Process Capability: History, Assumptions, and Challenges

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ASQ World Conference





Learning Objectives

- Evaluate the assumptions for Normal Capability Analysis
- 2. Run a Non-Normal (NN) Capability Analysis using different techniques
- 3. Determine what makes data Non-Normal
- 4. Assess the weaknesses of Normality tests
- 5. Learn how to deal with data coming from a measurement system with low discrimination

History of Capability Analysis

 Popularized by J. Juran in his Quality Control Handbook [1].

Process Capability =
$$6\sigma$$

 Capability ratio is the tolerance width divided by the process capability, Cp.

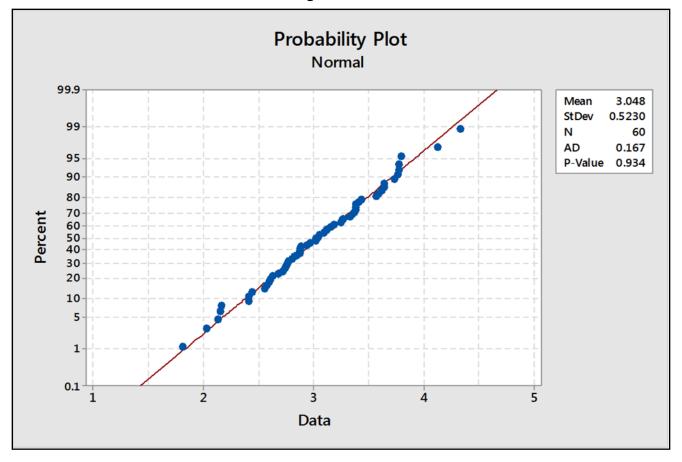


History of Capability Analysis

- Late 1980's, more capability indices were formally introduced.
- Kane [2] introduced Cpk.
- Capability indices can be translated to a defect or quality rate.

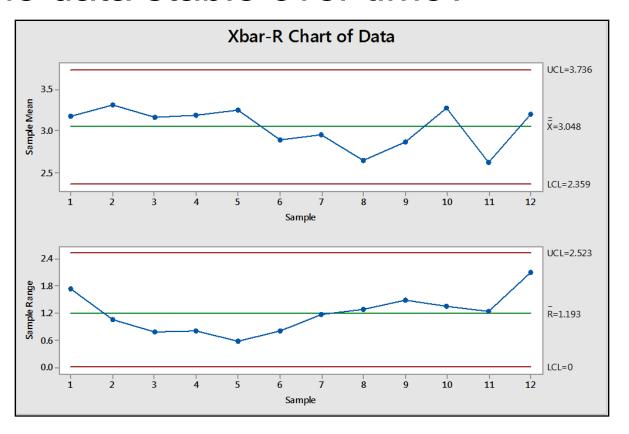


• Is the data normally distributed?





- Is the data normally distributed?
- Is the data stable over time?





- Is the data normally distributed?
- Is the data stable over time?
- Are we confident in our conclusions?

```
Potential (Within) Capability

Cp 1.04

CI for Cp (0.85, 1.22)

CPL 1.07

CPU 1.00

Cpk 1.00

CI for Cpk (0.80, 1.20)
```



- Is the data normally distributed?
- Is the data stable over time?
- Are we confident in our conclusions?
- How can we improve our process?

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Overall Capability
Pp 1.13
PPL 0.66
PPU 1.60
Ppk 0.66
```



Is the Data Normally Distributed?

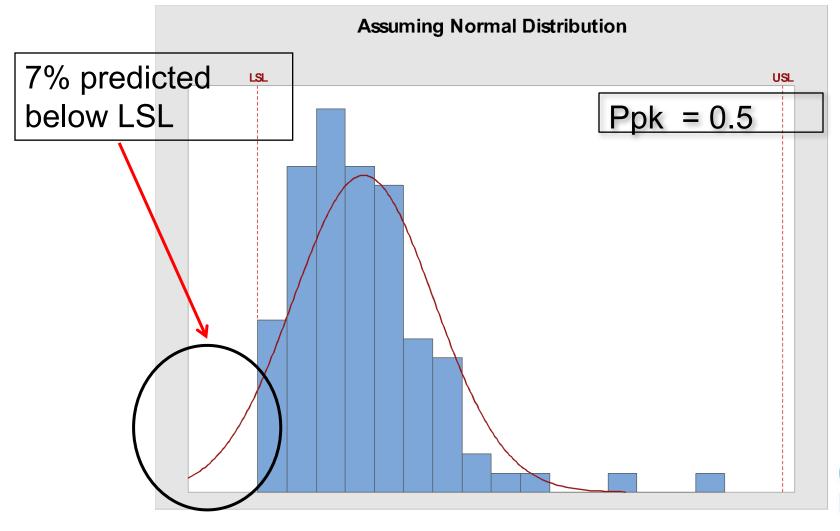
Why does it matter?

 Let's test how robust Capability Analysis is to Normality

 We will generate data from a Weibull distribution, and see how well Normality works in this case.

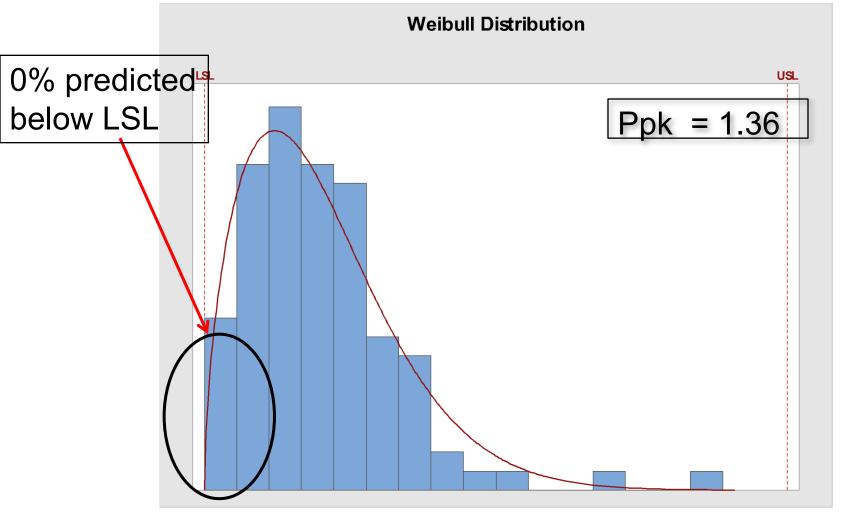


Is the Data Normally Distributed?



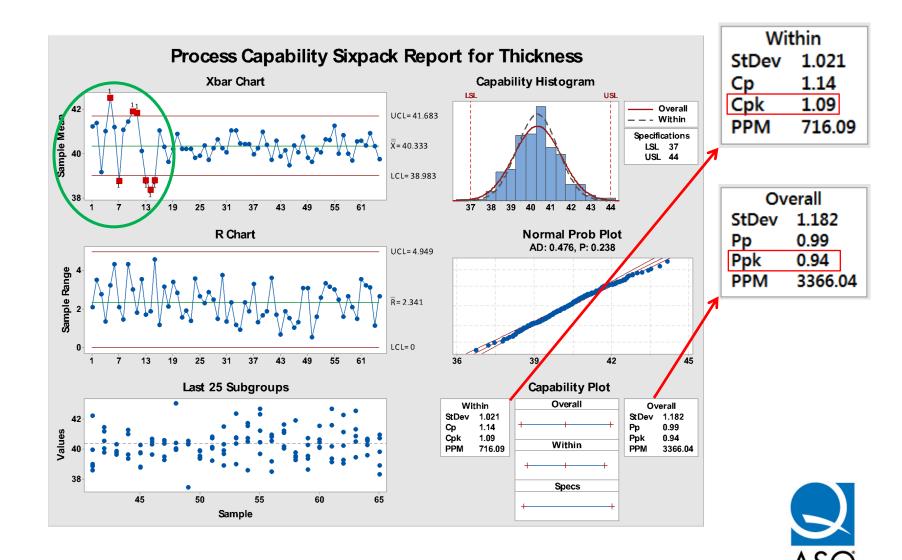


Is the Data Normally Distributed?

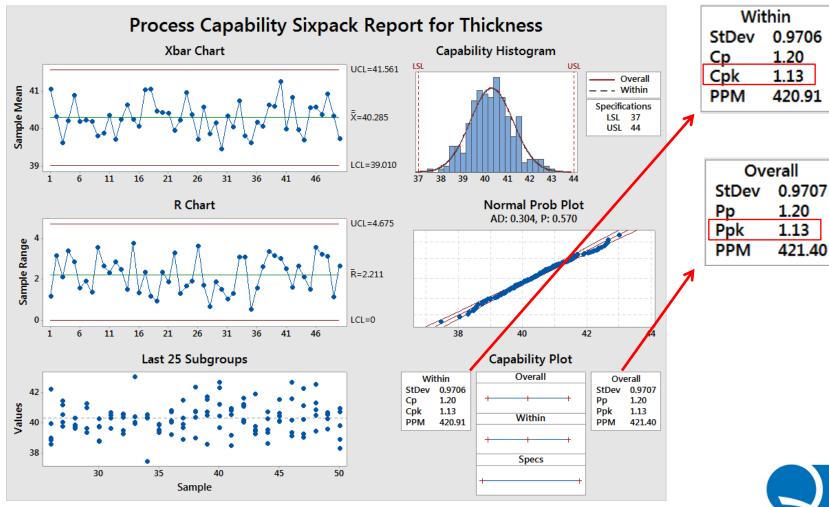




Is the Data Stable Over Time?



Is the Data Stable Over Time?





Are we confident in our conclusions?

Would I rather see this?

