Dissolution Workstation

Operator’s Manual

Agilent Technologies
Notices

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CAUTION

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Installation and Setup

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Requirements and Configuration

PC Requirements

The software is designed to run on a PC-based platform with the following minimum specifications:

- 1.5 GHz or faster Pentium 4 processor
- 1 GB of RAM or more
- 16X CD-ROM drive
- 1 USB port (2 if used with a 280-DS)
- 1 RS232 serial port (9-pin) or additional USB port for USB-to-serial adapter
- 60 GB of space on the hard drive
- 1280 x 960 at 16M colors (minimum)
- Microsoft Windows 7 (32-bit and 64-bit) operating system

Software Installation or Upgrade

NOTE If you are upgrading Dissolution Workstation, install the new version, ensure your data has transferred over, and then uninstall the previous version.

NOTE You must log on to the computer as an administrator to set up the software and run it for the first time.

NOTE If Windows User Access Control (UAC) displays during the installation process, click Allow to continue installation.
1 Insert the Dissolution Workstation CD and access the files contained on the CD.

2 Execute `setup.exe` and follow the on-screen prompts.

**NOTE**

When asked if you want to install a particular application (for example, Microsoft .Net Framework,) you are required to click **Yes** to install all software.

**NOTE**

On the Database Server screen, do not change the password.

### Local Security Policy

The Local Security Policy conforms with 21 CFR Part 11 physical requirement section 11.300 b. Internal IT requirements may differ from the settings outlined in this section. It may be necessary to coordinate the following configurations with the domain administrator.

For 21 CFR Part 11 compliance purposes, you must ensure that the following minimum requirements are met by your system's security policy. To configure your system's security policies, complete the following steps:

1. Click **Start > Run.**

2. Type `secpol.msc` and click **Enter** to run the Local Security Settings Manager. The Local Security Settings screen displays.

3. Click **Security Settings > Account Policies > Password Policy** and set the applicable security policy configuration.

<table>
<thead>
<tr>
<th>Policy</th>
<th>Security Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enforce Password</td>
<td>3 passwords remembered</td>
</tr>
<tr>
<td>History</td>
<td></td>
</tr>
<tr>
<td>Maximum Password</td>
<td>30 days</td>
</tr>
<tr>
<td>Length</td>
<td></td>
</tr>
</tbody>
</table>
1 Installation and Setup

<table>
<thead>
<tr>
<th>Policy</th>
<th>Security Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum Password Length</td>
<td>6 characters</td>
</tr>
<tr>
<td>Password Must Meet Complexity</td>
<td>Enabled</td>
</tr>
</tbody>
</table>

4 Click Security Settings > Account Policies > Account Lockout Policy. Configure the options.

<table>
<thead>
<tr>
<th>Policy</th>
<th>Security Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account lockout duration</td>
<td>0 minutes (infinite)</td>
</tr>
<tr>
<td>Account lockout threshold</td>
<td>3 invalid login attempts</td>
</tr>
<tr>
<td>Reset account lockout counter</td>
<td>99999 minutes</td>
</tr>
</tbody>
</table>

5 Click Security Settings > Local Policies > Audit Policy and set the options.

<table>
<thead>
<tr>
<th>Policy</th>
<th>Security Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit account logon events</td>
<td>Success, Failure</td>
</tr>
<tr>
<td>Audit account management</td>
<td>Success, Failure</td>
</tr>
<tr>
<td>Audit login events</td>
<td>Success, Failure</td>
</tr>
<tr>
<td>Audit policy change</td>
<td>Success, Failure</td>
</tr>
</tbody>
</table>
Starting Dissolution Workstation

In Windows 7, you must log on to the computer as an administrator to set up the software and run it for the first time.

Starting Dissolution Workstation

1. Double-click the Dissolution Workstation icon on the Windows desktop to start the software.
2. If your system has Windows Firewall enabled, the Windows Security Alert screen displays. Click Unblock to enable the program.

Dissolution Workstation Logon

1. From the logon screen, enter your credentials in the User ID and Password boxes.
2. Click OK.
3. Click Logon to initiate the software.

Figure 1  Logon
Adding Users to the Application

1 After successfully logging on to the software, click Tools > Options. The Configuration Dialog screen displays.

- To add a user to a group, select the Security tab on the Configuration Dialog screen.

To complete this section, you must be logged on as an administrator

2 Click User Administration at the bottom of the screen. The Local Users and Groups screen displays.

3 Double-click the Groups folder to expand the list of groups.

4 Double-click all eight of the groups that begin with Vk and ensure that your username is logged in and is identified as a member of these groups.

Figure 2  Local Users and Groups
5 To add a user to a group, click Add... from the respective group screen. The Select Users, Computers, or Group screen displays.

6 Enter your user identification in the empty box and click **Check Names**. Ensure your user identification and domain populate the empty field. Click **OK**.

7 Close the Local Users and Groups screen.

8 Click **OK** to close the Configuration Dialog screen.
1 Installation and Setup

Workstation Connections

There are various ways to connect your dissolution equipment to the Dissolution Workstation software. Each dissolution system requires at least one serial port, or a serial-to-USB adapter. Cable guides are listed with each connection diagram to aid in selecting the necessary cables for your configuration.

Since the software can control up to four complete dissolution systems, it is often necessary to add additional serial ports to the PC controlling the instruments. We recommend the use of either the Edgeport/8 (8 serial DB-9), or Edgeport/416 (4 USB 16 serial DB-9).

NOTE
When using the multiport device server, you can connect different dissolution systems based on port availability. This is true with daisy-chain or individual connection. See “Dissolution Apparatus / 8000 / Peristaltic Pump, Syringe Pump, or Syringe Pump and Filter Changer (Daisy-chain to MDS)” on page 26.

The following instructions refer to COM1, COM2, etc. It is acceptable to substitute different COM port numbers based on the physical layout of your system.

<table>
<thead>
<tr>
<th>Workstation Connection</th>
<th>Peripheral Equipment</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daisy-chain Connection to PC</td>
<td>8000 / peristaltic pump</td>
<td>see “Dissolution Apparatus / 8000 / Peristaltic Pump (Daisy-chain to PC)” on page 18</td>
</tr>
<tr>
<td></td>
<td>850-DS</td>
<td>see “Dissolution Apparatus / 850-DS (Daisy-chain to PC)” on page 19</td>
</tr>
<tr>
<td></td>
<td>8000 / syringe pump</td>
<td>see “Dissolution Apparatus / 8000 / Syringe Pump (Daisy-chain to PC)” on page 20</td>
</tr>
<tr>
<td></td>
<td>8000 / syringe pump / filter changer</td>
<td>see “Dissolution Apparatus / 8000 / Syringe Pump / Filter Changer (Daisy-chain to PC)” on page 21</td>
</tr>
<tr>
<td>Workstation Connection</td>
<td>Peripheral Equipment</td>
<td>Procedures</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Individual Connection to Multiport Device Server (MDS)</td>
<td>8000 / peristaltic pump</td>
<td>see “Dissolution Apparatus / 8000 / Peristaltic Pump (Individual to MDS)” on page 22</td>
</tr>
<tr>
<td></td>
<td>850-DS</td>
<td>see “Dissolution Apparatus / 850-DS (Individual to MDS)” on page 23</td>
</tr>
<tr>
<td></td>
<td>8000 / syringe pump</td>
<td>see “Dissolution Apparatus / 8000 / Syringe Pump (Individual to MDS)” on page 24</td>
</tr>
<tr>
<td></td>
<td>8000 / syringe pump / filter changer</td>
<td>see “Dissolution Apparatus / 8000 / Syringe Pump / Filter Changer (Individual to MDS)” on page 25</td>
</tr>
<tr>
<td>Daisy-chain Connection to Multiport Device Server (MDS)</td>
<td>8000 / peristaltic pump, syringe pump, or syringe pump and filter changer</td>
<td>see “Dissolution Apparatus / 8000 / Peristaltic Pump, Syringe Pump, or Syringe Pump and Filter Changer (Daisy-chain to MDS)” on page 26</td>
</tr>
<tr>
<td></td>
<td>850-DS</td>
<td>see “Dissolution Apparatus / 850-DS (Daisy-chain to MDS)” on page 27</td>
</tr>
</tbody>
</table>
1 Installation and Setup

