

PATfix[®] LNP Switcher Platform

Innovative Solution for LNP
Analysis in Process
Development



Product Information

The PATfix[®] LNP Switcher Platform is an all-in-one chromatographic platform that enables one-step analysis of lipid nanoparticle (LNP) formulations without sample pretreatment. It provides multiparameter insights into critical quality attributes, including encapsulation efficiency, nucleic acid integrity, particle size, lipid composition, nucleic acid-lipid adducts, and particle heterogeneity. Supporting multiple nucleic acid payloads, the dual-column valve-switching setup separates free and encapsulated components while enabling real-time characterization of LNPs. This innovation provides at-line, single-run readouts comparable to DLS, CE, and fluorescence assays, facilitating faster process monitoring and accurate quality control for nucleic acid-based therapeutics.

Product Overview

The PATfix LNP Switcher Platform performs multiple analyses in one step, facilitating continuous at-line analytics to enhance process development and quality control. The PATfix system simplifies analytical chromatography for non-experts, enabling fast integration for at-line analysis in process development.

The platform offers:

- The all-in-one analytical system features multiple detectors, including UV, conductivity, pH, MALS and optionally ELSD, controlled by PATfix software.
- Methods together with SOPs to run samples.
- The appropriate columns: CIMac OH and CIMac SDVB columns for LNP characterization

Introduction

Features and Benefits

- **All-in-One Solutions:** The PATfix LNP Switcher Platform integrates multiple analytical outputs into a single platform, streamlining the process and reducing the need for separate assays.
- **Streamlined Workflow:** No sample pretreatment required—enables complete analysis with a single injection, saving time and increasing throughput.
- **Direct Encapsulation Quantification of Multiple Payloads:** Provides instant, accurate measurement of all encapsulated payloads (DNA, RNA...) without relying on indirect techniques.
- **2D-Chromatography Capability:** Features advanced two-dimensional separation for deeper analysis of impurities and improved resolution.
- **User-Friendly Software:** Fully compliant with GDP 21 Part 11, ensuring ease of use and regulatory compliance.
- **Future-Ready:** Platform designed for future enhancements (e.g., lipid composition analysis), ensuring long-term flexibility and value.



CIMac analytical columns



Critical attributes in DSP



Integrated LNP analytical workflow



Multiple payload characterization



Nucleic acid integrity



Size distribution

The PATfix Software

The PATfix software streamlines analytical chromatography for everyday operations while retaining the necessary detail and complexity for higher-level tasks. Key features include:

- **Information Extraction:** Managed via user-defined templates, allowing for tailored data analysis.
- **Data Visualization:** Accelerates process development by providing clear and actionable insights.
- **Unified Database:** Creates a single database of chromatograms from multiple analytical systems, ensuring comprehensive data management.
- **Interactive Results Sharing:** Easily share results with colleagues, customers, and regulators through report generation that eases the paperwork.
- **Regulatory Compliance:** 21 CFR Part 11-compliant software with validated methods according to FDA and EMA guidelines for analytical chromatography.

PATfix LNP Switcher Methods

The growing complexity of LNP formulation and manufacturing demands precise analytical monitoring across multiple process stages to ensure optimal performance, stability, and quality of the final product.

The PATfix LNP Switcher Platform provides an integrated solution for rapid, accurate, and comprehensive LNP characterization, supporting both development and quality control.

Currently, LNP analytical methods included in the PATfix LNP Switcher Platform:

- Switcher
- Lipid Composition (coming soon)

The PATfix LNP methods include:

- Optimized and qualified analytical methods
- Guidelines for sample preparation and buffers, as well as analysis and data processing described in SOPs

Analytical columns

The PATfix LNP Switcher Platform utilizes two monolithic chromatography columns connected in series — the CIMac OH and CIMac SDVB — to enable comprehensive downstream analysis of LNP formulations.

CIMac OH

The CIMac OH column is a specialized monolithic chromatography column designed to reversibly bind LNPs. Integrated seamlessly into the PATfix LNP Switcher Platform, enabling real-time process analytics by selectively capturing LNPs from the flow-through, allowing for accurate quantification of unbound components such as free RNA.

Key Features:

- **Material:** Made from hydroxyl-functionalized methacrylate, providing high binding capacity and chemical stability under process conditions.
- **Application:** Enabling selective removal of lipid nanoparticles (LNPs) from complex mixtures.
- **Functionality:** Facilitates accurate quantification of unbound components such as free RNA or excipients, supporting real-time monitoring, process optimization, and quality control in LNP-based therapeutics.

CIMac SDVB

The CIMac SDVB column is a monolithic chromatography column designed to bind lipid nanoparticles (LNPs) through hydrophobic interactions. Integrated into the PATfix LNP Switcher Platform, it promotes LNP disruption and release of encapsulated components such as RNA.

- **Material:** Made from styrene-divinylbenzene functionalized methacrylate, providing strong hydrophobic interaction and structural stability.
- **Application:** Binds LNPs through hydrophobic attraction, causing particle disruption and content release.
- **Functionality:** Enables detection of encapsulated payloads by promoting LNP disruption, supporting real-time analysis of encapsulation efficiency.

