



**Installation Qualification,
Operational Qualification,
& Performance Qualification
Protocols
*for MeltView 2 Software***

May 7, 2019
(Revision 1.0.1)

Company: _____

Location: _____

Installation Qualification, Operation Qualification
& Performance Qualification Protocols for MeltView 2 Software
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§ Protocol Approval

Protocol Acceptance/Approval by Customer

I, the undersigned, agree that the procedures described herein are applicable to the MeltView 2 Software. Acceptance of the entire document is considered to be complete when the Certification of Qualification is reviewed and signed by the responsible parties.

Customer: _____

(Print Name and Title)

Signature: _____ Date: _____

Protocol Acceptance/Approval by Stanford Research Systems

I, the undersigned, agree that the procedures described in this document assembled by Stanford Research Systems Technical Support Services, are appropriate for the software defined in this protocol and reflect the current Stanford Research Systems (SRS) qualification procedure.

SRS's Representative: _____

(Print Name and Title)

Signature: _____ Date: _____

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1 Introduction

1.1 Objectives

This protocol is to be used for qualifying the installation, operation and performance of the Stanford Research Systems (SRS) MeltView 2 Software, located at the customer site shown on the title page. The protocol defines the requirements and acceptance criteria for the software in question. Successful completion of this Installation Qualification (IQ), Operating Qualification (OQ) and Performance Qualification (PQ) will provide the documented evidence to assure that the software has been installed and operated in accordance with SRS procedures and meet cGxP requirements.

1.2 Exclusions

This validation applies to the MeltView 2 Software, and not any 3rd party software that may be included in the package or the computer environment.

2 Acronyms and References

2.1 Acronyms and Definitions

CFR - Code of Federal (US) Regulations

cGxP - Abbreviation which includes current Good Manufacturing, Clinical and Laboratory Practices

Closed System - An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

FRS - Functional Requirements Specification

GUI - Graphical User Interface

IQ - Installation Qualification

LAN - Local Area Network

Open System - An environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

OQ - Operational Qualification

PQ - Performance Qualification

SDS - Software Design Specification

SOP - Standard Operating Procedure

2.2 References

FDA 21 CFR Part 11 Electronic Records, Electronic Signatures

GAMP 5 Guide for Validation of Automated Systems

3 System Description

The MeltView 2 Software comes in 2 editions: MeltView 2 (free) edition, and MeltView 2 *Pro* edition. Only the MeltView 2 *Pro* edition supports FDA 21 CFR Part 11. It consists of a database server (*MeltView server*) to manage data; an administration application (*MeltView-Admin*) to manage users and the system; and a main application (*MeltView*) to interface with the *MeltView server* and an SRS Optimelt instrument. The *MeltView server* is in fact a PostgreSQL database server with a database schema designed to work with MeltView applications. The MeltView data is stored on the PostgreSQL database server. With the default configuration, the database can be accessed from any system on the same local network; and that means users can run the *MeltView-Admin* and *MeltView* applications from any computer that is on the same LAN with the database server.

4 Procedure Test Plan

4.1 General

These IQ/OQ/PQ protocols will provide the documented verification that all key aspects of the MeltView 2 Software have been properly tested. The following items apply to all test steps in this IQ/OQ/PQ Protocol:

- Read each test case prior to performing the test.
- Follow the test steps listed in each test case.
- For each test instruction, document the results in the actual results column.
- Record *Pass* or *Fail* for each step in the test.
- Record the initials/date of each person performing the test under the Initial/Date column.

4.2 Exclusions

Even though the MeltView 2 Software comes in different editions, the tests outlined in the next sections cover only the MeltView 2 *Pro* edition. The MeltView 2 (free) edition is not designed to support FDA 21 CFR Part 11; therefore, it's excluded from these tests.

5 Installation Qualification (IQ)

The Installation Qualification (IQ) ensures that the MeltView 2 Software is installed with all required components to function correctly. The tests will cover the installation of MeltView 2 Pro *Server* and MeltView 2 Pro *Client* (32-bit & 64-bit) in which the components are each checked to be operational. Select the test case corresponds to the installer variation you use, either 32-bit or 64-bit. Plan 0.5-1 hour for the validation.

5.1 Test Case #1 – Verification of MeltView 2 Pro Server Installation

Purpose: To verify proper installation of the MeltView 2 Pro server.

