

# AGILENT 708-DS DISSOLUTION APPARATUS TRAINING MANUAL

## Table of Contents

<b>1.1.</b>	<b><i>The Apparatus</i></b> .....	<b>- 5 -</b>
<b>1.2.</b>	<b><i>The Firmware</i></b> .....	<b>- 6 -</b>
<b>1.3.</b>	<b><i>Optional Configurations</i></b> .....	<b>- 6 -</b>
<b>2.</b>	<b>INSTRUMENT SETUP</b> .....	<b>- 7 -</b>
<b>2.1.</b>	<b><i>Physical Setup</i></b> .....	<b>- 7 -</b>
2.1.1.	<b>Unpacking Equipment / Accessories</b> .....	- 7 -
2.1.2.	<b>Heater / Circulator Setup</b> .....	- 8 -
2.1.3.	<b>Communication / Power Cord Installation</b> .....	- 8 -
2.1.4.	<b>Instrument Power Up</b> .....	- 9 -
2.1.5.	<b>Leveling the Apparatus</b> .....	- 9 -
2.1.6.	<b>Heater / Circulator Power Up</b> .....	- 10 -
2.1.7.	<b>Dissolution Vessel Installation</b> .....	- 11 -
2.1.8.	<b>Manifold Installation</b> .....	- 11 -
2.1.9.	<b>Shaft / Evaporation Cover / DDM Installation</b> .....	- 12 -
2.1.10.	<b>Setting Paddle / Basket Heights</b> .....	- 14 -
<b>2.2.</b>	<b><i>Firmware Setup – Instrument Settings</i></b> .....	<b>- 15 -</b>
2.2.1.	<b>Apparatus ID Numbers, LCD Settings</b> .....	- 15 -
2.2.2.	<b>Setting the Date / Time</b> .....	- 16 -
2.2.3.	<b>Calibrating the Touch Screen</b> .....	- 16 -
2.2.4.	<b>Instrument Tolerances, Vessel Size, Enable Alarms/DDMs</b> .....	- 17 -
2.2.5.	<b>Manifold Configuration (Vessel Numbering)</b> .....	- 17 -
2.2.6.	<b>Print Options</b> .....	- 18 -
<b>3.</b>	<b>MEASUREMENT OF PHYSICAL PARAMETERS</b> .....	<b>- 18 -</b>
<b>3.1.</b>	<b><i>RPM, Wobble, Centering, Level, Verticality (Shaft and Vessel)</i></b> .....	<b>- 18 -</b>
3.1.1.	<b>RPM / Wobble</b> .....	- 19 -
3.1.2.	<b>Centering</b> .....	- 20 -
3.1.3.	<b>Vessel Table Level</b> .....	- 20 -
3.1.4.	<b>Shaft / Vessel Verticality</b> .....	- 21 -
<b>3.2.</b>	<b><i>Temperature(s)</i></b> .....	<b>- 21 -</b>
3.2.1.	<b>External Vessel Temperature (EVT) Probe</b> .....	- 21 -
3.2.2.	<b>AutoTemp - Vessel Temperatures</b> .....	- 22 -
<b>3.3.</b>	<b><i>Manual Operation (from Diagnostics)</i></b> .....	<b>- 23 -</b>
3.3.1.	<b>Verification of Apparatus Operation</b> .....	- 23 -

<b>4.</b>	<b>BASIC OPERATION .....</b>	<b>- 24 -</b>
4.1.	<i>Dissolution Medium – Filling Vessels, Media Change / Addition .....</i>	<i>- 24 -</i>
4.2.	<i>Manual Sampling, Evaporation Cover Options .....</i>	<i>- 25 -</i>
4.3.	<i>LCD Display (Touch Screen).....</i>	<i>- 26 -</i>
4.3.1.	<i>Operations from Main Screen.....</i>	<i>- 26 -</i>
4.3.2.	<i>Alphanumeric / Numeric / Date &amp; Time Entries.....</i>	<i>- 27 -</i>
<b>5.</b>	<b>OPTION DESCRIPTION (BASED ON CONFIGURATION) .....</b>	<b>- 28 -</b>
5.1.	<i>Lift Mechanism.....</i>	<i>- 28 -</i>
5.1.1.	<i>Automated .....</i>	<i>- 28 -</i>
5.1.2.	<i>Manual .....</i>	<i>- 28 -</i>
5.2.	<i>Auto Sampling.....</i>	<i>- 29 -</i>
5.2.1.	<i>Load / Eject Manifold .....</i>	<i>- 29 -</i>
5.2.2.	<i>Removing or Adjusting Cannulas / Probes.....</i>	<i>- 30 -</i>
5.2.3.	<i>Programming Manifold Depth .....</i>	<i>- 30 -</i>
5.3.	<i>AutoTemp.....</i>	<i>- 31 -</i>
5.3.1.	<i>Enabling Temperature Measurements .....</i>	<i>- 31 -</i>
5.3.2.	<i>Setting Tolerances .....</i>	<i>- 31 -</i>
5.3.3.	<i>Manifold Down Lead Time / Manifold Down Duration .....</i>	<i>- 32 -</i>
5.4.	<i>Dosage Delivery Modules (DDM).....</i>	<i>- 32 -</i>
5.4.1.	<i>Automated DDM .....</i>	<i>- 33 -</i>
5.4.2.	<i>Manual DDM .....</i>	<i>- 33 -</i>
5.5.	<i>708-DS Reports.....</i>	<i>- 34 -</i>
5.6.	<i>Alarms.....</i>	<i>- 34 -</i>
<b>6.</b>	<b>METHOD SETUP AND EXECUTION WITH THE 708-DS .....</b>	<b>- 36 -</b>
6.1.	<i>708-DS Method Setup (Stored) .....</i>	<i>- 36 -</i>
6.2.	<i>708-DS Test Execution (Stored Method).....</i>	<i>- 40 -</i>
6.3.	<i>708-DS Method Setup and Execution (Manual).....</i>	<i>- 41 -</i>
6.4.	<i>Screen Lock / Unlock .....</i>	<i>- 42 -</i>
6.5.	<i>Pause / Resume Test ... Media Change .....</i>	<i>- 43 -</i>
<b>7.</b>	<b>DIALOG, WARNING, AND POPUP ERROR SCREENS .....</b>	<b>- 44 -</b>
<b>8.</b>	<b>CLEANING / MAINTENANCE / TROUBLESHOOTING .....</b>	<b>- 44 -</b>



**8.1. Maintenance Due Icon (Calibration / PM due date alarms)..... - 44 -**

**8.2. Rinse Cups (for use with VK 8000)..... - 45 -**

**8.3. Vessels (TruAlign), Shafts, Evaporation Covers ..... - 45 -**

**8.4. Touch Screen Alignment Procedure..... - 46 -**

## Table of Figures

FIGURE 1-1. 708-DS DISSOLUTION APPARATUS.....	- 5 -
FIGURE 1-2. MAIN SCREEN .....	- 6 -
FIGURE 2-1. 708-DS HEATER / CIRCULATOR .....	- 8 -
FIGURE 2-2. BUILT-IN SELF TEST SCREEN .....	- 9 -
FIGURE 2-3. LEVEL ADJUSTMENT SCREWS .....	- 9 -
FIGURE 2-4. 708-DS LEVEL ADJUSTMENT .....	- 10 -
FIGURE 2-6. TRUALIGN VESSEL ORIENTATION .....	- 11 -
FIGURE 2-7. SAMPLE TUBING FASTENER.....	- 12 -
FIGURE 2-8. DOSAGE DELIVERY MODULE .....	- 13 -
FIGURE 2-9. COVER ALIGNER.....	- 13 -
FIGURE 2-10. 708-DS ACCESSORY INSTALLATION .....	- 13 -
FIGURE 2-11. SETTING PADDLE / BASKET HEIGHTS .....	- 14 -
FIGURE 2-12. INSTRUMENT SETTINGS SCREEN 1 .....	- 15 -
FIGURE 2-13. DATE AND TIME SCREEN.....	- 16 -
FIGURE 2-14. TOUCH SCREEN CALIBRATION.....	- 16 -
FIGURE 2-15. MANIFOLD CONFIGURATION SCREEN.....	- 17 -
FIGURE 2-16. 708-DS PRINTER .....	- 18 -
FIGURE 3-1. RPM AND WOBBLE MEASUREMENT ON A 708-DS.....	- 19 -
FIGURE 3-2. LEVEL VERIFICATION - TORPEDO LEVEL.....	- 20 -
FIGURE 3-4. 708-DS SAMPLE TEMPERATURE BUTTON.....	- 21 -
FIGURE 3-5. SAMPLE TEMPERATURES SCREEN.....	- 22 -
FIGURE 3-6. DIAGNOSTICS SCREEN 1 .....	- 23 -
FIGURE 3-7. DIAGNOSTICS SCREEN 2 .....	- 24 -
FIGURE 4-1. FILLING THE VESSEL OF A 708-DS .....	- 25 -
FIGURE 4-2. TAKING A MANUAL SAMPLE .....	- 25 -
FIGURE 4-3. 708-DS STANDARD EVAPORATION COVER .....	- 26 -
FIGURE 4-4. MAIN SCREEN .....	- 26 -
FIGURE 4-5. ALPHANUMERIC AND NUMERIC DATA ENTRY SCREENS.....	- 27 -
FIGURE 5-1. 708-DS MANUAL LIFT KNOB .....	- 28 -
FIGURE 5-2. INSTALLATION OF THE MANIFOLD .....	- 29 -
FIGURE 5-3. PADDLES/BASKETS SAMPLING DEPTH SCREEN.....	- 30 -
FIGURE 5-4. METHOD PROPERTIES SCREEN 3 .....	- 31 -
FIGURE 5-5. TOLERANCE SETTINGS.....	- 32 -
FIGURE 5-6. INSTRUMENT SETTINGS SCREEN 2 .....	- 33 -
FIGURE 5-7. 708-DS DDM – MANUAL.....	- 33 -
FIGURE 5-8. REPORT OPTIONS.....	- 34 -
FIGURE 6-1. METHOD PROPERTIES SCREEN 1 .....	- 36 -
FIGURE 6-2. METHOD PROPERTIES SCREEN 2 .....	- 37 -
FIGURE 6-3. METHOD PROPERTIES SCREEN 3 .....	- 38 -
FIGURE 6-4. METHOD PROPERTIES SCREEN 4 .....	- 39 -
FIGURE 6-5. TIMEPOINT PROPERTIES SCREEN.....	- 39 -
FIGURE 6-6. TEST START SCREEN.....	- 40 -
FIGURE 6-7. MANUAL OPERATION SCREEN .....	- 41 -
FIGURE 6-8. UNLOCK INSTRUMENT SCREEN.....	- 43 -
FIGURE 6-9. PAUSE METHOD SCREEN .....	- 43 -
FIGURE 8-1. REGULATORY CALIBRATION DATE SCREEN .....	- 44 -
FIGURE 8-2. 708-DS RINSE CUP.....	- 45 -

## Agilent 708-DS Overview

### 1.1. The Apparatus

Agilent's 708-DS Dissolution Apparatus has been carefully designed to provide an accurate, fast, flexible, and safe instrument to execute a variety of dissolution methods. The apparatus is capable of traditional Basket (USP Apparatus 1) and Paddle (USP 2) test methods, as well as Paddle over Disk (USP 5) and Rotating Cylinder (USP 6) experiments.



