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PRECISION AUTOMATION

CASE STUDY

Class 3 Medical Device Package and Label Inspection

In this case study, we look at how ensuring pharmaceutical and medical inspection compliance with machine vision increases reliability, decreases costs, and dramatically reduces contamination risks.

When in the care of a medical professional, you implicitly trust that the fresh gauze, fresh needles, new bottles of medication – any consumable for any medical equipment – are going to be clean, fresh, and sterile. The only way that will be true is if the package in which they have been stored has an unbroken, reliable seal that keeps the contents as pristine as when they left the factory.

Yet, FDA recalls show that current approaches to package sealing are inadequate. Too many seals fail, putting at risk lives, consumer health, and patient faith in the integrity of the materials used in their care. One failed package in a lot can cause a recall of the entire lot, even if all of the other package seals are intact, hurting product cost and potentially limiting supplies of critical consumables. Lawsuits can further raise the costs associated with failed seals.

Other applications, such as food and supplies for deployed military forces, also rely on intact hermetic seals. The common link between these applications is that failure of a seal can have serious consequences.

Most package seals are inspected manually. Operators are trained to detect voids, particles, hair, and wrinkles in the seal, as well as areas where the seal is too thin. Figure 2 offers a sample of the many possible defects in medical packaging. However, the time available for this inspection is limited: defects often must be detected within a window of less than 10 seconds. Humans are fallible and subject to fatigue; having little time for inspection increases the risk that a defect will be overlooked. What has been missing from the industry is a reliable, automated way to perform seal inspections.

The Challenge

Following an internal recall of Class 3 medical device package, a tier 1 medical device manufacturer needed an automated, advanced vision system to provide 100% inspection of the Tyvek seals on medical packages, including attributes such as shape, transparency, and color. Each package included eight products with four seals each, which needed to inspected within 12 seconds.

Figure 1. Automated medical package inspection system designed by DWFritz.

