



From: Stat-Ease, Inc.  
To: Whom it may concern  
Re: Design-Expert® Software, version 12 Validation

### **Statement on Design-Expert® Software, version 12 Validation Process**

Stat-Ease recognizes that our products must meet the needs and expectations of our customers. Some customers may want to obtain information on how we validate our software for market readiness, and may need information from us to help satisfy regulatory requirements. This document, and the accompanying Design-Expert® software version 12 Validation Manual, is intended to provide this information. The Design-Expert® software version 12 Validation Manual contains discussion of specific Design-Expert data files, documentation to recreate these files, printed output for manual comparison, and comparison files as needed from other software packages. The goal of the Validation Manual is to give the reader some insight into our rigorous validation procedures, as well as to provide a template for self-validation. You may choose to run the provided examples on your internal computer systems to fulfill your unique validation requirements.

#### ***Software Purpose:***

Design-Expert software is an off-the-shelf statistics package that allows technical professionals to create and analyze designed experiments (DOE). Key components of Design-Expert are its ease of use for the non-statistician and the depth of tools available for building DOE's and analyzing the resultant data. The standard designs include factorial, response surface and mixture designs. Data analysis is calculated using least squares regression via matrix algebra. Based on the data analysis, prediction equations are used to create graphical displays and may be used to run optimization scenarios.

#### ***Validation for Market Readiness:***

Stat-Ease, Inc. tests its software at each stage of product development, as well as before final release. During and after program development, data is exported from Design-Expert to independent statistics packages to verify statistics such as the ANOVA results and prediction equation coefficients. Calculations that cannot be replicated in other software packages are done by hand or computed calculation. (As a side note, although for some simple cases such as an orthogonal full factorial design, the ANOVA can be calculated by hand via the Yates algorithm, most of the calculations require regression via matrix manipulations. This is best done by software programs.)

Prior to shipment, each new update or upgrade is tested against a series of data files that rigorously test all aspects of the program. This testing consists of both internal and external testing procedures.

- a. Internal (White Box testing) – We have incorporated built-in testing for the math engine of Design-Expert. A series of test suites is run to exercise various extreme conditions of the program. Results are compared against known answers and differences flagged for manual examination.
- b. External (Black Box testing) – Each update or upgrade is also tested using an automated scripting program. These test scripts test not only the computational aspects of the program, but the user interface as well.



- c. Manual Testing – As specific problems are identified and fixed, we revisit those problems and manually try to reproduce them to confirm the solution. The test case may also be added to our automated test suite.
- d. Alpha Testing – During Alpha testing, a subset of the application is evaluated by internal users. Feedback is provided to the developers and changes are implemented as necessary.
- e. Beta Testing – External customers are asked to evaluate the pre-release product. Installation is tested on a variety of systems. Feedback is provided to the developers and changes are implemented as necessary. Some feedback may be used to develop future releases.
- f. Performance and Compatibility Testing – The software is evaluated for usage against the pre-determined system requirements. These include, but are not limited to, operating system, hardware configurations, and display settings. System requirements may be modified if needed.

***Final Release:***

A product is declared ready for release to the market when it has been accepted by both Stat-Ease's Program Development and Statistical Development groups. These groups must both be satisfied that the current state of the software will meet customer requirements based on the results of all testing. The tracking list of known program issues must be cleared in an approved manner.

***Final Statement:***

Stat-Ease wants to confirm its commitment to quality. We maintain validation records for all current versions of commercially released applications, including records of all modifications and issues found and addressed during the testing phase and subsequent deployment. These records are considered "Proprietary and Confidential" and are not made available to the general public.

*Martin Bezener*

Martin Bezener  
Stat-Ease, Inc.

November 25, 2019