

HAHN
AUTOMATION GROUP

Shifting from Manual Processes to Automation

Medical Device Assembly



Overview

When you think about "automation" and what it means for your business, what instantly comes to mind?

Perhaps that it's faster. It's ultimately cheaper. It requires less labor.

While these can certainly be true, what is often lost in translation is how these benefits impact the quality, accuracy, and repeatability that medical device manufacturers seek. In fact, the most important aspect of automation in the medical device industry is its ability to provide better consistency for your product, allowing you to uphold top quality offerings for every single customer.

At the same time, the vast jump from manual processes to a fully-automated station isn't necessarily the goal most of the time. Rather, the goal is to use automation in steps that will improve the manual process. We can add automation, in terms of testing and error-proofing, to manual stations to reap the benefits that automation offers while maintaining a semi-automated approach. And if full automation does make sense, we can develop a solution that works comfortably for your team.

Shifting from a manual to a semi-automated or fully-automated process can add immense value in terms of consistency and quality—and

now more than ever, it enables medical device companies to continue their critical operations.

In this e-book, we will look at examples from medical device manufacturers who reduced cycle times up to 75% and improved OEE scores by 22.5%, generating more revenue per piece. Most importantly, we will demonstrate the thought process behind transitioning from a manual to an automated approach that led to these results.



So, why did we create this e-book?

We want all of our clients—both new and existing—to feel more comfortable with the technology that goes into automation. Many customers are great examples of this, but two instantly come to mind. In this e-book, we'll call them "Harper" and "Monahan".

When Harper, a surgical device manufacturer, and Monahan, a manufacturer of catheters, initially thought about automation within their assembly process, they thought it meant “fully-automated.”

Instead, we offered them tailored solutions that steadily introduced automation into one process or step, after identifying a few stations where automation would have the best ROI. This significantly helped improve product consistency —and with this, Harper and Monahan realized a BIG benefit. Throughout this e-book, we'll go into further detail about our solutions.

In this e-book, we will walk you through the:

- Cons of all-manual processes within medical device assembly
- Benefits of weaving automation into your processes
- Top criteria for finding the right automation partner



All-Manual Processes in Medical Device Assembly

Cons

In the beginning, Monahan was operating an entirely manual inspection process for verifying the functions of flexing on a catheter device. Additional manual processes were used to test electrical properties and specific electrical contact points. Finally, a series of operators would check the leak, flow, and temperature measurement characteristics.

In total, the series required 15 steps, each completed by a different operator station, and the product was transported by hand. The entire process took approximately 20 minutes per device.

In general, all-manual processes result in:

- 1 Less consistency 
- 2 Lower productivity 
- 3 Higher cycle time 



These three factors have a negative influence on the number of devices that can be produced, as well as the amount of scraps, defects, and rejects that are created in the process.

Two other downsides to all-manual processes are inefficient cost allocation, as well as operator fatigue.

Cost allocation

In the US, an operator generally costs \$50-60k per year. This estimate is often used to determine how many years are needed before automation is less costly than hiring another operator.

It should be noted here that many of our customers do not eliminate operators. However, automation would allow those existing operators to be re-assigned to other beneficial areas (such as research initiatives), or re-skilled to complex areas where humans excel.

Operator fatigue

Yes, some operations cannot be automated. Nevertheless, adding automation can improve the ergonomics of tedious processes. According to labor laws and research into the effects of poor ergonomics, operator fatigue is a major issue for many of our customers. Automation can help reduce the risk of associated diseases (for instance, carpal tunnel).

Automation excels in three basic areas: dirty, dull, and dangerous. Dull as in repetitive functions; dirty as in areas that process contaminates may cause concern; dangerous in temperature, chemical, or other environmental risks.

To combat Monahan's dilemma, the HAHN Automation Group created a solution for a system that could complete all of the tasks with only two operators using vision technology and a linear indexing conveyor. This reduced the test cycle time to only 70 seconds. HAHN Automation Group also added an automated barcode reader — giving the customer the added ability to capture serialized test results for each part and store them for traceability. Finally, The HAHN Automation Group designed the equipment to incorporate a second product, allowing flexibility based on production efficiency.

