Quality Control Charts 3
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Summary of Webinars – Topics Covered

- First Webinar
  - Use of basic statistics
  - Charts and trend analysis
    - Introduction to Shewhart Charts
    - Determining Stanard Deviation
  - Process Capability Assessment
- Second Webinar
  - Construction of CUSUM Chart
  - Preparation of data
  - Plotting the Chart
  - Scaling the Chart
  - Identifying statistically significant trends: V-Masks
  - Tabular CUSUMS
- Third Webinar
  - Recap on estimating standard deviations and standard errors
  - Moving average and Exponentially Weighted Moving Average Charts
  - Scatter Plots and correlation
  - Other Charts – box and whisker plots, histograms, Pareto charts, pie charts, cause/effect (fishbone charts) and flow charts

Recap on Standard Deviations and Standard Errors – Process under Good Control

- Estimate of the within lot (sample) standard deviation S
- Calculate limits from standard error SE = S/ √N were n is the sample size tested
- Estimates of within lot standard deviation can be determined by:
    1. Average range $\bar{R}$ divided by unbiasing constant d_2 (works best for up to 10 to 12 samples in a set, for n = 10 d_2 = 3.0775; for n=13 d_2 = 3.336)
    2. Average standard deviation divided by unbiasing constant C_4 (for n = 200, C_4 = 0.998745)
    3. Pooled Standard deviation

Equal sample sizes - pooled standard deviation is the square root of the average variance (square of the standard deviation) of the lots being included in the calculation:

$$S_{(pooled)} = \sqrt{\frac{S_1^2 + S_2^2 + S_3^2 + \cdots S_k^2}{k}}$$

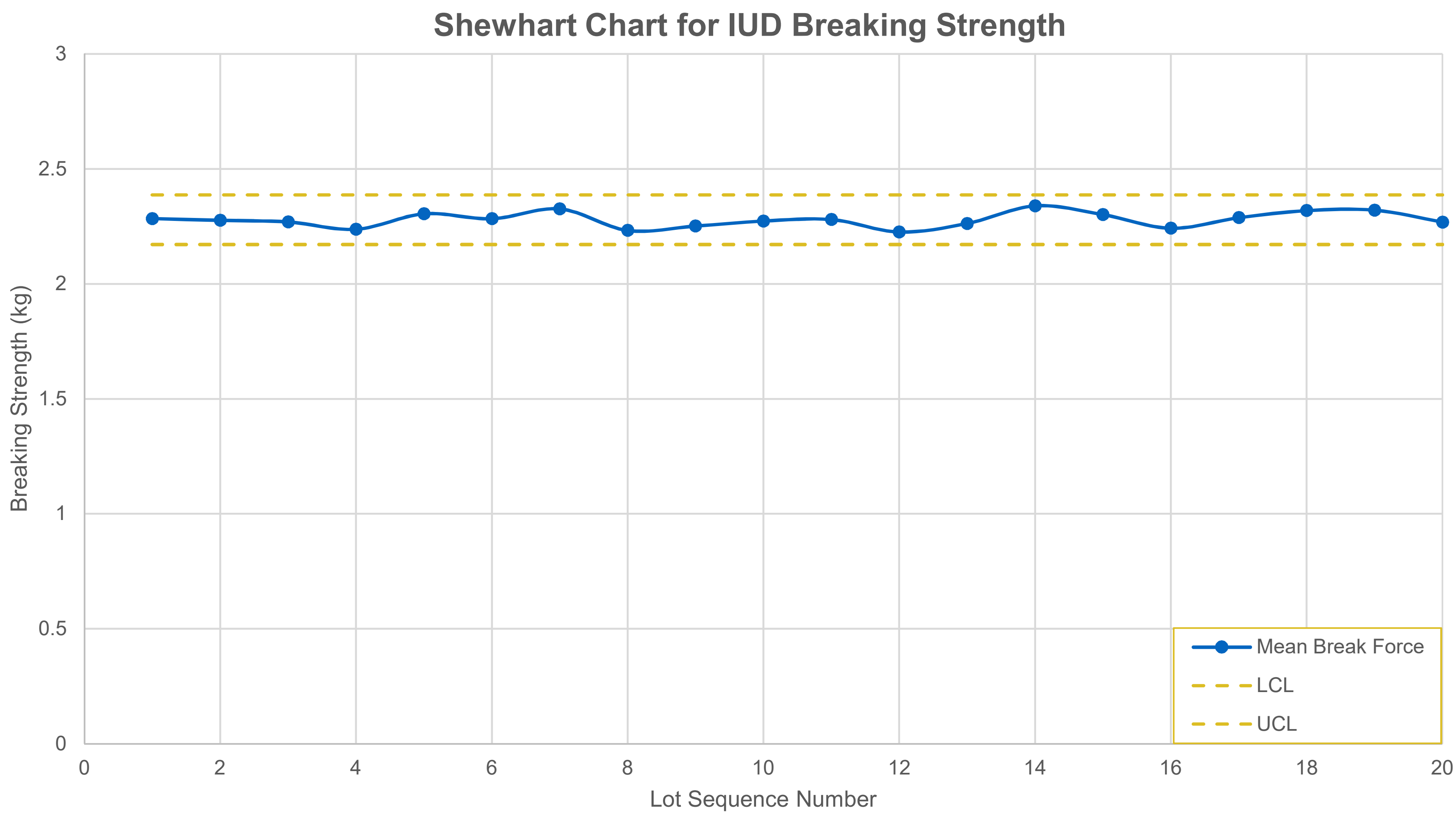
Unequal sample sizes – pooled standard deviation is given by

$$S_{(pooled)} = \sqrt{\frac{(n_1-1)S_1^2 + (n_2-1)S_2^2 + (n_3-1)S_3^2 + \cdots (n_k-1)S_k^2}{n_1 + n_2 + n_2 \ldots n_k - k}}$$

Comparison of Standard Error Calculations

- Example based on IUD breaking strength
- Simulated results based on subgroup sample size 20 and 20 lots

Method	Unbiasing Constant	Standard Error (kg)	LCL (kg)	UCL (kg)
Average range	$d_2 = 3.735$	0.0365	2.170	2.389
Average standard deviation	$c_4 = 0.9869$	0.0358	2.172	2.387
Pooled standard deviation	$c_4 = 1$	0.0359	2.171	2.387


Shewhart Chart for IUD Breaking Strength
Breaking Strength (kg)
Lot Sequence Number
Mean Break Force
LCL
UCL
0
0.5
1
1.5
2
2.5
3
0
2
4
6
8
10
12
14
16
18
20

Process With Lot to Lot Variability - Condom Burst Volumes and pressures

- Calculate the standard deviation of 15 to 20 lot means over a period when the process is considered under an acceptable level of control. Use this standard deviation as the standard error
- Estimate the standard error from the sequential differences between lot means using:

$$SE = \sqrt{\frac{1}{2(\mathrm{k}-1)} \sum_{j=1}^{\mathrm{k}-1} \left(y_j - y_{j+1}\right)^2}$$

Alternative Method to CUSUM for Detecting Small Shifts in Process Averages

Exponentially Weighted Moving Average Chart

(EWMA Chart)

ISO 7870-6:2016, Control charts — Part 6: EWMA control charts

Moving Average Charts

- Smooth out the impact of lot to lot variations
- Plot the moving average of, say, the last 5 lots against the lot sequence number
- For a Shewhart Chart adjust the control limits by using a standard error based on the standard deviation divided by the square root of the number of lots included in the average

  SE(moving average) = SE(mean) $/\sqrt{n}$

Example of Moving Average Calculation

Lot Sequence Number	Burst Volume (L)	
	Lot Average	Moving Average
1	37.46	37.46
2	38.95	38.21
3	38.39	38.27
4	37.26	38.02
5	38.01	38.01
6	37.23	37.97
7	33.73	36.924
8	34.11	36.07
9	32.95	35.21
10	37.03	35.01
11	34.01	34.37
12	37.56	35.13
13	41.67	36.64
14	37.95	37.64
15	36.03	37.44
16	36.93	38.03

EWMA Chart

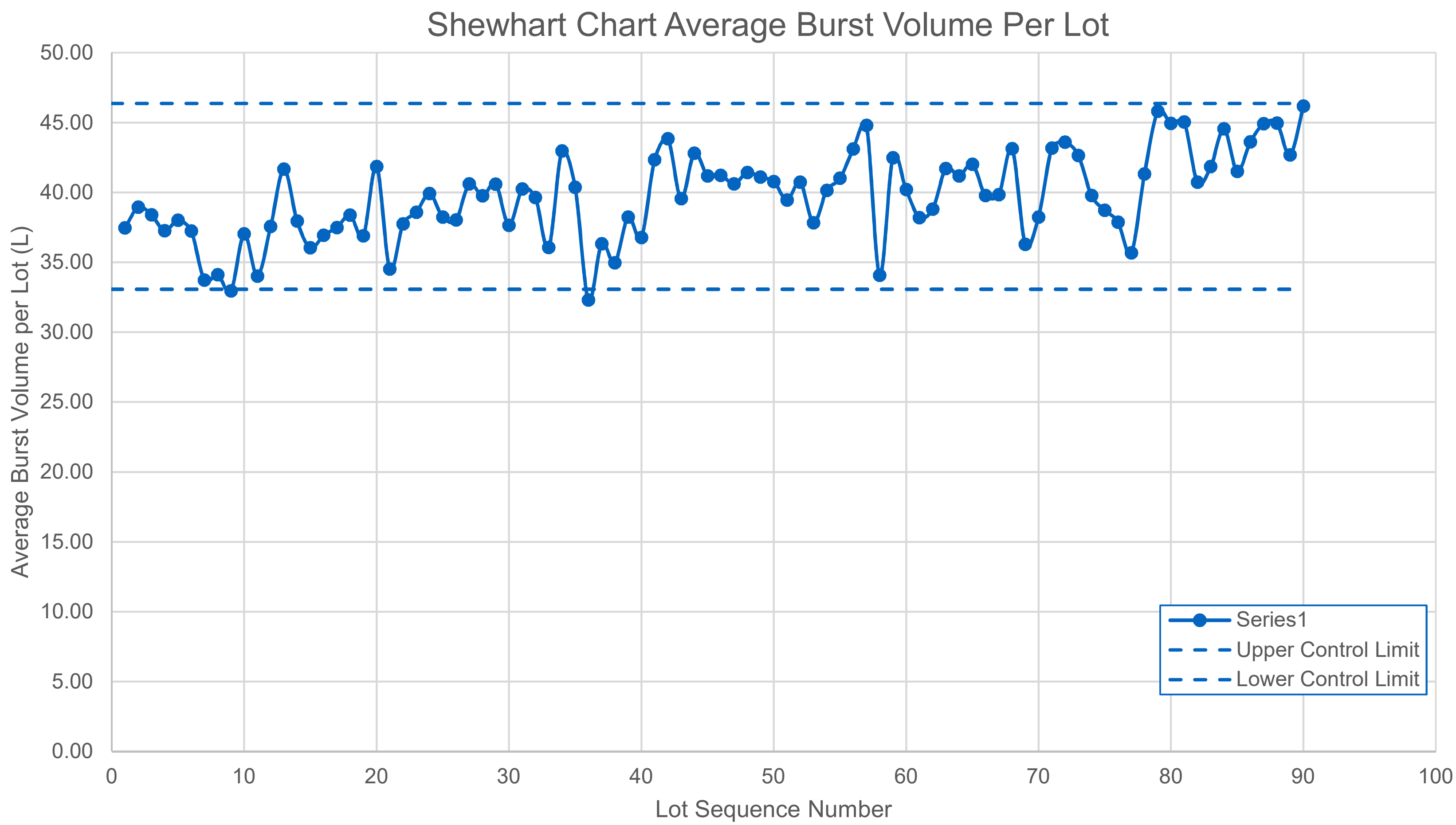
- Similar to a moving average chart but a weighted average giving emphasises most recent result results is used.
- Weighting is achieve using a factor λ which is selected based on experience and speed of response required
- λ has to be between 0 and 1
- Typically $\lambda = 0.2$ to 0.3
- Initial value EWMA(0) set as long term process mean
- $EWMA(t) = \lambda Y(t) + (1-\lambda)\, EWMA(t-1)$ for $t = 1, 2, 3, \ldots, n$

