OMNISEC

Unlock the power of advanced separations

Multi-detection SEC for you

Multi-detection Size Exclusion Chromatography (SEC) or Gel Permeation Chromatography (GPC) is an essential analytical technique for the characterization of macromolecules. It provides deep insights into your sample's absolute molecular weight, composition, size and structure.

A series of three different detectors delivers critical information about your sample:

Light scattering measures absolute molecular weight, independent of column retention volume or standards

Differential viscometry measures the intrinsic viscosity of a sample to determine size and structure

Refractive Index and UV-PDA detection measure the sample's concentration and composition.
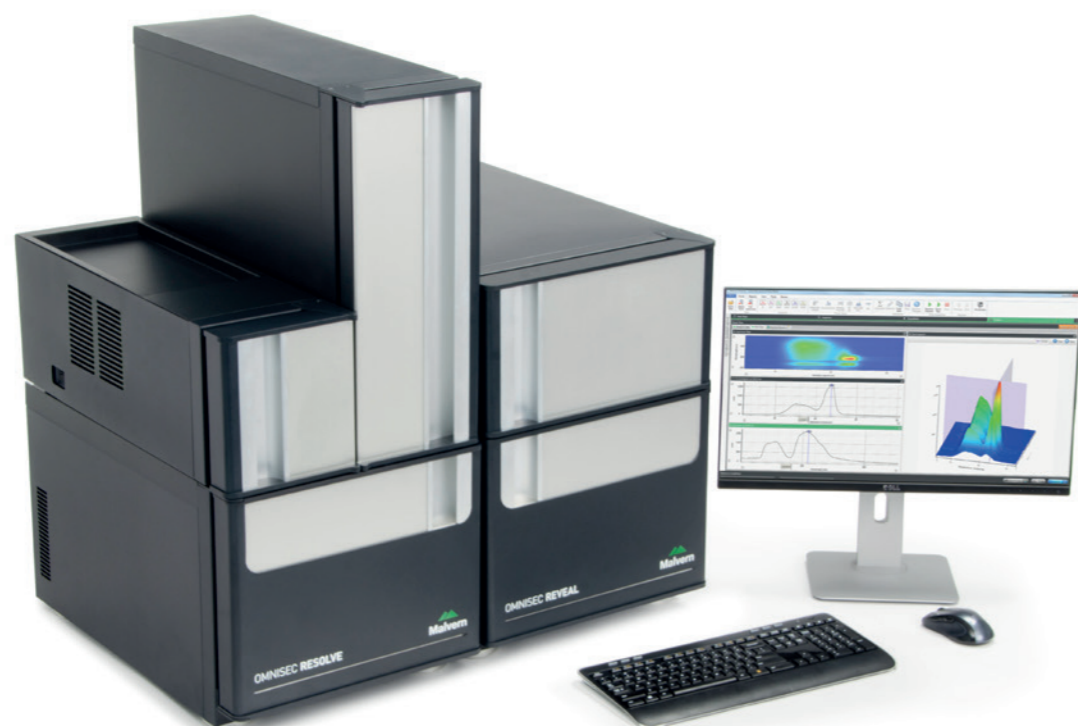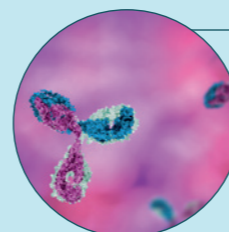
Malvern Panalytical's OMNISEC system was a powerful tool to confirm the identity of peaks by determination of the molecular weight of monomer, dimer and trimer species of a novel fusion protein.

*This could not be achieved unambiguously using SEC with conventional UV.*

Patrick Merky
Senior Scientist
Cobra Biologics

Bioscience and biopharmaceuticals

- Quantify key metrics in stability profiling and biosimilarity
- Streamline protein conjugation analysis- protein-protein, protein-polymers, glycoprotein,drug antibody ratios (DAR)
- Accurately measure monomer, fragments and higher order
- aggregates, independent of column retention volume, for protein, virus and VLP samples
- Directly measure AAV titer and percentage filled, as a replacement for qPCR and ELISA-based assays

Polymers, plastics, fibers and elastomers
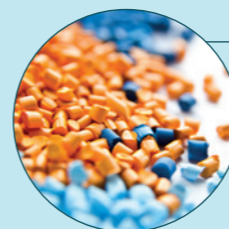
- Maintain product quality by understanding the effects of changing raw material supply, synthesis or manufacturing processes
- Gain insight into degradation products, additives or impurities
- Safeguard the performance of the final product by understanding the impact of conventional or advanced processing technologies on critical material properties

Academia

- SEC/GPC is an essential technique for a wide range of research themes, including polymers, biopolymers and proteins
- Establish the success of polymerization or polymer degradation
- Identify biocompatible and biodegradable polymers which can be used as substitutes for synthetic polymers
- Characterize currently unknown proteins or establish the properties and purity of samples

Paints, inks and coatings

- The efficacy of printed polymers is linked to their macromolecular properties, including molecular weight distribution and structure
- Understand the link between printing and the degradation of polymers

Foods and drinks

- Control the depolymerization of native polysaccharides to produce specific thickening properties
- Monitor the degradation of polysaccharides due to processing or blending of different source materials
- Molecular properties (MW, IV) relate directly to the bulk properties of food ingredients, impacting their mouthfeel and performance

Pharmaceuticals and drug delivery

- Polymeric excipient properties relate directly to a drug product's safety, quality and clinical efficacy
- Understand the clearance rates of topical solutions such as eye drops by measuring product viscosity
- Link the release rates of therapeutics to the structure of the drug carrier

Why use multi-detection SEC?

A modern research environment demands a complete understanding of a sample's molecular properties, including accurate and reliable measurements of molecular weight.

SEC is a well-established technique which separates the molecules in a sample according to their hydrodynamic volume as they enter and exit the pores of a porous gel matrix packed inside a chromatography column.

Like other HPLC-based techniques, this involves the use of a pump, a column and at least one detector to measure the sample as it elutes.

Although single detector GPC/SEC systems have been used for many years, multi-detection SEC provides the insight required to deliver the optimal performance for samples of today and the next generation.

