



Dissolution Workstation Software (G4974AA)

## Operator's Manual

# Notices

## Manual Part Number

79-9075 Rev C  
July 2018

## Copyright

© Agilent Technologies, Inc. 2018

No part of this manual may be reproduced in any form or by any means (including electronic storage and retrieval or translation into a foreign language) without prior agreement and written consent from Agilent Technologies, Inc. as governed by United States and international copyright laws.

Agilent Technologies, Inc.  
3501 Stevens Creek Blvd.  
Santa Clara, CA 95052 USA

## Warranty

The material contained in this document is provided "as is," and is subject to being changed, without notice, in future editions. Further, to the maximum extent permitted by applicable law, Agilent disclaims all warranties, either express or implied, with regard to this manual and any information contained herein, including but not limited to the implied warranties of merchantability and fitness for a particular purpose. Agilent shall not be liable for errors or for incidental or consequential damages in connection with the furnishing, use, or performance of this document or of any information contained herein. Should Agilent and the user have a separate written agreement with warranty terms covering the material in this document that conflict with these terms, the warranty terms in the separate agreement shall control.

## Technology Licenses

The hardware and/or software described in this document are furnished under a license and may be used or copied only in accordance with the terms of such license.

## Restricted Rights Legend

U.S. Government Restricted Rights. Software and technical data rights granted to the federal government include only those rights customarily provided to end user customers. Agilent provides this customary commercial license in Software and technical data pursuant to FAR 12.211 (Technical Data) and 12.212 (Computer Software) and, for the Department of Defense, DFARS 252.227-7015 (Technical Data - Commercial Items) and DFARS 227.7202-3 (Rights in Commercial Computer Software or Computer Software Documentation).

## Safety Notices

### CAUTION

A **CAUTION** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in damage to the product or loss of important data. Do not proceed beyond a **CAUTION** notice until the indicated conditions are fully understood and met.

### WARNING

A **WARNING** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in personal injury or death. Do not proceed beyond a **WARNING** notice until the indicated conditions are fully understood and met.

# Content

## 1 Introduction 7

## 2 Installation and Setup 9

### Requirements and Configuration 10

PC Requirements 10

Software Installation or Upgrade 10

Local Security Policy 11

### Starting Dissolution Workstation 13

Starting Dissolution Workstation 13

Dissolution Workstation Logon 13

Adding Users to the Application 14

### Workstation Connections 16

Dissolution Apparatus / 8000 / Peristaltic Pump (Daisy-chain to PC) 18

Dissolution Apparatus / 850-DS (Daisy-chain to PC) 19

Dissolution Apparatus / 8000 / Syringe Pump (Daisy-chain to PC) 20

Dissolution Apparatus / 8000 / Syringe Pump / Filter Changer (Daisy-chain to PC) 21

Dissolution Apparatus / 8000 / Peristaltic Pump (Individual to MDS) 22

Dissolution Apparatus / 850-DS (Individual to MDS) 23

Dissolution Apparatus / 8000 / Syringe Pump (Individual to MDS) 24

Dissolution Apparatus / 8000 / Syringe Pump / Filter Changer (Individual to MDS) 25

Dissolution Apparatus / 8000 / Peristaltic Pump, Syringe Pump, or Syringe Pump and Filter Changer (Daisy-chain to MDS) 26

Dissolution Apparatus / 850-DS (Daisy-chain to MDS) 27

## 3 Operation 29

### Log On to Dissolution Workstation 30

### Configuring Your System 33

Dissolution Apparatus 36

Fraction Collector 37

Syringe Pump 38

Filter Changer 39

## Content

Completing the Configuration	40
Copying a System Configuration	41
Deleting a System Configuration	41
Recovering a System Configuration	42
Serial Numbers	42
System Configuration Report	44
Editing an Existing System Configuration	45
Show Audit Trail	45
Verify Integrity	46
Import / Export XML File	46

### **Diagnostics / Manual Control 48**

Moving the Drive Unit for Apparatus 3 / Apparatus 7	50
Dips per Minute for Apparatus 3 / Apparatus 7	51
Moving the Drive Unit for Apparatus 1 / 2	51
Spindle Control for Apparatus 1 / 2	53
Cannula / Manifold for Apparatus 1 / 2	53
Dosage Delivery for Apparatus 1 / 2	54
Water Bath Temperature	54
Syringe Pump / Filter Changer	55
Valve Control (8000)	58
Valve Control (850-DS)	59
Peristaltic Pump	60
Replacement Media Pump	61

### **Method Editor 62**

Creating a Method	62
Copying Methods	74
Deleting Methods	74
Recovering a Method	75
Editing an Existing Method	75
Method Report	76
Audit Trail	76
Import / Export XML File	77



<b>Running the Method</b>	<b>79</b>
<b>Test Reports</b>	<b>84</b>
Electronic Signatures	85
<b>Clean System</b>	<b>86</b>
<b>Manual Sampling</b>	<b>87</b>
Eject Tray	89
Load Tray	89
Verify Timing	89
<b>MSDE Manager: Back up / Restore Database</b>	<b>90</b>
Backing up the Database	90
Restoring the Database	91
Tools	92
<b>Security (21 CFR Part 11 Compliance)</b>	<b>96</b>
Change User	96
Lock Application	96
Audit Trail	97
Permissions	98

This page was intentionally left blank, except for this message.



# 1 Introduction

Dissolution Workstation Software (G4974AA) integrates Agilent's dissolution apparatus and automated sampling components, allowing you to simultaneously control up to four systems of any configuration from a desktop PC. The software provides a mechanism for the user to build, edit, search, retrieve, and archive all dissolution methods and test reports from a single interface.

Method parameters, instrument and accessory information, and test data are captured and recorded within the software. View test status information in real time as the software progresses through the timepoints for each dissolution system. As part of 21 CFR Part 11 regulations, user changes to methods and system configurations are version controlled and documented.

Agilent's complete line of dissolution equipment is available for use with Dissolution Workstation Software. This includes Apparatus 1, 2, 3, 5, 6 and 7 and the associated pumps and automated sampling equipment.



## 2

# Installation and Setup

Requirements and Configuration	10
Starting Dissolution Workstation	13
Workstation Connections	16

## Requirements and Configuration

### PC Requirements

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

- Intel® Pentium™ G4560T minimum; Intel® Core™ i3-6100T or better preferred
- 4 GB of RAM (8 GB recommended)
- CD-ROM optical drive or USB 2.0 port (minimum) for software installation
- 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. Digi Edgeport USB-RS232 adapter recommended for multi-system connections.
- 20 GB of free hard drive space (minimum)
- Keyboard, mouse, and monitor with 1280 x 960 at 16M colors (minimum)
- Microsoft Windows 7 or 10 (32-bit or 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. See **“Backing up the Database”** on page 90 and **“Restoring the Database”** on page 91 for assistance.

#### 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

**NOTE**

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.

Policy	Security Setting
Enforce Password History	3 passwords remembered
Maximum Password Length	30 days
Minimum Password Length	6 characters
Password Must Meet Complexity Requirements	Enabled

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

Policy	Security Setting
Account lockout duration	0 minutes (infinite)
Account lockout threshold	3 invalid login attempts
Reset account lockout counter	99999 minutes

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

Policy	Security Setting
Audit account logon events	Success, Failure
Audit account management	Success, Failure
Audit login events	Success, Failure
Audit policy change	Success, Failure



## Starting Dissolution Workstation

### NOTE

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

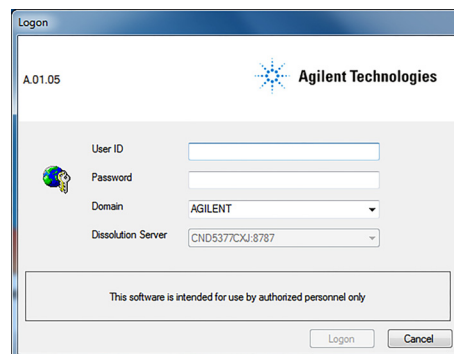


Figure 1. Logon

- 1 From the Logon screen, enter your credentials in the User ID and Password boxes.
- 2 Ensure the **domain** selected is appropriate and click **Logon** to initiate the software.

Adding Users to the Application

- 1 After successfully logging on to the software, click **Tools > Options**. The Configuration Dialog screen displays.
- 2 To add a user to a group, select the **Security** tab on the Configuration Dialog screen.

NOTE

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

- 3 Click **User Administration** at the bottom of the screen. The Local Users and Groups screen displays.

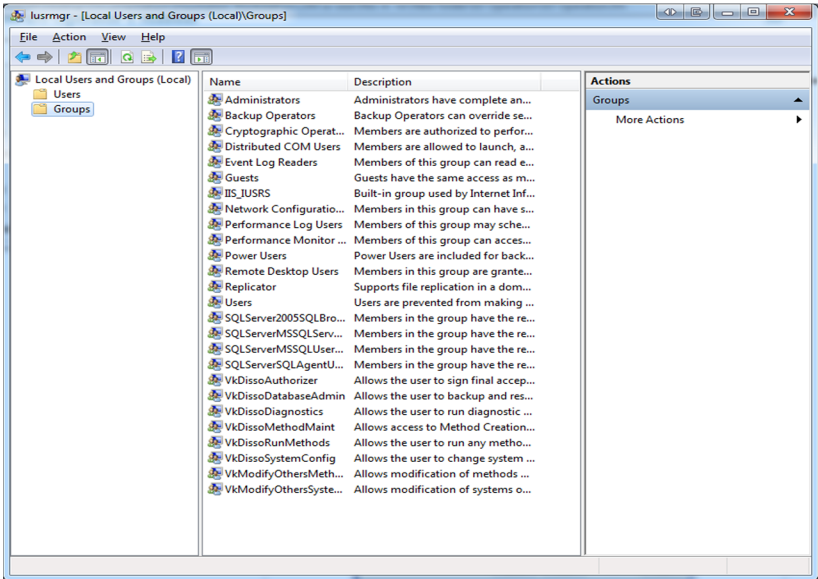


Figure 2. Local Users and Groups

- 4 Double-click the **Groups** folder to expand the list of groups.
- 5 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.
- 6 To add a user to a group, click **Add...** from the respective group screen. The Select Users, Computers, or Group screen displays.
- 7 Enter your user identification in the empty box and click **Check Names**. Ensure your user identification and domain populate the empty field. Click **OK**.
- 8 Close the Local Users and Groups screen.
- 9 Click **OK** to close the Configuration Dialog screen.

**NOTE**

It may be necessary to log in again to the application to reveal the newly granted permissions for the user.

---

## 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. It is recommended to use a multiport device server (USB to serial) that is appropriate for the number of connections to be made.

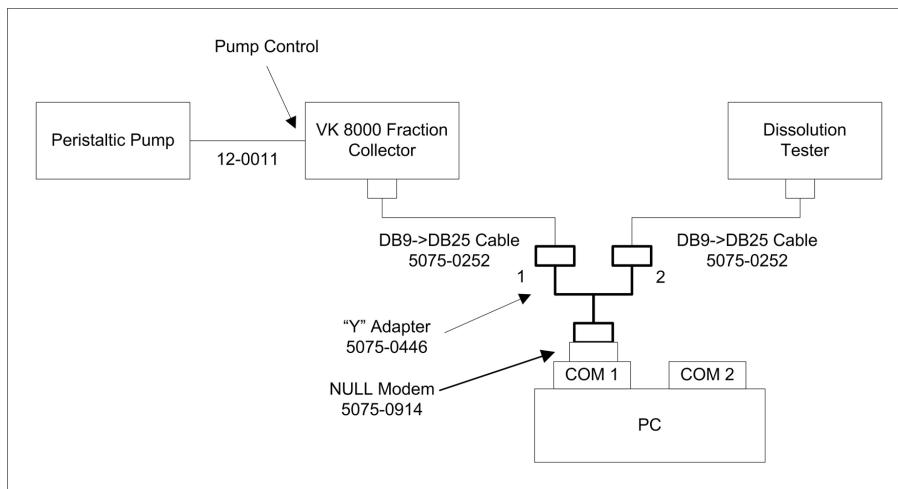
### NOTE

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

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.