PATfix System Hardware

Reliable analytical separation in LNP downstream processing requires advanced, purpose-built hardware.

LNP formulations contain target subspecies and related impurities that are difficult to distinguish using conventional methods, which cannot effectively separate multiple payloads or detect impurities.

The PATfix LNP Switcher Platform automates LNP analytics, replacing multiple traditional assays with a single one-step injection. This streamlined workflow enhances reliability, accuracy, and process consistency through an integrated platform.

The PATfix LNP Switcher Platform includes the hardware listed below to perform the required analyses.

Pump

The low-pressure gradient pump, equipped with an integrated degasser and mixer, features bio-inert ceramic pump heads. Quaternary buffer switching enables analytical methods with included cleaning in place (CIP) and column regeneration, ensuring robust performance.

Conductivity | pH Monitor

A contactless conductivity probe with a wide measuring range enables in-process monitoring of salt concentration gradients and facilitates tracking complex methods, including pH gradients.

Autosampler

The autosampler accommodates vials or microtiter plates. An automated needle wash ensures minimal carryover, while temperature control of the sample tray secures sample stability while waiting for analysis.

Column Thermostat

The column thermostat ensures additional robustness by reducing the risk of environmental temperature fluctuations affecting experimental outcomes and enables operation at temperatures ranging from 5 to 85 °C.

Multi-Wavelength UV Detector

Highly sensitive monitoring of up to 4 wavelengths in the 190–700 nm range is possible, while intelligent temperature control minimizes drift. It helps to detect impurity proteins and nucleic acids.

MALS Detector

Suitable for particle characterization like LNP, including heterogeneity assessment and size distribution.

ELSD (Optional)

Characterizes and quantifies lipid composition in LNP formulations, including non-UV-active lipids.

Relevant Application

Determination of encapsulation efficiency of multiple cargo LNPs

The LNP Switcher method accurately quantifies encapsulation efficiency in various LNP samples. Using a two-dimensional (2D) chromatographic setup with two complementary column chemistries, it effectively separates non-encapsulated nucleic acids from the encapsulated ones.

Challenge addressed:

- Direct measurement of encapsulation efficiency from LNPs—no sample pre-treatment or dyes needed.

Solution:

- 2D-chromatography with UV detection enables precise determination of encapsulation efficiency for single- or multiple-payload LNPs.

Table 1: Comparison of encapsulation efficiencies (EE) determined with the PATfix LNP Switcher Platform and the RiboGreen assay.

	PATfix LNP Switcher Platform		RiboGreen assay
	mRNA EE [%]	pDNA EE [%]	EE [%]
mRNA LNP	88 ± 2	NA	84 ± 4
pDNA LNP	NA	77 ± 2	80 ± 4
mRNA + pDNA LNP	65 ± 1	60 ± 1	71 ± 2
1 kb mRNA + 4 kb mRNA LNP	1 kb mRNA 75 ± 2	4 kb mRNA 79 ± 2	83 ± 3

The PATfix LNP Switcher (Table 1) and RiboGreen assay show comparable results for single-payload LNPs. Unlike RiboGreen, the PATfix LNP Switcher can quantify encapsulation efficiency of individual nucleic acids in multi-payload LNPs.

Figure 1: Absorbance at 260 nm signal of a) LNP encapsulating mRNA and pDNA and b) LNP encapsulating 1 kb mRNA and 4 kb mRNA.