```
Cpk 1.29
```

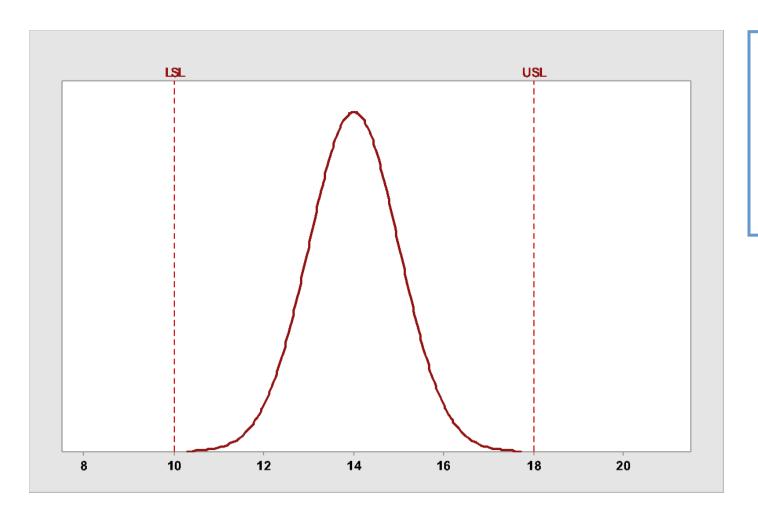
Or this?