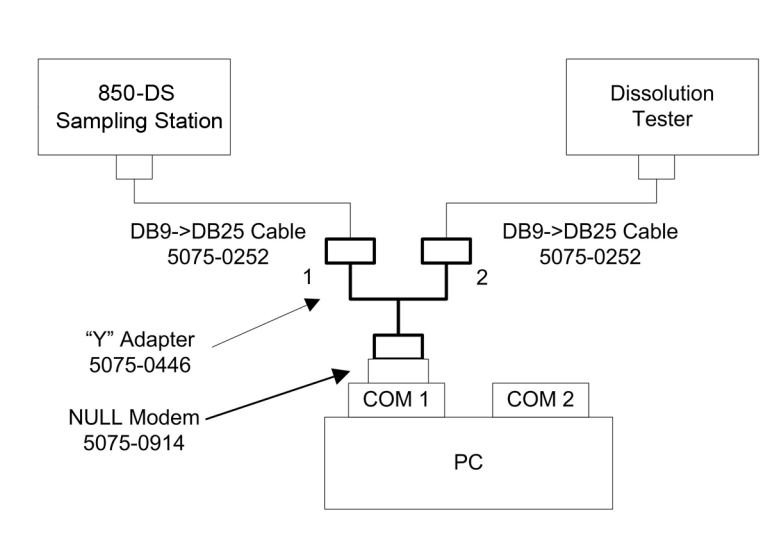
Workstation Connection	Peripheral Equipment	Procedures
<b>Daisy-chain Connection to PC</b>	8000 / peristaltic pump	see <a href="#">“Dissolution Apparatus / 8000 / Peristaltic Pump (Daisy-chain to PC)”</a> on page 18
	850-DS	see <a href="#">“Dissolution Apparatus / 850-DS (Daisy-chain to PC)”</a> on page 19
	8000 / syringe pump	see <a href="#">“Dissolution Apparatus / 8000 / Syringe Pump (Daisy-chain to PC)”</a> on page 20
	8000 / syringe pump / filter changer	see <a href="#">“Dissolution Apparatus / 8000 / Syringe Pump / Filter Changer (Daisy-chain to PC)”</a> on page 21
<b>Individual Connection to Multiport Device Server (MDS)</b>	8000 / peristaltic pump	see <a href="#">“Dissolution Apparatus / 8000 / Peristaltic Pump (Individual to MDS)”</a> on page 22
	850-DS	see <a href="#">“Dissolution Apparatus / 850-DS (Individual to MDS)”</a> on page 23
	8000 / syringe pump	see <a href="#">“Dissolution Apparatus / 8000 / Syringe Pump (Individual to MDS)”</a> on page 24
	8000 / syringe pump / filter changer	see <a href="#">“Dissolution Apparatus / 8000 / Syringe Pump / Filter Changer (Individual to MDS)”</a> on page 25
<b>Daisy-chain Connection to Multiport Device Server (MDS)</b>	8000 / peristaltic pump, syringe pump, or syringe pump and filter changer	see <a href="#">“Dissolution Apparatus / 8000 / Peristaltic Pump, Syringe Pump, or Syringe Pump and Filter Changer (Daisy-chain to MDS)”</a> on page 26
	850-DS	see <a href="#">“Dissolution Apparatus / 850-DS (Daisy-chain to MDS)”</a> on page 27

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



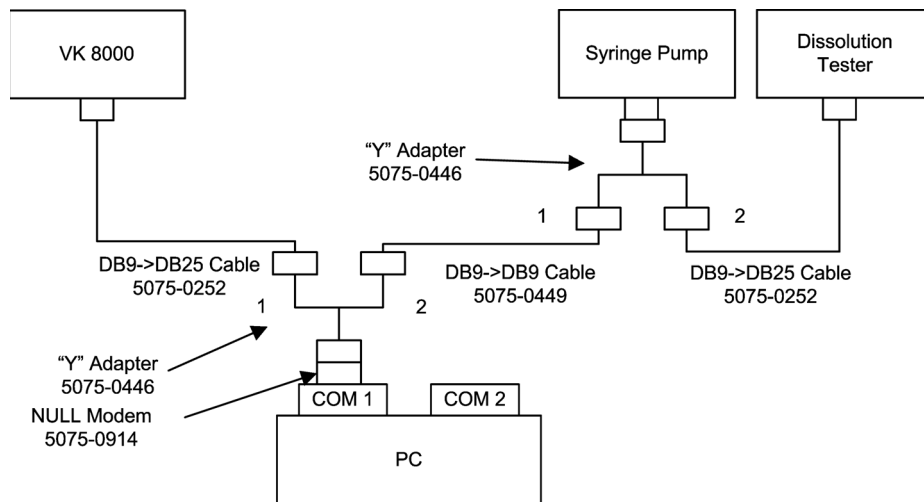
Part Number	Quantity
5075-0446	1
5075-0914	1
5075-0252	2
12-0011*	0
* supplied with pump	

## Dissolution Apparatus / 850-DS (Daisy-chain to PC)



Part Number	Quantity
5075-0446	1
5075-0914	1
5075-0252	2

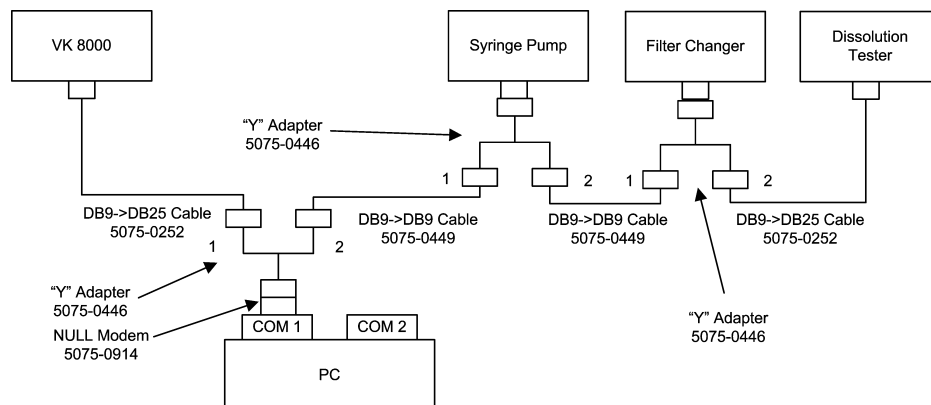
## Dissolution Apparatus / 8000 / Syringe Pump (Daisy-chain to PC)



Part Number	Quantity
5075-0446	2
5075-0914	1
5075-0252	2
5075-0449	1

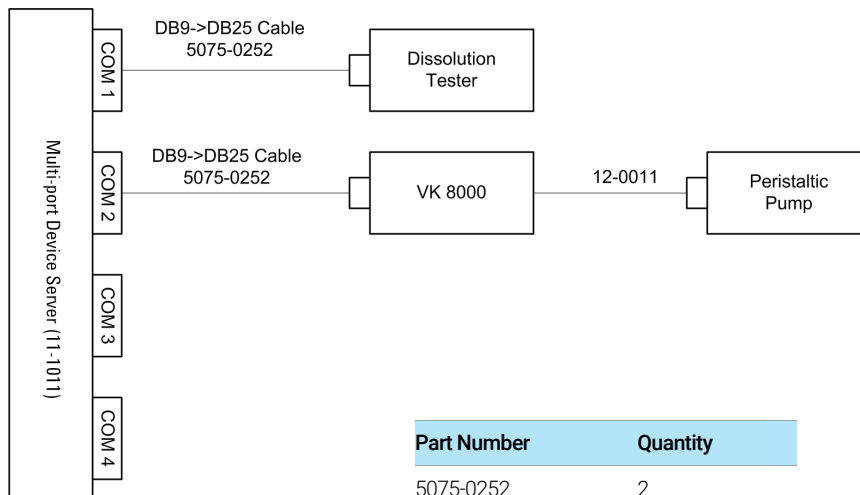


## Dissolution Apparatus / 8000 / Syringe Pump / Filter Changer (Daisy-chain to PC)



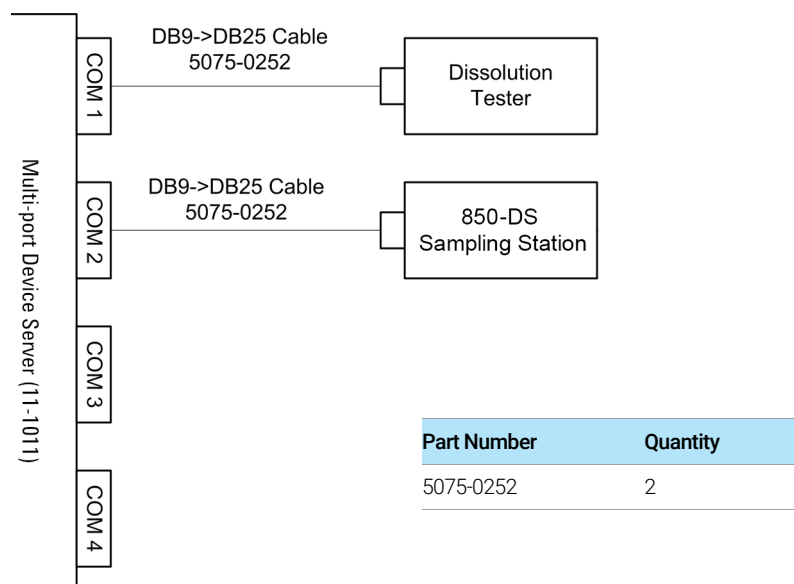
Part Number	Quantity
5075-0914	1
5075-0446	3
5075-0252	2
5075-0449	2

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

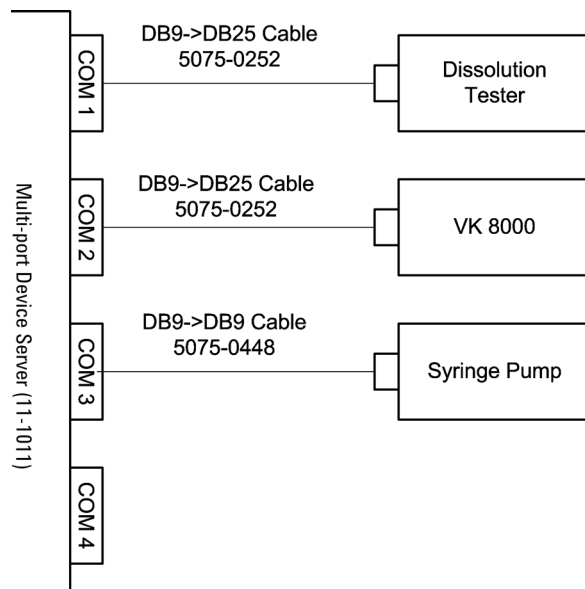


Part Number	Quantity
5075-0252	2
12-0011	0
* supplied with pump	

## Dissolution Apparatus / 850-DS (Individual to MDS)

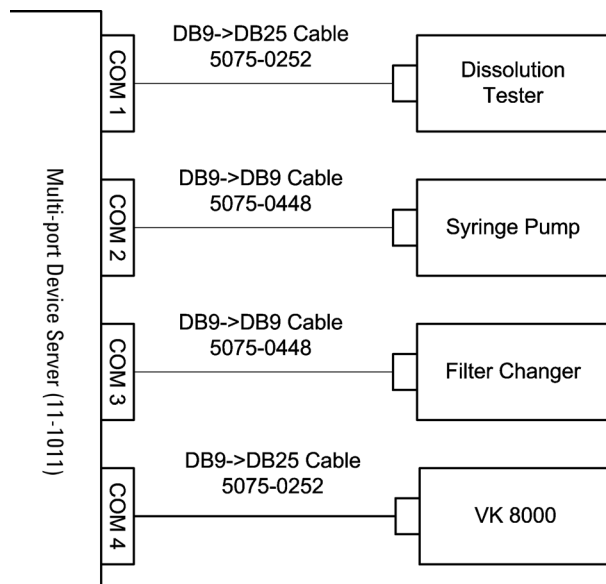


## Dissolution Apparatus / 8000 / Syringe Pump (Individual to MDS)



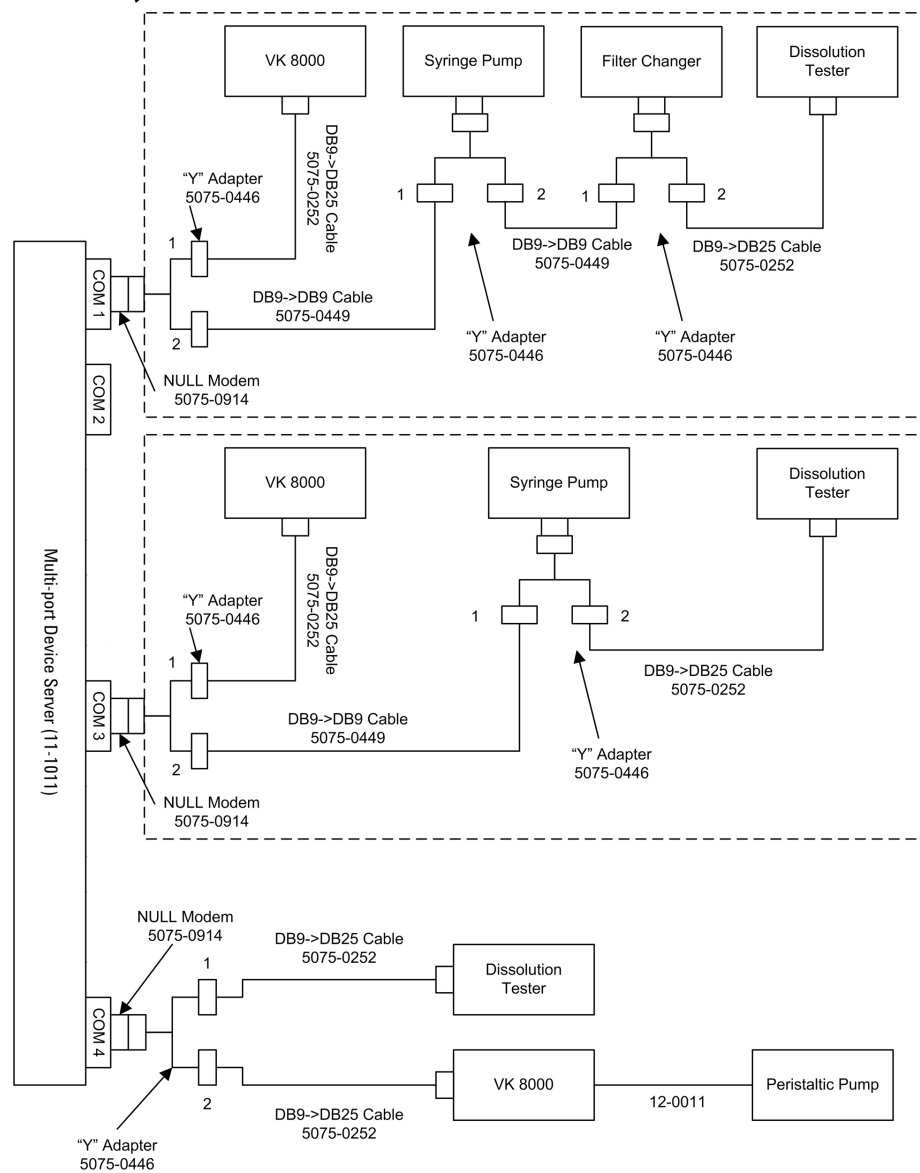
Part Number	Quantity
5075-0252	2
5075-0448	1

