PSI Sealing Parameters

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Medtronic CRDM Packaging Engineering
Medtronic, Inc.

- Medical Device Company
- Mission –
  - To alleviate pain, restore health, and extend lives
- Based in Minneapolis with sales and manufacturing locations all over the world with ~ 38,000 employees.
- Businesses
  - Cardiac Rhythm Disease Management
  - Spinal and Biologics
  - CardioVascular
  - Neuromodulation
  - Diabetes
  - Surgical Technologies
Did you ever wonder why…

• …after you develop sealing parameters for a blister package configuration on one sealer they do not work as well (or sometimes at all) on other sealers?
Blister Sealers
Control of Parameters

- **Temperature** input = temperature output controlled and monitored by the PLC before and during the sealing cycle
- **Dwell time** is controlled and monitored by the PLC during the sealing cycle
- **Pressure** – Input pressure is compressed air pressure (psi) to the sealer and it is controlled and monitored during the sealing cycle
- **Tolerances** – Each sealer has a unique parameter control capability (-xx / +xx).
Pressure (IP vs. DF)

• Noticed “identical” sealers gave different seal quality results with the same parameters (Temp / Dwell / Pressure)

• Noticed “identical” sealers operated differently at the same parameter settings
  – Speed
  – Sound

• Downforce (DF) appeared to be different at the same Input Pressure (IP)
Pressure Variations

Input Pressure vs. Downforce
‘Pressure Profiles’
How can I measure DF and identify the differences between sealers?

- Equipment - Load cell connected to a digital readout that held on the highest value achieved…like putting a scale under the sealing head.
- Decided to use a 10 second dwell time
- Manually recorded the “high” for a number of cycles at the same IP
- Change the IP and repeat
- PP (Pressure Profile) Process – Average DF at an IP across a range of IPs
- DF values varied significantly from sealer to sealer
- DF values had a linear relationship but angle varied
Pressure Profiles (PP)
Regression Equations

- Regression equations are unique for each sealer and are based upon the PP data.
- If the data is linear and the IP is known, a regression equation can be used to predict the DF that an IP can be expected to achieve.
- If the data is linear and the DF is known, a regression equation can be used to predict the IP required to achieve a specific DF.
- PP and Regression Equation tools can help reduce variation in the sealing process by making the DF equivalent from sealer to sealer.
## Regression Equation Test Tool

**Regression Equation Test Tool (MS EXCEL)**

<table>
<thead>
<tr>
<th>Sealer</th>
<th>IP Test Value</th>
<th>DF Test Value</th>
<th>Predicted DF (lbs)</th>
<th>Predicted IP (psi)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>49</td>
<td>2500</td>
<td>2505.8</td>
<td>48.9</td>
</tr>
<tr>
<td>B</td>
<td>45</td>
<td>2500</td>
<td>2524</td>
<td>44.5</td>
</tr>
<tr>
<td>C</td>
<td>37</td>
<td>2500</td>
<td>2480.3</td>
<td>37.4</td>
</tr>
<tr>
<td>D</td>
<td>32</td>
<td>2500</td>
<td>2525.6</td>
<td>31.6</td>
</tr>
<tr>
<td>E</td>
<td>34</td>
<td>2500</td>
<td>2497.2</td>
<td>34.1</td>
</tr>
<tr>
<td>F</td>
<td>31</td>
<td>2500</td>
<td>2515.8</td>
<td>30.7</td>
</tr>
<tr>
<td>G</td>
<td>28</td>
<td>2500</td>
<td>2533</td>
<td>27.5</td>
</tr>
<tr>
<td>H</td>
<td>29</td>
<td>2500</td>
<td>2502.8</td>
<td>29.0</td>
</tr>
<tr>
<td>I</td>
<td>27</td>
<td>2500</td>
<td>2489.3</td>
<td>27.2</td>
</tr>
</tbody>
</table>
Improved Pressure Profile

