

# **Quick Start**

**PASS  
Power Analysis  
and  
Sample Size  
System**

**Published by  
NCSS  
Dr. Jerry L. Hintze  
Kaysville, Utah**

# PASS Quick Start

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## About this manual

Congratulations on your purchase of the *PASS* package! *PASS* offers:

- Easy parameter entry.
- A comprehensive list of power analysis routines that are accurate and verified, yet are quick and easy to learn and use.
- Straightforward procedures for creating paper printouts and file copies of both the numerical and graphical reports.

Our goal is that with the help of this quick start manual, you will be up and running on *PASS* in less than one hour. **You should read the first eight chapters immediately.** After that, you will only need to refer to the chapters corresponding to the procedures you want to use. The discussion of each procedure includes one or more tutorials that will take you step-by-step through the tasks necessary to run the procedure.

I believe you will find that these user's guides provides a quick, easy, efficient, and effective way for first-time *PASS* users to get up and running.

I look forward to any suggestions you have to improve the usefulness of this manual and/or the *PASS* system. Meanwhile, good computing!

**Jerry Hintze, Author**

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# Preface

*PASS* (Power Analysis and Sample Size) is an advanced, easy-to-use statistical analysis software package. The system was designed and written by Dr. Jerry L. Hintze over the last fifteen years. Dr. Hintze drew upon his experience both in teaching statistics at the university level and in various types of statistical consulting.

The present version, written for 32-bit versions of Microsoft Windows (98, 2000, ME, NT, XP, etc.) computer systems, is the result of several iterations. Experience over the years with several different types of users has helped the program evolve into its present form.

NCSS maintains a website at [WWW.NCSS.COM](http://WWW.NCSS.COM) where we make the latest edition of *PASS* available for free downloading. The software is password protected, so only users with valid serial numbers may use this downloaded edition. We hope that you will download the latest edition routinely and thus avoid any bugs that have been corrected since you purchased your copy.

We believe *PASS* to be an accurate, exciting, easy-to-use program. If you find any portion which you feel needs to be changed, please let us know. Also, we openly welcome suggestions for additions and enhancements.

# Verification

All calculations used in this program have been extensively tested and verified. First, they have been verified against the original journal article or textbook that contained the formulas. Second, they have been verified against second and third sources when these exist.

# Table of Contents

## User's Guide - I

### Quick Start

- 1 Installation 1
- 2 Running PASS 7
- 3 PASS Home 11
- 4 Procedure Window 15
- 5 Output Window 33
- 6 Intro. to Power Analysis 41
- 7 Intro. to Proportions 51
- 8 Intro. to Means 55

### Proportions

#### One Proportion

- 100 Inequality
- 105 Non-Inferiority
- 110 Equivalence
- 115 Confidence Interval
- 120 Single-Stage Design
- 125 Two-Stage Design
- 130 Three-Stage Design
- 135 Post-Marketing Surveil.

#### Two Correlated Proportions

- 150 Inequality
- 155 Matched Case-Control
- 160 Non-Inferiority
- 165 Equivalence

#### Two Independent Proportions

- 200 Inequality
- 205 Inequality (Offset)
- 210 Non-Inferiority
- 215 Equivalence
- 220 Group Sequential
- 225 Mantel-Haenszel

#### Cluster-Randomized

- 230 Inequality
- 235 Non-Inferiority
- 240 Equivalence

#### Many Proportions

- 250 Chi-Square Test

### ROC Curves

- 260 One ROC Curve
- 265 Two ROC Curves

### References

### Index

## User's Guide - II

### Means

#### One-Mean

- 400 Inequality (Normal)
- 405 Inequality (Exponential)
- 410 Inequality (Simulation)
- 415 Non-Inferiority
- 420 Confidence Interval

#### Two Independent Means

- 430 Inequality (Normal)
- 435 Inequality (Exponential)
- 440 Inequality (Simulation)
- 445 Inequality - Ratios
- 450 Non-Inferiority – Diff's
- 455 Non-Inferiority - Ratios
- 460 Equivalence
- 465 Equivalence (Simulation)
- 470 Equivalence - Ratios
- 475 Group Sequential
- 480 Cluster Randomization

#### Two Correlated Means

- 490 Inequality (Simulation)
- 495 Equivalence (Simulation)

#### 2x2 Cross-Over

- 500 Inequality – Diff's
- 505 Inequality – Ratios
- 510 Non-Inferiority – Diff's
- 515 Non-Inferiority - Ratios
- 520 Equivalence – Diff's
- 525 Equivalence - Ratios

#### Higher-Order Cross-Over

- 530 Non-Inferiority – Diff's
- 535 Non-Inferiority - Ratios
- 540 Equivalence – Diff's
- 545 Equivalence - Ratios

### References

### Index

## User's Guide - III

### Many Means - ANOVA

- 550 One Way
- 555 One-Way (Simulation)
- 560 Factorial
- 565 Randomized Block
- 570 Repeated Measures

### Multiple Comparisons

- 575 Analytic
- 580 Pair-Wise (Simulation)
- 585 Trt. / Control (Sim.)
- 590 Contrast (Simulation)

### Multivariate Routines

- 600 Hotelling's T-Squared
- 605 MANOVA

### Simulation

- 630 Data Simulator

### Variance

- 650 One Variance
- 655 Two Variances

### Survival Analysis

- 700 Simple Log Rank
- 705 Advanced Log Rank
- 710 Group Sequential Log Rank

### Correlations

- 800 One Correlation
- 805 Two Correlations
- 810 Intraclass Correlation
- 815 Coefficient Alpha: 1
- 820 Coefficient Alpha: 2

### Regression

- 850 Cox Regression
- 855 Linear Regression
- 860 Logistic Regression
- 865 Multiple Regression
- 870 Poisson Regression

### Helps and Aids

- 900 Chi-Square Effect Size
- 905 Standard Deviation
- 910 Odds Ratio

### References

### Index



## CHAPTER 1

# Installation

## Before you install

### 1. Check system requirements

*PASS* runs on 32-bit Windows systems. This includes Windows 98, Windows ME, Windows NT 4.0, Windows 2000, and Windows XP. The recommended minimum system is a Pentium PC with 64 MB of memory.

*PASS* takes up about 80 MB of disk space. Once installed, *PASS* also requires about 20 MB of temporary disk space while it is running.

### 2. Find a home for *PASS*

Before you start installing, decide on a folder where you want to install *PASS*. By default, the setup program will install *PASS* in the NCSS97 (or NCSS2000) folder of your C drive. You may change this during the installation, but not after.

### 3. If you have a previous NCSS

*PASS* and *NCSS* have been combined into one physical program. Access to each program is controlled by separate serial numbers. If you have a serial number for *PASS*, but not for *NCSS*, *NCSS* will work as a demo for 30 days from the time the first procedure is accessed.

If *NCSS* is already installed on your system, instruct the installation program to place this new version in the same folder as your previous version (usually \Program Files\NCSS97). All appropriate files will be replaced.

## What install does

The installation procedure (Setup) creates the necessary folders and copies the *PASS/NCSS* program from the installation file, called SETUP.EXE, to those folders. The files in SETUP.EXE are compressed, so the installation program decompresses these files as it copies them to your hard disk.

The folders created by Setup are (either NCSS97 or NCSS2000 may be substituted below):

\NCSS97 (or your substitute folder) contains most of the program files.

\NCSS97\DATA contains the database files used by the tutorials. We recommend creating a sub-folder of this folder to contain the data for each project you work on. For example, you might create a folder called \NCSS\DATA\Project1.

\NCSS97\JUNK contains temporary files used by the program while it is running. Under normal operation, **PASS** will automatically delete temporary files. After finishing **PASS**, you can delete any files left in this folder.

\NCSS97\REPORT is the default folder in which to save your output. You can save the reports to any folder you wish.

\NCSS97\SETTINGS contains the files used to store your template files. These files are used by the **PASS** template system which is described in a later chapter.

\NCSS97\STS contains all labels, text, and online messages.

\NCSS97\PDF contains printable copies of the documentation in Acrobat PDF format.

Setup places a file called NCSS97.INI in your windows folder. This file contains all default settings, paths, and constants that are used by the system. This file is documented in README.WRI. The settings in this file may be viewed and edited by selecting Edit then Options from the spreadsheet menu.

## Installing PASS and NCSS

This section gives instructions for installing **PASS** and **NCSS** on your computer system. You must use the **NCSS/PASS** setup program to install **PASS** and **NCSS**. The files are compressed, so you cannot simply copy the files to your hard drive.

After running the Setup program, you should read the README.WRI file for late-breaking information before starting the program.

Follow these basic steps to install **PASS** on your computer system.

### **Step    Notes**

1. Make sure that you are using a 32-bit version of windows such as Windows 98, Windows Me, Windows NT 4.0, Windows 2000, or Windows XP.
2. If you are installing from a CD, insert the CD in the CD drive. The installation program should start automatically. If it does not, on the Start menu, select the Run command. Enter 'D:Setup'. You may have to substitute the appropriate letter for your CD drive if it is not D. If you are installing from a download, simply run the downloaded file (SETUP.EXE).
3. Once Setup starts, follow the instructions on the screen. **PASS** will be installed in the drive and folder you designate.

## If something goes wrong

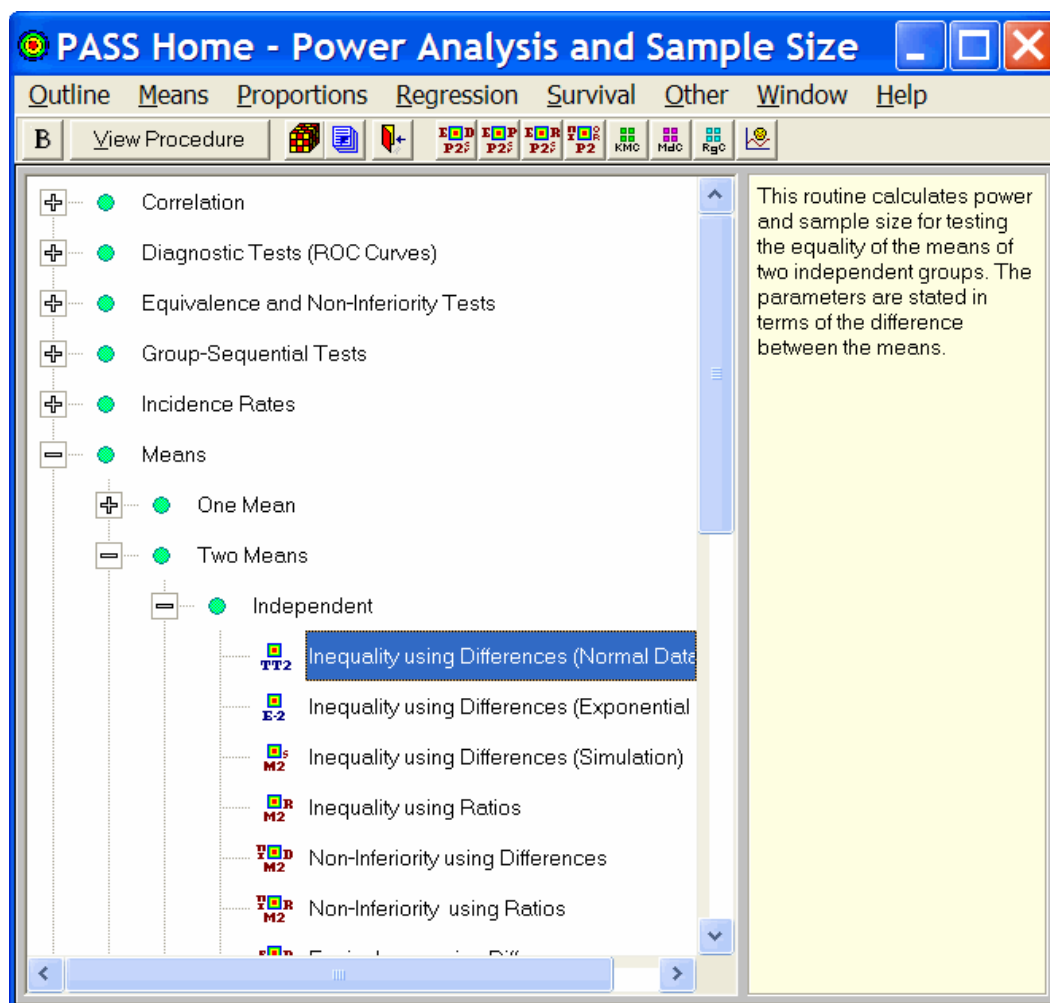
The installation procedure is automatic. If something goes wrong during installation, delete the \NCSS97 folder and start the installation process at the beginning. If trouble persists, contact our technical support staff as indicated below.



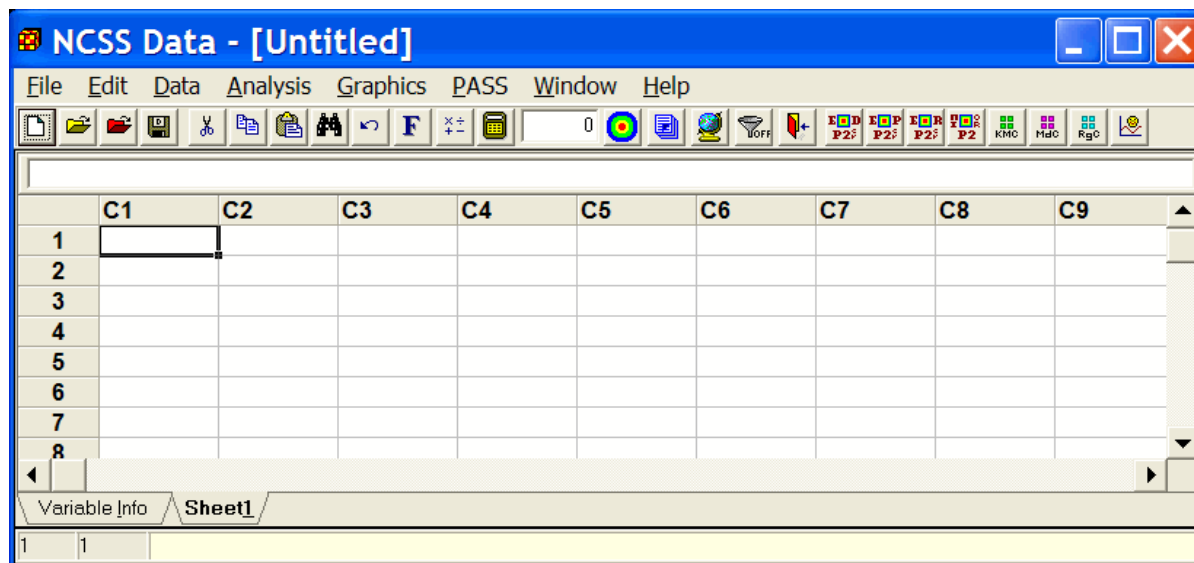
# Starting PASS

*PASS* may be started using your keyboard or your mouse using the same techniques that you use to start any other Windows application. You can start *PASS* by selecting *NCSS* from your Start menu using standard mouse or keyboard operations.

The first time you run *PASS*, enter your serial number in the pop-up window that appears when the program begins. If you have entered a serial number for *PASS* only (not for *NCSS*), the *PASS* Home window will appear.



If you have entered serial numbers for both *PASS* and *NCSS*, the *NCSS* spreadsheet window will appear.



To bring up the PASS Home window, click on the bull's-eye icon or select 'PASS Home' from the Window menu.

## Forcing the PASS Home screen to appear at startup

You can force the PASS Home window to appear when the program is run by taking the following steps:

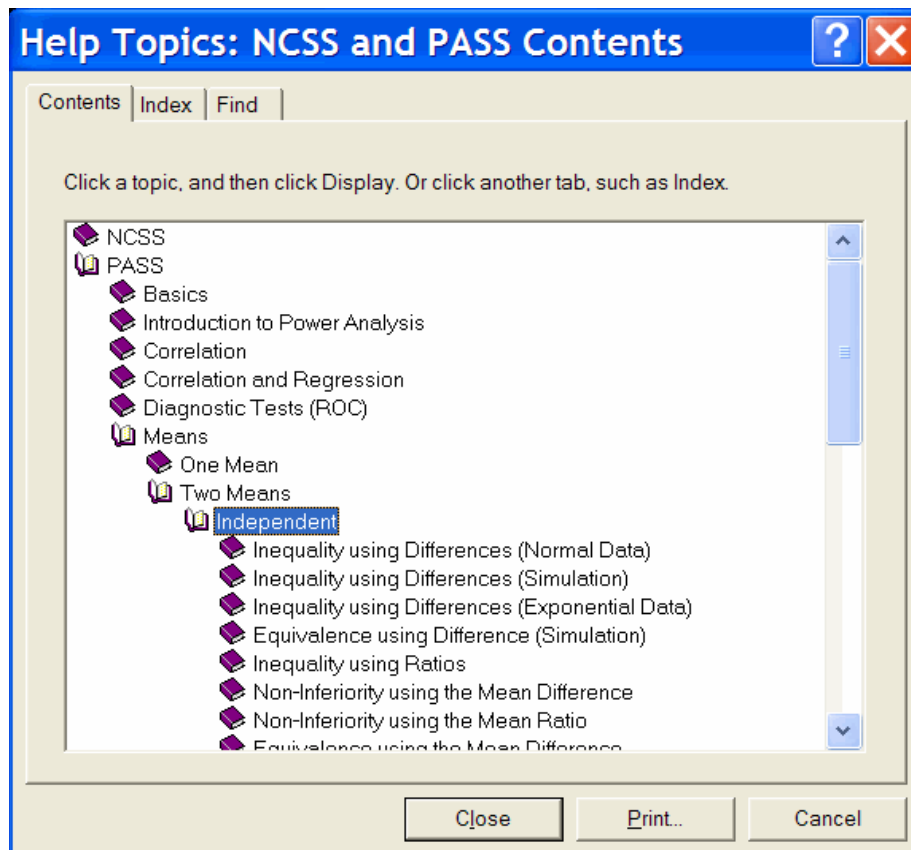
1. From the spreadsheet select Edit, then Options from the menus. Or, from the PASS Home window select Other, then Options from the menus.
2. Click on View tab.
3. Check the 'Show PASS Home Window' option.
4. Press the Ok button.

This will force the PASS Home window to appear first. You can view the spreadsheet at any time by clicking the yellow and orange dice icon or by selecting 'Data (Spreadsheet)' from the Window menu.

# Obtaining Help

## Online Help

To help you learn and use *PASS* efficiently, the material in the manuals is included in an online help system. To access this help system, select Help from the Help menu. When the help system is displayed, press the 'Contents' button at the top left of the window. This will display the following window with which you can browse the help system.



## Using Help

There are a few key features of our help system that, if you understand, will let you use the online help more efficiently. First, the Contents button brings up the table of contents of the help system. Use the Contents button to quickly navigate through the Help system. Second, each chapter was designed to be easily navigated. You can then proceed through a chapter section by section using the period and comma keys on your keyboard. Finally, you can use the Index and Find buttons to bring up an index of subjects.

## Printing Documentation

Obtaining a printed copy of the documentation is easy. Select 'View PDF File' from the Help menu. This will load and display the appropriate PDF file. From there, you can easily print a copy.

## Technical Support

To help us answer your questions more accurately, we may need to know about your computer system. Please have pertinent information about your computer and operating system available.

You can contact our technical support by calling **(801) 546-0445** between 8 a.m. and 5 p.m. (MST). You can contact us by email at **support@ncss.com**. Our goal is to respond to email within 24 hours.

## CHAPTER 2

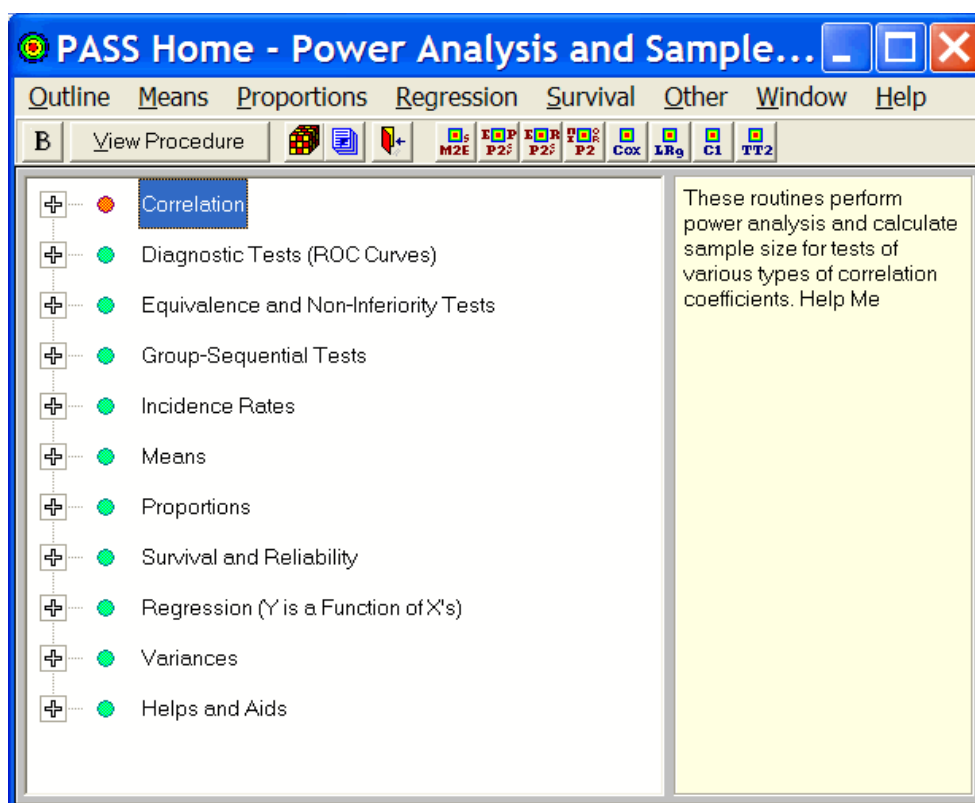
# Running PASS

## About this chapter

This chapter will show you how to start up and run a power analysis of the two-sample  $t$  test. It will give you a brief introduction to the windows used in *PASS*: the *PASS Home* window, the *procedure* window, and the *output* window.