## Dissolution Apparatus / 8000 / Syringe Pump / Filter Changer (Individual to MDS)

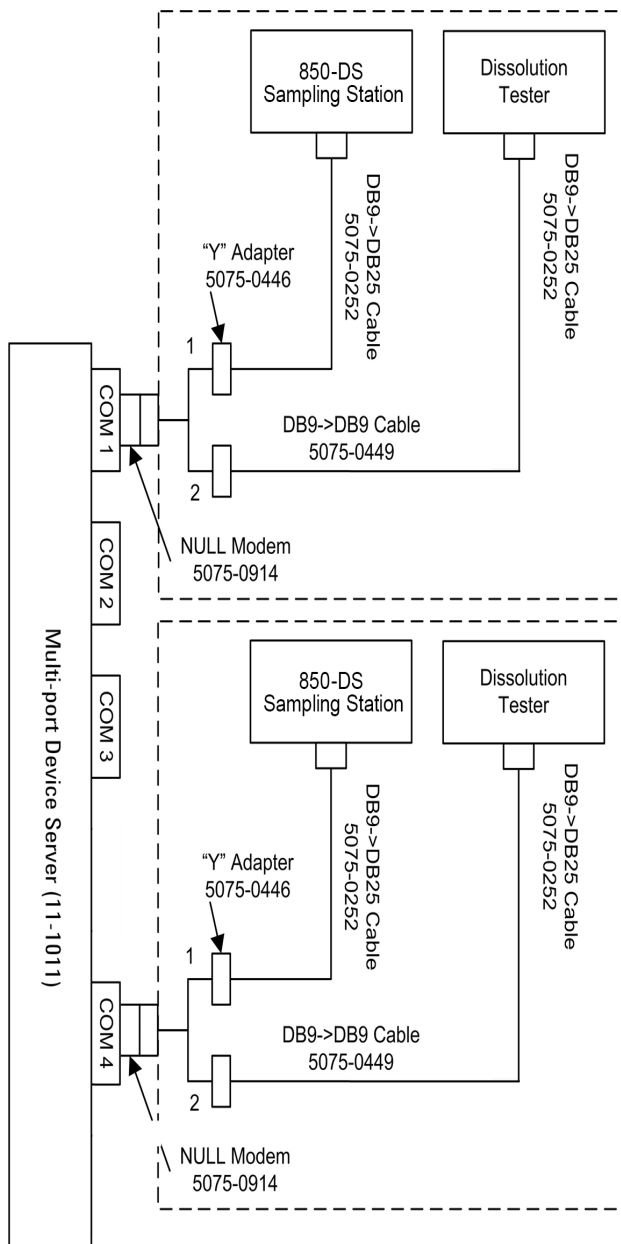


Part Number	Quantity
5075-0252	2
5075-0448	2

## 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)



This page was intentionally left blank, except for this message.





## 3

# Operation

Log On to Dissolution Workstation	30
Configuring Your System	33
Diagnostics / Manual Control	48
Method Editor	62
Running the Method	79
Test Reports	84
Clean System	86
Manual Sampling	87
MSDE Manager: Back up / Restore Database	90
Security (21 CFR Part 11 Compliance)	96

## Log On to Dissolution Workstation

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

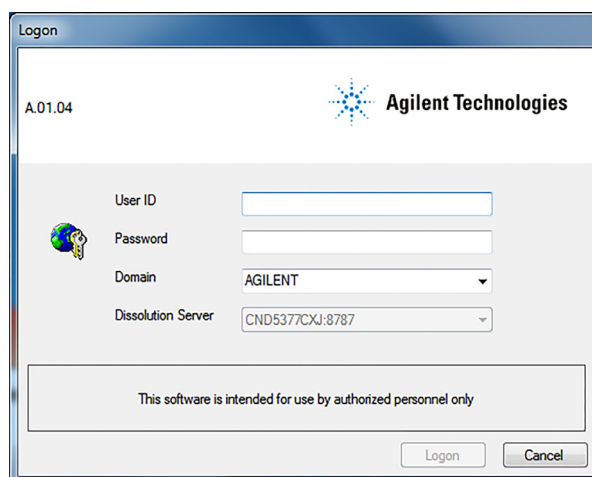


Figure 3. Logon

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

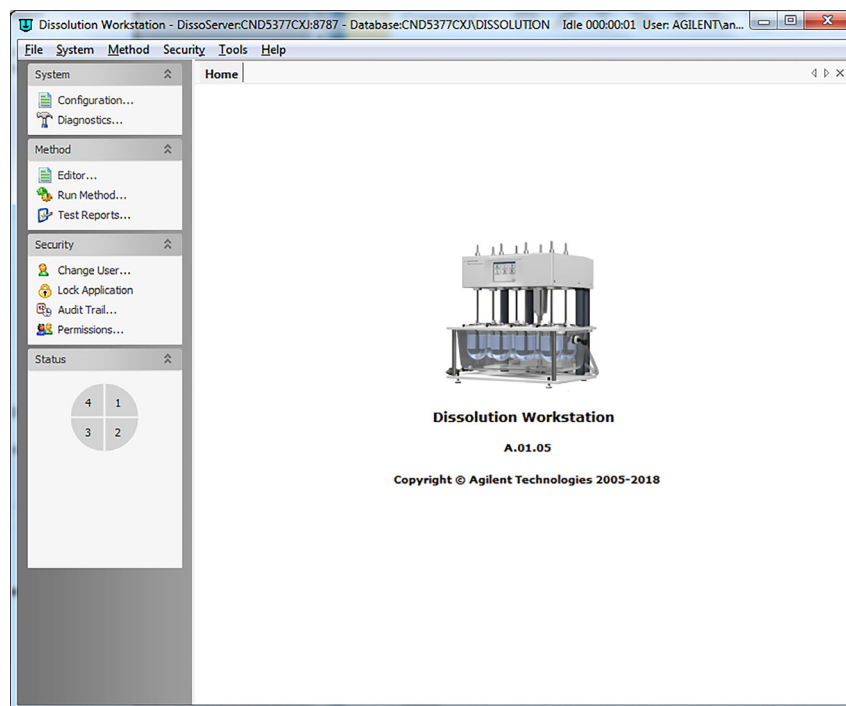


Figure 4. Dissolution Workstation

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

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

## 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.

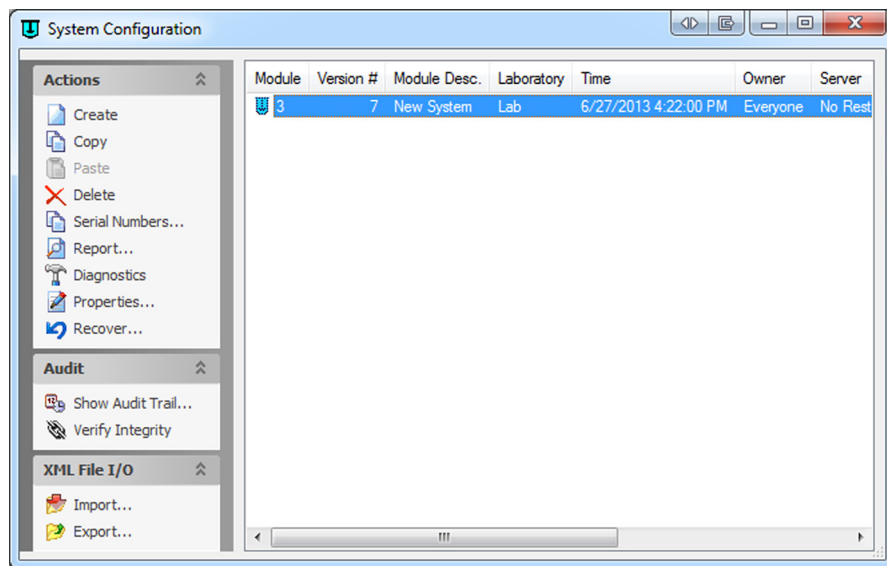
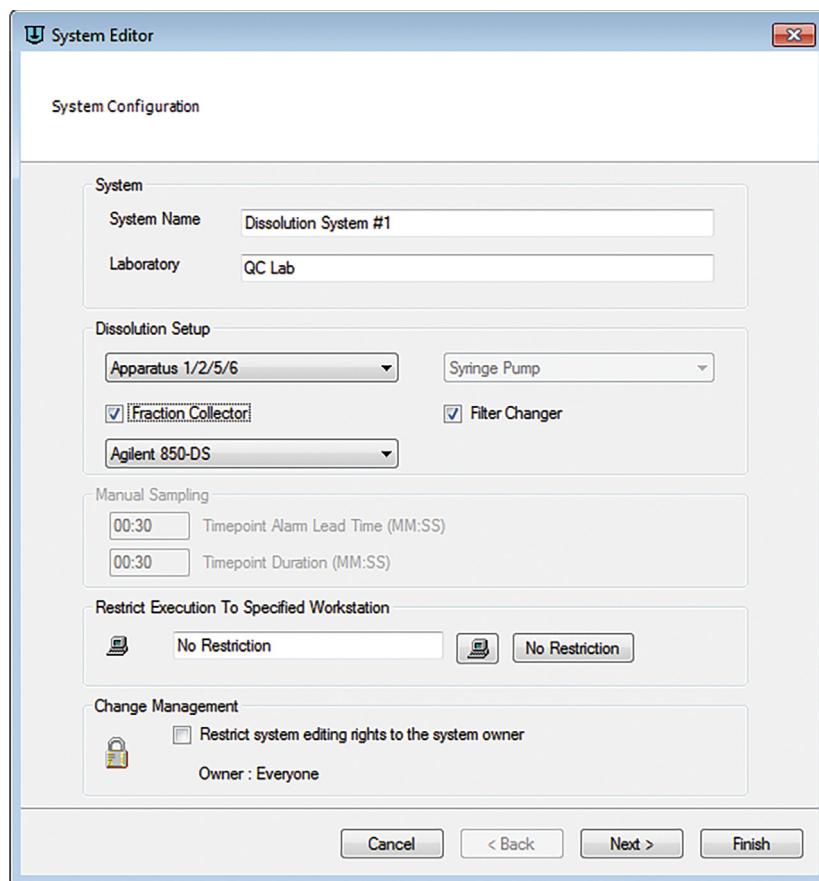


Figure 5. System Configuration

- 2 Click **Create**. The System Editor screen displays.




The screenshot shows the 'System Editor' window with the following configuration details:

- System Configuration**
  - System**
    - System Name: Dissolution System #1
    - Laboratory: QC Lab
  - Dissolution Setup**
    - Apparatus 1/2/5/6 (dropdown)
    - Syringe Pump (dropdown)
    - ☒ Fraction Collector
    - ☒ Filter Changer
    - Agilent 850-DS (dropdown)
  - Manual Sampling**
    - Timepoint Alarm Lead Time (MM:SS): 00:30
    - Timepoint Duration (MM:SS): 00:30
  - Restrict Execution To Specified Workstation**
    - Left workstation: No Restriction
    - Right workstation: No Restriction
  - Change Management**
    - ☐ Restrict system editing rights to the system owner
    - Owner: Everyone

At the bottom of the window are four buttons: Cancel, < Back, Next >, and Finish.

