

CI-97 Series Microbial Air Sampler 100 LPM Flow Rate Pharmaceutical & Industrial Grade



Drop & Vibration Tested
High Efficiency Sampler
Automatic Flow Control
Sample Data Reporting
Calibration Lockout
HEPA Filtered Exhaust
VHP Compatible
Alarms: Audible & Light Ring
with Sample Termination
AC or Battery Operation
Sample a Cubic Meter in
10 Minutes
Variable Duty Cycle for
Extended Sample Period
Unit-to-Unit Cloning
Active Directory / LDAP Login

USP <797>
ISO 14698 / BS EN 17141
21 CFR Part 11



The CI-97 is a high efficiency microbial air sampler that's suitable for biopharmaceutical cleanrooms and aseptic environments. It is fully compliant with 21 CFR Part 11, and has many advanced data integrity features. These include: username and password login; 50,000 onboard sample memory buffer; Audit Trail (pdf); audit log reporting; User Authenticator™ (Active Directory Login); and more.

Pharmaceutical and industrial grade, the enclosure is 304 stainless steel that weighs only 7 lbs. The design has been drop and vibration tested, and then passed a calibration. The CI-97 has an internal HEPA filtered exhaust, and incorporates an internal hot-wire anemometer that automatically adjusts flow rate ensuring the CI-97 is always within calibration. Combined with Climet's unique light ring, an audible alarm, and sample termination virtually eliminates the risk of deviation reports and investigations caused by interval calibration out-of-tolerance conditions.

A capacitive touch screen allows users to run ISO reports, view pdf reports, and provides pinch-to-zoom and scroll capabilities. The screen operates normally when used with a double-gloved hand.

The CI-97 uses the same inlet geometries as the rest of the CI-9x Family. Physical and biological collection efficiencies have been validated by an independent laboratory and compared against a high efficiency impingement sampler. Testing demonstrated *comparable* results (average percent recovery of 101.4%), with a correlation coefficient of 0.98, which is defined as a near perfect positive linear relationship (i.e., high stability or precision of measurement).

The sample head for a 90mm standard petri dish has 333 holes with a diameter of 0.57mm. This multi-jet design, and in particular the small inlet holes, provide a very low probability of two Microbe Carrying Particles entering the same inlet (Macher, 1989). The CI-97 has a theoretical d50 of 1.08 μm , and an experimental d50 of less than 1 μm (Yao, et al., 2006). This exceeds ISO 14698-1 and BS EN 17141 requirements and recommendations.

Applications Include:

Cleanroom Monitoring & Validation
Medical Device Manufacturing
Hospitals

Food & Beverage Processing
Pharmaceutical Manufacturing
Cosmetic Manufacturing


CLIMET
CLIMET INSTRUMENTS COMPANY

Revision 1.1 (May 2021)

CI-97 Series Specifications



If you have a specific technical requirement, please contact us. *We specialize in customizing our products to fit your needs.*

