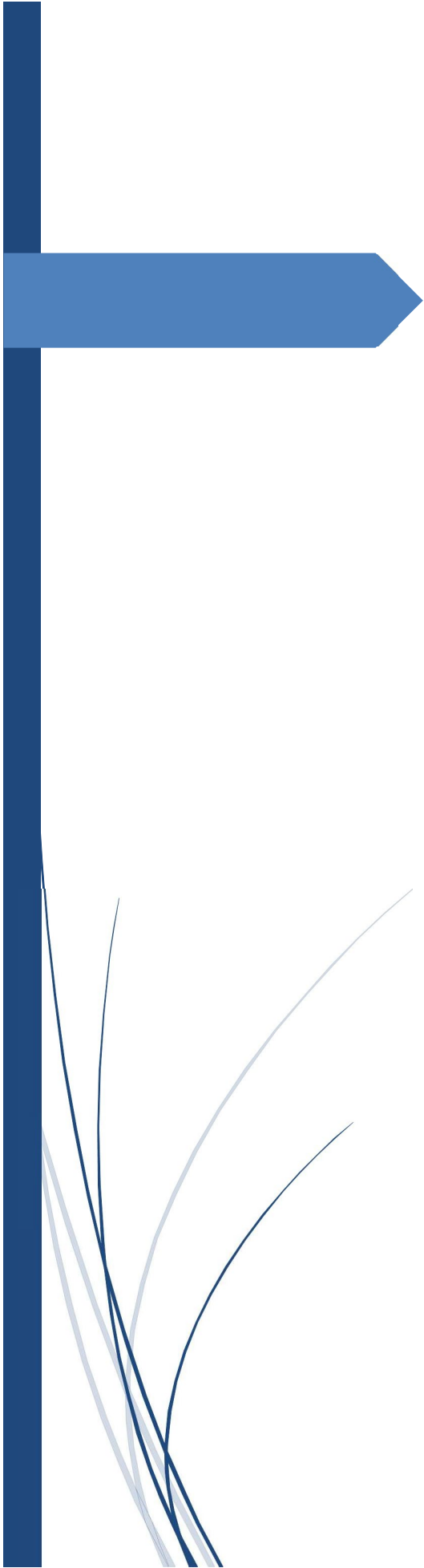




SigmaPlot v16 and SigmaStat v4

SigmaPlot Compliance: FDA Title 21 CFR Part 11

Grafiti SAVES

STATISTICAL ANALYTICS AND VISUALIZATION FOR ENGINEERING
AND SCIENCE



Table of Contents

Contents

<i>Table of Contents</i>	1
SigmaPlot 16 & SigmaStat 4.0 Development and Testing Procedures	2
Description of SigmaPlot	2
<i>New Features and Improvements Implemented in SigmaPlot 16</i>	2
<i>New Graph Type (Via a Macro)</i>	2
<i>UI Modifications for Improved User Experience</i>	2
<i>Analysis Features</i>	3
<i>Miscellaneous Items</i>	3
Description of SigmaStat	3
<i>New Features and Improvements Implemented in SigmaStat 4.0</i>	3
Software Methodology	5
Programming Languages Used	5
Development Tools Used	5
Product Compatibility	5
Software Quality Assurance	6
Test Procedures	6
Applications Used for Verification	6
Hardware and Software Testing Platforms	7
Independent Verification and Validation	7

SigmaPlot 16 & SigmaStat 4.0 Development and Testing Procedures

Grafiti LLC is committed to developing state-of-the-art software that enhances and improves the quality of scientific research. Grafiti LLC is the only scientific software company that offers a full range of scientific and engineering tools designed to meet the special needs of research scientists and engineers. Below is a summary of the procedures used by Grafiti LLC for developing and assuring high quality software for SigmaPlot 16, SigmaStat 4.0 and related products.

Project: SigmaPlot v16 and SigmaStat v4 for Windows

Project Manager: Steve Rubenstein

Description of SigmaPlot

SigmaPlot goes beyond financially oriented spreadsheets and the "bells and whistles" of business graphing software by making technical features the highest priority. A user can choose from a full range of graphing options: technical axis scales, multiple axes, multiple intersecting 3D graphs, and much more.

SigmaPlot offers an intuitive Microsoft Office and Windows compatible interface. To start, users just need to click the graph type and style buttons on the Create Graph ribbon tab and select their data; SigmaPlot automatically creates a graph. For interactive graph creation, the Graph Wizard leads users quickly through each step. All graph attributes are customizable by double-clicking on the graph and choosing properties from the easy-to-read UI controls on the Graph Properties dialog box. To help users see complex interactions in their 3-D data, the program powerfully renders multiple intersecting 3-D graphs with hidden line removal. A Regression Wizard automatically determines initial parameters to help fit data.

