

# MEDICAL MOLDING PER ISO 13485 AND ISO 14971 REQUIREMENTS

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## Abstract

The FDA is becoming more stringent in auditing medical device companies (MDCs) for compliance to CFR Part 820 (QSRs), ISO 13485 (Quality Systems) and ISO 14971 (Risk Management) standards. MDCs are responsible for ensuring that both internal and outsourced plastic component suppliers meet these regulations and standards. Correlation Technology (CT) is an effective means for MDCs to flow down these requirements to their molded part suppliers. CT is an effective and efficient technology that enables molders to comply with the Quality standards, to accomplish Risk Management at the component level and to demonstrate their compliance with these requirements to both the FDA and the MDCs.

## Introduction

The U.S. federal government regulates medical device companies through the Code of Federal Regulations (CFRs), Title 21, Part 820: Quality System Regulations (QSRs). The Food and Drug Administration (FDA) promulgates these requirements and conducts audits to ensure compliance to the QSRs, to ISO 13485 and ISO 14971.

It is crucial to MDCs that their internal and outsourced molding suppliers also conform to the flow down requirements of the QSRs and to the direct requirements of ISO 13485 and ISO 14971. Correlation Technology enables the molder to meet the requirements of the QSRs and the ISO standards. This protects the MDC, the molder and, ultimately, the end user.

## Quality System Regulations (QSRs)

The QSRs encourage outsourced component manufacturers to follow the QSRs (Sec. 820.1). In any event, each MDC is required to:

- “Establish and maintain procedures to ensure that all purchased ... product ... conform to specified requirements.” (Sec. 820.50)
- “Monitor and control ... component ... characteristics during production.” (Sec. 820.70)
- “... establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling and verifying the

acceptability of process capability and product characteristics.” (Sec. 820.250)

The QSRs apply directly to the MDC’s internal molders. The QSRs, through the above provisions, effectively apply to the MDC’s outsourced molders.

## ISO 13485 (Quality Systems)

ISO 13485 requires the MDC to flow down the requirements of the MDC’s Quality Management System (QMS) to the external component molder (Sec. 4.1).

## ISO 14971 (Risk Management)

ISO 14971 requires the MDC to flow down the requirements of its Risk Management System (RMS) to external component molders (Sec. 2.8). ISO 14971 applies during development, validation and production (Sec. 1, Scope). ISO 14971 requires the identification of characteristics related to the safety of the medical device and their limits. In the context of the molder, these characteristics are, at the least, the specification of the critical dimensions and their tolerances (Sec. 4.2).

ISO 14971 emphasizes the use of robust systems (Annex D.2.2.3) and suggests that Hazard Analysis and Critical Control Point methods be used to control and monitor manufacturing processes through their Critical Control Points (critical dimensions) and critical limits (tolerances) (Annex G.6).

## Current Problems

Molds are typically delivered to production or pre-production facilities for validation knowing that:

1. The molds cannot make good parts—usually because the molds are “steel-safe”; and,
2. Even if the delivered molds can make good parts (at one particular combination of press settings), they may not have adequate capability to handle normal press variation (process drift).

These conditions lead to one or more tuning cycles for the 1.) mold, 2.) design tolerances, 3.) design targets, 4.) GDT features, 5.) the press and 6.) the measurement system. These six factors, along with material, constitute the “total system” that needs to be validated. A change to any one of these seven factors causes one or more project

interactions with the remaining factors. Project interactions can and usually do result in additional tuning cycles. Multiple tuning cycles during development are expensive, delay time-to-market and are risky.

Simple and complex interactions (DOE response surfaces) between press settings (causes) and dimensions (effects) further compound the difficulty of validating the total system.

Every time a control knob is changed on a press, the values of the part dimensions change. Depending on the press settings selected by the process engineer, you can conclude that a mold dimension should be a.) increased, b.) left unchanged or c.) decreased during development.

This press setting dependency also holds true for tolerance relaxations. You can relax a tolerance for one combination of press settings and find that the relaxation was totally unnecessary for a different combination of press settings. This degrades quality. Unnecessarily.

