HAHN
AUTOMATION GROUP



# Maximizing Automation for Medical Device Manufacturers

With HAHN Automation Group

# Overview

With an intense focus on quality, medical device manufacturers require an equipment provider who is intimately familiar with the challenges they face and can accommodate the timeline and needs of their production teams—or, at least, they should.

That's because maximizing on the potential of automation in the medical device industry requires a unique approach that offers support throughout the entire project. In this ebook, we share the stories of four customers—all from segments within the medical device field—who partnered with the HAHN Automation Group for their skilled manufacturing needs. In each, we will explore what it means to identify where automation will be most beneficial, design equipment with flexibility, and offer support to solve the challenges facing medical device manufacturers today.

# Case Study 1

## Automated Assembly Preloads Needles for Ophthalmic Procedures

How the HAHN Automation Group helped a medical device manufacturer increase the efficiency and accuracy of a microscopic process.

# Case Study 1

Bringing a product to market often requires a shift from a manual process to an automated one. In this example, you can learn about how we helped a medical device manufacturer incorporate automation into their once tedious process.

We'll call this customer "Ava".

Ava, an ophthalmic device company, faced an inaccurate, manual process as well as increased demands for their ocular drug delivery systems. They needed an automated solution to replace their tabletop process, which relied heavily on operators and yielded only a 40% acceptance rate.

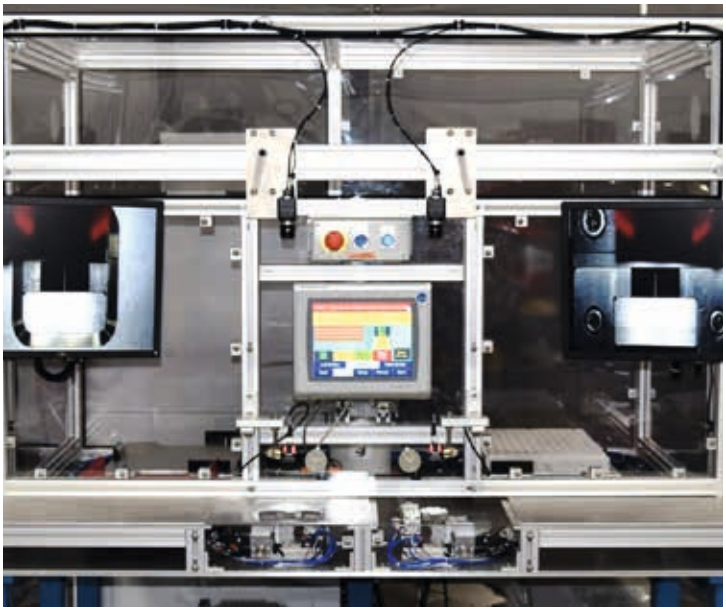
## Challenge

The challenge involved loading a needle hub assembly with a compact, cylindrical medicine. Due to the dimensions of the needle and the medication, the assembly required a push wire with a diameter of approximately .014", making it difficult for an operator to handle without damaging the needle or bending the push wire. These dimensions also meant it was hard for the operator to visually confirm that the medicine had been placed into the needle and was in the correct position.

With no previous experience leveraging automation equipment, Ava needed a partner who could assess their current process for solutions that would meet their expectations—while staying practical within the boundaries of their budget and operator expertise.

## Analysis of Alternatives

Prior to our solution, the assembly was done with an operator dependent, tabletop assembly station. It is important to note that our machine was their first piece of automation, and it took a lot of collaboration from both sides to work through this process.



# Solution

Given the delicate nature of the products, the HAHN Automation Group used a semi-automated approach that would minimize operator involvement in order to increase efficiency while providing feedback to confirm accuracy. The resulting system uses a robotic arm and four different sensors throughout the process to indicate the success of each step.

## Here is how the system works:

1. An operator loads the medicine from a tray into the machine nest. Once it is loaded, a sensor confirms the presence of the medicine.
2. The robot will then grab one of the needle hub assemblies from a pre-loaded tray and bring it to the nest. A swing arm clamp, transfer tube, and push wire are used to load the medicine into the needle at a specific depth. Sensors monitor the force to ensure the push wire is not bent in the process.
3. Finally, a fourth sensor performs a process verification that confirms that the medication has been loaded successfully.

## Results

The cycle time for the process is 10 seconds—a significant improvement over the 30 seconds per device achieved in the manual version of this process. Most importantly, though, the original 40% acceptance rate is now 90-93% with this semi-automated solution.