```
CI for Cpk (1.10, 1.48)
```

Both!

Confidence Intervals provide a better understanding of how much trust we can place in our results.

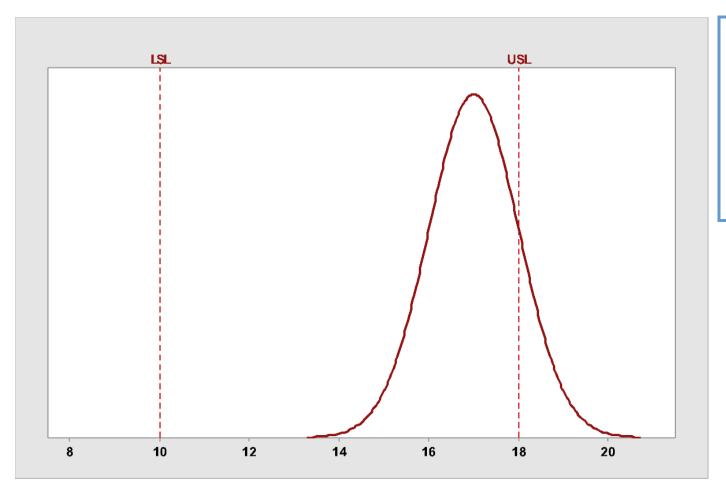




Mean = 14 StDev = 1

Pp = 1.33 Ppk = 1.33

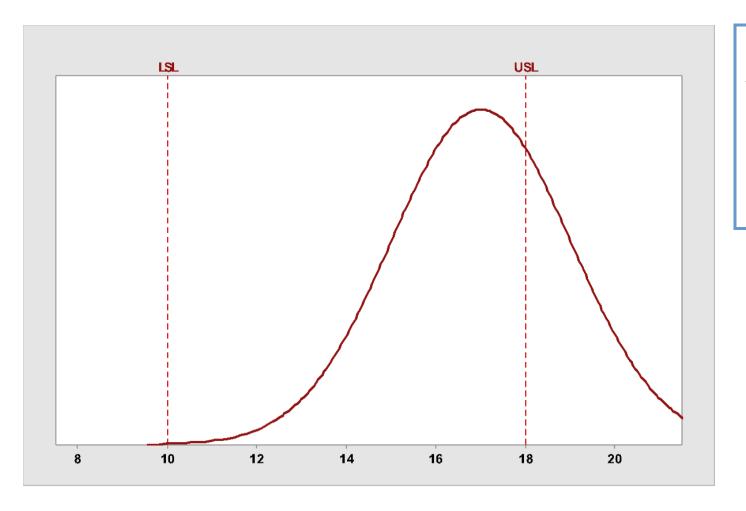




Mean = 17 StDev = 1

Pp = 1.33Ppk = 0.167





Mean = 17StDev = 2

Pp = 0.67Ppk = 0.083



So first how would we maximize Pp?

Let's look at the formula:

$$Pp = \frac{USL - LSL}{6\sigma} \leftarrow \text{Can we change the specs?}$$

$$\leftarrow \text{Can we change the Standard Deviation?}$$



Let's throw out a scenario:

$$LSL = 10$$

Standard Deviation(
$$\sigma$$
) = 1.5

$$Pp = \frac{USL - LSL}{6\sigma} = \frac{18 - 10}{6 * 1.5} = 0.88$$



$$LSL = 10$$

Target Ppk= 1.33

Standard Deviation(
$$\sigma$$
) = 1.0

Reduction of Variation by 33%

$$Pp = \frac{USL - LSL}{6\sigma} = \frac{18 - 10}{6 * 1} = 1.33$$



What have we learned so far? (Obj. 1)

- Capability analysis is sensitive to the following assumptions.
 - Distribution assumption
 - Stability of the process
- Look at confidence intervals.
- To improve the capability of a process you can:
 - Center the mean
 - Reduce the variation
 - Re-evaluate the specs



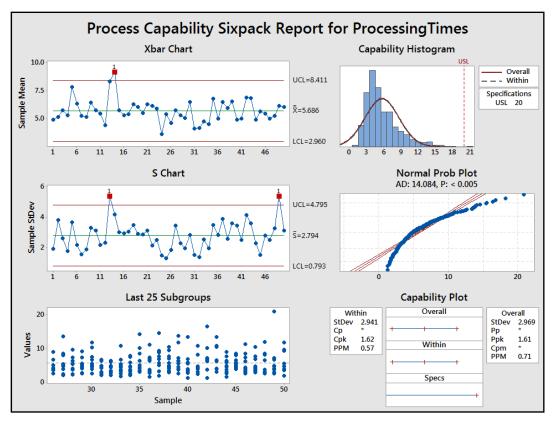
What to do when Data are not Normal?

- 1. Use a transformation
- 2. Find a Non-Normal (NN) distribution to model the data
- 3. Use a nonparametric method
- 4. Options above do not apply or are not feasible, ask yourself why is the data not normal?



NN Capability – Transformations

 Let's analyze the processing times (min) to complete a specific task.

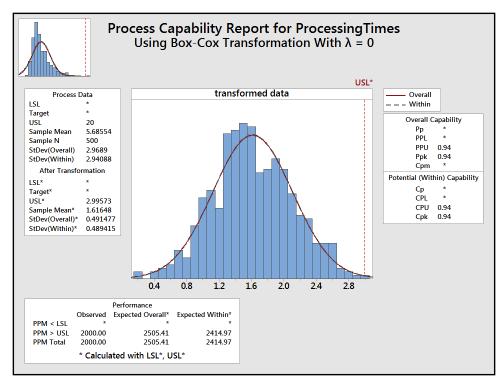




NN Capability – Transformations

The Box-Cox transformation

$$Y^* = Y^{\lambda}$$
 where $\lambda \in [-5, 5]$



Note: Except when

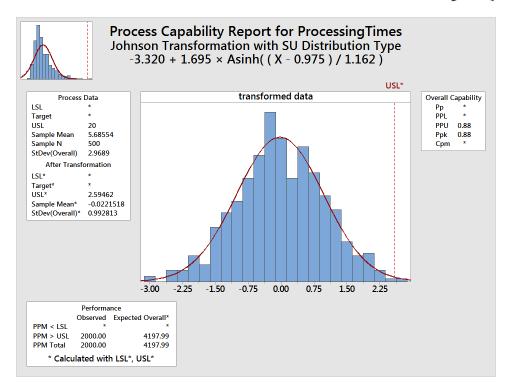
$$\lambda = 0, Y^* = In(Y)$$



NN Capability – Transformations

The Johnson transformation

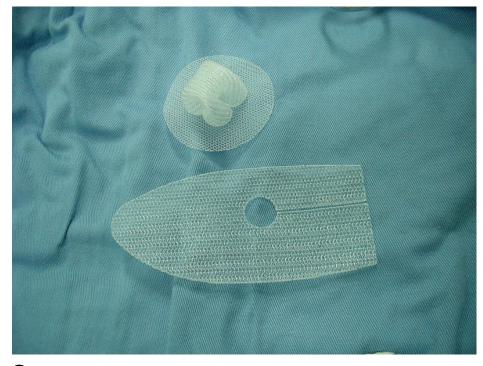
$$Y^* = a + b \cdot \ln(f(Y))$$



Note: Asinh(z) =

$$\ln(z + \sqrt{z^2 + 1})$$

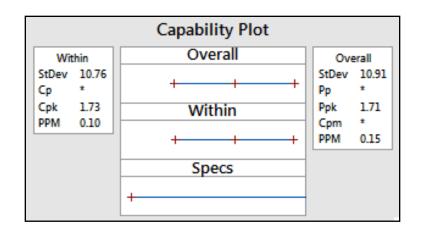
- Inguinal hernia surgery case study.
- The company wants to assess the process capability.
- LSL = 15 lbs. on a ball burst strength test.

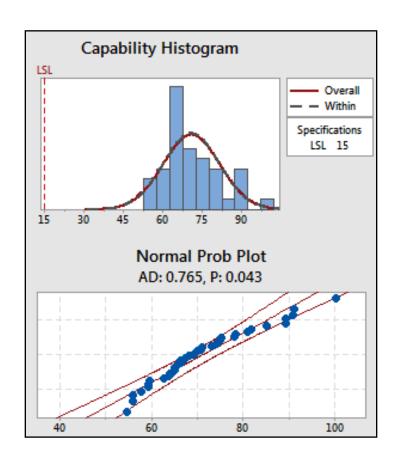


Source:

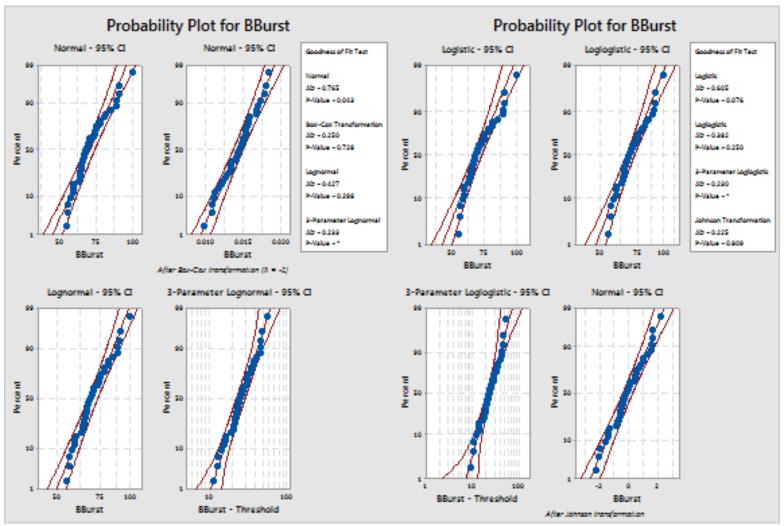
http://en.wikipedia.org/wiki/Inguinal hernia_surgery

- Underlying data is not normally distributed.
- Capability estimates are invalid.



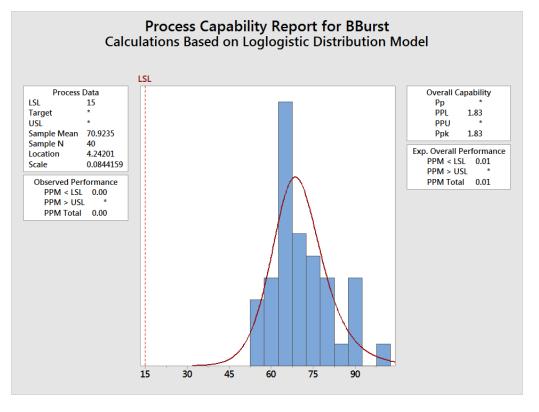








 Select the Loglogistic distribution to fit the data and estimate the capability of the process.





NN Capability – Nonparametric

- Use a nonparametric method to estimate the capability of the process
 - See McCormack et al. [3], larger sample sizes required
 - Treat the data as binary and perform a test for proportion



NN Capability – Nonparametric

• **Example.** A process measuring the wet weight of a product has to validate the process is capable.

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Test and CI for One Proportion: Pass or Fail
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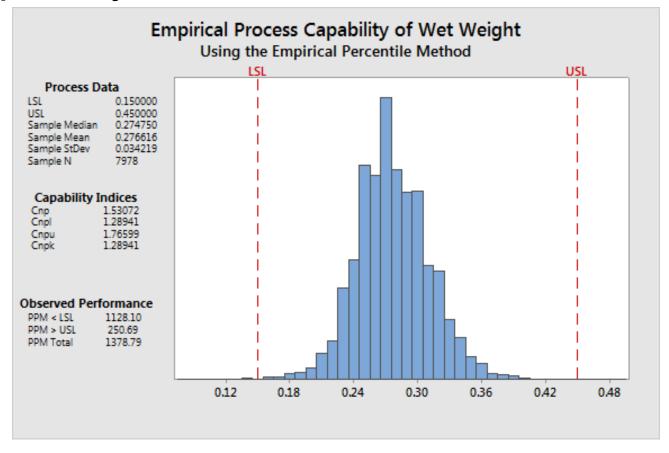
```
Event = P
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Variable	X	N	Sample p	95% Lower Bound
Pass or Fail	7967	7978	0.998621	0.997719



NN Capability – Nonparametric

Wet weight analysis using nonparametric capability.





