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Agilent Technologies

Dissolution Workstation Operational Instructions

P/N 70-9050
November 2010
Revision F

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First Edition (November 2010)
Dissolution Workstation Operational Instructions
Part Number 70-9050 Revision F
Printed in the United States of America

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Varian, Inc.
13000 Weston Parkway
Cary, North Carolina 27513-2250
800.229.1108
919.677.1108
Fax: 919.677.1138
www.varianinc.com

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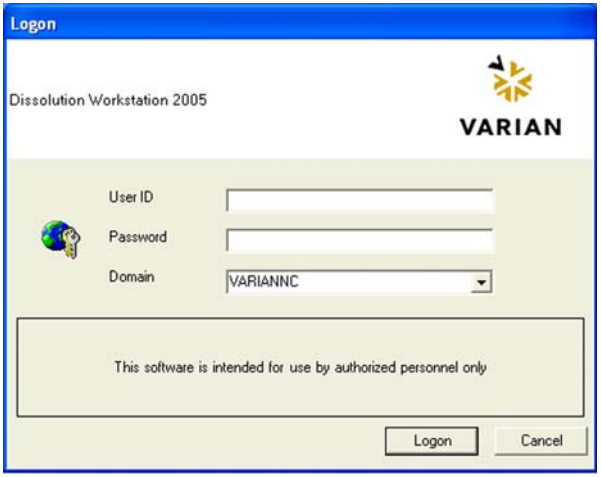
Operation

Logon to the Dissolution Workstation

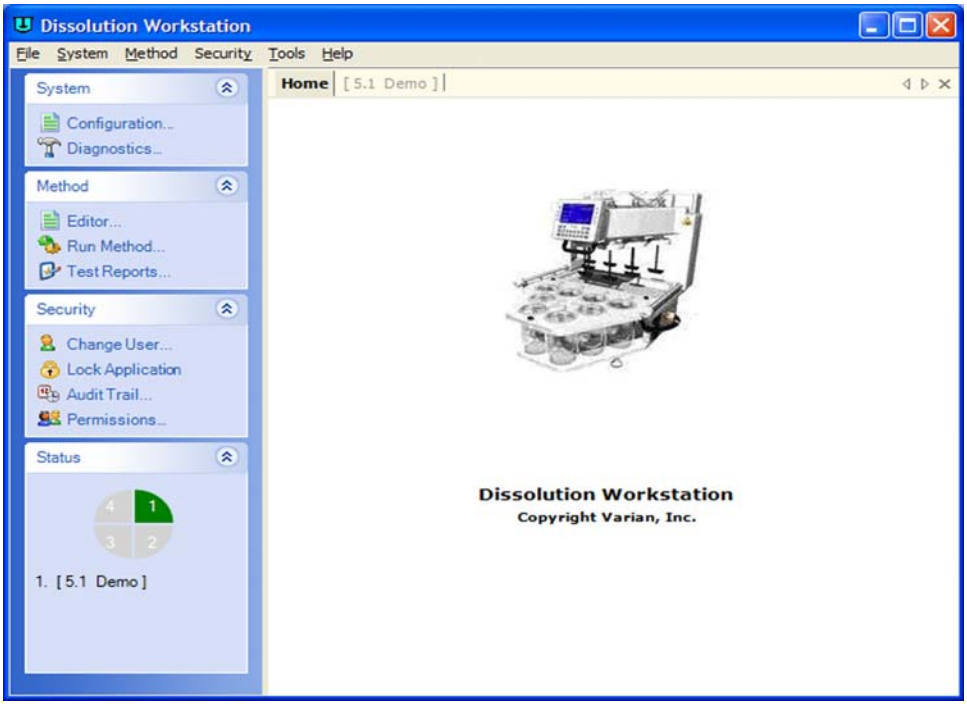
Step 1. Double-click the Dissolution Workstation icon on your desktop. The Logon screen displays.

FIGURE 1. Logon screen



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

FIGURE 2. Dissolution Workstation screen



Following is a description of the screen options listed on the navigation bar of the Dissolution Workstation screen:

Option		Description
System	Configuration	Use this option to configure the system. See “Configuring Your System” on page 8.
	Diagnostics	Use this option to check the diagnostics of a dissolution apparatus or accessory within the system. See “Manual Control / Diagnostics” on page 26.
Method	Editor	Use this option to create a method, change or delete method parameters, run a report of the method setup, view the method audit trail, and verify the integrity of the method. See “Method Editor” on page 41.
	Run Method	Use this option to run a method. See “Running the Method” on page 61.
	Test Reports	Use this option to run a report of the completed method. See “Test Reports” on page 65.
Security	Change User	To change the user, click **Change User**. The Logon screen displays. Enter the appropriate user identification and password and click Logon.
	Lock Application	To lock the dissolution workstation, click **Lock Application**. The Dissolution Workstation Locked screen displays. Click the lock or the link to unlock the screen. The Logon screen displays. Enter the appropriate user identification and password as applicable and click **Logon**.
	Audit Trail	Click **Audit Trail**. The Security Audit Trail screen displays. Click **Show Report** to display the report. Change the start date, end date, and / or user identification as desired and click **Retrieve Records** to change the parameters for the information displayed.
	Permissions	Use this option to view permissions assigned to the current user and the descriptions of the corresponding privileges. Click **Permissions**. The User Group Membership screen displays.
Status		Click one of the pie-shaped graphics under status to view the status of the corresponding dissolution system.

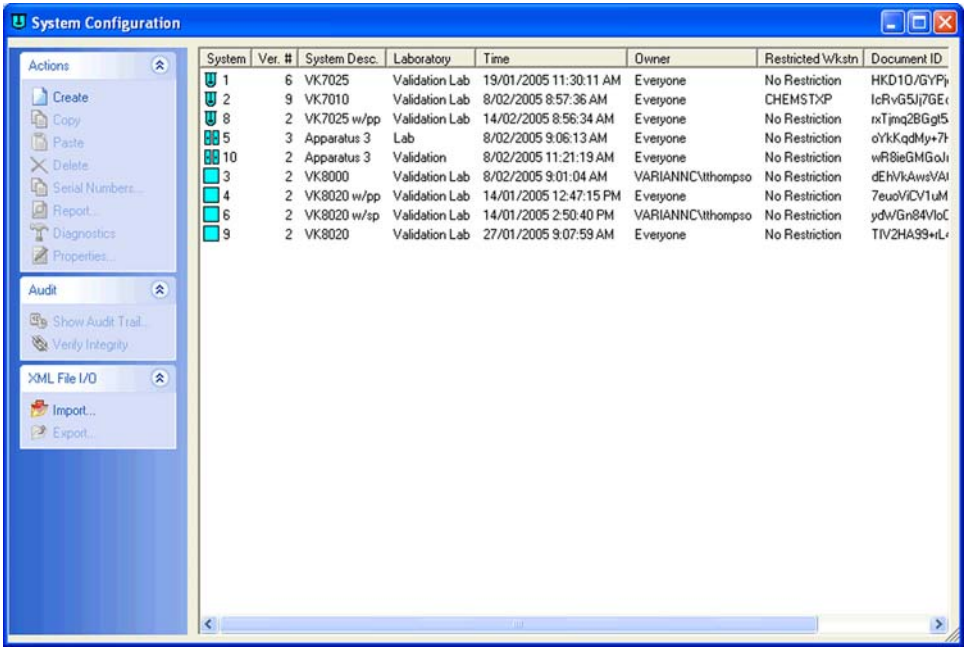
Configuring Your System

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.

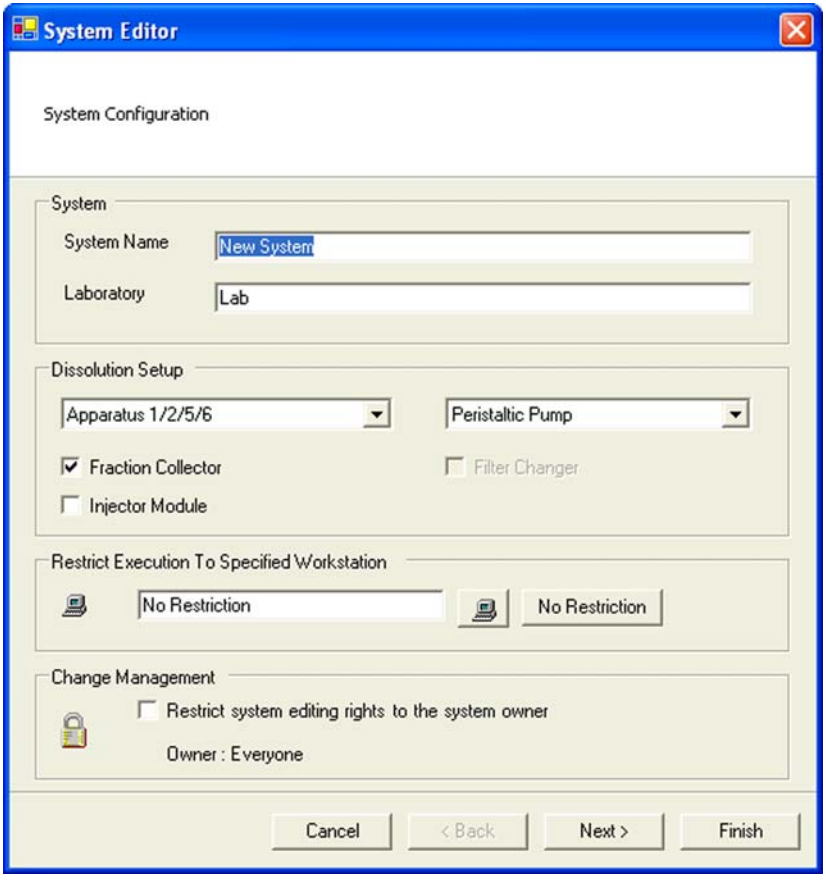
Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays.

FIGURE 3. System Configuration screen



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

FIGURE 4. System Editor screen



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.

