Process Capability/Medical Devices

Process capability is the long-term performance level of the process after it has been brought under statistical control. It is the ability of the combination of your 4 M's (machines, methods, materials, manpower) to produce a product that will consistently meet the design requirements and the customer expectation.

In this article we explain: How to calculate Cp, Cpk, Cpl and Cpu indices, Why you should know the Capability of Your and your supplier's Processes, The difference between Capability indices and Process performance indices, The relation between Process capability and defect rate and some assumptions and precautions while calculating process capability indices.

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Why this article has been expanded:

This article is devoted to the topic of process capability in a medical device converting environment, with the objective of making people aware of this subject and its significance to business success. Personal awareness is a prerequisite to personal action, and personal action is what we need for success.

- Medical device manufacturing (i.e., converting of medical tapes for surgical applications) is much different than manufacturing "rigid" items, such as components for a car. This is because most medical materials have an elongation factor (the materials stretch), so accurate and precise measurements usually demonstrate more variability because of elongation.

- This article will address issues like what is process capability, how to measure it, and how to calculate the process capability indices (Cp, Cpk).

- We will also attempt to explain the differences between process capability and process performance; the relationship between Cpk (or Ppk for small manufacturing runs), and non-conforming (defect) rate; and illustrate the four outcomes of comparing natural process variability with customer specifications.

- Lastly, a commentary is provided on precautions we should take while conducting process capability studies in a Medical Tape converting/ manufacturing environment.

What is Process Capability?

1. Process capability is the long-term performance level of the process after it has been brought under statistical control. In other words, process capability is the range over which the natural variation of the process occurs as determined by the system of common causes.

2. Process capability is also the ability of the combination of people, machine, methods, material, and measurements to produce a product that will consistently meet the design requirements or customer expectation.

What is a Process Capability Study?

Process capability study is a scientific and a systematic procedure that uses control charts to detect and eliminate the unnatural causes of variation until a state of statistical control is reached. When the study is completed, you can identify the natural variability of the process. Note: small sample sizes may distort a Cpk/ Ppk number. We will explain this later.

Why Should I know the Capability of My Processes?

- Process capability measurements allow us to summarize process capability in terms of meaningful percentages and metrics.

- To predict the extent to which the process will be able to hold tolerance or customer requirements. Based on the law of probability, you can compute how often the process will meet the specification or the expectation of your customer.

- You may learn that bringing your process under statistical control requires fundamental changes - even redesigning and implementing a new process that eliminates the sources of variability now at work.

- It helps you choose from among competing processes, the most appropriate one for meeting customers' expectation.

- Knowing the capability of your processes, you can be better at specifying the quality performance requirements for new machines, parts and processes.

Why Should I know the Capability of My Supplier's Processes?

1. To set realistic cost effective part specifications based upon the customer's needs and the costs associated by the supplier at meeting those needs.

2. To understand hidden supplier costs. Suppliers may not know or hide their natural capability limits in an effort to keep business. This could mean that unnecessary costs could occur such as sorting to actually meet customer needs.

3. To be pro-active. For example, a Cpk estimation made using injection molding pressure measurements during a molding cycle may help reveal a faulty piston pressure valve ready to malfunction before the actual molded part measurements go out of specifications. This saves time and money.

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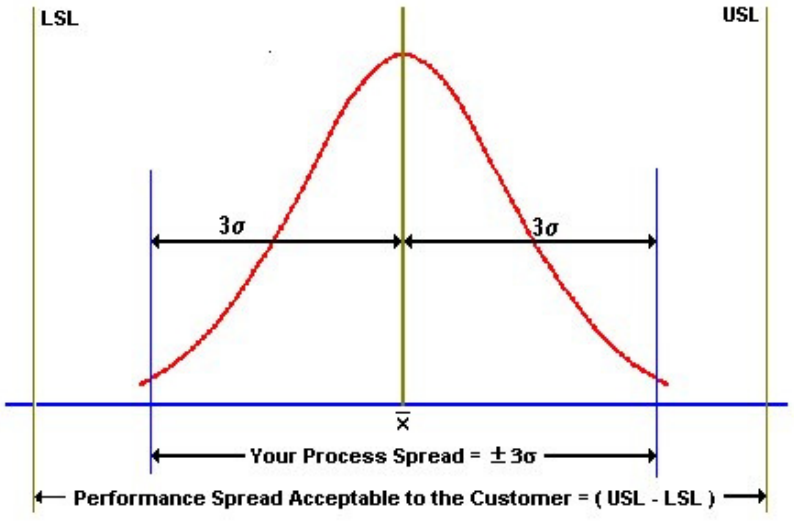
Measures of Process Capability - Process Capability Indices:

Cp, Cpk, Pp, and Ppk are the four most common and timed tested measures of process capability.

- Process capability indices measure the degree to which your process produces output that meets the customer's specification.
- Process capability indices can be used effectively to summarize process capability information in a convenient unitless system.
- Cp and Cpk are quantitative expressions that personify the variability of your process (its natural limits) relative to its specification limits (customer requirements).

Following are the graphical details and equations quantifying process capability:



Where :

USL = Upper Specification Limit

LSL = Lower Specification Limit

X-Bar = Mean of the Process

s = Standard Deviation of the Process

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INDEX	ESTIMATED EQUATION	USAGE
Cp	(USL - LSL) / 6s	Process Capability for two - sided specification limit, irrespective of process center.
Cpu	(USL - X-Bar) / 3s	Process Capability relative to upper specification limit.
Cpl	(X-Bar - LSL) / 3s	Process Capability relative to lower specification limit.
Cpk	Min. of (Cpu , Cpl) or Distance between mean of the process and the closest spec. limit / 0.5 of the process variability.	Process Capability for two - sided specification limit accounting for process centering.