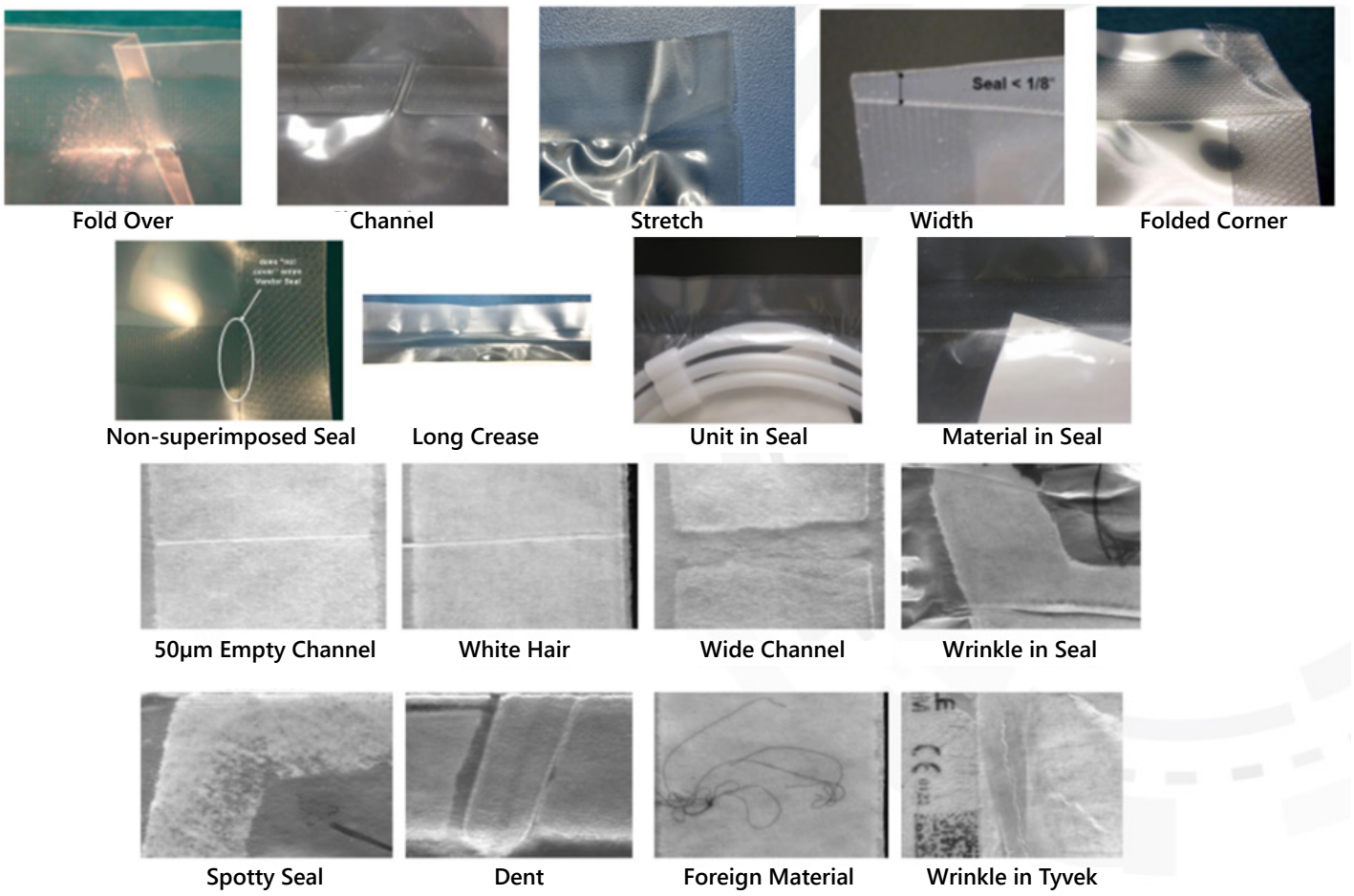

Figure 2 Understanding seal inspection requirements, including defect types, sizes, and packaging materials.

The Process

In a typical packaging line, after assembly, a package enters the labeling system where printed labels are applied to the pouch. Before application, labels must be inspected, oriented, and located correctly for placement on the pouch. Next, the system verifies the product's Unique Device Identifier (UDI) against the pouch label. Once verified, the system seals the product in the pouch and inspects the seal for breaches. Finally, the pouch is placed into a carton and another label is applied to the carton before being packed into a shipping box. As you can see, the process includes a number of opportunities for an error to occur.

To develop a system that optimizes this process and reduces opportunities for errors, our first step was to understand all of the defect types and sizes, as well as the different package materials. In this case, package materials included Poly-Poly and Poly-Tyvek, which require different lighting schemes to produce high-quality images.

We designed and built a prototype to obtain good images. Using the prototype, we studied the lighting and imaging schemes, gained a better understanding of the cycle time, assessed the number of images and processing time required for each defect, and modeled all of our collected data to determine the best tool for the project.

Obtaining good, high-contrast images of defects is critical. The specification on the defects highlighted in Figure 3 is 50-micron wide. Note the bubbles or voids next to the hair. Our system needed to differentiate and classify these defects.

To train our system, defects must be correctly marked and classified – a process called supervised learning. Regions that do not require inspection can be masked to reduce processing time. During the defect training, the confusion matrix showed an overlap between the good and bad scores attributed to two main issues:

1. We encountered bad parts classified as good.
2. The system was unable to identify a good sample.

To resolve these issues and obtain a cleaner confusion matrix, we collected enough representative samples of good

parts to train – a tedious process that requires attention to detail and significant customer collaboration. Incorrectly identifying, labeling, or classifying a defect will lead to an incorrect model. We confirmed these tests by obtaining correlation in the confusion matrix, ensuring a clean matrix with no false negatives or false positives, which produced the results shown in Figure 4.

With the lighting requirements established, we turned our attention to the material handling aspect of automation. For our prototype, we calibrated a 40mm lens to 11um pixel. This set up accommodates 1mm focal depth for excellent resolution of small particle defects. We also evaluated a larger pixel size to enhance speed and focal accommodation, which provided a larger field of view and faster inspection, but reduced signal on minimum size defects.

