

850-DS Dissolution Sampling Station

**Operator's Manual** 

### **Notices**

### **Manual Part Number**

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### **Safety Notices**

### **CAUTION**

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

### WARNING

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

# Content

1	Safety 7
	Electrical Hazards 8
	Warning 9 Caution 9
	Note 9
	Information Symbols 10
2	Introduction 11
	Serial Number Format 13
3	Setting Up the 850-DS 15
	Initial Setup 16
	Equipment Ratings / Environmental Requirements for Installation 17 Specification 18
	Equipment, Parts, and Accessories As Shipped 19
	Parts and Accessories 19 Wetted Parts List 20
	Connections 21
	Tubing 22
	Power Cord 23
	Apparatus Control Cable 23 Synchronized Start 24
	Initial Power Up 25
	Sample Tray Installation 25
	Updating 850-DS Language Screens 26

Optional Filter Module 27 Changing Trays / Needle Replacement 28 Operating the 850-DS 29 Startup Screen 30 Main Screen 32 Menu Screens 36 Methods 36 Method Properties (Apparatus 1/2/5/6) 38 Sample Collection Parameters (Apparatus 1/2/5/6) 40 Method Properties (Apparatus 3/7) 43 Timepoint Number Selection Timepoint Parameter Entry (Apparatus 1/2/5/6) 46 Timepoint Parameter Entry (Apparatus 3/7) Run Method Screen 1 48 Run Method Screen 2 49 Run Method Screen 3 51 Run Method Screen 4 52 Run Method Screen 5 52 850-DS Method Transfer (to another 850-DS) 53 Alarms 55 Calibration 56 Cleaning 60 Diagnostics 63 Diagnostics Screen 2 65 66 Diagnostics Screen 3 Diagnostic Screen 4 (Apparatus 1/2/5/6) 68 Diagnostic Screen 4 (Apparatus 3/7) 70 Instrument Settings Instrument Settings Screen 2 73 Manufacturing Configuration 77 Reports 78

User Access

79

### Content

Dialog Screens (Blue) 82 Warning Screens (Yellow) 84 Error Screens (Red) 86

### 5 Maintenance and Troubleshooting 91

### Preventive Maintenance 92

Clean System 92 Periodic Maintenance 92

### Printer Maintenance 93

Removing a Thermal Paper Roll 93 Inserting a Thermal Paper Roll 94 Thermal Printer Test 95

### Obtaining Warranty and Other Services 96

### Content

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# 1 Safety

Electrical Hazards 8

### 1 Safety

The Agilent 850-DS Dissolution Sampling Station has been designed and tested so that when used properly you have an accurate, fast, flexible, and safe instrument

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

Operation of a Agilent 850-DS involves the use of aqueous liquids and various pharmaceutical dosage forms. Unskilled, improper, or careless use of this instrument can create shock hazards, fire hazards, or other hazards which can cause death, serious injury to personnel, or severe damage to equipment and property.

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

Observe all relevant safety practices at all times.

## **Electrical Hazards**

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

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

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

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

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

# 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**



A depressed power button in the front of the unit (with green light) indicates main power on.



An extended power button in the front of the unit (with green light off) indicates main power off.



Indicates single-phase alternating current



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



Indicates specific equipment meets 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.

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

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

**C**N10149

Indicates the product complies with regulatory compliance requirements of New Zealand and Australia.

# 2 Introduction

Serial Number Format 13

### Introduction

2

The 850-DS allows you to autonomously collect samples from a dissolution apparatus. Samples may be collected into various sample holders including 15 mL test tubes, 2 mL vials, and 96-well plates. The vials and well plates may be conveniently placed on a sample tray that is compatible with Agilent HPLC autosamplers. The 850-DS provides two basic modes of collecting samples from a dissolution apparatus: manual control and method control. Manual control provides full control of the instrument through the Diagnostics screens. You can independently control all of the features of the instrument.

## CAUTION

In manual control as it is possible to pump volumes greater than those that the sample vessels may hold.

Method control allows you to enter all the parameters relevant to a sample collection; prime, sample, and purge volumes, sample collection times, and self cleaning. If using an Agilent dissolution apparatus, the 850-DS will fully control the dissolution apparatus through a serial interface.

## WARNING

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

## **CAUTION**

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

# Serial Number Format

The serial number contains 10 characters and follows this syntax:

# **CC1234xxxx**

Syntax Code	Meaning	Description
CC	Country of origin	$2\mbox{alpha}$ characters matching the required trade designation for the country of origin
12	Year of manufacture	'16' for 2016, '17' for 2017, etc.
34	Week of manufacture	'01' for week 1 to '52' for week 52

### 2 Introduction

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# 3 Setting Up the 850-DS

Initial Setup 16
Equipment, Parts, and Accessories As Shipped 19
Connections 21
Optional Filter Module 27
Changing Trays / Needle Replacement 28

# Initial Setup

Complete the following sections to initially set up the Agilent 850-DS and all other system components.

1 Prepare an area next to a dissolution apparatus where the Agilent 850-DS will be placed. The preferred location is on the right side of the dissolution apparatus.

Height	40 cm (60 cm with Filter Module)
Width	39.0 cm (48.0 cm with filter waste bin)
Depth	60.0 cm

- 2 Remove the Agilent 850-DS and all other system components from the packing material and place on a bench or table.
- **3** Inspect the equipment and accessories to ensure there has been no damage during shipment.
- **4** Orient the Agilent 850-DS and all other system components appropriately.

# Equipment Ratings / Environmental Requirements for Installation

- Electrical Supply: 100-240 V~ ±10%, 50/60 Hz, max. 2 A
- Temperature: 5 °C to 40 °C
- Humidity: max relative humidity 80% for temperatures up to 31 °C decreasing linearly to 50% relative humidity at 40°C
- Altitude: 2000 mPollution Degree: 2
- Installation Category: II
- Indoor use only

# **Specification**

Parameter	Specification
Operating Environment	5 to 40 °C
Humidity (non-condensing)	Not more than 80% RH
Power requirements	Voltage: 90-250 V, 50-60 Hz Current: 2.5-1.0 A
Dimensions	Height: 40.0 cm Height with filter module: 60 cm Width: 39.0 cm Width with filter waste bin: 48.0 cm Depth: 60.0 cm
Weight	27 kg
Interface	7" color touchscreen (English, Simplified Chinese, Spanish, Japanese, German, Hungarian, Portuguese, Russian) or PC controlled
Pumping system and speed	Rotary piston syringe pump, 8 syringes with adjustable 6-12 mL/min.
Sampling accuracy	2.5%*
Sample volume per vial/tube	0.1-14 mL (up to 28 mL with dual sample)
Sample frequency	Minimum of 2 minutes (under certain conditions)
Number of samples per test	Up to 36 (with manual tray exchange after every 12 samples)
Maximum run time	999 hours

<sup>\*</sup> The Sampling Accuracy specification is derived from the following conditions: 10 mL volume, DI  $\rm H_2O$ , 10 mL/min pump speed and 3-second Aspiration Dwell Time. This percentage may change based on the sampling parameters or volume, product formulation and type of dissolution media or when in line filters are used.

# Equipment, Parts, and Accessories As Shipped

# **Parts and Accessories**

Locate the following items, as applicable, for your system configuration:

Base Unit Components			
Part Number	Quantity	Description	
G7930-64000	1	850-DS base unit	
K1005-02066	1	Rack for 15mL test tubes	
K3090-00155	7	1/4-28 Male to 1/8" barb fitting	
3090-0160	8	1/4-28 Male to 1/4-28 Male tubing adapter	
33-9019	3	25' of 1/8" silicone tubing	
K1003-00232	1	2.5mm Hex key	
K1003-00233	1	3mm Hex key	
K1003-00234	1	1/4" slotted screwdriver	
K1003-00235	1	#1 Phillips screwdriver	
1150-7997	1	Stylus for touchscreen	
17-5001	1	Box of 100 15mL test tubes	
5075-0042	1	DB25 communications cable	
77-0001	1	Safety Manual and Documentation CD	
Power cord	1	Country-specific power cord	

Optional Accessory Kits			
Part Number	Quantity	Description	
K1005-05187	1	850-DS printer kit	
G7931A	1	850-DS filtration module	
K1001-01202	1	Kit for 2, 54-position LC trays, 2mL vials	
K1001-01203	1	Kit for 100-position LC tray, 2mL vials	
K1001-01204	1	Kit for well plate LC tray, 2 mL x 96 wells	
K1005-05212	1	Sample tray for 2mL vials (8 x 12)	

## **Wetted Parts List**

The following list of materials are those which come into contact with the media. Please ensure your media is compatible with these materials prior to use.