# Case Study 2

## Vision Inspection for Automated Sorting

How the HAHN Automation Group helped a contract manufacturer improve the accuracy of their inspection process for medical device components.

# Case Study 2

When supplying components to a medical device customer consistency is critical at every step. In this example, you can learn how we used automation to help a contract manufacturer improve the accuracy of their inspection process for medical device components.

We'll call this customer "Luna".

Luna is a contract manufacturer who supplies critical pins for medical device assembly. They were given eight weeks by their largest customer to improve the accuracy and reliability of their currently manual inspection process.

## Challenge

The stainless steel pins were .030" in diameter and required inspection for size, length, coating, and durability before shipment to the medical device manufacturer. Due to the small scale of the pins, not only was this task tedious and time consuming, but it was also prone to human error as each operator had a slightly different visualization of the criteria. In their search for an automated process, Luna hopes to eliminate this error and develop more consistent, reliable results.

## Analysis of Alternatives

Prior to our solution, the inspection was done by manually picking up the pins, placing them in front of a camera, and then inspecting each one individually. While it was not mentioned if Luna had tried any other solutions prior to coming to us, it was determined that Luna did not have the internal resources to properly develop a solution in such a condensed timeline.

# Solution

Automating this process began with a series of feasibility testing at HAHN Automation Group's vision lab. Engineers explored a variety of vision systems in order to determine whether or not they could accurately identify the pin features and satisfy the inspection requirements. Additional programming was also needed to accommodate three different types of pins in a single system.

## The system works like this:

1. Operators load pins into a feeding system where they fall from the hopper into a vibratory tray inside the station. The vibratory tray separates the pins.
2. A vision system above the tray locates the pins and communicates their position to the SCARA robot which transfers them into a custom, backlit nest.
3. Once in the nest, the pins are inspected by a vision system and deemed either "good" or "bad" based on the customer's original criteria.
4. The nest rotates to sort the pins accordingly by dropping them to the righthand side for a good pin and to the left side for a bad pin. There is a locked door to access the bad pins and help eliminate the risk of confusing them with the accepted components.

## Results

The end customer relies on these pins to ensure their devices operate correctly in the field, and the tolerance for acceptance is incredibly low. Therefore, Luna's top priority was a system that could improve reliability and consistency while reducing cycle time. With the machine being autonomous, the new system provides a higher level of confidence in the accuracy of the inspection process as well as producing a more consistent cycle time.

# Case Study 3

## Automated Equipment Provides Consistency to Coiling Process

How the HAHN Automation Group helped one medical device manufacturer remove variability from a complex, once manual process.

# Case Study 3

In this example, you can learn about how we helped a medical device manufacturer remove variability from a complex once manual process.

We'll call this customer "Rowan", a vascular device manufacturer.

## Challenge

Rowan was struggling to produce consistent results in a highly complex, manual sub-assembly of their device. The process called for an operator to manually coil a delicate, .020" thick wire around the exterior of a mandrel. Doing so required operators to feed, wind, clamp, coil, and cut the material before transferring the device to a welding station—all of which was done by hand leading to long cycle times, inaccuracies, and inconsistency among operators.

## Analysis of Alternatives

The original process not only required the manual coiling of the product, but it also required operators to transfer the part to a separate area for welding. This meant a larger footprint as well as more opportunity for the coil to be damaged as it was handled and passed between stations. So while not part of the initial request, it was determined that integrating the processes would yield a better ROI.

# Solution

The HAHN Automation Group worked closely with Rowan to assess their process, environment, and operators. Ultimately the HAHN Automation Group recommended a fully-automated system that would allow operators to load multiple mandrels at once, secure the device, wrap the mandrel with coils of precise spacing, and secure the final product with welding inside the same machine.

## The system works like this:

The system allows operators to load up to 13 mandrels into the machine at once where they are then indexed and set into position.

1. The wire is then coiled along the length of the mandrel and secured at each end.
2. Next the system welds the wire into place and inspects the device using integrated vision systems.
3. After inspection, the final product is released onto a returning conveyor where rejects are automatically separated into a reject chute, and approved devices are cycled out every 80 seconds.

