astro

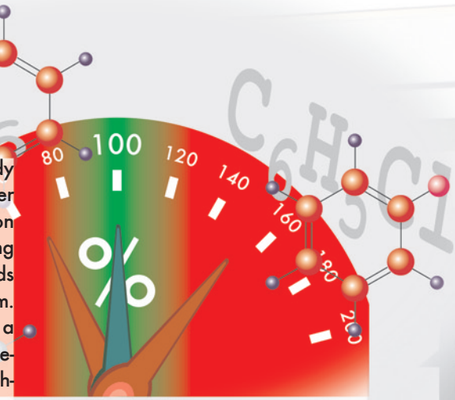
TOC

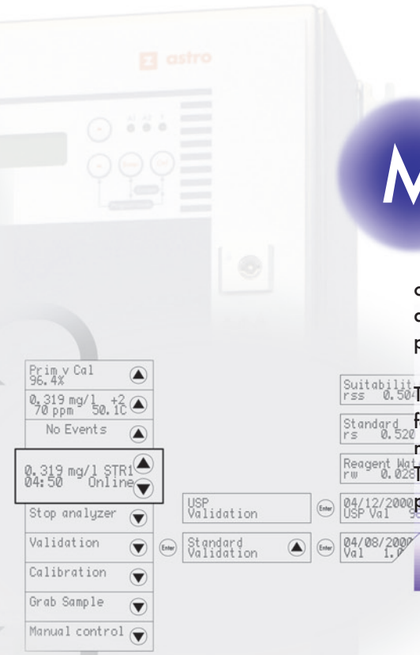
Pharmaceutical Industry Total Organic Carbon Analysis

With the introduction of the United States Pharmacopeia 24 regulation ‘643 Total Organic Carbon’ and the European Pharmacopeia regulation equivalent 2.2.44, the understanding of the TOC measurement is profoundly important to accomplish the Water for Injection and Purified Water requirements.

zellweger analytics

When measuring Total Organic Carbon, everybody assumes the measurement is at 100%. Neither 70% nor 150% should be accepted. The definition of the TOC parameter is; it is a sum-parameter measuring all carbon species of known or unknown origin. This holds unequivocally true for a pharmaceutical sample stream. Since there is no direct measurement for TOC available, a surrogate detection technique has to be employed. Therefore, it is paramount to utilize a surrogate detection technique, which is not another sum-parameter by its own definition such as conductivity. The exposure to various interferences commonly found in a sample stream or produced as an oxidation by-product, will have an adverse affect on the conductivity reading. Even though separation membranes are used to minimize interferences, halogenated organic compounds or chloramines will produce molecules small enough to pass through. Ozone, used for sterilization, renders erroneous measurements for conductivity-based TOC analyzers and remains in the water system for up to 48 hours.

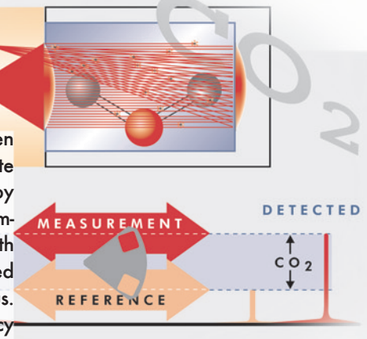




Meeting the USP/EP regulations involves three tiers: system calibration, USP/EP system suitability validation and a test solution (sample) limit test. An automated system calibration and validation at your choosen intervals, day of week and time of day, assures an accurate TOC measurement. In addition a manual multi-point calibration can optimize accuracy.

The USP/EP system suitability validation is easy to perform with intuitive step-by-step instructions, reporting the response efficiency percentage in less than 40 minutes. These first two tiers are the fundamental basis required to perform the test solution limit test.

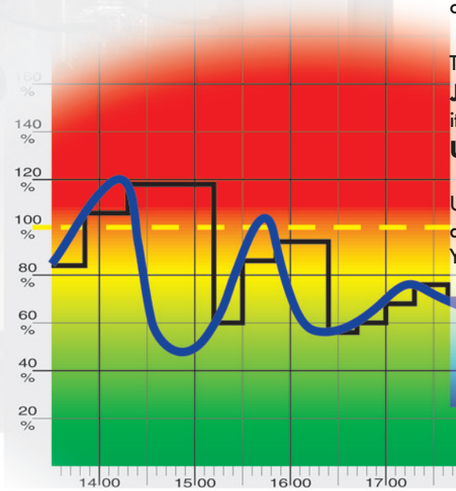
The direct proportional relationship between organic carbon and CO_2 requires a surrogate detection technique not prone to interference by any sample stream condition such as conductivity, pH, temperature or any other substance. This is accomplished with the well-established CO_2 specific non-dispersive infrared (NDIR) detector system installed in the autoTOC 1950plus. A proven technology providing superior analysis accuracy and reproducibility in a reliable system that is economic to operate. Unlike conductivity sensors, the NDIR detector calibration is performed with NIST traceable calibration standards in the range of operation. The CO_2 NDIR detector based TOC analysis method is preferred by ASTM, EN, EPA, ISO and Standard Methods.



