Agilent

280-DS (G7980AA) Mechanical Qualification System

Operator's Manual

Notices

Manual Part Number

70-9071 Rev D
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CAUTION

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Content

1 Safety

Notes, Cautions, and Warnings

Warning

WARNING

A 'Warning' message appears in the manual when failure to observe instructions or precautions could result in death or injury.

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

Caution

CAUTION

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

Note

NOTE

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

Information Symbols

Indicates single-phase alternating current

Indicates the product complies with the requirements of one or more European Union (EU) directives.

Indicates specific equipment meets standards of safety. 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.

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2 Introduction

The 280-DS Mechanical Qualification System (MQS) is a device which measures the critical physical parameters of a dissolution apparatus. A Windows®-based software interface captures data from and communicates through USB with two independent modules that comprise the physical part of the device. A hand-held temperature probe is included as an additional accessory.

The 280-DS MQS is capable of measuring the following parameters on a 1-liter dissolution apparatus: vessel plate level and vibration, bath or vessel temperatures, paddle or basket height, spindle shaft centering, spindle shaft verticality, spindle shaft wobble, spindle shaft speed (RPM), vessel verticality, and basket rim wobble.

The software interface, which is designed to run on Microsoft Windows 7 or 10 (32-bit and 64-bit), implements controls for the Electronic Records and Electronic Signatures Rule (21 CFR Part 11) established by the FDA. The interface also supports the mechanical qualification tests required by the ASTM, USP, Chinese Pharmacoepeoia and US FDA standards bodies for USP Apparatus 1 (Basket) and 2 (Paddle) dissolution apparatus.

3 Setting Up the 280-DS

Unpacking Your Equipment

The 280-DS consists of the Instrument Module (IM), Vessel Module (VM), temperature probe, module intercommunication cable, USB cable, and RPM magnetic clip, all packaged in a rugged, compression-resistant case.

A Windows-based PC running the 280-DS Workstation software powers and is connected to the Instrument Module (IM) with a USB cable. The IM connects to the Vessel Module (VM) through the module intercommunication cable. The VM is inserted into the vessel for all position-specific measurements. The IM is placed on an applicable flat surface (e.g., the vessel plate) and provides the temperature-probe interface.

Prior to use:

1. Remove all system components from the packing material.
2. Inspect the equipment and accessories to ensure there has been no damage during shipment.
3. Place the base unit and accessories on a clear, dry, level section of the bench top close to the dissolution apparatus.

280-DS Components

Vessel Module

The Vessel Module (VM) measures rotational speed, basket/shaft wobble, vessel centering, shaft verticality, vessel verticality, and basket/paddle height. Once properly positioned, this module provides reliable, repeatable measurements using innovative sensing technology.

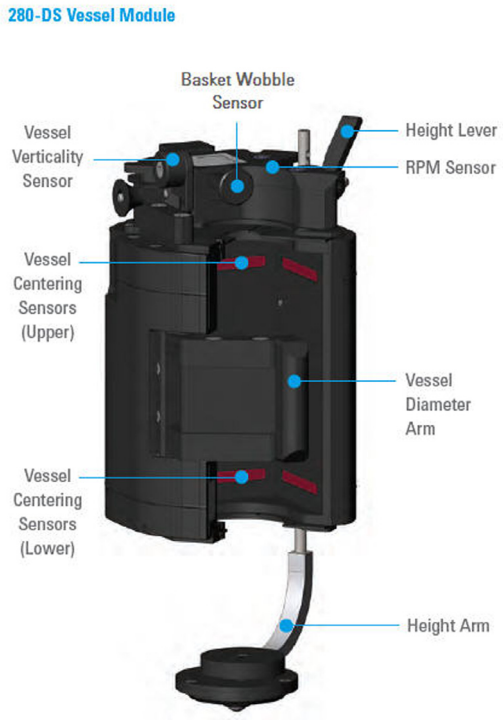

Figure 1. Vessel Module

Instrument Module

The 280-DS Instrument Module (IM) is used to record vessel plate level (x- and y-axis) and vibration (x-, y-, and z-axis) while also acting as a hub for the Vessel Module, temperature probe, and connection to the PC. Quantitative values for each parameter are recorded and visible in real-time via the software interface.

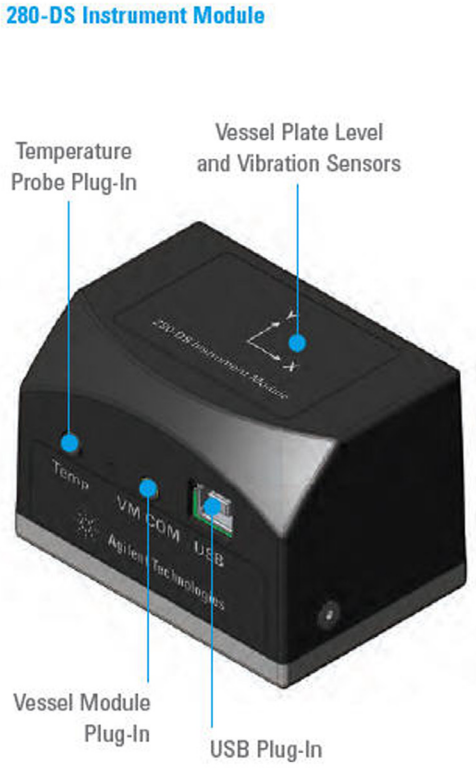

Figure 2. Instrument Module

Magnetic Clip

The magnetic clip is used in conjunction with the magnetic tachometer sensor to measure RPM. Each time the magnet passes the sensor, one rotation is counted.

Figure 3. Magnetic Clip

Temperature Probe

The temperature probe is used to verify the accuracy of the water bath and vessel temperature probes on the dissolution apparatus. It can also be used to record individual temperatures prior to beginning a dissolution test.

Figure 4. Temperature Probe

Setting up the 280-DS

Cable Connections

1 Connect the USB cable from the USB port on the Instrument Module to a USB port on the measurement computer.

2 Connect the 280-DS Vessel Module to the Instrument Module via the module intercommunication cable.

3 Optionally, connect the measurement computer to the dissolution apparatus using a 9/25 pin RS-232 cable (**"Preparing the Dissolution Apparatus"** on page 42).

NOTE

The online testing mode provides direct communication between the dissolution apparatus and the 280-DS Workstation software. This feature is only available for Agilent, Varian, or VanKel dissolution apparatus models.

For PCs without a 9-pin serial port, a USB-to-Serial adapter may be configured and used to communicate with the dissolution apparatus.

Power Cord Connections

1 Connect or verify connection of the AC power cord between the power receptacle on the PC and an AC electrical supply of the appropriate voltage. If using a laptop, the 280-DS can also be used when the laptop is on battery power.

NOTE

Please ensure your computer's battery is appropriately charged before using the 280-DS on battery power. The 280-DS draws power from the computer connected to it and will drain the battery faster than normal.

2 Connect or verify connection of the AC power cord between the power receptacle on the dissolution apparatus and an AC electrical supply of the appropriate voltage.

3 Turn on the PC and dissolution apparatus.

Requirements and Configuration

Environmental Requirements for Use

- Humidity: max relative humidity 75% non-condensing
- Indoor use only
- Temperature: 10 ºC to 35 ºC

PC Requirements

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

- 1.5 GHz or faster Pentium 4 processor
- 1 GB of RAM or more
- 16X CD-ROM drive
- 1 USB port (minimum)
- 10 GB of space on the hard drive
- 1280 x 960 at 16M colors (minimum)
- Windows 7 or 10 (32-bit or 64-bit) operating system

Software Installation

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

NOTE If Windows User Access Control (UAC) displays during the installation process, click **Allow** to continue installation.

1 Insert the 280-DS Workstation CD and access the files contained on the CD.
2 Execute **setup.exe** and follow the on-screen prompts.

NOTE When asked if you want to install the Microsoft .Net Framework, you are required to click Yes.

Upgrading 280-DS Workstation

1 Back up the original/current database using MSDE Manager (see **"Backing up the Database"** on page 93). Store this backup file in a safe location.
2 Log on to the PC as user with Administrator privileges.
3 Launch **setup.exe** from the 280-DS Workstation installation media and follow the instructions on screen.

Post-upgrade Cleanup Steps (Optional)

NOTE The following steps are not required to run the 280-DS Workstation software, but they will remove unnecessary programs and free some disk space on the computer.

1 Go to **Control Panel** > **Programs** > **Programs and Features**.
2 Select **Microsoft SQL Server 2005** and click **Uninstall**. Follow the on-screen instructions to remove this program.

Migrating 280-DS Data to different PC

NOTE

To move 280-DS Workstation software and data to another PC and use the latest version, you have to upgrade the previous/current installation first and then move the data to the new computer.

1. For a clean installation (e.g. no previous version of the software exists on the PC) of 280-DS Workstation, launch setup.exe from the installation media and follow the instructions on screen.
2. Back up the original/current database using MSDE Manager (see **"Backing up the Database"** on page 93). Store this backup file in a safe location.
3. On the original computer launch **setup.exe** from the installation media of the new version of 280-DS Workstation and follow the instructions on screen.
4. After upgrading 280-DS Workstation on the old computer, go to **Programs** > **Agilent** > **Dissolution** > **MSDE Manager** to create another backup of this database.
5. Transfer this database backup file (.bak) to the new computer (e.g. via USB stick).
6. On the new computer go to **Programs** > **Agilent** > **Dissolution** > **MSDE Manager** to restore the database.

CAUTION

This step will delete any data in the database of the new computer.

NOTE

It is not possible to merge data from two previously created databases.

Local Security Policy

NOTE

For 21 CFR Part 11 compliance purposes (physical requirement section 11.300 b), you must ensure that the following minimum requirements are met by your system's security policy.

Internal IT requirements may differ from the settings outlines in this section. It may be necessary to coordinate this configuration with the domain controller.

1. Click **Start** > **Run**.
2. Type secpol.msc and click **Enter** to run the Local Security Settings Manager. The Local Security Settings screen displays.
3. Click **Security Settings** > **Account Policies** > **Password Policy** and set the applicable security policy configuration.

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

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

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

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

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

Starting 280-DS Workstation

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

Starting 280-DS Workstation

1 Double-click the **280-DS Workstation** icon on the Windows desktop to start the software.

2 If your system has Windows Firewall enabled, the Windows Security Alert screen displays. Click **Unblock** to enable the program.

280-DS Workstation Logon

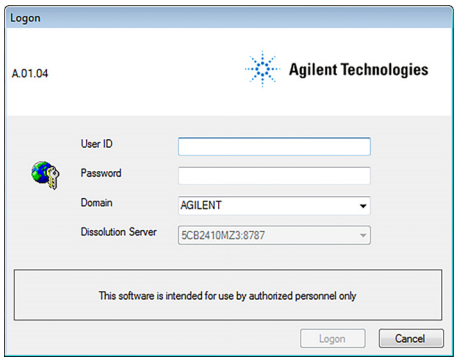

Figure 5. Logon

1 From the logon screen, enter your credentials in the User ID and Password boxes.

2 Click **OK**.

3 Click **Logon** to initiate the software.

Adding Users to the Application

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

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

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

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

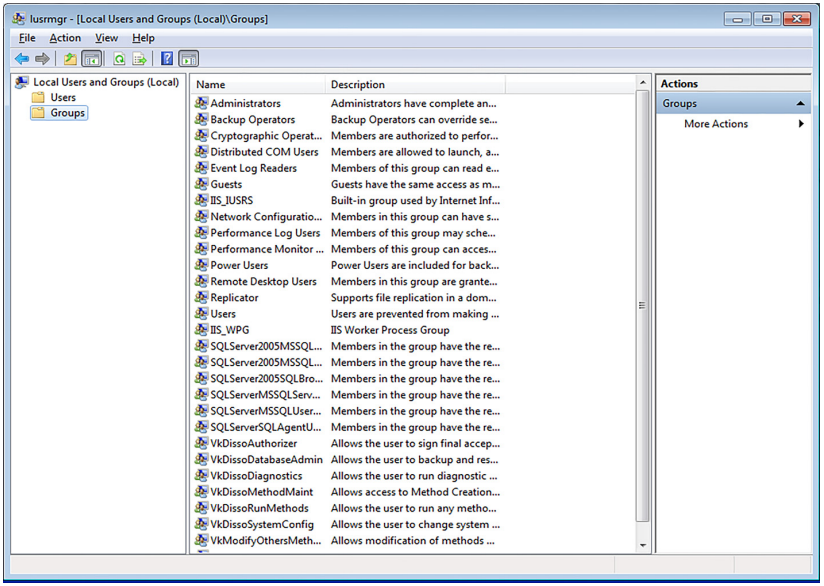

Figure 6. Local Users and Groups

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

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

5 To add a user to a group, click **Add...** from the respective group screen. The Select Users, Computers, Services Accounts, or Groups screen displays.