Notes:

1. If X-Bar is at target, then Cp = Cpk.
2. Cpk will always be equal to or less than Cp.

The Cpk, Ppk "Tug of War":

In 1991, ASQ / AIAG task force published the "Statistical Process Control" reference manual, which presented the calculations for capability indices (Cp, Cpk) as well as process performance indices (Pp, Ppk).
The difference between the two indices is the way the process standard deviation (s) is calculated.

Cpk uses s which is estimated using (R-Bar / d2) or (S-Bar / C2) .

Ppk uses the calculated standard deviation from individual data where s is calculated by the formula:

$$\sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1}}$$

So the next question is which metric is best to report Cpk or Ppk?

In other words, which standard deviation to use - estimated or calculated?
Although both indices show similar information, they have slightly different uses.

- Ppk attempts to answer the question "does my current production sample meet specification?" Process performance indices should only be used when statistical control cannot be evaluated. This is typical with few samples.

- On the other hand, Cpk attempts to answer the question "does my process in the long run meet specification?" Process capability evaluation can only be done after the process is brought into statistical control. The reason is simple: Cpk is a prediction, and one can only predict something that is stable.

The readers should note that Ppk and Cpk indices would likely be similar when the process is in a state of statistical control.
Notes:

1. As a rule of thumb a minimum of 30 to 50 randomly selected samples must be chosen for process performance studies (Ppk) and a minimum of 20 subgroups (of sample size, preferably of at least 3 or 5) must be chosen for process capability studies. We prefer 3 or 5 because it is easier to construct a "Median Chart" for ongoing control.

   Cpk for all critical product measurements considered important by the customer should be calculated at the beginning of initial production to determine the general ability of the process to meet customer specifications. Then, from time to time, over the life of the product, Cpks must be generated. A control chart (Median & Range or X Bar & R Chart) should be maintained to check statistical stability of the process (over several days or weeks) before capability is computed. (This may not always be possible in a short run environment). At ATL we use inference error as part of our expression of Cpk. For example, we could make a statement that we have a probable 3 defects per million, but our estimation may have a 5% error factor in the assumption. More on this later.

Process Capability and Defect Rate:

Using process capability indices it is easy to forget how much of product is falling beyond specification. The conversion curve presented here can be a useful tool for interpreting Cpk with its corresponding defect levels. The defect levels or parts per million nonconforming were computed for different Cpk values using the Z scores and the percentage area under the standard normal curve using normal deviate tables.

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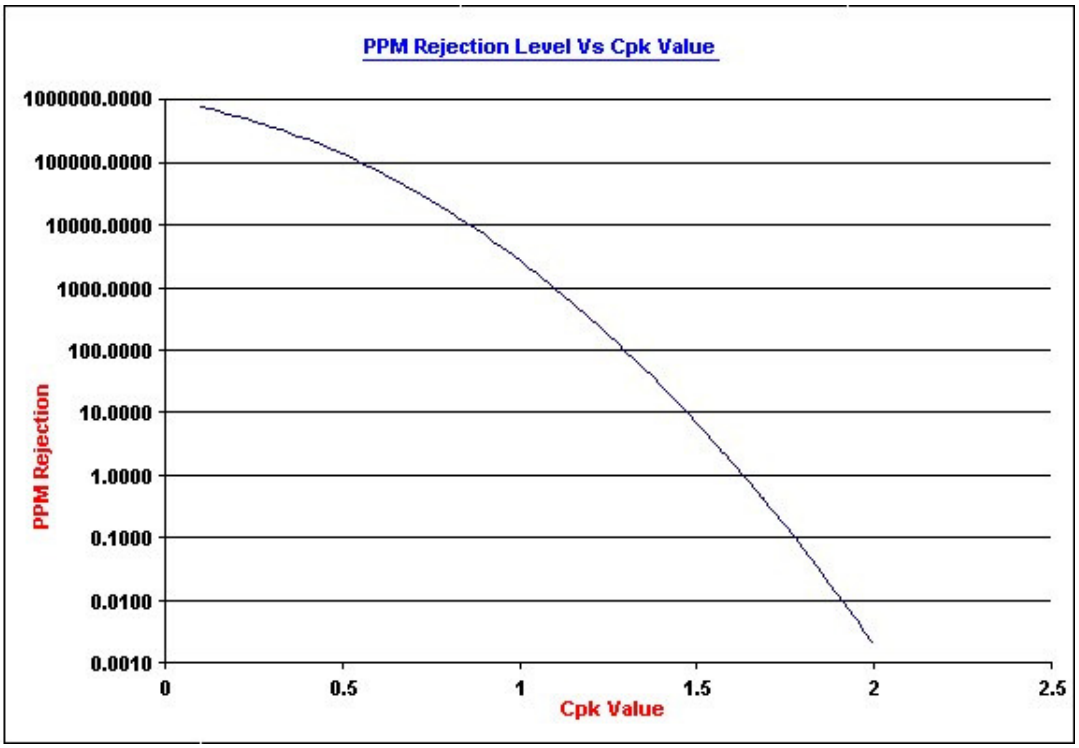
The table below presents the non-conforming parts per million (ppm) for a process corresponding to Cpk values if the process mean were at target.

Cpk Value	Sigma Value	Area under Normal Curve	Non Conforming ppm
0.1	0.3	0.235822715	764177
0.2	0.6	0.451493870	548506
0.3	0.9	0.631879817	368120
0.4	1.2	0.769860537	230139
0.5	1.5	0.866385542	133614
0.6	1.8	0.928139469	71860
0.7	2.1	0.964271285	35728
0.8	2.4	0.983604942	16395
0.9	2.7	0.993065954	6934
1.0	3.0	0.997300066	2700
1.1	3.3	0.999033035	967
1.2	3.6	0.999681709	318
1.3	3.9	0.999903769	96
1.333	3.999	0.999936360	64
1.4	4.2	0.999973292	27
1.5	4.5	0.999993198	6.8
1.6	4.8	0.999998411	1.6
1.666	4.998	0.999999420	0.58
1.7	5.1	0.999999660	0.34
1.8	5.4	0.999999933	0.06
1.9	5.7	0.999999988	0.012
2.0	6.0	0.999999998	0.002

The Cpk conversion curve for process with mean at target is shown next.

