Improve Vision System Seal Presence Inspection

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Abstract *The sterile packaging of implantable medical devices is crucial for ensuring patient safety, preventing post-operative infections, and maintaining the integrity of the device until implantation. Given that these devices are placed within the body, contamination with harmful microorganisms can lead to serious complications, including implant failure and life-threatening infections. Sterile packaging acts as a barrier against pathogens, maintaining the sterility of the device during storage and transportation. Vision systems play a critical role in the sterile barrier inspection of implantable medical device packaging by ensuring the integrity and quality of the packaging, which is essential to maintaining sterility. In the manufacturing plant, inefficiencies in the packaging process, particularly in seal inspection, result in compromised product quality and potential contamination risks. Manual inspections and outdated quality control systems are prone to human error, leading to undetected seal defects, rework, and product recalls. In addition to the sterility issue, in the specific case being studied through this project, the sealing inspection inefficiencies create a productivity burden and operators' burnout due to the extensive inspections.*

Key Terms *— DMADV Method, Seal Inspection, Vision Systems.*

PROBLEM STATEMENT

This section describes the persistent challenges in the seal presence inspection process within the Boxing Area of a Medical Device Manufacturing plant. The primary issue is the system's inconsistent ability to correctly identify seal presence, forcing operators to repeatedly inspect the same unit multiple times to obtain a PASS result, even for units that have a valid seal. This repeated inspection process not only increases the workload for operators but also delays the packaging process, impacting overall throughput and productivity. The need for re-inspection arises from the vision system requirements for lot reconciliation, meaning every unit in a production lot must be accounted for in the system before proceeding. This inefficiency not only slows down the process but also introduces the potential for human error and data inconsistencies. A key factor contributing to these inefficiencies is the vision system's difficulty in accurately detecting the "edges" of the sealed area on the pouches. The plant uses five distinct types of pouch materials, each requiring its unique inspection recipe, and the Tyvek Film recipe has been identified as the most problematic. Pouches sealed with Tyvek Film often require more than three (3) attempts to pass inspection due to the system's inability to clearly detect the seal. This problem is exacerbated by excessive brightness and inadequate lighting, leading to errors in seal presence detection. This could result in costly product recalls, regulatory compliance issues, and potential harm to patients. Therefore, addressing these inefficiencies is critical to improving operational efficiency, ensuring product quality, and maintaining regulatory compliance.

PROCESS DESCRIPTION

The packaging process begins with the seal presence inspection, followed by lot number verification, and then; the inspection of additional packaging components to complete a single final packaged unit. There are 10 identical stations in the area, these replicates are designed to provide flexibility during the packaging process, given that the manufacturing plant operates with a low-volume, high-mix product line. The vision system currently in place at the Boxing Area integrates a Windows 10 computer, Insight Explorer Version 5.6.1 Software, Cognex vision cameras, barcode readers, circuit boards, and triggers.

Specifically for the seal inspection, cameras use Insight Explorer, a tool named SurfaceFX. This technology uses lighting and software algorithms to create high-contrast images that enhance 3-dimensional features on a part. There are five different types of pouch material, therefore, different inspection jobs (recipes) are used for the seal presence inspection. See Figure 1 for the pouch material and sealed area visual references.

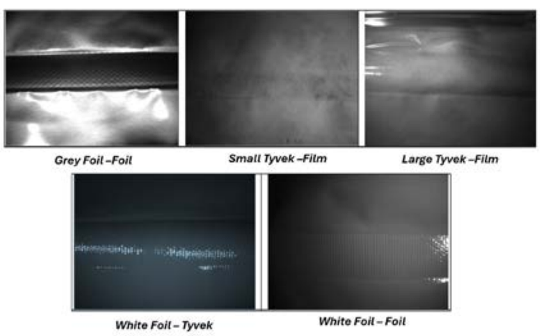

Figure 1
Different Pouch Materials and Sealed Areas

Each unit must be individually inspected by the operator, and the need for repeated inspections due to system errors leads to operational delays. Since the packaging process is intended to be continuous, these delays negatively impact productivity and disrupt the workflow. To address these issues, the ongoing investigation will explore potential improvements to the inspection recipes and lighting conditions as part of the problem-solving approach. During this research period, it is investigated how the DMADV methodology can support the design of a solution for the sealing inspection issues at the Boxing Area.

