Introduction

The resistance welding world encompasses a wide range of applications and part sizes. Within this unique world, competition for securing new orders and retaining existing business is increasing, especially in a down economy. One way to provide a competitive edge is to validate your resistance welding process. The automotive and medical device sectors have a long history of using the validation process. To ensure consistent resistance welding quality, the automotive companies require proof of resistance welding validation from their automotive sub-system suppliers. In addition, the Federal Food and Drug Administration (FDA) requires medical device manufacturers to validate all processes used to manufacture a medical device. Both sectors essentially employ the same validation process, but use different labels for each validation component. While this article uses a battery pack example to illustrate the resistance welding validation process, this basic validation process is applicable to all resistance welding applications regardless of the part size.

Validation and Verification Definitions

The terms *validation* and *verification* are often used interchangeably, but have very different meanings. *Validation* ensures that the <u>right product</u> was made. *Verification* ensures that the <u>product was made right</u>. FDA 21CFR820.3 provides the following detailed definitions:

Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fullfilled[1].

Process Validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications[2].

Design Validation means establishing by objective evidence that device specifications conform with user needs and intended use(s)[3].

Verification means confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled[4].

Why Validate?

There are four major reasons for validating the welding process:

One, for Six-Sigma oriented manufacturers, there is no resistance weld monitor or checker on the market today that can separate bad welds from good welds to a six-sigma confidence level. The only known means of determining weld quality without destroying 100% of the finished product is to validate the resistance welding process.

Two, for medical device manufacturers, the FDA mandates that all manufacturing processes and equipment be validated as part of the company's Quality System Regulation (QS)[5].

Three, the improvement to process yield through the reduction of product scrap and field failures far outweighs the cost of validating the resistance welding process.

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

Validation Components

The validation process consists of eight main components, beginning with the design process and ending with the product performance validation. See Figure-1.

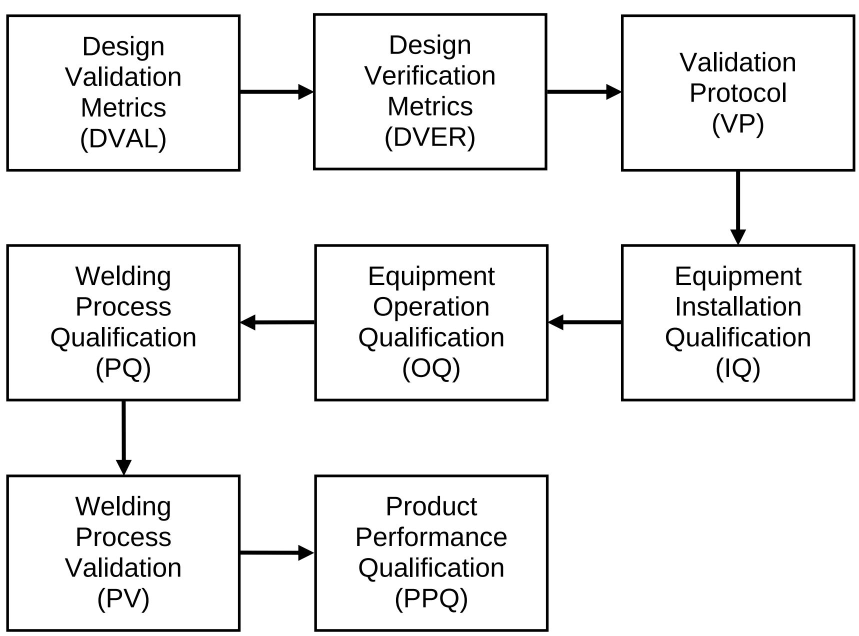

Figure-1, Validation Components

Design Validation (DVAL)

DVAL process begins with selecting the design validation metrics[6]. Design validation metrics should represent the stresses subjected on the final product by the end user. For example, a rechargeable power tool battery pack contains multiple parallel gap spot welds connecting individual battery cells together using nickel or nickel plated steel connecting straps to form a complete battery pack. See Figure-2.

