Medical Device Manufacturing

Ensuring High Quality Resistance Welds without the Need for Destructive Pull-Tests

WELD TEST APPLICATION NOTE SERIES

Challenge

How can the costs and risks associated with destructive pull-tests be eliminated?

Resistance welding is commonly used in medical device manufacturing to join two metal subcomponents together. In many cases the integrity of this joint is critical to the long term reliability of the device, such as, for example, the attachment of a wire lead within a pacemaker. For many implantable devices a product failure may ultimately be fatal to the patient. This makes it essential for the manufacturer to be able to verify the quality of the weld to ensure that defects are caught before their products are shipped. However, because of the nature of the welding process and the small dimensions of the parts involved, it is difficult to use visual inspection or other conventional methods to identify defects. Most means of evaluating the integrity of the bond, such as pull tests, result in the destruction of the joint and therefore are not suitable as in-line production screens. As a result, manufacturers generally rely on careful validation and tight process controls in combination with periodic sample checks to ensure the quality of their products.

The risks associated with this approach are significant. Perhaps most importantly, there is no direct data collected on the actual finished product to verify the robustness and long term quality of the welded joint. Instead, a sampling of parts from the same lot or batch is subjected to destructive tests to determine if the weld process meets strength and durability requirements. If the failure rate is sufficiently low in the test samples, the rest of the parts are assumed to be of good quality and are released for shipment. However, this does not ensure that no failed parts will be shipped, merely that the statistically predicted failure rate is acceptable. Unfortunately, if the process drifts out of control or if the sample size is insufficient to accurately represent the lot characteristics, a significantly larger field failure rate can occur. In such cases, it is impossible to identify which individual parts would be affected and the entire lot would need to be recalled and scrapped. Such an event would also expose the manufacturer to the potentially much larger liability associated with class-action lawsuits and FDA sanctions.

Clearly the traditional destructive testing approach is limited in its ability to ensure quality and provide adequate protection for both the manufacturer and consumer. While it is difficult to evaluate the quality of the joint once the weld process has been completed, it is possible to characterize the process itself by monitoring key process parameters while the joint is being welded. This produces a series of characteristic curves, called 'process

Typical Defects in Resistance Welds

- **Expulsions** – Overheating causes the metal to overheat and burst out of the weld zone.
- **Electrode Force** – Too little force can result in insufficient contact between the two metals to form a proper bond, while too much force can reduce interface resistance and alter the resistance heating profile
- **Burned Materials** – Materials can be burnt (i.e. oxidized) due to high energy exposure
- **Weak Bonding** – Materials may be insufficiently bonded due to low energy exposure
- **Electrode Conditions** – Oxidization (cleanliness), shape and alignment of the electrode correlate to the processes ability to achieve a perfect force area/mapping and electrical connection. The quality of the electrode also affects the energy profile.

the science of quality

signatures', which can be analyzed to reveal process deviations that result in defective parts. These can then be used to directly screen every part in real-time on the production floor to ensure that every welded joint is robust, providing the manufacturer with a detailed test record for each joint in every part that is shipped to a patient.

In a typical resistance weld application, a joint is formed by passing an electric current through the junction between two metal parts, where the local resistance generates enough heat to melt one or both metals. The current is supplied by means of a highly conductive electrode that presses down on the parts with a prescribed force. Two typical arrangements are illustrated in the figure below. Process signatures can be collected by installing a Sciemetric sigPOD PSV monitoring solution to measure the electric current and voltage, the force applied by the electrode, and its position. These high performance process monitors are able to accurately record each of these variables at a high sampling rate, which is important when the duration of the entire weld process is often measured in milliseconds. This provides the resolution necessary to capture all of the subtle features that may be correlated to the formation of defects during the weld process. These measurements produce a series of weld 'signatures', as shown in the figures below. From this set of basic curves, we can generate a series of secondary curves, including electrical power vs. time, resistance vs. time, and force vs. distance.

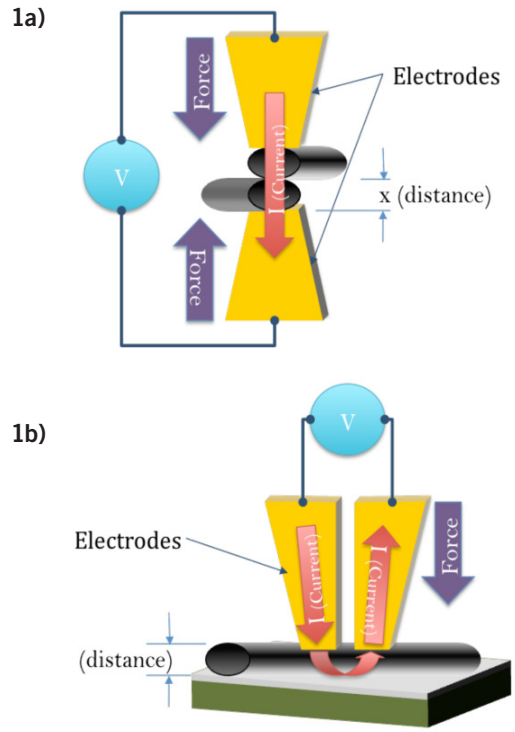

Figure 1: Illustration of two resistance weld configurations, for (a) welding two wires, and (b) for welding a wire to a printed circuit board (PCB).

