

GC

YL6500 Gas Chromatograph

*See the Performance
Feel the Difference*



The iDEA makes iDEAL !

YL's 5th-generation GC is starting to be a new powerful leader in a GC market. With strongly enhanced APCs (Advanced Pneumatic Control), installation of three units of inlet and detector for each enables to extend the various GC configurations to perform complex analyses.

YL6500 GC provides substantially reliable and precise data by every single part from the stable inlets to the extremely sensitive detectors as well as the innovative haptic touch pad strengthening user interface with a finger-tip. Moreover, an intuitive chromatography data system with user-friendly interface improves the ease of instrument control and a network (LAN) communication speeds up a data process.



Key Features

● View

- **Enlarged haptic color LCD (5.7")** showing all factors at a glance
- Classic and lab-suitable design
- Intuitive and user-friendly view by YL chromatography data system

● Verification

- High speed data process by network (LAN) communication
- **Enhanced APCs for all modules**
 - Increased precision in gas pressure and flow rate for more reliable results
 - Automatic compensation for temperature & pressure in installation condition
 - Pressure setpoint increment : **0.01 psi** / Pressure stability : **± 0.001 psi** (in constant pressure)
 - 4 column flow control modes: Constant pressure/ Constant flow, Programmed pressure (5 steps) / Programmed flow (5 steps)
- Shockproof design and stable structure against oven temperature changes
- Up to six APCs can be installed and up to **18 channels** of APC
- Upgraded column oven
 - Programming ramp/plateaus : **25 / 26**
 - Thermal stability : **± 0.01 °C**

● Variety

- Maximum no. of inlet / detector installation : **3**
- Various inlets available
 - Capillary Inlet (Split/Splitless Inlet)
 - Packed Inlet
 - On-Column Inlet (Temperature programming up to 5 steps)
- Various detectors with high sensitivity available
 - Flame Ionization Detector (FID)
 - Thermal Conductivity Detector (TCD)
 - Micro-Thermal Conductivity Detector (μ TCD)
 - Nitrogen Phosphorus Detector (NPD)
 - Flame Photometric Detector (FPD)
 - Electron Capture Detector (ECD)
 - Pulsed Discharge Detector (PDD)
 - Pulsed Flame Photometric Detector (PFPD)

● Value

- Saving user's valuable time with a high throughput autosampler
- Improved column conditioning function:
Automatic set of split flow up to 5 ml/min on column conditioning
- Sensitive leak detection (H₂)
- Prevention of oven malfunction (Over heating)
- Automatic stop when an oven door gets opened during operation.

