WHO/UNFPA PQ Programme

Webinar: Control Charts 2

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Summary of First Webinar – Topics Covered

- Use of basic statistics
- Charts and trend analysis
    - Introduction to Shewhart Charts
    - Determining Stanard Deviation
- Process Capability Assessment
- Discussion and questions

Scope of Second Webinar

- Shewhart Chart refresher
- Construction of CUSUM Chart
  - Preparation of data
  - Plotting the Chart
  - Scaling the Chart
  - Identifying statistically significant trends: V-Masks
- Tabular CUSUMS
- Questions and discussion

Shewhart Chart Refresher - Variables

Plot key values for each lot against a reference

- For example average burst volume against lot sequence number

Add action limits

- Mean ± 3 x standard error of the mean

Add warning limits if require

- Mean ± 2 x standard error of the mean

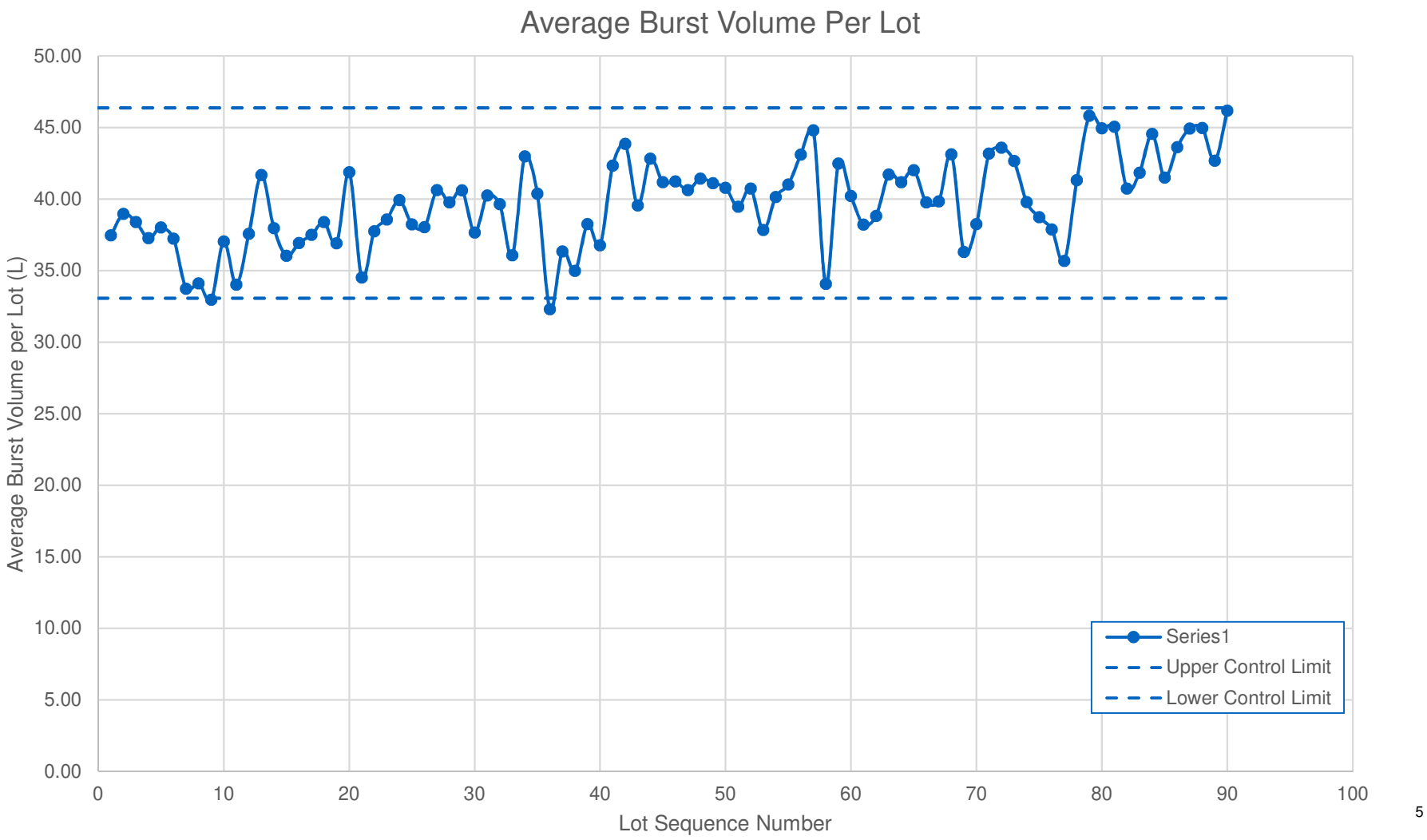
Calculation of standard error of the mean(SE)

Between sample differences are small

- Use an estimate of the within lot standard deviation (SD) and calculate standard error using $SE = SD\sqrt{N}$ where N is the sample size per lot

Between sample differences are significant

- Use the standard Deviation for a sequence of lot means when the process is considered under acceptable control


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

Shewhart Chart - Attributes

Number of plotting options

- Np chart – number of nonconforming units in sample
- P chart – proportion (p) of nonconforming units in sample
- C chart - total number of nonconformities in sample
- U chart – total number of nonconformities

Plot key values for each lot against a reference

- For example plot the number nonconforming condoms w.r.t. burst volume against lot sequence number

