Constructing Statistical Tolerance Limits for Non-Normal Data

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Statistical Tolerance Limits

- Consider a sample of *n* observations taken from a continuous population.

$$\{X_1, X_2, \ldots, X_n\}$$

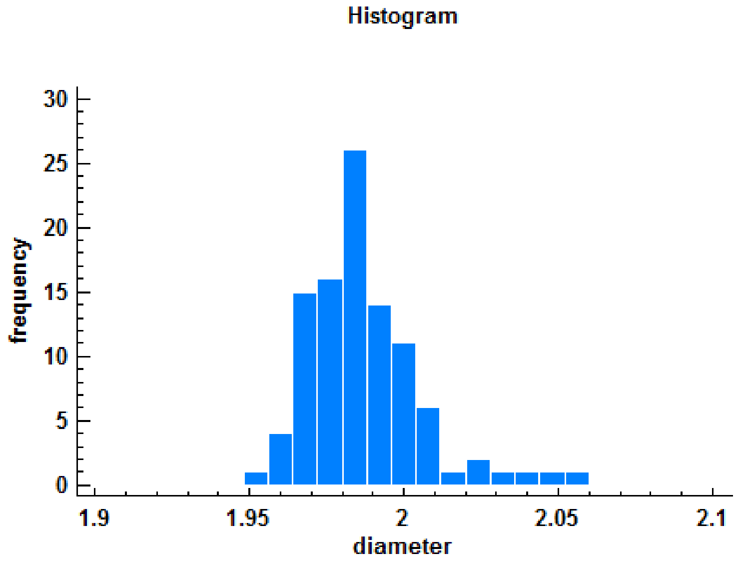
- Statistical tolerance limits create an interval that bounds a specified percentage of the population at a given level of confidence.

(such as 99% of the population with 95% confidence)

- These intervals are often used to demonstrate compliance with a set of requirements or specification limits.

Example: Medical Devices

- Consider the following measurements of the diameter of a sample n = 100 of medical devices:



- The specification limits are 2.0 ± 0.1

Assuming Normality

If we could assume that the data are a random sample from a normal distribution, then a 95% statistical tolerance interval for 99% of the underlying population would be given by:

$$\bar{x} \pm Ks$$

K depends on the level of confidence 100(1-α)% and the percentage of the population *P* to be bound.

General Approach for Constructing Statistical Tolerance Limits

- Step 1: Test data for normality.
  – If normal dist. is tenable, calculate normal tolerance limits.

- Step 2: If not normal, search for a normalizing transformation.
  – If acceptable transformation is found, calculate normal tolerance limits for transformed data and invert the limits.

- Step 3: If transformation approach fails, try alternative distributions such lognormal, extreme value or Weibull.
  – If a good fit is found, calculate tolerance limits using that distribution.

- Step 4: If all else fails, calculate nonparametric tolerance limits.

Step 1: Test for Normality

Distribution Fitting (Uncensored Data) - diameter

Distribution Fitting (Uncensored Data) - diameter

Data variable: diameter (mm)

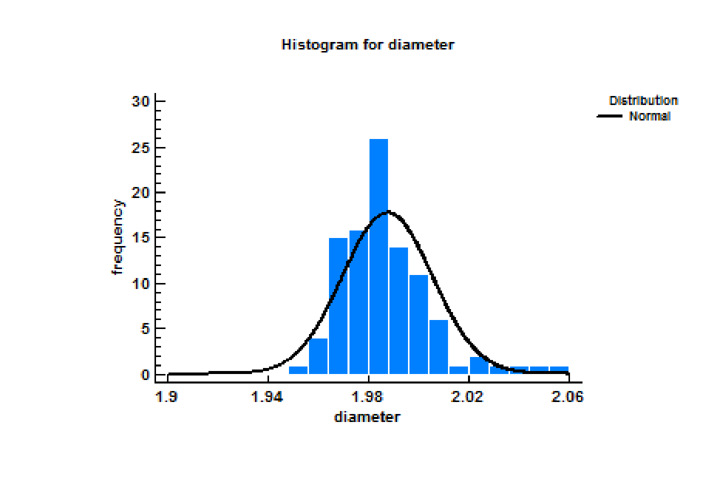
100 values ranging from 1.956 to 2.053

Fitted Distributions

Normal
mean = 1.98757
standard deviation = 0.0179749

The StatAdvisor

This analysis shows the results of fitting a normal distribution to the data on diameter. Th
distribution are shown above. You can test whether the normal distribution fits the data a
Tests from the list of Tabular Options. You can also assess visually how well the normal
Histogram from the list of Graphical Options. Other options within the procedure allow yc
critical values for the distribution. To select a different distribution, press the alternate mc



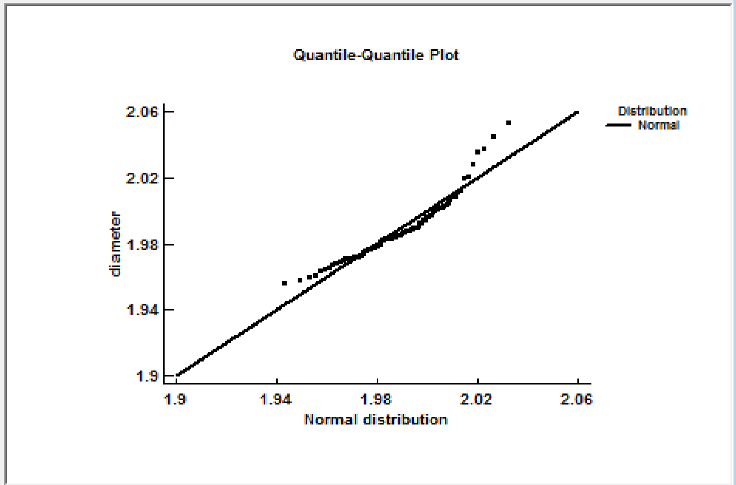
Tests for Normality for diameter

Test	*Statistic*	*P-Value*
Shapiro-Wilk W	0.918122	9.3174E-7

The StatAdvisor

This pane shows the results of several tests run to determine whether diameter can be ade
The Shapiro-Wilk test is based upon comparing the quantiles of the fitted normal distribut

Since the smallest P-value amongst the tests performed is less than 0.05, we can reject the
distribution with 95% confidence.