Using excessive weld heat can damage the electrical properties of each cell and the complete battery pack. Vibration encountered during shipping can cause separation of the connecting straps from the battery cells if the spot welds are weak. Once the battery pack is in the user's hands, the user will undoubtedly drop the battery pack onto a hard surface multiple times, subjecting the spot welds to a high impact force. Thus for the resistance welded battery pack, there at least three quantifiable validation metrics that depend on the resistance welding process, electrical properties, vibration, and impact.

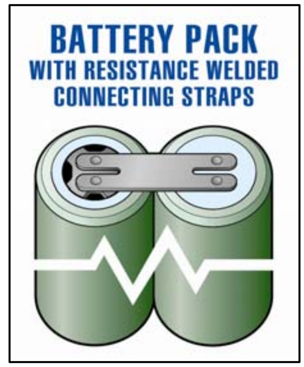

Figure-2

Design Verification (DVER)

DVER encompasses selecting verification metrics[7] that potentially correlate with the DVAL metrics. Note that it is impossible to establish high or low verification metric limits at this point in the overall validation process before conducting the Process Qualification (PQ) and Process Validation (PV). Establishing process limits before developing the welding process will result in unnecessarily scraping a large amount of useful product. To optimize and verify the resistance weld, use a quantifiable destructive test method such as a shear, tensile-shear, peel, or a fatigue cycle test. Note that a cross section of the weld will provide information about the bond type, but not the weld strength.

Using the battery pack example, there are several test options based on the physical limitations of testing the battery pack welded connections. Tensile testing is usually not very practical for a battery pack since there is limited connecting strap material to grip. Shear testing requires expensive shear equipment to precisely control the height of the shear tool in relation to the battery cell surface. The easiest option is to perform a 90° peel test. 90° peel testing the spot welds on each connecting strap requires isolating each spot weld. Cut each connecting strap in half and then cut each strap down the strap centerline in order isolate each spot weld. See Figure-3.

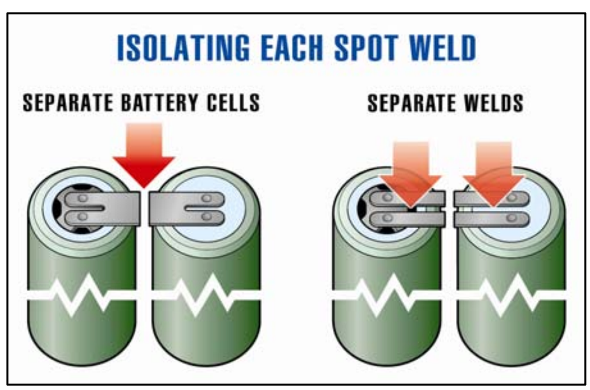

Figure-3

Carefully bend one cut section 90°, protecting the two spot welds with a metal bar so the two welds will not be stressed during the bending process. See Figure-4. Peel testing each weld separately provides quantitative weld strength information for optimizing and verifying each weld compared to peel testing both welds simultaneously. The PV validation step will determine the minimum 90° peel test magnitude necessary to ensure a successful resistance welding process validation.

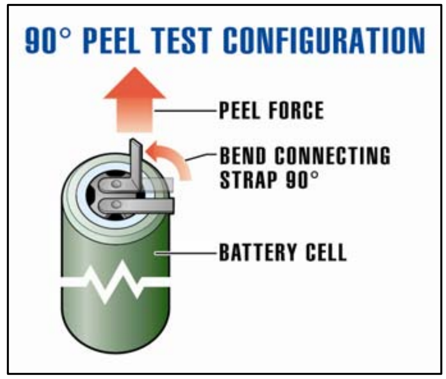

Figure-4

Validation Protocol (VP)

VP requires writing a validation protocol before starting the validation process. Validation protocols differ between industry sectors such as the medical device and automotive industries, but have the same basic components. Validation protocols also differ between manufacturers within the same industry sector. Figure-5 contains a comparison between the medical device and automotive sensor manufacturing validation steps.