Acceptance Criteria: The test case will demonstrate that:

- All documentation required to operate and maintain the system is present.
- The operating system required for use is either MS Windows 7 SP1, 8.1 or 10 with 64-bit architecture.
- The installer successfully finishes.
- The PostgreSQL database server is installed.
- The MeltView database schema is properly set up.

Step	Procedure	Expected Result	Actual Result	Pass/ Fail	Initial	Date
All documentation required to operate and maintain the system is present.						
1	Verify that all documentation required to operate and maintain the system is present.	All documentation required to operate and maintain the system is present.	<input type="checkbox"/> Documentation is present. <u>Document title</u> : <u>Revision</u> : <u>Document title</u> : <u>Revision</u> :			
The operating system required for use is either MS Windows 7 SP1, 8.1, or 10 with 64-bit architecture.						
2	- Go to Start > Run > type "msinfo32.exe". - Verify OS Name and System Type on the System Information window.	The OS Name shows either Windows 7 SP1, 8.1, or 10. The System Type shows x64.	<u>OS Name</u> : <u>System Type</u> :			
The installer successfully finishes.						
3	Record the installer version.	The installer version is recorded.	<u>Installer version</u> :			
4	- Run installer MeltView-<version>-Pro-server-x64.exe . - Select all components and proceed to the end.	Finish page is shown with no errors.	<input type="checkbox"/> Finish page is shown with no errors.			
The PostgreSQL database server is installed.						
5	- Go to Start > Run > type "services.msc". - Verify service postgresql-x64-10 exists and is running on Services window.	The postgresql-x64-10 service is present, and its status shows <i>Running</i> .	<input type="checkbox"/> The postgresql-x64-10 service is present. <input type="checkbox"/> Its status shows <i>Running</i> .			

Step	Procedure	Expected Result	Actual Result	Pass/ Fail	Initial	Date
The MeltView database schema is properly set up.						
6	Record PostgreSQL installation directory	PostgreSQL installation directory recorded.	PostgreSQL installation location <install_dir>:			
7	<ul style="list-style-type: none"> - Open CMD Prompt and type: <install_dir>\bin\psql -U postgres -d meltview - Provide the password for superuser postgres to log in. - Verify user postgres can log in. 	Successful login.	<input type="checkbox"/> Successful login.			

5.2 Test Case #2 – Verification of MeltView 2 Pro Client Installation (32-bit Version)

Purpose: To verify proper installation of the 32-bit version of MeltView 2 Pro client applications.

Prerequisites: MeltView 2 Pro server was NOT installed on a same host.

Acceptance Criteria: The test case will demonstrate that:

- The prerequisites have been met.
- All documentation required to operate and maintain the system is present.
- The operating system required for use is either MS Windows 7 SP1, 8.1 or 10.
- The installer successfully finishes.
- The MeltView-Admin application is properly installed.
- The MeltView main application is properly installed.

Step	Procedure	Expected Result	Actual Result	Pass/ Fail	Initial	Date
The prerequisites have been met.						
1	Go to Start > Run > type "services.msc". Verify service "postgresql-x64-10" DOES NOT exist on Services window.	The postgresql-x64-10 service is NOT present.	<input type="checkbox"/> The postgresql-x64-10 service is NOT present.			
All documentation required to operate and maintain the system is present.						
2	Verify that all documentation required to operate and maintain the system is present.	All documentation required to operate and maintain the system is present.	<input type="checkbox"/> Documentation is present. <u>Document title:</u> <u>Revision:</u> <u>Document title:</u> <u>Revision:</u>			
The operating system required for use is either MS Windows 7 SP1, 8.1, or 10.						
3	- Go to Start > Run > type "msinfo32.exe". - Verify OS Name on the System Information window.	The OS Name shows either Windows 7 SP1, 8.1, or 10.	<u>OS Name:</u>			
The installer successfully finishes.						
4	Record the installer version.	The installer version is recorded.	<u>Installer version:</u>			
5	- Run installer MeltView-<version>-Pro-client.exe .	Finish page is shown with no errors.	<input type="checkbox"/> Finish page is shown with no errors.			
The MeltView-Admin application is properly installed.						
6	- Go to Start > [All Programs (if Windows 7)] > SRS MeltView 2** start menu folder > click Admin . - Verify MeltView-Admin application can launch.	The MeltView-Admin application launches, showing Authentication dialog box.	<input type="checkbox"/> The MeltView-Admin application launches, showing Authentication dialog box.			