Molded medical components typically have a high number of critical dimensions, have tight tolerances and are produced in high-cavitation molds. These industry-typical conditions compound the difficulty of validating molded parts.

Many validation procedures incorrectly assume that if you can tightly control the three "largest" knobs on the press, then you are adequately controlling all dimensions.

High cavitation molds are used to reduce production costs. Some MDC validation procedures do not require the molder to determine process capability for all cavities in very high-cavitation molds. This creates potential exposure to the FDA and higher risk for the end user.

Molders "clamp down" the variation on press settings during validation. These special conditions may not be representative of process stability during production.

Under current procedures, validation must be repeated whenever the mold moves from press-to-press, supplier-to-supplier or country-to-country. Full revalidation is costly, time-consuming, unnecessary, and inefficient.

In-process inspection is redundant and unnecessarily expensive. It also typically samples only some fraction of the total number of critical dimensions, which increases risk and leads to potential degradation of quality.

Material is the seventh factor in the total molding "system". Lot-to-lot and supplier-to-supplier material variation during production is essentially ignored by most molders because of the cost and schedule delay incurred by evaluating material variation or alternate materials.

Cavity pressure sensors measure intermediate press variables that are typically not correlated to part dimensions. Cavity pressure sensors are therefore strategically misaligned with the MDC's requirement to purchase parts that meet dimensional specification. This

holds true for both the monitoring (accept/reject decisions) and control (press feedback) functions.

Molders can easily "grade" their mold suppliers on cost and schedule. Molders have a much more difficult time quantitatively grading their mold suppliers on the capacity of the mold to handle normal press variation.

## Correlation Technology Fundamentals

Correlation Technology (CT) is an established,<sup>1</sup> scientific, data-based method<sup>2</sup> for plastic injection molding that provides deep insight into the "total molding system". CT facilitates full or partial solutions to each of the above technological challenges.

CT is based on the fact that although the relationships between causes (press settings) and effects (dimensions) may be difficult or impossible to determine, the relationships between dimensions are consistent and predictable irrespective of changes in press settings within a normal process window.

Figure 1 is a correlation chart and is representative of correlations between dimensions. Figure 1 is based on data from a real mold run in a real press by a real operator with real parts measured with a real measurement system. Figure 1 shows the relationship between dimension 1 in cavity 1 versus dimension 1 in cavity 5. The data was generated using a 5 factor, 5 level (+1/0/-1/+1.5/-2), non-orthogonal, truncated DOE with 17 setups and 3 shots per setup. There is a different marker shape and color for each of the 17 setups in this Induced Variation Study (IVS).

The large number of shots (51) in this example is atypical and was done only to prove that a screening DOE is not required. The usual CT procedure is to measure 25 or 27 shots in a DOE format (5 or 9 setups, respectively).<sup>3</sup>

A regression line is fitted through the data using the method of least squares. The outer boundaries that bound the data can be determined using several methods including the calculation of 3-sigma limits.

Figure 1 illustrates the first key principle of CT that the relationships between dimensions are linear. A high degree of linearity is typical. In fact, if the data pattern does not exhibit a high degree of linearity, then we know

<sup>1</sup> CT is being used in the medical device and other industries. CT also has been proven for other processes and materials such as thermo-forming, LSR IM, die casting, and metal-working.

<sup>2</sup> CT is based on empirical data, not finite-element analysis or other theoretical CAE modeling software.

<sup>3</sup> A correlation study is not a DOE study. DOE determines (or tries to determine) the relationships between causes (press settings) and effects (dimensions). CT determines the relationships between effects (dimensions only). DOE only works for injection molding when there is a very small number of critical drawing dimensions and a very small number of cavities.

that the press is operating outside of the allowable process window. The allowable process window excludes shorts, flash, burnt plastic, pin-push deformation due to soft parts and other normally non-permissible processing conditions.