Add action limits

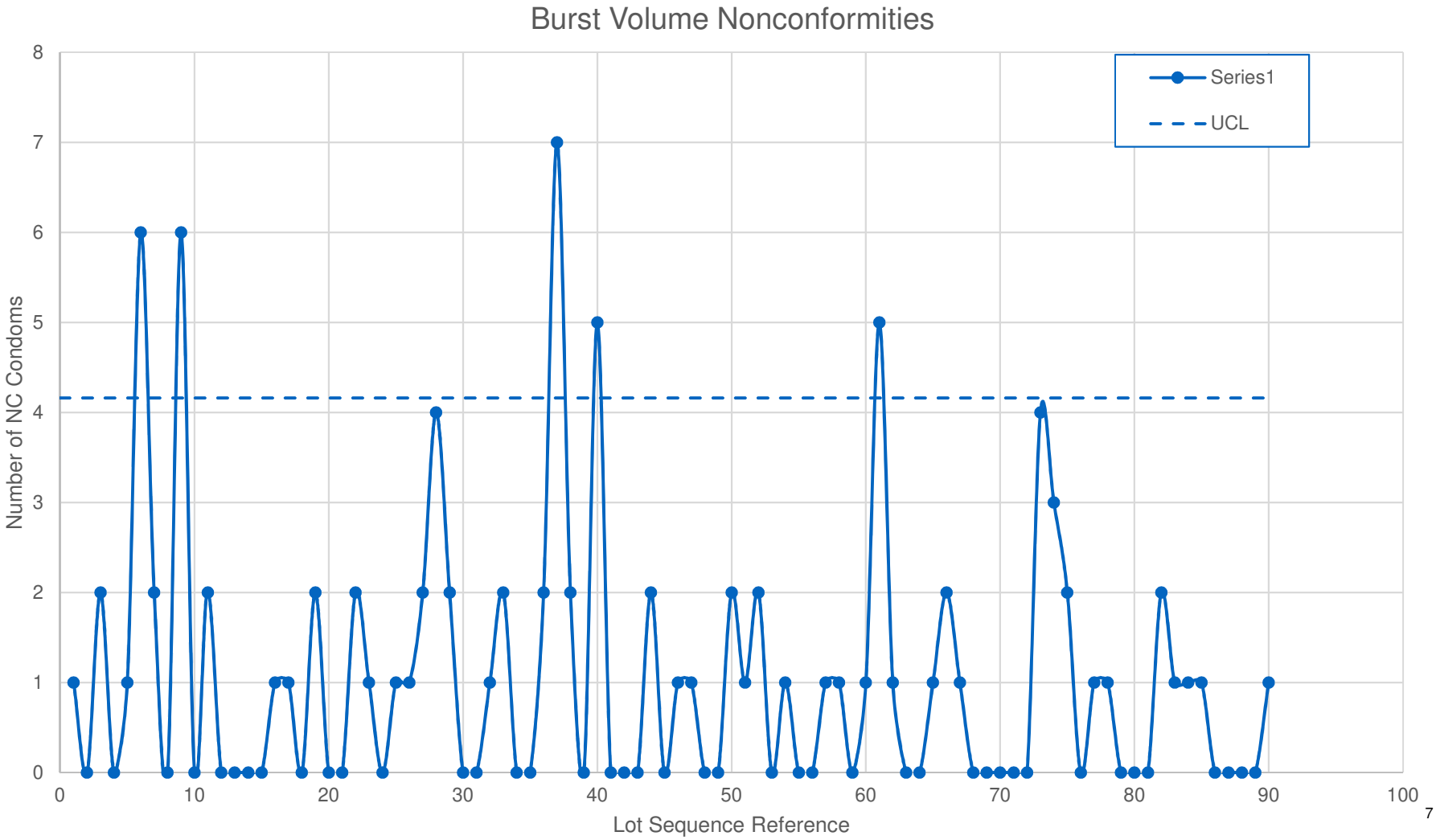
- Mean ± 3 x standard error of the mean

Add warning limits if required

- Mean ± 2 x standard error of the mean

Calculation of standard error of the mean(SE)

- P-chart SE =$\sqrt{(p(1-p)/N)}$ where p is fractional rate
- Np-chart SE = $\sqrt{(Np(1-p))}$ where Np is number of NCs
- C-chart SE = $\sqrt{(c)}$ where c is the number NCs per sample


Burst Volume Nonconformities
Series1
UCL
Number of NC Condoms
Lot Sequence Reference
0
1
2
3
4
5
6
7
8
0
10
20
30
40
50
60
70
80
90
100

Shewhart versus CUSUM Charts

- Shewhart charts are simple to design and plot, easy to understand and indicate when significant shifts in product quality occur
- Shewhart charts are not very good at flagging up small shifts in quality or when those shifts actually occur
- CUSUM charts are still relatively simple to plot, but are a lot more difficult to interpret but provide a lot more information about when changes occur
- Changes in quality are indicated by a change in the slope of the curve
- CUSUM charts can detect relatively small changes in quality and pinpoint when those changes occur, often to a specific lot
- Can be used to monitor the same properties as Shewhart charts, both variables and attributes
- **Reference: ISO 7870-4: 2011 Control charts — Part 4: Cumulative sum charts**

