

5000TOC Sensor

Standard Operating Procedure

for System Suitability Testing to meet USP 〈643〉 and EP 2.2.44

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IMPORTANT SAFETY INFORMATION

Please read thoroughly before operating the 5000TOC System Suitability Test Kit -

- 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 5000TOC Sensor for total organic carbon (TOC) measurement.

For all the Pharmaceutical Waters listed below, one of the acceptance criteria requirements for the water is to “meet the TOC requirement”. The USP and EP have established TOC tests as described in USP General Chapter <643> and EP Chapter 2.2.44, respectively. 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.

The types of water subject to TOC testing are:

- USP Purified Water
- USP Water for Injection
- EP Aqua Purificata (Purified Water) – TOC may be performed in lieu of oxidizable substances test
- EP Valde Aqua Purificata (Highly Purified Water)
- EP Aqua ad Iniectionabilia (Water for Injections).

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 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 5000TOC 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 of today’s TOC measurement systems share the technology of converting the organic carbon to CO₂, and the CO₂ is measured by various means. But the TOC test chapters do not require that the technology be limited to the conversion of organic carbon to CO₂. For example, if a technology utilized a means to convert organic carbon to CH₄, and the CH₄ were measured, this would be acceptable.

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. This reference to “easy (or hard-)to-oxidize” can be quite misleading depending on the technology employed, but the terms are commonplace.

In the case of many of today’s TOC analyzers, 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 analyzer 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 5000TOC Total Organic Carbon Sensor for use with the 770MAX meter as a TOC measurement device for USP and EP Pharmaceutical Waters listed above. This may be applicable to other waters also. This method is to be performed on a sensor and meter 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> and EP 2.2.44. For example, alternative concentrations or volumes of the stock solutions may be used. The only requirement is that the required final concentration is achieved.

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.

While conductivity measurements were common in pharmaceutical water systems, there was reluctance to abruptly delete the Oxidizable Substances Test in favor of TOC measurements. The technology for low-ppb TOC measurements was relatively new and the cost of TOC instrumentation was prohibitive. For these reasons, the USP permitted the use of either test until May 15, 1998. At that time, the Oxidizable Substances Test was deleted as a requirement for USP Purified Water and WFI, and USP General Chapter <643> TOC became the exclusive means to measure the organic impurity in USP Purified Water and Water for Injection.

Subsequently, in 2000, the EP implemented a TOC requirement (2.2.44) for their bulk waters. As of this printing, TOC is required for bulk WFI, and it is an optional test for Purified Water as an alternative to the Oxidizable Substances Test in the EU only. You should consult the current pharmacopoeia of interest.

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. This method, Total Organic Carbon, is described in General Chapter <643> in U.S. Pharmacopoeia, and in Test 2.2.44 of the European Pharmacopoeia.

The Thornton 5000TOC Sensor and 770MAX meter measures the amount of organic carbon in high purity waters by oxidizing organic carbon to CO₂ with appropriate UV radiation. The resulting increase in conductivity is used to calculate the amount of organic carbon present.

5. Apparatus Required

- Thornton 5000TOC Sensor (PN 58036001 or PN 58036002) with its associated instruction manual and installation kit.
- Thornton 770MAX Meter (various part numbers) with its associated instruction manual and patch cable.
- Thornton 5000TOC System Suitability Test and TOC Calibration Kit (58091525).
- Thornton 5000TOC System Suitability Solutions Kit (58091526).

6. Test Procedure

Note: Use a hold time in the 770MAX Analyzer to freeze the relay and analog outputs so that alarms are not triggered during any service procedures. Normal relay and analog output operation resumes when the set period has elapsed or when the hold time is reset to zero. Set the hold time by pressing “Menu” on the 770MAX main display. Scroll to “Set Hold time” by using the up/down arrows. Press “Enter”, then enter a time between 1 to 99 minutes, and press “Menu”. The hold time is now set.

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 5000TOC Sensor and 770MAX Meter according to their instruction manuals.
2. Run process water through the sensor for at least 30 minutes.