Pros

- 1 More consistency
- 2 Higher productivity
- 3 Lower cycle time
- 4 Better cost allocation
- 5 Less operator fatigue

Automation leads to increased OEE score

As we know, OEE (Overall Equipment Effectiveness) is the gold standard for measuring manufacturing productivity. Simply put, it identifies the percentage of manufacturing time that is truly productive.

Consider this: Say for example, an operator who conducts manual inspection is approximately 80% efficient, meaning out of every 10 part cycle, they assemble or inspect 2 items incorrectly. To get a higher percentage, some companies attempt to combat this by using multiple operators (where the second operator inspects the first operator's work), or by slowing down the cycle time thinking an operator with more time can improve quality output.

However, when evaluating OEE there are many variables involved, and being able to remove variability [through automation] is what will ultimately raise your production efficiency.

In Harper's case, they were previously using operators to assemble 144 devices into a plastic tray in order to count and inspect them before final assembly. This often led to inconsistent placement and inspection errors—receiving results less than 70% operator OEE. HAHN Automation Group's solution used a custom program, AI vision system to inspect, count, and identify errors that were recoverable in real-time with 99.5% OEE qualified process results.

Selecting the Right Automation Partner

So, perhaps you're considering automation for a few of your medical device assembly processes. When it comes to selecting the right automation partner, here are five things you should consider:

1 Specialty in medical devices

Many equipment providers claim they will adapt, but if the automation supplier isn't familiar with medical devices specifically, they won't be familiar with the processes and complexities of automating these products, as well as the regulatory requirements and project timelines. Many suppliers of automation are much more used to the less fluid nature of automotive or consumer products.

Some companies look for an automation partner that is even more specialized—for instance, Cognex is very specialized in vision solutions, while Keyence is very specialized in sensors. The best-case scenario is an automation company with a broad range of technology insight, who knows how to apply it specifically to the broader medical device industry's requirements.

2 Experienced in design & development

Prioritize someone with years of experience in design and development, and not just integration. In the example above, a Cognex or Keyence expert will ensure that their technology is programmed correctly, and an integrator will ensure that the technology works together. But none of these will be able to help troubleshoot how to automate or evaluate a process if there's a better way to accomplish the task.

Many times within the medical device industry, customers are doing things that have never been done before—an integrator alone will not have the experience to work with those applications and help with the requirements.

3 Flexibility

Does your prospective automation partner have a culture of being flexible? Medical devices are often new to the market, and customers must begin thinking about what their equipment needs before the product is finalized. Throughout the approval process, things change, and the automation company must be able to roll with those changes. If the automation company isn't flexible to accommodate changes in the project or product, the equipment won't have a dependable schedule or consistent results.

4 On-site laboratories

With regards to process development and device testing, an automation supplier should have labs on-site to help customers conduct feasibility that will mitigate risk before investing in a solution.

5 Capable of run-offs & installation

The ideal automation partner also needs to be able to do run-offs and installation—not rush things off the floor once the equipment is finished. This is pretty unique, as many automation suppliers want to ship equipment as soon as it is finished. However, in medical device manufacturing, customers sometimes like the option to conduct research on the equipment before it ships.

For instance, one of our clients asked for their equipment to remain with us for an additional three months, while we investigated some potential laser technology integration for future products. This proved beneficial as our customer was able to leverage our experts while efficiently testing out several of their ideas.

We know what you're up against.

The HAHN Automation Group fulfills the needs mentioned above. Many of our competitors are able to work with medical device manufacturers, but they do not specialize in it. We do. We are intimately familiar with the challenges you face, and we are set up to accommodate the timeline and needs of your production teams.

Ready to weave automation into your medical device assembly processes?

We'll be here for you every step of the way.

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