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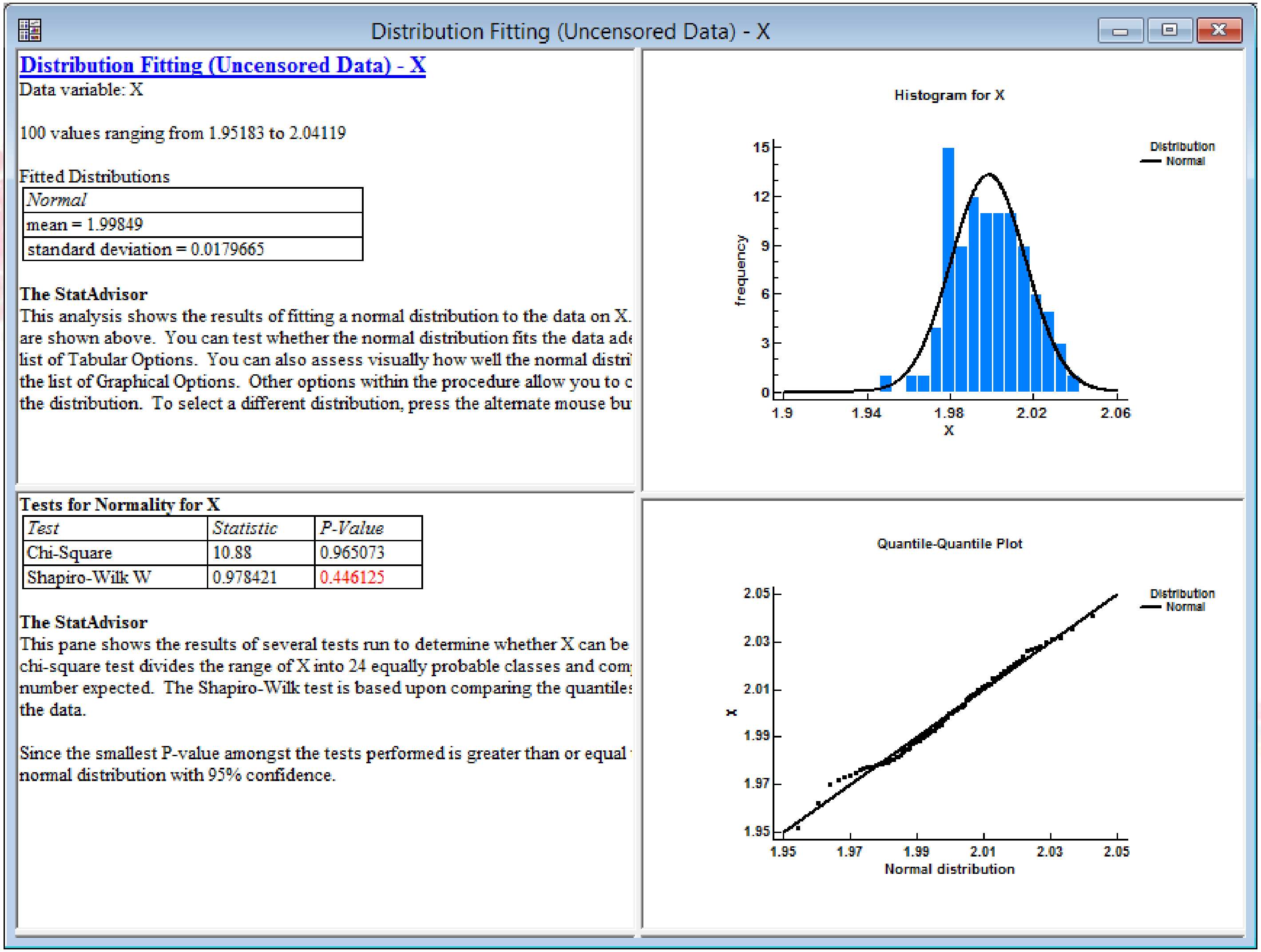
Tests for Normality

- Shapiro-Wilk test: recommended for sample sizes between 3 and 5000.

- Anderson-Darling test: recommended for sample sizes *n* > 5000.

- Chi-square test: recommended for heavily rounded data. NOTE: be sure to set up classes that match the rounding of the data.

Warning: Beware of rounded data



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Warning: Beware of rounded data

Distribution Fitting (Uncensored Data) - X

Distribution Fitting (Uncensored Data) - X

Data variable: X

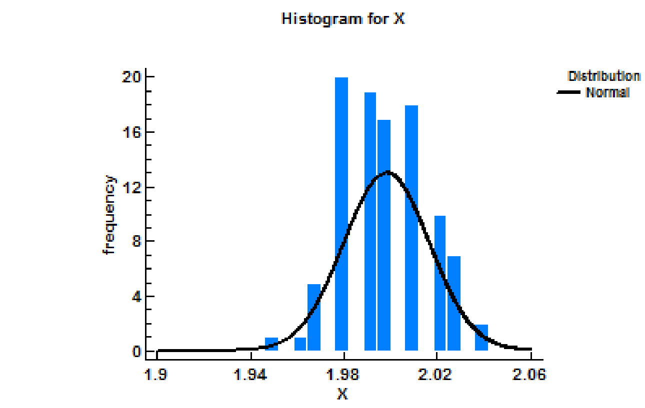
100 values ranging from 1.95 to 2.04

Fitted Distributions

Normal
mean = 1.9984
standard deviation = 0.0184073

The StatAdvisor

This analysis shows the results of fitting a normal distribution to the data on X.
are shown above. You can test whether the normal distribution fits the data ade
list of Tabular Options. You can also assess visually how well the normal distri
the list of Graphical Options. Other options within the procedure allow you to c
the distribution. To select a different distribution, press the alternate mouse bu



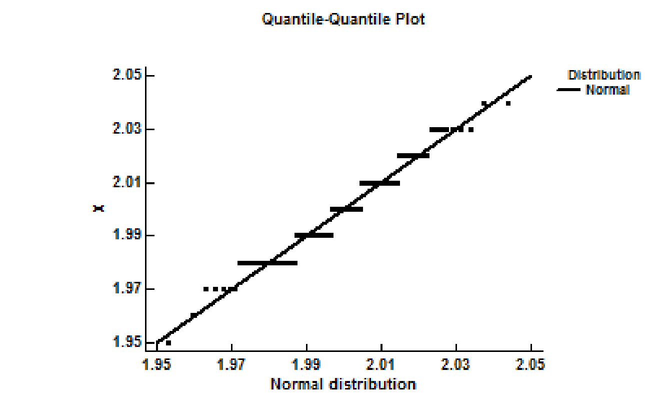
Tests for Normality for X

Test	*Statistic*	*P-Value*
Chi-Square	273.44	0.0
Shapiro-Wilk W	0.955381	0.0085267

The StatAdvisor

This pane shows the results of several tests run to determine whether X can be
chi-square test divides the range of X into 24 equally probable classes and com
number expected. The Shapiro-Wilk test is based upon comparing the quantiles
the data.

Since the smallest P-value amongst the tests performed is less than 0.05, we can
distribution with 95% confidence.