What have we learned? (Obj. 2)

- When data are Non-Normal, multiple techniques can be utilized:
 - Use a Johnson or Box-Cox transformation
 - Model the data with a Non-Normal distribution,
 e.g. Weibull, Lognormal, Smallest Extreme
 Value
 - With large sample sizes you can utilize nonparametric approaches
- If no approach works for your specific situation, investigate what makes data Non-Normal. How?



Why are the Data not Normal?

Case I. Nature of the beast – process near a boundary, naturally produces data that are skewed.

Case II. Mixture of distributions or a few outliers – process may not be in statistical control.



Why are the Data not Normal?

Case III. Large sample sizes – power of normality tests detects small departures from "perfect" normality.

Case IV. The number of significant digits is not sufficient to differentiate between parts, rendering the classic normality tests ineffective.

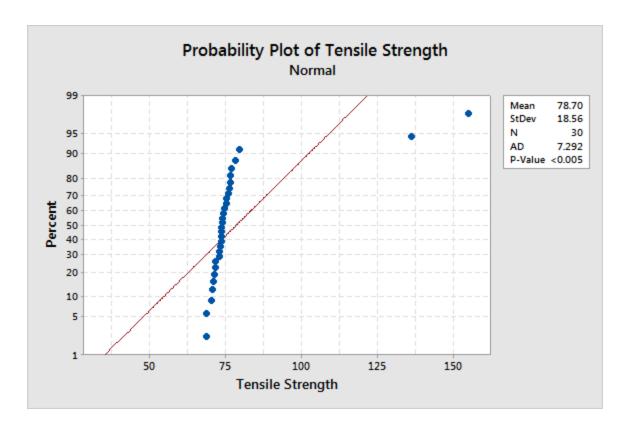


Normality Test Failed – Case I

 This scenario is typically straightforward, the selection of a non-normal distribution is typically done using a distribution identification tool or scientific knowledge about what distribution models a specific situation.

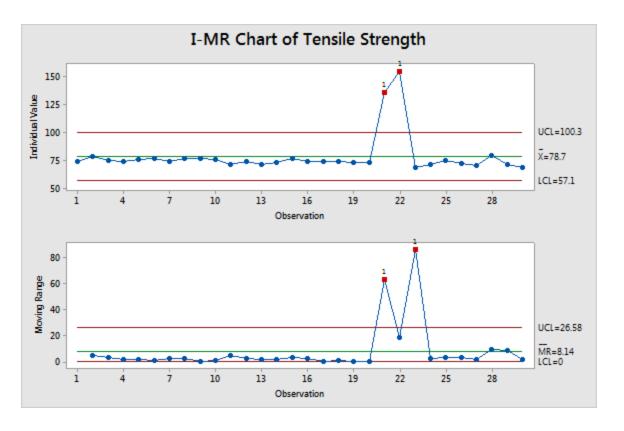


 The sample obtained to estimate the capability of a process can include data from different distributions.



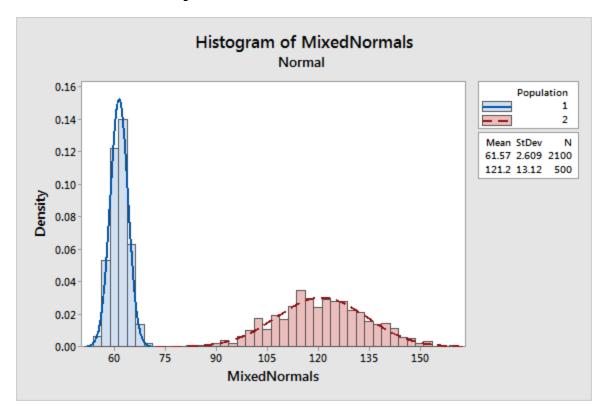


 Detection of multiple distributions can be done with a control chart.



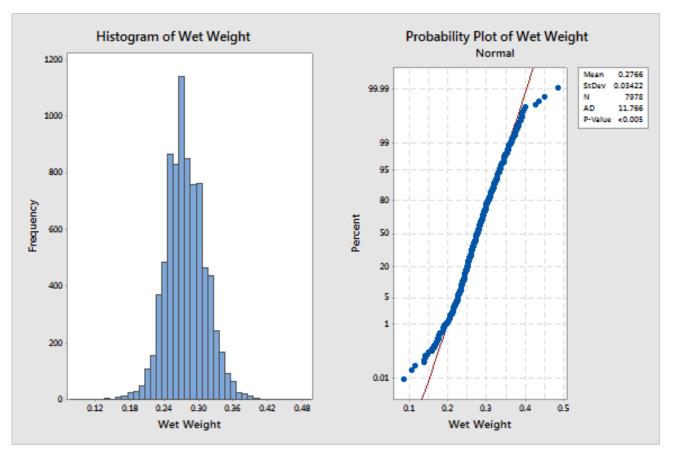


- What to do in a situation like this?
- Better control of the process. Implement corrective and preventive actions.



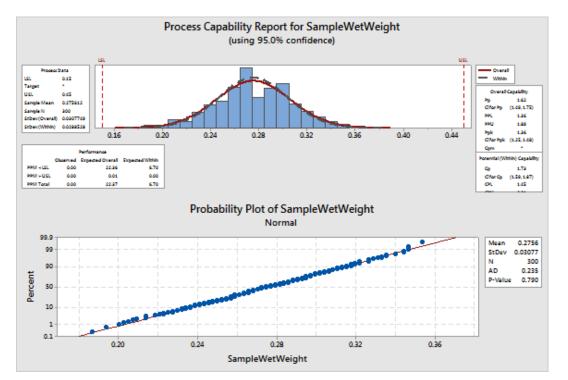


 Revisit the "Wet Weight" example with over 7,000 observations. Data looks normal.





- What is the issue?
- To quote G.E.P. Box in a slight different context: "All models are wrong, but some of them are useful."



Easy solution:
Use a
nonparametric
approach or
get a random
sample from
your data.

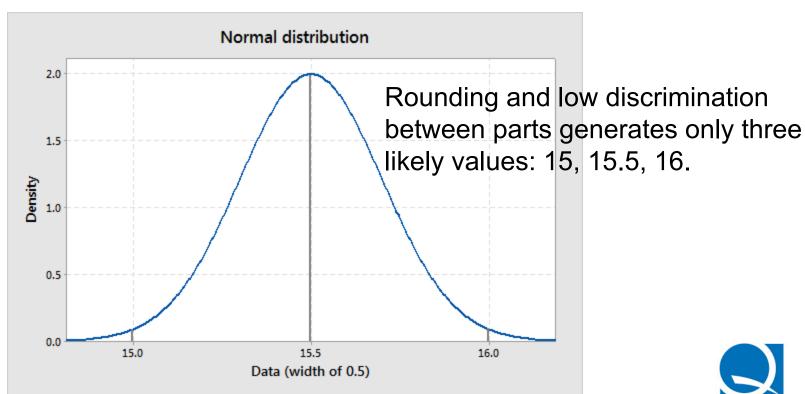


 Comparing the capability estimates for the overall defect level for all analyses done on this dataset.