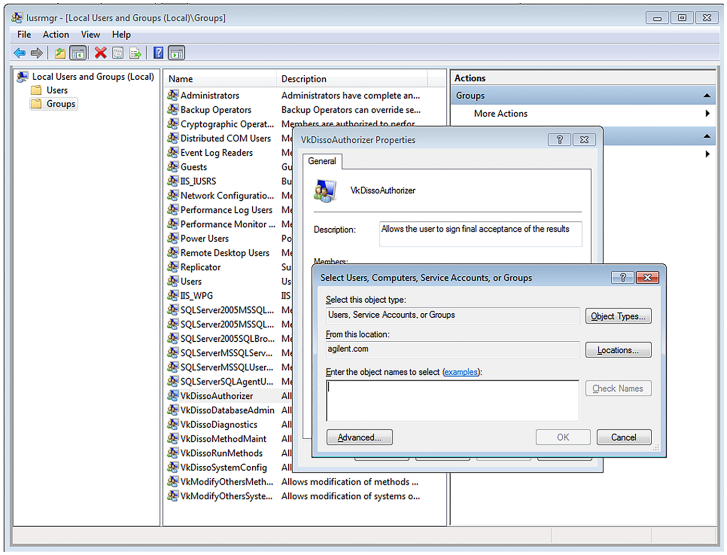

Figure 7. Adding a User

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

7 Close the Local Users and Groups screen.

8 Click **OK** to close the Configuration Dialog screen.

4 Operating the 280-DS

280-DS Workstation Logon

1 Double-click **280-DS Workstation** icon. The Logon screen displays.

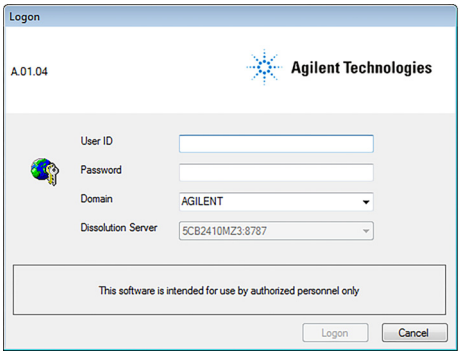

Figure 8. Logon

2 Enter your Windows credentials in the User ID and Password boxes.

3 Verify the domain and the dissolution server are correct and click **Logon**. The 280-DS Workstation screen displays:

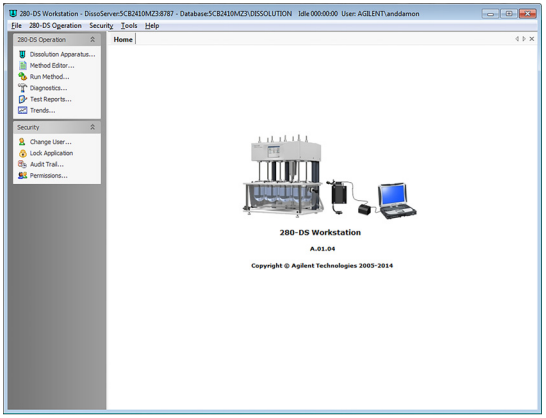

Figure 9. 280-DS Workstation Homescreen

The following options are available in the navigation bar on the 280-DS Workstation homescreen:

Option	Function
Dissolution Apparatus	Create a file for each dissolution apparatus. All relevant data including configuration and component serial numbers are stored within this file. See "Dissolution Apparatus" on page 30..
Method Editor	Create a test method to define parameters to be measured and their respective tolerances. See "Method Editor" on page 36..
Run Method	Begin a test using previously created apparatus and method. See "Run Method (Method Execution)" on page 41..
Diagnostics	Verify communication or view real-time data from the modules. See "Diagnostics" on page 78..
Test Reports	Search and retrieve previously executed tests based on various filtered criteria. See "Test Reports" on page 82..
Trends	Create custom reports showing performance over time for a particular dissolution apparatus, operator, or date range. See "Trends" on page 85..
Change User	Log on to the 280-DS Workstation software as a different user. See "Change User" on page 87..
Lock Application	Lock the 280-DS Workstation software. See "Lock Application" on page 87..
Audit Trail	Verify, filter, or create reports of logon information for the 280-DS Workstation software. See "Audit Trail" on page 88..
Permissions	View the rights and privileges for the current user of the 280-DS Workstation software. See "Permissions" on page 89..

280-DS Operation

Dissolution Apparatus

Click **Dissolution Apparatus** from the 280-DS Workstation homescreen to add or edit the dissolution apparatus being used for 280-DS test methods.

Option	Function
Create	Displays the Dissolution Apparatus editor screen to create a new dissolution apparatus entry.
Delete	Deletes the selected dissolution apparatus from the viewable list.
Report	Displays a summary report for the selected dissolution apparatus.
Properties	Displays the current settings for the selected dissolution apparatus.
Recover Deleted	Allows you to recover deleted dissolution apparatus which can be selected from a list of deleted items.
Show Audit Trail	Displays a list of all revisions to a specific dissolution apparatus with the ability to compare multiple versions and view the differences. **Note:** To create a report detailing version changes, highlight the desired versions (by clicking and holding the **CTRL** key) and click **Differences**.
Verify Integrity	Verifies that the data for the dissolution apparatus was not altered outside of the application.

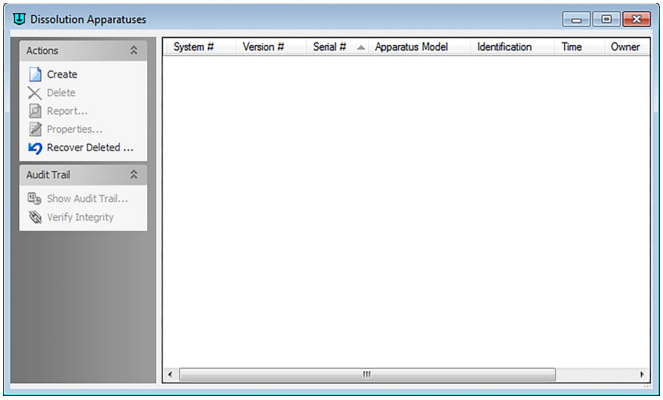

Figure 10. Dissolution Apparatuses

1 Click **Create** to enter a new instrument or, simply double-click an existing apparatus file to open the Configuration Editor and edit its current conditions.

NOTE

If an Agilent dissolution apparatus is connected to the computer, you can import its serial number and identification information by clicking **Download**.

2 Enter the applicable identification information for the dissolution apparatus in the provided fields.

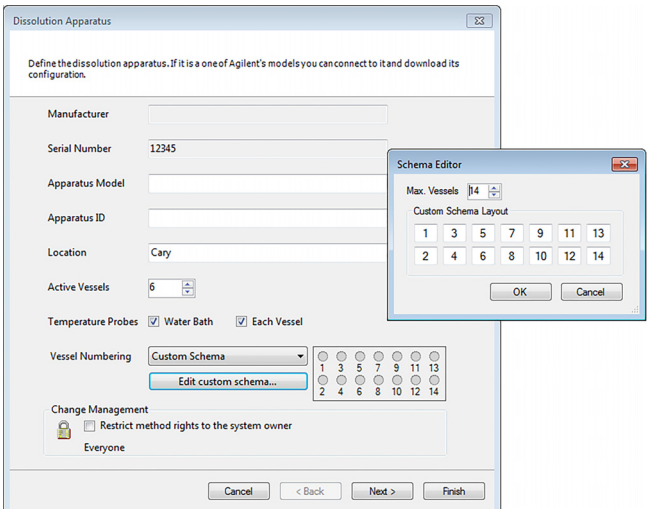

Figure 11. Identification Information

Option	Function
Manufacturer	Manufacturer of the dissolution apparatus.
Serial Number	Serial number associated with the dissolution apparatus.
Apparatus Model	Model number of the dissolution apparatus.
Apparatus ID	Any internal identification associated with the apparatus.
Location	Location of the dissolution apparatus.
Vessels	Number of vessels (between 1 and 14).
Temperature Probes	Specify temperature-measuring devices: bath and/or vessel.
Vessel Numbering	Available vessel-numbering schema (numbering) options.
Edit Custom Schema	If **Custom Schema** is selected from the drop-down options, you can click here to specify the number of vessel positions and how they should be numbered.
Change Management	Check the **Restrict method editing rights to the system owner** box to protect the method from outside editing.

3 Click **Next** to proceed to the next screen where you can enter the applicable shaft diameters.

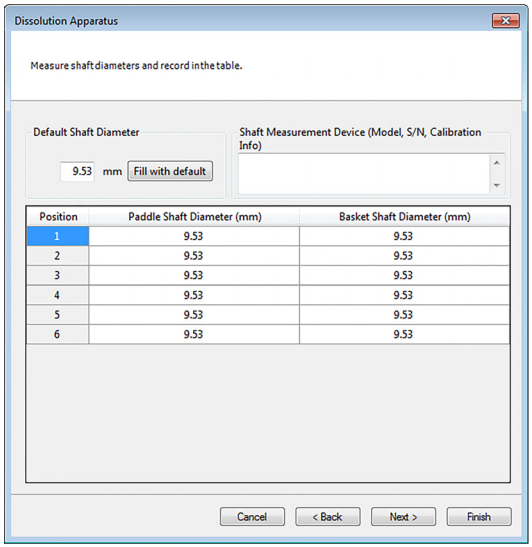

Figure 12. Dissolution Apparatus Shaft Diameters

Option	Function
Default Shaft Diameter	Enter the value manually and press **Fill with default** to fill the fields with the entered value. You can also enter each shaft diameter individually.
Shaft Measurement Device	Enter the model, serial number, and calibration information associated with the measurement device (e.g., caliper) used.

4 Click **Next** to proceed to the following screen where you can record serial numbers for any attachable parts such as baskets, paddles, shafts, vessels, or spin on/off shafts.

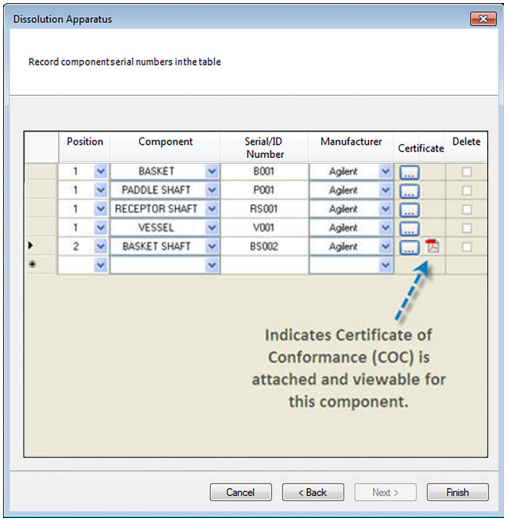

Figure 13. Component Serial Number

Option	Function
Position	Select a Position from the drop-down list (1 - 8).
Component	Select a Part Type from the drop-down list (Basket Shaft, Basket, Paddle Shaft, Receptor Shaft, Vessel).
Serial Number	Enter the serial number for the associated part.
Manufacturer	Enter the manufacturer of the accessory or select from the available options of the drop-down list.
Certificate	Click "..." to upload and link a certificate of conformance to the specified accessory. This file may be a .pdf, .doc, or image file (.jpeg, .gif, .bmp, .png).
Delete	Place a check in this box and confirm deletion to remove the specified component.

5 If you have made any changes, then upon completion of the wizard, you will be asked to explain or provide a reason for the change to comply with 21 CFR Part 11.

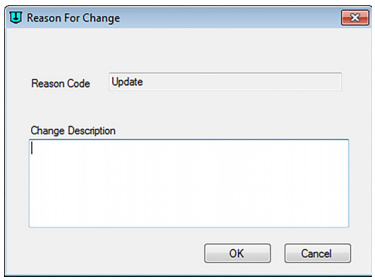

Figure 14. Reason for Change

NOTE

You can click **Cancel** at any time and no changes will be saved. You can also click **Finish** at any time to skip remaining steps.

Method Editor

From the 280-DS Workstation homescreen, click **Method Editor** to access the Test Methods screen.

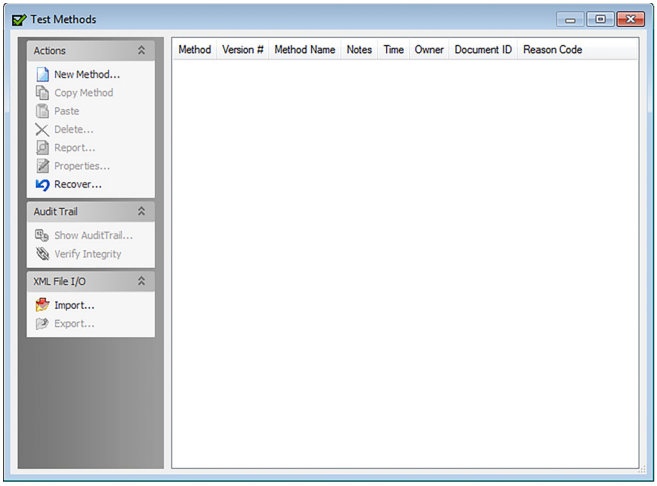

Figure 15. Test Methods

1 If an existing method is displayed in the list, double-click the entry to open the Method Editor. When editing a method, previously saved information displays in the fields.

2 If the list is blank, click New Method to enter a new method.

Option	Function
New Method	Displays the Method Editor screen.
Copy Method	Prepares the selected method to be copied.
Paste	Copies the selected method by creating a new method with the product name of the original method with the prefix *Copy of* before the file name.
Delete	Deletes the method from the viewable method list.
Report	Displays a printable summary of a particular method version.
Properties	Opens the selected method for editing.
Recover	Recovers deleted methods from the database.
Show Audit Trail	Displays a list of all of the revisions of the method. This allows you to compare two versions of a method and view the differences between them. **Note:** To create a report detailing version changes, highlight the desired versions (by clicking and holding the **CTRL** key) and click **Differences**.
Verify Integrity	Verifies that the method data has not been changed outside of the application.
Import	Imports an existing method into the Test Methods list.
Export	Exports a particular version of the selected method as an XML file.

Method Editor General Tab

1 Double-click a method or single-click a method and click **Properties** to open the Method Editor. The General tab is displayed by default.

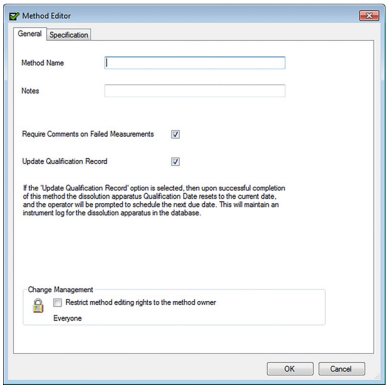

Figure 16. Method Editor General Tab

Option	Function
Method Name	Enter a method name.
Notes	Enter any applicable notes associated with the method.
Require Comments on Failed Measurements	When this option is enabled, you will be required to enter a comment when a value is acquired outside of the parameter specifications.
Update Qualification Record	When this option is selected, upon successful completion of the method, the dissolution apparatus qualification date is reset to the current date and you are prompted to schedule the next due date. An instrument log is maintained for the dissolution apparatus in the database.
Change Management	Check the **Restrict method editing rights to the method owner** box to protect the method from outside editing.

Method Editor Specification Tab

1 Click the **Specification** tab. The Specification page provides the list of available tests and fields for entering specification limits and or nominal values. Many default specifications (e.g., USP, FDA, ASTM) are available for your convenience. The pre-entered options will change and/or will be grayed out depending on your configuration.

2 Edit the default specifications by clicking on each one and modifying the values. If any adjustment is made to the pre-loaded specifications, Custom will display as the Compliance Specification. Place a check in the **n/a** box to exclude that test from the method.