New Features and Improvements Implemented in SigmaPlot 16

New Graph Type (Via a Macro)

- *Heat Map*

UI Modifications for Improved User Experience

- *The new and refreshed ribbon manager enhances the already commendable user experience in SigmaPlot.*
- *New Ribbons provide context sensitive feature groupings for enhanced functionality and ease of use.*
- *High Resolution Icons now have expanded tooltips containing hot keys.*

Analysis Features

- *You can now save result graph data with statistical reports.*
- *Option to revert to not saving result graph data with reports in case storage size becomes a problem. (Save result graph data with reports for anytime graph creation, turned on by default).*
- *Keep User Defined Transforms dialog up and running after pressing Run button.*
- *Option to dismiss UDT dialog after pressing Run button. Dismiss dialog after pressing the Run button, turned on by default.*

Miscellaneous Items

- *Changed clipboard format for Excel to CF_SYLK so numbers pasted from Excel have full precision.*
- *New and easy licensing system with the latest Sentinel Manager*
- *Hosted licensing service ensuring 24/7 uptime.*
- *Windows 11 compatibility and Server 2022 compatibility*
- *Removed older Microsoft VS 2005 Redistributable by removing Lead Tools and doing graph export using GDI +*

Description of SigmaStat

SigmaStat provides a wide range of powerful, yet easy-to-use statistical analyses specifically designed to meet the needs of research scientists and engineers.

With the features in the program, you are guided through the process of choosing the appropriate test to analyze your data, running the test, and interpreting the results in the test report.

For many tests, graphs are available to summarize the test results.

The editing features in the program allow you to customize the appearance of reports and graphs. Your results may be distributed using the large variety of file formats available for export.

New Features and Improvements Implemented in SigmaStat 4.0

- **Principal Components Analysis (PCA)** – Principal component analysis is a technique for reducing the complexity of high-dimensional data by approximating the data with fewer dimensions.
- **Analysis of Covariance (ANCOVA)** – Analysis of Covariance is an extension of ANOVA (Analysis of Variance) obtained by specifying one or more covariates as additional variables in the model.
- **Cox Regression** – This includes the proportional hazards model with stratification to study the impact of potential risk factors on the survival time of a population. The input data can be categorical.
- **One-Sample T-test** – Tests the hypothesis that the mean of a population equals a specified value.
- **Odds Ratio and Relative Risk tests** – Both tests the hypothesis that a treatment has no effect on the rate of occurrence of some specified event in a population. Odds Ratio is used in

retrospective studies to determine the treatment effect after the event has been observed. Relative Risk is used in prospective studies where the treatment and control groups have been chosen before the event occurs.

- Shapiro-Wilk Normality test – A more accurate test than Kolmogorov-Smirnov for assessing the normality of sampled data. Used in assumption checking for many statistical tests but can also be used directly on worksheet data.
- New Result Graph – ANOVA Profile Plots: Used to analyze the main effects and higher-order interactions of factors in a multi-factor ANOVA design by comparing averages of the least square means.
- New Probability Transforms – Thirty-four new functions have been added to SigmaStat's Transform language for calculating probabilities and scores associated with distributions that arise in many fields of study.
- New Interface Change – Nonlinear Regression: An easy-to-use wizard interface and more detailed reports.
- New Interface Change – Quick Transforms: An easier way of performing computations in the worksheet.
- New Interface Change – New User Interface: Allows the user to work more easily with Excel worksheets.
- Yates correction added to the Mann-Whitney test – Yates correction for continuity, or Yates chi-square test is used when testing for independence in a contingency table when assessing whether two samples of observations come from the same distribution.
- Improved Error Messaging – Improved error messages have added information when assumption checking for ANOVA has failed.
- Deming Regression – Deming regression allows for errors in both X and Y variables – a technique for method comparison where the X data is from one method and the y data the other. The Deming regression method extends the normal linear regression, where the X values are error-free, to the case where both X and Y (both methods) have error. Hypotheses can then be tested, slope different from for example, to determine if the methods are the same. For example, it might be used to compare two instruments designed to measure the same substance or to compare two algorithmic methods of detecting tumors in images. The graph compares the two methods to determine if they are different or the same. A report gives statistical results.
- Akaike Information Criterion (AICc) – The Akaike Information Criterion is now available in nonlinear regression reports. It is a goodness of fit criterion that also accounts for the number of parameters in the equation. It also is valid for non-nested equations that occur, for example, in enzyme kinetics analyses.
- New Probability Functions for Nonlinear Regression – A total of twenty-four probability functions have been added to the curve fit library. Automatic initial parameter estimates equations have been created for each.
- Nonlinear Regression Weighting – There are now seven different weighting functions built into each nonlinear regression equation (3D are slightly different). These functions are reciprocal y, reciprocal y squared, reciprocal x, reciprocal x squared, reciprocal predicted, reciprocal predicted squared and Cauchy. The iteratively reweighted least squares algorithm is used to allow the weights to change during each nonlinear regression iteration.
- Multiple Comparison Test Improvements – Two important improvements have been made. P values for the results of nonparametric ANOVA have been added. These did not exist before. Also, multiple comparison P values were limited to discrete choices (0.05, 0.01, etc.). This limitation no longer exists and any valid P value may be used.