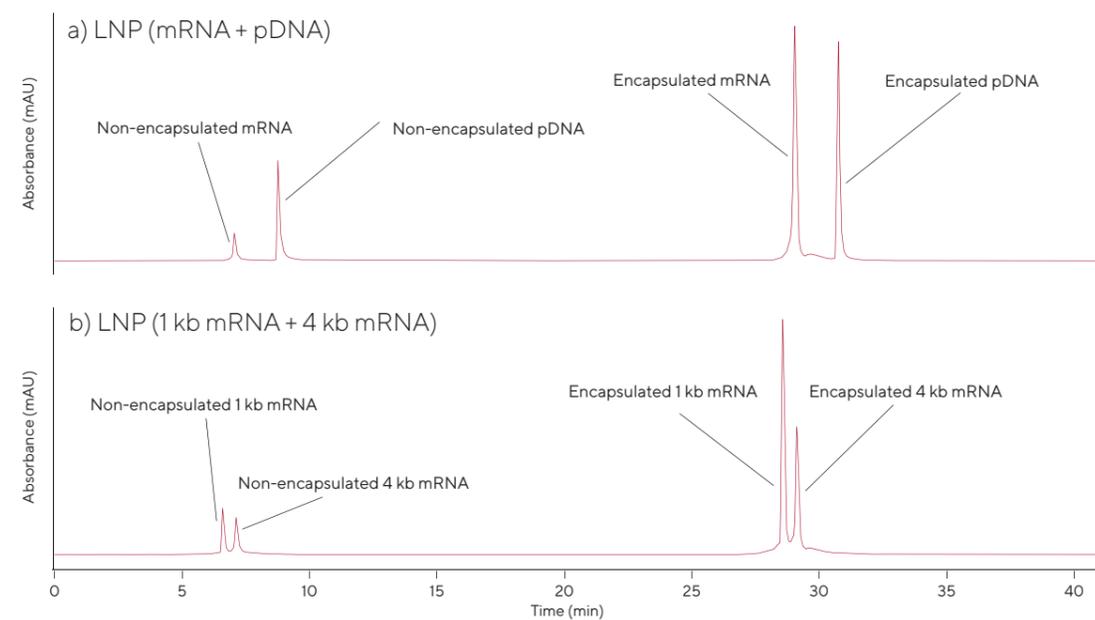


Figure 1a shows an example of co-encapsulated mRNA (mFix4) and pDNA (pFix5), with baseline-separated peaks enabling accurate quantification of all components. Figure 1b presents a chromatogram of LNPs co-encapsulating two mRNA species (1 kb eGFP and 4 kb mFix4), demonstrating clear separation of both encapsulated and non-encapsulated mRNA molecules by size.

Nucleic acid impurities in LNP samples can be detected using reverse-phase chromatography

The PATfix LNP Switcher Platform integrates a reversed-phase column that separates nucleic acids based on size and hydrophobicity, allowing for the effective detection of key LNP impurities—mRNA fragmentation and lipid–nucleic acid adducts.

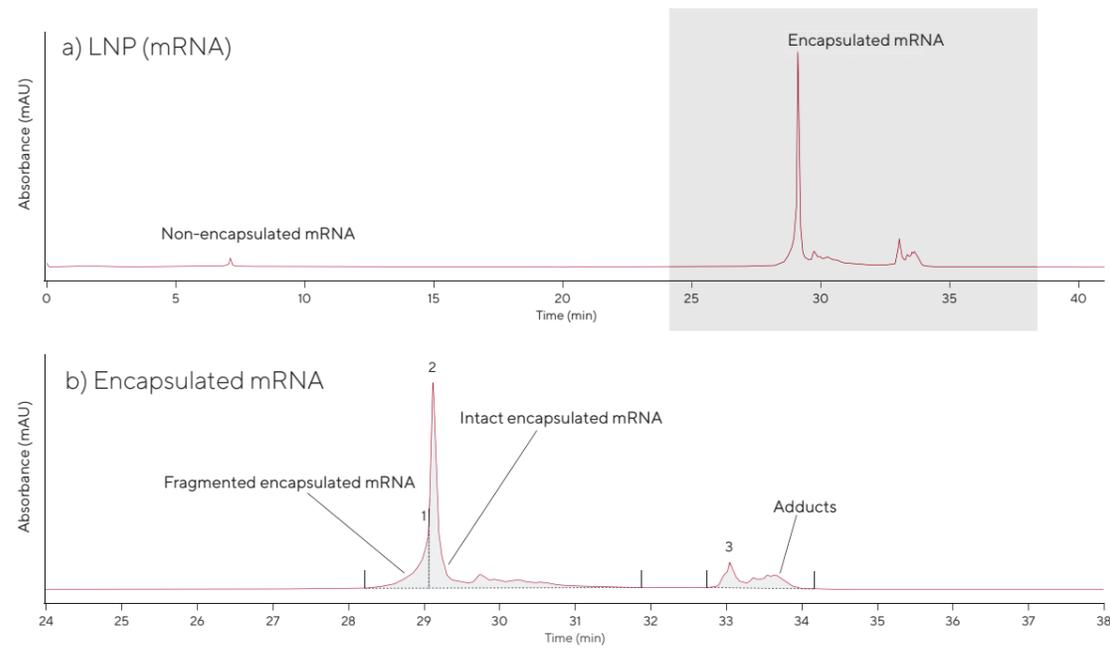
Challenge addressed:

- Standard methods struggle to detect and separate these impurities without extensive sample preparation or multiple assays.

Solution:

- The PATfix LNP Switcher Platform separates nucleic acids by size and hydrophobicity in a single assay without any sample pretreatment.

Figure 2: Absorbance at 260 nm signal of a) LNP encapsulating mRNA with grey area zoom in shown in b) with indicated fragmented and intact mRNA and adducts.



This approach allows for quantification of intact mRNA, fragmented nucleic acids, and lipid–nucleic acid adducts (see Figures 2a and 2b). In a thermal stability study (Figures 3 and Table 2), increasing temperature to 35°C led to higher levels of adducts and encapsulated mRNA, while intact mRNA decreased from 47% on day 0 to 21% after six days, reflecting progressive degradation.

Figure 3: Absorbance at 260 nm signal of LNP sample at Day 0, Day 2 and Day 6 of thermal stability study at 35°C.