Material	Component/Location
Polypropylene	Bulkhead and media reservoir
FEP	Tubing
PTFE	Syringe plunger
Glass	Syringe
PEEK	Valve manifolds and filter module blocks
FKM/FFKM	Valves
FKM or PTFF	Filter module 0-rings
Stainless Steel	Needles
Silicone	Replacement media/rinse ports
Santoprene	Replacement media/rinse ports
Novoprene	Peristaltic pump heads

# Connections

Complete the following sections to connect the necessary tubing and cables for the Agilent 850-DS.

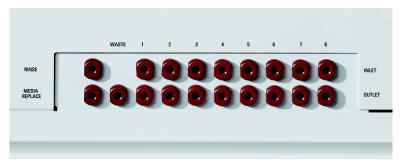


Figure 1. 850-DS Tubing Connections

# **Tubing**

- 1 Connect the three 1/4-28 male to 1/8" barb fittings to the three ports on the left side, nearest the rear of the instrument.
- 2 Using a length of 1/4" silicone tubing, connect the waste fitting to a suitable waste collection container. If media replacement will be used, use a length of 1/4" silicone tubing to connect to a suitable media container. The media must be kept at a suitable temperature by a device provided by the user. If the self-cleaning function will be used, use a length of 1/4" silicone tubing to connect to a suitable rinse media container.

## CAUTION

Ensure that the waste connection is not capable of siphoning back into the instrument. The inlet tubing must never fall below the level of waste in the container.

The media bottles should be located at the same bench level as the 850-DS or lower.

- **3** Connect up to 8 sample lines from a dissolution apparatus to the input connections on the left side of the Agilent 850-DS.
- 4 Connect up to 8 return lines from a dissolution apparatus to the output connections on the left side of the Agilent 850-DS. If applicable, connect the male-to-male tubing adapters to the fittings separately; then, attach the return tubing lines. This will prevent possible damage caused by excessive twisting of the tubing.

### NOTE

If connecting a dissolution apparatus using less than 8 positions, attach a barb fitting to the inlet and outlet ports of the unused positions. Cut appropriate lengths of silicone tubing and attach them to each barb fitting and route the tubing to an appropriate waste container.

### **Power Cord**

# CAUTION

Ensure the correct voltage has been supplied prior to connecting the power cables.

- **1** Attach the provided power cord to the back of the instrument.
- 2 Plug the cord into an electrical outlet of suitable voltage.

# **Apparatus Control Cable**

If connecting to an Agilent, Varian or VanKel dissolution apparatus, connect the DB25 communications cable from the RS232 port on the right rear of the Agilent 850-DS to the 25-pin port on the rear of the dissolution apparatus.

For 850-DS setup with an online UV Dissolution system, refer to the Operator's Manual or the help files in the software for the applicable system.

# **Synchronized Start**

To utilize the Synchronized Start feature of the 850-DS, connect a 9-9 pin null modem cable (5075-0449) from the AUX RS-232 port of one 850-DS to another 850-DS. The desired method may be initiated on both units by pressing **Synchronized Start** on the Start Options screen on one of the 850-DS units. The identical method to be executed must be loaded in the same method slot of each sampling station.

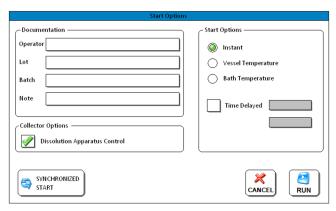


Figure 2. Start Options

# **Initial Power Up**

- 1 Make sure there are no obstructions inside the sample tray area of the Agilent 850-DS
- 2 Make sure the door is fully closed.
- **3** Turn on power using the front panel power switch. The unit will execute a self test and initialization.
- 4 Verify the unit passed the initialization and is at the Main screen.



Before operating the Agilent 850-DS, a sample collection tray with suitable test tubes, vials or well plates must be inserted. Failure to do so may cause liquids to be pumped into the base of the unit.

# Sample Tray Installation

1 From the 850-DS main screen, press **Eject** to eject the sample tray platform. The sample tray platform moves to the front of the 850-DS. The movement forward will pause and the unit will beep to alert the user that the tray platform will extend outside the unit.



Do not attempt to insert or remove the sample tray until movement of the platform has completed.

- 2 Load the 12 x 8 sample tray (for 16 x 100 mm test tubes) onto the platform.
- **3** Press **Eject**. The sample tray platform retracts the sample tray to the home position in the 850-DS.

# **Updating 850-DS Language Screens**

The 850-DS firmware can support several languages including:

- English
- Simplified Chinese
- Spanish
- Japanese
- German
- Hungarian
- Portuguese
- Russian

English is the default language setting. To update the language, contact your Agilent representative.

# Optional Filter Module

NOTE

The 850-DS Filter Module should only be installed by a certified Agilent representative.



Figure 3. Filter Module and Filter Plates

The Agilent 850-DS Dissolution Sampling Station can be optionally equipped with a filtering option that greatly improves dissolution sample processing through the use of specifically designed filter plates. The plates are consistent with filtration membranes and housing materials currently used for dissolution sampling. They are manufactured and sold by GE-Whatman specifically for use with the Agilent 850-DS. Each plate contains eight 25 mm disks incorporated on a flat cartridge. The compact arrangement of the filter disks on the plate also make it much easier for the automated equipment to process and filter samples over traditional automation-ready filters.

The Filter Module, when installed, may be easily disabled if not required for all dissolution methods. Media replacement may also be used with the Filter Module installed. Contact Agilent for assistance with filter validation or visit www.gelifesciences.com for complete filter plate availability and ordering.

# Changing Trays / Needle Replacement

The 850-DS can support various sample tray configurations. The standard needle block can support two trays - for test tube or 2 mL vial sample collection. Other alternative sample trays including Agilent HPLC sample trays and 96-well plates are also compatible. Use of these trays requires a modification to the needle block assembly of the 850-DS. This conversion should only be performed by qualified Agilent personnel. These sample tray kits are meant to be installed for extended use and are not designed for frequent exchanges.

Startup Screen 30 Main Screen 32 Menu Screens 36

#### 4

# Startup Screen



Figure 4. Startup Screen

The Startup screen provides initial information after you power on the instrument. The firmware version, LCD version, serial number and release date are displayed while a self-test is executed in the background. If the self-test completes successfully, a green check mark will be displayed for a few seconds and then the instrument will progress to the Main screen. If an error is encountered during the self-test, a red X will be displayed along with a short text description of the component causing the error. After approximately 10 seconds, the Startup screen will change over to the Main screen.

The following errors may be reported: DataFlash, Real Time Clock (RTC), Needle Motor, tray Motor, Syringe Pump Motor, Filter Clamp, and Filter Motor. If you encounter any of these errors, please contact Agilent for service See "Obtaining Warranty and Other Services" on page 96...

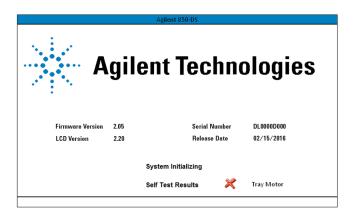


Figure 5. Startup Screen with Error

## Main Screen

The Main screen is the home screen for all instrument operations. The screen will configure itself to display the appropriate sample format based on selections from the Instrument screen. The Main screen displays the following information:

- instrument model
- · menu bar
- system date
- system time
- · current user mode
- screen lock state
- leak notification
- · alarm notification
- service due notification
- if connected, status of the dissolution apparatus (except when the apparatus is idle)

The sample tray may be ejected from this screen by pressing **Eject**. The tray may be retracted by pressing **Eject** again.

Several configurations are illustrated on the following pages.

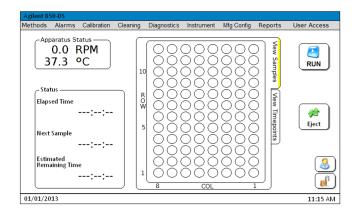


Figure 6. Main Screen in Idle Mode

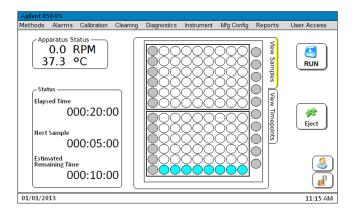


Figure 7. Main Screen with 2 mL Vial, 54-position Blocks Installed

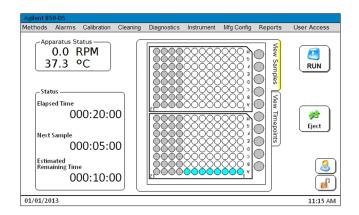


Figure 8. Main Screen with 96-well Plates Installed

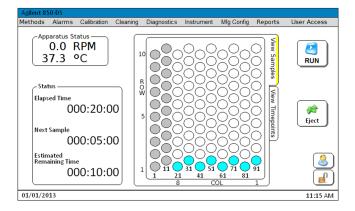


Figure 9. Main Screen with 2 mL, 100-position HPLC Tray Installed

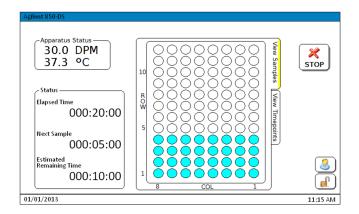


Figure 10. Main Screen with BIO-DIS (Apparatus 3)



Ensure the front door is open prior to ejecting the sample tray. Failure to do so may damage the door or cause injury.

