

PRODUCT NOTE

CCI Tester





LIGHTHOUSE Container Closure Integrity (CCI) Tester

The fastest, most sensitive and reliable container closure integrity testing throughout the complete lifecycle.

Container closure integrity (CCI) is essential to maintaining the sterility and stability of pharmaceutical products. As regulatory expectations continue to evolve, manufacturers are moving away from traditional destructive and probabilistic test methods toward validated, non-destructive, and deterministic approaches, as outlined in FDA guidance, USP <382> and <1207>, and EU GMP Annex 1.

The LIGHTHOUSE CCI Tester provides an automated, data-integrated solution for verifying the closure integrity of pharmaceutical containers using non-destructive laser-based headspace analysis.

The system consists of three main components:

- CCI Test Vessel (8 L, 40 L, or 50 L)
- CCIT Vessel Control Module
- FMS-Carbon Dioxide Headspace Analyzer

Together, these components deliver a deterministic, non-destructive, and quantitatively traceable method which can be validated to detect the smallest defects using CO₂ as a tracer gas.

System Architecture & Function



CCI Test Vessel

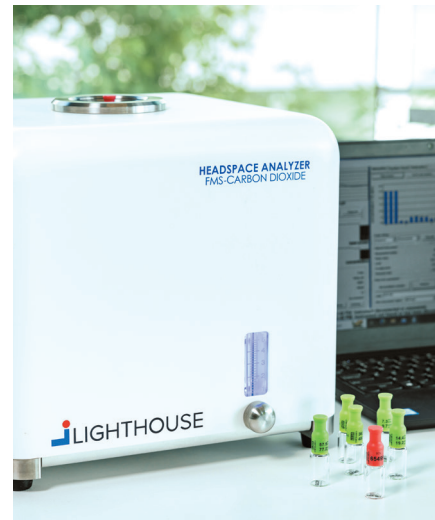
The CCI Test Vessel provides a simple, efficient, and robust means of preparing a wide range of container types for container closure integrity testing (CCIT).

LIGHTHOUSE offers CCI Test Vessels of various sizes, all capable of conditioning samples at pressures up to 20 psig (1.38 barg). The vessels are constructed from stainless steel and come equipped with a safety pressure relief valve, quick-connect fittings for ease of operation and safety, and an analog pressure gauge (for reference only).



CCIT Vessel Control Module

The CCIT Vessel Control Module controls and monitors the modified atmosphere inside a pressure vessel, executing pre-defined conditioning cycles to ensure reproducible testing. The module automates purging, pressurization, and venting steps—eliminating manual gas handling and ensuring complete data traceability.



FMS-Carbon Dioxide Headspace Analyzer

The FMS-Carbon Dioxide Headspace Analyzer performs high-sensitivity, laser-based measurement of the CO₂ concentration in the headspace of the test containers. Elevated CO₂ levels after conditioning a sample in the CCI Test Vessel with CO₂ as tracer gas indicate the presence of a leak pathway.



Data Integrity and Compliance

When paired with LIGHTHOUSE GxP Database software, all conditioning and measurement data are automatically stored in a 21 CFR Part 11-compliant database.

Authorized users can review and approve batch reports for complete audit trail documentation.

Applications

- Closure integrity testing in pharmaceutical vials, syringes, cartridges, and autoinjectors
- Method development and validation for CCIT protocols
- Routine quality control and process monitoring

Advantages

- Versatile non-destructive method:
 - test pharmaceutical containers from 1 mL syringes to 500 mL bottles
 - compatible with clear, amber and molded glass, and plastic containers
 - preserves valuable product samples
- Detect defects ranging from 0.1 micron to gross defects
- Fully automated and reproducible conditioning cycles
- Data logging and traceable execution of CCIT protocol and measurement results
- 21 CFR part 11-compliant data storage and reporting
- Scalable system—from development to production batches
- Robust stainless-steel construction of test vessel ensures durability and cleanliness



The LIGHTHOUSE CCIT method utilizes laser-based headspace analysis to measure changes in the headspace gas composition in a container that result from gas ingress due to a loss in container closure integrity. The CCI Test Vessel creates an environment that accelerates this gas ingress through an open defect.

Samples are exposed to CO₂ inside the test vessel under controlled overpressure conditions. Any ingress through a defect increases the CO₂ concentration, which is then detected using the FMS-Carbon Dioxide Headspace Analyzer.