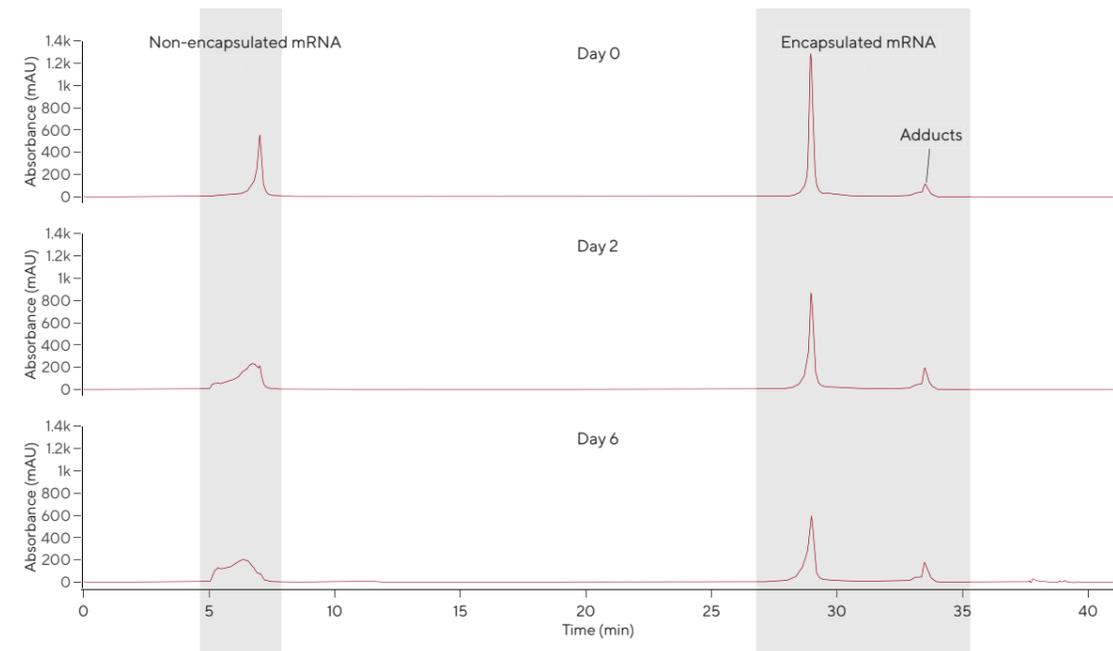


Table 2: Thermal stability study results.

Day	% encapsulation efficiency	Relative % encapsulated mRNA	% degraded encapsulated mRNA	% adducts (encapsulated mRNA)	% intact mRNA (of total)
0	66	100	16	12	47
2	55	81	25	20	30
6	49	70	37	22	21

MALS detector enables LNP size determination

Another key feature of the PATfix LNP Switcher Platform is its ability to estimate LNP size distribution using a MALS detector— enabling this analysis alongside encapsulation efficiency and nucleic acid integrity in a single assay.

Challenge addressed:

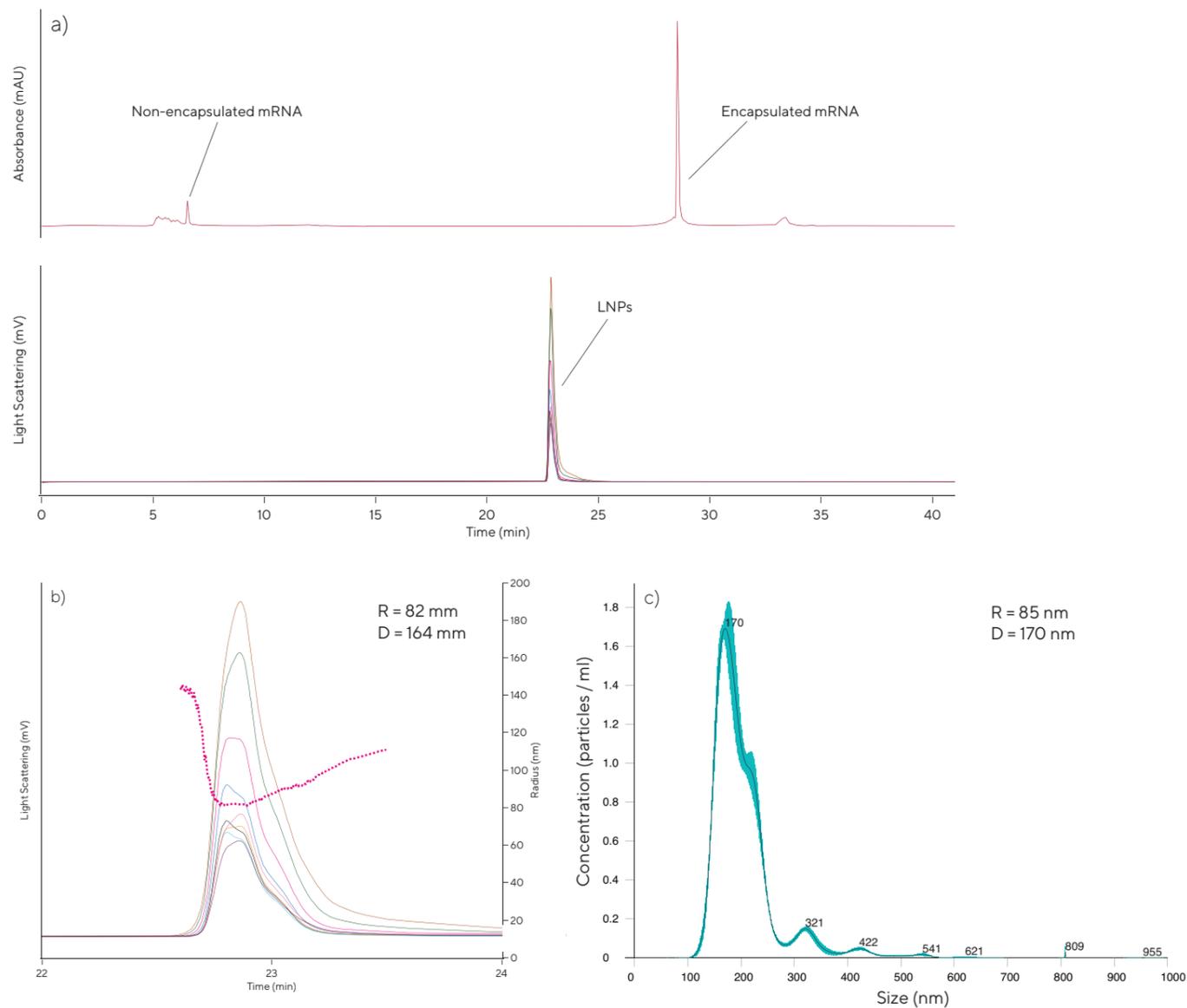
- Reliable measurement of LNP size and size distribution typically requires separate workflows, making it difficult to combine with encapsulation efficiency and nucleic acid integrity analysis in a single run.