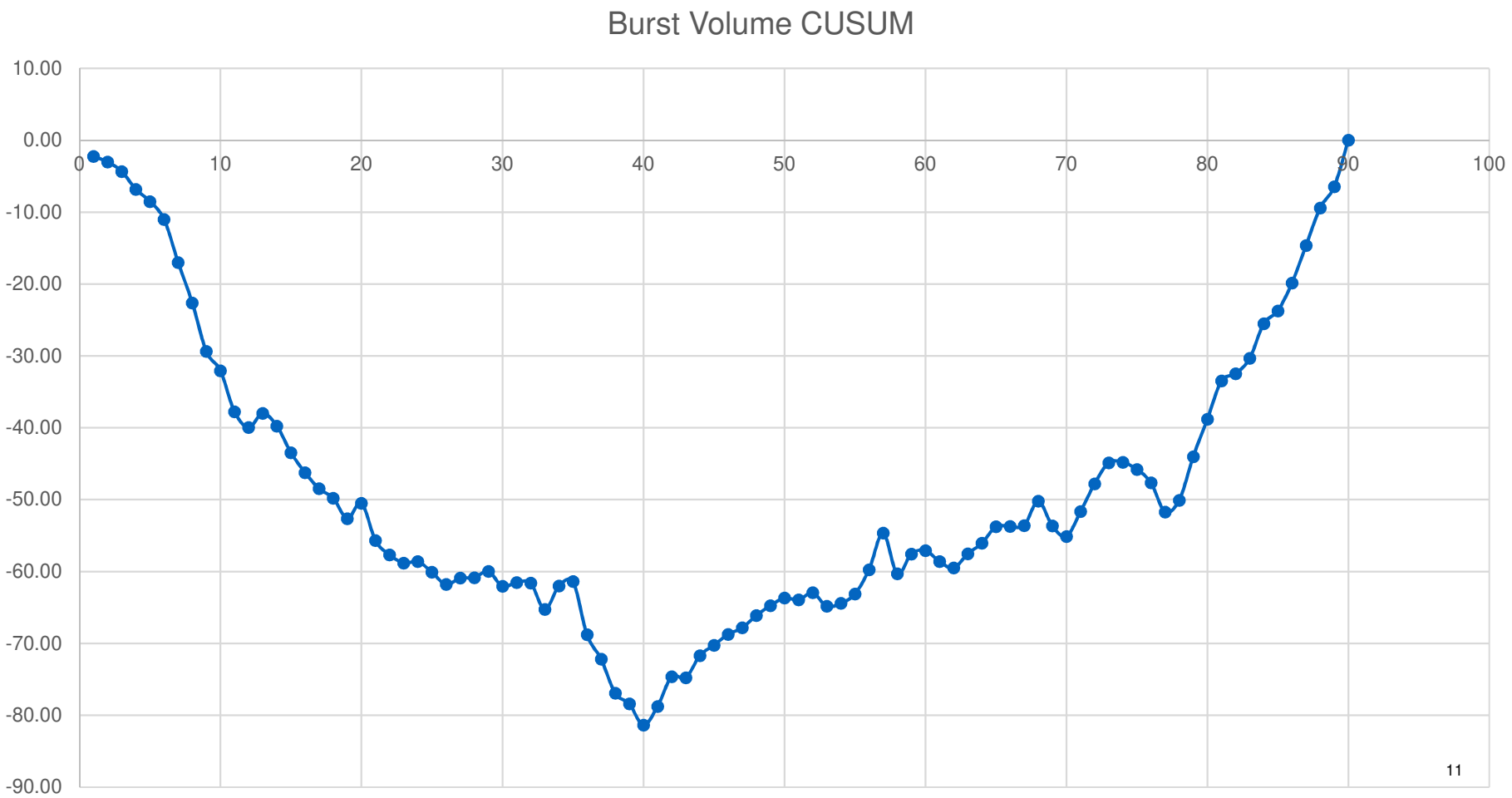
CUSUM Charts

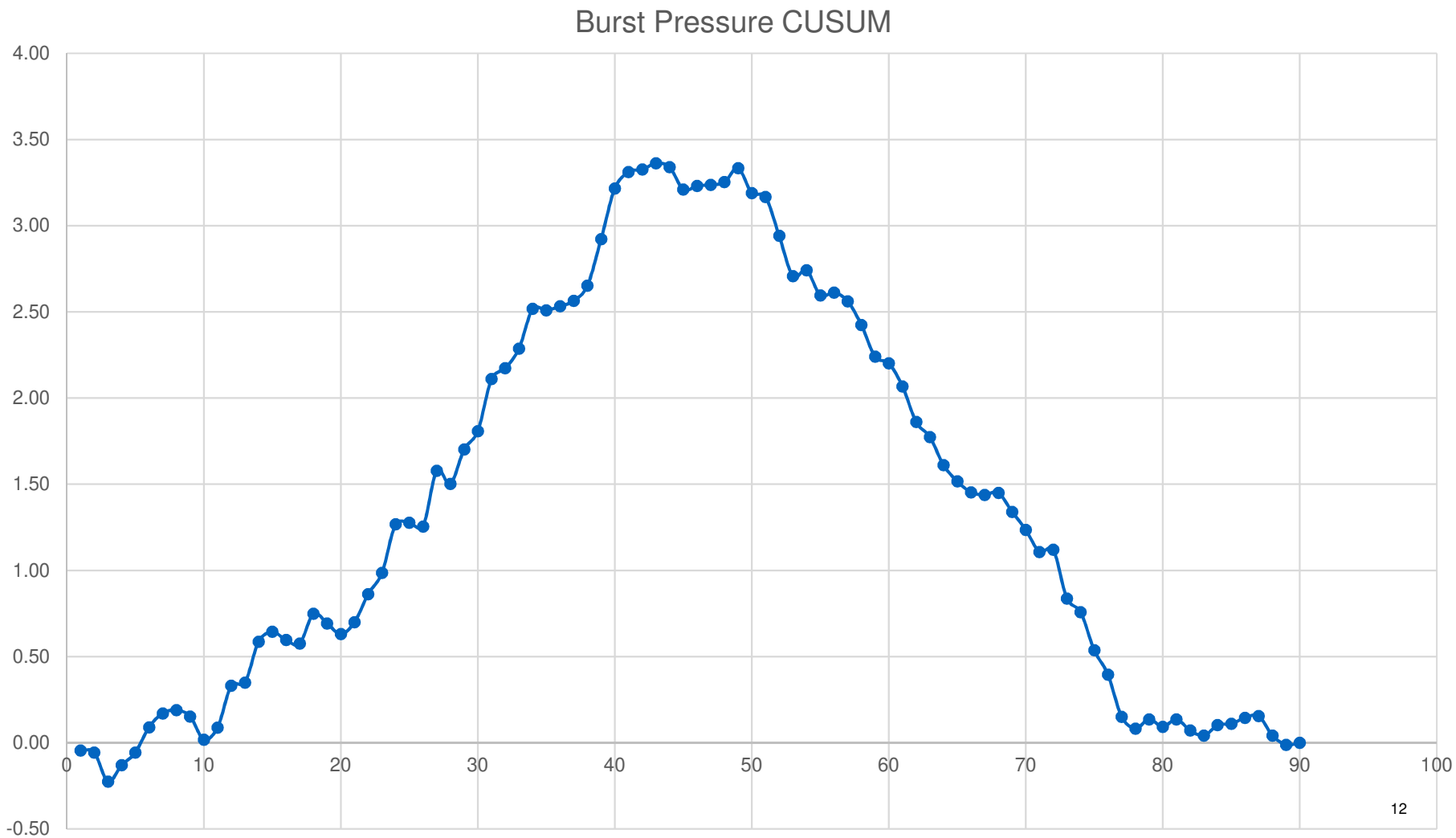
- CUSUM stands for Cumulative Sum
- Plot the sum of the differences between the measured value and a specified target or reference value
- CUSUM for sample i, is given by

$$CUSUM(i) = Value\ (i) - Target\ Value + CUSUM(i-1)$$

- Key steps in setting up a CUSUM chart for variables:
  - Step 1: Select the target or reference value
  - Step 2: Tabulate the results against the appropriate sequential reference value
  - Step 3: Subtract the target value from each value
  - Step 4: Progressively sum the differences
  - Step 5: Plot the CUSUM values against the reference values

Burst Properties			Lot Sequence Number	Target (Mean)	Vol - Target	CUSUM
