Hertzler Systems Inc.®
Turning Data into Knowledge

Statistical Qualifications Testing

Product QA/S GainSeeker® DMS
Version 6.200 and above
Date of origin February 7, 2001
Date of last edit October 14, 2021

This Statistical Qualifications test document is part of Hertzler Systems Inc. Master Validation and Verification Plan. Specifically it is the essential component of qualification testing for this product. QA/S GainSeeker® DMS software is a collection of programs which allow users to collect, manage and analyze defect data. At the heart of these programs is a collection of statistical calculations. According to ANSI/IEEE 1012-1986, qualification testing is formal testing designed to "demonstrate to the customer that the software meets its specified requirements." This Qualification Plan, therefore, will demonstrate to the customer that the software meets its specified requirements in the area of *statistical calculations.*

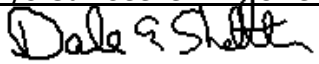
Hertzler established a baseline for statistical verification during the release for GainSeeker® DMS version 6.2. All statistical values produced by the software were identified and defined, and divided into four groups, as follows:

1. Six foundational values that form the core for most calculations performed by the program. These statistics were verified by an internal study conducted by Hertzler Systems Inc. staff. The statistics were then confirmed by using another statistical software package. The software package used to confirm these six values was MINITAB.
2. Two advanced statistical calculations that are very difficult to calculate. These are based on complex equations and they would be very difficult for the average user to validate. An internal study and comparison of values with those derived from another statistical software package validated these values. The software package used to validate these two values was MINITAB.
3. Statistical values that are derived from the six foundational values. These values are simple calculations. In most cases, error in these calculations would be obvious to both Hertzler staff and the customer. Because they are simple to verify, we have made no attempt to further verify these calculations. If customers wish to verify these for their own satisfaction, they will find the task time consuming but simple. With each revision, these values are compared with those calculated in previous versions to verify that the values have not changed.
4. Non-statistical values reported by the QA/S GainSeeker® DMS statistical engine. These values are simply reported settings or pass/fail conditions for other statistical values.

All four of these groups are identified in Appendix A.

This statistical list and groupings are referenced during the Requirements Phase of each GainSeeker® DMS development cycle. If product requirements/specifications are introduced with potential effect to the calculations portion of the code, the category of change is measured against which categories of statistics are affected in order to design a Statistical Qualifications Test Plan, which is then executed for that product release.

Product and Version: QA/S GainSeeker® DMS version 9.4.1

Signed: 

Title: Vice President of Product Development

Date: October 14, 2021

Appendix A

Group 1: Six foundational or difficult values validated by internal Hertzler Systems Inc. study and confirmed by another statistical software package

Internal Reference Number	Value	Description	Values used
14	Total Sample Size / Opportunities	Summation	Count
18	Total defects	Addition	Count
28	Total NCU	Addition	Count
312	LCL	Subtraction, Multiplication, Square Root	Mean, Total Sample Size
313	UCL	Subtraction, Multiplication, Addition, Square Root	Mean, Total Sample Size
314	Mean	Summation, Division	Count

Group 2: Two advanced statistical values validated by internal Hertzler Systems Inc. study and confirmed by another statistical software package

Internal Reference Number	Value	Description	Values used
23	Defect sigma	Logarithm, Interpolation	Total DPM
33	NCU Sigma	Logarithm, Interpolation	Total PPM

Group 3: Simplistic statistical values that do not normally undergo specific testing

Internal Reference Number	Value	Description	Values used
15	% zero values	Division, Multiplication	Count
16	Maximum value	Sort	Count
17	Minimum value	Sort	Count
19	Total defects cost	Addition, Multiplication	Total defects, Cost
20	Total sample cost	Addition, Multiplication	Count, Cost
21	% defects	Division, Multiplication	Total defects, Total Sample Size
22	% good samples	Division, Multiplication, Subtraction	Total defects, Total Sample Size
24	Total DPB/DPBO	Division, Multiplication	Total defects, Total Sample Size
25	Total DPM/DPMO	Division, Multiplication	Total defects, Total Sample Size
29	Total DPK/DPKO	Division, Multiplication	Total defects, Total Sample Size
30	Total PPK	Division, Multiplication	Total NCU, Total Sample Size
31	Total PPM	Division, Multiplication	Total NCU, Total Sample Size
32	Total PPB	Division, Multiplication	Total NCU, Total Sample Size
34	% NCU	Division, Multiplication	Total NCU, Total Sample Size
35	% good units	Division, Multiplication, Subtraction	Total NCU, Total Sample Size
37	Yield	Division, Multiplication, Subtraction	Total NCU, Total Sample Size
38	Total good units	Subtraction	Total NCU, Total Sample Size
39	Total good samples	Addition	Count
40	Total NCU cost	Addition, Multiplication	Total NCU, Cost
51	Cumulative Yield	Division, Multiplication, Subtraction	Total NCU, Total Sample Size
66	Total Samples NCU > 0	Addition	Count
67	% Samples NCU > 0	Addition, Division	Count
68	Bypassed Samples	Addition	Count
75	OEE Availabliity	Division	OEE SUM Downtime
76	OEE Quality	Division	OEE Sum (Good * Cycle Time), OEE Sum (Total * Cycle Time)
77	OEE Performance	Division, Multiplication	OEE Sum (Good * Cycle Time), OEE Sum Available Time, OEE Sum Scheduled Time
78	OEE	Mulitiplication	OEE Availability, OEE Quality, OEE Performance
79	OEE Sum Available Time	Addition	Available time
80	OEE Sum Scheduled Time	Addition	Scheduled time
81	OEE Sum (Good * Cycle Time)	Addition, Multiplication	Good parts, Cycle time
82	OEE Sum (Total * Cycle Time)		Total parts, Cycle time
92	OEE Sum Downtime	Addition, Multiplication	OEE Sum Available Time, OEE Sum Available Time

