

SPECIFICATIONS
LIGHT OBSCURATION
PARTICLE COUNTER
KL-05



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Outline

The light obscuration particle counter KL-05 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 in 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 Pharmacopeia (KP) and Chinese Pharmacopeia (ChP).

This unit incorporates regulatory compliance functions related to electronic records and electronic signatures as defined in the FDA's "21 CFR Part 11", "PIC/S GMP Annex 11" and the "Ministry of Health, Labor and Welfare Guidelines".

The features of the unit are as follows.

- Measurable particle size range of 1.3 µm to 100 µm.
- The rated flow rate is 25 mL/min (10 mL/min also available as a factory option).
- Built-in syringe pump enables measurement without connecting to other flow control systems.
- Up to 20 particle size ranges can be set.
- Internal storage capacity for several years worth of measurement data.
- USB flash drive enables backups and restoration of data saved on the unit.
- The measurement data can be exported in TSV (Tab Separated Values) or PDF (Portable Document Format) format by using the USB flash drive.
- Whether the measurement result is acceptable or not can be decided.
- Electronic signature function allows adding an electronic signature to measurement data.
- All major operations related to electronic recording such as measurement data creation, modification, deletion etc. can be recorded in an audit trail that can be viewed and printed.
- Automatic logout function after a certain period of inactivity.
- Expiration time of password can be set.
- Optional printer can be connected, for printout of measurement results etc.
- Access control for functions such as measurement data modification and deletion can be set for individual operators.
- Measurement results can be exported via serial communication or Ethernet.
- Optional external display can be connected.
- Small volume measurements are supported, and a 10 mL syringe is available as a factory option.
- Compliance with national pharmacopeia is available as a factory option.

* 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: 4.5 mW, wavelength: 790 nm)
Laser product class	Class 1, IEC 60825-1 (2014) Class 3B laser is used in the internal particle detection mechanism.
Light detector	Photodiodes
Materials of component parts exposed to sample fluid	
Flow cell	Synthetic quartz
Syringe	Borosilicate glass, PTFE
Syringe pump	Kel-F (PCTFE), PTFE
Tube / Packing / Connector	PFA, PTFE, PCTFE, perfluoro (fluorocarbon rubber)
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 (with PSL particles of refractive index 1.6 in pure water)
Measurable particle size range	1.3 μm to 100 μm (with PSL particles of refractive index 1.6 in pure water)
Size range	Can be set freely up to 20 increments within the measurable particle size range (0.1 μm steps)
Counting efficiency	100% \pm 5% (measuring PSL particles in the vicinity of 10 μm in pure water and comparing 5 μm and above count with reference unit)
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)
Size resolution	10% or less (in the vicinity of 10 μm PSL particles in pure water)
Sampling volume accuracy	Within \pm 2% (using 25 mL syringe, flow rate 25 mL/min, 10 mL measurement)

Sampling flow rate accuracy	Within $\pm 2\%$ (using 25 mL syringe, flow rate 25 mL/min, 10 mL measurement)
Maximum particle number concentration	10000 particles/mL (when the counting loss is 10% in the vicinity of 10 μm PSL particles in pure water)
Flow rate	25 mL/min
Syringe Volume	25 mL
Minimum measurable volume	0.2 mL
Sample fluid dead volume	0.5 mL or less (When using KL-04-S12, KL-04-S13, or KL-04-S14) 0.2 mL or less (When using KL-04-S11)
Sample container	
Maximum size (diameter)	79 mm (using JIS R3503-2007 300 mL beaker)
Maximum height	112 mm (using JIS R3503-2007 200 mL beaker)
Sample container plate	Internal diameter 77 mm, depth 10 mm
Sample fluid temperature range	+15°C to +30°C (no condensation on flow cell)
Sample INLET / OUTLET	
INLET	2 mm \times 4 mm dia. Flare processing
OUTLET	2 mm \times 3 mm dia. Flange processing
Maximum sample fluid pressure	50 kPa (gauge pressure)
Maximum sample fluid viscosity	30 mPa \cdot s (at 25°C)
Measurement conditions	
Measurement	
Drain flow rate	5 mL/min to 100 mL/min (1 mL/min steps)
Measurement volume	0.2 mL to 24.8 mL (0.1 mL steps)
Number of Measurements	1 time to 100 times (1 time steps)
Tare Volume	0.2 mL to 10.0 mL (0.1 mL steps)
Number of Pre Measurements	0 time to 10 times (1 times step)