Dissolution Apparatus / 8000 / Peristaltic Pump (Daisy-chain to PC)

**Part Number** | **Quantity**
--- | ---
5075-0446 | 1
5075-0914 | 1
5075-0252 | 2
12-0011* | 0

* supplied with pump
Dissolution Apparatus / 850-DS (Daisy-chain to PC)

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>5075-0446</td>
<td>1</td>
</tr>
<tr>
<td>5075-0914</td>
<td>1</td>
</tr>
<tr>
<td>5075-0252</td>
<td>2</td>
</tr>
</tbody>
</table>
1 Installation and Setup

Dissolution Apparatus / 8000 / Syringe Pump (Daisy-chain to PC)

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>5075-0446</td>
<td>2</td>
</tr>
<tr>
<td>5075-0914</td>
<td>1</td>
</tr>
<tr>
<td>5075-0252</td>
<td>2</td>
</tr>
<tr>
<td>5075-0449</td>
<td>1</td>
</tr>
</tbody>
</table>
Dissolution Apparatus / 8000 / Syringe Pump / Filter Changer (Daisy-chain to PC)

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>5075-0914</td>
<td>1</td>
</tr>
<tr>
<td>5075-0446</td>
<td>3</td>
</tr>
<tr>
<td>5075-0252</td>
<td>2</td>
</tr>
<tr>
<td>5075-0449</td>
<td>2</td>
</tr>
</tbody>
</table>

"Y" Adapter 5075-0446

NULL Modem 5075-0914
1 Installation and Setup

Dissolution Apparatus / 8000 / Peristaltic Pump (Individual to MDS)

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>5075-0252</td>
<td>2</td>
</tr>
<tr>
<td>12-0011</td>
<td>0</td>
</tr>
</tbody>
</table>

* supplied with pump
Dissolution Apparatus / 850-DS (Individual to MDS)

- DB9->DB25 Cable 5075-0252
  - Dissolution Tester

- DB9->DB25 Cable 5075-0252
  - 850-DS Sampling Station

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>5075-0252</td>
<td>2</td>
</tr>
</tbody>
</table>
1 Installation and Setup

Dissolution Apparatus / 8000 / Syringe Pump (Individual to MDS)

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>5075-0252</td>
<td>2</td>
</tr>
<tr>
<td>5075-0448</td>
<td>1</td>
</tr>
</tbody>
</table>
Dissolution Apparatus / 8000 / Syringe Pump / Filter Changer (Individual to MDS)

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>5075-0252</td>
<td>2</td>
</tr>
<tr>
<td>5075-0448</td>
<td>2</td>
</tr>
</tbody>
</table>
1 Installation and Setup

Dissolution Apparatus / 8000 / Peristaltic Pump, Syringe Pump, or Syringe Pump and Filter Changer (Daisy-chain to MDS)
Dissolution Apparatus / 850-DS (Daisy-chain to MDS)
1 Installation and Setup

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2

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Log On to Dissolution Workstation

1 Double-click the Dissolution Workstation icon on your desktop. The Logon screen displays.

![Logon Screen](image)

**Figure 3** Logon

2 Enter your user identification and password. Verify the domain is correct and click **Logon**. The Dissolution Workstation screen displays.
Figure 4  Dissolution Workstation
# Operation

The following options are available in the navigation bar on the Dissolution Workstation homescreen:

<table>
<thead>
<tr>
<th>Option</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Configuration</strong></td>
<td>Create a file for each dissolution apparatus. All relevant data including configuration and component serial numbers is stored within this file.</td>
</tr>
<tr>
<td><strong>Diagnostics</strong></td>
<td>Verify communication or view real-time data from the modules.</td>
</tr>
<tr>
<td><strong>Editor</strong></td>
<td>Create a test method to define parameters and tolerances to be verified.</td>
</tr>
<tr>
<td><strong>Run Method</strong></td>
<td>Begin a test using previously created apparatus and methods.</td>
</tr>
<tr>
<td><strong>Test Reports</strong></td>
<td>Search and retrieve previously executed tests based on various filtered criteria.</td>
</tr>
<tr>
<td><strong>Change User</strong></td>
<td>Log on to the Dissolution Workstation Software as a different user.</td>
</tr>
<tr>
<td><strong>Lock Application</strong></td>
<td>Lock the Dissolution Workstation Software.</td>
</tr>
<tr>
<td><strong>Audit Trail</strong></td>
<td>Verify, filter, or create reports of logon information for the Dissolution Workstation Software.</td>
</tr>
<tr>
<td><strong>Permissions</strong></td>
<td>View the rights and privileges for users of the Dissolution Workstation Software.</td>
</tr>
</tbody>
</table>
Configuring Your System

It is necessary to configure the components that will be used for automated sample collection. Systems can be added, modified, and removed from the database. All system configuration activity is recorded in the system audit log. The dissolution software allows the configuration of multiple systems. A maximum of four systems can be running methods at one time.

System configuration entails selecting the appropriate equipment and setting the communication and other physical properties of the system. Serial numbers are stored for each system to allow tracking of physical system changes.

1. From the navigation bar, click **Configuration**. The System Configuration screen displays.

![System Configuration Screen](image)

**Figure 5** System Configuration
2 Click **Create**. The System Editor screen displays.

![System Editor](image)

**Figure 6** System Editor
3  Click **Next**. Following is a description of the System Editor screen options:

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>System</td>
<td>System Name Enter a name for your system.</td>
</tr>
<tr>
<td></td>
<td>Laboratory Enter a laboratory name.</td>
</tr>
</tbody>
</table>
| Dissolution Setup          | Click the drop-down arrow on the Dissolution Setup box to select **Apparatus 3/7**, **Apparatus 1/2/5/6**, or **NONE**.  
|                            | Click the drop-down arrow in the Dissolution Setup box to select **Peristaltic Pump** or **Syringe Pump**.  
|                            | If your system configuration includes an 8000 or 850-DS, click **Fraction Collector**.          |
|                            | If your system configuration includes a syringe pump, once Syringe Pump is selected from the drop-down menu above, the Filter Changer option becomes active. Click **Filter Changer** if your system configuration includes a filter changer. |
| Restrict Execution To Specified Workstation | Click to display the name of the workstation or enter the name of the workstation connected to the system. Click **No Restriction** to allow the system to be run from any workstation.  
|                            | Note: the system must be physically connected.                                                 |
| Change Management          | If applicable, select the box under Change Management in order to restrict the system editing rights to the current user.  
|                            | Note: This option prevents system configuration modification by anyone other than the system owner or a user with **VkModifyOthersSystems** privilege. |

4  Click **Next**. The following sections describe the screens that display based on the selections entered on the System Editor screen.
2 Operation

**Dissolution Apparatus**

1 If applicable, either the BIO-DIS screen or the Dissolution Tester screen displays. Click Next. Depending on the chosen configuration, the following is a description of the screen options available for either Apparatus 1/2/5/6 or Apparatus 3/7:

<table>
<thead>
<tr>
<th>Dissolution Apparatus</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Comm Address</td>
<td>Enter the appropriate communication address for the dissolution apparatus.</td>
</tr>
<tr>
<td>Options</td>
<td>Click the appropriate dissolution apparatus options.</td>
</tr>
<tr>
<td></td>
<td>Using the up and down arrows, indicate the number of vessels.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BIO-DIS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Comm Address</td>
<td>Enter the appropriate communication address for the dissolution apparatus.</td>
</tr>
<tr>
<td>Rows</td>
<td>Using the up and down arrows, indicate the number of rows.</td>
</tr>
<tr>
<td>Sample Channels</td>
<td>Using the up and down arrows, indicate the number of sample channels.</td>
</tr>
<tr>
<td></td>
<td>Note: this setting must match the physical configuration of the instrument.</td>
</tr>
</tbody>
</table>

**NOTE**

The communication address (*PC port: instrument ID*) is comprised of the physical PC COM port (*PC port*) and the instrument address on the serial bus (*instrument ID*). For example: COM1:01.
Fraction Collector

1 If you selected Fraction Collector, the Fraction Collector screen displays. Enter the appropriate communication address for the fraction collector. When connecting to the PC, enter the com port and comm ID. Verify the comm ID on the fraction collector is set to the same value.

**NOTE**
The communication address \((PC\ port:\ instrument\ ID)\) is comprised of the physical PC COM port \((PC\ port)\) and the instrument address on the serial bus \((instrument\ ID)\). For example: COM1:01.

2 Using the up and down arrows, indicate the number of channels.
3 Verify the fraction collector is configured for the proper number of channels.
4 Click Next.
2 Operation

Syringe Pump

1 If you selected Syringe Pump, the Syringe Pump screen displays.

NOTE

There is no additional screen if you select Peristaltic Pump since no specific pump parameters are required.

Following is a description of the Syringe Pump screen options:

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comm Address</td>
<td>Enter the appropriate communication address for the syringe pump. When connecting to the PC, enter <strong>COMx:76</strong>. Note: If you are using an 850-DS, the com port for the syringe pump has to be same as the 850-DS. Do not change the comm ID of 76.</td>
</tr>
<tr>
<td>Current Level (8000 only)</td>
<td>Use the up and down arrows to indicate the motor power (current level). The recommended setting is 4.</td>
</tr>
<tr>
<td>Calibration Count</td>
<td>Use the up and down arrows to indicate the calibration count. This number refers to the number of steps the motor moves to lower the syringe for a full stroke. The recommended setting is 19300 (19000 for the 850-DS).</td>
</tr>
<tr>
<td>Plunger Speed</td>
<td>Use the up and down arrows to configure the syringe pump plunger to operate at a specific speed. Note: If an 8000 is configured, steps/sec is used. If an 850-DS is equipped, ml/min is displayed.</td>
</tr>
<tr>
<td>Aspiration Dwell</td>
<td>Use the up and down arrows to indicate the aspiration dwell time.</td>
</tr>
<tr>
<td>Prime Loss</td>
<td>Use the up and down arrows to indicate the prime loss volume. This parameter accounts for the volume of sample to travel from the dissolution vessel removed at the sample time point to the sample tubes or vials prior to collection.</td>
</tr>
<tr>
<td>Syringe Size</td>
<td>Click the drop-down arrow and select the syringe size.</td>
</tr>
</tbody>
</table>

2 Click Next.

3 If you selected Filter Changer, the Filter Changer screen displays.

4 Enter the appropriate communication address for the filter changer. When connecting to the PC, enter **COMx:75** (8000 only).
5 Click **Next**.

### Filter Changer

1 If you selected Filter Changer, the Filter Changer screen displays.

Following is a description of the Filter Changer screen options:

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comm Address</td>
<td>Enter the appropriate communication address for the syringe pump. When connecting to the PC, enter <strong>COMx:75</strong>. Note: If you are using an 850-DS, the com port for the syringe pump has to be same as the 850-DS. Do not change the comm ID of 75.</td>
</tr>
</tbody>
</table>

2 Click **Next**.
Completing the Configuration

1 After the final screen specific to your configuration, the Serial Numbers screen displays (see Figure 7, “Serial Numbers,” on page 40).

Figure 7 Serial Numbers

2 From the drop-down menu, select the type of accessory (for example: basket, shaft, paddle, vessel) in the box that corresponds to Type.
3 Enter the serial number for the item and click Add.
4 Repeat steps 2 and 3 for each item selected under Dissolution Setup on the System Editor screen (see “Dissolution Setup” on page 35).
5 Click **Finish**.

6 Repeat all the sections under “Configuring Your System” on page 33 for each additional system.

7 Close the System Configuration screen.

### Copying a System Configuration

To copy a system configuration, complete the following steps:

1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 5, “System Configuration,” on page 33).
2. Select the desired system configuration.
3. Click **Copy**.
4. Click **Paste**. A new system configuration displays. The description of the new system configuration is *Copy of*....
5. Close the System Configuration screen.
6. To edit the system configuration, see “Editing an Existing System Configuration” on page 44.

### Deleting a System Configuration

To delete a system configuration, complete the following steps:

1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 5, “System Configuration,” on page 33).
2. Select the desired system configuration.
3. Click **Delete**.
4. Click **Yes**.
5. Close the System Configuration screen.

**NOTE**

The system configuration is never physically deleted. It is only marked as deleted in the database.
Recovering a System Configuration

To recover a deleted system configuration, complete the following steps:

1. From the navigation bar, click **Configuration > Recover**. The System Configuration screen displays.
2. Select the desired system configuration.
3. Click **OK**.

Serial Numbers

To review or add serial numbers to the system configuration, complete the following steps:

1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 5, “System Configuration,” on page 33).
2. Select the desired system configuration.
3. Click **Serial Numbers**. The Serial Number Editor screen displays (see Figure 8, “Serial Number Editor,” on page 43).

**NOTE**

Alternately, you can double click the desired system configuration and double click **Next** until the Serial Numbers section of the System Editor displays or right click the desired system configuration and select **Serial Numbers**. Serial numbers can be added or deleted as a result of any of these actions.
Figure 8    Serial Number Editor

4 From the drop-down menu, select the type of accessory (for example: basket, shaft, paddle, vessel) in the box that corresponds to Type.

5 Enter the serial number for the item and click Add.

6 Repeat steps 4 and 5 for each item selected under Dissolution Setup (see “Dissolution Setup” on page 35).

7 Click OK. The Serial Number Editor screen closes.

System Configuration Report

To display a report of the system configuration, complete the following steps:

1 From the navigation bar, click Configuration. The System Configuration screen displays (see Figure 5, “System Configuration,” on page 33).

2 Select the desired system configuration.
3 Click **Report**.

Alternately, you can right click the desired system configuration and select **Report**. The Version Selection screen displays as a result of either of these actions.

4 Select the version. By default, the most recent report version displays.

5 Use the up and down arrows to indicate the desired report version and click **OK**.

6 The system report displays. The report can be printed, exported, searched, or verified.

---

**Editing an Existing System Configuration**

To display and edit the properties of an existing system configuration, complete the following steps:

1 From the navigation bar, click **Configuration**. The System Configuration screen displays (see **Figure 5**, “System Configuration,” on page 33).

2 Select the desired system configuration.

3 Click **Properties**. The System Editor screen displays (see **Figure 6**, “System Editor,” on page 34).

Alternately, you can double click the desired system configuration or right click the desired system configuration and select **Properties**. The System Editor screen displays as a result of any of these actions.