This approach is similar to a dye ingress test, but this deterministic method offers greater sensitivity than dye or other liquid ingress tests and is completely non-destructive.



Method Development Example

A development study on 15R vials with laser-drilled 5 μm defects demonstrated strong correlation between leak size and CO_2 ingress. Positive control vials with 5 μm laser-drilled defects showed > 450 torr ($\approx$ 600 mbar) increase in headspace CO_2 after conditioning in the CCI Test Vessel, confirming the sensitivity and reproducibility of the LIGHTHOUSE CCIT protocol (Figure 1).

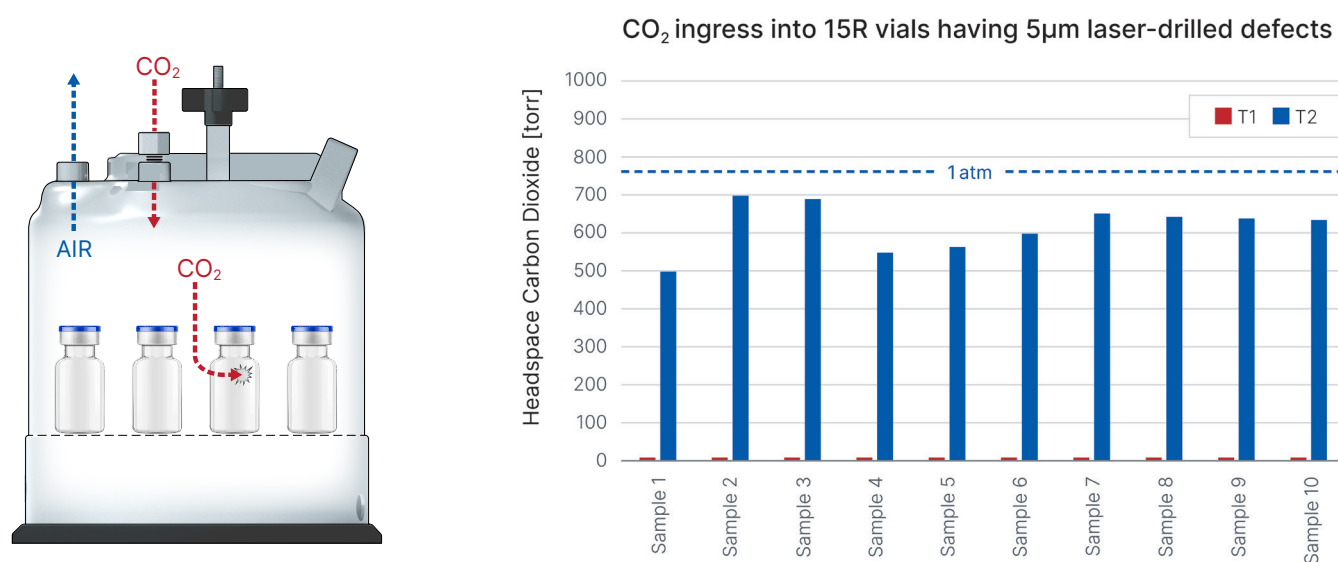


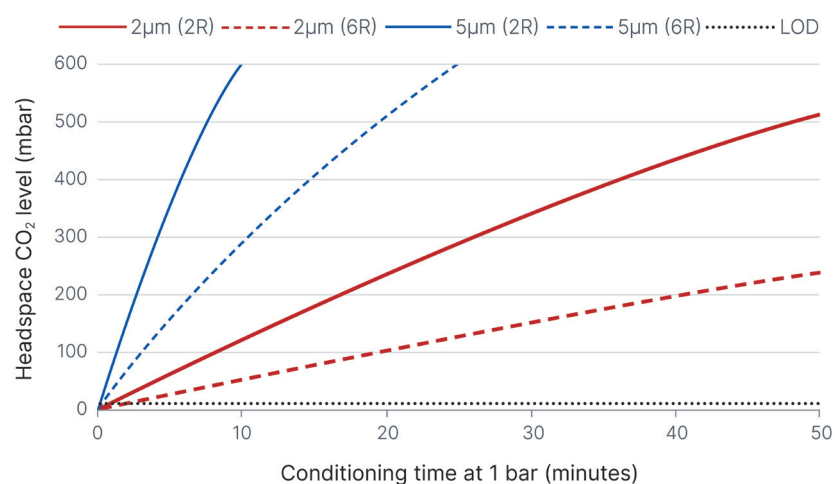
Figure 1. (left) CCI Test Vessel Demonstration. Samples are exposed to carbon dioxide in the CCI Test Vessel. Defective vials will reveal elevated headspace carbon dioxide levels. (right) All positive controls reveal near zero carbon dioxide levels before conditioning inside the CCI Test Vessel (T1, red). Elevated carbon dioxide levels can be seen in all positive controls after being exposed to carbon dioxide in the CCI Test Vessel (T2, blue).