Flushing	
Aspiration flow rate	5 mL/min to 100 mL/min (1 mL/min steps)
Drain flow rate	5 mL/min to 100 mL/min (1 mL/min steps)
Flush Volume	0.2 mL to 25.0 mL (0.1 mL steps)
Repeat	1 time to 100 times (1 time steps)
Measured value display	Cumulative value / Differential value
Error Information	Indicates sensor degradation / detection status deterioration
Display section	
Display method	10.4 in. TFT LCD (Anti Glare) (with LED backlight) XGA 1024 x 768
Display language	English / Japanese
Display items	Measurement screen, Calibration screen, Performance-test screen, Other various setting screens
LED	
START	Lights up in green when measurement starts
FLUSH	Lights up in white during flushing
Operation section	
Button	
START	Start measurement
FLUSH	Start flushing
Input / Output connectors	
Ethernet	10/100/1000BASE-T TCP/IP RJ-45 × 1
SERIAL	EIA-232C-E compliant
	Connector D-SUB 9 pin, male × 1
D-SUB	Maximum resolution WQXGA (2560 × 1600)
	Connector mini D-SUB 15 pin, female × 1
USB	Type A, female × 5 (front: 1 port, rear 4 ports)
Internal storage device	64 GB
Input device	Keyboard, 3-button mouse
Function	
Audit trail function	Record operation history
Electronic recording function	Save measured data in digital format
Electronic signature function	Create electronically signed data Identify the person who signed Transfer electronically signed data

Backup / Restore function

Backup various data in the USB memory
Restore backedup data from USB memory

Security function

Password registration for each operator
Set password expiration date
Automatic logout when you do not operate for a fixed time

Network / Printer / Serial Port Settings

Set network / printer / serial port

Snap shot

Taking snapshots of the screen

Calender

1970 to 2064 (adjusts for leap years), monthly difference ± 2 minutes
(normal temperature)

Environmental Requirements

Operational Environments

Indoor Use Only

Altitude

Up to 2000 m

Supply Voltage Fluctuations

100 V to 240 V AC $\pm 10\%$

Overvoltage Category II

Pollution Degree 2

Protection Class I

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)

Power switch

With electromagnetic reset function

Power

100 V to 240 V AC, 50/60 Hz, Approx. 80 VA

Dimensions

Approx. 366 mm (H) \times 360 mm (W) \times 236 mm (D) (excluding protruding parts)
Approx. 369 mm (H) \times 375 mm (W) \times 236 mm (D) (maximum)

Weight

Approx. 10 kg

Supplied accessories

PFA sampling tube (2 mm × 4 mm dia., length 10 cm) set (includes a nut) KL-04-S13	1
Drain tube (2 mm × 3 mm dia., length 150 cm) set (includes a connector and a piece of packing)	1
Mouse	1
Keyboard	1
Ferrite core	1
USB flash drive (8 GB) for backup	1
Power cord (2.5 m)	1
Cell cleaning brush (included in one case) KR-41-022	1
Cable clamp	1
CD-ROM for KL-05	1
Administrator manual and handling precautions	1
Liquid-borne particle counter usage precautions	1
Instruction sheet for “Transport and Installation”	1
Inspection certificate	1

Factory option

The standardization of units by the regional pharmacopeia

JP

Particle size calibration

Particle size calibration using particles from 1.3 μm to 100 μm which have domestic or international size traceability and uncertainty within ± 3%. However, for calibration of 4 μm and below, Rion employs an in-house method

Performance test Sample fluid volume accuracy test

Sample fluid flow rate accuracy test

Count ratio test, threshold accuracy test and particle size resolution test using Clintex (counting reference standard solution) manufactured by JSR Corporation

USP

Particle size calibration

Particle size calibration using particles from 1.3 μm to 100 μm (NIST standard reference substance with traceability). However, for calibration of 4 μm and below, Rion employs an in-house method.

