



Particle Counter
***Light Obscuration
Particle Counter***
KL-04 Ver 2.0

**Conforms to 21 CFR Part 11
Now With Audit Trail Function and
Enhanced Operator Management Function (Ver 2.0)***

**Upgrading from Ver 1.0 to Ver 2.0 possible.*



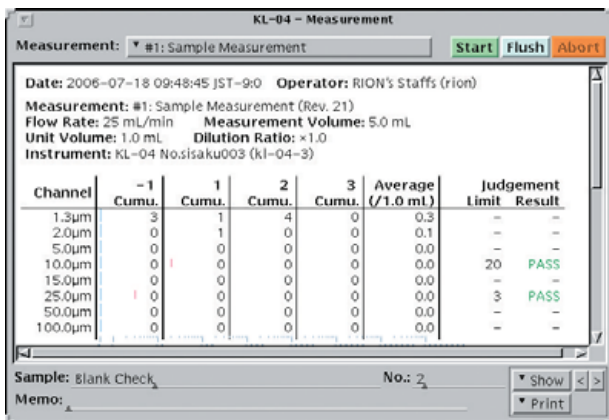
**Supports insoluble particulate matter test for injections
in accordance with United States Pharmacopeia
Suitable for quality control of injections**

- Data management principles as specified by Japanese Pharmacopeia (JP), United States Pharmacopeia (USP) and European Pharmacopeia (EP) possible (System standardization by optional particle size calibration and performance test)
- Supports automatic measurement and pass/fail evaluation according to pharmacopeia specifications
- Fully integrated system comprising sampler, sensor, controller and data storage
- Built-in hard disk can hold several years' worth of measurement data

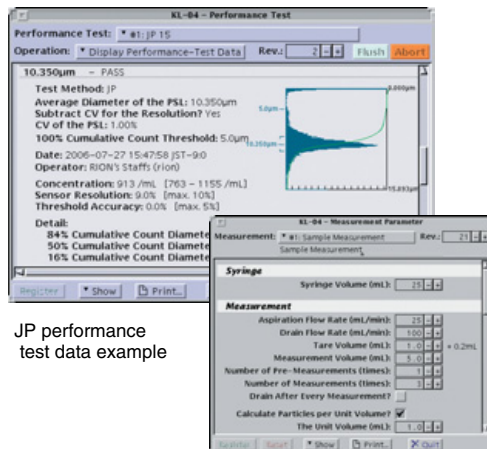
Screen display examples



Screen language can be switched to Japanese, English, or German



Automatic conversion for unit container and 1 mL

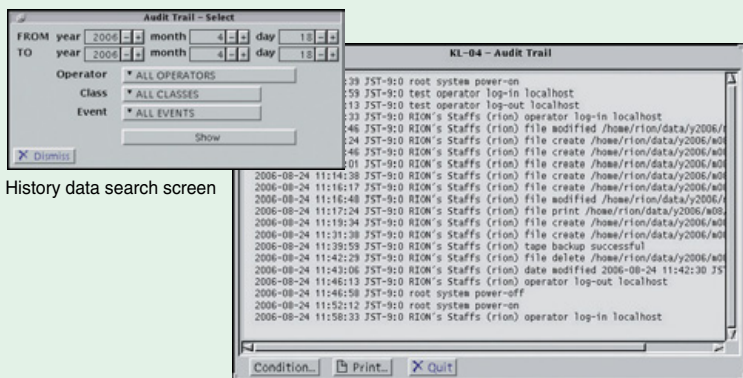


JP performance test data example

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

Audit Trail Function

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

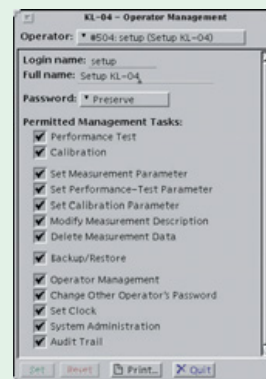


History data search screen

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

Specifications

Detection principle	Light-obscuration method
Light source	Laser diode (wavelength: 780 nm, max. rated output: 3 mW)
Laser product classification	Class 1, IEC 60825-1: 2001
Light detector	PIN type photodiodes
Materials of component parts exposed to sample fluid	
Sampling tube	PFA (SUS304 available as option)
Sensor area	Synthetic quartz, PFA, perfluoro
Syringe pump	Borosilicate glass, Kel-F (PCTFE), PTFE, PFA
Tube/packing/connector	PTFE, PCTFE
Sample container plate	Polyacetal
Calibration	Using polystyrene latex (PSL) particles (refractive index 1.6) in pure water
Measurable particle size range	1.3 to 100 µm (when using PSL particles in pure water)
Particle size division	1 to 20channels (freely selectable)
Sample flow rate	25 mL/min (10 mL/min available as factory option)
Maximum particle concentration	10 000 particles/mL (with 10 µm PSL particles, counting loss loss 10 %)
Counting efficiency	100 ± 5 % (when measuring PSL particles of 10 µm and comparing the count of more than 5 µm with a reference unit)
Sensor resolution	Less than or equal to 10 % (in the vicinity of 10 µm PSL particles)

Threshold accuracy	Within 5 % (when particle concentration is less than 6 000 particles/mL in the vicinity of 10 µm and 15 µm PSL particles.)
Flow rate accuracy	Within 2 % (when measuring 10 mL volume)
Sample volume accuracy	Within 2 % (when measuring 10 mL volume)
Syringe volume	25 mL
Sample fluid temperature range	+15 to +30 °C (no condensation on flow cell walls)
Sample fluid connectors	
Inlet	Supplied sampling tube to be connected to INLET on sensor
Outlet	2 × 3 dia. flanged tube to be connected to OUTLET on syringe pump
Power requirements	100 to 240 V AC, 50/60 Hz, approx. 100 W (Supplied power cord only for use in Japan, with 100 V AC)
Dimensions, weight	Approx. 363 (H) × 360 (W) × 236 (D) mm (excluding protruding parts), Approx. 14 kg

Optional Accessories	Printer (recommended for use with KL-04) Oki Electric Microline 22NR High speed (148 ppm) and high resolution (1200×600 dpi) PFA sampling tube (2 × 4 dia., length 100 mm) set (includes nut) SUS sampling tube (2 × 3 dia., length 100 mm) set (includes nut and 2 pieces of packing) SUS sampling tube (1 × 2 dia., length 100 mm) set (includes nut and 2 pieces of packing)
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* Specification subject to change without notice.



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