SARTORIUS

Product Datasheet

PATfix® mRNA Platform

Rapid, Tailor-Made At-Line Analytical Chromatography Solution

Product Information

Making informed decisions during mRNA process development relies on reliable quantification of mRNA and other molecules, eg vitro transcription components (IVT) or by-product impuritites from IVT to purification. However, collecting samples for offline analysis can be time-consuming and may deliver an incomplete picture of the production process due to throughput constraints and time delays.

The PATfix® mRNA analytical platform is designed to simplify analytical chromatography and make its application easier for process development scientists. By bringing this tool from QC to at-line monitoring, feedback from the process is instantaneous (5 – 15 minutes per sample), accelerating process development workflows. The user-friendly PATfix® software simplifies data processing, visualization, and sharing.

Features and Benefits

- End-to-end solution: The system, preset with multi-wavelength UV detectors, column thermostat, conductivity and pH sensors, and autosampler for high throughput applications, enables the tracking of raw materials, impurities, and mRNA quantification during IVT and purification
- Better control: The PATfix® mRNA platform is supported by specific columns, software, and protocols, empowering lab technicians to perform their own analyses for better control of timelines and data points
- Ready for use: The system includes validated analytical methods for mRNA analysis, buffer recipes, and data analysis algorithms
- Fast: The convective laminar flow offered by the compatible CIMac™ monolith columns allows analysis to be completed in less than 15 minutes

Introduction

Platform Overview

PATfix® HPLC analytical system is all it takes to accelerate your process development and have continuous at-line production monitoring and robust quality control of nucleic acid drug substances.

The PATfix® analytical platform is designed to simplify analytical chromatography for non-experts, making it accessible for at-line use during process development.

The platform offers:
- The preset HPLC with the recommended detectors
- Methods together with SOPs to run samples and perform at-line analysis
- The appropriate CIMac™ columns for mRNA process development and follow-up from IVT to purification
- mRNA standards for day-to-day system suitability testing (SST)

By bringing this tool from QC to at-line, feedback on process state is instantaneous (5 – 15 minutes per sample), accelerating process development workflows.

The user-friendly PATfix® software simplifies data processing, visualization, and sharing.

PATfix® mRNA Platform

Features

Pre-configured HPLC system built around CIMac™ columns

CIMac™ columns using monolith technology (convective laminar flow) for fast and high resolution analysis

Validated methods with SOPs, including buffer prep, standard and templates for data analysis

Benefits

From IVT to DSP, follow raw materials | impurities and and quantification of mRNA, just follow the guide

Sample run in 5 – 15 minutes, allowing at-line analysis and real-time feedback

Reliable and reproducible analytical chromatography for mRNA

Perfect tool to facilitate process development and production monitoring

PATfix® Software

The PATfix® software simplifies analytical chromatography for day-to-day operations while retaining the necessary detail and complexity for higher-level tasks
- Information extraction handled via user-defined templates
- Data visualization accelerates progress during process development
- A single database of chromatograms is created from multiple analytical systems
- Easily share interactive results with colleagues, customers, and regulators: report generation helps ease the paperwork load
- 21 CFR Part 11-compliant software with included pre-validated methods according to FDA | EMA guidelines on analytical chromatography

PATfix® mRNA Methods

Optimized analytical methods are a key component of a well-functioning analytical system.

Three orthogonal methods are included in the PATfix® mRNA platform:
- IVT monitoring
- mRNA production
- Quality control of drug substance (see "Relevant Applications" for further details)

The PATfix® mRNA methods include:
- Fully optimized and validated analytical methods (to run a sample and pre-set methods for analysis)
- Guidelines for buffer and sample preparation, including detailed SOPs
- An mRNA calibration standard, which enables accurate quantification of the mRNA species of interest as well as batch-to-batch and day-to-day performance tracking

Additional in-process robustness is supported by the conductivity and pH monitors, which ensure the analysis is being performed with correct buffers and gradients.

Analytical Columns

Choose between three CIMac™ columns to be included with the PATfix® mRNA platform.

CIMac PrimaS® Column — For the Quantification of mRNA, Capping Reagents, and Nucleotides
CIMac™ PrimaS is a multimodal chromatography column using monolith technology. It quantifies the depletion of individual nucleotides, capping reagent, and generation of mRNA throughout an IVT reaction and subsequent drug substance purification.

