

SPECIFICATIONS
LIGHT OBSCURATION PARTICLE COUNTER
KL-04A



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Outline

The light obscuration particle counter KL-04A detects particles suspended in a fluid and measures their size and number concentration 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), European Pharmacopeia (EP), and Korean Pharmacopoeia (KP).

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 μm .
- Sample fluid flow rate is 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.
- USB flash drive enables backups and restoration of data saved on the hard disk.
- The measurement data can be exported in TSV (Tab Separated Values) format by using the USB flash drive.
- A printer (PostScript 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), United States Pharmacopeia (USP) and Korean Pharmacopoeia (KP).

RION Co., Ltd. will carry 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.
- Data output to a computer is possible via a serial link, using the optional USB-RS-232C conversion cable.

* 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 (2007) 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 as 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 sample 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 detectable particle size	1.3 μm
Measurable particle size range	1.3 to 100 μm (when using PSL particles in pure water)
Size range	Selectable arbitrarily from 1 to 20 channels
Counting efficiency	100 \pm 5% (when measuring PSL particles of 10 μm in pure water and comparing the count of more than 5 μm with a reference unit)
Flow rate	25 mL / min (10 mL / min as factory option)
Maximum particle number concentration	10000 particles / mL (when the counting loss is 10% in the vicinity of 10 μm PSL particles in pure water)
Size resolution	10% or less (in the vicinity of 10 μm PSL particles in pure water)
Threshold accuracy	5% or less (when particle number concentration is less than 6000 particles / mL in the vicinity of 10 μm and 15 μm PSL particles in pure water)

Sampling flow rate accuracy

Within 2% (when measuring 10 mL volume)

Sampling 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 μm 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 μm .

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 μm , which are traceable and NIST standard reference materials. However, our own specified method will be carried out for calibration of less than 4 μm .

Performance-Test Sample volume accuracy test
Flow rate accuracy test
Counting accuracy test and Ratio value test using USP-PC-RS (USP Particle Count Reference Standard)
Sensor resolution test using calibrated particles of 10 μm .

KP

Calibration Particle size calibration using the calibrated particles of 1.3 to 100 μm 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 μm .

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.

EP

Calibration Applied to JP or USP*

Performance-Test Applied to JP or USP*

* EP has no regulations about Calibration and Performance-Test

Syringe pump

Measurement	Sampling flow rate	25 mL / min
	Range of drain flow rate	5 mL / min to 100 mL / min
Flushing	Range of sampling flow rate	5 mL / min to 100 mL / min
	Range of drain flow rate	5 mL / min to 100 mL / min

Sample container size

Maximum size (diameter)	Beaker 300 mL (JIS R 3503)
	Tall beaker 200 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 dead volume

0.5 mL or less
(Volume of air pocket from tip of sampling tube to detector section)

Maximum sample fluid pressure

0.5 kPa

Maximum sample fluid viscosity

30 mPa · s (at 25°C)

Sample fluid temperature range

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

Sample port

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

Display

6.5 inch color LCD

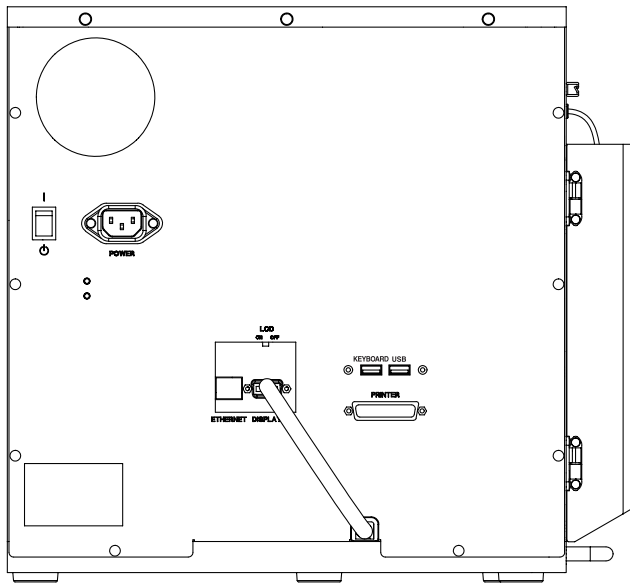
Input / Output connectors

PRINTER	Parallel port (IEEE1284 compatible, 25 pin D-sub female type connector) to connect to a printer (supporting PostScript Level 2 and above).
ETHERNET	Interface to connect to a LAN (10 / 100Base-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.