## Results

Learning to transition from a manual process to a fully-automated system can be a challenge on its own, and it is not always recommended. In this case, however, the benefits far outweighed the learning curve. After implementation, Rowan experienced better consistency in the coiling of their device that led to greater confidence in the accuracy and effectiveness of their product. This new process also significantly reduced the cycle time and footprint of the process as a whole. Additionally leveraging the integrated vision system allowed them to better isolate rejects.

# Case Study 4

## Fully-Automated System Produces Complex Device Every Four Seconds

How the HAHN Automation Group helped one medical device manufacturer exponentially improve their production process.

# Case Study 4

While quality often outweighs speed in the medical device industry, demand can create a need for both. In this example, you can learn about how we helped a medical device manufacturer leverage automation equipment to exponentially improve their production process.

We'll call this customer "Parker".

## Challenge

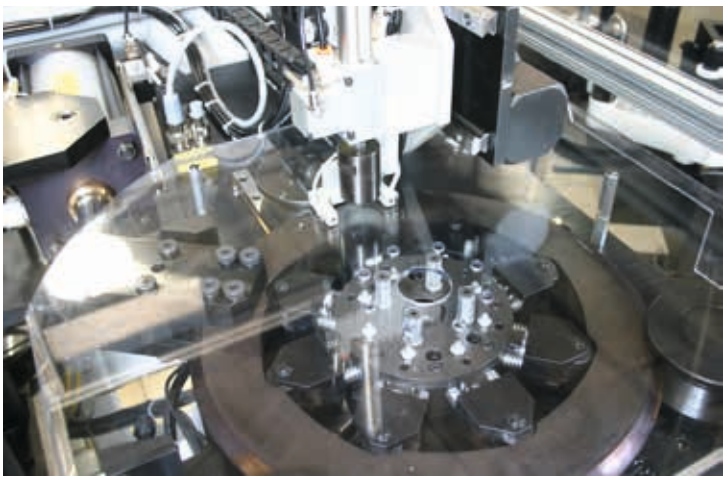
The device is a post-surgical product that applies continuous pressure to a wound. All of the components are clear, making the assembly tedious and inconsistent, as there are little to no distinguishing features on the components. Additionally, the multiple subassemblies required were causing operators to get carpal tunnel from the repetitive motions and amount of labor needed to meet current demand.

Manual assembly for the production of this product required over 200 operators. In their search for an automated process, Parker hopes to find a way to involve automation in the process for error-proofing, speed, and ergonomics.

## Analysis of Alternatives

Prior to the solution, operators manually assembled the medical device. Parker had semi-automated machines to make this process easier, however, it still was not producing the amount they needed. Additionally the operators were transferring subassemblies by hand, making it both time consuming and inaccurate.

At first, Parker was only looking for a welding solution to speed the production of a single sub-assembly. They believed the rest of the assembly was too complex to be automated. After careful on-site investigation on the process, our application engineers concluded that the entire assembly could be automated.



# Solution

In order to design a system that was fully-automated and fit the footprint of the production space, The HAHN Automation Group designed three dial machines. In it's final layout, the two outside dials feed into the third center one which assembles the final product.

## The system works like this:

1. Components are fed into the outside dials which complete two key sub-assemblies. As each dial rotates, the components are guided through a series of stations that involve adhesive dispensing, flexible material handling, precision joining, and testing.

2. The left dial uses sensors and a vision system to measure and cut a clear tube material, roughly, .060" in diameter, to a specified length. Dispensing technology is then used to glue the tube to a hub which is followed by UV curing.

3. The right dial leverages four SCARA robots to attach a clear support plate to a specified location on the device. This dial uses a series of vision systems and customized lighting to locate the clear components and ensure they are joined in the correct position and orientation. The sub-assembly is then sent through an integrated laser marker before moving to the third and final dial.

4. The middle dial simultaneously removes the two sub-assemblies from either side and produces the final product. The device is filled with air and an initial leak test is performed before the final product is released.

The entire system requires only 4-5 operators and provides a cycle time of four seconds.

## Results

From the perspective of Parker, they have a more accurate, efficient process that requires only a few operators rather than hundreds. With a 98.2% decrease in operators, the company is able to reallocate operators to research applications AND significantly reduce error. Additionally, moving to a cycle-time of 4 seconds helps ensure they meet production goals.

# Ready to Discuss Your Next Project?

The results speak for themselves. From stand-alone machines to full production lines, we have helped a diverse array of medical device manufacturers maximize automation to solve their most pressing production and testing challenges.

Learn more about how we can help you at
**www.hahnautomation.group**