



QSG GROUP

REAL TIME MONITORING INNOVATORS



PARTICLE COUNTER — A100 SERIES

TECHNICAL DATA SHEET

PARTICLE COUNTER A100

Portable instrument for airborne particle counting, ideal for cleanroom certification and monitoring (ISO 14644-1, EU GMP, China GMP) and gas and filter testing

Includes TrakPro™ Lite Secure Software for automated reporting.

COMPLIANCE AND STANDARDS

- ISO 21501-4:2018
- 21 CFR Part 11
- JIS B9921
- ISO 14644-1
- EU GMP
- China GMP
- CE Mark



INCLUDED ACCESSORIES

- Power cable
- Rechargeable battery
- 316 L Stainless steel isokinetic probe
- 3 m bev-a-line sampling tube
- Zero filter
- Printer paper
- USB cable
- Operating manual + Quick Start
- TrakPro Lite Secure Software
- ISO 21501-4:2018 calibration certificate issued by an ISO 17025 laboratory

OPTIONAL ACCESSORIES

ITEM DESCRIPTION		
	Sample Probe, Stainless Steel, Isokinetic (connects to instrument)	A001276 (28.3 L/min) A001277 (50 L/min) A001278 (100 L/min)
	Filter Scanning Probe (basic)	A001321 (28.3 L/min) A001304 (50 L/min) A001307 (100 L/min)
	Filter Scanning Probe (electronic with start/stop, LED, sound)	A001320 (28.3 L/min) A001308 (50 L/min) A001309 (100 L/min)
	Tubing, Superthane, Clear 3/8-inch ID x 1/2-inch OD (100 feet)	A001476 (28.3 or 50 L - 100 L/min models)
	Tubing, Superthane, Clear 1/2-inch ID x 5/8-inch OD (100 feet)	
	Printer Paper (10 rolls)	A001096
	Dual Battery Charger Supplied w/ US Power Cord (order international cord separately)	A001275
	Wireless (Wi-Fi®) / Bluetooth® 4.0 Dongle USB-A, 802.11b/g/n	A001279
	Case, Rolling Case, Heavy Duty, with foam inserts (can be used for shipping)	A001274
	High Pressure Diffuser for compressed gas testing	A001314 A001502

CHOOSE YOUR MODEL

MODEL	CODE	FLOW RATE	CHANNEL SIZE OPTIONS	RECOMMENDED MANUFACTURING APPLICATION
A100 - 31	A001264	1 CFM (28.3 LPM)	0.3 µm to 10 µm, (6) user selectable channels	Pharmaceutical, Semiconductor, Electronics, Aerospace, Optics, Automotive, Clean Manufacturing
A100 - 35	A001266	1.77 CFM (50 LPM)	0.3 µm to 10 µm, (6) user selectable channels	Pharmaceutical, Medical, Manufacturing
A100 - 50	A001268	3.5 CFM (100 LPM)	0.5 µm to 10 µm, (6) user selectable channels	Pharmaceutical, Medical, Manufacturing
A100 - 51	A001270	1 CFM (28.3 LPM)	0.5 µm to 10 µm, (6) user selectable channels	Pharmaceutical, Semiconductor, Electronics, Aerospace, Optics, Automotive, Clean Manufacturing
A100 - 55	A001272	1.77 CFM (50 LPM)	0.5 µm to 10 µm, (6) user selectable channels	Pharmaceutical, Medical, Manufacturing
A100-(xx) A	“A” suffix adds analog input and output to any model			

TECHNICAL PERFORMANCE

Light source	Laser diode
Internal pump	Patented flow control
Laser warranty	5 years
Instrument warranty	2 years
Calibration	Annual
Communications	Modbus TCP, Ethernet, USB, Wireless
Visual and audible alarms	Sampling, Alert, Sampling Complete
Zero Count	< 1 count / 5 minutes (95% UCL ISO 21501-4)
Internal memory	250,000 sampling records
Sample duration	1 s – 24 h (continuous)
Display	Intuitive multilingual GUI (9 languages, including Italian)
Alarm	Clean contact NO 0–60 V AC/DC, 0.5 A Continuous
Power Supply	100–240 VAC, 50–60 Hz, 24 VDC @ 5 A
Weight	4.3–5.2 kg (depending on battery)
Dimensions (H×W×D)	22.6 × 25 × 22.2 cm
Operating temperature	1–35 °C
Relative humidity	5–95% non-condensing
Storage temperature	–40 –70 °C
External construction	Stainless steel
Integrated Printer	Multilingual Thermal
Access control	Multi-level user with password and audit trail

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QUALITY AND COMPLIANCE - ANNEX 1