Figure 1-1. 708-DS Dissolution Apparatus



Beyond the scope of compendial devices, other vessel sizes and drug delivery mechanisms may be used with the 708-DS. These include 200, and 2000mL vessels sizes complete with appropriately scaled accessories. Also, stationary baskets and enhancer cells may be configured.

The apparatus itself has many different configuration possibilities. The 708-DS is available with a manual or automated lift mechanism to control the drive unit. Other additional options include: AutoTemp, Auto Sampling, Dosage Delivery Modules (DDM) and a Printer. Each of these will be explained in greater detail throughout this manual.

### 1.2. The Firmware

Setup and operation of the instrument is controlled via the LCD touch screen on the front of the unit. The Main screen, displayed after initialization occurs, provides the current status of several instrument parameters as well as a variety of “hotspots” and buttons to initiate operation.

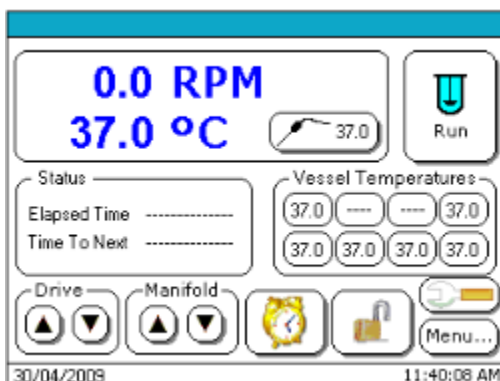


Figure 1-2. Main Screen

Press the ‘Menu...’ button from the Main screen to display the primary System Menu. From this screen, the user has the ability to configure the apparatus to their exact specifications. These options include method setup, instrument settings, diagnostic tests, and more.

### 1.3. Optional Configurations

As mentioned previously, the apparatus has an assortment of configurable options. While many of these are selected at the time of ordering, most may be added at a later time if and when laboratory testing needs change.

A manual or automated *Head Lift* mechanism is used to raise and lower the apparatus’ drive unit.



For automated sample collection, the *Auto Sampling* option is available which is comprised of a sampling manifold with sampling and return cannulas. The manifold may also include the *AutoTemp* option which includes individual temperature probes for each dissolution vessel.

For a hands-free test start, the newly designed *Dosage Delivery Module (DDM)* allows for simultaneous or sequential introduction of dosage forms. Lastly, a *Printer* may be included to document all critical apparatus settings and events.

## 2. Instrument Setup

### 2.1. Physical Setup

Once the 708-DS dissolution apparatus has been delivered to the laboratory where setup and installation will occur, the steps to begin unpacking and any applicable qualification begin. The following sections will proceed naturally through various procedures to ensure a smooth and methodical setup.

#### 2.1.1. Unpacking Equipment / Accessories

Upon delivery of the equipment, some portions of the apparatus will require some simple assembly. It is important to first inspect all pieces to ensure no damage has occurred during shipment. The following table includes many, if not all, of the accessories shipped with the unit:

708-DS Dissolution Apparatus	Heater / Circulator
Power Cords	6-pin Cable for Heater / Circulator
Bath Temperature Probe	External Vessel Temperature (EVT) Probe
Dissolution Vessels	Evaporation Covers
TruAlign™ Blank Vessel Position Covers	Evaporation Cover Plugs
DDM Assemblies	Basket Shaft Assemblies
Cover Aligners	Paddle Shaft Assemblies
DDM Alignment Shafts	Vessel Centering Tool
Shaft Locking Collars	Thermal Printer Paper
17-mm Open End Wrench	90° Allen Key (for Level Adjustment)
7/64" T-Handle Allen Wrench	Stainless Steel Tubing Clamps
Length of Plastic Tubing (1/2" OD)	25-mm Spheres
Clip-on Basket Height Gauge	Bubble Level
Technical Documentation CD	Rinse Cups

### 2.1.2. Heater / Circulator Setup

The 708-DS utilizes a water bath to heat and maintain temperature within the dissolution vessels. The water in the bath is heated and circulated by a Heater / Circulator (H/C) that is positioned behind the water bath. The H/C should be installed beneath the back of the vessel plate with the power outlet facing the rear and legs inserted into the holes of the base plate.



Figure 2-1. 708-DS Heater / Circulator

**NOTE:** To prevent damage to the heating elements, the unit should not be powered ON until the all tubing connections have been verified and the bath has been filled with water.

### 2.1.3. Communication / Power Cord Installation

Before turning the apparatus ON, the communication cables and power cords are installed. The 708-DS and its' accompanying H/C each have a power cord requiring connection to an outlet of the appropriate voltage.

The H/C communication cable is a 6-pin cable that connects the H/C to the position marked BATH HEATER on the rear of the apparatus. Also, the Bath Temperature probe is connected to the BATH TEMP port on the rear of the 708-DS and the probe is inserted into the hole in the center of the vessel plate (between the back middle vessel positions).

A unit not equipped with AutoTemp may include an additional External Vessel Temperature (EVT) Probe. This probe is inserted into the VESSEL TEMP jack on the rear of the apparatus drive unit. The other end of the probe is placed in the hole in the left side of the vessel plate toward the back.



### 2.1.4. Instrument Power Up

Once the cables have been connected, the apparatus is powered ON using the switch on the left side of the drive unit. Upon initialization, the instrument undergoes a brief “Self-Test” to ensure proper operation. At this time, the serial number, firmware version, firmware release date, and LCD version are displayed. A green check mark indicates the test was successful. A red “X” appears if any of the system components fail the test along with the status of each component. The error screen will appear until the condition is resolved and the internal routine completes successfully.



Figure 2-2. Built-in Self Test Screen

### 2.1.5. Leveling the Apparatus

Adjustment of the vessel plate level is performed by using the 90° Allen Key and the 17-mm open-end wrench supplied with the apparatus. The first step is to remove the black caps that cover the level adjustment screws on the front and rear of the base plate (see Figure 2-3).



Figure 2-3. Level Adjustment Screws

Raise the stability feet located toward the back on either side of the base plate so they are not touching the laboratory bench.

**NOTE:** It may be necessary to use the open-end wrench to loosen the nut(s) beneath the base plate to allow for adjustment of the leveling screws.

Adjust the two front leveling feet of the apparatus, while monitoring the vessel plate level, to achieve left-to-right level within tolerance. Then, adjust the leveling foot at the rear of the apparatus, while monitoring the vessel plate level, to achieve front-to-back level within tolerance. Once satisfactory level is attained, use the open-end wrench to tighten the nut(s) beneath the base plate. Lower the stability feet located toward the back on either side of the base plate until they touch the laboratory bench. Do not over-tighten to ensure level is maintained.



Figure 2-4. 708-DS Level Adjustment

The water bath is filled at this time – be sure to allow for displacement of the water when the vessels are installed. After filling the water bath to the appropriate height, re-verify the level front-to-back and left-to-right to ensure the previous setting has been maintained.

### 2.1.6. Heater / Circulator Power Up

With the water bath of the 708-DS filled to the appropriate height, turn on the power to the Heater / Circulator. The flow of water should begin immediately. If air is trapped in the loop, however, the unit may need to be primed.

**NOTE:** See the label on the rear of the H/C for instructions on priming – a tilt of the unit (arrow pointing down) should be sufficient to purge any air from the system.

If the red *Heater Error* LED is illuminated, it may be necessary to turn the unit OFF and back ON to re-initiate the internal pump. Once proper flow is established, examine all tubing connections in the loop to ensure no leaks are present. The *Pump On* LED should be lit up green indicating the pump is operating properly. The *Heater On* LED will be illuminated green if the water is being heated. As the water temperature approaches the target temperature, this LED will naturally cycle on / off.

### 2.1.7. Dissolution Vessel Installation

The 708-DS utilizes the TruAlign™ dissolution vessels. To install the vessels, raise the drive unit of the apparatus. Locate the vessels and carefully insert them into each position of the vessel plate. Rotate the two diagonal clips for each position over the vessel rim to secure it in place. If desired, use the point on the vessel collar (see Figure 2-6) to orient the vessels identically for each test.



Figure 2-6. TruAlign Vessel Orientation

For any unused vessel positions, locate the TruAlign blank vessel position covers. Place a cover over the vessel plate openings and rotate the two clips over the rim of the cover to secure it in place.

### 2.1.8. Manifold Installation

For an instrument configured with Auto Sampling or AutoTemp, the use of a manifold is required. To install the manifold, lift the drive unit of the 708-DS to its fully raised position. From the Main screen, press **Menu > Diagnostics**. Position the manifold so the center screw is aligned with the center receptor on the underside of the drive unit. Ensure the left and right alignment cylinders are also positioned correctly. Push the manifold up into the drive unit until resistance is met. While gently lifting upward, press **Load** from within the Manifold Control box on the touch screen. The internal drive slowly lifts the manifold to its fully raised position.

If the AutoTemp option is installed, attach the two 9-pin RS232 cables to the appropriate locations on the underside of the drive unit. If the manifold is configured with tubing and cannulas for Auto Sampling, locate the black tubing fasteners and attach them to the sample tubing wrap.

Affix a fastener to the bottom of the drive unit on either side of the center drive unit lift (see Figure 2-7). Attach the tubing to the clips located toward the back on the underside of the apparatus drive unit.



Figure 2-7. Sample Tubing Fastener

### 2.1.9. Shaft / Evaporation Cover / DDM Installation

Once the vessels and manifold have been installed, the remaining accessories are put into place on the apparatus. Locate the appropriate pieces to be configured as part of the apparatus: evaporation covers, DDMs / Cover Aligners / Evaporation Cover Plugs, receptor shafts, paddle or basket shafts, and shaft locking collars.

Lift the drive unit to its fully raised position. Insert a receptor shaft into each active spindle location. Place a shaft locking collar on the top of each shaft and slide it down until it rests on top of the spindle assembly on top of the drive unit. Slide an evaporation cover over the shafts (Basket or Paddle) to be installed and attach them to the already installed receptor shafts at each applicable position.

Locate the DDM assemblies, Cover Aligners, or Evaporation Cover Plugs to be installed.



**Figure 2-8. Dosage Delivery Module**



**Figure 2-9. Cover Aligner**

For all applicable positions, insert a DDM or Cover Aligner into the DDM Alignment Shaft hanging from the underside of the drive unit.

Attach the DDM or Cover Aligner to the evaporation cover by aligning the notch with the locking pin of the cover and pushing until fully seated.



**Figure 2-10. 708-DS Accessory Installation**

Ensure that the sampling port of the evaporation cover is aligned properly with the cannulas and probes of the manifold, if applicable.

For units without DDM Alignment Shafts, insert an Evaporation Cover Plug into the appropriate location of each cover.

### 2.1.10. Setting Paddle / Basket Heights

To complete the 708-DS accessory installation, it is necessary to properly set the Basket or Paddle shaft height –  $25 \pm 2\text{mm}$  from the bottom of the dissolution vessel.