Medical		Automotive	
Installation Qualification	IQ	Equip Set Up	-
Operation Qualification	OQ	Equip Dry Run	-
Process Qualification	PQ	DoE, Optimization Confirmation	MQ1.0 MQ1.5 MQ2.0
Process Validation	PV	Confirmation	R-R
Performance Qualification	PPQ	Environmental Tests	P-PAP

Figure-5, Medical device and automotive sensor industry validation steps

Equipment Installation Qualification (IQ)

IQ involves setting up the equipment in accordance with supplier installation drawings and specifications and verifying equipment calibration. Repeat the IQ after moving or relocating equipment. Set up includes verifying that the resistance welding power supply is connected to the correct mains voltage source using the manufacturer recommended wire diameter size over the connection distance. Insufficient mains connecting wire size can result in weld current, voltage, or power alarms on feedback controlled resistance welding power supplies. Non-feedback controlled power supplies may not provide the user with any alarms should the weld energy drop during the welding process.

Weld cables connecting the power supply transformer to the weld head in small scale welding can be a major source of energy loss over time, particularly if the weld cables are subjected to robotic motion. It is good practice to make a 4-terminal electrical resistance measurement of each weld cable after the cable installation as a baseline comparison when troubleshooting. For large scale weld head installations using copper bus bars and copper flexures instead of weld cables, verify that all bolted connections are securely tightened.

Verify that the air supply line feeding a pneumatic weld head is sized in diameter and length per the manufacturer's recommendation. An undersized or excessively long air supply line will result in poor weld head inertia follow up capability. Finally, verify that any welding fixtures and tooling properly support the weld parts and ensure a consistent part-to-electrode tip alignment within the specified product assembly tolerance.

It is very important to perform a calibration check at the beginning of the validation process. This step may be as simple as verifying the information on a calibration certificate from the welding equipment supplier to ensure that the welding equipment is still in calibration. Some six-sigma manufacturers insist on performing their own calibration check at the beginning and end of the validation process. For those manufacturers performing their own calibration measurements, use calibrated test equipment that is traceable to a known standard and has a resolution that is twice the smallest resolution of the measured parameter. Use a traceable standard power load when measuring the weld current, voltage, or power.

Operating Qualification (OQ)

OQ establishes manufacturing procedures and records for equipment calibration, cleaning, operation, and maintenance. The OQ also includes operator training procedures and records. Identify important welding equipment parameters that can affect the weld. The OQ does NOT qualify or validate the welding process. For a resistance weld, the most important welding equipment parameters are weld energy, time, and force. Verify that the entire welding system produces the programmed welding parameter magnitudes over their projected operating ranges on a repeatable basis and append the data to the OQ procedure. In the automotive sensor industry, the OQ may also involve operating an automatic welding station without weld energy or parts for a 24-hour "dry run".

Most weld heads do not come with a force calibration certificate relating actual weld force at the electrode tips to the programmed weld force setting, such as the input air pressure. Therefore, as part of the OQ process, measure the weld head static and dynamic forces using a calibrated load cell. Dynamically measuring the weld force can reveal an unwanted impulse force, which can negatively affect the resistance welding process. Gather dynamic weld force data using a sampling technique, where the sampling rate must be twice as fast as the smallest power supply weld time increment. For example, a minimum weld time of 1-ms requires two weld force data samples during the 1-ms weld period. Thus the sampling rate is 2-KHz. Figure-6 shows the weld head static force curves for both the right and left electrode used in the battery pack parallel gap resistance welding example.

