Master Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 28, 2017
Date

November 28, 2017
Date
Master Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

The spreadsheet has 18 tabs for performing confidence intervals the equivalence test. A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Validations

Eighteen separate validations were performed validating these tabs individually. They are:

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Tab Number</th>
<th>Tab Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>TE-17-2</td>
<td>1</td>
<td>1 Proportion – CI</td>
</tr>
<tr>
<td>TE-17-3</td>
<td>2</td>
<td>1 Rate – CI</td>
</tr>
<tr>
<td>TE-17-4</td>
<td>3</td>
<td>1 Average – CI</td>
</tr>
<tr>
<td>TE-17-5</td>
<td>4</td>
<td>1 Average – n</td>
</tr>
<tr>
<td>TE-17-6</td>
<td>5</td>
<td>1 Average – Equivalence</td>
</tr>
<tr>
<td>TE-17-7</td>
<td>6</td>
<td>1 Std. Dev. – CI</td>
</tr>
<tr>
<td>TE-17-8</td>
<td>7</td>
<td>1 RSD Normal - CI</td>
</tr>
<tr>
<td>TE-17-9</td>
<td>8</td>
<td>1 RSD Lognormal - Equivalence</td>
</tr>
<tr>
<td>TE-17-10</td>
<td>9</td>
<td>1 Std. Dev. – n</td>
</tr>
<tr>
<td>TE-17-11</td>
<td>10</td>
<td>2 Averages – CI</td>
</tr>
<tr>
<td>TE-17-12</td>
<td>11</td>
<td>2 Averages – n</td>
</tr>
<tr>
<td>TE-17-13</td>
<td>12</td>
<td>2 Averages – Equivalence</td>
</tr>
<tr>
<td>TE-17-14</td>
<td>13</td>
<td>2 Averages Paired – CI</td>
</tr>
<tr>
<td>TE-17-15</td>
<td>14</td>
<td>2 Averages Paired – n</td>
</tr>
<tr>
<td>TE-17-16</td>
<td>15</td>
<td>2 Averages Paired – Equivalence</td>
</tr>
<tr>
<td>TE-17-17</td>
<td>16</td>
<td>2 Std. Dev. – CI</td>
</tr>
<tr>
<td>TE-17-18</td>
<td>17</td>
<td>2 Averages – n</td>
</tr>
<tr>
<td>TE-17-19</td>
<td>18</td>
<td>2 Averages – Equivalence</td>
</tr>
</tbody>
</table>

The 18 reports are attached.

3.0 Testing

Testing was performed on two machines. The first one had Windows 10 and Excel 2016 installed. The second machine had Windows 7 and Excel 2007 installed. These represent the newest and oldest versions of Windows and Excel currently used.

4.0 Test Results

All tests passed in all 18 protocols. The validation has been successively completed.
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Proportion – CI Tab

Protocol Number: TE-17-2

Approvals:

___________________________________  November 15, 2017
Dr. Wayne A. Taylor  Date
Study Director

Ann B. Taylor  November 15, 2017
Ann B. Taylor  Date
President
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Proportion – CI Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Proportion – CI tab, this spreadsheet performs confidence intervals for the proportion conforming and nonconforming for attribute data. It is described in Appendix D of *STAT-12, Verification/Validation Sampling Plans for Proportion Nonconforming*. Appendix D also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-2, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 1 Proportion – CI Tab was written to validate the 1 Proportion – CI Tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 1 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 1 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Proportion – CI Tab

Protocol Number: TE-17-2
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Proportion – CI Tab

Protocol Number: TE-17-2

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 11, 2017
Date
Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests
1 Proportion – CI Tab

Protocol Number: TE-17-2

1.0 Introduction

The book Statistical Procedures for the Medical Device Industry by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Proportion – CI tab, this spreadsheet performs confidence intervals for the proportion conforming and nonconforming for attribute data. It is described in Appendix D of STAT-12, Verification/Validation Sampling Plans for Proportion Nonconforming. Appendix D also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

**Table 1: User Requirements for the 1 Proportion – CI tab of STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls**

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. The number of samples inspected and the number of nonconforming units can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>c. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no results are shown except possible the estimates. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Unless the sample size is a positive integer, no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>c. Unless the number of nonconforming units is a nonnegative integer, no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>d. If the number of nonconforming units &gt; sample size, no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input, the estimates of the proportion conforming and nonconforming are displayed.</td>
</tr>
<tr>
<td></td>
<td>b. When the number of nonconforming units is not 0 or equal to the sample size, confidence limits and statement are displayed for the 2-sided, upper and lower cases for both proportion conforming and nonconforming.</td>
</tr>
<tr>
<td></td>
<td>c. When the number of nonconforming units is 0, lower confidence limits and statement are displayed for the proportion conforming and upper confidence limits and statement are displayed for the proportion nonconforming.</td>
</tr>
<tr>
<td></td>
<td>d. When the number of nonconforming units is equal to the sample size, upper confidence limits and statement are displayed for the proportion conforming and lower confidence limits and statement are displayed for the proportion nonconforming.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-12 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX  Initials: XXX  Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 1 Proportion - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1c).
       <Insert screen shot here>
       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX  Initials: XXX  Date: XXX
   3.2. Change cell D6 to “49.99”, cell D8 to “300” and cell D10 to “0” (Req. 1a, 2a, 3a).
       <Insert screen shot here>
       Acceptance Criteria: The proportion conforming is estimated to be 100. The proportion nonconforming is estimated as zero. No confidence limits or statements are displayed. An error message is shown.
       Pass or Fail: XXXX  Initials: XXX  Date: XXX
   3.3. Change cell D6 to “100 (Req. 1a, 2a, 3a).
       <Insert screen shot here>
       Acceptance Criteria: The proportion conforming is estimated to be 100. The proportion nonconforming is estimated as zero. No confidence limits or statements are displayed. An error message is shown.
       Pass or Fail: XXXX  Initials: XXX  Date: XXX
3.4. Change cell D6 to “95” and cell D8 to “0” (Req. 1b, 2b).

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

3.5. Change cell D8 to “300.5” (Req. 1b, 2b).

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

3.6. Change cell D8 to “300” and cell D10 to “-1” (Req. 1b, 2c).

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

3.7. Change cell D10 to “10.5” (Req. 1b, 2c).

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

3.8. Change cell D10 to “301” (Req. 1c, 2d).

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

4. Results for valid input

4.1. Change cell D10 to “0” (Req. 3a, 3c).

Acceptance Criteria: The estimate of the proportion conforming is 100%. The lower confidence limit for the proportion conforming rounds to 99.0064%. A confidence statement for the lower limit is shown with the same value. The estimate of the proportion nonconforming is 0%. The upper confidence limit for the proportion nonconforming rounds to 0.9936%. A confidence statement for the upper limit is shown with the same value. No other confidence limits or statements are shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

4.2. Change cell D10 to “300” (Req. 3a, 3d).

Acceptance Criteria: No estimates, confidence limits or statements are displayed.
Acceptance Criteria: The estimate of the proportion conforming is 0%.
The upper confidence limit for the proportion conforming rounds to 0.9936%.
A confidence statement for the upper limit is shown with the same value.
The estimate of the proportion nonconforming is 100%.
The lower confidence limit for the proportion nonconforming rounds to 99.0064%.
A confidence statement for the lower limit is shown with the same value.
No other confidence limits or statements are shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

4.3. Change cell D10 to “1” (Req. 3a, 3b).

Acceptance Criteria: The estimate of the proportion conforming rounds to 99.6667%.
The two-side confidence limits for the proportion conforming round to 98.1569% and 99.9916%.
The upper confidence limit for the proportion nonconforming rounds to 99.9829%.
The lower confidence limit for the proportion nonconforming rounds to 98.4285%.
The estimate of the proportion nonconforming rounds to 0.3333%.
The two-side confidence limits for the proportion nonconforming round to 0.0084% and 1.8431%.
The upper confidence limit for the proportion nonconforming rounds to 1.5715%.
The lower confidence limit for the proportion nonconforming rounds to 0.0171%.
Confidence statements for the six cases are shown with the same values.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

5. Independence of tab

5.1. Copy the 1 Proportion – CI tab. Delete all tabs but the copy.

Acceptance Criteria: The estimate of the proportion conforming rounds to 99.6667%.
The two-side confidence limits for the proportion conforming round to 98.1569% and 99.9916%.
The upper confidence limit for the proportion nonconforming rounds to 99.9829%.
The lower confidence limit for the proportion nonconforming rounds to 98.4285%.
The estimate of the proportion nonconforming rounds to 0.3333%.
The two-side confidence limits for the proportion nonconforming round to 0.0084% and 1.8431%.
The upper confidence limit for the proportion nonconforming rounds to 1.5715%.
The lower confidence limit for the proportion nonconforming rounds to 0.0171%.
Confidence statements for the six cases are shown with the same values.

Pass or Fail: XXXX  Initials: XXX  Date: XXX
6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? yes no
   7.2. Save File and show name and date.
       Name of File:
       Data of File:

Signature: ________________________________ Date: XXX
## Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

### Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>3.2</td>
</tr>
<tr>
<td></td>
<td>b. The number of samples inspected and the number of nonconforming units can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>3.4, 3.5, 3.6, 3.7</td>
</tr>
<tr>
<td></td>
<td>c. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td></td>
<td>3.1</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is $\geq50%$ and $&lt;100%$, no results are shown except possible the estimates. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3 covers range</td>
</tr>
<tr>
<td></td>
<td>b. Unless the sample size is a positive integer, no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.4, 3.5 covers largest non-positive integer of zero and noninteger</td>
</tr>
<tr>
<td></td>
<td>c. Unless the number of nonconforming units is a nonnegative integer, no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.6, 3.7 covers largest negative integer of -1 and noninteger</td>
</tr>
<tr>
<td></td>
<td>d. If the number of nonconforming units $&gt; \text{sample size}$, no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.8 covers smallest integer $&gt; \text{sample size}$ of 301</td>
</tr>
</tbody>
</table>
Results for valid input:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 3 | a. For valid input, the estimates of the proportion conforming and nonconforming are displayed. 
   | 3.2, 4.1, 4.2, 4.3 |
|   | b. When the number of nonconforming units is not 0 or equal to the sample size, confidence limits and statement are displayed for the 2-sided, upper and lower cases for both proportion conforming and nonconforming. |
|   | 4.3 |
|   | c. When the number of nonconforming units is 0, lower confidence limits and statement are displayed for the proportion conforming and upper confidence limits and statement are displayed for the proportion nonconforming. |
|   | 4.1 |
|   | d. When the number of nonconforming units is equal to the sample size, upper confidence limits and statement are displayed for the proportion conforming and lower confidence limits and statement are displayed for the proportion nonconforming. |
|   | 4.2 |

Tabs:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
<tr>
<td></td>
<td>5.1</td>
</tr>
</tbody>
</table>
Appendix C: Verification of Results

4.1 From Minitab version 18.0.

Test and CI for One Proportion
Method
p: event proportion
Exact method is used for this analysis.

Descriptive Statistics

<table>
<thead>
<tr>
<th>N</th>
<th>Event</th>
<th>Sample p</th>
<th>95% Upper Bound for p</th>
</tr>
</thead>
<tbody>
<tr>
<td>300</td>
<td>0</td>
<td>0.000000</td>
<td>0.009936</td>
</tr>
</tbody>
</table>

Test
Null hypothesis \( H_0: p = 0.5 \)
Alternative hypothesis \( H_1: p \neq 0.5 \)

4.2 From Minitab version 18.0

Test and CI for One Proportion
Method
p: event proportion
Exact method is used for this analysis.

Descriptive Statistics

<table>
<thead>
<tr>
<th>N</th>
<th>Event</th>
<th>Sample p</th>
<th>95% Lower Bound for p</th>
</tr>
</thead>
<tbody>
<tr>
<td>300</td>
<td>300</td>
<td>1.000000</td>
<td>0.990064</td>
</tr>
</tbody>
</table>

Test
Null hypothesis \( H_0: p = 0.5 \)
Alternative hypothesis \( H_1: p \neq 0.5 \)

4.3 From Minitab version 18.0

Two-sided proportion nonconforming

Test and CI for One Proportion
Method
p: event proportion
Exact method is used for this analysis.

**Descriptive Statistics**

<table>
<thead>
<tr>
<th>N</th>
<th>Event</th>
<th>Sample p</th>
<th>95% CI for p</th>
</tr>
</thead>
<tbody>
<tr>
<td>300</td>
<td>1</td>
<td>0.003333</td>
<td>(0.000084, 0.018431)</td>
</tr>
</tbody>
</table>

**Test**

Null hypothesis  \( H_0: p = 0.5 \)
Alternate hypothesis  \( H_1: p \neq 0.5 \)

Upper proportion nonconforming

**Test and CI for One Proportion**

Method

\( p: \) event proportion

Exact method is used for this analysis.

**Descriptive Statistics**

<table>
<thead>
<tr>
<th>N</th>
<th>Event</th>
<th>Sample p</th>
<th>95% Upper Bound for p</th>
</tr>
</thead>
<tbody>
<tr>
<td>300</td>
<td>1</td>
<td>0.003333</td>
<td>0.015715</td>
</tr>
</tbody>
</table>

**Test**

Null hypothesis  \( H_0: p = 0.5 \)
Alternate hypothesis  \( H_1: p < 0.5 \)

Lower proportion nonconforming

**Test and CI for One Proportion**

Method

\( p: \) event proportion

Exact method is used for this analysis.

**Descriptive Statistics**

<table>
<thead>
<tr>
<th>N</th>
<th>Event</th>
<th>Sample p</th>
<th>95% Lower Bound for p</th>
</tr>
</thead>
<tbody>
<tr>
<td>300</td>
<td>1</td>
<td>0.003333</td>
<td>0.000171</td>
</tr>
</tbody>
</table>

**Test**

Null hypothesis  \( H_0: p = 0.5 \)
Alternate hypothesis  \( H_1: p > 0.5 \)
Appendix B

File: STAT-12 to 16 - Tab 1  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   ![Windows 10](image)

   **Alienware 17 R3**
   
   **PC name** Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

<table>
<thead>
<tr>
<th>Edition</th>
<th>Windows 10 Home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>1703</td>
</tr>
<tr>
<td>OS Build</td>
<td>15063.674</td>
</tr>
<tr>
<td>Product ID</td>
<td>00325-95916-23031-AAOEM</td>
</tr>
<tr>
<td>Processor</td>
<td>Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz</td>
</tr>
<tr>
<td>Installed RAM</td>
<td>16.0 GB (15.9 GB usable)</td>
</tr>
<tr>
<td>System type</td>
<td>64-bit operating system, x64-based processor</td>
</tr>
<tr>
<td>Pen and touch</td>
<td>No pen or touch input is available for this display</td>
</tr>
</tbody>
</table>

   1.3. Capture a screen shot showing the version of Excel used

   ![Microsoft Excel](image)
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

![Screen shot of Excel spreadsheet](image1.png)

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

![Screen shot of Excel spreadsheet](image2.png)

For those purchasing the book *Statistical Procedures for the Medical Device Industry*, this file contains the spreadsheets for calculating confidence intervals and equivalence tests per the formulas in the Appendices of the difference. Further information about the use of this spreadsheet is provided in the book.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass    Initials: WT    Date: 11/15/17
3. Check for Valid Parameters

3.1. Go to the 1 Proportion - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1c).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/15/17
3.2. Change cell D6 to “49.99”, cell D8 to “300” and cell D10 to “0” (Req. 1a, 2a, 3a).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>99.99%</th>
<th>90 ≤ Conf ≤ 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>300</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconforming Units</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Percent Conforming
- Estimate: 90%

2-Sided Case - 99.99% Confidence Interval for Percent Conforming
- Lower Limit: %
- Upper Limit: %

Lower 1-Sided Case - 99.99% Lower Confidence Limit for Percent Conforming
- Lower Limit: %

Upper 1-Sided Case - 99.99% Upper Confidence Limit for Percent Conforming
- Upper Limit: %

Percent Nonconforming
- Estimate: 0%

2-Sided Case - 99.99% Confidence Interval for Percent Nonconforming
- Lower Limit: %
- Upper Limit: %

Lower 1-Sided Case - 99.99% Lower Confidence Limit for Percent Nonconforming
- Lower Limit: %

Upper 1-Sided Case - 99.99% Upper Confidence Limit for Percent Nonconforming
- Upper Limit: %

Acceptance Criteria:
- The proportion conforming is estimated to be 100.
- The proportion nonconforming is estimated as zero.
- No confidence limits or statements are displayed.
- An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/15/17
3.3. Change cell D6 to “100 (Req. 1a, 2a, 3a).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>100 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Impacted</td>
<td>100</td>
</tr>
<tr>
<td>Number of Nonconforming Units</td>
<td>0</td>
</tr>
</tbody>
</table>

**Percent Conforming**

<table>
<thead>
<tr>
<th>Estimate</th>
<th>100 %</th>
</tr>
</thead>
</table>

**2-Sided Case - 100% Confidence Interval for Percent Conforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

**Lower 1-Sided Case - 100% Lower Confidence Limit for Percent Conforming**

| Lower Limit | % |

**Upper 1-Sided Case - 100% Upper Confidence Limit for Percent Conforming**

| Upper Limit | % |

**Percent Nonconforming**

<table>
<thead>
<tr>
<th>Estimate</th>
<th>0 %</th>
</tr>
</thead>
</table>

**2-Sided Case - 100% Confidence Interval for Percent Nonconforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

**Lower 1-Sided Case - 100% Lower Confidence Limit for Percent Nonconforming**

| Lower Limit | % |

**Upper 1-Sided Case - 100% Upper Confidence Limit for Percent Nonconforming**

| Upper Limit | % |

**Acceptance Criteria:**

The proportion conforming is estimated to be 100.
The proportion nonconforming is estimated as zero.
No confidence limits or statements are displayed.
An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/15/17
3.4. Change cell D6 to “95” and cell D8 to “0” (Req. 1b, 2b).

<table>
<thead>
<tr>
<th>STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAT-12, Verification/Validation Sampling Plans for Proportion Nonconforming</td>
</tr>
<tr>
<td>Appendix B: Lower Confidence Limit for Percent Conforming – Attribute Data</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidence Level</td>
<td>95 %</td>
</tr>
<tr>
<td>Number of Units Inspected</td>
<td>0</td>
</tr>
<tr>
<td>Number of Nonconforming Units</td>
<td>0</td>
</tr>
</tbody>
</table>

Percent Conforming

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimate</td>
<td></td>
</tr>
</tbody>
</table>

2-Sided Case - 95% Confidence Interval for Percent Conforming

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Limit</td>
<td></td>
</tr>
<tr>
<td>Upper Limit</td>
<td></td>
</tr>
</tbody>
</table>

Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Limit</td>
<td></td>
</tr>
</tbody>
</table>

Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td></td>
</tr>
</tbody>
</table>

Percent Nonconforming

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimate</td>
<td></td>
</tr>
</tbody>
</table>

2-Sided Case - 95% Confidence Interval for Percent Nonconforming

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Limit</td>
<td></td>
</tr>
<tr>
<td>Upper Limit</td>
<td></td>
</tr>
</tbody>
</table>

Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Limit</td>
<td></td>
</tr>
</tbody>
</table>

Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td></td>
</tr>
</tbody>
</table>

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/15/17
3.5. Change cell D8 to “300.5” (Req. 1b, 2b).

### Statistical Procedures for the Medical Device Industry

**STAT-12, Verification/Validation Sampling Plans for Proportion Nonconforming**

**Appendix D: Lower Confidence Limit for Percent Conforming – Attribute Data**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>300.5</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconforming Units Found</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

**Percent Conforming**

<table>
<thead>
<tr>
<th>Estimate</th>
<th>%</th>
</tr>
</thead>
</table>

**2-Sided Case - 95% Confidence Interval for Percent Conforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
</table>

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming**

<table>
<thead>
<tr>
<th>Upper Limit</th>
<th>%</th>
</tr>
</thead>
</table>

**Percent Nonconforming**

<table>
<thead>
<tr>
<th>Estimate</th>
<th>%</th>
</tr>
</thead>
</table>

**2-Sided Case - 95% Confidence Interval for Percent Nonconforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
</table>

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming**

<table>
<thead>
<tr>
<th>Upper Limit</th>
<th>%</th>
</tr>
</thead>
</table>

**Acceptance Criteria:**

No estimates, confidence limits or statements are displayed. An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/15/17
3.6. Change cell D8 to “300” and cell D10 to “-1” (Req. 1b, 2c).

### Statistical Procedures for the Medical Device Industry

**STAT-32: Verification/Validation Sampling Plans for Proportion Nonconforming**

**Appendix D: Lower Confidence Limit for Percent Conforming – Attribute Data**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>95%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Units Inspected</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>300</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Nonconforming Units</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-1</td>
</tr>
</tbody>
</table>

Number of nonconformities found is not a valid integer greater than or equal to zero.

#### Percent Conforming

<table>
<thead>
<tr>
<th>Estimate</th>
<th>%</th>
</tr>
</thead>
</table>

2-Sided Case - 95% Confidence Interval for Percent Conforming

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

Lower 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
</table>

Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming

<table>
<thead>
<tr>
<th>Upper Limit</th>
<th>%</th>
</tr>
</thead>
</table>

#### Percent Nonconforming

<table>
<thead>
<tr>
<th>Estimate</th>
<th>%</th>
</tr>
</thead>
</table>

2-Sided Case - 95% Confidence Interval for Percent Nonconforming

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
</table>

Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming

<table>
<thead>
<tr>
<th>Upper Limit</th>
<th>%</th>
</tr>
</thead>
</table>

**Acceptance Criteria:** No estimates, confidence limits or statements are displayed. An error message is shown.

**Pass or Fail:** Pass

**Initials:** WT

**Date:** 11/15/17
3.7. Change cell D10 to “10.5” (Req. 1b, 2c).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY

#### STAT 31: Verification/Validation Sampling Plans for Proportion Nonconforming

**Appendix D: Lower Confidence Limit for Percent Conforming – Attribute Data**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>95%</td>
<td>50</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Units Inspected</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Nonconforming Units</td>
<td>10</td>
</tr>
</tbody>
</table>

**Percent Conforming**

<table>
<thead>
<tr>
<th>Estimate</th>
<th>%</th>
</tr>
</thead>
</table>

**2-Sided Case - 95% Confidence Interval for Percent Conforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
</table>

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming**

<table>
<thead>
<tr>
<th>Upper Limit</th>
<th>%</th>
</tr>
</thead>
</table>

**Percent Nonconforming**

<table>
<thead>
<tr>
<th>Estimate</th>
<th>%</th>
</tr>
</thead>
</table>

**2-Sided Case - 95% Confidence Interval for Percent Nonconforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
</table>

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming**

<table>
<thead>
<tr>
<th>Upper Limit</th>
<th>%</th>
</tr>
</thead>
</table>

**Acceptance Criteria:**

No estimates, confidence limits or statements are displayed.

An error message is shown.

**Pass or Fail:** Pass

**Initials:** WT

**Date:** 11/15/17
3.8. Change cell D10 to “301” (Req. 1c, 2d).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>300</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconforming Units Found</td>
<td>301</td>
<td></td>
</tr>
</tbody>
</table>

**Percent Conforming**

- Estimate: %

**2-Sided Case - 95% Confidence Interval for Percent Conforming**

- Lower Limit: %
- Upper Limit: %

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming**

- Lower Limit: %

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming**

- Upper Limit: %

**Percent Nonconforming**

- Estimate: %

**2-Sided Case - 95% Confidence Interval for Percent Nonconforming**

- Lower Limit: %
- Upper Limit: %

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming**

- Lower Limit: %

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming**

- Upper Limit: %

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/15/17
4. Results for valid input

4.1. Change cell D10 to “0” (Req. 3a, 3c).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-12, Verification/Validation Sampling Plans for Proportion Nonconforming**

Appendix D: Lower Confidence Limit for Percent Conforming – Attribute Data

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>300</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconforming Units</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

**Percent Conforming**

<table>
<thead>
<tr>
<th>Estimate</th>
<th>100%</th>
</tr>
</thead>
</table>

2-Sided Case - 95% Confidence Interval for Percent Conforming

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>99.00636983542%</th>
</tr>
</thead>
</table>

2-Sided Case - 95% Confidence Interval for Percent Nonconforming

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
</table>

Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming

<table>
<thead>
<tr>
<th>Upper Limit</th>
<th>0.993630181%</th>
</tr>
</thead>
</table>

Acceptance Criteria: The estimate of the proportion conforming is 100%.
The lower confidence limit for the proportion conforming rounds to 99.0064%.
A confidence statement for the lower limit is shown with the same value.
The estimate of the proportion nonconforming is 0%.
The upper confidence limit for the proportion nonconforming rounds to 0.9936%.
A confidence statement for the upper limit is shown with the same value.
No other confidence limits or statements are shown.

Pass or Fail: Pass
Initials: WT
Date: 11/15/17
4.2. Change cell D10 to “300” (Req. 3a, 3d).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
<th>50 ≤ Conf ≤ 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>300</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconforming Units</td>
<td>300</td>
<td></td>
</tr>
</tbody>
</table>

**Percent Conforming**

<table>
<thead>
<tr>
<th></th>
<th>Estimate</th>
<th>0 %</th>
</tr>
</thead>
</table>

**2-Sided Case - 95% Confidence Interval for Percent Conforming**

<table>
<thead>
<tr>
<th></th>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
</table>

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming**

| | Lower Limit | 0.988050571 |

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming**

| | Upper Limit | 0.993690457 |

**Percent Nonconforming**

<table>
<thead>
<tr>
<th></th>
<th>Estimate</th>
<th>100 %</th>
</tr>
</thead>
</table>

**2-Sided Case - 95% Confidence Interval for Percent Nonconforming**

<table>
<thead>
<tr>
<th></th>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
</table>

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming**

| | Lower Limit | 99.00649666 |

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming**

| | Upper Limit | |

**Acceptance Criteria:**

The estimate of the proportion conforming is 0%.

The upper confidence limit for the proportion conforming rounds to 0.9936%.

A confidence statement for the upper limit is shown with the same value.

The estimate of the proportion nonconforming is 100%.

The lower confidence limit for the proportion nonconforming rounds to 99.0064%.

A confidence statement for the lower limit is shown with the same value.

No other confidence limits or statements are shown.

**Pass or Fail:** Pass

**Initials:** WT

**Date:** 11/15/17
4.3. Change cell D10 to “1” (Req. 3a, 3b).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**Appendix D: Lower Confidence Limit for Percent Conforming – Attribute Data**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconforming Units</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

**Percent Conforming**

- **Estimate:** 99.6666667%
- **2-Sided Case - 95% Confidence Interval for Percent Conforming**
  - **Lower Limit:** 98.458748%
  - **Upper Limit:** 99.595951%
- **Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming**
  - **Lower Limit:** 98.285449%
- **Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming**
  - **Upper Limit:** 99.962838%

**Percent Nonconforming**

- **Estimate:** 0.333333333%
- **2-Sided Case - 95% Confidence Interval for Percent Nonconforming**
  - **Lower Limit:** 0.000436393%
  - **Upper Limit:** 0.04325005%
- **Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming**
  - **Lower Limit:** 0.000636363%
- **Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming**
  - **Upper Limit:** 0.047145488%

**Acceptance Criteria:**

- The estimate of the proportion conforming rounds to 99.6667%.
- The two-side confidence limits for the proportion conforming round to 98.1569% and 99.9916%.
- The upper confidence limit for the proportion nonconforming rounds to 99.9829%.
- The lower confidence limit for the proportion nonconforming rounds to 98.4285%.
- The estimate of the proportion nonconforming rounds to 0.3333%.
- The two-side confidence limits for the proportion nonconforming round to 0.0084% and 1.8431%.
- The upper confidence limit for the proportion nonconforming rounds to 1.5715%.
- The lower confidence limit for the proportion nonconforming rounds to 0.0171%.

**Confidence statements for the six cases are shown with the same values.**

**Pass or Fail:** Pass

**Initials:** WT

**Date:** 11/15/17
5. Independence of tab

5.1. Copy the 1 Proportion – CI tab. Delete all tabs but the copy.

Acceptance Criteria: The estimate of the proportion conforming rounds to 99.6667%.
The two-side confidence limits for the proportion conforming round to 98.1569% and 99.9916%.
The upper confidence limit for the proportion nonconforming rounds to 99.9829%.
The lower confidence limit for the proportion nonconforming rounds to 98.4285%.
The estimate of the proportion nonconforming rounds to 0.3333%.
The two-side confidence limits for the proportion nonconforming round to 0.0084% and 1.8431%.
The upper confidence limit for the proportion nonconforming rounds to 1.5715%.
The lower confidence limit for the proportion nonconforming rounds to 0.0171%.
Confidence statements for the six cases are shown with the same values.

Pass or Fail: Pass
Initials: WT
Date: 11/15/17
6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? X yes no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 1 Windows 10.doc
       Data of File: November 15, 2017
       Signature: ___________________________ Date: 11/15/17
Appendix C

File: STAT-12 to 16 - Tab 1  Windows 7
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

![Gateway Computer](image-url)
1.2. Capture a screen shot showing the operating system including version number

Windows edition

Windows 7 Professional
Copyright © 2009 Microsoft Corporation. All rights reserved.
Service Pack 1
Get more features with a new edition of Windows 7

System

Rating: 5:5 Your Windows Experience Index needs to be refreshed
Processor: Intel® Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHZ
Installed memory (RAM): 4.00 GB
System type: 64-bit Operating System
Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

About Microsoft Office Excel

Microsoft® Office Excel® 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
First of Microsoft Office Professional 2007
© 2006 Microsoft Corporation. All rights reserved.


This product is licensed to:

Wayne Taylor
Taylor Enterprises, Inc.
Product ID: 81605-903-7132834-65427

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.

OK
System Info...
Tech Support...
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass        Initials: WT        Date: 11/13/17
3. Check for Valid Parameters
   
   3.1. Go to the 1 Proportion - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1c).

   Acceptance Criteria: Each time a message should be displayed that the cell is protected.
   
   Pass or Fail: Pass    Initials: WT    Date: 11/13/17
3.2. Change cell D6 to “49.99”, cell D8 to “300” and cell D10 to “0” (Req. 1a, 2a, 3a).

Acceptance Criteria: The proportion conforming is estimated to be 100. The proportion nonconforming is estimated as zero. No confidence limits or statements are displayed. An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
3.3. Change cell D6 to “100 (Req. 1a, 2a, 3a).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**Appendix D: Lower Confidence Limit for Percent Conforming – Attribute Data**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>90%</th>
<th>50% Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconforming Units Found</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

**Percent Conforming**

- **Estimate**: 100 %

**2-Sided Case - 100% Confidence Interval for Percent Conforming**

| Lower Limit | % |
| Upper Limit | % |

**Lower 1-Sided Case - 100% Lower Confidence Limit for Percent Conforming**

| Lower Limit | % |

**Upper 1-Sided Case - 100% Upper Confidence Limit for Percent Conforming**

| Upper Limit | % |

**Percent Nonconforming**

- **Estimate**: 0 %

**2-Sided Case - 100% Confidence Interval for Percent Nonconforming**

| Lower Limit | % |
| Upper Limit | % |

**Lower 1-Sided Case - 100% Lower Confidence Limit for Percent Nonconforming**

| Lower Limit | % |

**Upper 1-Sided Case - 100% Upper Confidence Limit for Percent Nonconforming**

| Upper Limit | % |

**Acceptance Criteria**: The proportion conforming is estimated to be 100. The proportion nonconforming is estimated as zero. No confidence limits or statements are displayed. An error message is shown.

**Pass or Fail**: Pass  
**Initials**: WT  
**Date**: 11/13/17
3.4. Change cell D6 to “95” and cell D8 to “0” (Req. 1b, 2b).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-12, Verification/Validation Sampling Plans for Proportion Nonconforming**

**Appendix D: Lower Confidence Limit for Percent Conforming – Attribute Data**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
<th>95 ≤ Cent ≤ 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconforming Units Found</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

**Percent Conforming**

Estimate %

2-Sided Case - 95% Confidence Interval for Percent Conforming

Lower Limit %

Upper Limit %

Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming

Lower Limit %

Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming

Upper Limit %

**Percent Nonconforming**

Estimate %

2-Sided Case - 95% Confidence Interval for Percent Nonconforming

Lower Limit %

Upper Limit %

Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming

Lower Limit %

Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming

Upper Limit %

**Acceptance Criteria:** No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: Pass

Initials: WT

Date: 11/13/17
3.5. Change cell D8 to “300.5” (Req. 1b, 2b).

<table>
<thead>
<tr>
<th>Statistic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidence Level</td>
<td>95%</td>
</tr>
<tr>
<td>Number of Units Inspected</td>
<td>300.5</td>
</tr>
<tr>
<td>Number of Nonconforming Units Found</td>
<td>0</td>
</tr>
</tbody>
</table>

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
3.6. Change cell D8 to “300” and cell D10 to “-1” (Req. 1b, 2c).

<table>
<thead>
<tr>
<th>STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAT-12, Verification/Validation Sampling Plans for Proportion Nonconforming</td>
</tr>
<tr>
<td>Appendix D: Lower Confidence Limit for Percent Conforming – Attribute Data</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>95</td>
<td></td>
<td></td>
</tr>
<tr>
<td>90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>85</td>
<td></td>
<td></td>
</tr>
<tr>
<td>80</td>
<td></td>
<td></td>
</tr>
<tr>
<td>70</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Units Inspected</th>
<th>300</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Number of Nonconforming Units Found</th>
<th>-1</th>
</tr>
</thead>
</table>

Number of nonconformities found is not a valid integer greater than or equal to zero.

**Percent Conforming**

<table>
<thead>
<tr>
<th>Estimate</th>
<th>%</th>
</tr>
</thead>
</table>

**2-Sided Case - 95% Confidence Interval for Percent Conforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming**

| Lower Limit | % |

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming**

| Upper Limit | % |

**Percent Nonconforming**

<table>
<thead>
<tr>
<th>Estimate</th>
<th>%</th>
</tr>
</thead>
</table>

**2-Sided Case - 95% Confidence Interval for Percent Nonconforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>%</td>
</tr>
</tbody>
</table>

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming**

| Lower Limit | % |

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming**

| Upper Limit | % |

**Acceptance Criteria:** No estimates, confidence limits or statements are displayed. An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/13/17
3.7. Change cell D10 to “10.5” (Req. 1b, 2c).

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/13/17
3.8. Change cell D10 to “301” (Req. 1c, 2d).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**
**STAT-12, Verification/Validation Sampling Plans for Proportion Nonconforming**
Appendix D: Lower Confidence Limit for Percent Conforming – Attribute Data

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>% 50% Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>300</td>
</tr>
<tr>
<td>Number of Nonconforming Units Found</td>
<td>301</td>
</tr>
</tbody>
</table>

**Percent Conforming**

Estimate: %

2-Sided Case - 95% Confidence Interval for Percent Conforming

Lower Limit: %
Upper Limit: %

Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming

Lower Limit: %

Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming

Upper Limit: %

**Percent Nonconforming**

Estimate: %

2-Sided Case - 95% Confidence Interval for Percent Nonconforming

Lower Limit: %
Upper Limit: %

Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming

Lower Limit: %

Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming

Upper Limit: %

**Acceptance Criteria:** No estimates, confidence limits or statements are displayed. An error message is shown.

**Pass or Fail:** Pass

**Initials:** WT

**Date:** 11/13/17
4. Results for valid input

4.1. Change cell D10 to “0” (Req. 3a, 3c).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>85</th>
<th>50 ≤ Conf ≤ 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>900</td>
<td></td>
</tr>
</tbody>
</table>

| Number of Nonconforming Units Found | 0 |

**Percent Conforming**

| Estimate | 100 % |

**2-Sided Case - 95% Confidence Interval for Percent Conforming**

| Lower Limit | % |
| Upper Limit | % |

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>99.00031957 %</th>
</tr>
</thead>
</table>

*With 95% confidence the percent conforming is greater than 99.00031957%.*

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming**

| Upper Limit | % |

**Percent Nonconforming**

| Estimate | 0 % |

**2-Sided Case - 95% Confidence Interval for Percent Nonconforming**

| Lower Limit | % |
| Upper Limit | % |

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming**

| Lower Limit | % |

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming**

<table>
<thead>
<tr>
<th>Upper Limit</th>
<th>0.99363429 %</th>
</tr>
</thead>
</table>

*With 95% confidence the percent nonconforming is less than 0.99363429%.*

Acceptance Criteria: The estimate of the proportion conforming is 100%.

The lower confidence limit for the proportion conforming rounds to 99.0064%.

A confidence statement for the lower limit is shown with the same value.

The estimate of the proportion nonconforming is 0%.

The upper confidence limit for the proportion nonconforming rounds to 0.9936%.

A confidence statement for the upper limit is shown with the same value.

No other confidence limits or statements are shown.

Pass or Fail: Pass

Initials: WT

Date: 11/13/17
4.2. Change cell D10 to “300” (Req. 3a, 3d).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-12, Verification/Validation Sampling Plans for Proportion Nonconforming**

**Appendix D: Lower Confidence Limit for Percent Conforming - Attribute Data**

| Confidence Level | 85% | 90% Conf. < 100%
| Number of Units Inspected | 300 |
| Number of Nonconforming Units Found | 200 |

**Percent Conforming**

| Estimate | 0% |

**2-Sided Case - 95% Confidence Interval for Percent Conforming**

| Lower Limit | % |
| Upper Limit | % |

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming**

| Lower Limit | % |

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming**

| Upper Limit | 0.9930004238% | With 95% confidence the percent conforming is less than 0.9930004238% |

**Percent Nonconforming**

| Estimate | 100% |

**2-Sided Case - 95% Confidence Interval for Percent Nonconforming**

| Lower Limit | % |
| Upper Limit | % |

**Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming**

| Lower Limit | 99.99000608% | With 95% confidence the percent nonconforming is greater than 99.99000608% |

**Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming**

| Upper Limit | % |

**Acceptance Criteria:**

The estimate of the proportion conforming is 0%. The upper confidence limit for the proportion conforming rounds to 0.9936%. A confidence statement for the upper limit is shown with the same value. The estimate of the proportion nonconforming is 100%. The lower confidence limit for the proportion nonconforming rounds to 99.0064%. A confidence statement for the lower limit is shown with the same value. No other confidence limits or statements are shown.

**Pass or Fail:** Pass

**Initials:** WT  
**Date:** 11/13/17
4.3. Change cell D10 to “1” (Req. 3a, 3b).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**Appendix D: Lower Confidence Limit for Percent Conforming – Attribute Data**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
</tr>
</thead>
</table>

| Number of Units Inspected | 300  |

| Number of Nonconforming Units Found | 1    |

### Percent Conforming

**Estimate**

99.66666667%

#### 2-Sided Case - 95% Confidence Interval for Percent Conforming

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>98.359737 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>99.990011 %</td>
</tr>
</tbody>
</table>

#### Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Conforming

| Lower Limit | 98.438544 % |

#### Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Conforming

| Upper Limit | 99.961037 % |

### Percent Nonconforming

**Estimate**

0.33333333%

#### 2-Sided Case - 95% Confidence Interval for Percent Nonconforming

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>0.008390 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>0.184326 %</td>
</tr>
</tbody>
</table>

#### Lower 1-Sided Case - 95% Lower Confidence Limit for Percent Nonconforming

| Lower Limit | 0.007963 %   |

#### Upper 1-Sided Case - 95% Upper Confidence Limit for Percent Nonconforming

| Upper Limit | 0.157453 %   |

**Acceptance Criteria:**

The estimate of the proportion conforming rounds to 99.6667%.
The two-side confidence limits for the proportion conforming round to 98.1569% and 99.9916%.
The upper confidence limit for the proportion nonconforming rounds to 99.9829%.
The lower confidence limit for the proportion nonconforming rounds to 98.4285%.
The estimate of the proportion nonconforming rounds to 0.3333%.
The two-side confidence limits for the proportion nonconforming round to 0.0084% and 1.8431%.
The upper confidence limit for the proportion nonconforming rounds to 1.5715%.
The lower confidence limit for the proportion nonconforming rounds to 0.0171%.
Confidence statements for the six cases are shown with the same values.

