FIG. 1

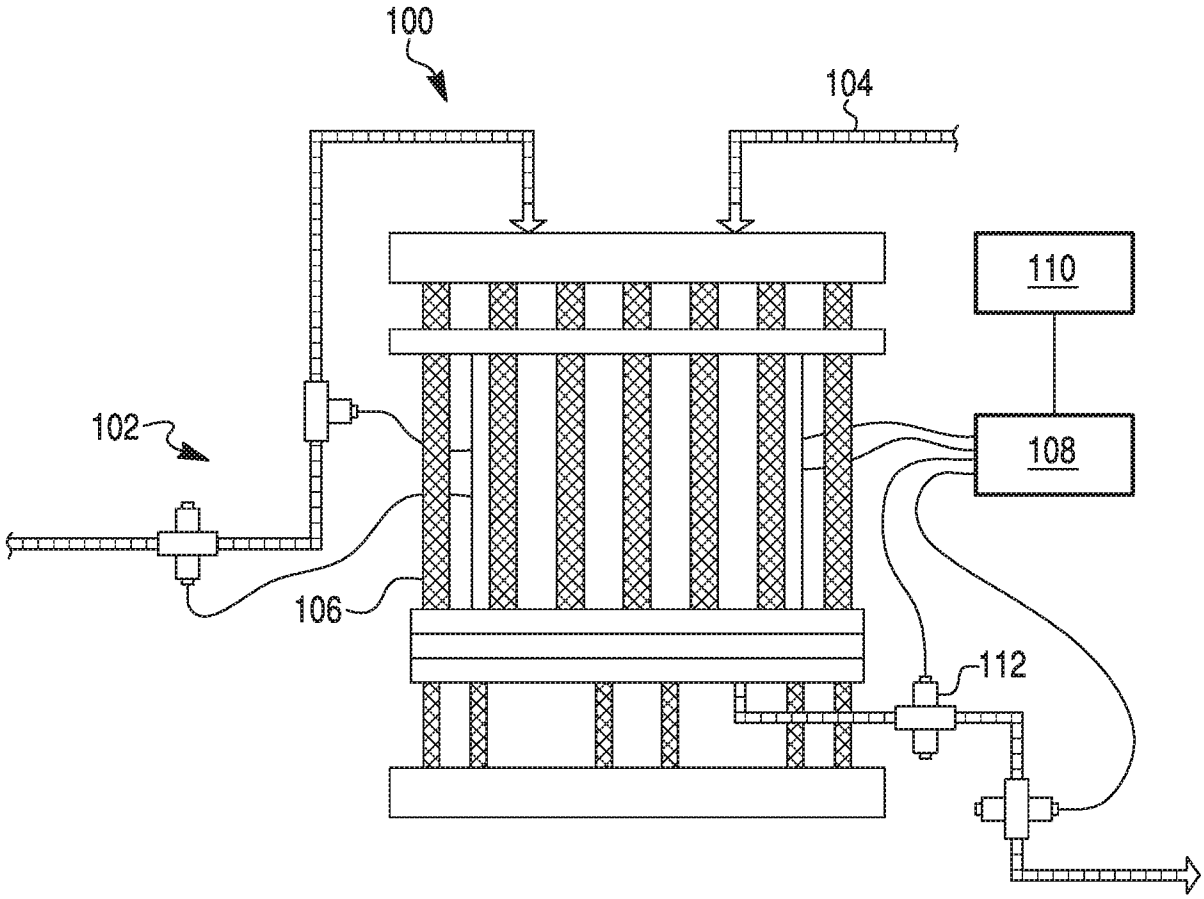


FIG. 2

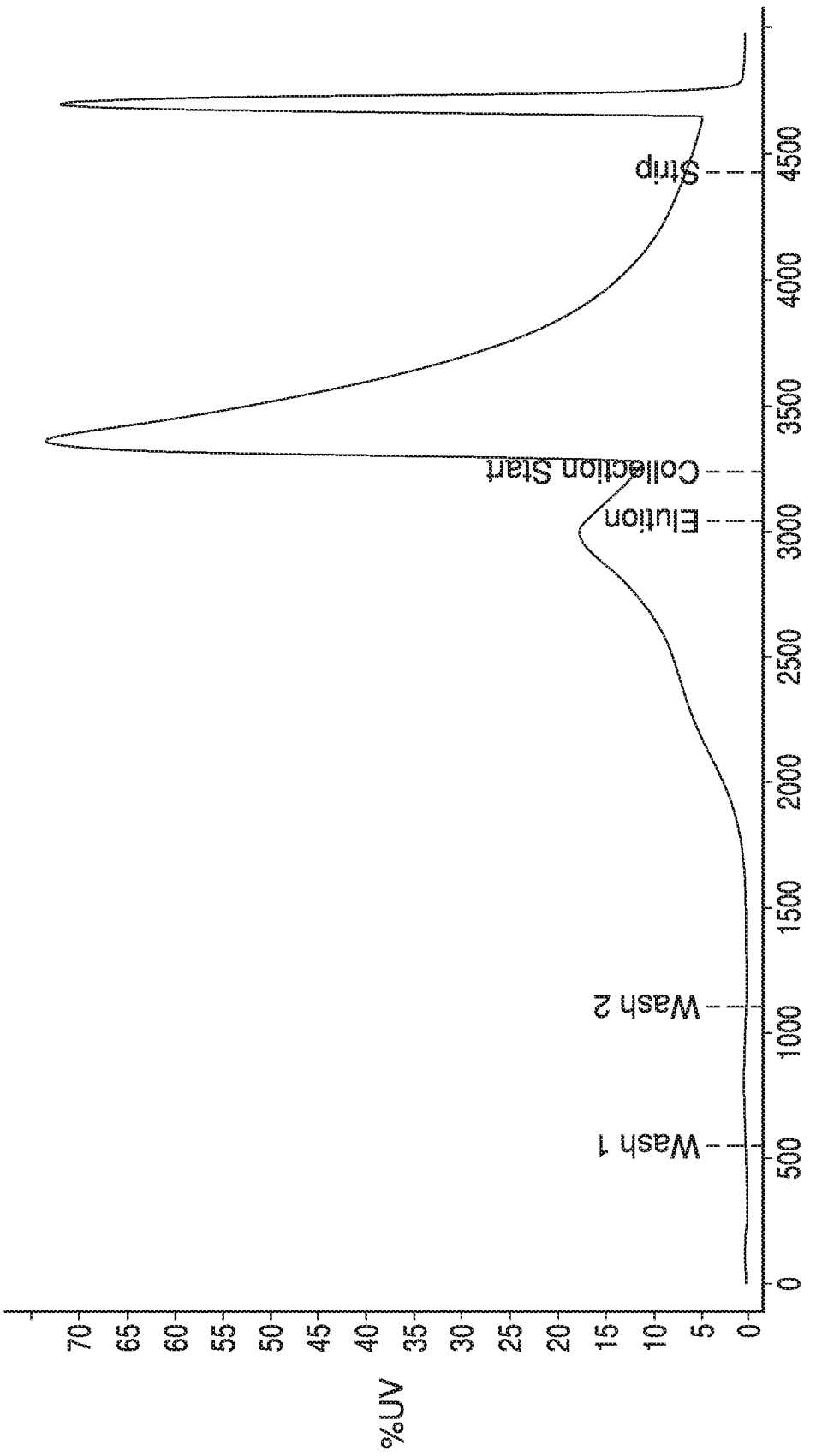

%UV
0
5
10
15
20
25
30
35
40
45
50
55
60
65
70
0
500
1000
1500
2000
2500
3000
3500
4000
4500
Wash 1
Wash 2
Elution
Collection Start
Strip