# Menu Screens

Option	Function
Methods	See "Methods" on page 36
Alarms	See "Alarms" on page 55
Calibration	See "Calibration" on page 56
Cleaning	See "Cleaning" on page 60
Diagnostics	See "Diagnostics" on page 63
Instrument	See "Instrument Settings" on page 71
Mfg Config	See "Manufacturing Configuration" on page 77
Reports	See "Reports" on page 78
User Access	See "User Access" on page 79

# Methods

Press **Methods** from the Main screen to create sample-collection methods.

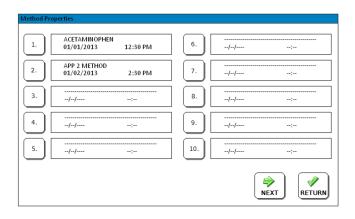


Figure 11. Method Properties Screen

The first four screens of Method Properties show memory locations 1 through 40. Ten methods are displayed per page and the method name and last save time and date are shown for all non-blank methods. Blank memory slots are indicated by a series of dashes.

Select a storage location for the method to be entered by pressing one of the **numbered memory locations**.

NOTE

Only the memory-location numbers are touchable on screen. The software will not respond if the method details in the box next to each memory location are touched.

## Method Properties (Apparatus 1/2/5/6)

NOTE

This screen is applicable to Apparatus 1/2/5/6 only. For Apparatus 3 or 7, advance to "Method Properties (Apparatus 3/7)" on page 43.

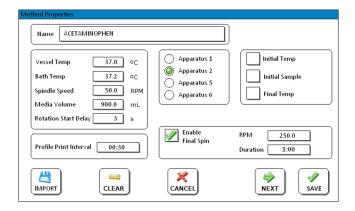


Figure 12. Instrument Parameters

Option	Function
Name	30-character field for the name of this method.
Vessel Temp	Desired vessel temperature for this method.
Bath Temp	Desired bath temperature for this method.
Spindle Speed	Desired spindle speed for this method.
Media Volume	Volume of media initially in the vessels.
Rotation Start Delay	Time after the start of the method before the spindle rotation begins.
Profile Print Interval	Specifies the frequency that dissolution apparatus operational parameters are printed on the optional printer.
Apparatus 1/2/5/6	Select the appropriate <b>apparatus type</b> .
Initial Temp	Takes a temperature reading of the vessels prior to dropping a dosage at the start of a method.
Initial Sample	Takes a sample prior to dropping a dosage at the start of a method.
Final Temp	Takes a temperature reading of the vessels at the end of the method.
Enable Final Spin	After the final timepoint, this option runs the spindles at a high speed in order to try to get all remaining drug into suspension.
RPM	Rotational speed used for the Final Spin.
Duration	Duration the final spin will be executed.
Clear	Erases all values entered and returns them to default values.
Import	Allows user to import method from SD card.
Cancel	Exits the method entry screens and returns to the Main screen without saving any parameters.
Save	Saves all method parameters and returns to the Main screen.

## Sample Collection Parameters (Apparatus 1/2/5/6)

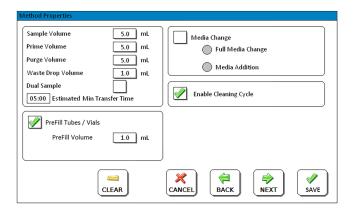


Figure 13. Sample Collection Parameters - Screen 1

Option	Function
Sample Volume	Volume to be collected into the sample test tubes / vials.
Prime Volume	Volume used to prime all of the sample collection lines prior to collecting a sample.
Purge Volume	Volume used to purge all of the sample collection lines after collecting a sample.
Waste Drop Volume	Volume used to rinse the sample needles prior to delivering each sample. This volume, in addition to the sample volume, should be accounted for if media replacement is enabled.
Dual Sample	When enabled, collects two consecutive samples for each timepoint. Uses the sample volume specified above. This option also halves the total number of timepoints available.
Estimated Min Transfer Time	This is a calculated estimate, based on the previously entered sample collection parameters, of how frequently samples may be taken.
Prefill Tubes / Vials	Use this option to fill each test tube or sample vial with the specified volume (in mL). This volume will be taken from the dissolution vessels and automatically replaced using the Media Replacement channel. The number of rows filled is based on the number of timepoints of the method. Ensure the media replacement line is connected and sufficient volume is available in the container to maintain initial vessel volume.
Media Change	When enabled, allows you to manually intervene for a media modification.

Option	Function
Full Media Change	Signifies that you will be removing the dosage and performing a complete replacement of media. A dialog box will display to prompt you to begin and to keep track of the total elapsed time. This option will pause the elapsed time of the dissolution method during the change.
Media Addition	Signifies that you will be adding a quantity of media to each vessel. A dialog will display to prompt you to begin as well as to keep track of the total elapsed time. This option will continue the elapsed time of the dissolution method during the change.
Enable Cleaning Cycle	When enabled, executes a cleaning cycle after the test has finished. The parameters for the cleaning routine are taken from the stored values on the Cleaning screen ("Cleaning" on page 60). A validated cleaning method should be performed after each dissolution test. This enables the 850-DS to perform at a high level for an extended period of time while reducing ongoing maintenance costs.
Clear	Erases all values entered and returns them to default values.

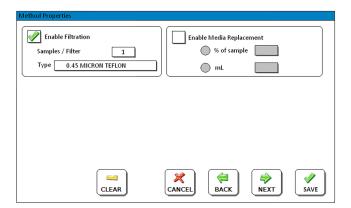


Figure 14. Sample Collection Parameters - Screen 2

4

Option	Function
Enable Filtration	If a Filter Module is installed, this enables filtering samples prior to collection. Ensure an adequate amount of 850-DS filter plates are installed prior to beginning the method.
Samples Per Filter	Specifies how many times to use filters before they are discarded. The filter plates are designed for single use only. The Samples Per Filter setting should be determined for each product and method as part of the system validation. The maximum number of uses per plate is 5 and a warning message will appear for any value greater than 2.
Туре	25-character field used to describe what type of filter is being used. Typically porosity and membrane type are described.
Enable Media Replacement	When enabled, pumps a specified amount of media back to the vessels after each timepoint. Media for this step is provided by the user via an external beaker or vessel.
% of Sample	Specifies that the volume to replace will be a percentage of the sample volume.
mL	Specifies that the volume to replace will be this absolute. For complete replacement, the sample + waste drop volume should be entered here.

### NOTE

The volume removed from the dissolution vessels at each sample timepoint equals the sample volume (mL) + waste drop volume (mL) + 0.2 mL (fixed needle purge). The sum of these values should be entered in mL if this option is selected for Media Replacement.

#### Example:

Sample volume = 1.5 mL; Waste drop volume = 0.3 mL; Needle purge (fixed) = 0.2 mL; Calculation: 1.5 + 0.3 + 0.2 = 2.0 mL Media replacement = 2.0 mL

# Method Properties (Apparatus 3/7)

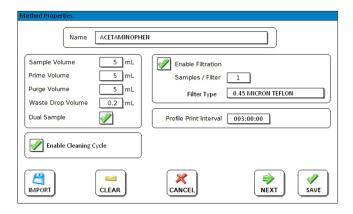


Figure 15. Sample Collection Parameters (Apparatus 3/7)

Option	Function
Sample Volume	Volume to be collected into the sample test tubes / vials.
Prime Volume	Volume used to prime all of the sample collection lines prior to collecting a sample.
Purge Volume	Volume used to purge all of the sample collection lines after collecting a sample.
Waste Drop Volume	Volume used to rinse the sample needles prior to delivering each sample. This volume, in addition to the sample volume, should be accounted for if media replacement is enabled.
Dual Sample	When enabled, collects two consecutive samples for each timepoint. Uses the sample volume specified above. This option also halves the total number of timepoints available.
Enable Filtration	If a Filter Module is installed, this enables filtering samples prior to collection. Ensure an adequate amount of 850-DS filter plates are installed prior to beginning the method.
Samples Per Filter	Specifies how many times to use each filter before they are discarded. The filter plates are designed for single use only. The Samples Per Filter setting should be determined for each product and method as part of the system validation. The maximum number of uses per plate is 5 and a warning message will appear for any value > 2.
Filter Type	25-character field used to describe what type of filter is being used. Typically porosity and membrane type are described.