## Starting *PASS*

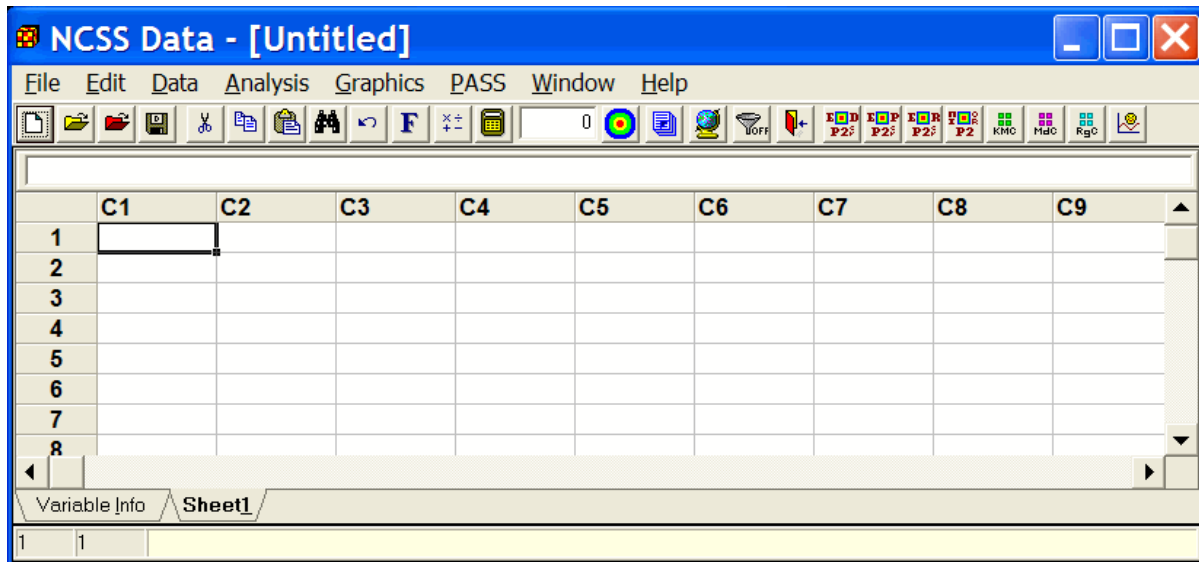
To start *PASS*, select *NCSS-PASS* from the Windows Start menu or double-click the *NCSS/PASS* icon. If you are licensed for *PASS*, but now for *NCSS*, the following *PASS Home* window will appear.



This window gives you access to all of the *PASS* procedures. Clicking on the plus sign or double-clicking on a phrase will expand the list so that you can see the procedures in that group. To load a specific procedure window, double-click on it or highlight it and click the View Procedure button.

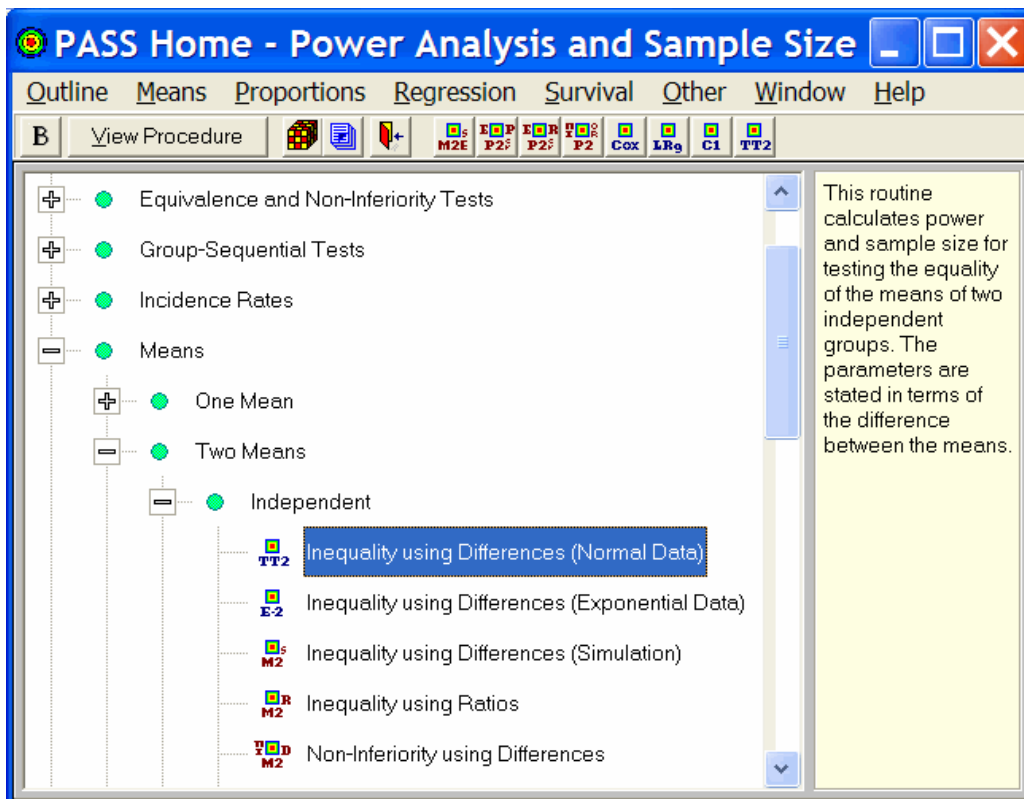
## 8 Running PASS

If you have previously installed *NCSS*, the *NCSS Data* window will appear first.



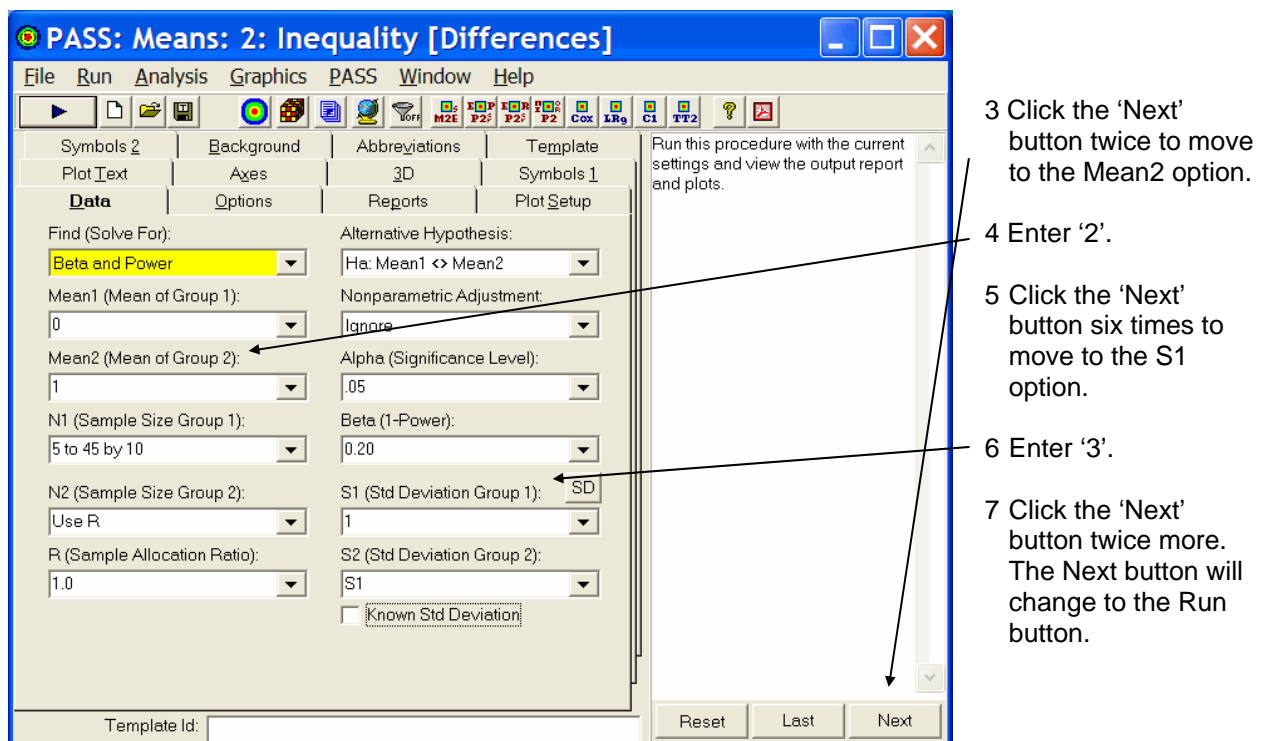
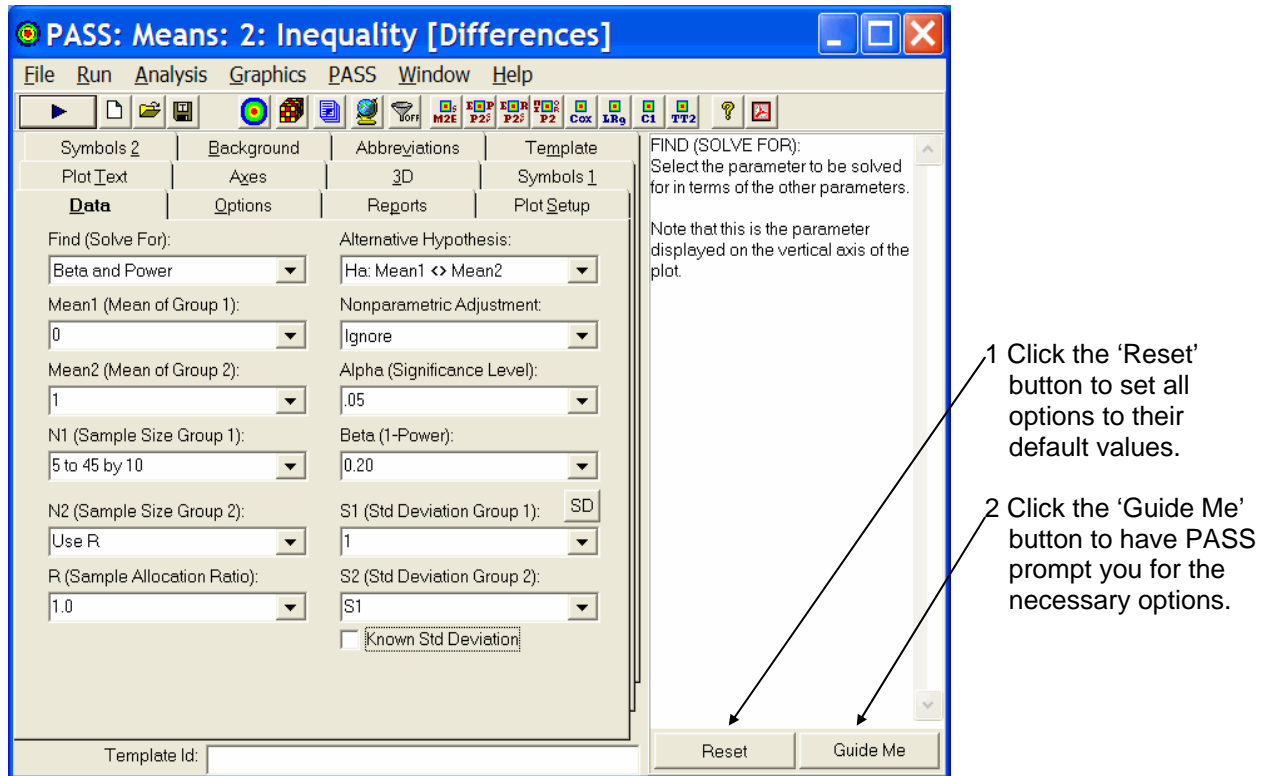
To bring up the PASS Home window, click on the bull's-eye icon or select 'PASS Home' from the Window menu.

The two-sample t-test is a procedure to test the inequality of two means from independent samples. Take the following steps to load this procedure. Expand the Means topic by double-clicking on the word 'Means'. Drilling down, double-click on 'Two Means', and then on 'Independent'. The first topic in the list is 'Inequality using Differences (Normal Data)'. This is the two-sample t-test. Double-click it.



The 'PASS: Means: 2: Inequality [Differences]' window will appear. Procedure windows let you specify, save, load, edit, and run an analysis.

We will run a power analysis using the default values except that the value of Mean2 will be 2 and the value of S1 will be 3.



## 10 Running PASS

The completed window will appear as follows.

**PASS: Means: 2: Inequality [Differences]**

File Run Analysis Graphics PASS Window Help

Symbols 2 Background Abbreviations Template  
Plot Text Axes 3D Symbols 1  
Data Options Reports Plot Setup

Find (Solve For): Beta and Power  
Mean1 (Mean of Group 1): 0  
Mean2 (Mean of Group 2): 2  
N1 (Sample Size Group 1): 5 to 45 by 10  
N2 (Sample Size Group 2): Use R  
R (Sample Allocation Ratio): 1.0  
Alternative Hypothesis: Ha: Mean1 <> Mean2  
Nonparametric Adjustment: Ignore  
Alpha (Significance Level): .05  
Beta (1-Power): 0.20  
S1 (Std Deviation Group 1): SD  
S2 (Std Deviation Group 2): S1  
☐ Known Std Deviation

Template Id: \_\_\_\_\_

Reset Last Run

S2 (Std Deviation):  
Enter an estimate of the standard deviation of group 2. The standard deviation must be a positive number.  
Enter S1 if you want to use the same value(s) as those for group 1.  
Press the 'SD' button to obtain help on estimating the standard deviation.  
You can enter a range of values such as 1,2,3 or 1 to 10 by 1.

8 Click the 'Run' button to calculate the power analysis and display the following report.

**NCSS Output - [PASS: Means: 2: Inequality [Differences] Output]**

File Edit View Format Window Help

Two-Sample T-Test Power Analysis

Page/Date/Time 1 10:22:02 AM

**Numeric Results for Two-Sample T-Test**  
Null Hypothesis: Mean1=Mean2. Alternative Hypothesis: Mean1<>Mean2  
The standard deviations were assumed to be unknown and equal.

Power	N1	N2	Allocation Ratio	Alpha	Beta	Mean1	Mean2	S1	S2
0.15387	5	5	1.000	0.05000	0.84613	0.0	2.0	3.0	3.0
0.42206	15	15	1.000	0.05000	0.57794	0.0	2.0	3.0	3.0
0.63673	25	25	1.000	0.05000	0.36327	0.0	2.0	3.0	3.0
0.78504	35	35	1.000	0.05000	0.21496	0.0	2.0	3.0	3.0
0.87852	45	45	1.000	0.05000	0.12148	0.0	2.0	3.0	3.0

**References**  
Machin, D., Campbell, M., Fayers, P., and Pinol, A. 1997. Sample Size Tables for Clinical Studies, 2nd Edition. Blackwell Science. Malden, MA.  
Zar, Jerrold H. 1984. Biostatistical Analysis (Second Edition). Prentice-Hall. Englewood Cliffs, New Jersey.

**Report Definitions**  
Power is the probability of rejecting a false null hypothesis. Power should be close to one.  
N1 and N2 are the number of items sampled from each population. To conserve resources, they should be small.  
Alpha is the probability of rejecting a true null hypothesis. It should be small.  
Beta is the probability of accepting a false null hypothesis. It should be small.  
Mean1 is the mean of populations 1 and 2 under the null hypothesis of equality.

Page 1/2 Line 2 Col 21

The **Output** window displays the output of the power analysis. It serves as a mini-word processor—allowing you to view, edit, save, and print your output.

You may want to scroll down to view the graph at the end of the report.

When you are finished, you can quit **PASS** by selecting *Exit* from the *File* menu.



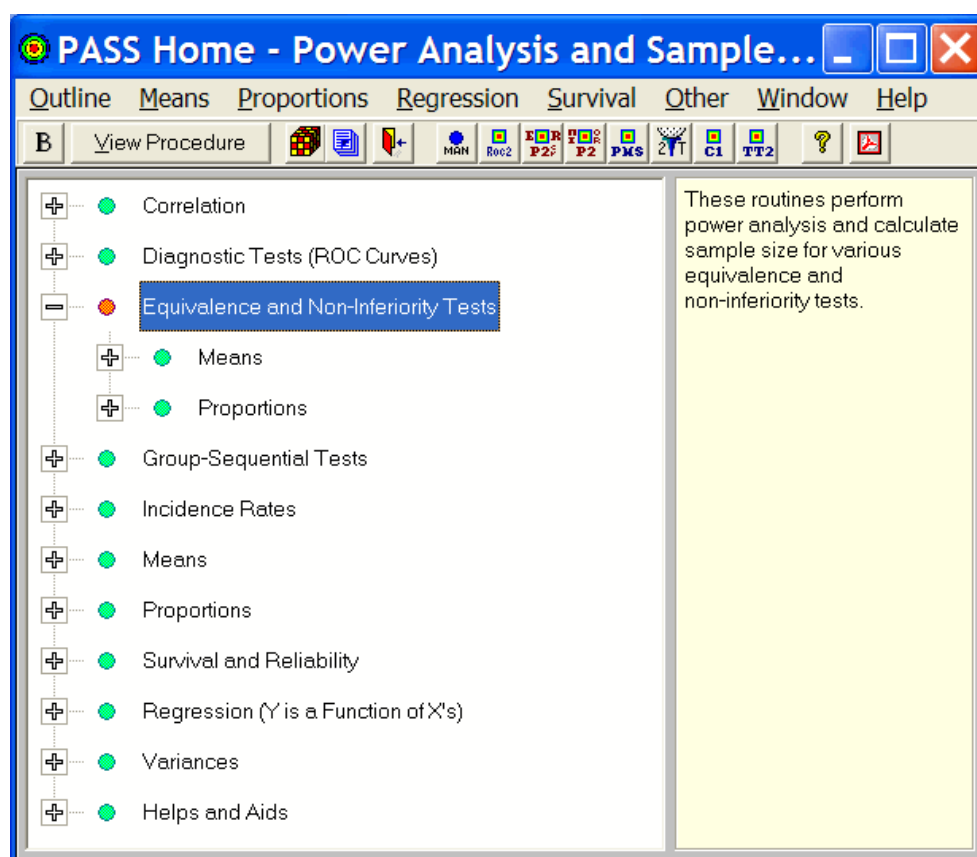
## CHAPTER 3

# PASS Home Window


## Introduction

The *PASS Home* window lets you quickly and easily find the appropriate procedure to be loaded. Using an outline format, it lists every procedure in *PASS* along with a brief statement that describes what the procedure is for and when it might be used.

The PASS Home window also lets you configure the eight procedure buttons that appear on the toolbars of the Data, Output, and Procedure windows. These buttons give you immediate access to your favorite procedures.



## Using the PASS Home

The PASS Home window is easy to use. It is loaded automatically if you are registered for *PASS*, but not *NCSS*. If you are registered for *NCSS*, press the bulls-eye icon  center top of the spreadsheet to load the PASS Home window. Alternatively, you can select the PASS Home option from the Window menu.

The PASS Home window has a set of menus, a toolbar, and a large display area. On the left side of the display area is an outline list of all the procedures in *PASS*. On the right side of the display area is the immediate help area that displays a brief statement explaining the currently selected item to the left.

## Menus

### Outline Menu

#### Collapse Outline

This option collapses the outline so that only the main heading is displayed.

#### Expand to First Level

This option expands the outline so that the main headings and first-level subheadings are displayed.

#### Expand All

This option completely expands the outline so that all entries are displayed.

#### Bold Text

This option toggles the bolding of the text.

#### Goto Selected Procedure

This option loads the currently selected procedure's window.

#### Close

This option closes the PASS Home window.

### Window Menu

This menu allows you to open other windows in the *PASS/NCSS* system such as the Data window or the Output window.

### Help Menu


This menu allows you to view the help system, modify your serial numbers, and load various portions of the printable (PDF) documentation.

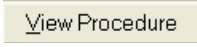
# Toolbar


The toolbar gives you one-click access to several of the menu items. The menu item assigned to each button on the toolbar is displayed when the mouse is held over the button for a few seconds.





The action caused by each of these icons is discussed next.


 This icon toggles the bolding of the text in the outline window.


 This icon causes the window of the currently selected procedure to be displayed. You can accomplish the same action by double-clicking on the procedure name.


 This icon causes the NCSS spreadsheet window to be displayed. You will find this useful when working with procedures that use the spreadsheet, such as the Repeated Measures ANOVA procedure.

 This icon causes the output window to be displayed.

 This icon closes all windows and exits the program.

 These buttons show up on all toolbars throughout the *NCSS/PASS* system. Clicking on them with the left mouse button will display that procedure. Clicking on one of these buttons with the right mouse button changes the button to the highlighted procedure.

 This icon loads the help system.

 This icon loads the file containing this chapter in PDF format.