FIG. 3

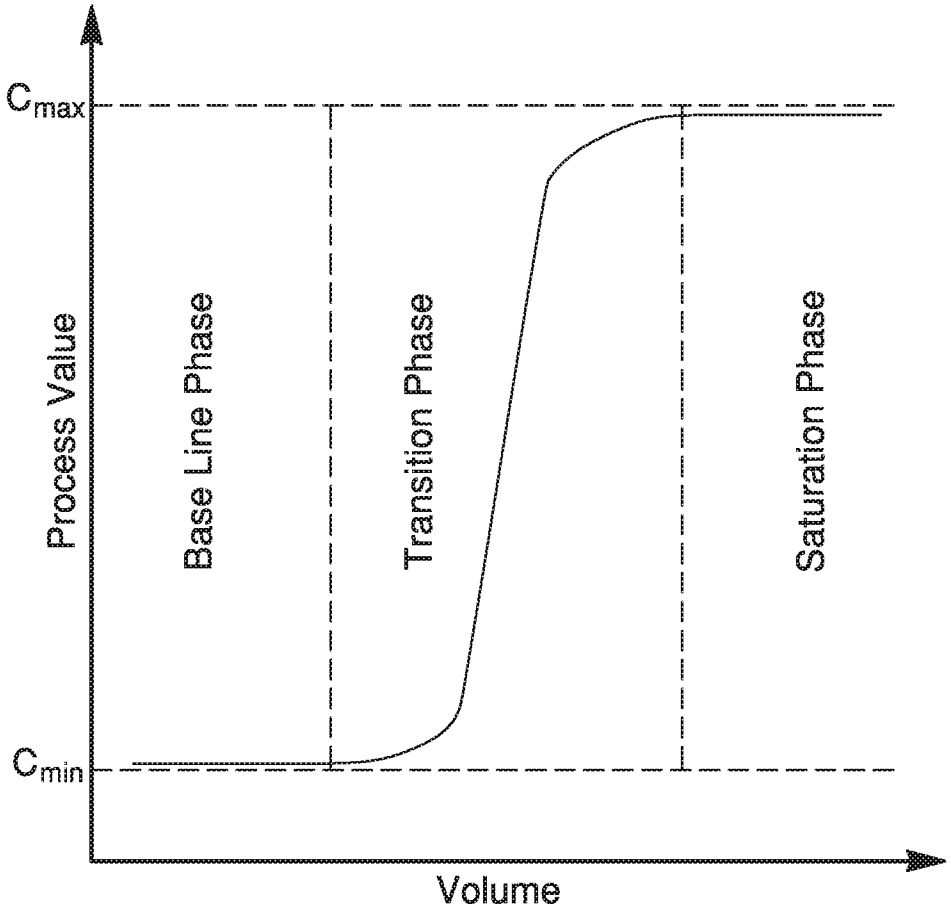

Cmax
Cmin
Process Value
Base Line Phase
Transition Phase
Saturation Phase
Volume

FIG. 4

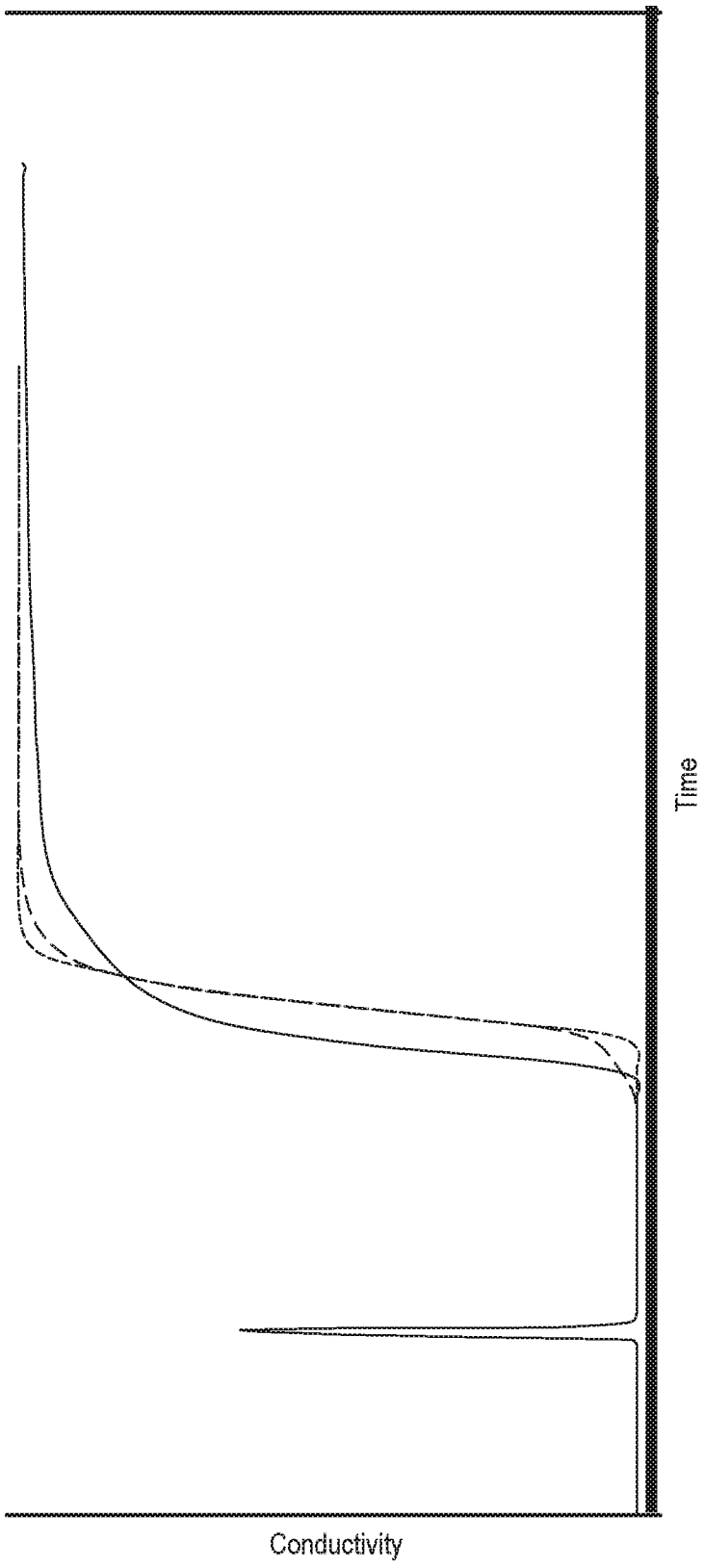


FIG. 5

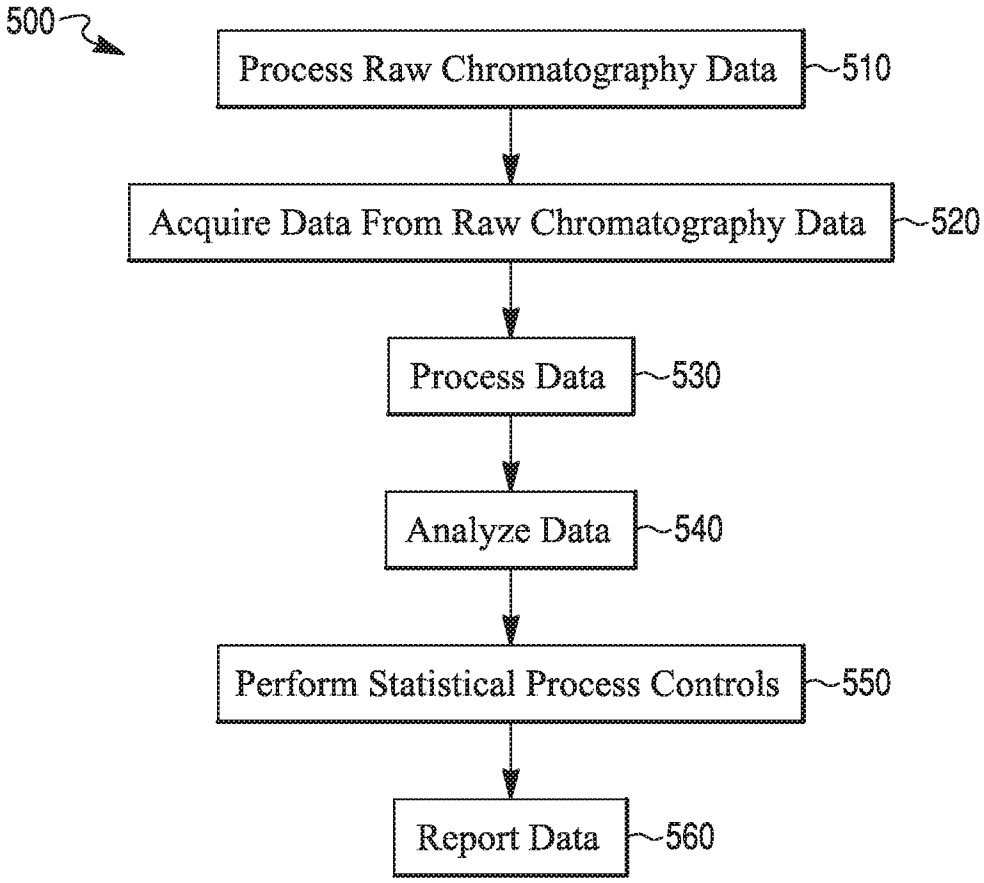

500
Process Raw Chromatography Data
510
Acquire Data From Raw Chromatography Data
520
Process Data
530
Analyze Data
540
Perform Statistical Process Controls
550
Report Data
560

FIG. 6

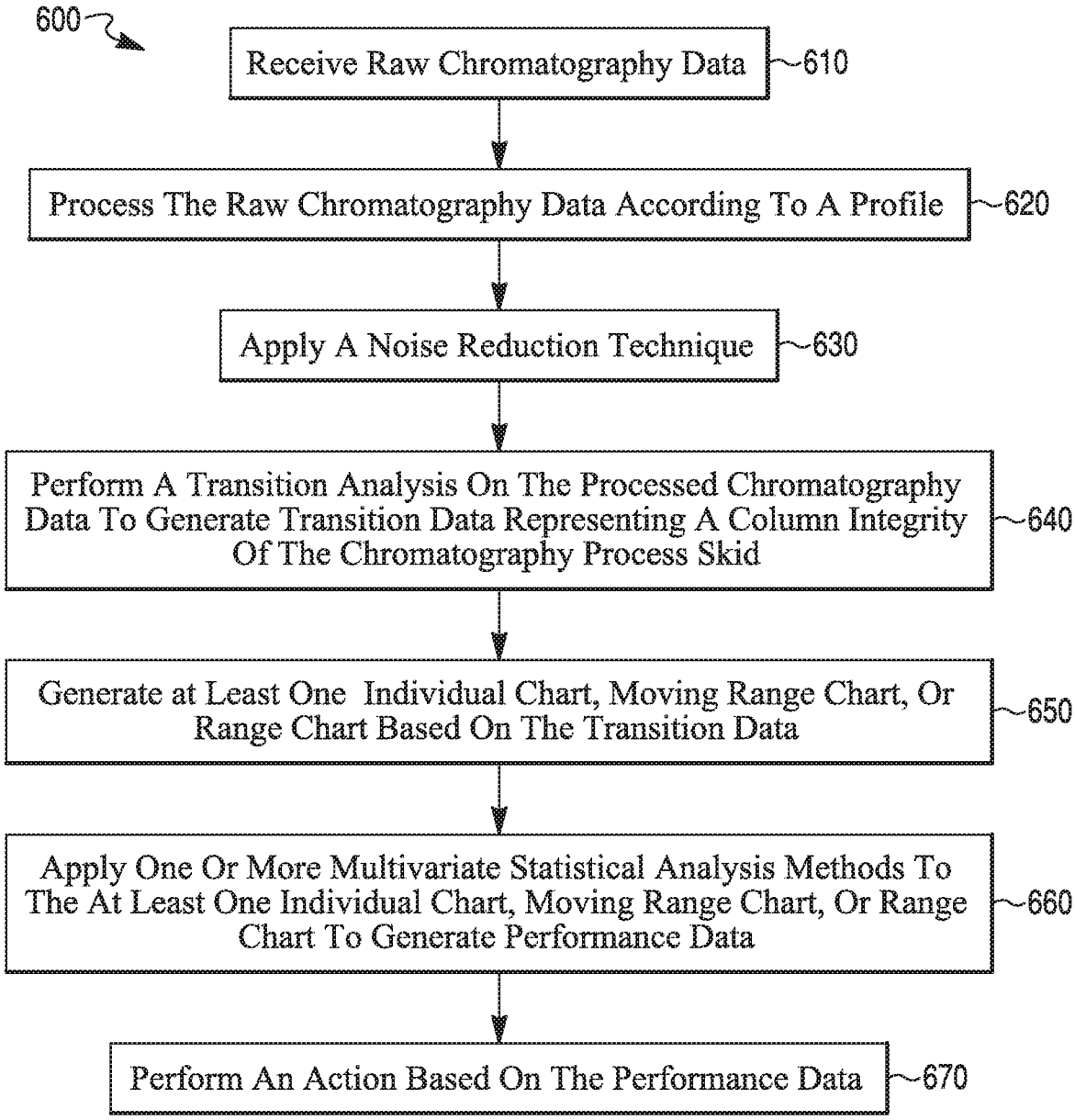

600
Receive Raw Chromatography Data
610
Process The Raw Chromatography Data According To A Profile
620
Apply A Noise Reduction Technique
630
Perform A Transition Analysis On The Processed Chromatography Data To Generate Transition Data Representing A Column Integrity Of The Chromatography Process Skid
640
Generate at Least One Individual Chart, Moving Range Chart, Or Range Chart Based On The Transition Data
650
Apply One Or More Multivariate Statistical Analysis Methods To The At Least One Individual Chart, Moving Range Chart, Or Range Chart To Generate Performance Data
660
Perform An Action Based On The Performance Data
670

FIG. 7

1000

1002 Volume (L)	1004 Cond (mS/cm)	1006 Volume (L)	1008 Logbook
170.6	0.04	24.05	CG002_START
180.1	0.04	24.05	Pump 1
180.6	0.12	24.05	Inlet 1
190.1	0.56	24.058	Outlet A
190.6	1.12	24.05	Flow 100 L/hour
200.1	1.46	115.67	CG002_END
200.6	1.52	115.67	CG003_START

FIG. 8

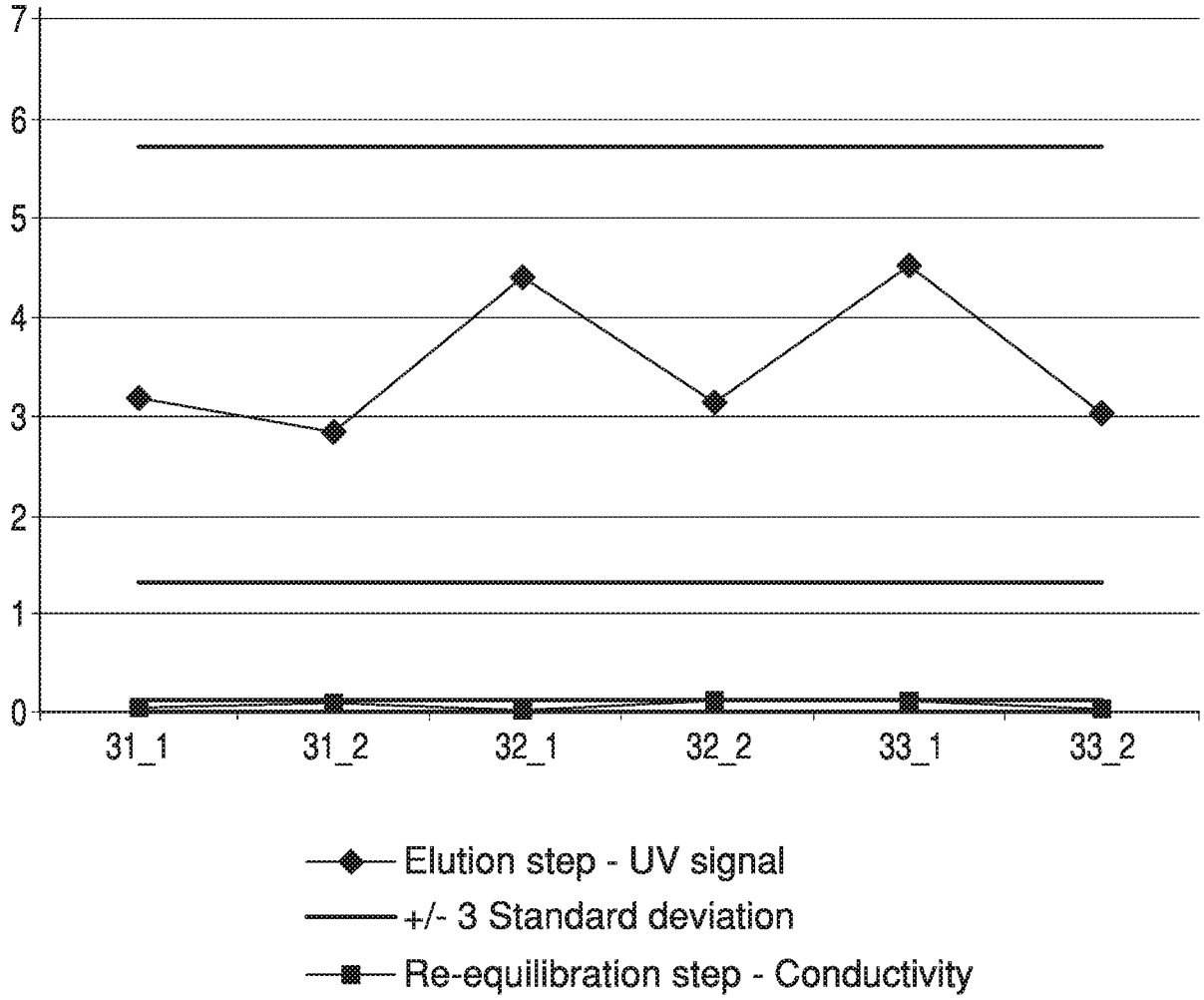

7
6
5
4
3
2
1
0
31_1
31_2
32_1
32_2
33_1
33_2
Elution step - UV signal
+/- 3 Standard deviation
Re-equilibration step - Conductivity