Option	Function
Enable Cleaning Cycle	When enabled, executes a cleaning cycle after the test has finished. The parameters for the cleaning routine are taken from the stored values on the Cleaning screen ("Cleaning" on page 60). A validated cleaning method should be performed after each dissolution test. This enables the 850-DS to perform at a high level for an extended period of time while reducing ongoing maintenance costs.
Clear	Erases all values entered and returns them to default values.
Save	Saves all method parameters and returns to the Main screen.

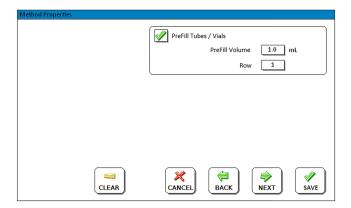


Figure 16. Prefill Tubes / Vials Apparatus 3 / 7

Option	Function
Prefill Tubes / Vials	Use this option to fill each test tube or sample vial with the specified volume (in mL). For Apparatus 3 / 7 units, this volume will be taken from the Row specified and automatically replaced using the Media Replacement channel. The number of sample tray rows filled is based on the number of timepoints of the method. Ensure the media replacement line is connected and sufficient volume is available in the container to maintain the initial vessel volume.

### **Timepoint Number Selection**

Up to 36 timepoints may be specified per method. This screen and the next allow you to define when samples are taken. Timepoints must be consecutively numbered. Entering zero for the time will delete a timepoint.

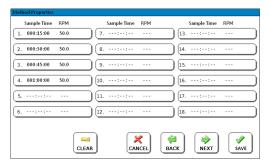


Figure 17. Timepoint Number Selection (Apparatus 1/2/5/6)

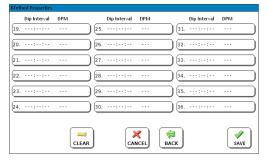


Figure 18. Timepoint Number Selection (Apparatus 3/7)

Option	Function
Clear	Erases all values entered and returns them to default values.
Save	Saves all method parameters and returns to the Main screen.
Cancel	Exits the timepoint entry screen and returns to the Main screen without saving any parameters.

## Timepoint Parameter Entry (Apparatus 1/2/5/6)

This screen specifies the time and the parameters to use for each sample collection.

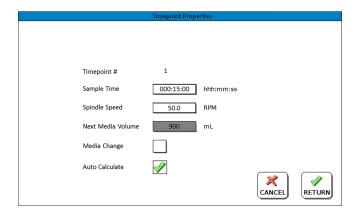


Figure 19. Timepoint Properties Screen (Apparatus 1/2/5/6)

Option	Function
Timepoint #	An indicator of the currently selected timepoint.
Timepoint	The amount of time to wait after the method starts before the sample will be collected.
Spindle Speed	The spindle speed to use just after this sample collection finishes.
Next Media Volume	The nominal volume present in the vessels after each sample cycle. This volume is used to determine the proper sample manifold position if used with an Agilent 708-DS. The Auto Calculate option can be enabled to automatically determine this value.
Media Change	Indicates that you will be performing either a full media change or a media addition after this timepoint.
Auto Calculate	Enable this option to have the firmware automatically determine the Next Media Volume based on the method parameters. If enabled, the Next Media Volume field will become inaccessible.

## Timepoint Parameter Entry (Apparatus 3/7)

This screen specifies the time and the parameters to use for each sample collection.

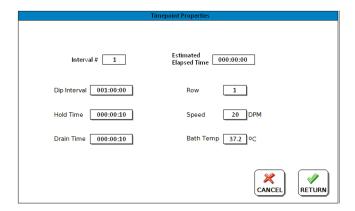


Figure 20. Timepoint Properties Screen (Apparatus 3/7)

Option	Function
Interval	The memory slot of the timepoint being configured.
Dip Interval	Duration of dipping time for each row.
Hold Time	Duration the inner sample tubes / sample holders are stopped at the bottom of the stroke before dipping begins.
Drain Time	Duration the inner sample tubes / sample holders drain over the outer media tubes after being lifted from the media.
Row	Enter the desired row number.
Speed	Enter the desired DPM.
Bath Temp	Enter the desired bath temperature.

#### **Run Method Screen 1**

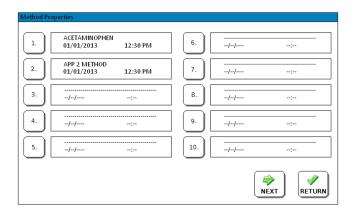


Figure 21. Selecting a Method (Apparatus 1/2/5/6)

The first four screens of Method Properties represent memory slots 1 through 40 (ten methods are displayed per page). The method name and last save time and date are shown for all non-blank methods. Empty slots are indicated by a series of dashes. You can use the following onscreen commands to navigate the screens:

Option	Function
Next	Advances to the next page of available methods.
Back	Returns to the previous page.
Return	Returns to the Main screen without any selections made.

### Run Method Screen 2

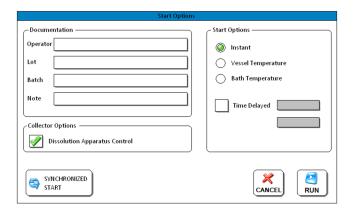


Figure 22. Method Start Parameters

This screen allows you to enter parameters that are stored with the method run. These parameters are available on a printout if your unit has the optional printer installed.

Option	Function
Operator	25-character field for operator name entry.
Lot	25-character field for lot information.
Batch	25-character field for batch information.
Note	25-character field for additional notes.
Dissolution Apparatus Control	Allows the Agilent 850-DS to control a dissolution apparatus.
	Note: Enable this option only if the Agilent 850-DS is connected to another Agilent/Varian/VanKel dissolution apparatus. If connected to a third-party dissolution apparatus with resident probes, do not check this box.
Instant	Start a method instantly.
Vessel Temperature	Will start a method once the vessels have achieved a stable temperature as specified in the method. For USP Apparatus 1 methods, you may install the 3-fin baskets to better equilibrate the media; the user will then be prompted to install the standard baskets with dosage forms to begin the test.

Option	Function
Bath Temperature	Will start a method once the bath has achieved a stable temperature as specified in the method to be run within the temperature tolerance settings of the 850-DS.
Time Delayed	Will start the method at the time and date specified.  Note: Time-delayed method starts are not allowed with the Synchronous Start option.
Synchronized Start	Allows two 850-DS collectors to execute the same method simultaneously. Each 850-DS must have the same method loaded in the same memory location. Methods may be transferred between 850-DS units using an SD card (See "850-DS Method Transfer (to another 850-DS)" on page 53.). A 9-9 pin null modem cable (5075-0449) connects one instrument to the other using the AUX RS-232 port.

NOTE

Time-delayed method starts are not permitted with the Synchronized Start option.

### **Run Method Screen 3**

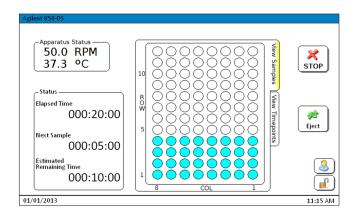


Figure 23. Run Method Screen 3

Option	Function	
RPM	Current spindle speed.	
°C	Current bath temperature.	
Elapsed Time	Current elapsed time since the start of the method.	
Next Sample	Time to the next sample collection time.	
Remaining Time	Time required to complete the current method.	
View Samples	Graphical indication of the method progress. The shaded circles indicate filled test tubes or vials.	
View Timepoints	Provides a view of the timepoints in the current running method.	
Stop	Press <b>STOP</b> to display the dialog screen confirming the choice to stop or continue the method.	
Eject	Press <b>Eject</b> to access the sample tray. The sample tray may be ejected during an active program as long as the system is not taking a sample. Press <b>RETURN</b> (on the screen displayed) to retract the tray prior to the next sample timepoint; otherwise, the sample will not be taken.	

#### **Run Method Screen 4**

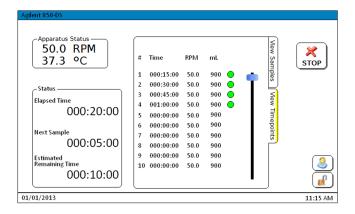


Figure 24. Run Method Screen 4

### **Run Method Screen 5**

This screen displays at the conclusion of a method when no errors have been encountered. The total elapsed time, the current time, and the current date are displayed.

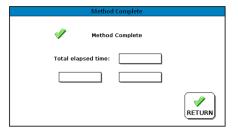


Figure 25. Run Method Screen 5

### 850-DS Method Transfer (to another 850-DS)

NOTE

You must use a 2GB or smaller SD card formatted as FAT16 or FAT32 to complete this procedure.

