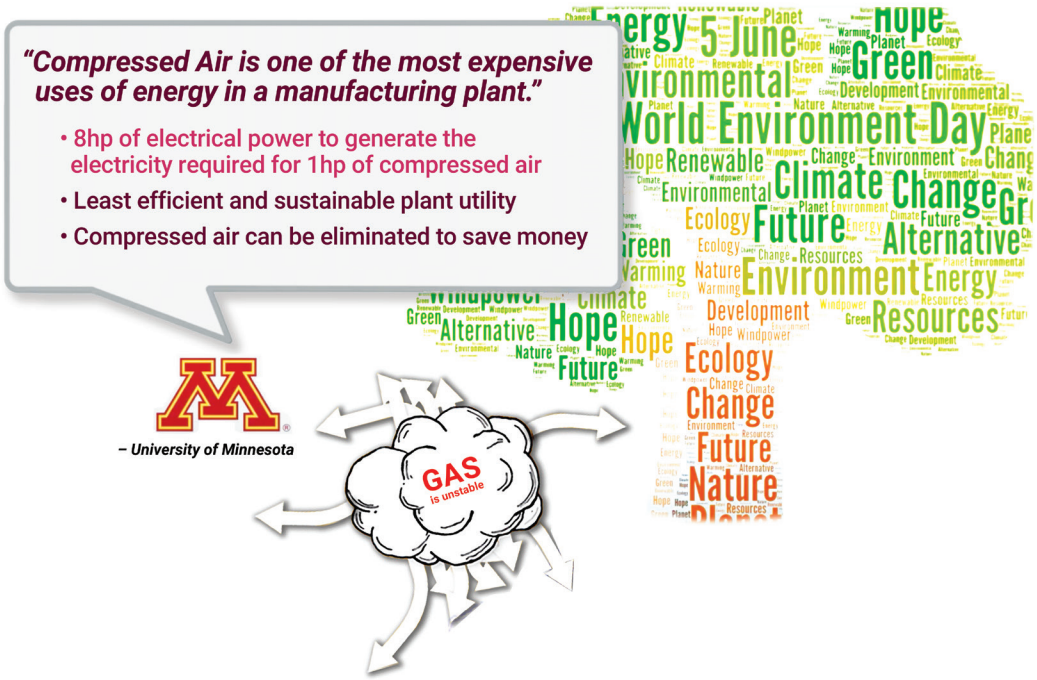
AlgorithmicControl™ AirFree® Technology

White Paper: Adopting Algorithms

A Compelling Case to Be Made for Upgrading to Algorithms

Makers of medical devices have been relying on unstable compressed air since the 1970s to run aspects of their production line, including the dispensing of fluids to assemble products. This White Paper has been written to show manufacturers it is time to end this outdated and risk-laden practice.



Compressed Air is Polluting Many Manufacturing Processes

There are many reasons to stop using fluid dispense systems running on compressed air. Among them is accuracy, or the lack thereof. Air is a gas, and as such it is ever-changing. Its volatility makes it very difficult for manufacturers to stabilize and increase the capacity of their production lines. Moreover, according to a study conducted by the University of Minnesota, compressed air is the most expensive item in a production facility.