Figure 6. System Editor

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

Option		Description
System	System Name	Enter a name for your system.
	Laboratory	Enter a laboratory name.
Dissolution Setup		<p>Click the <b>drop-down arrow</b> on the Dissolution Setup box to select Apparatus 3/7, Apparatus 1/2/5/6, or NONE.</p> <p>Click the <b>drop-down arrow</b> in the Dissolution Setup box to select Peristaltic Pump or Syringe Pump.</p> <p>If your system configuration includes an 8000 or 850-DS, click <b>Fraction Collector</b>.</p> <p>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 <b>Filter Changer</b> if your system configuration includes a filter changer (or the 850-DS includes the Filter Module).</p>
Manual Sampling		<p>Timepoint Alarm Lead Time (MM:SS) - The amount of time that the manifold lowers prior to the sample timepoint. This allows for equilibration of the temperature probes before vessel temperature measurements.</p> <p>Timepoint Duration (MM:SS) - This is the amount of time that the manifold remains at its sampling position after the sample timepoint. The sum of the Lead Time and Duration should total a minimum of 30 seconds for accurate temperature readings.</p>
Restrict Execution To Specified Workstation		<p>Click  to display the name of the workstation or enter the name of the workstation connected to the system. Click <b>No Restriction</b> to allow the system to be run from any workstation.</p> <p>Note: The system must be physically connected.</p>
Change Management		<p>If applicable, select the <b>box</b> under Change Management in order to restrict the system editing rights to the current user.</p> <p>Note: This option prevents system configuration modification by anyone other than the system owner or a user with VkModifyOthersSystems privilege.</p>

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

## 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:

### Dissolution Apparatus

<b>Comm Address</b>	Enter the appropriate communication address for the dissolution apparatus.
<b>Options</b>	Click the appropriate <b>dissolution apparatus options</b> . Using the up and down arrows, indicate the number of active vessel positions.

### BIO-DIS

<b>Comm Address</b>	Enter the appropriate communication address for the dissolution apparatus.
<b>Rows</b>	Using the up and down arrows, indicate the number of rows. Note: This setting must match the physical configuration of the instrument.
<b>Sample Channels</b>	Using the up and down arrows, indicate the number of sample channels. Note: This setting must match the physical configuration of the instrument.

#### 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**.

## 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:

Option	Description
<b>Comm Address</b>	Enter the appropriate communication address for the syringe pump. When connecting to the PC, enter COMx:76. 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.
<b>Current Level (8000 only)</b>	Use the up and down arrows to indicate the motor power (current level). The recommended setting is 4.
<b>Calibration Count</b>	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 default setting is 19300 (19000 for the 850-DS). To optimize volume accuracy, use the Calibration Count calculator to convert the 850-DS mL/stroke value to the appropriate Calibration Count value. This value should be adjusted (as needed) each time a volume calibration is performed on the 850-DS.
<b>Plunger Speed</b>	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.
<b>Aspiration Dwell</b>	Use the up and down arrows to indicate the aspiration dwell time. This is the time (in seconds) that the syringe pauses after pulling in liquid prior to dispensing. This time may need to be increased to maintain volume accuracy for certain types of dissolution media.
<b>Prime Loss</b>	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 to the sample tubes or vials prior to collection. The volume is moved through the sample lines prior to sample collection at each sample timepoint.
<b>Syringe Size</b>	Click the <b>drop-down arrow</b> and select the <b>syringe size</b> (10.0 mL for the 806 Syringe Pump; 1.0 mL for the 850-DS).

- 2 Click **Next**.
- 3 If you selected Filter Changer, the Filter Changer screen displays.

## Filter Changer

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

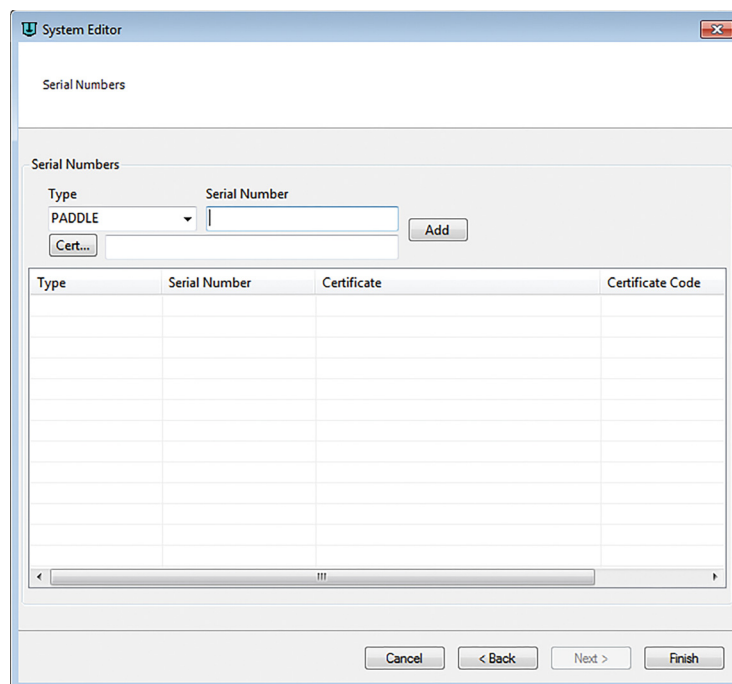
Following is a description of the Filter Changer screen options:

Option	Description
Comm Address	Enter the appropriate communication address for the filter changer. When connecting to the PC, enter COMx:75. Note: If you are using an 850-DS, the com port for the filter changer has to be same as the 850-DS. Do not change the comm ID of 75.

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 each individual accessory.
- 4 Optionally, click **Cert...** to store the link to a Certificate of Conformance for the specified accessory. This file may be a .pdf, .doc, or .xps file.
- 5 Click **Add** to store the accessory information.
- 6 Repeat steps 2-5 for each accessory.
- 7 Enter the serial number for the item and click **Add**.
- 8 Repeat steps 2 and 3 for each item selected under Dissolution Setup on the System Editor screen (see **"Dissolution Setup"** on page 35).

- 9 Click **Finish**.
- 10 Repeat all the sections under **"Configuring Your System"** on page 33 for each additional system.
- 11 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 45.

## 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 removed from the visible list of displayed configurations and may be recovered from the database at any time.

## 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.

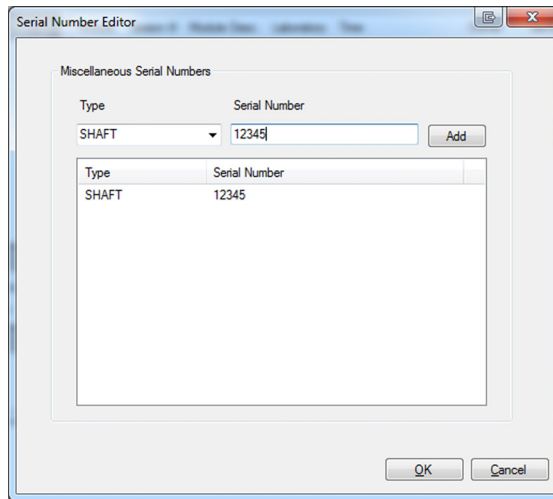


Figure 8. Serial Number Editor

- 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 accessory.
- 6 Optionally, click **Cert...** to store the link to a Certificate of Conformance for the specified accessory. This file may be a .pdf, .doc, or .xps file.
- 7 Click **Add** to store the accessory information.
- 8 Repeat steps 4-7 for each accessory.
- 9 Enter the serial number for the item and click **Add**.
- 10 Repeat steps 4 and 5 for each item selected under Dissolution Setup (see **"Dissolution Setup"** on page 35).
- 11 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**.

### NOTE

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).

### NOTE

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.

### NOTE

Alternately, 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.

### NOTE

Alternately, 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.
- 4 Close the System Configuration 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.

**NOTE**

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.

- 4 If applicable, indicate which version to export and click **OK**. The Export System to XML File screen displays.

**NOTE**

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.

**NOTE**

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.

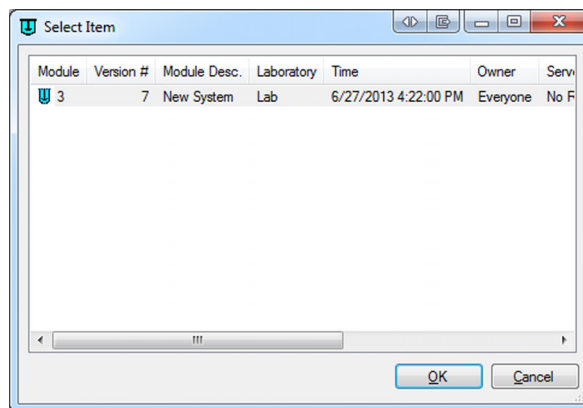
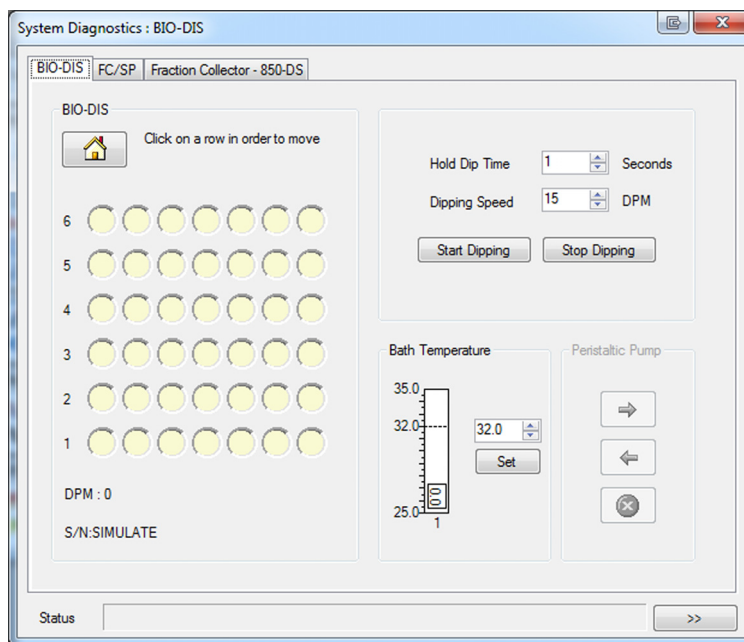


Figure 9. Select Item

- 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).



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

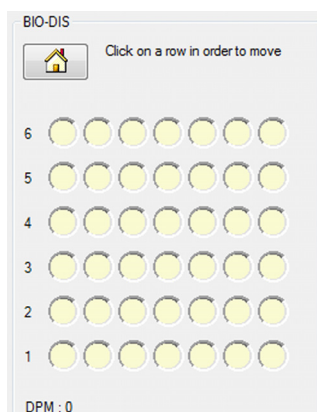
## NOTE

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.



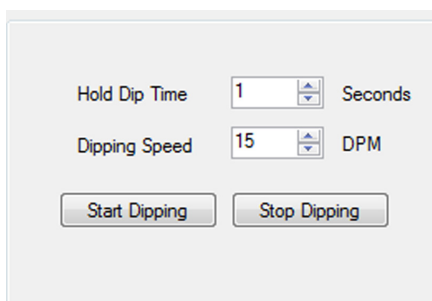
**Figure 11.** BIO-DIS Box

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


## 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.



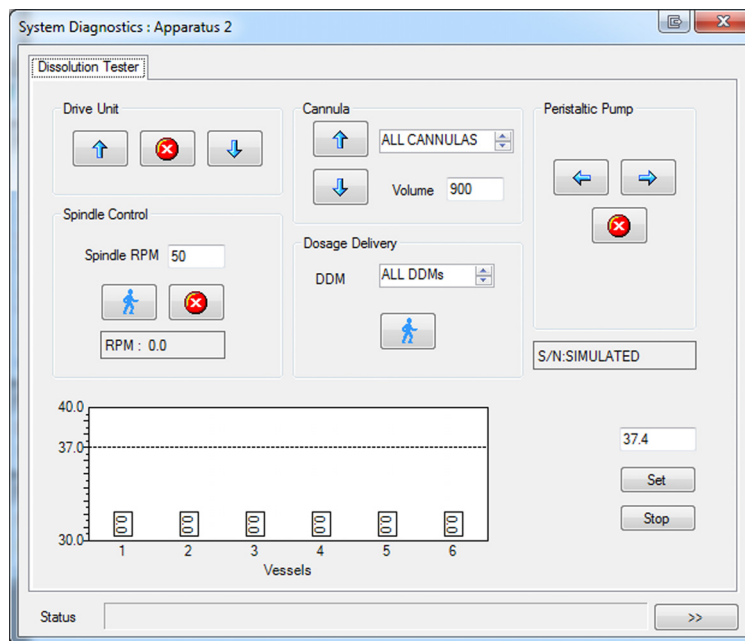
**Figure 12.** Dipping Speed Box

- 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).



**Figure 13.** Dissolution Tester

## 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  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.

### 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.

- 2 Click . The cannulas / manifold raise(s).
- 3 Click . The cannulas / manifold lower(s).

