

# The Role of Statistical Tolerance Analysis Tools in Dose Counter Optimization

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## Introduction

The 3M™ Integrated Dose by Dose Counter is a displacement driven dose counter for pMDIs. The counting mechanism is actuated (moved) by the travel of the valve as the patient depresses the canister into the actuator. Therefore, to ensure count accuracy, the mechanism had to be designed to be robust to both manufacturing and valve variation. This paper describes the tolerance analysis that was used to assess and optimize the counter mechanism to accommodate these expected variations.

## Methods

The counter mechanism was analyzed, and 61 interactions between components were identified as potentially important to functionality. These interactions were then simulated in the tolerance analysis to estimate the probability of the mechanism functioning as intended. The Crystal Ball software (version 7.3 by Oracle, Redwood Shores, California, USA) which uses Monte Carlo methods, was used to simulate the variability in component dimensions and analyze the results.

For a displacement driven counter, it is essential that valve travel and valve geometry are matched and synchronized with the counter to avoid undercounting. The dose counter achieves this through a component called the Indexer. It is the only part of the counter that needs to be customized to allow operation with valves having different travels and geometries.

The example illustrated in this paper analyses the clearance between the counter and the valve at rest. This is an essential step for the count to complete and reset ready for the next actuation. Failure to reset before the valve returns to rest can result in the actuation not registering and hence undercounting. To construct the tolerance stack for calculation of clearance between the counter and the valve (Figure 1), the contributing dimensions (Table 1) along with the tolerance are inputted into the tolerance analysis.

