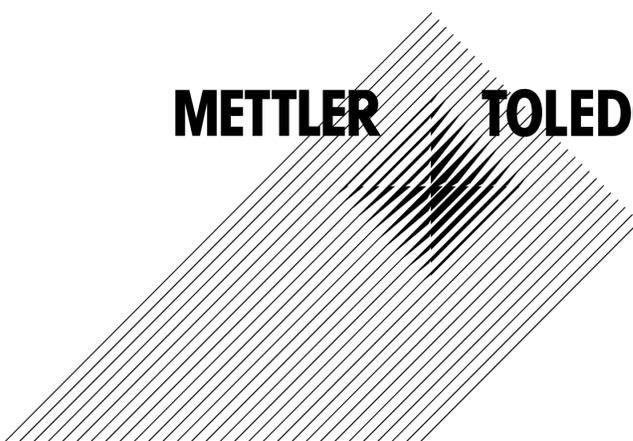


**4000TOC Sensor
Standard Operating Procedure
for System Suitability Testing to meet USP
〈643〉 and EP 2.2.44**

METTLER TOLEDO

The logo graphic consists of a series of parallel, slightly curved lines that create a sense of depth and movement, resembling a stylized 'M' or a series of steps. The lines are black and white, and they are arranged in a way that they appear to be receding into the distance.

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IMPORTANT SAFETY INFORMATION

Please read thoroughly before operating the CAL/SST Module-

- Follow all warnings, cautions, and instructions indicated on and supplied with this product.
- Install equipment as specified in this instruction manual. Follow appropriate local and national codes.
- Use only factory documented components for repair. Tampering or unauthorized substitution of parts and procedures can affect the performance and cause unsafe operation of your process as well as void factory warranties.
- Protective covers must be in place unless qualified personnel are performing maintenance.
- If this equipment is used in a manner not specified by the manufacturer, the protection provided by it against hazards may be impaired.
- Prior to shipping the sensor back to the factory for repair or re-calibration, water **MUST** be drained from sensor to avoid damage due to freezing.

WARNINGS:

- Installation of cable connections and servicing of this product require access to shock hazard voltage levels.
- Main power must employ a switch or circuit breaker as the disconnecting device for the equipment.
- Electrical installation must be in accordance with the National Electrical Code and/or any other applicable national or local codes.
- Safety and performance require that this instrument be connected and properly grounded through a three-wire power source.

This manual includes safety information with the following designations and formats:

WARNING: POTENTIAL FOR PERSONAL INJURY.

CAUTION: possible instrument damage or malfunction.

NOTE: important operating information.



Warning: UV RADIATION HAZARD
Apply power to UV lamp only when installed in housing in accordance with instruction manual.
DO NOT remove UV lamp from housing unless power is off.
Always protect eyes and skin from exposure to UV light

Definition of Equipment Symbols



On the instrument indicates: Warning risk of electric shock.



On the instrument indicates: Caution (refer to accompanying documents).



On the instrument indicates: There is alternating current present.

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1. Introduction

This procedure describes the method for performing a System Suitability Test using a Thornton 4000TOC Sensor for total organic carbon (TOC) measurement.

For all the Pharmaceutical Waters listed below, one of the acceptance criteria for the water is to “meet the TOC requirement”. Several pharmacopoeia have established TOC specifications (for example USP General Chapter <643>, EP Chapter 2.2.44, and JP XV Chapter 21). These chapters provide 1) guidance on the methodology for TOC testing, 2) criteria for establishing instrument acceptance, and 3) TOC limits for the sample to be tested.

Some types of water subject to TOC testing are (but not limited to):

- USP Purified Water
- USP Water for Injection
- EP Purified Water – TOC measurement may be performed in lieu of oxidizable substances test
- EP Highly Purified Water
- EP Water for Injections
- JP Purified Water
- JP Water for Injection
- ChP Water for Injection
- ChP Purified Water – TOC measurement may be performed in lieu of oxidizable substances test

The principal criteria to establish the acceptance of the instrument are 1) limit of detection less than 0.05 mg carbon/L, 2) calibration capability of the instrument, 3) capability to not include inorganic carbon (CO₂) in the TOC measurement, and 4) meeting System Suitability Testing periodically. This document focuses on the Standard Operating Procedure for performing the System Suitability Test on a Thornton 4000TOC Sensor.