## 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

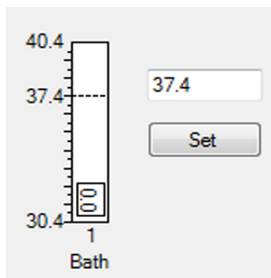
If your system configuration includes a V-series Dissolution Apparatus, open the individual DDMs by indicating a specific DDM location next to DDM.

- 2 Click . 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

- 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:

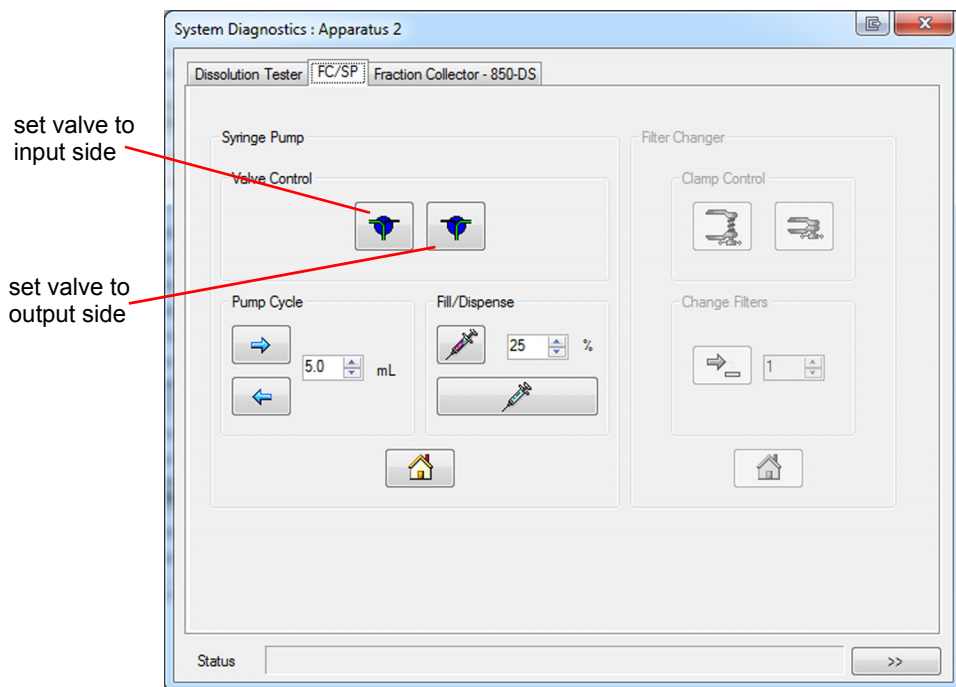




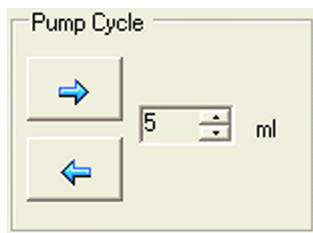
Figure 15. FC/SP

#### NOTE



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

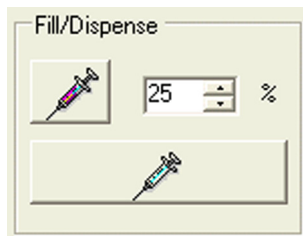
- 2 Click  (set valve to output side) in the Valve Control box. There is an audible click.
- 3 Click  (set valve to input side) in the Valve Control box. There is an audible click.

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





**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.





**Figure 17.** Fill/Dispense

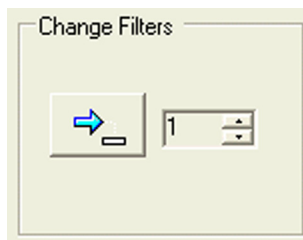
- 8 Click  to move the syringe plunger to the specified step position. The syringe fills to the percentage indicated.
- 9 Click  to dispense the syringe to the home position. The syringe empties.

## Filter Changer


To control the filter changer, complete the following steps:

- 1 Click  (open the filter changer clamp) in the Clamp Control box. The clamp opens.
- 2 Click  (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.



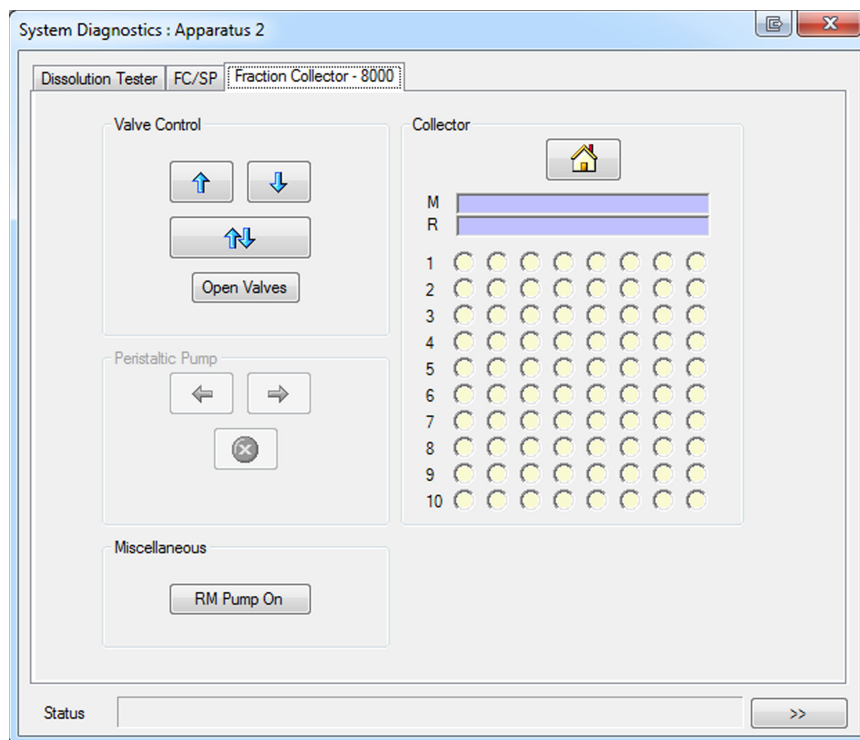
**Figure 18.** Change Filters

- 4 Click  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

### NOTE

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

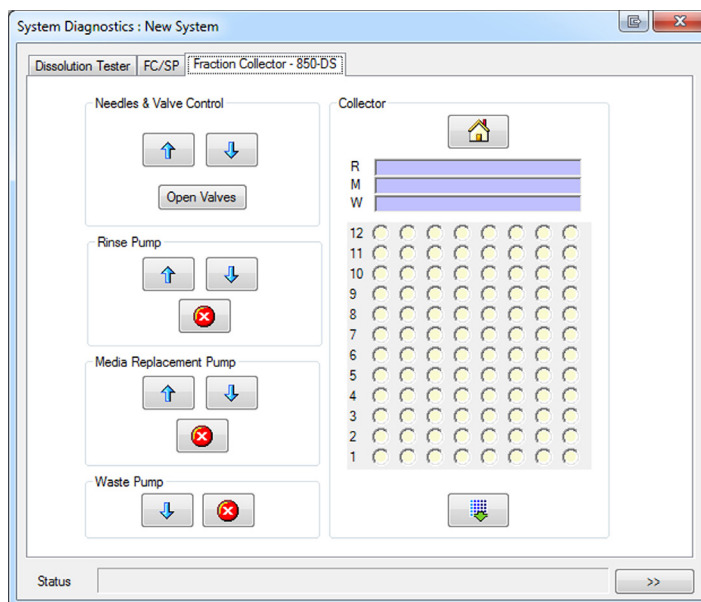
- 2 Click  (lower the valves) in the Valve Control box to lower the needles. The needles lower.
- 3 Click  (raise the valves) in the Valve Control box to lift the needles. The needles rise.

- 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.

## Valve Control (850-DS)


To control the valves, complete the following steps:



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



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





### 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 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 **Open Valves** in the Valve Control box. An audible click is heard.

## Peristaltic Pump

To control the peristaltic pump, complete the following steps:

- 1 Click  in the Peristaltic Pump box. The pump rotates toward the outlet channel of the peristaltic pump.
- 2 Click  (stop pumping) in the Peristaltic Pump box. The pumping stops.
- 3 Click  in the Peristaltic Pump box. The pump rotates toward the inlet channel of the peristaltic pump.
- 4 Click  (stop pumping) 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.

### 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.

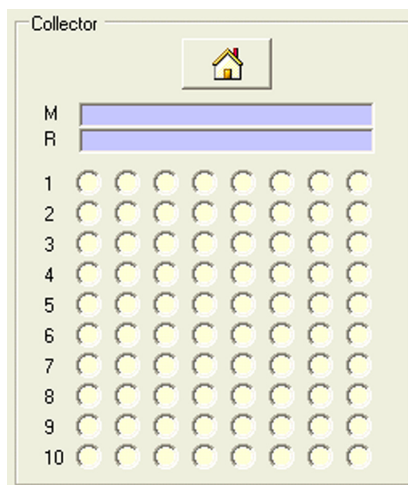



Figure 21. Collector Box - 8000

- 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.

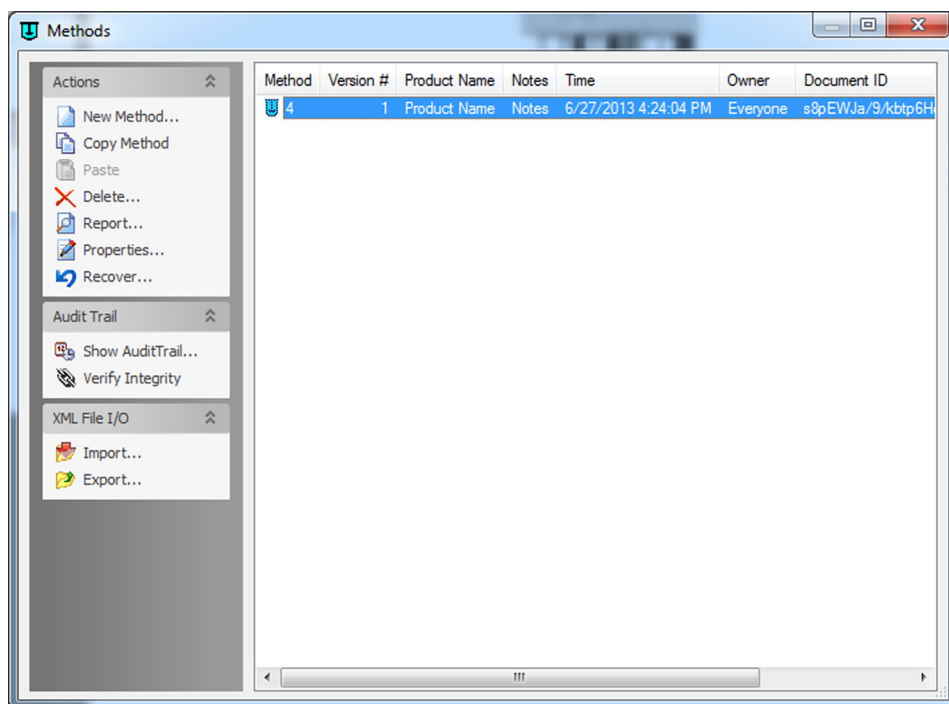
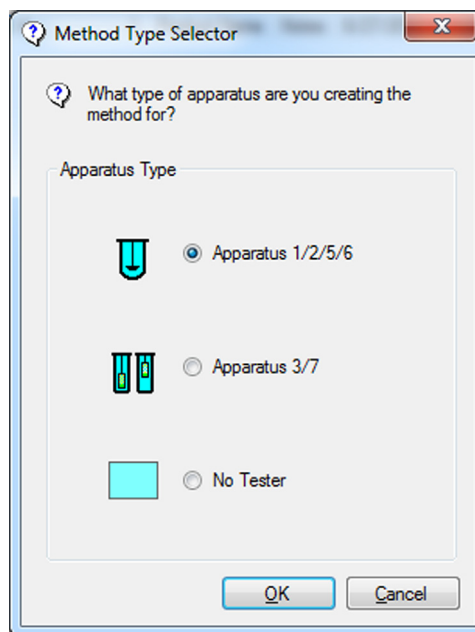


Figure 22. Methods

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



**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 64).

Select the **Parameters** tab.

