



GE Power & Water
Water & Process Technologies

Siemens 500 RL On-Line TOC Analyzer

Validation Support Package Volume I

Firmware Version 2.13

User Protocols:

- Installation Qualification Guidelines
- Operation Qualification Guidelines

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Revision History

Document Version	Software Version/Enhancement	Date
DVL 74000 Rev. A	1.00	August 2005
DVL 74000 Rev. B	1.01	October 2005
DVL 74000 Rev. C	1.02	November 2005
DVL 74000 Rev. D	1.03	January 2006
DVL 74000 Rev. E	1.10	February 2006
DVL 74000 Rev. F	1.12	August 2006
DVL 74001-01 Rev. A	1.30	December 2007
DVL 74001-02 Rev. A	2.00	February 2009
DVL 74001-03 Rev. A	2.02	June 2009
DVL 74001-04 Rev. A	2.10	May 2010
DVL 74001-05 Rev. A	2.11	September 2010
DVL 74001-06 Rev. A	2.12	August 2011
DVL 74001-07 EN Rev. A	2.13	September 2011

Trademarks and Patents

The following are trademarks of General Electric Company and may be registered in one or more countries: Sievers*, DataShare 500*, DataGuard*, Super **iOS** System*, and **iOS** System*.

Windows® and Excel® are registered trademarks of Microsoft Corporation.

The Analyzer described in this manual is covered by one or more patents issued to and owned or pending by General Electric Company, including the following:

US 7247498

US 6,271,043

US 5,976,468

US 5,837,203

US 5,443,991

EP 0 897 530

FR 0 897 530

GB 0 897 530

DE 697 02 516 0-08

and other patents pending

Validation Support Package Overview

The Validation Support Package (VSP) includes protocols, worksheets, and other information to allow users to easily validate a Sievers* 500 RL Total Organic Carbon (TOC) Analyzer for use in their processes. The package assists customers in developing the documents and testing to provide assurance that the Analyzer operates to specification and meets all regulatory requirements of their applications. The documents were designed to minimize the resources and time required for customer installation qualifications (IQ), operational qualifications (OQ), and to meet the requirements of their Performance Qualifications (PQ). The customer may modify these protocols to conform to company-specific requirements in accordance with the License Agreement.

The components of the VSP are listed in the Table of Contents. The protocols checklists, and worksheets have been divided into two volumes: Volume I includes Installation and Operation Qualification (IQ and OQ) Guidelines and Volume II includes the Performance Qualification (PQ) Guidelines and Firmware Revision History.

Additional supporting documentation is available for review at GE Analytical Instruments and includes, but is not limited to, the quality manual, engineering documents, software documentation, hardware requirements and specifications, and manufacturing and quality assurance procedures.

ISO 9001 Registration

GE Analytical Instruments is registered to ISO 9001. For a copy of the certificate, please visit our Web site at <http://www.geinstruments.com/> (Company tab > **ISO 9001 Certification**).

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This is a legal agreement between you (the user) and GE Analytical Instruments. This agreement gives the user certain limited rights to use the information and the documents of the Validation Support Package. The user does not become the owner of, and GE Analytical Instruments retains title to, all the information and documents. All rights not specifically granted in this license are expressly reserved by GE Analytical Instruments. If the user does not agree to be bound by the terms of this agreement, the user should return the Validation Support Package to GE Analytical Instruments within three days of receipt for a full refund.

Grant of License: GE Analytical Instruments grants the user the right to use this package to aid the user in validation of one Sievers 500 RL TOC Analyzer. This package is linked to that analyzer and may not be used to support additional instrumentation.

User is permitted to:

- Copy checklists, worksheets, and protocols as needed to validate the analyzer for any application.
- Modify any documents. An electronic version of the VSP is included in Volume II to provide a vehicle for modification of protocols and worksheets. *Any documents so modified must clearly state the GE Analytical Instruments document used as the source and clearly state that the original document has been modified.*

User is not permitted to:

- Use this document to validate any other instrumentation, regardless of whether it is a Sievers Analyzer or not.
- Make copies or modifications of paper or electronic versions of the documentation except as described above.
- Remove or obscure any copyright notices.

Site Licenses:

- User may purchase Site Licenses for additional Validation Support Packages.



Recommended Order of Validation

1. Installation Qualification (in VSP Volume I)

Installation Protocol and Checklist

Firmware Installation Verification Protocol and Checklist

Optional protocols:

- DataGuard Operation Verification Protocol and Checklist
- DataShare 500 Installation Verification for Firmware Protocol and Checklist
- 4-20 mA Output Operation Verification Protocol and Worksheet

2. Operation Qualification (in VSP Volume I)

Perform **either** a single-point **or** a multi-point calibration (protocols for both are provided) with verification protocol:

Either

- Single-Point Calibration and Verification Protocol
- Single-Point Calibration Worksheet
- Accuracy, Precision, and Verification Worksheet

Or

- Multi-Point Calibration and Verification Protocol
 - Multi-Point Calibration Worksheet
 - Accuracy, Precision, and Verification Worksheet
- System Suitability (Response Efficiency) Protocol and Worksheet
- JP Protocol and Worksheet (Optional)

3. Performance Qualification (in VSP Volume II)

Accuracy, Precision, and Verification Protocol and Worksheet (optional if Calibration Protocol has been performed)

Linearity LOD/LOQ Verification Protocol and Worksheet

And,

Either:

- Record the LOD/LOQ results from this Linearity LOD/LOQ Verification Protocol on the SAME *Linearity Verification Worksheet*

Or:

- Limit of Detection and Limit of Quantitation Verification Protocol Using Repetitive On-line Measurements Protocol
- Limit of Detection and Limit of Quantitation Verification Protocol Using Repetitive On-line Measurements Worksheet



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Method Specificity Verification Protocol and Worksheet

Method Robustness Protocol and Worksheet



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Validation Checklist for Sievers 500 RL TOC Analyzer

Company Name _____ Date _____
Analyst Name _____ Firmware Version _____
Analyzer Serial Number _____ Software Version _____

Protocol, Checklist, or Worksheet Name (VSP Vol Number)	Result: Pass/Fail, Complete/ Incomplete, or N/A	Date	Initial
Installation Protocol (Vol I)			
Installation Checklist (Vol I)			
Firmware Installation Verification Protocol (Vol I)			
Firmware Installation Verification Checklist (Vol I)			
DataGuard Operation Verification Protocol - optional (Vol I)			
DataGuard Operation Verification Checklist - optional (Vol I)			
DataShare 500 Installation Verification Protocol - optional (Vol I)			
DataShare 500 Installation Verification Checklist - optional (Vol I)			
4-20 mA Output Operation Verification Protocol - optional (Vol I)			
4-20 mA Output Operation Verification Worksheet - optional (Vol I)			



Protocol, Checklist, or Worksheet Name (VSP Vol Number)	Result: Pass/Fail, Complete/ Incomplete, or N/A	Date	Initial
Calibration and Verification Either: Single-Point Calibration and Verification Protocol (Vol I) Single-Point Calibration Worksheet (Vol I) Accuracy, Precision, and Verification Worksheet (Vol I) Or: Multi-Point Calibration and Verification Protocol (Vol I) Multi-Point Calibration Worksheet (Vol I) Accuracy, Precision, and Verification Worksheet (Vol I)			
System Suitability (Response Efficiency) Protocol (Vol I)			
System Suitability (Response Efficiency) Worksheet (Vol I)			
JP Protocol – optional (Vol I)			
JP Protocol Worksheet – optional (Vol I)			
Accuracy and Precision Protocol (Vol II) - optional if Calibration and Verification Protocol has been performed			
Accuracy and Precision Worksheet (Vol II) - optional if Calibration and Verification Protocol has been performed			



Protocol, Checklist, or Worksheet Name (VSP Vol Number)	Result: Pass/Fail, Complete/ Incomplete, or N/A	Date	Initial
Linearity LOD/LOQ Verification Protocol and Worksheet (Vol II) And, Either: Record the LOD/LOQ results from this Linearity LOD/LOQ Verification Protocol on the SAME <i>Linearity Verification Worksheet</i> (Vol II) Or: Limit of Detection and Limit of Quantitation Verification Protocol Using Repetitive On-line Measurements Protocol (Vol II) Limit of Detection and Limit of Quantitation Verification Protocol Using Repetitive On-line Measurements Worksheet (Vol II)			
Method Specificity Verification Protocol and Worksheet (Vol II)			
Method Robustness Protocol and Worksheet (Vol II)			

Performed By: _____

Date: _____

Reviewed By: _____

Date: _____

Validated By: _____

Date: _____



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A Note about Protocol Results

The TOC 500 Analyzer displays protocol results rounded to three significant digits. Some internal results calculations may be performed with non-rounded values. Therefore, small discrepancies may occur when comparing instrument-calculated results to manually-calculated results using Data History records, which are stored as rounded values.



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Installation Protocol for Sievers 500 RL TOC Analyzer

1. **Purpose:** To install a Sievers 500 RL TOC Analyzer.
2. **Scope:** This protocol is intended to document installation of a Sievers 500 RL TOC Analyzer, for validation purposes. A checklist is provided to assist with installation. Specific installation instructions and illustrations are detailed in the Analyzer's *Operation and Maintenance Manual*.

The information in this section is supplied with every Analyzer. If this package was purchased separately from an Analyzer or shipped separately, it does not contain the Analyzer materials.

3. **Materials:**

- 3.1. Sievers 500 RL TOC Analyzer shipping box and contents.
- 3.2. Accessories (e.g., printer) as appropriate for the configuration
- 3.3. *Installation Checklist* (see page 21)
- 3.4. The Analyzer's *Operation and Maintenance Manual* (Available as an electronic download, or optional print purchase)
- 3.5. *Validation Support Package (VSP) - Volume I*

4. **Definitions:** None

5. **Procedures:**

- 5.1. Unpack the box and verify that all of the following items have been received. Enter Yes, No, or NA and Initial and Date in the corresponding column of the Installation Checklist.
 - 5.1.1. Sievers 500 RL TOC Analyzer.
 - 5.1.2. *Analyzer Operation and Maintenance Manual*. (Available as an electronic download, or optional print purchase)
 - 5.1.3. *Validation Support Package (VSP) - Volume I (User Protocols: Installation Qualification Guidelines and Operation Qualification Guidelines)*.
 - 5.1.4. Certificate of Calibration.
 - 5.1.5. Accessories. Verify contents match list described in the "Installation" chapter in the Analyzer's *Operation and Maintenance Manual*.
 - 5.1.6. (Optional) DataGuard activation key.
 - 5.1.7. (Optional) DataShare activation key.
- 5.2. Complete the "Identification Records" section found on page 3 of the Analyzer's *Operation and Maintenance Manual* by recording the date of installation and the Analyzer serial number (found on the side of the Analyzer).



-
- 5.3. Confirm that the installation site meets the Analyzer's environmental requirements and mount the Analyzer on a wall or an appropriate rack, as described in the "Installation" chapter of the Analyzer's *Operation and Maintenance Manual* in the section called "Step 3: Select a Location for the Analyzer."
 - 5.4. Install power and control wiring.
 - 5.4.1. Connect the Analyzer to a grounded power source as described in the section called "Connecting to a Power Supply" under "Step 4: Install Power and Control Wiring" in the Analyzer's *Operation and Maintenance Manual*.
 - 5.4.2. (Optional) Connect the Analyzer to analog outputs and alarms as described in the section called "Installing the Analog Outputs and Alarms" under "Step 4: Install Power and Control Wiring" in the Analyzer's *Operation and Maintenance Manual*.
 - 5.5. Install the accessories and cables you will be using with the Analyzer, as described in the "Installation" chapter of the Analyzer's *Operation and Maintenance Manual* in the section called "Step 5: Install Accessories." Possible accessories and cables include:
 - 5.5.1. A printer.
 - 5.5.2. A USB flash memory drive.
 - 5.5.3. A serial cable.
 - 5.5.4. An Ethernet cable
 - 5.6. Connect the sample inlet system. Follow the instructions in the "Installation" chapter of the *Operation and Maintenance Manual* in the section called "Step 6: Connect the Sample Inlet System."
 - 5.7. Open the Analyzer front panel. You may need the key from the accessories kit to unlock the bottom latch on the front panel. Fill the DI water cartridge. Follow the instructions in the "Installation" chapter of the Analyzer's *Operation and Maintenance Manual* in the section called "Step 7: Fill the DI Water Cartridge."
 - 5.8. Power the Analyzer on and configure the basic settings in the firmware, as described in the "Installation" chapter of the *Operation and Maintenance Manual* in the section called "Step 8: Configure Basic Analyzer Settings." This step includes the following:
 - 5.8.1. Enabling DataGuard or Password protection (optional). If you activate DataGuard, record the administrator password in a secure location.
 - 5.8.2. Setting the Clock and Time Zone
 - 5.8.3. Naming the Analyzer
 - 5.8.4. Setting the Analyzer Mode
 - 5.8.5. Setting Up the Data History
 - 5.8.6. Setting Up the Printer (Optional)



- 5.8.7. Exporting and Printing System Settings
- 5.8.8. Setting Up Data I/O
- 5.8.9. Selecting a Pharmacopeia
- 5.9. Rinse the Analyzer down for 12 hours, as described in the “Installation” chapter of the Analyzer’s *Operation and Maintenance Manual* in the section called “Step 9: Rinsing the Analyzer.”
- 5.10. If you have the DataShare 500 software for PC, install it on your computer, following the instructions in the *DataShare 500 Operation and Maintenance Manual*.



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Installation Checklist for Sievers 500 RL TOC Analyzer

Company Name _____ Date _____

Analyst Name _____ Firmware Version _____

Analyzer Serial Number _____

Protocol Step No.	Description	Yes/No or N/A Initial & Date
5.1.1	Sievers 500 RL TOC Analyzer received	
5.1.2	<i>Analyzer Operation and Maintenance Manual</i> received (Printed from electronic download, or received as an optional print purchase)	
5.1.3	<i>Validation Support Package (VSP) Volume I</i> received (Printed from electronic download, or received as an optional print purchase)	
5.1.4	Certificate of Calibration received	
5.1.5	All accessories received	
5.1.6	DataGuard activation key (optional)	
5.1.7	DataShare activation key (optional)	
5.2	"Identification Records" section completed	
5.3	Installation site satisfies Analyzer environmental requirements, and Analyzer mounted	
5.4.1	Electrical wiring connected	
5.4.2	Inputs, outputs, and alarms connected (optional)	
5.5	Accessories installed (optional)	
5.6	Sample inlet system installed	
5.7	DI water cartridge filled	



Protocol Step No.	Description	Yes/No or N/A Initial & Date
5.8	Analyzer powered on and basic Analyzer settings configured	
5.8.1	DataGuard or Password Protection enabled (optional)	
5.8.2	Clock and time zone set	
5.8.3	Analyzer location named (optional)	
5.8.4	Analyzer mode set	
5.8.5	Data history settings configured	
5.8.6	Printer settings configured (optional)	
5.8.7	System settings exported and/or printed	
5.8.8	Binary inputs, alarms, and 4-20 mA output configured (optional)	
5.8.9	Pharmacopeia selected	
5.9	Analyzer has rinsed down for 12 hours	
5.10	(Optional) DataShare 500 Software installed	

Performed By: _____

Date: _____

Reviewed By: _____

Date: _____

Validated By: _____

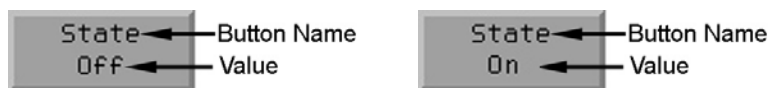
Date: _____



Firmware Installation Verification Protocol

- Purpose:** To verify firmware installation in a Sievers 500 RL TOC Analyzer.
- Scope:** This protocol applies to the Sievers 500 RL TOC Analyzer with Version 2.13 or later of the firmware, and walks through screens in the Analyzer's firmware to confirm correct firmware installation. When there are multiple menu paths that lead to a common destination, the appearance of the destination is only verified via the first menu path. In addition, menu paths are verified to the lowest possible level without activating an Analyzer function (e.g., no activities in this protocol result in changing settings or drawing sample through the Analyzer). This protocol assumes all Analyzer features are active. On some Analyzers, certain buttons may be grayed out to indicate that feature is not available.

This protocol refers extensively to the buttons that display on the Analyzer's screen. Some buttons contain both a button name and the current value for the setting. For example, the following are two states of the same button, and this protocol refers to either state as the **State** button:

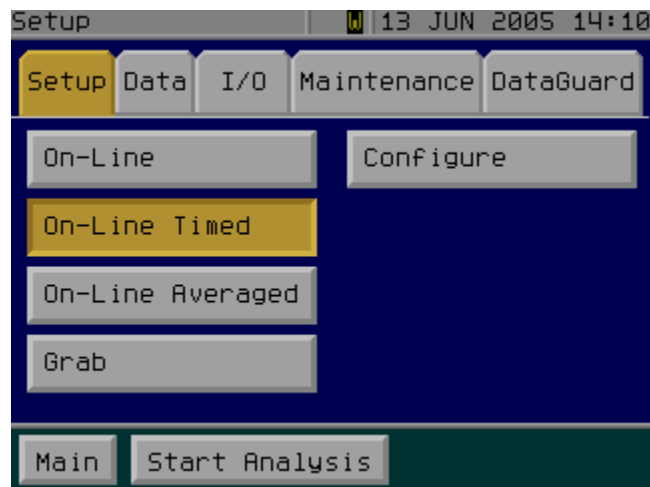


The screen images are provided to confirm menu and button choices; details like time, date, data, and the presence of warnings or errors are variable and will not be the same on your Analyzer's screen.

