

## ILLUMINATOR Headspace Inspection System

### Headspace inspection of pharmaceutical product

The ILLUMINATOR Headspace Inspection System is an automated 100% inspection machine designed to measure headspace oxygen, moisture, and carbon dioxide levels in sealed parenteral containers. ILLUMINATOR characterizes the physical headspace conditions of a container in a single compact and flexible platform and allows up to two measurement heads to be equipped at any one time.

The ILLUMINATOR Headspace Inspection System has been designed for process development studies and aseptic process simulations/media fill inspection. The system is ideal for collecting data related to the following applications:

- Characterizing headspace nitrogen purge efficiency when filling of oxygen-sensitive formulations
- Characterizing moisture content of lyophilized product during freeze dryer performance qualification
- Automated Media Fill Inspection
- CCI for small batch sizes with minimal rejects

### Headspace Laser Spectroscopy

The ILLUMINATOR 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 gas concentrations. Vials that do not meet the specified headspace conditions can then be identified and removed.

Lighthouse Instruments introduced the laser headspace technology into the pharmaceutical industry more than 20 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

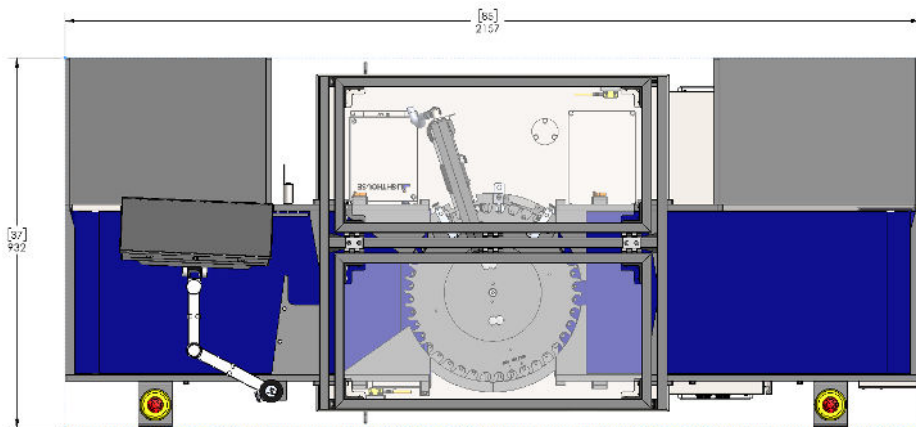
ILLUMINATOR is designed to operate using singlephase power and depending on the measurement type, compressed air or nitrogen. Utilities easily found in pharmaceutical production environments. This means you can install and get the Illuminator up and running with little utilities work in your plant.





## Reduced Footprint

ILLUMINATOR's compact and mobile design allows the user to move the system around a manufacturing plant for use in different locations for different applications. Its small footprint means it can be put in your plant where space is a premium. The castors equipped at the base of the Illuminator allow the device to be moved across designated process floors with ease.



## 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 user account utilization.

### NOMINAL SPECIFICATIONS

|                         |                                                           |  |
|-------------------------|-----------------------------------------------------------|--|
| STRUCTURE               | Compact single dial machine                               |  |
|                         | Up to two measurement sensors                             |  |
|                         | Tray load and un-load                                     |  |
| CONTAINER SIZES         | Vials ranging in size from 2R to 100R or 16.0mm to 50.0mm |  |
| CONTAINER COMPATIBILITY | Tubing or molded; amber or clear                          |  |
| MAXIMUM THROUGHPUT      | 100 containers per minute                                 |  |

### PHYSICAL AND ELECTRICAL

|                      |                                                           |                                                                                  |
|----------------------|-----------------------------------------------------------|----------------------------------------------------------------------------------|
| DIMENSIONS           | 1800 mm x 900 mm x 1200 mm (WxDxH)                        |                                                                                  |
| UTILITY REQUIREMENTS | Electrical Power: 200 – 240 VAC 1-phase, 15 amp, 50/60 Hz |                                                                                  |
|                      | CO <sub>2</sub> Measurement                               | No Gasses required                                                               |
|                      | Moisture/Pressure Measurement                             | Compressed dry air or compressed nitrogen required at 25 slpm @ >3.5barg         |
|                      | Oxygen Measurement                                        | Compressed air: 35 scfm at >5.5 barg<br>Compressed Nitrogen: 25 slpm @ >3.5 barg |

LIGHTHOUSE is the leading manufacturer and provider of optical, nondestructive 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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