

Crash Course: Heat Sealers and Sealer Validation



First Step

A consistently reliable seal is the holy grail of a successful medical device launch and life cycle. Finding the right equipment, properly calibrated and validated, with optimal performance into the future is a major effort. It is also one of our personal favorite projects: helping clients set up and validate their in-house seal capabilities.*

** If your organization has not yet implemented or planned for sealer validation in house, this will help you nail your plan. If your heat sealer station is up and running, this will help you gauge the health of your process.*

Prepare for In-house Heat Sealing

Have a Plan. Selecting suitable equipment—and an experienced engineering partner—can go a long way to ensure a smooth validation. Knowing your existing process or understanding a future process is key.

Be Ready. Packaging Compliance Labs performs and oversees many in-house installations and validations. A common oversight can lead to disappointment—and delays, when the equipment arrives. Ensure that proper hookups and surfaces are installed and correctly placed prior to equipment selection and delivery.

Find the Right Heat Sealer

Packaging Compliance Labs engineers often look to Pennsylvania firm, Packworld USA, for custom, compact heat sealers. “We love the technology, the quality, the reliability of the PackworldUSA products. We’ve found their products to be matched by their customer service and quick response times in delivering us the right solution for each client setting,” stated Sarah Rosenblum of PCL. “PackworldUSA and Packaging Compliance Labs share a commitment to unexpected speed without compromising quality.”



PackworldUSA assembles their mainstay, smaller sized sealers to a certain point of completion, where universal construction ends and customization begins. Conversations with packaging engineers and the client finalize the specifications. The partially assembled sealers are then finished based on the customized specifications for the client application and setting.

If you are considering options for an in-house sealing station, an easy way to compare what you're getting is to look at similarly sized equipment. A smaller PackworldUSA heat sealing machine, such as model PW3416, weighs about 100 lbs. Other heat sealers might look about the same, yet weigh half that. This can indicate less robust components. While weight alone doesn't always signal quality, it is a factor in heat sealers. Quality can be indicated by weight and the size of the air cylinders, transformer and other operational components.

A particularly unique—and appealing—feature of PackworldUSA sealers is their temperature control technology.

Brandon Hoser of PackworldUSA explained, “Traditional thermocouple technology measures at a single point about the size of a thumbnail. If operators seal material on or off the singular point, you'll get different results. We use technology that doesn't rely on thermocouples. Our TOSS Technology with PIREG® temperature control has the ability to read and drive the temperature by interpreting the heat seal band itself. It acts as a large resistance temperature detector, knowing that X resistance = Y temperature, while measuring the whole length and width of the heat seal band. The benefit is a faster response, a precise result and more consistent heat seals.”

Packaging Compliance Labs finds value in the TOSS Technology. Rosenblum added, “Having confidence that equipment can quickly and sustainably establish and maintain the right conditions to produce consistent seals in sterile medical device packaging is a big deal.”

Understand Calibration

To really understand heat sealing temperatures of a machine, you need an independent NIST-calibrated device to verify what you think is happening. This is where thermocouples are needed. Hoser clarified, “While we do not need thermocouples to operate our machines, they are used as a calibration instrument.”

Thermocouple placement is important along with consistency in your process. The most accurate recording is obtained when the thermocouple junction is placed in the centerline of the heat seal band width. So if your heat seal band is 8mm wide, aim to place the junction 4mm in from the edge. The same can be said about what layer within the build up a thermocouple is placed. It could be put on the surface of PTFE tape which contacts the material or directly on the heat seal band. Whichever method, consistency is required to ensure the best results.

PackworldUSA's heat sealers get from ambient to sealing temperature within 400ms; however, thermocouples do not measure temperature this quickly. Even the quick response thermocouples take about 10 seconds to start stabilizing towards an accurate temperature reading, it is recommended running a 15-20 second dwell during temperature validation to ensure an accurate reading. A common mistake is trying to record temperature within a typical sealing time such as 2-4 seconds. Time and pressure are less tricky as there are ports on the machine which connect appropriate NIST calibrated devices.

Control the Process

User-friendly PackworldUSA touch screen controls were developed through customer feedback. They are able to run in 21 CFR Part 11 compliance. The compliance capability involves user-defined security access and data logging features. Far from fluff, ease of use and convenience save time and engage technicians more productively in their work.

Aiming for foolproof operation has less to do with distrust than practical reality. All humans make mistakes. When those humans are busy, stressed or interrupted, the risk of blunders grows. Better a few alarms than a massive setback or injury.

PackworldUSA sealers, for example, use two stages of air pressure when the machine is cycled. A low pressure of 5-7 PSI actuates the bars to a nearly closed position. Then, a much higher pressure is initiated for the sealing cycle once a limit switch is met. This ensures only film thickness materials can be inserted or else an alarm is triggered. This mitigates issues when the curious technician says, "Maybe I can heat seal my pen." For each run, set recipes that have been programmed into the machine ensure that only those authorized can make any change to the recipe. This protects all aspects of production and validation

Train your Team

Proper training is a must-have for anyone on your team who may interact with the seal process. Don't skip or skimp on your investment or your production floor's ability to produce compliant product.

Know your Application

And select your heat sealer accordingly.

A common misconception is that getting a big sealer is a better idea. For example, logic might ask, “Why can’t I seal these 4-inch foil pouches with my 36-inch sealer? I’ll have more versatility for big or small packages!” More often than not, it takes more than that to produce consistent quality with such a size discrepancy. Talk with an engineer about a properly scaled process and whether it could be made to accommodate your scenario. If it’s possible, then the exact criteria can be set. If not, you can rule it out without wasting time or produce and identify a more suited machine for the task.

Formalize the Process and Approach

Impulse heat-sealing technology is able to accommodate a broader selection of materials. But you’ve got to know the properties for each material and how those properties behave. Hoser explained, “If you seal a poly bag, you’ll likely experience constant heat fails. A cooling cycle is required in the process. The material must heat to its melting point. The sterile seal does not form until the molten portion solidifies. If the equipment opens prior to reaching the proper cooled temperature, the pouch or bag seal will shrivel. Not only is the seal unsuitable, it is visible. PackworldUSA impulse heat sealers incorporate a cooling cycle to mitigate operator risks such as handling the packaging before the seal is completely cooled.