

## VISTA In-Line Headspace Inspection System

### SYSTEM SPECIFICATIONS

The VISTA Headspace Inspection System is an automated in-line 100% inspection machine designed to simultaneously monitor oxygen, pressure, and moisture levels in sealed parenteral containers. VISTA characterizes the physical headspace conditions of a container in a single compact and flexible platform using a patented laser-based detection method developed with funding from the Food and Drug Administration. Light from a near-infrared laser is passed through a container in the region above the product and below the cap (headspace region). Diode laser sensors are designed to monitor the absorption wavelength of the headspace oxy-

gen and moisture molecules to determine headspace concentrations of oxygen and moisture as well as the headspace pressure. Vials that have elevated levels of oxygen, pressure, or moisture can then be identified and rejected.

#### Applications include:

- In-line 100% container closure integrity testing, vacuum leak detection
- Real-time monitoring of oxygen levels during the filling of oxygen-sensitive product
- In-line 100% moisture inspection of freeze dried vials

#### NOMINAL SPECIFICATIONS

Measurement Range	0 to 21% (Oxygen) 0 to 1.0 atm (Pressure) 0 to 30mbar (Moisture)
Throughput	200 vials per minute
Container Sizes	1 to 200 mL
Container Compatibility	Tubing or molded; amber or clear

#### PHYSICAL AND ELECTRICAL

Dimensions (HxWxD)	207 x 91 x 128 cm (6.8'x3'x4.2')
Automation Control System	PLC (AB, Siemens, Mitsubishi)
Power Requirements	208/400 VAC 3-phase, 30 Amps
Sensor Control	Microprocessor



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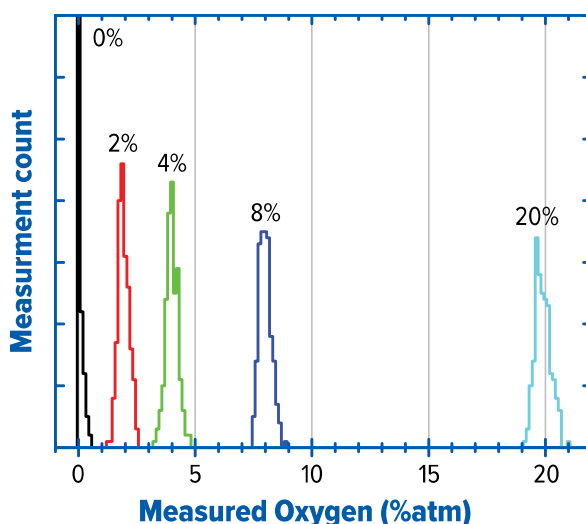
## OXYGEN PERFORMANCE DATA

Performance of an automated oxygen measuring system is assessed using a set of oxygen standards at 0, 2, 4, 8, and 20% oxygen with a balance of nitrogen at 1 atmosphere. The oxygen concentration was measured two hundred consecutive times in each of these certified oxygen vial standards using the VISTA Headspace Inspection System at a speed of 120 vials/minute. The VISTA System 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 measured oxygen concentration and standard deviation

were calculated for each of the five standards and are presented in Table 1. Figure 1 plots histograms of the 200 measurements made on each oxygen standard. The non-destructive nature of the measurement enables a full statistical documentation of system performance. In addition to measuring different concentrations, the measurement time or machine speed is an important parameter for automated applications. Performance data can be generated at different line speeds as required.

SPEED 120 VPM N=200			
ACTUAL (% O <sub>2</sub> )	MEAN (% O <sub>2</sub> )	ERROR (% O <sub>2</sub> )	ST DEV (% O <sub>2</sub> )
0.0	0.1	0.1	0.1
2.0	2.0	0.0	0.2
4.0	4.1	0.1	0.3
8.0	8.1	0.1	0.3
20.1	20.0	0.0	0.3

**Table 1. Performance data for 10mL (22mm diameter) vial.**



**Figure 1. Histograms of 200 measurements for 10mL oxygen vial standards at 0, 2, 4, 8, and 20% run at 120 vials per minute.**