PROJECT OBJECTIVES

Among the project objectives there is to reduce re-inspection rates by 50% (reducing time of inspection for a single unit). Minimize the need for repeated inspections, thereby reducing delays and improving the efficiency of the packaging process. The current rate of re-inspection will be measured and confirmed during the Measure Phase of this project.

It is also pursued as part of the objectives of the project to improve the Quality Assurance / Seal inspection Accuracy. Meaning that the system must only report a pass result when identifying the seal edges.

PROJECT SCOPE

The project will seek a reduction of the re-inspection rates (time of inspection of a single unit/ inspection attempts to obtain and pass result) and improve seal presence inspection accuracy by conducting an investigation to identify the causes impacting the system's ability to accurately detect the seal edges, particularly for Tyvek Film material and other problematic pouch materials, if any. The project will also cover the design/proposal of updates or new hardware/ software (system) for the inspection. This could include lighting conditions, new recipes, and different hardware, among other.

Out of the scope of the project objectives will be to qualify the new solution. Testing will be made in a validation environment where is to be proved or tested the alternatives found during the project activities.

LITERATURE REVIEW

This chapter will introduce vision systems and their benefits in the regulated industry of medical devices. Specific hardware and software will also be detailed to support the understanding on system selection as part of the project development.

Vision Systems: Overview and Application in Sealing Presence Inspection for Medical Devices

The Vision System are automated technology designed to capture, process, and analyze visual data. Equipped with high-resolution cameras and sophisticated software, they mimic human vision but with greater precision, speed, and consistency. In manufacturing, vision systems are crucial in quality control, particularly in processes requiring high accuracy and repeatability, such as sealing presence inspection of sterile medical devices. In general, vision systems can offer:

1. Automated Inspection: They provide continuous, automated inspection of product seals, ensuring that each seal is present, intact, and compliant with quality standards.
2. Accuracy and Speed: Vision systems can detect even minute defects in seals, such as gaps, wrinkles, or incomplete adhesion, all while operating at high speeds suitable for fast-paced production lines.
3. Real-time Monitoring: These systems offer real-time feedback, immediately alerting operators to seal defects, which helps minimize production errors.
4. Documentation: Vision systems store image data, enabling traceability and providing a record for quality control audits and regulatory compliance.

Benefits of Vision Systems in Sealing Presence Inspection

1. Enhanced Quality Control: Vision systems ensure that every package's seal is inspected for integrity/presence, reducing the risk of contamination in sterile medical devices.
2. Regulatory Compliance: Medical device manufacturing companies must comply with stringent safety and sterility standards, such as ISO 11607. Vision systems help meet these standards by validating the presence and integrity of seals.
3. Cost Reduction: By identifying defects early in the production process, vision systems help avoid costly recalls and reworks, ensuring that only properly sealed devices are distributed to the market.
4. Consistency: Unlike manual inspections, vision systems maintain consistent quality over time, eliminating variations caused by human error [1].

In conclusion, vision systems are essential in medical device manufacturing for sealing presence inspection, ensuring product sterility and compliance while enhancing efficiency and reducing costs.

Cognex Cameras IS2802 and IS3801 and Insight Vision Suite in Medical Device Seal Inspection

The Cognex IS2802 and IS3801 cameras, along with the Insight Vision Suite, play a crucial role in ensuring seal integrity during the manufacturing of medical devices. See Figure 2 for Cognex camera IS2800. These advanced vision systems are specifically designed to detect sealing defects in packaging, which is vital for maintaining the sterility and safety of medical products. During research, the following camera models were identified as adequate and offering capabilities that conform to the requisites of a medical device seal inspection [2].

Cognex IS2802 and IS3801 Capabilities

- High-Resolution Imaging
- Real-Time Inspection
- Advanced Lighting Systems
- Color Image Processing

Figure 2
Cognex Camera Model IS2800

Insight Vision Suite Function

Insight Vision Suite is an advanced vision system configuration, monitoring, and control software used to program, manage, and optimize the performance of industrial cameras such as the IS2802 and IS3801. The software enables key parameters to be configured, image analysis to be performed and custom solutions to be developed for automated inspection such as packaging sealing inspection in medical devices [3].

