VARIAN

Varian 400-DS Automated Apparatus 7 Operator's Manual

P/N 70-9051
May 2007
Revision A

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First Edition (May 2007)
Varian 400-DS Automated Apparatus 7 Operator's Manual
Part Number 70-9051 Revision A
Printed in the United States of America

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Chapter 1 Safety Practices and Hazards

The Varian 400-DS Automated Apparatus 7 has been carefully designed so that when used properly you have an accurate, fast, flexible, and safe instrument.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Operation of a Varian 400-DS Automated Apparatus 7 involves the use of solid dosage forms and aqueous liquids. Unskilled, improper, or careless use of this instrument can create shock hazards, fire hazards, or other hazards which can cause death, serious injury to personnel, or severe damage to equipment and property.

Information on safety practices is provided with your instrument and operation manuals. Before using your instrument or accessories, you must thoroughly read these safety practices.

Observe all relevant safety practices at all times.

Electrical Hazards

Warning

The tester contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.

Warning

The apparatus should be disconnected from AC power before conducting cleaning or maintenance.

Panels or covers that are retained by fasteners which require the use of a tool for removal may be opened only by Varian-trained, Varian-qualified, or Varian-authorized service engineers. Consult the manuals or product labels supplied with the instrument to determine which parts are operator accessible.

Application of the wrong supply voltage, connection of the instrument to an incorrectly wired supply outlet, or lack of proper electrical grounding can create a fire hazard or a potentially serious shock hazard and could seriously damage the instrument and any attached ancillary equipment.

Always use a three-wire outlet with ground connection which is adequately rated for the load. The installation must comply with local, state, and federal safety regulations.

Do not connect the instrument to the main power supply until you have made sure that the operating voltage is correctly set for the main power supply in the specific outlet in your laboratory to which the equipment will be connected.

Reciprocation Hazard

The Varian 400-DS Automated Apparatus 7 contains a magnetic plate that reciprocates up and down during operation. Trapping an appendage between the evaporation cover and this plate could cause injury.

Other

Other specific warnings and cautions appear in the manuals where appropriate. These notifications detail the specific hazard, describe how to avoid it, and specify the possible consequences of not heeding the warning or caution.

Warning

A 'Warning' message appears in the manual when failure to observe instructions or precautions could result in death or injury. Symbols depicting the nature of the specific hazard are also placed alongside warnings.

These symbols may be used on warning labels attached to the instrument. When you see one of these symbols you must refer to the relevant operation or service manual for the correct procedure referred to by that warning label.

The meaning of the symbols that appear alongside warnings in this manual are as follows:

Electrical shock

Pinch point

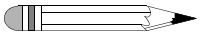
Caution
Refer to accompanying documents

Read all warnings and cautions carefully and observe them at all times.

Caution

A 'Caution' message appears in the manual when failure to observe instructions could result in damage to equipment (Varian supplied and/or other associated equipment).

A 'Note' appears in the manual to give advice or information.



Information Symbols

I	Switches main power on
0	Switches main power off
	Indicates single-phase alternating current
	Indicates the product complies with the requirements of one or more European Union (EU) directives
	Indicates specific equipment meets consensus-based standards of safety to provide assurance, required by OSHA, that these products are safe for use in the workplace for North America
	Indicates that this product must not be disposed of as unsorted municipal waste (see "WEEE Directive" on page 17)

General

CE Compliant Products

The Varian 400-DS Automated Apparatus 7 has been designed to comply with the requirements of the Electro-magnetic Compatibility (EMC) Directive and the Low Voltage Directive (LVD) of the EU.

Varian, Inc. has confirmed that each product complies with the relevant directives by testing a prototype against the prescribed European Norm (EN) standards.

Proof that a product complies with the directives is indicated by:

- the CE marking appearing on the rear of the product.
- the documentation package that accompanies the product containing a copy of the declaration of conformity. This declaration is the legal declaration by Varian, Inc. that the product complies with the directives, and also shows the EN standards to which the product was tested to demonstrate compliance. The declaration of conformity is signed by the representative of the manufacturing plant.

cTUVus - U.S. and Canadian Product Approvals

The Varian 400-DS Automated Apparatus 7 has been designed to comply with North American safety requirements.

This product has been tested and certified for the North American market by TUV Rheinland of North America, Inc.. The TUVus mark signifies that this product has been tested to U.S. standards and certified for the U.S. market. The cTUV mark signifies that this product has been tested to Canadian standards and certified for the Canadian market. When the two marks are coupled, the cTUVus mark signifies that this product has been tested to standards and certified for both markets.

WEEE Directive

All Varian products that are subject to the WEEE directive shipped after August 13, 2005 are compliant with the WEEE marking requirements. Such products are marked with the "crossed out wheelie bin" WEEE symbol shown on page 15 in accordance with European Standard EN 50419.

This symbol on the product or on its packaging indicates that this product must not be disposed of as unsorted municipal waste. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.

For more information on collection, reuse, and recycling systems, please contact your local/regional waste administration, your local distributor, or Varian, Inc.

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Chapter 2 Introduction

The patented Varian 400-DS Automated Apparatus 7 is ideal for extended-release products or any dosage form requiring release profiling at multiple pH levels. The 13 test samples traverse the two rows of corresponding cells filled with media. The Varian 400-DS Automated Apparatus 7 fills and dispenses media automatically, without operator intervention. A report can be generated to provide hard-copy documentation of the testing progress and conditions.

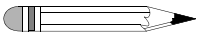
All parameters are controlled via the PC. Up to 4 units can be pre-programmed to withdraw samples at designated timepoints. Samples can be collected in pre-capped HPLC vials for direct transfer to an HPLC system. Septa are pierced using the exclusive needle manifold, which lowers and raises at each sample point. Sample trays are available in 1.5 mL and 4 mL sizes.

Caution

Panels or covers that are retained by fasteners which require the use of a tool for removal may be opened only by Varian-trained, Varian-qualified, or Varian-authorized service engineers.

Conventions Used in this Manual

- Items you are asked to press are in bold. For example, “press **H** on the keypad”.
- Key sequences you are asked to press appear like this: **MENU** > **0** > **8**.



Note

Remember to return the warranty card supplied with this manual. Completing and returning the card ensures your right to protection under the terms and conditions of your warranty. It also enables us to better assist you in the event of any problems. Additionally, it guarantees you will be informed of any issues that arise concerning your equipment, such as upgrades, retrofits, or regulatory changes.

USP Physical Parameters

In addition to the apparatus suitability test, you must monitor several physical parameters, such as stroke distance, dip speed, and temperature. A Certificate of Compliance is included with your Varian 400-DS. Contact the Laboratory Services Department for more information on USP physical parameters.

Specifications

Your tester is designed for indoor use. It is suitable for the categories stated below:

Environmental Specifications

Temperature	15 - 40 °C
Humidity (%RH non-condensing)	not more than 80
Physical site	clean dry level bench
Support weight	150 lb. (68 kg) min.

Engineering Specifications

Variable	Specification
Voltage Requirements	115 VAC/60 Hz 230 VAC/50 Hz
Current Requirements	115 VAC - 8.0 AMP 230 VAC - 8.0 AMP
Circuit Breaker	115 VAC - 8.0 AMP, 250 VAC, 50-60 Hz 230 VAC - 8.0 AMP, 250 VAC, 50-60 Hz
Power Consumption (Max Loaded)	600 W
Reciprocation	5 - 35 DPM
Reciprocation Accuracy	± 0.5%
Reciprocation Resolution	± 0.1 DPM
Speed Selection	Via PC software
Temperature Range	Ambient to 50 °C

Variable	Specification
Temperature Measurement Accuracy	± 0.2 °C
Communications	RS232, USB, and Ethernet
Sampling	Automated sampling driven through PC software
Sample Holder Material	PEEK and titanium
Status Indicator	LEDs
Dimensions	Height: 24.00 inches (60.9 cm) Width: 20.00 inches (50.8 cm) Depth: 22.00 inches (55.8 cm)
Weight	130.3 lbs (59.1 kg)

Accessories

Following is a list of accessories that ship with the Varian 400-DS. All items are pictured in the protective foam packaging on the following page.

Label	Item	Quantity
	Varian 400-DS	1
A	AC power cord	1
B	Sample cells	13
C	Cell heater jackets	13
D	Sample holders	13
F	25' roll of tubing	1
G	Sample tray with 12 rows	1
H	Additional sample tray row for calibration	1
J	Magnetic plate	1
K	Evaporation cover	1
E	1.5 mm Allen wrench	1
E	9/64" Allen wrench	1
M	Modified temperature probe	1
N	Sample vials, 12x32, Qty. 100	2
O	Sample vials, 15x35, Qty. 100	1
P	Level	1
Q	Sample holder extraction tools	1
R	RS232 cable	1
	User manual CD	1

FIGURE 1. Accessory Tray 1

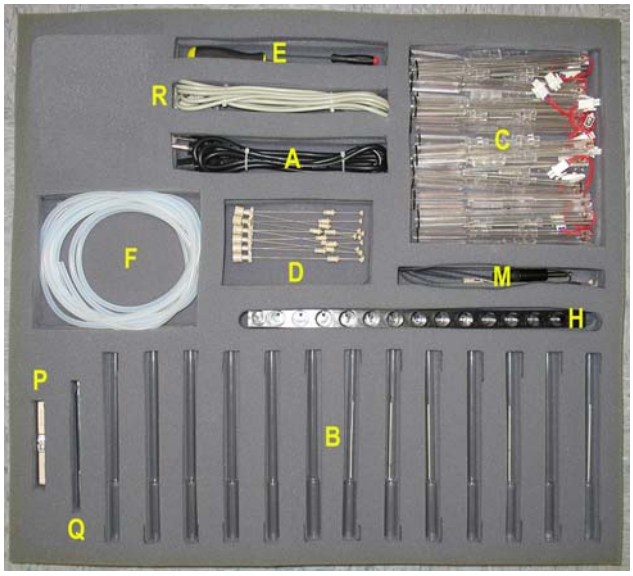
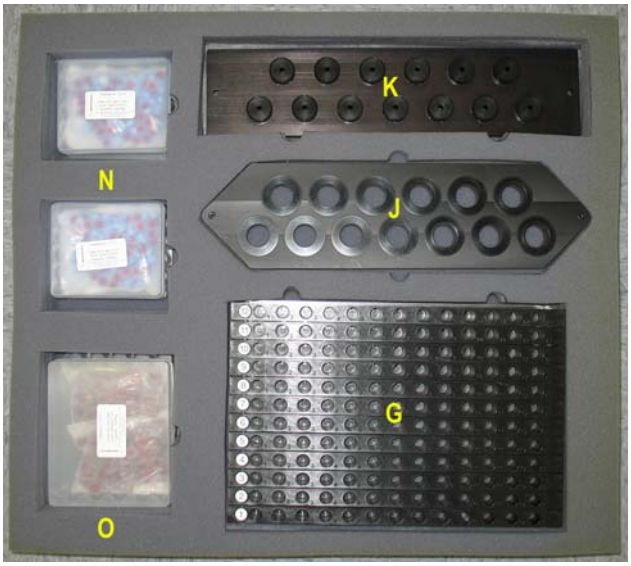


FIGURE 2. Accessory Tray 2



Chapter 3 Installation and Setup

Unpacking Your Equipment

The Varian 400-DS is shipped in one crate. The crate contains the apparatus and accessories.