It is key to note that there are no press settings on Figure 1. There are no pressures, temperatures, speeds or times. There are only dimensional data points with each (x,y) data point consisting of two part dimensions from one shot. There is a separate correlation chart for each dimension in each cavity. All correlation charts have the same x-axis dimension. This dimension is the Predictor Dimension (PD). Selecting the PD is discussed later.

The Operating Point is the point where the dimensions are located on the regression line. Figure 2 illustrates the second key CT principle that changes to press settings move the Operating Point along the regression line but cannot move it off the regression line. Changes to press settings move the Operating Point along the regression line like sliding a bead along a wire. You can slide along the wire but you can't get off of it.

Figure 2 also illustrates the third key CT principle. Measurement error accounts (when there is no defective GDT) for nearly all of the data dispersion perpendicular to the regression line. The smaller the measurement error, the more tightly the data fits to the linear regression line.<sup>4</sup>

If the data exhibits wide dispersion around the regression line, then we know that either the measurement system is incapable or that the design has poor GDT features. In some cases, these conditions matter. In other cases, they do not matter. CT charts enable the project team to make the decision whether or not it matters.

Figure 3 superimposes structure on the regression line. The "spec. box" consists of the upper and lower specification limits for the critical dimension (on the y-axis) and the PD (on the x-axis).<sup>5</sup>

The principles behind the use of the regression line and spec. box are simple. There are only three alternatives;

1. If the regression line is completely inside of the spec. box, as illustrated in Figure 4, then it is only possible to make good parts in the process window. The critical dimension is called a "robust" dimension;
2. If the regression line is completely outside of the spec. box, as illustrated in Figure 5, then it is only possible to make bad parts in the process window. The critical dimension is called a "defect" dimension; and,

3. If the regression line is partially inside and partially outside of the spec. box, as illustrated in Figures 6 and 3, then the PD must be constrained in order produce only good parts. The critical dimension is called a "constraining" dimension.

All robust dimensions never need to be measured. All defect dimensions must be fixed. Constraining dimensions reduce the size of the Operating Range (the producibility window for the process engineer).

## Characterizing the Mold

CT works for single-cavity, multi-cavity and family molds. Figure 7 is a representation of a mold with four critical dimensions—A, B, C and PD—where PD is the Predictor Dimension. The PD is the dimension that is the statistically-best predictor of all other dimensions across all cavities.<sup>6</sup> The relationships shown in Figure 7 cover the entire universe of possible press settings in the process window. The relationships are defined by regression lines fitted through the IVS data for each critical dimension.

Figure 8 illustrates that when you know the value of the PD, then you know the value of all other dimensions. The cost savings potential during production is obvious.

Figure 9 illustrates how the Operating Range (OR) and Operating Target (OT) are determined for a mold with four dimensions. The OR is the range of the PD where all dimensions are in spec. The OR is the range where all of the arrows overlap. The OR is bounded by the Upper Operating Limit (UOL) and Lower Operating Limit (LOL).

The OT is the value of the PD that provides the highest Cpk for the system of dimensions. The OT is located at the center of the OR. The OT is the point of highest quality. The Operating Capability (Opk) of the mold is calculated using the same formulas as for Cpk, but the UOL and LOL are used in place of spec. limits.

The entire system of dimensions is condensed down to one dimension—the PD. The entire system of Cpk's is condensed down to one metric—Opk. The entire system of specification limits is condensed down to one set of production limits—UOL and LOL.

When the PD is within the OR, then all dimensions are in spec. When the PD is outside of the OR, then one or more part dimensions will be out-of-spec.

The PD, the Operating Range and the Operating Target characterize the mold. The Mold Characterization (MC) is press independent. This means the MC travels with the mold from press-to-press, molder-to-molder and country-to-country. The press settings will probably have to be adjusted to get the PD to the OT when the press is changed, but that is easy to do after MC.

<sup>4</sup> This has been observed in IM case studies with measurement systems accurate to one-hundredth of a thousandth of an inch.

<sup>5</sup> The large "dot" is the Target Intersection and is the point of intersection of the design target values for the critical and PD dimensions.