The purpose and the value of the System Suitability Test are based on the premise that TOC measurements are not direct measurements of organic carbon, but they are indirect measurements of other carbon-based chemicals. Most TOC measurement systems share the technology of converting the organic carbon to CO₂, and the CO₂ is measured by various means.

The System Suitability Test intention is to challenge the instrument by verifying that it responds equally to two types of chemicals that challenge its measurement capability. In this case, the two chemicals specified in the pharmacopoeial chapters are sucrose and 1,4-benzoquinone. They are commonly referred to as easy-to-oxidize and hard-to-oxidize chemicals, respectively.

In the case of many of today’s TOC measurement systems, there are two key mechanisms for the conversion of organic carbon to CO₂:

- The ability to break carbon-carbon, carbon-hydrogen, and carbon-oxygen bonds. These are the most prevalent chemical bonds found in organic impurities. The strength of each bond depends on the molecule and bond type. Regardless, these bonds need to be broken to form CO₂.
- The ability to oxidize molecular organic carbon (in oxidation states ranging from -4 to +2) to its oxidized form, CO₂, where the oxidation state of carbon is +4. Therefore, electrons are required to be removed from each carbon, and electron acceptors such as the hydroxyl radical (OH·) are formed in water in the presence of deep UV light.

Since organic carbon appears in various forms in nature and subsequently in water systems, a wide variety of oxidation states and chemical forms are found in water systems. The challenge to the TOC measurement system is to oxidize two chemicals equally. Because of their quite different chemical structure, sucrose and 1,4-benzoquinone will challenge the bond-breaking and oxidation capability of the TOC measurement technology. Note that the same concept of the challenge would still apply if another technology were to be applied (such as conversion to CH₄).

The standard solution is a theoretically easy-to-oxidize solution that gives an instrument response at the attribute limit – in this case 500 µg Carbon/L. The technology is qualified by challenging the capability of the instrument using a theoretically difficult-to-oxidize solution in the system suitability portion of the method.

2. Scope

This document provides a procedure to qualify the Thornton 4000TOC Total Organic Carbon Sensor for use with the M300TOC transmitter as a TOC measurement device for various compendial Pharmaceutical waters listed above. This may be applicable to other waters also. This method is to be performed on a sensor and transmitter that has been calibrated. The acceptance of this measurement system for quality attribute testing is dependent on its location(s) in the water system. The instrument location (or the sampling point) must reflect the quality of the water used in the production process.

This procedure describes one acceptable method to determine system suitability. Alternative procedures may be acceptable if they meet the fundamental requirements of USP <643>, EP 2.2.44, etc.

3. Background

On November 15, 1996, the requirements for testing specific attributes of USP Purified Water and WFI were modified to reflect changes in instrumentation and quality testing. The two profound changes were:

- The elimination of tests for chloride, ammonia, sulfate, carbon dioxide, and calcium and subsequent replacement by uncompensated conductivity and temperature measurements. This is described in USP <645>.
- The option to perform TOC measurements instead of the Oxidizable Substance Test for USP Purified Water and WFI. Eventually, the Oxidizable Substances Test was deleted for these bulk waters.

The major impetus for these changes was the opportunity to eliminate costly, labor-intensive tests that were qualitative at best, and replace them with quantitative tests that represented current industry norms. The on-line versatility of these measurements made these new tests more attractive. Later, other major pharmacopoeias have adopted similar requirements. You should consult the pharmacopoeia of interest for current requirements.

4. Principle of Analysis

Organic impurities are introduced into the water from the source water, purification processes, components in the distribution system, and from biofilm in the system. TOC is an indirect measure of organic molecules measured as carbon. TOC can also be used as a process control attribute to monitor the performance of unit operations comprising the purification and distribution system.

The Thornton 4000TOC Sensor and M300TOC transmitter measures and reports the amount of organic carbon in high purity waters by oxidizing organic carbon to CO₂ with appropriate UV radiation. The resulting change in conductivity is used to calculate the amount of organic carbon present.