CIMac™ Oligo dT18 Column — Affinity-based Titre Determination (For Use During mRNA Production)
CIMac™ Oligo dT18 is an affinity column with dT18 oligonucleotides grafted to the monolith surface. mRNA with a polyA tail binds to the column under high salt conditions, while impurities (nucleotides, capping reagents, DNA template, enzymes) do not bind to the column and flow through. This allows rapid and simple at-line determination of mRNA titre (< 5 minutes).

CIMac™ SDVB Column — For mRNA Integrity Characterization and Contaminants Detection (For Use During QC)
CIMac™ SDVB is a reverse-phase monolithic column used with an ion-pairing reagent. This analytical method uses an acetonitrile gradient at elevated temperatures to drive separation by size enabling detection of RNA fragmentation (stability) and dsRNA.

PATfix® System Hardware

Designing a suitable hardware set-up for reproducible analytical separation of large biomolecules is not trivial. Complex IVT mixtures are composed of the target molecule (mRNA), process-related impurities (nucleotides, capping reagent, and DNA template), and product-related impurities (abortive fragments and dsRNA), all with similar biophysical characteristics.

The PATfix® mRNA platform includes the hardware listed below to realize the required analyses.

Pump
The low pressure gradient pump with integrated degasser and mixer has bio-inert ceramic pump heads. Quaternary buffer switching allows analytical methods with included cleaning in place (CIP) and column regeneration, essential for robust performance.

Conductivity | pH Monitor
A contactless conductivity probe with a wide measuring range allows in-process monitoring of salt concentration gradients and tracking challenging 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 in queue 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 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, and intelligent temperature control minimizes drift.

(Optional) Fluorescence Detector
For process development tasks based on innovative or challenging nucleic acid samples, where additional characterization power is required, the fluorescence detector is key to determining contaminants such as residual enzymes with intrinsic tryptophan fluorescence.

(Optional) MALS Detector
Suitable for groups working on lipid nanoparticle characterization

Relevant Applications

IVT Reaction Monitoring Using CIMac PrimaS®

Optimizing the IVT reaction for high mRNA yield requires construct-specific considerations. To achieve this, all key components need to be separated and quantified (Figure 1). This enables rapid DoE execution to find optimal IVT conditions for a high yield mRNA production process.

The PATfix® mRNA analytical platform is specifically designed to tackle these challenges.

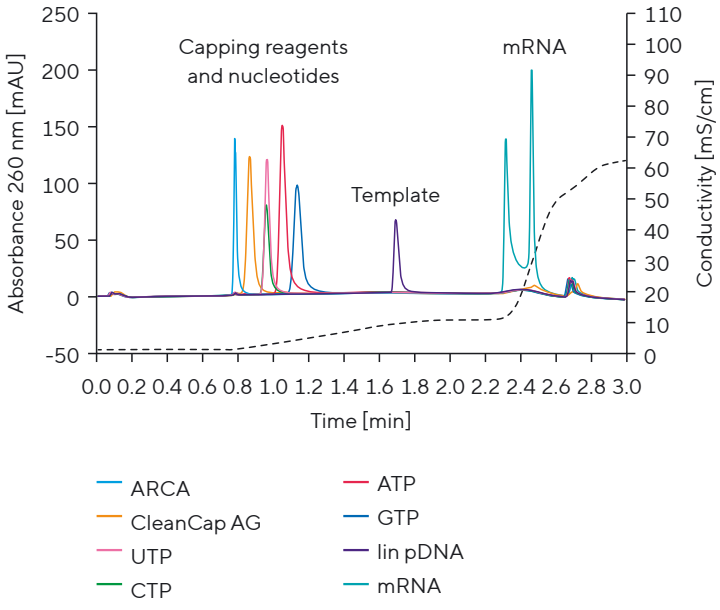
Monitoring IVT Components

- Individual nucleotide concentrations
  - Including CTP and UTP
- Capping reagent
- DNA template
- mRNA product

Optimizing IVT Conditions

- Buffer type and pH
- Salt(s) type and concentration
- Additives such as DTT
- T7 polymerase concentration
- Linear template concentration
- Reaction temperature
- Reaction time