- 1 Insert an SD card into the SD card slot on the back of the 850-DS.
- 2 Select the **Reports** tab from the 850-DS main screen.



Figure 26. Reports Screen

- **3** Press **SD Card** in the "Print Method..." row. Allow the method to save to the SD card.
- 4 Eject the SD card.
- **5** On 850-DS where you want to import the method, insert the SD card on the back of the unit.

- 6 Select the **Methods** tab from the 850-DS main screen.
- 7 Select an **open location** where the imported method should be stored (press **number**).
- 8 Press IMPORT. Allow method to upload from SD card.

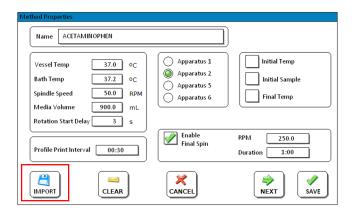


Figure 27. Import Method

## **Alarms**

Press **Alarms** from the Main screen to configure alarms on the 850-DS.

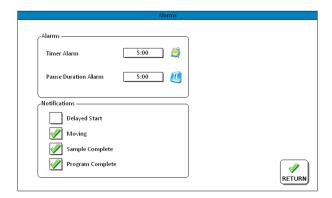


Figure 28. Alarm Screen

Option	Function	
Timer Alarm	This alarm acts in a manner similar to a laboratory countdown timer. Once a value is entered and you press <b>RETURN</b> , the alarm will start a countdown to zero. You do not need to remain on this screen for the alarm to remain active. Once the timer value reaches zero, an alarm will sound and a dialog box will display to indicate that the alarm has expired.	
Pause Duration Alarm	This option sets the duration that you are allowed while performing media changes and additions. The duration of a pause is recorded and printed on the optional printer.	
Delayed Start	Beeps prior to starting a method when you have selected <b>Delayed Start</b> .	
Moving	Beeps prior to any tray movements of the Agilent 850-DS.	
Sample Complete	Beeps at the end of each sample timepoint.	
Program Complete	Beeps at the conclusion of a method.	

### Calibration

Press Calibration from the Main screen to calibrate the 850-DS.

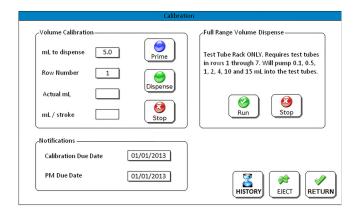


Figure 29. Calibration Screen

#### **Volume Calibration**

The Agilent 850-DS uses a syringe pump to deliver accurate volumes from 0.1 mL to 14.0 mL. A volume calibration function is available to compensate for pump delivery speed, tubing length, and media viscosity. Volume accuracy is a function of pump speed and aspiration dwell time. To improve volume accuracy, try using slower pump speeds. The pump speed and aspiration dwell time are set on the second Instrument Settings screen. See "Instrument Settings Screen 2" on page 73...

NOTE

Agilent recommends calibrating using a volume of 10 mL. If that does not provide acceptable performance, you may perform a calibration at the typical sample collection volume. Although the Agilent 850-DS can dispense volumes as low as 0.1 mL, it is not recommended to calibrate with volumes less than 2 mL.

Stop

Option		Description
Volume Calibration	mL to Dispense	Enter volume (in mL) to be collected in sample tubes / vials during the volume calibration procedure.
	Row Number	Specify the row where the sample volume should be collected.
	Actual mL	Enter the average sample volume collected (in mL) during the volume calibration procedure.
	mL / Stroke	Automatically calculated value based on volume calibration parameters. This value is stored until the next volume calibration is performed. No user entry is required/permitted.
	Prime	Primes (fills) the sample tubing lines prior to executing the volume calibration procedure. This ensures the lines are sufficiently filled and an accurate sample volume is collected.
	Dispense	Dispenses the programmed volume (in mL) into the specified row. Pressing <b>Dispense</b> displays an onscreen dialog that guides the user through the volume calibration process.    Volume Calibration   Prior to performing this volume calibration, ensure that:   Sample cannulsa are sufficiently submerged.   Clean, dry test tubes have been weighed and placed in the specified row.   The volume to be collected does not exceed the sample container capacity.    Figure 30.Volume Calibration Pre-check
		Volume Calibration  To complete the volume calibration:  1. Record the gross weight of each sample.  2. Calculate the net weight of each sample.  3. Calculate each sample volume using the density of the media.  4. Calculate the average volume and enter it in the Actual mt. field.  Operator  Figure 31. Volume Calibration Completion

Stops the volume calibration procedure.

#### Full Range Volume Dispense

This function allows the user to verify the full range accuracy of the pump and is only supported for 15 mL test tubes. Begin with a tray containing seven rows of clean, dry test tubes whose initial weight has been taken. Pressing **Run** will start a pumping cycle where 0.1 mL, 0.5 mL, 1.0 mL, 2.0 mL, 4.0 mL, 10 mL, and 15 mL will be dispensed into the corresponding first seven rows. When complete, gravimetric analysis may be done as above to determine the actual volumes delivered.

Option		Description
Full Range Volume Dispense	Run	Starts the Full Range Volume Dispense cycle.
	Stop	Stops the cycle immediately.
Notifications	Calibration Due Date	Enter the date that instrument calibration is due. On the due date, a reminder notification (wrench icon) will display. The wrench icon will remain visible on the Main screen as long as the current date is past the calibration date. Enter a future date to remove the reminder icon.
	Preventative Maintenance Due Date	Enter the date that preventative maintenance is due. On the due date, a reminder notification (wrench icon) will display. The wrench icon will remain visible on the Main screen as long as the current date is past the PM date. Enter a future date to remove the reminder icon.
History		This screen displays the details of the previous 20 volume calibrations performed on the instrument including date, time, pump speed, and operator. The complete log of calibrations may be printed pressing <b>PRINT</b> on this screen.
		Figure 32.Volume Calibration History

### Cleaning

Press Cleaning on the Main screen to access the cleaning cycle on the 850-DS.

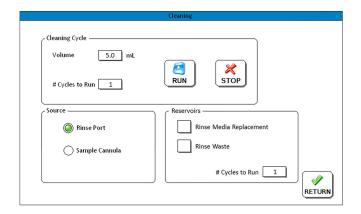


Figure 33. Cleaning Parameters Screen

#### NOTE

A validated cleaning method should be performed after each dissolution test. This enables the 850-DS to perform at a high level for an extended period of time while reducing ongoing maintenance costs. Cleaning methods are formulation dependant. If you need help determining appropriate cleaning solution and cycles, contact the Dissolution Hotline at dissolution.hotline@agilent.com.

The Agilent 850-DS can perform a manual or an automated flush of all of the tubing. This screen allows a manual cleaning cycle to be started. If Enable Cleaning Cycle is selected in a method, the parameters entered on this screen are used to control the cleaning cycle.

Option		Description
Cleaning Cycle	Volume	Enter the volume that will be pumped though the tubing.
	# Cycles to Run	This controls how many times the above volume will be repeated.
	Run	Starts a cleaning cycle with the entered parameters.
	Stop	Stops a cleaning cycle.
Source	Rinse Port	This selects the rinse port as the source of the rinse media. Connect an appropriate container to the Agilent 850-DS rinse port with a length of 1/4 inch tubing. At the start of the cleaning cycle, an internal pump fills the rinse reservoir on the tray assembly. The needles are lowered into the rinse media and the specified volume is pumped from the needles through the sample tubing and then through the return tubing. All lines will then be purged with air to eliminate as much liquid from the tubing as possible.
	Sample Cannula	Selects the sample cannula as the inlet source. At the start of a cleaning cycle, the syringe pump moves the volume specified from the sample cannula through the return tubing. A smaller fixed volume of 0.7 mL will be pumped through the needles into the waste row. All lines will then be purged with air to eliminate as much liquid from the tubing as possible. It is the responsibility of the user to properly submerge the sample cannulas in the appropriate rinse solution prior to this cycle.
Reservoirs	Rinse Media Replacement	Enable this option to rinse the internal media replacement reservoir after each test with rinse solution. The reservoir will be filled and emptied based on the number of cycles defined.
	Rinse Waste	Enable this option to rinse the internal waste reservoir after each test with rinse solution. The reservoir will be filled and emptied based on the number of cycles defined.
	# Cycles to Run	This value defines how many times the appropriate reservoirs will be filled and emptied with rinse solution at the conclusion of each test. Rinsing of these reservoirs serves to prepare the system for the next test as well as flush the internal volume sensors to prevent long term damage.

### CAUTION

Ensure that the rinse connection is not capable of siphoning back into the instrument. The inlet tubing must never fall below the level of rinse in the container.

The media bottles should be located at the same bench level as the 850-DS or lower.

### **Diagnostics**

Press **Diagnostics** on the Main screen to access diagnostics on the 850-DS.

