Increase Quantity Per Production Orders for OBI Intraocular Lenses

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Abstract

The right order quantity can often drive your costs down and the quality up. This is because larger orders tend to give you more influence and control at a factory level. Factories are rarely totally independent and often rely on other people and services in the supply chain that often influence the focus of a factory. Smaller quantities can almost never really give you the necessary attention to both reduce costs as well as improve quality. [1].

To pursue the increase in production order size and to have a structured change management, the DMAIC methodology was used. As know it, DMAIC is a data-driven quality strategy used to improve processes. The term DMAIC stands for the five main steps in the process: Define, Measure, Analyze, Improve and Control.

To make business more competitive it is important to ensure higher utilization of the resources because can reduce unit costs [2]

Introduction

Intraocular Lenses are medical devices that are implanted inside the eye to replace the eye's natural lens when it is removed during cataract surgery [3] [4]. A cataract is a clouding of the normally clear lens of the eye. Product OBI is one of two model part of the initial manufacturing process of Intraocular Lenses (IOLs). OBI product increase arises with the launch of new IOLs designs. The new IOLs designs represent an innovation for the customers (patients) necessities for cataract surgery treatment and eye conditions.

It is requested to increase model OBI production orders from 675 units to 3465 units. This represent a benefit for the process in terms of more outcome quantity, time of processes and many others. Planning forecast for next year of this model will require approximately the double of the current production.

Background

The intent of this project is to increase process efficiency and capacity for the generation of OBI Intraocular Lenses (IOLs). The increase in the formulation quantity only intends to expand the quantity for the OBI acrylic material. There is no impact to the formulation component, product ingredients and the percentage of the final materials composition. Material amount will increase but material composition will need to remain the same to comply with CQA established to release the OBI IOLs.

This project will be conducted to increase the capacity of produce OBI model. Changes include increase formulation volume used to in the process of OBI acrylic material. Current formulation mixing is 700 grams. This change is to scale up the formulation mixing amount to 3,500 grams

Problem

The main objective of this design project is to present a strategic and cost-effective production order increase for the OBI material for the IOLs Medical Device Industry. This increase in production orders quantity is a business need due to the launch of new product.

Methodology

The DMAIC methodology will be used to develop the formulation process increase for the OBI model.
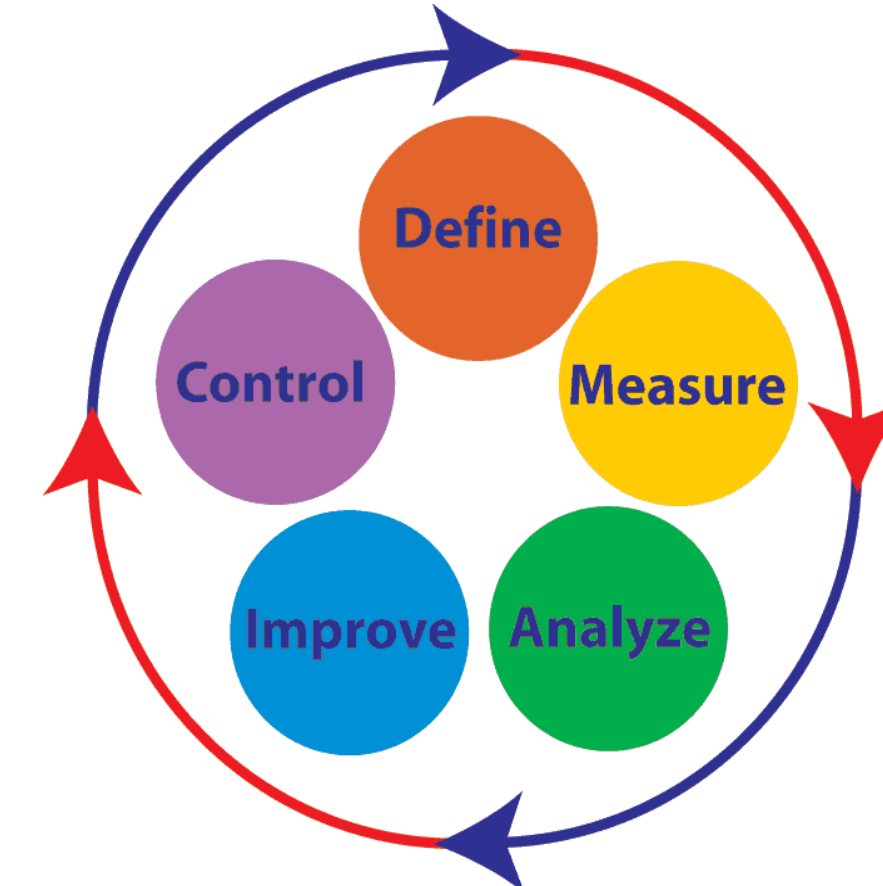
In the Define phase, the problem statement and objective are established. The Scope and Boundaries, Risks, Financial Impact, Critical to Quality (CTQ)/Final Project Objective (FPO) Metric of Success, Stakeholders, Milestone Timing, and Resources requirements are determined and stated. This phase will align the current and proposed process path.