Step 1. Open the crate and check the contents for damage, which may have occurred during shipping. Shipping damage rarely occurs, but if it does contact both the carrier who delivered the instruments and the Dissolution Systems Service Department. Though claims for damage should be filed with the carrier, we can help you file a claim.

Step 2. Remove the top of the crate.

Step 3. Remove one side of the crate and lift the accessories box out of the crate.

Step 4. Disassemble the other three sides of the crate.

Step 5. Remove any cushioning material and tape. If any item is missing, contact the Dissolution Systems Service Department or your local representative for replacements.

Step 6. Carefully remove the apparatus from the base of the shipping crate.

Warning

Because of its heavy weight, two people should lift the apparatus. Lift by holding underneath the base of the unit on each side. Support feet are located at each corner of the unit. Hands should be positioned between the support feet to ensure they are not trapped when lowering.

Step 7. Place the apparatus on a clean, dry, and level section of the bench.

Warning

The electrical connection at the back of the apparatus is the primary disconnect for the instrument. The apparatus should be positioned to allow accessibility to the power cords and circuit breaker switch for easy disconnection.

Leveling Your Apparatus

Step 1. Place the level provided in the accessory kit on the vessel table.

Step 2. Check the level of the instrument in the front and rear center of the unit as well as the left and right sides.

Step 3. The apparatus has adjustable feet under each corner. These may be screwed in or out to raise or lower each leg. Adjust the feet so the bubble inside the level is within the circle at all four points.

Electrical Connection

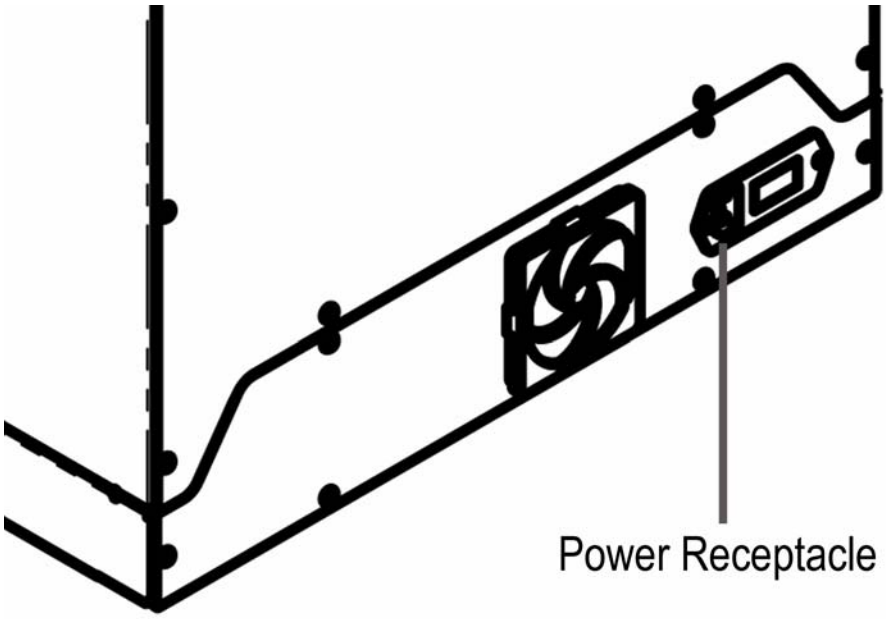
Warning

Ensure the apparatus is configured for the voltage available in your laboratory. Check the serial number tag on the rear panel of the instrument to confirm the voltage requirement. The electrical connection at the back of the apparatus is the primary disconnect for the instrument.

Step 1. Verify the Varian 400-DS is off.

Step 2. Connect the power cord between the receptacle on the drive unit rear panel and an outlet of the appropriate voltage.

FIGURE 3. Diagram of the electrical connection



Setting up Your PC

The 400-DS Workstation software requires Microsoft Windows® 2000 or Windows XP® to be installed on your computer. For instructions on installing the operating system, refer to the documentation supplied with Windows®.

Minimum PC Configuration

- Windows® 2000 SP6 or Windows XP® SP1
- 10 GB free hard disk drive space
- 256 MB RAM
- 1024 x 768 pixel display resolution
- 2x USB port (optional)

If the PC is not equipped with a standard serial port, a USB-to-serial converter must be purchased.

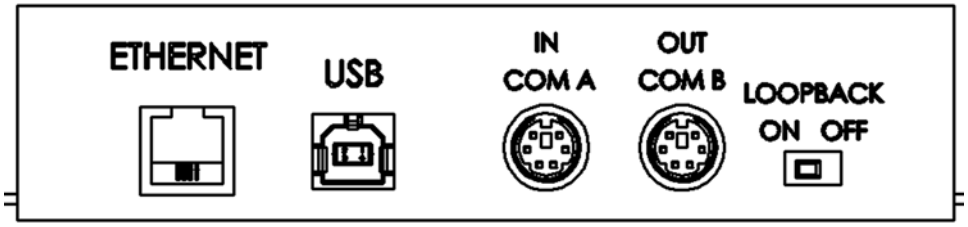
If Varian is installing the 400-DS Workstation software for you, note that the installation of a Windows® operating system is not included as part of the standard instrument installation.

Setting up Your PC

The monitor, keyboard, mouse, and printer/plotter are connected to the PC via cables which plug into the back of the PC. Consult your monitor and printer manuals for details of their individual cabling requirements.

Cable Connections

FIGURE 4. Diagram of cable connections



Caution

The Varian 400-DS can be connected to the PC using an RS232, USB, or Ethernet cable. Do not connect more than one type of cable. Communication errors may occur.

Single System Setup

Step 1. Connect a cable between COM1 on the PC and the left serial port (IN COM A) on the rear of the Varian 400-DS Automated Apparatus 7.

Step 2. Ensure the loop back switch (located to the right of the right serial port) is switched to the left (ON).

Multiple System Setup

Step 1. Connect a cable between COM1 on the PC and the left serial port (IN COM A) on the rear of the Varian 400-DS Automated Apparatus 7.

Step 2. Ensure the loop back switch (located to the right of the right serial port) is switched to the right (OFF).

Step 3. Connect a 6-pin mini-DIN cable between the right serial port (OUT COM B) of the first apparatus and the left serial port of the second apparatus.

Step 4. If this is the final Varian 400-DS Automated Apparatus 7 in the series, ensure the loop back switch (located to the right of the right serial port) is switched to the left (ON).

If this is not the final Varian 400-DS Automated Apparatus 7 in the series, ensure the loop back switch (located to the right of the right serial port) is switched to the right (OFF).

Step 5. Repeat steps 3 and 4 for each additional apparatus.

Setting Up the Varian 400-DS

Step 1. Locate the 1.5 mm Allen wrench to install the sample heater jackets.

Step 2. Install the first cell heater by placing it over the thermistor at the desired cell position of the Varian 400-DS.

Step 3. While holding the jacket in place, use the Allen wrench to tighten the screw.

Step 4. Insert the 2-pin plug for the heater in the appropriate location on the sample heater jacket.

Step 5. Repeat steps 2 - 4 to install the sample heater jackets for the remaining cell positions.

Step 6. Install the magnetic plate on the reciprocation guide rod, which is the shorter rod in the middle of the 3 rods on the Varian 400-DS.

Step 7. Tighten the bolt on each end of the magnetic plate using the 9/64" Allen wrench.

Step 8. Install the guide rod stabilizers on top of the magnetic plate using the two longer guide rods for alignment.

Step 9. Tighten the two bolts on each stabilizer plate using the 9/64" Allen wrench.

Step 10. Locate the sample cells and sample holders provided with your instrument.

Step 11. Remove the sample cells and holders from the packing material to ensure no damage occurred during shipment.

Step 12. To install a sample cell in the heater jacket, slide one end through the magnetic lift plate.

Step 13. Use the finger tabs on the heater jacket to spread it open.

Step 14. Continue to lower the sample cell until it is secure and completely covers the bottom cell seal.

Caution

Be careful when sliding the sample cells over the O-ring seals as damage can occur. Ensure the cell and seal are properly aligned before applying pressure.

Step 15. With the magnet at the top, insert the sample holder into the sample cell.

Step 16. Repeat steps 12 - 15 to install the remaining sample cells and holders.

Step 17. Replace the evaporation cover and tighten the two thumb screws.

Initial Power Up

Step 1. Ensure the circuit breaker on the rear of the instrument is on.

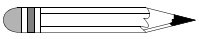
Step 2. Turn on the power switch on the front panel and ensure the integrated red LED illuminates.

Step 3. Repeat steps 1 and 2 for each Varian 400-DS Automated Apparatus 7.

Step 4. Turn on the PC, monitor, and printer. Verify the PC power light illuminates and the Microsoft ® Windows®XP or Windows® 2000 initializes.

Software Installation

Note



To complete the installation of the 400-DS Workstation software, you must log on to the PC as an administrator. Attaching the Database and Local Security Policy are included as part of the software installation procedures. The CD contains all of the requirements for an installation.

To install the software, complete the following steps:

Step 1. Install the 400-DS Workstation CD and access the files.

Step 2. Execute the file **setup.exe** and follow the on-screen prompts.

Step 3. When asked if you want to install the Microsoft .Net Framework V1.1, you *must* click **Yes**.

Step 4. After the installation has successfully completed, install the license dongle by plugging it into an open USB port.

FIGURE 5. License dongle

Attaching the Database

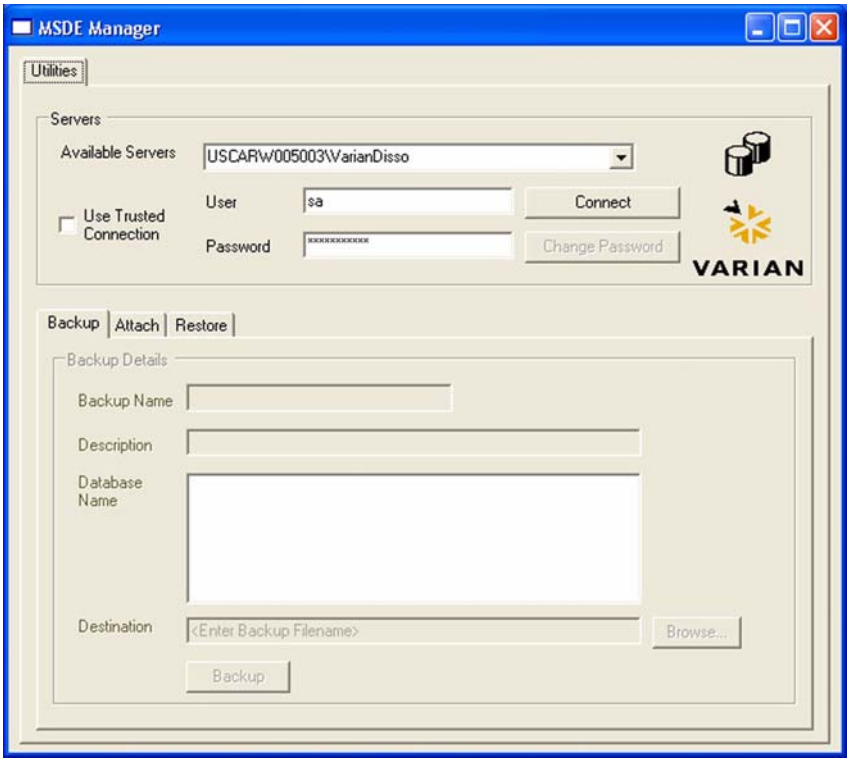
Note

This section is only required when upgrading an existing installation.