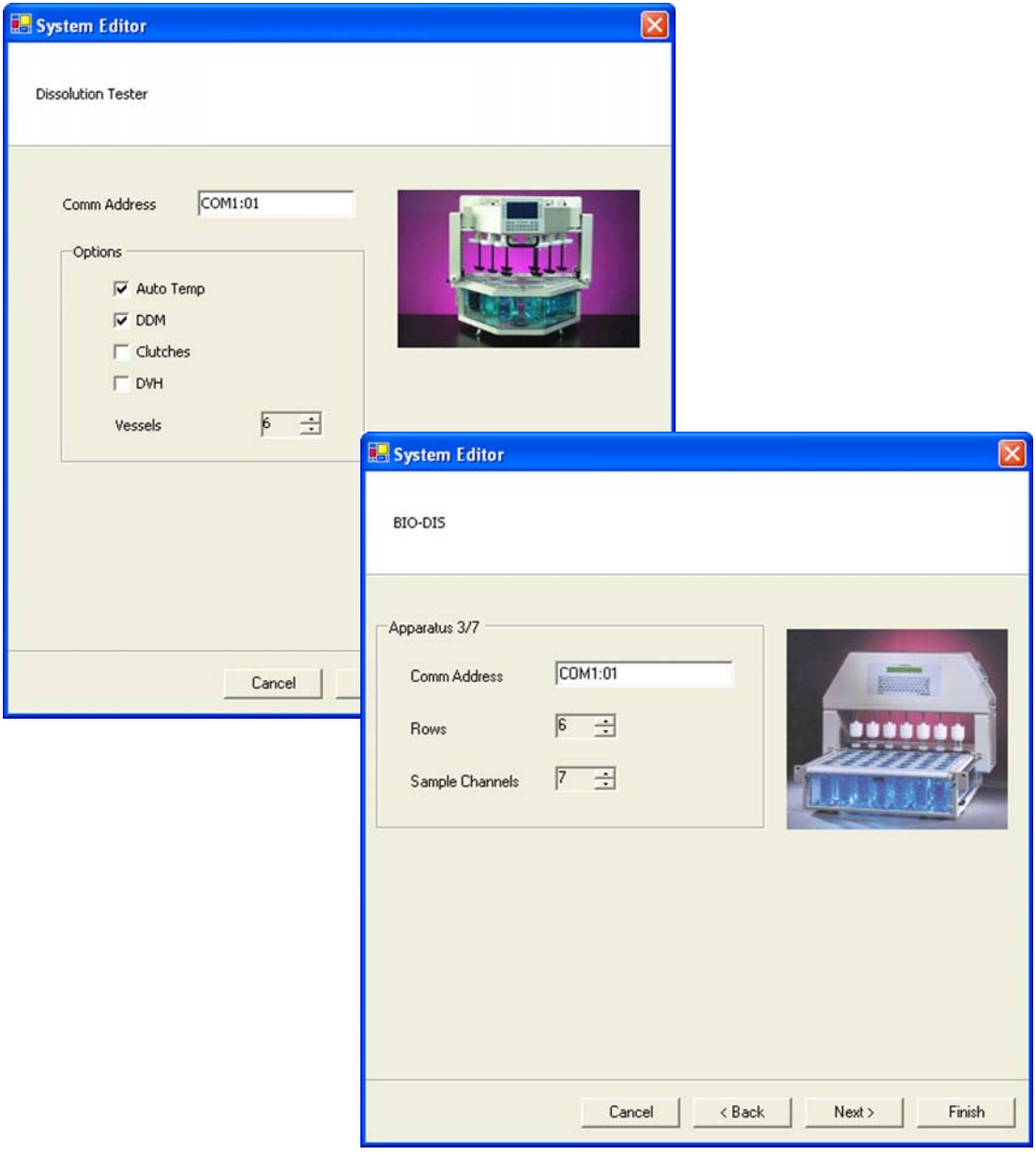
Option	Description
Dissolution Setup	Click the drop-down arrow on the Dissolution Setup box to select Apparatus 3/7, Apparatus 1/2/5/6, or NONE.
	Click the drop-down arrow in the Dissolution Setup box to select Peristaltic Pump or Syringe Pump.
	If your system configuration includes a VK 8000 or VK 8020, click Fraction Collector. If your system configuration includes a VK 8020, click Injector Module. 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.**

Step 3. Click **Next**. The following sections describe the screens that display based on the selections entered on the System Editor screen.

Dissolution Apparatus

Step 1. If applicable, either the BIO-DIS screen or the Dissolution Tester screen displays (see Figure 5, “BIO-DIS screen and Dissolution Tester screen,” on page 11).

FIGURE 5. BIO-DIS screen and Dissolution Tester screen



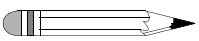
Following is a description of the BIO-DIS screen options and the Dissolution Tester screen options:

BIO-DIS		**Dissolution Tester**	
Comm Address	Enter the appropriate communication address for the dissolution apparatus. **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.**	Comm Address	Enter the appropriate communication address for the dissolution apparatus. **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.**
Rows	Using the up and down arrows, indicate the number of rows. **Note: this setting must match the physical configuration of the instrument.**	Options	Click the appropriate dissolution tester options. Using the up and down arrows, indicate the number of vessels.
Sample Channels	Using the up and down arrows, indicate the number of sample channels. **Note: this setting must match the physical configuration of the instrument.**		

Step 2. Click **Next**.

Syringe Pump / Filter Changer

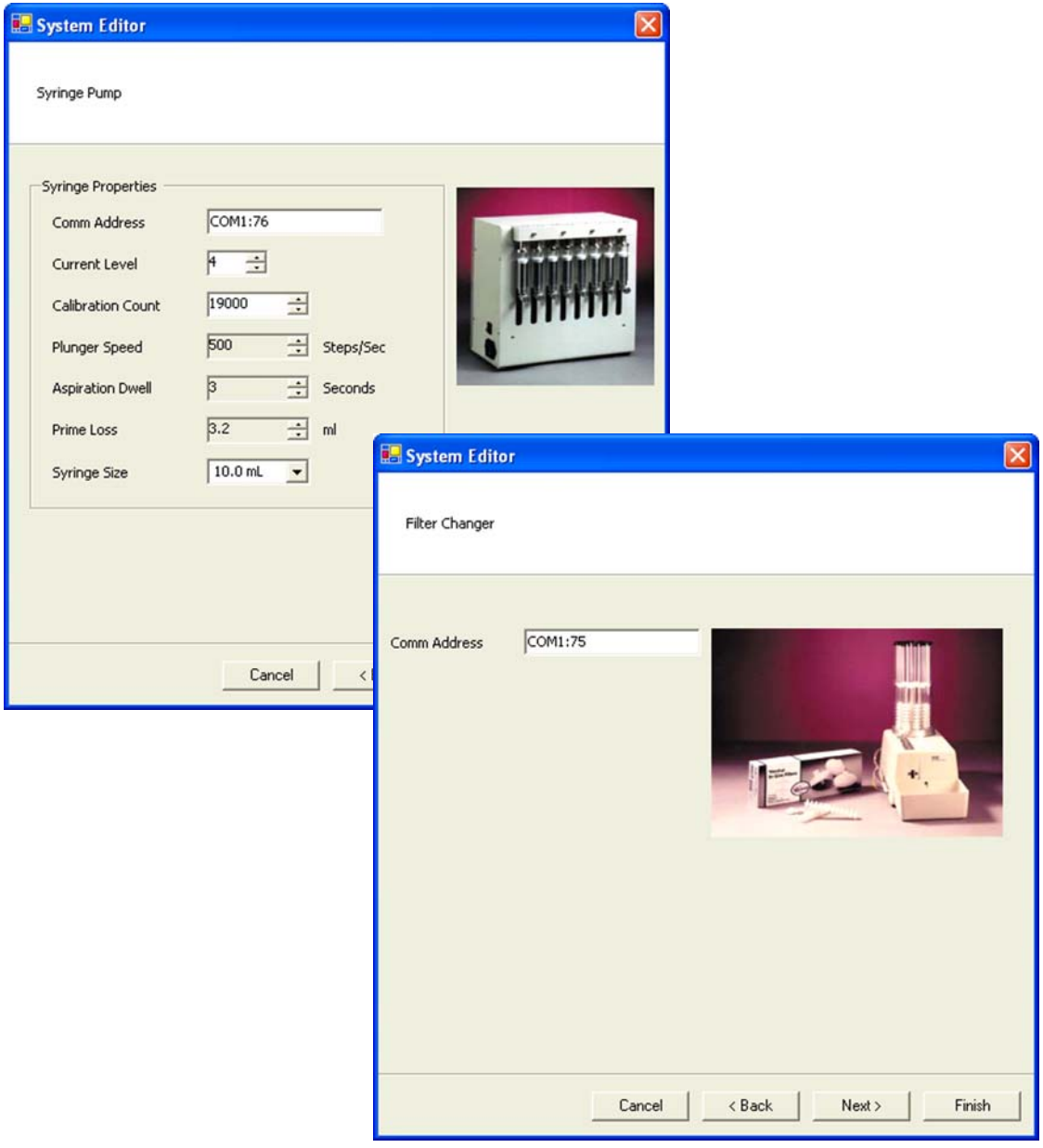
Step 1. If you selected Syringe Pump, the Syringe Pump screen displays (see Figure 6, “Syringe Pump and Filter Changer screens,” on page 13).



Note

There is not an additional screen if you select Peristaltic Pump because there are not any specifications to enter for the pump.

FIGURE 6. Syringe Pump and Filter Changer screens



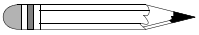
Following is a description of the Syringe Pump screen options:

Option	Description
Comm Address	Enter the appropriate communication address for the syringe pump. When connecting to the PC, enter **COM*x*:76**. **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*). In this case *x* is the physical port number and 76 is the logical instrument identification number.**
Current Level	Use the up and down arrows to indicate the motor power (current level). The recommended setting is 4.
Calibration Count	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.
Plunger Speed	Use the up and down arrows to configure the syringe pump plunger to operate at a specific speed. The recommended setting is 500.
Aspiration Dwell	Use the up and down arrows to indicate the aspiration dwell time.
Prime Loss	Use the up and down arrows to indicate the prime loss volume.
Syringe Size	Click the drop-down arrow and select the syringe size.

Step 2. Click **Next**.

Step 3. If you selected Filter Changer, the Filter Changer screen displays (see Figure 6, “Syringe Pump and Filter Changer screens,” on page 13).

Enter the appropriate communication address for the filter changer. When connecting to the PC, enter **COM*x*:75**.



Note

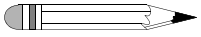
The communication address (*PC port: instrument ID*) is comprised of the physical PC COM port (*PC port*) and the instrument address on the serial bus (*instrument ID*). In this case *x* is the physical port number and 75 is the logical instrument identification number.

Click **Next**.

Fraction Collector

Step 1. If you selected Fraction Collector, the Fraction Collector screen displays (see Figure 7, “Fraction Collector and Injector Configuration screens,” on page 16).

Step 2. Enter the appropriate communication address for the fraction collector. When connecting to the PC, enter **COM*x*:02**. Verify the communication port identification number on the fraction collector is set to 02.



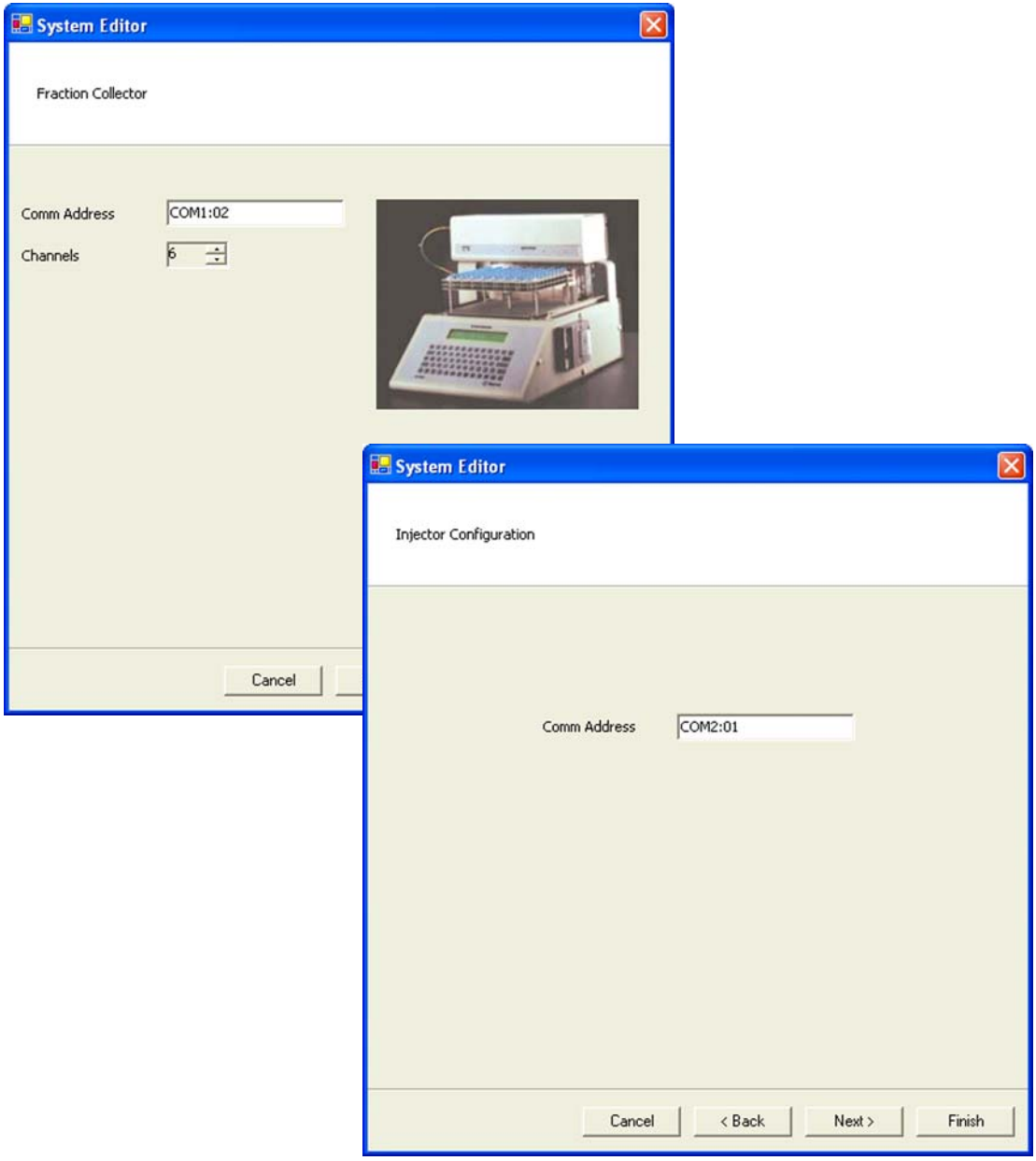
Note

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*). In this case *x* is the physical port number and 02 is the logical instrument identification number.