A feasibility test has been run to challenge the process CQA and established base on statistic procedure the requirements to move into process operational and performance qualification. This feasibility test helps to run a capability analysis of current CQA of the process to demonstrate data normality.

Critical Process Parameter (CPP) established

Process Equipment	Process Parameter	Unit	Process Range	Nominal
Curing Bath	Temperature	°C	76 - 80	78
	Curing time	Hours	17.5 – 18.5	18
Curing Oven	Temperature	°C	87 - 93	90
	Curing time	Hours	21.5 – 22.5	22
Annealing Oven	Temperature	°C	54 - 66	60
	Vacuum pressure	Torr	0 - 5	N/A
	Annealing cycle	Days	10-11	11

Table 4
Critical Quality Attributes (CQA) to be measure

CQA#	Quality Feature
CQA1	Thickness
CQA2	Cosmetic Inspection
CQA3	Haze
CQA4	FTIR
CQA5	Monomer Residuals
CQA6	UV-Vis
CQA7	Refractive Index

In the Analyze phase, data gather from the operational qualification will provide a behavior of the change challenging the worst-cases. Data gather from the performance qualification will give the objective evidence that the process is reproducible and repeatable under nominal conditions.

In the last phase, Control, the improved process will be monitored and evaluated against the overall yield expectation that is 83.5%. In addition, the most notable changes in the process will be observed for zero nonconformities through the quality system.

Results and Discussion

Thickness Results

Individual Value Plot of Thickness (OQ)
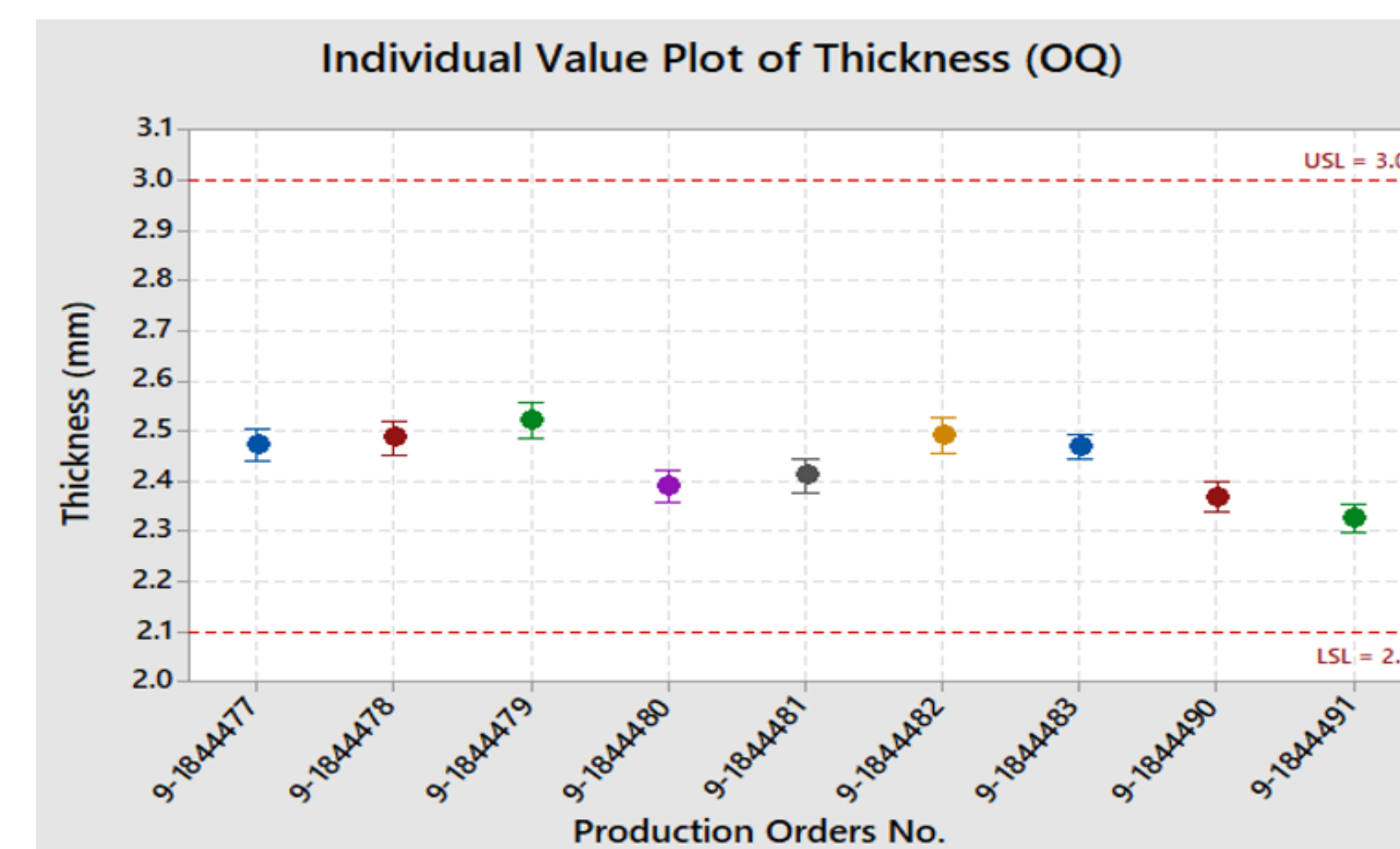
Cosmetic Inspection Results

