Optimized Design for Electrochemical Test Product Preparation

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Abstract

This project aims to improve the processing time of the Electrochemical Performance Test Preparation Process using the DMAIC methodology integrated with Design for Reliability and Manufacturability tools. Time studies and Design tools established a baseline for processing time and complexity. Concept Engineering generated innovative process designs, while the Analytic Hierarchy Process objectively evaluated proposed concepts. The implemented improvements resulted in a 22.31% reduction in process time and a complexity penalty score decrease from 263 to 100. In the medical device industry, where product demand is high, such process improvements significantly reduce time to patient and increase production capacity—ultimately supporting market growth and competitiveness.

Introduction

Continuous Glucose Monitoring (CGM) sensors play a critical role in diabetes management by measuring glucose levels and transmitting data to external devices such as Automatic Insulin Delivery (AID) systems or mobile applications. As demand for CGM devices grows, ensuring their reliability and performance before reaching the patient becomes increasingly important. This research addresses inefficiencies in the Electrochemical Performance Testing (EPT) preparation process, which involves multiple manual steps that are time-consuming and labor-intensive. The goal is to improve processing time and reduce complexity, ultimately supporting faster product release and increased manufacturing capacity.

Background

Electrochemical testing is a standard method used to validate the functionality of CGM sensors under simulated real-use conditions. Studies have emphasized the importance of minimizing manual operations to improve efficiency, reduce errors, and maintain high standards for quality and safety. Continuous improvement is vital for manufacturers to remain competitive, meeting regulatory standards, such as FDA-enforced current Good Manufacturing Practices (cGMP) [1]. One of the most widely used methodologies for process optimization is DMAIC (Define, Measure, Analyze, Improve, Control), part of the Six Sigma framework. DMAIC offers a structured, data-driven approach to identify inefficiencies, analyze root causes, implement solutions, and sustain improvements. Though standardized, its application varies and requires understanding of process inputs, variables, and outputs. In manufacturing, DMAIC is proven to reduce waste, downtime, and variability while improving efficiency and quality. This study applies DMAIC principles to enhance the Electrochemical Performance Testing (EPT) preparation process for CGM sensors in a medical device environment.

Problem

The EPT preparation process for a new product takes about 30 minutes longer than the legacy version, increasing time by ~10%. This highly manual process reduces efficiency and increases the risk of product damage. As a manufacturing site, it is expected to improve performance and lower costs in new products. This project applies DMAIC and Design for Reliability and Manufacturability (DRM) tools to reduce processing time.

Methodology

This research applies the DMAIC methodology, a systematic improvement cycle from Six Sigma widely used for optimizing and stabilizing manufacturing processes. DMAIC is highly structured and data-driven, focusing on reducing waste, minimizing downtime, and increasing efficiency and productivity. The methodology consists of five sequential phases: Define, Measure, Analyze, Improve, and Control [2]. Each phase uses specific tools and approaches to guide the project and ensure measurable improvements.

- Define: The project begins with identifying the problem clearly and unambiguously. A well-constructed problem statement guides the effort, alongside defined project goals aligned with the problem. Identifying the customer, whether internal or external, and understanding their requirements is critical. The key outcome of this phase is a Project Charter that outlines the problem, objectives, and success criteria.
- Measure: This phase focuses on gathering accurate data about the current process to establish baseline performance. A data collection strategy is developed to capture relevant metrics, which are crucial for understanding the process's existing condition. The main deliverable here is quantified process data that reflects current performance levels.
- Analyze: Using the collected data, this phase investigates the root causes of the problem. It identifies factors or conditions that affect the process and contribute to inefficiencies or defects. Root cause analysis tools help isolate underlying issues that must be addressed. The key output is a detailed understanding of the problem's causes.
- Improve: Based on the root causes identified, this phase develops, tests, and implements solutions to eliminate or reduce the problems. Solutions are evaluated for cost-effectiveness and expected impact on process performance. The goal is to optimize the process by removing bottlenecks, reducing waste, and enhancing efficiency.
- Control: The final phase ensures that the improvements are sustained over time. It involves monitoring process performance, establishing control plans, and standardizing procedures to maintain gains and prevent regression. Continuous oversight confirms that the process remains stable and meets defined quality standards.

