Improve Vision System Seal Presence Inspection

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Abstract

Sterile packaging of implantable medical devices is essential for patient safety, preventing infections, and ensuring the integrity of the device until implantation. Regulatory standards demand strict protocols to maintain sterility during storage and transportation. Vision systems play a vital role in inspecting the packaging, using advanced imaging to detect defects that could compromise the sterile barrier. These systems provide real-time feedback, minimizing human error and improving accuracy. In manufacturing, inefficiencies in manual inspections are leading to compromised product quality, increasing costs, and regulatory risks, highlighting the need for automated solutions to ensure consistent packaging and sterility.

Key Terms — DMADV methodology

Problem Statement

This chapter discusses the challenges in the seal presence inspection process within the Boxing Area of a Medical Device Manufacturing plant, where packaging is critical to maintaining product sterility. The inspection relies on Cognex cameras and barcode readers integrated into a custom software system to detect seal presence. However, inefficiencies arise due to the system's inconsistent ability to identify seals, requiring multiple inspections of valid units and slowing the packaging process. A key issue is the difficulty in detecting the edges of pouches, particularly with Tyvek Film, due to poor lighting calibration. These inefficiencies not only delay production but also increase the risk of releasing improperly sealed pouches, leading to potential quality risks, recalls, and regulatory issues.

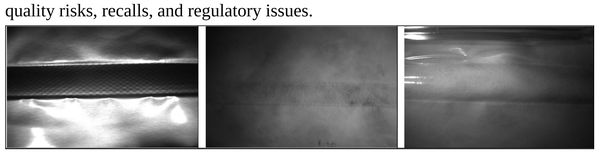

Figure 1: Different Seal Types Inspected

Methodology

To execute the design and implementation of the *Seal Inspection Improvements* for the boxing area, the DMADV methodology was used. This methodology is part of Six Sigma's tools to execute a project successfully. The abbreviation of DMADV stands for the five phases that compose the methodology: define, measure, analyze, design, and verify. In Table 1, there is a brief definition of the five phases of the DMADV methodology.

Table 1: DMAVD Methodology

DEFINE	Define the process and establish goal
MEASURE	Measure to determine process needs
ANALYZE	Analyze the data to find the best design
DESIGN	Design and test the process
VERIFY	Ensure that design meets the design input requirements to achieve the goal

Results and Discussion

DEFINE PHASE

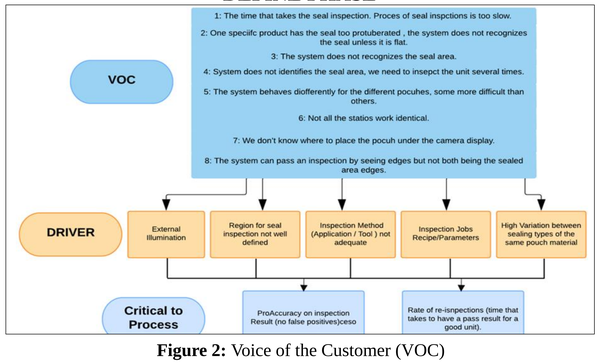

Figure 2: Voice of the Customer (VOC)

Results and Discussion (Continue)

Figure 2: The VOC captures and translates customer needs from the Boxing Area into measurable requirements for seal inspection improvements. Key issues identified include too many re-inspections, inconsistencies between different seal types, and inconsistencies within Boxing Area stations.

MEASURE PHASE

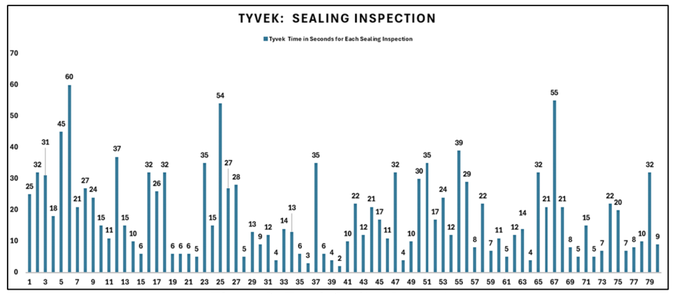

Figure 3: Tyvek Sealing Inspection

Figure 3: 80 units were evaluated with an average inspection time of 18.25 seconds. The high standard deviation of 13.04 seconds indicates significant variability and inconsistencies in the process, possibly due to factors like equipment handling, staff training, or product condition.

