Medical Molding: Revalidation of Injection Molding Processes Using Universal Setup Data

A validation strategy based on universal setup data and the four plastics variables can greatly reduce the cost of revalidation and ensure more consistent part quality.

Bob Reese • *Contributing Writer*

For many medical molders, the cost of revalidation prevents them from moving molds between presses. The result is high costs and inefficiencies in press use. This article will present strategies for dramatically reducing revalidation costs using universal setup sheets and in-cavity data. These techniques are used successfully by highly respected medical device manufacturers and custom molders.

In most injection molding applications, a mold is validated to run in a particular machine. Moving the mold to another press is often required for operational efficiency, but this usually requires revalidation. Depending on the application, revalidation can be very expensive. Costs include press time, material, engineering time, metrology and inspection, documentation, and in the event of a failure, the costs of repeating the entire cycle. When all of these costs are taken into account, it is not unusual for a revalidation effort to exceed $10,000.

In many cases, costs can dramatically be reduced through the use of universal setup data. The data usually is gathered through one of the following tools:

- Universal setup sheets based on machine independent setup parameters;
- Normalized stroke and injection pressure sensor data; and/or
- In-cavity pressure and temperature sensor data.

Traditional Revalidation Cycle

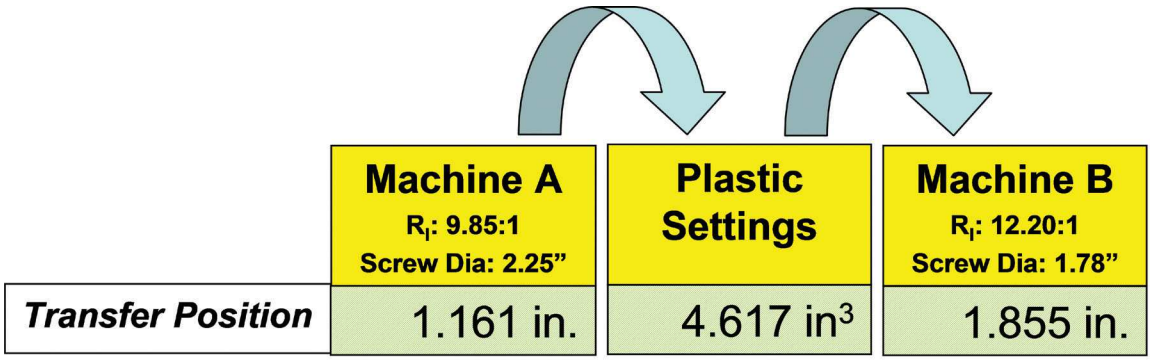
The traditional approach to revalidating a molding process closely follows the strategy for the initial process validation, and looks something like this:

- Installation Qualification (IQ): In simple terms, demonstrating that the press and auxiliaries have been installed, calibrated, and maintained properly.
- Operational Qualification (OQ): Here, a process is built on the new press, and process limits are defined. This often involves multiple trials and metrology. Designed experiments are used frequently here. While the processing conditions from the original press are referenced, in many ways the process is rebuilt from scratch.
- Performance Qualification (PQ): Parts are produced under normal production conditions to verify that the process will consistently produce acceptable product. A heightened level of part inspection generally is used to demonstrate part acceptability.

In the traditional revalidation cycle, the OQ and PQ both involve significant costs. It is important to note that parts from the PQ can be used for production once the revalidation is approved. However, if the revalidation fails, these parts must be scrapped, sorted or reworked, and the revalidation process starts over. This can add significantly to the cost of revalidation, making it even more important that steps be taken early to ensure success of the revalidation.