<sup>6</sup> Computational software does the statistical computations and selects the PD. The software ranks each part dimension based on its statistical ability to predict all other dimensions. The ranking is based on calculated, average correlation coefficients between each part dimension and all other part dimensions.

## Tuning the Molding System

If any molded dimension is a defect or does not meet Cpk requirements, then the system must be adjusted to bring the non-complying dimension(s) into spec. There are multiple ways to increase Cpk/Opk. The most common are to adjust press settings, relax design tolerances, change design targets, improve GDT, adjust the mold and improve the measurement system. Transferring in excess process capability from a mating part is also an option.

Figure 9 can also be used to illustrate that tolerances must be relaxed in a specific order to increase the size of the Operating Range. This functionality increases the size of the producibility window, reduces the number tolerance relaxation cycles from many to one and preserves maximum design integrity.

Figure 10 illustrates how to tune the mold in one and only one tuning cycle. Operator #1 concludes that the cavity size must be increased. Operator #2 concludes that the cavity size must be decreased. This is because they are operating at different points along the regression line. In fact, the optimum steel change is the Tooling Offset illustrated in Figure 10. The Tooling Offset is determined independently from press settings.

## Computational Software

Computational software is used to characterize the mold.<sup>7</sup> Figure 11 illustrates the Rankings Table used to select the PD. Figure 12 illustrates computation of the Operating Range and Operating Target. Figure 13 illustrates optimum tooling adjustments. Figure 14 illustrates the optimum order to relax tolerances. Figure 14 also specifies the increase in Operating Range (producibility window) that will be achieved for each successive, prioritized tolerance relaxation.

### Correlation Technology Reduces the Cost of Molded Medical Device Components

CT reduces the number of design target, design tolerance, GDT, press and measurement system tuning cycles during development. This reduces cost, shortens development time and reduces risk.

CT greatly reduces the cost (typically 95-99%) of in-process inspection during production by greatly decreasing the number of measurements required in the Quality Plan.

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<sup>7</sup> Mold characterization would not be practical without computers and computational software. Selecting the PD, alone, can require tens of thousands of calculations.

CT enables automated part monitoring and/or automated press control during production using the PD to achieve dimension compliance and highest quality.

CT typically reduces cycle time by 4-5%.

### Correlation Technology Application to ISO 14971

CT reduces risk by:

- Ensuring that component-level part dimensions meet specification;
- Ensuring that technically sound statistical techniques are used; and,
- Providing procedures that can be included in the molder's Quality and Risk Management Systems.

CT is applicable to development and production (ISO 14971, Sec. 1). CT analysis and procedures include all critical dimensions per the requirements of the Risk Management Plan (Sec. 4). CT enables robust molding systems (Annex D.2.2.3). CT enables Hazard Analysis (Annex G6). The PD is the "Critical Control Point (CCP)" that encompasses all part dimensions (Annex G.6.2). The Upper and Lower Operating Limits are the "critical limits" for the CCP (Annex G.6.3).

Monitoring solely the PD (in one cavity) accomplishes monitoring all critical part dimensions in all cavities to ensure that all critical dimensions meet specification (Annex G.6.4). The PD/CCP, in conjunction with a feedback control system, enables a robust molding system (Annex D.2.2.3).

The following is a list of common risk factors for injection molded parts. CT mitigates or eliminates these risks and helps control remaining risk.

#### Mold Risk Factors

- Multiple mold tuning cycles are reduced to a single tuning cycle by using the Offset Table.
- Mold tuning decisions are valid for any combination of press settings in the process window when using the Offset Table.
- Mold-makers deliver the highest quality mold with highest Opk by using the Offset Table.
- Opk gives the molder and mold maker confidence that the mold has adequate capability to handle normal press variation.
- Wear rates are predictable using shifts in the regression lines, enabling proactive action (PM).
- The effect of blocked cavities is quickly assessed using shifts in the regression lines.

#### Press and Press Setting Risk Factors

- The mold characterization transfers along with the mold from press-to-press, supplier-to-supplier and

country-to-country. This enables faster, cheaper, lower risk re-validation.