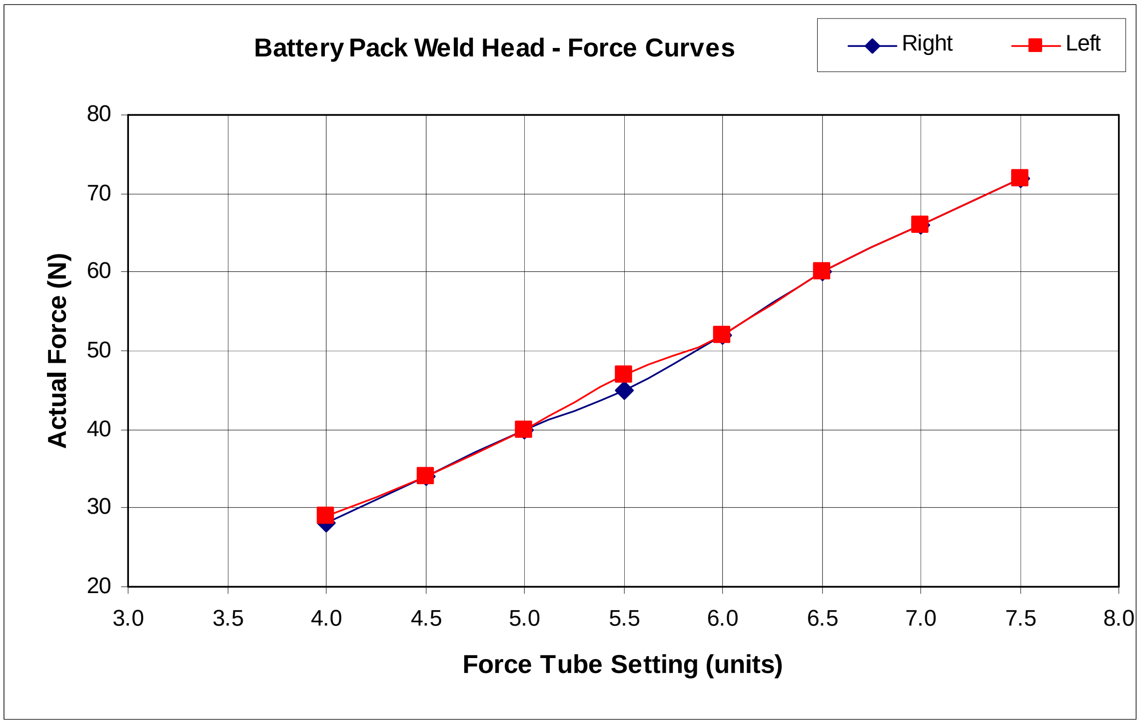

Figure-6, Weld head force curves

Process Qualification (PQ)

PQ involves discovering the important welding parameters, optimizing the welding parameters, choosing the lot run and sample sizes, and conducting a series of confirmation runs.

Discovery – Conduct a Taguchi L9, L12, or L18 Design of Experiment (DoE) to find out which welding parameters affect the chosen DVER weld verification metrics[8]. The Taguchi DoE method quickly identifies the most important welding parameters with minimal parts.

Optimization – Optimize the welding parameters using the DoE results. Note that the Taguchi DoE model can't identify welding parameter interactions and therefore may not produce the best optimized DoE results. If the results of the Taguchi DoE models are not satisfactory, eliminate the insignificant welding parameters and then conduct a full-factorial DoE using a maximum of four welding parameters. A full-factorial DoE will reveal welding parameters interactions and the optimized weld parameter values. Figure-7 shows the interaction results on 90°peel strength for just one spot weld. Note the strong interaction between weld force and time and weld force and current. For the single spot weld shown in Figure-7, use a weld force of 50-N, a weld time of 10-ms, and a weld current of 2.1-KA. Repeat this optimization process for the remaining battery pack spot welds.