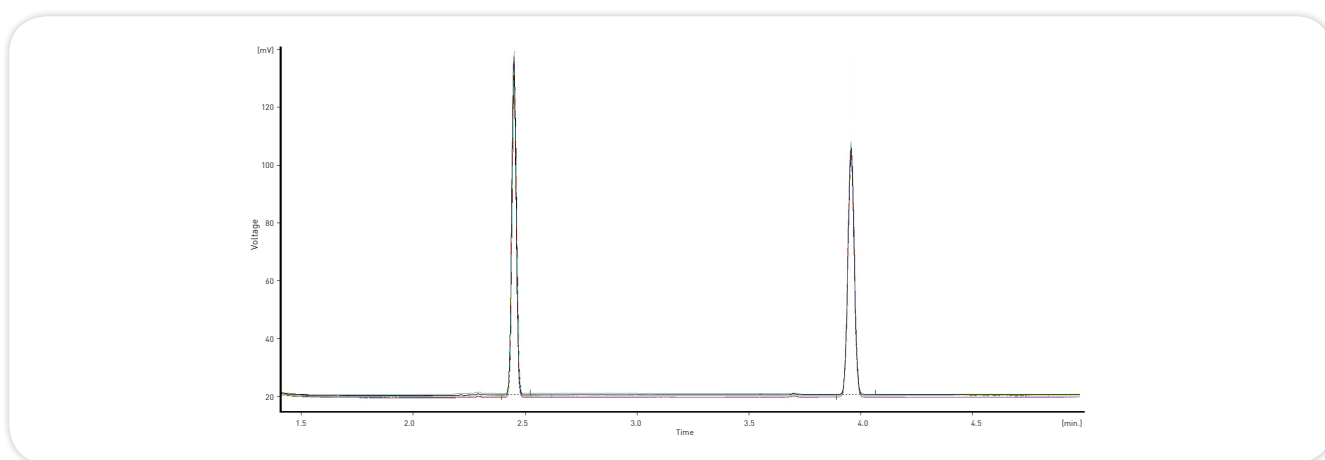


Feel the Difference

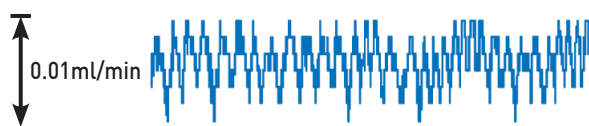
● Exceptional Reproducibility

The strongly enhanced APC with increased precision of gas pressure and flow rate assures an accurate result, especially in the reproducibility. The following chromatograms overlaid 11 times of injections verify the superior reproducibility in retention time.

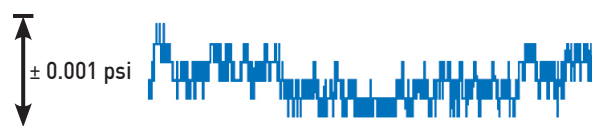
Number of Injection	1	2	3	4	5	6	7	8	9	10	11
RT (min) of Peak 1	2.4541	2.4538	2.4519	2.4531	2.4526	2.4544	2.4531	2.4525	2.4542	2.4531	2.4525
RSD (%)	0.0334										
RT (min) of Peak 2	3.9576	3.9569	3.9565	3.9579	3.9559	3.957	3.9572	3.9555	3.9582	3.9571	3.9576
RSD (%)	0.0207										



Flow Stability

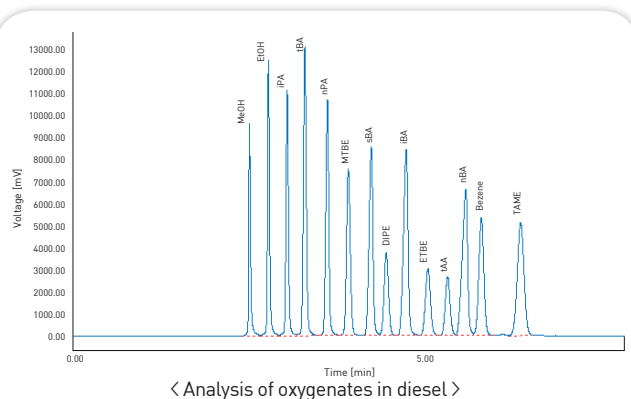


Pressure Stability



● The Ultimate in Gas Chromatography

The powerful programming function of oven temperature, pressure and flow rate enables to shorten retention time and reduce decomposition and loss of samples. Moreover, the swift and accurate control of valve switching time in settable point up to 0.01 min allows analyzing complex samples containing various components that can not be separated by one column or detected by one detector reversing column flow precisely (Backflush) with no loss of peak area values.



■ Analysis condition

- Column: HP-1, 30 m x 0.53 mm
TCEP μ -packed column, 56 cm x 1/16"
- Injector : 230 °C
- Column flow : 3.5ml/min, Split ratio : 20 : 1
- Oven : 60 °C [6.8 min] \rightarrow 8 °C/min \rightarrow 120 °C [10 min]
- FID : 250 °C
- 1st column switching time(backflush) : 0.23 min
- 2nd column switching time : 6.65 min
- Valve Temp : 100 °C

Dedicated Applications

YL's accumulated experience in gas chromatography and devotion for customers' satisfactions led to supply one stop solution for various dedicated applications. You only need to let us know what to analyze, and then every single component that is required to analyze your sample will be configured right away at an economical price.

? Why is it called "dedicated applications" ?

We provide all you need !

- Properly configured GC (Inlets, Detectors, Valves, Methanizers, etc.)
- Suitable sample preparation system/accessories
- Standard solutions
- Chromatography data system with saved methods
- Analytical columns
- Accessories (Traps, Syringes, etc.)
- Related application notes

● Residual Solvent Analysis

Organic residual solvents used in the manufacture of pharmaceuticals and found in the inks used for the printing of packaging materials for food and drug products are known to be hazardous to human health if ingested. The YL Residual Solvent Analyzer can accurately and efficiently detect and quantify residual solvents.

