
Achieving ROI from ozone sanitizing

Advantages of the ORBISPHERE C1100 ozone sensor system

Ozone is an extremely fast and efficient oxidizer commonly used as a microbial disinfectant in pharmaceutical grade water systems.

The main benefits of ozone as a disinfectant include the following facts:

- Ozone is extremely efficient, acting 3,000 times faster than chlorine
- Ozone is easily removed after the disinfection process is complete
- Ozone reduces residual TOC levels
- Ozone inherently reduces endotoxin levels
- Ozone oxidizes inorganic materials (nitrites, sulfides, etc.)

As a result, ozonation of pharmaceutical water systems is now the preferred method for disinfection by a number of leading pharmaceutical manufacturers.

Achieving return-on-investment from ozone sanitizing

The primary financial advantage of using ozone for sanitization is the reduced duration of required sanitization cycles, enabling pharmaceutical manufacturers to get the most up-time and flexibility from the water system.

However, to realize a successful return-on-investment in an ozone sanitizing system, the efficacy and speed of the ozonation process must be demonstrated.

To do this, accurate and reliable measurement of the ozone sanitization level reached during the sanitization process is critical.



Since ozone has a very short half-life, decaying rapidly as it is drawn through the water sampling system; an accurate measurement can only be achieved if the ozone sensor measures directly into the water system, avoiding the uncertainties introduced by off-line or extractive sampling.

The ORBISPHERE C1100 ozone sensor is uniquely designed to work effectively at elevated and fluctuating sample water pressures so that it

may be placed into the pipe directly in contact with the ozonated water.

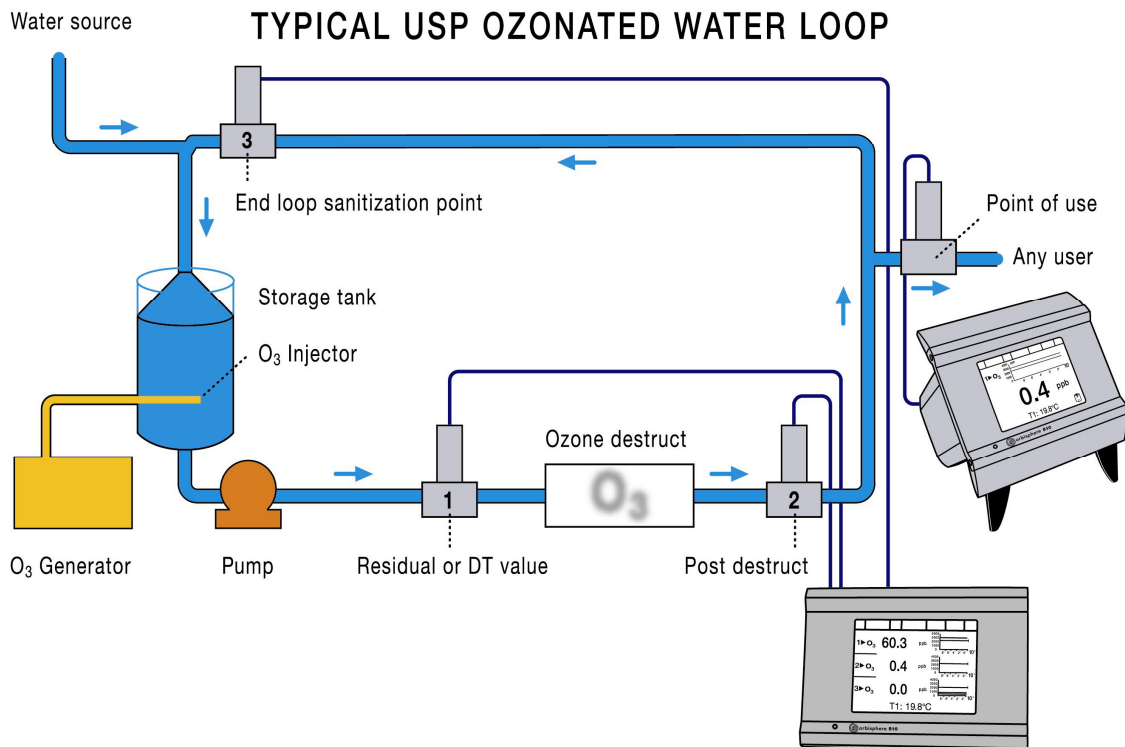
This direct in-line sampling is facilitated using the ORBISPHERE C1100 self-sealing 'ProAcc' valve, combined with Varivent™ housing, as shown left.

Regulatory mandate

The United States Food and Drug Administration (FDA) considers residual ozone to be an “added substance” and the United States Pharmacopeia (USP) clearly states that water for injection (WFI) shall contain “no added substance.”