Revalidation Using Universal Setup Data

Revalidation of the process using universal setup data differs in



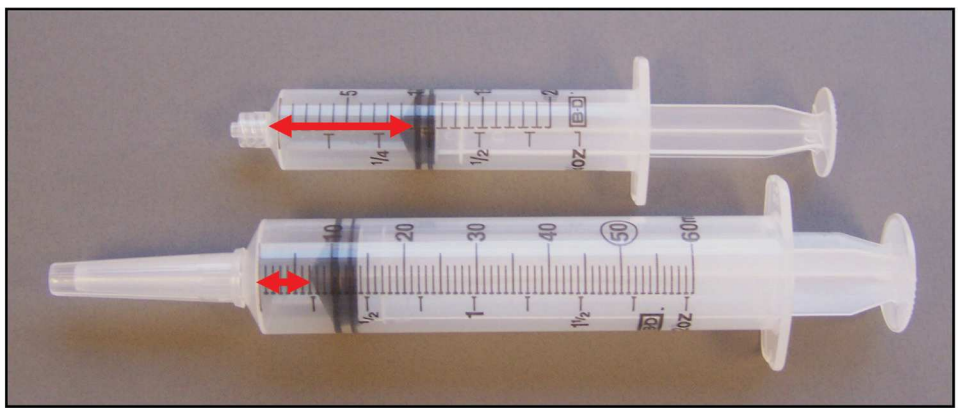


Figure 1: Linear screw movement can be converted to volume by multiplying times the cross sectional area of the screw. This is like using different-sized syringes to deliver the same volume.

two ways from the traditional revalidation.

First, during the IQ, the suitability of the press for the given mold is analyzed.

For example:

- The shot size should use 20 to 80 percent of the barrel's capacity to maintain control of shot size, fill speed, and melt consistency;
- The clamp should be adjustable to within 10 to 20 percent of that required for the mold to ensure full clamping without crushing vents;
- The mold should cover two-thirds of the distance between the tie bars to avoid excessive platen deflection;
- The injection unit should have enough fill speed to match the mold's fill time requirement, and a first stage pressure greater than that required to fill the mold;
- The press performance, such as load sensitivity and pressure response time, is sufficient;
- Any material dryer should have appropriate residence time; and
- The mold temperature controller should have sufficient volumetric flow to ensure adequate cooling.

By considering these factors as part of the IQ, the potential for successful transfer of the original process is greatly improved, and the risk of a costly revalidation failure is reduced.

Second, during the OQ, the original process is matched in terms of the four plastics variables instead of trying to build a new process. The concept is simple yet powerful: If the melt temperature, flow rate into the mold, plastic pressure in the cavity, and cooling rate are matched, we will get the same part. This is usually much quicker, and results in parts that more closely match the original process. Also, since we are matching the original process, the need for a full OQ is eliminated. Instead, we duplicate the original process and use the original OQ. This greatly reduces the time and cost of the revalidation.

Note that the PQ strategy is unchanged from the traditional revalidation. The PQ provides assurance that the part quality remains consistent. Again, if the revalidated process is approved, the parts made during the PQ can be accepted, and the most significant cost becomes the additional inspection performed during this stage.

How It Works: Matching the Four Plastics Variables

The core of this revalidation strategy revolves around matching the four plastics variables on any press in which the mold runs, and documenting the process in machine-independent terms.

Let's review these one at a time.

Melt Temperature:

This is the temperature of the melt as it's delivered from the injection unit into the mold. This can differ significantly from the barrel temperature settings. The best way to measure the melt tem-