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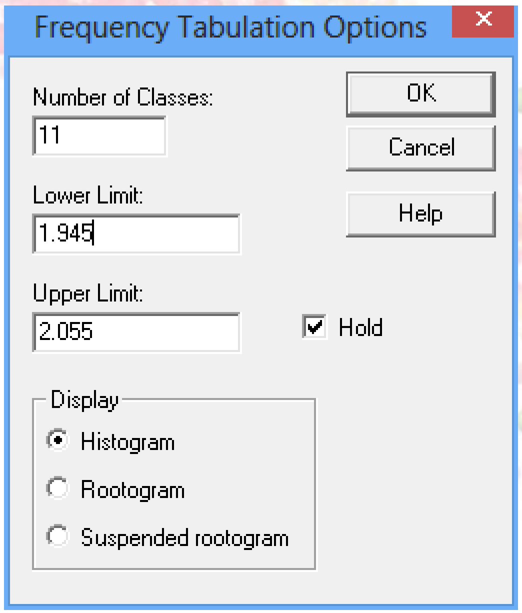
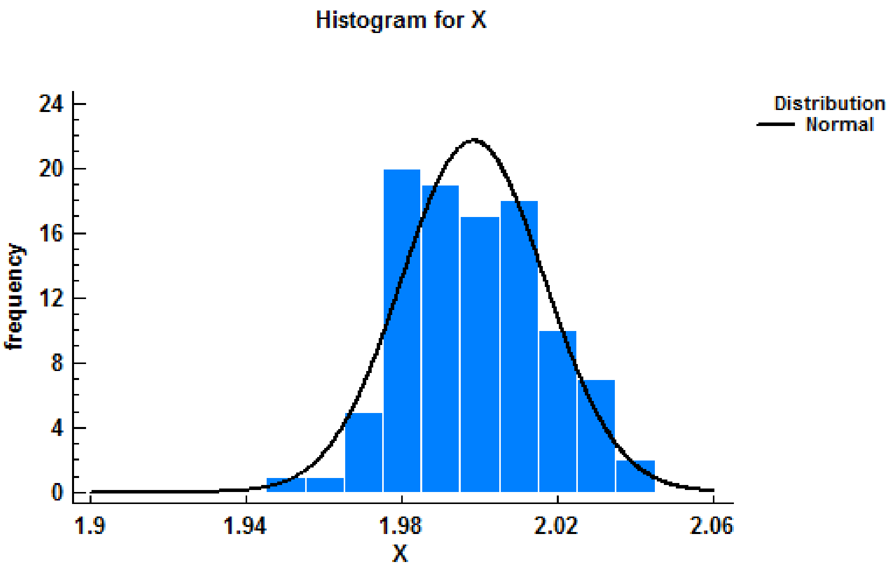
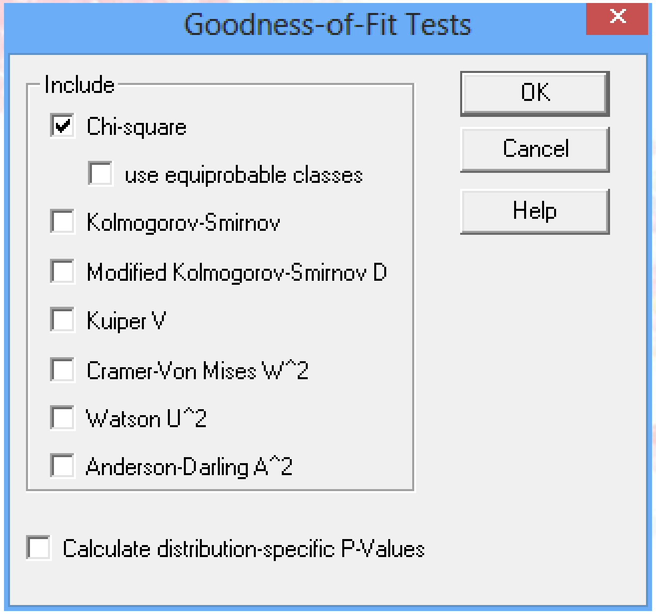
Solution: bin the data

- Be sure classes match the rounding





Run chi-square test



Goodness-of-Fit Tests for X

Chi-Square Test

	Lower	*Upper*	*Observed*	*Expected*	
	Limit	*Limit*	*Frequency*	*Frequency*	*Chi-Square*
at or below		1.965	2	3.48	0.63
	1.965	1.975	5	6.70	0.43
	1.975	1.985	20	13.15	3.57
	1.985	1.995	19	19.34	0.01
	1.995	2.005	17	21.33	0.88
	2.005	2.015	18	17.64	0.01
	2.015	2.025	10	10.94	0.08
	2.025	2.035	7	5.08	0.72
above	2.035		2	2.34	0.05

Chi-Square = 6.37593 with 6 d.f. P-Value = 0.382421

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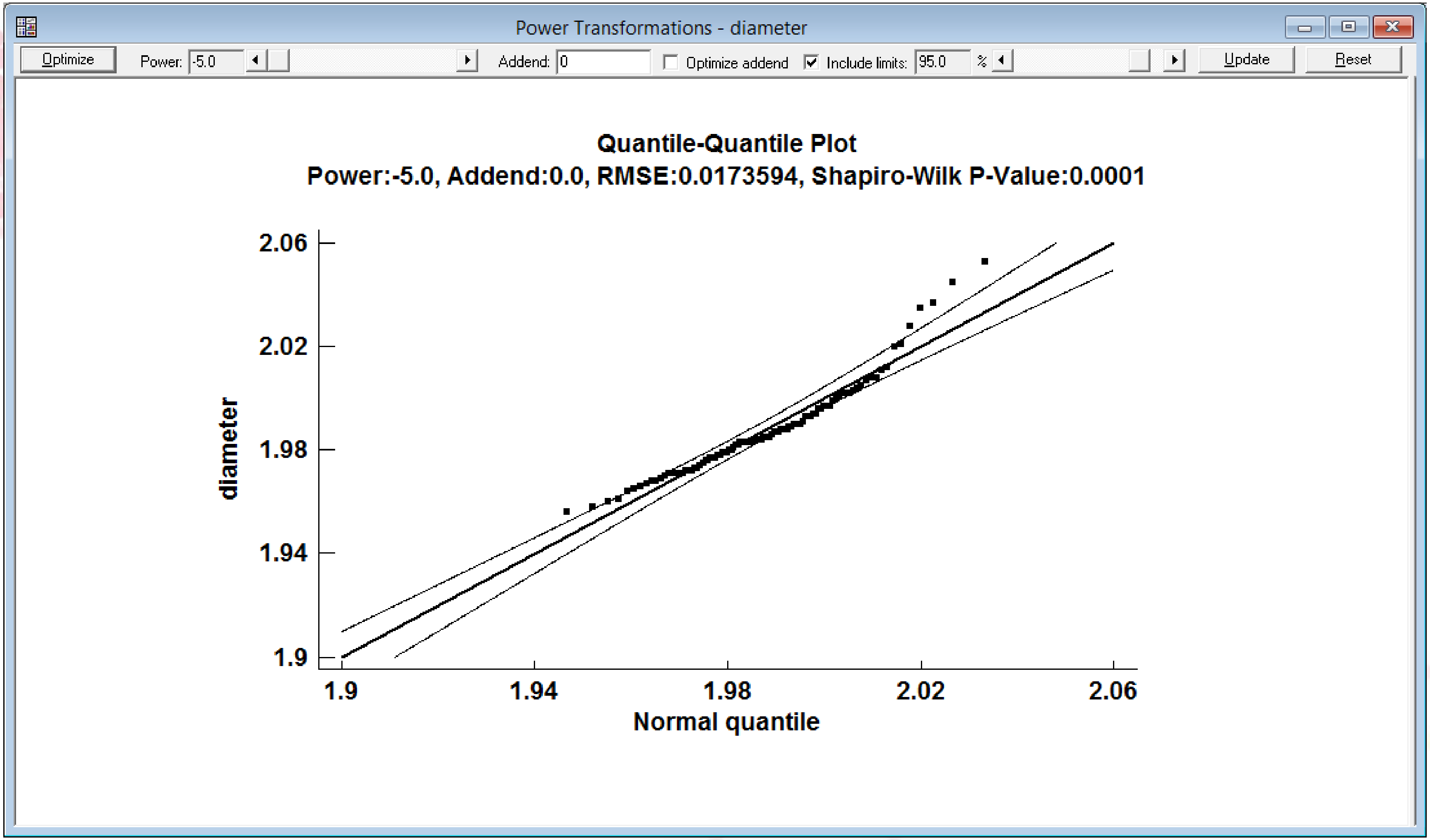
Step 2: Search for normalizing transformation

- If *X* does not follow a normal distribution, it may be possible to find a power *p* such that X^p is normally distributed.

- If so, normal tolerance limits may be constructed for X^p and then inverted to create limits for *X*.

- The general method of Box and Cox may be used to find the best value of *p*.