Step	Procedure	Expected Result	Actual Result	Pass/ Fail	Initial	Date
	<p><i>** If you name the start menu folder differently, use that name.</i></p>					
The MeltView main application is properly installed.						
7	<p>- Go to Start > [All Programs (if Windows 7)] > SRS MeltView 2 start menu folder > click MeltView.</p> <p>- Verify MeltView application can launch.</p> <p><i>** If you name the start menu folder differently, use that name.</i></p>	The MeltView application launches, showing Authentication dialog box.	<input type="checkbox"/> The MeltView application launches, showing Authentication dialog box.			

5.3 Test Case #3 – Verification of MeltView 2 Pro Client Installation (64-bit Version)

Purpose: To verify proper installation of the 64-bit version of MeltView 2 Pro client applications.

Acceptance Criteria: The test case will demonstrate that:

- All documentation required to operate and maintain the system is present.
- The operating system required for use is either MS Windows 7 SP1, 8.1 or 10 with 64-bit architecture.
- The installer successfully finishes.
- The MeltView-Admin application is properly installed.
- The MeltView main application is properly installed.

Step	Procedure	Expected Result	Actual Result	Pass/ Fail	Initial	Date
All documentation required to operate and maintain the system is present.						
1	Verify that all documentation required to operate and maintain the system is present.	All documentation required to operate and maintain the system is present.	<input type="checkbox"/> Documentation is present. <u>Document title:</u> <u>Revision:</u> <u>Document title:</u> <u>Revision:</u>			
The operating system required for use is either MS Windows 7 SP1, 8.1 or 10.						
2	Go to Start > Run > type "msinfo32.exe". Verify OS Name and System Type on the System Information window.	The OS Name shows either Windows 7 SP1, 8.1 or 10. The System Type shows x64.	<u>OS Name:</u> <u>System Type:</u>			
The installer successfully finishes.						
3	Record the installer version.	The installer version is recorded.	<u>Installer version:</u>			
4	Run installer MeltView-<version>-Pro-client-x64.exe .	Finish page is shown with no errors.	<input type="checkbox"/> Finish page is shown with no errors.			
The MeltView-Admin application is properly installed.						
5	- Go to Start > [All Programs (if Windows 7)] > SRS MeltView 2** start menu folder > click Admin . - Verify MeltView-Admin application can launch. <i>** If you name the start menu folder differently, use that name.</i>	The MeltView-Admin application launches, showing Authentication dialog box.	<input type="checkbox"/> The MeltView-Admin application launches, showing Authentication dialog box.			
The MeltView main application is properly installed.						
6	- Go to Start > [All Programs (if Windows 7)] > SRS MeltView 2** start menu folder > click MeltView .	The MeltView application launches, showing Authentication dialog box.	<input type="checkbox"/> The MeltView application launches, showing Authentication dialog box.			

Step	Procedure	Expected Result	Actual Result	Pass/ Fail	Initial	Date
	<p>- Verify MeltView application can launch. <i>** If you name the start menu folder differently, use that name.</i></p>					

6 Operational Qualification (OQ)

The Operational Qualification (OQ) ensures that the MeltView 2 Software operate as expected. The tests will validate key operations of the software with positive test cases. They will cover the main functionalities of the MeltView-Admin and the MeltView main application. These 2 client applications operate in conjunction with a database server that installed by MeltView 2 Pro server installer. Plan 1-2 hour for these validations.

6.1 Test Case #4 – Verification of MeltView-Admin Operation

Purpose: To verify proper operation of the MeltView-Admin application.

Acceptance Criteria: The test case will demonstrate that:

- The default `admin` user can log in and change password.
- New users can be added.
- Existing users can be updated.
- System configuration can be updated.
- Audit trail properly displays relevant information.
- Database can be backed up.
- Database can be restored.

