

PATROL UPLC Process Analysis System for Process Development

The PATROL UPLC® Process Analysis System for Process Development is an integrated system solution designed and engineered to perform lab and pilot scale online and atline reaction monitoring in the process development laboratory in a fully automated and compliant-ready manner.

PATROL UPLC PROCESS ANALYSIS SYSTEM FOR PROCESS DEVELOPMENT FEATURES

Total system delay volume	<120 µL with binary configuration, with standard 50 µL mixer or <400 µL, with standard 100 µL mixer with quaternary configuration
Integrated leak management	Leak sensors as standard and safe leak handling
System synchronization	Injection synchronization between pump and the sample manager enhances retention time reproducibility
Operating flow rate range	0.010 to 2.000 mL/min, in 0.001-mL increments
Maximum operating pressure	15,000 psi up to 1.0 mL/min, 9,000 psi up to 2.0 mL/min
pH range	pH 2 to 10
Unattended operation	Leak sensors as standard and safe leak handling, full 96-hour diagnostic data display through console software
Cycle time	<15 s inject-to-inject with binary configuration, <30 s inject-to-inject with quaternary configuration
Solvent storage	Solvent trays accommodate up to four chromatographic solvents, three Process Sample Manager wash solvents, and one Solvent Manager seal wash solvent

BINARY SOLVENT MANAGER (BSM)

Number of solvents	Up to four, in any combination of two: A1 or A2, and B1 or B2
Solvent conditioning	Vacuum degassing (six-channels): one channel per solvent, and two channels for the Process Sample Manager (PSM) diluent and sample wash solvents
Gradient formation	High pressure mixing, binary gradient
Pump seal wash	Equipped with a programmable active wash system to flush the rear of the high pressure seals and the plungers
Gradient profiles	11 gradient curves [including linear, step (2), concave (4), and convex (4)]
Primary check valves	Intelligent Intake Valves (<i>i</i> ² Valve)
Flow ramping	Automatic

Flow accuracy	±1.0% at 0.500 mL/min, as per Waters AQT/SystemsQT protocol
Flow precision	0.075 %RSD or ±0.01 min SD (0.500 to 2.000 mL/min), whichever is greater using premixed solvent
Compressibility compensation	Automatic, no user intervention required
Priming	Wet priming runs at a flow rate of 4 mL/min
Pump composition accuracy	±0.5% absolute (full scale), from 5% to 95% of flow rates from 0.5 to 2.0 mL/min
Pump composition precision	0.15 %RSD or ±0.04 min SD, whichever is greater, based on retention time
Primary wetted materials	316 stainless steel, UHMWPE, sapphire, ruby, FEP, PTFE, ETFE, diamond-like coating, PEEK and PEEK alloys, titanium alloys

QUATERNARY SOLVENT MANAGER (QSM) AND BIOQUATERNARY SOLVENT MANAGER (BIOQSM)*

Number of solvents	One to four, in any combination as standard Expanded solvent choices with optional six-port solvent select valve
Solvent conditioning	Integrated vacuum degassing, four chambers Two additional for the PSM diluent and sample wash solvents
Gradient formation	Low-pressure mixing, quaternary gradient
Gradient profiles	11 gradient curves [including linear, step (2), concave (4), and convex (4)]
Primary check valve	Intelligent Intake Valve (<i>i</i> ₂ Valve)
Flow accuracy	±1.0% at 0.5 to 2.0 mL/min
Flow precision	0.075 %RSD or ±0.020 min SD, whichever is greater, based on six
Composition ripple (baseline noise)	<1.0 mAU (<0.1 mAU with optional 250.0-µL mixer)
Composition accuracy	±0.5% absolute (full scale) from 5% to 90% from 0.5 to 2.0 mL/min
Composition precision	<0.15 %RSD or ±0.04 min SD, whichever is greater, based on six replicate
Compressibility compensation	Automatic, no user intervention required
Priming	Wet priming can run at flow rates up to 4 mL/min
Pump seal wash	Equipped with a wash system to flush the rear of the high pressure seal and the plunger
Flow ramping	Range: 0.01 to 30.00 min to reach 2.0 mL/min
Default	0.45 min to reach 2.0 mL/min
Primary wetted materials	Titanium (bioQSM), or 316 L stainless steel (bioQSM) and/or PPS, fluoropolymer, fluorelastomer, UHMWPE blend, sapphire, ruby, zirconia, Nitronic 60, DLC, PEEK, and PEEK blend
Unattended operation	Leak sensors, full 96-hour diagnostic display through console software