In terms of programming available through the Insight Vision Suite, a key component of this suite is the ViDi EL Classify tool, which is specifically designed for deep learning-based classification tasks. It allows users to classify complex image patterns beyond simple pass/fail criteria. This flexibility is particularly beneficial for tasks like seal presence inspection where subtle variations can occur. Instead of rigid rule-based inspections, ViDi EL Classify can learn from examples and accurately distinguish between correct and defective seals, even in challenging conditions where traditional vision systems may struggle [4].

Both the IS2802 and IS3801 cameras offer advanced solutions for automated inspection of seals, with specific applications in the medical device industry and other areas requiring high accuracy in quality control.

METHODOLOGY

To execute the design and implementation of the Seal Inspection Improvements for the Boxing Area, the DMADV methodology was employed. This methodology is part of Six Sigma's tools and supports the successful execution of projects. 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
DMADV Methodology

Table 1: DMADV Methodology	
Define	Define the process and establish goals
Measure	Measure to determine process needs
Analyze	Analyze the data to find the best design
Design	Design and test the process
Verify	Ensure that the design output meets the design input requitements to achieve the goal

The DMADV methodology can be effectively applied to redesign the inspection process to meet stringent quality and regulatory requirements. The project begins with the Define phase, where the specific needs for accuracy and reliability in seal detection are identified. During the Measure phase, current inspection outputs are assessed to highlight inefficiencies and performance gaps. In the Analyze phase, root causes of seal detection failures such as inadequate lighting and faulty inspection recipes are to be investigated. The Design phase focuses on creating new inspection or design modifications to the current system to incorporate advanced technologies, optimal lighting conditions, and tailored inspection recipes to enhance accuracy and reduce the need for re-inspections. Finally, in the Verify phase will be limited to confirming that the improved vision system and application adequately identify the sealed area meeting the established project goal.

Define phase: In the Define phase of the DMADV methodology, the primary objective is to clearly establish the project goals and provide a comprehensive understanding of the process challenges. This phase involves identifying the specific problems related to seal presence inspection, such as accuracy issues or inefficiencies that lead to re-inspections. It also includes planning the project scope, which outlines the boundaries of the project and the aspects of the inspection process that will be targeted for improvement. All strategies and goals must align with the organization's overall expectations and regulatory requirements, ensuring that the final design not only enhances the inspection process but also meets industry standards for quality and safety in medical device packaging. This alignment is essential for gaining stakeholder support and securing necessary resources throughout the project.

Measure phase: In the Measure phase of the DMADV methodology, the inefficiency of the sealing inspection process will be evaluated through detailed time studies to gather precise quantitative data. This information will be crucial for the Analyze phase.

Analyze phase: In the Analyze phase of the DMADV methodology, an analysis will be conducted to identify the root cause of the inefficiencies observed in the sealing inspection. The findings will serve as the foundation for proposing improvements aimed at optimizing the efficiency of the process.

Design phase: The Design phase will serve for the selection of the hardware and software suitable for the seal presence inspection of the different pouch material. An inspection tool adequate for the detection of seal presence should be also selected to avoid repeated inspection and current inefficiencies.

Verify phase: The Verify phase will be intended to test and confirm that system (hardware, software and inspection tool) is adequate for the seal presence inspection. Testing should be representative of the production environment and sampling size / acceptance criteria determined by risk analysis.

RESULTS AND DISCUSSION

This chapter presents the analysis of results and discussion of the problem established on the Problem Statement and how the design and implementation of the Seal Inspection Improvements for the boxing area were achieved using the DMADV methodology for this project.

Define

In this section, it will define the goal of this research using DMADV methodology for the design of the Seal Inspection Improvements for the boxing area. Voice of the Customer (VOC) is the tool used for the Define phase of this project. It plays a critical role since the VOC ensures that customer needs and expectations, in this case the Boxing Area, are captured and translated into the proposal that is seeking this project as alternative for the seal inspection improvements. The VOC data is then used to translate subjective customer feedback into measurable requirements. Customer expectations are quantified (e.g., inspection time, defect rates (re-inspections)) to set design specifications and performance metrics. In summary, the VOC was focused on the seal inspection, and the inputs were basically grouped in too many re-inspections, inconsistencies between the different seal types that arrive to the boxing area, and inconsistencies within the stations at the Boxing Area. Refer to Figure 3 for the VOC results.

