

Pharmaceutical Purified Water

Perspectives in Pure Water Analytics



6 News

THORNTON

Leading Pure Water Analytics

Purified Water for emergency eye wash stations

An emergency eye wash manufacturer incorporates USP Purified Water in its portable eye wash stations. The on-line 770MAX analyzer with the 5000TOC Sensor helps assure consistent performance and quality of their product.

Fendall's decision for TOC and conductivity analysis

The Fendall Company, located in Platteville, Wisconsin, is the world leader in portable emergency eye care products, and they are the designer and producer of the first self-contained, gravity-fed emergency eye wash station. When they decided to purchase a TOC and conductivity analysis system for continuous monitoring of their on-site USP (US Pharmacopoeia) Purified Water production system, Fendall turned to their water analysis equipment suppliers, Mettler-Toledo Thornton, Inc. of Bedford, Massachusetts and Total Water Treatment, Inc. of Madison, Wisconsin for the right solution.

USP compliance and lower maintenance

According to Ron Geil, Director of Operations for the Fendall Company, they specified the 770MAX Multiparameter Analyzer, 5000TOC Total Organic Carbon Sensor and Conductivity sensor since these instruments meet the requirements for measuring USP (643) Total Organic Carbon and USP 645 Water Conductivity. With the THORNTON system, Fendall can confirm that their water treatment facility is in compliance with USP Purified Water requirements. Plus, the USP grade water provided in their eye wash stations allows Fendall to age-date their products, thereby providing lower maintenance costs for their customers and gives Fendall a clear advantage over other systems on the market. Joseph Oravetz of Total Water



METTLER TOLEDO

PAT initiatives are driving the industry forward for higher product quality

Recent developments in TOC monitoring of on-line instruments to fulfill the USFDA's goal of increasing manufacturing efficiency.

PAT initiative

In recent months, the use of PAT (Process Analytical Technology) terminology has consumed the vocabulary of Pharmaceutical professionals. At its core, the PAT initiative is designed to address manufacturing-related quality issues in the Pharmaceutical industry by encouraging process innovation. Admittedly, this is no easy task in a typically risk-adverse industry, but, with the innovations presented by PAT, pharmaceutical manufacturers are rapidly embracing it as a means of increasing efficiency and profitability. And the on-line Total Organic Carbon (TOC) monitoring process is no exception. Increasingly, Pharmaceutical manufacturers are taking a hard look at the viability of laboratory TOC testing relative to labor costs, sample contamination, etc. and comparing it to continuous, on-line monitoring. They are quickly coming to the conclusion that the benefits of on-line monitoring far outweigh the lab methods in speed of response, coupled with the ability to trend the data and control the variability in the production process. Further, today's lower cost per station for on-line TOC monitoring also enables companies to monitor many more points in the process rather than taking one measurement at the end of the production line.

PAT principles for TOC measurements

Clearly, the PAT initiative has caused a major shift from finished-product testing to in-process testing as a means of evaluating final product quality. Although the ter-



770MAX and 5000TOC sensor connected to water system.

Treatment noted that they designed a water purification system for Fendall to include continuous monitoring capability with on-line measurements in a compact, reliable package. That's where the 770MAX Multiparameter Analyzer and the 5000TOC and conductivity sensors came in. The 770MAX analyzer can accept simultaneous inputs from a variety of Thornton sensors, so the 5000TOC and conductivity sensors were quickly and easily installed on the water treatment system.

Fendall's confidence

Ron Geil confirms that the THORNTON system provides Fendall the confidence that Purified Water quality criteria are being met while alerting plant personnel well in advance of any routine maintenance requirements. This allows Mettler-Toledo Thornton Inc. to be part of Fendall's company philosophy of ensuring that their products can and do make a difference in the outcome of a chemical injury to the eye.



Fendall portable emergency eye wash station.

Customer benefits at a glance

- Competitive advantage
- Possibility to age-date the product
- Lower maintenance costs
- Simultaneous inputs for a variety of sensors
- Easy installation

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and TOC measurements for quality and profitability

ing technology help advance the use
S FDA's PAT initiative while increas-

minology used in PAT may be new and unique, the Pharmaceutical industry is already very familiar with the continuous monitoring processes for water quality parameters (some suggest it may even be one of the original examples of PAT). Indeed, this industry has monitored conductivity for many years and has employed numerous measurement points along the production process. However, with the advent of new TOC monitoring technology, it is now possible to apply PAT principles for TOC measurements while improving the bottom line, and THORNTON's new 5000TOC Sensor with the 770MAX Multi-parameter Analyzer helps meet this need.

