

Light Obscuration Particle Counter

# Liquid-Borne Particle Counter

## KL-04A





## Conforms to Method 1 "Light Obscuration Particle Count Test" in insoluble particulate matter test for injections conducted by the Japanese Pharmacopeia

Counts insoluble particulate  
matter in injections performed  
at pharmaceutical plants, etc.

### Features

- Data management principles as specified by Japanese Pharmacopeia (JP), United States Pharmacopeia (USP), European Pharmacopeia (EP), Korean Pharmacopeia (KP) and Chinese Pharmacopoeia (ChP) can be selected (option)
- Can be connected to an external system, such as LIMS (Laboratory Information Management System), to output measurement data (option) (USB-RS232C conversion cable required)
- USB memory is used for data output and system back up
- Conforms to 21 CFR Part 11 by the American FDA  
Enhanced audit trail and operator management functions
- Measurable particle size range: 1.3 to 100  $\mu\text{m}$ , flow rate: 25 mL/min (10 mL/min is factory option), size range : enables setting of up to 20 channels
- Supports automatic measurement and pass/ fail evaluation according to pharmacopeia specifications
- Small volume ampoule measurement is possible with the setting range of measurement volume from 0.2 mL
- Fully integrated system comprising sampler, sensor, controller and data storage
- Built-in hard disk can hold over ten years worth of measurement data

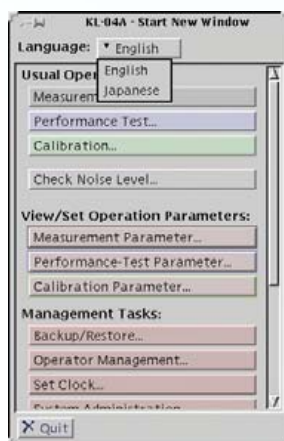
### JP: Standardization of "Light Obscuration Particle Counter"

Instrument	Verify the calibration, the sample volume accuracy, the flow rate accuracy, and the counting accuracy at least once a year.
Calibration	5 $\mu\text{m}$ , 10 $\mu\text{m}$ and 25 $\mu\text{m}$ PSL particles are to be included.
Sample volume accuracy	Use the weighing method to measure volumes (within 5 %)
Sample flow rate	Within the range specified by the manufacturer
Sensor	Particle Count Reference Standard Suspension Using (10 $\mu\text{m}$ PSL particle, within 1 000 particle/mL $\pm$ 10 %) to conduct the following tests: <ul style="list-style-type: none"> <li>• Permissible sensor resolution: within 10 %</li> <li>• Particle counting accuracy: 763 to 1 155 particles/mL</li> <li>• Threshold setting accuracy: within 5 %</li> </ul>

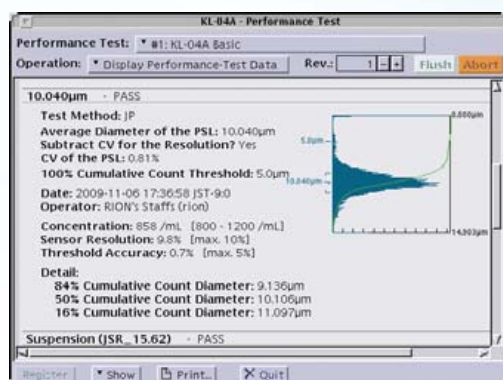
### Criteria for JP, USP, EP, KP and ChP Insoluble Particulate Matter Tests

		JP/KP/ChP	USP/EP
Large volume	10 $\mu\text{m}$ or more	No more than 25 particles/mL (100 mL or more)	No more than 25 particles/mL (over 100 mL)
	25 $\mu\text{m}$ or more	No more than 3 particles/mL (100 mL or more)	No more than 3 particles/mL (over 100 mL)
Small volume	10 $\mu\text{m}$ 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 $\mu\text{m}$ or more	No more than 600 particles/container (Less than 100 mL)	No more than 600 particles/container (100 mL or less)

## Screen display examples



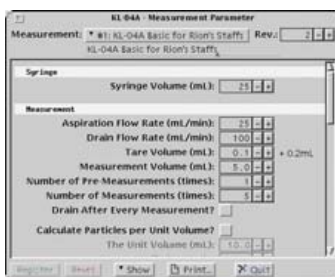
Screen language can be switched to Japanese or English



JP performance test data example

Channel	-1 Cumu.	1 Cumu.	2 Cumu.	3 Cumu.	Average (/1.0 ml)	Judgement
1.3µm	3	2	3	5	0.7	-
2.0µm	0	1	0	2	0.2	-
5.0µm	0	0	0	1	0.1	-
10.0µm	0	0	0	1	0.1	5 PASS
20.0µm	0	0	0	0	0.0	2 PASS
50.0µm	0	0	0	0	0.0	-
100.0µm	0	0	0	0	0.0	-

Automatic conversion for unit container and 1 mL



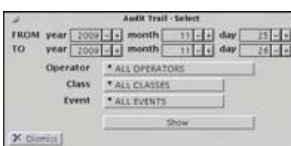
Measurement parameter  
(One aspiration action can be used for multiple measurements; within 25 mL)



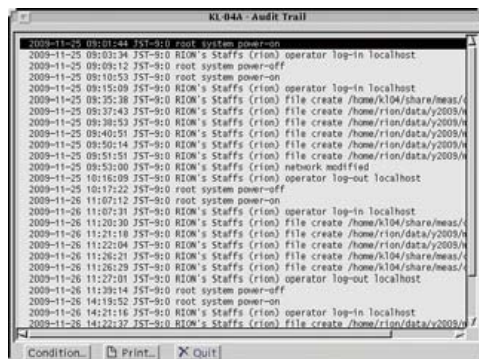
Measurement parameter  
(Selection of performance test data)

## Audit Trail Function

This function records information about time stamp (local time), operator, and operation event. History data can be displayed, printed, and searched.