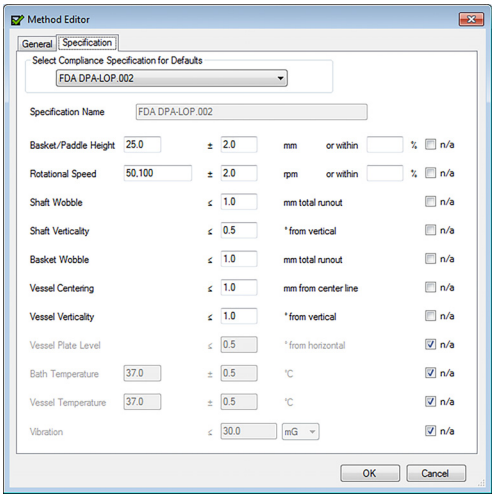

Figure 17. Specification Tab

NOTE Separate additional RPMs in the Rotational Speed box by using a comma, space, or semicolon.

3 You can click **OK** or **Cancel** on any page of this sequence. If you have changed the method, you will be asked for a reason for the change. After you enter a reason for the change, the method data, new or modified, is saved to the database. If you created a new method, the method version will be indicated by the number 1. If you modified a method, its version will be increased by 1

instead.

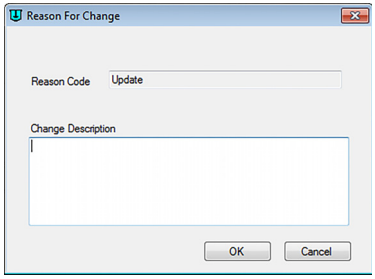

Figure 18. Reason for Change

NOTE

You can click the **Cancel** at any time and no changes will be saved.

Run Method (Method Execution)

From the 280-DS Workstation homescreen, click **Run Method** to run a method.

Select Test Method

The illustration in the figure below depicts the connection between the 280-DS modules and the PC.

1 Ensure the 280-DS IM and VM cables are connected.

2 Click **Next** to open the connection.

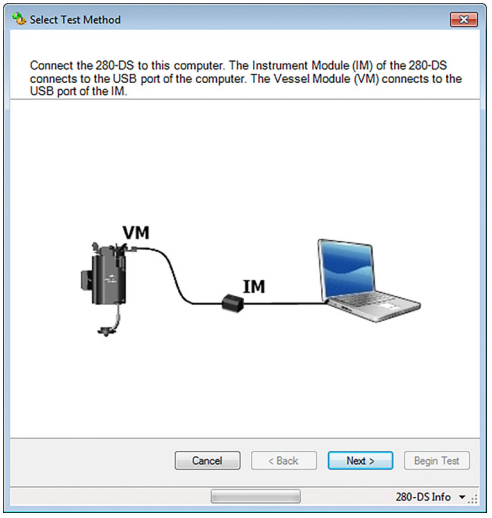

Figure 19. Select Test Method

Preparing the Dissolution Apparatus

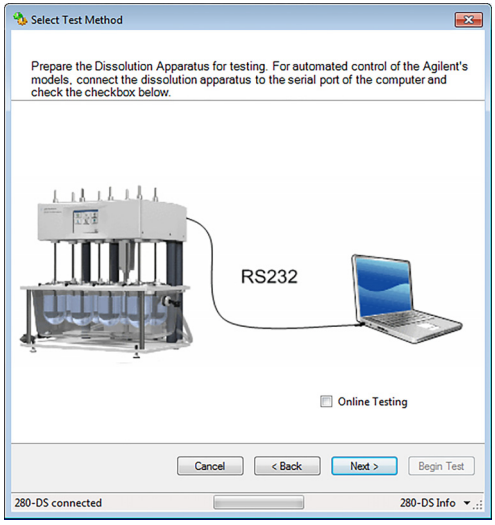

Figure 20. Prepare the Dissolution Apparatus

The preparation screen allows you to select either online (connected to an Agilent, Varian, or VanKel dissolution apparatus) or offline testing.

1 Select **Online Testing** or leave it unchecked.

NOTE

If Online Testing is enabled, the software will search for an available dissolution apparatus. If this option is left disabled, you will be prompted to select the Dissolution Apparatus from the list of existing configurations. Online Testing is only available with Agilent and supported Varian or VanKel dissolution apparatus.

2 Click **Next** to continue.

Selecting the Dissolution Apparatus

1 Select the dissolution apparatus to be measured, if applicable.

2 Click **Next** to continue.

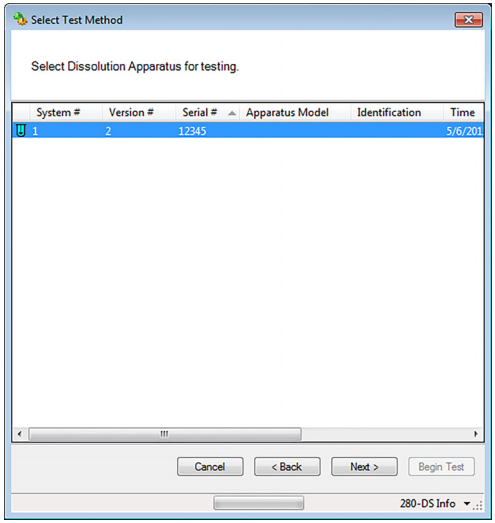

Figure 21. Select the Dissolution Apparatus

Selecting Test Method

The screen displays a list of available methods.

1 Select the method to be executed.

2 Click **Next** to continue.

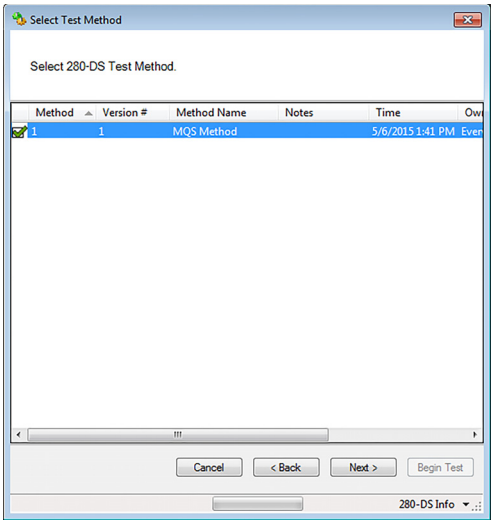

Figure 22. Select the 280-DS Test Method

Selecting the Stirring Element

1 Select the applicable stirring element for the test and check the boxes next to the positions you want to test.

2 Click **Next** to continue.

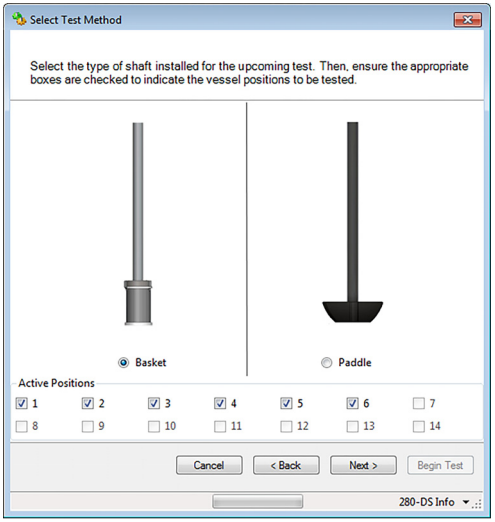

Figure 23. Stirring Element and Vessel Positions

NOTE

If any of the Active Positions are unchecked, the software will notify you that the dissolution apparatus qualification record will not be updated since no positions are being tested.

For any test procedure executed with less than the complete set of active vessels, FOR REFERENCE ONLY will appear on the final test report.

Method Summary and Dissolution Assembly Summary

1 Review and/or print a report of the method and dissolution apparatus. The Method tab is displayed by default.

2 When finished, click **Begin Test** to begin testing.

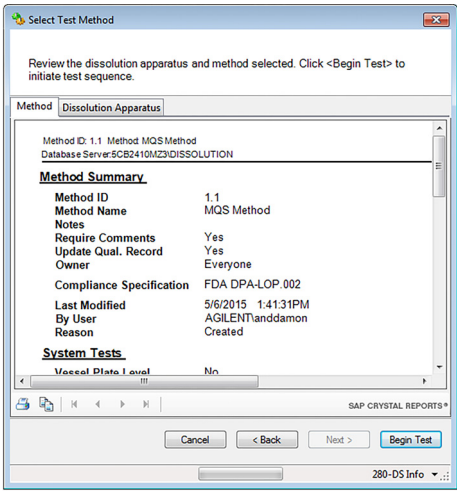

Figure 24. Method Summary Tab

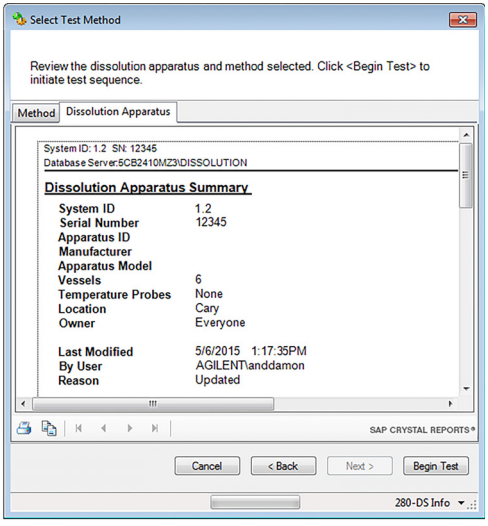

Figure 25. Dissolution Apparatus Tab

Running a Method

NOTE

When you click **Begin Test**, the software will guide you through the sequence of tests defined within the method. See “Method Editor” on page 36..

Activity Log

While running a method, an activity log is created. You can check the activity log at any time by clicking the **Activity Log** tab. You can also print the activity log before exiting the method if Print Activity Log is enabled.

Instrument Module Position on the Vessel Plate

If a vessel plate level test is required, the software prompts you to place the 280-DS Instrument Module (IM) on the vessel plate as shown in the figure below.

1 Position the IM on the vessel plate in an appropriate location.

2 Click **Run** to start data collection.

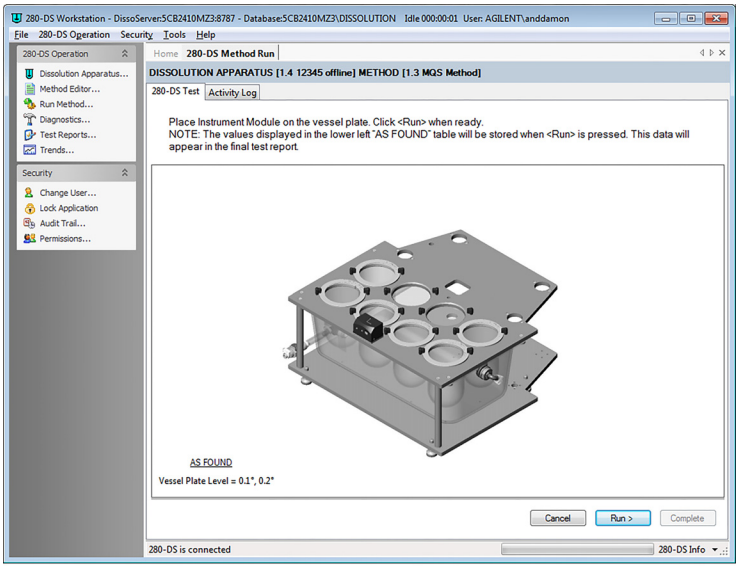

Figure 26. IM Position on Vessel Plate

NOTE

The AS FOUND values displayed on the lower left of the screen will be recorded on the test report when you click **Run**. This data is updated in real time.

Vessel Plate Level Measurement

1 While on the Vessel Plate Level Measurement page, you can adjust the vessel plate if it is not level. A green check mark displays on the screen if an acceptable level has been verified.

2 Click **Accept** to record the result.

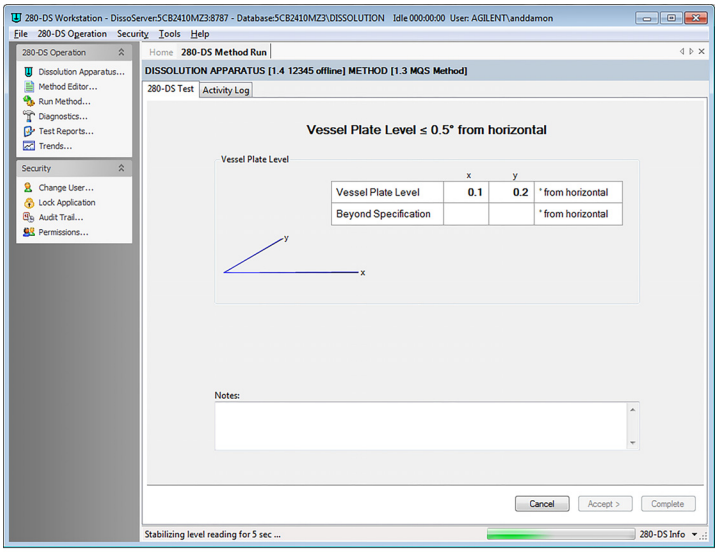

Figure 27. Vessel Plate Level Measurement

NOTE

If you select **Require Comments on Failed Measurements** when setting up a method, you will be required to enter a comment with an explanation for any failed result.

Vessel Module Vessel Centering Arm Placement

CAUTION **Ensure the manifold and evaporation covers on the dissolution apparatus are removed prior to using the Vessel Module. Refer to the applicable section in the documentation of your dissolution apparatus for removal instructions.**

If any of the shaft/vessel alignment tests are required then the software prompts you to zero the encoder of the diameter arm of the Vessel Module.

1 Hold the Vessel Module in a way that does not restrict the movement of the diameter arm (**Figure 28** on page 51).

CAUTION **Do not place a finger in the cavity in the bottom of the Vessel Module. Doing so can contaminate the lenses inside and cause invalid readings.**

2 Click **Zero** to continue the test.

NOTE Prior to measuring parameters within the dissolution vessel, please ensure that the vessel orientation at each active location is properly established.