Step 3. Using the up and down arrows, indicate the number of channels.

Step 4. Verify the fraction collector is configured for the proper number of channels.

FIGURE 7. Fraction Collector and Injector Configuration screens



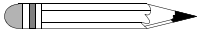
Step 5. Click **Next**.

Injector Module

Step 1. If you selected Injector Module, the Injector Configuration screen displays (see Figure 7, “Fraction Collector and Injector Configuration screens,” on page 16).

Step 2. Enter the appropriate communication address for the injector module. When connecting to the PC, enter **COM*x*:01**.

Note



Ensure the communication port identification number and the physical bus for the injector module are different from the rest of the equipment.

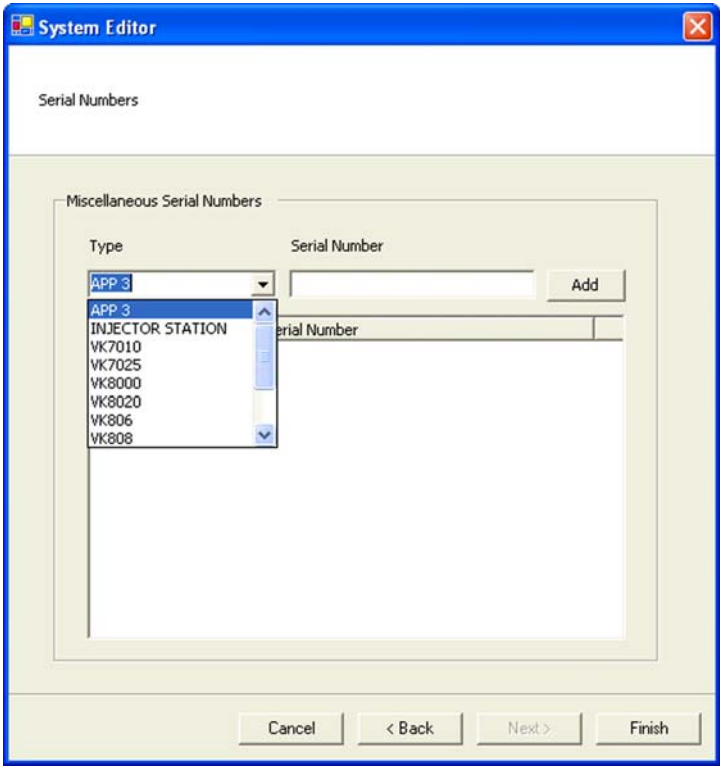
The communication address (*PC port: instrument ID*) is comprised of the physical PC COM port (*PC port*) and the instrument address on the serial bus (*instrument ID*). In this case *x* is the physical port number and 01 is the logical instrument identification number.

Step 3. Click **Next**.

Completing the Configuration

Step 1. After the final screen specific to your configuration, the Serial Numbers screen displays (see Figure 8, “Serial Numbers screen,” on page 18).

FIGURE 8. Serial Numbers screen



Step 2. Enter the type of peripheral equipment and / or supplies (for example: basket, shaft, paddle, vessel, syringe pump, filter changer, injector station, and collector) in the box that corresponds to Type and press **Tab**.

Step 3. Enter the serial number for the item and click **Add**.

Step 4. Repeat steps 2 and 3 for each item selected under Dissolution Setup on the System Editor screen (see “Dissolution Setup” on page 10).

Step 5. Click **Finish**.

Step 6. Repeat all the sections under “Configuring Your System” on page 8 for each additional system.

Step 7. Close the System Configuration screen.

Copying a System Configuration

To copy a system configuration, complete the following steps:

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 3, “System Configuration screen,” on page 8).

Step 2. Select the desired system configuration.

Step 3. Click **Copy**.

Step 4. Click **Paste**. A new system configuration displays. The description of the new system configuration is *Copy of...*.

Step 5. Close the System Configuration screen.

Step 6. To edit the system configuration, see “Editing an Existing System Configuration” on page 22.

Deleting a System Configuration

To delete a system configuration, complete the following steps:

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 3, “System Configuration screen,” on page 8).

Step 2. Select the desired system configuration.

Step 3. Click **Delete**.

Step 4. Click **Yes**.

Step 5. Close the System Configuration screen.

Note

The system configuration is never physically deleted. It is marked as deleted in the database.

Serial Numbers

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

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 3, “System Configuration screen,” on page 8).

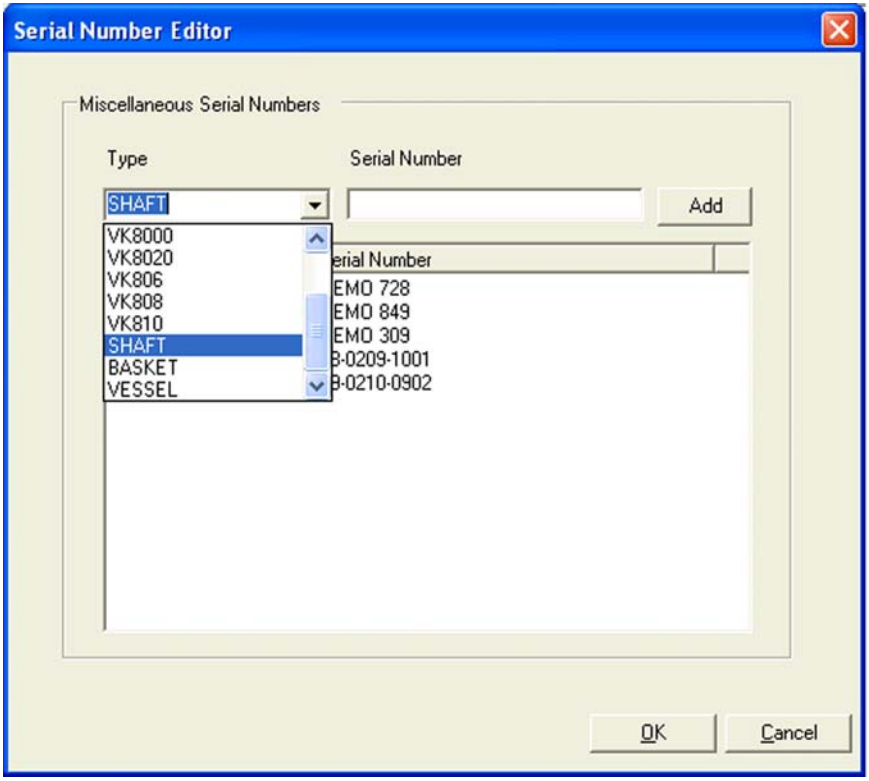
Step 2. Select the desired system configuration.

Step 3. Click **Serial Numbers**. The Serial Number Editor screen displays (see Figure 9, “Serial Number Editor screen,” on page 21).

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 9. Serial Number Editor screen



Step 4. Enter the type of peripheral equipment and / or supplies (for example: basket, shaft, paddle, vessel, syringe pump, filter changer, injector station, and collector) in the box that corresponds to Type and press **Tab**.

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

Step 6. Repeat steps 4 and 5 for each item selected under Dissolution Setup (see “Dissolution Setup” on page 10).

Step 7. Click **OK**. The Serial Number Editor screen closes.

System Configuration Report

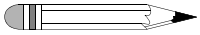
To display a report of the system configuration, complete the following steps:

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 3, “System Configuration screen,” on page 8).

Step 2. Select the desired system configuration.

Step 3. Click **Report**. By default, the most recent report version displays.

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.

Step 4. Use the up and down arrows to indicate the desired report version and click **OK**.

Step 5. 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:

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 3, “System Configuration screen,” on page 8).

Step 2. Select the desired system configuration.

Step 3. Click **Properties**. The System Editor screen displays (see Figure 4, “System Editor screen,” on page 9).

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.

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

Step 5. Close the System Configuration screen.

Show Audit Trail

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

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 3, “System Configuration screen,” on page 8).

Step 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.

Step 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:

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 3, “System Configuration screen,” on page 8).

Step 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.

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

Step 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:

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 3, “System Configuration screen,” on page 8).

Step 2. Select the desired system configuration.

Step 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.

Step 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.

Step 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:

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 3, “System Configuration screen,” on page 8).

Step 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.

Step 3. Select the appropriate directory and file name and click **Open**. The system configuration displays on the System Configuration screen.

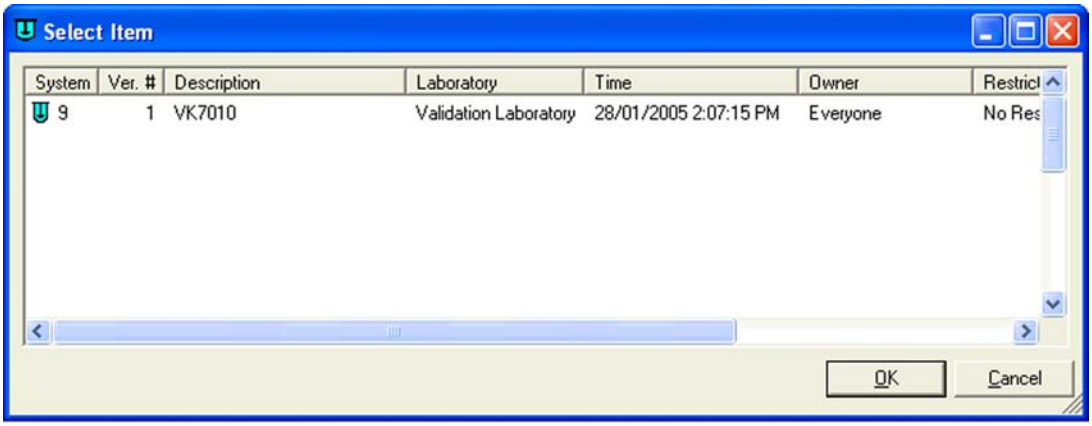
Step 4. Close the System Configuration screen.

Manual Control / Diagnostics

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.