- Cable between load cell and digital readout
- Rotary sealer twisted cable
- Wireless transmitter between load cell and digital readout
- PC based
- 60 reading per second x 10 seconds x 10 cycles x 14 IPs = 84000 data points per sealer per PP. Lots of data!
- Developed a Macro in EXCEL to load the PP data into a multiple-sheet EXCEL template file. The data is then automatically processed, summarized and displayed in chart format.
Pressure Profile Equipment
### Input Pressure bar/psi

<table>
<thead>
<tr>
<th>Pressure (bar)</th>
<th>1.0/15</th>
<th>1.4/20</th>
<th>1.7/25</th>
<th>2.1/30</th>
<th>2.4/40</th>
<th>2.8/50</th>
<th>3.1/55</th>
<th>3.4/60</th>
<th>3.8/65</th>
<th>4.1/70</th>
<th>4.5/75</th>
<th>4.8/80</th>
</tr>
</thead>
</table>

### Stable DF Av. (2.0 to 9.0 sec)

<table>
<thead>
<tr>
<th>Pressure (bar)</th>
<th>1463</th>
<th>1910</th>
<th>2312</th>
<th>2761</th>
<th>3161</th>
<th>4028</th>
<th>4478</th>
<th>4884</th>
<th>5345</th>
<th>5775</th>
<th>6255</th>
<th>6698</th>
<th>7131</th>
</tr>
</thead>
</table>

### Std. Dev.

<table>
<thead>
<tr>
<th>Pressure (bar)</th>
<th>8.6</th>
<th>9.5</th>
<th>4.7</th>
<th>5.0</th>
<th>5.5</th>
<th>5.6</th>
<th>7.8</th>
<th>7.7</th>
<th>9.8</th>
<th>10.4</th>
<th>12.7</th>
<th>11.7</th>
<th>29.8</th>
<th>75.8</th>
</tr>
</thead>
</table>

### Average minus 3 Std. Dev.

<table>
<thead>
<tr>
<th>Pressure (bar)</th>
<th>1437</th>
<th>1881</th>
<th>2298</th>
<th>2746</th>
<th>3144</th>
<th>3599</th>
<th>4005</th>
<th>4454</th>
<th>4855</th>
<th>5313</th>
<th>5737</th>
<th>6220</th>
<th>6609</th>
<th>6904</th>
</tr>
</thead>
</table>

### Time to low Std. Dev.

<table>
<thead>
<tr>
<th>Pressure (bar)</th>
<th>1.27</th>
<th>1.42</th>
<th>1.70</th>
<th>1.87</th>
<th>2.00</th>
<th>2.05</th>
<th>2.07</th>
<th>2.08</th>
<th>2.05</th>
<th>2.05</th>
<th>2.13</th>
<th>2.18</th>
<th>2.25</th>
</tr>
</thead>
</table>

### Av. TtoP (Time to Pressure)

<table>
<thead>
<tr>
<th>Pressure (bar)</th>
<th>1.94</th>
</tr>
</thead>
</table>
Better PP Tool

- Ability to “see” what is happening to the pressure parameter during the sealing cycle
- More useful means and standard deviations
- Time to Pressure (TtoP) or to a stable DF
- Sealer to sealer DF differences can be as little as a few pounds to a several thousand pounds at the same IP.
Visual Evaluation of Seals

How good is good?
Visual Requirements

- Visual characteristics and requirements are often used as accept/reject criteria.
- Accept/Reject (attributes) data is not a good way to identify changes in output when looking for minor changes.
- Large sample size required to “see” incremental improvements.
- Developed a Visual Scoring Method.
Visual Scoring Method

- Rejectable characteristics
- Undersealed characteristics
- Oversealed characteristics
- Define criteria in incremental shades of goodness based upon visual examination
- Assigned numerical values to the shades
- This method was later borrowed, adapted and used for the round robin testing of original version of ASTM F1886, Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection.
**Visual Scoring Method for Blister Package Seals**