FIG. 9

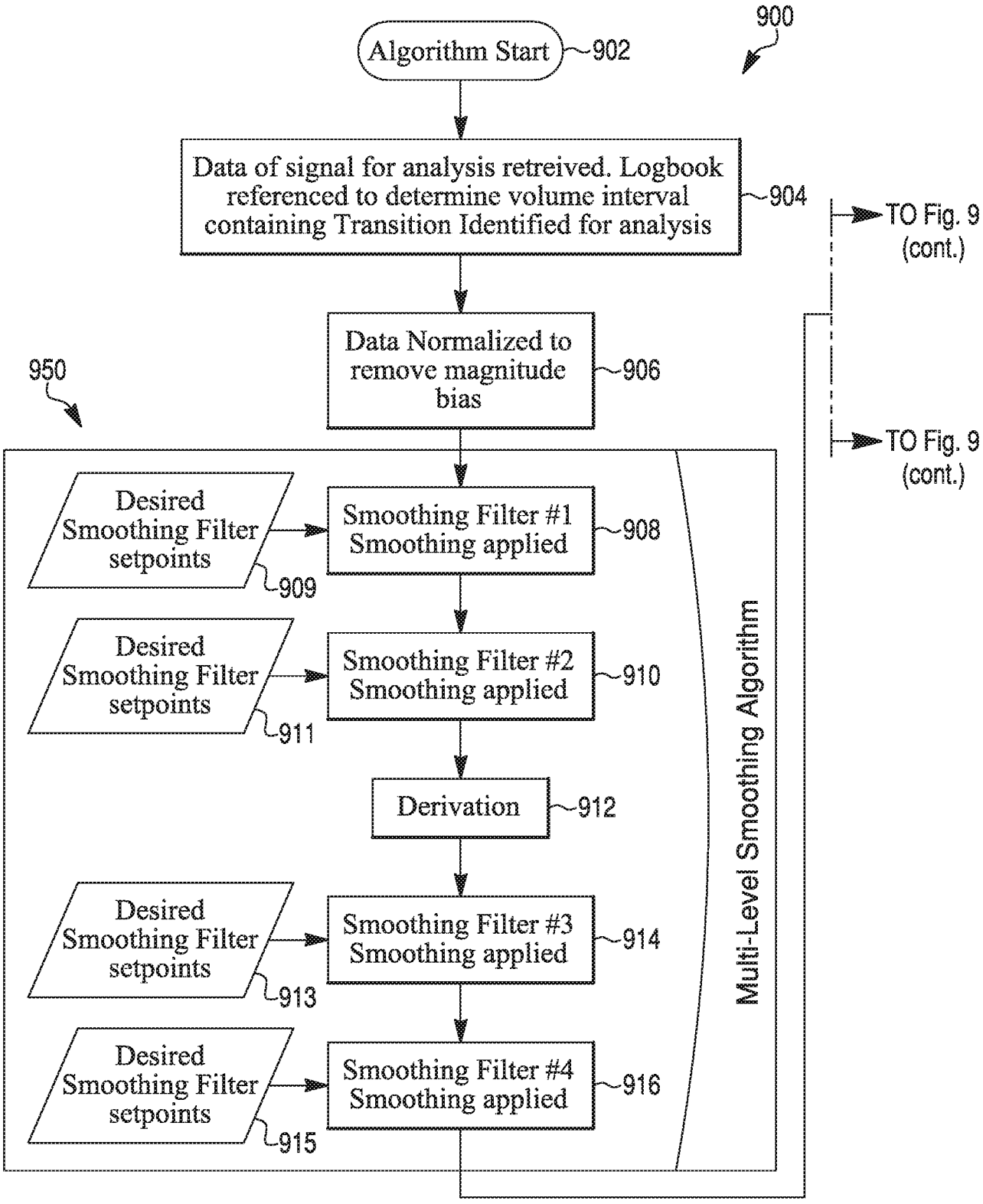

900
Algorithm Start
902
Data of signal for analysis retreived. Logbook referenced to determine volume interval containing Transition Identified for analysis
904
TO Fig. 9 (cont.)
Data Normalized to remove magnitude bias
906
950
TO Fig. 9 (cont.)
Desired Smoothing Filter setpoints
909
Smoothing Filter #1 Smoothing applied
908
Desired Smoothing Filter setpoints
911
Smoothing Filter #2 Smoothing applied
910
Derivation
912
Desired Smoothing Filter setpoints
913
Smoothing Filter #3 Smoothing applied
914
Desired Smoothing Filter setpoints
915
Smoothing Filter #4 Smoothing applied
916
Multi-Level Smoothing Algorithm

FIG. 9 (cont.)

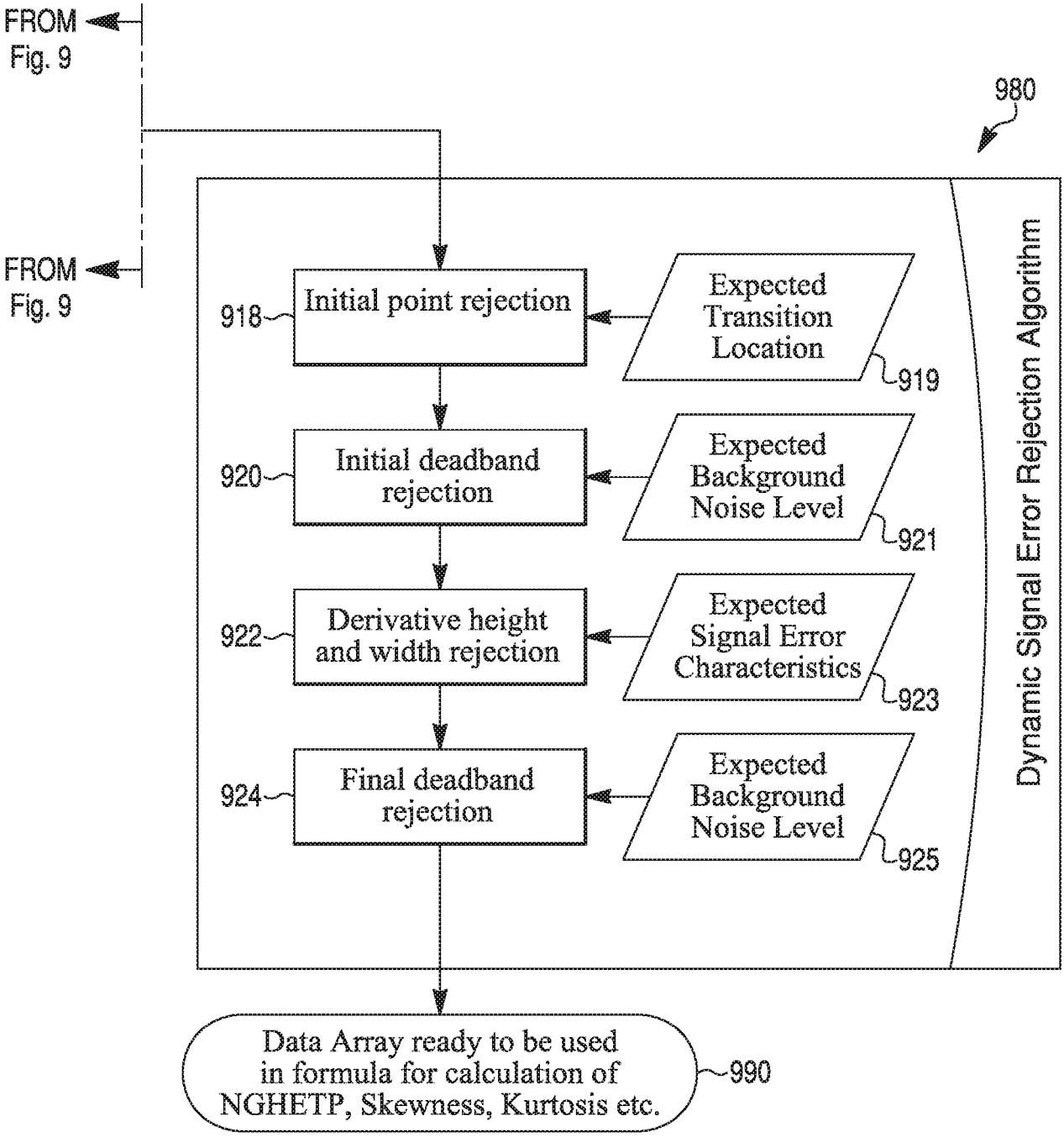

FROM Fig. 9
FROM Fig. 9
980
Dynamic Signal Error Rejection Algorithm
918
Initial point rejection
Expected Transition Location
919
920
Initial deadband rejection
Expected Background Noise Level
921
922
Derivative height and width rejection
Expected Signal Error Characteristics
923
924
Final deadband rejection
Expected Background Noise Level
925
Data Array ready to be used in formula for calculation of NGHETP, Skewness, Kurtosis etc.
990

FIG. 10

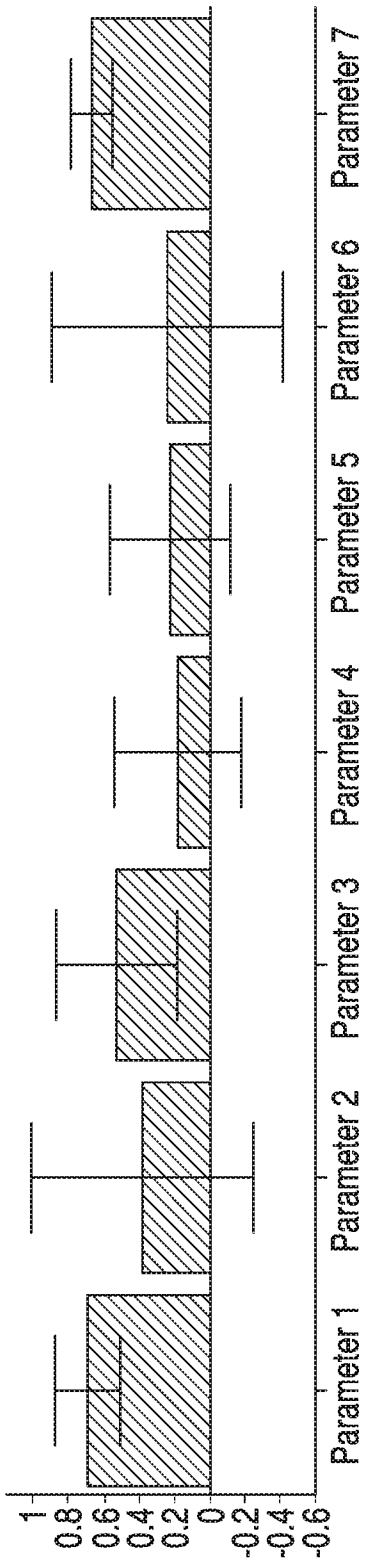

1
0.8
0.6
0.4
0.2
0
-0.2
-0.4
-0.6
Parameter 1
Parameter 2
Parameter 3
Parameter 4
Parameter 5
Parameter 6
Parameter 7