2a) Voltage vs. Time **2b) Current vs. Time** **2c) Force vs. Time** **2d) Distance vs. Time**

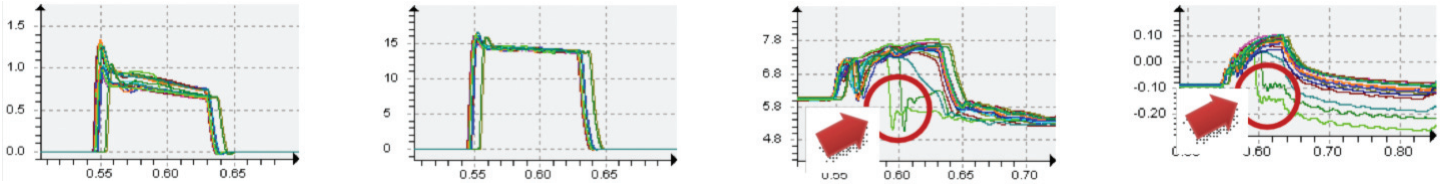

Figure 2: Typical process signatures obtained from a resistance welding process: (a) voltage vs. time, (b) current vs. time, (c) force vs. time, and (d) distance vs. time. The signatures from defective welds are clearly distinguishable in the Force vs. Time and Distance vs. Time plots, as highlighted by the red circles.

3a) Electric Power vs. Time **3b) Resistance vs. Time** **3c) Force vs. Distance**

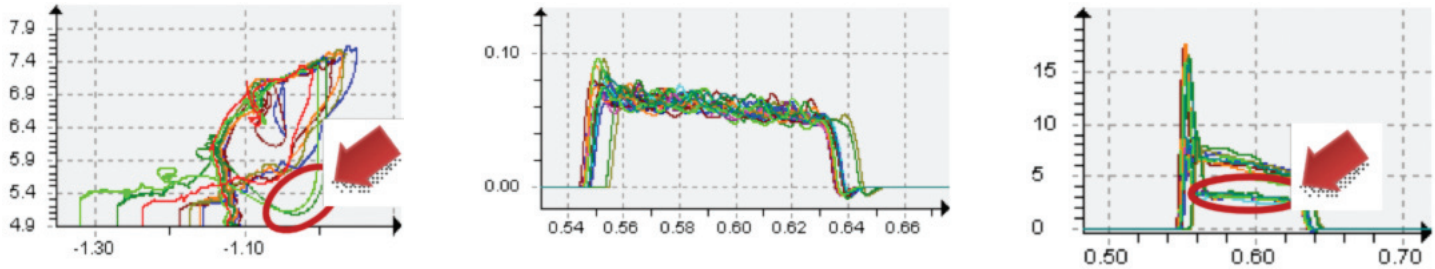

Figure 3: Plots of (a) series resistance (current divided by voltage) and (b) electric power (current multiplied by voltage), and (c) force vs. distance corresponding to the graphs shown in Figure 1. In these cases, the signatures from defective welds are clearly distinguishable in the Electric Power vs. Time and Force vs. Distance plots, as highlighted by the red circles. This illustrates how clearly defective welds can be identified based on the process signatures.

Solution

Apply Process Signature Verification to Monitor Weld Quality and Detect Defects in Real Time, on Every Part

Resistance welds are susceptible to a number of defects that can result in an inferior joint. In the case of implantable medical devices, these are exacerbated somewhat by the small dimensions of the parts involved, and the types of materials that must be used to survive in the harsh environment within the human body. Amongst the most common defect mechanisms is the formation of a weak bond due to an expulsion of overheated molten material from the weld pool. This is particularly problematic in medical device welds where the amount of material is small to begin with, and any loss of material has a significant impact on the joint that is produced. To make matters worse, the small dimensions tend to make it more difficult to avoid overheating, making the process less tolerant to small changes in variables such as pulse width, peak current, and electrode force.

These types of events are easily identified by the process signatures. For example, both the distance vs. time and the force vs. time curves will reveal the sudden loss of material, where the force will dip suddenly as the material is expelled from the weld pool. This is illustrated in the weld signatures shown in Figures 4 and 5below. Furthermore, the conditions that can lead to an expulsion are also visible in the process signatures. For example, if the contact resistance at the joint is high, perhaps due to the presence of surface oxides on the metals, excess heat will be generated. This will be reflected in both the resistance vs. time and the electric power vs. time curves. Other failure modes, for example insufficient heating due to excess electrode pressure causing a low contact resistance, can be detected and characterized using process signature analysis. All of these tests can be applied in real time on the sigPOD, using the powerful built-in analysis functions to ensure that each and every weld is robust. Furthermore, the detailed data, including all waveforms, can be automatically uploaded to Sciemetric's QualityWorX database, providing a comprehensive test record that demonstrates the quality of every joint, in every device that is shipped. This provides an unsurpassed level of protection against the potential repercussions arising from field failures caused by unforeseen defect mechanisms.