Method	Cpk	Defect rate	Yield
One proportion	N/A	0.14%	99.86%
Nonparametric percentile method	1.29*	0.14%	99.86%
Normal method	1.45	0.0022%	99.9978%

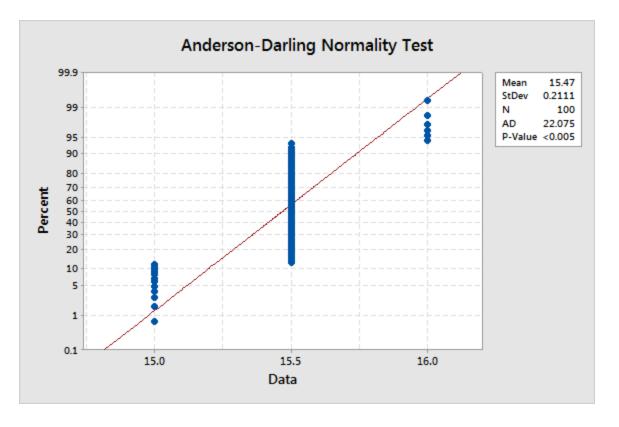


 Low discrimination of the measurement system.



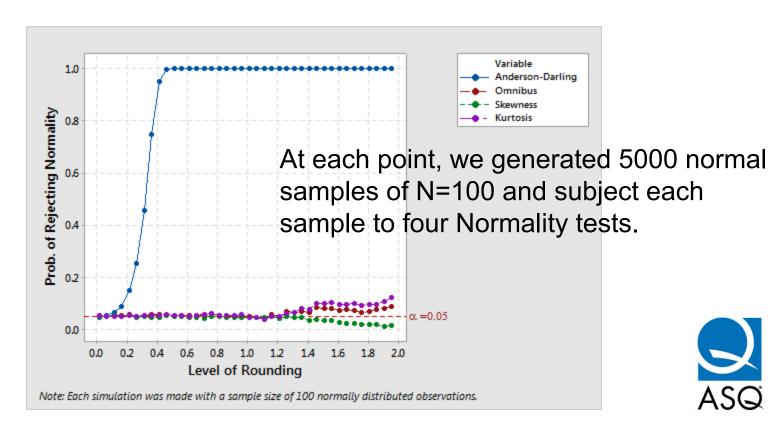


 Ties lead to the Anderson-Darling (AD) test failing normality.

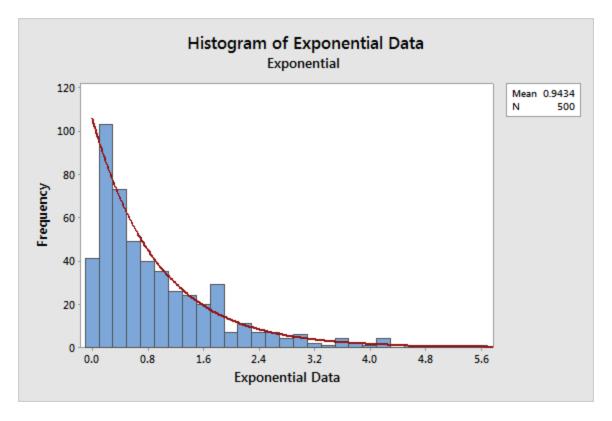




 For heavily rounded datasets the Skewness (SK), Kurtosis (KT), Omnibus (OB) tests may be preferred.

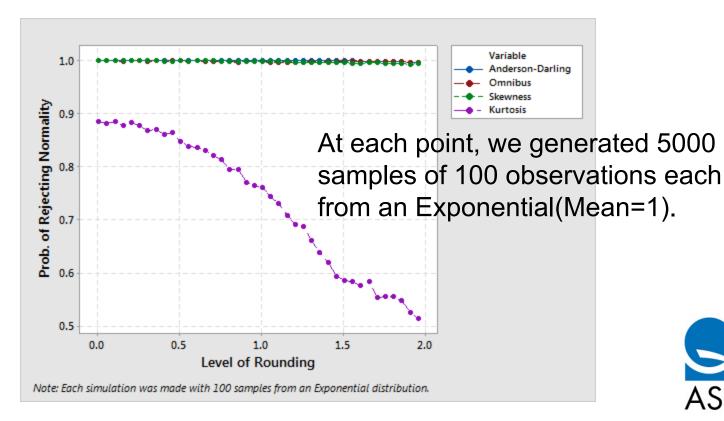


 Let's consider now a highly skewed distribution, namely the exponential distribution.

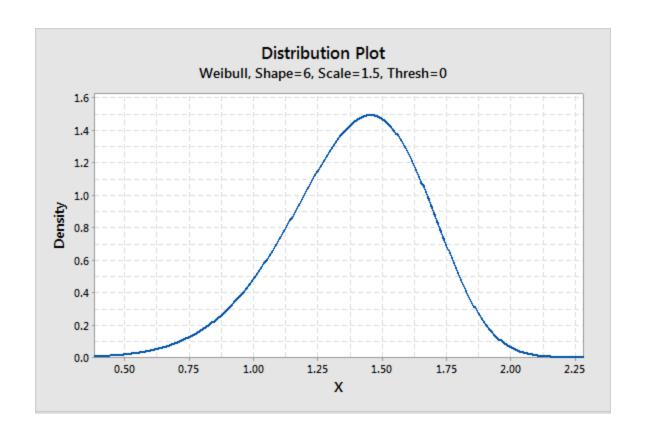




 The AD seems to perform as well as the OB and SK tests, but its detection of non-normal data comes as a consequence of rounding.

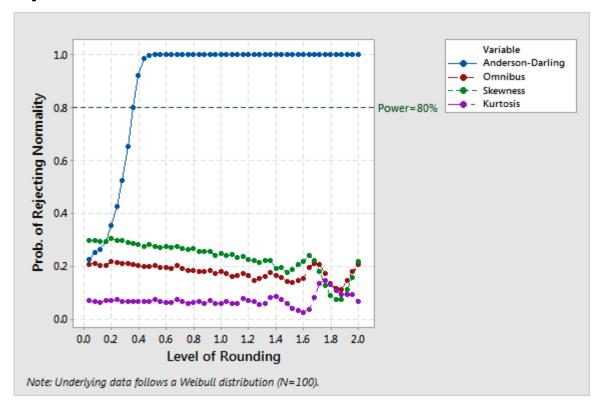


 What if the data is not severely skewed but still not normally distributed?





 The only test that seems to consistently reject normality (AD) does it as a consequence of ties, not effective detection.





What Normality Test to Use?

- Skewness fails to reject normality at the expected α level when the data are normal.
- Skewness has good power and is less sensitive to the degree of rounding.
- The Omnibus and Skewness tests have similar behavior.



What have we learned? (Obj. 3, 4)

- The nature of the data can make the use of the normal distribution inappropriate.
- Lack of controls in a process can produce samples that mix data from different distributions.
- Large sample sizes can make normality tests too sensitive.
- As the level of rounding increases, classic normality tests become less effective.