- A light scattering detector: the heart of an advanced GPC/SEC system. Light scattering enables absolute molecular weight calculation, independent of structure and sample retention volume

- A viscometer: probes the very structure of a molecule to give a sample's intrinsic viscosity. No other detector can match its sensitivity to structural changes

- A refractive index (RI) or ultraviolet (UV) detector: concentration measurement is the first step in any advanced GPC/SEC measurement. Combining RI and UV allows compositional information to be unlocked
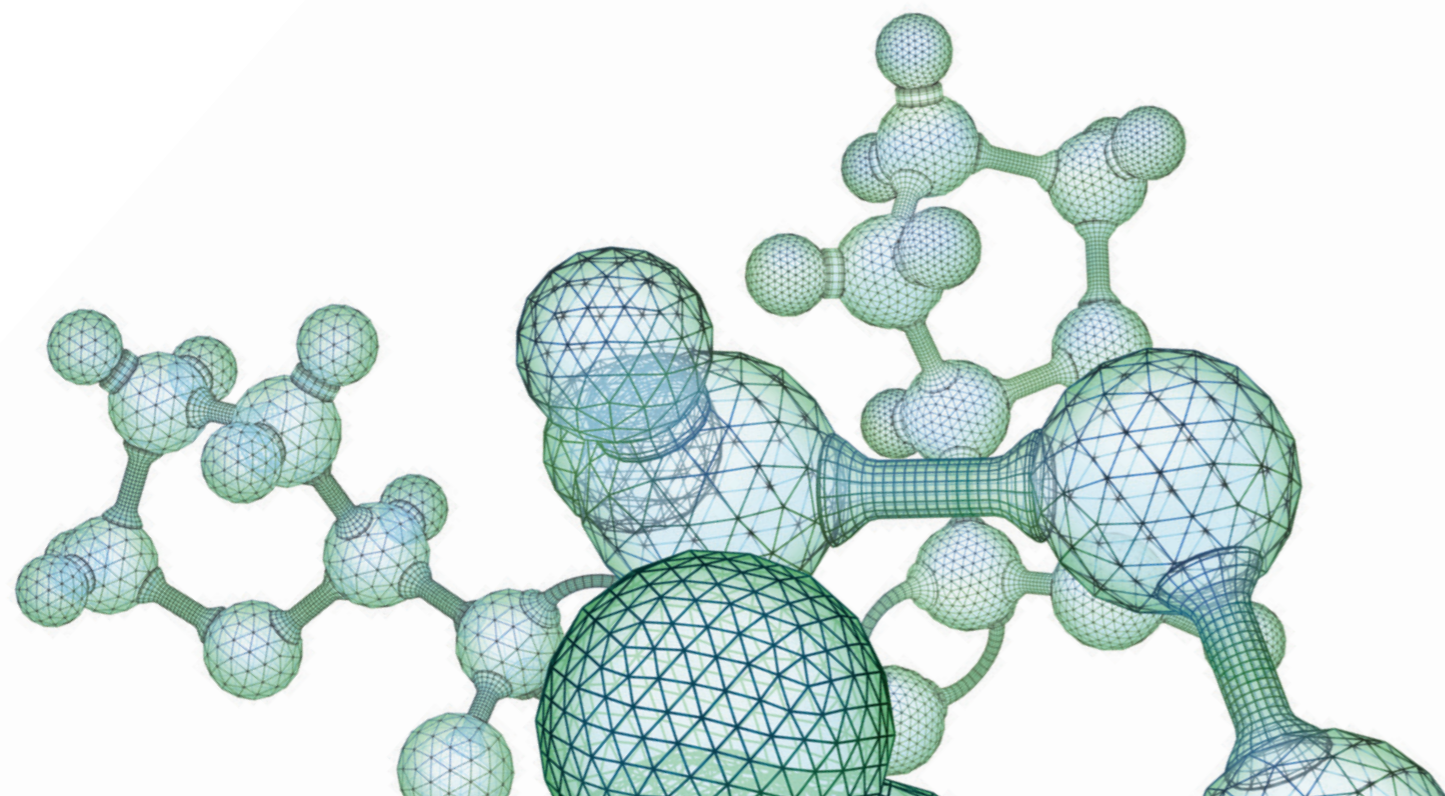
OMNISEC multi-detector system

The ultimate in advanced detection is the combination of all these detectors to get a complete understanding of the molecule being investigated

Differential viscometer
- Intrinsic viscosity
- True molecular weight (universal calibration)
- Structure and conformation
- Mark-Houwink plot
- M-H a and K parameters
- Hydrodynamic radius (Rh)

Refractive index (RI) UV-PDA
- Concentration
- Recovery
- Composition
- Impurities
- Relative molecular weight (conventional calibration)

Static light scattering
- Absolute molecular weight
- Molecular weight moments (M_n, M_w, M_z, M_p)
- Radius of gyration (Rg)

A new standard in GPC/SEC

Our complete and integrated gel permeation / size exclusion chromatography solution comprises:

OMNISEC RESOLVE
an integrated pump, degasser, autosampler and column oven for managing the separation within a single advanced unit

OMNISEC REVEAL
an integrated multi-detector module

OMNISEC software - for easy and intuitive sample analysis

SEC-MALS 20 - for additional light scattering insights.

Quicker, simpler, safer

- Autosampler temperature control (4°C - 60°C) protects proteins from degradation and improves polymer dissolution
- Waste-free injections from vials or 96 well micro-titer plates mean less volume of precious samples is required
- Low volume degasser enables faster mobile phase exchanges for increased system productivity
- Inert (316 stainless steel) viscometer pressure transducers for wide pH range use
- System temperature control (up to 65°C) reduces operating backpressure
- Revolutionary user-exchangeable viscometer capillary module reduces service time and costs

Gives better results

- The new, incredibly sensitive light scattering detector enables measurements of molecular weights as low as 200 g/mol, injection masses as low as 100 ng of material, and samples with low dn/dc
- Integrated detector module minimizes inter-detector band broadening
- Column and detector temperature control (20°C - 65°C) improves resolution and baseline stability
- Flexible autosampler delivers accurate and precise volumes for unparalleled data reproducibility