**Visual Characteristics Rating Scale**

| Score | Acceptable | Package seal meets highest visual requirements.
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Undersealed Slope</td>
<td>Acceptable - Package seal meets requirements. Undersealed: Oversealed:</td>
</tr>
<tr>
<td>4</td>
<td>Undersealed</td>
<td>Acceptable - Package seal meets requirements. Undersealed: Oversealed:</td>
</tr>
<tr>
<td>3</td>
<td>Undersealed</td>
<td>Acceptable - Package seal meets requirements. Undersealed: Oversealed:</td>
</tr>
<tr>
<td>2</td>
<td>Undersealed</td>
<td>Acceptable - Package seal meets minimum requirements. Undersealed: Oversealed:</td>
</tr>
<tr>
<td>1</td>
<td>Rejectable</td>
<td>Package seal does not meet minimum requirements. Undersealed: Oversealed:</td>
</tr>
</tbody>
</table>

(See Visual Characteristics Rating Scale)
Sealing Parameter Development

Typical ways and a better way
How are sealing parameters typically developed and transferred?

- Parameters recommended by suppliers
- Trial and Error
- DOE
- Reuse parameters previously developed for that package on another sealer.
- Combinations of the 3-parameter set of T/D/P (IP) can vary significantly but still yield acceptable seals.
Set Point, Process Limits and Machine Tolerances

- Undersealed Reject
- Set point
- Lower Sealer Tolerances
- Upper Sealer Tolerances
- Oversealed Reject

- Undersealed Reject
- Set point
- Lower Sealer Tolerances
- Upper Sealer Tolerances
- Oversealed Reject

- Undersealed Reject
- Set point
- Lower Sealer Tolerances
- Upper Sealer Tolerances
- Oversealed Reject
Sealing Process Questions

• Is there one “best” sealing parameter set?
  – For each package configuration?
  – For each package configuration on each sealer?
  – For all package configurations on all sealers?
    • Is that possible?

• How robust is a sealing parameter set (resistance to produce rejects)?

• How can I show or explain how good my process is?
New Definitions

• psi vs. DF-PSI or DF-PSI Value
  – psi = Compressed air pressure (IP) to sealer
    • to be precise, this parameter is unique to each sealer
  – DF-PSI, a Universal Sealing Parameter = Seal pressure in lbs/in² applied to the sealing flange of the tray
    • the DF-PSI Value removes the sealer from the parameter set
  – DF-PSI Parameter Set = Temp / Dwell / DF-PSI Value

• Worst Case Testing (ISO 11607:2006)
  – Worst Case, One-Parameter-Out concept
Using the DF-PSI Sealing Parameter Set

• What if we used a DF-PSI Value instead of an IP to define the pressure parameter.
  – Temp = 225°F / Dwell = 4.5 second / **Pressure = 175** versus
  – Temp = 225°F / Dwell = 4.5 second / **Pressure = 31 psi**

• To produce a seal with the selected DF-PSI value you must convert DF-PSI to DF. Use the formula: $DF = DF-PSI \times \text{in}^2$ (seal surface area).
  – Example: $DF = 175 \times 10.19 \text{ in}^2 = 1783.25$ or **1783 lbs (DF)**
Using the DF-PSI Sealing Parameter Set (cont.)

- Then using the DF-known regression equations to find the IP required for each sealer to produce 1783 lbs of DF.

- Let's say you want to seal this package on 3 different sealers.
  - Sealer A example: \( IP = -2.26 + 0.0187 \times 1783 = 31.08 \) or 31 psi (IP)
  - Sealer B example: \( IP = -4.52 + 0.0141 \times 1783 = 20.62 \) or 21 psi (IP)
  - Sealer C example: \( IP = 3.52 + 0.0102 \times 1783 = 21.71 \) or 22 psi (IP)

- Set each sealer’s PLCs to the IP identified by the regression equation and seal sample packages.

- The result will be nearly identical seal quality from all three sealers.
What Do I Need to Develop a DF-PSI Sealing Parameter Set?