## Customizing the Toolbars

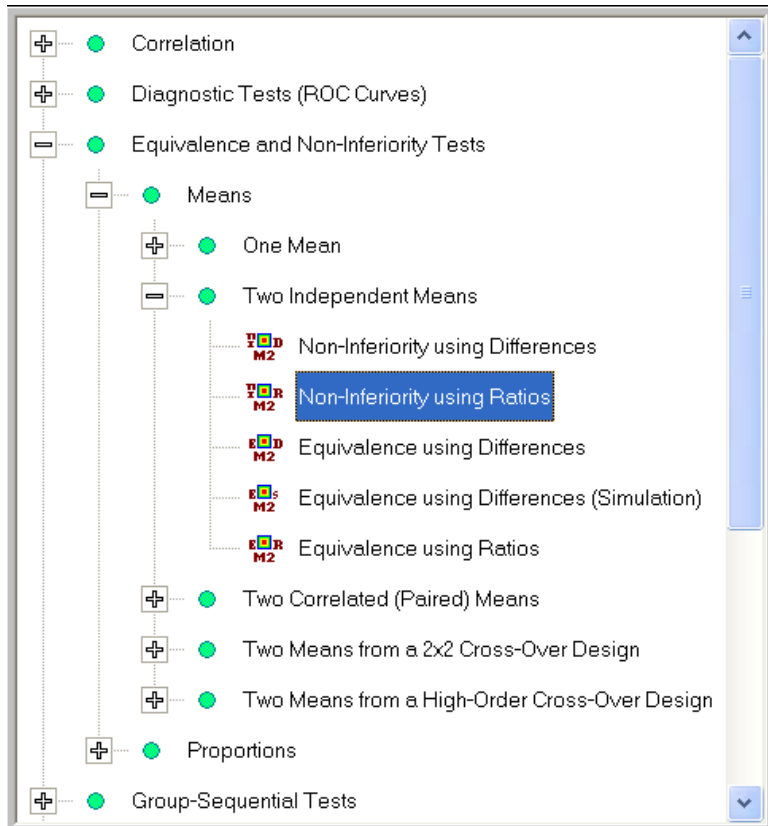
The eight procedure buttons that show up on all toolbars throughout the program may be changed here. The process of assigning one of these eight buttons a new procedure is as follows:

- 1 Find and select the procedure in the outline section (left-side of main window) of the PASS Home window.
- 2 Click on the button you want to assign the procedure to with the right-mouse button.

That's it. The icon of the selected procedure will now appear in all toolbars throughout the program.

# Outline

The outline expands and contracts as you either click on a plus or minus sign, or double-click on a topic. This gives you quick, intuitive access to all of the procedures in *PASS*.



In the example shown here, we clicked on “Equivalence and Non-Inferiority Tests”, then on “Means”, then on “Two Independent Means”, and finally on “Non-Inferiority using Ratios” to highlight it. If we double-clicked on “Non-Inferiority using Ratios”, that procedure would be displayed.

## CHAPTER 4

# Procedure Window

## Introduction

All *PASS* procedures are controlled by a *procedure* window that contains all of the settings, options, and parameters that control the input and output of the program. These options are separated into groups called *panels*. A particular panel is viewed by pressing the corresponding tab that appears near the top of the window. For example, in the window below, the Data panel is active. Other panels are Options, Reports, and Plot Setup.

The values of all options available for a procedure are referred to as a *template*. A template may be stored for future use in a *template file*. By creating and saving template files (often referred to as *templates*), you can tailor each procedure to your own specific needs. For example, you may want to your plots to be bar charts. This capability can be saved as a template. Each time you use a procedure, you simply load your template and run the analysis you have preset. You do not have to set all the options every time. The specific operations needed to do these are shown later.

Note that at most six procedure windows can be opened at a time. Also note that you can widen the window to increase the size of the immediate help window by dragging the corners of the window.

The screenshot shows the **PASS: Means: 2: Inequality [Differences]** window. The window has a menu bar (File, Run, Analysis, Graphics, PASS, Window, Help) and a toolbar with various icons. Below the toolbar are several tabs: Symbols 2, Background, Abbreviations, Template, Plot Text, Axes, 3D, Symbols 1, Data (active), Options, Reports, and Plot Setup. The **Data** panel contains the following settings:

- Find (Solve For):** Beta and Power
- Mean1 (Mean of Group 1):** 0
- Mean2 (Mean of Group 2):** 1
- N1 (Sample Size Group 1):** 5 to 45 by 10
- N2 (Sample Size Group 2):** Use R
- R (Sample Allocation Ratio):** 1.0
- Alternative Hypothesis:** Ha: Mean1 <> Mean2
- Nonparametric Adjustment:** Ignore
- Alpha (Significance Level):** .05
- Beta (1-Power):** 0.20
- S1 (Std Deviation Group 1):** SD
- S2 (Std Deviation Group 2):** S1
- ☐ Known Std Deviation

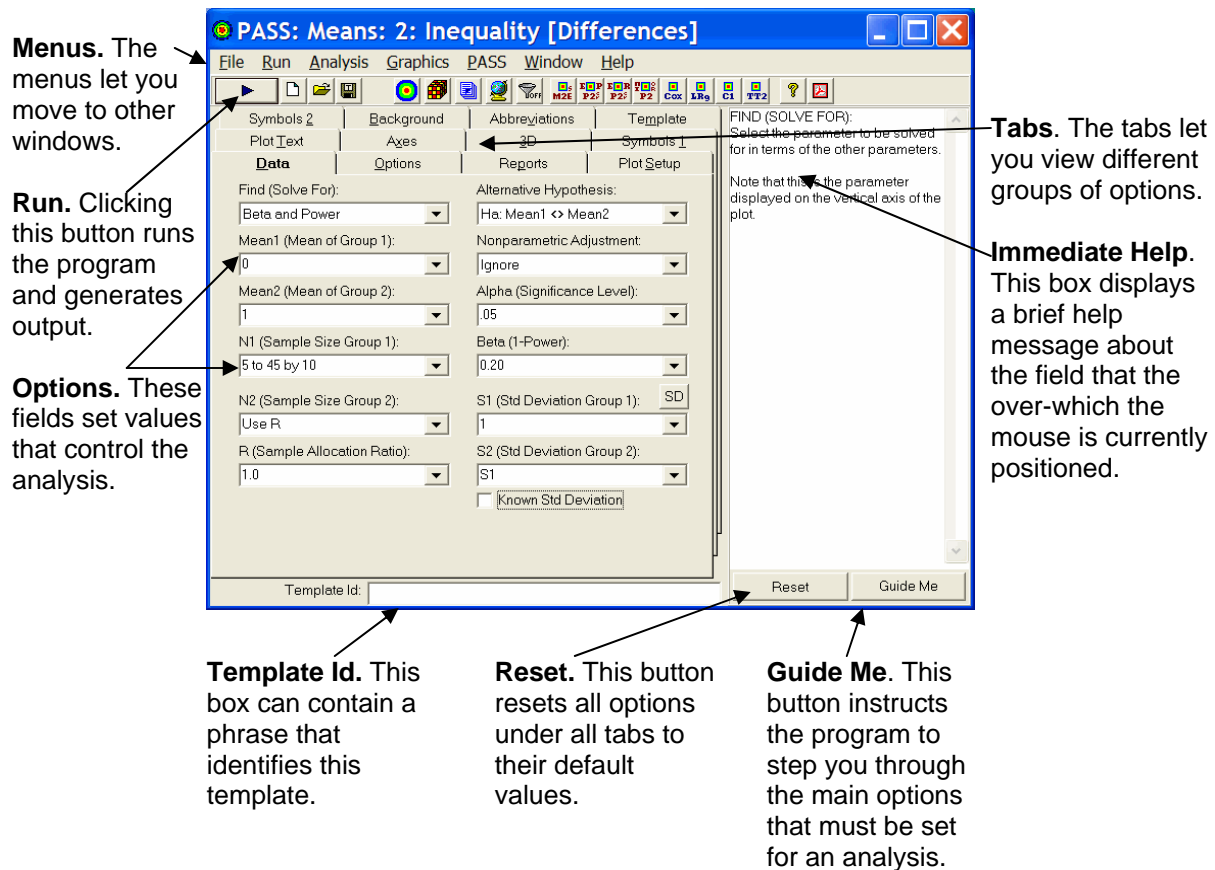
On the right side of the window, there is a **FIND (SOLVE FOR):** section with the text: "Select the parameter to be solved for in terms of the other parameters. Note that this is the parameter displayed on the vertical axis of the plot." At the bottom of the window, there is a **Template Id:** field and two buttons: **Reset** and **Guide Me**.

## Default Template

Whenever you close a procedure, the current settings are automatically saved in a default template file named *default*. This template file is automatically loaded when the procedure is next opened. This allows you to continue using the template without resetting all of the options.

## Procedure Window Anatomy

This section explains the various objects found on the template.



# Menus

The menus provide a convenient way to transfer from module to module within the *PASS* system. Each set of menus will be briefly described here.

## File Menu

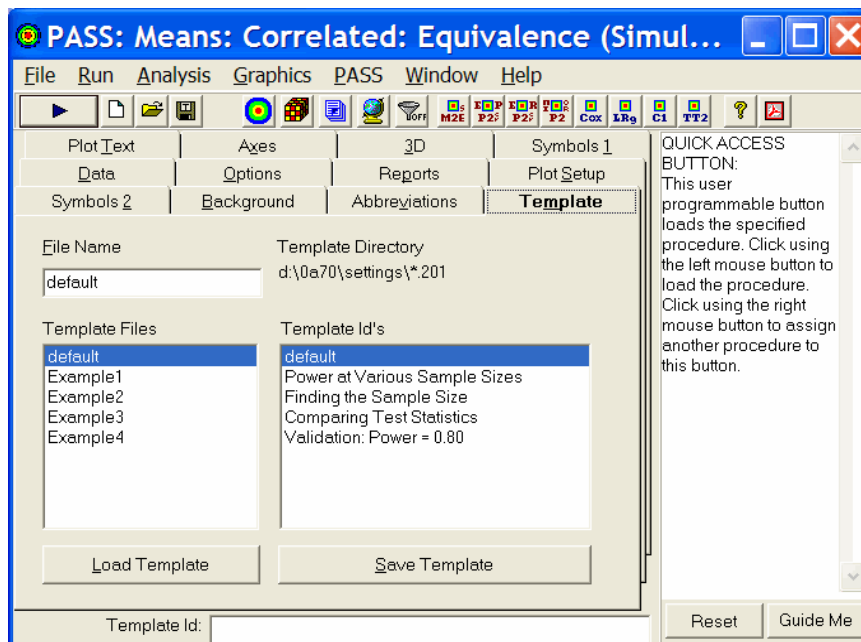
The File Menu is used for initializing, loading, and saving a copy of a template. Each set of options for a procedure, called a *template*, may be saved for future use. In this way, you do not have to set the options every time you use a procedure. Instead, you set the options the first time, save them as a template, and re-use the template whenever you re-use the procedure.

### New Template (Reset)

This menu item resets all options to their default values. It performs the same function as the Reset buttons.

### Open Template Panel

This option sets the Template panel as the active procedure panel. The Template panel lets you load or save template files. It displays all templates associated with this procedure along with the Template Id (the optional phrase at the bottom of the window).



### Save Template (button)

To save a template, enter the name you want to give the template file in the File Name box. You may also enter an identifying phrase in the box at the bottom of the window since this will be displayed along side of the file names. Finally, press the Save Template button to save the file.

Note that there is no automatic connection between the template in memory and the copy on

the disk. If you want to save the changes you have made to a template, you must use the Save Template option to save them.

### Load Template (button)

To load a template file, select it from the list of files given in the Template Files box. Once the desired file is selected, press the Load Template button to load the template.

### Save Template

This option saves the current option settings to the template file that is currently specified in the File Name option of the Template panel. You can be viewing any panel of the procedure when you issue this command—you do not have to be viewing the Template panel.

The template files are stored in the Settings folder. You can erase any unwanted template files by deleting them from this folder using the Windows Explorer program.

The template files for each procedure have different file name extensions. Thus, you can use the same name for a template saved from the T-Test procedure as for a template saved from the Multiple Regression procedure. For example, if the ‘Save Template’ command is issued in the window shown above, the current settings will be saved in a file called ‘default.201’ in the Settings folder.

The Save button on the toolbar provides this same operation. It may be more convenient than selecting this menu item.

### Close Procedure

This option closes this procedure window.

### Printer Setup

This option lets you set various printer options.

### Exit NCSS and PASS

This option terminates the *NCSS/PASS* system. Before using this option, you should save all datasheets, templates, and output documents that you want to keep.

### Run Menu

This menu controls the execution of the program.

### Run Procedure

The Run Procedure option runs the analysis, displaying the output in the Output document of the word processor. After you have set all options to their appropriate values, select this option to perform the analysis.

Note that the procedure may also be run by pressing the *F9* function key or by pressing the left-most key on the toolbar (the dark-blue-arrow button).

### Abort

After starting a procedure, you may find that it is taking longer than you anticipated to finish. You can stop the running of the procedure by pressing this button. The red stop-sign icon that appears on the top right of the screen may be pressed for the same purpose.

### Analysis and Graphics Menus

These menus allow you to transfer to various *NCSS* procedures. You can load these procedure windows, but when you try to run them, you will receive an error message indicating that you do not have a license for this procedure (unless you have purchased a license for *NCSS*).



## PASS Menu

This menu allows you to directly load any of the various *PASS* procedures.

## Window Menu

This menu lets you display any of the other windows in the *NCSS/PASS* system that are currently open such as the Output window, the Data (Spreadsheet) window, the Navigator window, or any procedure windows.

### Output

Select this option to display the output window.

### Data (Spreadsheet)

Select this option to display the *NCSS* spreadsheet.

### Navigator

Select this option to display the *NCSS* navigator window.

### Reset Window Positions

Occasionally, *NCSS/PASS* windows will be loaded, but will not display. This menu item will load the Options window to a tab that will let you reset the position of all program windows.

## Help Menu

This menu gives you access to the *PASS* documentation.

### Help...

This option loads the help system. Once loaded, press the Contents button to obtain a table of contents window.

### About...

This option show you which products are licensed and when your version was released.

### Serial Numbers...

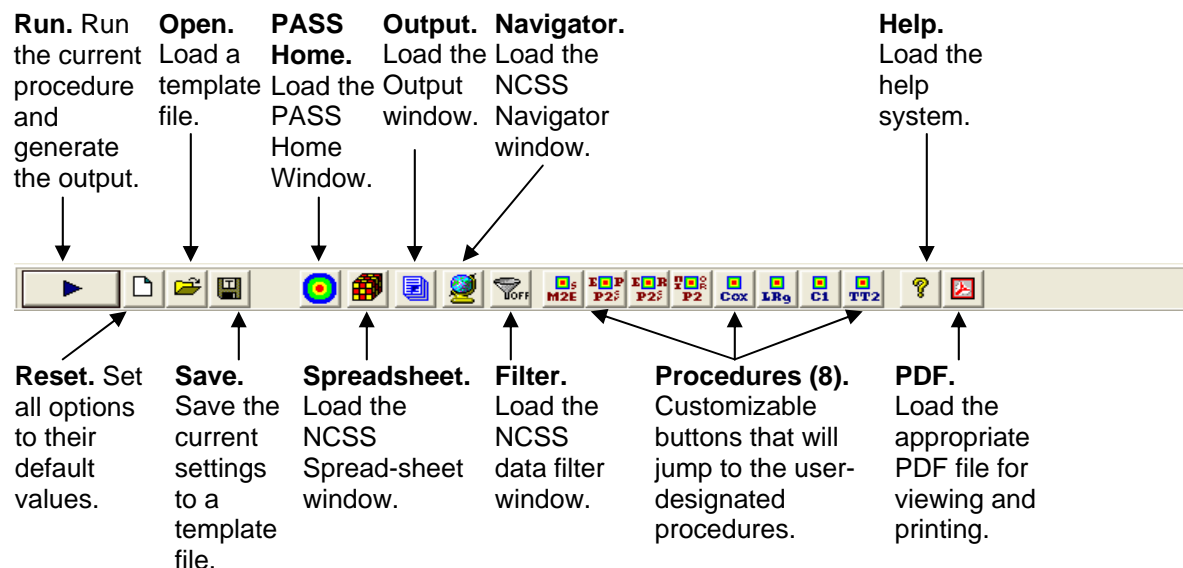
This option loads the serial number screen. Use this when you need to change one of your serial numbers.

### View PDF File...

This option loads the PDF file that documents this procedure. This file may then be printed.

# Toolbar

The toolbar is a series of small buttons that appear just below the menus at the top of the procedure window. Each of these buttons provides quick access to a menu item.



## Important Tip for PASS Users

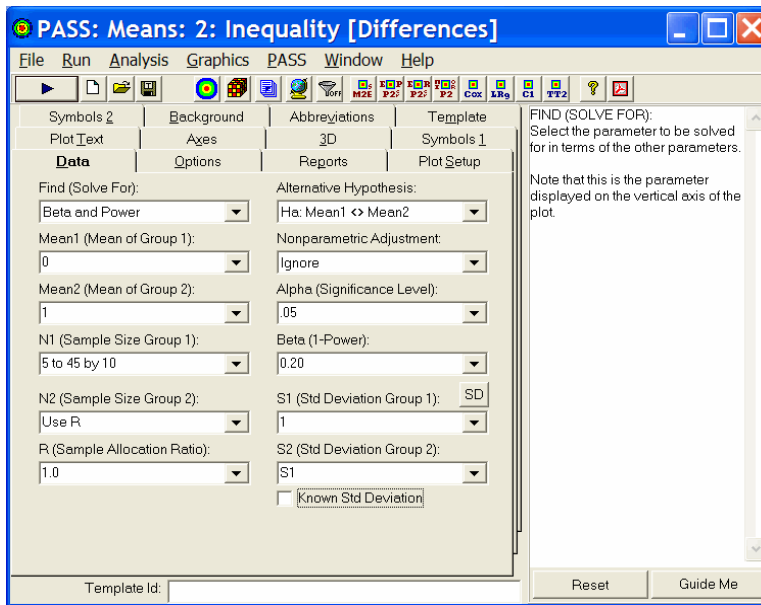
The Procedures (8) buttons are a series of eight buttons that can be changed to your favorite procedures by right clicking on any of these buttons.

# The Panel Tabs

The procedure window contains several sets of options (panels). Each panel is displayed by clicking on the appropriate tab. We will now describe the purpose and operation of each panel.

## Data tab

This tab displays most of the options specific to the procedure. This is where you set the values of power, sample size, alpha, etc. These options are described in detail in the chapters corresponding to each procedure. Once you have set the options, click the **Run** button to generate the output.



## Entering Multiple Values

In most cases, boxes that are extra wide allow you to enter multiple values. When this is done, a separate analysis is made for each combination of all multiple values. For example, if you enter four sample sizes and three alpha values, the resulting report will contain  $3 \times 4 = 12$  rows, one for each combination.

You can enter multiple options using list or the *to-by* syntax. The *to-by* syntax is most easily described by an example.

The *to-by* phrase *20 to 100 by 20*

is translated to the values: *20,40,60,80,100*.

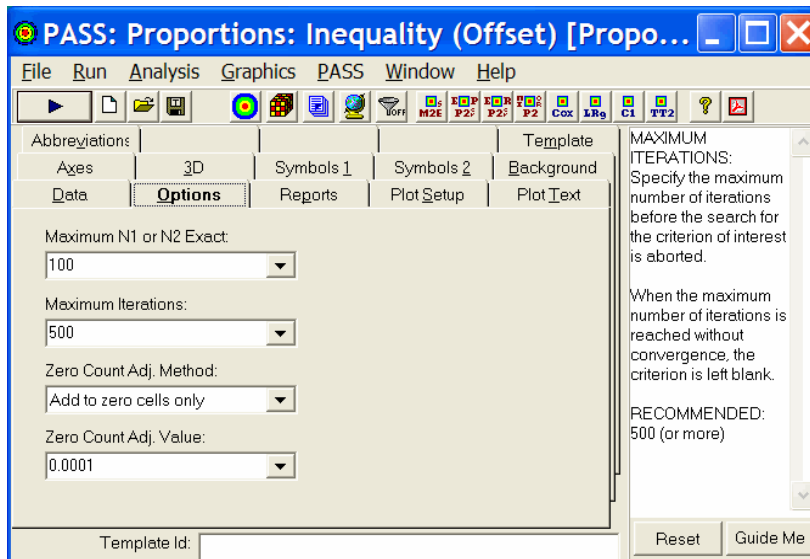
## Find (Solve For)

Specify the parameter that is to be solved for in terms of the other parameters. For example, you might want to solve for power or sample size.

In most cases, the algorithm for the calculating the power is programmed within **PASS**. When other parameters (such as sample size or difference) are selected, a binary search is conducted using the power algorithm. These searches can be time consuming, so the best place to start is with this option set to 'Beta and Power'.

## Options tab

The Options window presents the parameters that control the searching process.

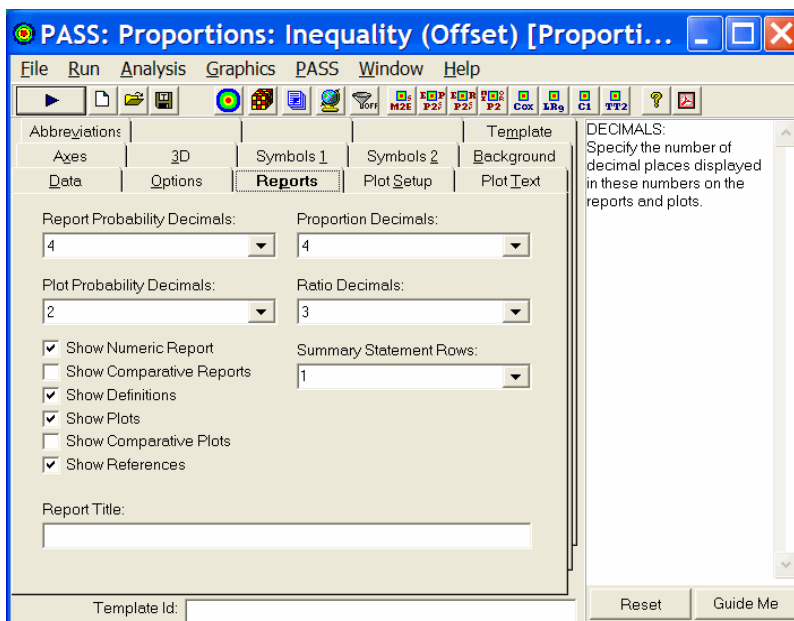


### Maximum Iterations.

This option specifies the maximum number of iterations before a search for the parameter of interest is halted. When the maximum number of iterations is reached without convergence, the criterion is left blank. We recommend that at least 500 iterations be specified.