Condition	Yield %
Low	93.7
Nominal	91.6
High	97.6

Haze Test Results

OQ Run	Production Order	Specification: No buttons with a haze level 5 or greater				
		Haze Level 1 Button Qty	Haze Level 2 Button Qty	Haze Level 3 Button Qty	Haze Level 4 Button Qty	Haze Level 5 Button Qty
1	9-1844477	0	35	58	20	0
2	9-1844478	0	17	45	51	0
3	9-1844479	0	28	53	32	0
4	9-1844480	0	19	57	37	0
5	9-1844481	0	27	65	21	0
6	9-1844482	0	17	53	43	0
7	9-1844483	0	38	65	10	0
8	9-1844490	0	47	51	15	0
9	9-1844491	0	27	59	27	0

Fourier Transform Infrared Spectroscopy (FTIR)

Individual Value Plot of FTIR Test Results
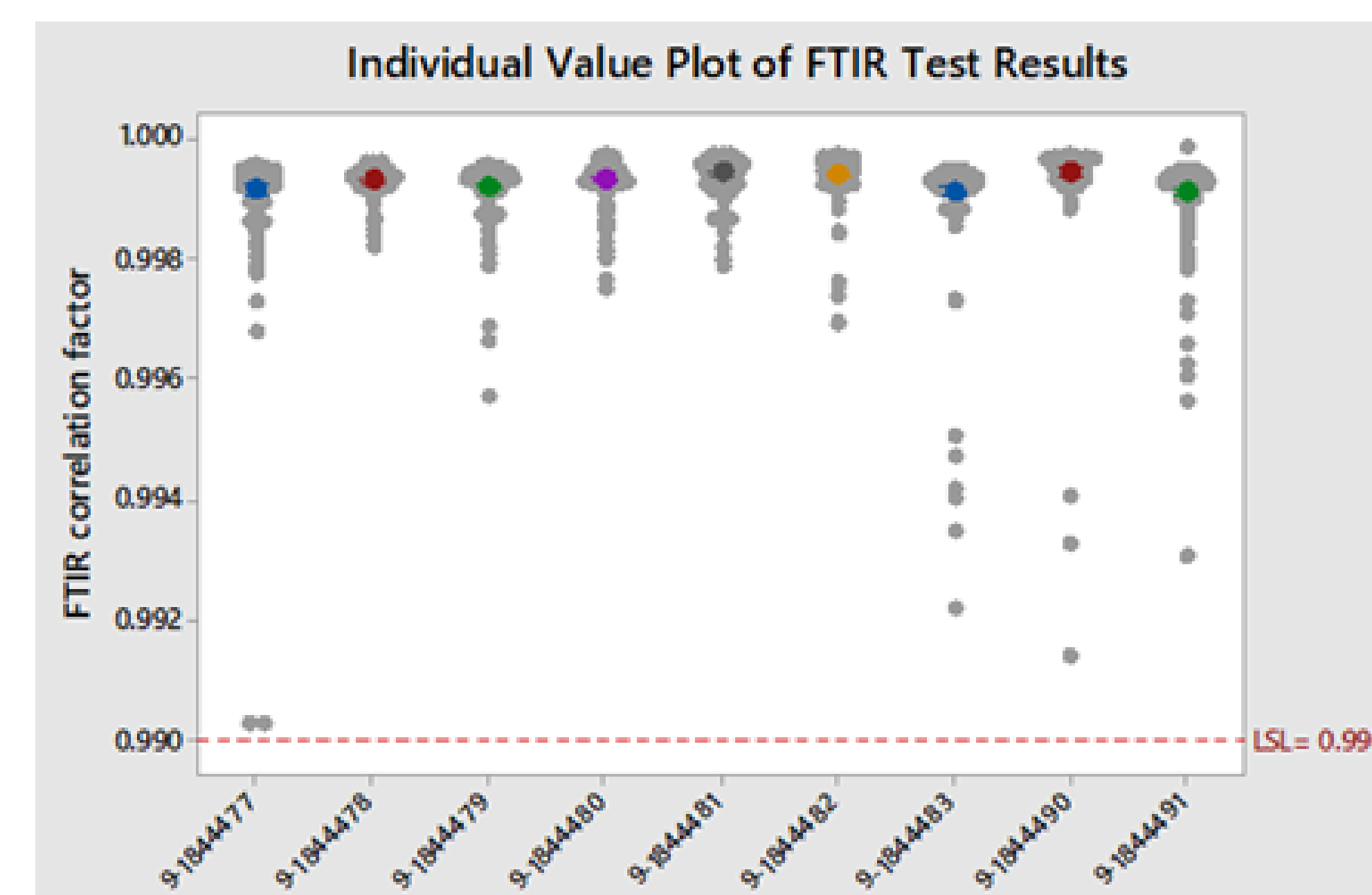
Refractive Index Results

OQ Run	PO	n	Specification (nD)	Acceptance Criteria	P_{pk}	OQ Result
1	9-1844477					Pass
2	9-1844478	48			1.74	Pass
3	9-1844479					Pass
4	9-1844480		1.473 - 1.475	N = 48 $P_{pk} \geq 0.882$		Pass
5	9-1844481	48			1.04	Pass
6	9-1844482					Pass
7	9-1844483					Pass
8	9-1844490	48			1.10	Pass
9	9-1844491					Pass

Results and Discussion

Monomer Residual Levels

Condition	Monomer	n	Mean (%)	Spec (%)	Acceptance Criteria	P_{pk}