Figure 28. Proper Hand Position to Zero Diameter Arm

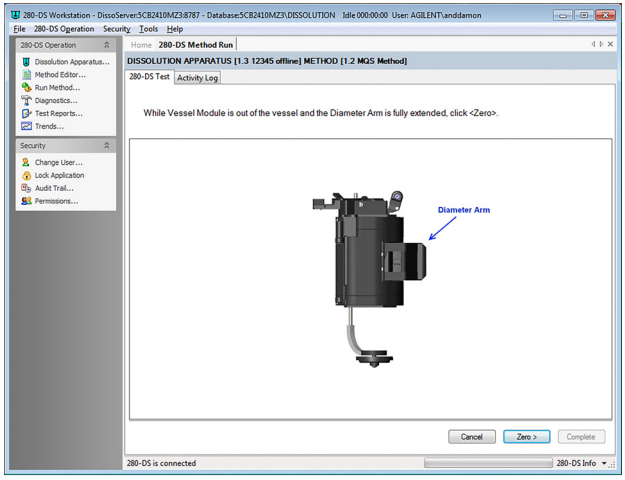

Figure 29. VM Vessel Centering Arm Placement

Vessel Module Placement

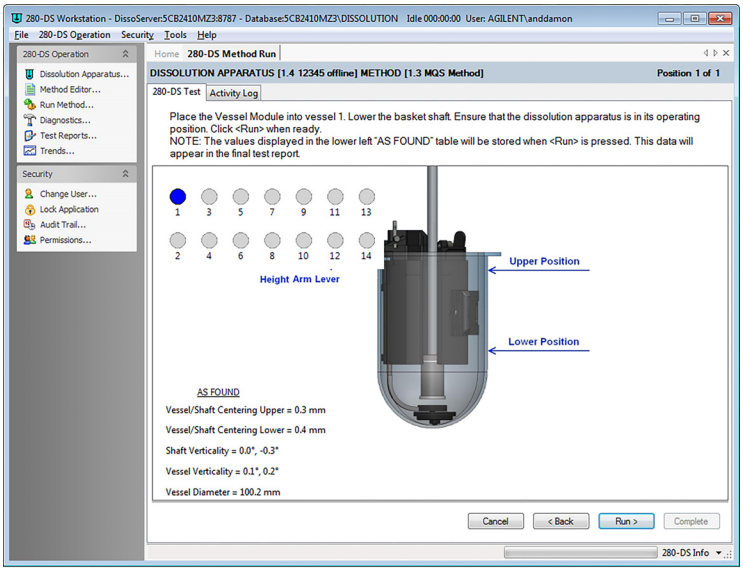

Figure 30. Position for Vessel Module Placement

1 Pull back the vessel diameter arm lever and insert the Vessel Module into the dissolution vessel and position it as illustrated by the software. Ensure that the height arm extension reaches the bottom-middle of the dissolution vessel.

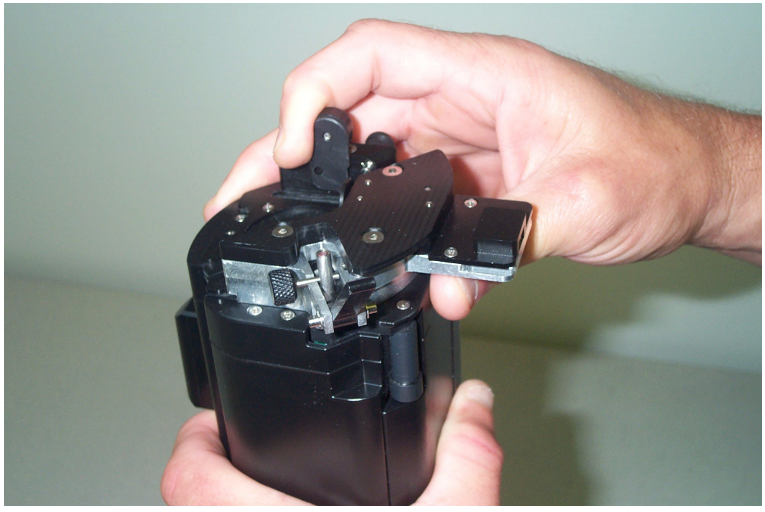

Figure 31. Diameter Measurement Arm Lever

CAUTION **The diameter measurement arm should be either retracted or held manually during the insertion process.**

NOTE

You may need to adjust the height arm of the Vessel Module to allow for the extension to reach the bottom-center of the dissolution vessel. To adjust the travel of this arm, adjust the pin setting as shown in **Figure 32**.

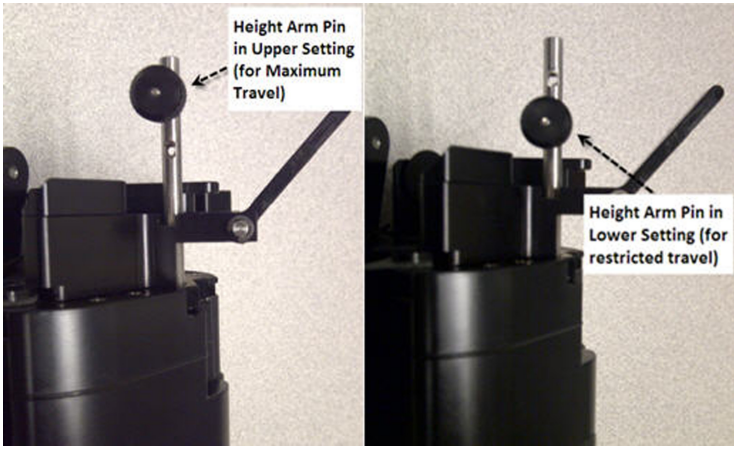

Figure 32. Height Arm Pin

2 Slowly lower the Vessel Module into the vessel until it is seated properly.

NOTE For an EaseAlign vessel, ensure that you are lowering it down into the vessel so it is oriented with the vessel diameter arm going into the DDM cutout on the EaseAlign centering ring. Once lowered, turn the Vessel Module so that the arm lever doesn't contact the EaseAlign ring posts.

NOTE For 7025 and 7030 models, evaporation covers must be removed prior to VM insertion.

For 708-DS, 709-DS, 7000 and 7010 models, it is necessary to remove the sampling manifold and evaporation covers prior to VM insertion.

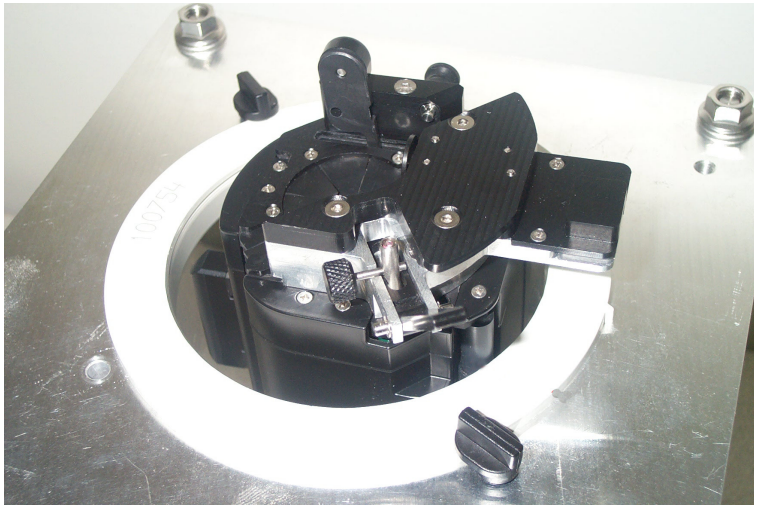

Figure 33. Inserting the Vessel Module

3 Slowly release the vessel diameter arm. Push down until the underside of the top of the Vessel Module touches the top of the vessel collar. Ensure that the Vessel Module height arm extension is touching the bottom of the vessel.

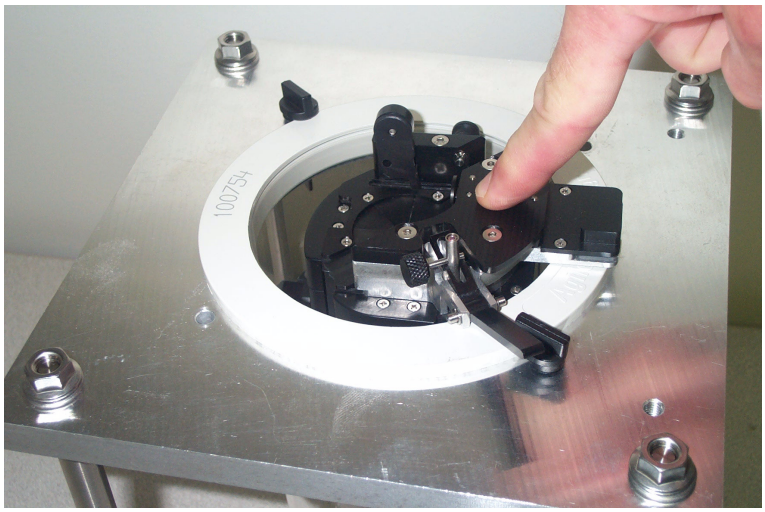

Figure 34. VM Resting at the Bottom of the Vessel

4 Lower the paddle or basket to the operating position.

5 Check the AS FOUND values to ensure the shaft has been detected and the VM is properly seated. The AS FOUND values are displayed to ensure proper placement. The AS FOUND values will be stored and displayed on the final report when you select Run.

6 Click **Run** to move on to the first in-vessel test.

WARNING **The Vessel Module contains several components that are spring loaded. Use care to avoid pinching or damaging the vessel when releasing the diameter arm.**

Paddle or Basket Height

1 To measure the height, push the height lever to move the height arm extension to the bottom of the paddle or basket.

2 Hold for a few seconds until the Accept button is available for selection and release it. The maximum reading is recorded as basket/paddle height.

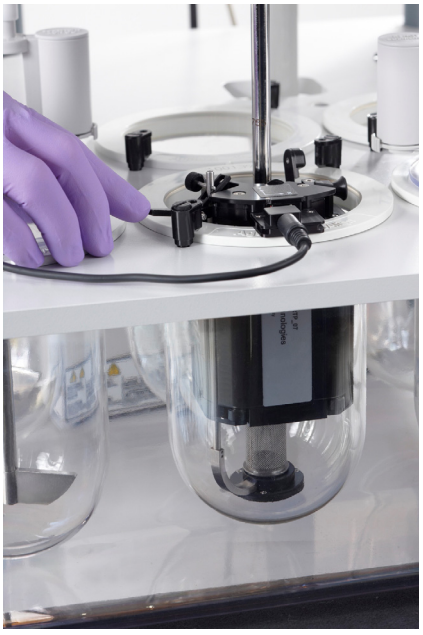

Figure 35. Paddle or Basket Height

3 Click **Accept** to store the value and continue to the next screen.

NOTE

If a basket or paddle is not at the desired position, you can adjust and re-measure it by clicking **Reset** to repeat the test. Ensure that the Vessel Module height arm extension is touching the bottom-center of the vessel.

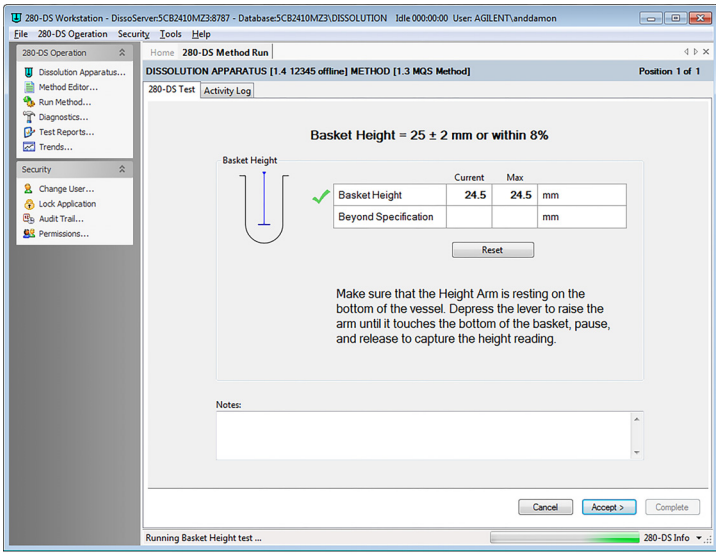

Figure 36. Paddle / Basket Height

Vessel / Shaft Verticality and Vessel Centering

The following tests will be executed simultaneously on this screen:

- Vessel Verticality - 2 points, 90 deg. apart
- Shaft Verticality - 2 points, 90 deg. apart
- Vessel / Shaft Centering (Upper and Lower) - Upper and Lower vessel position

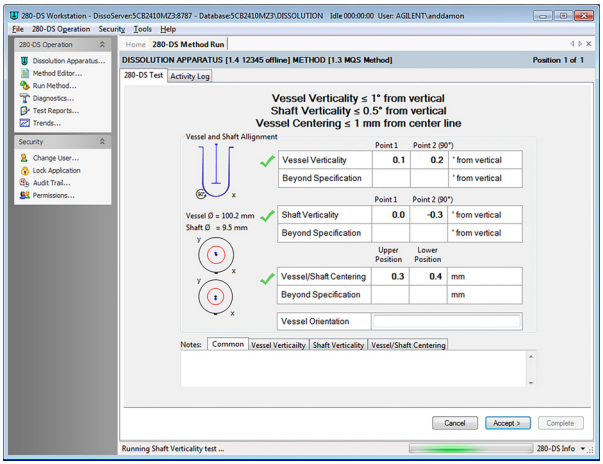

Figure 37. Verticality and Centering Measurement

NOTE You can make adjustments to the dissolution apparatus at any time prior to clicking **Accept** to optimize the performance of the instrument.

1 Once satisfactory results have been achieved, you can document the Vessel Orientation in the open text field. The description you enter will be displayed on the report and stored for future reference.

NOTE Comments entered under the Common tab apply to all of the tests while
comments entered under the Vessel Verticality, Shaft Verticality, or Vessel/Shaft Centering tabs apply only to the individual test.

2 Click **Accept** to continue to the next screen.

Shaft Wobble Test Preparation

After alignment is complete, the shaft wobble test begins.

NOTE

If the dissolution apparatus is used in Offline Mode, the prompt page instructs you to start the spindle rotation at the predefined speed.