## Reports tab

This tab displays the options that control the output reports.



### Decimals

These options set the number of decimal places in corresponding values of the numeric and graphic output.

### Summary Statement Rows

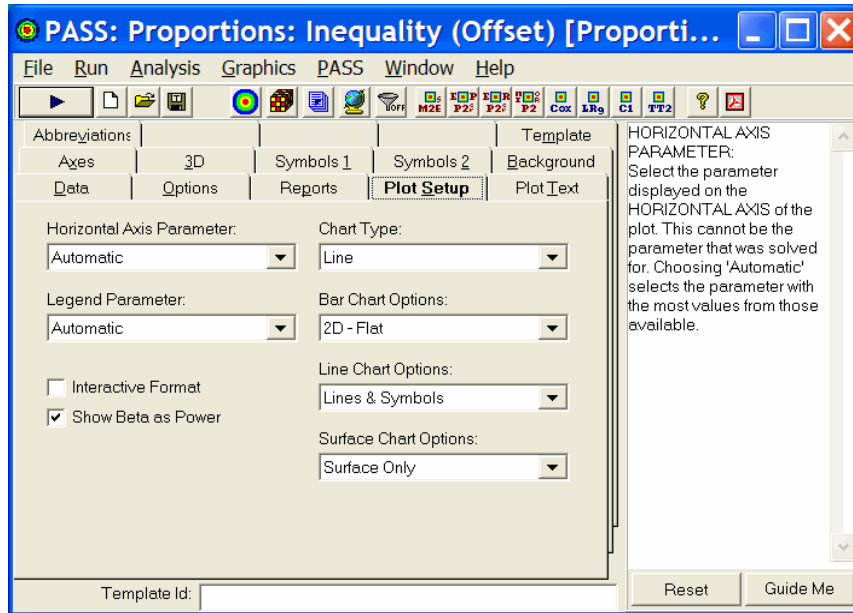
The Summary Statement is a paragraph that can be output for each row of the report. When you do not need this output, you can reduce the number of rows accordingly. To eliminate the text output completely, set this value to zero.

### Show ...

These options control whether the corresponding item is displayed in the output.

## Plot Setup tab

This tab displays options that control the plots, including which parameters are shown on the axes and the type of plot that is displayed.



### Horizontal Axis Parameter

This option selects which of the parameters from the Data tab is displayed across the horizontal axis. Note that you cannot select the parameter that was listed in the Find option. Also, you would normally only select a parameter that has multiple entries.

When this option is set to *Automatic*, the parameter with the most values is selected.

### Legend Parameter

A separate line is drawn for each value of this parameter. The lines are labeled in the legend. When this option is set to *Automatic*, the parameter with the second most values is selected.

### Show Beta as Power

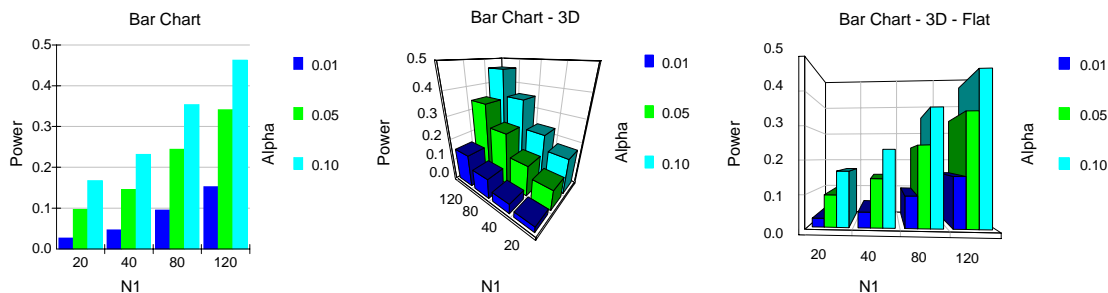
This option controls whether Beta or Power is displayed on the plots.

### Chart Type

This option controls the type of chart that is displayed. Bar charts, line charts, and surface charts are available.

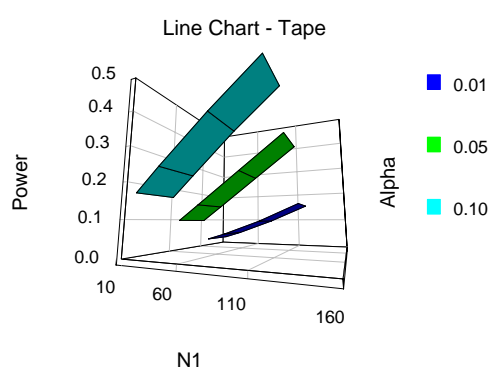
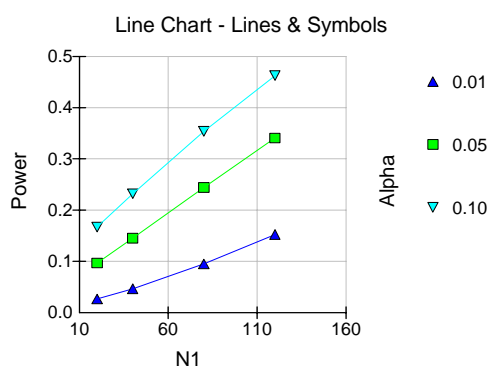
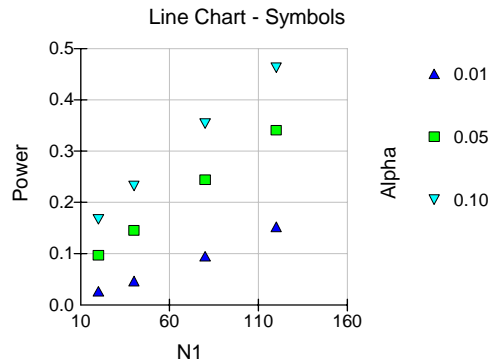
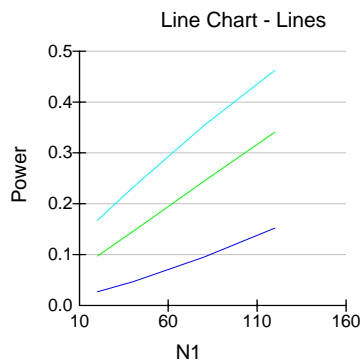
### Bar Chart Options

These chart types are available when Chart Type is set to Bar.



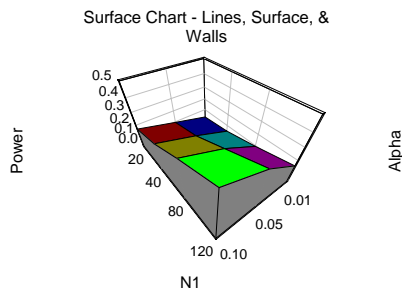
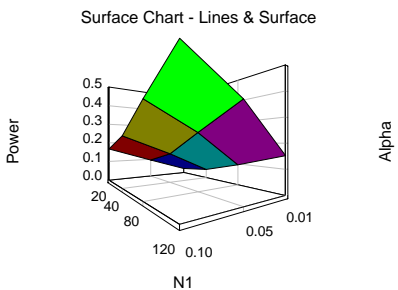
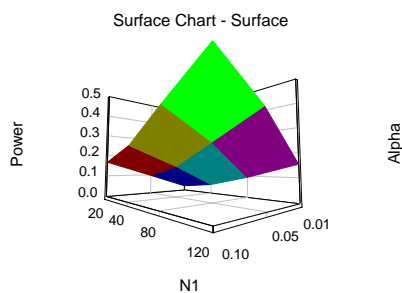
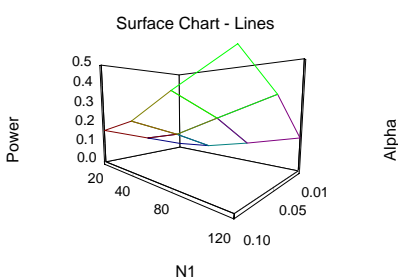
## Line Chart Options

These chart types are available when Chart Type is set to Line.



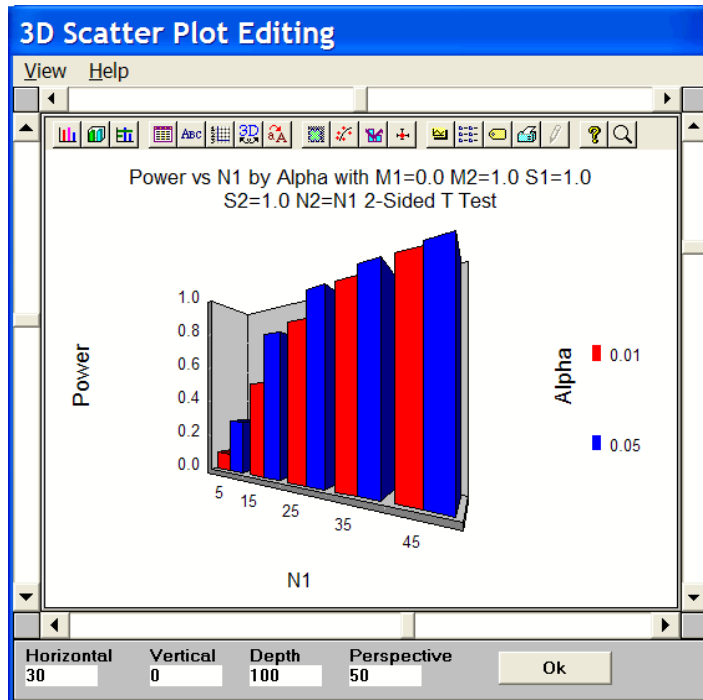
## Surface Charts

These chart types are available when Chart Type is set to Surface.



## Interactive Format

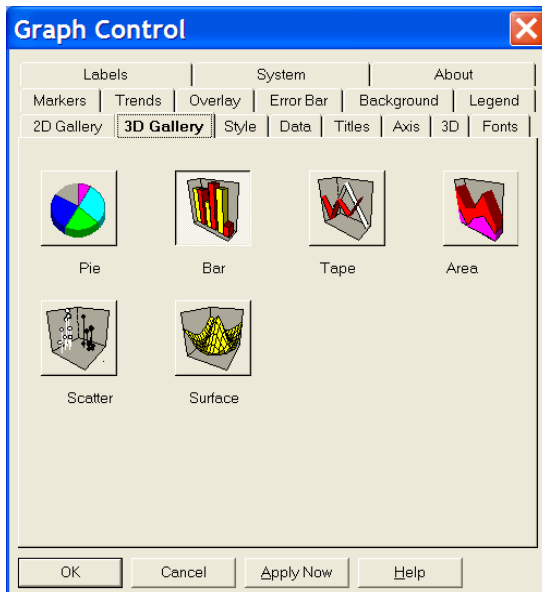
This option controls whether the plot may be reformatted interactively after it has been generated. When checked, this option allows charts to be formatted interactively using the following window.



The four scroll bars around the edge of this window control the vertical axis, horizontal axis, depth, and perspective. The current values of these parameters are shown in the boxes at the bottom of the screen.

Once you are finished editing chart, click the *Ok* button to proceed.

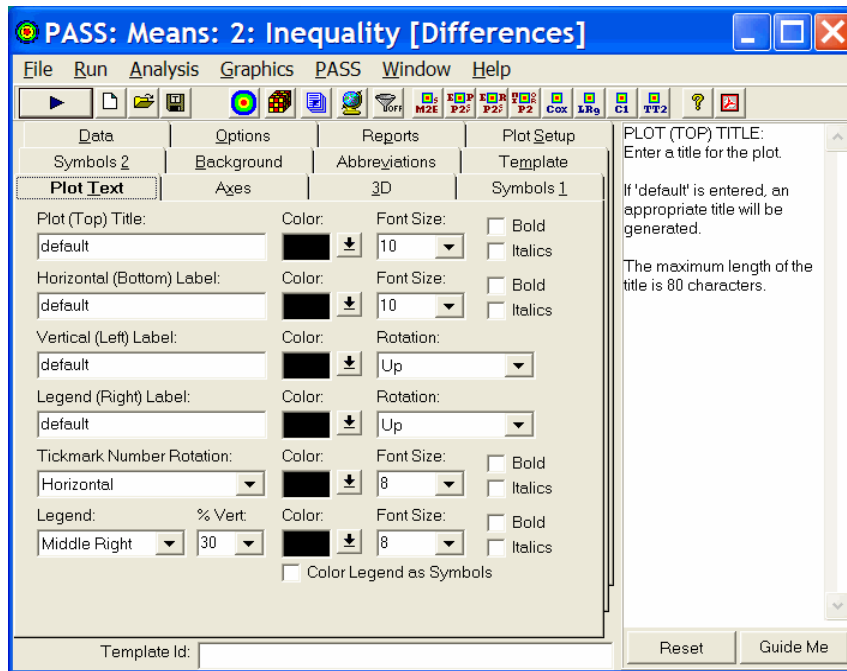
Each of the buttons along the top of the Scatter Plot Editing Window will display a different tab of the Graph Control window. Each tab provides options which allow detailed modification of the chart.



We will not document these options here since most of them are not necessary to the running of *PASS*. If you want to explore these options further, choose the Help button at the bottom of the window. This will bring up a special help system that describes all graphics options in detail.

## Plot Text tab

This window controls the titles and labels of the plots.



### Plot Title - Legend Label

The title and label options specify the text, color, and font size of the corresponding value displayed on the plot.

### Tickmark Number Rotation

This option specifies whether the reference values are shown vertical or horizontal.

### Legend

This option sets the position of the legend

### % Vert

Specify the size of the legend area as a percentage of the maximum possible. This option lets you shrink a legend that is too large

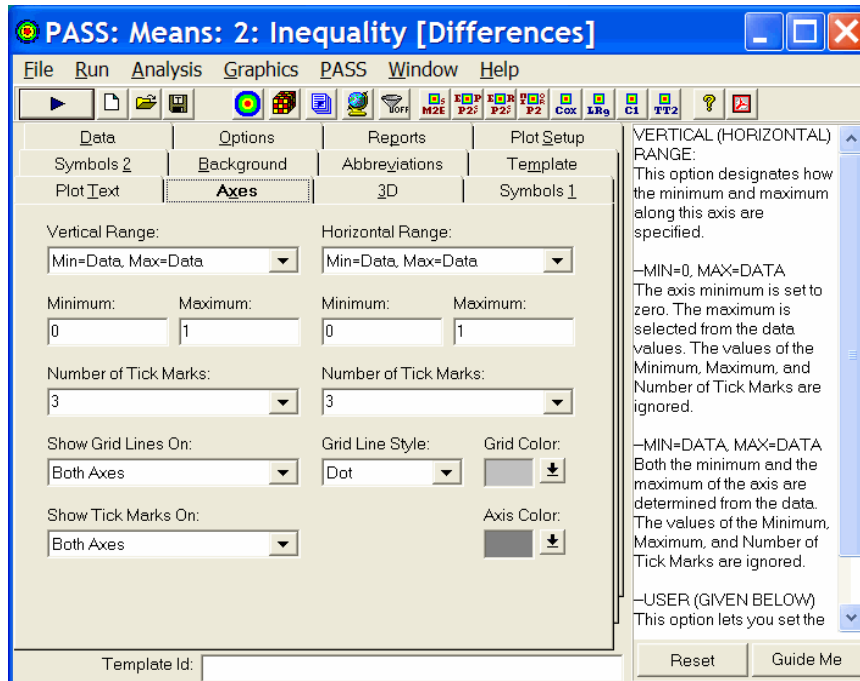
### Color Legend as Symbols

Normally, text in the legend is displayed using the color selected by the Color option. This option indicates that each legend entry is to be displayed in the corresponding group color.



## Axes tab

This tab displays options that control the chart axes.



## Vertical / Horizontal Range

This option designates how the minimum and maximum along this axis are specified. Available options are:

**Min=0, Max=Data.** The axis minimum is set to zero. The maximum is selected from the data values. The values of the Minimum, Maximum, and Number of Tick Marks are ignored.

**Min=Data, Max=Data.** Both the minimum and the maximum of the axis are determined from the data. The values of the Minimum, Maximum, and Number of Tick Marks are ignored.

**User.** This option lets you set the Minimum, Maximum, and Number of Tick Marks to scale the axis. These options determine which of the axes have grid lines displayed. This option is particularly useful when you want to make sure that the axis displaying power values displays a grid between zero and one.

## Minimum and Maximum.

Specify the axis minimum or maximum to be used when the Vertical (or Horizontal) Range option is set to User.

## Number of Tick Marks

Specify the number of tick marks along this axis. This value is used when Vertical (or Horizontal) Range is set to User.

## Show Grid Lines On

These options determine which of the axes have grid lines displayed.

## Grid Line Style

Specify the pattern of the line. This option only works when the line width is 20.

## Grid Color

Specify the color of the grid line.

## Show Tick Marks On

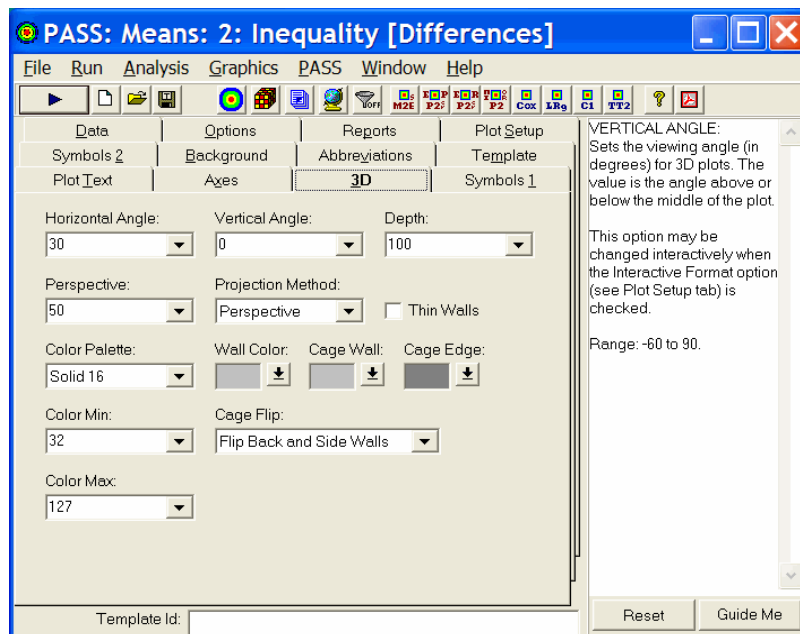
These options control which of the axes have tick marks displayed.

## Axis Color

Specify the color of the Axis line.

## 3D tab

This tab displays options that control the 3D charts.



## Horizontal Angle

This option sets the horizontal viewing angle (in degrees) for 3D plots. It represents an angle around the base of the plot.

The range of values is -180 to 180 degrees. This option may be changed interactively when the Interactive Format option is checked.

## Vertical Angle

This option sets the vertical viewing angle (in degrees) for 3D plots. It represents an angle above or below a point halfway up the graph. Values may range from -60 to 90 degrees.

This option may be changed interactively when the Interactive Format option is checked.

## Depth

This option sets the projected depth of 3D plots. Depth is a percentage of 100, calculated to provide equal increments in the X and Z directions. Values may range from 5 to 400. This option may be changed interactively when the Interactive Format option is checked.

## Perspective

This option sets the degree of perspective foreshortening in 3D plots. Perspective is the perceived distance of the viewer from the graph. The range of values is 0 to 100. This option may be changed interactively when the Interactive Format option is checked.

## Projection Method

Sets the projection method of 3D-type charts.

## Off

No graph is drawn.

**Isometric**

The graph is drawn, but no perspective is attempted.

**Perspective**

The axes are tilted to give a 3D perspective to the plot.

**Thin Walls**

This option specifies whether the walls of the axis grid that form the background of the chart are thick or thin.

**Color Palette**

Specify a color palette for the surface chart. Using a setting of, say, Black to Red will allow the surface plot to show a continuous array of red hues from lowest to highest.

**Wall Color**

Specify the color of the wall.

**Cage Wall**

Specify the color of the cage (grid) wall.

**Cage Edge**

Specify the color of the cage (grid) edge.

**Color Min**

Specifies the number of the color to be associated with the lowest numerical value. Possible values are 32 to 127. A value near 50 usually works well. Note that this option only works with 128-color palettes.

**Color Max**

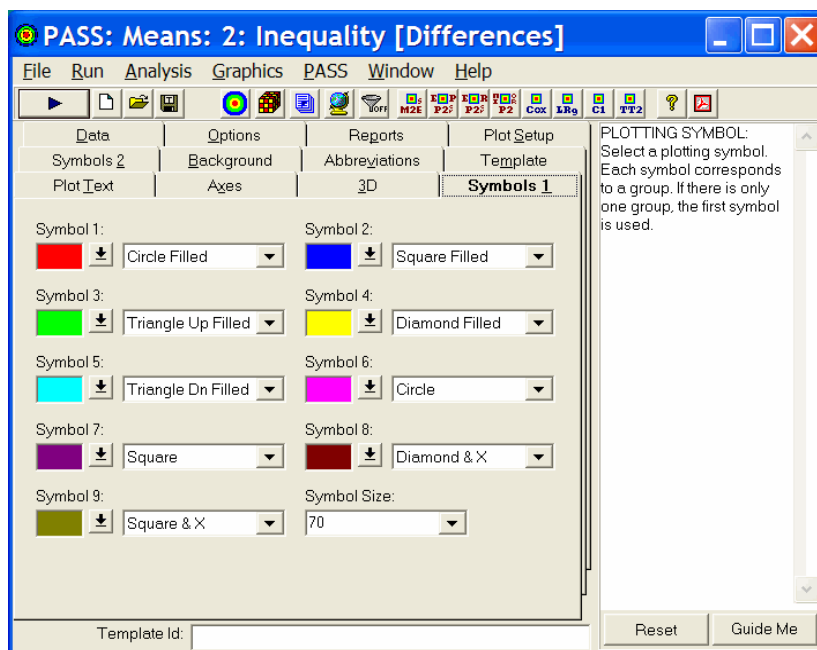
Specifies the number of the color to be associated with the largest numerical value. Possible values are 32 to 127. A value near 120 usually works well. Note that this option only works with 128-color palettes.