5. Apparatus Required

- Thornton 4000TOC Sensor (PN's 58 036 021 and 58 036 022,) with its associated instruction manual and installation kit.
- Thornton M300TOC Transmitter (various part numbers) with associated instruction manual and patch cable.
- Thornton CAL/SST Kit (58 091 559).
- Thornton System Suitability Solutions Kit (58 091 526).

6. Test Procedure

Note: Use the 'Hold Outputs' function in the M300TOC Transmitter to hold the relay and analog outputs so that alarms are not triggered during any service procedures. On the M300 TOC, go to Path: Menu/Configure/Hold Outputs and set "Hold Outputs Now" to Yes. This setting will hold all relay and analog outputs at their current value until set back to 'No', but not to exceed a maximum of 60 minutes.

Caution: Be sure to adjust the inlet needle valve to less than 3 turns from the closed position before re-installing into the process line!

Throughout the test procedure, the units "ppb" or "ppb Carbon" and "µg Carbon/L" will appear. They are identical for this procedure. "ppb" (or ppm) is the common terminology used throughout the industry, though it is not a recognized SI unit. "µg Carbon/L" (or mg Carbon/L) are the units referred to in the pharmacopoeia.

6.1. System Preparation

1. Prior to this test, install and operate the 4000TOC Sensor and M300TOC transmitter according to their instruction manuals.
2. Run process water through the sensor for at least 30 minutes.

6.2. Install CAL/SST Module (part no. 58 091 559)

CAL/SST Module 58 091 559 provides the equipment needed to perform a system suitability test on the 4000TOC Sensor (PN's 58 036 021 and 58 036 022). Components contained in this kit include the pump module, a mounting bracket, connecting tubing equipped with quick-disconnect fittings, a universal power supply and assorted tools. This kit is designed for use with Thornton Standard Solution bottles included in the System Suitability Solutions Kit (p/n 58 091 526).

TOC Calibration and SST Kit Installation and Setup

1. Remove the mounting bracket from the carrying case and place on top of the 4000TOC Sensor to be tested. See Figure 1.
2. Connect the CAL/SST Module to the mounting bracket. Ensure that the bracket and module are aligned to the left side of the sensor so that UV Lamp power button is accessible and the indicating LED's are visible.
3. Remove the 60 micron filter assembly from the 4000TOC inlet.
4. Attach the threaded end of connection tube equipped with the male quick-disconnect fitting to the 4000TOC Sample Inlet connection. After the threaded connection is made, push the quick-disconnect fitting into mating connector found on the top right side of the Cal/SST pump module. Ensure proper connection is made.
5. Set selector valve on CAL/SST pump module to "SST/TOC CAL" position. Figure 1 shows the proper installation of the CAL/SST pump module.
6. Verify the pump switch is in the off position. The switch is located on the right side of the module.
7. Connect the Universal Power Supply to the pump and to 100–240 VAC 50-60 Hz power. The kit includes a universal AC adaptor with assorted international standard connectors. Select the appropriate AC connector, and install it onto the AC adaptor and connect to the AC supply.