Statlets - Power Transformations



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Power plus Addend

- If a simple power transformation does not work, an addend can be estimated as well:

$$X^t = (X + \Delta)^p$$

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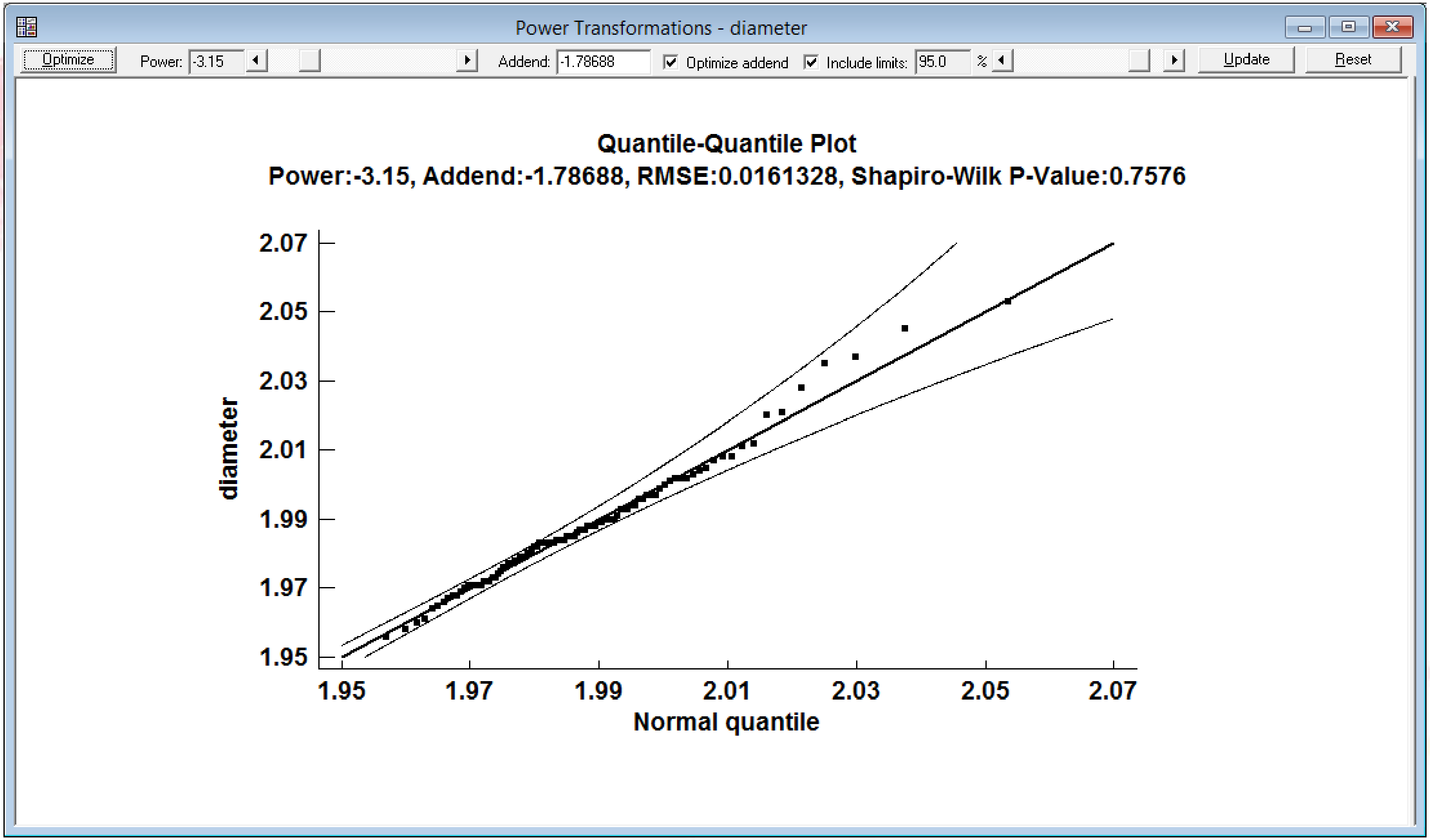
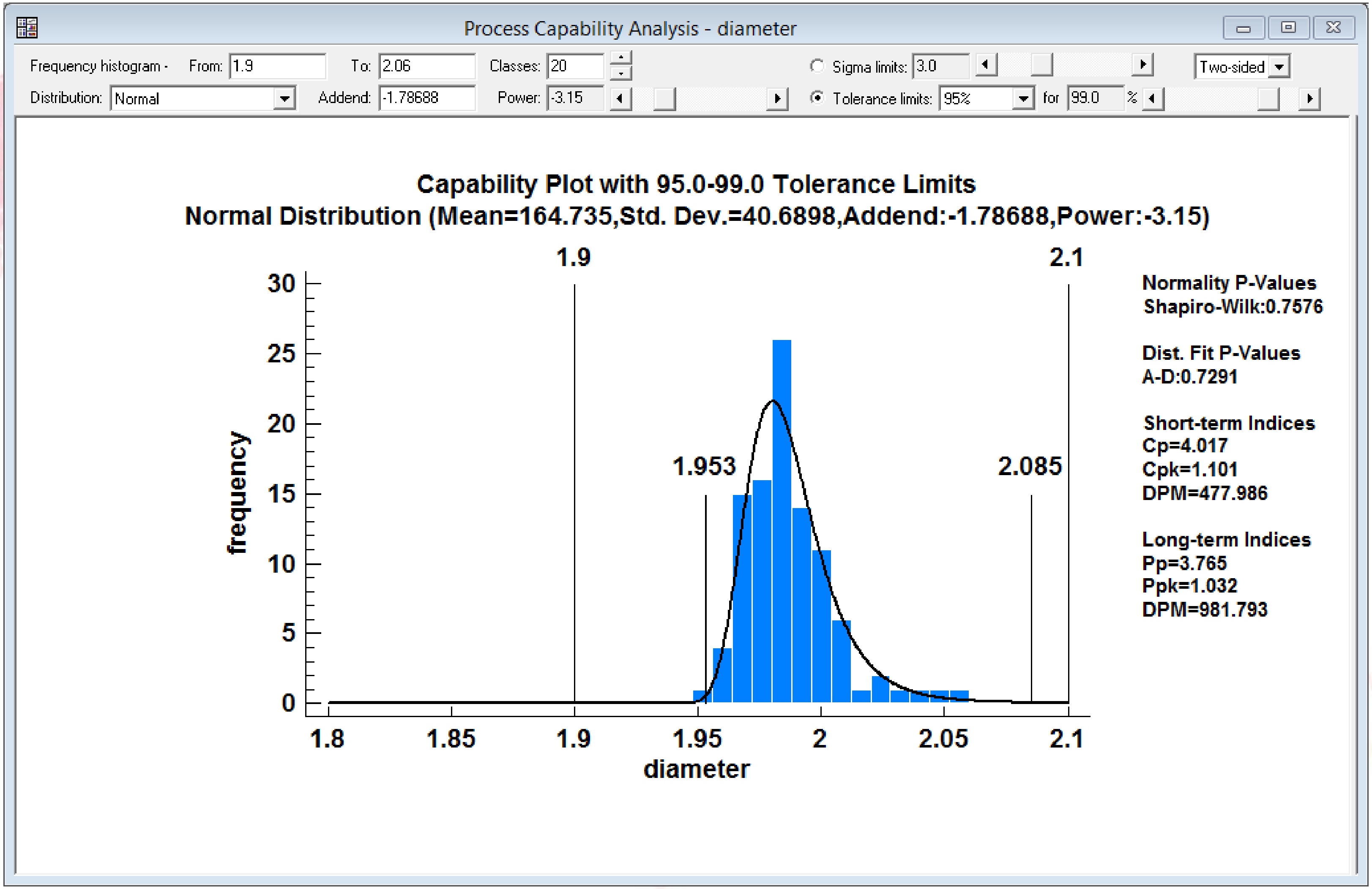
Power plus Addend