Example of EWMA Calculation

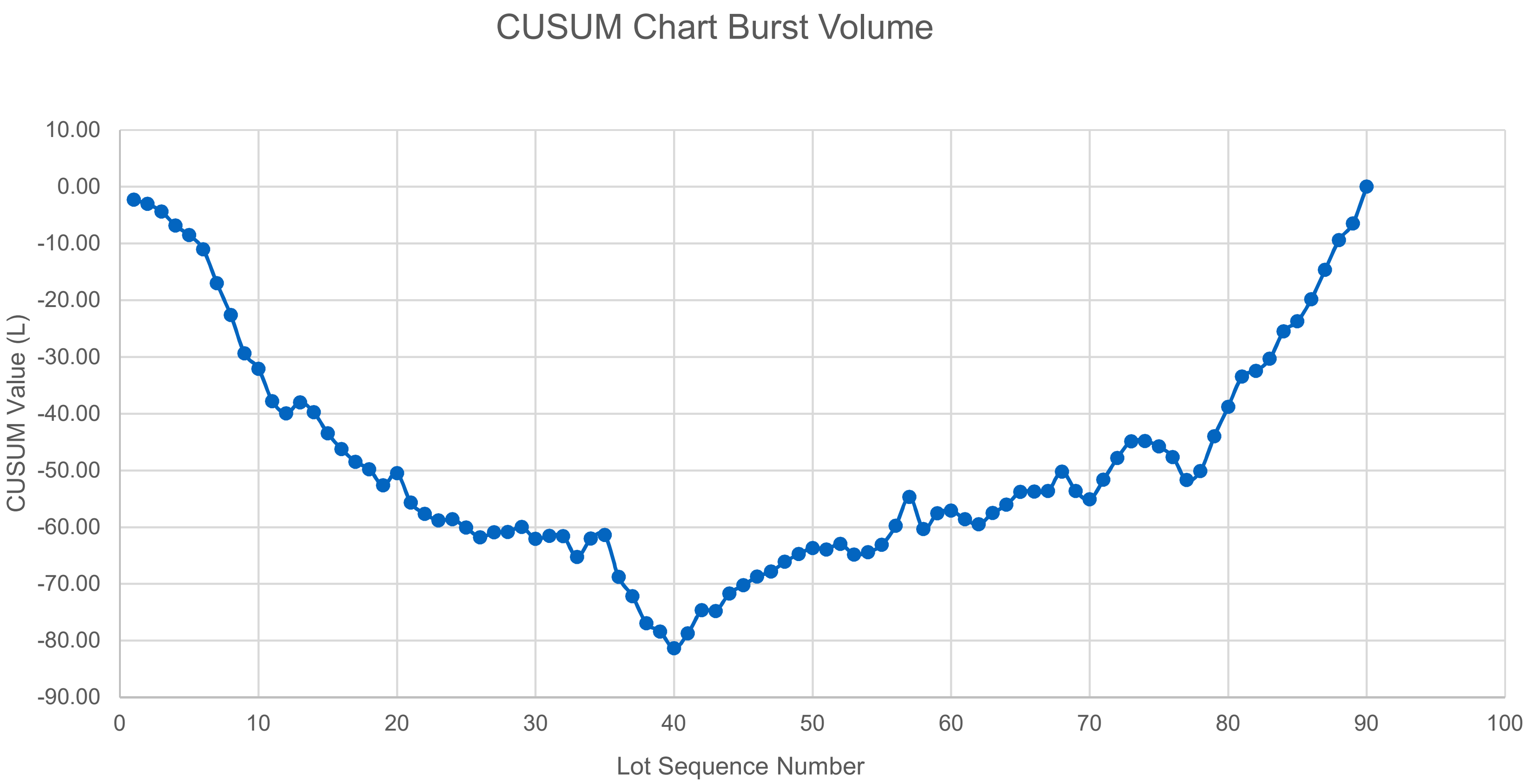
λ	0.3	
Lot Sequence Number	Burst Volume	
	Lot Average	EWMA
		39.72
1	37.46	39.042
2	38.95	39.01
3	38.39	38.83
4	37.26	38.36
5	38.01	38.26
6	37.23	37.95
7	33.73	36.68
8	34.11	35.91
9	32.95	35.02
10	37.03	35.62
11	34.01	35.14
12	37.56	35.87
13	41.67	37.61
14	37.95	37.71
15	36.03	37.21
16	36.93	37.12