Process Capability/Medical Devices



Explanation: A process with Cpk of 2.0 (+/- 6 sigma capability), i.e., the process mean is 6 sigma away from the nearest specification can be expected to have no more than 0.002 nonconforming parts per million.

This process is so good that even if the process mean shifts by as much as +/- 1.5 sigma the process will produce no more than 3.4 non-conforming parts per million.

Medical devices manufactured with a Cpk of > 2 usually are "tooling dominant". These are films or liners and not medical foam, and usually do not require island placement(s) (a process that combines two or more webs that come together, possibly at different speeds). In other words, the more variables in the medical device (layers or components), the more likely the process will exhibit greater variability. So a Cpk between 1.33 and 1.66 is likely.

The next section provides the reader with some practical clarifications on Process Capability (Voice of the process) and Specification (Expectations of the customer).

Natural Variability versus Specifications for Process Capability:

As seen from the earlier discussions, there are three components of process capability:

2. Design specification or customer expectation (Upper Specification Limit, Lower Specification Limit)

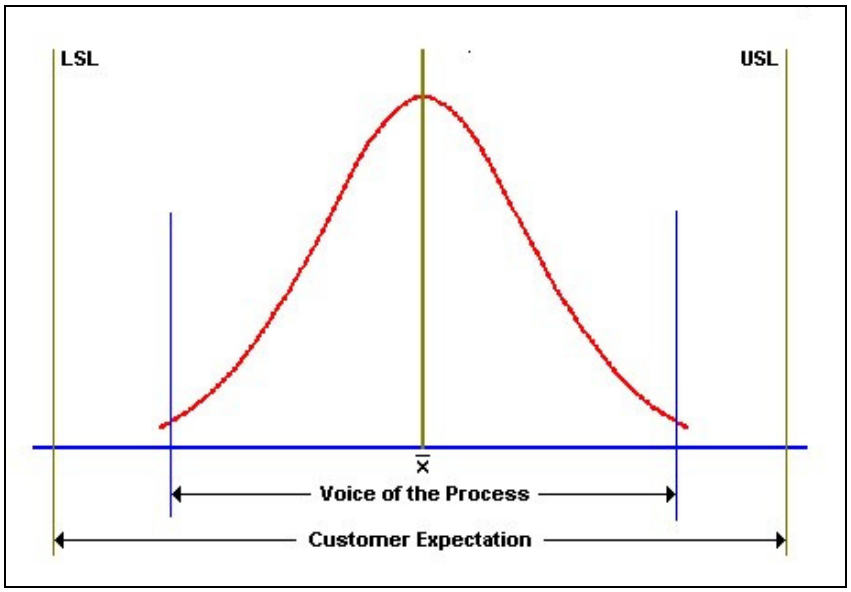
3. The centering of the natural process variation (X-Bar)

4. Spread of the process variation (s)

A minimum of four possible outcomes can arise when the natural process variability is compared with the design specifications or customer expectations:

Case 1: Cpk > 1.33 (A Highly Capable Process)

This process should produce less than 64 non-conforming parts per million (ppm)



A Highly Capable Process: Voice of the Process < Specification (or Customer Expectations).

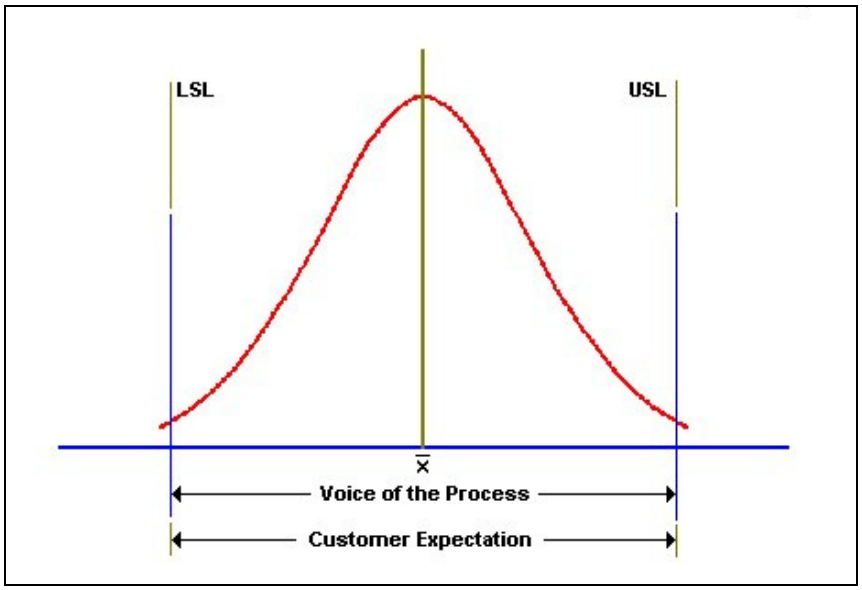
This process will produce conforming products as long as it remains in statistical control. The process owner can claim that the customer should experience least difficulty and greater reliability with this product. This should translate into higher profits.

Note: Cpk values of 1.33 or greater are considered to be industry benchmarks. This means that the process is contained within four standard deviations of the process specifications.

Case 2: Cpk = 1 to 1.33 (A Barely Capable Process)

This process will produce greater than 64 ppm but less than 2700 non-conforming ppm.

This process has a spread just about equal to specification width. It should be noted that if the process mean moves to the left or the right, a significant portion of product will start falling outside one of the specification limits. This process must be closely monitored.