FIG. 11

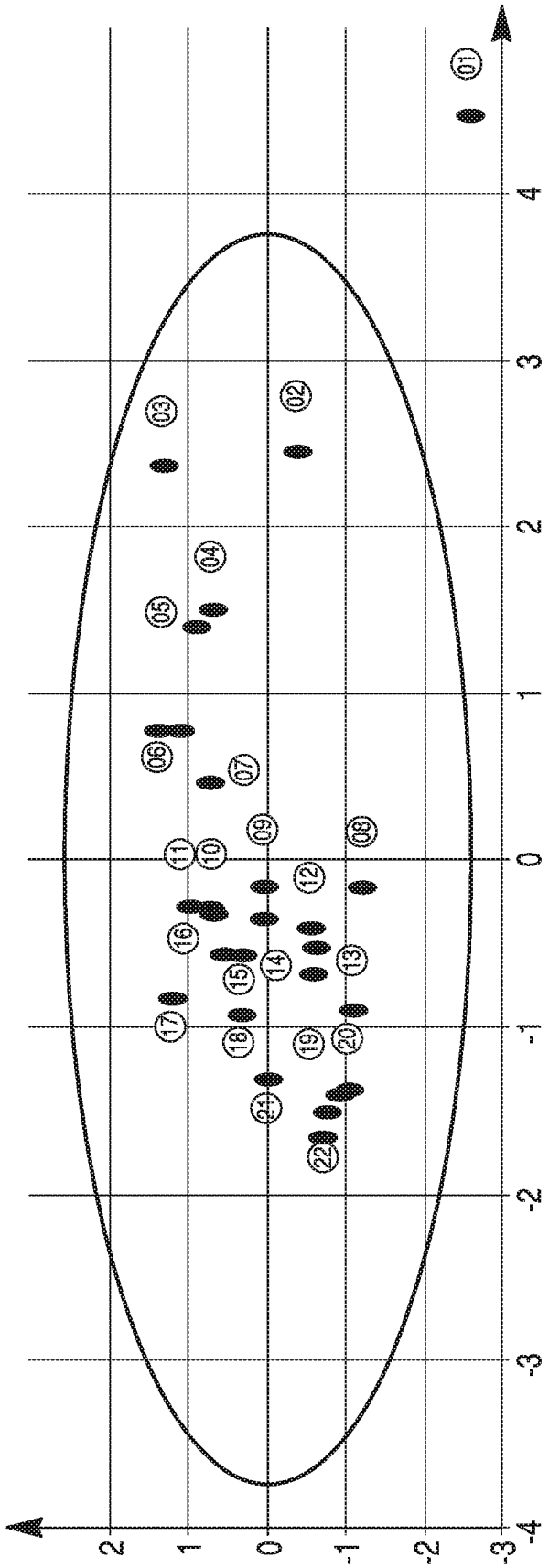

01
02
03
04
05
06
07
08
09
10
11
12
13
14
15
16
17
18
19
20
21
22
4
3
2
1
0
-1
-2
-3
-4
2
1
0
-1
-2
-3

FIG. 12

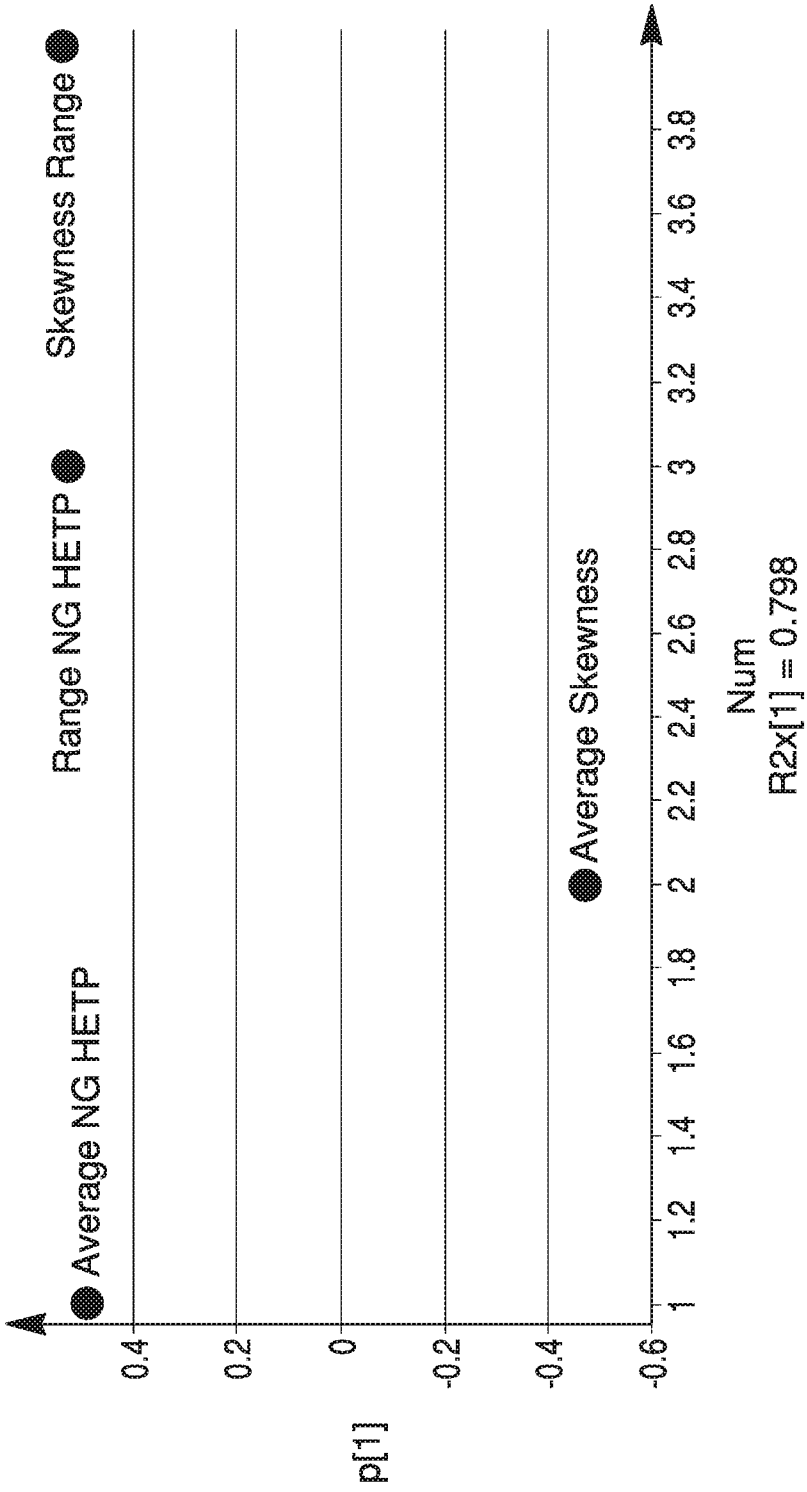

Average NG HETP
Range NG HETP
Skewness Range
Average Skewness
p[1]
0.4
0.2
0
-0.2
-0.4
-0.6
1
1.2
1.4
1.6
1.8
2
2.2
2.4
2.6
2.8
3
3.2
3.4
3.6
3.8
Num
R2x[1] = 0.798