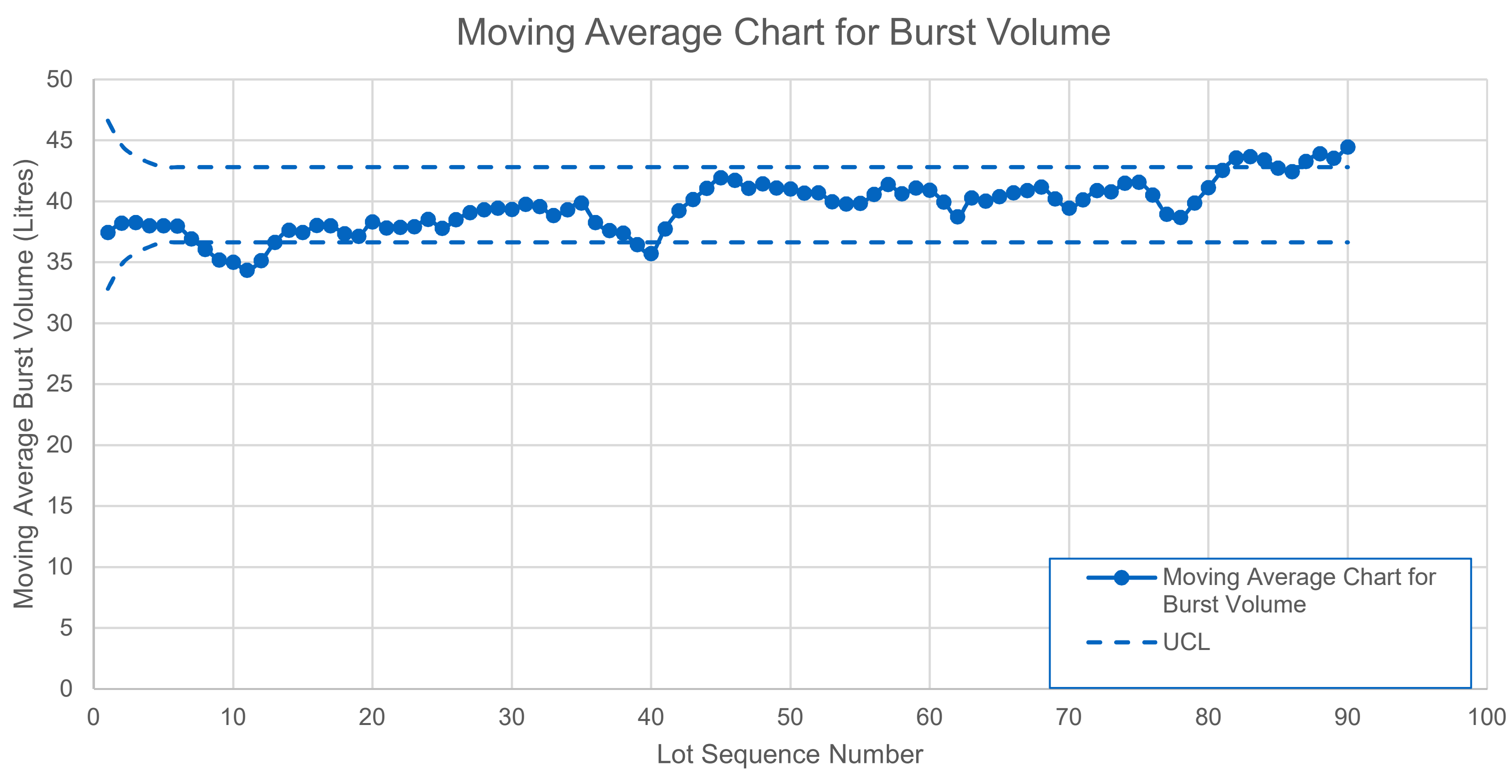
Setting Control Limits for EWMA Charts

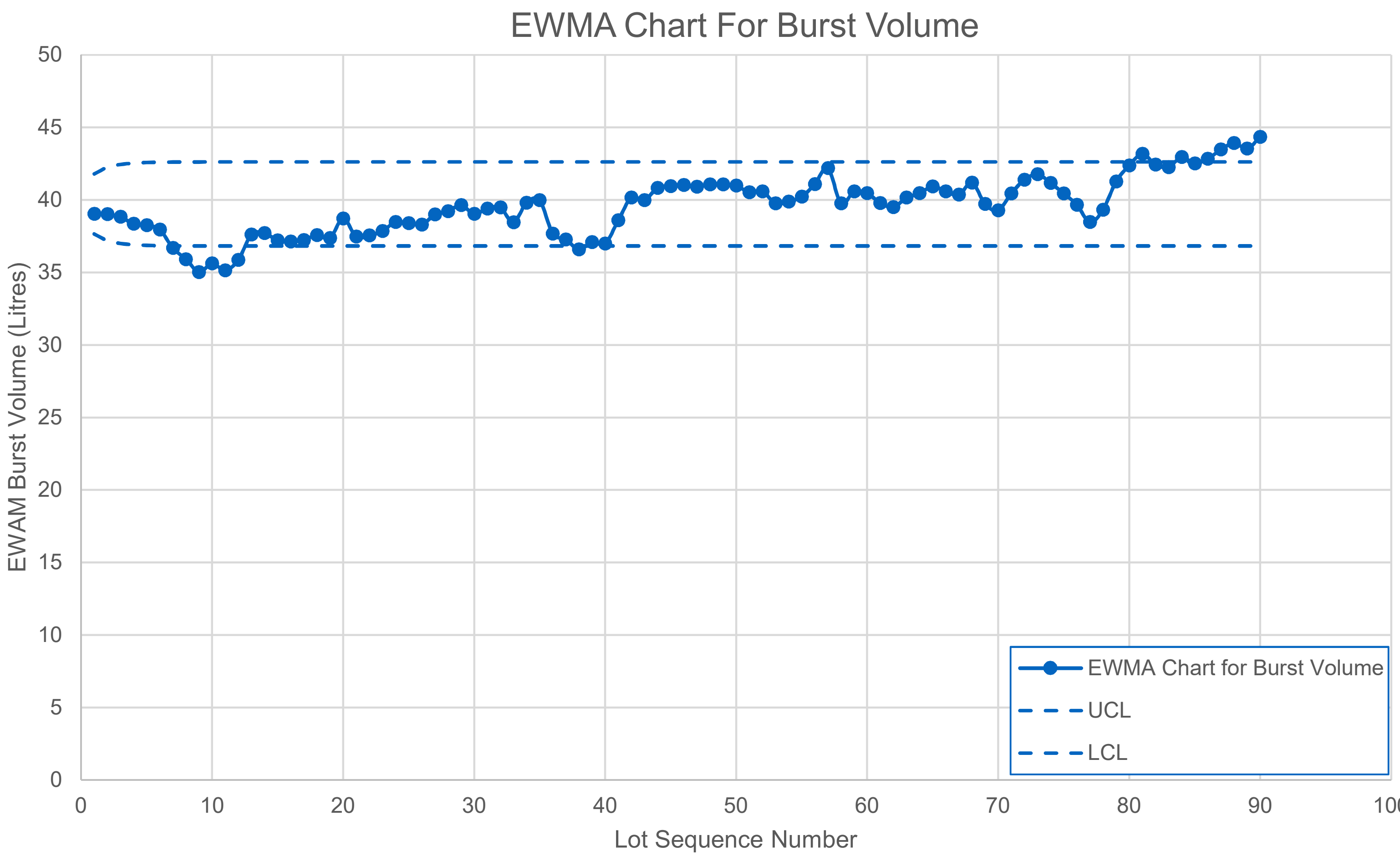
- UCL= EWMA(0) + 3 * $SE_{(EWMA)}$
- LCL = EWMA(0) - 3 * $SE_{(EWMA)}$
- $SE_{(EWMA)} = \mathrm{SE}\sqrt{\frac{\lambda}{2-\lambda}[1-(1-\lambda)^{2i}]}$
- For large i, $(1-\lambda)^{2i}$ tends to zero hence
- $SE_{(EWMA)} \approx \mathrm{SE}\sqrt{\frac{\lambda}{2-\lambda}}$



Shewhart Chart Average Burst Volume Per Lot
Average Burst Volume per Lot (L)
50.00
45.00
40.00
35.00
30.00
25.00
20.00
15.00
10.00
5.00
0.00
0
10
20
30
40
50
60
70
80
90
100
Lot Sequence Number
Series1
Upper Control Limit
Lower Control Limit


CUSUM Chart Burst Volume
10.00
0.00
-10.00
-20.00
-30.00
-40.00
-50.00
-60.00
-70.00
-80.00
-90.00
CUSUM Value (L)
0
10
20
30
40
50
60
70
80
90
100
Lot Sequence Number


Moving Average Chart for Burst Volume
Moving Average Burst Volume (Litres)
Lot Sequence Number
0
5
10
15
20
25
30
35
40
45
50
0
10
20
30
40
50
60
70
80
90
100
Moving Average Chart for Burst Volume
UCL

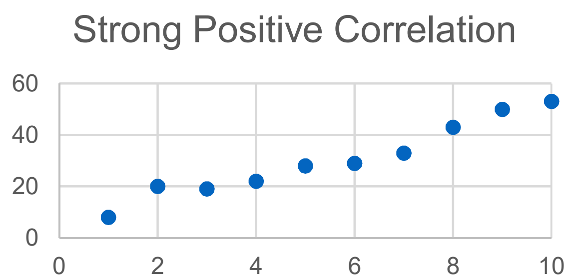

EWMA Chart For Burst Volume
EWAM Burst Volume (Litres)
0
5
10
15
20
25
30
35
40
45
50
0
10
20
30
40
50
60
70
80
90
100
Lot Sequence Number
EWMA Chart for Burst Volume
UCL
LCL

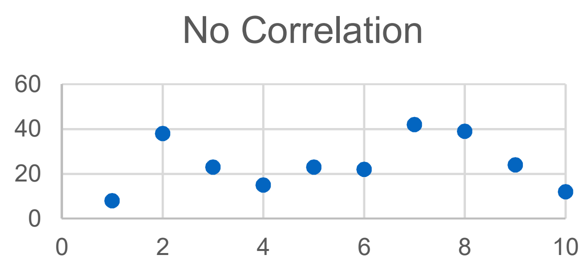
Charts for Reviewing and Analysing Results

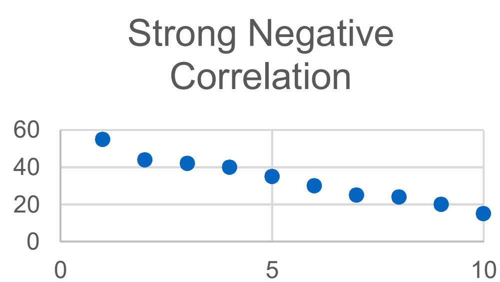
- Scatter Plots and Correlation – understanding relationships between properties and process/formulation variables
- Box and Whisker Plots, and histograms – distribution of results within datasets
- Bar Charts (including Pareto and Pie Charts) – comparing datasets

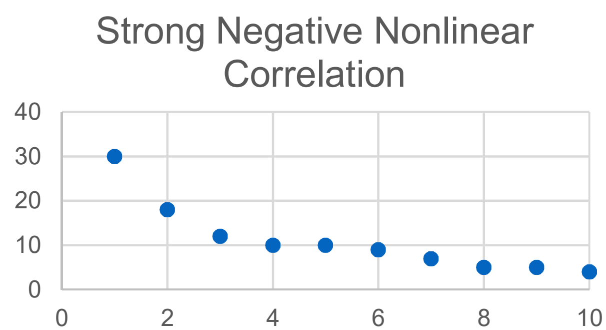
Scatter Plots

- Allow potential correlation between a dependent variable (e.g. burst volume) and an independent variable (e.g. condom thickness) to be examined
- Easy to plot in Excel and various statistical packages