- Materials:**
 - Sievers 500 RL TOC Analyzer
 - Firmware Installation Verification Checklist* (see page 49)
- Definitions:** None
- Procedure:**
 - Power the Analyzer on. Make sure analysis is stopped and the **Main** screen is displayed. Depending on the mode in which the Analyzer was last operated, the **Main** screen should display either a graph (On-line modes) or a chart (Grab mode) of data.
 - If DataGuard is active, enter your login and password now.
 - Press the **Menu** button, select the **Maintenance** tab, and press the **System Info** button. Locate the firmware version number and record it on the *Firmware Installation Verification Checklist*. Complete the rest of the information at the top of the checklist.
 - For each menu indicated below, enter Yes, No, or NA and Initial and Date in the corresponding column of the *Firmware Installation Verification Checklist*. Do **not** configure any settings during this protocol; this protocol assumes default values for all settings.

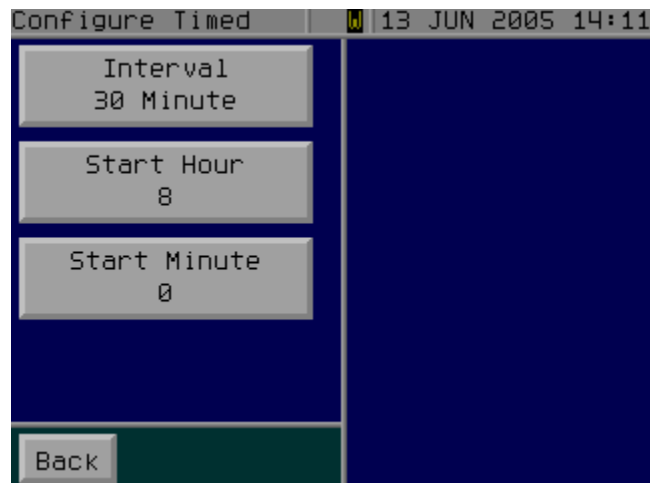


- 5.5. Press the **Back** button, and then select the **Setup** tab. The following buttons should display:



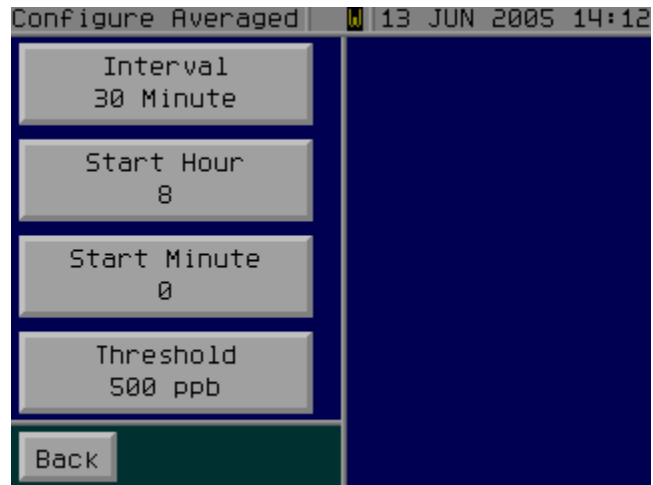
Note: If you select **On-Line**, the **Configure** button is un-selectable. Also, on base model systems (those without an **iOS** or Super **iOS**), the **Grab** button is un-selectable.

- 5.6. Press the **On-Line Timed** button, then press the **Configure** button. The following buttons should display:

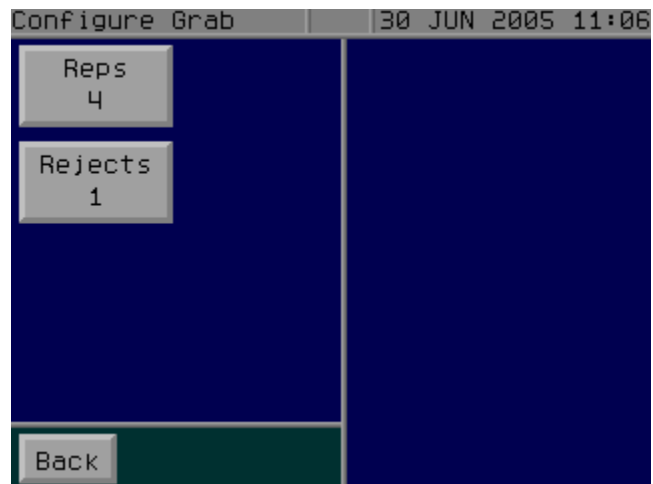




- 5.7. Press the **Back** button, press the **On-Line Averaged** button, and then press the **Configure** button. The following buttons should display:

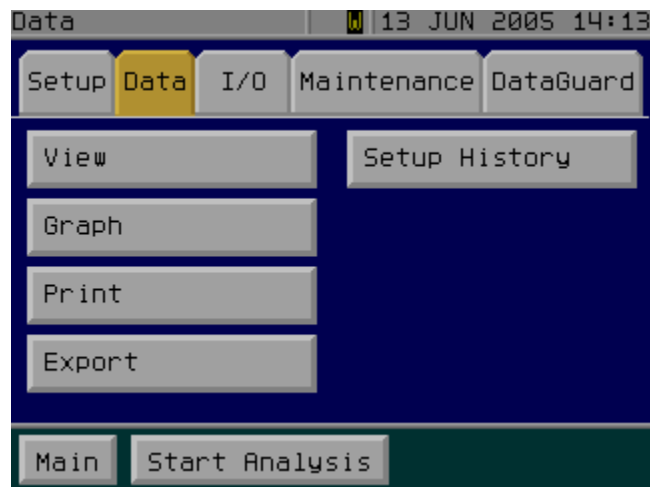


- 5.8. Press the **Back** button, press the **Grab** button, and then press the **Configure** button (skip this step if your Analyzer does not have an **iOS** or Super **iOS**). The following buttons should display:



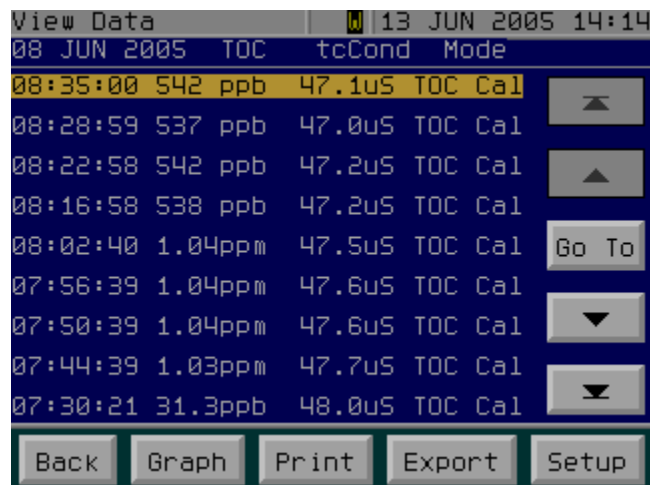


- 5.9. Press the **Back** button, then select the **Data** tab. The following buttons should display:



Note: The **Print Archive** and **Export Archive** buttons display only if DataGuard has been enabled or if **Archive Data** is set to **On**.

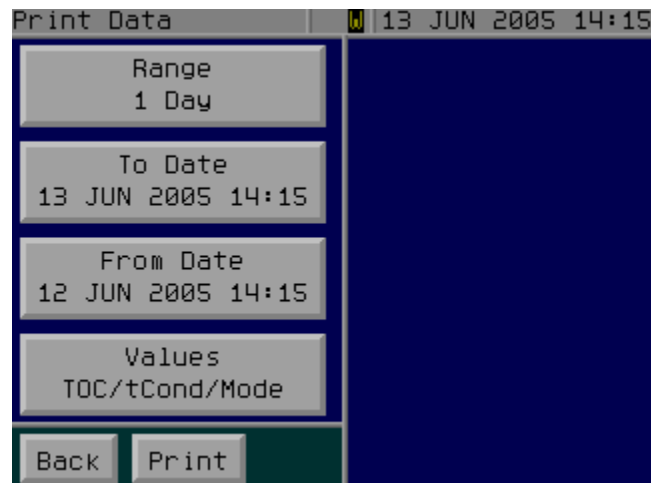
- 5.10. Press the **View** button. The following buttons should display:



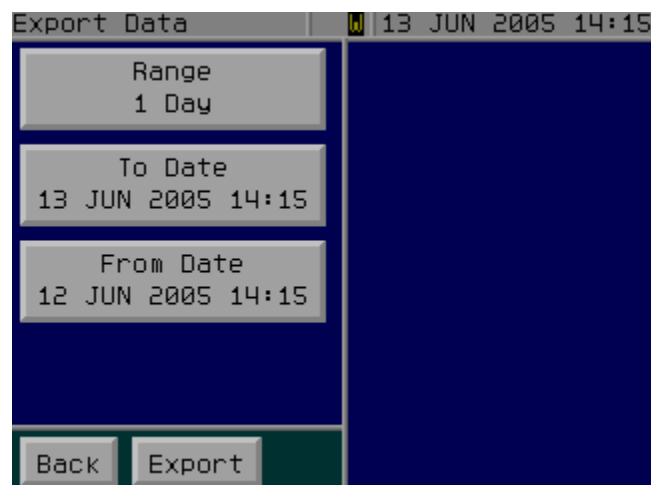
- 5.11. Press the **Graph** button. The following buttons should display:



5.12. Press the **Back** button, then press the **Print** button. The following buttons should display:

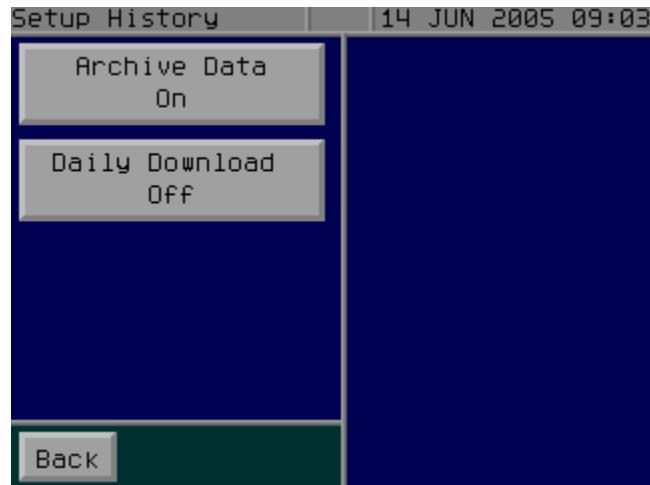


5.13. Press the **Back** button, then press the **Export** button. The following buttons should display:



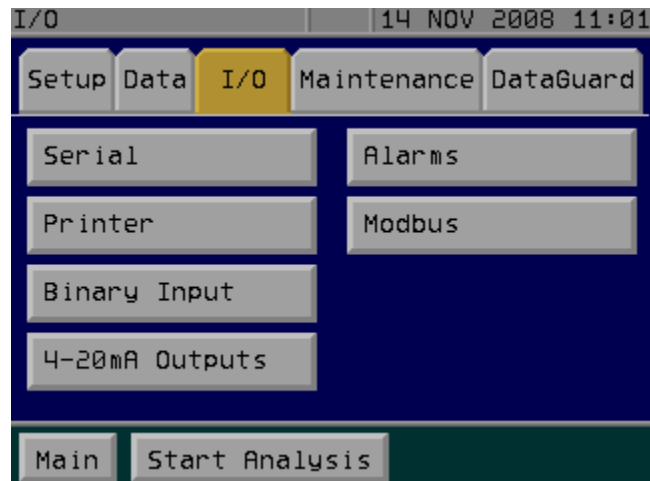


- 5.14. Press the **Back** button twice, and then press the **Setup History** button. The following buttons should display:

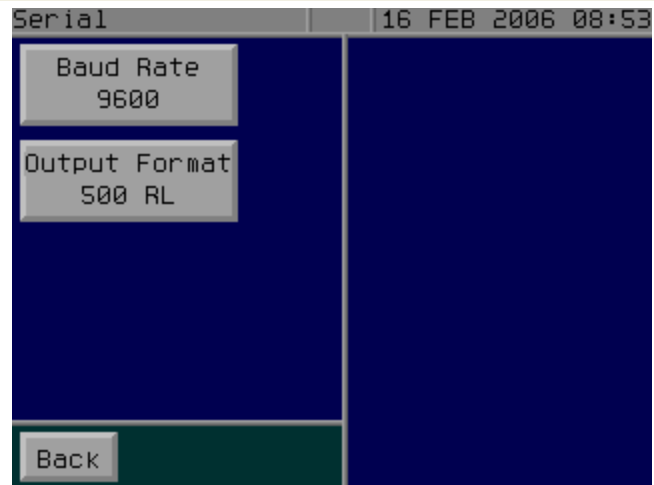


Note: The **Daily Download** option is set to **Off** by default; when it is set to **On**, the **Download Time** button also displays.

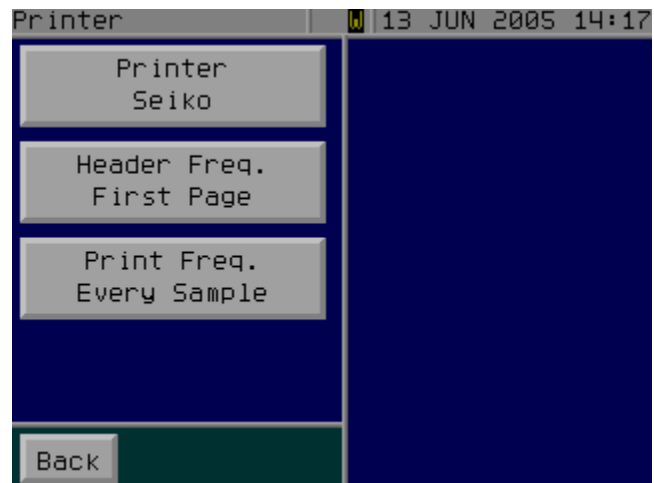
- 5.15. Press the **Back** button, and then select the **I/O** tab. The following buttons should display:



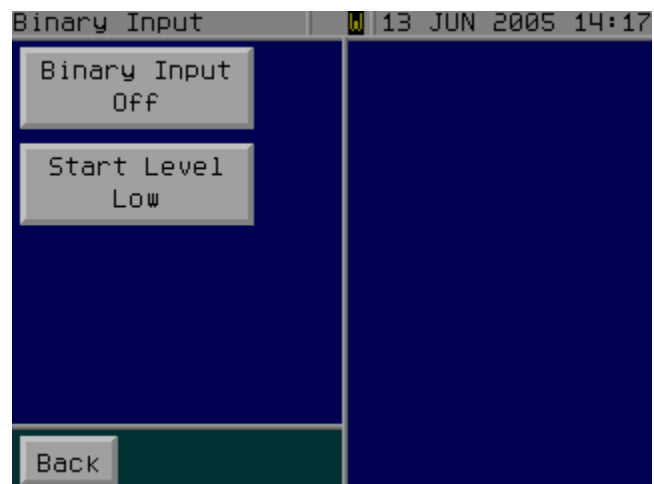
- 5.16. Press the **Serial** button. The following buttons should display:



5.17. Press the **Back** button, then press the **Printer** button. The following buttons should display:

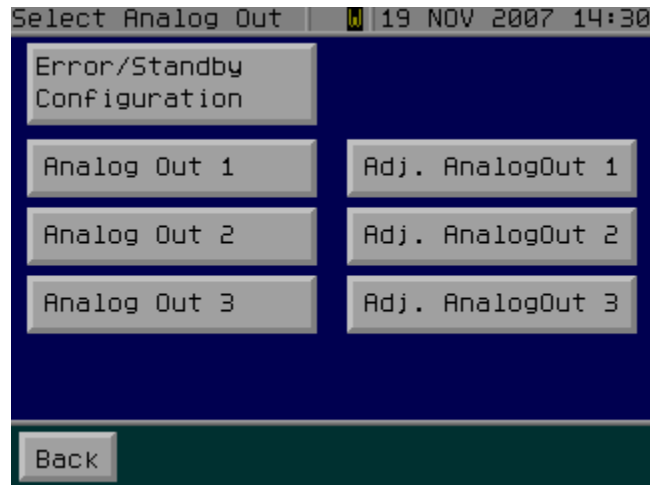


5.18. Press the **Back** button, then press the **Binary Input** button. The following buttons should display:





- 5.19. Press the **Back** button, then press the **4-20 mA Outputs** button. The following buttons should display:



- 5.20. Press the **Adj. AnalogOut 1** button. The following buttons should display:

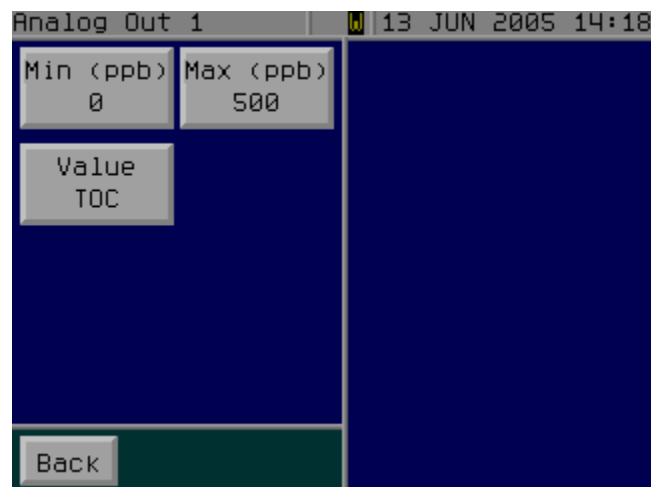




- 5.21. Press the **Back** button, and then press the **Error/Standby Configuration** button. The following buttons should display:



- 5.22. Press the **Back** button, and then press the **Analog Out 1** button. The following buttons should display:

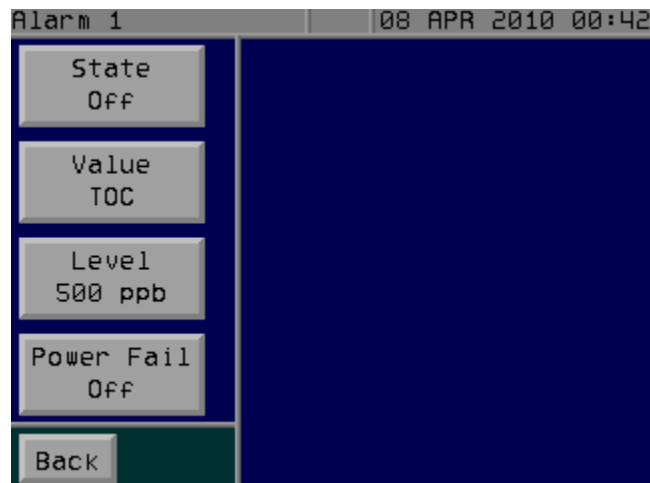




- 5.23. Press the **Back** button, press the next **Back** button, and then press the **Alarms** button. The following buttons should display:

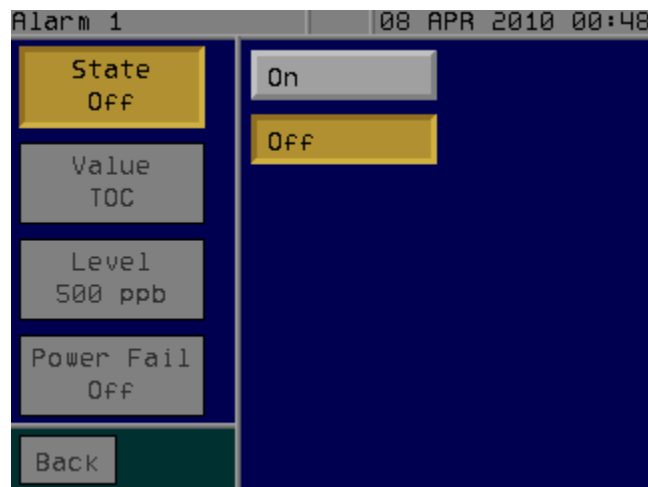


- 5.24. Press the **Alarm 1** button. The following buttons should display:

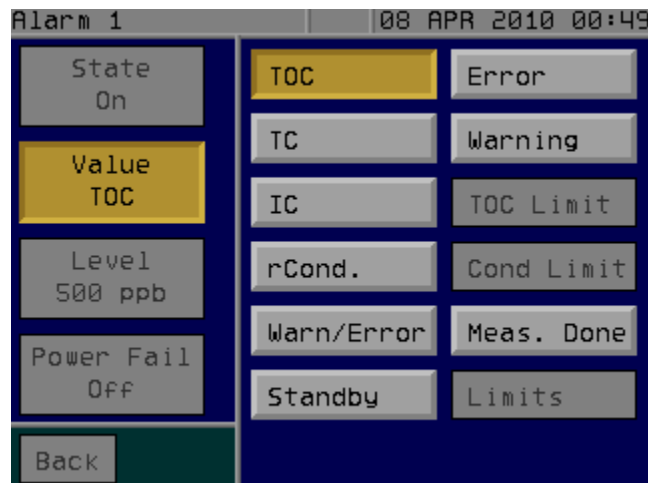




- 5.25. Press the **State** button. The following buttons should display:



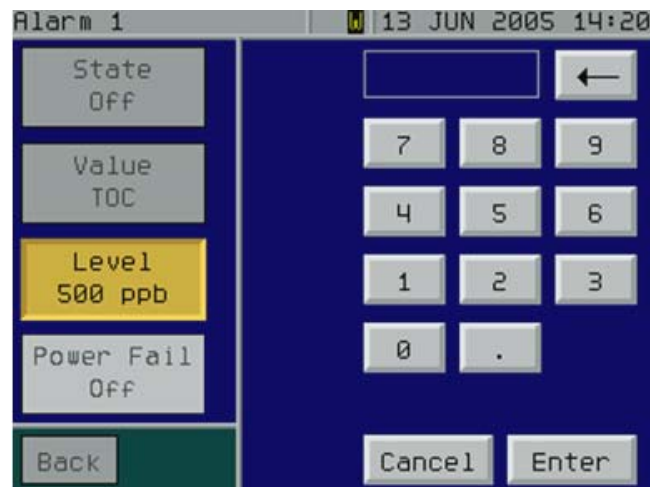
- 5.26. Select the currently highlighted State **On** or **Off** button, and then press the **Value** button. The following buttons should display:



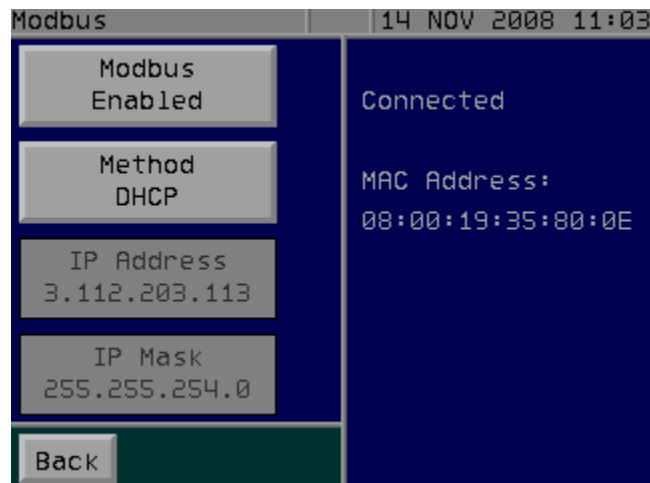
NOTE: A **Break In** button also displays only if Password Protection or DataGuard has been activated. Additionally, the following buttons will be grayed out if the Conductivity and System Suitability options are *NOT active*: **rCond**, **TOC Limit**, **Cond Limit**, and **Limits**. Of these buttons, the last three (**TOC Limit**, **Cond Limit**, and **Limits**) will also be grayed out when Conductivity is active—but, *the data history is empty*. In this case, the buttons will become active as soon as the first data point is generated in Data History.



- 5.27. Press the **TOC** button, and then press the **Level** button. The following buttons should display:



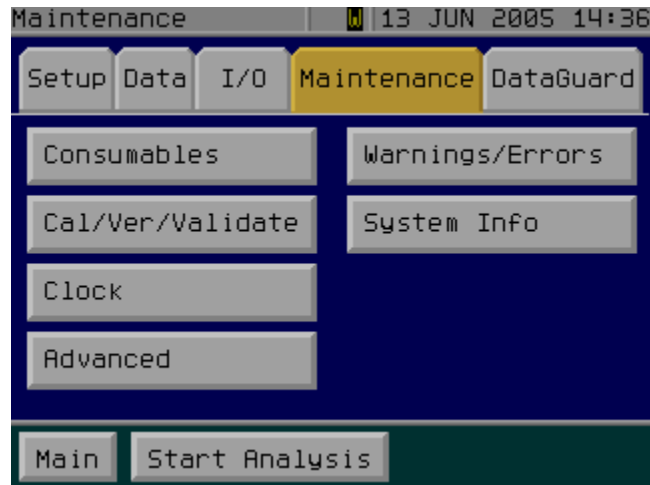
- 5.28. Press the **Cancel** button and then press the **Back** button to display the **Select Alarm** screen. Press the **Back** button to display the **I/O** screen, and then press the **Modbus** button.



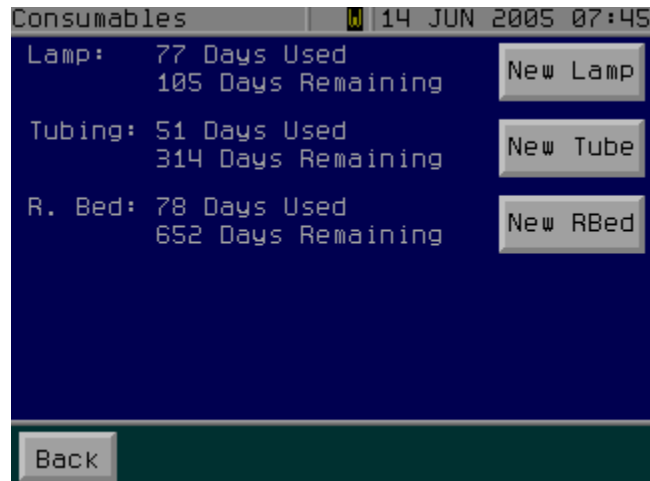
Note: The values for the MAC Address and IP Address will depend on your network settings. The addresses shown here are examples only.



- 5.29. Press the **Back** button and then press the **Maintenance** tab. The following buttons should display.

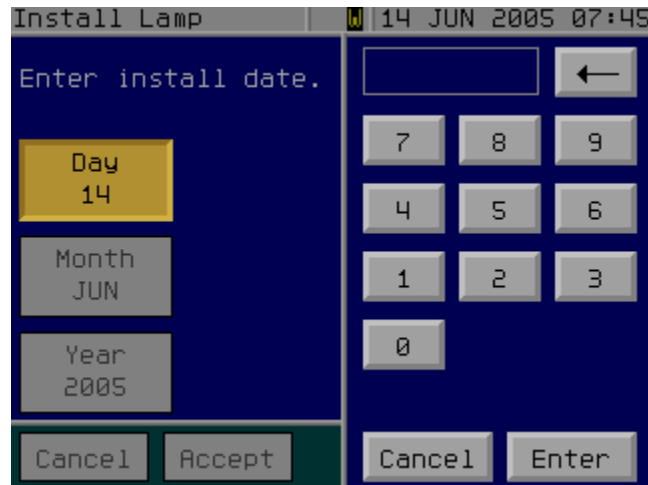


- 5.30. Press the **Consumables** button. The following buttons should display:

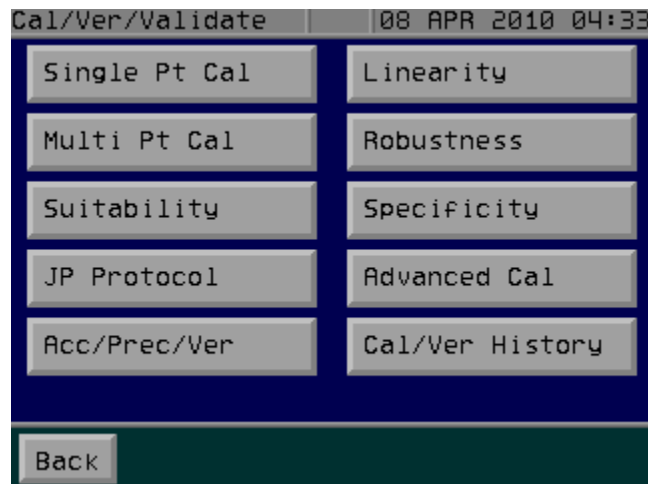




- 5.31. Press the **New Lamp** button, then press the **Day** button. The following buttons should display:



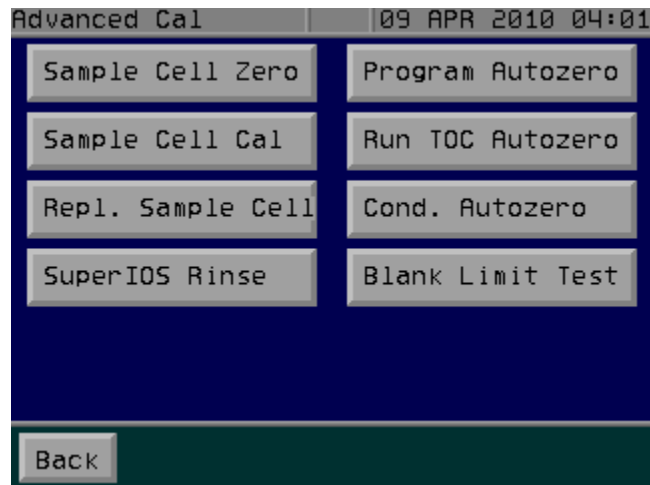
- 5.31.1. Press the **Cancel** button on the *Keypad* side, and then press the **Cancel** button on the *Enter Install Date* side to return to the Consumables screen.
- 5.32. Press the **Back** button to return to the **Maintenance** tab, and then press the **Cal/Ver/Validate** button. The following buttons should display:



Note: The following buttons will be grayed out, if the corresponding option is NOT activated: **Suitability**, **JP Protocol**, **Linearity**, **Robustness**, and **Specificity**.



5.33. Press the **Advanced Cal** button. The following buttons should display:



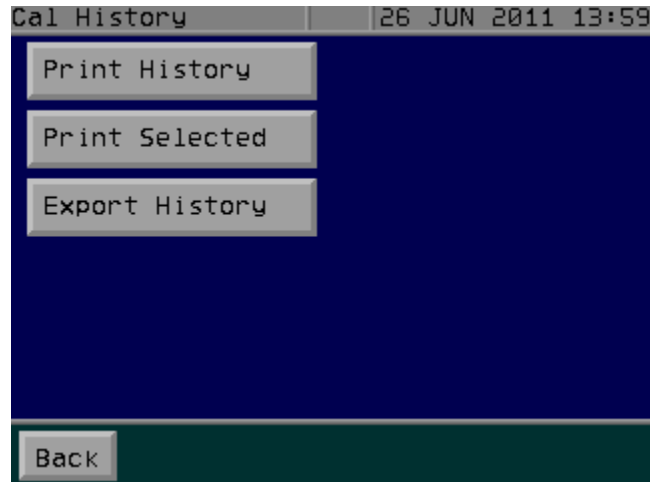
Note: The following buttons will be grayed out if the corresponding option is NOT activated: **Sample Cell Zero**, **Sample Cell Cal**, and **Repl. Sample Cell**.

5.34. Press the **Program Autozero** button. The following buttons should display:





- 5.35. Press the **Back** button to return to the **Advanced Cal** screen, and then press the **Back** button on this screen to display the **Ca/Ver/Validate** screen. Press the **Ca/Ver History** button. The following buttons should display:

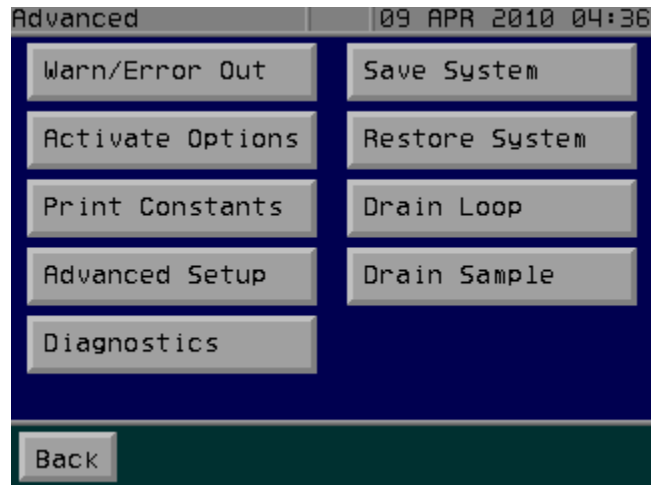


- 5.36. Press the **Back** button to return to the **Cal/Ver/Validate** screen, and then press the **Back** button to display the **Maintenance** tab. Press the **Clock** button. The following buttons should display:

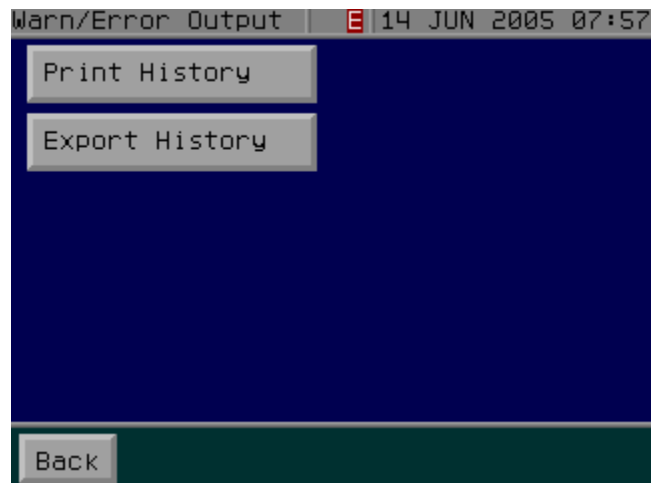




- 5.37. Press the **Back** button, then press the **Advanced** button. The following buttons should display:

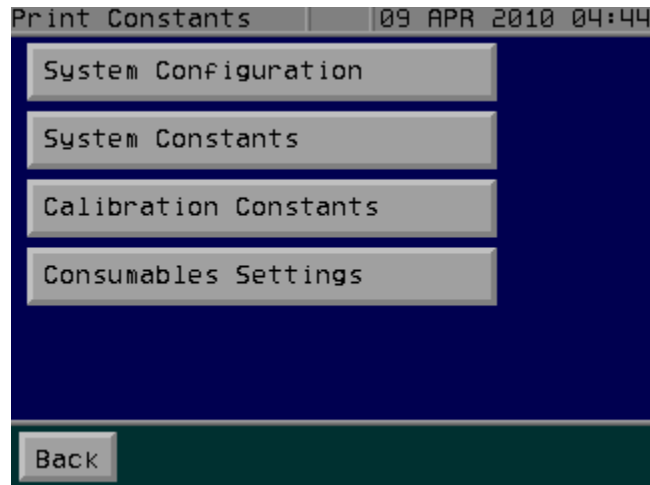


- 5.38. Press the **Warn/Error Out** button. The following buttons should display:





- 5.39. Press the **Back** button, and then press the **Print Constants** button. The following buttons* should display:



Note: The Cond. Stage 1 Table also displays when conductivity is activated and one or more of the following Pharmacopeia settings are selected: USP WFI/PW, EP WFI/HPW, CP WFI, IP WFI, EP PW, CP PW, or IP PW.