4 Select the appropriate tabs and change the relevant information in the same manner that the system was created.

5 Click **Finish** to close the System Configuration screen. If you have made any changes, then upon completion of the wizard, you will be asked to explain or provide a reason for the change to comply with 21 CFR Part 11.
Show Audit Trail

To display the audit trail for a system configuration, complete the following steps:

1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 5, “System Configuration,” on page 33).

2. Select the system configuration and click **Show Audit Trail**. The System Audit Trail screen displays.

Alternate, you can right click the desired system configuration and select **Show Audit Trail**. The System Audit Trail screen displays as a result of either of these actions.

3. Select two or more versions and click **Differences** in the navigation bar. A change report displays. The report can be printed or exported.

Verify Integrity

To verify that the system configuration has not been changed outside of the Dissolution Workstation program, complete the following steps:

1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 5, “System Configuration,” on page 33).

2. Select the system configuration and click **Verify Integrity**. Either the data is verified successfully or the user is directed to contact their system administrator.

Alternate, you can right click the desired system configuration and select **Verify Integrity**. The integrity of the system configuration is checked as a result of either of these actions.

3. Click **OK** to close the Data Verification screen.

Import / Export XML File

To use an existing system configuration from one Dissolution Workstation computer on a different Dissolution Workstation computer, you can export and import the system configuration as an XML file.

To export the system configuration, complete the following steps:

1. From the navigation bar, click Configuration. The System Configuration screen displays (see Figure 5, “System Configuration,” on page 33).
2. Select the desired system configuration.
3. Click Export. The Version Selection screen displays.
4. If applicable, indicate which version to export and click OK. The Export System to XML File screen displays.

Alternately, you can right click the desired system configuration and select Export. The Version Selection screen displays as a result of either of these actions.

Each time a system configuration is saved, a new version is created. To export a version other than the most recently saved, indicate the appropriate version number on the Version Selection screen.

5. Indicate the directory and file name and click Save. The code is saved as an XML file.

To import the XML file at another Dissolution Workstation, complete the following steps:

1. From the navigation bar, click Configuration. The System Configuration screen displays (see Figure 5, “System Configuration,” on page 33).
2. Click Import. The Import System from XML File screen displays.

Alternately, you can right click the desired system configuration and select Import. The Import System from XML File screen displays as a result of either of these actions.
3 Select the appropriate directory and file name and click **Open**. The system configuration displays on the System Configuration screen.

4 Close the System Configuration screen.
Diagnostics / Manual Control

To check the diagnostics of a dissolution apparatus, complete the procedures on the following pages. These procedures are performed on one system at a time. Repeat the procedures as applicable for each additional system.

1 Click **Diagnostics**. The Select Item screen displays.

![Select Item](image.png)  
**Figure 9** Select Item
2 Select the desired system and click OK. The System Diagnostics screen displays. Depending on the entered system configuration, the tabs may vary (see Figure 10, “System Diagnostics—BIO-DIS,” on page 49).

![System Diagnostics - BIO-DIS](image)

**Figure 10** System Diagnostics—BIO-DIS

If your system is not responding correctly, click for additional diagnostics. The screen expands to display the raw serial communications between the instruments.
Moving the Drive Unit for Apparatus 3 / Apparatus 7

To move the dissolution apparatus drive unit, complete the following steps:

1. Select the **BIO-DIS** tab (see Figure 10, “System Diagnostics—BIO-DIS,” on page 49).

2. Click any vessel position corresponding to the desired row in the BIO-DIS box (see Figure 11, “BIO-DIS Box,” below). The drive unit moves to the indicated row.

3. Click . The drive unit returns to the home position.

Figure 11  BIO-DIS Box
Dips per Minute for Apparatus 3 / Apparatus 7

To set the dips per minute, complete the following steps:

1. Click any vessel position corresponding to the desired row in the BIO-DIS box (see Figure 11, “BIO-DIS Box,” on page 50). The drive unit moves to the indicated row.

2. Using the up and down arrows in the box that corresponds to Dipping Speed, set the dips per minute to 15 and click Start Dipping. Dipping begins.

3. Click Stop Dipping. The dipping stops.

4. Click . The drive unit returns to the home position.
Moving the Drive Unit for Apparatus 1 / 2

To move the dissolution apparatus drive unit, complete the following steps:

1. Select the **Dissolution Tester** tab (see **Figure 13**, “Dissolution Tester,” on page 52).

   ![Dissolution Tester](image)

   **Figure 13**  Dissolution Tester

   If your system is not responding correctly, click for additional diagnostics. The screen expands to display the raw serial communications between the instruments.

2. Click in the Drive Unit box. The drive unit raises.

3. Click . The drive unit stops.

4. Click . The drive unit lowers.
Spindle Control for Apparatus 1 / 2

To set the RPM, complete the following steps:

1. Using the up and down arrows in the box that corresponds to Spindle RPM, set the RPM to the desired speed and click 🔁. The spindles begin to turn at the entered RPM.
2. Click 🔁. The spindles stop.

Cannula / Manifold for Apparatus 1 / 2

To raise or lower the cannulas / manifold, complete the following steps:

1. Using the up and down arrows, set the cannula position to all cannulas and the volume to 900.
2. Click 🔁. The cannulas / manifold raise(s).
3. Click 🔽. The cannulas / manifold lower(s).

NOTE
If your system configuration includes a V-series Dissolution Apparatus, set the volume and individually raise and lower the cannulas by changing the cannula position.
Dosage Delivery for Apparatus 1 / 2

To open the DDMs, complete the following steps:

1. Using the up and down arrows, set the DDM to all DDMs.

**NOTE**

If your system configuration includes a V-series Dissolution Apparatus, open the individual DDMs by indicating a specific DDM location next to DDM.

2. Click \( \text{open} \). The DDMs open.

Water Bath Temperature

To set the actual temperature of the water bath, complete the following steps:

1. Use the up and down arrows in the Bath Temperature box to set the water bath temperature to \( 37.0 \) °C (see the sample screen below).

![Figure 14 Water Bath Temperature](image)

2. Click Set.
Syringe Pump / Filter Changer

Syringe Pump

To control the syringe pump, complete the following steps:

1. Select the **FC/SP** tab. The following screen displays:

   ![Figure 15 FC/SP](image)

   **NOTE**

   If your system is not responding correctly, click for additional diagnostics. The screen expands to display the raw serial communications between the instruments.

2. Click (set valve to output side) in the Valve Control box. There is an audible click.
## 2 Operation

3 Click 
(set valve to input side) in the Valve Control box. There is an audible click.

4 In the Pump Cycle box, use the up and down arrows to enter a volume in milliliters to draw into the syringes.

![Pump Cycle](image)

**Figure 16** Pump Cycle

5 Click in the Pump Cycle box to pull from the sampling cannulas. The syringe pump completes the pump cycle.

6 Click in the Pump Cycle box to pull from the return cannulas. The syringe pump completes the pump cycle.

7 In the Fill / Dispense box, use the up and down arrows to enter a percentage of the syringe to fill.

![Fill/Dispense](image)

**Figure 17** Fill/Dispense

8 Click to move the syringe plunger to the specified step position. The syringe fills to the percentage indicated.

9 Click to dispense the syringe to the home position. The syringe empties.
Filter Changer

To control the filter changer, complete the following steps:

1. Click \( \text{open the filter changer clamp} \) in the Clamp Control box. The clamp opens.

2. Click \( \text{close the filter changer clamp} \) in the Clamp Control box. The clamp closes.

3. In the Change Filters box, use the up and down arrows to enter the number of filters to be replaced.

4. Click \( \text{to expel the filters} \). The entered number of filters are expelled and replaced with new filters.
Valve Control (8000)

To control the valves, complete the following steps:

1. Select the **Fraction Collector** tab. The following screen displays:

![Figure 19 Fraction Collector - 8000](image)

   **NOTE** If your system is not responding correctly, click for additional diagnostics. The screen expands to display the raw serial communications between the instruments.