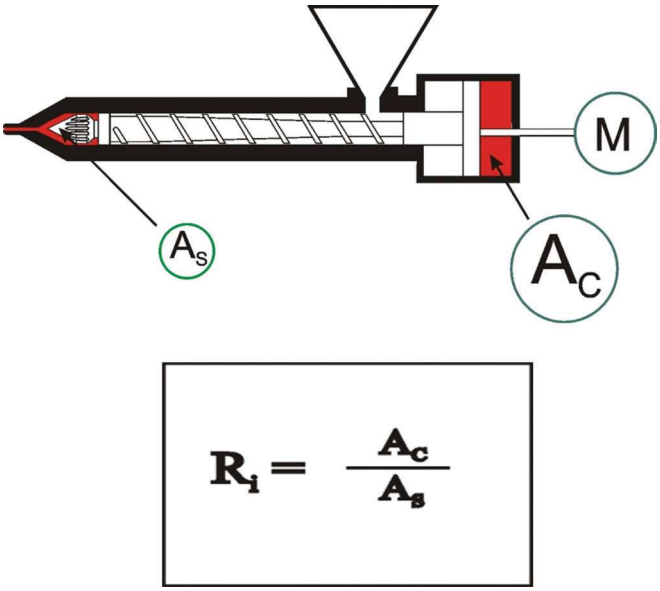


Figure 2: The intensification ratio (Ri) is multiplied by the hydraulic pressure to calculate the plastic pressure ahead of the screw.

perature is with a melt probe inserted into a purge collected from a continuously running cycle. Newer, low-mass probes make this possible without preheating of the probe. Using the melt temperature from the original process, the barrel temperature settings on the new press can be adjusted to match the melt temperature.

Flow Rate:

In its simplest terms, matching the flow rate means putting the same volume of material in the cavity in the same amount of time. The easiest way to match the flow rate from the original process is by matching the fill-only part weight and fill time. The fill-only part is created by turning off second-stage (hold) pressure. The resulting shot should generally be 95 to 98 percent full, and should match the size and weight of the fill-only part from the documented process.

It also can be useful to convert the linear shot size on the barrel to a volumetric measurement by multiplying it by the cross-sectional area of the screw. This also can be done with linear injection speed to convert it to volumetric fill speed. This can be used to closely match volumetric shot size and fill speed between presses. Figure 1 (on page 63) illustrates the concept of volumetric shot measurement.