- 5.40. Press the **Back** button, then press the **Advanced Setup** button. The following buttons should display:



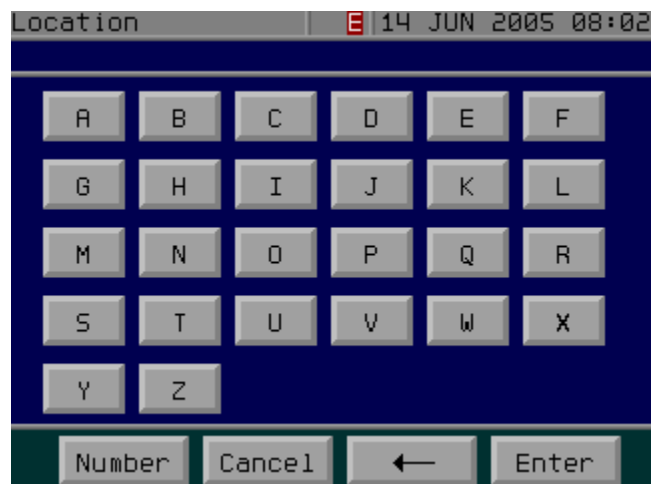


- 5.41. Press the **Contrast Adjust** button. The following buttons should display:



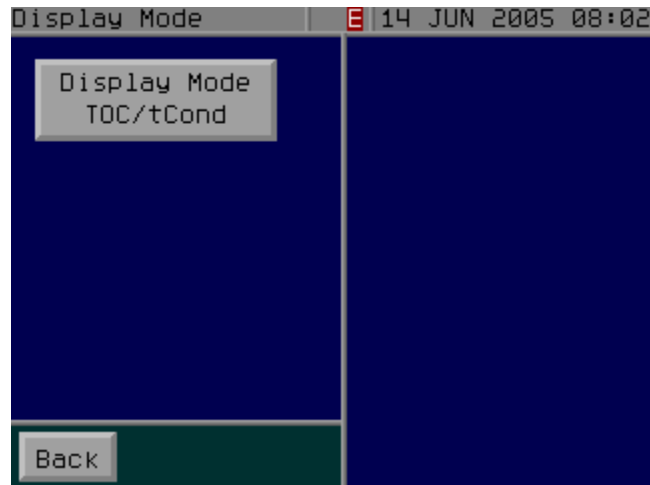
Note: The **Contrast** button may be grayed out, depending on the kind of display that is in your Analyzer.

- 5.42. Press the **Back** button, then press the **Location** button. The following buttons should display:

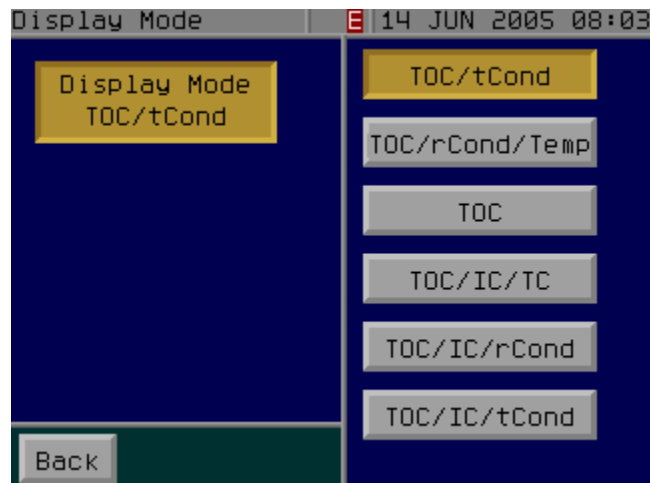




- 5.43. Press the **Cancel** button, then press the **Display Mode** button. The following buttons should display:



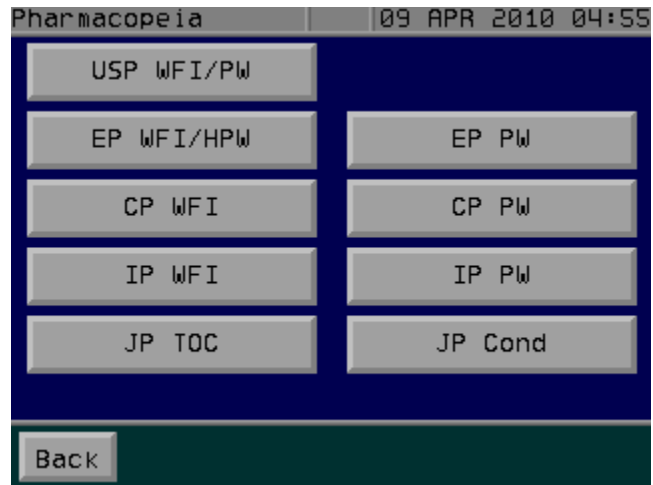
- 5.44. Press the **Display Mode** button. The following buttons should display:



Note: The following buttons will be grayed out if Conductivity is NOT activated: **TOC/tCond**, **TOC/rCond/Temp**, **TOC/IC/rCond**, and **TOC/IC/TC**.

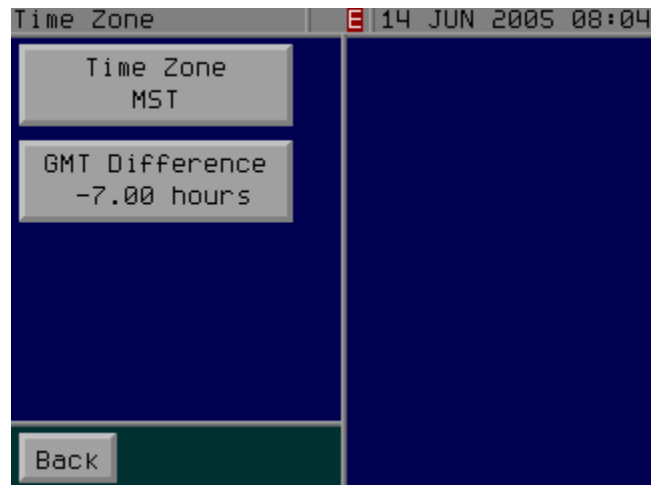


- 5.45. Press the **Back** button, and then press the **Pharmacopeia** button. The following buttons should display:



Note: The JP Cond button will be grayed out if this option is NOT activated.

- 5.46. Press the **Back** button, then press the **Time Zone** button. The following buttons should display:

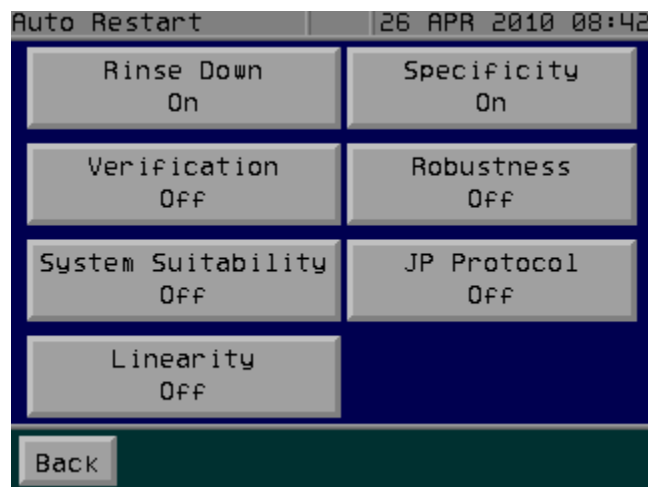




- 5.47. Press the **Back** button, then press the **Flow Sensor** button (skip this step if your Analyzer does not have an **iOS** or **Super iOS**). The following buttons should display:



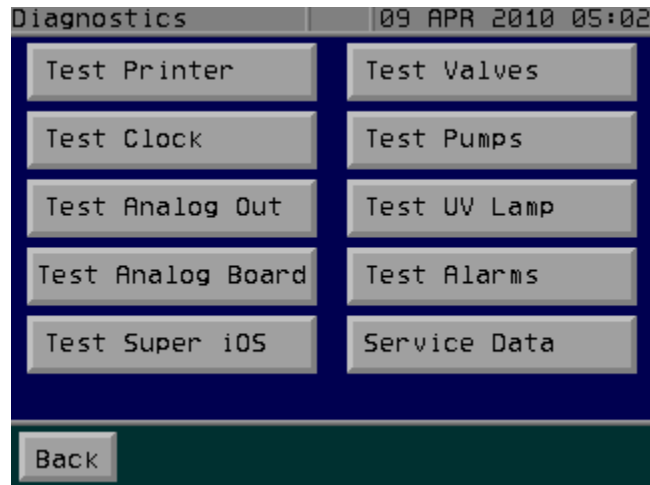
- 5.48. Press the **Back** button, then press the **Auto Restart** button. The following buttons should display*:



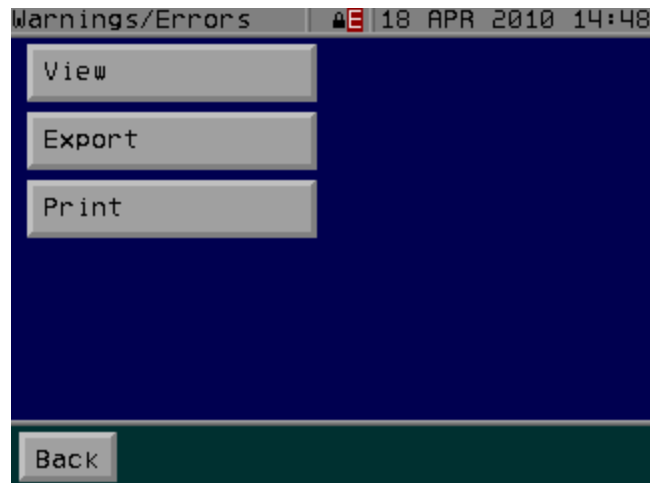
Note: On systems with a Standard **iOS** or without an **iOS**, only the **Rinse Down** button displays. Also, the following buttons only display if their corresponding options are *active*: **System Suitability**, **Linearity**, **Specificity**, **Robustness**, and **JP Protocol**.



- 5.49. Press the **Back** button to return to the **Advanced Setup** screen, and then press the **Back** button on this screen. Press the **Diagnostics** button. The following buttons should display:



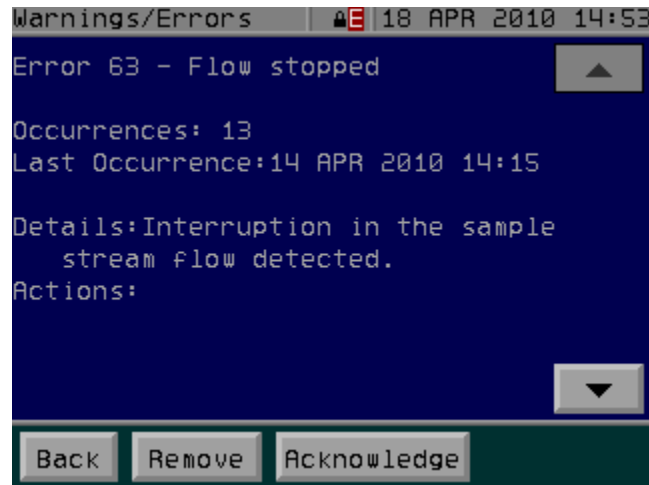
- 5.50. Press the **Back** button to return to the **Advanced** screen, and then press the next **Back** button to display the **Maintenance** tab.
- 5.51. Press the **Warnings/Errors** button. The following buttons should display:



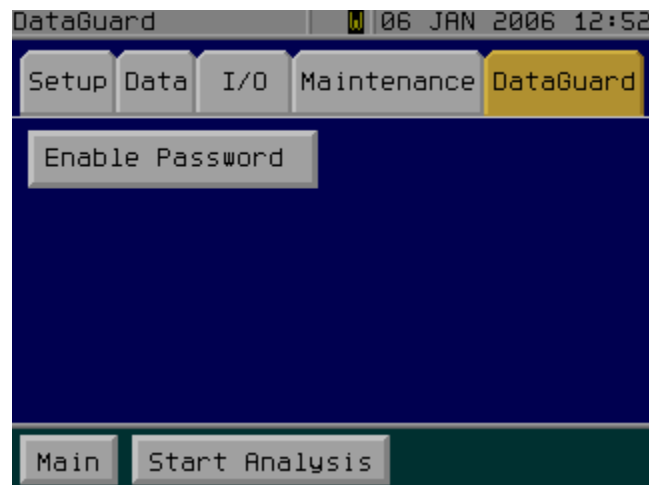
Note: If there are no warning or errors, the **View** button appears grayed out and is de-activated.



- 5.51.1. Press the **View** button. The following screen should display. The data displayed will vary according to the warnings and error history for your Analyzer.



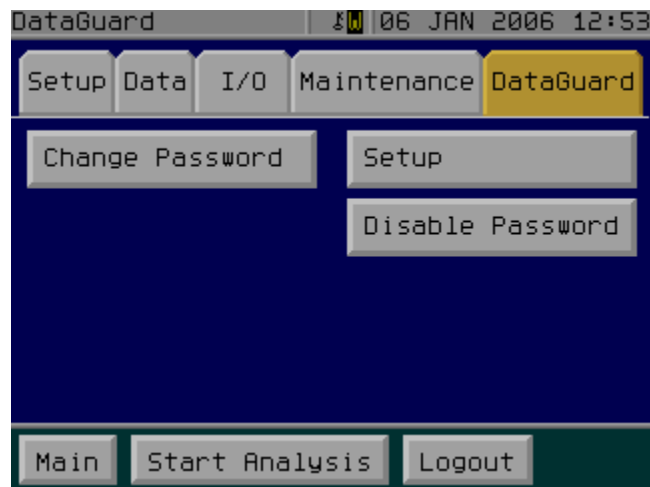
- 5.51.2. Verify that the **Acknowledge** button displays on the lower portion of the screen. Press the **Back** button to return to the **Warnings/Error** screen.
- 5.52. If neither DataGuard nor Password protection has been activated, proceed with this section. If Password protection has been enabled, proceed to Section 5.53. If DataGuard has been enabled, proceed to Section 5.54.
- 5.52.1. Press the **Back** button and select the **DataGuard** tab. If neither DataGuard nor Password Protection are active, the following buttons should display:



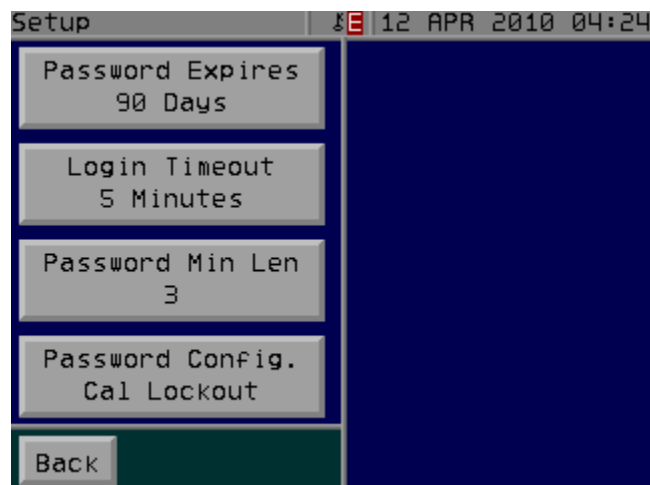
- 5.52.2. This completes the firmware installation verification. You should not complete the following sections.
- 5.53. Select the **DataGuard** tab. This section assumes Password protection is activated.