Performance test Sample fluid volume accuracy test

Sample fluid flow rate accuracy test

Count accuracy test and ratio value test using USP-PC-RS

Particle size resolution test using calibrated 10 μm particles

EP

Particle size calibration

Compliant with JP or USP

Performance test Compliant with JP or USP

Note: EP does not have stipulations for particle size calibration and performance testing

KP

Particle size calibration

Particle size calibration using particles from 1.3 μm to 100 μm which have domestic or international size traceability and uncertainty within $\pm 3\%$. However, for calibration of 4 μm and below, Rion employs an in-house method

Performance test Sample fluid volume accuracy test

Sample fluid flow rate accuracy test

Count ratio test, threshold accuracy test and particle size resolution test using Clintex (counting reference standard solution) manufactured by JSR Corporation

ChP

Particle size calibration

Compliant with JP or USP

Performance test Sample fluid volume accuracy test

Sample fluid flow rate accuracy test

Particle size resolution test and counting tolerance test using a counting reference standard solution manufactured by Beijing Hai'an Hongmeng Standard Substance Technology Limited Li-ability Company

Compliant with 10 mL syringe volume

The syringe volume 10 mL

The rated flow rate 10 mL/min

Measurement

Drain Flow Rate 5 mL/min to 100 mL/min (1 mL/min steps)

Measurement Volume

0.2 mL to 9.8 mL (0.1 mL steps)

Number of Measurement

1 time to 100 times (1 time steps)

Tare Volume 0.2 mL to 9.8 mL (0.1 mL steps)

Number of Pre-Measurement

0 time to 10 times (1 time steps)

Flushing

Aspiration Flow Rate

5 mL/min to 100 mL/min (1 mL/min steps)

Drain Flow Rate 5 mL/min to 100 mL/min (1 mL/min steps)

Flush Volume 0.2 mL to 10.0 mL (0.1 mL steps)

Repeat 1 time to 100 times (1 time steps)

Sample fluid volume accuracy

Within $\pm 5\%$

(when measuring a volume of 9.6 mL or 0.5 mL with a 10 mL syringe)

Sample fluid flow rate accuracy

Within $\pm 5\%$

(when measuring a volume of 9.6 mL or 0.5 mL with a 10 mL syringe)

* A USP with a 10 mL syringe measures and evaluates a volume of 0.5 mL.

The rated flow rate 10 mL/min changing

The rated flow rate 10 mL/min

Sample fluid volume accuracy

Within $\pm 2\%$

(when measuring a volume of 10 mL with a 25 mL syringe)

Within $\pm 5\%$

(when measuring a volume of 9.6 mL or 0.5 mL with a 10 mL syringe)

Sample fluid flow rate accuracy

Within $\pm 2\%$

(when measuring a volume of 10 mL with a 25 mL syringe)

Within $\pm 5\%$

(when measuring a volume of 9.6 mL or 0.5 mL with a 10 mL syringe)

* A USP with a 10 mL syringe measures and evaluates a volume of 0.5 mL.

The rated flow rate 10 mL/min Addition

The rated flow rate 10 mL/min

Sample fluid volume accuracy

Within $\pm 2\%$

(when measuring a volume of 10 mL with a 25 mL syringe)

Within $\pm 5\%$

(when measuring a volume of 9.6 mL or 0.5 mL with a 10 mL syringe)

Sample fluid flow rate accuracy

Within $\pm 2\%$

(when measuring a volume of 10 mL with a 25 mL syringe)

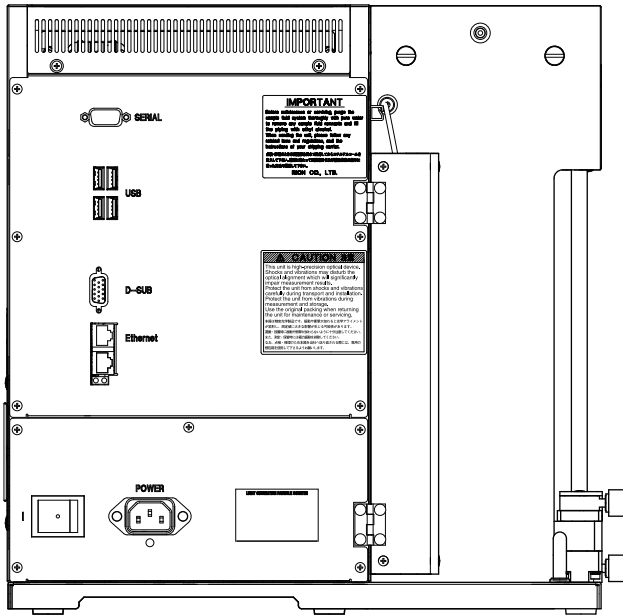
Within $\pm 5\%$

(when measuring a volume of 9.6 mL or 0.5 mL with a 10 mL syringe)