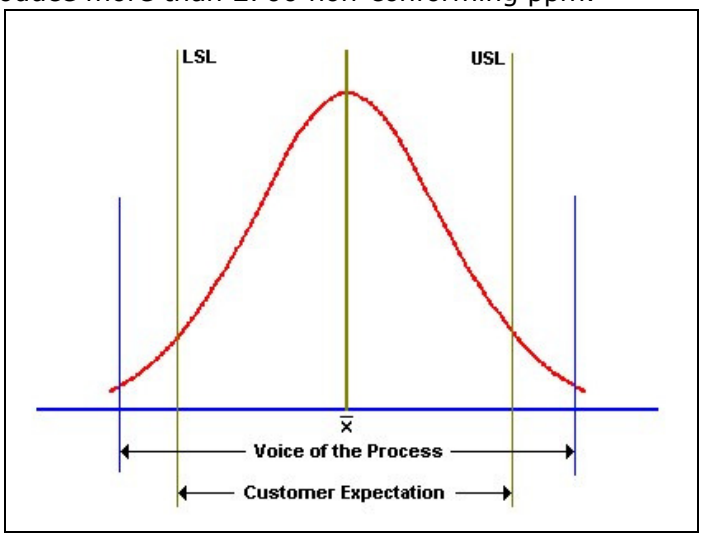


A Barely Capable Process: Voice of the Process = Customer Expectations

Note: This process is contained within three to four standard deviations of the process specifications.
At ATL, we would expect a "barely capable process" outcome if a customer would specify a target value with a tolerance of +/- .010". This is seldom obtainable without very special tooling (which is a cost driver). In most cases, +/- .030" would usually result in capable process capability (> 1.33), and would also result is a lower sell price to the customer. If you are an engineer designing a medical device it is wise to keep this fact in perspective.

ATL quality/ engineering works with customers to establish cost effective tolerances. This is part of a function known a A.P.Q.P. (Advanced Product Quality Planning).

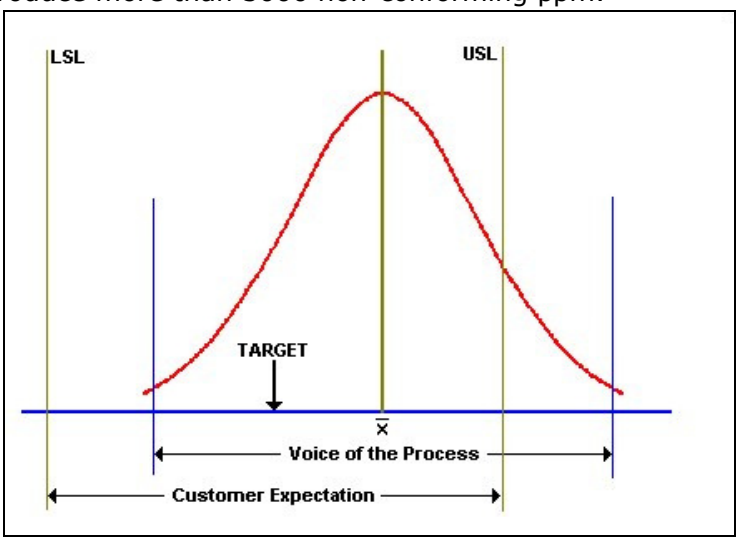
Case 3: Cpk < 1 (The Process is not Capable)
This process will produce more than 2700 non-conforming ppm.



A Non-Capable Process: Voice of the Process > Customer Expectations.

It is impossible for the current process to meet specifications even when it is in statistical control. If the specifications are realistic, an effort must be immediately made to improve the process (i.e. reduce variation) to the point where it is capable of producing consistently within specifications.

Case 4: Cpk < .9 (The Process is not Capable – worse than the one shown above)
This process will produce more than 5000 non-conforming ppm.



The variability (s, or sigma) and specification width is assumed to be the same as in case 3, but the process average is off-center. In such cases, adjustment is required to move the process mean back to target. If no action is taken, a substantial portion of the output will fall outside the specification limit even though the process might be in statistical control.

Assumptions, Conditions and Inference Error:

Capability indices described in this article strive to represent (with a single number) the capability of a process. Much has been written in the literature about the pitfalls of these estimates. Following are some of the precautions the readers should exercise while calculating and interpreting process capability:

1. The indices for process capability discussed are based on the assumption that the underlying process distribution is approximately bell shaped or normal. Yet in some situations the underlying process distribution may not be normal. For example, flatness, pull strength, waiting time, elongation, etc., might naturally follow a skewed distribution. For these cases, calculating Cpk the usual way might be misleading. Many researchers have contributed to the understanding of this problem. Readers are requested to refer to John Clements article titled
"Process Capability Calculations for Non-Normal Distributions" for details.

2. The process / parameter in question must be in statistical control. It is both author's experiences that there is tendency to want to know the capability of the process before statistical control is established. The presence of special causes of variation make the prediction of process capability difficult and the meaning of Cpk unclear. At ATL we measure "inference error". This is one way we can predict Cpk or Ppk with a statement of how likely we are to be correct (in percentage terms). This is demonstrated on pages 13 and 15 near the bottom of the page.

3. The data chosen for process capability study should attempt to encompass all natural variations. For example, one supplier might report a very good process capability value using only ten samples produced on one day, while another supplier of the same commodity might report a somewhat lesser process capability number using data from longer period of time that more closely represent the process. If one were to compare these process index numbers when choosing a supplier, the best supplier might not be chosen.

Important: The number of samples used has a significant influence on the accuracy of the Cpk estimate. At ATL we call this inference error. See pages 13 and 15.
For example, for a random sample of size n = 100 drawn from a known normal population of Cpk = 1, the Cpk estimate can vary from 0.90 to 1.10 (with 95 % confidence). Therefore smaller samples may result in even larger variations of the Cpk statistics. In other words, the practitioner must take into consideration the sampling variation's influence on the computed Cpk number.

