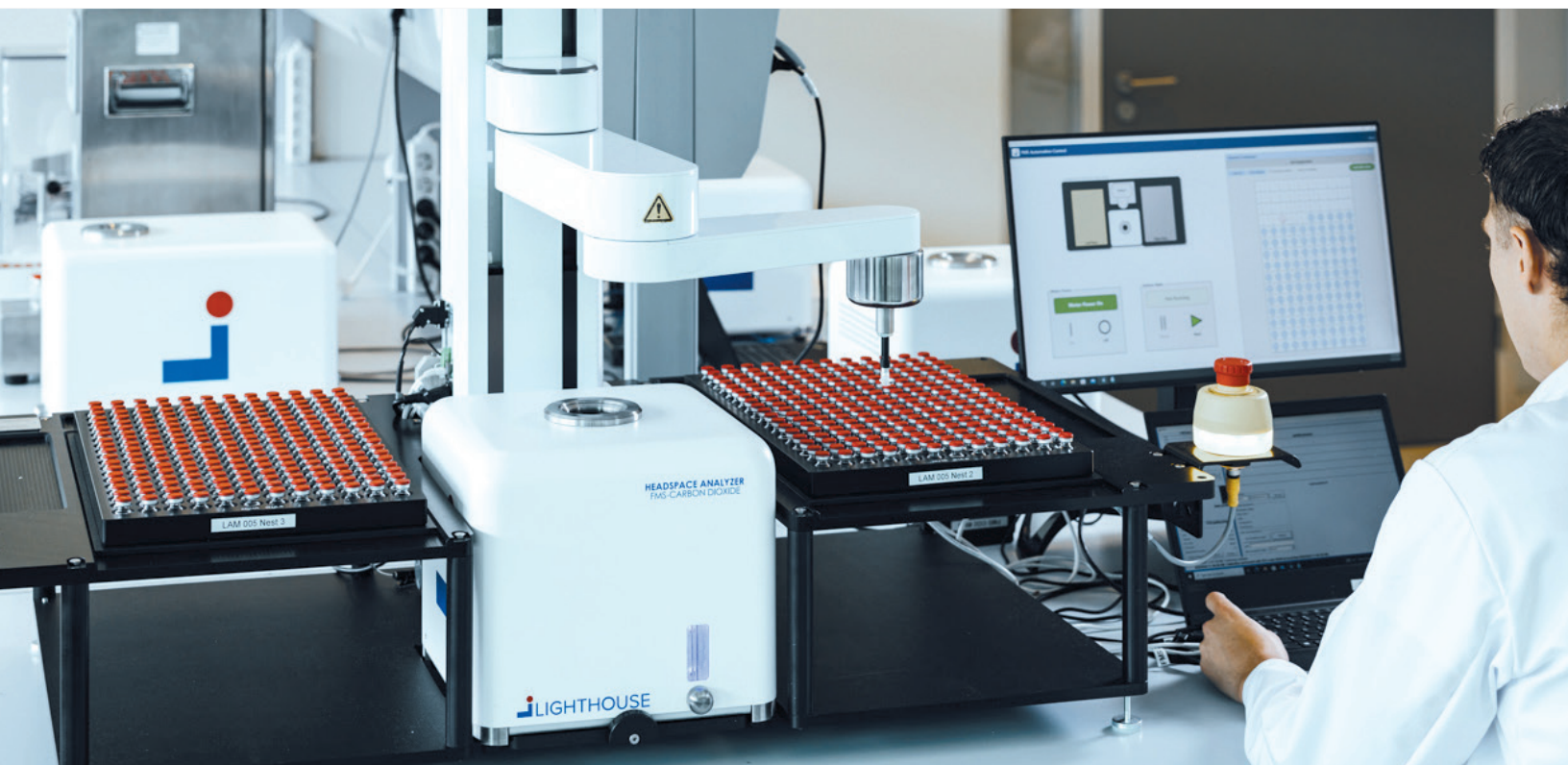


PRODUCT NOTE

FMS Automation Module

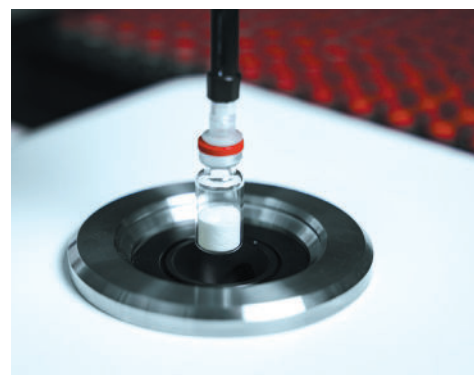
Collaborative Automated Sample Handler
for LIGHTHOUSE Headspace Analyzers





FMS Automation Module

With the LIGHTHOUSE FMS Automation Module, pharmaceutical groups can now test larger sample sets with their FMS Headspace Analyzer and collect statistically significant data while freeing analysts' time for more critical work.



RELIABLE & REPRODUCIBLE

The vacuum gripper picks up the vial, places the vial into the FMS Headspace Analyzer, and returns the vial to its original position in the rack. The robot eliminates the manual, error-prone task of sample handling. This ensures that every sample is tested and that the measurement results are assigned to the correct vial. The measurement data can be viewed locally in real-time or remotely when using the LIGHTHOUSE GxP database viewer.