Tested	Average Volume	Nonconforming				
						0
315	37.46	1	1	39.72	-2.26	-2.26
315	38.95	0	2	39.72	-0.77	-3.03
315	38.39	2	3	39.72	-1.33	-4.36
315	37.26	0	4	39.72	-2.46	-6.82
315	38.01	1	5	39.72	-1.71	-8.53
315	37.23	6	6	39.72	-2.49	-11.02
315	33.73	2	7	39.72	-5.99	-17.01
315	34.11	0	8	39.72	-5.61	-22.62
315	32.95	6	9	39.72	-6.77	-29.39
315	37.03	0	10	39.72	-2.69	-32.08
315	34.01	2	11	39.72	-5.71	-37.79
315	37.56	0	12	39.72	-2.16	-39.95
315	41.67	0	13	39.72	1.95	-38.00
315	37.95	0	14	39.72	-1.77	-39.77
315	36.03	0	15	39.72	-3.69	-43.45
315	36.93	1	16	39.72	-2.79	-46.24
315	37.49	1	17	39.72	-2.23	-48.47


Burst Volume CUSUM
10.00
0.00
-10.00
-20.00
-30.00
-40.00
-50.00
-60.00
-70.00
-80.00
-90.00
0
10
20
30
40
50
60
70
80
90
100
11