If basket shafts have been installed, locate the clip-on basket height gauge. Clip the gauge onto the bottom of the basket shaft. Place the drive unit in its operating position (fully lowered). With the shaft locking collar loose, carefully lower the shaft until the bottom of the basket height gauge rests against the bottom of the vessel. Ensure the shaft locking collar is flush against the top of the spindle assembly by rotating the shaft until resistance is met. Tighten the shaft locking collar securely with the 7/64" T-handle allen wrench. Repeat for all active vessel positions.

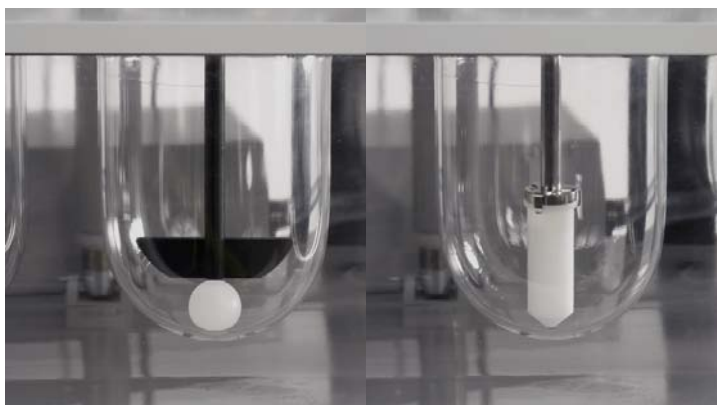


Figure 2-11. Setting Paddle / Basket Heights

For units with paddle shafts installed, locate the 25-mm height spheres. Place a sphere in each vessel. Place the drive unit in its operating position (fully lowered). With the shaft locking collar loose, carefully lower the shaft until the bottom of the paddle blade rests against the height sphere. Ensure the shaft locking collar is flush against the top of the spindle assembly by rotating the shaft until resistance is met. Tighten the shaft locking collar securely with the 7/64" T-handle allen wrench. Repeat for all active vessel positions.

## 2.2. Firmware Setup – Instrument Settings

Once the apparatus' accessory set up is complete, the instrument firmware is configured to best meet the needs of the laboratory. The following sections will proceed naturally through various screens to program specific settings and parameters.

### 2.2.1. Apparatus ID Numbers, LCD Settings

From the Main screen, press **Menu > Instrument**. The screen shown in Figure 2-12 is displayed:

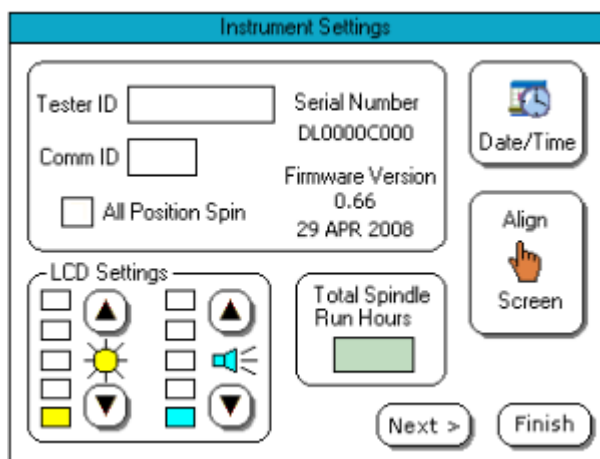


Figure 2-12. Instrument Settings Screen 1

From this screen, the following actions are performed:

- Touch anywhere inside the Tester ID box to enter a unique identification number for the 708-DS.
- Touch anywhere inside the Comm ID box and enter an appropriate communication identification number (default is **01**).
- Place a check in the **All Position Spin** box to allow for spindle rotation with the drive unit raised (useful for RPM / wobble verification with some measurement devices).
- Adjust the LCD settings by pressing the up / down arrows to adjust the brightness of the screen and the volume when buttons are pressed.

### 2.2.2. Setting the Date / Time

From the Instrument Settings screen shown above in Figure 2-12, press the **Date / Time** box to set the current date and time.

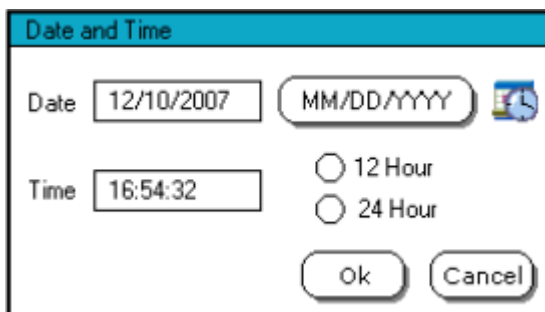


Figure 2-13. Date and Time Screen

Enter the current date by pressing anywhere in the **Date** box. Press **Ok** when finished. Press the format button (MM/DD/YYYY) to toggle between alternate date formats. Select the format that is most appropriate. Enter the current time by pressing anywhere in the **Time** box. Press **Ok** when finished.

### 2.2.3. Calibrating the Touch Screen

To calibrate the LCD touch screen of the 708-DS dissolution apparatus, press the **Align Screen** button from the Instrument Settings screen shown in Figure 2-12. Follow the on-screen prompts to execute this routine by pressing the 3 circles displayed in succession. Verify the screen calibration values by pressing the 4 different circles in the screen corners.

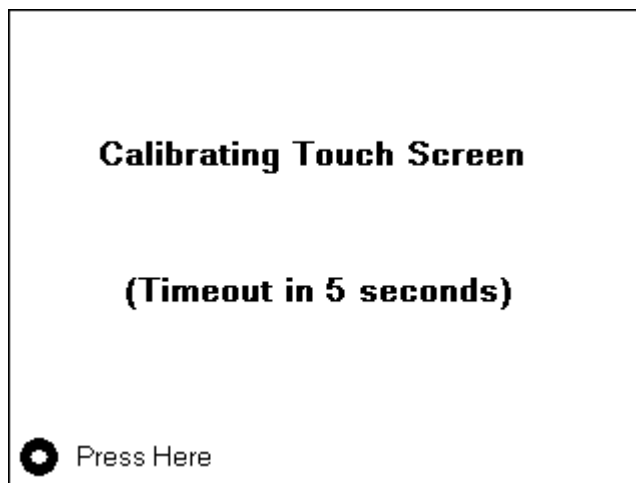


Figure 2-14. Touch Screen Calibration



When complete, the calibration values are stored in non-volatile memory for further use. If the **Align Screen** button was pressed inadvertently, the calibration routine will abort after 5 seconds if the screen is not touched.

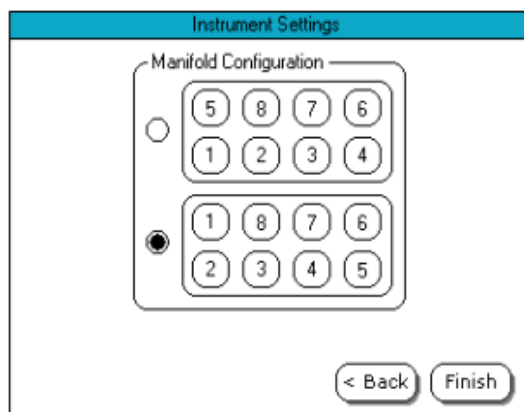
#### 2.2.4. Instrument Tolerances, Vessel Size, Enable Alarms/DDMs

From the Instrument Settings screen shown in Figure 15, press **Next**. From this screen, the following actions are performed:

- Press anywhere inside the Temperature Tolerances box to enter a temperature tolerance (in °C). Press **Ok** when finished.
- Press anywhere inside the Speed Tolerance box to enter a speed tolerance (in RPM). Press **Ok** when finished.
- Select the size of the vessels (in mL) configured as part of the dissolution apparatus by pressing the appropriate circle.
- Press anywhere inside the Number Active box to indicate the number of active vessel positions. Press **Ok** when finished.
- Place a check in the **Enable Alarms** box to activate the alarms of the apparatus.
- Place a check in the **Enable DDM** box if the apparatus is configured with dosage delivery modules and their use is desired when running programs.

Each of the tolerances programmed on this screen will trigger the appropriate error messages and warnings to display when deviations greater than these occur. The settings are stored and applied to each method executed with the apparatus.

#### 2.2.5. Manifold Configuration (Vessel Numbering)



From the Instrument Settings screen shown in Figure 2-12, press **Next** twice. The Manifold Configuration screen displays.

This screen offers the user two options to number the vessel positions for all tests conducted with the 708-DS.

Select the desired option by touching the appropriate circle.

Figure 2-15. Manifold Configuration Screen

Press **Finish** > **Main** when complete to return to the Main screen.

### 2.2.6. Print Options

If the instrument includes a Printer, press **Menu > Reports** from the Main screen. This screen allows the user to print the results of the last test, the contents of stored methods, or the current instrument settings. The printer is also enabled or disabled from this screen by using the Enable Printer check box.



Figure 2-16. 708-DS Printer

To print the results of the most recently executed method, ensure there is a check in the Enable Printer box and press **Last Run Results**.

To print the parameters of any of the stored methods, ensure there is a check in the Enable Printer box and press **Print Method**. Select the number that corresponds to the method to be printed. Available methods have a name associated with them. Methods yet to be configured have a series of dashes (-----) in the name field.

To print the current 708-DS instrument settings, ensure there is a check in the Enable Printer box and press **Print Instrument Settings**. All the instrument configuration parameters and their current values are documented on the printout.

## 3. Measurement of Physical Parameters

### 3.1. RPM, Wobble, Centering, Level, Verticality (Shaft and Vessel)

Periodic verification of certain physical parameters is critical for all dissolution apparatus. Each laboratory has specific guidelines and procedures to follow that detail the frequency of these measurements. The following sections will suggest how to perform these steps with the 708-DS dissolution apparatus. The primary tools used in these descriptions will be Agilent's QA II Station and/or VK 5010. Other similar calibrated devices may also be utilized.

### 3.1.1. RPM / Wobble

To measure and record the RPM and Wobble, the **All Position Spin** feature is enabled. This allows for the spindles to rotate while the drive unit is in a raised position. Press **Menu > Instrument** from the Main screen. To enable this function, place a check in the **All Position Spin** box.

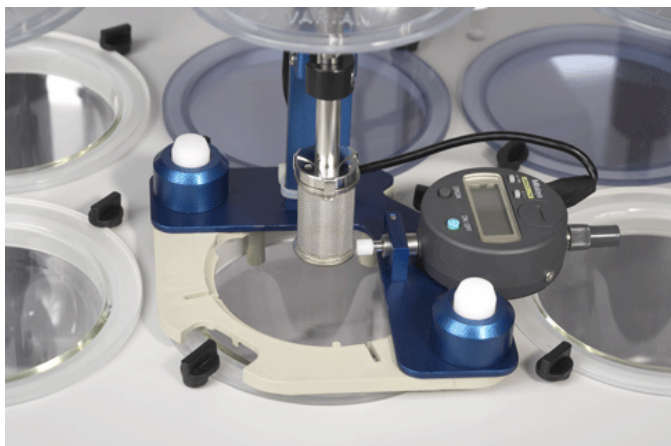


Figure 3-1. RPM and Wobble Measurement on a 708-DS

Raise the shaft to an appropriate level by pulling up on the shaft locking collar of the vessel position to be measured. If necessary, the evaporation covers may be lifted out of the way. To do this, raise the DDM alignment shaft until the o-ring is inside the drive unit. This keeps the covers from interfering with the RPM / Wobble measurement.