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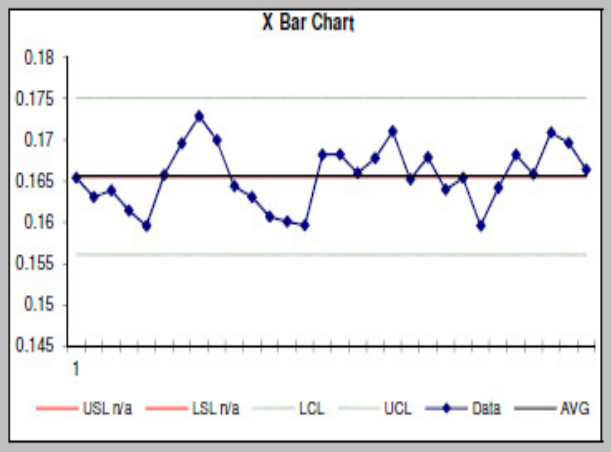
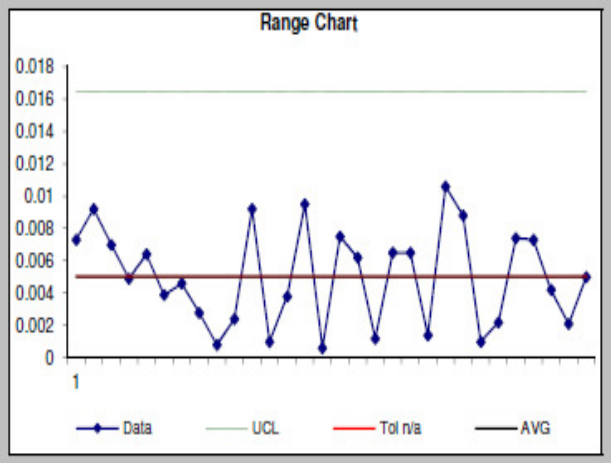
Real Time Example:

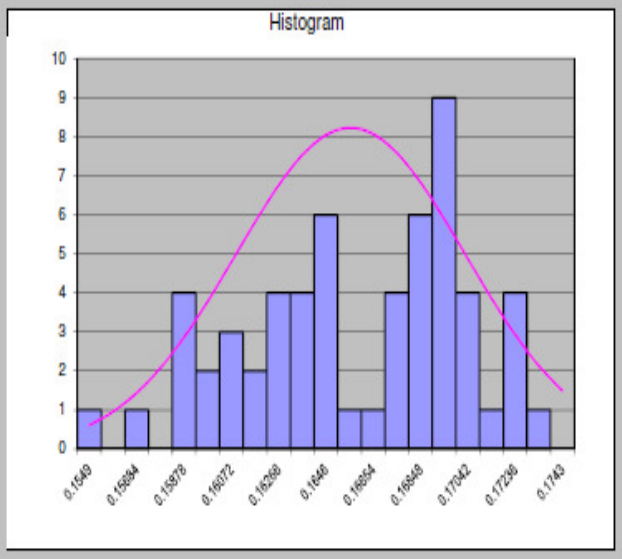
ATL Capability Study Customer XXXX: .160" +/- .030", Job 80257, Part XXXX-XX, Delta Press

ATL Control Charts





Process Distribution



One or more points are outside the control limits	Pass
More than 9 points in a row on one side of the avg	Pass
Six points in a row increasing or decreasing	Fail
14 points in a row alternating up and down	Pass
More than 2/3rd of pts outside 2 sigma	Pass
More than 1/3rd of pts outside 1 sigma	Fail
15 pts in a row within 1 sigma of centerline	Pass
8 pts in a row more than 1 sigma from centerline	Pass

Process Data		Potential (Rbar/d_2) Capability	
USL	0.1900	Cp	2.24
LSL	0.1300	CpU	1.82
# of Samples	60	CpL	2.65
# of Sub Groups	30	Cpk	1.82
Sub Group Size	2		
Max Value	0.1743	Potential (Indiv.) Capability	
Min Value	0.1549	Pp	2.13
Range	0.0194	PpU	1.73
X Double Bar	0.1656	PpL	2.53
R Bar	0.0050	Ppk	1.73
St. Dev. (Rbar/d_2)	0.0045		
St. Dev. (Indiv.)	0.0047	X Bar R Chart Limits	
Individuals UCL X	0.1751	UCL X	0.1695
Individuals LCL X	0.1561	LCL X	0.1505
Individuals UCL R	0.0165	UCL R	0.0165
Normality Test	Normal		
		X Median Chart Limits	
Pre-Control Limits		UCL X	0.1751
Upper PC line	0.1750	LCL X	0.1561
Lower PC line	0.1450	UCL R	0.0165

Capability Ratio Summary	Standard Deviation Summary		Cpk Summary	
Tolerance Used:	Sigma	0.0047	Cpk 1	1.73
47.0%	6 Sigma	0.0282	Cpk 2	2.53

% > USL 0.00%	% < LSL 0.00%	Total % Out Of Tol 0.00%
Inference Prediction Error/ Samp. Population		11.9%
Acceptable ( )	Not Acceptable ( )	QA Initials

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Let's examine the actual short-term process capability on page 12. There is a wealth of information on this one page. We will examine the capability from an "individuals measurements reading" basis (not using sub-groups), and we will examine the same data using sub-groups of two measurements.

Our high limit is .1900", our low limit is .1300". The center of our specification is .1600".
Our highest measurement reading taken is .1743", our lowest is .1549".
Our measurement average (X Double Bar) is .1656" (slightly higher than the spec center).

60 measurements were taken:
When using individuals measurements, the standard deviation is .0047".
When using subgroups of two measurements, the standard deviation is .0045".
Our forecast is that 99.73% of all production will use 47% of the allowed tolerance.

The process capability for invividuals is 1.73.
The process capability for subgroups of two is 1.82 (slightly better).

What does the above all mean?
The process capability for subgroups of two is better because the standard deviation for subgroups of two is less than that of individuals measurements (.0045" vs .0047"). This doesn't mean much for a study that has a relatively high Cpk (> 1.33). But for jobs with slightly less Cpk it is important to weigh the Cpk, Ppk, Control Limits for the X-Bar Chart, and Control Limits for the Range Chart.

When determining whether or not to let a process continue, always determine STABILITY first, then PROCESS CAPABILITY second. For the chart on page 12 we have both.