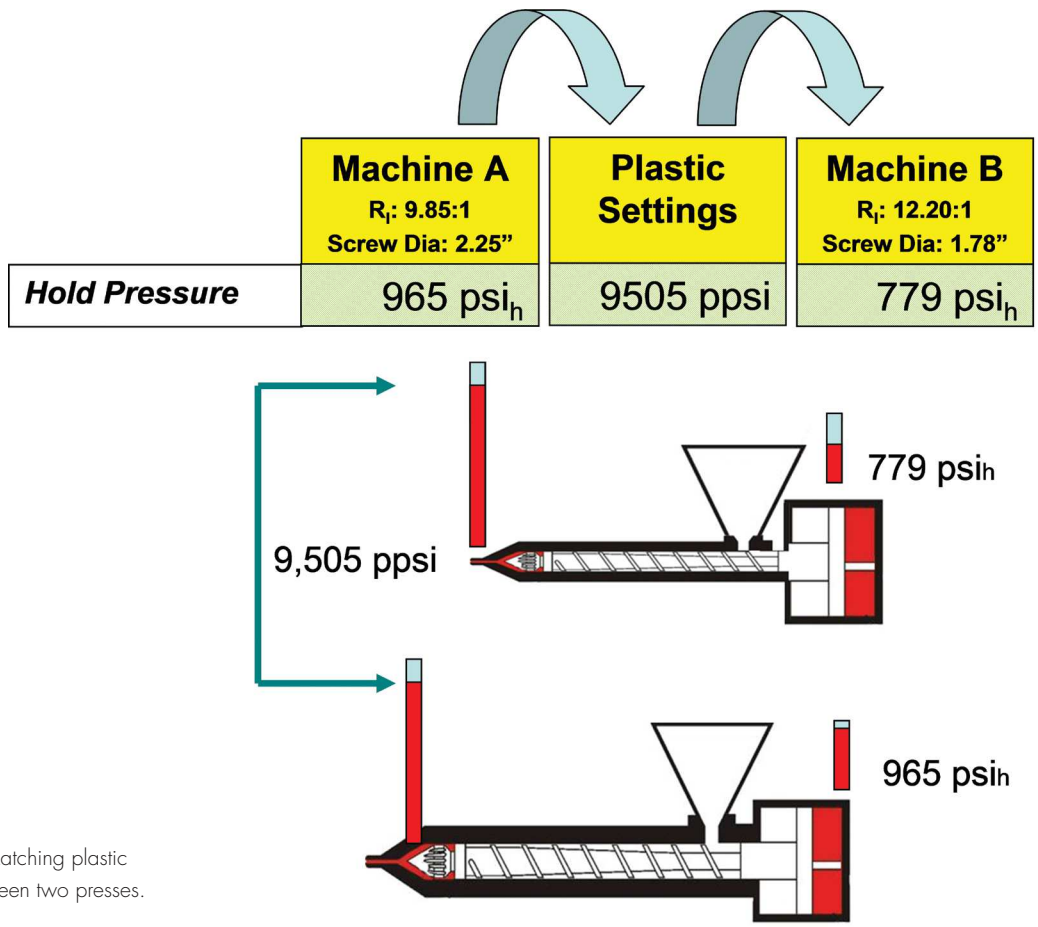


Figure 3: Matching plastic pressure between two presses.