A100 is fully compliant to EU GMP ANNEX 1



ANNEX 1		TSI A100
3.1 - PQS requirements	PQS must support a Contamination Control Strategy (CCS)	Provides viable air monitoring data supporting the implementation of the Contamination Control Strategy within the Pharmaceutical Quality System
3.2 - Data integrity	Data must be attributable, legible, contemporaneous, original and accurate (ALCOA principles)	Generates traceable microbiological data which supports data integrity requirements when managed within compliant data systems
4.12 - Cleanroom classification	Cleanroom classification must be demonstrated and maintained	Enables verification of cleanroom classification through quantitative viable air sampling
4.16 - Monitoring of cleanrooms	Environmental monitoring required to demonstrate state of control	Supports environmental monitoring programs through repeatable and controlled sampling of airborne microorganisms
5.2 - Equipment design	Equipment must be designed to minimize contamination risk	Is designed for use in controlled environments with minimal disruption of airflow and reduced contamination risk
5.3 - Cleanability and decontamination	Equipment must be cleanable and suitable for disinfection	Supports routine cleaning and disinfection procedures in GMP environments
5.35 - Calibration	Measuring equipment must be calibrated and controlled	Provides controlled and calibrated airflow ensuring accurate and reproducible sampled air volumes
8.10 - Environmental monitoring in aseptic processes	Environmental monitoring required during aseptic operations	Enables viable air monitoring during aseptic processing when positioned in critical areas
8.11 - Monitoring during interventions	Monitoring must cover interventions and operator activity	Can be deployed near interventions to assess contamination risks associated with operator activity
9.22 - Active air sampling	Active air sampling must be performed using validated methods	Performs quantitative active air sampling with controlled airflow and defined volumes, supporting method validation
9.24 - Monitoring in Grade A	Monitoring in Grade A expected during operations	Supports monitoring strategies in Grade A environments through defined and repeatable sampling frequencies
9.26 - Monitoring locations and methods	Sampling locations must be representative and justified	Enables representative sampling at critical process locations through flexible positioning
9.33 - Data evaluation and trending	Data must be trended and evaluated	Provides reliable data suitable for trending and evaluation when managed within EM or LIMS systems
9.34 - Alert and action limits	Alert and action levels must be defined and monitored	Generates results that support comparison against alert and action limits within environmental monitoring programs

SERVICES AND SUPPORT

01

ISO 21501-4:2018 Annual Calibration and Verification

- Annual calibration performed at an ISO/IEC 17025 (ILAC-MRA) accredited laboratory.
- Issuance of an internationally recognized calibration certificate, fully accepted during GMP/ISO inspections or audits.
- Performance verification in accordance with ISO 21501-4:2018 and JIS B9921 standards (counting efficiency, linearity, coincidence loss, flow stability).

02

Warranty

- 5-year laser warranty.
- 2-year instrument warranty, including:
 - Repairs or replacements of manufacturing defects;
 - Remote technical assistance;
 - TrakPro™ Lite Secure Software updates, where applicable.

03

Scheduled Maintenance

- Option to sign periodic maintenance contracts with scheduled functional checks (every 6 or 12 months).
- Visual and functional inspection of the optical system and pump assembly.
- Cleaning and mechanical verification with a compliance report.

04

Repair Services and Technical Support

- Certified internal technical service for repairs, upgrades, and retrofits.
- Availability of original TSI® spare parts and components ready for delivery to minimize downtime.
- Loaner instrument option in case of prolonged repair.
- On-site or remote technical support, including video sessions or remote access.
- Validation, to ensure the Company's protection during inspections.

05

Documentation and Traceability

- Every intervention is accompanied by a detailed technical report (checks performed, reference instruments, test results, LAT/ILAC traceability).
- Digital history of all maintenance and calibration activities accessible upon request.
- Documentation compliant with regulatory requirements.

**Particle counters will be delivered
with a calibration certificate
compliant with ISO 21501-4:2018
issued by an ISO 17025:2018 laboratory.**

ALTIORLAB
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ADVANTAGES OF USING AN ISO/IEC 17025 ACCREDITED LABORATORY:

- ❖ **Full Inspection and Regulatory Validity:** the issued certificates have full value during audits and inspections by bodies such as AIFA, EMA, FDA, or notified bodies, ensuring full compliance with GMP and GxP requirements.
- ❖ **International Recognition (ILAC-MRA):** test reports and calibration certificates are globally recognized and accepted, avoiding duplications and disputes.
- ❖ **Guaranteed Metrological Traceability:** every measurement is traceable to national and international standards, ensuring data consistency and reliability.
- ❖ **Certified Technical Competence:** laboratory personnel, procedures, and instrumentation are periodically verified by an independent accreditation body.
- ❖ **Risk Reduction in Audits:** The use of an accredited laboratory protects the company during audits by providing objective and certified evidence of measurement quality.
- ❖ **Alignment with international quality standards:** ensures compliance with key regulations and guidelines (ISO 9001, ISO 14644, GMP, GDP).

DELIVERY TIME _____ Approximately 6/8 weeks from order date.

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info@qsgroup.it
+39 0362 1857411

Legal and operative site:
Via Torquato Tasso, 5 | Barlassina (MB)

Latina branch:
Via dei Marrucini, 13 | Latina (LT)

Lugano branch:
Via Canova, 9 | Lugano (CH)

Paris branch:
105, Avenue Raymond Poincaré, Paris