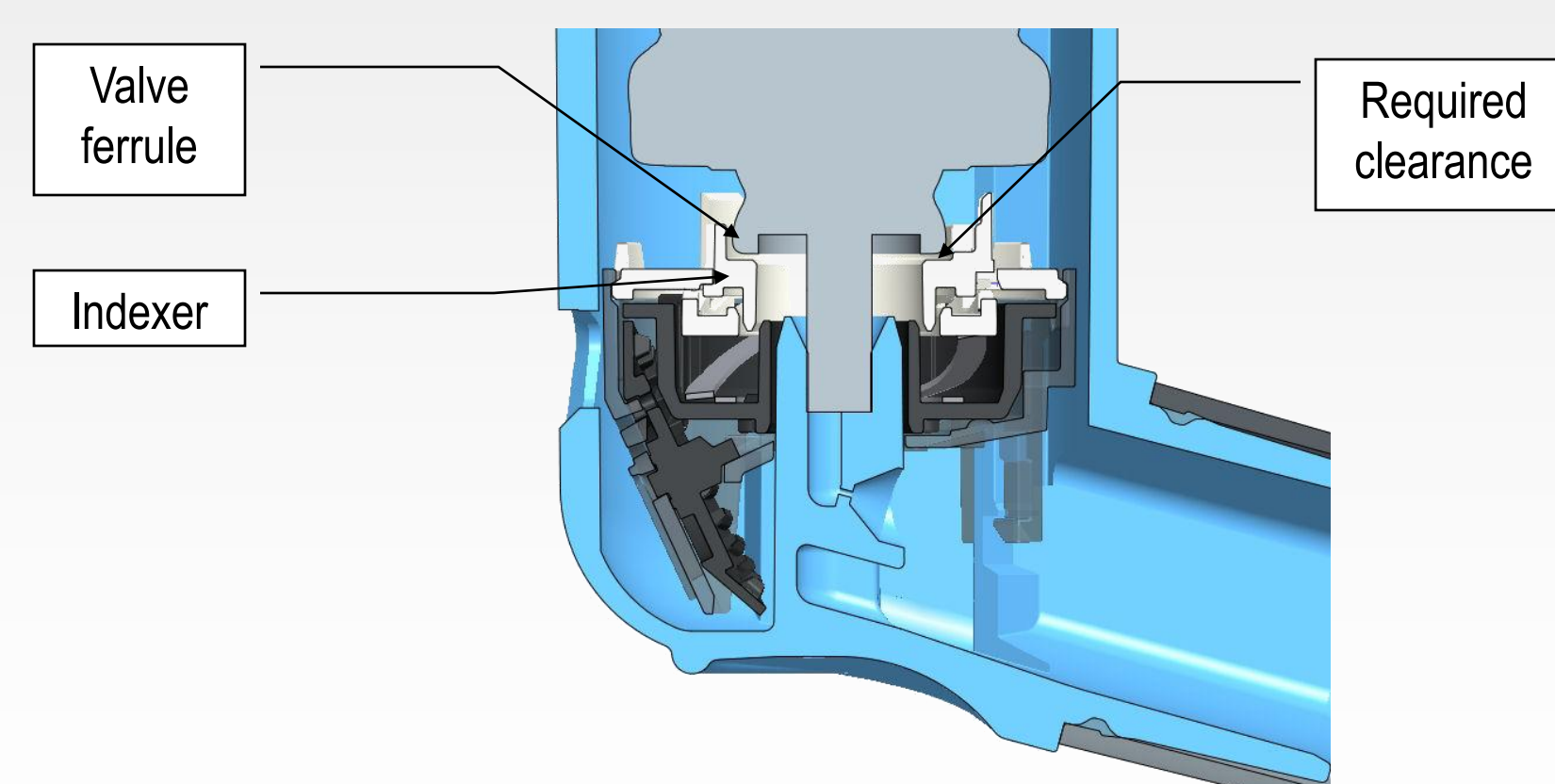


Figure 1 Valve ferrule to indexer clearance at rest

Table 1 Tolerance analysis input dimensions

Dimension	Description	Nominal
A1	Dose counter support to stem datum	1.95 mm
B1	Underside of housing to lid surface	7.50 mm
C1	Lid clipping features to tooth datum	0.50 mm
C2	Lid tooth height	1.00 mm
D1	Teeth ring outer tooth recess	0.10 mm
D2	Teeth ring inner tooth protrusion	0.29 mm
E1	Indexer height (Customizable)	2.45 mm
F1	Valve stem length at rest (valve specific)	7.80 mm

The expected variation for each dimension between the tolerances can then be chosen from standard statistical distributions or bespoke distributions (Figure 2).

