RION

GREEN

Light Obscuration Particle Counter

Liquid-Borne Particle Counter

KL-05

Conforms to Method 1 "Light Obscuration Particle Count Test" in insoluble particulate matter testing for injections in accordance with the Japanese Pharmacopeia

Serves for measurement of insoluble particles in injections, for example at pharmaceutical plants

Features

- Compliant with insoluble particulate matter testing for injections in accordance with the Japanese Pharmacopeia (JP), United States Pharmacopeia (USP), European Pharmacopeia (EP), Korean Pharmacopeia (KP) and Chinese Pharmacopoeia (ChP).
- Supports small volume measurement (USP 787). Special small size sample stand available as option, for 10 mL syringes and ampoules etc.
- Compliant with FDA's 21 CFR Part 11. Comprehensive operator and password management functions, as well as electronic signature support.
- Serial communication function allows output of measurement data to a Laboratory Information Management Systems (LIMS) etc.
- Measurement results can be output as PDF or text file (tab delimited) format.
- Large 10.4 inch LCD panel provides information in an easy to read format.
- Integrated SSD storage improves data access speed.
- Measurable particle size range 1.3 µm to 100 µm, flow rate 25 mL/min (10 mL/min available as factory option), with up to 20 particle size range settings.
- Light source uses semiconductor laser with three-year guarantee. (under normal use and proper handling)

Standardization of "Light Obscuration Particle Counter" in JP

The following validation tests need to be carried out at least once per year.

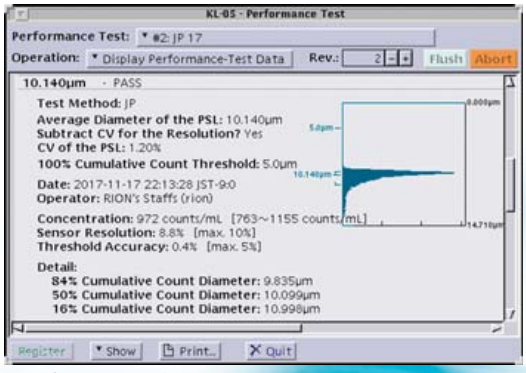
Calibration	Particle size sensitivity measurement using 5 µm, 10 µm, and 25 µm PSL particles
Sample fluid volume accuracy	Weighing method assessment of measurement volume; within 5 %
Sample flow rate	Range as specified by manufacturer
Count accuracy (Conduct the following tests using counting reference standard solution)	
Particle size resolution	Within 10 %
Count ratio	763 to 1155 particles/mL
Threshold setting accuracy	Within ±5 %

Criteria for JP, USP, EP, KP and ChP Insoluble Particulate Matter Tests

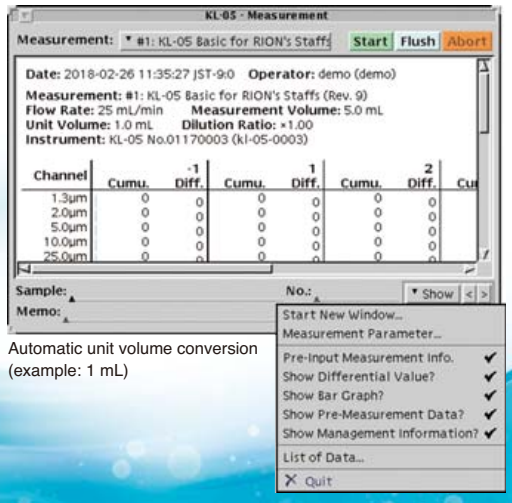
		JP/KP/ChP	USP/EP
Large volume	10 µm or more	No more than 25 particles/mL (100 mL or more)	No more than 25 particles/mL (over 100 mL)
	25 µm or more	No more than 3 particles/mL (100 mL or more)	No more than 3 particles/mL (over 100 mL)
Small volume	10 µm or more	No more than 6 000 particles/container (Less than 100 mL)	No more than 6 000 particles/container (100 mL or less)
	25 µm or more	No more than 600 particles/container (Less than 100 mL)	No more than 600 particles/container (100 mL or less)

Sample display screens

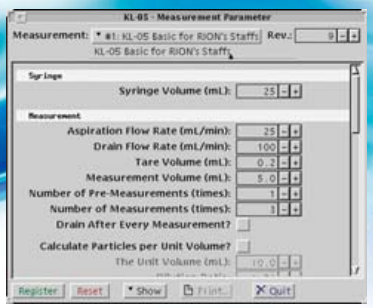
Screen language can be switched to Japanese or English



JP performance test data example



Automatic unit volume conversion (example: 1 mL)

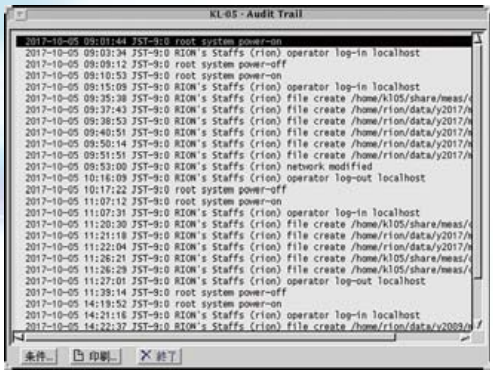


One aspiration action can be used for multiple measurements (within 25 mL)

Audit trail function

Produces a reliable record of who performed which operation at what time. Audit trail data can be displayed, printed, and searched.