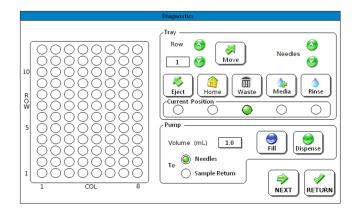


Figure 34. Diagnostics Screen 1

This screen allows manual control of all the sample handling parameters. Tray movement, needle position, and syringe pump control are available. The tray image on the left side will change to indicate which tray type is currently configured. As the tray is moved to valid rows, the appropriate row in the tray image will be filled to provide feedback for row position.

Option		Description
Row Position	Row Indicator	Pressing the <b>numeric row indicator</b> will display the numeric entry screen. Enter the desired row number and press <b>RETURN</b> .
	Up Arrow	Increments the current row number by one.
	Down Arrow	Decrements the current row number by one.
	Move	Moves the tray to the position indicated in the row indicator field.
Needle Position	Up Arrow	Raises the needles.
	Down Arrow	Lowers the needles.
Tray Position	Eject	Moves the tray to the eject position.
	Home	Performs a home of the needles, tray, and pump in order.
	Waste	Moves the tray to the waste row of the waste block.
	Media	Moves the tray to the media-replacement row of the waste block.
	Rinse	Moves the tray to the rinse-row of the waste block.
	Current Position	An indicator that shows the current position of the tray. If the tray has been moved to a particular row number, this indicator will be blank and the tray position will be indicated on the tray image.
Pump Control	Volume	Press the <b>numeric indicator</b> and enter the volume to be dispensed.
	Fill	Aspirates the requested volume into the syringe pump.
	Dispense	Pumps the contents of the syringe pump to the selected location.
	To: Needles	The requested volume is aspirated from the sample cannula and pumped out to the needles.
	To: Sample Return	The requested volume is aspirated from the sample cannula and pumped out to the return lines.

# Diagnostics Screen 2

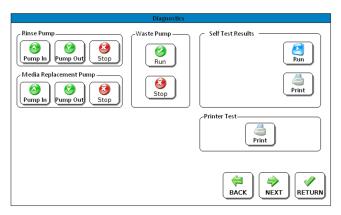


Figure 35. Diagnostics Screen 2

Option		Description
Rinse Pump	Pump In	Activates the pump to fill the rinse row.
	Pump Out	Activates the pump to empty the rinse row.
	Stop	Stops the pump.
Media Replacement Pump	Pump In	Activates the pump to fill the media-replacement row.
	Pump Out	Activates the pump to empty the media-replacement row.
	Stop	Stops the pump.
Waste Pump	Run	Activates the waste pump (empties the waste row).
	Stop	Stops the pump.
Self Test Results	Run	Runs the self-test routine.
	Print	Prints the results of the self-test routine.
Printer Test	Print	Conducts a test to ensure the printer is functioning properly.

## **Diagnostics Screen 3**

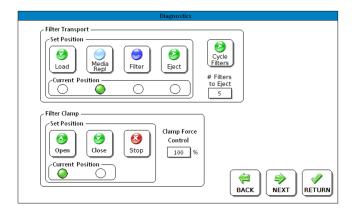


Figure 36. Diagnostics Screen 3

This screen allows manual control of the optional Filter Module (if installed). The filter may be moved to one of four positions and the filter clamp may be opened and closed.

Option		Description
Filter Transport	Load	Moves the filter transport plate to the load position. This is the location of the filters that are placed in the inlet stack.
	Media Repl	Moves the filter transport plate to the media replacement position. This position allows the filter clamp plates to clamp on themselves. This position is not directly under the new filters in order to minimize any carryover or contamination between a used filter and the new ones in the stack. This position is used when a media replacement is being performed.
	Filter	Moves the filter transport plate to the filter position. This position allows the filter clamp plates to seal on the filter and pump samples through it.
	Eject	Moves the filter transport plate to the eject position.
	# Filters to Eject	Pressing the <b># Filters to Eject</b> indicator will display the numeric entry screen. Enter the number and press <b>RETURN</b> .
	Cycle Filters	Will cycle the filter transport plate between the load and eject position for # Filters to Eject times. This may be used to empty the inlet stack or verify operation.
Filter Clamp	Open	Opens the filter clamp plates. The clamp mechanism will stop automatically when it reaches its open position.
	Close	Closes the filter clamp plates.
		Caution: Care should be used with this function as damage may occur if there are any obstructions in the clamping path.
	Stop	Turns off the clamp motor. The plates remain in their current position.
	Clamp Force Control	This parameter adjusts the amount of power the motor receives from 90 to 100%. Values below this result in poor clamping and are thus not allowed.

# Diagnostic Screen 4 (Apparatus 1/2/5/6)

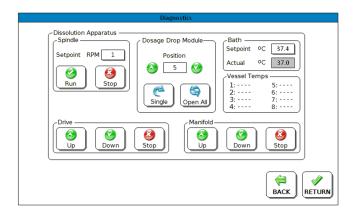


Figure 37. Diagnostics Screen 4 (Apparatus 1/2/5/6)

Option		Description
Spindle	Setpoint RPM	Pressing the <b>RPM indicator</b> will display the numeric entry screen. Enter the desired RPM and press <b>RETURN</b> .
	Run	Starts the spindles.
	Stop	Stops the spindles.
Dosage Drop Module (DDM)	Position	Pressing the <b>Position indicator</b> will display the numeric entry screen. Enter the desired number and press RETURN.
	Up Arrow	Increments the DDM position.
	Down Arrow	Decrements the DDM position.
	Single	Actuates the individual DDM selected by the position indicator.
	Open All	Actuates all DDM modules simultaneously.
Bath	Setpoint	Pressing the <b>Setpoint indicator</b> will display the numeric entry screen. Enter the desired temperature and press RETURN. The dissolution apparatus bath setpoint will be updated to the value entered.
	Actual	Displays the current actual bath temperature.
Vessel Temperatures		If a manifold is installed and lowered, the current vessel temperatures are displayed here.

Option		Description
Drive	Up	Raises the drive unit
	Down	Lowers the drive unit.
Manifold	Up	Raises the manifold.
	Down	Lowers the manifold.

# Diagnostic Screen 4 (Apparatus 3/7)

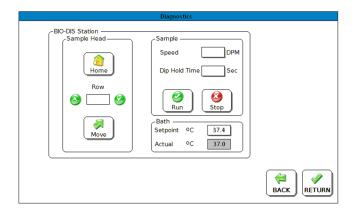


Figure 38. Diagnostics Screen 4 (Apparatus 3/7)

Option		Description
Sample Head	Home	Returns the drive unit to the home position.
	Row	Enter the desired row number.
	Move	Moves the drive unit to the entered row.
Sample	Speed	Enter the desired speed in DPM.
	Dip Hold Time	Stops the inner sample tubes / sample holders at the bottom of the stroke for the length of time entered.
	Run	Begins manual dipping.
	Stop	Stops manual dipping.
Bath	Setpoint	Pressing the <b>Setpoint indicator</b> will display the numeric entry screen. Enter the desired temperature and press Return. The dissolution apparatus bath setpoint will be updated to the value entered.
	Actual	Displays the current actual bath temperature.

### **Instrument Settings**

The following screens show the parameters that influence the setup and operation of the Agilent 850-DS. These parameters apply to all methods and modes of operation.

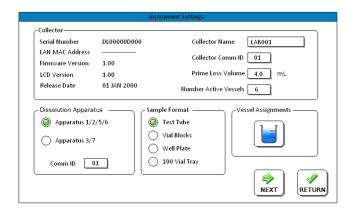


Figure 39. Instrument Settings Screen 1

Option		Description
Collector	Serial Number	Manufacturer-assigned serial number.
	LAN MAC Address	MAC address that will be used for LAN communications.
	Firmware Version	Version of the firmware installed on the instrument.
	Release Date	Release date of the firmware.
	Collector Name	A 25-character field to describe the instrument.
	Collector Comm ID	A 2-digit numeric field that is used when a PC or other instrument is communicating with the Agilent 850-DS.
		Note: If multiple instruments are connected together, each unit must have a unique Comm ID.
	Prime Loss Volume	The volume in mL that is pumped at the beginning of each sample point. This volume represents the volume in the tubing between the sample collector and the needles. Pumping this volume to the return lines first ensures that the volume aspirated at the sample time is what is actually delivered to the sample tubes / vials instead of the volume remaining in the lines after prime.
	Number Active Vessels	Enter the number of active vessel positions on the dissolution apparatus. This value is important if the vessel temperature start is used.
Dissolution Apparatus	Apparatus 1/2/5/6	Sets the operating mode to expect an Apparatus 1/2/5/6 instrument to be connected to the Agilent 850-DS.
	Apparatus 3/7	Sets the operating mode to expect an Apparatus 3/7 instrument to be connected to the Agilent 850-DS.
	Comm ID	Communications ID of the attached Agilent dissolution apparatus.
Sample Format	Test Tubes	Indicates a rack holding an array of 8 x 12 test tubes or vials is installed.
	Vial Blocks	Indicates a rack holding two 9 x 6 blocks with 2 mL vials is installed.
	Well Plate	Indicates a rack holding two 96-position well plates is installed.
	100-vial Tray	Indicates a rack holding an array of 10 x 10 (offset spacing) for 2 mL vials is installed.