- Tools
- Development Process
- Understanding of the concept
- Use the process and apply the tools
DF-PSI Development Tools

- Blister sealers with known good parameter control capability
- Pressure Profile Equipment
- Pressure Profile Data Evaluation Method
- Regression Equations
- DOE
- Visual Rating Scale
- Statistical Software
The Process

• Perform Pressure Profiles on sealers.
• Develop Regression Equations for sealers.
• Regression Equation Examples:
  – Sealer A
    • DF = 121 + 53.4 * IP (IP-known equation)
    • IP = -2.26 + .0187 * DF (DF-known equation)
  – Sealer B
    • DF = -9.4 + 90.8 * IP (IP-known equation)
    • IP = 0.0110 + 0.011 * DF (DF-known equation)
• Determine individual sealer tolerances for all three parameters
The Process (cont.)

• Identify seal surface area of all trays (in²)
• Find a good parameter set for your materials, tooling, equipment and process.
  – DOEs. Suggest locking 1 parameter i.e. dwell time.
• Verify your parameter set output on different package configurations using the same sealer.
• Verify your parameter set output on different sealers.
The Process (cont.)

• Performance chart your sealing process.

• Validate your process.
  – IQ + OQ + PQ = Validated process

• Monitor the output in manufacturing

• Investigate changes in the output over time
Understanding the Concept

• DF-PSI Key Formula
  \[ \text{DF-PSI (lbs./ in}^2\text{)} = \frac{\text{DF (lbs)}}{\text{Seal Area (in}^2\text{)}} \]

• Example of a DF-PSI Sealing Parameter Set:
  \[125^\circ\text{F (107.2}^\circ\text{C)} / 4.5 \text{ Sec} / 175 \text{ DF-PSI}\]
Using the Process and Tools

- You have multiple sealers and multiple package configurations
- You are using the same materials on all
- You have done Pressure Profiles and developed the regression equations for each sealer
- You have developed a rating method to evaluate the output of your process
- You have performed three DOEs to find your best sealing parameter set
Using the Process and Tools (cont.)

• The following 4 slides show an example of the results you obtained using the DF-PSI sealing parameter development process.
  – Determine the parameter set
  – Confirm the parameter set
    • Single package configuration
    • Multiple package configurations
  – Chart the sealing process performance
Combined Results of 3 DOEs

Contour Plot of ValueM vs DF-PSI, Temp

ValueM

- < 1.5
- 1.5 - 2.1
- 2.1 - 2.7
- 2.7 - 3.3
- 3.3 - 3.9
- 3.9 - 4.5
- 4.5 - 5.1
- 5.1 - 5.7
- 5.7 - 6.3
- 6.3 - 6.9
- 6.9 - 7.5
- > 7.5

HealthPack
Initial Confirmation Run

Histogram of initial test package

Normal

Mean 5.5
StDev 0.9958
N 120

VISUAL SCORING METHOD FOR BLISTER PACKAGE SEALS

(Acceptable Slope)

(See Visual Characteristics Rating Scale)

1 - Undersealed Reject

2/8

2

3

4

4/6

5

3/7

Oversealed Reject - 1/9

HealthPack
### Six Tray Type Confirmation Runs

Temp=225°F, Dwell=4.5 sec, DF-PSI=175

#### One-way ANOVA: Package Types A through F

<table>
<thead>
<tr>
<th>Source</th>
<th>DF</th>
<th>SS</th>
<th>MS</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor</td>
<td>5</td>
<td>5.244</td>
<td>1.049</td>
<td>1.26</td>
<td>0.279</td>
</tr>
<tr>
<td>Error</td>
<td>714</td>
<td>594.083</td>
<td>0.832</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>719</td>
<td>599.328</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