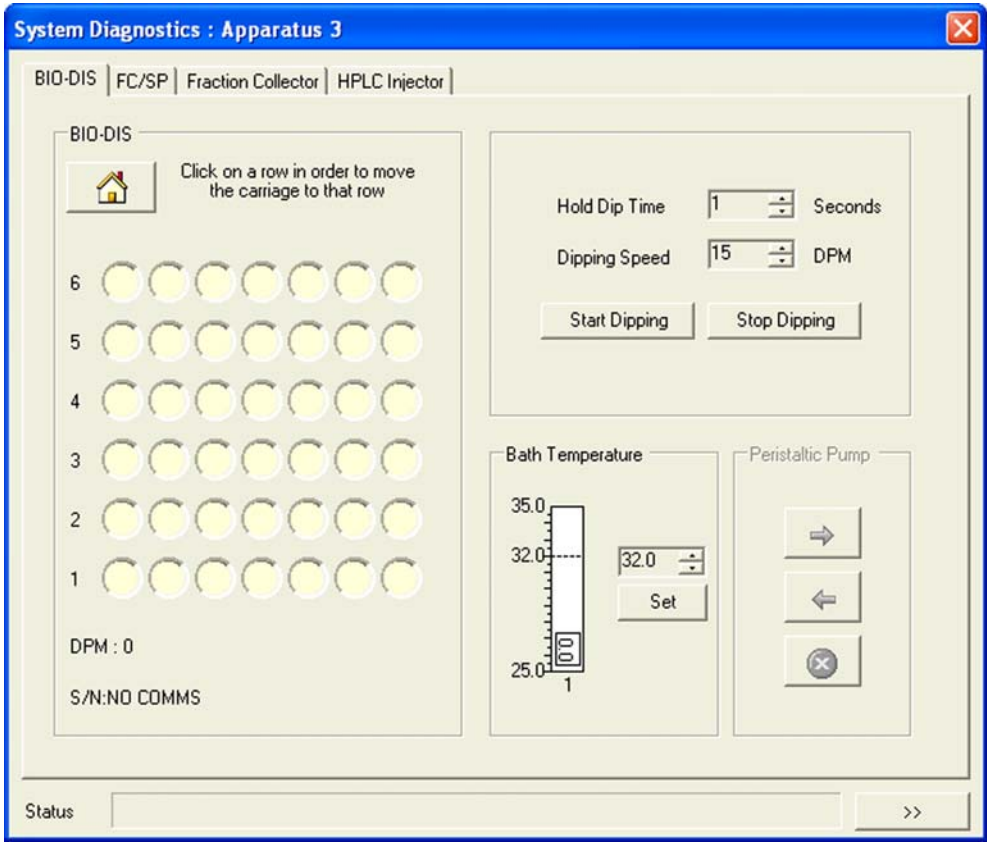
Step 1. Click **Diagnostics**. The Select Item screen displays.

FIGURE 10. Select Item screen



Step 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 11, “System Diagnostics BIO-DIS tab,” on page 27).

FIGURE 11. System Diagnostics BIO-DIS tab



Note

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

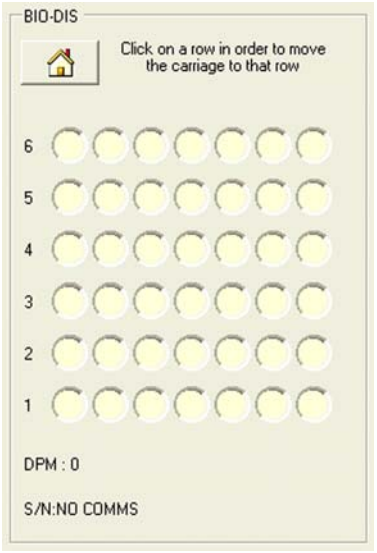
Moving the Drive Unit for Apparatus 3 / Apparatus 7

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

Step 1. Select the **BIO-DIS** tab (see Figure 11, “System Diagnostics BIO-DIS tab,” on page 27).

Step 2. Click any vessel position corresponding to the desired row in the BIO-DIS box (see Figure 12, “BIO-DIS box,” below). The drive unit moves to the indicated row.

FIGURE 12. BIO-DIS box



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

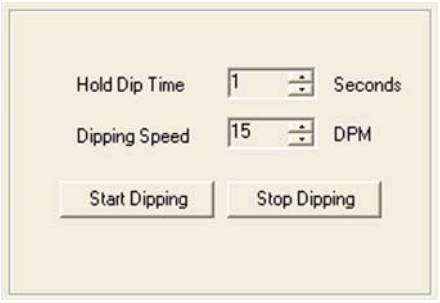
Dips per Minute for Apparatus 3 / Apparatus 7

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

Step 1. Click any vessel position corresponding to the desired row in the BIO-DIS box (see Figure 12, “BIO-DIS box,” on page 28). The drive unit moves to the indicated row.

Step 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 13. Dipping Speed box



Step 3. Click **Stop Dipping**. The dipping stops.

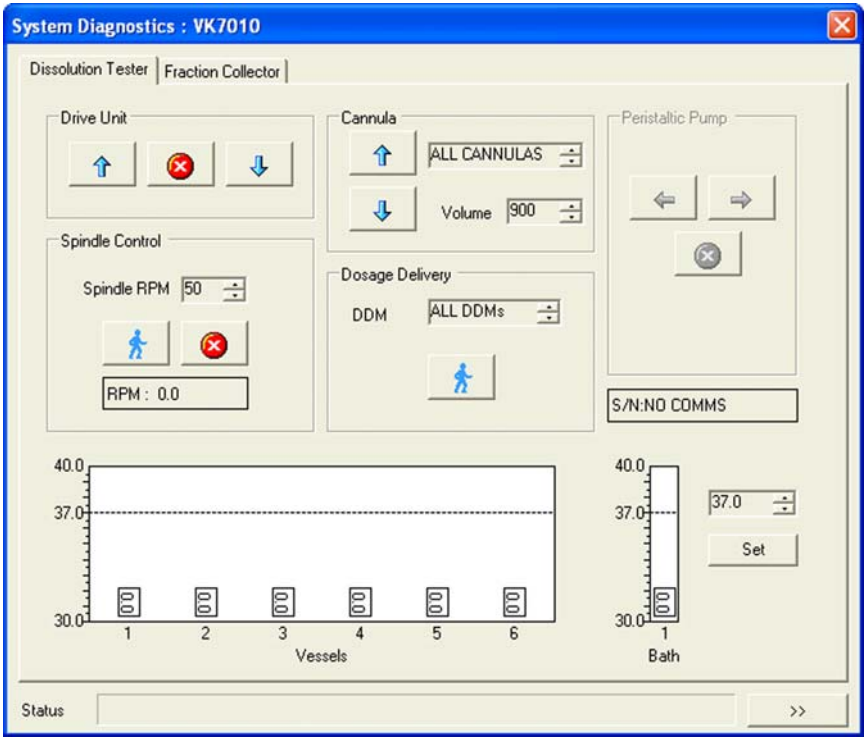
Step 4. Click  . The drive unit returns to the home position.

Moving the Drive Unit for VK 70xx

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

Step 1. Select the **Dissolution Tester** tab (see Figure 14, “Dissolution Tester tab,” on page 30).

FIGURE 14. Dissolution Tester tab



Note

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

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

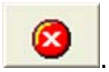
Step 3. Click  . The drive unit stops.

Step 4. Click  . The drive unit lowers.

Spindle Control for VK 70xx

To set the RPM, complete the following steps:

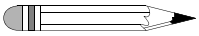
Step 1. Using the up and down arrows in the box that corresponds to Spindle RPM, set the RPM to the desired speed and click  . The spindles begin to turn at the entered RPM.

Step 2. Click  . The spindles stop.

Cannula / Manifold for VK 70xx

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

Step 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 Tester, set the volume and individually raise and lower the cannulas by changing the cannula position.

Step 2. Click  . The cannulas / manifold raise(s).

Step 3. Click  . The cannulas / manifold lower(s).

Dosage Delivery for VK 70xx

To open the DDMs, complete the following steps:

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

Note

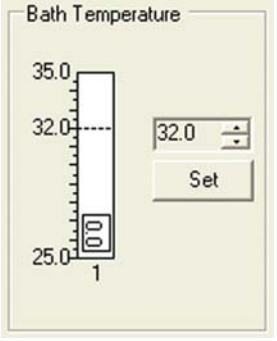
If your system configuration includes a V-series Dissolution Tester, open the individual DDMs by indicating a specific DDM location next to DDM.

Step 2. Click  . The DDMs open.

Water Bath Temperature

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

Step 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).



Step 2. Click **Set**.

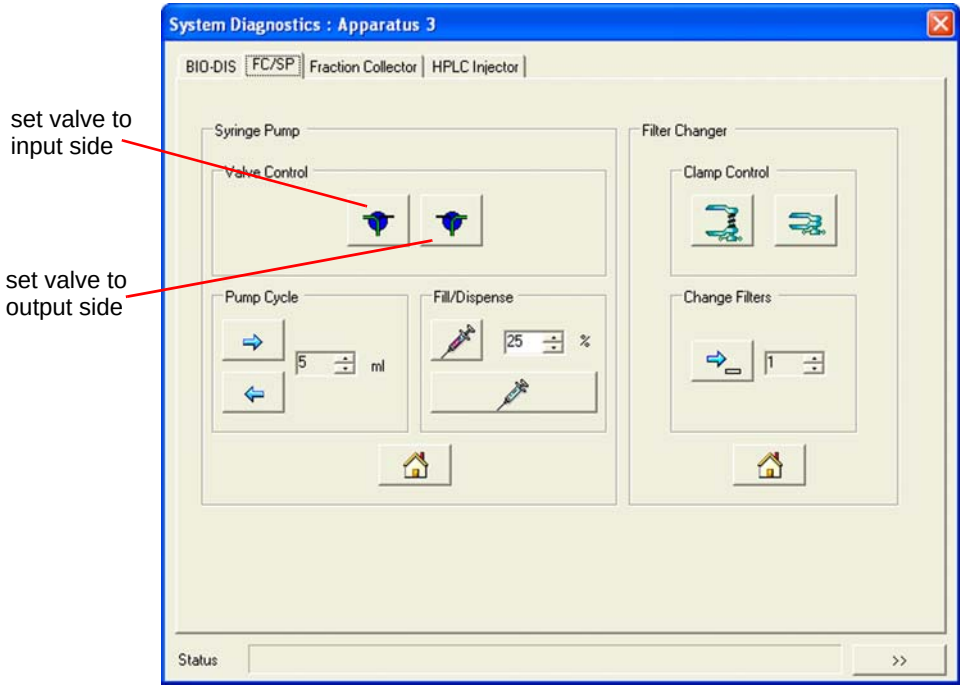
Syringe Pump / Filter Changer

Syringe Pump

To control the syringe pump, complete the following steps:

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

FIGURE 15. FC/SP tab



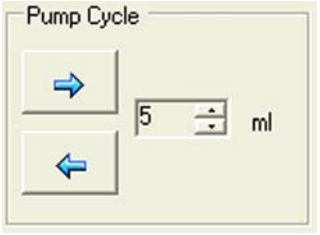
Note

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

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

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

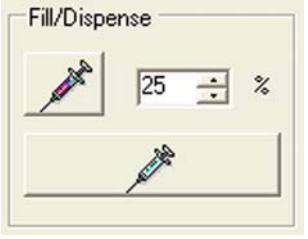
Step 4. In the Pump Cycle box, use the up and down arrows to enter a volume in milliliters to draw into the syringes.



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

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

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



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

Step 9. Click  to dispense the syringe to the home position. The syringe empties.

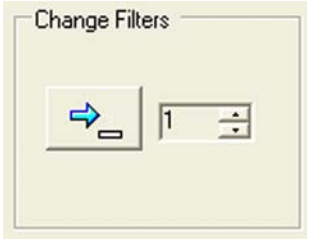
Filter Changer

To control the filter changer, complete the following steps:

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

Step 2. Click  (close the filter changer clamp) in the Clamp Control box. The clamp closes.

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



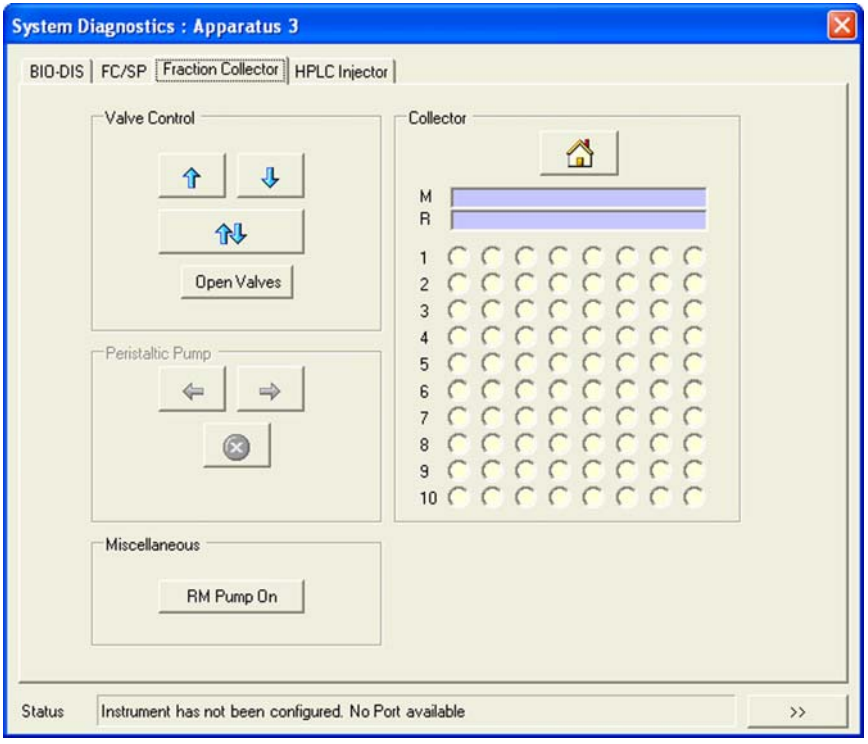
Step 4. Click  to expel the filters. The entered number of filters are expelled and replaced with new filters.