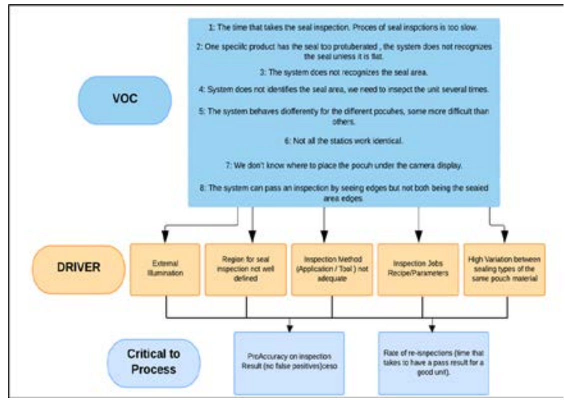

Figure 3
VOC Results

Measure

During the Measure phase of the DMADV methodology, the variability in the sealing inspection of the most problematic pouch material will be measured. In this second phase, the objective is to collect accurate data that will allow us to analyze the performance of the process. Figure 4 graphically presents the evaluated Tyvek units along with the time (in seconds) that took to perform the sealing inspection for each pouch. This visual analysis will support the identification of patterns and variations in inspection times, providing valuable information to understand the consistency of the process and detect opportunities for improvement. Based on this information, more in-depth analysis will be allowed during subsequent phases of the project.

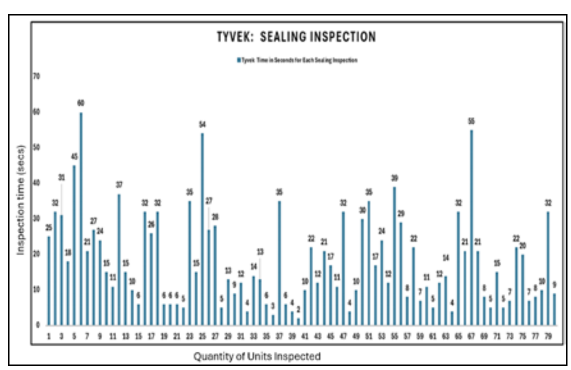

Figure 4
Tyvek – Film Inspections Behavior

As is shown in Figure 4, a total of 80 units were evaluated, and the average inspection time calculated was 18.25 seconds. However, there was notable variability in the times between different inspections, indicating inconsistencies in the process. The standard deviation was 13.04 seconds, reflecting a high dispersion in inspection times. This level of variability is not ideal, as a high standard deviation suggests that the process is inconsistent and potentially inefficient. This variability may be influenced by various factors such as equipment handling, staff training, or possible variations in the condition of the sealed products. In terms of the quantity of re-inspections, the average was 4 times of inspections for a single unit. The maximum re-inspections were 12 times and the minimum 1 time.

Grey and White Foil Materials were also evaluated to have a comparison between behavior observed against the Tyvek – Film pouch which was reported as the most problematic material. Refer to Figure 5 for Grey and White Foil inspections behaviors.

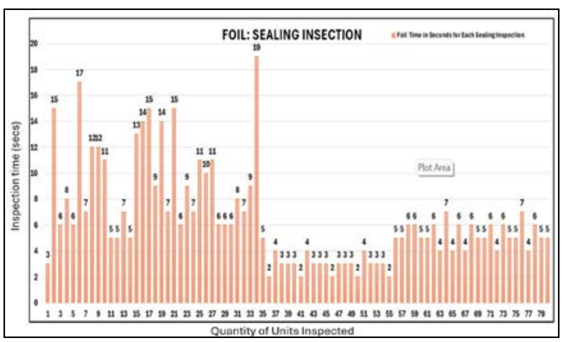

Figure 5
Grey and White Foil Inspections Behavior

Grey and White Foil Materials as is observed in Figure 5, a total of 80 units were evaluated. Two types of foil pouch material were evaluated: Grey Foil-Foil from data points 1 to 34 and White Foil-Foil from data points 35 to 80.

For the Grey Foil the average inspection time calculated was 9.44 seconds. On the other side, there is the White Foil with an average inspection time calculated of 4 seconds. As discussed during the Define section, and gathered from the VOC, the seal types behave differently during the seal inspection. There was also variability in the times between different inspections, indicating inconsistencies in the process. The standard deviation was 3.97 and 1.42 seconds, respectively. This does not reflect great dispersion in inspection times.

All data gathered, including Tyvek and Foil, will serve as the basis for a more detailed analysis in the following phases, aiming to identify the root causes of this variability and subsequently propose improvements to optimize process consistency. Throughout the project, will seek to minimize this variability to ensure that the sealing process meets established quality standards and remains efficient in terms of time and resources.