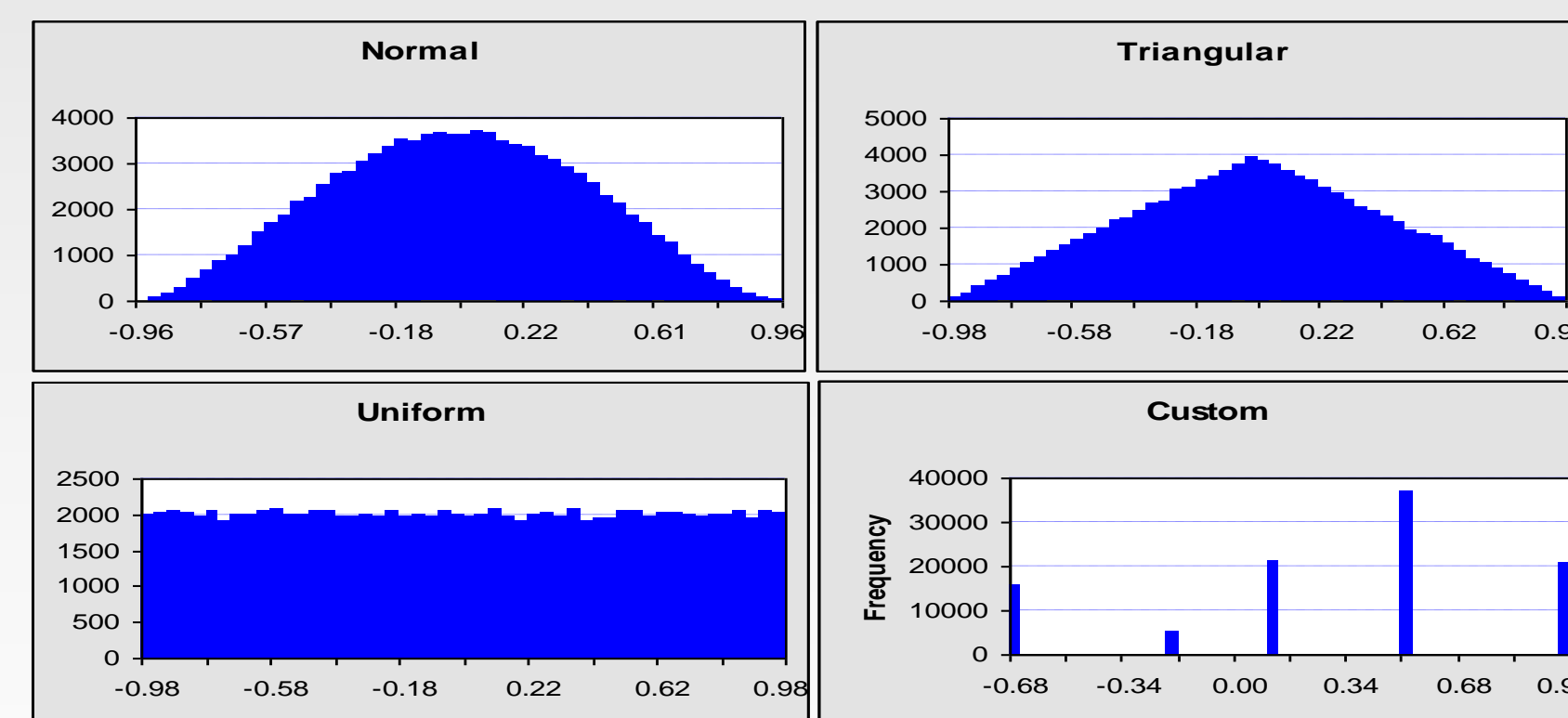


Figure 2 Example distributions between the tolerance limits

During the development of the counter the dimensional tolerances had to be predicted based on expected manufacturing capability. A uniform distribution was used for the dose counter components to represent the worst case multi-cavity manufacturing variation. A valve in full scale manufacture was used in this example and hence actual manufacturing data was available. The data showed a normal distribution around the mean would be suitable. To analyze suitability of other valves dimension F1 can be replaced with either predicted or actual valve data, and if required the indexer (E1) customized to match.

## Results

The simulation was run 100,000 times and the results stored for analysis of the expected probability of clearance at rest to allow the counter to reset. Examples of the possible data analysis techniques and their benefits are presented. The first example in Figure 3 is an overlay of two distributions, the counter rest point and the valve rest point, from a common datum.