Solution:

- It measures the light scattering of LNPs from nine different angles. LNP size can be determined using mathematical modeling.

Figure 4: (a) Chromatogram of LNP encapsulated mRNA, MALS signal (overlay of 9 MALS angles) (b) zoom-in of MALS measurement with LS radius of gyration calculation (c) NTA analysis of LNP encapsulated mRNA.

Figures 4a and 4b show the size and size distribution of mRNA-encapsulating LNPs measured by MALS, with light scattering recorded at nine angles. A Berry model fit was applied to calculate LNP size, which closely aligned with results from NTA analysis (Figure 4c).



Hardware Components

UV Absorbance Detector

Detection	
Detector type	Multiwavelength detector
Detection channels	4 digital
Light source	Deuterium (D2) lamp with integrated GLP chip
Wavelength range	190–700 nm
Spectral bandwidth	< 8 nm at H α line (FWHM) Note: digital bandwidth 1–32 nm
Wavelength accuracy	\pm 2 nm
Wavelength precision	0.1 nm
Wavelength verification	Internal holmium filter and deuterium lines
Noise	\pm 30 μ AU at 254 nm
Drift	1500 μ AU/h at 254 nm
Linearity	> 1.6 AU at 274 nm, typically 2.5 AU
Time constants	0.0 / 0.01 / 0.02 / 0.05 / 0.1 / 0.2 / 0.5 / 1.0 / 2.0 / 5.0 / 10.0 s
Integration time	Automatic (5–1000 ms)

Communication

Interfaces	LAN (RJ-45), RS-232 (SUB-D 9), multi-pin connector, analog (RCA cinch connector)
Control	PATfix [®] software
Inputs	Error (IN), Start (IN), Autozero, Event 1–2
Outputs	Error (OUT), +5 V, Valve +24 V, Valve (OUT), Start (OUT)
Analog outputs	1 x 0–5 V scalable, 20 bit, offset adjustable

Technical parameters

GLP	Detailed report including lamp recognition, operating hours, lamp operating hours, number of lamp ignitions
Display	N/A
Ambient conditions	Temperature range 4–40 °C, 39.2–104 °F, humidity: below 90 %

General

Power supply	100 – 240 V, 50 – 60 Hz, 75 W
Dimensions (W x H x D)	361 mm x 158 mm x 523 mm
Weight	12.2 kg
Leak sensor	Yes

Analytical Pressure-Proof UV Flow Cell Cartridge (For Aqueous and High Salt Condition)

Technical	
Path length	10 mm
Connection	1/16"
Volume	10 µL
Wetted parts	Titanium, Quartz, PEEK
Maximum flow rate	20 mL/min
Maximum pressure	300 bar

High Sensitivity UV Flow Cell Cartridge

Technical data	
Path length	50 mm
Connection	1/16"
Flow cell volume	6 µL illuminated volume (2 µL dispersion volume)
Wetted parts	PEEK/quartz (SUPRASIL)/Teflon®/stainless steel
Maximum flow rate	5 mL/min
Maximum pressure	50 bar

Pump OH

General information	
Variant	Quaternary low-pressure gradient pump
Delivery system	Dual-piston pump
Pulsation compensation	Active pressure and pulsation compensation
Pulsation	< 2 % Amplitude (typically: < 1.3 %) or 3 bar (0.3 MPa), whatever is greater, at 1 mL/min ethanol, at all pressures > 10 bar (1 MPa)
Flow rate range	0.01-10 mL/min 0.1-6 mL/min (recommended)
Flow rate increment	0.01 mL/min
Flow rate accuracy	< 1 % (measured at 5-80 % of flow range, using ethanol)
Flow rate precision	0.1 % RSD (based on the retention time at constant room temperature)
Flushing piston seal	Standard
Gradient range	0-100 %
Maximum delivery pressure	400 bar
System protection	Soft start, programable P _{max}
Wetted materials	Sapphire, ruby, ceramic, FKM

