LIGHTHOUSE

THE SCIENCE
OF PHARMACEUTICAL
MANUFACTURING

PRODUCT NOTE

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, pressure 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:

- 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
- 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 introduced the laser headspace technology into the pharmaceutical industry more than 30 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.

UTILITIES

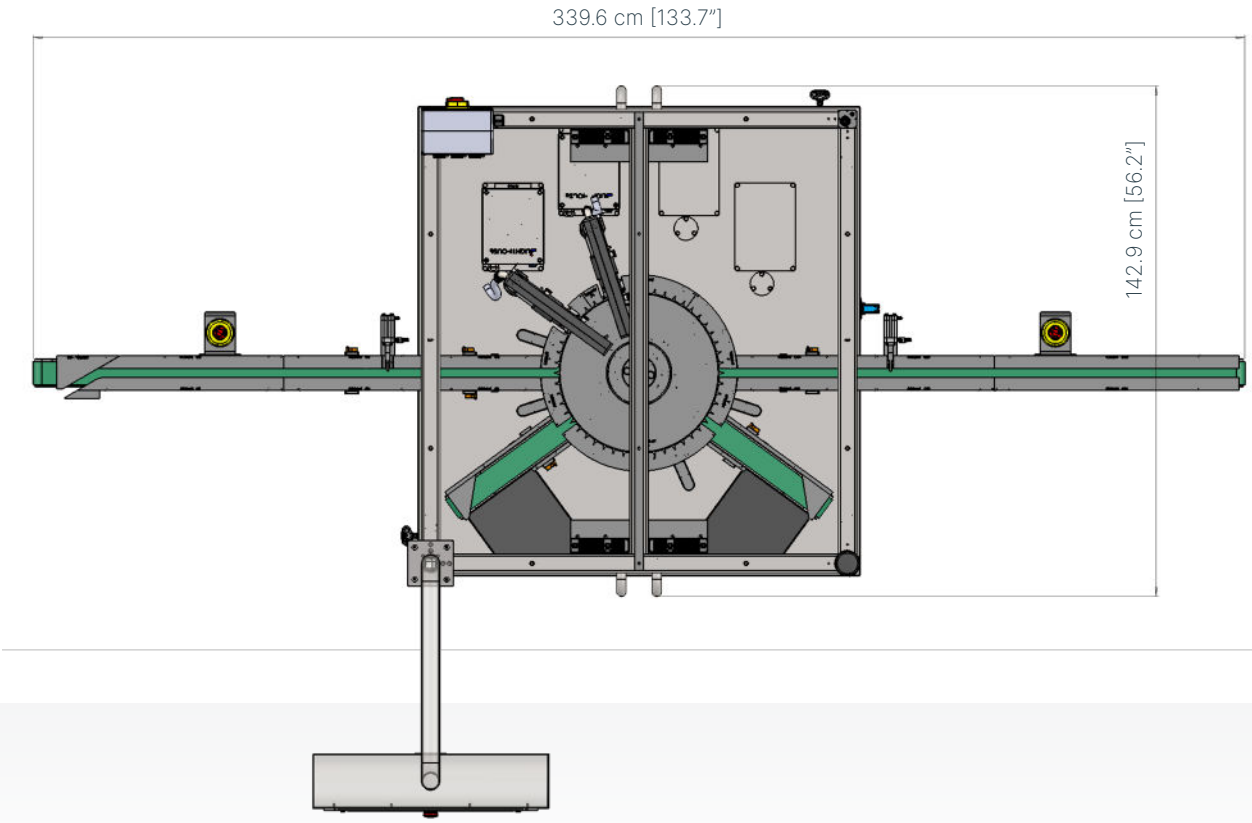
Pulsar is designed to operate using single-phase power and a minimum amount of compressed air and nitrogen, utilities easily found in pharmaceutical production environments. This means you can install and get Pulsar up and running with little utilities work in your plant.

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 files. 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	
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 16.0mm to 62.0mm diameter
Container Compatibility	Tubing or molded; amber or clear
Maximum Throughput	300 containers per minute
PHYSICAL AND ELECTRICAL	
Dimensions	340 cm x 143 cm (134” x 56”)
Automated Control System	Siemens or Rockwell PLC
Utility Requirements	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

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