**Cage Flip**

This option controls whether the back and side walls of the graph cage are allowed to switch to the opposite edge for better viewing as the graph is rotated.

## Symbols 1 and 2 tabs

These tabs specify the appearance of up to fifteen symbols. If more than fifteen symbols are needed, the first fifteen are repeated.

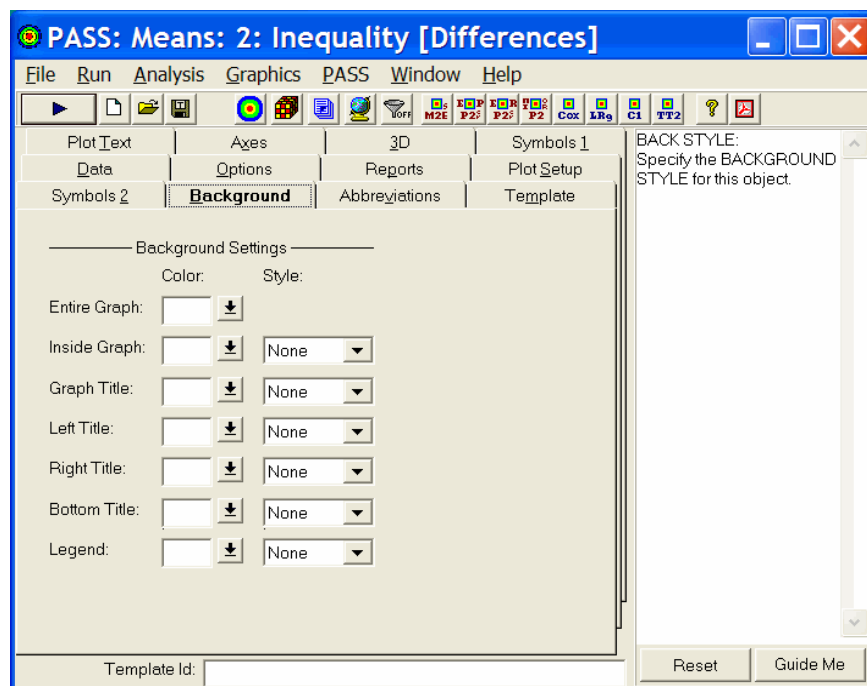


## Symbol

These options specify the color, size, and shape of the plotting symbols.

## Background tab

These options specify the style and color of various portions of the graph.



## Abbreviations tab

These tabs specify the abbreviations that are used for the parameters in the titles of the plots. It is usually necessary to keep these abbreviations as short as possible since the title can only contain 80 characters.

The screenshot shows the 'PASS: Means: 2: Inequality [Differences]' window with the 'Abbreviations' tab selected. The window has a menu bar (File, Run, Analysis, Graphics, PASS, Window, Help) and a toolbar with various icons. The main area is divided into two columns of dropdown menus for selecting abbreviations for different parameters. On the right, there is a text area for entering a custom abbreviation with a warning about the 80-character limit. At the bottom, there are buttons for 'Reset' and 'Guide Me'.

Parameter	Abbreviation
Test Title:	Alpha:
T Test	Alpha
Mean1:	Beta:
M1	Beta
Mean2:	Sample Size Group 1:
M2	N1
Standard Deviation 1:	Sample Size Group 2:
S1	N2
Standard Deviation 2:	Power:
S2	Power

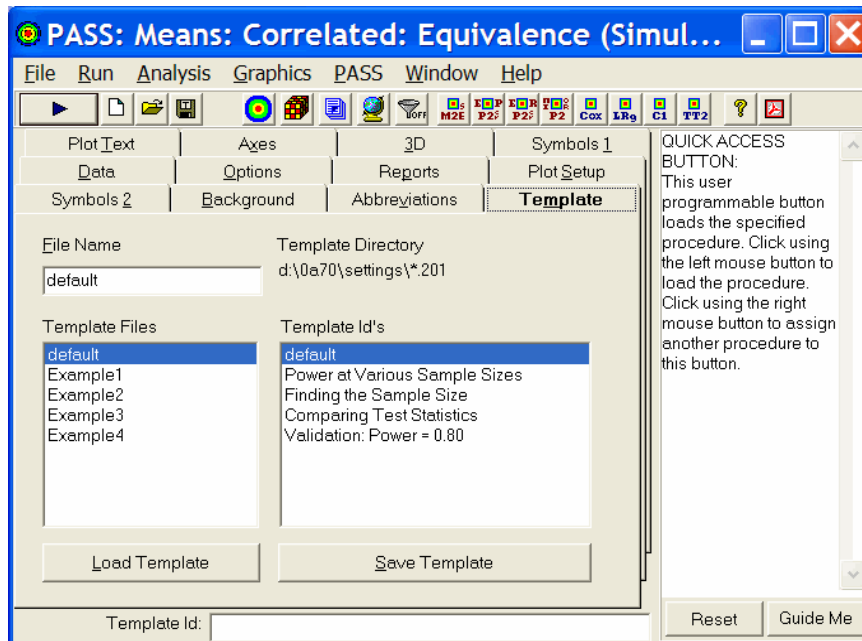
ABBREVIATION:  
Enter the character(s) to be used for this parameter on the plots in labels and titles. Remember that plot titles are limited to just 80 characters, so brevity is important here.

Template Id:

Reset Guide Me

## Template tab

This tab displays the options necessary to load and save templates. The *template* refers to the settings of all options under all tabs. Templates are stored in files in the *Settings* subdirectory.



### File Name

This box contains the name of the template file. Standard file naming conventions must be followed. A two or three character file extension is supplied by *PASS*. All you need to enter is the file name.

### Template Files

Select a template file from this list of previously saved templates. The file's name will be entered in the File Name box at the top of this window. You can then press the *Load Template* button to load the settings stored in this file into this template or the *Save Template* button to save the settings.

### Template Id's

This box contains a list of the template id's corresponding to the template name. Remember that the template id is entered in the text box at the bottom of the window.

### Load Template

This button will load the file whose name shows in the File Name box.

### Save Template

This button will save the settings of the all options to the template file named in the File Name box.

## CHAPTER 5

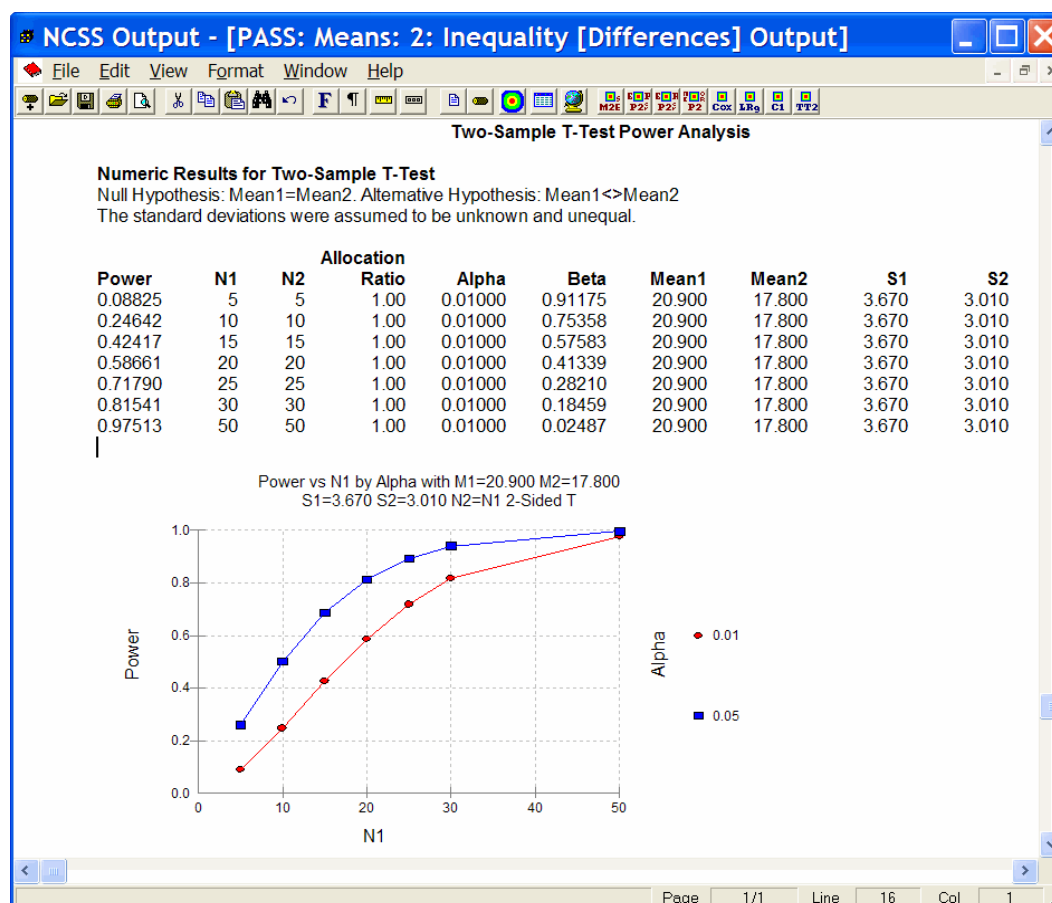
# Output Window

## Introduction

*PASS* sends all statistics and graphics output to its built-in word processor from where they can be viewed, edited, printed, or saved. Reports and graphs are saved in rich text format (RTF). Since RTF is a standard document transfer format, these files may be loaded directly into your word processor for further processing. You can also cut and paste data onto an **NCSS** datasheet for further analysis. This chapter covers the basics of our built-in word processor.

## Viewing the output

The output of the Example1 template of the Two-Sample T-Test program is shown below. The output window is in full-screen mode. The screen will look similar to this. Note that the actual size of your screen depends on the resolution of your monitor, so it may vary.



# Documents

The *PASS* word processor maintains two documents: *Output* and *Log*. Although both of these documents allow you to view your data, the *Output* document serves as a viewer while the *Log* document serves as a recorder.

You can load additional documents as well. For example, you might want to view the output from a previous analysis to compare the results with the current analysis. To do this, you open a third document that is actually the log file from a previous analysis.

All *PASS* documents are stored in the RTF format. This is a common format that is used by most word processors, including MS-Word and MS-Write. When you save a *PASS* report, you will be able to load that report directly into your own word processor. All text, formatting, and graphics will appear in your word processor ready for further editing. You can then save the document in your word processor's native format. In this way, you can easily transfer the output of a *PASS* procedure to almost any format you desire.

## Output Document

The Output document displays the output report from the current analysis. Whenever you run a *PASS* procedure, the resulting reports and graphs are displayed in the Output document. Each new run clears the existing Output document, so if you want to save a report, you must do so before running the next report.

The Output document provides four main functions: display, print, save to the Log document, and save as an RTF file.

## Log Document

The Log document provides a place to store a permanent record of your analysis. Since the Output document is erased by each new analysis, you need a place to store your permanent work. The Log document serves this purpose. When you have a report or graph that you want to keep, copy it from the Output document to the Log document.

The Log document provides four main word processing functions: load, display and edit, print, and save. When you load a file into the Log document, you can add new output to it. In this way, you can record your work on a project in a single file, even though your work on that project is spread out over several days.

# File Menu

The File Menu is used for opening, saving, and printing *PASS* word processor files. All options apply to the currently active document (the document whose title bar is selected). We will now discuss each of the options on this menu.

## New

This option opens an empty document. You might use this when you want to make notes about your analysis.

## New Log

This option opens an empty log document. You might use this when you want to start a new project.



## Open

This option opens an existing file. When this item is selected, the Open Report File dialog box appears. Note that no connection is maintained between a loaded file and its image on the disk. If you make changes to a file, you must save those changes to the disk.

## Open Log

This option opens an existing log file. When this item is selected, the Open Report File dialog box appears. The requested file is loaded into the Log document. Note that no connection is maintained between a loaded file and its image on the disk. If you make changes to a file, you must save those changes to the disk.

You might use this option when you want to continue using a certain file as the Log file.

## Toggle Auto-Log

When Auto-Log is on, the contents of the Output document are automatically copied to the Log document. The Output document remains unchanged. If you want to keep a copy of all the output that has been placed in the Log document, you will still need to save it manually.

This function allows you to automatically save all output for further use.

## Add Output to Log

Selecting this option copies the contents of the Output document to the Log document. The Output document remains unchanged. This allows you to save the current output document for further use.

## Save As

This option lets you save the contents of the currently active document to a designated file using the RTF format. Note that only the active document is saved. Also note that all file names should have the “RTF” extension so that other systems can recognize their format.

## Printer Setup

This option allows you to set printing options on your printer.

## Print Preview

This option displays the output report as it will appear on the printed page. Use it to preview your report before printing it out.

## Print...

This option lets you print the entire document or a range of pages. When you select this option, a Print Dialog box will appear that lets you control which pages are printed.

## Close Document

Minimizes the document that is currently being viewed. Note that this option does not clear the document, it simply minimizes it.

## Exit

This option exits the *NCSS/PASS* system. All documents and databases are closed.

# Edit Menu

This menu contains options that let you edit a document.

## Undo

This item reverses the last edit action. It is particularly useful for replacing something that was accidentally deleted.

## Cut

This item copies the currently selected text to the Windows clipboard and erases it from the document. You can paste the information from the clipboard to a different location in the current document, into another document, into a datasheet in the spreadsheet, or into another application. The selected text is erased.

## Copy

This item copies the currently selected text from the document to the Windows clipboard. You can paste this information from the clipboard to a different location in the current document, into another document, into a datasheet in the spreadsheet, or into another application. The selected text is not modified.

## Paste

This item copies the contents of the clipboard to the current document at the insertion point. This command is especially useful for moving selected information from the Output document to the Log document.

## Select All

This item selects the entire document. Although you can select a portion of the document using the mouse or a shift-arrow key, this is much faster if you want to select the entire document.

## Toggle Page Break

Changes the status of the page break on the line at which the insertion point resides. If a page break exists (shown by a horizontal line), it is removed. If a page break does not currently exist at that point, one is added.

Note that *PASS* does not repaginate your document for you. Once you make changes, it will be up to you to repaginate your document.

## Find

This item opens the Search dialog box. You can specify text that you want to search for. This is especially useful when you are looking for a certain topic or data value in a large report.

## Find Next

This item continues finding the text you entered in the Search Dialog box.

## Replace

This item opens the Search and Replace dialog box. This allows you to make repetitive changes. For example, you might want to change the name of one of the variables to a more useful name.

## Goto Section

This item does not modify the document. Instead, it lets you reposition the insertion point to one of the major topics. When *PASS* runs a procedure, it stores the major report topics in this list box. You can quickly position the view to a desired topic using this screen.

## View Menu

The *View Menu* lets you designate which editing tools you want to use.

### Ruler

This option controls whether the ruler and the tabs bar are displayed. The ruler displays the physical dimensions of the document. The tabs bar, found just below the ruler bar, lets you set the margins and tabs of your document. Only the currently selected part of your document is affected by a change in the tabs and margins.

### Format Toolbar

This option controls whether the Format Toolbar is displayed. The function of each of the buttons is discussed below.

### Status Bar

This option controls whether the Status Bar is displayed at the bottom of the output window.

### Show All

Selecting this menu item causes the Ruler, Tabs Bar, Format Toolbar, and Status Bar to be displayed.

### Hide All

Selecting this menu item causes the Ruler, Tabs Bar, Format Toolbar, and Status Bar to be hidden. This gives you more screen space to view your output.

### Redraw

Occasionally the Output Window becomes cluttered. If this happens, select this option to redisplay the output.

## Format Menu

This menu lets you set the format for a selected block of text.

### Font

This option displays the Replace Font dialog box, which lets you specify the font and style of the selected text.

### **Paragraph**

This option displays the Paragraph dialog box, which lets you specify the tabs and margins of the selected text.

### **Format Markers**

Indicates whether the (usually hidden) tab arrows and the end-of-paragraph marks are displayed in the document. Note that these characters are never printed.

## **Window Menu**

This menu lets you designate how you want the documents arranged on the screen and which window you want displayed on top of your output desktop.

### **Cascade**

This item arranges the documents in a cascading display from the upper left to the lower right of the screen.

### **Tile Horizontally**

This item arranges the documents horizontally down the word processor window.

### **Tile Vertically**

This item arranges the documents vertically across the word processor window.

### **Arrange Icons**

When a document is minimized, it is represented as an icon at the bottom of the word processor window. This option arranges all document icons. It is usually applied when the word processor window has been resized.

### **Current Output**

This item causes the Output window to be displayed.

### **Log**

This item causes the Log window to be displayed.

### **View Data (Spreadsheet)**

Causes the Spreadsheet window to be displayed.

### **View Navigator**

Causes the *NCSS/PASS* Navigator window to be displayed.

# Help Menu

This menu controls the display of the serial numbers and help system.

## Help

This item displays the help system.

## About

This item displays the release date and version number of your software.

## Serial Numbers

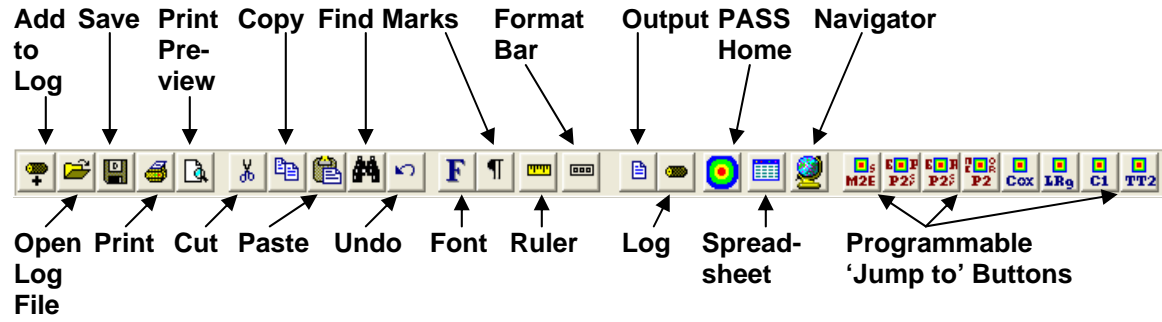
This item displays the *NCSS/PASS* Registration window where your serial numbers can be modified.

## View PDF File...

This option loads the PDF file that documents this procedure. This file may then be printed.

# Toolbar

The toolbar is a series of small buttons that appear just below the menus at the top of the procedure window. Each of these buttons provides quick access to a menu item.



## CHAPTER 6

# Introduction to Power Analysis

## Overview

A statistical test's *power* is the probability that it will result in statistical significance. Since statistical significance is the desired outcome of a study, planning to achieve high power is of prime importance to the researcher. Because of its complexity, however, an analysis of power is often omitted.

**PASS** calculates statistical power and determines sample sizes. It does so for a broad range of statistical techniques, including the study of means, variances, proportions, survival curves, correlations, bioequivalence, analysis of variance, log rank tests, multiple regression, and contingency tables.

**PASS** was developed to meet several goals, including ease of learning, ease of use, accuracy, completeness, interpretability, and appropriateness. It lets you study the influence of sample size, effect size, variability, significance level, and power on your statistical analysis.

# Brief Introduction to Power Analysis

Statistical power analysis must be discussed in the context of *statistical hypothesis testing*. Hence, this discussion starts with a brief introduction to statistical hypothesis testing, paying particular attention to topics that relate to power analysis and sample size determination. Although the theory behind hypothesis testing is general, its concepts can be reviewed by discussing simple case: testing whether a proportion is greater than a known standard.

Following the usual terminology of statistical hypothesis testing, define two complementary hypotheses

$$H_0: P \leq P_0 \text{ vs. } H_1: P > P_0$$

where  $P$  is the response proportion in the population of interest and  $P_0$  is the known standard value.

$H_0$  is called the *null hypothesis* because it specifies that the difference between the two proportions is zero (null).

$H_1$  is called the *alternative hypothesis*. This is the hypothesis of interest to us. Our motivation for conducting the study is to provide evidence that the alternative (or research) hypothesis is true. We do this by showing that the null hypothesis is unlikely—thus establishing that the alternative hypothesis (the only possibility left) is likely.

Outcomes from a statistical test may be categorized as follows:

1. Reject  $H_0$  when  $H_0$  is true. That is, conclude that  $H_0$  is unlikely when it is true. This constitutes a decision error known as the *Type-I error*. The probability of this error is alpha ( $\alpha$ ) and is often referred to as the *significance level* of the hypothesis test.
2. Do not reject  $H_0$  when  $H_0$  is false. That is, conclude that  $H_0$  is likely when it is false. This constitutes a decision error known as the *Type-II error*. The probability of this error is beta ( $\beta$ ). *Power* is  $1 - \beta$ . It is the probability of rejecting  $H_0$  when it is false.
3. Reject  $H_0$  when  $H_0$  is false. This is a correct decision.
4. Do not reject  $H_0$  when  $H_0$  is true. This is also a correct decision.

The basic steps in conducting a study that is analyzed with a hypothesis test are:

1. Specify the statistical hypotheses,  $H_0$  and  $H_1$ .
2. Run the experiment on a given number of subjects.
3. Calculate the value of a test statistic, such as the sample proportion.
4. Determine whether the sample values favor  $H_0$  or  $H_1$ .



## Binomial Probability Table

In the current example, suppose that a random sample of ten individuals is selected, that is  $N = 10$ . The number of individuals,  $R$ , with the characteristic of interest is counted. Hence,  $R$  is the test statistic. A table of binomial probabilities gives the probability that  $R$  takes on each of its eleven possible values for various values for  $P$ .

