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

May 7, 2019
(Revision 1.0.1)
§ 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.

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Initial</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Verify that all documentation required to operate and maintain the system is present.</td>
<td>All documentation required to operate and maintain the system is present.</td>
<td>Documentation is present.</td>
<td>![ ]</td>
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<tr>
<td></td>
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<td>Document title:</td>
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<td>Revision:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>- Go to Start &gt; Run &gt; type “msinfo32.exe”. - Verify <strong>OS Name</strong> and <strong>System Type</strong> on the <strong>System Information</strong> window.</td>
<td>The OS Name shows either Windows 7 SP1, 8.1, or 10. The System Type shows x64.</td>
<td>OS Name:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>System Type:</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>3</td>
<td>Record the installer version.</td>
<td>The installer version is recorded.</td>
<td>Installer version:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>- Run installer <strong>MeltView-&lt;version&gt;-Pro-server-x64.exe</strong>. - Select all components and proceed to the end.</td>
<td><strong>Finish</strong> page is shown with no errors.</td>
<td>![ ]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>The postgresql-x64-10 service is present. Its status shows Running.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>- Go to Start &gt; Run &gt; type “services.msc”. - Verify service <strong>postgresql-x64-10</strong> exists and is running on <strong>Services</strong> window.</td>
<td>The postgresql-x64-10 service is present, and its status shows Running.</td>
<td>![ ]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>The postgresql-x64-10 service is present. Its status shows Running.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step</td>
<td>Procedure</td>
<td>Expected Result</td>
<td>Actual Result</td>
<td>Pass/Fail</td>
<td>Initial</td>
<td>Date</td>
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<tr>
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</tr>
<tr>
<td>6</td>
<td>Record PostgreSQL installation directory</td>
<td>PostgreSQL installation directory recorded.</td>
<td>PostgreSQL installation location <code>&lt;install_dir&gt;</code>:</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>- Open CMD Prompt and type: <code>&lt;install_dir&gt;\bin\psql -U postgres -d meltview</code>&lt;br&gt;- Provide the password for superuser <code>postgres</code> to log in.&lt;br&gt;- Verify user <code>postgres</code> can log in.</td>
<td>Successful login.</td>
<td>✔️ Successful login.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Initial</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Go to Start &gt; Run &gt; type “services.msc”. Verify service “postgresql-x64-10” DOES NOT exist on Services window.</td>
<td>The postgresql-x64-10 service is <strong>NOT</strong> present.</td>
<td>❑ The postgresql-x64-10 service is <strong>NOT</strong> present.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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. | ❑ Documentation is present.  
  **Document title:**  
  **Revision:**  
  **Document title:**  
  **Revision:** |         |        |      |
| 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.  
  **OS Name:** | *OS Name:* |         |        |      |
| 4    | Record the installer version. | The installer version is recorded. | Installer version: |         |        |      |
| 5    | - Run installer **MeltView-<version>-Pro-client.exe**.  
  - **Finish** page is shown with no errors. | Finish page is shown with no errors. | ❑ Finish page is shown with no errors. |         |        |      |
| 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. | ❑ The MeltView-Admin application launches, showing Authentication dialog box. |         |        |      |
The MeltView main application is properly installed.