The headspace gas ingress CCIT method can be customized for each product's critical leak size. Using validated mathematical models (Figure 2), users can predict gas ingress rates from container design, headspace, and defect dimensions, ensuring each product is tested with the most appropriate and sensitive CCIT protocol.

The results highlight the effectiveness of the LIGHTHOUSE CCIT solution in rapidly identifying container integrity defects. With automated conditioning, high-sensitivity headspace analysis, and non-destructive testing, the system supports confident decision-making throughout method development and quality control.

Figure 2. Gas Ingress Model. Validated mathematical models can be used to define the rate of gas ingress, for a specific product configuration and critical leak size.



Technical Specifications

Test Vessel Options

Specification	8 L Vessel	40 L Vessel	50 L Vessel*
Outer Dimensions	230 mm OD × 350mm H	360 mm OD × 895 mm H	670 mm L x 575 mm H
Inner Dimensions	228 mm ID × 175 mm H	300 mm ID × 360 mm H	550 mm L x 350 mm ID
Weight	7 kg (15.4 lb)	25.8 kg (56.8 lb)	40 kg (88.2 lb)
Closure	Single bolt	Six swing bolts	Four swing bolts
Sample Shelves (optional)	1 fixed shelf for vials/bottles, syringe/autoinjector stands	Up to 4 stackable trays or 2 or 3 shelves	2 x FMS automation module racks
Max Pressure	Up to 20 psig (1.38 barg)	Up to 20 psig (1.38 barg)	Up to 20 psig (1.38 barg)
Material	Stainless steel (electropolished)	Stainless steel (electropolished)	Stainless steel (glass bead blasted and passivated)
Certifications	ASME "UM", CE Pressure Directive	ASME "UM", CE Pressure Directive	ASME "UM", CE Pressure Directive

* For use in combination with the FMS Automation Module

Typical Sample Capacity

Container Type	8 L Vessel	40 L Vessel	50 L Vessel*
Syringes	120	3,000	—
2R/4R (16 mm OD) vials	120	1,000	588
6R/8R (22 mm OD) vials	80	500	320
10R/15R (24 mm OD) vials	60	450	300
20R/30R (30 mm OD) vials	40	280	192
100 mL (47 mm OD) vials	15	120	—
250 mL (50 mm OD) vials	—	38	—
500 mL (80 mm OD) vials	—	28	—

* For use in combination with the FMS Automation Module





FMS Headspace Analyzer and CCIT Vessel Control Module

Category	Specification	Description
	Measurement Range	0.0 – 1.0 atm CO ₂
	Typical measurement time	5.0 seconds
	Sample Types	Syringes, autoinjectors, ampoules, vials, bottles
	Dimensions (W × D × H)	29 × 30 × 30 cm (11.5" x 12" x 14")
	Weight	13.6 kg (30 lbs)
	Power Requirements	110–240 VAC, 50/60 Hz, 60 W
	Security	Password-protected users with configurable access levels
	User Interface	PC
	Data Management	Integration with LIGHTHOUSE GxP Database (21 CFR Part 11 compliant)
	Recipe Management	User-defined test samples conditioning recipes
	Dimensions (W × D × H)	30 × 35 × 28 cm (12" x 14" x 11")
	Weight	8.2 kg (18 lbs)
	Power Requirements	110–240 VAC, 50/60 Hz, 60 W
	Gas Supply	External CO ₂ source required and pressured air
	Security	Password-protected users with configurable access levels
	User Interface	Built-in touchscreen display
	Data Management	Integration with LIGHTHOUSE GxP Database (21 CFR Part 11 compliant)

CONTACT US

Lighthouse Instruments, LLC
 2050 Avon Court
 Charlottesville, Virginia 22902
 United States of America
Office • +1 (434) 293-3081
Email • info@lighthouseinstruments.com
www.lighthouseinstruments.com

Lighthouse Instruments, B.V.
 Wisselwerking 22
 1112 XP, Diemen
 The Netherlands
Office • +31 (0)20 7051 050
Email • euinfo@lighthouseinstruments.com