Once the basic installation is complete, complete the following steps to attach the database files:

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

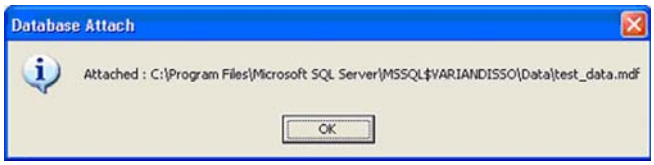
FIGURE 6. MSDE Manager screen



Step 2. Select a machine name from the list of available servers. When connecting to a database installation on a local machine, the encrypted password is automatically entered in the password box. When connecting to a remote database, your system administrator may have to provide you with a password.

Step 3. Click **Connect** to connect to the server or local PC.

Step 4. Select the **Attach** tab on the MSDE Manager screen and attach the database by clicking **Attach**. Leave all the values at their default settings. After successful attachment, the Database Attach screen displays.

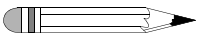


Step 5. Click **OK**.

Step 6. Close the MSDE Manager screen.

Local Security Policy

For 21 CFR Part 11 compliance purposes, you *must* ensure that the following minimum requirements are met by your system's security policy.



Note

It may be necessary to coordinate the following configurations with the domain administrator.

Step 1. Click **Start** > **Run** to run the Local Security Settings Manager. Type **secpol.msc** and press **Enter**. The Local Security Settings manager displays.

Step 2. Click **Security Settings** > **Account Policies** > **Password Policy** and set the following security policy configuration:

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

Step 3. Click **Security Settings** > **Account Policies** > **Account Lockout Policy** and set the following configuration:

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

Step 4. Click **Security Settings** > **Local Policies** > **Audit Policy** and set the following configuration:

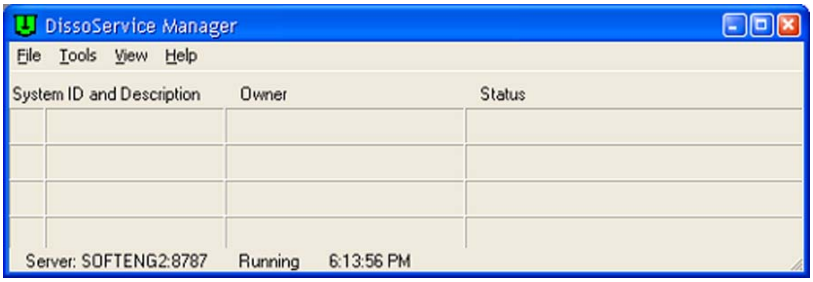
Policy	Security Setting
Audit account logon events	Success, Failure
Audit account management	Success, Failure
Audit logon events	Success, Failure
Audit policy change	Success, Failure

Step 5. Close the Local Security Settings Management screen.

E-mail Notification Configuration (Optional)

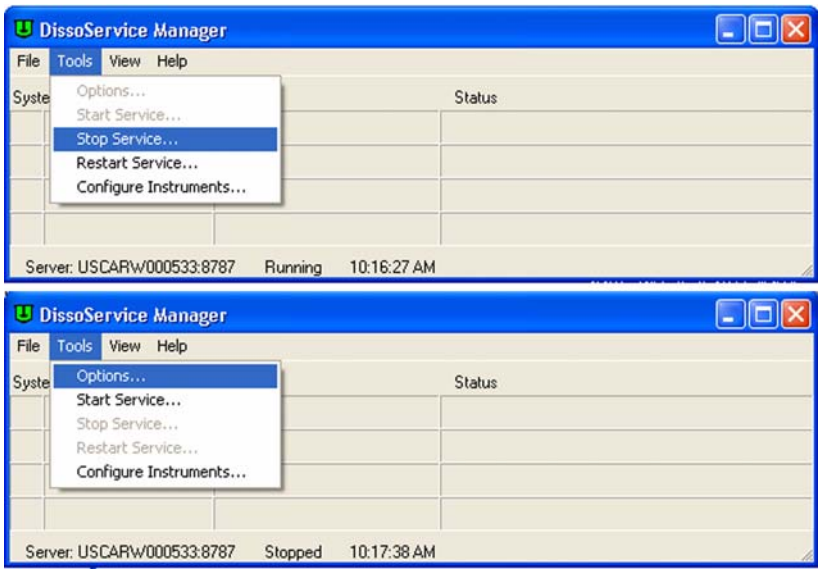
Step 1. On the computer which is hosting the DissoService, click **Start** > **All Programs** > **Varian** > **Dissolution** > **Service Manager**. The DissoService Manager screen displays.

FIGURE 7. DissoService Manager screen



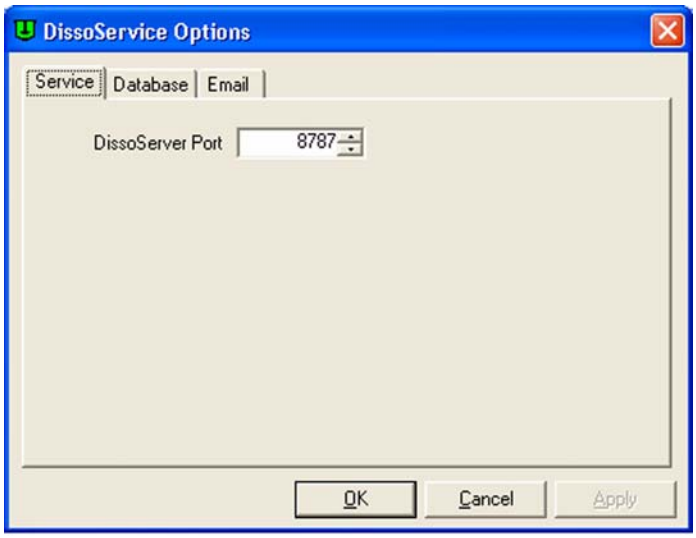
Step 2. On the toolbar, click **Tools** and select **Stop Service**. The Options item on the Tools menu enables after the service stops (see Figure 8, "Tools menu," on page 38).

FIGURE 8. Tools menu



Step 3. On the toolbar, click **Tools** > **Options**. The DissoService Options screen displays (see Figure 9, "DissoService Options screen," on page 39).

FIGURE 9. DissoService Options screen



Step 4. Configure the SMTP server address.

Note

The e-mail alert software assumes the use of an SMTP server which does not require authentication for sending. Most e-mail servers only require authentication for receiving (POP3), but allow sending from any system on the same domain without the use of a password.

If your corporate server does not require passwords, provide the address of the corporate SMTP server in order for Dissolution Server to send e-mail. Enter the SMTP server address as either a name (for example, server.domain.com) or as an IP address (for example, 192.168.1.1).

If your corporate SMTP server requires passwords, consider installing Microsoft Internet Information Server (IIS) to a server on your intranet through which other Dissolution Servers could send e-mails. IIS includes a SMTP server which allows unrestricted e-mail sending.

Step 5. Once you have configured the SMTP server address, click **OK** to save the settings.

Step 6. On the toolbar, click **Tools** and select **Start Service**.

Starting 400-DS Workstation

Step 1. Double-click the **400-DS Workstation** icon on the Windows desktop to start the software.

Step 2. If your system has Windows Firewall installed, the following displays:

Click **Unblock** to enable the program.

Dissolution Server Selection

Note

A dissolution server must be selected when logging into a server for the first time. The same user ID and password that was used to log on to Windows should be used to log on to the 400-DS Workstation software.

Step 1. From the logon screen, enter a domain user identification and password.

Step 2. Click the drop-down arrow corresponding to Dissolution server and select **Add New**. The Add New Dissolution Server screen displays (see Figure 11, "Add New Dissolution Server screen," on page 42).

FIGURE 10. Logon screen

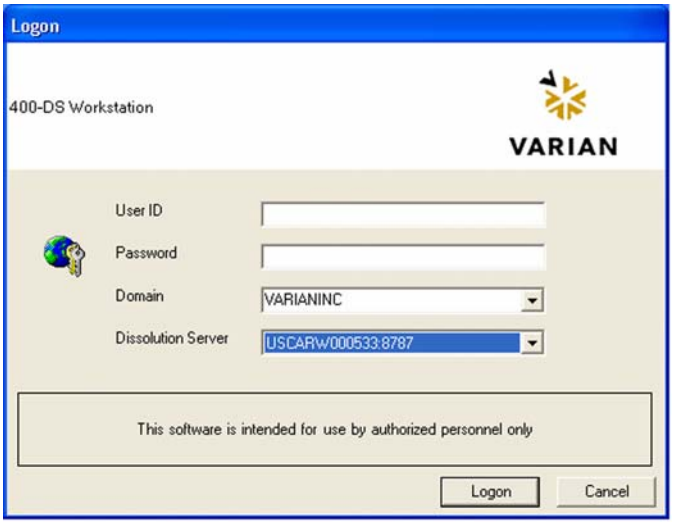


FIGURE 11. Add New Dissolution Server screen

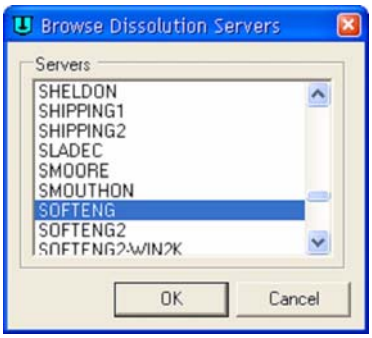
Step 3. If you know the domain name of the computer on which the Dissolution Server is installed, enter the name in the Server Name box.

Alternately, click the network browse button (…) to select a server from a list of computers on your network (see Figure 12, "Browse Dissolution Servers screen," below).

Note

If your network has a large number of systems connected, browsing the network may take several minutes.

FIGURE 12. Browse Dissolution Servers screen



Step 4. The default server port is 8787, but may be changed to any other port. Coordinate the selection of a port number with your I.T. department to satisfy any port restriction requirements they may have.

Step 5. Click **OK**.

Step 6. Click **Logon** on the Logon screen.