● VOC Analysis

The YL VOC Analyzer accurately tests the presence of VOCs and measures their concentration. The analyzer contains all necessary reagents and equipment for conducting the analyses including detailed procedures and protocols for conducting the tests. These protocols are in full compliance with approved U.S. EPA methods.

● Pyrolysis GC Analysis

The YL Pyrolysis-GC system is a state of the art system for obtaining information on the ingredients found in various non-volatile and low-soluble polymers such as nylon, wax, paint, film, wood and plastic products. The targeted material or sample is heated to be fragmented into its individual constituents, which are then separated and identified by the GC System.

● Natural Gas Analysis

Analysis of natural gas requires a very complicating configuration because it contains low level of oxygen (< 3%), isomers and compounds more than C4 which are not needed for analysis results. YL Natural Gas Analyzer can be configured in ideal with accurate valve switching venting unnecessary components and collecting significant things in time to the appropriate columns and detectors.

● TOGA (Transformer Oil Gas Analysis)

Oil based transformer insulating fluids are known to release combustible gases, which can decrease the efficiency of the insulating fluid while creating a dangerous situation. The YL TOGA System is a state of the art system for efficiently and accurately monitoring the buildup of combustible gases in the insulating oils of transformer. Such monitoring can prevent an accident from occurring, as well as ensure that the insulating oil is functioning under optimal conditions.

● Fatty Acid Analysis

In the food industry, the quality management for products is conducted by analyzing esterified fatty acids to determine the ratio of saturated fatty acids and unsaturated fatty acids in fat. For fatty acids have many isomers to be separated, they are commonly analyzed by gas chromatograph after esterified to Fatty Acid Methyl Esters (FAMES) to avoid peak tailings in a direct injection of fatty acid and column clogging.

It's very important to set an oven program because the polar or moderately polar capillary columns used in this analysis have low temperature limit. The order of peaks must be identified first for the eluted peaks of fatty acids are different in the use of polar or moderately polar capillary columns. YL Fatty Acid Analyzer is suitable to analyze various fatty acids and provide all the solution from the preparation to the method set-up.

● Refinery Gas Analysis

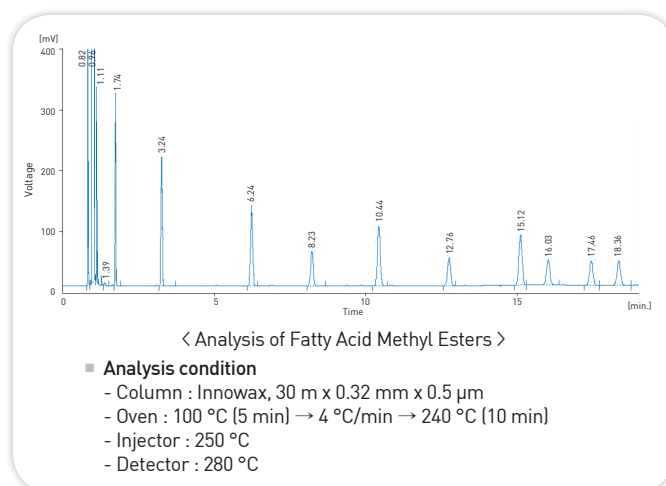
Refinery gas is a mixture of gases generated during refinery processes which are used to process crude oil into various petroleum products. Analyzing refinery gas has been getting very important in environmental fields because there are several components or chemicals in it that can potentially harm the environment if released unchecked. Due to the fact of installation detectors and inlets up to 3, YL Refinery Gas Analyzer can configure several columns, switching and sampling valves as well as the appropriate detectors to analyze the complex and difficult refinery gas samples.

See the Performance

Newly designed and highly sophisticated electronic board for each detector reduces a noise level 2~5 times lower than traditional YL's detectors. In addition, powerfully enhanced electronic circuit enables to detect weak signals for improvement of data process of samples in trace level.