Software Methodology

Software functionality is segmented into features and bug fixes. The most difficult features were implemented first, so we had time to test them.

From start to finish, the product planning and development cycle includes:

1. Concept (marketing and feasibility)
2. Requirements (Statement of Requirements, SOR)
3. Design (external and internal specifications)
4. Planning (Creation of Microsoft Project file)
5. Development (Tracking of the project using Microsoft Project)
6. Testing and documentation of features for each build
7. Beta Testing
8. Product release

Programming Languages Used

- Visual C++, Microsoft Visual Basic

Development Tools Used

- Microsoft Visual Studio 2010 using Microsoft Foundation Classes version 9.
- Wise for Windows installer 6.0
- IBM/Rational ClearCase
- Elementool Bug Tracking System
- Oxygen 15.2
- MathType 6.9
- Fullshot 9.5.1.9

Product Compatibility

- Microsoft Windows 8 & 11
- MS Windows Vista
- Microsoft Office 2003 and up (paste to PowerPoint Slide, Insert Graphs into Word, and other macros)

- SPSS (up to ver. 19)
- IE 6 and up, for use with the SigmaPlot WebViewer

Software Quality Assurance

Grafiti LLC is committed to ensuring high quality software by using the SQA process, a planned and systematic set of activities that ensures that software processes and products conform to requirements, standards, and procedures. It includes the following disciplines:

- Quality assurance
- Quality engineering
- Verification and validation
- Error detection and reporting
- Error tracking, Corrective action and further error regression

Test Procedures

Manual tests are executed to exercise and evaluate SigmaPlot to demonstrate that it satisfies the specified requirements. These tests also identify differences between expected and actual results by using a broad set of test procedures.

Test procedures are derived from external specification documents and are guidelines to follow while testing the product.

The results of statistical procedures available in SigmaPlot and SigmaStat have been validated by using results in over fifteen published works and other statistical software applications, including SPSS, SPLUS, R, and SYSTAT. The comparative studies with other statistical software were used to validate over 250 results. A SigmaStat notebook of sample data sets for each statistical procedure is maintained and used to check the consistency of the statistical results in over 190 test configurations as our software is modified over time.

A SigmaPlot macro is used to run the NIST (National Institute of Standards and Technology) nonlinear regression equations and data sets to compare to published results and our software results. The macro also has the capability to check the consistency of our software results over time as programming is modified. The NIST reference database consists of twenty-seven data sets and models with various degrees of difficulty and with various starting conditions to test the global behavior and accuracy of the nonlinear regression algorithms in SigmaPlot and SigmaStat.

Applications Used for Verification

- SYSTAT
- SigmaStat
- SPSS
- Adobe Photoshop
- Adobe Illustrator

- GS Tools
- Corel Draw
- MS Office products (Word, Access, Excel)
- R

Hardware and Software Testing Platforms

- SigmaPlot 16 is tested on the QA Lab on Pentium 4 and higher personal computer systems.
- SigmaPlot 16 is designed and verified to work properly with the following operating systems:
- Windows 8 to 11
- Windows Vista

Independent Verification and Validation

Grafiti LLC is committed to providing a beta testing process whereby the products of the software development life cycle phases are independently reviewed, verified, and validated by organizations that are completely independent of Grafiti LLC. Approximately 20 scientists and engineers have participated in beta testing of each release of SigmaPlot version 16 and SigmaStat version 4.0 and their feedback is invaluable for the increase of overall quality of the product.