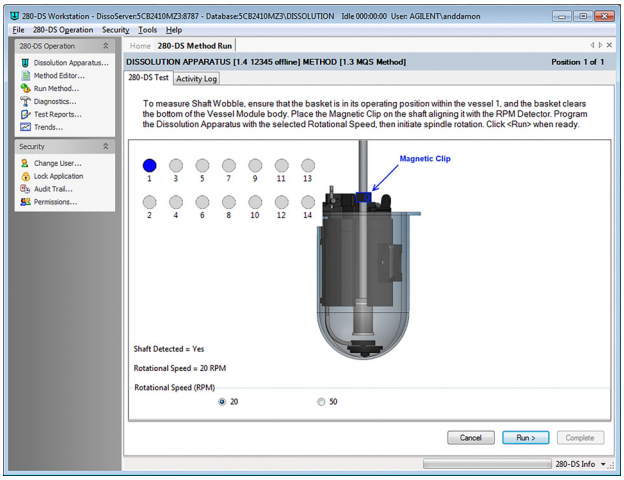

Figure 38. Shaft Wobble Test Preparation

1 Place the magnetic clip in the appropriate position as illustrated by the software. Click the desired radio button to specify **20** or **50** RPM.

NOTE

If the dissolution apparatus is offline then the rotation has to be manually initiated before you click Run.

2 Click **Run** to continue to the next screen where the test begins.

Shaft Wobble Measurement

The shaft wobble test measures wobble above the paddle blade or basket over a stability period while the spindles rotate with a predefined speed of 20 or 50 RPM.

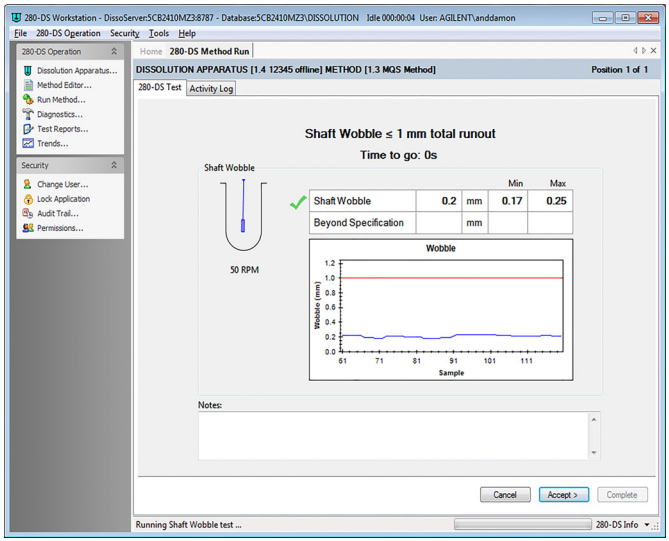

Figure 39. Shaft Wobble Measurement

1 Once the value stabilizes, click **Accept** to store it and continue to the next screen.

RPM Detection Magnetic Clip Placement

1 If applicable, place the magnetic clip in the appropriate position as illustrated by the software.

2 If the dissolution apparatus is offline, you will be prompted to start the spindle rotation with an appropriate speed. Otherwise, rotation will begin automatically.

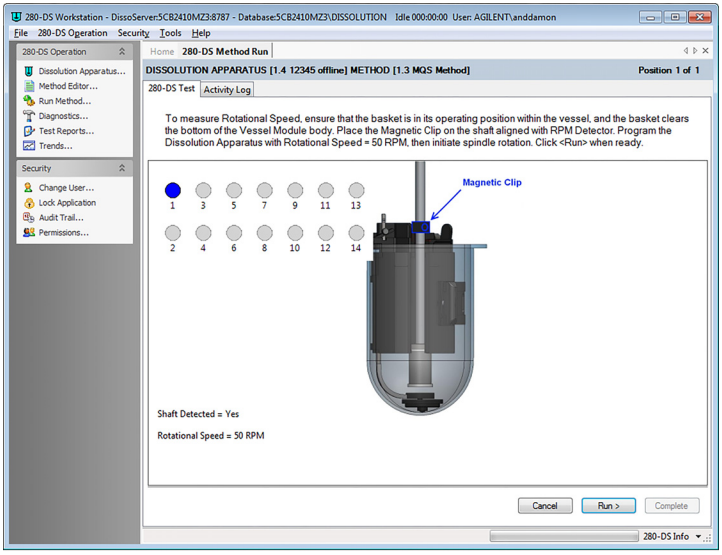

Figure 40. RPM Detection Magnet Placement

3 Click **Run** to continue to the next screen and start the test.

RPM Measurement

The Rotational Speed Test measures actual RPM against the target RPM over a stability period until the value sufficiently stabilizes.

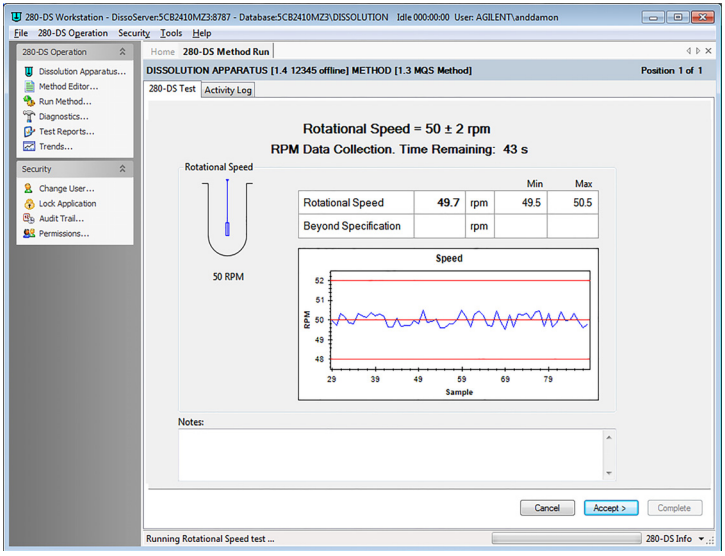

Figure 41. RPM Measurement

1 Click **Accept** to store the RPM value and continue to the next screen.

Basket Rim Wobble Test (Baskets Only)

1 Position the lower rim of the basket at the level of the basket wobble sensor as illustrated by the software. If the dissolution apparatus is offline, it is necessary to manually initiate spindle rotation at the pre-selected speed of 20 or 50 RPM.

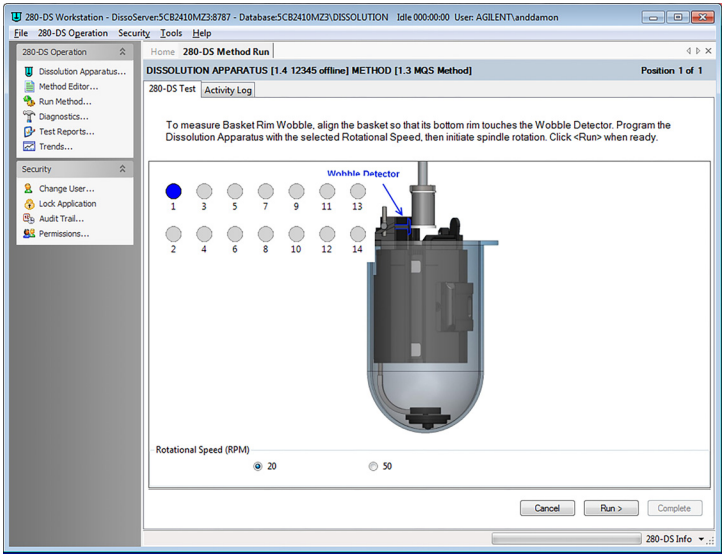

Figure 42. Basket Placement for Rim Wobble Test

2 Click **Run** to continue to the next screen and start the test.

Basket Wobble Measurement

The Basket Wobble test measures the runout at the lower rim of the basket over a stability period while the spindles rotate at the specified RPM.

1 Click **Run** to start this test.

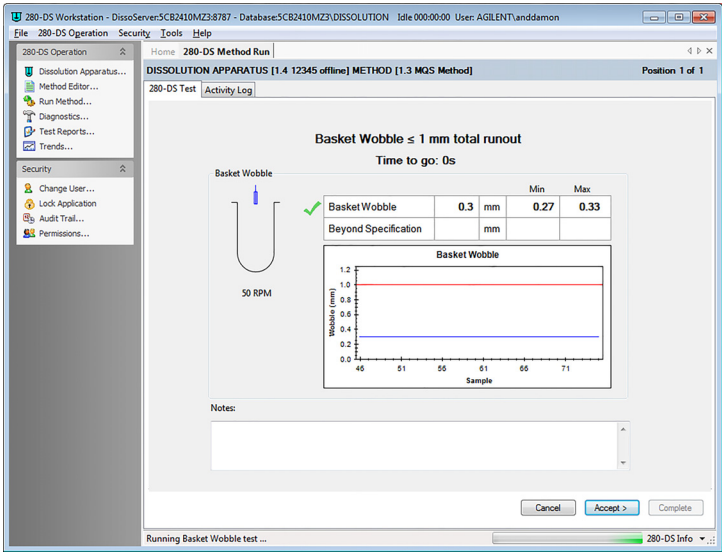

Figure 43. Basket Wobble Measurement

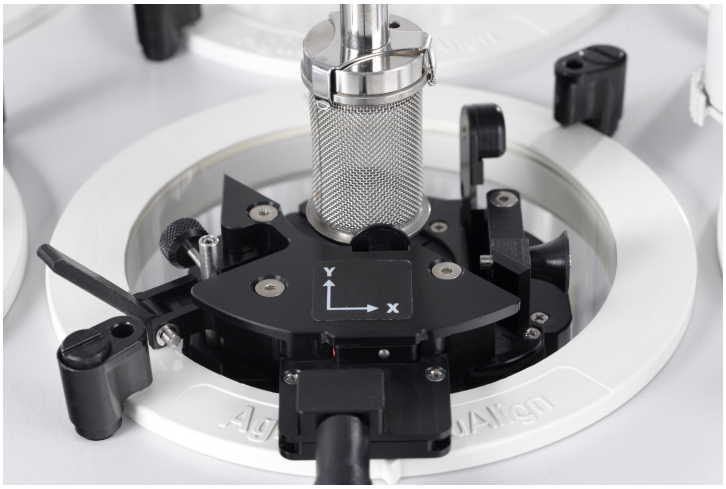

Figure 44. Basket Rim Wobble Measurement

2 Click **Accept** to continue to the next screen.

NOTE

The steps previously described for VM measurements are repeated for each position specified during the method setup. See “Method Editor” on page 36.

Paddle / Basket Shaft Removal

1 Raise the drive unit or individual shaft (if possible) to raise the paddle or basket out of the vessel.

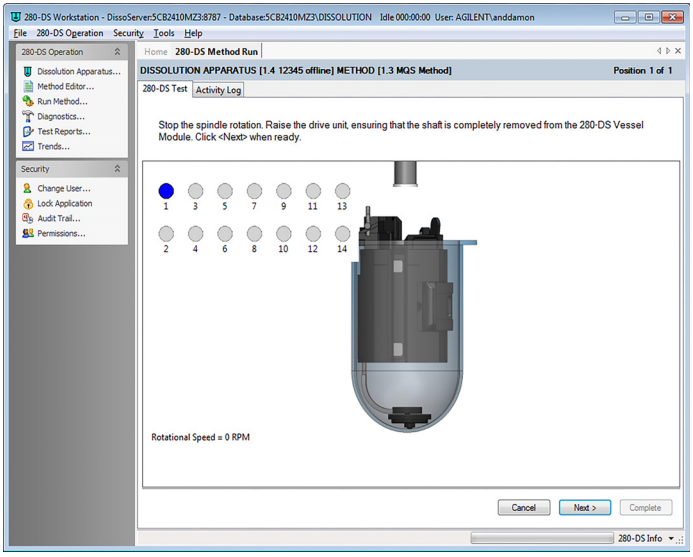

Figure 45. Paddle / Basket Raise

2 Click **Next** to continue to the next vessel position, if applicable.

CAUTION **If paddles are installed, it is necessary to orient the paddle blade so it fits through the opening of the 280-DS VM prior to raising the dissolution apparatus or shaft.**

Completion of the Mechanical Qualification for the Position

1 Raise the drive unit as instructed by the software.

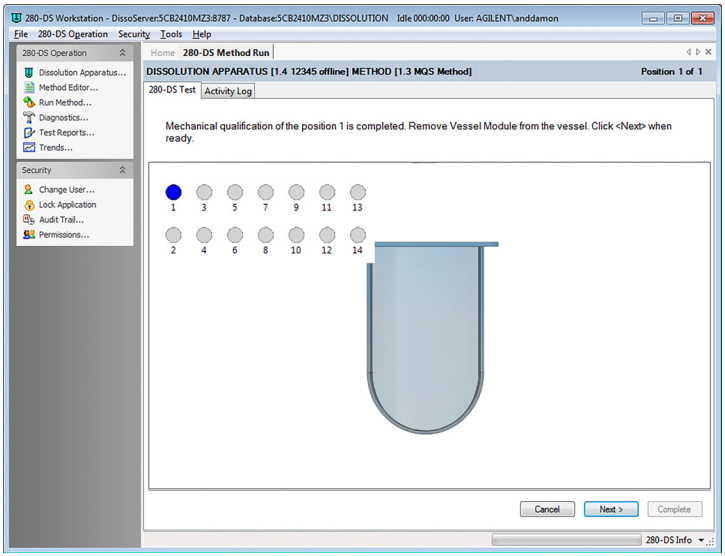

Figure 46. Completion of the Mechanical Qualification

2 The Mechanical Qualification for the individual vessel position is complete. Click **Next** to continue to next action of the test sequence.

Temperature Probe Placement

1 If the dissolution apparatus has a water bath and a probe to monitor its temperature, you will be prompted to set the temperature to the target value. If the dissolution apparatus is in the Online Mode, the temperature will be set automatically.

NOTE

Heating the water bath can be a lengthy process so it is recommended to preheat the bath prior to beginning the measurement sequence.