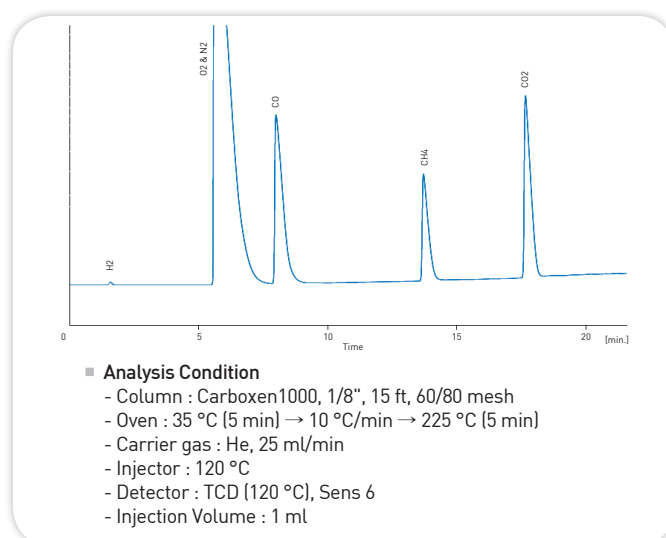
● Flame Ionization Detector (FID)

A Flame Ionization Detector measures the quantity of ions which are produced when a sample coming out from a column is flamed by hydrogen and air. So, this is to be used to detect any organic compounds which can be ionized by hydrogen/air flame. With linear dynamic range of seven orders, the function of auto ignition can start an ignition automatically at a setting temperature. In addition, a unified interconnector with high conductivity delivers very stable signals to electronic parts to maximize the sensitivity.



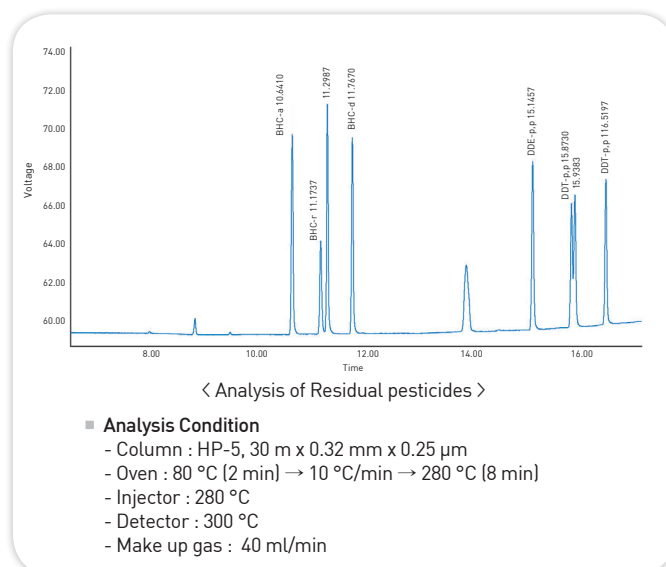
● Thermal Conductivity Detector (TCD)

A Thermal Conductivity Detector is introduced as a universal detector because it can detect every compound which has different thermal conductivity from that of carrier gas. It is recommended to use carrier gas such as hydrogen (H₂) or helium (He) that has a big difference of thermal conductivity from that of sample components. The especially stabilized design of TCD against shock with superior thermal conductivity creates extremely stable baseline as well as minimized noise level. Also, YL's unique filament protection reduces its maintenance substantially.



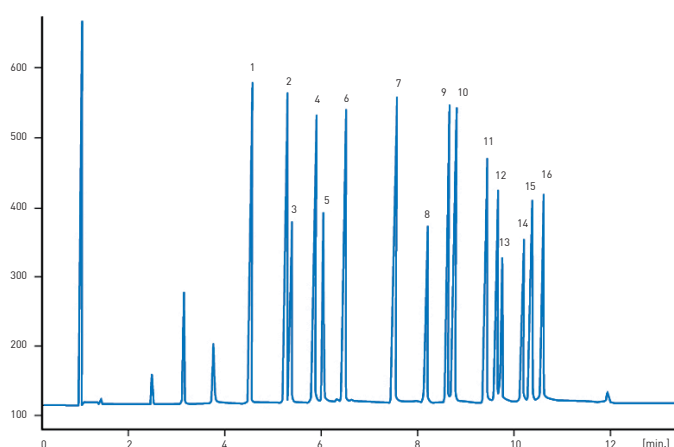
● Electron Capture Detector (ECD)

An Electron Capture Detector is used for detecting electron-absorbing components such as halogenated compounds. Our remarkably advanced ECD structure maximizes electron capture efficiency and the micro-volume cell increased detecting performance as well as sensitivity.