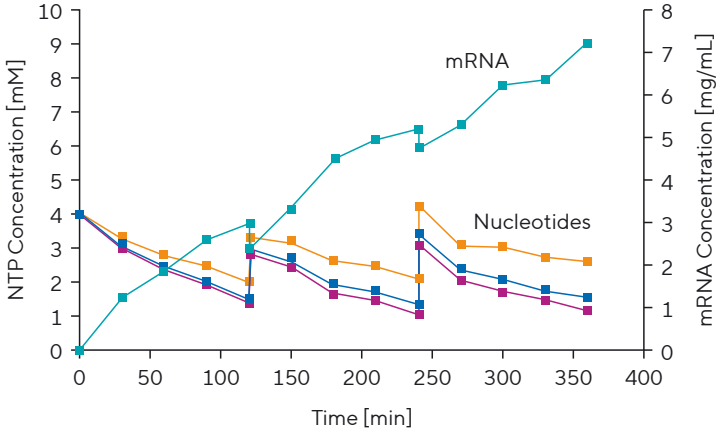
Figure 1: *Separation of IVT Components*



Conquering the IVT Process

- Doubling mRNA yield
- Fed-batch reaction optimization (Figure 2)
  - Timing
  - Amount | feed rate

Figure 2: *Improving mRNA Yield With a Fed-Batch Approach to IVT*



mRNA Production Monitoring Using CIMac™ Oligo dT18

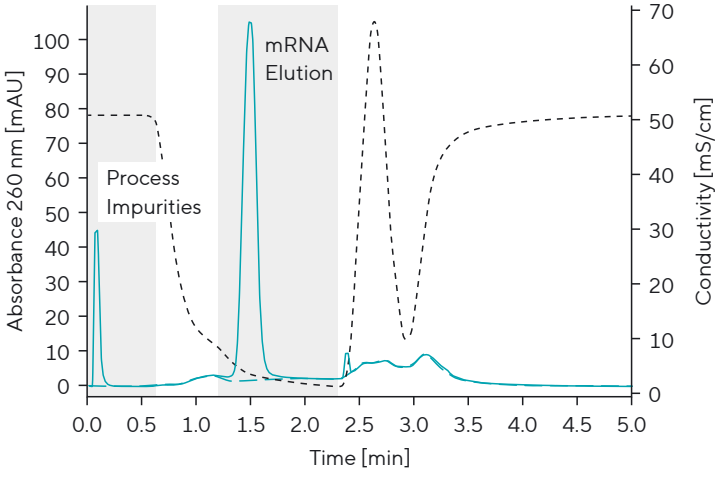
At-line mRNA production monitoring requires a unique blend of simplicity and information on the key process parameter—mRNA titre (Figure 3). The PATfix® mRNA platform can be implemented to monitor both processes, mRNA production and purification.

This makes it a perfect analytical tool for in-process control. Speed is an important parameter when choosing process analytics; this method takes only 5 minutes, so process insights are almost instantaneous.

Simple and Fast Analytics

- mRNAs with polyA tail
- Process impurities (nucleotides, capping reagent, DNA template, abortive fragments, and enzymes)

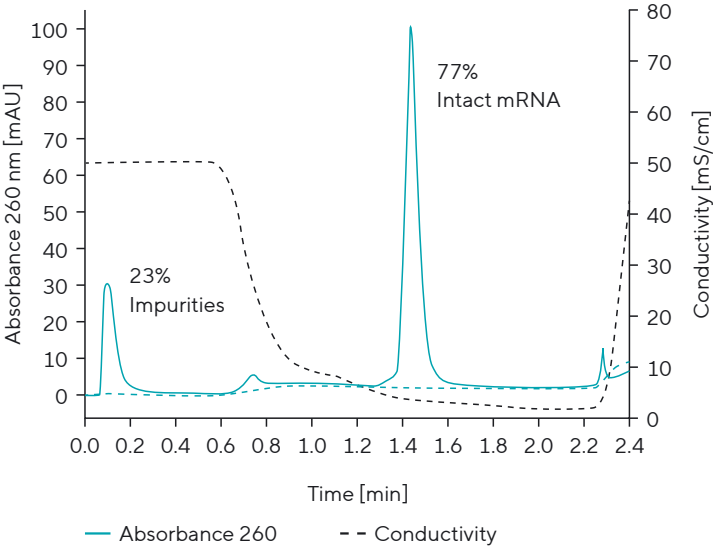
Figure 3: *mRNA Production Monitoring*



Quantification

- Simple, fast at-line quantification
- Process step recovery monitoring (load, wash, elution, CIP fraction mass balance)
- Process yield monitoring
- Monitoring mRNA recovery vs. process impurity removal (nucleotides, enzymes, template, abort products) (Figure 4)

