RESPONSE SURFACE METHODS (RSM) ACHIEVE DESIGN FOR SIX SIGMA (DFSS) GOALS FOR MEDICAL DEVICE MANUFACTURING

By Mark J. Anderson, PE, CQE, Stat-Ease, Inc. (mark@statease.com)

INTRODUCTION

Using response surface methods (RSM) for statistical design of experiments (DOE),[1,2] engineers at a major medical device manufacturer (USA-based) successfully modeled a key process for their flagship product. The RSM model then became the foundation for development of robust specifications to ensure quality at six sigma levels. Furthermore, RSM optimization tools pinpointed potential for doubling the production rate while halving the variation in a critical attribute, thus meeting objectives of the company's design for six sigma (DFSS) program.

DETAILS ON THE EXPERIMENT DESIGN

The manufacturing team performed a 50-run, Box-Behnken design (BBD) on five critical process factors known to affect their results. For proprietary reasons, the factors cannot be revealed, but they were selected from experiments that screened such things as pressures, speeds, distances, flows and environmental factors that influenced product performance. The BBD is a popular template for RSM because it requires only three-levels of each process factor and only a fraction of all the possible combinations. Details on RSM, and the BBD in particular, can be found in reference 1. Figure 1 shows a BBD on three factors.

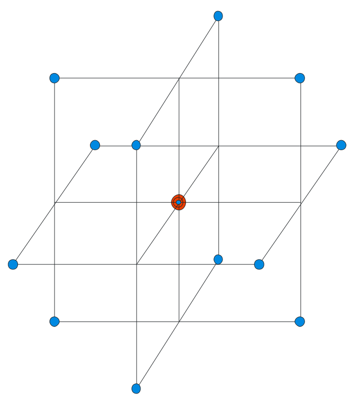

Figure 1: Box-Behnken design on three factors

The BBD is comprised of planes intersecting at a center point with outlying points at the extreme vertices in each of the factor dimensions. This selection of points suffices to fit a second-order polynomial equation, called a "quadratic model" in the parlance of RSM. The quadratic generally provides an adequate fit of data from experiments done for purposes of process optimization.

ANALYZING THE RESULTS AND INTERPRETING THEM

Four key responses, coded as "Y_i", were measured on a number of parts made at each process setup dictated by the BBD template. They included measures of weight, rates and visual integrity (quantified against established inspection criteria on a scale from 1 to 5).

For competitive reasons, specific details cannot be provided on the response levels achieved by this optimization project, but these revelations and the following explanations should suffice for illustrating the experimental method and statistical tools for generating useful response surface models.

Aided by statistical software,[3] the medical device engineers modeled the averaged results. Mathematical transformations provided more precise and normal fits for some responses, for example, the square root for Y_1, for which the model form is shown below (actual coefficients disguised by β's ("beta"), but signed plus or minus true to actual form).

$$\mathrm{Sqrt}(Y_1) = \beta_0 - \beta_1 A + \beta_2 B - \beta_3 C - \beta_4 D + \beta_{12} AB - \beta_{23} BC - \beta_{11} A^2 - \beta_{22} B^2 + \beta_{33} C^2$$

This predictive equation is designed for factors coded from -1 at the low to +1 to the high end of the ranges depicted in Figure 1. For example, to predict the result with factors all set high, plug in 1 for A, B, C and D:

$$\mathrm{Sqrt}(Y_1) = \beta_0 - \beta_1 (1) + \beta_2 (1) - \beta_3 (1) - \beta_4 (1) + \beta_{12} (1)(1) - \beta_{23} (1)(1) - \beta_{11} (1^2) - \beta_{22} (1^2) + \beta_3 (1^2)$$

This case fortuitously reduces to the addition of all the coefficients β ("beta") produced via least-squares regression. The resulting value must then be untransformed by squaring it, thus returning to the original units of measure. From this model, responses can be predicted over the entire experimental region and plotted.

To gain perspective on the models, it helps to view the perturbation of the predicted responses caused by changing only one factor at a time from the center point of the experimental region. For example, see from Figure 2 that the first response (untransformed) varies primarily as a function of factors B and C.

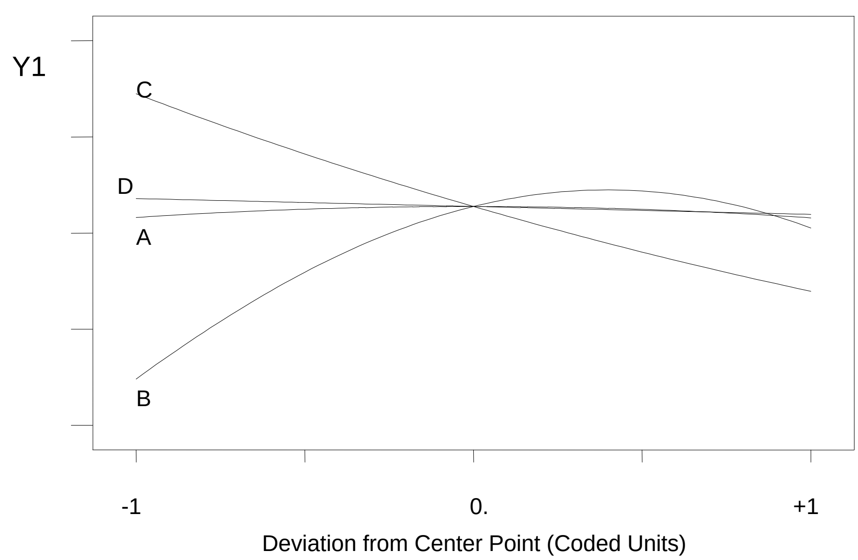

Figure 2: Perturbation plot for first response (Y1)

Only two factors can be displayed on a plot and thus B and C become the best candidates for providing a picture of response Y1 – see Figure 3 for a 3D display.