S = 0.9122  R-Sq = 0.88%  R-Sq. (adj.) = 0.18%

Pooled St. Dev = 0.9122

#### Individual Value Plot of Score by Pkg Type

Individual 95% CIs For Mean Based on Pooled St. Dev

<table>
<thead>
<tr>
<th>Level</th>
<th>N</th>
<th>Mean</th>
<th>St. Dev</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pkg B</td>
<td>120</td>
<td>5.7083</td>
<td>1.0075</td>
<td>5.40</td>
</tr>
<tr>
<td>Pkg C</td>
<td>120</td>
<td>5.6833</td>
<td>0.8598</td>
<td>5.55</td>
</tr>
<tr>
<td>Pkg A</td>
<td>120</td>
<td>5.5000</td>
<td>0.9958</td>
<td>5.70</td>
</tr>
<tr>
<td>Pkg D</td>
<td>120</td>
<td>5.4917</td>
<td>0.8096</td>
<td>5.85</td>
</tr>
<tr>
<td>Pkg E</td>
<td>120</td>
<td>5.5333</td>
<td>0.8786</td>
<td></td>
</tr>
<tr>
<td>Pkg F</td>
<td>120</td>
<td>5.5667</td>
<td>0.9050</td>
<td></td>
</tr>
</tbody>
</table>
Sealing Process Performance Chart
Showing Nominal Set Points, Accept / Reject Boundaries, Machine Tolerance Capability and Upper and Lower 1-Parameter-Out Limits

**Nominal Set Points**
- Temp = 225°F
- Dwell = 4.5 sec.
- IP = DF@175 PSI

**Lower 1-Parameter-Out Limit**
- Temp = *212°F*
- Dwell = N
- IP = N
- N = 3.0
- N = 103 PSI

*Lowest sealer setting

**Upper 1-Parameter-Out Limit**
- Temp = 257°F
- Dwell = N
- IP = N
- N = 11.0
- N = *287 PSI

*Max achievable as installed

**Machine Capability**
- Temp = ± 1.8°F
- Dwell = -0.0 to +.4 sec.
- IP = ± 1.5 psi

ACCEPPTS

Undersealed
Rejects

Oversealed
Rejects
Advantages of the DF-PSI Sealing Parameter Set

• DF-PSI parameter is a universal sealing input (all sealers, all package configurations)
  – IP ties the parameter to a specific sealer and package configuration.
• Single sealing parameter set for all package types on any sealer
• Consistent output across all locations
• Sealer change-out is easily accomplished
Advantages of the DF-PSI Sealing Parameter Set (cont.)

- OQ portion of the validation (bulk of the work) need be done only one time for a material combination, and then mathematically applied to each sealer and verified at PQ.
- The seal quality that was qualified and tested in design is accurately being produced in manufacturing.
Transferring Sealing Parameters

- Manufacturing facilities all around the world
  - Different levels of expertise and focus
- Over 30 sealers in just one Business Unit
- Need to improve and simplify the sealing parameter development, transfer and implementation process
- Make the sealing process and sealing process validation (required by ISO11607) easy for manufacturing…”no worries”!
$ Why use the DF-PSI Method? $

Develop sealing parameter set for each package type on each sealer

1. IQ
2. Determine Pkg Type(s)
3. T&E or DOE (T+D+IP)
4. Process Qual or OQ
5. Process Validation or PQ
6. Monitor Output

Develop PSI sealing parameter set one time and re-verify each time

1. IQ (PP Data + Regression Equations)
2. Determine Parameter Set (PSI)
3. DOE (T+D+PSI) Convert to IP for each sealer)
4. Process Qual or OQ
5. Process Validation or PQ
6. Monitor Output
7. Repeat as often as is required
Making it Work for You

• Visual scoring descriptions can be revised to better suit to your materials
• Different scoring scale can be used if it suits your materials better
• Pressure Profile and Regression Equation steps can be eliminated if your sealer DF is measured and controls the process.
  – Some sealers have this option.
Recommendations

• To Sealer Manufacturers
  – Consider added DF control capabilities to your sealers rather than or in addition to controlling the IP.
  – This will be useful to your customers.

• To Lid Converters
  – Consider using a DF-PSI Value when recommending sealing parameters to your customers.
  – Develop ranges of parameter sets with varying Temperature, Dwell Time and DF-PSI value.
  – This will be useful to your customers.
Takeaways

• Input Pressure is a **sealer parameter**, it is not a **sealing parameter**.

• DF-PSI is part of a **universal sealing parameter set** and is appropriate for all sealers and all package configurations that use a particular material combination (adhesive, lid, tray material, etc.).

• The DF-PSI Value can be mathematically converted into a unique IP on each sealer for each package configuration to achieve consistent seal quality from sealer to sealer.

• Know your sealing process.
Questions