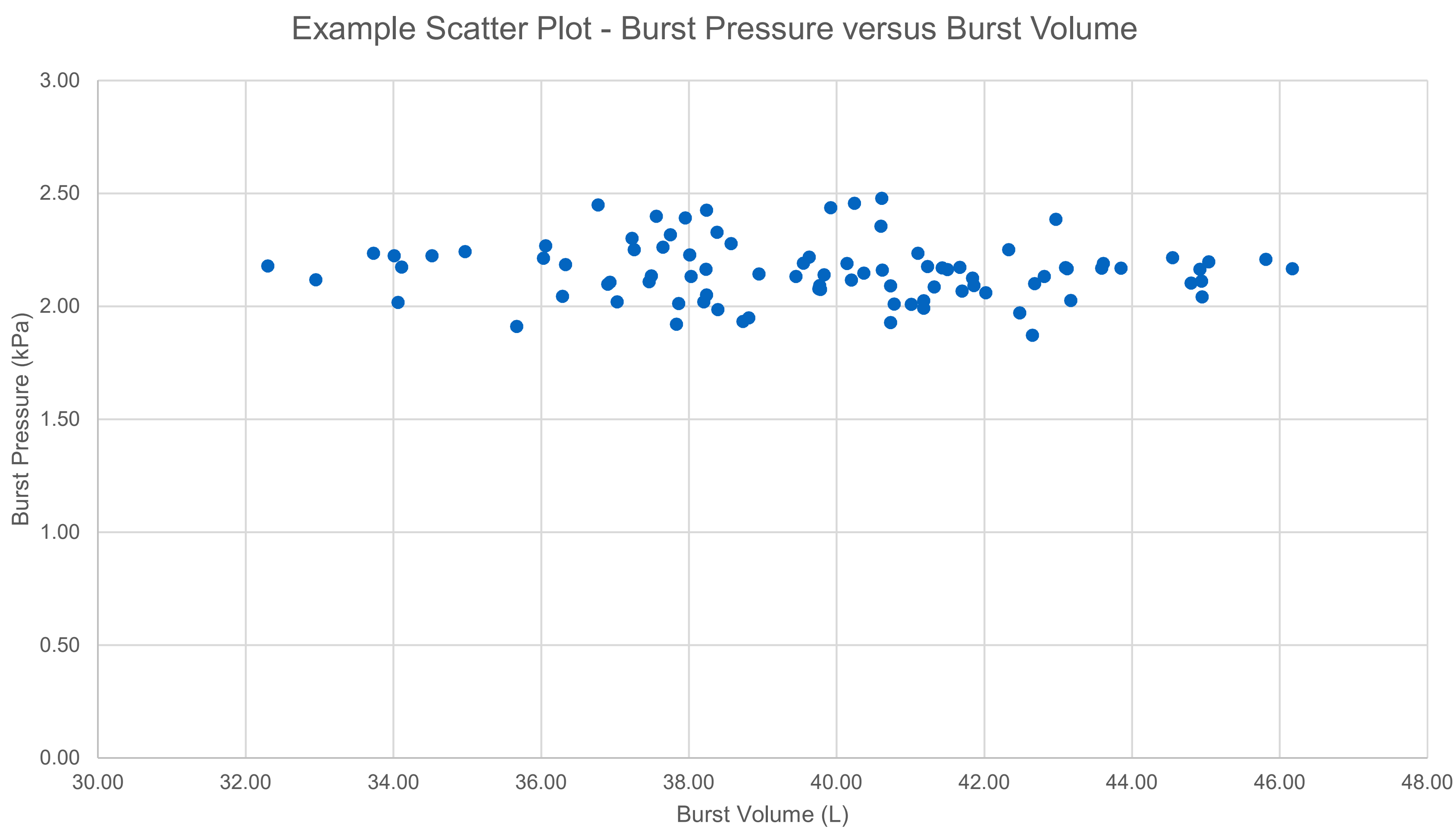


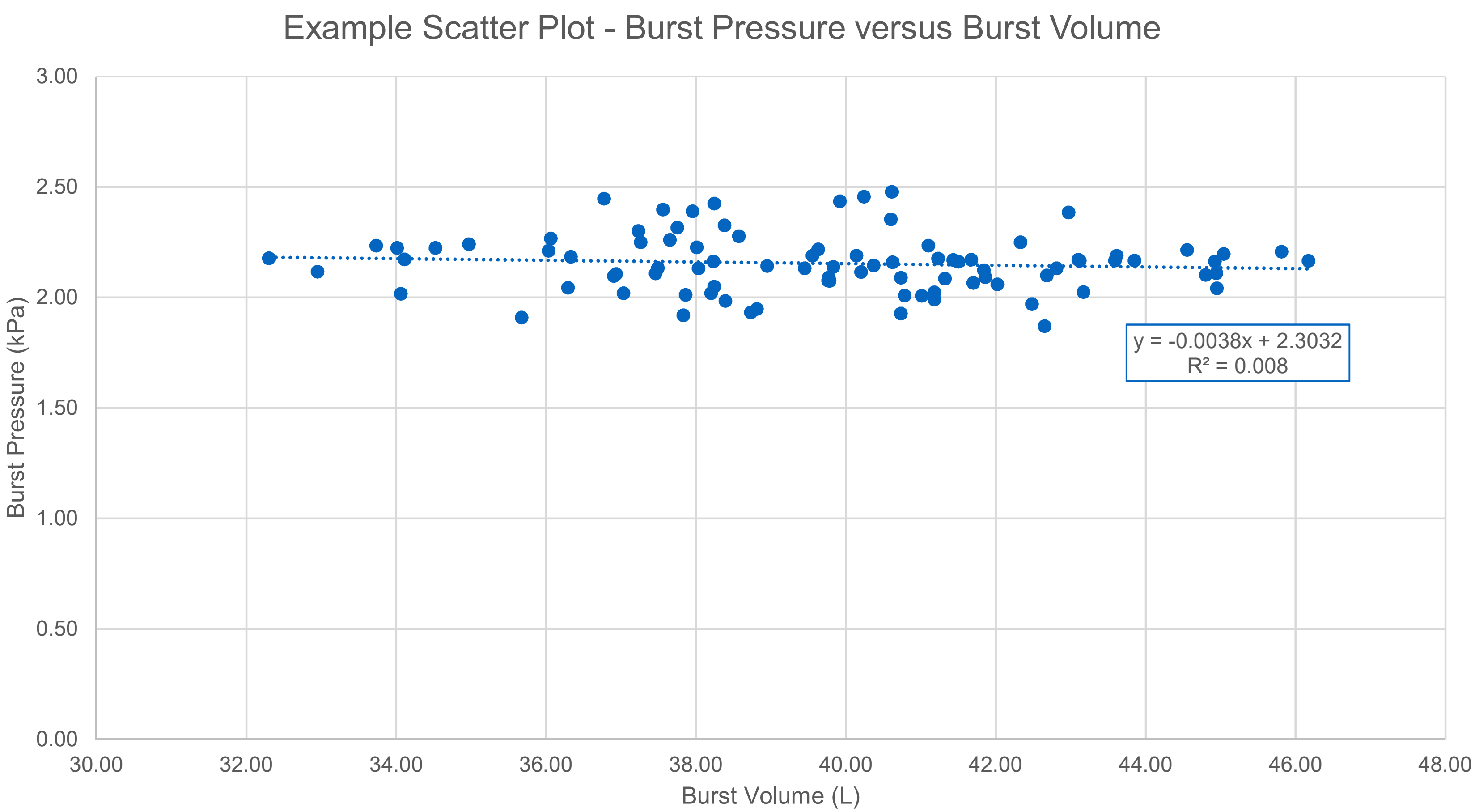


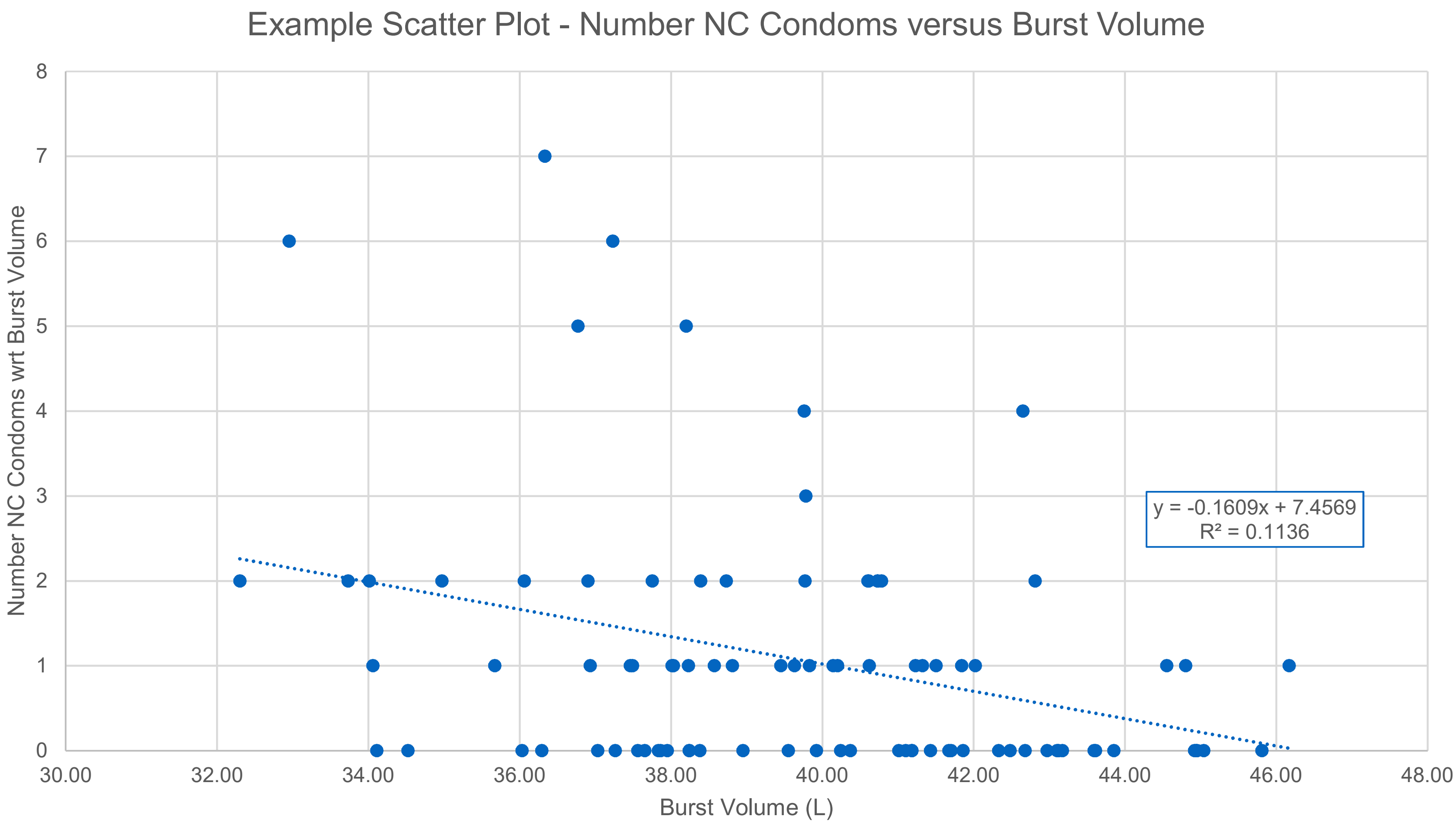


Linear Regression

- Fit the best straight line to the data using the method of least squares (y = ax + b)
  - Minimise the sum of the squares of the residuals (residual = actual Y value – calculated y)
- Procedures for linear regression available in most statistical software packages and Excel
- Parameters determined:
  - Slope of line (a)
  - Intercept with Y-axis (b)
  - Regression Coefficient R - value between -1 to +1
  - Coefficient of Determination R^2 – value between 0 and 1
- The above parameters can be used for extrapolation and interpolation
- Excel methods
  1. Add trendline to scatter plot and format to include equation, coefficient of determination and extrapolate to determine predicted values
  2. Use =SLOPE(known_y's, known_x's), =INTERCEPT(known_y's, known_x's) and =CORREL(array1, array2) functions in spreadsheet to calculate parameters
  3. Use the regression function in the Analysis ToolPak


Example Scatter Plot - Burst Pressure versus Burst Volume
Burst Pressure (kPa)
3.00
2.50
2.00
1.50
1.00
0.50
0.00
30.00
32.00
34.00
36.00
38.00
40.00
42.00
44.00
46.00
48.00
Burst Volume (L)


Example Scatter Plot - Burst Pressure versus Burst Volume
Burst Pressure (kPa)
3.00
2.50
2.00
1.50
1.00
0.50
0.00
30.00
32.00
34.00
36.00
38.00
40.00
42.00
44.00
46.00
48.00
Burst Volume (L)
y = -0.0038x + 2.3032
R² = 0.008


Example Scatter Plot - Number NC Condoms versus Burst Volume
Number NC Condoms wrt Burst Volume
Burst Volume (L)
8
7
6
5
4
3
2
1
0
30.00
32.00
34.00
36.00
38.00
40.00
42.00
44.00
46.00
48.00
y = -0.1609x + 7.4569
R² = 0.1136

Nonlinear Correlation

- Fit a curve to nonlinear data
- Limited number of equations available in Excel for nonlinear regression plots using the “add trendline” option
- Statistical packages use iterative methods to minimise the sum of squares of the residuals for specific equations (pre-specified or user inputted) to determine best fit parameters
- Examples:

  Degradation processes can often be modelled by an exponential decay function:

  $P_t = P_0 e^{-kt}$

  Burst pressures versus time at a storage temperatures of 70 °C can often be modelled using an equation of the form:

  $\boldsymbol{P_t = (P_0 - P_\infty)e^{-kt} + P_\infty}$

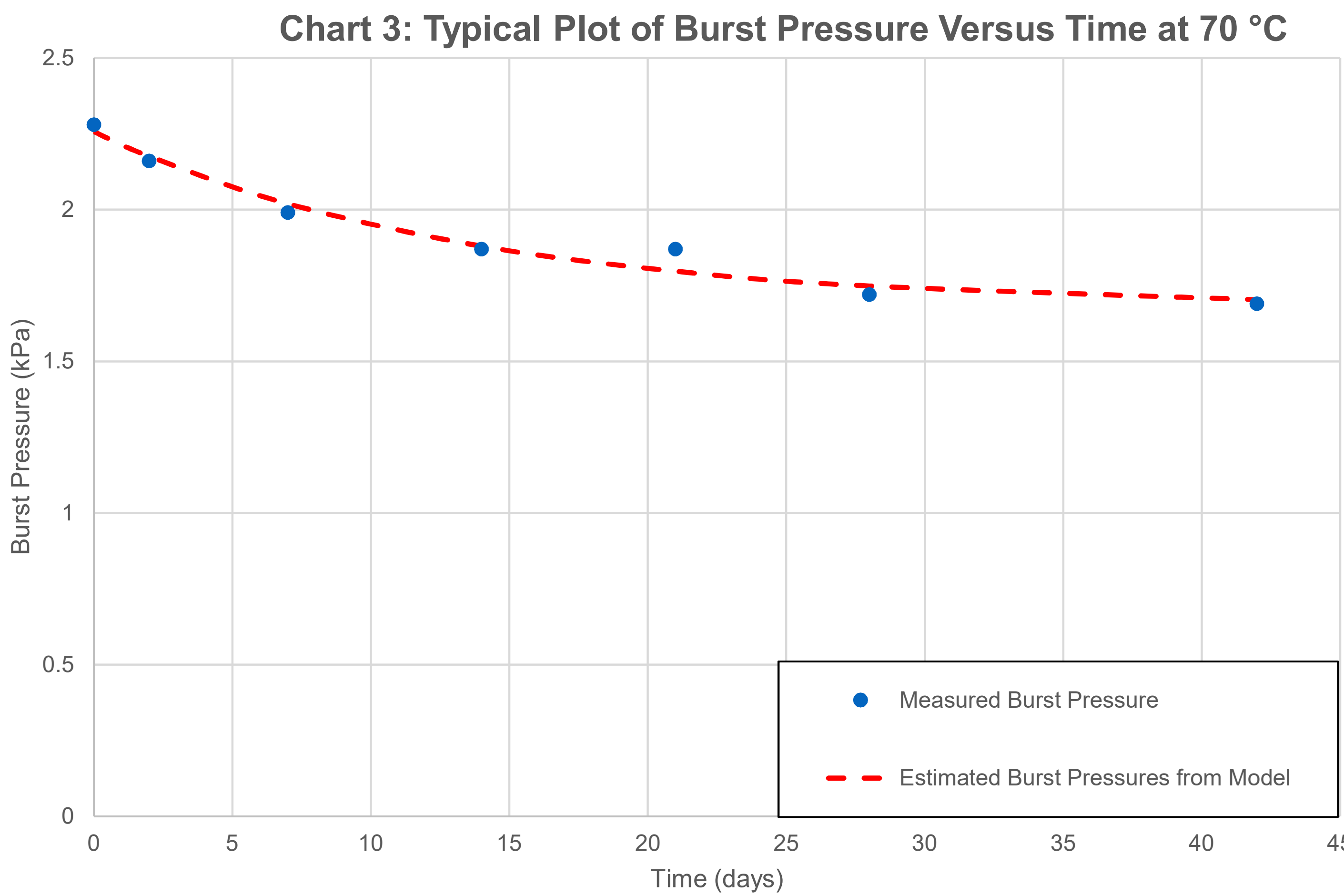


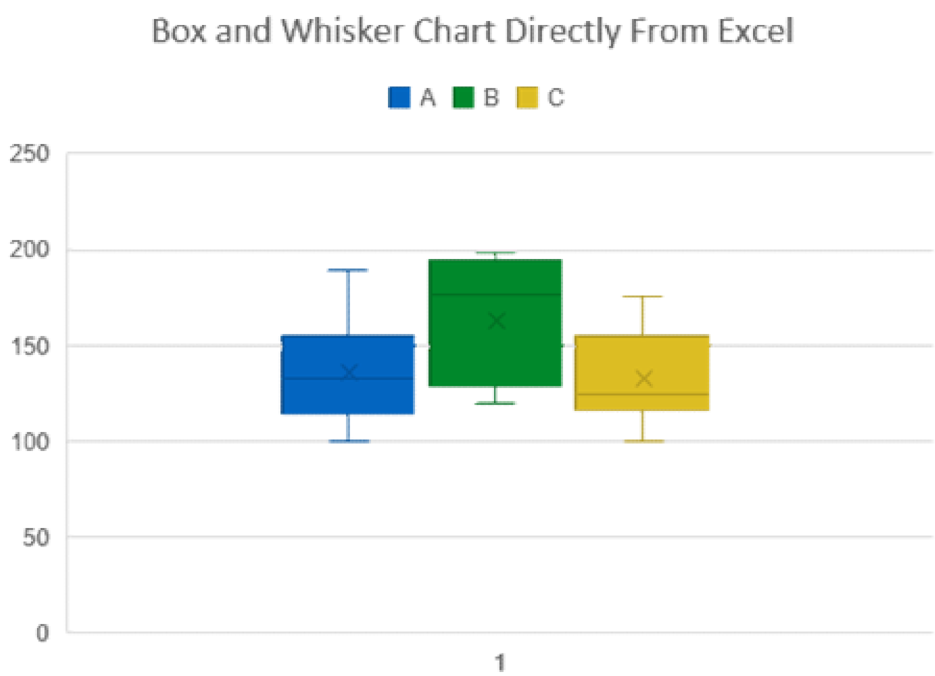
Chart 3: Typical Plot of Burst Pressure Versus Time at 70 °C
Burst Pressure (kPa)
2.5
2
1.5
1
0.5
0
0
5
10
15
20
25
30
35
40
45
Time (days)
Measured Burst Pressure
Estimated Burst Pressures from Model

Box and Whisker Plots

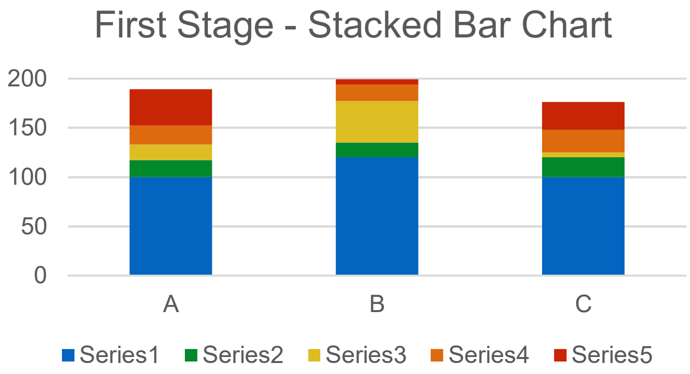
- Box and whisker plots are a graphical way of displaying datasets to show their distribution
- The plots are based on quartiles and upper and lower values; not dependent on specific distributions such as the assumption of normality
- Five values are used to construct a box and whisker plot
  - Lowest value in the dataset: lower whisker
  - First or lower quartile (median of the lower half of the dataset): bottom of the box
  - Median or second quartile (middle value of the dataset): line in the box
  - Upper or third quartile (median value of the upper half of the dataset): top of the box
  - Maximum value in the dataset: upper or top whisker
- Box and whisker plots can be generated directly in newer versions of Excel or manually in older versions or by using statistical software packages

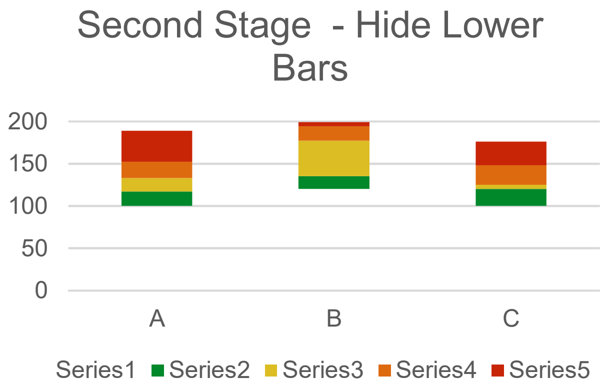
Example Box and Whisker Plot from Excel

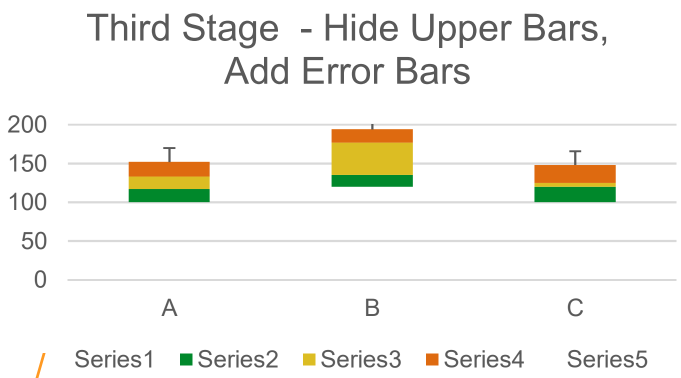
A	B	C
133	195	132
117	199	100
189	177	170
152	194	125
157	123	120
119	120	121
118	135	148
100	194	162
136	120	136
112	135	113
149	185	121
110	183	107
172	156	176