Place the QA II Station RPM / Wobble gauge (with the Ease Align adapter attached) on the vessel rim. It is necessary to orient the gauge so that the corner cutouts of the Ease Align adapter are positioned where the vessel rim clips are. Attach the RPM clip to the shaft in front of the RPM sensor. Place the pointer of the wobble gauge on the lower rim of the basket or just above the paddle blade depending on the apparatus installed. Activate the spindles at the desired RPM and record the values.

Spindle rotation may be initiated in a variety of ways including:

- From the Main screen, press the RPM hotspot, enter the desired spindle speed and press **Ok**.
- From the Main screen, press **Menu > Diagnostics**. Touch anywhere inside the RPM box, enter the desired spindle speed, press **Ok**, and then press **Run**.

Move the RPM / Wobble gauge and repeat this procedure for all applicable vessel positions for each spindle speed desired.

### 3.1.2. Centering

To verify the shaft of each active position of the apparatus is in the “center” of each vessel, place the appropriate gauge on the shaft at the desired vessel position. Locate the gauge on the shaft at the point where centering is to be verified – ensure the gauge remains on the cylindrical portion of the vessel.

Agilent’s VK 5010 can be utilized for this measurement and provides a printout with the distance from the centerline (in mm). The Vessel Centering Tool included with the 708-DS can be used for a quick “go / no-go” verification with the help of the Ease Align adapter (QA II Station accessory).

Move the centering gauge and repeat this procedure for all applicable vessel positions.

### 3.1.3. Vessel Table Level

Adjustment of the vessel table level for the unit has been discussed in *Section 2.1.5*. Verification of the level can be performed by placing a digital or bubble level in the middle of the vessel plate.

If a non-quantitative level is used (e.g. torpedo level), the front-to-back level, as well as the right-to-left level should be verified.



Figure 3-2. Level Verification - Torpedo Level

### 3.1.4. Shaft / Vessel Verticality

The verticality of each shaft of the instrument is verified using an appropriate leveling device. This measurement is taken by placing a level against each shaft while the spindles are idle. For this measurement, the drive unit is placed in operating position (fully lowered). The shaft verticality measurement may be taken on a portion of the shaft raised above the drive unit. Other similar methods may be used to verify this parameter.

If applicable, the vessel verticality measurement is also taken according to the description outlined in the ASTM 2503-07 Mechanical Calibration of Dissolution Apparatus 1 and 2 protocol. Alternate level devices may be utilized to perform this measurement. Move the appropriate tool and repeat this procedure for all applicable vessel positions.

## 3.2. Temperature(s)

### 3.2.1. External Vessel Temperature (EVT) Probe

Versions of the 708-DS dissolution apparatus that are not configured with the AutoTemp option may include an EVT Probe that allows for individual vessel temperatures to be recorded and printed. The EVT Probe is stored on the left side of the vessel plate behind the water bath.

To take and record measurements with this device, place the probe in one of the dissolution vessels. Allow the temperature of the probe to equilibrate (approximately 30 seconds). Press the **Sample Temperature** button (shown in Figure 3-4).

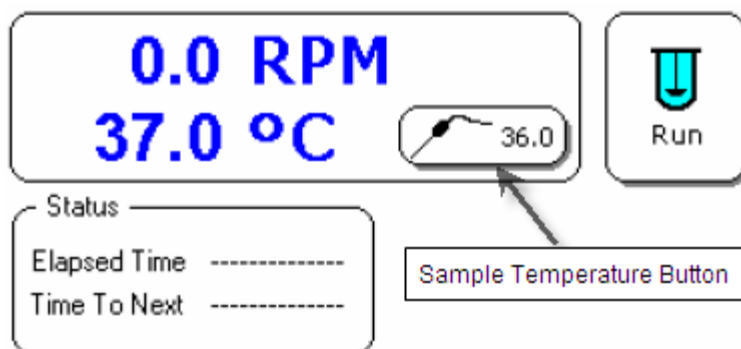
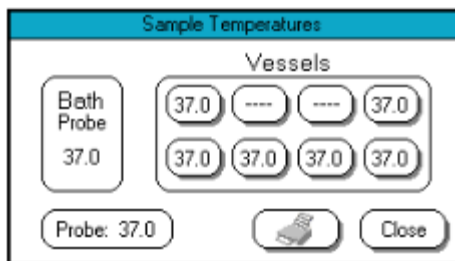


Figure 3-4. 708-DS Sample Temperature Button

The Sample Temperatures window displays. The current Bath Temperature is displayed in the Bath Probe region. The current EVT Probe temperature is displayed in the Probe region.



**Figure 3-5. Sample Temperatures Screen**

Initially, all vessel positions will display “---”. To record the temperature of an individual vessel, press the appropriate location in the Vessels region diagram. The “---” is replaced by the temperature of the medium in the vessel.

If a position that has a temperature recorded is pressed again, the value will toggle back to “---”. Any vessel positions that are not active will beep when an attempt to record a temperature is made. Pressing the printer icon will send the recorded values to the printer. Press **Close** to return to the Main screen.

### 3.2.2. AutoTemp - Vessel Temperatures

If the AutoTemp option is installed on the 708-DS dissolution apparatus with a printer, it is possible to have the initial and final temperatures documented on the report printout. Vessel temperatures at each sample time point may also be documented. Specific details regarding enabling of this option will be discussed in Section 6 of this manual (Method Setup and Execution...). For any manual or pre-programmed dissolution method, it is required to allow at least 30 seconds of equilibration time in the dissolution medium to achieve an accurate temperature reading.

Individual vessel temperatures are displayed at any time by lowering the manifold. It is important to ensure that the temperature probes are immersed sufficiently into the dissolution medium (minimum of 2 cm). The level that the manifold is lowered at any time is dependent on the volume and the apparatus being used. These settings are programmed from within the Calibration menu and are explained in detail in Section 5.1.

### 3.3. Manual Operation (from Diagnostics)

The Diagnostics menu offers a convenient way to operate many basic functions of the instrument. The following sections will describe how to best utilize this option.

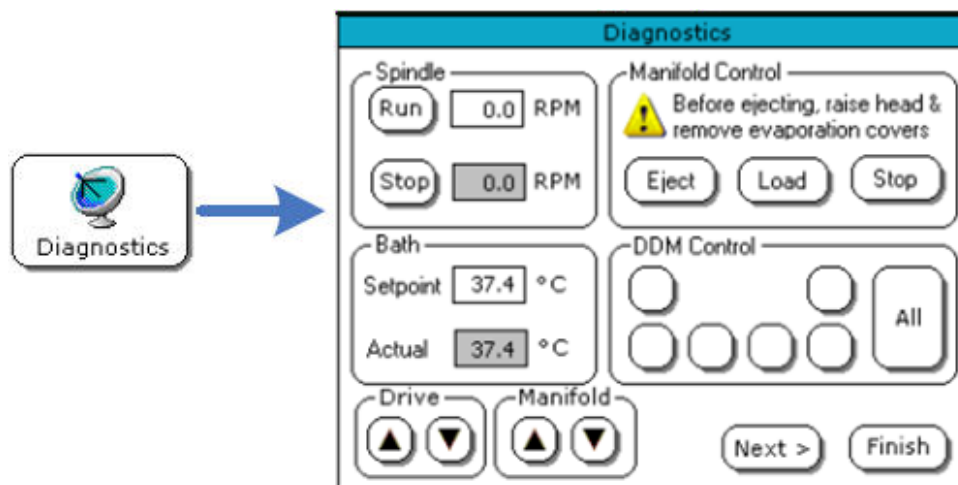


Figure 3-6. Diagnostics Screen 1

#### 3.3.1. Verification of Apparatus Operation

As shown in Figure 3-6, several operations are performed from the initial Diagnostics screen within the firmware. To access this screen, press **Menu > Diagnostics** from the Main screen. This screen allows the user to perform the following operational verifications, including:

- Spindle Speed verification(s) – Run / Stop from Spindle region
- Bath Temperature setting (H/C operation) – Setpoint in Bath region
- Drive Unit operation – Up / Down arrows within Drive region
- Manifold operation – Up / Down arrows within Manifold region
- DDM operation (individual or collective) – Appropriate vessel position button or “All” from within DDM Control region

The Manifold Control (Eject / Load) option, explained in greater detail in Section 2.1.8, is also available from this screen.

Press **Next** from the initial Diagnostics screen to display the screen shown in Figure 3-7.

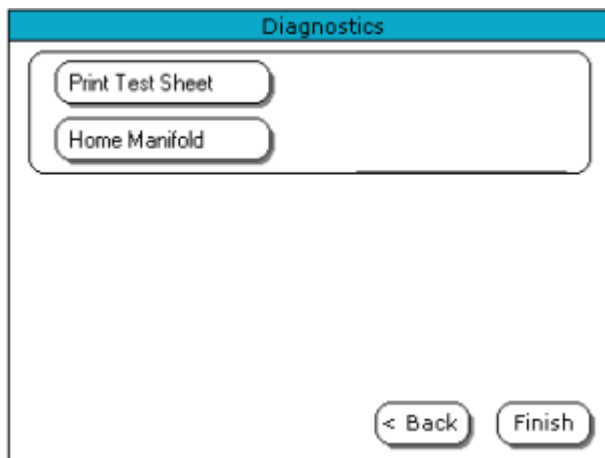


Figure 3-7. Diagnostics Screen 2

The second Diagnostics screen provides the user with a way to test the operation of the Printer (**Print Test Sheet**) or reset the position of the manifold (**Home Manifold**).

## 4. Basic Operation

### 4.1. Dissolution Medium – Filling Vessels, Media Change / Addition

All dissolution tests require some type of medium to be added to each dissolution vessel. The design of the 708-DS dissolution apparatus simplifies this process.

First, the evaporation cover – which in the majority of cases is attached to the DDM Alignment shaft – can be temporarily lifted out of the way (see Figure 4-1). This is done by raising the alignment shaft until the o-ring is inside the drive unit.

The dissolution media can now be delivered to the vessel while the drive unit is in its operating position.

For a media change or media addition method, this is an especially beneficial feature that prevents the raising and subsequent lowering of the drive unit.





Figure 4-1. Filling the vessel of a 708-DS

Secondly, the recessed drive unit design of the 708-DS dissolution apparatus offers vertical and horizontal clearance to the vessel plate for access to the vessels.

#### ***4.2. Manual Sampling, Evaporation Cover Options***

A 708-DS dissolution apparatus that is not equipped with the Auto Sampling option for unattended sample collection will require the analyst to retrieve samples manually.

The evaporation cover design provides easy access to the appropriate dissolution sampling zone with the traditional manual sampling cannula.



