JMP Clinical Installation and Operation Qualification (IQ/OQ)

These instructions describe the process for qualifying the installation and operation of JMP Clinical 8 on your Windows desktop machine. They include 4 major sections:

- Step 1: Installation Qualification
- Step 2: Operation Qualification
- <u>Step 3: NIST Testing</u>
- Step 4: Run a Simple Analysis

Note: When you open JMP Clinical for the first time, a JMP script that generates the dialogs for all of the JMP Clinical processes is run by default. This step automatically generates new files. Because this discrepancy will be found and reported by the SAS Install Qualification Tool 9.4 utility, **you must run the installation qualification before you open JMP Clinical for the first time**.

These instructions assume you have completed the installation of JMP Clinical as described in step 2c of the **Installation Instructions for JMP Clinical**.

Step 1: Installation Qualification

The SAS Install Qualification Tool 9.4 utility enables you to qualify the integrity of any SAS software installation. This program, which is installed along with the other SAS programs in your order, examines and compares them with the programs that were supposed to be installed. Any deviations are reported.

In the example shown here, JMP Clinical was installed on a newly staged work station.

To Select Start > SAS > SAS Install Qualification Tool 9.4 to start the utility, as shown below:



The program opens and begins scanning and validating the installed files, as shown below:

S Install Qualification Tool	-	×
Validating file 457 of 19157		
2%		
0 files with validation errors.		

Note: This process might take some time. Please be patient.

An HTML file containing the results is generated when the scan is complete. The name and path and a link to the file are displayed in a summary window, as shown below:

S Install Qualification Tool	-		×			
Validation complete. See <u>C:Program Files/SASHome/InstallMisc/InstallLogs/ValidationReport_2020-10-3</u>	<u>0-06.44.4</u>	7 <u>.html</u> for	details			
100%						
0 files with validation errors.						

Note: The name of the output file contains both the date and the time at which the validation scan was run. This file is always placed in the C:\Program Files\SASHome\InstallMisc\InstallLogs directory.

In this example, there were zero (0) validation errors.

At Either click on the link or navigate to the output file to view the results, partially shown below:

6	€ SAS Install Qualification × +	\checkmark		_		×		
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SA Wh too use add Hor val cha File	SAS Install Qualification Results SASHOME Path: C:\Program Files\SASHome When the SAS Installation Qualification Tool is run, the resulting validation is based on the state of the system at the time the initial installation completed. The tool's validation detects most manual modifications that the user makes to the SAS software components after the initial installation. So, for example, when the sadditional files as having changed. However, modifications that the user makes to the configuration files (such as sasv9.cfg or INI files) will be flagged by the tool as having different checksum values as compared to the files that were originally installed on the system. In addition, renewing your SAS license will cause the tool to flag files that have changed, such as the core.sas7bcat file. Since these kinds of changes are expected, if any are found during the validation, they will be listed in the "Excluded Files" section.							
Γ	Checksum Validation Passed:-					-		
	[1] SOFTWARE CODE: FILE: PRE-INSTALL CHECKSUM: POST-INSTALL CHECKSUM:	aacomp \SASFoundation\9.4\aacomp\sasexe\sasastor.dll e43070ac357902f9b6c13260e49afba4 e43070ac357902f9b6c13260e49afba4						
	[2] SOFTWARE CODE: FILE: PRE-INSTALL CHECKSUM: POST-INSTALL CHECKSUM:	aacomp \ SASFoundation\9.4\aacomp\sasexe\sashpsbr.dll 1d0bdf6005ee6a471bd4363bb4adcc1c 1d0bdf6005ee6a471bd4363bb4adcc1c						
	[3] SOFTWARE CODE: FILE: PRE-INSTALL CHECKSUM: POST-INSTALL CHECKSUM:	aacomp \ SASFoundation\9.4\aacomp\sasexe\sasmkxpx.dll 7ee3506a653f9d541089d4b7bfb02214 7ee3506a653f9d541089d4b7bfb02214						
	[4] SOFTWARE CODE: FILE: PRE-INSTALL CHECKSUM: POST-INSTALL CHECKSUM:	<pre>aacomp \SASFoundation\9.4\aacomp\sasexe\sasnlobr.dll c67f298df1cdc269e9bba3b85eccdbb7 c67f298df1cdc269e9bba3b85eccdbb7</pre>				~		

A Proceed to <u>Step 2: Operation Qualification</u>.

Step 2: Operation Qualification

Tool to start > SAS > SAS Operational Qualification Tool to start the utility, as shown below:



A DOS window appears. A prompt directs you to specify the directory in which to place the output file.

At Enter the name and path to the directory in which to place the file.

Note: You should note the name and location so that you can document them at a later date.

If the directory does not exist, it will be created. In this example, we specify a new Operation_Qualification_Results directory on the C drive.