2. Click ![lower阀门.png](image) (lower the valves) in the Valve Control box to lower the needles. The needles lower.
3 Click (raise the valves) in the Valve Control box to lift the needles. The needles rise.

4 Click in the Valve Control box to rinse the valves. The valves move up and down repeatedly.

5 Click **Open Valves** in the Valve Control box. An audible click is heard. When the valves are open, the green lights on the front panel of the dispensing arm illuminate.
2 Operation

Valve Control (850-DS)

To control the valves, complete the following steps:

1. Select the **Fraction Collector - 850-DS** tab. The following screen displays:

   ![Fraction Collector - 850-DS](image)

   **Figure 20** Fraction Collector - 850-DS

   If your system is not responding correctly, click for additional diagnostics. The screen expands to display the raw serial communications between the instruments.

2. Click \( \downarrow \) (lower the valves) in the Valve Control box to lower the needles. The needles lower.

3. Click \( \uparrow \) (raise the valves) in the Valve Control box to lift the needles. The needles rise.

4. Click **Open Valves** in the Valve Control box. An audible click is heard. When the valves are open, the green lights on the front panel of the dispensing arm illuminate.
Peristaltic Pump

To control the peristaltic pump, complete the following steps:

1. Click the arrow icon in the Peristaltic Pump box. The pump rotates toward the outlet channel of the peristaltic pump.

2. Click the stop pumping icon in the Peristaltic Pump box. The pumping stops.

3. Click the arrow icon in the Peristaltic Pump box. The pump rotates toward the inlet channel of the peristaltic pump.

4. Click the stop pumping icon in the Peristaltic Pump box. The pumping stops.

Replacement Media Pump

In the Miscellaneous box, click RM Pump On. The pump runs. Click again to turn off the RM pump.
2 Operation

Moving the Fraction Collector Dispensing Position

To control the fraction collector dispensing arm, complete the following steps:

1. Click any vessel position corresponding to the desired row in the Collector box. The desired row is moved into position.

![Collector Box - 8000](image)

Figure 21  Collector Box - 8000

2. In the Collector box, click . The dispensing arm returns to the home position.
Method Editor

Creating a Method

To create a new method, complete the following steps:

1. From the navigation bar, click **Editor**. The Methods screen displays.

![Methods Screen](image)

**Figure 22** Methods
2 Operation

2 Click New Method. The Method Type Selector screen displays.

![Method Type Selector](image)

**Figure 23** Method Type Selector

3 Select Apparatus 1/2/5/6, Apparatus 3/7, or No Tester and click OK. The Method Editor screen displays (see Figure 24, “Method Editor,” on page 65).
4 Select the **Parameters** tab.
2 Operation

Following is a description of the Parameters tab options:

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Information</td>
<td></td>
</tr>
<tr>
<td>Product Name</td>
<td>Enter the name of the product.</td>
</tr>
<tr>
<td>Notes</td>
<td>Enter any relevant notes regarding the sample.</td>
</tr>
<tr>
<td>User Defined Labels</td>
<td></td>
</tr>
<tr>
<td>Label 1</td>
<td>The fields in this area have default values of LOT, BATCH, and GROUP.</td>
</tr>
<tr>
<td>Label 2</td>
<td>These fields are customizable; enter the information that best serves the</td>
</tr>
<tr>
<td>Label 3</td>
<td>needs of the method parameters.</td>
</tr>
<tr>
<td>Sampling Parameters</td>
<td></td>
</tr>
<tr>
<td>Sample Volume</td>
<td>Enter the sample volume in milliliters.</td>
</tr>
<tr>
<td>Prime Volume</td>
<td>Use this option to set the amount of drawn medium necessary to fill the</td>
</tr>
<tr>
<td></td>
<td>sampling lines of the entire system.</td>
</tr>
<tr>
<td>Purge Volume</td>
<td>Use this option to set a purge volume in milliliters that ensures all</td>
</tr>
<tr>
<td></td>
<td>stranded medium is properly expelled.</td>
</tr>
<tr>
<td>Active Channels</td>
<td>Enter the number of vessel positions used for sampling.</td>
</tr>
<tr>
<td>Samples / Filter</td>
<td>Enter the number of samples each filter should process before being</td>
</tr>
<tr>
<td></td>
<td>discharged.</td>
</tr>
<tr>
<td>Replacement Volume</td>
<td>If your system configuration includes the VK 8000 with replacement media</td>
</tr>
<tr>
<td></td>
<td>option, enter the replacement volume in milliliters.</td>
</tr>
<tr>
<td>Waste Drop Vol</td>
<td>Enter the desired waste drop volume in milliliters.</td>
</tr>
<tr>
<td></td>
<td>Note: the drop volume is an amount of sample that is dispensed through the</td>
</tr>
<tr>
<td></td>
<td>VK 8000 needles prior to dispensing samples into the collection tubes to</td>
</tr>
<tr>
<td></td>
<td>ensure the needles are purged completely.</td>
</tr>
<tr>
<td>Dual Sample</td>
<td>Click Dual Sample to pull two samples into two consecutive rows at a</td>
</tr>
<tr>
<td></td>
<td>single sample timepoint.</td>
</tr>
<tr>
<td>Option</td>
<td>Description</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Error Tolerance (±)</td>
<td>Temperature Enter the desired temperature fluctuation limit (±). If the vessel/water bath temperature goes over or under the set temperature by the amount of this tolerance, an error is recorded as part of the results. If your system configuration includes AutoTemp, the system checks the vessel temperature at each sample timepoint. For system configurations other than the VK 7030, the system continuously checks the water bath temperature.</td>
</tr>
<tr>
<td>Speed</td>
<td>Enter the desired speed fluctuation limit (±). If the RPM goes over or under the set speed by the amount of this tolerance, an error is recorded as part of the results.</td>
</tr>
<tr>
<td>Clean System After Method Run Enable</td>
<td>Adds a cleaning cycle to the end of the dissolution method.</td>
</tr>
<tr>
<td>Clean System After Method Run Vol.</td>
<td>Specifies the volume of rinse solution to be pumped through the sampling lines during the cleaning cycle.</td>
</tr>
<tr>
<td>Clean System After Method Run Cycles</td>
<td>Specifies the number of rinse cycles to be executed.</td>
</tr>
<tr>
<td>Clean System After Method Run Rinse Port</td>
<td>For 850-DS use only. Specifies that the rinse solution will be pumped from the rinse port of the 850-DS (automated).</td>
</tr>
<tr>
<td>Clean System After Method Run Sample Cannula</td>
<td>Specifies that the rinse solution will be pumped from the sample cannulas. Requires manual placement of appropriate rinse tray.</td>
</tr>
<tr>
<td>Profile Interval</td>
<td>Enter the timepoint in hh:mm format at which the temperature and speed settings are recorded. Note: profile measurements are optional. Values are always recorded at sample timepoints independent of this setting.</td>
</tr>
<tr>
<td>Change Management</td>
<td>If applicable, select the box under Change Management in order to restrict the method editing rights to the current user or any user with VkModifyOthersMethod.</td>
</tr>
</tbody>
</table>
5 Select the **BIO-DIS** or **Dissolution** tab. Following is a description of the BIO-DIS and Dissolution tab options:

### BIO-DIS tab

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Row</td>
<td>Use the up and down arrows to indicate the row number for which the parameters are being set. After clicking Add to List, use the up and down arrows to indicate the next row.</td>
</tr>
<tr>
<td>Speed</td>
<td>Use the up and down arrows to indicate the desired dips per minute (DPM) for each applicable row of the Apparatus 3 / Apparatus 7.</td>
</tr>
<tr>
<td>Type</td>
<td>Note: disregard this option.</td>
</tr>
<tr>
<td>Dip Interval</td>
<td>Enter the desired duration for dipping in hhh:mm:ss format.</td>
</tr>
<tr>
<td>Hold</td>
<td>Enter the desired duration for the dip to remain at the bottom of the stroke in mm:ss format.</td>
</tr>
<tr>
<td>Drain</td>
<td>Enter the desired duration for the apparatus to remain at the top of the stroke after dipping in mm:ss format.</td>
</tr>
<tr>
<td>Bath Temperature</td>
<td>Enter the desired water bath temperature, if applicable, in °C.</td>
</tr>
</tbody>
</table>

### Dissolution tab

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bath Temperature</td>
<td>Enter the desired water bath temperature, if applicable, in °C. Note: this option is disabled if your system configuration includes a VK 7030 or 709-DS.</td>
</tr>
<tr>
<td>Apparatus Type</td>
<td>Use the drop-down arrow to select the apparatus type (Paddles or Basket).</td>
</tr>
<tr>
<td>Vessel Temperature</td>
<td>Enter the desired vessel temperature, as applicable, in degrees Celsius. Note: this value is used to determine temperature errors at sample timepoints as well as for a vessel temperature start (see “Vessel Temperature Start” on page 84).</td>
</tr>
<tr>
<td>Spindle RPM</td>
<td>Enter an appropriate speed for the dissolution apparatus spindles.</td>
</tr>
</tbody>
</table>
### Dissolution tab

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final Spin RPM</td>
<td>If applicable, enter an appropriate speed for the final spin.</td>
</tr>
<tr>
<td>Final Spin Duration</td>
<td>If applicable, enter the duration of the final spin in mm:ss format.</td>
</tr>
<tr>
<td>Media Volume</td>
<td>Enter the volume of the media in the vessels.</td>
</tr>
<tr>
<td>Vessel Temperature</td>
<td>Enable Measure Initial Temperature and/or Measure Final Temperature to take the initial and final vessel temperatures during the method.</td>
</tr>
<tr>
<td>Vessel Table Level</td>
<td>Enable Pre-Test Level Verification to verify the vessel table level prior to starting a test (requires a 280-DS Instrument Module).</td>
</tr>
<tr>
<td>Operation Checks</td>
<td>Enable Pre-test verification of apparatus components and environment to document the acceptable condition of accessories (MQ requirement).</td>
</tr>
<tr>
<td>Vibration Monitoring</td>
<td>Check this box to enable the detection of transient and persistent vibration levels. Requires the 280-DS Instrument Module.</td>
</tr>
<tr>
<td>Frequency Bandwidth of Interest</td>
<td>Defines the range of frequencies that the software will monitor to detect above-threshold amplitudes.</td>
</tr>
<tr>
<td>Transient Event Threshold</td>
<td>Defines the limit of the vibration resultant amplitude above which the vibration is considered abnormal. Vibration amplitude threshold can be defined as acceleration measured in mG or displacement measured in mm. Transient event will be detected if the amplitude goes up and quickly resets down.</td>
</tr>
<tr>
<td>Persistent Event Threshold</td>
<td>Defines the limit of the vibration resultant amplitude above which the vibration is considered abnormal. Vibration amplitude threshold can be defined as acceleration measured in mG or displacement measured in mm. Persistent event will be detected if the resultant amplitude goes up and stays up over defined period of time.</td>
</tr>
</tbody>
</table>

### NOTE

Resultant amplitude is the magnitude of the X, Y, and Z axis amplitudes detected by the 280-DS 3-axis accelerometer:

\[
\sqrt{x^2 + y^2 + z^2}
\]
6 For the Apparatus 3 / Apparatus 7, click **Add To List**.

7 For Apparatus 1 / 2, select the **Sample Timepoints** tab and program the appropriate timepoints (see Figure 25, “Sample Timepoints,” on page 70).

---

**Figure 25** Sample Timepoints
Following is a description of the Sample Timepoints tab options:

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>Enter the desired sample timepoint in hh:mm:ss format.</td>
</tr>
<tr>
<td>Comment</td>
<td>Enter any information relevant to the timepoint.</td>
</tr>
<tr>
<td>Type</td>
<td>Click the drop-down arrow to select either Sample or Sample + Media Change as applicable for your method.</td>
</tr>
<tr>
<td>Add Timepoint</td>
<td>Once the information is added under Time, Comment, and Type, click <strong>Add Timepoint</strong> to include the timepoint in the method. Repeat this process for all desired timepoints.</td>
</tr>
</tbody>
</table>

Note: Media change timepoint is a manual media change. It can be media addition or full media replacement. This radio button becomes available to differentiate when Media Change is specified. Selecting Media Addition will maintain a continuous elapsed time while selecting Full Media Replacement assumes the dosage form has been removed from the media and will therefore pause the elapsed time during the change.
8 Select the **Notifications** tab.
Select the **Auto Export** tab.
Following is a description of the Auto Export tab options:

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto Export</td>
<td>Folder Define folder location where exported data should be saved.</td>
</tr>
<tr>
<td>Destination</td>
<td>File Name Prefix Specify custom file name prefix for name of exported files.</td>
</tr>
<tr>
<td>Export Options</td>
<td>Specify the data types to be exported to the defined location. Place a check in each box to have the data type exported.</td>
</tr>
</tbody>
</table>
Copying Methods

To copy a method, complete the following steps:

1. From the navigation bar, click Editor. The Methods screen displays (see Figure 22, “Methods,” on page 63).
2. Select the desired method.
3. Click Copy Method.
4. Click Paste. A new method displays. The description of the new method is Copy of...
5. To change any of the parameters of the method, see “Editing an Existing Method” below.

Deleting Methods

To delete a method, complete the following steps:

1. From the navigation bar, click Editor. The Methods screen displays (see Figure 22, “Methods,” on page 63).
2. Select the desired method.
3. Click Delete.
4. Click Yes.

Recovering a Method

To recover a deleted method, complete the following steps:

1. From the navigation bar, click Editor > Recover. The Select Deleted Method(s) To Recover screen displays.
2. Select the desired method.
3. Click OK.
2 Operation

Editing an Existing Method

To edit a method already entered on the Dissolution Workstation, complete the following steps:

1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 22, “Methods,” on page 63).

2. Click the desired method.

3. Click **Properties** on the navigation bar. The Method Editor screen displays (see Figure 24, “Method Editor,” on page 65).

   **NOTE**

   Alternately, you can double click the desired method or right click the desired method and select **Properties**. The Method Editor screen displays as a result of any of these actions.

4. Select the appropriate tabs and change the relevant information in the same manner that the method was created.
Method Report

To display a report of the method parameters, complete the following steps:

1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 22, “Methods,” on page 63).

2. Select the desired system configuration.

3. Click **Report**. The Version Selection screen displays.

4. If applicable, indicate which version and click **OK**.

5. The method report displays. The report can be printed, exported, searched, verified, and / or signed.

**NOTE**

Each time a method is saved, a new version is created. To create a report of a version other than the most recently saved, indicate the appropriate version number on the Version Selection screen.

Audit Trail

Once a method has completed, the results are available for review, audited modification, and electronic signature. The software maintains complete history for all runs executed on the system. Results can be previewed and printed.

**Show Audit Trail**

To display the audit trail for a method, complete the following steps:

1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 22, “Methods,” on page 63).

