

PULSAR Headspace CCI Inspection Lease System

100% inspection of pharmaceutical product

Upsets in production can impact a company's ability to release product to market. Leasing an inspection platform to perform 100% container closure integrity (CCI) inspection of affected batches can avoid the costly decision to scrap valuable product.

The PULSAR Headspace CCI Inspection Lease System is an automated 100% CCI inspection machine designed to inspect the CCI of sealed parenteral containers through the measurement of headspace oxygen and/or pressure. PULSAR characterizes the physical headspace conditions of a container in a single compact and flexible platform and is designed to address the following applications:

- 100% CCI inspection of freeze dried product having a vacuum or partial nitrogen pressure headspace
- 100% CCI inspection of modified headspace liquid and powder products

The PULSAR Headspace CCI Inspection Lease System is designed for quick configuration and

can often be delivered and installed on site within a timeline of 12 weeks.

Headspace Laser Spectroscopy

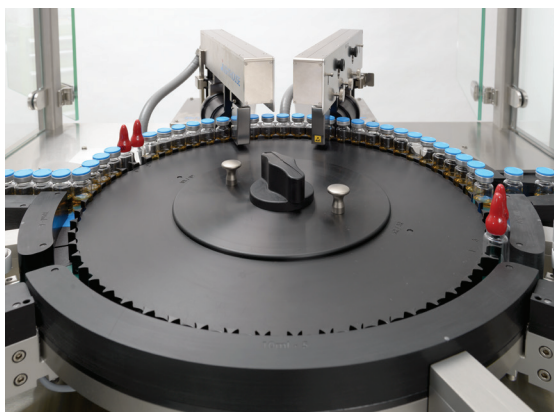
The PULSAR Headspace Inspection System uses a patented laser-based detection method developed with funding from the Food and Drug Administration. Light from a near-infrared laser is passed through a container in the region above the product and below the cap (headspace region). Diode laser sensors are designed to monitor the absorption wavelength of the headspace oxygen and moisture molecules to determine headspace concentrations of oxygen and moisture as well as the headspace pressure. Vials that have elevated levels of oxygen and/or pressure due to a leak 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 sen-



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sors 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.

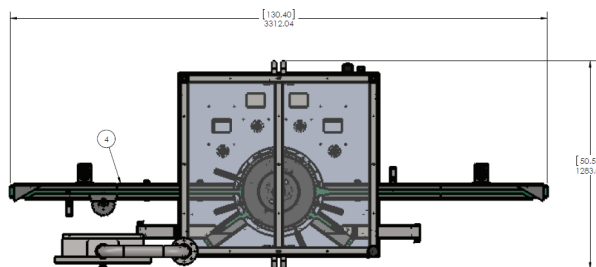
Utilities

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 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

Structure	Compact single dial machine Two reject lanes, Measured Reject, Not Measured Reject Up to four measurement sensors Rotary table load and un-load (Optional)
Container Sizes	Vials ranging in size from 2R to 50R, or 16.0mm to 38.0mm
Container Compatibility	Tubing or molded; amber or clear
Maximum Throughput	150 containers per minute

PHYSICAL AND ELECTRICAL

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