Step	Procedure	Expected Result	Actual Result	Pass /Fail	Initial	Date
The default admin user can log in and change password.						
1	- Record the database server IP address (127.0.0.1 for local host) and Port number. - Verify server information is recorded.	Data server IP address and Port number recorded.	<u>Server IP</u> : <u>Server Port</u> :			
2	- Go to Start > [All Programs (if Windows 7)] > SRS MeltView 2** start menu folder > click Admin . - Enter <code>admin / admin</code> for username and password on Authentication dialog box. Enter server IP address and port number. - Verify the Password Change dialog box open. <i>** If you name the start menu folder differently, use that name.</i>	The Change Password dialog box opens.	<input type="checkbox"/> The Change Password dialog box opens.			
3	- Enter a new password and retype to confirm it. - Verify user <code>admin</code> can log in.	User <code>admin</code> can log in.	<input type="checkbox"/> User <code>admin</code> can log in.			
New users can be added.						
4	- Click Users icon on the side panel, then click New User button. Provide username, first & last name, and optionally other user information.	Success message box shows "New user is successfully added".	<input type="checkbox"/> Success message box shows "New user is successfully added".			

Step	Procedure	Expected Result	Actual Result	Pass /Fail	Initial	Date
	Select user permissions. Click Add User . - Verify the new user is added.					
Existing uses can be updated.						
5	- Click Users icon on the side panel, then click on the newly created user under Username list. - Update any user information fields. Update user permissions. Click Apply . - Verify user data can be updated.	- <i>Success</i> message box shows "User data is successfully updated". - Updated data is displayed on the User panel after clicking OK on Success message box.	<input type="checkbox"/> <i>Success</i> message box shows "User data is successfully updated". <input type="checkbox"/> Updated data is displayed on the User panel after clicking OK on <i>Success</i> message box.			
System configuration can be updated.						
6	- Click System icon on the side panel, then click on Security Policy item under System Configuration list. - Change any field on the Security Policy panel. - Verify data can be updated.	- <i>Success</i> message box shows "Security policy is successfully updated". - Updated data is displayed on the Security Policy panel after clicking OK on the Success message box.	<input type="checkbox"/> <i>Success</i> message box shows "Security policy is successfully updated". <input type="checkbox"/> Updated data is displayed on the Security Policy panel after clicking OK on the Success message box.			
7	- Click System icon on the side panel, then click on Signing Configuration item under System Configuration list. - Check/uncheck any item under Signing Reason column on the Signing Configuration panel. - Optionally click New Reason to add a new signing reason. - Click Apply . - Verify data can be updated.	- <i>Success</i> message box shows "Signing configuration is successfully updated". - Updated data is displayed on the Signing Configuration panel after clicking OK on the Success message box.	<input type="checkbox"/> <i>Success</i> message box shows "Signing configuration is successfully updated". <input type="checkbox"/> Updated data is displayed on the Signing Configuration panel after clicking OK on the Success message box.			
8	- Click System icon on the side panel, then click on Report Options item under System Configuration list. - Check/uncheck any item under Page Header and Page Footer groups on the Report Options panel. - Optionally click Upload to upload a company logo. - Click Apply . - Verify data can be updated.	- Logo image is displayed if an image is uploaded. - <i>Success</i> message box shows "Report options are successfully updated". - Updated data is displayed on the Report Options panel after clicking OK on the Success message box.	<input type="checkbox"/> Logo image is displayed after uploading. <input type="checkbox"/> <i>Success</i> message box shows "Report options are successfully updated". <input type="checkbox"/> Updated data is displayed on the Report Options panel after clicking OK on the Success message box.			
9	- Click System icon on the side panel, then click on License item under System Configuration list.	- The Save License Request Form dialog box is showed to save the request as a file.	<input type="checkbox"/> The Save License Request Form dialog box is showed to save the request as a file.			