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Initial</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7</strong></td>
<td>- Go to <strong>Start</strong> &gt; [All Programs (if Windows 7)] &gt; <strong>SRS MeltView 2</strong> [<strong>start menu folder &gt; click MeltView.</strong>] - Verify MeltView application can launch. <strong>If you name the start menu folder differently, use that name.</strong></td>
<td>The MeltView application launches, showing Authentication dialog box.</td>
<td>☑ The MeltView application launches, showing Authentication dialog box.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Initial</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Verify that all documentation required to operate and maintain the system is present.</td>
<td>All documentation required to operate and maintain the system is present.</td>
<td>❑ Documentation is present. Document title: Revision: Document title: Revision:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Go to Start &gt; Run &gt; type &quot;msinfo32.exe&quot;. Verify OS Name and System Type on the System Information window.</td>
<td>The OS Name shows either Windows 7 SP1, 8.1 or 10. The System Type shows x64.</td>
<td>OS Name: System Type:</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>3</td>
<td>Record the installer version.</td>
<td>The installer version is recorded.</td>
<td>Installer version:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Run installer MeltView-&lt;version&gt;-Pro-client-x64.exe.</td>
<td>Finish page is shown with no errors.</td>
<td>❑ Finish page is shown with no errors.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>- Go to Start &gt; [All Programs (if Windows 7)] &gt; SRS MeltView 2** start menu folder &gt; click Admin. - Verify MeltView-Admin application can launch. **If you name the start menu folder differently, use that name.</td>
<td>The MeltView-Admin application launches, showing Authentication dialog box.</td>
<td>❑ The MeltView-Admin application launches, showing Authentication dialog box.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>- Go to Start &gt; [All Programs (if Windows 7)] &gt; SRS MeltView 2** start menu folder &gt; click MeltView.</td>
<td>The MeltView application launches, showing Authentication dialog box.</td>
<td>❑ The MeltView application launches, showing Authentication dialog box.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step</td>
<td>Procedure</td>
<td>Expected Result</td>
<td>Actual Result</td>
<td>Pass/Fail</td>
<td>Initial</td>
<td>Date</td>
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</tr>
<tr>
<td></td>
<td>- Verify MeltView application can launch. <strong>If you name the start menu folder differently, use that name.</strong></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Initial Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>- Record the database server IP address (127.0.0.1 for local host) and Port number. - Verify server information is recorded.</td>
<td>Data server IP address and Port number recorded.</td>
<td>Server IP:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>- Go to Start &gt; [All Programs (if Windows 7)] &gt; SRS MeltView 2** start menu folder &gt; click Admin. - Enter admin / admin for 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.</td>
<td>The Change Password dialog box opens.</td>
<td>□ The Change Password dialog box opens.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>- Enter a new password and retype to confirm it. - Verify user admin can log in.</td>
<td>User admin can log in.</td>
<td>□ User admin can log in.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

New users can be added.