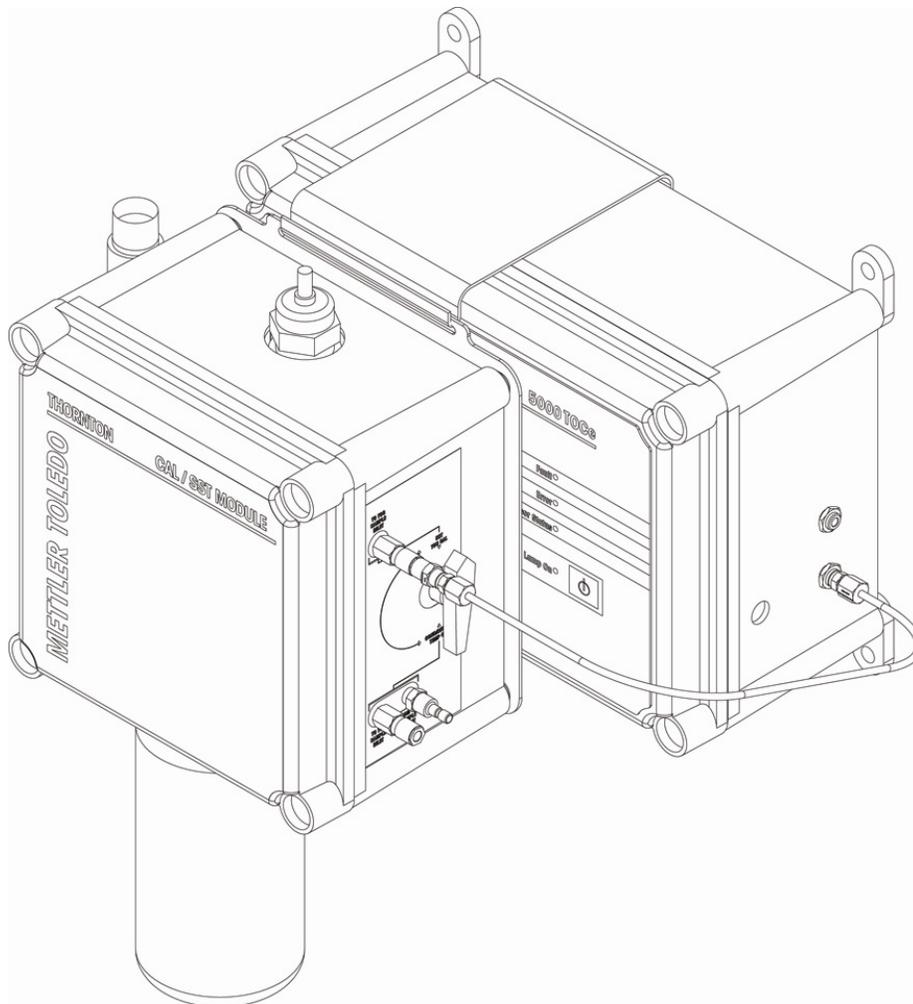


Figure 1. CAL/SST Pump Module Installation and Setup

Attaching System Suitability Standards bottles to the CAL/SST Pump Module

When required by the procedure, an SST Standard solution bottle can be attached to the CAL/SST Pump Module as follows:

1. Remove the threaded grey, protective cap from the bottom of the CAL/SST Pump Module.
2. Wearing clean protective gloves to avoid contamination, insert a silicone suction tube onto the suction fitting located in the bottle receptacle as shown in Figure 2. A fresh suction tube should be used for each SST test. Protective gloves and a replacement suction tube are provided with each SST solution kit.
3. Break the protective seal on the SST solution bottle and remove cap. Set cap aside for re-use if any SST solutions remain after completion of the test.
4. Insert free end of the suction tube into the mouth of the bottle while raising the bottle into place. Screw SST solution bottle directly into the solution bottle receptacle at the base of the CAL/SST pump module.

The CAL/SST module is now ready to perform the SST test. Go to section 6.3. Purge 4000TOC Sensor.

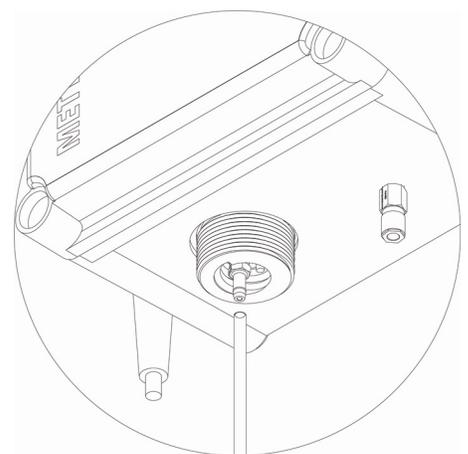


Figure 2. Suction Tube installation

6.3. Purge 4000TOC Sensor

1. Process water, known to be low TOC, is ideal for flushing the 4000TOC Sensor.
2. Remove the seal from one of the two bottles of Reagent Water supplied with the System Suitability Solutions Kit.

3. Install the Reagent Water bottle onto the SST test device according to section 6.2. Always ensure that reusable components have been properly rinsed before use.
4. Turn off the process water supply to the 4000TOC Sensor using the shut off valve (recommended in the 4000TOC Sensor Instruction Manual). Ensure the process water supply is turned of by viewing the discharge line at the atmospheric drain.
5. Using 5/16" and 3/8" wrenches, remove the nut on the process supply tube at the inlet to the 4000TOC Sensor.
6. Hold the ferrule end of the Sensor tubing from the pump to direct its water flow away from potentially sensitive items. If necessary, direct the spray into a suitable container.
7. Turn on the pump, allowing water to flow from the ferrule end of the Sensor tube for 10 to 20 seconds.
8. Turn off pump.
9. Connect the nut end of the Sensor tubing to the inlet of the Sensor and tighten it with the 5/16" and 3/8" wrenches.
10. Turn on the pump. Note water dripping from the sensor discharge tubing at the atmospheric drain.