● Pulsed Discharge Detector (PDD)

PDD is to analyze trace level of halogenated compounds. PDD has two different modes, one is PDECD and the other is PDHID. The PDECD is a selective detector for monitoring high electron affinity compounds such as freons, chlorinated pesticides, and other halogen compounds. For this type of compound, the minimum detectable quantity (MDQ) is at the femtogram (10^{-15}) or picogram (10^{-12}) level. The PDD is similar in sensitivity and response characteristics to a conventional radioactive ECD, and can be operated at temperatures up to 400°C. For operation in this mode, He and CH₄ are introduced just upstream from the column exit. The other mode, the PDHID is an universal, non-destructive, high sensitivity detector. The response to both inorganic and organic compounds is linear over a wide range. Response to fixed gases is positive (increase in standing current), with an MDQ in the low ppb range.



- | | |
|-----------------------|------------------------|
| 1. α - BHC | 2. γ - BHC |
| 3. β - BHC | 4. Heptachlor |
| 5. δ - BHC | 6. Aldrin |
| 7. Heptachlor epoxide | 8. Endosulfan I |
| 9. 4, 42 - DDE | 10. Dieldrin |
| 11. Endrin | 12. 4, 42 - DDD |
| 13. Endosulfan II | 14. 4, 42 - DDT |
| 15. Endrin aldehyde | 16. Endosulfan sulfate |

- **Analysis condition**
 - Column : HP- 608, 30 mm x 0.53 mm x 0.5 μ m
 - Oven temp : 100 °C (2 min) \rightarrow 12 °C/min \rightarrow 280 °C
 - Detector : PDECD, D-2, 300 °C
 - Carrier : Helium, 8 ml/min
 - Injector : 1 μ l, split 15 : 1, 280 °C

● Nitrogen Phosphorous Detector (NPD)

A Nitrogen Phosphorous Detector is a specific detector which gives a strong response to organic compounds containing Nitrogen or Phosphorus. The detector is based on the principle of ionization of the analyte in presence of a heated alkali source.

● Pulsed Flame Photometric Detector (PFPD)

A Pulsed Flame Photometric Detector is to selectively analyze compounds containing Sulfur or Phosphorous but provides more than 10 times higher sensitivity and selectivity compared to a traditional FPD. It also requires low gas consumption ensuring detector stability for minimized maintenance.

● Flame Photometric Detector (FPD)

A Flame Photometric Detector is similar to the FID in that the sample exits the analytical column into a hydrogen diffusion flame. But FPD analyzes the spectrum of light emitted by the compounds as they luminescence in the flame and detects selectively substances containing Sulfur or Phosphorous.

● Micro-Thermal Conductivity Detector (μ -TCD)

A Micro-Thermal Conductivity Detector is operated in a same principle as TCD but a smaller cell to improve sensitivity. The detector cell includes two separate nickel/iron filaments, capable of independent or referenced (differential) operation. Cell volume and geometry are optimized for capillary chromatography and enhanced sensitivity at low flow rates. (Recommended total flow rate: 2-10 ml/min.) Thermal stability is maintained to $\pm 0.02^\circ\text{C}$, resulting in a stable and noise-free signal.

Save your time, Upgrade your life in laboratories

YL3000A Series Autosampler

Newly launched YL3000A series autosampler offers both reliability and superior performance for all GC/GC-MS applications reaching customer's requirement with the improved sample and solvent capacity, which means you can analyze your samples more quickly and get reproducible data. Innovative run-all-samples mode makes the operation simpler than ever, so you only need to load your samples and run the analysis without extra downtime. Its sophisticated sampling techniques provide the variable needle depths to draw the sample anywhere within the vial allowing you to use various types of syringes with volume from 0.5 to 100 ul to cover the widest range of applications.