Type C: \Operation_Qualification_Results at the prompt, as shown below:



A Click Enter to start the test.

Each step is listed in the DOS window as the test proceeds, as shown below:

I SAS Operational Qualification Tool	-	×
Please specify a directory where the output files should go [.1: C:\Operation Oualification Results		~
Running test base:tstbase:tstsgl		
Running test base:tstbase:tstrpt		
Running test base:tstbase:tsttab		
Running test base:tstbase:tstuni01		
Running test base:tstbase:tstrank		
Running test base:tstbase:tststan		
Running test base:tstbase:tstsum		
Running test base:tstbase:tsttps		
Running test base:tstbase:tstcalen		
Running test base:tstbase:tstchrt		
Running test base:tstbase:tstcmp		
		V

The DOS window closes when the test is complete.

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File Home Share	e View					~ 🕐
← → * ↑ □ > T	his PC > Local Disk (C:) > Operation_Qualif	ication_Results > 🗸 진	Search Operati	on_Qua	lificatio	م.
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Music						
💻 This PC 🂣 Network						
1 item						==

All of the results are placed in a folder within this directory. The name of the folder lists the date on which the test was performed.

Den the folder containing your results.

Test results are summarized in the sasoq.pdf file.

℃ Open the sasoq.pdf file.



SAS Operational Qualification - Windows

In this example, 131 tests were performed and passed. There were no failures.

Deroceed to <u>Step 3: NIST Testing</u>.

Step 3: NIST Testing

To assist customer operational qualification (OQ) efforts, JMP provides a set of tests based on the StRD in an extensible framework. These tests are available for download.

Download the NIST Testing Framework

Open your web browser and navigate to the JMP A Commitment to Quality web page (<u>https://www.jmp.com/en_us/software/quality-statement.html</u>).

Note: The example shown here is for JMP Clinical 8, which includes JMP 15.2.1. Your installation might be different. Be sure to select the NIST Testing Framework that matches the version of JMP that is included in your JMP Clinical Installation. Open JMP Clinical and click **About JMP Clinical** on the **Settings** tab to find the version of JMP that you have.



Note: JMP provides a tool for verifying the installation of JMP (circled in red, above). Because JMP Clinical contains components not found in standard JMP, this test is not valid for use with JMP Clinical. **Do not use this tool because it will notify you of warnings, errors, and inconsistencies.** The SAS Install Qualification Tool 9.4 utility already run in <u>Step 1: Installation Qualification</u> is more than sufficient.

A Click on the link to the JMP 15: NIST Testing Framework (circled in blue, above).

You must have a registered SAS profile to download software from this site. If you do not have a SAS Profile, you must create one before proceeding further. Follow the online instructions for registering a SAS Profile.

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\leftrightarrow \rightarrow O \textcircled{a} https://www.sas.com/profile/ui/#/sign-in?fromURI=https:%2F%2Fauth.sas.com/profile/ui/#/sign-in?fromURI=https:%2F%2Fauth.sas.com/profile/ui/#/sign-in?fromURI=https:%2F%2Fauth.sas.com/profile/ui/#/sign-in?fromURI=https:%2F%2Fauth.sas.com/profile/ui/#/sign-in?fromURI=https:%2F%2Fauth.sas.com/profile/ui/#/sign-in?fromURI=https:%2F%2Fauth.sas.com/profile/ui/#/sign-in?fromURI=https:%2F%2Fauth.sas.com/profile/ui/#/sign-in?fromURI=https:%2F%2Fauth.sas.com/profile/ui/#/sign-in?fromURI=https:%2F%2F%2Fauth.sas.com/profile/ui/#/sign-in?fromURI=https:%2F%2F%2F%2F%2F%2F%2F%2F%2F%2F%2F%2F%2F%	m9 🛄 🖈 📬	= <i>l</i> ~	È	
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New user?				
A SAS Profile gives you to SAS communities, to software downloads am newsletters and more.	u quick and easy a echnical support, id hot fixes, training	ICCESS g,		
Remember me Creat Next	e profile			
Users authenticating with single sign on using their corporate login credentials will be passing their name, email address and country to SAS under the terms of the SAS Privacy Statement and agree to comply with the SAS Terms of Use. Forgot password? Need help?				
Privacy Statement Terms of Use and Legal Information				
Copyright © SAS Institute Inc. All rights reserved.				~

Downloads

JMP 15 Validation

JMP provides information and tools to support customer testing and validation. The following items are available for download:

- Assessing the Numerical Accuracy of JMP a white paper describing the NIST testing framework, and numerical validation for JMP software (September 2019)
- 2. The JMP Development Process: A Process for Quality a white paper describing the JMP development and testing environment
- An extendable testing framework and set of tests based on the NIST (National Institute of Standards and Technology) standard for software validation (September 2019)
- 4. JMP Installer Validation a script used to validate the set of installer files versus a benchmark file

To begin the download process, select the item in the table below which best meets your needs.