Figure 1
DMAIC Methodology

In this study, DMAIC was combined with Design for Reliability and Manufacturability (DRM) tools to target inefficiencies in the Electrochemical Performance Testing (EPT) preparation process for Continuous Glucose Monitoring (CGM) sensors. The approach allowed for a structured analysis of manual preparation steps, identification of process bottlenecks, and implementation of optimized workflows aimed at reducing processing time and complexity while maintaining quality and safety standards.

Results and Discussion

Define Phase

Project Charter
Problem Statement – EPT preparation process of the new introduced product is half an hour longer than the legacy product (~10% additional time).
Project Goals – The goal of the project is to decrease the EPT product preparation time for the new introduced product by at least 15% (approximately 7.5% lower than the legacy product).
Customers – As the project is intended to optimize a destructive process (the product is used for destructive test as a process monitor) and not for human use, the customers are identified as Operations Division of the Manufacturing Site. As a regulated company, Quality and Engineering teams must be also included as project stakeholders.
Impacted Metrics – Process Time.

Figure 2
Project Charter

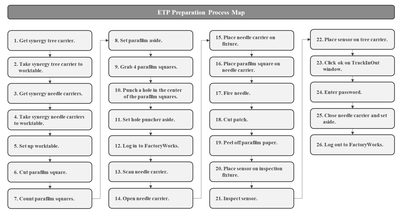

Figure 3
EPT Preparation Process Map

Measure Phase

No.	Element	AVG per Observation (sec)	AVG per Observation (min)	AVG per Lot (min)
1	Get synergy tree carrier	15.00	0.25	4.00
2	Take synergy tree carrier to work table	10.00	0.17	2.67
3	Get synergy needle carriers	8.00	0.13	0.00
4	Take synergy needle carriers to work table	5.00	0.08	0.00
5	Set up work table	21.00	0.35	0.35
6	Cut parafilm square	6.00	0.10	0.00
7	Count parafilm squares	6.00	0.10	0.00
8	Set parafilm aside	6.00	0.10	0.00
9	Grab 4 parafilm squares	5.00	0.08	0.00
10	Punch a hole in the center of the parafilm square	13.50	0.23	0.00
11	Set hole puncher aside	2.00	0.03	0.00
12	Log in to FactoryWorks	10.50	0.18	0.18
13	Scan needle carrier	5.22	0.09	27.40
14	Open needle carrier	3.77	0.06	19.77
15	Place needle carrier on fixture	1.25	0.02	6.58
16	Place parafilm square on needle carrier	5.75	0.10	30.17
17	Fire needle	4.20	0.07	22.05
18	Cut patch	15.25	0.25	80.06
19	Peel off parafilm paper	5.50	0.09	28.88
20	Place sensor on inspection fixture	2.73	0.05	14.36
21	Inspect sensor	4.42	0.07	23.21
22	Place sensor on tree carrier	5.61	0.09	29.45
23	Click ok on TrackInOut window	2.11	0.04	11.09
24	Enter password	4.94	0.08	25.92
25	Close needle carrier and set aside	4.86	0.08	25.49
26	Log out of FactoryWorks	8.00	0.13	0.13
			Total Time (min)	*353.25*
			Total Time (hr)	*5.86*