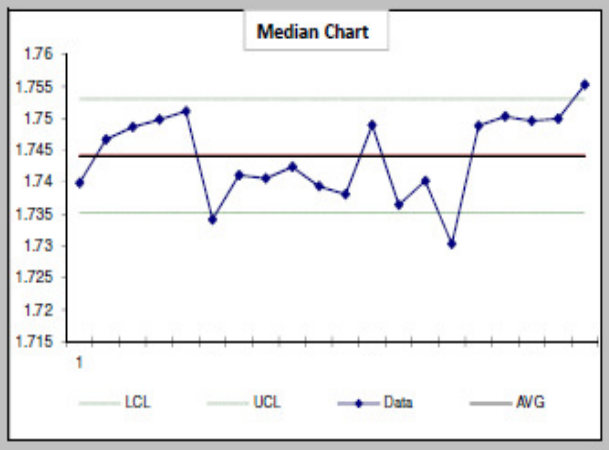
Here is our interpretation:
The process center is very near the specification mid-point.
The standard deviation is small.
The plot points have a normal distribution (stability).
The UCLX for individuals is .1751". This is far away from the spec high limit of .1900".
The UCLX for subgroups of two is .1695". This is far away from the spec high limit of .1900".
The LCLX for individuals is .1561". This is far away from the spec low limit of .1300".
The LCLX for subgroups of two is .1505". This is far away from the spec low limit of .1300".
The total percentage of tolerance used is 47%.
The Cpk is 1.82 (< one defect per million, see pages 6 and 7).
The Ppk is 1.73 (< one defect per million, see pages 6 and 7).
The projected % of product above high limit is zero.
The projected % of product below low limit is zero.
The inference error is 11.9% (the capability forecast should be correct 88.1% of the time).

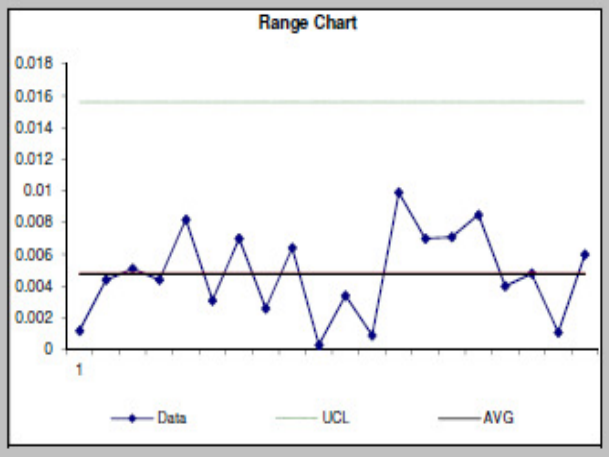
Process Capability/Medical Devices

Let's now look at a process that is not as good:

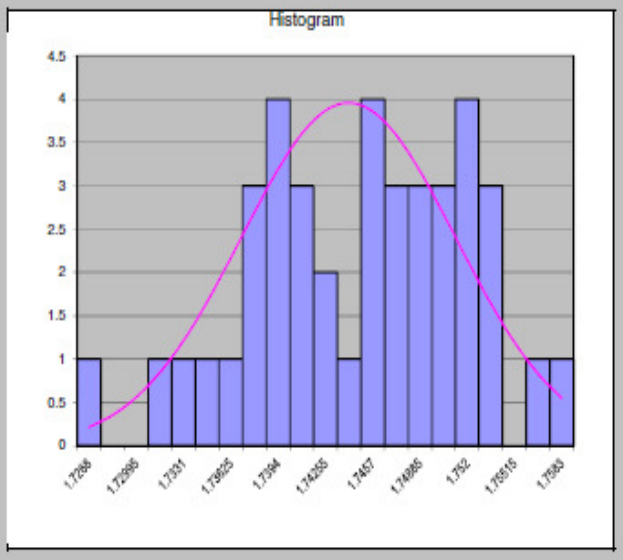
ATL Capability Study, Gear Side, 1.75" dim +/- 0.030", Job 80128, Part# XXXX-XX, Delta Press

Control Charts





Process Distribution



X Double Bar Plus 3 Sigma	1.7655
X Double Bar Minus 3 Sigma	1.7227
Shewhart -Six points in a row increasing or decreasing	Pass
Shewhart -14 points in a row alternating up and down	Pass
Shewhart - More than 2/3rd of pts outside 2 sigma	Pass
Median UCL w/ .50 Sigma (Floor Chart Option)	1.7552
Median LCL w/ .50 Sigma (Floor Chart Option)	1.7330
Median UCL Range w/ .50 Sigma (Floor Chart Option)	0.0198

Capability Ratio Summary	Standard Deviation Summary		Cpk Summary	
Tolerance Used:	Sigma	0.0071	Cpk 1	1.68
71.4%	6 Sigma	0.0429	Cpk 2	1.12

Process Data	
USL	1.7800
LSL	1.7200
# of Samples	40
# of Sub Groups	20
Sub Group Size	2
Max Value	1.7583
Min Value	1.7268
Range	0.0315
X Double Bar	1.7441
R Bar	0.0048
St. Dev. (Rbar/d_2)	0.0042
St. Dev. (Indiv.)	0.0071
Individuals UCL X	1.7531
Individuals LCL X	1.7351
Individuals UCL R	0.0156
Normality Test	Normal

Pre-Control Limits	
Upper Pre-Control	1.7650
Lower Pre-Control	1.7350

Potential (Rbar/d_2) Capability	
Cp	2.36
CpU	2.83
CpL	1.90
Cpk	1.90

Potential (Indiv.) Capability	
Pp	1.40
PpU	1.68
PpL	1.12
Ppk	1.12

X Bar R Chart Limits	
UCL X	1.7590
LCL X	1.7410
UCL R	0.0156

X Median Chart Limits	
UCL X	1.7531
LCL X	1.7351
UCL R	0.0156

% > USL 0.00%	% < LSL 0.04%	Total % Out Of Tol 0.04%

Inference Prediction Error/ Samp. Population 22.1%

Acceptable ( ) Not Acceptable ( ) QA Initials _____

Process Capability/Medical Devices

For the capability study on page 14:
Our high limit is 1.7800", our low limit is 1.7200". The center of our specification is 1.7500".
Our highest measurement reading taken is 1.7583", our lowest is 1.7268".
Our measurement average (X Double Bar) is 1.7441" (slightly lower than the spec center).