- The effects of DOE and project interactions are eliminated.
- Optimum (highest quality) press settings are obtained at the Operating Target.
- All press control “knobs” are included in CT analysis instead of only the three largest “knobs”.
- Operator deviation from the optimum press settings becomes immediately apparent when the PD is measured.

#### Part Design Risk Factors

- Design integrity is preserved by using tolerance relaxations only when necessary and in the proper order per the Tolerance Relaxation Table.
- Improper GDT design practices, which confound measurement results, are identified through data patterns so they can be eliminated.

#### Metrology Risk Factors

- Measurement and data recording errors are identified through data patterns and eliminated.
- Unnecessary changes to the measurement system are avoided. Necessary changes are identified.

#### Material Change Risk Factors

- It becomes quick and easy, and therefore inexpensive, to identify the effects of lot-to-lot, supplier-to-supplier and replacement material variation. This is done by adding a few new data points based on the new material to the existing correlation charts via the software and visually reviewing the new correlation charts.
- If material changes have changed the correlation relationships, then either A.) a separate Operating Range can be used for each material or B.) a combined (overlapping) Operating Range can be used that accommodates several materials.

#### Production Inspection Risk Factors

- When the PD is monitored, all critical dimensions are effectively monitored during production—not just the in-process dimensions.
- Cpk's no longer need to be ignored in some percentage of cavities in very high cavitation molds because CT inherently includes all cavities.
- Molders can stop relying on non-predictive and potentially misleading in-process dimensions such as the last dimension to fill, an overall dimension, the most “sensitive” dimension or weight.

#### Language, Geographic and Cultural Risk Factors

- Everyone—across the engineering disciplines and up and down the supply chain—is on the same page, speaking the same language, looking at the

same charts and tables and coming to the same, data-based conclusions at the same time.

#### Pressure Sensor Monitoring and Control Risk Factors

- Using the PD to monitor (accept/reject) dimensions is directly aligned with the MDC's objective of purchasing parts that meet spec. Monitoring cavity pressure profiles is risky because pressure profiles (or their integrals) are not generally correlated to dimensions.
- Control methods using pressure sensors do not produce the highest quality Cpk's and may consistently produce unacceptably low Cpk's.

#### Mold Supplier Evaluation Risk Factors

- CT enables MDCs and molders to use Opk to scientifically rank the technical performance of their mold suppliers to weed out low performers.

### **Simulation Capabilities of Correlation Technology Reduce Risk**

CT uses the real part data generated in the IVS when CT functions in the simulation mode. The CT software is used to simulate changes to design targets, design tolerances, the mold, and press settings without incurring the time, cost and risk of actually doing so. CT simulation is an extremely powerful tool that ensures that the risk mitigation plan actually reduces the targeted risks.

### **Conclusions**

Correlation Technology is a valuable tool that enables medical device companies to flow down the requirements of CFR Part 820, ISO 13485 and ISO 14971 to their internal and outsourced plastic injection molding suppliers. CT is a valuable tool that enables injection molding suppliers to comply with the CFR regulations and ISO standards. CT enables both MDCs and molders to demonstrate compliance to FDA requirements during audit. CT provides higher quality component parts that ultimately benefit the end user.

### **References**

1. Algoryx web site at [www.algoryx.com](http://www.algoryx.com), *Applications, Professional Societies, Technical Papers.*
2. Algoryx web site at [www.algoryx.com](http://www.algoryx.com), *Applications, Books and Magazines.*
3. U.S. patent numbers 6,687,558; 7,072,808; 7,187,992; 7,239,991; and 7,321,848. Other patents pending and granted in the U.S. and other countries.