OMNISEC software

Powerful by design, yet easy and intuitive to use

Workflow-focused software

OMNISEC software has been designed with your priorities in mind to make GPC/SEC analysis easy and intuitive. The software guides you smoothly through setup, data acquisition and analysis in an intuitive workflow.
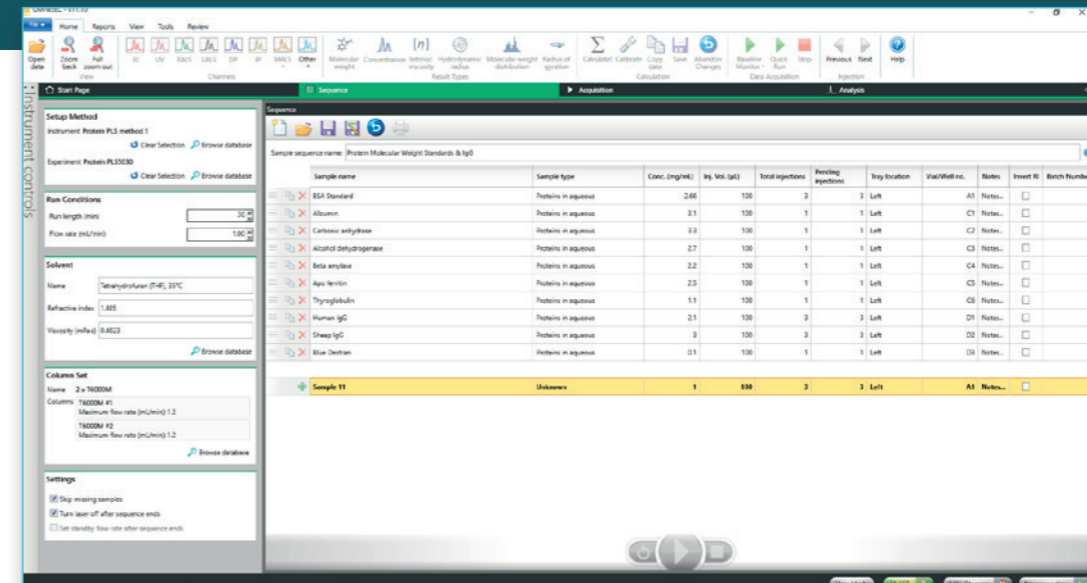
- Fully automated system setup, acquisition and shut down, so running your samples is as simple as inserting your vials or plates and pressing 'Start'
- Just one click takes you from raw data to results
- With fully-customizable reporting features, you can clearly see the data that's most important to you
- Optional 21 CFR Part 11 compliant security package, to ensure peace of mind for those working in regulated environments
- State-of-the-art band broadening corrections
- Conventional and Universal calibration enabling the use of traditional column retention volume

methods. Can be used as the preferred method of analysis or to help in method transfer to light scattering techniques (Optional)

- Compositional analysis of conjugates and copolymers to measure the concentration and associated material parameters of two components within a sample (Optional)
- Particle titer and Percentage full measurements for drug delivery vectors, including Adeno-associated virus (AAVs)
- Widely used for the measurement of Drug:antibody ratios (DARs)

OMNISEC REVEAL overview

Integrated multi-detector module

OMNISEC REVEAL is an integrated multi-detector module for advanced GPC/SEC measurements, incorporating refractive index, UV/Vis absorbance, light scattering and intrinsic viscosity detectors. The high sensitivity and measurement quality provided by OMNISEC REVEAL ensures maximum return on your investment.

OMNISEC REVEAL can act as a standalone detector connected to your existing GPC/SEC system, or can work in combination with the OMNISEC RESOLVE module to provide a complete GPC/SEC solution.

Its integrated design keeps all the detectors in one compartment, affording multiple advantages:
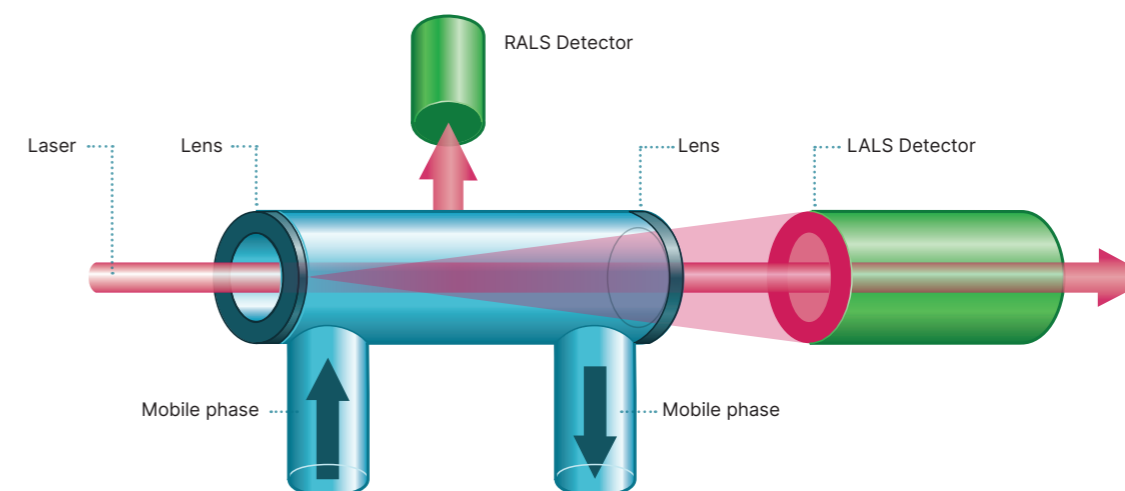
- Inter-detector tubing is minimized, reducing band broadening to improve data quality and result accuracy

- The detectors and the inter-detector tubing are all maintained at the same temperature to further improve data quality by maintaining baseline stability

OMNISEC REVEAL detectors

Detector modules

Light scattering

The unique light scattering detector combines the sensitivity of 90° Right Angle Light Scattering (RALS) with the accuracy of 7° Low-Angle Light Scattering (LALS). This makes it the ideal choice for measuring precious samples where only small injections can be afforded, or samples with low dn/dc, while its 18 µL flow cell maintains sample resolution.