Tolerance Limits



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Step 3: Find an Alternative Distribution

- Statgraphics will calculate statistical tolerance limits for the following distributions:
  - Normal
  - Lognormal
  - Weibull
  - Cauchy
  - Exponential
  - 2-parameter exponential
  - Gamma
  - Laplace
  - Largest extreme value
  - Pareto
  - Smallest extreme value

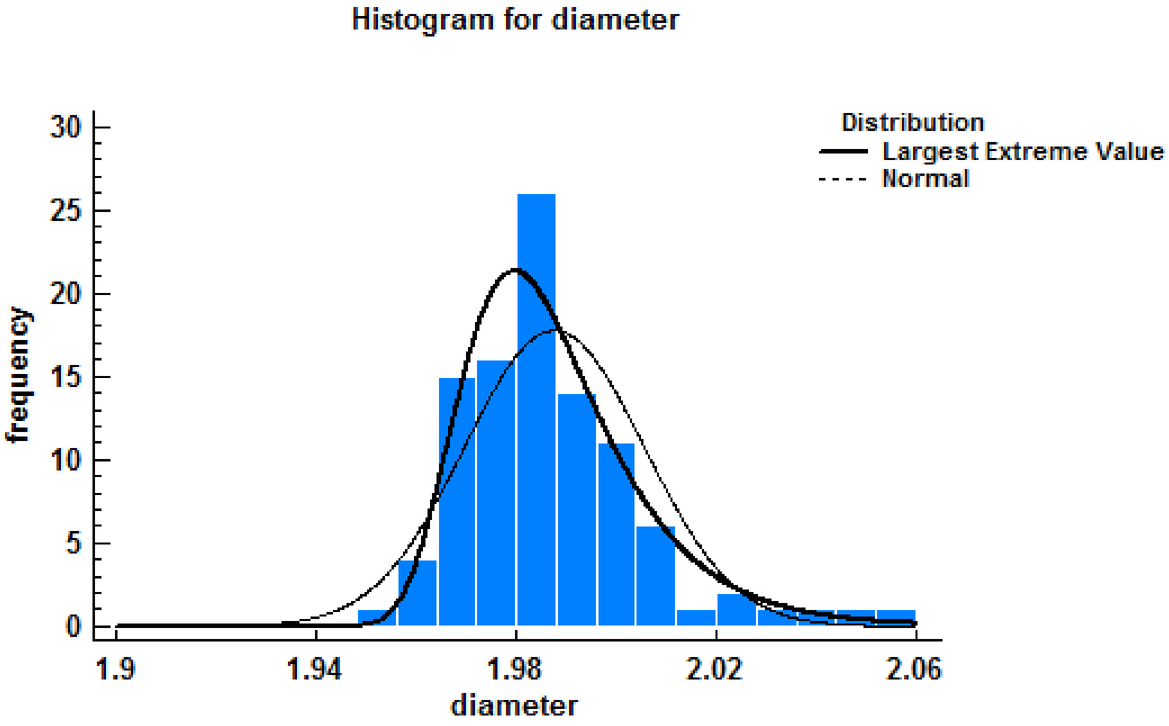
Distribution Fitting

- Comparison of alternative distributions

Comparison of Alternative Distributions

Distribution	*Est. Parameters*	*Log Likelihood*	*A^2*
Largest Extreme Value	2	270.696	0.309344
Laplace	2	266.126	0.925591
Loglogistic	2	265.245	0.844609
Logistic	2	264.939	0.881328
Inverse Gaussian	2	261.022	1.83356
Lognormal	2	261.02	1.85076
Gamma	2	260.846	1.86193
Normal	2	260.484	1.93765
Cauchy	2	257.124	1.37669
Smallest Extreme Value	2	234.823	6.71728
Weibull	2	161.746	
Pareto	1	-131.127	44.7816
Exponential	1	-168.691	45.1176

Fitted Distributions



Goodness-of-Fit

- To test goodness-of-fit for alternative distributions, Anderson-Darling test is popular.

- Be sure to use "modified" form of the test, which adjusts the test statistics and P-value to account for estimated parameters.

Goodness-of-Fit Tests for diameter

Anderson-Darling A^2

	Largest Extreme Value	*Normal*
A^2	0.309344	1.93765
Modified Form	0.315531	1.95262
P-Value	>=0.10*	0.0000564085*

*Indicates that the P-Value has been compared to tables of critical values specially constructed for fitting the selected distribution. Other P-values are based on general tables and may be very conservative (except for the Chi-Square Test).