6.2. Install System Suitability Test and TOC Calibration Kit (part no. 58091525)

System Suitability Kit 58091525 provides the apparatus needed to perform a system suitability test on the 5000TOC sensor (models 58036001 and 58036002). Components included in this kit include a bracket assembly, transfer cap assembly, assorted fittings, 30cc plastic syringe, positive displacement pump and a universal power supply. This kit is designed for use with Thornton Standard Solution bottles included in the System Suitability Solutions Kit (p/n 58091526).

Bracket Assembly and Pump Installation

1. Remove the three individual brackets from the aluminum carrying case.
2. Attach the flat front cover bracket to the U-shaped top bracket, aligning the front cover bracket holes with the studs located on the top bracket.
3. Do not tighten thumb screws at this time.
4. Attach L-shaped bottle bracket to the stud located on the right. Place the bottle bracket over the thumb screw and slide it to the left, so that the smaller diameter slot is under the thumb screw. Hold the bracket and tighten the thumb screw to secure the bottle bracket. Figure 1 shows proper orientation of all three bracket components.
5. Remove the pump assembly from the aluminum carrying case.
6. Attach the pump assembly (with integral bracket) to the left stud, aligning the large diameter hole in the pump bracket over the thumb screw. Place the pump assembly bracket over the thumb screw and slide it to the left, so that the smaller diameter slot is under the thumb screw. Tighten to secure the pump. The pump should lay flat on the front cover bracket.

7. Install tube fittings onto the threaded connections, labeled 'Inlet' and 'Outlet', on the top side of the pump. Pump inlet and outlet tubing should only be installed when starting a system suitability test. This will eliminate the possibility of contaminating tubing and fittings.

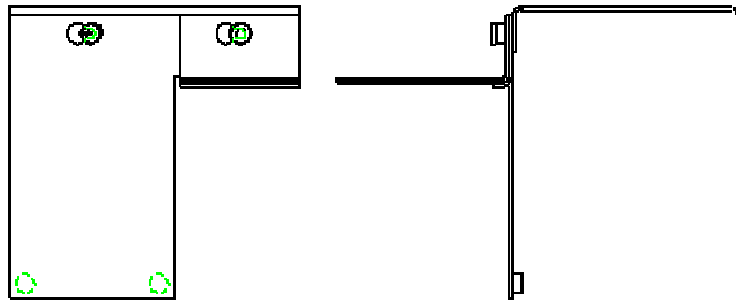
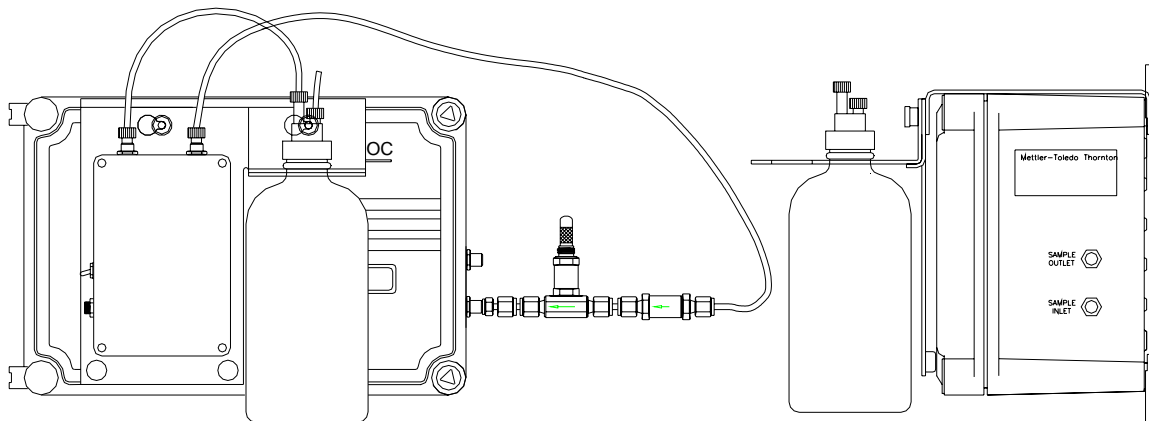


Figure 1. Bracket Assembly

System Suitability Apparatus Installation

1. Carefully place the assembled bracket, with pump, over the 5000TOC Sensor. Slide the assembly to the left slightly, leaving the 'UV Lamp On' key accessible. Figure 2 shows the proper location and orientation of the System Suitability Apparatus.