FIG. 13

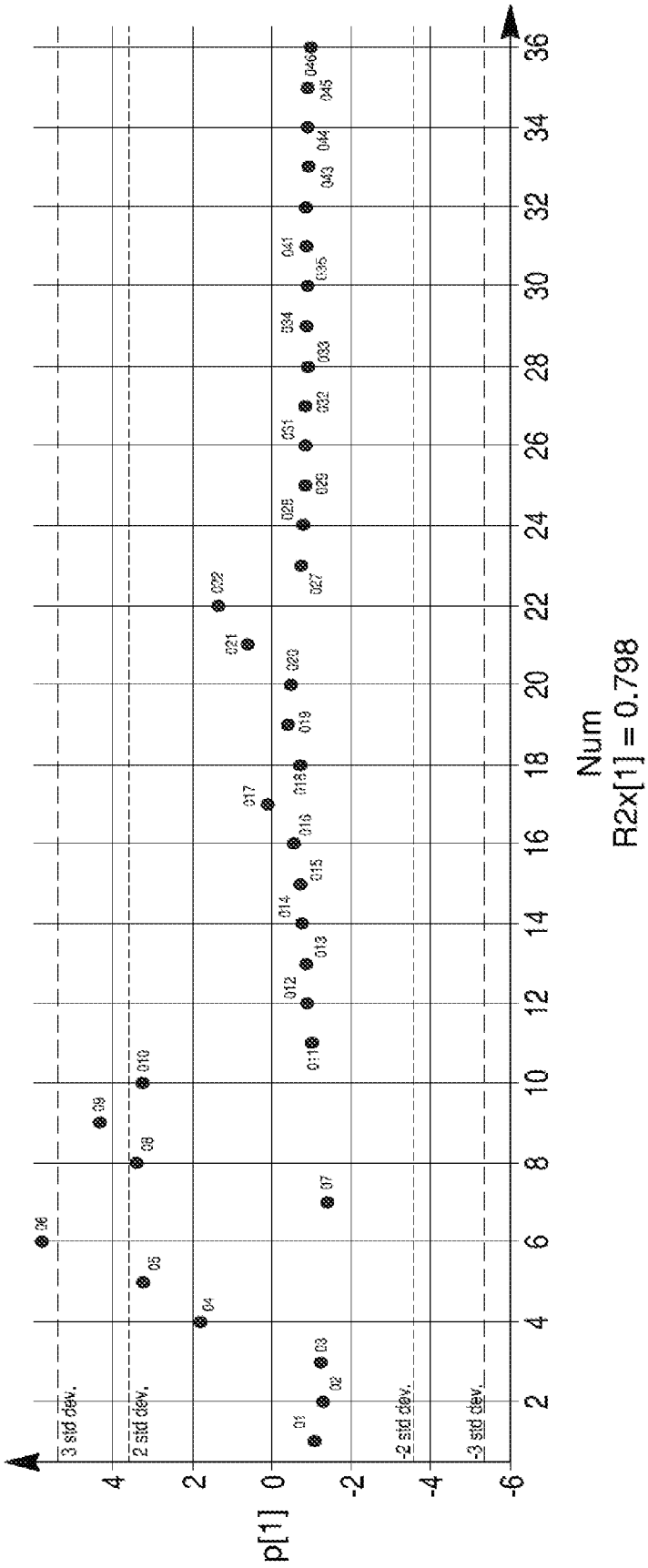


FIG. 14

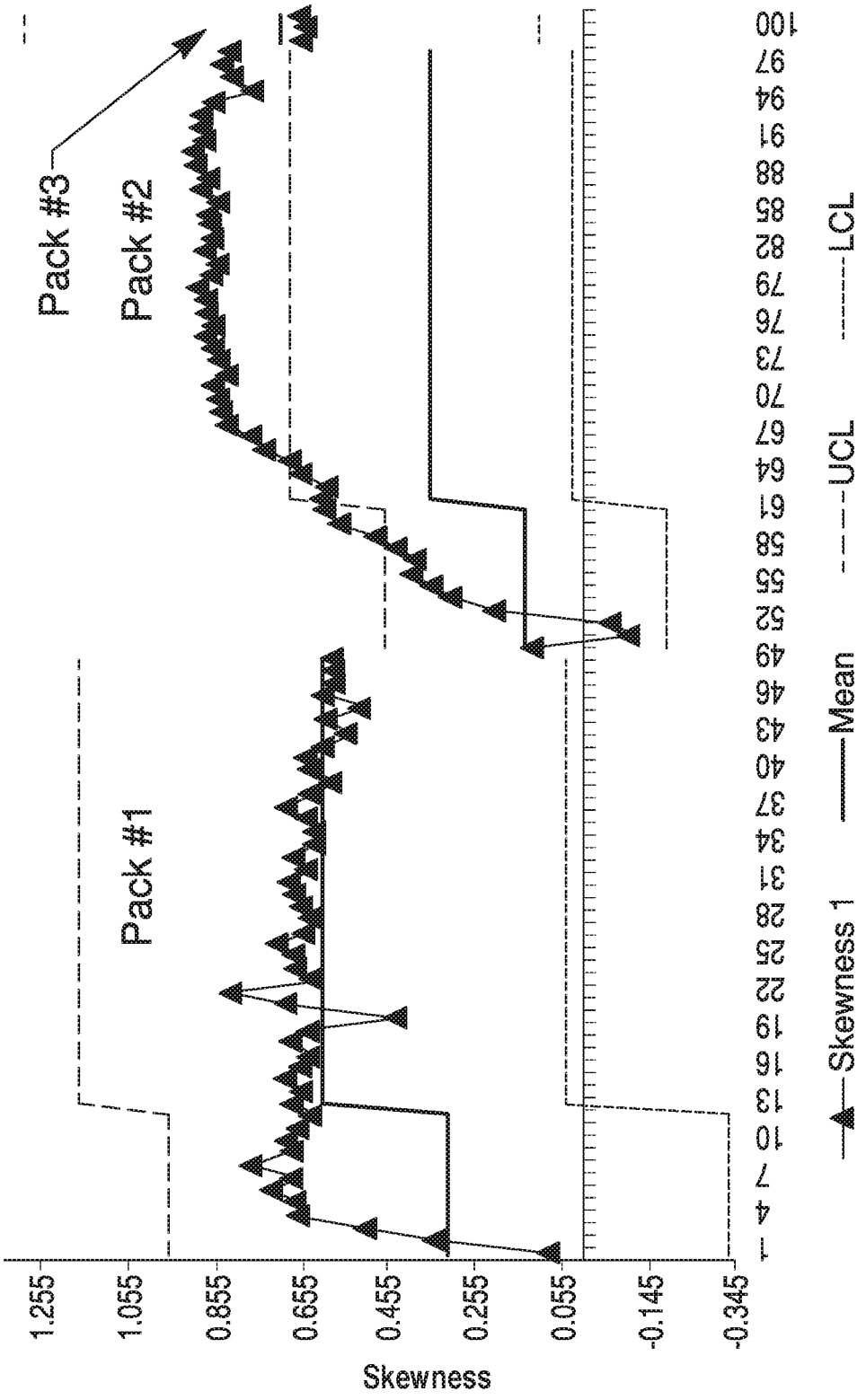

Pack #3
Pack #2
Pack #1
1.255
1.055
0.855
0.655
0.455
0.255
0.055
-0.145
-0.345
Skewness
1
4
7
10
13
16
19
22
25
28
31
34
37
40
43
46
49
52
55
58
61
64
67
70
73
76
79
82
85
88
91
94
97
100
Skewness 1
Mean
UCL
LCL

FIG. 15

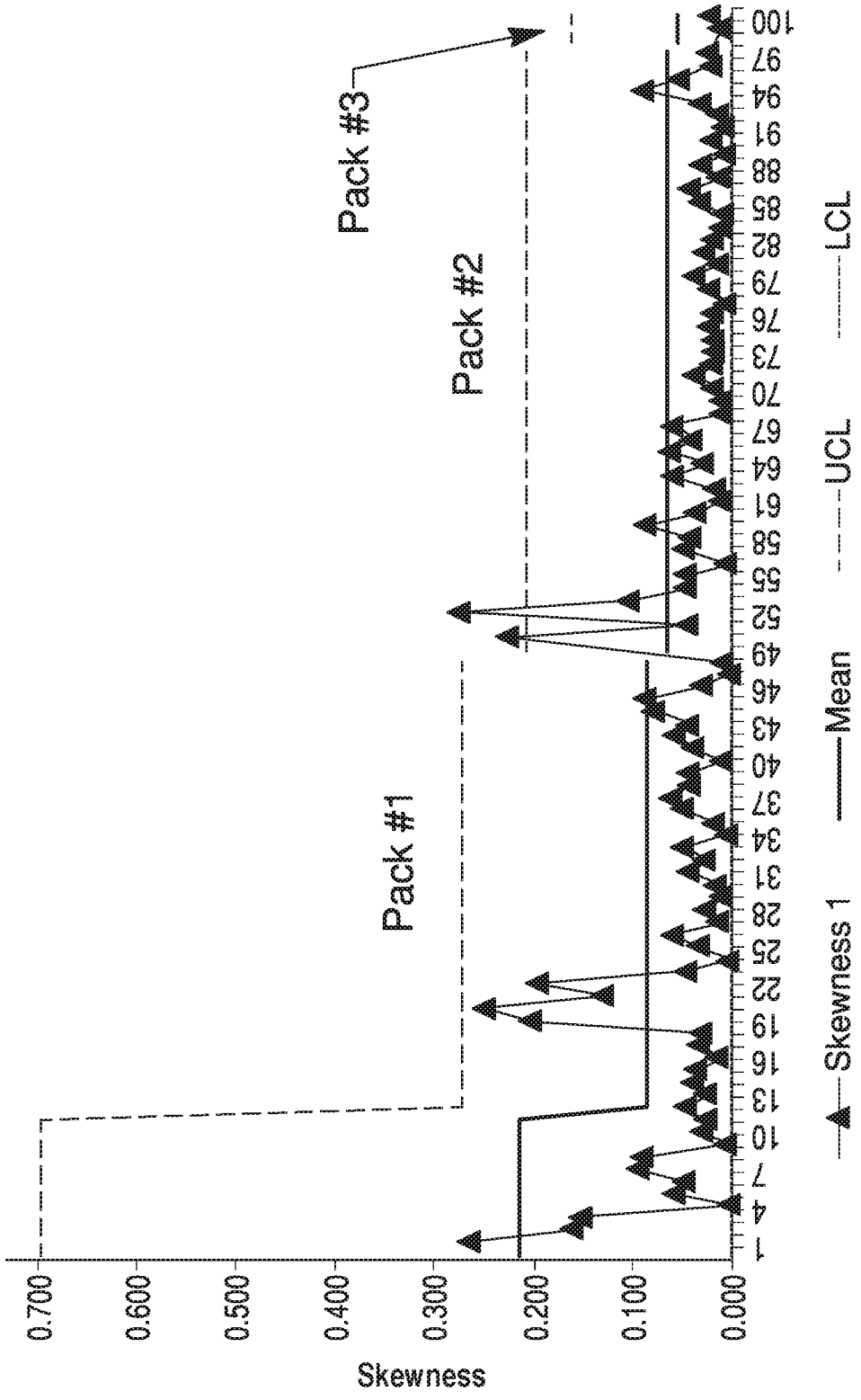

Pack #3
Pack #2
Pack #1
0.700
0.600
0.500
0.400
0.300
0.200
0.100
0.000
Skewness
1
4
7
10
13
16
19
22
25
28
31
34
37
40
43
46
49
52
55
58
61
64
67
70
73
76
79
82
85
88
91
94
97
100
Skewness 1
Mean
UCL
LCL

FIG. 16

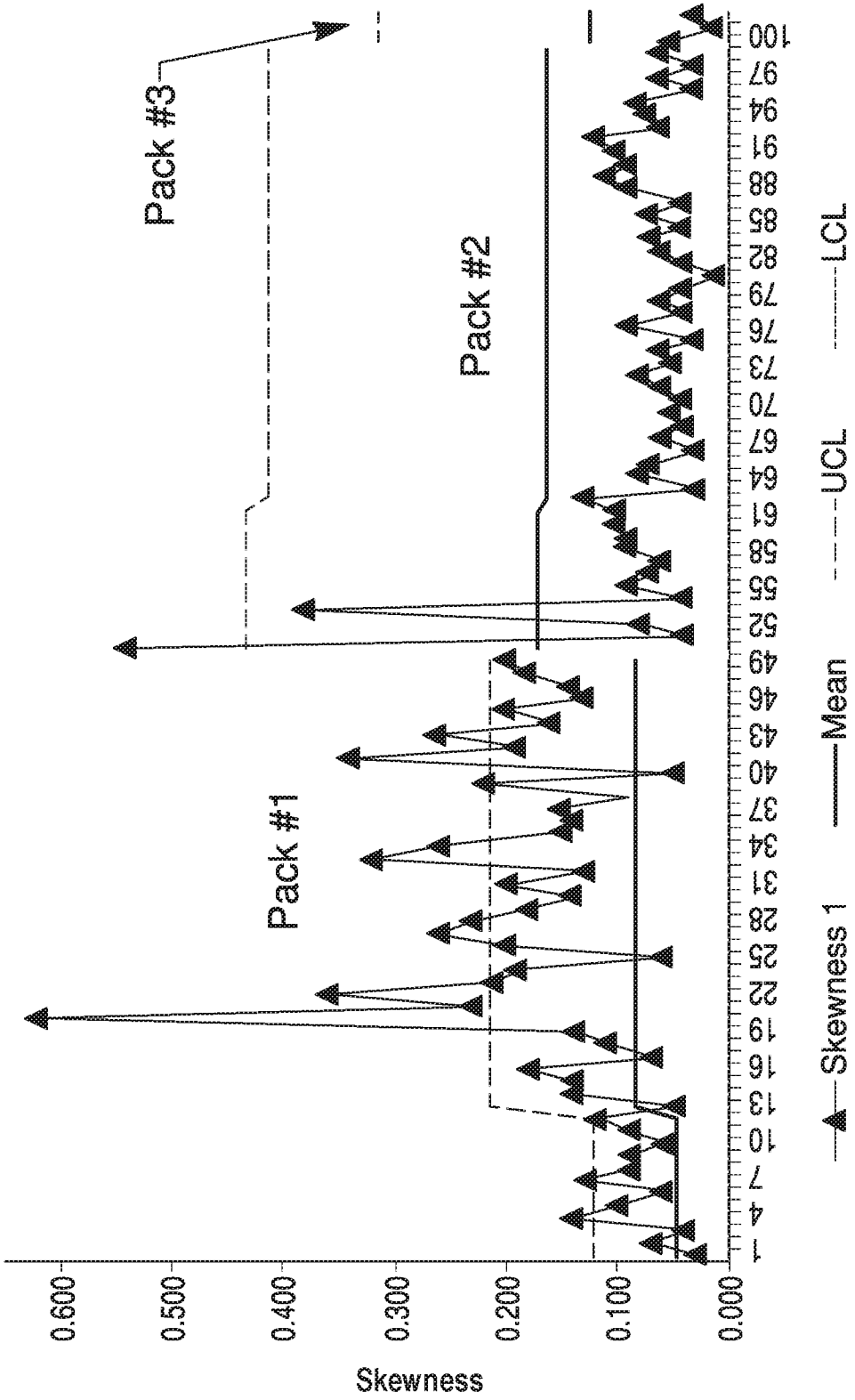

Pack #3
Pack #2
Pack #1
Skewness
0.600
0.500
0.400
0.300
0.200
0.100
0.000
1
4
7
10
13
16
19
22
25
28
31
34
37
40
43
46
49
52
55
58
61
64
67
70
73
76
79
82
85
88
91
94
97
100
Skewness 1
Mean
UCL
LCL