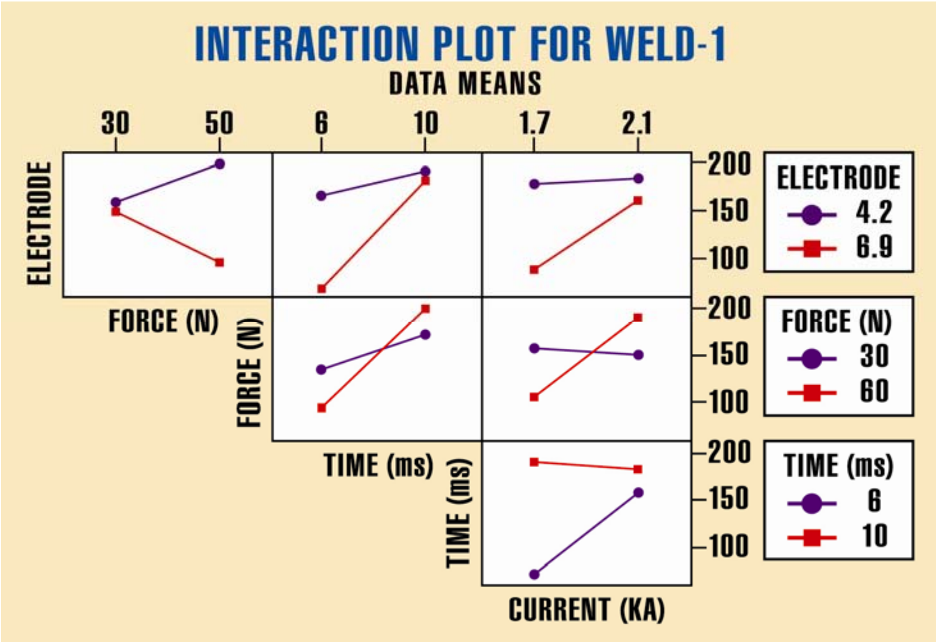

Figure-7, Interaction Diagram for one Battery Pack Spot Weld

Lot Run and Sample Sizes - Select the lot run and the sample sizes[9,10]. A true sampling plan for determining sample size based on the lot run size is rarely implemented. Unfortunately, sample size selection is usually based on:

- "We have always done it this way before"
- "A sample size of 30 sounds like a statistically significant number"
- "Inspect 2-samples at the beginning and end of each lot run"

Use a statistically significant variable data sampling plan from MIL-STD-414[11] or ISO-3951[12] to measure the process capability. Resistance welding electrode tips wear and oxidize over the lot run and may negatively affect the DVER metrics. Capture differences between vendor supplied weld parts by using a separate lot run for each vendor. Figure-8 is representative of a typical resistance welding process over time. Within the first group of 30-parts, the weld quality metric, x-bar, is relatively high and the distribution fairly tight. After welding more than 30 parts, the electrode tips mushroom and become contaminated with plating and oxides. The total population or lot run weld quality metric, µ, decreases in comparison to the 30-part weld quality metric, x-bar. In addition, the total population distribution is much wider than the limited 30-part sample. Neither population follows a perfect Gaussian distribution so there is no value in using an upper control limit. Setting the Lower Control Limit (LCL) based on the 30-part sample will result in an unacceptable Cpk for the total population since the LCL is inside of the total population distribution.

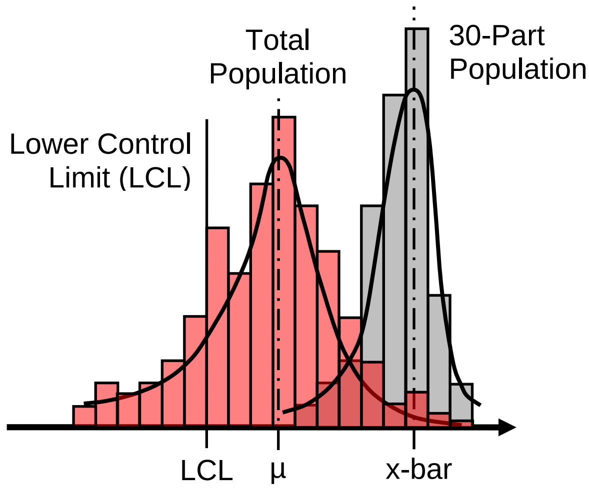

Figure-8, Typical Resistance Welding Distribution over Time

Confirmation Runs – Establish the capability of the welding system by making real parts at your automation vendor's facility before transferring the welding process to your own manufacturing facility. Conduct the confirmation run using one of two protocols.