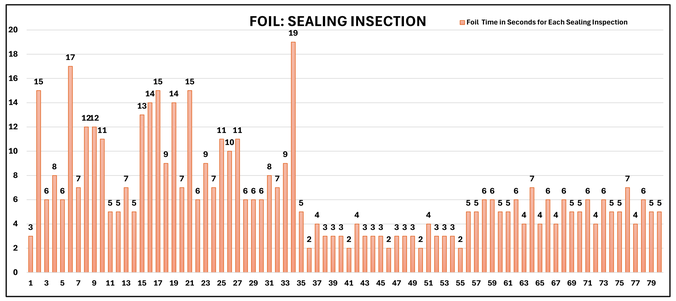

Figure 4: Foil Sealing Inspection

Figure 4: 80 units were evaluated, with Grey Foil-Foil (data points 1-34) averaging 9.44 seconds and White Foil-Foil (data points 35-80) averaging 4 seconds for inspection. The standard deviations were 3.97 and 1.42 seconds, respectively, indicating some variability. This data will inform further analysis to identify and reduce inconsistencies, aiming to optimize process efficiency and quality.

ANALYZE PHASE

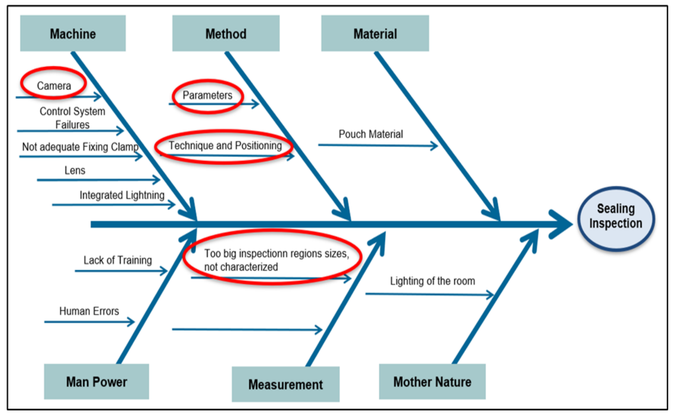

Figure 5: Fish Bone Diagram

Figure 5: The Fishbone tool identifies key causes of the sealing inspection problem across six categories. Focus areas include Machine (Camera), Method (Parameters, Technique, Position), and Measurement (Inspection region sizes). These will be analyzed to implement effective improvements.

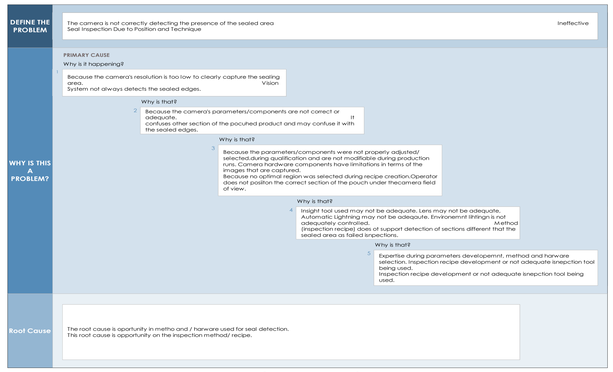

Figure 6: 5 Why's

Figure 6: The 5 Why's tool suggests that the Design Phase should evaluate different camera hardware, including lighting and lenses. Additionally, the inspection tool and parameters need assessment to better distinguish the sealed area from other sections of the product.

