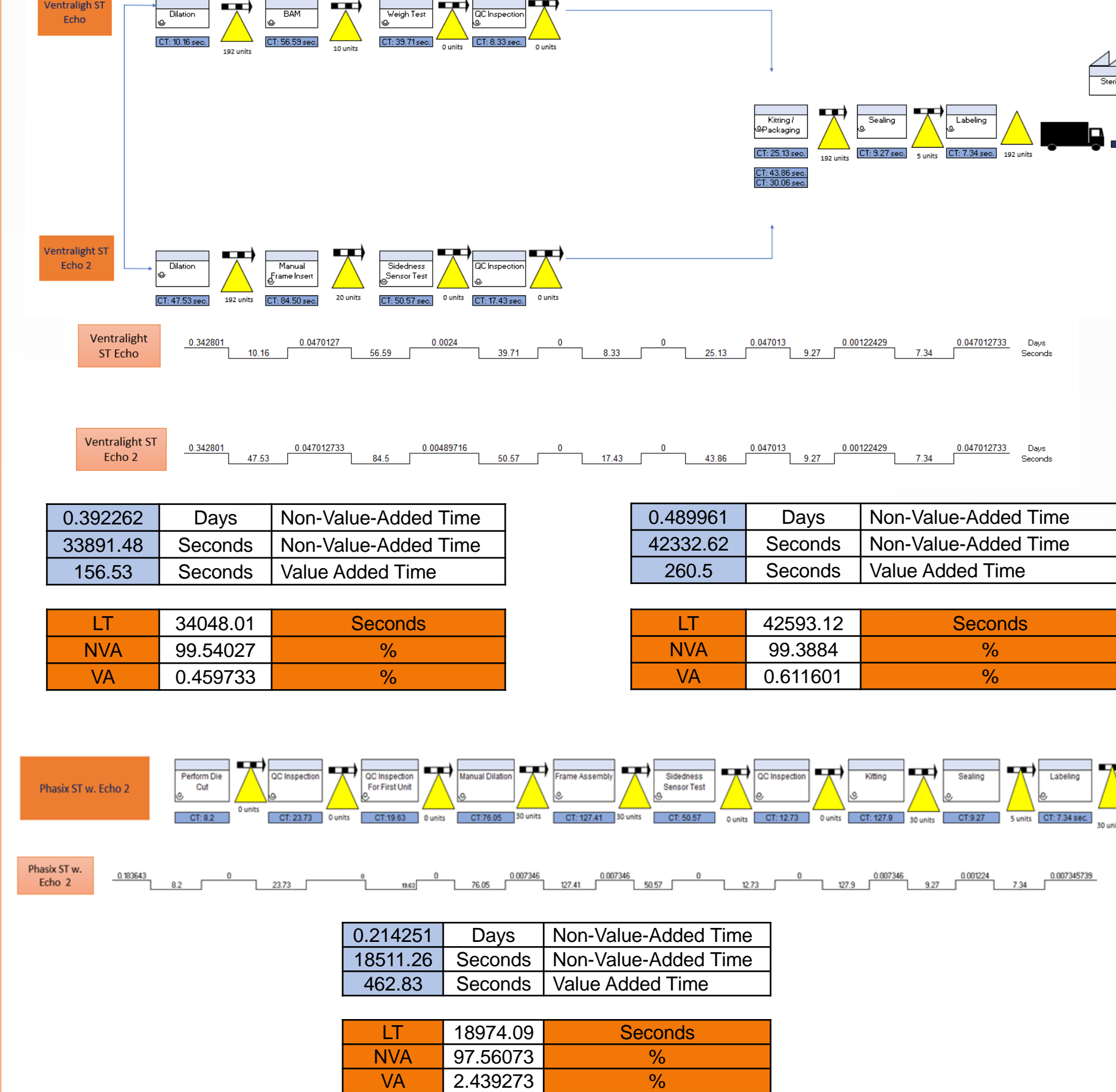


The I-MR charts were used to monitor the mean and variation present in the individual data collected for the products. For VST Echo the variation of the process is under control, and when looking at the individual graph we see that all the data are within the control limits, but it presents a special cause because there are 8 data below and 10 above the average. For VST with Echo 2, since the control limits on the Moving Range are out of statistical control, data presented on the Individual Value will not be reliable. As for Phasix ST with Echo 2, data in the Moving Range shows a random pattern, we conclude that the process variation is in control. The Individual graph is also in statistical control since no data is exceeding the limits.