Protocol 1 – Weld one or more lot runs making no changes to the welding parameters during the confirmation run. For the battery pack example, collect PQ data using DVER metrics such as the peak or RMS weld voltage, current, force, displacement, and 90° peel strength for each weld. Retain a statistically significant sample of complete battery packs for measuring the Process Validation (PV) data that include measuring the electrical parameters for each welded and packaged battery pack before and after subjecting the battery pack to a specified number of tumbling cycles. The tumbling test simulates the impact forces encountered during shipping and handling. To conduct a tumbling test, place completed battery packs in drum that rotates about a horizontal axis. The drum speed affects how the battery packs impact each other and the inside surface of the drum.

Protocol 2 – Weld one lot run using welding parameters that represent a low weld energy condition. Weld a second lot run using welding parameters that represent a high weld energy condition. Collect the same data required in Protocol 1.

Data Analysis – Test PQ lot run consistency by using the appropriate statistical metrics to mathematically verify process consistency. If multiple lot run populations are not statistically identical, then there is a difference in the part quality between vendors, operator methods, or automation stations. Do not set process limits at this time since correlation has not been established between the PQ data and the PV data.

Process Validation (PV)

PV establishes that the welding process consistently produces a part or product meeting its predetermined specification. PV involves correlating the PQ data with the PV data. In the case of the battery pack example, look for correlations between the PQ weld voltage, current, force, displacement, and the 90° peel test data with the PV data, comprising battery pack electrical parameters and tumbling cycles.

Unfortunately, the weld voltage, current, force, or displacement PQ data did not correlate with the PV data, so monitoring these parameters does not provide a viable method of ensuring resistance weld quality during production. However, the 90° peel test PQ data correlated directly with the PV tumble cycling failures. Below a minimum 90° peel test value, some connecting strap welds within the welded battery pack separated from one or more battery cells during the PV tumbling cycle test. A close examination of the failed battery packs revealed that the failures occurred near the end of the lot run when the electrode tips increased in diameter (mushrooming) and contained a high degree of connecting strap material. To set the LCL value, find the minimum 90° peel strength value within the lot run population of non-failures and use the minimum value for the LCL. In addition, reduce the manufacturing lot size to eliminate the possibility of connecting strap failures caused by electrode tip wear.

Thus, the resistance welding process was validated by documented evidence that resistance welding consistency could be assured by 90° peel testing welded battery packs using a statistically significant sampling plan and then comparing the results against a proven Lower Control Limit (LCL) value and by limiting the manufacturing lot size.

Product Performance Qualification (PPQ)

PPQ establishes with documented evidence that the finished product meets all requirements for functionality and safety. PPQ incorporates a series of environmental tests used to simulate the operating environment of the finished product. PPQ environmental tests include, but are not limited to: life cycling, temperature, vibration, humidity, impact, and shipping. Assuming that no failures occur, the product is considered to be validated. Should weld failures occur during PPQ, the basic product design for weldability, DVER metrics, or DVAL metrics are potentially faulty.

Conclusion

Resistance welding validation is no longer limited to the realm of medical device or automotive sensor manufacturing. Validation is a proven systematic method to improve process and product quality, reduce product scrap and field failures, and enhance the competitiveness of your product. Six-sigma oriented manufacturers are quickly discovering the economic benefits of establishing and maintaining validation over their resistance welding processes.

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