6.4. Setting Sample Flow Rate

1. Press the Menu key on the M300TOC keypad.
2. Scroll to the Configure menu and press Enter.
3. Select TOC Setup and press enter.
4. Select TOC General parameters and press enter.
5. Press enter to accept the default settings displayed on the first screen. The 'Off' selection for Set Flow Rate should now be flashing.
6. Select 'Yes' by pressing ▲ or ▼ to activate Set Flow Rate option. This immediately initiates the Set Flow Rate mode at the sensor. It will stay in this mode until the user changes the "Set Flow Rate: Yes" back to "Set Flow Rate: No". If the user does not set the flow rate once he has initiated the Set Flow Rate mode, the M300TOC will time out after ~8 minutes, at which time the mode automatically goes back to "Set Flow Rate: No" and the instrument returns to the measurement display screen.
7. In this mode, the LEDs on the front cover of the 4000TOC Sensor act as a bar-graph indicator as described below. The flow rate is set by adjusting the inlet needle valve installed on the sample inlet connection of the 4000TOC Sensor (see Figure 3).
8. Turn the inlet needle valve adjustment knob counterclockwise to gradually increase flow and clockwise to gradually decrease the flow.

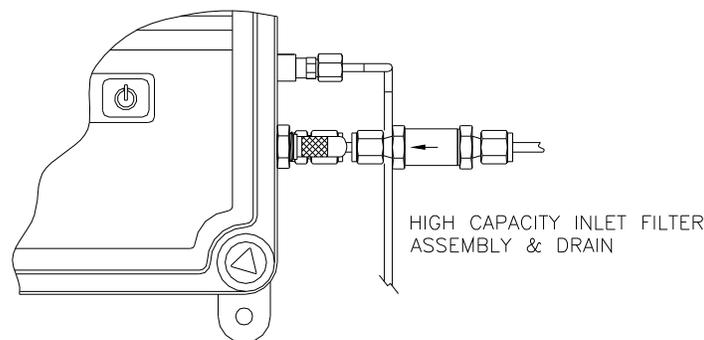
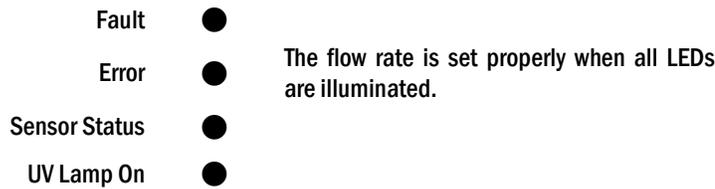


Figure 3. High Capacity Inlet Filter Assembly and Side-Mounted Needle Valve

9. The flow rate value is indicated by the four LEDs (lights) on the front of the 4000TOC sensor.



● = LED illuminated

- 10. When the flow rate is at 20 mL/minute (± 0.5 ml/minute), all four LEDs will be on.
- 11. If the flow rate is too high, the top LEDs will be on. Turn the adjustment knob clockwise.
- 12. If the flow rate is too low, the bottom LEDs will be on. Turn the adjustment knob counterclockwise.
- 13. If the flow rate is far from 20 mL/minute, only the top (Fault) LED or the bottom (UV Lamp) LED will be on.
- 14. As the flow rate approaches the correct value, more LEDs will turn on. For example, if the flow rate is too high, as the adjustment knob is turned clockwise, first the Fault LED will be on, then the Fault and Error LEDs will be on, then the Fault, Error and Sensor Status LEDs will be on and finally all four LEDs will be on when the flow rate is 20 mL/min.