5.53.1. The following buttons should display on the **DataGuard** tab:



5.53.2. Press the **Setup** button. The following buttons should display:

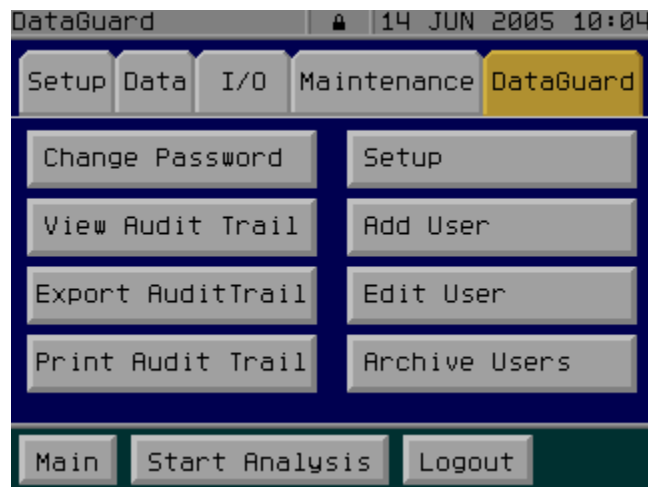


5.53.3. Press the **Back** button to return to the **DataGuard** tab. This completes the firmware installation verification. You should not complete the following sections.

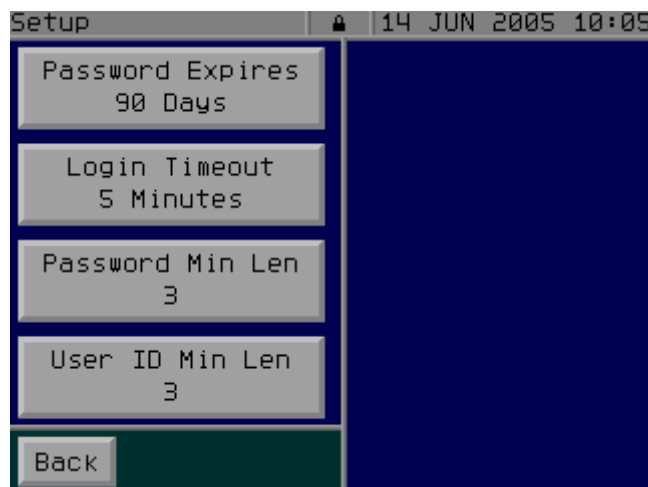
5.54. Select the **DataGuard** tab. This section assumes DataGuard is activated.



5.54.1. The following buttons should display on the **DataGuard** tab:



5.54.2. Press the **Setup** button. The following buttons should display:



5.54.3. Press the **Back** button to return to the **DataGuard** tab. This completes the firmware installation verification.



Firmware Installation Verification Checklist

Company Name _____ Date _____

Analyst Name _____ Firmware Version _____

Analyzer Serial Number _____

Protocol Step No.	Description	Yes/No or NA Initial/Date
5.3	Firmware version recorded on worksheet	
5.5	Setup tab displays correctly	
5.6	Configure (On-Line Timed) screen displays correctly	
5.7	Configure (On-Line Averaged) screen displays correctly	
5.8	Configure (Grab) screen displays correctly	
5.9	Data tab displays correctly	
5.10	View Data screen displays correctly	
5.11	Graph Data screen displays correctly	
5.12	Print Data screen displays correctly	
5.13	Export Data screen displays correctly	
5.14	Setup History screen displays correctly	
5.15	I/O tab displays correctly	
5.16	Serial screen displays correctly	
5.17	Printer screen (type) displays correctly	
5.18	Binary Input screen displays correctly	
5.19	4-20mA Output screen displays correctly	
5.20	Adj. Analog Out screen displays correctly	
5.21	Error/Standby Configuration screen displays correctly	
5.22	Analog Out 1 screen displays correctly	



Protocol Step No.	Description	Yes/No or NA Initial/Date
5.23	Select Alarm screen displays correctly	
5.24	Alarm 1 screen displays correctly	
5.25	State buttons display correctly	
5.26	Value buttons display correctly	
5.27	Level keypad displays correctly	
5.28	Modbus screen displays correctly	
5.29	Maintenance tab displays correctly	
5.30	Consumables screen displays correctly	
5.31	New Lamp (Day) screen displays correctly	
5.32	Cal/Ver/Validate screen displays correctly	
5.33	Advanced Cal screen displays correctly	
5.34	Program Autozero screen displays correctly	
5.35	Cal History screen displays correctly	
5.36	Clock screen displays correctly	
5.37	Advanced screen displays correctly	
5.38	Warn/Error Out screen displays correctly	
5.39	Print Constants Screen displays correctly	
5.40	Advanced Setup screen displays correctly	
5.41	The Contrast button displays. It may be active or inactive (grayed out).	
5.42	Location screen displays correctly	
5.43	Display Mode screen displays correctly	
5.44	Display Mode (value) screen displays correctly	
5.45	Pharmacopeia screen displays correctly	



Protocol Step No.	Description	Yes/No or NA Initial/Date
5.46	Time Zone screen displays correctly	
5.47	Flow Sensor screen displays correctly	
5.48	Auto Restart screen displays correctly	
5.49	Diagnostics screen displays correctly	
5.51	Warnings/Error screen displays correctly	
5.51.2	Acknowledge button displays correctly	
5.52.1	DataGuard tab displays correctly (<i>Password and DataGuard not active</i>)	
5.53.1	DataGuard tab displays correctly (<i>Password active</i>)	
5.53.2	Setup screen displays correctly	
5.54.1	DataGuard tab displays correctly (<i>DataGuard active</i>)	
5.54.2	Setup screen displays correctly	

Performed By: _____

Date: _____

Reviewed By: _____

Date: _____

Validated By: _____

Date: _____



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DataGuard Operation Verification Protocol

- 1. Purpose:** To verify DataGuard installation in a Sievers 500 RL TOC Analyzer.
- 2. Scope:** This protocol applies to Sievers 500 RL TOC Analyzers with Version 2.11 or later of the firmware and with the optional DataGuard feature enabled. If you have not purchased the DataGuard option from GE Analytical Instruments, or if you are only using the Password Protection feature, do not perform this protocol.

This protocol assumes that DataGuard has already been activated on the Analyzer.

Note: Any operations requiring a login will be recorded in the audit trail.

- 3. Materials:**
 - 3.1. Sievers 500 RL TOC Analyzer
 - 3.2. *DataGuard Operation Verification Checklist* (see page 57)
- 4. Definitions:** None
- 5. Procedure:**
 - 5.1. For each menu indicated below, enter Yes, No, or NA and Initial and Date in the corresponding column of the *DataGuard Operation Verification for Firmware Checklist*.
 - 5.2. Power the Analyzer on. Make sure analysis is stopped and the **Main** screen is displayed.
 - 5.3. Press the **Login** button.
 - 5.3.1. Enter the administrator-level Login ID you created during the installation process, and then press **Enter**.
 - 5.3.2. Enter the Password for the administrator-level Login ID you created during the installation process, and then press **Enter**.
 - 5.4. Press the **Menu** button and then select the **DataGuard** tab.
 - 5.5. Create a test user and confirm a duplicate User ID cannot be created.
 - 5.5.1. Press the **Add User** button.
 - 5.5.2. For the User ID, type `VS` and press **Enter**. The following error should display: "Length Error. The minimum string length is 3 characters." (The minimum length may have been adjusted to a value longer than 3 by the administrator.) Press **OK**.
 - 5.5.3. The **User ID** screen displays again. This time, type `VSPTEST` and press **Enter**.



-
- 5.5.4. For the Password, type **TE** and press **Enter**. The following error should display: "Length Error. The minimum string length is 3 characters." (The minimum length may have been adjusted to a value longer than 3 by the administrator.) Press **OK**.
 - 5.5.5. The Password screen displays again. This time, type **TEST** and press **Enter**.
 - 5.5.6. Re-enter the Password, **TEST**, and press **Enter**.
 - 5.5.7. After the new user's Password has been verified, the **Add User** screen displays. Make sure the following values are set:
 - **User Level** should be set to Operator
 - **User Status** should be set to Active
 - **Password Expired** should be set to True
 - 5.5.8. If you need to adjust any of the values, press the appropriate button and select the value. When you are done, press the **Back** button to continue.
 - 5.5.9. Press the **Add User** button. For the User ID type **VSPTEST** and then press the **Enter** button. The following error message should display: "The ID has been used. Please try again." Press the **OK** button and then press the **Cancel** button.
 - 5.5.10. Press the **Logout** button.
 - 5.6. Confirm the proper functioning of the test user account.
 - 5.6.1. Press the **Login** button.
 - 5.6.2. For the User ID, type **VSPTEST** and then press **Enter**.
 - 5.6.3. For the Password, type **TES** and then press **Enter**. The following error message should display: "Invalid Password. The Password is Invalid. Please re-enter a password." Press **OK**.
 - 5.6.4. The **Password** screen displays again. This time, type **TEST** and press **Enter**. The following message should display: "Password Expired. Your password has expired. Please enter a new one." Press **OK**.
 - 5.6.5. In the **Old Password** screen, enter the old password (**TEST**) and press **Enter**.
 - 5.6.6. In the **New Password** screen, type **TESTB** and press **Enter**.
 - 5.6.7. When the **New Password** screen displays again, type **TESTA** and press **Enter**. The following error message should display: "The password was not verified. Please try again." Press **OK**.
 - 5.6.8. The **New Password** screen displays again. This time, type **TESTB** and then press **Enter**.
 - 5.6.9. Verify the Password by re-typing **TESTB** and press **Enter**. The **Main** screen should display.



- 5.7. Press the **Menu** button and then select the **DataGuard** tab. All the buttons except for **Change Password** should be gray, to show that they are unavailable to the TESTVSP User ID, which only has a User Level of Operator.
- 5.8. Press the **Change Password** button.
 - 5.8.1. Enter the old password (TESTB) and then press **Enter**.
 - 5.8.2. For the new password, type TEST and then press **Enter**.
 - 5.8.3. Re-enter TEST to verify the Password and press **Enter**.
 - 5.8.4. Press the **Logout** button.
- 5.9. Press the **Login** button and enter the user information for the administrator-level User ID.
- 5.10. Verify user account management activities.
 - 5.10.1. Press the **Menu** button and then select the **DataGuard** tab.
 - 5.10.2. Press the **View Audit Trail** button.
 - 5.10.3. The most recent entry (at the top of the screen) should show an Action of **User Login** for the administrator-level user account. Scroll through the list if you wish to see other audit trail entries, and push the **Back** button when you are done.
 - 5.10.4. Press the **Export AuditTrail** button. Attach the USB flash memory drive to the Analyzer's USB drive, and then push the USB button. The Analyzer will initialize the USB drive and then export the data. When the export is complete, the following message displays: "Audit trail data has been exported or printed. Press **OK** to erase the data. Press **Cancel** to keep the Data." Press the **Cancel** button to keep the data for now. You should not erase the Audit Trail unless you are archiving the exported file in a manner that complies with regulation 21 CFR Part 11.
 - 5.10.5. To confirm successful export of the Audit Trail, remove the USB drive from the Analyzer, attach it to your PC, and open the exported file using a spreadsheet program, such as Microsoft Excel. The file is saved on the USB flash memory drive in the following file path:

```
Sievers/500<serial number>/Audit_<date>000.csv
```

where <serial number> is the serial number of your Analyzer and <date> is the date that the Audit Trail was exported.
 - 5.10.6. Press the **Edit User** button. Scroll to select the VSPTEST user account and press the **OK** button.
 - 5.10.7. Press the **User Status** button and select **Inactive**.
 - 5.10.8. Press the **Back** button and then press the **Back** button.
 - 5.10.9. Press the **Archive Users** button. Make sure the USB flash memory drive is attached to the Analyzer, or make sure there is a serial connection between the Analyzer and your computer. Press the **USB** or the **Serial** button to archive the **Inactive** users and remove the accounts from the user list.



- 5.10.10. Press the **Edit User** button. The VSPTEST user account should no longer be in the list. Press the **Back** button.
- 5.11. Confirm the Login Timeout setting is honored.
 - 5.11.1. Press the **Setup** button.
 - 5.11.2. Press the **Login Timeout** button. Make note of the current value of the setting, as you will re-enter it in a few steps.
 - 5.11.3. Using the number pad, type 1 and press **Enter**. Press the **Back** button.
 - 5.11.4. Allow the login session to timeout.
 - 5.11.5. When you have been logged out, press the **Login** button and enter the user information for the administrator-level User ID.
 - 5.11.6. Press the **Menu** button, select the **DataGuard** tab, and press the **Setup** button.
 - 5.11.7. Press the **Login Timeout** button. Using the number pad, type the value that was previously recorded here and press **Enter**.
 - 5.11.8. Press the **Back** button and then press the **Logout** button.



DataGuard Operation Verification Checklist

Company Name _____ Date _____

Analyst Name _____ Firmware Version _____

Analyzer Serial Number _____

Protocol Step No.	Description	Yes/No or NA Initial/Date
5.2	Analyzer is powered on and analysis is stopped	
5.3	Login with administrator-level User ID is successful	
5.5.2	DataGuard rejects User ID with insufficient number of characters	
5.5.3	VSPTTEST User ID is created	
5.5.4	DataGuard rejects Password with insufficient number of characters	
5.5.5	TEST Password is accepted	
5.5.6	TEST Password is verified successfully	
5.5.7	Edit User screen values are appropriately set	
5.5.9	Duplicate User ID is rejected	
5.6.3	Invalid Password is rejected	
5.6.4	Password is accepted and expiration notice displays	
5.6.7	Incorrect password is not verified	
5.6.9	Correct password is verified and Main screen displays	
5.7	Only the Change Password button is available to VSPTTEST user	
5.8	Password is changed successfully	



Protocol Step No.	Description	Yes/No or NA Initial/Date
5.10.3	Audit Trail shows recent activity	
5.10.4	Audit Trail exports successfully	
5.10.6	VSPTTEST User ID set to Inactive	
5.10.8	User ID list archived	
5.10.9	VSPTTEST User ID removed from user list	
5.11.4	Login session times out correctly	
5.11.7	Login Timeout value restored	

Performed By: _____

Date: _____

Reviewed By: _____

Date: _____

Validated By: _____

Date: _____



DataShare 500 Software Installation Verification Protocol

- 1. Purpose:** To verify installation of DataShare 500 software, for use with a Sievers 500 RL TOC Analyzer.
- 2. Scope:** This procedure applies to Version 1.12 or later of DataShare 500 software and supplements the explanation of the operation of the software in the *DataShare 500 Operation and Maintenance Manual*. This protocol assumes DataShare 500 has been installed according to the Installation Protocol.

Note: The screen illustrations in which the focus is on a specific program menu or submenu may not show the entire DataShare 500 screen.

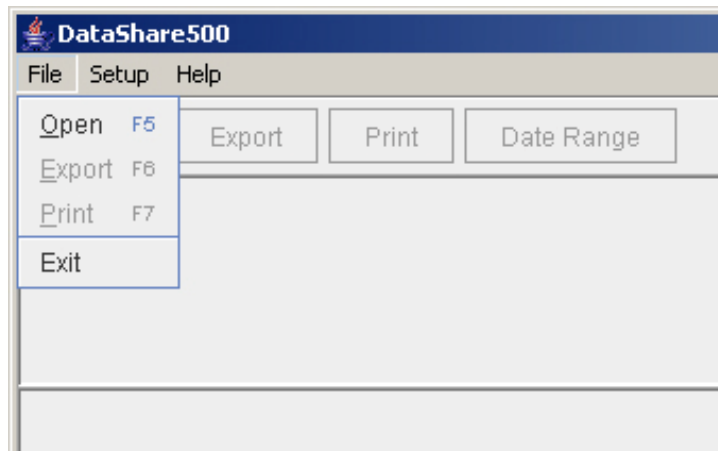
3. Materials:

- 3.1. *DataShare 500 Installation Verification Worksheet* (see page 61)

4. Definitions: None

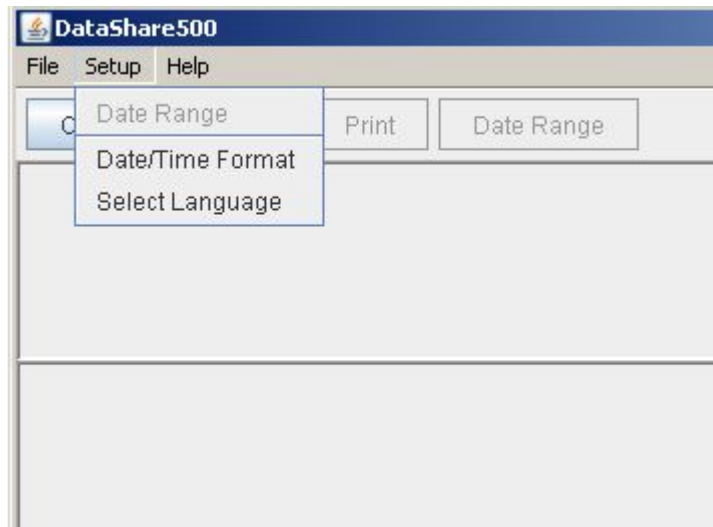
5. Procedure:

- 5.1. Double-click the **DataShare 500** icon on the desktop to open DataShare 500 (or click the **Start** menu → **Programs** → **Sievers** → **DataShare 500**).
- 5.2. For each menu indicated below, enter Yes, No, or NA and Initial and Date in the corresponding column of the *DataShare 500 Software Installation Verification Checklist*.
- 5.3. Select **Help** → **About**. Record the software version number at the top of the *DataShare 500 Installation Verification Worksheet*. Click **OK**.
- 5.4. Select the **File** menu. The following menu should display:

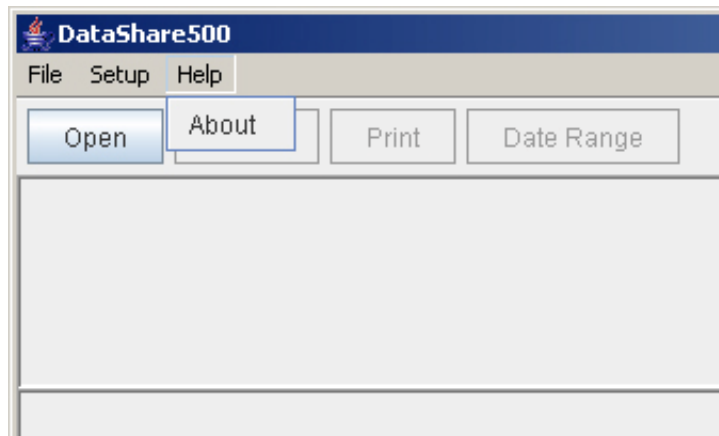




- 5.5. Select the **Setup** menu. The following menu should display:



- 5.6. Select the **Help** menu. The following menu should display:



- 5.7. Select **File** → **Open**. Navigate to the directory called "Example Data" within the DataShare 500 Directory. Choose the sample HistData file and click the **Open** button.
- 5.7.1. The data from the example file should display on-screen.
- 5.7.2. Click the **Print** button at the top of the DataShare 500 screen, then click **OK** in the print dialog box. The **Print Preview** window should display. Close the window by clicking the close box (**X**) in the upper right corner.
- 5.8. Select **File** → **Exit**. DataShare 500 should close.
- 5.9. This concludes the DataShare 500 Software Installation Verification protocol.