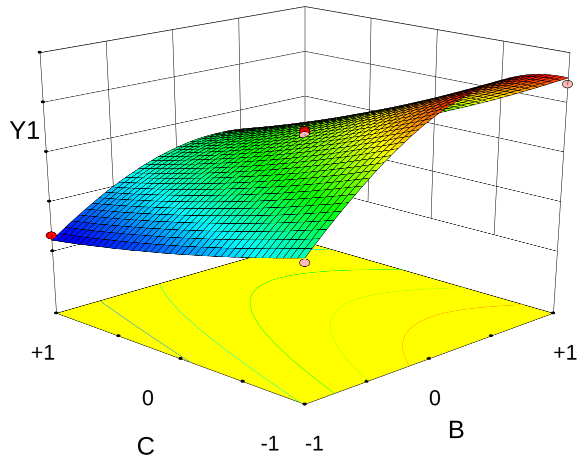

Figure 3: Response surface for Y1 as a function of factors B and C

In similar fashion the other three responses were explored graphically. However, the real test came by overlaying the contour plots for all four responses with each of them controlled as tightly as possibly around their targeted values. Figure 4 reveals a “sweet spot” where all specifications can be achieved, for example at the flagged location in the space mapped by factors B and C (others set at center points for this ‘slice’ of the experimental space). Notice how only some specifications are limiting factors. This is good to know.

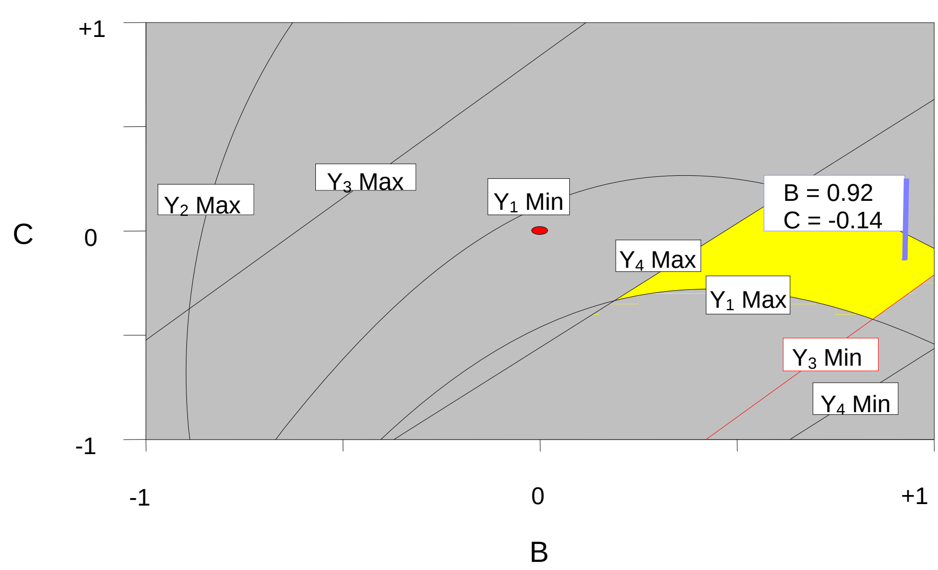

Figure 4: Overlay plot reveals window of operability

Numerical optimization provided by the statistical software pinpointed the most desirable combination of factors based on their predictive models.

RSM MODEL PREDICTIONS CONFIRMED

The manufacturer’s design for six sigma (DFSS) protocol mandated follow-up studies to confirm runs based on models derived from the BBD RSM experiments. The confirmation runs demonstrated that input parameters did indeed control critical outputs. The engineers then confirmed with a high level of statistical confidence that targeted performance could be achieved for optimum process with fast cycle time and high yield.

Given the success of this project, the manufacture intends to continue their DOE RSM work on developing models for other medical device products, thus achieving similar improvements in throughput while meeting the requirements of robust design for six sigma.

REFERENCES

1. Anderson, M.J. & Whitcomb, P.W., *DOE Simplified, Practical Tools for Effective Experimentation*, *Second Edition*, Productivity Press, New York, NY, 2007.

2. Anderson, M.J. &Whitcomb, P.W., *RSM Simplified, Optimizing Processes Using Response Surface Methods for Design of Experiments*, Productivity Press, New York, NY, 2005.

3. Vaughn, N.A., et al, *Design-Expert® software*, Stat-Ease, Inc, Minneapolis, MN.