### **Key Words**

CFR Part 820, QMS, ISO 13485, ISO 14971

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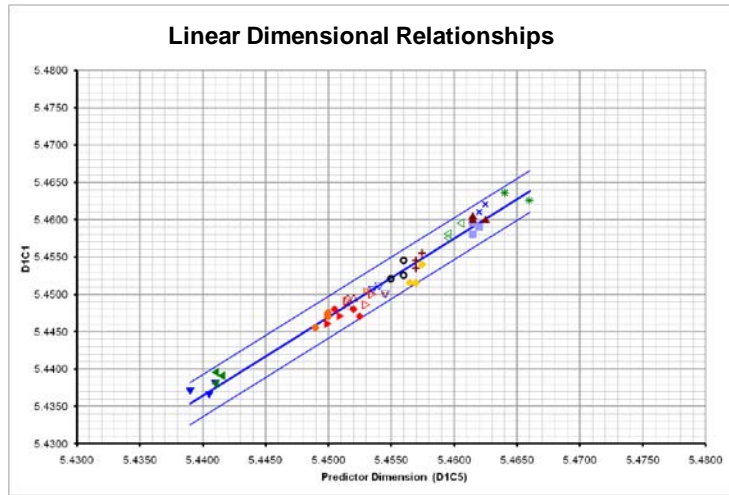