HIGHER THROUGHPUT AND GREATER CAPACITY

The FMS Headspace Analyzers provide accurate and precise headspace measurement data in only 5 seconds. Using the FMS Automation Module, the system has a throughput as high as 300 samples per hour. The work cell holds 2 sample racks with a capacity of 120 large vials up to 588 small vials. This combination of rapid analysis and large vial capacity ensures the highest productivity and fastest turnaround.

FLEXIBLE & VERSATILE

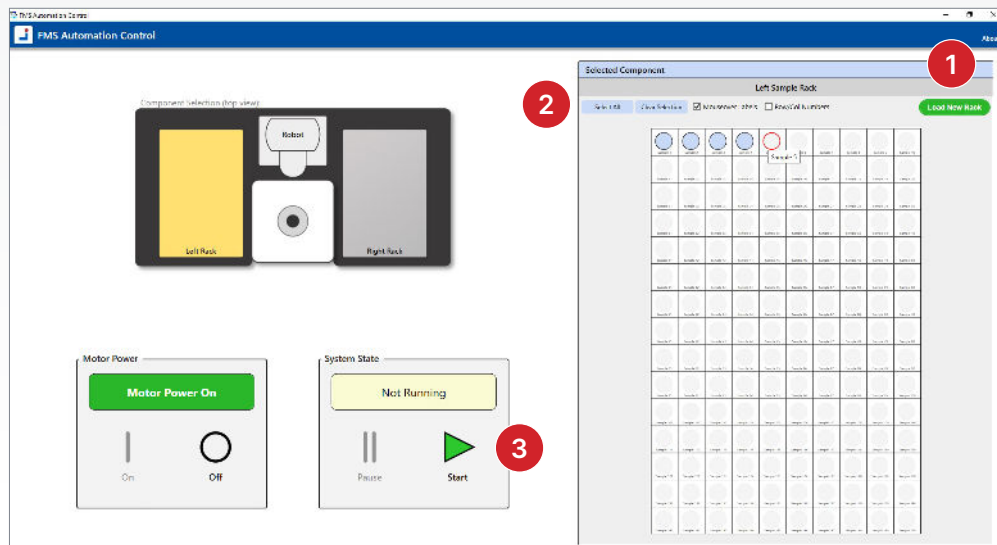
The FMS Automation Module is very flexible and can be used with FMS-Oxygen, FMS-Carbon Dioxide or FMS-Moisture/Pressure analyzers. This design ensures that

the FMS Automation Module can be used for the widest range of applications, including Container Closure Integrity Testing (CCIT), nitrogen purge optimization, lyo cycle optimization, stability testing or inspection of sterile product.