<p>| 4    | - Click Users icon on the side panel, then click New User button. Provide username, first &amp; last name, and optionally other user information. | Success message box shows &quot;New user is successfully added&quot;. | □ Success message box shows &quot;New user is successfully added&quot;. | | |</p>
<table>
<thead>
<tr>
<th>Step</th>
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<th>Actual Result</th>
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<th>Date</th>
</tr>
</thead>
</table>
|      | Select user permissions. Click **Add User**.  
- Verify the new user is added. | | | | | |
|      | Existing users 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. | - **Success** message box shows “User data is successfully updated”.  
- Updated data is displayed on the **User** panel after clicking **OK** on **Success** message box. | - **Success** message box shows “User data is successfully updated”.  
- Updated data is displayed on the **User** panel after clicking **OK** on **Success** 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. | - **Success** message box shows “Security policy is successfully updated”.  
- Updated data is displayed on the **Security Policy** panel after clicking **OK** on **Success** message box. | - **Success** message box shows “Security policy is successfully updated”.  
- Updated data is displayed on the **Security Policy** panel after clicking **OK** on **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. | - **Success** message box shows “Signing configuration is successfully updated”.  
- Updated data is displayed on the **Signing Configuration** panel after clicking **OK** on **Success** message box. | - **Success** message box shows “Signing configuration is successfully updated”.  
- Updated data is displayed on the **Signing Configuration** panel after clicking **OK** on **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.  
- **Success** message box shows “Report options are successfully updated”.  
- Updated data is displayed on the **Report Options** panel after clicking **OK** on **Success** message box. | - Logo image is displayed after uploading.  
- **Success** message box shows “Report options are successfully updated”.  
- Updated data is displayed on the **Report Options** panel after clicking **OK** on **Success** message box. | | | |
<p>| 9    | - Click <strong>System</strong> icon on the side panel, then click on <strong>License</strong> item under System Configuration list. | - The <strong>Save License Request Form</strong> dialog box is showed to save the request as a file. | - The <strong>Save License Request Form</strong> dialog box is showed to save the request as a file. | | | |</p>
<table>
<thead>
<tr>
<th>Step</th>
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</thead>
</table>
| 10   | - 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”. | ❑ Information message box shows “Successfully installed License to Server”. |         |         |      |
|      | Audit trail properly display relevant information. | | | | | |
| 11   | - 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. | - The audit trail data is displayed.  
- The detailed information is displayed. | ❑ The audit trail data is displayed.  
❑ The detailed information is displayed. | | | |
|      | Database can be backed up. | | | | | |
| 12   | - Click **Maintenance** icon on the side panel, then select **Database Backup** under Operation list.  
- On the **Database Backup** panel, provide credentials for **postgres** user, specify backup base name and location, select **Now** for backup time, and click **Start Backup**. | - Success 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 *.dat.gz, rolesinfo, toc.dat files. | ❑ Success 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 *.dat.gz, rolesinfo, toc.dat files. | | | |
| 13   | - Click **Maintenance** icon on the side panel, then select **Database Backup** under Operation list.  
- On the **Database Backup** panel, provide credentials for **postgres** user, specify backup base name and location, and select **Scheduled** for backup time. | - Backup ran on the scheduled date/time and Success message box shows “The backup is complete. Database is backed up to directory <location\baseName-timestamp>“. | ❑ Backup ran on the scheduled time and Success message box shows “The backup is complete. Database is backed up to directory <location\baseName-timestamp>“. | | | |
<table>
<thead>
<tr>
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<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>- On the Scheduler dialog box, select option <strong>One Time</strong>. Then select a <strong>Start</strong> 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 <strong>OK</strong> to save. - Click <strong>Start Backup</strong>.</td>
<td>- The directory <code>&lt;location\baseName\timestamp&gt;</code> is created with content such as <code>.dat.gz</code>, <code>rolesinfo</code>, <code>toc.dat</code> files.</td>
<td>❑ The directory <code>&lt;location\baseName\timestamp&gt;</code> is created with content such as <code>.dat.gz</code>, <code>rolesinfo</code>, <code>toc.dat</code> files.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Repeat the previous step with a recurring option (<strong>Daily</strong>, <strong>Weekly</strong>, <strong>Monthly</strong>).</td>
<td>- Backup ran and no message boxes shown. - Logs text box shows “Success: Database is backed up to <code>&lt;location\baseName\timestamp&gt;</code>”. - The directory <code>&lt;location\baseName\timestamp&gt;</code> is created with content such as <code>.dat.gz</code>, <code>rolesinfo</code>, <code>toc.dat</code> files. - Next backup countdown message is shown.</td>
<td>❑ Backup ran and no message boxes shown. ❑ Logs text box shows “Success: Database is backed up to <code>&lt;location\baseName\timestamp&gt;</code>”. ❑ The directory <code>&lt;location\baseName\timestamp&gt;</code> is created with content such as <code>.dat.gz</code>, <code>rolesinfo</code>, <code>toc.dat</code> files. ❑ Next backup countdown message is shown.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>- Click <strong>Maintenance</strong> icon on the side panel, then select <strong>Database Restore</strong> under Operation list. - On the <strong>Database Restore</strong> panel, provide credentials for <code>postgres</code> user, specify the backup directory, and click <strong>Start Restore</strong>. - Click <strong>Yes</strong> on the Confirmation message box to proceed.</td>
<td>- User is logged out. - <strong>Success</strong> message box shows “Restoring is complete. Database is restored from &lt;backupDirectory&gt;”.</td>
<td>❑ User is logged out. ❑ <strong>Success</strong> message box shows “Restoring is complete. Database is restored from &lt;backupDirectory&gt;”.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Database can be restored.
### 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.

