

Specifications

Model	
LS-07 Series	Wavelength: 763 nm Measurement target: oxygen (%)
LS-14 Series	Wavelength: 1,382 nm Measurement target: moisture (mg/L, Torr), pressure (Torr)
LS-21 Series	Wavelength: 763 nm Measurement target: oxygen (%)
(2 Measurement Units Installed)	Wavelength: 1,382 nm Measurement target: moisture (mg/L, Torr), pressure (Torr)
Hardware	
Container size	φ12-30 mm *Custom-made holders for smaller/bigger containers available
Processing speed	From pressing the Start button until the holder returns: 97 seconds for 10 vials *When measurement time per vial is 5 seconds
	Typical Processing Speed/Container: 9 seconds Measurement Time: 1-5 seconds
Operation	Intermittent operation by constant-pitch feeding Automatic from carriage to measurement
Workpiece Supply	Supply by dedicated holder
Workpiece Feeding (drive)	Single-axis robot
Measurement Unit	Two units can be installed
	The height and width are manually adjustable using the position indication dial
Workpiece rotation mechanism	Rotated during measurement
Utility	
Power Supply	100 V, single phase
Nitrogen Purge	Optional (purged only during measurement)
Compressed Air	Not Required
Operation buttons	Operation, Emergency Stop, Nitrogen ON/OFF, Independent Measurement (without automated feeding)
Touch Panel	10" Display / Windows 10 installed / Various settings / Operations / Sound alarm
Software	
Display Language	English and Japanese *Other languages can also be supported
OS	Windows 10
Calibration	Automatic and multipoint calibration available
	Calibration containers (standards) are supplied with the system on installation Calibration time: Approx. 58 seconds (for two-point calibration)
Measurement Functions	Manual or consecutive measurement, report output available
Defectives Handling	Setting the tolerance and display of those beyond the value
Other	
Interface (Output)	Two USB ports, one LAN port
Operation	Screen touch with voice guidance
10-sample Holder	Specific holder is supplied for each container size
	Numbering on the holder to specify the container set position
Device Startup Time	50 seconds (From power on until the screen is displayed)
Device Shutdown Time	26 seconds (Until the device completely shuts down)
Size	640 (W) x 575 (D) x 600 (H) mm
Weight	35 kg (body 34.3 kg + one holder piece 0.7 kg)
Extensibility	Scale-up: Laboratory, semi-automated and fully-automated models
	Simultaneous measurement by multiple measurement units available

 JAPAN MACHINERY COMPANY

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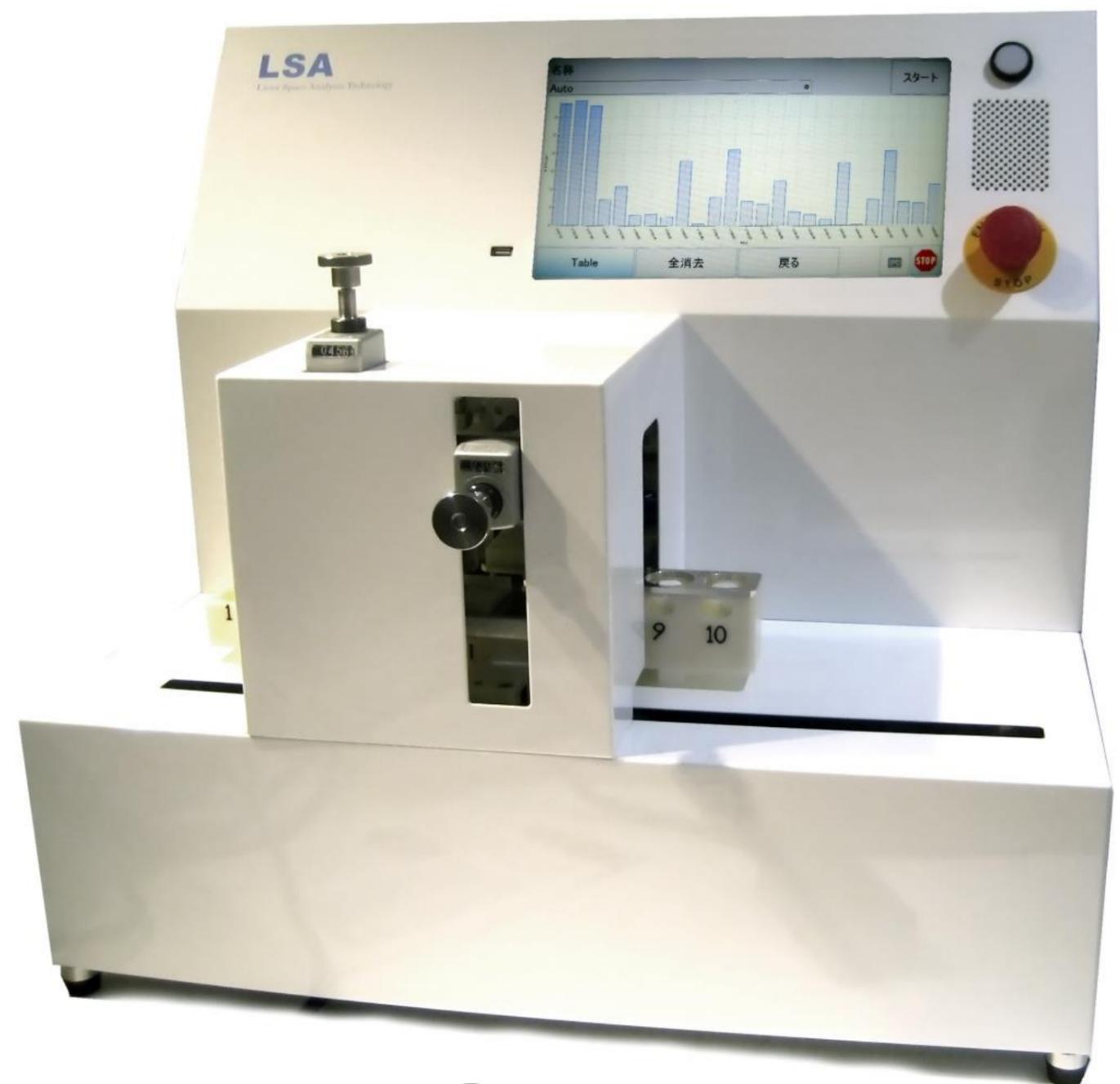
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For Completely Non-Destructive and Rapid Container Closure Integrity Test