Figure 4: *Percentage of Intact mRNA vs. Impurities*



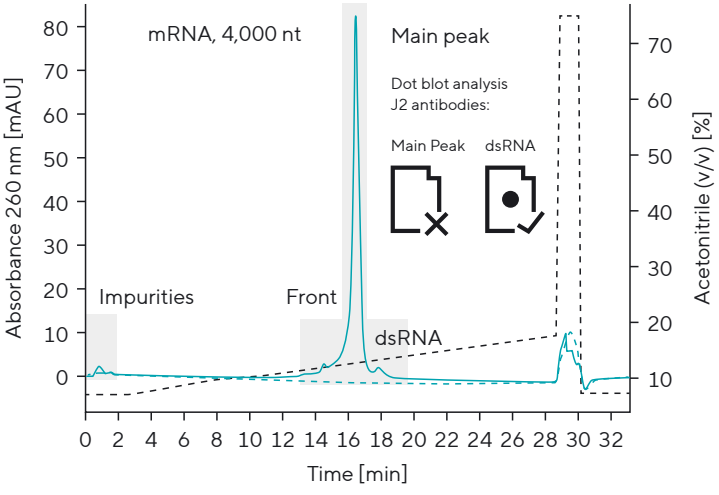
Quality Control of Drug Substance Using CIMac™ SDVB

Product-related impurity detection is crucial for:
- Developing process workflows (removal of impurities such as dsRNA)
- Process scale-up and validation
- Drug substance stability

Abortive transcripts, degraded | split mRNA, and dsRNA (e.g., due to 3' extension) represent some of the main product-related impurities that must be removed during the downstream process. Monitoring the same impurities during drug substance formulation and stability studies is equally important. A robust platform that considers these impurities—even during process development—can be of great value when quickly establishing quality control analytics.

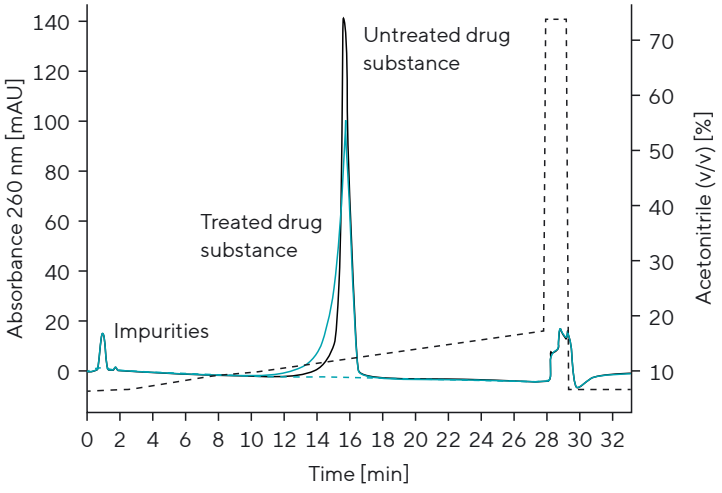
Product impurity detection:
- Distinguish between drug substance and product impurities (Figure 5)
  - mRNA drug substance
  - Product-related impurities
  - dsRNA (e.g., due to 3' extension)
  - Abortive fragments

Figure 5: *Size Separation to Distinguish Between Drug Substance (mRNA, 4,000 nt) and Process-Related Impurities*



Separation by size allows for integrity studies (Figure 6):
- During processing | purification
- Final formulation
- Stability
- Storage

Figure 6: *Stability Monitoring Using a Forced Degradation Study*



Note: A forced degradation study (pH 11, 60 min) of mRNA (4,000 nt). Fronting of the main peak, due to the emergence of shorter fragments eluting before the main, intact mRNA can be observed

Technical Specifications

Hardware Components

UV Absorbance Detector

Detection	
Detector type	Multi-wavelength detector
Detection channels	4 digital
Light source	Deuterium (D2) lamp with integrated GLP chip
Wavelength range	190 – 700 nm
Spectral bandwidth	< 8 nm at Hα line (FWHM) Note: digital bandwidth 1 – 32 nm
Wavelength accuracy	± 2 nm
Wavelength precision	0.1 n
Wavelenght verification	Internal holmium filter and deuterium lines
Noise	± 30 µAU at 254 nm
Drift	1,500 µAU/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 – 1,000 ms)
Communication	
Interfaces	LAN (RJ-45), RS-232 (SUB-D 9), multi-pin connector, analog (RCA cinch connector)
Control	Front panel, mobile control, software, event control, analog, terminal protocol
Inputs	Error (IN), start (IN), autozero, event 1 – 2
Outputs	Error (OUT), + 5 V, valve + 24 V, valve (OUT), start (OUT)
Analog outputs	1 × 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	Mobile control (optional)
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 × H × D)	361 × 158 × 523 mm
Weight	12.2 kg
Leak sensor	Yes