• Features

- The self-aligning "plug and play" :
YL3000A series autosampler mounts in seconds without tools. It can be easily moved between GCs when workloads change (easy positioning / removal/re-positioning).
- Full-color touch screen interface :
It provides easier system accessibility and usability. Touch screen eliminates drilldown while simplifying instrument control for the entry-level users and experienced users.
- The greatest solvent capacity :
The autosampler supports the use of 6 solvent vials of 10ml each (total capacity: 60ml) to allow longer unattended operations.
- Double wash step capability:
Including pre- and post-wash solvent in addition to A, B... F solvents, you can also choose for a combination of A+B, A+C.... F+E solvents for superior analytical performance(carry-over free).
- Syringe illumination :
To keep always the sample under control, for easy check against air bubbles in method validation.
- Integrated bar code reader :
To offer you full and detailed sample tracking.
- SyringeID :
A proprietary technology based on RFID tags. This is to identify syringes in a univocal way to prevent errors when mounting a syringe (i.e.: no syringe volume mismatch possibility) and keep track of the syringe consumption.

■ 3 models at a glance !

	YL3000A	YL3100A	YL3200A
Sample Capacity	121 vials, 2 ml	15 vials, 2 ml	209 vials, 2 ml
Solvent Capacity	6 solvent vials of 10 ml each (Total Capacity : 60 ml)		
Double Wash Step	○	○	○
Dual Injection	○	○	○
Variable Needle Depth	○	○	○
Syringe Illumination	○	-	○
Control Pad	Full-color Touch Screen	Keypad	Full-color Touch Screen
Integrated Bar Code Reader	-	-	○
Syringe ID	-	-	○



YL3000A Autosampler



YL3100A Autoinjector



YL3200A Autosampler

Sample Preparation System

- **Versa Automated Headspace Vial Sampler**

Static headspace is one of the most popular techniques due to its versatility for analyzing volatile organic compounds (VOCs) in a complex variety of matrices. This is due to the elimination of tedious sample preparation steps and prevents contamination problems that are common to other sample introduction techniques. Versa is the perfect solution for applications which require all the advantages of headspace analysis and is economical to fit any budget.



Versa

- **HT3 Automated Static and Dynamic Headspace System**

The HT3™ combines Static and Dynamic Headspace analysis techniques into one easy-to-use unit, saving you time, bench space and money. Built on proven static headspace technology, the HT3™ provides increased sensitivity from 50 to 100 times with the Dynamic Headspace option (dependant on compound), accurate and precise results with electronically controlled flow and pressure and single scheduling for multiple methods and techniques.



HT3

- **YL2000H / YL2100H Static Headspace Autosampler**

YL2000H, available in GC or GC/MS, is useful to analyze drinking water, waste water, soil (EPA 5021), industrial waste, etc. The YL2000H eliminates tubing, dead volume and sample absorption. The injection tower transports vials to the 6 position incubator for orbital agitation at the programmed temperature. The heated syringe then samples the headspace vial and injects directly into the GC.

- YL2000H : 42 vials, 20 ml, Touch pad
- YL2100H : 14 vials, 20 ml, Keypad



YL2000H

- **HT280T Headspace, Liquid and SPME Autosampler**

The HT280T is a single unit combining static headspace analysis, liquid sample injection and SPME (Solid Phase Microextraction). It can save your time and money, increase analysis flexibility.



HT280T

- **Stratum Purge and Trap Concentrator**

The Stratum Purge and Trap Concentrator (PTC) is a sample preparation instrument used to remove Volatile Organic Compounds (VOCs) out of aqueous and solid sample types using Helium or Nitrogen. The VOCs are deposited onto a sorbent trap which is then heated thus releasing the VOCs into a Gas Chromatograph (GC) system.



Stratum

- **AquaTek 100 Waters-only Autosampler**

The AQUATek 100 is a Purge and Trap (P&T) Autosampler that automates the sample preparation steps for the analysis of liquid samples via purge and trap. The system is capable of preparing samples such as drinking water and wastewater.



AquaTek 100

- **Atomx Automated VOC Sample Prep System**

The Atomx combines an Autosampler and Purge and Trap into a single instrument for the analysis of VOCs in soils and waters. This is the first of its kind and the only system that employs a unique methanol extraction automation feature for high level soils in accordance with USEPA Method 5035. Extractasol clean-up step (patent pending) in the Atomx reduces carryover or cross contamination normally associated with high-level water or soil analysis.



Atomx

Others

● Pyrolyzer, Pyroprobe 5000 series

Pyrolysis coupled with YL6500 GC allows you to analyze the samples which were previously unsuitable for analysis without extractions or derivatizations. By using pyrolysis, samples such as paint, adhesives, tapes, caulk, food packaging, rubber, plastic, papers, ink, coating and a full range of household products can be analyzed for qualitative and quantitative information.



