

## PULSAR Headspace Inspection System

### **100% inspection of pharmaceutical product**

The PULSAR Headspace Inspection System is an automated 100% inspection machine designed to measure headspace oxygen, moisture, and carbon dioxide levels in sealed parenteral containers. PULSAR characterizes the physical headspace conditions of a container in a single compact and flexible platform.

Aseptic manufacturing facilities implement various analytical systems and inspection processes to ensure the quality of finished product and to monitor production processes. The PULSAR Headspace Inspection System has been designed to address the following applications:

- Headspace oxygen monitoring during the filling of oxygen-sensitive formulations
- 100% moisture inspection of freeze dried product
- Automated media fill inspection

### **Headspace Laser Spectroscopy**

The PULSAR Headspace Inspection System uses 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 target headspace molecules to determine headspace concentrations. Vials that do not meet the specified headspace conditions can then be identified and rejected.

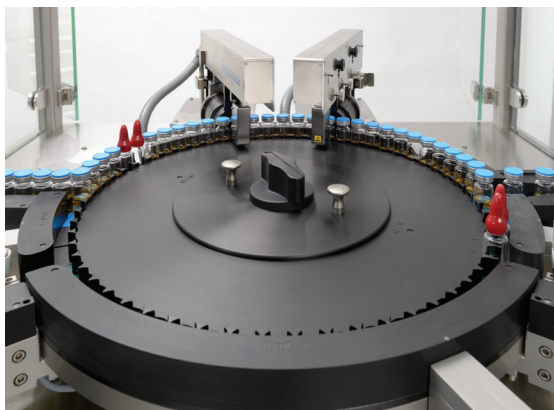
LIGHTHOUSE Instruments introduced the laser headspace technology into the pharmaceutical industry more than 15 years ago and has the largest installed base of laser-based headspace systems worldwide.

### **Patented Calibration System**

Four permanently mounted Standard Calibration Vials (SCVs) are used to configure the sensors at start up. Following the initial configuration, the SCVs maintain a continuous check of sensor calibration and functionality ensuring that the sensors are operating correctly and verifying their calibration.



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### Utilities

Pulsar is designed to operate using single-phase power and a minimum amount of compressed air and nitrogen, utilities easily found in pharmaceutical production environments. This means you can install and get Pulsar up and running with little utilities work in your plant.

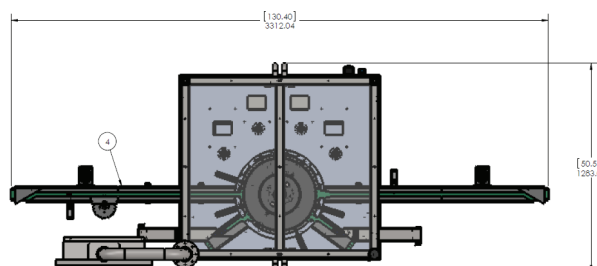
### Reduced Footprint

Pulsar's compact design allows the user to wheel the system into place without removing doorways or using large equipment. Its small footprint means it can be put in your plant where space is a premium.

### 21CFR Part 11 Compliant

### Database Solution

Lighthouse offers a database solution which is compliant with 21CFR Part 11. The solution logs all measurements, alarms, and changes in machine settings. A reports package allows the user to either print reports or export them as Excel, Word or PDF file. Reports include a Batch Report, Measurements, Alarms, Settings Changes and an Audit Trail Report. The latter combines the Alarms Report, Settings Changes and all operator actions in one report. The solution supports Active Directory connectivity.





## NOMINAL SPECIFICATIONS

<b>Structure</b>	Compact single dial machine
	Two reject lanes, Measured Reject, Not Measured Reject
	Up to four measurement sensors
	Rotary table load and un-load (Optional)

<b>Container Sizes</b>	Vials ranging in size from 2R to 50R, or 16.0mm to 38.0mm
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<b>Container Compatibility</b>	Tubing or molded; amber or clear
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<b>Maximum Throughput</b>	150 containers per minute
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## PHYSICAL AND ELECTRICAL

<b>Dimensions</b>	331,2 cm x 128,3 cm
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<b>Automated Control System</b>	Siemens PLC
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<b>Utility Requirements</b>	Electrical Power: 200 – 240 VAC 1-phase, 15 amp, 50/60 Hz
	Compressed Air: 35 scfm @ >5.5 barg
	Compressed Nitrogen: 25 slpm @ >3.5 barg

LIGHTHOUSE is the leading manufacturer and provider of optical, non-destructive headspace analysis systems and provider of measurement services for applications specific to the pharmaceutical industry. As a science-based company, we provide our clients with knowledge and expertise gained from analyzing and inspecting millions of finished sterile drug samples from pharmaceutical facilities around the world.

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