OMNISEC REVEAL key features and benefits

Market-leading light scattering detection

- Measure low molecular weight samples with greater accuracy (down to 200 g/mol)

- Work at lower sample concentrations (newly synthesized polymers and proteins) with no impact to data quality

- Measure low dn/dc samples with unsurpassed accuracy and sensitivity

- High sensitivity Refractive index

- Greater accuracy and less subjectivity at lower concentrations

- Measure lower concentrations of highly viscous materials to prevent column overload

Self-Balancing Viscometer detector

- Improved data quality and accuracy

- Integrated robust differential viscometer

- Measure Intrinsic Viscosity (IV) of samples to determine structure and conformation

- Robust to all GPC solvents and a wide pH range, broadening available applications

Fully-integrated detector module

- Excellent temperature control and reduced inter-detector volume results in the highest-quality data

- Improved separation quality and resolution

- Unrivalled baseline stability on all detectors for greater sensitivity to low sample concentrations

All detectors in series

- Detectors are placed in series rather than in parallel. This avoids splitting the sample and risking data quality

Refractive index
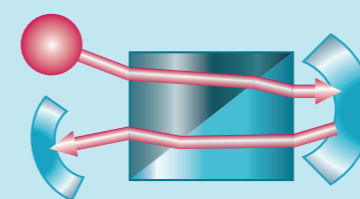
OMNISEC REVEAL's refractive index detector measures the concentration of almost any solute. Its robust flow cell allows it to be run in series with other detectors, maximizing sensitivity and minimizing band broadening.

Intrinsic viscosity
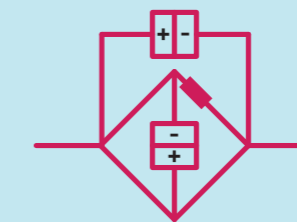
The new pressure transducers in OMNISEC REVEAL's differential viscometer improve baseline stability, sensitivity and robustness. Their 316 stainless steel construction ensures solvent and pH compatibility. It has an interchangeable capillary module for fast user replacement and the ability to self-balance for simple, automatic setup.

UV/Vis
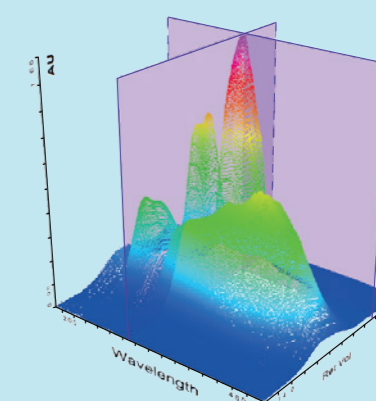
The UV/Vis photodiode array (PDA) covers wavelengths of 190 nm - 900 nm, opening up absorbance measurements to a wider application range.
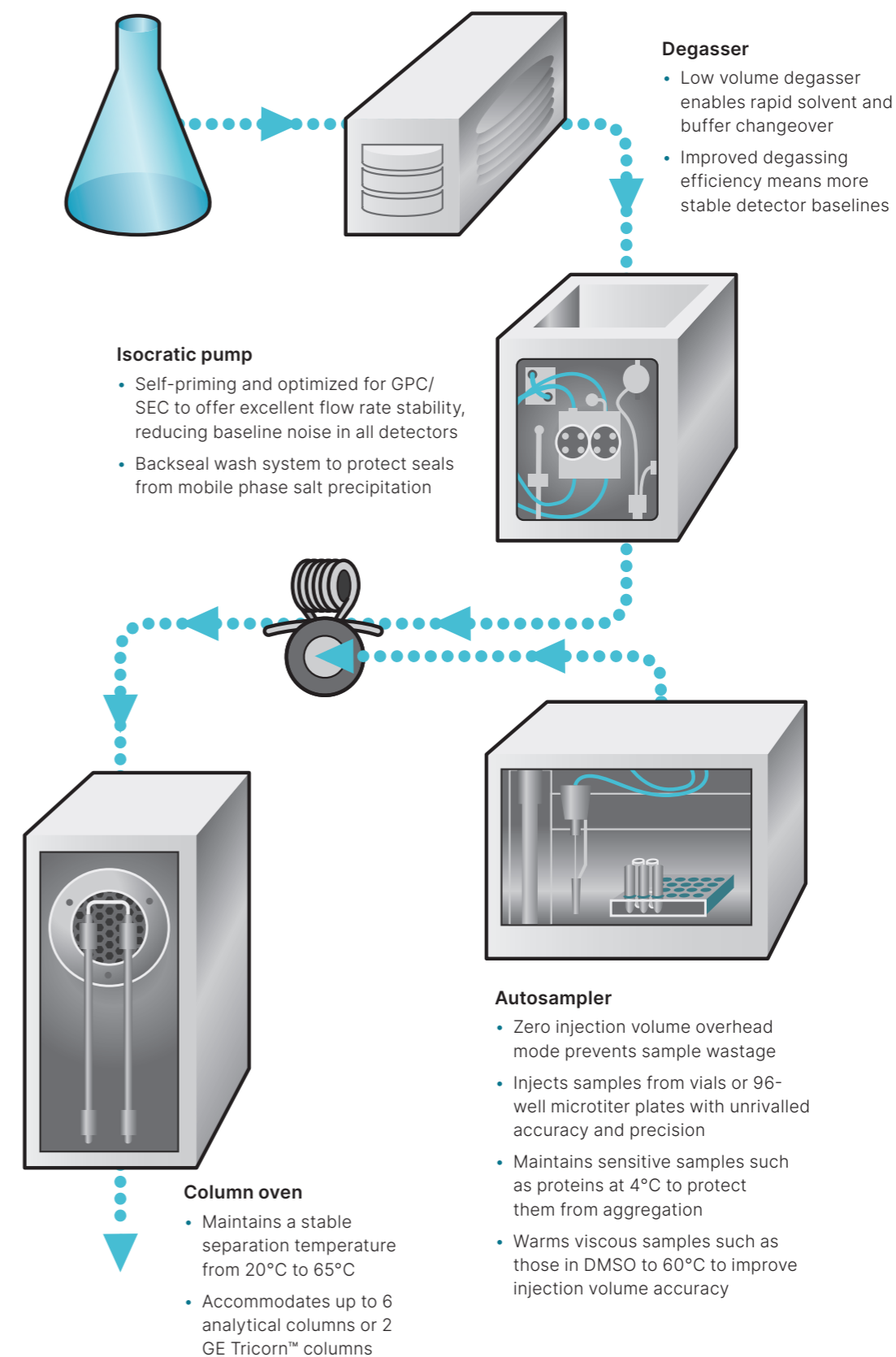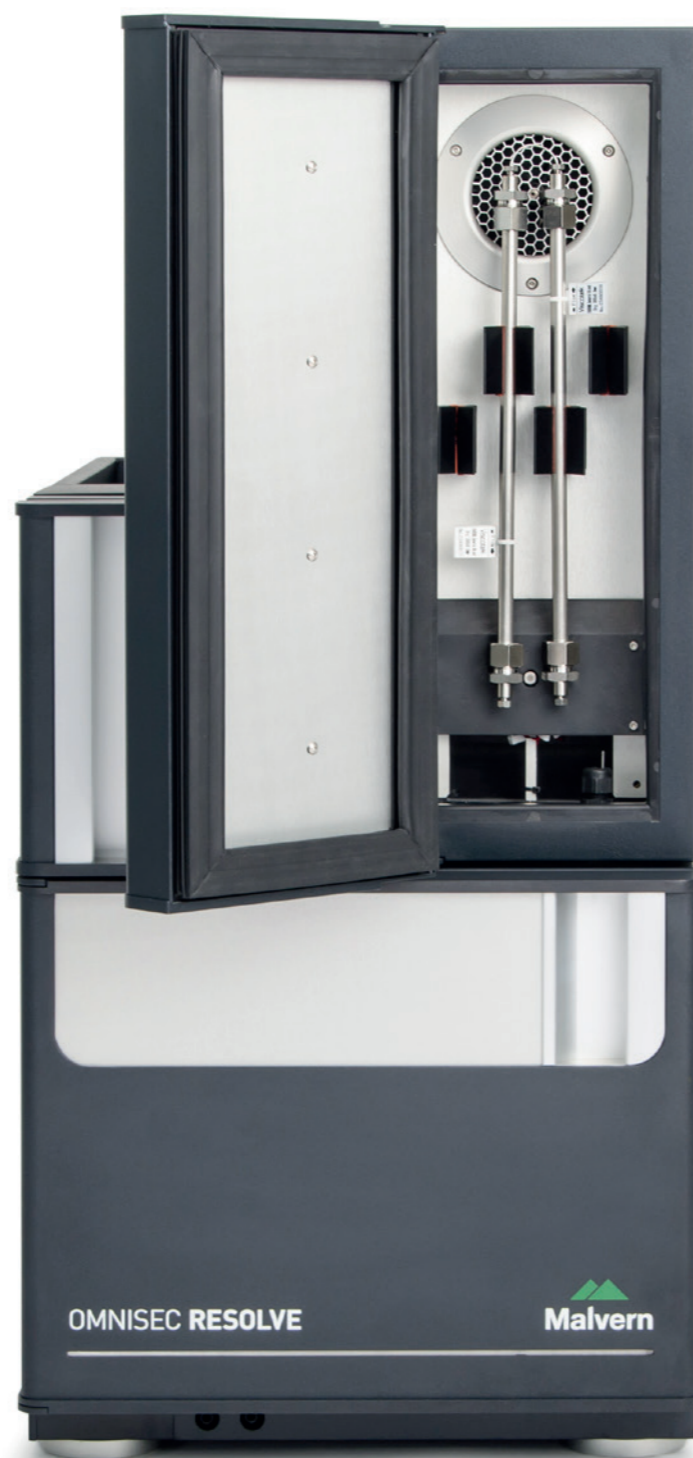
OMNISEC RESOLVE overview

