Latest Advances in iQ Series Ultrasonic Systems

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Challenges facing Medical Device Manufacturing

- Process Repeatability
- Validation Calibration
- Manufacturing Costs
An experiment was performed comparing parts welded on a standard pneumatic welder and Dukane’s new Servo welder with Melt-Match® technology. Standard deviation of the pull strength was measured.
Experiment

Typical Poly-carbonate filter housing.
Provided to Dukane by a major medical device manufacturer.
Experiment

Common ultrasonic shear joint design.
Experiment

High quality pull test fixture was developed
Experiment

Test Results

<table>
<thead>
<tr>
<th>Filter housing test results</th>
<th>Dukane</th>
<th>Customer</th>
<th>Customer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Servo</td>
<td>Servo</td>
<td>Pneumatic</td>
</tr>
<tr>
<td>Average Standard Deviation</td>
<td>1.80%</td>
<td>1.90%</td>
<td>6.60%</td>
</tr>
</tbody>
</table>

3/23/2009
Process Repeatability

How does it work?

• Precision control of the collapse speed.
• “Melt Match® Technology”
Distance vs. Time
for Different Weld Speed Profiles

- Constant
- Linearly Increasing
- Linearly Decreasing
- S-Curve
- Custom
Force vs. Time
for Different Weld Speed Profiles

- Constant
- Linearly Increasing
- Linearly Decreasing
- S-Curve
- Custom

Force (lb.)

Time (s)
Power vs. Time
for Different Weld Speed Profiles

- Constant
- Linearly Increasing
- Linearly Decreasing

Time (s)
Power vs. Time
for Different Weld Speed Profiles

Power (W)

Time (s)

S-Curve
Custom

0 0.05 0.10 0.15 0.20 0.25 0.30 0.35 0.40 0.45 0.50

0 50 100 150 200 250 300 350 400 450 500

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Challenges facing Medical Device Manufacturing

- Process Repeatability
- Stronger Bonds
- Validation Calibration
- Manufacturing Costs
Stronger Bonds

- Early experimentation was done using AWS standard I-beam test bars.
- We discovered that optimizing the collapse speed during the weld and the hold phase, created stronger pull test results.
**Stronger Bonds**

**Melt Phase**

- Collapsing too slow allows for material degradation
- Collapsing too fast may cause cold forming.
- Matching the collapse speed during the melt phase of the process is critical to producing superior bond strength.
- The ultrasonic propagation is allowed to penetrate deeper into the bond area.
Stronger Bonds

Hold Phase

• Typical pneumatic welders continue to move during hold phase
• Servo welder has the ability to either stop OR continue collapse at a specified speed for a specified distance during the hold phase
• This “controlled” collapse during the Hold Phase significantly improves repeatability of the collapse distance and of the pull strength
This spreadsheet contains results for welding machined Polycarbonate pieces on a pneumatic DPC system and a servo system. Both systems used the same stack and generator. The results are contained in tabs in this file.

### Key results:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Servo</th>
<th>Pneumatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collapse standard deviation (in.)</td>
<td>0.0004</td>
<td>0.0013</td>
</tr>
</tbody>
</table>

AWS I-Beams were welded
How does it work?

- Precise control of the collapse speed. “Melt Match Technology”
- iQ Series patented digital power supply
  - 0.5 msec sample rate, fastest in the industry
How does it work?

- Precise control of the collapse speed. “Melt Match Technology”
- iQ Series patented digital power supply
  - .5 m/sec sample rate, fastest in the industry
- Robust Mechanical design
  - ultra rigid support
Challenges facing Medical device manufacturing

- Process Repeatability
- Stronger Bonds
- Validation Calibration
- Manufacturing Costs
Medical Device Manufactures need to verify that the weld process controls are in tolerance.

**Six primary controls**

- Amplitude
- Time
- Distance
- Trigger Force
- Power
- Weld pressure/speed
Validation Calibration

Typical industry methods for Validation

- Amplitude - *Dial Indicator*
- Time - *Scope*
- Distance - *Gage Blocks*
- Trigger Force - *Force Gage*
- Power - *Watt Meter*
- Weld pressure/speed - *Pneumatic gage?*
• Weld pressure/speed - *Pneumatic gage?*

Current pneumatic devices attempt to control the weld speed via air pressure or a proportional valve device. However, actual collapse speed during the weld is a variable (out of control)

Therefore, validating the air pressure does not ensure the collapse speed is accurate and consistent.
Validation Calibration