**Pass or Fail:** Pass

**Initials:** WT

**Date:** 11/13/17
5. Independence of tab

5.1. Copy the 1 Proportion – CI tab. Delete all tabs but the copy.

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Acceptance Criteria:**

The estimate of the proportion conforming rounds to 99.6667%.
The two-side confidence limits for the proportion conforming round to 98.1569% and 99.9916%.
The upper confidence limit for the proportion nonconforming rounds to 99.9829%.
The lower confidence limit for the proportion nonconforming rounds to 98.4285%.
The estimate of the proportion nonconforming rounds to 0.3333%.
The two-side confidence limits for the proportion nonconforming round to 0.0084% and 1.8431%.
The upper confidence limit for the proportion nonconforming rounds to 1.5715%.
The lower confidence limit for the proportion nonconforming rounds to 0.0171%.

Confidence statements for the six cases are shown with the same values.

**Pass or Fail:** Pass

**Initials:** WT

**Date:** 11/13/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? X yes no
   7.2. Save File and show name and date.

Name of File: STAT-12 to 16 - Tab 1 Windows 7.doc
Data of File: November 13, 2017

Signature: ________________________________ Date: 11/13/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Rate – CI Tab

Protocol Number: TE-17-3

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 16, 2017
Date

November 16, 2017
Date
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Rate – CI Tab

Report Number: TE-17-3

1.0 Introduction

The book Statistical Procedures for the Medical Device Industry by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Rate – CI tab, this spreadsheet performs confidence intervals for rates. It is described in Appendix E of STAT-13, Verification/Validation Sampling Plans for Rate of Nonconformities. Appendix E also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-3, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 1 Rate – CI Tab was written to validate the 1 Rate – CI Tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 2 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 2 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Rate – CI Tab

Protocol Number: TE-17-3
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Rate – CI Tab

Protocol Number: TE-17-3

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 11, 2017
Date

November 11, 2017
Date
Validation Protocol for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Rate – CI Tab

Protocol Number: TE-17-3

1.0 Introduction
The book Statistical Procedures for the Medical Device Industry by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Rate – CI tab, this spreadsheet performs confidence intervals for rates. It is described in Appendix E of STAT-13, Verification/Validation Sampling Plans for Rate of Nonconformities. Appendix E also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | **Input of Data:**  
  a. The confidence level can be entered into the highlighted cell of the spreadsheet  
  b. The sample size inspected and the number of nonconformities can be entered into the highlighted cells of the spreadsheet.  
  c. The units of measure can be entered into the highlighted cells of the spreadsheet.  
  d. Only the highlighted yellow cells can be changed.  |
| 2  | **Data Checking:**  
  a. Unless the confidence level is ≥50% and <100%, no results are shown except possible the estimate. An error message is displayed.  
  b. Unless the sample size is a positive number, no results are shown. An error message is displayed.  
  c. Unless the number of nonconformities is a nonnegative integer, no results are shown. An error message is displayed.  |
| 3  | **Results for valid input:**  
  a. If units of measure have been entered, the units are displayed as nonconformities per the units of measure. Otherwise, the units are displayed as nonconformities per quantity.  
  b. For valid input, the estimate of the rate is displayed.  
  c. When the number of nonconforming units is not 0, confidence limits and statement are displayed for the 2-sided, upper and lower.  
  d. When the number of nonconforming units is 0, upper confidence limits and statement are displayed for the rate.  |
| 4  | **Tabs:**  
  a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.  |
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-13 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
        <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
        <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
        <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
        <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
        <Insert screen shot here>

        Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
        Pass or Fail: XXXX  Initials: XXX  Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 1 Rate - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).
        <Insert screen shot here>

        Acceptance Criteria: Each time a message should be displayed that the cell is protected.
        Pass or Fail: XXXX  Initials: XXX  Date: XXX
   3.2. Change cell D6 to “49.99”, cell D8 to “300” and cell D10 to “0” (Req. 1a, 2a, 3a, 3b).
        <Insert screen shot here>

        Acceptance Criteria: The rate is estimated to be 0
        No confidence limits or statements are displayed.
        An error message is shown.
        Pass or Fail: XXXX  Initials: XXX  Date: XXX
   3.3. Change cell D6 to “100” (Req. 1a, 2a, 3a, 3b).
        <Insert screen shot here>

        Acceptance Criteria: The rate is estimated to be 0
        No confidence limits or statements are displayed.
        An error message is shown.
        Pass or Fail: XXXX  Initials: XXX  Date: XXX
3.4. Change cell D6 to “95”, cell D8 to “0” and cell D12 to “units” (Req. 1b, 1c, 2b, 3a).

Acceptance Criteria: No estimates, confidence limits or statements are displayed. The units displayed are nonconformities per units. An error message is shown.

Pass or Fail: XXXX Initials: XXX Date: XXX

3.5. Change cell D8 to “1.5” and cell D10 to “-1” (Req. 1b, 2c).

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: XXXX Initials: XXX Date: XXX

3.6. Change cell D10 to “1.5” (Req. 1b, 2c).

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: XXXX Initials: XXX Date: XXX

4. Results for valid input

4.1. Change cell D10 to “0” (Req. 3b, 3c).

Acceptance Criteria: The estimate of the rate is 0. The upper confidence limit for the rate rounds to 1.99715. A confidence statement for the upper limit is shown with the same value. No other confidence limits or statements are shown.

Pass or Fail: XXXX Initials: XXX Date: XXX

4.2. Change cell D10 to “1” (Req. 3b, 3d).

Acceptance Criteria: The estimate of the rate rounds to 0.666667. The two-side confidence limits for the rate round to 0.0168785 and 3.71443. The upper confidence limit for the rate rounds to 3.16258. The lower confidence limit for the rate rounds to 0.0341955. Confidence statements for the six cases are shown with the same values.

Pass or Fail: XXXX Initials: XXX Date: XXX

5. Independence of tab

5.1. Copy the 1 Rate – CI tab. Delete all tabs but the copy (Req. 4a).

Acceptance Criteria: The estimate of the rate rounds to 0.666667. The two-side confidence limits for the rate round to 0.0168785 and 3.71443. The upper confidence limit for the rate rounds to 3.16258.
The lower confidence limit for the rate rounds to 0.0341955.
Confidence statements for the six cases are shown with the same values.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

6. Comments
6.1. None

7. Saving and Signing File
7.1. Determine if all tests passed
    All Test Cases for Computer Pass?  yes  no

7.2. Save File and show name and date.
    Name of File:
    Data of File:

Signature: ________________________________  Date: XXX
# Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

## Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>3.2</td>
</tr>
<tr>
<td></td>
<td>b. The sample size inspected and the number of nonconformities can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>3.4, 3.5, 3.6</td>
</tr>
<tr>
<td></td>
<td>c. The units of measure can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td></td>
<td>3.1</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is $\geq 50%$ and $&lt; 100%$, no results are shown except possible the estimate. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3, 3.4 covers less than 50, 100 and valid value</td>
</tr>
<tr>
<td></td>
<td>b. Unless the sample size is a positive number, no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.4 covers lower bound of zero</td>
</tr>
<tr>
<td></td>
<td>c. Unless the number of nonconformities is a nonnegative integer, no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.5, 3.6 covers negative and noninteger</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. If units of measure have been entered, the units are displayed as nonconformities per the units of measure. Otherwise, the units are displayed as nonconformities per quantity.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3, 3.4 covers units entered and not entered</td>
</tr>
<tr>
<td></td>
<td>b. For valid input, the estimate of the rate is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3, 4.1, 4.2</td>
</tr>
<tr>
<td></td>
<td>c. When the number of nonconforming units is not 0, confidence limits and statement are displayed for the 2-sided, upper and lower.</td>
</tr>
<tr>
<td></td>
<td>4.1</td>
</tr>
<tr>
<td></td>
<td>d. When the number of nonconforming units is 0, upper confidence limits and statement are displayed for the rate.</td>
</tr>
<tr>
<td></td>
<td>4.2</td>
</tr>
<tr>
<td></td>
<td>Tabs:</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>4</td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
<tr>
<td></td>
<td>5.1</td>
</tr>
</tbody>
</table>
Appendix C: Verification of Results

4.1 From Minitab version 18.0.

Confidence Interval for One-Sample Poisson Rate Method

λ: Poisson rate of Sample

µ: Poisson mean of Sample

Observation length: 1.5

Exact method is used for this analysis.

Descriptive Statistics

<table>
<thead>
<tr>
<th>N</th>
<th>Total Occurrences</th>
<th>Sample Rate</th>
<th>Sample Mean</th>
<th>95% Upper Bound for λ</th>
<th>95% Upper Bound for μ</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1.99715</td>
<td>2.99573</td>
</tr>
</tbody>
</table>

4.2 From Minitab version 18.0

Two sided rate

Confidence Interval for One-Sample Poisson Rate Method

λ: Poisson rate of Sample

µ: Poisson mean of Sample

Observation length: 1.5

Exact method is used for this analysis.

Descriptive Statistics

<table>
<thead>
<tr>
<th>N</th>
<th>Total Occurrences</th>
<th>Sample Rate</th>
<th>Sample Mean</th>
<th>95% CI for λ</th>
<th>95% CI for μ</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>0.666667</td>
<td>1</td>
<td>(0.0168785, 3.71443)</td>
<td>(0.0253178, 5.57164)</td>
</tr>
</tbody>
</table>

Upper rate

Confidence Interval for One-Sample Poisson Rate Method

λ: Poisson rate of Sample

µ: Poisson mean of Sample

Observation length: 1.5
Exact method is used for this analysis.

**Descriptive Statistics**

<table>
<thead>
<tr>
<th>N</th>
<th>Total Occurrences</th>
<th>Sample Rate</th>
<th>Sample Mean</th>
<th>95% Upper Bound for ( \lambda )</th>
<th>95% Upper Bound for ( \mu )</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>0.666667</td>
<td>1</td>
<td>3.16258</td>
<td>4.74386</td>
</tr>
</tbody>
</table>

Lower rate

**Confidence Interval for One-Sample Poisson Rate Method**

\( \lambda \): Poisson rate of Sample  
\( \mu \): Poisson mean of Sample  
Observation length: 1.5

Exact method is used for this analysis.

**Descriptive Statistics**

<table>
<thead>
<tr>
<th>N</th>
<th>Total Occurrences</th>
<th>Sample Rate</th>
<th>Sample Mean</th>
<th>95% Lower Bound for ( \lambda )</th>
<th>95% Lower Bound for ( \mu )</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>0.666667</td>
<td>1</td>
<td>0.0341955</td>
<td>0.0512933</td>
</tr>
</tbody>
</table>
Appendix B

File: STAT-12 to 16 - Tab 2  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   About
   
   Windows 10

   Alienware 17 R3
   PC name Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

   Edition Windows 10 Home
   Version 1703
   OS Build 15063.674
   Product ID 00325-95916-23031-AAOEM
   Processor Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz
   Installed RAM 16.0 GB (15.9 GB usable)
   System type 64-bit operating system, x64-based processor
   Pen and touch No pen or touch input is available for this display

   1.3. Capture a screen shot showing the version of Excel used

   About Microsoft® Excel® 2016
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass

Initials: WT

Date: 11/16/17
3. Check for Valid Parameters

3.1. Go to the 1 Rate - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.
Pass or Fail: Pass  Initials: WT  Date: 11/16/17
3.2. Change cell D6 to “49.99”, cell D8 to “300” and cell D10 to “0” (Req. 1a, 2a, 3a, 3b).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>49.99</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>300</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconformities Found</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Units of Measure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Rate of Nonconformities**

<table>
<thead>
<tr>
<th>Estimate</th>
<th>0 nonconformities per quantity</th>
</tr>
</thead>
</table>

**2-Sided Case - 49.99% Confidence Interval**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>nonconformities per quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>nonconformities per quantity</td>
</tr>
</tbody>
</table>

**Lower 1-Sided Case - 49.99% Lower Confidence Limit**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>nonconformities per quantity</th>
</tr>
</thead>
</table>

**Upper 1-Sided Case - 49.99% Upper Confidence Limit**

<table>
<thead>
<tr>
<th>Upper Limit</th>
<th>nonconformities per quantity</th>
</tr>
</thead>
</table>

**Acceptance Criteria**: The rate is estimated to be 0
The units displayed are nonconformities per quantity.
No confidence limits or statements are displayed.
An error message is shown.

**Pass or Fail**: Pass
**Initials**: WT
**Date**: 11/16/17
3.3. Change cell D6 to “100” (Req. 1a, 2a, 3a, 3b).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-13, Verification/Validation Sampling Plans for Rate of Nonconformities**

**Appendix E: Upper Confidence Limit for Rate of Nonconformities**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>100</td>
</tr>
<tr>
<td>Number of Nonconformities Found</td>
<td>0</td>
</tr>
<tr>
<td>Units of Measure</td>
<td>nonconformities per quantity</td>
</tr>
</tbody>
</table>

**Rate of Nonconformities**

| Estimate | 0 nonconformities per quantity |

**2-Sided Case - 100% Confidence Interval**

| Lower Limit | nonconformities per quantity |
| Upper Limit | nonconformities per quantity |

**Lower 1-Sided Case - 100% Lower Confidence Limit**

| Lower Limit | nonconformities per quantity |

**Upper 1-Sided Case - 100% Upper Confidence Limit**

| Upper Limit | nonconformities per quantity |

**Acceptance Criteria:**

The rate is estimated to be 0

The units displayed are nonconformities per quantity.

No confidence limits or statements are displayed.

An error message is shown.

**Pass or Fail:** Pass

**Initials:** WT

**Date:** 11/16/17
3.4. Change cell D6 to “95”, cell D8 to “0” and cell D12 to “units” (Req. 1b, 1c, 2b, 3a).

Acceptance Criteria: No estimates, confidence limits or statements are displayed.
The units displayed are nonconformities per units.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/16/17

3.5. Change cell D8 to “1.5” and cell D10 to “-1” (Req. 1b, 2c).

Acceptance Criteria: No estimates, confidence limits or statements are displayed.
The units displayed are nonconformities per units.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/16/17
3.6. Change cell D10 to “1.5” (Req. 1b, 2c).

<table>
<thead>
<tr>
<th>Rate of Nonconformities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Estimate</strong></td>
<td>nonconformities per units</td>
</tr>
<tr>
<td><strong>Lower Limit</strong></td>
<td>nonconformities per units</td>
</tr>
<tr>
<td><strong>Upper Limit</strong></td>
<td>nonconformities per units</td>
</tr>
</tbody>
</table>

2-Sided Case - 95% Confidence Interval

<table>
<thead>
<tr>
<th>Rate of Nonconformities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lower 1-Sided Case - 95% Lower Confidence Limit</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Upper 1-Sided Case - 95% Upper Confidence Limit</strong></td>
<td></td>
</tr>
</tbody>
</table>

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: Pass  
Initials: WY  
Date: 11/16/17
4. Results for valid input

4.1. Change cell D10 to “0” (Req. 3b, 3c).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY

STAT-13, Verification/Validation Sampling Plans for Rate of Nonconformities

**Appendix E: Upper Confidence Limit for Rate of Nonconformities**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>% 50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>1.5</td>
</tr>
<tr>
<td>Number of Nonconformities Found</td>
<td>0</td>
</tr>
<tr>
<td>Units of Measure</td>
<td>units</td>
</tr>
</tbody>
</table>

**Rate of Nonconformities**

- Estimate: 0 nonconformities per units

**2-Sided Case - 95% Confidence Interval**

- Lower Limit: nonconformities per units
- Upper Limit: nonconformities per units

**Lower 1-Sided Case - 95% Lower Confidence Limit**

- Lower Limit: nonconformities per units

**Upper 1-Sided Case - 95% Upper Confidence Limit**

- Upper Limit: 1.997154849 nonconformities per units
  - With 95% confidence the rate of nonconformities is less than 1.99715484903999 per units.

**Acceptance Criteria:**

- The estimate of the rate is 0.
- The upper confidence limit for the rate rounds to 1.99715.
- A confidence statement for the upper limit is shown with the same value.
- No other confidence limits or statements are shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/16/17
4.2. Change cell D10 to “1” (Req. 3b, 3d.

<table>
<thead>
<tr>
<th>STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAT-13, Verification/Validation Sampling Plans for Rate of Nonconformities</td>
</tr>
<tr>
<td>Appendix E: Upper Confidence Limit for Rate of Nonconformities</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>95 ≤ Conf &lt; 100</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Units Inspected</th>
<th>1.5</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Number of Nonconformities Found</th>
<th>2</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Units of Measure</th>
<th>units</th>
</tr>
</thead>
</table>

Rate of Nonconformities

<table>
<thead>
<tr>
<th>Estimate</th>
<th>0.666666667 nonconformities per units</th>
</tr>
</thead>
</table>

2-Sided Case - 95% Confidence Interval

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>0.016879839 nonconformities per units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Limit</td>
<td>3.714428907 nonconformities per units</td>
</tr>
</tbody>
</table>

With 95% confidence the rate of nonconformities is between 0.01687985388661933 and 3.7144289729026 per units.

Lower 1-Sided Case - 95% Lower Confidence Limit

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>0.03419953 nonconformities per units</th>
</tr>
</thead>
</table>

With 95% confidence the rate of nonconformities is greater than 0.0341995291917064 per units.

Upper 1-Sided Case - 95% Upper Confidence Limit

<table>
<thead>
<tr>
<th>Upper Limit</th>
<th>3.162576346 nonconformities per units</th>
</tr>
</thead>
</table>

With 95% confidence the rate of nonconformities is less than 3.16257634559372 per units.

Acceptance Criteria: The estimate of the rate rounds to 0.666667. The two-side confidence limits for the rate round to 0.0168785 and 3.71443. The upper confidence limit for the rate rounds to 3.16258. The lower confidence limit for the rate rounds to 0.0341955. Confidence statements for the six cases are shown with the same values.

Pass or Fail: Pass Initials: WT Date: 11/16/17
5. Independence of tab

5.1. Copy the 1 Rate – CI tab. Delete all tabs but the copy (Req. 4a)

Acceptance Criteria: The estimate of the rate rounds to 0.666667.
The two-side confidence limits for the rate round to 0.0168785 and 3.71443.
The upper confidence limit for the rate rounds to 3.16258.
The lower confidence limit for the rate rounds to 0.0341955.
Confidence statements for the six cases are shown with the same values.

Pass or Fail: Pass    Initials: WT    Date: 11/16/17
6. Comments

   6.1. None

7. Saving and Signing File

   7.1. Determine if all tests passed

      All Test Cases for Computer Pass?           X  yes   no

   7.2. Save File and show name and date.

      Name of File:  STAT-12 to 16 - Tab 2  Windows 10.doc
      Data of File:  November 16, 2017

      Signature: ________________________________ Date: 11/16/17
Appendix C

File: STAT-12 to 16 - Tab 2  Windows 7
Appendix A: Test Script

1. Document System Used

   1.1. Capture a screen shot showing the computer make and model

![Computer Screen Shot]

MODEL: P-7811FX
1015841R008506503BA2200
SNID: 63500095422
S/N: F2688 010 02654 Made in China
1.2. Capture a screen shot showing the operating system including version number

![Windows 7 Professional](image)

**Windows edition**
- Windows 7 Professional
- Copyright © 2009 Microsoft Corporation. All rights reserved.
- Service Pack 1
- Get more features with a new edition of Windows 7

**System**
- Rating: 5.5 Your Windows Experience Index needs to be refreshed
- Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHz
- Installed memory (RAM): 4.00 GB
- System type: 64-bit Operating System
- Pen and Touch: No Pen or Touch input is available for this display

1.3. Capture a screen shot showing the version of Excel used

![Microsoft Office Excel](image)

**About Microsoft Office Excel**
- Microsoft® Office Excel® 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
- Port of Microsoft Office Professional 2007
- © 2006 Microsoft Corporation. All rights reserved.


This product is licensed to:
- Wayne Taylor
- Taylor Enterprises, Inc.
- Product ID: 81605-903-7132834-65427

**View the Microsoft Software License Terms**

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
3. Check for Valid Parameters

3.1. Go to the 1 Rate - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
3.2. Change cell D6 to “49.99”, cell D8 to “300” and cell D10 to “0” (Req. 1a, 2a, 3a, 3b).

Acceptance Criteria: The rate is estimated to be 0
The units displayed are nonconformities per quantity.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/13/17
3.3. Change cell D6 to “100” (Req. 1a, 2a, 3a, 3b).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>50%</th>
<th>50% ≤ Cert &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconformities Found</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Units of Measure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Rate of Nonconformities**

<table>
<thead>
<tr>
<th>Estimate</th>
<th>0 nonconformities per quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Sided Case - 100% Confidence Interval</td>
<td></td>
</tr>
<tr>
<td>Lower Limit</td>
<td>nonconformities per quantity</td>
</tr>
<tr>
<td>Upper Limit</td>
<td>nonconformities per quantity</td>
</tr>
</tbody>
</table>

| Lower 1-Sided Case - 100% Lower Confidence Limit | |
| Lower Limit | nonconformities per quantity |

| Upper 1-Sided Case - 100% Upper Confidence Limit | |
| Upper Limit | nonconformities per quantity |

**Acceptance Criteria:**
The rate is estimated to be 0
The units displayed are nonconformities per quantity.
No confidence limits or statements are displayed.
An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/13/17
3.4. Change cell D6 to “95”, cell D8 to “0” and cell D12 to “units” (Req. 1b, 1c, 2b, 3a).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95 %</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconformities Found</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Units of Measure</td>
<td>units</td>
<td></td>
</tr>
</tbody>
</table>

Number of units inspected is not a valid number greater than zero.

Acceptance Criteria: No estimates, confidence limits or statements are displayed.
The units displayed are nonconformities per units.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
3.5. Change cell D8 to “1.5” and cell D10 to “-1” (Req. 1b, 2c).

Acceptance Criteria: No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/13/17
3.6. Change cell D10 to “1.5” (Req. 1b, 2c).

### Acceptance Criteria:
- No estimates, confidence limits or statements are displayed.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/13/17
4. Results for valid input
   4.1. Change cell D10 to “0” (Req. 3b, 3c).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
<th>50 ≤ Coef &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconformities Found</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Units of Measure</td>
<td>units</td>
<td></td>
</tr>
</tbody>
</table>

**Rate of Nonconformities**

| Estimate | 0 nonconformities per units |

**2-Sided Case - 95% Confidence Interval**

| Lower Limit | nonconformities per units |
| Upper Limit | nonconformities per units |

**Lower 1-Sided Case - 95% Lower Confidence Limit**

| Lower Limit | nonconformities per units |

**Upper 1-Sided Case - 95% Upper Confidence Limit**

| Upper Limit | 1.997154849 nonconformities per units |

Acceptance Criteria: The estimate of the rate is 0.
The upper confidence limit for the rate rounds to 1.99715.
A confidence statement for the upper limit is shown with the same value.
No other confidence limits or statements are shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
4.2. Change cell D10 to “1” (Req. 3b, 3d).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-13, Verification/Validation Sampling Plans for Rate of Nonconformities**

**Appendix E: Upper Confidence Limit for Rate of Nonconformities**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Units Inspected</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>Number of Nonconformities Found</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Units of Measure</td>
<td>units</td>
<td></td>
</tr>
</tbody>
</table>

**Rate of Nonconformities**

- **Estimate:** 0.666666667 nonconformities per units

**2-Sided Case - 95% Confidence Interval**

- **Lower Limit:** 0.016878539 nonconformities per units
- **Upper Limit:** 3.714428927 nonconformities per units

With 95% confidence, the rate of nonconformities is between 0.016875830557249 and 3.7144292736004 per units.

**Lower 1-Sided Case - 95% Lower Confidence Limit**

- **Lower Limit:** 0.03419553 nonconformities per units

With 95% confidence, the rate of nonconformities is greater than 0.0341955206072242 per units.

**Upper 1-Sided Case - 95% Upper Confidence Limit**

- **Upper Limit:** 3.162576346 nonconformities per units

With 95% confidence, the rate of nonconformities is less than 3.16257634596295 per units.

**Acceptance Criteria:**

The estimate of the rate rounds to 0.666667.

The two-side confidence limits for the rate round to 0.0168785 and 3.71443.

The upper confidence limit for the rate rounds to 3.16258.

The lower confidence limit for the rate rounds to 0.0341955.

Confidence statements for the six cases are shown with the same values.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/13/17
5. Independence of tab

5.1. Copy the Rate – CI tab. Delete all tabs but the copy (Req. 4a)

Acceptance Criteria:
The estimate of the rate rounds to 0.666667.
The two-side confidence limits for the rate round to 0.0168785 and 3.71443.
The upper confidence limit for the rate rounds to 3.16258.
The lower confidence limit for the rate rounds to 0.0341955.
Confidence statements for the six cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File
   7.1. Determine if all tests passed
         All Test Cases for Computer Pass? X yes no
   7.2. Save File and show name and date.
         Name of File: STAT-12 to 16 - Tab 2 Windows 7.doc
         Date of File: November 13, 2017

   Signature: [Signature] Date: 11/13/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – CI Tab

Protocol Number: TE-17-4

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 21, 2017
Date

November 21, 2017
Date
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – CI Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Average – CI tab, this spreadsheet performs confidence intervals for the average. It is described in Appendix A of *STAT-14, Verification/Validation Sampling Plans for Average*. Appendix A also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-4, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 1 Average – CI Tab was written to validate the 1 Average – CI Tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 3  Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 3  Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – CI Tab

Protocol Number: TE-17-4
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – CI Tab

Protocol Number: TE-17-4

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 11, 2017
Date

November 11, 2017
Date
Validation Protocol for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
1 Average – CI Tab

Protocol Number: TE-17-4

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Average – CI tab, this spreadsheet performs confidence intervals for the average. It is described in Appendix A of *STAT-14, Verification/Validation Sampling Plans for Average*. Appendix A also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | **Input of Data:**  
|    | a. The confidence level can be entered into the highlighted cell of the spreadsheet  
|    | b. The name of the variable can be entered into the highlighted cell of the spreadsheet.  
|    | c. The data can be entered into the highlighted cells of the spreadsheet.  
|    | d. Only the highlighted yellow cells can be changed. |
| 2  | **Data Checking:**  
|    | a. Unless the confidence level is \( \geq 50\% \) and \(< 100\% \), no confidence intervals are shown. An error message is displayed.  
|    | b. Only valid numbers in the data fields are used.  
|    | c. If no valid data is entered, the sample size is zero and no results are shown. An error message is displayed.  
|    | d. If there is a single valid data point, the sample size is one and only the average is shown. An error message is displayed.  
|    | e. If there are two or more valid data points but the standard deviation is zero, the sample size, average and standard deviation are shown but no confidence intervals are shown. An error message is displayed. |
| 3  | **Results for valid input:**  
|    | a. For valid input with at least two data points and non-zero standard deviation, the sample size, average, standard deviation and confidence intervals are displayed. |
| 4  | **Tabs:**  
|    | a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same. |
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-14 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX Initials: XXX Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 1 Average - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).
       <Insert screen shot here>
       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX Initials: XX Date: XXX
   3.2. Change cell D6 to “49.99”, cell B9 to 1 and B10 to 2 (Req. 1a, 2a).
       <Insert screen shot here>
       Acceptance Criteria: The sample size is 2
       The average is 1.5
       The standard deviation rounds to 0.7071.
       No confidence limits or statements are displayed.
       An error message is shown.
       Pass or Fail: XXXX Initials: XX Date: XXX
   3.3. Change cell D6 to “100” (Req. 1a, 2a).
       <Insert screen shot here>
       Acceptance Criteria: The sample size is 2
       The average is 1.5
       The standard deviation rounds to 0.7071.
       No confidence limits or statements are displayed.
       An error message is shown.
3.4. Change cell D6 to “95”, cell B9 to “A”, cell B10 to “1.1” and cell B8 to “Control 2” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample size is 0.
No estimates, confidence limits or statements are displayed.
The name of the variable is displayed above the results.
An error message is shown.

3.5. Change cell B11 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.
The average is 1.
No standard deviation, confidence limits or statements are displayed.
An error message is shown.

3.6. Copy cell B11 into cells B12 to B208 (Req. 1c, 2e).

Acceptance Criteria: The sample size is 198.
The average is 1.
The standard deviation is 0.
No confidence limits or statements are displayed.
An error message is shown.

4. Results for valid input

4.1. Delete cells B9 to B208. Copy cells D11:D30 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample size is 20.
The average rounds to 1.9992.
The standard deviation rounds to 0.0885.
The two-side confidence limits for the average round to 1.9578 and 2.0406.
The upper confidence limit for the average rounds to 2.0334.
The lower confidence limit for the average rounds to 1.9650.
Confidence statements for the three cases are shown with the same values.

5. Independence of tab

5.1. Copy the 1 Average – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.
The average rounds to 1.9992.
The standard deviation rounds to 0.0885.
The two-side confidence limits for the average round to 1.9578 and 2.0406. The upper confidence limit for the average rounds to 2.0334. The lower confidence limit for the average rounds to 1.9650. Confidence statements for the three cases are shown with the same values.

Pass or Fail: XXXX Initials: XX Date: XXX

6. Comments
6.1. None

7. Saving and Signing File
7.1. Determine if all tests passed
   All Test Cases for Computer Pass? yes no
7.2. Save File and show name and date.
   Name of File:
   Data of File:

Signature: ________________________________ Date: XXX
Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is met with justification the test cases cover the requirement.

Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | Input of Data:  
   a. The confidence level can be entered into the highlighted cell of the spreadsheet  
      3.2, 3.3  
   b. The name of the variable can be entered into the highlighted cell of the spreadsheet.  
      3.4  
   c. The data can be entered into the highlighted cells of the spreadsheet.  
      3.4, 3.5, 3.6 – all data cells used  
   d. Only the highlighted yellow cells can be changed.  
      3.1 |
| 2  | Data Checking:  
   a. Unless the confidence level is ≥50% and <100%, no confidence intervals are shown. An error message is displayed.  
      3.2, 3.3 – covers both sides  
   b. Only valid numbers in the data fields are used.  
      3.4  
   c. If no valid data is entered, the sample size is zero and no results are shown. An error message is displayed.  
      3.4  
   d. If there is a single valid data point, the sample size is one and only the average is shown. An error message is displayed.  
      3.5  
   e. If there are two or more valid data points but the standard deviation is zero, the sample size, average and standard deviation are shown but no confidence intervals are shown. An error message is displayed.  
      3.6 |
| 3  | Results for valid input:  
   a. For valid input with at least two data points and non-zero standard deviation, the sample size, average, standard deviation and confidence intervals are displayed.  
      4.1 |
| 4  | Tabs:  
   a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.  
      5.1 |
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as shown in Appendix A of STAT-14.

If the alternative "≠" is selected, the following output appears in the Session window. With 95% confidence, the average is between 1.9578 and 2.0406.

One-Sample T: Control 2
Descriptive Statistics

<table>
<thead>
<tr>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
<th>95% CI for μ</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>1.9992</td>
<td>0.0885</td>
<td>0.0198</td>
<td>(1.9578, 2.0406)</td>
</tr>
</tbody>
</table>

μ: mean of Control 2

If the alternative ">" is selected, the following output appears in the Session window. With 95% confidence, the average is greater than 1.9650.

One-Sample T: Control 2
Descriptive Statistics

<table>
<thead>
<tr>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
<th>95% Lower Bound for μ</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>1.9992</td>
<td>0.0885</td>
<td>0.0198</td>
<td>1.9650</td>
</tr>
</tbody>
</table>

μ: mean of Control 2

If the alternative "<" is selected, the following output appears in the Session window. With 95% confidence, the average is less than 2.0334.

One-Sample T: Control 2
Descriptive Statistics

<table>
<thead>
<tr>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
<th>95% Upper Bound for μ</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>1.9992</td>
<td>0.0885</td>
<td>0.0198</td>
<td>2.0334</td>
</tr>
</tbody>
</table>

μ: mean of Control 2
Appendix B

File: STAT-12 to 16 - Tab 3  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   ![About Windows 10](image)

   **Alienware 17 R3**
   **PC name** Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

   - **Edition**: Windows 10 Home
   - **Version**: 1703
   - **OS Build**: 15063.674
   - **Product ID**: 00325-95916-23031-AAOEM
   - **Processor**: Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz
   - **Installed RAM**: 16.0 GB (15.9 GB usable)
   - **System type**: 64-bit operating system, x64-based processor
   - **Pen and touch**: No pen or touch input is available for this display

   1.3. Capture a screen shot showing the version of Excel used
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass Initials: WT Date: 11/16/17
3. Check for Valid Parameters

3.1. Go to the 1 Average - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass

Initials: WT

Date: 11/16/17
3.2. Change cell D6 to “49.99”, cell B9 to 1 and B10 to 2 (Req. 1a, 2a).

Acceptance Criteria: The sample size is 2
The average is 1.5
The standard deviation rounds to 0.7071.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass       Initials: WT        Date: 11/16/17
3.3. Change cell D6 to “100” (Req. 1a, 2a).

Acceptance Criteria: The sample size is 2
The average is 1.5
The standard deviation rounds to 0.7071.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass     Initials: WT     Date: 11/16/17
3.4. Change cell D6 to “95”, cell B9 to “A”, cell B10 to “1.1” and cell B8 to “Control 2” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample size is 0.
No estimates, confidence limits or statements are displayed.
The name of the variable is displayed above the results.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/16/17
3.5. Change cell B11 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.
The average is 1
No standard deviation, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/16/17
3.6. Copy cell B11 into cells B12 to B208 (Req. 1c, 2e).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-14, Verification/Validation Sampling Plans for Average**

**Appendix A: Confidence Limits for the Average**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>95</td>
<td>60 ≤ Conf &lt; 100</td>
</tr>
</tbody>
</table>

**Control 2**

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Average</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>198</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

**2 Sided Case - 95% Confidence Interval**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Lower 1 Sided Case - 95% Lower Confidence Limit**

<table>
<thead>
<tr>
<th>Lower Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Upper 1 Sided Case - 95% Upper Confidence Limit**

<table>
<thead>
<tr>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

| 200 | 1 |
| 201 | 1 |
| 202 | 1 |
| 203 | 1 |
| 204 | 1 |
| 205 | 1 |
| 206 | 1 |
| 207 | 1 |
| 208 | 1 |
| 209 | 1 |

**Acceptance Criteria:**

- The sample size is 198.
- The average is 1
- The standard deviation is 0.
- No confidence limits or statements are displayed.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/16/17
4. Results for valid input

4.1. Delete cells B9 to B208. Copy cells D11:D30 from the example data set tab to cell B9. (Req. 3a).

STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY
STAT-14, Verification/Validation Sampling Plans for Average
Appendix A: Confidence Limits for the Average

Acceptance Criteria: The sample size is 20.
The average rounds to 1.9992.
The standard deviation rounds to 0.0885.
The two-side confidence limits for the average round to 1.9578 and 2.0406.
The upper confidence limit for the average rounds to 2.0334.
The lower confidence limit for the average rounds to 1.9650.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass Initials: WT Date: 11/16/17
5. Independence of tab

5.1. Copy the 1 Average – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.
The average rounds to 1.9992.
The standard deviation rounds to 0.0885.
The two-side confidence limits for the average round to 1.9578 and 2.0406.
The upper confidence limit for the average rounds to 2.0334.
The lower confidence limit for the average rounds to 1.9650.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass    Initials: WT    Date: 11/16/17
6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass?  X  yes  no
   7.2. Save File and show name and date.
       Name of File:  STAT-12 to 16 - Tab 3 Windows 10.doc
       Date of File:  November 16, 2017

Signature: ________________________________ Date: 11/16/17
Appendix C

File: STAT-12 to 16 - Tab 3  Windows 7
Appendix A: Test Script

1. Document System Used

1.1. Capture a screen shot showing the computer make and model

![Gateway Computer Back Panel](image-url)
1.2. Capture a screen shot showing the operating system including version number

Windows edition

Windows 7 Professional
Copyright © 2009 Microsoft Corporation. All rights reserved.
Service Pack 1
Get more features with a new edition of Windows 7

System

Rating: 5.0 Your Windows Experience Index needs to be refreshed
Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHz
Installed memory (RAM): 4.00 GB
System type: 64-bit Operating System
Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

About Microsoft Office Excel

Microsoft® Office Excel® 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
© 2007 Microsoft Corporation. All rights reserved.


This product is licensed to:

Wayne Taylor
Taylor Enterprises, Inc.
Product ID: 81605-903-7132834-65427

View the Microsoft Software License Terms

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass         Initials: WT         Date: 11/13/17
3. Check for Valid Parameters

3.1. Go to the 1 Average - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17

3.2. Change cell D6 to “49.99”, cell B9 to 1 and B10 to 2 (Req. 1a, 2a).

Acceptance Criteria: The sample size is 2
The average is 1.5
The standard deviation rounds to 0.7071.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
3.3. Change cell D6 to “100” (Req. 1a, 2a).

Acceptance Criteria: The sample size is 2
The average is 1.5
The standard deviation rounds to 0.7071.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17

3.4. Change cell D6 to “95”, cell B9 to “A”, cell B10 to “1..1” and cell B8 to “Control 2” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample size is 0.
No estimates, confidence limits or statements are displayed.
The name of the variable is displayed above the results.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
3.5. Change cell B11 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.
The average is 1
No standard deviation, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/13/17
3.6. Copy cell B11 into cells B12 to B208 (Req. 1c, 2e).

<table>
<thead>
<tr>
<th>Control 2</th>
<th>Sample Size</th>
<th>Average</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>198</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

The standard deviation is zero.

Acceptance Criteria: The sample size is 198.
The average is 1
The standard deviation is 0.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
4. Results for valid input

4.1. Delete cells B9 to B208. Copy cells D11:D30 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample size is 20.
The average rounds to 1.9992.
The standard deviation rounds to 0.0885.
The two-side confidence limits for the average round to 1.9578 and 2.0406.
The upper confidence limit for the average rounds to 2.0334.
The lower confidence limit for the average rounds to 1.9650.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass Initials: WT Date: 11/13/17
5. Independence of tab

5.1. Copy the 1 Average – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.
The average rounds to 1.9992.
The standard deviation rounds to 0.0885.
The two-side confidence limits for the average round to 1.9578 and 2.0406.
The upper confidence limit for the average rounds to 2.0334.
The lower confidence limit for the average rounds to 1.9650.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop
       was taken instead.

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass?   X yes    no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 3 Windows 7.doc
       Data of File: November 13, 2017

Signature: ________________________________ Date: 11/13/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – n Tab

Protocol Number: TE-17-5

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 21, 2017
Date
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – n Tab

Report Number: TE-17-5

1.0 Introduction

The book Statistical Procedures for the Medical Device Industry by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Average – n tab, this spreadsheet calculates sample sizes for 1 sample equivalence test for the average. It is described in Appendix B of STAT-14, Verification/Validation Sampling Plans for Average. Appendix B also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-5, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 1 Average – n Tab was written to validate the 1 Average – n Tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 4 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 4 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – n Tab

Protocol Number: TE-17-5
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – n Tab

Protocol Number: TE-17-5

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 11, 2017
Date

November 11, 2017
Date
1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Average – CI Tab, this spreadsheet calculates sample sizes for 1 sample equivalence test for the average. It is described in Appendix B of *STAT-14, Verification/Validation Sampling Plans for Average*. Appendix B also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
## 2.0 Requirements

Table 1 lists the user requirements to be validated.

