

FMS-Oxygen Headspace Analyzer

SYSTEM SPECIFICATIONS

The FMS-Oxygen Headspace Analyzer is a non-destructive gas analyzer for monitoring headspace oxygen concentration in sealed parenteral containers. This compact benchtop analyzer utilizes a patented laser absorption technique developed with funding from the Food and Drug Administration. Light from a near-infrared laser is tuned to match an internal absorption frequency of the oxygen molecule and passed through a container in the headspace above the product. The amount of laser light absorbed is proportional to the oxygen concentration in the headspace. This non-destructive measurement method allows for the rapid analysis of 100% of product.

Benchtop systems are used for at-line process

monitoring and laboratory applications. Systems can be mounted on carts and wheeled from line to line for in-process monitoring and troubleshooting activities or be permanently situated in laboratories for product development, release testing, and QC investigations.

Applications include:

- Leak detection
- Container closure integrity studies
- IPC monitoring of oxygen levels during the filling of oxygen-sensitive product
- Optimization and validation of purging systems on filling lines
- Oxygen degradation studies
- Stability trends, end-of-shelf life studies

NOMINAL SPECIFICATIONS

Measurement Range	0 to 25% Oxygen
Measurement Time	1 second
Container Sizes	1 to 2000 mL
Container Compatibility	Tubing or molded; amber or clear

PHYSICAL AND ELECTRICAL

Dimensions (WxDxH)	30.5 x 30.5 x 29.2 cm (12"x12"x11.5")
Weight	13.6 kg (30 lbs)
Power Requirements	110-240 VAC, 50/60 Hz, 60W
Controller	PC



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PERFORMANCE DATA

Performance Data

Six 10 mL clear glass vials were prepared with known oxygen concentrations of 0, 1, 2, 4, 8, and 20.1% with a balance of nitrogen. The empty vials were evacuated, back filled with known certified oxygen gas mixtures, and flame sealed for stability. The oxygen concentration in each of these certified oxygen vial standards was measured one hundred times using the FMS-Oxygen Headspace Analyzer. The FMS-Oxygen analyzer measures the absorption of laser light by oxygen molecules in the container headspace. The amplitude of the absorption signal is proportional to the oxygen concentration. The mean mea-

sured oxygen concentration and standard deviation were calculated for each of the six standards and are presented in Table 1 along with the minimum and maximum of the 100 measurements. Figure 1 is a plot of the measured versus known oxygen in each vial. The non-destructive nature of the measurement enables a full statistical documentation of system performance. From an application point-of-view, the non-destructive measurement enables multiple measurements on the same sample over time (over the full shelf life, for example), and 100% analysis of a batch giving insight into process variability and optimization.

KNOWN OXYGEN (% O ₂)	MEASURED OXYGEN (% O ₂)	ST DEV (% O ₂)	MIN (% O ₂)	MAX (% O ₂)
20.00	19.97	0.05	19.88	20.07
8.00	7.98	0.05	7.87	8.09
4.00	3.98	0.04	3.87	4.10
2.00	1.99	0.05	1.88	2.17
1.01	1.02	0.05	0.93	1.15
0.00	0.05	0.03	0.00	0.14

Table 1. Performance data-10mL clear tubing vial (22mm diameter) -- N=100

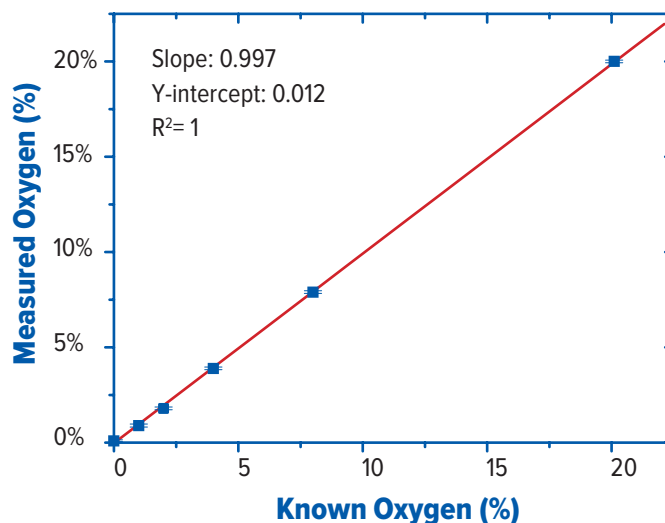


Figure 1. Plot of Measured Oxygen vs. Known Oxygen with linear regression fit

