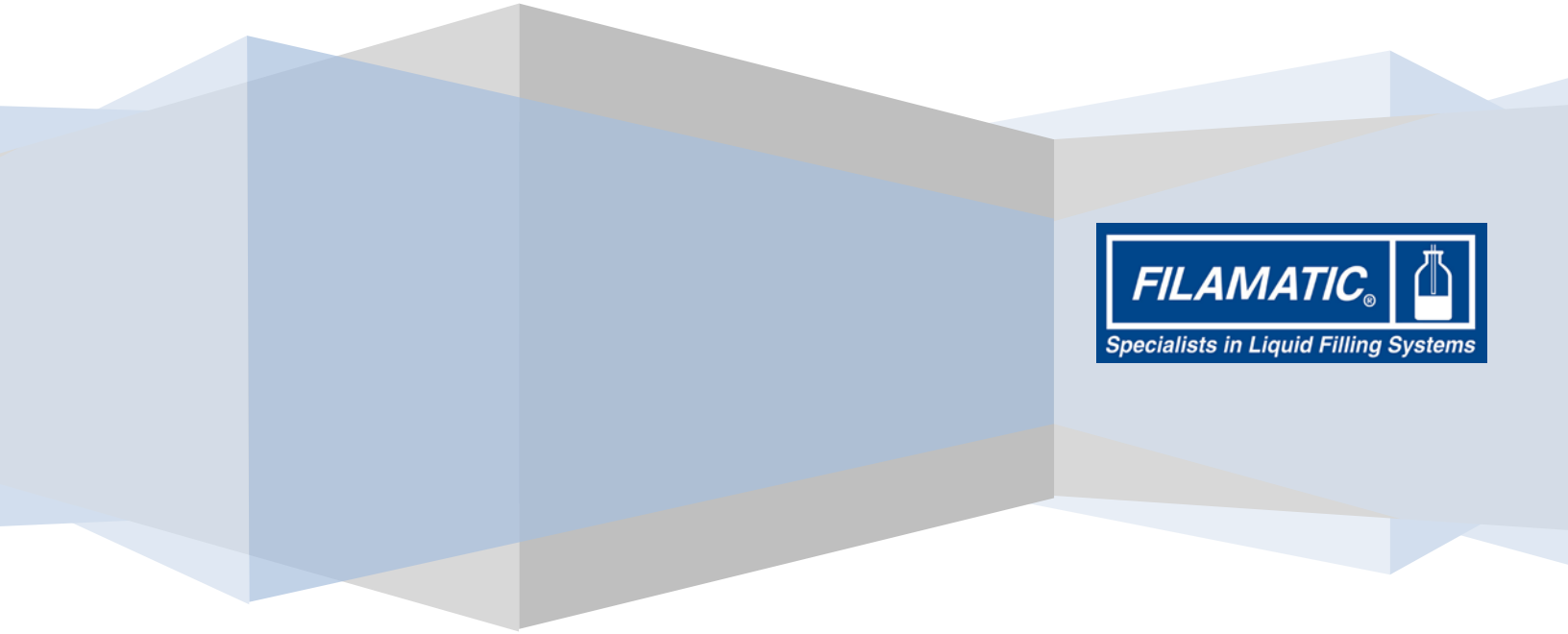
Whitepaper by Jack Chopper

Dirty Dishes, the FDA and the Fire Department



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The dishwasher lied to me! The green “Clean” indicator was illuminated, yet as I removed the warm and dry dishes, I could still see remnants of today’s dinner on several of them. How could this be, I wondered? I had loaded the dishes carefully, made sure that they were spaced properly, and that each item had its own location and that no two items were nested. I had used high-quality detergent, the dirty sides of the dishes were facing the spray arms, and I pre-rinsed the heavily soiled items. Since I was in the adjacent room while the dish washing machine supposedly did its job, it sure seemed as if the machine had gone through the time necessary to successfully and properly clean the dishes. Yet a failure! How could this be?

My mind immediately began compiling a list of possibilities as to why the dishes weren’t clean, even though the machine clearly indicated that they were. I thought: “Something’s wrong mechanically”: Spray arm not rotating, clogged nozzles, a pump restriction… something. Although unfamiliar with the appliance’s nerve center, I did find enough online information to conduct a few tests. Thanks to modern digital controls and manual test functions pre-programmed into the dishwasher’s embedded controller, a quick series of diagnostic tests eliminated all three of my conjectures. What now?