Valve Control

To control the valves, complete the following steps:

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

FIGURE 16. Fraction Collector tab



Note

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

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

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

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

Step 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.

Peristaltic Pump

To control the peristaltic pump, complete the following steps:

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

Step 2. Click  (stop pumping) in the Peristaltic Pump box. The pumping stops.

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

Step 4. Click  (stop pumping) in the Peristaltic Pump box. The pumping stops.

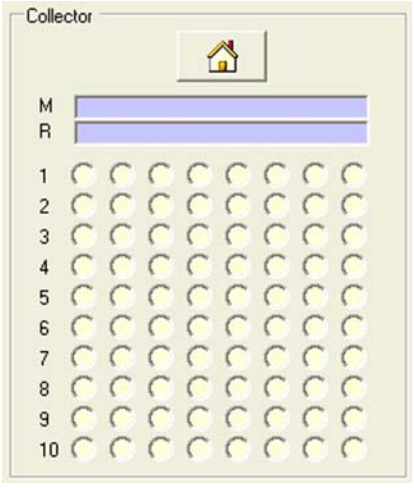
Replacement Media Pump

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

Moving the Fraction Collector Dispensing Arm

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

Step 1. Click any vessel position corresponding to the desired row in the Collector box. The dispensing arm moves to the desired row.



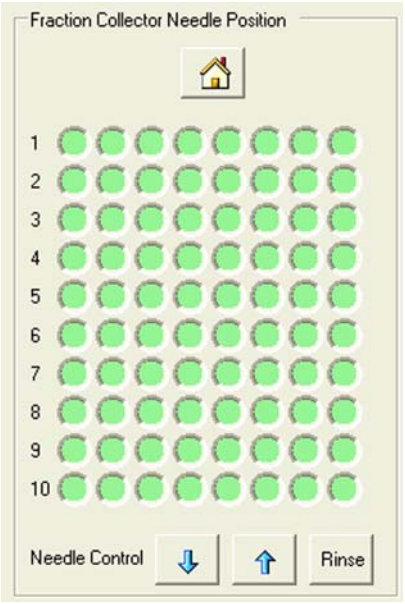
Step 2. In the Collector box, click  . The dispensing arm returns to the home position.

Injector Module

To control the injector module, complete the following steps:

Step 1. Select the **HPLC Injector** tab.

Step 2. In the Fraction Collector Needle Position box, click the desired vial position in the appropriate row. The fraction collector dispensing arm moves to the appropriate row and the needle moves to the desired vial position.



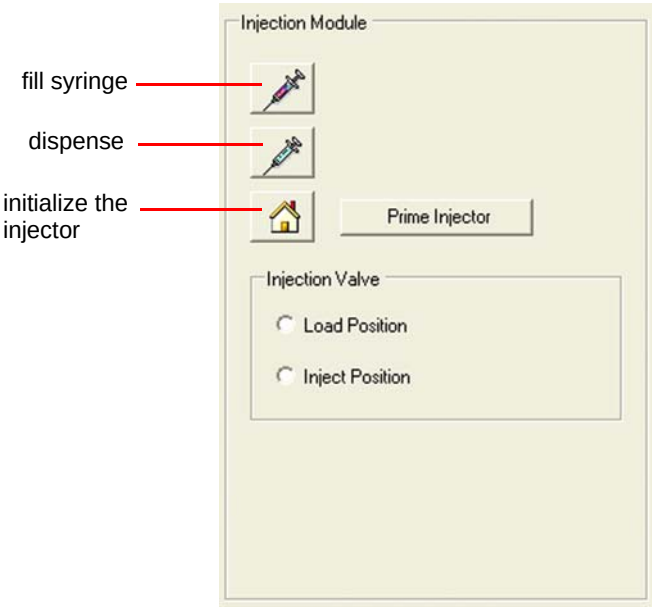
Step 3. Click  to lower the needle. The needle lowers.

Step 4. Click  to raise the needle. The needle raises.

Step 5. Click 

to rinse the needle.

Step 6. In the Injection Module box, click  (fill syringe). The syringe fills.



Step 7. Click  (dispense). The syringe dispenses.

Step 8. Click  (initialize the injector). The Injector initializes.

Step 9. Click **Prime Injector**. The sample line is primed.

Step 10. In the Injection Valve box, select **Inject Position**. The valve moves to the inject position.

Step 11. Select **Load Position**. The valve moves to the load position.

Manual Sample

Step 1. From the system status screen, click **Manual** and select **Sample**. The Manual Sampling Properties screen displays.

Step 2. Enter the appropriate information and click **OK**. The system collects sample in the indicated row.

Manual Injection

Step 1. From the system status screen, click **Manual** and select **Injection**. The Manual Injection Settings screen displays.

Step 2. Click **OK**. The system initializes.

Step 3. Click the desired vial position on the appropriate row and click **OK**. The system injects from the proper vial.

Step 4. If desired, select **Injection** to inject another sample.

Step 5. When you are finished, click **STOP** on the system status screen.

Method Editor

All test parameters are entered via the Method Editor screen.

Function	**Procedure**
Create a new method	See “Creating a Method” on page 42.
Copy a method	See “Copying Methods” on page 56.
Delete a method	See “Deleting Methods” on page 57.
Edit an existing method	See “Editing an Existing Method” on page 57.
Run a report of the method setup	See “Method Report” on page 58.

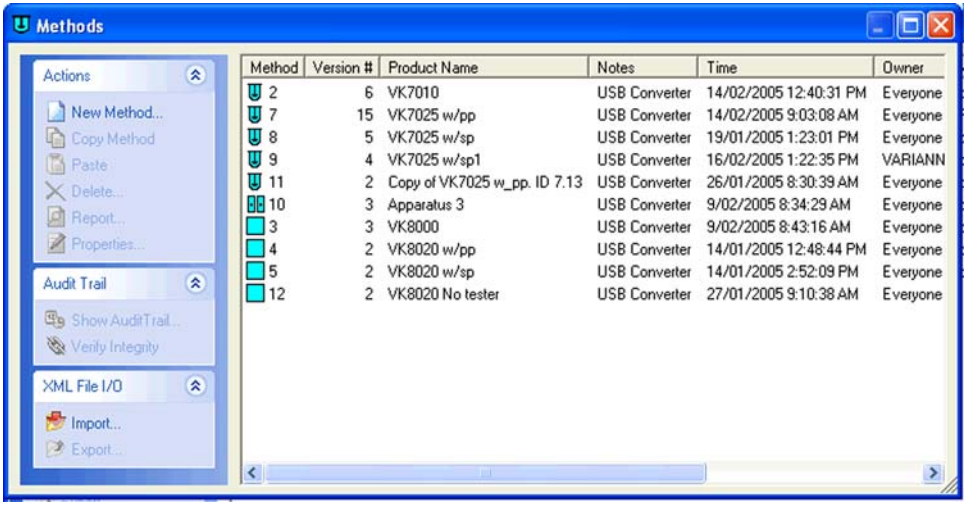
Function	Procedure
View the method audit trail	See “Show Audit Trail” on page 58.
Verify the integrity of a method	See “Verify Integrity” on page 59.
Import or export the method between two Dissolution Workstations	See “Import / Export XML File” on page 59.

Creating a Method

To create a new method, complete the following steps:

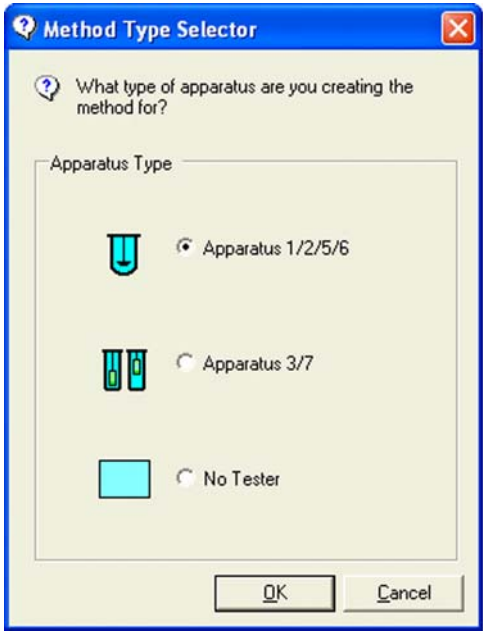
Step 1. From the navigation bar, click **Editor**. The Methods screen displays.

FIGURE 17. Methods screen



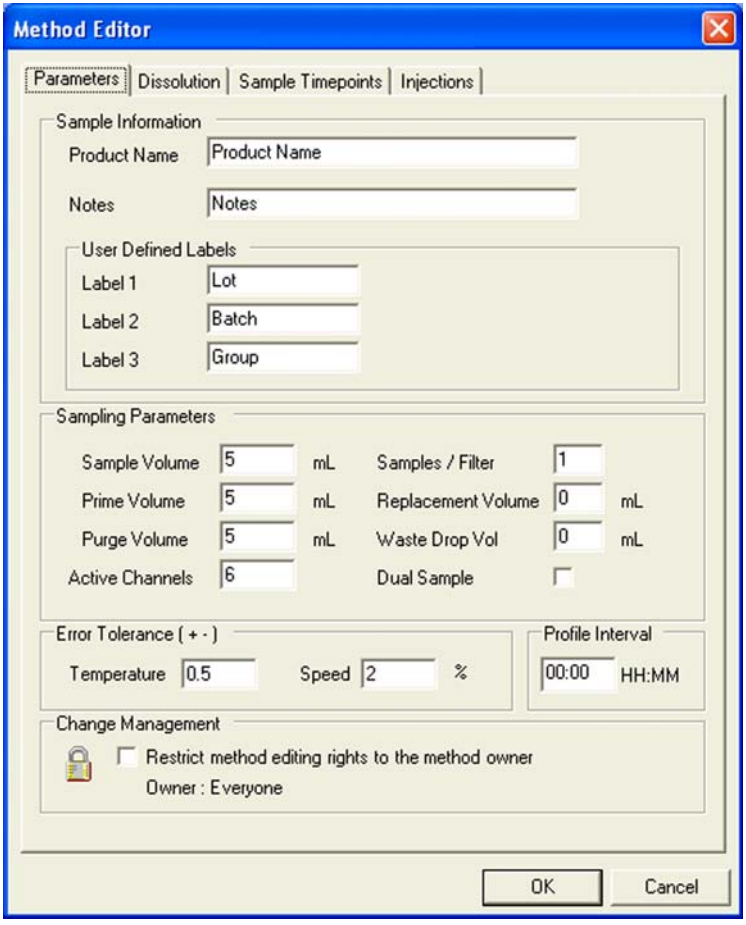
Step 2. Click **New Method**. The Method Type Selector screen displays.

FIGURE 18. Method Type Selector screen



Step 3. Select Apparatus 1/2/5/6, Apparatus 3/7, or No Tester and click **OK**. The Method Editor screen displays (see Figure 19, “Method Editor screen,” on page 44).

FIGURE 19. Method Editor screen



Step 4. Select the **Parameters** tab.