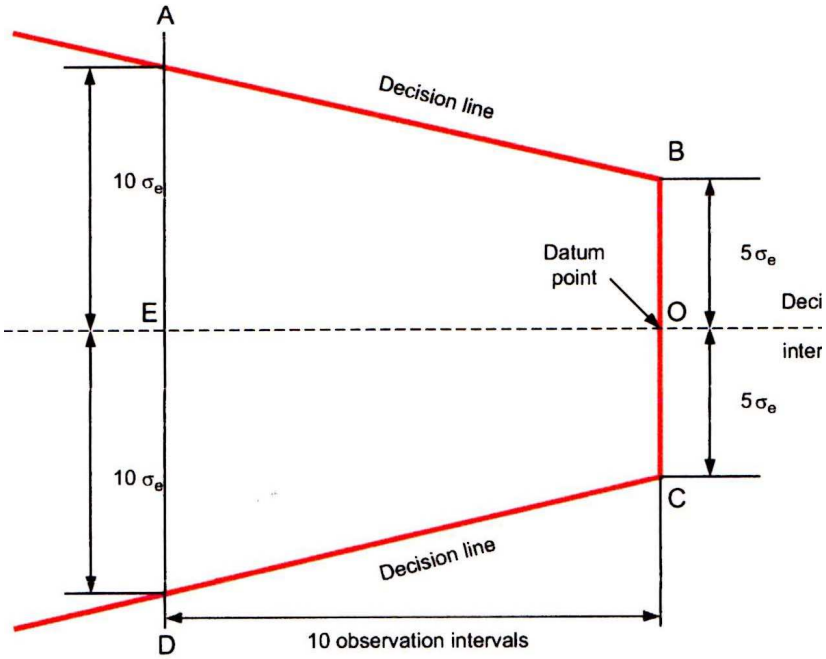

Burst Pressure CUSUM
4.00
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
-0.50
0
10
20
30
40
50
60
70
80
90
100

Scaling the Chart

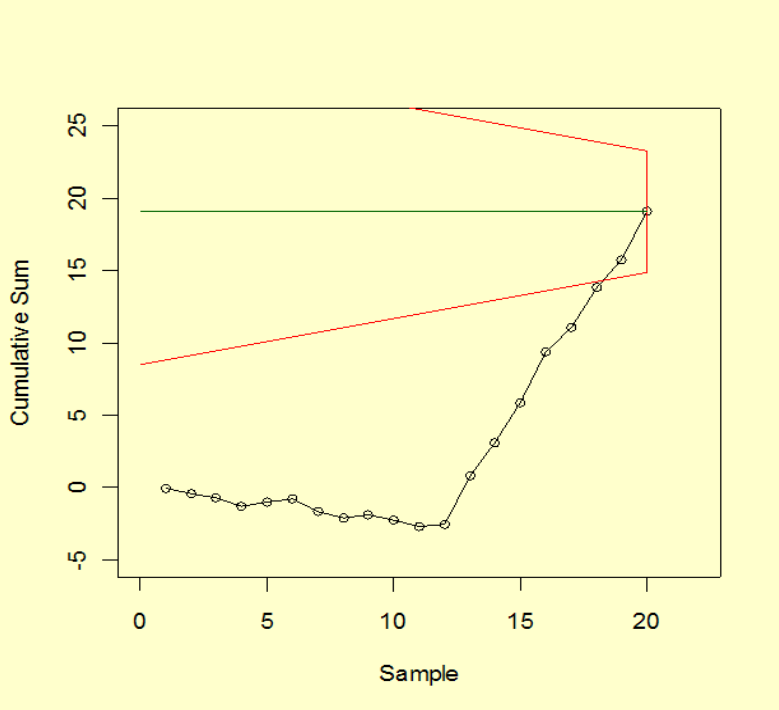
- The vertical scale of a CUSUM chart is important - it can exaggerate or supress the apparent magnitude of the shifts in properties
- Choose a convenient plotting interval for the horizontal axis
- Make the same interval on the vertical axis equal to twice the standard error

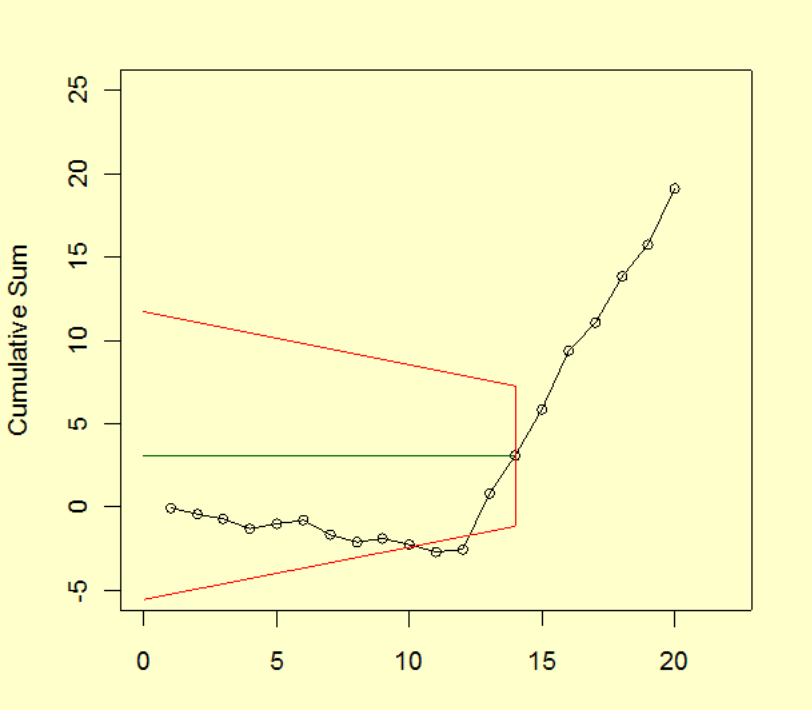
CUSUM Charts –V Mask

- The CUSUM suggests that there are possibly two points at which statistically significant changes in slope have occurred
- The V-Mask is used to confirm if the changes are statistically significant