FIG. 17

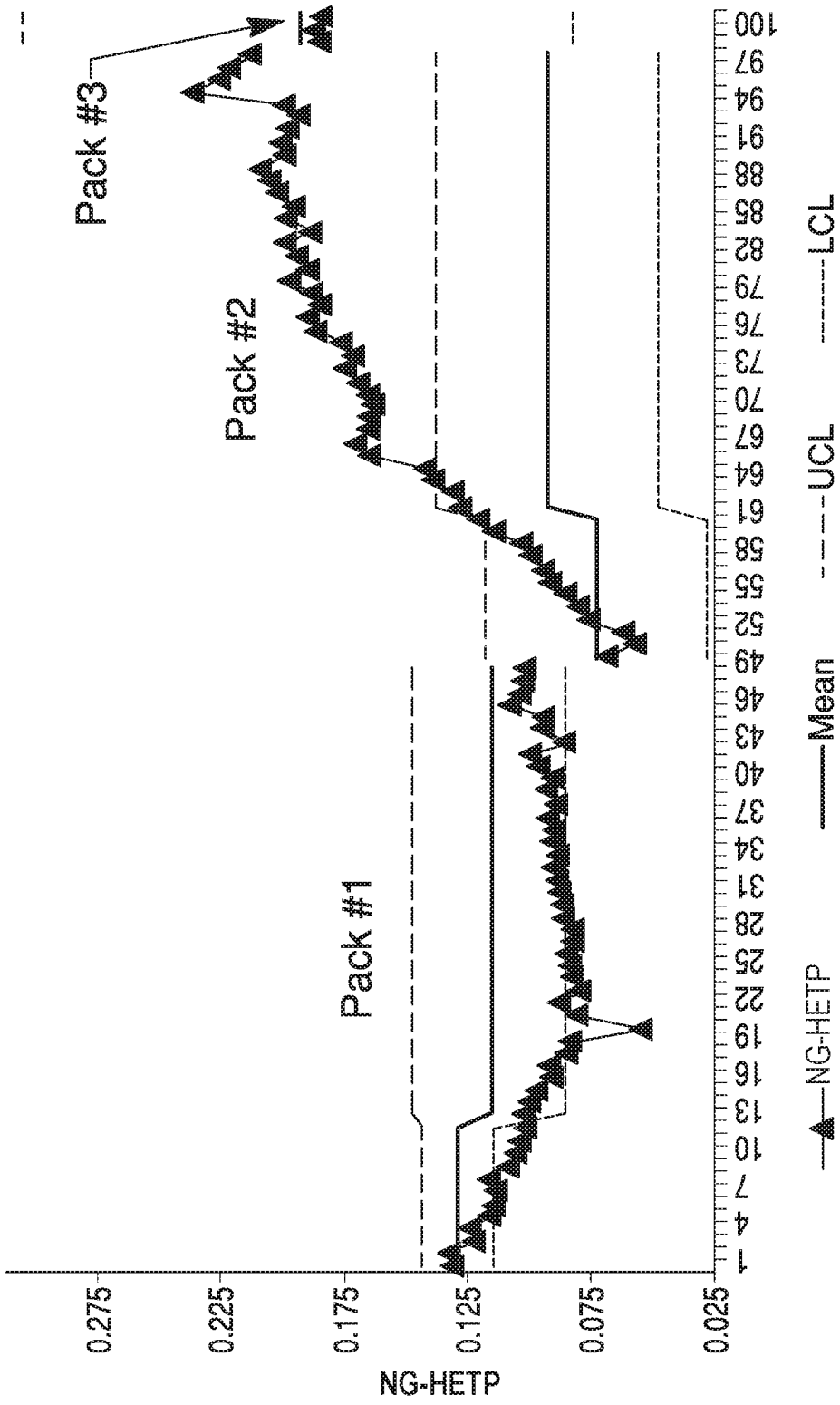

Pack #3
Pack #2
Pack #1
NG-HETP
0.275
0.225
0.175
0.125
0.075
0.025
1
4
7
10
13
16
19
22
25
28
31
34
37
40
43
46
49
52
55
58
61
64
67
70
73
76
79
82
85
88
91
94
97
100
NG-HETP
Mean
UCL
LCL

FIG. 18

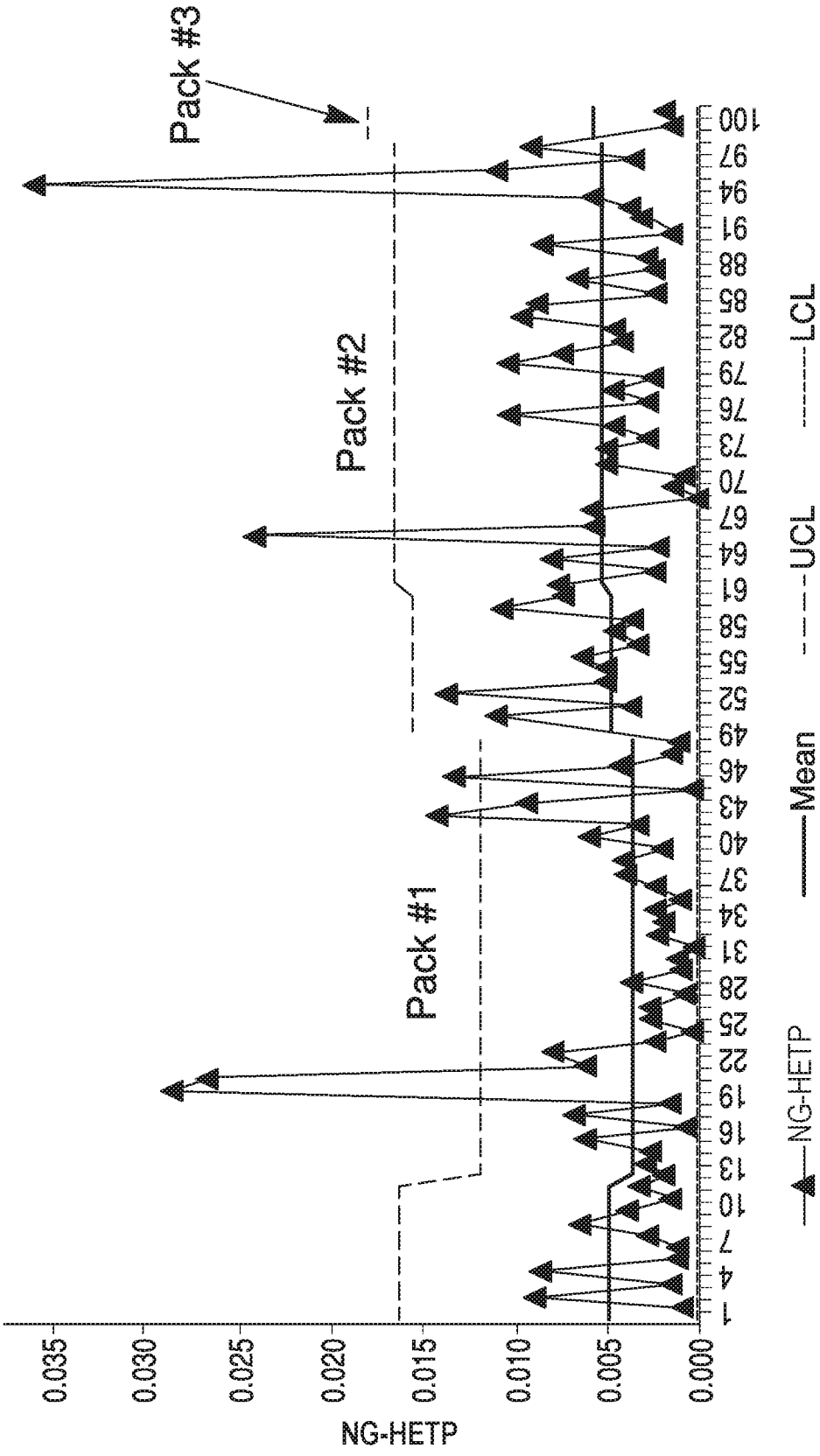

Pack #3
Pack #2
Pack #1
NG-HETP
0.035
0.030
0.025
0.020
0.015
0.010
0.005
0.000
1
4
7
10
13
16
19
22
25
28
31
34
37
40
43
46
49
52
55
58
61
64
67
70
73
76
79
82
85
88
91
94
97
100
NG-HETP
Mean
UCL
LCL

FIG. 19

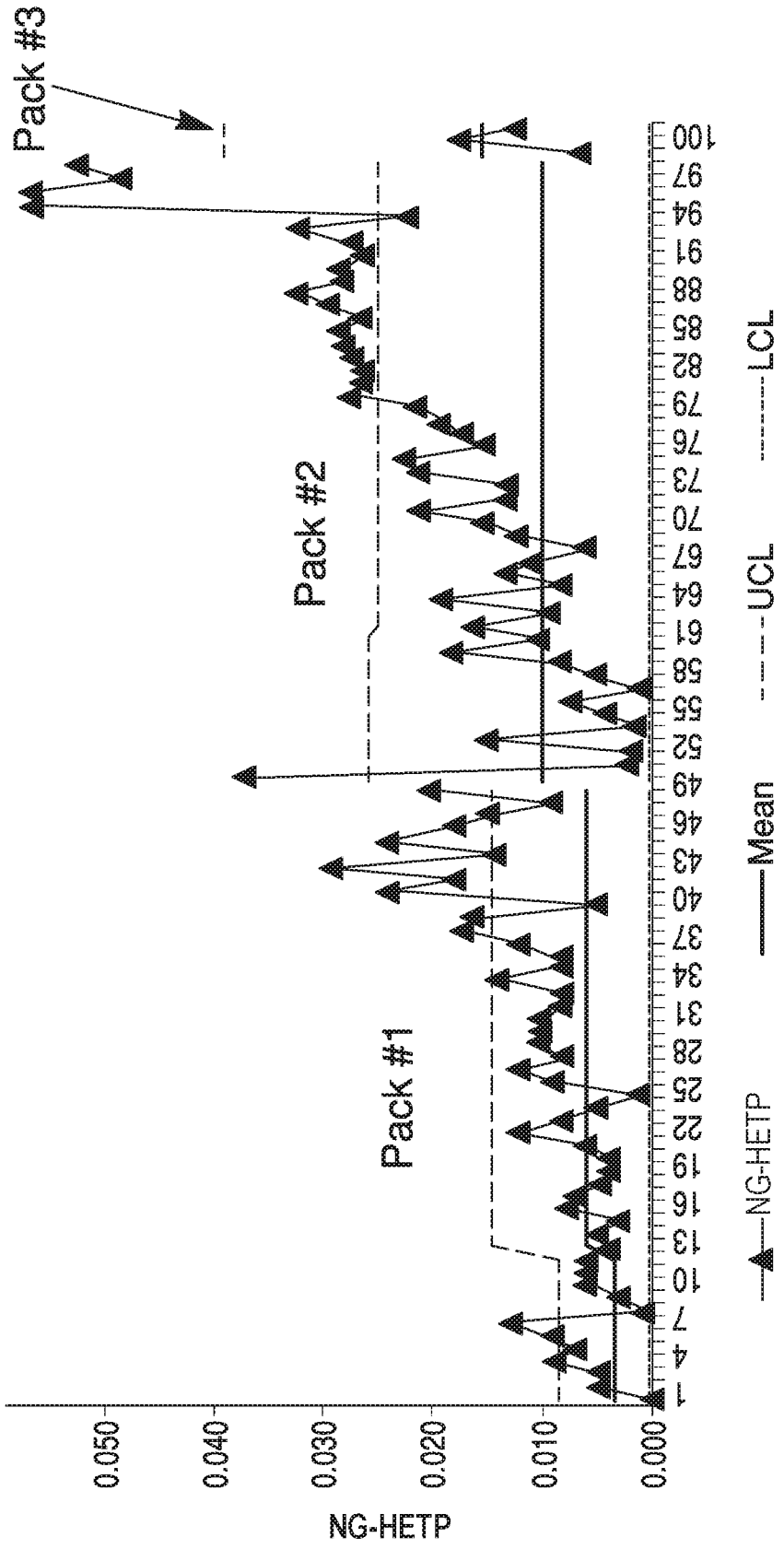

Pack #3
Pack #2
Pack #1
NG-HETP
0.050
0.040
0.030
0.020
0.010
0.000
1
4
7
10
13
16
19
22
25
28
31
34
37
40
43
46
49
52
55
58
61
64
67
70
73
76
79
82
85
88
91
94
97
100
NG-HETP
Mean
UCL
LCL