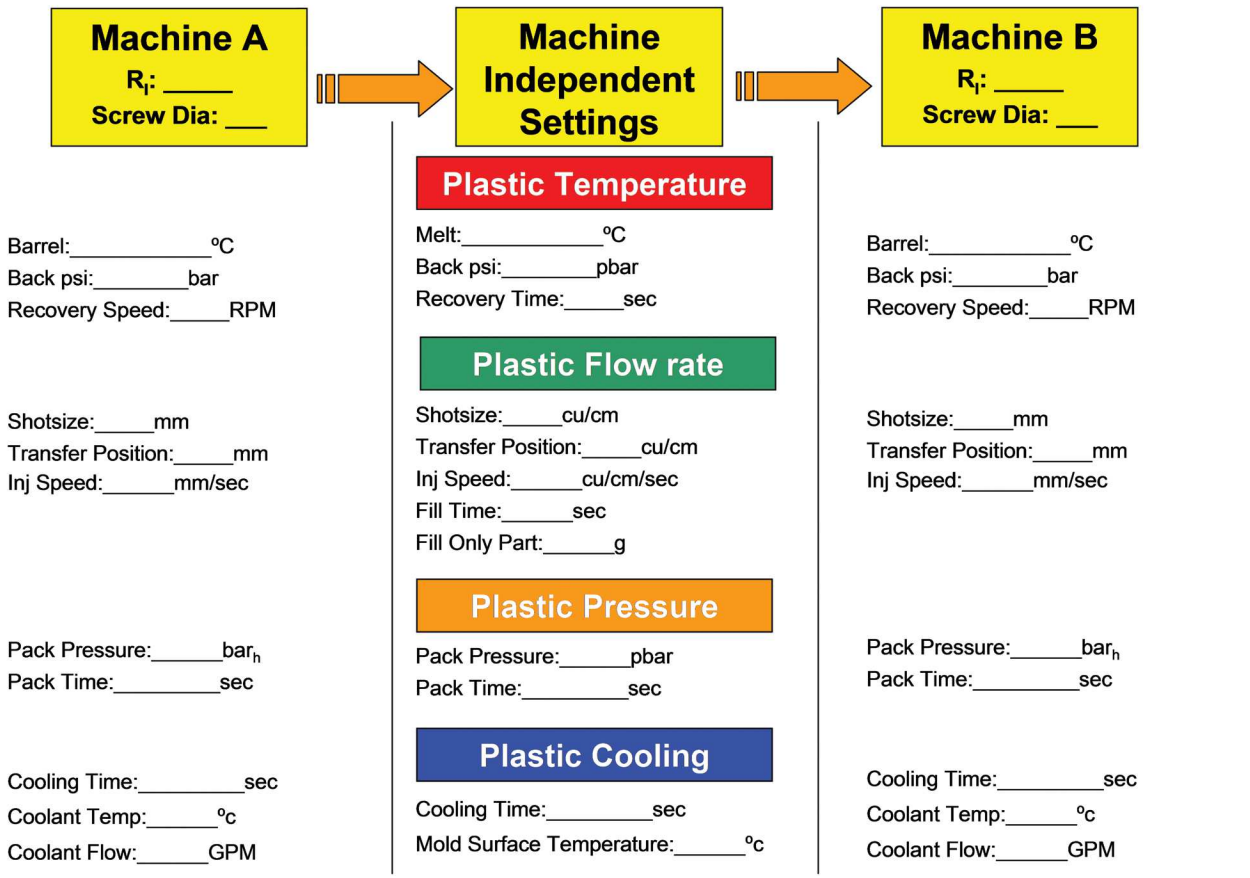


Figure 4: The machine independent setup sheet (center) is used to duplicate the process on another press by matching the four plastics variables.

Plastic Pressure:
After the cavity is full, it is pressurized to pack out the part. This usually is done during hold, using second-stage pressure. While most molds do not have cavity pressure sensors to measure the exact pressure in the cavity, matching plastic pressure inside the barrel usually is sufficient. While most electric presses convert injection force directly into plastic pressure in the barrel, on hydraulic presses the plastic pressure usually must be converted from the hydraulic pressure.

The first step in converting hydraulic pressure to plastic pressure requires calculation of the intensification ratio. The intensification ratio is the area of the injection cylinder divided by the area of the screw (see Figure 2). This is then multiplied by the hydraulic pressure to calculate plastic pressure in the barrel.

The second-stage plastic pressure from the original process is calculated from the hydraulic hold pressure setting used on the original press. Next, the plastic pressure is converted to the hydraulic pressure to be used for the hold pressure on the new press (see Figure 3). This can be repeated for backpressure as well.

Cooling Rate/Time:
The cooling rate is controlled by the temperature of the mold surface. The mold surface temperature can be measured by breaking cycle during production and quickly taking surface temperature measurements using a surface temperature probe. The surface temperature can be taken on the original process, then matched on the new press.

The Universal Setup Sheet

The universal setup sheet documents the process using the four plastics variables (see Figure 4). Using this setup sheet, the process can be duplicated on another press. The universal setup sheet is created by converting the press settings from the original process into machine-independent settings. Then the machine-independent settings can be converted into settings to be used on another press.

Because the process is being matched during the mold transfer, it is not necessary to perform a separate OQ when revalidating the process on another press. This saves considerable time and cost.

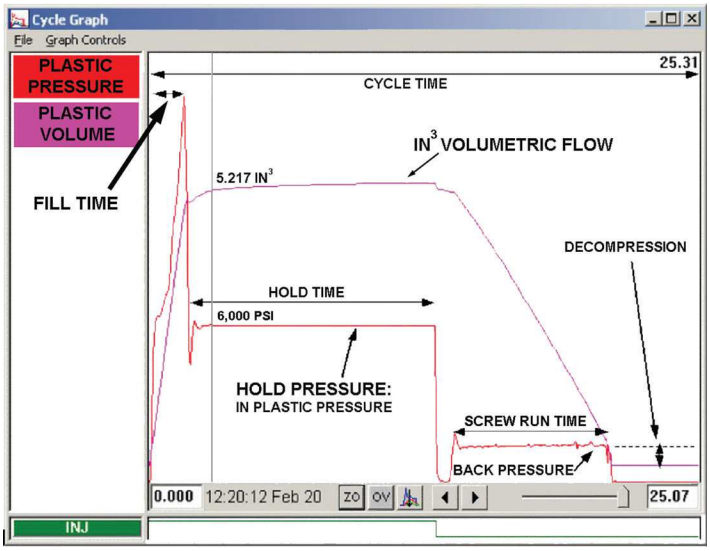


Figure 5: An example of some of the information contained in normalized stroke and injection pressure data.