Low	EA/EMA	48	0.0249	≤ 0.3		2.01
	EGDMA	48	0.0004	≤ 0.1		141.19
	TFEMA	48	0.0011	≤ 0.05		1.27
	UV	*1	*1	≤ 0.3		*1
	YD	48	0.0001	≤ 0.05		3.10
	UVAM	*1	*1	≤ 0.03		*1
Nominal	EA/EMA	48	0.0376	≤ 0.3		1.14
	EGDMA	48	0.0025	≤ 0.1		1.74
	TFEMA	48	0.0044	≤ 0.05		1.23
	UV	48	0.0029	≤ 0.3	$P_{pk} \geq 0.781$	1.58
	YD	48	*2	≤ 0.05		*2
	UVAM	48	0.0012	≤ 0.03		1.46
High	EA/EMA	48	0.0278	≤ 0.3		2.25
	EGDMA	48	0.0016	≤ 0.1		43.35
	TFEMA	48	0.0042	≤ 0.05		1.81
	UV	48	*3	≤ 0.3		*3
	YD	48	0.0004	≤ 0.05		123.12
	UVAM	48	*3	≤ 0.03		*3

Conclusions

This project indirectly reduces the lead time of the final product because the output of the initial step increase. Therefore, there will be no shortage of OBI buttons supply. Expectations for flawless implementation were accomplished because yield target is complying without any major or unknown process defects/issues.

Future Work

Continue optimizing the existing procedure with operations time reduction, and re-use of process aids.

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