Capability with Rounded Data

- There a few approaches to estimate the capability of a process:
 - 1. Classic approach
 - 2. Adjust the estimates considering the bias induced by the measurement system
 - 3. Handle the data as being intervalcensored



Classic Capability Estimates

 The rounded data, denoted Y*, is assumed to be normally distributed:

$$\hat{\mu} = \frac{1}{n} \sum_{i=1}^{n} Y_i^* \qquad \hat{\sigma} = \sqrt{\frac{\sum_{i=1}^{n} (Y_i^* - \bar{Y})^2}{n-1}}$$

Proceed to estimate Cpk as usual.



Adj. Estimates - Sheppard's Correction

 Sheppard [5] describes the bias in the estimation of the standard deviation when the data is rounded.

$$\hat{\sigma} = \sqrt{\frac{\sum_{i=1}^{n} (Y_i^* - \bar{Y})^2}{n-1} - \frac{w^2}{12}}$$

where w is the width (incremental unit) of the measurement system.



Estimates from Interval-Censored Data

 Suppose we don't know the exact value that corresponds to the true measurement but we know the interval in which it must be.

Observed Values				
5.1		Start	End	Frequency
5.1	Converted to	4.95	5.05	2
5.0	Converted to	5.05	5.15	3
5.2		5.15	5.25	1
5.1				
5.0				



Estimates from Interval-Censored Data

We get the following estimates:

Variable Start: Start End: End

Frequency: Frequency

Censoring Information Count Interval censored value 6

Estimation Method: Maximum Likelihood (MLE)

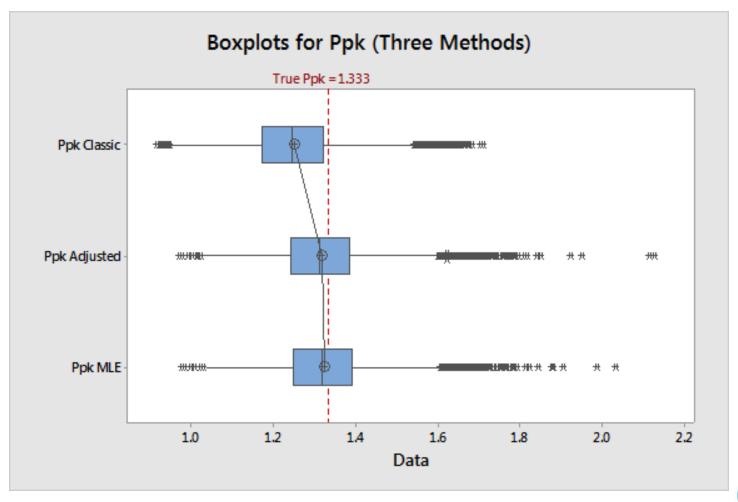
Distribution: Normal

Parameter Estimates

		Standard	95.0% No	rmal CI
Parameter	Estimate	Error	Lower	Upper
Mean	5.08345	0.0278668	5.02883	5.13807
StDev	0.0619204	0.0218490	0.0310086	0.123648

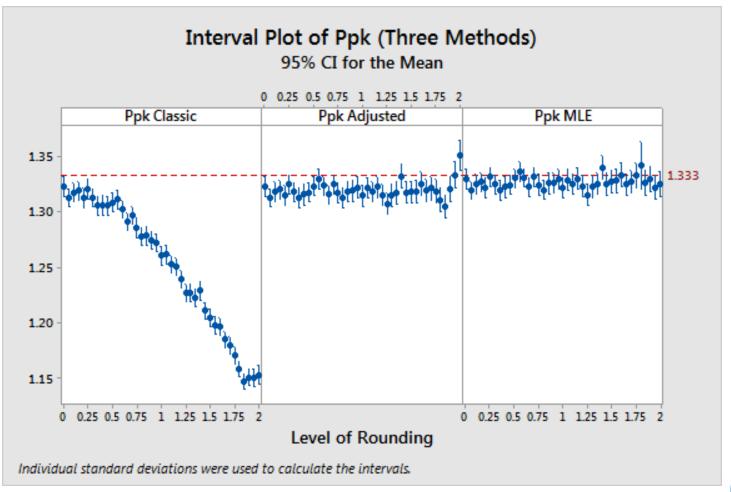


Capability with Rounded Data





Capability with Rounded Data





What was the last lesson? (Obj. 5)

- Rounded data makes classic normality tests fail. [They reject all the time no matter what type of data you have]
- Rounded normal data should be symmetric, thus making skewness and omnibus tests extremely useful.
- Other issues in the data may not be captured by these tests.



What was the last lesson? (Obj. 5)

- Using interval-censored data with Maximum Likelihood Estimates (MLEs) seem to produce better estimates across the board.
- MLEs are asymptotically unbiased. [As the sample size grows larger, the bias of the estimates becomes negligible]
- The simplicity of Sheppard's adjustment to estimate σ makes it compelling too.

- The ultimate goal of a capability analysis is to estimate the defective level of a process.
- When the interest of an analysis is on the estimation of defects, the distribution assumption will be an important one.
- Another important assumption is ensuring the process is stable and in control.



- Of the two assumptions, normality is the one typically violated in practice.
- Non-normal (NN) capability analysis requires:
 - Using a transformation
 - Finding an alternative distribution that fits the data
 - Using a nonparametric approach which requires a large sample size



- Classic normality tests (AD, KS, SW)
 typically reject normality when the data is
 heavily-rounded regardless of the
 underlying distribution.
- When using a gauge with low discrimination, use different tests to check for normality, e.g. Skewness or the Omnibus test.



- If no evidence exists of the rounded data not being normal, assume normality.
- Utilize interval-censoring (MLE) to estimate the mean and standard deviation.



References

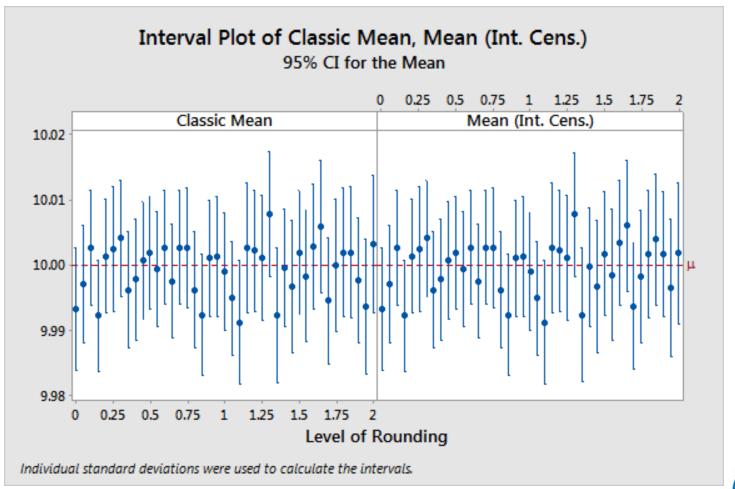
- Juran, J.M., Godfrey, A.M. "Juran's Quality Handbook". 5th edition, McGraw-Hill. New York, 1999.
- 2. Kane, V.E. (1986) "Process Capability Indices". *Journal of Quality Technology*, 18, 41-52.
- 3. McComack, D.W., Harris, I.R., Hurwitz, A.M., and Spagon, P.D. (2000) "Capability Indices for Non-normal data", *Quality Engineering*. 12(4), 489-495.
- 4. Schneeweiss, H., Komlos, J., and Ahmad, A.S. (2006) "Symmetric and Assymetric Rounding." Working paper.
- 5. Sheppard, W.F. (1898). "On the calculation of the most probable values of frequency constants for data arranged according to equidistant division of a scale." *Proceedings of the London Mathematical Society.* 29, 231-258.
- 6. Tricker, A.R. (1984) "Effects of Rounding on the Moments of a Probability Distribution." *Journal of the Royal Statistical Society. Series D (The Statistician)*. 33(4), 381-390.