4

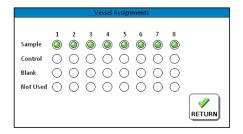


Figure 40. Vessel Assignment Screen

Vessel Assignments

This screen allows you to enter a category for each vessel's usage.
These categories are used for reporting only.

### **Instrument Settings Screen 2**

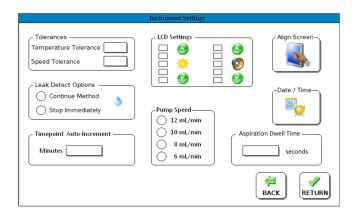


Figure 41. Instrument Settings Screen 2

Option		Description
Tolerances	Temperature Tolerance	Displays the numeric entry screen. Enter the desired tolerance and press Return. Temperatures that are outside of this tolerance to their respective setpoints will raise an error condition. These errors will be reported through dialog screens and on the optional printer.
	Speed Tolerance	Displays the numeric entry screen. Enter the desired tolerance and press Return. Spindle speeds that are outside of this tolerance to their respective setpoints will raise an error condition. These errors will be reported through dialog screens and on the optional printer.
Leak Detect Options	Continue Method	If a leak is detected, a notification will be shown on the Main screen, bu otherwise all running methods will continue uninterrupted.
	Stop Immediately	If a leak is detected a notification will be shown and any currently running method will be aborted.
Timepoint Auto-increment		This value controls the auto populate feature of method timepoint entry. After the first timepoint is entered, all subsequent timepoints wi have this value added to them.
LCD Settings	Brightness Up	Increases the brightness of the LCD backlight.
	Brightness Down	Decreases the brightness of the LCD backlight.
	Speaker Up	Increases the volume of the internal speaker.
	Speaker Down	Decreases the volume of the internal speaker.
Pump Speed		Sets the speed of the syringe pump to the selected rate. Use slower speeds for higher viscosity media or media containing surfactant. Higher pump speeds may be used for less viscous media. The pump speed may also be reduced to improve volume accuracy.
Aspiration Dwell Time		Sets the time (in seconds) that the syringe pauses after pulling in liquic prior to dispensing. This setting may need to be increased to maintain volume accuracy for certain types of dissolution media. The Dwell Time is automatically adjusted (3-second minimum) when filtration is enabled.

### 4 Operating the 850-DS

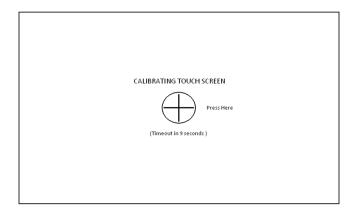


Figure 42. Touch Screen Calibration Screen

Option	Description
Align Screen	Starts the touchscreen alignment routine. Follow the instructions on the screen to calibrate the touchscreen. If the screen is not touched for 10 seconds, the Agilent 850-DS will return to the Instrument Settings screen.

Option	Description
Date / Time	Pressing <b>Data / Time</b> will display the Date and Time setting screen.

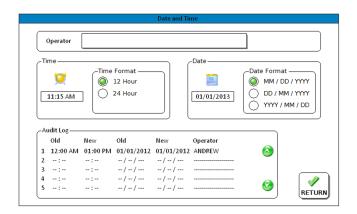


Figure 43. Date and Time Change Screen

Option		Description
Operator		30-character field for the operator name. Any change of the date or time requires an operator's name. The name is used in the audit log as described below.
Time	Time Field	Pressing the <b>time</b> will display the numeric entry screen. Enter the desired time and press Return.
	Time Format	Select either <b>12- or 24-hour time format</b> to be used in all displays and printouts.
Date	Date Field	Pressing the <b>date</b> will display the numeric entry screen. Enter the desired date and press Return.
	Date Format	Select one of the three <b>date formats</b> to be used in all displays and printouts.
Audit Log		The audit log shows the last ten time or date changes and who made them. The up and down arrows scroll through the list.
Return		Returns to the Instrument Settings screen.

## **Manufacturing Configuration**

NOTE

The Mfg. Config. menu can only be accessed by a certified Agilent representative. The options enabled or disabled on this screen control functions visible to the user when operating the 850-DS.

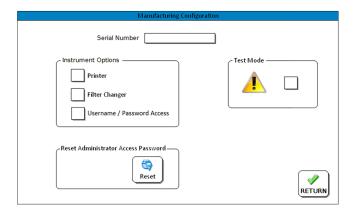


Figure 44. Mfg Config Screen

### Reports

Press **Reports** from the Main screen to print or export reports on the 850-DS. Reports can be printed on the optional printer, exported through the auxiliary serial port (AUX RS-232), or saved to an SD card inserted in the back SD card slot.



Figure 45. Reports

Option	Function	
Last Run Results	Prints the last run results. Select the <b>destination</b> by pressing the appropriate button.	
Print Method	Displays the select method screen. Once a method has been selected, prints the method parameters. Select the <b>destination</b> by pressing the appropriate button.	
Print Instrument Settings	Prints the instrument settings. Select the <b>destination</b> by pressing the appropriate button.	
Enable Printer	A toggle function that enables or disables the printer. If the printer is not enabled, all printing functions are suppressed.	
Return	Returns to the Main screen.	

NOTE

In order to print reports to the printer, the optional printer must be enabled. All other functions are available with the Enable Printer function deselected

### **User Access**

Press **User Access** from the Main screen to assign the system access level, modify functionality of the User Levels and, if enabled, regulate individual user access. The 850-DS firmware supports a system-based level of control or access to specific functions based on individual users. This distinction is governed by the Username/Password Access feature (see User Access screen on **page 80**).

If the Username/Password Access feature is enabled, individual users are assigned a Name, Password, and User Level and must log in to access the 850-DS firmware. Specific functionality is based on their User Level which is defined by an Administrator of the system.

If the Username/Password Access feature is disabled, an Administrator may toggle between the three available access levels available on the 850-DS. The current access level is indicated by a green circle. Any user may change the access level to a lower setting (e.g., Advanced User to User) without entering a password. Any changes to a higher level (e.g., Advanced User to Administrator) require a password.

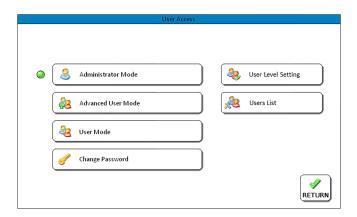


Figure 46. User Access

Option	Function	
Change Password	Allows an administrator to change the password. Displays the password change screen. The new password must be entered correctly twice before it will be changed. The default password is 12345.	
User Level Setting	This screen allows an Administrator to define access to specific functions of the 850-DS based on the User Group assigned to the system or individual user. The system settings are stored when Save is pressed.	
Users List	This screen allows an Administrator to create, modify and define access for users of the 850-DS. A total of 20 individual users may be stored. Each user is assigned a User Level (Administrator, Advanced User, or User) that determines what functions may be accessed. An individual Name and Password is assigned to each user at the time of creation.	

### 4 Operating the 850-DS

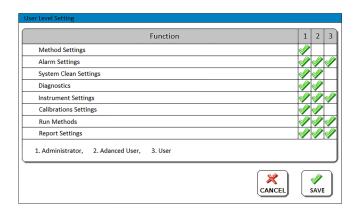


Figure 47. User Level Setting

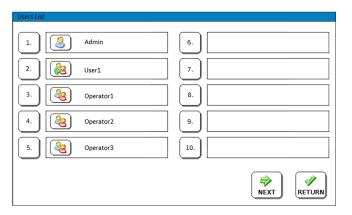


Figure 48. Users List

### **Dialog Screens (Blue)**



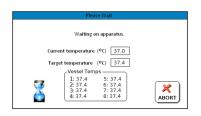
#### Password Reset

Displays after the Administrator Access password has been reset to factory default.



#### Memory Access

Displays when memory is being accessed. Typically it will be displayed when saving or retrieving methods.



#### Waiting on Heating - Vessel Temperature Start

Displays when a method is running and the 850-DS is waiting on the dissolution apparatus for temperatures to reach a setpoint or become stable. The current temperature, the target temperature, and the vessel temperatures are displayed.