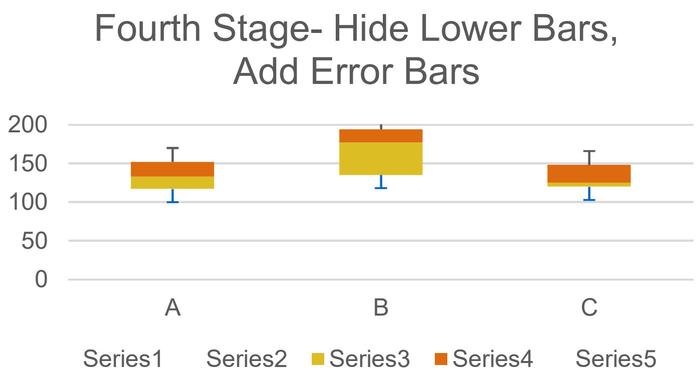


Steps to Construct Box and Whisker Charts in Older Versions of Excel







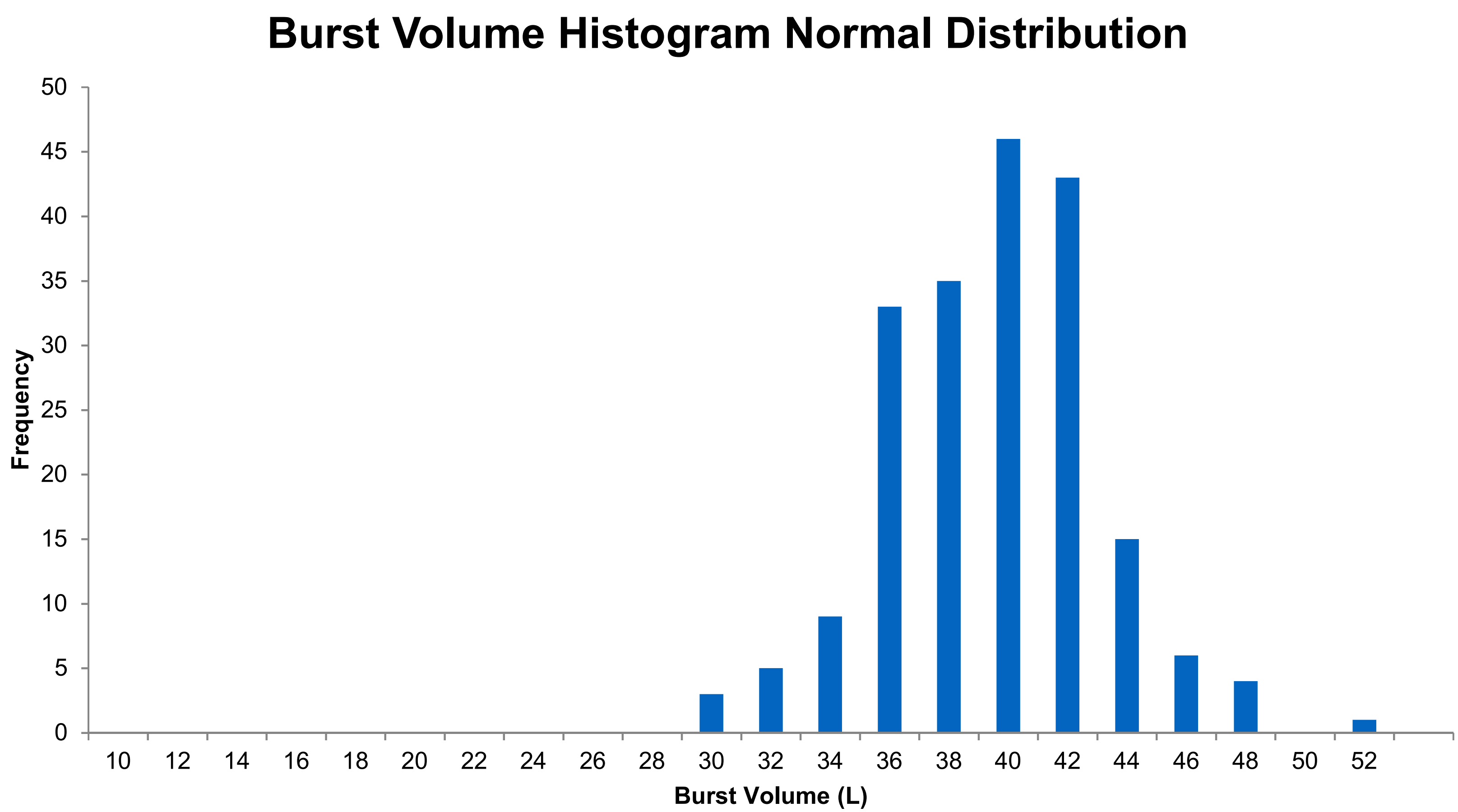


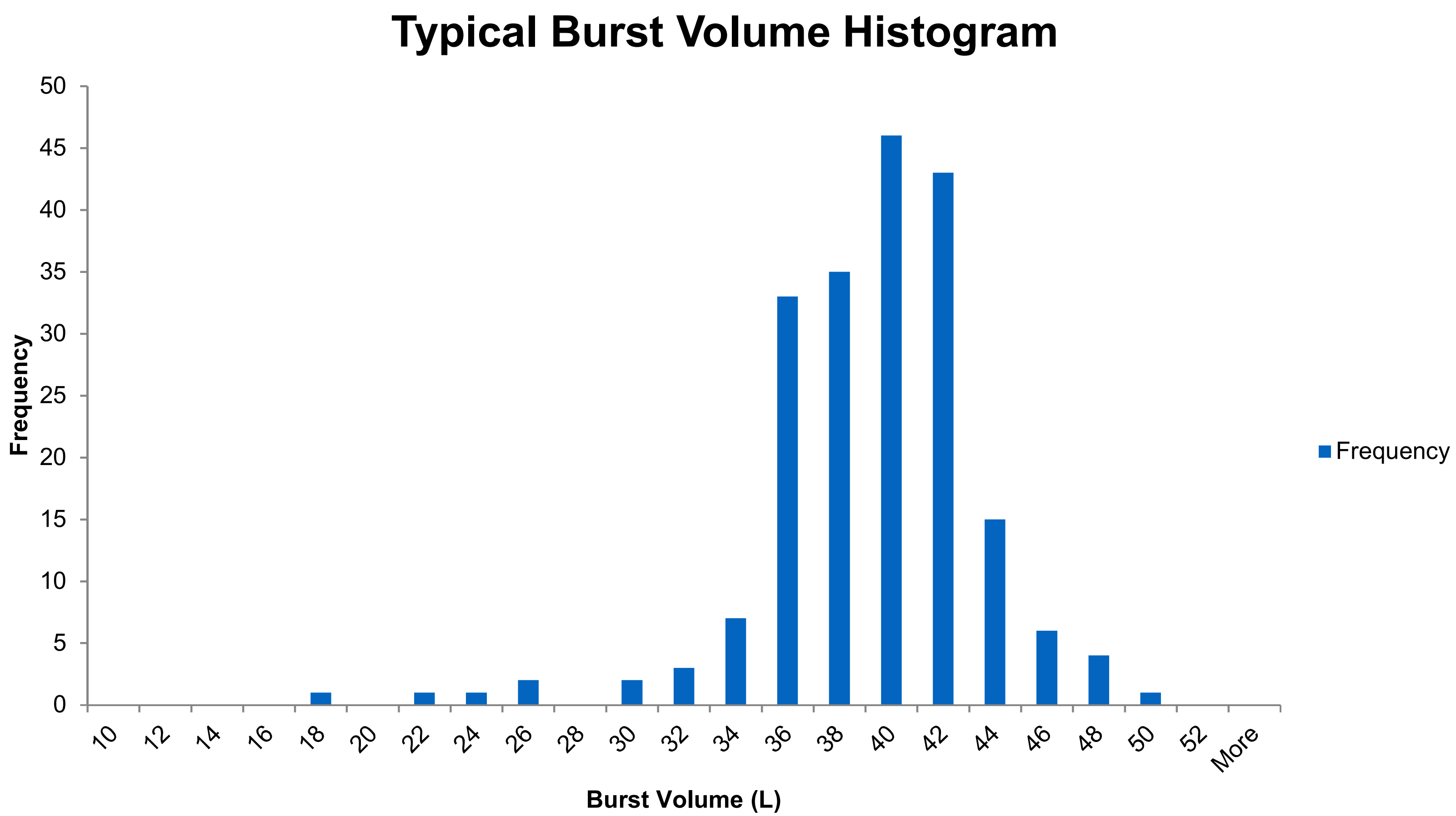
Histograms

- Used to visualise and compare distributions within datasets
- Extremely useful for reviewing distributions of burst data
- Burst tester software generally allows histograms to be printed out directly
- Procedure to generate a histogram
    - Select bin size for burst volumes and pressures
    - Sort data into bins by frequency
    - Plot histograms by frequency verses bin identity
- Histogram procedures available in statistical software will automatically sort and plot data
- Excel has fully automatic function for plotting histograms in the Analysis ToolPak add in