To achieve the stated objectives, we implemented a novel approach that eliminated the need for template creation while successfully identifying:

- Presence/absence of printed content
- Detection of gross defects
- Reading and grading of barcode patterns
- Reading and quality grading of OCR text

The system acquired and processed images in motion at 150mm/sec, sending highly suspect bad samples to a reject bin. By achieving this impressive rate, our system reduced cycle times to 12 seconds per cycle.

The next step is inspecting for label defects. Sometimes, when labels are printed, ink may run out, ink bleeding can occur, or there might be issues with the label material that causes print defects. If a nurse or doctor cannot read a label, or if the part in the package does not match the label, these are major problems. What if a defective or incorrect device goes into the patient? Fixation screws, for example,

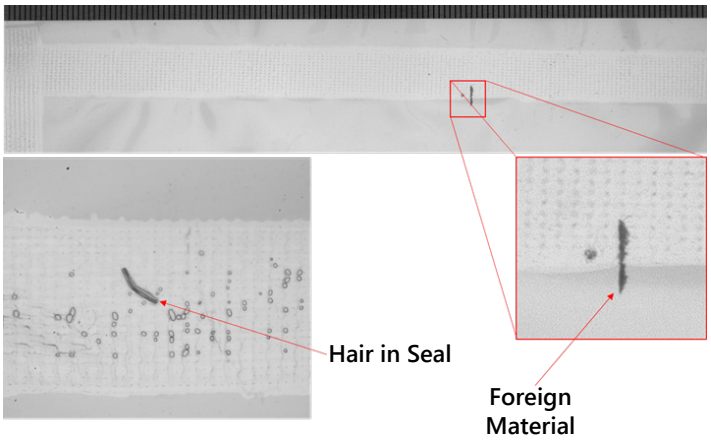

Figure 3. Area scan image of defects and voids in package seals.

Automated Medical Packaging System Highlights

- Defect inspection and classification
- Package flatness of +/-1 mm over 1 feet x 2 feet area maintained [these packages are loaded with parts]
- 11 micron pixel resolution to capture 50 micron diameter defects
- 150mm/sec part movement
- 12 seconds cycle time
- Up to 400 images taken per cycle
- Custom strobe lighting

come in different lengths, but when the variance is only 1mm difference, these parts have a high susceptibility to incorrect packaging.

Label inspection includes legibility and OCR for cross verification. We used an original PDF to create the label as a baseline or template and then we subtracted all incoming labels. Any difference between the baseline and test image will show up in pixel counting or blob analysis. For human readable, QR code, unique device identification, we can apply OCR and compare to the device number.

For detecting label issues, images are key. We used Mitsubishi KD-CX series Contact Image Sensor to scan the label running at 20ppm at 600dpi. This sensor and throughput can be used with both manual application and a robot to pick-and-place the label.

The Final Solution

A bank of nine cameras with dual-channel illumination capture up to 400 high-contrast images per package for defect inspection and classification. The low angle light channel highlights adhesion defects, while the high angle light channel detects foreign material, glazed seals, pinholes, and other non-adhesion defects. Real-time analysis of the images provides feedback to the system, directing rejects into a separate bin and allowing only the good packages to pass.

DWFritz Automation specializes in creating reliable custom seal inspection systems for use in verifying the package integrity of critical supplies and materials. These systems increase seal reliability while simultaneously reducing inspection costs. Two key technologies perfected by DWFritz are fundamental to the success of the inspection stations.