Step	Procedure	Expected Result	Actual Result	Pass /Fail	Initial	Date
	<ul style="list-style-type: none"> - Provide the information for the License Request form on the License Request and Installation panel. - Click Save Request Form. - Verify data can be saved. 	- The file is successfully saved when clicking Save .	<input type="checkbox"/> The file is successfully saved when clicking Save .			
10	<ul style="list-style-type: none"> - Click System icon on the side panel, then click on License item under System Configuration list. - Click Install License button on the License Request and Installation panel. - Provide the license file on the Open dialog box and click Open. - Click Yes on the confirmation window. - Verify the license can be installed. 	- Information message box shows "Successfully installed License to Server".	<input type="checkbox"/> Information message box shows "Successfully installed License to Server".			
Audit trail properly display relevant information.						
11	<ul style="list-style-type: none"> - Click Audit Trail icon on the side panel, then select one or more logs (Users, Instruments, Measurements, Logins, Maintenance) on the Audit panel. - Verify the data is displayed. - Click on one of the rows. Verify the detailed information is displayed. 	<ul style="list-style-type: none"> - The audit trail data is displayed. - The detailed information is displayed. 	<ul style="list-style-type: none"> <input type="checkbox"/> The audit trail data is displayed. <input type="checkbox"/> The detailed information is displayed. 			
Database can be backed up.						
12	<ul style="list-style-type: none"> - Click Maintenance icon on the side panel, then select Database Backup under Operation list. - On the Database Backup panel, provide credentials for <code>postgres</code> user, specify backup base name and location, select Now for backup time, and click Start Backup. 	<ul style="list-style-type: none"> - <i>Success</i> message box shows "The backup is complete. Database is backed up to directory <location\baseName-timestamp>". - The directory <location\baseName-timestamp> is created with content such as <code>*.dat.gz</code>, <code>rolesinfo</code>, <code>toc.dat</code> files. 	<ul style="list-style-type: none"> <input type="checkbox"/> <i>Success</i> message box shows "The backup is complete. Database is backed up to directory <location\baseName-timestamp>". <input type="checkbox"/> The directory <location\baseName-timestamp> is created with content such as <code>*.dat.gz</code>, <code>rolesinfo</code>, <code>toc.dat</code> files. 			
13	<ul style="list-style-type: none"> - Click Maintenance icon on the side panel, then select Database Backup under Operation list. - On the Database Backup panel, provide credentials for <code>postgres</code> user, specify backup base name and location, and select Scheduled for backup time. 	<ul style="list-style-type: none"> - Backup ran on the scheduled date/time and <i>Success</i> message box shows "The backup is complete. Database is backed up to directory <location\baseName-timestamp>". 	<input type="checkbox"/> Backup ran on the scheduled time and <i>Success</i> message box shows "The backup is complete. Database is backed up to directory <location\baseName-timestamp>".			

Step	Procedure	Expected Result	Actual Result	Pass /Fail	Initial	Date
	<ul style="list-style-type: none"> - On the Scheduler dialog box, select option <i>One Time</i>. Then select a <i>Start</i> date and time that is a couple of minutes past the current date/time (This would allow the next backup to start in a couple of minutes). Click OK to save. - Click Start Backup. 	<ul style="list-style-type: none"> - The directory <location\baseName-timestamp> is created with content such as *.dat.gz, rolesinfo, toc.dat files. 	<ul style="list-style-type: none"> <input type="checkbox"/> The directory <location\baseName-timestamp> is created with content such as *.dat.gz, rolesinfo, toc.dat files. 			
14	<ul style="list-style-type: none"> - Repeat the previous step with a recurring option (<i>Daily, Weekly, Monthly</i>). 	<ul style="list-style-type: none"> - Backup ran and no message boxes shown. - Logs text box shows "Success: Database is backed up to <location\baseName-timestamp>". - The directory <location\baseName-timestamp> is created with content such as *.dat.gz, rolesinfo, toc.dat files. - Next backup countdown message is shown. 	<ul style="list-style-type: none"> <input type="checkbox"/> Backup ran and no message boxes shown. <input type="checkbox"/> Logs text box shows "Success: Database is backed up to <location\baseName-timestamp>". <input type="checkbox"/> The directory <location\baseName-timestamp> is created with content such as *.dat.gz, rolesinfo, toc.dat files. <input type="checkbox"/> Next backup countdown message is shown. 			
Database can be restored.						
15	<ul style="list-style-type: none"> - Click Maintenance icon on the side panel, then select Database Restore under Operation list. - On the Database Restore panel, provide credentials for postgres user, specify the backup directory, and click Start Restore. - Click Yes on the Confirmation message box to proceed. 	<ul style="list-style-type: none"> - User is logged out. - <i>Success</i> message box shows "Restoring is complete. Database is restored from <backupDirectory>". 	<ul style="list-style-type: none"> <input type="checkbox"/> User is logged out. <input type="checkbox"/> Success message box shows "Restoring is complete. Database is restored from <backupDirectory>". 			

6.2 Test Case #5 – Verification of MeltView Operation

Purpose: To verify proper operation of the MeltView main client application.

Prerequisites: Following items must be available in advance:

- A new user has been added with permissions: *Operate, View Data, Sign, View Audit, & Calibrate*. The *Reset password* checkbox is checked when adding the user.
- An SRS Optimelt instrument (e.g. MPA100) is available and physically connected to the computer.