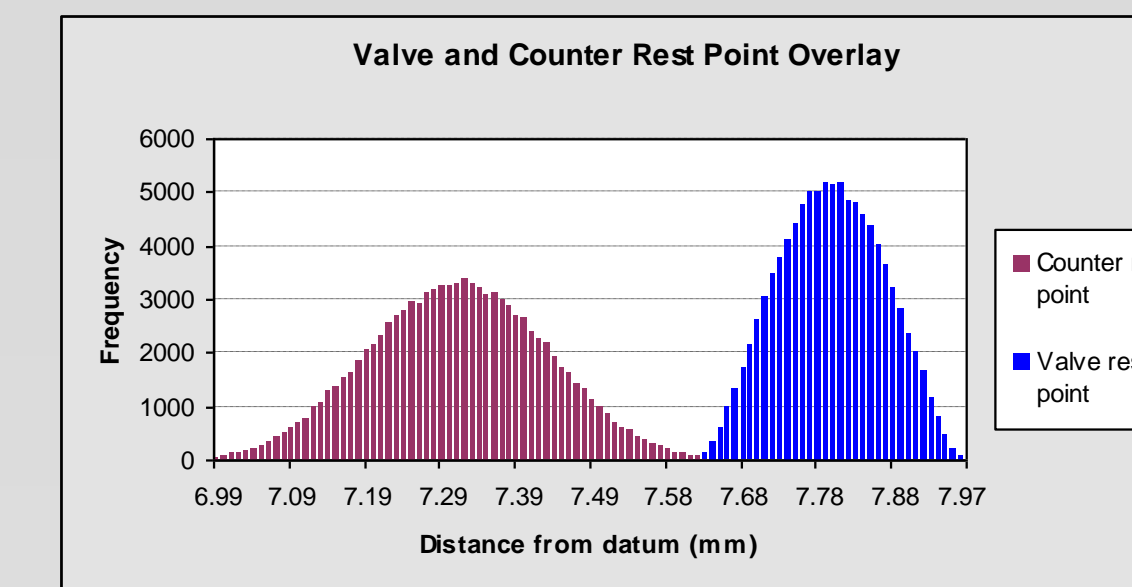


Figure 3 Overlay of valve and counter rest positions

The clearance between the counter and valve for each of the iterations is shown in Figure 4, calculated by subtracting the valve rest point from the counter rest point for each iteration. The probability of clearance can be calculated, and in this case shows that there is no probability of interference.

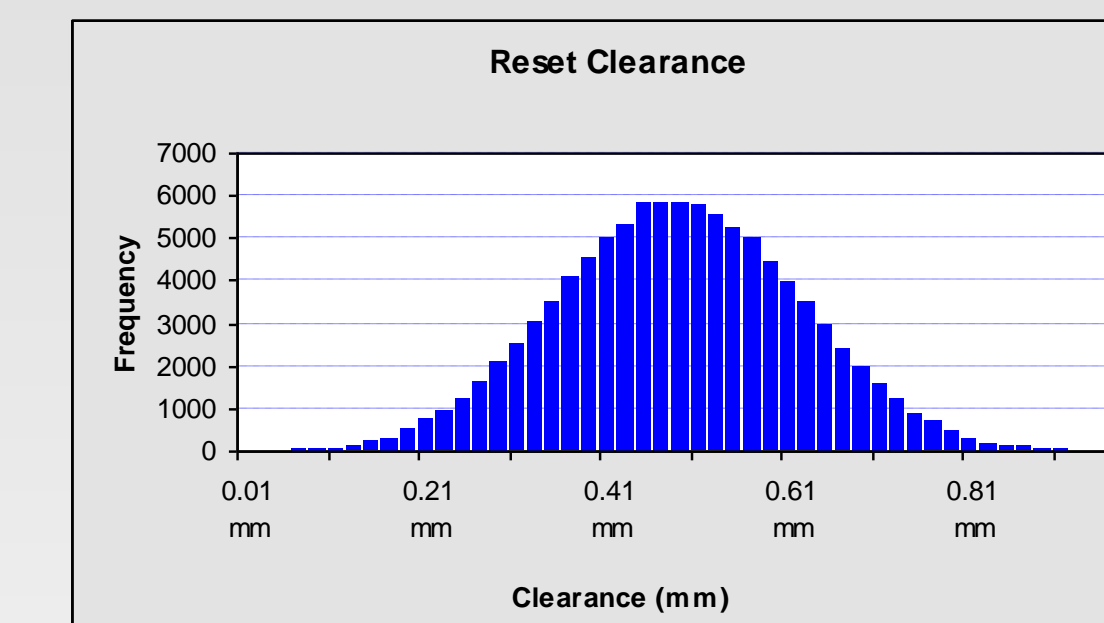


Figure 4 Clearance between the counter and ferrule at reset

The most likely case is a 0.5mm clearance between the components. The data therefore confirms compatibility between the valve and dose counter.