CUSUM Charts – Use of V Mask





Tabular CUSUMs

- Maintaining CUSUM charts can be tedious – need periodic resetting unless running exactly at the target value
- Using V-masks in conjunction with computer screens is difficult
- Tabular CUSUM techniques developed for computer use
- Essentially integrate the principles of the V-mask into the table
- Procedure:

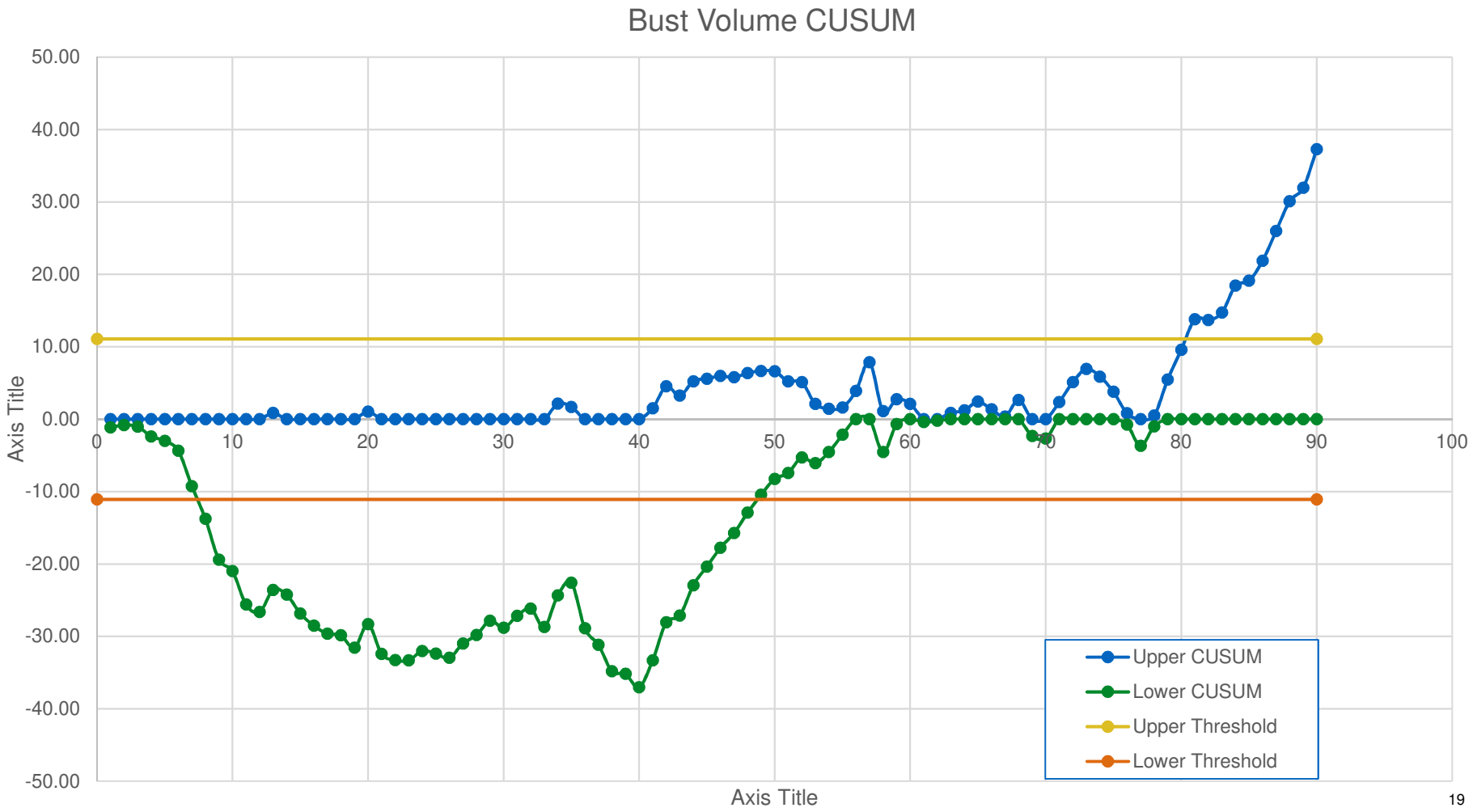
  Set upper (positive) target limit as Target Upper = Target + $f\sigma_e$ where f typically = 0.5

  Set lower (negative) target limit as Target Lower = Target – $f\sigma_e$ where f typically = 0.5

  Set decision limits at "± $h\sigma_e$ where h typically = 5
- Separately calculate and sum the positive and negative differences between the Value – Target Upper and Value - Target Lower
- Reset the upper CUSUM to 0 if it goes negative and keep at 0 until it becomes positive again
- Reset the lower CUSUM to 0 if it becomes positive and keep it at 0 until it becomes negative again