Laser Space Analysis Technology

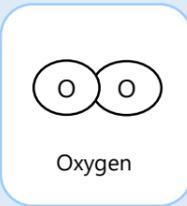


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The Laser Space Analyzer **LSA**[®] Enables Consecutive, Easy and Accurate Headspace Analysis

Measurement Target

Measurement Principle: Frequency Modulation Spectroscopy Theory



Oxygen Concentration

- Laser Wavelength: 763 nm
- Laser Power: 0.6 mW



Absolute humidity / Pressure

- Laser Wavelength: 1,382 nm
- Laser Power: 5.6 mW

*For pressure measurement, LSA converts the measured water molecule level into pressure value, based on FM Spectroscopy Theory.

Container Integrity Test USP39-NF34 1207.2 Compliant

Listed in USP 1207.2 2.2 as Laser Gas Headspace Analysis

Testing decompressed containers for lyophilized formulations

2.2.2 APPLICATION Lines 14-18

- A test results not meeting specification could not be due to package leakage, or could result from improper package filling or assembly processes that caused the package headspace to be out of specification.

- A test result that meets specification may confirm package integrity if enough time has elapsed since product-package preparation for measurable leakage to have occurred, assuming that the initial preparation of the test sample met manufacturing standards.

× FAIL

- Change in pressure / oxygen concentration is measured with the lapse of time.
- There could be leakage from the container. Problems in the filling / assembly stages could be found.

✓ PASS

- Change in pressure / oxygen concentration with the lapse of time is within the tolerance.
- No leakage from the container. There is no problem in the filling / assembly stages. By using a decompression chamber, products plugged under atmospheric-pressure also can be measured.

Advantages

Compliant with "Laser Gas Headspace Analysis Method" listed in USP <1207.2>

- ✓ **Highest Detection Limit**
 - φ 0.1 um pinholes can be detected.
- ✓ **Shortest Measuring Time:**
 - Several seconds per container (default measurement time: 5 seconds).
- ✓ **Completely Non-Destructive:**
 - Enables multiple measurements and follow-up test on the same sample; you do not need to waste your valuable samples anymore.

Compatible with Most Containers

- Height and width of the measuring unit are adjustable to the size of your containers



Time-Saving Consecutive Test

- 10-sample holder for each container type is produced and supplied
- Measurement completes in typically several seconds per container
- Consecutive measurement can prevent errors due to the multiple operators



Applications

Nitrogen Substitution Rate Confirmation



- The measured oxygen concentration can be referred to for optimization of the nitrogen filling
- Can check validated nitrogen substitution amount