JMP 15 Validation						
Platform	Description	Request Download	Size	Release Date	ReadME	
Macintosh & Windows	NIST Testing Framework and both white papers listed above (August 2020)	JMPValidation-15.zip	561 KB	2020-09	txt	

For questions you may have about this download, please contact our Product Support Group

- A Click JMPValidation-15.zip for the Windows NIST testing framework (circled above).
- Aread the License Agreement and click I Accept (not shown).
- ⁽¹⁾ Follow the directions listed in the successive windows to download the Windows NIST testing framework to the default C:\JMPValidation-15 directory.
- ⁽¹⁾ Navigate into the C:\Users\jmptest\Downloads\JMPValidation-15 directory.

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	≪ Users → j	jmptest > Downloads > JMP\	/alidation-15 →	✓ ♂ Search JMPValidat	ion-15 🔎
 ✓ Quick access ✓ Desktop ✓ Downloads ✓ Documents ✓ Pictures 	Nan *	ISL JMPNumericalAccuracy-15 JMPQuality	Type File folder PDF File PDF File	Compressed size 272 KB 125 KB	Password Size No No
 Music Videos OneDrive 					
💻 This PC					
3 items	<				

A This directory contains two white papers and the JSL folder. Open the JSL folder.

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Note: Before you can run this test, you must open JMP Clinical. The RunNISTTests.jsl NIST testing framework utility (contained in the JSL directory) is a jsl script and must be run in JMP.

Open JMP Clinical

⁻[↑] Click Start > SAS > JMP Clinical 8 to open JMP Clinical.

SAS Operational Qualification Tool
Please specify a directory where the output files should go [.]: C:
Running test base:tstbase:tstsql
Running test base:tstbase:tstrpt
Running test base:tstbase:tsttab
Running test base:tstbase:tstuni01
Running test base:tstbase:tstrank
Running test base:tstbase:tststan
Running test base:tstbase:tstsum
Running test base:tstbase:tsttps
Running test base:tstbase:tstcalen
Running test base:tstbase:tstchrt
Running test base:tstbase:tstcmp

When JMP Clinical opens for the first time, several windows open. One of these windows indicates that a JMP script is generating all of the process dialogs. When the Dialog Generator has finished, this window will close, leaving the JMP Clinical main window open.

JMP Clinical must contain at least one study in order for the NIST testing utility to run successfully. If you have a study loaded, proceed to <u>Run the NIST Testing Framework</u>. If no studies are loaded you must run the Add Study report to add either the Nicardipine sample study, included with JMP Clinical, or your own study before proceeding further. Refer to the Add Study documentation¹ in the JMP Clinical User Guide for instructions on adding the Nicardipine study.

Run the NIST Testing Framework

- [∽][⊕] Go back to the C:\JMPValidation-15\JSL directory.
- A Click and drag the RunNISTTests.jsl file into a JMP window to open the script in JMP.

B RunNISTTests - JMP Clinical	_		×				
File Edit Tables DOE Analyze Graph Tools View Window Help							
1 /*			^				
2 NIST Test Runner							
3 4 Will everyte colorted tests/ /testYYY isl files							
5 Test scripts make calls to							
6 ut assert(Expc(TEST), EXPECTED VALUE)							
8 Will open and check selected tests//testXXX.jmp files.							
10 */							
<pre>11 ut copyright date = "2020";</pre>							
<pre>12 if(!(JMPVersion()=="15.0.0" JMPVersion()=="15.1.0" JMPVersion()=="15.2</pre>	2.0" J	MPVersi	lon(
<pre>13NIST_dlg = dialog(title("Alert"),</pre>							
14 vlist(
15 textbox("Inis version of the NISI test suite is intended for .	JMP 15,	JMP 15.	1,				
17 blist(
18 hutton("OK"), hutton("Cancel")							
19							
20)							
21);							
<pre>22 if(arg(_NIST_dlg[3])==-1,throw())</pre>							
23);							
24							
25 ut notImplemented = expr(Dialog("Feature Not Implemented Yet", Button("OK") of ut have fet Default Disastery();)));						
<pre>26 ut nome = Get Default Directory(); 27 pist home = ut home;</pre>							
28							
<pre>29 ut test exclude = {}; genrpt=1; NIST Driver = 1;</pre>							
<pre>30 include(ut home "NISTDriverFunctions2.JSL");</pre>							
31							
32 {ut all files, ut test scripts, ut group scripts, ut_all} = ut FileStartup	o(files	in dire	cto				
33							
34 // JSL unit test GUI code							
<pre>35 uttime_bxsel=0; utst_bxsel="N"; strtebx=repeat(" ",60);</pre>							
36 Newwindow("NIST STRD",							
38 nbx = PanelBox("Filters")							
39 PanelBox("Scripts/Tables".							
<pre>40 selectedUTs = ListBox({},width(if(hostis(Mac).320.255)).nlines</pre>	5(15)).						
41)							
42),							
<pre>43 borderBox(left(8), right(8),</pre>							
<pre>44 lineupbox(ncol(3), spacing(10),</pre>							
45 ButtonBox("Run all",			\sim				
<			>				

^{1.} For JMP Clinical 8 (used for this example), these instructions can be found at <u>https://</u> www.jmp.com/support/downloads/JMPC80_documentation/Content/JMPCUserGuide/ <u>PR_L_ST_0001.htm</u>.