Acceptance Criteria: The test case will demonstrate that:

- The new user can log in and change password.
- Connects to an SRS Optimelt instrument.
- Acquires data from the SRS Optimelt instrument.
- Views acquired measurements.
- Signs off on a measurement.
- Generates PDF report for a measurement.
- Views audit trail.

Step	Procedure	Expected Result	Actual Result	Pass /Fail	Initial	Date
The new user can log in and change password.						
1	<ul style="list-style-type: none"> - Record the database server IP address (127.0.0.1 for local host) and Port number. - Record newly added user. 	<ul style="list-style-type: none"> - Data server IP address and Port number recorded. - New user is recorded. 	<u>Server IP:</u> <u>Server Port:</u> <u>Username:</u> <u>First/Last Name:</u>			
2	<ul style="list-style-type: none"> - Go to Start > [All Programs (if Windows 7)] > SRS MeltView 2** start menu folder > click MeltView. - Enter new user's username and password on Authentication dialog box. - Enter server IP address and port number. - Verify the Password Change dialog box open. ** If you name the start menu folder differently, use that name. 	The Change Password dialog box opens.	<input type="checkbox"/> The Change Password dialog box opens.			
3	<ul style="list-style-type: none"> - Enter a new password and retype to confirm it. - Verify user can log in. 	<ul style="list-style-type: none"> - User can log in. - User's first name is displayed on the top right corner. - Connection dialog box is displayed. 	<input type="checkbox"/> User can log in. <input type="checkbox"/> User's first name is displayed on the top right corner. <input type="checkbox"/> Connection dialog box is displayed.			
Connects to an SRS Optimelt instrument.						

Step	Procedure	Expected Result	Actual Result	Pass /Fail	Initial	Date
4	<ul style="list-style-type: none"> - Power on the Optimelt instrument if it's not on. - Click Refresh button on the Connection dialog box. - Verify the Optimelt instrument is available. 	The Optimelt instrument is displayed on the Connection dialog box with status "Available".	<input type="checkbox"/> The Optimelt instrument is displayed on the Connection dialog box with status "Available".			
5	<ul style="list-style-type: none"> - Select the Optimelt instrument on the Connection dialog box, and click Connect. - Verify the instrument is connected. 	<ul style="list-style-type: none"> - The Connection dialog box closes. - Camera box shows live image from the instrument. - The temperature reading matches that on the instrument. 	<ul style="list-style-type: none"> <input type="checkbox"/> The Connection dialog box closes. <input type="checkbox"/> Camera box shows live image from the instrument. <input type="checkbox"/> The temperature reading matches that on the instrument. 			
Acquires data from the SRS Optimelt instrument.						
6	<ul style="list-style-type: none"> - Add a Phenacetin sample from SRS's Melting Point Standards package (O100MPS) to the capillary tubes, and place the tubes in the Optimelt instrument. - On the Control panel (located on the right side), enter <i>Chemical Name, Batch Number, Notes</i> (optional), <i>Start Temperature 130°C, Stop Temperature 140°C, Heating Rate 5°C/min</i>. - Click Start. - Verify melting starts and finishes. 	<ul style="list-style-type: none"> - Temperature reading increases to the Start Temperature. - <i>Melting</i> status is displayed during sample melting. Melt plots are displayed with data. - Camera box shows images of melting progress. - <i>New Data View</i> status is displayed at the end of melting. 	<ul style="list-style-type: none"> <input type="checkbox"/> Temperature reading increases to the Start Temperature. <input type="checkbox"/> <i>Melting</i> status is displayed during sample melting. Melt plots are displayed with data. <input type="checkbox"/> Camera box shows images of melting progress. <input type="checkbox"/> <i>New Data View</i> status is displayed at the end of melting. 			
Views acquired measurements						
7	<ul style="list-style-type: none"> - Go to Measurement menu > select Browse Data. - Verify newly acquired data is available. 	<ul style="list-style-type: none"> - New data is displayed on Data table with provided info (chemical, batch, etc.) and melting measurements (onset, clear, single temperatures). 	<input type="checkbox"/> New data is displayed on Data table with provided info (chemical, batch, etc.) and melting measurements (onset, clear, single temperatures).			
8	<ul style="list-style-type: none"> - Click on the row with newly acquired data. - Verify the detailed information is available. 	<ul style="list-style-type: none"> - Detailed information is displayed on the Selected Row Details panel. 	<input type="checkbox"/> Detailed information is displayed on the Selected Row Details panel.			
9	<ul style="list-style-type: none"> - Select a data row on the Data table, and click Open. - Verify acquired data can be viewed. 	<ul style="list-style-type: none"> - An information popup shows "Measurement data is successfully loaded from Server" or "Measurement data is already open". - The open data shows on the main window with images, plots, 	<ul style="list-style-type: none"> <input type="checkbox"/> An information popup shows "Measurement data is successfully loaded from Server" or "Measurement data is already open". <input type="checkbox"/> The open data shows on the main window with images, plots, temperature reading, parameters. 			