Configurations	<p>CI-97: 100 LPM Enclosure is 304 Stainless Steel, and includes mounts for a tripod.</p> <p> 100% VHP Compatible: Internals are leak tested with external exhaust port. Recommend VHP exposure while engaged at least quarterly, monthly preferred, to sanitize interior and mitigate risk of cross contamination.</p> <p>950097000x: CI-97 with Aluminum Sample Head, HEPA Filtered External Exhaust, 90mm Petri Dish, 100 LPM</p> <p>950097010x: CI-97 with Stainless Steel Sample Head, HEPA Filtered External Exhaust, 90mm Petri Dish, 100 LPM</p> <p>(x): 1=115V USA, 2=230V EU, 3=230V UK</p>
Performance	<p>Stainless Steel Grade 304: Highest tensile strength, temperature resistance, and corrosion resistance.</p> <p>Flow Control: Electronic, automatic closed loop</p> <p>HEPA Filtered Exhaust: YES, and factory tested & certified to ISO Class 3</p> <p>Cleaning: Compatible with common cleaning and sterilization procedures. Recommend quarterly VHP while engaged</p> <p>Display: Capacitive (cell phone-type) touch screen with pinch-to-zoom and scroll capabilities</p> <p>Sample Control: Continuous sample or variable duty cycle to cover extended monitoring</p> <p>Network Time Server: Yes, compatible. ALCOA: ensures <i>contemporaneous</i> reporting</p>
Programming & Memory	<p>Unit ID: User Selectable</p> <p>Sample Programming: 300 Programs, 300 User IDs & 1,000 Location IDs (factory expandable)</p> <p>Security: 5 user access levels</p> <p>Sample Volumes: 1 liter increments, with 10 liter minimum ($1\text{m}^3 = 1,000$ liters)</p> <p>Calibration: Calibration Lockout (user enabled).</p> <p>Programmable Delay: 5 second minimum (user programmable)</p> <p>Sample Termination Lockout: User enabled. Prevents sample from terminating</p> <p>Altitude Compensation: Yes, user input</p> <p>Unit-to-Unit Cloning: Yes</p>
Sample Memory Buffer	<p>Solid state onboard sample memory buffer -- 50,000 samples</p>
Reporting	<p>Data Interface: Wired Ethernet, RS-232, USB 2.0 Type A port (Data Export), and another USB 2.0 Type B (RNDIS only)</p> <p>- The USB Type A port (Data Export) can be disabled in the user settings, or factory disabled at no charge upon request.</p> <p>Metadata: Date, Time, Unit ID, User ID, Model#, Serial#, Program Name, Location ID, Sample Volume (L), Flow Rate (LPM), Sample Type (Continuous or Segmented), Number of Segments, Sample Duration (start and end timestamp with duration), Alarm Status, Calibration Date, and Calibration Due Date</p> <p>User Audit Trail: Yes</p> <p>PDF Reports: GMP metadata reports, audit logs, stored data, program settings, and audit trail</p> <p>All sample data is made in *.CSV format, with a 32-bit hash to mitigate data manipulation/corruption.</p> <p>Sample data seamlessly integrates into MODA or other LIMS without the need for middleware.</p>
Alarms	<p>Flow Rate: Light Ring, audible alarm, and sample termination if not +/-5% of stated flow rate (ISO 21501-4:2018.)</p> <p>Low Battery indicator: If battery charge is insufficient to run a sample, a notification will appear</p>
Sample Heads	<p>100 LPM with standard 90 mm petri dish @ 333 holes at a 0.57 mm with inlet velocity of 19.5 m/s</p> <p>Theoretical $d_{50} = 1.08 \mu\text{m}$ with an experimental $d_{50} < 1 \mu\text{m}$ (<i>exceeds ISO 14698-1 and BS EN 17141 requirements</i>)</p> <p>Both sampling heads are autoclavable @ 134°C for 20 minutes</p>
Electrical	<p>Lithium-ion rechargeable battery, with internal battery charger. Battery Operation of 8+ hours (typical), and 6 hours continuous sampling. Battery Recharge time of 3.5-4 hours. Wall Power is Universal 100-240 VAC Input</p>
Dimensions & Weight	<p>8.526"(H) x 6.5" (W) x 8.44"(L) (22.43 cm x 16.51 cm x 21.44 cm)</p> <p>Weight with battery installed and aluminum sample head: 7 lbs. (3.175 kg)</p>
Environmental	<p>Temperature: 0-36°C operational</p> <p>0-90% relative humidity, non-condensing</p>
Accessories	<p>Included: Battery (interchangeable with CI-x70), power supply with cord, aluminum sample head, aluminum sample head dust cap, validation document, IQ/OQ Docs, USB flash drive, user manual, and quick start guide.</p> <p>Optional: Stainless steel sample head, remote sampling and compressed gas accessories, hard shell carrying case, and optional CI-312 external spare battery charger.</p>

* Standard warranty is 2-years. Recommend calibration interval at least every 12 months (ISO 21501-4).