Advanced Vision System

DWFritz has extensive experience designing and building advanced vision systems that are tuned to the needs of

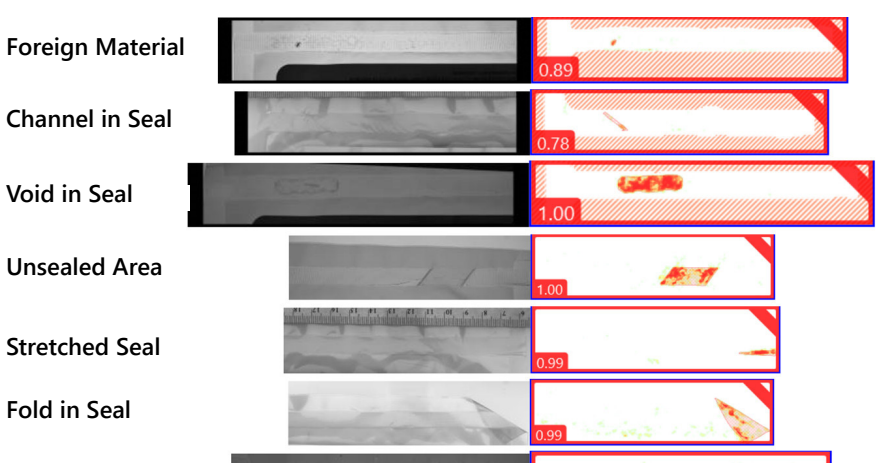

Figure 4. Package seal inspection results show the raw image (left) vs the processed images (right).

specific inspection targets, including measuring imperfections lower than 100 microns. The individual challenges inherent in seal inspection, including shape, transparency, and color, will determine the final custom configuration. By carefully choosing the right light sources and camera setups, any package seal can be reliably inspected.

The cameras typically form a black-and-white image. Color cameras can be used, although color sensors can often be more effective if color is part of the inspection protocol. Cameras can be set up for area or line scans.

Images collected during a scan are stitched together to create a single image in which defects can be detected. Image processing consists of advanced algorithms executed on multiple processors that identify the defects. These algorithms are tuned to the specific nature of the images for each product being inspected, with care taken to identify all defects while minimizing any false positives. To reduce the amount of required processing, images can be auto-cropped to narrow down the area of interest.

Lighting is provided by strobes in order to freeze the scan motion of the moving target. Difficult color and transparency situations can be handled with custom lighting that can expose the defects of interest. While most visible defects are detected with high-angle bright-field lighting, tough defects like blond or gray hair on white backgrounds can be picked up using low-angle dark-field illumination. And if visible light isn't effective for a particular defect, both infrared and ultraviolet lighting options are available.

Sophisticated strobe controllers ensure the proper light levels, strobe timing, and strobe duration, with care taken to ensure that a strobe for one camera does not interfere with the light being captured by another camera.

Advanced Gantry System

Imaging is done with fixed cameras; the scan is created by a vacuum chuck that lifts the target and transports it over a series of cameras using a sophisticated gantry design. A typical arrangement is to have a row of cameras in the X direction and one in the Y direction, allowing both seal dimensions to be viewed. One camera is dedicated to target registration so that the chuck is positioned correctly when picking up the target, whose initial position may vary slightly from item to item.

While most seals are rectangular, or almost rectangular, it is also possible to build a custom arrangement that will inspect non-rectangular seals. The gantry can be programmed to move in non-rectilinear trajectories.

While the chuck can move at speeds up to 260mm/s, offering quick, efficient image capture, image blurring can cause a significant bottleneck. To overcome this challenge, we strobe high-intensity lighting for short periods, preventing pixel blur due to imaging in motion. This limits the speed of motion during imaging to 150mm/sec, but produces much higher resolution images and acceptable cycle times.

The Results

The automated inspection system inspects 100% of the packages, capturing defects in the order of 50-microns, and meeting the pass criteria of 99% confidence level with a 5% confidence interval. The system can be tailored to the requirements of the package type, the application , and other production requirements. For high-volume commercial inspection, the station can be appended to the end of the packaging machine, minimizing both handling and area footprint. Standalone stations also can be installed for laboratory and other settings where inspection is performed in isolation.

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Established in 1973, DWFritz Automation is a leading global provider of precision metrology, inspection, and assembly solutions for advanced manufacturing. We design, build, and support engineer-to-order automation systems and high-speed, non-contact metrology products, as well as offer world-class build-to-print manufacturing services.

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