2. Select the method and click **Show Audit Trail**. The Method Audit Trail screen displays.

**NOTE**

Alternately, you can right click the desired method and select **Show Audit Trail**. The Method Audit Trail screen displays as a result of either of these actions.
3 Select two or more versions and click **Differences** in the navigation bar. A change report displays. The report can be printed or exported.

**Verify Integrity**

To verify that the method has not been changed outside of the application, complete the following steps:

1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 22, “Methods,” on page 63).
2. Select the method and click **Verify Integrity**. Either the data is verified successfully or the user is directed to contact their system administrator.

**NOTE**

Alternately, you can right click the desired method and select **Verify Integrity**. The integrity of the method is checked as a result of either of these actions.

**Import / Export XML File**

To use an existing method from one Dissolution Workstation on a different Dissolution Workstation, you can export and import the method as an XML file.

To export the method, complete the following steps:

1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 22, “Methods,” on page 63).
2. Select the desired method.
3. Click **Export**. The Version Selection screen displays.

**NOTE**

Alternately, you can right click the desired method and select **Export**. The Version Selection screen displays as a result of either of these actions.
4 If applicable, indicate which version to export and click **OK**. The Export Method to XML File screen displays.

**NOTE**

Each time a method is saved, a new version is created. To export a version other than the most recently saved, indicate the appropriate version number on the Version Selection screen.

5 Indicate the directory and file name and click **Save**. The code is saved as an XML file which displays in Notepad.

6 Close the Notepad file.

To import the XML file at another Dissolution Workstation, complete the following steps:

1 From the navigation bar, click **Editor**. The Methods screen displays (see Figure 22, “Methods,” on page 63).

2 Click **Import**. The Import Method from XML File screen displays.

**NOTE**

Alternately, you can right click the desired method and select **Import**. The Import Method from XML File screen displays as a result of either of these actions.

3 Select the appropriate directory and file name and click **Open**. The method displays on the Method screen.
Running the Method

1 From the navigation bar, click Run Method. The Select System Step 1 of 2 screen displays.

![Select System Step 1 of 2](image)

**Figure 27** Select System Step 1 of 2
2 Select the desired system to run the method and click **Next**. The Select Method Step 2 of 2 screen displays (see **Figure 28**, “Select Method Step 2 of 2,” on page 81).

![Select Method Step 2 of 2](image)

**Figure 28** Select Method Step 2 of 2
3 Select the desired method to run and click **Finish**. The system status screen displays (see Figure 29, “System Status,” below).

![System Status Screen](image)

**Figure 29**  System Status

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Start</strong></td>
<td>See “Running the Method” on page 80.</td>
</tr>
<tr>
<td><strong>Stop</strong></td>
<td>See “Running the Method” on page 80.</td>
</tr>
<tr>
<td><strong>Diagnostics</strong></td>
<td>See “Diagnostics / Manual Control” on page 48.</td>
</tr>
<tr>
<td><strong>Load Method</strong></td>
<td>See “Editing an Existing Method” on page 76.</td>
</tr>
<tr>
<td><strong>Test Report</strong></td>
<td>See “Test Reports” on page 85.</td>
</tr>
<tr>
<td><strong>Clean</strong></td>
<td>See “Clean System” on page 87.</td>
</tr>
<tr>
<td><strong>Manual</strong></td>
<td>See “Manual Sampling” on page 88.</td>
</tr>
</tbody>
</table>
4 Click **Start**. The Method Start Options screen displays.

![Method Start Options](image)

**Figure 30** Method Start Options
Following is a description of the Method Start Options screen options:

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>Enter the product name.</td>
</tr>
<tr>
<td>Notes</td>
<td>Enter any appropriate notation.</td>
</tr>
<tr>
<td>Label 1</td>
<td>Enter the appropriate information based on the user-defined labels (see “User Defined Labels” on page 66).</td>
</tr>
<tr>
<td>Label 2</td>
<td></td>
</tr>
<tr>
<td>Label 3</td>
<td></td>
</tr>
<tr>
<td>Dosage Introduction</td>
<td>Choose DDM or Manual depending on your configuration.</td>
</tr>
<tr>
<td>Temperature Delayed Start</td>
<td></td>
</tr>
<tr>
<td>Vessel Temperature Start</td>
<td>As applicable select Vessel Temperature Start or Bath Temperature Start. Ensure the current date displays in the Time Delayed Start box.</td>
</tr>
<tr>
<td>Bath Temperature Start</td>
<td></td>
</tr>
<tr>
<td>Time Delayed Start</td>
<td>Use this option to program a delayed start. Enter the desired date and time to start the method.</td>
</tr>
</tbody>
</table>

5 Ensure the dongle is inserted into the USB port.

NOTE

If the dongle (HASP security key) is not inserted into the USB port, the method will not run.

6 Click OK to start the method.

7 When the method is complete, click Test Report. The test report displays. The report can be printed, exported, searched, verified, and/or signed.
Test Reports

To display a report of the completed method, complete the following steps:

1. From the navigation bar, click Test Reports. The Test Report Selection screen displays.

![Test Report Selection screen](image)

**Figure 31** Test Report Selection screen

By default, the test report dialog only shows tests done in the previous week. To view tests completed earlier than the previous week, click the Start Date and/or End Date drop-down arrows to indicate date range for a test report selection and click Filter Date and System.

Additionally, you can select a system name from the System combo box to restrict the selection to a particular system.

To restrict the selection to a particular test identification, enter the value in the Test ID Filter box and click Filter Test ID.

2. Click a test in the list to select it.
2 Operation

3 From the navigation bar in the **Test Report Selection** dialog, click **Show Report**. The report for the selected test displays.

4 Using the buttons on the report toolbar, you can do the following:

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sign</td>
<td>Adds electronic signature to test report.</td>
</tr>
<tr>
<td>Verify</td>
<td>Click to verify integrity of test report. The data verification ensures the report has not been modified outside of the application.</td>
</tr>
<tr>
<td>Options</td>
<td>Click to specify the optional parameters to display on the test report.</td>
</tr>
</tbody>
</table>

**Electronic Signatures**

When the user is satisfied with the results, the results can be electronically signed. The software allows multiple electronic signings of a set of results. Each signing is accomplished using the signature dialog box shown. The user authenticity is determined by testing the user identification and password against the Windows security database.

Electronic signatures are permanently linked to the results. The software always requires the signature to be executed using all the signature components. Any attempts to sign a set of results using an invalid user identification, password, or any combination thereof that is incorrect is automatically recorded to the system audit trail.
Clean System

From the system status screen, click **Clean**. All instruments initialize. Media is pulled and expelled through the valves. If applicable, the filters are replaced.