**Table 1: User Requirements for the 1 Average – n tab of STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls**

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. $\Delta_{RQL}$ can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>c. $\Delta_{AQL}$ can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>d. The standard deviation can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>e. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is $\geq 50%$ and $&lt;100%$, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Unless $\Delta_{RQL}$ and $\Delta_{AQL}$ are valid numbers and $\Delta_{RQL} &gt; \Delta_{AQL} \geq 0$, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>c. Unless $\sigma$ is a valid number and $\sigma &gt; 0$, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input, the sample size is displayed.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-14 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX      Initials: XXX      Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 1 Average - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).
       <Insert screen shot here>
       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX      Initials: XXX      Date: XXX
   3.2. Change cell C6 to “49.99”, cell C8 to 0.1, cell C10 to 0.025 and C12 to 0.1 (Req. 1a-d, 2a).
       <Insert screen shot here>
       Acceptance Criteria: The sample size is not displayed.
       An error message is shown.
       Pass or Fail: XXXX      Initials: XXX      Date: XXX
   3.3. Change cell C6 to “100” (Req. 1a, 2a).
       <Insert screen shot here>
       Acceptance Criteria: The sample size is not displayed.
       An error message is shown.
       Pass or Fail: XXXX      Initials: XXX      Date: XXX
   3.4. Change cell C6 to “95” and cell C8 to “0..1” (Req. 1b, 2b).
       <Insert screen shot here>
Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX
3.5. Change cell C8 to “0.1” and cell C10 to “0..025” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX
3.6. Change cell C10 to “0.1” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX
3.7. Change cell C10 to “0.025” and C12 to “0..1” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX
3.8. Change cell C12 to “0” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

4. Results for valid input
4.1. Change cell C12 to “0.1” (Req. 3a).

Acceptance Criteria: The sample size is 21.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

5. Independence of tab
5.1. Copy the 1 Average – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 21.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

6. Comments
6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass?       yes               no
   7.2. Save File and show name and date.
       Name of File:
       Data of File:
       Signature: ________________________________ Date: XXX
## Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

### Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. $\Delta_{\text{RQL}}$ can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>c. $\Delta_{\text{AQL}}$ can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>3.5, 3.6</td>
</tr>
<tr>
<td></td>
<td>d. The standard deviation can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>3.7, 3.8</td>
</tr>
<tr>
<td></td>
<td>e. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td></td>
<td>3.1</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is $\geq 50%$ and $&lt; 100%$, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. Unless $\Delta_{\text{RQL}}$ and $\Delta_{\text{AQL}}$ are valid numbers and $\Delta_{\text{RQL}} &gt; \Delta_{\text{AQL}} \geq 0$, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.4, 3.5, 3.6</td>
</tr>
<tr>
<td></td>
<td>c. Unless $\sigma$ is a valid number and $\sigma &gt; 0$, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.7, 3.8</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input, the sample size is displayed.</td>
</tr>
<tr>
<td></td>
<td>4.1</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
<tr>
<td></td>
<td>5.1</td>
</tr>
</tbody>
</table>
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as shown in Appendix B of STAT-14.
Appendix B

File: STAT-12 to 16 - Tab 4  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   ![About Windows 10](image)

   Alienware 17 R3
   PC name: Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

   Edition: Windows 10 Home
   Version: 1703
   OS Build: 15063.674
   Product ID: 00325-95916-23031-AAOEM
   Processor: Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz
   Installed RAM: 16.0 GB (15.9 GB usable)
   System type: 64-bit operating system, x64-based processor
   Pen and touch: No pen or touch input is available for this display

   1.3. Capture a screen shot showing the version of Excel used

   ![About Microsoft Excel](image)
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass

Initials: WT

Date: 11/21/17
3. Check for Valid Parameters

3.1. Go to the 1 Average - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.
Pass or Fail: Pass          Initials: WT          Date: 11/21/17
3.2. Change cell C6 to “49.99”, cell C8 to 0.1, cell C10 to 0.025 and C12 to 0.1 (Req. 1a-d, 2a).

Acceptance Criteria: The sample size is not displayed. An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/21/17

3.3. Change cell C6 to “100” (Req. 1a, 2a).

Acceptance Criteria: The sample size is not displayed. An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/21/17
3.4. Change cell C6 to “95” and cell C8 to “0..1” (Req. 1b, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass  Initials: WT  Date: 11/21/17

3.5. Change cell C8 to “0.1” and cell C10 to “0..025” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass  Initials: WT  Date: 11/21/17
3.6. Change cell C10 to “0.1” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass  Initials: WT  Date: 11/21/17

3.7. Change cell C10 to “0.025” and C12 to “0.1” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass  Initials: WT  Date: 11/21/17
3.8. Change cell C12 to “0” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/21/17

4. Results for valid input

4.1. Change cell C12 to “0.1” (Req. 3a).

Acceptance Criteria: The sample size is 21.

Pass or Fail: Pass Initials: WT Date: 11/21/17
5. Independence of tab

5.1. Copy the 1 Average – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 21.

Pass or Fail: Pass  Initials: WT  Date: 11/21/17
6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass?       X    yes                      no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 4 Windows 10.doc
       Data of File: November 21, 2017
       Signature: ________________________________ Date: 11/21/17
Appendix C

File: STAT-12 to 16 - Tab 4  Windows 7
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

![Gateway Computer Make and Model](image-url)
1.2. Capture a screen shot showing the operating system including version number

![Windows 7 Professional]

- Windows 7 Professional
- Copyright © 2009 Microsoft Corporation. All rights reserved.
- Service Pack 1
- Get more features with a new edition of Windows 7

1.3. Capture a screen shot showing the version of Excel used

![About Microsoft Office Excel]

- Microsoft Office Excel® 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
- © 2006 Microsoft Corporation. All rights reserved.

- This product is licensed to:
  Wayne Taylor
  Taylor Enterprises, Inc.
- Product ID: 81605-903-7132834-65427
- [View the Microsoft Software License Terms]
- Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
3. Check for Valid Parameters

3.1. Go to the 1 Average - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.
Pass or Fail: Pass     Initials: WT     Date: 11/13/17

3.2. Change cell C6 to "49.99", cell C8 to 0.1, cell C10 to 0.025 and C12 to 0.1 (Req. 1a-d, 2a).

Acceptance Criteria: The sample size is not displayed.  An error message is shown.
Pass or Fail: Pass     Initials: WT     Date: 11/13/17
3.3. Change cell C6 to “100” (Req. 1a, 2a).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/13/17

3.4. Change cell C6 to “95” and cell C8 to “0..1” (Req. 1b, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/13/17

3.5. Change cell C8 to “0.1” and cell C10 to “0..025” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/13/17
3.6. Change cell C10 to “0.1” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/13/17

3.7. Change cell C10 to “0.025” and C12 to “0.1” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/13/17

3.8. Change cell C12 to “0” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/13/17
4. Results for valid input
   4.1. Change cell C12 to “0.1” (Req. 3a).

   **STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

   **STAT-14, Verification/Validation Sampling Plans for Average**

   **Appendix B: Equivalence Test for the Average**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
<th>Chance of failing at ΔCL</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>ΔUL</td>
<td>0.1</td>
<td>A difference that has a 95% chance of failing</td>
<td>ΔUL &gt; ΔCL ≥ 0</td>
</tr>
<tr>
<td>ΔOL</td>
<td>0.025</td>
<td>A difference that has a 95% chance of passing</td>
<td>ΔOL ≤ ΔCL ≤ 0</td>
</tr>
<tr>
<td>σ</td>
<td>0.1</td>
<td>Estimate of standard deviation</td>
<td>α &gt; 0</td>
</tr>
</tbody>
</table>

   **Sample Size:** 21
   Number of samples for each group for 95% confidence equivalence test.

   **Acceptance Criteria:** The sample size is 21.
   **Pass or Fail:** Pass
   **Initials:** WT
   **Date:** 11/13/17

5. Independence of tab
   5.1. Copy the 1 Average – n tab. Delete all tabs but the copy. (Req. 4a)

   **STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

   **STAT-14, Verification/Validation Sampling Plans for Average**

   **Appendix B: Equivalence Test for the Average**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
<th>Chance of failing at ΔCL</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>ΔUL</td>
<td>0.1</td>
<td>A difference that has a 95% chance of failing</td>
<td>ΔUL &gt; ΔCL ≥ 0</td>
</tr>
<tr>
<td>ΔOL</td>
<td>0.025</td>
<td>A difference that has a 95% chance of passing</td>
<td>ΔOL ≤ ΔCL ≤ 0</td>
</tr>
<tr>
<td>σ</td>
<td>0.1</td>
<td>Estimate of standard deviation</td>
<td>α &gt; 0</td>
</tr>
</tbody>
</table>

   **Sample Size:** 21
   Number of samples for each group for 95% confidence equivalence test.

   **Acceptance Criteria:** The sample size is 21.
   **Pass or Fail:** Pass
   **Initials:** WT
   **Date:** 11/13/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? X yes no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 4 Windows 7.doc
       Data of File: November 13, 2017

Signature: ________________________________ Date: 11/13/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – Equivalence Tab

Protocol Number: TE-17-6

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 22, 2017
Date

November 22, 2017
Date
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – Equivalence Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Average – Equivalence tab, this spreadsheet performs an equivalence test for the average. It is described in Appendix B of *STAT-14, Verification/Validation Sampling Plans for Average*. Appendix B also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-6, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 1 Average – Equivalence Tab was written to validate the 1 Average – Equivalence Tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 5 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 5 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – Equivalence Tab

Protocol Number: TE-17-6
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Average – Equivalence Tab

Protocol Number: TE-17-6

Approvals:

Dr. Wayne A. Taylor
Study Director

November 11, 2017
Date

Ann B. Taylor
President

November 11, 2017
Date
Validation Protocol for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
1 Average – Equivalence Tab

Protocol Number: TE-17-6

1.0 Introduction

The book Statistical Procedures for the Medical Device Industry by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Average – Equivalence tab, this spreadsheet performs an equivalence test for the average. It is described in Appendix B of STAT-14, Verification/Validation Sampling Plans for Average. Appendix B also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
## 2.0 Requirements

Table 1 lists the user requirements to be validated.

### Table 1: User Requirements for the 1 Average – Equivalence tab of STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. The target can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>c. The difference can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>d. The name of the variable can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>e. The data can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>f. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ( \geq 50% ) and (&lt;100%), no equivalence intervals or conclusions are shown. An error message is shown.</td>
</tr>
<tr>
<td></td>
<td>b. Unless the target is a valid number and the difference is a valid number ( &gt; 0 ), no conclusions are shown. An error message is shown.</td>
</tr>
<tr>
<td></td>
<td>c. Only valid numbers in the data fields are used.</td>
</tr>
<tr>
<td></td>
<td>d. If no valid data is entered, the sample size is zero and no results are shown. An error message is shown.</td>
</tr>
<tr>
<td></td>
<td>e. If there is a single valid data point, the sample size is one and only the average is shown. An error message is shown.</td>
</tr>
<tr>
<td></td>
<td>f. If there are two or more valid data points but the standard deviation is zero, the sample size, average and standard deviation are shown but no equivalence intervals and conclusions are shown. An error message is shown.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input with at least two data points and non-zero standard deviation, the sample size, average, standard deviation, confidence intervals and conclusions are displayed.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-14 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
        <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
        <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
        <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
        <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
        <Insert screen shot here>
        Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
        Pass or Fail: XXXX  Initials: XXX  Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 1 Average - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1f).
        <Insert screen shot here>
        Acceptance Criteria: Each time a message should be displayed that the cell is protected.
        Pass or Fail: XXXX  Initials: XXX  Date: XXX
   3.2. Change cell E6 to “49.99”, cell B13 to 10, B14 to 11, cell E8 to 10 and cell E10 to 1 (Req. 1a-c, 2a).
        <Insert screen shot here>
        Acceptance Criteria: The sample size is 2
        The average is 10.5
        The standard deviation rounds to 0.7071.
        No confidence limits or statements are displayed.
        An error message is shown.
        Pass or Fail: XXXX  Initials: XXX  Date: XXX
   3.3. Change cell E6 to “100” (Req. 2a).
        <Insert screen shot here>
        Acceptance Criteria: The sample size is 2
        The average is 10.5
        The standard deviation rounds to 0.7071.
        No confidence limits or statements are displayed.
        An error message is shown.
3.4. Change cell E6 to “95” and cell E8 to “10.0” (Req. 2b).

Acceptance Criteria: The sample size, average, standard deviation and equivalence limits are shown. No conclusions are shown. An error message is shown.

3.5. Change cell E8 to “10.0” and cell E10 to “0” (Req. 2b).

Acceptance Criteria: The sample size, average, standard deviation and equivalence limits are shown. No conclusions are shown. An error message is shown.

3.6. Change cell E10 to “1”, cell B13 to “A”, cell B14 to “10.0” and cell B12 to “Control 2” (Req. 1d, 2c, 2d).

Acceptance Criteria: The sample size is 0.
No estimates, equivalence limits or statements are displayed.
The name of the variable is displayed above the results.
An error message is shown.

3.7. Change cell B15 to “10” (Req. 2c, 2e).

Acceptance Criteria: The sample size is 1.
The average is 10
No standard deviation, equivalence limits or statements are displayed.
An error message is shown.

3.8. Copy cell B15 into cells B16 to B212 (Req. 1e, 2c, 2f).

Acceptance Criteria: The sample size is 198.
The average is 10
The standard deviation is 0.
No equivalence limits or statements are displayed.
An error message is shown.

4. Results for valid input

4.1. Delete cells B13 to B212. Copy cells D10:D30 from the example data set tab to cell B12. Set cell E8 to “2” and cell E10 to “0.1”. (Req. 3a).

Acceptance Criteria: The sample size is 20.
The average rounds to 1.9992.
The standard deviation rounds to 0.0885.
The two-sided equivalence limits for the average round to 1.964984 and 2.033416.
The upper confidence limit for the average rounds to 2.033416.
The lower confidence limit for the average rounds to 1.964984.
Confidence statements for the three cases are shown with the same values.
All three cases pass.

Pass or Fail: XXXX        Initials: XXX                     Date: XXX

4.2. Change cell E10 to “0.02”. (Req. 3a)

<Insert screen shot here>

Acceptance Criteria: All three cases fail.
Pass or Fail: XXXX        Initials: XXX                     Date: XXX

5. Independence of tab

5.1. Copy the 1 Average – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

<Insert screen shot here>

Acceptance Criteria: The sample size is 20.
The average rounds to 1.9992.
The standard deviation rounds to 0.0885.
The two-sided equivalence limits for the average round to 1.964984 and 2.033416.
The upper confidence limit for the average rounds to 2.033416.
The lower confidence limit for the average rounds to 1.964984.
Confidence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: XXXX        Initials: XXX                     Date: XXX

6. Comments

6.1. None

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass? yes no

7.2. Save File and show name and date.

Name of File:

Data of File:

Signature: ________________________________ Date: XXX

7
Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is met with justification the test cases cover the requirement.

Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet 3.2</td>
</tr>
<tr>
<td></td>
<td>b. The target can be entered into the highlighted cell of the spreadsheet 3.2</td>
</tr>
<tr>
<td></td>
<td>c. The difference can be entered into the highlighted cell of the spreadsheet 3.2</td>
</tr>
<tr>
<td></td>
<td>d. The name of the variable can be entered into the highlighted cell of the spreadsheet. 3.6</td>
</tr>
<tr>
<td></td>
<td>e. The data can be entered into the highlighted cells of the spreadsheet. 3.8</td>
</tr>
<tr>
<td></td>
<td>f. Only the highlighted yellow cells can be changed. 3.1</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is $\geq 50%$ and $&lt;100%$, no equivalence intervals or conclusions are shown. An error message is displayed. 3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. Unless the target is a valid number and the difference is a valid number $&gt; 0$, no conclusions are shown. An error message is displayed. 3.4, 3.6</td>
</tr>
<tr>
<td></td>
<td>c. Only valid numbers in the data fields are used. 3.6, 3.7, 3.8</td>
</tr>
<tr>
<td></td>
<td>d. If no valid data is entered, the sample size is zero and no results are shown. An error message is displayed. 3.6</td>
</tr>
<tr>
<td></td>
<td>e. If there is a single valid data point, the sample size is one and only the average is shown. An error message is displayed. 3.7</td>
</tr>
<tr>
<td></td>
<td>f. If there are two or more valid data points but the standard deviation is zero, the sample size, average and standard deviation are shown but no equivalence intervals and conclusions are shown. An error message is displayed. 3.8</td>
</tr>
<tr>
<td></td>
<td>Results for valid input:</td>
</tr>
<tr>
<td>---</td>
<td>------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>a. For valid input with at least two data points and non-zero standard deviation, the sample size, average, standard deviation, confidence intervals and conclusions are displayed.</td>
</tr>
<tr>
<td></td>
<td>4.1, 4.2</td>
</tr>
<tr>
<td></td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
<tr>
<td></td>
<td>5.1</td>
</tr>
</tbody>
</table>
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as shown in Appendix B of STAT-14.

The average and standard deviation come from Appendix A:

![Descriptive Statistics](image1)

For the two-sided case:

![Equivalence Test](image2)

The two-sided equivalence limits for the average are $2 - 0.035016 = 1.964984$ and $2 + 0.033416 = 2.033416$. 
For the lower case:

The lower equivalence limit for the average rounds to $2 - 0.035016 = 1.964984$.

For the upper case:

The upper equivalence limit for the average rounds to $2 + 0.033416 = 2.033416$. 
Appendix B

File: STAT-12 to 16 - Tab 5 Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   About

   Windows 10

   Alienware 17 R3
   PC name Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

   Edition  Windows 10 Home
   Version  1703
   OS Build 15063.674
   Product ID 00325-95916-23031-AAOEM
   Processor Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz
   Installed RAM 16.0 GB (15.9 GB usable)
   System type 64-bit operating system, x64-based processor
   Pen and touch No pen or touch input is available for this display

   1.3. Capture a screen shot showing the version of Excel used

   About Microsoft® Excel® 2016
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass      Initials: WT      Date: 11/22/17
3. Check for Valid Parameters

3.1. Go to the 1 Average - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1f).

<table>
<thead>
<tr>
<th>Date</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass

Initials: WT

Date: 11/22/17
3.2. Change cell E6 to “49.99”, cell B13 to 10, B14 to 11, cell E8 to 10 and cell E10 to 1 (Req. 1a-c, 2a).

Acceptance Criteria: The sample size is 2
The average is 10.5
The standard deviation rounds to 0.7071.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/22/17
3.3. Change cell E6 to “100” (Req. 2a).

Acceptance Criteria: The sample size is 2  
The average is 10.5  
The standard deviation rounds to 0.7071.  
No confidence limits or statements are displayed.  
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/22/17
3.4. Change cell E6 to “95” and cell E8 to “10..0” (Req. 2b).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-14, Verification/Validation Sampling Plans for Average**

**Appendix B: Equivalence Test for the Average**

<table>
<thead>
<tr>
<th>Confidence Level:</th>
<th>97%</th>
<th>50 &lt; Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target:</td>
<td>10.0</td>
<td></td>
</tr>
<tr>
<td>Difference for Determining If Equivalent:</td>
<td>0</td>
<td>Δ_{dcl} &gt; 0</td>
</tr>
</tbody>
</table>

### Data

<table>
<thead>
<tr>
<th>Data</th>
<th>Sample Size</th>
<th>Average</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>2</td>
<td>10.5</td>
<td>0.707106781</td>
</tr>
<tr>
<td>11</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**2-Sided Case - 95% Equivalence Interval**

- **Lower Limit**: 7.343124243
- **Upper Limit**: 13.6568756

The 95% confidence equivalence interval is from 7.3431242426248 to 13.6568757573375.

**Lower 1-Sided Case - 95% Lower Equivalence Bound**

- **Lower Limit**: 7.343124243

The 95% confidence lower equivalence bound is 7.3431242426248.

**Upper 1-Sided Case - 95% Upper Equivalence Bound**

- **Upper Limit**: 13.65687576

The 95% confidence upper equivalence bound is 13.6568757573375.

**Acceptance Criteria:**
The sample size, average, standard deviation and equivalence limits are shown.
No conclusions are shown.
An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/22/17
3.5. Change cell E8 to “10.0” and cell E10 to “0” (Req. 2b).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-14, Verification/Validation Sampling Plans for Average**

**Appendix B: Equivalence Test for the Average**

<table>
<thead>
<tr>
<th>Confidence Level:</th>
<th>% 50 &lt; Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target:</td>
<td>1.0</td>
</tr>
<tr>
<td>Difference for Determining If Equivalent:</td>
<td>Δ&lt;sub&gt;eq&lt;/sub&gt; &gt; 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>11</td>
<td>2</td>
</tr>
</tbody>
</table>

Sample Size: 2
Average: 10.6
Standard Deviation: 0.707106781

### 2-Sided Case - 95% Equivalence Interval

- **Lower Limit**: 7.343124243
- **Upper Limit**: 13.65687576

The 95% confidence equivalence interval is from 7.3431242426248 to 13.65687573375.

### Lower 1-Sided Case - 95% Lower Equivalence Bound

- **Lower Limit**: 7.343124243

The 95% confidence lower equivalence bound is 7.3431242426248.

### Upper 1-Sided Case - 95% Upper Equivalence Bound

- **Upper Limit**: 13.65687576

The 95% confidence upper equivalence bound is 13.65687573375.

**Acceptance Criteria:**
- The sample size, average, standard deviation and equivalence limits are shown.
- No conclusions are shown.
- An error message is shown.

**Pass or Fail:** Pass
**Initials:** WT
**Date:** 11/22/17
3.6. Change cell E10 to “1”, cell B13 to “A”, cell B14 to “10..0” and cell B12 to “Control 2” (Req. 1d, 2c, 2d).

**Acceptance Criteria:**
- The sample size is 0.
- No estimates, equivalence limits or statements are displayed.
- The name of the variable is displayed above the results.
- An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/22/17
3.7. Change cell B15 to “10” (Req. 2c, 2e).

Acceptance Criteria: The sample size is 1.
The average is 10
No standard deviation, equivalence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass   Initials: WT   Date: 11/22/17
3.8. Copy cell B15 into cells B16 to B212 (Req. 1e, 2c, 2f).

**Acceptance Criteria:**
- The sample size is 198.
- The average is 10.
- The standard deviation is 0.
- No equivalence limits or statements are displayed.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/22/17
4. Results for valid input

4.1. Delete cells B13 to B212. Copy cells D10:D30 from the example data set tab to cell B12. Set cell E8 to “2” and cell E10 to “0.1”. (Req. 3a).

<table>
<thead>
<tr>
<th>Control</th>
<th>Sample Size</th>
<th>Average</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control 2</td>
<td>20</td>
<td>1.9992</td>
<td>0.0885</td>
</tr>
</tbody>
</table>

Two-Sided Case - 95% Equivalence Interval

<table>
<thead>
<tr>
<th>Control 2</th>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.964984</td>
<td>2.03341677</td>
<td></td>
</tr>
</tbody>
</table>

The 95% confidence interval is from 1.96498323 to 2.03341617680252. Equivalence demonstrated. Equivalence interval within 1.9 and 2.1.

Acceptance Criteria:
- The sample size is 20.
- The average rounds to 1.9992.
- The standard deviation rounds to 0.0885.
- The two-sided equivalence limits for the average round to 1.964984 and 2.033416.
- The upper confidence limit for the average rounds to 2.033416.
- The lower confidence limit for the average rounds to 1.964984.
- Confidence statements for the three cases are shown with the same values. All three cases pass.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
4.2. Change cell E10 to “0.02”. (Req. 3a)

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-14, Verification/Validation Sampling Plans for Average**

**Appendix B: Equivalence Test for the Average**

<table>
<thead>
<tr>
<th>Confidence Level:</th>
<th>95%</th>
<th>50 &lt; Corf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target:</td>
<td>2</td>
<td>Δ&lt;sub&gt;Equ&lt;/sub&gt; &gt; 0</td>
</tr>
<tr>
<td>Difference for Determining if Equivalent:</td>
<td>0.02</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Control 2</th>
<th>Control 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size</td>
<td>20</td>
</tr>
<tr>
<td>Average</td>
<td>1.9992</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.00494876</td>
</tr>
</tbody>
</table>

2-Sided Case - 95% Equivalence Interval

| 1.9650 | 1.9693 |
| 1.9726 | 1.9779 |

- Lower Limit: 1.964963823
- Upper Limit: 2.033416177

The 95% confidence equivalence interval is from 1.964963823 to 2.033416177.

Equivalence not demonstrated. Equivalence interval goes outside 1.98 and 2.02.

Lower 1-Sided Case - 95% Lower Equivalence Bound

| 1.9952 | 2.1848 |
| 2.0108 | 2.0168 |

- Lower Limit: 1.964963823
- Upper Limit: 2.033416177

The 95% confidence lower equivalence bound is 1.964963823.

Equivalence not demonstrated. Lower equivalence bound is below 1.98.

Upper 1-Sided Case - 95% Upper Equivalence Bound

| 1.9857 | 2.1848 |
| 2.0108 | 2.0168 |

- Lower Limit: 1.964963823
- Upper Limit: 2.033416177

The 95% confidence upper equivalence bound is 2.033416177.

Equivalence not demonstrated. Upper equivalence bound is above 2.02.

Acceptance Criteria: All three cases fail.

Pass or Fail: Pass

Initials: WT

Date: 11/22/17
5. Independence of tab

5.1. Copy the 1 Average – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.
The average rounds to 1.9992.
The standard deviation rounds to 0.0885.
The two-sided equivalence limits for the average round to 1.964984 and 2.033416.
The upper confidence limit for the average rounds to 2.033416.
The lower confidence limit for the average rounds to 1.964984.
Confidence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass
Initials: WT
Date: 11/22/17
6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? X yes no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 5 Windows 10.doc
       Data of File: November 22, 2017
       Signature: ________________________________ Date: 11/22/17
Appendix C

File: STAT-12 to 16 - Tab 5  Windows 7
Appendix A: Test Script

1. Document System Used

1.1. Capture a screen shot showing the computer make and model

![Gateway Computer](image-url)
1.2. Capture a screen shot showing the operating system including version number

![Windows 7 Professional](image)

- Rating: 5.5 - Your Windows Experience Index needs to be refreshed
- Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHz
- Installed memory (RAM): 4.00 GB
- System type: 64-bit Operating System
- Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

![Microsoft Office Excel](image)

- Microsoft Office Excel 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
- Port of Microsoft Office Professional 2007
- © 2006 Microsoft Corporation. All rights reserved.


This product is licensed to:

Wayne Taylor
Taylor Enterprises, Inc.
Product ID: 81605-903-7132834-65427

View the Microsoft Software License Terms

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass

Initials: WT

Date: 11/13/17
3. Check for Valid Parameters

3.1. Go to the 1 Average - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1f).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass Initials: WT Date: 11/13/17
3.2. Change cell E6 to “49.99”, cell B13 to 10, B14 to 11, cell E8 to 10 and cell E10 to 1 (Req. 1a-c, 2a).

Acceptance Criteria: The sample size is 2
The average is 10.5
The standard deviation rounds to 0.7071.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
3.3. Change cell E6 to “100” (Req. 2a).

Acceptance Criteria: The sample size is 2
The average is 10.5
The standard deviation rounds to 0.7071.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
3.4. Change cell E6 to “95” and cell E8 to “10..0” (Req. 2b).

Acceptance Criteria: The sample size, average, standard deviation and equivalence limits are shown. No conclusions are shown. An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
3.5. Change cell E8 to “10.0” and cell E10 to “0” (Req. 2b).

Acceptance Criteria: The sample size, average, standard deviation and equivalence limits are shown. No conclusions are shown. An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
3.6. Change cell E10 to “1”, cell B13 to “A”, cell B14 to “10..0” and cell B12 to “Control 2” (Req. 1d, 2c, 2d).

### Acceptance Criteria:
- The sample size is 0.
- No estimates, equivalence limits or statements are displayed.
- The name of the variable is displayed above the results.
- An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/13/17
3.7. Change cell B15 to “10” (Req. 2c, 2e).

Acceptance Criteria:
The sample size is 1.
The average is 10
No standard deviation, equivalence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
3.8. Copy cell B15 into cells B16 to B212 (Req. 1e, 2c, 2f).

**Acceptance Criteria:**
- The sample size is 198.
- The average is 10
- The standard deviation is 0.
- No equivalence limits or statements are displayed.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/13/17
4. Results for valid input

4.1. Delete cells B13 to B212. Copy cells D10:D30 from the example data set tab to cell B12. Set cell E8 to “2” and cell E10 to “0.1”. (Req. 3a).

Acceptance Criteria: The sample size is 20.
The average rounds to 1.9992.
The standard deviation rounds to 0.0885.
The two-sided equivalence limits for the average round to 1.964984 and 2.033416.
The upper confidence limit for the average rounds to 2.033416.
The lower confidence limit for the average rounds to 1.964984.
Confidence statements for the three cases are shown with the same values.
All three cases pass.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
4.2. Change cell E10 to “0.02”. (Req. 3a)

Acceptance Criteria: All three cases fail.

Pass or Fail: Pass        Initials: WT        Date: 11/13/17
5. Independence of tab

5.1. Copy the 1 Average – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria:

The sample size is 20.
The average rounds to 1.9992.
The standard deviation rounds to 0.0885.
The two-sided equivalence limits for the average round to 1.964984 and 2.033416.
The upper confidence limit for the average rounds to 2.033416.
The lower confidence limit for the average rounds to 1.964984.
Confidence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass
Initials: WT
Date: 2017-11-13
6. Comments

6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass?   X   yes   no

7.2. Save File and show name and date.

Name of File: STAT-12 to 16 - Tab 5 Windows 7.doc
Data of File: November 13, 2017

Signature: ________________________________ Date: 11/13/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Std. Dev. – CI Tab

Protocol Number: TE-17-7

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 22, 2017
Date

November 22, 2017
Date
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Std. Dev. – CI Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Std. Dev. – CI tab, this spreadsheet performs confidence intervals for the standard deviation. It is described in Appendix I of *STAT-15, Verification/Validation Sampling Plans for Standard Deviation and RSD*. Appendix I also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-7, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 1 Std. Dev. – CI Tab was written to validate the 1 Std. Dev. – CI Tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 6 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 6 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Std. Dev. – CI Tab

Protocol Number: TE-17-7
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Std. Dev. – CI Tab

Protocol Number: TE-17-7

Approvals:

Dr. Wayne A. Taylor
Study Director

November 11, 2017
Date

Ann B. Taylor
President

November 11, 2017
Date
Validation Protocol for Excel Spreadsheet:  
STAT-12 to 16 - Confidence Intervals and Equivalence Tests  
1 Std. Dev. – CI Tab

Protocol Number: TE-17-7

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Std. Dev. – CI tab, this spreadsheet performs confidence intervals for the standard deviation. It is described in Appendix I of *STAT-15, Verification/Validation Sampling Plans for Standard Deviation and RSD*. Appendix I also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. The name of the variable can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>c. The data can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Only valid numbers in the data fields are used.</td>
</tr>
<tr>
<td></td>
<td>c. If no valid data is entered, the sample size is zero and no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>d. If there is a single valid data point, the sample size is one but the standard deviation and confidence intervals are not shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>e. If there are two or more valid data points but the standard deviation is zero, the sample size and standard deviation are shown but no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input with at least two data points and non-zero standard deviation, the sample size, standard deviation and confidence intervals are displayed.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-15 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
   <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
   <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
   <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download
       the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
   <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the
       version and date.
   <Insert screen shot here>
   Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
   Pass or Fail: XXXX       Initials: XXX       Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 1 Std. Dev. - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).
   <Insert screen shot here>
   Acceptance Criteria: Each time a message should be displayed that the cell is protected.
   Pass or Fail: XXXX       Initials: XX        Date: XXX
   3.2. Change cell D6 to “49.99”, cell B9 to 1 and B10 to 2 (Req. 1a, 2a).
   <Insert screen shot here>
   Acceptance Criteria: The sample size is 2
   The standard deviation rounds to 0.7071.
   No confidence limits or statements are displayed.
   An error message is shown.
   Pass or Fail: XXXX       Initials: XX        Date: XXX
   3.3. Change cell D6 to “100” (Req. 1a, 2a).
   <Insert screen shot here>
   Acceptance Criteria: The sample size is 2
   The standard deviation rounds to 0.7071.
   No confidence limits or statements are displayed.
   An error message is shown.
   Pass or Fail: XXXX       Initials: XX        Date: XXX
3.4. Change cell D6 to “95”, cell B9 to “A”, cell B10 to “1..1” and cell B8 to “Diameter” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample size is 0.  
No estimates, confidence limits or statements are displayed.  
The name of the variable is displayed above the results.  
An error message is shown.

Pass or Fail: XXXX  Initials: XX  Date: XXX

3.5. Change cell B11 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.  
No standard deviation, confidence limits or statements are displayed.  
An error message is shown.

Pass or Fail: XXXX  Initials: XX  Date: XXX

3.6. Copy cell B11 into cells B12 to B208 (Req. 1c, 2e).

Acceptance Criteria: The sample size is 198.  
The standard deviation is 0.  
No confidence limits or statements are displayed.  
An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

4. Results for valid input

4.1. Delete cells B9 to B208. Copy cells D29:D58 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample size is 20.  
The standard deviation rounds to 0.00095.  
The two-sided confidence limits for the standard deviation rounds to 0.00072 and 0.00139.  
The upper confidence limit for the standard deviation rounds to 0.00130.  
The lower confidence limit for the standard deviation rounds to 0.00075.  
Confidence statements for the three cases are shown with the same values.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

5. Independence of tab

5.1. Copy the 1 Std. Dev. – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.  
The standard deviation rounds to 0.00095.  
The two-sided confidence limits for the standard deviation rounds to 0.00072 and 0.00139.  
The upper confidence limit for the standard deviation rounds to 0.00130.  
The lower confidence limit for the standard deviation rounds to 0.00075.  
Confidence statements for the three cases are shown with the same values.
6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? yes no
   7.2. Save File and show name and date.
       Name of File:
       Data of File:
       Signature: ________________________________ Date: XXX
Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

**Table 2: Test Cases Matching User Requirements**

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. The name of the variable can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>c. The data can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>3.4, 3.5, 3.6 – all data cells used</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td></td>
<td>3.1</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3 – covers both sides</td>
</tr>
<tr>
<td></td>
<td>b. Only valid numbers in the data fields are used.</td>
</tr>
<tr>
<td></td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>c. If no valid data is entered, the sample size is zero and no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>d. If there is a single valid data point, the sample size is one but the standard deviation and confidence intervals are not shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.5</td>
</tr>
<tr>
<td></td>
<td>e. If there are two or more valid data points but the standard deviation is zero, the sample size and standard deviation are shown but no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.6</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input with at least two data points and non-zero standard deviation, the sample size, standard deviation and confidence intervals are displayed.</td>
</tr>
<tr>
<td></td>
<td>4.1</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
<tr>
<td></td>
<td>5.1</td>
</tr>
</tbody>
</table>
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as described in Appendix I of STAT-15. Note that there are typographical errors on page 471. The output shown on page is for 95% confidence and does not match the text describing the result for 90% confidence. The text description is correct.
Appendix B

File: STAT-12 to 16 - Tab 6  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   ![Windows 10 About](image)

   **Alienware 17 R3**
   - PC name: Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

<table>
<thead>
<tr>
<th>Edition</th>
<th>Windows 10 Home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>1703</td>
</tr>
<tr>
<td>OS Build</td>
<td>15063.674</td>
</tr>
<tr>
<td>Product ID</td>
<td>00325-95916-23031-AAOEM</td>
</tr>
<tr>
<td>Processor</td>
<td>Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz</td>
</tr>
<tr>
<td>Installed RAM</td>
<td>16.0 GB (15.9 GB usable)</td>
</tr>
<tr>
<td>System type</td>
<td>64-bit operating system, x64-based processor</td>
</tr>
<tr>
<td>Pen and touch</td>
<td>No pen or touch input is available for this display</td>
</tr>
</tbody>
</table>

   1.3. Capture a screen shot showing the version of Excel used

   ![Microsoft Excel 2016](image)
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass
Initials: WT
Date: 11/22/17
3. Check for Valid Parameters

3.1. Go to the 1 Std. Dev. - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
3.2. Change cell D6 to “49.99”, cell B9 to 1 and B10 to 2 (Req. 1a, 2a).

Acceptance Criteria: The sample size is 2
The standard deviation rounds to 0.7071.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17

3.3. Change cell D6 to “100” (Req. 1a, 2a).

Acceptance Criteria: The sample size is 2
The standard deviation rounds to 0.7071.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
3.4. Change cell D6 to “95”, cell B9 to “A”, cell B10 to “1.1” and cell B8 to “Diameter” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample size is 0.
No estimates, confidence limits or statements are displayed.
The name of the variable is displayed above the results.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17

3.5. Change cell B11 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.
No standard deviation, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
3.6. Copy cell B11 into cells B12 to B208 (Req. 1c, 2e).

Acceptance Criteria: The sample size is 198.
The standard deviation is 0.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass   Initials: WT   Date: 11/22/17
4. Results for valid input

4.1. Delete cells B9 to B208. Copy cells D29:D58 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample size is 20.
The standard deviation rounds to 0.00095.
The two-sided confidence limits for the standard deviation rounds to 0.00072 and 0.00139.
The upper confidence limit for the standard deviation rounds to 0.00130.
The lower confidence limit for the standard deviation rounds to 0.00075.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
5. Independence of tab

5.1. Copy the 1 Std. Dev. – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.
The standard deviation rounds to 0.00095.
The two-sided confidence limits for the standard deviation rounds to 0.00072 and 0.00139.
The upper confidence limit for the standard deviation rounds to 0.00130.
The lower confidence limit for the standard deviation rounds to 0.00075.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass
Initials: WT
Date: 11/22/17
6. Comments

6.1. 4.1 states to copy from D29:D58 is typo and should be D39:D58

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass? X yes no

7.2. Save File and show name and date.

Name of File: STAT-12 to 16 - Tab 6 Windows 10.doc
Data of File: November 22, 2017

Signature: ________________________________ Date: 11/22/17
Appendix C

File: STAT-12 to 16 - Tab 6  Windows 7
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
1.2. Capture a screen shot showing the operating system including version number

![Windows 7 Professional]

Windows 7 Professional
Copyright © 2009 Microsoft Corporation. All rights reserved.
Service Pack 1
Get more features with a new edition of Windows 7

1.3. Capture a screen shot showing the version of Excel used

![Microsoft Office Excel]

Microsoft Office Excel 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)

Port of Microsoft Office Professional 2007
© 2006 Microsoft Corporation. All rights reserved.


This product is licensed to:
Wayne Taylor
Taylor Enterprises, Inc.
Product ID: 81605-903-7132834-65427

View the Microsoft Software License Terms

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass

Initials: WT

Date: 11/13/17
3. Check for Valid Parameters
   
   3.1. Go to the 1 Std. Dev. - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

   ![Image of Excel spreadsheet showing statistical procedures]

   Acceptance Criteria: Each time a message should be displayed that the cell is protected.
   
   Pass or Fail: Pass   Initials: WT   Date: 11/13/17
3.2. Change cell D6 to “49.99”, cell B9 to 1 and B10 to 2 (Req. 1a, 2a).

<table>
<thead>
<tr>
<th>Confidence Level:</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>49.99 %</td>
</tr>
<tr>
<td></td>
<td>50 ± Conf &lt; 100</td>
</tr>
</tbody>
</table>

Acceptance Criteria:  
The sample size is 2  
The standard deviation rounds to 0.7071.  
No confidence limits or statements are displayed.  
An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/13/17

3.3. Change cell D6 to “100” (Req. 1a, 2a).

<table>
<thead>
<tr>
<th>Confidence Level:</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100 %</td>
</tr>
<tr>
<td></td>
<td>50 ± Conf &lt; 100</td>
</tr>
</tbody>
</table>

Acceptance Criteria:  
The sample size is 2  
The standard deviation rounds to 0.7071.  
No confidence limits or statements are displayed.  
An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/13/17
3.4. Change cell D6 to “95”, cell B9 to “A”, cell B10 to “1..1” and cell B8 to “Diameter” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample size is 0.
No estimates, confidence limits or statements are displayed.
The name of the variable is displayed above the results.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/13/17

3.5. Change cell B11 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.
No standard deviation, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/13/17
3.6. Copy cell B11 into cells B12 to B208 (Req. 1c, 2e).

