

Hydrogen Peroxide (H₂O₂) Gas Concentration Analyzer

PHARMACEUTICAL



- Continuously measures sub-ppb levels of H₂O₂
- Built-in software to comply with 21 CFR Part 11
- Patented cavity ring-down spectroscopy (CRDS) technology
- Infrequent maintenance
- No wet chemistry or consumables required

The **Picarro PI2114 gas concentration analyzer** ensures ultra-low residual hydrogen peroxide levels to help avoid oxidation and safeguard drug stability in isolated GMP pharmaceutical manufacturing applications. High-potency API and biologics manufacturing and aseptic fill and finish require sterile, isolated production environments. Vaporized hydrogen peroxide (vHP) is widely used for sterilization and decontamination. But if the residual hydrogen peroxide level remains too high after decontamination and aeration, the drug product can oxidize and degrade.

The Picarro PI2114 gas concentration analyzer can continuously measure hydrogen peroxide (H₂O₂) levels as low as 3 ppb, with precision better than 1 ppb. The analyzer is optimized for GMP applications. Installation

and operation qualification is quick and easy, as is validation with commercially available surrogate gases.

The PI2114 analyzer includes built-in software to comply with 21 CFR Part 11 for clinical and commercial manufacturing. And it can be configured to automatically output measurement data in digital format or through optional analog outputs to a SCADA control system or data logging device.

Operating the PI2114 analyzer is easy and inexpensive. It does not require wet chemistry or consumables. Patented Picarro cavity ring-down spectroscopy (CRDS) technology has no moving parts and incorporates wavelength monitoring. This provides long-term stability and reliability, for infrequent calibration and maintenance.

PI2114 Performance Specifications	H ₂ O ₂
Precision (1σ, 10 sec/300 sec) @ 1 ppm [H ₂ O ₂]	3 ppb/1 ppb
Lower Detection Limit (300 sec, 3σ)	<3 ppb
Accuracy	±5% of reading
Zero Accuracy (1 year)	-5 ppb/+10 ppb
Measurement Range	0–100 ppm
Measurement Interval	~10 sec
Response Times @ 1 ppm [H ₂ O ₂]	Fall Time (90–10%): <1 min Rise Time (10–90%): <1 min

PI2114 System Specifications	
Measurement Technique	Cavity Ring-Down Spectroscopy
Measurement Cell Temperature Control	±0.005°C
Measurement Cell Pressure Control	±0.0002 atm
Sample Temperature	-10 to 45°C
Sample Flow Rate	<1 slm at 760 Torr, no filtration required
Sample Pressure	300 to 1000 Torr (40 to 133 kPa)
Sample Humidity	<99% R.H. non-condensing @40°C, no drying required
Temperature	10 to 35°C (operating) -10 to 50°C (storage)
Ambient Humidity	<99% R.H. non-condensing
Other Gases Measured	H ₂ O, CH ₄
Accessories	Pump (external, included), keyboard & mouse (included), LCD monitor (optional)
Communication Interfaces	RS-232, Ethernet, USB, analog 4-20mA
Fittings	1/4" Swagelok® PFA Fittings
Dimensions	17" w x 8.38" h x 21" d (43.2 x 17.9 x 53.3 cm) including feet, not including small external pump module, 7.5" w x 4" h x 11" d (19 x 10.2 x 28 cm)
Weight	73 lbs (33.2 kg) including pump
Power Requirements	100–240 VAC, 47–63 Hz (auto-sensing), <260 W start up (total): 110 W (analyzer), 35 W (pump) at steady state
Certifications	CE Mark, CDRH, 21 CFR Part 11 Compliant
Country of Manufacture	USA
System Validation	Includes software wizard for analyzer validation using CH ₄ as surrogate gas standard