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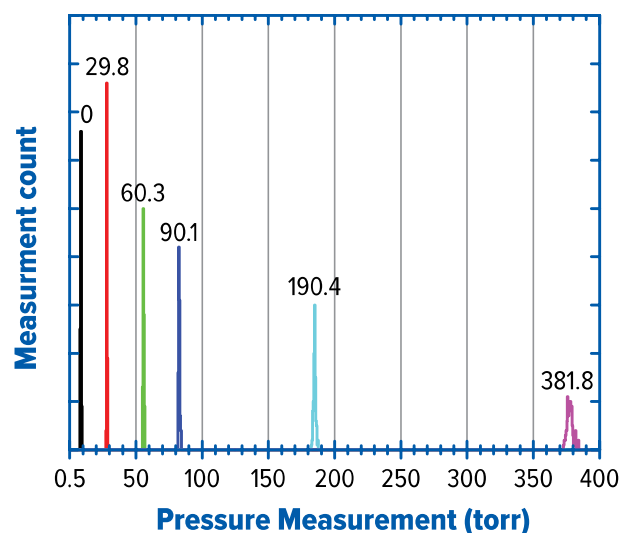
### PRESSURE PERFORMANCE DATA

Performance of an automated pressure measuring system is assessed using a set of pressure standards covering a pressure range of 0 to 700 torr. Eight 10 mL clear glass vials were prepared with known headspace nitrogen pressures of 0, 30, 60, 90, 190, 380, 600, and 700 torr. The total headspace pressure was measured one hundred consecutive times in each of these standards using the VISTA Headspace Inspection System at a speed of 150 vials/minute. The VISTA System measures the absorption of laser light by water vapor mole-

cules in the container headspace. The width of the absorption signal is related to the total headspace pressure. The mean measured headspace pressure and standard deviation were calculated for each of the eight standards and are presented in Table 2. Figure 2 plots histograms of the 100 measurements made on each pressure standard. The non-destructive nature of the measurement enables a full statistical documentation of system performance.

ACTUAL (TORR)	MEAN (TORR)	ERROR (TORR)	ST DEV (TORR)
0	9	9	0.2
30	28	-2	0.2
60	56	-4	0.4
90	83	-7	0.5
190	185	-5	0.9
382	378	-4	2.2
594	606	12	4.7
699	723	24	8.6

**Table 2** Pressure performance data for automated measurements at 150 vials per minute.



**Figure 2.** Histograms of 100 measurements for pressure standards from 0 to 380 torr run at 150 vials per minute.

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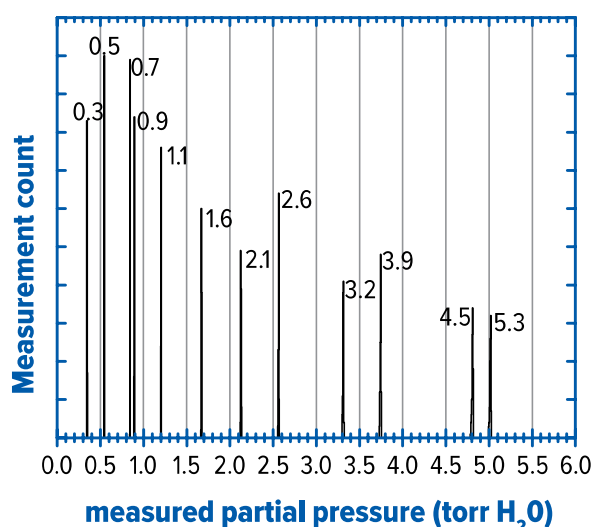
### MOISTURE PERFORMANCE DATA

Performance of an automated headspace moisture measuring system is assessed using a set of moisture standards with 0.3 to 5.3 torr of moisture. Twelve 10 mL clear glass vials were prepared with known headspace moisture (water vapor) concentrations. The headspace moisture was measured one hundred consecutive times in each of these moisture standards using the VISTA Headspace Inspection System at a speed

of 150 vials/minute. The VISTA System 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 concentration. The mean measured headspace moisture and standard deviation were calculated for each of the standards and are presented in Table 2. Figure 2 plots histograms of the 100 measurements made on each moisture standard. The non-destructive nature of the measurement enables a full statistical documentation of system performance.

ACTUAL (TORR)	MEAN (TORR)	ERROR (TORR)	ST DEV (TORR)
0.3	0.3	0.0	0.001
0.5	0.5	0.0	0.001
0.7	0.8	0.1	0.001
0.9	0.9	0.0	0.001
1.1	1.2	0.1	0.002
1.6	1.7	0.1	0.002
2.1	2.1	0.0	0.003
2.6	2.6	0.0	0.003
3.2	3.3	0.1	0.005
3.9	3.7	-0.2	0.004
4.5	4.8	0.3	0.007
5.3	5.0	-0.3	0.007

**Table 3. Moisture performance data for automated measurements at 150 vials per minute.**



**Figure 3. Histograms of 100 measurements for moisture standards containing 0.3 to 5.3 torr of water vapor run at 150 vials per minute.**