

Bringing Your Product to the Next Level



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Agenda

- Evaluation during characterization
- Considerations for sample size
- Accelerate evaluation and testing process
- Reducing the design validation burden
- Selecting best combination of variables



Typical Design Process

- Quickly write requirements, so we can get to the fun work
- Play with design and material options in lab
- Project manager forces validation to begin
- Hope requirements and design match, and are reflected in the test protocol
- Test product in a way it was not tested before



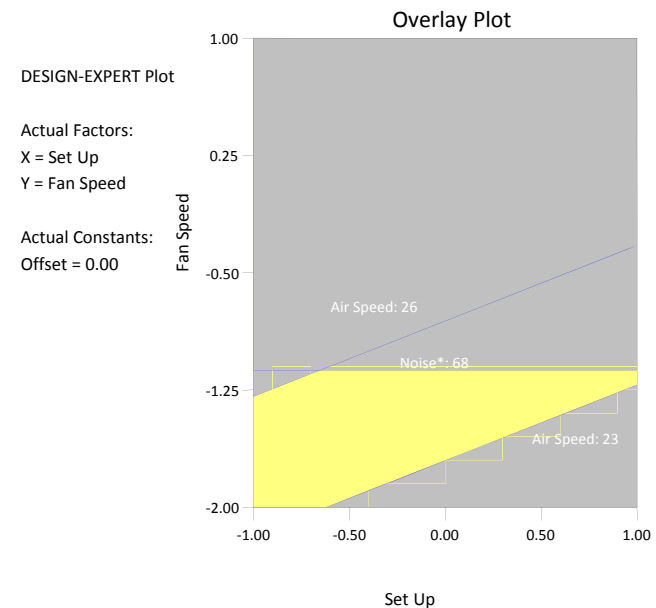
Characterization Evaluation

- Robustness features need to be evaluated during characterization testing (OQ)
- Evaluating only design parameters restricts the design too early, potentially operating in a small window. Look beyond the obvious.



Characterization Evaluation

- For example: The yellow space is a capable window of operation. Different robust features can change the size.



Characterization Evaluation

- Assuming higher is better, the right side is good performing.
- What if we are the red line (12 psi) and Parts “moves” to the left?

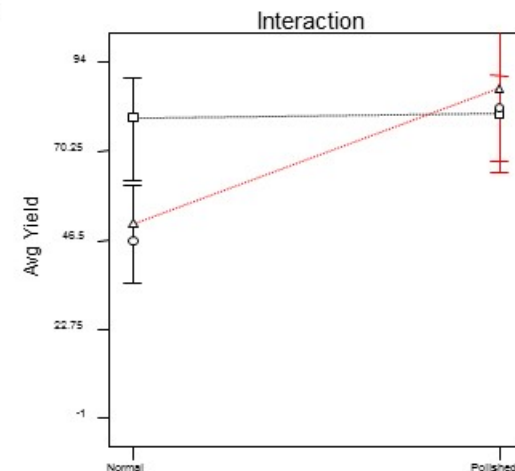
Design-Expert® Software
Original Scale
Avg Yield

○ Design Points

□ B- 10

△ B+ 12

Actual Factors
C: Temp = 420



A: Parts



Characterization Evaluation

- The efficiency of Design of Experiments (DOE) allows this evaluation to occur with very limited impact on test cost or duration.



Sample Size Considerations

- Sample size is a complex topic.
- Designers often feel the extra redundant tests will not increase technical learning, just statistical confidence.
- Why not use these extra tests to learn more?



Sample Size Considerations

- DOE takes advantage of “hidden replication” to reduce sample size beyond what most expect. This is a vital aspect of a well designed test.
- Simply put – working within your sample size procedures, we can be highly effective and efficient.



Accelerating the Process

- The evaluation and testing phases are the long portion of most schedules.
- It is often a mysterious black box, which is done when the engineer says it is done.
 - Or when forced by the project manager.
- How can we still learn, but be smart with our time and budget?



Accelerating - Evaluation

- If evaluation is done One Factor at a Time, this is extremely time consuming. In addition, it misses potential interaction effects
- Strategically combining similar variables (plus robustness factors) can effectively reduce test quantities by several factors.



Accelerating - Testing

- Specifically here, we are talking about qualification testing.
- If we can reduce our variable set through prior DOE testing (which was reduced during the evaluation process), then our qualification can be as small as reasonable – with support.



Accelerating - Testing

- Too often, qualification tests are reduced or shortened without strong support which creates a schedule risk.
- Surprises during qualification lead to high pressure meetings, hard decisions, report justifications, and ultimately the repeat of the failed test. This assumes no design changes are made.

Reducing Burden

- Design validation is the core of technical information being reviewed by the FDA.
- The burden happens when improper tests are run, and when tests fail.
- Well constructed requirements with appropriate evaluation leads to smooth validation.



Reducing Burden

- Expected design validation methods are anticipated while writing requirements.
This helps in two ways:
 - “How to test” is understood, which ensures evaluation tests are relevant
 - Ensuring requirement conflict is identified



Selecting Variable Combinations

- The design intent needs to be explained during design reviews, document sign off and with FDA.
- Having a basis for design decisions and why combinations are selected is a major benefit to the design process.



Selecting Variable Combinations

- What design parameter settings are least sensitive to:
 - Humidity
 - Temperature
 - Electrical voltage spikes
- And how do you know?



Conclusion

- DOE work during evaluation can ensure a stable and high performing product, in an efficient manner. Being real about our risks is key.
- If you want more information, visit our website.
 - www.PerrysSolutions.com
 - If interested, email us to be on our quarterly newsletter where we share recent trends and learning points