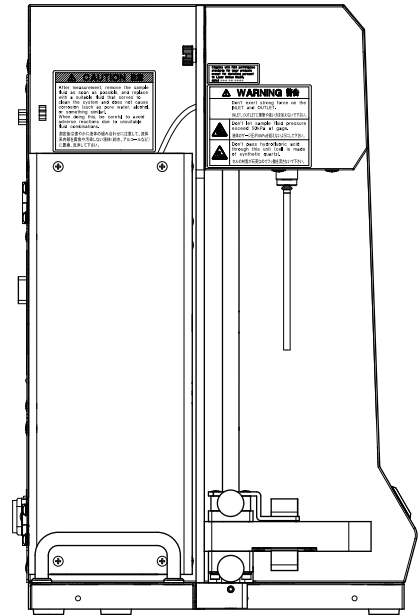
* A USP with a 10 mL syringe measures and evaluates a volume of 0.5 mL.

Optional accessories

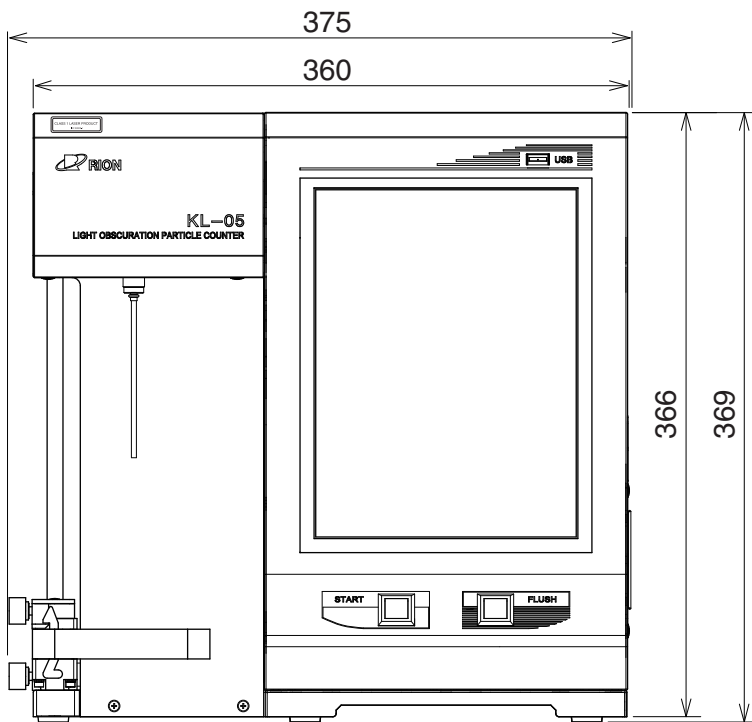
PFA Sampling tube (2 mm × 4 mm dia., length 10 cm) set (includes a nut)	KL-04-S14
SUS Sampling tube (2 mm × 3 mm dia., length 10 cm) set (includes a nut and 2 pieces of packing)	KL-04-S12
SUS Sampling tube (1 mm × 2 mm dia., length 10 cm) set (includes a nut and 2 pieces of packing)	KL-04-S11
Electromagnetic stirrer set	KL-05-S21
Cell cleaning brush (2 pieces)	KR-41-022
25 mL syringe	
10 mL syringe	
USB flash drive (8 GB)	
USB flash drive (32 GB)	
Printer	
USB cable for printer, Type A to Type B (2 m)	
External display	
Sample stand adapter for small volume containers	KL-05-S22
USB-RS-232C conversion cable	
Communication cable	CC-61A
Communication cable	CC-63A



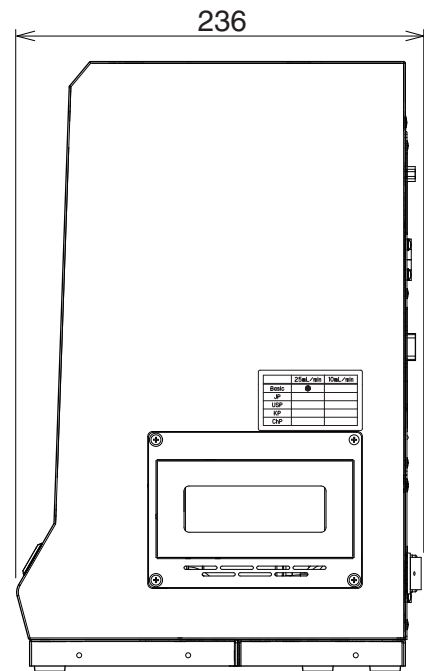
Rear view



Left side view



Front view



Right side view

Unit: mm

Dimensional Drawings

Specifications subject to change without notice