To further analyze the results, a sensitivity chart was used to illustrate the relative importance of the dose counter dimensions to the variance of the distribution shown in Figure 4. The sensitivity chart for this example is shown in Figure 5.

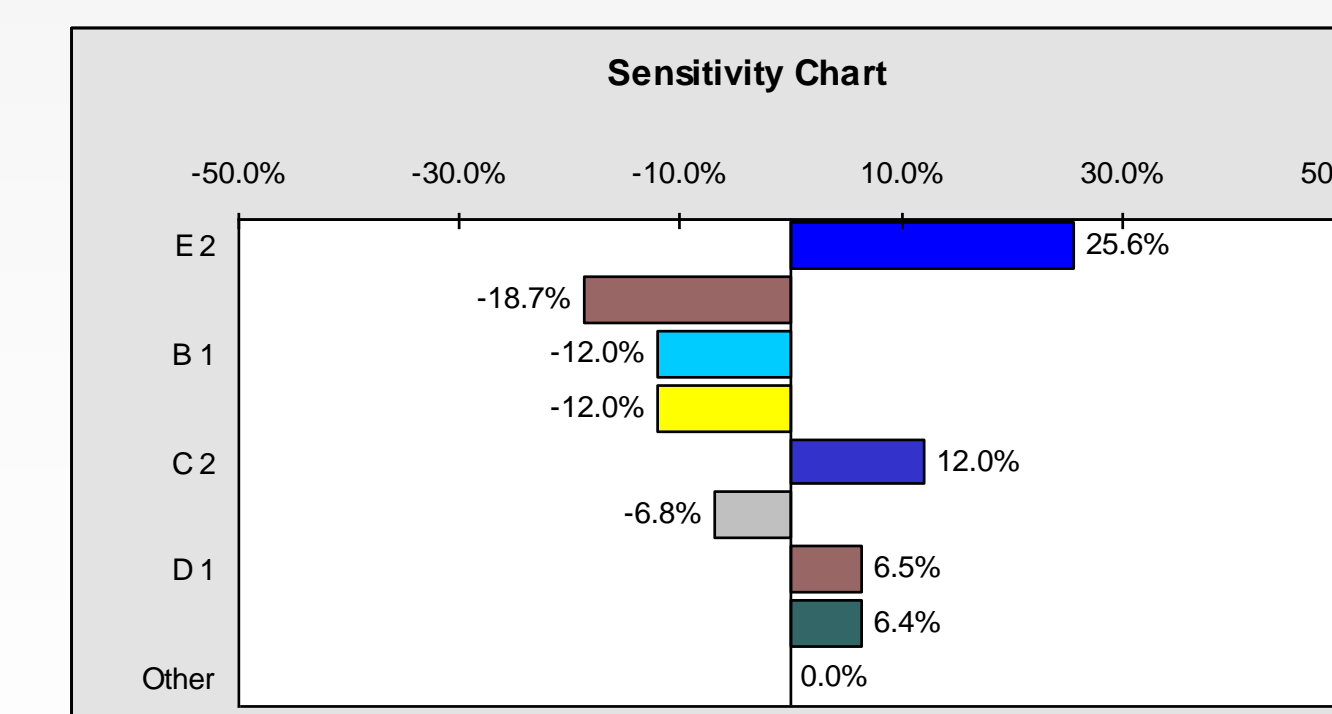


Figure 5 Sensitivity chart

From Figure 5, identification of the main sources contributing to variation allowed a targeted approach to optimization of component dimensions and tolerances. When a change needed to be made to a component dimension, a correlation chart as shown in Figure 6 was utilized.