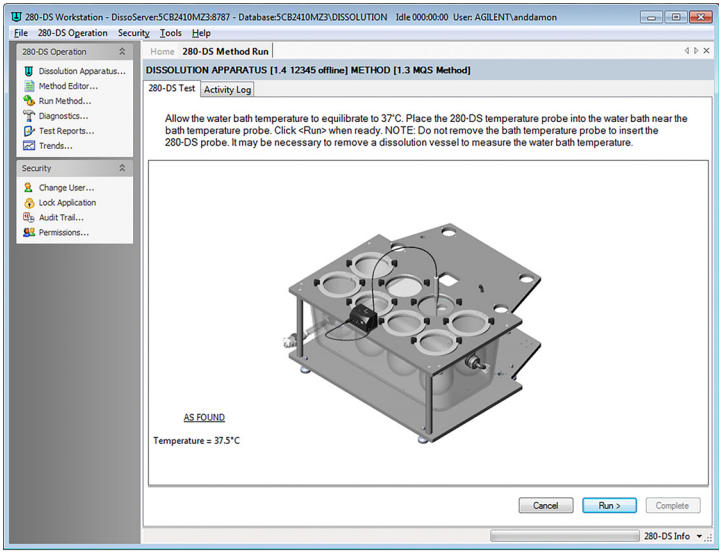

Figure 47. Temperature Probe Placement

2 Click **Run** to continue to the next screen and run the test.

Bath Temperature Measurement

The Bath Temperature Measurement page displays the reading of the 280-DS temperature probe and the bath temperature reading of the dissolution apparatus, if it is online.

1 If the dissolution apparatus is offline, then you must enter the bath temperature as reported on its display. Although a successful test requires reaching the target temperature, you can accept the result at anytime.

NOTE If applicable, do not remove the bath temperature probe of the dissolution apparatus from the water bath for this measurement. Instead, remove one of the rear dissolution vessels for access to the water bath.

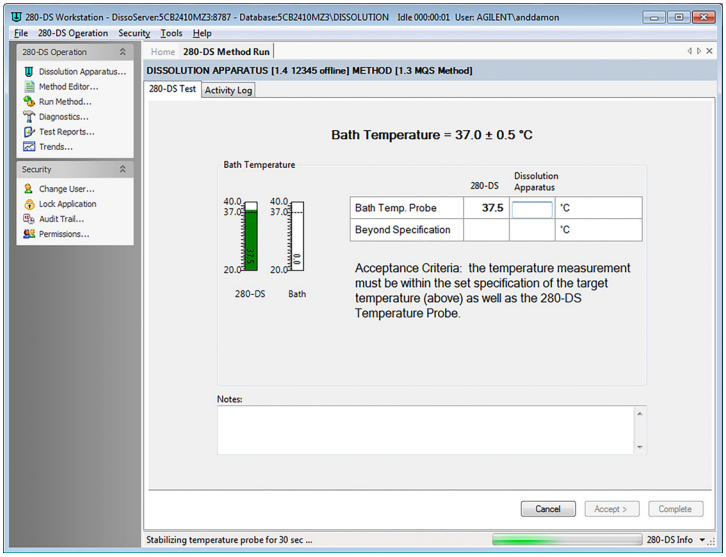

Figure 48. Bath Temperature Measurement

2 After 30 seconds, the reading stabilizes. Click **Accept** to continue to the next screen.

Vessel Temperature Probe Placement

1 If the dissolution apparatus has vessel temperature probes, lower them into position. You will be prompted to wait until the temperature of the water in the vessel reaches the target value. If the dissolution apparatus is online, the temperature will be detected automatically.

NOTE

Since heating is a lengthy process, it is recommended to preheat the water bath before using the 280-DS.

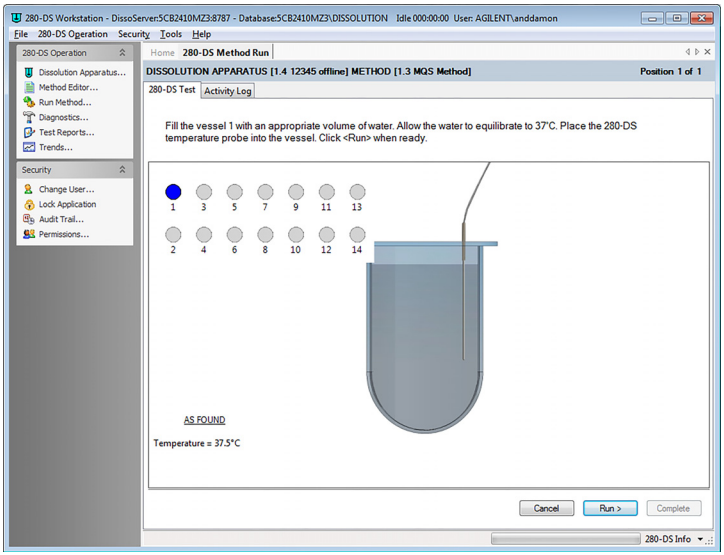

Figure 49. Vessel Temperature Probe Placement

2 Click **Run** to continue to the next screen and start the test.

Vessel Temperature Measurement

The vessel temperature measurement page displays the reading of the 280-DS temperature probe and the vessel temperature reading of the dissolution apparatus if it is online.

1 If the dissolution apparatus is offline, enter the vessel temperature as it is displayed on its front panel or elsewhere. Although a successful test requires the target temperature to be reached, you can accept the result at any time.

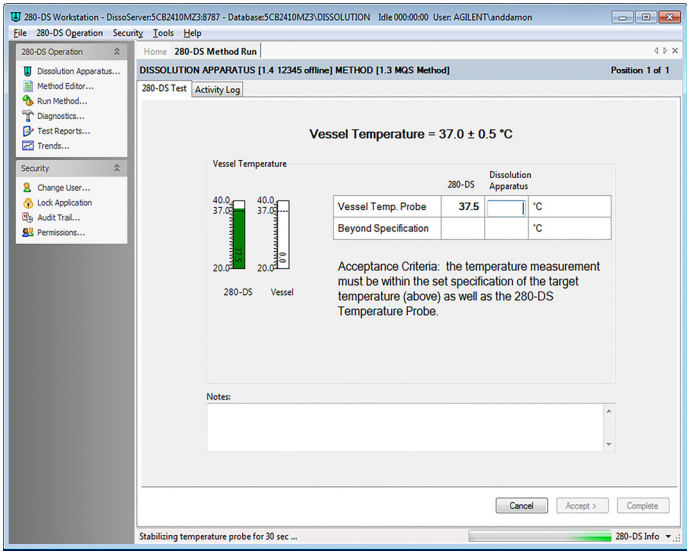

Figure 50. Vessel Temperature Measurement

2 Click **Accept** to continue to the next page.

Instrument Module Placement for Vibration

If a vibration test is required, it will be the last test in the sequence.

1 The 280-DS Test tab is selected by default. Use the check boxes to specify the desired RPMs for the vibration test.

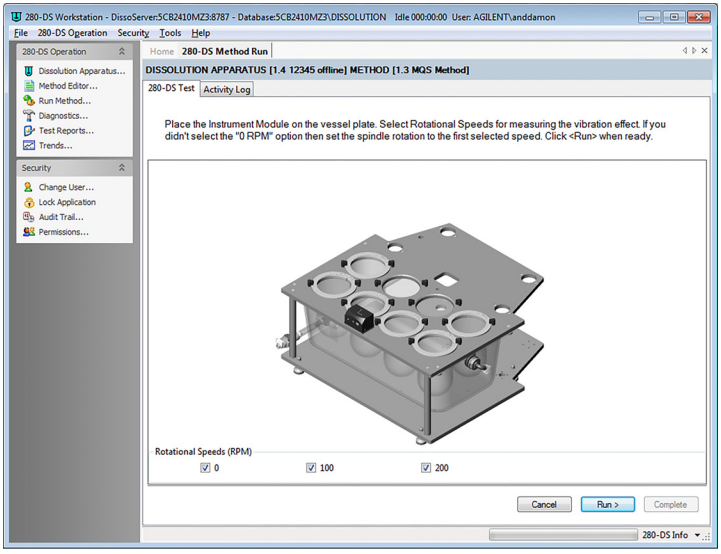

Figure 51. IM Placement for Vibration Test

2 Click **Run** to continue to the next screen. If more than one RPM has been selected, the software will proceed through each test individually.

Vibration Measurement

The Vibration test identifies three frequencies with the highest acceleration and calculates the velocity and displacement for these frequencies.

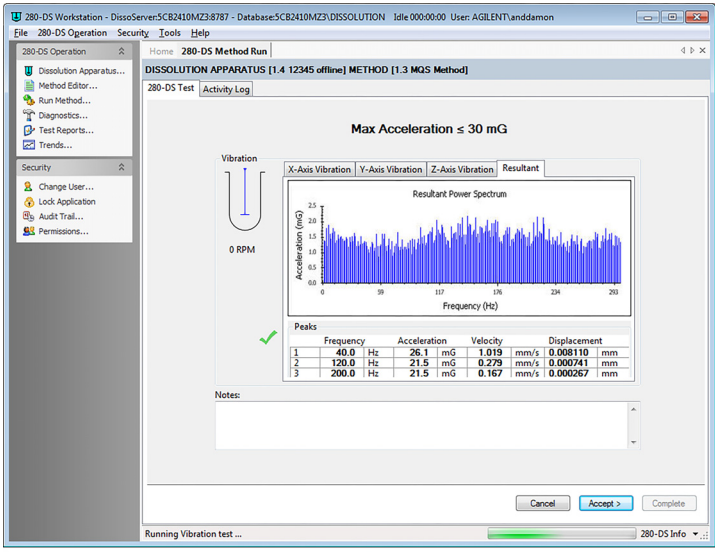

Figure 52. Resultant Vibration Display

Option	Function
X-Axis Vibration	Measures and displays vibration recorded on X-axis.
Y-Axis Vibration	Measures and displays vibration recorded on Y-axis.
Z-Axis Vibration	Measures and displays vibration recorded on Z-axis.
Resultant	Calculates and displays resultant vibration of all axes.

1 Click **Accept** to store the vibration values and continue to the next screen. The software will continue to guide you through all selected RPMs.

Test Completion

1 Upon completion of the test sequence:

- If the method has the Update Qualification Record option selected (**"Update Qualification Record"** on page 38) and all of the parameters have passed the specification, you can specify the next qualification due date.
- If any of the tests failed, then the dissolution apparatus is marked Out of Calibration and the old calibration due date cannot be updated.
- If Update Qualification Record is not selected then the old qualification due date remains and will be displayed for reference only.

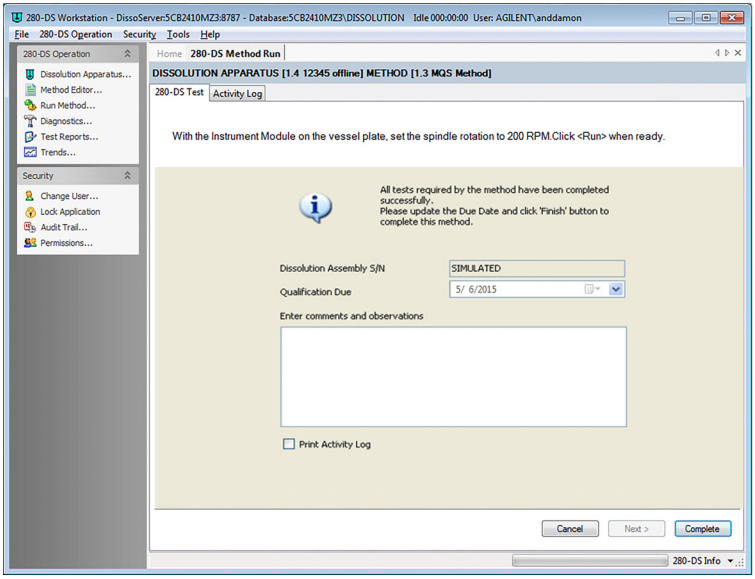

Figure 53. Test Completion Screen - Successful

2 Click **Complete** to update the physical parameters and display the Method Completion screen. When the test is complete, the report is compiled and displayed on screen. See "Test Reports" on page 82..

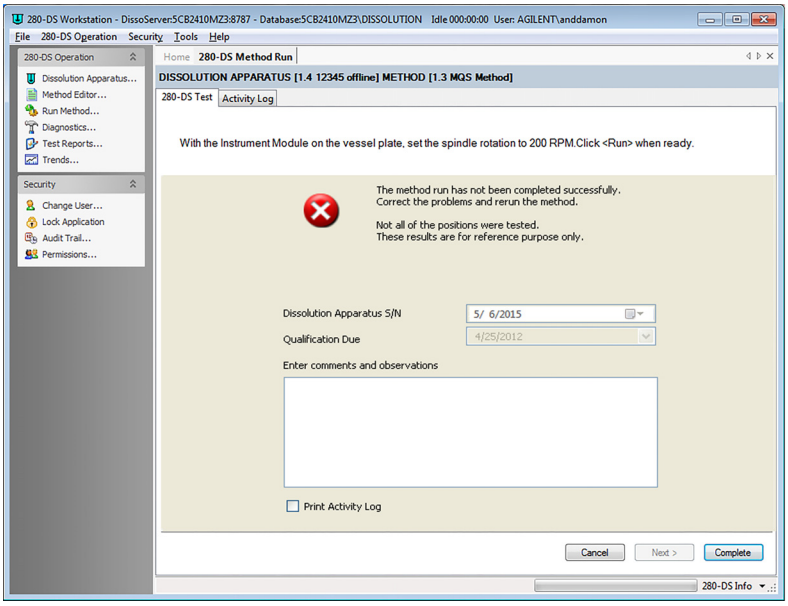

Figure 54. Test Completion Screen - Unsuccessful

Test Cancellation

You can cancel the method any time by clicking **Cancel**. Before exiting the method run, you will be required to provide an explanation or reason for the cancellation.

NOTE

Until the first test and its results are accepted you may cancel the test without providing an explanation.

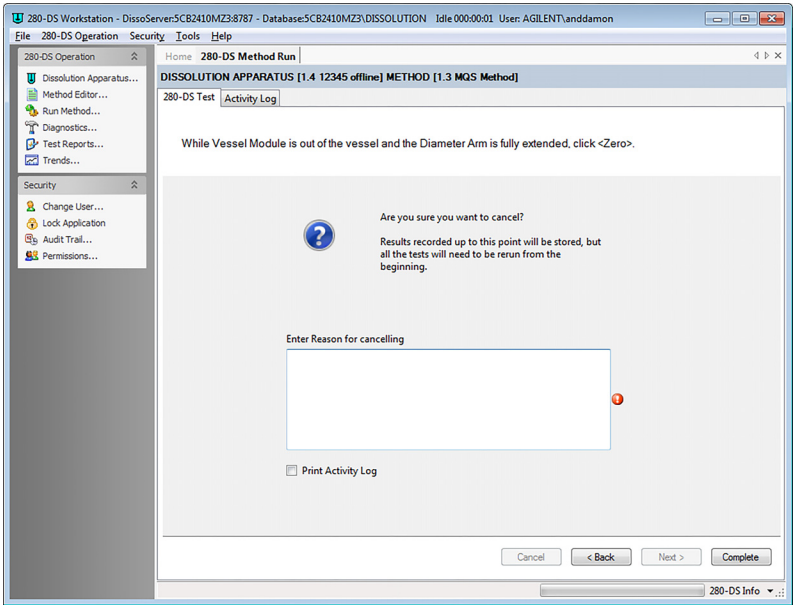

Figure 55. Method Cancelling

Diagnostics

Current Status Tab

Click **Diagnostics** from the 280-DS homescreen to access software diagnostics. When you select Diagnostics, the software automatically connects to the 280-DS if it is present and live data streams are initiated.