**Figure 32** Clean System

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning Cycle</td>
<td><strong>Volume</strong> Specify the amount of rinse solution to be cycled through the system (in mL).</td>
</tr>
<tr>
<td></td>
<td><strong>Cycles</strong> Indicate the number of cycles to be executed to thoroughly rinse the system.</td>
</tr>
<tr>
<td>Source</td>
<td><strong>Rinse Port</strong> Select this option to pull the rinse solution from the Rinse Port (850-DS only).</td>
</tr>
<tr>
<td></td>
<td><strong>Sample Cannula</strong> Select this option to pull the rinse solution from the sampling cannulas. Manual intervention is required to properly position a rinse tray or cups beneath each sampling cannula.</td>
</tr>
</tbody>
</table>
Manual Sampling

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampling Parameters</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Sample Volume</strong> Enter the sample volume in milliliters.</td>
</tr>
<tr>
<td></td>
<td><strong>Prime Volume</strong> Use this option to set the amount of drawn medium necessary</td>
</tr>
<tr>
<td></td>
<td>to fill the sampling lines of the entire system.</td>
</tr>
<tr>
<td></td>
<td>Enter the prime volume in milliliters.</td>
</tr>
<tr>
<td></td>
<td><strong>Purge Volume</strong> Use this option to set a purge volume in milliliters that</td>
</tr>
<tr>
<td></td>
<td>ensures all stranded medium is properly expelled.</td>
</tr>
<tr>
<td></td>
<td>Enter the purge volume in milliliters.</td>
</tr>
<tr>
<td></td>
<td><strong>Samples / Filter</strong> Enter the number of samples each filter should process</td>
</tr>
<tr>
<td></td>
<td>before being discharged.</td>
</tr>
<tr>
<td></td>
<td><strong>Replacement Volume</strong> If your system configuration includes a fraction</td>
</tr>
<tr>
<td></td>
<td>collector with replacement media option, enter the replacement volume in</td>
</tr>
<tr>
<td></td>
<td>milliliters.</td>
</tr>
<tr>
<td>Option</td>
<td>Description</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Waste Drop Vol</td>
<td>Enter the desired waste drop volume in milliliters. Note: the drop volume is an amount of sample that is dispensed through the VK 8000 needles prior to dispensing samples into the collection tubes to ensure the needles are purged completely.</td>
</tr>
<tr>
<td>Dual Sample</td>
<td>Click <strong>Dual Sample</strong> to pull two samples into two consecutive rows at a single sample timepoint.</td>
</tr>
<tr>
<td>Error Tolerance (±)</td>
<td>Temperature</td>
</tr>
<tr>
<td></td>
<td>Enter the desired temperature fluctuation limit (±). If the vessel / water bath temperature goes over or under the set temperature by the amount of this tolerance, an error is recorded as part of the results.</td>
</tr>
<tr>
<td></td>
<td>If your system configuration includes AutoTemp, the system checks the vessel temperature at each sample timepoint.</td>
</tr>
<tr>
<td></td>
<td>For system configurations other than the VK 7030, the system continuously checks the water bath temperature.</td>
</tr>
<tr>
<td></td>
<td>Speed</td>
</tr>
<tr>
<td></td>
<td>Enter the desired speed fluctuation limit (±). If the RPM goes over or under the set speed by the amount of this tolerance, an error is recorded as part of the results.</td>
</tr>
<tr>
<td>Profile Interval</td>
<td>Enter the timepoint in hh:mm format at which the temperature and speed settings are recorded.</td>
</tr>
<tr>
<td></td>
<td>Note: profile measurements are optional. Values are always recorded at sample timepoints independent of this setting.</td>
</tr>
<tr>
<td>Fraction Collector Row</td>
<td>Specify the sample tray row where the sample should be delivered.</td>
</tr>
<tr>
<td>Dissolution Tester RPM</td>
<td>Specify the speed (RPM) of the dissolution apparatus.</td>
</tr>
<tr>
<td>Dissolution Tester Bath</td>
<td>Specify the bath temperature of the dissolution apparatus.</td>
</tr>
<tr>
<td>Vessel Volume</td>
<td>Specify the volume of media contained in the dissolution vessels.</td>
</tr>
</tbody>
</table>
MSDE Manager: Back up / Restore Database

Backing up the Database

To back up the database, complete the following steps:

1. Click **Start > All Programs > Agilent > Dissolution > MSDE Manager**. The MSDE Manager screen displays.

2. Click **Connect** to connect to the database.

3. The DB Utility screen displays indicating the database has connected successfully.

4. Ensure the name of the database appears and is highlighted in the Database Name field. If this field is empty, select the **Attach** tab and click **Attach** to attach to the database.

---

**Figure 33** MSDE Manager Screen
5 Click ... to specify a destination for the backup file.

6 Click **Backup**. The back-up file is written to the designated file location.

---

**Restoring the Database**

The Dissolution Workstation database can be restored from a previous back-up file. Ensure the Dissolution Workstation program is not running and that no other program is using the database during the restoration.

To restore the database, complete the following steps:

1 Click **Start** > **All Programs** > **Agilent** > **Dissolution** > **MSDE Manager**. The MSDE Manager screen displays.

2 Click **Connect** to connect to the database.

3 On the Restore tab, click **...** to search for the back-up file.
2 Operation

4 Select the appropriate file and click **Open**.

5 Click **Restore**. The previous back-up file is restored.

Tools

Configuration Dialog

Select **Tools > Options** from the Dissolution Workstation homescreen to display the Configuration Dialog screens.

![Configuration Dialog Security Tab](image)

**Figure 35** Configuration Dialog Security Tab
Database Tools

Select **Tools > Options > Database** from Dissolution Workstation to display the Database Tools screens.

![Database Tools](image)

**Figure 36** Database Tools

<table>
<thead>
<tr>
<th>Option</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dissolution Server</td>
<td>Name of the dissolution server where the database is located.</td>
</tr>
<tr>
<td>Integrated Security</td>
<td>Allows you to assume responsibility for administrating database access.</td>
</tr>
<tr>
<td>Change DB Settings</td>
<td>Updates the current settings of the database.</td>
</tr>
</tbody>
</table>
Email

Select **Tools > Email** from Dissolution Workstation to display the Database Tools screens.

![Configuration Dialog](image)

**Figure 37** Email

<table>
<thead>
<tr>
<th>Option</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Server</td>
<td>Specify name of outgoing mail server</td>
</tr>
<tr>
<td>Port</td>
<td>Specify the SMTP host port number.</td>
</tr>
<tr>
<td>User Name</td>
<td>Enter the user name if the SMTP server requires authentication.</td>
</tr>
<tr>
<td>Password</td>
<td>Enter the password IF the SMTP server requires authentication.</td>
</tr>
<tr>
<td>From</td>
<td>Enter a return address for the email.</td>
</tr>
<tr>
<td>To</td>
<td>Enter a destination address for the email.</td>
</tr>
<tr>
<td>Test</td>
<td>Test the email configuration settings.</td>
</tr>
</tbody>
</table>
Miscellaneous

Select **Tools > Miscellaneous** from Dissolution Workstation to display the Database Tools screens.

![Configuration Dialog]

**Figure 38** Miscellaneous

<table>
<thead>
<tr>
<th>Option</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use Simulated Instruments</strong></td>
<td>Runs the software in a simulation mode with simulated instruments. No official data is acquired in this mode.</td>
</tr>
<tr>
<td><strong>Idle Minutes</strong></td>
<td>Amount of time before the software locks automatically. Setting this value to 0 disables this feature.</td>
</tr>
</tbody>
</table>
Security (21 CFR Part 11 Compliance)

Change User

1 To change the current user account logged in to the software, click Change User from the Dissolution homescreen.
2 Enter login information and click Logon.

Lock Application

1 To lock the application, click Lock Application from the Dissolution Workstation homescreen.
2 To unlock, click the lock icon and log back into the software.

Figure 39  Lock Application
Audit Trail

Click **Audit Trail** from the Dissolution Workstation homescreen to access the Security Audit Trail screen.

![Security Audit Trail](image)

**Figure 40** Security Audit Trail

<table>
<thead>
<tr>
<th>Option</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Show Report</strong></td>
<td>Creates a detailed report of Security Audit Trail activity based on the date range specified.</td>
</tr>
<tr>
<td><strong>Retrieve Records</strong></td>
<td>Allows for record retrieval of the specified Security Audit Trail activity.</td>
</tr>
</tbody>
</table>
2  Operation

Permissions

Review the permissions granted to the current user.

Figure 41  Permissions
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