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Initial</th>
<th>Date</th>
</tr>
</thead>
</table>
| 1    | - Record the database server IP address (127.0.0.1 for local host) and Port number.  
- Record newly added user. | - Data server IP address and Port number recorded.  
- New user is recorded. | Server IP:  
Server Port:  
Username:  
First/Last Name: | | | |
| 2    | - 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. | | | |
| 3    | - Enter a new password and retype to confirm it.  
- Verify user can log in. | | User can log in.  
User’s first name is displayed on the top right corner.  
Connection dialog box is displayed. | | | |

Connects to an SRS Optimelt instrument.
<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Initial</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>- Power on the Optimelt instrument if it’s not on.</td>
<td>The Optimelt instrument is displayed on the Connection dialog box with status “Available”.</td>
<td>❑ The Optimelt instrument is displayed on the Connection dialog box with status “Available”.</td>
<td></td>
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<tr>
<td></td>
<td>- Click <strong>Refresh</strong> button on the Connection dialog box.</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>- Verify the Optimelt instrument is available.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>- Select the Optimelt instrument on the Connection dialog box, and click <strong>Connect</strong>.</td>
<td>- The Connection dialog box closes.</td>
<td>❑ The Connection dialog box closes.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Verify the instrument is connected.</td>
<td>- Camera box shows live image from the instrument.</td>
<td>❑ Camera box shows live image from the instrument.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>- Verify melting starts and finishes.</td>
<td>- The temperature reading matches that on the instrument.</td>
<td>❑ The temperature reading matches that on the instrument.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Acquires data from the SRS Optimelt instrument.</td>
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<tr>
<td>6</td>
<td>- Add a <strong>Phenacetin</strong> sample from SRS’s <strong>Melting Point Standards</strong></td>
<td>Temperature reading increases to the Start Temperature.</td>
<td>Temperature reading increases to the Start Temperature.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>package (O100MPS) to the capillary tubes, and place the tubes in the Optimelt instrument.</td>
<td>- <strong>Melting</strong> status is displayed during sample melting. Melt plots are displayed with data.</td>
<td>❑ Melting status is displayed during sample melting. Melt plots are displayed with data.</td>
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<td></td>
<td>- On the <strong>Control</strong> panel (located on the right side), enter <strong>Chemical Name, Batch Number, Notes</strong> (optional), <strong>Start Temperature 130°C, Stop Temperature 140°C, Heating Rate 5°C/min.</strong></td>
<td>- Camera box shows images of melting progress.</td>
<td>❑ Camera box shows images of melting progress.</td>
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<tr>
<td></td>
<td>- Click <strong>Start</strong>.</td>
<td>- <strong>New Data View</strong> status is displayed at the end of melting.</td>
<td>❑ <strong>New Data View</strong> status is displayed at the end of melting.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Verify melting starts and finishes.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Views acquired measurements</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>7</td>
<td>- Go to <strong>Measurement</strong> menu &gt; select <strong>Browse Data</strong>.</td>
<td>New data is displayed on <strong>Data</strong> table with provided info (chemical, batch, etc.) and melting measurements (onset, clear, single temperatures).</td>
<td>❑ New data is displayed on <strong>Data</strong> table with provided info (chemical, batch, etc.) and melting measurements (onset, clear, single temperatures).</td>
<td></td>
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<tr>
<td></td>
<td>- Verify newly acquired data is available.</td>
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<tr>
<td>8</td>
<td>- Click on the row with newly acquired data.</td>
<td>Detailed information is displayed on the <strong>Selected Row Details</strong> panel.</td>
<td>❑ Detailed information is displayed on the <strong>Selected Row Details</strong> panel.</td>
<td></td>
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<tr>
<td></td>
<td>- Verify the detailed information is available.</td>
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<td></td>
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<tr>
<td>9</td>
<td>- Select a data row on the **Data table, and click <strong>Open</strong>.</td>
<td>An information popup shows “Measurement data is successfully loaded from Server” or “Measurement data is already open”.</td>
<td>❑ An information popup shows “Measurement data is successfully loaded from Server” or “Measurement data is already open”.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>- Verify acquired data can be viewed.</td>
<td>- The open data shows on the main window with images, plots,</td>
<td>❑ The open data shows on the main window with images, plots, temperature reading, parameters.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step</td>
<td>Procedure</td>
<td>Expected Result</td>
<td>Actual Result</td>
<td>Pass/Fail</td>
<td>Initial</td>
<td>Date</td>
</tr>
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</tr>
<tr>
<td></td>
<td></td>
<td>temperature reading, parameters.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Signs off on a measurement.</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
| 10   | - Select a data row on the Data table, and click the Sign button.  
- Verify user can sign. | - The Signing dialog box opens. | ❑ The Signing dialog box opens. | | | |
| 11   | - Provide password, select Signing Reason, write comments (optional) on the Signing dialog box, and click OK.  
- Verify the signing successful. | - Signing dialog box closes. 
- Signed column of the Data table for the signed record shows Yes.  
- Selecting the signed record shows detailed signature information on the Selected Row Details panel. | ❑ Signing dialog box closes. 
❑ Signed column of the Data table for the signed record shows Yes.  
❑ Selecting the signed record shows detailed signature information on the Selected Row Details panel. | | | |
|      | Generates PDF report for a measurement. | | | | | |
| 12   | - Select a data row on the Data table, and click the Report button.  
- Verify saving report is available. | The Save File dialog box opens. | ❑ The Save File dialog box opens. | | | |
| 13   | - Provide a file name on the Save File dialog box, and click Save.  
- Verify the report is saved. | - An information popup shows “The PDF report has been successfully saved to <location>“.  
- Opening the PDF file from Windows File Explorer shows information about the selected record. | ❑ An information popup shows “The PDF report has been successfully saved to <location>“.  
❑ Opening the PDF file from Windows File Explorer shows information about the selected record. | | | |
|      | Views audit trail. | | | | | |
| 14   | - 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. | - The audit trail data is displayed.  
- The detailed information is displayed. | ❑ The audit trail data is displayed.  
❑ 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.
The server is continuously available for login from MeltView-Admin and MeltView main application – Availability test.