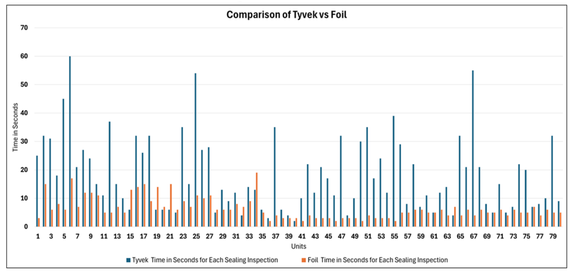

Figure 7: Comparison of Tyvek vs Foil

Figure 7: Based on the analysis of the figure # the project will focus on optimizing the sealing inspection of Tyvek pouches to reduce inspection time and improve accuracy, enhancing process efficiency and product quality.

DESIGN PHASE

Figure 8: Overview of ViDi Vision Tool and parameters preliminary selected

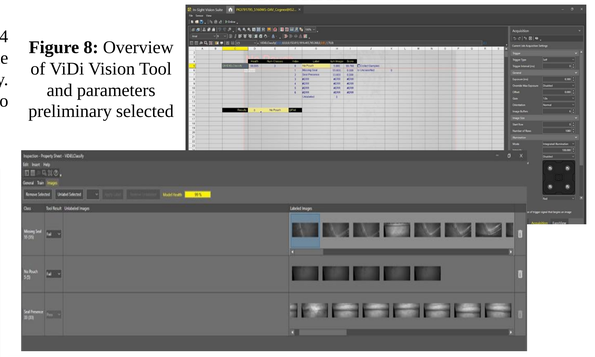

Figure 9: Camera IS2800 Model - New Cognex Camera which works with Insight Vision Suite application and not with the current software used at Boxing, Insight Explore

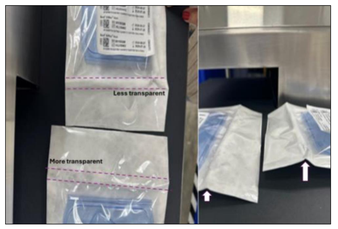

Figure 10: Levels of Transparency and Seal Shape

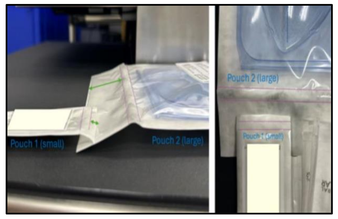

Figure 11: Pouch Sizes and Distance from Sealed Area to Pouch edge

Figure 12: Images Acquired for Inspection Categorization

Figure 13: Inspection Tool Optimization

VERIFY PHASE

Table 2: Proposed System Testing Results Summary for Tyvek film and Grey Foil-Foil

Type of Material	Categories created in the inspection recipe	Samples inspected per category	Pass at First Inspection (One trigger Ave. 3 sec / unit))
Tyvek Film	Seal Presence	50 samples	Pass
	Missing Seal	50 samples	Pass
	No Pouch	20 samples	Pass
Grey Foil - Foil	Seal Presence	50 samples	Pass
	No Seal	50 samples	Pass
	No Pouch	20 samples	Pass

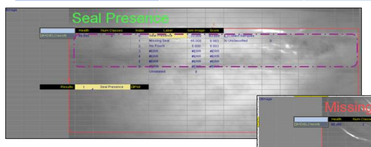

Figure 14: Tyvek Film Seal Presence Category Inspection Results

Figure 15: Tyvek Film Missing Seal Category Inspection Results

Figure 16: Tyvek Film No Pouch Category Inspection Results

Conclusions

In conclusion, during the verify Phase, it was demonstrated that vision system and inspection tool proposed complies with the intended use. The system can report the correct results (categories) at first inspection (one camera trigger).

The inspection of each unit is taking in average 3 seconds / unit and is just requiring one inspection to obtain the correct result.

	Current System	Proposed System
Inspection Time (Ave.)	Tyvek=18.25s Foil = 9.44s	Tyvek= 3s Foil= 3s
Inspection attempts	Tyvek = 4	Tyvek = 1

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