Real-time TOC measurements

The new TOC technology in the 5000TOC Sensor allows continuous monitoring in a real-time environment, thus enabling the end-user to more finely tune their production process and provide immediate feedback regarding the condition of the water loop. Let's look at one example. Current versions of older "batch" type instruments (green line) can take considerable amounts of time to produce results (anywhere from 5 to 30 minutes) while continuous measurements (blue line) provide a steady stream of pharmaceutical water system status information yielding much faster responses to changes in conditions.

Further, the TOC monitoring process can be quickly and easily verified, lending validity to the measurements in-process rather than at the final point of production. This validation process represents

ongoing assurance that the measurements obtained from the TOC sensor accurately represent the analyzed sample.

Return on investment

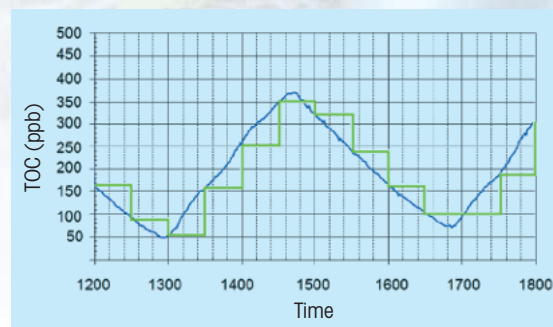
Ultimately, these improvements lead to rapid return on investment over off-line lab sampling methods through the following:

- Reducing production cycle times
- Improving efficiency by managing product variability
- Preventing rejects, scrap, and re-processing
- Increasing automation and reducing human errors
- Facilitating continuous quality enhancements that yield positive relationships with regulatory agencies

While PAT can appear intimidating at first glance, it is clear that the Pharmaceutical industry has already benefited from many of the concepts incorporated in PAT, and the 5000TOC Sensor and 770MAX can help you maximize PAT's benefits.

FDA on PAT (Process Analytical Technology):

PAT is a system for designing, analyzing and controlling manufacturing through timely measurements of critical quality and performance attributes of raw and in-process materials and processes with the goal of ensuring final product quality



Real-time TOC measurement (blue)
versus older "batch" type measurement (green).

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Training and Technical Services

On-site instrument operation and calibration training workshops

THORNTON's Operator Training Courses are tailored to each customer's requirements. The course is conducted in a classroom setting where interaction between instructor and participants is encouraged. Each attendee is supplied with material detailing the course content. Instruments are provided for hands-on participation. The areas covered in this training program focus on THORNTON instrumentation, calibration, and maintenance specific to your facility. Additional technical topics may be added or substituted as requested.

Traceable instrument calibration

THORNTON offers instrument calibration and validation services traceable to national standards, industry guidelines

and/or regulatory requirements. Services using factory-trained technicians are available at our facilities in Bedford, Massachusetts or on-site at your location. Each calibrated/validated instrument is supplied with the appropriate calibration documents.

Specialized conductivity calibrations

Choose one of seven unique conductivity calibrations to fit your application needs, from standard calibrations to customer-specified temperature and ASTM verification points. System calibrations are also available where the instrument and sensors are calibrated together optimizing system accuracy.

Service and calibration contracts

A THORNTON representative will provide on-site service for items covered under the agreement. These services include, but are not limited to:

- Calibration/validation of instrument and sensor system
- Issuance of appropriate documentation
- Identification and verification of all software revisions
- Minor repairs or adjustment of instruments at a discounted labor rate
- Installation and validation support services
- TOC test services
- On-Site System Suitability Testing

| Tradeshows | Location | Dates January to June 2006 |
|------------------|-----------------------|----------------------------|
| SPWCC | Santa Clara, CA, USA | February 13 – 15 |
| Interphex PR | San Juan, Puerto Rico | February 16 – 17 |
| SEMI – China | Shanghai, China | March 21 – 23 |
| Interphex East | New York, NY, USA | March 21 – 23 |
| SEMICON – Europa | Munich, Germany | April 4 – 6 |
| UPW – PA | Philadelphia, PA, USA | April 10 – 11 |

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