⁻ Click Edit > Run Script to open the NIST Strd - JMP window.

🛃 NIST	StRD - JMP (Clinical		-		×
8	Menus are av above. Click, menu.	ailable in hover or u	the auto-h use the Alt	ide me key to	nu strip access th	ie 🚫
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NIST/AI	NOVA/testAt	mAgWtFit	tYX.jsl			
NIST/AI	NOVA/testSil	RstvFitMo	d.jsl			
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A Click Run all to run the tests.

A series of windows will open and close as JMP runs through all of the tests. A summary window appears when all of the tests have run.



A Click **OK** to view the JMP Journal containing the test results (shown below).

🐏 NIST Test Report - JMP Clinical	- 0	×
Menus are available in the auto-hide menu strip above use the Alt key to access the menu. You can turn off auto-hiding in Preferences. Open Pro	e. Click, hover o eferences	Í ⊗
Build/Run Details Version: 15.2.1 Build Date: Sep 11 2020, 07:34:01, Release, JMP Run Date: 10/30/2020, 12:20:51 PW VIST Test Summary Files = 77 Tests = 583 Successes = 583 Failures = 0 Elapsed Time = 15:35 seconds		~
4 Details		
NIST/ANOVA/testAtmAgWtFitMod.jsl		
NIST/ANOVA/testAtmAgWtFitYX.jsl		
NIST/ANOVA/testSiRstvFitMod.jsl		
NIST/ANOVA/testSiRstvFitYX.jsl		
NIST/ANOVA/testSmLs01FitMod.jsl		
NIST/ANOVA/testSmLs01FitYX.jsl		
NIST/ANOVA/testSmLs02FitMod.jsl		
NIST/ANOVA/testSmLs02FitYX.jsl		
NIST/ANOVA/testSmLs03FitMod.jsl		
NIST/ANOVA/testSmLs03FitYX.jsl		
NIST/ANOVA/testSmLs04FitMod.jsl		
NIST/ANOVA/testSmLs04FitYX.jsl		
NIST/ANOVA/testSmLs05FitMod.jsl		
NIST/ANOVA/testSmLs05FitYX.jsl		~

In this example, 583 tests were run and passed. No tests failed.

Note: You should save this journal (click File > Save as) for later documentation.

Step 4: Run a Simple Analysis

- As a final check for JMP Clinical, we shall run a simple analysis.
- A Open JMP Clinical.
- ${}^{\ensuremath{\textcircled{}}}$ From the JMP Clinical main window, click the Reviews tab.



Click the Start a new Review icon to open the Review Builder.

A Select DM Distribution from the list of Clinical Reports and click OK.



The DM Distribution dialog opens with the included Nicardipine sample data loaded.

Menus are available in the auto-hide menu strip above. Click, hover or u		
You can turn off auto-hiding in Preferences. Open Preferences		
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Results Perform treatment comparison analysis for demographic variables Create additional distributions for selected variables Set Age Groups Age Groups *Group 1 Ø< Age <=39		
Results Perform treatment comparison analysis for demographic variables Create additional distributions for selected variables Set Age Groups Age Groups *Group 1 0<		
Results Perform treatment comparison analysis for demographic variables Create additional distributions for selected variables Set Age Groups Age Groups *Group 1 Øc< Age <=39		
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Results Perform treatment comparison analysis for demographic variables Create additional distributions for selected variables Set Age Groups Age Groups *Group 1 0<		
Results Perform treatment comparison analysis for demographic variables Create additional distributions for selected variables Set Age Groups Age Groups Age Group 1 Ø<< Age <=39		
Results Perform treatment comparison analysis for demographic variables Create additional distributions for selected variables Set Age Groups Age Groups Age Groups *Group 1 Ø<= Age <=39		

Click Run.

A Results window (partially shown below) opens, showing an analysis dashboard and the distribution results.



- ^o Click on the bottom bar of the Age distribution panel (corresponds to all subjects younger than 20 years of age). The bar will change color.
- A Click Profile Subjects.

A Profile Subjects window appears.



If these analyses run as shown, JMP Clinical has been successfully installed.