**Figure 2. System Suitability Apparatus
(shown with solution bottle installed)**

2. Verify the pump switch is in the off position.
3. Connect the Universal Power Supply to the pump and to 100–240 VAC 50-60 Hz power. The kit includes a North American AC power cord. Replace or adapt the power cord as necessary and in accordance with local regulations.
4. Clean the Transfer Cap and the Open Top Cap using deionized or process water (water to be tested). These parts are identified in the parts description for the System Suitability Pump Kit.
5. Assemble as shown in Figure 2. Without touching the lower 7 ½" (20 cm) of the tubing, carefully insert the bottle tube (plain tube without nut and ferrule from 5000TOC System Suitability Solutions Kit) into the thumb fitting on the Transfer Cap fitting with 6 ¼" (16 cm) extending from bottom of Transfer Cap. Do not allow the lower end of the bottle tube to become contaminated. If the tube will not slide through the thumb fitting, inspect the ferrule immediately below it.
6. Connect the other end of the bottle tube to the "Inlet" fitting on the pump.

7. Connect the plain end of the Sensor Tube (tube with nut and ferrule from the 5000TOC System Suitability Solutions Kit) to the "Outlet" fitting on the pump.

IMPORTANT NOTE:

When the pump is first put into service, or after extended storage, it may need to be primed by injecting reagent water into the inlet fitting with the syringe provided. Place the pump in its normal vertical position with the inlet tube from the bottle removed from the inlet fitting and the outlet tube placed to discharge into a container. Draw reagent water into the syringe, place the tip of the 30cc syringe into the pump inlet fitting, turn on the pump and push about 10 ml of water into the fitting or until water appears at the outlet fitting. Excess water will run from the inlet fitting. Turn off the pump. Reattach the tube from the bottle to the pump inlet fitting and proceed.

6.3. Purge 5000TOC Sensor

1. Process water, known to be low TOC, is ideal for flushing the 5000TOC Sensor.
2. Remove the seal from one of the two bottles of Reagent Water supplied with the System Suitability Solutions Kit.
3. Place the Reagent Water bottle into the holder notch on the bracket.
4. Clean the bottom of the transfer cap and the bottom of the transfer tube with de-ionized water or the process water to be tested.
5. Remove the solid cap from the Reagent Water container and install the transfer cap.
6. The end of the bottle tube should be near the bottom of the Reagent Water container.
7. Turn off the process water supply to the 5000TOC Sensor using the shut off valve (recommended in the 5000TOC Sensor Instruction Manual). Ensure the process water supply is turned off by viewing the discharge line at the atmospheric drain.
8. Using 5/16" and 3/8" wrenches, remove the nut on the process supply tube at the inlet to the 5000TOC Sensor.
9. 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.
10. Turn on the pump, allowing water to flow from the ferrule end of the Sensor tube for 10 to 20 seconds.
11. Turn off pump.
12. 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.
13. 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 770MAX keypad.
2. Scroll to the Measurements menu and press Enter.
3. Select the measurement letter (A, B, C...) for the TOC measurement of interest.
4. Press Page Down (twice) until the "Push 5 for TOC menu" appears.
5. Press Enter to activate Set Flow Rate option.
6. Press Arrow up or Arrow down to select "Set Flow Rate: Yes". 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 770MAX will time out, 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 5000TOC 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 5000TOC Sensor (see Figure 3).
8. Turn the inlet needle valve adjustment knob counterclockwise to gradually increase flow and clockwise to gradually decrease the flow.