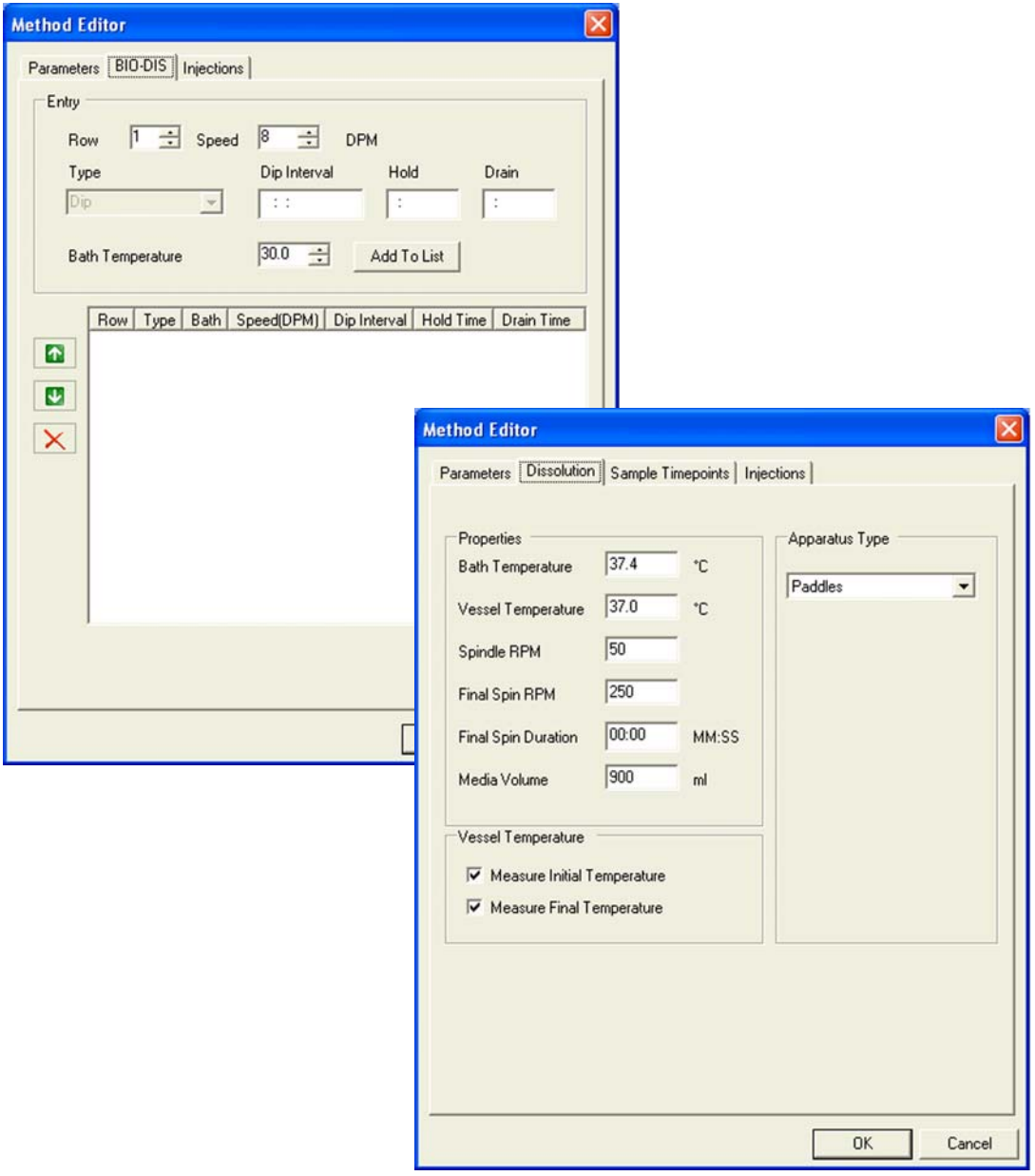
Following is a description of the Parameters tab options:

Option		Description
Sample Information	Product Name	Enter the name of the product.
	Notes	Enter any relevant notes regarding the sample.
	User Defined Labels Label 1 Label 2 Label 3	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.
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.
	Replacement Volume	If your system configuration includes the VK 8000 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 VK 8000 needles prior to dispensing samples into the collection tubes to ensure the needles are purged completely.***
	Dual Sample	Click **Dual Sample** to pull two samples into two consecutive rows at a single sample timepoint.

Option		Description
Error Tolerance (±)	Temperature	Enter the desired temperature fluctuation limit (±). If the vessel / water bath temperature goes over or under the set temperature (see “Vessel Temperature” on page 48) 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 (±). If the RPM goes over or under the set speed (see “Spindle RPM” on page 48) by the amount of this tolerance, an error is recorded as part of the results.
Profile Interval		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.**
Change Management		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.

Step 5. Select the **BIO-DIS** or **Dissolution** tab (see Figure 20, “BIO-DIS tab and Dissolution tab,” on page 47).

FIGURE 20. BIO-DIS tab and Dissolution tab



Step 6. Following is a description of the BIO-DIS and Dissolution tab options:

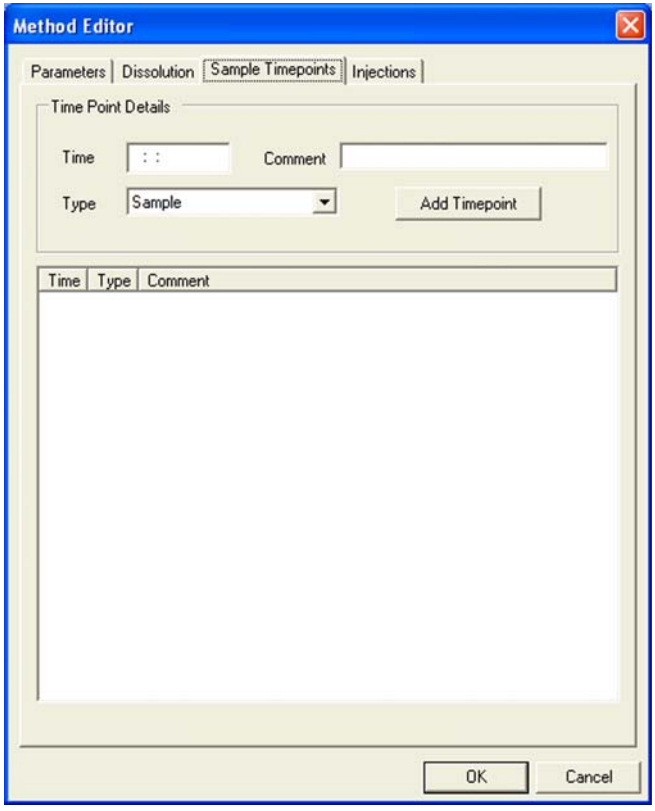
BIO-DIS tab		**Dissolution tab**	
Option	**Description**	**Option**	**Description**
Row	Use the up and down arrows to indicate the row number for which the parameters are being set. After clicking Add to List, use the up and down arrows to indicate the next row.	Bath Temperature	Enter the desired water bath temperature, if applicable, in °C. ***Note: this option is ignored if your system configuration includes a VK 7030.***
Speed	Use the up and down arrows to indicate the desired dips per minute (DPM) for each applicable row of the Apparatus 3 / Apparatus 7.	Vessel Temperature	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 64).
Type	***Note: disregard this option.***	Spindle RPM	Enter an appropriate speed for the dissolution tester spindles.
Dip Interval	Enter the desired duration for dipping in hhh:mm:ss format.	Final Spin RPM	If applicable, enter an appropriate speed for the final spin.
Hold	Enter the desired duration for the dip to remain at the bottom of the stroke in mm:ss format.	Final Spin Duration	If applicable, enter the duration of the final spin in mm:ss format.

BIO-DIS tab		Dissolution tab	
Option	**Description**	**Option**	**Description**
Drain	Enter the desired duration for the apparatus to remain at the top of the stroke after dipping in mm:ss format.	Media Volume	Enter the volume of the media in the vessels.
Bath Temperature	Enter the desired water bath temperature in degrees Celsius.	Vessel Temperature	Click Measure Initial Temperature and / or Measure Final Temperature to take the initial and final vessel temperatures during the method.
		Apparatus Type	Use the drop-down arrow to select the apparatus type.

Step 7. For the Apparatus 3 / Apparatus 7, click **Add To List**.

Step 8. For the VK 70xx, select the **Sample Timepoints** tab and program the appropriate timepoints (see Figure 21, “Sample Timepoints tab,” on page 50).

FIGURE 21. Sample Timepoints tab

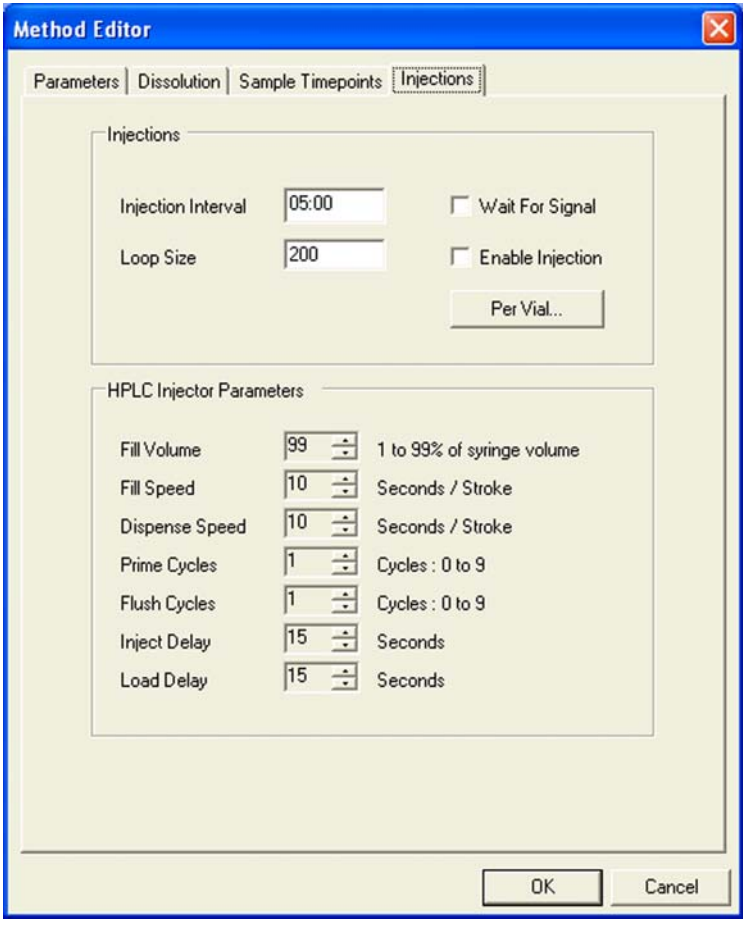


Following is a description of the Sample Timepoints tab options:

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

Step 9. Select the **Injections** tab.

FIGURE 22. Injections tab



Following is a description of the Injections tab options:

Option		Description
Injections	Injection Interval	Enter the duration between injections. The time desired timepoints for injections in mm:ss format.
	Loop Size	Enter the loop volume in microliters associated with your injector.
	Wait for Signal	If your system configuration includes a VK 8020, select Wait for Signal to synchronize with external HPLC hardware (optional).
	Enable Injection	If your system configuration includes a VK 8020, select Enable Injection to create an injection sequence. The Injection List Generation Options screen displays (see Figure 23, “Injection List Generation Options screen,” on page 53). Enter the injection group size according to the channel configuration of the VK 8000. Enter a value between 0 and 8 for the Standards injected before and after group. If required, select Limit generated list to number of timepoints. Click **OK** to close the Injection List Generation Options screen. The HPLC Injection List screen displays (see Figure 24, “HPLC Injection List screen,” on page 54).
	Per Vial	Click **Per Vial**. The HPLC Injection List screen displays (see Figure 24, “HPLC Injection List screen,” on page 54).