OMNISEC RESOLVE is a combined pump, degasser, autosampler and column oven for mobile phase delivery and sample injection.

What benefits does the complete OMNISEC GPC/SEC system provide?

- One solution from a single manufacturer with an intuitive software package that handles everything from instrument control to data acquisition and data analysis

- Unattended operation using the autosampler, even with sensitive samples such as proteins, thanks to its temperature control

OMNISEC RESOLVE key features and benefits

- Low pulsation pump provides unparalleled baseline stability

- Low volume degasser reduces downtime with rapid solvent changeover and equilibration

- Temperature-controlled autosampler (4°C to 60°C) protects fragile samples from degradation and reduces the viscosity of samples in high viscosity samples such as DMSO

- Zero overhead autosampler minimizes the waste of precious samples

- Integrated column oven ensures high-quality separations and component resolution

OMNISEC **RESOLVE**

Malvern

Degasser
- Low volume degasser enables rapid solvent and buffer changeover
- Improved degassing efficiency means more stable detector baselines

Isocratic pump
- Self-priming and optimized for GPC/SEC to offer excellent flow rate stability, reducing baseline noise in all detectors
- Backseal wash system to protect seals from mobile phase salt precipitation

Autosampler
- Zero injection volume overhead mode prevents sample wastage
- Injects samples from vials or 96-well microtiter plates with unrivalled accuracy and precision
- Maintains sensitive samples such as proteins at 4°C to protect them from aggregation
- Warms viscous samples such as those in DMSO to 60°C to improve injection volume accuracy

Column oven
- Maintains a stable separation temperature from 20°C to 65°C
- Accommodates up to 6 analytical columns or 2 GE Tricorn™ columns

OMNISEC REVEAL ULTRA -
Bringing the advantages of multi-detection to UPLC separations

The best of both worlds combining the information-rich data from advanced multi-detection with the high resolution and speed afforded by UPLC separations it is now possible to get the best of both worlds – more detailed and faster sample analysis.

Complete flexibility to connect to any UPLC-SEC system.

OMNISEC REVEAL ULTRA can be included on any UPLC-SEC system, whatever the manufacturer, offering fantastic flexibility to upgrade any existing system which may already be a key part of your workflow.

More than triple the throughput of your SEC systems and reduce sample consumption by up to a factor of five!

Transferring from HPLC-SEC to UPLC-SEC based separations dramatically lowers the volume of sample required while increasing the resolution and detection levels in addition to offering new insights and shorter development times.