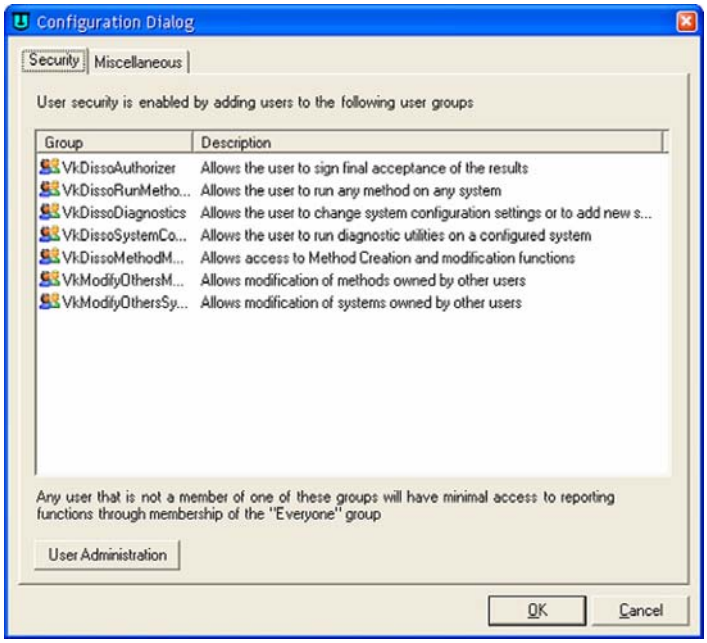
Step 7. After successfully logging onto the software, click **Tools** > **Options**. The Configuration Dialog screen displays (see Figure 13, "Configuration Dialog screen," on page 43).

Configuring the Application - Adding Users

Note

In order to configure the application, it is necessary to be logged on as an administrator.

FIGURE 13. Configuration Dialog screen



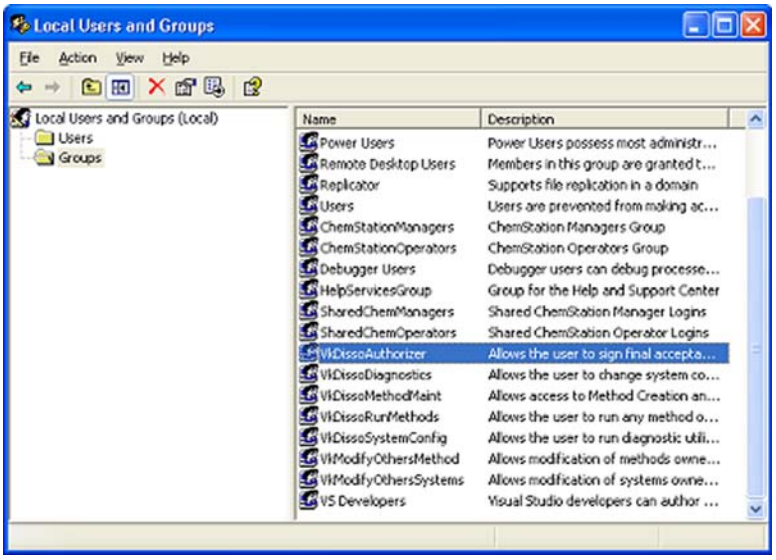
Step 1. To add a user to a group, select the Security tab on the Configuration Dialog screen.

Note

Only an administrator can add users.

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

FIGURE 14. Local Users and Groups screen



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

Step 4. Click **Add...** to add users to the group. The Select Users, Computers, or Groups screen displays.

Step 5. Enter the names of the users to add to the group and click **OK**.

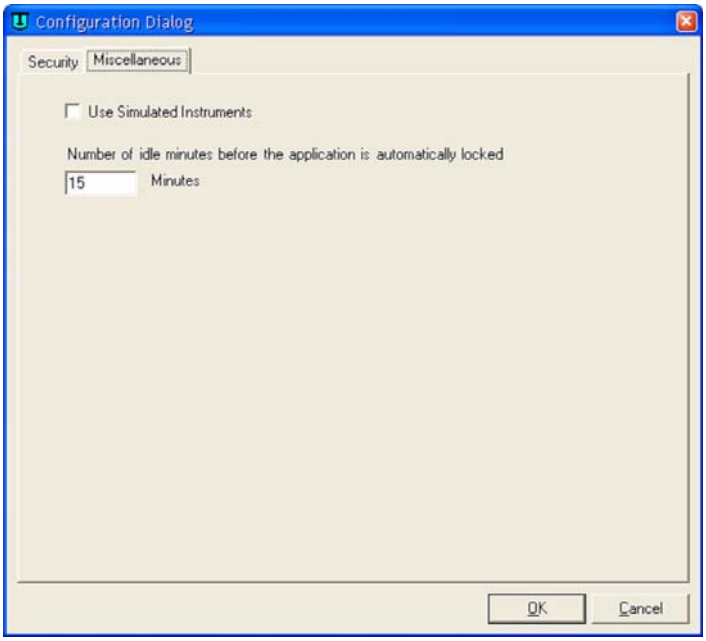
Step 6. Repeat steps 3-5 as appropriate for each group that requires new users.

Step 7. Close the window.

Step 8. Select the **Miscellaneous** tab (see Figure 15, "Miscellaneous tab," on page 45). To run the software without physically connecting instruments, check the **Use Simulated Instruments** box. The system operates in simulation mode.

Step 9. Enter an appropriate length of time in minutes the application can be idle before locking.

FIGURE 15. Miscellaneous tab



Step 10. Click **OK**. The application has been configured.

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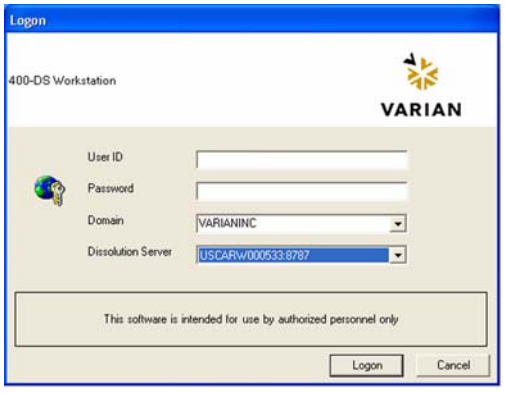
Chapter 4 Operation

Log on to the Varian 400-DS Workstation

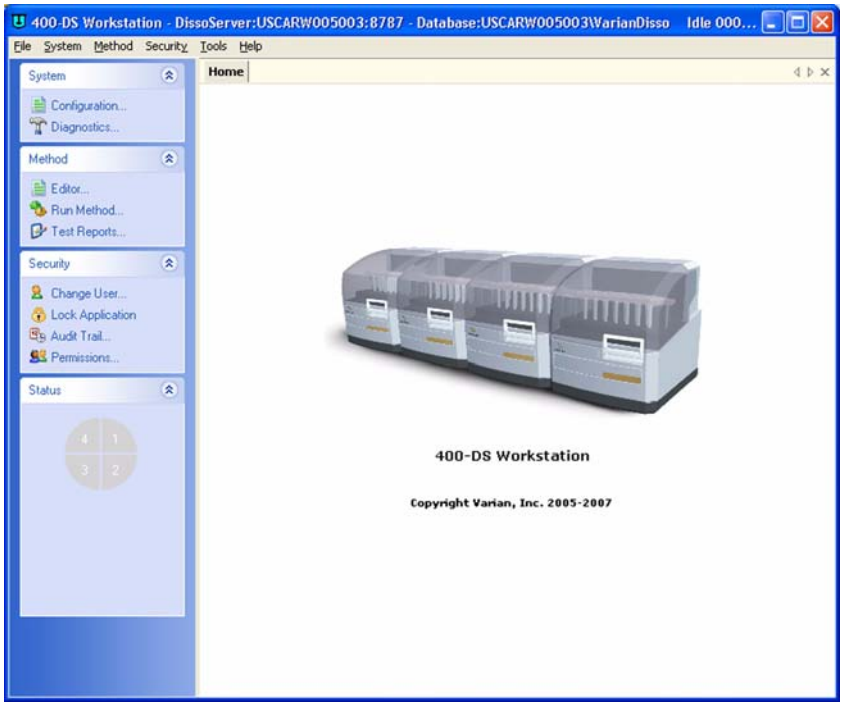
Step 1. Double-click the **Varian 400-DS Workstation** icon on your desktop. The Logon screen displays.

FIGURE 16. Logon screen



Step 2. Enter your user identification and password. Verify the domain is correct and click **Logon**. The 400-DS Workstation screen displays.

FIGURE 17. 400-DS Workstation screen



Following is a description of the screen options listed on the navigation bar of the 400-DS Workstation screen:

Option		**Description**
System	Configuration	Use this option to configure the system. See "Configuring Your System" on page 50.
	Diagnostics	Use this option to check the diagnostics of a dissolution apparatus or accessory within the system. See "Manual Control/Diagnostics" on page 64.
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 69.
	Run Method	Use this option to run a method. See "Running the Method" on page 82.
	Test Reports	Use this option to run a report of the completed method. See "Test Reports" on page 87.
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 400-DS Workstation screen, click **Lock Application**. The 400-DS 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.

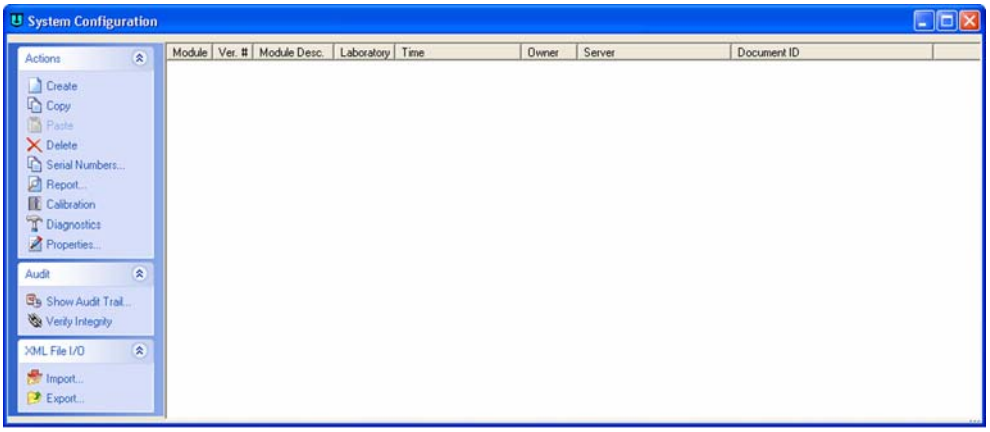
Configuring Your System

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.

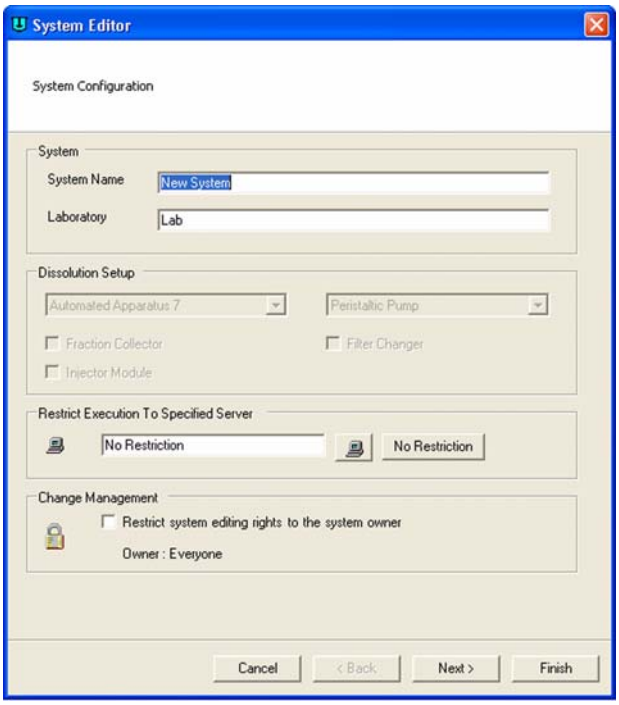
Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays.