Option		Description
HPLC Injector Parameters	Fill Volume	Enter the percent of the injector syringe to fill between 1 and 99%.
	Fill Speed	Enter the desired seconds per stroke to fill the syringe.
	Dispense Speed	Enter the desired seconds per stroke to dispense the syringe.
	Prime Cycles	Enter the number of prime cycles between 0 and 9.
	Flush Cycles	Enter the number of flush cycles between 0 and 9.
	Inject Delay	Enter the duration of the inject delay in seconds.
	Load Delay	Enter the duration of the load delay in seconds.

FIGURE 23. Injection List Generation Options screen

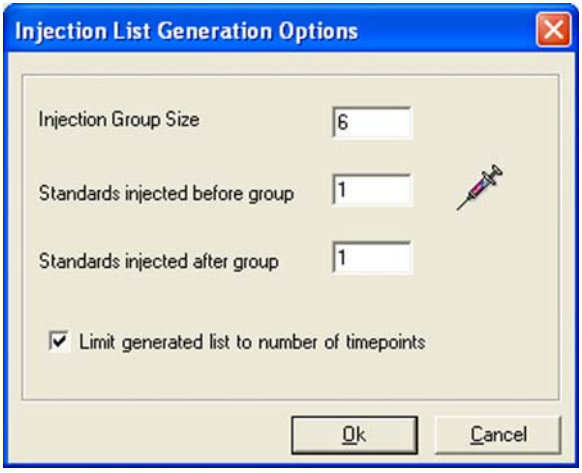
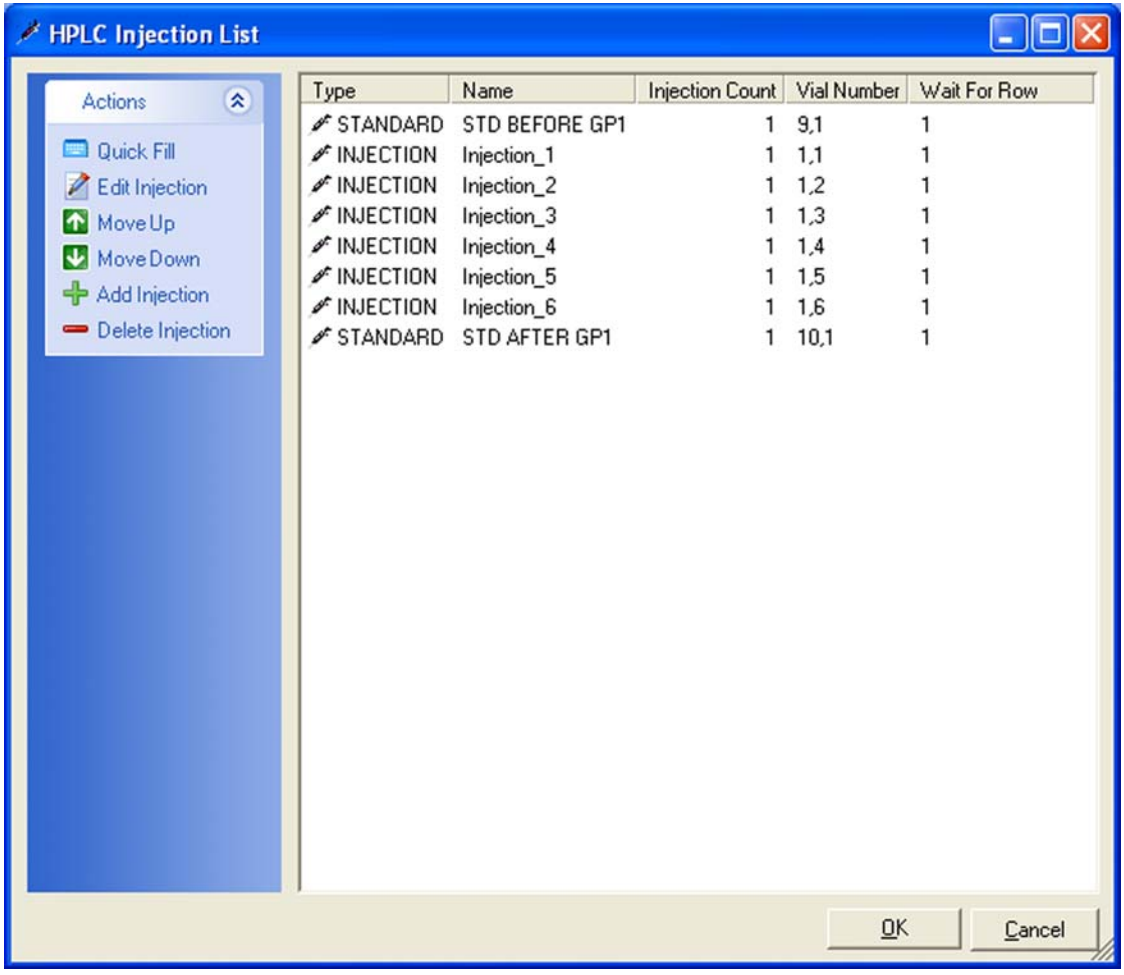


FIGURE 24. HPLC Injection List screen



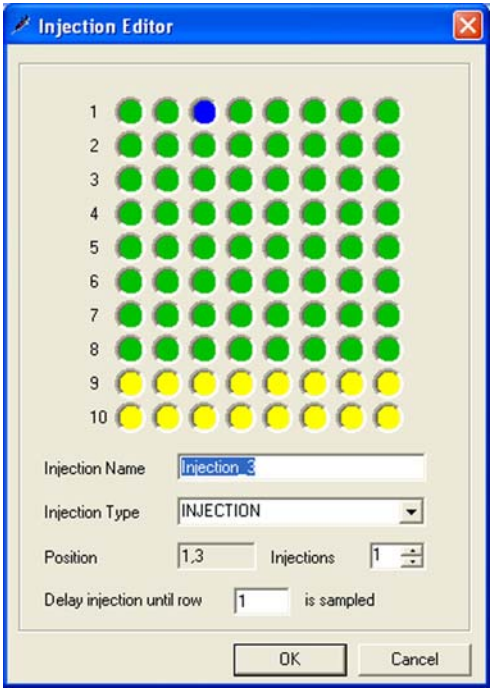
Following is a description of the screen options listed on the navigation bar of the HPLC Injection List screen:

Option	Description
Quick Fill	To automatically generate the injection list, click **Quick Fill**. The Injection List Generation Options screen displays (see Figure 23, “Injection List Generation Options screen,” on page 53) with preset injections. See “Enable Injection” on page 52.
Edit Injection	To change the vessel position and or row of a specific injection, click the injection and click Edit Injection. The Injection Editor screen displays (see Figure 25, “Injection Editor screen,” on page 56). Click the desired vessel position in the appropriate row and click **OK**. The Injection Editor screen closes and the new injection displays on the HPLC Injection List screen (see Figure 24, “HPLC Injection List screen,” on page 54) in place of the previous value.
Move Up Move Down	To change the order of the injections, click an injection and click either **Move Up** or **Move Down** as appropriate to reposition the injection in the list.
Add Injection	To add an injection, click **Add Injection**. The Injection Editor screen displays. Click the desired vessel position in the appropriate row and click **OK**. The Injection Editor screen closes and the injection displays on the HPLC Injection List screen (see Figure 24, “HPLC Injection List screen,” on page 54).
Delete Injection	To delete an injection, click the appropriate injection and click **Delete Injection** from the navigation bar.

Step 10. Click **OK** to close the HPLC Injection List screen.

Step 11. Click **OK** to close the Method Editor screen.

FIGURE 25. Injection Editor screen



Copying Methods

To copy a method, complete the following steps:

Step 1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 17, “Methods screen,” on page 42).

Step 2. Select the desired method.

Step 3. Click **Copy Method**.

Step 4. Click **Paste**. A new method displays. The description of the new method is *Copy of...*.

Step 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:

Step 1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 17, “Methods screen,” on page 42).

Step 2. Select the desired method.

Step 3. Click **Delete**.

Step 4. Click **Yes**.

Editing an Existing Method

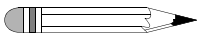
To edit a method already entered on the Dissolution Workstation, complete the following steps:

Step 1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 17, “Methods screen,” on page 42).

Step 2. Click the desired method.

Step 3. Click **Properties** on the navigation bar. The Method Editor screen displays (see Figure 19, “Method Editor screen,” on page 44).

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.

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

Method Report

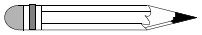
To display a report of the method parameters, complete the following steps:

Step 1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 17, “Methods screen,” on page 42).

Step 2. Select the desired system configuration.

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

Step 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.

Step 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:

Step 1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 17, “Methods screen,” on page 42).

Step 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.

Step 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:

Step 1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 17, “Methods screen,” on page 42).

Step 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:

Step 1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 17, “Methods screen,” on page 42).

Step 2. Select the desired method.

Step 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.

Step 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.

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

Step 6. Close the Notepad file.

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

Step 1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 17, “Methods screen,” on page 42).

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

Note

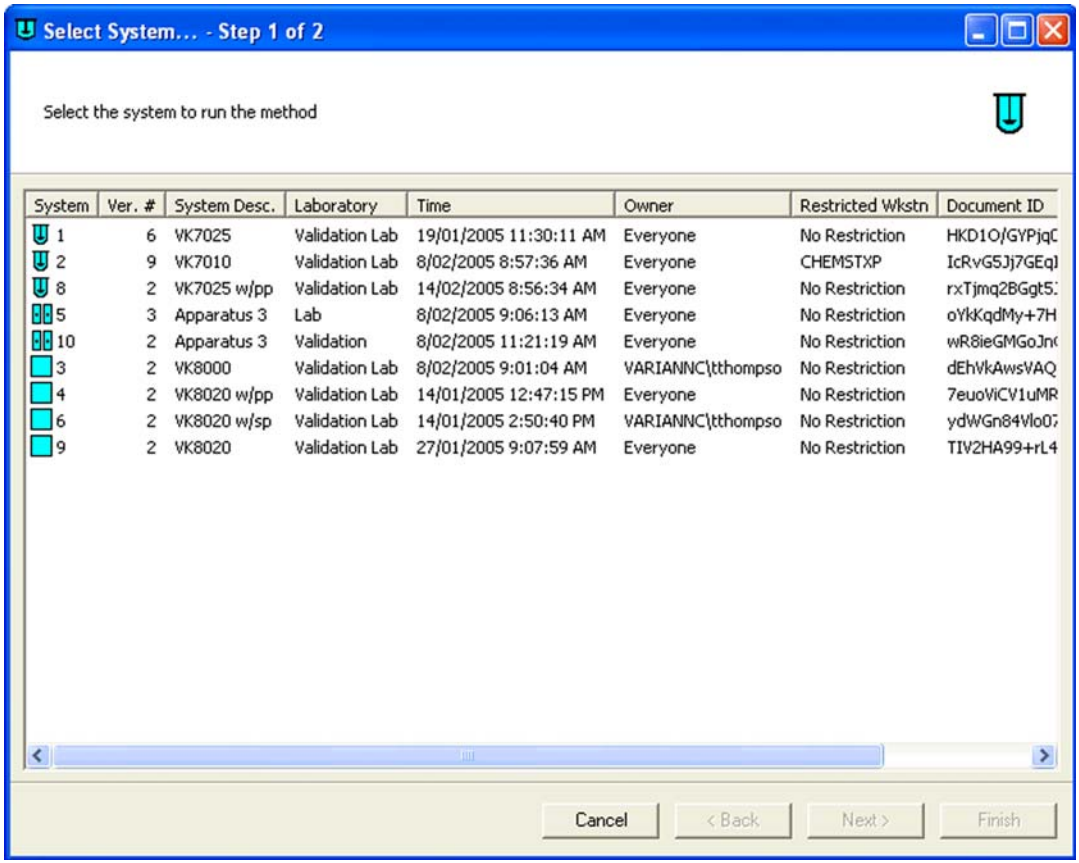
Alternately, you can right click the desired method and select Import. The Import Method from XML File screen displays as a result of either of these actions.