Audit trail search sample screen



Audit trail display sample screen

Operator management function

Functions such as deletion and modification of measurement data, as well as display and printing of audit trail data can be access controlled by operator management.

Operator management sample screen

Specifications

Optical system	Light-obscuration method
Light source	Laser diode (rated output 4.5 mW, wavelength 790 nm)
Laser product class	Class 1, IEC 60825-1
Light detector	Photodiode
Fluid-contacting materials	
Flow cell	Synthetic quartz
Syringe	Borosilicate glass, PTFE
Syringe pump	Kel-F (PCTFE), PTFE
Tube, packing, joint	PFA, PTFE, PCTFE, Perflo (special fluorine rubber)
Particle size ranges	1 to 20 ranges from 1.3 μm to 100 μm (in 0.1 μm steps)
Counting efficiency	100 % ±5 %
Maximum particle number concentration	10,000 particles/mL (10 μm vicinity PSL particles, coincidence loss max. 10%)
Sampling volume accuracy	
25 mL syringe, flow rate 25 mL/min	within ±2 % (when measuring 10 mL)
25 mL syringe, flow rate 10 mL/min ＊Factory option	within ±2 % (when measuring 10 mL)
10 mL syringe, flow rate 10 mL/min ＊Factory option	within ±5 % (when measuring 0.5 mL)
Minimum measurable volume	0.2 mL ＊Depending on sampling tube in use, dead volume must be added to aspiration

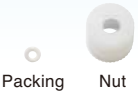
Maximum sample fluid pressure	50 kPa (gauge pressure)
Maximum sample fluid viscosity	30 mPa-s (at 25°C)
Power requirements	100 V to 240 V AC, 50/60 Hz, approx. 80 VA
Environmental condition for operation	15°C to 30°C, 20% to 80% RH (no condensation)
Dimensions and weight	Approx. 366 (H) x 375 (W) x 236 (D) mm, approx. 10 kg
Supplied accessories	PFA sampling tube set (2 mm dia. x 4 mm dia., length 10 cm) Drain tube set (2 mm dia. x 3 mm dia., length 150 cm) USB flash drive (8 GB), power cord (Japan domestic, 2.5 m), mouse, Keyboard, ferrite core, cell cleaning brushes (in case), cable clamp

Optional accessories	• PFA sampling tube set (2 mm dia. x 4 mm dia., length 10 cm) (with nut) KL-04-S14 • 25 mL syringe 5ZSY60P0 ＊Capacity test required after replacement. • 10 mL syringe 5ZSY61P0 ＊Capacity test required after replacement. • USB flash drive (32 GB) 5ZUBA200 • Printer LP-S280DN ＊Recommended model (alternative: HL-L2360DN) • USB cable for printer, Type A to Type B (2 m) 5WUSB200 • External display (21.5 in) E2282HD-B1 • USB - RS-232C converter cable 59RSAQ00 • Communication cable CC-61A, CC-63A

Option

SUS sampling tube set
(with nut and 2 packings)

KL-04-S12	φ2 mm×φ3 mm, Length100 mm
KL-04-S11	φ1 mm×φ2 mm, Length100 mm



Sample stand adapter for small volume containers KL-05-S22

This sample stand is designed to hold small volume containers during measurement. Containers between 8 and 20 mm in width can be used.

Electromagnetic stirrer unit KL-05-S21

Rapidly rotating the stirrer bar that is mounted on the sample stand of the KL-05 enables you to equalize the samples.

Stirring capacity	1 to 800 mL
Rotational frequency	130 to 1 000 rpm (single step switch)
Stirring power	3 W
Environmental conditions	−10 to + 120 °C (for less than 40 % humidity) −10 to + 95 °C (for 100 % humidity)
Dimensions of main body	16(H) ×48(W) ×48(D)mm
Weight of main body	Approx. 200 g
Input power	Supplied through the attached control unit

＊ Includes one stirrer bar

Compressing chamber JCC-54
(Custom-made product)

JCC-54 added to the KL-05 enables you to measure samples during pressurization.

Supported types of sample fluid	Fluids where the fluid or its gases will not corrode the materials of the unit
Chamber pressure (inside)	50 kPa
Materials of parts exposed to sample	PTFE, PAF, PP, FKM (Fluoro rubber)
Dimension, weight	340(H) × 245(W) × 245(D)mm, Approx. 12 kg

CLINTEX CTX10410
(standard particle concentration)

Particle size	10.14 µm
Guaranteed particle concentration	1000 particles/mL ±10 %

Support for validation works

We can support your validation works (IQ, OQ, PQ) for KL-05.

Work flow chart

1 Discussion with customers
(Confirmation of IQ, OQ and PQ)

2 Preparation and approval of IQ, OQ and PQ implementation plans

Required documents
- Test result reports in accordance with respective pharmacopeia
- Calibration certificates
- Traceability charts
- Instruction manuals

3 Implementation of IQ, OQ and PQ operations

4 Preparation of IQ, OQ and PQ implementation records

＊ Specifications subject to change without notice.

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