Higher resolution; faster sample analysis

New insights

- Better resolve and characterize the molecular properties and size distribution of proteins, low molecular weight polymers and oligomers due to the improved resolution available through UPLC separations
- Identify and characterize aggregates and fragments hidden by standard HPLC-SEC/GPC

Enhanced sample characterization

- Absolute molecular weight of samples independent of retention volume or any calibration standards
- Get enhanced structural information such as conformation and molecular density for more detailed characterization and better sample differentiation
- Identify incremental changes in molecular weight, size and structure resulting from processes such as degradation or aggregation

Reduced analysis costs

- The improved resolution and separations process offered by UPLC columns means significant savings can be made in sample loadings, with a more than 10x reduction in sample mass loading for full characterization

Shorter development time

- Perform data collection more-than three times faster than HPLC-SEC/GPC, enabling higher sample throughput and more rapid method development
- Combining the faster data collection with improved resolution leads to faster product iteration and development

Operational cost savings

- Reduce solvent use by up to 80%, saving costs and lessening exposure to hazardous chemicals

Column Oven

Autosampler

Pump
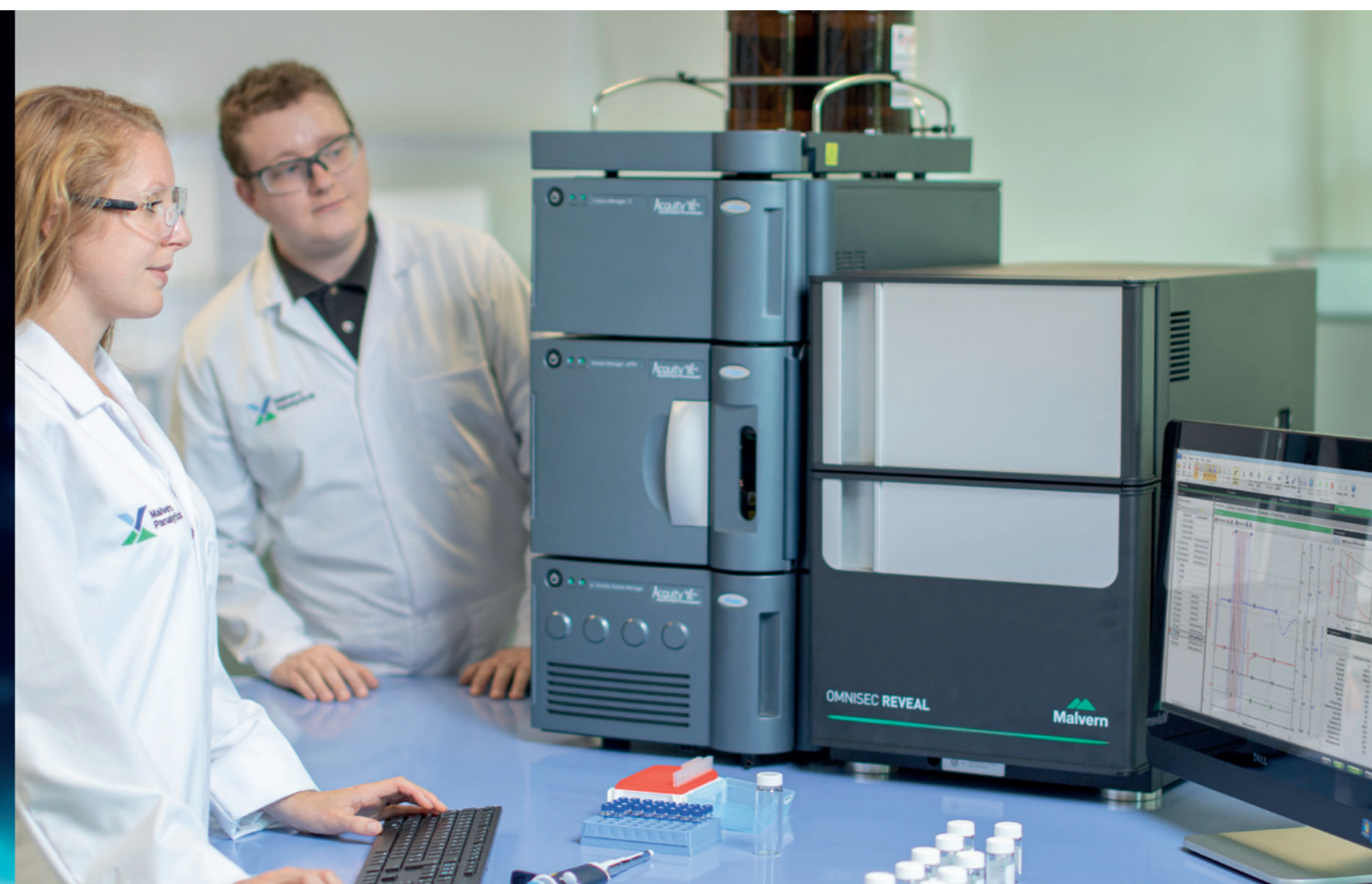
OMNISEC REVEAL ULTRA

Integrated detectors: leading the way in UPLC multi-detection analysis

- Connect with any UPLC/UHPLC system to convert a standard system into a advanced multi-detection suite
- OMNISEC REVEAL ULTRA builds on the already optimized integrated detector module design
- All detectors connected in series with the minimum interdetector dead volume
- Minimize band broadening and maximize sensitivity!
- REVEAL ULTRA RI detector contains an optimized flow path and improved detector optics
- Flow path design prevents peak dispersion of the narrow peaks produced by UPLC-SEC separations when compared to HPLC-SEC
- Complete flexibility to run either HPLC-SEC or UPLC-SEC with no system modifications
- Designed for method development and transfer to new UPLC-SEC separations

Waters ACQUITY APC

Faster separation with improved resolution

- Waters ACQUITY Advanced Polymer Chromatography (APC™) System is a breakthrough technology that defines the ultimate in size-based chromatographic separations, delivering more information about your polymers faster than ever before
- Since its introduction the Waters APC has streamlined and enhanced the analysis of low to mid molecular weight polymers
- Combining this advanced separations system with the OMNISEC REVEAL ULTRA detector brings light scattering and viscometry to APC setups offerering superior information about polymers and oligomers when compared with a conventional single-detector measurement
- The latest enhancements to Malvern Panalytical's OMNISEC REVEAL ULTRA detector platform now brings these two class leading technologies together. This means better characterization, improved asset utilization, and a superior solution for achieving innovation and sustainability goals

Waters

THE SCIENCE OF WHAT'S POSSIBLE.™

SEC-MALS 20 detector

Molecular size and absolute molecular weight

The SEC -MALS 20 is a modular multi-angle light scattering (MALS) detector for the OMNISEC system. It serves as a powerful additional detector which complements RALS/LALS or can be used as the sole light scattering detector.