	Very LOW	LOW	NEAR SET	SET	NEAR SET	HIGH	Very HIGH
Fault	○	○	○	●	●	●	●
Error	○	○	●	●	●	●	○
Sensor Status	○	●	●	●	●	○	○
UV Lamp On	●	●	●	●	○	○	○

● = LED illuminated

○ = LED not illuminated

Figure 4. LED Indicator for Flow rate

- 15. When the flow rate is set correctly, all LEDs will be on.
- 16. Go to the M300TOC transmitter and change “Set Flow Rate: Yes” to “Set Flow Rate: No”, then press ◀ and ▶ simultaneously to escape from the current menu function and return to Measurement Mode. The flow rate setting operation is now complete.

6.5. Worksheet Preparation

Note: The information for Table 1 and Table 2 can be found in the menus of the M300TOC. Press the ‘Info’ key, then press ▲ or ▼ to select ‘Model/Software Revision’. Use the ▲ or ▼ keys to scroll through the available information.

- 1. Fill in Table 1 (located in Section 8) of the System Suitability Worksheet. Enter the date and the M300TOC and 4000TOC Sensor part number and serial number. The M300TOC part number and serial number is for reference only. The TOC sensor may undergo the System Suitability Test with another M300TOC transmitter.
- 2. Fill in Table 2 of the System Suitability Worksheet for the M300TOC and 4000TOC Sensor software revisions. The M300TOC and 4000TOC Sensor software revisions are for reference only.
- 3. Fill in Table 3 of the System Suitability Worksheet. Enter the date of preparation, date of expiration, lot number, and prepared concentration of each solution.

6.6. Reagent Water Measurement

1. Allow the Reagent Water to be pumped through the instrument for at least 5 minutes before collecting data for use in the calculations.
2. Verify that one measurement on the M300TOC is displaying a TOC measurement in one of the following measurement units: "TOC Auto", "TOC ppb C", "gC/L Auto" or "gC/L micro".
3. Verify that one measurement on the M300TOC is displaying resistivity or conductivity measurement.
4. Collect three consecutive TOC readings, at least 10 seconds apart.
5. Record these TOC readings in Table 4 of the System Suitability Worksheet under Reagent Water. These values are R_w .
6. Record the conductivity (or resistivity) in the bottom of Table 4 in the System Suitability Worksheet.
7. Turn the pump off.

6.7. Standard Solution Measurement

In the pharmacopoeia, the Standard Solution is defined as the 0.50 mg of carbon/L (500 ppb) solution, prepared from Sucrose.

1. Remove the seal and cap from the 500 ppb (nominal) Sucrose System Suitability Solution bottle.
2. Replace the Reagent Water bottle with the 500 ppb Sucrose Solution bottle.
3. Turn on the pump. Adjust the flowrate per the Setting Sample Flow Rate Section 6.4.
4. Allow the Sucrose System Suitability Solution to be pumped through the instrument for at least 5 minutes before collecting data for use in the calculations.
5. Collect three consecutive TOC readings, at least 10 seconds apart.
6. Record these TOC readings in Table 4 of the System Suitability Worksheet under Sucrose. These values are R_s .
7. Record the conductivity (or resistivity) in the bottom of Table 4 in the System Suitability Worksheet.
8. Turn the pump off.

6.8. System Suitability Solution Measurement

In the pharmacopoeia, the System Suitability Solution is defined as the 0.50 mg of carbon/L (500 ppb) solution, prepared from 1,4-Benzoquinone solution.

1. Remove the seal and cap from the 500 ppb (nominal) 1,4-Benzoquinone System Suitability Solution bottle.
2. Replace the Sucrose bottle with the 1,4-Benzoquinone, System Suitability Solution bottle.
3. Turn on the pump. Adjust the flowrate per the Setting Sample Flow Rate Section 6.4.
4. Allow the 500 ppb 1,4-Benzoquinone System Suitability Solution to be pumped through the instrument for at least 5 minutes before collecting data for use in the calculations.
5. Collect three consecutive TOC readings, at least 10 seconds apart.
6. Record these TOC readings in Table 4 of the System Suitability Worksheet under 1,4-Benzoquinone. These values are R_{ss} .
7. Record the conductivity (or resistivity) in the bottom of Table 4 in the System Suitability Worksheet.
8. Turn the pump off.