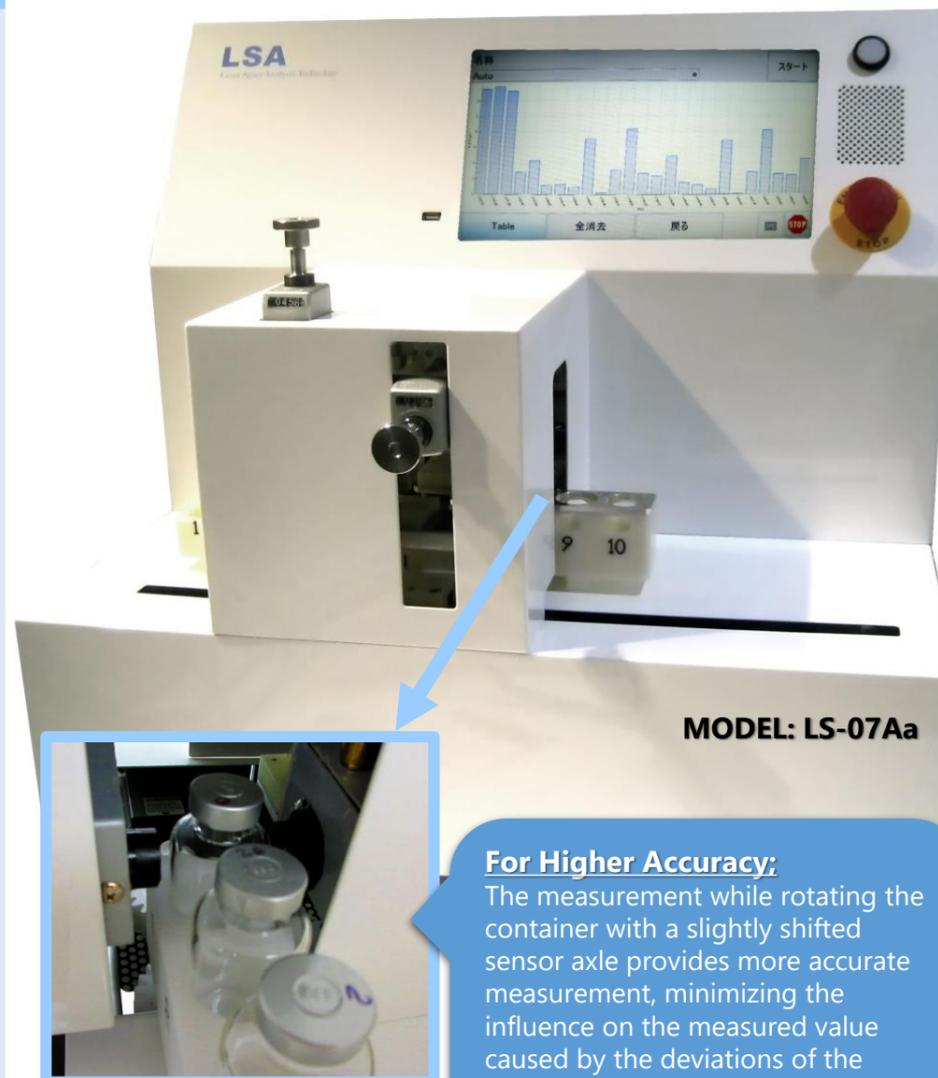
What can the inappropriate substitution rate tell us?

- Nitrogen gas substitution power can be insufficient
- The rubber cap can be not properly plugged, etc.

Quality Assurance and Hot/Cold Spot Confirmation for Lyophilized Formulations



- Predicts the degree of dryness of a lyophilized formulation from the moisture content in the headspace
- Mapping of moisture level of the lyophilized formulation chamber



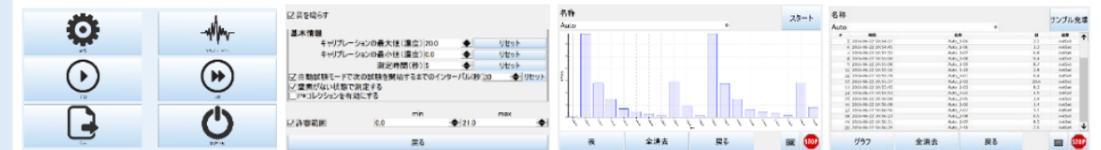
For Higher Accuracy:

The measurement while rotating the container with a slightly shifted sensor axle provides more accurate measurement, minimizing the influence on the measured value caused by the deviations of the thickness of each container.

*Patent Pending

User-friendly Software

- **Touch Panel Operation**
Simple and user-friendly interface
- **Manual Measurement and Automated Consecutive Measurement Available**
Enables efficient measurement
- **Measurement Data**
Graphs, tables and report export available
- **Automatic Centering Function**
Always catch the output waveform accurately
- **"Clear Level"**
Thresholds can be set for measuring vials with adhesive powder inside, or colored vials.
- **Calibration**
Automatic and multipoint calibration available
You can specify a value close to the measured value and improve accuracy.
- **Display Language**
English and Japanese
*Other languages can also be supported
- **CFR 21 Part 11 Compliant Version Available**



Reliability

Typical measurement accuracy (actual values)

SD when measuring the φ 30 mm transparent vial with 20% oxygen inside;

- Approx. ± 0.1 when measurement time / vial is 10 seconds
- Approx. ± 0.15 when measurement time / vial is 5 seconds

*Measurement accuracy depends on the size, thickness accuracy, transparency, color, etc., of the container