

# Hydrogen Peroxide (H<sub>2</sub>O<sub>2</sub>) Gas Concentration Analyzer

Continuous Monitoring for Sterilization  
& Bio-Decontamination Processes

# PICARRO



Avoid Oxidation of Sensitive Pharmaceuticals!

- Continuously measures parts-per-billion (ppb) levels of H<sub>2</sub>O<sub>2</sub>
- Built-in software to comply with electronic records regulations
- Aeration cycle real time monitoring
- Infrequent maintenance, no wet chemistry or consumables required

## Safeguard Sensitive Biologics Throughout the Production Cycle

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. Production environment decontamination with vaporized hydrogen peroxide (VHP) has become the industry standard. While VHP technology offers many performance and safety benefits, residual hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) can easily oxidize pharmaceutical products. Biologic products can be especially vulnerable, often showing significant oxidation even when exposed to low levels of H<sub>2</sub>O<sub>2</sub> (ppb range).

The Picarro PI2114 analyzer can continuously measure H<sub>2</sub>O<sub>2</sub> 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 built-in software of the PI2114, designed to assist with 21 CFR part 11 compliance, offers strict regulations on electronic records, time stamps and audit trails. Combined with detailed validation reports, software and system documentation, the PI2114 offers comprehensive and tightly controlled data management software that complies with pharmaceutical and commercial manufacturing regulations.

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 providing long-term stability and reliability plus infrequent calibration and maintenance.

PI2114 Performance Specifications	Specifications**
<b>Precision (1σ, 10 sec)</b> <b>Precision (1σ, 300 sec)</b>	<3 ppb + 0.1% of reading <1 ppb + 0.1% of reading
<b>Lower Detection Limit (3σ, 300 sec)</b>	<3.0 ppb
<b>Zero Drift* (72 hours)</b> <b>Zero Drift (1 month)</b>	±2.5 ppb -5 ppb/+10 ppb
<b>Accuracy</b>	±5% of reading
<b>Measurement Range</b>	0–100 ppm
<b>Measurement Interval</b>	~10 sec
<b>Response Time</b> (Rise/Fall Time 10–90% / 90–10%)	<1 min

\* Picarro analyzers do not require a zero reference gas or zero cartridge to operate or meet specifications.

\*\* Specifications and an instrument-specific testing report (Certificate of Compliance) provided with every analyzer purchase.

## 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 <sub>2</sub> O, CH <sub>4</sub>
Accessories	Pump (external, included), keyboard & mouse (included), LCD monitor (optional)
Communication Interfaces	RS-232, Ethernet, USB, analog 4-20mA, Modbus
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
Country of Manufacture	USA
System Validation	Includes software wizard for analyzer validation using CH <sub>4</sub> as surrogate gas standard

## Software and User Accounts Regulations

Regulations Features	Not Signed In	Picarro Sign In	Operator	Technician	Administrator
<b>Config Menu/Settings</b> (requires additional sign in to access validation or user admin)		✓			
<b>View Data Viewer</b>	✓		✓	✓	✓
<b>Change Displayed Data</b>		✓	✓	✓	✓
<b>Quit Measuring</b>			✓	✓	✓
<b>Configure 4-20mA Output</b>		✓			
<b>H<sub>2</sub>O<sub>2</sub> Validation</b>				✓	✓
<b>Change displayed data</b> (full access)					✓
<b>User Administration</b>					✓

## PI2114 Validation Report

**Picarro PI2114 Validation Report**

**Analyzer:** [REDACTED]

**Operated by:** (username: admin)

**Start Time:** 2020-08-26 09:36:27 (GMT+800)

**Signed by:** (username: admin)

**Signature Time:** 2020-08-26 10:45:21 (GMT+800)

**Summary**

	Acceptance criteria	Result	Status
Zero H <sub>2</sub> O <sub>2</sub>	>=5ppb and < 10ppb	-1.255 ppb	Pass
CH <sub>4</sub> slope	> 0.25 and < 1.05	0.988988	Pass
Calibrant 1 CH <sub>4</sub>	< 5% (7.058 ± 0.3528 ppm)	1.77% (8.931 ppm)	Pass
Calibrant 2 CH <sub>4</sub>	< 5% (50.88 ± 2.544 ppm)	1.28% (50.227 ppm)	Pass
Calibrant 3 CH <sub>4</sub>	< 5% (100.4 ± 5.02 ppm)	1.10% (99.291 ppm)	Pass

**Details**

Step	Zero Air	Calibrant 1	Calibrant 2	Calibrant 3
Internal cylinder ID	cylinder1	cylinder2	cylinder3	cylinder4
Certified CH <sub>4</sub> (ppm)	N/A	7.058±2.0%	50.88±2.0%	100.4±2.0%
Allowed CH <sub>4</sub> Tolerance (ppm) (certified ± 5%)	0±1	6.7032 - 7.4088	48.336 - 53.424	95.36 - 105.42
Observed average CH <sub>4</sub> (ppm)	0.009	6.931	50.227	99.291
CH <sub>4</sub> SD (ppm)	0.0936	0.1113	0.1172	0.1225
CH <sub>4</sub> deviation (%) (certified - observed)	N/A	1.771	1.284	1.104
Observed H <sub>2</sub> O (ppb)	-1.255	-1.656	-3.070	-4.661
Observed H <sub>2</sub> O (%)	0.002	0.003	0.001	0.001

CH<sub>4</sub> slope: 0.988988 CH<sub>4</sub> R<sup>2</sup>: 0.999990  
 CH<sub>4</sub> intercept (ppm): 0.034 Zero air CH<sub>4</sub> (ppm): 0.008  
 H<sub>2</sub>O<sub>2</sub> equivalent (ppb): 0.48 H<sub>2</sub>O<sub>2</sub> measured zero (ppb): -1.255

**PICARRO**

© 2021 PICARRO, INC.  
41-0030 Rev. C

LIT CODE: PI2114-DS18-V1.5-210212

3105 Patrick Henry Drive, Santa Clara, CA 95054 | 408-962-3900 | sales@picarro.com | picarro.com