FIGURE 18. System Configuration screen



Step 2. Click **Create**. The System Editor screen displays (see Figure 19, "System Editor screen," on page 51).

FIGURE 19. System Editor screen



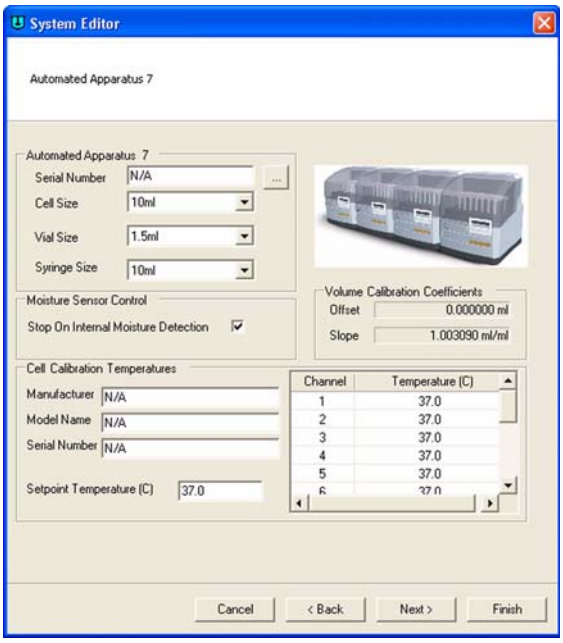
Following is a description of the System Editor screen options:

Screen Section	Parameter	Description
System	System Name	Enter a name for your system.
	Laboratory	Enter a laboratory name.

Screen Section	Parameter	Description
Restrict Execution To Specified Server		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 400-DS Workstation screen displays.

FIGURE 20. 400-DS Workstation screen



Following is a description of the 400-DS Workstation screen options:

Screen Section	Parameter	Response
Varian 400-DS Automated Apparatus 7	Serial Number	Click **...** to display the serial numbers of all connected instruments. Highlight the appropriate serial number and click **Select**.
	Cell Size	Click the drop-down arrow to indicate the appropriate cell size.
	Vial Size	Click the drop-down arrow to indicate the appropriate vial size.
	Syringe Size	Click the drop-down arrow to indicate the appropriate syringe size.
Cell Calibration Temperatures	Manufacturer	Enter the manufacturer of the calibrated temperature probe.
	Model Name	Enter the model name of the calibrated temperature probe.
	Serial Number	Enter the serial number of the calibrated temperature probe.
	Set Point Temperature (ºC)	Enter the set point for the cell temperature. Enter the temperature for each cell as determined from the diagnostic (see "Cell Calibration Temperatures" on page 62).
Moisture Sensor Control	Stop On Internal Moisture Detection	Check this option to shut down the system when moisture is detected. **Note: Enabling this option is recommended.**
Volume Calibration Coefficient	Offset	The current offset displays in this area.
	Slope	The current slope displays in this area.

Step 4. Click **Next**. The Serial Numbers screen displays.

Step 5. Enter the serial number for the sample cells, sample holders, etc. and click **Add**.

Step 6. Click **Finish**.

Step 7. Repeat all the sections under "Configuring Your System" on page 50 for each additional system.

Step 8. 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 18, "System Configuration screen," on page 50).

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 56.

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 18, "System Configuration screen," on page 50).

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 18, "System Configuration screen," on page 50).

Step 2. Select the desired system configuration.

Step 3. Click **Serial Numbers**. The Serial Number Editor screen displays.

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.

Step 4. Enter the serial number for the sample cells, sample holders, etc. and click **Add**.

Step 5. 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 18, "System Configuration screen," on page 50).

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

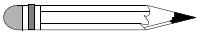
To display and edit the properties of an existing system configuration, complete the following steps:

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 18, "System Configuration screen," on page 50).

Step 2. Select the desired system configuration.

Step 3. Click **Properties**. The System Editor screen displays (see Figure 19, "System Editor screen," on page 51).

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.

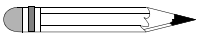
Show Audit Trail

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 18, "System Configuration screen," on page 50).

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 400-DS Workstation program, complete the following steps:

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 18, "System Configuration screen," on page 50).

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 400-DS Workstation computer on a different 400-DS 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 18, "System Configuration screen," on page 50).

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 400-DS Workstation, complete the following steps:

Step 1. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 18, "System Configuration screen," on page 50).

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.

System Calibration

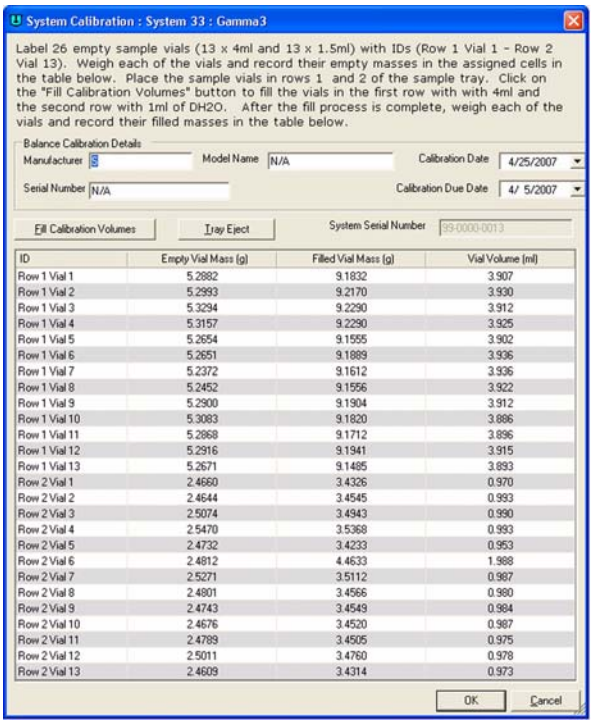
Step 1. Place the Media A tube into a suitable container with deionized water.

Step 2. From the navigation bar, click **Configuration**.

Step 3. Select desired configuration.

Step 4. Click **Calibration**. The System Calibration screen displays.

FIGURE 21. System Calibration screen



Step 5. Label 13 empty 4 mL sample vials (Row 1 Vial 1 - Row 1 Vial 13).

Step 6. Label 13 empty 1.5 mL sample vials (Row 2 Vial 1 - Row 2 Vial 13).

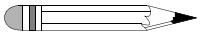
Step 7. Weigh each of the vials and record the empty masses in the assigned cells in the table.

Step 8. Place the sample vials in row 1 (4 mL) and row 2 (1.5 mL) of the sample tray.

Step 9. Click **Fill Calibration Volumes** to fill the vials in the first row with 4 mL and the second row with 1 mL of deionized water.

Step 10. After the fill process is complete, weigh each of the vials and record their filled masses in the table. The vial volume calculates and displays in the table automatically.

Step 11. Click **OK**. The Reason for Change screen displays.



Note

The software performs a Least Squares Fit analysis. The volume deviation from the curve is 1.5% of the vial volume. An automated error message is generated if the calibration fails.

Step 12. Enter a reason code and change description and click **OK**.

Step 13. Highlight the appropriate system.

Step 14. Click **Properties**.

Step 15. Click **Next** and ensure the Volume Calibration Coefficients are visible.

Step 16. Click **Finish**.

Step 17. Close the System Configuration screen.

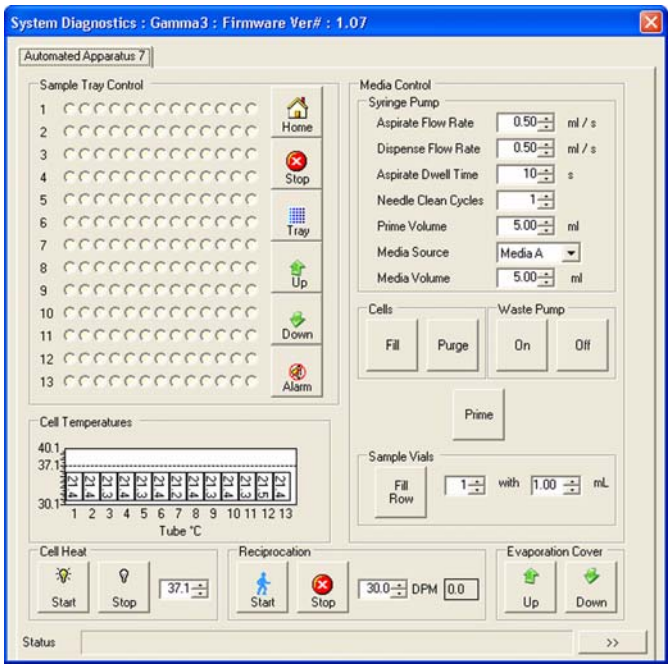
Cell Calibration Temperatures

Step 1. Place the rinse media line into a suitable container holding deionized water.

Step 2. From the navigation bar, click **Diagnostics**. The Select Item screen displays.

Step 3. Select the desired system and click **OK**. The System Diagnostics screen displays.

FIGURE 22. System Diagnostics screen



Step 4. In the Cells box under Media Control, click **Fill**. Media moves into the cells.

Step 5. In the Cell Heat box, set the cell temperature to an appropriate temperature.

Step 6. Click

. DO THE SAMPLE CELLS CONTAIN LIQUID? displays.

Step 7. Click **Yes**. The temperatures display in the Cell Temperature box.

Step 8. Set the reciprocation rate and click **Run**.

Step 9. Allow the media to equilibrate to the set temperature.

Step 10. In the Evaporation Cover box, click the up arrow to raise the evaporation cover.

Step 11. Remove the two thumb screws from the evaporation cover and remove the evaporation cover.

Step 12. Remove the sample holder for cell 1 and replace with the modified temperature probe.

Step 13. Allow 3 - 5 minutes for the temperature to stabilize.

Step 14. Note the temperatures for use at step 23.

Step 15. Repeat steps 12 - 14 for each additional cell.

Step 16. Replace the sample holders and the evaporation cover.

Step 17. Stop reciprocation and cell heating.

Step 18. Under the Media Control box, click **Purge**. The media in all cells purges.

Step 19. Close the Diagnostics screen.

Step 20. From the navigation bar, click **Configuration**. The System Configuration screen displays (see Figure 18, "System Configuration screen," on page 50).

Step 21. Select the appropriate system and click **Next**.

Step 22. Enter the set point temperature as appropriate based on the cell calibration temperatures.

Step 23. Enter the temperature values for each cell (as noted in step 14) into the cell calibration field.

Step 24. Click **Finish**. The Reason for Change screen displays.

Step 25. Enter a reason code and change description and click **OK**.

Step 26. 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.

