

FMS-Carbon Dioxide Headspace Analyzer

SYSTEM SPECIFICATIONS

The FMS-Carbon Dioxide analyzer is a non-destructive gas analyzer for monitoring carbon dioxide headspace pressure in sealed parenteral containers. This compact 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 carbon dioxide and is passed through the headspace above the product. The amount of laser light absorbed is proportional to the carbon dioxide concentration in the headspace. This measurement method allows for the rapid analysis of 100% of product. 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:

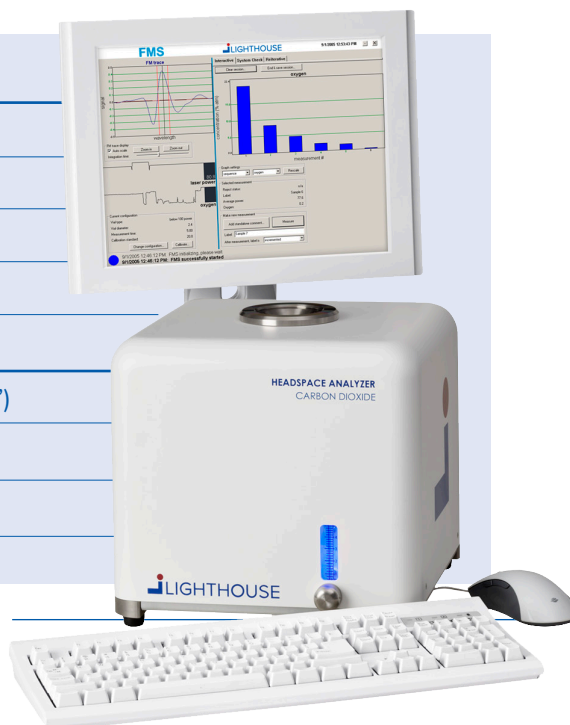
- Analytical media fill inspection
- Detection of microbial growth in sterile containers
- Container closure integrity studies
- Monitoring of vials stored on dry ice
- Optimization and validation of purging systems on filling lines
- IPC monitoring of CO₂ levels during the filling of CO₂ purged products

NOMINAL SPECIFICATIONS

Measurement Range	0 to 760 torr
Measurement Time	5 seconds
Container Sizes	1 to 100 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 of the system for measuring carbon dioxide in the headspace was assessed using a set of standards filled with 7.6, 15.2, 30.4, 60.8, and 152 torr of carbon dioxide. The standards were made from a 10mL vial that is 23mm in diameter. The empty vials were evacuated, backfilled with known NIST certified carbon dioxide mixtures, and flame sealed. The FMS-Carbon Dioxide analyzer measures the absorption of laser light by carbon dioxide in the container headspace. A mean CO₂ pressure, standard deviation, maximum reading and minimum reading were determined from the data set and are displayed in Table 1. Figure 1 shows a linearity plot for the

carbon dioxide data in Table 1. The non-destructive nature of the measurement enables a full statistical documentation of system performance. From an application perspective, the non-destructive measurement enables multiple measurements on the same container over time, even over the entire shelf life. Because carbon dioxide is a byproduct of microbial growth, the FMS-Carbon Dioxide analyzer can be used to monitor microbial growth in sealed containers. In addition the FMS-Carbon Dioxide analyzer can be used for 100% analysis of a batch, providing insight into process variability and allowing for optimization.

ACTUAL (TORR)	MEAN (TORR)	ST DEV (TORR)	MIN (TORR)	MAX (TORR)
7.6	7.4	0.2	7.2	7.5
15.2	14.4	0.3	14.2	14.8
30.4	29.6	0.0	29.6	29.7
60.8	59.3	0.2	59.1	59.6
152.0	146.8	0.0	146.8	146.9

Table 1. Performance data-10mL clear tubing vial (23mm diameter)

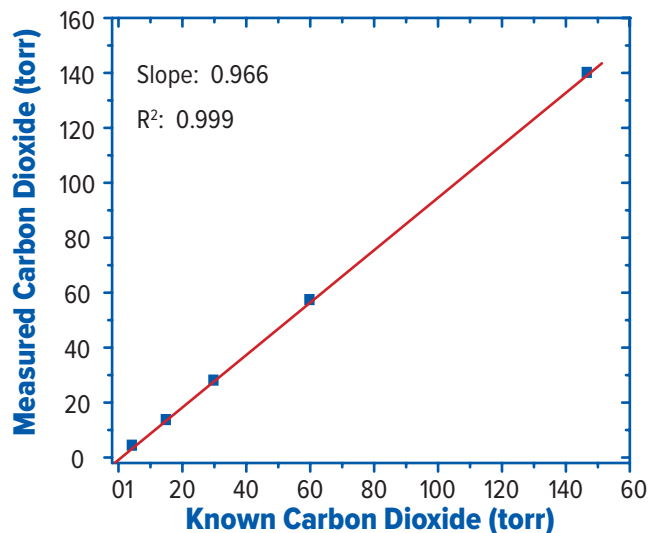


Figure 1: Linearity of pressure measurements on a 10mL vial