101	Maximum pareto category	Sort	Group by
102	Minimum pareto category	Sort	Group by
204	Maximum DPU group	Sort	Group by
205	Minimum DPU group	Sort	Group by
306	Nominal Gate	Addition, Division	Gate
307	Tolerance Gate	Addition, Division	Gate
308	% above Gate	Division, Multiplication	Count, Sort
309	% below Gate	Division, Multiplication	Count, Sort
310	% in Gate	Division, Multiplication	Count, Sort
311	% out of Gate	Division, Multiplication	Count, Sort
315	Maximum included	Division, Multiplication	Count, Sort
316	Minimum included	Division, Multiplication	Count, Sort
317	% above control	Division, Multiplication	Count, Sort
318	% below control	Division, Multiplication	Count, Sort
319	% in control	Division, Multiplication	Count, Sort
320	% out of control	Division, Multiplication	Count, Sort
322	Total excluded	Division, Multiplication	Count, Sort
323	Total included	Division, Multiplication	Count, Sort

Group 4: Non-statistical values reported by QA/S GainSeeker® DMS

Internal Reference Number	Value
0	Process Label
1	Part Number Label
2	Cost per unit
3	Opportunities per unit
4	Filter contents
5	Filter
6	High date/time queried
7	Low date/time queried
8	Defects in relation to
9	Cost from
10	Selected defects
11	High Date/Time retrieved
12	Low Date/Time retrieved
13	Number of samples
27	DPM method
36	Current date/time
41	Current date
42	Current time
43	High date queried
44	High time queried
45	High date retrieved
46	High time retrieved
47	Low date queried
48	Low time queried
49	Low date retrieved
50	Low time retrieved
53	Standard sample size
54	Date period
55	SQL query statement
56	Decimal places
57	Decimal places for cost
58	DPM best estimate
59	DPM conservative
60	DPM no zero
61	Show empty bars
62	Amount of time to display
63	Memo
64	Sum NCU
65	Total units
69	Last Process
70	Last Event
71	Last Sample Size
72	Last Sum Defects
73	Last Note
74	Last Part Number
84	OEE Acceptable value
85	OEE Acceptable Availability value
86	OEE Acceptable Performance value
87	OEE Acceptable Quality value
88	OEE Goal value
89	OEE Goal Availability value

90	OEE Goal Performance value
91	OEE Goal Quality value
93	Windows Login name
94	Retrieval name
100	Sort by
103	Drill-down conditions
200	Group by
201	Improvement start date
202	Improvement start value
203	Improvement Goal
206	Goal Yield
207	Acceptable Yield
300	Sample size constant
301	Data type
302	Exclude Outliers
303	Standardized
304	Lower Gate
305	Upper Gate
321	Chart in control
324	Default data type
325	Scale control data
326	Brushed data
327	External data

Statistical changes made between DMS version 7.7 and DMS version 8.4

1. Additional statistics have been added to report the Maximum Value and Minimum Value for DPM and Pareto analysis.
2. A new statistic was added for Cumulative Yield to the DMS Charts and Reports and Dynamic Reports modules.
3. The following new statistics were added to the Dynamic Reports module: Amount of time to display, Date period, Decimal places, Decimal places for cost, Default data type, Description, DPM best estimate, DPM conservative, DPM no zero, Maximum DPU group, Maximum Pareto category, Minimum DPU group, Minimum Pareto category. Memo, Scale control data, Show empty bars, SQL query statement, Standard Sample size, Sum NCU, Total Units.
4. The values for % above Control, % below Control, % in Control, and % out of Control used to always report zero when excluding outliers. In version 8, these values are reported the same for both including and excluding outliers.
5. The statistics that report percentages changed to report the value to two decimal places.
6. The Chart type statistic (# 26) was removed in the Dynamic Reports.
7. Several statistic labels were changed for capitalization or to make the label more clear.
8. Several statistic values changed from True/False to Yes/No and from Not Set to Not set.
9. There is a new statistic for Control chart scaling in Dynamic Reports. The value of this statistic can affect the following other statistics: Maximum included (#315), Maximum value (#16), Mean (#314), Minimum included (#316), Minimum value (#17), LCL (#312), UCL (#313), Lower gate (#304), Upper gate (#305)

Statistical changes made between DMS version 8.4 and DMS version 8.9

None.

Statistical changes made in DMS version 9.1

1. OEE can now be calculated with just one or two of the three OEE components (Availability, Performance, and Quality). Some reported OEE values may change if using this new setting to calculate OEE.

Statistical changes made between DMS version 9.2 and DMS version 9.3

None.

Statistical changes made in DMS version 9.3.2

1. Cost statistics can now be optionally displayed without a currency symbol. Reported cost values will change if this new option is turned on.

Statistical changes made between DMS version 9.4 and DMS version 9.4.1

None.