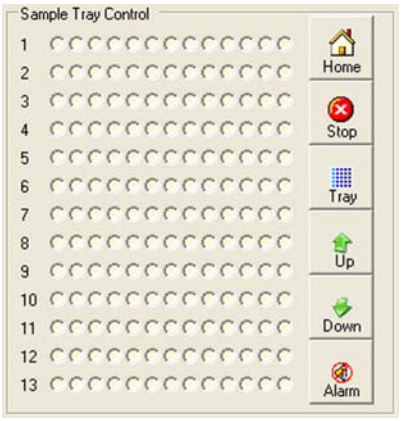
Step 1. From the navigation bar, click **Diagnostics**. The Select Item screen displays.

Step 2. Select the desired system and click **OK**. The System Diagnostics screen displays (see Figure 22, "System Diagnostics screen," on page 62).

Verifying Sample Tray Control

Step 1. Click any vessel position corresponding to the desired row in the Sample Tray Control box. The tray moves and the indicated row raises.

FIGURE 23. Sample Tray Control box



Step 2. Click

under the Sample Tray Control box. The drive unit returns to the home position.

Step 3. Click

to stop the movement.

Step 4. Click

to eject or retract the sample tray.

Step 5. Click

to raise the evaporation cover.

Step 6. Click

to lower the evaporation cover.

Step 7. Click

to turn off any audible alarm.

Media Control

Step 1. Under the Media Control box, set the following parameters:

Option	Description
Aspirate Flow Rate (mL/s)	Use the up and down arrows to indicate the rate at which the media is pulled into the syringe.
Dispense Flow Rate (mL/s)	Use the up and down arrows to indicate the rate at which the media is dispensed from the syringe.
Aspirate Dwell Time (s)	Use the up and down arrows to indicate the duration of time the plunger holds at the top of the stroke before dispensing. **Note: The time specified is for full syringe volume. For smaller syringe volumes, it is calculated proportionately.**
Needle Clean Cycles	Use the up and down arrows to indicate the number of times the unit performs the cleaning cycle.
Prime Volume (mL)	Use the up and down arrows to indicate the volume to be pulled before taking measurement.
Media Source	Use the drop-down arrow to indicate the source of the media.
Media Volume	Use the up and down arrows to indicate the desired volume of the media.

Step 2. Under the Media Control box, click **Prime**.

Step 3. Under the Cells box, click **Fill**. The media moves into the cells.

Step 4. Under the Sample Vials box, use the up and down arrows to indicate the desired row number to sample into and the desired volume.

Step 5. Under the Sample Vials box, click **Fill Row**. The media moves from the cell into the sample vial.

Step 6. Under the Waste Pump box, click **On** to turn on the waste pump.

Step 7. Under the Waste Pump box, click **Off** to turn off the waste pump.

Verifying the Cell Temperature

Step 1. In the Cell Heat box, use the up and down arrows to set the media cell temperature to an appropriate temperature (see the sample screen below).

Step 2. Click

. DO THE SAMPLE CELLS CONTAIN LIQUID? displays.

Step 3. Click **Yes**. The temperatures display in the Cell Temperature box.

Step 4. As applicable, click

.

Step 5. Under the Cells box, click **Purge** to purge the remaining media from the tube.

Caution

Do not click Fill more than one time without purging in between. The media will overflow the cells.

Reciprocation

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

Step 1. Click any vessel position corresponding to the desired row in the Sample Tray Control box (see Figure 23, "Sample Tray Control box," on page 65). The drive unit moves to the indicated row.

Step 2. In the Reciprocation box, use the up and down arrows in the box that corresponds to DPM, to set the dips per minute to **15** and click

. Dipping begins.

FIGURE 24. Reciprocation box

Step 3. Click

. The dipping stops.

Step 4. Click

under the Sample Tray Control box. The drive unit returns to the home position.

Controlling the Evaporation Cover

To raise the evaporation cover, click

in the Evaporation Cover box.

To lower the evaporation cover, click

in the Evaporation Cover box.

Method Editor

All test parameters are entered via the Method Editor screen.

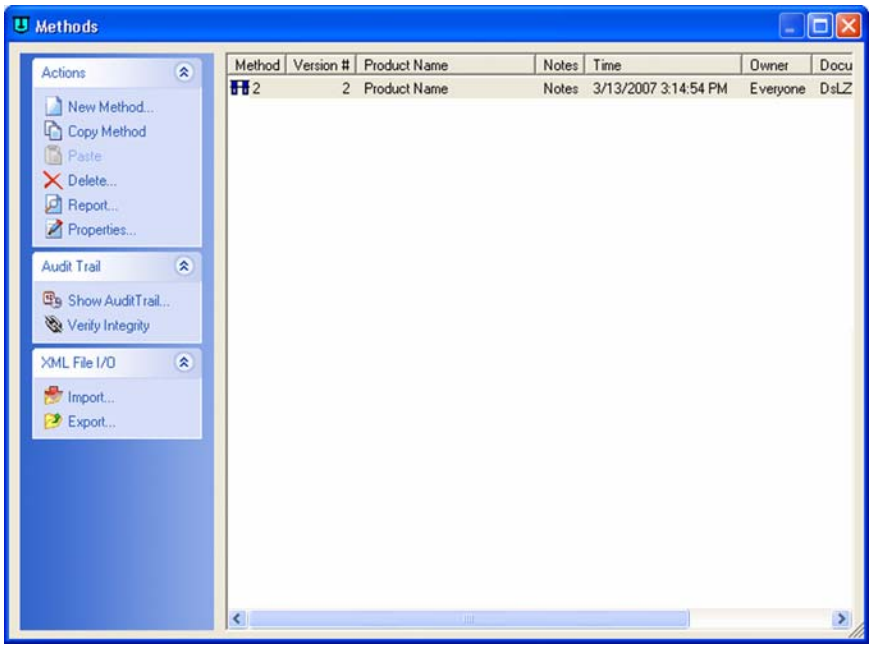
Function	**Procedure**
Create a new method	See "Creating a Method" on page 70.
Copy a method	See "Copying Methods" on page 77.
Delete a method	See "Deleting Methods" on page 77.
Edit an existing method	See "Editing an Existing Method" on page 78.
Run a report of the method setup	See "Method Report" on page 78.
View the method audit trail	See "Show Audit Trail" on page 79.
Verify the integrity of a method	See "Verify Integrity" on page 80.
Import or export the method between two 400-DS Workstations	See "Import/Export XML File" on page 80.

Creating a Method

To create a new method, complete the following steps:

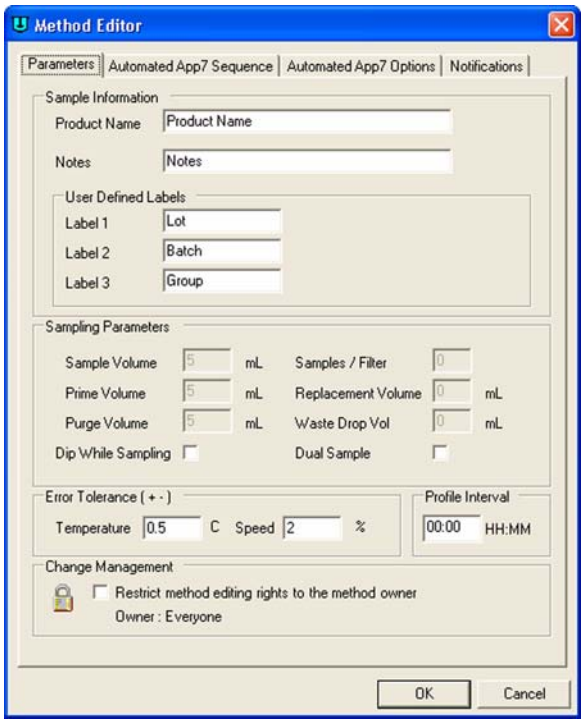
Step 1. From the navigation bar, click **Editor**. The Methods screen displays.

FIGURE 25. Methods screen



Step 2. Click **New Method**. The Method Editor screen displays.

FIGURE 26. Method Editor screen



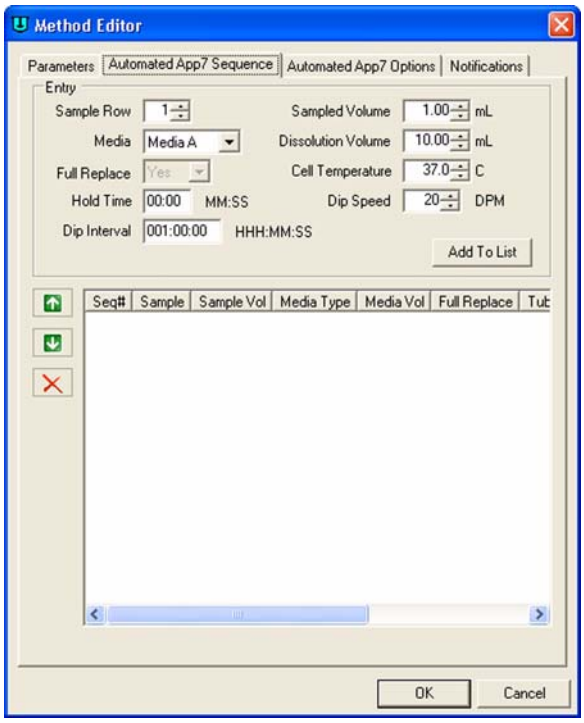
Step 3. Select the **Parameters** tab.

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.
Error Tolerance (±)	Temperature	Enter the desired temperature fluctuation limit (±). If the tube temperature goes over or under the set temperature (see "Verifying the Cell Temperature" on page 67) by the amount of this tolerance, an error is recorded as part of the results.
	Speed	Enter the desired speed fluctuation limit (±). If the RPM goes over or under the set speed (see "Reciprocation" on page 68) 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 4. Select the **Automated App7 Sequence** tab (see Figure 27, "Automated App7 Sequence tab," on page 73).

FIGURE 27. Automated App7 Sequence tab



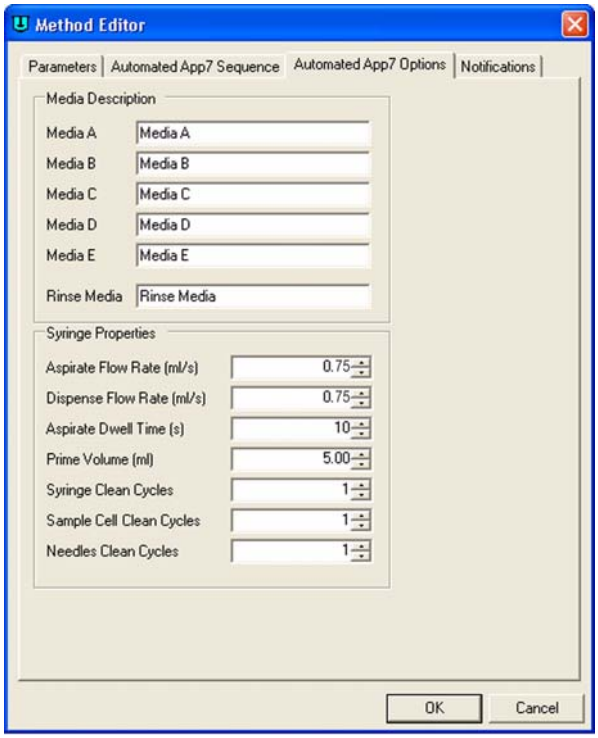
Following is a description of the Automated App7 Sequence tab options:

Option	Description
Sample 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.
Media	Use the drop-down arrows to indicate Media A, Media B, Media C, Media D, or Media E.
Sampled Volume (mL)	Use the up and down arrows to indicate appropriate volume based on your vial size.
Dissolution Volume (mL)	Use the up and down arrows to indicate appropriate volume based on your cell size.