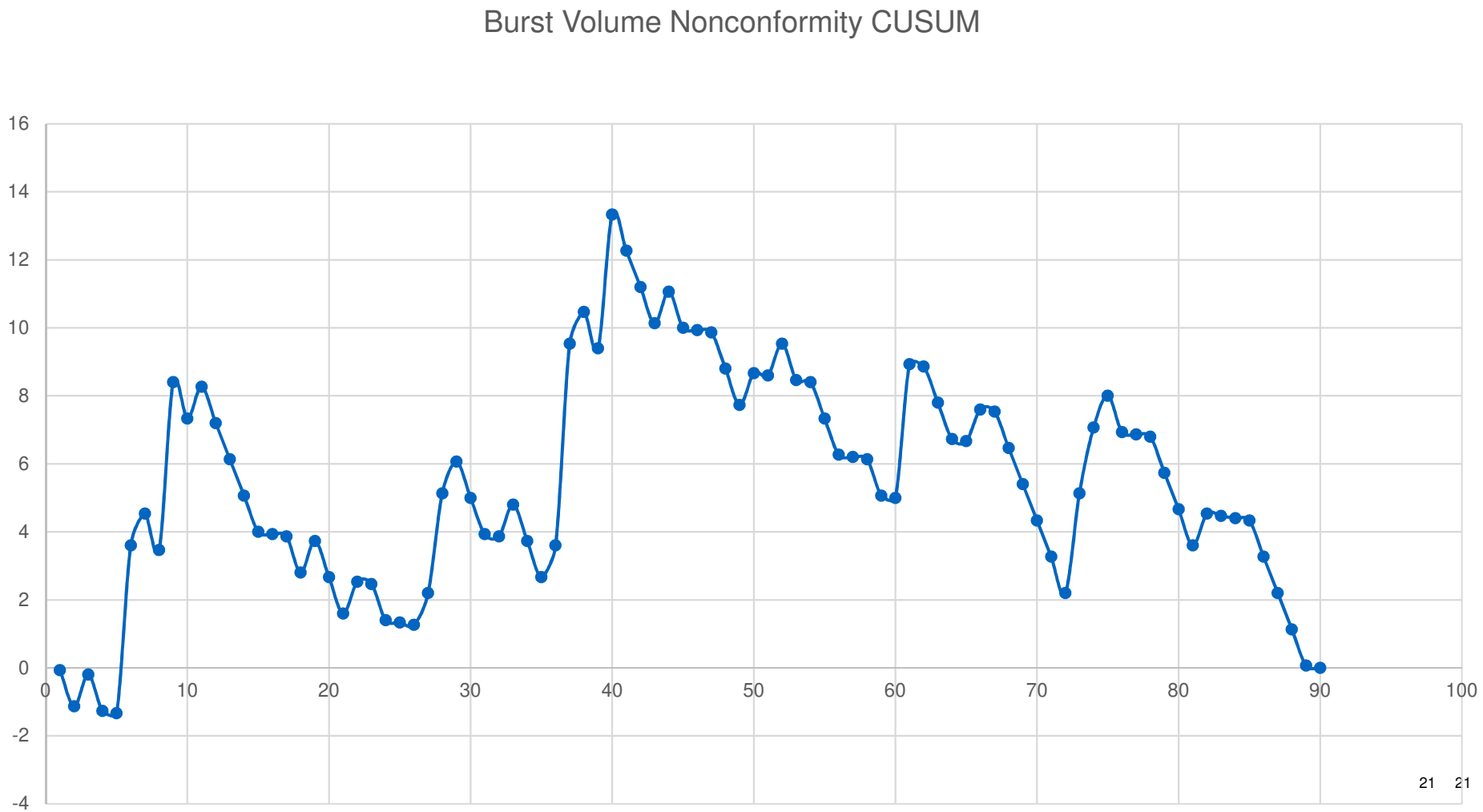
Lot Sequence Number	Target Mean	Burst Volume	Standard Deviation	Upper Target	Lower Target	Upper Difference	Lower Difference	CUSUM	
								Upper	Lower
								0	0
1	39.72	37.46	2.21686	40.8281	38.61124	-3.3681	-1.15124	0	-1.15124
2	39.72	38.95	2.21686	40.8281	38.61124	-1.8781	0.338763	0	-0.81247
3	39.72	38.39	2.21686	40.8281	38.61124	-2.4381	-0.22124	0	-1.03371
4	39.72	37.26	2.21686	40.8281	38.61124	-3.5681	-1.35124	0	-2.38495
5	39.72	38.01	2.21686	40.8281	38.61124	-2.8181	-0.60124	0	-2.98618
6	39.72	37.23	2.21686	40.8281	38.61124	-3.5981	-1.38124	0	-4.36742
7	39.72	33.73	2.21686	40.8281	38.61124	-7.0981	-4.88124	0	-9.24866
8	39.72	34.11	2.21686	40.8281	38.61124	-6.7181	-4.50124	0	-13.7499
9	39.72	32.95	2.21686	40.8281	38.61124	-7.8781	-5.66124	0	-19.4111
10	39.72	37.03	2.21686	40.8281	38.61124	-3.7981	-1.58124	0	-20.9924
11	39.72	34.01	2.21686	40.8281	38.61124	-6.8181	-4.60124	0	-25.5936
12	39.72	37.56	2.21686	40.8281	38.61124	-3.2681	-1.05124	0	-26.6448
13	39.72	41.67	2.21686	40.8281	38.61124	0.841903	3.058763	0.841903	-23.5861
14	39.72	37.95	2.21686	40.8281	38.61124	-2.8781	-0.66124	0	-24.2473
15	39.72	36.03	2.21686	40.8281	38.61124	-4.7981	-2.58124	0	-26.8286
16	39.72	36.93	2.21686	40.8281	38.61124	-3.8981	-1.68124	0	-28.5098
17	39.72	37.49	2.21686	40.8281	38.61124	-3.3381	-1.12124	0	-29.631
18	39.72	38.38	2.21686	40.8281	38.61124	-2.4481	-0.23124	0	-29.8623
19	39.72	36.9	2.21686	40.8281	38.61124	-3.9281	-1.71124	0	-31.5735
20	39.72	41.86	2.21686	40.8281	38.61124	1.031903	3.248763	1.031903	-28.3247