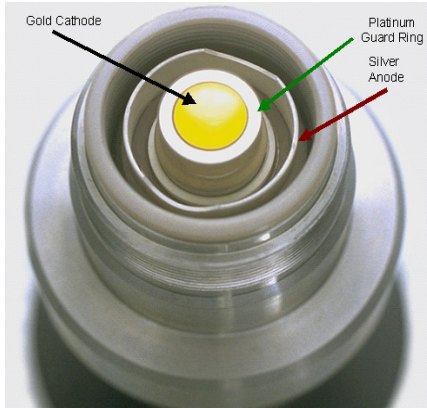
In order to meet this regulatory requirement, it is necessary to demonstrate that ozone used for disinfection has been completely removed. Furthermore, for purified water (PW) used in manufacturing, it is also necessary to demonstrate complete removal of the ozone, unless the manufacturer wishes to list ozone as an ingredient in the finished product.

Therefore, ozone levels should always be monitored pre- and post-UV destruct. In addition, to ensure and demonstrate the efficacy of the ozonation process, ozone should also be monitored at the end of the water distribution system as shown below:



Lowest detection limit

To meet the demanding requirements of post-UV destruct ozone analysis, the ORBISPHERE C1100 ozone sensor employs a unique three-electrode design consisting of a silver anode, gold center cathode and a platinum guard ring (shown left).



These pure metal electrodes are highly refined, and offer the best signal-to-noise ratio in the industry. With a signal detection limit in picoamps, the ORBISPHERE C1100 ozone sensor has the best detection limit at better than 1 ppb DO₃.

This level of performance is critical in post-destruct ozone measurements to demonstrate that the ozone has been completely removed.

Most reproducible measurement

The three electrode design also results in a much more stable measurement than systems employing only two electrodes. With a fixed zero measurement, and less sample-to-sample fluctuation, the detection limits are greatly improved, allowing for a more reproducible and more sensitive measurement than competitive systems.

Furthermore, the ORBISPHERE precision-machined sensors are more reproducible than plastic molded sensors that may deform during heating and cooling cycles. As a result, more consistent results may be expected between different ORBISPHERE sensors than can be achieved with competitive systems.

Fastest response time

In addition to improving sensor stability, the function of the platinum guard ring is also to stop non-specific ozone interactions at the cathode. Only the representative sample ozone impinging directly at the cathode membrane interface is analyzed.

As a result, the guard ring electrode reduces signal noise from both dissolved O₂ and dissolved O₃ in the electrolyte reservoir. This improves response time because there is no lag effect of dissolved gases in the electrolyte.

Lowest cost of ownership

In addition to improving the reproducibility and response time of the measurement, the platinum guard ring also serves to protect the cathode surface from ozone interactions that are not specific to the measurement.

The guard ring acts as a barrier, protecting the cathode not only from ozone in the electrolyte, but also from other potential impurities in the reservoir. By preventing non-specific ozone interactions and reducing the number of impurities that can reach the cathode surface, the useful lifetime between maintenance intervals of the sensor is greatly increased. Thus, two to five times less frequent service is required for an ORBISPHERE C1100 ozone sensor than for competitive systems, resulting in a lower long-term cost of ownership for the system.

Easiest calibration

The ORBISPHERE C1100 dissolved ozone sensor is the only system that can be calibrated using the atmosphere as the calibration standard. Unlike competitive systems that require calibration against a wet chemical test run on a grab sample, the ORBISPHERE system may be very accurately calibrated using an automated process by exposing the sensor to the atmosphere.

Advantages of this method are convenience, speed, and independence from fluctuating ozone concentrations. Furthermore the integrated air calibration is the only method that is truly NIST-traceable.

21 CFR Part 11

The ORBISPHERE C1100 ozone sensor system includes software that supports 21 CFR Part 11 compliance. In addition, multiple communication options (RS485, Profibus DP, Ethernet and USB), diagnostic tools that help in preventative maintenance planning, and IP65 stainless steel transmitters, create a system that is compatible with pharmaceutical process environments.

Conclusion

The ORBISPHERE C1100 ozone sensor system is clearly the performance leader in ozone analysis for pharmaceutical water systems. The system provides many key advantages including:

- In-process mounting for accurate ozone sensing
- Lowest method detection limits
- Highest reproducibility
- Fastest response time
- Lowest serviceability costs
- Easiest calibration

Choosing an ORBISPHERE ozone analysis system will enable pharmaceutical manufacturers to realize the return-on-investment manufacturers are seeking from deploying an ozone sanitization system and will provide the lowest long-term cost of ownership of any ozone analysis system currently available today.