Option	Description
Cell Temperature	Enter the desired tube temperature in degrees Celsius. This can be entered for the first timepoint.
Hold Time (mm:ss)	Enter the desired duration for the dip to remain at the bottom of the stroke in mm:ss format.
Dip Speed (DPM)	Use the up and down arrows to indicate the desired dips per minute (DPM) for each applicable row of the 400-DS.
Dip Interval (hhh:mm:ss)	Enter the desired duration for dipping in hhh:mm:ss format.

Step 5. Select the **Automated App7 Options** tab.

FIGURE 28. Automated App7 Options tab

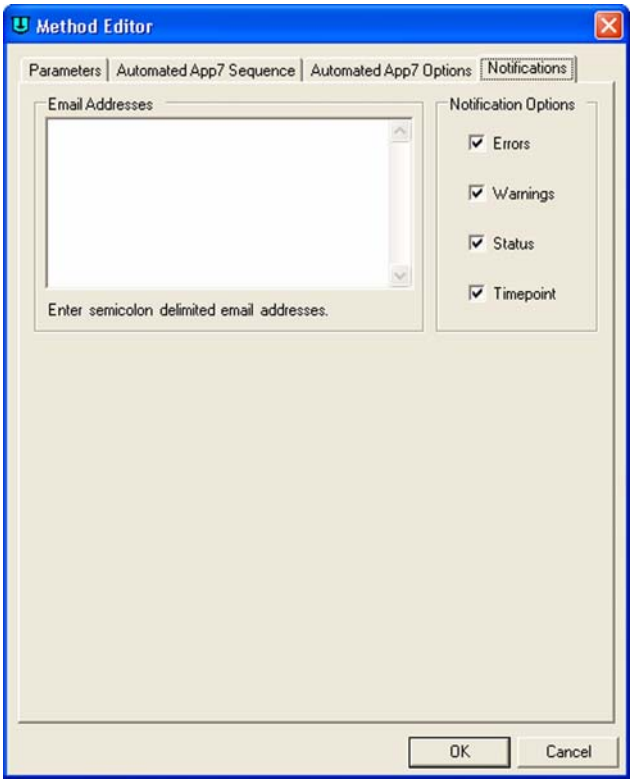


Following is a description of the Automated App7 Options tab options:

Screen Section	Parameter	Description
Media Description	Media A Media B Media C Media D Media E Rinse Media	Enter descriptions as appropriate for the different medias.
Syringe Properties	Aspirate Flow Rate (mL/s)	Use the up and down arrows to indicate the rate at which the media is pulled into the syringe.
	Dispense Flow Rate (mL/s)	Use the up and down arrows to indicate the rate at which the media is dispensed from the syringe.
	Aspirate Dwell Time (s)	Use the up and down arrows to indicate the duration of time the plunger holds at the top of the stroke before dispensing. **Note: The time specified is for full syringe volume. For smaller syringe volumes, it is calculated proportionately.**
	Prime Volume (mL)	Use the up and down arrows to indicate the volume to be pulled before taking measurement.
	Syringe Clean Cycles	Use the up and down arrows to indicate the number of times to rinse the syringe between samples.
	Sample Cell Clean Cycles	Use the up and down arrows to indicate the number of times to rinse the sample cell between samples.
	Needles Clean Cycles	Use the up and down arrows to indicate the number of times to rinse the needles between samples

Step 6. Select the **Notifications** tab (see Figure 29, "Notifications tab," on page 76).

FIGURE 29. Notifications tab



Step 7. Enter appropriate e-mail address(es) to receive notification of system operation.

Step 8. Indicate which options would require notification.

Step 9. Click **OK** to close the Method Editor screen.

Step 10. Close the Methods 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 25, "Methods screen," on page 70).

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" on page 78.

Deleting Methods

To delete a method, complete the following steps:

Step 1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 25, "Methods screen," on page 70).

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 400-DS Workstation, complete the following steps:

Step 1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 25, "Methods screen," on page 70).

Step 2. Click the desired method.

Step 3. Click **Properties** on the navigation bar. The Method Editor screen displays (see Figure 26, "Method Editor screen," on page 71).

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 25, "Methods screen," on page 70).

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 25, "Methods screen," on page 70).

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 25, "Methods screen," on page 70).

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 400-DS Workstation on a different 400-DS 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 25, "Methods screen," on page 70).

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 400-DS Workstation, complete the following steps:

Step 1. From the navigation bar, click **Editor**. The Methods screen displays (see Figure 25, "Methods screen," on page 70).

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

Note

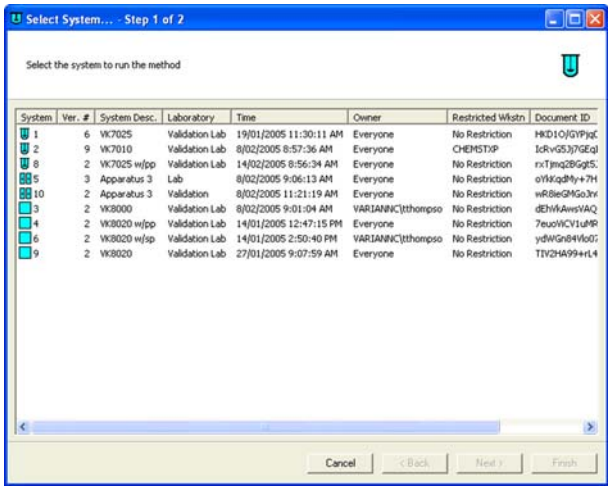
Alternately, you can right-click the desired method and select Import. The Import Method from XML File screen displays as a result of either of these actions.

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

Running the Method

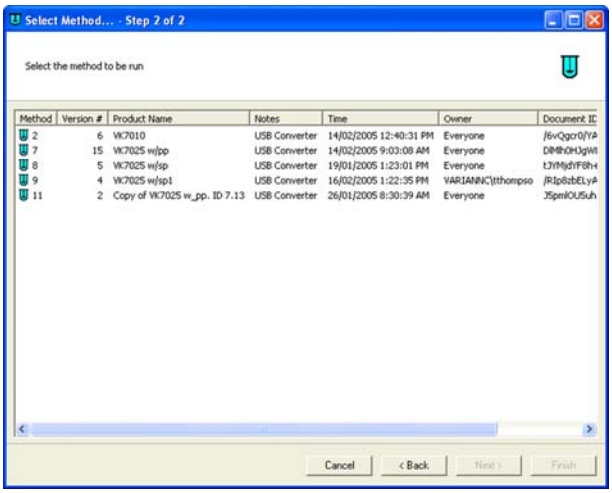
Step 1. From the navigation bar, click **Run Method**. The Select System Step 1 of 2 screen displays (see Figure 30, "Select System Step 1 of 2 screen," on page 82).

FIGURE 30. Select System Step 1 of 2 screen



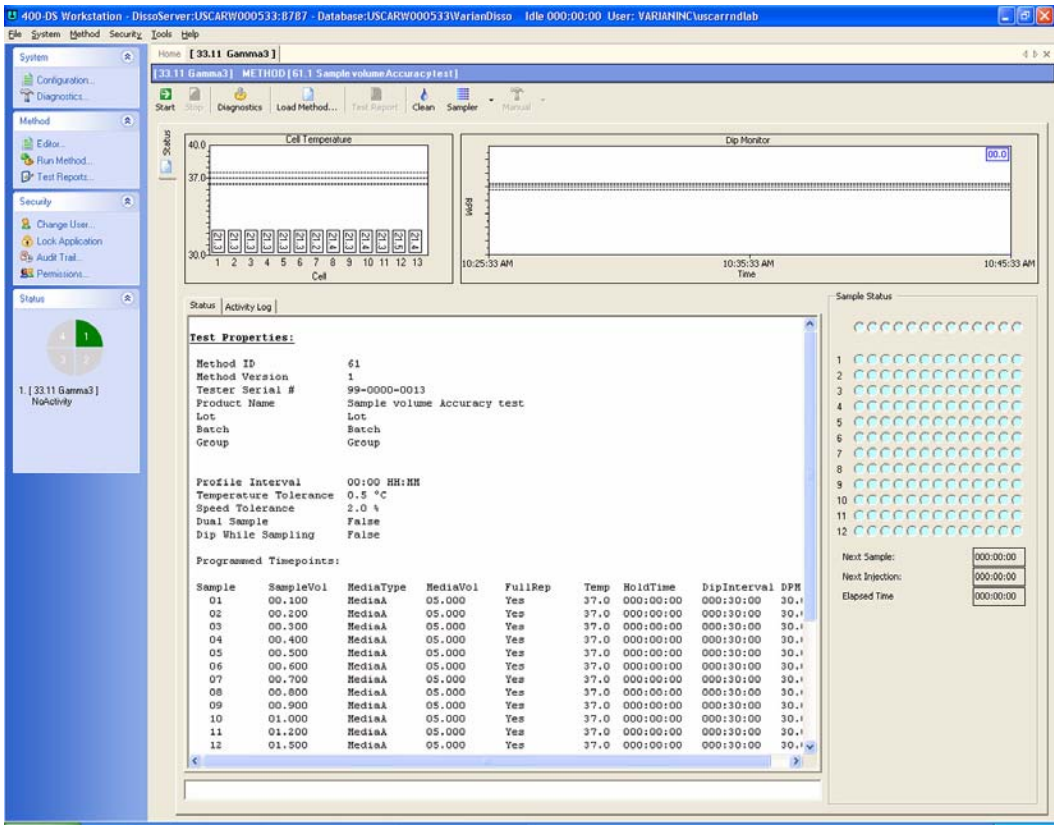
Step 2. Select the desired system to run the method and click **Next**. The Select Method Step 2 of 2 screen displays.