**Method Editor**

Parameters | Dissolution | Sample Timepoints | Prefill | Notifications | Auto Export

**Sample Information**

Product Name:

Notes:

**User Defined Labels**

Label 1:

Label 2:

Label 3:

**Sampling Parameters**

Sample Volume:  mL    Samples / Filter:

Prime Volume:  mL    Replacement Volume:  mL

Purge Volume:  mL    Waste Drop Vol:  mL

Active Channels:     Dual Sample: ☐

**Error Tolerance (+ -)**

Temperature:     Speed:  %

**Profile Interval**

HH:MM

**Clean System After Method Run**

☐ Enable    Vol.:  mL    Cycles:     ☐ Rinse Port  
☒ Sample Cannula

**Change Management**

☐ Restrict method editing rights to the method owner  
 Owner: Everyone

OK Cancel

Figure 24. Method Editor

Following is a description of the Parameters tab options:

Option	Description
<b>Sample Information</b>	
<b>Product Name</b>	Enter the name of the product.
<b>Notes</b>	Enter any relevant notes regarding the sample.
<b>User Defined Labels</b>	The fields in this area have default values of LOT, BATCH, and GROUP. These fields are customizable; enter the information that best serves the needs of the method parameters. Prior to beginning each test, blank fields with these labels will display allowing for entry of test-specific information. See "Method Start Options" on page 82.
<b>Label 1</b>	
<b>Label 2</b>	
<b>Label 3</b>	

Option		Description
Sampling Parameters	Sample Volume	Enter the sample volume in milliliters.
	Prime Volume	Use this option to set the amount of drawn medium necessary to fill the sampling lines of the entire system. Enter the prime volume in milliliters.
	Purge Volume	Use this option to set a purge volume in milliliters that ensures all stranded medium is properly expelled. Enter the purge volume in milliliters.
	Active Channels	Enter the number of vessel positions used for sampling.
	Samples / Filter	Enter the number of samples each filter should process before being discharged. Enter zero (0) if no filtration using the filter changer/module is required for this method or no filter changer/module is configured.
	Replacement Volume	If your system configuration includes the a sampling station with replacement media option, enter the replacement volume in milliliters.
	Waste Drop Vol	Enter the desired waste drop volume in milliliters. Note: The drop volume is an amount of sample that is dispensed through the sampling station needles prior to dispensing samples into the collection tubes to ensure the needles are purged completely from the previous timepoint.
	Dual Sample	Enable Dual Sample to pull two samples into consecutive rows at a single sample timepoint.
Error Tolerance ( $\pm$ )	Temperature	Enter the desired temperature fluctuation limit ( $\pm$ ). 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.
	Speed	Enter the desired speed fluctuation limit ( $\pm$ ). 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.

Option	Description	
<b>Clean System After Method Run</b>	<b>Enable</b>	Adds a cleaning cycle to the end of the dissolution method.
	<b>Vol.</b>	Specifies the volume of rinse solution to be pumped through the sampling lines during the cleaning cycle.
	<b>Cycles</b>	Specifies the number of rinse cycles to be executed.
	<b>Rinse Port</b>	For 850-DS use only. Specifies that the rinse solution will be pumped from the rinse port of the 850-DS (automated).
	<b>Sample Cannula</b>	Specifies that the rinse solution will be pumped from the sample cannulas. Requires manual placement of an appropriate rinse tray by the user.
<b>Profile Interval</b>	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.	
<b>Change Management</b>	If applicable, select the <b>box</b> under Change Management in order to restrict the method editing rights to the current user or any user with VkModifyOthersMethod.	

- 4 Select the **BIO-DIS** or **Dissolution tab**. Following is a description of the BIO-DIS and Dissolution tab options:

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

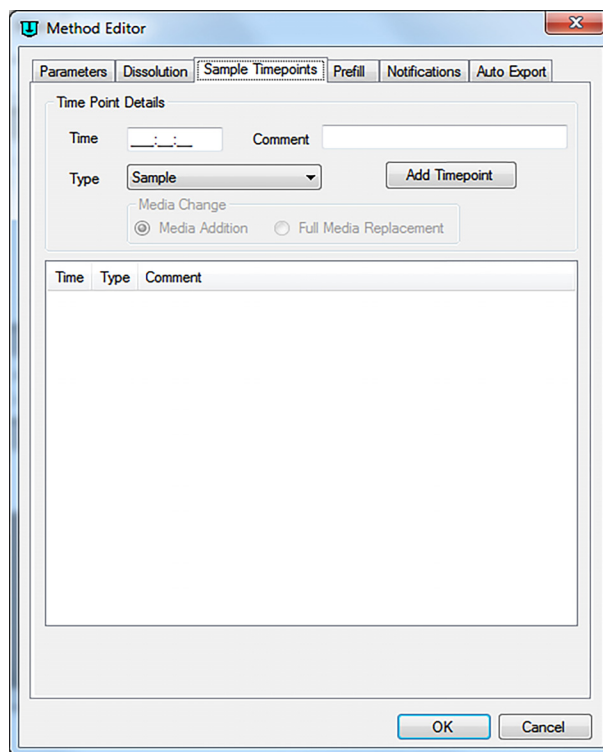
Dissolution tab		
Option		Description
Bath Temperature		Enter the desired water bath temperature, if applicable, in °C.
Apparatus Type		Use the drop-down arrow to select the <b>apparatus type</b> (Paddles, Baskets, Paddle over Disk, or Rotating Cylinder).
Vessel Temperature		Enter the desired vessel temperature, as applicable, in °C. Note: This value is used to determine temperature errors at sample timepoints as well as for a vessel temperature start (see <b>“Temperature Delayed Start”</b> on page 83).
Spindle RPM		Enter an appropriate speed for the dissolution apparatus spindles.
Final Spin RPM		If applicable, enter an appropriate speed for the final spin.
Final Spin Duration		If applicable, enter the duration of the final spin in mm:ss format.
Media Volume		Enter the volume of the media in the vessels.
Vessel Temperature		Enable Measure Initial Temperature and / or Measure Final Temperature to take the initial and final vessel temperatures during the method.
Vessel Table Level		Enable Pre-Test Level Verification to verify the vessel table level prior to starting a test (requires a 280-DS Instrument Module).
Operation Checks		Enable Pre-test verification of apparatus components and environment to document the acceptable condition of accessories (MQ requirement).
Vibration Monitoring	Enable Vibration Monitoring	Check this box to enable the detection of transient and persistent vibration levels. Requires the 280-DS Instrument Module.
	Frequency Bandwidth of Interest	Defines the range of frequencies that the software will monitor to detect above-threshold amplitudes.
	Transient Event Threshold	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.
	Persistent Event Threshold	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 exceeds the threshold as averaged over the defined period of time.

**NOTE**

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

$$\sqrt{x^2 + y^2 + z^2}$$

- 5 For the Apparatus 3 / Apparatus 7, click **Add To List**.
- 6 For Apparatus 1 / 2 / 5 / 6, select the **Sample Timepoints** tab and program the appropriate timepoints (see [Figure 25](#), "Sample Timepoints," on page 68).



**Figure 25.** Sample Timepoints



Following is a description of the Sample Timepoints tab options:

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

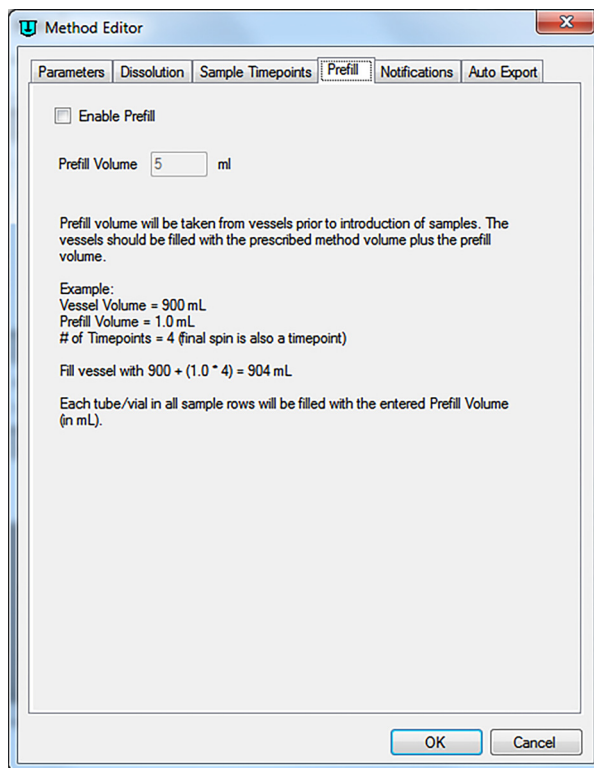
7 Select the **Prefill** tab.

Figure 26. Prefill

Option	Description
<b>Prefill</b>	Place a check in the box to enable the Prefill option.
<b>Prefill Volume</b>	<p>Enter volume (in mL) to dispense into the sample tray prior to the method start. This volume will be automatically removed from the dissolution vessels and delivered into the number of sample rows equivalent to the number of time points in the method (including final spin, if applicable).</p> <p>The vessels should be filled with an appropriate volume to account for the Prefill volume as needed. For example:</p> <p>Vessel Volume = 900 mL Prefill Volume = 1.0 mL # of Timepoints = 3 + Final Spin = 4 total Fill each dissolution vessel with <math>900 + (1.0 * 4) = 904</math> mL</p> <p>Each tube/vial in all sample rows will be filled with the entered Prefill Volume (in mL).</p>

8 Select the **Notifications** tab.

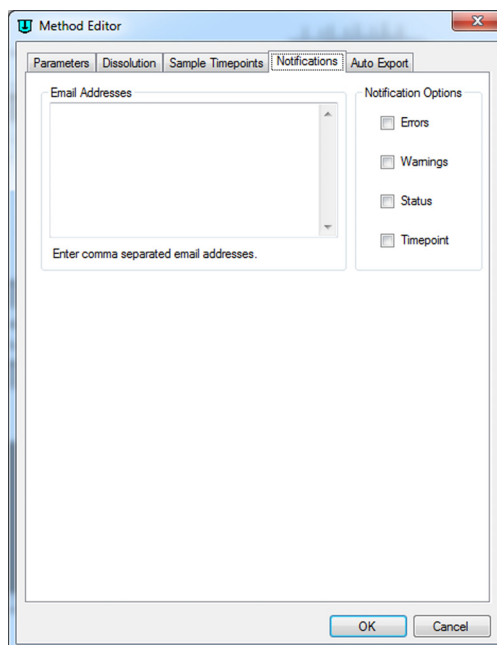
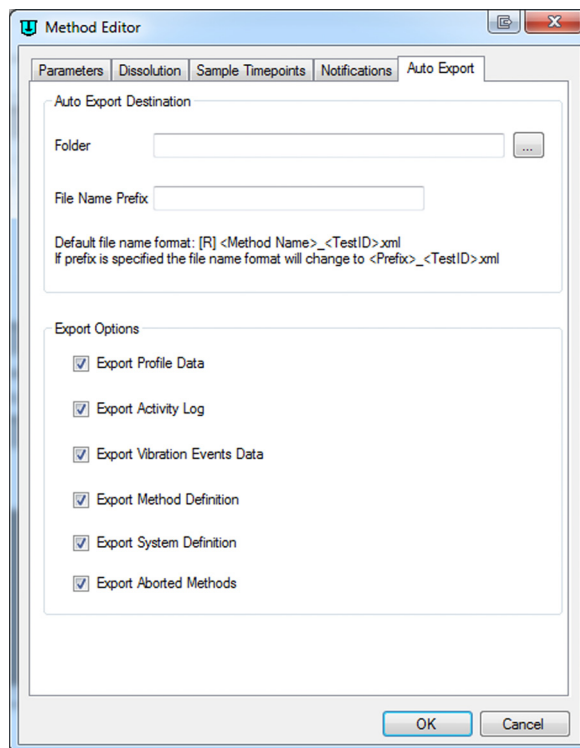


Figure 27. Notifications Tab

Option		Description
<b>Email Addresses</b>		List valid Email address(es) where the specified notifications should be sent. Separate multiple Email addresses with commas. to properly configure Email address settings. See "Email" on page 94. to properly configure Email-address settings.
<b>Notification Options</b>	<b>Errors</b>	Notifies user of any errors detected during the dissolution test.
	<b>Warnings</b>	Notifies user of warnings encountered during the dissolution method.
	<b>Status</b>	Notifies user of the program status at key points during the dissolution method.
	<b>Timepoint</b>	Notifies user of the completion of each sample timepoint during the dissolution method.

9 Select the **Auto Export** tab.



**Figure 28.** Auto Export

Following is a description of the Auto Export tab options:

Option		Description
Auto Export Destination	Folder	Define folder location where exported data should be saved.
	File Name Prefix	Specify custom file name prefix for name of exported files.
Export Options	Specify the data types to be exported to the defined location. Place a check in each box to have the data type exported.	

**10** Click **OK** to close the Method Editor.

## 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 62).
- 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 62).
- 2 Select the desired **method**.
- 3 Click **Delete**.
- 4 Click **Yes**.

### NOTE

The system configuration is never physically deleted. It is only removed from the visible list of displayed configurations and may be recovered from the database at any time.

## 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**.

## 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 62).
- 2 Click the desired **method**.
- 3 Click **Properties** on the navigation bar. The Method Editor screen displays (see [Figure 24](#), "Method Editor," on page 64).

### 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 62).
- 2 Select the desired **system configuration**.
- 3 Click **Report**. The Version Selection screen displays.
- 4 If applicable, indicate which version and click **OK**.

### 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.

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

## 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 62).
- 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 62).
- 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 62).
- 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 62).
- 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.