Acceptance Criteria: The sample size is 198.
The standard deviation is 0.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
4. Results for valid input

4.1. Delete cells B9 to B208. Copy cells D29:D58 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample size is 20.
The standard deviation rounds to 0.00095.
The two-sided confidence limits for the standard deviation rounds to 0.00072 and 0.00139.
The upper confidence limit for the standard deviation rounds to 0.00130.
The lower confidence limit for the standard deviation rounds to 0.00075.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
5. Independence of tab

5.1. Copy the 1 Std. Dev. – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.
- The standard deviation rounds to 0.00095.
- The two-sided confidence limits for the standard deviation rounds to 0.00072 and 0.00139.
- The upper confidence limit for the standard deviation rounds to 0.00130.
- The lower confidence limit for the standard deviation rounds to 0.00075.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.
   6.2. 4.1 states to copy from D29:D58 is typo and should be D39:D58

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass?       X  yes   no
   7.2. Save File and show name and date.
       Name of File:  STAT-12 to 16 - Tab 6 Windows 7.doc
       Date of File:  November 13, 2017
       Signature: ________________________________ Date: 11/13/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 RSD Normal. – CI Tab

Protocol Number: TE-17-8

Approvals:

___________________________________         November 22, 2017
Dr. Wayne A. Taylor
Study Director

___________________________________         November 22, 2017
Ann B. Taylor
President

___________________________________         November 22, 2017
Date

___________________________________         November 22, 2017
Date
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 RSD Normal. – CI Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 RSD Normal. – CI tab, this spreadsheet performs confidence intervals for the relative standard deviation. It is described in Appendix J of *STAT-15, Verification/Validation Sampling Plans for Standard Deviation and RSD*. Appendix J also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol
Protocol Number: TE-17-8, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 1 RSD Normal. – CI Tab was written to validate 1 RSD Normal. – CI Tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing
The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 7  Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 7 Windows 7. It is included as Appendix C.

4.0 Test Results
All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 RSD Normal. – CI Tab

Protocol Number: TE-17-8
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals
and Equivalence Tests

1 RSD Normal. – CI Tab

Protocol Number: TE-17-8

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 11, 2017
Date

November 11, 2017
Date
Validation Protocol for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
1 RSD Normal. – CI Tab

Protocol Number: TE-17-8

1.0 Introduction

The book Statistical Procedures for the Medical Device Industry by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 RSD Normal. – CI tab, this spreadsheet performs confidence intervals for the relative standard deviation. It is described in Appendix J of STAT-15, Verification/Validation Sampling Plans for Standard Deviation and RSD. Appendix J also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
## 2.0 Requirements

Table 1 lists the user requirements to be validated.

**Table 1: User Requirements for the 1 RSD Normal, – CI tab of STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls**

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. The name of the variable can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>c. The data can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is $\geq 50%$ and $&lt;100%$, no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Only valid numbers in the data fields are used.</td>
</tr>
<tr>
<td></td>
<td>c. If no valid data is entered, the sample size is zero and no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>d. If there is a single valid data point, the sample size is one, the average is shown but the standard deviation, RSD and confidence intervals are not shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>e. If there are two or more valid data points but the average is zero or negative, the sample size, average and standard deviation are shown but not the RSD and confidence intervals. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>f. If there are two or more valid data points but the standard deviation is zero, the sample size, average, standard deviation and RSD are shown but no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input with at least two data points and non-zero standard deviation, the sample size, average, standard deviation, RSD and confidence intervals are displayed.</td>
</tr>
<tr>
<td></td>
<td>b. If the RSD $&gt; 33%$, a warning is displayed.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-15 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX Initials: XXX Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 1 RSD Normal - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).
       <Insert screen shot here>
       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX Initials: XX Date: XXX
   3.2. Change cell D7 to “49.99”, cell B10 to 1 and B11 to 2 (Req. 1a, 2a, 3b).
       <Insert screen shot here>
       Acceptance Criteria: The sample size is 2
       The average is 1.5.
       The standard deviation rounds to 0.7071.
       The RSD rounds to 47.14.
       No confidence limits or statements are displayed.
       An error message is shown.
       A warning is shown RSD > 33%
       Pass or Fail: XXXX Initials: XX Date: XXX
   3.3. Change cell D7 to “100” (Req. 1a, 2a, 3b).
       <Insert screen shot here>
       Acceptance Criteria: The sample size is 2
       The average is 1.5.
       The standard deviation rounds to 0.7071.
The RSD rounds to 47.14
No confidence limits or statements are displayed.
An error message is shown.
A warning is shown RSD > 33%

Pass or Fail: XXXX    Initials: XX    Date: XXX

3.4. Change cell D7 to “95”, cell B10 to “A”, cell B11 to “1..1” and cell B9 to “Diameter” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample size is 0.
No estimates, confidence limits or statements are displayed.
The name of the variable is displayed above the results.
An error message is shown.

Pass or Fail: XXXX    Initials: XX    Date: XXX

3.5. Change cell B12 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.
The average is 1.
No standard deviation, RSD, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: XXXX    Initials: XX    Date: XXX

3.6. Enter -11 into cell B13 (Req. 1c, 2e).

Acceptance Criteria: The sample size is 2.
The average is -5.
The standard deviation rounds to 8.485.
The RSD is not displayed.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: XXXX    Initials: XXX    Date: XXX

3.7. Copy cell B12 into cells B13 to B209 (Req. 1c, 2f).

Acceptance Criteria: The sample size is 198.
The average is 1.
The standard deviation and RSD are 0.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: XXXX    Initials: XXX    Date: XXX

4. Results for valid input

4.1. Delete cells B10 to B209. Copy cells D29:D58 from the example data set tab to cell B10. (Req. 3a).

Acceptance Criteria: The sample size is 20.
The average is 0.12517.
The standard deviation rounds to 0.000950402.
The RSD rounds to 0.7593%.
The two-sided confidence limits for the RSD rounds to 0.5774% and 1.109%.
The upper confidence limit for the RSD rounds to 1.041.
The lower confidence limit for the RSD rounds to 0.603.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: XXXX  Initials: XXX  Date:  XXX

5. Independence of tab

5.1. Copy the 1 RSD Normal - CI tab. Delete all tabs but the copy. (Req. 4a)

<Insert screen shot here>

Acceptance Criteria:  The sample size is 20.
The average is 0.12517.
The standard deviation rounds to 0.000950402.
The RSD rounds to 0.7593%.
The two-sided confidence limits for the RSD rounds to 0.5774% and 1.109%.
The upper confidence limit for the RSD rounds to 1.041.
The lower confidence limit for the RSD rounds to 0.603.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: XXXX  Initials: XX  Date:  XXX

6. Comments

6.1. None

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass?  yes  no

7.2. Save File and show name and date.

Name of File:

Data of File:

Signature:  ________________________________  Date:  XXX
# Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

## Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | **Input of Data:**  
|    | a. The confidence level can be entered into the highlighted cell of the spreadsheet  
|    |   3.2, 3.3  
|    | b. The name of the variable can be entered into the highlighted cell of the spreadsheet.  
|    |   3.4  
|    | c. The data can be entered into the highlighted cells of the spreadsheet.  
|    |   3.4, 3.5, 3.6, 3.7 – all data cells used  
|    | d. Only the highlighted yellow cells can be changed.  
|    |   3.1  |
| 2  | **Data Checking:**  
|    | a. Unless the confidence level is ≥50% and <100%, no confidence intervals are shown. An error message is displayed.  
|    |   3.2, 3.3 – covers both sides  
|    | b. Only valid numbers in the data fields are used.  
|    |   3.4  
|    | c. If no valid data is entered, the sample size is zero and no results are shown. An error message is displayed.  
|    |   3.4  
|    | d. If there is a single valid data point, the sample size is one, the average is shown but the standard deviation, RSD and confidence intervals are not shown. An error message is displayed.  
|    |   3.5  
|    | e. If there are two or more valid data points but the average is zero or negative, the sample size, average and standard deviation are shown but not the RSD and confidence intervals. An error message is displayed.  
|    |   3.6  
|    | f. If there are two or more valid data points but the standard deviation is zero, the sample size, average, standard deviation and RSD are shown but no confidence intervals are shown. An error message is displayed.  
<p>|    |   3.7  |</p>
<table>
<thead>
<tr>
<th></th>
<th>Results for valid input:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>a. For valid input with at least two data points and non-zero standard deviation, the sample size, average, standard deviation, RSD and confidence intervals are displayed.</td>
</tr>
<tr>
<td></td>
<td>4.1</td>
</tr>
<tr>
<td></td>
<td>b. If the RSD &gt; 33%, a warning is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
<tr>
<td></td>
<td>5.1</td>
</tr>
</tbody>
</table>
Appendix C: Verification of Results

4.2 2-sided case:

From http://www1.fpl.fs.fed.us/covnorm.dcd.html.

---

What is the desired confidence level for the interval?
(for example, 95 for 95% confidence)

95

What is the sample size, n?

20

What is the sample mean?

0.12517

What is the sample standard deviation?
(The sum of squares divisor in the standard deviation calculation should be n - 1 rather than n.)

0.000950402

---

Disclaimer

The estimated coefficient of variation is 0.7593E-02.
The lower confidence bound on the COV is 0.5774E-02.
The upper confidence bound on the COV is 0.1109E-01.
1-sided lower case:

From http://www1.fpl.fs.fed.us/covlow.html

THIS SOFTWARE IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND. THE AU
SOFTWARE OR DOCUMENTATION IN TERMS OF THEIR CORRECTNESS, RELIABILITY
PARTY INVOLVED WITH THE CREATION OR DISTRIBUTION OF THE SOFTWARE BE L

Sorry about that.

What is the desired confidence level?
(for example, 95 for 95% confidence)

95

What is the sample size, $n$?

20

What is the sample mean?

0.12517

What is the sample standard deviation?
(The sum of squares divisor in the standard deviation calculation should be $n - 1$ rather than $n$.)

0.00950401577173958

Execute the program

Disclaimer

The estimated coefficient of variation is $0.7593E-02$.

The lower confidence bound on the COV is $0.6027E-02$. 
1-sided upper case:

From http://www1.fpl.fs.fed.us/covup.html

Exact one-sided upper confidence bound for a no

THIS SOFTWARE IS PROVIDED ‘AS IS’ WITHOUT WARRANTY OF ANY KIND. THE AUTHOR
SOFTWARE OR DOCUMENTATION IN TERMS OF THEIR CORRECTNESS, RELIABILITY, CUR
PARTY INVOLVED WITH THE CREATION OR DISTRIBUTION OF THE SOFTWARE BE LIABL
Sorry about that.

What is the desired confidence level?
(for example, 95 for 95% confidence)

95

What is the sample size, n?

20

What is the sample mean?

0.12917

What is the sample standard deviation?
(The sum of squares divisor in the standard deviation calculation should be n - 1 rather than n.)

0.0096401577173668

Execute the program

Disclaimer

The estimated coefficient of variation is 0.7593E-02.
The upper confidence bound on the COV is 0.1041E-01.
Appendix B

File: STAT-12 to 16 - Tab 7 Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   About
   Windows 10

   Alienware 17 R3
   PC name: Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

   Edition: Windows 10 Home
   Version: 1703
   OS Build: 15063.674
   Product ID: 00325-95916-23031-AAOEM
   Processor: Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz
   Installed RAM: 16.0 GB (15.9 GB usable)
   System type: 64-bit operating system, x64-based processor
   Pen and touch: No pen or touch input is available for this display

   1.3. Capture a screen shot showing the version of Excel used
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass
Initials: WT
Date: 11/22/17
3. Check for Valid Parameters

3.1. Go to the 1 RSD Normal - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
3.2. Change cell D7 to “49.99”, cell B10 to 1 and B11 to 2 (Req. 1a, 2a, 3b).

Acceptance Criteria: The sample size is 2
The average is 1.5.
The standard deviation rounds to 0.7071.
The RSD rounds to 47.14
No confidence limits or statements are displayed.
An error message is shown.
A warning is shown RSD > 33%

Pass or Fail: Pass
Initials: WT
Date: 11/22/17
3.3. Change cell D7 to “100” (Req. 1a, 2a, 3b).

Acceptance Criteria: The sample size is 2
The average is 1.5.
The standard deviation rounds to 0.7071.
The RSD rounds to 47.14
No confidence limits or statements are displayed.
An error message is shown.
A warning is shown RSD > 33%

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
3.4. Change cell D7 to “95”, cell B10 to “A”, cell B11 to “1..1” and cell B9 to “Diameter” (Req. 1b, 1c, 2b, 2c).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY
STAT-15, Verification/Validation Sampling Plans for Standard Deviation and RSD
Appendix J: Upper Confidence Limit for Relative Standard Deviations
Normal estimator of RSD - Requires Estimated RSD ≤ 33%

<table>
<thead>
<tr>
<th>Confidence Level:</th>
<th>% 50 ± Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Diameter</td>
</tr>
<tr>
<td></td>
<td>Sample Size</td>
</tr>
<tr>
<td></td>
<td>Average</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
</tr>
<tr>
<td></td>
<td>RSD</td>
</tr>
<tr>
<td>Diameter</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
</tr>
<tr>
<td>1..1</td>
<td></td>
</tr>
</tbody>
</table>

There is not at least two valid data points.

### Acceptance Criteria:
- The sample size is 0.
- No estimates, confidence limits or statements are displayed.
- The name of the variable is displayed above the results.
- An error message is shown.

**Pass or Fail:** Pass  **Initials:** WT  **Date:** 11/22/17
3.5. Change cell B12 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.
The average is 1.
No standard deviation, RSD, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/22/17
3.6. Enter -11 into cell B13 (Req. 1c, 2e).

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Sample Size</th>
<th>Average</th>
<th>Standard Deviation</th>
<th>RSD</th>
</tr>
</thead>
<tbody>
<tr>
<td>z</td>
<td>2</td>
<td>-5</td>
<td>8.485261374</td>
<td>%</td>
</tr>
</tbody>
</table>

Acceptance Criteria:  
- The sample size is 2.  
- The average is -5.  
- The standard deviation rounds to 8.485.  
- The RSD is not displayed.  
- No confidence limits or statements are displayed.  
- An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/22/17
3.7. Copy cell B12 into cells B13 to B209 (Req. 1c, 2f).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-15, Verification/Validation Sampling Plans for Standard Deviation and RSD**

**Appendix I: Upper Confidence Limit for Relative Standard Deviations**

**Normal estimator of RSD - Requires Estimated RSD ≤ 33%**

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Sample Size</th>
<th>Average</th>
<th>Standard Deviation</th>
<th>RSD</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>198</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Acceptance Criteria: The sample size is 198.
The average is 1.
The standard deviation and RSD are 0.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
4. Results for valid input

4.1. Delete cells B10 to B209. Copy cells D29:D58 from the example data set tab to cell B10. (Req. 3a).

Acceptance Criteria: The sample size is 20.

The average is 0.12517.

The standard deviation rounds to 0.000950402.

The RSD rounds to 0.7593%.

The two-sided confidence limits for the RSD rounds to 0.5774% and 1.109%.

The upper confidence limit for the RSD rounds to 1.041.

The lower confidence limit for the RSD rounds to 0.603.

Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
5. Independence of tab

5.1. Copy the 1 RSD Normal - CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.
The average is 0.12517.
The standard deviation rounds to 0.000950402.
The RSD rounds to 0.7593%.
The two-sided confidence limits for the RSD rounds to 0.5774% and 1.109%.
The upper confidence limit for the RSD rounds to 1.041.
The lower confidence limit for the RSD rounds to 0.603.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
6. Comments
   6.1. 4.1 states to copy from D29:D58 is typo and should be D39:D58

7. Saving and Signing File
   7.1. Determine if all tests passed
   All Test Cases for Computer Pass? X yes no

   7.2. Save File and show name and date.
   Name of File: STAT-12 to 16 - Tab 7 Windows 10.doc
   Data of File: November 22, 2017

   Signature: ________________________________ Date: 11/22/17
Appendix C

File: STAT-12 to 16 - Tab 7  Windows 7
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

![Gateway Computer Image]
1.2. Capture a screen shot showing the operating system including version number

![Windows 7 Professional](image1)

- Rating: 5.5
- Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26 GHz 2.27 GHz
- Installed memory (RAM): 4.00 GB
- System type: 64-bit Operating System
- Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

![Microsoft Office Excel](image2)

- Version: Microsoft Office Excel 2007 (12.0.6776.5000)
- Publisher: Microsoft Office Professional 2007
- Copyright: © 2006 Microsoft Corporation. All rights reserved.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass    Initials: WT    Date: 11/13/17
3. Check for Valid Parameters
   3.1. Go to the 1 RSD Normal - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass   Initials: WT   Date: 11/13/17
3.2. Change cell D7 to “49.99”, cell B10 to 1 and B11 to 2 (Req. 1a, 2a, 3b).

Acceptance Criteria: The sample size is 2
The average is 1.5.
The standard deviation rounds to 0.7071.
The RSD rounds to 47.14
No confidence limits or statements are displayed.
An error message is shown.
A warning is shown RSD > 33%

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
3.3. Change cell D7 to “100” (Req. 1a, 2a, 3b).

Acceptance Criteria: The sample size is 2
The average is 1.5.
The standard deviation rounds to 0.7071.
The RSD rounds to 47.14
No confidence limits or statements are displayed.
An error message is shown.
A warning is shown RSD > 33%

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
3.4. Change cell D7 to “95”, cell B10 to “A”, cell B11 to “1..1” and cell B9 to “Diameter” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample size is 0.
No estimates, confidence limits or statements are displayed.
The name of the variable is displayed above the results.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
3.5. Change cell B12 to “1” (Req. 1c, 2d).

Acceptance Criteria:
- The sample size is 1.
- The average is 1.
- No standard deviation, RSD, confidence limits or statements are displayed.
- An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/13/17
3.6. Enter -11 into cell B13 (Req. 1c, 2e).

Acceptance Criteria:
- The sample size is 2.
- The average is -5.
- The standard deviation rounds to 8.485.
- The RSD is not displayed.
- No confidence limits or statements are displayed.
- An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/13/17
3.7. Copy cell B12 into cells B13 to B209 (Req. 1c, 2f).

Acceptance Criteria:
- The sample size is 198.
- The average is 1.
- The standard deviation and RSD are 0.
- No confidence limits or statements are displayed.
- An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
4. Results for valid input

4.1. Delete cells B10 to B209. Copy cells D29:D58 from the example data set tab to cell B10. (Req. 3a).

Acceptance Criteria: The sample size is 20.
- The average is 0.12517.
- The standard deviation rounds to 0.000950402.
- The RSD rounds to 0.7593%.
- The two-sided confidence limits for the RSD rounds to 0.5774% and 1.109%.
- The upper confidence limit for the RSD rounds to 1.041.
- The lower confidence limit for the RSD rounds to 0.603.

Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/13/17
5. Independence of tab

5.1. Copy the 1 RSD Normal - CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.
The average is 0.12517.
The standard deviation rounds to 0.000950402.
The RSD rounds to 0.7593%.
The two-sided confidence limits for the RSD rounds to 0.5774% and 1.109%.
The upper confidence limit for the RSD rounds to 1.041.
The lower confidence limit for the RSD rounds to 0.603.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass       Initials: WT       Date:   11/13/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.
   6.2. 4.1 states to copy from D29:D58 is typo and should be D39:D58

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? X yes no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 7 Windows 7.doc
       Data of File: November 13, 2017
       Signature: ________________________________ Date: 11/13/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 RSD Lognormal. – CI Tab

Protocol Number: TE-17-9

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 22, 2017
Date
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 RSD Lognormal. – CI Tab

1.0 Introduction

The book Statistical Procedures for the Medical Device Industry by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 RSD Lognormal. – CI tab, this spreadsheet performs confidence intervals for the relative standard deviation. It is described in Appendix J of STAT-15, Verification/Validation Sampling Plans for Standard Deviation and RSD. Appendix J also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-9, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 1 RSD Lognormal. – CI Tab was written to validate 1 RSD Lognormal. – CI Tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 8 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 8 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 RSD Lognormal – CI Tab

Protocol Number: TE-17-9
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 RSD Lognormal. – CI Tab

Protocol Number: TE-17-9

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 11, 2017
Date
1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 RSD Lognormal. – CI tab, this spreadsheet performs confidence intervals for the relative standard deviation. It is described in Appendix J of *STAT-15, Verification/Validation Sampling Plans for Standard Deviation and RSD*. Appendix J also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
### 2.0 Requirements

Table 1 lists the user requirements to be validated.

**Table 1: User Requirements for the 1 RSD Lognormal, – CI tab of STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls**

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | Input of Data:  
  a. The confidence level can be entered into the highlighted cell of the spreadsheet  
  b. The name of the variable can be entered into the highlighted cell of the spreadsheet.  
  c. The data can be entered into the highlighted cells of the spreadsheet.  
  d. Only the highlighted yellow cells can be changed. |
| 2  | Data Checking:  
  a. Unless the confidence level is ≥50% and <100%, no confidence intervals are shown. An error message is displayed.  
  b. Only valid numbers in the data fields are used.  
  c. If no valid data is entered, the sample size is zero and no results are shown. An error message is displayed.  
  d. If there is a single valid data point, the sample size is one, but the standard deviation of the logs, RSD and confidence intervals are not shown. An error message is displayed.  
  e. If any value is zero or negative, the sample size is shown, but standard deviation of the logs, RSD and confidence intervals are not shown. An error message is displayed.  
  f. If there are two or more valid data points but the standard deviation of the logs is zero, the sample size, standard deviation of the logs and RSD are shown but no confidence intervals are shown. An error message is displayed. |
| 3  | Results for valid input:  
  a. For valid input with at least two data points and non-zero standard deviation, the sample size, standard deviation of the logs, RSD and confidence intervals are displayed.  
  b. If the RSD < 10%, a warning is displayed. |
| 4  | Tabs:  
  a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same. |
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA.

All individuals performing the testing described below shall have a thorough knowledge of STAT-15 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
   Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
   Pass or Fail: XXXX  Initials: XXX  Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 1 RSD Lognormal - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).
       <Insert screen shot here>
   Acceptance Criteria: Each time a message should be displayed that the cell is protected.
   Pass or Fail: XXXX  Initials: XX  Date: XXX
   3.2. Change cell D7 to “49.99”, cell B10 to 1 and B11 to 1.1 (Req. 1a, 2a, 3b).
       <Insert screen shot here>
   Acceptance Criteria: The sample size is 2
   The standard deviation of the logs rounds to 0.0674.
   The RSD rounds to 6.747
   No confidence limits or statements are displayed.
   An error message is shown.
   A warning is shown RSD < 10%
   Pass or Fail: XXXX  Initials: XX  Date: XXX
   3.3. Change cell D7 to “100” (Req. 1a, 2a, 3b).
       <Insert screen shot here>
   Acceptance Criteria: The sample size is 2
   The standard deviation of the logs rounds to 0.0674.
   The RSD rounds to 6.747
   No confidence limits or statements are displayed.
An error message is shown.
A warning is shown RSD < 10%

Pass or Fail: XXXX   Initials: XX   Date: XXX

3.4. Change cell D7 to “95”, cell B10 to “A”, cell B11 to “1..1” and cell B9 to “Diameter” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample size is 0.
No estimates, confidence limits or statements are displayed.
The name of the variable is displayed above the results.
An error message is shown.

Pass or Fail: XXXX   Initials: XX   Date: XXX

3.5. Change cell B12 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.
No estimates, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: XXXX   Initials: XX   Date: XXX

3.6. Enter -11 into cell B13 (Req. 1c, 2e).

Acceptance Criteria: The sample size is 2.
The standard deviation of the logs is not displayed.
The RSD is not displayed.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: XXXX   Initials: XXX   Date: XXX

3.7. Copy cell B12 into cells B13 to B209 (Req. 1c, 2f).

Acceptance Criteria: The sample size is 198.
The standard deviation of the logs and RSD are 0.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: XXXX   Initials: XXX   Date: XXX

4. Results for valid input

4.1. Delete cells B10 to B209. Copy cells D29:D58 from the example data set tab to cell B10. (Req. 3a).

Acceptance Criteria: The sample size is 20.
The standard deviation of the logs rounds to 0.0076016.
The RSD rounds to 0.76017%.
The two-sided confidence limits for the RSD rounds to 0.6% and 1.1%.
The upper confidence limit for the RSD rounds to 1.0.
The lower confidence limit for the RSD rounds to 0.6.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: XXXX   Initials: XXX   Date: XXX
5. Independence of tab

5.1. Copy the 1 RSD Lognormal - CI tab. Delete all tabs but the copy. (Req. 4a)

<Insert screen shot here>

Acceptance Criteria: The sample size is 20.
The standard deviation of the logs rounds to 0.0076016.
The RSD rounds to 0.76017%.
The two-sided confidence limits for the RSD rounds to 0.6% and 1.1%.
The upper confidence limit for the RSD rounds to 1.0.
The lower confidence limit for the RSD rounds to 0.6.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: XXXX Initials: XX Date: XXX

6. Comments

6.1. None

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass? yes no

7.2. Save File and show name and date.

Name of File:

Data of File:

Signature: ________________________________ Date: XXX
Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is met with justification the test cases cover the requirement.

Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | Input of Data:  
    a. The confidence level can be entered into the highlighted cell of the spreadsheet 
       3.2, 3.3  
    b. The name of the variable can be entered into the highlighted cell of the spreadsheet. 
       3.4  
    c. The data can be entered into the highlighted cells of the spreadsheet. 
       3.4, 3.5, 3.6, 3.7 – all data cells used  
    d. Only the highlighted yellow cells can be changed.  
       3.1 |
| 2  | Data Checking:  
    a. Unless the confidence level is ≥50% and <100%, no confidence intervals are shown. An error message is displayed. 
       3.2, 3.3 – covers both sides  
    b. Only valid numbers in the data fields are used.  
       3.4  
    c. If no valid data is entered, the sample size is zero and no results are shown. An error message is displayed.  
       3.4  
    d. If there is a single valid data point, the sample size is one, the average is shown but the standard deviation, RSD and confidence intervals are not shown. An error message is displayed.  
       3.5  
    e. If there are two or more valid data points but the average is zero or negative, the sample size, average and standard deviation are shown but not the RSD and confidence intervals. An error message is displayed.  
       3.6  
    f. If there are two or more valid data points but the standard deviation is zero, the sample size, average, standard deviation and RSD are shown but no confidence intervals are shown. An error message is displayed.  
       3.7 |
<table>
<thead>
<tr>
<th></th>
<th>Results for valid input:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>a. For valid input with at least two data points and non-zero standard deviation, the sample size, average, standard deviation, RSD and confidence intervals are displayed.</td>
</tr>
<tr>
<td></td>
<td>4.1</td>
</tr>
<tr>
<td></td>
<td>b. If the RSD &gt; 33%, a warning is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
<tr>
<td></td>
<td>5.1</td>
</tr>
</tbody>
</table>
Appendix C: Verification of Results

4.2 2-sided case:

From http://www1.fpl.fs.fed.us/covln.html.

Confidence bounds for a lognormal distribution

THIS SOFTWARE IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, THE AUTHORITY, SOFTWARE OR DOCUMENTATION IN TERMS OF THEIR CORRECTNESS, RELIABILITY, CREDIBILITY, OR APPLICABILITY. NO PARTY INVOLVED WITH THE CREATION OR DISTRIBUTION OF THE SOFTWARE BE LIABLE

Sorry about that.

What is the desired confidence level for the interval? (for example, 95 for 95% confidence)

95

What is the sample size, n?

20

What is the sample standard deviation of the natural logs of the data values? (The sum of squares divisor in the standard deviation calculation should be n - 1 rather than n.)

0.007601625

Execute the program

Disclaimer

The lower confidence bound is 0.006.
The upper confidence bound is 0.011.
1-sided case:

From http://www1.fpl.fs.fed.us/covln.html.

THIS SOFTWARE IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND. THE AUTHOR OR DISTRIBUTOR DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF THE SOFTWARE IS WITH THE USER.

What is the desired confidence level for the interval? (for example, 95 for 95% confidence)

What is the sample size, n?

What is the sample standard deviation of the natural logs of the data values? (The sum of squares divisor in the standard deviation calculation should be n - 1 rather than n.)

[Enter value]

[Execute the program]

Disclaimer

The lower confidence bound is 0.006.
The upper confidence bound is 0.010.
Appendix B

File:  STAT-12 to 16 - Tab 8  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   ![Windows 10](image)

   **About Windows 10**

   **Alienware 17 R3**
   
   **PC name** Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

<table>
<thead>
<tr>
<th>Edition</th>
<th>Windows 10 Home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>1703</td>
</tr>
<tr>
<td>OS Build</td>
<td>15063.674</td>
</tr>
<tr>
<td>Product ID</td>
<td>00325-95916-23031-AAOEM</td>
</tr>
<tr>
<td>Processor</td>
<td>Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz</td>
</tr>
<tr>
<td>Installed RAM</td>
<td>16.0 GB (15.9 GB usable)</td>
</tr>
<tr>
<td>System type</td>
<td>64-bit operating system, x64-based processor</td>
</tr>
<tr>
<td>Pen and touch</td>
<td>No pen or touch input is available for this display</td>
</tr>
</tbody>
</table>

   1.3. Capture a screen shot showing the version of Excel used

   ![Excel](image)
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass

Initials: WT

Date: 11/22/17
3. Check for Valid Parameters

3.1. Go to the 1 RSD Lognormal - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
3.2. Change cell D7 to “49.99”, cell B10 to 1 and B11 to 1.1 (Req. 1a, 2a, 3b).

Acceptance Criteria: The sample size is 2
The standard deviation of the logs rounds to 0.0674.
The RSD rounds to 6.747
No confidence limits or statements are displayed.
An error message is shown.
A warning is shown RSD < 10%

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
3.3. Change cell D7 to “100” (Req. 1a, 2a, 3b).

Acceptance Criteria: The sample size is 2
- The standard deviation of the logs rounds to 0.0674.
- The RSD rounds to 6.747
- No confidence limits or statements are displayed.
- An error message is shown.
- A warning is shown RSD < 10%

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
3.4. Change cell D7 to “95”, cell B10 to “A”, cell B11 to “1..1” and cell B9 to “Diameter” (Req. 1b, 1c, 2b, 2c).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**Appendix J: Upper Confidence Limit for Relative Standard Deviations**

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Log(Values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td></td>
</tr>
</tbody>
</table>

Acceptance Criteria:
- The sample size is 0.
- No estimates, confidence limits or statements are displayed.
- The name of the variable is displayed above the results.
- An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/22/17
3.5. Change cell B12 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1. No estimates, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/22/17
3.6. Enter -11 into cell B13 (Req. 1c, 2e).

Acceptance Criteria:
The sample size is 2.
The standard deviation of the logs is not displayed.
The RSD is not displayed.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/22/17
3.7. Copy cell B12 into cells B13 to B209 (Req. 1c, 2f).

Acceptance Criteria:
The sample size is 198.
The standard deviation of the logs and RSD are 0.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
4. Results for valid input

4.1. Delete cells B10 to B209. Copy cells D29:D58 from the example data set tab to cell B10. (Req. 3a).

Acceptance Criteria:

- The sample size is 20.
- The standard deviation of the logs rounds to 0.0076016.
- The RSD rounds to 0.76017%.
- The two-sided confidence limits for the RSD rounds to 0.6% and 1.1%.
- The upper confidence limit for the RSD rounds to 1.0.
- The lower confidence limit for the RSD rounds to 0.6.

Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/22/17
5. Independence of tab

5.1. Copy the 1 RSD Lognormal - CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.
- The standard deviation of the logs rounds to 0.0076016.
- The RSD rounds to 0.76017%.
- The two-sided confidence limits for the RSD rounds to 0.6% and 1.1%.
- The upper confidence limit for the RSD rounds to 1.0.
- The lower confidence limit for the RSD rounds to 0.6.
- Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass Initials: WT Date: 11/22/17
6. Comments
   6.1. In 3.2-3.4 references to cell D7 should have been E7.
   6.2. 4.1 states to copy from D29:D58 is typo and should be D39:D58

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass?       X  yes       no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 8 Windows 10.doc
       Data of File: November 22, 2017
       Signature: ________________________________ Date: 11/22/17
Appendix C

File: STAT-12 to 16 - Tab 8  Windows 7
Appendix A: Test Script

1. Document System Used

1.1. Capture a screen shot showing the computer make and model

![Gateway Computer](image-url)
1.2. Capture a screen shot showing the operating system including version number

![Windows 7 Professional](image1)

- Rating: 5/5 Your Windows Experience Index needs to be refreshed
- Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHz
- Installed memory (RAM): 4.00 GB
- System type: 64-bit Operating System
- Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

![Microsoft Office Excel](image2)

- Microsoft Office Excel 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
- Copyright © 2006 Microsoft Corporation. All rights reserved.

This product is licensed to:
Wayne Taylor
Taylor Enterprises, Inc.
Product ID: 81605-903-713283-65427

View the Microsoft Software License Terms

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass     Initials: WT     Date: 11/14/17
3. Check for Valid Parameters
   
   3.1. Go to the 1 RSD Lognormal - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

   **Acceptance Criteria:** Each time a message should be displayed that the cell is protected.

   **Pass or Fail:** Pass  
   **Initials:** WT  
   **Date:** 11/14/17
3.2. Change cell D7 to “49.99”, cell B10 to 1 and B11 to 1.1 (Req. 1a, 2a, 3b).

Acceptance Criteria:
- The sample size is 2
- The standard deviation of the logs rounds to 0.0674.
- The RSD rounds to 6.747
- No confidence limits or statements are displayed.
- An error message is shown.
- A warning is shown RSD < 10%

Pass or Fail: Pass  
Initials: WT  
Date: 11/14/17

3.3. Change cell D7 to “100” (Req. 1a, 2a, 3b).

Acceptance Criteria:
- The sample size is 2
- The standard deviation of the logs rounds to 0.0674.
- The RSD rounds to 6.747
- No confidence limits or statements are displayed.
- An error message is shown.
- A warning is shown RSD < 10%

Pass or Fail: Pass  
Initials: WT  
Date: 11/14/17
3.4. Change cell D7 to “95”, cell B10 to “A”, cell B11 to “1...1” and cell B9 to “Diameter” (Req. 1b, 1c, 2b, 2c).

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Log(Values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td></td>
</tr>
</tbody>
</table>

Acceptance Criteria: The sample size is 0.  
No estimates, confidence limits or statements are displayed.  
The name of the variable is displayed above the results.  
An error message is shown.

Pass or Fail: Pass       Initials: WT       Date: 11/14/17
3.5. Change cell B12 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.
No estimates, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass     Initials: WT     Date: 11/14/17
3.6. Enter -11 into cell B13 (Req. 1c, 2e).

Acceptance Criteria: The sample size is 2.
The standard deviation of the logs is not displayed.
The RSD is not displayed.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/14/17
3.7. Copy cell B12 into cells B13 to B209 (Req. 1c, 2f).

Acceptance Criteria:
- The sample size is 198.
- The standard deviation of the logs and RSD are 0.
- No confidence limits or statements are displayed.
- An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17
4. Results for valid input

4.1. Delete cells B10 to B209. Copy cells D29:D58 from the example data set tab to cell B10. (Req. 3a).

Acceptance Criteria:
The sample size is 20.
The standard deviation of the logs rounds to 0.0076016.
The RSD rounds to 0.76017%.
The two-sided confidence limits for the RSD rounds to 0.6% and 1.1%.
The upper confidence limit for the RSD rounds to 1.0.
The lower confidence limit for the RSD rounds to 0.6.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass   Initials: WT   Date: 11/14/17
5. Independence of tab

5.1. Copy the 1 RSD Lognormal - CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.
The standard deviation of the logs rounds to 0.0076016.
The RSD rounds to 0.76017%.
The two-sided confidence limits for the RSD rounds to 0.6% and 1.1%.
The upper confidence limit for the RSD rounds to 1.0.
The lower confidence limit for the RSD rounds to 0.6.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass Initials: WT Date: 11/14/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.
   6.2. In 3.2-3.4 references to cell D7 should have been E7.
   6.3. 4.1 states to copy from D29:D58 is typo and should be D39:D58

7. Saving and Signing File
   7.1. Determine if all tests passed
         All Test Cases for Computer Pass? X yes no
   7.2. Save File and show name and date.
         Name of File: STAT-12 to 16 - Tab 8 Windows 7.doc
         Data of File: November 14, 2017

         Signature: [Signature] Date: 11/14/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Std. Dev. – n Tab

Protocol Number: TE-17-10

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 22, 2017
Date
1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Std. Dev. – n tab, this spreadsheet calculates sampling plans for the standard deviation. It is described in Appendix G of *STAT-15, Verification/Validation Sampling Plans for Standard Deviation and RSD*. Appendix G also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-9, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 1 Std. Dev. – n Tab was written to validate 1 Std. Dev. – n Tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 9 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 9 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Std. Dev. – n Tab

Protocol Number: TE-17-10
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

1 Std. Dev. – n Tab

Protocol Number: TE-17-10

Approvals:

Dr. Wayne A. Taylor
Study Director

November 11, 2017

Date

Ann B. Taylor
President

November 11, 2017

Date
Validation Protocol for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
1 Std. Dev. – n Tab

Protocol Number: TE-17-10

1.0 Introduction
The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 1 Std. Dev. – n tab, this spreadsheet calculates sampling plans for the standard deviation. It is described in Appendix G of *STAT-15, Verification/Validation Sampling Plans for Standard Deviation and RSD*. Appendix G also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

Table 1: User Requirements for the 1 Std. Dev. – n tab of
STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. RQL can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>c. AQL can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no sampling plan is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Unless RQL and AQL are valid numbers and RQL &gt; AQL &gt; 0, no sampling plan is shown. An error message is displayed.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input, the sample size and acceptance criteria are displayed.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-15 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX Initials: XXX Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 1 Std. Dev - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).
       <Insert screen shot here>
       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX Initials: XXX Date: XXX
   3.2. Change cell C6 to “49.99”, cell C8 to 3, cell and C10 to 2 (Req. 1a-c, 2a).
       <Insert screen shot here>
       Acceptance Criteria: The sampling plan is not displayed. An error message is shown.
       Pass or Fail: XXXX Initials: XXX Date: XXX
   3.3. Change cell C6 to “100” (Req. 1a, 2a).
       <Insert screen shot here>
       Acceptance Criteria: The sampling plan is not displayed. An error message is shown.
       Pass or Fail: XXXX Initials: XXX Date: XXX
   3.4. Change cell C6 to “95” and cell C8 to “3.0” (Req. 1b, 2b).
       <Insert screen shot here>
Acceptance Criteria: The sampling plan is not displayed.
An error message is shown.
Pass or Fail: XXXX    Initials: XXX    Date: XXX
3.5. Change cell C8 to “3” and cell C10 to “2.0” (Req. 1c, 2b).

Acceptance Criteria: The sampling plan is not displayed.
An error message is shown.
Pass or Fail: XXXX    Initials: XXX    Date: XXX
3.6. Change cell C10 to “3” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: XXXX    Initials: XXX    Date: XXX
3.7. Change cell C10 to “0” (Req. 1c, 2b).

4. Results for valid input
4.1. Change cell C12 to “2” (Req. 3a).

Acceptance Criteria: The sample size is 35
Sa rounds to 2.395.
Pass or Fail: XXXX    Initials: XXX    Date: XXX

5. Independence of tab
5.1. Copy the 1 Std. Dev. – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 35
Sa rounds to 2.395.
Pass or Fail: XXXX    Initials: XXX    Date: XXX

6. Comments
6.1. None

7. Saving and Signing File
7.1. Determine if all tests passed
| All Test Cases for Computer Pass? | yes | no |

7.2. Save File and show name and date.

Name of File: 

Data of File: 

Signature: ________________________________ Date: XXX
# Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

### Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. RQL can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.4</td>
</tr>
<tr>
<td></td>
<td>c. AQL can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.5, 3.6, 3.7</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td></td>
<td>3.1</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. Unless RQL and AQL are valid numbers and RQL &gt; AQL &gt; 0, no sampling plan is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.4, 3.5, 3.6, 3.7</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input, the sample size and acceptance criteria are displayed.</td>
</tr>
<tr>
<td></td>
<td>4.1</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
<tr>
<td></td>
<td>5.1</td>
</tr>
</tbody>
</table>
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as shown in Appendix G of STAT-15.
Appendix B

File: STAT-12 to 16 - Tab 9  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   About
   Windows 10

   Alienware 17 R3
   PC name Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

   Edition Windows 10 Home
   Version 1703
   OS Build 15063.674
   Product ID 00325-95916-23031-AAOEM
   Processor Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz
               2.59 GHz
   Installed RAM 16.0 GB (15.9 GB usable)
   System type 54-bit operating system, x64-based processor
   Pen and touch No pen or touch input is available for this display

   1.3. Capture a screen shot showing the version of Excel used

   About Microsoft® Excel® 2016
   Product ID: 00351-70007-85073-AAO24
   Session ID: 1366ED0D-4501-68D2-AC70-DB6OA572FDFC
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass Initials: WT Date: 11/22/17
3. Check for Valid Parameters

3.1. Go to the 1 Std. Dev - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.
Pass or Fail: Pass Initials: WT Date: 11/22/17

3.2. Change cell C6 to “49.99”, cell C8 to 3, cell and C10 to 2 (Req. 1a-c, 2a).

Acceptance Criteria: The sampling plan is not displayed.
An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/22/17
3.3. Change cell C6 to “100” (Req. 1a, 2a).

