

comparing online TOC analyzers and sensors



Figure 1. Examples of TOC Analyzers and Sensors

To minimize process and regulatory risks, it is critical to select a Total Organic Carbon (TOC) instrument that is most suitable for its intended use. For the pharmaceutical industry, the US FDA states in regulation 21 CFR 211.194, “The suitability of all testing methods used shall be verified under actual conditions of use.”

Using a TOC sensor (**Figure 1**) in an application requiring a TOC analyzer can result in greater product and regulatory risks, increased product costs from out-of-specification (OOS) results, and associated product recall. Conversely, using a TOC analyzer when the use of a sensor is more appropriate could result in excess use of capital, consumables, and maintenance expenses. When assessing the selection of a TOC analyzer or sensor, **Table 1** is helpful for understanding the general characteristics of the devices and their common “intended use” applications.

evaluating intended use and accuracy

TOC sensors are less accurate than TOC analyzers. If the intended use of the TOC instrument is for regulatory reporting, managing an important process control variable, real-time release, or other critical-to-quality product attributes, then accuracy is essential. In those situations, a TOC analyzer is appropriate. On the other hand, if the intended use is for general TOC monitoring—not for making critical quality decisions—then other characteristics may be more important than accuracy and a TOC sensor may be appropriate. Sensors are typically used to monitor a

Table 1. General Characteristics of TOC Analyzers and Sensors

TOC Analyzers	TOC Sensors
General Characteristics	
Larger footprint	Smaller footprint
Usually based in a lab	Usually portable
More expensive	Less expensive
Complex method	Simple method
Requires operator skill	Easy to operate
Performance	
More accurate	Less accurate
Fast response	Faster response
Extremely sensitive	Less sensitive
Absolute measurement	Relative measurement
Good standards performance	Bad standards performance
Technology	
Membrane conductometric	Direct conductivity
Intended Use	
Measures a change	Indicates a change
Controls a process	Monitors a process
Primary measurement	Secondary measurement
CTQ – critical to quality	FIO – for information only
Used to solve	Used to troubleshoot
Used to verify or validate	Used to diagnose
Used to manage quality	Used for trending

process while analyzers are more suited to manage a process. Data from sensors are used for information only. **Table 2** demonstrates suitability of analyzers and sensors for various uses and roles in ultrapure water (UPW) applications.

Table 2. Intended Use– TOC Analyzers vs. Sensors

	Analyzers	Sensors
Documentation	IQ/OQ/PQ	IQ/OQ
Water Release	Suitable	High Risk
Cleaning Validation	Suitable	High Risk
Diagnostics (for information only)	Suitable	Suitable
Process Control	Suitable	High Risk
Water Monitoring	Suitable	Risky

TOC technologies

TOC analysis in water involves measuring the initial CO₂ (inorganic carbon, or IC), completely oxidizing all organics to CO₂, and then measuring the total post oxidation CO₂ concentration (total carbon, or TC).
 $TC - IC = TOC$.

Some TOC sensors only partially oxidize the organics to CO₂, which explains their poor recovery of the difficult-to-oxidize with UV light compounds like methanol and urea.

Other TOC analyzers and sensors oxidize the organics completely to CO₂. TOC sensors all measure the CO₂ directly by conductivity cells (Direct Conductivity, or DC method) and can produce false positive and false negative TOC results. In contrast, TOC analyzers remove the CO₂ by diffusion through a selective membrane into deionized (DI) water and then measure the ionized CO₂ by a conductivity cell (membrane conductometric, or MC method.)

Figure 2 shows the recovery performance of different organics in water as a function of sensor and analyzer.

on-line TOC sensors and analyzers

TOC sensors are small, portable, fast, and less expensive than analyzers. Sievers* CheckPoint TOC Sensor offers next-generation enhancements of these features, and is the first and only TOC measuring device to offer battery operation.

Figure 2 shows the TOC performance differences between analyzers and sensors. It summarizes the

results of a study on the response of various classes or organics in three TOC sensors—the Anatel A-643, the Thornton 5000, and the CheckPoint—and two TOC analyzers—the Sievers 500 RL and Sievers 900. The compounds selected were those either known to exist in UPW or that emulated classes of compounds that might exist in UPW water.

All sensors showed false high recoveries for chlorine, sulfur, and nitrogen containing organics and low recovery of the organic acid. The Thornton 5000 only partially oxidized the organics and reported low methanol recoveries as a result. In addition, the sensors showed different recoveries for the hard-to-oxidize urea, a compound of great importance to semiconductor processing. These sensors are also sensitive to trace amounts of non-organic ions, and this causes difficulty with standards and system suitability testing.

The Sievers M9¹, 900, and 500 RL Series TOC Analyzers that use the membrane conductometric method report close to 100% recovery of all the test compounds.

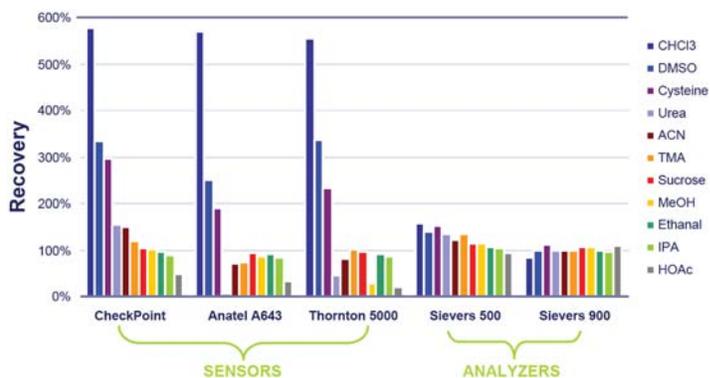


Figure 2. TOC Sensor and Analyzer Recovery Data

conclusions

- Both TOC analyzers and sensors serve important, but different roles in today's UPW applications (**Table 2**).
- Accuracy and intended use are critical considerations in selecting a TOC instrument.
- TOC analyzers using the MC method are more accurate than sensors, and should be applied to critical quality decisions involving regulatory reporting, measuring product quality, real-time release, managing process control limits, and performing system validation.
- TOC sensors that use the DC method, regardless of manufacturer, are inherently inaccurate with many classes of organic compounds and should not be

relied upon for regulatory reporting or critical-to-quality processes. Their appropriate use is for general trending, troubleshooting, and general diagnostics.

Reference

1. SUEZ, *Sievers M9 and 900 Equivalency Report*, 300 00290, 2018.