<b>R</b>	<b>P</b>								
	<b>0.1</b>	<b>0.2</b>	<b>0.3</b>	<b>0.4</b>	<b>0.5</b>	<b>0.6</b>	<b>0.7</b>	<b>0.8</b>	<b>0.9</b>
0	0.349	0.107	0.028	0.006	0.001	0.000	0.000	0.000	0.000
1	0.387	0.376	0.121	0.040	0.010	0.002	0.000	0.000	0.000
2	0.194	0.302	0.233	0.121	0.044	0.011	0.001	0.000	0.000
3	0.057	0.201	0.267	0.215	0.117	0.042	0.009	0.001	0.000
4	0.011	0.088	0.200	0.251	0.205	0.111	0.037	0.006	0.000
5	0.001	0.026	0.103	0.201	0.246	0.201	0.103	0.026	0.001
6	0.000	0.006	0.037	0.111	0.205	0.251	0.200	0.088	0.011
7	0.000	0.001	0.009	0.042	0.117	0.215	0.267	0.201	0.057
8	0.000	0.000	0.001	0.011	0.044	0.121	0.233	0.302	0.194
9	0.000	0.000	0.000	0.002	0.010	0.040	0.121	0.376	0.387
10	0.000	0.000	0.000	0.000	0.001	0.006	0.028	0.107	0.349

Let us discuss in detail the interpretation of the values in this table for the simple case in which a coin is flipped ten times and the number of heads is recorded. The column parameter  $P$  is the probability of obtaining a head on any one toss of the coin. When dealing with coin tossing, one would usually set  $P = 0.5$ , but this does not have to be the case. The row parameter  $R$  is the number of heads obtained in ten tosses of a coin.

The body of the table gives the probability of obtaining a particular value of  $R$ . One way to interpret this probability value is as follows: conduct a simulation in which this experiment is repeated a million times for each value of  $P$ . Using the results of this simulation, calculate the proportion of experiments that result in each value of  $R$ . This proportion is recorded in this table. For example, when the probability of obtaining a head on a single toss of a coin is 0.5, ten flips of a coin would result in five heads 24.6% of the time. That is, as the procedure is repeated (flipping a coin ten times) over and over, 24.6% of the outcomes would be five heads.

## Calculating the Significance Level, Alpha

We will now explain how the above table is used to set the significance level (the probability of a type-I error) to a pre-specified value. Recall that a type-I error occurs when an experiment results in the rejection of the null hypothesis when, in fact, the null hypothesis is true. By studying the table, the impact of using different *rejection regions* can be determined. A rejection region is a simple rule that states which values of the test statistic will result in the null hypothesis being rejected.

For example, suppose we want to test  $P_0 = 0.5$ . That is, the null hypothesis is that  $P = 0.5$  and the alternative hypothesis is that  $P > 0.5$ . Suppose the rejection region is  $R$  equal to 8, 9, or 10. That is,  $H_0$  is rejected if  $R = 8, 9, \text{ or } 10$ . From the above table, the probability of obtaining 8, 9, or 10 heads in 10 tosses when  $P = 0.5$  is calculated as follows:

$$\begin{aligned} P(R = 8, 9, 10 \mid P = 0.5) &= P(R = 8 \mid P = 0.5) + P(R = 9 \mid P = 0.5) + P(R = 10 \mid P = 0.5) \\ &= 0.044 + 0.010 + 0.001 = 0.055. \end{aligned}$$

That is, 5.5% of these coin tossing experiments using this decision rule result in a type-I error. By setting the rejection criterion to  $R = 8, 9, \text{ or } 10$ , alpha has been set to 0.055.

It is extremely important to understand what alpha means, so we will go over its interpretation again. If the probability of obtaining a head on a single toss of a coin is 0.5, then 5.5% of the experiments that use the rejection criterion of  $R = 8, 9, \text{ or } 10$  will result in the false conclusion that  $P > 0.5$ .

The key features of this definition that are often overlooked by researchers are:

1. **The value of alpha is based on a particular value of  $P$ .** Note that we used the assumption “if the probability of obtaining a head is 0.5” in our calculation of alpha. Hence, if the actual value of  $P$  is 0.4, our calculations based on the assumption that  $P$  is 0.5 are wrong. Mathematicians call this a conditional probability since it is based on the condition that  $P$  is 0.5. Alpha is 0.055 if  $P$  is 0.5.

Often, researchers think that setting alpha to 0.05 means that the probability of rejecting the null hypothesis is 0.05. Can you see what is wrong with this statement? They have forgotten to mention the key fact that this statement is based on the assumption that  $P$  is 0.5!

2. **Alpha is a statement about a proportion in multiple experiments.** Alpha tells us what percentage of a large number of experiments will result in 8, 9, or 10 heads. Alpha is a statement about what to expect from future experiments. It is not a statement about  $P$ . Occasionally, researchers conclude that the alpha level is the probability that  $P = 0.5$ . This is not what is meant. Alpha is not a statement about  $P$ . It is a statement about future experiments, given a particular value of  $P$ .

## Interpreting $P$ Values

The term *alpha value* is often used interchangeably with the term *p value*. Although these two terms are closely related, there is an important distinction between them. A *p value* is the largest value of alpha that would result in the rejection of the null hypothesis for a particular set of data. Hence, while the value of alpha is set during the planning of an experiment, the *p value* is calculated from the data after experiment has been run.

## Calculating Power and Beta

We will now explain how to calculate the power. Recall that power is the probability of rejecting a false null hypothesis. A false  $H_0$  means that  $P$  is some value other than  $P_0$ . In order to compute power, we must know the actual value of  $P$ .

Returning to our coin tossing example, suppose the actual value of  $P$  is 0.7. What is the power and beta value of this testing procedure? The decision rule is to reject the null hypothesis when  $R$  is 8, 9, or 10. From the above probability table, the probability of obtaining 8, 9, or 10 heads in 10 tosses of a coin when probability of a head is actually 0.7 is

$$\begin{aligned} P(R = 8, 9, 10 \mid P = 0.7) &= P(R = 8 \mid P = 0.7) + P(R = 9 \mid P = 0.7) + P(R = 10 \mid P = 0.7) \\ &= 0.233 + 0.121 + 0.028 \\ &= 0.382 \end{aligned}$$

This is the power. The value of a type-II error is  $1.000 - 0.382$ , which is 0.618. That is, if  $P$  is 0.7, then 38.2% of these coin tossing experiments will reject  $H_0$ , while 61.8% of them will result in a type-II error.

It is extremely important to understand what beta means, so we will go over its interpretation again. If the probability of obtaining a head on the toss of a coin is 0.7, then 61.8% of the experiments that use the rejection criterion of  $R = 8, 9$ , or 10 will result in the false conclusion that  $P = 0.5$ .

The key features of this definition that are often overlooked by researchers are:

1. **The value of beta is based on a particular value of  $P$ .** Note that we used the assumption “if the probability of obtaining a head is 0.7” in our calculation of beta. Hence, if the actual value of  $P$  is 0.6, our calculation based on the assumption that  $P$  was 0.7 is wrong.
2. **Beta is a statement about the proportion of experiments.** Beta tells us what percentage of a large number of experiments will result in 8, 9, or 10 heads. Beta is a statement about what we can expect from future experiments. It is not a statement about  $P$ .
3. **Beta depends on the value of alpha.** Since the rejection region (8, 9, or 10 heads) depends on the value of alpha, beta depends on alpha.
4. **You cannot make both errors at the same time.** A type-II error can only occur when a type-I error did not occur, and vice versa.

## Specifying Alternative Values of the Parameters

We have noted a great deal of confusion about specifying the values of the parameters under the alternative hypothesis. The alternative hypothesis is usually that the value of one parameter is different from another. The hypothesis does not usually specify how different. It simply gives the direction of the difference. The power is calculated at specified alternative values. These values should be considered as values at which the power is calculated, not as the true value.

## Effect Size

The *effect size* is the size of the change in the parameter of interest that can be detected by an experiment. For example, in the coin tossing example, the parameter of interest is  $P$ , the probability of a head. In calculating the sample size, we would need to state what the baseline probability is (probably 0.5) and how large of a deviation from  $P$  that we want to detect with our experiment. We would expect that it would take a much larger sample size to detect a deviation of 0.01 than it would to detect a deviation of 0.40.

Selecting an appropriate effect size is difficult because it is subjective. The question that must be answered is: what size change in the parameter would be of interest? Note that, in power analysis, the effect size is not the actual difference. Instead, the effect size is the change in the parameter that is of interest or is to be detected. This is a fundamental concept that is often forgotten after the experiment is run.

After an experiment is run that leads to non-significance, researchers often ask, “What was the experiment’s power?” and “How large of a sample size would have been needed to detect significance?” To compute the power or sample size, they set the effect size equal to the amount that was seen in their experiment. This is incorrect. When performing a power analysis after an experiment has completed, the effect size is still the change in the parameter that would be of interest to other scientists. It is not the change that was actually observed!

Often, the effect size is stated as a percentage change rather than an absolute change. If this is the case, you must convert the percentage change to an absolute change. For example, suppose that you are designing an experiment to determine if tossing a particular coin has exactly a 50% chance of yielding a head. That is,  $P_0$  is 0.50. Suppose your gambling friends are interested in whether a certain coin has a 10% greater chance. That is, they are concerned with the case where  $P$  is 0.55 or greater. The effect size is  $|0.50 - 0.55|$  or 0.05.

## Types of Power Analyses

There are several types of power analyses. Often, power analysis is performed during the design phase of a study to determine the sample size. This type of study would determine the value of  $N$  for set values of  $\alpha$  and  $\beta$ . Another type of power analysis is a post hoc analysis, which is done after the study is concluded. A post hoc analysis studies such questions as:

1. What sample size would have been needed to detect a specific effect size?
2. What is the smallest effect size that could be detected with this sample size?
3. What was the power of the test procedure?

These and similar questions may be answered using power analysis. By considering these kinds of questions after a study is concluded, you can gain important insights into how to make your research more efficient and effective.

## Nuisance Parameters

Statistical hypotheses usually make statements about one or more parameters from a set of one or more probability distributions. Often, the hypotheses leave other parameters of the probability distribution unspecified. These unspecified parameters are called ‘nuisance’ parameters.

For example, a common clinical hypothesis is that the response proportions of two drugs are equal. The null hypothesis is that the difference between these two drugs is zero. The alternative is that the difference is non-zero. Note that the actual values of the two proportions are not stated in the hypothesis—just their difference. The actual values of the proportions will be needed to compute the power. That is, different powers will result for the case when  $P_1 = 0.05$  and  $P_2 = 0.25$  and for the case  $P_1 = 0.50$  and  $P_2 = 0.70$ . In this example, the proportion difference ( $D = P_1 - P_2$ ) is the parameter of interest. The baseline proportion,  $P_1$ , is a nuisance parameter.

Another example of a nuisance parameter occurs when using the t-test to test whether the mean is equal to a particular value. When computing the power or sample size for this test, the hypothesis specifies the value of the mean. However, the value of the standard deviation is also required. In this case, the standard deviation is a nuisance parameter.

When performing a power analysis, you should state all your assumptions, including the values of any nuisance parameters that were used. When you do not have any idea as to reasonable values for nuisance parameters, you should use a range of possible values so that you can analyze how sensitive the results are to the values of the nuisance parameters. Also, do not be tempted to use the nuisance parameter’s value from a previous (or pilot) study. Instead, a reasonable strategy is to compute a confidence interval and use the confidence limit that results in the largest sample size.

## Choice of Test Statistics

Many hypothesis tests can be tested with a variety of test statistics. For example, statisticians often have to decide between the t-test and the Wilcoxon test when testing means. Similarly, when testing whether two proportions are equal, they have to decide whether to use a z-test or an exact test. If they choose a z-test, they have to decide whether to apply a continuity correction.

In most cases, each test statistic will have a different power. Thus, it should be obvious that you must compute the power of the test statistic that will be used in the analysis. A sample size based on the t-test will not be accurate for a nonparametric test.

The next question is usually “Which test statistic should I use?” You might say “The one that requires the smallest sample size.” However, other issues besides power must be considered. For example, consideration must be given to whether the assumptions of the test statistic will be met by the data. If your data is binary, it is probably unreasonable to assume that they are continuous.

These are simple principles, but they are often overlooked.

# Types of Hypotheses

Hypothesis tests work this way. If the null hypothesis is rejected, the alternative hypothesis is concluded to be true. However, if null hypothesis is not rejected, no conclusion is reached--the null hypothesis is not concluded to be true. The only way that a conclusion is reached is if the null hypothesis is rejected.

Because of this, it is very important that the null and alternative hypotheses be constructed so that the conclusion of interest is associated with the alternative hypothesis. That way, if the null hypothesis is rejected, the study reaches the desired conclusion.

There are several types of hypotheses. These include inequality, equivalence, non-inferiority, and superiority hypotheses. In the statistical literature, these terms are used with completely different meanings, so it is important to define what is meant by each. We have tried to adopt names that are associated with the alternative hypothesis, since this is the hypothesis of interest.

It is important to note that even though two sets of hypotheses may be similar, they often will have different power and sample size requirements. For example, an equivalence test (see below) appears to be the simple reverse of a two-sided test of inequality, yet the equivalence test requires a much larger sample size to achieve the same power as the inequality test. Hence, you cannot select the sample size for an inequality test and then later decide to run an equivalence test.

Each of the sections to follow will give a brief definition along with an example based on the difference between two proportions.

## Inequality Hypothesis

The term 'inequality' represents the classical one-sided and two-sided hypotheses in which the alternative hypothesis is simply that the two values are unequal. These hypotheses are called tests of superiority by Julious (2004), emphasizing the one-sided versions.

### Two-Sided

When the null hypothesis is rejected, the conclusion is simply that the two parameters are unequal. No statement is made about how different. For example, 0.501 and 0.500 are unequal, as are 0.500 and 0.800. Obviously, even though the former are different, the difference is not large enough to be of practical importance in most situations.

$$H_0: p_1 - p_2 = 0 \text{ vs. } H_1: p_1 - p_2 \neq 0 \text{ or } H_1: p_1 - p_2 < 0 \text{ or } p_1 - p_2 > 0$$

### One-Sided

These tests offer a little more information than the two sided tests since the direction of the difference is given. Again, no indication is made about how much higher (or lower) the superior value is to the inferior.

$$H_0: p_1 - p_2 \leq 0 \text{ vs. } H_1: p_1 - p_2 > 0 \text{ or } H_0: p_1 - p_2 \geq 0 \text{ vs. } H_1: p_1 - p_2 < 0$$

## Non-Inferiority Hypothesis

These tests are a special case of the one-sided inequality tests. The term ‘non-inferiority’ is used to indicate that one treatment is not worse than another treatment. That is, one proportion is not less than another proportion by more than a trivial amount called the ‘margin of equivalence’.

For example, suppose that a new drug is being developed that is less expensive and has fewer side effects than the standard drug. Producers must show that its effectiveness is no worse than the drug it is to replace.

When testing two proportions in which a higher proportion is better, the non-inferiority of treatment 1 as compared to treatment 2 is expressed as

$$H_0: p_1 - p_2 \leq -\delta \text{ vs. } H_1: p_1 - p_2 > -\delta \text{ or } H_0: p_1 \leq p_2 - \delta \text{ vs. } H_1: p_1 > p_2 - \delta$$

where  $\delta > 0$  is called the margin of equivalence. Note that when  $H_0$  is rejected, the conclusion is that the first proportion is not less than the second proportion by more than  $\delta$ .

Perhaps an example will help introduce this type of test. Suppose that the current treatment for a disease works 70% of the time. Unfortunately, this treatment is expensive and occasionally exhibits serious side-effects. A promising new treatment has been developed to the point where it can be tested. One of the first questions that must be answered is whether the new treatment is as good as the current treatment. In other words, do at least 70% of subjects respond to the new treatment?

Because of the many benefits of the new treatment, clinicians are willing to adopt the new treatment even if it is slightly less effective than the current treatment. They must determine, however, how much less effective the new treatment can be and still be adopted. Should it be adopted if 69% respond? 68%? 65%? 60%? There is a percentage below 70% at which the difference between the two treatments is no longer considered ignorable. After thoughtful discussion with several clinicians, it is decided that if a response of at least 63% is achieved, the new treatment will be adopted. The difference between these two percentages is called the *margin of equivalence*. The margin of equivalence in this example is 7% (which is ten percent of the original 70%).

The developers must design an experiment to test the hypothesis that the response rate of the new treatment is at least 0.63. The statistical hypothesis to be tested is

$$H_0: p_1 - p_2 \leq -0.07 \text{ versus } H_1: p_1 - p_2 > -0.07$$

Notice that when the null hypothesis is rejected, the conclusion is that the response rate is at least 0.63. Note that even though the response rate of the current treatment is 0.70, the hypothesis test is about a response rate of 0.63. Also, notice that a rejection of the null hypothesis results in the conclusion of interest.

## Superiority Hypothesis

These tests are a special case of the one-sided inequality tests. The term ‘superiority’ is used to indicate that one treatment is better than another by more than a trivial amount called the ‘margin of equivalence’. For example, suppose that a new drug is being developed that is thought to have superior performance to the existing drug. Producers must show that its effectiveness is better than the drug it is to replace.

When testing two proportions in which a higher proportion is better, the superiority of treatment 1 over treatment 2 is expressed as

$$H_0: p_1 - p_2 \leq \delta \text{ vs. } H_1: p_1 - p_2 > \delta \text{ or } H_0: p_1 \leq p_2 + \delta \text{ vs. } H_1: p_1 > p_2 + \delta$$

where  $\delta > 0$  is called the margin of equivalence. Note that when  $H_0$  is rejected, the conclusion is that the first proportion is higher than the second proportion by more than  $\delta$ .

## Equivalence Hypothesis

The term ‘equivalence’ is used here to represent tests designed to show that response rates of two treatments do not differ by more than a trivial amount called the ‘margin of equivalence’. These tests are the reverse of the two-sided inequality test.

The typical set of hypotheses are

$$H_0: p_1 - p_2 \leq \delta_L \text{ or } p_1 - p_2 \geq \delta_U \text{ vs. } H_1: \delta_L \leq p_1 - p_2 \leq \delta_U$$

where  $\delta_L < 0$  and  $\delta_U > 0$  are called the *equivalence limits*.

Suppose 70% of subjects with a certain disease respond to a certain drug. The company that produces the drug has decided to open a new facility in another city. They must show that the drug produced in the new facility is equivalent (all most the same) as that produced in existing facilities. After thoughtful discussion with several clinicians and regulatory agencies, it is decided that if the response rate of the drug produced at the new facility is between 65% and 75%, the new facility will go into production. In this case, the *margin of equivalence* is 5%.

The statistical hypothesis to be tested is

$$H_0: |p_1 - p_2| \geq 0.05 \text{ vs. } H_1: |p_1 - p_2| < 0.05$$



## Chapter 7

# Proportions

## Introduction

This chapter introduces power analysis and sample size calculation for proportions. When the response is binary, the results for each group may be summarized as proportions. Usually, hypothesis tests are conducted to compare two proportions.

There are many issues that must be considered when designing experiments that use proportions. For example, will the proportions be analyzed directly, or will they be converted into differences, ratios, or odds ratios? Which test statistic will be used? Will the design use independent groups or will subjects be measured twice? Will the study have an active control?

The various answers to these and other questions result in a large number of situations. This chapter will introduce you to the issues that are common to all the tests of proportions.

## Designs

There are several experimental designs for comparing two proportions. You can use a one-sample design to compare a sample proportion to a specific value. You can compare proportions from two independent samples using independent, stratified, cluster-randomized, or group-sequential designs. You can compare two correlated proportions. And finally, you can compare several categories in a contingency table.

## Comparing Proportions

Two proportions may be compared by considering their difference, ratio, or odds ratio. Each of these cases may lead to different test statistics with different powers and sample size requirements.

Assume that  $p_1$  is the response proportion of the experimental group and  $p_2$  is the response proportion of the control (standard or reference) group. Mathematically, these alternative parameterizations are

<u>Parameter</u>	<u>Computation</u>
Difference	$\delta = p_1 - p_2$
Ratio	$\phi = p_1 / p_2$
Odds Ratio	$\psi = \frac{p_1 / (1 - p_1)}{p_2 / (1 - p_2)}$

Once you know  $p_1$  and  $p_2$ , you can calculate any of these values, and you can easily change from one parameterization to another. Thus, the choice of which parameter you use may seem arbitrary. However, since different parameterizations lead to different test statistics, the choice can lead to a different power and sample size. These parameterizations will be discussed next.

## Difference

The difference  $\delta = p_1 - p_2$  is perhaps the most common method of comparing two proportions. This parameter is easy to interpret and communicate. It gives the absolute impact of the treatment. However, there are subtle difficulties that can arise with its use.

One difficulty occurs when the event of interest is rare. If a difference of 0.001 is reported for an event with a baseline probability of 0.40, we would dismiss this as being trivial. That is, there is usually little interest in a treatment that decreases the probability from 0.400 to 0.399. However, if the baseline probability of a disease is 0.002, a 0.001 decrease in the disease probability would represent a 50% reduction. Thus, the interpretation of the difference depends on the baseline probability of the event.

When planning studies, the value of  $p_2$  is usually known and the power is calculated at various values of  $\delta$ . The value of  $p_1$  is then calculated using  $p_1 = p_2 + \delta$ . Because of the requirement that  $0 < p_1 < 1$ , the values of  $\delta$  are restricted to the interval  $-p_2 < \delta < 1 - p_2$ , not  $-1 < \delta < 1$  as you might expect. Likewise, the values of  $p_2$  are restricted to  $0 < p_2 < 1 - \delta$  if  $\delta > 0$  and  $-\delta < p_2 < 1$  if  $\delta < 0$ .

