

**SPECIFICATIONS**  
LIGHT OBSCURATION PARTICLE COUNTER  
**KL-04**



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# Outline

The Light Obscuration Particle Counter KL-04 detects particles suspended in a fluid and measures their size and numbers using the light-obscuration method.

The unit is an automatic particle measurement system specially designed for process step control and quality management for example at medical production. The light-obscuration principle is optimal for performing insoluble particulate matter tests for injections as prescribed by the Japanese Pharmacopeia (JP), United States Pharmacopeia (USP), and European Pharmacopeia (EP).

The unit also provides compliance with regulations for electronic records and signatures, such as “21 CFR Part 11: Electronic Records; Electronic Signatures” by the American FDA. However, signature support is provided for handwritten signatures only.

The features of the unit are as follows.

- Measurable particle size range of 1.3 to 100  $\mu\text{m}$ .
- Rated sample fluid flow of 25 mL / min.
- Built-in syringe pump enables measurement without connecting to other flow control systems.
- Able to set 20 channels of measurable particle size range.
- Built-in hard disk can save several years of measurement data.
- Built-in tape drive enables backups and restoration of data saved on the hard disk.
- Measurement data can be transferred by connecting to networks. Also the measurement data can be exported in TSV (Tab Separated Values) format by using the built-in floppy disk drive.
- A printer (Post Script Level 2 and above) can be connected to print out the measurement results.
- Conformance with the Instrument Standardization (Calibration, Performance-Test) of the Japanese Pharmacopeia (JP) and the United States Pharmacopeia (USP).

RION Co., Ltd. carries out a standardized system test (Calibration, Performance-Test) as a factory option.

- Whether the measurement result is acceptable or not can be decided.
- An external display can be connected.
- All major operations affecting electronic records such as measurement data creation, modification, and deletion are recorded as audit trail information which can be viewed and printed.
- Access control for functions such as measurement data modification and deletion can be set for individual operators.

\* All company names and product names mentioned in this specifications are trademarks or registered trademarks of their respective owners.

# Specifications

Optical system	Light-obscuration method
Light source	Laser diode (rated output: 3 mW, wavelength: 780 nm)
Laser product classification	Class 1, IEC 60825-1 (2001) Class 3B laser is used in the internal particle detection mechanism.
Light detector	PIN type photodiodes
Materials of component parts exposed to sample fluid	
Sampling tube:	PFA, (SUS304 is option)
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
Allowable fluid type	Fluids which do not cause corrosion to the parts in contact with the fluid
Calibration	Using polystyrene latex (PSL) particles (refractive index 1.6) in pure water
Minimum particle size	1.3 $\mu\text{m}$
Measurable particle size	1.3 to 100 $\mu\text{m}$ (when using PSL particles in pure water)
Particle size division	Selectable arbitrarily from 1 to 20 channels
Counting efficiency	100 $\pm$ 5% (when measuring PSL particles of 10 $\mu\text{m}$ in pure water and comparing the count of more than 5 $\mu\text{m}$ with a reference unit)
Sample flow rate	25 mL / min (10 mL / min is factory option)
Maximum particle number concentration	10000 particles / mL (when the counting loss is 10% in the vicinity of 10 $\mu\text{m}$ PSL particles in pure water)
Sensor resolution	Less than or equal to 10% (in the vicinity of 10 $\mu\text{m}$ PSL particles in pure water)
Threshold accuracy	Within 5% (when particle number concentration is less than 6000 particles / mL in the vicinity of 10 $\mu\text{m}$ and 15 $\mu\text{m}$ PSL particles in pure water)
Flow rate accuracy	Within 2% (when measuring 10 mL volume)
Sample volume accuracy	Within 2% (when measuring 10 mL volume)

## Instrument Standardization at each regional pharmacopeia (factory option)

### JP

Calibration	Particle size calibration using the calibrated particles of 1.3 to 100 $\mu\text{m}$ which have domestic and international traceability have a margin of error of less than 3%. However, our own specified method will be carried out for the calibration of less than 4 $\mu\text{m}$ .
Performance-Test	Sample volume accuracy test Flow rate accuracy test Particle counting accuracy test, threshold accuracy test and sensor resolution test using Clintex (Particle Count Reference Standard Suspension), which is manufactured by JSR.

### USP

Calibration	Particle size calibration using the calibrated particles of 1.3 to 100 $\mu\text{m}$ , which are traceable and NIST standard reference materials. However, our own specified method will be carried out for calibration of less than 4 $\mu\text{m}$ .
Performance-Test	Sample volume accuracy test Flow rate accuracy test Counting accuracy test and Ratio value test using USP-PC-RS Sensor resolution test using calibrated particles of 10 $\mu\text{m}$ .