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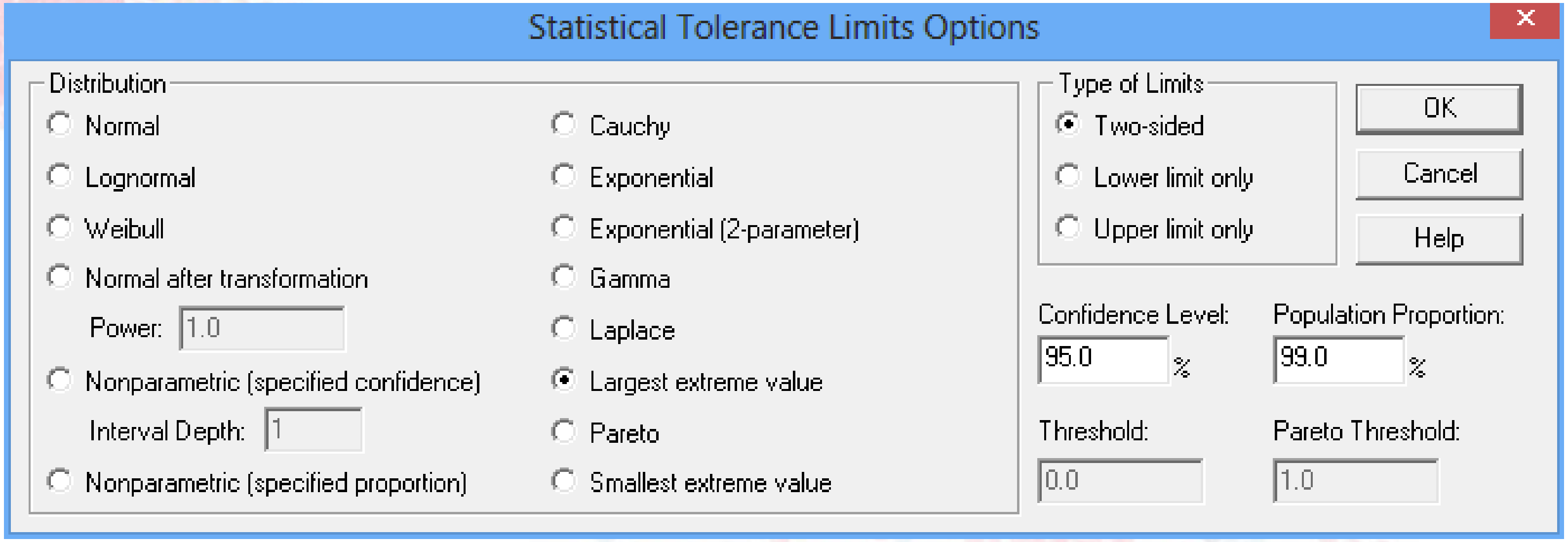
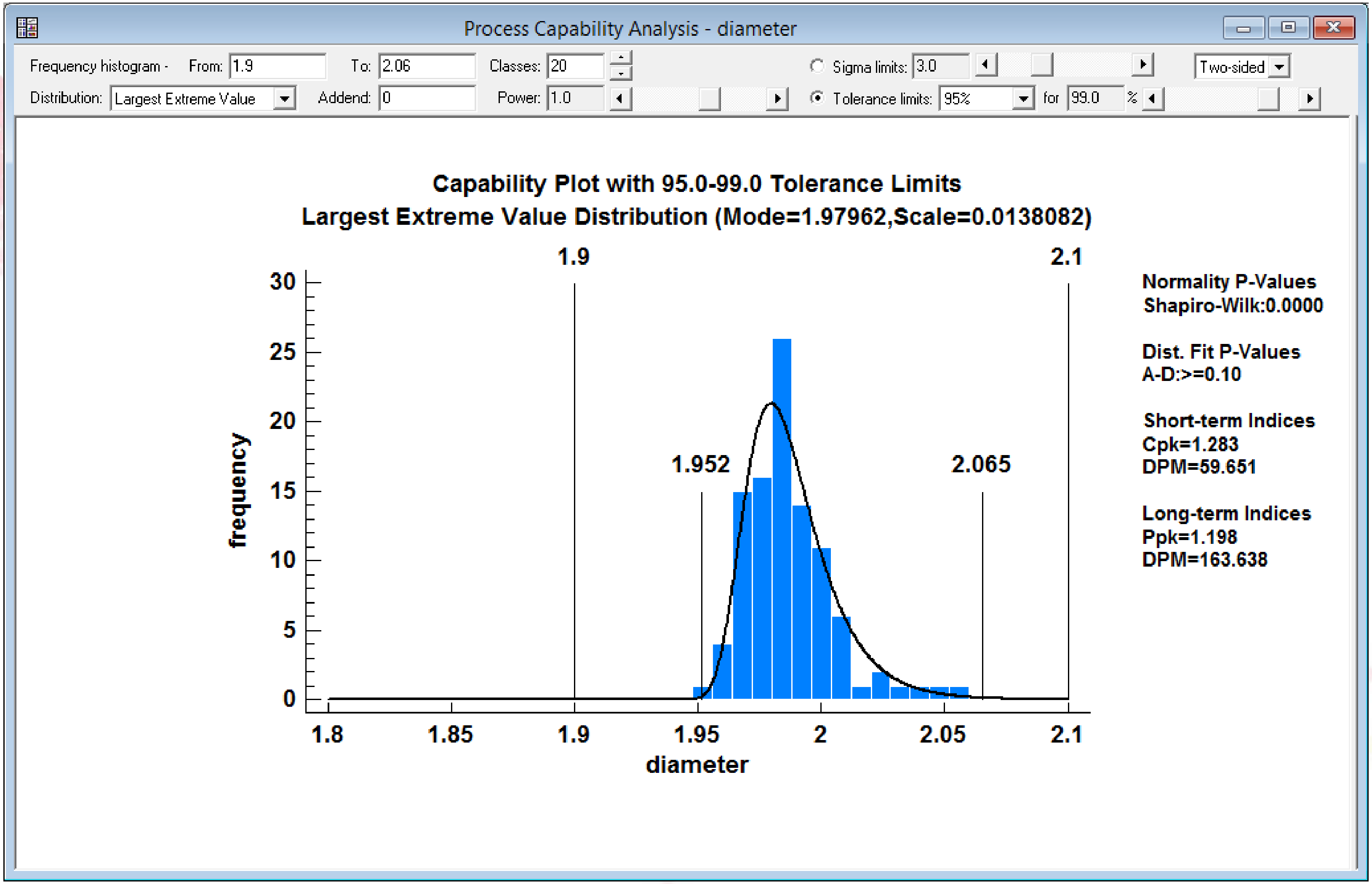
Tolerance Limits



Tolerance Limits



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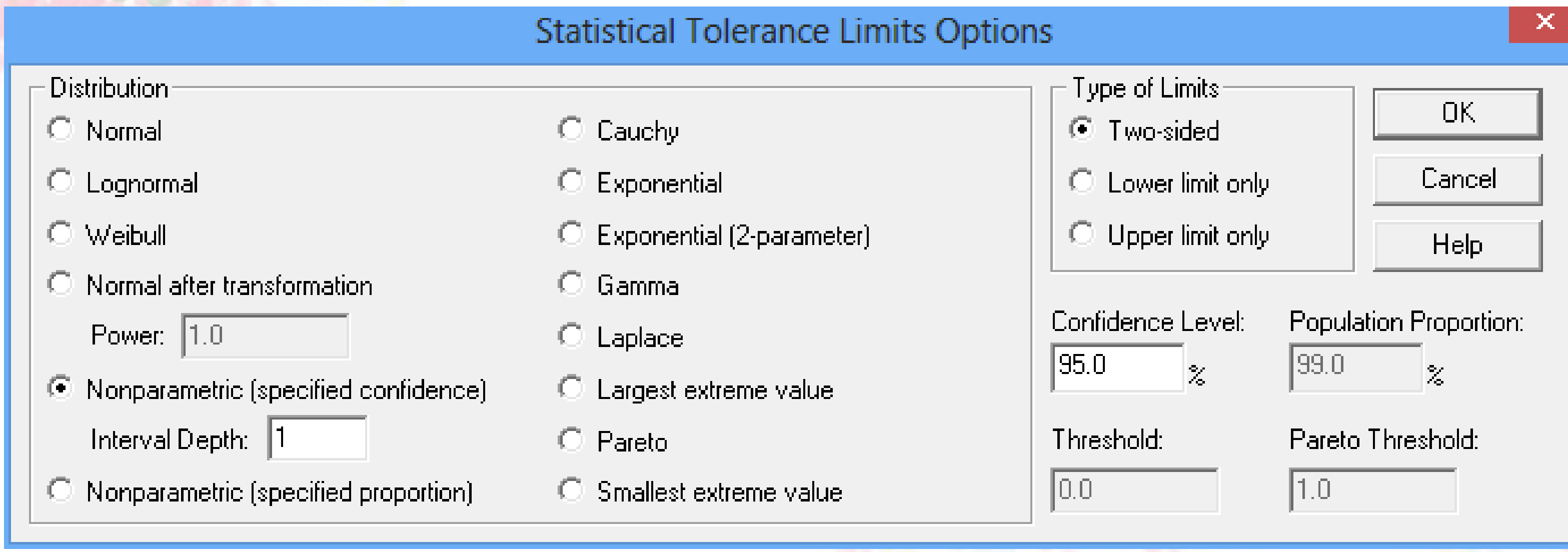
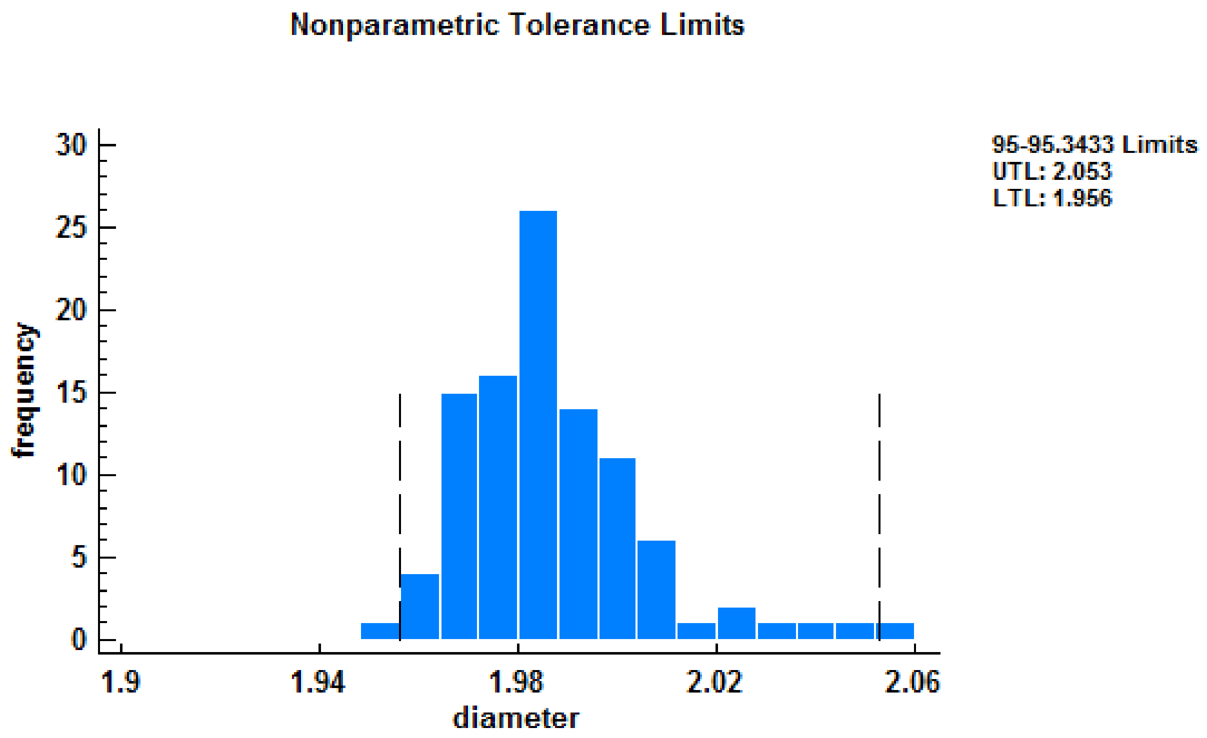
Step 4: Nonparametric Limits