● Rapid Oven Cooler (ROC)

Rapid Oven Cooler is the simple, affordable and easy to be installed on most GC and GC-MS available on the market. It considerably reduces dead time between sequential runs and ensures highly stable GC oven temperatures, down to 20°C, very rapidly to increase lab productivity. Analyzing very volatile compounds, it's strongly recommended to improve highly significant resolution.



● Gas Sampling Valve

In order to obtain accurate results in gas analysis, it is necessary to equip with a gas sampling valve in the front of column. The gas sampling valve enables manual or automatic gas sample injection and flow switching. Our gas sampling valve is operated by an air actuator which opens and closes it. The air actuator is useful in situations where any spark could be dangerous or where there is no electricity available. They are small, relatively inexpensive, very rugged, dependable, and field-serviceable.



● Purge Housing

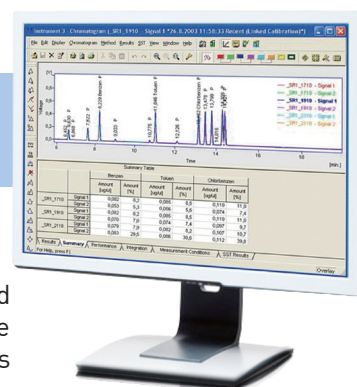
When you analyze samples of O₂, N₂, etc with low concentration of a few ppms, the purge housing is very useful for this analysis. Purge housings eliminate any possible diffusion from the atmosphere into the valve, or safely vent fugitive emissions from the valve.



Chromatography Data System

YL-Clarity / Autochro 2

The sophisticated YL-Clarity and Autochro 2 chromatography data system is easy to use and offers extensive data management plus full control of the entire YL Chromatographs. The software is designed for 21 CFR Part 11 Compliance and fully compatible with all Windows OS.



● 21 CFR Part 11 Compliance

■ User accounts

It sets up access rights and passwords (including their parameters e.g., minimum length, validity, etc.). Each user can define the appearance of own station.

■ Audit trail

It records selected events and operations into a special file and selected operations directly into a chromatogram.

■ Electronic signature

Each chromatogram can be signed electronically. Signature selection is based on the username or the signature certificate.

● Data Acquisition

■ Overlay

It simultaneously displays a virtually unlimited number of chromatograms and their mathematical modification; for example, mutual deductions or derivations of any order.

■ Measuring

Simultaneous data acquisition from up to four independent chromatographs, each can acquire data from up to 12 detectors.

● Data Management

■ Integration

The integration parameters can be changed by entering global parameters or interactively, through direct graphic modification of the baseline.

■ Calibration

Internal and external standard calculation methods, calibration of groups of peaks and reference peaks method for better identification.

■ Postrun

It automatically displays, prints, exports and starts other programs after the completion of a measurement.

■ User calculations

Using the integrated editor you can create your own columns from original columns and individual mathematical functions.

■ Optional

SST (System Suitability Test)
Validation Kit
NGA (Natural Gas Analysis)