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Initial</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>- Record the database server IP address (127.0.0.1 for local host) and Port number. &lt;br&gt; - Verify server information is recorded.</td>
<td>Data server IP address and Port number recorded.</td>
<td>Server IP: &lt;br&gt; Server Port:</td>
<td>Pass</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>- Launch MeltView-Admin app. Log in with a valid administrator user. &lt;br&gt; - Browse different data (Users, System, Audit Trail). &lt;br&gt; - Verify the user logs in and can browse data.</td>
<td>- The user can log in. &lt;br&gt; - The user can browse different data (Users, System, Audit Trail).</td>
<td>❑ The user can log in. &lt;br&gt; ❑ The user can browse different data (Users, System, Audit Trail).</td>
<td>Fail</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>- Launch MeltView app. Log in with a valid user. &lt;br&gt; - Browse different data. &lt;br&gt; - Acquire melting point data. &lt;br&gt; - Verify the user can log in, acquire data and browse data.</td>
<td>The user can log in. &lt;br&gt; The user can acquire data. &lt;br&gt; The user can browse different data.</td>
<td>❑ The user can log in. &lt;br&gt; ❑ The user can acquire data. &lt;br&gt; ❑ The user can browse different data.</td>
<td>Fail</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>- Repeat step 2 &amp; 3 for different time of the day, multiple days. &lt;br&gt; - Verify the steps work every time.</td>
<td>The steps work every time.</td>
<td>❑ The steps work every time.</td>
<td>Fail</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The users can log in on MeltView-Admin and MeltView main application from different locations without issues – Accessibility test.

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Initial</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>- Perform step 2 &amp; 3 on a computer that is on the same LAN with the database server. &lt;br&gt; - Verify the steps work every time.</td>
<td>The steps work every time.</td>
<td>❑ The steps work every time.</td>
<td>Fail</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>- Repeat step 5 for multiple computers that are on the same LAN with the database server. &lt;br&gt; - Verify the steps work every time.</td>
<td>The steps work every time.</td>
<td>❑ The steps work every time.</td>
<td>Fail</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Multiple users log in and perform operations on MeltView-Admin and MeltView main application at a same time – Load test

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Initial</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>- Perform step 2 &amp; 3 on multiple computers that are on the same LAN with the database server at a same time. &lt;br&gt; - Verify the steps work every time.</td>
<td>The steps work every time.</td>
<td>❑ The steps work every time.</td>
<td>Fail</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
§ 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: ___________________________