DataShare 500 Installation Verification Checklist

Company Name _____ Date _____

Analyst Name _____ Firmware Version _____

Analyzer Serial Number _____ Software Version _____

Protocol Step No.	Description	Yes/No or NA Initial/Date
5.1	Software launches successfully	
5.3	Software version number recorded	
5.4	File menu displays correctly	
5.5	Setup menu displays correctly	
5.6	Help menu displays correctly	
5.7.1	Example data displays on-screen correctly	
5.7.2	Print preview window displays correctly	
5.8	DataShare 500 exits successfully	

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

Validated By: _____ Date: _____



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4-20mA Output Operation Verification Protocol

1. **Purpose:** To verify the operation of 4-20mA outputs on a Sievers 500 RL TOC Analyzer.
2. **Scope:** This protocol applies to Sievers 500 RL TOC Analyzers with firmware version 2.11 or later. This protocol assumes familiarity with the functionality of 4-20mA output and supplemental tools, such as a digital multimeter.

Note: The accuracy of the multimeter can affect the results of this protocol. This protocol is an optional part of the Analyzer's operation qualification.

3. **Materials:**

- 3.1. *4-20mA Output Verification Worksheet* (see page 65)
- 3.2. Digital multimeter, or other device capable of measuring current from 0-20 mA
- 3.3. ESD wrist strap

4. **Definitions:** None

5. **Procedure:**

- 5.1. (Optional) If **DataGuard** is enabled, log in to the Analyzer with a UserID that has a User Level of Quality Assurance or Administrator and the appropriate Password. If **Password** protection is enabled, log in to the Analyzer with the UserID and Password.
- 5.2. Turn off power to the Analyzer.
- 5.3. Open the Analyzer front panel.
- 5.4. Take ESD precautions; put on the ESD wrist strap provided in the Analyzer's accessories kit, and attach the alligator clip to a metal component in the Analyzer.
- 5.5. Remove the electronics cover by loosening the two captive screws.
- 5.6. Connect wiring from one of the 4-20 mA outputs on TB 3 to the digital multimeter. For instructions on connecting wiring to the 4-20 mA outputs, consult the "Installation" chapter of the Analyzer's *Operation and Maintenance Manual*.
- 5.7. Close the Analyzer front panel as much as possible without pinching the multimeter wires. If necessary, you can completely close the Analyzer front panel.
- 5.8. Restore power to the Analyzer.
- 5.9. Press the **Menu** button, select the **Setup** tab, and press the **On-Line** button.
- 5.10. Select the **I/O** tab, and then push the **4-20mA Outputs** button.



-
- 5.11. Press the **Error/Standby Configuration** button. Make sure the values for each button are different. By default, the value for Error is 2.5 mA, the value for Standby is 1.0 mA, and the value for Warning is 2.5 mA.
 - 5.12. Depending on which 4-20 mA output you have wired, select output 1, 2, or 3 by pressing the appropriate button. Configure the output for TOC, and set the Max and Min values to encompass the expected range of your water system. Record the Max and Min values on the worksheet.

Note: To ensure accurate results, select Max and Min values that reflect an appropriate range of your water system. If you enter a range too great, for example, you may not meet the 3% acceptance criterion.

- 5.13. Press the **Back** button and then press the **Start Analysis** button.
- 5.14. The multimeter should read 1.0 mA (or the value you set for Standby), and it will continue to show this value until the first measurement is displayed.
- 5.15. After approximately 14 minutes, the Analyzer will display a TOC measurement and the multimeter will reflect the reading.
- 5.16. The current displayed by the multimeter can be confirmed as matching the Analyzer's measurement as follows:

$$\text{TOC (ppb) from 4-20 mA Output} = \left(\frac{\text{Current} - 4 \text{ mA}}{16 \text{ mA}} \right) (\text{Max ppb} - \text{Min ppb})$$

- 5.17. Calculate the % Error between the Analyzer TOC value and the value displayed by the multimeter as follows:

$$\% \text{ Error} = \frac{\text{TOC from 4 - 20 mA output} - \text{TOC Value from Analyzer}}{\text{TOC value from Analyzer}} \times 100$$

- 5.18. Acceptance criterion: the % Error should be $\pm 3\%$.



4-20 mA Output Operation Verification Worksheet

Company Name _____ Date _____

Analyst Name _____ Firmware Version _____

Analyzer Serial Number _____

Max value _____

Min value _____

Analyzer terminal block pins used: _____

Current displayed by multimeter in standby: _____

Current displayed by multimeter for measurement: _____

TOC value displayed by Analyzer _____

Value of 4-20mA current converted to TOC (ppb): _____

% Error _____

$$\text{TOC (ppb) from 4-20 mA Output} = \left(\frac{\text{Current} - 4 \text{ mA}}{16 \text{ mA}} \right) (\text{Max ppb} - \text{Min ppb})$$

$$\% \text{ Error} = \frac{\text{TOC from 4 - 20 mA Output} - \text{TOC Displayed by Analyzer}}{\text{TOC Value from Analyzer}} \times 100$$

Acceptance criterion: % Error \pm 3% Pass Fail

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

Validated By: _____ Date: _____



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Single-Point Calibration and Verification Protocol

1. **Purpose:** To calibrate and verify the calibration of a Sievers 500 RL TOC Analyzer.
2. **Scope:** This procedure applies to all Sievers 500 RL TOC Analyzers. Standards solutions should be purchased directly from GE Analytical Instruments. The analyst performing this protocol should be familiar with the terminology and operation of the Analyzer. The Analyzer must be equipped with a Super **iOS** or standard **iOS** to perform this protocol. The protocol assumes the Analyzer's conductivity feature is active. If the conductivity feature is not active, a conductivity standard will not be used and the fields on the worksheet pertaining to conductivity measurements will not be applicable.

The Analyzer is calibrated at the factory and should require re-calibration only once per year. When replacing items that affect analysis, such as the UV lamp, perform a verification of the calibration; only re-calibrate if verification indicates that a new calibration is necessary.

Note: Only a single-point calibration or a multi-point calibration needs to be performed. Do not perform both types of calibration.

3. **Materials:**
 - 3.1. Sievers 500 RL TOC Analyzer
 - 3.2. *Single-Point Calibration Worksheet* (see page 73)
 - 3.3. *Accuracy, Precision, and Verification Worksheet* (see page 75)
 - 3.4. Single-point calibration standards from GE Analytical Instruments, comprising of:
 - 2 vials of TOC Calibration Blank
 - 1 vial of 1.5 ppm TOC (as KHP)
 - 1 vial of 25 $\mu\text{S}/\text{cm}$ Conductivity Standard (as HCl) — optional, only if the conductivity feature is active
 - 3.5. Accuracy, Precision, and Verification standards set from GE Analytical Instruments, comprising of:
 - 1 vial of Verification Blank
 - 1 vial of 500 ppb C Accuracy/Precision and Verification Standard (as Sucrose)
 - 1 vial of 25 $\mu\text{S}/\text{cm}$ Conductivity Standard (as HCl) — Optional, only if the conductivity feature is active

Note: 1ppm = 1 mg C/L, 1ppb = 1 μg C/L

All standards should be warmed to room temperature prior to use.



- 3.6. Flush standards vial set of four TOC Calibration blank standards from GE Analytical Instruments — Optional, but recommended for running before, after, or before and after protocols run using the Super iOS.

4. Definitions:

- 4.1. DI — deionized
- 4.2. IC — inorganic carbon
- 4.3. TC — total carbon
- 4.4. TOC — total organic carbon
- 4.5. Vial Set — a standards set in a cartridge, for use with the Sievers Super iOS System

5. Procedure:

- 5.1. (Optional) If **DataGuard** is enabled, log in to the Analyzer with a UserID that has a User Level of Quality Assurance or Administrator and the appropriate Password. If **Password** protection is enabled, log in to the Analyzer with the UserID and Password.
- 5.2. If the Analyzer is taking measurements, press the **Stop Analysis** button.
- 5.3. Export the current system settings, in the event they need to be re-loaded or referred to in the future (**Maintenance** → **Advanced** → **Save System**). Make sure that the USB flash memory drive is attached to the Analyzer's USB port.
- 5.4. Press the **Back** button to display the **Maintenance** screen, and then push the **Cal/Ver/Validate** button.
- 5.5. Press the **Single Pt Cal** button.
- 5.6. If you have a Super iOS System:
 - 5.6.1. The **Select Rinse** screen appears. Select one of the following rinse options, and then press the **Next** button:
 - No Rinse
 - Before
 - After
 - Before and After
 - 5.6.2. If you have selected **No Rinse** or **After**, and there are vials in the Super iOS, remove them now. Press **Next** to continue. Wait for the Analyzer to drain each of the Super iOS vial chambers (about 2 minutes).
 - 5.6.3. If you have selected to run a rinse, the Analyzer will prompt you to do one of the following:
 - Insert the Super iOS Flush vial set into the Super iOS.



- Or, if using individual, press **Next** for additional instructions. Insert the individual vials in the Super **iOS**, and then press **No Set** to proceed.

5.6.4. Do one of the following:

- If you have a purchased vial set, insert the *Single-Point Calibration Standards* cartridge into the Super **iOS** System with the label facing away from the Analyzer, and then press the **Next** button. Proceed to Step **5.8**
- If you have purchased individual vials rather than a vial set in a cartridge, confirm the value shown on the Conductivity Standard label. Then, make sure the vials are inserted into the **iOS** System vial ports in the following order.

Port 1 = TOC Calibration Blank

Port 2 = TOC Calibration Blank

Port 3 = TOC Calibration Standard (1.50 ppm KHP)

Port 4 = Conductivity Standard

Press the **Next** button, and then press the **No Set** button.

*If the label of the Conductivity Standard shows a value of 25 $\mu\text{S}/\text{cm}$ HCl, (or your configuration does not measure for conductivity), press **Next** to continue. Proceed to Step 5.8.*

If the label on the Conductivity Standard shows a different value, press **Edit**, enter the value, press **Enter**, and then press **Next** to continue. Proceed to Step 5.8.

5.7. If you have a standard **iOS** System:

- 5.7.1. Open the door to the **iOS** System and wait 30 seconds for water to drain.
- 5.7.2. Insert the first TOC Calibration Blank into the **iOS** System and press the **Next** button.
- 5.7.3. When prompted, remove the TOC Calibration Blank from the **iOS** System, insert the second TOC Calibration Blank, and then press the **Next** button.
- 5.7.4. When prompted, remove the TOC Calibration Blank from the **iOS** System, insert the TOC Calibration Standard (1.50 ppm KHP), and then press the **Next** button.
- 5.7.5. When prompted, remove the TOC Calibration Standard (1.50 ppm KHP) from the **iOS** System. Confirm the value of the Conductivity Standard and insert the vial into the **iOS** System. If the label shows a value of 25 $\mu\text{S}/\text{cm}$ HCl, press **Next** to continue. If the label shows a different value, press **Edit**, enter the value, and then press **Enter**. Press **Next** to continue. If your configuration does not measure conductivity, you will not be prompted to enter a conductivity value and you can skip this step.

5.8. After the last standard has been analyzed, the Calibration Summary screen appears. Part 1 of the summary screen displays the data for the TOC standard. Part 2 of the summary displays the data for the conductivity standard. Record the data on the *Single-Point Calibration Worksheet*.

- 5.8.1. (Optional) If you have a printer, press the **Print** button and attach the printout to the *Single-Point Calibration Worksheet*.



-
- 5.9. The Analyzer indicates if the calibration *passed* or *failed*.
- 5.9.1. If the calibration passed, press the **Apply** button to accept the calibration. Proceed to Step 5.10 to verify the calibration.
- 5.9.2. If the calibration failed, press the **Cancel** button to reject the calibration. You may need to perform the calibration procedure again. However, first consult the chapter called "Troubleshooting" in the Analyzer's *Operation and Maintenance Manual* to determine if there is a problem with the Analyzer.

The summary screens show data collected for each of the vials, as well as several calculated values.

Exp is expected value. For **RW IC** (TOC Calibration Blank), this is the measured value for the TC channel, with the UV lamp off. For **1.50ppm TOC** (TOC Calibration Standard), this is the expected value for RW plus 1.5 ppm. For **25.00 S/cm tCond** (Conductivity Standard), this is the certified value of the standard, as shown on the vial label.

Diff is percent difference between the average and expected value.

Adj is the adjusted value, with the new calibration applied.

- 5.10. Press **Exit**.
- 5.11. Remove the calibration standards from the **iOS** System.
- 5.12. If you have a Super **iOS** system, and selected the **After** or **Before and After** option, the Analyzer will prompt you to insert the rinse cartridge or vials into the Super **iOS** system to continue the Rinse activity. Take out the rinse cartridge or vials when completed.
- 5.13. Press the **Acc/Prec/Ver** button.
- 5.14. If you have a Super **iOS** System:
- 5.14.1. The **Select Rinse** screen appears. Select one of the following rinse options, and then press the **Next** button :
- No Rinse
 - Before
 - After
 - Before and After
- 5.14.2. If you have selected **No Rinse** or **After**, and there are vials in the Super **iOS**, remove them now. Press **Next** to continue. Wait for the Analyzer to drain each of the Super **iOS** vial chambers (about 2 minutes).
- 5.14.3. If you have selected to run a rinse, the Analyzer will prompt you to do one of the following:
- Insert the Super **iOS** Flush vial set into the Super **iOS**.
 - Or, if using individual flush vials, press **Next** for additional instructions. Insert the individual vials in the Super **iOS**, and then press **No Set** to proceed.



5.14.4. Do one of the following:

- If you have a purchased vial set, insert the *Accuracy, Precision, and Verification* standards cartridge into the Super **iOS** System with the label facing away from the Analyzer and press **Next**.
- If you have purchased individual vials rather than a vial set in a cartridge, confirm the value shown on the Conductivity Standard label. Then, make sure the vials are inserted into the **iOS** System vial ports in the following order. Then, press the **Next** button, and then press the **No Set** button:

Port 1 = empty

Port 2 = Verification Blank

Port 3 = Accuracy/Precision and Verification Standard (500 ppb sucrose)

Port 4 = Conductivity Standard

*If the label of the Conductivity Standard shows a value of 25 $\mu\text{S}/\text{cm}$ HCl, (or your configuration does not measure for conductivity), press **Next** to continue.*

*If the label on the Conductivity Standard shows a different value, press **Edit**, enter the value, press **Enter**, and then press **Next** to continue.*

Go to step 5.16

5.15. If you have a standard **iOS** System:

5.15.1. Insert the Verification Blank into the **iOS** System, and then press **Next**.

5.15.2. When prompted, remove the Verification Blank from the **iOS** System, insert the Accuracy/Precision and Verification Standard, and then press **Next**.

5.15.3. When prompted, remove the Accuracy/Precision and Verification Standard from the **iOS** System, insert the Conductivity Standard, and then press **Next**.

Confirm the value of the Conductivity Standard and insert the vial into the **iOS** System. If the label shows a value of 25 $\mu\text{S}/\text{cm}$ HCl, press **Next** to continue. If the label shows a different value, press **Edit**, enter the value, press **Enter**, and then press **Next**. If your configuration does not measure conductivity, you will not be prompted to enter a conductivity value and you can skip this step.

5.16. After the last standard has been analyzed, the Verification Summary screen is displayed. Part 1 of the summary screen displays the data for the TOC standard. Part 2 of the summary displays the data for the conductivity standard. Record the data on the *Accuracy, Precision, and Verification Worksheet*.

5.16.1. (Optional) If you have a printer, press the **Print** button and attach the printout to the *Accuracy, Precision, and Verification Worksheet*.

Note: If necessary for your operating procedure, retain the data and record for the Accuracy, Precision, and Verification Protocol and Worksheet is VSP Volume II.