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

Technical Data	
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
Eluents	Limitations: Use of NaOH limited to 1 M NaOH for max 15 min continuous

High Sensitivity UV Flow Cell Cartridge (For Reverse Phase Condition)

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
Eluents	Limitations: Use of NaOH limited to 0.1 M NaOH for max 15 min continuous

Pump

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	0.001 – 10 mL/min
	0.02 – 6 mL/min (recommended)
Flow rate increment	0.001 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, carbon-fiber-reinforced PTFE, FKM, PEEK, sapphire, aluminum oxide (Al_2O_3)
Eluents	Limitations: ▪ Concentrated oxidizing acids (such as nitric acid solution, sulfuric acid), halogenated acids (such as hydrofluoric acid, hydrobromic acid), hydrochloric acid ▪ Organic solvents (acetonitrile, methanol, isopropanol) in concentrations > 75 % ▪ Tetrahydrofuran and methylene chloride cause swelling effect on wetted parts

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)
Wetted materials	PEEK, Tefzel®, Teflon® AF
Vacuum chamber	Polypropylene and stainless steel
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	IP20
General	
Power supply	Power input: 100 – 240 V
	Output: 50 – 60 Hz
	Maximum power consumption: 100 W
Dimensions (W × H × D)	361 × 208.2 × 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 ceramic
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	0.1%
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	0.001 mL/min – 10 mL/min
	0.02 – 10 mL/min (recommended)
Maximum pressure	400 bar (40 MPa, 5,800 psi) – ceramic

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; 1 µL increment
Sample loop	100 µL | 500 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

Sample Injection	
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%
Injection volumes	Full loop filling: max. 10,000 µL
	Partial loop filling: 5,000 µL (50% of loop volume)
	Microliter pickup: max. 4,625 µL (50% loop volume — 1.5x needle volume)
	0.1 µL increment for all injection modes
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 VA
Dimensions (W × H × D)	377 × 300 × 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 – 1,060 mbar

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

Column Thermostat Monitor

Thermostatting				
Temperature range	5 – 85 °C			
Heating | cooling rate	2 °C/min			
Temperature accuracy	±0.2 °C			
Temperature stability	±0.1 °C			
Column Compartment				
Column dimensions	Max. number	Max. length* [mm]	Max. outer diameter* [mm]	Matching column [mm]
	8	160	12	125 × 4.6 ID with precolumn
	4	325	12	300 × 4.6 ID
	1	325	35	300 × 16 ID
Dimensions, internal (W × H × D)	90 × 390 × 47 mm			
Safety	Self-check and auto-calibration at power-on, selectable turn-off temperature			
Leak sensor	Gas sensor, adjustable sensitivity, acoustic signal, turn-off switch			
Communication				
Interfaces	LAN interface			
Control	Optional for stand-alone functionality: Mobile control			
General				
Power supply	90 – 230 V, 50 – 60 Hz, 100 W			
Dimensions (W × H × D)	150 × 470 × 310 mm			
Weight	8.4 kg			

* Total outer dimensions of the column including screw caps

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 1,200 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 × H × D) | weight	260 × 420 × 210 mm | 16 kg	

Optional MALS Detector

Sample cell volume	63 µL
Pressure stability	Up to 5 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 10^9 Da depending on sample
Radius of gyration range	Approx. 8 nm to 250 nm depending on sample
Laser specifications	660 nm (red)
	2.5 – 50 mW adjustable
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, universal power input
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*
Dimensions (W × H × D)	46 × 26 × 16 cm
Shipping weight	17 kg