The SEC-MALS 20 is also flexible enough to easily be combined with any existing GPC/SEC system, for direct measurements of absolute molecular weight and size.
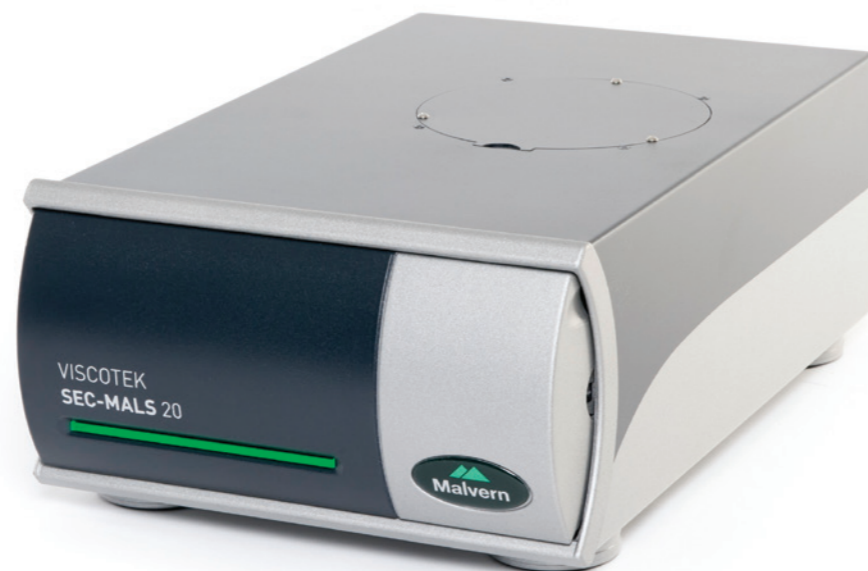
The key to the performance of the SEC-MALS 20 detector is its vertical flow cell with radial optics. This ensures:

- Reduced detector noise at low angles
- Reduced need for detector cleaning
- Fixed, constant and known measurement angles, regardless of solvent type
- One cell for all solvents, so no need to switch or remove the cell between assays
- Reduced band broadening and tailing compared with other MALS detectors, thanks to its low volume
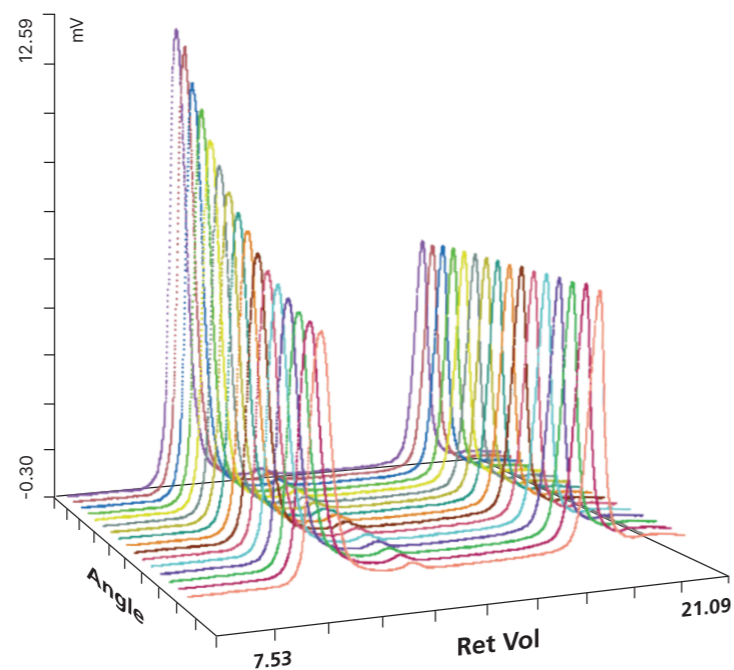
MALS signals from an aggregated protein and monomer

SEC-MALS 20
detector specifications

SEC-MALS Detector system	
Parameter	Specification
Laser type	Diode
Laser wavelength	660 nm
Laser power	120 mW max, 100 mW to cell
Laser lifetime	>10,000 hours
Number of scattering angles	20 or 9
Scattering angle positions	12°, 20°, 28°, 36°, 44°, 52°, 60°, 68°, 76°, 84°, 90°, 100°, 108°, 116°, 124°, 132°, 140°, 148°, 156°, 164°
Cell volume	63 µL
Scattering volume	<7.8 nL
Analog signals accepted	4 x ±10 V 24 bit
Data acquisition rate	5 Hz
Molecular weight range	<1000 up to more than 10^7 g/mol*
Molecular weight accuracy	±2% for NIST standard SRM 1478
Radius of gyration range	10 nm - 150 nm* using SEC[†]
Limit of quantification	1 µg Polystyrene 105 kDa, 2 µg BSA[††]
Analysis models	Zimm, Berry, Debye
Fit order	1st to 5th
Detector range	4000 mV at 24 bit
Linear range	4000 mV at 24 bit
Baseline noise	<0.05 mV at 90°
Baseline drift	<0.05 mV/hour at 90°
Temperature range	10°C above ambient up to 60°C
Voltage	90-250 V, 50/60 Hz
Power usage	60 W
Dimensions	16 cm x 26 cm x 46 cm (h, w, d)
Weight	16.5 kg
21 CFR Part 11	OMNISEC software compliant

* Sample dependent

† 10 nm - 500 nm when used FFF separations

†† Chromatography dependent. Data collected under standard SEC conditions (two x 8 mm x 300 mm SEC columns)

Product specifications at a glance

OMNISEC System

Parameter	Specification
Parameters measured	Molecular weight (Mn, Mw, Mz), dispersity (Mw/Mn), Hydrodynamic radius (viscosity), Radius of gyration, Intrinsic viscosity, Mark-Houwink a & K, Weight fraction, Concentration (per peak, total and composition), dn/dc, dA/dc, Sample composition, Titer, % full AAV, DAR
Optional Software features	21 CFR Part 11, Column Calibration, Compositional Analysis
Recommended computer specification	Windows ® 10 64bit OS, 4th generation i7 processor, 8GB physical memory and 1TB hard drive & DVD drive
Data collection rate	100 Hz
Patents	US 14/599,033, US20140060162A1 & EP2619543B1, US20140144214A1 & EP2619544A1