- Can specify either the population percentage or the confidence level, but not both.



- Tolerance interval is [$X_{(d)}$, $X_{(n-d+1)}$]

Nonparametric Limits



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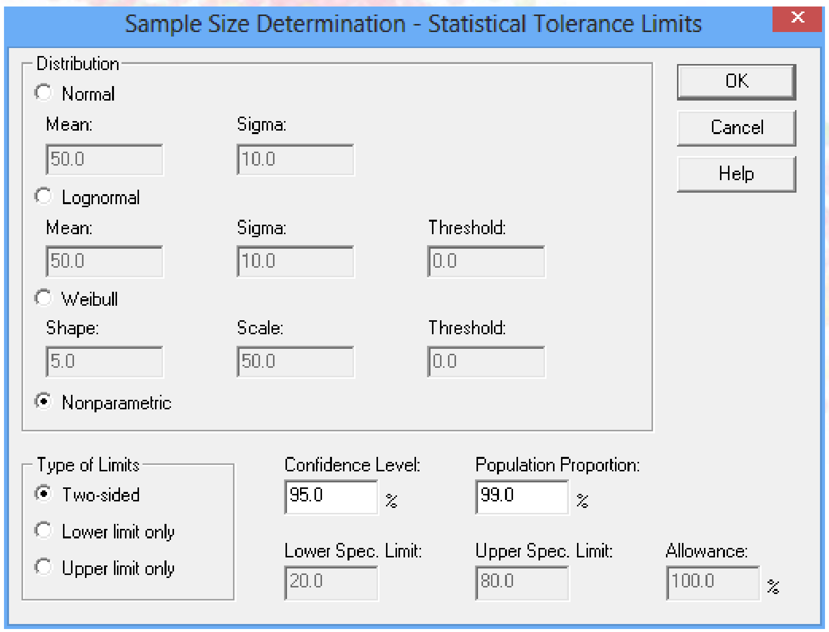
Sample Size Determination – Nonparametric Limits

- How large a sample is needed so that the range [min, max] forms a 95-99 tolerance interval?



Sample Size Determination (Statistical Tolerance Intervals)

Conf. Level	*Pop. Percentage*	*Distribution*
95.0%	99.0%	

The required sample size is 473.

Lower tolerance limit	*Upper tolerance limit*
smallest observation	largest observation

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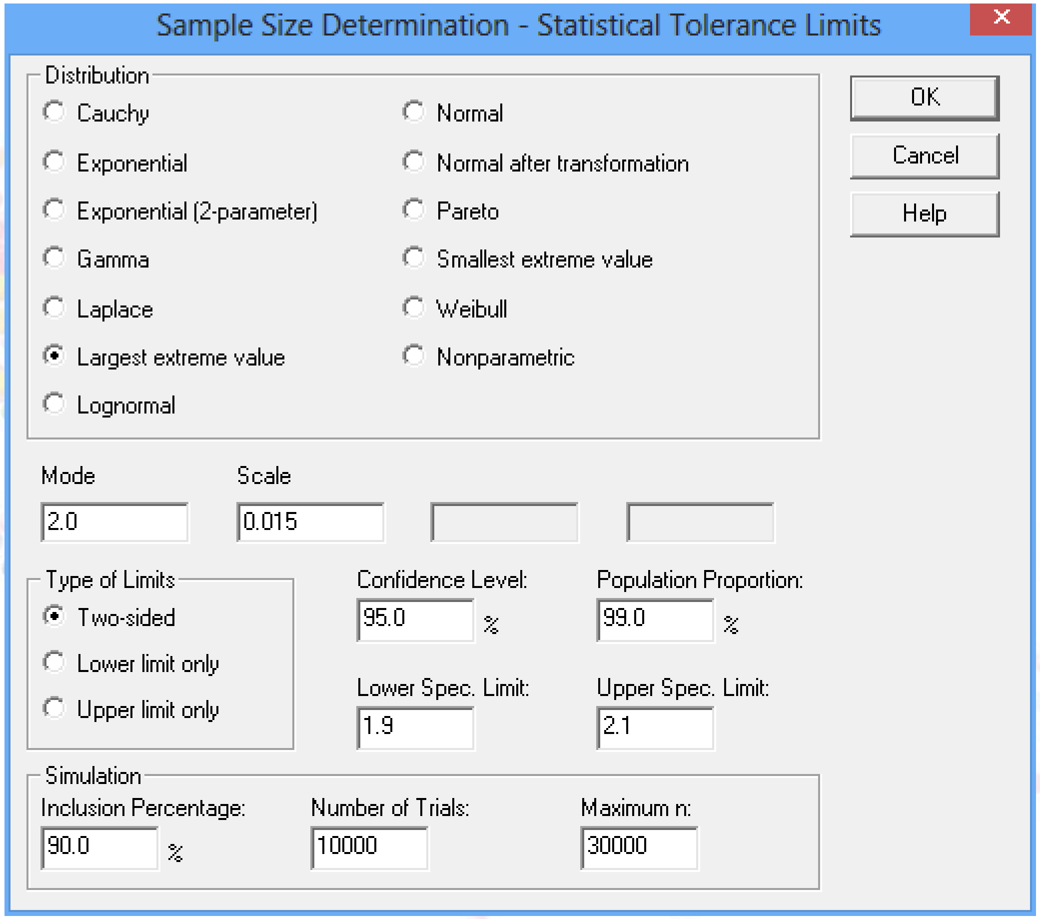
Sample Size Determination – Parametric Limits

- How large should *n* be when fitting a normal or some other distribution?