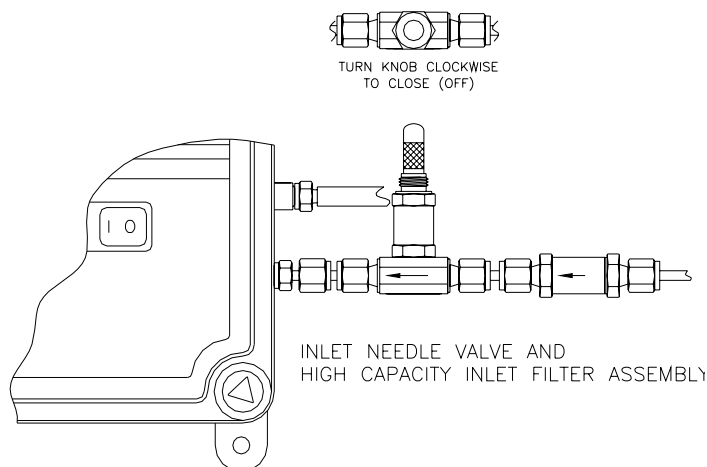


FIGURE 3. Inlet Needle Valve and Filter Location

9. The flow rate value is indicated by the four LEDs (lights) on the front of the 5000TOC sensor.

- Fault ●
 - Error ●
 - Sensor Status ●
 - UV Lamp On ●
- The flow rate is set properly when all LEDs are illuminated.

● = LED illuminated

10. When the flow rate is at 20 mL/minute ($\pm 5\%$), 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 770MAX and change "Set Flow Rate: Yes" to "Set Flow Rate: No". The flow rate setting operation is now complete.

6.5. Worksheet Preparation

1. Fill in Table 1 (located in Section 8) of the System Suitability Worksheet. Enter the date and the 770MAX and 5000TOC Sensor part number and serial number. The 770MAX part number and serial number is for reference only. The TOC sensor may undergo the System Suitability Test with another 770MAX meter.
2. Fill in Table 2 of the System Suitability Worksheet for the 770MAX and 5000TOC Sensor software revisions. This is found in the menus of the 770MAX. Scroll to Other Menus, then scroll to Software Revs, and press Enter. Press page down to view all of the software revisions in the 770MAX meter and 5000TOC Sensor. There may not be a version number for Options 1 and Options 2. The 770MAX and 5000TOC 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 770MAX 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 770MAX is displaying resistivity or conductivity measurement in one of the following measurement units: " Ω -cm Auto", " Ω -cm Kilo", " Ω -cm Mega", "S/cm Auto", "S/cm nano", "S/cm micro".
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 500 ppb, as Sucrose, solution.

1. Remove the seal and cap from the 500 ppb (nominal), as Sucrose, System Suitability Solution bottle.
2. Replace the previous bottle with the 500 ppb, as Sucrose, System Suitability 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 500 ppb, as 1,4-Benzoquinone solution.

1. Remove the seal and cap from the 500 ppb (nominal), as 1,4-Benzoquinone, System Suitability Solution bottle.
2. Replace the previous bottle with the 500 ppb, as 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, as 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 5000TOC 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 bottle tubing from the reagent water bottle by removing the transfer cap from the bottle.
7. Turn on the pump for 10 to 20 seconds to remove residual water.
8. Disconnect all the tubes from the pump. Retain the transfer cap, but dispose of the tubing.
9. Remove the bottle and bracket from the 5000TOC Sensor.
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	
5000TOC Sensor Part Number	
5000TOC Sensor Serial Number	
770MAX Model Number*	
770MAX Serial Number*	
Comments	

* For reference only

Table 2. 770MAX and 5000TOC Software Revision*

Feature**	Version
770MAX Main program	
770MAX Measurements	
770MAX Display Rev	
770MAX Options 1***	
770MAX Options 2***	
TOC Revision	
Comments	

* For reference only

** The version numbers of these features are found in the 770MAX menus under Other Menus/software Revs.

*** For Option 1 and Option 2, depending on the 770MAX Part Number and the associated hardware, these versions may not be installed.

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 ($\mu\text{S/cm}$)		Conductivity ($\mu\text{S/cm}$)		Conductivity ($\mu\text{S/cm}$)	
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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