## IMPROVE



These Spaghetti Diagrams shows the proposed re-layout. By implementing this re-layout, the reduced space calculated for Echo PS™ Positioning System with Ventrailight™ ST Mesh is 11 feet (29.7%), for VST with Echo 2 is 5 feet (14.3%) and for Phasix™ ST Mesh with Echo 2™ Positioning System is 145 feet (74.7%). This adds for a total reduction of 161 feet (60.20%). It was obtained a free space for machines and stations of 1,750 square feet. In BD, each square foot generates \$5,132 annually, therefore BD could be using this new free area to generate an additional \$8,981,000 annually.



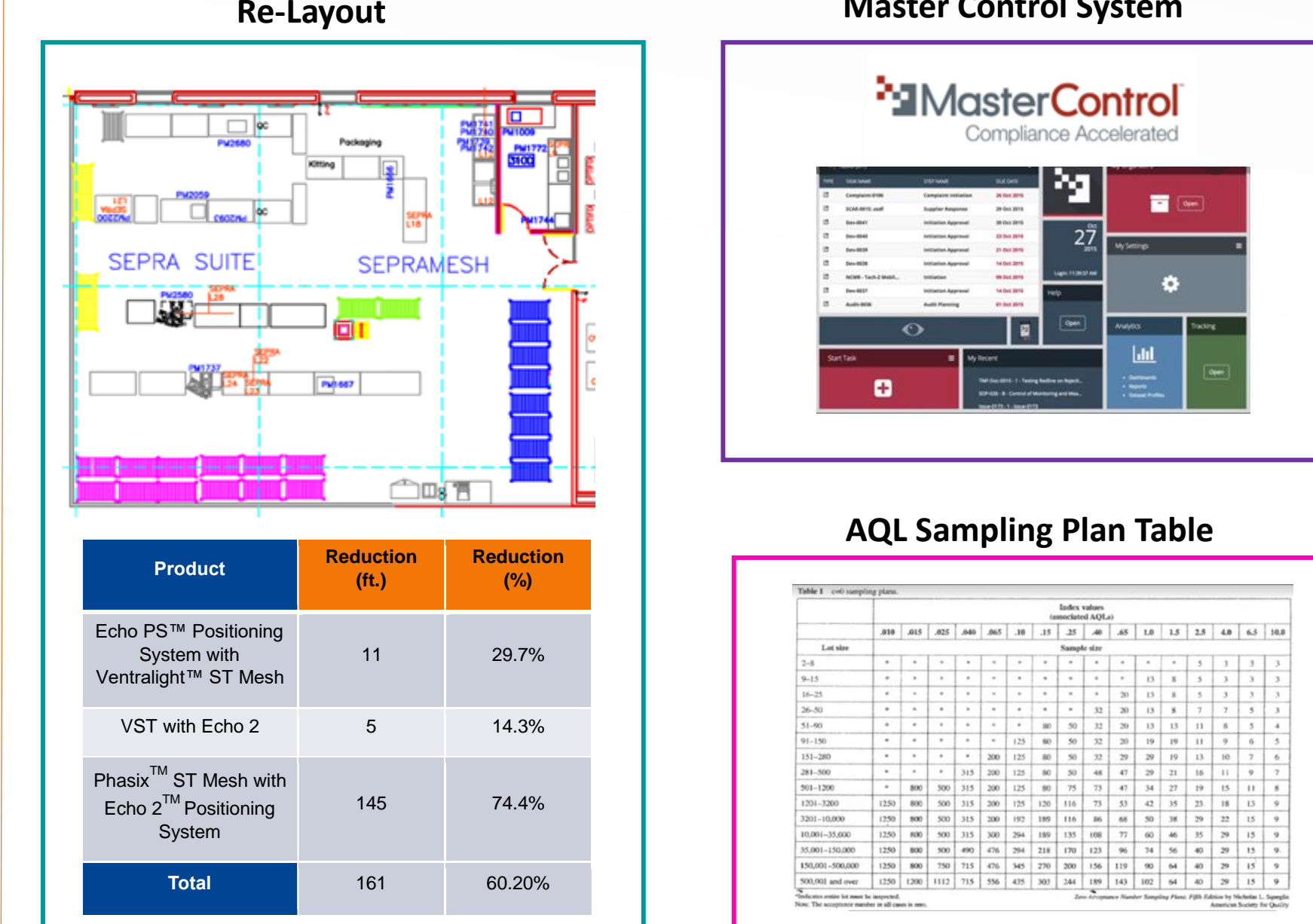
The above images show the proposed VSM for the products evaluated during the project execution. The manufacturing processes remain the same as the current state. However, the project team suggested for the units of the product to be inspected using a sampling plan with an AQL of 0.65 for a lot size of 151-280 which equals to a sample size of 29 units for the lot. The lot sizes of this product averages in 200 units, currently the lots are being inspected at a 100% (which means every single unit in the lot is inspected by a quality operator). The inventory present in the current VSM's are mainly due to the wait caused by lack of availability in quality operators to inspect the whole lot. By diminishing the inspection from 100% to a sample size of 29 to all three (3) products there will be an increase in the availability of Quality Operators to inspect the required units as the manufacturing processes are completed. The suggestion could result in an increase of \$4,076.87 of production for VST Echo, \$8,446.13 for VST with Echo 2 and \$34,748.04 for Phasix ST with Echo 2 per lot. Using as a reference that BD Humacao manufactured in 2021 45 lots of VST Echo, 52 lots of VST with Echo 2, and 4 lots of Phasix ST with Echo 2, the total amount BD could be gaining from implementing these changes per years is of \$677,188.86.