Degasser module	
Degasser channels	2 channels, Teflon® AF
Degasser max. flow rate	10 mL/min
Degasser method	Gas permeation using Teflon® AF amorphous fluoropolymer membrane
Degasser efficiency	< 0.5 ppm dissolved O ₂ at 1 mL/min
Degassing chamber volume	480 µL volume per channel
Eluents	Limitations: THF, DMSO, hydrochloric acid and halogenated hydrocarbons, in particular hexafluoroisopropanol (HFIP). > 1M NaOH for prolonged time Pump wetted materials are compatible with salt buffers and common organic solvents (ACN, MeOH, IPA and EtOH). Pump shouldn't be left in high concentration organic solvents and high salts for prolonged time.
Wetted materials	PEEK, Tefzel®, Teflon® AF
Vacuum pump	Low hysteresis

Communication	
Interfaces	LAN, Pin header connectors (Analog IN, Start IN, Error IN)
Control	PATfix® software
Analog input	0-10 V
Analog control input	Flow rate
Level event outputs	8 event outputs (TTL, OC, Relays) and 24 V
GLP	RFID pump head detection, detailed report
Display	3 LEDs
Leak sensor	Yes
Protection type	IP-20

General	
Power supply	Power input: 100-240 V Output: 50-60 Hz Maximum power consumption: 100 W
Dimensions (W × H × D)	361 mm x 208 mm x 523 mm
Weight	12.7 kg
Leak sensor	Yes
Temperature range	4-40 °C (39.2-104 °F)
Air humidity	Below 90 %, non-condensing

Quaternary Low-Pressure Gradient

Setup	
Pump type	Quaternary analytical HPLC pump with degasser
Pump Head	10 mL/min ceramic
Degasser	4 channels, Teflon® AF
Special feature	Automatic adaption of LPG cycle time
Weight	12.7 kg
Gradient type	Low-pressure gradient
Gradient range	0–100 % 1–99 % (recommended)
Minimum increment	1 %
Gradient precision	± 0.3 % (measured at 1 mL/min, 150 bar, tracer: ethanol/caffeine) ± 2 % (1–99 %, measured at 5–50% of the flow range, tracer: water/caffeine)
Gradient repeat accuracy	< 0.1 % RSD (measured at 1 mL/min, 0.5 % RSD overall, based on retention time at constant room temperature)
Mixing volume	250 µL (metal-free)
Delay volume	410 µL (metal-free)

10 mL Pump Head

Flow rate range	0.01–10 mL/min 0.1–6 mL/min (recommended)
Maximum pressure	400 bar (40 MPa, 5800 psi) - ceramic

Pump SDVB

Solvent conveyance	
Variant	Quaternary low-pressure gradient pump
Delivery system	Dual-piston pump
Pulsation compensation	Active pressure and pulsation compensation
Pulsation	< 2 % Amplitude (typically: < 1–3 %) or 3 bar (0,3 MPa), whatever is greater, at 1 mL/min ethanol, at all pressures > 10 bar (1 MPa, 147 psi)
Flow rate range	0.01–10 mL/min 0.1–6 mL/min (recommended)
Flow rate increment	0.01 mL/min
Flow rate accuracy	< 1 % (measured at 5–80 % of flow range, using ethanol)
Flow rate precision	0.1 % RSD (based on the retention time at constant room temperature)
Flushing piston seal	Standard
System protection	Soft start, P _{min} und P _{max} are programmable
Wetted materials	Stainless steel, GFP (graphite fiber reinforced PTFE), sapphire, ruby, ceramic, FKM, PEEK, Zirconium oxide, Systec AF TM, PTFE

Degasser module	
Degasser channels	2 channels, Teflon® AF
Degasser max. flow rate	10 mL/min
Degasser method	Gas permeation using Teflon® AF amorphous fluoropolymer membrane
Degasser efficiency	< 0.5 ppm dissolved O ₂ at 1 mL/min
Degassing chamber volume	480 µL volume per channel
Eluents	Limitations: hydrochloric acid and halogenated hydrocarbons, in particular hexafluoroisopropanol (HFIP), salt buffers
Wetted materials	PEEK, Tefzel®, Teflon® AF
Vacuum pump	Low hysteresis

Communication	
Interfaces	LAN, Pin header connectors (Analog IN, Start IN, Error IN)
Control	LAN, Analog and event control, Mobile Control
Analog input	0–10 V
Analog control input	Flow rate
Level event outputs	8 event outputs (TTL, OC, Relais) and 24 V
Programming	19 programs, 9 program links, 1 WAKE UP program
GLP	RFID pump head detection, detailed report
Display	3 LEDs
Leak sensor	Yes
Protection type	IP-20