FIG. 20

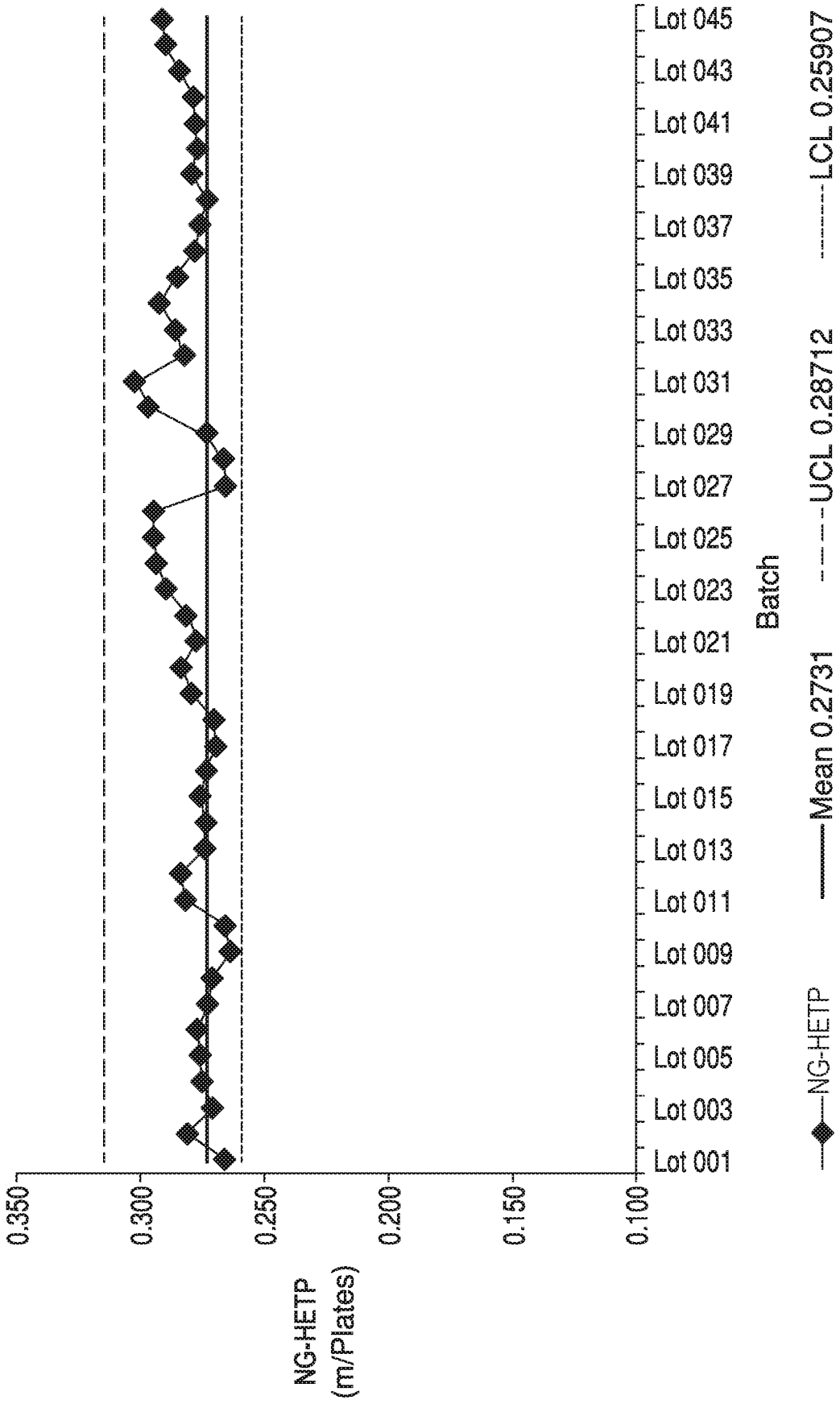

0.350
0.300
0.250
0.200
0.150
0.100
NG-HETP (m/Plates)
Lot 001
Lot 003
Lot 005
Lot 007
Lot 009
Lot 011
Lot 013
Lot 015
Lot 017
Lot 019
Lot 021
Lot 023
Lot 025
Lot 027
Lot 029
Lot 031
Lot 033
Lot 035
Lot 037
Lot 039
Lot 041
Lot 043
Lot 045
Batch
NG-HETP
Mean 0.2731
UCL 0.28712
LCL 0.25907

FIG. 21

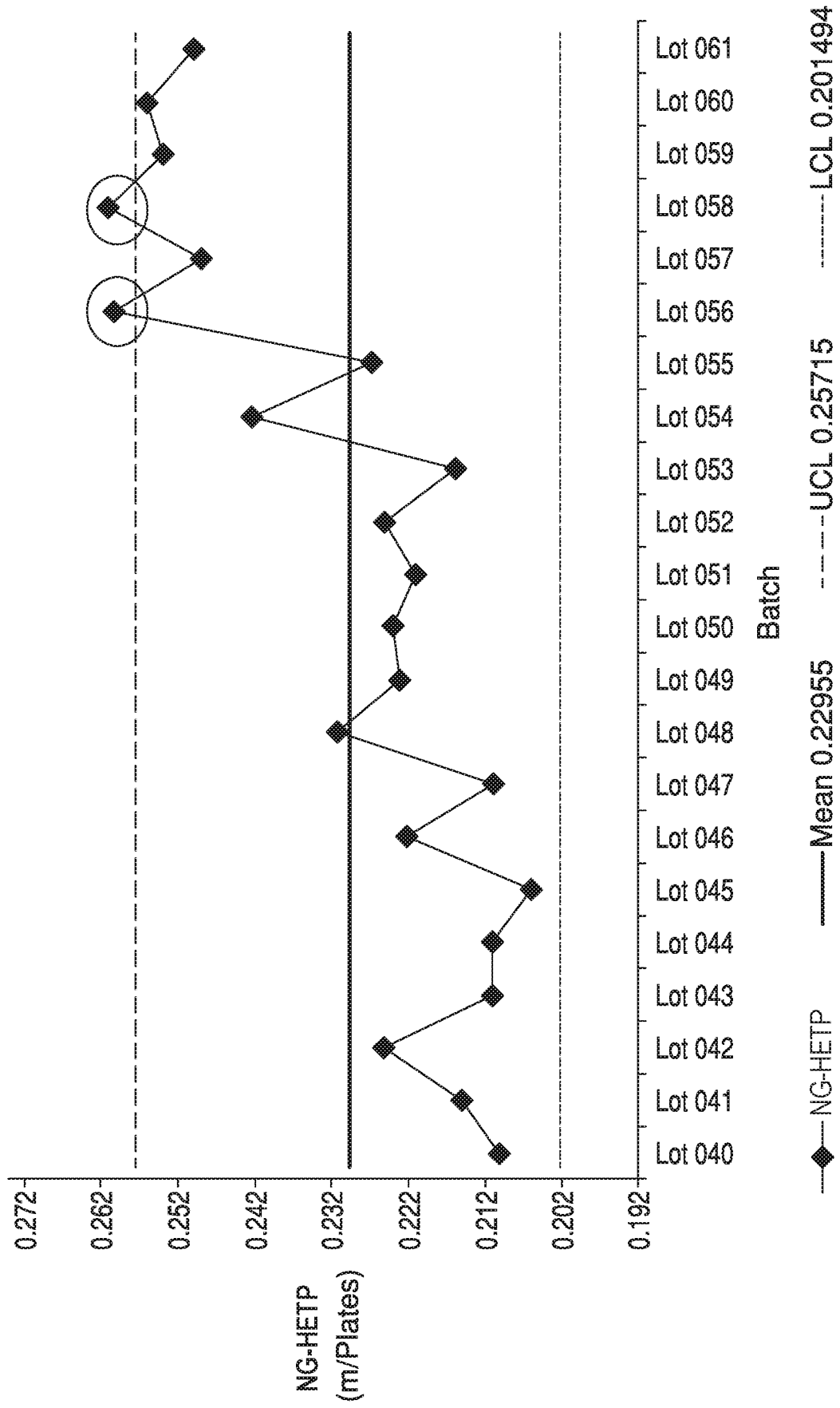

NG-HETP (m/Plates)
0.272
0.262
0.252
0.242
0.232
0.222
0.212
0.202
0.192
Lot 061
Lot 060
Lot 059
Lot 058
Lot 057
Lot 056
Lot 055
Lot 054
Lot 053
Lot 052
Lot 051
Lot 050
Lot 049
Lot 048
Lot 047
Lot 046
Lot 045
Lot 044
Lot 043
Lot 042
Lot 041
Lot 040
Batch
NG-HETP
Mean 0.22955
UCL 0.25715
LCL 0.201494

FIG. 22

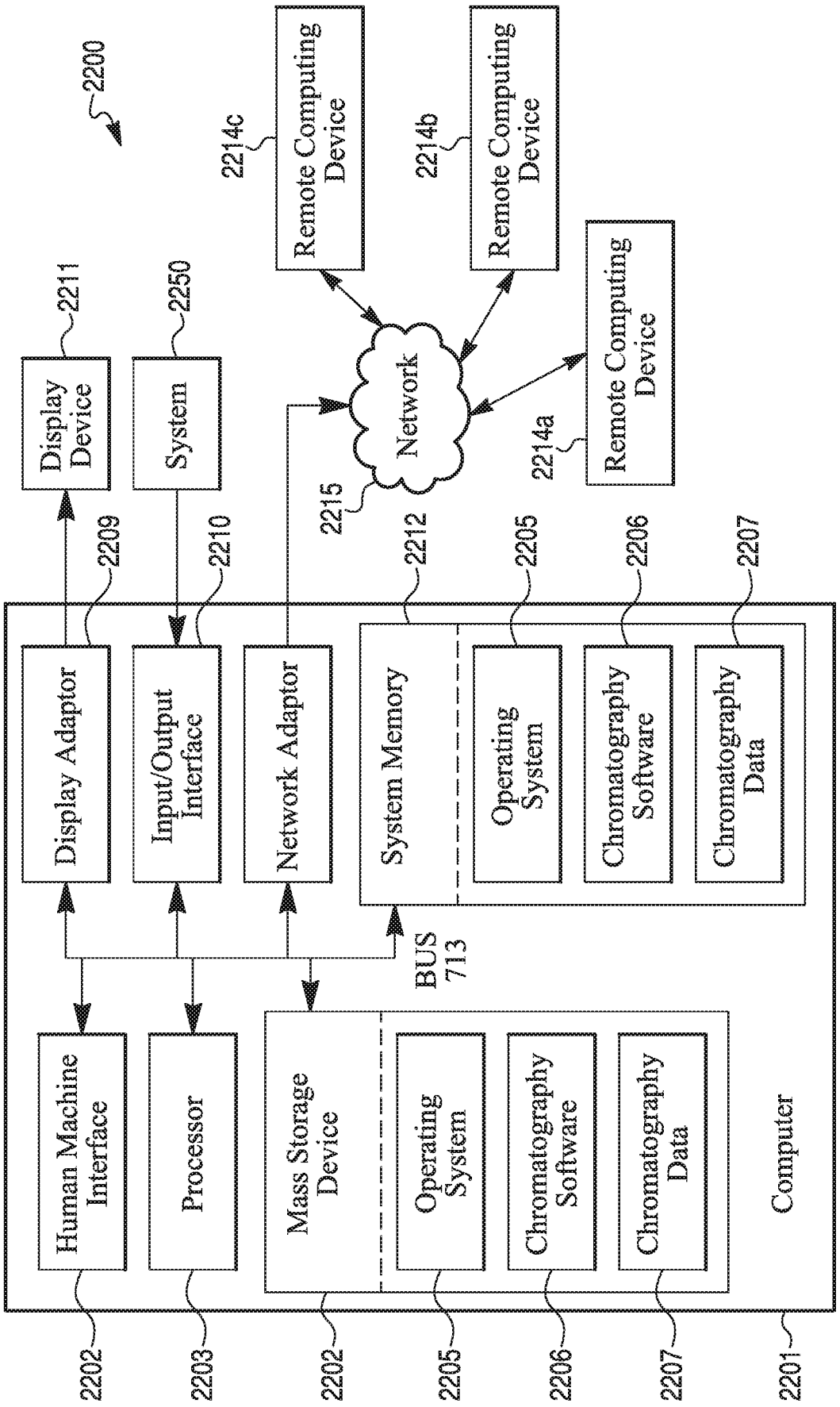
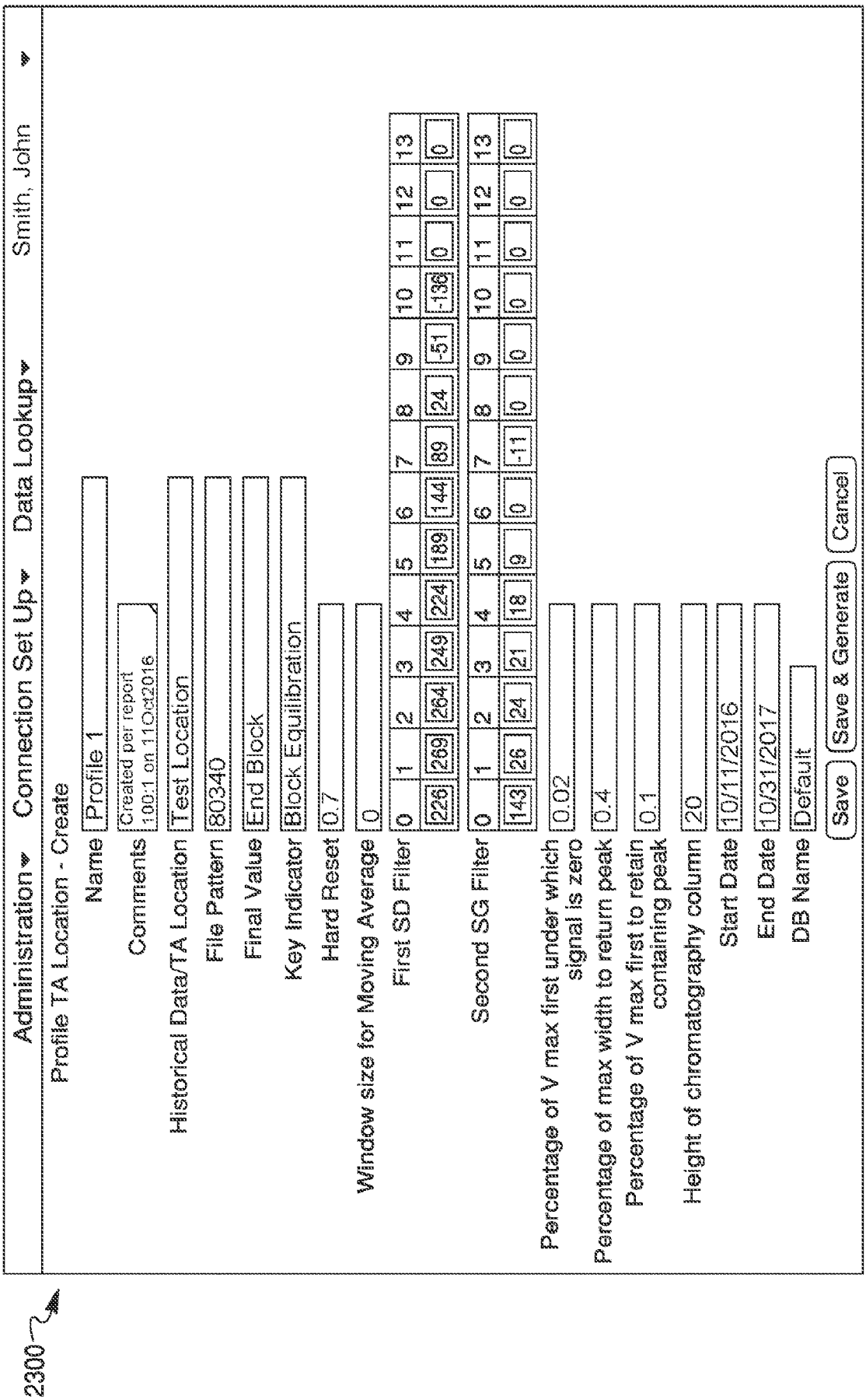