Figure 4
Baseline Process Time Study

Voices	Quality Team	Operations Team	Operations Team	Average
Sensor Flex is damaged (ej. nicked or cut) inadvertently during the sensor preparation (use of scissors)	10	10	10	10.00
Operators gets pinch or cut during the sensor preparation (incorrect use of tool or instrument)	10	10	10	10.00
Sensor Flex is damaged (ej. nicked or cut) inadvertently during the sensor preparation (use of tweezers)	10	10	6	8.67
Cut compatible with current design of BTS Rack Carrier	6	10	10	8.67
Lower shelf barcode must be readable	2	10	10	7.33
Unit is ejected without the fixture lid	6	6	6	6.00
Reduce actual processing time	2	10	6	6.00
Sensor Flex is damaged (ej. nicked or cut) inadvertently during the sensor preparation (use of hand)	6	6	2	4.67
Fixture is incorrectly used by operator (unit is incorrectly placed into the fixture)	6	6	2	4.67
Semi Automated process	2	6	6	4.67
Sensor ejection downwards	10	0	2	4.00
Parafilm is misaligned in the tool. Operator ejects the sensor into the parafilm.	2	2	6	3.33
Units falls/dropped during sensor ejection. Fixture in not fixed to the table	6	2	2	3.33
Ability to expand to process multiple units at the same time	2	2	6	3.33
Manual process	2	2	6	3.33
No programmable logic	2	6	2	3.33
Fixture is incorrectly used by operator (fixture is incorrectly assembled)	6	2	0	2.67
Operators forget to punch hole into the parafilm prior to placing it into the tool. Operator ejects the sensor into the parafilm.	2	0	6	2.67
Operators forget to place the parafilm in the ejection tool. Device adhere to the fixture	2	0	0	0.67
Unit is incorrectly placed into the Synergy Rack	2	0	0	0.67
Unit falls from the rack (unit dropped) during transport. Unit is not correctly placed into the Rack	2	0	0	0.67
Operator places more than 6 units into a Rack	2	0	0	0.67
Improve punching process on Parafilm	0	0	2	0.67
Operator prepares a unit that does not belong to the Sterilization Monitor	0	0	0	0.00
Total Points per Team	100	100	100	100

Figure 5
Prioritized Voice of Customer

Analyze Phase

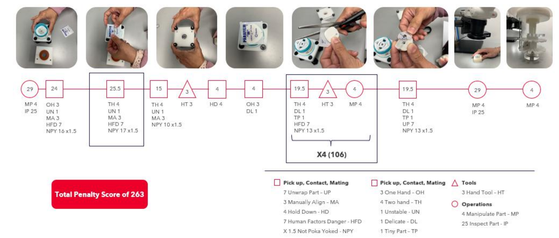

Figure 6
DfMA Tool Applied to Current Process

Improve Phase

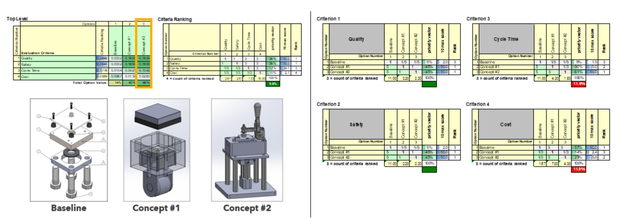

Figure 7
Concept Engineering and Analytic Hierarchy Process (AHP)

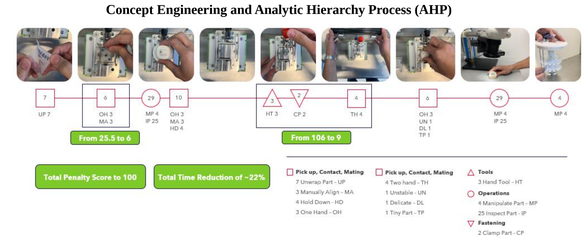

Figure 8
DfMA Tool Applied to Improved Process

Control Phase

The Control phase ensured sustainability by updating the Process Operation Description and setting up a dedicated workstation for the new fixture. A hyper care period supported operator training and stabilized the process during initial adoption.

Conclusions

This research successfully applied the DMAIC methodology combined with Design for Reliability and Manufacturability (DRM) tools to improve the Electrochemical Performance Test (EPT) preparation process. A process time reduction of 22.32% was achieved, exceeding the initial goal of 15%, while addressing key inefficiencies and reducing complexity. Customer requirements were integrated into the solution, ensuring both functional improvements and alignment with user needs.

Standardization efforts, including updates to the Process Operation Description and monitoring during the hyper care period, helped sustain the improvements. In a high-demand medical device environment, such enhancements contribute to reduced lead time, increased manufacturing capacity, and improved operational efficiency. This work demonstrates how structured problem-solving can drive meaningful impact, supporting the broader mission to deliver high-quality products that improve patient outcomes and promote company growth.

Future Work

The ETP preparation process improvement was successfully implemented. The next steps for the design project consist to evaluate the potential expansion of this solution to other manual processes across the manufacturing site. In the same way, the current implementation will be continuously monitored for minor improvement opportunities leveling the project to its maximum benefit.

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