Figure 1

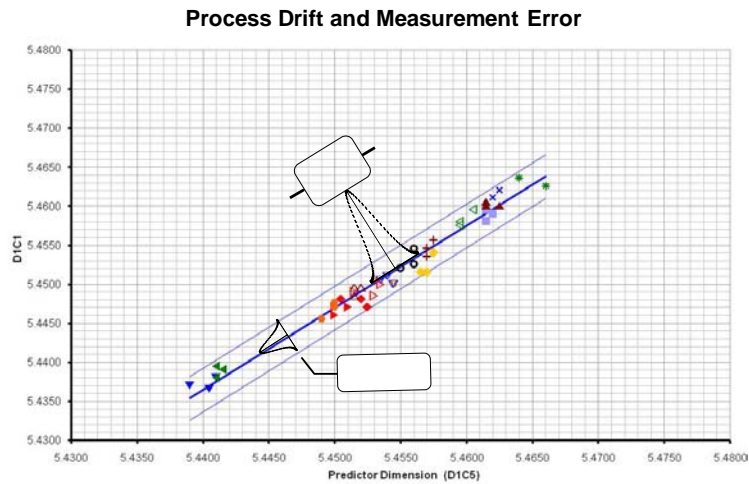


Figure 2

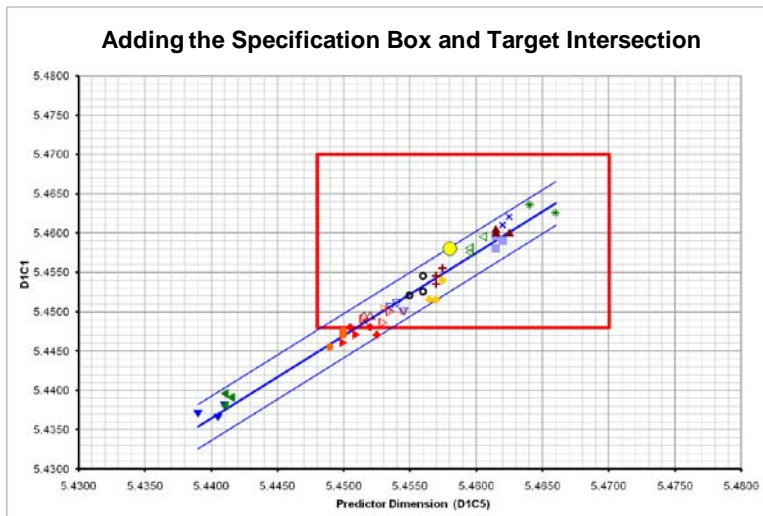


Figure 3

### Robust Critical Dimension

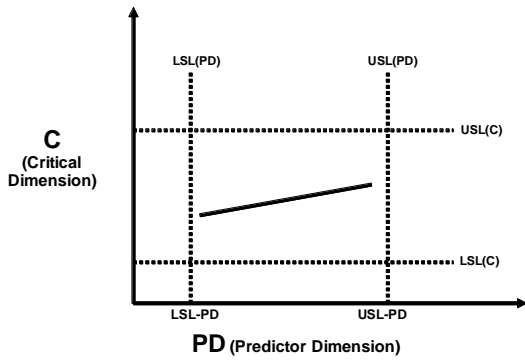


Figure 4

### Defect Critical Dimension

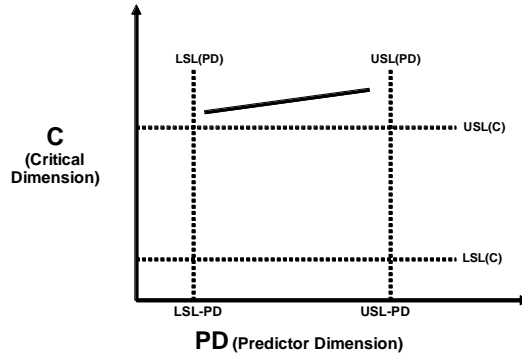


Figure 5

### Constraining Critical Dimension

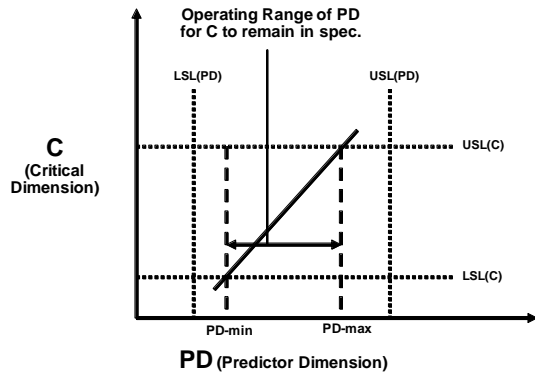


Figure 6

### Four Critical Dimensions

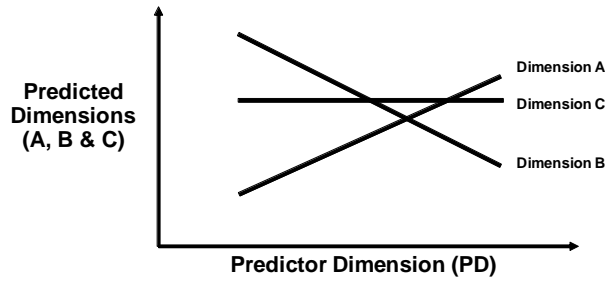


Figure 7

### The PD Predicts All Other Dimensions

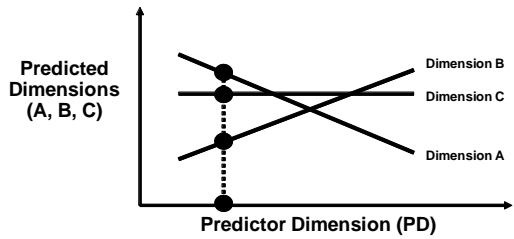


Figure 8

### Operating Range and Operating Target

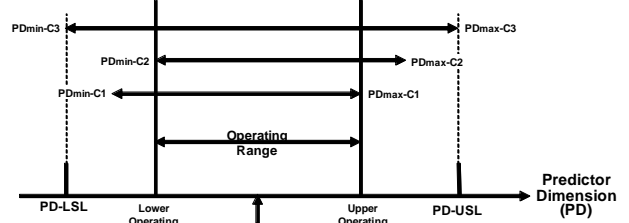


Figure 9

### Tuning the Mold Independently from Press Settings

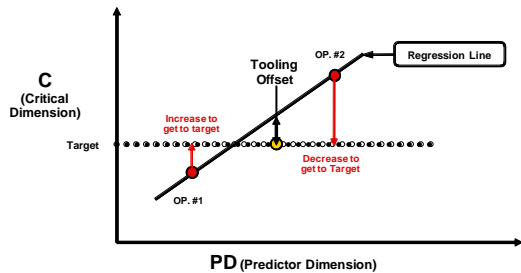


Figure 10

<u>Unranked</u>			<u>Ranked</u>		<b>Best Predictor</b>	<b>User Predictor</b>
<u>Col. No.</u>	<u>Variable</u>	<u>Metric</u>	<u>Variable</u>	<u>Metric</u>	<u>Data Column No.</u>	<u>Data Column No.</u>
1	D1C1	98.0	D1C1	98.0	1	5
2	D1C2	97.8	D1C5	97.9		
3	D1C3	97.2	D1C2	97.8		
4	D1C4	97.7	D1C7	97.8	<b>Best Predictor</b>	<b>User Predictor</b>
5	D1C5	97.9	D1C4	97.7	<u>Variable</u>	<u>Variable</u>
6	D1C6	97.5	D1C6	97.5	D1C1	D1C5
7	D1C7	97.8	D1C3	97.2		
8	D1C8	96.5	D1C8	96.5		
9	D2C1	95.7	D2C2	96.4		
10	D2C2	96.4	D2C1	95.7		

Figure 11

**Operating Range and Operating Target**

<u>Variable Name</u>	<u>Data Column</u>	<u>Pmin</u>	<u>Pmax</u>	<u>Lower Op. Limit</u>	<u>Upper Op. Limit</u>
D1C1	1	5.4538	5.4691	5.4617	5.4647
D1C2	2	5.4512	5.4647	9	2