- 5.17. The Analyzer calibration is verified based on the accuracy data. Acceptance criteria are as follows:

TOC Precision: RSD of last three measurements of 500 ppb standard $\leq 3\%$

Conductivity Precision: RSD of last three compensated conductivity measurements on the 25 $\mu\text{S}/\text{cm}$ standard $\leq 2\%$

TOC Accuracy: % Difference $\leq \pm 7\%$

Conductivity Accuracy: % Difference $\pm 2\%$

Standard deviation and relative standard deviation are calculated as follows:

$$\text{Standard Deviation} = \sqrt{\frac{n \sum x^2 - (\sum x)^2}{n(n-1)}}$$

Σ = Sum of
 x = Each Result
 n = Number of Measurements in a set
(# of repetitions - # of rejections)

$$\text{Relative Standard Deviation (RSD)} = \frac{\text{Standard Deviation}}{\text{Measured TOC Concentration}} \times 100$$

The percent different is calculated as follows:

$$\% \text{ Diff} = \frac{\text{Measured Concentration} - \text{Expected Standard Concentration}}{\text{Expected Standard Concentration}} \times 100\%$$

- 5.18. Press **Exit**.
- 5.19. If you have a Super **iOS** system, and selected the **After** or **Before and After** option, the Analyzer will prompt you to remove the standards, and to insert the rinse cartridge or vials into the Super **iOS** system to continue the Rinse activity. Take out the rinse cartridge or vials when completed.
- 5.20. If you have a standard **iOS** System, remove the standards and slide the **iOS** door closed.



Single-Point Calibration Worksheet

Company Name _____ Date _____
 Analyst Name _____ Firmware Version _____
 Analyzer Serial Number _____ Standards Expiration Date _____
 Standards Set Lot No. (optional) _____

Rep	RW IC (ppb)	RW2 TOC (ppb)	1.50 ppm TOC	25.00 µS/cm tCond
1	_____	_____	_____	_____
2	_____	_____	_____	_____
3	_____	_____	_____	_____
Avg	_____	_____	_____	_____
Exp	_____	_____	_____	_____
Diff	_____	_____	_____	_____
Adj	_____	_____	_____	_____

Calibration Results: Passed Failed

Calibration Action: Applied Canceled

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

Validated By: _____ Date: _____



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Accuracy, Precision, and Verification Worksheet

Company Name _____ Date _____
 Analyst Name _____ Firmware Version _____
 Analyzer Serial Number _____ Standards Expiration Date _____
 Standards Set Lot No. (optional) _____

Rep	RW TOC (ppb)	500 ppb TOC	25.00 μ S/cm tCond
1	_____	_____	_____
2	_____	_____	_____
3	_____	_____	_____
Avg	_____	_____	_____

	RW	TOC	Conductivity		
Avg	_____	_____	_____		
Adj Standard Concentration	_____	N/A	N/A		
SD	N/A	_____	_____		
RSD	N/A	_____	_____	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Accuracy	N/A	_____	_____	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

Acceptance criteria:

- TOC Precision: RSD of last three measurements of 500 ppb standard \leq 3%
- Conductivity Precision: RSD of last three compensated conductivity measurements on 25 μ S/cm standard \leq 2%
- TOC Accuracy: % Difference \leq \pm 7%
- Conductivity Accuracy: % Difference \leq \pm 2%

Performed By: _____ Date: _____
 Reviewed By: _____ Date: _____
 Validated By: _____ Date: _____



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Multi-Point Calibration and Verification Protocol

1. **Purpose:** To calibrate and verify the calibration of a Sievers 500 RL TOC Analyzer.
2. **Scope:** This procedure applies to all Sievers 500 RL TOC Analyzers. Standards solutions should be purchased directly from GE Analytical Instruments. The analyst performing this protocol should be familiar with the terminology and operation of the Analyzer. The protocol assumes the Analyzer's conductivity feature is active. If the conductivity feature is not active, a conductivity standard will not be used and the fields on the worksheet pertaining to conductivity measurements will not be applicable.

The Analyzer is calibrated at the factory and should require re-calibration only once per year. When replacing items that affect analysis, such as the UV lamp, perform a verification of the calibration; only re-calibrate if verification indicates that a new calibration is necessary.

Note: Only a single-point calibration **or** a multi-point calibration needs to be performed. Do not perform both types of calibration.

3. **Materials:**
 - 3.1. Sievers 500 RL TOC Analyzer
 - 3.2. *Multi-Point Calibration Worksheet* (see page 85)
 - 3.3. *Accuracy, Precision, and Verification Worksheet* (see page 87)
 - 3.4. Multi-point calibration standards (*Calibration Set A* and *Calibration Set B*) from GE Analytical Instruments, comprising of:
 - 3 vials of TOC Calibration Blank
 - 1 vial of 1.5 ppm* TOC (as KHP)
 - 1 vial of 25 $\mu\text{S}/\text{cm}$ Conductivity Standard (as HCl) — optional, only if the conductivity feature is active
 - 1 vial of 1.0 ppm TOC (as KHP)
 - 1 vial of 500 ppb TOC (as KHP)
 - 3.5. Accuracy, Precision, and Verification standards set from GE Analytical Instruments, comprising of:
 - 1 vial of Verification Blank
 - 1 vial of 500 ppb C Accuracy/Precision and Verification Standard (as Sucrose)
 - 1 vial of 25 $\mu\text{S}/\text{cm}$ Conductivity Standard (as HCl) — optional, only if the conductivity feature is active
- 1ppm = 1 mg C/L, 1ppb = 1 μg C/L



All standards should be warmed to room temperature prior to use.

- 3.6. Flush standards vial set of four TOC Calibration blank standards from GE Analytical Instruments — Optional, but recommended for running before, after, or before and after protocols run using the Super iOS.

4. Definitions:

- 4.1. DI — deionized
- 4.2. IC — inorganic carbon
- 4.3. TC — total carbon
- 4.4. TOC — total organic carbon
- 4.5. Vial Set — a standards set in a cartridge, for use with the Sievers Super iOS System

5. Procedure:

- 5.1. (Optional) If **DataGuard** is enabled, log in to the Analyzer with a UserID that has a User Level of Quality Assurance or Administrator and the appropriate Password. If **Password** protection is enabled, log in to the Analyzer with the UserID and Password.
- 5.2. If the Analyzer is taking measurements, press the **Stop Analysis** button.
- 5.3. Export the current system settings, in the event they need to be re-loaded or referred to in the future (**Maintenance** → **Advanced** → **Save System**). Make sure that the USB flash memory drive is attached to the Analyzer's USB port.
- 5.4. Press the **Back** button to display the **Maintenance** screen, and then push the **Cal/Ver/Validate** button.
- 5.5. Press the **Multi Pt Cal** button.
- 5.6. If you have a Super iOS System:
 - 5.6.1. The **Select Rinse** screen appears. Select one of the following rinse options, and then press the **Next** button:
 - No Rinse
 - Before
 - After
 - Before and After
 - 5.6.2. If you have selected **No Rinse** or **After**, and there are vials in the Super iOS, remove them now. Press **Next** to continue. Wait for the Analyzer to drain each of the Super iOS vial chambers (about 2 minutes).



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- 5.6.3. If you have selected to run a rinse, the Analyzer will prompt you to do one of the following:
- Insert the Super **iOS** Flush vial set into the Super **iOS**.
 - Or, if using individual flush vials, press **Next** for additional instructions. Insert the individual vials in the Super **iOS**, and then press **No Set** to proceed.
- 5.6.4. Do one of the following:
- If you have purchased vial sets, insert the *Calibration Set A* cartridge into the Super **iOS** System with the label facing away from the Analyzer and press **Next**.
When prompted by the Analyzer, remove the first cartridge and insert the cartridge containing *Calibration Set B* into the Super **iOS** System with the label facing away from the Analyzer. Press the **Next** button.
 - If you have purchased individual vials rather than a vial set in a cartridge, confirm the value shown on the Conductivity Standard label. Then, make sure the vials are inserted into the **iOS** System vial ports in the following order. Then, press the **Next** button, and then press the **No Set** button:
Port 1 = TOC Calibration Blank
Port 2 = TOC Calibration Blank
Port 3 = TOC Calibration Standard (1.50 ppm KHP)
Port 4 = Conductivity Standard

*If the label of the Conductivity Standard shows a value of 25 $\mu\text{S}/\text{cm}$ HCl, (or your configuration does not measure for conductivity), press **Next** to continue.*

*If the label on the Conductivity Standard shows a different value, press **Edit**, enter the value, press **Enter**, and then press **Next** to continue.*

When prompted by the Analyzer, remove the first four vials and insert the next three vials (Port 1 should be empty) into the Super **iOS** System vial ports in the following order, and then press the **Next** button.

Port 1 = empty
Port 2 = TOC Calibration Blank
Port 3 = TOC Calibration Standard (1.0 ppm KHP)
Port 4 = TOC Calibration Standard (500 ppb KHP)
- 5.6.5. Press the **Next** button, and then press the **No Set** button.
- 5.6.6. Proceed to Step 5.8.
- 5.7. If you have a standard **iOS** System:
- 5.7.1. Open the door to the **iOS** System and wait 30 seconds for water to drain.
- 5.7.2. Insert the first TOC Calibration Blank into the **iOS** System, and then press **Next**.



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- 5.7.3. When prompted, remove the TOC Calibration Blank from the **iOS** System, insert the second TOC Calibration Blank, and then press **Next**.
 - 5.7.4. When prompted, remove the TOC Calibration Blank from the **iOS** System, insert the TOC Calibration Standard (1.50 ppm KHP), and then press **Next**.
 - 5.7.5. When prompted, remove the TOC Calibration Standard (1.50 ppm KHP) from the **iOS** System. Confirm the value of the Conductivity Standard and insert the vial into the **iOS** System. If the label shows a value of 25 $\mu\text{S}/\text{cm}$ HCl, press **Next** to continue. If the label shows a different value, press **Edit**, enter the value, and then press **Enter**. Press **Next** to continue. If your configuration does not measure conductivity, you will not be prompted to enter a conductivity value and you can skip this step.
 - 5.7.6. When prompted, remove the Conductivity Standard from the **iOS** System, insert the third TOC Calibration Blank, and then press **Next**.
 - 5.7.7. When prompted, remove the TOC Calibration Blank from the **iOS** System, insert the TOC Calibration Standard (1.0 ppm KHP), and then press **Next**.
 - 5.7.8. When prompted, remove the TOC Calibration Standard (1.0 ppm KHP) from the **iOS** System, insert the TOC Calibration Standard (500 ppb KHP), and then press **Next**.
 - 5.8. After the last standard has been analyzed, the Calibration Summary screen appears. Part 1 of the summary screen displays the data for the TOC standard. Part 2 of the summary displays the data for the conductivity standard. Part 3 of the summary displays data for the blank, 1.0 ppm standard, and 500 ppb standard. Record the data on the *Multi-Point Calibration Worksheet*.
 - 5.8.1. (Optional) If you have a printer, press the **Print** button and attach the printout to the *Multi-Point Calibration Worksheet*.
 - 5.9. The Analyzer indicates if the calibration passed.
 - 5.9.1. If the calibration passed, press the **Apply** button to accept the calibration and continue.
 - 5.9.2. If the calibration failed, press the **Cancel** button to reject the calibration. You may need to perform the calibration procedure again. However, first consult the chapter called "Troubleshooting" in the Analyzer's *Operation and Maintenance Manual* to determine if there is a problem with the Analyzer.

The summary screens show data collected for each of the vials, as well as several calculated values.

Exp is expected value. For **RW IC** (TOC Calibration Blank), this is the measured value for the TC channel, with the UV lamp off. For **1.50ppm TOC** (TOC Calibration Standard), this is the expected value for RW2 plus 1.5 ppm. For **1.00ppm TOC** and **500 ppb TOC** (TOC Calibration Standards), this is the expected value for RW3 plus 1.00 ppm or 500 ppb, respectively. For **25.00 S/cm tCond** (Conductivity Standard), this is the certified value of the standard, as shown on the vial label.

Diff is percent difference between the average and expected value.

Adj is the adjusted value, with the new calibration applied.



-
- 5.10. Press **Exit**.
- 5.11. If you have a Super **iOS** system, and selected the **After** or **Before and After** option, the Analyzer will prompt you to remove the standards, and to insert the rinse cartridge or vials into the Super **iOS** system to continue the Rinse activity. Take out the rinse cartridge or vials when completed.
- 5.12. If you have a standard **iOS** System, remove the standards and slide the **iOS** door closed.
- 5.13. Press the **Acc/Prec/Ver** button.
- 5.14. If you have a Super **iOS** System:
- 5.14.1. The **Select Rinse** screen appears. Select one of the following rinse options, and then press the **Next** button:
- No Rinse
 - Before
 - After
 - Before and After
- 5.14.2. If you have selected **No Rinse** or **After**, and there are vials in the Super **iOS**, remove them now. Press **Next** to continue. Wait for the Analyzer to drain each of the Super **iOS** vial chambers (about 2 minutes).
- 5.14.3. If you have selected to run a rinse, the Analyzer will prompt you to do one of the following:
- Insert the Super **iOS** Flush vial set into the Super **iOS**.
 - Or, if using individual flush vials, press **Next** for additional instructions. Insert the individual vials in the Super **iOS**, and then press **No Set** to proceed.
- 5.14.4. Do one of the following:
- If you have purchased vial sets, insert the *Accuracy Precision Verification standards* cartridge into the Super **iOS** System with the label facing away from the Analyzer and press **Next**.
 - If you have purchased individual vials rather than a vial set in a cartridge, confirm the value shown on the Conductivity Standard label. Then, make sure the vials are inserted into the **iOS** System vial ports in the following order. Then, press the **Next** button, and then press the **No Set** button:
Port 1 = empty
Port 2 = Verification Blank
Port 3 = Accuracy/Precision and Verification Standard (500 ppb sucrose)
Port 4 = Conductivity Standard
- If the label of the Conductivity Standard shows a value of 25 $\mu\text{S}/\text{cm HCl}$, (or your configuration does not measure for conductivity), press **Next** to continue.*



If the label on the Conductivity Standard shows a different value, press **Edit**, enter the value, press **Enter**, and then press **Next** to continue.

- 5.15. If you have a standard **iOS** System:
- 5.15.1. Insert the Verification Blank into the **iOS** System, and then press **Next**.
 - 5.15.2. When prompted, remove the Verification Blank from the **iOS** System, insert the Accuracy/Precision and Verification Standard, and then press **Next**.
 - 5.15.3. When prompted, remove the Accuracy/Precision and Verification Standard from the **iOS** System, insert the Conductivity Standard, and then press **Next**.
Confirm the value of the Conductivity Standard and insert the vial into the **iOS** System. If the label shows a value of 25 $\mu\text{S}/\text{cm}$ HCl, press **Next** to continue. If the label shows a different value, press **Edit**, enter the value, press **Enter**, and then press **Next**. If your configuration does not measure conductivity, you will not be prompted to enter a conductivity value and you can skip this step.
- 5.16. After the last standard has been analyzed, the Verification Summary screen appears. Part 1 of the summary screen displays the data for the TOC standard. Part 2 of the summary displays the data for the conductivity standard. Record the data on the *Multi-Point Calibration Worksheet*.
- 5.16.1. (Optional) If you have a printer, press the **Print** button and attach the printout to the *Multi-Point Calibration Worksheet*.

Note: If necessary for your operating procedure, retain the data and record for the Accuracy, Precision, and Verification Protocol and Worksheet is VSP Volume II.

- 5.17. The Analyzer calibration is verified based on the accuracy data. Acceptance criteria are as follows:
- TOC Precision: RSD of last three measurements of 500 ppb standard $\leq 3\%$
- Conductivity Precision: RSD of last three compensated conductivity measurements on the 25 $\mu\text{S}/\text{cm}$ standard $\leq 2\%$
- TOC Accuracy: % Difference $\leq \pm 7\%$
 - Conductivity Accuracy: % Difference $\leq \pm 2\%$

Standard deviation and relative standard deviation are calculated as follows:

$$\text{Standard Deviation} = \sqrt{\frac{n \sum x^2 - (\sum x)^2}{n(n-1)}}$$

Σ = Sum of
 x = Each Result
 n = Number of Measurements in a set
(# of repetitions - # of rejections)



$$\text{Relative Standard Deviation (RSD)} = \frac{\text{Standard Deviation}}{\text{Measured TOC Concentration}} \times 100$$

The percent different is calculated as follows:

$$\% \text{ Diff} = \frac{\text{Measured Concentration} - \text{Expected Standard Concentration}}{\text{Expected Standard Concentration}} \times 100\%$$

- 5.18. If you have a Super **iOS** system, and selected the **After** or **Before and After** option, the Analyzer will prompt you to remove the standards, and to insert the rinse cartridge or vials into the Super **iOS** system to continue the Rinse activity. Take out the rinse cartridge or vials when completed.
- 5.19. If you have a standard **iOS** System, remove the standards and slide the **iOS** door closed.