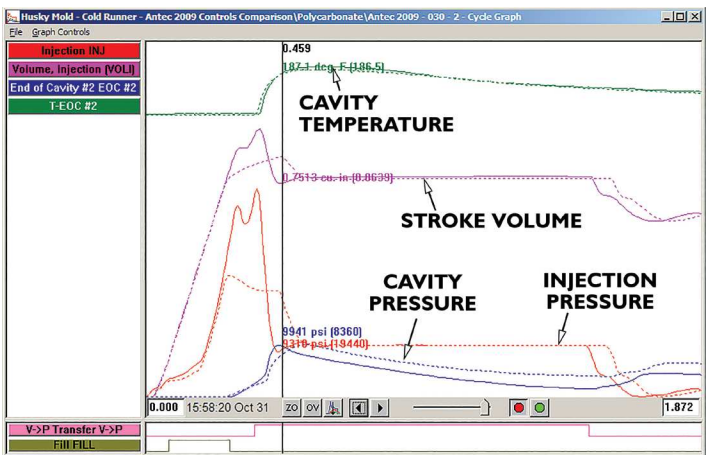


Figure 6: An example of cavity pressure and cavity temperature data. Note in this thin-walled part example that the cavity pressure and cavity temperature data match the original "template," producing a part consistent with the original process. To do so, the stroke and injection pressure have had to deviate.

Normalize Stroke and Injection Pressure Data

Much of the information contained in the universal setup sheet is contained in normalized stroke and injection pressure data. This data is read from a stroke sensor that measures the position of the screw during injection, and from a hydraulic sensor that measures pressure in the injection cylinder. For electric presses, the data from the load cell on the screw is used.

Volumetric stroke data is calculated by multiplying the linear stroke data by the cross sectional area of the screw. This is used to measure the volumetric flow rate and the total volume of material delivered during injection. Hydraulic pressure is multiplied by the intensification ratio to calculate plastic pressure.

The types of information contained in normalized stroke and hydraulic data are shown in Figure 5. This can be used in place of the universal setup sheet for many settings. However, melt temperature and cooling rate data must still be measured separately.

In addition to the universal setup information, the normalized stroke and injection pressure data contains useful information about pressure response, as shown in Figure 6. It also can be used to detect problems such as pressure limited filling or load sensitivity.

The Role of In-Cavity Data

For most molds, the universal setup sheet, along with normalized stroke and injection pressure data, are sufficient for duplicating a process on another press. However, for 10-20 percent of the most challenging molds, in-cavity data is needed to fully match the four plastics variables and thereby match part quality.

Two types of sensors are useful for gathering in-cavity data. The cavity pressure sensor provides precise information regarding pressure and flow rate, as well as indirect indication of melt temperature and cooling rate. The cavity temperature sensor provides precise information regarding mold temperature and flow rate, as well as indirect indication of melt temperature. The cavity temperature sensor provides very little information regarding pressure inside the mold.

Matching in-cavity data provides the greatest assurance of producing identical parts when a mold is moved between presses.

Summary

A validation strategy based on universal setup data and the four plastics variables can greatly reduce the cost of revalidation and ensure more consistent part quality. These techniques have been used for years by some of the most respected medical device manufacturers in the world, and have withstood the scrutiny of audits. ❖

Bob Reese graduated from Tarrant County College in Fort Worth, Texas, with an associate degree in business management and industrial electronics. In addition, he has completed numerous training sessions on injection molding machines, shop floor and facilities management, hydraulics and ISO internal auditing. Reese has completed the RJG Master Molder Certification Program and the Train the Trainer Certification Program and is an RJG consultant/trainer. Reese worked with RJG staff and products for many years during his employment with Perlos Inc., where he designed and implemented robust repeatable processes to produce thin-walled plastic components. He has done extensive machine testing to evaluate molding machines for accuracy and repeatability. During his time in the industry, Reese has been responsible for day-to-day production activities, including injection-molding parts, part decoration and assembly. In addition, he has worked on mold design projects and was responsible for approving tool designs prior to manufacture. Reese has more than 30 years of hands-on experience in the injection-molding industry.

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