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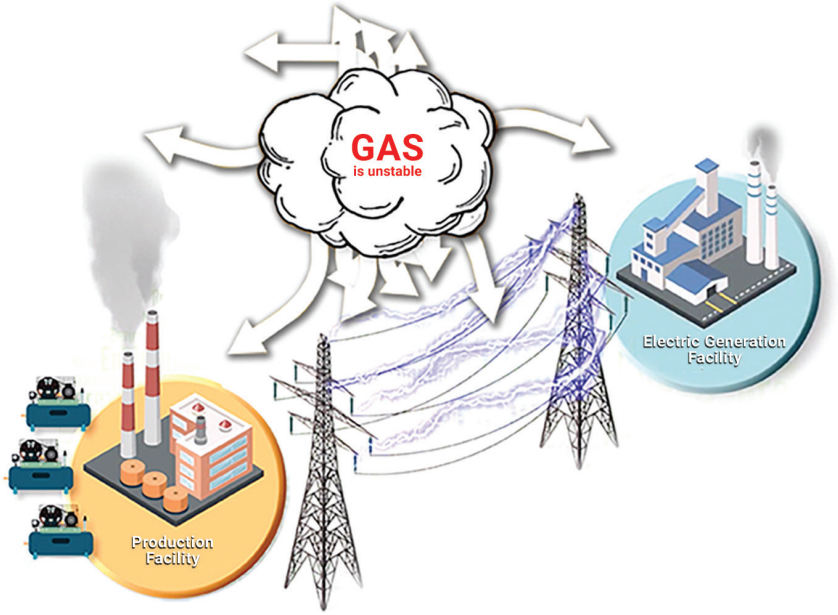
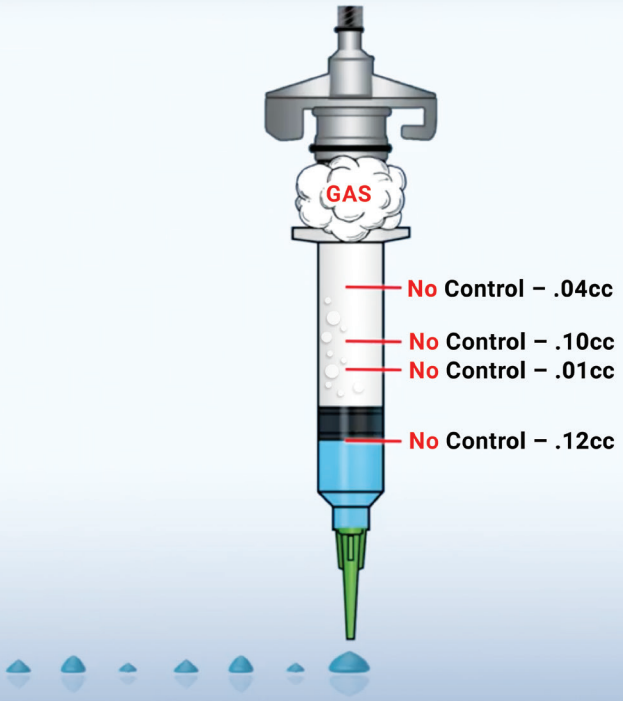
Besides the unpredictability and high cost of compressed air, the compressors themselves, and their plumbing systems, vary from facility to facility. Another problem with the plumbing is its tendency to fill up with moisture, with some of it getting shot up into the reservoirs holding adhesives, which can alter their bonding properties. This is not desirable under any circumstances, but it poses greater risks when manufacturers are working with cyanoacrylate (super glue), as moisture is the catalyst that starts the cure cycle.





In this erratic and unsafe environment, process validation, which is critical when manufacturing medical devices, becomes extremely challenging to duplicate from R&D to production. Even if it is duplicated initially, it often begins performing unpredictably not long after production begins. This puts production personnel in an untenable position because the process had been validated. Under conditions like these, manufacturers cannot expect to duplicate validation processes globally, or to quantify them in work instructions.