Servo Press w/ Melt-Match technology

- Amplitude - Indicator
- Time - Scope
- Distance - Gage Blocks
- Trigger Force - Force Gage
- Power - Watt Meter
- Weld Speed - *Simple gage blocks can be used to verify speed.*

Distance / Time = Speed (mm/seconds)
Validation Calibration

**FDA compliant**

- Simplified Validation Servo vs pneumatic
- No operator controls - eliminates unauthorized machine adjustments
- All mechanical adjustments require tool.
Challenges facing Medical device manufacturing

- Process Repeatability
- Stronger Bonds
- Validation Calibration
- Simplified Manufacturing Costs
Challenges facing Medical device manufacturing

- Process Repeatability
- Stronger Bonds
- Validation Calibration
- Simplified Manufacturing Costs
Manufacturing Costs

Dr Robin Kent. Plastics Technology, Introduction to Energy Management For Plastics Processors, 37,p. (Jan, 2009)
Manufacturing Costs

Cost of Compressed Air

Compressed air is used in almost every facility and manufacturing plant. The cost of generation, however, is often overlooked by plant managers, maintenance, and production. Air is not free. Ultrasound can be used to save $10,000’s, even $100,000’s annually in energy savings.

According to a U.S. Department of Energy survey, between 10% and 30% of electricity consumed is for compressed air. Most manufacturing facilities use compressed air. A significant amount of energy is lost due to waste and air leaks.

The typical compressed air system uses only 50% of its air supply for production. The rest is wasted or lost to air leaks.

CRTL Systems Inc.

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Manufacturing Costs

Pneumatic Costs

Typical application, 8 cycles per minute, using a 3 diameter air cylinder at 5” stroke requires 4080 cubic feet of air per 8 hour shift.
Manufacturing Costs

Servo cost vs Pneumatic

- Typical application 8 cycles per minute, using a 3 diameter air cylinder at 4” stroke uses 118 cubic feet of air per 8 hour shift.
- Clean room environments - Servo welder produces no additional air volume to filter.
- Reduced Calibration intervals
- Repeatability
Challenges facing Medical device manufacturing

- Process Repeatability
- Stronger Bonds
- Validation Calibration
- Simplified Manufacturing Costs
- Green
Hands on demonstration

Remote connection using *IQ Explorer* User Interface

Local area network

Network configuration allows multiple local or remote *iQ* Systems and users

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Why is this new technology so important to the industry?

- Increased Repeatability
- FDA Compliance
- Green for the Environment

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Developed and Manufactured by Dukane at Worldwide Corporate Headquarters
St Charles, IL

• System Patents
  – #7,475,801- Granted
  – 2007/0257087- Application
  – Provisional Patent - converting into Application
Comparison of Collapse Distance Repeatability For Pneumatic and Servo Welders (round filters Polycarbonate parts)

<table>
<thead>
<tr>
<th></th>
<th>Pneumatic</th>
<th>Servo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Collapse (in.)</td>
<td>0.0179</td>
<td>0.0172</td>
</tr>
<tr>
<td>Standard Deviation (in.)</td>
<td>0.0016</td>
<td>0.0001</td>
</tr>
</tbody>
</table>
Comparison of Pull Strength Repeatability For Pneumatic and Servo Welders (round filters Polycarbonate parts)

<table>
<thead>
<tr>
<th>Normalized Data to compensate for uneven Collapse Distance</th>
<th>Pneumatic</th>
<th>Servo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Pull Strength per Inch of Weld Depth (Collapse Distance) (lb./in.)</td>
<td>56,730</td>
<td>57,610</td>
</tr>
<tr>
<td>Standard Deviation (lb./in.)</td>
<td>8600 (15.2%)</td>
<td>1140 (2.0%)</td>
</tr>
</tbody>
</table>
Typical Distance vs. Time Graph for Servo Welder
Typical Power vs. Time Graph for Servo Welder
Typical Force vs. Time Graph for Servo Welder
iQ Series

Trigger by Power

Power, W

Transducer

Power Output

Programmable Trigger Point

Force on Part, N

Stack Contacts Part

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iQ Hand Probe with Time & Energy

Trigger by Power Amplitude setting screen

Trigger by Power Power level setting screen

Trigger by Power Timeout setting screen
Compact design

iQ Series
Acknowledgements

iQ Series of Ultrasonic Generators and Presses are the results of several years of intense R&D investment by Dukane corporation.

Many talented engineers have contributed to this effort.
Questions?

- Workcell
- Servo
- MeltMatch™
- Mini Press
- New Hand Probe

[Dukane Logo]