Acceptance Criteria: The sampling plan is not displayed. An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/22/17

3.4. Change cell C6 to “95” and cell C8 to “3..0” (Req. 1b, 2b).

Acceptance Criteria: The sampling plan is not displayed. An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/22/17

3.5. Change cell C8 to “3” and cell C10 to “2..0” (Req. 1c, 2b).

Acceptance Criteria: The sampling plan is not displayed. An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/22/17
3.6. Change cell C10 to “3” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/22/17

3.7. Change cell C10 to “0” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/22/17
4. Results for valid input

4.1. Change cell C12 to “2” (Req. 3a).

Acceptance Criteria: The sample size is 35
Sa rounds to 2.395.

Pass or Fail: Pass
Initials: WT
Date: 11/22/17
5. Independence of tab

5.1. Copy the 1 Std. Dev. – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 35  
Sa rounds to 2.395.

Pass or Fail: Pass  
Initials: WT  
Date: 11/22/17

6. Comments

6.1. None

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass?  
X yes  
no

7.2. Save File and show name and date.

Name of File:  STAT-12 to 16 - Tab 9 Windows 10.doc

Data of File:  November 22, 2017

Signature:  [Signature]  
Date:  11/22/17
Appendix C

File: STAT-12 to 16 - Tab 9  Windows 7
Appendix A: Test Script

1. Document System Used

1.1. Capture a screen shot showing the computer make and model
1.2. Capture a screen shot showing the operating system including version number

Windows edition

Windows 7 Professional
Copyright © 2009 Microsoft Corporation. All rights reserved.
Service Pack 1
Get more features with a new edition of Windows 7

System

Rating: 5/5 Your Windows Experience Index needs to be refreshed
Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHZ 2.27 GHZ
Installed memory (RAM): 4.00 GB
System type: 64-bit Operating System
Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

Microsoft® Office Excel® 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
Port of Microsoft Office Professional 2007
© 2006 Microsoft Corporation. All rights reserved.


This product is licensed to:
Wayne Taylor
Taylor Enterprises, Inc.
Product ID: 81605-903-7132834-65427

View the Microsoft Software License Terms

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
3. Check for Valid Parameters

3.1. Go to the 1 Std. Dev - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17

3.2. Change cell C6 to “49.99", cell C8 to 3, cell and C10 to 2 (Req. 1a-c, 2a).

Acceptance Criteria: The sampling plan is not displayed. An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17

3.3. Change cell C6 to “100” (Req. 1a, 2a).

Acceptance Criteria: The sampling plan is not displayed. An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
3.4. Change cell C6 to “95” and cell C8 to “3.0” (Req. 1b, 2b).

Acceptance Criteria: The sampling plan is not displayed. An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17

3.5. Change cell C8 to “3” and cell C10 to “2.0” (Req. 1c, 2b).

Acceptance Criteria: The sampling plan is not displayed. An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17

3.6. Change cell C10 to “3” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail:  Pass  Initials: WT  Date: 11/14/17
3.7. Change cell C10 to “0” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass    Initials: WT    Date: 11/14/17

4. Results for valid input
4.1. Change cell C12 to “2” (Req. 3a).

Acceptance Criteria: The sample size is 35
Sa rounds to 2.395.

Pass or Fail: Pass    Initials: WT    Date: 11/14/17
5. Independence of tab

5.1. Copy the 1 Std. Dev. – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 35
Sa rounds to 2.395.
Pass or Fail: Pass Initials: WT Date: 11/14/17

6. Comments

6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass? X yes no

7.2. Save File and show name and date.

Name of File: STAT-12 to 16 - Tab 9 Windows 7.doc
Data of File: November 14, 2017

Signature: [Signature] Date: 11/14/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages – CI Tab

Protocol Number: TE-17-11

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 28, 2017
Date

November 28, 2017
Date
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages – CI Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages – CI tab, this spreadsheet performs confidence intervals for the difference between two averages. It is described in Appendix A of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix A also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-11, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 2 Averages – CI Tab was written to validate 2 Averages – CI Tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 10 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 10 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages – CI

Protocol Number: TE-17-11
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages – CI Tab

Protocol Number: TE-17-11

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 11, 2017
Date

November 11, 2017
Date
Validation Protocol for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
2 Averages – CI Tab

Protocol Number: TE-17-11

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages – CI tab, this spreadsheet performs confidence intervals for the difference between two averages. It is described in Appendix A of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix A also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

**Table 1: User Requirements for the 2 Averages – CI tab of STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls**

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. The name of the variables can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>c. The data can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Only valid numbers in the data fields are used.</td>
</tr>
<tr>
<td></td>
<td>c. If no valid data is entered, the sample sizes are zero and no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>d. If there is a single valid data point in one of the groups, the sample size is one and only the averages and difference are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>e. If there are two or more valid data points but the standard deviations are both zero, the sample sizes, averages, standard deviations and difference are shown but no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input with at least two data points and non-zero standard deviation, the sample sizes, averages, standard deviations, difference and confidence intervals are displayed.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA.

All individuals performing the testing described below shall have a thorough knowledge of STAT-16 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>

       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX Initials: XXX Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 2 Averages - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).
       <Insert screen shot here>

       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX Initials: XX Date: XXX

   3.2. Change cell C6 to “49.99”, cell B9 to 1, B10 to 2, cell C9 to 1 and C10 to 2 (Req. 1a, 2a).
       <Insert screen shot here>

       Acceptance Criteria: Both sample sizes are 2
       Both averages are 1.5
       Both standard deviations round to 0.7071.
       The difference is zero.
       No confidence limits or statements are displayed.
       An error message is shown.
       Pass or Fail: XXXX Initials: XX Date: XXX

   3.3. Change cell C6 to “100” (Req. 1a, 2a).
       <Insert screen shot here>

       Acceptance Criteria: Both sample sizes are 2
       Both averages are 1.5
       Both standard deviations round to 0.7071.
       The difference is zero.
No confidence limits or statements are displayed. An error message is shown.

Pass or Fail: XXXX Initials: XX Date: XXX

3.4. Change cell C6 to “95”, cell B9 to “A”, cell B10 to “1..1”, cell B8 to “Strength - New””, cell C9 to “A”, cell C10 to “1..1” and cell C8 to “Strength - Old” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample sizes are 0. No estimates, confidence limits or statements are displayed. The name of the variables are displayed above the results. An error message is shown.

Pass or Fail: XXXX Initials: XX Date: XXX

3.5. Change cell B11 to “1” and cell C11 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample sizes are 1. The averages are 1. The difference is 0. No standard deviation, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: XXXX Initials: XX Date: XXX

3.6. Copy cell B11 into cells B12 to B208 and copy cell C11 into cells C12 to C208 (Req. 1c, 2e).

Acceptance Criteria: The sample sizes are 198. The averages are 1. The standard deviations are 0. The difference is zero. No confidence limits or statements are displayed. An error message is shown.

Pass or Fail: XXXX Initials: XXX Date: XXX

4. Results for valid input

4.1. Delete cells B9 to B208 and C9 to C208. Copy cells C69:D88 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample sizes are 20. The first average rounds to 10.11. The second average rounds to 9.37. The first standard deviation rounds to 1.52. The second standard deviation rounds to 1.39. The difference rounds to 0.739. The two-side confidence limits for the average round to -0.196 and 1.674. The upper confidence limit for the average rounds to 1.518. The lower confidence limit for the average rounds to -0.040. Confidence statements for the three cases are shown with the same values.

Pass or Fail: XXXX Initials: XXX Date: XXX
5. Independence of tab
   5.1. Copy the 2 Averages – CI tab. Delete all tabs but the copy. (Req. 4a)

   ![Insert screen shot here]

   **Acceptance Criteria:**
   - The sample sizes are 20.
   - The first average rounds to 10.11.
   - The second average rounds to 9.37.
   - The first standard deviation rounds to 1.52.
   - The second standard deviation rounds to 1.39.
   - The difference rounds to 0.739.
   - The two-side confidence limits for the average round to -0.196 and 1.674.
   - The upper confidence limit for the average rounds to 1.518.
   - The lower confidence limit for the average rounds to -0.040.

   Confidence statements for the three cases are shown with the same values.

   **Pass or Fail:** XXXX  **Initials:** XX  **Date:** XXX

6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed

   **All Test Cases for Computer Pass?**  yes  no

   7.2. Save File and show name and date.

   **Name of File:**

   **Data of File:**

   **Signature:** ________________________________  **Date:** XXX
### Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

#### Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | **Input of Data:**  
|    | a. The confidence level can be entered into the highlighted cell of the spreadsheet  
|    |   3.2, 3.3  
|    | b. The name of the variables can be entered into the highlighted cell of the spreadsheet.  
|    |   3.4  
|    | c. The data can be entered into the highlighted cells of the spreadsheet.  
|    |   3.4, 3.5, 3.6 – all data cells used  
|    | d. Only the highlighted yellow cells can be changed.  
|    |   3.1  |
| 2  | **Data Checking:**  
|    | a. Unless the confidence level is $\geq50\%$ and $<100\%$, no confidence intervals are shown. An error message is displayed.  
|    |   3.2, 3.3 – covers both sides  
|    | b. Only valid numbers in the data fields are used.  
|    |   3.4  
|    | c. If no valid data is entered, the sample sizes are zero and no results are shown. An error message is displayed.  
|    |   3.4  
|    | d. If there is a single valid data point in one of the groups, the sample size is one and only the averages and difference are shown. An error message is displayed.  
|    |   3.5  
|    | e. If there are two or more valid data points but the standard deviations are both zero, the sample sizes, averages, standard deviations and difference are shown but no confidence intervals are shown. An error message is displayed.  
|    |   3.6  |
| 3  | **Results for valid input:**  
|    | a. For valid input with at least two data points and non-zero standard deviation, the sample sizes, averages, standard deviations, difference and confidence intervals are displayed.  
|    |   4.1  |
| 4  | **Tabs:**  
|    | a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.  
|    |   5.1  |
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as shown in Appendix A of STAT-16.

If the alternative “≠” is selected, the following output appears in the Session window. With 95% confidence, the difference is between -0.196 and 1.674.

Two-Sample T-Test and CI: Strength - New, Strength - Old

Descriptive Statistics

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength - New</td>
<td>20</td>
<td>10.11</td>
<td>1.52</td>
<td>0.34</td>
</tr>
<tr>
<td>Strength - Old</td>
<td>20</td>
<td>9.37</td>
<td>1.39</td>
<td>0.31</td>
</tr>
</tbody>
</table>

Estimation for Difference

<table>
<thead>
<tr>
<th>Difference</th>
<th>95% CI for Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.739</td>
<td>(-0.196, 1.674)</td>
</tr>
</tbody>
</table>

If the alternative “>” is selected, the following output appears in the Session window. With 95% confidence, the difference is greater than -0.040.

Two-Sample T-Test and CI: Strength - New, Strength - Old

Descriptive Statistics

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength - New</td>
<td>20</td>
<td>10.11</td>
<td>1.52</td>
<td>0.34</td>
</tr>
<tr>
<td>Strength - Old</td>
<td>20</td>
<td>9.37</td>
<td>1.39</td>
<td>0.31</td>
</tr>
</tbody>
</table>

Estimation for Difference

<table>
<thead>
<tr>
<th>Difference</th>
<th>95% Lower Bound for Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.739</td>
<td>-0.040</td>
</tr>
</tbody>
</table>

If the alternative “<” is selected, the following output appears in the Session window. With 95% confidence, the difference is less than 1.518.

Two-Sample T-Test and CI: Strength - New, Strength - Old

Descriptive Statistics

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength - New</td>
<td>20</td>
<td>10.11</td>
<td>1.52</td>
<td>0.34</td>
</tr>
<tr>
<td>Strength - Old</td>
<td>20</td>
<td>9.37</td>
<td>1.39</td>
<td>0.31</td>
</tr>
</tbody>
</table>

Estimation for Difference

<table>
<thead>
<tr>
<th>Difference</th>
<th>95% Upper Bound for Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.739</td>
<td>1.518</td>
</tr>
</tbody>
</table>
Appendix B

File: STAT-12 to 16 - Tab 10  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   ![Windows 10 About](image)

   **Alienware 17 R3**
   
   **PC name** Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

<table>
<thead>
<tr>
<th>Edition</th>
<th>Windows 10 Home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>1703</td>
</tr>
<tr>
<td>OS Build</td>
<td>15063.674</td>
</tr>
<tr>
<td>Product ID</td>
<td>00325-95916-23031-AAOEM</td>
</tr>
<tr>
<td>Processor</td>
<td>Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz</td>
</tr>
<tr>
<td>Installed RAM</td>
<td>16.0 GB (15.9 GB usable)</td>
</tr>
<tr>
<td>System type</td>
<td>64-bit operating system, x64-based processor</td>
</tr>
<tr>
<td>Pen and touch</td>
<td>No pen or touch input is available for this display</td>
</tr>
</tbody>
</table>

   1.3. Capture a screen shot showing the version of Excel used

   ![Microsoft Excel 2016 About](image)
2. **Download Spreadsheet and Open**

   2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

   ![Spreadsheet Download and Open](Image)

   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

   ![Spreadsheet Version and Date](Image)

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass  Initials: WT  Date: 11/23/17
3. Check for Valid Parameters

3.1. Go to the 2 Averages - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/23/17
3.2. Change cell C6 to “49.99”, cell B9 to 1, B10 to 2, cell C9 to 1 and C10 to 2 (Req. 1a, 2a).

Acceptance Criteria: Both sample sizes are 2
Both averages are 1.5
Both standard deviations round to 0.7071.
The difference is zero.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass       Initials: WT       Date: 11/23/17
3.3. Change cell C6 to “100” (Req. 1a, 2a).

Acceptance Criteria: Both sample sizes are 2
Both averages are 1.5
Both standard deviations round to 0.7071.
The difference is zero.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass    Initials: WT    Date: 11/23/17
3.4. Change cell C6 to “95”, cell B9 to “A”, cell B10 to “1..1”, cell B8 to “Strength - New”, cell C9 to “A”, cell C10 to “1..1” and cell C8 to “Strength - Old” (Req. 1b, 1c, 2b, 2c).

### Acceptance Criteria:
- The sample sizes are 0.
- No estimates, confidence limits or statements are displayed.
- The name of the variables are displayed above the results.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/23/17
3.5. Change cell B11 to “1” and cell C11 to “1” (Req. 1c, 2d).

<table>
<thead>
<tr>
<th>Confidence Level: 95%</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength - New</td>
<td>Strength - Old</td>
</tr>
<tr>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Statistical Procedures for the Medical Device Industry**

**Appendix A: Confidence Limits for the Difference between Two Averages**

**Acceptance Criteria:**
The sample sizes are 1.
The averages are 1.
The difference is 0.
No standard deviation, confidence limits or statements are displayed.
An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/23/17
3.6. Copy cell B11 into cells B12 to B208 and copy cell C11 into cells C12 to C208 (Req. 1c, 2e).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-16, Statistical Techniques for Equivalence Testing**

Appendix A: **Confidence Limits for the Difference between Two Averages**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Strength - New**

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>198</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>1</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0</td>
</tr>
</tbody>
</table>

**The standard deviation of the two groups are zero.**

<table>
<thead>
<tr>
<th>Strength - Old</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size</td>
</tr>
<tr>
<td>Average</td>
</tr>
<tr>
<td>Standard Deviation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Difference (Strength - New - Strength - Old)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference</td>
</tr>
</tbody>
</table>

**2-Sided Case - Confidence Interval**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lower 1-Sided Case - Lower Confidence Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Limit</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Upper 1-Sided Case - Upper Confidence Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Limit</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Acceptance Criteria:**

- The sample sizes are 198.
- The averages are 1
- The standard deviations are 0.
- The difference is zero.
- No confidence limits or statements are displayed.
- An error message is shown.

**Pass or Fail:** Pass

**Initials:** WT

**Date:** 11/23/17
4. Results for valid input

4.1. Delete cells B9 to B208 and C9 to C208. Copy cells C69:D88 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side confidence limits for the average round to -0.196 and 1.674.
The upper confidence limit for the average rounds to 1.518.
The lower confidence limit for the average rounds to -0.040.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass    Initials: WT    Date: 11/23/17
5. Independence of tab

5.1. Copy the 2 Averages – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.74.
The two-side confidence limits for the average round to -0.196 and 1.674.
The upper confidence limit for the average rounds to 1.518.
The lower confidence limit for the average rounds to -0.040.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass
Initials: WT
Date: 11/23/17
6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
         All Test Cases for Computer Pass? X yes no
   7.2. Save File and show name and date.
         Name of File: STAT-12 to 16 - Tab 10 Windows 10.doc
         Data of File: November 23, 2017
         Signature: ________________________________ Date: 11/23/17
Appendix C

File:  STAT-12 to 16 - Tab 10  Windows 7
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

![Gateway Computer Label](image-url)
1.2. Capture a screen shot showing the operating system including version number

Windows edition
Windows 7 Professional
Copyright © 2009 Microsoft Corporation. All rights reserved.
Service Pack 1
Get more features with a new edition of Windows 7

System
Rating: 5.5 Your Windows Experience Index needs to be refreshed
Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHz
Installed memory (RAM): 4.00 GB
System type: 64-bit Operating System
Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

Microsoft Office Excel 2007 (12.0.6776.5000) SP3 MOS (12.0.6777.5000)
© 2006 Microsoft Corporation. All rights reserved.

This product is licensed to:
Wayne Taylor
Taylor Enterprises, Inc.
Product ID: 81605-903-7132834-65427

View the Microsoft Software License Terms

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
3. Check for Valid Parameters

3.1. Go to the 2 Averages - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  
Initials: WT  
Date: 11/14/17
3.2. Change cell C6 to “49.99”, cell B9 to 1, B10 to 2, cell C9 to 1 and C10 to 2 (Req. 1a, 2a).

<table>
<thead>
<tr>
<th>Confidence Level:</th>
<th>49.99%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison Group</td>
<td>Reference Group</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Acceptance Criteria: Both sample sizes are 2  
Both averages are 1.5  
Both standard deviations round to 0.7071.  
The difference is zero.  
No confidence limits or statements are displayed.  
An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/14/17
3.3. Change cell C6 to “100” (Req. 1a, 2a).

**Acceptance Criteria:**
- Both sample sizes are 2
- Both averages are 1.5
- Both standard deviations round to 0.7071.
- The difference is zero.
- No confidence limits or statements are displayed.
- An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17
3.4. Change cell C6 to “95”, cell B9 to “A”, cell B10 to “1..1”, cell B8 to “Strength - New”, cell C9 to “A”, cell C10 to “1..1” and cell C8 to “Strength - Old” (Req. 1b, 1c, 2b, 2c).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY

STAT-16, Statistical Techniques for Equivalence Testing

**Appendix A: Confidence Limits for the Difference between Two Averages**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strength - New</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1..1</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Strength - Old</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1..1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Strength - New**
  - Sample Size: 0
  - Average
  - Standard Deviation

- **Strength - Old**
  - Sample Size: 0
  - Average
  - Standard Deviation

- **Difference (Strength - New - Strength - Old)**
  - Difference

- **2-Sided Case - Confidence Interval**
  - Lower Limit
  - Upper Limit

- **Lower 1-Sided Case - Lower Confidence Limit**
  - Lower Limit

- **Upper 1-Sided Case - Upper Confidence Limit**
  - Upper Limit

Acceptance Criteria: The sample sizes are 0.
No estimates, confidence limits or statements are displayed.
The name of the variables are displayed above the results.
An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/14/17
3.5. Change cell B11 to “1” and cell C11 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample sizes are 1.  
The averages are 1.  
The difference is 0.  
No standard deviation, confidence limits or statements are displayed.  
An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/14/17
3.6. Copy cell B11 into cells B12 to B208 and copy cell C11 into cells C12 to C208 (Req. 1c, 2e).

### Acceptance Criteria:

- The sample sizes are 198.
- The averages are 1.
- The standard deviations are 0.
- The difference is zero.
- No confidence limits or statements are displayed.
- An error message is shown.

**Pass or Fail:** Pass

**Initials:** WT

**Date:** 11/14/17
4. Results for valid input

4.1. Delete cells B9 to B208 and C9 to C208. Copy cells C69:D88 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side confidence limits for the average round to -0.196 and 1.674.
The upper confidence limit for the average rounds to 1.518.
The lower confidence limit for the average rounds to -0.040.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass    Initials: WT    Date: 11/14/17
5. Independence of tab

5.1. Copy the 2 Averages – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side confidence limits for the average round to -0.196 and 1.674.
The upper confidence limit for the average rounds to 1.518.
The lower confidence limit for the average rounds to -0.040.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File
   7.1. Determine if all tests passed
       
       All Test Cases for Computer Pass?   X   yes   no

   7.2. Save File and show name and date.
       
       Name of File:  STAT-12 to 16 - Tab 10 Windows 7.doc
       Data of File:  November 14, 2017

Signature: ________________________________  Date:  11/14/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages – n Tab

Protocol Number: TE-17-12

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 28, 2017
Date

November 28, 2017
Date
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages – n Tab

Report Number: TE-17-12

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages – n tab, this spreadsheet calculates sample sizes for a 2-sample equivalence test for the average. It is described in Appendix B of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix B also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-12, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 2 Averages – n Tab was written to validate 2 Averages – n of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 11  Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 11  Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages – n

Protocol Number: TE-17-12
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages – n Tab

Protocol Number: TE-17-12

Approvals:

Dr. Wayne A. Taylor
Study Director

November 11, 2017
Date

Ann B. Taylor
President

November 11, 2017
Date
Validation Protocol for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
2 Averages – n Tab

Protocol Number: TE-17-12

1.0 Introduction

The book Statistical Procedures for the Medical Device Industry by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages – n tab, this spreadsheet calculates sample sizes for a 2-sample equivalence test for the average. It is described in Appendix B of STAT-16, Statistical Techniques for Equivalence Testing. Appendix B also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | Input of Data:  
  a. The confidence level can be entered into the highlighted cell of the spreadsheet  
  b. $\Delta_{RQL}$ can be entered into the highlighted cell of the spreadsheet.  
  c. $\Delta_{AQL}$ can be entered into the highlighted cells of the spreadsheet.  
  d. The standard deviation can be entered into the highlighted cells of the spreadsheet.  
  e. Only the highlighted yellow cells can be changed. |
| 2  | Data Checking:  
  a. Unless the confidence level is $\geq$50% and $<100\%$, no sample size is shown. An error message is displayed.  
  b. Unless $\Delta_{RQL}$ and $\Delta_{AQL}$ are valid numbers and $\Delta_{RQL} > \Delta_{AQL} \geq 0$, no sample size is shown. An error message is displayed.  
  c. Unless $\sigma$ is a valid number and $\sigma > 0$, no sample size is shown. An error message is displayed. |
| 3  | Results for valid input:  
  a. For valid input, the sample size is displayed. |
| 4  | Tabs:  
  a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same. |
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA.

All individuals performing the testing described below shall have a thorough knowledge of STAT-16 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX    Initials: XXX    Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 2 Averages - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).
       <Insert screen shot here>
       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX    Initials: XXX    Date: XXX
   3.2. Change cell C6 to “49.99”, cell C8 to 2, cell C10 to 0.5 and C12 to 1.5 (Req. 1a-d, 2a).
       <Insert screen shot here>
       Acceptance Criteria: The sample size is not displayed.
       An error message is shown.
       Pass or Fail: XXXX    Initials: XXX    Date: XXX
   3.3. Change cell C6 to “100” (Req. 1a, 2a).
       <Insert screen shot here>
   3.4. Change cell C6 to “95” and cell C8 to “2.0” (Req. 1b, 2b).
       <Insert screen shot here>
Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX
3.5. Change cell C8 to “2” and cell C10 to “0..5” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX
3.6. Change cell C10 to “2” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX
3.7. Change cell C10 to “-0.01” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX
3.8. Change cell C10 to “0.5” and C12 to “1..5” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX
3.9. Change cell C12 to “0” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

4. Results for valid input
4.1. Change cell C12 to “1.5” (Req. 3a).

Acceptance Criteria: The sample size is 23.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

5. Independence of tab
5.1. Copy the 2 Averages – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX  Initials: XXX  Date: XXX
Acceptance Criteria: The sample size is 23.
Pass or Fail: XXXX  Initials: XXX  Date: XXX

6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? yes no
   7.2. Save File and show name and date.
       Name of File:
       Data of File:

   Signature: _______________________________  Date: XXX
## Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

### Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | Input of Data:  
|    | a. The confidence level can be entered into the highlighted cell of the spreadsheet  
|    |   3.2, 3.3  
|    | b. $\Delta_{RQL}$ can be entered into the highlighted cell of the spreadsheet  
|    |   3.4  
|    | c. $\Delta_{AQL}$ can be entered into the highlighted cells of the spreadsheet.  
|    |   3.5, 3.6  
|    | d. The standard deviation can be entered into the highlighted cells of the spreadsheet.  
|    |   3.7, 3.8  
|    | e. Only the highlighted yellow cells can be changed.  
|    |   3.1  |
| 2  | Data Checking:  
|    | a. Unless the confidence level is $\geq$50% and $<100\%$, no sample size is shown. An error message is displayed.  
|    |   3.2, 3.3  
|    | b. Unless $\Delta_{RQL}$ and $\Delta_{AQL}$ are valid numbers and $\Delta_{RQL} > \Delta_{AQL} \geq 0$, no sample size is shown. An error message is displayed.  
|    |   3.4, 3.5, 3.6, 3.7  
|    | c. Unless $\sigma$ is a valid number and $\sigma > 0$, no sample size is shown. An error message is displayed.  
|    |   3.8, 3.9  |
| 3  | Results for valid input:  
|    | a. For valid input, the sample size is displayed.  
|    |   4.1  |
| 4  | Tabs:  
|    | a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.  
|    |   5.1  |
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as shown in Appendix B of STAT-16.
Appendix B

File: STAT-12 to 16 - Tab 11 Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   About Windows 10

   Alienware 17 R3
   PC name Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

   Edition Windows 10 Home
   Version 1703
   OS Build 15063.674
   Product ID 00325-95916-23031-AAOEM
   Processor Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz
   Installed RAM 16.0 GB (15.9 GB usable)
   System type 64-bit operating system, x64-based processor
   Pen and touch No pen or touch input is available for this display

   1.3. Capture a screen shot showing the version of Excel used
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass
Initials: WT
Date: 11/23/17
3. Check for Valid Parameters

3.1. Go to the 2 Averages - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  
Initials: WT  
Date: 11/23/17
3.2. Change cell C6 to “49.99”, cell C8 to 2, cell C10 to 0.5 and C12 to 1.5 (Req. 1a-d, 2a).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/23/17

3.3. Change cell C6 to “100” (Req. 1a, 2a).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/23/17
3.4. Change cell C6 to “95” and cell C8 to “2.0” (Req. 1b, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass     Initials: WT     Date: 11/23/17

3.5. Change cell C8 to “2” and cell C10 to “0.5” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass     Initials: WT     Date: 11/23/17
3.6. Change cell C10 to “2” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass    Initials: WT    Date: 11/23/17

3.7. Change cell C10 to “-0.01” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass    Initials: WT    Date: 11/23/17
3.8. Change cell C10 to “0.5” and C12 to “1.5” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/23/17

3.9. Change cell C12 to “0” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/23/17
4. Results for valid input

4.1. Change cell C12 to “1.5” (Req. 3a).

Acceptance Criteria: The sample size is 23.
Pass or Fail: Pass
Initials: WT
Date: 11/23/17
5. Independence of tab

5.1. Copy the 2 Averages – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 23.

Pass or Fail: Pass  Initials: WT  Date: 11/23/17
6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? x yes no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 11 Windows 10.doc
       Data of File: November 23, 2017
       Signature: ________________________________ Date: 11/23/17
Appendix C

File: STAT-12 to 16 - Tab 11  Windows 7
Appendix A: Test Script

1. Document System Used

   1.1. Capture a screen shot showing the computer make and model
1.2. Capture a screen shot showing the operating system including version number

Windows edition

Windows 7 Professional
Copyright © 2009 Microsoft Corporation. All rights reserved.
Service Pack 1
Get more features with a new edition of Windows 7

System
Rating: 5.5 Your Windows Experience Index needs to be refreshed
Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHz
Installed memory (RAM): 4.00 GB
System type: 64-bit Operating System
Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

About Microsoft Office Excel

Microsoft Office Excel 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
The Office System 2007
© 2006 Microsoft Corporation. All rights reserved.


This product is licensed to:
Wayne Taylor
Taylor Enterprises, Inc.
Product ID: 81605-903-7132834-65427

View the Microsoft Software License Terms

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.

[OK] [System Info] [Tech Support]
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass  
Initials: WT  
Date: 11/14/17
3. Check for Valid Parameters

3.1. Go to the 2 Averages - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.
Pass or Fail: Pass Initials: WT Date: 11/14/17

3.2. Change cell C6 to “49.99”, cell C8 to 2, cell C10 to 0.5 and C12 to 1.5 (Req. 1a-d, 2a).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/14/17
3.3. Change cell C6 to “100” (Req. 1a, 2a).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

Statistical Techniques for Equivalence Testing

Appendix B: Equivalence Test for Two Averages

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
<th>Chance of failing at $\Delta_{LOL}$</th>
<th>$50 \leq \text{Conf} &lt; 100$</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>2</td>
<td>A difference that has a 100% chance of failing $\Delta_{LOL}$</td>
<td></td>
</tr>
<tr>
<td>5%</td>
<td>0.5</td>
<td>A difference that has a 95% chance of passing $\Delta_{LOL}$</td>
<td></td>
</tr>
<tr>
<td>$\sigma$</td>
<td>1.5</td>
<td>Estimate of standard deviation $\sigma &gt; 0$</td>
<td></td>
</tr>
</tbody>
</table>

Sample Size

This is the number of samples for each group for 100% confidence equivalence studies.

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17

3.4. Change cell C6 to “95” and cell C8 to “2.0” (Req. 1b, 2b).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

Statistical Techniques for Equivalence Testing

Appendix B: Equivalence Test for Two Averages

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
<th>Chance of failing at $\Delta_{LOL}$</th>
<th>$50 \leq \text{Conf} &lt; 100$</th>
</tr>
</thead>
<tbody>
<tr>
<td>95%</td>
<td>2</td>
<td>A difference that has a 95% chance of failing $\Delta_{LOL}$</td>
<td></td>
</tr>
<tr>
<td>5%</td>
<td>0.5</td>
<td>A difference that has a 95% chance of passing $\Delta_{LOL}$</td>
<td></td>
</tr>
<tr>
<td>$\sigma$</td>
<td>1.5</td>
<td>Estimate of standard deviation $\sigma &gt; 0$</td>
<td></td>
</tr>
</tbody>
</table>

Sample Size

This is the number of samples for each group for 95% confidence equivalence studies.

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17

3.5. Change cell C8 to “2” and cell C10 to “0.5” (Req. 1c, 2b).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

Statistical Techniques for Equivalence Testing

Appendix B: Equivalence Test for Two Averages

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
<th>Chance of failing at $\Delta_{LOL}$</th>
<th>$50 \leq \text{Conf} &lt; 100$</th>
</tr>
</thead>
<tbody>
<tr>
<td>95%</td>
<td>2</td>
<td>A difference that has a 95% chance of failing $\Delta_{LOL}$</td>
<td></td>
</tr>
<tr>
<td>5%</td>
<td>0.5</td>
<td>A difference that has a 95% chance of passing $\Delta_{LOL}$</td>
<td></td>
</tr>
<tr>
<td>$\sigma$</td>
<td>1.5</td>
<td>Estimate of standard deviation $\sigma &gt; 0$</td>
<td></td>
</tr>
</tbody>
</table>

Sample Size

This is the number of samples for each group for 95% confidence equivalence studies.

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17
3.6. Change cell C10 to “2” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass  Initials: WT  Date: 11/14/17

3.7. Change cell C10 to “-0.01” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass  Initials: WT  Date: 11/14/17

3.8. Change cell C10 to “0.5” and C12 to “1.5” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass  Initials: WT  Date: 11/14/17
3.9. Change cell C12 to “0” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass
Initials: WT
Date: 11/14/17

4. Results for valid input

4.1. Change cell C12 to “1.5” (Req. 3a).

Acceptance Criteria: The sample size is 23.
Pass or Fail: Pass
Initials: WT
Date: 11/14/17
5. Independence of tab

5.1. Copy the 2 Averages – n tab. Delete all tabs but the copy. (Req. 4a)

<table>
<thead>
<tr>
<th>Acceptance Criteria: The sample size is 23.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pass or Fail: Pass</td>
</tr>
<tr>
<td>Initials: WT</td>
</tr>
<tr>
<td>Date: 11/14/17</td>
</tr>
</tbody>
</table>

![Table of statistical procedures for the medical device industry](image-url)
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File
   7.1. Determine if all tests passed
   All Test Cases for Computer Pass?  X  yes  no

   7.2. Save File and show name and date.
   Name of File:  STAT-12 to 16 - Tab 11 Windows 7.doc
   Data of File:  November 14, 2017

Signature: ________________________________ Date: 11/14/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages – Equivalence Tab

Protocol Number: TE-17-13

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 28, 2017
Date

November 28, 2017
Date
1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages – Equivalence tab, this spreadsheet performs equivalence intervals and tests for the difference between two averages. It is described in Appendix B of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix B also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-13, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 2 Averages – Equivalence Tab was written to validate 2 Averages – Equivalence tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 12 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 12 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages – Equivalence Tab

Protocol Number: TE-17-13
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages – Equivalence Tab

Protocol Number: TE-17-13

Approvals:

Dr. Wayne A. Taylor
Study Director

November 14, 2017
Date

Ann B. Taylor
President

November 14, 2017
Date
Validation Protocol for Excel Spreadsheet: 
STAT-12 to 16 - Confidence Intervals and Equivalence Tests 
2 Averages – Equivalence Tab 

Protocol Number: TE-17-13

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages – Equivalence tab, this spreadsheet performs equivalence intervals and tests for the difference between two averages. It is described in Appendix B of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix B also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

Table 1: User Requirements for the 2 Averages – Equivalence tab of STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. The difference can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>c. The name of the variables can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>d. The data can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>e. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no equivalence intervals or tests are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Unless the difference is &gt; 0%, no equivalence intervals or tests are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>c. Only valid numbers in the data fields are used.</td>
</tr>
<tr>
<td></td>
<td>d. If no valid data is entered, the sample sizes are zero and no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>e. If there is a single valid data point in one of the groups, the sample size is one and only the averages and difference are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>f. If there are two or more valid data points but the standard deviations are both zero, the sample sizes, averages, standard deviations and difference are shown but no equivalence intervals or tests are shown. An error message is displayed.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input with at least two data points and non-zero standard deviation, the sample sizes, averages, standard deviations, difference and equivalence intervals and tests are displayed.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-16 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
        <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
        <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
        <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX Initials: XXX Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 2 Averages - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).
       <Insert screen shot here>
       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX Initials: XX Date: XXX
   3.2. Change cell E6 to “49.99”, cell B11 to 1, B12 to 2, cell C11 to 1 and C12 to 2 (Req. 1a, 2a).
       <Insert screen shot here>
       Acceptance Criteria: Both sample sizes are 2
       Both averages are 1.5
       Both standard deviations round to 0.7071.
       The difference is zero.
       No equivalent limits and tests are displayed.
       An error message is shown.
       Pass or Fail: XXXX Initials: XX Date: XXX
   3.3. Change cell E6 to “100” (Req. 1a, 2a).
       <Insert screen shot here>
       Acceptance Criteria: Both sample sizes are 2
       Both averages are 1.5
       Both standard deviations round to 0.7071.
       The difference is zero.
No equivalent limits and tests are displayed. 
An error message is shown.

Pass or Fail: XXXX    Initials: XX    Date: XXX

3.4. Change cell E6 to “95” and cell E8 to “0” (Req. 1b, 2b).

<Insert screen shot here>

Acceptance Criteria: Both sample sizes are 2
Both averages are 1.5
Both standard deviations round to 0.7071.
The difference is zero.
Equivalence limits are shown.
No conclusions are shown.
An error message is shown.

Pass or Fail: XXXX    Initials: XX    Date: XXX

3.5. Change cell E8 to “2”, cell B11 to “A”, cell B12 to “1..1”, cell B10 to “Strength - New””, cell C11 to “A”, cell C12 to “1..1” and cell C10 to “Strength - Old” (Req. 1c, 1d, 2c, 2d).

<Insert screen shot here>

Acceptance Criteria: The sample sizes are 0.
No estimates, equivalence limits and tests are displayed.
The name of the variables are displayed above the results.
An error message is shown.

Pass or Fail: XXXX    Initials: XX    Date: XXX

3.6. Change cell B13 to “1” and cell C13 to “1” (Req. 1d, 2e).

<Insert screen shot here>

Acceptance Criteria: The sample sizes are 1.
The averages are 1.
The difference is 0.
No standard deviation, equivalence limits and test are displayed.
An error message is shown.

Pass or Fail: XXXX    Initials: XX    Date: XXX

3.7. Copy cell B13 into cells B14 to B210 and copy cell C13 into cells C14 to C210 (Req. 1d, 2f).

<Insert screen shot here>

Acceptance Criteria: The sample sizes are 198.
The averages are 1
The standard deviations are 0.
The difference is zero.
No equivalence limits and tests are displayed.
An error message is shown.

Pass or Fail: XXXX    Initials: XXX    Date: XXX

4. Results for valid input

4.1. Delete cells B11 to B210 and C11 to C210. Copy cells C69:D88 from the example data set tab to cell B11. (Req. 3a).

<Insert screen shot here>
Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side equivalence limits for the average round to -0.039602 and 1.5176.
The upper equivalence limit for the average rounds to 1.5176.
The lower equivalence limit for the average rounds to -0.039602.
Equivalence statements for the three cases are shown with the same values.
All three cases pass.