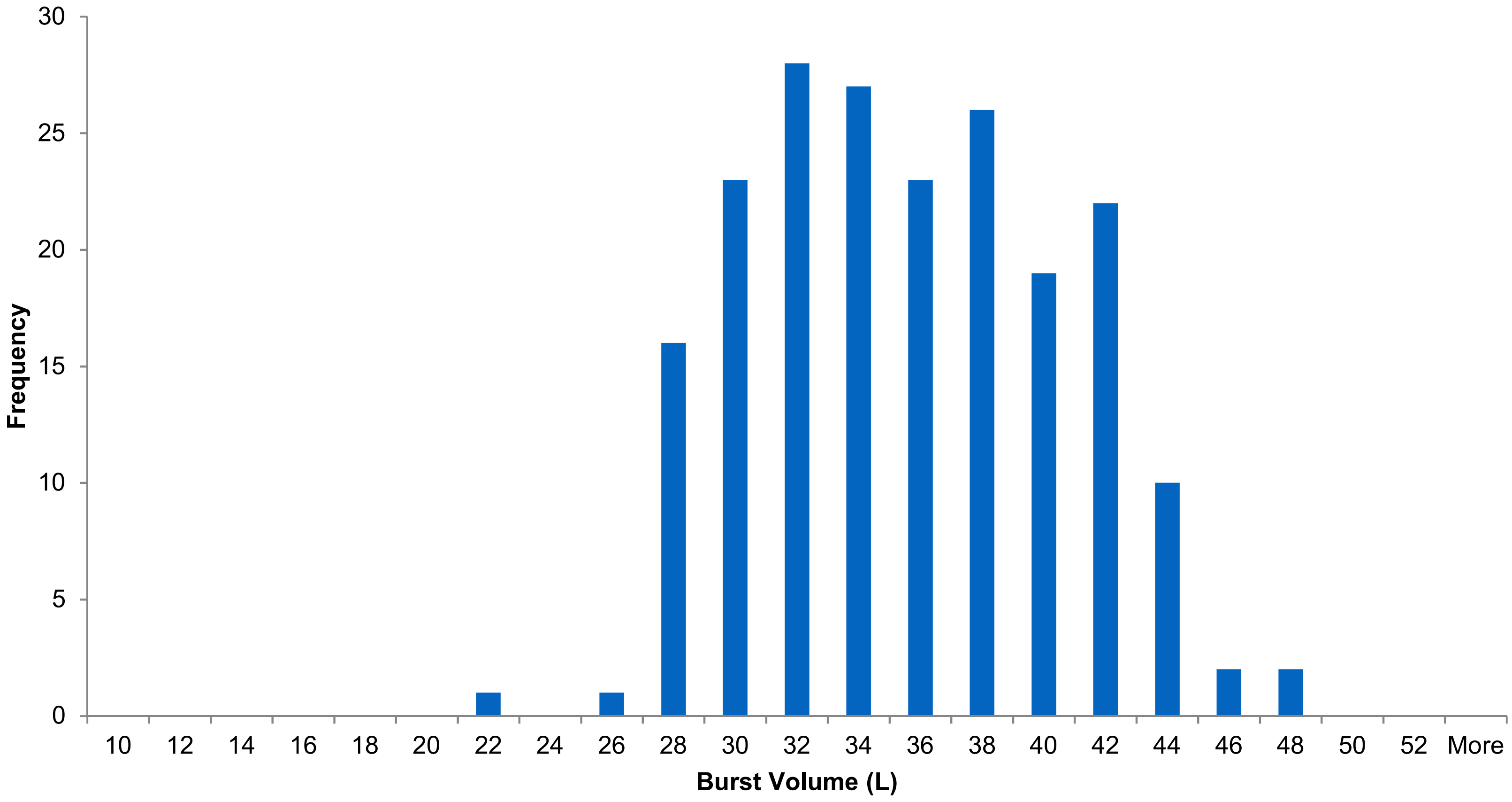
Example Burst Volume Data

Sample Number	Burst Voume (L)		Bin Limits (L)	Frequency
1	28.38		10	0
2	39.14		12	0
3	35.67		14	0
4	41.55		16	0
5	39.33		18	0
6	38.43		20	1
7	37.30		22	4
8	42.86		24	4
9	41.73		26	14
10	40.84		28	23
11	35.43		30	30
12	42.24		32	22
13	40.48		34	7
14	38.71		36	16
15	36.87		38	19
16	31.26		40	27
17	34.10		42	20
18	37.43		44	7
19	35.06		46	2
20	35.32		48	3
21	46.29		50	0
22	38.14		52	1
23	34.61			

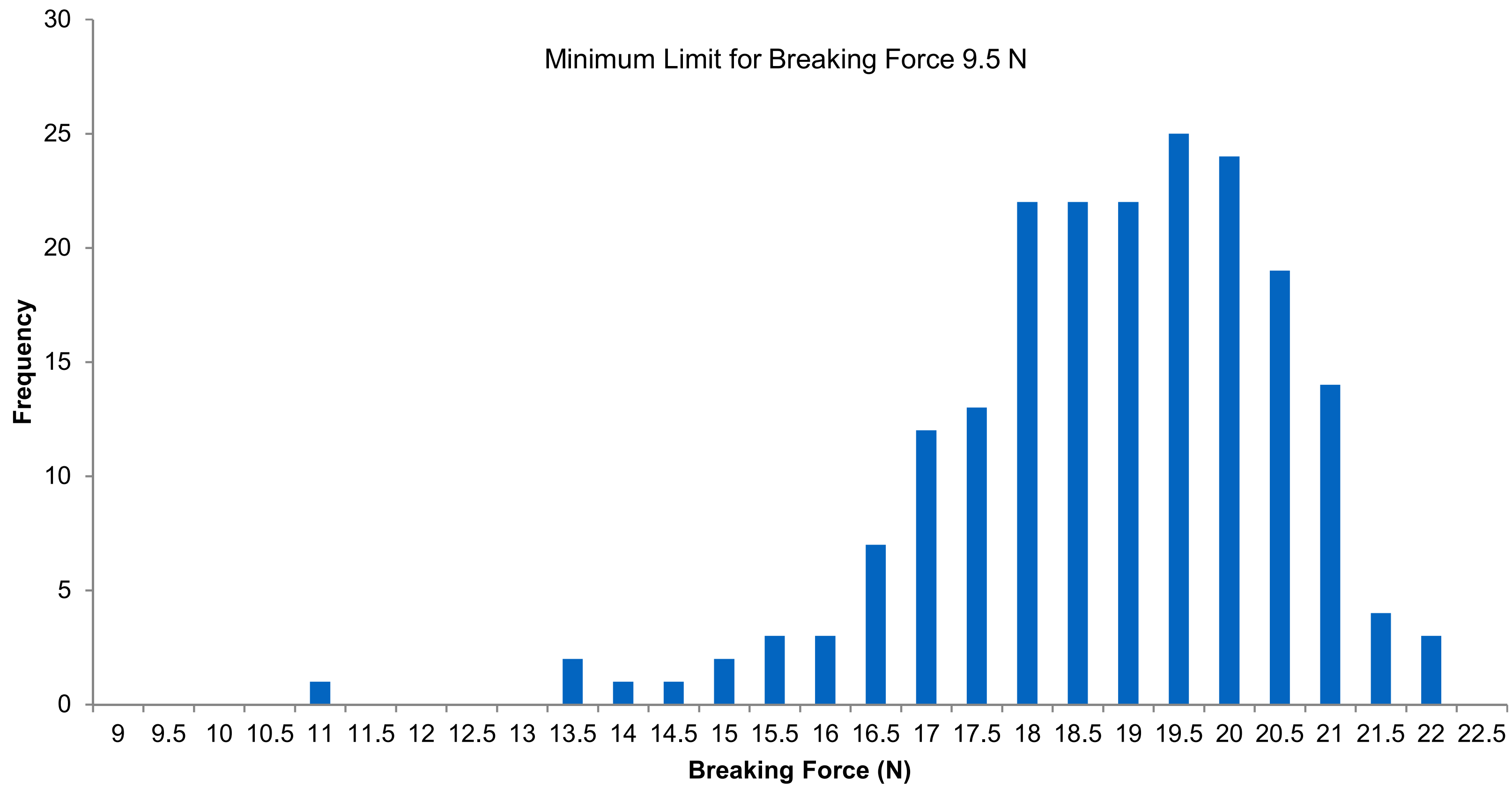

Burst Volume Histogram Normal Distribution
Frequency
50
45
40
35
30
25
20
15
10
5
0
10 12 14 16 18 20 22 24 26 28 30 32 34 36 38 40 42 44 46 48 50 52
Burst Volume (L)


Typical Burst Volume Histogram
Frequency
50
45
40
35
30
25
20
15
10
5
0
10
12
14
16
18
20
22
24
26
28
30
32
34
36
38
40
42
44
46
48
50
52
More
Burst Volume (L)
Frequency

Example Bimodal Burst Volume Histogram



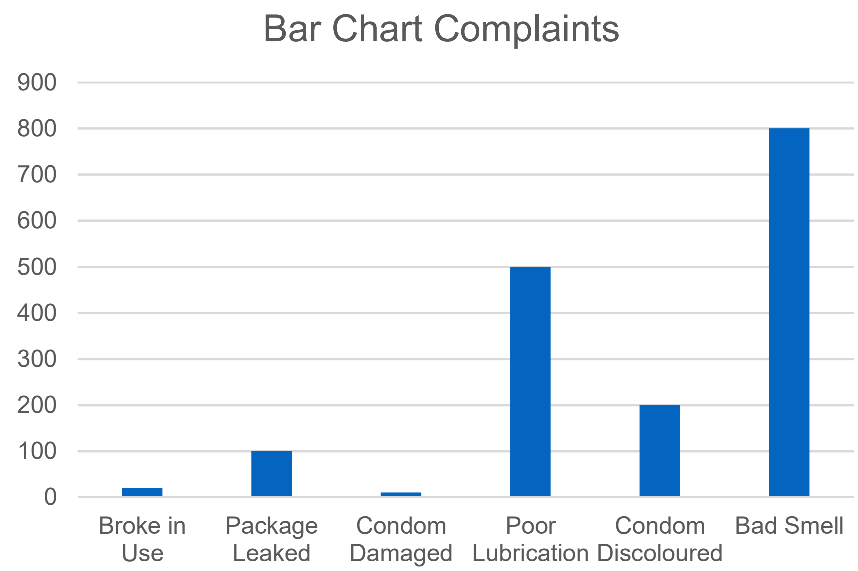
Histogram of IUD Breaking Force



Bar Charts

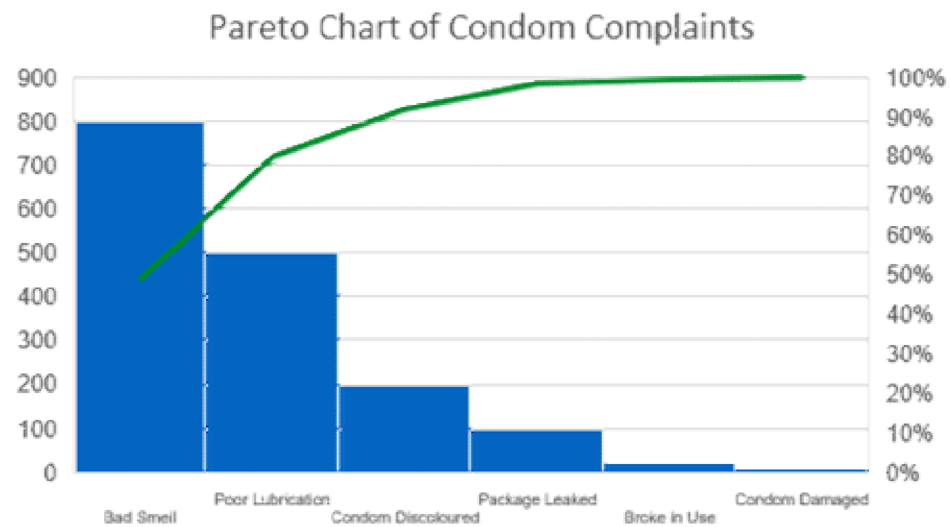
- Used to compare differences between data for different samples, lots, etc
- Example condom complaints:

Condom Complaint Type	Number of Complaints
Broke in Use	20
Package Leaked	100
Condom Damaged	10
Poor Lubrication	500
Condom Discoloured	200
Bad Smell	800



Pareto Charts

- Named after the Pareto principle (80/20 rule) first observed by Italian economist Vilfredo Pareto in 1895
- Pareto chart contains both bars and a line graph
- Individual values are represented in descending order by bars
- Cumulative total is represented by the line graph



Pie Charts


Pie Chart of Condom Complaints
20
100
10
500
200
800
Broke in Use
Package Leaked
Condom Damaged
Poor Lubrication
Condom Discoloured
Bad Smell