Figure 4-2. Taking a Manual Sample



The various ports of the standard evaporation cover of the 708-DS dissolution apparatus are described in Figure 4-3.

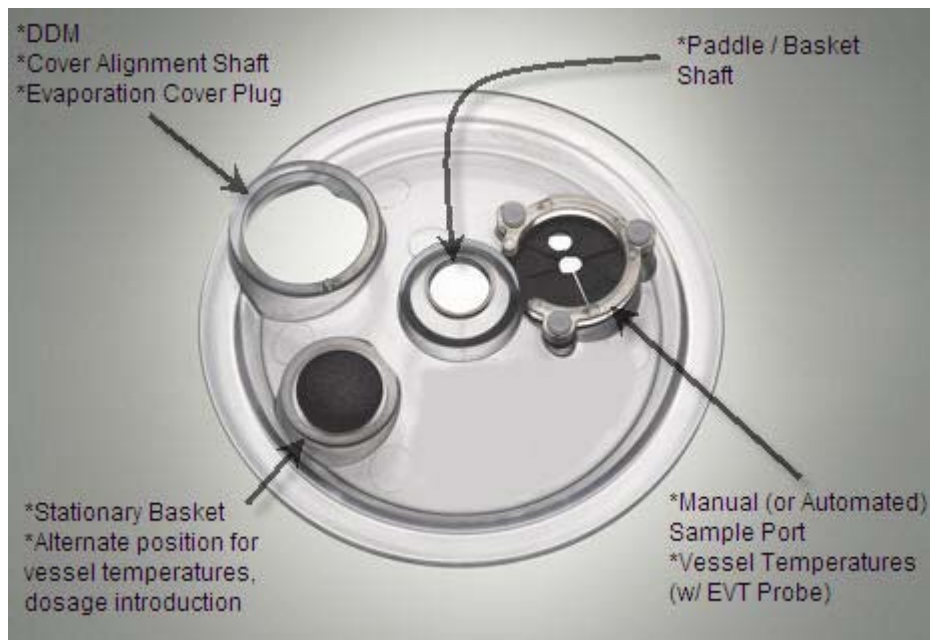


Figure 4-3. 708-DS Standard Evaporation Cover

### 4.3. LCD Display (Touch Screen)

#### 4.3.1. Operations from Main Screen

From the Main screen, several operations are available without navigating any further. This is done by pressing the “hotspots” and easy access buttons on the touch screen.

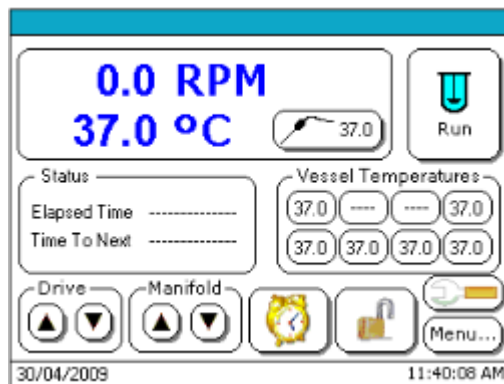


Figure 4-4. Main Screen

A summary of the operations available and their associated “hotspot” or button is listed below:

- Spindle activation at desired RPM – the area over the large font displaying spindle speed
- Bath temperature adjustment – the area over the large font displaying the bath temperature
- Measurement and documentation of vessel temperatures – the Sample Temperature button (shown in Figure 23)
- Method Start options (Manual or Method) – the Run button
- Raise / Lower the drive unit – Drive UP / DOWN buttons
- Raise / Lower the manifold – Manifold UP / DOWN buttons
- View timer alarm settings – Alarm button
- Secure (lock) touch screen – Lock button
- Maintenance due notification – Wrench button (reminder only)
- Access Main menu – Menu button

#### 4.3.2. Alphanumeric / Numeric / Date & Time Entries

Various screens of the 708-DS dissolution apparatus firmware require the entries to be made. The left-hand image displayed in Figure 4-5 shows an example of the instrument keyboard interface. As keys are pressed, they appear in the upper box of the display. The left arrow serves as the backspace key. Spaces, periods, and dashes are provided as valid characters. Pressing CLEAR will remove all characters from the open field. If Cancel is pressed, the data entry field is cleared and the user is returned to the window from which this screen was called.

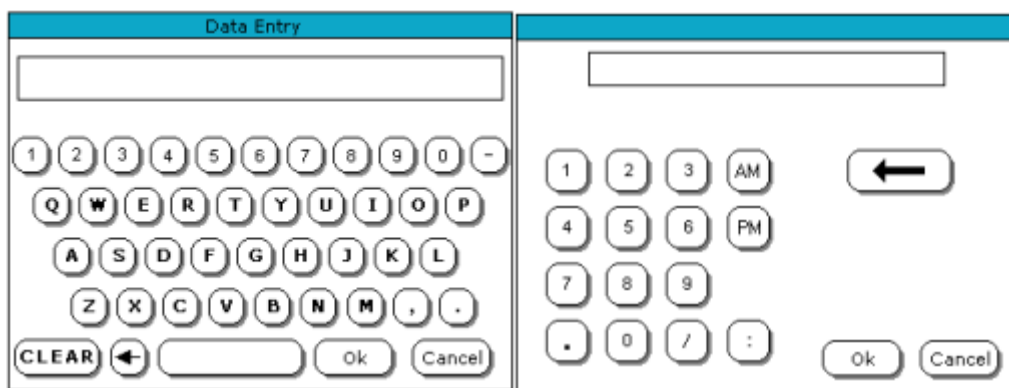


Figure 4-5. Alphanumeric and Numeric Data Entry Screens

The numeric entry screen is a specialized subset of the alphanumeric keyboard – optimized for numeric, date, and time data entry. As keys are pressed, they appear in the upper box of the display. The valid data entry range for the particular value being entered will appear just below the display. The maximum data value string length is 25 characters. Additional special function keys are defined in the following list:

- ← Backspace and deletes one character
- / Used as a separator in date entries
- : Used as a separator in time entries
- **AM** Designates morning when entering time in 12-hour format
- **PM** Designates afternoon when entering time in 12-hour format

## 5. Option Description (Based on Configuration)

### 5.1. Lift Mechanism

#### 5.1.1. Automated

The drive unit of the 708-DS dissolution apparatus configured with an automated lift mechanism enables the user to raise and lower the drive unit. These controls are available on the Main screen as well as the first Diagnostics screen. The movement of the drive unit is performed by pressing and holding the UP / DOWN arrows within the respective Drive box. A quick double-tap of the UP arrow will lift the drive unit to its fully raised position without having to hold the button.

#### 5.1.2. Manual

Alternatively, the drive unit of the 708-DS dissolution apparatus may be configured with a manual lift mechanism to raise and lower the drive unit.

The manual lift is governed by a knob on the right side of the instrument.

To adjust the position of the drive unit, loosen the knob and raise or lower to the desired position.

Then, tighten the knob to secure the drive unit in position.



Figure 5-1. 708-DS Manual Lift Knob

## 5.2. Auto Sampling

The Auto Sampling option of the 708-DS dissolution apparatus allows the laboratory analyst to perform unattended dissolution methods. This requires use of Agilent's VK 8000 Dissolution Sampling Station and a Agilent Peristaltic or Syringe Pump to move the sample to the collector. A Filter Changer may also be added for use with a Syringe Pump for automated filtration. A manifold and its associated internal drive are included with the 708-DS if this option is configured. The following sections discuss or reference details of the manifold and its operation.

### 5.2.1. Load / Eject Manifold

The manifold of the 708-DS dissolution apparatus is installed and removed with the touch of a button. This initial installation procedure is described in Section 2.1.8 of this manual.



Figure 5-2. Installation of the Manifold

For the purposes of cleaning, maintenance, or just to create additional space for manual testing, the manifold may be ejected from the drive unit. To remove the manifold, it is important to first perform the following steps:

- Lift the drive unit to its fully raised position
- Disconnect the two thermistor RS232 cables (if AutoTemp is installed)
- Remove the sample tubing from the black fasteners
- Remove the evaporation covers

After these steps have been completed, press **Eject** to fully lower the manifold until it is free from the drive unit. Be sure to “catch” the manifold

as it is released. The Manifold Control screen is available from the Main screen by pressing **Menu > Diagnostics**.

### 5.2.2. Removing or Adjusting Cannulas / Probes

The manifold of the apparatus may contain up to two cannulas and one probe per vessel position depending on the options configured. To adjust or remove these items, simply loosen the thumbscrew on the individual position of the manifold and modify the location of the cannula / probe accordingly.

### 5.2.3. Programming Manifold Depth

For a 708-DS that is configured with the Auto Sampling and/or AutoTemp options, the appropriate Sampling Depth must be defined. This will ensure the proper depth of the manifold is achieved to remove samples and/or record vessel temperatures depending on the media volume and apparatus installed (e.g. Paddles).

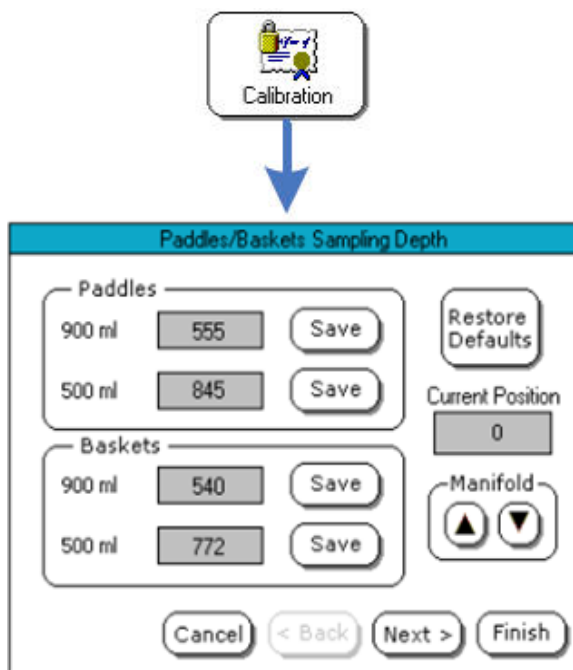


Figure 5-3. Paddles/Baskets Sampling Depth Screen

First, install the desired apparatus (1, 2, 5, or 6) and properly set the height of the accessory.

Place the appropriate amount of media in the vessels. Lower the dissolution apparatus to its operating position.

From the Main screen of the 708-DS, press **Menu**. From the Menu screen, press **Calibration**. The Paddles/Baskets Sampling Depth screen displays.

For Apparatus 5 or 6, press **Next**. The Rotating Cylinder / Paddle over Disk Sampling Depth screen displays.

Lower the manifold incrementally by pressing the **DOWN** arrow inside the Manifold box. The Current Position value increases. Once the sample cannulas have reached the proper sampling location, press the **Save** button that corresponds to the media volume and the installed apparatus.

The number visible in the Current Position box is properly stored in the appropriate location.