Step	Procedure	Expected Result	Actual Result	Pass /Fail	Initial	Date
		temperature reading, parameters.				
Signs off on a measurement.						
10	<ul style="list-style-type: none"> - Select a data row on the Data table, and click the Sign button. - Verify user can sign. 	<ul style="list-style-type: none"> - The Signing dialog box opens. 	<ul style="list-style-type: none"> <input type="checkbox"/> The Signing dialog box opens. 			
11	<ul style="list-style-type: none"> - Provide password, select <i>Signing Reason</i>, write comments (optional) on the Signing dialog box, and click OK. - Verify the signing successful. 	<ul style="list-style-type: none"> - Signing dialog box closes. - Signed column of the Data table for the signed record shows <i>Yes</i>. - Selecting the signed record shows detailed signature information on the Selected Row Details panel. 	<ul style="list-style-type: none"> <input type="checkbox"/> Signing dialog box closes. <input type="checkbox"/> Signed column of the Data table for the signed record shows <i>Yes</i>. <input type="checkbox"/> Selecting the signed record shows detailed signature information on the Selected Row Details panel. 			
Generates PDF report for a measurement.						
12	<ul style="list-style-type: none"> - Select a data row on the Data table, and click the Report button. - Verify saving report is available. 	The Save File dialog box opens.	<ul style="list-style-type: none"> <input type="checkbox"/> The Save File dialog box opens. 			
13	<ul style="list-style-type: none"> - Provide a file name on the Save File dialog box, and click Save. - Verify the report is saved. 	<ul style="list-style-type: none"> - An information popup shows "The PDF report has been successfully saved to <location>". - Opening the PDF file from <i>Windows File Explorer</i> shows information about the selected record. 	<ul style="list-style-type: none"> <input type="checkbox"/> An information popup shows "The PDF report has been successfully saved to <location>". <input type="checkbox"/> Opening the PDF file from <i>Windows File Explorer</i> shows information about the selected record. 			
Views audit trail.						
14	<ul style="list-style-type: none"> - Go to Measurement menu > select Browse Audit Trail. - Select one or more logs (Users, Instruments, Measurements, Logins, Maintenance) on the Audit Trail dialog box. - Verify the data is displayed. - Click on one of the rows. Verify the detailed information is displayed. 	<ul style="list-style-type: none"> - The audit trail data is displayed. - The detailed information is displayed. 	<ul style="list-style-type: none"> <input type="checkbox"/> The audit trail data is displayed. <input type="checkbox"/> The detailed information is displayed. 			

7 Performance Qualification (PQ)

The Performance Qualification (PQ) of the MeltView 2 Software ensures that the software works in a production environment without issues. The software will undergo the Availability, Accessibility and Load tests to simulate live conditions. Since the tests make sure that the software work over a long period of time, plan about 1 week for the PQ.

7.1 Test Case #6 – Verification of MeltView 2 Software Performance

Purpose: To verify the performance of the MeltView 2 Software as a whole, including the MeltView database server, the MeltView-Admin application, and the MeltView main application.


Prerequisites: Following items must be available in advance:

- Multiple users have been added with all permissions or various permissions.
- One or more SRS Optimelt instruments (e.g. MPA100) are available and physically connected to one or more computers.

Acceptance Criteria: The test case will demonstrate that:

- The server is continuously available for login from MeltView-Admin and MeltView main application – Availability test.
- The users can log in on MeltView-Admin and MeltView main application from different locations without issues – Accessibility test.
- Multiple users log in and perform operations on MeltView-Admin and MeltView main application at a same time – Load test.

Action Definitions: Following actions are defined as short-hands.

