Process Validation Procedure for (Insert Customer Name)

Scope & Objective: This process validation procedure applies to all medical device components manufactured at Altek in which a process validation is required by the customer to help ensure compliance to FDA regulations, and other industry (e.g. Aerospace), Customer, product or process needs and/or requirements. The objective is to furthermore understand, mitigate and manage the risk associated with New Product Introduction and ongoing Order Fulfillment, including but not limited to the management of Key Product Characteristics, Critical Items and Special Customer requirements.

Part #:	Rev Level:
Performed by:	Date:

Procedure:

(A) Low Side Range Process Window Study

1. Choose factors to manipulate on the low side:
   - Factor A = e.g. First stage pressure
   - Factor B = e.g. Cooling time
2. Manipulate factors to the low side range.
   - Cycle in process, allowing process to stabilize.
   - Adjust factor A downward until product is out of tolerance, then slowly adjust factor A upward until product falls back within tolerance.
   - Adjust factor B downward until product is out of tolerance, then slowly adjust factor B upward until product falls back within tolerance.
3. Run process on the low side range for 1 hour.
   - Perform in-process inspection for critical dimensions at the beginning of the run, and every 15 minutes during the run to ensure that product is within tolerance. Measure parts from multiple cavities within the tool.
   - Bag and label (shot # and cavity #) the specific parts that are used for the in-process inspection, so they can be referenced in the future. Document critical dimension inspection on a measurement sheet.
   - Print or document copy of processing parameters used to perform this test. Specifically the settings used for variable factors A & B.
   - Package all products and documentation from this study and label box as "*Part #; Low Range process window study*" and seal.

**Verify completion of Low Range Study: Initials_____ Date_____

Comments: _____
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(B) High Side Range Process Window Study

4. Choose factors to manipulate on the high side:
   - Factor A = e.g. First stage pressure
   - Factor B = e.g. Cooling time
5. Manipulate factors to the high side range.
   - Cycle in process, allowing process to stabilize.

- Adjust factor A upward until product is out of tolerance, then slowly adjust factor A downward until product falls back within tolerance.
- Adjust factor B upward until product is out of tolerance, then slowly adjust factor B downward until product falls back within tolerance.

6. Run process on the high side range for 1/2 hour.
   - Perform in-process inspection for critical dimensions at the beginning of the run, and every 15 minutes during the run to ensure that product is within tolerance. Measure parts from multiple cavities within the tool.
   - Bag and label (shot # and cavity #) the specific parts that are used for the in-process inspection, so they can be referenced in the future. Document critical dimension inspection on a measurement sheet.
   - Print or document copy of processing parameters used to perform this test. Specifically the settings used for variable factors A & B.
   - Package all products and documentation from this study and label box as "*Part #; High Range process window study*" and seal.

**Verify completion of High Range Study: Initials_____ Date_____

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(C) Optimal Range Process Window Study

7. Identify the most optimal midpoint settings for factors A: e.g. First Stage Pressure & B: e.g. Cooling time
8. Cycle in process, allowing process to stabilize.
9. Verify that product is producing at nominal or optimal point within the tolerance levels for critical dimensions and features through in-process inspection.
10. Collect and label 30 consecutive shots for SPC and CpK Study.
    - Label parts for Shot #, and for the Cavity # for each consecutive shot.
    - It is imperative that parts are labeled within time sequence and by cavity, as shots 1-30 will be used for an SPC and CpK analysis.
11. Run additional samples to be used for fully dimensioned first article analysis.
    - Full first article analysis will be conducted on each mold cavity.
12. Print or document copy of processing parameters used to perform this test. Specifically the settings used for variable factors A & B.
13. Package all products from this study and label box as "*Part #; Optimal Range process window study*" and seal.
    - Tear machine down and proceed to data analysis phase.

**Verify completion of Optimal Range Window Study: Initials_____ Date_____

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(D) Analysis of Data & Corrective Action

14. Altek and Customer to analyze low range, high range, optimal midpoint, SPC, CpK, and First Article data.
    - Seek to identify product with a narrow processing window (if any) and/or features that are out of print tolerance, and determine corrective actions to be taken. The options to be evaluated are processing parameter changes, modifications to the tool, and changes to the print tolerance for non-critical dimensions.
15. Re-perform 30 Piece Optimal Process Window Study for any product that has been modified or improved.
    - This step is to validate improvements.
16. Record nominal processing parameters.
    - Document SWIs to reflect optimal process. Label SWI as a "lock down" process.
    - Document process parameter sheet to reflect optimal process settings and label as a "lock down" process.

**Verify completion of data analysis & corrective action: Initials_____ Date_____

Comments:_____
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(E) Standard Process Validation Runs

Run (3) four-hour process validation runs on each of the Customer Molds. The runs will be consecutive, and in the same mold press respective to each Mold. Please follow the procedure outlined below in performing the tests. (Validation process not to proceed until released by Customer)

Validation Run #1

17. Dry only enough material for next four-hour run.
18. Set up machine.
19. Identify the most optimal midpoint settings that were developed in the previous study.
20. Cycle in process, allowing process to stabilize.
21. Perform in-process inspection for critical dimensions.
    - Measure critical dimensions on 1 part from each cavity for every shot.
    - Bag and label each part for shot # and cavity #) so they can be referenced in the future.
22. Document critical dimension inspection on a measurement sheet.
23. Run process for 4- hours. At end of 4-hour run perform the following task:
    - Purge and remove material.
    - Shut machine off.
    - Remove program from machine.
    - Remove water lines from mold (leave mold in press).
24. Allow press to cool for at least 2-hours.
25. Place all products and documentation from first 4-hour validation run in a box and label *"Part #; 4-hour validation run #1"*.

**Verify completion of validation run # 1: Initials_____ Date_____

Comments:_____
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Validation Run #2 (Repeat steps 17 through 25 from above)

26. Dry only enough material for next four-hour run.
27. Set up machine per new job process
28. Perform second 4-hour validation run.
29. Repeat machine tear down cool down process.
30. Place all products and documentation from the second 4-hour validation run in a box and label *"Part #; 4-hour validation run #2"*.

**Verify completion of validation run # 2: Initials_____ Date_____

Comments:_____
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Validation Run #3 (Repeat steps 17 through 25 from above)

31. Dry only enough material for next four-hour run.
32. Set up machine per new job process
33. Perform second 4-hour validation run.
34. Place all products and documentation from the third 4-hour validation run in a box and label *"Part #; 4-hour validation run #3"*.

**Verify completion of validation run # 3: Initials_____ Date_____

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Full Production

35. After validation run #3, maintain production and move directly into high volume production run.

In the event of inconsistency between this document and the customer's validation RFQ, this document will take precedence.

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Reviewed and approved: Altek Date

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Reviewed and approved: Customer Date

REVISION HISTORY

Rev. #	Date	Description of Revision Completed	Authorized by:
A	11-9-2005	Created	Dave Stallings
B	1-11-2010	Renamed and Simplified form	Mike Marzetta

Use the above table to track any and all revisions to the document. When you make changes this table should be updated. Be specific in the description category as it may be used for future understanding.