Automatic Packaging Inspection System

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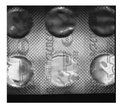
Abstract

Blister packaging is very common and very popular in the pharmaceutical and medical devices industry. This high increase in the use of this type of packaging provides a large variety of designs for cosmetic appearance and at the same time it has become more important to ensure the integrity of the packaging for the health and safety of the patients using the products. The key process or manufacturing step to ensure the product integrity is the quality inspection process that is one of the most important in medical devices and pharmaceutical industry. There are many ways to inspect the quality and integrity of these packages to provide and to ensure that high quality standards, government regulations and the market standards are met. Vision inspection systems are one of the more powerful and flexible adapted to improve the performance of inspections for high quality product. Vision systems are being used for other industries as well like in [1]an online defects inspection method for float glass fabrication, for example. This article is a synopsis of the whole investigation, analysis, design, debugging and implementation process of a vision system to inspect blister packaging with the highly probability to prevent packaging leaks.

Introduction

There are many blisters designs, different foil materials, blister materials, and sealing methodologies or parameters to meet the criteria defined for each blister and foil combinations to keep the product integrity by design, for this reason there are many ways in which a blister could be incorrectly sealed or damaged, causing a critical quality related issue. To inspect these sealed blisters there are visual methods and manual destructive methods that are based on sampling and not on 100% of the product. This type of inspection could allow some defects to reach the patients after product manufacturing and quality inspections performed. Being a sample inspection, performed by subjective interpretation criteria of a person based on standards add some challenges to really detect 100% of the defects. Even though there are specific procedures and criteria to perform this type of inspections, it still inconsistent depending on the personnel inspecting. For such challenge, a vision system would be an possible solution to inspect 100% the quality of the packages and help reduce leaks incidences.


Background

This design project was conducted in a Medical Devices Company located in Juana Diaz, Puerto Rico. One of the main concerns the Company is facing now-a-days is the cost of quality related to packaging, as this is considered a good device being rejected by its package. Also, the possible complains and patients' dangers associated to any possible defect caused by packaging integrity.

Problem

Currently the primary quality offender for first pass metrics was package "leaks". Can a vision system be consider to inspect for leaks in the package?

Methodology

The methodology followed in this project was the DMAIC Improvement cycle as per Figure 1, which stands for Define, Measure, Analyze and Improve

Figure 1. DMAIC

Define
During this phase the number of lots with nonconformance during final quality inspection was the source of the information. The first offender becomes our primary objective which was out of control at the moment.

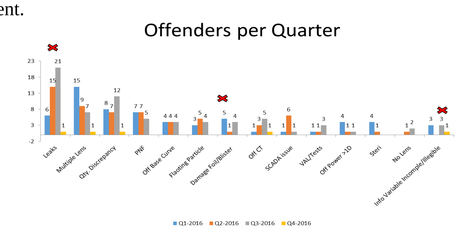


Figure 2. Packaging Defects Pareto

Measure
During this phase a Sub-Pareto was used in order to understand and classified leaks root causes.

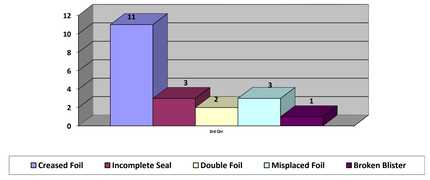


Figure 3. Leaks Defects Pareto

Analyze
During this phase 300 samples of rejected blisters with defects were analyzed and classified within their corresponding defect group to understand the visual aspect if any of these defects. During the analysis all these defects were identified and confirmed to be generated during the packaging and sealing process. All identified and confirmed defects were recorded. No additional tools were necessary.

Samples Defects Clasification						
		Defect				
Defects Category	Qty	No Visible	Visible	Very Visible	Placement(Blister/Foil)	Bottom/Top
Creased Foil	163			x	Foil	Top
Misplaced Foil	72			x	Foil/Blister	Top
Double Foil	33	x			N/A	N/A
Incomplete Seal	18	x			N/A	N/A
Broken Blister	14		x		Blister	Bottom

Table 1. Visual Defects Classification

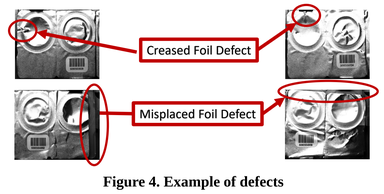


Figure 4. Example of defects

Methodology

Improve
It was identified that the rejected samples have visible defects, which were later identified that these visible defects were responsible for the 80% of the "leaks defects". These product were processed and transferred as good product in the packaging stage. To prevent these type of defects that caused the 80% of the identified leaks a vision system was proposed.
The vision system prototype was designed using Solid Works. The vision system prototype was built as designed and provided with every mechanical part adjustable to be able to setup the cameras and lighting during development. The components used were lighting controller, two cameras, CIO-Micro for camera triggers and I/Os and 4 white led for illumination.

Figure 5. Prototype Design

Figure 6. Prototype Built

Figure 7. Prototype Panel

Image processing techniques and algorithms were utilized in order to process the blister packages for defects detection. Some of the tools utilized were Blob, Mask, Edge detection, Surface Flaw detection, Filters, etc. The minimum contrast values and the smoothing parameters were very important during testing and fine tuning. The results of some tests are in Figure 8 and Figure 9.

Figure 8. Images of good package processed through various algorithms: Passed

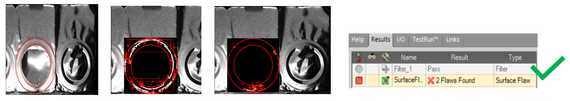


Figure 9. Images of rejected sample processed through various algorithms: Failed

Control
APIS vision system is approved by upper management to be installed in a first line before October 31st , 2018.

- Camera and Illumination baseplate for the line is completed(Figure 10).

Figure 10. APIS station design

- Implementation plan is in process awaiting for line and production availability coordination to schedule activities to install the system and validate it as an additional control for packaging defects.

Results and Discussion

As part of the test performed to confirm the vision system effectiveness and consistency for correct blister packaging inspection it was defined a sampling plan:

- **n = 288; a = 0; r = 1; AQL = 0.018%, LTPD:0.80**

This sampling plan was used for good blisters and the rejected samples. To develop the software algorithms and setup the system in the most reliable manner to reduce the false rejects and to

Results and Discussion

Ensure the system is able to reject the samples rejected. During the first test performed the vision system could effectively and consistently inspect and pass the 288 good blisters packaging providing a reliable result and confirming that the system won't cause additional yield losses. In the second test performed with 288 rejected samples the system could performed as expected and effectively inspected and rejected the 288 identified as bad packaging.

Conclusions

Passing the two final tests performed with the sampling plan selected with a sample size 288 samples for each of the test with results of zero (0) in both tests runs with the vision system developed and the setups applied in the prototype, we can conclude and state with 90% confidence that the defect rate for the characteristic under consideration is no more that the sampling plan's LTPD. For such reason we have a 90% confidence on the reliability and effectiveness of the vision system to consistently inspect the 100% of the production in line and to provide a huge improvement to Final QA inspection findings by detecting and rejecting these defects in the manufacturing line.

Future Work

To provide a vision system to measure the sealing area to provide sealing dies degrading monitoring and maintenance prediction or alert in case requires to change or clean the sealing dies before the seal process is affected.

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