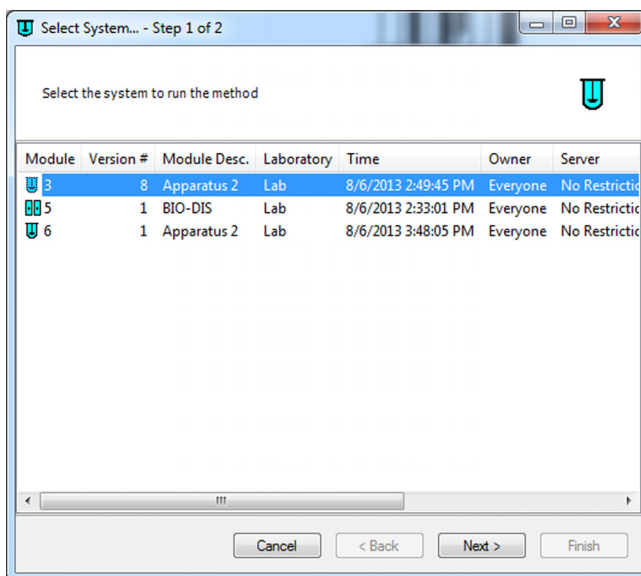
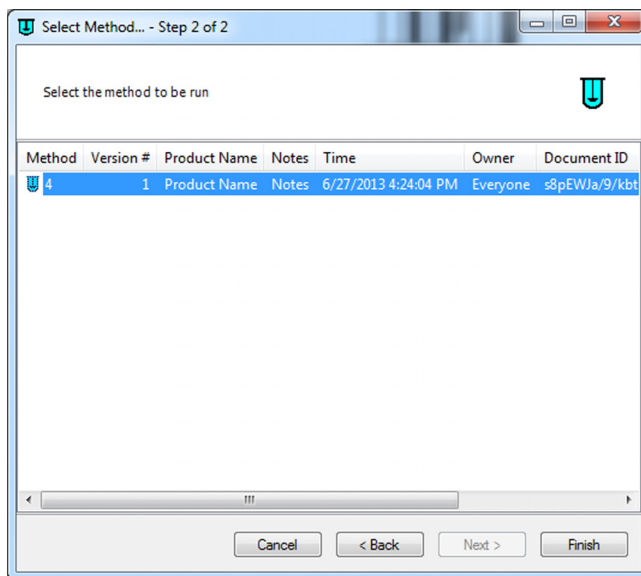


Figure 29. Select System Step 1 of 2

- 2 Select the desired **system** to run the method and click **Next**. The Select Method Step 2 of 2 screen displays (see **Figure 30**, "Select Method Step 2 of 2," on page 80).



**Figure 30.** Select Method Step 2 of 2

- 3 Select the desired **method** to run and click **Finish**. The system status screen displays (see Figure 31, “System Status,” below).

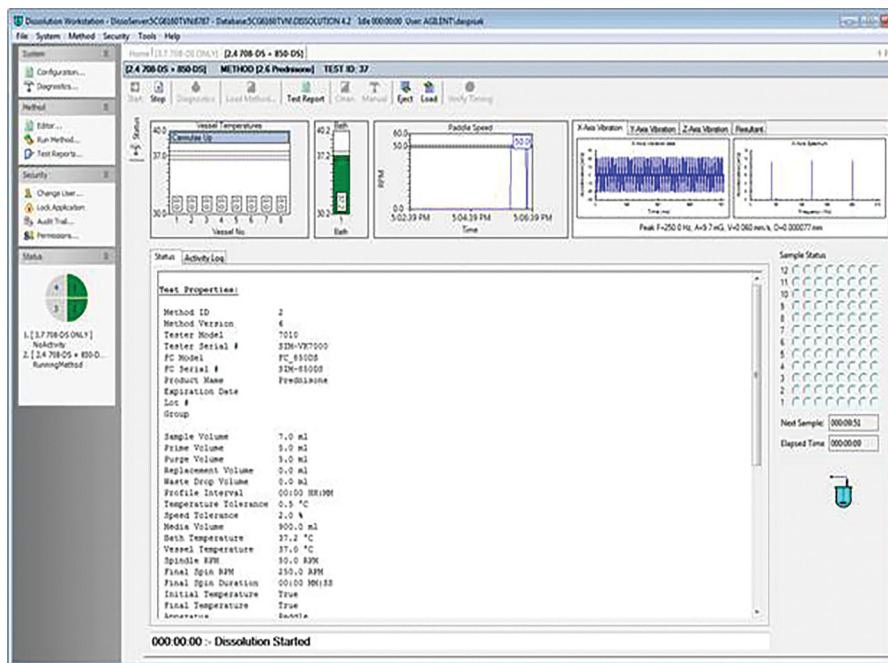
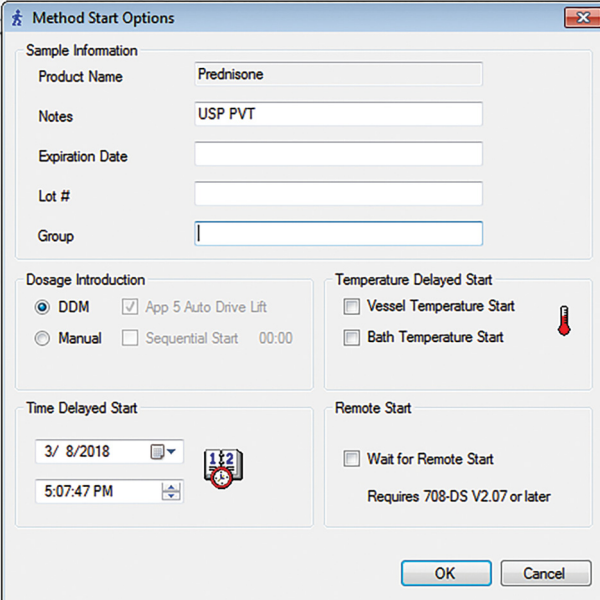


Figure 31. System Status

Option	Description
Start	See “Running the Method” on page 79..
Stop	See “Running the Method” on page 79..
Diagnostics	See “Diagnostics / Manual Control” on page 48..
Load Method	See “Editing an Existing Method” on page 75..
Test Report	See “Test Reports” on page 84..
Clean	See “Clean System” on page 86..
Manual	See “Manual Sampling” on page 87..
Eject	See “Eject Tray” on page 89..
Load	See “Load Tray” on page 89..
Verify Timing	See “Verify Timing” on page 89..

- 4 Click **Start**. The Method Start Options screen displays.



The image shows a software dialog box titled "Method Start Options". It contains several sections for configuring a method start:

- Sample Information:** Includes text boxes for "Product Name" (filled with "Prednisone"), "Notes" (filled with "USP PVT"), "Expiration Date", "Lot #", and "Group".
- Dosage Introduction:** Features radio buttons for "DDM" (selected) and "Manual". The "DDM" option has a checked checkbox for "App 5 Auto Drive Lift". The "Manual" option has an unchecked checkbox for "Sequential Start" and a time field set to "00:00".
- Temperature Delayed Start:** Includes checkboxes for "Vessel Temperature Start" and "Bath Temperature Start", each accompanied by a thermometer icon.
- Time Delayed Start:** Contains a date field set to "3/ 8/2018" and a time field set to "5:07:47 PM", both with dropdown arrows. A clock icon is also present.
- Remote Start:** Includes a checkbox for "Wait for Remote Start" and the text "Requires 708-DS V2.07 or later".

At the bottom right, there are "OK" and "Cancel" buttons.

Figure 32. Method Start Options

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

Option		Description
Product Name		Enter the product name.
Notes		Enter any appropriate notation.
User-Defined Labels		Enter the appropriate test-specific information based on the user-defined labels (see <b>"User Defined Labels"</b> on page 64).
Dosage Introduction		Choose <b>DDM</b> or <b>Manual</b> depending on your configuration.
	App 5 Auto Drive Lift	Ensure this box is enabled for USP Apparatus 5 methods where it is necessary to raise the apparatus drive unit to insert transdermal devices at the beginning of each test
	Sequential Start	<b>Note:</b> For manual methods only.  Enable this option to introduce dosage forms sequentially either manually or using the DDM; the actual interval is entered in the method.
Temperature Delayed Start	Bath Temperature Start	As applicable, select <b>Vessel Temperature Start</b> or <b>Bath Temperature Start</b> . Ensure the current date displays in the Time Delayed Start box.
	Vessel Temperature Start	
Time Delayed Start		Use this option to program a delayed start. Enter the desired date and time to start the method.
Remote Start		<b>Note:</b> For 708-DS only.  Place a check in the Wait for Remote Start box to require the user to initiate the test by pressing <b>Start</b> on the 708-DS touch screen.

- 5 Ensure the dongle is inserted into the USB port.

#### NOTE

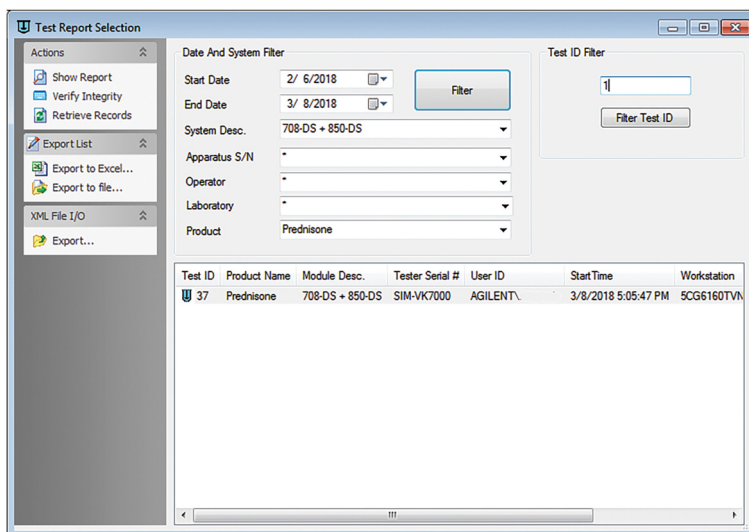
If the license dongle (security key) is not inserted into the USB port, the method will not run.

- 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.



**Figure 33.** Test Report Selection screen

### NOTE

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**.

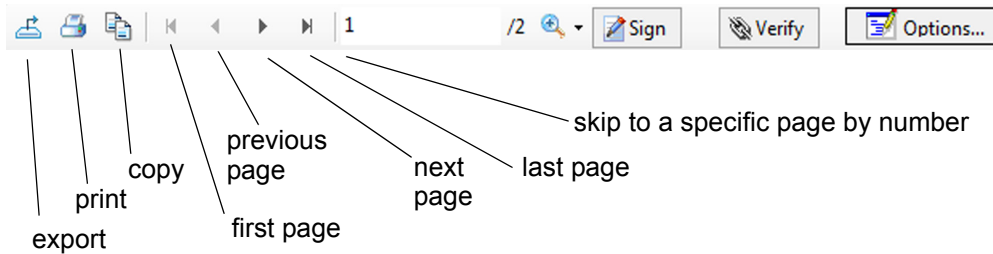
Additionally, you can select from a variety of filtering criteria including System Description, Apparatus Serial Number, Operator, Laboratory, or Product.

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.
- 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:



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

## 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.

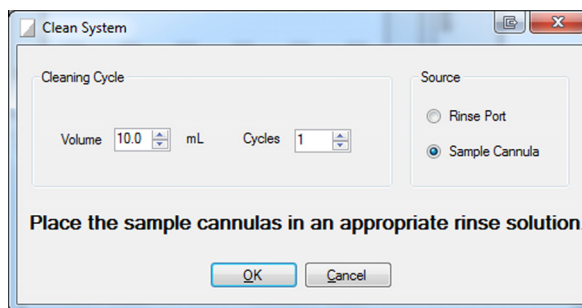


Figure 34. Clean System

Option		Description
Cleaning Cycle	Volume	Specify the amount of rinse solution to be cycled through the system (in mL).
	Cycles	Indicate the number of cycles to be executed to thoroughly rinse the system.
Source	Rinse Port	Select this option to pull the rinse solution from the Rinse Port (850-DS only).
	Sample Cannula	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.

## Manual Sampling

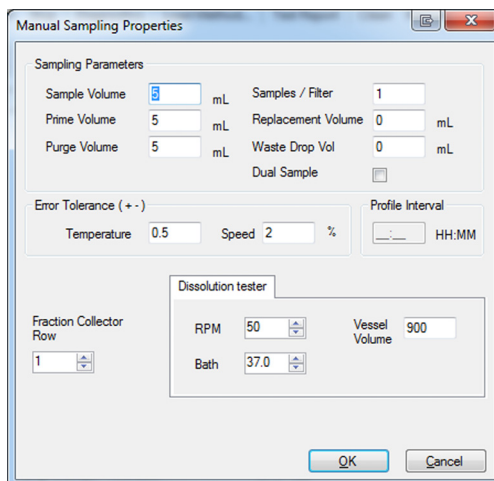


Figure 35. Manual Sampling Properties

Option		Description
Sampling Parameters	Sample Volume	Enter the sample volume in milliliters.
	Prime Volume	Use this option to set the amount of drawn medium necessary to fill the sampling lines of the entire system. Enter the prime volume in milliliters.
	Purge Volume	Use this option to set a purge volume in milliliters that ensures all stranded medium is properly expelled. Enter the purge volume in milliliters.
	Samples / Filter	Enter the number of samples each filter should process before being discharged.
	Replacement Volume	If your system configuration includes a fraction collector with replacement media option, enter the replacement volume in milliliters.
	Waste Drop Vol	Enter the desired waste drop volume in milliliters. Note: The drop volume is an amount of sample that is dispensed through the autosampler needles prior to dispensing samples into the collection tubes to ensure the needles are purged completely.
	Dual Sample	Click <b>Dual Sample</b> to pull two samples into two consecutive rows at a single sample timepoint.