The system will reliably test a wide range of samples, including tubing or molded glass vials, either clear or amber, and that are empty, liquid filled, powder filled, or lyophilized.

COMPACT & EFFICIENT DESIGN

The complete system will fit on a standard 30" (76 cm) deep lab bench and makes the most efficient use of your limited lab space.



Simple Interface Eliminates the Learning Curve

LIGHTHOUSE pre-configures the FMS and FMS Automation Module software with a pull-down menu that lists every vial format that is available. By simply selecting one of these formats, the FMS Automation Module and FMS analyzer are configured correctly for the chosen vial format.

The LIGHTHOUSE GxP database ensures that measurement data is saved immediately and ensures both data integrity and easy fully protected access. The measurement data is displayed on the local control PC and also on any PC on the local network with the LIGHTHOUSE GxP database viewer software.

1. Press the **Load New Rack** button. A window will prompt the user to load the sample labels from a CSV file.
2. Press **Select All** button or select specific samples to be tested.
3. Press the **Start** button to begin automated headspace analysis.

FULLY INTEGRATED AND PRE-CONFIGURED

The FMS Headspace Analyzer, the robot arm and the sample racks are integrated into a work cell that is controlled by a single PC. This plug-and-play design provides a versatile and adaptable system that is quickly converted to different vial sizes and can easily swap out one type of FMS Headspace Analyzer for another.