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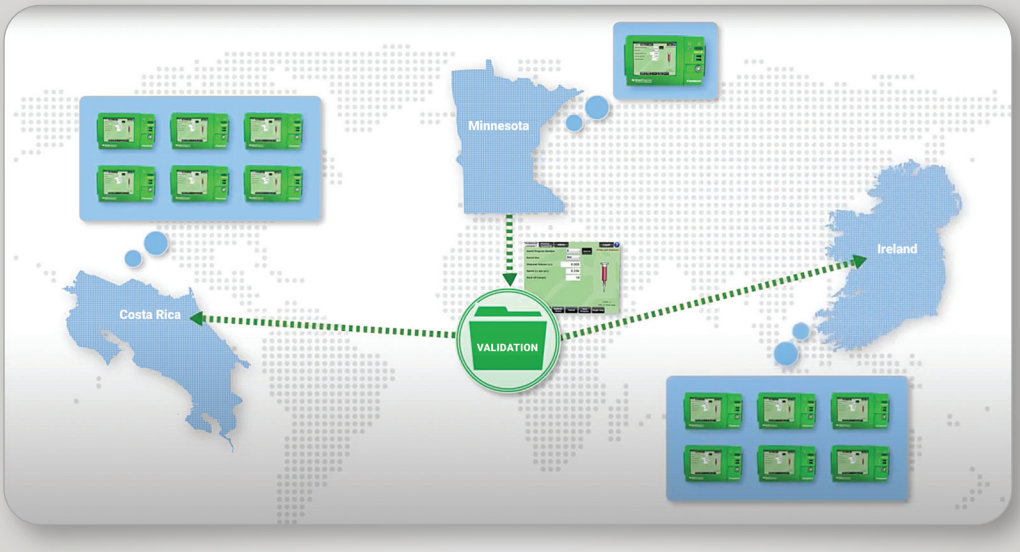
The Risks to Validation and Medical Devices are Very Real

Because validation plays such an important role in this industry, medical device makers must do everything possible to remove actual and potential risks from the assembly process. One key area for them to focus on is the application of assembly fluids used to bond products. Should adhesives fail, the consequences can be catastrophic, causing people to be harmed and large fines to be levied, which can result in lawsuits and public outcry.

This is why fluid dispense systems used to apply these essential bonds must be 100% repeatable, performing exactly the same from R&D validation to full production, workstation to workstation, and facility to facility. They must also be capable of being documented. Fluid dispense systems running on compressed air cannot achieve this level of precision and control. The only way to attain it is with the use of algorithms.



The Impact Algorithms are Having on the World is Indisputable

Algorithms are at the core of many of today's most sought after products. The effects algorithms are having can be felt in homes and vehicles, and in offices and production lines. Today's industry disruptors—Google, Uber, Amazon, Apple—are enjoying great success thanks in large part to their embrace and utilization of algorithms.

Businesses and consumers are steady buyers of technology benefiting from algorithms. Not surprising, since they make products better and, as a result, more desirable. Smartphones are a good example of this. Why do people continually upgrade to the next version? Because of the algorithms optimizing them, which help offer each new generation of smartphones with the next level up in technology, performance and security.

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Medical Device Makers Can Now Benefit From Algorithms

Fishman® design engineers developed a product, the SmartDispenser,® that distinguishes itself from all other fluid dispense systems by being able to apply algorithms to a mechanical drive system via a PCB and voltage. This unique ability not only results in accuracy, but it also assures each SmartDispenser® performs exactly the same workstation to workstation, facility to facility, country to country. Furthermore, SmartDispensers® can be quantified, controlled, duplicated, and documented in work instructions as well as in medical validation documentation. All of which is vital when delivering adhesives in a validated assembly process.

Time to Upgrade to the Industry's Most Innovative Fluid Dispense System

Medical Device Validation makes it imperative for engineers around the world to do all they can to ***eliminate both actual and potential risks*** from the assembly process. The only way to accomplish this is by applying algorithms to a mechanical drive system. This makes the SmartDispenser® with AlgorithmicControl™ and patented AirFree® Technology the most logical upgrade from 1970s compressed air technology.

It also proves accuracy should not be the main decision point when selecting a fluid dispense system. The principal driver is finding a technological solution that removes the many threats posed by the use of compressed air. Only when such a system is installed can medical device makers be in the best position to comply with FDA validation directives. As this White Paper has shown, that singular solution is the SmartDispenser® from Fishman® Corporation.

For more information on the SmartDispenser® with AlgorithmicControl™ and patented AirFree® Technology, and any of the other innovative solutions from Fishman® Corporation, please visit *fishmancorp.com*.

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