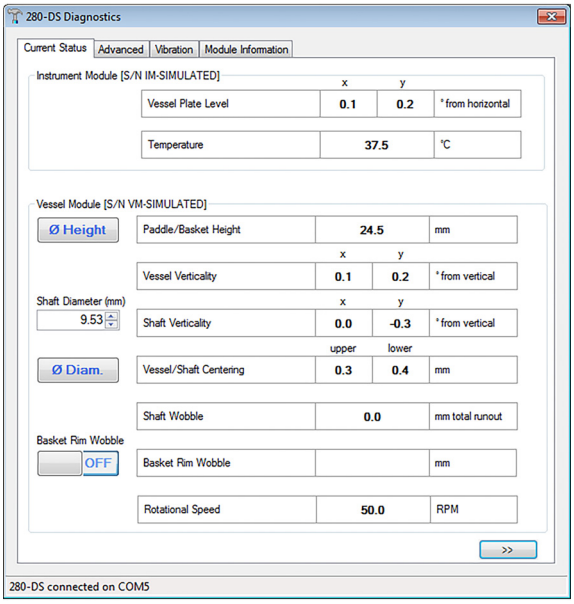

Figure 56. Current Status Tab

Advanced Tab

The Advanced tab provides advanced diagnostic features for the Instrument Module and Vessel Module and displays the values coming from the connected 280-DS modules. From this tab, you can start and stop the stream of data, change the rate of collection, switch between full precision (no calibrated data values applied), and raw data (normal operation) modes. You can also send zeroing commands and turn on/off the auxiliary LEDs for basket wobble measurement. Any of the streaming values can be plotted on the running chart by clicking on grid value. All the communication with 280-DS can be monitored, saved, and exported to a tab-delimited spreadsheet.

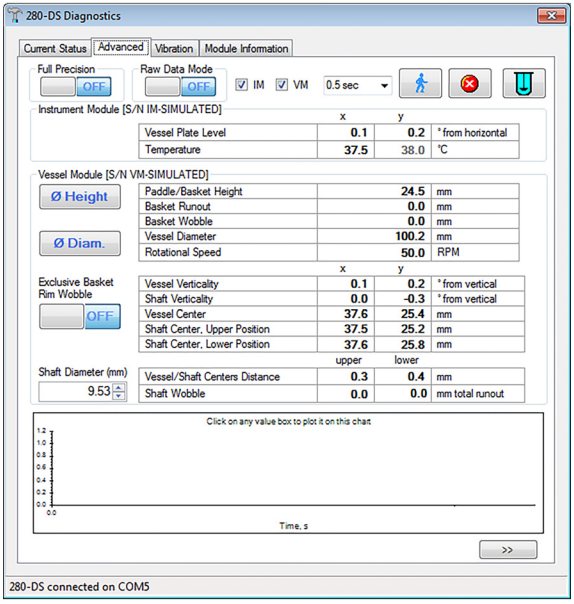

Figure 57. Advanced Tab

Vibration Tab

When you select the Vibration tab, the vibration data stream from 280-DS Instrument Module starts and other measurement data streams from Vessel Module and Instrument Module stop. This allows you to stop and restart the vibration data in order to take a snapshot of the data.

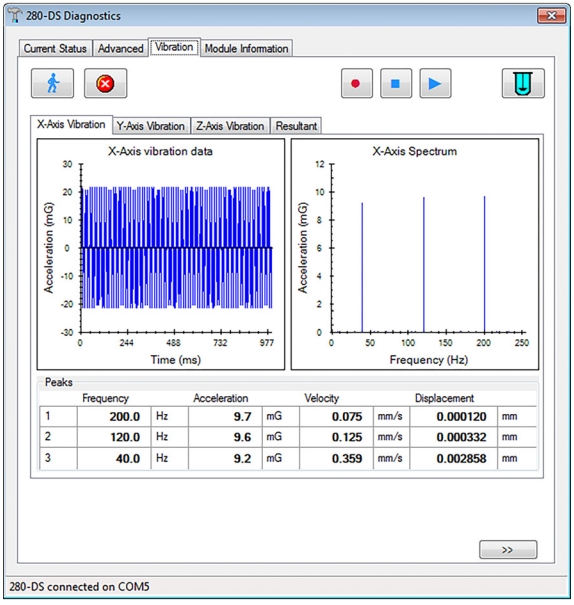

Figure 58. Vibration Tab

The vibration data can be recorded and replayed. When you click ● and select the output file, the accelerometer data is saved as the tab-delimited, three column spreadsheet. Each column represents acceleration on the X-, Y-, and Z-axis. To stop the recording, click ■ and to see the recorded data, click ▶.

NOTE You can record up to 60 seconds of the data stream.

Module Information Tab

When you select the Module Information tab, Instrument Module and Vessel Module manufacturing and calibration data is downloaded from the devices. Each device can hold up to 20 previous calibration records.

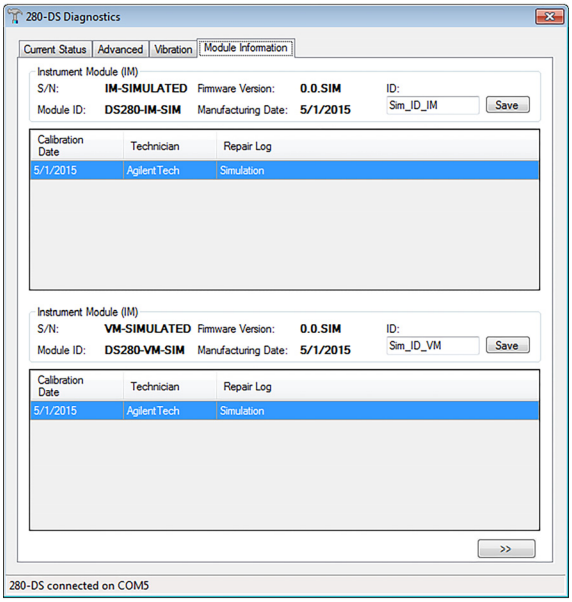

Figure 59. Module Information Tab

If an Agilent dissolution apparatus is connected to the same PC, it can be controlled from the software through the dialog box.

When you click from the Advanced or Vibration tab, the software automatically tries to connect to the dissolution apparatus. If the dissolution apparatus connection is successful, you are able to set up a temperature and spindle speed that can be monitored.

Test Reports

Click **Test Reports** from the 280-DS Workstation homescreen to set up and access reports. Various filtering criteria is available to display the desired test reports stored in the database.

Report Selection

- Date range (inclusive), apparatus serial number, for operator, laboratory
- Due date (all dissolution apparatus)
- Date range and 280-DS module serial numbers
- Test ID / Status

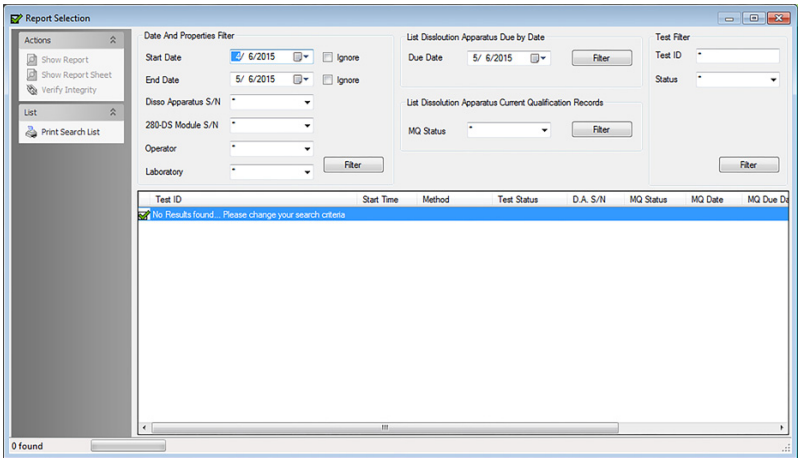

Figure 60. Reports Selection Screen

Option	Function
Filter	Testing data / results reports can be displayed based on date range, dissolution apparatus serial number, 280-DS module, operator, laboratory, due date, report status, test ID, and test status by selecting the applicable option and clicking **Filter**.
Print Search List	Creates a printable version of the report selection list, which is visible on screen.

Show Report

When you double-click a row in the table, the results report displays. The results report consists of a compliance Mechanical Qualification Report Sheet and detailed report.

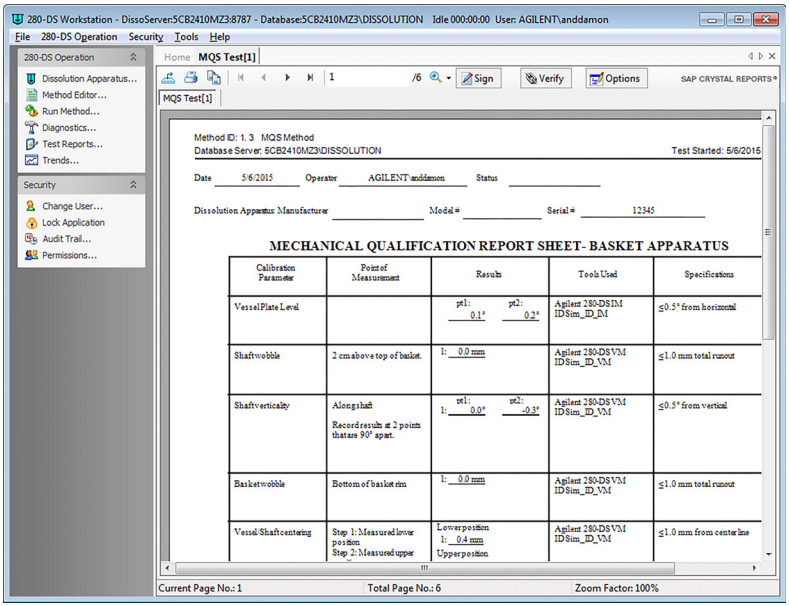

Figure 61. Show Result

Option	Function
Sign	Select to electronically sign the report. You will have to enter your User ID and Password to sign the report.
Verify	Executes data verification.
Options	Select **Options** to select which options will display (Show Report Sheet, Show Detailed Report, Show Run Log).

Show Report Options

Check the box next to the data to be displayed on each report (Show Report Sheet, Show Detailed Report, Show Run Log).

Verify Report Integrity

To verify report Integrity, return to the 280-DS Workstation homescreen and click **Test Reports...**. The Verify Report Integrity option at the top of the screen prompts the software to check the checksum of the results data to verify that it was not altered from outside of the application. See “Verify Integrity” on page 30..

Trends

When you select **Trends** from the 280-DS Workstation homescreen, a menu displays that allows you to define which trend graphs to plot. Trend graphs are plotted per dissolution apparatus, per measurement (all by default), over a time period (previous year by default).

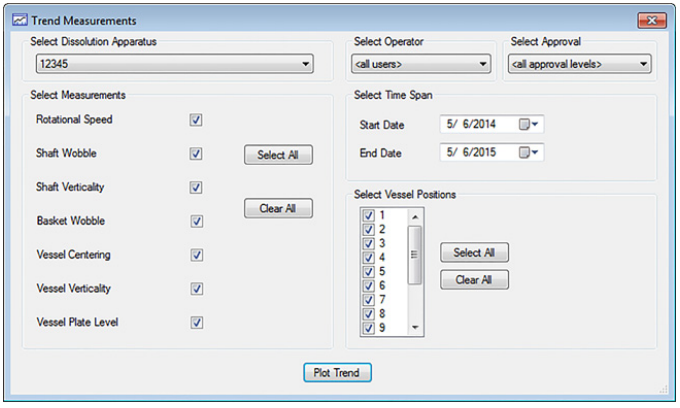

Figure 62. Trend Measurements

For each test, the overall trending and per-position trending is displayed.

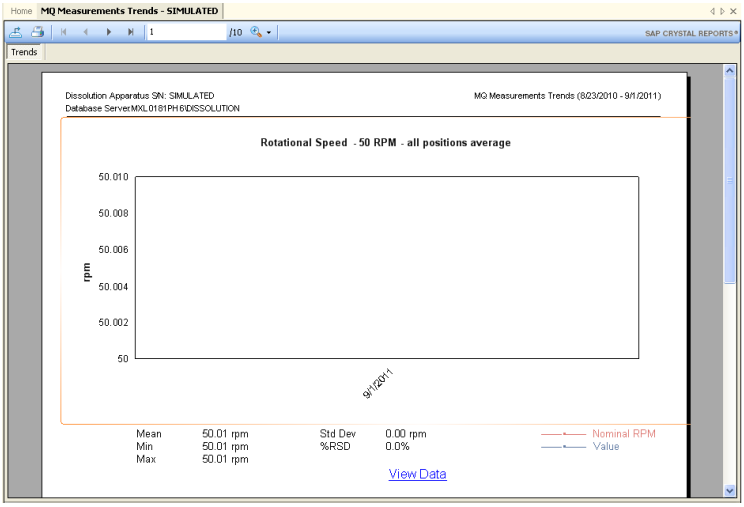

Figure 63. MQ Measurements Trends

Security (21 CFR Part 11 Compliance)

Change User

1 To change the current user account logged in to the software, click **Change User** from the 280-DS Workstation homescreen.