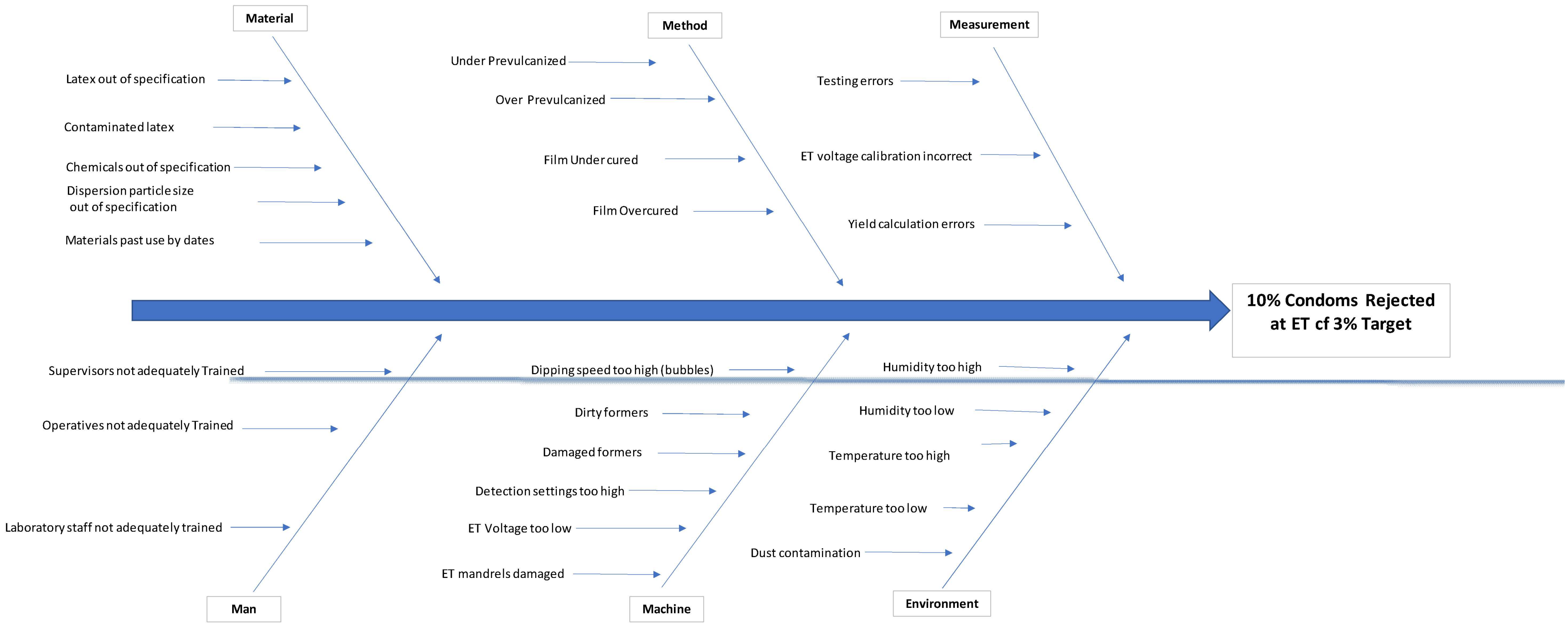
Charts for Trouble Shooting and process management

- Fishbone chart
- Flow charts

Fishbone (Ishikawa) Diagram

- Used, for example, in cause and effect analysis to assist in identifying root causes of problems
- Help capture potential reasons for quality issues
- Assist in presentation and discussion of quality issues
- Popularised in the 1960s by Kaoru Ishikawa (Kawasaki Shipyards)
- Used by Mazda in the development of the MX5 sports car
- Templates available to assist in preparing the diagrams, often using prespecified headings (e.g. for manufacturing – 5Ms (Man, Machine, Material, Method, Measurement)
- When used for brain storming meetings best done on a white/black board

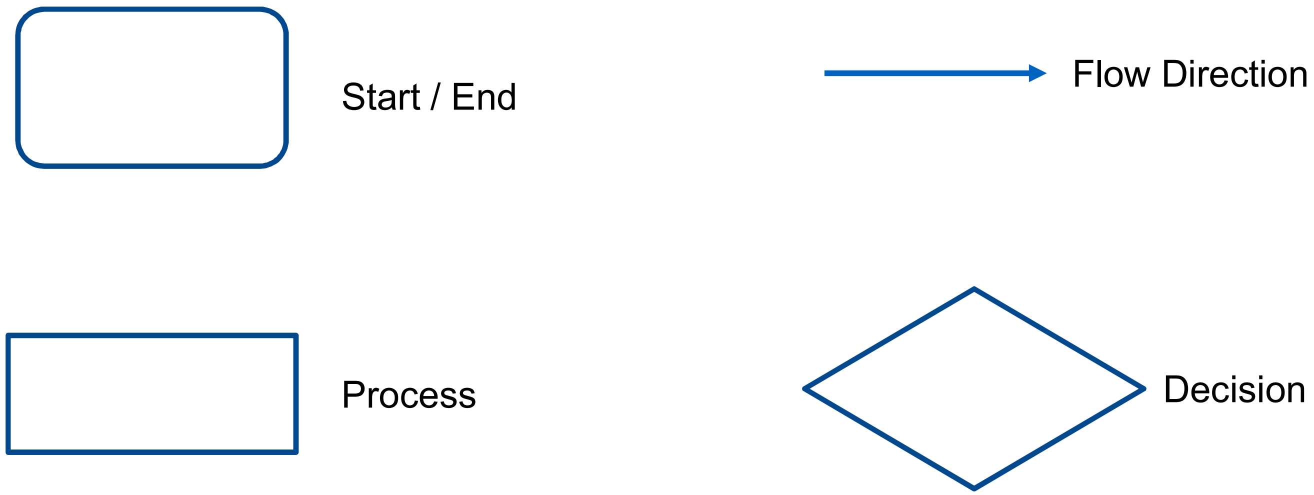
Example of a Fishbone Chart



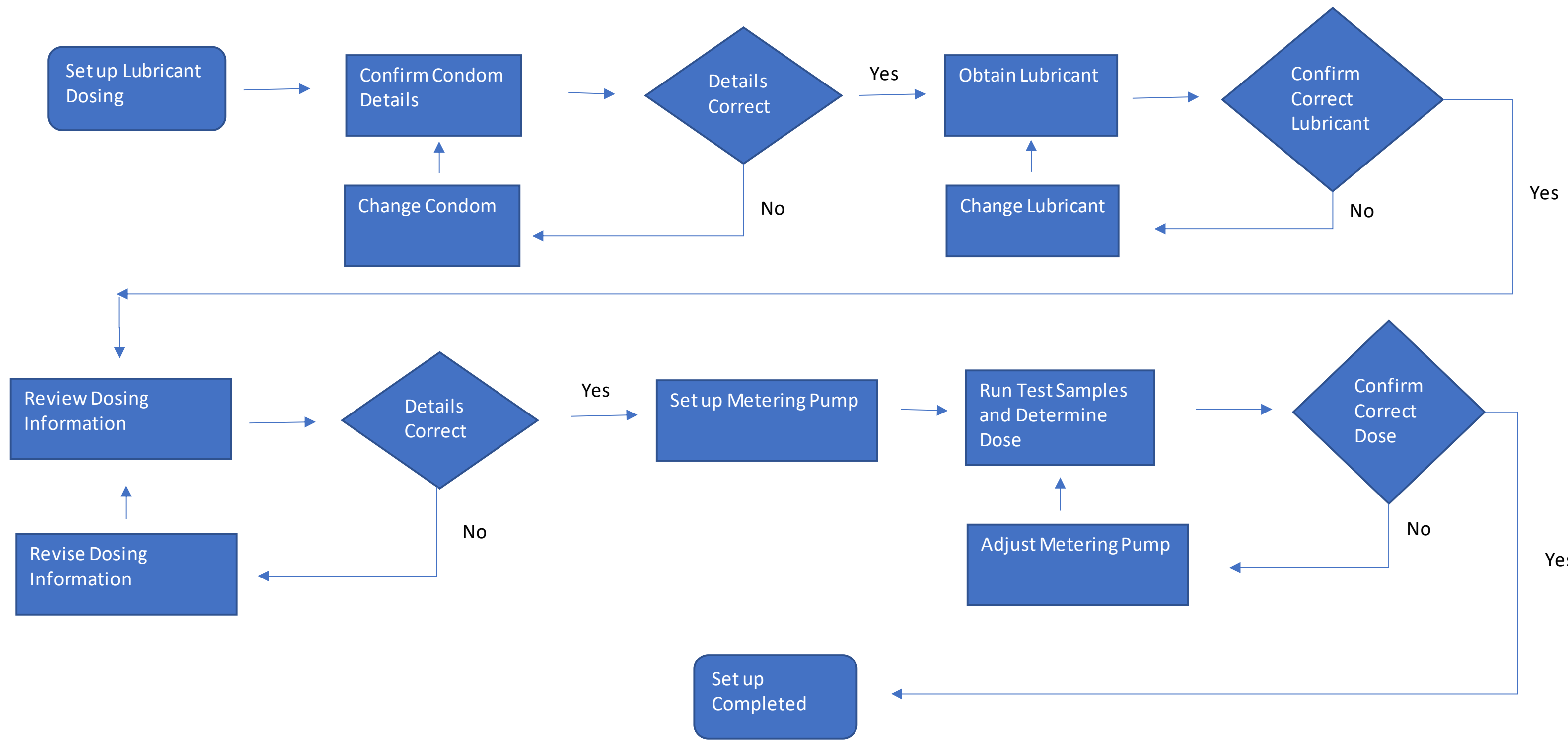
Flow Charts

- Many different types of flowcharts
  - Manufacturing process flow charts
  - Management procedures flow charts
  - Materials flow charts
  - Program flow charts
  - The flow chart for switching rules in Figure 1 of ISO 2859-1:1999
  - Document flow charts
- ISO standard ISO 5807:1985, Information processing — Documentation symbols and conventions for data, program and system flowcharts, program network charts and system resources charts
  - Defines symbols to be used in information processing documentation and gives guidance on conventions tor their use in data flowcharts, program flowcharts, system flowcharts, program network charts, system resources charts
  - Convention for symbols
  - Different layout styles

Symbol Convention



Simple Example of a Flow Chart



Conclusions

There are many types of charts that can be used to visualise and help understand results, data and processes

- Shewhart Charts for routine monitoring of quality and properties
- CUSUM and EWMA charts for detecting small shifts in quality and trouble shooting quality problems
- Scatter plots and regression analysis to understand relationships between product properties and formulation/process variables
- Histograms and Box and Whisker plots for displaying and investigating data distributions
- Bar, Pareto and pie charts for understanding and presenting information on product quality issues, complaints and adverse events, etc
- Fishbone charts to assist cause effect analysis
- Flow charts for representing processes, procedures and decision making

Questions and discussions

Thank you for your attention