ADDITIONAL SLIDES

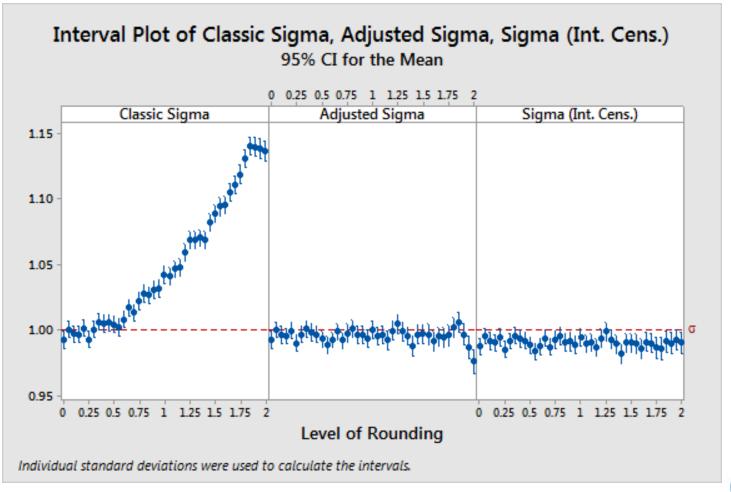


Capability with Rounded Data (N=100)



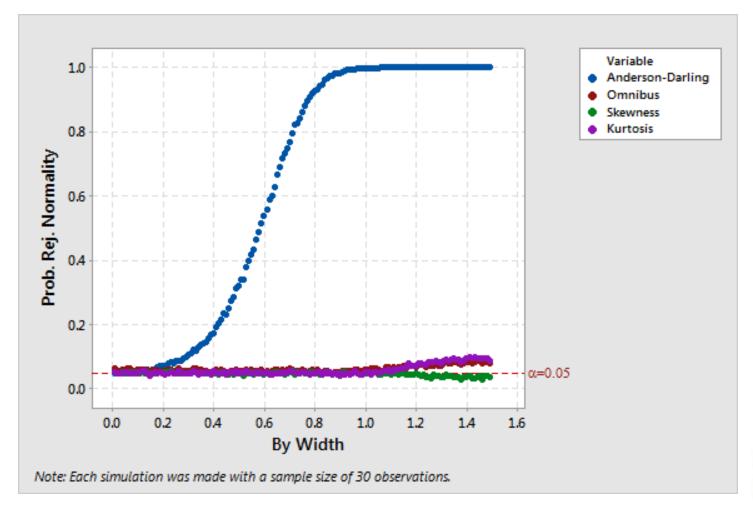


Capability with Rounded Data (N=100)



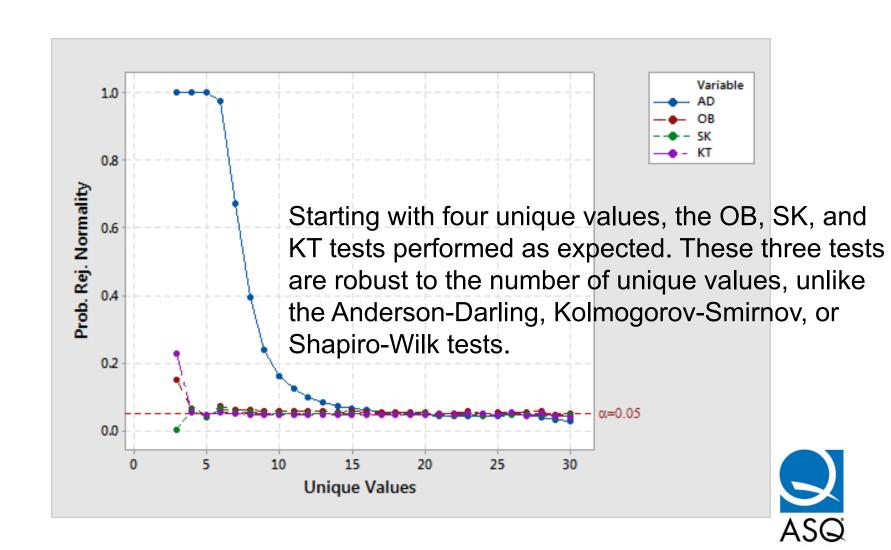


Normality tests for Normal data (N=30)

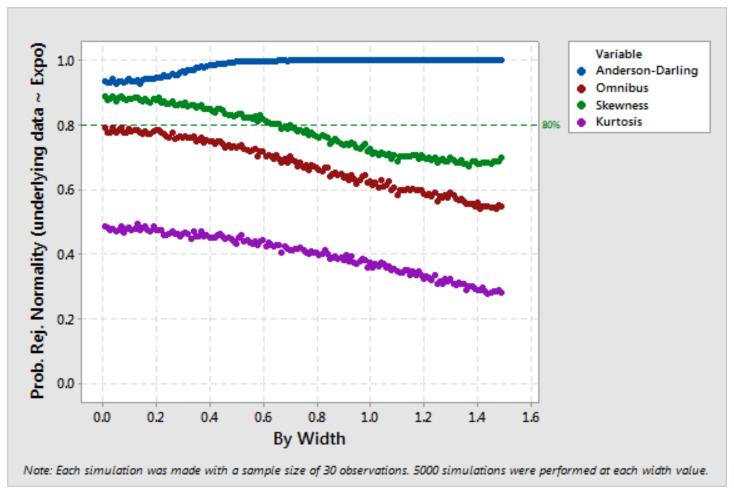




Normality tests performance (Ties)

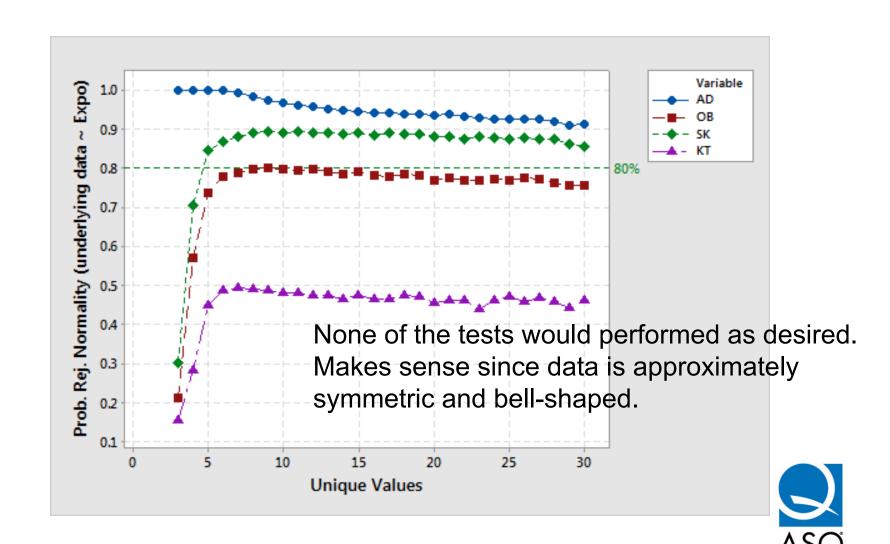


Normality tests for Expo data (N=30)