40 measurements were taken:
When using individuals measurements, the standard deviation is .0071".
When using subgroups of two measurements, the standard deviation is .0042".
Our forecast is that 99.73% of all production will use 71.4% of the allowed tolerance.

The process capability for individuals is 1.12.
The process capability for subgroups of two is 1.90 (much better because of smaller sigma).

What does the above all mean?
The process capability for subgroups of two is better because the standard deviation for subgroups of two is less than that of individuals measurements (.0042" vs .0071"). This is very important because standard deviation for individuals can trick you (because of small sample size). For jobs with small sample sizes (< 100) it is important to weigh the Cpk, Ppk, Control Limits for the X-Bar Chart, and Control Limits for the Range Chart. In other words, the Ppk could be poor, and the Cpk could be good. This does happen.

When determining whether or not to let a process continue, always determine STABILITY first, then PROCESS CAPABILITY second. For the chart on page 14 we have both (stability and capability) with subgroups of two and individuals, but because of the small sample size and process shifts (at start-up of production), false readings can be given.

Here is our interpretation:
The process center is very near the specification mid-point. The standard deviation is okay.
The plot points have a normal distribution (stability).
The UCLX for individuals is 1.7531". This is far away from the spec high limit of 1.7800".
The UCLX for subgroups of two is 1.759". This is far away from the spec high limit of 1.780".
The LCLX for individuals is 1.7351". This is far away from the spec low limit of 1.7200".
The LCLX for subgroups of two is 1.7410". This is far away from the spec low limit of 1.720".
The total percentage of tolerance used is 71.4%.
The Cpk is 1.90 (< one defect per million, see pages 6 and 7).
The Ppk is 1.12 (approximately 966 defects per million, see pages 6 and 7).
The projected % of product above high limit is zero.
The projected % of product below low limit is .04% (4/100th of one percent).
The inference error is 22.1% (the capability forecast will be correct 77.9% of the time).

So, do not let the individuals Ppk of 1.12 stop production. Give it the green light, instruct the operators to center the process and work on reducing variation, and then re-evaluate.

Process Capability/Medical Devices

Factors that contribute to variability in a (disposable) medical device manufacturing (converting) process.

In other words, what ATL (and you) should consider when establishing tolerances in a product:

Backing
A relatively thin flexible material to which the adhesive is applied. Theoretically any material, which is reasonably flat, relatively thin and flexible, can be used as a tape backing. Sometimes referred to as carrier.

Back-size
A material applied to the backside of a tape to provide a release surface or heat seal property.

Caliper
Thickness of a tape, backing, or adhesive, usually measured in mils (1/1000 of an inch).

Coating Weight
The amount of a solution applied to a sheet in the tape making process. The units are usually in grains per 24 square inches.

Cohesion
(Cohesive strength, internal bond) The ability of the adhesive to resist splitting. Good cohesion is necessary for clean removal.

Converting
The actual operation of changing a jumbo into a finished product by slitting, short roll winding, die cutting, etc.

Corona Treatment
It is a process which uses an electrical spark discharge to modify a surface in order to increase adhesion (usually of ink to a film surface, such as a plastic bag).

Curling
The tendency of a tape to curl back on itself when unwound from the roll and allowed to hang from the roll.

Delamination
A separation or splitting of the tape such as separation of the backing into two distinct layers.

Double-Coated
The adhesive is applied on both sides of the backing, which serves principally as a carrier for the adhesive.

Elastic Memory
A tendency of some tape backings to return to their original length after being elongated.

Elongation
(stretch) - The distance a tape will stretch lengthwise before breaking, expressed as a percentage of original length.

Film
Uniform, homogeneous, plastic webs.

Foam
A soft, cushiony material formed by creating bubbles in base materials, such as natural or synthetic rubbers, or other elastomeric materials. Can be either closed cell or open cell (air passage).

Hardband
A mound like swelling on the outer layers of a roll lengthwise to the tape. Usually caused by uneven backing caliper.

High Liner Release
When the tape release from the liner is difficult, or above the expected result.

Hot Melt
(Pressure Sensitive Adhesive) - An adhesive applied to the backing in a hot molten from which cools to form a conventional pressure sensitive adhesive.

Kiss Cut
A type of die cutting where the cutter is adjusted to only cut the material and leave the liner or backing untouched.

Lamination
A combination of two or more materials, which function as one backing on web.

Lifting
A situation where a section of tape has pulled away from the surface to which it has been applied, even though no outside stress is applied.

Liner
A paper or film with a release coating used to protect an adhesive from exposure before use.

Low Liner Release
The tape release from the liner is easy, or below the expected result.

Memory
The ability of a fiber or tape to return to its original form after being stressed or elongated.

Migration
The movement, over a long period of time, of an ingredient from one component to another, when the two are in surface contact. Plasticizers that are apt to migrate into the tape adhesive may cause the adhesive to soften.

Monomer
Simple chemical compounds with functional groups capable of being linked to each other or other functional groups, to form more complex compounds (called polymers).

Non-Woven Materials
Paper, tissues" or synthetic (e.g. polyester) non-woven fabrics.

Occlusive
To prevent moisture from passing through.

Oozing
"Squeezing out" of the adhesive from the sides of a roll of tape resulting in sticky edges and often edge transfer during unwind. Usually caused by too high winding tension.

Opaqueness
The ability of a tape to prevent the transmission of light.

Peel Adhesion
The force per unit width, expressed in oz/in width, required to break the bond between a tape and a surface when peeled back at a standard rate and condition.

