

FMS-Moisture/Pressure Headspace Analyzer

SYSTEM SPECIFICATIONS

The FMS-Moisture/Pressure analyzer is a non-destructive gas analyzer for simultaneously monitoring moisture partial pressure and total 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 the water molecule and passed through a container in the headspace above the product. The amount of laser light absorbed is proportional to the water vapor concentration in the headspace, while the width of the absorption signal is related to the headspace pressure. This mea-

surement 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:

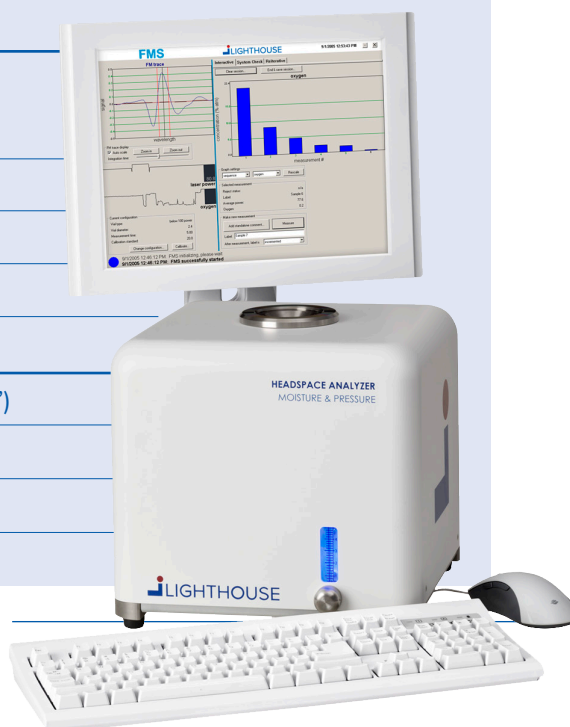
- Vacuum leak Detection
- Container closure integrity studies
- Lyo moisture determination
- Freeze dryer validation, cycle optimization,
- Stability trends, end-of-shelf life studies
- Water vapor permeability studies

NOMINAL SPECIFICATIONS

| | |
|-------------------------|---|
| Measurement Range | 0 to 1.0 atm (Total Pressure) 0 to 25 torr (Moisture Pressure) |
| 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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PRESSURE PERFORMANCE DATA

Performance of the system for measuring total headspace pressure was assessed using a set of pressure standards filled with 0, 30, 60, 90, 190, 380, 600 and 700 torr of nitrogen. The standards were made from a 10mL vial that is 22mm in diameter. Each standard was measured 100 times with the FMS-Moisture/Pressure Headspace Analyzer. The FMS-Moisture/Pressure analyzer measures the absorption of laser light by water vapor molecules in the container headspace. The width of the absorption signal is related to the nitrogen pressure. A mean concentration, 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 pressure data in Table 1.

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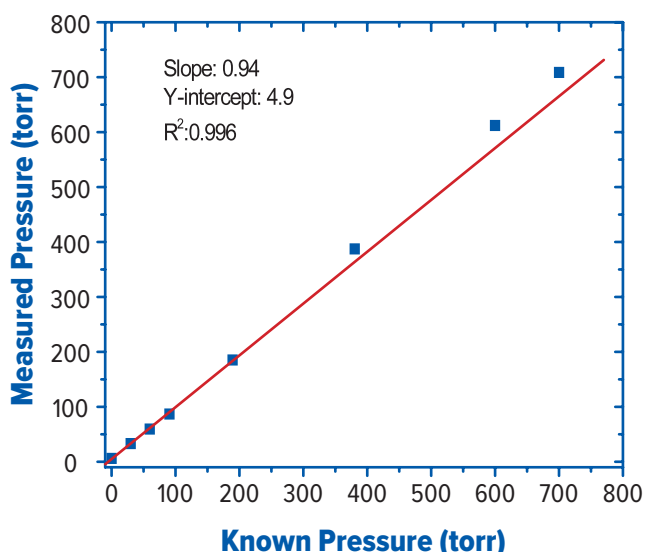


Figure 1 Linearity of pressure measurements on a 10mL vial.

| ACTUAL (TORR) | MEAN (TORR) | ST DEV (TORR) | MIN (TORR) | MAX (TORR) |
|----------------------|--------------------|----------------------|-------------------|-------------------|
| 0 | 6 | 0.2 | 5.9 | 6.4 |
| 30 | 33 | 0.2 | 32.8 | 33.3 |
| 60 | 60 | 0.5 | 58.7 | 60.4 |
| 90 | 87 | 0.3 | 86.3 | 87.4 |
| 189 | 185 | 1.7 | 182.3 | 187.3 |
| 380 | 387 | 1.8 | 385.5 | 390.8 |
| 600 | 612 | 5.5 | 602.6 | 619.6 |
| 700 | 709 | 7.7 | 690.3 | 715.2 |

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

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MOISTURE PERFORMANCE DATA

Performance of the system for measuring water vapor pressure was assessed using a set of moisture standards filled with 0.1, 0.5, 1.0, 2.1, 3.9, and 10.1 torr of water vapor. The standards were made from a 10mL vial that is 22mm in diameter. Each standard was measured 100 times with the FMS-Moisture/Pressure Headspace Analyzer. The FMS-Moisture/Pressure analyzer measures the absorption of laser light by water vapor molecules in the container headspace. The amplitude of the absorption signal is proportional to the headspace moisture. A mean concentration, standard deviation, maximum reading and minimum read-

ing were determined from the data set and are displayed in Table 2. Figure 2 shows a linearity plot for the moisture data in Table 2. 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.

| ACTUAL (TORR) | MEAN (TORR) | ST DEV (TORR) | MIN (TORR) | MAX (TORR) |
|--------------------------|------------------------|--------------------------|-----------------------|-----------------------|
| 0.1 | 0.13 | 0.004 | 0.13 | 0.14 |
| 0.5 | 0.49 | 0.005 | 0.48 | 0.49 |
| 1.0 | 0.94 | 0.004 | 0.93 | 0.96 |
| 2.1 | 2.00 | 0.006 | 1.99 | 2.04 |
| 3.9 | 3.67 | 0.012 | 3.65 | 3.71 |
| 10.1 | 9.94 | 0.027 | 9.86 | 10.00 |

Table 2. Known and Measured Moisture

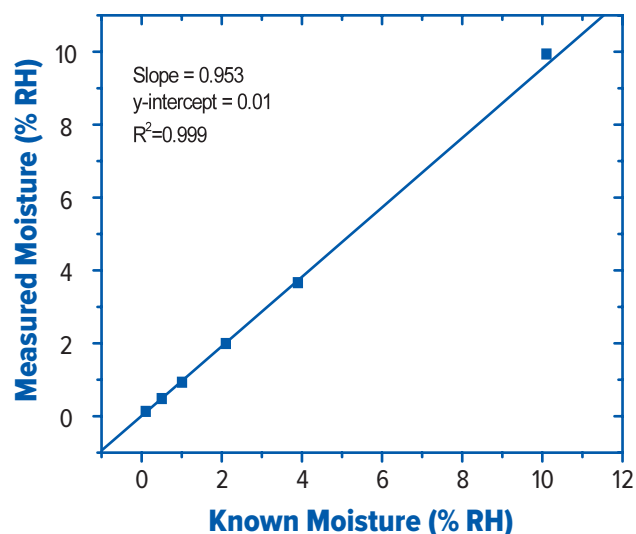


Figure 2. Linearity for moisture measurements in a 10mL vial.