History data search screen



History data display

## Operator Management Function

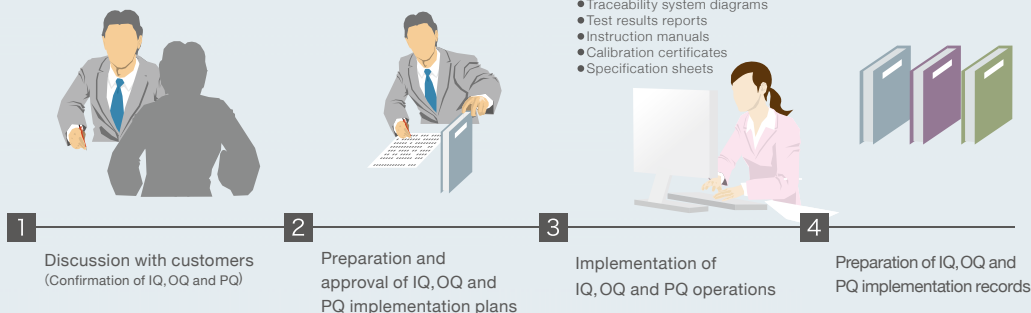
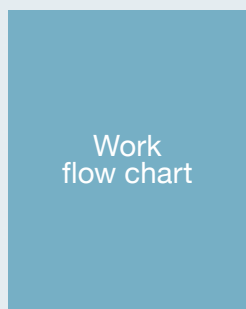
Functions such as deletion and modification of measurement data and display and printing of audit trail data can be access controlled by operator management.



Operator management screen

## Support for validation works

We can support your validation works (IQ, OQ, PQ) for KL-04A.



- Required documents
- Traceability system diagrams
  - Test results reports
  - Instruction manuals
  - Calibration certificates
  - Specification sheets



## Specifications

Optical method	Light-obscurtion method
Light source	Laser diode (rated output: 3 mW, wavelength: 780 nm)
Laser product class	Class1, IEC 60825-1
Light detector	PIN type photodiodes
Materials of parts exposed to sample	
Sampling tube	PFA
Sensor area	Synthetic quartz, PFA, perfluoro (fluorocarbon rubber)
Syringe pump	Borosilicate glass, Kel-F (PCTFE), PTFE, PFA
Tube/packing/connector	PTFE, PCTFE
Sample container plate	Polyacetal
Counting efficiency	100 ± 5 %
Measurable particle size range	1.3 to 100 μm (when using PSL particles in pure water)
Allowable fluid type	Fluids which do not cause corrosion to the parts in contact with the fluid
Calibration	Using PSL particles (refractive index 1.6) in pure water
Size range	Selectable arbitrarily from 1 to 20 channels
Flow rate	25 mL/min (10 mL/min is the factory option)

Maximum particle number concentration	10 000 particles/mL (when the counting loss is 10 % in the vicinity of 10 μm PSL particles in pure water)
Maximum sample pressure	50 kPa
Input/Output connectors	
PRINTER	Parallel interface to connect to a printer (IEEE 1284 compatible, 25 pin D-sub female type connector) USB Interface (USB 2.0, type A, female type connector)
Printer to be connected	Supporting PostScript Level 2 and above
USB	Interface to connect to equipment that supports USB devices (USB 2.0, type A, female type connector, 4 ports)
Power	100 to 240 V AC, 50/60 Hz, approx. 100 VA
Environmental conditions for operation	+15 to + 30 °C, 20 to 80 % RH (no condensation)
Dimensions, weight	Approx. 363(H)×360(W)×236(D)mm (excluding protruding parts), Approx. 13 kg
Supplied accessories	PFA sampling tube (ø2 mm×4 mm, length 10 cm) set Drain tube (ø 2mm×3 mm, length 1.5 m) set (includes a connector and a piece of packing) USB memory, Power code (2.5 m), Mouse, Keyboard, Cell cleaning brushes, Screw (for mounting electromagnetic stirrer)

Optional Accessories	Printer (PostScript Level 2 or above), Printer cable (parallel), Electromagnetic stirrer, stirrer bar PFA sampling tube (ø2 mm×4 mm, length 10 cm) set (includes a nut) (KL-04-S14) SUS sampling tube (ø2 mm×3 mm, length 10 cm) set (includes a nut and 2 pieces of packing) (KL-04-S12) SUS sampling tube (ø1 mm×2 mm, length 10 cm) set (includes a nut and 2 pieces of packing) (KL-04-S11) Seat, USB memory, USB-RS232C conversion cable
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## Options

### Electromagnetic Stirrer Unit

Rapidly rotating the stirrer bar that is mounted on the sample stand of the KL-04A 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 XP-54 (Custom-made product)

XP-54 added to the KL-04A 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

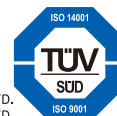
(standard particle concentration)

Particle size	10.14 μm
Guaranteed particle concentration	1 000 particles/mL ± 10 %



### PRINTER

- PostScript Level 2 or above
- Monochrome laser printer



\* Specifications subject to change without notice.

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