OMNISEC RESOLVE

	Parameter	Specification
	Dimensions (w, d, h)	42 cm x 64 cm x 89 cm (w, d, h)
	Weight	62 kg
	Power requirements	600 W
Pump	Principle	Isocratic pump with continuous backseal washing
	Flow rate range	0.01 mL/min - 10 mL/min
	Flow rate accuracy	±1% mL/min
	Pressure range	0 - 5000 PSI (34.5 MPa)
	Pulsation	0.1456% @ 1 mL/min in water
Degasser	Degassing capacity	>90%
	Volume	960 µL
Autosampler	Number of samples	Up to 192
	Sample container types	HPLC vials; 96-well microtiter plates
	Temperature control range	4°C - 60°C
	Injection volume range	1 µL - 300 µL
	Injection volume accuracy	>99.5%
	Injection volume precision	<0.3% RSD in full loop mode <0.5% RSD in partial loop mode <1% RSD in µL pickup mode
	Injection overhead volume	0 µL in µL pickup mode
	Syringe volume	250 µL standard
Column oven	Column capacity	6 x analytical columns (2 x Tricorn 10/300 GL)
	Temperature control range	20°C - 65°C

OMNISEC REVEAL

	Parameter	Specification
	Dimensions (w, d, h)	42 cm x 64 cm x 60 cm (w, d, h)
	Weight	40 kg
	Power requirements	600 W
	Detector temperature control range	20°C - 65°C
Differential refractive index detector	Dynamic range	±2.5 ×10^{-4} RIU
	Baseline noise	<10^{-7} RIU
	Baseline drift	<3×10^{-7} RIU/hr
	Minimum quantifiable mass (HPLC-SEC)	100 ng of 100 kDa molecular weight polystyrene in THF* 100ng of BSA in PBS*
	Minimum quantifiable mass (UPLC-SEC)	5 ng of 100 kDa molecular weight polystyrene in THF** 40ng of BSA in PBS**
	Flow cell volume	12 µL
	Wavelength	640 nm
Diode-array-based UV/Vis spectrometer	Baseline noise	2×10^{-5} AU
	Baseline drift	5×10^{-4} AU/hr
	Wavelength range	190 nm - 900 nm
	Wavelength accuracy	<1 nm
	Wavelength resolution	0.6 nm
	Number of wavelengths	1024
	Flow cell volume	7.5 µL
	Path length	10 mm
Light scattering detector	Principle	RALS/LALS
	Operating angles	90° & 7°
	Dynamic range	2500 mV
	Baseline noise	<0.1 mV
	Baseline drift	<0.2 mV/hr
	Minimum quantifiable mass (HPLC-SEC)	100 ng of 100 kDa molecular weight polystyrene in THF* 100ng of BSA in PBS*
	Minimum quantifiable mass (UPLC-SEC)	5 ng of 100 kDa molecular weight polystyrene in THF** 40ng of BSA in PBS**
	Molecular weight range	200 g/mol to more than 10^7 g/mol
	Flow cell volume	18 µL
	Laser	50 mW
	Laser wavelength	640 nm
4-capillary differential viscometer	Principle	4-capillary Wheatstone bridge with self-balancing mechanism and user-exchangeable capillaries
	Differential pressure dynamic range	5000 Pa
	Differential pressure baseline noise	0.3 Pa
	Inlet pressure dynamic range	100 kPa
	Inlet pressure baseline noise	0.01 kPa
	Baseline drift	<0.2 kPa
	Minimum quantifiable mass (HPLC-SEC)	0.5 µg of 100kDa molecular weight polystyrene in THF*
	Minimum quantifiable mass (UPLC-SEC)	100 ng of 100 kDa molecular weight polystyrene in THF**
	Detector volume	17 µL/capillary
	"Delay reservoir" volume	8 mL per column
	Protection	Firmware-based transducer overpressure protection

*   Data collected under standard SEC/GPC conditions (two x 8 mm x 300 mm SEC/GPC columns)
**   Data collected under standard UPLC conditions (one x 4.6 mm x 150 mm UPLC column)

About Malvern Panalytical

We draw on the power of our analytical instruments and services to make the invisible visible and the impossible possible.

Through the chemical, physical and structural analysis of materials, our high precision analytical systems and top-notch services support our customers in creating a better world. We help them improve everything from the energies that power us and the materials we build with, to the medicines that cure us and the foods we enjoy.

We partner with many of the world's biggest companies, universities and research organizations. They value us not only for the power of our solutions, but also for the depth of our expertise, collaboration and integrity.

We are committed to Net Zero in our own operations by 2030 and in our total value chain by 2040. This is woven into the fabric of our business, and we help our employees and customers think about their part in creating a healthier, cleaner, and more productive world.

With over 2300 employees, we serve the world, and we are part of Spectris plc, the world-leading precision measurement group.

Malvern Panalytical. We're BIG on small™

Service & Support

Malvern Panalytical provides the global training, service and support you need to continuously drive your analytical processes at the highest level. We help you increase the return on your investment with us, and ensure that as your laboratory and analytical needs grow, we are there to support you.

Our worldwide team of specialists adds value to your business processes by ensuring applications expertise, rapid response and maximum instrument uptime.

- Local and remote support
- Full and flexible range of support agreements
- Compliance and validation support
- Onsite or classroom-based training courses
- e-Learning training courses and web seminars
- Sample and application consultancy
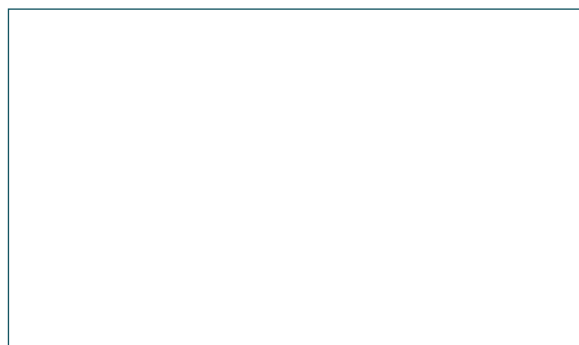
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