### EP

Calibration	Applied to JP or USP*
Performance-Test	Applied to JP or USP*

\* EP has no regulations about Calibration and Performance-Test

## Sample container size

Maximum size (diameter)	Beaker 300 mL (JIS R 3503)
Maximum height	Tall beaker 200 mL (JIS R 3503)
Sample container plate	Internal diameter 77 mm, depth 5 mm

## Sample fluid temperature range

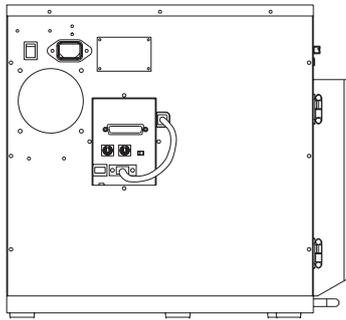
+15 to +30°C (no condensation on flow cell)

## Sample fluid connectors

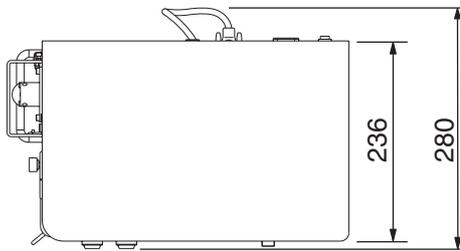
INLET	Sample fluid inlet Sampling tube provided is to be connected to the INLET within the sensor area.
OUTLET	Sample fluid outlet 2×3 dia. flange tube is to be connected to the OUTLET of the syringe pump.

Display	6 inch color TFT LCD
Input / Output connectors	
PRINTER	Parallel port (IEEE1284 compatible, 25 pin D-sub female type connector) to connect to a printer (supporting Post Script Level 2 and above).
MOUSE	Connector for the mouse provided.
KEYBOARD	Connector for the keyboard provided.
ETHERNET	Interface to connect to a LAN (10Base-T)
DISPLAY	Interface to connect to a display. (Analogue RGB, 15 pin high density D-sub female type connector, Resolution: 640×480 pixels, Scanning frequency: vertical 60 Hz/horizontal 31.5 kHz) Connected to the built-in display when shipped.
Recording device	
Floppy disk drive	Write specified data to a floppy disk (3.5inch 2HD)
Tape drive	Back up and restore data on magnetic tape.
Power requirement	100 to 240 V AC, 50 / 60 Hz, Approx. 100 VA
Environmental requirements	
Operational Environments	
	Indoor Use Only
Altitude	Up to 2000 m
Supply Voltage Fluctuations	
	100 to 240 V AC ±10%
Installation Category	2
Pollution Degree	2
Ambient conditions for operation	
	+15 to +30°C, 20 to 80% RH (no condensation)
Ambient conditions for storage	
	-10 to +50°C, less than or equal to 90% RH (no condensation and no freezing of internal piping)
Dimensions	369 (H) × 400 (W) × 280 (D) mm (maximum) 363 (H) × 360 (W) × 236 (D) mm (excluding protruding parts)
Weight	Approx. 14 kg

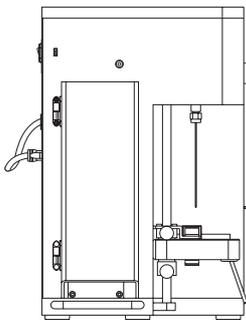
Supplied Accessories	PFA Sampling tube (2×4 dia., length 100 mm) set (includes a nut)	1
	Drain tube (2×3 dia., length 1500 mm) set (includes a connector and a piece of packing)	1
	Mouse	1
	Keyboard	1
	Power cord	1
	Tape cartridge	1
	Cell cleaning brushes (includes case)	2
	Screw (M4×10) for mounting electromagnetic stirrer	1
	Instruction manual	1
	Instruction manual (for Administrator)	1
	Liquid-Borne Particle Counter Usage Precautions	1
	Inspection Certificate	1
Optional Accessories	PFA Sampling tube (2×4 dia., length 100 mm) set (includes a nut)	
	SUS Sampling tube (2×3 dia., length 100 mm) set (includes a nut and 2 pieces of packing)	
	SUS Sampling tube (1×2 dia., length 100 mm) set (includes a nut and 2 pieces of packing)	



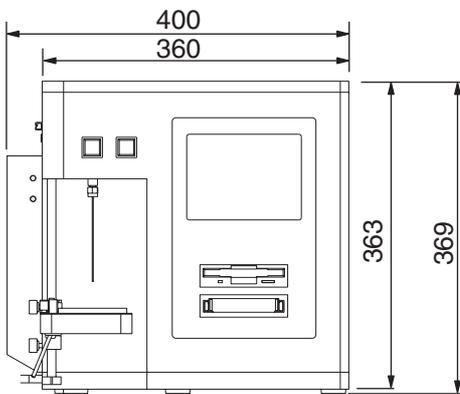
Rear View



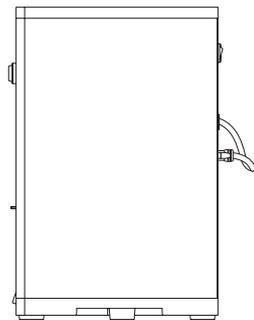
Top View



Left Side View



Front View



Right Side View

Unit: mm

### Dimensional Drawings

Specifications subject to change without notice