Permeable
To allow gasses or moisture to pass through.

Pinhole
Very small hole, which may permit the passage of light, moisture, or electrical current.

Polycoated
Covered with a layer of polyethylene film, usually applied as a liquid on paper for adhesive liner use.

Polyethylene (PE)
Tough, stretchy film having very good low temperature characteristics.

Polyester (PET)
A strong non-stretchable film having good resistance to moisture, solvents, oils, caustics, and many other chemicals.

Polymer
A large molecule built up of repetitive smaller chemical units, commonly used in adhesive compounding.

Polyolefin
A general term used to cover a family of resins such as polyethylene and polypropylene.

Polypropylene.
Cousin of polyethylene, with similar properties, but stronger and having a higher temperature resistance.

Polyvinyl Chloride (PVC)
A usually thin transparent film with excellent resistance to acids, water, and organic solvents. Usually formulated with a migratable plasticizer to make flexible.

Porosity
Permeability of a surface (tape backing) to a liquid or gas or a measure of % void space within a material such as foam.

Pressure-Sensitive
A term commonly used to designate a distinct category of adhesive tapes and adhesives, which are aggressively and permanently tacky at room temperature and firmly adhere to a variety of dissimilar surfaces upon mere contact without the need of more than finger or hand pressure.

Primer
Material interposed between a backing and an adhesive or other coating which anchors the two incompatible materials together.

Printability
The ability of a tape to accept and hold a printed legend, and especially to resist offset of the printing when rewound into a roll after printing.

Quick Stick
(Initial Adhesion, Wet Grab) - The property of a pressure sensitive adhesive, which allows it to adhere to a surface under very light pressure. It is determined by the ability of the adhesive to quickly wet the surface contacted.

Release Coating
A coating applied to the backing on the side opposite the adhesive, which provides ease of unwind and prevents delamination or tearing, or to a film or paper to produce a release liner.

Release Liner
A web or sheet of material covering the adhesive side of a tape. It is removed prior to application.

Resistance
The ability of a tape to resist exposure to varying conditions after application and to perform satisfactorily.

Shear Adhesion
The ability of a tape to resist the static forces applied in the same plane as the backing, usually on a vertical test panel.

Telescoping
A sideways sliding of the tape layers, one over the other, such that the roll looks like a funnel.

Tensile Strength (TS)
The force required to break a piece of tape by pulling opposite ends of the piece.

Machine Direction Tensile
TS measured parallel to the length of the tape. Cross Direction Tensile - TS measure at right angles to the length.

Transfer
Normally refers to adhesive transfer, but sometimes said of any tape component which moves from its proper place to some other position during either unwind or removal

Transparency
The ability of a tape to allow transmission of light.

Void
A bare uncoated area on either the adhesive or release coated side of the page.

Washboard Effect
A condition when a surface has a definite corrugated or ridged surface.

Water Dispersible
A tape where the adhesive will dissolve completely under the proper chemical environment and the backing will break up into extremely small pieces.

Web
The long, continuous sheet of material, which is drawn through the processes of making tape.

Wicking
A device similar to a wick that conveys liquid by capillary action.

Wrinkles
Small ridges or furrows formed on the surface of a roll of tape and often resulting in jagged edges on the slit roll.

Juran.

What is the Dominant Variable? Processes (Cpk's) are influenced by various input variables like environment, skill, setup and many more.

Often one variable is more important than all others combined and such a variable is called the **dominant variable**. In the book "Juran on Quality by Design", Juran classifies these dominant variables into five types, which we have listed below:

Setup-dominant: Processes, which once set-up, will exhibit stability and reproducibility over repeated cycles of operations are known to be setup-dominant processes.

These processes must be so designed that importance is given for precise setup and validation before operations proceed, because there is no real control during the repeated cycle of operation that will impact the quality of the output.

For example: in the printing process, once the setup is made and approved the operator has no influence on the spellings, font size or other parameters on the printed matter.

Similarly, in the manufacture of medical devices that are die-cut to an exact size the rotary die plays a vital role and is also called a **tool dominant process**.

Time-dominant: In this case the process is known to change progressively with time. This is typical of machining processes wherein there is wear out of tools over a period of time, similarly consumption of consumables, heating up.

The process design must take into consideration the periodic evaluation and adjustment of the process. Process Control charts are most commonly used for time dominant processes.

In a medical device environment we may experience a similar time-dominant effect when "packing" a die with foam. The foam will wear out after a given time cycle. ATL's process development must take into consideration the periodic evaluation and adjustment of the process to account for size changes and the "consumable" (die packing) wears out.

Component Dominant: The main variable in this case is the quality of the input materials and components. This is typical in assembly processes (like the assembly of mechanical and electronic items). For medical devices, sealing units (temperatures) may vary over time periods. Also hot melt glue devices need to be monitored.

Worker Dominant: When the quality of the output depends mainly on the skill and knack possessed by the workers, it is called a worker dominant process.

For these processes the candidates employed are almost always qualified with the basic skill sets. The design for control of these processes must emphasize aptitude testing, training, certification and quality rating of workers.

Training and certification is indeed important for all types of processes, but in this case it is even more important. At ATL, critical processes require the training necessary to perform the task at hand. This is in accordance with FDA Systems Validation Protocol and ISO-13485.

Information Dominant: In this case the processes are of "job shop" or "short run" nature, wherein there are frequent changes in the products that need to be produced.

Since the job information changes frequently, the design for process control should concentrate on providing an information system that can deliver accurate, up-to date information on just how each job differs from the others. This would mean that medical devices that are color coded or serialized for traceability need up-to-date information.

About the authors.

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ATL Pharmaceutical/ Medical is ISO-13485 Registered, and compliant to FDA 21 CFR 210, 211, 820, ISO-14971:2012, and MDD 93/42 EEC.

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Any questions? Please contact ATL and we will be glad to help you in your design/ manufacturing/ compliance endeavors.

If you are not already on our website, please visit us at:

www.atlco.com

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