- Different approaches to the problem.
  1. Choose *n* so that the probability of including P^*% or more of the population in the tolerance interval is small, where $P^* > P$.
  2. Choose *n* so that the probability of the entire tolerance interval being within the specification limits is large.

Example: LEV Distribution



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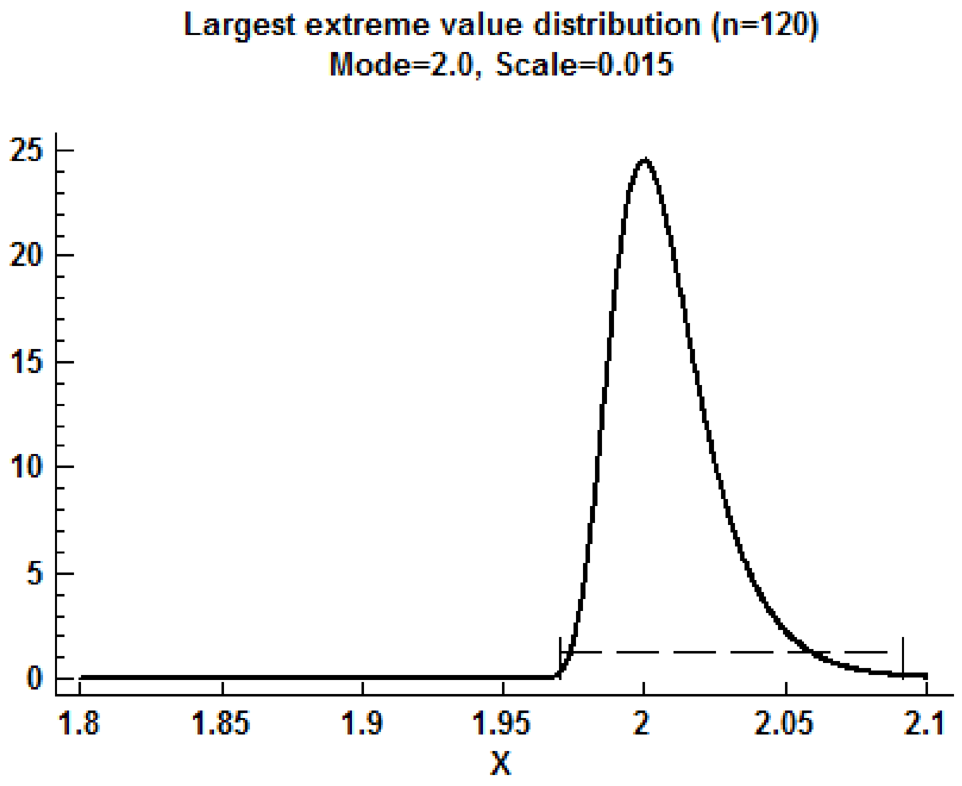
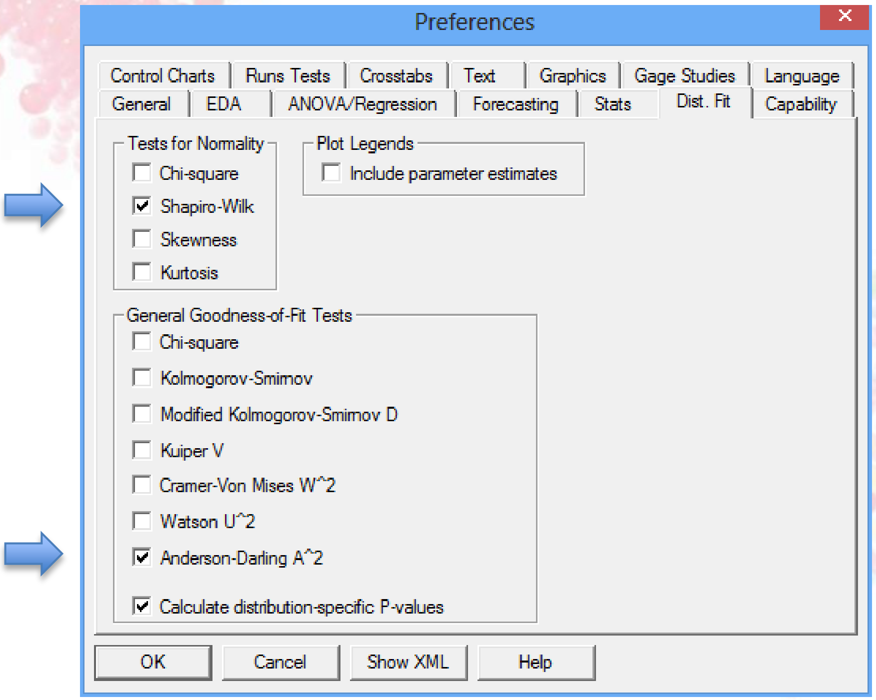
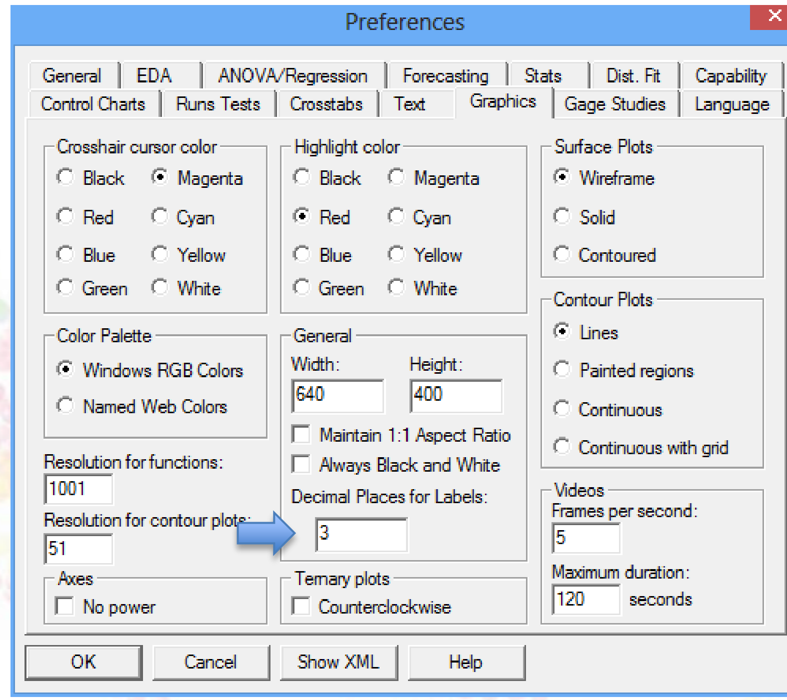
Requires *n*=120 Observations



System Preferences





References

- Video, slides and sample data may be found at www.statgraphics.com/webinars.

- Hahn, G.J., Meeker, W.Q. and Escobar, L.A. (2017) Statistical Intervals: A Guide for Practitioners and Researchers, second edition. Wiley, New York.