D1C3	3	5.4531	5.4670		
D1C4	4	5.4497	5.4650		
D1C5	5	Predictor	Predictor		
D1C6	6	5.4511	5.4698		
D1C7	7	5.4512	5.4668		
D1C8	8	5.4565	5.4658		
D2C1	9	5.4617	5.4700		
D2C2	10	5.4584	5.4700		

Operating Range  
0.0030

Operating Target  
5.4632

Data Is Not Constrained

Figure 12

**Mold Tuning Offsets**

<u>Dimension Name</u>	<u>Vertical Offset</u>
D1C1	-0.0026
D1C2	0.0010
D1C3	-0.0011
D1C4	0.0017
D1C5	Predictor
D1C6	-0.0012
D1C7	-0.0001
D1C8	-0.0023
D2C1	-0.0096
D2C2	-0.0072
D2C3	-0.0073
D2C4	-0.0073

Figure 13

**Tolerance Relaxation Table**

<u>Variable Name</u>	<u>Col. No.</u>	<u>Ranked Pmin's</u>	<u>Individ. Gain</u>	<u>Cumul. Gain</u>	<u>Variable Name</u>	<u>Col. No.</u>	<u>P-max's</u>	<u>Individ. Gain</u>	<u>Cumul. Gain</u>
D2C8	16	5.4643	0.0025	0.0025	D1C2	2	5.4647	0.0003	0.0003
D2C1	9	5.4617	0.0004	0.0029	D1C4	4	5.4650	0.0008	0.0011
D2C5	13	5.4613	0.0024	0.0053	D1C8	8	5.4658	0.0010	0.0021
D2C4	12	5.4590	0.0001	0.0054	D1C7	7	5.4668	0.0002	0.0023
D2C6	14	5.4589	0.0001	0.0054	D1C3	3	5.4670	0.0011	0.0035
D2C7	15	5.4588	0.0004	0.0059	D2C5	13	5.4682	0.0010	0.0044
D2C2	10	5.4584	0.0004	0.0063	D1C1	1	5.4691	0.0006	0.0050
D2C3	11	5.4580	0.0015	0.0078	D1C6	6	5.4698	0.0002	0.0053
D1C8	8	5.4565	0.0027	0.0105	D2C1	9	5.4700	0.0000	0.0053
D1C1	1	5.4538	0.0007	0.0112	D2C2	10	5.4700	0.0000	0.0053
D1C3	3	5.4531	0.0018	0.0130	D2C3	11	5.4700	0.0000	0.0053
D1C2	2	5.4512	0.0000	0.0131	D2C4	12	5.4700	0.0000	0.0053
D1C7	7	5.4512	0.0001	0.0132	D2C6	14	5.4700	0.0000	0.0053

Figure 14