Analyze

In the Analyze phase of the DMADV methodology, a comprehensive examination of the factors influencing the objectives of our project was conducted, keeping in mind that the specific issue being evaluated is the performance of cameras in sealing presence inspections. During this phase, various analytical tools and methodologies to evaluate and system performance when comparing different pouch materials. The goal is to identify key insights and improvement opportunities related to the cameras, ensuring that the solutions align with established requirements and deliver optimal results in the inspection process.

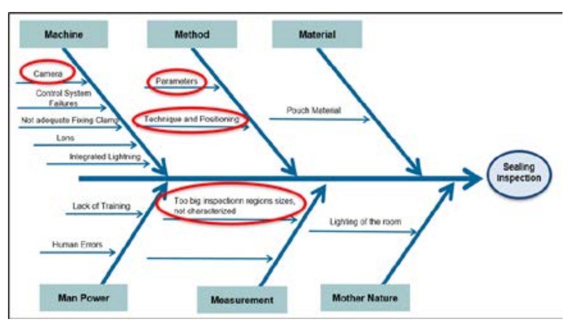

Figure 6
Fishbone Tool

The Fishbone tool (see Figure 6) analyzes the causes affecting the sealing inspection problem. Examination of the six categories identified key contributions to the issue, which are crucial for its resolution. These causes include, in the Machine category, Camera in the Method category, Parameters and Technique and Position. Measurement was also a contributing factor emphasizing that there are too big inspection region sizes, which were not characterized. These four key areas will be the focus for analysis to implement effective improvements and ultimately resolve the sealing inspection problem.

Design

In the Design phase of the DMADV methodology, the hardware / software and inspection tool proposed for the seal presence inspection at Boxing will be explained. Each pouch material will need specific parameters for the optimum recognition if the sealed area. For purposes of this project, the Design will be focused on the Tyvek Film pouch material which is the most inefficient as identified in previous phases.

Hardware

In term of the hardware, the evaluation pointed to a new Cognex Camera which works with Insight Vision Suite application and not with the current software used at Boxing, Insight Explore. See Figure 8 for the Cognex Camera IS2800 Model.

Figure 8
Camera Model IS288

This was selected taking into consideration the difficulties to observe and find conventional tools to inspect the Tyvek-Film seal presence having the variable that the manufacturing plant has. for example:

1. No control of external lightning,
2. No control of the seal type. Figure 9 exhibits different seal types having different levels of transparency and more/less convex shapes in the sealed area. This contributes to the difficulties in detecting the seal presence.
3. The length between the sealed area and the edge of the pouch and the gap (distance) between the sealed area and the unit inside the pouch is extremely variable. See Figure 10. There is no visual/physical guideline to place specifically the sealed are below the specific region within the camera field if view, where the sealed area should be evaluated.

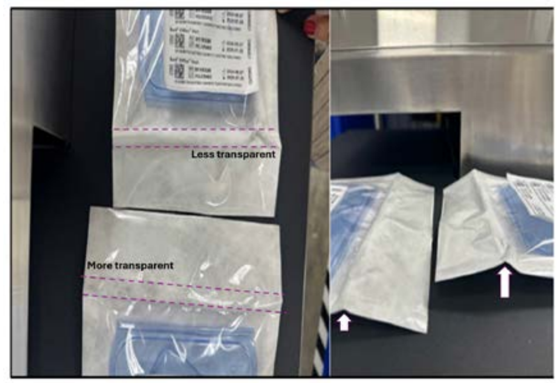

Figure 9
Levels of Transparency and Seal Shape

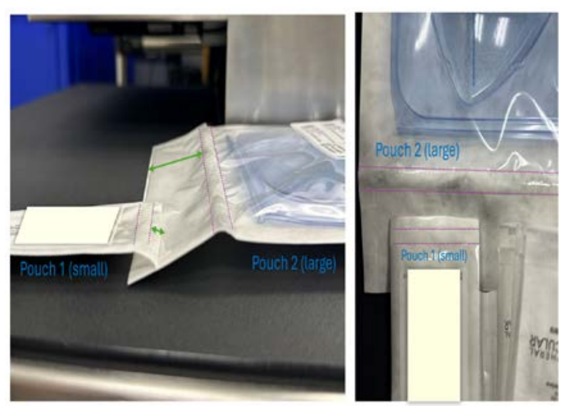

Figure 10
Pouch Sizes and Distance from Sealed Area to Pouch edge

Software and Inspection Tool

Insight Vision Suite brings new inspection tools, such as ViDi Classify which works with Artificial Intelligence to work. ViDi EL Classify identifies and sorts of parts based on multiple features or characteristics, enabling users to classify defects into different categories and correctly identify parts with variation. This application supports an easy and user-friendly workflow to setup your vision tool. The steps will consist of:

1. Acquire Images. See Figure 11.
2. Optimize Vision tools and Customize Application (Exposure, Light Color, Banks Enable, Mode, create categories for Pass/Fail results). Refer to Figure 12.

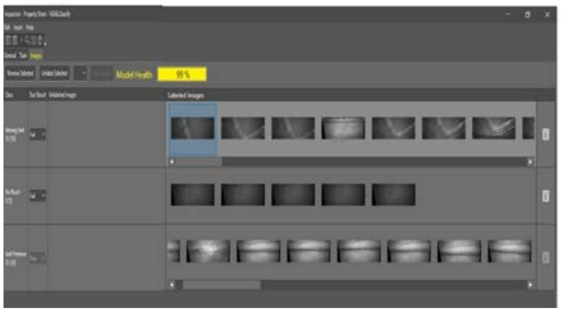

Figure 11
Images Acquired for Inspection Categorization

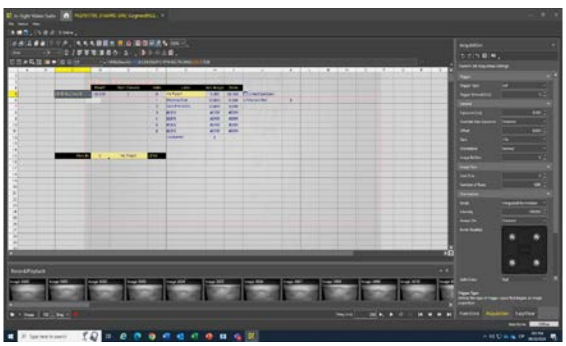

Figure 12
Inspection Tool Optimization

Verify

In the Verify phase of the DMADV methodology, the selected hardware / software and inspection tool for the seal presence of medical devices was tested to confirm adequacy for its intended use. Testing plan is developed taking into consideration the criticality of the inspection and considering that results are evaluated as attribute (Pass/Fail). Only two (2) types of pouch material were tested during the Verify phase. One of the materials is the Tyvek – Film, considered the most problematic; and the other one was the Grey Foil-Foil. The Grey Foil – Foil is the most used pouch material. The testing using Grey Foil pouch material allows the project to demonstrate that the vision system solution proposed is inclusive, versatile and a great alternative for the seal presence inspection at the manufacturing plant being impacted by this project.

Risk Analysis and Acceptance Criteria

Considering the potential failure mode of having a bad–sealed unit, meaning that there is a sterility breach, the severity rating is 9 but with a low frequency, the Risk Quadrant is 2 (Moderate Risk). This means that for a Confidence / Reliability level of 95%/ 97.5% 120 units were tested per pouch material (C=0). C=0 means that during the testing, the system is required to identify and categorize the units with only one trigger (first-pass acceptance, or rejection). Acceptance criteria for the testing execution were focused on confirming that the system is capable of identifying and categorizing the units inspected according to what was trained. The categorization needed to be correct at the first pass of inspection. After execution, the average time of inspection (first pass acceptance criteria) was in average is 3 secs/unit. See Table 2 below for testing design and results.

Table 2
Testing Design and Results

Type of Material	Categories	Qty. of Samples	Pass at First Inspection
Tyvek Film	Seal Presence	50	Pass
	Missing Seal	50	Pass
	No Pouch	20	Pass
Grey Foil - Foil	Seal Presence	50	Pass
	No Seal	50	Pass
	No Pouch	20	Pass

Seal Presence Testing

Seal Presence was identified as long as the seal area (both edges of the seal) were under the region of inspection (red rectangle), every time this requirement was met the inspection was reported as Pass under the category of “Seal Presence”. See Figure 13. This category also covered the inspection of small Tyvek-Film pouches (Figure 14). All figures in this section were taken from the system, the results (Seal Presence, Missing Seal and

No Pouch) messages at the top left corner of the spreadsheet are given by the system automatically.