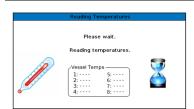
#### Waiting on Heating - Bath Temperature Start

Displays when a method is running and the 850-DS is waiting on the dissolution apparatus for temperatures to reach a setpoint or become stable. The elapsed time, current temperature, and the bath temperature are displayed.



#### Time Delayed Start

Displays when a time delayed method start has been selected. The expected start time is displayed so you know how long it will be until the method begins.



#### Reading Temperatures

Displays during any temperature-read events on an Agilent dissolution apparatus. Temperature-read events typically last about 40 seconds.



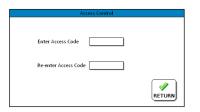
#### Method Stop Confirmation

Displays after you have pressed STOP while a method is running. It allows you to confirm your intentions to stop or continue running the method.



#### Change Media

Notifies you that it is time to add or change media during a method. The elapsed time is shown in the dialog. If the Pause Duration Alarm ("Pause Duration Alarm" on page 55) time entered in the Alarms screen is exceeded, then an error will be generated and noted in the method log.



#### Access Control

Used when changing access levels or when locking the display. It serves as a generic password entry screen. You must enter access codes correctly twice before any changes will be accepted.



#### Cleaning Cycle Complete

Displays when the cleaning cycle is complete.



#### User Login

Displays when Lock s pressed from the 850-DS Main screen if the Username/Password Access feature is enabled. The individual user must enter their Name and Password to gain access to their predefined functions.



#### **Configure User Authority**

Displays when a number is pressed from the Users List screen. This screen is used to create, modify or delete users. Each user is assigned a Name, Password, and User Level from this screen.

### Warning Screens (Yellow)



#### Apparatus 1 / 6 Auto Head

Displayed for USP Apparatus 1 or 6 that have an automated drive-unit lift. You are prompted to attach the appropriate dosage form. The head is automatically lowered after you press RETURN.



#### Apparatus 1 / 6 Manual Head

Displayed for USP Apparatus 1 or 6 methods on units that have a manual drive-unit lift. You are prompted to attach the appropriate dosage form and lower the drive unit manually. The method will resume after you press RETURN.



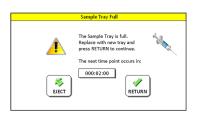
#### Manual Dosage Drop

Displayed for USP Apparatus 2 or 5 methods on units that do not have the dosage delivery modules (DDMs) installed. After you insert the dosage and press RETURN, the method will resume.



#### **Head Raised**

Generic message on units that have a manual head lift. At any time the head is not fully lowered, this prompt will display.



#### Sample Tray Full

Used on methods that have more timepoints than will fit on one sample rack. After you replace the rack with a fresh one and press RETURN, the method will continue. If the tray is not retracted prior to the next timepoint, sample collection will be skipped.



#### Sample Tray Ejected

Displayed if the tray is ejected during an program. Press **RETURN** to retract the tray prior to the next timepoint. If the tray is not retracted prior to the next timepoint, sample collection will be skipped.



#### 709-DS Preheat Special Condition

Displays when connected to an Agilent 709-DS running an Apparatus 1/6 method. In order to achieve reliable start conditions, finned baskets must be used during pre-heat. Press **RETURN** to start the pre-heat cycle.



#### Alarm Time Expired

Notifies you that the alarm time has expired.



#### Clear Method Confirmation

Confirmation that all data from a method will be erased and replaced with default values. This prevents you from accidentally erasing methods.



#### Service Due

Displays when either the Calibration Date Preventative Maintenance Date ("Calibration" on page 56) has passed. This dialog appears once. After this screen has been cleared, the service due wrench icon appears in the lower right corner of the Main screen. The service due icon will remain visible until the corresponding date has been updated in the Calibration Screen.



#### User Delete Confirmation

Displays when an attempt is made to delete a user from the Users List using the Configure User Authority screen. Only an Administrator has the ability to delete users from the 850-DS.

### **Error Screens (Red)**



#### Method Error

This screen appears at the conclusion of a method when errors have been encountered. The total elapsed time, the current time, and the current date are displayed.



#### **Invalid Data**

Displayed when data has been entered that is outside of the acceptable limits. Press **RETURN** to re-enter the data. The prompts in the data entry screens will inform you of the valid data ranges.



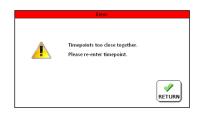
#### Method Not Supported

Displayed when the loaded method requires hardware or options that are not installed. For example, if a method requires filtration and no Filter Module is installed.



#### **Printer Out of Paper**

This dialog is displayed when the printer is out of paper. The paper status is only checked at the beginning of a print request, not continuously during a print. See "Printer Maintenance" on page 93..



#### **Timepoints Too Close**

This dialog is displayed when entering timepoints and the minimum transfer time is not met. Increase the timepoint spacing or reduce the sampling volume parameters to meet the minimum transfer time parameter.



#### Not Valid Tray Position

This dialog is only displayed when in Diagnostics. It is displayed if the tray is not in a valid position when a pumping action has been requested (e.g. dispensing a volume through the needles, but the tray is in the home or eject position). Moving the tray to a valid row will resolve this issue.



#### Clock Audit Log

Displayed if a change to either the time or date has been requested and no operator has been entered. Operator names are required for clock changes and for saving into the audit log.



#### Filter Clamp Plates Open

This dialog is displayed on units with a Filter Module installed. If a pumping action has been requested and the filter clamp plates are in the open position, this error will appear. Usually, this is encountered during diagnostics. Navigate to the Filter Module section of the Diagnostics screen (See "Diagnostics Screen 2" on page 65.) and close the clamp plates. Once closed, normal pumping is allowed.



#### Filter Plate Warning

Displayed if a value > 2 is entered for the number of samples to filter prior to filter plate replacement. Saturation may occur and volume inaccuracy or system performance could deteriorate under certain conditions. Proper filter validation should be performed to ensure acceptable performance.





#### Filter Transport Conflict

This dialog is displayed on units with a Filter Module installed. If in the Diagnostics Screen, a filter transport move is requested and the clamp plates are closed, this error will be displayed. The transport can't move while the clamp plates are closed. Navigate to the Filter Module section of the Diagnostics screen (See "Diagnostics Screen 2" on page 65.) and open the clamp plates. Once opened, normal filter transport movement is allowed.

### 4 Operating the 850-DS

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# 5 Maintenance and Troubleshooting

Preventive Maintenance 92
Printer Maintenance 93
Obtaining Warranty and Other Services 96

### Preventive Maintenance

Preventive maintenance intervals may vary depending on the frequency of instrument usage.

### Clean System

The Agilent 850-DS can perform an automated flush of all the tubing. Refer to "Cleaning" on page 60 for instructions on how to run the cleaning cycle. A validated cleaning method should be performed after each dissolution test. This enables the 850-DS to perform at a high level for an extended period of time while reducing ongoing maintenance costs.

### **Periodic Maintenance**

During a visual inspection of unit, check for:

- Loose or missing hardware
- Signs of wear on pulleys and belts
- Tubing blockages
- Operation of needles
- · Signs of wear in the syringes

### Printer Maintenance

### Removing a Thermal Paper Roll

NOTE

A red line on the side of the paper roll indicates the paper supply is almost exhausted. Replacement is recommended when the red line is visible. If the paper roll is not changed and the paper supply is exhausted, the 850-DS gets an out-of-paper signal from the printer, and displays an error on the screen.

1 Place fingers on each side of the printer panel and pull forward to expose the paper chamber and the paper roll, or empty core inside.



Figure 49. Accessing the Printer Panel

**2** Use your fingers to remove the small roll or core.

NOTE

The empty core is disposable. Each new roll includes a cardboard core.

### Inserting a Thermal Paper Roll

NOTE

Only a 58 mm wide x 13.65 meter (maximum) long thermal printer paper roll can be used in the printer. For an FDA environment, it must also meet the ten-year retention requirement. Ordering replacement paper from Agilent is recommended.

1 With the paper chamber exposed, insert the paper roll so the leading edge of the paper will feed over the top of the printer panel.



Figure 50. Inserting a Thermal New Paper Roll

2 Keeping the paper centered, close the printer panel and snap it into place.



Figure 51. Closing the Printer Chamber

**3** To verify that the paper is not skewed or jammed, press the button on the top-left of the printer panel to feed some paper. If paper does not feed, re-open the panel and re-center the paper.



Figure 52. Feeding Paper

### **Thermal Printer Test**

In the second Diagnostics screen, under Printer Test, press to print sample text and verify the printer is functioning properly.

# 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.

### In This Book

- Chapter 1 Safety
- Chapter 2 Introduction
- Chapter 3 Setting Up the 850-DS
- Chapter 4 Operating the 850-DS
- Chapter 5 Maintenance and Troubleshooting

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