PROCESS SAMPLE MANAGER (PSM)

Maximum sample capacity	32 available sites for process and control samples
Internal sample capacity	32 positions for standard 8-mL vials
External sampling	1 port standard*
Number of sample injections	Up to 60 injections per sample vial
Sample access	Total random access
Injection mode	Full-loop injection only
Injection loop volumes	1- μ L, 2- μ L, or 5- μ L sample loops only
Dilution range	Up to 1:100
Injection precision (without dilution)	< or =0.5 %RSD for caffeine peak area, full-loop injection
Injection precision with dilution	< or =1.0 %RSD for caffeine peak area, full-loop injection 1 to 50 dilution factor
Dilution linearity	> or =0.999 coefficient of deviation 1 to 50 dilution factor
Sample carryover	< or = 0.01% of the previous injection for caffeine
Needle wash solvent consumption	Variable (configured by user)
Sample wash solvent consumption	Variable (configured by user)
Diluent solvent consumption	Variable (configured by user)
Minimum injection cycle time	Variable depending injection mode (configured by user)
Minimum on-line sample volume	Variable based on injection mode, tubing ID and length required (configured by user)
Maximum at-line sample consumed per analysis (vial)	100 μ L
Sample compartment temperature control	4.0 to 40.0 °C programmable in 0.1 °C increments
Sample compartment temperature stability	\pm 0.5 °C from set point measured at the control sensor
Sample compartment temperature accuracy	\pm 1.0 °C from set point measured at the control sensor
Sample compartment temperature distribution	\pm 3 °C from set point as measured in air, not in a vial
Sample compartment cooling time	<60 minutes from 30 to 4 °C

COLUMN MANAGEMENT (CM-A AND CM-AUX)

Column capacity	CM-A: Two columns, as standard (maximum length of 150 mm with filter or guard column) or four columns (maximum length of 50 mm) can be supported with optional tubing kit, up to 4.6 mm internal diameter (I.D.) CM-Aux: Two columns (maximum length of 150 mm, with filter or guard column); one CM-Aux unit can be configured with one CM-A for support of up to four columns
Switching valves	Two injector-style, nine-port, eight-position valves (CM-A only); provides programmable, automatic, random access switching, waste and bypass positions for rapid solvent changeover
Column compartment(s)	4.0 to 90.0 °C, settable in 0.1 °C increments temperature range Two independent heat/cool zones per module, up to four zones in stacked configuration with one CM-A Aux unit (see ACQUITY UPLC® H-Class and H-Class Bio System Specifications Guide for conditions)
Column compartment(s) temperature accuracy	±0.5 °C (see ACQUITY UPLC H-Class and H-Class Bio System Specifications Guide for conditions)
Column compartment(s) temperature stability	±0.3 °C (see ACQUITY UPLC H-Class and H-Class Bio System Specifications Guide for conditions)
Solvent conditioning	Active pre-heating as standard
Column tracking	eCord™ Technology column information management tracks and archives column usage history

PATROL UPLC PROCESS ANALYSIS SYSTEM INSTRUMENTAL CONTROL

External communications	Ethernet interfacing via RJ45 connection to host PC
External control	Empower® Software
User diagnostics	Available through software on host PC; system control via console software
Connections INSIGHT®	Provides real-time monitoring, automatic notification of instrument performance, and diagnostic information allowing for quicker problem resolution
PATROL UPLC options	OPC communications (object linking and embedding (OLE) for process control)

ENVIRONMENTAL SPECIFICATIONS

Acoustic noise	<65 dBA, system
Operating temperature range	4.0 to 40.0 °C (39.2 to 104.0 °F)
Operating humidity range	20% to 80% non condensing

ELECTRICAL SPECIFICATIONS

Power requirement 100 to 240 VAC

Line frequency 50 to 60 Hz

Power consumption

BSM	360 VAC
QSM	360 VAC
PSM	450 VAC
CM-A	400 VAC

PATROL UPLC PROCESS ANALYSIS SYSTEM CART (OPTIONAL)

Physical dimensions

Cart

Width:	78.7 cm (31 inches)
Height:	165.1 cm (65 inches)
Depth:	81.3 cm (32 inches)

Waters

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