General	
Power supply	Power input: 100–240 V Output: 50–60 Hz Maximum power consumption: 100 W
Dimensions (W × H × D)	361 mm x 208 mm x 523 mm
Weight	See "Device Variants" below
Leak sensor	Yes
Temperature range	4–40 °C (39.2–104 °F)
Air humidity	Below 90 %, non-condensing

Quaternary Low-Pressure Gradient

Setup	
Pump type	Quaternary analytical HPLC pump with degasser
Pump Head	10 mL/min, stainless steel
degasser	4 channels, Teflon® AF
Special feature	Automatic adaption of LPG cycle time
weight	12.7 kg

Gradient formation	
Gradient type	Low-pressure gradient
Gradient range	0-100 % 1-99 % (recommended)
Minimum increment	1 %
Gradient precision	± 0,3 % (measured at 1 mL/min, 150 bar, tracer: ethanol/cafeine) ± 2 % (1-99 %, measured at 5-50% of the flow range, tracer: water/cafeine)
Gradient repeat accuracy	< 0.1 % RSD (measured at 1 mL/min, 0.5 % RSD overall, based on retention time at constant room temperature)
Mixing volume	200 µL
Delay volume	360 µL

10 mL Pump Head

Flow rate range	0.01 mL/min-10 mL/min 0.1-6 mL/min (recommended)
Maximum pressure	862 bar (86 MPa, 12500 psi) – stainless steel

Autosampler

Sample injection	
Max. plate vial height	47 mm (incl. septa or capmat)
Sample capacity	108 standard autosampler vials
Injection volume range	1 - 1000 µL programmable
Sample loop	100 µL/1000 µL
Dispenser syringe	250 µL
Headspace pressure	Built-in compressor, only for sample vials with septum
Switching time inj. valve	< 100 ms
Piercing needle precision	± 0.6 mm
Sample tray cooling	With cooling function 4 - 40 °C
Vial detection	Missing vial/well plate detection by sensor
Needle wash	Programmable: wash between injections and wash between vial
Wetted materials	Tefzel® (ETFE), Glass, Teflon® (PTFE), Kel-F® (PCTFE), stainless steel, PEEK
Injection modes	Full loop filling, partial loop filling and microliter pickup, PASATM (pressure-assisted sample aspiration)
Injection precision	RSD (Relative Standard Deviation): Full loop filling < 0.3 % Partial loop filling at injection volumes > 5 µL: < 0.5 % Microliter pickup at injection volumes > 5 µL: < 1.0 %
Sample carryover	<0.05 % with needle cleaning
Injections per vial	Max. 9 injections
Injection cycle time	Min. 7 s from the same vial, 14 s from different vials; <60 s for >100 µL sample injection in all injection modes, incl. 300 µL needle wash
Analysis time	Max. 9 h, 59 min, 59 s

Communication	
Interfaces	LAN, ANALOG
Control	Ethernet (LAN)
Inputs	2 programmable TTL inputs (next injection, freeze, stop)
Outputs	1 programmable relay output (inject marker, auxiliary, alarm)

General	
Power requirements	95 - 240 V AC +/- 10%, 50 - 60 Hz
Power consumption	200 W
Dimensions (W × H × D)	377 mm × 300 mm × 575 mm
Weight	32 kg
Stackable weight (Maximum weight on top)	65 kg
Leak sensor	None
Ambient conditions	Temperature range: 10 - 40 °C; 50 - 104 °F Air humidity: 20 - 80 %

Conductivity Monitor

Detector type	Conductivity monitor
Conductivity	0.1-999 mS/cm
Accuracy	<5 % scale end value
Precision in measured range (0.1-300 mS/cm)	<2 % of full scale or ≤5 mS/cm for higher values
Linearity	±1 % scale end value
pH measured range	pH 2-12
pH precision	±0.2 pH in temperature range 4-25 °C
pH accuracy	±0.5 pH in temperature range 4-25 °C
pH drift	Maximum 0.02 pH/h at pH 4
Maximum data rate	5 Hz (LAN, RS-232, Analog)
Outputs	LAN, RS-232, Analog
Analog output	Conductivity, pH
Control	Manual: front panel
Protection type	IP 20
Temperature range	4 - 40 °C; 39.2 - 104 °F
Air humidity	Below 90%, non-condensing
Air pressure	84 - 106 kPa; 840 - 1060 mbar
Power supply	100-240 V, 50-60 Hz, max. 20 W
Dimensions (W × H × D)	121x129x187 mm
Weight	3.2 kg

pH Measuring Kit

Maximum flow rate	80 mL/min
Delay volume	80 µL

Conductivity Flow Cell, Analytical

Flow cell type	Conductivity flow cell
Biocompatible	Yes
Fiber optics version	No
Capillary connection	1/16"
Wetted materials	PEEK
Flow cell volume	30 µL
Maximum flow rate	10 mL/min
Maximum pressure	160 bar

Valve unifier

Valve drive

Function	Column selection, Eluent selection, Fraction collection, Injection, Sample selection, Bypass, Reverse flow
Port number	depending on valve
Position	2-position and multi-position valves supported (max. 16 pos.)