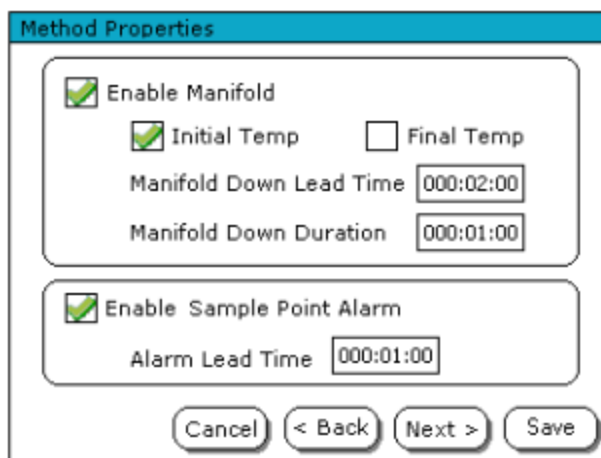
Repeat these steps to properly set the manifold sampling depth for any subsequent apparatus (i.e., 1, 2, 5, or 6) / volume combination.

### 5.3. AutoTemp

The AutoTemp option of the 708-DS dissolution apparatus includes temperature probes at each active vessel location. This enables the analyst to have documented temperature values at the beginning and end of the dissolution method as well as any pre-programmed sample time points. Basic use of this option is described in Section 3.2.2.

#### 5.3.1. Enabling Temperature Measurements

To enable initial and final vessel temperature measurements, place a check in the appropriate boxes from the Method Properties screen shown in Figure 5-4.



The screenshot shows a window titled "Method Properties" with a blue header. It contains two main sections, each enclosed in a rounded rectangle. The first section is titled "Enable Manifold" and has a checked checkbox. Below it are two sub-sections: "Initial Temp" with a checked checkbox and "Final Temp" with an unchecked checkbox. Below these are two time input fields: "Manifold Down Lead Time" set to "000:02:00" and "Manifold Down Duration" set to "000:01:00". The second section is titled "Enable Sample Point Alarm" with a checked checkbox. Below it is an "Alarm Lead Time" input field set to "000:01:00". At the bottom of the window are four buttons: "Cancel", "< Back", "Next >", and "Save".

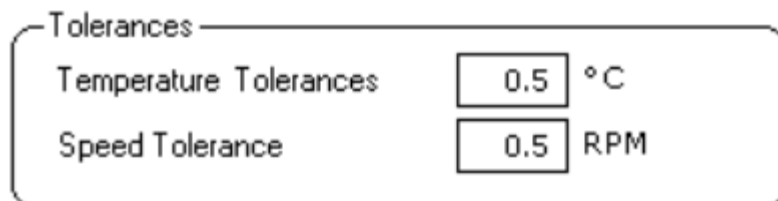
Figure 5-4. Method Properties Screen 3

Details of how to setup the method are discussed in Section 6 of this manual. Section 3.2.2 offers details regarding the recommended manifold lead time and duration for vessel temperature measurements at individual sample time points.

#### 5.3.2. Setting Tolerances

Programmable tolerances for various method parameters are defined within the firmware of the apparatus. These are set up from screen 2 of the Instrument Settings. Detailed explanation on how to navigate to this screen and enter the values is discussed in Section 2.2.4.

As mentioned, each of the tolerances programmed on this screen will trigger the appropriate error messages and warnings to display when deviations greater than these occur. The settings are stored and applied to each method executed with the 708-DS dissolution apparatus.



Tolerances	
Temperature Tolerances	0.5 °C
Speed Tolerance	0.5 RPM

Figure 5-5. Tolerance Settings

If the alarms of the apparatus are enabled, an out of tolerance value will cause an alarm, but not stop the dissolution method. The specific parameters and their tolerances that fall into this category are:

- Temperature – Bath and Vessel
- Spindle Speed (RPM)

### 5.3.3. Manifold Down Lead Time / Manifold Down Duration

The measurement of vessel temperatures is performed by individual temperature probes located on the manifold. Two additional parameters are available to ensure accurate temperature reporting at sample time points. They are both related to the control of the manifold and are displayed in the screen shown in Figure 5-4.

The **Manifold Down Lead Time** is the time, in seconds, that the thermistors are allowed to equilibrate in solution before a temperature reading is taken. The **Manifold Down Duration** is the amount of time, in seconds, that the manifold remains at its sampling position. For example, let's assume a sample time point is setup for 30 minutes, and the Lead Time and Duration are setup for 30 seconds. These settings would trigger the manifold to lower at 29:30 and remain in position until 30:30. To allow for sufficient equilibration time of each probe in the dissolution media, the sum of the Lead Time and Duration must be no less than thirty (30) seconds. The vessel temperature is sent to the printer, if enabled, at the end of the Manifold Down Duration.

## 5.4. Dosage Delivery Modules (DDM)

The Dosage Delivery Module option of the 708-DS dissolution apparatus offers the user a mechanism to introduce dosage forms into the vessels in a consistent, repeatable manner.



### 5.4.1. Automated DDM

To use the DDMs in an automated fashion, they first must be enabled from the Instrument Settings Screen 2. The screen is shown in Figure 5-6 and the enabling of the option is discussed in Section 2.2.4 of this manual.

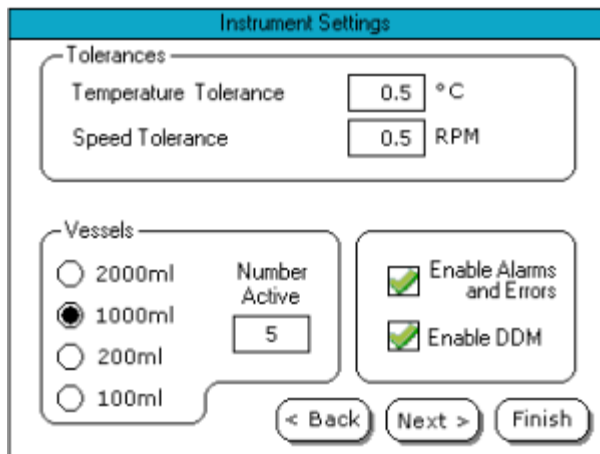


Figure 5-6. Instrument Settings Screen 2

Depending on the apparatus installed (e.g., Baskets, Paddles), the DDMs can be programmed to open simultaneously or sequentially. Sequential delivery is most often preferred when pulling manual samples to allow for additional time between vessels. The time between dosage drops is called the *DDM increment* and will be addressed specifically in Section 6 of this manual.

### 5.4.2. Manual DDM

An alternative to automated DDM use is to hand-actuate the individual doors at the start of the dissolution method.



Figure 5-7. 708-DS DDM – Manual

The small lever on the outside of the solenoid valve acts to trigger the opening of the DDM door and releases the dosage form into the vessel.

### 5.5. 708-DS Reports

The printer of the 708-DS enables the analyst to document critical test results as well as current instrument settings. The print options, shown here in Figure 5-8, are explained in detail in Section 2.2.6 of this manual.

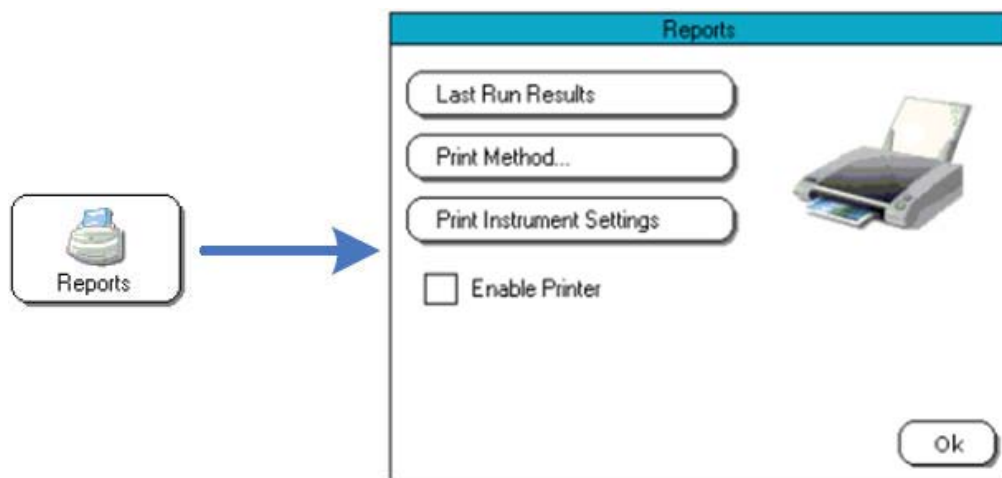


Figure 5-8. Report Options

The Serial and ID number of the instrument is contained on each printout. Printouts created from executed methods display the model number of the apparatus and the title “Run Report.” At individual time points or print intervals, the elapsed time, spindle speed (RPM), and temperatures (if applicable) are printed. The current volume of the method is also printed at each time point. These values are sent to the printer just before the time point or programmed interval to give the user a snapshot of the instrument status.

### 5.6. Alarms

The firmware of the instrument has the ability to notify the user of out of tolerance issues, upcoming events (e.g., sample time points), and other important occurrences. These are controlled through the Alarms managed by the instrument’s firmware. The Enable Alarms box appears on Instrument Settings screen 2 shown in Figure 5-6. Placing a check in this box permits audible notification of the event.

In addition to error / warning messages, out of tolerance values, etc., there are other useful alarms that may be programmed by the user as helpful reminders. Examples of these are:

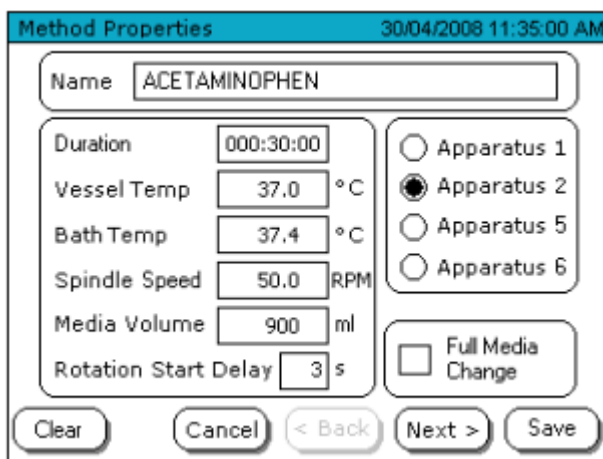


- **Timer Alarm:** This alarm functions as a countdown timer. Once the duration is entered, in HH:MM:SS, and Ok is pressed, the timer counts down to zero. At the time of expiration, an alarm is sounded and a dialog appears on the touch screen of the 708-DS. The alarm will sound until Ok is pressed to clear the dialog. To access this function from the Main screen, press **Menu > Alarms**. An alarm button will appear on the Main screen if the Timer Alarm is active.
- **Pause Duration Alarm:** This setting allows the user to set a maximum pause period while running a method. When a ongoing method is paused, a timer will begin counting. If the time the method is paused exceeds the Pause Duration, an alarm will sound and a message will be sent to the printer. This is especially useful to track the time that a Media Change / addition takes during applicable methods. Entering 00:00 in this field disables the alarm. To access this function from the Main screen, press **Menu > Alarms**.
- **Sample Time Point Alarm:** From within the method setup options (Method Properties Screen 3), a notification is enabled to alert to user to upcoming sample time points. Enabling this feature activates the sample notification dialog as well as audible alarms. The **Alarm Lead Time**, setup in conjunction with the time point alarm, allows the user to determine how long before the time point the notification dialog appears. This is discussed in greater detail in Section 6 of this manual.