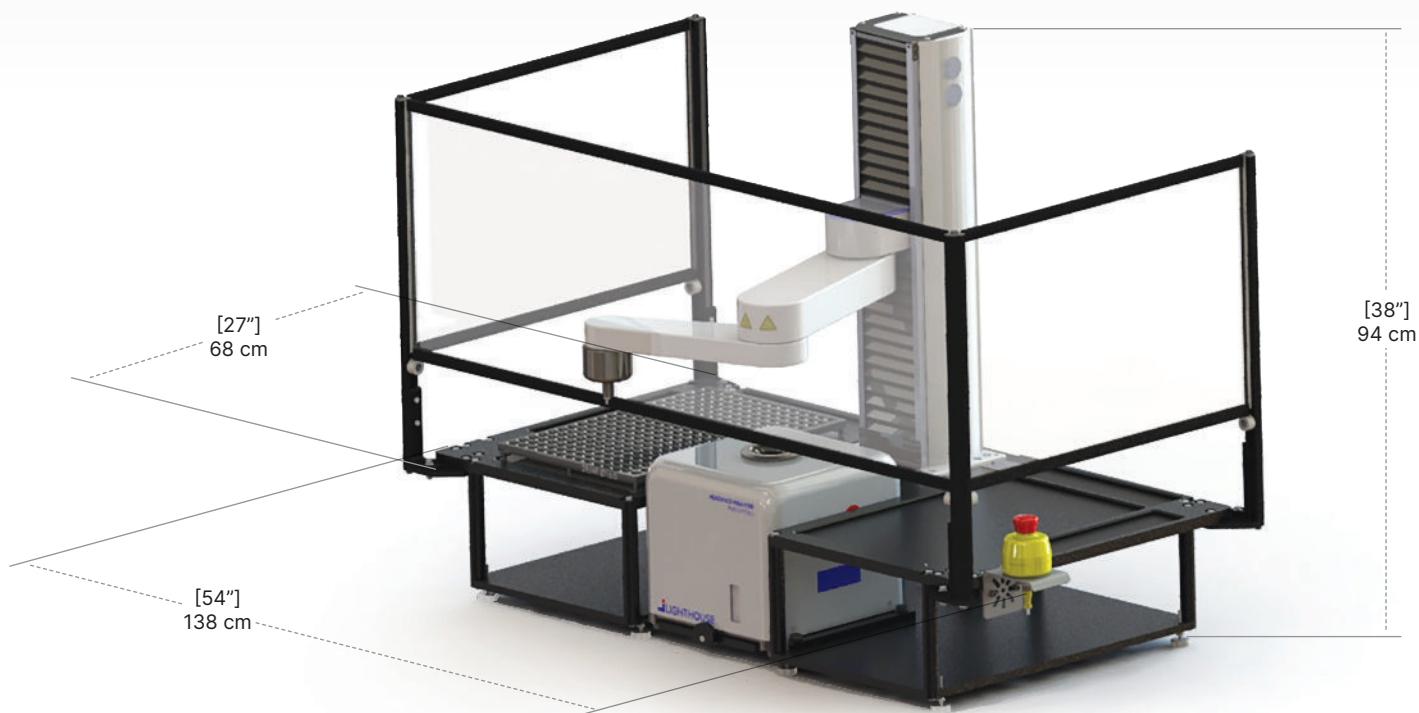


System Specifications: FMS Automation Module

Headspace Analysis	Automated headspace analysis using the current generation (FMS-3) headspace analyzers: ➤ FMS-Oxygen ➤ FMS-Carbon Dioxide ➤ FMS-Moisture/Pressure
Capacity	Capacity for common vial diameters (2 racks): ➤ 2R/4R, 2 mL vials (16 mm OD): 588 vials ➤ 6R/8R, 5 mL vials (22 mm OD): 300 vials ➤ 10R/15R, 10 mL vials (24 mm OD): 300 vials ➤ 20R/25R, 20 mL vials (30 mm OD): 192 vials ➤ 50R, 30 mL vials (40 mm OD): 108 vials
Max Throughput	200-300 samples per hour
Walk-away time	Estimated at 250 samples/hour, one 5-second measurement per sample: ➤ 2.3 hrs for 16 mm OD vials ➤ 1.2 hrs for 22 mm OD vials ➤ 0.8 hrs for 30 mm OD vials
Sample rack format	LIGHTHOUSE supplies 4 racks for each size vial
Supported sample formats	➤ Glass vials (molded or tubing) or plastic vials ➤ Clear or amber glass ➤ Sample weight up to 250 g ➤ Liquid, powder, or lyophilized product fill ➤ Vial format suitability evaluated on a per-format basis
Dimensions (w x d x h)	138 cm x 68 cm x 94 cm 54" x 27" x 38"
Power requirements	Robot power supply 100-240VAC at 50/60Hz, 500 W FMS power supply 100-240VAC at 50/60Hz, 60 W



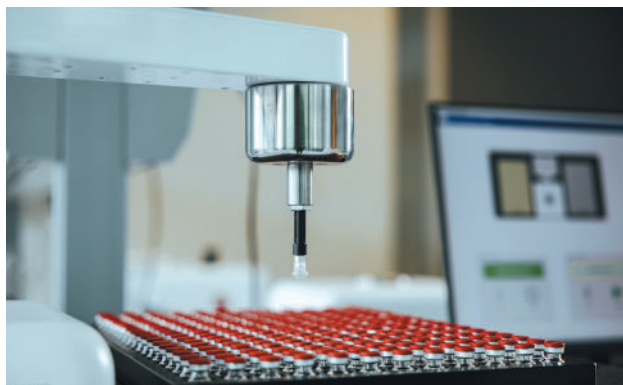
Dimensions



SUGGESTED WORKFLOW

- LIGHTHOUSE provides four sample racks for each vial size chosen.
- Two racks are placed in the upper active testing section.
- The two additional racks are filled and stored in the lower section.
- When the upper racks are completed, transfer the lower racks into position, load the new sample label files, and continue the testing session.

Using this approach, the LIGHTHOUSE FMS Automation Module provides the most efficient workflow while minimizing manual intervention and maximizing productivity.





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