Communication

Interfaces	LAN, display, terminal strip
Control	Display, software, event control
Inputs	Binary control; Home, Backward/Inject, Forward/Load, Start IN
Outputs	Trigger out, Event

General

Power supply	External DC 24V, 65 W
Dimensions (W x H x D)	80 mm x 123 mm x 192 mm
Weight	1.9 kg
Ambient conditions	Temperature range: 4–40 °C; 39.2–104 °F below 90 % humidity (non-condensing)

Multiposition valve

Function	Fraction collection, Eluent selection, Sample selection
Capillary connection	1/16"
Bore size	0.75 mm
Thread	10-32 UNF
Max. pressure [bar]	240 bar
Max. pressure [MPa]	24 MPa
Port number	8
Positions	Multiposition
Stator material	PEEK
Rotor material	PEEK
Material	Biocompatible
Operated	electrical by valve drive

General

Dimensions	Valve diameter: 42 mm
Weight	0.2 kg
Ambient conditions	Temperature range: 4–40 °C; 39.2–104 °F; below 90 % humidity (non-condensing)

Optional MALS Detector

Sample cell volume	63 µL
Pressure stability	Up to 10 bar
Light scattering volume	< 7.8 nL
Wetted parts	Glass, PTFE + 25 % carbon, stainless steel, titan
Solvent compatibility	Aqueous and organic solvents with the same flow cell
Light scattering angles	28° – 156° at 9 angles 0 – 4 V at 24 bit 0.24 µV resolution
Signal processing	DSP on every single photo detector, different filter algorithms possible
Molar mass range	10 ³ to 10 ⁶ Da depending on sample
Radius of gyration range	Approx. 8 nm to 250 nm depending on sample
Laser specifications	630 nm (red)
Laser life time	Approx. 10.000 hours
Safety functions	Vapor sensor Leak sensor
Cell temperature control	10 °C above room temperature Up to 60 °C Stability +/- 0.01 °C at 35 °C
Power requirements	100 – 240 V @ 50 – 60 Hz, 155 W
Electronic inputs outputs	Error in/out, injection ready in/out, ethernet interface
Environmental conditions	20 – 80 % relative humidity (noncondensing) at an ambient temperature range of 4 – 30 °C (*) (*) When the laser is activated above 10 °C
Dimensions (D x W x H)	460 mm x 260 mm x 160 mm
Shipping weight	17 kg

Optional Fluorescence Detector

Light source	Xenon lamp	
Wavelength range	200 to 650 nm	
Spectral bandwidth	20 nm	
Wavelength accuracy	2 nm	
Wavelength reproducibility	0.2 nm	
S/N	Water Raman peak S/N 1200 min.	
Cell (capacity, pressure resistance, material)	12 µL; 2 MPa (approx. 20 kgf/cm ²); SUS316L, PTFE (fluororesin), quartz	
Simultaneous Monitoring of Wavelengths	Measured wavelength	Any two wavelengths between 200 and 650 nm (Four wavelengths can be set from LabSolutions)
	Sampling period	0.5 s per wavelength
Operational ambient temperature range	4 to 35 °C	
Dimensions (W x H x D)	260 mm x 420 mm x 210 mm	
Weight	16 kg	

Software

Software name	PATfix®	
Version	3.0 or latest	
Compliance	21 CFR Part 11	
License	Perpetual, per system	
System architecture	.NET Framework	
Operating system	Windows 11 or latest	
Database	SQLite	
Display language	English	
Client server	Client server functionality	
Supported instruments	Detector MWD 2.1 Detector MALS 3601/3609 Detector RF-20A Interface box IFU 2.1 Autosampler AS 6.1L Pump P 2.1S/P 4.1S Pump P 6.1L LPG Pump P 6.1L HPG Monitor CM 2.1S/pH 2.1S	
Instrument connection	RS-232, Ethernet, USB	
Recommended PC hardware	PC	Memory: minimum 4 GB, recommended 8 GB CPU: minimum 1 CPU core @ 2 GHz speed, multi-core CPU recommended Onboard (integrated) graphics 256 GB for installation and data storage, SSD is highly recommended Monitor: minimum 1680 × 768, recommended 1920 x 1080
Chromatography definitions	European Pharmacopeia (EP)	
Security	SSL certificate (optional)	
Authentication	Local (integrated), Domain (optional)	
Max. number of users	No restrictions	
Setup format	MSI installer	
Main features	Instrument control, integration, calibration, templates, reports, peak fitting, radius calculation, method revision history	
Data export	CSV	
Operation	Sequence or manual run	

LNP Switcher Platform

Switcher	
Columns chemistry	CIMac OH and CIMac SDVB
Method	Quantitative
Attribute	Encapsulation Efficiency (%) Size distribution Nucleic acid quantification Nucleic acid integrity
LOQ (mRNA)	LOQ = 50 ng
Linearity Range	0.1-100 ug/mL
Precision	RSD < 15%, According to EP and FDA guidelines.
Accuracy	RSD < 15%, According to EP and FDA guidelines.

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

Slovenia

Sartorius BIA Separations d.o.o.
Mirce 21
5270 Ajdovščina
Phone +386 59 699 500

USA

Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178



For more information, visit

www.sartorius.com

www.biaseparations.com