## 6. Method Setup and Execution with the 708-DS

### 6.1. 708-DS Method Setup (Stored)

This section discusses how to set up and store a dissolution method. A total of five (5) dissolution methods may be stored in the memory of the instrument. To begin, from the Main screen of the 708-DS, press **Menu > Method Editor**. The Select Method screen displays. Press a number (1-5) corresponding to the stored location of the Method. The first Method Properties screen displays.



The screenshot shows the 'Method Properties' screen with the following fields and controls:

- Name:** ACETAMINOPHEN
- Duration:** 000:30:00
- Vessel Temp:** 37.0 °C
- Bath Temp:** 37.4 °C
- Spindle Speed:** 50.0 RPM
- Media Volume:** 900 ml
- Rotation Start Delay:** 3 s
- Apparatus Selection:**
  - Apparatus 1
  - Apparatus 2
  - Apparatus 5
  - Apparatus 6
- Full Media Change:**
- Buttons:** Clear, Cancel, < Back, Next >, Save

Figure 6-1. Method Properties Screen 1

Press anywhere inside the **Name** box and create a title to describe the Method to be created. Press **Ok** when finished.

Press anywhere inside the **Duration** box and enter the minimum time (in HHH:MM:SS) for the Method. Press **Ok** when finished.

**NOTE:** The time entered as the test duration will be superseded by the sum of the final time point and final spin if it is greater.

If vessel temperature probes are configured, press anywhere inside the **Vessel Temp** box and enter the appropriate vessel temperature (in °C) for the Method. Press **Ok** when finished.

Press anywhere inside the **Bath Temp** box and enter the appropriate bath temperature (in °C) for the Method. Press **Ok** when finished.

Press anywhere inside the **Spindle Speed** box and enter an appropriate value (in RPM) for the Method. Press **Ok** when finished.

Press anywhere inside the **Media Volume** box and enter an appropriate value (in mL) for the Method. Press **Ok** when finished.

If the Method includes Apparatus 2 or 5, press anywhere inside the **Rotation Start Delay** box and enter an appropriate value (in seconds) for this value. Press **Ok** when finished. This time will delay the rotation of the spindles to allow for the dosage forms to travel to the bottom of the vessel.

Select the Apparatus to be used (1, 2, 5, or 6) as part of the dissolution method by pressing the appropriate circle.

If applicable, place a check in the **Full Media Change** box indicating the desire to temporarily halt the elapsed timer when the Method is paused to change the media.

**NOTE:** A **Pause Duration Alarm** may be setup from the Alarms screen (**Menu > Alarms** from the Main screen) to alert the user that the maximum pause duration has been exceeded.

Press **Next**. The second Method Properties screen displays. Place a check in the **Enable Final Spin** box if the method includes a final (i.e., infinity) spin. If applicable, press anywhere inside the **Final Spin RPM** box and enter an appropriate value (in RPM) for the final spin of the Method. Press **Ok** when finished.

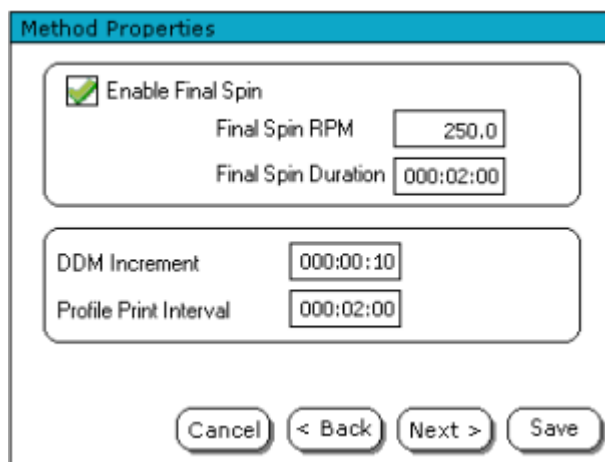


Figure 6-2. Method Properties Screen 2

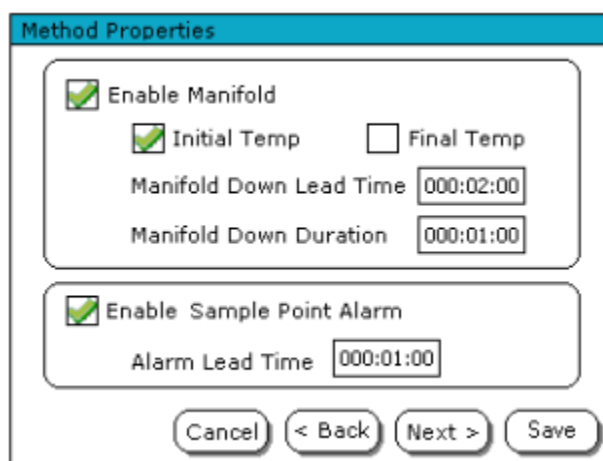
If applicable, press anywhere inside the **Final Spin Duration** box and enter an appropriate time (in HHH:MM:SS) for the length of the final spin of the Method. Press **Ok** when finished.

If DDMs are configured, press anywhere inside the **DDM Increment** box and enter the time (in MM:SS) desired between dosage introduction. Enter 00:00 for a simultaneous start. Press **Ok** when finished.

If the instrument is configured with a printer, press anywhere inside the **Profile Print Interval** box to enter an appropriate frequency (in HHH:MM:SS) to print the current test conditions (e.g., RPM, Bath Temperature). Press **Ok** when finished.

**NOTE:** A maximum of 100 'events' may be stored and printed during a method.

Press **Next**. The third Method Properties screen displays. If applicable, place a check in the **Enable Manifold** box to set the desired raising / lowering times of the sample manifold.



The screenshot shows a dialog box titled "Method Properties". It contains two main sections. The first section is titled "Enable Manifold" and has a checked checkbox. Below it are two sub-sections: "Initial Temp" with a checked checkbox and "Final Temp" with an unchecked checkbox. There are two time input fields: "Manifold Down Lead Time" set to "000:02:00" and "Manifold Down Duration" set to "000:01:00". The second section is titled "Enable Sample Point Alarm" with a checked checkbox, and it has an "Alarm Lead Time" input field set to "000:01:00". At the bottom of the dialog are four buttons: "Cancel", "< Back", "Next >", and "Save".

Figure 6-3. Method Properties Screen 3

Place a check in the **Initial Temp** box if the apparatus contains vessel temperature probes and it is desired to measure and record initial test temperatures in all vessels. Place a check in the **Final Temp** box if the unit is equipped with vessel temperature probes and it is desired to measure and record final test temperatures in all vessels.

If applicable, press anywhere inside the **Manifold Down Lead Time** box and enter an appropriate time (in MM:SS) to lower the manifold before each sample time point. Press **Ok** when finished. If applicable, press anywhere inside the **Manifold Down Duration** box and enter an appropriate time (in MM:SS) to keep the manifold at the sampling position after each sample time point. Press **OK** when finished.

**NOTE:** The sum of the **Manifold Down Lead Time** and **Manifold Down Duration** must be  $\geq 30$  seconds to ensure stable vessel temperature measurements.

Place a check in the **Enable Sample Point Alarm** box to activate visual and audible notifications before each sample time point. If applicable, press anywhere inside the **Alarm Lead Time** box and enter an appropriate time (in MM:SS) before each sample time point to notify the user of the upcoming event. Press **Ok** when finished.

Press **Next**. The fourth and final Method Properties screen displays.

Method Properties					
hhh:mm:ss	RPM	mL	hhh:mm:ss	RPM	mL
1.000:05:00	50.0	900	7.000:00:00	0.0	900
2.000:10:00	50.0	900	8.000:00:00	0.0	900
3.000:15:00	50.0	900	9.000:00:00	0.0	900
4.000:20:00	50.0	900	10.000:00:00	0.0	900
5.000:30:00	50.0	900	11.000:00:00	0.0	900
6.000:00:00	0.0	900	12.000:00:00	0.0	900

Figure 6-4. Method Properties Screen 4

Press the button that corresponds to the appropriate sample time point to be programmed. The Timepoint Properties screen displays.

Press anywhere inside the **Timepoint** box and enter an appropriate time (in HHH:MM:SS) for the sample time point. Press **Ok** when finished.

Press anywhere inside the Spindle RPM box and enter an appropriate value for the spindle speed (in RPM). Press **Ok** when finished. The value entered will cause the RPM to change at the time point and continue at that rate until the next time point is reached.

Press anywhere inside the Media Volume box and enter an appropriate value for the media volume (in mL). This value determines the depth of the manifold at each time point. Press **Ok** when finished.

Timepoint Properties	
Timepoint	<input type="text"/>
Next Spindle RPM	<input type="text"/>
Next Media Volume	<input type="text"/>
<input type="button" value="Ok"/> <input type="button" value="Cancel"/>	

Figure 6-5. Timepoint Properties Screen

Repeat the previous steps to setup all remaining sample time points.

Press **Save** to store the Method. The Select Method screen displays. Press **Return** to return to the Menu screen.

To print the Method, press **Reports > Print Method...** Place a check in the **Enable Printer** box, if necessary. Press a number (1-5) corresponding to the

stored location of the Method to be printed. Press **Ok** > **Main** to return to the Main screen.

## 6.2. 708-DS Test Execution (Stored Method)

This section discusses how to execute a stored dissolution method. To begin, from the Main screen of the instrument, press **Run**. The Select Start Type screen displays. Press **Method**. The Select Method screen displays. Press a number (1-5) corresponding to the stored location of the Method to be executed. The Start Options screen displays.

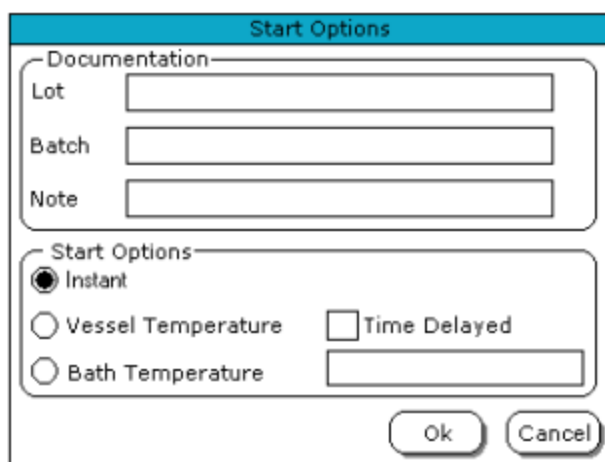


Figure 6-6. Test Start Screen

If applicable, press anywhere inside the Lot, Batch, and Note boxes to enter any supporting data for the Method to be executed.

Select the Start Type to be used (Instant, Bath Temperature, or Vessel Temperature) by pressing the appropriate circle. A Vessel Temperature start requires the AutoTemp option. The manifold will lower and begin the test when all vessels have attained the desired temperature. A Bath Temperature start will cause the apparatus to begin the method when the water bath selected start temperature is reached.