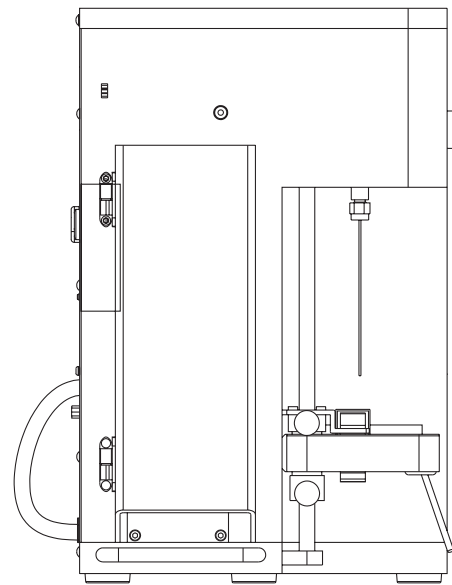
KEYBOARD	Interface to connect to a keyboard For connection of supplied keyboard	
USB (2 front panel ports, 1 rear-panel port)	For connecting devices with USB interface (USB 2.0, type A female connector) For connection of supplied mouse, USB flash drive etc.	
Power	100 V to 240 V AC, 50 / 60 Hz, Approx. 100 VA	
Environmental Requirements		
Operational Environments	Indoor Use Only	
Altitude	Up to 2000 m	
Supply Voltage Fluctuations	100 V to 240 V AC $\pm 10\%$	
Installation Category	2	
Pollution Degree	2	
Environmental conditions for operation	+15°C to +30°C, 20% to 80% RH (no condensation)	
Environmental conditions for storage	-10°C to +50°C, 90% RH or less (no condensation and no freezing of internal piping)	
Dimensions	Approx. 369 (H) \times 400 (W) \times 280 (D) mm (maximum) Approx. 363 (H) \times 358.5 (W) \times 236 (D) mm (excluding protruding parts)	
Weight	Approx. 13 kg	
Supplied accessories	PFA sampling tube (2 mm \times 4 mm dia., length 10 cm) set (includes a nut)	1
	Drain tube (2 mm \times 3 mm dia., length 1.5 m) set (includes a connector and a piece of packing)	1
	Mouse	1
	Keyboard	1
	Power cord	1
	USB flash drive (for backup)	1
	Cell cleaning brush (included in one case)	2
	Screw (M4 \times 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

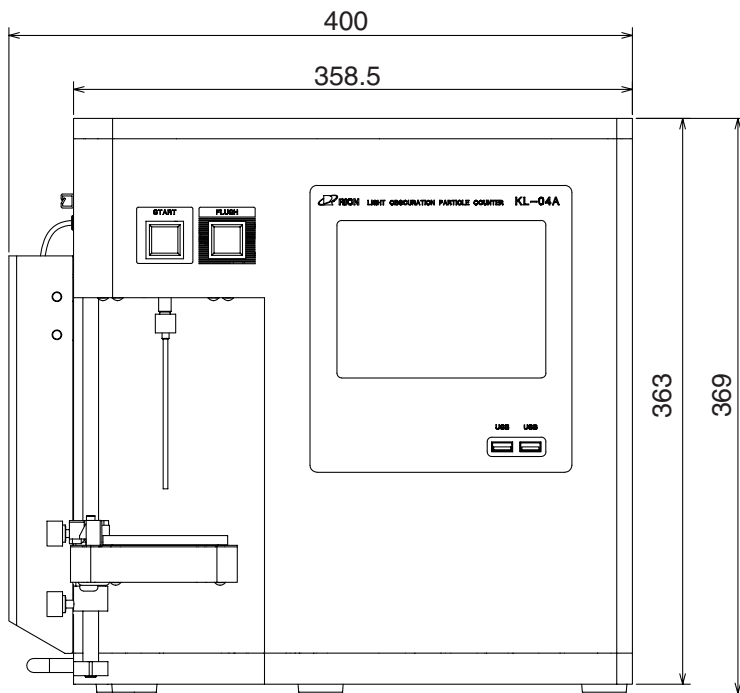
- PFA Sampling tube (2 mm × 4 mm dia., length 10 cm) set
(includes a nut)
- SUS Sampling tube (2 mm × 3 mm dia., length 10 cm) set
(includes a nut and 2 pieces of packing)
- SUS Sampling tube (1 mm × 2 mm dia., length 10 cm) set
(includes a nut and 2 pieces of packing)
- Electromagnetic stirrer HP40107
- Stirring bar
- USB flash drive
- USB-RS-232C conversion cable
- Printer (support PostScript Level 2 and above)
- Printer cable (parallel)



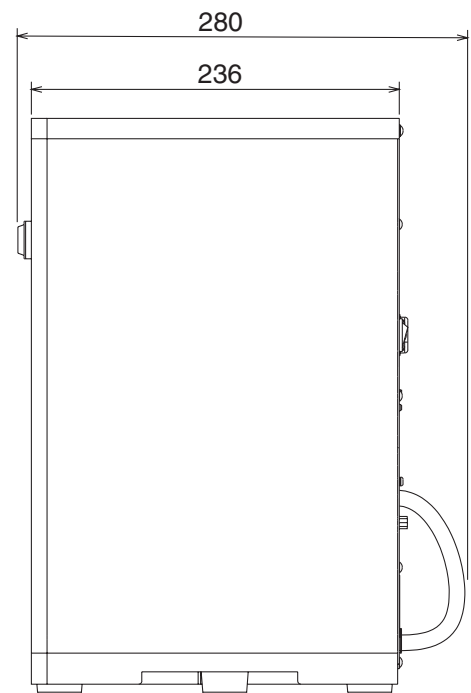
Rear view



Left side view



Front view



Right side view

Unit: mm

Dimensional Drawings

Specifications subject to change without notice