* When the laser is activated above 10 °C

Optional Fraction Collector

Fraction Collection	
Fractionation modes	Drop counting, time intervals, volume intervals, level
Max. flow rate	25 mL/min or 125 mL/min
Fraction capacity	Depends on rack type
Diverter valve	Drop former (NC): 110 µL waste (NO): 130 µL
Wetted materials	Valve: PEEK and perfluoroelastomer (FFKM)
	Supplied ferrules: ETFE
	Supplied valve tubing: PTFE
	Supplied drain tubing: vinyl
Fractionation control	Operator: direct communication via ethernet (TCP | IP)
Maximum test tube height	160 mm
RFID rack recognition	No
Number of racks	1
Capillary connection	1/16" or 1/8"
Communication	
Control	LAN
Technical Parameters	
Conformity	CE, CSA
Display	Touch screen LCD displays
Ambient conditions	0 – 40 °C (32 – 104°F)
General	
Power supply	100 – 240 VAC, 50 – 60 Hz, max. 1 A
Dimensions (W × H × D)	311 × 330 × 355 mm
Weight	7.1 kg
Rack Type	**Fraction Capacity**
15 mL centrifuge tubes	72
1.5 mL microcentrifuge tubes	60
50 mL centrifuge tubes	36
24 and 96-well plates	2

Software

Software name	PATfix®
Version	2.0.23075
Compliance	21 CFR Part 11
License	Perpetual, per system
System architecture	.NET Framework
Operating system	Windows 11 | 10
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
	Column thermostat CT 2.1
	Valve unifier VU 4.1
	Monitor CM 2.1S | pH 2.1S
	Fraction collector foxy R1
	Monitor mikron 81
Instrument connection	RS-232, ethernet, USB
Recommended PC hardware	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 1,680 × 768, recommended 1,920 × 1,080
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

mRNA Platform

IVT Reaction Monitoring Method

Column chemistry	PrimaS
Method	Quantitative
Attribute	NTPs (ATP | GTP | CTP | UTP)
	Capping reagent (ARCA | CleanCap)
	Lin pDNA
	mRNA (size independent)
LOQ mRNA	12 ng
Precision	RSD ≤ 15%, According to EP and FDA guidelines
Accuracy	RSD ≤ 15%, According to EP and FDA guidelines

mRNA Production Method

Column chemistry	Oligo dT
Method	Quantitative
Attribute	PolyA mRNA (size independent)
LOQ mRNA	4 ng
Precision	RSD ≤ 15%, According to EP and FDA guidelines
Accuracy	RSD ≤ 15%, According to EP and FDA guidelines

Product QC Method

Column chemistry	SDVB
Method	Qualitative
Attribute	mRNAs (50 nt – 10,000 nt)
	Impurities: dsRNA, fragmented mRNA, IVT components

mFix4-mRNA Standard

Description	4,000 nt long uncapped polyadenylated mRNA analog

System Requirements

Computer and Operating System

Architecture	Minimum Requirements
Operating system	Windows 11 | 10 | 8.1 | 7
CPU	Minimum 1 CPU core @ 2 GHz speed, multi-core CPU recommended
RAM	Minimum 4 GB, recommended 8 GB
Graphics	Onboard (integrated) graphics
Free disk space	256 GB for installation and data storage
	The program uses approx. 1 GB of disk space
	The chromatogram file size ranges between 2 and 5 MB
	SSD instead of HDD is highly recommended
Interfaces and PC slots	LAN connection
Monitor	Minimum 1680 × 768, recommended 1920 × 1080

Bench Space and Socket Requirements

PATfix®-Model-mRNA	
Lab footprint (W × D × H)	80 × 70 × 100 cm
Number of electrical sockets	7
Fluorescence Detector	
Additional lab footprint (W × D × H)	30 × 70 × 40 cm
Number of additional electrical sockets	1
MALS Detector	
Additional lab footprint (W × D × H)	30 × 70 × 20 cm
Number of additional electrical sockets	1
Fraction Collector	
Additional lab footprint (W × D × H)	40 × 70 × 50 cm
Number of additional electrical sockets	1
All-in-One PC and Monitor	
Additional lab footprint (W × D × H)	40 × 70 × 60 cm
Number of additional electrical sockets	1

Maximum Power Draw Requirements

PATfix®-Model-mRNA	
Device	**Max. Power Consumption [W]**
UV-Vis detector	65
Pump	100
Conductivity monitor	60
Autosampler	200
Column thermostat	100
Other	65
Total	590
Optional Components	
Device	**Max. Power Consumption [W]**
Computer	90
Fraction collector	240
FLD detector	400
MALS detector	155

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

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

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

For more information, visit
www.sartorius.com

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