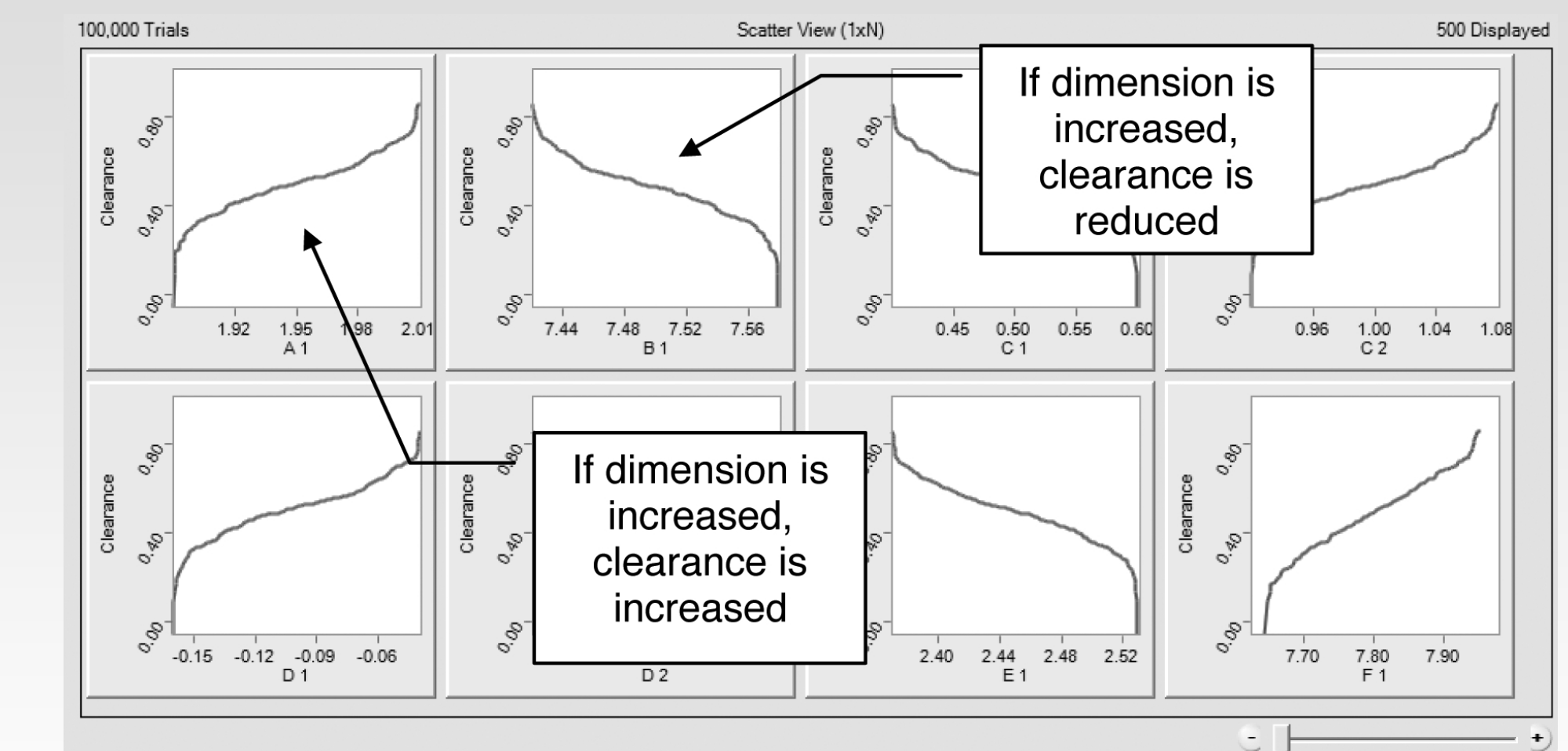


Figure 6 Correlation chart

The correlation chart illustrated the effect changing a dimension would have on clearance, enabling a targeted approach to design modification when used with the sensitivity chart.

## Conclusions

The utilization of Crystal Ball software to run Monte Carlo simulation techniques allows complex tolerance stacks to be analyzed in detail. This study demonstrates the use of tolerance analysis tools which enabled dose counter component design optimization to accommodate variations in valve dimensions, reducing the risk of compatibility failure upon commercial manufacture.