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Multi-Point Calibration Worksheet

Company Name _____

Date _____

Analyst Name _____

Firmware Version _____

Analyzer Serial Number _____

Standards Expiration Date _____

Standards Set A Lot No. (optional) _____

Standards Set B Lot No. (optional) _____

Rep	RW IC (ppb)	RW2 TOC (ppb)	1.50 ppm TOC	25.00 μ S/cm tCond
1	_____	_____	_____	_____
2	_____	_____	_____	_____
3	_____	_____	_____	_____
Avg	_____	_____	_____	_____
Exp	_____	_____	_____	_____
Diff	_____	_____	_____	_____
Adj	_____	_____	_____	_____

Rep	RW3 TOC (ppb)	1.00 ppm TOC	500 ppb TOC
1	_____	_____	_____
2	_____	_____	_____
3	_____	_____	_____
Avg	_____	_____	_____
Exp	_____	_____	_____
Diff	_____	_____	_____
Adj	_____	_____	_____



Calibration Results: Passed Failed

Calibration Action: Applied Canceled

Performed By: _____

Date: _____

Reviewed By: _____

Date: _____

Validated By: _____

Date: _____



Accuracy, Precision, and Verification Worksheet

Company Name _____ Date _____
 Analyst Name _____ Firmware Version _____
 Analyzer Serial Number _____ Standards Expiration Date _____
 Standards Set Lot No. (optional) _____

Rep	RW TOC (ppb)	500 ppb TOC	25.00 μ S/cm tCond
1	_____	_____	_____
2	_____	_____	_____
3	_____	_____	_____
Avg	_____	_____	_____

	RW	TOC	Conductivity		
Avg	_____	_____	_____		
Adj TOC Standard Concentration	_____	_____	_____		
SD	<u>N/A</u>	_____	_____		
RSD	<u>N/A</u>	_____	_____	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail
Accuracy	<u>N/A</u>	_____	_____	<input type="checkbox"/> Pass	<input type="checkbox"/> Fail

Acceptance criteria:

- TOC Precision: RSD of last three measurements of 500 ppb standard $\leq 3\%$
- Conductivity Precision: RSD of last three compensated conductivity measurements on 25 μ S/cm standard $\leq 2\%$
- TOC Accuracy: % Difference $\leq \pm 7\%$
- Conductivity Accuracy: % Difference $\leq \pm 2\%$

Performed By: _____ Date: _____
 Reviewed By: _____ Date: _____
 Validated By: _____ Date: _____



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System Suitability (Response Efficiency) Verification Protocol

1. **Purpose:** To perform a system suitability verification test on the Sievers 500 RL TOC Analyzer.
2. **Scope:** This procedure applies to all Sievers 500 RL TOC Analyzers. Standard solutions should be purchased directly from GE Analytical Instruments. This protocol uses benzoquinone as the suitability compound and sucrose as the standard. The Analyzer must be equipped with a Super **iOS** or standard **iOS** to perform this protocol.
3. **Materials:**
 - 3.1. Sievers 500 RL TOC Analyzer
 - 3.2. *System Suitability Worksheet* (see page 93)
 - 3.3. System suitability standards set from GE Analytical Instruments, comprising of:
 - 1 vial of Reagent Water Blank — Rw
 - 1 vial of 500 ppb TOC (as USP Sucrose) — Rs
 - 1 vial of 500 ppb TOC (as USP 1,4-Benzoquinone) — Rss

Note: 1ppm = 1 mg C/L, 1ppb = 1 µg C/L

All standards should be warmed to room temperature prior to use.

 - 3.4. Flush standards vial set of four TOC Calibration blank standards from GE Analytical Instruments — Optional, but recommended for running before, after, or before and after protocols run using the Super **iOS**.
4. **Definitions:**
 - 4.1. Vial Set — a standards set in a cartridge, for use with the Sievers Super **iOS** System
5. **Procedure:**
 - 5.1. (Optional) If **DataGuard** is enabled, log in to the Analyzer with a UserID that has a User Level of Quality Assurance or Administrator and the appropriate Password. If **Password** protection is enabled, log in to the Analyzer with the UserID and Password.
 - 5.2. If the Analyzer is taking measurements, press the **Stop Analysis** button.
 - 5.3. Press the **Menu** button, select the **Maintenance** tab, press the **Cal/Ver/Validate** button, and press the **Suitability** button.



-
- 5.4. If you have a Super **iOS** System:
- 5.4.1. The **Select Rinse** screen appears. Select one of the following rinse options, and then press the Next button:
- No Rinse
 - Before
 - After
 - Before and After
- 5.4.2. If you have selected **No Rinse** or **After**, and there are vials in the Super **iOS**, remove them now. Press **Next** to continue. Wait for the Analyzer to drain each of the Super **iOS** vial chambers (about 2 minutes).
- 5.4.3. If you have selected to run a rinse, the Analyzer will prompt you to do one of the following:
- Insert the Super **iOS** Flush vial set into the Super **iOS**.
 - Or, if using individual flush vials, press **Next** for additional instructions. Insert the individual vials in the Super **iOS**, and then press **No Set** to proceed.
- 5.4.4. Do one of the following:
- If you have a purchased vial set, insert the *System Suitability* standards cartridge into the Super **iOS** System with the label facing away from the Analyzer and press **Next**.
 - If you have purchased individual vials rather than a vial set in a cartridge, confirm the value shown on the Conductivity Standard label. Then, make sure the vials are inserted into the **iOS** System vial ports in the following order. Then, press the **Next** button, and then press the **No Set** button:
Port 1 = RW Reagent Water Control
Port 2 = Rs Standard Solution
Port 3 = Rss System Suitability Solution
Port 4 = Rinse Water
- 5.4.5. Proceed to Step 5.6.
- 5.5. If you have a standard **iOS** System:
- 5.5.1. Open the door to the **iOS** System and wait 30 seconds for water to drain.
- 5.5.2. Insert the Reagent Water (Rw) into the **iOS** System, and then press **Next**.
- 5.5.3. When prompted, remove the Reagent Water (Rw) from the **iOS** System, insert the 500 ppb Sucrose Standard (Rs), and then press **Next**.
- 5.5.4. When prompted, remove the 500 ppb Sucrose Standard (Rs) from the **iOS** System, insert the 500 ppb Benzoquinone Standard (Rss), and then press **Next**.
- 5.5.5. When prompted, remove the 500 ppb Benzoquinone Standard (Rss) from the **iOS** System, insert the Rinse Water standard, and then press **Next**.



- 5.6. After the last standard has been analyzed, the System Suitability summary screen appears. The Analyzer indicates if the system suitability passed or failed based on the following criteria:

Acceptance criteria for USP System Suitability is response efficiency between 85% and 115%.

Response efficiency is calculated as follows:

$$RE = \frac{(R_{ss} - R_w)}{(R_s - R_w)} \times 100$$

Response Limit is calculated as follows:

$$\text{Response Limit} = R_s - R_w$$

- 5.7. Complete the *System Suitability Worksheet* based on the data displayed on-screen.
- 5.7.1. Record the Average TOC of the Reagent Water (R_w).
 - 5.7.2. Record the Average TOC of the 500 ppb Sucrose Standard (R_s).
 - 5.7.3. Record the Average TOC of the 500 ppb Benzoquinone Standard (R_{ss}).
 - 5.7.4. Record the Response Efficiency.
 - 5.7.5. Record the Response Limit.
 - 5.7.6. Check the Pass or Fail check box, based on the results.
 - 5.7.7. Check either the Apply or Cancel check box.
- 5.8. Click the **Apply** button if you want the new data to be saved as the Analyzer's response limit.
- If you accept the Response Limit, this new value determines when to trigger the Analyzer's Response Limit alarm, when activated (see "Setting Alarm Values" in the Analyzer's *Operation and Maintenance Manual*). Press the **Yes** button to confirm that you want to accept the new value.
- 5.9. Press the **Exit** button.
- 5.10. If you have a Super **iOS** system, and selected the **After** or **Before and After** option, the Analyzer will prompt you to remove the standards, and to insert the rinse cartridge or vials into the Super **iOS** system to continue the Rinse activity. Take out the rinse cartridge or vials when completed.
- 5.11. If you have a standard **iOS** System, remove the standards and slide the **iOS** door closed.



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System Suitability Worksheet

Company Name _____ Date _____
 Analyst Name _____ Firmware Version _____
 Analyzer Serial Number _____ Standards Expiration Date _____
 Standards Set Lot No. (optional) _____

Average TOC of Reagent Water (Rw) _____
 Average TOC of 500 ppb Sucrose Standard (Rs) _____
 Average TOC of 500 ppb Benzoquinone Standard (Rss) _____
 Response Efficiency _____
 Response Limit _____

$$\text{Response Efficiency} = \frac{(R_{ss} - R_w)}{(R_s - R_w)} \times 100$$

$$\text{Response Limit} = R_s - R_w$$

Acceptance criteria for USP System Suitability is response efficiency between 85% and 115%

Pass Fail

Indicate whether the response efficiency results were applied or canceled:

Apply Cancel

Performed By: _____ Date: _____
 Reviewed By: _____ Date: _____
 Validated By: _____ Date: _____



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JP Protocol

- 1. Purpose:** To verify that the Sievers 500 Series TOC Analyzer meets the testing requirements outlined by the Japanese Pharmacopeia (JP) monographs; JP <2.59> Total Organic Carbon (TOC) for Water Injection and Purified Water and JP <2.51> Conductivity (COND).

Note: Before you begin this protocol, ensure that you have selected the appropriate Pharmacopeia setting. Refer to the *500 RL TOC Analyzer Operations and Maintenance Manual*. To run this protocol for JP TOC *only*, you must first select the **JP TOC** button on the **Pharmacopeia** screen (**Menu > Maintenance > Advanced > Advanced Setup > Pharmacopeia**).

To also run this protocol for JP Conductivity, select the **JP Cond** button. The **JP Cond** button will set up the Analyzer for both JP TOC and JP Conductivity. To run the protocol for JP Conductivity, you must also ensure that the temperature of the conductivity cell inside the instrument is less than 30°.

- 2. Scope:** This procedure applies to all Sievers 500 TOC Analyzers. This protocol uses Sodium Dodecyl Benzene Sulfonate as the standard. Potassium Chloride is also used as a standard when verifying conductivity. TOC Test Standards solutions should be purchased from GE Analytical Instruments. The Conductivity Standards **MUST** be prepared by the customer onsite. The analyst performing this protocol should be familiar with the terminology and operation of the Analyzer. This protocol should require approximately 1-1/2 to 2 hours to perform.

- 3. Materials:**

- 3.1. Sievers 500 Series TOC Analyzer
- 3.2. *JP Protocol Worksheet* (page 101)
- 3.3. One of the following JP Protocol standards sets, based on the pharmacopeia setting of the Analyzer:
 - 3.3.1. JP Protocol for TOC Test Standards set from GE Analytical Instruments, comprising of:
 - 1 empty vial (for alignment)
 - 1 vial of Reagent Water Blank
 - 1 vial of 500 ppb TOC, as Sodium Dodecyl Benzene Sulfonate (SDBS)



- 3.3.2. JP Protocol for TOC Test Standards set from GE Analytical Instruments, PLUS a Conductivity Standard prepared by customer.

JP Protocol for TOC Test Standards set from GE Analytical Instruments, comprising of:

- 1 empty vial (for alignment)
- 1 vial of Reagent Water Blank
- 1 vial of 500 ppb TOC, as SDBS

Plus, Conductivity Standard prepared by customer onsite:

- 1 vial of 29.4 $\mu\text{S}/\text{cm}$ (0.2 mM) Potassium Chloride (KCl)

- 3.4. Flush standards vial set of four TOC Calibration blank standards from GE Analytical Instruments – Optional, but recommended for running before, after, or before and after protocols run using the **Super iOS**.

Note: All standards should be warmed to room temperature prior to use.

4. Definitions:

- 4.1. TOC – Total organic carbon
- 4.2. DI – Deionized
- 4.3. IC– Inorganic Carbon
- 4.4. JP Protocol – This protocol is designed to meet the requirements of the Japanese Pharmacopeia (JP) monograph JP <2.59> Total Organic Carbon (TOC) for Water Injection only, or the Japanese Pharmacopeia (JP) monographs JP <2.59> Total Organic Carbon (TOC) for Water Injection and Purified Water and JP <2.51> Conductivity (COND).

The Analyzer will run the protocol based on the Pharmacopeia setting you have selected. To run the protocol for JP Conductivity, you must also ensure that the temperature of the conductivity cell inside the instrument is less than 30° and prepare the Conductivity Standard onsite. Refer to the *500 RL TOC Analyzer Operations and Maintenance Manual* for more information on selecting the appropriate Pharmacopeia settings.

- 4.5. Vial Set – A standards set in a cartridge for use with the Sievers **Super iOS** system

5. Procedure:

- 5.1. (Optional) If **DataGuard** is enabled, log in to the Analyzer with a UserID that has a User Level of Quality Assurance or Administrator and the appropriate Password. If **Password** protection is enabled, log in to the Analyzer with the UserID and Password.



- 5.2. If the Analyzer is taking measurements, stop analysis.
- 5.3. Press the **Menu** button, select the **Maintenance** tab, press the **Cal/Ver/Validate** button, and then press the **JP Protocol** button.
- 5.4. If you have a **Super IOS** system:
- 5.4.1. The **Select Rinse** screen appears. Select one of the following rinse options, and then press the **Next** button:
- No Rinse
 - Before
 - After
 - Before and After
- 5.4.2. If you have selected **No Rinse** or **After**, and there are vials in the Super **iOS**, remove them now. Press **Next** to continue. Wait for the Analyzer to drain each of the Super **iOS** vial chambers (about 2 minutes).
- 5.4.3. If you have selected to run a rinse, the Analyzer will prompt you to do one of the following:
- Insert the Super **iOS** Flush vial set into the Super **iOS**. Press **Next** to continue.
- Or, if using individual flush vials, press **Next** for additional instructions. Insert the individual vials in the Super **iOS**, and then press **No Set** to proceed.
- 5.4.4. Do one of the following:
- If you have a purchased vial set, insert the JP Protocol TOC Test standards cartridge into the Super **iOS** System with the label facing away from the Analyzer and press **Next**.

Note: To perform the JP TOC and Conductivity Protocol, you MUST purchase the JP TOC Test Standards in a bag. There is no Super iOS Cartridge with a Conductivity vial available.

Insert the individual vials into the Super iOS system in the following order:

- Port 1 = Leave empty
- Port 2 = Reagent Water (Rw) Blank Standard
- Port 3 = SDBS Standard
- Port 4 = KCL Standard (Optional, only if the pharmacopeia is set to include JP TOC and Conductivity. This standard MUST be prepared by the customer onsite.)

Press the **Next** button, and then press the **No Set** button.



Note: Open the cartridge or vials bag and avoid touching the septa to protect against introducing foreign particles.

5.4.5. If you have a standard **iOS** system:

Slide the **iOS** system door open, and then wait for the water to drain (about 30 seconds).

Open the vials bag and avoid touching the septa to protect against introducing foreign particles.

Note: The Conductivity Standard will NOT be in the bag. It must be prepared onsite.

Insert the Reagent Water (RW) standard into the **iOS** System, and then press **Next**.

When prompted by the Analyzer, remove the RW standard and insert the SDBS standard into the **iOS** System, and press **Next**.

(Optional, only if the pharmacopeia is set to include JP TOC *and* Conductivity) Remove the SDBS standard, and insert the KCl standard into the **iOS** system, and press **Next**.

When the measurements are completed, remove the vial from the **iOS** System, and slide the door closed.

5.5. After the last standard has been analyzed, the JP Protocol screen appears. The Analyzer indicates whether the JP TOC protocol passed¹ or failed based on the following criteria:

TOC Blank Average \leq 250 ppb

Blank-Corrected Average \geq 450 ppb

where,

SDBS Average - TOC Blank Average = Blank-Corrected Average

The Analyzer will also report separately (**only** if JP Conductivity pharmacopeia is active) whether the JP TOC and Conductivity Protocol passed or failed based on the following criteria:

KCl is $\leq \pm$ 5%

RSD < 2%

Sample temperature is between 15°C to 30°

5.6. Complete the *JP Protocol Worksheet* with the pass or fail information.

5.7. Press the **Exit** button.

¹ The Pass/Fail test uses rounded values.



- 5.8. If you have a Super **iOS** system, and selected the **After** or the **Before and After** option, the Analyzer will prompt you to remove the standards, and to insert the rinse cartridge or vials into the Super **iOS** system to continue the Rinse activity. Take out the rinse cartridge or vials when completed.
- 5.9. If you have a standard iOS System, remove the standards and slide the **iOS** door closed.



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JP Protocol Worksheet

Company Name _____ Date _____
 Analyst Name _____ Firmware Version _____
 Analyzer Serial Number _____ Standards Expiration Date _____
 Standards Set Lot No. _____

JP Protocol

SDBS Average – TOC Blank Average = SDBS Blank-Corrected Average

TOC Blank Average _____
 SDBS Average _____
 SDBS Blank-Corrected Average _____

Acceptance Criteria for JP Protocol TOC (Only):

- TOC Blank Average \leq 250 ppb
- Blank-Corrected Average \geq 450 ppb

Pass Fail

JP Conductivity

Average Temperature-Corrected Conductivity of 29.4 μ S/cm _____
 Temperature _____
 RSD _____
 Difference _____

Acceptance Criteria for JP Protocol TOC and Conductivity:

- TOC Blank Average \leq 250 ppb
- Blank-Corrected Average \geq 450 ppb
- Conductivity Difference \pm 5%
- RSD \leq 2%
- Sample temperature is between 15°C to 30°C

Pass Fail

Performed By: _____ Date: _____
 Reviewed By: _____ Date: _____
 Validated By: _____ Date: _____



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