Because typical values of  $\delta$  are usually between -0.2 and 0.2, the allowable values of  $p_2$  are restricted to be between 0.2 and 0.8. When the values of  $p_2$  are outside this range, it may be more convenient to use the odds ratio.

## Ratio

The (risk) ratio,  $\phi = p_1 / p_2$ , gives the relative change in the probability of the outcome under each of the hypothesized values. This parameter is direct and easy to interpret. To compare the ratio with the difference, examine the case where  $p_1 = 0.1437$  and  $p_2 = 0.0793$ . One should consider which number is more enlightening,  $\delta = -0.0644$ , or  $\phi = 55.18\%$ . In many cases, the relative change (the ratio) is easier to interpret than the absolute change (the difference).

When planning studies, the value of  $p_2$  is usually known and the power is calculated at various values of  $\phi$ . The value of  $p_1$  is then calculated using  $p_1 = p_2 \times \phi$ . Because of the requirement that  $0 < p_1 < 1$ , the values of  $\phi$  are restricted to the interval  $0 < \phi < 1 / p_2$ , not  $0 < \phi < \infty$  as you might expect. Likewise, the values of  $p_2$  are restricted to  $0 < p_2 < 1 / \phi$  if  $\phi > 1$  and  $0 < p_2 < 1$  if  $\phi < 1$ .

Because typical values of  $\phi$  are usually between 0.5 and 1.5, the values of  $p_2$  are restricted to be between 0 and 0.667. When the values of  $p_2$  are outside this range, it may be more convenient to use the odds ratio.

## Odds Ratio

Chances are usually communicated as long-term proportions or probabilities. In betting, chances are often given as odds. For example, the odds of a horse winning a race might be set at 10-to-1 or 3-to-2. Odds can easily be translated into probabilities, and vice versa. An odds of 3-to-2 means that the event is expected to occur three out of five times. That is, an odds of 3-to-2 (1.5) translates to a probability of winning of 0.60.

The odds of an event are calculated by dividing the event risk by the non-event risk. Thus the odds are

$$Odds_1 = \frac{p_1}{1 - p_1} \text{ and } Odds_2 = \frac{p_2}{1 - p_2}$$

For example, if  $p$  is 0.6, the odds are  $0.6/0.4 = 1.5$ . Rather than represent the odds as a decimal amount, it is re-scaled into whole numbers. Thus, instead of presenting the odds as 1.5-to-1, they present as 3-to-2.

Two odds could be compared by considering their difference, but it is more convenient in many situations to form their ratio. Thus, another way to compare proportions is to compute the ratio of their odds. The odds ratio is

$$\begin{aligned} \psi &= \frac{Odds_1}{Odds_2} \\ &= \frac{\frac{p_1}{1 - p_1}}{\frac{p_2}{1 - p_2}} \end{aligned}$$

Unlike the difference and the ratio, the odds ratio is not restricted by the value of  $p_2$ . The range of possible values of the odds ratio is  $-\infty < \psi < \infty$ . Because of the freedom in specifying the parameters, the odds ratio is a popular parameterization, even though it is not as easy to interpret as the difference and the ratio.

## Specifying the Proportions – Very Important!

It is important to understand the interpretation of  $p_1$  and  $p_2$  within *PASS*. Suppose  $p_1$  represents the proportion in the treatment group and  $p_2$  represents the proportion in the control group. In most hypothesis tests, these values are equal under the null hypothesis and different under the alternative hypothesis. Thus, under the null hypothesis, all that is needed is the value of  $p_1$  or  $p_2$ , but not both. Under the alternative hypothesis, both values are necessary. So, when the input screen asks for  $p_2$  and the difference, these values should be interpreted as follows. The value of  $p_2$  is actually the value of both  $p_1$  and  $p_2$  under  $H_0$ . Under  $H_1$ , the value of  $p_1$  is calculated from  $p_2$  and  $\delta$  using the formula  $p_1 = p_2 + \delta$ .

Also, it is important to understand what we mean by ‘under  $H_1$ ’ in the above discussion. Notice that  $H_1$  does not specify the exact value of  $p_1$ . Instead, it specifies a range of values. For example,  $H_1$  might be  $p_1 > p_2$  or  $p_1 - p_2 > \delta$ . However, even though  $H_1$  gives a range of values for  $p_1$ , the power is computed at a specific value of  $p_1$ .

Selecting an appropriate value for  $p_1$  must be done very carefully. We recommend the following approach. Select a value of  $p_1$  that represents the change from  $p_2$  that you want the experiment to detect. When you calculate a sample size, it is interpreted as the sample size necessary to detect a difference of at least  $p_1 - p_2$  when the significance level is  $\alpha$  and the power is  $1 - \beta$ .

The important point is that  $p_1$  is not the value you anticipate obtaining from an experiment. Instead, it is that value of  $p_1$  at which you want to compute the power. This is a very important distinction! This is why, when investigating the power after an experiment is run, we recommend that you do not simply plug in the values of  $p_1$  and  $p_2$  from that experiment. Rather, you use values that represent the size of the difference that you want to detect.

## Chapter 8

# Means

## Introduction

This chapter introduces power analysis and sample size calculation for tests that compare means. In many situations, the results for each treatment group are summarized as means. There are many issues that must be considered when designing experiments for comparing means. For example, are the means independent or correlated? Which test statistic to use? Will a parametric or nonparametric test be used? Are the data normally distributed? Are there more than two treatment groups? The answers to these and other questions result in a large number of situations.

## Specifying the Means

Assume that  $\mu_1$  is the mean of an experimental group and  $\mu_2$  is the mean of a control (standard or reference) group. Suppose  $\delta$  represents their difference. That is,  $\delta = \mu_1 - \mu_2$ . In most hypothesis tests, the null hypothesis ( $H_0$ ) is  $\delta = 0$  and the alternative hypothesis ( $H_1$ ) is  $\delta \neq 0$ . Since  $H_0$  assumes that  $\delta = 0$ , all that is really needed to compute the power is the value of  $\delta$  under  $H_1$ . So, when the input screen asks for  $\mu_1$  and  $\mu_2$ , these values should be interpreted as follows. The value of  $\mu_1$  is actually the value of both  $\mu_1$  and  $\mu_2$  under  $H_0$ . Under  $H_1$ , the values of  $\mu_1$  and  $\mu_2$  provide the value of  $\delta$  at which the power is calculated.

The above discussion is summarized in the following chart.

Input Parameter	Under $H_0$	Under $H_1$
Mean1	$\mu_1, \mu_2$	$\mu_1$
Mean2	ignored	$\mu_2$

Also, it is important to understand what we mean by ‘under  $H_1$ ’ in the above discussion.  $H_1$  defines a range of values for  $\delta$  at which the power can be computed. To compute the power, the specific values of  $\delta$  must be determined. Thus, there is not a single power value. Instead, there are an infinite number of power values possible, depending on the value of  $\delta$ .

Selecting an appropriate value for  $\mu_1$  must be done very carefully. We recommend the following approach. Select a value of  $\mu_1$  that represents the change from  $\mu_2$  that you want the experiment to detect. When you calculate a sample size, it is interpreted as the sample size necessary to detect a difference of at least  $\delta$  when the significance level is  $\alpha$  and the power is  $1 - \beta$ .

It is important to realize that  $\delta$  is not the value you anticipate obtaining from the experiment. Instead, it is that value of  $\delta$  at which you want to compute the power. This is a very important distinction! This is why, when investigating the power after an experiment is run, we recommend that you do not simply plug in the values of  $\mu_1$  and  $\mu_2$  from that experiment. Rather, you use values that represent the size of the difference that you want to detect.

## Specifying the Standard Deviation

Usually, statistical hypotheses about the means make no direct statement about the standard deviation. However, the standard deviation is a parameter in the normal distribution, so its value must be specified. For this reason, it is called a *nuisance parameter*.

Even though it is not of primary interest, an estimate of the standard deviation is necessary to perform a power analysis. Finding such an estimate is difficult not only because it is required before the data are available, but also because the physical interpretation of the standard deviation is vague. How do you estimate a quantity without data and without a clear understanding of what it is? This section will try to help.

## Understanding the Standard Deviation

The standard deviation has two general interpretations. First, it is similar to the average absolute difference between each observation and the mean. Second, it is the average absolute difference between every pair of observations.

The standard deviation of a population of values is calculated using the formula

$$\sigma_X = \sqrt{\frac{\sum_{i=1}^N (X_i - \mu_X)^2}{N}}$$

where  $N$  is the number of items in the population,  $X$  is the variable being measured, and  $\mu_X$  is the mean of  $X$ . This formula indicates that the standard deviation is the square root of an average of the squared differences between each value and the mean. The differences are squared to remove the sign so that negative values will not cancel out positive values. After summing up these squared differences and dividing by  $N$ , the square root is taken to put the result back in the original scale. Bottom line—the standard deviation can be thought of as the average absolute difference between the data values and their mean.

## Estimating the Standard Deviation

Our task is to find a rough estimate of the standard deviation to use in a power analysis. Several possible methods could be used. These include using the results of a previous study or a pilot study, using the range, using the coefficient of variation, etc. *PASS* includes a Standard Deviation Estimator procedure that will help you obtain a standard deviation estimate based on these methods. It is loaded from the PASS-Other menu. Remember that as the standard deviation increases, the power decreases. Hence, an increase in the standard deviation will cause an increase in the sample size. To be conservative in sample size calculation, you should use a large value for the standard deviation.

# Simulation

Most of the formulas used in *PASS* were derived by analytic methods. That is, based on a series of assumptions, a formula for the power and sample size is derived mathematically. This formula is then programmed and made available in *PASS*. Unfortunately, the formula is only as realistic as the assumptions upon which it is based. If the assumptions are inaccurate in a certain situation, the power calculations may also be inaccurate. An alternative to using analytic methods is to use *simulation* (or *Monte Carlo*) techniques. Because of the speed of modern computers, simulations can now be run in minutes that would have taken days or weeks only a few years ago.

In power analysis, *simulation* refers to the process of generating several thousand random samples that follow a particular distribution, calculating the test statistic from each sample, and tabulating the distribution of these test statistics so that the significance level and power of the procedure may be estimated.

The steps to a simulation study are

1. Specify how the study is carried out. This includes specifying the randomization procedure, the test statistic that is used, and the significance level that will be used.
2. Generate random samples from the distributions specified by the null hypothesis. Calculate each test statistic from the simulated data and determine if the null hypothesis is accepted or rejected. Tabulate the number of rejections and use this to calculate the test's significance level.
3. Generate random samples from the distributions specified by the alternative hypothesis. Calculate the test statistics from the simulated data and determine if the null hypothesis is accepted or rejected. Tabulate the number of rejections and use this to calculate the test's power.
4. Repeat steps 2 and 3 several thousand times, tabulating the number of times the simulated data leads to a rejection of the null hypothesis. The significance level is the proportion of simulated samples in step 2 that lead to rejection. The power is the proportion of simulated samples in step 3 that lead to rejection.

## How Large Should the Simulation Be?

As the number of simulations is increased, the precision and running time of the simulation will be increased also. This section provides a method for estimating of the number simulations needed to achieve a given precision.

Each simulation iteration (or simulation) generates a binary outcome: either the null hypothesis is rejected or not. Thus, the significance level and power estimates each follow the binomial distribution. This knowledge makes it a simple matter to compute confidence intervals for the significance level and power values.

The following table gives one-half the width of a 95% confidence interval for the power when the estimated value is either 0.50 or 0.95.

Simulation Size M	Half-Width when Power = 0.50	Half-Width when Power = 0.95
100	0.100	0.044
500	0.045	0.019
1000	0.032	0.014
2000	0.022	0.010
5000	0.014	0.006
10000	0.010	0.004
50000	0.004	0.002
100000	0.003	0.001

Notice that a simulation size of 1000 gives a precision of plus or minus 0.014 when the true power is 0.95. Also, as the simulation size is increased beyond 5000, there is only a small amount of additional accuracy achieved. Since most sample-size studies require an accuracy of within one or two percentage points, simulation sizes from 2000 to 10000 should be ample.

## You are Running Two Simulations

It is important to realize that when you run a simulation in *PASS*, you are actually running two separate simulations: one to estimate the significance level and the other to estimate the power. The significance-level simulation is defined by the input parameters labeled 'H0'. The power simulation is defined by the input parameters labeled 'H1'. Even though you have complete flexibility as to what distributions you use in each of these simulations, it usually makes sense to use the same distributions for both simulations—only changing the values of the means.

## Unequal Standard Deviations

One of the subtle problems that can make the results of a simulation study misleading is to specify unequal standard deviations unknowingly when you are investigating another feature, such as the amount of skewness. It is well known that if the standard deviations differ (a situation called heteroskedasticity), the accuracy of the significance level and power is doubtful. When investigating the power of the t or F tests in non-normal situations, care must be taken to insure that the standard deviations of the groups remain about the same. Otherwise, the effects of skewness and heteroskedasticity cannot be separated.



## Finding the Hypothesized Means

It is important to set the mean difference of each simulation carefully. In the case of analytic formulas, the mean difference is specified easily and directly. Usually, the mean difference is set to zero under the null hypothesis and to a non-zero value under the alternative hypothesis. You must make certain that you follow this pattern when setting up a simulation.

For most distributions, the means are set explicitly (the exception is the multinomial distribution, where this is impossible). Hence, for both the null and alternative simulations, it is relatively simple to calculate the mean difference. You must do this! We will now present two examples showing how this is done.

For the first example, consider the case of a simulation being run to compare two independent group means using the two-sample t-test. Suppose the *PASS* setup is as follows. Note that N(40 2) stands for a normal distribution with a mean of 40 and a standard deviation of 2.

<u>Distribution</u>	<u>PASS Input</u>	<u>Mean Value of Simulated Data</u>
Group 1 Distribution   H0	N(40 2)	40.0
Group 2 Distribution   H0	N(40 2)	40.0
Group 1 Distribution   H1	N(42 2)	42.0
Group 2 Distribution   H1	N(40 2)	40.0

The mean difference under H0 is  $40 - 40 = 0$ , which is as it should be. The mean difference under H1 is  $42 - 40 = 2$ . Hence, the power is being estimated for a mean difference of 2.

Next we will consider a more complicated example. Suppose the *PASS* setup is as follows. Note that N(40 2)[70];K(0)[30] specifies a mixture distribution made up of 70% from a normal distribution with a mean of 40 and a standard deviation of 2 and 30% from a constant distribution with a value of 30.

<u>Distribution</u>	<u>PASS Input</u>	<u>Mean Value of Simulated Data</u>
Group 1 Distribution   H0	N(40 2) [70];K(0)[30]	$40(0.7) + 30(0.3) = 37.0$
Group 2 Distribution   H0	N(40 2) [70];K(0)[30]	$40(0.7) + 30(0.3) = 37.0$
Group 1 Distribution   H1	N(42 2) [70];K(0)[30]	$42(0.7) + 30(0.3) = 38.4$
Group 2 Distribution   H1	N(40 2) [70];K(0)[30]	$40(0.7) + 30(0.3) = 37.0$

The mean difference under H0 is  $37.0 - 37.0 = 0$ , which is as it should be for the null hypothesis. The mean difference under H1 is  $38.4 - 37.0 = 1.4$ . Hence, the power is being estimated by simulation for a mean difference of 1.4.

You must always be aware of what the mean differences are under both the null and alternative hypotheses.

## Adjusting the Significance Level

When faced with the task of designing an experiment that will have a specific significance level for a situation that does not meet the usual assumptions, there are several possibilities.

1. A statistician could be hired to find an appropriate testing procedure.
2. A nonparametric test could be run that (hopefully) corrects for the implausible assumptions.
3. The regular parametric test could be run, relying on the test's 'robustness' to correct for the implausible assumptions.
4. A simulation study could be conducted to determine an appropriate adjustment to the significance level so that the actual significance level is at the required value.

We will now present an example of how to do the simulation adjustment alluded to in item 4, above.

The two-sample t-test is known to be robust to the violation of some assumptions, but it is susceptible to inaccuracies when the data contain outliers. A mixture of two normal distributions will be used to generate data with outliers. The mixture will draw 95% of the data from a normal distribution with a mean of 0 and a standard deviation of 1. The other 5% of the data will come from a normal distribution with a mean of zero and a standard deviation of 10. A simulation study using 10,000 iterations and a sample size of 100 per group produced the following results when the nominal significance level was set to 0.05.

<b>Nominal</b>	<b>Actual</b>	<b>Lower 95%</b>	<b>Upper 95%</b>	
<b><u>Alpha</u></b>	<b><u>Alpha</u></b>	<b><u>Confidence</u></b>	<b><u>Confidence</u></b>	<b><u>Power</u></b>
0.050	0.045	0.041	0.049	0.816
0.055	0.051	0.047	0.055	0.843
0.060	0.057	0.053	0.062	0.835

The actual alpha level of the t-test is 0.045, which is below the target value of 0.05. When the nominal alpha level is increased to 0.055, the actual alpha is 0.051—close to the desired level of 0.05. Hence, an adjustment could be applied as follows. Analyze the data with the two-sample t-test even though they contain outliers. However, instead of using an alpha of 0.050, use an alpha of 0.055. When this is done, the simulation shows that the actual alpha will be at the desired 0.05 level.

There is one limitation to this method: the resulting test procedure is not necessarily efficient. That is, it may be possible to derive a testing procedure that is more efficient (requires a smaller sample size to achieve the same power). For example, in this example, a test based on the trimmed mean may be more efficient in the presence of outliers. However, if you do not have the time or ability to derive an alternative test, this adjustment allows you to obtain reasonable testing procedure that achieves a desired significance level and power.

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# Index

Note that most index entries are of the form “chapter-page”. If no chapter is given, the entry refers to the introductory chapters. A list of chapters is given in the Table of Contents.

- 2x2 cross-over: mean difference, 500-1; non-inferiority, 510-1; ratio, 505-1
- 3D parameters, 28
- 3D tab, 28
- Abbreviations tab, 31
- Abort, 18
- Accrual time: log-rank, 705-5
- All-contrasts power, 590-4
- All-pair power, 580-5, 585-4
- Alpha, 44; adjusting, 60; MANOVA, 605-10; multiple comparisons, 580-2, 585-2, 590-1
- Alpha spending function: means, 475-1; proportions, 220-1; survival, 710-1
- Alternative hypothesis, 42, 55
- Analysis of variance: fixed effects ANOVA, 560-1; one-way, 550-1; randomized block, 560-1
- ANOVA: factorial, 560-1; fixed effects, 560-1; multiple comparisons, 575-2, 580-3; multiple contrasts, 590-2; one-way, 550-1; randomized block, 560-1; repeated measures, 570-1; simulation, 555-1; three-way, 560-1; two-way, 560-1
- Any-contrast power, 590-4
- Any-pair power, 580-5, 585-4
- : ANOVA, 550-2; Mann-Whitney, 430-4; MANOVA, 605-1; repeated measures, 570-2; t-test, 430-4; , 410-3, 410-4, 410-5
- AUC: ROC curve, 260-2; ROC curves, 265-1, 265-5
- Autocorrelation, 570-27
- Average absolute deviation: standard deviation estimator, 905-3
- Axes tab, 27
- Axis: horizontal, 23
- Axis color, 28
- Axis maximum, 27
- Axis minimum, 27
- Background tab, 30
- Balaam's design, 530-1, 530-2, 535-1, 535-2, 540-2
- Bar Chart Options, 23
- : , 105-8
- Best: multiple comparisons, 575-5
- Beta, 45; log-rank survival test, 700-5; , 105-12; , 410-7; , 410-6, 410-10; show power, 23; simulating a, 630-3; , 410-6, 410-10
- Between standard deviation, 570-15
- Bimodal data: simulating, 630-23
- Binomial, 43, 100-2; proportion, 115-1; simulating a, 630-5
- Binomial tests, 100-4
- Binormal model: ROC curve, 260-2; ROC curves, 265-2
- Bioequivalence: proportions, 215-1
- Blackwelder: risk ratio, 205-29
- Blocks, 560-9
- Bonferroni test, 590-3
- Bootstrap test: simulation, 410-4, 490-5, 495-6
- Brownian motion: group sequential, 475-5; proportions, 220-5; survival, 710-6
- Cage edge, 29
- Cage flip, 29
- Cage wall, 29
- Carryover effects, 570-3
- Case-control: matched, 255-1
- Cauchy: simulating a, 630-5
- Cell means, 560-1
- Chart Type, 23
- Charts: interactive formatting, 25
- Chi-square: estimator, 900-1; one variance, 650-1
- Chi-square test, 250-1; proportions, 200-6
- Circularity, 570-14
- Clinical trial: three-stage, 130-1
- Clinical trials, 120-2
- Cluster randomization: equivalence, 240-1; means, 480-1; proportions, 230-1; proportions, 240-1; non-inferiority, 235-1
- Clusters: cluster randomization, 480-3
- Cochran-Mantel-Haenszel, 225-1
- Coefficient alpha, 815-1, 1
- Coefficient of variation, 905-10; cross-over, 505-3; mean ratio, 445-2, 455-3, 470-4, 515-4, 535-4
- Cohort study, 135-1
- Color: axis, 28; grid lines, 27
- Color max, 29
- Color min, 29
- Color of legend, 26
- Color palette, 29
- Comparisons: multiple comparisons, 575-1; one-way, 550-1
- Comparisonwise: error rate, 580-2, 585-2, 590-1
- Compound symmetry, 570-14
- Confidence coefficient: mean, 420-2, 420-3; proportion, 115-2
- Confidence interval: mean, 420-1; proportion, 115-1
- Constant: simulating a, 630-6
- Consumer's risk, 405-1
- Contingency table, 250-1; chi-square, 900-1
- Continuity correction, 100-5; proportions, 220-8; two proportions, 205-8
- Contrast coefficients, 550-7
- Contrast matrix, 570-11
- Contrasts, 550-1, 590-1; MANOVA, 605-6; multiple, 590-2
- Control: multiple comparisons, 575-2, 585-1
- Controlled variables: multiple regression, 865-5