That’s when it dawned on me. I remembered answering the telephone while loading the dishwasher, and because I was sidetracked, I had forgotten to load several dishes that were still on the table. Later, I had stopped the dishwasher to add those laggards to the load and had underestimated where the machine was in its cycle. Mystery solved!

The above vignette illustrates the vagaries associated with machine validation. The dishwasher had checked off all of its duties as completed and, confidently announced: “Mission accomplished! The dishes are now clean!” Only the operator, in this case yours truly, was there to say: ”Not so fast Mr. Whirlpool!”

I’m a controls guy, and in the routine course of my work, I engage with folks involved in validation efforts. In its most rudimentary form, the word validation is used to describe an entire suite of specifications, documentation, design and testing efforts. This custom-written ecosystem serves to ensure that we’ve adequately described, designed, built, and tested an amalgam that will predictably perform the required functions, and that the produced results are accurate and repeatable. Perhaps more importantly, the protocols that are generated as an end product from the validation will provide a baseline—any future changes must reference these–thereby ensuring effective lifecycle management.

Validation efforts are rarely exciting, yet they are very important tools—tools that are far more involved than many think. For a moment, let’s mull over the complexities associated with: laser surgery, the lab doing your bloodwork, the service center working on your car’s airbags, the avionics guiding virtually every commercial airliner, etc. I certainly hope that this equipment and their surrounding protocols have been thoroughly evaluated, tested, documented, and such.

There are those who are generally turned-off by anything to do with validation, and I can see why that could be—and I'll concede that some efforts towards validating machines are misdirected, misleading and sometimes focused on the wrong areas. Unfortunately, at times, it seems that we encounter more miscues than we would or should expect.

When I look back at the validation efforts in which I've participated, I can't recall a single time when I was asked questions regarding the control system's limitations. Evaluating the limitations of such systems seems like fertile discovery ground to me, yet we usually seem to be focused on whether or not the machine does the job as described, rather than the unintended consequences of an operator merely following protocol(s), or ignoring clues as something goes awry. In summary form: simply because the car is equipped with airbags, anti-lock brakes and collision avoidance systems, doesn't relieve the driver from his/her utmost responsibility of operating the vehicle safely. But I'm sure there are those who see these technologies as providing license to do just that. But—having an idea of the systems' limitations might dampen their unwarranted enthusiasm, even if only a little.

We have come to rely so heavily on technology that it is easy to forget that it is people interacting with technology that make things happen. People are what keep it going. Machines, especially the more flexible ones, require people to perform changeovers, adjustments and analyses. With validated machines, the confines inside which these same people are allowed to operate are usually stringent and unambiguous. Our seemingly unabated confidence in technology has all but removed responsibilities formerly entrusted to personnel. And therein lies the problem.

When done properly, there is no doubt that technology is dependable and robust. Within its limitations, it serves well. But when conditions collude such that even the most creative author couldn't possibly have contrived the arrangement, we rely on the operators and users, rather than the technology to notice the problem. I could easily fill a short novel with unique and unlikely scenarios which I've personally witnessed—things such as a threaded cap finding its way into the most unlikely spot, fooling the machine into an incorrect reference point, but doing so inconsistently. Or the time where an actuator inexplicably performed actions that it shouldn't have. The results had all of the earmarks of a computer code problem, yet in reality it was an arcane combination of a faulty shielded cable, a loose connection on a motor and building service ground that together—presented a mixture where a formerly robust and dependable control system faltered miserably.

My research indicates that the FDA flavor of validation is rooted in the 1970's, when two individuals championed the idea in order to improve the quality of pharmaceuticals. Today we all assume that problem to be solved, and we confidently consume products to help us lead better, more productive lives. Validation efforts are generally performed such that they provide objective proof that the machine or device performs the job it was intended to perform. Objective proof is the operative phrase, such that an opinion is never the deciding factor. Good or bad, test protocols are written by real people who are often biased by their own positive and negative experiences. It takes a focused and experienced technical author to remain dispassionate while authoring specification and testing documentation.

Technology is almost always rule-based; add the human factor and we can approach perfection. Here's the take away: most police officers will tell you that a nosy neighbor is often better than any alarm system, but most fire department personnel will tell you that a monitored alarm system with smoke detectors offers the best protection. So, combining the technology of a monitored alarm system with the human qualities offered by a nosy neighbor will protect your house far more effectively than either one by itself.

Please keep this in mind during your next validation effort.