Technical Specifications


Column Oven			
YL6500 GC Oven System Module	<ul style="list-style-type: none"> - Usable volume : 14L - Temperature operating range : 4°C above ambient to 450°C or more - Cooling down option : - 80°C ~ 450°C (with LN₂ cryogenic cooling) - 55°C ~ 450°C (with LCO₂ cryogenic cooling) - Temperature set-point : 1°C - Temperature programming : 25 ramps/26 plateaus - Maximum heating rate : 100°C/min - Maximum run time : 9,999min - Temperature program method : Maximum up to 20 - Temperature stability : ±0.01°C (Isothermal), ±0.1°C (Gradient) 		
Inlet			
Packed Inlet	<ul style="list-style-type: none"> - Maximum Temperature : 450°C - Total flow setting range : 0.1~ 100ml/min 	<ul style="list-style-type: none"> - Pressure setting range : 0.01 ~ 100psi - Pressure stability < ± 0.05psi - Temperature stability < ±0.1°C - Flow stability < ±0.05ml/min - Temperature setpoint : 1°C 	
Capillary Inlet (Split/Splitless Inlet)	<ul style="list-style-type: none"> - Maximum Temperature : 400°C - Total flow setting range : 0.1 ~ 400ml/min N₂ - 0 ~ 1000ml/min He - Splitless time setpoint : 0.01min 		
On-Column Inlet	<ul style="list-style-type: none"> - Maximum Temperature : 450°C - Temperature programming up to 5 steps 		
Detector (Data Acquisition Rate : 200 Hz)			
	Maximum Temp.	MDL	Others
Flame Ionization Detector	450°C	2.0 pg carbon/sec	Linearity : 10 ⁷
Thermal Conductivity Detector	400°C	2.5 ng/ml (Standard) 400 pg/ml (uTCD)	<ul style="list-style-type: none"> - Flow through cell : 4 Rhenium-Tungsten filaments - Filament protection
Electron Capture Detector	400°C	10 fg/sec	Linearity : > 10 ⁴
Nitrogen Phosphorous Detector	400°C	< 0.4 pg N/sec (Azobenzene) < 0.2 pg P/sec (Malathion)	Linearity for N : > 10 ⁴ Linearity for P : > 10 ⁴
Flame Photometric Detector	300°C	< 20 pg S/sec < 0.5 pg P/sec	Linearity for S : Calibration curve is compulsory Linearity for P : > 10 ⁵
Pulsed Discharge Detector	400°C	(PDHID) : - Organic compound : low ppb - Permanent gas : low ppm (PDECD) : 10 ⁻¹⁵	(PDHID) : Linearity 10 ⁵ (PDECD) : Linearity 10 ⁵
Autosampler			
YL3000A Series Autosampler		HT280T (Headspace, Liquid Autosampler, SPME)	
<ul style="list-style-type: none"> □ Syringe Volume: 0.5, 1, 5, 10, 25, 50 and 100ul □ Tray Capacity <ul style="list-style-type: none"> - YL3000A : 121 vials, 2ml - YL3100A: 15 vials, 2ml - YL3200A: 209 vilas, 2ml(2 removable racks) □ Electrical Control : LAN and TTL, RS232(Optional) □ Filling/Injection Speed : 1~100ul/sec □ Internal Standard Volume: as low as step of 0.1 ul □ Washing Solvent Capacity : 6 x 10 ml vials 		<ul style="list-style-type: none"> □ Liquid Operation : <ul style="list-style-type: none"> - Tray Capacity : 110 vials of 2 or 2.5ml - Air bubble removal up to 15 strokes - Viscosity time from 1 to 15 secs - Sequence maximum 15 steps □ Headspace Operation: <ul style="list-style-type: none"> - Incubation Oven : 6 positions - Tray Capacity : 40 vials, 10 or 20ml - Syringe Temperature : 40 ~ 170°C - Sampling Repeats : Up to 15 □ SPME Operation <ul style="list-style-type: none"> - Tray Capacity : 40 vials, 10 or 20ml - Oven Temperature : 40 ~ 150°C - Shaker Speed : 320 ~ 720rpm 	
Versa Static Headspace Autosampler		Stratum Purge & Trap Concentrator	
<ul style="list-style-type: none"> □ Autosampler Capacity: 20-Position □ Platen Heater: Single position; ambient to 200°C □ Vial Size: 22mL vials □ Sample Loop: (Standard) 1mL Silco[®] coated loop. (Option) 100, 250, 500µL as well as 2, 3, and 5mL 		<ul style="list-style-type: none"> □ Cycle Time: The cycle time for the unit is 17 minutes when using an 11 minute purge time. □ Trap Furnace: Ambient to 350°C □ Gas Requirements: 99.999% Helium or Nitrogen □ Electronic Mass Flow Controller: 5mL/min to 500mL/min. 	
HT3 Static & Dynamic Headspace Autosampler			
<ul style="list-style-type: none"> □ Autosampler Capacity: 60-positions □ Platen Heater: Up to 10 vials simultaneously heated up to 300° C □ Vial Size: 9, 12, 22mL vials accepted 			



YL6500 Gas Chromatograph



YL INSTRUMENT CO., LTD.

The iDEA makes iDEAL!  KOREA MADE

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These Products are manufactured by Young Lin ISO 9001-certified facility that is periodically audited by the registering body to ensure compliance