Indirect and direct conductivity TOC measurements are batch type analysis methods that can experience reporting intervals of up to 60 minutes. The higher the TOC concentration, the longer the analysis interval. The more you depend on the measurement the less it becomes available. The 1950plus is the only continuous on-line TOC analyzer on the market today.

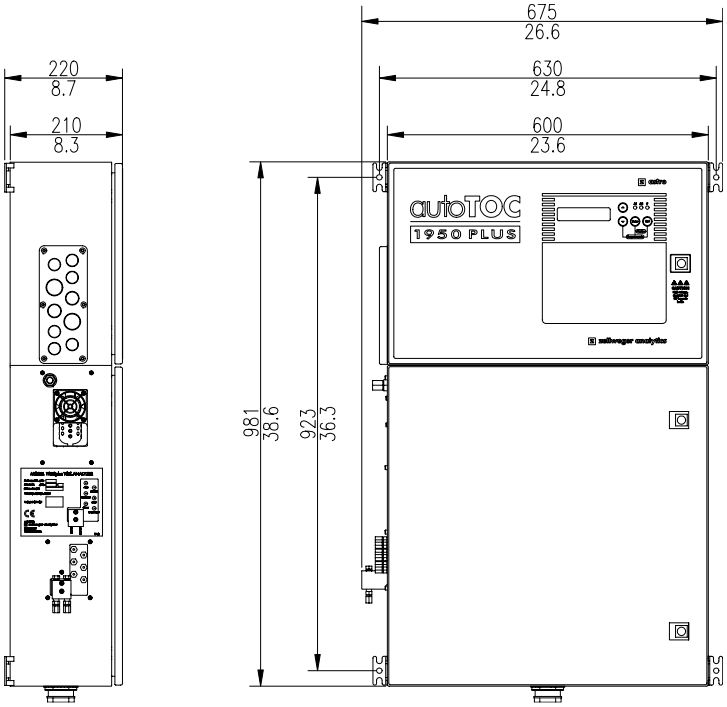
The 1950plus software features the **USP/EP WATER JUDGE** providing a continuous and instant water quality evaluation. Based on USP/EP sample limit test, the **USP/EP WATER JUDGE** reports pass or fail.

Ultimately, the difference made by a continuous, accurate analysis you can react to, shows up on your bottom line. You be the judge.



astro

SPECS



Operation

Analysis method: UV/Persulfate oxidation with acid sparging for TIC removal, followed by CO_2 NDIR detector measurement

Measurement range: 0–2 / 5 mg/l TOC
Process Control Range: 0–200 % USP Limit Test Pass/Fail Monitoring

Response time: T90 ≤ 5 minutes *

Performance specifications established with range configuration 0–5000 µg/l (0–5 mg/l) and determined at measured value:

Accuracy/Repeatability/Linearity:
≤ ± 4 % or 8 µg/l (whichever is greater) *

Method Detection Limit per EPA Appendix B to Part 136: ≤ 0.005 mg/l at range 0–5 mg/l *

Signal drift (60 days): < 2% with auto clean and auto calibration *

Ambient temperature: 5–40°C (41–104°F)

* At 25°C (77°F)

Enclosure

Cold rolled steel epoxy powder coated IP56 (NEMA 4)
Optional stainless steel IP56 (NEMA 4X)

Weight: 54 kg (120 lb)

User connections

5 function mapped alarm relays,
3 A @ 250 VAC / 0.5 A @ 30 VDC

2 parameter mapp. 4–20 mA analog outputs

1 multi-function RS232 serial port

Samples

Single-stream, fast loop inlet
(optional: Dual-stream or multi-stream sequencer for up to 6 streams)

Inlet pressure: 0.15–6 bar (2–87 psig)
Outlet pressure: ambient

Inlet temperature: 2–70°C (36–158°F) at a flow rate of 25-200 ml/minute

Extended Inlet temperature: 2–100°C (36–212°F) with a 3000 mm (120 in) long, 6 mm (1/4 in) O.D. stainless steel sample inlet tube at a flow rate of 25–60 ml/minute

Electrical connections

115 or 230 VAC, 50/60 Hz, 500 VA

Carrier gas

Clean, CO_2 free air or Nitrogen at 2.8–6.2 bar (40–90 psig)

INTERNATIONAL H.Q.

Zellweger Analytics S. A.
33 Rue du Ballon
F-93165 Noisy-le-Grand / CEDEX
France
Tel: ++ 33 (1) 48 15 80 80
Fax: ++ 33 (1) 48 15 80 00

U.S. H.Q.

Zellweger Analytics, Inc.
100 Park Avenue
League City, TX 77573
USA
Tel: ++ 281 316 7700
Fax: ++ 281 316 7800