2200
2214c
Remote Computing Device
2214b
Remote Computing Device
2214a
Remote Computing Device
2211
Display Device
2250
System
2215
Network
2209
2210
2212
2205
2206
2207
Display Adaptor
Input/Output Interface
Network Adaptor
System Memory
Operating System
Chromatography Software
Chromatography Data
BUS 713
Human Machine Interface
Processor
Mass Storage Device
Operating System
Chromatography Software
Chromatography Data
Computer
2202
2203
2202
2205
2206
2207
2201

FIG. 23


2300
Administration
Connection Set Up
Data Lookup
Smith, John
Profile TA Location - Create
Name
Profile 1
Comments
Created per report 100:1 on 11Oct2016
Historical Data/TA Location
Test Location
File Pattern
80340
Final Value
End Block
Key Indicator
Block Equilibration
Hard Reset
0.7
Window size for Moving Average
0
First SD Filter
0 1 2 3 4 5 6 7 8 9 10 11 12 13
226 269 264 249 224 189 144 89 24 -51 -136 0 0 0
Second SG Filter
0 1 2 3 4 5 6 7 8 9 10 11 12 13
143 26 24 21 18 9 0 -11 0 0 0 0 0 0
Percentage of V max first under which signal is zero
0.02
Percentage of max width to return peak
0.4
Percentage of V max first to retain containing peak
0.1
Height of chromatography column
20
Start Date
10/11/2016
End Date
10/31/2017
DB Name
Default
Save
Save & Generate
Cancel

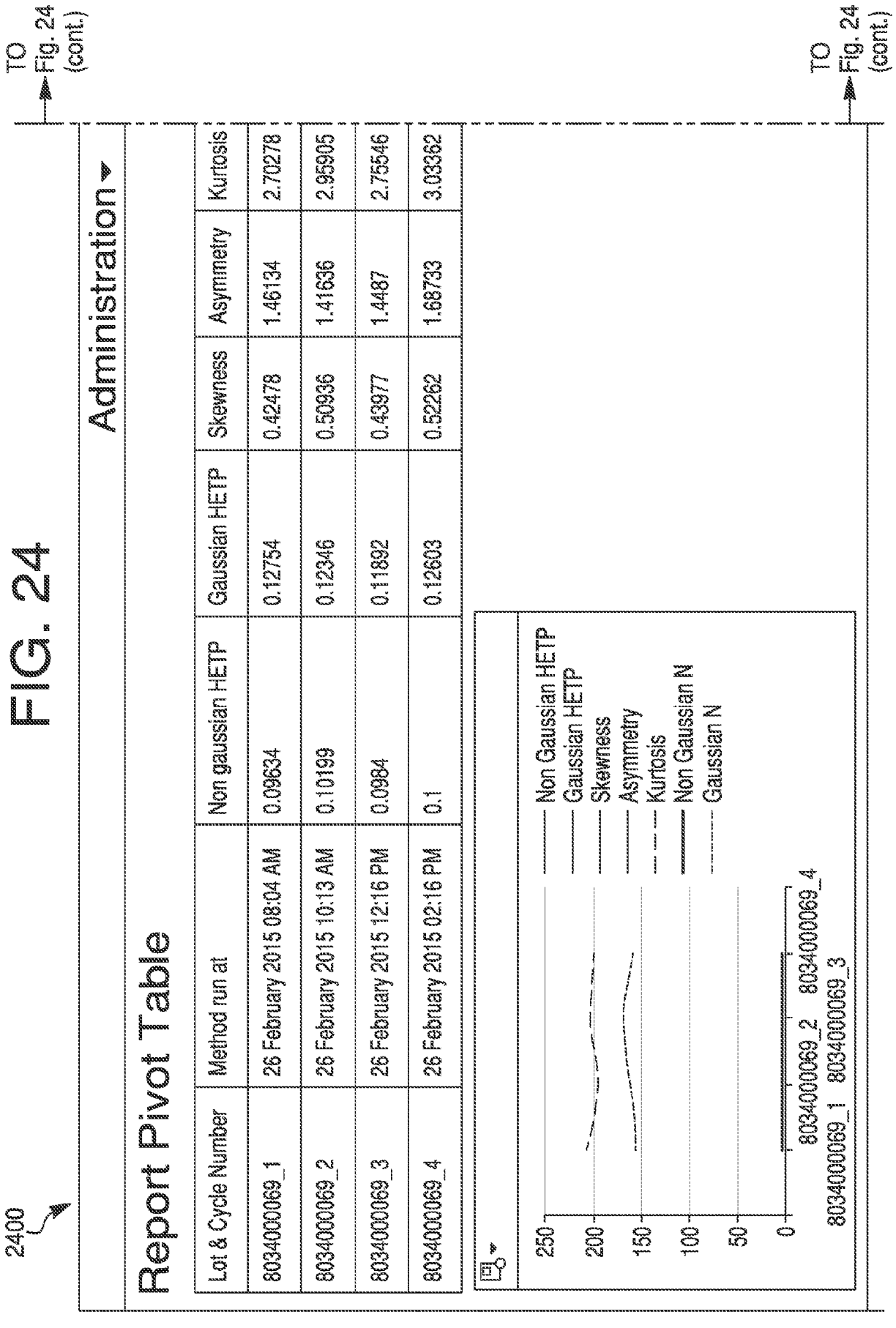
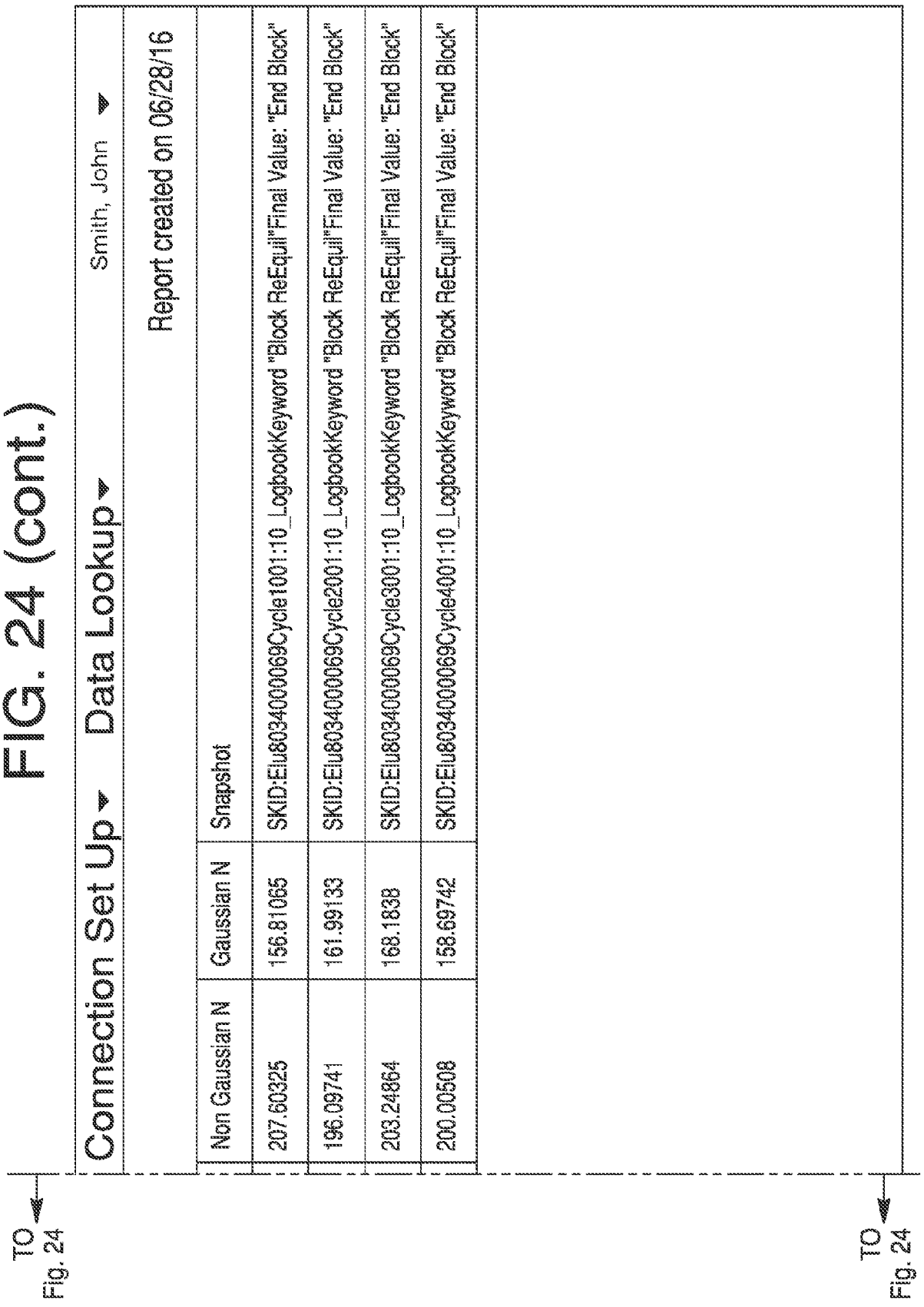

2400
TO Fig. 24 (cont.)
Administration
Report Pivot Table
Lot & Cycle Number
Method run at
Non gaussian HETP
Gaussian HETP
Skewness
Asymmetry
Kurtosis
8034000069_1
26 February 2015 08:04 AM
0.09634
0.12754
0.42478
1.46134
2.70278
8034000069_2
26 February 2015 10:13 AM
0.10199
0.12346
0.50936
1.41636
2.95905
8034000069_3
26 February 2015 12:16 PM
0.0984
0.11892
0.43977
1.4487
2.75546
8034000069_4
26 February 2015 02:16 PM
0.1
0.12603
0.52262
1.68733
3.03362
250
200
150
100
50
0
8034000069_1
8034000069_2
8034000069_3
8034000069_4
Non Gaussian HETP
Gaussian HETP
Skewness
Asymmetry
Kurtosis
Non Gaussian N
Gaussian N
TO Fig. 24 (cont.)

FIG. 24

FIG. 24 (cont.)


TO Fig. 24
Connection Set Up
Data Lookup
Smith, John
Report created on 06/28/16
Non Gaussian N
Gaussian N
Snapshot
207.60325
156.81065
SKID:Elu8034000069Cycle1001:10_LogbookKeyword "Block ReEquil"Final Value: "End Block"
196.09741
161.99133
SKID:Elu8034000069Cycle2001:10_LogbookKeyword "Block ReEquil"Final Value: "End Block"
203.24864
168.1838
SKID:Elu8034000069Cycle3001:10_LogbookKeyword "Block ReEquil"Final Value: "End Block"
200.00508
158.69742
SKID:Elu8034000069Cycle4001:10_LogbookKeyword "Block ReEquil"Final Value: "End Block"
TO Fig. 24