Product	Additional Time for Production	Reduction	Cost Per Unit	Profits Per Lot	Profits Per Year
VST Echo	1.59 hrs.	14.41%	\$141.46	+\$4,076.87	+\$183,459.15
VST with Echo 2	8.35 hrs.	41.37%	\$102.31	+\$8,446.13	+\$354,737.5
Phasix ST with Echo 2	5.27 hrs.	48.48%	\$358.37	+\$34,748.04	+\$138,992.2
<b>TOTAL</b>					<b>\$677,188.86</b>

## CONTROL

Having completed and analyzed all the prior phases (Define, Measure, Analyze and Improved) the project members created a control plan to ensure the proper implementation of the suggestions made in the Improve phase. This final phase also aids in maintaining the implementations over time. The group generated a plan to implement the proposed Value Stream Map processes and the proposed Spaghetti Diagrams layout. Refer to the table below to view the control plan suggested for the company to be able to implement and maintain the suggestion found in the Improve phase of the project.

Recommendations	Maintenance
<b>Area Re-Layout</b>	BD Humacao will hire contractors that will perform the necessary activities to correctly execute the re-layout plan. BD Humacao should also form a team of engineers to oversee the movements and ensure that BD protocols are followed.
<b>Implement Sampling plan for Quality Inspections</b>	The team suggest implementing a sampling plan for the lots of the products. The lots are currently being inspected at a 100%. By using an AQL Table with an AQL of 65% (0.65) for a lot size of 151 to 280 units, the sample size is 29 units each lot. This provides additional time available for the quality operators to inspect other lots, instead of having them wait for each lot to be inspected at a 100%.
<b>Training</b>	Training shall be made available to all employees affected by these changes. Project team members will properly train manufacturing operators, line leads and area supervisor. Digital training will be created for Quality and Manufacturing engineers that may take the training online using BD Humacao's system MasterControl as an option.
<b>Monthly Audits</b>	The project team members recommend that BD Humacao perform monthly audits for the first three (3) months of the improvements to verify that the suggestions are being maintained.
<b>Organize Quality Operators Priorities</b>	The team suggest assigning each quality operator to inspect specific products. This way each product has a designated quality operator to inspect the unit samples and reduce the amount of inventory left waiting to be inspected.



Product	Reduction (ft)	Reduction (%)
Echo PS™ Positioning System with Ventrailight™ ST Mesh	11	29.7%
VST with Echo 2	5	14.3%
Phasix™ ST Mesh with Echo 2™ Positioning System	145	74.4%
<b>Total</b>	<b>161</b>	<b>60.20%</b>

In conclusion for this DMAIC based project, Define and Measure served as the fundamental base to fully understand the problem at hand, comprehend the current process flow and begin to analyze the behavior of the processes being evaluated. The data collected was then analyzed in Chapter four and showed that the manufacturing processes executed that resulted in the cycle times obtained where under statistical control meaning that the processes were reliable. The following Chapter Improve allowed the group to dig deeper into finding the root causes for the problem on hand and figure out ways to solve it. Lastly the Control Phase served as a closing chapter to provide a Control Plan that may be set in place to implement and maintain the suggestions provided by the team.

## RECOGNITION

The project team members will give a special recognition to the people who provided support and aided in the progression of the completion of this project. A special thanks to Oscar J. Rivera for always being at the best disposition and for providing the team members mentorship and guidance through the course of this six (6) months long project. Oscar saw through each step of the phases of the project and supported the team. The team would also like to mention Orlando Rivera and Stephanie Rodriguez for providing the group with sponsorship and clarifying doubts that surged through out the course of the project.