Lot Sequence Number	Target Mean	Vol - Target	CUSUM	Vol CUSUM	Burst Volume	Standard Deviation	Upper Target	Lower Target	Upper Difference	Lower Difference	CUSUM	
											Upper	Lower
70	39.72	-1.48	-55.12	-55.1167	38.24	2.21686	40.8281	38.61124	-2.5881	-0.37124	0	-2.69247
71	39.72	3.45	-51.67	-51.6663	43.17	2.21686	40.8281	38.61124	2.341903	4.558763	2.341903	0
72	39.72	3.87	-47.80	-47.796	43.59	2.21686	40.8281	38.61124	2.761903	4.978763	5.103807	0
73	39.72	2.93	-44.87	-44.8657	42.65	2.21686	40.8281	38.61124	1.821903	4.038763	6.92571	0
74	39.72	0.06	-44.81	-44.8053	39.78	2.21686	40.8281	38.61124	-1.0481	1.168763	5.877614	0
75	39.72	-0.99	-45.79	-45.795	38.73	2.21686	40.8281	38.61124	-2.0981	0.118763	3.779517	0
76	39.72	-1.86	-47.65	-47.6547	37.86	2.21686	40.8281	38.61124	-2.9681	-0.75124	0.811421	-0.75124
77	39.72	-4.05	-51.70	-51.7043	35.67	2.21686	40.8281	38.61124	-5.1581	-2.94124	0	-3.69247
78	39.72	1.60	-50.10	-50.104	41.32	2.21686	40.8281	38.61124	0.491903	2.708763	0.491903	-0.98371
79	39.72	6.09	-44.01	-44.0137	45.81	2.21686	40.8281	38.61124	4.981903	7.198763	5.473807	0
80	39.72	5.22	-38.79	-38.7933	44.94	2.21686	40.8281	38.61124	4.111903	6.328763	9.58571	0
81	39.72	5.32	-33.47	-33.473	45.04	2.21686	40.8281	38.61124	4.211903	6.428763	13.79761	0
82	39.72	1.01	-32.46	-32.4627	40.73	2.21686	40.8281	38.61124	-0.0981	2.118763	13.69952	0
83	39.72	2.12	-30.34	-30.3423	41.84	2.21686	40.8281	38.61124	1.011903	3.228763	14.71142	0
84	39.72	4.83	-25.51	-25.512	44.55	2.21686	40.8281	38.61124	3.721903	5.938763	18.43332	0
85	39.72	1.78	-23.73	-23.7317	41.5	2.21686	40.8281	38.61124	0.671903	2.888763	19.10523	0
86	39.72	3.89	-19.84	-19.8413	43.61	2.21686	40.8281	38.61124	2.781903	4.998763	21.88713	0
87	39.72	5.20	-14.64	-14.641	44.92	2.21686	40.8281	38.61124	4.091903	6.308763	25.97903	0
88	39.72	5.23	-9.41	-9.41067	44.95	2.21686	40.8281	38.61124	4.121903	6.338763	30.10094	0
89	39.72	2.96	-6.45	-6.45033	42.68	2.21686	40.8281	38.61124	1.851903	4.068763	31.95284	0
90	39.72	6.45	0.00	4.76E-13	46.17	2.21686	40.8281	38.61124	5.341903	7.558763	37.29474	0


Bust Volume CUSUM
50.00
40.00
30.00
20.00
10.00
0.00
-10.00
-20.00
-30.00
-40.00
-50.00
Axis Title
0
10
20
30
40
50
60
70
80
90
100
Axis Title
Upper CUSUM
Lower CUSUM
Upper Threshold
Lower Threshold

CUSUMs for Attributes

- Same principles as CUSUMs for variables
- Same attributes as for Shewhart charts
  - Step 1: Select the target or reference value e.g. the average number of nonconforming condoms w.r.t. burst volume in the sample
  - Step 2: Tabulate the results against the appropriate sequential reference values
  - Step 3: Subtract the target value from each value
  - Step 4: Progressively sum the differences
  - Step 5: Plot the CUSUM values against the reference values
- Standard errors determined using binomial model or Poisson model as for Shewhart charts


Burst Volume Nonconformity CUSUM
16
14
12
10
8
6
4
2
0
-2
-4
0
10
20
30
40
50
60
70
80
90
100
21
21

Conclusions

Shewhart charts provide a simple and effective method of monitoring condom quality

- Use for average burst volumes and pressures, nonconforming condoms with respect to freedom from holes, burst properties and package integrity

CUSUM chart are more complex to set up and maintain but can detect relatively small shifts in quality and pinpoint when these changes occur

- Use for trouble shooting quality problems and monitoring quality when formulation and process changes are made

Questions and discussions

Thank you for your attention