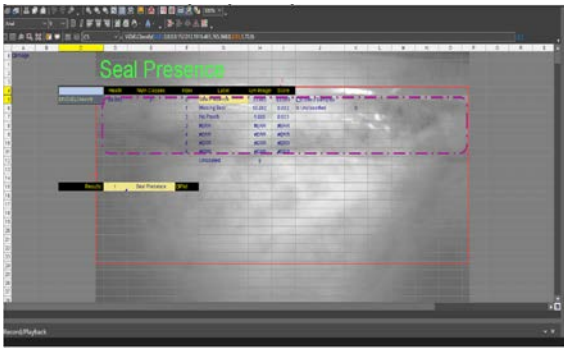

Figure 13
Seal Presence Recognition

System was trained to also accept smaller Tyvek pouches, which have the pouch end inside the inspection region. Pouch end pointed with an arrow in Figure 14.

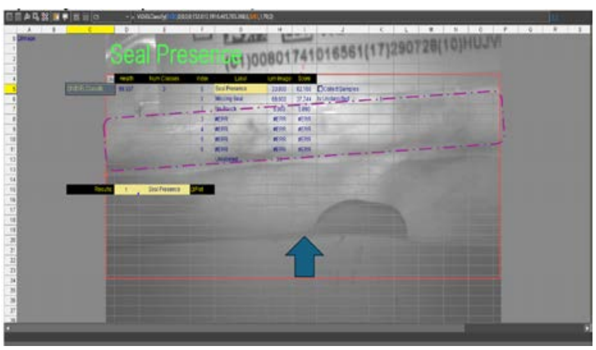

Figure 14
Small Pouches Seal Presence Detection

Missing Seal Testing

This category covered the units not adequately positioned under the inspection region (seal not having both edges under the region of inspection), the non-sealed units, and the badly positioned units when the product (Figure 15) or label is under the inspection region. This category also covered the inspection of different pouch materials confirming that no seal was identified (Figure 16). Figure 16 shows a unit tray (pointed with an arrow) captured inside the inspection region. The sealed area is partially out of the inspection region.

No Seal Testing

In this category, the system was challenged without placing pouched products under the camera. Confirming no seal is detected. Refer to Figure 17.

Figure 15
Product Under the Inspection Region & Sealed Area Partially Out

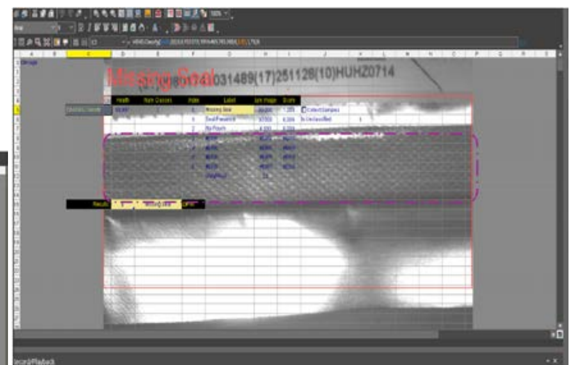

Figure 16
Grey Foil inspected with Tyvek Recipe (Seal Not Recognized)

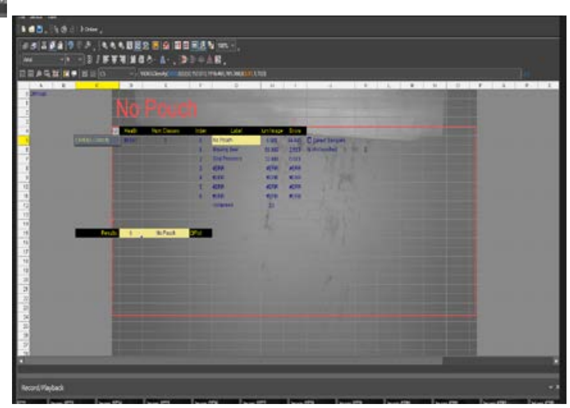

Figure 17
No Pouch Under Inspection Region

CONCLUSION

Testing execution was successful confirming that the system is adequate for the intended use. There was a reduction of greater than 50% of inspection time for both pouch materials, and attempts were reduced to the acceptance at first inspection. Refer to Table 3 for summary of results.

Table 3
Results Summary

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

Therefore, system proposed meets objectives. Manufacturing Plant should now prepare for system qualification / implementation.

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