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

Running the Method

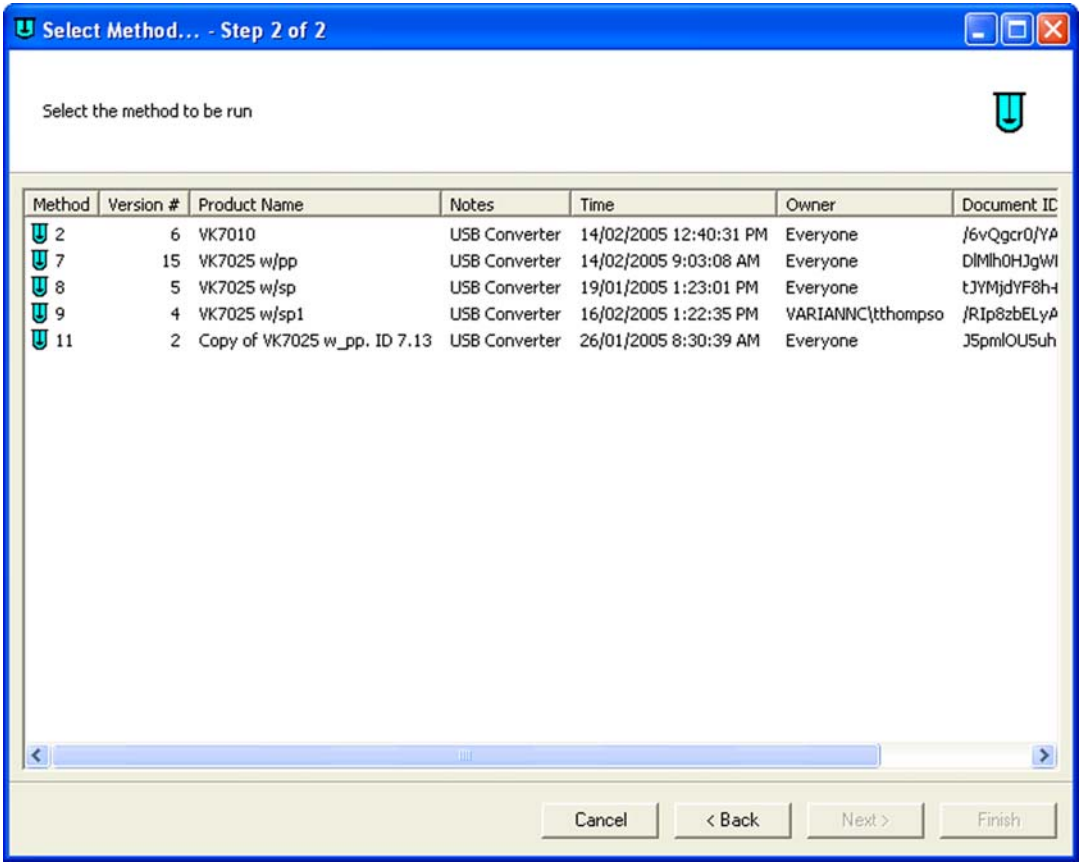
Step 1. From the navigation bar, click **Run Method**. The Select System Step 1 of 2 screen displays.

FIGURE 26. Select System Step 1 of 2 screen



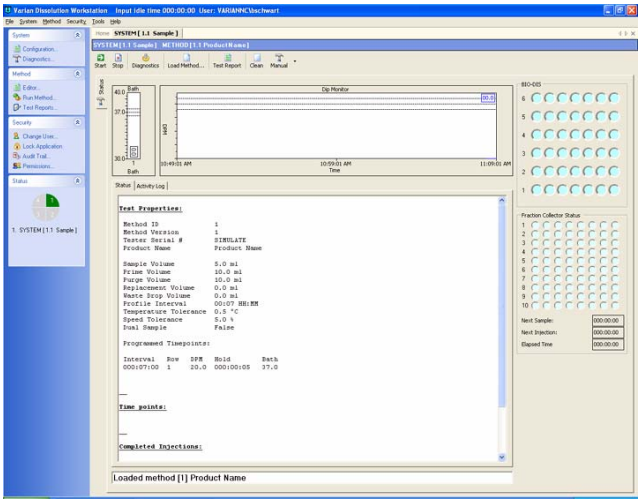
Step 2. Select the desired system to run the method and click **Next**. The Select Method Step 2 of 2 screen displays (see Figure 27, “Select Method Step 2 of 2 screen,” on page 62).

FIGURE 27. Select Method Step 2 of 2 screen



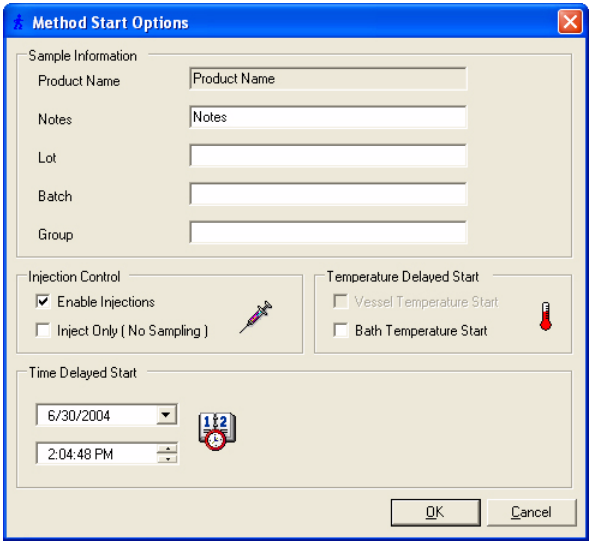
Step 3. Select the desired method to run and click **Finish**. The system status screen displays (see Figure 28, “System status screen,” on page 63).

FIGURE 28. System status screen



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

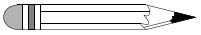
FIGURE 29. Method Start Options screen



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

Option	Description
Product Name	Enter the product name.
Notes	Enter any appropriate notation.
Label 1 Label 2 Label 3	Enter the appropriate information based on the user-defined labels (see “User Defined Labels” on page 45).
Injection Control Enable Injections Inject Only (No Sampling)	As applicable select enable injections to run an injection sequence and / or Inject Only to make injections without sampling. ***Note: if your system configuration includes a VK 8020, this option allows you to run dissolution without making HPLC injections.*** ***If your system configuration does not include a VK 8020, this option is disabled.***
Temperature Delayed Start Vessel Temperature Start Bath Temperature Start	As applicable select Vessel Temperature Start or Bath Temperature Start. Ensure the current date displays in the Time Delayed Start box. ***Note: vessel temperature start is applicable only with the VK 70xx.***
Time Delayed Start	Use this option to program a delayed start. Enter the desired date and time to start the method.

Step 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.

Step 6. Click **OK** to start the method.

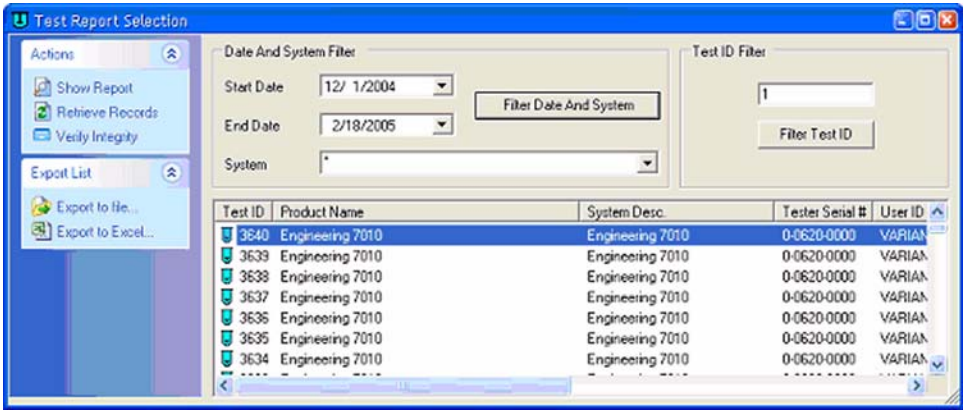
Step 7. When the method is complete, click **Test Report**. The test report displays. The report can be printed, exported, searched, verified, and / or signed.

Test Reports

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

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

FIGURE 30. 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 Date and System**.

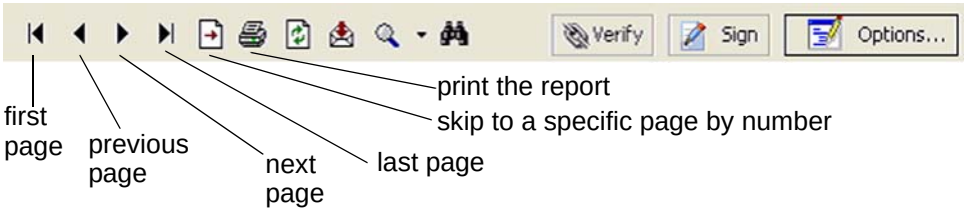
Additionally, you can select a system name from the **System** combo box to restrict the selection to a particular system.

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

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

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

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



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 NT 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.

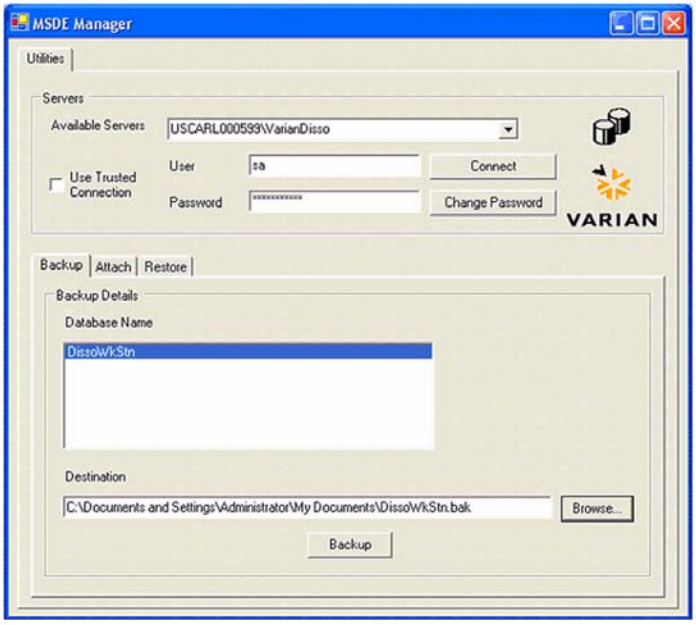
MSDE Manager: Back up / Restore

Backing up the Database

To back up the database, complete the following steps:

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

FIGURE 31. MSDE Manager Screen



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

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

Step 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.

Step 5. Click **Browse** to specify a destination for the backup file.

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

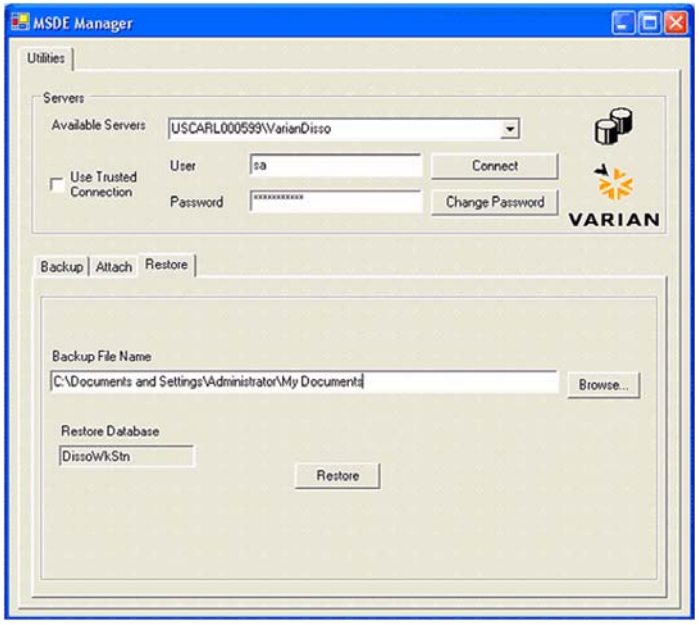
Restoring the Database

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:

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

FIGURE 32. MSDE Manager Screen



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

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

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

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

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