Pass or Fail: XXXX Initials: XXX Date: XXX

4.2. Change cell E8 to “0.02” (Req. 3a).

<Insert screen shot here>

Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side equivalence limits for the average round to -0.039602 and 1.5176.
The upper equivalence limit for the average rounds to 1.5176.
The lower equivalence limit for the average rounds to -0.039602.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: XXXX Initials: XXX Date: XXX

5. Independence of tab

5.1. Copy the 2 Averages – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

<Insert screen shot here>

Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side equivalence limits for the average round to -0.039602 and 1.5176.
The upper equivalence limit for the average rounds to 1.5176.
The lower equivalence limit for the average rounds to -0.039602.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: XXXX Initials: XX Date: XXX

6. Comments

6.1. None
7. Saving and Signing File
   
   7.1. Determine if all tests passed
       
       All Test Cases for Computer Pass?  yes  no
       
   7.2. Save File and show name and date.

       Name of File:
       
       Data of File:
       
       Signature: ________________________________  Date:  XXX
## Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

### Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Input of Data:</strong></td>
</tr>
<tr>
<td>1</td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet . 3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. The difference can be entered into the highlighted cell of the spreadsheet . 3.4</td>
</tr>
<tr>
<td></td>
<td>c. The name of the variables can be entered into the highlighted cell of the spreadsheet . 3.5</td>
</tr>
<tr>
<td></td>
<td>d. The data can be entered into the highlighted cells of the spreadsheet . 3.5, 3.6, 3.7 – all data cells used</td>
</tr>
<tr>
<td></td>
<td>e. Only the highlighted yellow cells can be changed . 3.1</td>
</tr>
<tr>
<td></td>
<td><strong>Data Checking:</strong></td>
</tr>
<tr>
<td>2</td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no equivalence intervals or tests are shown. An error message is displayed . 3.2, 3.3 – covers both sides</td>
</tr>
<tr>
<td></td>
<td>b. Unless the difference is &gt; 0%, no equivalence intervals or tests are shown. An error message is displayed . 3.4</td>
</tr>
<tr>
<td></td>
<td>c. Only valid numbers in the data fields are used . 3.5</td>
</tr>
<tr>
<td></td>
<td>d. If no valid data is entered, the sample sizes are zero and no results are shown. An error message is displayed . 3.5</td>
</tr>
<tr>
<td></td>
<td>e. If there is a single valid data point in one of the groups, the sample size is one and only the averages and difference are shown. An error message is displayed . 3.6</td>
</tr>
<tr>
<td></td>
<td>f. For valid input with at least two data points and non-zero standard deviation, the sample sizes, averages, standard deviations, difference and equivalence intervals and tests are displayed. An error message is displayed . 3.7</td>
</tr>
</tbody>
</table>
| 3 | Results for valid input:  
a. For valid input with at least two data points and non-zero standard deviation, the sample sizes, averages, standard deviations, difference and confidence intervals are displayed.  
4.1, 4.2 |
|---|---|
| 4 | Tabs:  
a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.  
5.1 |
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as shown in Appendix A and B of STAT-16.

Equivalence Test: Mean(Strength - New) - Mean(Strength - Old)
(LEL = Lower Equivalence Limit, UEL = Upper Equivalence Limit)

95% CI for Equivalence of Mean(Strength - New) and Mean(Strength - Old): (-0.039602, 1.5176)
CI is within the equivalence interval of [-2, 2]. Can claim equivalence.

Test: Mean(Strength - New) - Mean(Strength - Old) > Lower Limit

95% Lower bound for Mean(Strength - New) - Mean(Strength - Old): -0.039602
Lower bound is greater than -2. Can claim Mean(Strength - New) - Mean(Strength - Old) > -2.
Test: Mean(Strength - New) - Mean(Strength - Old) < Upper Limit

95% Upper bound for Mean(Strength - New) - Mean(Strength - Old): 1.5176
Upper bound is less than 2. Can claim Mean(Strength - New) - Mean(Strength - Old) < 2.

### Two-Sample T-Test and CI: Strength - New, Strength - Old

#### Descriptive Statistics

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>Std Dev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength - New</td>
<td>20</td>
<td>10.11</td>
<td>1.52</td>
<td>0.34</td>
</tr>
<tr>
<td>Strength - Old</td>
<td>20</td>
<td>9.37</td>
<td>1.39</td>
<td>0.31</td>
</tr>
</tbody>
</table>

#### Estimation for Difference

Difference: 0.739 (95% CI for Difference)

- If the alternative "≠" is selected, the following output appears in the Session window. With 95% confidence, the difference is between -0.196 and 1.674.

#### Two-Sample T-Test and CI: Strength - New, Strength - Old

#### Descriptive Statistics

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>Std Dev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength - New</td>
<td>20</td>
<td>10.11</td>
<td>1.52</td>
<td>0.34</td>
</tr>
<tr>
<td>Strength - Old</td>
<td>20</td>
<td>9.37</td>
<td>1.39</td>
<td>0.31</td>
</tr>
</tbody>
</table>

#### Estimation for Difference

Difference: 0.739 (95% Lower Bound for Difference)

- If the alternative "<" is selected, the following output appears in the Session window. With 95% confidence, the difference is less than 0.040.

#### Two-Sample T-Test and CI: Strength - New, Strength - Old

#### Descriptive Statistics

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>Std Dev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength - New</td>
<td>20</td>
<td>10.11</td>
<td>1.52</td>
<td>0.34</td>
</tr>
<tr>
<td>Strength - Old</td>
<td>20</td>
<td>9.37</td>
<td>1.39</td>
<td>0.31</td>
</tr>
</tbody>
</table>

#### Estimation for Difference

Difference: 0.739 (95% Upper Bound for Difference)

- If the alternative "≤" is selected, the following output appears in the Session window. With 95% confidence, the difference is less than 1.518.
Appendix B

File: STAT-12 to 16 - Tab 12  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   About
   Windows 10

   Alienware 17 R3
   PC name Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

   Edition Windows 10 Home
   Version 1703
   OS Build 15063.674
   Product ID 00325-95916-23031-AAOEM
   Processor Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz
   Installed RAM 16.0 GB (15.9 GB usable)
   System type 64-bit operating system, x64-based processor
   Pen and touch No pen or touch input is available for this display

   1.3. Capture a screen shot showing the version of Excel used

   | Product ID: 00351-70007-85073-AA024 |
   | Session ID: 1366EC0D-4501-48D2-AC70-DB60A572FDFC |

   About Microsoft® Excel® 2016
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive.Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
3. Check for Valid Parameters

3.1. Go to the 2 Averages - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/25/17
3.2. Change cell E6 to “49.99”, cell B11 to 1, B12 to 2, cell C11 to 1 and C12 to 2 (Req. 1a, 2a).

Acceptance Criteria: Both sample sizes are 2
Both averages are 1.5
Both standard deviations round to 0.7071.
The difference is zero.
No equivalent limits and tests are displayed.
An error message is shown.

Pass or Fail: Pass   Initials: WT   Date: 11/25/17
3.3. Change cell E6 to “100” (Req. 1a, 2a).

<table>
<thead>
<tr>
<th>Comparison Group</th>
<th>Reference Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Acceptance Criteria:
- Both sample sizes are 2
- Both averages are 1.5
- Both standard deviations round to 0.7071.
- The difference is zero.
- No equivalent limits and tests are displayed.
- An error message is shown.

Pass or Fail: Pass  
Initials: WY  
Date: 11/25/17
3.4. Change cell E6 to “95” and cell E8 to “0” (Req. 1b, 2b).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference for Determining If Equivalent</td>
<td>0</td>
<td>Data &gt; 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comparison Group</th>
<th>Reference Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size 2</td>
<td>2</td>
</tr>
<tr>
<td>Average 1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Standard Deviation 0.7071</td>
<td>0.7071</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reference Group</th>
<th>Comparison Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size 2</td>
<td>2</td>
</tr>
<tr>
<td>Average 1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Standard Deviation 0.7071</td>
<td>0.7071</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Difference</th>
<th>0</th>
</tr>
</thead>
</table>

Acceptance Criteria:
Both sample sizes are 2
Both averages are 1.5
Both standard deviations round to 0.7071.
The difference is zero.
Equivalence limits are shown.
No conclusions are shown.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/25/17
3.5. Change cell E8 to “2”, cell B11 to “A”, cell B12 to “1..1”, cell B10 to “Strength - New”, cell C11 to “A”, cell C12 to “1..1” and cell C10 to “Strength - Old” (Req. 1c, 1d, 2c, 2d).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY

**STAT-16, Statistical Techniques for Equivalence Testing**

**Appendix B: Equivalence Test for Two Averages**

<table>
<thead>
<tr>
<th>Strength - New</th>
<th>Strength - Old</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength - New</td>
<td>Delta</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample Size</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difference (Strength - New - Strength - Old)</td>
<td>Difference</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Sided Case - Equivalence Interval</td>
<td>Lower Bound</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Bound</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower 1 Sided Case - Lower Equivalence Bound</td>
<td>Lower Bound</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper 1 Sided Case - Upper Equivalence Bound</td>
<td>Upper Bound</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Acceptance Criteria: The sample sizes are 0. No estimates, equivalence limits and tests are displayed. The name of the variables are displayed above the results. An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/25/17
3.6. Change cell B13 to “1” and cell C13 to “1” (Req. 1d, 2e).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**APPENDIX B: EQUIVALENCE TEST FOR TWO AVERAGES**

<table>
<thead>
<tr>
<th>Strength - New</th>
<th>Strength - Old</th>
</tr>
</thead>
<tbody>
<tr>
<td>New</td>
<td>Old</td>
</tr>
<tr>
<td>New</td>
<td>Old</td>
</tr>
<tr>
<td>New</td>
<td>Old</td>
</tr>
<tr>
<td>New</td>
<td>Old</td>
</tr>
<tr>
<td>New</td>
<td>Old</td>
</tr>
<tr>
<td>New</td>
<td>Old</td>
</tr>
</tbody>
</table>

**Acceptance Criteria:**
- The sample sizes are 1.
- The averages are 1.
- The difference is 0.
- No standard deviation, equivalence limits and test are displayed.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/25/17
3.7. Copy cell B13 into cells B14 to B210 and copy cell C13 into cells C14 to C210 (Req. 1d, 2f).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY

**STAT-16, Statistical Techniques for Equivalence Testing**  
**Appendix B: Equivalence Test for Two Averages**

<table>
<thead>
<tr>
<th>Strength - New</th>
<th>Strength - Old</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3</td>
<td>1.3</td>
</tr>
<tr>
<td>1.2</td>
<td>1.1</td>
</tr>
<tr>
<td>1.1</td>
<td>1.0</td>
</tr>
<tr>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>2.0</td>
<td>2.0</td>
</tr>
</tbody>
</table>

**Confidence Level:** 95%  
50 ≤ Conf < 100  

**Difference for Determining if Equivalent:**  
Delta > 0

**Strength - New**
- Sample Size: 198
- Average: 1
- Standard Deviation: 0

**Strength - Old**
- Sample Size: 198
- Average: 1
- Standard Deviation: 0

**Difference (Strength - New - Strength - Old)**
- Difference: 0

**2-Sided Case - Equivalence Interval**
- Lower Bound
- Upper Bound

**Lower 1-Sided Case - Lower Equivalence Bound**
- Lower Bound

**Upper 1-Sided Case - Upper Equivalence Bound**
- Upper Bound

**Acceptance Criteria:**  
The sample sizes are 198.  
The averages are 1  
The standard deviations are 0.  
The difference is zero.  
No equivalence limits and tests are displayed.  
An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/25/17
4. Results for valid input

4.1. Delete cells B11 to B210 and C11 to C210. Copy cells C69:D88 from the example data set tab to cell B11. (Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side equivalence limits for the average round to -0.039602 and 1.5176.
The upper equivalence limit for the average rounds to 1.5176.
The lower equivalence limit for the average rounds to -0.039602.
Equivalence statements for the three cases are shown with the same values.
All three cases pass.

Pass or Fail: Pass  Initials: WT  Date: 11/25/17
4.2. Change cell E8 to “0.02” (Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side equivalence limits for the average round to -0.039602 and 1.5176.
The upper equivalence limit for the average rounds to 1.5176.
The lower equivalence limit for the average rounds to -0.039602.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass
Initials: WT
Date: 11/25/17
5. Independence of tab

5.1. Copy the 2 Averages – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side equivalence limits for the average round to -0.039602 and 1.5176.
The upper equivalence limit for the average rounds to 1.5176.
The lower equivalence limit for the average rounds to -0.039602.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass  Initials: WT  Date: 11/25/17
6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass?   |   yes   |   no
       X

   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 12 Windows 10.doc
       Data of File: 25 November 2017

       Signature: ________________________________ Date: 11/25/17
Appendix C

File: STAT-12 to 16 - Tab 12  Windows 7
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

![Gateway Computer](image-url)
1.2. Capture a screen shot showing the operating system including version number

![Windows 7 Professional](image)

**System**
- Rating: 5.5 Your Windows Experience Index needs to be refreshed
- Processor: Intel(R) Core(TM) 2 Duo CPU P8400 @ 2.26GHz 2.27 GHz
- Installed memory (RAM): 4.00 GB
- System type: 64-bit Operating System
- Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

![Microsoft Excel Version](image)
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
Pass or Fail: Pass  Initials: WT  Date: 11/14/17
3. Check for Valid Parameters

3.1. Go to the 2 Averages - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17
3.2. Change cell E6 to “49.99”, cell B11 to 1, B12 to 2, cell C11 to 1 and C12 to 2 (Req. 1a, 2a).

<table>
<thead>
<tr>
<th></th>
<th>Comparison Group</th>
<th>Reference Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Average</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.7071</td>
<td>0.7071</td>
</tr>
</tbody>
</table>

Acceptance Criteria: Both sample sizes are 2
Both averages are 1.5
Both standard deviations round to 0.7071.
The difference is zero.
No equivalent limits and tests are displayed.
An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/14/17
3.3. Change cell E6 to “100” (Req. 1a, 2a).

### Acceptance Criteria:
- Both sample sizes are 2
- Both averages are 1.5
- Both standard deviations round to 0.7071.
- The difference is zero.
- No equivalent limits and tests are displayed.
- An error message is shown.

### Pass or Fail:
- Pass

### Initials:
- WT

### Date:
- 11/14/17
3.4. Change cell E6 to “95” and cell E8 to “0” (Req. 1b, 2b).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-156, Statistical Techniques for Equivalence Testing**

**Appendix B: Equivalence Test for Two Averages**

Confidence Level: 95%

<table>
<thead>
<tr>
<th>Difference for Determining if Equivalent</th>
<th>Delta &gt; 0</th>
<th>Delta &lt; 0</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Reference Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>*</td>
<td></td>
</tr>
</tbody>
</table>

Acceptance Criteria:
- Both sample sizes are 2
- Both averages are 1.5
- Both standard deviations round to 0.7071.
- The difference is zero.
- Equivalence limits are shown.
- No conclusions are shown.
- An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17
3.5. Change cell E8 to “2”, cell B11 to “A”, cell B12 to “1..1”, cell B10 to “Strength - New”, cell C11 to “A”, cell C12 to “1..1” and cell C10 to “Strength - Old” (Req. 1c, 1d, 2c, 2d).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY

**STAT-16, Statistical Techniques for Equivalence Testing**  
Appendix B: Equivalence Test for Two Averages

<table>
<thead>
<tr>
<th></th>
<th>47.5</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Confidence Level:</strong></td>
<td>95%</td>
<td>Delta &gt; 0</td>
</tr>
<tr>
<td><strong>Difference for Determining if Equivalent:</strong></td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Strength - New</th>
<th>Strength - Old</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>4.1</td>
</tr>
</tbody>
</table>

- **Strength - New**
  - Sample Size: 0
  - Average
  - Standard Deviation

- **Strength - Old**
  - Sample Size: 0
  - Average
  - Standard Deviation

<table>
<thead>
<tr>
<th>Difference (Strength - New - Strength - Old)</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Sided Case - Equivalence Interval</td>
<td></td>
</tr>
<tr>
<td>Lower Bound</td>
<td></td>
</tr>
<tr>
<td>Upper Bound</td>
<td></td>
</tr>
<tr>
<td>Lower 1-Sided Case - Lower Equivalence Bound</td>
<td></td>
</tr>
<tr>
<td>Lower Bound</td>
<td></td>
</tr>
<tr>
<td>Upper 1-Sided Case - Upper Equivalence Bound</td>
<td></td>
</tr>
<tr>
<td>Upper Bound</td>
<td></td>
</tr>
</tbody>
</table>

Acceptance Criteria: The sample sizes are 0.  
No estimates, equivalence limits and tests are displayed.  
The name of the variables are displayed above the results.  
An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: Pass
3.6. Change cell B13 to “1” and cell C13 to “1” (Req. 1d, 2e).

Acceptance Criteria: The sample sizes are 1. The averages are 1. The difference is 0. No standard deviation, equivalence limits and test are displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/14/17
3.7. Copy cell B13 into cells B14 to B210 and copy cell C13 into cells C14 to C210 (Req. 1d, 2f).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-16, Statistical Techniques for Equivalence Testing**

Appendix B: Equivalence Test for Two Averages

<table>
<thead>
<tr>
<th>Strength - New</th>
<th>Strength - Old</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

- **Confidence Level:**
  - 95% 50% Conf < 100
- **Difference for Determining if Equivalent:**
  - Delta > 0

**Strength - New**

- **Sample Size:** 198
- **Average:** 1
- **Standard Deviation:** 0

**Strength - Old**

- **Sample Size:** 198
- **Average:** 1
- **Standard Deviation:** 0

**Difference** (Strength - New - Strength - Old)

- **Difference:** 0

**2-Sided Case - Equivalence Interval**

- **Lower Bound**
- **Upper Bound**

**Lower 1-Sided Case - Lower Equivalence Bound**

- **Lower Bound**

**Upper 1-Sided Case - Upper Equivalence Bound**

- **Upper Bound**

Acceptance Criteria:

- The sample sizes are 198.
- The averages are 1
- The standard deviations are 0.
- The difference is zero.
- No equivalence limits and tests are displayed.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/14/17
4. Results for valid input

4.1. Delete cells B11 to B210 and C11 to C210. Copy cells C69:D88 from the example data set tab to cell B11. (Req. 3a).

Acceptance Criteria:

The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side equivalence limits for the average round to -0.039602 and 1.5176.
The upper equivalence limit for the average rounds to 1.5176.
The lower equivalence limit for the average rounds to -0.039602.
Equivalence statements for the three cases are shown with the same values.
All three cases pass.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17
4.2. Change cell E8 to “0.02” (Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side equivalence limits for the average round to -0.039602 and 1.5176.
The upper equivalence limit for the average rounds to 1.5176.
The lower equivalence limit for the average rounds to -0.039602.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass    Initials: WT    Date: 11/14/17
5. Independence of tab

5.1. Copy the 2 Averages – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample sizes are 20.
The first average rounds to 10.11.
The second average rounds to 9.37.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The difference rounds to 0.739.
The two-side equivalence limits for the average round to -0.039602 and 1.5176.
The upper equivalence limit for the average rounds to 1.5176.
The lower equivalence limit for the average rounds to -0.039602.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass    Initials: WT    Date: 11/14/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop
   was taken instead.

7. Saving and Signing File
   7.1. Determine if all tests passed
   All Test Cases for Computer Pass?  X  yes  no

   7.2. Save File and show name and date.
   Name of File:  STAT-12 to 16 - Tab 12 Windows 7.doc
   Data of File:  November 14, 2017

   Signature:  [Signature]  Date:  11/14/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages Paired – CI Tab

Protocol Number: TE-17-14

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 28, 2017
November 28, 2017
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
2 Averages Paired – CI Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages Paired – CI tab, this spreadsheet performs confidence intervals for the difference between two averages when observations are paired. It is described in Appendix C of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix C also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol
Protocol Number: TE-17-14, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 2 Averages Paired – CI Tab was written to validate 2 Averages Paired – CI tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing
The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 13 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 13 Windows 7. It is included as Appendix C.

4.0 Test Results
All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages Paired – CI Tab

Protocol Number: TE-17-14
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages Paired – CI Tab

Protocol Number: TE-17-14

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 11, 2017
Date
1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages Paired – CI tab, this spreadsheet performs confidence intervals for the difference between two averages when observations are paired. It is described in Appendix C of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix C also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
## 2.0 Requirements

Table 1 lists the user requirements to be validated.

### Table 1: User Requirements for the 2 Averages Paired – CI tab of STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. The name of the variable can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>c. The data can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Only valid numbers in the data fields are used.</td>
</tr>
<tr>
<td></td>
<td>c. If no valid data is entered, the sample size is zero and no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>d. If there is a single valid pair of data point in one of the groups, the sample size is one and only the average difference is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>e. If there are two or more valid pairs of data but the standard deviation of the differences is zero, the sample size, average difference and standard deviation of the differences are shown but no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input with at least two pairs of data and non-zero standard deviation of the differences, the sample size, average difference, standard deviation of the differences and confidence intervals are displayed.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-16 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
   Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
   Pass or Fail: XXXX  Initials: XXX  Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 2 Averages Paired - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).
       <Insert screen shot here>
   Acceptance Criteria: Each time a message should be displayed that the cell is protected.
   Pass or Fail: XXXX  Initials: XX  Date: XXX
   3.2. Change cell D6 to “49.99”, cell C9 to 1, C10 to 2, cell D9 to 2 and D10 to 1 (Req. 1a, 2a).
       <Insert screen shot here>
   Acceptance Criteria: The sample size is 2.
The average difference is 0.
The standard deviation of the differences rounds to 1.414.
No confidence limits or statements are displayed.
An error message is shown.
   Pass or Fail: XXXX  Initials: XX  Date: XXX
   3.3. Change cell D6 to “100” (Req. 1a, 2a).
       <Insert screen shot here>
   Acceptance Criteria: The sample size is 2.
The average difference is 0.
The standard deviation of the differences rounds to 1.414.
No confidence limits or statements are displayed.
An error message is shown.
3.4. Change cell D6 to “95”, cell C9 to “A”, cell C10 to “1”, cell D8 to “Old Method”, cell D9 to “1”, cell D10 to “1..1” and cell D8 to “New Method” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample size is 0.
No estimates, confidence limits or statements are displayed.
The name of the variables are displayed next to the difference header.
An error message is shown.

3.5. Change cell C11 to “1” and cell D11 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.
The average difference is 0.
No standard deviation of the differences, confidence limits or statements are displayed.
An error message is shown.

3.6. Copy cell C11 into cells C12 to C208 and copy cell D11 into cells D12 to D208. Enter A into cells B9 to B208. (Req. 1c, 2e).

Acceptance Criteria: The sample sizes are 198.
The average difference is 0.
The standard deviation of the differences is 0.
No confidence limits or statements are displayed.
An error message is shown.

4. Results for valid input

4.1. Delete cells B9 to B208, C9 to C208 and D9 to D208. Copy cells C95:E114 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample size is 20.
The average difference rounds to 0.00160.
The standard deviation of the differences rounds to 0.01708.
The two-side confidence limits for the average round to -0.00640 and 0.00960.
The upper confidence limit for the average rounds to 0.00821.
The lower confidence limit for the average rounds to -0.00501.
Confidence statements for the three cases are shown with the same values.

5. Independence of tab

5.1. Copy the 2 Averages Paired – CI tab. Delete all tabs but the copy. (Req. 4a)
Acceptance Criteria: The sample size is 20.
The average difference rounds to 0.00160.
The standard deviation of the differences rounds to 0.01708.
The two-side confidence limits for the average round to -0.00640 and 0.00960.
The upper confidence limit for the average rounds to 0.00821.
The lower confidence limit for the average rounds to -0.00501.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: XXXX Initials: XX Date: XXX

6. Comments
6.1. None

7. Saving and Signing File
7.1. Determine if all tests passed
    All Test Cases for Computer Pass? yes no

7.2. Save File and show name and date.
    Name of File:
    Data of File:
    Signature: ________________________________ Date: XXX
# Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

## Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Input of Data:</strong></td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet 3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. The name of the variable can be entered into the highlighted cell of the spreadsheet. 3.4</td>
</tr>
<tr>
<td></td>
<td>c. The data can be entered into the highlighted cells of the spreadsheet. 3.4, 3.5, 3.6 – all data cells used</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed. 3.1</td>
</tr>
<tr>
<td>2</td>
<td><strong>Data Checking:</strong></td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no confidence intervals are shown. An error message is displayed. 3.2, 3.3 – covers both sides</td>
</tr>
<tr>
<td></td>
<td>b. Only valid numbers in the data fields are used. 3.4</td>
</tr>
<tr>
<td></td>
<td>c. If no valid data is entered, the sample size is zero and no results are shown. An error message is displayed. 3.4</td>
</tr>
<tr>
<td></td>
<td>d. If there is a single valid pair of data point in one of the groups, the sample size is one and only the average difference is shown. An error message is displayed. 3.5</td>
</tr>
<tr>
<td></td>
<td>e. If there are two or more valid pairs of data but the standard deviation of the differences is zero, the sample size, average difference and standard deviation of the differences are shown but no confidence intervals are shown. An error message is displayed. 3.6</td>
</tr>
<tr>
<td>3</td>
<td><strong>Results for valid input:</strong></td>
</tr>
<tr>
<td></td>
<td>a. For valid input with at least two pairs of data and non-zero standard deviation of the differences, the sample size, average difference, standard deviation of the differences and confidence intervals are displayed. 4.1</td>
</tr>
<tr>
<td>4</td>
<td><strong>Tabs:</strong></td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same. 5.1</td>
</tr>
</tbody>
</table>
4.1 From Minitab version 18.0 as shown in Appendix C of STAT-16.

If the alternative “≠” is selected, the following output appears in the Session window. With 95% confidence, the difference is between -0.00640 and 0.00960.

**Paired T-Test and CI: New Method, Old Method**

**Descriptive Statistics**

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Method</td>
<td>20</td>
<td>1.00545</td>
<td>0.02091</td>
<td>0.00468</td>
</tr>
<tr>
<td>Old Method</td>
<td>20</td>
<td>1.00385</td>
<td>0.02307</td>
<td>0.00516</td>
</tr>
</tbody>
</table>

**Estimation for Paired Difference**

<table>
<thead>
<tr>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
<th>95% CI for μ difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00160</td>
<td>0.01708</td>
<td>0.00382</td>
<td>(-0.00640, 0.00960)</td>
</tr>
</tbody>
</table>

μ difference: mean of (New Method - Old Method)

If the alternative “>” is selected, the following output appears in the Session window. With 95% confidence, the difference is greater than -0.00501.

**Paired T-Test and CI: New Method, Old Method**

**Descriptive Statistics**

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Method</td>
<td>20</td>
<td>1.00545</td>
<td>0.02091</td>
<td>0.00468</td>
</tr>
<tr>
<td>Old Method</td>
<td>20</td>
<td>1.00385</td>
<td>0.02307</td>
<td>0.00516</td>
</tr>
</tbody>
</table>

**Estimation for Paired Difference**

<table>
<thead>
<tr>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
<th>95% Lower Bound for μ difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00160</td>
<td>0.01708</td>
<td>0.00382</td>
<td>(-0.00501)</td>
</tr>
</tbody>
</table>

μ difference: mean of (New Method - Old Method)

If the alternative “<” is selected, the following output appears in the Session window. With 95% confidence, the difference is less than 0.00821.

**Paired T-Test and CI: New Method, Old Method**

**Descriptive Statistics**

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Method</td>
<td>20</td>
<td>1.00545</td>
<td>0.02091</td>
<td>0.00468</td>
</tr>
<tr>
<td>Old Method</td>
<td>20</td>
<td>1.00385</td>
<td>0.02307</td>
<td>0.00516</td>
</tr>
</tbody>
</table>

**Estimation for Paired Difference**

<table>
<thead>
<tr>
<th>Mean</th>
<th>StDev</th>
<th>SE Mean</th>
<th>95% Upper Bound for μ difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00160</td>
<td>0.01708</td>
<td>0.00382</td>
<td>0.00821</td>
</tr>
</tbody>
</table>

μ difference: mean of (New Method - Old Method)
Appendix B

File: STAT-12 to 16 - Tab 13  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   ![](image1)

   Alienware 17 R3
   PC name Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

<table>
<thead>
<tr>
<th>Edition</th>
<th>Windows 10 Home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>1703</td>
</tr>
<tr>
<td>OS Build</td>
<td>15063.674</td>
</tr>
<tr>
<td>Product ID</td>
<td>00325-95916-23031-AAOEM</td>
</tr>
<tr>
<td>Processor</td>
<td>Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz</td>
</tr>
<tr>
<td>Installed RAM</td>
<td>16.0 GB (15.9 GB usable)</td>
</tr>
<tr>
<td>System type</td>
<td>64-bit operating system, x64-based processor</td>
</tr>
<tr>
<td>Pen and touch</td>
<td>No pen or touch input is available for this display</td>
</tr>
</tbody>
</table>

   1.3. Capture a screen shot showing the version of Excel used

   ![](image2)
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass Initials: WT Date: 11/26/17
3. Check for Valid Parameters

3.1. Go to the 2 Averages Paired - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/26/17
3.2. Change cell D6 to “49.99”, cell C9 to 1, C10 to 2, cell D9 to 2 and D10 to 1 (Req. 1a, 2a).

### Acceptance Criteria:
- The sample size is 2.
- The average difference is 0.
- The standard deviation of the differences rounds to 1.414.
- No confidence limits or statements are displayed.
- An error message is shown.

### Pass or Fail
- **Pass**
- **Initials:** WT
- **Date:** 11/26/17

3.3. Change cell D6 to “100” (Req. 1a, 2a).

### Acceptance Criteria:
- The sample size is 2.
- The average difference is 0.
- The standard deviation of the differences rounds to 1.414.
- No confidence limits or statements are displayed.
- An error message is shown.

### Pass or Fail
- **Pass**
- **Initials:** WT
- **Date:** 11/26/17
3.4. Change cell D6 to “95”, cell C9 to “A”, cell C10 to “1”, cell C8 to “New Method”, cell D9 to “1”, cell D10 to “1..1” and cell D8 to “Old Method” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample size is 0.
No estimates, confidence limits or statements are displayed.
The name of the variables are displayed next to the difference header.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: XXX
3.5. Change cell C11 to “1” and cell D11 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample size is 1.
The average difference is 0.
No standard deviation of the differences, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass    Initials: WT    Date: 11/26/17
3.6. Copy cell C11 into cells C12 to C208 and copy cell D11 into cells D12 to D208. Enter A into cells B9 to B208. (Req. 1c, 2e).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-16, Statistical Techniques for Equivalence Testing**

**Appendix C: Confidence Limits for the Difference between Two Averages - Paired Data**

<table>
<thead>
<tr>
<th>Unit</th>
<th>New Method</th>
<th>Old Method</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Acceptance Criteria:
- The sample sizes are 198.
- The average difference is 0.
- The standard deviation of the differences is 0.
- No confidence limits or statements are displayed.
- An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/26/17
4. Results for valid input

4.1. Delete cells B9 to B208, C9 to C208 and D9 to D208. Copy cells C95:E114 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria:
The sample size is 20.
The average difference rounds to 0.00160.
The standard deviation of the differences rounds to 0.01708.
The two-side confidence limits for the average round to -0.00640 and 0.00960.
The upper confidence limit for the average rounds to 0.00821.
The lower confidence limit for the average rounds to -0.00501.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass Initials: WT Date: 11/26/17
5. Independence of tab

5.1. Copy the 2 Averages Paired – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 20.
The average difference rounds to 0.00160.
The standard deviation of the differences rounds to 0.01708.
The two-side confidence limits for the average round to -0.00640 and 0.00960.
The upper confidence limit for the average rounds to 0.00821.
The lower confidence limit for the average rounds to -0.00501.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/26/17

6. Comments

6.1. None

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass?   X yes   no

7.2. Save File and show name and date.

Name of File: STAT-12 to 16 - Tab 13 Windows 10.doc

Data of File: November 26, 2017

Signature: ________________________________ Date: 11/26/17
Appendix C

File: STAT-12 to 16 - Tab 13  Windows 7
Appendix A: Test Script

1. Document System Used

1.1. Capture a screen shot showing the computer make and model
1.2. Capture a screen shot showing the operating system including version number

Windows edition

Windows 7 Professional
Copyright © 2009 Microsoft Corporation. All rights reserved.
Service Pack 1
Get more features with a new edition of Windows 7

System

Rating: 5.5 Your Windows Experience Index needs to be refreshed
Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHz
Installed memory (RAM): 4.00 GB
System type: 64-bit Operating System
Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

About Microsoft Office Excel

Microsoft Office Excel 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
Fort of Microsoft Office Professional 2007
© 2006 Microsoft Corporation. All rights reserved.


This product is licensed to:
Wayne Taylor
Taylor Enterprises, Inc.
Product ID: 81605-903-7132834-65427

View the Microsoft Software License Terms

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.

OK
System Info...
Tech Support...
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/ equivalence_tests.html](http://www.variation.com/procedures/ equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass   Initials: WT   Date: 11/14/17
3. Check for Valid Parameters

3.1. Go to the 2 Averages Paired - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass Initials: WT Date: 11/14/17

3.2. Change cell D6 to “49.99”, cell C9 to 1, C10 to 2, cell D9 to 2 and D10 to 1 (Req. 1a, 2a).

Acceptance Criteria: The sample size is 2.
The average difference is 0.
The standard deviation of the differences rounds to 1.414.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/14/17
3.3. Change cell D6 to “100” (Req. 1a, 2a).

Acceptance Criteria:  
The sample size is 2.
The average difference is 0.
The standard deviation of the differences rounds to 1.414.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/14/17

3.4. Change cell D6 to “95”, cell C9 to “A”, cell C10 to “1”, cell C8 to “New Method”, cell D9 to “1”, cell D10 to “1...1” and cell D8 to “Old Method” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria:  
The sample size is 0.
No estimates, confidence limits or statements are displayed.
The name of the variables are displayed next to the difference header.
An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/14/17
3.5. Change cell C11 to “1” and cell D11 to “1” (Req. 1c, 2d).

<table>
<thead>
<tr>
<th>Unit</th>
<th>New Method</th>
<th>Old Method</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1</td>
<td>1.1</td>
<td>0</td>
</tr>
</tbody>
</table>

Acceptance Criteria: The sample size is 1.
The average difference is 0.
No standard deviation of the differences, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17
3.6. Copy cell C11 into cells C12 to C208 and copy cell D11 into cells D12 to D208. Enter A into cells B9 to B208. (Req. 1c, 2e).

Acceptance Criteria: The sample sizes are 198.
The average difference is 0.
The standard deviation of the differences is 0.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17
4. Results for valid input

4.1. Delete cells B9 to B208, C9 to C208 and D9 to D208. Copy cells C95:E114 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample size is 20.
- The average difference rounds to 0.00160.
- The standard deviation of the differences rounds to 0.01708.
- The two-side confidence limits for the average round to -0.00640 and 0.00960.
- The upper confidence limit for the average rounds to 0.00821.
- The lower confidence limit for the average rounds to -0.00501.
- Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
5. Independence of tab

5.1. Copy the 2 Averages Paired – CI tab. Delete all tabs but the copy. (Req. 4a)

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Average Difference</th>
<th>Standard Deviation</th>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>0.00160</td>
<td>0.01708</td>
<td>-0.00640</td>
<td>0.00821</td>
</tr>
</tbody>
</table>

Acceptance Criteria: The sample size is 20. The average difference rounds to 0.00160. The standard deviation of the differences rounds to 0.01708. The two-side confidence limits for the average round to -0.00640 and 0.00960. The upper confidence limit for the average rounds to 0.00821. The lower confidence limit for the average rounds to -0.00501. Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass    Initials: WT    Date: 11/14/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass?  X yes  no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 13 Windows 7.doc
       Data of File: November 14, 2017

       Signature: ________________________________ Date: 11/14/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages Paired – n Tab

Protocol Number: TE-17-15

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

___________________________________         November 28, 2017
Study Director

___________________________________         November 28, 2017
President
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
2 Averages Paired – n Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages Paired – n tab, this spreadsheet calculates sample sizes for a 2-sample equivalence test for the average. It is described in Appendix D of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix D also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-15, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 2 Averages Paired – n Tab was written to validate 2 Averages Paired – n tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 14 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 14 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages Paired – n Tab

Protocol Number: TE-17-15
Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages Paired – n Tab

Protocol Number: TE-17-15

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 11, 2017
Date
Validation Protocol for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
2 Averages Paired – n Tab

Protocol Number: TE-17-15

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages Paired – n tab, this spreadsheet calculates sample sizes for a 2-sample equivalence test for the average. It is described in Appendix D of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix D also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

Table 1: User Requirements for the 2 Averages Paired – n tab of
STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. $\Delta_{RQL}$ can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>c. $\Delta_{AQL}$ can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>d. The standard deviation of the differences can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>e. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is $\geq50%$ and $&lt;100%$, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Unless $\Delta_{RQL}$ and $\Delta_{AQL}$ are valid numbers and $\Delta_{RQL} &gt; \Delta_{AQL} \geq 0$, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>c. Unless $\sigma$ is a valid number and $\sigma &gt; 0$, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input, the sample size is displayed.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-16 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX Initials: XXX Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 2 Averages Paired - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).
       <Insert screen shot here>
       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX Initials: XXX Date: XXX
   3.2. Change cell C6 to “49.99”, cell C8 to 0.02, cell C10 to 0.005 and C12 to 0.02 (Req. 1a-d, 2a).
       <Insert screen shot here>
       Acceptance Criteria: The sample size is not displayed.
       An error message is shown.
       Pass or Fail: XXXX Initials: XXX Date: XXX
   3.3. Change cell C6 to “100” (Req. 1a, 2a).
       <Insert screen shot here>
       Acceptance Criteria: The sample size is not displayed.
       An error message is shown.
       Pass or Fail: XXXX Initials: XXX Date: XXX
   3.4. Change cell C6 to “95” and cell C8 to “0.02” (Req. 1b, 2b).
       <Insert screen shot here>
Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX Initials: XXX Date: XXX

3.5. Change cell C8 to “0.02” and cell C10 to “0.005” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX Initials: XXX Date: XXX

3.6. Change cell C10 to “0.02” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX Initials: XXX Date: XXX

3.7. Change cell C10 to “-0.001” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX Initials: XXX Date: XXX

3.8. Change cell C10 to “0.005” and C12 to “0.02” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX Initials: XXX Date: XXX

3.9. Change cell C12 to “0” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX Initials: XXX Date: XXX

4. Results for valid input

4.1. Change cell C12 to “0.02” (Req. 3a).

Acceptance Criteria: The sample size is 21.

Pass or Fail: XXXX Initials: XXX Date: XXX

5. Independence of tab

5.1. Copy the 2 Averages Paired – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 21.

Pass or Fail: XXXX Initials: XXX Date: XXX
Acceptance Criteria: The sample size is 21.
Pass or Fail: XXXX  Initials: XXX  Date: XXX

6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
      All Test Cases for Computer Pass? yes no
   7.2. Save File and show name and date.
       Name of File:
       Data of File:

Signature: ________________________________ Date: XXX
Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is met with justification the test cases cover the requirement.

Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Input of Data:</td>
</tr>
<tr>
<td>1</td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet 3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. $\Delta_{RQL}$ can be entered into the highlighted cell of the spreadsheet 3.4</td>
</tr>
<tr>
<td></td>
<td>c. $\Delta_{AQL}$ can be entered into the highlighted cells of the spreadsheet. 3.5, 3.6</td>
</tr>
<tr>
<td></td>
<td>d. The standard deviation can be entered into the highlighted cells of the spreadsheet. 3.7, 3.8</td>
</tr>
<tr>
<td></td>
<td>e. Only the highlighted yellow cells can be changed. 3.1</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is $\geq$50% and $&lt;100%$, no sample size is shown. An error message is displayed. 3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. Unless $\Delta_{RQL}$ and $\Delta_{AQL}$ are valid numbers and $\Delta_{RQL} \geq \Delta_{AQL} \geq 0$, no sample size is shown. An error message is displayed. 3.4, 3.5, 3.6, 3.7</td>
</tr>
<tr>
<td></td>
<td>c. Unless $\sigma$ is a valid number and $\sigma &gt; 0$, no sample size is shown. An error message is displayed. 3.8, 3.9</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input, the sample size is displayed. 4.1</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same. 5.1</td>
</tr>
</tbody>
</table>
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as shown in Appendix D of STAT-16.
Appendix B

File: STAT-12 to 16 - Tab 14  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   ![About Windows 10]

   **Alienware 17 R3**
   PC name: Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

   - **Edition**: Windows 10 Home
   - **Version**: 1703
   - **OS Build**: 15063.674
   - **Product ID**: 00325-95916-23031-AAOEM
   - **Processor**: Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz
   - **Installed RAM**: 16.0 GB (15.9 GB usable)
   - **System type**: 64-bit operating system, x64-based processor
   - **Pen and touch**: No pen or touch input is available for this display

   1.3. Capture a screen shot showing the version of Excel used
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

---

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass  
Initials: WT  
Date: 11/27/17
3. Check for Valid Parameters

3.1. Go to the 2 Averages Paired - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/27/17
3.2. Change cell C6 to "49.99", cell C8 to 0.02, cell C10 to 0.005 and C12 to 0.02 (Req. 1a-d, 2a).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/27/17

3.3. Change cell C6 to "100" (Req. 1a, 2a).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/27/17
3.4. Change cell C6 to “95” and cell C8 to “0.02” (Req. 1b, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass  Initials:  WT  Date:  11/27/17

3.5. Change cell C8 to “0.02” and cell C10 to “0.005” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass  Initials:  WT  Date:  11/27/17
3.6. Change cell C10 to “0.02” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/27/17

3.7. Change cell C10 to “-0.001” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/27/17
3.8. Change cell C10 to “0.005” and C12 to “0.02” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/27/17

3.9. Change cell C12 to “0” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Passed Initials: WT Date: 11/27/17
4. Results for valid input

4.1. Change cell C12 to “0.02” (Req. 3a).

Acceptance Criteria: The sample size is 21.
Pass or Fail: Pass
Initials: WT
Date: 11/27/17
5. Independence of tab

5.1. Copy the 2 Averages Paired – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 21.
Pass or Fail: Pass Initials: WT Date: 11/27/17

6. Comments

6.1. None

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass? X yes no

7.2. Save File and show name and date.

Name of File: STAT-12 to 16 - Tab 14 Windows 10.doc
Data of File: November 27, 2017

Signature: ____________________________ Date: 11/27/17
Appendix C

File: STAT-12 to 16 - Tab 14  Windows 7
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

![Image of Gateway computer]
1.2. Capture a screen shot showing the operating system including version number

![Windows 7 Professional screen shot]

Rating: 5.5 Your Windows Experience Index needs to be refreshed
Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHz
Installed memory (RAM): 4.00 GB
System type: 64-bit Operating System
Pen and Touch: No Pen or Touch Input is available for this display

1.3. Capture a screen shot showing the version of Excel used

![Excel version screen shot]

Microsoft Office Excel 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
Part of Microsoft Office Professional 2007
© 2006 Microsoft Corporation. All rights reserved.

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

![Downloaded Spreadsheet](image1.png)

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

![Spreadsheet Section](image2.png)

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
3. Check for Valid Parameters

3.1. Go to the 2 Averages Paired - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.
Pass or Fail: Pass  Initials: WT  Date: 11/14/17

3.2. Change cell C6 to “49.99”, cell C8 to 0.02, cell C10 to 0.005 and C12 to 0.02 (Req. 1a-d, 2a).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass  Initials: WT  Date: 11/14/17
3.3. Change cell C6 to “100” (Req. 1a, 2a).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
<th>Chance of falling at ( \Delta_{AGL} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \Delta_{AGL} )</td>
<td>0.00</td>
<td>A difference that has a 95% chance of failing</td>
</tr>
<tr>
<td>( \Delta_{pg} )</td>
<td>0.005</td>
<td>A difference that has a 95% chance of passing</td>
</tr>
<tr>
<td>( \sigma )</td>
<td>0.02</td>
<td>Estimate of standard deviation of paired differences</td>
</tr>
</tbody>
</table>

Sample Size: This is the number of samples for each group for 95% confidence equivalence studies.

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17

3.4. Change cell C6 to “95” and cell C8 to “0.02” (Req. 1b, 2b).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
<th>Chance of falling at ( \Delta_{AGL} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \Delta_{AGL} )</td>
<td>0.02</td>
<td>A difference that has a 95% chance of failing</td>
</tr>
<tr>
<td>( \Delta_{pg} )</td>
<td>0.005</td>
<td>A difference that has a 95% chance of passing</td>
</tr>
<tr>
<td>( \sigma )</td>
<td>0.02</td>
<td>Estimate of standard deviation of paired differences</td>
</tr>
</tbody>
</table>

Sample Size: This is the number of samples for each group for 95% confidence equivalence studies.

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17

3.5. Change cell C8 to “0.02” and cell C10 to “0.005” (Req. 1c, 2b).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>95%</th>
<th>Chance of falling at ( \Delta_{AGL} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \Delta_{AGL} )</td>
<td>0.02</td>
<td>A difference that has a 95% chance of failing</td>
</tr>
<tr>
<td>( \Delta_{pg} )</td>
<td>0.005</td>
<td>A difference that has a 95% chance of passing</td>
</tr>
<tr>
<td>( \sigma )</td>
<td>0.02</td>
<td>Estimate of standard deviation of paired differences</td>
</tr>
</tbody>
</table>

Sample Size: This is the number of samples for each group for 95% confidence equivalence studies.

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
3.6. Change cell C10 to “0.02” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/14/17

3.7. Change cell C10 to “-0.001” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/14/17

3.8. Change cell C10 to “0.005” and C12 to “0.02” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/14/17
3.9. Change cell C12 to “0” (Req. 1d, 2c).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/14/17

4. Results for valid input

4.1. Change cell C12 to “0.02” (Req. 3a).

Acceptance Criteria: The sample size is 21.

Pass or Fail: Pass Initials: WT Date: 11/14/17
5. Independence of tab

5.1. Copy the 2 Averages Paired – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 21.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File
   7.1. Determine if all tests passed

   All Test Cases for Computer Pass?  X  yes  no

   7.2. Save File and show name and date.

   Name of File:  STAT-12 to 16 - Tab 14 Windows 7.doc
   Data of File:  November 14, 2017

   Signature:  ________________________________  Date:  11/14/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages Paired – Equivalence Tab

Protocol Number: TE-17-16

Approvals:

Dr. Wayne A. Taylor
Study Director
Date
November 28, 2017

Ann B. Taylor
President
Date
November 28, 2017
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages Paired – Equivalence Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages Paired – Equivalence tab, this spreadsheet performs equivalence intervals and tests for the difference between two averages when values are paired. It is described in Appendix D of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix D also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-16, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 2 Averages Paired – Equivalence Tab was written to validate 2 Averages Paired – Equivalence tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 15 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 15 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages Paired – Equivalence Tab

Protocol Number: TE-17-16
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Averages Paired – Equivalence Tab

Protocol Number: TE-17-16

Approvals:

Dr. Wayne A. Taylor
Study Director

November 14, 2017
Date

Ann B. Taylor
President

November 14, 2017
Date
Validation Protocol for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
2 Averages Paired – Equivalence Tab

Protocol Number: TE-17-16

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Averages Paired – Equivalence tab, this spreadsheet performs equivalence intervals and tests for the difference between two averages when values are paired. It is described in Appendix D of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix D also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

Table 1: User Requirements for the 2 Averages Paired – Equivalence tab of STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Input of Data:</strong></td>
</tr>
<tr>
<td>1</td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. The difference can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>c. The name of the variables can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>d. The data and labels can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>e. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td></td>
<td><strong>Data Checking:</strong></td>
</tr>
<tr>
<td>2</td>
<td>a. Unless the confidence level is $\geq 50%$ and $&lt; 100%$, no equivalence intervals or tests are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Unless the difference is $&gt; 0%$, no equivalence intervals or tests are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>c. Only valid pairs of numbers in the data fields are used.</td>
</tr>
<tr>
<td></td>
<td>d. If no valid pairs are entered, the sample size is zero and no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>e. If there is a single valid pair, the sample size is one and only the average difference is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>f. If there are two or more valid pairs but the standard deviation of the differences is zero, the sample size, average difference, and standard deviation of the differences are shown but no equivalence intervals or tests are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td><strong>Results for valid input:</strong></td>
</tr>
<tr>
<td>3</td>
<td>a. For valid input with at least two pairs and non-zero standard deviation, the sample size, average difference, standard deviation of the differences and equivalence intervals and tests are displayed.</td>
</tr>
<tr>
<td></td>
<td><strong>Tabs:</strong></td>
</tr>
<tr>
<td>4</td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-16 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX Initials: XXX Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 2 Averages Paired - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).
       <Insert screen shot here>
       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX Initials: XX Date: XXX
   3.2. Change cell E6 to “49.99”, cell C11 to 1, C12 to 2, cell D11 to 1 and D12 to 2 (Req. 1a, 2a).
       <Insert screen shot here>
       Acceptance Criteria: The sample size is 2
       The average difference is 0
       The standard deviation of the differences is 0.
       No equivalent limits and tests are displayed.
       An error message is shown.
       Pass or Fail: XXXX Initials: XX Date: XXX
   3.3. Change cell E6 to “100” (Req. 1a, 2a).
       <Insert screen shot here>
       Acceptance Criteria: The sample size is 2
       The average difference is 0
       The standard deviation of the differences is 0.
No equivalent limits and tests are displayed. An error message is shown.

Pass or Fail: XXXX    Initials: XX    Date: XXX

3.4. Change cell E6 to “95” and cell E8 to “0” (Req. 1b, 2b).

<Insert screen shot here>

Acceptance Criteria: The sample size is 2
The average difference is 0
The standard deviation of the differences is 0.
Equivalence limits are shown.
No conclusions are shown.
An error message is shown.

Pass or Fail: XXXX    Initials: XX    Date: XXX

3.5. Change cell E8 to “0.02”, cell C11 to “A”, cell C12 to “1..1”, cell C10 to “New Method”, cell D11 to “A”, cell D12 to “1..1” and cell D10 to “Old Method” (Req. 1c, 1d, 2c, 2d).

<Insert screen shot here>

Acceptance Criteria: The sample size is 0.
No estimates, equivalence limits and tests are displayed.
The name of the variables are displayed above the results.
An error message is shown.

Pass or Fail: XXXX    Initials: XX    Date: XXX

3.6. Change cell C13 to “1” and cell D13 to “1” (Req. 1d, 2e).

<Insert screen shot here>

Acceptance Criteria: The sample size is 1.
The average difference is 0
No standard deviation, equivalence limits and test are displayed.
An error message is shown.

Pass or Fail: XXXX    Initials: XX    Date: XXX

3.7. Copy cell C13 into cells C14 to C210 and copy cell D13 into cells D14 to D210. Fill cells B11:210 with “A”. (Req. 1d, 2f).

<Insert screen shot here>

Acceptance Criteria: The sample size is 198.
The average difference is 0
The standard deviation of the differences is 0.
No equivalence limits and tests are displayed.
An error message is shown.

Pass or Fail: XXXX    Initials: XXX    Date: XXX

4. Results for valid input

4.1. Delete cells B11:D210. Copy cells D95:E114 from the example data set tab to cell C11. (Req. 3a).

<Insert screen shot here>

Acceptance Criteria: The sample sizes are 20.
The average difference is 0.0016.
The standard deviation of the differences rounds to 0.01708.
The two-side equivalence limits for the average round to -0.0050051 and 0.0082051.
The upper equivalence limit for the average rounds to 0.0082051.
The lower equivalence limit for the average rounds to -0.0050051.
Equivalence statements for the three cases are shown with the same values.
All three cases pass.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

4.2. Change cell E8 to “0.002” (Req. 3a).

Acceptance Criteria: 
The sample sizes are 20.
The average difference is 0.0016.
The standard deviation of the differences rounds to 0.01708.
The two-side equivalence limits for the average round to -0.0050051 and 0.0082051.
The upper equivalence limit for the average rounds to 0.0082051.
The lower equivalence limit for the average rounds to -0.0050051.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

5. Independence of tab

5.1. Copy the 2 Averages – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: 
The sample sizes are 20.
The average difference is 0.0016.
The standard deviation of the differences rounds to 0.01708.
The two-side equivalence limits for the average round to -0.0050051 and 0.0082051.
The upper equivalence limit for the average rounds to 0.0082051.
The lower equivalence limit for the average rounds to -0.0050051.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: XXXX  Initials: XX  Date: XXX

6. Comments

6.1. None

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass? yes no

7.2. Save File and show name and date.

Name of File:
## Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

### Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Input of Data:</strong></td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet 3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. The difference can be entered into the highlighted cell of the spreadsheet 3.4</td>
</tr>
<tr>
<td></td>
<td>c. The name of the variables can be entered into the highlighted cell of the spreadsheet. 3.5</td>
</tr>
<tr>
<td></td>
<td>d. The data and labels can be entered into the highlighted cells of the spreadsheet. 3.5, 3.6, 3.7 – all data cells used</td>
</tr>
<tr>
<td></td>
<td>e. Only the highlighted yellow cells can be changed. 3.1</td>
</tr>
<tr>
<td>2</td>
<td><strong>Data Checking:</strong></td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no equivalence intervals or tests are shown. An error message is displayed. 3.2, 3.3 – covers both sides</td>
</tr>
<tr>
<td></td>
<td>b. Unless the difference is &gt; 0%, no equivalence intervals or tests are shown. An error message is displayed. 3.4</td>
</tr>
<tr>
<td></td>
<td>c. Only valid pairs of numbers in the data fields are used. An error message is displayed. 3.5</td>
</tr>
<tr>
<td></td>
<td>d. If no valid pairs are entered, the sample size is zero and no results are shown. An error message is displayed. 3.5</td>
</tr>
<tr>
<td></td>
<td>e. If there is a single valid pair, the sample size is one and only the average difference is shown. An error message is displayed. 3.6</td>
</tr>
<tr>
<td></td>
<td>f. If there are two or more valid pairs but the standard deviation of the differences is zero, the sample size, average difference, and standard deviation of the differences are shown but no equivalence intervals or tests are shown. An error message is displayed. 3.7</td>
</tr>
<tr>
<td></td>
<td>Results for valid input:</td>
</tr>
<tr>
<td>---</td>
<td>--------------------------</td>
</tr>
<tr>
<td>3</td>
<td>a. For valid input with at least two pairs and non-zero standard deviation, the sample size, average difference, standard deviation of the differences and equivalence intervals and tests are displayed.</td>
</tr>
<tr>
<td></td>
<td>4.1, 4.2</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
<tr>
<td></td>
<td>5.1</td>
</tr>
</tbody>
</table>
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as shown in Appendix A and B of STAT-16.

---

**Equivalence Test: Mean(New Method) - Mean(Old Method)**

(LEL = Lower Equivalence Limit, UEL = Upper Equivalence Limit)

95% CI for Equivalence of Mean(New Method) and Mean(Old Method): \((-0.0050051, 0.0082051)\)

CI is within the equivalence interval of \((-0.02, 0.02)\). Can claim equivalence.

---

**Test: Mean(New Method) - Mean(Old Method) > Lower Limit**

95% Lower bound for Mean(New Method) - Mean(Old Method): \(-0.0050051\)

Lower bound is greater than -0.02. Can claim Mean(New Method) - Mean(Old Method) > -0.02.
Test: Mean(New Method) - Mean(Old Method) < Upper Limit

95% Upper bound for Mean(New Method) - Mean(Old Method): 0.0082051
Upper bound is less than 0.02. Can claim Mean(New Method) - Mean(Old Method) < 0.02.

If the alternative "≠" is selected, the following output appears in the Session window. With 95% confidence, the difference is greater than -0.00501.

Paired T-Test and CI: New Method, Old Method
Descriptive Statistics
Sample N Mean SDev SE Mean
New Method 20 1.00545 0.02091 0.00468
Old Method 20 1.00385 0.02307 0.00516

Estimation for Paired Difference
Mean SDev SE Mean 95% CI for μ difference
0.00160 0.01708 0.00382 (0.00160, 0.00360)
μ difference: mean of (New Method - Old Method)

If the alternative "<" is selected, the following output appears in the Session window. With 95% confidence, the difference is less than 0.00821.

Paired T-Test and CI: New Method, Old Method
Descriptive Statistics
Sample N Mean SDev SE Mean
New Method 20 1.00545 0.02091 0.00468
Old Method 20 1.00385 0.02307 0.00516

Estimation for Paired Difference
Mean SDev SE Mean 95% Upper Bound for μ difference
0.00160 0.01708 0.00382 0.00821
μ difference: mean of (New Method - Old Method)
Appendix B

File: STAT-12 to 16 - Tab 15  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   ![Windows 10]
   
   **About**
   
   **Windows 10**
   
   **Alienware 17 R3**
   
   **PC name** Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

   **Edition** Windows 10 Home
   **Version** 1703
   **OS Build** 15063.674
   **Product ID** 00325-95916-23031-AAOEM
   **Processor** Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz
   **Installed RAM** 16.0 GB (15.9 GB usable)
   **System type** 64-bit operating system, x64-based processor
   **Pen and touch** No pen or touch input is available for this display

   1.3. Capture a screen shot showing the version of Excel used

   ![Microsoft Excel 2016 MSO](image)
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass  Initials: WT  Date: 11/27/17
3. Check for Valid Parameters
   3.1. Go to the 2 Averages Paired - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

   ![Excel Spreadsheet Image]

   Acceptance Criteria: Each time a message should be displayed that the cell is protected.

   Pass or Fail: Pass  
   Initials: WT  
   Date: 11/27/17
3.2. Change cell E6 to “49.99”, cell C11 to 1, C12 to 2, cell D11 to 1 and D12 to 2 (Req. 1a, 2a).

Acceptance Criteria: The sample size is 2
The average difference is 0
The standard deviation of the differences is 0.
No equivalent limits and tests are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/27/17

3.3. Change cell E6 to “100” (Req. 1a, 2a).

Acceptance Criteria: The sample size is 2
The average difference is 0
The standard deviation of the differences is 0.
No equivalent limits and tests are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/27/17
3.4. Change cell E6 to “95” and cell E8 to “0” (Req. 1b, 2b).

**Acceptance Criteria:**
- The sample size is 2
- The average difference is 0
- The standard deviation of the differences is 0.
- Equivalence limits are shown.
- No conclusions are shown.
- An error message is shown.

**Pass or Fail:** Pass

**Initials:** WT

**Date:** 11/27/17
3.5. Change cell E8 to “0.02”, cell C11 to “A”, cell C12 to “1.1”, cell C10 to “New Method”, cell D11 to “A”, cell D12 to “1.1” and cell D10 to “Old Method” (Req. 1c, 1d, 2c, 2d).

Acceptance Criteria: The sample size is 0.
No estimates, equivalence limits and tests are displayed.
The name of the variables are displayed above the results.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/27/17
3.6. Change cell C13 to “1” and cell D13 to “1” (Req. 1d, 2e).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-16, Statistical Techniques for Equivalence Testing**

**Appendix D: Equivalence Test for Two Averages - Paired Data**

### Acceptance Criteria:
- The sample size is 1.
- The average difference is 0.
- No standard deviation, equivalence limits and test are displayed.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/27/17
3.7. Copy cell C13 into cells C14 to C210 and copy cell D13 into cells D14 to D210. Fill cells B11:210 with “A”. (Req. 1d, 2f).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY

#### Appendix D: Equivalence Test for Two Averages - Paired Data

<table>
<thead>
<tr>
<th>Unit</th>
<th>New Method</th>
<th>Old Method</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

**Difference (New Method - Old Method)**

- **Sample Size**: 198
- **Average**: 0
- **Standard Deviation**: 0

**2-Sided Case - Equivalence Interval**

- **Lower Bound**: 0
- **Upper Bound**: 0

**Lower 1-Sided Case - Lower Equivalence Bound**

- **Lower Bound**: 0

**Upper 1-Sided Case - Upper Equivalence Bound**

- **Upper Bound**: 0

**Acceptance Criteria:**

- The sample size is 198.
- The average difference is 0
- The standard deviation of the differences is 0.
- No equivalence limits and tests are displayed.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/27/17
4. Results for valid input

4.1. Delete cells B11:D210. Copy cells D95:E114 from the example data set tab to cell C11. (Req. 3a).

<table>
<thead>
<tr>
<th>Test</th>
<th>New Method</th>
<th>Old Method</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.006</td>
<td>0.983</td>
<td>0.023</td>
<td>0.017</td>
</tr>
<tr>
<td>1.009</td>
<td>0.985</td>
<td>0.024</td>
<td>0.017</td>
</tr>
<tr>
<td>1.006</td>
<td>0.983</td>
<td>0.023</td>
<td>0.017</td>
</tr>
<tr>
<td>1.009</td>
<td>0.985</td>
<td>0.024</td>
<td>0.017</td>
</tr>
<tr>
<td>1.006</td>
<td>0.983</td>
<td>0.023</td>
<td>0.017</td>
</tr>
<tr>
<td>1.009</td>
<td>0.985</td>
<td>0.024</td>
<td>0.017</td>
</tr>
<tr>
<td>1.006</td>
<td>0.983</td>
<td>0.023</td>
<td>0.017</td>
</tr>
<tr>
<td>1.009</td>
<td>0.985</td>
<td>0.024</td>
<td>0.017</td>
</tr>
</tbody>
</table>

Acceptance Criteria:
The sample sizes are 20.
The average difference is 0.0016.
The standard deviation of the differences rounds to 0.01708.
The two-side equivalence limits for the average round to -0.0050051 and 0.0082051.
The upper equivalence limit for the average rounds to 0.0082051.
The lower equivalence limit for the average rounds to -0.0050051.
Equivalence statements for the three cases are shown with the same values.
All three cases pass.

Pass or Fail: Pass
Initials: WT
Date: 11/27/17
4.2. Change cell E8 to “0.002” (Req. 3a).

### Acceptance Criteria:
- The sample sizes are 20.
- The average difference is 0.0016.
- The standard deviation of the differences rounds to 0.01708.
- The two-side equivalence limits for the average round to -0.0050051 and 0.0082051.
- The upper equivalence limit for the average rounds to 0.0082051.
- The lower equivalence limit for the average rounds to -0.0050051.
- Equivalence statements for the three cases are shown with the same values.
- All three cases fail.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/27/17
5. Independence of tab

5.1. Copy the 2 Averages – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample sizes are 20.
The average difference is 0.0016.
The standard deviation of the differences rounds to 0.01708.
The two-side equivalence limits for the average round to -0.0050051 and 0.0082051.
The upper equivalence limit for the average rounds to 0.0082051.
The lower equivalence limit for the average rounds to -0.0050051.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass  Initials: WT  Date: 11/27/17
6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? X yes no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 15 Windows 10.doc
       Data of File: November 27, 2017

   Signature: ________________________________ Date: 11/27/17
Appendix C

File: STAT-12 to 16 - Tab 15  Windows 7
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
1.2. Capture a screen shot showing the operating system including version number

![Windows 7 Professional](image)

- Windows 7 Professional
- Copyright © 2009 Microsoft Corporation. All rights reserved.
- Service Pack 1
- Get more features with a new edition of Windows 7

1.3. Capture a screen shot showing the version of Excel used

![Excel Version](image)

- Microsoft Office Excel 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
- Portable Document Format version 1.5, © 1983-2003 Adobe Systems Incorporated. All rights reserved.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/eq
uivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass Initials: WT Date: 11/14/17
3. Check for Valid Parameters

3.1. Go to the 2 Averages Paired - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass Initials: WT Date: 11/14/17
3.2. Change cell E6 to “49.99”, cell C11 to 1, C12 to 2, cell D11 to 1 and D12 to 2 (Req. 1a, 2a).

Acceptance Criteria: The sample size is 2
The average difference is 0
The standard deviation of the differences is 0.
No equivalent limits and tests are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17

3.3. Change cell E6 to “100” (Req. 1a, 2a).

Acceptance Criteria: The sample size is 2
The average difference is 0
The standard deviation of the differences is 0.
No equivalent limits and tests are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
3.4. Change cell E6 to “95” and cell E8 to “0” (Req. 1b, 2b).

Acceptance Criteria: The sample size is 2
The average difference is 0
The standard deviation of the differences is 0.
Equivalence limits are shown.
No conclusions are shown.
An error message is shown.

Pass or Fail: Pass    Initials: WT    Date: 11/14/17
3.5. Change cell E8 to “0.02”, cell C11 to “A”, cell C12 to “1..1”, cell C10 to “New Method”", cell D11 to “A”, cell D12 to “1..1” and cell D10 to “Old Method” (Req. 1c, 1d, 2c, 2d).

Acceptance Criteria: The sample size is 0.
No estimates, equivalence limits and tests are displayed.
The name of the variables are displayed above the results.
An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/14/17
3.6. Change cell C13 to “1” and cell D13 to “1” (Req. 1d, 2e).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-16, Statistical Techniques for Equivalence Testing**

**Appendix D: Equivalence Test for Two Averages - Paired Data**

<table>
<thead>
<tr>
<th>Unit</th>
<th>New Method</th>
<th>Old Method</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>A</td>
<td>A</td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>1.1</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

**Acceptance Criteria:**
- The sample size is 1.
- The average difference is 0.
- No standard deviation, equivalence limits and test are displayed.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/14/17
3.7. Copy cell C13 into cells C14 to C210 and copy cell D13 into cells D14 to D210. Fill cells B11:210 with “A”. (Req. 1d, 2f).

Acceptance Criteria:  
The sample size is 198.  
The average difference is 0  
The standard deviation of the differences is 0.  
No equivalence limits and tests are displayed.  
An error message is shown.

Pass or Fail:  Pass  
Initials:  WT  
Date:  11/14/17
4. Results for valid input

4.1. Delete cells B11:D210. Copy cells D95:E114 from the example data set tab to cell C11. (Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The average difference is 0.0016.
The standard deviation of the differences rounds to 0.01708.
The two-side equivalence limits for the average round to -0.0050051 and 0.0082051.
The upper equivalence limit for the average rounds to 0.0082051.
The lower equivalence limit for the average rounds to -0.0050051.
Equivalence statements for the three cases are shown with the same values. All three cases pass.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
4.2. Change cell E8 to “0.002” (Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The average difference is 0.0016.
The standard deviation of the differences rounds to 0.01708.
The two-side equivalence limits for the average round to -0.0050051 and 0.0082051.
The upper equivalence limit for the average rounds to 0.0082051.
The lower equivalence limit for the average rounds to -0.0050051.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass Initials: WT Date: 11/14/17
5. Independence of tab

5.1. Copy the 2 Averages – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample sizes are 20.
The average difference is 0.0016.
The standard deviation of the differences rounds to 0.01708.
The two-side equivalence limits for the average round to -0.0050051 and 0.0082051.
The upper equivalence limit for the average rounds to 0.0082051.
The lower equivalence limit for the average rounds to -0.0050051.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass    Initials: WT    Date: 11/14/17
6. Comments

6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass? X yes no

7.2. Save File and show name and date.

Name of File: STAT-12 to 16 - Tab 15 Windows 7.doc
Data of File: November 14, 2017

Signature: ___________________________ Date: 11/14/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – CI Tab

Protocol Number: TE-17-17

Approvals:

Dr. Wayne A. Taylor
Study Director

November 28, 2017

Ann B. Taylor
President

November 28, 2017
Validation Report for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – CI Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from [www.variation.com/procedures](http://www.variation.com/procedures). One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Std. Dev. – CI tab, this spreadsheet performs confidence intervals for the ratio of two standard deviations. It is described in Appendix E of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix E also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-17, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 2 Std. Dev. – CI Tab was written to validate 2 Std. Dev. – CI tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 16 Windows 10. It is included as Appendix B. The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 16 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – CI Tab

Protocol Number: TE-17-17
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – CI Tab

Protocol Number: TE-17-17

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 14, 2017
Date
Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests
2 Std. Dev. – CI Tab

Protocol Number: TE-17-17

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Std. Dev. – CI tab, this spreadsheet performs confidence intervals for the ratio of two standard deviations. It is described in Appendix E of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix E also documents the formulas used and results from other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

**Table 1: User Requirements for the 2 Std. Dev. – CI tab of
STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls**

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. The name of the variables can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>c. The data can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is $\geq 50%$ and $&lt;100%$, no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Only valid numbers in the data fields are used.</td>
</tr>
<tr>
<td></td>
<td>c. If no valid data is entered, the sample sizes are zero and no results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>d. If there is a single valid data point in one of the groups, the sample size is one and no other results are shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>e. If there are two or more valid data points but the standard deviations are both zero, the sample sizes, standard deviations and ratio are shown but no confidence intervals are shown. An error message is displayed.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input with at least two data points per group and a non-zero standard deviation, the sample sizes, standard deviations, ratio and confidence intervals are displayed.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA.

All individuals performing the testing described below shall have a thorough knowledge of STAT-16 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
        <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
        <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
        <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
        <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
        <Insert screen shot here>
        Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
        Pass or Fail: XXXX    Initials: XX    Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 2 Std. Dev. - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).
        <Insert screen shot here>
        Acceptance Criteria: Each time a message should be displayed that the cell is protected.
        Pass or Fail: XXXX    Initials: XX    Date: XXX
   3.2. Change cell C6 to “49.99”, cell B9 to 1, B10 to 2, cell C9 to 1 and C10 to 2 (Req. 1a, 2a).
        <Insert screen shot here>
        Acceptance Criteria: Both sample sizes are 2
        Both standard deviations round to 0.7071.
        The ratio is 1.
        No confidence limits or statements are displayed.
        An error message is shown.
        Pass or Fail: XXXX    Initials: XX    Date: XXX
   3.3. Change cell C6 to “100” (Req. 1a, 2a).
        <Insert screen shot here>
        Acceptance Criteria: Both sample sizes are 2
        Both standard deviations round to 0.7071.
        The ratio is 1.
        No confidence limits or statements are displayed.
        An error message is shown.
3.4. Change cell C6 to “95”, cell B9 to “A”, cell B10 to “1..1”, cell B8 to “Strength - New”, cell C10 to “1..1” and cell C8 to “Strength - Old” (Req. 1b, 1c, 2b, 2c).

Acceptance Criteria: The sample sizes are 0.
No estimates, confidence limits or statements are displayed.
The name of the variables are displayed above the results.
An error message is shown.

3.5. Change cell B11 to “1” and cell C11 to “1” (Req. 1c, 2d).

Acceptance Criteria: The sample sizes are 1.
No standard deviations, ratio, confidence limits or statements are displayed.
An error message is shown.

3.6. Copy cell B11 into cells B12 to B208 and copy cell C11 into cells C12 to C208 (Req. 1c, 2e).

Acceptance Criteria: The sample sizes are 198.
The standard deviations are 0.
No ratio, confidence limits or statements are displayed.
An error message is shown.

4. Results for valid input

4.1. Delete cells B9 to B208 and C9 to C208. Copy cells C69:D88 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.523.
The second standard deviation rounds to 1.393.
The ratio rounds to 1.09336.
The two-side confidence limits for the standard deviation round to 0.688 and 1.738.
The upper confidence limit for the standard deviation rounds to 1.610.
The lower confidence limit for the standard deviation rounds to 0.743.
Confidence statements for the three cases are shown with the same values.

5. Independence of tab

5.1. Copy the 2 Std. Dev. – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample sizes are 20.
Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.523.
The second standard deviation rounds to 1.393.
The ratio rounds to 1.09336.
The two-side confidence limits for the standard deviation round to 0.688 and 1.738.
The upper confidence limit for the standard deviation rounds to 1.610.
The lower confidence limit for the standard deviation rounds to 0.743.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: XXXX Initials: XX Date: XXX

6. Comments
6.1. None

7. Saving and Signing File
7.1. Determine if all tests passed
All Test Cases for Computer Pass? yes no

7.2. Save File and show name and date.
Name of File:
Data of File:

Signature: ____________________________ Date: XXX
## Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is met with justification the test cases cover the requirement.

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | **Input of Data:**  
   a. The confidence level can be entered into the highlighted cell of the spreadsheet  
      3.2, 3.3  
   b. The name of the variables can be entered into the highlighted cell of the spreadsheet.  
      3.4  
   c. The data can be entered into the highlighted cells of the spreadsheet.  
      3.4, 3.5, 3.6 – all data cells used  
   d. Only the highlighted yellow cells can be changed.  
      3.1 |
| 2  | **Data Checking:**  
   a. Unless the confidence level is \( \geq 50\% \) and \(<100\%\), no confidence intervals are shown. An error message is displayed.  
      3.2, 3.3 – covers both sides  
   b. Only valid numbers in the data fields are used.  
      3.4  
   c. If no valid data is entered, the sample sizes are zero and no results are shown. An error message is displayed.  
      3.4  
   d. If there is a single valid data point in one of the groups, the sample size is one and no other results are shown. An error message is displayed.  
      3.5  
   e. If there are two or more valid data points but the standard deviations are both zero, the sample sizes, standard deviations and ratio are shown but no confidence intervals are shown. An error message is displayed.  
      3.6 |
| 3  | **Results for valid input:**  
   a. For valid input with at least two data points per group and a non-zero standard deviation, the sample sizes, standard deviations, ratio and confidence intervals are displayed.  
      4.1 |
| 4  | **Tabs:**  
   a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.  
      5.1 |
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as shown in Appendix A of STAT-16.
Appendix B

File: STAT-12 to 16 - Tab 16  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   ![Windows 10 About](image)

   **Alienware 17 R3**
   **PC name**  Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

<table>
<thead>
<tr>
<th>Edition</th>
<th>Windows 10 Home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>1703</td>
</tr>
<tr>
<td>OS Build</td>
<td>15063.674</td>
</tr>
<tr>
<td>Product ID</td>
<td>00325-95916-23031-AAOEM</td>
</tr>
<tr>
<td>Processor</td>
<td>Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz</td>
</tr>
<tr>
<td>Installed RAM</td>
<td>16.0 GB (15.9 GB usable)</td>
</tr>
<tr>
<td>System type</td>
<td>64-bit operating system, x64-based processor</td>
</tr>
<tr>
<td>Pen and touch</td>
<td>No pen or touch input is available for this display</td>
</tr>
</tbody>
</table>

   1.3. Capture a screen shot showing the version of Excel used
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

![Spreadsheet download image]

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

![Spreadsheet open image]

---

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-12 to 16: Confidence Intervals and Equivalence Tests**

Dr. Wayne A. Taylor

For those purchasing the book Statistical Procedures for the Medical Device Industry, this file contains the spreadsheets for calculating confidence intervals and equivalence tests per the formulas in the Appendices of the difference. Further information about the use of this spreadsheet is provided in the book.

**Book Link:** [http://www.variation.com/procedures](http://www.variation.com/procedures)

Copyright © 2017 Taylor Enterprises, Inc. All rights reserved.

Revision 1: 11/9/2017

[www.variation.com](http://www.variation.com);
[info@variation.com](mailto:info@variation.com)

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass

Initials: WT

Date: 11/28/17
3. Check for Valid Parameters

3.1. Go to the 2 Std. Dev. - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  
Initials: WT  
Date: 11/28/17
3.2. Change cell C6 to “49.99”, cell B9 to 1, B10 to 2, cell C9 to 1 and C10 to 2 (Req. 1a, 2a).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>Comparison Group</th>
<th>Reference Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sample Size</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Standard Deviation</td>
<td>0.7071</td>
</tr>
</tbody>
</table>

Acceptance Criteria: Both sample sizes are 2
Both standard deviations round to 0.7071.
The ratio is 1.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass    Initials: WT    Date: 11/28/17
3.3. Change cell C6 to “100” (Req. 1a, 2a).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison Group</td>
<td>Reference Group</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Acceptance Criteria: Both sample sizes are 2
Both standard deviations round to 0.7071.
The ratio is 1.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
3.4. Change cell C6 to “95”, cell B9 to “A”, cell B10 to “1..1”, cell B8 to “Strength - New”, cell C9 to “A”, cell C10 to “1..1” and cell C8 to “Strength - Old” (Req. 1b, 1c, 2b, 2c).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY

#### STAT-16, Statistical Techniques for Equivalence Testing

**Appendix E: Confidence Limits for the Ratio of Two Standard Deviations**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>%</th>
<th>50 ≤ Conf ≤ 100</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Strength - New</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Strength - Old</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>Sample Size</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>Standard Deviation</td>
</tr>
</tbody>
</table>

- Strength - New
- Sample Size: 0
- Standard Deviation

- Strength - Old
- Sample Size: 0
- Standard Deviation

### Acceptance Criteria:

The sample sizes are 0.
No estimates, confidence limits or statements are displayed.
The name of the variables are displayed above the results.
An error message is shown.

**Pass or Fail:** Pass
**Initials:** WT
**Date:** 11/28/17
3.5. Change cell B11 to “1” and cell C11 to “1” (Req. 1c, 2d).

<table>
<thead>
<tr>
<th>Strength - New</th>
<th>Strength - Old</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>1.1</td>
</tr>
</tbody>
</table>

Acceptance Criteria: The sample sizes are 1.
No standard deviations, ratio, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/28/17
3.6. Copy cell B11 into cells B12 to B208 and copy cell C11 into cells C12 to C208 (Req. 1c, 2e).

Acceptance Criteria: The sample sizes are 198.
The standard deviations are 0.
No ratio, confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass    Initials: WT    Date: 11/28/17
4. Results for valid input

4.1. Delete cells B9 to B208 and C9 to C208. Copy cells C69:D88 from the example data set tab to cell B9. (Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.523.
The second standard deviation rounds to 1.393.
The ratio rounds to 1.09336.
The two-side confidence limits for the standard deviation round to 0.688 and 1.738.
The upper confidence limit for the standard deviation rounds to 1.610.
The lower confidence limit for the standard deviation rounds to 0.743.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
5. Independence of tab

5.1. Copy the 2 Std. Dev. – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.523.
The second standard deviation rounds to 1.393.
The ratio rounds to 1.09336.
The two-side confidence limits for the standard deviation round to 0.688 and 1.738.
The upper confidence limit for the standard deviation rounds to 1.610.
The lower confidence limit for the standard deviation rounds to 0.743.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
6. Comments
   6.1. None

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? X yes no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 16 Windows 10.doc
       Data of File: November 28, 2017

Signature: ________________________________ Date: 11/28/17
Appendix C

File: STAT-12 to 16 - Tab 16  Windows 7
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

![Gateway Computer](image-url)
1.2. Capture a screen shot showing the operating system including version number

Windows edition

Windows 7 Professional

Copyright © 2009 Microsoft Corporation. All rights reserved.

Service Pack 1

Get more features with a new edition of Windows 7

System

Rating: 5.5 Your Windows Experience Index needs to be refreshed

Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHz

Installed memory (RAM): 4.00 GB

System type: 64-bit Operating System

Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

About Microsoft Office Excel

Microsoft® Office Excel® 2007 (12.0.6776.5000) SF3 MSO (12.0.6777.5000)

Port of Microsoft Office Professional 2007
© 2006 Microsoft Corporation. All rights reserved.


This product is licensed to:

Wayne Taylor
Taylor Enterprises, Inc.

Product ID: 81605-903-7132834-65427

View the Microsoft Software License Terms

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass Initials: WT Date: 11/14/17
3. Check for Valid Parameters

3.1. Go to the 2 Std. Dev. - CI tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass        Initials: WT        Date: 11/14/17
3.2. Change cell C6 to “49.99”, cell B9 to 1, B10 to 2, cell C9 to 1 and C10 to 2 (Req. 1a, 2a).

Acceptance Criteria:
- Both sample sizes are 2
- Both standard deviations round to 0.7071.
- The ratio is 1.
- No confidence limits or statements are displayed.
- An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17
3.3. Change cell C6 to “100” (Req. 1a, 2a).

Acceptance Criteria: Both sample sizes are 2
Both standard deviations round to 0.7071.
The ratio is 1.
No confidence limits or statements are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
3.4. Change cell C6 to “95”, cell B9 to “A”, cell B10 to “1..1”, cell B8 to “Strength - New”, cell C9 to “A”, cell C10 to “1..1” and cell C8 to “Strength - Old” (Req. 1b, 1c, 2b, 2c).

**STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY**

**STAT-16, Statistical Techniques for Equivalence Testing**

**Appendix E: Confidence Limits for the Ratio of Two Standard Deviations**

<table>
<thead>
<tr>
<th>Confidence Level:</th>
<th>95%</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Strength - New</th>
<th>Strength - Old</th>
<th>( \Delta )</th>
<th>( \Delta )</th>
</tr>
</thead>
<tbody>
<tr>
<td>1..1</td>
<td>1..1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

50 ± Conf < 100

- **Strength - New**
  - Sample Size: 0
  - Standard Deviation: 0

- **Strength - Old**
  - Sample Size: 0
  - Standard Deviation: 0

- **Ratio (Strength - New / Strength - Old)**
  - Ratio

- **2-Sided Case - Confidence Interval**
  - Lower Limit
  - Upper Limit

- **Lower 1-Sided Case - Lower Confidence Limit**
  - Lower Limit

- **Upper 1-Sided Case - Upper Confidence Limit**
  - Upper Limit

Acceptance Criteria: The sample sizes are 0. No estimates, confidence limits or statements are displayed. The name of the variables are displayed above the results. An error message is shown.

