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Laser and Resistance Welding - Process Validation Fundamentals-1
By David Steinmeier

Process Validation Definition
Microjoining "Process Validation" is the act of verifying the entire laser or resistance welding system by *independent* measurements. Process validation is also known as "Process Qualification". Validation seeks to ensure that the welds produced by the welding system fall within the quality limits specified by the manufacturer or the consumer.

Why Validate?
There are three major reasons for validating the welding process:

One, for medical product manufacturers, the Food and Drug Administration (FDA) *requires* that all manufacturing processes and equipment be validated on a periodic basis as part a company's "Good Manufacturing Practices" or "GMP".

Two, for Six-Sigma manufacturers, there is *no* laser or resistance weld monitor or checker on the market today that can separate bad welds from good welds to a 100% confidence level. The only known means of determining weld quality to a 100% confidence level is to destructively test every weld joint by tensile, shear, or cross-section, leaving no product available for shipping to customers. Validation can establish a measured confidence level in the weld joint quality.

Three, validation is a good marketing tool. Manufacturers capable of proving their joining quality level to their customers have a substantial advantage over their competition.

Validation Components
Four major components comprise the validation process as shown in Figure 1.

- Verify equipment calibration.
- Optimize the welding process.
- Correlate the weld strength.
- Set weld window limits.

Validation Timetable
Each validation component requires verification or re-verification on a periodic basis as shown in Table 1. Note that any significant design or manufacturing process changes requires complete re-validation.

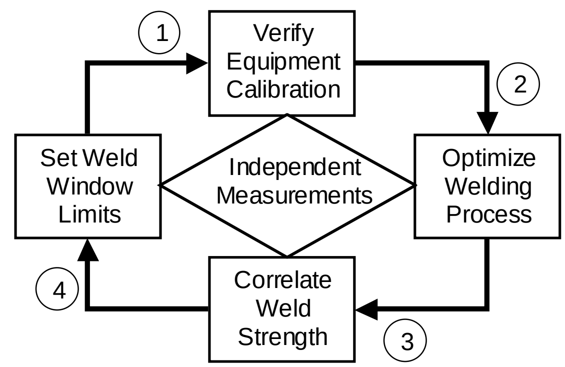

Figure 1 - Validation components.

Validation Components	Process Development	Periodically	Yearly	Process Changes
Calibration	✓	✓	✓	✓
Optimization	✓			✓
Correlation	✓	✓		✓
Limit Setting	✓			✓

Table 1- Validation timetable.

Step 1 – Verify Equipment Calibration
Welding and monitoring equipment factory specifications must be verified before developing the welding process. Assuming that the factory calibration on new welding or monitoring equipment is correct, could lead to costly development process errors. Certified *factory independent technicians*, using measurement instruments that are NIST traceable, should perform all calibrations.

If the equipment parameters fall within the factory specifications, the equipment can be tagged as calibrated. The calibration tag must include a date code indicating the next factory recommended calibration date. If the equipment is out of specification, re-calibrate and tag immediately.

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Step 2 - Optimize the Welding Process
Use the Design of Experiment (DoE) process to identify and optimize the key welding variables. For a detailed description on how to use the DoE process, please retrieve the DoE microTips for laser and resistance welding at: http://www.microjoining.com/microTip_Library.htm.

Figure 2 shows a typical microjoining response surface generated during the optimization process.

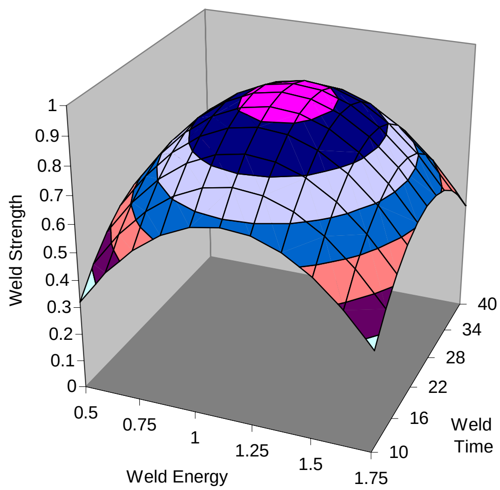

Figure 2 - DoE generated response surface.

Step 3 – Correlate Weld Strength
Based on your target weld quality confidence level, use a sampling table like MIL-STD-105 to establish the total welds required and the maximum permissible failures. Try to use a total welds number that represents your desired lot run quantity without cleaning resistance welding electrodes or the laser focusing lens during the lot run.

Collect electrical and mechanical welding parameters for each weld. Resistance welding parameters include peak weld current and voltage, dynamic force, and part displacement. Laser parameters derived from the focusing lens include peak and average power. Tensile or shear test each weld sample using test fixtures and automated testing equipment to minimize measurement errors and measurement variations.

Correlate the weld parameter data with the tensile or shear test data. *Important* – Extrapolating the correlation study results beyond the range of the weld study is invalid due to continued electrode oxide buildup and focusing lens contamination. Figure 3 shows a scatter plot and regression line for 200 resistance welds.

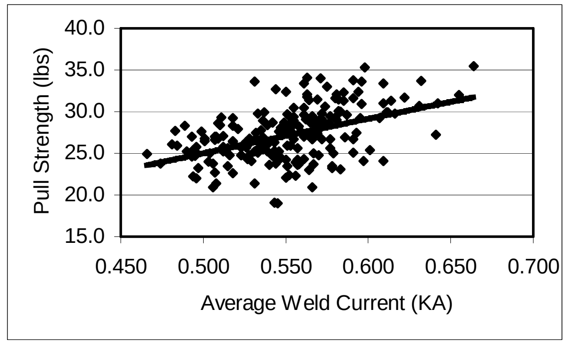

Figure 3 – Weld data from a 200-weld correlation study.

Step 4 – Set Weld Window Limits
In order to set weld window limits, weld quality must first be defined for the product in terms of how the product will be used by the end customer. For example, the product represented in Figure 3 is not subjected to any severe environmental conditions. However, the customer can drop the product numerous times. Drop testing the product produced a minimum weld tensile strength requirement of 12 lbs, which corresponds to a 6.3 sigma process control level. Arbitrarily raising the minimum weld strength to 20 lbs to ensure a higher “safety margin” reduces the sigma level to 3.8, resulting in lost profit by rejecting good parts.

Based on the actual data in Figure 3, the lower weld current limit can be safely set to 0.450 KA and still ensure that the weld quality never falls below 12 lbs. To prevent electrode sticking to the parts, the upper weld current limit should be set to 0.650 KA.

For laser welding applications, the lower limit should be based on the minimum peak power required to maintain weld quality. The degree of acceptable weld splash or expulsion determines the peak power upper limit setting

Conclusion
Validation is no longer limited to the realm of medical product manufacturing. Six-sigma oriented manufacturers are quickly discovering the economic benefits of establishing and maintaining validation over their resistance and laser welding processes.