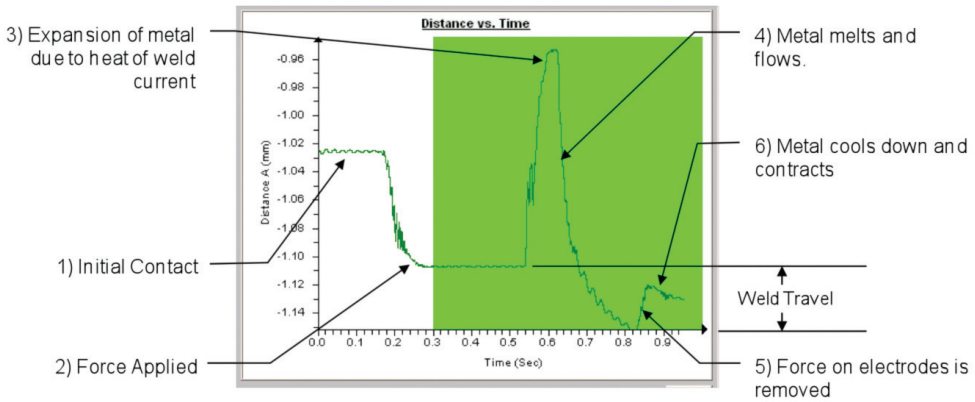

Figure 4: Plot of distance vs. time during a resistance welding process. The Peak to Peak of the distance waveform indicates the combined effect of the metals expanding and melting.

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Achievement

By installing Sciemetric's sigPOD PSV monitoring solution to measure, analyse, and record critical process variables on a resistance weld station, it is possible to evaluate the quality of the welded joint on a part-by-part basis. Defects such as the weakened joints caused by expulsions can be readily detected in real-time on the production floor without the need for destructive testing by analysing the process signatures on the sigPOD. This allows manufacturers to reduce product costs by eliminating the unnecessary capital and excess scrap associated with the traditional approach of destructive testing. It also provides test coverage on 100% of all shipped material, dramatically reducing the risk of critical field failures at the welded joint. Finally, all of the detailed data can be uploaded to a QualityWorX database to provide a comprehensive test record for every joint, in every part shipped to a patient.

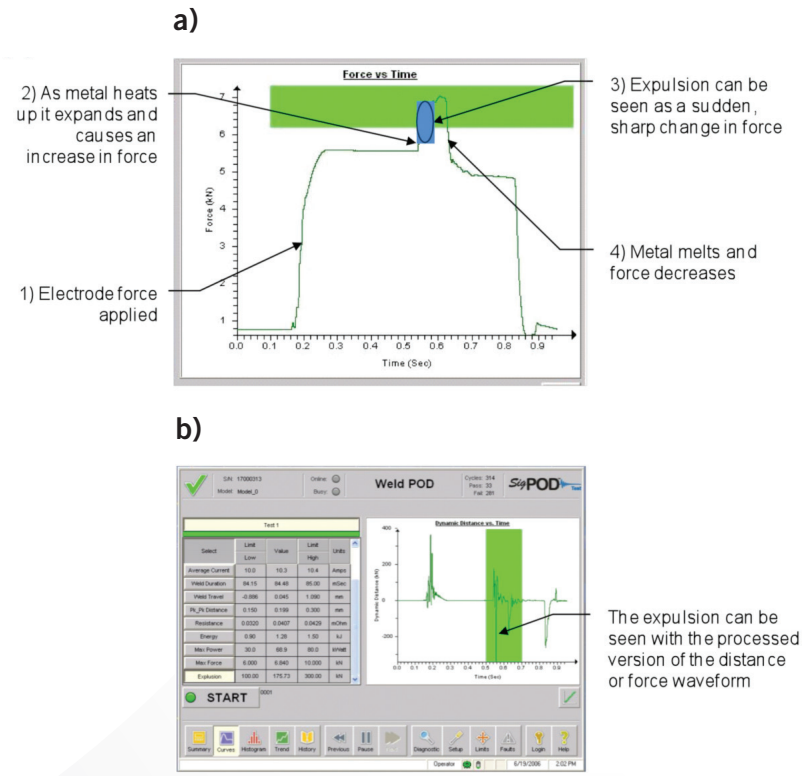

Figure 5: Force vs. time weld signature showing evidence of an expulsion event. Detection of these rapid changes in force can be enhanced by looking at the derivative of the force vs. time signature, as illustrated in (b).

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