FIGURE 31. Select Method Step 2 of 2 screen



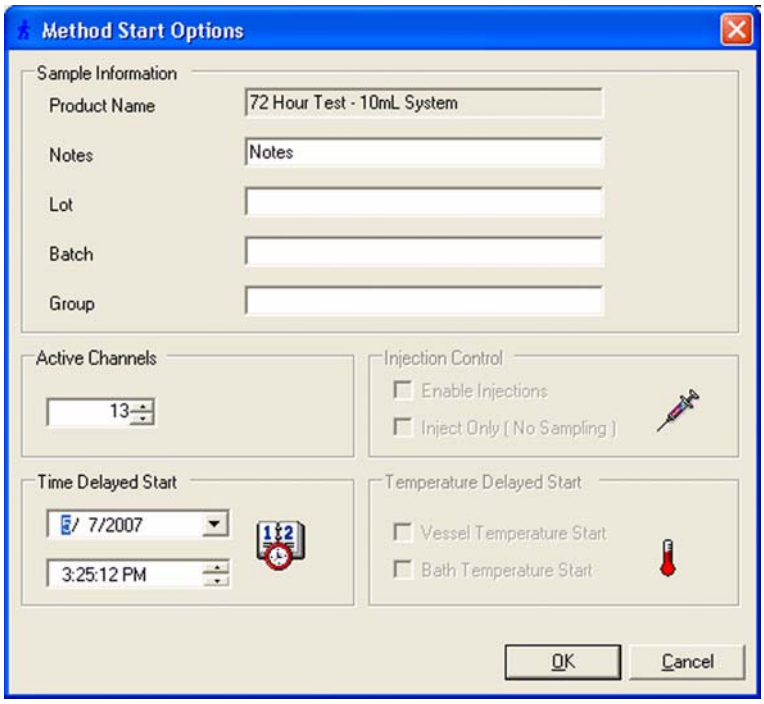
Step 3. Select the desired method to run and click **Finish**. The system status screen displays.

FIGURE 32. System status screen



Step 4. Click **Start**. The Method Start Options screen displays (see Figure 33, "Method Start Options screen," on page 85).

FIGURE 33. Method Start Options screen

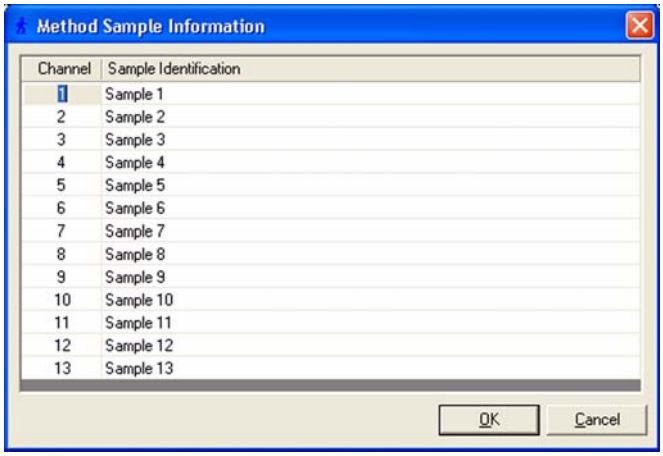


Following is a description of the Method Start Options screen options:

Screen Section	Parameter	Description
Sample Information	Product Name	Enter the product name.
	Notes	Enter any appropriate notation.
	Label 1	Enter the appropriate information based on the user-defined labels (see "User Defined Labels" on page 72).
	Label 2	
	Label 3	
Active Channels		Enter the number of active heating channels. **Note: Heating channels are counted from left to right.**

Screen Section	Parameter	Description
Injection Control	Enable Injections	N/A
	Inject Only (No Sampling)	
Temperature Delayed Start	Vessel Temperature Start	N/A
	Bath Temperature Start	
Time Delayed Start		Use this option to program a delayed start. Enter the desired date and time to start the method.

Step 5. Click **OK**. The Method Sample Information screen displays.



Step 6. Enter the sample information, if applicable.

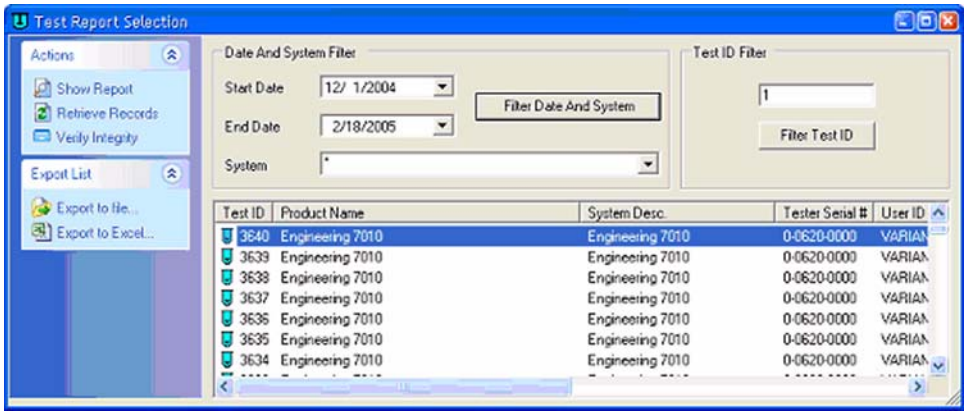
Step 7. When the method is complete, click **Test Report**. The test report displays. The report can be printed, exported, searched, verified, and/or signed.

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 34. 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**.

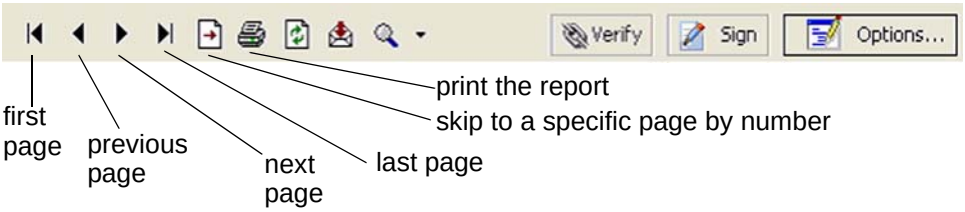
Additionally, you can select a system name from the **System** combo box to restrict the selection to a particular system.

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 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

. All instruments initialize. Media is pulled from the Rinse Media Container and cells are filled and expelled through the valves. The cells are aspirated and purged.

Chapter 5 Maintenance

Periodic Maintenance

Warning

The tester contains electrical circuits, devices, and components operating at dangerous voltages. Contact with these circuits, devices, and components can cause death, serious injury, or painful electric shock.

Warning

The apparatus should be disconnected from AC power before conducting cleaning or maintenance.

Periodic maintenance intervals may vary depending on frequency of instrument usage.

Routine Maintenance (to be Performed Between Each Dissolution Method

- All parts of the 400-DS exposed to the dissolution medium should be cleaned after each use. Parts made from stainless steel are particularly susceptible to surface corrosion if not cleaned immediately after use. If any stainless steel parts show signs of surface discoloration, lightly wipe the surface with a soft cloth or nonabrasive pad to remove it.
- Execute the Clean System cycle using the 400-DS Workstation software ("Clean System" on page 88). Ensure an appropriate cleaning solution is in place to thoroughly rinse the media lines and sample cells.
- If an alternate cleaning solution is used, it is recommended that all the media lines are rinsed with deionized water at the end of the cleaning procedure.

Sample Holders

- Clean sample holders thoroughly after each use and place them in an ultrasonic bath for a few minutes, if necessary.
- When using corrosive materials such as hydrochloric acid or medium containing salts, be sure to rinse the holders with deionized water immediately after use. Dry completely with a soft towel or cloth (preferably lint-free).
- Do not clean the sample holders with abrasive cleansers or cloths. Use deionized water whenever possible. If you must use cleanser or solvent, be sure that it is as mild as possible, non-abrasive, and fully compatible with fluorocarbons and stainless steel before use.
- It is suggested that the sample holders are cleaned by hand. Use of a laboratory dishwasher is NOT recommended.
- Handle with care at all times.
- Store the sample holders properly between each use.

Non-Routine Maintenance (to be Performed at Pre-Determined Intervals)

It is recommended that the following procedures be performed by a properly trained service technician.

- Remove and inspect all sample cells for signs of damage. Replace as necessary. Clean the sample cells thoroughly, especially the area that typically covers the seal.
- Clean the entire external surface of the instrument including top cover and syringe pump window.
- Inspect and clean the air filter(s). Replace if necessary.
- Inspect all sample cell holder seals. Re-grease the o-rings, if necessary, using a pre-approved lubricant (e.g. Krytox®). Replace any o-rings that appear dried or cracked.
- Inspect all external media lines. Replace if necessary.
- Check the magnet plate for free play.
- Check the evaporation mechanism for free play.
- Inspect the evaporation cover seals.
- Remove, inspect, and clean the needles. Place them in an ultrasonic bath for a few minutes, if necessary.
- Verify the following limit switch/alarm operations: home position, top cover (open/close), front door, and sample tray (lift empty sample row). See "Verifying Sample Tray Control" on page 65.
- Verify proper operation of all LEDs (4 total).

Open the front door (sample tray compartment) of the Varian 400-DS.

- Lubricate reciprocation slide rail using a pre-approved lubricant. Using the Diagnostics portion of the software ("Manual Control/Diagnostics" on page 64), move the sample tray from row to row to work in the lubricant.
- Inspect the front door bumper.
- Inspect waste line (front view).

Power OFF the 400-DS and disconnect the power cord. Remove the back cover of the 400-DS to perform the following:

- Lubricate the ball screw on syringe pump.
- Lubricate all moving pieces of syringe pump.
- Inspect the main drive belt.
- Inspect/clean the waste row.
- Inspect/clean the waste tubing.
- Inspect all internal stainless steel components for signs of discoloration. Lightly wipe the surface with a soft cloth to remove, if necessary.
- Lubricate the main rails.
- Inspect the waste line (rear view).
- Check lift blocks for free play.

Chapter 6 Service and Warranty

The warranty is provided by Varian, Inc. or one of its authorized representatives.

Service and Warranty Information

Varian dissolution products carry a one-year warranty on parts and labor. The Dissolution Systems Service Department (or one of its representatives) will, at its option, either repair or replace any mechanical and electrical components in your instrument which prove to be defective. During the first year of warranty coverage, there is no charge for the labor to repair your unit. The Dissolution Systems Service Department (or one of its representatives) will determine the best site to repair the unit, either onsite or returned to Varian, Inc. Any onsite warranty services are provided only at the initial installation point. Installation and onsite warranty services are available only in Dissolution Systems service travel areas.

Exclusions and Limitations

Excluded from this warranty are expendable or consumable items such as, but not limited to, paddles, baskets, vessels, and acrylic water baths. Also excluded are defects from improper or inadequate maintenance by the customer, user-induced chemical action or contamination, unauthorized modification or misuse, and improper site preparation and maintenance.

Operation of software is not warranted to be uninterrupted or error-free.

Obtaining Warranty Service

To obtain warranty service in the United States, contact the Dissolution Systems Service Department at 800.229.1108 to obtain authorization to return units for repair. At the option of the customer, onsite warranty service is available, but travel charges may be incurred. The customer should prepay all shipping charges for products returned to the Dissolution Systems Service Department (unless otherwise authorized), and Varian, Inc. will pay all charges for return to the customer.

Warranty Limitations

Varian, Inc. makes no other warranty, either express or implied, with respect to this product. Specifically disclaimed are any implied warranties of merchantability and fitness for a particular use. In no event will Varian, Inc. be liable for any indirect, incidental, or consequential damages arising from the use of this product. This warranty gives you specific legal rights which may vary from state to state or province to province, so you may have other rights and some of these exclusions may not apply to you.

Exclusive Remedies

The remedies provided herein are the customer's sole and exclusive remedies. In no event shall Varian, Inc. or its representatives be liable for any direct, indirect, special, incidental, or consequential damages, whether based on contract, tort, or any other legal theory. Some states or provinces do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

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