Option		Description
Error Tolerance ( $\pm$ )	Temperature	Enter the desired temperature fluctuation limit ( $\pm$ ). 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.
	Speed	Enter the desired speed fluctuation limit ( $\pm$ ). 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.
Profile Interval		This option is not applicable for the Manual Sampling operation.
Fraction Collector Row		Specify the sample tray row where the sample should be delivered.
Dissolution Tester	RPM	Specify the speed (RPM) of the dissolution apparatus.
	Bath	Specify the bath temperature of the dissolution apparatus.
	Vessel Volume	Specify the volume of media contained in the dissolution vessels.

## Eject Tray

**NOTE**

850-DS only.

Ejects the sample tray of the fraction collector. This operation may be utilized during a test to remove already collected samples - the tray must be reloaded prior to the next sample timepoint or it will be skipped.

## Load Tray

**NOTE**

850-DS only.

Loads the sample tray of the fraction collector (850-DS only).

## Verify Timing

**NOTE**

850-DS only.

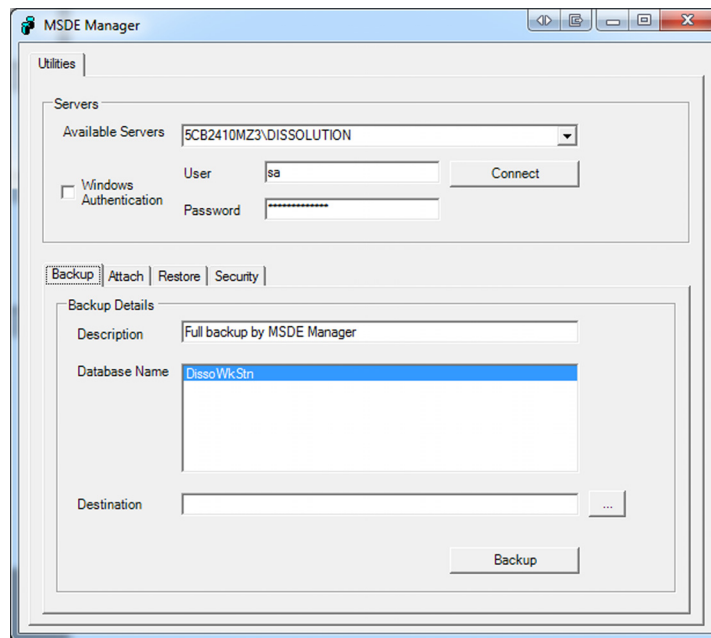
Ensures the sample timepoints of the loaded method are sufficiently spaced based on all of the method parameters.

## 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.



**Figure 36.** MSDE Manager Screen

- 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.
- 5 Click ... to specify a destination for the backup file.

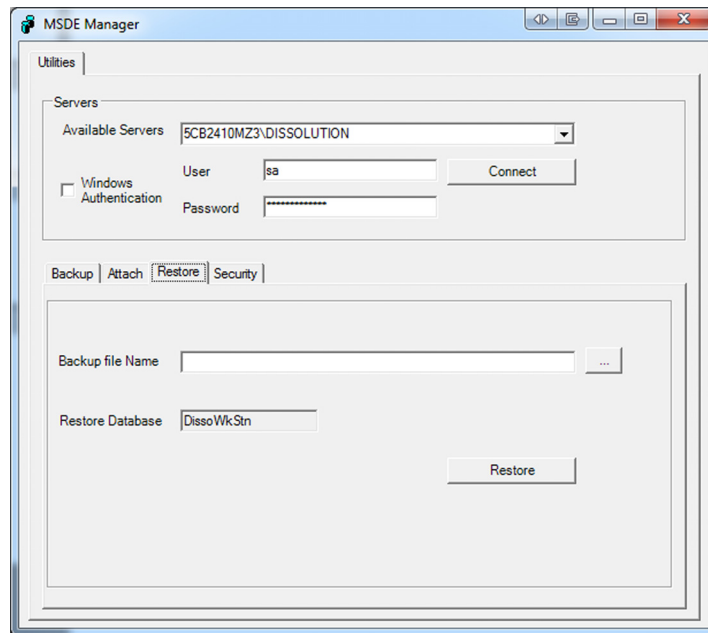
- 6 Click **Backup**. The back-up file is written to the designated file location.

## 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.



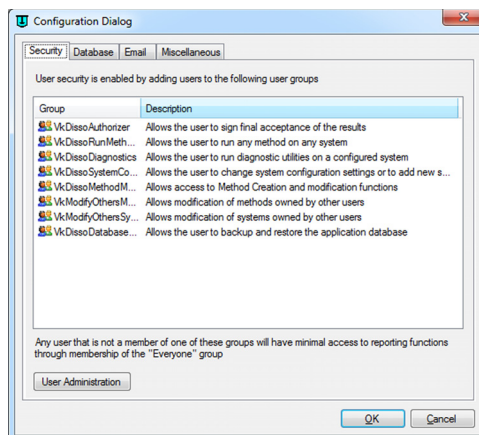
**Figure 37.** MSDE Manager Screen

- 2 Click **Connect** to connect to the database.
- 3 On the Restore tab, click ... to search for the back-up file.
- 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.



**Figure 38.** Configuration Dialog Security Tab



## Database Tools

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

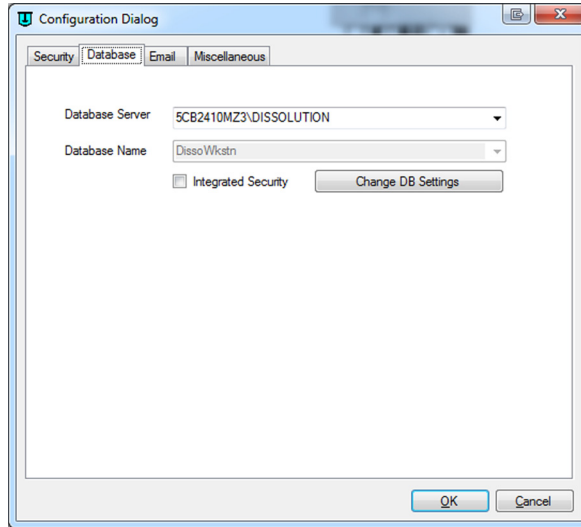


Figure 39. Database Tools

Option	Function
<b>Dissolution Server</b>	Name of the dissolution server where the database is located.
<b>Integrated Security</b>	Allows you to assume responsibility for administering database access.
<b>Change DB Settings</b>	Updates the current settings of the database.

Email

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

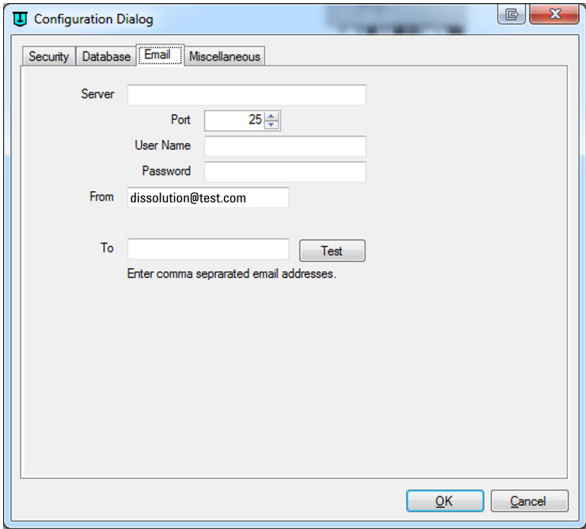


Figure 40. Email

Option	Function
Server	Specify name of outgoing mail server
Port	Specify the SMTP host port number.
User Name	Enter the user name if the SMTP server requires authentication.
Password	Enter the password IF the SMTP server requires authentication.
From	Enter a return address for the email.
To	Enter a destination address for the email.
Test	Test the email configuration settings.

## Miscellaneous

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

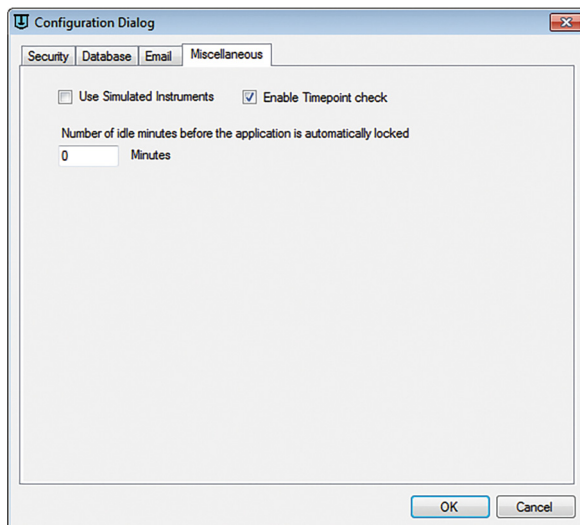


Figure 41. Miscellaneous

Option	Function
Use Simulated Instruments	Runs the software in a simulation mode with simulated instruments. No official data is acquired in this mode.
Idle Minutes	Amount of time before the software locks automatically. Setting this value to 0 disables this feature.
Enable Timepoint Check	Allows the software to perform an integrity check of the sample timepoint frequency prior to running each program.

## 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.

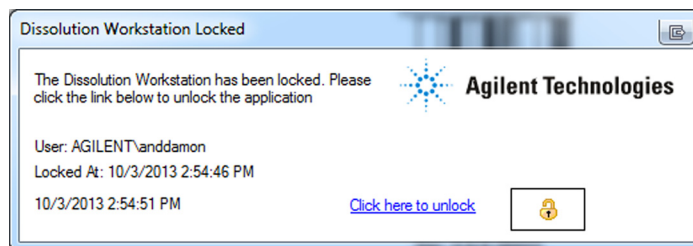


Figure 42. Lock Application

# Audit Trail

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

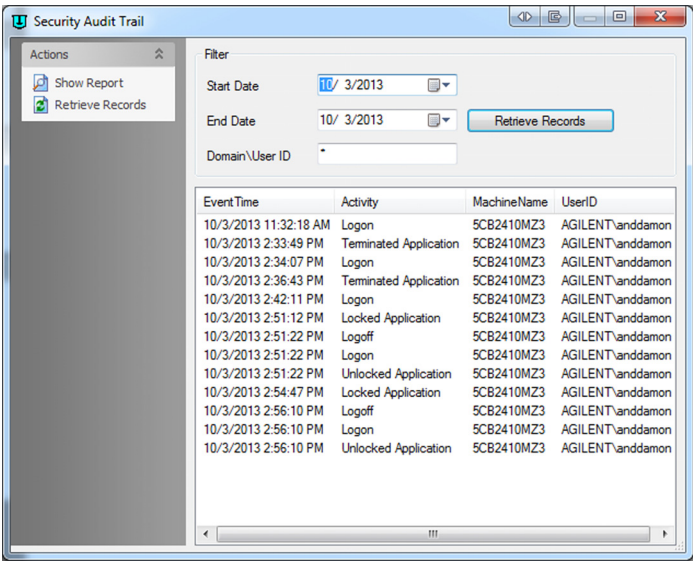


Figure 43. Security Audit Trail

Option	Function
Show Report	Creates a detailed report of Security Audit Trail activity based on the date range specified.
Retrieve Records	Allows for record retrieval of the specified Security Audit Trail activity.

## Permissions

Review the permissions granted to the current user.

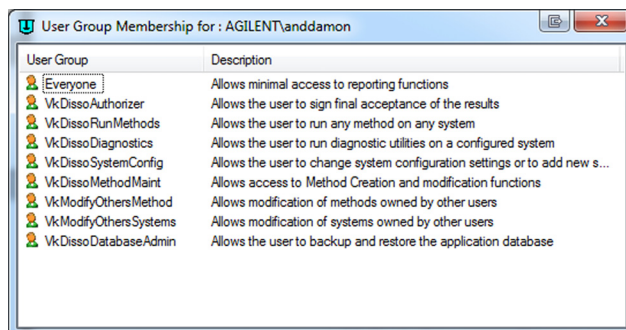


Figure 44. Permissions

## In This Book

- Chapter 1 Introduction
- Chapter 2 Installation and Setup
- Chapter 3 Operation

[www.agilent.com](http://www.agilent.com)

© Agilent Technologies, Inc. 2018

Rev C, July 2018