2 Enter login information and click **Logon**.

Lock Application

1 To lock the application, click **Lock Application** from the 280-DS Workstation homescreen.

2 To unlock, click the **lock icon** and log back into the software.

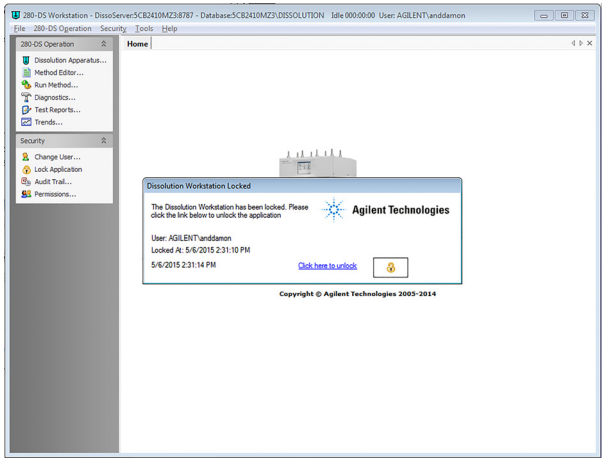

Figure 64. Lock Application

Audit Trail

Click **Audit Trail** from the 280-DS Workstation homescreen to access the Security Audit Trail screen.

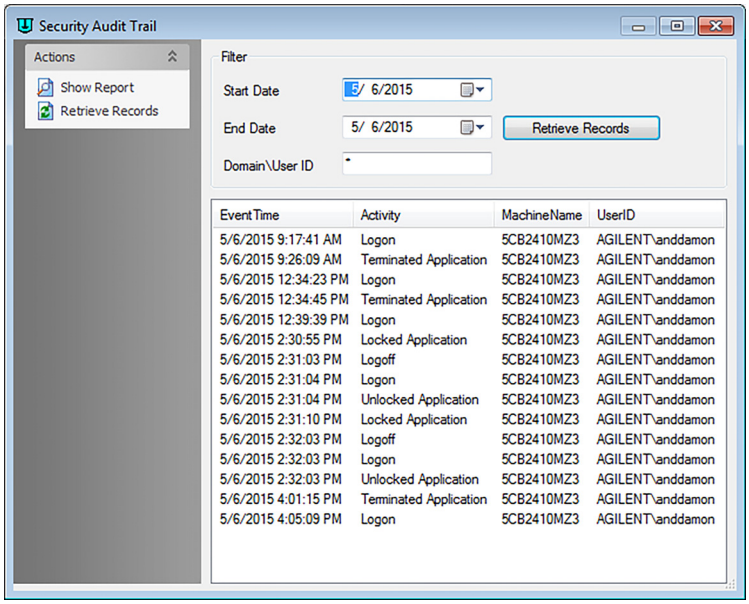

Figure 65. Security Audit Trail

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

Permissions

Review the permissions granted to the current user.

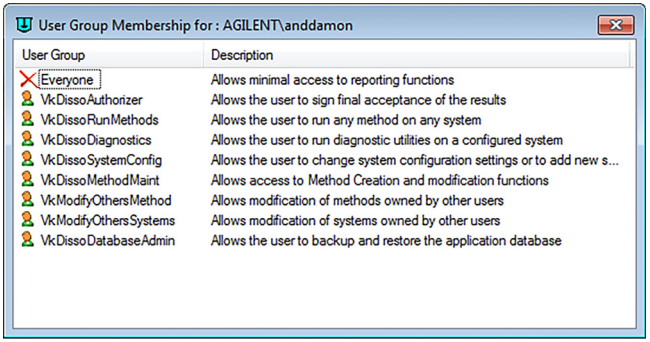

Figure 66. Permissions

Tools

Configuration Dialog

Select **Tools** > **Options** from the 280-DS Workstation homescreen to display the Configuration Dialog screens.

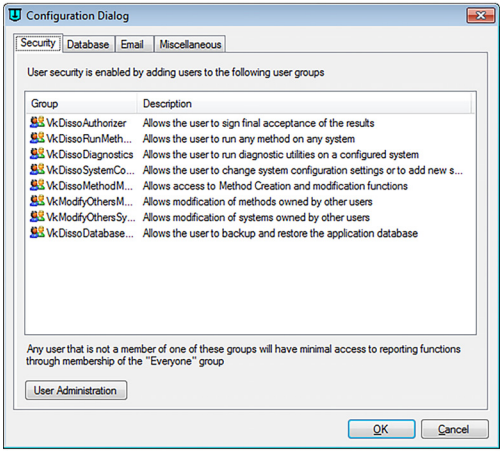

Figure 67. Configuration Dialog Security Tab

Option	Function
User Groups	Review the permissions granted to each user group.
User Administration	Modify the permissions granted to each user and/or group.

Database Tools

1 Select **Tools** > **Options** from the 280-DS Workstation to display the Configuration Dialog screen.

2 Select the **Database** tab to view the following screen:

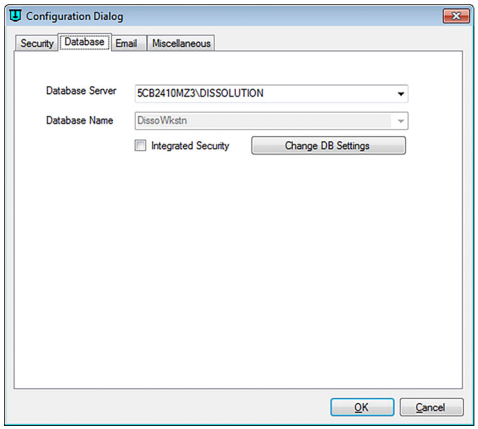

Figure 68. Database Tools

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

NOTE

Database backup and restore functions can be performed manually (**"Database Backup and Restore Functions"** on page 93) or automatically using scripts provided by Agilent. If this utility is desired, please contact an Agilent representative for guidance.

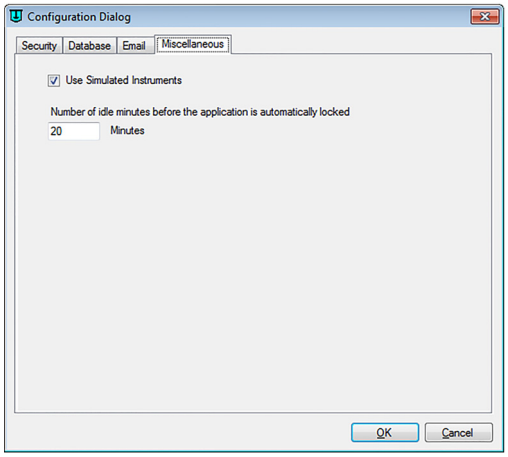

Figure 69. Configuration Dialog Miscellaneous Tab

Option	Function
Use Simulated Instruments	Runs the software in a simulation mode where the 280-DS modules do not have to be connected. No official data is acquired in this mode.
Idle Minutes	Amount of time before the software locks automatically. Setting this value to 0 disables this feature.

Database Backup and Restore Functions

Backing up the Database

1 From the PC desktop, click **Start** > **All Programs** > **Agilent** > **Dissolution** > **MsdeManager**. The MSDE Manager screen displays.

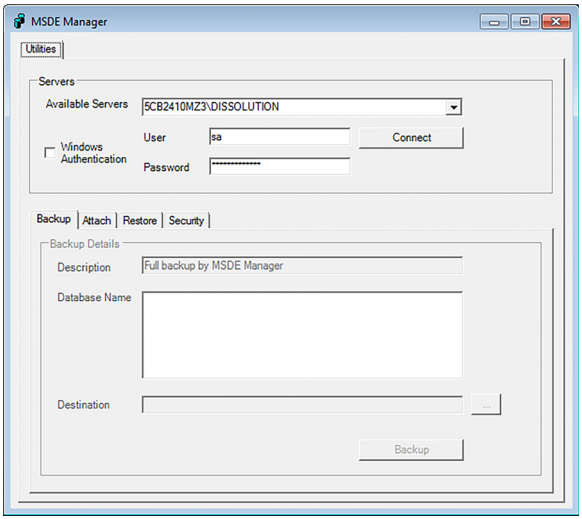

Figure 70. MSDE Manager

2 Select the appropriate Server where the database is located and click **Connect**. The DB Utility screen displays indicating the database is connected successfully.

3 From the Backup tab, click "..." to browse for the desired backup location. The default location is:

C:\Program Files\Microsoft SQL Server\MSSQL$DISSO\Backup\DissoWkStn.bak.

4 Click **Backup** to initiate the database backup process. A DissoWkStn.bak file will be created in the specified destination.

Restoring the Database

1 From the PC desktop, click **Start** > **All Programs** > **Agilent** > **Dissolution** > **MsdeManager**. The MSDE Manager screen displays.

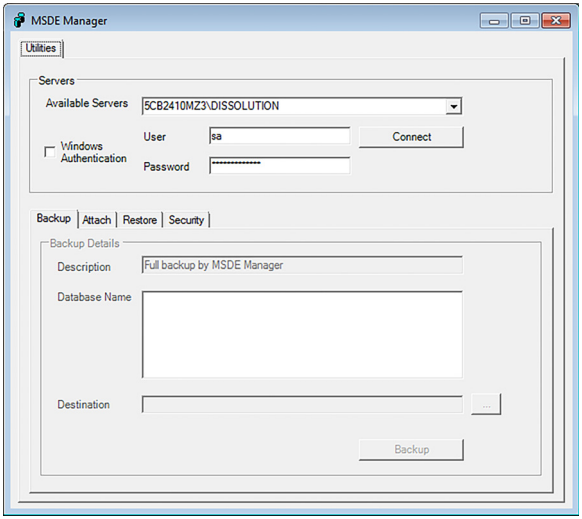

Figure 71. MSDE Manager

2 Select the appropriate Server where the database is located and click **Connect**. The DB Utility screen displays indicating the database has connected successfully.

3 Click the **Restore** tab and click "**...**" to browse for the desired backup file (.bak).

4 Click **Restore** to restore the database to the specified destination.

5 Troubleshooting and Maintenance

Preventive Maintenance

Recalibration

Agilent recommends the 280-DS be calibrated on a 6-month interval. In addition, the documentation of the calibration cycle due date should be consistent with the procedures of the end user and in consideration of the proper handling and care of the system. The calibration interval should be consistent with your SOPs and documented on the individual Instrument Module (IM) and Vessel Module (VM) certificates.

To keep the instrument at optimum performance within the calibration period, please refer to the following information:

- The unit is designed to be stored, transported, and shipped in its original carrying case.
- As with any delicate instrument or calibrated device, excessive shipping or mishandling may warrant more frequent recalibration.
- Ultimately the end-user is responsible for establishing a calibration interval and Agilent will accommodate more or less frequent calibrations based on usage or needs.
- Agilent provides AS FOUND measurements for each parameter upon recalibration to assist you in assuring the integrity of your mechanical parameter measurements.

Recalibration of the 280-DS must be performed by an Agilent repair center. To initiate this process, please contact Agilent's Customer Service to initiate a Service Request.

Troubleshooting

NOTE See “Diagnostics” on page 78. for basic troubleshooting.

The following is a troubleshooting guide which may help you with common problems. For other problems, please contact your local Customer Care Center. Contact information can be found at www.agilent.com under your country using the Contact Us link. Place your service request using the displayed phone number or E-mail address.

Symptom	Probable Cause	Suggested Solution
The 280-DS is not responding.	There might be a problem with the connection between the 280-DS and the computer.	• Ensure the USB cable is plugged in. • Ensure the IM cable is plugged in. • Look inside the VM and confirm that the red LEDs are flashing.
	The 280-DS driver is not installed properly.	• In Windows Device Manager, verify that the 280-DS is located on a COM port when it is plugged into a USB port.
		• Ensure the USB port on the computer is functioning.
Diagnostics is not working properly.	Problem with Windows OS or VM/IM cable connections.	• Reboot the PC • Ensure all module connections are secure and the red LEDs are flashing within the VM.
Improper centering / verticality values or any other unexpected values from measurements.	VM diameter arm was not zeroed.	• Ensure it is zeroed properly. See “Vessel Module Vessel Centering Arm Placement” on page 50.
	Module not properly installed.	• Re-zero the VM and reseat the module within the vessel.

Symptom	Probable Cause	Suggested Solution
	Dirty lenses on the Vessel Module.	• Clean the lenses inside of the Vessel Modules with a lens-cleaning cloth.
Can't connect to the dissolution apparatus.	The dissolution apparatus is not supported (i.e., non-Agilent/ Varian/VanKel) or the firmware version on the dissolution apparatus is not supported.	• Contact Agilent to update the firmware on the apparatus (if possible).
	Serial-to-USB cable drivers were not installed properly.	• Reinstall the cable drivers, if necessary.
	Serial port not functioning properly.	• Verify status of serial port using Device Manager (**Control Panel** > **Administrative Tools** > **Computer Management**).
RPM value is not displaying.	The magnetic clip is not in the proper position.	• The top of the RPM clip needs to be slightly above the VM. See "RPM Detection Magnetic Clip Placement" on page 62..
Paddle/Basket height is not reading properly.	Height arm extension not seated on bottom middle of the dissolution vessel. Need to select the proper pin height.	• Ensure that the height arm extension is oriented in the center of the VM. Ensure the proper pin setting of the VM is selected. See "Height Arm Pin" on page 54..
The VM doesn't fit in the vessel.	Need to use a 1L and/or an open-head apparatus.	• Ensure 1L vessels are being used. • The VM should fit any open-head design apparatus. The VM will not fit on a dissolution apparatus with a closed-head design.
	The sampling manifold and/or evaporation covers must be removed.	• Remove the manifold and evaporation covers of your dissolution apparatus. Please consult the Operator's Manual of your dissolution apparatus for applicable instructions.

Symptom	Probable Cause	Suggested Solution
Cannot perform functions within the software (e.g., create system/method, run method, etc.).	User does not have proper rights/access to desired function.	• Administrator must add desired user to individual Vk groups to grant access/privileges to specific software functions via User Administration (Tools > Options). See "Adding Users to the Application" on page 25.
User cannot log on to software.	Incorrect password or domain.	• Verify the correct password has been entered and the proper domain is selected from the software login screen.
Data not updating in real-time or SIMULATED is displayed as the serial number of dissolution apparatus.	Use Simulated Instruments option enabled.	• Disable the **Use Simulated Instruments** option under Tools > Options > Miscellaneous. See "Use Simulated Instruments" on page 92..

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6 Service and Warranty

Service and Warranty Information

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

Obtaining Warranty and Other Services

To place a service order (warranty or other services), please contact your local Customer Care Center. Contact information can be found at www.agilent.com under your country using the Contact Us link. Place your service request using the displayed phone number or E-mail address.

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