Place a check in the **Time Delayed** box if it is desired to delay the test start to a specific time. If applicable, press anywhere inside the **Time Delayed** rectangle to enter the desired date and time to begin the test. Press **Ok** when finished.

Press **Ok** from the Start Options screen to begin the Method. Ensure the appropriate pre-test measurements occur, if applicable, and the **Stop** button appears in place of the **Run** button once the test begins.

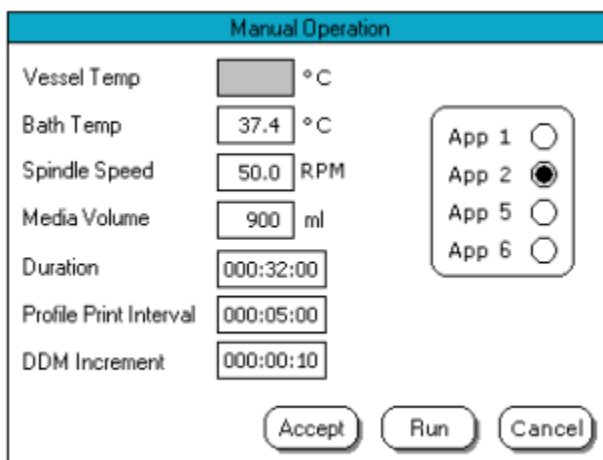


To pause the test for a media change (optional), press **Stop > Pause Method**. When ready to continue the test, press **Resume Method**. To stop the test press **Stop > Stop Method**.

At the conclusion of the test, a Method Complete notification displays. Press **Ok** to return to the Main screen.

### 6.3. 708-DS Method Setup and Execution (Manual)

This section discusses how to set up and store a Manual dissolution method within the firmware. A single dissolution method may be stored in the memory of the instrument in this manner. To begin, from the Main screen of the 708-DS, press **Run**. The Select Start Type screen displays. Press **Manual**. The Manual Operation screen displays.



The screenshot shows the 'Manual Operation' screen with the following parameters and controls:

- Vessel Temp**: A greyed-out input box followed by '°C'.
- Bath Temp**: An input box containing '37.4' followed by '°C'.
- Spindle Speed**: An input box containing '50.0' followed by 'RPM'.
- Media Volume**: An input box containing '900' followed by 'ml'.
- Duration**: An input box containing '000:32:00'.
- Profile Print Interval**: An input box containing '000:05:00'.
- DDM Increment**: An input box containing '000:00:10'.
- Application Selection**: A vertical list of radio buttons labeled 'App 1', 'App 2', 'App 5', and 'App 6'. 'App 2' is selected.
- Buttons**: 'Accept', 'Run', and 'Cancel' buttons are located at the bottom of the screen.

Figure 6-7. Manual Operation Screen

If the AutoTemp option is configured press anywhere inside the **Vessel Temp** box and enter the appropriate vessel temperature (in °C) for the Method. Press **Ok** when finished.

Press anywhere inside the **Bath Temp** box and enter the appropriate bath temperature (in °C) for the Method. Press **Ok** when finished.

Press anywhere inside the **Spindle Speed** box and enter an appropriate value (in RPM) for the Method. Press **Ok** when finished.

Press anywhere inside the **Media Volume** box and enter an appropriate value (in mL) for the Method. Press **Ok** when finished.

Press anywhere inside the **Duration** box and enter the minimum time for the Method (in HHH:MM:SS). Press **Ok** when finished.

If the unit is configured with a printer, press anywhere inside the **Profile Print Interval** box to enter an appropriate frequency (in HHH:MM:SS) to print the current test conditions (e.g., RPM, Bath Temperature). Press **Ok** when finished.

**NOTE:** A maximum of 100 'events' may be stored and printed during a method.

If DDMs are configured, press anywhere inside the **DDM Increment** box and enter the time (in MM:SS) desired between dosage introduction. Enter 00:00 for a simultaneous start. Press **Ok** when finished.

Select the Apparatus to be used (1, 2, 5, or 6) as part of the dissolution method by pressing the appropriate circle.

Press **Accept** to store the Method parameters and return to the Main screen or press **Run** to begin the dissolution test instantly. Press **Cancel** to return to the Main screen without storing the Method parameters.


If **Run** is chosen to begin the test, ensure the **Stop** button appears in its place once the test begins. To pause the test for a media change (optional), press **Stop > Pause Method**. When ready to continue the test, press **Resume Method**. To stop the test press **Stop > Stop Method**.

When the elapsed time equals the test duration, the Method Complete notification displays on the touch screen. Press **Ok** to return to the Main screen.


#### 6.4. Screen Lock / Unlock

This section of the manual describes how to lock the touch screen of the 708-DS dissolution apparatus. To prevent uncontrolled access to the functions of the

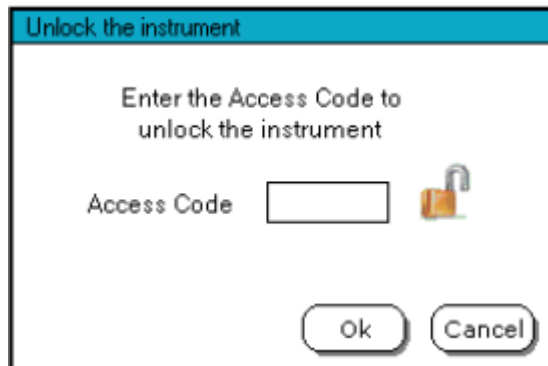


instrument, press the  button on the Main screen. At this time, a dialog will appear requesting an access code. Once the code has been entered, confirmed, and OK is pressed, the Main screen displays with the icon now in the "locked"



state (  ). Further changes to the instrument are prohibited until the access code is entered or the unit is powered OFF and ON.

To unlock the instrument, press the closed lock icon to display the dialog requesting the access code.



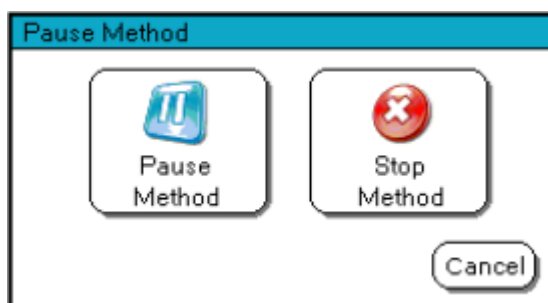
**Figure 6-8. Unlock Instrument Screen**

Once the access code has been entered and **Ok** is pressed, the unit returns to the Main screen with the unlocked icon displayed.

The instrument will also appear in a locked state if it is being controlled remotely. This is the case when connected to a VK 8000 or Agilent’s UV Dissolution Software, for example. The words “Remote Control” will also flash at the bottom of the display in this instance. Pressing any buttons under these circumstances will result in a “beep”, but no actions will occur.

### **6.5. Pause / Resume Test ... Media Change**

While a dissolution method is underway, the test may be stopped or paused. To do this, press the **Stop** button on the Main screen during the method.



**Figure 6-9. Pause Method Screen**

At this point, the ongoing test will continue. To temporarily halt the test, press the **Pause Method** button. This brings up a dialog that displays a timer indicating how long the method has been paused along with the **Resume Method** button. During a pause, the spindles will stop, and if Full Media Change has been enabled, the elapsed timer will stop counting. The drive unit and manifold may be raised / lowered at this time. If the Pause Duration Alarm time is exceeded, an alarm will sound and an error dialog will appear.

When the **Resume Method** button is pressed, the test will continue. The amount of time the method was paused is sent to the printer and the Main screen is displayed.

Pressing **Stop > Stop Method** while a test is in progress causes the method to cease. The message “Test Aborted By User” is sent to the printer in this case.

## 7. Dialog, Warning, and Popup Error Screens

The firmware of the instrument contains various screens that notify the user of impending events, out-of-tolerance warnings, and operational errors that may occur during routine use. Refer to the *Agilent 708-DS Operator’s Manual* for detailed descriptions of the screens that may appear. If the description is not sufficient or the error cannot be cleared, contact Agilent’s Dissolution Service Department. Be sure to provide information regarding the error received as well as the serial number and model number of the instrument.

## 8. Cleaning / Maintenance / Troubleshooting

The following sections discuss the procedures to care for and maintain the 708-DS dissolution apparatus. It is recommended that a Agilent technician performs regular Preventative Maintenance on the unit as well as any additional system components attached to the instrument.

### 8.1. Maintenance Due Icon (Calibration / PM due date alarms)

The firmware is equipped with a feature to setup and subsequently notify the user of calibration and maintenance due on the instrument. These settings are available from the Main screen by pressing **Menu > Calibration > Next > Next**. The Regulatory Calibration Date screen displays.

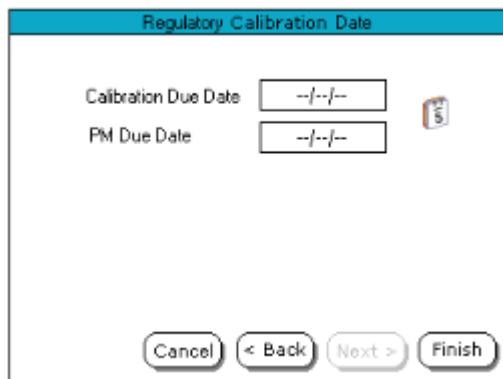



Figure 8-1. Regulatory Calibration Date Screen

From this screen, the user enters the appropriate due dates for instrument calibration and / or preventative maintenance (PM). A service due dialog appears on the Main screen when these dates arrive. The  icon remains displayed on the Main screen until the dates are updated.

## **8.2. Rinse Cups (for use with VK 8000)**

If the 708-DS is configured with a VK8000 Dissolution Sampling Station or is part of an online software solution, the sample lines require a routine rinsing after each test. Easy-to-attach rinse cups are provided to make the flushing of the tubing simple and efficient.



**Figure 8-2. 708-DS Rinse Cup**

To achieve this, fill the rinse cups with the cleaning solution desired and attach a cup to each shaft.

The sample cannulas must be sufficiently immersed in the solution. The return cannulas can either be contained in the cup or allowed to drip into the vessel.

The bottom of the cup rests on either the paddle blade or the basket clip attachment.

Then, activate the pump configured with the system until the tubing loop is sufficiently cleansed.

Finally, detach the rinse cups, place them in their transport tray, dispose of the waste, and rinse the cups to be ready for their next use.

## **8.3. Vessels (TruAlign), Shafts, Evaporation Covers**

The dissolution accessories that accompany the 708-DS require equivalent care as with previous Agilent models or other traditional apparatus. This includes the TruAlign vessels (glass), basket and paddle shafts, and evaporation covers. The components are primarily the same and thus the cleaning procedures used in the past should be carried forward.

#### ***8.4. Touch Screen Alignment Procedure***

The LCD Display of the 708-DS relies on an internal calibration procedure to ensure the touch screen remains accurate. If it appears that the positioning has drifted slightly, the user may execute a quick and easy routine to re-calibrate the screen. This procedure is described in detail in Section 2.2.3 of this manual.

*END OF DOCUMENT*