- Launch MeltView-Admin app: Go to **Start** > [**All Programs** (if Windows 7)] > **SRS MeltView 2**** start menu folder > click **Admin**.
- Launch MeltView app: Go to **Start** > [**All Programs** (if Windows 7)] > **SRS MeltView 2**** start menu folder > click **MeltView**.
- Log in with a user <abc>: On the Authentication dialog box, provide username, password of user <abc>, server IP address and server port, and click OK to log in. To bring up the Authentication dialog box, click on the  icon.
- Browse data (on MeltView-Admin app): Click on either **Users**, **System**, or **Audit Trail** icon on the side panel. On the **Users** panel, click on different username to view the information. On the **System** panel, click on different items to view different system settings. On the **Audit Trail** panel, select different log options to view the audit logs.
- Browse data (on MeltView app): Go to the **Measurement** menu, select **Browse Data**. On the **Data** dialog box, select different data record to view the detailed information.
- Acquire melting point data (on MeltView app): Go to the **Operate** menu and select **Connect**. On the Connection dialog box, click **Refresh**, select an Optimelt instrument, and click **Connect**. Charge the capillary tubes with a sample, and place the tubes in the Optimelt instrument. Provide information for the acquisition such as *Chemical*, *Batch*, *Start Temperature*, *Stop Temperature*, *Heating Rate*. Click **Start** to start acquiring the data.

** If you name the start menu folder differently, use that name.

Step	Procedure	Expected Result	Actual Result	Pass /Fail	Initial	Date
The server is continuously available for login from MeltView-Admin and MeltView main application – Availability test.						
1	<ul style="list-style-type: none"> - Record the database server IP address (127.0.0.1 for local host) and Port number. - Verify server information is recorded. 	Data server IP address and Port number recorded.	<u>Server IP:</u> <u>Server Port:</u>			
2	<ul style="list-style-type: none"> - Launch MeltView-Admin app. Log in with a valid administrator user. - Browse different data (Users, System, Audit Trail). - Verify the user logs in and can browse data. 	<ul style="list-style-type: none"> - The user can log in. - The user can browse different data (Users, System, Audit Trail). 	<input type="checkbox"/> The user can log in. <input type="checkbox"/> The user can browse different data (Users, System, Audit Trail).			
3	<ul style="list-style-type: none"> - Launch MeltView app. Log in with a valid user. - Browse different data. - Acquire melting point data. - Verify the user can log in, acquire data and browse data. 	<ul style="list-style-type: none"> The user can log in. The user can acquire data. The user can browse different data. 	<input type="checkbox"/> The user can log in. <input type="checkbox"/> The user can acquire data. <input type="checkbox"/> The user can browse different data.			
4	<ul style="list-style-type: none"> - Repeat step 2 & 3 for different time of the day, multiple days. - Verify the steps work every time. 	The steps work every time.	<input type="checkbox"/> The steps work every time.			
The users can log in on MeltView-Admin and MeltView main application from different locations without issues – Accessibility test.						
5	<ul style="list-style-type: none"> - Perform step 2 & 3 on a computer that is on the same LAN with the database server. - Verify the steps work every time. 	The steps work every time.	<input type="checkbox"/> The steps work every time.			
6	<ul style="list-style-type: none"> - Repeat step 5 for multiple computers that are on the same LAN with the database server. - Verify the steps work every time. 	The steps work every time.	<input type="checkbox"/> The steps work every time.			
Multiple users log in and perform operations on MeltView-Admin and MeltView main application at a same time – Load test						
7	<ul style="list-style-type: none"> - Perform step 2 & 3 on multiple computers that are on the same LAN with the database server at a same time. - Verify the steps work every time. 	The steps work every time.	<input type="checkbox"/> The steps work every time.			

§ Protocol Certification

Installation, Operational and Performance Qualification of the MeltView 2 Software *Certification*

The Installation, Operational and Performance Qualification final report for the Stanford Research Systems MeltView 2 Software, Version _____, has been reviewed and the software was found to meet the requirements necessary to be used in the customers' laboratory.

Final Report

Authorized SRS Representative:

Reviewed by: _____

(Print Name and Title)

Signature: _____ Date: _____

Authorized Customer Representative:

Reviewed by: _____

(Print Name and Title)

Signature: _____ Date: _____

Customer QA Representative (if applicable):

Reviewed by: _____

(Print Name and Title)

Signature: _____ Date: _____