Pass or Fail: Pass

Initials: WT

Date: 11/14/17
3.5. Change cell B11 to “1” and cell C11 to “1” (Req. 1c, 2d).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY

**STAT-16, Statistical Techniques for Equivalence Testing**  
Appendix E: Confidence Limits for the Ratio of Two Standard Deviations

<table>
<thead>
<tr>
<th>Confidence Level:</th>
<th>95%</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength - New</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strength - Old</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>A</td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

**Strength - New**
- Sample Size: 1
- Standard Deviation: 1

**Strength - Old**
- Sample Size: 1
- Standard Deviation: 1

**Ratio (Strength - New / Strength - Old)**
- Ratio: 1

**2-Sided Case - Confidence Interval**
- Lower Limit
- Upper Limit

**Lower 1-Sided Case - Lower Confidence Limit**
- Lower Limit

**Upper 1-Sided Case - Upper Confidence Limit**
- Upper Limit

**Acceptance Criteria:**
- The sample sizes are 1.
- No standard deviations, ratio, confidence limits or statements are displayed.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/14/17
3.6. Copy cell B11 into cells B12 to B208 and copy cell C11 into cells C12 to C208 (Req. 1c, 2e).

<table>
<thead>
<tr>
<th>Confidence Level: 95%</th>
<th>50 ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Strength - New**

<table>
<thead>
<tr>
<th>A</th>
<th>A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Strength - Old**

<table>
<thead>
<tr>
<th>A</th>
<th>A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Ratio (Strength - New / Strength - Old)**

<table>
<thead>
<tr>
<th>A</th>
<th>A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**2-sided Case - Confidence Interval**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Lower 1-sided Case - Lower Confidence Limit**

<table>
<thead>
<tr>
<th>Lower Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

**Upper 1-sided Case - Upper Confidence Limit**

<table>
<thead>
<tr>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

Acceptance Criteria: The sample sizes are 198. The standard deviations are 0. No ratio, confidence limits or statements are displayed. An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
4. **Results for valid input**

4.1. Delete cells B9 to B208 and C9 to C208. Copy cells C69:D88 from the example data set tab to cell B9. (Req. 3a).

**Acceptance Criteria:**
- The sample sizes are 20.
- The first standard deviation rounds to 1.523.
- The second standard deviation rounds to 1.393.
- The ratio rounds to 1.09336.
- The two-side confidence limits for the standard deviation round to 0.688 and 1.738.
- The upper confidence limit for the standard deviation rounds to 1.610.
- The lower confidence limit for the standard deviation rounds to 0.743.
- Confidence statements for the three cases are shown with the same values.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/14/17
5. Independence of tab

5.1. Copy the 2 Std. Dev. – CI tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.523.
The second standard deviation rounds to 1.393.
The ratio rounds to 1.09336.
The two-side confidence limits for the standard deviation round to 0.688 and 1.738.
The upper confidence limit for the standard deviation rounds to 1.610.
The lower confidence limit for the standard deviation rounds to 0.743.
Confidence statements for the three cases are shown with the same values.

Pass or Fail: Pass Initials: WT Date: 11/14/17
6. Comments
   6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File
   7.1. Determine if all tests passed
       All Test Cases for Computer Pass? X yes no
   7.2. Save File and show name and date.
       Name of File: STAT-12 to 16 - Tab 16 Windows 7.doc
       Data of File: November 14, 2017
       Signature: ________________________________ Date: 11/14/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – n Tab

Protocol Number: TE-17-18

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

November 28, 2017
Date

November 28, 2017
Date
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – n Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Std. Dev. – n tab, this spreadsheet calculates sample sizes for a 2-sample equivalence test for the standard deviation. It is described in Appendix F of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix F also documents the formulas used.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-18, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 2 Std. Dev. – n Tab was written to validate 2 Std. Dev. – n tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 17 Windows 10. It is included as Appendix B. The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 17 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – n Tab

Protocol Number: TE-17-18
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – n Tab

Protocol Number: TE-17-18

Approvals:

___________________________________         November 14, 2017
Dr. Wayne A. Taylor Date
Study Director

___________________________________         November 14, 2017
Ann B. Taylor Date
President
Validation Protocol for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
2 Std. Dev. – n Tab

Protocol Number: TE-17-18

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Std. Dev. – n tab, this spreadsheet calculates sample sizes for a 2-sample equivalence test for the standard deviation. It is described in Appendix F of STAT-16, *Statistical Techniques for Equivalence Testing*. Appendix F also documents the formulas used.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
# 2.0 Requirements

Table 1 lists the user requirements to be validated.

**Table 1: User Requirements for the 2 Std. Dev. – n tab of STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls**

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Input of Data:</td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>b. RQL can be entered into the highlighted cell of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>c. AQL can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td>2</td>
<td>Data Checking:</td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>b. Unless RQL and AQL are valid numbers and RQL &gt; AQL &gt; 0, no sample size is shown. An error message is displayed.</td>
</tr>
<tr>
<td>3</td>
<td>Results for valid input:</td>
</tr>
<tr>
<td></td>
<td>a. For valid input, the sample size is displayed.</td>
</tr>
<tr>
<td>4</td>
<td>Tabs:</td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
</tbody>
</table>
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-16 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
        <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
        <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
        <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
        <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
        <Insert screen shot here>

       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX    Initials: XXX    Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 2 Std. Dev. - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).
        <Insert screen shot here>
       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX    Initials: XXX    Date: XXX
   3.2. Change cell C6 to “49.99”, cell C8 to 1.2 and cell C10 to 1 (Req. 1a-c, 2a).
        <Insert screen shot here>
       Acceptance Criteria: The sample size is not displayed. An error message is shown.
       Pass or Fail: XXXX    Initials: XXX    Date: XXX
   3.3. Change cell C6 to “100” (Req. 1a, 2a).
        <Insert screen shot here>
   3.4. Change cell C6 to “95” and cell C8 to “1..2” (Req. 1b, 2b).
        <Insert screen shot here>
3.5. Change cell C8 to “1.2” and cell C10 to “1..0” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX   Initials: XXX   Date: XXX

3.6. Change cell C10 to “1.2” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX   Initials: XXX   Date: XXX

3.7. Change cell C10 to “0” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: XXXX   Initials: XXX   Date: XXX

4. Results for valid input

4.1. Change cell C10 to “1” (Req. 3a).

Acceptance Criteria: The sample size is 328.

Pass or Fail: XXXX   Initials: XXX   Date: XXX

4.2. Change cell C8 to “1.44” and cell C10 to “1.2” (Req. 3a).

Acceptance Criteria: The sample size is 328.

Pass or Fail: XXXX   Initials: XXX   Date: XXX

5. Independence of tab

5.1. Copy the 2 Std. Dev. – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 328.

Pass or Fail: XXXX   Initials: XXX   Date: XXX

6. Comments

6.1. None
7. Saving and Signing File

7.1. Determine if all tests passed

| All Test Cases for Computer Pass? | yes | no |

7.2. Save File and show name and date.

Name of File: ________________________________

Data of File: Date: XXX

Signature: ________________________________ Date: XXX
## Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is meet with justification the test cases cover the requirement.

### Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Input of Data:</strong></td>
</tr>
<tr>
<td></td>
<td>a. The confidence level can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. RQL can be entered into the highlighted cell of the spreadsheet</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.4</td>
</tr>
<tr>
<td></td>
<td>c. AQL can be entered into the highlighted cells of the spreadsheet.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.5, 3.6</td>
</tr>
<tr>
<td></td>
<td>d. Only the highlighted yellow cells can be changed.</td>
</tr>
<tr>
<td></td>
<td>3.1</td>
</tr>
<tr>
<td>2</td>
<td><strong>Data Checking:</strong></td>
</tr>
<tr>
<td></td>
<td>a. Unless the confidence level is ≥50% and &lt;100%, no sample size is shown.</td>
</tr>
<tr>
<td></td>
<td>An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.2, 3.3</td>
</tr>
<tr>
<td></td>
<td>b. Unless RQL and AQL are valid numbers and RQL &gt; AQL &gt; 0, no sample size is shown.</td>
</tr>
<tr>
<td></td>
<td>An error message is displayed.</td>
</tr>
<tr>
<td></td>
<td>3.4, 3.5, 3.6, 3.7</td>
</tr>
<tr>
<td>3</td>
<td><strong>Results for valid input:</strong></td>
</tr>
<tr>
<td></td>
<td>a. For valid input, the sample size is displayed.</td>
</tr>
<tr>
<td></td>
<td>4.1, 4.2</td>
</tr>
<tr>
<td>4</td>
<td><strong>Tabs:</strong></td>
</tr>
<tr>
<td></td>
<td>a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.</td>
</tr>
<tr>
<td></td>
<td>5.1</td>
</tr>
</tbody>
</table>
Appendix C: Verification of Results

4.1 From Minitab version 18.0.

Power and Sample Size
Test for Two Standard Deviations
Testing (StDev 1 / StDev 2) = 1 (versus >)
Calculating power for (StDev 1 / StDev 2) = ratio
α = 0.05
Method: F Test

Results

<table>
<thead>
<tr>
<th>Ratio</th>
<th>Sample Size</th>
<th>Target Power</th>
<th>Actual Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>328</td>
<td>0.95</td>
<td>0.950252</td>
</tr>
</tbody>
</table>

The sample size is for each group.

Power Curve for Two Standard Deviations
Appendix B

File: STAT-12 to 16 - Tab 17  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   About

   Windows 10

   Alienware 17 R3
   PC name Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

   Edition Windows 10 Home
   Version 1703
   OS Build 15063.674
   Product ID 00325-95916-23031-AAOEM
   Processor Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz
   2.59 GHz
   Installed RAM 16.0 GB (15.9 GB usable)
   System type 64-bit operating system, x64-based processor
   Pen and touch No pen or touch input is available for this display

   1.3. Capture a screen shot showing the version of Excel used
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass

Initials: WT

Date: 11/28/17
3. Check for Valid Parameters

3.1. Go to the 2 Std. Dev. - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.
Pass or Fail: Pass Initials: WT Date: 11/28/17

3.2. Change cell C6 to "49.99", cell C8 to 1.2 and cell C10 to 1 (Req. 1a-c, 2a).

Acceptance Criteria: The sample size is not displayed.
An error message is shown.
Pass or Fail: Pass Initials: WT Date: 11/28/17
3.3. Change cell C6 to “100” (Req. 1a, 2a).

Acceptance Criteria:
The sample size is not displayed. 
An error message is shown.
Pass or Fail: Pass  
Initials: WT  
Date: 11/28/17

3.4. Change cell C6 to “95” and cell C8 to “1..2” (Req. 1b, 2b).

Acceptance Criteria:  
The sample size is not displayed. 
An error message is shown.
Pass or Fail: Pass  
Initials: WT  
Date: 11/28/17

3.5. Change cell C8 to “1,2” and cell C10 to “1..0” (Req. 1c, 2b).

Acceptance Criteria:  
The sample size is not displayed. 
An error message is shown.
Pass or Fail: Pass  
Initials: WT  
Date: 11/28/17
3.6. Change cell C10 to “1.2” (Req. 1c, 2b).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>AQL</td>
<td>1.2</td>
</tr>
<tr>
<td>RQL</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/28/17

3.7. Change cell C10 to “0” (Req. 1c, 2b).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>AQL</td>
<td>0</td>
</tr>
<tr>
<td>RQL</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Acceptance Criteria: The sample size is not displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/28/17
4. Results for valid input

4.1. Change cell C10 to “1” (Req. 3a).

Acceptance Criteria: The sample size is 328.
Pass or Fail: Pass Initials: WT Date: 11/28/17

4.2. Change cell C8 to “1.44” and cell C10 to “1.2” (Req. 3a).

Acceptance Criteria: The sample size is 328.
Pass or Fail: Pass Initials: WT Date: 11/28/17
5. Independence of tab

5.1. Copy the 2 Std. Dev. – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 328.
Pass or Fail: Pass Initials: WT Date: 11/28/17

6. Comments

6.1. In 3.5 should say Change cell C8 to “1.2” rather than “1,2”.

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass? X yes no

7.2. Save File and show name and date.

Name of File: STAT-12 to 16 - Tab 17 Windows 10.doc
Data of File: November 28, 2017

Signature: ___________________________ Date: 11/28/17
Appendix C

File: STAT-12 to 16 - Tab 17  Windows 7
Appendix A: Test Script

1. Document System Used

1.1. Capture a screen shot showing the computer make and model

![Gateway Laptop Label](image-url)
1.2. Capture a screen shot showing the operating system including version number

![Windows 7 Professional](image1.png)

System

<table>
<thead>
<tr>
<th>Rating</th>
<th>5.5 Your Windows Experience Index needs to be refreshed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processor</td>
<td>Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHz</td>
</tr>
<tr>
<td>Installed memory (RAM)</td>
<td>4.00 GB</td>
</tr>
<tr>
<td>System type</td>
<td>64-bit Operating System</td>
</tr>
<tr>
<td>Pen and Touch</td>
<td>No Pen or Touch Input is available for this Display</td>
</tr>
</tbody>
</table>

1.3. Capture a screen shot showing the version of Excel used

![Microsoft Office Excel](image2.png)
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from [http://www.variation.com/procedures/equivalence_tests.html](http://www.variation.com/procedures/equivalence_tests.html). Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass
Initials: WT
Date: 11/14/17
3. Check for Valid Parameters

3.1. Go to the 2 Std. Dev. - n tab. Double click on at least 10 non-yellow cells on tab (Req. 1d).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17

3.2. Change cell C6 to “49.99”, cell C8 to 1.2 and cell C10 to 1 (Req. 1a-c, 2a).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/14/17
3.3. Change cell C6 to “100” (Req. 1a, 2a).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/14/17

3.4. Change cell C6 to “95” and cell C8 to “1..2” (Req. 1b, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/14/17

3.5. Change cell C8 to “1,2” and cell C10 to “1..0” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/14/17
3.6. Change cell C10 to “1.2” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17

3.7. Change cell C10 to “0” (Req. 1c, 2b).

Acceptance Criteria: The sample size is not displayed. An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/14/17
4. Results for valid input

4.1. Change cell C10 to “1” (Req. 3a).

Acceptance Criteria: The sample size is 328.
Pass or Fail: Pass Initials: WT Date: 11/14/17

4.2. Change cell C8 to “1.44” and cell C10 to “1.2” (Req. 3a).

Acceptance Criteria: The sample size is 328.
Pass or Fail: Pass Initials: WT Date: 11/14/17
5. Independence of tab

5.1. Copy the 2 Std. Dev. – n tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample size is 328.
Pass or Fail: Pass  Initials: WT  Date: 11/14/17

6. Comments

6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

6.2. In 3.5 should say Change cell C8 to “1.2” rather than “1,2”.

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass?  X yes  no

7.2. Save File and show name and date.

Name of File:  STAT-12 to 16 - Tab 17 Windows 7.doc
Data of File:  November 14, 2017

Signature:  [Signature]  Date:  11/28/17
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – Equivalence Tab

Protocol Number: TE-17-19

Approvals:

Dr. Wayne A. Taylor  
Study Director  

Ann B. Taylor  
President  

November 28, 2017  
Date  

November 28, 2017  
Date
Validation Report for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – Equivalence Tab

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests - Protected.xls*. This spreadsheet is password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Std. Dev. – Equivalence tab, this spreadsheet performs equivalence intervals and tests for the ratio between two standard deviations. It is described in Appendix F of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix F also documents the formulas used and how to perform the analysis using other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Protocol

Protocol Number: TE-17-19, Validation Protocol for Excel Spreadsheet: STAT-12 to 16 - Confidence Intervals and Equivalence Tests, 2 Std. Dev. – Equivalence Tab was written to validate 2 Std. Dev. – Equivalence tab of this spreadsheet. It can be found in Appendix A. It lists the requirements, test cases and a matrix linking the tests to the requirements demonstrating complete coverage of the requirements.

3.0 Testing

The test script was executed on two machines. The first one had Windows 10 and Excel 2016 installed. The results were saved in the file STAT-12 to 16 - Tab 18 Windows 10. It is included as Appendix B.

The second machine had Windows 7 and Excel 2007 installed. The results were saved in the STAT-12 to 16 - Tab 18 Windows 7. It is included as Appendix C.

4.0 Test Results

All tests passed on both machines as shown in Appendices B and C. The validation has been successively completed.
Appendix A

Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – Equivalence Tab

Protocol Number: TE-17-19
Validation Protocol for Excel Spreadsheet:

STAT-12 to 16 - Confidence Intervals and Equivalence Tests

2 Std. Dev. – Equivalence Tab

Protocol Number: TE-17-19

Approvals:

Dr. Wayne A. Taylor
Study Director

Ann B. Taylor
President

___________________________________         November 28, 2017
Dr. Wayne A. Taylor
Date

___________________________________         November 28, 2017
Ann B. Taylor
Date
Validation Protocol for Excel Spreadsheet:
STAT-12 to 16 - Confidence Intervals and Equivalence Tests
2 Std. Dev. – Equivalence Tab

Protocol Number: TE-17-19

1.0 Introduction

The book *Statistical Procedures for the Medical Device Industry* by Dr. Wayne Taylor (2017) includes several Excel Spreadsheets that can be downloaded from www.variation.com/procedures. One of these spreadsheets is *STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls*. The tabs on the spreadsheet are password protected to prevent changes. The first tab displays the information below. The version being validated is Revision 1 with a date of 11/9/2017.

On the 2 Std. Dev. – Equivalence tab, this spreadsheet performs equivalence intervals and tests for the ratio between two standard deviations. It is described in Appendix F of *STAT-16, Statistical Techniques for Equivalence Testing*. Appendix F also documents the formulas used and how to perform the analysis using other software packages.

A key property of the spreadsheet is that tabs are independent of each other so tabs can be copied and the copied tab performs correctly and tabs can be deleted without affecting other tabs.
2.0 Requirements

Table 1 lists the user requirements to be validated.

Table 1: User Requirements for the 2 Std. Dev. – Equivalence tab of STAT-12 to 16 - Confidence Intervals and Equivalence Tests – Protected.xls

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | Input of Data:  
     a. The confidence level can be entered into the highlighted cell of the spreadsheet  
     b. The ratio can be entered into the highlighted cell of the spreadsheet  
     c. The name of the variables can be entered into the highlighted cell of the spreadsheet.  
     d. The data can be entered into the highlighted cells of the spreadsheet.  
     e. Only the highlighted yellow cells can be changed. |
| 2  | Data Checking:  
     a. Unless the confidence level is \( \geq 50\% \) and \(< 100\%\), no equivalence intervals or tests are shown. An error message is displayed.  
     b. Unless the ratio is \( > 1 \), no equivalence intervals or tests are shown. An error message is displayed.  
     c. Only valid numbers in the data fields are used.  
     d. If no valid data is entered, the sample sizes are zero and no results are shown. An error message is displayed.  
     e. If there is a single valid data point in one of the groups, the sample size is one but nothing else is displayed. An error message is displayed.  
     f. If there are two or more valid data points in each group but the standard deviations are both zero, the sample sizes and standard deviations are shown but no ratio, equivalence intervals or tests are shown. An error message is displayed. |
| 3  | Results for valid input:  
     a. For valid input with at least two data points and non-zero standard deviations, the sample sizes, standard deviations, ratio and equivalence intervals and tests are displayed. |
| 4  | Tabs:  
     a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same. |
3.0 Test Environment

All testing will be performed at the facilities of Taylor Enterprises, Inc. (TEI), Libertyville, IL USA

All individuals performing the testing described below shall have a thorough knowledge of STAT-16 and associated spreadsheet and be proficient in its use.

The spreadsheet does not include any macros. All functionality is through equations including the standard functions included with Excel that have remained unchanged since early versions of Excel. The purpose of this document is to describe the validation of this spreadsheet across a range of systems. The validation tests described in the following sections shall be performed on a newer system with Windows 10 / Excel 2016 and an older system with Windows 7 / Excel 2007.

4.0 Test Script

For each system run the test script in Appendix A. The test script includes instructions for documenting the system used, the downloading of the spreadsheet and test cases to run.

Make a copy of Appendix A in a separate Word document for each system. Copy the evidence of each test case into this word file. All test cases should be run by the same person on a single day. When done save the file, print it, and then sign and date the printed copy.

The first two items in the test script document the computer, operating system and version of Excel used. They are not linked to the requirements. The remaining test cases are designed to cover all the requirements. A matrix showing the linkage is provided in Appendix B.

Appendix C provides evidence of the correct results for the test cases compared to Minitab, version 18 (www.minitab.com).
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model
       <Insert screen shot here>
   1.2. Capture a screen shot showing the operating system including version number
       <Insert screen shot here>
   1.3. Capture a screen shot showing the version of Excel used
       <Insert screen shot here>

2. Download Spreadsheet and Open
   2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.
       <Insert screen shot here>
   2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.
       <Insert screen shot here>
       Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”
       Pass or Fail: XXXX    Initials: XXX    Date: XXX

3. Check for Valid Parameters
   3.1. Go to the 2 Std. Dev. - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).
       <Insert screen shot here>
       Acceptance Criteria: Each time a message should be displayed that the cell is protected.
       Pass or Fail: XXXX    Initials: XX    Date: XXX
   3.2. Change cell E6 to “49.99”, cell B11 to 1, B12 to 2, cell C11 to 1, C12 to 2 and cell E8 to “2” (Req. 1a, 2a).
       <Insert screen shot here>
       Acceptance Criteria: Both sample sizes are 2
       Both standard deviations round to 0.7071.
       The ratio is 1.
       No equivalent limits and tests are displayed.
       An error message is shown.
       Pass or Fail: XXXX    Initials: XX    Date: XXX
   3.3. Change cell E6 to “100” (Req. 1a, 2a).
       <Insert screen shot here>
       Acceptance Criteria: Both sample sizes are 2
       Both standard deviations round to 0.7071.
       The ratio is 1.
       No equivalent limits and tests are displayed.
       An error message is shown.
3.4. Change cell E6 to “95” and cell E8 to “1” (Req. 1b, 2b).

Acceptance Criteria: Both sample sizes are 2
Both standard deviations round to 0.7071.
The ratio is 1.
Equivalence limits are shown.
No conclusions are shown.
An error message is shown.

3.5. Change cell E8 to “2”, cell B11 to “A”, cell B12 to “1..1”, cell B10 to “Strength - New” , cell C11 to “A”,
cell C12 to “1..1” and cell C10 to “Strength - Old” (Req. 1c, 1d, 2c, 2d).

Acceptance Criteria: The sample sizes are 0.
No estimates, equivalence limits and tests are displayed.
The name of the variables are displayed above the results.
An error message is shown.

3.6. Change cell B13 to “1” and cell C13 to “1” (Req. 1d, 2e).

Acceptance Criteria: The sample sizes are 1.
No standard deviations, ratio, equivalence limits and test are displayed.
An error message is shown.

3.7. Copy cell B13 into cells B14 to B210 and copy cell C13 into cells C14 to C210 (Req. 1d, 2f).

Acceptance Criteria: The sample sizes are 198.
The standard deviations are 0.
No ratio0, equivalence limits and tests are displayed.
An error message is shown.

4. Results for valid input

(Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The ratio rounds to 1.09336.
The two-side equivalence limits for the average round to 0.743 and1.610.
The upper equivalence limit for the average rounds to 1.610.
The lower equivalence limit for the average rounds to 0.743.
Equivalence statements for the three cases are shown with the same values. All three cases pass.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

4.2. Change cell E8 to “1.1” (Req. 3a).

<Insert screen shot here>

Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The ratio rounds to 1.0936.
The two-side equivalence limits for the average round to 0.743 and 1.610.
The upper equivalence limit for the average rounds to 1.610.
The lower equivalence limit for the average rounds to 0.743.
Equivalence statements for the three cases are shown with the same values. All three cases fail.

Pass or Fail: XXXX  Initials: XXX  Date: XXX

5. Independence of tab

5.1. Copy the 2 Averages – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

<Insert screen shot here>

Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The ratio rounds to 1.0936.
The two-side equivalence limits for the average round to 0.743 and 1.610.
The upper equivalence limit for the average rounds to 1.610.
The lower equivalence limit for the average rounds to 0.743.
Equivalence statements for the three cases are shown with the same values. All three cases fail.

Pass or Fail: XXXX  Initials: XX  Date: XXX

6. Comments

6.1. None

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass? yes no

7.2. Save File and show name and date.

Name of File:

Data of File:

Signature: ________________________________  Date: XXX
Appendix B: Test Matrix

Table 2 shows for each requirement the tests that demonstrate the requirement is met with justification the test cases cover the requirement.

Table 2: Test Cases Matching User Requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1  | Input of Data:  
  a. The confidence level can be entered into the highlighted cell of the spreadsheet  
     3.2, 3.3  
  b. The ratio can be entered into the highlighted cell of the spreadsheet  
     3.4  
  c. The name of the variables can be entered into the highlighted cell of the spreadsheet.  
     3.5  
  d. The data can be entered into the highlighted cells of the spreadsheet.  
     3.5, 3.6, 3.7 – all data cells used  
  e. Only the highlighted yellow cells can be changed.  
     3.1  |
| 2  | Data Checking:  
  a. Unless the confidence level is ≥50% and <100%, no equivalence intervals or tests are shown. An error message is displayed.  
     3.2, 3.3 – covers both sides  
  b. Unless the ratio is > 1, no equivalence intervals or tests are shown. An error message is displayed.  
     3.4  
  c. Only valid numbers in the data fields are used.  
     3.5  
  d. If no valid data is entered, the sample sizes are zero and no results are shown. An error message is displayed.  
     3.5  
  e. If there is a single valid data point in one of the groups, the sample size is one but nothing else is displayed. An error message is displayed.  
     3.6  
  f. If there are two or more valid data points in each group but the standard deviations are both zero, the sample sizes and standard deviations are shown but no ratio, equivalence intervals or tests are shown. An error message is displayed.  
     3.7 |
<table>
<thead>
<tr>
<th></th>
<th>Results for valid input:</th>
</tr>
</thead>
</table>
| 3 | a. For valid input with at least two data points and non-zero standard deviations, the sample sizes, standard deviations, ratio and equivalence intervals and tests are displayed.  
   | 4.1, 4.2                  |
| 4 | Tabs:                    |
|   | a. Tabs are independent of each other so tab can be copied and all other tab deleted with tab results remaining the same.  
   | 5.1                      |
Appendix C: Verification of Results

4.1 From Minitab version 18.0 as shown in Appendix A and B of STAT-16.

Test and CI for Two Variances: Comparison Group, Reference Group

Method

\( \sigma_1 \): standard deviation of Comparison Group

\( \sigma_2 \): standard deviation of Reference Group

Ratio: \( \sigma_1 / \sigma_2 \)

F method was used. This method is accurate for normal data only.

Descriptive Statistics

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>StDev</th>
<th>Variance</th>
<th>90% CI for ( \sigma )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison Group</td>
<td>20</td>
<td>1.523</td>
<td>2.319</td>
<td>(1.209, 2.087)</td>
</tr>
<tr>
<td>Reference Group</td>
<td>20</td>
<td>1.393</td>
<td>1.940</td>
<td>(1.106, 1.909)</td>
</tr>
</tbody>
</table>

Ratio of Standard Deviations

<table>
<thead>
<tr>
<th>Estimated Ratio</th>
<th>90% CI for Ratio using F</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.09336</td>
<td>(0.743, 1.610)</td>
</tr>
</tbody>
</table>

Test

Null hypothesis \( H_0: \sigma_1 / \sigma_2 = 1 \)

Alternative hypothesis \( H_1: \sigma_1 / \sigma_2 \neq 1 \)

Significance level \( \alpha = 0.1 \)

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Test Statistic</th>
<th>DF1</th>
<th>DF2</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td>1.20</td>
<td>19</td>
<td>19</td>
<td>0.701</td>
</tr>
</tbody>
</table>

Test and CI for Two Variances: Comparison Group, Reference Group
Appendix B

File: STAT-12 to 16 - Tab 18  Windows 10
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

   ![Windows 10 About](image)

   **Alienware 17 R3**
   PC name Wayne-Dell

   1.2. Capture a screen shot showing the operating system including version number

<table>
<thead>
<tr>
<th>Edition</th>
<th>Windows 10 Home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>1703</td>
</tr>
<tr>
<td>OS Build</td>
<td>15063.674</td>
</tr>
<tr>
<td>Product ID</td>
<td>00325-95916-23031-AAOEM</td>
</tr>
<tr>
<td>Processor</td>
<td>Intel(R) Core(TM) i7-6700HQ CPU @ 2.60GHz 2.59 GHz</td>
</tr>
<tr>
<td>Installed RAM</td>
<td>16.0 GB (15.9 GB usable)</td>
</tr>
<tr>
<td>System type</td>
<td>64-bit operating system, x64-based processor</td>
</tr>
<tr>
<td>Pen and touch</td>
<td>No pen or touch input is available for this display</td>
</tr>
</tbody>
</table>

1.3. Capture a screen shot showing the version of Excel used

   ![Microsoft Excel](image)
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass
Initials: WT
Date: 11/28/17
3. Check for Valid Parameters

3.1. Go to the 2 Std. Dev. - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
3.2. Change cell E6 to “49.99”, cell B11 to 1, B12 to 2, cell C11 to 1, C12 to 2 and cell E8 to “2” (Req. 1a, 2a).

Acceptance Criteria: Both sample sizes are 2
Both standard deviations round to 0.7071.
The ratio is 1.
No equivalent limits and tests are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
3.3. Change cell E6 to “100” (Req. 1a, 2a).

Acceptance Criteria: Both sample sizes are 2
Both standard deviations round to 0.7071.
The ratio is 1.
No equivalent limits and tests are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
3.4. Change cell E6 to “95” and cell E8 to “1” (Req. 1b, 2b).

### STATISTICAL PROCEDURES FOR THE MEDICAL DEVICE INDUSTRY

**STAT-10, Statistical Techniques for Equivalence Testing**  
**Appendix F: Equivalence Test for the Ratio of Two Standard Deviations**

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>% 95 % ≤ Conf &lt; 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratio for Determining if Equivalent</td>
<td>1</td>
</tr>
<tr>
<td>Comparison Group</td>
<td>Sample Size</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reference Group</th>
<th>Sample Size</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>0.707196781</td>
</tr>
</tbody>
</table>

| Ratio (Comparison Group / Reference Group) | 1 |

#### 2-Sided Case - Equivalence Interval

| Lower Bound | 0.078717177 |
| Upper Bound | 12.7002047 |

#### 1-Sided Case - Lower Equivalence Bound

| Lower Bound | 0.078717177 |
| Upper Bound | 12.7002047 |

**Acceptance Criteria:**
- Both sample sizes are 2
- Both standard deviations round to 0.7071.
- The ratio is 1.
- Equivalence limits are shown.
- No conclusions are shown.
- An error message is shown.

**Pass or Fail:** Pass  
**Initials:** WT  
**Date:** 11/28/17
3.5. Change cell E8 to “2”, cell B11 to “A”, cell B12 to “1..1”, cell B10 to “Strength - New”, cell C11 to “A”, cell C12 to “1..1” and cell C10 to “Strength - Old” (Req. 1c, 1d, 2c, 2d).

Acceptance Criteria: The sample sizes are 0. No estimates, equivalence limits and tests are displayed. The name of the variables are displayed above the results. An error message is shown.

Pass or Fail: Pass Initials: WT Date: 11/28/17
3.6. Change cell B13 to “1” and cell C13 to “1” (Req. 1d, 2e).

Acceptance Criteria:
- The sample sizes are 1.
- No standard deviations, ratio, equivalence limits and test are displayed.
- An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/28/17
3.7. Copy cell B13 into cells B14 to B210 and copy cell C13 into cells C14 to C210 (Req. 1d, 2f).

Acceptance Criteria: The sample sizes are 198.
The standard deviations are 0.
No ratio0, equivalence limits and tests are displayed.
An error message is shown.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
4. Results for valid input

4.1. Delete cells B11 to B210 and C11 to C210. Copy cells C69:D88 from the example data set tab to cell B11. (Req. 3a).

Acceptance Criteria:

- The sample sizes are 20.
- The first standard deviation rounds to 1.52.
- The second standard deviation rounds to 1.39.
- The ratio rounds to 1.09336.
- The two-side equivalence limits for the average round to 0.743 and 1.610.
- The upper equivalence limit for the average rounds to 1.610.
- The lower equivalence limit for the average rounds to 0.743.
- Equivalence statements for the three cases are shown with the same values. All three cases pass.

Pass or Fail: Pass Initials: WT Date: 11/28/17
4.2. Change cell E8 to “1.1” (Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The ratio rounds to 1.09336.
The two-side equivalence limits for the average round to 0.743 and 1.610.
The upper equivalence limit for the average rounds to 1.610.
The lower equivalence limit for the average rounds to 0.743.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
5. Independence of tab

5.1. Copy the 2 Averages – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The ratio rounds to 1.09336.
The two-side equivalence limits for the average round to 0.743 and 1.610.
The upper equivalence limit for the average rounds to 1.610.
The lower equivalence limit for the average rounds to 0.743.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass initials: WT Date: 11/28/17

6. Comments

6.1. None

7. Saving and Signing File

7.1. Determine if all tests passed

All Test Cases for Computer Pass? X yes no

7.2. Save File and show name and date.
Taylor Enterprises, Inc.  

Name of File: STAT-12 to 16 - Tab 18 Windows 10.doc  
Data of File: November 28, 2017

Signature: ________________________________ Date: 11/28/17
Appendix C

File: STAT-12 to 16 - Tab 18 Windows 7
Appendix A: Test Script

1. Document System Used
   1.1. Capture a screen shot showing the computer make and model

![Gateway Computer Back Panel](image-url)
1.2. Capture a screen shot showing the operating system including version number

![Windows 7 Professional]

Copyright © 2009 Microsoft Corporation. All rights reserved.
Service Pack 1
Get more features with a new edition of Windows 7

System
Rating: 5/5 Your Windows Experience Index needs to be refreshed
Processor: Intel(R) Core(TM)2 Duo CPU P8400 @ 2.26GHz 2.27 GHz
Installed memory (RAM): 4.00 GB
System type: 64-bit Operating System
Pen and Touch: No Pen or Touch Input is available for this Display

1.3. Capture a screen shot showing the version of Excel used

![Microsoft Office Excel]

Microsoft Office Excel 2007 (12.0.6776.5000) SP3 MSO (12.0.6777.5000)
Part of Microsoft Office Professional 2007
© 2006 Microsoft Corporation. All rights reserved.


This product is licensed to:
Wayne Taylor
Taylor Enterprises, Inc.
Product ID: 81605-903-7132834-65427

View the Microsoft Software License Terms

Warning: This computer program is protected by copyright law and international treaties. Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under the law.
2. Download Spreadsheet and Open

2.1. Download the spreadsheet from http://www.variation.com/procedures/equivalence_tests.html. Download the protected version. Save it to the hard drive. Capture a screen shot showing the file downloaded.

2.2. Double click the spreadsheet to open it. Capture a screen shot of the section of the first tab showing the version and date.

Acceptance Criteria: The following is displayed “Revision 1: 11/9/2017”

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
3. Check for Valid Parameters

3.1. Go to the 2 Std. Dev. - Equivalence tab. Double click on at least 10 non-yellow cells on tab (Req. 1e).

Acceptance Criteria: Each time a message should be displayed that the cell is protected.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
3.2. Change cell E6 to “49.99”, cell B11 to 1, B12 to 2, cell C11 to 1, C12 to 2 and cell E8 to “2” (Req. 1a, 2a).

Acceptance Criteria:  
Both sample sizes are 2  
Both standard deviations round to 0.7071.  
The ratio is 1.  
No equivalent limits and tests are displayed.  
An error message is shown.

Pass or Fail:  Pass  
Initials: WT  
Date: 11/28/17
3.3. Change cell E6 to “100” (Req. 1a, 2a).

Acceptance Criteria: Both sample sizes are 2
Both standard deviations round to 0.7071.
The ratio is 1.
No equivalent limits and tests are displayed.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/28/17
3.4. Change cell E6 to “95” and cell E8 to “1” (Req. 1b, 2b).

### Acceptance Criteria:
- Both sample sizes are 2
- Both standard deviations round to 0.7071.
- The ratio is 1.
- Equivalence limits are shown.
- No conclusions are shown.
- An error message is shown.

### Pass or Fail:
Pass

### Initials:
WT

### Date:
11/28/17
3.5. Change cell E8 to “2”, cell B11 to “A”, cell B12 to “1..1”, cell B10 to “Strength - New”, cell C11 to “A”, cell C12 to “1..1” and cell C10 to “Strength - Old” (Req. 1c, 1d, 2c, 2d).

Acceptance Criteria: The sample sizes are 0.
No estimates, equivalence limits and tests are displayed.
The name of the variables are displayed above the results.
An error message is shown.

Pass or Fail: Pass
Initials: WT
Date: 11/28/17
3.6. Change cell B13 to “1” and cell C13 to “1” (Req. 1d, 2e).

Acceptance Criteria: The sample sizes are 1.
No standard deviations, ratio, equivalence limits and test are displayed.
An error message is shown.

Pass or Fail: Pass  
Initials: WT  
Date: 11/28/17
3.7. Copy cell B13 into cells B14 to B210 and copy cell C13 into cells C14 to C210 (Req. 1d, 2f).

### ACCEPTANCE CRITERIA:
- The sample sizes are 198.
- The standard deviations are 0.
- No ratio, equivalence limits and tests are displayed.
- An error message is shown.

### PASS OR FAIL:
- Pass

<table>
<thead>
<tr>
<th>Strength</th>
<th>New</th>
<th>Old</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>1.1</td>
<td>1.1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

### INITIALS:
- WT

### DATE:
- 11/28/17
4. Results for valid input

4.1. Delete cells B11 to B210 and C11 to C210. Copy cells C69:D88 from the example data set tab to cell B11. (Req. 3a).

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>New</th>
<th>Ratio</th>
<th>New</th>
<th>Strength</th>
<th>New</th>
<th>Strength</th>
<th>New</th>
<th>Ratio</th>
<th>New</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Acceptance Criteria:

The sample sizes are 20.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The ratio rounds to 1.09336.
The two-side equivalence limits for the average round to 0.743 and 1.610.
The upper equivalence limit for the average rounds to 1.610.
The lower equivalence limit for the average rounds to 0.743.
Equivalence statements for the three cases are shown with the same values.
All three cases pass.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
4.2. Change cell E8 to “1.1” (Req. 3a).

Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The ratio rounds to 1.09336.
The two-side equivalence limits for the average round to 0.743 and 1.610.
The upper equivalence limit for the average rounds to 1.610.
The lower equivalence limit for the average rounds to 0.743.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
5. Independence of tab

5.1. Copy the 2 Averages – Equivalence tab. Delete all tabs but the copy. (Req. 4a)

Acceptance Criteria: The sample sizes are 20.
The first standard deviation rounds to 1.52.
The second standard deviation rounds to 1.39.
The ratio rounds to 1.09336.
The two-side equivalence limits for the average round to 0.743 and 1.610.
The upper equivalence limit for the average rounds to 1.610.
The lower equivalence limit for the average rounds to 0.743.
Equivalence statements for the three cases are shown with the same values.
All three cases fail.

Pass or Fail: Pass  Initials: WT  Date: 11/28/17
6. Comments

6.1. Per 1.1, could not get a screen shot showing make and model, so a picture from the bottom of the laptop was taken instead.

7. Saving and Signing File

7.1. Determine if all tests passed

<table>
<thead>
<tr>
<th>All Test Cases for Computer Pass?</th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
</table>

7.2. Save File and show name and date.

Name of File: STAT-12 to 16 - Tab 18 Windows 7.doc

Data of File: November 28, 2017

Signature: [Signature]  Date: 11/28/17