6.9. Rinse Sensor and System Suitability Test Kit

1. Replace the previous bottle with the Reagent Water. If necessary, use the second bottle of Reagent Water or your process water.
2. Turn on the pump
3. Rinse the system for at least 5 minutes to flush the system.
4. Turn off the pump.

5. Disconnect the Sensor tubing from the Sensor. The 4000TOC Sensor may be returned to operation with the Process Water.

Caution: Be sure to adjust the inlet needle valve to less than 3 turns from the closed position before re-installing into the process line!

6. Remove the reagent water bottle from the SST test device.
7. Turn on the pump for 10 to 20 seconds to remove residual water.
8. Disconnect all the tubes from the pump.
9. Remove the SST device from the 4000TOC sensor, and re-pack into carry case.

10. Reconnect the process water line, and turn on the user installed shut-off valve.
11. Verify there is no leak at the process water line, and verify water dripping at the atmospheric drain.
12. Adjust the flow rate per the Setting Sample Flow Rate Section. (Section 6.4)

7. Calculations

7.1. Limit Response and System Suitability Response

1. The limit response is the corrected Standard Solution response. Fill in Table 5 of the System Suitability Worksheet.
2. Calculate the limit response by subtracting the Reagent Water TOC response from the response of the Sucrose Standard Solution. This is $R_s - R_w$.
3. Record the value $R_s - R_w$ in Table 5 of the System Suitability Worksheet.
4. Calculate the corrected System Suitability Solution response by subtracting the Reagent Water TOC response from the System Suitability Solution TOC response. This is $R_{ss} - R_w$.
5. Record the value $R_{ss} - R_w$ in Table 5 of the System Suitability Worksheet.

7.2. Response Efficiency

1. Fill in Table 6 from the System Suitability Worksheet using the following formula:

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

2. Record the Response Efficiency in the System Suitability Worksheet.

7.3. System Suitability Test Acceptance

1. Fill in Table 7 of the System Suitability Worksheet.
2. Verify that the Reagent Water is <100 ppb.
3. The system is suitable if the Response Efficiency is not less than 85% and not more than 115%*.

* These values are correct at time of printing. Consult your pharmacopeia for current requirements.

8. System Suitability Worksheet

Table 1. TOC System

Date of test	
4000TOC Sensor Part Number	
4000TOC Sensor Serial Number	
M300TOC Model Number*	
M300TOC Serial Number*	
Comments	

* For reference only

Table 2. M300TOC and 4000TOC Software Revision*

Feature**	Version
4000TOC FW (Firmware) Version	
4000TOC SW (Software) Version	
M300TOC Master Version	
M300TOC Comm Version	
Comments	

* For reference only

** The version numbers of these features are found in the M300TOC by pressing the Info key and selecting 'model/Software Revision'.

Table 3. Solution Information

Material	Date of Preparation	Date of Expiration	Lot number	Concentration*
Reagent Water				
Sucrose				
1,4-Benzoquinone				
Comments				

* This is the labeled or prepared concentration. This is not the concentration as measured by the TOC system.

Table 4. Data from TOC Measurements

Reagent Water (R _w)		Sucrose (R _s)		1,4-Benzoquinone (R _{ss})	
Reading	ppb	Reading	ppb	Reading	ppb
1		1		1	
2		2		2	
3		3		3	
Average R _w		Average R _s		Average R _{ss}	
Conductivity (μS/cm)		Conductivity (μS/cm)		Conductivity (μS/cm)	
Comments					

Table 5. Response Calculations

Standard Solution (sucrose) response* = $R_s - R_w =$ _____ ppb - _____ ppb = _____ ppb	
System Suitability (1,4-benzoquinone) response = $R_{ss} - R_w =$ _____ ppb - _____ ppb = _____ ppb	
Comments	

* Standard Solution response = Limit Response

Table 6. Response Efficiency Calculation

Response Efficiency (%) = $RE = 100 \times \left(\frac{R_{ss} - R_w}{R_s - R_w} \right) = 100 \times \left(\frac{\text{_____} - \text{_____}}{\text{_____} - \text{_____}} \right) = \text{_____} \%$	
Comments	

Table 7. System Suitability Test Acceptance

Is $R_w < 100$ ppb?		
Is $85\% \leq RE \leq 115\%$?		
Performed By:		Date:
Reviewed By:		Date:
Comments		

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