## 2 Index

---

- Correlated proportions: equivalence, 165-1; McNemar test, 150-1
- Correlation: cluster randomization, 480-3; intraclass, 810-1; linear regression, 855-1; one, 800-1; two, 805-1
- Correlation coefficient, 800-1
- Correlation tolerance: paired means using simulation, 490-11
- Covariance: Hotelling's T<sup>2</sup>, 600-5; MANOVA, 605-11
- Covariance matrix, 570-14
- Covariate: logistic regression, 860-6
- Cox regression, 850-1
- Creating data: simulation, 630-1
- Cronbach's alpha, 815-1, 1
- Coefficient of variation, 525-4, 545-5
- Equivalence tests, 540-3
- Hypothesis, 545-3
- Cross-over: Balaam's design, 540-2; equivalence, 520-1, 525-1, 540-1, 545-1; higher order, 535-1, 540-1; higher-order, 530-1; mean difference, 500-1; non-inferiority, 510-1, 515-1, 530-1, 535-1; ratio, 505-1, 525-1, 535-1; repeated measures, 570-46
- Cubic: contrast, 550-7
- Customizing toolbars, 13
- Data, 38; simulation of, 630-1
- Data Tab, 21
- Decimals, 22
- Default: template, 16
- Depth, 28
- Diagnostic testing: ROC curve, 260-1
- Difference: equivalence, 110-4, 165-3, 460-1, 520-1, 540-1; non-inferiority, 105-4, 160-3, 450-1, 530-1; proportion, 100-6; proportions, 52, 200-3, 205-3, 210-4, 215-4
- Discordant pairs, 150-2
- Distribution: combining, 630-16; mixing, 630-16
- Distributions: simulating paired, 490-2; simulation, 630-1
- Documentation, 19, 39
- Donner & Klar: cluster randomization, 230-2
- Double exponential, 400-7
- Drift: group sequential, 475-5; proportions, 220-5
- Dunn's test, 590-3; power, 590-4
- Dunnett's test, 585-3; multiple comparisons, 575-3
- Dunnett's test, 585-1
- Dunn's test: power, 590-1
- Edit menu, 36
- Effect size, 46; ANOVA, 560-3, 560-7; chi-square, 900-1, 900-2; chi-square test, 250-2; multiple regression, 865-3; one-way ANOVA, 550-3; randomized block, 560-2
- Effect Size: one-way ANOVA, 550-13
- Balaam's design, 545-2
- Equivalence: cluster randomization, 240-1; correlated proportions, 165-1; cross-over, 520-1, 525-1, 540-1, 545-1; difference, 460-1; hypothesis, 215-4, 215-5; limits, 495-8; margin, 450-9; Mean, 520-1; mean ratio, 470-1; means, 465-1; paired means, 495-1; proportion, 110-1; proportions, 165-1, 215-1; ratio, 165-6; ratio, 470-1; simulation, 495-3; t-test, 465-3
- Equivalence hypothesis, 50
- Equivalence margin: non-inferiority, 455-4
- Error rates: multiple comparison, 580-2, 585-2, 590-1
- Errors, 42
- Exit, 18
- Experimentwise: error rate, 580-2, 585-2, 590-1
- Exponential: log-rank, 705-3; means, 435-1; simulating a, 630-7
- Exponential data: simulation, 410-28
- Exponential mean, 405-1
- Exponential test: simulation, 410-5
- Exposed, 255-5
- Exposure, 870-1
- Exposure probability: matched case-control, 255-3
- F: simulating a, 630-8
- Factor: fixed, 560-5; random, 560-5
- Factorial ANOVA, 560-1
- Familywise: error rate, 580-2, 585-2, 590-1
- Farrington - Manning test: difference, 210-11; equivalence, 215-11; non-inferiority, 210-11; ratio, 215-11
- Farrington-Manning test: two proportions, 205-11
- File menu, 34
- File Menu, 17
- File Name: template file, 32
- Files: template, 32
- : , 105-12
- Finite population correction: t test, 400-6
- Finite population size, 420-2; proportion, 115-2
- Fisher's Exact test: proportions, 200-5
- Fisher-z transformation, 805-1
- Fixed factor, 560-5
- Fleming: one-stage design, 120-1
- Folders, 1
- Follow-up: log-rank, 705-4
- Fonts: changing, 37
- Format menu, 37, 40
- Formatting: charts interactively, 25
- FPR: ROC curve, 260-6; ROC curves, 265-1, 265-6
- F-test: Geisser-Greenhouse, 570-4; one-way, 555-2; simulation, 555-1; two variances, 655-1
- Games-Howell: multiple comparison, 580-1
- Games-Howell test, 580-4
- Gamma: simulating, 630-24; simulating a, 630-9
- Gart - Nam test: difference, 210-13; equivalence, 215-12; non-inferiority, 210-13; ratio, 215-12
- Gart-Nam test: two proportions, 205-12
- Geisser-Greenhouse, 570-1
- Geisser-Greenhouse F-test, 570-4
- General linear multivariate model: MANOVA, 605-2
- General Linear Multivariate Model, 570-3
- Generating data, 630-1
- Goodness of fit, 250-1; chi-square, 900-1
- Grid color, 27
- Grid line style, 27
- Grid lines, 27
- Group Sample Size, 555-5
- Group sample size pattern, 580-10
- Group sequential test: log-rank, 710-1; means, 475-1; proportions, 220-1; survival, 710-1
- Hazard rate: Cox regression, 850-1

- Hazard rates: log-rank, 700-2, 705-2  
 Hazard ratio: group sequential, 710-2  
 Help menu, 39  
 Help system, 5  
 Cross-over, 545-1  
 Home window, 11  
 Horizontal Axis, 23  
 Hotelling's T2, 600-1  
 Hotelling-Lawley trace, 570-7, 605-1; MANOVA, 605-5  
 Hotelling-Lawley trace, 570-1  
 Hypergeometric, 100-2  
 Hypotheses: ANOVA, 560-4; non-inferiority, 415-2; offset proportions, 205-5; superiority, 415-2; types, 48  
 Hypothesis: difference, 210-4, 215-4; equivalence, 50, 110-4, 165-3, 215-4, 215-5; inequality, 48; introduction, 42; means, 55; non-inferiority, 49, 105-4, 105-5, 160-3, 160-6, 450-2; odds ratio, 110-6, 210-5, 215-5; , 410-7; one variance, 650-3; ratio, 110-5, 210-5, 215-5; superiority, 50, 105-4; Superiority, 210-4  
 Hypothesis testing: introduction, 42  
 Hypothesized mean, 550-14  
 Hypothesized means, 550-6; randomized block, 560-4  
 Icons, 12, 13  
 Incidence rate, 135-2  
 Independence test, 250-1  
 Inequality: 2x2 cross-over, 500-1; correlated proportions, 150-1; hypothesis, 48; mean ratio, 445-1; proportion, 100-1; proportions, 200-1, 205-1  
 Installation, 1  
 Interactive Charts, 25  
 Interactive Format, 25  
 Intercept: linear regression, 855-1  
 Interim analysis: means, 475-1; proportions, 220-1; survival, 710-1; three-stage, 130-1  
 Intraclass correlation, 810-1  
 Intracluster correlation: cluster randomization, 230-2, 480-3; cluster randomization, 235-3  
 Isometric, 29  
 Iterations: maximum, 22  
 Kruskal-Wallis: multiple comparisons, 580-1; simulation, 555-1  
 Kruskal-Wallis test, 580-4, 585-4; multiple comparisons, 585-1; simulation, 555-3  
 Labels of plots, 26  
 Lachin: log-rank test, 705-1  
 Lan-DeMets: means, 475-1; proportions, 220-1; survival, 710-1  
 Latin square: ANOVA, 560-19  
 Legend, 23, 26  
 Legend color, 26  
 Likelihood ratio test: proportions, 200-8  
 Likert-scale: simulating, 630-22; simulating a, 630-10; simulation, 410-23  
 Line Chart options, 24  
 Linear: contrast, 550-7  
 Linear model, 570-3  
 Linear model: ANOVA, 560-2  
 Linear regression, 855-1; correlation, 800-1  
 Load template, 32  
 Log: cross-over, 515-3, 525-3, 545-4; mean ratio, 445-2, 455-2  
 Log file, 34  
 Log transformation: cross-over, 505-2, 535-4; ratio, 470-3  
 Logistic, 400:7  
 Logistic regression, 860-1  
 Logit: logistic regression, 860-2  
 Log-rank: group sequential test, 710-1  
 Log-rank test, 700-1, 705-1  
 Log-rank Non-Inferiority test, 705-15  
 Mann-Whitney test, 430-1, 430-18; equivalence, 465-6; equivalence, 465-1; non-inferiority, 450-6; simulation, 440-4  
 MANOVA, 605-1  
 Mantel Haenszel test: proportions, 200-7  
 Mantel-Haenszel, 225-1  
 Margin of equivalence, 455-4; difference, 450-9  
 Matched case-control, 135-2, 255-1  
 Max time: sequential survival, 710-9  
 Maximum: on axis, 27  
 Maximum Iterations, 22  
 McNemar test, 150-1  
 Mean: confidence interval, 420-1; cross-over, 505-1; equivalence, 470-1, 525-1; exponential, 405-1; non-inferiority, 515-1; simulation, 410-1  
 Mean difference: 2x2 cross-over, 500-1; cross-over, 510-1  
 Mean ratio: equivalence, 545-1; inequality, 445-1; non-inferiority, 455-1  
 Means: contrasts, 590-1; cross-over, 540-1; equivalence, 460-1, 465-1; exponential, 435-1; group sequential test, 475-1; hypothesized, 550-6; introduction, 55; MANOVA, 605-1; multiple comparisons, 585-1; non-inferiority, 450-1, 530-1; one-way, 555-1; paired, 490-1, 495-1; simulation, 59; simulation, 440-1  
 Means matrix: MANOVA, 605-5  
 Means matrix, 570-7  
 Measurement error, 560-2  
 Menu: edit, 36; file, 34; format, 37; help, 39; view, 37; window, 38  
 Menus, 12, 17; file, 17  
 Miettinen - Nurminen test: difference, 210-9, 215-9; equivalence, 215-9, 215-10; non-inferiority, 210-9; proportions, 205-9; Ratio, 215-10  
 Minimum: on axis, 27  
 Minimum detectable difference: multiple comparisons, 575-10; one-way ANOVA, 550-19; t-test, 400:13; two-sample t test, 430-15  
 Monte Carlo, 57, 630-1  
 MTBF: exponential mean, 405-1  
 Multinomial: chi-square, 900-4; simulating a, 630-10  
 Multiple comparisons, 575-1; Dunnett's test, 585-1; Games-Howell, 580-1; pair-wise, 580-1; power, 580-5, 585-4  
 Multiple contrasts, 590-1; power, 590-4  
 Multiple regression, 865-1  
 Navigator, 38  
 NCSS: quitting, 18

## 4 Index

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- New Template, 17
- Nominal alpha: group sequential test of means, 475-13
- Noncentrality: one-way ANOVA, 550-3
- noncentrality parameter: one-way ANOVA, 550-4
- Non-inferiority: correlated proportions, 160-1; cross-over, 510-1, 515-1, 530-1; difference, 160-3; hypotheses, 450-2; hypotheses, 415-2; log-rank test, 705-15; mean difference, 450-1; mean ratio, 455-1; odds ratio, 210-5; paired means, 415-1, 490-8, 490-18; paired means, 415-2; proportion, 105-1; ; cluster randomization, 235-1; proportions, 210-1; ratio, 160-6, 210-5; z test, 210-7
- Non-Inferiority: simulation, 440-6
- Non-inferiority hypothesis, 49
- Non-Inferiority test: simulation, 440-17
- Non-inferiority tests, 510-3, 530-3, 535-3
- Non-null: proportions, 205-1
- Nonparametric: Mann-Whitney, 430-8; t-test, 400:7; Wilcoxon test, 400:1
- Normal: contaminated, 630-21; simulating, 630-19; simulating a, 630-11
- Nuisance parameter, 56; correlated proportions, 160-7, 165-7
- Nuisance parameters, 47
- Null case: proportions, 200-1
- Null hypothesis, 42, 55
- O'Brien-Fleming: means, 475-1; proportions, 220-1; survival, 710-1
- Odds ratio: equivalence, 110-6; logistic regression, 860-2; Mantel-Haenszel, 225-2; matched case-control, 255-1; McNemar test, 150-3; non-inferiority, 210-5; non-inferiority, 105-6; proportion, 100-7; proportions, 53, 200-3, 205-4, 215-5
- Odds ratio estimator, 910-1
- Offset: proportions, 205-1
- One-way ANOVA, 550-1
- Open Template, 17
- Options tab, 22
- Outliers: multiple comparisons, 580-26; simulation, 440-18, 555-19
- Outline window, 14
- Output: word processor, 33
- P value, 44
- Paired designs, 415-1
- Paired means: equivalence, 495-1; simulation, 490-1
- Paired proportions: non-inferiority, 160-1
- Paired t-test, 490-1
- Paired t-test, 400:14; assumptions, 400:3; non-inferiority, 415-1
- Paired t-tests, 400:1
- Pairwise comparisons: multiple comparisons, 575-8
- Pair-wise comparisons, 580-1
- Panel, 15
- PASS: starting, 7
- PASS Home, 11
- Password, 19, 39
- Patient entry: log-rank, 705-3
- PDF files, 19, 39
- Perspective, 28, 29
- Phase I trials, 120-2
- Phase II trials, 120-2
- Phi: matched case-control, 255-5
- Pillai-Bartlett trace, 570-6, 605-1; MANOVA, 605-4
- Pillai-Bartlett trace, 570-1
- Planned Comparisons, 550-1
- Plot Setup tab, 23
- Plot Text tab, 26
- Pocock: means, 475-1; proportions, 220-1; survival, 710-1
- Poisson: incidence, 135-1; simulating a, 630-11
- Poisson regression, 870-1
- Population size: t-test, 400:6
- Post-marketing surveillance, 135-1
- Power, 45; introduction, 41; means, 55; multiple comparisons, 580-5, 585-4; multiple contrasts, 590-4
- Prevalence: correlated proportions, 160-2, 165-2
- Print, 35
- Procedure Window, 15
- Producer's risk, 405-1
- Projection method, 28
- Proportion: confidence interval, 115-1; difference, 100-6; equivalence, 110-1; inequality, 100-1; non-inferiority, 105-1; odds ratio, 100-7; ratio, 100-6
- Proportional hazards regression, 850-1
- Proportions: Chi-square test, 200-6; cluster randomization, 240-1; inequality, 230-1; cluster randomization, 235-1; comparing, 51; correlated, 160-1, 165-1; difference, 52; equivalence, 215-1; Farrington - Manning test, 210-11; Fisher's exact, 200-5; Gart - Nam test, 210-13; group sequential test, 220-1; independent, 200-1; inequality, 200-1, 205-1; interim analysis, 220-1; interpretation, 54; introduction, 51; logistic regression, 860-1; matched case control, 255-1; McNemar test, 150-1; Miettinen - Nurminen test, 210-9, 215-9; non-inferiority, 160-1, 210-1; odds ratio, 53; odds ratio estimator, 910-1; offset, 205-1; paired, 160-1; ratio, 52; single-stage, 120-1; stratified, 225-1; superiority, 210-1; three-stage, 130-1; two-stage, 125-1
- Quadratic: contrast, 550-7
- Quitting, 35
- Random factor, 560-5
- Random number pool size, 495-13; paired means using simulation, 490-11
- Random numbers, 580-6, 585-5, 590-5, 630-1
- Randomized block ANOVA, 560-1
- Range on axis, 27
- Rating data: ROC curve, 260-3
- Ratio: cross-over, 505-1; equivalence, 110-5, 165-6; Farrington - Manning test, 215-11; Gart - Nam test, 215-12; inequality, 445-1; means, 445-1; Miettinen - Nurminen test, 215-10; non-inferiority, 160-6, 210-5, 455-2, 515-1, 535-1; proportion, 100-6, 105-5; proportions, 52, 200-3, 205-4, 215-5
- Ratios: equivalence, 470-1
- Regression: Cox, 850-1; linear, 855-1; logistic, 860-1; multiple, 865-1; Poisson, 870-1
- Rejection region, 44
- Repeated measures, 570-1



- Reports tab, 22
- Risk ratio: Blackwelder, 205-29; equivalence, 165-6
- ROC curve, 260-1
- ROC curves, 265-1
- Rotation of tickmarks, 26
- R-squared, 865-1; added, 865-5; logistic regression, 860-8
- RTF, 35
- RTF files, 33
- Ruler, 37
- Run menu, 18
- Sample size: introduction, 41
- Save template, 18, 32
- Score test: equivalence, 215-9, 215-10, 215-11, 215-12; Farrington - Manning test, 210-11, 215-11; Gart - Nam test, 210-13, 215-12; Miettinen - Nurminen test, 210-9, 215-9, 215-10; non-inferiority, 210-9, 210-11, 210-13; proportions, 205-9
- Sensitivity: correlated proportions, 160-2, 165-2; ROC curve, 260-1
- Serial numbers, 19, 39
- Show Beta as Power, 23
- Show tick marks, 28
- Sign test: simulation, 410-4, 490-5, 495-5
- Significance level, 44; adjusting, 60; multiple comparisons, 580-2, 585-2, 590-1
- Simon: two-stage, 125-1
- Simulation, 57, 630-1; equivalence, 465-1, 495-1; means, 440-1; multiple comparisons, 580-1, 580-5, 585-1, 585-5; multiple contrasts, 590-1, 590-5; one mean, 410-1; one-way, 555-1; paired means, 490-1, 495-1; random number generation, 580-6, 585-5, 590-5; size, 58; syntax, 630-16
- Single-stage design, 120-1
- Skewed data: one-way, 555-22; simulation, 410-14, 410-17, 440-20
- Skewed distribution: simulating a, 630-13
- Slope: linear regression, 855-1
- Specificity: correlated proportions, 160-2, 165-2; ROC curve, 260-1
- Spending functions: means, 475-2; proportions, 220-2
- Standard deviation, 56; estimator, 905-1; interpretation, 905-1; means, 550-13; one, 650-1; two, 655-1
- Standard deviation, 400:4
- Starting PASS, 3, 7
- Stratified designs, 225-1
- Student's T: simulating a, 630-12
- Style: grid line, 27
- Summary Statements, 22
- Superiority: hypotheses, 450-2; proportion, 105-4; proportions, 210-1, 210-4
- Superiority hypothesis, 50
- Superiority tests, 510-3, 530-3, 535-3
- Support, 5, 6
- Surface Chart options, 24
- Survival: log-rank, 700-1, 705-1
- Symbols, 30
- Symbols tab, 30
- System requirements, 1
- T: simulating a, 630-12
- Tab: abbreviations, 31
- Tabs, 21; axes, 27; data, 21; options, 22; plot setup, 23; reports, 22; symbols, 30; template, 32
- Tech support, 5, 6
- Template, 15; load, 32; save, 32
- Template Files, 32
- Template Id, 32
- Template tab, 32
- Templates, 17; automatic, 16; default, 16; loading, 17; new, 17; save, 18; saving, 17
- Test statistics, 47
- Text output, 22
- Thin Walls, 29
- Three-stage design, 130-1
- Tick marks, 27; show, 28
- Tickmark rotation, 26
- Titles of plots, 26
- Toolbar, 13, 20, 37, 40
- Treatment versus control: multiple comparisons, 575-2
- Trimmed t-test: equivalence, 465-5, 465-6; simulation, 440-3
- T-test: assumptions, 400:3; cluster randomization, 480-1; cross-over, 500-4, 510-4, 520-4, 540-4; equivalence, 215-8, 460-2, 465-3; equivalence, 520-4; equivalence, 540-4; non-inferiority, 210-8, 415-1, 415-5, 450-2, 450-5, 510-4; proportions, 200-8, 215-8; simulation, 410-1, 490-4, 495-4; simulation, 440-1; simulation, 440-2
- T-tests: assumptions, 430-4; one mean, 400:1; paired, 400:1; two means, 430-1
- Tukey-Kramer: simulation, 580-1
- Tukey-Kramer test, 580-3; multiple comparisons, 575-8
- Tukey's lambda: simulating a, 630-13
- : , 235-8, 235-11, 235-13, 235-15
- Two-sample t-test, 430-1; simulation, 440-2
- Two-Stage design, 125-1
- Type-I error, 42
- Type-II error, 42
- Uniform: simulating a, 630-14
- : , 235-12; repeated measures, 570-53; ROC Curves, 265-12; t-test, 400:17; two-sample t-test, 430-20
- Variance: one, 650-1
- Variances: two, 655-1
- Vertical viewing angle, 28
- View menu, 37
- Viewing angle: horizontal, 28; vertical, 28
- Wall color, 29
- Weibull: simulating a, 630-15
- Welch test: power, 590-4
- Welch's test: equivalence, 465-1; simulation, 440-3
- Welch's t-test: non-inferiority, 450-5
- Wilcoxon test, 400:7, 400:15, 415-8, 450-11; assumptions, 400:3; non-inferiority, 415-5; paired, 415-1; simulation, 410-3, 410-21, 490-1, 490-4, 495-5
- Wilcoxon test, 400:1
- Wilks' Lambda, 570-6, 605-1; MANOVA, 605-3
- Wilks' Lambda, 570-1
- Window menu, 38

## 6 Index

---

Winsorized test: equivalence, 465-5

Within standard deviation, 570-15

Within-subjects design: repeated measures, 570-2

Word processor: built in, 33

Z test: equivalence, 215-7; non-inferiority, 210-7;  
proportions, 205-7, 215-7

Z test - proportion -equivalence, 110-8

Z tests, 100-4

Zeros: two proportions, 205-19