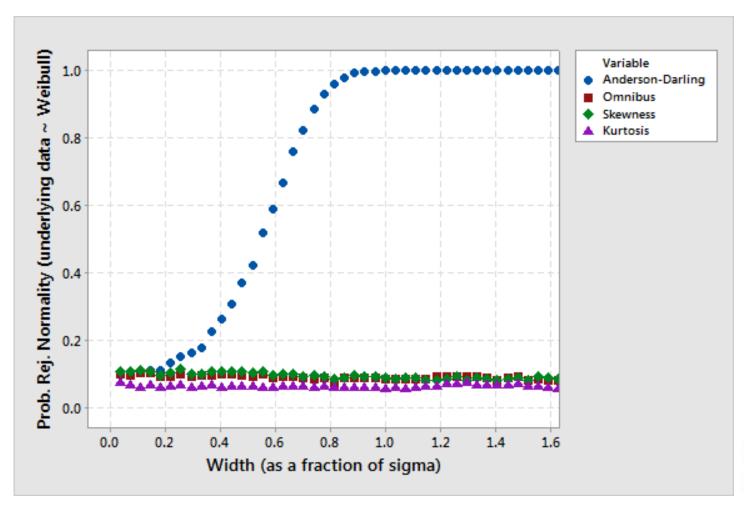




Normality tests performance (Expo)

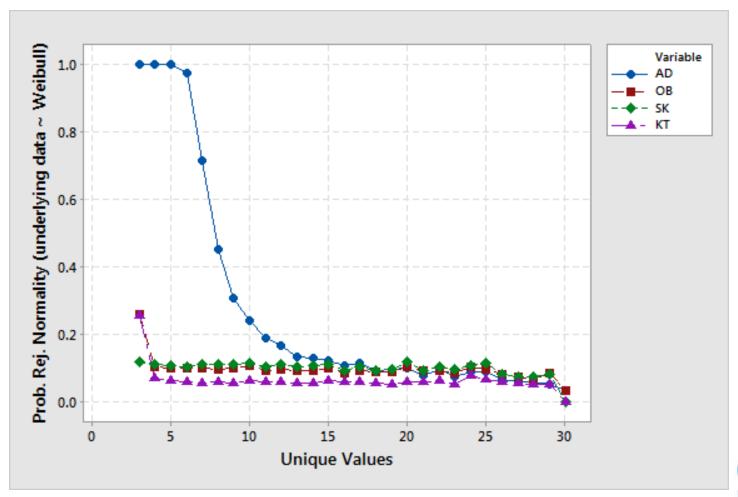


Normality tests for Weibull data (N=30)



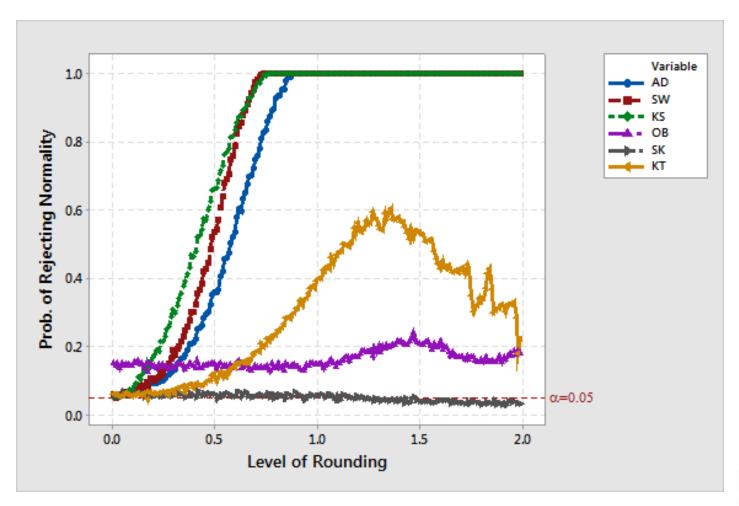


Normality tests performance (Weibull)





Comparison of Classic Normality Tests





A medical device manufacturer builds a blood glucose measurement apparatus for diabetics to use at home. The reading has to be truncated so that it is easy for the customer to read and understand. They measure a standard solution on 100 devices to set a baseline. The specs are [99, 136].

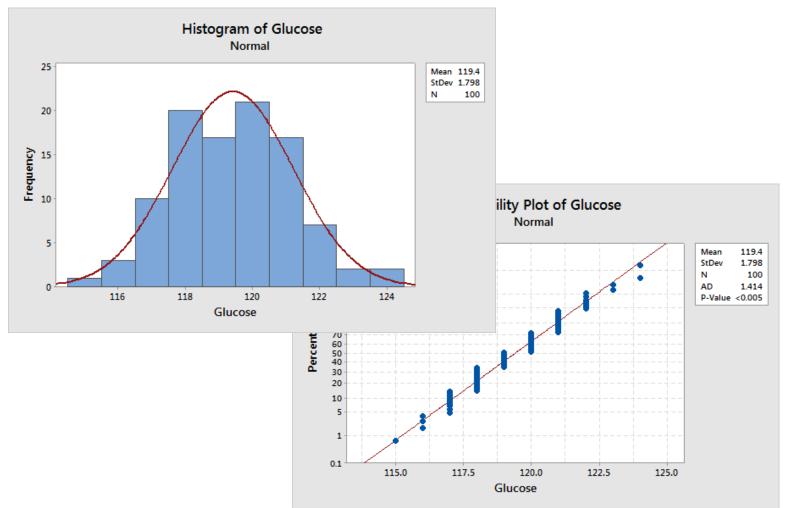


Data

```
122 121 119 119 123 116 119 120 119 121
118 120 118 120 117 116 120 118 121 120
117 118 119 120 118 118 120 119 120 123
120 117 119 121 120 121 118 117 119 118
120 120 120 122 118 120 117 119 121 117
121 118 117 118 122 119 120 120 120 118
122 119 121 118 118 119 118 121 119 120
116 122 120 117 124 117 120 121 120 115
124 121 118 119 118 121 119 118 122 121
117 118 122 121 121 121 121 119 118 119
```



Classic Normality tests fail.





 Try an alternative normality test instead, such as the Skewness test.

Total number of observations in Glucose = 100

Data Display



Convert the data to the following format.

Start	End	Frequency
114.5	115.5	1
115.5	116.5	3
116.5	117.5	10
117.5	118.5	20
118.5	119.5	17
119.5	120.5	21
120.5	121.5	17
121.5	122.5	7
122.5	123.5	2
123.5	124.5	2



• Treat the data as interval-censored and analyze it with Parametric Distribution Analysis to get the estimates of μ and σ .

Parametric Distribution Analysis-Arbitrary Censoring			
C1 Glucose C3 Start	St <u>a</u> rt variables:	_	F <u>M</u> ode
C4 End C5 Frequency	Start	÷	Estimate
	E <u>n</u> d variables:		<u>T</u> est
	End	Α.	<u>G</u> raphs
		*	Results
	Frequency columns (optional):		Options
ll .	Frequency	÷	Storage
	By variable:		
, 1	Assumed distribution: Normal	•	
Select			
			<u>O</u> K
Help			Cancel



 Finally, with the estimates of 119.41 for the mean and 1.766 for the standard deviation proceed to estimate Ppk as usual.

$$Ppk = min\left[\frac{USL - \hat{\mu}}{3\hat{\sigma}}, \frac{\hat{\mu} - LSL}{3\hat{\sigma}}\right] = 3.13$$

